

VOLUME I OF II (Brief pages 1-68 and Addendum pages Appx1-484)

No. 2024-1285

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

NON-CONFIDENTIAL BRIEF FOR APPELLANT APPLE INC.

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April 5, 2024

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PATENT CLAIMS AT ISSUE**U.S. Patent No. 10,912,502 (dependent claim 22, independent claim 28)**

19. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);

four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;

a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;

optically transparent material within each of the openings; and

one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.

20. The user-worn device of claim 19 further comprising a thermistor.

21. The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.

22. The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.

...

28. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;

a thermistor configured to provide a temperature signal;

a protrusion arranged above the interior surface, the protrusion comprising:

a convex surface;

a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and

a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;

at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities;

one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen

saturation measurement of the user, the one or more processors further configured to receive the temperature signal;

a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;

a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user;

a storage device configured to at least temporarily store at least the measurement; and

a strap configured to position the user-worn device on the user.

U.S. Patent No. 10,945,648 (dependent claims 12, 24 and 30)

8. A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes;

a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;

a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;

a separate optically transparent window extending across each of the openings;

one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;

a housing; and

a strap configured to position the housing proximate tissue of the user when the device is worn.

...

12. The user-worn device of claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation.

20. A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:

a plurality of light emitting diodes (LEDs);

at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;

a protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and

one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

...

24. The user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light-piping.

...

30. The user-worn device of claim 20, wherein the protrusion further comprises of one or more chamfered edges

CERTIFICATE OF INTEREST

Counsel for Appellant Apple Inc. certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Apple Inc.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

None.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes (file separate notice; see below) No N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

Already filed.

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

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CERTIFICATE OF SERVICE

CERTIFICATE OF COMPLIANCE

CONFIDENTIAL MATERIAL OMITTED

The material omitted from pages 14-15, 28, 33, and 41 and addendum pages Appx62, Appx67, Appx74, Appx176, Appx179, Appx205-206, Appx211, Appx278-286, Appx304-306, Appx309, Appx311-316, Appx318, Appx320-328, Appx332-340, Appx426-427, and Appx473-474 contains information that Intervenor Masimo Corporation and Cercacor Laboratories, Inc. designated as Confidential Business Information under the Administrative Protective Order in effect in ITC Investigation No. 1276. The material omitted from page 62 and addendum pages Appx9, Appx36, Appx41-44, Appx46-48, Appx108, Appx119, Appx121-122, Appx150-151, Appx153-154, Appx156-158, Appx187-190, Appx192-194, Appx196, Appx198, Appx218, Appx220-222, Appx265-276, and Appx373 contains confidential competitively sensitive product information subject to the Administrative Protective Order; and the material omitted from Appx404-405, Appx457, Appx460-461, and Appx464 contains confidential competitively sensitive financial and sales information subject to the Administrative Protective Order.

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STATEMENT OF RELATED CASES

There have been no previous appeals from Investigation No. 337-TA-1276 (the “Investigation”). This Court’s decision in this appeal may affect the following pending case: *Apple Inc. v. Masimo Corp.*, No. 1:22-cv-01378 (D. Del.).¹

JURISDICTIONAL STATEMENT

This appeal concerns the Commission’s Final Determination, dated October 26, 2023, relating to U.S. Patent Nos. 10,945,648 (“’648 patent”) and 10,912,502 (“’502 patent”). Appx360-483. Apple timely appealed on December 26, 2023. *See* 19 U.S.C. § 1337(c), (j); *see also* C.A. Dkt. 1. This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(6).

INTRODUCTION

The International Trade Commission exceeded its statutory authority by issuing an injunction in a case where the requisite “domestic industry” was non-existent. The Commission compounded that fundamental error by issuing a series of substantively defective patent rulings. Apple respectfully submits that this Court should correct the Commission’s errors and ensure the agency observes the jurisdictional limitations Congress prescribed.

¹ The Patent Trial and Appeal Board previously denied institution of *inter partes* review on both patents at issue in this appeal. *See Apple Inc. v. Masimo Corp.*, Nos. IPR2022-01273, -01274, -01275, -01276 (P.T.A.B.).

On September 18, 2020, Apple launched its Series 6 Apple Watch—the first to include a feature measuring the user’s blood oxygen levels alongside the smartwatch’s host of existing health and wellness features.² Fitting a blood oxygen feature into Watch while adhering to Apple’s meticulous design standards was a technological feat that required tens of thousands of engineer hours. Six days after Watch’s launch, Intervenor Masimo Corporation and Cercacor Laboratories, Inc. (“Masimo”)—best known for their products used in hospitals and doctors’ offices—brushed off a twelve-year-old patent application and applied for new claims manifestly written to ensnare Apple’s new Watch. The result was the ’502 and ’648 patents at issue, which (as ITC Chairman Johanson explained in dissent) include “late added claims ... added by amendment years after the original priority date” that “reach beyond any disclosure fairly described by the specification and figures.” Appx424-425 n.43.

Masimo rushed to use these unsupported claims as the basis for an investigation in front of the Commission. But because the Commission is “fundamentally a trade forum, not an intellectual property forum,” Masimo was required to show it actively “engaged in steps leading to the exploitation of ... intellectual property.” *John Mezzalingua Assocs., Inc. v. ITC*, 660 F.3d 1322, 1328

² This brief uses the term “Watch” to refer to Apple Watch.

(Fed. Cir. 2011) (internal quotation marks omitted). Specifically, Masimo was required by statute to identify an existing “article” that practiced its asserted patents and domestic investment in that article. *See* 19 U.S.C. § 1337(a)(2)-(3); *see also infra* p. 25 (collecting case law and statutory language requiring article to exist at time complaint was filed).³

Masimo had no such article, nor any other item that remotely resembled the specific combination of elements in the new claims. Rather, Masimo filed a complaint that relied on CAD drawings of a supposed “Masimo Watch” and a promise that a physical “sample” of the “Masimo Watch” was “available on request.” In fact, no “Masimo Watch” matching the CAD drawings was available then or ever, and Masimo ultimately conceded no such item existed.

Masimo’s concession revealed that the basis for initiating the Investigation was a serious misrepresentation—i.e., the complaint did not identify an existing article that practiced Masimo’s patents, and Masimo could not have made a significant investment in an item that never existed. But the ALJ (and eventually the Commission) allowed Masimo to prevail on the theory that Masimo had provided *circumstantial* evidence that it had at one time possessed *different* pre-complaint items that practiced the patents—even though the ALJ did not find that

³ Consistent with this Court’s precedent, *e.g.*, *John Mezzalingua*, 660 F.3d at 1324, this brief refers to this statute as “Section 337.”

any of the specific items Masimo eventually put forth actually did so. This was error. The part of Section 337 at issue here requires a showing that the requisite article “*exists.*” 19 U.S.C. § 1337(a)(2).⁴ Nothing in that statutory language or this Court’s precedent permits the Commission to use its extraordinary injunctive powers to protect a hypothetical domestic industry “article” that theoretically *might* exist in the future.

Finally, even if the statutory requirement to identify an “article” that practices the asserted patents somehow could be satisfied by mere expectation, hope, or speculation, Masimo could not have satisfied the parallel requirement to show “significant” investment “with respect to the articles protected by the patent[.]” 19 U.S.C. § 1337(a)(3). It is not possible to provide concrete evidence of investment when the complainant fails to identify an item that qualifies as an “article.” Further, Masimo admitted that the funds it purportedly invested included some unspecified amount of money spent on at least two items that concededly *do not* practice the patents—a clear violation of the statutory language.

This case thus presents a vivid illustration of what happens when the Commission fails to properly exercise its jurisdictional gatekeeping responsibilities. To protect a “domestic industry” that did not actually exist, the

⁴ Emphasis added unless otherwise noted.

Commission issued an import ban against a flagship device made by a company headquartered in California that directly or indirectly employs over a half-million American employees. This outcome is precisely what the domestic industry requirement is intended to prevent: an opportunistic exploitation of the Commission's vast injunctive powers to harm a real domestic industry—and the public interest—without any commensurate benefit to U.S. trade.

Beyond domestic industry, the Commission's ruling was fatally flawed on the patent merits. For example, the Commission's obviousness ruling contravenes this Court's precedent that while a prior art reference need only disclose *one* of the embodiments claimed in a patent to render the patent obvious, a patent must enable *all* embodiments covered by the claims. *E.g., In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994).

The Commission's decision also ignores that a patent is unenforceable when, as here, “a patentee's conduct constitutes an egregious misuse of the statutory patent system.” *Personalized Media Commc'ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023) (quotation marks omitted). Masimo lay in wait for over a decade, only to file its applications six days after Apple released the accused products—a move plainly intended to exploit Apple's own innovation and commercial success.

The Commission both exceeded its authority and issued a series of flawed substantive rulings. The Commission's decision cannot stand.

STATEMENT OF ISSUES ON APPEAL

1. Whether the Commission erred in concluding that Masimo established an existing domestic industry, including by:
 - a. holding Masimo satisfied the technical prong, even though the item identified in the complaint as the purported “article” admittedly never existed and the Commission's decision relied on cobbled together circumstantial evidence to find that Masimo somehow possessed a patent-practicing “article,” and
 - b. holding Masimo satisfied the economic prong, even though Masimo concededly relied on investments made in several items that admittedly do not practice the patents at issue—and even as to the items relied upon, offered only rank speculation and made-for-litigation spreadsheets.
2. Whether the Commission erred in concluding the five remaining patent claims (out of 103 originally-asserted) were not invalid, including by
 - a. with regards to obviousness, requiring Apple to show that the relevant prior art disclosed/enabled more than the patents

themselves, and disregarding *KSR*'s ordinary creativity standard,
and

- b. with regard to written description, endorsing precisely the kind of post-hoc mixing-and-matching of unrelated elements that this Court has rejected.
3. Whether the Commission erred in concluding the accused products infringed the five remaining claims, where the Commission's ruling rested on claim constructions of terms like "over," "above," and "through" that flout their plain meanings.
4. Whether the Commission erred in rejecting Apple's prosecution laches defense, where Masimo strategically waited over a decade to submit its continuation applications and only did so after Apple invested immense resources to develop the accused products.

STATEMENT OF THE CASE

A. The Parties

Appellant Apple Inc. designs and manufactures consumer electronic devices, including iPhone, iPad, and, as relevant here, Apple Watch. Based in Cupertino, California, Apple has more than 90,000 U.S. employees and additionally supports more than "450,000 jobs through its 9,000 U.S. suppliers." Appx25410(¶ 101). In

2023 alone, Apple devoted nearly \$30 billion—over half of its total operating expenses—to research and development.⁵

Intervenor Masimo Corporation is a medical technology company, which has since its founding focused on products for the clinical setting. Appx40233(140:8-14). At the time of this Investigation, Masimo’s clinical products accounted for almost all its revenue. Appx70593(99:15-23). Intervenor Cercacor Laboratories is a spin-off of Masimo that conducts research and development of technologies for use in clinical settings and licenses its technology to Masimo. Appx3708(¶¶ 19-20); Appx40186(93:12-20).

B. The Patents

Masimo’s operative complaint alleged infringement of 103 claims in five patents. Appx3703(¶ 3). All five asserted patents describe devices that use light to non-invasively measure physiological parameters such as an individual’s blood oxygen saturation, a method called pulse oximetry. Appx70020; Appx70034-70035.

Ultimately, the Commission’s finding of a Section 337 violation rested on only five claims—all from the ’648 or ’502 patents. Those patents share a lead inventor (Jeroen Poeze) and a specification. Along with a third patent not at issue

⁵ Apple Inc., Form 10-K at 3, 23 (Sept. 30, 2023), *available at* <https://tinyurl.com/4mahjry4>

here (U.S. Patent 10,912,501 (“’501 patent”)), they are collectively referred to in the record as the “Poeze patents.” *E.g.*, Appx366.⁶

The Poeze patents all claim priority to an application filed on July 3, 2008. Appx366. The figures in the shared specification depict a bulky fingertip sensor attached by cable to a separate monitor. For example:

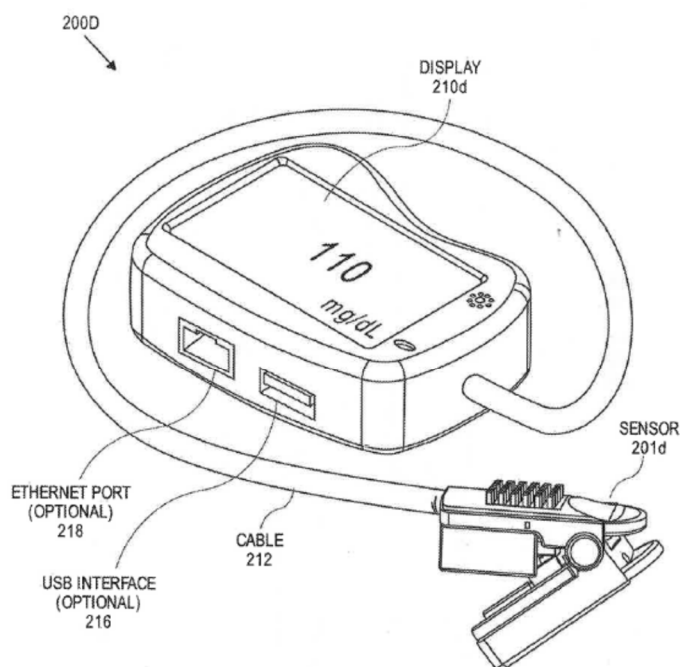


FIG. 2D

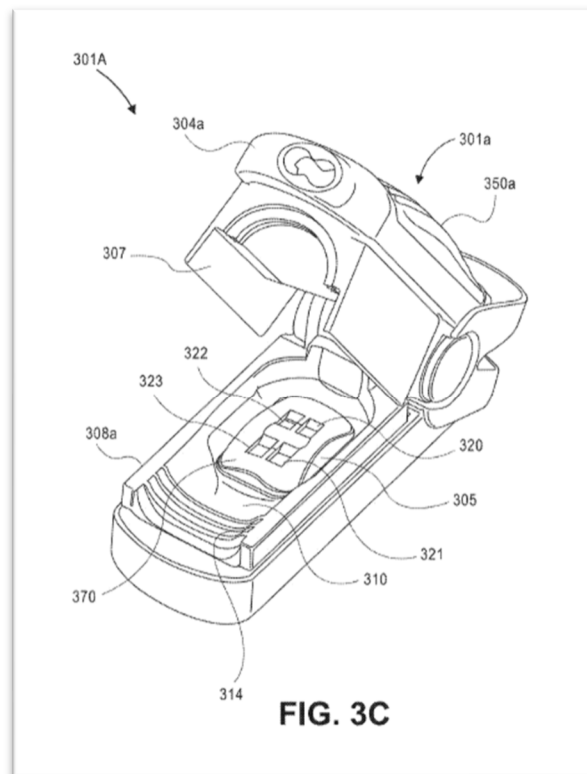
Appx511(Fig. 2D).

Although the ’502 and ’648 patents relied on an over twelve-year-old specification, the claims themselves were not submitted to the Patent Office until September 24, 2020, roughly one week after the first accused product (Apple

⁶ This brief follows the ALJ and Commission’s convention of citing to the specification of the ’501 patent. *See, e.g.*, Appx25, Appx415 n.36.

Watch Series 6) was released to the public. Appx597; Appx708; Appx70356-70369.

The five remaining claims at issue share certain overlapping limitations. For example, all require a “user-worn device” that can measure oxygen or oxygen saturation. Appx368-371. Similarly, all require variations of a single limitation—using transmissive windows (or optically transparent windows) that extend across or exist within openings in a protrusion comprising a convex surface. *Id.* Figure 3C depicts Sensor 301A with openings (320-323) in a protrusion (305):



Appx514(Fig. 3C).

C. The Products

1. **Apple's Accused Products.** Masimo's operative complaint alleges infringement by versions of Watch capable of measuring blood oxygen, starting with Watch Series 6. Appx372-373. The Series 6 is pictured below:



Appx52501-52514; Appx70782.⁷

When Apple released the first Watch (“Series 0”) nine years ago, it was praised as “the first wearable computer.”⁸ Today, millions of consumers use Watch to stay connected and fulfill a host of other needs from navigation to payment. *E.g.*, Appx25387-25388(¶¶ 27-28). Watch also includes numerous

⁷ It is undisputed that the blood oxygen functionality of each Watch product is “materially identical for the purposes of infringement in this investigation.” Appx372-373.

⁸ Manjoo, “Apple Watch Review: Bliss, but Only After a Steep Learning Curve,” *N.Y. Times* (Apr. 8, 2015), <https://tinyurl.com/e7bnxtmz>.

health and wellness tools, such as fall detection, which automatically makes an emergency call after a user has a hard fall and is unresponsive. Appx25404(¶ 81). Two such features—the ECG application and the Irregular Rhythm Notification—have been shown to alert users that they may suffer from a possibly fatal heart-condition called atrial fibrillation (AFib). Appx25351-25353(¶¶ 14-17).

Watch’s combination of utility and wellness has made it ideal for use in major medical studies, including studies led by the American Heart Association, the Mayo Clinic, and Johns Hopkins. Appx25398-25400(¶¶ 59-62, 69).⁹ Watch plays an important role in facilitating such studies, as it is a product that the test subjects may already own (reducing expenses) and researchers can review multiple health and wellness metrics at the same time (as opposed to other measurement tools, which may provide only one type of data). Appx25395-25396(¶¶ 51, 55).

Of Watch’s many facets, the feature accused of infringement is the Blood Oxygen feature. Medical journals have praised the accuracy of the Blood Oxygen feature, *see* C.A. Dkt. 30 at Add.24-41, and numerous medical professionals and organizations like the American Heart Association explained to the Commission the importance of Watch—including its pulse oximetry feature—to public health

⁹ *See also* <http://tinyurl.com/ycyzj5mw> (discussing Apple Women’s Health Study), *cited at* Appx25302-25303.

and medical research, *see* Appx24278-24284; Appx24287-24293; Appx24200; Appx24196.

2. Masimo’s Purported “Articles.” To invoke the Commission’s jurisdiction, Masimo had to satisfy the domestic industry requirement. *See infra* pp. 23-26. This required showing an “actual article” existing at the time of the complaint that practices the asserted claims and has been the subject of significant domestic investment. *Id.*

Masimo’s complaint pointed to the purported “Masimo Watch” as the Section 337 “article” for the patents at issue here and attached CAD drawings allegedly depicting the device. Appx63-65 & n.15; Appx2741-2758. The complaint said, repeatedly, that a “Masimo Watch” “sample ... is ***available upon request.***” *E.g.*, Appx14129; Appx3718-3727(¶¶ 47, 54, 61, 68). It was not. Masimo has since conceded that the specific device pictured in those drawings ***never actually existed.*** C.A. Dkt. 25-1 at 6-7. Instead, during discovery, Masimo identified dozens of ***different*** objects as the “physicals” it would rely on to satisfy the technical prong. Appx6853-6854; Appx6943-6948. At the evidentiary hearing, Masimo narrowed to six separate alleged “articles” it contended practiced the ’502 and ’648 patents: “RevA,” “RevD,” three “RevE” items, and the alleged commercial version of the “Masimo Watch” named “W1.” The ALJ refused to consider the W1—the only watch product Masimo has ever sold (albeit in

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negligible quantities)—because it was undisputedly created months after the operative complaint was filed. *See* Appx64.

Of the five remaining items, there is no direct evidence that any satisfied the key requirement of the remaining claims at the time the complaint was filed—i.e., a “user-worn” device configured to non-invasively measure oxygen or oxygen saturation. *See, e.g.*, Appx66-68; Appx87-89 (relying on “circumstantial evidence” showing “prototype devices with designs that are *consistent with* the asserted domestic industry products”). Only one of those five items even existed before the complaint’s filing in the form relied upon at the hearing: the RevA (left below). It is plainly different from the “Masimo Watch” pled in the complaint (right below):

Masimo CBI



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Masimo CBI



Appx65024-65025; Appx2741; Appx2750.

Masimo separately submitted two physical items intended to serve as the “article” for a patent not at issue here. Those are called “Wings” and “Circle,” and are pictured at left and right below.

Masimo CBI



Appx70835; Appx65022-65023; Appx65018-65019.

D. Prior Proceedings

1. In January 2020, Masimo sued Apple in the Central District of California, asserting numerous patent and trade secret claims—none of which directly overlaps with this case. *Masimo Corp. v. Apple Inc.*, No. 20-cv-00048, ECF No. 1 (C.D. Cal.). Since then, this Court has affirmed the invalidation of the vast majority of the asserted patent claims, and a trial on the trade secret claims resulted in JMOL for Apple on half of Masimo’s alleged trade secrets. A jury note revealed that all but one juror were prepared to rule in Apple’s favor on the remaining claims. *Id.* ECF No. 1713. Re-trial is set for October 2024. *Id.* ECF No. 1926.

2. Displeased with the fact it could take “many years just to get to trial” in Article III proceedings, Masimo CEO Joe Kiani “authorized Masimo to seek an investigation by the ITC” into whether Apple infringed patents not asserted in the California action. C.A. Dkt. 25-2 at ¶34. Masimo filed its original complaint on June 30, 2021, and an amended complaint early the following month. *See generally* Appx3696-3739.¹⁰

Masimo had not produced its own watch at the time the complaint was filed. As Mr. Kiani represented to this Court, “Masimo expected to launch the W1 during the pendency of the ITC investigation.” C.A. Dkt. 25-2 at ¶35.

¹⁰ All references to “the complaint” refer to the July 2021 amended complaint.

3. ALJ Bhattacharyya held a five-day hearing in June 2022. Appx8.

The ALJ subsequently issued a Final Initial Determination finding a violation of Section 337 as to only two claims, claim 24 and 30 of the '648 patent. Appx340.¹¹

The ALJ relied on circumstantial evidence to conclude that Masimo's asserted physical items, except the W1, satisfied the domestic industry requirement's technical prong. Appx66-68; Appx87-89. The ALJ also found the domestic industry's economic prong was satisfied, based on three vague spreadsheets that Masimo admittedly created for purposes of the litigation. Appx316-318. The ALJ acknowledged the economic prong finding relied in part on expenditures for the Wings and Circle devices, even though those items concededly do not practice the asserted claims of the patents on appeal. Appx308-309.

4. Apple and Masimo both cross-petitioned the Commission for review of the ALJ's ruling. Appx364. As relevant here, the Commission granted review on (1) the domestic industry requirement and obviousness as those issues relate to all remaining claims, and (2) written description "with regard to claim 28 of the '502 patent and claim 12 of the '648 patent." Appx365. "In connection with its

¹¹ The ALJ flatly rejected Masimo's assertion that Apple had deliberately copied Masimo's patented technology. Appx403; *see also* Appx158-159 ("[T]he undersigned finds no significant credible evidence that Apple copied Masimo's patented technology."). Masimo did not challenge that finding in front of the Commission. Appx404.

review,” the Commission asked the parties to brief over a dozen specific questions, including numerous questions related to domestic industry. Appx24314-24315.

The Commission’s decision issued on October 26, 2023. Appx483. The Commission affirmed the ALJ’s finding as to a violation of claims 24 and 30 of the ’648 patent. Appx381-382; Appx394; Appx482. In a split decision, it also reversed the ALJ’s findings of invalidity based on lack of written description for several other claims. Appx412-413; Appx419-425; *see also* Appx424-425 n.43 (Chairman Johanson’s dissenting statement). The Commission ultimately found a violation of Section 337 that rested on five claims: claims 22 and 28 of the ’502 patent, and claims 12, 24, and 30 of the ’648 patent. Appx482.

Despite asking the parties to brief numerous issues related to the alleged “Masimo Watch” domestic industry, the Commission’s 123-page decision devoted fewer than three pages to the issue. Appx425-427. The Commission said nothing about Apple’s arguments regarding why the technical prong was not satisfied, holding only it was *not* adopting (1) the ALJ’s finding that Masimo had shown a domestic industry in the process of being established or (2) Masimo’s request to consider post-complaint evidence. Appx426. The Commission discussed the economic prong only briefly, and did not address the ALJ’s decision to rely on expenditures related to Wings and Circles. Appx425-427.

5. Apple timely appealed and sought an emergency stay pending appeal. *See* C.A. Dkts. 5, 7. This Court granted Apple’s request for an immediate, administrative stay. C.A. Dkt. 19. That stay ended after Customs and Border Protection issued a ruling permitting the importation and sale of a redesigned version of the accused products that removed the Blood Oxygen feature. *See* C.A. Dkt. 33. That removal eliminated the ability of new Watch customers to access this feature and jeopardized health studies that rely on that feature. *See supra* pp. 12-13. This Court’s order ending the stay noted “the recent [Customs] ruling” and stated that it “reach[ed] no conclusion on the merits.” C.A. Dkt. 33 at 2.

SUMMARY OF THE ARGUMENT

1. The Commission exceeded its statutory jurisdiction by holding Masimo satisfied the domestic industry requirement’s economic and technical prongs.

To satisfy the technical prong, Masimo was required by statute to identify an “article” that practiced the patent and that existed at the time the complaint was filed. Masimo undisputedly has never had a physical item that matched the CAD drawings in its complaint and failed to provide direct evidence of a single pre-complaint item practicing the asserted patents. The Commission found the technical prong satisfied only by relying on circumstantial evidence showing that devices somehow “consistent with” the five specific items Masimo eventually

identified as the supposed “article” practiced the patents—i.e., not the specific RevA, RevD, or three RevE items themselves. Nothing in the statute or this Court’s case law supports this erroneous result.

To satisfy the economic prong, Masimo was required by statute to show it made significant investments in the United States “with respect to” the “article[]” protected by the patent. But Masimo could not possibly show investment in the purely hypothetical item identified in the complaint. Contriving a Potemkin “industry,” Masimo improperly lumped together Masimo’s expenses for multiple items, including items that undisputedly do not practice the patents at issue. That approach is impossible to square with the text of Section 337 or this Court’s case law. The Commission similarly erred by allowing Masimo to prove its expenses based on three made-for-litigation spreadsheets (without any underlying contemporaneous support) that used a wholly invented methodology that even Masimo’s CFO was unable to explain.

2. The Commission also erred by holding the five remaining (of 103 original) asserted claims not invalid. For example, the Commission concluded Lumidigm did not render obvious the use of a “user-worn device” that measures oxygen or oxygen saturation because Lumidigm allegedly does not enable measuring blood oxygen *at the wrist*—a location-specific requirement that appears

nowhere in the claims. This ruling violates this Court’s precedent establishing that an obviousness reference cannot be required to disclose more than the patent itself.

The Commission also committed legal error by, *inter alia*, holding that Lumidigm did not render obvious the use of multiple “transmissive windows” or “optically transparent material” extending across multiple openings. Lumidigm expressly references the use of “fiber optic faceplates,” and undisputed expert testimony establishes that a skilled artisan would have known that there were just two ways to implement such faceplates—including using an individual faceplate for each opening. Under basic *KSR* principles, because only two alternatives were known in the art and a skilled artisan would have known how to implement them, both would have been obvious.

The asserted claims are invalid for the additional reason that they lack written description support. The Commission committed a cross-cutting legal error by holding the written description requirement satisfied by multiple unconnected disclosures. In addition, regarding claim 28 of the ’502 patent and claim 12 of the ’648 patent, the two-Commissioner majority erred by diverging from the ALJ’s well-reasoned finding that the specification does not disclose two sets of LEDs emitting at the same two wavelengths.

3. The Commission also erred in finding infringement, particularly because its ruling depended on improperly construing ordinary words like “over,” “above,” and “through.”

4. Moreover, Masimo’s suit was barred by prosecution laches. After a twelve-year delay, Masimo opportunistically acted six days after Watch Series 6 launched. While Masimo has had every chance to justify this undue delay, Masimo has provided no explanation. The only reason apparent in the record is that Masimo tailored its new claims—claims that reach far beyond any disclosure in the written description—to target Apple.

ARGUMENT

I. STANDARD OF REVIEW

The Commission “review[ed] the ALJ’s decision in part,” meaning this Court has jurisdiction over both the Commission’s express holdings and the “unreviewed parts” of the ALJ’s ruling. *Microsoft Corp. v. ITC*, 731 F.3d 1354, 1358 (Fed. Cir. 2013). This Court “review[s] the [Commission’s] legal conclusions” (including claim construction) “*de novo* and its factual findings for substantial evidence.” *Apple Inc. v. ITC*, 725 F.3d 1356, 1361 (Fed. Cir. 2013). “[T]he question of whether the domestic industry requirement is satisfied presents issues of both law and fact.” *Motiva, LLC v. ITC*, 716 F.3d 596, 600 (Fed. Cir. 2013). “Whether a claim satisfies the written description requirement is a question

of fact.” *Indivior UK Limited v. Dr. Reddy’s Laboratories S.A.*, 18 F.4th 1323, 1326 (Fed. Cir. 2001). Because “[o]bviousness is a question of law based on underlying facts,” this Court reviews the Commission’s “obviousness determination without deference and its factual findings for substantial evidence.” *Apple*, 725 F.3d at 1361.

This Court reviews a ruling regarding prosecution laches for abuse of discretion, but “review[s] the legal standard applied by the [tribunal] *de novo*.” *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 728-729 (Fed. Cir. 2010).

Although this Court has accorded *Chevron* deference to the Commission’s reasoned interpretation of the term “article” in 19 U.S.C. § 1337, *Microsoft*, 731 F.3d at 1358, such deference does not apply here, where the agency did not “analyze or explain why the statute should be interpreted in a particular manner,” *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1318 (Fed. Cir. 2017) (en banc). To the extent that the Supreme Court holds courts should be more discerning in deferring to agencies, *see Loper Bright Enterprises v. Raimondo*, No. 22-451 (U.S.), this case presents a vivid example of where no deference is due.

II. THE COMMISSION ERRED BY HOLDING THE DOMESTIC INDUSTRY REQUIREMENT SATISFIED

Section 337 grants the Commission the extraordinary power to bar the importation and sale of products that infringe a patent. This authority, however,

depends on a critical threshold requirement: the party invoking the Commission’s authority must identify an “article”—that is, a tangible item—that practices the patent and has been the subject of significant domestic investment. 19 U.S.C. § 1337(a)(2)-(3); *see also Broadcom Corp. v. ITC*, 28 F.4th 240, 249-250 (Fed. Cir. 2022) (describing “technical prong” and “economic prong”); *infra* pp. 27-44. This gating rule, which is known as the domestic industry requirement, ensures that the Commission’s jurisdiction will only be invoked to protect genuine domestic innovation and not just speculative aspiration.

While Section 337 allows a complainant to invoke the Commission’s authority by showing a domestic industry “in the process of being established,” 19 U.S.C. § 1337(a)(2), a physical article is still required. This is because (1) the statute still requires the in-process domestic industry to “relat[e] to the articles protected by the patent,” *id.*, and (2) demonstrating the existence of “articles protected by the patent” requires actual articles that practice the patent, *Microsoft*, 731 F.3d at 1361; *accord ClearCorrect Operating, LLC v. ITC*, 810 F.3d 1283, 1286-1287 (Fed. Cir. 2015) (statutory term “article” requires a “material thing”). In any event, this is a moot point, because the Commission’s decision rested only on the theory that Masimo demonstrated that a domestic industry “*exists*” and

expressly declined to adopt the ALJ’s finding on the “in the process of being established.” Appx426.¹²

Domestic industry depends not only on the existence of a patent-practicing article, but existence *at the time the complaint was filed*. See *Philip Morris Prods. S.A. v. ITC*, 63 F.4th 1328, 1341 n.4 (Fed. Cir. 2023) (“The filing date of the complaint is the ‘relevant date at which to determine if the domestic industry requirement’ is satisfied.”); see also *Motiva*, 716 F.3d at 601 n.6 (similar). This requirement flows directly from the text of the statute, which provides that the Commission only has jurisdiction to “investigate [an] alleged violation” of Section 337 and nowhere empowers the Commission to initiate investigations based on speculative *future violations*. See 19 U.S.C. § 1337(b), (c). Limiting the Commission’s jurisdiction to *existing* violations is also consistent with jurisdictional requirements in Article III courts. See, e.g., *GAF Bldg. Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996) (“later events may not create jurisdiction where none existed at the time of filing”).

¹² This Court only reviews the bases of the ALJ opinion that the Commission adopted—here, that an industry “exists.” See *Genentech, Inc. v. ITC*, 122 F.3d 1409, 1422 (Fed. Cir. 1997) (issues “not adopted by the Commission” are not before Court on appeal); *Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984) (similar); see also *DHS v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (“It is a foundational principle of administrative law that judicial review of agency action is limited to the grounds that the agency invoked when it took the action.” (quotation marks omitted)).

Accordingly, the Commission could not have ruled in Masimo's favor without finding that the "Masimo Watch" identified in Masimo's complaint as the purported article both (1) actually existed when the suit was filed and (2) had been the subject of significant domestic investment. There is now no dispute, however, that the item identified in the complaint *never* existed and that Masimo's only attempt to show investment was to point to money spent on the development of *multiple other* items—several of which Masimo has never even argued practice the '502 and '648 patents. Even if the Commission's acceptance of Masimo's technical prong evidence was proper (it was not), the Commission violated the plain text of the statute by relying on a *broader* array of supposed "articles" when analyzing the economic prong (i.e., both the "Masimo Watch" items and Wings and Circle).

If the Commission's decision is affirmed, the door of the agency's "trade forum" will be opened to complainants who lack an actual domestic industry but possess pleading creativity and CAD software. That is not what Congress intended and not what the statutory text permits.

A. The Commission Erred By Holding That Masimo Satisfied The Technical Prong

1. The Commission exceeded its statutory authority by holding the technical prong satisfied even though the supposedly patent-practicing device identified in the complaint was hypothetical

As relevant here, Section 337 requires a patentee to “provide evidence ... relat[ing] to an *actual article* that practices the patent, ... manufactured domestically or abroad.” *Microsoft*, 731 F.3d at 1362 (quoting 19 U.S.C. § 1337(a)(2)-(3)). It is not enough that a *hypothetical article* embodies the patent; the question is whether the patented invention was “actually implemented.” *Id.* at 1361-1364; *accord Broadcom*, 28 F.4th at 250 (rejecting suggestion that a “hypothetical device” could constitute an “article”).

Here, there is no dispute that Masimo does not have, and has never had, a Masimo Watch “article” matching the description in the operative complaint. Masimo initiated this litigation by claiming that “the Masimo Watch is protected by one or more claims” of the asserted patents and that CAD “‘drawings’ of the Masimo Watch ... are attached.” Appx3718-3727(¶¶ 47, 54, 61, 68); Appx3732-3733(¶¶ 86, 89). But CAD drawings are not “articles” as this Court has interpreted that term. To the contrary, an “article” as used in Section 337 requires a “material thing.” *ClearCorrect*, 810 F.3d at 1286-1287. Just as the digital dental models at issue in *ClearCorrect* were not Section 337 “articles,” *id.* at 1287, 1295, electronic

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CAD files of an alleged “watch” device fall short of the mark. Any other interpretation would render Section 337 nonsensical. For example, 19 U.S.C. § 1337(i) provides that the Commission may order “any article imported in violation” of Section 337 seized and forfeited—a CAD drawing does not move in commerce and cannot be seized or forfeited. *ClearCorrect*, 810 F.3d at 1295. Faced with this logic, even Masimo now concedes that the CAD drawings “are not patent-practicing articles.” C.A. Dkt. 25-1 at 7.

The operative complaint also stated that a physical sample of the Masimo Watch was available for inspection “upon request.” Appx3718(¶ 47). But Masimo was unable to produce a single physical item until more than three months after the complaint was filed, Appx14130, and each device Masimo ultimately produced was admittedly different from the purported “article” pictured in the complaint, Appx70624-70625(173:11-175:11) (Masimo’s corporate representative testifying that he was unaware of “Masimo CBI” the complaint’s CAD drawings); Appx40548-40549(454:3-455:13) (similar). In fact, as the ALJ found, the watch Masimo now refers to as the “W1” was not actually built until “several months after the complaint was filed.” Appx64.

Apple raised these points in its petition for review to the Commission. *See* Appx23640-23652; *see also* Appx25252-25260. The Commission in turn asked the parties to brief what “evidence and argument ... presented to the ALJ that

shows that [Masimo] w[as] developing, as of the filing of the Complaint, the Masimo Watch and that the Masimo Watch would practice” the patents-in-suit. Appx24314. But the Commission’s ultimate ruling included no analysis regarding the technical prong. Rather than enforce the actual article requirement—or explain why it was permissible for Masimo to rely on a fictitious product in its complaint—it left the ALJ’s erroneous decision in place without a word. *See* Appx374. Even in front of this Court, the Commission’s attorneys have not identified a single precedent where the Commission has claimed the authority to wield its powers when the complainant admits that the purported “article” identified in its complaint never existed. *See* C.A. Dkt. 23 at 4-8. For good reason: the statute only grants the Commission authority to investigate an “alleged violation” that has already occurred, not one that never happened.

2. The Commission exceeded its statutory authority by holding that the technical prong was satisfied based on circumstantial evidence that a patent-practicing article existed at the time of the complaint

Although the ALJ could not identify any device that matched the purported article described in the complaint, the ALJ concluded that five other items (the RevA sensor, the RevD sensor, and three RevE sensors) satisfied the technical prong (i.e., qualified as “articles protected by claims of the Poeze patents”). Appx88.

Even for those items, however, Masimo failed to offer any direct evidence that they could practice the asserted claims at the time the complaint was filed. Rather, the ALJ asserted that “*circumstantial evidence*” showed that “prototype devices with designs that are *consistent with* the asserted domestic industry products”—i.e., *not* the specific RevA, RevD, and RevE items that Masimo identified or produced during discovery—“were operational before the filing of the complaint and subject to testing.” Appx89 n.22. The ALJ also acknowledged that little, if any, evidence existed that the actual RevA, RevD, or RevE items offered into evidence could measure blood oxygen saturation before the complaint—again relying on circumstantial evidence to speculate that they could measure blood oxygen as the claims require. Appx66-67.

“Mere speculation is not substantial evidence.” *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382 (Fed. Cir. 2019). If a patent-practicing physical article actually existed at the time of the complaint, the Commission should not have needed to resort to circumstantial evidence and speculative inferences—especially where all evidence about the supposed article was within Masimo’s possession. Apple is not aware of any case where this Court has found the actual article requirement satisfied by such speculation. For good reason—the inquiry is a yes/no question. The technical prong is satisfied only when an industry “relating to the articles protected by the patent ... *exists*.” 19 U.S.C. § 1337(a)(2); *accord*

Microsoft, 117 F.3d at 1362. If the best evidence a complainant can muster is that a qualifying article *might* have existed, it is merely inviting speculation, which necessarily does not meet its burden. Simply put, the respondent, the Commission, and this Court should be able to *see* the claimed domestic industry article.

3. At a bare minimum, the Commission’s technical prong finding was not supported by substantial evidence

Even if Masimo could theoretically prevail by relying on an “article” not identified in its complaint that no one can be certain existed before the complaint, the evidence Masimo presented did not come close to satisfying even this weakened standard. There is no non-speculative evidence in the record that (1) four of the five items the ALJ relied on existed when the complaint was filed or (2) *any* item practiced the asserted claims.

a. The only theoretically viable “article” is RevA, as all other items were not shown to exist before the filing of the complaint

While the ALJ rightly ignored evidence regarding the W1 because “this product [was] made in December 2021, several months after the complaint was filed,” the ALJ (and the Commission) erred by considering other alleged articles that similarly post-dated Masimo’s complaint.¹³

¹³ The Commission has occasionally considered post-complaint evidence. *See Certain Televisions, Remote Controls, and Components Thereof*, Inv. No. 337-TA-1263, Comm’n Op., 2022 WL 17486245, at *13 (ITC Nov. 30, 2022). While this

Of the five purported “articles” relied on—RevA, RevD, and three separate RevE devices—four were not shown to exist when the complaint was filed. The Commission granted Masimo a filing date of July 12, 2021. Appx361 n.1. Masimo’s Director of Sensor Design testified the RevD sensor runs software that did not exist until **July 30**, 2021, weeks after the complaint was filed. Appx40553-40554(459:4-460:7). Without software, the RevD item was not operational at all and could not have practiced the asserted patents (e.g., it could not measure any physiological parameters). Appx40554(460:8-12). The same Masimo engineer likewise confirmed one of the RevE sensors (CPX-0020C (Appx65016-65017)) “was created in **September** 2021,” more than two months after the complaint was filed. Appx89; Appx40552-40553(458:1-459:3). The best Masimo could muster on the remaining two RevE sensors (CPX-0019C (Appx65014-65015) and CPX-0065C (Appx65032-65033)) was that they were created sometime “**between** May and September” of 2021. Appx89; Appx40492(398:20-23). Because Masimo had the burden to establish the existence of a patent-practicing article at the time of the complaint, *see supra* p. 25, a showing that two of the alleged articles *could have* been created before the complaint is logically insufficient to prove that they were.

rule is impossible to square with the plain language of Section 337, *see supra* p. 25, the Commission’s decision disclaimed reliance on post-complaint evidence in this case, Appx426.

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In any event, these two RevE sensors were indisputably altered after the complaint when they were loaded with their current software in *October* 2021. Appx89 n.23; Appx70511-70513.

b. The RevA device was neither user-worn nor configured to detect oxygen saturation

The RevA (CPX-0052) is the only one of the five purported articles that arguably existed in its produced form at the time the complaint was filed. *See* Appx64 (ALJ finding the RevA was built in November 2020). But there was no evidence that RevA practiced the asserted claims.

First, Masimo produced no evidence the RevA was “user-worn”—a requirement of all remaining live claims, *see infra* p. 10. To the contrary, the RevA lacked even a strap, or any other means to allow a user to wear the device.

Masimo CBI



Appx65024-65025. Because the device “do[es] not have [a] strap,” Appx68, it indisputably could not have been worn by a user, and there was no basis to conclude that it practiced any asserted patent.

While the ALJ found RevA satisfied the “user-worn” limitation because the item has “*attachment mechanisms* for a strap,” Appx68, the fact that an item *could* theoretically have been modified in a way that allowed it to be attached to a user does not make it “user-worn,” *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1262 (Fed. Cir. 2013) (“a device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim”). No one would call a smartphone “user worn” merely because it *could be* attached to a strap and worn around the arm.

The ALJ also relied on vague testimony from Masimo witnesses that the RevA had straps “at one point in time,” and that *other* “RevA” devices were used in certain tests in 2020 and 2021 suggesting they were “user-worn.” Appx68. But there is no reliable basis on which to conclude evidence of one “RevA” device is indicative of another. To the contrary, Masimo conceded not all “RevA” sensors were created equal. *See infra* p. 35.

Second, RevA was not configured to measure blood oxygen—another requirement of all remaining claims. *See* Appx704(46:22-24); Appx705(47:13-16); Appx815(45:45-47, 46:15-16, 34-36, 45-48). The only meaningful evidence regarding the RevA item’s functionality came from Apple’s experts, both of whom testified that—based on a demonstration from one of Masimo’s employees—the item was *not* shown to be measuring physiological parameters (like blood oxygen

or pulse rate). Appx41351-41353(1254:4-1256:1); Appx41355(1258:9-25); Appx41218-41220(1122:3-1124:23). Rather, RevA reported (1) alleged pulse rates ranging from 52 to 140 within a short period of time, notwithstanding that the subject was seated and stationary, and (2) purported blood oxygen measurements of 100 percent—which Apple’s expert and Masimo’s engineer confirmed the device is capped to display if “it didn’t know what else to report.” Appx41218-41220(1122:3-1124:23); Appx41351-41353(1254:4-1256:1); Appx70949 (citing RX-0265C-RX-0270C); Appx40543-40544(449:13-450:9); Appx40541-40546(447:12-452:14); Appx70956. Masimo, in contrast, made no attempt to show live at the hearing or through recorded demonstrations that RevA met this requirement—it did not even introduce any source code for the device. It cannot be the case that such an item satisfied Masimo’s obligation to identify an article that practices the patents.

Rather than address Apple’s evidence regarding the capabilities of the specific RevA item at issue (or Masimo’s lack of evidence), the ALJ relied on “internal testing” by Masimo using “prototype designs *consistent with* the RevA sensor.” Appx66-67. To be clear, Masimo identified numerous articles during discovery that purportedly included “RevA” sensors, several of which were admittedly *not* operable when the complaint was filed. Appx70518-70559 (identifying CPX-0053C and CPX-0055C as “RevA” devices); Appx70489

(describing CPX-0053C and CPX-0055C (MASITC_P_53 and MASITC_P_55) as “not operational as of the Filing Date of the Amended Complaint”). In any event, testimony about other “RevA” sensors (or other items that were similar in some way to the specific RevA item at issue here) says nothing about the RevA item labeled as CPX-0052—the item on which Masimo relied to show possession of a patent-practicing article at the time of the complaint. The ALJ’s decision acknowledged as much, noting that the only evidence linking the testing to the specific RevA proffered (or any of the other four purported articles) was the fact that the blood oxygen testing described by one Masimo employee *happened* to occur around the same time as those items were purportedly being developed. Appx67 n.16. Neither the ALJ nor the Commission has identified a case where such a slender reed has satisfied the actual article requirement. *See, e.g.*, C.A. Dkt. 23 at 4-8.

c. Even if the non-RevA articles had existed at the time of the complaint, Masimo likewise did not prove that they would have practiced the asserted claims

Even if RevD and the three RevE items had existed at the time of the complaint (and they did not, *supra* pp. 31-33), none of those items would have practiced the asserted claims. *First*, no substantial evidence supports a finding that RevD was user worn; the ALJ expressly found RevD “do[es] not have [a] strap[.]” Appx68. The ALJ found the “user-worn” limitation satisfied based only on the

same facially insufficient testimony and descriptions of testing of *other* devices discussed above in the context of RevA. *See supra* pp. 33-34. *Second*, no substantial evidence supports the ALJ's conclusion (Appx66-68) that RevD and RevE devices measure blood oxygen. Again, the ALJ's finding rested on the same "circumstantial" evidence of "*other* prototype Masimo Watch devices," not the actual articles proffered. *See supra* pp. 34-36. But for such circumstantial evidence to be probative, there would need to be evidence suggesting the operation of one sensor is properly correlated with another. No such evidence was presented. If all "RevE" items were created equal, for example, there would have been no need for Masimo to rely on *three* different units in an attempt to meet its burden to show *one* patent-practicing article.

B. The Commission Committed Legal Error By Holding That Masimo Satisfied The Economic Prong

1. The Commission ignored the statutory command to consider only investments made "with respect to the articles protected by the patent"

As relevant here, Section 337 limits the Commission's jurisdiction to those cases where the moving party has demonstrated "significant" investment "in the United States, *with respect to the articles protected by the patent.*" 19 U.S.C.

§ 1337(a)(3)(B).¹⁴ Congress’s instruction is clear—the only investments that count under the economic prong are those made to support the same domestic industry “article” that satisfies the technical prong. This Court recognized as much in *Microsoft*; it was “not enough” that Microsoft had made substantial investments in an item *related* and important to the patent-practicing article (e.g., its operating system) because the operating system standing alone did not actually practice the claimed invention. 731 F.3d at 1361; accord *InterDigital Communications, LLC v. ITC*, 707 F.3d 1295, 1297 (Fed. Cir. 2013) (“‘[T]he significant employment of labor or capital’ that is required to show the existence of a domestic industry must exist ‘with respect to the articles protected by the patent.’”). The Commission itself reached a similar result just two years ago, holding a patentee cannot meet its economic prong burden by “aggregating investments in different domestic products that practice different patents.” *Certain Electronic Stud Finders*, Inv. No. 337-TA-1221, Comm’n Op., 2022 WL 834280, at *28 (ITC Mar. 14, 2022).

Here, Masimo purported to meet its burden by relying on its employment and capital expenditures in making over a half-dozen prototypes of the W1. See Appx314-315; Appx53491; Appx53497; Appx53499. But the only supposed

¹⁴ Section 337(a)(3) provides three ways to satisfy the economic prong. The ALJ relied only on (a)(3)(B)—i.e., “significant employment of labor or capital” “with respect to the articles protected by the patent.” See Appx324.

“article” identified in the complaint (the “Masimo Watch”) never existed. *See supra* pp. 13, 28. Accordingly, Masimo could not possibly show that it had made a significant investment in that item by relying on money spent on *other* prototypes.

Moreover, Masimo should not have prevailed even had it shown that the RevA, RevD, and three RevE items were cognizable “articles.” This is because it exceeded its statutory authority under Section 337 (and violated *Microsoft* and *Stud Finders*) by relying on the expenditures for at least two *other* devices (“Circle” and Wings”) that undisputedly do not practice the Poeze patents to show investments “with respect to articles protected by the patent.” *Cf.* Appx309 (ALJ noting “[c]omplainants have not asserted that the Circle sensor or the Wings sensor practice claims of the Poeze patents”).

The ALJ (and by extension, the Commission) permitted this legally erroneous approach in light of testimony from Masimo’s CFO that “Masimo’s financial records did not track expenditures at” a sufficient level of detail to separate out Circles/Wings from the other purported articles. Appx308. But Masimo cannot reasonably be excused from meeting its statutory burden to satisfy the economic prong because it failed to maintain detailed records.

The ALJ also reasoned that Wings’ and Circle’s expenditures could be counted because they were part of a single “product design that was continuously developed in the years leading up to the filing of the complaint” and other items in

that product line did practice the patents. Appx308. But this distinction too makes little sense, as Wings/Circles were at least distinct enough from the other supposed articles that they concededly did not map on to the same patents. If Section 337's requirement that the patentee must demonstrate an investment "with respect to the articles protected by the patent" has any force, it must be to draw the line between investments in physical devices that practice the patent and those that do not.

2. The Commission failed to enforce the statutory requirement that labor and capital investment in the "article" must be "significant"

Masimo separately failed in its obligation to prove that "*significant* employment of labor or capital [was]" expended on the purported "Masimo Watch." *See* 19 U.S.C. § 1337(a)(2)(B); *InterDigital*, 707 F.3d at 1298. This Court has interpreted that language to require a "quantitative analysis in order to determine whether there has been" an "increase in quantity" in expenditures "by virtue of the claimant's asserted commercial activity in the United States." *Lelo v. ITC*, 786 F.3d 879, 883 (Fed. Cir. 2015). The complainant cannot meet this requirement by relying on "generic" numbers—it must concretely identify, for example, "the magnitude of labor expended to produce" the article. *Id.* at 884-885 (reversing finding of domestic industry where "there is an absence of evidence that connects [] cost[s] ... to an increase of investment or employment in the United States").

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Here, the ALJ rejected nearly all of Masimo's evidence of expenditures, finding only that the economic prong was satisfied based on **Masimo CBI** in alleged domestic labor and capital expenses. *E.g.*, Appx322. The only documents in the record that supported these purported expenditures were three post-hoc spreadsheets (Appx53491, Appx53497, Appx53499), all apparently prepared by the same Masimo personnel using an unexplained methodology (Appx40579-40580(485:20-25, 486:8-15)).

Those self-serving documents do not support "significant investment" even when assessed under the substantial evidence standard, as they appear to lack any basis in reality. Specifically, the spreadsheets calculated alleged labor costs by multiplying individual employee salaries by a wholly invented percentage supposedly representing the amount of time that each employee spent working on "Masimo Watch." *See* Appx53491, Appx53497, Appx53499. Thus, for example, when calculating executive labor, Masimo's spreadsheets assumed that each of nine executives devoted precisely the same percentage of their time (e.g., **Masimo CBI** **Masimo CBI**) to the Masimo Watch project for each of six quarters, Q3 2019 through Q1 2021. *See* Appx53492.

Masimo did not produce any contemporaneous documents such as time sheets or other employment records to support these percentages. Masimo's CFO testified that he had not prepared any of the data compilations Masimo relied upon,

and was “not aware of any criteria ... used to make the[] time estimates.”

Appx40613-40614(519:21-520:7). Even Masimo’s economic expert admitted that he did not independently verify Masimo’s data. Appx40653(559:12-19); Appx40660(566:14-17).

The ALJ brushed aside the unexplained spreadsheets on the grounds that “[a] *precise accounting is not necessary*” to satisfy the economic prong analysis and that Masimo simply failed to maintain more “detailed information” in its “financial records.” Appx317. But that forgiving approach suffers from the same basic flaws as the ALJ’s decision to aggregate expenditures—it rewards bad (or non-existent) bookkeeping and undermines Congress’ requirement that the patentee demonstrate the existence of significant investment in labor and capital. *See supra* pp. 39-40. While “a precise accounting” may not be necessary, *some* accounting should be. Having chosen to calculate its labor expenditures using a post-hoc time-based allocation, Masimo cannot rely on a *lack* of records to demonstrate the reliability of that allocation. *See Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm’n Op. at 38-46 (ITC Aug. 1, 2007) (excluding unreliable figures from economic prong calculations).

C. Allowing The Commission’s Decision To Stand Upsets The Statute’s Careful Balance and Gives Patentees Unprecedented Access To The Commission’s Extraordinary Powers

The Commission is an attractive forum for patentees because, *inter alia*, it is easier for a patentee to obtain a permanent injunction there than in federal court. The agency does not require the showing of irreparable harm that the Supreme Court required in *eBay v. MercExchange* for Article III proceedings. *See Spansion v. ITC*, 629 F.3d 1331, 1358 (Fed. Cir. 2010). In addition, a patentee risks very little by pursuing an investigation in front of the Commission, as the Commission’s rulings on patent issues (e.g., invalidity) have no preclusive effect in other forums. *See Texas Instruments v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996). This presents “a highly exploitable opportunity for [patentees] with a relatively weak case ... since they have the option to potentially go to court twice, or litigate in both courts simultaneously, over the same issue.” Duescher, Note, *Controlling the Patent Trolls*, 96 J. Pat. & Trademark Off. Soc’y 614, 618-619 (2014).

The domestic industry requirement is a necessary bulwark against abuse of the Commission’s powers. It serves the essential role of protecting “the purpose of the Commission [which] is to adjudicate trade disputes between U.S. industries and those who seek to import goods from abroad.” *John Mezzalingua*, 660 F.3d at 1327-1328; *see also* Chien, *Protecting Domestic Industries at the ITC*, 28 Santa

Clara Computer & High Tech L.J. 169, 177-178 (2011) (technical prong “underscores Congress’ interest in preventing unfair competition between domestic and foreign suppliers of the specified article”). Unless that requirement is scrupulously enforced, any entity that holds a U.S. patent—whether it be a non-practicing entity, a foreign government, or an opportunistic manufacturer looking to gain a foothold in a new market—can take a gamble at invoking the Commission’s extraordinary powers (for example, asserting 103 weak patent claims) with minimal negative downside.

The Commission failed to police the domestic industry boundary line. Unless this Court steps in, Congress’s statutory scheme will be vitiated. Indeed, if the Commission is no longer serving its critical role of protecting “an industry in the United States,” 19 U.S.C. § 1337(a)(2), the Commission’s resolution of patent-infringement disputes without a jury would likely violate the Seventh Amendment. *See Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 584 U.S. 325, 344 (2018) (reserving ruling on whether “infringement actions[] can be heard in a non-Article III forum”).¹⁵

¹⁵ Apple reserves the right to raise this—and other constitutional challenges—directly at a future point in this litigation.

III. THE COMMISSION ERRED BY CONCLUDING THAT THE ASSERTED CLAIMS ARE NOT INVALID

A. The Disputed Limitations Of The '648 And '502 Patents Are Obvious In Light Of Lumidigm

The Commission's holding that the five remaining claims (out of 103 claims originally asserted) were not invalid as obvious rested on two grounds, both of which disregarded the teachings of the "Lumidigm" prior art reference.

Specifically, the Commission erred in (1) requiring Lumidigm to enable more than the patents and (2) holding that Lumidigm does not teach the use of windows/transparent material that cover or are within openings positioned over photodiodes (the "windows" limitation).

1. The Commission erred by requiring the prior art to enable more than the patents disclose themselves

The ALJ (and, by extension the Commission) erred by holding that Lumidigm did not render obvious claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent, all of which claim the use of a "user-worn" device configured to measure the user's oxygen saturation. Appx119-123; Appx382 (adopting ALJ's ruling without modification). The ALJ reasoned that Lumidigm did not satisfy the "user-worn" limitation because it allegedly did not enable taking a blood oxygen measurement *at the wrist*. *E.g.*, Appx122. But no asserted claim requires taking a measurement at the wrist—nor could it, as the specification makes no such disclosure. The ALJ committed legal error by

requiring Lumidigm to render obvious *more* than the asserted patents disclose or the asserted claims require.¹⁶

When the asserted claims describe a wide range of embodiments (here, “user-worn devices”), a prior art reference invalidates the claims so long as it discloses and enables even a single embodiment. *See, e.g., Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001); *In re Theresa*, 720 F. App’x 634, 637 (Fed. Cir. 2018). Thus, for example, if a claim describes marking a label with “pre-set words or pre-set symbols,” it can be obvious in light of prior art that “disclosed the use of pre-determined words ... even without a reference to symbols.” *Theresa*, 720 F. App’x at 637. Similarly, a claim that generally describes “titanium base alloys” is anticipated by prior art that discloses a single type of alloy. *See Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985).

By contrast, “[a] patentee who chooses broad claim language must make sure the broad claims are fully enabled,” meaning that a patent claim is invalid if it does not provide enough detail to enable all embodiments. *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). This requirement ensures that “the

¹⁶ The Commission’s counsel’s opposition to Apple’s motion for a stay pending appeal incorrectly asserted this argument was waived. There was no way to know the ALJ would make this error prior to her decision, and Apple raised the issue promptly in its petition to the Commission. *See Appx23629-23634*. The Commission’s decision itself made no finding of waiver.

public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.” *Id.* Thus, for example, if the asserted claims purport to cover a method for integrating user images into both movies and video games, the underlying patent must provide enough detail to permit that technique to be used in both movies and video games. *Id.*

Taking these two legal principles together, it cannot be the case that a party seeking to establish invalidity must show that a prior art reference discloses more than the patent-at-issue. Such a rule would mean that a patent is granted greater protection if it uses generic claim language to claim a broadly worded invention without explaining how a skilled artisan can reproduce that invention. *See Sitrick*, 516 F.3d at 999 (“Enabling the full scope of each claim is ‘part of the quid pro quo of the patent bargain.’”). This Court has accordingly rejected the argument that an obviousness reference is not enabling when the patent owner “did not provide the type of detail in his specification that he now argues is necessary in prior art references.” *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994); *accord In re Paulsen*, 30 F.3d 1475, 1481 n.9 (Fed. Cir. 1994) (rejecting argument that prior art was not enabling where “under the enablement standard that AST would have us apply to Yokoyama, the ’456 patent itself would be non-enabling”).

Here, the ALJ’s invalidity ruling is directly contrary to cases like *Sitrick*, *Epstein*, and *Paulsen*. Specifically, although the ALJ found Lumidigm

“contemplate[d] blood oxygen measurement in a wristwatch as one implementation,” the ALJ held the asserted claims not obvious because “the evidence of record fail[ed] to show that one of ordinary skill would have been enabled to measure oxygen saturation in the Lumidigm wristwatch.” *E.g.*, Appx119-120. In so ruling, the ALJ went out of her way to emphasize the “significant difficulty of performing pulse oximetry at the wrist” in particular. Appx120-122.

However, none of Masimo’s asserted claims recites or requires taking a measurement at the wrist—nor could they, since the specification does not disclose or describe such a measurement. This is unsurprising, as the device pictured in the specification is a finger-clip sensor. *See supra* p. 9. Indeed, Masimo’s CEO testified that Masimo “did not have feasibility” to make a device that could measure blood oxygen at the wrist (due to issues with power consumption) “until maybe 2016, 2017”—eight years after the July 2008 priority date. *See* Appx40243(150:3-12); Appx40240-40241(147:21-148:2); Appx40207(114:13-19).

If the Commission had followed this Court’s precedent, Apple should have prevailed on the “user-worn” limitation so long as it could show the wearable Lumidigm device could take a blood oxygen measurement anywhere on the body. That is precisely what the ALJ found—Lumidigm discloses “measurements of ‘oxygenation and/or hemoglobin levels in the blood,’ and states that such

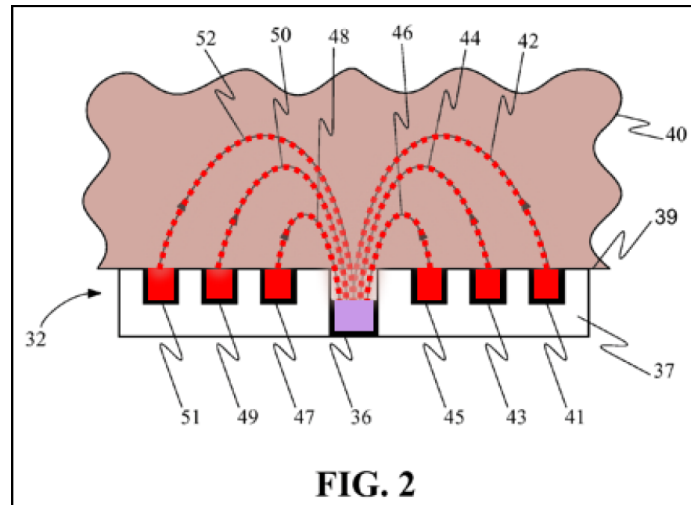
functionalities are ‘especially suitable when the biometric sensor is comprised by a portable device, such as a portable electronic device.’” Appx119 (quoting Appx70417-70418(17:64-18:2, 19:18-28)).

Here, the evidence established that Lumidigm’s sensor can be incorporated into any “portable electronic device.” Appx70401-70406(Figs. 8A-E, Fig. 9); Appx70410(3:35-37); Appx70414-70415(11:60-12:2, 12:56-13:14); Appx41302-41303(1205:12-1206:7); Appx41248(1152:4-24). The ALJ further, and rightly, found that the disclosed pulse oximetry functionality was “clearly applicable to the user-worn wristwatch” embodiment. Appx95. Given this express disclosure of a wrist-worn device for taking an oxygen saturation measurement, Lumidigm is *presumed* to enable pulse oximetry on the wrist. *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008). The ALJ erred in finding this presumption overcome where unrebutted expert testimony confirmed a person of ordinary skill “would not have needed any additional information to make [pulse oximetry functionality] work” on the wrist. Appx41313. In any event, nothing in Lumidigm suggests that the wristwatch embodiment could not be worn elsewhere on the body (e.g., upper arm or ankle); if Lumidigm’s wristwatch could measure blood oxygen *anywhere* on the body (it could), it would disclose (and enable) the claimed subject matter. Had the Commission followed *Stirick*, *Epstein*, and *Paulsen*, it could not have ruled in Masimo’s favor on this issue.

2. Lumidigm renders obvious transmissive windows extending across openings and within openings

Each asserted claim describes a user-worn device with “transmissive windows” or “optically transparent material” arranged across or within openings positioned over photodiodes such that the openings are covered with the transparent material. Appx704(46:38-39, 46:51-54) (’502 patent, claim 22); Appx705(48:1-3) (claim 28); Appx815(45:63-64, 46:15-16) (’648 patent, claim 12); Appx815(46:42-45, 46:59-61) (claim 24); Appx816(47:6-7) (claim 30). The Commission erred by holding that Lumidigm did not render obvious “transmissive windows” or “optically transparent material” (a) *extending* across openings (a limitation that appeared in all asserted claims except claim 22) or (b) *within* each opening (a limitation that appears only in claim 22).

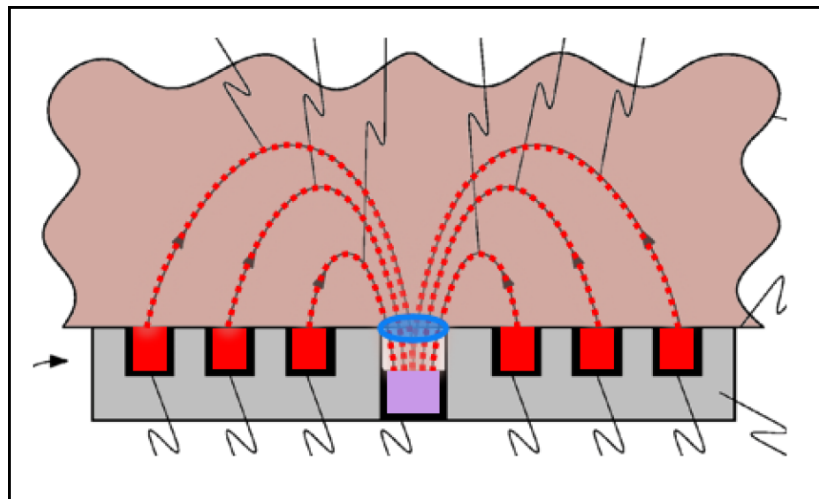
As background, Lumidigm is directed to a device with “multiple light sources, a light detector, and a processor configured to operate the light sources and light detector to perform distinct functions,” including a “biometric identification function.” Appx70389(Abstract). As shown in Figure 2 below, Lumidigm discloses holes or openings housing its light detectors (annotated in purple in the agency record). *See also* Appx70412(8:2-3) (noting light detectors are “recessed from the sensor surface 39 in optically opaque material”).



Appx70867.

Lumidigm further explains that its sensor can incorporate “an optical relay (not shown) between the sensor surface 39 and the skin 40” that “transfers the light ... from the skin back to the detector(s),” and that this optical relay can include “fiber-optic face plates,” “individual optical fibers,” and “fiber bundles.”

Appx70412(8:19-26). Figure 2 below was annotated to depict the described optical relay in blue:



Appx70876.

Based on the foregoing, the ALJ rightly concluded that “Lumidigm clearly discloses an ‘optical relay’ that is transmissive and is positioned above an opening for a detector.” Appx136. As a result of this finding, the ALJ concluded that Lumidigm satisfied the “windows” limitation for claim 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent. Appx388-389. The Commission disagreed, concluding that Lumidigm did not render obvious transparent material “extended across” or “arranged over” openings. Appx394-398. Specifically, the Commission concluded Lumidigm did not teach a skilled artisan to use “separate” windows over each opening (as opposed to using a single window to cover the entire surface). Appx396. Put slightly differently, the Commission held that while the prior art may have rendered obvious one window for one opening, separate windows for separate openings would not have been obvious.

The Commission’s analysis violates *KSR*. While the specific example described in Figure 2 involved a single photodetector in a single cavity with a single optical relay, Lumidigm discloses other embodiments with multiple detectors and cavities. Appx70395-70400(Figs. 3-7B); Appx70413(9:12-45). Lumidigm further discloses that its optical relays can consist of “fiber-optic face *plates*,” Appx70412(8:19-26). Apple’s expert (Dr. Warren) testified—without contradiction—that the face plate could be implemented as either (1) a single face

plate or (2) individual face plates over each opening. *See* Appx41318-41319(1221:16-1222:2) (“[A] person of skill would know that you could do an individual faceplate for each of the individual openings.”); Appx41318(1221:19-21) (use of a separate window within each opening was “quite well-known”). Because the evidence showed that only a small number of alternatives (two) were known in the art to solve the design problem of how to cover multiple openings and a skilled artisan would know how to implement them, both alternatives are obvious. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007); *see also Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1341 (Fed. Cir. 2020) (finding obviousness where there were “two known, finite, predictable solutions for solving the same problem”). Notably, Masimo’s expert did not dispute that only a limited number of possible variations existed when discussing the “windows” limitation. *See generally* Appx41427-41443(1329:14-1346:2). Although Apple raised the *KSR* issue, the Commission’s final decision failed to address it. *See CFRD Research, Inc. v. Matal*, 876 F.3d 1330, 1347-1349 (Fed. Cir. 2017) (agency failed to “perform a proper obviousness analysis” where it failed to consider the fact that there “were two predictable choices” that could have been employed to solve a particular design problem).¹⁷

¹⁷ In opposing Apple’s motion for a stay pending appeal, both Masimo and the Commission erroneously suggested that the *KSR* argument was not presented

Finally, the Commission separately erred by affirming the ALJ's conclusion that Lumidigm did not render obvious claim 22 of the '502 patent's requirement that there be "optically transparent material within each of the openings." Appx394; *see also* Appx128. As Apple's expert testified, "[t]he notion of an optically transparent material is ... quite well-known where the material is *in each* of the openings." Appx41291(1194:1-7); Appx41318(1221:19-21); Appx41319(1222:3-9). A skilled artisan would have understood that an optical relay—particularly if it were in the form of "fiber bundle[s]"—could be placed within the openings and used to "essentially direct the light from a portion of the tissue straight to the detector as a means to optimize the detection process." Appx41318-41319(1221:16-1222:25). Neither the ALJ nor the Commission substantively addressed Dr. Warren's testimony on this point. Nor can the Commission retroactively address this error on appeal, as "[a]n agency must defend its actions based on the reasons it gave when it acted." *DHS*, 140 S. Ct. at 1907, 1910.

below. When Masimo challenged the ALJ's ruling on the "windows" limitation, Apple timely explained that the ruling comported with *KSR* in its response to Masimo's petition. Appx24099-24100.

B. The Remaining Claims Lack Sufficient Written Description Support

1. The ALJ erred by mixing-and-matching unlinked elements to find multiple LEDs, four photodiodes, protrusions with “Openings” or “Holes,” and opaque materials (all claims)

The ALJ’s decision (which the Commission adopted without modification) contained a sweeping, legal error that affected all relevant claims—it found the written description requirement satisfied only by linking together unrelated elements from different embodiments. This Frankenstein-like approach cannot be squared with this Court’s rule that the written description requirement is not satisfied by an “amalgam of disclosures plucked selectively from the [original] application.” *Novozymes A/S v. Dupont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013). Rather, a valid patent’s “specification must present each claim as an ‘integrated whole,’” *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, at *3 (Fed. Cir. July 14, 2021), so that a reader of the original application with “no foreknowledge” of the later claims would still understand their scope, *Novozymes*, 723 F.3d at 1349.

Here, the five remaining claims require (a) sets of LEDs, each with multiple LEDs (Appx704-705(46:51-54, 47:14-48:24)); Appx815(46:15-16)), or multiple LEDs (Appx815-816(46:59-61, 47:6-7)); (b) four photodiodes; and (c) a protrusion with a plurality of “openings” or “holes” positioned or arranged over the photodiodes, Appx161-162. All but claim 30 of the ’648 patent require that the

protrusion must either (1) have “openings” lined with or defined by an opaque material or (2) include an opaque material. Appx704-705(46:51-54, 47:14-48:24); Appx815(46:15-16, 46:59-61). None of these unique combinations appears in the specification. *See* Appx41343-41345. Instead, the ALJ relied on elements taken from four separate embodiments. *See* Appx164-165 (citing Appx507 (Sensor 101 (Fig. 1)), Appx514 (Sensor 301A (Figure 3C)), Appx523 (Sensor 701 (Figure 7B)), and Appx540 (Process 1300 (Fig. 13))).

For example, only Sensor 301A discloses the four photodiodes with separate openings in a protrusion aligned over each photodiode required by each remaining claim. Appx163-164. Sensor 301A, however, does not disclose several other limitations, including (1) the number of emitters or LEDs; (2) a protrusion comprising opaque material; or (3) protrusion openings “lined with opaque material” or “defined by an opaque surface.” Accordingly, the ALJ was forced also to rely on Sensor 101’s disclosure of an emitter with three or more LEDs and Process 1300’s disclosure of an equal number of emitters and photodiodes. Appx164. And because none of those three embodiments disclosed opaque surfaces in the protrusion, the ALJ had to turn to a fourth embodiment—Sensor 701—that disclosed a protrusion and a separate “shielding enclosure 790b” beneath the protrusion. *See* Appx162-164 (citing Appx523 (Fig. 7B)).

Nothing in the specification teaches modifying Sensor 301A along the specific lines proposed by the ALJ. Instead, the ALJ relied on a single, generic line from the specification: “The features of the sensors 701 can be implemented with any of the sensors 101, 201, 301 described above,” Appx163-164 (quoting Appx584(26:25-26)). This, of course, says nothing about how Sensor 101 or Process 1300 interacts with Sensor 301A. It also does not provide any guidance about *how* Sensor 701 could be combined with 301A to produce a working pulse oximeter. Indeed, it provides no real guidance at all because the specification describes Sensors 101, 201, 301, and 701 having a galaxy of potential features, many with numerous possible variations. *See, e.g.,* Appx577-578(11:4-13:47)].

At most, the single sentence the ALJ identified would allow the reader to “work[] backward from a knowledge of the claims” to find written description support. *Novozymes*, 723 F.3d at 1349. But while this backwards-looking approach makes “very clear what route one would travel through the forest of the specification to arrive at the claimed invention,” it is barred by this Court’s case law. *Id.*; accord *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (written description must sufficiently “convey to a person of skill in the art that the patentee had possession of the claimed invention *at the time of the application*”).

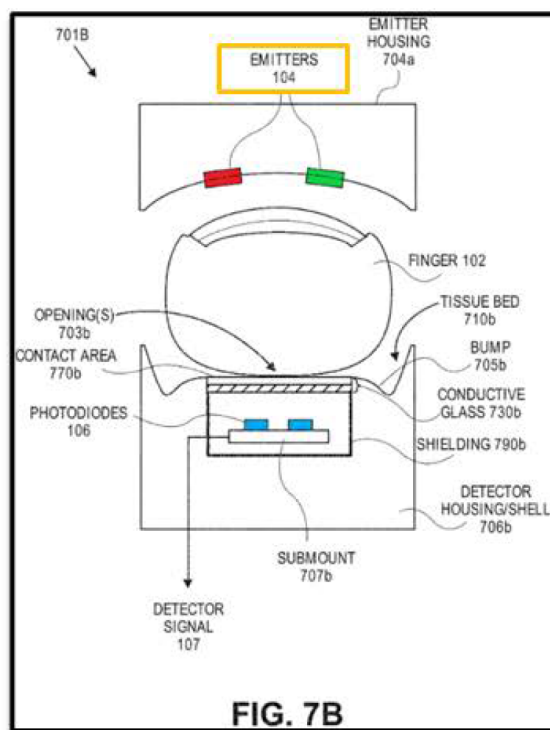
2. The specification does not disclose two sets of LEDs, each set emitting at the same two wavelengths ('502 patent, cl. 28; '648 patent, cl. 12)

The ALJ and Chairman Johanson's dissent rightly concluded that the Poeze specification failed to provide written description support for the limitations requiring two separate sets of LEDs, each set with a first LED "configured to emit light at a first wavelength" and a second LED "configured to emit light at a second wavelength." Appx168-169; *see also* Appx424-425 n.43. This is because, as the ALJ found, nothing in the specification clearly discloses "matching wavelengths between [the] sets of LEDs." Appx168-169; *see also* Appx41344(1247:13-17) (similar statement from Apple's expert).

The two-Commissioner majority came to a contrary result by relying on Figures 7A and 7B in the specification, which both feature an emitter (a set of LEDs) numbered 104. The majority reasoned that (1) "[t]he fact that the ... emitters share the number ... suggests that they are the same" and (2) if the two emitters are the same, "**they must** emit ... at the same two respective wavelengths." Appx421-422.

"The hallmark of written description is disclosure," *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1017 (Fed. Cir. 2022), and nothing in the specification states that the emitters 104 must be identical. To the contrary, as Chairman Johanson explained, "the specification and figures use 'emitters' as a

broad term for any light source of any frequency” and “element 104 is used inconsistently in the figures.” Appx424-425 n.43 (Chairman Johanson, dissenting) (citing Appx522-523(Figs. 7A, 7B)). For example, in Figure 7A, element 104 refers to two *different* “LEDs 104” emitting light in two *different* wavelengths. See Appx522(Fig. 7A). As Mr. Kiani (a named inventor) testified, pulse oximetry requires at least “using *two* wavelengths of light.” Appx40173; Appx40188; Appx40247; see also Appx70034; Appx70056-70057 (similar statement in prior art textbook)]. Even Dr. Madisetti distinguished the two “Emitters 104,” in Figure 7B, using different colors:



Appx65268.

IV. THE COMMISSION ONLY FOUND INFRINGEMENT BY CONSTRUING CLAIM TERMS CONTRARY TO THEIR ORDINARY MEANINGS

Masimo's apparent attempt to map the asserted claims onto the accused products was not a complete success, as there are several claim terms that simply do not describe Watch under any normal understanding of the English language. The ALJ (and by extension, the Commission) nonetheless found infringement by making several notable claim construction errors that contorted common words like "above," "over," and "through" in ways inconsistent with their plain meaning. And by unduly expanding the scope of these claim terms, they allowed Masimo to enforce patent rights that went far beyond the written description of the patents-in-suit.

First, the accused products do not infringe at least claims 22 and 28 of the '502 patent, and claims 24 and 30 of the '648 patent, because each claim requires a protrusion, openings, or holes situated "**over**" or "**above**" the "photodiodes" or "interior surface" of the device, when the device is "configured to" measure blood oxygen saturation. Appx23161; Appx704-705(46:22-44, 46:51-54, 47:14-48:23); Appx815-816(46:34-48, 46:59-61, 47:6-7).

There can be no dispute that the accused products are capable of measuring blood oxygen saturation **only** when Watch is "facing up"—i.e., when the alleged protrusion (the back crystal) is **under** or **below** the photodiodes. *See* Appx41 ("[t]here is no dispute regarding the orientation of the Accused Products"); *see also*

Appx41024-41025 (discussing Watch orientation); Appx50030 (same); Appx70322-70355 (same). Nor is there any dispute that every embodiment depicted in the shared specification has the opposite orientation—the protrusion is spatially positioned on top of or higher than the photodiodes. *See* Appx583(24:27-33).

The ALJ found only infringement by adopting an idiosyncratic and counterintuitive reading of “over” and “above”—*i.e.*, that (1) “over” means “an arrangement where one feature covers another—not the relative arrangement of these features in a vertical direction”; and (2) “above” “refers to a position relative to the device’s features and not to its orientation relative to the Earth.” Appx34-35; Appx46; Appx50-51.

The only evidence the ALJ relied on for her novel construction of “over,” however, was Masimo’s expert’s testimony referencing the term “bandage over a wound” and the ALJ’s personal views regarding the “common usage of the term” in related fields (e.g., a “mask over one’s mouth”). Appx34-35; Appx40796.

These strained extrinsic analogies refer to *tangible* objects (a bandage, mask, or filter) that cover other objects. The relevant claims address the *absence of material*—*i.e.*, “openings” and “holes” in the protrusion—oriented “over” and “above” photodiodes. *See, e.g.*, Appx704(46:51-54); Appx815(46:59-61). “Openings” and “holes” cannot *cover* anything. Similarly, the ALJ’s construction

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of “above” to vaguely mean “a position relative to the device’s features and not to its orientation relative to the Earth” is no construction at all; it does not answer what “relative” “position” is required.

Second, the accused products do not infringe any relevant claim, because they lack “openings ... through the protrusion” (Appx704(46:51-54); Appx705(47:14-48:24)) or “through holes” (Appx815(46:15-16, 59-61); Appx816(47:6-7)) in their final assembled form. The trial testimony established that the holes drilled into Watch’s backside are **Apple product information** — creating a continuous, uninterrupted surface. *E.g.*, Appx40997-40998.

The ALJ found infringement only by construing “openings” and “holes” to encompass “openings and holes that include material.” Appx36. But that ignores that the claim language requires “*through* holes” and “openings ... *through*” the protrusion. In normal parlance, the word “through” refers to something moving from one end of something to another. *See, e.g.*, Oxford English Dictionary Online (2024 ed.) (“From one end, side, or surface of (something) to another”). To use one of the ALJ’s own examples, a skylight may be an opening “*in* a roof after a glass window is installed,” but no ordinary English speaker would state that the glass skylight is an opening *through* the roof—that phrasing would suggest that the interior of the house is open to the elements. Neither Masimo, its expert nor

the ALJ explained how the ALJ's ultimate construction could be squared with the "through" limitation.

V. THE COMMISSION ERRED BY PERMITTING MASIMO TO ENFORCE THE ASSERTED CLAIMS DESPITE MASIMO'S UNREASONABLE, PREJUDICIAL DELAY IN PROSECUTION

As Apple explained in its petition for review, the ALJ erred in concluding that the doctrine of prosecution laches does not bar enforcement of the '648 and '502 patents. Appx23713-23714; *see also* Appx23692-23693. Laches applies when "(1) the patentee's delay in prosecution ... [is] unreasonable and inexcusable under the totality of circumstances" and "(2) the accused infringer ... suffered prejudice attributable to the delay." *Personalized Media*, 57 F.4th at 1354.

Masimo's conduct satisfies both conditions.

As to the first factor, Masimo delayed for twelve years in filing the asserted claims—with no reason for doing so other than strategic gamesmanship. Specifically, Masimo filed the original provisional applications to which the '502 and '648 patents claim priority in summer 2008, and continued to file related continuations and continuations-in-part until July 1, 2010. Appx597-598; Appx708-709. Masimo then lay in wait and did not file a new application in the chain for five years until December 2015—immediately following the release of the original Watch Series 0 in April 2015. Appx597-598; Appx708-709; Appx70001 (showing April 2015 release of Watch Series 0). Masimo

subsequently embarked on a pattern of filing new applications to track the launches of subsequent Apple releases. Appx597-598; Appx708-709; Appx70781 (September 2019 release date of Series 5 and September 2018 release date of Series 4); Appx40230-40231(137:15-138:10) (acknowledging Watch release dates). Ultimately, Masimo delayed until September 24, 2020—twelve years after the original provisional application, but only six days after the first of the accused products launched—to file the applications that became the '502 and '648 patents. Appx597; Appx708; Appx70356-70369 (September 2020 release of Series 6).

Neither Masimo's patent prosecution attorney nor CEO (and named inventor) offered any explanation for why the patent applications were not filed earlier. Appx41125-41126(1029:12-1030:17); Appx40246(153:16-23). The only apparent explanation is that Masimo intended to draft the claims only after reviewing Apple's products—an inference borne out by the fact that Masimo's prosecution attorney admitted that he had viewed “nonpublic teardowns of the Apple Watch Series 6 during prosecution” of the '502 and '648 patents.

Appx41127(1031:13-22). As Chairman Johanson noted, several asserted claims from 2020 “reach beyond any disclosure fairly described by the specification and figures” from 2008. Appx424-425 n.43. Such a lengthy, unjustifiable delay satisfies the first laches factor. *See, e.g., Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) (noting the

Supreme Court has applied doctrine of patent laches in cases “involv[ing] a nine-and-a-half-year delay and an eight-year delay”); *see also Sonos, Inc. v. Google LLC*, 2023 WL 6542320, at *16 (N.D. Cal. Oct. 6, 2023) (finding “inexcusable delay” prong met where patents-in-suit issued “over thirteen years after [the patentee] had filed the provisional application” and “well after [the purported infringer] had ... brought the claimed invention to the market”).

The ALJ (and, by extension, the Commission) found Masimo did not engage in unreasonable delay for two basic reasons. *First*, the ALJ placed heavy weight on the fact that this Court has not previously found laches on a similar set of facts. Appx178. But Masimo’s conduct resembles that of patentees in previous cases finding laches. *See Hyatt v. Hirshfeld*, 998 F.3d 1347, 1357 (Fed. Cir. 2021) (inventor “had delayed years and sometimes multiple decades after his alleged priority dates to submit claims”); *In re Bogese*, 303 F.3d 1362, 1369 (Fed. Cir. 2002) (affirming finding of laches where inventor “filed twelve continuation applications over an eight-year period”); *Hynix Semiconductor Inc. v. Rambus Inc.*, 2007 WL 4209386, at *4 (N.D. Cal. Nov. 26, 2007) (evidence that patentee “repeatedly delayed issuing its patents or informing others about them until the ... industry committed to making infringing products” and “was drafting its claims to cover technologies as they developed” supported laches). Moreover, this Court has never required a party to identify factually-identical precedent to prevail on an

equitable defense; rather, it has emphasized that tribunals should consider the “totality of circumstances” in concluding whether the patentee’s delay was unreasonable. *Symbol Techs.*, 422 F.3d at 1386. As explained, the facts here warrant a finding of undue delay.

Second, the ALJ believed that the mere fact that “there was continuous prosecution activity” in the intervening period between original provisional applications and the applications for the ’648 and ’502 patents weighed against laches. Appx177-178. But the ALJ did not identify any case that denied laches under similar facts, where the patentee’s delay was lengthy and inexplicable except as gamesmanship. Moreover, since the ALJ’s decision issued, more recent case law *has* found laches under comparable circumstances. *See Sonos*, 2023 WL 6542320, at *1-2, 11, 26-27 (laches where patentee relied on “a daisy chain of continuation applications” to claim priority to a thirteen-year-old application). Thus, contrary to the ALJ’s determination otherwise, Appx178, this is one of the “egregious cases of misuse of the statutory patent system” in which a finding of prosecution laches is appropriate. *Symbol Techs.*, 422 F.3d at 1385.

As to the second factor, even the ALJ did not deny that Apple suffered significant prejudice due to Masimo’s misconduct. A purported infringer can satisfy this factor by showing it “invested in, worked on, or used the claimed technology during the period of delay.” *Personalized Media*, 57 F.4th at 1357.

Between when the original provisional applications were filed in 2008 and the relevant applications were filed in 2020, Apple expended tremendous time and cost in developing Watch, and improving on the technology from generation to generation. Appx41019-41022(923:7-926:6); Appx41029-41030(933:12-934:10); Appx41050-41051(954:23-955:9); Appx41058-41062(962:15-966:7). But for Masimo’s actions, Apple could have gone in a different direction to avoid potential conflict with the asserted claims. This Court has refused to condone a strategy like Masimo’s—lying in wait until use of the allegedly patented technology “was engrained and widespread” before pulling the rug out from under unsuspecting manufacturers. *Personalized Media*, 57 F.4th at 1357.¹⁸

CONCLUSION

The Commission’s decision should be reversed or, at minimum, vacated and remanded.

¹⁸ In ruling on Apple’s request for a stay pending appeal, the Commission for the first time asserted that Apple has waived its laches defense by failing to adequately raise the issue in Apple’s petition for review. Appx27236-27237. But since neither the Commission’s nor the ALJ’s substantive rulings rested on this ground, this Court cannot rely on it. *DHS*, 140 S. Ct. at 1907. In any event, Apple *did* raise the issue in its petition. Appx23713-23714; *see also* Appx23692-23693.

Respectfully submitted,

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STATUTORY ADDENDUM

(Pursuant to Fed. R. App. P. 28(f))

19 U.S.C. § 1337. Unfair practices in import trade**(a) Unlawful activities; covered industries; definitions**

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

(A) Unfair methods of competition and unfair acts in the importation of articles (other than articles provided for in subparagraphs (B), (C), (D), and (E)) into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is—

(i) to destroy or substantially injure an industry in the United States;

(ii) to prevent the establishment of such an industry; or

(iii) to restrain or monopolize trade and commerce in the United States.

(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

(C) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that infringe a valid and enforceable United States trademark registered under the Trademark Act of 1946 [15 U.S.C. 1051 et seq.].

(D) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of a semiconductor chip product in a manner that constitutes infringement of a mask work registered under chapter 9 of title 17.

(E) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consigner, of an article that constitutes infringement of the exclusive rights in a design protected under chapter 13 of title 17.

(2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.

(3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned—

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

(4) For the purposes of this section, the phrase “owner, importer, or consignee” includes any agent of the owner, importer, or consignee.

(b) Investigation of violations by Commission

(1) The Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative. Upon commencing any such investigation, the Commission shall publish notice thereof in the Federal Register. The Commission shall conclude any such investigation and make its determination under this section at the earliest practicable time after the date of publication of notice of such investigation. To promote expeditious adjudication, the Commission shall, within 45 days after an investigation is initiated, establish a target date for its final determination.

(2) During the course of each investigation under this section, the Commission shall consult with, and seek advice and information from, the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and such other departments and agencies as it considers appropriate.

(3) Whenever, in the course of an investigation under this section, the Commission has reason to believe, based on information before it, that a matter, in whole or in part, may come within the purview of part II of subtitle IV of this chapter, it shall promptly notify the Secretary of Commerce so that such action may be taken as is otherwise authorized by such part II. If the Commission has reason to believe that the matter before it (A) is based solely on alleged acts and effects which are within the purview of section 1671 or 1673 of this title, or (B) relates to an alleged copyright infringement with respect to which action is prohibited by section 1008 of title 17, the Commission shall terminate, or not institute, any investigation into the matter. If the Commission has reason to believe the matter before it is based in part on alleged acts and effects which are within the purview of section 1671 or 1673 of this title, and in part on alleged acts and effects which may, independently from or in conjunction with those within the purview of such section, establish a basis for relief under this section, then it may institute or continue an investigation into the matter. If the Commission notifies the Secretary or the administering authority (as defined in section 1677(1) of this title) with respect to a matter under this paragraph, the Commission may suspend its investigation during the time the matter is before the Secretary or administering authority for final decision. Any final decision by the administering authority under section 1671 or 1673 of this title with respect to the matter within such section 1671 or 1673 of this title of which the Commission has notified the Secretary or administering authority shall be conclusive upon the Commission with respect to the issue of less-than-fair-value sales or subsidization and the matters necessary for such decision.

(c) Determinations; review

The Commission shall determine, with respect to each investigation conducted by it under this section, whether or not there is a violation of this section, except that the Commission may, by issuing a consent order or on the basis of an agreement between the private parties to the investigation, including an agreement to present the matter for arbitration, terminate any such investigation, in whole or in part, without making such a determination. Each determination under subsection (d) or (e) shall be made on the record after notice and opportunity for a hearing in conformity with the provisions of subchapter II of chapter 5 of title 5. All legal and equitable defenses may be presented in all cases. A respondent may raise any counterclaim in a manner prescribed by the Commission. Immediately after a counterclaim is received by the Commission, the respondent raising such counterclaim shall file a notice of removal with a United States district court in which venue for any of the counterclaims raised by the party would exist under section 1391 of title 28. Any counterclaim raised pursuant to this section shall relate back to the date of the original complaint in the proceeding before the Commission. Action on such counterclaim shall not delay or affect the proceeding under this section, including the legal and equitable defenses that may be raised under this subsection. Any person adversely affected by a final determination of the Commission under subsection (d), (e), (f), or (g) may appeal such determination, within 60 days after the determination becomes final, to the United States Court of Appeals for the Federal Circuit for review in accordance with chapter 7 of title 5. Notwithstanding the foregoing provisions of this subsection, Commission determinations under subsections (d), (e), (f), and (g) with respect to its findings on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the amount and nature of bond, or the appropriate remedy shall be reviewable in accordance with section 706 of title 5. Determinations by the Commission under subsections (e), (f), and (j) with respect to forfeiture of bonds and under subsection (h) with respect to the imposition of sanctions for abuse of discovery or abuse of process shall also be reviewable in accordance with section 706 of title 5.

* * *

(i) Forfeiture

(1) In addition to taking action under subsection (d), the Commission may issue an order providing that any article imported in violation of the provisions of this section be seized and forfeited to the United States if—

(A) the owner, importer, or consignee of the article previously attempted to import the article into the United States;

(B) the article was previously denied entry into the United States by reason of an order issued under subsection (d); and

(C) upon such previous denial of entry, the Secretary of the Treasury provided the owner, importer, or consignee of the article written notice of—

(i) such order, and

(ii) the seizure and forfeiture that would result from any further attempt to import the article into the United States.

(2) The Commission shall notify the Secretary of the Treasury of any order issued under this subsection and, upon receipt of such notice, the Secretary of the Treasury shall enforce such order in accordance with the provisions of this section.

(3) Upon the attempted entry of articles subject to an order issued under this subsection, the Secretary of the Treasury shall immediately notify all ports of entry of the attempted importation and shall identify the persons notified under paragraph (1)(C).

(4) The Secretary of the Treasury shall provide—

(A) the written notice described in paragraph (1)(C) to the owner, importer, or consignee of any article that is denied entry into the United States by reason of an order issued under subsection (d); and

(B) a copy of such written notice to the Commission.

(j) Referral to President

(1) If the Commission determines that there is a violation of this section, or that, for purposes of subsection (e), there is reason to believe that there is such a violation, it shall—

(A) publish such determination in the Federal Register, and

(B) transmit to the President a copy of such determination and the action taken under subsection (d), (e), (f), (g), or (i), with respect thereto, together with the record upon which such determination is based.

(2) If, before the close of the 60-day period beginning on the day after the day on which he receives a copy of such determination, the President, for policy reasons, disapproves such determination and notifies the Commission of his disapproval, then, effective on the date of such notice, such determination and the action taken under subsection (d), (e), (f), (g), or (i) with respect thereto shall have no force or effect.

(3) Subject to the provisions of paragraph (2), such determination shall, except for purposes of subsection (c), be effective upon publication thereof in the Federal Register, and the action taken under subsection (d), (e), (f), (g), or (i), with respect thereto shall be effective as provided in such subsections, except that articles directed to be excluded from entry under subsection (d) or subject to a cease and desist order under subsection (f) shall, until such determination becomes final, be entitled to entry under bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury. If the determination becomes final, the bond may be forfeited to the complainant. The Commission shall prescribe the terms and conditions under which bonds may be forfeited under this paragraph.

(4) If the President does not disapprove such determination within such 60-day period, or if he notifies the Commission before the close of such period that he approves such determination, then, for purposes of paragraph (3) and subsection (c) such determination shall become final on the day after the close of such period or the day on which the President notifies the Commission of his approval, as the case may be.

ADDENDUM

(Pursuant to Fed. Cir. R. 28(c))

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CONFIDENTIAL MATERIAL OMITTED

The material omitted from Addendum pages Appx9, Appx36, Appx41-44, Appx46-48, Appx108, Appx119, Appx121-122, Appx150-151, Appx153-154, Appx156-158, Appx187-190, Appx192-194, Appx196, Appx198, Appx218, Appx220-222, Appx265-276, and Appx373 contains confidential competitively sensitive product information subject to the Administrative Protective Order in effect in ITC Investigation No. 1276; the material omitted from Appx62, Appx67, Appx74, Appx176, Appx179, Appx205-206, Appx211, Appx278-286, Appx304-306, Appx309, Appx311-316, Appx318, Appx320-328, Appx332-340, Appx426-

427, and Appx473-474 contains information that complainants Masimo Corporation and Cercacor Laboratories, Inc. designated as Confidential Business Information under the Administrative Protective Order; and the material omitted from Appx404-405, Appx457, Appx460-461, and Appx464 contains confidential competitively sensitive financial and sales information subject to the Administrative Protective Order.

**CONTAINS CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO PROTECTIVE ORDER**

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS THEREOF**

Inv. No. 337-TA-1276

FINAL INITIAL DETERMINATION ON VIOLATION OF SECTION 337

Administrative Law Judge Monica Bhattacharyya

(January 10, 2023)

Appearances:

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Pursuant to the Notice of Investigation (EDIS Doc. ID 749538), 86 Fed. Reg. 46275-76 (Aug. 18, 2021), and Commission Rule 210.42, this is the administrative law judge's final initial determination on violation in the matter of *Certain Light-Based Physiological Measurement Devices and Components Thereof*, Commission Investigation No. 337-TA-1276. 19 C.F.R. § 210.42(a)(1)(i).

For the reasons discussed herein, it is the undersigned's final initial determination that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,945,648.

It is also the undersigned's final initial determination that there has been no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof with respect to U.S. Patent Nos. 10,912,501, U.S. Patent No. 10,912,502, U.S. Patent No. 10,687,745, and U.S. Patent No. 7,761,127.

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The following abbreviations may be used in this Initial Determination:

| | |
|-----------------|--|
| Tr. | Hearing Transcript |
| Dep. Tr. | Deposition Transcript |
| JX | Joint Exhibit |
| CX | Complainants' exhibit |
| CPX | Complainants' physical exhibit |
| CDX | Complainants' demonstrative exhibit |
| RX | Respondents' exhibit |
| RPX | Respondents' physical exhibit |
| RDX | Respondents' demonstrative exhibit |
| CPHB | Complainants' pre-hearing brief (EDIS Doc. ID 770786) |
| CIB | Complainants' corrected initial post-hearing brief (EDIS Doc. ID 775422) |
| CRB | Complainants' post-hearing reply brief (EDIS Doc. ID 775058) |
| RPHB | Respondents' corrected pre-hearing brief (EDIS Doc. ID 770874) |
| RIB | Respondents' second corrected initial post-hearing brief (EDIS Doc. ID 779376) |
| RRB | Respondents' corrected post-hearing reply brief (EDIS Doc. ID 779379) |

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I. BACKGROUND

A. Procedural History

The Commission instituted this investigation in response to a complaint filed by Complainants Masimo Corporation and Cercacor Laboratories, Inc. on June 30, 2021, with an amended complaint filed on July 12, 2021 (the “Amended Complaint,” EDIS Doc. ID 746186), and supplemented on July 19, 2021. Notice of Investigation at 1, EDIS Doc. No. 749538 (Aug. 13, 2021); 86 Fed. Reg. 46275-76 (Aug. 18, 2021). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, by reason of infringement of certain claims of U.S. Patent No. 10,912,501 (“the ’501 patent”), U.S. Patent No. 10,912,502 (“the ’502 patent”), U.S. Patent 10,945,648 (“the ’648 patent”), U.S. Patent No. 10,687,745 (“the ’745 patent”), and U.S. Patent No. 7,761,127 (“the ’127 patent”). *Id.* The Commission ordered institution of this investigation to determine “whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products . . . by reason of infringement of one or more of claims 1-9 and 11-30 of the ’501 patent; claims 1-2, 4-6, 8-12, 14-22, 24-26, and 28-30 of the ’502 patent; claims 1-17 and 19-30 of the ’648 patent; claims 1-6, 8-9, 11, 14, 20-24, and 26-27 of the ’745 patent; and claims 7-9 of the ’127 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337.” *Id.* at 2. The investigation was instituted upon publication of the Notice of Investigation in the *Federal Register* on Monday, August 18, 2021. 86 Fed. Reg. 46275-76.

Respondent Apple Inc. filed a response to the Amended Complaint and Notice of Investigation on September 7, 2021 (the “Response to Complaint”), disputing Complainants’

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allegations with respect to infringement and domestic industry and asserting affirmative defenses of invalidity and unenforceability. *See* EDIS Doc. ID 752521.¹

Pursuant to Order No. 3 (Sept. 1, 2021), the target date of this investigation was set to be December 16, 2022. On September 13, 2021, the investigation was assigned by then Chief Administrative Law Judge Bullock to the undersigned. *See* Notice to the Parties, EDIS Doc. ID 751531 (Sept. 13, 2021). Pursuant to Order No. 5 (Sept. 22, 2021), the target date was extended to January 16, 2023. *See* Comm'n Notice (Oct. 12, 2021), EDIS Doc. ID 754020.

A technology tutorial and *Markman* hearing was held on February 17, 2022. *See Markman* Tr., EDIS Doc. ID 763489.²

Pursuant to Order No. 25 (Mar. 23, 2022), Complainants withdrew their allegations of infringement with respect to claims 2, 4, 5, 7, 11, 16, 19, 20, and 22-30 of the '501 patent, claims 1-2, 4-6, 8-12, 14-18, 20, 25, and 26 of the '502 patent, claims 3, 4, 6, 7, 9, 10, 13-17, 19, 22, and 25-28 of the '648, and claims 1, 3-6, 8, 11, 14, 20-24, and 26 of the '745 patent. *See* Comm'n Notice, EDIS Doc. ID 768023 (Apr. 12, 2022). Pursuant to Order No. 33 (May 20, 2022), Complainants withdrew their allegations of infringement with respect to claims 1, 3, 6, 8, 9, 13-15, 17, 18, and 21 of the '501 patent, claims 19, 21, 24, 29, and 30 of the '502 patent, claims 1, 2, 5, 8, 11, 20, 21, 23, and 29 of the '648, and claim 2 of the '745 patent. *See* Comm'n Notice, EDIS Doc. ID 772826 (Jun. 10, 2022).

¹ The affirmative defenses based on inequitable conduct were stricken pursuant to Order No. 9 (Dec. 20, 2021), and Respondent was subsequently granted leave to add certain inequitable conduct defenses pursuant to Order No. 23 (Mar. 23, 2022).

² All of the claim construction disputes raised at the *Markman* hearing were subsequently mooted by the withdrawal of asserted claims or by agreement of the parties. *See infra*.

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An evidentiary hearing was held on June 6-10, 2022. The parties filed initial post-hearing briefs on June 27, 2022, and filed post-hearing reply briefs on July 11, 2022. Additional exhibits were admitted pursuant to Order No. 50 (Jun. 16, 2022) and Order No. 56 (Aug. 31, 2022). The hearing transcript was amended pursuant to Order No. 51 (Jun. 23, 2022) and Order No. 52 (Jun. 27, 2022). The parties' post-hearing briefs were amended pursuant to Order No. 54 (Jul. 14, 2022), Order No. 55 (Jul. 14, 2022), and Order No. 57 (Aug. 31, 2022).

Pursuant to Order No. 58 (Sept. 12, 2022), Order No. 59 (Oct. 24, 2022), and Order No. 61 (Dec. 9, 2022), the target date was extended to May 10, 2023. *See* Comm'n Notice, EDIS Doc. ID 787448 (Jan. 6, 2023).

B. The Parties

1. Complainants

The Complainants are Masimo Corporation (“Masimo”) and Cercacor Laboratories, Inc. (“Cercacor”) (collectively, “Complainants”). Notice of Investigation at 2. Masimo and Cercacor are both Delaware corporations having their principal places of business in Irvine, California. Complaint ¶ 9. Masimo is the owner of the '501 patent (JX-0001), '502 patent (JX-0002), '648 patent (JX-0003), and '745 patent (JX-0009). *Id.* ¶ 4. Cercacor is the owner of the '127 patent (JX-0007). *Id.* Masimo and Cercacor have rights to each of the asserted patents through a cross-licensing agreement. *Id.* ¶¶ 4, 77; CX-1612C.

2. Respondent

The Respondent is Apple Inc. (“Apple”). Notice of Investigation at 2. Apple is a California corporation having its principal place of business in Cupertino, California. Response to Complaint ¶ 21.

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C. Asserted Patents

The '501 patent, '502 patent, and '648 patent share a common specification, claiming priority to an application filed on July 3, 2008. JX-0001; JX-0002; JX-0003. These patents are entitled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” naming inventors Jeroen Poeze *et al.*, and are referenced herein as the “Poeze patents.” *Id.*

The '745 patent is entitled “Physiological Monitoring Devices, Systems, and Methods,” and claims priority to an application filed on June 28, 2016, naming inventor Ammar Al-Ali. JX-0009.

The '127 patent is entitled “Multiple Wavelength Sensor Substrate” and issued from an application filed on March 1, 2006, naming inventors Ammar Al-Ali *et al.* JX-0007.

D. Products at Issue

The products at issue are “wearable electronic devices with light-based pulse oximetry functionality and components thereof.” Notice of Investigation at 2.

1. Accused Products

Complainants accuse Apple Watch products of infringing the asserted patents, including the Apple Watch Series 6, the Apple Watch Series 7, and certain prototype Apple Watch products [REDACTED] (“Next Generation Apple Watches”). CIB at 37-39. Apple has stipulated to the importation of the Apple Watch Series 6, Apple Watch Series 7, and Next Generation Apple Watches (collectively, the “Accused Products”). *See* CX-0128C (Stipulation Regarding Importation and Inventory) at ¶¶ 2-4; CX-1259C (Stipulation Relating to Next-Generation Watches) at ¶¶ 5-6. The parties have stipulated that the Accused Products are materially identical for the purposes of infringement in this investigation. *See* Joint Stipulation of Facts at ¶¶ 11-13, EDIS Doc. ID 770692 (May 13, 2022); CX-1259C at ¶¶ 7-8.

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2. Domestic Industry Products

With respect to the '501, '502, '648, and '745 patents, Complainants rely on certain “Masimo Watch” products. CIB at 26-35. These Masimo Watch products include certain prototypes identified as the “Circle Sensor” (CPX-0021C), the “Wings Sensor” (CPX-0029C), the “RevA sensor” (CPX-0052C), the “RevD sensor” (CPX-0058C), the “RevE sensors” (CPX-0019C, CPX-0020C, CPX-0065C), and a product identified as the Masimo W1 Watch (CPX-0146C). CIB at 30-35. With respect to the '127 patent, Complainants rely on certain of Masimo’s rainbow® sensors. *Id.* at 36.

E. Witness Testimony

The undersigned received testimonial evidence in this investigation in the form of live testimony and deposition designations.

1. Fact Witnesses

The first witness at the hearing was Joe Kiani, the chairman and chief executive officer of Masimo and Cercacor. Tr. at 79-189. Complainants also presented testimony from Mohamed Diab, an engineer at Masimo, *id.* at 190-246; Ammar Al-Ali, who oversees technology development at Masimo, *id.* at 247-340; and Bilal Muhsin, who is the chief operating officer of Masimo. *Id.* at 341-89. Complainants further presented testimony from Stephen Scruggs, the director of sensor design at Masimo, *id.* at 390-479; Micah Young, who is Masimo’s chief financial officer and executive vice president, *id.* at 481-520; and Jeroen Hammarth, the chief financial officer of Cercacor. *Id.* at 521-33.

Apple presented testimony from several of its employees, including Vivek Venugopal, an optical engineer, *id.* at 816-49; Saahil Mehra, who manages product design for the Apple Watch health sensors, *id.* at 850-94; Ueyn Block, who worked on the optical architecture for the Apple

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Watch health sensors, *id.* at 895-917; Stephen Waydo, who is the director of a human interface device (HID) health group at Apple, *id.* at 918-51; Brian Land, who leads a health sensing hardware group at Apple, *id.* at 952-92; and Paul Mannheimer, a sensor architect and scientist at Apple, *id.* at 993-1025. Apple's counsel also examined Scott Cromar, the prosecuting attorney for the '501 patent, '502 patent, and '648 patent. *Id.* at 1026-41. Apple further presented testimony from Robert Rowe, who was the named inventor of certain asserted prior art. *Id.* at 1141-53; *see id.* at 1174:3-1175:7 (no cross-examination for Mr. Rowe).

2. Expert Witnesses

Complainants rely on the testimony of Daniel McGavock, who was admitted as an expert in financial matters, offering testimony regarding economic domestic industry, bond, and commercial success. Tr. at 533-76 (expert qualification at 534:25-535:6), 1416-42. With respect to the '127 patent, Complainants rely on the testimony of Jack Goldberg, who was admitted as an expert in the field of physiological monitoring technologies. *Id.* at 612-63 (expert qualification at 614:3-11), 1391-1408. With respect to the '501 patent, '502 patent, '648 patent, and '745 patent, Complainants rely on the testimony of Vijay Madiseti, who was admitted as an expert in the field of physiological monitoring technologies. *Id.* at 664-813 (*voir dire* and expert qualification at 666:10-674:12). Complainants also rely on the testimony of Robert Stoll, who was admitted as an expert on Patent Office practice and procedure. *Id.* at 1409-15 (expert qualification at 1409:23-1410:4).

Apple relies on the testimony of Majid Sarrafzadeh, who was admitted as an expert in physiological monitoring technologies including the design of pulse oximetry sensors, with respect to the '745 patent and '127 patent. *Id.* at 1042-1138 (expert qualification at 1046:5-12). With respect to the '501 patent, '502 patent, and '648 patent, Apple relies on the testimony of

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Steven Warren, who was admitted as an expert in biomedical engineering, medical monitoring systems, biomedical instrumentation, biomedical optics, light issue interaction, diagnostic systems, wearable sensors, and biomedical signal processing. *Id.* at 1181-1282 (expert qualification at 1187:20-1188:11). Apple also relies on the testimony of Vincent Thomas, who was admitted as an expert in the field of economics and financial analysis, with respect to the economic prong of the domestic industry requirement. *Id.* at 1282-1389 (expert qualification at 1283:11-17).

3. Deposition Designations

Complainants submitted several designated deposition transcripts that were received into evidence without a sponsoring witness: CX-0273C (Amor Dep. Tr.); CX-0281C (Block Dep. Tr.); CX-0275C (Caldbeck Dep. Tr.); CX-0283C (Charbonneau-Lefort Dep. Tr.); CX-0285C (Dua Dep. Tr.); CX-0287C (Land Dep. Tr.); CX-0289C (Mannheimer Dep. Tr.); CX-0291C (Mehra Dep. Tr.); CX-0293C (Rollins Dep. Tr.); CX-0279C (Rowe Dep. Tr.); CX-0295C (Shui Dep. Tr.); CX-0297C (Venugopal Dep. Tr.); CX-0299C (Waydo Dep. Tr.). *See* Tr. at 291:22-299:5. Apple also submitted several designated deposition transcripts that were received into evidence without a sponsoring witness: RX-1195C (Abdul-Hafiz Dep. Tr.); RX-1296C (Al-Ali Dep. Tr.); RX-1200C (Diab Dep. Tr.); RX-1201C (Hammarth Dep. Tr.); RX-1202C (Kaufman Dep. Tr.); RX-1204C (Kiani Dep. Tr.); RX-1206C (Muhsin Dep. Tr.); RX-1209C (Scruggs Dep. Tr.); RX-1210C (Scruggs 2nd Dep. Tr.); RX-1211C (Young Dep. Tr.). *See* Tr. at 1323:24-1324:20.

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II. JURISDICTION AND IMPORTATION

A. Personal Jurisdiction

Apple has submitted to the personal jurisdiction of the Commission by answering the Complaint and Notice of Investigation, participating in discovery, appearing at hearings, and filing motions and briefs. *See Certain Miniature Hacksaws*, Inv. No. 337-TA-237, USITC Pub. No. 1948, Initial Determination at 4, 1986 WL 379287, *1 (Oct. 15, 1986), *not reviewed in relevant part by Comm'n Action and Order*, 1987 WL 450871 (Jan. 15, 1987). Apple does not dispute the Commission's jurisdiction in this investigation. *See RIB* at 18.

B. In Rem Jurisdiction and Importation

The Commission has *in rem* jurisdiction over the accused products by virtue of their importation into the United States. *See Sealed Air Corp. v. U.S. Int'l Trade Comm'n*, 645 F.2d 976, 985-86 (C.C.P.A. 1981) (holding that the ITC's jurisdiction over imported articles is sufficient to exclude such articles). Apple has stipulated to the importation of the Accused Products. CX-0128C at 1-2; CX-1259C ¶¶ 5-6. Apple does not dispute the Commission's jurisdiction in this investigation. *See RIB* at 18.

III. LEGAL STANDARDS

A. Infringement

Section 337(a)(1)(B)(i) prohibits “the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17.” 19 U.S.C. §1337(a)(1)(B)(i). The Commission has held that the word “infringe” in Section 337(a)(1)(B)(i) “derives its legal meaning from 35 U.S.C. § 271, the section of the Patent Act that defines patent infringement.”

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Certain Elec. Devices with Image Processing Sys., Components Thereof, and Associated Software, Inv. No. 337-TA-724, Comm'n Op. at 13-14, EDIS Doc. ID 467105 (Dec. 21, 2011).

Infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). The preponderance of the evidence standard “requires proving that infringement was more likely than not to have occurred.” *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

1. Claim Construction

“An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996) (citation omitted). “[T]he construction of claims is simply a way of elaborating the normally terse claim language[] in order to understand and explain, but not to change, the scope of the claims.” *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000) (alterations in original) (quoting *Scripps Clinic v. Genentech, Inc.*, 927 F.2d 1565, 1580 (Fed. Cir. 1991)). “[O]nly those [claim] terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.” *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). The words of a claim “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in art” as of the date that the patent application was filed. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

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2. Direct and Indirect Infringement

A patent claim is directly infringed when a respondent “makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention” without consent of the patent owner. 35 U.S.C. § 271(a)

In addition to direct infringement, a respondent may be liable for indirect infringement, including induced infringement, which is defined in section 271(b) of the Patent Act: “Whoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). *See DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (en banc) (“To establish liability under section 271(b), a patent holder must prove that once the defendants knew of the patent, they actively and knowingly aided and abetted another’s direct infringement.”) (citations omitted). “The mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.” *Id.* (citations omitted). The Supreme Court has held that induced infringement “requires knowledge that the induced acts constitute patent infringement.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011). In *Suprema, Inc. v. Int’l Trade Comm’n*, the Federal Circuit upheld the Commission’s interpretation of the section 337 language “articles that infringe” in the context of induced infringement, holding that the statute “covers goods that were used by an importer to directly infringe post-importation as a result of the seller’s inducement.” 796 F.3d 1338, 1352-53 (Fed. Cir. 2015).

Another form of indirect infringement is contributory infringement, defined in section 271(c) of the Patent Act: “Whoever offers to sell . . . or imports into the United States a component of a patented machine, . . . or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or

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especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.” 35 U.S.C. § 271(c). The intent requirement for contributory infringement requires that respondent knows “that the combination for which [the] component was especially designed was both patented and infringing.” *Global-Tech*, 563 U.S. at 763. A violation of section 337 based on contributory infringement requires that “the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another’s direct infringement.” *Spansion, Inc. v. Int’l Trade Comm’n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

3. Literal Infringement and the Doctrine of Equivalents

A complainant must prove either literal infringement or infringement under the doctrine of equivalents. Literal infringement requires the patentee to prove that the accused device meets each and every limitation of the asserted claim(s). *Frank’s Casing Crew & Rental Tools, Inc. v. Weatherford Int’l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004). “If even one limitation is missing or not met as claimed, there is no literal infringement.” *Elkay Mfg. Co. v. EBCO Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999). Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). Under the doctrine of equivalents, “a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997).

B. Invalidity

It is the respondents’ burden to prove invalidity, and the burden of proof never shifts to

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the patentee to prove validity. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1380 (Fed. Cir. 2008). “Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through facts supported by clear and convincing evidence” *SRAM Corp. v. AD-II Eng’g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006); *see also Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 100-114 (2011) (upholding the “clear and convincing” standard for invalidity).

The clear and convincing evidence standard placed on the party asserting an invalidity defense requires a level of proof beyond the preponderance of the evidence. Although not susceptible to precise definition, “clear and convincing” evidence has been described as evidence that produces in the mind of the trier of fact “an abiding conviction that the truth of a factual contention is ‘highly probable.’” *Price v. Symsek*, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (quoting *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988)).

1. Anticipation

Pursuant to 35 U.S.C. § 102, a patent claim is invalid as anticipated if:

- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
- (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

35 U.S.C. § 102 (2012). “A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily

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present, or inherent, in the single anticipating reference.” *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citations omitted).

2. Obviousness

Section 103 of the Patent Act states:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a) (2012).

“Obviousness is a question of law based on underlying questions of fact.” *Scanner Techs.*, 528 F.3d at 1379. The underlying factual determinations include: “(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness.” *Id.* at 1380 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). These factual determinations are often referred to as the “*Graham* factors.”

A critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-21 (2007). In *KSR*, the Supreme Court rejected the Federal Circuit’s rigid application of a “teaching-suggestion-motivation” test—while the Court stated that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does,” it described a more flexible analysis:

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Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

Id. at 418. Applying *KSR*, the Federal Circuit has held that, where a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, “the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device . . . and would have had a reasonable expectation of success in doing so.” *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

In addition to demonstrating that a reason exists to combine prior art references, the challenger must demonstrate that the combination of prior art references discloses all of the limitations of the claims. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010), *abrogated on other grounds by Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014) (upholding finding of non-obviousness based on substantial evidence that the asserted combination of references failed to disclose a claim limitation); *Velandar v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (explaining that a requirement for a finding of obviousness is that “all the elements of an invention are found in a combination of prior art references”).

3. Indefiniteness

“The Patent Act requires that a patent specification ‘conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention.’” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014)

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(quoting 35 U.S.C. § 112, ¶ 2). “[T]he second paragraph of § 112 contains two requirements: first, [the claim] must set forth what the applicant regards as his invention, and second, it must do so with sufficient particularity and distinctness, *i.e.*, the claim must be sufficiently definite.” *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1348 (Fed. Cir. 2002) (citation and internal quotation marks omitted) (alteration in original). A claim does not satisfy the second requirement and is thereby indefinite “if read in light of the specification delineating the patent, and the prosecution history, [the claim] fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 534 U.S. at 901. Indefiniteness is a question of law, subject to a determination of underlying facts. *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1343-44 (Fed. Cir. 2016). The party challenging the validity of a claim bears the burden of establishing indefiniteness. *Id.*

4. Written Description

Under 35 U.S.C. § 112, ¶ 1, the specification must provide a written description of the claimed invention that “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). Determining whether the written description requirement has been satisfied “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art” to determine whether the specification “show[s] that the inventor actually invented the invention claimed.” *Id.*

5. Enablement

The enablement requirement is set forth in 35 U.S.C. § 112, ¶ 1 and provides in pertinent part that the specification shall describe “the manner and process of making and using [the

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invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention].”

The “enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.” *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

C. Inequitable Conduct

A patent containing a claim obtained through inequitable conduct is unenforceable. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288-89 (Fed. Cir. 2011) (en banc). “Moreover, the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family.” *Id.* (citing *Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804, 808-12 (Fed. Cir. 1990)).

“To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO.” *Id.* at 1287. The failure to disclose a reference to the PTO constitutes inequitable conduct only if “the applicant *made a deliberate decision* to withhold a known material reference.” *Id.* at 1290 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995)) (internal quotation marks omitted; emphasis in original). “In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Id.* Inequitable conduct based on the failure to disclose a reference requires a showing of “but for” materiality for the reference. *Id.* at 1291. The “but for” materiality requirement is satisfied “if the PTO

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would not have allowed a claim had it been aware of the undisclosed prior art.” *Id.* In determining whether “but for” materiality requirement is satisfied, the “the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.” *Id.* at 1291-92.

While deceptive intent may be inferred solely from circumstantial evidence, “[t]o meet the clear and convincing evidence standard, the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence.’” *Id.* (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

D. Domestic Industry

In patent-based proceedings under section 337, a complainant must establish that an industry “relating to the articles protected by the patent . . . exists or is in the process of being established” in the United States. 19 U.S.C. § 1337(a)(2). Under Commission precedent, the domestic industry requirement of section 337 consists of a “technical prong” and an “economic prong.” *See, e.g., Alloc, Inc. v. Intl Trade Comm’n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003).

To meet the technical prong, the complainant must establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40 at 17-18, EDIS Doc. ID 230409 (Apr. 11, 2005). “The test for satisfying the ‘technical prong’ of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims.” *Alloc*, 342 F.3d at 1375.

With respect to the “economic prong,” subsection (3) of Section 337(a) provides:

For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –

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- (A) significant investment in plant and equipment;
- (B) significant employment of labor or capital; or
- (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

Expenditures may be counted toward satisfaction of the domestic industry requirement “as long as those investments pertain to the complainant’s industry with respect to the articles protected by the asserted IP rights.” *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm’n Op. at 68, 2015 WL 6755093, at *36 (Oct. 30, 2015); accord, e.g., *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Prods. Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm’n Op., 2016 WL 10987364, at *40 (Jan. 6, 2016) (“Navico’s allocation methodology reasonably approximates the warranty and technical customer support expenditures relating to the LSS-1 product.”) (citing *Certain Ground Fault Circuit Interrupters and Prods. Containing Same*, Inv. No. 337-TA-739, Comm’n Op. at 74-75, 79-81 (June 8, 2012)).

Subsections (A), (B), and (C) are listed in the disjunctive, and accordingly, the domestic industry investments in plant and equipment or labor and capital can include expenditures that relate to engineering or research and development. *Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same*, Inv. No. 337-TA-1097, Comm’n Op. at 14, EDIS Doc. ID 649139 (June 29, 2018) (“[T]he text of the statute, the legislative history, and Commission precedent do not support narrowing subsections (A) and (B) to exclude non-manufacturing activities, such as investments in engineering and research and development.”).

Whether a complainant satisfies the economic prong is not analyzed according to a rigid mathematical formula. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm’n Op.

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at 39, EDIS Doc. ID 279161 (Aug. 1, 2007). The decision is made on a case-by-case basis and requires “an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace.” *Id.* Although Section 337(a)(3) describes the economic activities as “significant” and “substantial,” a complainant does not need to show any “minimum monetary expenditure,” and a complainant does not “need to define or quantify the industry itself in absolute mathematical terms.” *Stringed Musical Instruments & Components Thereof* (“*Stringed Musical Instruments*”), Inv. No. 337-TA-586, Comm’n Op. at 26, EDIS Doc. ID 300615 (May 16, 2008). “A precise accounting [of the complainant’s domestic investments] is not necessary, as most people do not document their daily affairs in contemplation of possible litigation.” *Id.* at 17.

The Commission has held that “[o]rdinarily, the relevant date at which to determine if the domestic industry requirement of section 337 is satisfied is the filing date of the complaint.” *Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing the Same*, Inv. No. 337-TA-1073, Comm’n Op. at 6-7, EDIS Doc. ID 684974 (Aug. 12, 2019). In *Stringed Musical Instruments*, the Commission held that a domestic industry is in the process of being established when (1) a complainant takes “the necessary tangible steps to establish such an industry in the United States,” and (2) there is a “significant likelihood that the industry requirement will be satisfied in the future.” Inv. No. 337-TA-586, Comm’n Op. at 14-17, EDIS Doc. ID 300615 (May 16, 2008).

IV. POEZE PATENTS

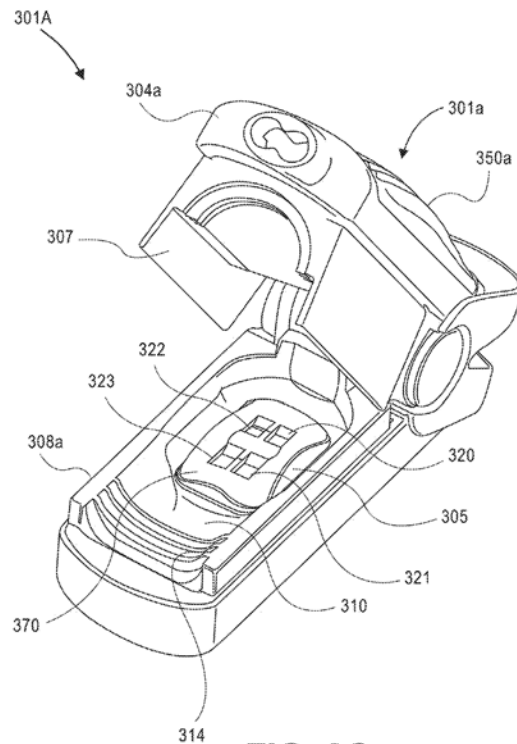
The ’501 patent, ’502 patent, and ’648 patent are entitled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” sharing a common specification and naming inventors Jeroen Poeze *et al.* JX-0001; JX-0002; JX-0003. These patents are

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collectively referred to herein as the “Poeze patents.” The Poeze patents issued from applications filed on September 24, 2020, claiming priority to earlier patent applications, with the earliest provisional application filed on July 3, 2008. *See Id.*

A. Specification

The Poeze patents’ specification describes non-invasive physiological sensors for measuring blood constituents or analytes using multi-stream spectroscopy. JX-0001 at 7:18-26. These sensors use an emitter that can use optical radiation at different wavelengths to measure blood analytes like glucose, hemoglobin, or oxygen saturation. *Id.* at 12:13-13:58. The sensors are connected to handheld or portable monitoring devices that can be attached to a patient’s body. *Id.* at 16:31-17:19. In one embodiment, the housing is designed to receive a patient’s finger, which can be placed on a protrusion (305) that includes openings or windows (320, 321, 322, and 323) that allow light from the emitter to reach photodetectors. *Id.* at 19:13-20:15.



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Id. at Fig. 3C. One portion of the housing may include LEDs that emit optical radiation passing through a finger before being received by the photodetectors on the other portion of the housing.

Id. at 26:30-27:41.

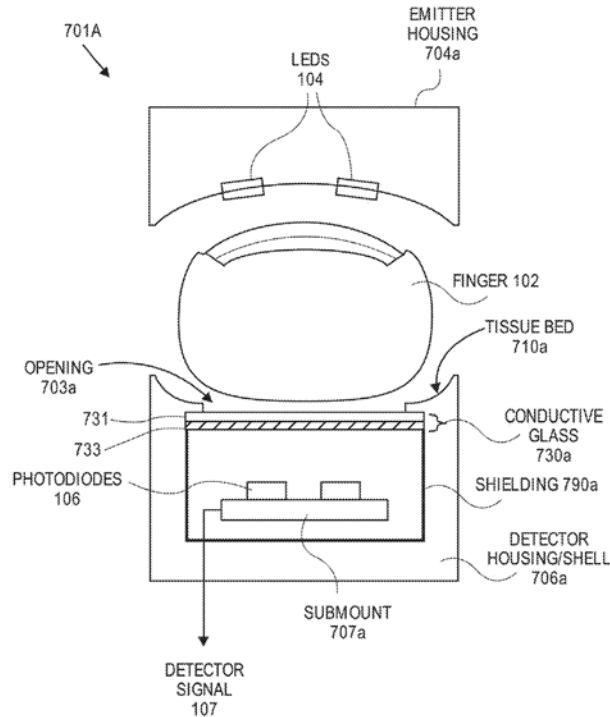


FIG. 7A

Id. at Fig. 7A.

B. Asserted claims

Masimo asserts claim 12 of the '501 patent, which depends from claim 1. *See* CIB at 53-

66. Claims 1 and 12 of the '501 patent are recited below:

1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:

at least three light emitting diodes (LEDs);

at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;

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a protrusion arranged over the interior surface, the protrusion comprising a convex surface and a plurality of openings extending through the protrusion and positioned over the three photodiodes, the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion; and

one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.

JX-0001 at 45:2-19.

12. The user-worn device of claim 1, wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape.

Id. at 46:4-8.

Masimo also asserts claim 22 of the '502 patent, which depends from claims 19, 20, and 21, and claim 28, a separate independent claim. *See* CIB at 66-77. These claims of the '502 patent are recited below:

19. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);

four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;

a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;

optically transparent material within each of the openings; and

one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.

20. The user-worn device of claim 19 further comprising a thermistor.

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21. The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.
22. The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.

JX-0002 at 46:22-54.

28. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:
- a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;
 - a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
 - four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
 - a thermistor configured to provide a temperature signal;
 - a protrusion arranged above the interior surface, the protrusion comprising:
 - a convex surface;
 - a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and
 - a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;
 - at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities;
 - one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal;

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- a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;
- a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user;
- a storage device configured to at least temporarily store at least the measurement; and
- a strap configured to position the user-worn device on the user.

Id. at 47:13-23.

Masimo further asserts claim 12 of the '648 patent, which depends from claim 8, and claims 24 and 30, which depend from claim 20. *See* CIB at 77-83. These claims of the '648 patent are recited below:

8. A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:
 - a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
 - a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
 - four photodiodes;
 - a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;
 - a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;
 - a separate optically transparent window extending across each of the openings;
 - one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;
 - a housing; and

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a strap configured to position the housing proximate tissue of the user when the device is worn.

JX-0003 at 45:45-46:3.

12. The user-worn device of claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation.

Id. at 46:15-16.

20. A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:

a plurality of light emitting diodes (LEDs);

at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;

a protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and

one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

Id. at 46:34-49.

24. The user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping.

Id. at 46:59-61.

30. The user-worn device of claim 20, wherein the protrusion further comprises one or more chamfered edges.

Id. at 47:6-7.

C. Level of Ordinary Skill in the Art

The parties have stipulated to a level of ordinary skill in the art for the Poeze patents:

[A] person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two

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years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Joint Stipulation of Facts ¶ 12, EDIS Doc. ID 770692 (May 13, 2022).

D. Claim Construction

The parties dispute the construction of the terms “over”/”above” and the terms “openings”/”through holes” in the claims of the Poeze patents. *See* CIB at 42-53; RIB at 26-39; CRB at 13-19; RRB at 23-34.³

1. “over”/“above”

Several of the asserted claims of the Poeze patents contain limitations describing a protrusion that is “arranged over” or “arranged above” an interior surface. *See* ’501 patent claim 1 (“a protrusion arranged over the interior surface”); ’502 patent claim 28 (“a protrusion arranged above the interior surface”). Other limitations describe openings that are “positioned over” or “arranged over” photodiodes. *See* ’501 patent claim 1 (“a plurality of openings extending through the protrusion and positioned over the three photodiodes”); ’502 patent claim 19 (“each opening positioned over a different one associated with each of the four photodiodes”); ’648 claim 20 (“each through hole including a window and arranged over a different one of the at least four photodiodes”).

³ The parties both argue that certain claim construction arguments were waived because they were not previously raised, *see* RIB at 37-38, CRB at 19 n.4, RRB at 31 n.17, 33 n.22, but these claim construction disputes were clearly addressed in the parties’ pre-hearing briefs and pertain to the plain and ordinary meaning of the terms at issue. *See* CPBH at 39-43; RPHB at 8-15. Ground Rule 9.2 does not preclude parties from citing additional evidence that was admitted at the hearing to support arguments that are consistent with their pre-hearing briefs.

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Apple interprets the “over” and “above” limitations to require that the claimed features be arranged vertically when the claimed device is in use. RIB at 26-34. Complainants argue that these terms refer to “the configuration of features of the device relative to each other, not to the position of the device relative to the Earth.” CIB at 43. Both parties purport to rely on the ordinary meaning of these terms, without proposing any explicit construction. CIB at 42-49; RRB at 21.

Apple relies on the preambles of the asserted claims describing “a user-worn device configured to non-invasively measure a physiological parameter” to argue that the orientation of the claimed features must be considered when a device is in use. RIB at 27-28. Complainants dispute this interpretation, arguing that “configured to” refers to the design of the product, not the orientation of components. CIB at 45. Complainants argue that the devices described in the specification do not have a fixed orientation and that the embodiments of the invention show “that the protrusion is arranged over the photodiodes and their interior surface by extending across that surface.” *Id.* at 43. Complainants note that the patent specification describes a variety of measurement sites without reference to any specific orientation. CRB at 14 (citing JX-0001 at 8:21-23, 10:15-27, 10:62-11:3, 11:45-55). Complainants cite an example in one embodiment of a material described as “over” the glass layer when it is depicted as below the layer in Figure 7A. *Id.* at 45-46 (citing JX-0001 at 27:59-62, Fig. 7A). Dr. Madisetti testified that Complainants’ interpretation is consistent with the ordinary meaning of “over,” citing the example of a bandage over a wound, explaining that “the Band-Aid is always over the scratch [ir]respective of the orientation of my hand.” Tr. at 701:22-18.

Complainants also cite extrinsic evidence in Apple patents and prior art using the terms “over” and “above” to describe the arrangement of features similar to those claimed in the Poeze

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patents. CIB at 46-49. *See, e.g.*, U.S. Patent No. 10,687,718 (CX-0118) at 32:17-23 (“For example, a back surface may comprise a first semi-circular protrusion that extends over the portions of the back surface.”), 35:38-55 (FIG. 222A depicts . . . a protrusion 2202 disposed over an optical opening 2204.”); U.S. Patent App. Pub. No. 2021/0093237 (CX-0103) at ¶ 0065 (“In some embodiments, windows 1220 over the emitters may be integral with the back cover 107 and windows 120 over the detectors may be inset within the back cover 107.”); U.S. Patent App. Pub. No. 2017/03255744 (CX-1806) at ¶ 0044 (“For example, the back surface can include one or more cavities having a corresponding opening and a protrusion located over each of the openings.”); U.S. Patent No. 4,224,948 (RX-0670) at 9:51-56 (“wherein said first and second light obstructing means comprise a pair of annular rings extending above the surface of the lower face of said case whereby said rings are in contact with the skin of the wearer”).

Apple argues that Complainants’ interpretation of the “over” and “above” limitations would render these terms meaningless. RRB at 23-24. Apple cites figures in the specification that consistently describe the claimed protrusion and openings located on top of the photodiodes. *Id.* at 24-26 (citing JX-0001 at 24:28-33, Figures 3C, 4C, 7B). Apple argues that the specification’s use of the term “over” within the phrase “spread over” is irrelevant to the meaning of the claim phrases “positioned over” and “arranged over.” RIB at 25-26. Apple further argues that in the Apple patents and patent applications using the term “over,” the descriptions refer to devices that are depicted in a face-down position, not when they are configured to measure blood oxygen. *Id.* at 26-28. Apple argues that the “configured to” language in the claims requires that that the features have a specific orientation when the device is in use. *Id.* at 28-29.

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In consideration of the parties' arguments and the evidence of record, the undersigned agrees with Complainants that the claim limitations using the terms "over" and "above" do not require a vertical arrangement of features in the context of the Poeze patents. The terms "over" and "above" are commonly understood words with ordinary meanings that can be understood by a lay judge. *See Phillips*, 415 F.3d at 1314. The undersigned agrees with Apple that the word "over" may be used to describe a vertical arrangement, but "over" can also be used to describe an arrangement where one feature covers another, as recognized by Dr. Madisetti's example of a bandage over a wound. Tr. (Madisetti) at 701:22-18. This is a common usage of the term "over" in the field of wearable medical equipment, *e.g.*, a mask over one's mouth, or in the field of optical sensors, *e.g.*, a filter over a lens. This is consistent with how the term "over" is used in the asserted claims of the Poeze patents, describing "a protrusion arranged over the interior surface" and openings "positioned over" or "arranged over" photodiodes. In the context of this claim language, the term "over" refers to an arrangement where one feature covers another—not the relative arrangement of these features in a vertical direction.⁴ The ordinary meaning of the claim language does not restrict the orientation of these features, and whether the claimed photodiodes

⁴ The term "above" is only used in asserted claim 28 of the '502 patent to refer to "a protrusion arranged above the interior surface." The undersigned agrees with Complainants that the patent specification does not require any specific orientation of the device and that the term "above" thus refers to a position relative to the device's features and not to its orientation relative to the Earth. *See CIB* at 43-49; *CRB* at 15-16. This is also consistent with the usage of the term in a prior art reference relied upon for invalidity purposes by Apple where the term "above" is used to refer to rings that extend beyond a surface, regardless of vertical orientation. *See RX-0670* (Cramer) at claim 5 ("a pair of annular rings extending above the surface of the lower face of said case"). It is also consistent with the testimony of Apple's expert, Dr. Warren, that "[a] detector can't detect light without some sort of opening above it." Tr. (Warren) at 1193:5-6; *see also RIB* at 61 (same). Apple argues that "Cramer does not disclose restrictions on orientation" (*RRB* at 29) but this fact weighs against Apple's proposed construction: if the Cramer device can be in any orientation, the term "above" should have a meaning independent from orientation.

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are facing upward or downward in relation to the Earth does not affect a device's satisfaction of this limitation.⁵

Accordingly, the undersigned finds that the terms “over” and “above” have their plain and ordinary meaning and do not require a vertical arrangement of features in a particular orientation.

2. “openings”/“through holes”

Several of the asserted claims (or claims from which the asserted claims depend) contain limitations describing “openings” that extend “through the protrusion.” *See* ’501 patent claim 1 (“a plurality of openings extending through the protrusion”); ’502 patent claim 19 (“separate openings extending through the protrusion”), claim 28 (“a plurality of openings in the convex surface, extending through the protrusion”); ’648 patent claim 8 (“a plurality of openings provided through the protrusion and the convex surface”). Claim 20 of the ’648 patent describes “a plurality of through holes, each through hole including a window.”

Apple argues that the claimed “openings” or “through holes” must not contain any material, such as glass or plastic. RIB at 34-39; RRB at 30-34; *id.* at 30 n.16 (“openings—like holes—require an absence of material”). Complainants submit that the claimed “openings” or “through holes” can contain a window of transparent material. CIB at 49-53; CRB at 17-18. Both parties purport to rely on the ordinary meaning of these terms, without proposing any explicit construction. CIB at 53; RRB at 30-31.

Complainants cite evidence in the claims and specification of the Poeze patents that the claimed “openings” and “through holes” can contain a window of transparent material. CIB at

⁵ Apple’s arguments regarding the “configured to” language of the claim preambles are thus irrelevant to the construction of this limitation.

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49-51. Complainants submit that the purpose of these openings is to allow light to pass through, citing claim 1 of the '501 patent, which describes "the plurality of openings configured to allow light to reach the photodiodes." JX-0001 at claim 1. Complainants cite examples in the claims and specification of the Poeze patents describing transparent windows in the relevant openings and through holes. CIB at 49-51. Complainants further identify Apple patents that refer to "openings" and "windows." *Id.* at 52-53. In reply, Apple cites testimony of its engineers describing [REDACTED]. RRB at 33-34. Apple argues that an opening or a hole is "an absence of material, into which something can be placed." *Id.* at 32.

In consideration of the parties' arguments and the evidence of record, the undersigned agrees with Complainants that the ordinary meaning of "openings" and "through holes" in the context of the Poeze patents does not preclude transparent material placed in the claimed "openings" or "through holes." An "opening" or "hole" can refer to an absence of material, but this is not necessarily a requirement. For example, a skylight would still be an "opening" in a roof after a glass window is installed, and a swimming hole is still a "hole" when it is filled with water. The undersigned agrees with Complainants that the ordinary meaning of the terms "opening" and "hole" can include openings and holes that include material.

The claims and specification of the Poeze patents use the terms "openings" and "holes" in a way that is consistent with this ordinary meaning by referring to "openings" and "through holes" that may contain transparent material. *See, e.g.*, '502 patent claim 19 ("optically transparent material within each of the openings"), claim 28 ("a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings"); '648 patent claim 8 ("a separate optically transparent window extending across each of the

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openings”), claim 20 (“each through hole including a window”). The specification explicitly provides that “[t]he openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors.” JX-0001 at 8:26-30; *see also* JX-0001 at 19:38-48 (describing “openings or windows,” which “allow light to pass from the measurement site to the photodetectors”), 27:20-27 (“One or more components of conductive glass 730b can be provided in the openings 703.”). Figure 7B depicts conductive glass provided in the identified opening:

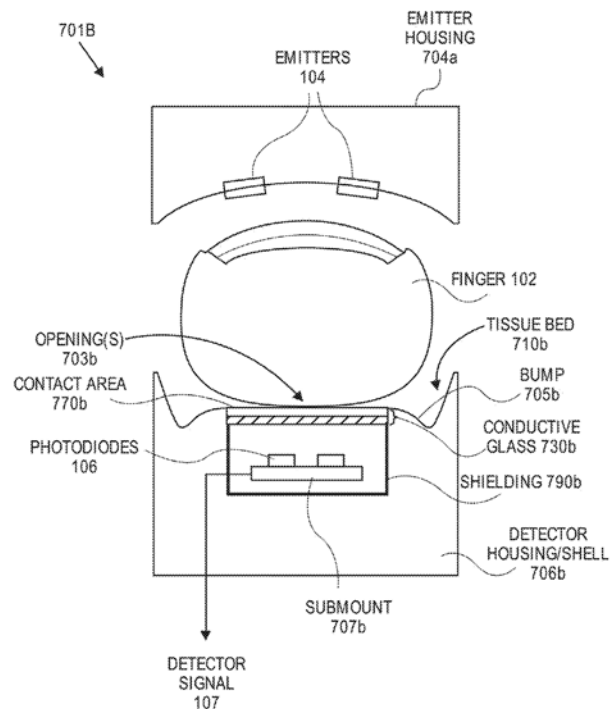


FIG. 7B

JX-0001 at Fig. 7B; *see id.* at 27:13-32. In view of these disclosures, the undersigned agrees with the testimony of Dr. Madisetti that the claimed “openings” and “through holes” in the Poeze patents can be made of glass or transparent material that allows light to pass through to the detectors. *See* Tr. (Madisetti) at 702:8-703:10.

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Apple argues that a “window” is something different from an “opening” or “hole,” RIB at 37-38, but none of the statements in the specification cited by Apple suggest that an “opening” can no longer be referred to as an “opening” when filled with glass or covered by a window. To the contrary, the specification describes conductive glass that “can be provided in the openings.” JX-0001 at 27:20-22. The claims of the Poeze patents repeatedly describe “windows extending across . . . the openings.” ’502 patent claim 28; *see also* ’648 patent claim 8 (same); ’648 patent, claim 20 (“each through hole including a window”). Claim 19 of the ’502 patent describes “optically transparent material within each of the openings.” The intrinsic evidence supports Complainants’ interpretation of these terms to include “openings” and “through holes” that contain transparent material allowing for the transmission of light to the photodiodes.

Accordingly, the undersigned finds that the claimed “openings” and “through holes” can contain transparent material.

E. Infringement

Complainants allege that the Accused Products infringe claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, and claims 12, 24, and 30 of the ’648 patent. CIB at 53-83. There is no dispute with respect to the structure and operation of the Accused Products, and Apple only disputes infringement with respect to the “over”/”above” and “openings”/”through holes” limitations addressed above in the context of claim construction. RIB at 26-39; RRB at 20-34. Based on the evidence of record, and because Apple’s proposed claim constructions have been rejected, the undersigned finds that these limitations are met, and that the Accused Products thus infringe each of the asserted claims, as discussed below.⁶

⁶ Apple’s opening brief argues, in addition, that there is no indirect infringement of claim 28 of the ’502 patent. *See* RIB at 39-40. Complainants do not provide any argument regarding indirect infringement.

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1. '501 Patent Claim 12⁷

- a. Element [1 preamble]: “A user-worn device configured to noninvasively measure a physiological parameter of a user, the user-worn device comprising:”⁸**

There is no dispute that the Accused Products meet the limitations of the preamble of claim 1, which requires “[a] user-worn device configured to non-invasively measure a physiological parameter of a user.” *See* CIB at 59-60. Dr. Madisetti determined that the Accused Products are watches configured to measure blood oxygen saturation, relying on Apple’s marketing materials and technical documentation. Tr. (Madisetti) at 679:12-680:5; CX-0281C (Block Dep. Tr.) at 71:21-72:5, 87:10-14, 177:10-178:7, 251:4-7; CX-1451 (Apple Watch advertisement) at 1:49; CX-1406 (Apple Watch User Guide); CX-1726 (Apple Watch Series 7 Technical Specifications). The evidence of record shows that this limitation is met.

- b. Element [1A]: “at least three light emitting diodes (LEDs)”**

There is no dispute that each of the Accused Products contains a sensor module with at least three LEDs. *See* CIB at 60-61. Dr. Madisetti identified four clusters of LEDs in each Accused Product, with each cluster containing three LEDs of different wavelengths. Tr. (Madisetti) at 680:6-22; CX-1548C (Apple Watch teardown photographs); CX-0281C (Block Dep. Tr.) at 65:5-67:20; CX-0026C (Apple Engineering Requirement Specification) at 7-8, 30-

Apple does not explain why an indirect infringement finding is needed to find a violation as to claim 28 of the ‘502 patent, or as to any other asserted claim (which are all apparatus claims).

⁷ Because claim 12 of the ‘501 patent depends from claim 1, the infringement, technical prong and invalidity analyses address the limitations of both claims 1 and 12. *See* CIB at xxvi.

⁸ The parties have stipulated that all preambles of all asserted claims are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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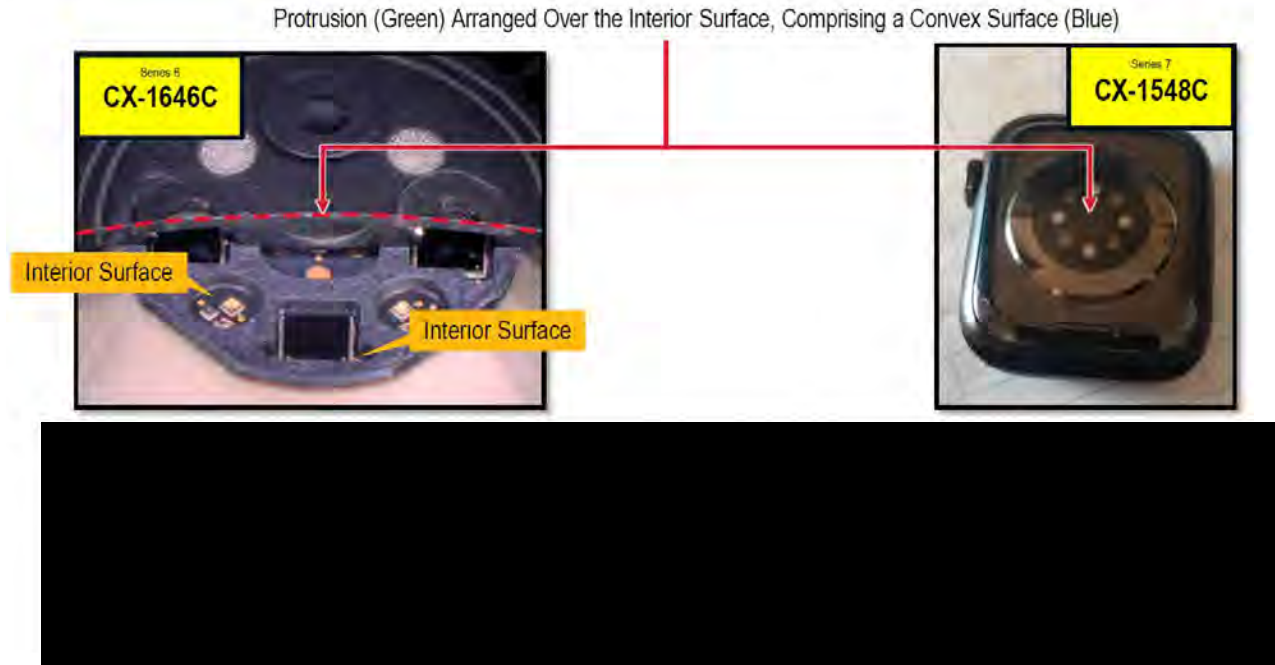
32; CX-0059C (Apple Watch Series 7 Engineering Drawings) at 1-3. The evidence of record shows that this limitation is met.

c. Element [1B]: “at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user”

There is no dispute that each of the Accused Products contains at least three photodiodes on an interior surface that are configured receive light that has passed through the user’s tissue. *See* CIB at 61-62. Dr. Madisetti identified four photodiodes arranged on Apple Watch sensor boards that are configured to receive light emitted from the LEDs after it has passed through the user’s tissue. Tr. (Madisetti) at 680:23-681:11; CX-0281C (Block Dep. Tr.) at 70:13-16, 86:2-87:18; CX-0026C (Apple Engineering Requirement Specification) at 7-8, 30-32; CX-0059C (Apple Watch Series 7 Engineering Drawings) at 1-3. The evidence of record shows that this limitation is met.

d. Element [1C]: “a protrusion arranged over the interior surface, the protrusion comprising a convex surface”

Complainants identify a domed surface in the Accused Products as the claimed protrusion with a convex surface. CIB at 54-57. Dr. Madisetti identified this domed surface arranged over the interior surface of the Accused Products where the photodiodes are located. Tr. (Madisetti) at 681:12-682:11.



CDX-0011C.016 (citing CX-1646C at 4; CX-1548C at 3; CX-0063C at 1).

Apple argues that the identified protrusion is not “over” the interior surface when the Accused Products are being used for blood oxygen monitoring (with the photodiodes pointed down toward the user’s wrist). RIB at 26-34; RRB at 21-29. There is no dispute regarding the orientation of the Accused Products, but as discussed above in the context of claim construction, the claim term “over” does not require a particular vertical arrangement—the protrusion is “over” the interior surface because it is covering the interior surface.

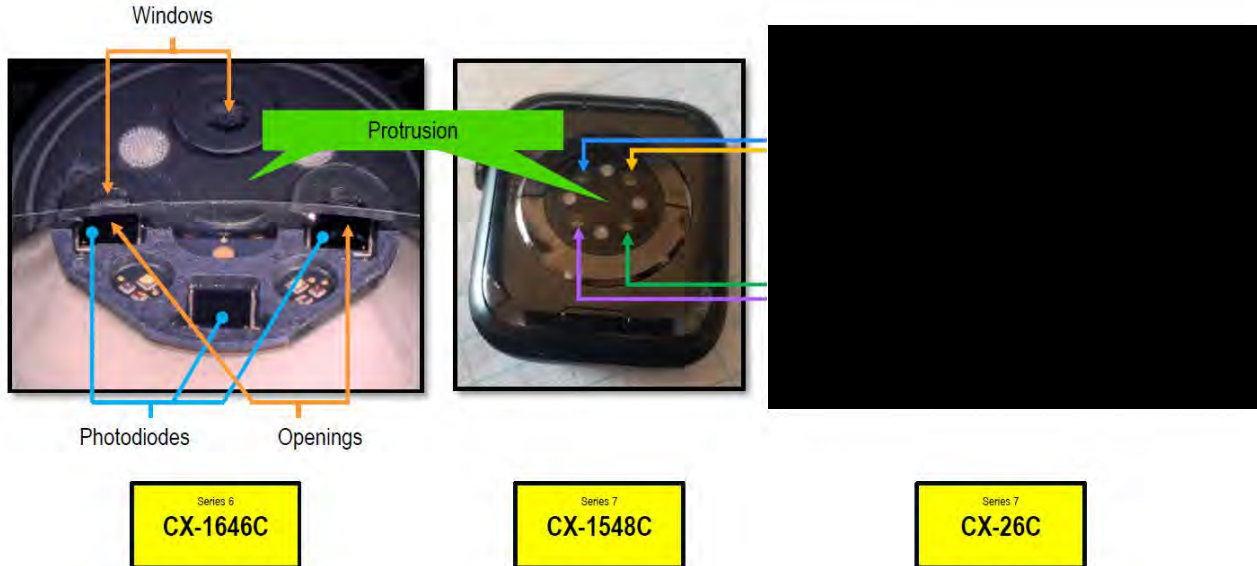
Accordingly, the undersigned finds that the Accused Products meet the limitation requiring “a protrusion arranged over the interior surface.”

e. Element [1D]: “a plurality of openings extending through the protrusion and positioned over the three photodiodes”

Complainants identify openings in the Accused Products that are positioned over the four photodiodes. CIB at 57-59. Dr. Madisetti identified evidence [REDACTED]

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[REDACTED] that allow light to pass through to the photodiodes. Tr. (Madisetti) at 682:12-683:17.



CDX-0011C.017 (citing CX-1646C at 4; CX-1548C at 3; CX-0026C at 8, 31).

Apple argues that the alleged “openings” do not infringe this limitation because they are

[REDACTED]

RIB at 34-39; RRB at 29-34. Apple engineer Ueyn Block explained: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. (Block) at 901:16-902:3. Apple also argues that the openings are not positioned “over” the photodiodes when the Accused Products are being used for blood oxygen monitoring (with the photodiodes pointed down toward the user’s wrist). RIB at 26-39; RRB at 21-29.

As discussed above in the context of claim construction, the undersigned finds that the claimed “openings” can contain transparent material. The fact that the openings in the Accused

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Products [REDACTED] does not mean that these are not “openings” in accordance with the claim language. There is no dispute that the [REDACTED] within the openings is transparent and allows for light to reach the photodiodes. *See* CX-0281C (Block) at 272:2-9. There is also no dispute that each opening has an opaque lateral surface separating the opening from the surrounding material. *See* CIB at 62-64; Part IV.E.1.f (Element 1E) *infra*.

The undersigned also finds that the openings are positioned “over” the four photodiodes. As discussed above in the context of claim construction, the claim term “over” does not require a particular vertical arrangement—the openings are positioned “over” the photodiodes because they are aligned with the photodiodes and covering them.

Accordingly, the Accused Products meet the plurality of openings” limitation of ’501 patent claim 1.

- f. Element [1E]: “the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion”**

There is no dispute that the Accused Products have opaque lateral surfaces in their alleged openings that are configured to avoid light piping. *See* CIB at 62-64. Apple engineers described a [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] *see also* CX-0070C at 1; CX-0189C at 2; CX-1548C

at 3; CX-0072C at 26, 29-30. Dr. Madisetti considered this evidence to identify [REDACTED]

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█ as opaque lateral surfaces meeting this limitation. Tr. (Madisetti) at 683:18-685:3. The evidence of record shows that this limitation is met.

- g. Element 1[F]: “one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user”**

There is no dispute that the Accused Products have processors that receive signals from the photodiodes and calculate measurements of physiological parameters. *See* CIB at 64-65. Dr. Madisetti identifies an █ application processor running Apple’s █ algorithm to calculate oxygen saturation and pulse rate. Tr. (Madisetti) at 685:4-25; *see* CX-0013C (Apple Engineering Requirements Specification) at 12; CX-0100C (Apple Engineering Requirements Specification) at 6-31; CX-0072C at 3 (Apple Watch Series 6 BOM); CX-1726 (Apple Watch Series 7 Technical Specifications) at 2; CX-0299C (Waydo Dep. Tr.) at 38:10-40:6, 50:11-52:4. The evidence of record shows that this limitation is met.

- h. Element [12]: “wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape”**

Claim 12 of the ’501 patent depends from claim 1, further requiring that “the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape.” There is no dispute that the Accused Products meet this limitation. *See* CIB at 65-66. As discussed above, Dr. Madisetti identified a convex protrusion in the Accused Products, and Apple documents and testimony confirm that the protrusion is designed █. *See* Tr. (Madisetti) at 686:1-18; CX-0281 (Block Dep. Tr.) at 200:6-14; CX-0063C (Apple Watch Series 7 Engineering Drawings) at 1; CX-1548C (photographs of Apple Watch Series 7) at 3;

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CX-0070C (Apple Watch Series 7 Engineering Drawings) at 1; CX-0010 (Apple website) at 3.

The evidence of record shows that this limitation is met.

Accordingly, because each limitation of claims 1 and 12 are satisfied, the Accused Products infringe claim 12 of the '501 patent.

2. '502 Patent Claim 22⁹

- a. Element [19 preamble]: “A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:”**

There is no dispute that the Accused Products meet the limitations of the preamble of '502 patent claim 19, which requires “[a] user-worn device configured to non-invasively measure an oxygen saturation of a user.” *See* CIB at 67. The relevant evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

- b. Element [19A]: “a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs)”**

There is no dispute that each of the Accused Products contains clusters of LEDs, with each cluster containing three LEDs. *See* CIB at 68. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

⁹ Because claim 22 of the '502 patent depends from claims 19, 20, and 21, the infringement, technical prong and invalidity analyses address the limitations of claims 19, 20, 21, and 22. *See* CIB at xxvii.

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- c. Element [19B]: “four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user”**

There is no dispute that each of the Accused Products contains four photodiodes configured to receive light that has been attenuated by tissue of the user. *See* CIB at 68. The relevant evidence was discussed above in the context of the “photodiodes” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

- d. Element [19C]: “a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue”**

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface, as discussed above in the context of the “protrusion” limitation of ’501 patent claim 1. *See* CIB at 66. With respect to the ’502 patent claim 19 limitation requiring “openings extending through the protrusion,” Complainants identify the same “openings” that are discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. *See* CIB at 66-67. Complainants further identify the same [REDACTED] discussed above in the context of the “opaque lateral surfaces” limitation of ’501 patent claim 1. *Id.*

Apple disputes infringement of this limitation based on its erroneous proposed constructions of the claim terms “over” and “openings.” *See* RIB at 26-39; RRB at 21-34. These arguments have been rejected, however, as discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1 and in the claim construction analysis above. *See* Part IV.D, *supra*. Accordingly, the undersigned finds that the Accused Products meet the limitation in ’502 patent claim 19 requiring a “protrusion” including “openings extending

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through the protrusion” that are “lined with opaque material,” and “each opening positioned over” the photodiodes.

e. Element [19D]: “optically transparent material within each of the openings”

There is no dispute that each of the Accused Products contains optically transparent material within each of the identified openings. *See* CIB at 68. The evidence for the presence of [REDACTED] in these openings was discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

f. Element [19E]: “one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user”

There is no dispute that each of the Accused Products contain processors that receive signals from the photodiodes and output measurements of oxygen saturation. *See* CIB at 68. The relevant evidence was discussed above in the context of the “processors” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

g. Element [20]: “further comprising a thermistor”

Claim 20 of the ’502 patent depends from claim 19, further requiring a thermistor. There is no dispute that the Accused Products include a thermistor. *See* CIB at 68-69. Dr. Madisetti identified a [REDACTED] of the Accused Products. Tr. (Madisetti) at 688:18-689:8; *see* CX-0026C (Apple Engineering Requirement Specification) at 31; CX-1548C (Apple Watch teardown photographs) at 37; CX-0059C (Apple Watch Series 7 Engineering Drawings) at 1-5. The evidence of record shows that this limitation is met.

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- h. Element [21]: “wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal”**

Claim 21 of the '502 patent depends from claim 20, further requiring that “the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user device responsive to the temperature signal.” There is no dispute that the Accused Products [REDACTED]

[REDACTED]. See CIB at 69-70. Dr. Madisetti identified Apple documents and testimony showing that a processor in the Accused Products [REDACTED]

[REDACTED] Tr. (Madisetti) at 689:17-690:16 (citing CX-0100C (Apple Engineering Requirement Specification) at 8; *see also* CX-0281C (Block Dep. Tr.) at 62:3-64:17; CX-0283C (Charonneau-LeFort Dep. Tr.) at 78:4-79:18, 123:6-12; CX-0299C (Waydo Dep. Tr.) at 84:2-85:22; CX-0285C (Dua Dep. Tr.) at 139:1-15. The evidence of record shows that this limitation is met.

- i. Element [22]: “wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs”**

Claim 22 of the '502 patent depends from claim 21, further requiring that “the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.” There is no dispute that the plurality of emitters in the Accused Products comprise four sets of three LEDs. See CIB at 70-71. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

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Accordingly, because each limitation of claims 19, 20, 21, and 22 are satisfied, the undersigned finds that the Accused Products infringe claim 22 of the '502 patent.

3. '502 Patent Claim 28

- a. Element [28 preamble]: “A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:”**

There is no dispute that the Accused Products meet the limitations of the preamble of '502 patent claim 28, which requires “[a] user-worn device configured to non-invasively measure an oxygen saturation of a user.” *See* CIB at 72. The relevant evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

- b. Element [28A]: “a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength”**

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 72. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

- c. Element [28B]: “a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength”**

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 72. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1, and Dr. Block confirmed that the wavelengths in each of the LED groups is the same--

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containing one infrared LED, one red LED, and one green LED. *See* CX-0281C (Block Dep. Tr.) at 65:5-67:20. The evidence of record shows that this limitation is met.

- d. Element [28C]: “four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user”**

There is no dispute that each of the Accused Products contains four photodiodes arranged in a quadrant configuration receiving light that has been attenuated by tissue of the user. *See* CIB at 72-73. The relevant evidence was discussed above in the context of the “photodiodes” limitation of ’501 patent claim 1, and Dr. Madisetti identified photographs of the sensor board of the Accused Products showing the quadrant configuration of the photodiodes. Tr. (Madisetti) at 692:3-16; CX-1548C. The evidence of record shows that this limitation is met.

- e. Element [28D]: “a thermistor configured to provide a temperature signal”**

There is no dispute that each of the Accused Products contains a thermistor that provides a temperature signal. *See* CIB at 73. The relevant evidence was discussed above in the context of ’502 patent claim 20. The evidence of record shows that this limitation is met.

- f. Element [28E]: “a protrusion arranged above the interior surface, the protrusion comprising: a convex surface”**

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface, as discussed above in the context of the “protrusion” limitation of ’501 patent claim 1. *See* CIB at 71. Apple disputes infringement of this limitation based on its erroneous proposed construction of the term “above.” *See* RIB at 26-34; RRB at 21-29. These arguments have been rejected, however, as discussed above in the context of the “protrusion” limitation of ’501 patent claim 1 and in the claim construction analysis above. *See* Part IV.D.1, *supra*.

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Accordingly, the undersigned finds that the Accused Products meet the limitation in '502 patent claim 28 requiring a "protrusion arranged over the interior surface."

- g. Element [28F]: "a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping"**

With respect to the "plurality of openings" limitation of '502 patent claim 28, Complainants identify the same "openings" that are discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. *See* CIB at 71. There is no dispute that these openings are aligned with the four photodiodes. *See id.* Apple disputes infringement of this limitation based on its erroneous proposed construction of the term "openings." *See* RIB at 34-39; RRB at 29-34. These arguments have been rejected, however, as discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. Accordingly, the undersigned finds that the Accused Products meet the limitation in '502 patent claim 28 requiring a "plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes." Further, there is no dispute that the Accused Products have opaque surfaces surrounding the openings that are configured to reduce light piping, as discussed above in the context of the "opaque lateral surface" limitation of '501 patent claim 1. *See* CIB at 71. Accordingly, the evidence shows that this limitation is met by the Accused Products.

- h. Element [28G]: "a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings"**

There is no dispute that each of the Accused Products contains transmissive windows extending across each of the identified openings. *See* CIB at 73. The evidence for the presence of transparent windows in these openings was discussed above in the context of the "plurality of

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openings” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

- i. Element [28H]: “at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities”**

There is no dispute that each of the Accused Products contains an opaque wall between the interior surface and the protrusion that forms a cavity for the photodiodes. *See* CIB at 74. Dr. Madisetti identified the opaque wall in photographs of the Accused Products. Tr. (Madisetti) at 692:17-693:13; *see* CX-1646C (Complaint Exhibit 18) at 4; CX-0026C (Apple Engineering Requirement Specification) at 7-8, 30-32; CX-0059C (Apple Watch Series 7 Engineering Drawings) at 1-3; *see also* CX-0283C (Charbonneau-Lefort Dep. Tr.) at 87:5-8, 105:22-106:7. The evidence of record shows that this limitation is met.

- j. Element [28I]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal”**

There is no dispute that each of the Accused Products contains processors that receive signals from the photodiodes and output measurements of oxygen saturation, and there is no dispute that the processors receive a temperature signal. *See* CIB at 74. The relevant evidence was discussed above in the context of the “processors” limitations of ’501 patent claim 1 and ’502 patent claim 21. The evidence of record shows that this limitation is met.

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k. Element [28J]: “a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network”

There is no dispute that the Accused Products have a network interface that can wirelessly communicate oxygen saturation measurements to a mobile phone or electronic network. *See* CIB at 74-75. Dr. Madisetti identifies Bluetooth and Wi-Fi interfaces that communicate SpO₂ measurements to an Apple iPhone. Tr. (Madisetti) at 693:14-694:11; *see* CX-0010 (Apple website) at 5; CX-1726 (Apple Watch Series 7 Technical Specifications) at 21. This operation of the Accused Products was confirmed by the testimony of Apple engineers. *See* CX-0299C (Waydo Dep. Tr.) at 74:20-75:17 (SpO₂ measurements “stored in the HealthKit database on the Watch will also eventually make its way to the phone” via “Wi-Fi or Bluetooth”); CX-0285C (Dua) at 144:9-14 (“the heart rate along with the SpO₂ that’s measured at the same time are both communicated to the iPhone”). The evidence of record shows that this limitation is met.

l. Element [28K]: “a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user”

There is no dispute that the Accused Products have a touch-screen display that shows oxygen saturation measurements. *See* CIB at 75-76. Dr. Madisetti identified Apple documents showing that Apple Watches have touch-screen displays that can show an SpO₂ measurement. Tr. (Madisetti) at 694:12-22 (citing CX-1407 at 3); *see also* CX-0281C (Block Dep. Tr. at 237:11-238:8); CX-0010 (Apple webpage). The evidence of record shows that this limitation is met.

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m. Element [28L]: “a storage device configured to at least temporarily store at least the measurement”

There is no dispute that the Accused Products store the blood oxygen measurement in memory. *See* CIB at 76. Apple engineers confirmed that the SpO2 values are stored in the memory of the Accused Products. *See* CX-0299C (Waydo Dep. Tr.) at 74:17-19; CX-0285C (Dua Dep. Tr.) at 131:8-15; *see also* CX-1726 at 1-2 (identifying memory in Apple Watch Series 7). The evidence of record shows that this limitation is met.

n. Element [28M]: “a strap configured to position the user-worn device on the user”

There is no dispute that the Accused Products have a strap. *See* CIB at 76. Dr. Madisetti identified a strap configured to hold the Accused Products in place on a user’s wrist. Tr. (Madisetti) at 695:11-20; *see* CX-0010 (Apple website) at 4; CX-1726 (Apple Watch Series 7 Technical Specifications) at 3. The evidence of record shows that this limitation is met.

Accordingly, because each limitation of the claim is satisfied, the undersigned finds that the Accused Products infringe claim 28 of the ’502 patent.

4. ’648 Patent Claim 12¹⁰

a. Element [8 preamble]: “A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:”

There is no dispute that the Accused Products meet the limitations of the preamble of ’648 patent claim 8, which requires “[a] user-worn device configured to non-invasively determine measurements of a physiological parameter of a user.” *See* CIB at 77. The relevant

¹⁰ Because claim 12 of the ’648 patent depends from claim 8, the infringement, technical prong and invalidity analyses address the limitations of claims 8 and 12. *See* CIB at xxix.

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evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

- b. Element [8A]: “a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength”**

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 78. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

- c. Element [8B]: “a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength”**

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 78. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1 and the “second set of LEDs” limitation of '502 patent claim 28. The evidence of record shows that this limitation is met.

- d. Element [8C]: “four photodiodes”**

There is no dispute that each of the Accused Products contains four photodiodes. *See* CIB at 78. The relevant evidence was discussed above in the context of the “photodiodes” limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

- e. Element [8D]: “a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material”**

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface, which includes a portion with opaque material. *See* CIB at 78. The relevant

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evidence was discussed above in the context of the “protrusion” and “openings” limitations of ’501 patent claim 1. The evidence of record shows that this limitation is met.

f. Element [8E]: “a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes”

With respect to the “plurality of openings” limitation of ’648 patent claim 8, Complainants identify the same “openings” that are discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. *See* CIB at 77. There is no dispute that these openings are aligned with the four photodiodes. *See id.* Apple disputes infringement of this limitation based on its erroneous proposed construction of the term “openings.” *See* RIB at 34-39; RRB at 29-34. These arguments have been rejected, however, as discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1 and in the claim construction analysis above. *See* Part IV.D.2, *supra*. Accordingly, the undersigned finds that the Accused Products meet the limitation in ’648 patent claim 8 requiring a “a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes.”

g. Element [8F]: “a separate optically transparent window extending across each of the openings”

There is no dispute that each of the Accused Products contains optically transparent windows extending across each of the identified openings. *See* CIB at 78. The evidence for the presence of transparent windows in these openings was discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

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h. Element [8G]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user”

There is no dispute that each of the Accused Products contains processors that receive signals from the photodiodes and output measurements of oxygen saturation. *See* CIB at 79.

The relevant evidence was discussed above in the context of the “processors” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

i. Element [8H]: “a housing”

There is no dispute that the Accused Products have a housing. *See* CIB at 79.

Dr. Madisetti identified a photograph of the housing for the Accused Products. Tr. (Madisetti) at 697:17-24 (citing CX-1548C at 3). The evidence of record shows that this limitation is met.

j. Element [8I]: “a strap configured to position the housing proximate tissue of the user when the device is worn”

There is no dispute that the Accused Products have a strap. *See* CIB at 80. The relevant evidence was discussed above in the context of the “strap” limitation of ’502 patent claim 28.

The evidence of record shows that this limitation is met.

k. Element [12]: “the physiological parameter comprises oxygen or oxygen saturation”

There is no dispute that the Accused Products meet the limitations of ’648 patent claim 12, which depends from claim 8 and requires that “the physiological parameter comprises oxygen or oxygen saturation.” *See* CIB at 80. The relevant evidence was discussed above in the context of the preamble and the “physiological parameter” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

Accordingly, because each of the limitations of claims 8 and 12 are satisfied, the undersigned finds that the Accused Products infringe claim 12 of the ’648 patent.

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5. '648 Patent Claim 24¹¹

- a. Element [20 preamble]: “A user-worn device configured to non-invasively determine measurements of a user’s tissue, the user-worn device comprising:”**

There is no dispute that the Accused Products meet the limitations of the preamble of '648 patent claim 20, which requires “[a] user-worn device configured to non-invasively determine measurements of a user’s tissue.” *See* CIB at 81. The relevant evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

- b. Element [20A]: “a plurality of light emitting diodes (LEDs)”**

There is no dispute that each of the Accused Products has LEDs. *See* CIB at 82. The relevant evidence was discussed above in the context of the “LEDs” limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

- c. Element [20B]: “at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user”**

There is no dispute that each of the Accused Products contains four photodiodes arranged in quadrants. *See* CIB at 82. The relevant evidence was discussed above in the context of the “photodiodes” limitation of '501 patent claim 1 and the “photodiodes” limitation of '502 patent claim 28. The evidence of record shows that this limitation is met.

- d. Element [20C]: “a protrusion comprising a convex surface”**

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface. *See* CIB at 80-81. The relevant evidence was discussed above in the context of

¹¹ Because claim 24 of the '648 patent depends from claim 20, the infringement, technical prong and invalidity analyses address the limitations of claims 20 and 24. *See* CIB at xxix.

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the “protrusion” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

- e. **Element [20D]: “a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes”**

With respect to the ’648 patent claim 20 limitation requiring “a plurality of through holes,” Complainants identify the holes in the protrusion that are discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. *See* CIB at 81. Apple disputes infringement of this limitation based on its erroneous proposed constructions of the claim terms “over” and “through holes.” *See* RIB at 26-39; RRB at 21-34. These arguments have been rejected, however, as discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1 and in the claim construction analysis above. *See* Part IV.D, *supra*.

Accordingly, the undersigned finds that the Accused Products meet the limitation in ’648 patent claim 20 requiring a “a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes.”

- f. **Element [20E]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user”**

There is no dispute that each of the Accused Products contains processors that receive signals from the photodiodes and output measurements of oxygen saturation. *See* CIB at 82.

The relevant evidence was discussed above in the context of the “processors” limitation of ’501 patent claim 1. The evidence of record shows that this limitation is met.

- g. **Element [24]: “wherein the protrusion comprises opaque material configured to substantially prevent light piping”**

Claim 24 of the ’648 patent depends from claim 20, further requiring that “the protrusion comprises opaque material configured to substantially prevent light piping.” There is no dispute

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that the identified protrusion in the Accused Products has a coating and ink that is configured to prevent light piping, as discussed above in the context of the “opaque lateral surface” limitation of ’501 patent claim 1. *See* CIB at 82. The evidence of record shows that this limitation is met.

Accordingly, because each of the limitations of claims 20 and 24 are satisfied, the undersigned finds that the Accused Products infringe claim 24 of the ’648 patent.

6. ’648 Patent Claim 30

Claim 30 of the ’648 patent depends from claim 20, further requiring that “the protrusion further comprises one or more chamfered edges.” There is no dispute that the identified protrusion in the Accused Products has chamfered edges. *See* CIB at 82-83. Dr. Madisetti identified chamfered edges on engineering drawings for the Accused Products. Tr. (Madisetti) at 699:4-19; CX-0063C (Apple Watch Series 7 Engineering Drawings) at 2; *see also* CX-1548C (Apple Watch Series 7 Photographs) at 3; CX-0070C (Apple Watch Series 7 Engineering Drawings) at 1. The evidence of record shows that this limitation is met.

Accordingly, because each of the limitations of claims 20 and 30 are satisfied, the undersigned finds that the Accused Products infringe claim 30 of the ’648 patent.

F. Domestic Industry—Technical prong

The domestic industry products that Complainants rely on for the Poeze patents are the RevA sensor (CPX-0052C), the RevD sensor (CPX-0058C), the RevE sensors (CPX-0019C, CPX-0020C, CPX-0065C), and the Masimo W1 (CPX-0146C). CIB at 26-35. Complainants allege that the RevA, RevD, RevE, and Masimo W1 devices practice claim 12 of the ’501 patent and claims 12, 24, and 30 of the ’648 patent; and that the RevD, RevE, and Masimo W1 devices

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practice claim 28 of the '502 patent. CIB at 85-117. For the reasons discussed below, the evidence shows, by a preponderance, that Complainants have satisfied the technical prong with respect to certain claims of the Poeze patents.

1. Consideration of Post-Complaint Evidence

As an initial matter, the parties dispute whether evidence of post-complaint activities can be considered in the context of the domestic industry requirement. *See* RIB at 18-21; RRB at 17-18, 154; CRB at 11-13.

Apple argues that the only evidence that should be considered with respect to the alleged domestic industry is evidence of activities that pre-date the filing of the complaint, citing Commission precedent requiring that satisfaction of the domestic industry requirement be assessed at the time of the complaint. RIB at 18-21. Apple relies on *Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing the Same* (“*Thermoplastic-Encapsulated Electric Motors*”), where the Commission stated that “[o]rdinarily, the relevant date at which to determine if the domestic industry requirement of section 337 is satisfied is the filing date of the complaint.” Inv. No. 337-TA-1073, Comm’n Op. at 6-7, EDIS Doc. ID 684974 (Aug. 12, 2019). Apple argues that the date of the complaint is the relevant timeframe for evaluating the domestic industry, and that the Commission has held that it “will consider post-complaint evidence regarding domestic industry only in very specific circumstances, *i.e.*, ‘when a significant and unusual development has occurred after the complaint has been filed.’” *Certain Collapsible Sockets for Mobile Electronic Devices and Components Thereof*, Inv. No. 337-TA-1056, Comm’n Op. at 15 n.10, EDIS Doc. ID 649819 (July 9, 2018) (quoting *Certain Television Sets, Television Receivers, Television Tuners, and*

Components Thereof, Inv. No. 337-TA-910, Comm'n Op. at 72, EDIS Doc. ID 568157 (Oct. 30, 2015)).

With respect to the technical prong, Complainants contend that post-complaint evidence can be considered in this investigation because the Masimo W1 (a post-complaint product) has been shown to practice claims of the asserted patents, in contrast to the post-complaint products in *Thermoplastic-Encapsulated Electric Motors*. CRB at 12. With respect to the economic prong, Complainants also distinguish the facts in *Thermoplastic-Encapsulated Electric Motors* because [REDACTED] *Id.*

Complainants further argue that Masimo has made certain investments that represent significant and unusual developments, including investments in [REDACTED] [REDACTED] and the acquisition of Sound United. *See* Tr. (Scruggs) at 433:13-15; Tr. (McGavock) at 543:16-544:14, 545:3-17; Tr. (Al-Ali) at 323:18-324:25; Tr. (Muhsin) at 344:14-345:1; CX-1637 (Masimo 2021 Earnings Presentation) at 19-20; Tr. (Young) at 482:14-25.

Consistent with Commission precedent, evidence regarding Complainants' post-complaint activities will not be considered with respect to the domestic industry in this investigation.

The Commission has held that, "as a general matter, the only activities that are relevant to the determination of whether a domestic industry exists or is in the process of being established are those that occurred before the complaint was filed." *Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op., 2012 WL 13171643, at *3 (Jan. 20, 2012). However, "in appropriate situations, based on the specific facts and circumstances of an investigation, the Commission may consider activities and investments beyond the filing of the

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complaint.” *Id.*¹² The Commission has held that such “facts and circumstances” may be shown by “a significant and unusual development” such as circumstances pertaining to “bankruptcy, a change in patent ownership, manufacturing, or licensing activity.” *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm’n Op., 2015 WL 6755093 (Oct. 30, 2015). Where there has been no showing of significant and unusual developments, the Commission has held that it would be error to “consider[] evidence as of the close of discovery, rather than as of the complaint filing date.” *Certain Televisions, Remote Controls, and Components Thereof*, Inv. No. 337-TA-1263, Comm’n Op., 2022 WL 17486245, at *13 (Nov. 30, 2022) (“*Certain Televisions*”).

Complainants have not made a showing of significant and unusual developments in the present investigation.¹³ Complainants rely on developments with respect to the manufacturing of “Masimo Watch” products, CIB at 289-90, but to the extent that the Commission has considered post-complaint evidence due to unusual developments regarding manufacturing, this has been in circumstances involving the cessation of domestic manufacturing. *See, e.g., Certain Video Graphics Display Controllers, and Products Containing Same*, Inv. No. 337-TA-412, Initial Determination at 12-13, EDIS Doc. ID 172529 (May 17, 1999) (unreviewed in relevant part); *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376,

¹² The Federal Circuit has similarly affirmed the Commission’s use of the complaint’s filing date for assessing domestic industry under the facts and circumstances of the cases at issue. *See Bally/Midway Mfg. v. U.S. Int’l Trade Comm’n*, 714 F.2d 1117, 1120 (Fed Cir. 1983) (holding that, “under the circumstances of this case,” the proper date for assessing the domestic “industry” was the filing date of the complaint, where a different position would undercut the purposes of Section 337); *Motiva, LLC v. Int’l Trade Comm’n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013) (affirming Commission’s use of the complaint’s filing date as the relevant date for the domestic industry determination).

¹³ Apple argues that Complainants have waived any contention regarding “significant and unusual developments” because this argument was not raised in Complainants’ pre-hearing brief. *See* RRB at 154. Complainants did not waive this argument. *See* CPHB at 229-231.

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Comm'n Op. 4, 10-13, EDIS Doc. ID 44138 (Aug. 21, 1997). Masimo's post-complaint progress towards the manufacture of "Masimo Watch" products appears to be consistent with Masimo's pre-complaint plans and projections for these products—there is nothing significant or unusual about these developments. *See* RIB at 19. Accordingly, post-complaint evidence regarding the alleged domestic industry will not be considered. *Cf. Certain Televisions, 2022 WL 17486245, Comm'n Op. at *13* (holding that, in the context of considering whether the technical prong of the domestic industry had been shown, the ID erred to the extent post-complaint evidence was considered).¹⁴

Masimo's asserted pre-complaint domestic industry products are the RevA (CPX-0052C), RevD (CPX-0058C), and RevE prototypes (CPX-0019C, CPX-0020C, CPX-0065C). There is no dispute that the RevA and RevD sensors were made before the filing of the complaint—Mr. Scruggs explained that Masimo built the RevA sensor in November 2020, and the RevD sensor in April 2021. *Tr. (Scruggs) at 396:2-13, 397:7-24*. Masimo contends that two of the RevE prototypes were created pre-complaint. *See* CRB at 31-32.¹⁵

The undersigned will not consider any evidence regarding the Masimo W1 product, because this product made in December 2021, several months after the complaint was filed. *See Tr. (Kiani) at 124:5-24; Tr. (Scruggs) at 398:24-399:400:2*.

¹⁴ The underlying Initial Determination reviewed by the Commission, like the investigation here, included a claim for a domestic industry in the process of being established. *See Certain Televisions, Remote Controls, and Components Thereof, Inv. No. 337-TA-1263, Initial Determination, at 89-92, 144-145* (June 28, 2022) (EDIS Doc. ID 775506).

¹⁵ Apple contends that the software installed on the RevD sensor has a most recent date of July 30, 2021, and that the software installed on the RevE sensors was not loaded until September and October 2021, with an earliest "known date" of July 9, 2021—after the filing of the complaint. *See* RIB at 42-43. This issue is discussed *infra* in the context of whether a domestic industry existed at the time of the complaint.

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A limitation-by-limitation analysis for the RevA, RevD, and RevE devices is set forth below.

2. '501 Patent Claim 12

a. Element [1 preamble]: “A user-worn device configured to noninvasively measure a physiological parameter of a user, the user-worn device comprising:”

The preamble of '501 patent claim 1 requires “[a] user-worn device configured to non-invasively measure a physiological parameter of a user.” Complainants submit that the RevA, RevD, and RevE devices meet this limitation because they are configured to measure the oxygen saturation and pulse rate of a user. CIB at 86-87; *see also* CIB at 30-35. Complainants rely on testimony from Mr. Scruggs and Mr. Muhsin describing the functionality of each of the Masimo devices. Tr. (Scruggs) at 407:22-408:4, 410:1-4, 405:8-406:11; Tr. (Muhsin) at 346:6-15. Dr. Madisetti observed a demonstration of the RevA, RevD, and RevE by Mr. Scruggs and determined that these devices each calculate oxygen saturation. Tr. (Madisetti) at 715:20-716:21; CDX-0011C.054. Mr. Al-Ali described internal testing of the oxygen saturation measurements of Masimo’s prototype sensors that was presented in October 2020. Tr. (Al-Ali) at 272:16-277:13; CX-0378C at 32. He described this presentation as relating to a sensor with a design consistent with the RevA device (CPX-0052C). *See* Tr. (Al-Ali) at 270:17-22 (referencing *id.* at 260:11-25:14 (discussing CX-0375C; CPX-0052C)). He also described testing of other prototype Masimo Watch devices in early 2021. Tr. (Al-Ali) at 265:15-268:21, 276:12-278:3; CX-0433C. Mr. Al-Ali further described testing of RevE devices in June 2021. Tr. (Al-Ali) at 316:2-317:20; CX-0494C. Masimo submits that the test results for the domestic industry products show a degree of accuracy that is consistent with FDA guidance. CIB at 85 (citing CX-0269).

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Apple argues that Complainants have not met their burden to show that any of the domestic industry products measure oxygen saturation. RIB at 46-52. Apple submits that Complainants failed to identify the source code in the domestic industry products that calculates any physiological parameter. *Id.* at 47-48; *see* Tr. (Sarrafzadeh) at 1124:24-1125:11. Apple's experts testified that their observations of demonstrations of the domestic industry products were insufficient to determine whether oxygen saturation or pulse rate were being measured. Tr. (Warren) at 1254:8-1256:25; Tr. (Sarrafzadeh) at 1122:20-1126:20. They further testified that certain measurements of blood oxygen relied upon by Complainants were "inconsistent" with reference measurements from another Masimo device. Tr. (Sarrafzadeh) at 1126:7-20; Tr. (Warren) at 1256:2-25; RDX-0008.149C.

With respect to the RevA and RevD sensors, Apple disputes whether these are "user-worn" devices, because the devices were produced without a strap or any other means for being worn by a user. RIB at 45-46. Complainants submit that each of these sensors includes mechanisms for attaching a strap, and Mr. Scruggs testified that they each had straps "at one point in time." Tr. (Scruggs) at 405:8-406:3, 406:23-407:18; CIB at 89.

In consideration of this evidence, the undersigned finds that Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices measure blood oxygen saturation. The testimony of Masimo's witnesses is credible regarding the design and testing of these products with respect to measuring blood oxygen, and is supported by the results of the testing described in Masimo's documents. In particular, Mr. Al-Ali explicitly identified testing of blood oxygen functionality conducted in 2020 using prototype designs consistent with the RevA sensor, additional testing in the timeframe of the RevD devices in early 2021, and further testing of RevE devices in June 2021. Tr. (Al-Ali) at 260:11-25:14, 265:15-268:21, 270:17-22,

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276:12-278:3, 315:16-316:18; CX-0375C; CX-0378C; CX-0433C; CX-0494C.¹⁶ Dr. Madisetti observed a demonstration of the RevA, RevD, and RevE by Mr. Scruggs and determined that these devices each calculate oxygen saturation. Tr. (Madisetti) at 715:20-716:21; CDX-0011C.054.¹⁷ Apple’s experts also attended a demonstration of the RevA, RevD, and RevE by Mr. Scruggs, although their observations were inconclusive. Tr. (Warren) at 1254:4-1256:25; Tr. (Sarrafazadeh) at 1122:20-1126:20; RDX-0007C.154; RX-1470; *see* Tr. (Warren) at 1258:9-17 (“My opinion is that these DI articles do not implement the functionality in that’s in the claims, because I was not able to establish that they were producing physiological parameters.”).¹⁸ The testimony of Mr. Ali-Ali regarding Masimo’s internal testing, together with Dr. Madisetti’s testimony, credibly indicate that Masimo’s sensors are configured to make oxygen saturation measurements. *See* Tr. (Ali-Ali) at 272:16-275:12, 276:12-278:3, 318:15-22;

¹⁶ This testing included a [REDACTED] that, Mr. Ali-Ali explained, provided measurements “well within acceptable numbers for a hospital product.” *See* Tr. (Ali-Ali) at 274:11-275:3. Apple argues that this testing is not clearly linked to the specific domestic industry prototypes produced, CRB at 41-42, but the timing of these testing results matches with the development of the RevA, RevD, and RevE devices, and the fact that Masimo was able to test the blood oxygen functionality of multiple prototypes during this time is strong circumstantial evidence that the RevA, RevD, and RevE devices were capable of measuring blood oxygen, particularly given the evidence that these devices were not separate products, but part of an iterative design process. *See, e.g.*, Tr. (Scruggs) at 394:13-398:23. Moreover, as discussed *infra*, a domestic industry in the process of being established does not require the current existence of a physical article. Thus, this testing also strongly supports a finding that Masimo had, at the time of filing the complaint, taken necessary tangible steps to develop a product that will practice this limitation of the patent and a significant likelihood of success in doing so.

¹⁷ Apple cites the fact that Dr. Madisetti was unable to identify the correct Masimo source code at hearing. *See* CRB at 33-34. This does not undercut the demonstrated evidence that Masimo tested its devices to measure blood oxygen saturation.

¹⁸ Apple’s experts identified differences in the oxygen saturation measurements of a commercially available pulse oximeter in comparison to the Masimo W1, but this post-complaint device is not being considered as part of the asserted domestic industry. *See* RDX-0008.149C. Moreover, the variation in the measurements appears to be consistent with FDA guidance regarding pulse oximetry—an FDA document identified by Complainants states: “For example, if an FDA-cleared pulse oximeter reads 90%, then the true oxygen saturation in the blood is generally between 86%-94%.” CX-0269 (FDA Safety Communication) at 4.

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CX-0378C at 32; CX-0494C; Tr. (Madisetti) at 715:20-716:20; CDX-0011C.054. The evidence of record is sufficient to show, by a preponderance, that the RevA, RevD, and RevE sensors measure blood oxygen.

With respect to the “user-worn” limitation, there is no dispute that the RevE sensors have straps that allow these devices to be worn. *See* Tr. (Scruggs) at 408:20-409:14; CPX-0019C; CPX-0020C; CPX-0065C. The RevA and RevD sensors produced in discovery do not have straps, but these devices have attachment mechanisms for a strap, and Mr. Scruggs testified that these devices had straps “at one point in time.” Tr. (Scruggs) at 405:8-406:3, 406:23-407:18, 460:13-17. Moreover, as discussed above, Mr. Al-Ali described testing relating to the Masimo’s RevA and RevD sensors in the fall of 2020 and early 2021. Tr. (Al-Ali) at 260:11-25:14, 265:15-268:21, 270:17-22, 276:12-278:3. His description of this testing suggests that the devices were “user-worn.” *See Id.* at 278:5-13 (describing placement of devices on user’s wrist).¹⁹ The evidence is sufficient to show, by a preponderance, that the RevA, RevD, and RevE sensors meet the “user-worn” limitation.

Accordingly, a preponderance of the evidence of record shows that the RevA, RevD, and RevE sensors meet the limitations of the preamble of ’501 patent claim 1.

b. Element [1A]: “at least three light emitting diodes (LEDs)”

There is no dispute that the RevA, RevD, and RevE devices each contain a sensor module with at least three LEDs. *See* CIB at 89-91; RIB at 45-54. Dr. Madisetti identified two clusters of LEDs in each of these devices, with each cluster containing four or five LEDs. Tr. (Madisetti) at 711:14-712:4, 712:20-713:15; CDX-0011C.09 (citing CX-1111C (RevA CAD); CX-1124C

¹⁹ The testing data for the sensor consistent with the RevA device includes “Motion Analysis,” including “Walking/Running.” CX-0378C at 27.

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(RevD CAD); CX-1125C (RevE CAD); *see* CPX-0052C (RevA); CPX-0058C (Rev D); CPX-0019C, CPX-0020C, CPX-0065C (RevE). The evidence of record shows that this limitation is met by the RevA, RevD, and RevE devices.

c. Element [1B]: “at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user”

Dr. Madisetti identified at least three photodiodes on an interior surface in each of the RevA, RevD, and RevE devices. Tr. (Madisetti) at 712:5-19. He relied on photographs and schematics of the devices to identify the photodiodes. *Id.*; CDX-0011C.050 (for RevA citing CPX-0052C; CX-0661C (photo)); CX-0473C (schematic) at 1, 3; CX-1111C (CAD) at 3, 5, 6; for RevD citing CPX-0058C; CX-0389C (schematic) at 1, 3; CX-1124C (CAD) at 3-4, 8; for RevE citing CPX-0019C, CPX-0020C, CPX-0065C; CX-0653C, CX-0655C, CX-0676C (photos); CX-0390C (schematic) at 1, 3; CX-1125C (CAD) at 2, 6, 7); *see generally* CIB at 91-92.

Apple argues that the evidence produced by Complainants is insufficient to show that these devices each have at least three photodiodes, because these elements are not visible from the outside of the devices and the schematics and technical drawings are allegedly unreliable. RIB at 52-54. Mr. Scruggs admitted that there were certain discrepancies between Masimo’s CAD files and the actual RevA, RevD, and RevE sensors, recognizing that the devices represented “what we were able to manufacture at the time.” RX-1209C (Scruggs Dep. Tr.) at 91:18-92:24; *see also* Tr. (Scruggs) at 465:2-467:18 (confirming “there are some differences” between the CAD files and the prototype products). Dr. Warren was unable to confirm whether the devices had photodiodes through a visual inspection. Tr. (Warren) at 1259:12-23.

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In consideration of the parties' arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices each have at least three photodiodes meeting this claim limitation. Although there are some discrepancies between the physical prototypes and Masimo's schematics and technical drawings, there is no evidence that the layout of the photodiodes is inaccurate. Mr. Scruggs testified that "the essential meat and potatoes stuff, like the sensor, it's very accurately reflected" by the CAD drawings, because "that's very important for the devices." Tr. (Scruggs) at 467:2-7, 477:9-478:8; *see also* Tr. (Al-Ali) at 313:144-314:7 (confirming the accuracy of the CAD drawings for the RevE sensors).

Accordingly, the evidence shows, by a preponderance, that each of the RevA, RevD, and RevE devices meet the "at least three photodiodes" limitation of '501 patent claim 1.

d. Element [1C]: "a protrusion arranged over the interior surface, the protrusion comprising a convex surface"

There is no dispute that the RevA, RevD, and RevE devices each contain a convex protrusion. *See* CIB at 92-93. Dr. Madisetti identified convex protrusions in each of these devices, relying on photographs and the physical devices. Tr. (Madisetti) at 713:16-714:7; CDX-0011C.051 (citing CX-0813C (RevA); CX-0815C (RevD); CX-0812C (RevE); *see* CPX-0052C (RevA); CPX-0058C (Rev D); CPX-0019C, CPX-0020C, CPX-0065C (RevE). The evidence of record shows that this limitation is met by the RevA, RevD, and RevE devices.

e. Element [1D]: "a plurality of openings extending through the protrusion and positioned over the three photodiodes"

In the convex protrusion of the RevA, RevD, and RevE devices, Dr. Madisetti identified openings with transparent windows, relying on technical drawings and the physical devices. Tr. (Madisetti) at 714:8-24; CDX-0011C.052 (citing CX-1111C (RevA); CX-1124C (RevD); CX-

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1125C (RevE)); *see* CPX-0052C (RevA); CPX-0058C (Rev D); CPX-0019C, CPX-0020C, CPX-0065C (RevE); CIB at 93-95. Apple argues that these features are not “openings,” referencing its non-infringement arguments for this limitation. RRB at 43. This argument is inconsistent with the claim construction for “openings” adopted above, and accordingly, the evidence shows that the RevA, RevD, and RevE devices meet the plurality of openings” limitation of ’501 patent claim 1.

f. Element [1E]: “the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion”

Mr. Scruggs described a “light barrier” present in the RevA, RevD, and RevE devices that is a “black feature that surrounds the emitters so it separates the LEDs from the photodiodes.” Tr. (Scruggs) at 400:3-24; CDX-005C.002. He explained that the light barrier was configured “so that light would travel only into the skin and . . . to minimize light traveling within the sensor.” *Id.* Dr. Madisetti identified these features in technical drawings for the RevA, RevD, and RevE devices and testified that these were opaque lateral surfaces configured to allow light to reach the photodiodes and to avoid light piping through the protrusion. Tr. (Madisetti) at 714:25-19; CDX-0011C.053 (citing CX-1111C (RevA); CX-1124C (RevD); CX-1125C (RevE)).

Apple argues that the evidence produced by Complainants is insufficient to show that these devices have the claimed opaque lateral surfaces, because these features are not visible from the outside of the devices, and the schematics and technical drawings are allegedly unreliable. RIB at 52-54; RRB at 43-44. For the same reasons discussed above in the context of the “at least three photodiodes” limitation, Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices each have opaque lateral surfaces meeting this

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claim limitation. The undersigned finds Mr. Scruggs's testimony regarding these features to be credible and Masimo's CAD drawings to be reliable with respect to these features.

Accordingly, the evidence shows by a preponderance that each of the RevA, RevD, and RevE devices meet the "opaque lateral surface" limitation of '501 patent claim 1.

g. Element [1F]: "one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user"

Dr. Madisetti identifies processors in the RevA, RevD, and RevE devices that receive signals from photodiodes and calculate oxygen saturation. Tr. (Madisetti) at 715:20-716:21. Dr. Madisetti relies on documentation for each of these products. *Id.*; CDX-0011C.054 (for RevA: CX-0701C at 2, CPX-012C, and CX-0836C at 4; for RevD: CX-0710C at 2-3, CX-1062C at 48, and CX-1074C; for RevE: CX-0705C at 2-3, CX-1062C at 30, 35). Mr. Scruggs described the measurement of oxygen saturation and pulse rate in each iteration of the Masimo Watch. Tr. (Scruggs) at 393:17-394:3. He described the sensor board of the RevA device including two processors on the sensor board responsible for calculating the pulse oximetry measurement. *Id.* at 406:4-11. He also identified two processors on the sensor board of the RevD device. *Id.* at 408:11-19.

As discussed above in the context of the preamble, Apple argues that Complainants have not met their burden to show that any of the domestic industry products measure oxygen saturation. RIB at 46-52. For the reasons discussed above, however, the undersigned finds that Complainants have met their burden to show, by a preponderance, that the RevA, RevD, and RevE devices calculate oxygen saturation. The record evidence further shows, by a preponderance, that the RevA, RevD, and RevE each contain processors for receiving signals from the photodiodes and calculating oxygen saturation.

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Accordingly, the evidence shows that each of the RevA, RevD, and RevE devices meet the “one or more processors” limitation of ’501 patent claim 1.

h. Element [12]: “wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape”

Claim 12 of the ’501 patent depends from claim 1, further requiring that “the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape.” There is no dispute that this limitation is practiced by the RevA, RevD, and RevE devices. *See* CIB at 102. As discussed above, Dr. Madisetti identified a convex protrusion in these products, and his analysis confirms that the protrusion is designed to contact a user’s wrist and conform the skin into a concave shape. *See* Tr. (Madisetti) at 716:24-717:13; CDX-0011C.055 (citing CX-0813C (RevA); CX-0815C (RevD); CX-0812C (RevE)).

Accordingly, because each limitation of claims 1 and 12 are satisfied by a preponderance of the evidence, the undersigned finds that the RevA, RevD, and RevE devices practice claim 12 of the ’501 patent.

3. ’502 Patent Claim 28

a. Element [28 preamble]: “A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:”

The preamble of ’502 patent claim 28 requires “[a] user-worn device configured to non-invasively measure an oxygen saturation of a user.” The parties’ disputes with respect to this preamble are the same as those addressed above in the context of the preamble of ’501 patent claim 1. *See* CIB at 102; RIB at 54. As discussed above in the context of the preamble of ’501

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patent claim 1, Complainants have shown by a preponderance of the evidence that the RevD and RevE devices are user-worn devices that measure blood oxygen saturation, meeting the limitations of the preamble of '502 patent claim 28.²⁰

- b. Element [28A]: “a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength”**

There is no dispute that the RevD and RevE devices contain LEDs, as discussed above in the context of the “LEDs” limitation of '501 patent claim 1. *See* CIB at 103. Dr. Madisetti identified two clusters of LEDs in each of these devices, with each cluster containing four or five LEDs. Tr. (Madisetti) at 711:14-712:4, 712:20-713:15; CDX-0011C.09 (citing CX-1111C (RevA CAD); CX-1124C (RevD CAD); CX-1125C (RevE CAD); CX-1128C (Masimo W1 CAD); *see* CPX-0052C (RevA); CPX-0058C (Rev D); CPX-0019C, CPX-0020C, CPX-0065C (RevE)). Complainants rely on the testimony of Mr. Scruggs with respect to the wavelengths of light in these LEDs, identifying clusters of four LEDs in the RevD and RevE devices with wavelengths of [REDACTED] Tr. (Scruggs) at 406:23-407:18, 408:20-409:14. Apple argues that Dr. Madisetti did not identify any evidence of these wavelengths and that the arrangement of the LEDs could not be confirmed by a visual inspection, RIB at 55, but Mr. Scruggs’s testimony and Masimo’s schematics are sufficient to show, by a preponderance, that the RevD and RevE devices meet this limitation of '502 patent claim 28.

²⁰ Complainants do not assert that the RevA device practices claim 28 of the '502 patent. *See* CIB at 102-112.

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- c. Element [28B]: “a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength”**

As discussed above in the context of the “LEDs” limitation of ’501 patent claim 1 and the “first set of LEDs” limitation of ’502 patent claim 28, the evidence shows that the RevD and RevE devices each have two separate clusters of LEDs, and Mr. Scruggs described these clusters as having the same sets of wavelengths. *See* Tr. (Scruggs) at 406:23-407:18, 408:20-409:14, 410:5-24. Accordingly, the evidence shows, by a preponderance, that the RevD and RevE devices meet the “second set of LEDs” limitation of ’502 patent claim 28.

- d. Element [28C]: “four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user”**

With respect to the “four photodiodes” limitation of ’502 patent claim 28, Complainants rely on the same evidence discussed above in the context of the “at least three photodiodes” limitation of ’501 patent claim 1. *See* CIB at 103-04. Complainants identify a “quadrant configuration” in schematics of these products that were reviewed by Dr. Madisetti. *Id.* (citing CDX-0011C.050; CX-1111C; CX-1124C; CX-1125C; CX-1128C). Apple argues that Complainants’ evidence with respect to this limitation is unreliable, *see* RIB at 54-55, but for the same reasons discussed above in the context of the “at least three photodiodes” limitation of ’501 patent claim 1, the undersigned finds that Complainants have shown by a preponderance of the evidence that the RevD and RevE devices each have four photodiodes arranged in a quadrant configuration that meet this claim limitation.

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e. Element [28D]: “a thermistor configured to provide a temperature signal”

Dr. Madisetti identified thermistors in the RevD and RevE devices, relying on schematics and technical drawings. Tr. (Madisetti) at 720:21-721:5; CDX-0011C.059 (for RevD citing CX-1124C (CAD) at 3, 8; CX-0536C (schematic) at 1, 3; CX-0710C (schematic) at 3, 7; for RevE citing CX-1125C (CAD) at 2, 7; CX-0705C (schematic) at 3, 7; CX-0390C (schematic) at 3).

Mr. Scruggs identified two thermistors in the RevD and RevE devices. Tr. (Scruggs) at 406:23-407:18 (RevD), 408:20-409:14 (RevE); *see generally* CIB at 104-106.

Apple argues that the evidence produced by Complainants is insufficient to show that these devices have the claimed thermistors, because these features are not visible from the outside of the devices, and the schematics and technical drawings are allegedly unreliable. RIB at 54-55. For the same reasons discussed above in the context of the photodiode limitations of ’501 patent claim 1, the undersigned finds Mr. Scruggs’s testimony regarding these features to be credible and Masimo’s CAD drawings to be reliable with respect to these features.

Accordingly, the undersigned finds that each of the RevD and RevE devices meet the “thermistor” limitation of ’502 patent claim 28.

f. Element [28E]: “a protrusion arranged above the interior surface, the protrusion comprising: a convex surface”

There is no dispute that each of the RevD and RevE devices contain a protrusion comprising a convex surface that is arranged above the interior surface, as discussed above in the context of the “protrusion” limitation of ’501 patent claim 1. *See* CIB at 106. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

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- g. Element [28F]: “a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping”**

There is no dispute that each of the RevD and RevE devices have a “plurality of openings” extending through the protrusion and aligned with the photodiodes, as discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1, and these openings are defined by opaque surfaces, as discussed above in the context of the “opaque lateral surface” limitation of ’501 patent claim 1. *See* CIB at 106. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

- h. Element [28G]: “a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings”**

There is no dispute that each of the RevD and RevE devices have a “plurality of transmissive windows,” as discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. *See* CIB at 106-07. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

- i. Element [28H]: “at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities”**

There is no dispute that each of the RevD and RevE devices contain an opaque wall between the interior surface and the protrusion, as discussed above in the context of the “opaque lateral surface” limitation of ’501 patent claim 1. *See* CIB at 107-08. Dr. Madisetti further identifies cavities formed by the opaque wall and the protrusion, relying on schematics and technical drawings. Tr. (Madisetti) at 721:6-25; CDX-0011C.060 (for RevD citing CX-1124C (CAD); CX-0666C (schematic); for RevE citing CX-1125C (CAD); CX-1038C (schematic)).

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The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

- j. Element [28I]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal”**

There is no dispute that each of the RevD and RevE devices contain processors that receive signals from the photodiodes, as discussed above in the context of the “processors” limitation of ’501 patent claim 1. *See* CIB at 108. Apple disputes whether these processors calculate oxygen saturation, RIB at 54, but as discussed above in the context of the preamble of the ’501 patent claim 1, a preponderance of the evidence shows that the RevD and RevE devices measure and calculate oxygen saturation. Moreover, there is no dispute that the processors receive a temperature signal, as discussed above in the context of the “thermistor” limitation. *See id.* at 104-108. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

- k. Element [28J]: “a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network”**

There is no dispute that the RevD and RevE devices contain network interfaces that can communicate with a mobile device via Bluetooth. *See* CIB at 108-110. Dr. Madisetti identified evidence that these devices have a network interface. Tr. (Madisetti) at 722:1-24; CDX-0011C.061 (citing CX-0709C (RevD and RevE sensor board schematic); CX-0836C (RevE demonstration photographs) at 9, 12, 13). Mr. Scruggs described the wireless communication capability of the RevD and RevE devices. Tr. (Scruggs) at 406:23-407:18, 408:20-409:14. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

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l. Element [28K]: “a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user”

There is no dispute that the RevD and RevE devices have a touch-screen display that shows oxygen saturation measurements. *See* CIB at 111. Dr. Madisetti identified evidence that these devices have touch-screen displays that can show an SpO2 measurement. Tr. (Madisetti) at 722:1-24; CDX-0011C.061 (citing CPX-058C (RevD device); CX-1062C (photographs); CPX-019C, CPX-020C, CPX-065C (RevE devices); CX-1068C, CX-1069C, CX-1072C (RevE device videos)). The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

m. Element [28L]: “a storage device configured to at least temporarily store at least the measurement”

There is no dispute that the RevD and RevE devices store the blood oxygen measurement in memory. *See* CIB at 111. Dr. Madisetti identified evidence that these devices have memory to store the SpO2 measurement. Tr. (Madisetti) at 722:1-24; CDX-001C.061 (citing CX-0709C (RevD and RevE sensor board schematic)). The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

n. Element [28M]: “a strap configured to position the user-worn device on the user”

There is no dispute that the RevE have straps for a user’s wrist. *See* CIB at 112; CPX-019C, CPX-020C, CPX-065C. With respect to the RevD device, Complainants identify a mechanism for attaching a strap and rely on Mr. Scruggs’s testimony that it had a strap “at some point.” *See* Tr. (Scruggs) at 406:23-407:18. As discussed above in the context of the preamble of ’501 patent claim 1, the undersigned finds that a preponderance of the evidence shows that the RevD device also had a strap.

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Accordingly, because each limitation of the claim is satisfied, the undersigned finds that the RevD and RevE products practice claim 28 of the '502 patent.

4. '648 Patent Claim 12

- a. Element [8 preamble]: “A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:”**

The preamble of '648 patent claim 8 requires “[a] user-worn device configured to non-invasively determine measurements of a physiological parameter of a user.” The parties’ disputes with respect to this preamble are the same as those addressed above in the context of the preamble of '501 patent claim 1. *See* CIB at 112; RIB at 55-56. As discussed above in the context of the preamble of '501 patent claim 1, the undersigned finds that Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices are user-worn devices that measure blood oxygen saturation, meeting the limitations of the preamble of '502 patent claim 28.

- b. Element [8A]: “a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength”**

There is no dispute that the RevA, RevD, and RevE devices each contain LEDs, as discussed above in the context of the “LEDs” limitation of '501 patent claim 1. *See* CIB at 112-13. Apple disputes whether the LEDs meet each of these limitations, *see* RIB at 56, but as discussed in the context of the “first set of LEDs” limitation of '502 patent claim 28, the evidence shows that the LEDs are arranged in clusters in the RevD and RevE devices and have a first and second wavelength. In addition, the evidence shows that the LEDs in the RevA device

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have wavelengths that are the same as the RevD and RevE devices, as discussed by Mr. Scruggs.

See Tr. (Scruggs) at 405:8-406:3.

- c. **Element [8B]: “a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength”**

There is no dispute that the RevA, RevD, and RevE devices each contain clusters of LEDs, as discussed above in the context of the “LEDs” limitation of ’501 patent claim 1. *See* CIB at 112-13. Moreover, the undersigned finds that there is a second set of LEDs in the RevD and RevE devices meeting his limitation, as discussed in the context of the “second set of LEDs” limitation of ’502 patent claim 28. *See* CIB at 113. In addition, the evidence shows that there is a second set of LEDs in the RevA device with the same wavelengths as the first set, as discussed by Mr. Scruggs. *See* Tr. (Scruggs) at 405:8-406:3.

- d. **Element [8C]: “four photodiodes”**

Complainants identify four photodiodes in each of the RevA, RevD, and RevE devices, citing the same evidence discussed above in the context of the “photodiodes” limitation of ’501 patent claim 1. *See* CIB at 113. Apple disputes whether the evidence is sufficient to show the presence of these photodiodes, *see* RIB at 56, but the evidence shows, by a preponderance, that the RevA, RevD, and RevE devices each contain four photodiodes, for the reasons discussed above in the context of the “photodiodes” limitation of ’501 patent claim 1.

- e. **Element [8D]: “a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material”**

There is no dispute that the RevA, RevD, and RevE devices each contain a protrusion comprising a convex surface, which includes a portion with opaque material, as discussed above in the context of the “protrusion” and “openings” limitations of ’501 patent claim 1. *See* CIB at

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113. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

f. Element [8E]: “a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes”

Complainants identify a “plurality of openings” in the RevA, RevD, and RevE devices, citing the same evidence discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. *See* CIB at 113. Apple disputes this limitation based on its erroneous construction for the term “openings.” *See* RRB at 46. As discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1, the evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

g. Element [8F]: “a separate optically transparent window extending across each of the openings”

There is no dispute that the RevA, RevD, and RevE devices each contain optically transparent windows extending across each of the identified openings, as discussed above in the context of the “plurality of openings” limitation of ’501 patent claim 1. *See* CIB at 113-14. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

h. Element [8G]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user”

There is no dispute that the RevA, RevD, and RevE devices each contain processors that receive signals from the photodiodes, as discussed above in the context of the “processors” limitation of ’501 patent claim 1. *See* CIB at 114. Apple disputes whether these processors calculate oxygen saturation, RIB at 56, but as discussed above in the context of the preamble of the ’501 patent claim 1, a preponderance of the evidence shows that the RevA, RevD, and RevE

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devices measure and calculate oxygen saturation. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

i. Element [8H]: “a housing”

There is no dispute that the RevA, RevD, and RevE devices each have a housing. *See* CIB at 114-15. Dr. Madisetti identified photographs of the housing for the RevA, RevD, and RevE devices. Tr. (Madisetti) at 725:19-726:1; CDX-0011C.066 (citing CX-0661C; CX-1058C; CX-1415C; CX-0784C); *see also* CPX-052C; CPX-058C; CPX-019C; CPX-020C; CPX-065C. Mr. Scruggs also testified that the RevA, RevD, and RevE devices each have a housing. Tr. (Scruggs) at 405:8-06:3, 406:23-407:18, 408:20-409:14. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

j. Element [8I]: “a strap configured to position the housing proximate tissue of the user when the device is worn”

There is no dispute that the RevE devices have straps for a user’s wrist. *See* CIB at 115; CPX-019C, CPX-020C, CPX-065C. In addition, as discussed above in the context of the preamble of ’501 patent claim 1, the undersigned finds that the record evidence is sufficient to find that the RevA and RevD devices had straps.

k. Element [12]: “the physiological parameter comprises oxygen or oxygen saturation”

Claim 12 of the ’648 patent depends from claim 8 and requires that “the physiological parameter comprises oxygen or oxygen saturation.” There is no dispute with respect to this limitation, except to the extent that Apple disputes the satisfaction of the preamble limitation regarding the measurement of a physiological parameter. *See* CIB at 115; RIB at 56. The undersigned finds that the RevA, RevD, and RevE devices are configured to determine

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measurements of blood oxygen for the same reasons discussed above in the context of the preamble and the “physiological parameter” limitation of ’501 patent claim 1.

Accordingly, because each limitation of the claim is satisfied, the undersigned finds that the RevA, RevD, and RevE devices practice claim 12 of the ’648 patent.

5. ’648 Patent Claim 24

- a. Element [20 preamble]: “A user-worn device configured to non-invasively determine measurements of a user’s tissue, the user-worn device comprising:”**

The preamble of ’648 patent claim 20 requires “[a] user-worn device configured to non-invasively determine measurements of a user’s tissue.” The parties’ disputes with respect to this preamble are the same as those addressed above in the context of the preamble of ’501 patent claim 1. *See* CIB at 115; RIB at 55-56. As discussed above in the context of the preamble of ’501 patent claim 1, Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices are user-worn devices that measure blood oxygen saturation, meeting the limitations of the preamble of ’648 patent claim 20.

- b. Element [20A]: “a plurality of light emitting diodes (LEDs)”**

There is no dispute that the RevA, RevD, and RevE devices each contain LEDs, as discussed above in the context of the “LEDs” limitation of ’501 patent claim 1. *See* CIB at 115.

- c. Element [20B]: “at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user”**

With respect to the “four photodiodes” limitation of ’648 patent claim 20, Complainants rely on the same evidence discussed above in the context of the “four photodiodes” limitation of ’502 patent claim 28 for the RevD and RevE devices. *See* CIB at 115-16. Complainants further

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submit that the RevA has four photodiodes arranged in a quadrant configuration, citing a photograph and technical drawings. *See* CX-0661C (photo); CX-0473C (schematic) at 1, 3; CX-1111C (CAD). Apple argues that Complainants' evidence with respect to this limitation is unreliable, *see* CIB at 56, but for the same reasons discussed above in the context of the "at least three photodiodes" limitation of '501 patent claim 1, Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices each have four photodiodes arranged in a quadrant configuration that meet this claim limitation.

d. Element [20C]: "a protrusion comprising a convex surface"

There is no dispute that the RevA, RevD, and RevE devices each contain a protrusion comprising a convex surface, which includes a portion with opaque material, as discussed above in the context of the "protrusion" limitation of '501 patent claim 1. *See* CIB at 116. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

e. Element [20D]: "a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes"

Complainants identify "through holes" in the RevA, RevD, and RevE devices, citing the same evidence discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. *See* CIB at 116. Apple disputes this limitation based on its erroneous construction for the term "openings." *See* RRB at 46. As discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1, the evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

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f. Element [20E]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user”

There is no dispute that the RevA, RevD, and RevE devices each contain processors that receive signals from the photodiodes, as discussed above in the context of the “processors” limitation of ’501 patent claim 1. *See* CIB at 116-17. Apple disputes whether these processors calculate oxygen saturation, RIB at 56, but as discussed above in the context of the preamble of the ’501 patent claim 1, a preponderance of the evidence shows that the RevA, RevD, and RevE devices measure and calculate oxygen saturation. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

g. Element [24]: “wherein the protrusion comprises opaque material configured to substantially prevent light piping”

Claim 24 of the ’648 patent depends from claim 20, further requiring that “the protrusion comprises opaque material configured to substantially prevent light piping.” There is no dispute that the identified protrusion in the RevA, RevD, and RevE devices meets this limitation, as discussed above in the context of the “opaque lateral surface” limitation of ’501 patent claim 1. *See* CIB at 117.

Accordingly, because each of the limitations of claims 20 and 24 are satisfied, the undersigned finds that the RevA, RevD, and RevE devices practice claim 24 of the ’648 patent.

6. ’648 Patent Claim 30

Claim 30 of the ’648 patent depends from claim 20, further requiring that “the protrusion further comprises one or more chamfered edges.” There is no dispute that the identified protrusions in the RevA, RevD, and RevE devices have chamfered edges. *See* CIB at 117. Dr. Madisetti identified chamfered edges on engineering drawings for the RevA, RevD, and

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RevE. Tr. (Madisetti) at 726:2-14; CDX-0011C.067 (citing CX-1111C (RevA); CX-1124C (RevD); CX-1125C (RevE)).

Accordingly, because each of the limitations of claims 20 and 30 are satisfied, the undersigned finds that the RevA, RevD, and RevE devices practice claim 30 of the '648 patent.

7. Domestic Industry Existing at the Time of the Complaint

Apple argues that no patent-practicing domestic industry article existed at the time of the complaint. RIB at 42-45; RRB at 12-14. Complainants dispute Apple's contentions. CRB at 30-32. As discussed above, Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices practice claim 12 of the '501 patent and claims 12, 24, and 30 of the '648 patent, and that the RevD and RevE devices also practice claim 28 of the '502 patent.

With respect to a domestic industry that is alleged to exist at the time of the complaint, the Commission has held that a domestic industry article must exist at that time. *See Thermoplastic-Encapsulated Electric Motors*, Comm'n Op. at 9, EDIS Doc. ID 684974 ("Both Federal Circuit law and Commission precedent require the existence of actual 'articles protected by the patent' in order to find that a domestic industry exists.") (citing *Microsoft Corp. v. Int'l Trade Comm'n*, 731 F.3d 1354 (Fed. Cir. 2013) ("[a] company seeking section 337 protection must . . . provide evidence that . . . relates to an actual article that practices the patent")); *id.* at 10 (finding that no domestic industry "exists" relating to the articles protected by the patent where evidence failed to show "the presence of an article protected by the patent at the time of the complaint").

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In consideration of the parties' arguments, the undersigned finds that the RevA, RevD, and RevE devices have been shown to be articles protected by claims of the Poeze patents existing at the time of the complaint. As discussed *supra*, although the RevA and RevD devices were produced in discovery without a strap, a preponderance of the evidence shows that these devices were user-worn devices before the filing of the complaint. *See* Tr. (Scruggs) at 405:8-406:3, 406:23-407:18, 460:13-17; Tr. (Al-Ali) at 260:11-25:14, 265:15-268:21, 270:17-22, 276:12-278:3; CX-0378C at 27.

Apple further argues that the laptop Mr. Scruggs used to display the oxygen saturation measurement from the RevA sensor during discovery was not used with this sensor before the filing of the complaint, RIB at 43-44, but this laptop is not part of the domestic industry article protected by the identified claims of the Poeze patents (Complainants do not assert that the RevA practices claim 22 of the '502 patent, which requires a display). *See* CRB at 30-31. Mr. Scruggs's laptop was part of the demonstration showing that the RevA sensor was configured as required by the claims, *see* Tr. (Madisetti) at 757:16-23; CX-0836C (demonstration photos) at 4, but the laptop is not part of the domestic industry article—the RevA had the required configuration even in the absence of the laptop.²¹

With respect to the RevD sensor, Apple argues that software was loaded on this device on July 30, 2021, after the complaint was filed. RIB at 42-43; *see* Tr. (Scruggs) at 459:4-460:7; Tr. (Sarrafzadeh) at 1121:9-24; RX-1183C.0035-39. As discussed above, however, Mr. Al-Ali described testing of RevD sensors in early 2021—before the filing of the complaint. Tr. (Al-Ali)

²¹ As described by Mr. Al-Ali, an October 2020 presentation describes internal testing of the oxygen saturation measurements of prototype sensors consistent with the RevA design. Tr. (Al-Ali) at 272:16-277:13; CX-0378C at 32.

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at 276:17-278:13. A preponderance of the evidence thus shows that the RevD existed prior to the complaint.²²

With respect to the RevE devices, Apple argues that the software installed on these devices has a “known date” of July 9, 2021, and this software was loaded on these devices in September and October 2021. *See* RIB at 42-43; Tr. (Scruggs) at 457:12-25, 458:1-459:2, 460:23-461:16; Tr. (Sarrafzadeh) at 1121:9-24; RX-1183C.0035-39. At the hearing, Mr. Scruggs could not specifically identify a date when the RevE devices were made, stating that they were “built between May and September 2021,” a range of dates that includes the date the complaint was filed. Tr. (Scruggs) at 398:20-23; *see id.* at 458:1-459:3 (admitting that CPX-0020C was created in September 2021). The evidence shows that at least one of the RevE devices produced (CPX-0019C) existed at the time of the complaint—the evidence shows that software was loaded on this device on July 9, 2021,²³ which pre-dates the filing date of the amended complaint, July 12, 2021, as recognized in the Commission’s Notice of Institution. 86 Fed. Reg. 46275.²⁴ Moreover, Mr. Al-Ali described testing of RevE devices (though not the

²² Apple’s arguments focus on the physical devices produced in discovery, *e.g.*, CPX-0058C, which were loaded with specific software, but the circumstantial evidence regarding testing shows, by a preponderance of the evidence, that prototype devices with designs that are consistent with the asserted domestic industry products were operational before the filing of the complaint and subject to testing. *See* Tr. (Ali-Ali) at 272:16-275:12, 276:12-278:3, 318:15-22; CX-0378C at 32; CX-0494C; n.16 *supra*.

²³ Complainants acknowledge that these devices were altered after the filing of the complaint with “different firmware versions prior to and subsequent to that version for development,” but have represented that the July 9 version of the software was restored in October 2021. *See* RX-1183C.0037-.0039; Tr. (Scruggs) at 457:9-21 (software was installed on physical 19 on July 9, 2021).

²⁴ The original complaint was filed on June 30, 2021, with a redacted public version of an amended complaint filed July 7, 2021, a full confidential version of the amended complaint filed on July 12, 2021, and a supplement to the complaint filed on July 19, 2021. *See* EDIS Doc. ID 745713, 746186, 746514, 747244. *See In re Samsung Electronics Co., Ltd.*, 2 F.4th 1371, 1376 (Fed. Cir. 2021) (amended complaints supersede the original complaint); *Nolen v. Lufkin Indus., Inc.*, 466 Fed. Appx. 895, 898 (Fed. Cir. 2012) (“Generally, an amended pleading supersedes the original for all purposes”).

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specific devices produced) in June 2021. Tr. (Al-Ali) at 316:2-317:20 (citing CX-0494C and explaining “that data was collected on June 29th). This record is sufficient to show, by a preponderance of the evidence, that RevE devices existed and practiced asserted claims of Poeze patents at the time the complaint was filed.

* * *

Accordingly, Complainants have shown that the technical prong of the domestic industry requirement is satisfied with respect to a domestic industry existing at the time of the complaint for the Poeze patents.

8. Domestic Industry in the Process of Being Established

Complainants have separately alleged that there is a domestic industry in the process of being established. CIB at 305-09; *see* Amended Complaint ¶ 86. In *Certain Stringed Musical Instruments & Components Thereof* (“*Stringed Instruments*”), the Commission held that a domestic industry is in the process of being established when (1) a complainant takes “the necessary tangible steps to establish such an industry in the United States,” and (2) there is a “significant likelihood that the industry requirement will be satisfied in the future.” Inv. No. 337-TA-586, Comm’n Op. at 14-17, EDIS Doc. ID 300615 (May 16, 2008). The Commission recently declined to adopt an ID’s finding that a currently existing article must exist at the time of the complaint to show a domestic industry in the process of being established. *Certain Televisions, Remote Controls, and Components Thereof*, Comm’n Op., Inv. No. 337-TA-1263, 2022 WL 17486245, at *15 (Nov. 30, 2022) (“The Commission, however, does not adopt the ID’s finding that a currently existing physical article must exist at the time of the complaint filing to show a domestic industry in the process of being established.”). The Commission further found that a domestic industry in the process of being established had not been shown because

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the record lacked sufficient evidence of a future physical article that would practice the patent. *See id.* (Roku failed to produce “sufficient evidence of how . . . [the] domestic industry device . . . *will operate* so as to allow the parties to probe in discovery, and the Commission to make a determination, as to whether Gazelle *will practice* the ‘875 patent”) (emphasis added).²⁵ The Commission’s discussion indicates that a physical article practicing the patent need not yet exist to prove a “process of being established claim.”²⁶

Following this guidance, the evidence of record shows, by a preponderance, that the technical prong of the domestic industry requirement is satisfied based on an industry in the process of being established. As discussed *supra*, the evidence shows that the RevA device practices claim 12 of the ‘501 patent and claims 12, 24, and 30 of the ‘648 patent. Similarly, the RevD and RevE devices meet all of the limitations of claim 12 of the ‘501 patent, claim 28 of the ‘502 patent, and claims 12, 24, and 30 of the ‘648 patent.

Even if certain of the Masimo Watch prototypes were missing limitations of the Poeze patents, *e.g.*, the “user-worn” limitation in the claim preambles, the evidence shows that at the

²⁵ *See also id.* (“Respondents have had no opportunity to evaluate . . . whether Roku’s future promised product actually would practice the claims of the ‘875 patent”) (quoting ID with approval); *id.* (finding that Roku failed to meet its burden of showing “that there was a significant likelihood that the Gazelle Remote (or any other physical article) would practice one or more claims of the ‘875 patent in the future”); *id.* (“Evidence of a complainant’s progress towards an article that will practice one or more claims of the asserted patent as of the complaint filing date is relevant to whether the complainant has taken the necessary tangible steps to establish an industry, and whether there is a significant likelihood that the domestic industry requirement will be satisfied in the future”).

²⁶ At the time the parties filed their post-hearing briefs, the Commission had not yet addressed in this manner “the circumstances, if any, in which a complainant can demonstrate a domestic industry in the process of being established absent the existence of a protected article.” *Thermoplastic-Encapsulated Motors*, Comm’n Op. at 11-12, 2019 WL 9596564, at *7 (EDIS Doc. ID 684974); *cf. Certain Mobile Devices with Multifunction Emulators*; Inv. No. 337-TA-1170, Initial Determination at 148-52, EDIS Doc. ID 738549 (Mar. 16, 2021) (finding satisfaction of the technical prong in the absence of a physical article based on complainants’ “tangible and necessary steps to practice the claim” and a “significant likelihood that the practice will occur.”), *reviewed and taking no position on this issue*, Comm’n Notice, EDIS 747056 (July 16, 2021).

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time of the complaint, Masimo had taken necessary “tangible steps” in engineering and research and development towards a product that practiced claims of the Poeze patents. As described above, Masimo’s design documents and testing results show that the Masimo Watch prototypes in development meet the limitations of the Poeze patents.²⁷ Mr. Scruggs described the development process for Masimo Watch prototypes as an iterative process. *See id.* at 393:12-20 (“we’ve designed, built, and tested many iterations of the Masimo Watch”), 402:2-12 (describing “the progression of the different sensor designs”); *see also* Tr. (Muhsin) at 342:25-343:7 (describing “many iterations of wrist sensors”), 345:2-7 (describing “[m]any iterations on the watch through the design phases”); Tr. (Al-Ali) at 275:13-276:11 (describing ongoing testing of sensor designs, and with each subsequent design, “[i]t gets a little bit better”). Thus, even if the evidence were insufficient to show that the RevA, RevD, and RevE devices existing at the time of the complaint practiced each of the limitations of the asserted claims, the evidence would be sufficient to show a domestic industry in the process of being established.

Accordingly, the undersigned finds that Complainants have satisfied the technical prong with respect to claim 12 of the ’501 patent, claim 28 of the ’502 patent, and claims 12, 24, and 30 of the ’648 patent, for a domestic industry in the process of being established based on the RevA, RevD, and RevE devices.

²⁷ Apple argues that its experts were not allowed certain access to the prototypes (*see* RIB at 48-49), but Complainants produced schematics, source code, and the data from Masimo’s testing regarding these prototypes in discovery, and provided witnesses for deposition. *See* CRB at 29-30, 33-34. Many of Apple’s complaints regarding domestic industry discovery were addressed in the context of Apple’s motion for sanctions and Apple’s motion to strike domestic industry contentions. *See* Order No. 31 (Apr. 8, 2022); Order No. 32 (May 5, 2022). The record shows that Apple was provided a reasonable opportunity to evaluate whether Masimo’s development activities would result in a product practicing the asserted claims. *See Certain Televisions, Remote Controls, and Components Thereof*, Inv. No. 337-TA-1263, Comm’n Op., 2022 WL 17486245, at *15 (Nov. 30, 2022) (noting that respondents should be given an “opportunity to evaluate in fact or expert discovery whether [complainant]’s future promised product actually would practice the claims”).

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G. Invalidity – Anticipation/Obviousness

Apple alleges that the asserted claims of the Poeze patents are invalid as anticipated in view of U.S. Patent No. 7,620,212 (RX-0411), entitled “Electro-Optical Sensor,” which issued from an application filed on August 12, 2003, identifying assignee Lumidigm, Inc. (RX-0411 is referenced herein as “Lumidigm”). RIB at 67-103. There is no dispute that Lumidigm is prior art to the Poeze patents.

Apple further alleges that the asserted claims of the Poeze patents are invalid as obvious in view of Lumidigm alone or in combination with U.S. Patent No. 5,766,131 (RX-0666, “Seiko ’131”), which issued from an application filed on July 30, 1996; U.S. Patent No. 4,224,948 (RX-0670, “Cramer”), which issued from an application filed on November 24, 1987, the textbook *Design of Pulse Oximeters* by J.G. Webster (RX-0035, “Webster”), published in 1997; and/or U.S. Patent No. 9,001,047 (RX-0673, “Apple ’047”), which issued from an application filed on January 4, 2008. RIB at 67-103. There is no dispute that these references are prior art to the Poeze patents.

The undersigned finds that Lumidigm does not anticipate any asserted claim of the Poeze patents at least because, as discussed below, it does not include the required “protrusion” with a “convex” surface as set forth in all asserted claims. Accordingly, the relevant analysis for all asserted claims is an obviousness assessment. For the reasons discussed below, the evidence shows, clearly and convincingly, that ’501 patent claim 12 is invalid as obvious. Apple has not shown, clearly and convincingly, that any of the asserted claims of the ’502 patent or the ’648 patent is invalid as obvious.

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1. '501 Patent Claim 12

- a. Element [1 preamble]: “A user-worn device configured to noninvasively measure a physiological parameter of a user, the user-worn device comprising:”**

Apple submits that Lumidigm discloses a “user-worn device configured to noninvasively measure a physiological parameter of a user” in Figure 8B, a “biometric reader” that “is built into the case of a wristwatch.” RX-0411 at 11:60-12:2; *see* Tr. (Warren) at 1207:23-1208:13; RDX-8C.23.

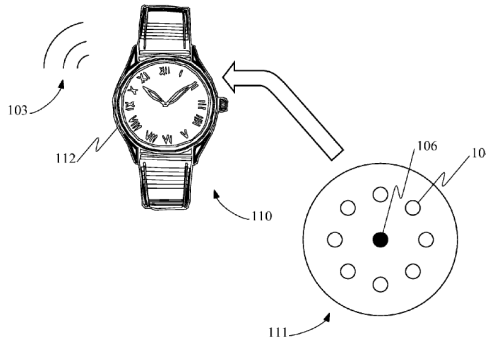


FIG. 8B

This device “operates based upon signals detected from the skin in the area of the wrist.” RX-0411 at 11:60-63. Apple submits that Lumidigm discloses embodiments in which the sensor is incorporated into a user-worn wristwatch, and that in certain embodiments, Lumidigm’s sensor uses those signals to “measure physiological parameters, based on the ‘concentration of a substance in the individual’s tissue,’ including ‘oxygenation and/or hemoglobin levels in the blood.’” RIB at 70 (citing RX-0411 at 19: 16-28, 11:61-64, Tr. (Warren) at 1208:1-13, 1214:12-1215:4); *see also* RIB at 68.

Complainants argue that Lumidigm fails to disclose non-invasively measuring a physiological parameter in the wristwatch embodiment of Figure 8B. CIB at 124-26. Complainants submit that the “biometric reader” of Lumidigm is used to identify a user based on “tissue spectral data” and not to measure a physiological parameter. *Id.* (citing RX-0411 at

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10:42-59, 5:30-44, 11:15-28, 11:60-61); *see* Tr. (Madisetti) at 1340:17-25, 1341:8-12.

Complainants argue that the “extended functionality” of Lumidigm is not disclosed in connection with the wristwatch embodiment. *See* Tr. (Madisetti) at 1330:6-8, 1330:20-1331:11, 1340:17-1341:14. Complainants describe these functionalities as part of a “brainstorming session,” relying on the testimony of Robert Rowe, one of the named inventors of Lumidigm. *See* Tr. (Rowe) at 1146:18-1147:3.

In consideration of the parties’ arguments, the undersigned finds that Lumidigm meets the limitations of the preamble of ’501 patent claim 1 by disclosing a user-worn wristwatch embodiment with a biometric sensor configured to measure a physiological parameter. *See* RX-0411 at 3:35-47, 11:60-12:2, 19:18-28; Tr. (Warren) at 1208:1-12; RDX-8.20 (identifying, *inter alia*, incorporation of a “alcohol-monitor function” and a “bilirubin-monitor function”). Lumidigm describes the measurement of such parameters as a non-invasive “spectroscopic function.” *Id.* at 3:45-47, 19:18-28. The undersigned agrees with Complainants that the primary focus of Lumidigm is a biometric sensor for identification, but Lumidigm clearly discloses additional “extended functionality” using “the spectral-analysis capabilities of the biometric sensor,” including where “the spectral analysis is used to identify a physiological state of an individual.” *Id.* at 18:26-28. Lumidigm provides that “identification of such a physiological state may be made by measuring the spectral variation of a measured spectrum for light scattered by the tissue of the individual, and comparing it with a reference spectral variation.” *Id.* at 18:29-32. Lumidigm describes, *inter alia*, examples of a bilirubin monitor and a blood-alcohol monitor. *Id.* at 19:29-50.

These disclosures of physiological monitoring are in the “extended functionality” section of the Lumidigm specification, which are clearly applicable to the user-worn wristwatch

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embodiment, with the specification stating that the extended functionalities are “especially suitable when the biometric sensor is comprised by a portable device, such as a portable electronic device.” *Id.* at 17:67-18:2. The specification explicitly identifies “a watch” as an example of a “portable electronic device having extended functionality.” *Id.* at 3:21-37. These extended functionalities, in combination with biometric functions, are also reflected in the claims of the Lumidigm patent, which claim a device “further configured to operate the biometric sensor to perform a nonbiometric function,” and providing a limited set of nonbiometric functions including “an alcohol-monitor function, a bilirubin-monitor function,” and “a hemoglobin-monitor function.” *Id.* at 25:35-45 (claims 11 and 12).

Complainants cite evidence that the Lumidigm inventors never developed a device with the described extended functionalities, *see* CIB at 126-27, but “the invention in a prior art publication need not have actually been made or performed to satisfy enablement.” *In re Antor Media Corp.*, 689 F.3d 1282, 1290 (Fed. Cir. 2012). Moreover, there is a “presumption . . . that both the claimed and unclaimed disclosures in a prior art patent are enabled.” *Amgen Inc. v. Hoechst Marison Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003).²⁸

²⁸ While this statement in *Amgen* arose in the context of an anticipation analysis, it is relevant to obviousness as well. While a non-enabled prior art reference can be used in an obviousness analysis for what it teaches, “the evidence of record must still establish that a skilled artisan could have made the claimed invention.” *Raytheon Techs. Corp. v. GE Co.*, 993 F.3d 1374, 1381 (Fed. Cir. 2021) (“even though a non-enabling reference can play a role in an obviousness analysis, the evidence of record must still establish that a skilled artisan could have made the claimed invention”). The Federal Circuit has held that “[i]n the absence of . . . other supporting evidence to enable a skilled artisan to make the claimed invention, a standalone § 103 reference must enable the portions of its disclosure being relied upon . . . the same standard applied to anticipatory references.” *Id.* at 1381. This holding indicates that the same presumption applied to asserted anticipation references can be applied to an embodiment disclosed in a prior art obviousness reference. *See also In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005) (“when a *prima facie* case of obviousness is deemed made . . . rebuttal may take the form of evidence that the prior art does not enable the claimed subject matter . . . [t]he applicant has the burden of coming forward with evidence in rebuttal”).

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Complainants identify evidence that measuring blood oxygen at the wrist would have been unlikely to be successful at the time of the Poeze patents, *see* CIB at 127-29, but claim 1 of the '501 patent is not limited to blood oxygen—the preamble limitations can be met by a device that measures any “physiological parameter.” Lumidigm describes functionality for measuring several different physiological parameters, *e.g.*, hemoglobin levels, bilirubin, and blood alcohol, and Complainants have not offered any evidence to rebut the presumption that these functionalities are enabled by Lumidigm’s disclosure.²⁹ Accordingly, the undersigned finds that Lumidigm clearly and convincingly discloses the preamble limitation of claim 1.

b. Element [1A]: “at least three light emitting diodes (LEDs)”

There is no dispute that Lumidigm discloses at least three LEDs. *See* CIB at 71-72. Lumidigm describes a “sensor assembly” that “comprises a plurality of light sources.” RX-0411 at 6:22-24. Lumidigm explicitly states that these light sources “may comprise light emitting diodes (‘LEDs’).” *Id.* at 6:38-43. There are more than three light sources depicted in the wristwatch embodiment in Figure 8B, and Lumidigm provides that “FIG. 8B again shows the equidistant-sensor geometry of FIG. 4 for illustrative purposes only; more generally, any of the sensor geometries previously disclosed or other equivalent configurations can be used for this application.” *Id.* at 11:65-12:2. One such alternative to the sensor geometry of Figure 4 is depicted in Figure 6, which shows 3 light sources:

²⁹ Complainants’ arguments regarding blood oxygen are discussed *infra* in relation to the '502 and '648 patents. As set forth therein, the undersigned agrees with Complainants that there is no prior art enablement of a wristwatch that measures blood oxygen.

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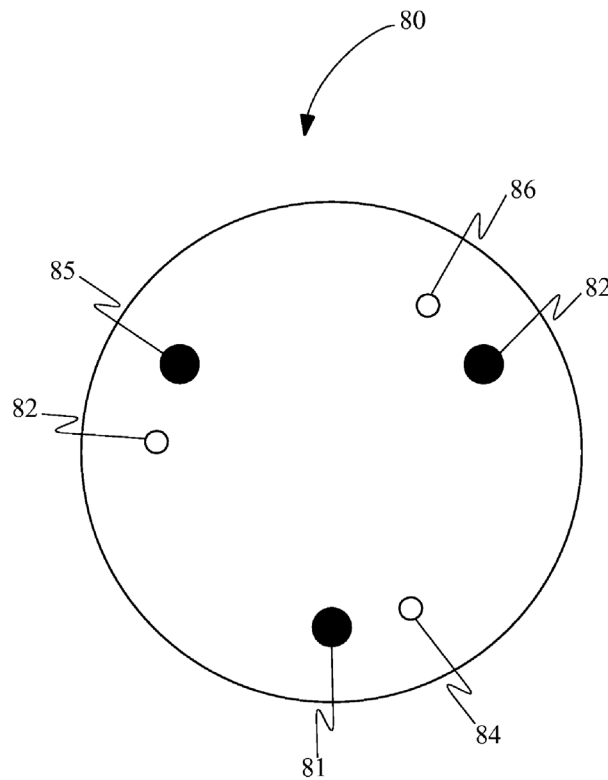


FIG. 6

Id. at Fig. 6, 9:12-25 (identifying “light sources 82, 84, 86”). Moreover, Lumidigm explicitly discloses that “any of the sensor geometries previously disclosed or other equivalent configurations can be used for” the wristwatch embodiment. *Id.* at 11:65-12:2. Given this explicit statement, the evidence indicates that Lumidigm discloses the wristwatch embodiment using the sensor geometry of Figure 6.

- c. Element [1B]: “at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user”**

Apple contends that Lumidigm discloses “at least three photodiodes.” RIB at 72-74; *see* Tr. (Warren) at 1208:25-1209:17. Apple cites to Figure 6 of Lumidigm, depicted above, which shows “three detectors 81, 83, 85.” RX-0411 at 9:15-18. Lumidigm also discloses that “[t]he detector type and material is chosen to be appropriate to the source wavelengths and the

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measurement signal and timing requirements,” providing examples of “PbS, PbSe, InSb, InGaAs, . . . ,” and for a “spectral range from about 350 nm to about 1100 nm, a suitable detector material is silicon.” *Id.* at 6:56-63. Dr. Warren testified at the hearing that a detector made of indium gallium arsenide (InGaAs) or silicon would be a photodiode. *Tr.* (Warren) at 1209:14-17. This testimony is corroborated by references to silicon photodiodes in other prior art references. *See* RX-0035.0053 (“The photodetector is a silicon photodiode”); RX-1221 (“silicon NPN planar epitaxial phototransistors”).

Apple further contends that the photodiodes disclosed in Lumidigm are “arranged on an interior surface,” citing Figure 2, which depicts “the detector 36 recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32.” RX-0411 at 8:1-4.

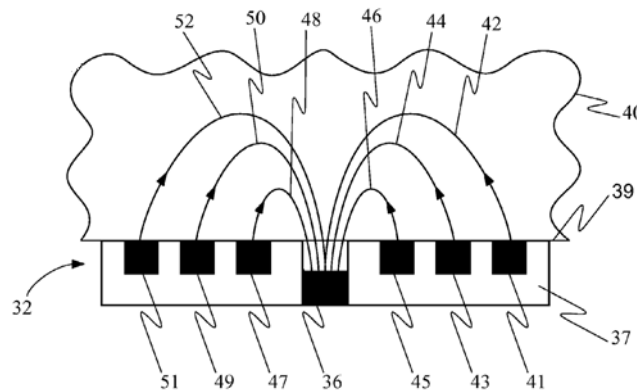


FIG. 2

Id. at Fig. 2; RIB at 73-74. Lumidigm describes this “optical geometry” as a “diffuse reflectance sampling geometry where the light sources and detector lie on the same side of the tissue.” RX-0411 at 7:12-14. While one detector is depicted in Figure 2, Apple cites Lumidigm’s disclosure that “[t]he detector 36 may comprise a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements.” *Id.* at 4:54-56.

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Complainants argue that there is no explicit disclosure of photodiodes in Lumidigm and there is no disclosure of three photodiodes arranged on an interior surface in connection with the wristwatch embodiment. CIB at 130; CRB at 46.

In consideration of the parties' arguments, the undersigned finds that Lumidigm meets the "at least three photodiodes" limitation of '501 patent claim 1. Lumidigm clearly discloses silicon detectors, and Complainants fail to offer any rebuttal to Mr. Warren's testimony, corroborated by other prior art disclosures, that the silicon detectors are photodiodes. *See* Tr. (Warren) at 1209:14-17. Three photodiodes are explicitly disclosed in Figure 6 of Lumidigm. *See* RX-0411 at 9:15-25. As discussed above, Lumidigm contains an express disclosure that "any of the sensor geometries previously disclosed or other equivalent configurations can be used for" the wristwatch embodiment. *Id.* at 11:65-12:2.

Although there is no explicit depiction of three detectors arranged on an interior surface like the single detector in the cross-section of Figure 2, the Federal Circuit has held that "a reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015). Relying on this precedent, the Federal Circuit upheld a finding of anticipation based on prior art that "explicitly contemplates the combination of the disclosed functionalities." *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1343 (Fed. Cir. 2016). Lumidigm's Figure 2 is a cross-sectional view of the arrangement of light sources and detector depicted in Figure 3, *id.* at 8:33-42, and the arrangement of three light sources and three detectors in Figure 6 is one specifically disclosed alternative to Figure 3. *See id.* at 9:12-25; Tr. (Warren) at 1211:15-20 (cross-section for Fig. 6 would be similar to Fig.

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2).³⁰ As recognized by Dr. Warren, Lumidigm expressly discloses the use of these source-detector arrangements in the wristwatch embodiment. *See* Tr. (Warren) at 1214:12-1215:4; RX-0411 at 11:65-12:2.³¹ Accordingly, the undersigned finds that Lumidigm’s disclosures meet this limitation in the context of Lumidigm’s wristwatch embodiment.

d. Element [1C]: “a protrusion arranged over the interior surface, the protrusion comprising a convex surface”

Apple contends that Lumidigm discloses a protrusion meeting the limitations of ’501 patent claim 1. RIB at 74-75. Apple points to sensor head 32 depicted in Figure 2 of Lumidigm, citing a statement in the specification that “[t]he sensor head 32 may also have a compound curvature on the optical surface to match the profile of a device in which it is mounted, to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons.” RX-0411 at 7:57-63. Apple relies on Dr. Warren’s testimony that a person of ordinary skill in the art would read the disclosure of a “compound curvature” and “realize that a practical implementation of this would be a convex surface.” Tr. (Warren) at 1211:2-8.

Complainants argue that Lumidigm’s sensor head 32 is flat, and there is no explicit disclosure of a protrusion comprising a convex surface. RIB at 130-32. Dr. Madisetti testified that Lumidigm’s description of curvature to match the profile of a wristwatch would likely result in a concave shape, citing the deposition testimony of Robert Rowe, one of the Lumidigm

³⁰ Figures 3, 4, and 6 all depict source-detector arrangements in a circular shape that appears the same as the back of the wristwatch depicted in Figure 8B. *See* RX-0411 at Fig. 3, Fig. 4, Fig. 6, Fig. 8B.

³¹ In addition, the evidence shows that Figure 2 depicts sensor surface 39 above an “interior surface” where detector 36 is located. *See* RX-0411 at 8:1-4 (“FIG. 2 illustrates a sensor-head geometry wherein the detector 36 is recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32.”); Tr. (Warren) at 1209:19-1210:11; RIB at 73-74.

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inventors. Tr. (Madisetti) at 1331:12-1332:24 (citing CX-0279C (Rowe Dep. Tr.) at 69:8-21). Complainants further argue that the statement regarding Lumidigm’s wristwatch embodiment describing different configurations of “sensor geometries” only refers to the arrangement of light sources and detectors—not to the shape of the surface of the sensor head. CIB at 132.

In consideration of the parties’ arguments, the undersigned finds that the evidence fails to show, clearly and convincingly, that Lumidigm alone discloses the claimed “protrusion comprising a convex surface” limitation of ’501 patent claim 1. As depicted in Figure 2 of Lumidigm, sensor surface 39 of sensor head 32 is flat. While the description of “compound curvature” in Lumidigm’s specification allows for the possibility of a convex shape, this is insufficient to show that this limitation is inherent in Lumidigm. *See Guangdong Alison Hi-Tech Co. v. Int’l Trade Comm’n*, 936 F.3d 1353, 1364 (Fed. Cir. 2019) (“An element may be inherently disclosed only if it is necessarily present, not merely probably or possibly present, in the prior art.” (internal quotations removed)). Apple has not shown, clearly and convincingly, that a convex protrusion is either explicitly or inherently disclosed in Lumidigm.

Apple further contends that modifying Lumidigm to include the claimed protrusion would be obvious because a protrusion with a convex surface was a “well-known idea” in the prior art. RIB at 104-107. Dr. Warren testified that “it was already well-known that a convex curvature itself could be a useful element in increasing signal quality.” Tr. (Warren) at 1211:2-8. He further identified convex protrusions in prior art references Seiko 131 and Cramer. *Id.* at 1230:18-1233:14; RDX-8C.67. Seiko 131 provides that “[w]hen the outside surface of the light transmittance plate is a convex surface, pressure is applied to the light transmittance plate by simply holding the outside surface of the light transmittance plate lightly against the body

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surface, and positive contact between the body surface and outside surface of the light transmittance plate can therefore be improved.” RX-0666 at 3:22-28.

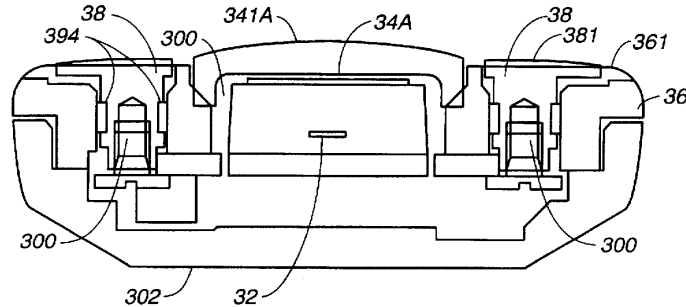


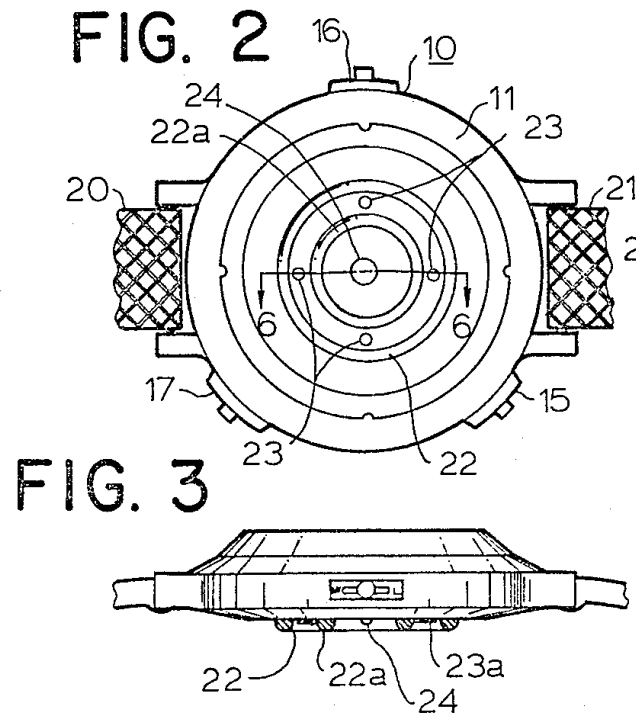
FIG. 28

Id. at Fig. 28, 19:5-8 (“outside surface 341A of light transmittance plate 34A may also be convex as shown in FIG. 28.”). Dr. Warren testified that “the purpose of this convex surface, as stated in Seiko, is to move residual blood out of the way and increase the quality of the measurement.”

Tr. (Warren) at 1231:4-8; RDX-8.67.

Cramer discloses raised portions identified as “boss 22” and “boss 22A,” wherein “boss 22 serves to isolate the infra-red detector from ambient light” and “boss 22A prevents direct transmission of light between source 24 and detectors 23.” RX-0670 at 5:45-51.

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Id. at Fig. 2, Fig. 3. Cramer further states that “[t]he coaxial arrangement of these three elements provides a relatively large contact surface area resulting in not only effective sensing of a pulse rate but minimum discomfort to the wearer.” *Id.* at 5:48-51. Cramer also states that “[t]he circular array of the detector 23 allows the detection of pulses in a substantial arteriolar-capillary bed within the hemispherical region denoted in Fig. 6 for increased signal to noise ratio and energy utilization.” *Id.* at 5:51-56. Another prior art reference, U.S. Patent No. 4,880,304 (RX-0665, “Nippon”), describes an embodiment where “the portion of the sensor face containing the LEDs and the optical detector protrudes into the tissue slightly, thereby increasing the signal strength of the detected signal.” RX-0665 at 5:12-17, Fig. 3b; Tr. (Warren) at 1245:8-16 (Nippon . . . conveys the idea that, if the detector protrudes slightly into tissue, not only can you get more repeatable coupling, but you can increase the sensitivity of the sensor”).

Complainants argue that the claimed protrusion is not obvious in view of Lumidigm. CIB at 130-36. Dr. Madisetti testified that Lumidigm’s description of curvature to match the

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profile of a wristwatch would likely result in a concave shape, citing the deposition testimony of Robert Rowe, one of the Lumidigm inventors. Tr. (Madisetti) at 1331:12-1332:24 (citing CX-0279C (Rowe Dep. Tr.) at 69:8-21). Complainants argue that the reference to curvature on Lumidigm’s “optical surface” is not the same as Lumidigm’s “sensor surface 39.” CIB at 131. Complainants further argue that the statement regarding Lumidigm’s wristwatch embodiment describing different configurations of “sensor geometries” only refers to the arrangement of light sources and detectors—not to the shape of the surface of the sensor head. *Id.* at 132; *see* Tr. (Rowe) at 1152:7-21 (referring to the “sensor geometries previously disclosed as Figs. 3 through 7,” without referencing Figure 2). Complainants argue that there is no motivation to modify Lumidigm to have a convex surface, because such a shape would not match the profile of a user’s wrist and would add to the form factor of a wristwatch. RIB at 133-34; Tr. (Madisetti) at 1331:20-25. In addition, Dr. Madisetti identified a prior art reference expressing skepticism of pulse oximetry when there are “[v]ariations in contact pressure between the sensor and the skin,” which would be caused by a convex protrusion. Tr. (Madisetti) at 1338:6-13; CDX-0012C.013 (citing CX-1733 at 2:47-57). Joe Kiani testified that Cercacor engineers had preferred concave surfaces for noninvasive sensors before conducting experiments showing that a convex protrusion produced a better signal. Tr. (Kiani) at 98:9-99:16.

With respect to Cramer, Complainants submit that the convex protrusions are annular rings that are not compatible with the other limitations of the Poeze patents (including Element 1[D] of the ‘501 patent), such as “openings” or “holes” through the protrusion. CIB at 144-46; CRB at 59. With respect to Seiko 131, Complainants submit that the identified convex protrusion is merely a single transparent window without “openings” or “holes” or “opaque lateral surfaces” (as required by Element [1E] of the ‘501 patent). CIB at 148-49 (identifying

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“transparent window” in Seiko 131). Complainants further note that Seiko 131 describes a sensor worn on a user’s finger, not on the wrist. CRB at 59. Complainants argue that Apple has failed to identify any reason or motivation to modify Lumidigm’s wristwatch to incorporate a convex protrusion as disclosed in Cramer or Seiko 131. CIB at 133-34, 151-52; CRB at 60. Complainants further argue that Apple has failed to show that any such combination would have a reasonable expectation of success. CIB at 135, 152-53.

In reply, Apple argues that the “optical surface” described by Lumidigm is the same as the “sensor surface 39” depicted in Figure 2. RRB at 53. Apple further identifies Lumidigm’s disclosure of an optical relay “between the sensor surface 39 and the skin 40,” wherein “[t]he surface of the light relay can be contoured to fit specific product applications and ergonomic requirements.” RX-0411 at 8:19-28. Apple disputes Complainants’ interpretation of Mr. Rowe’s testimony. RRB at 53-54. Apple further argues that Lumidigm expressly discloses the use of other “geometries” with its wristwatch embodiment. *Id.* Apple submits that there is no evidence that the prior art “taught away” from convex protrusions and cites prior art references recognizing the benefits of convex surfaces applying pressure to a user’s skin. *Id.* at 55. Apple argues that both Cramer and Seiko 131 disclose convex protrusions and a person of ordinary skill would have been motivated to combine these structures with Lumidigm with a reasonable expectation of success. *Id.* at 60-62.

In consideration of the parties’ arguments, the undersigned finds that Lumidigm’s disclosure that the optical surface of its sensor head “may also have a compound curvature,” together with prior art knowledge, would have provided one of ordinary skill in the art reason to implement the optical surface in a convex shape for the reasons that are explicitly disclosed in Lumidigm: “to match the profile of a device in which it is mounted, to incorporate ergonomic

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features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons.” RX-0411 at 7:57-63. In particular, Dr. Warren offers credible testimony that one of ordinary skill in the art would have recognized the benefits of a convex surface at the time of the Poeze patents in terms of signal quality, which is consistent with the disclosures in several prior art references. *See* Tr. (Warren) at 1244:11-1246:3. Seiko 131 identifies a convex surface that improves “positive contact between the body surface and outside surface of the light transmittance plate.” RX-0666 at 3:22-28, Fig. 28.³² Prior art reference Nippon similarly describes increased signal strength from a protrusion into the tissue. *See* RX-0665 at 5:12-17, Fig. 3b; RIB 117, 146; Tr. (Warren) at 1245:8-16. These prior art disclosures show, clearly and convincingly, that one of ordinary skill in the art would have had “technical or stylistic reasons” for implementing a convex curvature for Lumidigm’s sensor surface. *See* Tr. (Warren) at 1233:1-14; RX-0411 at 7:57-63.³³

The evidence of “teaching away” offered by Complainants is not supported by the record evidence. Dr. Madisetti cites a prior art reference that raises concerns about “[v]ariations in contact pressure between the sensor and the skin,” but this reference does not discuss convex surfaces. *See* CX-1733 at 2:47-57. Mr. Kiani’s testimony that concave surfaces were preferred before the invention of the Poeze patents is not corroborated by any evidence from the relevant

³² Lumidigm also discloses a “force sensing functionality . . . to ensure firm contact between the sensor and the skin,” RX-0411 at 8:11-14, which addresses a stated goal of Seiko 131 to achieve “sufficient pressure against light transmittance plate 34A.” RX-0666 at 19:8-13.

³³ The undersigned agrees with Apple that the “optical surface” and “sensor surface 39” refer to the same surface in the context of Lumidigm’s Figure 2. *See* RRB at 53-54. In addition, Figure 2 depicts sensor surface 39 above an “interior surface” where detector 36 is located. *See* RX-0411 at 8:1-4 (“FIG. 2 illustrates a sensor-head geometry wherein the detector 36 is recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32.”).

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timeframe.³⁴ Even if a concave shape would be more likely to conform to the shape of a user's wrist, as argued by Complainants, this does not establish that one of ordinary skill in the art would have avoided a convex shape. As discussed above, several prior art references describe technical benefits associated with a convex protrusion for sensors on the skin.³⁵

The undersigned also finds that one of ordinary skill in the art would have been able to implement a convex optical surface in Lumidigm's wristwatch with a reasonable expectation of success. *See* Tr. (Warren) at 1238:1-6. Lumidigm explicitly discloses that its sensor head could have a "compound curvature on the optical surface." *See* RX-0411 at 7:57-63.³⁶

³⁴ Complainants cite evidence from Apple's [REDACTED] several years after the priority date for the Poeze patents. This evidence is addressed *infra* in the context of objective indicia of non-obviousness.

³⁵ There is no evidence that the "form factor" of a convex protrusion would have been relevant to persons of ordinary skill in the art at the time of the Poeze patents—the only evidence that Complainants cite is Dr. Madisetti's conclusory testimony and a statement from Apple's prehearing brief related to the development of the Apple Watch, [REDACTED]. *See* CIB at 134; RRB at 55. In any case, this issue would not preclude a reason to modify Lumidigm in the manner described above. *See Allied Erecting and Dismantling Co., Inc., v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) ("a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine") (internal quotation omitted).

³⁶ It is unclear whether Apple argues for a specific physical combination of Lumidigm and Cramer, *e.g.*, by applying Cramer's structure of annular rings and photodiodes to the Lumidigm wristwatch. *See* RIB at 103-113. However, to the extent this combination is proposed, Apple does not explain how this combination would fit with the multiple LED/multiple photodiode arrangement relied upon for claim elements [1A] and [1B], particularly because Cramer's raised annular rings are designed to separate Cramer's single LED from Cramer's set of equidistant four photodiodes. *See* RX-0679 at 5:46-48 ("The boss 22A prevents direct transmission of light between source 24 and detectors 23."). In contrast, claim 1 requires at least three LEDs. Similar issues exist for the "protrusion" elements of the '502 and '648 patents, which also require multiple LEDs and photodiodes. *See* CIB at 143 (claim must be considered as a whole). Moreover, the evidence does not clearly and convincingly show that Cramer discloses a protrusion with openings or through holes within it over photodiodes (as required for Elements [1D], [19C], [28F], [8E], [20C-D]). *See* CIB at 144-146. Dr. Warren states that Cramer "describes what it calls a raised boss area, which is essentially a convex protrusion" that "consists of two concentric raised annular areas of opaque material." Tr. (Warren) at 1231:18-22. Dr. Madisetti similarly testified that the alleged protrusion is "just two rings." Tr. (Madisetti) at 1334:23-1335:2. The evidence does not clearly and convincingly show that the two raised rings of Cramer would be considered a single "protrusion."

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Based on the above, the evidence shows clearly and convincingly that Lumidigm's disclosure of an optical surface that can have "compound curvature" would have provided a reason for one of ordinary skill in the art to modify the optical surface of Lumidigm's wristwatch embodiment to form a "protrusion comprising a convex surface," and this modification would have had a reasonable expectation of success.

e. Element [1D]: "a plurality of openings extending through the protrusion and positioned over the three photodiodes"

With respect to the "plurality of openings" limitation, Apple cites to Lumidigm Figure 2, which depicts "the detector 36 recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32." RX-0411 at 8:1-4. While one detector is depicted in Figure 2, Apple cites Lumidigm's disclosure that "[t]he detector 36 may comprise a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements." *Id.* at 4:54-56. Apple submits that Lumidigm thus discloses openings positioned over one photodiode or multiple photodiodes. RIB at 75-76.

Apple further contends that the use of openings and holes for photodiodes was well known in the art and disclosed in Cramer and Seiko 131. RIB at 107-110. Dr. Warren testified that openings over photodiodes were well-known at the time of the Poeze patents, recognizing that "[a] detector can't detect light without some sort of opening above it." Tr. (Warren) at 1192:25-1193:6. He identified U.S. Patent No. 3,769,974 (RX-0473, "Smart") as a prior art reference with an example of an opening for a photodiode. *Id.* at 1193:7-18; RDX-8C.10; *see* RX-0473 at Fig. 1, 3:17-19 ("An annular inner wall 59 is formed of opaque epoxy and blocks the direct transmission of light from the diodes 16 to the phototransistor sensor 28."). In Seiko 131, Apple identifies an opening between the detector and the user's tissue. RIB at 108 (citing RX-0666 at Fig. 28). With respect to Cramer, Apple cites a datasheet for a detector identified in

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Cramer—the CLT 2160 detector, which was described by Dr. Warren as a “can detector” that includes an opening between the photodiode and the surface of the detector. Tr. (Warren) at 1231:23-1232:9, 1234:3-8; *see* RX-0670 at 5:33-35 (“A suitable detector is the type CLT 2160 photo diode produced by Clairex Electronics, Inc.”); RX-1221 (CLT 2160 datasheet).

Complainants dispute Lumidigm’s disclosure of this limitation, arguing that there is no protrusion meeting the limitations of the claim and because three photodiodes are not explicitly disclosed in the configuration of Figure 2 or in connection with the wristwatch embodiment. CIB at 138.

With respect to Seiko 131, Complainants argue that there is only one photodiode and one opening, which does not extend through the light transmittance plate identified as the claimed convex surface. CIB at 148-49; CRB at 60-61. With respect to Cramer, Complainants argue that the openings over the photodiodes are between the “boss 22” and “boss 22A” that are identified as convex protrusions and thus do not extend through these protrusions. CIB at 145-46. Complainants further argue that the CLT 2160 datasheet is undated and was not authenticated by any witness. CRB at 63-64.

In consideration of the parties’ arguments, the evidence clearly and convincingly shows that Lumidigm meets the “plurality of openings . . . positioned over the three photodiodes” limitation of ’501 patent claim 1. As discussed above, the undersigned agrees with Complainants that there is no convex protrusion in Lumidigm, but Lumidigm discloses an opening extending through a protrusion that is positioned over a detector in Figure 2, and as discussed above in the context of the “at least three photodiodes” limitation, Lumidigm clearly shows that the placement of the detector in Figure 2 corresponds to the source-detector arrangement of Figure 3, and that the arrangement of three sources and three detectors in Figure

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6 is a disclosed alternative to Figure 3 for use in the wristwatch embodiment. *See* RX-0411 at 7:5-9:25, 11:65-12:2, Fig. 2, Fig. 3, Fig. 4, Fig. 6, Fig. 8B. Under this arrangement, there is an opening positioned over each photodiode. *See* Tr. (Warren) at 1211:15-20 (cross-section in Fig. 6 would be similar to Fig. 2, with each photodiode recessed an opening over each photodiode). Dr. Warren's testimony and the disclosures in prior art references such as Smart also confirm that such openings over photodiodes were known in the art at the time of the Poeze patents. *See* Tr. (Warren) at 1192:25-1193:18; RX-0473 at 3:17-19, Fig. 1.

Further, as discussed in Part IV.E.1.d *supra*, a person of skill in the art would have reason to implement to modify the optical surface 39 of Lumidigm to form a "protrusion comprising a convex surface." This modified optical surface of the sensor head, like the optical surface of Lumidigm shown in Fig. 2, would extend over the photodiodes and the openings over them. *See* Tr. (Warren) at 1210:13-1211:14; *id.* at 1212:4-10 (sensor head would have same number of openings as photodiodes); RIB at 75. Accordingly, the evidence clearly and convincingly shows that this limitation of '501 patent claim 1 is met by Lumidigm's disclosures.

- f. **Element [1E]: "the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion"**

With respect to the "opaque lateral surface" limitation, Apple again cites to Lumidigm Figure 2, which depicts "the detector 36 recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32." RX-0411 at 8:1-4. Lumidigm further provides that "[t]he recessed placement of detector 36 minimizes the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue." *Id.* at 8:4-7. Lumidigm notes that "reflections from the top surface of tissue (known as 'specular' or 'shunted' light) are

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detrimental to most optical measurements.” *Id.* at 7:66-8:1. The effect of the recessed placement of the detector is described as an “optical blocking effect.” *Id.* at 8:7-10.

Complainants argue that Lumidigm’s disclosure of “optical blocking” is directed to light that is reflected off the surface of the tissue, which is distinct from “light piping.” CIB at 139-40; *see* Tr. (Madisetti) at 1340:8-10. Complainants cite the specification of the Poeze patents, which describes “light piping (e.g., light that bypasses measurement site 102).” JX-001 at 22:48-50. At the hearing, Mr. Kiani described light piping as “light that goes from the LED directly to the photodetector, without going through the tissue.” Tr. (Kiani) at 100:14-24.

The evidence clearly and convincingly shows that Lumidigm meets the “opaque lateral surface” limitation of ’501 patent claim 1. There is no dispute that Lumidigm discloses an opaque lateral surface in the opening for a detector in Figure 2. Complainants argue that Lumidigm fails to explicitly recognize that this surface is “configured to avoid light piping,” but Dr. Warren testified at the hearing that the “shunted” light described in Lumidigm “is what is called light piping in this matter.” Tr. (Warren) at 1212:22-1213:3. The undersigned finds Dr. Warren’s testimony on this issue to be credible and convincing, and Lumidigm’s descriptions of reflections that are “specular” or “shunted” light are consistent with the meaning of “light piping” as that term is used in the context of the Poeze patents, because Lumidigm recognizes that this light bypasses the measurement site inside the user’s tissue. *See* JX-0001 at 22:48-50; RX-0411 at 7:66-8:7. This is also consistent with Mr. Kiani’s testimony regarding “light piping,” because the “shunted” light described in Lumidigm goes from the emitters to the detector without passing through the tissue. Tr. (Kiani) at 100:14-24 (goal is to avoid light that has not gone “through the tissue”). Moreover, Lumidigm expressly discloses that the placement

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of the detector creates an “optical blocking effect” that avoids “specular” or “shunted” light, *id.* at 7:66-8:10, and the evidence shows that this configuration would avoid light piping.

Apple also points to lateral surfaces in other prior art references, arguing that this limitation is obvious in combination with Seiko 131 or Cramer. Apple cites lateral surfaces around the photodiode disclosed in Seiko 131. RIB at 108 (citing RX-0666 at 10:30-36, Fig. 28). With respect to Cramer, Apple relies on the datasheet for the CLT 2160 detector, which was described by Dr. Warren as a “can detector” that “would be made from aluminum or stainless steel or some material that was impervious to light as a means to prevent light piping.” Tr. (Warren) at 1231:23-1232:9, 1234:3-8; *see* RX-0670 at 5:33-35 (“A suitable detector is the type CLT 2160 photo diode produced by Clairex Electronics, Inc.”); RX-1221 (CLT 2160 datasheet). Apple also cites Cramer’s disclosure of “light blocking rings” that “isolate the photo detector from direct view from the light source and from view of the ambient light when the lower face is in contact with the wearer’s body e.g. the wrist.” RX-0670 at 2:46-51. One of these rings identified as “boss 22A prevents direct transmission of light between source 24 and detectors 23.” *Id.* at 5:46-48. Apple further cites disclosures in Webster recognizing the problem of an “optical shunt,” which is “when some of the light from the LEDs reaches the photodiode without passing through an arteriolar bed.” RX-0035.0202. Webster recommends that “[o]ximeter probes should be manufactured of black opaque material that does not transmit light, or enclosed in an opaque plastic housing.” *Id.*

Complainants argue that the alleged opaque lateral surfaces in Seiko 131 were not previously identified in Apple’s prehearing brief or in any hearing testimony and are not supported by any teachings in Seiko 131. CRB at 63. With respect to Cramer, Complainants

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argue that there is no explicit disclosure of opaque material and further argue that the CLT 2160 datasheet is unreliable. *Id.* at 63-64.

Because the claimed opaque lateral surfaces are set forth in Lumidigm, it is unnecessary to address whether they are disclosed by Lumidigm in combination with Seiko 131 or Cramer. However, the undersigned agrees with Complainants that Apple has failed to identify any opaque lateral surfaces in Seiko 131.³⁷ With respect to Cramer, the undersigned agrees with Apple that one of ordinary skill in the art would have recognized that the CLT 2160 detectors have opaque lateral surfaces. *See* Tr. (Warren) at 1234:3-8; RX-1221.³⁸ Webster’s reference to an “optical shunt” is consistent with the description of light piping discussed above.

Accordingly, the undersigned finds that the “opaque lateral surface” limitation of ’501 patent claim 1 is disclosed in Lumidigm in the context of Lumidigm’s wristwatch embodiment.

g. Element [1F]: “one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user”

With respect to the “one or more processors” limitation, Apple cites to Lumidigm’s disclosure that its “portable electronic device comprises an electronic arrangement for performing a standard function of the portable electronic device, a biometric sensor, and a processor,” and “[t]he processor is configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor.” RX-0411 at 3:21-31; RIB at 77-79. Lumidigm further discloses that after light signals are detected, “the signals can be digitized and

³⁷ Regardless of whether Apple’s contentions are timely, Apple’s shading of unlabeled structures in Figure 28 of Seiko 131 that are allegedly opaque lateral surfaces does not appear to be supported by the evidence of record. *See* RIB at 108.

³⁸ The undersigned finds the CLT 2160 datasheet to be reliable evidence. Complainants have not identified any timely-raised objection to the admission of RX-1221, and this exhibit appears to be reliable on its face.

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recorded by standard techniques,” and “[t]he recorded data can then be processed directly or converted.” *Id.* at 9:58-62. A schematic for managing the functionality of the biometric sensor is illustrated in Figure 9, which depicts a “computer system” with “hardware elements that are electrically coupled via bus 342, which is also coupled with the biometric sensor 356.” *Id.* at 12:56-66, Fig. 9. “The hardware elements include processor 332” and a “processing acceleration unit 346 such as a DSP or special-purpose processor.” *Id.* at 12:66-13:14; *see* Tr. (Warren) at 1213:4-1214:1.

Complainants argue that Lumidigm fails to explicitly disclose that its processor calculates a measurement of a physiological parameter and does not explicitly describe a processor in the “wristwatch” embodiment. CRB at 49; *see* CIB at 124-29.

In consideration of the parties’ arguments, the undersigned finds that Lumidigm meets the “one or more processors” limitation of ’501 patent claim 1. Complainants’ arguments were addressed above in the context of the preamble, and as discussed above, Lumidigm teaches that the “wristwatch” embodiment is one of the “portable devices” suitable for functionalities including the measurement of a physiological parameter. *See* RX-0411 at 3:35-47, 11:60-12:2, 19:18-28. With respect to the processing hardware depicted in Figure 9, Lumidigm explicitly notes that some of the components could be used in portable devices. *Id.* at 12:58-61. Moreover, a “processor” is explicitly claimed in Lumidigm as part of a “portable electronic device,” where the processor “is further configured to operate the biometric sensor to perform a nonbiometric function,” including a “spectrometer function,” with examples provided of “an alcohol-monitor function, a bilirubin-monitor function,” and “a hemoglobin-monitor function.”

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Id. at 25:32-45 (claims 10, 11, 12).³⁹ Dr. Warren testified that this limitation is met by Lumidigm with respect to calculating a measurement of a physiological parameter. *See* Tr. (Warren) at 1213:4-1214:1. Accordingly, Lumidigm clearly discloses a “processor” that receives signals from a sensor and calculates a measurement of a physiological parameter.

The undersigned further finds that, to the extent Lumidigm does not disclose such a processor, one of ordinary skill in the art would have had a reason to implement such calculations and a reasonable expectation of success in Lumidigm’s “wristwatch” embodiment, because Lumidigm explicitly notes that its extended functionality is “especially suitable” for mobile devices. *See id.* at 17:67-18:2.

Accordingly, the undersigned finds that the “one or more processors” limitation of ’501 patent claim 1 is met by Lumidigm.

h. Element [12]: “wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape”

Claim 12 of the ’501 patent depends from claim 1, further requiring that “the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape.” As discussed above in the context of the “protrusion” limitation of ’501 patent claim 1, the undersigned finds that a convex protrusion is neither explicitly nor inherently disclosed in Lumidigm but that one of ordinary skill in the art would have reason to modify Lumidigm’s optical surface to form a convex protrusion.

Apple contends that this limitation is obvious in view of Lumidigm alone or in combination with Seiko 131 or Cramer, because a person of ordinary skill in the art would have

³⁹ As discussed above in the context of the preamble, there is a presumption that these functions are enabled, and Complainants have not provided evidence rebutting Lumidigm’s enablement of measurements for physiological parameters other than blood oxygen.

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understood that a convex protrusion would conform the user's tissue into a concave shape. RIB at 79, 106. Dr. Warren described the limitation in claim 12 as "an obvious statement," recognizing that "if you have a convex surface and you position it next to tissue, any pressure at all will conform the tissue into a concave shape." Tr. (Warren) at 1214:2-11. Complainants do not raise any arguments with respect to claim 12 that are significantly different from those addressed above in the context of claim 1. *See* CRB at 46-47, 71-73. Accordingly, in view of the unrebutted testimony of Dr. Warren, the undersigned finds that one of ordinary skill in the art would have known that a convex surface in contact with the tissue of the user would conform the tissue into a concave shape.

As discussed above, Lumidigm explicitly discloses a user-worn wristwatch device configured to non-invasively measure physiological parameters of a user that meets the limitations of claim 1 requiring at least three LEDs, at least three photodiodes, a plurality of openings for each photodiode with opaque lateral surfaces, and a processor configured to calculate measurements of physiological parameters, and the evidence shows that one of ordinary skill in the art would have reason to modify the optical surface of the sensor head in Lumidigm's wristwatch to form the claimed protrusion comprising a convex surface based on Lumidigm's explicit suggestion of a sensor head with a "compound curvature" for "technical or stylistic reasons." RX-0411 at 7:57-63. For these and the other reasons discussed above, the evidence thus shows that a combination of elements disclosed in Lumidigm and known in the prior art would have yielded a wristwatch meeting each limitation of claims 1 and 12, and one of ordinary skill in the art would have had a reasonable expectation of success in making such a combination. Further, as discussed *infra*, secondary considerations of non-obviousness do not

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weigh significantly against a finding that claim 12 of the '501 patent is obvious. Accordingly, the undersigned finds that claim 12 of the '501 patent is invalid as obvious.

2. '502 Patent Claim 22

As discussed below, the evidence fails to clearly and convincingly show that claim 22 of the '502 patent is rendered obvious by Lumidigm alone or in combination with other prior art.

a. Element [19 preamble]: “A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:”

The preamble of '502 patent claim 19 requires “[a] user-worn device configured to non-invasively measure an oxygen saturation of a user.” As discussed above in the context of the preamble of '501 patent claim 1, Lumidigm discloses a user-worn wristwatch embodiment with a biometric sensor configured to measure a physiological parameter. *See* RX-0411 at 3:35-47, 11:60-12:2, 19:18-28, claim 12. With respect to measuring oxygen saturation, Apple cites Lumidigm’s teaching that “changes in blood flow cause spectroscopic changes that may be detected” with its biometric sensor, noting that “these spectroscopic changes are correlated with oxygenation and/or hemoglobin levels in the blood.” RX-0411 at 19:22-26. Apple relies on Dr. Warren’s opinion that one of ordinary skill in the art would have been able to implement pulse oximetry functionality in Lumidigm’s wristwatch. *Tr.* (Warren) at 1216:10-25. Dr. Warren points to efforts by his students to measure blood oxygen at the wrist as early as 2002, *id.* at 1195:24-1196:10, and Apple cites prior art reflectance pulse oximeters that existed decades before the Poeze patents. *See* RX-0484.

Complainants argue that Lumidigm’s disclosure is insufficient to teach a blood oxygen measurement in a wristwatch. CIB at 126-29; CRB at 44-46. Dr. Madisetti characterizes Lumidigm’s description of an oxygen saturation measurement as “vague” and “aspirational.” *Tr.*

(Madisetti) at 1330:20-1331:11. Complainants further argue that a person of ordinary skill would not have known how to implement the measurement of oxygen saturation or any other physiological parameter in Lumidigm’s wristwatch embodiment and that Lumidigm provides no motivation for doing so. CIB at 128-29; Tr. (Madisetti) at 1340:20-1341:14. Complainants argue that implementing such functionalities in a wristwatch would not have a reasonable expectation of success, citing testimony from Apple engineers expressing skepticism that blood oxygen could be measured at the wrist. CIB at 129. Complainants cite evidence that Apple took [REDACTED]. See CRB at 86-87.

In reply, Apple argues that using Lumidigm’s wristwatch to measure a physiological parameter such as blood oxygen would have been obvious to one of skill in the art. RRB at 51-52. Apple cites evidence that Dr. Warren experimented with measuring pulse oximetry on the wrist with his students at Kansas State University in 2002. Tr. (Warren) at 1195:24-1196:10, 1216:10-25; RX-0632 (2002 photograph); RX-0504 (2005 poster); RX-0508 (2005 article). Apple submits that the development timeline for implementing pulse oximetry in the Apple Watch is not relevant to the obviousness of the Poeze patents, because the [REDACTED] [REDACTED]. RIB at 144-46; RRB at 68-69.

In consideration of the parties’ arguments, the undersigned finds that the evidence of record fails to show that one of ordinary skill would have been enabled to measure oxygen saturation in the Lumidigm wristwatch. As discussed above in the context of the ’501 patent, Lumidigm describes “extended functionality” including measurements of “oxygenation and/or hemoglobin levels in the blood,” and states that such functionalities are “especially suitable when the biometric sensor is comprised by a portable device, such as a portable electronic device.”

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RX-0411 at 17:64-18:2, 19:18-28. The specification explicitly identifies “a watch” as an example of a “portable electronic device having extended functionality.” *Id.* at 3:21-37.

Lumidigm thus contemplates blood oxygen measurement in a wristwatch as one implementation of its “extended functionality,” but the Federal Circuit has held that “when the prior art includes a method that appears, on its face, to be capable of producing the claimed composition,” the patentee may rebut this evidence by presenting “sufficient reason or authority or evidence, on the facts of the case, to show that the prior art method would not produce or would not be expected to produce the claimed subject matter.” *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005); Part IV.G.1.a *supra* (discussing additional relevant authority).

In rebuttal to Lumidigm’s blood oxygen disclosure, Complainants have presented persuasive evidence that persons of ordinary skill in the art would not have expected to successfully measure blood oxygen in a wristwatch at the time of the Poeze patents. *See* CIB at 126-29; CRB at 44-46. Mr. Rowe, the “primary inventor” of Lumidigm, *see* Tr. (Rowe) at 1146:18-1147:3, acknowledged that he never made a device that calculated blood oxygen at Lumidigm, Inc. CX-0297C (Rowe Dep. Tr.) at 118:4-119:8.⁴⁰ Complainants have also cited testimony from numerous Apple engineers describing the significant difficulty of performing pulse oximetry at the wrist. *See* Tr. (Mannheimer) at 1012:12-1013:6 (admitting that in 2014, he believed that pulse oximetry at the wrist would be a challenge, that he “did not know if it could be done,” that “the wrist is just enormously different from the physiological perspective,” and

⁴⁰ There is little to no technical description of the blood oxygen functionality in Lumidigm, let alone in the wristwatch embodiment specifically. *See* CIB at 126; RX-0411 at 19:24-28.

that the signal at the wrist is “enormously weak”⁴¹; *see also id.* at 998:21-999:6 (products he previously worked on “operated on a much more vascularized tissue bed, usually fingers or forehead . . . [t]he wrist is “just an incredibly different beast”); CX-0299C (Waydo Dep. Tr.) at 166:4-167:5 (“The wrist is one of the most difficult places on the body to do almost every physiological measurement”); CX-0295C (Shui Dep. Tr.) at 108:13-21 [REDACTED]

[REDACTED]
[REDACTED]. The blood oxygen measurement described in Lumidigm is characterized as relying on “spectrographic changes that may be detected” by its biometric sensor, which are “correlated with oxygenation and/or hemoglobin levels.” RX-0411 at 19:22-26. The testimony of Apple engineers shows the difficulty in calculating blood oxygen from such spectra if obtained at the wrist, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]; Tr. (Land) at 983:2-12 [REDACTED]
[REDACTED]; *see* CIB at 169-171.

Apple counters this evidence with Dr. Warren’s testimony describing pulse oximetry experiments at Kansas State University in 2002-05, RRB at 52-53, but there is little evidence that wrist-based blood oxygen levels were successfully measured in a watch-type environment. With

⁴¹ Dr. Mannheimer had worked on pulse oximetry technology at Nellcor from 1987 to 2008, before joining Apple. *See* Tr. (Mannheimer) at 994:9-25, 1009:2-8. He was hired by Apple because of his “extensive experience” in pulse oximetry and biosensing in general. Tr. (Land) at 963:10-15.

respect to the work done with Professor Warren’s undergraduate students cited by Respondents (*see* RRB at 52), Dr. Warren testified that his students “worked with [these sensors] on their wrists” (Tr. at 1216:23-25) and took measurements from various locations on the body, including wrists (Tr. at 1186:8-16, 1196:8-10, RDX-8.88). He provided no testimony regarding the results of those measurements. Apple also does not identify measurements of oxygen saturation at the wrist in the corroborating documents provided by Dr. Warren. *See* RIB at 64-67; RRB at 52-53; CRB at 45-46; RX-0504 (referencing wrist as a “viable” measuring site but only presenting data from finger and head); RX-0508.0007, .0012 (referencing “different body locations (*e.g.*, wrist, forehead or ear lobe) that have noticeably different vascular profiles” and presenting data from the thumb). Apple also argues that methods for pulse oximetry were well-known at the time of the Poeze patents, RRB at 51, but Apple’s evidence for prior art blood oxygen measurements relies on measurements at other locations on the body—not at the wrist. *See, e.g.*, RX-0484 (describing measurement of blood oxygen at the finger).^{42,43}

On the evidence of record, the presumption of enablement is overcome with respect to configuring Lumidigm’s wristwatch to measure blood oxygen at the time of the Poeze patents.

⁴² Apple argues that its engineers’ testimony related solely to “adding that known functionality into the limited space of a small consumer device” (RRB at 47), but the testimony at issue indicates broader signal issues.

⁴³ Mr. Kiani testified at the hearing that he could have done a “conventional pulse oximeter” on the wrist “30 years ago” (Tr. (Kiani) at 114:20-22), but this testimony is less persuasive on this issue than the testimony of the Apple engineers, particularly given Mr. Kiani’s testimony that many conventional pulse oximetry devices do not work. *See* Tr. (Kiani) at 102:20-21, 121:18-24. As discussed above, Apple documents [REDACTED], CX-0177C at 13.

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Accordingly, Apple has not shown that the preamble limitations of '502 patent claim 19 are met by Lumidigm.⁴⁴

b. Element [19A]: “a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs)”

There is no dispute that Lumidigm discloses a plurality of emitters. *See* RIB at 80-82; CIB at 123. As discussed above in the context of the LEDs limitation of '501 patent claim 1, Lumidigm discloses “a plurality of light sources” that “may comprise light emitting diodes (‘LEDs’),” including “sets of LEDs.” RX-0411 at 6:22-53. Lumidigm discloses several configurations with light sources arranged in sets of at least two:

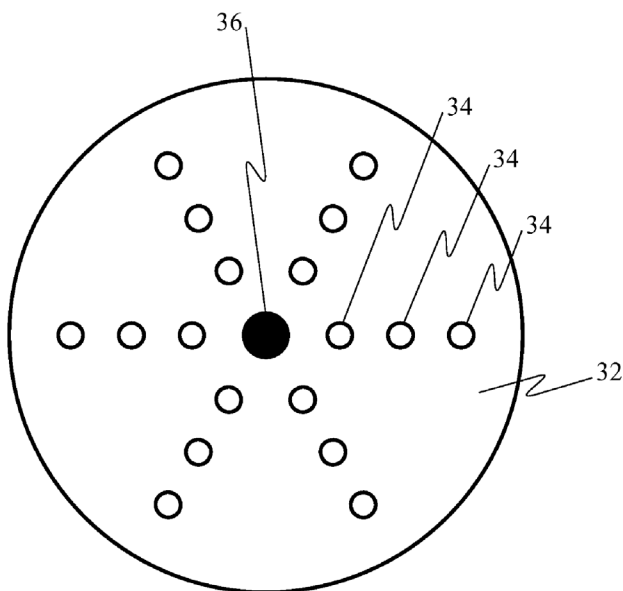


FIG. 3

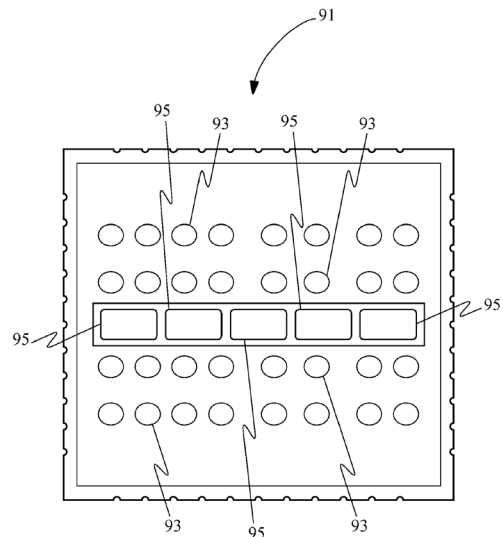


FIG. 7A

Id. at 8:33-42 (Fig. 3), 9:26-34 (Fig. 7A); *see also* RIB at 81 (identifying Figs. 3, 5, 7A, and 7B).

Lumidigm explicitly discusses the benefits of pairs of light sources, noting that two light sources

⁴⁴ The evidence regarding the difficulty in achieving blood oxygen measurements at the wrist, as discussed above, also shows the lack of clear and convincing evidence of a reasonable expectation of success for the asserted obviousness arguments.

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having the same wavelength “can be combined to increase the resulting signal-to-noise ratio of the measurement,” while two light sources with different wavelengths can “provide unique and useful information about the tissue optical properties.” *Id.* at 7:34-53.

c. Element [19B]: “four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user”

As discussed above in the context of the “photodiodes” limitation of ’501 patent claim 1, the evidence shows that Lumidigm discloses silicon detectors that are photodiodes, and the sensor geometries disclosed in Lumidigm’s specification can be used in the “wristwatch” embodiment in a configuration for receiving light that has been attenuated by tissue of the user. *See* RX-0411 at 6:56-63, 11:65-12:2. Lumidigm discloses two specific configurations with arrays of at least four detectors:

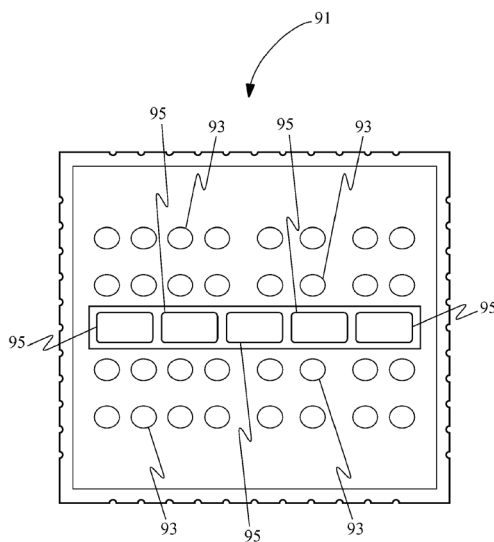


FIG. 7A

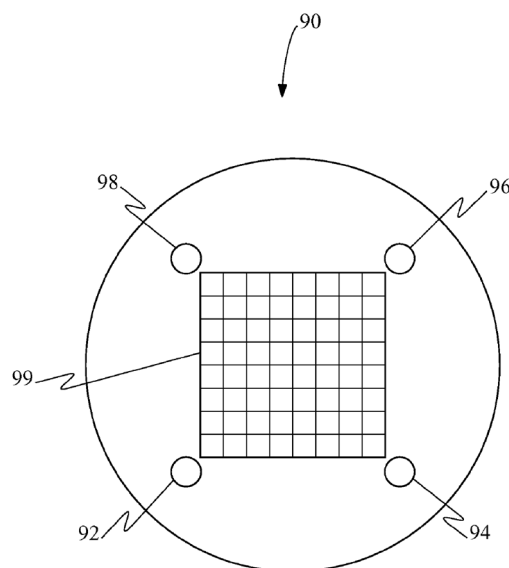


FIG. 7B

Id. at 9:26-45, Fig. 7A, Fig. 7B; Tr. (Warren) at 1221:10-15; RDX-8.37; RIB at 82. Lumidigm describes the benefits of such detector arrays, wherein “[t]he signal detected at each of the array

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elements then represents a different source-detector separation with respect to the light from a given light source.” *Id.* at 9:39-41.

- d. Element [19C]: “a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue”**

As discussed above in the context of the “protrusion” limitation of ’501 patent claim 1, Lumidigm’s disclosures provide a reason to modify the optical surface of Lumidigm to form a protrusion comprising a convex surface. *See* Part IV.E.1.d. However, the evidence does not clearly and convincingly show how or why the “array”-type detectors in Lumidigm relied upon by Apple for Element [19B] would be formed with separate openings through the protrusion for individual photodiodes in the array. *See* RIB at 82; CIB at 143 (noting requirement to treat each claim as an integrated whole); CRB at 55 (same). For this limitation, Apple simply refers to the reasoning provided for the three-photodiode configuration relied upon for Element [1B] (which relies on the single diode example in Figure 2 of Lumidigm), but that configuration does not appear similar to the “array” configurations cited by Respondents for Element [19B], and no clear and convincing testimony linking Figs. 7A and 7B to separate “openings” through the protrusion for individual (or subsets of) diodes in an array has been provided.⁴⁵ *See* RIB at 72-

⁴⁵ Lumidigm explains that “detector 36” may be “a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements.” RX-0411 at 6:54-56. Fig. 2 shows a single opening over detector 36 which, if anything, would appear to suggest a single opening over an array, rather than separate openings over individual diodes in the array. While Apple argues that the Figs. 7A and 7B are merely “illustrative,” and that Lumidigm’s sensor “can include any number and arrangement of photodiodes” (RIB at 82), Apple did not clearly present any other specific LED/photodiode arrangement in its analysis of Element [19B] for assessment in view of the claim as a whole. *See* Tr. (Warren) at 1221:10-15 and RDX-8.37; RIB at 82.

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74, 83-84; RX-0411 at 9:26-45 (discussing the “detector array” structure); CIB at 143 (arguing that Apple does not show obviousness based on claim as an integrated whole).

With regard to Figure 7B, Dr. Warren testified with regard to a different limitation that “one of ordinary skill could essentially choose any four of the photodiodes within this arrangement . . . and then include an opening over each one” (Tr. (Warren) at 1225:23-1226:1) but this testimony of what one of ordinary skill in the art could theoretically do is insufficient to clearly and convincingly show that Lumidigm discloses this arrangement, or provide a reason for one of ordinary skill in the art to modify Lumidigm to do so. *See Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (“The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether ‘they would have been motivated to do so.’”).

Apple also argues that Element [19C] is rendered obvious based on a combination with Cramer, which Apple contends includes four diodes in a circular array, with separate openings with opaque lateral surfaces positioned over each of the photodiodes. *See RIB* at 108-110. As discussed above in Part IV.E.1.d, the evidence does not clearly and convincingly show that one of skill in the art would have a reason to combine the specific structures of Cramer with Lumidigm, and Cramer only includes one LED (which would not meet the “plurality of emitters” requirement of Element [19A])). *See n.36 supra*.

e. Element [19D]: “optically transparent material within each of the openings”

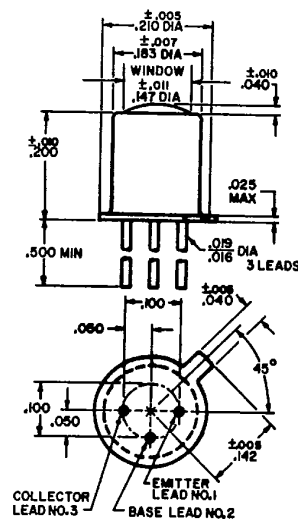
With respect to the “optically transparent material” limitation of ’502 patent claim 19, Apple identifies Lumidigm’s disclosure of “an optical relay (not shown) between the sensor surface 39 and the skin 40” that “transfers the light . . . from the skin back to the detector(s).” RX-0411 at 8:19-23; RIB at 84-85. Lumidigm provides examples of these optical relays, including “fiber-optic face plates and tapers, individual optical fibers and fiber bundles, light

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pipes and capillaries, and other mechanisms known to one of skill in the art.” *Id.* at 8:23-26.

Dr. Warren testified at the hearing that one of ordinary skill in the art would understand an “optical relay” to be an optically transparent material. Tr. (Warren) at 1221:16-1222:25; RIB at 84-85.

Apple further argues that this limitation would be obvious because the use of transparent materials within openings was well-known at the time of the Poeze patents. RIB at 111-113; Tr. (Warren) at 1193:23-1194:14, 1221:16-1222:9; RDX-8C.11 (citing RX-0670; RX-0665; RX-0666; RX-0667; RX-0648). Apple also points to the “light transmittance plate” disclosed in Seiko 131, wherein “[a] transparent window is formed on the top of sensor frame 36 . . . by means of light transmittance plate 34, which is a glass plate.” RX-0666 at 10:30-32. With respect to Cramer, Apple identifies the datasheet for the CLT 2160, which depicts a “window on top of can.” RX-1221; *see* RX-0670 at 5:33-35.



PHYSICAL DIMENSIONS — in accordance with JEDEC (T018) outline except for window on top of can.
All dimensions in inches. Collector electrically connected to case. Leads gold plated Kovar.

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RX-1221. Apple further argues that Cramer discloses a further layer of clear transparent windows between the detectors and the skin. Tr. (Warren) at 1234:22-1235:12; RDX-8C.73 (citing RX-0670 at Fig. 6).

Complainants argue that Lumidigm’s disclosure of an “optical relay” does not meet the “optically transparent material” limitation and is not disclosed in connection with Lumidigm’s “wristwatch” embodiment. CIB at 138-39. Dr. Madisetti does not agree with Dr. Warren’s opinions with respect to this limitation. *See* Tr. (Madisetti) at 1330:2-5.⁴⁶ Complainants argue that Seiko 131 fails to disclose multiple openings or optically transparent material within multiple openings. CIB at 148-49. Complainants argue that with respect to Cramer, the alleged windows are between the annular rings and are not “within” the openings. CIB at 146-47.

In consideration of the parties’ arguments, the undersigned finds that Lumidigm clearly discloses “optically transparent material” over openings associated with photodiodes, but the evidence does not clearly and convincingly show a reason to incorporate such material “within” each opening. Lumidigm describes an optical relay that is comprised of optically transparent material. *See* RX-0411 at 8:19-26; *see* Tr. (Warren) at 1221:16-1222:25. The optical relay in Lumidigm is not “within” the opening depicted in Figure 2, however—it is located “between the sensor surface 39 and the skin 40.” RX-0411 at 8:19-26, Fig. 2.⁴⁷ Apple appears to have

⁴⁶ Complainants argue that Apple should be precluded from arguing that Lumidigm discloses a “lens” because this contention was not disclosed in Apple’s pre-hearing brief, RIB at 138-39, but there was no objection to Dr. Warren’s testimony regarding a “lens” at the hearing, and Apple explains that the testimony merely represents Dr. Warren’s opinion that one of ordinary skill in the art would understand Lumidigm’s “optical relay” to be a “lens.” RRB at 57-58.

⁴⁷ Seiko 131 similarly discloses a “light transmittance plate” that is positioned above its sensor but is not “within” any opening. *See* RX-0666 at 10:30-32. Cramer also discloses annular windows that do not appear to be associated within “each” opening. *See* Tr. (Warren) at 1234:22-1235:12; RDX-8C.73 (citing RX-0670 at Fig. 6).

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identified transparent windows within an opening in Cramer’s preferred photodiode, the CLT 2160, but did not provide a clear and convincing reason to modify Lumidigm to include such material within the openings or to incorporate the CLT 2160 photodiode in Lumidigm. *See* RX-0670 at 5:33-35, Fig. 6; RX-1221; RIB at 112-113.^{48,49}

- f. Element [19E]: “one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user”**

As discussed above in the context of the preamble limitations, the evidence indicates that one of skill in the art would not have been enabled to use the Lumidigm wristwatch embodiment to measure oxygen saturation. In particular, Lumidigm only discloses that spectroscopic changes correlated with oxygenation “may be detected according to the methods described above.” RX-0411 at 19:22-26. Complainants have presented credible evidence that one of ordinary skill in the art would not have been able to successfully implement this detection in a wristwatch at the time of the Poeze patents. *See* CIB at 126-29; CRB at 44-46. Accordingly, for the same reasons discussed above in the context of the preamble, Apple has not shown by clear and convincing evidence that the “one or more processors” limitation of ’502 patent claim 19 is met by Lumidigm.

⁴⁸ As discussed above in the context of the “opaque lateral surfaces” limitation of ’501 patent claim 1, the undersigned finds the CLT 2160 datasheet to be reliable evidence for the structure of the photodiode disclosed in Cramer. *See* Part IV.G.1.f *supra*.

⁴⁹ Apple identifies a similar “can package” photodiode with a window described in Webster. RX-0035.0094-95 (“In the can package . . . , the photodiode chip is mounted on a metallic stem and is sealed with a cap that has a window to allow incident light to reach the semiconductor surface.”).

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g. Element [20]: “further comprising a thermistor”

Claim 20 of the '502 patent depends from claim 19, further requiring a thermistor. With respect to this limitation, Apple identifies Lumidigm's disclosure of “preprocessing steps” including “performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature, humidity, and pressure.” RX-0411 at 14:21-28. Lumidigm notes that “[t]hese and other techniques are well known in the art,” *id.* at 14:29, and Dr. Warren testified that “a person of ordinary skill would realize that such a temperature measurement could easily be done with a thermistor.” Tr. (Warren) at 1223:1-20. Apple identifies examples of suitable thermistors in Webster, which explicitly discloses a thermistor to compensate for LED temperature changes: “One way to compensate for LED temperature changes is to have a temperature sensor built into the probe along with the LEDs and photodiode.” RX-0035.0085 (citation omitted). A thermistor is also identified as part of an oxygen sensor in a different chapter of Webster. *Id.* at 42. Apple submits that one of ordinary skill in the art would have been motivated to use one of the thermistors disclosed in Webster in Lumidigm's wristwatch embodiment with a reasonable expectation of success. RIB at 123-24; Tr. (Warren) at 1239:22-1240:3.

Complainants argue that Lumidigm fails to disclose or suggest a thermistor. *See* CIB at 140. With respect to Webster, Complainants submit that the two thermistors identified by Apple are in separate chapters describing different devices. *Id.* at 153-54; *see* Tr. (Madisetti) at 1336:5-18.

In consideration of the parties' arguments, the undersigned finds that Lumidigm includes an explicit suggestion to account for environmental influences including temperature in the operation of its biometric sensor, *see* RX-0411 at 14:21-28, and Apple has shown that one of

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ordinary skill in the art would have had reason to use a thermistor to achieve this goal. *See* Tr. (Warren) at 1223:1-20. Moreover, the undersigned finds that one of ordinary skill in the art would have had a reasonable expectation of success adding a thermistor to Lumidigm’s wristwatch embodiment, because it involves “the mere application of a known technique to a piece of prior art ready for the improvement.” *KSR*, 500 U.S. at 417. In the context of accounting for environmental influences, Lumidigm recognizes that “[t]hese and other techniques are well known in the art,” *id.* at 14:29, and this is corroborated by Webster, which describes the use of a thermistor to “compensate for LED temperature changes.” RX-0035.0085. In a separate chapter, Webster also discloses a thermistor that is used with an oxygen sensor. *Id.* at 42. The undersigned agrees with Complainants that Apple has failed to show that any of the thermistors disclosed in Webster could be directly implemented in Lumidigm’s device, but “it is not necessary that [two pieces of prior art] be physically combinable to render obvious” the asserted patent. *Allied Erecting and Dismantling Co., Inc. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (quoting *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983)). The disclosures in Webster provide clear evidence that thermistors would have been known to persons of ordinary skill in the art to measure the temperature described in Lumidigm.

h. Element [21]: “wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal”

Claim 21 of the ’502 patent depends from claim 20, further requiring that “the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user device responsive to the temperature signal.” The evidence shows that this limitation to be met for the same reasons discussed above in the context of ’502 patent claim 20. In particular, Lumidigm explicitly discloses “preprocessing steps” including

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“performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature, humidity, and pressure.” RX-0411 at 14:21-28. One of ordinary skill in the art would have recognized that these preprocessing steps would have been performed by the processor disclosed in Lumidigm, as discussed above in the context of the “one or more processors” limitation, using a temperature signal from a thermistor, as discussed above in the context of ’502 patent claim 20.

i. Element [22]: “wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs”

Claim 22 of the ’502 patent depends from claim 21, further requiring that “the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.” As discussed above in the context of the “plurality of emitters” limitation, Lumidigm discloses “a plurality of light sources” that “may comprise light emitting diodes (‘LEDs’),” including “sets of LEDs.” RX-0411 at 6:22-53. Figure 7A of Lumidigm discloses an embodiment with four sets of eight LEDs. *Id.* at 9:26-34 (Fig. 7A). *See* Tr. (Warren) at 1220:13-1221:6; RDX-8.36. As discussed above, the Figure 7A embodiment also meets the “four photodiodes” requirement of element [19B]. *See* RDX-8.37 (identifying Figure 7A and 7B as meeting the four photodiodes limitation).

* * *

For the reasons discussed above, the evidence fails to clearly and convincingly disclose a combination of elements meeting the limitations of claim 22 of the ’502 patent, and Apple has not shown a reasonable expectation of success in achieving a combination of these elements in Lumidigm’s wristwatch embodiment.

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3. '502 Patent Claim 28

As discussed below, the evidence fails to clearly and convincingly show that claim 28 of the '502 patent is rendered obvious by Lumidigm alone or in combination with other prior art.

a. Element [28 preamble]: “A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:”

For the same reasons discussed above in the context of the preamble limitations of '502 patent claim 19 (Element 19 [Preamble]), the preamble limitations of '502 patent claim 28 are not met by Lumidigm because one of ordinary skill in the art would not have been enabled to measure oxygen saturation using the Lumidigm watch embodiment.

b. Element [28A]: “a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength”

With respect to the first LEDs limitation of '502 patent claim 28, Apple identifies Lumidigm's disclosure that its light sources “can each have the same wavelength characteristics or can be comprised of sources with different center wavelengths in a spectral range from about 300 nm to about 10,000 nm.” RX-0411 at 6:43-46; RIB at 88-90. Lumidigm provides that “the collection of light sources 34 can include some sources that have the same wavelengths as others and some sources that are different.” *Id.* at 6:46-48. Lumidigm explicitly discusses the benefits of pairs of light sources, noting that two light sources having the same wavelength “can be combined to increase the resulting signal-to-noise ratio of the measurement,” while two light sources with different wavelengths can “provide unique and useful information about the tissue optical properties.” *Id.* at 7:34-53. There is no dispute that Lumidigm thus discloses LEDs emitting at different wavelengths, and Apple identifies the sensor geometries in Figs. 3, 5-6, and 7A-B of Lumidigm as meeting this limitation. RIB at 89-90. Lumidigm provides that “any of

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the sensor geometries previously disclosed or other equivalent configurations can be used” in the wristwatch embodiment. *Id.* at 11:65-12:2.

- c. Element [28B]: “a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength”**

With respect to the second LEDs limitation of ’502 patent claim 28, Apple identifies Lumidigm’s disclosure of “sets of LEDs . . . with differing wavelength characteristics that lie within the spectral range from about 350 nm to about 1100 nm.” RX-0411 at 6:48-55. Lumidigm explicitly discusses the benefits of pairs of light sources, noting that two light sources having the same wavelength “can be combined to increase the resulting signal-to-noise ratio of the measurement,” while two light sources with different wavelengths can “provide unique and useful information about the tissue optical properties.” *Id.* at 7:34-53. Apple further cites U.S. Patent Application No. 10/262,403, which is incorporated by reference in Lumidigm, *see* RX-0411 at 1:40-44, and explicitly discloses multiple sets of LEDs with the same wavelengths emitted by LEDs in each set. *See* RX-0460 at ¶ 54, Fig. 6. There is no dispute that Lumidigm thus discloses a second set of LEDs emitting at the same wavelengths as the first set of LEDs, and Apple identifies the sensor geometries in Figs. 3, 5-6, and 7A-B of Lumidigm as meeting this limitation. Lumidigm states that in “any of the sensor geometries previously disclosed or other equivalent configurations can be used” in the wristwatch embodiment. *Id.* at 11:65-12:2.

- d. Element [28C]: “four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user”**

As discussed above in the context of the “photodiodes” limitations of ’501 patent claim 1 and ’502 patent claim 19, the undersigned finds that Lumidigm discloses silicon detectors that

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are photodiodes. *See* RX-0411 at 6:56-63, 9:26-45. With respect to the claimed “quadrant configuration,” Apple points to Lumidigm’s Figure 7B, where detectors are arranged in a two-dimensional array. *See* Tr. (Warren) at 1225:13-1226:1; RDX-8C.44; RX-0411 at 9:34-45, Fig. 7B; RIB at 91.

e. Element [28D]: “a thermistor configured to provide a temperature signal”

As discussed above in the context of ’502 patent claims 20 and 21, the undersigned finds that Lumidigm, in combination with Webster, provides a reason to modify Lumidigm to include a thermistor and shows a reasonable expectation of success. *See* RX-0411 at 14:21-28; RX-0035.0085.

f. Element [28E]: “a protrusion arranged above the interior surface, the protrusion comprising: a convex surface”

As discussed above in the context of the “protrusion” limitation of ’501 patent claim 1, the undersigned finds that one of skill in the art would have reason to modify Lumidigm to achieve this limitation, and a reasonable expectation of success. *See* RX-0411 at 4:54-56, 8:1-10, Fig. 2; RX-0666 at 19:5-8, Fig. 28; RX-0670 at 5:45-51, Fig. 3, Fig. 6.

g. Element [28F]: “a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping”

As discussed above in the context of the “plurality of openings” limitation of claim 22 (Element [19C]), the evidence fails to clearly and convincingly show a plurality of openings aligned with the four photodiodes in the context of the “four photodiode” embodiments relied upon by Apple for Element [28C].

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h. Element [28G]: “a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings”

As discussed above in the context of the “optically transparent material” limitation of ’502 patent claim 19 (Element [19D]), Lumidigm clearly discloses an “optical relay” that is transmissive and is positioned above an opening for a detector. *See* RX-0411 at 8:19-26; *see* Tr. (Warren) at 1221:16-1222:25. Lumidigm discloses a single window, but Dr. Warren suggests that “a person of skill would know that you could do an individual faceplate for each of the individual openings as a means to provide light but still optimize the process.” Tr. (Warren) at 1221:1-1222:25. Dr. Warren identifies several prior art references with such windows extending across openings over photodiodes. *Id.* at 1193:23-1194:14; RDX-8C.11 (citing RX-0670; RX-0666; RX-0667).

i. Element [28H]: “at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities”

For the reasons discussed above in the context of the “opaque lateral surface” limitation of ’501 patent claim 1 and the “opaque material” limitation of ’502 patent claim 19 (Elements [1E] and [19C]), the undersigned finds Lumidigm, in combination with the other prior art, discloses the requirements of this limitation. *See* RX-0411 at 7:66-8:11, Fig. 2; RX-0670 at 2:46-51, 5:33-35, 5:46-48, Fig. 3, Fig. 6; RX-1221.

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- j. Element [28I]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal”**

As discussed above in the context of the “one or more processors” limitation of ’502 patent claim 19 (Element [19E]), Lumidigm does not disclose a processor configured to calculate an oxygen saturation measurement.^{50,51}

- k. Element [28J]: “a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network”**

With respect to the “network interface” limitation, Apple identifies a “communications system 344” disclosed in Lumidigm and depicted on Figure 9, which “may comprise a wired, wireless, modem, and/or other type of interfacing connection and permits data to be exchanged with external devices.” RX-0411 at 13:9-12, Fig. 9. In the context of a key fob embodiment, Lumidigm discloses “short-range wireless techniques based upon RF signals 103 . . . to communicate between the fob and a corresponding reader.” *Id.* at 11:38-42. In this embodiment, the transmission can be “a simple confirmed or denied signal” or “the most recent measured spectrum is transmitted to the reader and the comparison and decision is accomplished at the reader or at a host to which the reader is connected.” *Id.* at 11:49-55. Apple further

⁵⁰ As discussed above in the context of the “one or more processors” limitation of ’501 patent claim 1 (Element [1F]), Lumidigm does disclose a “processor” that receives signals from a sensor and outputs measurements indicative of physiological parameters. *See* RX-0411 at 12:56-13:14.

⁵¹ As discussed above in the context of the “thermistor” limitations of ’502 patent claims 20 and 21 (Elements [20] and [21]), the evidence shows that one of ordinary skill in the art would have reason to incorporate a thermistor in the Lumidigm wristwatch embodiment. *See* RX-0411 at 14:21-28; RX-0035.0085.

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submits that “RF signals 103” are depicted in Figure 8B in the context of the wristwatch embodiment.

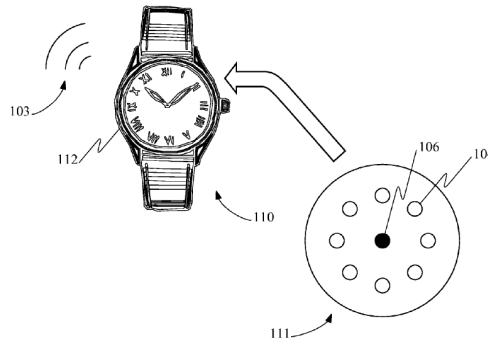


FIG. 8B

Id. at Fig. 8B; RIB at 94-95. Complainants dispute whether Lumidigm discloses this limitation in combination with the wristwatch embodiment and/or the extended functionality for measuring physiological parameters. CIB at 141-42; CRB at 51.

In consideration of the parties’ arguments, the undersigned finds that Lumidigm clearly discloses a network interface for wireless communication with an electronic network in its wristwatch embodiment. *See* RX-0411 at 11:38-55, Fig. 8B. This does not include the communication of an oxygen saturation measurement, however, because no such measurement is disclosed in Lumidigm, for the reasons discussed above in the context of the preamble of ’502 patent claim 19 (Element [19 preamble]).

- I. Element [28K]: “a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user”**

With respect to the “user interface comprising a touch-screen display” limitation, Apple points to Lumidigm’s disclosure of embodiments of “a personal electronic device that may be configured with biometric capability in the form of a PDA” and “a combined cellular telephone/PDA.” RX-0411 at 12:21-48, Fig. 8D, Fig. 8E. Apple argues that such devices were

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known to have touchscreen displays. RIB at 95-96; *see* Tr. (Warren) at 1226:23-1227:3. Apple further cites an embodiment disclosed in Lumidigm wherein the portable electronic device can access the internet “to display the retrieved information on the portable electronic device.” RX-0411 at 21:29-33. Apple further asserts the widespread availability of touch-screen user interfaces, and Dr. Warren testified that a person of ordinary skill would have been able to incorporate a touch-screen into any portable device. RIB at 129-33; *see* Tr. (Warren) at 1226:23-1227:5. Apple identifies a touch-screen disclosed in U.S. Patent No. 9,001,047 (RX-0673, “Apple ’047), and Dr. Warren testified that it would have been obvious to incorporate such a touch-screen with the display of a blood oxygen measurement disclosed in Lumidigm. Tr. (Warren) at 1240:4-1242:9. Apple also identifies certain references to “touch buttons” in Webster. RIB at 133 (citing RX-0035 at 114, 137, 218-223).

Complainants argue that Lumidigm provides no clear disclosure of a touch-screen in combination with its wristwatch embodiment and/or the extended functionality for measuring physiological parameters. CIB at 141-42; CRB at 51. With respect to Apple ’047, Complainants argue that there is no disclosure of a user-worn device or any display of a physiological parameter such as an oxygen saturation measurement. CIB at 156-57; *see* Tr. (Madisetti) at 1337:3-11. Complainants argue that Apple has failed to show any motivation to combine or likelihood of success in adding a touch-screen to the wristwatch embodiment in Lumidigm. CIB at 157; CRB at 84-85.

In consideration of the parties’ arguments, the undersigned agrees with Complainants that Lumidigm fails to disclose a touch-screen user interface for display of an oxygen saturation measurement in conjunction with the wristwatch embodiment, and Apple has not clearly and convincingly shown that this addition would be obvious. Dr. Warren’s testimony on this issue is

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conclusory. *See* Tr. (Warren) at 1226:22-1227:7, 1240:4-17, 1241:1-17; RDX-8.83-84. Apple relies on Lumidigm’s identification of certain portable electronic devices with screens, but with no reference to touch-screen input. *See* RIB at 131 (citing RX-0411 Figs. 8B-8E, 3:35-37, 21:29-36). Moreover, the cellular phone and PDA embodiments are identified as separate from the wristwatch embodiment, with no suggestion that parts of these different portable electronic devices should be combined. *See id.* at 10:42-13:26. Lumidigm’s wristwatch embodiment is depicted as an analog clock face with no screen for displaying any measurement. *See id.* at 11:60-12:2, Fig. 8B.⁵²

The undersigned further finds that Apple has not clearly and convincingly identified a reason one of ordinary skill would have combined Lumidigm’s wristwatch with the touch-screen interface disclosed in Apple ’047 and shown that such a combination would have had a reasonable expectation of success. Dr. Warren’s testimony on these issues is conclusory and fails to offer any reason for adding a touch-screen to Lumidigm’s wristwatch—he merely offers his opinion that a touch-screen “is a well-known mechanism” and that “a person of ordinary skill would realize that, to add the features of . . . [a] touchscreen to Lumidigm, they could look to a number of references, but . . . Apple would be an obvious choice.” Tr. (Warren) at 1240:4-1242:9. With respect to this limitation, Dr. Warren appears to have relied on the “touch-screen display” in the claim language as his only reason for incorporating this feature, and the Federal Circuit has held that such an approach is inadequate to prove obviousness. *See InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (reversing jury’s finding of

⁵² As discussed above regarding Element [28J], Lumidigm discloses a network interface for wirelessly communicating the measurement of a physiological parameter from the wristwatch to an external device (where it can be read). *See* Element [28J] *supra*; RX-0411 at 11:38-55; RIB at 94-95.

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obviousness where expert used the asserted patent as a “roadmap” and her “testimony primarily consisted of conclusory references to her belief that one of ordinary skill in the art could combine these references, not that they would have been motivated to do so.”).

Apple ’047 also fails to disclose any use of a touch-screen in a wristwatch—it is primarily directed to “a rectangular touch screen display with a portrait view and a landscape view.” *See* RX-0673 at 2:53-3:57 (describing embodiments of rectangular touch screen displays), Fig. 2; *see* Tr. (Warren) at 1240:18-25 (describing Apple ’047). Apple’s prior art touch-screen does not appear to be compatible with the wristwatch disclosed in Lumidigm, which has an analog clock face with a circular shape, and Dr. Warren did not provide testimony addressing this issue. *See* RX-0411 at Fig. 8B. Moreover, to the extent that Apple relies on Webster, Apple has not shown that any of the displays or user interfaces identified in Webster are touch-screens. *See* RX-0035 at 114, 137, 218-223.⁵³

m. Element [28L]: “a storage device configured to at least temporarily store at least the measurement”

With respect to the “storage device” limitation, Apple identifies Lumidigm’s disclosure of computer hardware elements in Figure 9, including storage device 338, memory 348, and computer-readable storage medium 340b. RX-0411 at 12:63-13:9. Lumidigm provides that “[t]he storage devices typically hold information defining the stored spectra as well as any personalized-setting information that may be used.” *Id.* at 13:12-14. Complainants dispute this limitation, arguing that there is no clear disclosure of the storage devices in Figure 9 in

⁵³ Complainants argue that Apple failed to cite Webster with respect to this limitation in its pre-hearing brief. *See* CRB at 84. The undersigned agrees with Complainants that this contention is untimely, but even if these disclosures in Webster were considered, it would not change the determination regarding obviousness.

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combination with the wristwatch embodiment and/or the extended functionality for measuring physiological parameters. CIB at 141-42; CRB at 51.

In consideration of the parties' arguments, the undersigned finds that Lumidigm discloses a storage device configured to store measurements from its biometric sensor. As discussed above in the context of the "one or more processors" limitation of '501 patent claim 1, Lumidigm explicitly notes that some of the components in Figure 9 could be used in portable devices, which includes the "wristwatch" embodiment. RX-0411 at 13:21-37 (identifying a "second set of embodiments" involving "a portable electronic device having extended functionality," and including "a cellular telephone, a personal digital assistant, an electronic fob, and a watch" as examples of the "electronic arrangement"), 2:58-61, 17:67-18:2. Lumidigm explicitly provides that "[t]he storage devices typically hold information defining the stored spectra," and the blood oxygen measurement described in Lumidigm is defined by "spectroscopic changes" that are "correlated with oxygenation." *Id.* at 13:12-14, 19:24-26. Accordingly, the "storage device" limitation of '502 patent claim 28 is disclosed in Lumidigm, except to the extent that this limitation requires storage of an oxygen saturation measurement.

n. Element [28M]: "a strap configured to position the user-worn device on the user"

With respect to the "strap" limitation, Apple identifies the strap depicted in Lumidigm's "wristwatch" embodiment. *See* RX-0411 at 11:60-64, Fig. 8B. There is no dispute that Lumidigm meets the "strap" limitation of '502 patent claim 28.

* * *

For the reasons discussed above, the evidence fails to clearly and convincingly disclose a combination of elements meeting the limitations of claim 28 of the '502 patent, and Apple has

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not shown a reasonable expectation of success in achieving a combination of these elements in Lumidigm's wristwatch embodiment.

4. '648 Patent Claim 12

As discussed below, the evidence fails to clearly and convincingly show that claim 12 is obvious in view of Lumidigm alone or in combination with other asserted prior art.

a. Element [8 preamble]: "A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:"

For the same reasons discussed above in the context of the preamble limitations of '501 patent claim 1 (Element 1[A]), Lumidigm meets the preamble limitations of '648 patent claim 8 requiring a "user-worn device configured to non-invasively determine measurements of a physiological parameter of a user."

b. Element [8A]: "a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength"

For the same reasons discussed above in the context of Element [28A] of the '502 patent, the evidence shows that this limitation is met by Lumidigm.

c. Element [8B]: "a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength"

For the same reasons discussed above in the context of Element [28B] of the '502 patent, the evidence shows that this limitation is met by Lumidigm.

d. Element [8C]: "four photodiodes"

For the same reasons discussed above in the context of the "four photodiodes" limitations of '502 patent claim 19 (Element [19B]), the undersigned finds that the "four photodiodes" limitation of '648 patent claim 8 is met by Lumidigm.

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- e. Element [8D]: “a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material”**

For the same reasons discussed above in the context of the “protrusion” and “opaque lateral surface” limitations of ’501 patent claim 1 (Elements [1C], [1D], and [1E]), the evidence shows that Lumidigm, in view of the prior art, provides a reason to modify the optical surface to form a “protrusion comprising a convex surface” with a portion of the protrusion (the openings) comprising an opaque material.

- f. Element [8E] and Element [8F]: “a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes” and “a separate optically transparent window extending across each of the openings”**

For the same reasons discussed above in the context of the “plurality of openings” limitations of ’502 patent claim 19 (Element [19C]), the evidence fails to show, clearly and convincingly, a “plurality of openings” with a “separate optically transparent window extending across each of the openings” in combination with the “four photodiodes” embodiments of Lumidigm relied upon by Apple. *See* RIB at 82, 91, 98.

- g. Element [8G]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user”**

For the same reasons discussed above in the context of the “one or more processors” limitation of ’501 patent claim 1 (Element [1F]), the undersigned finds that the “one or more processors” limitation of ’648 patent claim 8 is met by Lumidigm.

- h. Element [8H]: “a housing”**

With respect to the “housing” limitation, Apple identifies Lumidigm’s disclosure that “the biometric reader 111 is built in the case of a wristwatch 112.” RX-0411 at 11:60-64, Fig.

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8B. There is no dispute that Lumidigm thus discloses a housing in its “wristwatch” embodiment.

The evidence shows that this limitation is met by Lumidigm.

i. Element [8I]: “a strap configured to position the housing proximate tissue of the user when the device is worn”

For the same reasons discussed above in the context of the “strap” limitation of ’502 patent claim 28 (Element [28M]), the evidence shows that the “strap” limitation of ’648 patent claim 8 is met by Lumidigm.

j. Element [12]: “wherein the physiological parameter comprises oxygen or oxygen saturation”

’648 patent claim 12 depends from claim 8 and further requires that “the physiological parameter comprises oxygen or oxygen saturation.” For the same reasons discussed above in the context of the preamble limitations of ’502 patent claim 19, this limitation is not met by Lumidigm, because the evidence shows that one of ordinary skill would not have been able to successfully configure Lumidigm’s wristwatch to measure blood oxygen.

5. ’648 Patent Claim 24

As discussed below, the evidence fails to clearly and convincingly show that claim 24 of the ’648 patent is rendered obvious by Lumidigm alone or in combination with other prior art.

a. Element [20 preamble]: “A user-worn device configured to non-invasively determine measurements of a user’s tissue, the user-worn device comprising:”

Complainants dispute this limitation on the grounds that Lumidigm does not disclose measurement of a “physiological parameter” (*see* CIB at 124-125). For the same reasons discussed above in the context of the preamble limitations of ’501 patent claim 1, Lumidigm discloses the preamble limitations of ’648 patent claim 20 requiring a “user-worn device configured to non-invasively determine measurements of a user’s tissue.” Moreover, the preamble language of Element [20 preamble] does not necessarily require measurement of a

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“physiological parameter,” only “measurements of a user’s tissue.” Lumidigm clearly shows that the biometric functionality of the wristwatch embodiment requires “measurements of a user’s tissue,” and Complainants do not dispute that the wristwatch embodiment of Lumidigm performs biometric functionality. *See* RX-0411 at 5:30-44 (describing biometric identification of an individual based on comparing “tissue spectral data taken at the time of use and compared to stored tissue spectral data from prior *measurement*”) (emphasis added); CIB at 125 (describing Lumidigm’s wristwatch as “identifying a user or authorizing them to do something using ‘tissue spectral data’”).

b. Element [20A]: “a plurality of light emitting diodes (LEDs)”

For the same reasons discussed above in the context of Element [1A] of the ’501 patent claim 1, this limitation is met by Lumidigm.

c. Element [20B]: “at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user”

For the same reasons discussed above in the context of Element [28C] of the ’502 patent, the evidence shows that this limitation is met by Lumidigm.

d. Element [20C]: “a protrusion comprising a convex surface”

For the same reasons discussed above in the context of the “protrusion” limitation of ’501 patent claim 1 (Element [1C]), the evidence clearly and convincingly shows that Lumidigm’s disclosures, in view of the prior art, provide a reason to modify Lumidigm’s “optical surface” to form a protrusion comprising a convex surface, and a reasonable expectation of success in doing so.

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- e. Element [20D]: “and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes”**

For the same reasons discussed above in the context of Element [19C] of the '502 patent, the evidence is insufficient to show, clearly and convincingly, that the prior renders obvious a protrusion comprising a plurality of through holes where each through hole is “arranged over a different one of the at least four photodiodes,” in combination with all other elements of this claim.

- f. Element [20E]: “one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user”**

For the same reasons discussed above in the context of the preamble of '502 patent claim 19, the undersigned finds that the “one or more processors” limitation of '648 patent claim 20 is not met by Lumidigm, because one of ordinary skill would not have been able, without undue experimentation, to configure Lumidigm's wristwatch to determine measurements of oxygen saturation.

- g. Element [24]: “wherein the protrusion comprises opaque material configured to substantially prevent light piping”**

Claim 24 of the '648 patent depends from claim 20, further requiring that “the protrusion comprises opaque material configured to substantially prevent light piping.” For the same reasons discussed above in the context of the “opaque lateral surface” limitation of '501 patent claim 1 (Element [1E]), the undersigned finds that “opaque material configured to substantially prevent light piping” is disclosed by Lumidigm, but not in combination with all the other elements of claim 20.

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6. '648 Patent Claim 30

Claim 30 of the '648 patent depends from claim 20, further requiring that “the protrusion further comprises one or more chamfered edges.” Apple contends that chamfered edges were well-known in the art. *See* Tr. (Warren) at 1228:24-1229:10. Apple further submits that chamfered edges are depicted in Seiko 131 and in Cramer. *See* RX-0666 at Fig. 5; RX-0670 at Fig. 3; Tr. (Warren) at 1236:3-16. Dr. Warren explained that such features would be implemented for comfort, in accordance with Lumidigm’s teaching that modifications to the sensor surface could be made “to incorporate ergonomic features.” Tr. (Warren) at 1228:24-1229:10 (quoting RX-0411 at 7:57-63). Dr. Warren further testified that “a person of ordinary skill would understand that chamfered edges have been around for many decades as a means to soften transitions between surfaces and make items such as watches more wearable.” *Id.* at 1236:17-1237:3.

Complainants argue that Lumidigm fails to disclose or suggest a chamfered edge. CIB at 142-43. Complainants argue that the chamfered edges disclosed in Cramer are not on the alleged protrusions. *Id.* at 147. Similarly, Complainants argue that the chamfered edges disclosed in Seiko 131 are not on the alleged protrusion. *Id.* at 150. Complainants argue that Apple has failed to show why a person of ordinary skill would have been motivated to use a chamfered edge in Lumidigm’s wristwatch embodiment with a reasonable expectation of success. CRB at 76-78.

In consideration of the parties’ arguments, the evidence shows that chamfered edges were known in the prior art, and one of ordinary skill in the art would have reason to implement a chamfered edge on the sensor surface of Lumidigm’s wristwatch for ergonomic reasons with a reasonable expectation of success. The record contains numerous examples of chamfered edges

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in the prior art, including on the front face of Lumidigm’s wristwatch and on the back face of Cramer’s wristwatch. *See* RX-0411 at Fig. 8B; RX-0670 at Fig. 3.⁵⁴ This is clear evidence that chamfered edges were used in wristwatches and would have been known to persons of ordinary skill in the art. *See* Tr. (Warren) at 1228:24-1229:10, 1236:17-1237:3. Lumidigm provides an express motivation to modify the curvature of its sensor surface “to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons.” RX-0411 at 7:58-63.

Although the prior art provides a reason to incorporate a chamfered edge into a protrusion on the back face of a wristwatch, with a reasonable expectation of success, the evidence fails to show that this limitation in combination with the other limitations of claim 30 (including all limitations of independent claim 20) are rendered obvious. Accordingly, Apple has not shown that claim 30 of the ’648 patent is invalid for obviousness.

7. Objective Indicia of Non-Obviousness

Complainants contend that the asserted claims of the Poeze patents are not obvious in view of certain objective indicia of non-obviousness, including skepticism and failure of others, unexpected results, copying, and commercial success. CIB at 158-75; CRB at 85-96. For the

⁵⁴ Complainants argue that the chamfered edges in Cramer are not on the alleged convex portions of the protrusion, CIB at 147, but claim 30 does not require the chamfered edge and the convex surface to be on the same part of the protrusion—the claim language recites “a protrusion comprising a convex surface,” and “wherein the protrusion further comprises one or more chamfered edges.” *See* ’648 patent claim 20, claim 30.

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reasons set forth below, the evidence regarding the objective indicia of non-obviousness do not weigh significantly against an obviousness finding.

a. Skepticism and Unexpected Results for Convex Protrusions

Complainants contend that there was skepticism in the industry for convex protrusions, citing evidence from Apple’s development of the Apple Watch wherein Apple engineers identified [REDACTED]

[REDACTED] See CX-1789C; CX-1790C. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] CX-0114C at 2-3. An Apple patent application

filed in July 2016 described benefits of a convex protrusion: “A convex shape can enable improved contact with the user’s skin and can be more comfortable for the user than other shapes.” CX-1569 at 9:35-37. Another Apple patent filed in May 2016 described a protrusion “configured to create pressure to skin.” CX-1806 at ¶ [0033]. “By applying localized pressure to the individual’s skin, the pressure gradient across arterial walls can be reduced, which can lead to an increase in pulsatile (AC) signal.” *Id.* at ¶ [0032].

Complainants also contend that the results of a convex protrusion were unexpected within Cercacor. See CIB at 162. Mr. Kiani testified that Cercacor engineers were surprised that they achieved a stronger signal when trying to measure hemoglobin and glucose levels using a protrusion that applied pressure to a finger. Tr. (Kiani) at 98:9-99:16. Complainants argue that this result conflicts with a prior art patent, U.S. Patent No. 6,801,799 (CX-1733, “Mendelson”), which warned against pressure on the skin during pulse oximetry measurements. See CX-1733 at 2:47-57 (“[V]ariations in contact pressure between the sensor and the skin can cause large

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errors in reflection pulse oximetry (as compared to transmission pulse oximetry) since some of the blood near the superficial layers of the skin may be normally displaced away from the sensor housing towards deeper subcutaneous structures.”); *see* Tr. (Madisetti) at 1374:9-12.

Complainants also cite the testimony of Robert Rowe, one of the Lumidigm inventors, who described a shape that matches the skin, *e.g.*, a concave shape to match a cylindrical body part, as a way to achieve “good coupling.” RX-0279C (Rowe Dep. Tr.) at 69:8-21.

Apple disputes Complainants’ interpretation of Apple’s engineering documents, asserting that Apple engineers [REDACTED].
RRB at 66-67. [REDACTED]

[REDACTED] Tr. (Block)
at 905:23-907:24. With respect to the documents describing the effect of [REDACTED]

[REDACTED] CX-0281C (Block Dep. Tr.) at 218:16-219:5. Apple argues that there is no evidence in the prior art for skepticism regarding a convex protrusion. RIB at 146-47; RRB at 67-68. Apple submits that the Mendelson patent cited by Dr. Madisetti does not disclose or discuss a convex protrusion. *See* Tr. (Warren) at 1244:18-1245:7 (discussing CX-1733/RX-0688). Apple cites another prior reference, Nippon, which describes the benefits of pressure on the skin for increasing signal strength. RX-0665 at 5:12-17, Fig. 3b; *see* Tr. (Warren) at 1245:8-16. Apple further cites the convex protrusions disclosed in Seiko 131 and Cramer. *See* RX-0666 at 3:22-28, 19:6-8, Fig. 28; RX-0670 at 5:45-51, Fig. 3, Fig. 6; *see* Tr. (Warren) at 1194:15-1195:5, 1245:1-1246:12. Apple argues that Mr. Kiani’s surprise regarding the effect of a convex protrusion does not reflect the knowledge of one of skill in the art. RRB at 67. Apple disputes Complainants’ characterization of Mr. Rowe’s testimony, which did not explicitly reference any

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concave shape. *Id.* With respect to the Apple patent applications describing convex protrusion, Apple argues that these features were not individually claimed to be novel. *Id.* at 68.

In reply, Complainants argue that Mendelson teaches the undesirability of displacing blood away from the sensor, which would be caused by a convex protrusion. CRB at 91. Complainants contend that Nippon fails to disclose a convex protrusion and was considering during the prosecution of the Poeze patents. *Id.* at 91-92. Complainants submit that Mr. Rowe's testimony is consistent with the teachings in Mendelson and that Mr. Kiani's testimony regarding the surprising benefits of a convex protrusion is consistent with the advantages described in Apple's patent applications. *Id.* at 92-94.

In consideration of the parties' arguments, the evidence does not show that there was skepticism in the industry regarding convex surfaces. As discussed above in the context of the "protrusion" limitation of '501 patent claim 1, there is no evidence in the prior art that convex surfaces were disfavored before the invention of the Poeze patents. The parties have identified prior art physiological sensors with concave, convex, and flat surfaces, which is convincing evidence that the shape of the sensor surface was a design choice for persons of ordinary skill in the art "to match the profile of a device in which it is mounted, to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons." RX-0411 at 7:57-63; *see also* RX-0666 at 3:22-28, Fig. 28; RX-0670 at 5:45-51, Fig. 3; RX-0665 at 5:12-17, Fig. 3b. The Apple engineering documents that Complainants cite to show alleged skepticism are not clearly directed to the accused convex protrusions, and the undersigned agrees with Apple that this evidence should be discounted in view of the evidence that the back surface of the Apple Watch had a convex shape even before the pulse oximetry feature was implemented. *See* RRB at 66-67.

In addition, the undersigned finds that Complainants have not shown that a gain in signal strength with convex surfaces was an unexpected result that demonstrates non-obviousness.

Complainants have identified evidence that both Cercacor engineers and Apple engineers were

but the evidence in the prior art is mixed on the question of whether this result should have been unexpected. *Compare* CX-1733 at 2:47-57 (describing “large errors” caused by “variations in contact pressure”) to RX-0665 at 5:12-17 (recognizing that a detector that “protrudes into the tissue slightly” has the effect of “increasing the signal strength of the detected signal.”).⁵⁵

Moreover, to the extent that an improvement in signal strength is attributable to the increased pressure caused by a convex protrusion, the record shows that this effect was recognized in the prior art: Seiko 131 identifies a convex surface that improves “positive contact between the body surface and outside surface of the light transmittance plate.” RX-0666 at 3:22-28, Fig. 28.; and Nippon describes increased signal strength from a protrusion into the tissue. RX-0665 at 5:12-17, Fig. 3b. The Federal Circuit has discounted evidence of unexpected results when the result was produced by a feature known in the prior art. *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1385 (Fed. Cir. 2015) (“[T]he offered secondary consideration actually results from something other than what is both claimed and novel in the claim, so there is no nexus to the merits of the claimed invention.” (citing *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (internal quotations removed)).

⁵⁵ In the pulse oximeter described in the specification of the Poeze patents, the benefits of a convex protrusion are attributed to the reduced thickness of the finger—not the pressure on the skin. *See* JX-0001 at 21:9-34 (describing signal gain in the context of the Beer Lambert law, which relates transmittance to the path length traveled by the light: “In an embodiment where the protrusion 305 is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm.”).

b. Skepticism and Failures Measuring Pulse Oximetry at the Wrist

Complainants further cite evidence that the [REDACTED] [REDACTED] in the Apple Watch is evidence that measuring pulse oximetry at the wrist would have been non-obvious. CIB at 165-72; CRB at 85-88. Complainants identify evidence that Apple [REDACTED] [REDACTED] See CX-1793C ([REDACTED]). Paul Mannheimer was hired to be Apple’s sensor architect in 2014, and he expressed skepticism that pulse oximetry could be successfully implemented in a wristwatch. Tr. (Mannheimer) at 996:25-997:5. Stephen Waydo, the director of Apple’s team for health algorithms, also expressed skepticism that blood oxygen could be measured on the wrist, calling the development this feature “extremely challenging.” Tr. (Waydo) at 938:21-24. This skepticism was shared by other Apple engineers. See CX-0295C (Shui Dep. Tr.) at 108:13-21; CX-0283C (Lefort) at 198:8-199:2. Apple did not implement a blood oxygen feature in any of the first six Apple Watches that were commercially released from 2015 to 2019. Tr. (Mannheimer) at 1013:7-20. [REDACTED] [REDACTED] CX-0177C at 13; see Tr. (Mannheimer) at 1015:9-19; Tr. (Land) at 982:3-983:12. Apple engineers filed for a patent on a sensor window design for the Apple Watch in July 2016, which issued as U.S. Patent No. 10,702,211 in July 2020. CX-1569. The first Apple Watch with a pulse oximetry feature was released in September 2020: the Apple Watch Series. RX-0333.

Apple argues that the skepticism of its engineers regarding the implementation of pulse oximetry in the Apple Watch was related to “[REDACTED] [REDACTED].” RRB at 52-53. Dr. Warren cited

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evidence that his own students had built pulse oximeters that could take measurements at the wrist as early as 2002. Tr. (Warren) at 1216:10-25; RX-0632; RX-0504; RX-0508. Apple further argues that the evidence regarding the Apple Watch is irrelevant, because the Poeze Patents provide no teachings for measuring blood oxygen on the wrist. RRB at 68.

In consideration of the parties' arguments, the undersigned finds that the skepticism of Apple engineers regarding pulse oximetry at the wrist (and discussed in Part IV.G.2.a *supra*) is consistent with the finding *supra* that Lumidigm's wristwatch embodiment, as modified in view of the combinations Apple proposes, does not disclose or render obvious a device for measuring blood oxygenation at the wrist. However, while this evidence is highly relevant to the obviousness determination for the reasons discussed in Parts IV.G.2-6 above,⁵⁶ this evidence does not weigh significantly in terms of objective indicia of non-obviousness because the asserted claims apply to any "user-worn device," including user-worn devices that are not on the wrist. See *Therasense Inc. v. Becton Dickinson and Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010) (objective evidence of non-obviousness should be "commensurate in scope with the claims which the evidence is offered to support"); *id.* (evidence of long-felt but unsolved need to solve "short fill" problem did not weigh against obviousness finding where the claims "are not limited to sensors that prevent short fill"); '501 patent at 11:45-48 ("In some embodiments, the measurement site 102 is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand."); *id.* at 8:21-23 (discussing "measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like"); *id.* at 10:22-24

⁵⁶ As discussed *supra*, Apple's obviousness arguments rely on the wristwatch embodiment of Lumidigm as the primary reference.

("[m]any of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on the patient, such as the patient's arm").⁵⁷

c. Apple's Alleged Copying of Masimo Technology

Complainants further allege that Apple copied Masimo's patented technology in its development of the pulse oximetry feature in the Apple Watch. CIB at 172-73; CRB at 94-96.

Complainants cite testimony and evidence showing that Apple [REDACTED]

[REDACTED] See Tr. (Waydo) at 945:10-946:6; CX-0125C; CX-0126C. Beginning in 2013, Apple met with Masimo employees [REDACTED] See CX-1793C

([REDACTED]); CX-0185C at 20 ([REDACTED]

[REDACTED]); Tr. (Kiani) at 104:14-22, 107:1-108:18. Apple hired several Masimo employees, including Masimo's Chief Medical Officer, Michael O'Reilly, and one of the named inventors of the Poeze patents, Steve Lamego. See Tr. (Kiani) at 110:23-111:23; CX-1615C. Complainants allege that Apple sought to obtain Masimo's technology by hiring Dr. Mannheimer from Nellcor, a Masimo competitor that was found to have infringed Masimo's patents in 2004. CIB at 168-

69. Complainants submit that Apple has provided no credible explanation for the convex shape of the back crystal in the design of the Apple Watch and argue that an inference of copying is appropriate. CRB at 95. Complainants cite evidence that [REDACTED]

[REDACTED]. See CX-0285C (Dua Dep. Tr.) at 105:22-107:9; CX-0096C. Complainants further submit that [REDACTED]

⁵⁷ In addition, the asserted claim of the '501 patent is not limited to devices that perform pulse oximetry.

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[REDACTED]

See Tr. (Waydo) at 932:19-933:4; CX-0127C; CX-0097C at 3; CX-0094C.

Apple argues that the pulse oximetry features of the Apple Watch could not have been copied from the Poeze patent claims, because the applications reciting these claims were not filed until after the Apple Watch Series 6 had been released. RIB at 140. Apple further argues that it could not have copied the patented features from any Masimo product, because the first Masimo product embodying the asserted claims was not released to the public until January 2022—during discovery in this investigation. *Id.* Apple’s engineers have consistently testified that they did not copy Masimo or any other company’s technology. *Id.* at 140-41 (citing Tr. (Block) at 902:10-12, 914:1-7; Tr. (Waydo) at 932:6-9, 933:8-11; Tr. (Land) at 972:19-22, 991:23-25; Tr. (Venugopal) at 833:13-17; Tr. (Mehra) at 893:15-17; Tr. (Mannheimer) at 1007:22-1008:7; CX-0283C (Charbonneau-Lefort Dep. Tr.) at 171:21-173:8, 201:10-19; CX-0285C (Dua Dep.) at 160:20-161:5). Apple contends that [REDACTED] [REDACTED] was not related to the development of the pulse oximetry feature for the Apple Watch and argues that there is no evidence that this product practices any asserted claim. RIB at 142.

[REDACTED]

[REDACTED] *Id.* at 143; RRB at 70 (citing Tr. (Diab) at 243:9-17; Tr. (Scruggs) at 446:8-23). Apple submits that none of the employees hired from Masimo contributed to the design of the pulse oximetry feature in the Apple Watch. RIB at 142-43. (citing Tr. (Land) at 972:23-973:3, Tr. (Waydo) at 950:1-15; Tr. (Venogupal) at 833:14-17. Apple explains that [REDACTED] [REDACTED] during the development of the Apple Watch to avoid the disclosure of information regarding an “unreleased feature.” CX-0285C (Dua Dep. Tr.) at

105:22-107:9. With respect to Dr. Waydo's discussion of [REDACTED]
[REDACTED], Apple submits that this was related to the problem of taking measurements during motion, which was not implemented in the Apple Watch. CX-0299C (Waymo Dep. Tr.) at 173:3-174:8; Tr. (Waydo) at 932:6-18.

In consideration of the parties' arguments, the undersigned finds no significant credible evidence that Apple copied Masimo's patented technology. Complainants accuse numerous former Masimo employees of copying Masimo's technology but fails to identify the patented features that were allegedly copied. Complainants' theory that Apple's hiring of Dr. Mannheimer from Nellcor was motivated by a desire to copy Masimo's technology lacks evidentiary support. The allegation that Apple copied the convex shape of the Apple Watch's back crystal from Masimo is purely speculative, and as discussed above, such convex surfaces were known in the prior art. Complainants fail to identify which features of the [REDACTED] [REDACTED] pulse oximeters used as benchmarks were allegedly copied by Apple, and there is no evidence that any of these products practices asserted claims of the Poeze patents. Complainants' allegations are insufficient to demonstrate copying. *See Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Not every competing product that arguably falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent."); *see also Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) ("Our case law holds that copying requires evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a

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replica, or access to the patented product combined with substantial similarity to the patented product.”).

d. Commercial Success of Apple Watch Products

Complainants allege that the commercial success of the Apple Watch Series 6 and 7 products is objective evidence of non-obviousness. CIB at 173-75; CRB at 95-96. According to Complainants’ expert Daniel McGavock, sales of the Apple Watch Series 6 far exceeded the sales of previous Apple Watches, and Apple advertised the blood oxygen feature as the key differentiator of the Series 6 over the Series 5. Tr. (McGavock) at 1416:10-21, 1422:8-1425:13; CX-0252; CX-1451; CX-1532; CX-1289. Mr. McGavock referenced third party reviews identifying the blood oxygen feature as the key feature for the Apple Watch Series 6. Tr. (McGavock) at 1418:21-1419:8 (citing CX-1634; CX-1301). Dr. Madisetti agreed with Mr. McGavock that there was a nexus between the blood oxygen feature of Apple Watch Series 6 and its commercial success. Tr. (Madisetti) at 1380:14-1381:4.

Apple argues that the commercial success of the Apple Watch Series 6 and 7 is attributable to many features. RIB at 144; RRB at 71; *see* Tr. (Warren) at 1242:16-25; Tr. (Land) at 970:10-971:6. According to Deidre Caldbeck, Apple’s Director of Product Marketing for the Apple Watch, pulse oximetry is “not even in the top 30 use apps on Apple Watch.” CX-0275 (Caldbeck Dep. Tr.) at 65:21-22, 66:3-12. Apple argues that its marketing materials describe many different features of the Apple Watch Series 6 in addition to pulse oximetry. *See, e.g.*, CX-1447; CX-0252; CX-1532; CX-1451. Apple further points out that Mr. McGavock cited certain third-party reviews of the Apple Watch that criticized the pulse oximetry feature of the Apple Watch Series 6. *See* Tr. (McGavock) at 550:20-551:17 (citing CX-1616; CX-1293; CX-1409).

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In consideration of the parties' arguments and the record evidence, the undersigned finds that the Apple Watch Series 6 was commercially successful and that this may be due in some part to its blood oxygen monitoring features. There is no dispute that the Apple Watch Series 6 was commercially successful. *See* Tr. (McGavock) at 1419:9-1420:1; CX-1285 (*AppleInsider*: "Apple Watch far outsold all other smartwatches in Q4 2020"). Apple's marketing materials upon introduction of the Apple Watch Series 6, as well as certain third-party reviewers, identified the measurement of blood oxygen as a key new feature. *See, e.g.*, CX-0252; CX-1289; CX-1451; CX-1301 (*New York Times*: "The new Apple Watch can be summed up in two words: blood oxygen."); CX-1643 (*Independent*: "it's the blood oxygen sensor that dominated the introduction, and which is the new feature that Apple has spent the most time talking about.").

The evidence does not persuasively indicate, however, that the sales of the Apple Watch Series 6 are largely attributable to the blood oxygen feature, as market analysts have recognized the Apple Watch's "blend of sleek design, good usability on a small screen, and a growing portfolio of health and fitness apps." CX-1644 (Strategy Analytics). Moreover, it is not clear that the Apple Watch Series 6 was significantly more successful than other smartwatches, because the growth in Apple's smartwatch sales from 2020 to 2021 is in line with the growth of smartwatch sales across the industry. *See id.* (Apple's growth in smartwatch sales is 46%, and the overall industry growth in smartwatch sales is 47%). This evidence shows that much of the success of the Apple Watch Series 6 can be attributed to the growing market for smartwatches rather than the specific implementation of the pulse oximetry feature claimed in the patents-at issue. *See id.* ("Online sales of fitness-led devices that help to support personal healthcare remain popular and are the main driver of the smartwatch boom."); *see also* CX-0275 (Caldbeck Dep.) at 65:21-22, 66:3-12 (blood oxygen app in Apple Watch is "not even in the top 30 used

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apps on Apple Watch”). The Federal Circuit has discounted evidence of commercial success in such circumstances, where “the evidence does not show that the commercial success was the result of claimed and novel features.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1313 (Fed. Cir. 2006) (recognizing that the commercial success was due in part to “aesthetic appeal and improved comfort” and features that were known in the prior art).

The undersigned thus finds that there is little evidence of a significant nexus between Apple’s commercial success and the allegedly nonobvious features of the asserted Poeze patent claims, particularly for claim 12 of the ‘501 patent (which is not limited to blood oxygen measurements). Accordingly, this commercial success does not meaningfully affect the obviousness analysis discussed above.

H. Invalidity – Written Description and Enablement

Apple contends that the asserted claims of the Poeze patents are invalid for lack of written description and/or enablement pursuant to 35 U.S.C. § 112, relying on the testimony of Dr. Warren. RIB at 147-53; RRB at 73-76; Tr. (Warren) at 1246:24-1248:4. Complainants dispute Apple’s allegations, identifying support in the specification of the Poeze patents and relying on the testimony Dr. Madisetti. CIB at 175-83; CRB at 100-105; Tr. (Madisetti) at 1347:14-1353:25. For the reasons discussed below, the evidence shows, clearly and convincingly, that ’502 patent claim 28 and ’648 patent claim 12 are invalid for lack of written description. The evidence does not show, clearly and convincingly, that the other asserted claims are invalid for lack of written description and/or lack of enablement.

1. Combination of LEDs, Photodiodes, and Openings (All Asserted Claims)

Apple argues that all of the asserted claims of the Poeze patents are invalid for lack of written description because the specification fails to disclose an embodiment that includes “(a)

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multiple LEDs, (b) multiple photodiodes, and (c) a protrusion with a plurality of openings, positioned or arranged over the photodiodes, each of which includes an opaque lateral surface or is lined with an opaque material.” RIB at 148. Apple further argues that the specification fails to disclose sets of three or more LEDs or three or more photodiodes. *Id.* at 147-51; RRB at 73-75; *see* Tr. (Warren) at 1246:24-1247:7

Complainants identify Fig. 7B of the Poeze patents, which depicts two emitters 104, two photodiodes 106, one or more opening(s) 703, a protrusion 705b that is a “convex bump,” and a shielding enclosure 790. JX-001 at 27:13-41.

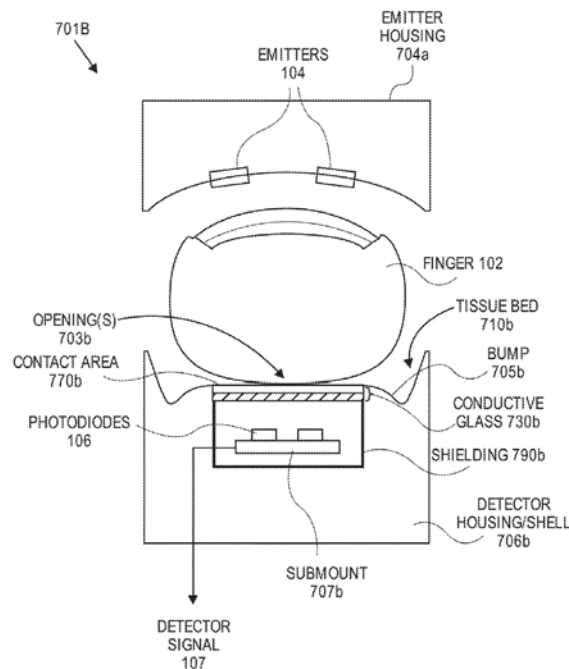


FIG. 7B

Id. at Fig. 7B. Figure 7B depicts two emitters and two detectors. *Id.* There are “one or more openings 703b,” and “each of the openings 703 can include a separate window of the conductive glass 703b.” *Id.* at 27:18-24. The specification provides that “shielding enclosure 790b . . . can have all the features of the shielding enclosure 790a.” *Id.* at 27:28-29. “The shielding or

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enclosure a can include an opaque material to not only reduce electrical noise, but also ambient optical noise.” *Id.* at 27:1-3. The specification expressly provides that the sensors 701 depicted in Figure 7A and 7B “can be implemented with any of the sensors 101, 201, 301 described above.” *Id.* at 26:25-26. One embodiment of sensor 301 is depicted in Figure 3C, which shows four photodetectors in four separate openings. *Id.* at 19:38-48.

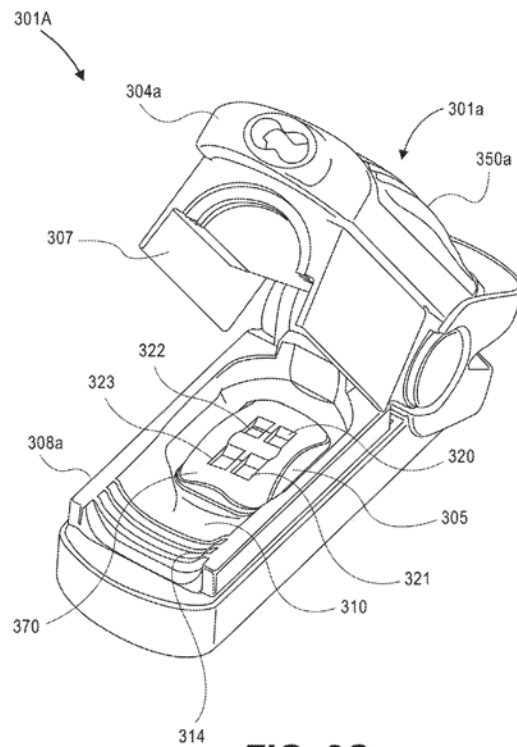


FIG. 3C

Id. at Fig. 3C. Complainants cite a disclosure from another part of the specification describing a “system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106.” *Id.* at 44:22-29, Fig. 21. Moreover, in Figure 13, “n emitters and n detectors are shown,” although “the number of emitters and detectors need not be the same in certain implementations.” *Id.* at 33:37-39, Fig. 13. Dr. Madisetti testified that these disclosures

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provide full written description support for multiple LEDs, three or more photodiodes, and opaque lateral surfaces. Tr. (Madisetti) at 1347:18-1349:6.

In consideration of the parties' arguments, the evidence fails to show, clearly and convincingly, that the asserted claims reciting three or more LEDs, three or more photodiodes, and a protrusion with a plurality of openings over the photodiodes with opaque lateral surfaces lack written description. The specification of the Poeze patents expressly states that Figure 3C and Figure 7B are not distinct embodiments—"[t]he features of the sensors 701 can be implemented with any of the sensors 101, 201, 301 described above. JX-001 at 26:25-26. Figure 3C clearly depicts four photodiodes in separate openings. *Id.* at 19:38-48, Fig. 3C. Figure 7B clearly depicts these openings in a convex protrusion with opaque lateral surfaces. *Id.* at 27:13-41, Fig. 7B. Although Figure 7B only depicts two emitters, the specification describes sensor 101 including an emitter 104, which "can include one or more sources of optical radiation, such as LEDs" *Id.* at 12:5-9. In one embodiment, "the emitter 104 can emit optical radiation at three (3) or more wavelengths" *Id.* at 12:35-44. Moreover, the specification discloses that the number of emitters can match the number of detectors in the context of Figure 13, which is described as "an example multi-stream operation of the system of FIG. 1." *Id.* at 6:45-47, 33:37-39, Fig. 1, Fig. 13. In view of these disclosures, the evidence fails to clearly and convincingly show that the inventors lacked possession of a device with three or more LEDs, three or more photodiodes, and a protrusion with a plurality of openings over the photodiodes with opaque lateral surfaces. *Cf. Invidior Inc. v. Dr. Reddy's Labs., S.A.*, 930 F.3d 1325, 1349 (Fed. Cir. 2019) (finding disclosure "reasonably conveyed to a skilled artisan" the claimed films, and noting that "[t]he specification need not recite the claimed invention *in haec verba*").

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Accordingly, the undersigned finds that Apple has not shown by clear and convincing evidence that the asserted claims of the Poeze patents are invalid for lack of written description with respect to the limitations requiring three or more LEDs, three or more photodiodes, and a protrusion with a plurality of openings over the photodiodes with opaque lateral surfaces.

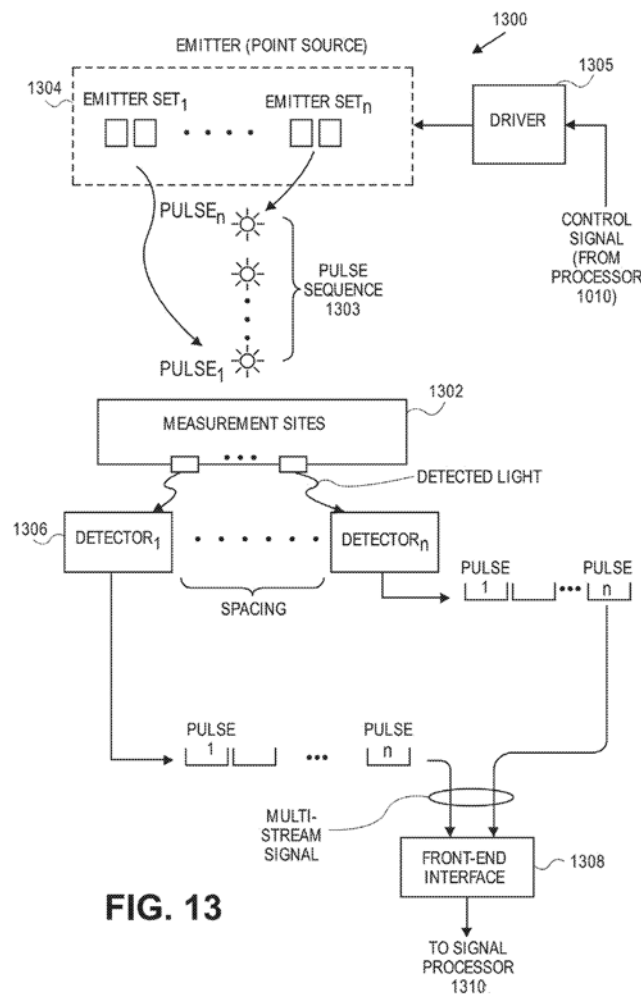
2. Four Sets of at Least Three LEDs ('502 patent claim 22)

Apple contends that '502 patent claim 22 is invalid for lack of written description, because the specification fails to disclose four sets of at least three LEDs. RIB at 151; RRB at 75. Dr. Warren testified that he found no such disclosure in the specification of the Poeze patents. Tr. (Warren) at 1247:8-12. Apple argues that Figure 7B only depicts two emitters and the specification's reference to "sets of optical sources" is insufficient to disclose the claimed "at least four emitters . . . wherein each of the plurality of emitters comprises a respective set of at least three LEDs." JX-002 at claim 22.

Complainants argue that Dr. Warren's conclusory testimony is insufficient to show lack of written description. CIB at 180. Dr. Madisetti identified disclosures in the specification where multiple emitters are disclosed and the emitters are described as sets of optical sources. Tr. (Madisetti) at 1349:7-1350:3. In particular, the specification provides that "the emitter 104 can include one or more sources of optical radiation, such as LEDs" JX-001 at 12:5-8. And "[i]n an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation." *Id.* at 12:9-12. The specification incorporates by reference a patent application, U.S. Application No. 2006/0211924, which describes an array of emitters. *Id.* at 12:16-20. Figure 13 describes sets of emitters that are numbered to match the number of detectors. *Id.* at 33:37-39, Fig. 13.

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Here, the evidence of record fails to show, clearly and convincingly, that four sets of at least three LEDs claimed in '502 patent claim 22 lack written description in the specification of the Poeze patents. Although there is no explicit disclosure of the claimed four sets of at least three LEDs, the specification provides that “the emitter 104 can include one or more sources of optical radiation, such as LEDs” JX-001 at 12:6-9. The specification also provides that the “emitter 104 can include sets of light-emitting diodes (LEDs) as its optical source.” JX-001 at 13:16-17; *see also id.* at 12:9-12 (“In an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.”). Figure 13 depicts multiple “emitter set(s)” numbered 1 through n. *Id.* at 33:18-51.



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Id. at Fig. 13. As discussed above, Figure 13 provides written description support for at least four sets of emitters, because the number of emitters matches the number of detectors, and the specification discloses at least four detectors. *See id.* at 33:37-39, Fig. 13. The specification further provides written description support for three LEDs in each set by referring to “sets of light-emitting diodes (LEDs)” with both “sets” and “LEDs” plural. *See id.* at 13:16-17; *see also id.* at 12:9-12 (“sets of optical sources”). Apple has not identified any reason that one of ordinary skill would read the plural “LEDs” as being limited to sets of two, and sets of three or more would be consistent with the disclosure that the emitters can be arranged in an array. *See id.* at 12:17-25.⁵⁸ In view of these disclosures, the evidence fails to clearly and convincingly show that the inventors lacked possession of a device with four sets of at least three LEDs. *Cf. Invidior v. Dr. Reddy’s Labs.*, 930 F.3d at 1349.

Accordingly, Apple has not shown by clear and convincing evidence that ’502 patent claim 22 is invalid for lack of written description with respect to the claimed four sets of three LEDs.

3. Separate Sets of LEDs Emitting at a First Wavelength and a Second Wavelength (’502 patent claim 28; ’648 patent claim 12)

Apple contends that ’502 patent claim 28 and ’648 patent claim 12 are invalid for lack of written description, because the specification fails to disclose separate sets of LEDs emitting at the same “first wavelength” and “second wavelength.” RIB at 151-52; RRB at 75. Dr. Warren testified that he found no disclosure for this limitation in the specification of the Poeze patents. *Tr. (Warren)* at 1247:13-17. Apple argues that the specification’s reference to “sets of optical

⁵⁸ U.S. Patent Application Publication No. 2006/0211924 is incorporated by reference as an example of emitters arranged in an array.

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sources” is insufficient to disclose the claimed two sets of LEDs each with “an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength.” JX-002 at claim 28; JX-003 at claim 12.

Complainants argue that Dr. Warren’s testimony is conclusory and insufficient to show lack of written description. CIB at 179. Dr. Madisetti identified disclosures in the specification of the Poeze patents “including sets of LEDs with different wavelengths.” Tr. (Madisetti) at 1349:7-1350:3. In their briefing, Complainants point to the two emitters depicted in Figures 7A and 7B and the disclosure that “[i]n an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.” JX-001 at 12:9-12, Fig. 7A, Fig. 7B. Complainants also cite other disclosures describing different arrangements of emitters. *See id.* at 9:60-63, 12:13-25, 13:16-21, 21:51-54, 33:30-38, 38:8-22.

In consideration of the parties’ arguments, the evidence of record shows, clearly and convincingly, that there is insufficient written description support for the limitations in ’502 patent claim 28 and ’648 patent claim 12 describing two sets of LEDs that each have LEDs emitting light at the same “first wavelength” and the same “second wavelength.” This limitation does not merely require that there be two sets of LEDs, each emitting light at two different wavelengths—the claim language requires matching wavelengths in each set of LEDs, and there is no such disclosure in the specification of the Poeze patents. Complainants primarily rely on a disclosure in the specification that “[i]n an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.” JX-001 at 12:9-12; CIB at 180. Another part of the specification describes an embodiment where “the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED.” *Id.* at 9:60-62. But while these portions of the specification describe sets of

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LEDs that are capable of emitting at different wavelengths, there is no disclosure of two separate sets of LEDs using the same wavelengths in each set.⁵⁹

The specification repeatedly describes multiple wavelengths of light in sets of LEDs, but there is no disclosure of matching wavelengths between sets of LEDs. When describing emitters that are capable of emitting visible and near-infrared optical radiation, the specification describes two different wavelengths, three different wavelengths, or up to eight different wavelengths. *Id.* at 12:60-13:7. The specification does not describe any two LEDs having the same wavelength, however, instead emphasizing “a variety of wavelengths of visible or near-infrared optical radiation.” *Id.* Similarly, when describing emitters using super luminescent LEDs and top emitting LEDs, the specification describes the different capabilities of these LEDs. *See id.* at 13:16-25 (describing “top-emitting LEDs emitting light at about 850 nm to 1350 nm” for optical radiation and “SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power.”).

Consistent with Dr. Warren’s testimony, these disclosures would not convey to persons of ordinary skill in the art that sets of LEDs with matching wavelengths were part of the alleged invention—there is no suggestion that two LEDs emit the same wavelengths or any benefit ascribed to such a pairing. This is similar to the claim limitation that was found invalid for lack of written description in *Purdue Pharma L.P. v. Faulding Inc.*, where the Federal Circuit found “nothing in the written description . . . that would suggest to one skilled in the art that the [claimed] ratio is an important defining quality of the formulation, nor does the disclosure even

⁵⁹ As discussed above in the context of obviousness, LEDs meeting this limitation are explicitly disclosed in the prior art in Lumidigm. *See* RX-0411 at 6:43-48. The Federal Circuit has held, however, that “it is the specification itself that must demonstrate possession,” and “a description that merely renders the invention obvious does not satisfy the requirement.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010).

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motivate one to calculate the ratio.” 230 F.3d 1320, 1327 (Fed. Cir. 2000); *see also Ariad*, 598 F.3d at 1352 (noting that a description that “merely renders the invention obvious does not satisfy the requirement”).⁶⁰

Accordingly, the evidence shows, clearly and convincingly, that ’502 patent claim 28 and ’648 patent claim 12 are invalid for lack of written description.

4. Touch-Screen Display (’502 patent claim 28)

Apple contends that ’502 patent claim 28 is invalid for lack of enablement, because the specification fails to enable a “touch-screen display” that “displays indicia responsive” to any “measurement.” RIB at 152; RRB at 75-76. Dr. Warren testified that he only found two brief references to touch-screens in the patent specification. Tr. (Warren) at 1247:18-23. Apple argues that these disclosures are insufficient to enable a person of ordinary skill in the art to use a touch-screen on a user-worn device to display an oxygen saturation measurement. RIB at 152. Complainants argue that the specification discloses a touch-screen as one example of a user interface and further provides that physiological measurements can be shown on a display. CIB at 181-82; CRB at 104; *see* Tr. (Madisetti) at 1352:5-24, 1381:7-1382:8.

⁶⁰ Complainants argue that Dr. Warren’s testimony at hearing was conclusory, but the specification clearly supports Dr. Warren’s testimony that there is no disclosure in the specification of two sets of LEDs with matching wavelengths. *See* Tr. (Warren) at 1247:13-17. And Dr. Madisetti did not address this limitation in his rebuttal testimony, only identifying disclosures in the specification describing “sets of LEDs with different wavelengths” but failing to offer any opinion as to whether these disclosures support the claimed two sets of LEDs using the same two wavelengths. *See* Tr. (Madisetti) at 1349:7-1350:3, 1350:22-1352:4. Moreover, the written description analysis is not limited to expert testimony. *See, e.g., University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 927 (Fed. Cir. 2004) (“[A] patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification. After all, it is in the patent specification where the written description requirement must be met.”).

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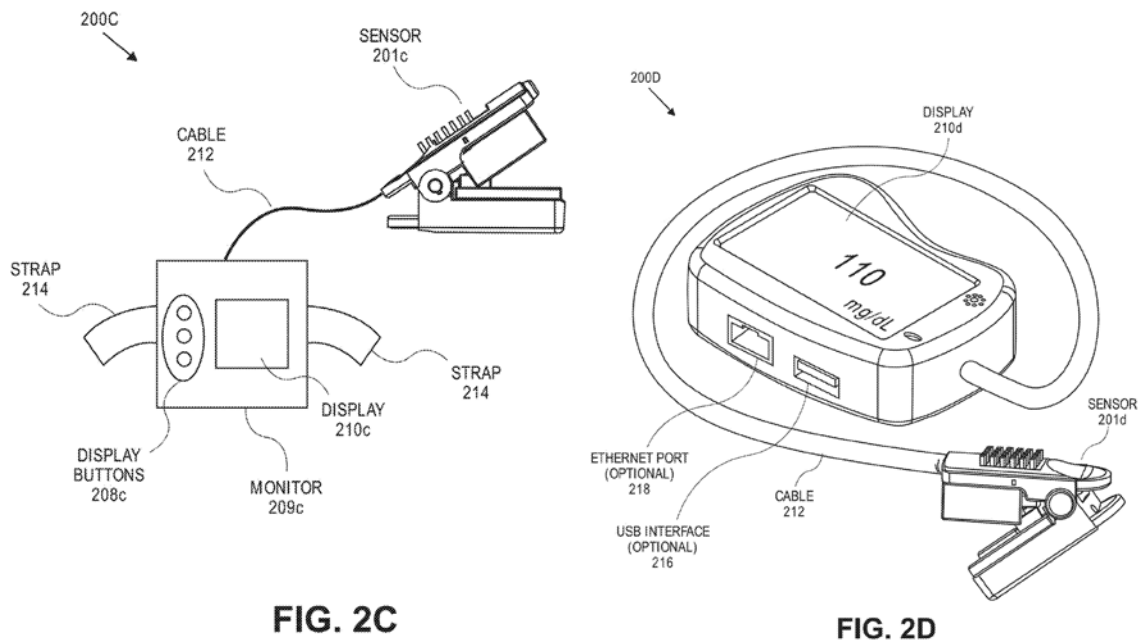
In consideration of the parties' arguments, the undersigned finds that the evidence fails to show, clearly and convincingly, the lack of an enabling disclosure for the claimed "touch-screen display" in the specification of the Poeze patents.

To prove a claim is invalid for lack of enablement, "a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'" *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1084 (Fed. Cir. 2021) (internal quotations omitted). Whether undue experimentation is needed is "not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Id.* (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)). The "*Wands*" factors are: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 1084. The Federal Circuit has stated that "after the challenger has put forward evidence that some experimentation is needed to practice the patented claim, the factors set forth in *Wands* then provide the factual considerations that a court may consider when determining whether the amount of that experimentation is either 'undue' or sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out." *Amgen*, 987 F.3d at 1084-85.

Here, Apple has not presented any argument regarding the majority of the *Wands* factors, instead citing to a single sentence of expert testimony regarding the lack of explicit guidance in the specification. Apple does not provide, for example, any supporting evidence regarding the state of the prior art with respect to touchscreens and their use, or the quantity of experimentation

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necessary.⁶¹ Further, the specification discloses a monitoring device 200a that includes a display 210a and “can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.” JX-001 at 17:20-26. The specification also discloses a monitor 209b, which “can include display 210b that can indicate a measurement for glucose,” and “[o]ther analytes and forms of display can also appear on the monitor 209b.” *Id.* at 17:67-18:3. This monitor is part of the claimed user-worn device, as “the monitor 209b can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient’s belt, arm, leg, or the like.” *Id.* at 17:56-59.



Id. at Fig. 2C, Fig. 2D. Although these features are described in the context of different figures, the specification provides that “certain of the features of the monitoring devices 200 shown in FIGS. 2A through 2D can be combined with features of the other monitoring devices shown.” *Id.* at 16:39-42. Dr. Madisetti reviewed the disclosures of the patent and testified that “the

⁶¹ To the contrary, Dr. Warren elsewhere testified that a touchscreen “could be incorporated in any visual depiction for a portable device.” Tr. (Warren) at 1226:25-1227:7.

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touchscreen display and indicia of measurement are fully enabled in the asserted claims.” Tr. (Madisetti) at 1381:7-1382:8.

In view of the above, Apple has not shown, clearly and convincingly, that ’502 patent claim 28 is invalid for lack of enablement with respect to the claimed “touch-screen display.”

5. Light Piping (’501 patent claim 12, ’502 patent claim 28, ’648 patent claim 24)

Apple contends that ’501 patent claim 12, ’502 patent claim 28, and ’648 patent claim 24 are invalid for lack of enablement with respect to limitations describing opaque surfaces that “avoid” or “reduce” “light piping.” RIB at 152-53; RRB at 76. Apple further contends that ’648 patent claim 24 is invalid for lack of written description with respect to being “configured to substantially prevent light piping.” *Id.* Dr. Warren testified that the specification only provides “a vague correlation” between the use of opaque materials and the reduction of light piping. Tr. (Warren) at 1247:24-1248:4.

Complainants argue that Dr. Warren’s conclusory testimony is insufficient to meet Apple’s clear and convincing burden. CIB at 182. Complainants submit that the specification explicitly teaches the use of a hard opaque plastic to reduce light piping. *Id.* at 183 (citing JX-0001 at 7:65-8:7, 43:32-36). Complainants further cite an embodiment described in the specification wherein adding height “assists in deflecting light piping through the sensor.” JX-0001 at 25:47-62. Dr. Madisetti reviewed these disclosures and offered his opinion that the written description and enablement requirements have been met for each of the “light piping” limitations. Tr. (Madisetti) at 1350:4-21, 1352:25-1353:11.

In consideration of the parties’ arguments, the evidence of record fails to show, clearly and convincingly, that the specification of the Poeze patents fails to enable the “light piping” limitations of the asserted claims or lacks adequate written description with respect to ’648

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patent claim 24. As with the “touchscreen” arguments, Apple has not presented any argument regarding the majority of the *Wands* factors, instead citing to a single sentence of expert testimony regarding the lack of explicit guidance in the specification. *See* RIB at 152-53; CRB at 104-105. Moreover, the specification explicitly teaches that “[t]he protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise,” and “[s]uch light noise includes light piping.” JX-0001 at 7:65-8:7. In reference to the Figure 3 embodiments, a “noise shield” is disclosed that “may be configured to reduce noise, such as from ambient light and electromagnetic noise.” *Id.* at 43:30-33. The specification provides that the noise shield “may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.” *Id.* at 43:33-36. This teaching is also referenced in the context of Figures 7A and 7B, where the specification describes a “shielding enclosure” that “can include an opaque material to not only reduce electrical noise, but also ambient optical noise.” *Id.* at 27:1-3.⁶² *See generally* CIB at 182-183.

In view of the above, Apple has failed to show by clear and convincing evidence that any asserted claims are invalid for lack of enablement with respect to the “light piping” limitations.

Further, the undersigned finds that Apple has not shown by clear and convincing evidence that ’648 patent claim 24 is invalid for lack of written description with respect to being “configured to substantially prevent light piping.” Apple’s written description argument is unclear and appears to be based on the same issues discussed with regard to enablement. *See* RIB at 152-53. For the reasons discussed *supra*, including the specification’s descriptions

⁶² In another embodiment where “an extension” is used “to increase the height of [a] partially cylindrical protrusion,” “the added height assists in deflecting light piped through the sensor.” JX-001 at 25:43-62.

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regarding light piping and the lack of sufficient expert testimony or other record evidence, Apple has not met its burden.

I. Prosecution Laches and Unclean Hands

Apple argues that the Poeze patents are unenforceable due to prosecution laches and the doctrine of unclean hands because of Complainants' delays in patent prosecution. RIB at 153-59; RRB at 77-79.

Apple submits that the provisional applications that led to the Poeze patents were filed in July and August 2008, and Masimo continued to file related continuations and continuations-in-part through July 2010. *See* JX-001; JX-002; JX-003. After a five-year gap (and after the first Apple Watch was released), Masimo filed a new continuation application in December 2015. *See* U.S. Patent App. No. 14/981,290 (cited in JX-001; JX-002; JX-003). Masimo then filed several additional continuation applications between December 2018 and March 2020,⁶³ and then filed the applications leading to the three asserted Poeze patents on September 24, 2020, within days of the release of the Apple Watch Series 6. *See* JX-001; JX-002; JX-003; RX-0333 (9/15/20 press release announcing Apple Watch Series 6).

Apple argues that the twelve-year delay between the 2008 filings of the original provisional applications and the 2020 filings of the continuation applications for the Poeze patents warrants a determination that the patents are unenforceable due to prosecution laches. RIB at 153-59. Apple submits that Masimo has provided no credible explanation for the long delay in filing the continuation applications and that the totality of the circumstances shows that Masimo lacked diligence in prosecuting the Poeze patents. *Id.* at 155-57. Apple argues that the

⁶³ Apple argues that these continuation applications were filed after the release of version of the Apple Watch in 2018 and 2019. *See* RDX-1.16.

timing of Masimo’s patent application filings shows that the delays in prosecution were intentional—taking advantage of the growth in the market for wearable technology and allowing Masimo to draft claims targeting Apple Watch products after their release. *Id.* at 156-57.

Apple submits that it has suffered prejudice due to Masimo’s patent prosecution delays, because Apple invested heavily in the development of the Apple Watch products, including the blood oxygen feature. RIB at 157-58; RRB at 78. Apple argues that Masimo gained an improper litigation advantage by waiting to draft its patent claims until after the release of the Apple Watch Series 6, noting that the prosecuting attorney for the Poeze patents admitted that he had [REDACTED] of the Apple Watch Series 6 during prosecution. *See* Tr. (Cromar) at 1031:13-22. Apple argues that the prosecution of other patents in the family of the Poeze patents is irrelevant to the inquiry into whether Masimo was diligent with respect to the prosecution of the asserted Poeze patents. RRB at 77-78.

Apple argues that Masimo’s conduct with respect to the prosecution of the Poeze patents meets the legal requirements for unenforceability due to prosecution laches and also that this conduct should bar Complainants’ claims for relief in this investigation under the doctrine of unclean hands. RIB at 158-59; RRB at 77-79.

Complainants argue that Apple has failed to meet its burden with respect to prosecution laches or unclean hands. CIB at 183-85; CRB at 105-108. Complainants submit that the prosecution of applications in the family of the Poeze patents was continuous throughout the alleged 12-year period identified by Apple. CIB at 183-84. Mr. Cromar testified that there were “a dozen applications being actively prosecuted” during the alleged five-year “gap” between 2010 and 2015. Tr. (Cromar) at 1039:7-12. Complainants’ expert on PTO practice and procedure, Robert Stoll, testified that there was a “continuous unbroken chain of patent

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prosecution” in the family of the Poeze patents. Tr. (Stoll) at 1415:2-10. Complainants argue that the legal precedent requires considering diligence with respect to all of these related patent applications. CRB at 106. Complainants dispute Apple’s timeline tying patent application filings to versions of the Apple Watch, which were released every year from 2015 to 2020. *Id.* at 106-107. Complainants argue that there is nothing improper about drafting claims to cover competitors’ products. *Id.* at 107-108. Complainants further argue that there can be no prejudice to Apple because the specification of the Poeze patents was published in February 2010. *See* CX-0137 (U.S. Patent Pub. No. 2010/0030040).

In consideration of the parties’ arguments, the undersigned finds that Apple has not carried its burden to show that the Poeze patents should be found unenforceable due to prosecution laches or unclean hands. To establish a defense of prosecution laches, an accused infringer must show: (1) that the patentee’s delay in prosecution was unreasonable and inexcusable under the totality of circumstances, and (2) that the accused infringer suffered prejudice attributable to the delay. *Cancer Rsch. Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 728-29 (Fed. Cir. 2010). The Federal Circuit has held that “an examination of the totality of the circumstances[] include[s] the prosecution history of all of a series of related patents.” *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1386 (Fed. Cir. 2005) (“*Symbol Techs.*”).

Here, the record evidence is insufficient to support a finding of unreasonable or inexcusable delay with respect to the prosecution of the Poeze patents. Apple cites a five-year delay in the filing of continuation applications between 2010 and 2015, but there was continuous prosecution activity in the family of the Poeze patents during this time. *See* Tr. (Cromar) at

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1038:7-19.⁶⁴ The fact that the 2015 continuation application could have been filed earlier is not a sufficient basis for finding of prosecution laches, as the Federal Circuit has recognized that “[t]here are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of laches, and ... [t]he doctrine should be applied only in egregious cases of misuse of the statutory patent system . *Symbol Techs.*, 422 F.3d at 1385. The next application in the Poeze patent family was a divisional application (U.S. Patent Application No. 16/212,537) filed in December 2018, and the Federal Circuit has held that “[f]iling a divisional application in response to a requirement for restriction” is a “legitimate reason for refiling a patent application . . . even when one defers the filing of a divisional application until just before the issuance of the parent application.” *Id.* In the context of this continuous prosecution activity in the family of the Poeze patents, Apple’s arguments tying certain patent application filings to release dates for the Apple Watch is unpersuasive. *See* RDX-1C.16. Apple has failed to identify actions by Masimo that resemble the type of conduct recognized by the Federal Circuit as unjustifiable prosecution delay, such as refiling applications containing previously-allowed claims, repetitive filing of applications that were merely placeholders, or a “consistent pattern of receiving a rejection on an application, filing a continuation application without any amendments, and abandoning the original application.” *See Hyatt v. Hirshfeld*, 998 F.3d 1347, 1361-62, 1366-69 (Fed. Cir.

⁶⁴ U.S. Patent Application No. 12/497,523, filed on July 2, 2009, issued as U.S. Patent No. 8,347,825 on May 7, 2013; U.S. Patent Application No. 12/497,528, filed on July 2, 2009, issued as U.S. Patent No. 8,577,431 on November 5, 2013; and U.S. Patent Application No. 12/829,352, filed on July 1, 2010, issued as U.S. Patent No. 9,277,880 on March 8, 2016. *See* JX-0001 (identifying continuation applications); JX-004 at 418-26 (information disclosure statement identifying Masimo’s pending patent applications and issued patents).

2021).⁶⁵ The record evidence in this investigation is insufficient to support a finding of prosecution laches.

Moreover, because the undersigned does not find evidence of bad faith conduct by Masimo during the prosecution of the Poeze patents, there is no basis for any finding of unclean hands. Apple's unclean hands defense is based solely on Masimo's alleged misconduct during the prosecution of the Poeze patents, RIB at 158-59, and Apple does not argue that any particular conduct would be the basis for a finding of unclean hands without a finding of inequitable conduct.

V. U.S. PATENT NO. 10,687,745

The '745 patent is entitled "Physiological Monitoring Devices, Systems, and Methods," naming inventor Ammar Al-Ali and issuing from an application filed on March 31, 2020, claiming priority to a provisional application filed on July 2, 2015, and a non-provisional application filed on June 28, 2016. JX-009.

A. Specification

The specification of the '745 patent describes a method for pulse oximetry wherein an emitter irradiates a surface area on the skin. *See* JX-009 at 6:21-54, Fig. 2. The patent refers to this method as "three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue . . . as compared to the 2D point optical source approach." *Id.* at 6:21-26.

⁶⁵ Apple points to evidence that Masimo's patent prosecution counsel had [REDACTED] during prosecution, Tr. (Cromar) at 1031:13-22, but the Federal Circuit has held that "there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988). Moreover, Apple has not provided evidence showing that newly asserted claim limitations were specifically drawn to the Accused Products.

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In one embodiment, a “light diffuser 304 receives the optical radiation emitted from the emitter 302 and spreads the optical radiation over an area.” *Id.* at 7:42-44.

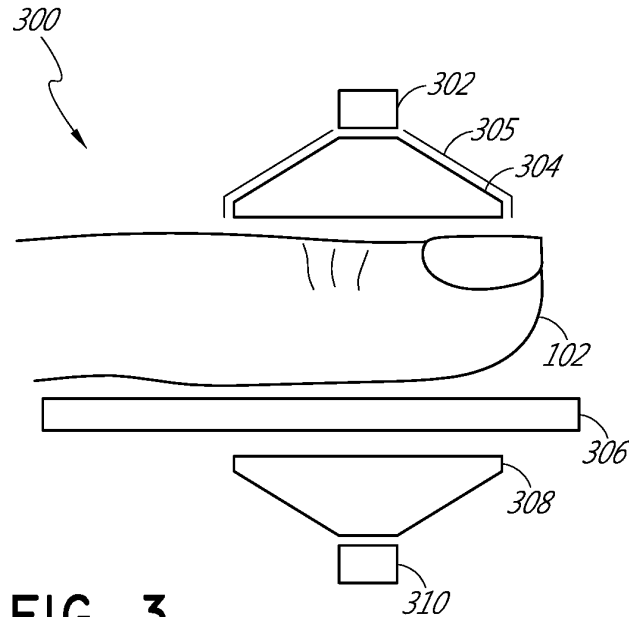


FIG. 3

Id. at Fig. 3. The specification provides examples of the diffuser distributing light “in a predefined geometry (e.g., a rectangle, square, or circle).” *Id.* at 8:9-12. The specification further describes a “light concentrator 308,” which “is a structure to receive the emitted optical radiation, after attenuation by the tissue measurement site 102.” *Id.* at 9:11-18.

In a separate embodiment, a “3D sensor 700 can be placed on a portion of the patient’s body that has relatively flat surface, such as, for example a wrist, because emitter 702 and detector 710 are located on the same side of the tissue measurement site 102.” *Id.* at 10:40-51.

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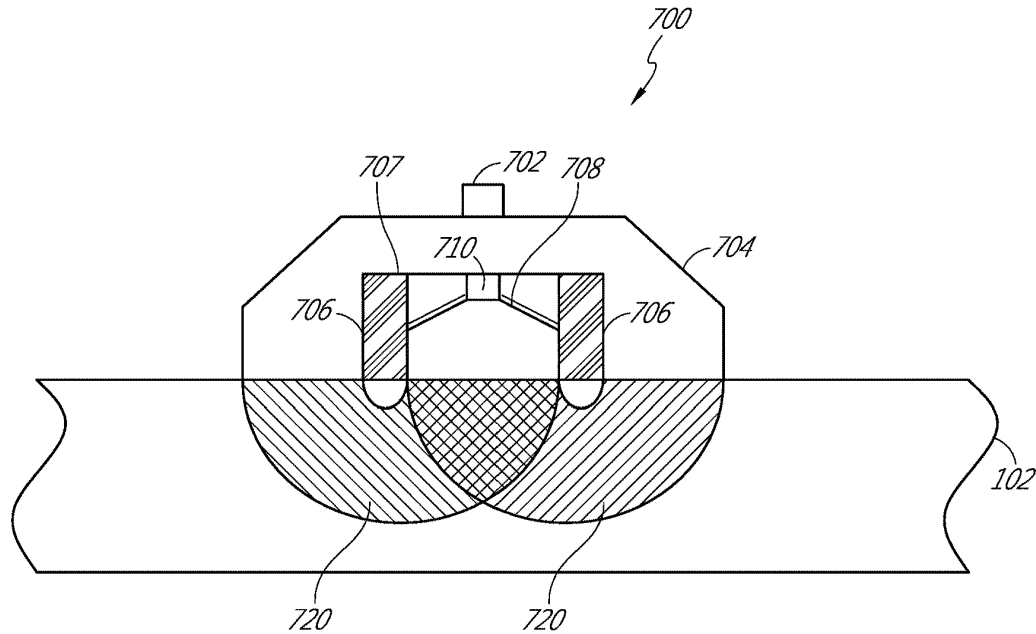


FIG. 7A

Id. at Fig. 7A. This embodiment includes a “light diffuser 704” that “receives the optical radiation emitted from the emitter 702 and homogenously spreads the optical radiation over a wide, donut-shaped area.” *Id.* at 10:65-11:9, Fig. 7B. This embodiment further comprises a “light blocker 706” that “includes an annular ring having a cover portion 707 sized and shaped to form a light isolation chamber for the light concentrator 708 and the detector 710.” *Id.* at 11:11-13.

B. Claims

Complainants assert infringement of claims 9 and 27, and they rely on claim 18 for domestic industry. Claim 9 depends from claim 1, recited below:

1. A physiological monitoring device comprising:
 - a plurality of light-emitting diodes configured to emit light in a first shape;
 - a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape

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by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue;

a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light;

a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue; and

a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal.

JX-009 at 15:31-61.

9. The physiological monitoring device of claim 1, wherein the physiological parameter comprises oxygen saturation.

Id. at 16:21-23. Claim 18 depends from claim 15, recited below:

15. A physiological monitoring device comprising:

a plurality of light-emitting diodes configured to emit light proximate a wrist of a user;

a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a tissue measurement site on the wrist of the user when the physiological monitoring device is in use;

a light block having a circular shape;

a plurality of photodiodes configured to detect at least a portion of the light emitted from the plurality of light-emitting diodes after the light passes through the light diffusing material and a portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are further configured to output at least one signal

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responsive to the detected light, and wherein the plurality of light-emitting diodes and the plurality of photodiodes are arranged in a reflectance measurement configuration;

wherein the light block is configured to optically isolate the plurality of light-emitting diodes from the plurality of photodiodes by preventing at least a portion of light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the portion of the tissue measurement site;

a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal; and

wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor.

Id. at 16:36-17:3.

18. The physiological monitoring device of claim 15, wherein the physiological parameter comprises oxygen saturation.

Id. at 17:10-12. Claim 27 depends from claim 20, recited below:

20. A system configured to measure one or more physiological parameters of a user, the system comprising:

a physiological monitoring device comprising:

a plurality of light-emitting diodes configured to emit light in a first shape;

a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue;

a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light;

a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

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a light block configured to prevent at least a portion of light from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue; and

a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal; and

a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data.

Id. at 17:20-18:18.

27. The system of claim 20, wherein at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength.

Id. at 16:21-23.

C. Level of Ordinary Skill in the Art

The parties have stipulated to the same level of ordinary skill in the art for the '745 patent as the Poeze patents:

[A] person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Joint Stipulation of Facts ¶ 10, EDIS Doc. ID 770692 (May 13, 2022).

D. Claim Construction

The parties dispute the construction of the term “second shape” in claims 1 and 20, but they agree that the differences between their proposed constructions do not affect any disputed

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issue. *See* CIB at 185-86; RIB at 163-64. Accordingly, this term shall be construed to have its plain and ordinary meaning, which the parties agree is “a shape different from the first shape.” *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (Claims must be construed “only to the extent necessary to resolve the controversy.”).

E. Infringement

Complainants allege that the Accused Products infringe claims 9 and 27 of the '745 patent, relying on a theory of induced infringement with respect to claim 27. CIB at 188-202. Apple only disputes infringement with respect to the “first shape” and “second shape” limitations. RIB at 164-73; RRB at 81-88. For the reasons discussed below, the undersigned finds that Complainants have not shown, by a preponderance of the evidence, that the Accused Products infringe claims 9 or 27 of the '745 patent.

1. '745 Patent Claim 9

a. Element [1 preamble]: “A physiological monitoring device comprising”

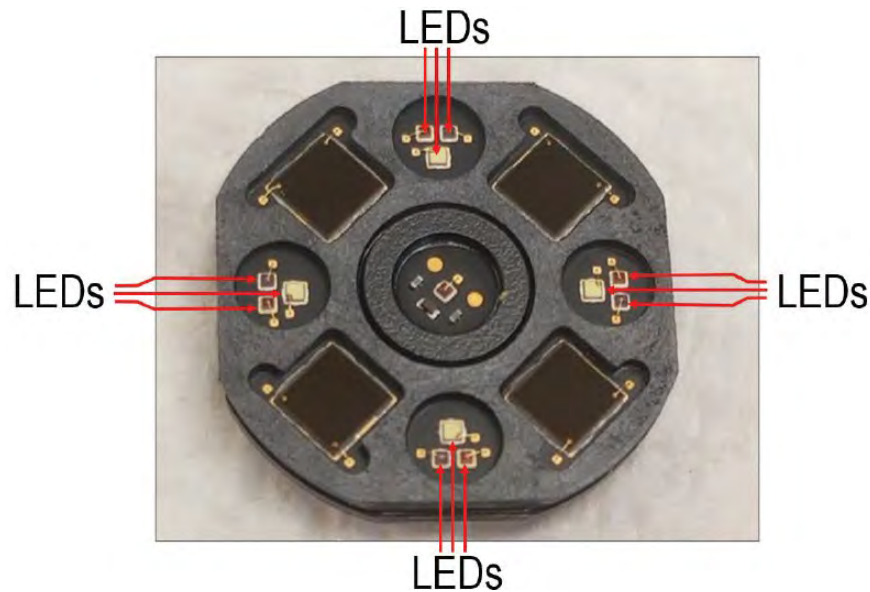
There is no dispute that each of the Accused Products is a “physiological monitoring device” as required by the preamble of claim 1. *See* CIB at 188.⁶⁶ Dr. Madisetti identified evidence that the Accused Products are devices that can measure blood oxygen. Tr. (Madisetti) at 729:24-730:6; CDX-0011C.073; CX-0241C (Apple Watch Series First Look); CX-1532 at 4-5 (Apple Watch Series 6 Press Release); CX-1447 at 7 (Apple Watch Series 7 website); CX-1449 at 2 (Apple Watch Series 7 website). Accordingly, the evidence of record shows that the preamble limitations are met by the Accused Products.

⁶⁶ The parties have stipulated that the preambles of the asserted patent claims are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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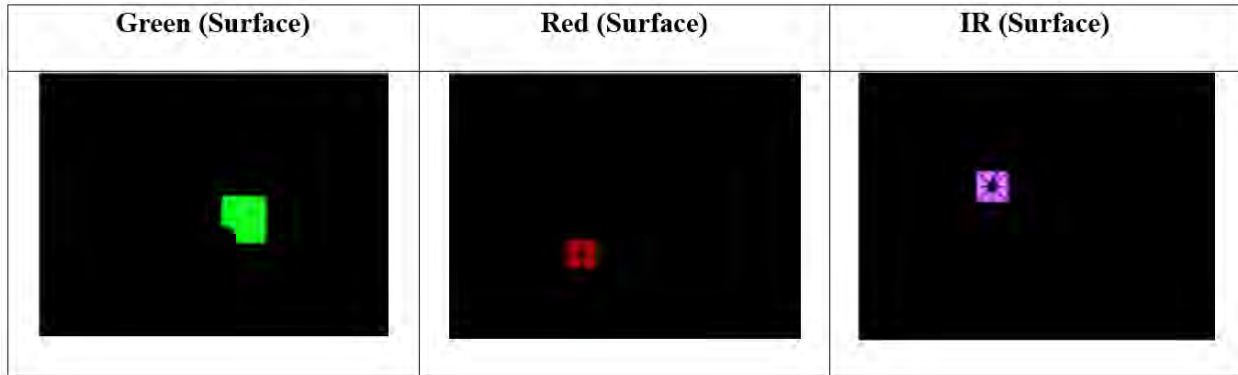
b. Element [1A] “a plurality of light-emitting diodes configured to emit light in a first shape”

There is no dispute that each of the Accused Products has a plurality of light-emitting diodes emitting light in a shape. *See* CIB at 188-90. Dr. Madisetti identified four sets of red, infrared, and green LEDs on the sensor board of the Accused Products. *Tr.* (Madisetti) at 730:7-731:1.

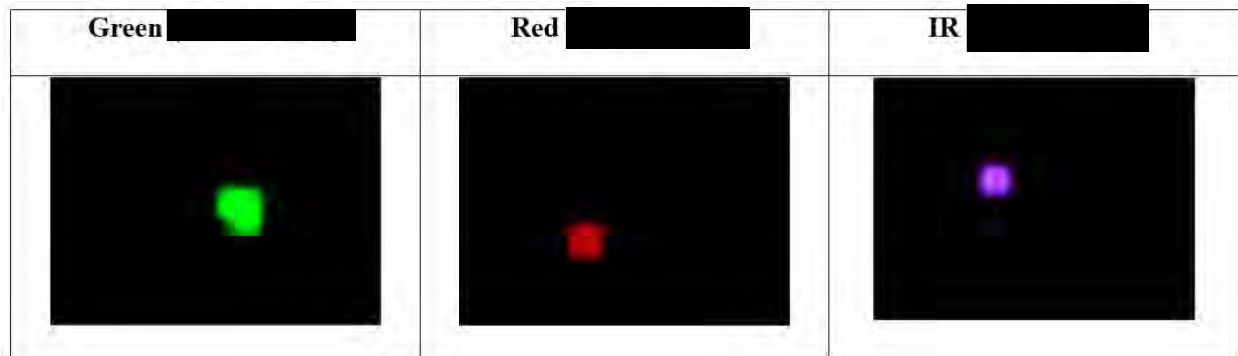


CDX-0011C.074 (labeling LEDs on CX-1548C at 37); *see also* CX-0281C (Block Dep. *Tr.*) at 83:11-85:16 (identifying LEDs in the Accused Products); *Tr.* (Mehra) at 855:4-856:14 (describing LEDs in the Accused Products); CX-0057C at 2 (Series 6 schematic); CX-0059C at 2 (Series 7 schematic).

Dr. Madisetti also used a camera to capture images of the light emitted by the LEDs in the Accused Products. *Tr.* (Madisetti) at 724:14-729:23, 730:7-731:1.



CDX-0011C.074 (citing CX-1546C at 5, 15, 1); CIB at 189-90. Dr. Madisetti also captured images of the light 2mm from the LEDs—before passing through a [REDACTED] Tr. (Madisetti) at 745:5-25.



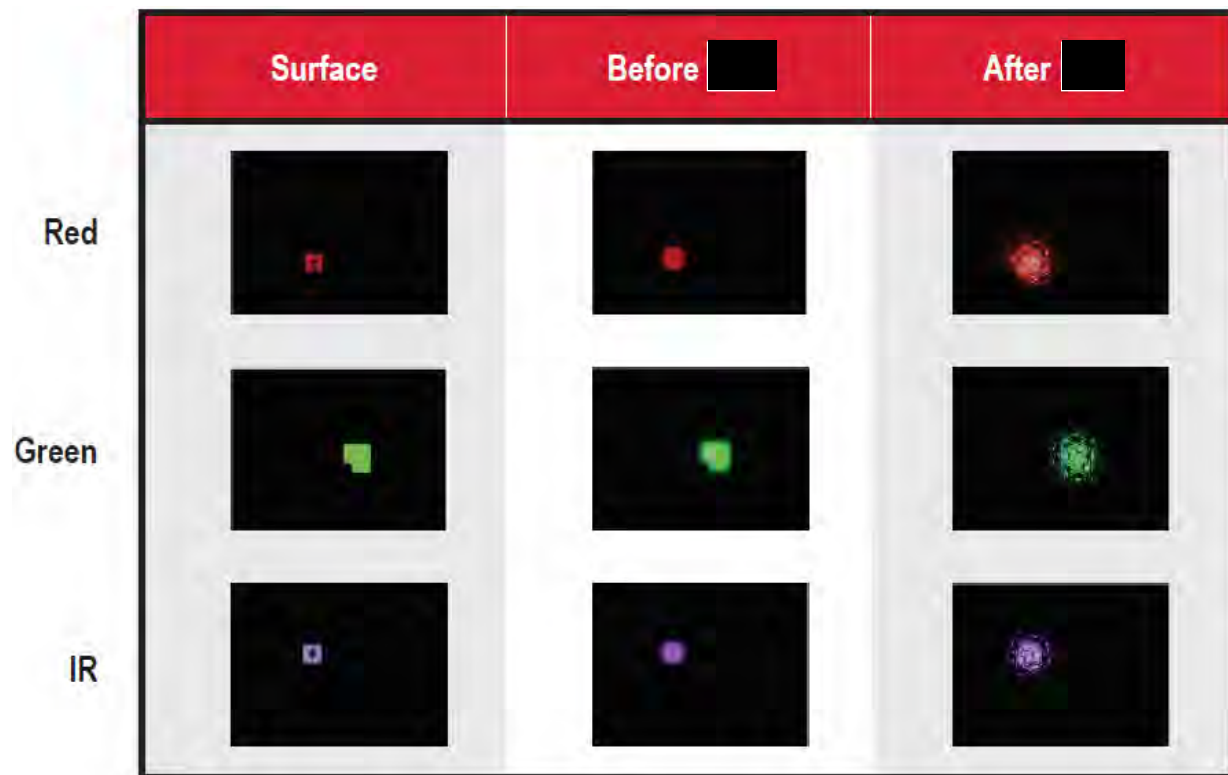
CX-1546C at 5, 15, 1; *see* CDX-0011C.091; CIB at 189-90.⁶⁷ There is no dispute that this light is emitted in a shape, and accordingly, the evidence of record shows that this limitation is met.

⁶⁷ As discussed *infra* in the context of the “material” limitation, the relevant “first shape” is the shape of the light before passing through the lens.

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- c. **Element [1B]: “a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue”**

With respect to the “material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user,” Dr. Madisetti identified a [REDACTED] [REDACTED] that is positioned between the LEDs and the wrist of the user. Tr. (Madisetti) at 731:25-732:24; CDX-0011C.076. Dr. Madisetti used a camera to capture images of the light 2mm from the LEDs—before passing through [REDACTED]. Tr. (Madisetti) at 745:5-25; CDX-0011C.091 (citing CX-1546C at 5, 15, 1). He also captured images of the light after passing through [REDACTED] and compared the shape of the light at three locations—at the LEDs, before [REDACTED], and after [REDACTED]. Tr. (Madisetti) at 732:25-733:18, 747:3-12.



CDX-0011C.091 (citing CX-154C at 1, 5, 15). He offered his opinion that the “first shape” at the surface of the LEDs and before [REDACTED] is different from the “second shape” after [REDACTED]. Tr. (Madisetti) at 732:25-733:18, 747:3-12. He testified at the hearing: “So you can see clearly with our naked eye that the shapes before [REDACTED], which is the first shape, and the second shape, which is after [REDACTED], are different.” *Id.* at 733:15-17.

Apple argues that this limitation is not infringed for two reasons: (1) the “first shape” emitted by the LEDs is not the same “first shape” entering [REDACTED]; and (2) [REDACTED] is not configured to change the “first shape” into a “second shape.” RIB at 164-73; RRB at 81-88. These two issues are addressed separately below:

(i) “first shape”

Apple argues that the plain language of the claim requires the “first shape” of the light emitted at the LEDs to be the same “first shape” of the light received by [REDACTED]. RIB at 164-65. Apple points to Figure 7A, where there is no gap between the emission of light at LED 702 and the light diffuser 704 where the light is received. JX-009 at 10:65-11:2, Fig. 7B; *see* Tr. (Sarrafzadeh) at 1112:22-1113:10. Apple engineer Dr. Venugopal testified that the LEDs in the Accused Products “have a square shape” and emit light that “is square in shape.” Tr. (Venugopal) at 830:4-5, 830:19-22. He further explained that the light emitted from the LEDs “spreads significantly in all direction[s] based on the physics of the LED surface and spreads towards the microlens array and assumes a generally circular shape.” *Id.* at 830:25-831:3. Apple’s expert Dr. Sarrafzadeh offered opinions that are consistent with Dr. Venugopal’s testimony, identifying the square shape of light emitted from the LEDs, which “changes to more of a circular shape, as expected by Lambertian emission.” Tr. (Sarrafzadeh) at 1115:2-15. He described the shape of the light at the LEDs as “more of a square shape-ish” and “a concave

polygon.” *Id.* at 1115:25-1116:11. He described the shape of the light received by [REDACTED] as “more of a closer to a circle shape” and a “convex polygon.” *Id.* Relying on “fundamentals of geometry,” he testified that “concave polygons are fundamentally different from convex polygons.” *Id.* He offered his opinion that “the shape that is emitted at the surface of LED is fundamentally different from the shape that is received by [REDACTED], as we saw in the three examples, and we know that because of physics.” *Id.* at 1116:23-1117:8.

Complainants disagree with Apple’s interpretation of this claim language, arguing that the designation of the “first shape” in the claims does not require that the shape be unchanged between the LEDs and [REDACTED]. CIB at 186. Complainants submit that the specification only discusses changes in shape caused by the “beam shaper” that receives light from the LEDs before reaching the user’s skin. *See* JX-009 at 7:42-56. Complainants identify a gap between the light emitter and the beam shaper depicted in Figure 3 of the specification, arguing that Apple’s interpretation of the claim language would exclude this embodiment. CIB at 187; *see* JX-009 at Fig. 3. Dr. Madisetti reviewed the disclosures in the specification and offered his opinion that the claims “do not require the material to receive light in the same shape that was emitted by the LEDs.” Tr. (Madisetti) at 746:13-747:2. Complainants argue that the “first shape” is any shape emitted from the LEDs in between the LEDs and the material. *See* CRB at 110 (“In the claims, the ‘first shape’ refers to any shape of light emitted by the LEDs before the claimed ‘material’ changes it into a second shape.”).

In consideration of the parties’ arguments, the undersigned finds that the language of claim 1 does not require that the emitted light has the same “first shape” at the surface of the LEDs as it has at the surface of the “material configured to change the first shape into a second shape.” The first limitation of the claim provides that the LEDs are “configured to emit light in a

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first shape,” but the term “emit” is not necessarily limited to the surface of the LEDs. There is light “emitted” from the LEDs described in several other limitations of the claim—light that has been changed into a second shape is described as “light emitted from one or more of the plurality of light-emitting diodes,” and certain light that is affected by the light block is also described as “light emitted from the plurality of light-emitting diodes.” *See* JX-009 at 15:38-41, 15:54-57. Accordingly, while Apple has offered a plausible interpretation of the claim language to refer to the shape of light at the surface of the LEDs, it is clear from other limitations of the claim that the term “emit” is not limited to this meaning.⁶⁸

The specification of the ’745 patent supports this interpretation of the “first shape” limitation. When describing the Figure 3 embodiment that is shown with a gap between the emitter and the light diffuser, the specification provides that “[t]he light diffuser 304 receives the optical radiation emitted from the emitter 302 and spreads the optical radiation over an area.” JX-009 at 7:42-44, Fig. 3. The same language is used in the context of Figure 7A, which does not show a gap between the emitter and the light diffuser: “The light diffuser 704 receives the optical radiation emitted from the emitter 702 and homogenously spreads the optical radiation over a wide, donut-shaped area.” *Id.* at 10:65-11:2, Fig. 7A. In both embodiments the light “emitted from” the LEDs is the light received at the light diffuser, which takes this light and spreads it into a wide shape. The spreading and/or shaping of light by the light diffuser is

⁶⁸ Claim 15 also refers to light that has passed through a light diffusing material as “light emitted from one or more of the plurality of light-emitting diodes,” and certain light that is affected by the light block is also described as “light emitted from the plurality of light-emitting diodes.” *See* JX-009 at 16:44-63.

emphasized in the specification,⁶⁹ and there is no discussion in the specification of the shape of the light at the surface of the LEDs.

The undersigned thus finds that the reading of the “first shape” limitation that most naturally aligns with the patent’s description of the invention is that the light emitted by the LEDs in a “first shape” refers to the shape of the light that is received by the light diffuser, *i.e.* the claimed “material,” which is “configured to change the first shape into a second shape.”⁷⁰ The undersigned thus finds that both Complainants’ and Apple’s proposed constructions are incorrect. The “first shape” does not refer to “any” shape of the light between the LEDs and the light diffuser, as proposed by Complainants (*see* CRB at 110), and there is no separate requirement that the shape of the light at the surface of the LEDs be the same as the shape of the light that is received by the light diffuser, as proposed by Apple. Accordingly, there is no basis for Apple’s non-infringement argument regarding the “first shape.”

(ii) “second shape”

With respect to the “second shape,” Apple submits that [REDACTED] is not configured to change the shape of the light passing through it. RIB at 170-73; RRB at 86-87. Dr. Venugopal testified that “[REDACTED] [REDACTED].” Tr. (Venugopal) at 831:4-9. With respect to the shape of the light passing through [REDACTED], he testified that “[REDACTED] [REDACTED].” *Id.* Reviewing Dr. Madisetti’s images of the light before and after [REDACTED],

⁶⁹ The specification describes “the disclosed systems, devices and methods to implement three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue at the measurement site 102 as compared to the 2D point optical source approach,” which is described as “conventional pulse oximetry.” JX-009 at 6:21-25, 5:41-43, Fig. 1, Fig. 2.

⁷⁰ The cases that Apple cites regarding antecedent basis are consistent with this construction, *see* RIB at 164, because the two limitations of the claim refer to the same “first shape.”

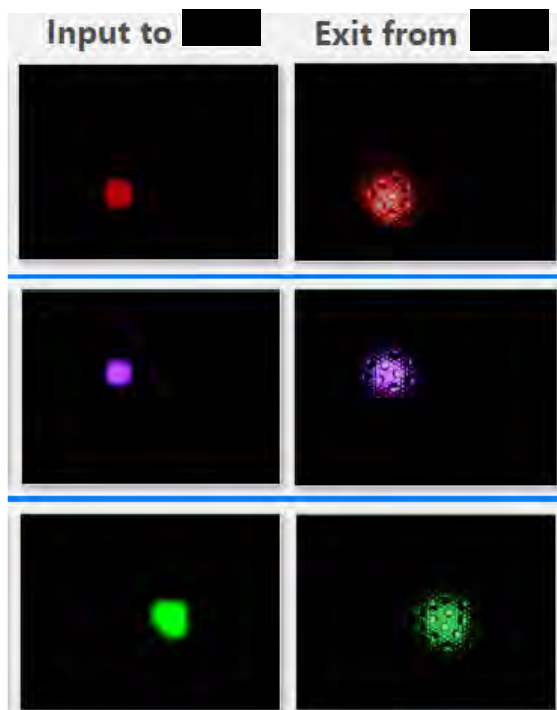
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Dr. Sarrafzadeh offered his opinion that these were the same shape: “the input to [REDACTED] shapes are more or less a circular form, and as they exit [REDACTED] they are also more or less a circular form.” Tr. (Sarrafzadeh) at 1118:1-11. Dr. Sarrafzadeh acknowledges that there are “dark spots” in the [REDACTED] images, but he explains that these are variations in intensity rather than shape. *Id.* at 1119:24-1120:4. Apple further argues that Dr. Madisetti failed to explicitly analyze the difference between the “first shape” before [REDACTED] and the “second shape” after [REDACTED]. RIB at 172-73.

In reply, Complainants cite Dr. Madisetti’s testimony that there is a change in shape between the images before [REDACTED] and after [REDACTED]. *See* Tr. (Madisetti) at 747:3-12; CDX-0011C.091. Complainants dispute Dr. Sarrafzadeh’s analysis of the dark spots in Dr. Madisetti’s images and argue that there is no support for his testimony that intensity variations are not a change in shape. CRB at 115. Complainants cite the ’745 patent specification’s discussion of a circle and donut as distinct shapes, arguing that a shape is not solely defined by its perimeter. JX-009 at 10:65-11:2. Complainants argue that the difference in shape before and after [REDACTED] is “self-evident,” and “readily apparent.” CIB at 194; CRB at 118.

In consideration of the parties’ arguments, the undersigned finds that Complainants have failed to carry their burden to prove infringement with respect to the “second shape” limitation. The undersigned agrees with Apple that Dr. Madisetti’s analysis with respect to this limitation was unreliable and conclusory. *See* RIB at 160-62. His primary infringement analysis compared the images of the light at the LEDs with images of light after [REDACTED], *see* Tr. (Madisetti) at 733:5-18; CDX-0011C.077, but as discussed above, the relevant “first shape” is immediately before [REDACTED], because it is [REDACTED] that must be configured to change the light from the “first shape” to the “second shape.” When Dr. Madisetti compared images of light immediately

before and after [REDACTED], he only offered conclusory testimony that “you can clearly see that the shape changes.” Tr. (Madisetti) at 747:3-12; CDX-0011C.091. Complainants rely on this testimony and argue that the difference between the shapes is “self-evident” or “readily apparent.” CIB at 194; CRB at 118. Apple disputes Complainants’ contentions, however, and Dr. Sarrafzadeh describes the shapes of the two sets of images as “more or less circular,” with shapes that are “relatively the same.” *Id.* at 1118:1-24.



RDX-0007.144C (citing CX-0307iC).

The undersigned finds that neither Dr. Madisetti nor Dr. Sarrafzadeh have disclosed a reliable methodology for identifying shapes or determining whether one shape is different from another. Their testimony at hearing comparing the “first shape” images to the “second shape” images was conclusory and unreliable, with Dr. Madisetti failing to even identify the allegedly different shapes that he observed. Indeed, on cross-examination, Dr. Madisetti was presented with several shape outlines and was asked for his opinion on whether the shapes were the same

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or different. Tr. (Madisetti) at 782:6-783:12. Despite Complainants' argument that changes in shape are "self-evident," Dr. Madisetti could not offer an opinion as to whether certain at least somewhat different images represented a change in "shape." *Id.* (stating that he could not say whether RDX-12.3 and RDX-12.5 showed a change in shape); *see also id.* at 1384:23-1385:10 (indicating that images in RDX-12.5 were known to him from his own testing). Dr. Madisetti's inability to compare such shapes underscores the lack of any reliable methodology in his infringement analysis. *See* RIB at 168-69.⁷¹

Moreover, the '745 patent specification describes shapes that are "substantially rectangular, square, circular, oval, or annular, among others." JX-009 at 3:12-14; *see also id.* at 8:9-12 ("a predefined geometry (e.g., a rectangle, square, or circle)"). Another part of the specification describes "a wide, donut-shaped area." *Id.* at 10:65-11:2.⁷² Dr. Madisetti did not use any such descriptors to identify shapes in his images of the emitted light in Accused Products—he only offered conclusory opinions that certain shapes were "different" or observing

⁷¹ The specification indicates that that a diffuser may provide a "defined area shape" only in some embodiments of the invention. *See* JX-009 at 3:5-14 ("In certain embodiments of the present disclosure, the diffuser comprises glass, ground glass, glass beads, opal glass, or a microlens-based, band-limited, engineered diffuser that can deliver efficient and uniform illumination. ***In some embodiments, the diffuser is further configured to define a surface area shape*** by which the emitted spread light is distributed onto a surface of the tissue measurement site. The defined surface area shape can include, by way of non-limiting example, a shape that is substantially rectangular, square, circular, oval, or annular, among others."). This language also indicates that light diffusion, in itself, does not necessarily provide changes in "shape." This is reflected in claim 15 of the '745 patent, which is asserted for domestic industry (as part of dependent claim 18) but not for infringement, requiring a "light diffusing material" without any limitations regarding the shape of the light. *Id.* at 16:36-17:3.

⁷² All of these references to shapes in the specification refer to the "second shape" after the light diffuser, which is projected on to the skin. There is no discussion of the "first shape" of light before the light diffuser, except in the context of prior art "point optical sources," wherein the measurement site is an "irradiated circular area of the point optical source." JX-009 at 5:54-0, Fig. 1.

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“changes” between images. *See* Tr. (Madisetti) at 733:5-18, 747:3-12.⁷³ The undersigned agrees with Complainants that there are differences in the emitted light before and after [REDACTED],⁷⁴ but Complainants have failed to present sufficient credible evidence that these differences represent two different “shapes.” A preponderance of the evidence does not support a finding that the Accused Products meet this limitation.

In addition, there is no evidence in the record that Apple configured [REDACTED] to change the shape of the light. Dr. Venugopal testified that [REDACTED] for the Apple Watch Series 6 was designed “[REDACTED] [REDACTED].” Tr. (Venugopal) at 826:13-829:14. Apple engineering documents corroborate Dr. Venugopal’s testimony—showing that Apple considered [REDACTED] [REDACTED]. RX-0895C at 317. Complainants are not required to prove intent with respect to an apparatus claim, but the Apple engineering documents in the record are consistent with Dr. Venugopal’s testimony that light passing through [REDACTED] [REDACTED].” Tr. (Venugopal) at 831:4-9. It is Complainants’ burden to prove that [REDACTED] is configured to change the emitted light from a first shape to a second shape, and a preponderance of the evidence does not support a finding that the Accused Products meet this limitation.

⁷³ Although it is not clear that he applied any reliable methodology, Dr. Sarrafzadeh was more willing to describe specific shapes in the images of the Accused Products, such as “a square shape,” “square shape-ish,” “closer to a circle shape,” or “more or less a circular form.” Tr. (Sarrafzadeh) at 1115:17-1118:11.

⁷⁴ One visible difference between the images is the pattern of light and dark spots in the “second shape” images. *See* CX-0307iC at 10-21. Dr. Sarrafzadeh stated that the images have “light there, but the cameras don’t show them” due to camera “deficiencies.” Tr. (Sarrafzadeh) at 1118:4-8, 1119:24-1120:4. Dr. Madisetti’s testing shows that there is light in the dark spots when viewed with a lower intensity threshold. CX-0307iC at 11 (images showing no dark spots with “intensity threshold at 0.05”); *see* RRB at 86-87. In any case, it is unclear whether such spots indicate a change in “shape.”

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- d. **Element [1C]: “a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light”**

There is no dispute that each of the Accused Products has four photodiodes configured to detect light after it passes through a user’s tissue, outputting signals responsive to the detected light. *See* CIB at 196-77; *see* Tr. (Madisetti) at 733:19-734:15; CDX-0011C.078 (citing CX-1548C (Apple Watch Series 7 photograph) at 37; CX-1646C (Apple Watch Series 6 photograph); CX-0059C (Apple Watch Series 7 CAD drawings) at 2; CX-0057C (Apple Watch Series 6 CAD drawings); CX-0281C (Block Dep. Tr.) at 7:21-72:5; CX-0297C (Venugopal Dep. Tr.) at 95:5-96:11; CX-0299C (Waydo Dep. Tr.) at 28:22-29:8). The evidence of record shows that this limitation is met.

- e. **Element [1D]: “a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface”**

There is no dispute that each of the Accused Products has a surface with a dark-colored coating positioned between the photodiodes and the user’s skin, with openings above each photodiode allowing light to pass through. *See* CIB at 197; Tr. (Madisetti) at 734:16-735:18; CDX-0011C.079 (citing CX-0070C (Apple Watch Series 7 Specification) at 5; CX-0068C (Apple Watch Series 6 Specification) at 5; CX-0297C (Venugopal Dep. Tr.) at 188:16-189:1, 192:14-194:15; CX-0291C (Mehra Dep. Tr.) at 105:20-106:14, 111:19-112:8); *see also* Tr. (Block) at 901:13-902:3. The evidence of record shows that this limitation is met.

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- f. **Element [1E]: “a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue”**

There is no dispute that each of the Accused Products has an optical barrier that blocks light from the LEDs from reaching the photodiodes without first reaching the user’s tissue. *See* CIB at 198; Tr. (Madisetti) at 735:19-736:19; CDX-0011C.080 (citing CX-0059C (Apple Watch Series 7 CAD drawings) at 1; CX-0057C (Apple Watch Series 6 CAD drawings) at 1; CX-0297C (Venugopal Dep. Tr.) at 92:6-93:3; CX-0281C (Block Dep. Tr.) at 59:5-20, 61:3-6, 81:5-22). The evidence of record shows that this limitation is met.

- g. **Element [1F]: “a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal”**

There is no dispute that each of the Accused Products has a processor that receives and processes signals from the photodiodes and determines an oxygen saturation measurement. *See* CIB at 199; Tr. (Madisetti) at 736:20-737:12; CDX-0011C.081 (citing CX-0013C (ASIC schematic) at 12; CX-0100C (██████████ ERS) at 7; CX-0299C (Waydo Dep. Tr. at 38:19-2, 39:2-6, 50:11-14, 68:12-21, 72:10-22, 73:16-19). The evidence of record shows that this limitation is met.

- h. **Element [9]: “wherein the physiological parameter comprises oxygen saturation”**

Claim 9 of the ’745 patent depends from claim 1, “wherein the physiological parameter comprises oxygen saturation.” There is no dispute that each of the Accused Products measures oxygen saturation. *See* CIB at 199; Tr. (Madisetti) at 737:13-23; CDX-0011C.082 (citing CX-1447 (Apple Watch Series 7 website) at 7; CX-1532 (Apple Watch Series 6 website) at 4). The evidence of record shows that this limitation is met.

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Accordingly, the evidence does not show infringement of claim 9 because Complainants have not proven, by a preponderance, that the Accused Products have a material that is configured to change emitted light from a “first shape” into a “second shape,” as required by claim 1.

2. '745 Patent Claim 27

a. Element [20 preamble]: “A system configured to measure one or more physiological parameters of a user, the system comprising: a physiological monitoring device comprising:”

The preamble of claim 20 of the '745 patent requires “[a] system configured to measure one or more physiological parameters of a user,” including “a physiological monitoring device.” The alleged “system” is an Accused Product in communication with an Apple iPhone. *See* CIB at 199-200. As discussed above in the context of the preamble of '745 patent claim 1, there is no dispute that the Accused Products are devices that can measure blood oxygen. *See* CIB at 201. Moreover, there is no dispute that the Accused Products can be used with an Apple iPhone. *Id.*; *see* Tr. (Madisetti) at 738:25-740; CDX-0011C.085 (citing CX-1271 (Apple website) at 1; CX-0010 (Apple website) at 2-3; CX-0299C (Waydo Dep. Tr.) at 74:6-75:17). The evidence of record shows that this limitation is met.

b. Element [20A]: “a plurality of light-emitting diodes configured to emit light in a first shape”

Claim 20 has a “plurality of light-emitting diodes” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has a plurality of light-emitting diodes emitting light in a shape. *See* CIB at 201. The evidence of record shows that this limitation is met.

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- c. **Element [20B]: “a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue”**

Claim 20 has a “material configured to change the first shape into a second shape” limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the undersigned finds that Complainants have not shown that the Accused Products have a material that is configured to change emitted light from a “first shape” into a “second shape.”

- d. **Element [20C]: “a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light”**

Claim 20 has a “plurality of photodiodes” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has four photodiodes configured to detect light after it passes through a user’s tissue, outputting signals responsive to the detected light. *See* CIB at 201. The evidence of record shows that this limitation is met.

- e. **Element [20D]: “a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface”**

Claim 20 has a “surface comprising a dark-colored coating” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has a surface with a dark-colored coating positioned between the

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photodiodes and the user's skin, with openings above each photodiode allowing light to pass through. *See* CIB at 201. The evidence of record shows that this limitation is met.

- f. **Element [20E]: “a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue”**

Claim 20 has a “light block” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has an optical barrier that blocks light from the LEDs from reaching the photodiodes without first reaching the user's tissue. *See* CIB at 201. The evidence of record shows that this limitation is met.

- g. **Element [20F]: “a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal”**

Claim 20 has a “processor” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has a processor that receives and processes signals from the photodiodes and determines an oxygen saturation measurement. *See* CIB at 201. The evidence of record shows that this limitation is met.

- h. **Element [20G]: “a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data”**

There is no dispute that an Apple iPhone is a processing device with a user interface, storage device, and wireless interface that can wirelessly communicate with the Accused

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Products, receive oxygen saturation data and present an oxygen saturation measurement on a touch-screen display. *See* CIB at 201; Tr. (Madisetti) at 740:6-24; CDX-0011C.086 (citing CX-0010C (Apple website) at 5; CX-1492 (Apple website) at 4; CX-0299C (Waydo Dep. Tr.) at 74:11-75:17). The evidence of record shows that this limitation is met.

- i. Element [27]: “wherein at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength”**

Claim 27 of the '745 patent depends from claim 20, further requiring that “at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength.” There is no dispute that the Accused Products contain green (525 nm), red (660 nm), and infrared (850 nm) LEDs. *See* CIB at 202; Tr. (Madisetti) at 740:25-741:14; CDX-0011C.087 (citing CX-0059C (Apple Watch Series 7 drawing) at 2; CX-0057C (Apple Watch Series drawing) at 2; CX-0297C (Venugopal Dep. Tr.) at 53:1-55:14). The evidence of record shows that this limitation is met.

Accordingly, the evidence does not show direct infringement of claim 27 because Complainants have not proven, by a preponderance, that the Accused Products have a material that is configured to change emitted light from a “first shape” into a “second shape,” as required by claim 20 (from which claim 27 depends).

3. Induced Infringement

Complainants contend that Apple induces infringement of '745 patent claim 27 by importing the Accused Products to be used in connection with Apple iPhones. CIB at 199-200.

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Complainants submit that Apple had knowledge of the '745 patent as of the filing of the original complaint on June 30, 2021. *See* CX-1254C (Apple interrogatory responses) at 35.

Complainants identify documentation from Apple instructing users how to connect the Accused Products with Apple iPhones. *See* CX-1727 (Apple Watch User Guide) at 1. Dr. Madisetti identified documentation from Apple instructing users how to pair an Apple Watch with an iPhone and use the Health app to monitor blood oxygen on the iPhone. Tr. (Madisetti) at 738:25-740:5; CDX-0011C.085 (citing CX-1727 (Apple Watch User Guide) at 1; CX-0010 (Apple website) at 2-3; CX-0299C (Waydo Dep. Tr.) at 74:11-75:17).

Apple argues that Complainants failed to carry their burden to show that Apple had the necessary specific intent for induced infringement. RRB at 88. Apple argues that there is no testimonial evidence that Apple actively induced its users to infringe or that Apple knew that its users' actions would constitute infringement. *Id.*

In consideration of the parties' arguments, the undersigned finds that a preponderance of the evidence supports a finding that Apple knew of the alleged infringement of claim 27 as of the filing of the Complaint, which contained allegations of infringement (including a claim chart for claim 27) similar to the evidence presented at the hearing. *See* Complaint Exhibit 18 (June 30, 2021). In addition, there is no dispute that Apple has provided instructions to its users for pairing the Accused Products with Apple iPhones to monitor blood oxygen through Apple's Health app. *See* CX-1727 (Apple Watch User Guide) at 1; CX-0010 (Apple website) at 2-3; CX-0299C (Waydo Dep. Tr.) at 74:11-75:17. The Commission has found induced infringement based on similar evidence when there has been an underlying finding of direct infringement. *See, e.g., Certain Beverage Brewing Capsules*, Inv. No. 337-TA-929, Comm'n Op. at 17-21, EDIS Doc. ID 577827 (Apr. 5, 2016).

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The undersigned finds that Apple has not induced infringement of claim 27, however, because Complainants have not shown underlying direct infringement of this claim.

F. Domestic Industry—Technical Prong

The domestic industry products that Complainants rely on for the '745 patent are the Circle sensor (CPX-0021C) and the Wings sensor (CPX-0029C),⁷⁵ the RevA sensor (CPX-0052C), the RevD sensor (CPX-0058C), and the RevE sensors (CPX-0019C, CPX-0020C, CPX-0065C)(collectively, “the '745 DI Products”). CIB at 203.⁷⁶ Complainants allege that each of the '745 DI Products practices '745 patent claim 18, which depends from claim 15. *Id.* at 203-11.

1. '745 Patent Claim 18

a. Element [15 preamble]: “A physiological monitoring device comprising:”

There is no specific dispute that each of the '745 DI Products is a “physiological monitoring device” as required by the preamble of claim 15. *See* CIB at 204; RIB at 175-77.⁷⁷ Mr. Scruggs testified that each of the '745 DI Products “supported the ability to measure oxygen saturation and pulse rate.” Tr. (Suggs) at 393:17-20. Dr. Madisetti also observed a demonstration by Dr. Scruggs of the RevA, RevD, and RevE devices measuring oxygen saturation. Tr. (Madisetti) at 749:23-750:11. Dr. Madisetti also relied on a demonstration by Mr. Scruggs of the Circle and Wings sensors connected to a Rad-97 monitor. *Id.* at 754:24-

⁷⁵ Complainants assert that the Circle sensor and Wings sensor practice the '745 patent when connected to a Rad-97 monitor (CPX-0014a). CIB at 203, 209-10.

⁷⁶ Complainants also rely on the Masimo W1 as a domestic industry product, but for the reasons discussed *supra* in the context of the Poeze patents, evidence regarding this product will not be considered.

⁷⁷ Apple disputes whether certain of the '745 DI Products were operable before the filing of the Complaint, *see* RIB at 174-75, and this issue is addressed *infra*, Section VII.

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755:3. For these reasons and those discussed below with regard to Element [15H], the evidence of record shows that this limitation is met.

b. Element [15A]: “a plurality of light-emitting diodes configured to emit light proximate a wrist of a user”

There is no dispute that each of the ’745 DI Products has a plurality of light-emitting diodes. *See* CIB at 204. Dr. Madisetti identified the LEDs in each of the ’745 DI Products. Tr. (Madisetti) at 750:22-751:11; CDX-0011C.098. Mr. Scruggs testified that the ’745 DI Products each contain LEDs. Tr. (Scruggs) at 393:12-394:3. The evidence of record shows that this limitation is met.

c. Element [15B]: “a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a tissue measurement site on the wrist of the user when the physiological monitoring device is in use”

Mr. Scruggs identified “a diffusing media above the LEDs” in the ’745 DI Products, which is [REDACTED] for the Circle, Wings, RevA, RevD, and RevE sensors. Tr. (Scruggs) at 401:2-13. Dr. Madisetti observed the [REDACTED] “diffusing the light” in a demonstration by Mr. Scruggs. Tr. (Madisetti) at 760:18-22; *see also* RX-0266C (demonstration of RevA sensor); RX-0267C (demonstration of RevD sensor); RX-0268C (demonstration of RevE sensor). Dr. Madisetti identified the location of the diffusing material in each of the ’745 DI Products. Tr. (Madisetti) at 751:12-752:2; CDX-011C.099 (citing CX-1132C (Circle CAD) at 2; CX-0656C (Circle photo); CX-1137C (Wings CAD) at 6; CX-0658C (Wings photo); CX-111C (RevA CAD); CX-0661C (RevA photo); CX-1058C (RevD photo) at 442; CX-0666C (RevD photo); CX-1125C (RevE CAD) at 2; CX-0653C (RevE photo); CX-0655C (RevE photo); CX-0676C (RevE photo); CX-1058C (RevE photo) at 593). Complainants

further submit that this material is located on the side of the product that contacts the user's wrist in each of the '745 DI Products, thus meeting this limitation. CIB at 205-07.

Apple argues that Dr. Madisetti's analysis of photos and images is insufficient to prove that the material above the LEDs in the '745 DI Products is a "light diffusing material." RIB at 175-76. Dr. Sarrafzadeh called this analysis "unscientific" and "unreliable given that the components are actually quite small." Tr. (Sarrafzadeh) at 1127:1-1128:4; RDX-7C.0162. Dr. Sarrafzadeh further testified that [REDACTED] is not always a diffusing material." Tr. (Sarrafzadeh) at 1127:15-1128:8. Apple further argues that the documentation for the '745 DI Products is unreliable because of certain discrepancies between the physical exhibits and Masimo's schematics. RIB at 175.

In consideration of the parties' arguments, the undersigned finds that Complainants have shown, by a preponderance of the evidence, that the '745 DI Products have a "light diffusing material" meeting this limitation. Mr. Scruggs described the diffusing material in each of the '745 DI Products, noting the "milky color" above the LEDs. Tr. (Scruggs) at 401:2-13. He specifically identified the [REDACTED] material in the Circle, Wings, RevA, RevD, and RevE sensors. *Id.* Dr. Madisetti confirmed the location of the material identified by Mr. Scruggs in photos and schematics of each of the '745 DI Products. Tr. (Madisetti) at 751:12-752:2. Dr. Sarrafzadeh raises some questions regarding the reliability of Dr. Madisetti's analysis, but the appearance of the '745 DI Products in videos and photographs is consistent with Mr. Scruggs's testimony. *See* CDX-011C.099. On this record, a preponderance of the evidence supports a finding that each of the '745 DI Products meets this claim limitation with a light diffusing material positioned between the LEDs and the user's wrist.

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d. Element [15C]: “a light block having a circular shape”

There is no dispute that each of the '745 DI Products has a light block that forms a circular shape around the LEDs. *See* CIB at 207. Dr. Madisetti identified the circular light block photographs and schematics of each of the '745 DI Products. Tr. (Madisetti) at 752:3-10; CDX-0011C.100. Mr. Scruggs described a “light barrier . . . that surrounds the emitters so it separates the LEDs from the photodiodes.” Tr. (Scruggs) at 400:9-12. The evidence of record shows that this limitation is met.

e. Element [15D]: “a plurality of photodiodes configured to detect at least a portion of the light emitted from the plurality of light-emitting diodes after the light passes through the light diffusing material and a portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block”

There is no dispute that each of the '745 DI Products has photodiodes that are arranged in a circular array around the light block that are configured to detect light that is reflected from the user's skin. *See* CIB at 207-08. Dr. Madisetti identified the arrangement of photodiodes in photographs and schematics of each of the '745 DI Products. Tr. (Madisetti) at 752:22-754:8; CDX-0011C.101. The evidence of record shows that this limitation is met.

f. Element [15E]: “wherein the plurality of photodiodes are further configured to output at least one signal responsive to the detected light”

There is no specific dispute that the photodiodes in each of the '745 DI Products are configured to output a signal responsive to detected light. *See* CIB at 208; RIB at 175-77. Dr. Madisetti identified circuit diagrams showing the output of the photodiodes in the RevA, RevD, and RevE devices. Tr. (Madisetti) at 754:9-755:6; CDX-0011C.102 (citing CX-0701C (RevA diagram) at 2, 6; CX-0710C (Rev D diagram) at 3, 7; CX-0705C (RevE diagram). With

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respect to the Circle and Wings sensors, Dr. Madisetti relied on a demonstration by Mr. Scruggs showing these sensors outputting oxygen saturation information to a separate Rad-97 monitor. Tr. (Madisetti) at 754:24-755:3. Mr. Scruggs explained that “the signal from the photodiodes was transmitted through a cable to the Rad-97 instrument.” Tr. (Scruggs) at 403:18-404:2 (describing Circle sensor), 404:14-19 (describing Wings sensor). For these reasons, and those discussed in relation to Element [15H], the evidence of record shows that this limitation is met.

g. Element [15F]: “wherein the plurality of light-emitting diodes and the plurality of photodiodes are arranged in a reflectance measurement configuration”

There is no dispute that the photodiodes in each of the '745 DI Products are located on the same side as the LEDs and are thus arranged to detect light that is reflected from the user's wrist. *See* CIB at 209; Tr. (Madisetti) at 755:7-25; CDX-0011C.103. The evidence of record shows that this limitation is met.

h. Element [15G]: “wherein the light block is configured to optically isolate the plurality of light-emitting diodes from the plurality of photodiodes by preventing at least a portion of light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the portion of the tissue measurement site”

There is no dispute that the light block in each of the '745 DI Products separates the LEDs from the photodiodes, blocking at least a portion of light from reaching the photodiodes without first reaching the user's skin. *See* CIB at 209; Tr. (Madisetti) at 756:1-15; CDX-0011C.104. The evidence of record shows that this limitation is met.

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- i. Element [15H]: “a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal”**

Dr. Madisetti identified processors for each of the '745 DI Products that receive and process signals from the photodiodes. Tr. (Madisetti) at 756:16-757:13; CDX-0011C.105. For the Circle sensor and Wings sensor, Mr. Scruggs explained that the relevant processor is in the Rad-97 instrument, which is connected to the sensors via a cable. Tr. (Scruggs) at 403:11-404:2 (“So the Circle sensor gathered the raw physiological data from the wrist using the LEDs and detectors, and the signal from the photodiodes was transmitted through a cable to the Rad-97 instrument. And then the Rad-97 instrument uses its processors, and the Masimo SET pulse oximetry algorithm to calculate oxygen saturation and pulse rate.”), 405:1-7 (same for Wings sensor). Dr. Madisetti also relied on a demonstration by Mr. Scruggs of the Circle and Wings sensors connected to a Rad-97 monitor. *Id.* at 754:24-755:3. Dr. Madisetti also observed a separate demonstration by Dr. Scruggs of the RevA, RevD, and RevE devices measuring oxygen saturation. Tr. (Madisetti) at 749:23-750:11. Mr. Al-Ali described internal testing of the oxygen saturation measurements of Masimo sensors at the time of the RevA sensors. Tr. (Al-Ali) at 271:16-277:13; CX-0378C at 32. He also described testing relevant to the RevD sensors and the RevE sensors. Tr. (Al-Ali) at 276:12-278:3, 316:2-317:20; CX-0494C. Complainants submit that this evidence shows that each of the '745 DI Products has a processor that receives and processes signals from the photodiodes to calculate oxygen saturation. CIB at 209-11; CRB at 121.

Apple argues that the evidence in the record is insufficient to show that any of the '745 DI Products calculates oxygen saturation. RIB at 176-77. As discussed above in the context of the Poeze patents, Apple submits that Complainants failed to identify the source code in the

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domestic industry products that calculates any physiological parameter. *Id.* at 47-48; *see* Tr. (Sarrafzadeh) at 1124:24-1125:11. Dr. Sarrafzadeh offered his opinion that the evidence presented by Complainants was insufficient to determine whether the '745 DI Products calculated oxygen saturation. Tr. (Sarrafzadeh) at 1122:20-1126:20. He specifically highlights an erroneous oxygen saturation reading of "81" during a demonstration of the Wings sensor. *Id.* at 1124:12-23. With respect to the Circle sensor and Wings sensor, Apple argues that the claim limitation is not satisfied because the identified "processor" is not in the sensor but in the separate Rad-97 instrument. RIB at 177; RRB at 91.

In consideration of the parties' arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that each of the '745 DI Products has a processor that receives signals from the photodiodes and determines an oxygen saturation measurement. With respect to the Circle sensor and Wings sensor, claim 15 does not preclude the "physiological-monitoring device" from comprising a sensor that is connected to a separate instrument via a cable. As discussed above in the context of the Poeze patents, the testimony of Mr. Scruggs and Mr. Al-Ali regarding the design, testing, and operation of Masimo's products is sufficient to show that the '745 DI Products measure oxygen saturation. The demonstrations of the '745 DI Products during discovery further confirm the operation of these products, and the minor inconsistencies identified by Dr. Sarrafzadeh do not refute Complainants' affirmative evidence that these products measure oxygen saturation.

Accordingly, the evidence shows by a preponderance that each of the '745 DI Products has a processor that receives signals from the photodiodes and determines an oxygen saturation measurement.

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j. Element [15I]: “wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor”

There is no specific dispute that the '745 DI Products are configured to transmit oxygen saturation data to an additional processor. *See* CIB at 211; RIB at 175-77. For the Circle and Wings sensors, Dr. Madisetti identified Wi-Fi and Bluetooth functionality in the Rad-97 instrument that would facilitate transmission of oxygen saturation data. Tr. (Madisetti) at 758:8-11; CDX-0011C.107 (citing CX-0679 at 96, 99). For the RevA sensor, Dr. Madisetti identified a laptop that received oxygen saturation data during a demonstration by Mr. Scruggs. Tr. (Madisetti) at 757:16-23; CDX-0011C.106 (citing CX-0836C (demonstration photos) at 4). Dr. Madisetti identified two separate processors in the RevD and RevE sensors, explaining that oxygen saturation data is sent from the [REDACTED] processor to the [REDACTED] processor. Tr. (Madisetti) at 757:14-758:6; CDX-0011C.106 (citing CX-0709C (RevD schematic) at 3). For the RevE sensor, Dr. Madisetti further identifies a phone that received oxygen saturation during a demonstration by Mr. Scruggs. Tr. (Madisetti) at 757:24-758:4; CDX-0011C.106 (citing CX-0836C (demonstration photos) at 8-13). For these reasons, and those discussed in relation to Element [15H], the evidence of record shows that this limitation is met by the '745 DI Products.

k. Element [18]: “wherein the physiological parameter comprises oxygen saturation”

Claim 18 of the '745 patent depends from claim 15, “wherein the physiological parameter comprises oxygen saturation.” As discussed above in the context of the “processor” limitation, the undersigned finds that the '745 DI Products measure oxygen saturation.

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Accordingly, because each limitation of claims 15 and 18 are satisfied, the evidence shows, by a preponderance, that each of the '745 DI Products practice claim 18 of the '745 patent.

2. Status of DI Products at the Time of the Complaint

Apple argues that no patent-practicing domestic industry article existed at the time of the complaint. RIB at 174-75; RRB at 12-14. Complainants dispute Apple's contention. CRB at 119-20. Specifically, Apple disputes whether the Circle and Wings sensors were operable with the Rad-97 monitor before the complaint was filed. RIB at 174-75. Apple further disputes whether the RevA sensor was operable with a laptop before the complaint was filed. *Id.* Complainants rely on Mr. Scruggs's testimony that the Circle sensor, Wings sensor, RevA sensor, and RevD sensor were built before the complaint was filed. Tr. (Scruggs) at 394:12-397:24. Complainants further rely on Mr. Al-Ali's testimony regarding clinical testing of Masimo Watch devices. Tr. (Al-Ali) at 262:7-264:13, 268:22-278:13, 313:14-318:22. Mr. Scruggs also testified that the Circle sensor was used in clinical studies at Masimo in October 2019. Tr. (Scruggs) at 475:8-15.

In consideration of the parties' arguments, the undersigned finds that at least the RevA, RevD, and RevE sensors were articles protected by the '745 patent that existed before the filing of the complaint. As discussed above in the context of the Poeze patents, the record evidence is sufficient to show that the RevA, RevD, and RevE devices existed prior to the filing of the complaint. Apple argues that the laptop Mr. Scruggs used to display the oxygen saturation measurement from the RevA sensor was not used with the RevA sensor before the filing of the complaint, RIB at 174, but this laptop is not part of the domestic industry article protected by claim 18 of the '745 patent. Mr. Scruggs's laptop was only used to demonstrate the final

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limitation of claim 15 [15I], which requires that the RevA sensor is “configured to transmit physiological parameter data to a separate processor.” *See* Tr. (Madisetti) at 757:16-23; CX-0836C (demonstration photos) at 4. Mr. Scruggs’s laptop was part of the demonstration showing that the RevA sensor was configured as required by the claims, but the laptop is not part of the domestic industry article—the RevA had the required configuration even in the absence of the laptop.⁷⁸ With respect to the RevD and RevE sensors, Apple argues that software was loaded on these devices after the complaint was filed, RIB at 42-43, but as discussed above in the context of the Poeze patents, *supra* Section IV.F.7, the evidence shows that these devices were tested before the filing of the complaint. *See* Tr. (Al-Ali) at 276:17-278:13, 316:2-317:20 (citing CX-0494C). Moreover, at least one of the RevE devices produced in discovery (CPX-0019C) can be considered to represent devices that existed at the time of the complaint, based on software that is dated July 9, 2021.

With respect to the Circle sensor and the Wings sensor, the associated Rad-97 monitor is necessary to the practice of the “determine a physiological parameter” limitation [15H], and the protected domestic industry article thus comprises the sensors together with the Rad-97 monitor. Although Complainants have identified some evidence that the Circle and Wings sensors were used in testing in 2019 and 2020, there is no evidence that these sensors were used together with the identified Rad-97 monitor in those tests. *See* Tr. (Scruggs) at 475:8-15; Tr. (Al-Ali) at 262:7-263:10. Mr. Scruggs explained how the Circle and Wings sensor could have worked with the Rad-97, but he never confirmed that these sensors were used with a Rad-97 monitor at any time

⁷⁸ As described by Mr. Al-Ali, an October 2020 presentation describes internal testing of the oxygen saturation measurements of prototype sensors consistent with the RevA design. Tr. (Al-Ali) at 272:16-277:13; CX-0378C at 32.

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before the filing of the complaint. *See* Tr. (Scruggs) at 403:11-404:2 (“It could work with many of the Masimo instruments. One example of that would be the Rad-97.”). Complainants have not shown that the asserted domestic industry articles—the Circle sensor connected to the Rad-97 monitor and the Wings sensor connected to the Rad-97 monitor—existed as articles protected by claim 18 of the ’745 patent before the filing of the complaint.

Accordingly, Complainants have shown that at least with respect to the RevA, RevD, and RevE sensors, domestic industry articles protected by the ’745 patent existed before the filing of the complaint, and Complainants have thus satisfied the technical prong for the ’745 patent with respect to a domestic industry existing at the time of the complaint.

Moreover, for the same reasons discussed above in the context of the Poeze patents, *supra* Part IV.F.7-8, the evidence shows satisfaction of the technical prong for a domestic industry in the process of being established. In particular, the evidence shows, by a preponderance, that Masimo has taken the necessary tangible steps to develop a product that will practice claim 18 of the ’745 patent and shows a significant likelihood that this product development will lead to a device that practices the claim.

G. Invalidity – Obviousness

Apple contends that claims 9 and 27 of the ’745 patent are obvious in view of the Apple Watch Series 0 and that claims 9, 18, and 27 of the ’745 patent are obvious in view of U.S. Patent No. 8,670,819 to Iwamiya *et al.* (RX-0130, “Iwamiya”) in combination with U.S. Patent No. 9,392,946 to Sarantos *et al.* (RX-0366, “Sarrantos”) and U.S. Patent No. 8,998,815 to Venkatraman *et al.*, (RX-0368, “Venkatraman”). RIB at 178-201; RRB at 94-110. Complainants dispute Apple’s allegations of obviousness, identifying certain objective indicia of non-obviousness in support of their arguments. CIB at 212-34; CRB at 121-33.

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1. Apple Watch Series 0

The Apple Watch Series 0 was the first commercial Apple Watch, and Apple submits that it went on sale to the public on April 24, 2015, citing an Apple press release and the testimony of Apple and Masimo witnesses. RX-0023 (Apple Press Release); Tr. (Block) at 910:22-911:2; Tr. (Kiani) at 138:1-4. Complainants dispute whether Apple has shown that the Apple Watch Series 0 was publicly available before the priority date of the '745 patent in July 2015. CIB at 212-13. Complainants argue that the press release only describes an expected release date and that Apple's witness testimony is uncorroborated. *Id.*; CRB at 123.

The record shows clear and convincing evidence that the Apple Watch Series 0 was publicly on sale by April 24, 2015. Apple's press release represents that the Apple Watch will be "Available for Purchase Online April 24." RX-0023. Complainants argue that the statement in this press release was made in advance of the release date, but the April 2015 release date for the Apple Watch Series 0 was further corroborated by the testimony of Dr. Block and Dr. Venugopal. Tr. (Block) at 910:22-24 ("It was released in the spring of 2015."); Tr. (Venugopal) at 818:10-15 ("The first customer ship for Series 0 was in April of 2015."). Complainants have identified no evidence that the announced release date for the Apple Watch Series 0 was delayed and no reason to doubt the testimony of Apple's witnesses—when Mr. Kiani was asked about his knowledge of the release of the first Apple Watch, he testified that "I don't remember the exact timing, but I'm sure those dates are correct." Tr. (Kiani) at 138:1-4. The evidence thus shows that the Apple Watch Series 0 was publicly available in April 2015, which qualifies it as prior art under 35 U.S.C. § 102(a)(1).

Complainants further argue that Apple has failed to introduce reliable evidence for the structure and operation of the Apple Watch Series 0, identifying several discrepancies between

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the product photos relied upon by Dr. Sarrafzadeh and the features described in Apple schematics. CIB at 213-18. The undersigned agrees with Apple, however, that the discrepancies identified by Complainants are irrelevant to the asserted claims of the '745 patent. *See* RRB at 95-97. The parties' disputes regarding the structure and operation of the Apple Watch Series 0 that are relevant to the limitations of the asserted claims are addressed below.

a. '745 patent, claim 9

(i) Element [1 preamble]: "A physiological monitoring device comprising"

Apple contends that the Apple Watch Series 0 is a "physiological monitoring device" because it contains a heart rate sensor. RIB at 179; *see* Tr. (Sarrafzadeh) at 1092:7-13; Tr. (Waydo) at 937:2-8; Tr. (Land) at 957:5-15; RX-0396.0011C (Apple specification). Complainants do not specifically dispute this preamble limitation. *See* CIB at 212-24; CRB at 122-27.

(ii) Element [1A]: "a plurality of light-emitting diodes configured to emit light in a first shape"

Apple contends that the Apple Watch Series 0 has four LEDs that emit light in a shape. RIB at 179; *see* Tr. (Sarrafzadeh) at 1092:15-21; Tr. (Land) at 959:3-13; Tr. (Block) at 897:15-898:1. Dr. Venugopal testified that the Apple Watch Series 0 contained green and infrared LEDs, and the shape of the LEDs was square. Tr. (Venugopal) at 819:1-7, 820:16-821:11; RX-0392C.006 (Apple specification) at Fig. 2. Complainants do not specifically dispute this limitation. *See* CIB at 212-24; CRB at 122-27.

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- (iii) **Element [1B]: “a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue”**

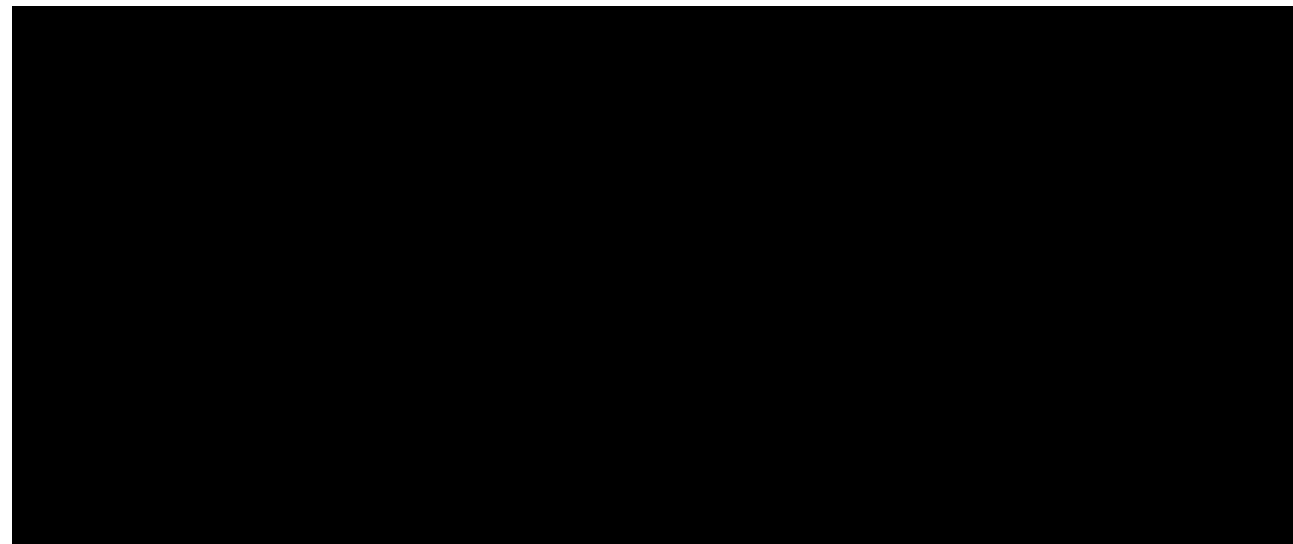
Apple submits that the Apple Watch Series 0 has a “Fresnel lens” positioned between the LEDs and the user’s wrist, which changes the shape of the light from the LEDs. RIB at 108-81. Dr. Venugopal identified the Fresnel lens as part of the Apple Watch Series 0. Tr. (Venugopal) at 819:1-7. Apple relies on an engineering requirement specification document for Apple’s “Generation 1” optical sensing module, which was identified by Dr. Venugopal as applying to the Apple Watch Series 0 through 3. *Id.* at 820:10-15 (citing RX-0392C). Dr. Venugopal explained that “[t]he Fresnel lens had two purposes,” which were “cosmetic obscuration” and “to have light emitted from the green LED to be collimated.” *Id.* at 821:12-21. The green light is “positioned under the optical center,” and “gets restricted to a certain angle so that most of it gets out of the window.” *Id.* at 821:22-4, 822:22-25; RX-0392C.007 at Fig. 3. With respect to the infrared LED in the optical sensing module, Dr. Venugopal explained that “because it is not passing through an optical center, gets thrown off in a different direction, and it exits the watch and hits the skin a little bit further away.” Tr. (Venugopal) at 823:4-9. He testified that the infrared light “has a crescent shape.” *Id.* Dr. Sarrafzadeh relied on the Apple specification document and offered his opinion that the “Fresnel lens has these grooves as highlighted here, and these grooves take the shape of the LED and transform that into a crescent type of a shape.” Tr. (Sarrafzadeh) at 1092:23-1093:8 (citing RX-0392C); *see* RDX-7.86C, RDX-7.87C.

Complainants argue that the testimony of Dr. Venugopal and Dr. Sarrafzadeh are insufficient to show that the Apple Watch Series 0 meets this limitation by clear and convincing

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evidence. CIB at 220-22. Complainants contend that there are no documents or testing to corroborate Apple’s contention that the Fresnel lens changes the shape of the infrared light in the Apple Watch Series 0. *Id.* Complainants further cite an Apple patent (naming Dr. Venugopal among the inventors) describing a Fresnel lens whose effect is for a “light emitter to retain its optical power, collection efficiency, beam shape, and collection area such that the light undergoes minimal change.” CX-1806 at ¶ 53.

Apple argues in reply that Dr. Sarrafzadeh’s opinions are corroborated by the placement of the infrared LED in relation to the Fresnel lens shown in Apple’s engineering documents, highlighting a close-up of the lens and the placement of the LEDs. RRB at 99-100.



RX-0392C.00 at Fig. 2. Apple submits that Dr. Sarrafzadeh and Dr. Venugopal explained how the offset placement of the infrared LED causes a change in shape as the light passes through a crescent-shaped portion of the Fresnel lens. *See* Tr. (Sarrafzadeh) at 1093:4-8; Tr. (Venugopal) at 823:4-9.

In consideration of the parties’ arguments, the undersigned finds that Apple has failed to offer clear and convincing evidence that the Fresnel lens changes the shape of the light emitted by the infrared LED in the Apple Watch Series 0. Dr. Sarrafzadeh’s testimony is conclusory—

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he asserts that the grooves on the Fresnel lens transforms the light “into a crescent type of a shape,” but he merely showed a demonstrative with a drawing of a crescent that was not shown to be the result of any testing or observation of the Apple Watch Series 0. Tr. (Sarrafzadeh) at 1093:4-8; RDX-7.87C; Tr. (Madisetti) at 1358:3-5. Dr. Venugopal explained how the Fresnel lens collimates the green light at the optical center while throwing off the infrared light in a different direction because it is off-center, but he only offers a short conclusory statement about the shape of the infrared light: “It has a crescent shape.” Tr. (Venugopal) at 821:22-823:9. Changing the shape of the infrared light is not one of the two purposes that Dr. Venugopal described for the Fresnel lens. *See id.* at 821:12-21.⁷⁹ The record contains no images of the light passing through the Fresnel lens or any explanation for why Apple would have designed the Fresnel lens to change the shape of the infrared light, and the conclusory testimony of Dr. Sarrafzadeh and Dr. Venugopal falls short of the clear and convincing standard necessary to prove invalidity. *See Motorola Mobility, LLC v. Int’l Trade Comm’n*, 737 F.3d 1345, 1349 (Fed. Cir. 2013) (where expert’s testimony was “a single sentence, without explanation,” finding that the ALJ and Commission did not “act unreasonably in finding this conclusory sentence did not rise to the level of clear and convincing evidence”).

- (iv) Element [1C]: “a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light”**

Apple contends that the Apple Watch Series 0 has two photodiodes that detect light after it interacts with the user’s tissue. RIB at 181; *see* Tr. (Sarrafzadeh) at 1093:9-12; Tr. (Land) at

⁷⁹ The Apple patent application cited by Complainants is consistent with Dr. Venugopal’s testimony that the purpose of the Fresnel lens is to obscure internal components and to retain optical power. *See* CX-1806 at ¶ 53.

959:3-13; Tr. (Venugopal) at 819:1-7; RX-0392C.006 at Fig. 2. Complainants do not specifically dispute this limitation. *See* CIB at 212-24; CRB at 122-27.

- (v) **Element [1D]: “a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface”**

Apple submits that the Apple Watch Series 0 has a [REDACTED] back crystal, which is positioned between the photodiodes and the user’s wrist and has openings to allow light reflected from the tissue to reach the photodiodes. RIB at 181-82; RRB at 101; *see* Tr. (Sarrafzadeh) at 1093:13-21; Tr. (Land) at 959:3-13. Dr. Sarrafzadeh testified that “the first layer of the [REDACTED] [REDACTED] is a dark-colored coating.” Tr. (Sarrafzadeh) at 1093:13-21; RDX-7.89C.⁸⁰ In the alternative, he offered his opinion that “one of ordinary skill knows that you can easily and low-tech add dark-colored coating to it.” *Id.* Apple argues that dark-colored coatings were well-known in the prior art and would have been obvious to a person of ordinary skill in the art. RRB at 101 (citing RX-0366 (Sarantos) at 17:12-16; RX-0035.0202 (Webster)). Complainants dispute Apple’s contentions, arguing that there is no evidence that the [REDACTED] surface of the Apple Watch Series 0 has layers and that Dr. Sarrafzadeh’s testimony is insufficient to establish that adding a dark-colored coating would have been obvious. CIB at 222-23.


In consideration of the parties’ arguments, the undersigned agrees with Complainants that Apple has failed to show, clearly and convincingly, that the [REDACTED] back crystal of the Apple Watch Series 0 is a “coating.” There is no evidence that the [REDACTED] back crystal

⁸⁰ Complainants note that the image on RDX-7.89C is an Apple Watch Series 1, not an Apple Watch Series 0. *See* CIB at 215.

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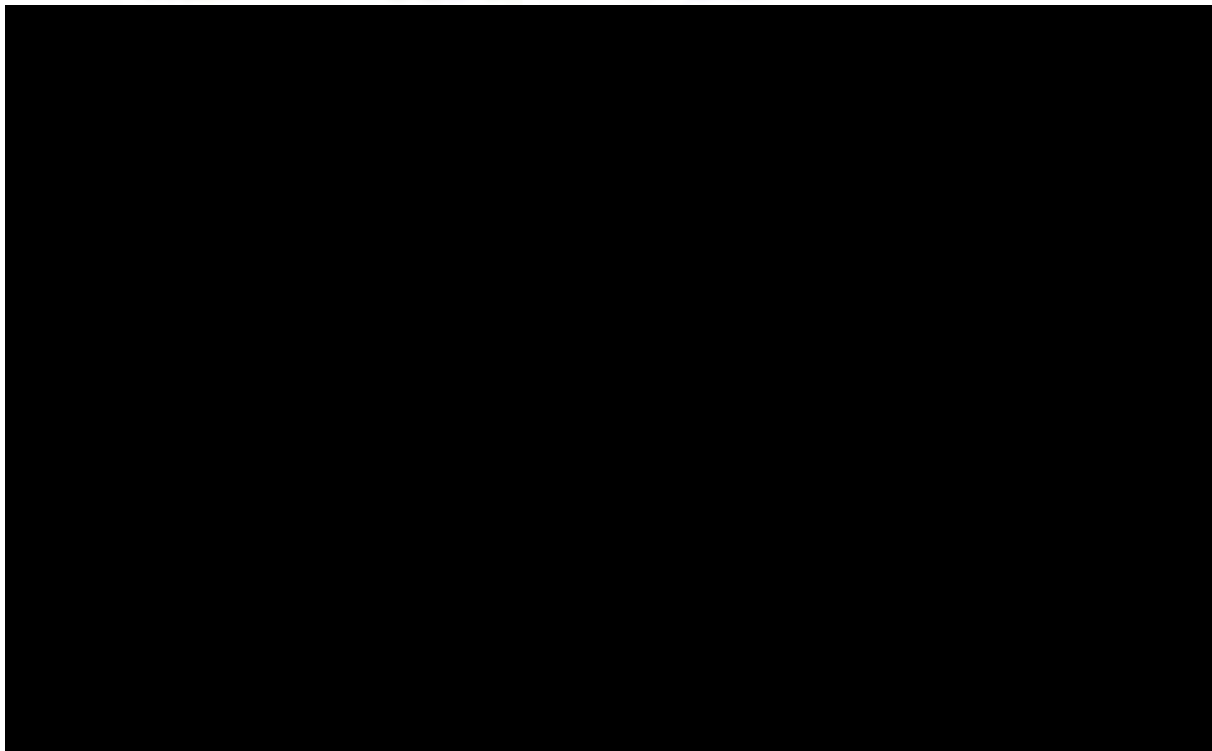
comprises layers that can be described as a “coating,” and Apple has failed to offer clear and convincing evidence that one of ordinary skill in the art would have added a dark-colored coating to the surface of the back crystal in the Apple Watch Series 0. *See, e.g.*, JX-0009 at 9:32-34 (referring to a “top surface coated with a light-absorbing material”). Dr. Sarrafzadeh offers conclusory testimony that a person of ordinary skill in the art would have been able to add a “low-tech” coating to the Apple Watch Series 0, but even if this opinion were reliable, Dr. Sarrafzadeh fails to identify any reason to add such a coating. Such testimony is insufficient to carry Apple’s burden to prove obviousness by clear and convincing evidence. *See InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (reversing obviousness finding where expert’s “testimony primarily consisted of conclusory references to her belief that one of ordinary skill in the art could combine these references, not that they would have been motivated to do so.”).

- (vi) **Element [1E]: “a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue”**

With respect to the “light block” limitation, Apple relies on an Apple specification that depicts blocks labeled “

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RX-0396C.0017 at Fig. 6. [REDACTED]

[REDACTED].” Tr. (Land)

at 961:22-962:13; *see also* Tr. (Sarrafczadeh) at 1093:22-1094:3. Complainants argue that the Apple specification cited by Mr. Land is unreliable, because it is dated July 2013—two years before the release of the Apple Watch Series 0—and it does not show the convex back surface that is in the final product. CIB at 216-17; CRB at 127; *see* Tr. (Madisetti) at 1356:10-22.

In consideration of the parties’ arguments, the undersigned finds that Apple has shown by clear and convincing evidence that the Apple Watch Series 0 meets the “light block” limitation of the ’745 patent claim 1. Mr. Land identified the Apple engineering requirement specification document as one that corresponds to the Apple Watch Series 0. Tr. (Land) at 961:7-21 (identifying RX-0396C). He described the optical path diagram in that document as “a schematic for some of the major elements in the Apple Watch.” *Id.* at 961:22-962:13. The fact

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that the diagram does not show other features of the Apple Watch, such as the curved back crystal, is irrelevant to this limitation. Mr. Land's testimony and the diagram from Apple's specification clearly show that the Apple Watch Series 0 had the claimed "light block."

(vii) Element [1F]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

Apple contends that the Apple Watch Series 0 has a processor that receives signals from the photodiodes and calculates a pulse rate. RIB at 183; *see* Tr. (Sarrafzadeh) at 1094:4-9; Tr. (Land) at 959:3-13; RX-0392C.011. Complainants do not specifically dispute this limitation. *See* CIB at 212-24; CRB at 122-27.

(viii) Element [9]: "wherein the physiological parameter comprises oxygen saturation"

Claim 9 of the '745 patent depends from claim 1, "wherein the physiological parameter comprises oxygen saturation." The Apple Watch Series 0 does not measure oxygen saturation, but Dr. Sarrafzadeh offered his opinion that pulse oximetry would have been obvious to a person of ordinary skill in the art because such devices have been known since the 1970s. Tr. (Sarrafzadeh) at 1094:10-17. Apple cites testimony from Dr. Mehra that "pulse oximetry as a feature is essentially heart rate sensing, but comparing the amplitude of the signal at two different colors of light or wavelengths of light." Tr. (Mehra) at 852:7-17. Dr. Waydo testified that Apple's later development of a blood oxygen sensor built on its work on heart rate detection, because "the blood oxygen sensor is a PPG of photoplethysmography sensor, much like the heart rate sensors." Tr. (Waydo) at 923:12-23. Dr. Mannheimer testified that "putting a couple of LEDs in a Series 0 watch form factor" would produce a blood oxygen measurement, "but not to the level that we were looking for." Tr. (Mannheimer) at 1015:9-19.

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Complainants argue that Apple failed to identify what modifications to the Apple Watch Series 0 would be necessary to measure oxygen saturation. CIB at 218-20. Complainants further identify evidence that Apple engineers expressed skepticism regarding Apple's likelihood of success in implementing an oxygen saturation measurement in the Apple Watch. *See* Tr. (Mannheimer) at 1012:12-16; CX-0299C (Waydo Dep. Tr.) at 166:4-167:5; CX-0295C (Shui Dep. Tr.) at 108:15-21. Complainants argue that it is unlikely that one of ordinary skill in the art would have been successful in modifying the Apple Watch Series 0 to measure oxygen saturation when the record shows that Apple's team of engineers worked for several years after the Apple Watch's release to implement this feature. CIB at 220.

In consideration of the parties' arguments, the undersigned finds that Apple has failed to offer clear and convincing evidence that one of ordinary skill in the art would have modified the Apple Watch Series 0 to measure oxygen saturation with a reasonable expectation of success. Apple cites the testimony of its engineers that adding some LEDs would make it possible to measure oxygen saturation, but there is no clear explanation of the modifications that would be necessary. *See* Tr. (Mannheimer) at 1015:9-19. The Federal Circuit has found such generalized arguments for combining prior art features to be insufficient, holding that it may be necessary to provide "a clear, evidence-supported account of the contemplated workings of the combination" as "a prerequisite to adequately explaining and supporting a conclusion that a relevant skilled artisan would have been motivated to make the combination and reasonably expect success in doing so." *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017). Here, Apple has failed to explain how the addition of LEDs for measuring blood oxygen would have been implemented, and whether these modifications would affect other limitations of the '745

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patent—such as the Fresnel lens that Apple relies on for the “second shape” limitation.⁸¹ In addition, the record contains testimony from multiple Apple engineers expressing skepticism regarding the implementation of pulse oximetry in the Apple Watch. *See* Tr. (Mannheimer) at 1012:12-16; CX-0299C (Waydo Dep. Tr.) at 166:4-167:5; CX-0295C (Shui Dep. Tr.) at 108:15-21. Apple has thus failed to show how one of ordinary skill in the art would have modified the Apple Watch Series 0 to measure blood oxygen and has failed to show, clearly and convincingly, that that there would have been a reasonable expectation of success in making any such modifications.

Accordingly, the evidence fails to show that claim 9 of the ’745 patent is obvious in view of the Apple Watch Series 0, because Apple has not clearly and convincingly shown that the Apple Watch Series 0 has a material that changes emitted light from a “first shape” to a “second shape,” or that it would have been obvious for one of ordinary skill in the art to modify the Apple Watch Series 0 to have a “dark-colored coating” or to measure oxygen saturation.

b. ’745 Patent Claim 27

(i) Element [20 preamble]: “A system configured to measure one or more physiological parameters of a user”

The preamble of claim 20 of the ’745 patent requires “[a] system configured to measure one or more physiological parameters of a user,” including “a physiological monitoring device.” As discussed above in the context of the preamble of ’745 patent claim 1, there is no dispute that the Apple Watch Series 0 is a “physiological monitoring device” because it contains a heart rate sensor. *See* RIB at 184.

⁸¹ When Apple implemented a blood oxygen feature in the Apple Watch Series 6, the Fresnel lens was removed in favor of a microlens array. *See* Tr. (Venugopal) at 836:3-838:25.

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(ii) Element [20A]: “a plurality of light-emitting diodes configured to emit light in a first shape”

Claim 20 has a “plurality of light-emitting diodes” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that the Apple Watch Series 0 has four LEDs that emit light in a shape. *See* RIB at 179, 185.

(iii) Element [20B]: “a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue”

Claim 20 has a “material configured to change the first shape into a second shape” limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the undersigned finds that Apple has not shown that the Apple Watch Series 0 has a material that changes a “first shape” into a “second shape.”

(iv) Element [20C]: “a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light”

Claim 20 has a “plurality of photodiodes” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that the Apple Watch Series 0 has two photodiodes that detect light after it interacts with the user’s tissue. *See* RIB at 181, 185.

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- (v) **Element [20D]: “a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface”**

Claim 20 has a “surface comprising a dark-colored coating” limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, Apple has not shown that the Apple Watch Series 0 has a surface comprising a dark-colored coating or that one of ordinary skill in the art would have added such a coating.

- (vi) **Element [20E]: “a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue”**

Claim 20 has a “light block” limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the evidence shows that the Apple Watch Series 0 has a light block that prevents at least a portion of light from the LEDs from reaching the photodiodes.

- (vii) **Element [20F]: “a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal”**

Claim 20 has a “processor” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that the Apple Watch Series 0 has a processor that receives signals from the photodiodes and calculates a pulse rate. *See* RIB at 183, 185.

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- (viii) **Element [20G]: “a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data”**

Apple contends and provided testimony that the Apple Watch Series 0 wirelessly communicates with an Apple iPhone comprising a user interface including a touch-screen display, a storage device, and a wireless interface. RIB at 185; *see* Tr. (Sarrafzadeh) at 1095:17-1096:5. Complainants dispute whether Apple has shown that an iPhone could display the pulse rate measurement of an Apple Watch Series 0, however, arguing that Apple failed to identify any application on the iPhone for presenting any visual feedback responsive to any physiological parameter data. CIB at 223.⁸² In his testimony, Dr. Sarrafzadeh stated that the Apple Watch could wirelessly communicate with a cell phone such as an iPhone, and that “the app can provide a visual feedback to show the physiological parameters,” thus showing that this limitation is met. *See* Tr. (Sarrafzadeh) at 1095:17-1096:5; RDX-7.94C. While Dr. Sarrafzadeh did not identify a particular app for these application, his testimony is unrebutted, and Apple’s public statements at the time of the release of the Apple Watch Series 0 described “Apple Watch’s health and fitness features” and offered customers assistance “to pair their Apple Watch with their iPhone.” RX-0023.

⁸² Apple argues that this argument has been waived, RRB at 102, but Complainants’ pre-hearing brief includes a contention that “Apple provides no evidence to show how an iPhone meets the elements within [20G].” CPHB at 164.

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- (ix) Element [27]: “wherein at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength”**

Claim 27 of the '745 patent depends from claim 20, further requiring that “at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength.” Apple submits that the Apple Watch Series 0 has green and infrared LEDs. RIB at 185; *see* Tr. (Sarrafzadeh) at 1096:6-10; Tr. (Land) at 959:3-13; Tr. (Venugopal) at 819:1-7, 820:16-821:11; RX-0392C.006 (Apple specification) at Fig. 2. Complainants do not specifically dispute this limitation. *See* CIB at 212-24; CRB at 122-27.

For the reasons discussed above, the evidence of record fails to show that claim 27 of the '745 patent is obvious in view of the Apple Watch Series 0. Apple has not shown, clearly and convincingly, that the Apple Watch Series 0 has a material that changes emitted light from a “first shape” to a “second shape,” and Apple has not shown, clearly and convincingly, that it would have been obvious to modify the Apple Watch Series 0 to have a “dark-colored coating” as required by the limitations of claim 20.

2. Iwamiya

U.S. Patent No. 8,670,819 is entitled “Optical Biological Information Detecting Apparatus and Optical Biological Information Detecting Method,” naming inventors Hiroshi Iwamiya and Shuji Nakajima, and assignee Casio Computer Co. Ltd. RX-0130 (“Iwamiya”). Iwamiya issued on March 11, 2014, from an application filed on June 29, 2010, *id.*, and

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accordingly it is prior art to the '745 patent pursuant to 35 U.S.C. § 102(a)(1). Apple contends that claims 9, 18, and 27 of the '745 patent are obvious in view of Iwamiya in combination with other prior art patents. RIB at 186-99; RRB at 102-09.

a. '745 Patent Claim 9

(i) Element [1 preamble]: “A physiological monitoring device comprising”

There is no dispute that Iwamiya discloses a “physiological monitoring device” because it discloses an “optical biological information detecting apparatus.” RX-0130; *see* RIB at 186; Tr. (Sarrafzadeh) at 1098:8-12; Tr. (Madisetti) at 1359:8-1365:6.

(ii) Element [1A]: “a plurality of light-emitting diodes configured to emit light in a first shape”

There is no dispute that Iwamiya discloses light-emitting diodes emitting light in a shape. RX-0130 at 6:7-11, Fig. 4; *see* RIB at 186; Tr. (Sarrafzadeh) at 1098:13-18; RDX-7.100C; Tr. (Madisetti) at 1359:8-1365:6.

(iii) Element [1B]: “a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue”

There is no dispute that Iwamiya discloses an “annular light guide unit” that is positioned between the light-emitting diodes and a user’s wrist and changes the shape of the light into an annular shape. RX-0130 at 6:11:14 (“an annular guide unit 7 that guides the observation light emitted from the light emitting units 6 and annularly diffuses and irradiates the observation light with respect to a skin H”), 6:22-31 (describing location of light guide unit 7), *see* RIB at 186-87; Tr. (Sarrafzadeh) at 1098:19-1099:2; RDX-7.101C; Tr. (Madisetti) at 1359:8-1365:6.

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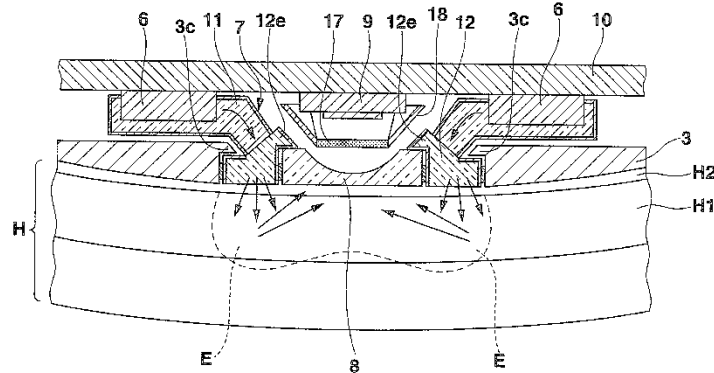


FIG.4

RX-0130 at Fig. 4.

- (iv) **Element [1C]: “a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light”**

There is no dispute that Iwamiya discloses a plurality of photodiodes that output a signal responsive to light that is reflected from a user’s tissue. RX-0130 at 8:20-23, Fig. 4; *see* RIB at 187-88; Tr. (Sarrafzadeh) at 1099:3-6, 1105:12-16; RDX-7.102C; Tr. (Madisetti) at 1359:8-1365:6.

- (v) **Element [1D]: “a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface”**

Apple identifies a “light shielding frame” that surrounds the photodiodes in Iwamiya, RX-0130 at 8:38-42, and Dr. Sarrafzadeh testifies that it would have been obvious to add a dark-colored coating to this surface, and one example of such a coating is disclosed in Sarantos. Tr.

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(Sarrafzadeh) at 1099:7-15; RDX-7.103C (citing RX-0366 at 17:6-16, Fig. 22).⁸³

Dr. Sarrafzadeh submits that both Iwamiya and Sarantos are wrist-worn physiological monitoring devices, and one of ordinary skill in the art would have been motivated to add a dark-colored coating to Iwamiya to enhance the light shielding. Tr. (Sarrafzadeh) at 1100:15-1101:4.

Dr. Sarrafzadeh testified that one of ordinary skill in the art would have expected success in implementing the “low-tech” and “low cost” addition of a dark-colored coating. *Id.* at 1101:5-10. Dr. Sarrafzadeh further cites Webster’s disclosure that “black opaque material” can be an effective light shield. *Id.* at 1100:22-1101:4; RDX-7.109C; RX-0035 at 202.

Complainants argue that one of ordinary skill in the art would not have been motivated to add a dark-colored coating to Iwamiya because Iwamiya discloses “light shielding” that uses a reflective material. *See* Tr. (Madisetti) at 1361:9-12 (citing RX-0130 at 18:61-65). In reply, Apple argues that the reflective light shielding is disclosed in a separate embodiment of Iwamiya that is not relevant to the Figure 4 embodiment identified by Dr. Sarrafzadeh. RRB at 106-07.

In consideration of the parties’ arguments, the undersigned finds that the evidence clearly and convincingly shows a reason to use a dark-colored coating for the “light shielding frame” in Figure 4. Dr. Sarrafzadeh convincingly explains that one of ordinary skill in the art would have reason to use a dark-colored coating, such as that disclosed in Sarantos, to improve the light-shielding properties of the Figure 4 embodiment, and that one of ordinary skill in the art would have expected success in implementing this change. While Iwamiya discloses a reflective light shielding component with respect to another embodiment (RX-0130 at 18:61-65), this does not

⁸³ Sarantos is U.S. Patent No. 9,392,946, which names inventors Chris W. Sarantos and Peter W. Richards, and issued from an application filed on May 28, 2015. RX-0366. Accordingly, Sarantos is prior art to the ’745 patent pursuant to 35 U.S.C. § 102(a)(2).

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teach away from the use of other light shielding options or enhancements known in the art, particularly with respect to the Figure 4 embodiment, which does not mention “reflective” shielding. *See, e.g., Syntex (U.S.A.) LLC v. Apotex*, 407 F.3d 1371, 1379 (Fed. Cir. 2005) (“What a reference teaches a person of ordinary skill is not . . . limited to what a reference specifically ‘talks about’ . . . a reference will teach way when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the applicant’s invention . . .”).

- (vi) **Element [1E]: “a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue”**

There is no dispute that Iwamiya discloses reflection layers 13 and 15 that are light blocks configured to prevent light from the light-emitting diodes from reaching the photodiodes without first reaching the tissue. RX-0130 at 6:67-7:3, 7:45-49, Fig. 3; *see* RIB at 189-90; Tr. (Sarrafzadeh) at 1099:16-21; RDX-7.104C; Tr. (Madisetti) at 1359:8-1365:6.

- (vii) **Element [1F]: “a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal”**

There is no dispute that Iwamiya discloses a CPU that receives and processes signals from the photodiodes and “outputs the data as biological information” that represents a physiological parameter. RX-0130 at 9:40-43, Fig. 10; *see* RIB at 190-91; Tr. (Sarrafzadeh) at 1099:22-1100:1; RDX-7.105C; Tr. (Madisetti) at 1359:8-1365:6.

- (viii) **Element [9]: “wherein the physiological parameter comprises oxygen saturation”**

Claim 9 of the ’745 patent depends from claim 1, “wherein the physiological parameter comprises oxygen saturation.” Dr. Sarrafzadeh testified that this limitation is obvious in view of

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Iwamiya's disclosure of a measurement of "biological information," because oxygen saturation is a type of biological information. Tr. (Sarrafzadeh) at 1100:2-8; RDX-7.106C; *see* RX-0130 at 9:1-7. Apple further submits that the prior art Sarantos reference explicitly discloses a measurement of oxygen saturation, explaining that "[i]f multiple light-emitting devices are used . . . photoplethysmographic techniques may also be used to measure other physiological parameters besides heart rate, such as blood oxygenation levels." RX-0366 at 13:44-47; *see* Tr. (Sarrafzadeh) at 1100:9-14. Dr. Sarrafzadeh offered his opinion that one of ordinary skill in the art would have been motivated to use the teaching in Sarantos to measure oxygen saturation in Iwamiya because both references describe wrist-worn physiological monitoring devices, and measuring oxygen saturation would enhance Iwamiya's device. Tr. (Sarrafzadeh) at 1100:15-20, 1101:12-19. Dr. Sarrafzadeh also offered his opinion that such a combination would be successful based on Sarantos's suggestion and the existence of oxygen saturation measurement devices in the prior art. *Id.* at 1101:20-1102:1.

Complainants argue that Iwamiya's disclosure of a measurement of "biological information" is insufficient to show a measurement of oxygen saturation. CIB at 225-26. Dr. Madisetti explained that Iwamiya only disclosed the use of one wavelength of light, which would be insufficient for measuring oxygen saturation. Tr. (Madisetti) at 1359:22-1361:1; CDX-0012C.065. Moreover, the only "biological information" disclosed in Iwamiya is heart rate. RX-0130 at 9:1-7 ("pulse wave"); *see* Tr. (Madisetti) at 1360:2-4. Complainants further identify an optical filter disclosed in Iwamiya that would block light below 900nm, which would preclude the wavelengths necessary for pulse oximetry. CIB at 227 (citing RX-0130 at 8:42-47, 18:55-60). Sarantos is also not primarily designed for the wavelengths necessary for pulse oximetry, noting that "[t]he aspect ratios and dimensional values discussed herein are tailored

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based on the green/yellow light spectrum and are not tailored for use in other spectrums, such as the red or infrared spectra.” RX-0336 at 18:48-51. Complainants further argue that Apple has failed to identify a reason for combining Iwamiya and Sarantos or to show that such a combination would have a reasonable expectation of success. CIB at 228-30; CRB at 128-29.

In consideration of the parties’ arguments, the undersigned finds that Apple has failed to show by clear and convincing evidence that it would have obvious for one of ordinary skill to combine Iwamiya and Sarantos to measure oxygen saturation. Because Iwamiya only discloses the use of one wavelength of light, the evidence indicates that one of ordinary skill in the art would not have been able to use the device in Iwamiya to measure oxygen saturation. Tr. (Madisetti) at 1359:22-1361:1. Moreover, Iwamiya operates at wavelengths that are not appropriate for pulse oximetry. See RX-0130 at 8:42-47; CIB at 227 (Iwamiya blocks light below 900 nm). Sarantos includes a suggestion to use multiple emitters with PPG sensors to measure blood oxygenation levels, but the only reason that Dr. Sarrafzadeh identifies for adding such a feature is that it “would enhance, by way of example, what the biological information of Iwamiya is.” Tr. (Sarrafzadeh) at 1101:12-19. The Federal Circuit has held that such generic expert testimony is insufficient for obviousness. See *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (where expert testified that a motivation would have been “to build something better,” the court found that “[t]his testimony is generic and bears no relation to any specific combination of prior art elements.”).⁸⁴

⁸⁴ Moreover, Apple fails to explain how the multiple emitters described in Sarantos would have been implemented in Iwamiya in a way that is compatible with the annular light guide that is necessary to meet the “second shape” limitation. See *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017) (reversing a finding of obviousness where the record lacked “a clear, evidence-supported account of the contemplated workings of the combination”).

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Apple also has not clearly and convincingly shown that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Iwamiya to measure oxygen saturation—the record contains testimony from multiple Apple engineers expressing skepticism regarding the implementation of pulse oximetry in a wrist-worn device. *See* Tr. (Mannheimer) at 1012:12-16; CX-0299C (Waydo Dep. Tr.) at 166:4-167:5; CX-0295C (Shui Dep. Tr.) at 108:15-21.

Accordingly, Apple has failed to show that claim 9 of the '745 patent is obvious in view of Iwamiya in combination with Sarantos, because Apple has not shown, clearly and convincingly, that it would have been obvious to one of ordinary skill in the art to modify the device disclosed in Iwamiya with the teachings in Sarantos regarding a measurement of oxygen saturation with a reasonable expectation of success.

b. '745 Patent Claim 18

(i) Element [15 preamble]: “A physiological monitoring device comprising:”

There is no dispute that Iwamiya discloses a “physiological monitoring device” as required by the preamble of claim 15, as discussed above in the context of the preamble of claim 1. *See* RIB at 193.

(ii) Element [15A]: “a plurality of light-emitting diodes configured to emit light proximate a wrist of a user”

There is no dispute that Iwamiya discloses light emitting diodes, as discussed above in the context of claim 1. *See* RIB at 193. Moreover, there is no dispute that Iwamiya discloses a device that is worn on the wrist. *See* RX-0130 at 4:54-5, Fig. 4.

(iii) Element [15B]: “a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a

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**tissue measurement site on the wrist of the user when the
physiological monitoring device is in use”**

There is no dispute that Iwamiya discloses an “annular light guide” that “annularly diffuses and irradiates the observation light.” RX-0130 at 6:10-14, Fig. 4; *see* Tr. (Sarrafzadeh) at 1103:10-15; RDX-7.116C. Moreover, there is no dispute that this annular light guide is positioned between the light-emitting diodes and the user’s wrist, as discussed above in the context of claim 1. *See* RIB at 193.

(iv) Element [15C]: “a light block having a circular shape”

There is no dispute that Iwamiya discloses reflection layers 13 and 15 that are light blocks, as discussed above in the context of claim 1. *See* RIB at 193-94. Figures 2 and 3 of Iwamiya show that these light blocks are arranged around the annular light guide in a circular shape. RX-0130 at 6:67-7:3, 7:45-49, Fig. 2, Fig. 3; *see* Tr. (Sarrafzadeh) at 1103:16-21; RDX-7.117C.

**(v) Element [15D]: “a plurality of photodiodes configured to detect
at least a portion of the light emitted from the plurality of
light-emitting diodes after the light passes through the light
diffusing material and a portion of the tissue measurement site
encircled by the light block, wherein the plurality of
photodiodes are arranged in an array having a spatial
configuration corresponding to a shape of the portion of the
tissue measurement site encircled by the light block”**

There is no dispute that Iwamiya discloses a plurality of photodiodes configured to detect light that is reflected from a user’s tissue, as discussed above in the context of claim 1. *See* RIB at 194-95. Iwamiya further describes “the plural light receiving units **9** preferably disposed on the same circumference centered on an optical axis of the scattered light taking unit **8**.” RX-0130 at 14:39-41, Fig. 4; *see* Tr. (Sarrafzadeh) at 1103:22-1104:5; RDX-7.118C. Dr. Sarrafzadeh testified that he believes this limitation is indefinite but that “using Masimo’s

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interpretation,” this limitation is disclosed by Iwamiya. See Tr. (Sarrafzadeh) at 1103:23-5; RDX-7.118C.

Complainants argue that the disclosure in Iwamiya identified by Apple is insufficient to teach a plurality of photodiodes “arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block.” CIB at 232; CRB at 130-31. Complainants submit that Iwamiya only depicts a single light receiving unit. See Tr. (Madisetti) at 1364:7-8. Complainants further cite a statement in the prosecution history of a parent application to the ’745 patent explaining that the plurality of detectors “must include sufficient detectors to represent such shapes.” CX-1760 at 322; see Tr. (Madisetti) at 1366:13-1367:19.

In consideration of the parties’ arguments, the undersigned finds that Iwamiya clearly discloses “plural light receiving units.” See RX-0130 at 14:36-41; Tr. (Sarrafzadeh) at 1103:23-1104:5; RDX-7.118C (citing RX-0130 at 14:39-41). These plural light receiving units are further described as “disposed on the same circumference centered on an optical axis of the scattered light taking unit.” *Id.* at 14:39-41; Tr. (Sarrafzadeh) at 1103:23-1104:5; RDX-7.118C. This disclosure of “plural” photodiodes that are “on the same circumference” at least renders the limitation requiring “a spatial configuration corresponding to a shape . . . encircled by the light block” to be *prima facie* obvious. See CRB at 131 (to meet [15D], “a plurality of photodiodes would need to be arranged in a circular-shaped array”). Iwamiya’s “plural light receiving units” is a plurality,⁸⁵ and the “same circumference” corresponds to a shape encircled by the light block. See RX-0130 at 14:36-41.

⁸⁵ Complainants cite statements in the prosecution history of a parent application to the ’745 patent where the applicant suggested that up to six detectors may be needed to represent a circular shape. See CX-1760

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- (vi) **Element [15E]: “wherein the plurality of photodiodes are further configured to output at least one signal responsive to the detected light”**

There is no dispute that the photodiodes in Iwamiya are configured to output a signal responsive to the detected light, as discussed above in the context of claim 1. *See* RIB at 195.

- (vii) **Element [15F]: “wherein the plurality of light-emitting diodes and the plurality of photodiodes are arranged in a reflectance measurement configuration”**

There is no dispute that the light-emitting diodes in Iwamiya are arranged in a reflectance measurement configuration with the photodiodes on the same side of the tissue. *See* RIB at 195; Tr. (Sarrafzadeh) at 1104:11-15; RDX-7.119C; Tr. (Madisetti) at 1359:8-1365:6.

- (viii) **Element [15G]: “wherein the light block is configured to optically isolate the plurality of light-emitting diodes from the plurality of photodiodes by preventing at least a portion of light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the portion of the tissue measurement site”**

There is no dispute that the light blocks in Iwamiya are configured to prevent light from the light-emitting diodes from reaching the photodiodes without first reaching the tissue, as discussed above in the context of claim 1. *See* RIB at 195-96.

- (ix) **Element [15H]: “a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal”**

There is no dispute that Iwamiya discloses a CPU that receives and processes signals from the photodiodes and determines a physiological parameter, as discussed above in the context of claim 1. *See* RIB at 196.

at 322. Both a “plural” and a “plurality” could include six photodiodes. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“In cases involving overlapping ranges, we and our predecessor courts have consistently held that even a slight overlap in range establishes a prima facie case of obviousness.”).

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- (x) Element [15I]: “wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor”**

Apple relies on Venkatraman in combination with Iwamiya for the limitation requiring that the physiological parameter can be transmitted to a separate processor. RIB at 196-97.⁸⁶ Venkatraman discloses a biometric device that can communicate with a secondary device (e.g., a smartphone) through a wired or wireless connection. RX-0368 at 30:66-31:35. “The biometric monitoring device may send biometric and other data to the smartphone in real-time or with some delay.” *Id.* at 57:44-46. Venkatraman describes numerous benefits to using a biometric device with a smartphone app. *See id.* at 57:20-59:13. Dr. Sarrafzadeh testified that it would have been obvious to one of ordinary skill in the art to combine Iwamiya’s device with the secondary device of Venkatraman because such connections were well known to enhance such devices. Tr. (Sarrafzadeh) at 1105:24-1106:7, 1108:9-18. Dr. Sarrafzadeh also testified that a person of ordinary skill in the art would have had a reasonable expectation of success, “because adding these external devices was known for quite a bit of time.” *Id.* at 1106:8-11, 1108:19-23. Complainants do not dispute that the evidence shows a reason to combine Iwamiya with Venkatraman, and a reasonable expectation of success, with regard to this limitation. *See* Tr. (Madisetti) at 1359:8-1365:6.

- (xi) Element [18]: “wherein the physiological parameter comprises oxygen saturation”**

Claim 18 of the ’745 patent depends from claim 15, “wherein the physiological parameter comprises oxygen saturation.” Apple submits that the measurement of oxygen saturation is

⁸⁶ Venkatraman is U.S. Patent No. 8,998,815, which names inventors Subramaniam Venkatraman and Shelten Gee Jao Yuen, and issued on April 7, 2015. RX-0368. Accordingly, Venkatraman is prior art to the ’745 patent pursuant to 35 U.S.C. § 102(a)(1).

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obvious in view of Iwamiya in combination with Sarantos. *See* RIB at 197. For the reasons discussed above in the context of claim 9, Apple not shown, clearly and convincingly, that it would have been obvious to one of ordinary skill in the art to modify the device disclosed in Iwamiya with the teachings in Sarantos to implement a measurement of oxygen saturation with a reasonable expectation of success.

Accordingly, the evidence fails to clearly and convincingly show that claim 18 of the '745 patent is obvious in view of Iwamiya in combination with Sarantos and Venkatraman.

c. '745 Patent Claim 27

(i) Element [20 preamble]: “A system configured to measure one or more physiological parameters of a user, comprising:”

The preamble of claim 20 of the '745 patent requires “[a] system configured to measure one or more physiological parameters of a user,” including “a physiological monitoring device.” As discussed above in the context of the preamble of '745 patent claim 1, the evidence shows that Iwamiya discloses a “physiological monitoring device” because it contains a heart rate sensor. *See* RIB at 186, 197.

(ii) Element [20A]: “a plurality of light-emitting diodes configured to emit light in a first shape”

Claim 20 has a “plurality of light-emitting diodes” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses light-emitting diodes emitting light in a shape. *See* RIB at 186, 197.

(iii) Element [20B]: “a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the

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plurality of light-emitting diodes is projected towards the tissue”

Claim 20 has a “material configured to change the first shape into a second shape” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses an “annular light guide unit” that is positioned between the light-emitting diodes and a user’s wrist and changes the shape of the light from a first shape to a second shape. *See* RIB at 186-87, 197

- (iv) **Element [20C]: “a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light”**

Claim 20 has a “plurality of photodiodes” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses a plurality of photodiodes that output a signal responsive to light that is reflected from a user’s tissue. *See* RIB at 187-88, 197.

- (v) **Element [20D]: “a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface”**

Claim 20 has a “surface comprising a dark-colored coating” limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the undersigned finds that one of ordinary skill in the art would have had a reason to use a dark-colored coating in the device disclosed in Iwamiya and would have had a reasonable expectation of success.

- (vi) **Element [20E]: “a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting**

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diodes from reaching the plurality of photodiodes without first reaching the tissue”

Claim 20 has a “light block” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses light blocks configured to prevent light from the light-emitting diodes from reaching the photodiodes without first reaching the tissue. *See* RIB at 189-90, 197.

(vii) Element [20F]: “a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal”

Claim 20 has a “processor” limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses a CPU that receives and processes signals from the photodiodes to determine a physiological parameter. *See* RIB at 190-91, 197.

(viii) Element [20G]: “a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data”

Apple relies on Venkatraman in combination with Iwamiya for the limitation that the physiological parameter can be transmitted to a separate processing device. RIB at 197-98; Tr. (Sarrafazadeh) at 1108:1-23; RDX-7.129C. Apple identifies disclosures in Venkatraman describing a connection between a biometric monitoring device and a smartphone. *See* RX-0368 at 30:66-31:35, 57:20-59:13. Complainants argue that Apple has failed to show that Venkatraman discloses a “touch-screen display configured to present visual feedback responsive to the physiological parameter data.” CRB at 132.

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In consideration of the parties' arguments, and for the reasons discussed above in the context of claim 15, the undersigned finds that one of skill in the art would have reason to connect the biometric device in Iwamiya with a smartphone as taught in Venkatraman with a reasonable expectation of success. *See* Tr. (Sarrafzadeh) at 1105:24-1106:11. The undersigned finds that one of ordinary skill in the art would have understood that a smartphone is a processing device comprising a user interface, a storage device, and a network interface. *See id.* at 1108:1-8. Moreover, Venkatraman explicitly discloses a smartphone app that displays biometric information on a touchscreen. *See* RX-0368 at 57:54-58:6 (“The user may be able to see these and other metrics on the dashboard . . . They may be able to access previous days by pressing a button or icon on a touchscreen.”). Accordingly, each of the elements of the “processing device” limitation are clearly disclosed in Venkatraman, and one of ordinary skill would have reason to connect the biometric device in Iwamiya with a smartphone as taught in Venkatraman with a reasonable expectation of success.

- (ix) Element [27]: “at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength”**

Claim 27 of the '745 patent depends from claim 20, further requiring that “at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength.” There is no dispute that Iwamiya only discloses the use of one wavelength of light. *See* Tr. (Madisetti) at 1359:22-1366:1; RX-0130 at 10:34-38. Apple contends that this limitation would have been obvious to one of ordinary skill in the art in view of Iwamiya in combination with Sarantos, which provides

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that “it may be desirable to include separate light-emitting devices that are each able to emit different wavelengths of light” to measure other physiological parameters, such as blood oxygenation levels. RX-0366 at 13:44-58. Complainants argue that Apple has failed to show that one of ordinary skill in the art would have combined Iwamiya with Sarantos with a reasonable expectation of success. CIB at 228-30; CRB at 128-30.

For the same reasons discussed above in the context of ’745 patent claim 9, the undersigned finds that Apple has not shown by clear and convincing evidence that one of ordinary skill would have been able to combine Iwamiya and Sarantos to use two wavelengths of light with a reasonable expectation of success. The only specific motivation for using multiple emitters disclosed in Sarantos is for measuring oxygen saturation, *see* RX-0366 at 13:44-47, and as discussed *supra*, the evidence does not clearly and convincingly show that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Iwamiya to measure oxygen saturation.

Accordingly, the evidence fails to show that claim 27 of the ’745 patent is obvious in view of Iwamiya in combination with Sarantos, because Apple has not shown, clearly and convincingly, that one of ordinary skill in the art would have had a reason to modify the device disclosed in Iwamiya with the teachings in Sarantos regarding the use of two wavelengths with a reasonable expectation of success.

3. Objective Considerations of Non-Obviousness

Complainants contend that certain objective indicia discussed above in the context of the Poeze patents support a finding of non-obviousness for the claims of ’745 patent, including Apple’s skepticism and failures in implementing wrist-based pulse oximetry and the commercial

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success of the Apple Watch Series 6. CIB at 233-34; CRB at 132-33. Apple disputes whether this evidence is relevant to the obviousness of the '745 patent claims. RIB at 199-201; RRB at 109-110.

For the reasons discussed above in the context of the Poeze patents, this evidence does not weigh significantly against a finding of obviousness.⁸⁷ For the reasons discussed above, however, the evidence does not provide a clear and convincing showing of obviousness for the claims of '745 patent.

H. Invalidity – Written Description and Enablement

Apple contends that the asserted claims of the '745 patent are invalid for lack of written description and/or indefiniteness pursuant to 35 U.S.C. § 112. RIB at 201-04; RRB at 110-11.

1. Written Description (Claims 1, 9, 20, 27)

Apple argues that claims 1 and 20 of the '745 patent, from which asserted claims 9 and 27 depend, are invalid for lack of written description with respect to a “surface comprising a dark-colored coating . . . wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface” in an embodiment where the sensors are in a reflectance configuration. RIB at 201-02. In the context of the fingertip sensor 300 depicted in Figures 3 and 4, the specification describes a “light-absorbing detector filter 306 “having a top surface coated with a “light-absorbing material” that “can be a black opaque material or coating or any other dark color or coating configured to absorb light.” JX-009 at 9:31-36, Fig. 3, Fig. 4A. The specification describes a separate embodiment depicted in Figures 7A and 7B that is “a 3D reflective pulse oximetry sensor 700”

⁸⁷ The evidence of commercial success is not relevant because the Accused Products have not been shown to practice claims of the '745 patent.

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with an annular “light block 706.” *Id.* at 10:40-51, Fig. 7A, Fig. 7B. Dr. Sarrafzadeh testified that “there is no description on how to combine these embodiments in the description of the patent.” Tr. (Sarrafzadeh) at 1110:24-1111:2. Apple argues that the specification thus fails to describe the claimed invention “as an integrated whole” with a dark-colored coating used with a reflectance sensor. RIB at 202; RRB at 110 (citing *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013)).

Complainants submit that the specification explicitly links the two embodiments together: “In other embodiments, for example, as describe [sic] below with respect to FIGS. 7A and 7B, the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site 102.” JX-009 at 7:4-14. Dr. Madisetti identified a light concentrator (labeled 308 and 708 in the specification) that is common to both the Figure 3 and Figure 7 embodiments and “links all these embodiments together.” Tr. (Madisetti) at 1365:7-1366:8 (citing JX-009 at 9:30-40).

Complainants argue that these disclosures show that the two embodiments are not distinct but are linked together. CIB at 235-36; CRB at 133-34.

The evidence fails to show, clearly and convincingly, a lack of adequate written description support for the “dark-colored coating” limitations of claims 1 and 20. The undersigned agrees with Complainants that the specification describes common elements in the Figure 3 fingertip sensor and the Figure 7 reflectance sensor, explicitly suggesting that “the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site,” thus supporting Dr. Madisetti’s opinion that one of ordinary skill would link these embodiments. JX-009 at 7:4-14; Tr. (Madisetti) at 13:65:7-1366:8. Moreover, with respect to the light blocker 706 in the Figure 7 embodiment, the specification explicitly provides that “[t]he light blocker 706 and the cover 707 can be made of any material that optically isolates the light concentrator 708

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and the detector 710.” *Id.* at 11:14-16, Fig. 7B.⁸⁸ This disclosure of “any material” for light blocking further supports Dr. Madisetti’s opinion that the “light-absorbing material” described earlier in the specification in reference to Figure 4A, including “a black opaque material or coating or any other dark color or coating configured to absorb light,” is linked to the Figure 7 embodiment. JX-009 at 9:31-36; Tr. (Madisetti) at 1365:7-1366:8; CDX-0012C.081. The Federal Circuit has held that “the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba.*” *Ariad*, 598 F.3d at 1352 (citations removed). Apple’s argument that the dark-colored coating is distinct from the reflectance sensor embodiment is unconvincing in view of these disclosures in the specification.

Accordingly, based on the evidence of record, Apple has not shown clearly and convincingly that claims 1 or 20 of the ’745 patent are invalid for lack of written description.

2. Indefiniteness (Claims 15, 18)

Apple argues that claim 15 of the ’745 patent, from which asserted claim 18 depends, is invalid for indefiniteness with respect to the limitation requiring a plurality of photodiodes “arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block.” RIB at 202-04; RRB at 110-11. Dr. Sarrafzadeh testified that one of ordinary skill in the art would not have been able to determine which shape corresponds to an arrangement of photodiodes, providing an example of four photodiodes that could correspond to many different shapes. Tr. (Sarrafzadeh) at 1111:3-18; RDX-7.134C. Apple argues that this ambiguity regarding how a spatial configuration

⁸⁸ Figure 7 also appears to show shows a positioning of a surface of the light blocker 706 between the tissue and photodiode, similar to the positioning of element 306 in Fig. 3.

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corresponds to a shape renders this limitation indefinite, because one of skill in the art would not be able to determine the scope of the invention with reasonable certainty. RIB at 202-04 (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 57 U.S. 898, 910 (2014)).

Complainants argue that Apple has not met its clear and convincing burden to prove indefiniteness. CIB at 236-38. Complainants submit that Dr. Sarrafzadeh failed to consider the surrounding claim language and other evidence in the intrinsic record defining the scope of this limitation. *Id.* at 237-38. Complainants submit that the “shape” of the configuration of photodiodes is defined by the light block, which has “a circular shape.” *See* JX-009 at 16:43-52. Complainants further rely on statements in the prosecution history of the ’745 patent that discuss “sufficient detectors to represent such shapes,” with an example that “six or more detectors could be arranged in an annular shape and meet the recited limitation.” CX-1760 at 322; *see also id.* (indicating that two or three detectors would be insufficient). Dr. Madisetti relied on these disclosures and offered his opinion that this limitation “would be understood by a person having ordinary skill in the art as requiring a sufficient number of detectors, such that when arranged together in an array can match -- have a close similarity or present the at least partially circular shape of the irradiated portion of the tissue measurement site.” Tr. (Madisetti) at 1366:13-1367:19.

In consideration of the parties’ arguments, the undersigned agrees with Complainants that Apple has not shown, clearly and convincingly, that the claimed arrangement of photodiodes in a “spatial configuration corresponding to a shape” is indefinite. In particular, Dr. Sarrafzadeh’s testimony relying on hypothetical shapes drawn through an arrangement of photodiodes fails to read this term within the context of claim 15’s surrounding language. *See* CIB at 236-37. The “shape” referenced in this limitation is “a shape of the portion of the tissue measurement site

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encircled by the light block.” To determine whether a device meets this limitation, one of ordinary skill in the art would not draw arbitrary shapes around the photodiodes, as Dr. Sarrafzadeh appears to suggest, but would rather assess this limitation in relation to the “tissue measurement site encircled by the light block.” *See* Tr. (Madisetti) at 1366:13-1367:10. Apple has failed to show that one of ordinary skill in the art would be unable to determine whether the limitation is met by comparing the arrangement of photodiodes to the shape of the encircled tissue.⁸⁹

Accordingly, Apple has not shown by clear and convincing evidence that claim 15 of the ’745 patent is invalid for indefiniteness.

I. Prosecution Laches

Apple contends that the asserted claims of the ’745 patent are unenforceable due to prosecution laches. RIB at 204-05. Apple identifies the filing dates for provisional applications and continuation applications in the family of the ’745 patent and ties them to the release dates for Apple Watch products. *Id.* Apple argues that the ’745 patent should be held unenforceable due to prosecution laches because the application for the ’745 patent was filed nearly five years after the first provisional patent application in the family, and during this timeframe Apple invested heavily in the development of Apple Watch products and growing the market for wearable technology. *Id.*; RRB at 112.

Complainants argue that Apple has failed to show any unreasonable or unexplained delay in the prosecution of the ’745 patent. CIB at 238-39. Mr. Stoll described a “continuous

⁸⁹ As discussed above in the context of the domestic industry requirement, this limitation is met by photodiodes arranged in a circular array around the light block in the ’745 DI Products. As discussed above in the context of obviousness, this limitation is, at least, *prima facie* obvious in view of Iwamiya’s description of “plural light receiving units” that are “disposed on the same circumference” as the light block.

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unbroken chain of patent prosecution.” Tr. (Stoll) at 1415:2-10; *see* CX-1760 (’745 patent prosecution history). Complainants submit that the filing dates for applications in the ’745 patent family in 2015, 2016, 2018, 2019, and 2020 demonstrate active prosecution of patents in this family. CRB at 134.

In consideration of the parties’ arguments, the undersigned finds that Apple has failed to show that the ’745 patent should be found unenforceable due to prosecution laches. As discussed above in the context of the Poeze patents, prosecution laches requires a showing of unreasonable and inexcusable delay, and evidence sufficient to make that showing is lacking here. The record shows continuous prosecution activity from the filing of the original provisional application in 2015 to the issuance of the ’745 patent in 2020. *See* JX-009; CX-1760. Apple’s arguments tying certain patent application filings to release dates for the Apple Watch is unpersuasive, and the timeline is not consistent with Apple’s allegations that Masimo drafted claims to cover the Apple Watch. *See* CIB at 204-05.⁹⁰ Apple has not identified delay in the prosecution of the ’745 patent that would warrant a finding of prosecution laches.

VI. U.S. PATENT NO. 7,761,127

The ’127 patent is entitled “Multiple Wavelength Sensor Substrate,” naming inventors Ammar Al-Ali, Mohamed Diab, Marcelo Lamego, James P. Coffin, and Yassir Abdul-Hafiz and claiming priority to a provisional application filed on March 1, 2005, and a non-provisional application filed on March 1, 2006. JX-007.

⁹⁰ As discussed above, the Apple Watch Series 0 is prior art to the ’745 patent, so any claims drafted to cover this product would have been invalid as anticipated. In addition, the ’745 patent issued before the release of the Apple Watch Series 6 and the other Accused Products in this investigation, so the claims of the ’745 patent could not have been drafted based on any released Apple Watch with a blood oxygen feature.

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A. Specification

The specification of the '127 patent describes a physiological sensor with emitters transmitting radiation at multiple wavelengths and a thermal mass that stabilizes a bulk temperature for the emitters. JX-007 at Abstract, 10:22-26, Fig. 12. “A temperature sensor 1230 is thermally coupled to the thermal mass 1220” to measure the bulk temperature. *Id.* at 10:26-31. The specification explains that the wavelengths of the light emitters “are determinable as a function of the drive currents 1210 and the bulk temperature 1202.” *Id.*

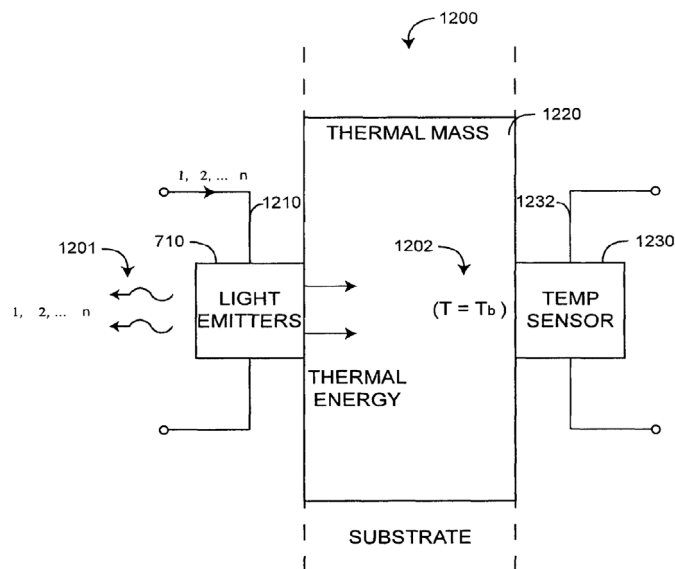


FIG. 12

Id. at Fig. 12. In particular, the operating wavelength λ_a of each light emitter is determined according to a function of the bulk temperature T_b , the drive current for the light emitter I_{drive} , and the total drive current for all light emitters ΣI_{drive} . *Id.* at 10:32-39.

The specification describes one embodiment where LEDs are mounted on a substrate, which is “configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful.” *Id.*

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at 10:67-11:4. A substrate depicted in Figure 14 has “a component layer 1401, inner layers 1402-1405, and a solder layer 1406.” *Id.* at 11:5-10.

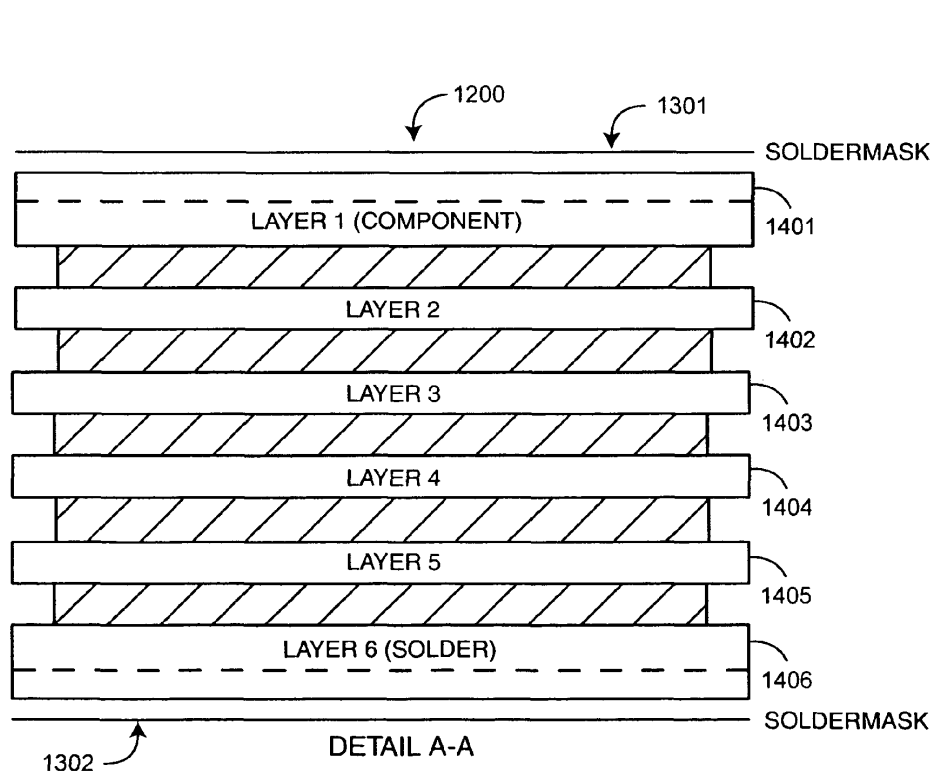


FIG. 14

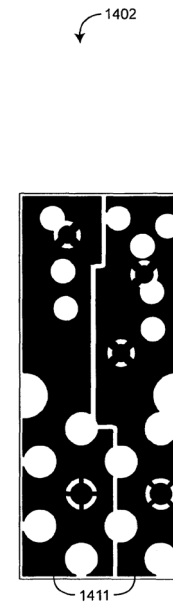


FIG. 18

Id. at Fig. 14, Fig. 18. Figure 18 depicts inner layer 1402 having “substantial metallized areas 1411 that provide a thermal mass 1220 (FIG. 12) to stabilize a bulk temperature for the emitter array 700 (FIG. 12).” *Id.* at 11:10-13.

B. Claims

Complainants assert claim 9 of the '127 patent, which depends from claim 7. The limitations of these claims are recited below:

7. A physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient, the physiological sensor comprising:

a thermal mass;

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a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass, the sources having a corresponding plurality of operating wavelengths, the thermal mass disposed within the substrate;

a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature; and

a detector capable of detecting light emitted by the light emitting sources after tissue attenuation, wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths.

JX-007 at 19:35-53.

9. The physiological sensor of claim 7 wherein the temperature sensor comprises a thermistor.

Id. at 19:58-59.

C. Level of Ordinary Skill in the Art

There is no dispute regarding the appropriate level of ordinary skill in the art for the '127 patent in this investigation. *See* CIB at 239; RIB at 209. Dr. Sarrafzadeh testified that a person of ordinary skill in the art would be a person with “working knowledge of physiological monitoring and thermal management technology, ... a Bachelor of Science in an academic discipline emphasizing design of electrical and thermal technologies in combination with training or at least one or two years of related work experience with processing of data information, including but not limited to physiological monitoring technology” and “if somebody had a Master of Science in relevant academic discipline with less than a year of related work experience, that would qualify.” Tr. (Sarrafzadeh) 1047:17-1048:4. Mr. Goldberg used this same level of ordinary skill for his analysis. *See* Tr. (Goldberg) at 1391:22-24.

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D. Claim Construction

The parties have agreed that a “plurality of wavelengths” is “two or more operating wavelengths.” *See* CIB at 239; RIB at 209; Updated Joint Proposed Claim Construction Chart at 1, EDIS Doc. ID 763856 (Feb. 23, 2022).

In their post-hearing briefs, the parties dispute the construction of two terms in claim 7 of the ’127 patent: “thermal mass” and “bulk temperature for the thermal mass.” CIB at 239-47; RIB at 213-15; CRB at 135-41; RRB at 114-23.⁹¹

1. “thermal mass”

“[A] thermal mass” is the first limitation in the body of claim 7, and the term “thermal mass” also appears in the “plurality of light emitting sources” limitation, requiring a substrate of the light emitting sources to be “thermally coupled to the thermal mass,” and in the “temperature sensor” limitation of claim 7, which requires “a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature.” JX-007 at 19:39-48.⁹²

Apple contends that a “thermal mass” is a component that stabilizes a bulk temperature. RIB at 213-14; RRB at 116-19. Apple states that the claimed thermal mass “stabilizes a bulk

⁹¹ Complainants argue that Apple never identified the terms “thermal mass” and “bulk temperature” during claim construction but relied on certain constructions to argue non-infringement. CIB at 239. Apple argues that Complainants’ proposed claim constructions are untimely and that, “[p]rior to Complainants’ initial post-hearing brief, no party requested constructions of ‘thermal mass’ or ‘bulk temperature for the thermal mass.’” RRB at 114. Given that, *inter alia*, both parties addressed claim construction in their initial post-hearing briefs, and testimony regarding this issue was presented at the hearing without objection, the parties’ claim construction arguments will be considered. *See, e.g.*, Tr. (Goldberg) at 618:9-21, 624:10-25; Tr. (Sarrafzadeh) at 1069:2-14, 1081:20-1082:8.

⁹² These limitations mirror disclosures in the specification, wherein “[a] temperature sensor 130 is thermally coupled to the thermal mass 1220, wherein the temperature sensor 1232 provides a temperature sensor output 1232 responsive to the bulk temperature 1202 so that the wavelengths are determinable as a function of the drive currents 1210 and the bulk temperature 1202.” JX-007 at 10:26-31.

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temperature,” such that “the thermistor is then able to meaningfully measure that ‘bulk temperature.’” RIB at 213. Apple argues that the term “thermal mass” does not refer simply to “the physical property of ‘thermal mass’ that is possessed by all objects with mass.” *Id.* Apple further contends that the existence of a thermal mass cannot simply be assumed “if the sensor estimates wavelength using a temperature measurement.” RRB at 117. In the context of invalidity, Apple argues that Complainants’ interpretation of the “thermal mass” limitation would cover any circuit board with multiple layers. RIB at 234-35. Apple submits that the consistent disclosures in the specification of the ’127 patent requires that the “thermal mass” is a component that stabilizes a bulk temperature. *Id.* at 213-14; RRB at 116-19.

Complainants propose to construe “thermal mass” to mean a “mass that provides a bulk temperature that can be used to reliably estimate the operating wavelengths of the LEDs.” CIB at 240-44; CRB at 136-38. Complainants argue that the term “thermal mass” is “described in terms of the ability to estimate wavelength from the temperature measurement of the thermal mass.” CIB at 243. Complainants do not specifically dispute that the “thermal mass” stabilizes a bulk temperature but argue that the temperature is not required to be constant—only sufficient to be used to reliably estimate the operating wavelengths of the LEDs. *Id.* at 234-44; CRB at 136-37. Complainants also argue that there is no basis for any requirement that the “thermal mass” have a minimum thickness. CIB at 234; CRB at 136.

Upon review of the parties’ submissions, the undersigned finds that the term “thermal mass” refers to a mass that stabilizes a bulk temperature. This is consistent with the use of the term within the specification, which provides that “[a] thermal mass 1220 is disposed proximate

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to the emitters 710 so as to stabilize a bulk temperature 1202 for the emitters.” *Id.* at 10:24-26.⁹³

The specification further describes a substrate that is “configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful.” *Id.* at 10:67-11:4. In a specific embodiment, a layer of a substrate is described as having “substantial metallized areas 1411 that provide a thermal mass 1220 (FIG. 12) to stabilize a bulk temperature for the emitter array 700 (FIG. 12).” *Id.* at 11:10-13.

The specification thus clearly describes a “thermal mass” that stabilizes a bulk temperature, and the parties do not appear to dispute this fact, although only Apple’s construction explicitly incorporates temperature stabilization. *See* RRB at 116-17; CIB at 240 (citing the specification’s disclosures that the “thermal mass” as “disposed proximate the emitters so as to stabilize a bulk temperature for the emitters” and “relatively significant so as to stabilize and normalize the bulk temperature.”).⁹⁴ Both Dr. Sarrafzadeh and Mr. Goldberg agreed that the ’127 patent describes the claimed thermal mass as stabilizing a bulk temperature. *See* Tr. (Sarrafzadeh) at 1069:7-22; Tr. (Goldberg) at 643:4-12.⁹⁵

⁹³ Claims 1 and 26 include “thermal mass” limitations that mirror these specification disclosures, describing “a thermal mass disposed proximate to the emitters and within the substrate so as to stabilize a bulk temperature for the emitters.” JX-007 at 19:9-11 (claim 1), 21:5-7 (claim 26).

⁹⁴ In the context of invalidity, Complainants argue that prior art references lack a “thermal mass” that “would stabilize a bulk temperature of the substrate,” or a component “that functions as a thermal mass by stabilizing a bulk temperature.” CIB at 279, 281.

⁹⁵ The parties also agree that the term “thermal mass,” as used in the patent, does not correspond simply to a physical property possessed by any mass. *See* Tr. (Goldberg) at 639:24-640:3 (noting distinction between “thermal mass in the context of the patent or the thermal mass . . . as a scientific principle of physics”); Tr. (Sarrafzadeh) at 1071:17-21 (distinguishing between “thermal mass of the patent” and the physical property of thermal mass of “any material”); RRB at 124-25.

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While Complainants do not explicitly dispute that the claimed thermal mass stabilizes a bulk temperature, they argue that Apple’s interpretation of stabilization is too narrow, requiring a minimum thickness for the thermal mass or stabilization at a constant temperature. CIB at 243; CRB at 136. Apple’s proposed construction does not require a minimum thickness or a constant temperature, however. *See* RRB at 118-19. Dr. Sarrafzadeh merely offered his opinion that certain metal layers could not be a “thermal mass” where “[t]hey are not really thick enough to provide any . . . thermal stability.” Tr. (Sarrafzadeh) at 1066:4-9.⁹⁶ The undersigned thus agrees with Apple that the claimed “thermal mass” is a mass that stabilizes a bulk temperature.⁹⁷

Complainants fail to explain why their proposed construction omits any requirement for temperature stabilization, arguing only that the “thermal mass” is a “mass that provides a bulk temperature that can be used to reliably estimate the operating wavelengths of the LEDs.” CIB at 240; *see* CRB at 136-38. Complainants further define “bulk temperature” to be “a single temperature used to estimate the operating wavelengths of all the LEDs.” CIB at 244. Substituting this definition into Complainants’ construction of “thermal mass,” Complainants’ proposed definition of “thermal mass” becomes “a mass that provides a single temperature used to estimate the operating wavelengths of all the LEDs, that can be used to reliably estimate the

⁹⁶ He also observed temperature variations in a circuit board, finding that it was “not at a uniform temperature through time or spatially” and that the temperature “is not stabilized.” *Id.* at 1078:23-1079:9. Dr. Sarrafzadeh’s analysis is consistent with Apple’s proposed construction and the specification’s description of “a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature.” JX-007 at 10:67-11:4, 11:10-13.

⁹⁷ Apple’s proposed construction describes the “thermal mass” as a “component” that stabilizes a bulk temperature, RIB at 213-14, but Apple does not explain why the claim term “mass” has been replaced with the word “component,” which does not appear in the claims or the relevant portions of the specification. Complainants have used the word “mass” in their proposed construction, *see* CIB at 240, and there does not appear to be any meaningful dispute regarding the meaning of the word “mass.” Accordingly, the undersigned shall construe the term “thermal mass” without substituting another word for “mass.”

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operating wavelengths of the LEDs” —or, effectively, “a mass that provides a single temperature used to reliably estimate the operating wavelengths of all the LEDs.” Complainants also make clear that the “single temperature” required for a bulk temperature need not be a uniform temperature but is simply a “single measurement.” *See* CIB at 246 (“bulk temperature” need not be a “uniform or average temperature.”); *id.* at 247 (explaining that bulk temperature “is a single measurement for the thermal mass”).

The intrinsic evidence fails to indicate that any mass of a non-uniform temperature, from which a single temperature measurement can be provided to estimate the operating wavelengths of all LEDs is, *ipso facto*, a “thermal mass.”

First, Complainants’ construction merely restates the language in the “temperature sensor” limitation of claim 7 while providing no meaning to the limitation requiring a “thermal mass.” *See* JX-007 at 19:45-48 (claim 7 requiring “a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature”). The Federal Circuit has held that “[i]t is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.” *Wasica Finance GmbH v. Continental Automotive Systems, Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017).

Further, the prosecution history of the ‘127 patent weighs against Complainants’ approach. Complainants rely on the prosecution history to show that the claims of the ‘127 patent were distinguished from prior art without a “thermal mass,” CIB at 242, CRB at 137-38, but it is clear from this record that the examiner did not understand the term “thermal mass” to only require an estimate of the operating wavelengths of the LEDs based on a single temperature measurement. In the relevant portion of the prosecution history of the ‘127 patent, the examiner

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considered a prior art reference, U.S. Patent No. 5,259,381 to Cheung et al. (RX-0406, “Cheung”), finding that Cheung “discloses all the elements of the current invention . . . except for the sensor comprising a thermal mass disposed proximate the emitters, wherein the thermal mass stabilizes a bulk temperature of the emitters.” JX-008 at 363, 433 (MASITC_00077988, 00078058) (rejecting, *inter alia*, prosecution claim 5, which ultimately issued in amended form as claim 7).⁹⁸ When discussing the prosecution history at the hearing, Mr. Goldberg agreed that “Cheung does not have a thermal mass.” Tr. (Goldberg) at 1395:13-15. Despite the lack of a “thermal mass,” the examiner recognized that Cheung discloses a “temperature sensor” and a method for “determining a plurality of operating wavelengths of the light emitting sources so that one or more physiological parameters can be determined based upon the operating wavelengths.” JX-008 at 362 (MASITC_00077987); *see* RX-0406 at Abstract (“[A] temperature sensor (50) is included in the sensor (12) to produce a signal indicative of sensor temperature. This signal is interpreted by the oximeter circuitry including, for example, a microcomputer (16), where the effect of temperature on wavelength is compensated for.”). In response to this rejection and following an interview with the examiner, Complainants’ counsel amended all of the independent claims of the ’127 patent. JX-008 at 399-407.⁹⁹

Cheung’s temperature sensor measures a single temperature that is used to “accurately determine” the wavelengths of two LEDs for oxygen saturation measurements. *See* RX-0406 at

⁹⁸ Prosecution claim 5 at that time required, *inter alia*, “a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature” and the determination of “one or more physiological parameters of a patient based upon the operating wavelengths.” JX-008, at 38 (MASITC_00077663).

⁹⁹ In response to rejections based on obviousness in view of Cheung in combination with additional prior art references, including U.S. Patent No. 6,360,113 (“Dettling ’113”) and U.S. Patent Pub. No. 2002/0154665 (“Funabashi et al. ’665”), the claims were amended to specify that the thermal mass is disposed within a substrate. *See* JX-008 at 363-64, 399-407.

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13:20-32 (“[A] temperature sensor 50 . . . is employed to produce a signal that indicates the temperature of sensor assembly 48. . . . [T]his signal, when combined with information about the coding resistor 52 value, allows microcomputer 16 to accurately determine the wavelengths of the light emitted by LEDs 40 and 42 and subsequently produce an accurate determination of oxygen saturation.”); RRB at 115 (quoting Cheung). Complainants’ proposed construction would thus fail to distinguish claim 7’s requirement for a “thermal mass” over a reference that the examiner (and Complainants’ expert) recognized does not have a thermal mass. Accordingly, Complainants’ proposed construction is unsupported—a “thermal mass” is not merely any mass from which a single temperature measurement can be used to estimate the operating wavelengths of the LEDs.¹⁰⁰

* * *

Accordingly, “thermal mass” shall be construed to mean a mass that stabilizes a bulk temperature.

2. “bulk temperature for the thermal mass”

The “temperature sensor” limitation of claim 7 describes “a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature.” JX-007 at 19:45-

¹⁰⁰ To the extent Complainants seek to argue that their proposed construction requires, in addition, “reliably” estimating wavelength in a manner that improves over Cheung (*see* CIB at 285), such an addition is not supported by the evidence. As discussed above, the examiner viewed Cheung as meeting the claim requirements except for that of a “thermal mass” stabilizing a bulk temperature. Complainants’ proposed claim construction, moreover, does not include any proviso requiring a greater degree of accuracy than Cheung. Complainants’ infringement analysis also does not provide any comparison of the Accused Products to the accuracy provided in Cheung. Moreover, even if greater accuracy were shown in the Accused Products, the evidence shows that there are multiple ways to achieve greater accuracy in wavelength estimation apart from inclusion of a thermal mass, and some of these methods can be used in combination with a temperature measurement. *See* RRB at 115-16; RX-0035.0086. The existence of a thermal mass does not simply follow, as a matter of logic, from reliable wavelength estimation using, *inter alia*, a single temperature measurement. *See* RIB at 114-115.

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48. As discussed above in the context of “thermal mass,” the specification provides that “[a] thermal mass 1220 is disposed proximate to the emitters 710 so as to stabilize a bulk temperature 1202 for the emitters.” *Id.* at 10:24-26. The specification further provides that “[a] temperature sensor 130 is thermally coupled to the thermal mass 1220, wherein the temperature sensor 1230 provides a temperature sensor output 1232 responsive to the bulk temperature 1202 so that the wavelengths are determinable as a function of the drive currents 1210 and the bulk temperature 1202.” *Id.* at 10:26-31. The specification describes two distinct methods for determining the wavelengths of the emitters, distinguishing between a method using the bulk temperature (T_b) and a method using the temperatures of individual light emitters (T_a). *Id.* at 10:32-48. In a “bulk temperature” embodiment, a thermistor is used “to determine the bulk temperature of LEDs 801 (FIG. 8) mounted on the substrate 1200,” and “[t]he substrate 1200 is configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful.” *Id.* at 10:67-11:4.

Apple does not propose an explicit construction for “bulk temperature” but argues that the “bulk temperature for the thermal mass” should follow the ‘ordinary usage of the adjective ‘bulk,’ which is the majority or greater part.’ RIB at 215. Apple, in support, cites certain deposition testimony of one of the named inventors indicating that it is an “average” or “representative” temperature. *Id.* (citing RX-1195C (Abdul-Hafiz Dep. Tr.) at 99:1-19 (“[T]he bulk temperature means . . . I call it the representative temperature . . . a representative temperature of the whole bulk, and that’s what we call bulk temperature.”)) Apple also relies on a statement made by Complainants’ counsel at the Markman hearing that “people understand bulk is the vast majority.” Markman H’rng Tr. at 42:6-9. Apple further distinguishes a “bulk temperature” from “a local temperature” for one part of the mass. RIB at 215 (“the temperature

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sensor measures a ‘bulk temperature’ that is different from a regular temperature measurement by a temperature sensor, which is a local temperature measurement”); *see also* RIB at 214-15; RRB at 116-19.

Complainants argue that a “bulk temperature” is “a single temperature used to estimate the operating wavelength of all the LEDs.” CIB at 244. Complainants argue that the claimed bulk temperature does not need to be an average temperature or a uniform temperature for the thermal mass, relying on the claim language describing the “bulk temperature” as a single temperature used to estimate the operating wavelengths of all the LEDs. CIB at 244-47; CRB at 138-41. Complainants argue that the “bulk temperature” is not necessarily an “average” temperature, but rather is a “single, ‘representative’ measurement.” CIB at 244-45.

Complainants rely on the testimony of Yassir Abdul-Hafiz, one of the named inventors, who described a “bulk temperature” as the “representative temperature,” which is different from a “local temperature” at a “spot that we are measuring.” RX-1195C (Abdul-Hafiz Dep. Tr.) at 99:1-15. He further explained that the temperature of a “thermal mass” can be “a representative temperature of the whole bulk, and that’s what we call bulk temperature.” *Id.* at 99:16-19. His co-inventor Mr. Diab described the “bulk temperature” as a “baseline that is defined by this substrate, and what we found in this invention is that if you measure that baseline and -- with a certain quality for the substrate, . . . you can have a very good correlation to the inside temperature of each LED.” RX-1200C (Diab Dep. Tr.) at 137:12-138:8.

In consideration of the parties’ arguments, the undersigned construes “bulk temperature of the thermal mass” to mean a representative temperature for the thermal mass. The parties do not appear to dispute that the “bulk temperature” claimed in the ’127 patent is a representative temperature for the thermal mass, in accordance with Mr. Abdul-Hafiz’s testimony. This

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construction is also consistent with the “bulk temperature” embodiment in the specification, where a thermistor is used “to determine the bulk temperature of LEDs 801 (FIG. 8) mounted on the substrate 1200,” and “[t]he substrate 1200 is configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful.” *Id.* at 10:67-11:4.¹⁰¹ Complainants’ proposed construction improperly reads out the “thermal mass” from the limitation “bulk temperature for the thermal mass.” This is improper, for the same reasons discussed above in the context of the construction for “thermal mass,” because it would fail to give meaning to these terms and would be inconsistent with the prosecution history. Complainants’ proposed construction requiring only that the bulk temperature be used to estimate the operating wavelength of all the LEDs would be met by Cheung, which does not include a “thermal mass.” *See* RX-0406 at 13:20-32.¹⁰²

* * *

Accordingly, “bulk temperature for the thermal mass” shall be construed to mean a representative temperature for the thermal mass.

E. Infringement

Complainants allege that the Accused Products infringe claim 9 of the ‘127 patent, relying on the testimony of Mr. Goldberg. CIB at 248-66; CRB at 141-54; Tr. (Goldberg) at 612:9-626:16. Apple disputes whether the Accused Products meet the limitations requiring a

¹⁰¹ Complainants argue that Apple’s proposed interpretation of this limitation would read out the preferred embodiment in the specification using a single thermistor, CIB at 246-47, but Apple agrees that “a ‘bulk temperature’ could be measured by a properly positioned single thermistor if the thermal mass were stabilized at the bulk temperature.” RRB at 122.

¹⁰² Complainants’ proposed construction would also be superfluous, because the subsequent language in the claim already requires “the operating wavelengths dependent on the bulk temperature.” *See* JX-007 at 19:45-49.

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“thermal mass” and a temperature sensor “capable of determining a bulk temperature for the thermal mass,” relying on the testimony of Dr. Sarrafzadeh. RIB at 209-24; RRB at 114-30; Tr. (Sarrafzadeh) at 1064:8-1084:5. For the reasons discussed below, the undersigned finds that the Accused Products have not been shown to infringe claim 9 of the ’127 patent by a preponderance of the evidence.

1. Element [7 preamble]: “physiological sensor”

There is no dispute that the Accused Products meet the limitations of the preamble of claim 7, describing “[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient.”¹⁰³ Complainants identify evidence that the Accused Products have LEDs capable of emitting light to a user’s wrist that is reflected back to photodiodes and used to determine blood oxygen levels. CIB at 254; Tr. (Goldberg) at 616:4-16; CDX-0013C.007; CX-1724 at 3. Accordingly, the evidence shows that the Accused Products have physiological sensors that meet the preamble limitations of claim 7.

2. Element [7A]: “a thermal mass”

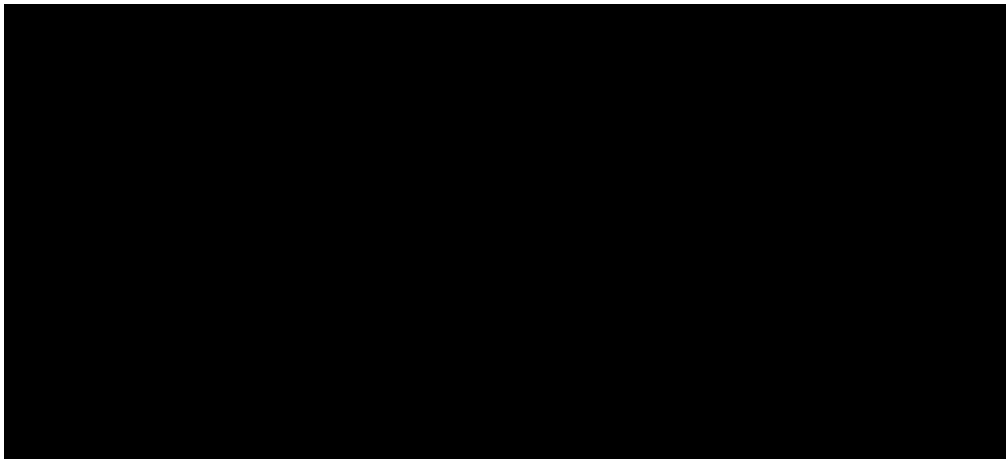
Mr. Goldberg identified [REDACTED]” of a printed circuit board (“PCB”) in the Accused Products, which Complainants identify as the claimed “thermal mass.” CIB at 254-58; Tr. (Goldberg) at 617:9-618:21. Mr. Goldberg identified “[REDACTED] [REDACTED].” Tr. (Goldberg) at 617:9-21.

¹⁰³ The parties have stipulated that the preambles of the asserted patents are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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CDX-0013C.008 (citing CX-0193C). He further identified “[REDACTED]
[REDACTED]” Tr. (Goldberg) at 617:9-21.



CDX-0013C.008 (citing CX-0195C). Mr. Goldberg performed tests confirming that the [REDACTED]
[REDACTED] in the Accused Products are coupled to each other and to the LEDs and a thermistor. Tr.
(Goldberg) at 20:17-021:15; CDX-0013C.013 (citing CX-0839C; CX-0840C).

Mr. Goldberg further identified an Apple document describing a [REDACTED]
[REDACTED].” Tr. (Goldberg) at 622:4-18;

CDX-0013C.015 (citing CX-0012C at 22). He cites another [REDACTED]
[REDACTED],

explaining “that there’s a balance in the thermal properties of the printed circuit board that needs
to be maintained in order for such formulations to work.” Tr. (Goldberg) at 622:22-623:7; CDX-
0013C.016 (citing CX-0011C at 23). Complainants note that in this document, Apple uses the

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term “thermal mass.” CX-0011C at 23. Mr. Goldberg recognized that the Accused Products use a single thermistor to measure the temperature of the PCB, and “the thermal mass is configured in a manner that the thermal coupling between the LEDs and the thermistor are such that the bulk temperature as measured by the thermistor is meaningful, and that meaningfulness has to do with being able to use that bulk temperature to determine the operating wavelengths.” Tr. (Goldberg) at 624:7-25. Complainants argue that [REDACTED] [REDACTED] that allows for the measurement of a single temperature that can be used to reliably estimate the wavelengths of the plurality of LEDs. CRB at 141-43, 147-48.

Apple argues that Mr. Goldberg failed to show that the Accused Products have the accused “thermal mass.” RIB at 218-19. Apple cites testimony from named inventor Mohamed Diab, who agreed that “some form of experiment” would be necessary to determine whether an object stabilizes temperatures in accordance with the invention. *See* Tr. (Diab) at 238:15-19. Apple argues that Mr. Goldberg only performed tests regarding thermal conductivity, which are not sufficient to show temperature stabilization. *See* Tr. (Sarrafzadeh) at 1070:22-1071:5, 1080:11-1081:18; RDX-7.70. Apple submits that Complainants have failed to articulate what thermal properties would be sufficient to establish that a “thermal mass” stabilizes a bulk temperature. RRB at 123-24. With respect to the use of the term “thermal mass” in an Apple presentation, Dr. Mannheimer explained that the term referred to a physical property related to an object’s heat capacity, and not to the “thermal mass” referenced in the ’127 patent. CX-0289C (Mannheimer Dep. Tr.) at 148:8-156:1; *see also* CX-0291C (Mehra Dep. Tr.) at 180:8-182:17 (“I don’t know what that refers to”); Tr. (Sarrafzadeh) at 1071:13-1072:7 (“the thermal mass here is not the thermal mass of the patent”). [REDACTED]

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[REDACTED]

[REDACTED] Tr. (Sarrafzadeh) at 1074:8-1078:22; RDX-7.65C; RDX-7.66C.

[REDACTED]

CX-0322b-C.0010.

Apple also argues that the [REDACTED] in the PCB of the Accused Products do not comprise a “thermal mass” because [REDACTED] to stabilize a bulk temperature. RIB at 215-19. Apple relies on the testimony of one of its engineers, Saahil Mehra, who testified that the

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]. Tr. (Sarrafzadeh) at 1065:16-1066:9; RDX-7.49. Dr. Sarrafzadeh compared the thickness of the [REDACTED] in the Accused Products with the thickness of Masimo’s early rainbow® sensors, finding that the “rainbow sensor thickness is [REDACTED]” than the Accused Products. Tr. (Sarrafzadeh) at 106:10-21; RDX-7.51C. Dr. Sarrafzadeh submits that because the Accused Products have more LEDs than the rainbow sensors, thicker layers would likely be needed to provide the same level of thermal stability. Tr. (Sarrafzadeh) at 1067:4-13. He relied on testimony from Masimo engineers discussing the thickness of the rainbow sensor boards to support his opinion. *Id.* at 1068:14-25. Apple cites the testimony of Mr. Diab, who was asked whether Masimo designed the rainbow sensor circuit boards to be “as thin as possible.” RX-1200C (Diab Dep. Tr.) at 108:12-15. At the hearing, Mr. Diab testified that whether a mass of [REDACTED] is sufficient to stabilize a bulk temperature depends on “how much heat you are pumping into the sensor, and that[] typically has to do with the number of LEDs.” Tr. (Diab) at 238:9-14.

In consideration of the parties’ arguments, the undersigned finds that Complainants have not shown, by a preponderance of the evidence, that [REDACTED] in the PCB of the Accused Products meet the “thermal mass” limitation. As discussed above, “thermal mass” has been construed to mean a mass that stabilizes a bulk temperature. Complainants have failed to show temperature stabilization in the Accused Products. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Complainants disagree with Dr. Sarrafzadeh’s opinion regarding temperature stabilization, but they rely only on attorney argument to characterize [REDACTED] See CRB at 142-43. [REDACTED]

[REDACTED] RX-0093C.0009-10.

Mr. Goldberg admitted that he “did not do any tests that address stabilization or normalization.” Tr. (Goldberg) at 649:4-11; *see also id.* at 618:1-21 (disagreeing with Apple’s understanding that stabilization and normalization were required for a “thermal mass.”).

Complainants rely on the fact the Accused Products use a single temperature sensor to determine the wavelengths of the LEDs but as discussed above in the context of claim construction, this is insufficient to prove the existence of a “thermal mass”—during prosecution, for example, the examiner recognized that the Cheung prior art estimated such wavelengths without a “thermal mass.” *See* JX-008 at 363; RX-0406 at 13:20-32. Complainants have failed to present any affirmative evidence of temperature stabilization, and accordingly, they have not met their burden to show that the Accused Products contain a “thermal mass.”¹⁰⁴

¹⁰⁴ Complainants also acknowledge that the presence of metallized layers does not show the existence of a thermal mass. *See* CRB at 162 (rejecting argument that “*any* metallized layers in a PCB can be a thermal mass”).

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There is further evidence in the record to support a finding of non-infringement with respect to the “thermal mass” limitation. Dr. Mehra testified that [REDACTED] of the PCB in the Accused Products [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Tr. (Sarrafzadeh) at 1065:15-1066:21; RDX-7.49C; RX-0087C; RX-0338C.¹⁰⁵ A preponderance of the evidence does not support a finding that the Accused Products meet the “thermal mass” limitation.

3. Element [7B]: “a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass”

With respect to the “plurality of light emitting sources” limitation, Mr. Goldberg identified 4 sets of 3 LEDs in the Accused Products, which are attached to the [REDACTED] of the PCB with thermally conductive epoxy. Tr. (Goldberg) at 618:22-619:9; CDX-0013C.09 (citing CX-0057C; CX-0025C; CX-0198C at 17-18; CX-0199C). Mr. Goldberg further conducted testing to show that the LEDs are thermally coupled to the [REDACTED] of the PCB. 620:17-621:15; CDX-0013C.013 (citing CX-0839C; CX-0840C). Apple only disputes infringement with respect to the “thermal mass” within this limitation. *See* CIB at 258-59; RIB at 215-19. Accordingly, the evidence shows that the “plurality of light emitting sources” limitation is met by the Accused Products.

¹⁰⁵ Apple argues that the rainbow® sensors were designed to be [REDACTED], RRB at 126-27, citing the testimony of Mohamed Diab who stated at his deposition: “I think that was one of the requirements.” RX-1200C (Diab Dep. Tr) at 108:12-15.

4. Element [7C]: “the sources having a corresponding plurality of operating wavelengths”

With respect to the “plurality of operating wavelengths” limitation, Mr. Goldberg identified red, green, and infrared LEDs in the Accused Products. Tr. (Goldberg) at 619:10-17; CDX-0013C.010 (citing CX-0057C; CX-0025C). There is no dispute with respect to this limitation. *See* CIB at 259. Accordingly, the evidence shows that the “plurality of operating wavelengths” limitation is met by the Accused Products.

5. Element [7D]: “the thermal mass disposed within the substrate”

With respect to the “thermal mass disposed within the substrate” limitation, Mr. Goldberg identified the [REDACTED] within the PCB substrate of the Accused Products. Tr. (Goldberg) at 619:18-620:3; CDX-0013C.011 (citing CX-0105C; CX-0193C). Apple does not dispute that the [REDACTED] are disposed within the PCB substrate, but as discussed above, Complainants have not shown that these layers comprise a “thermal mass.” *See* CIB at 260-61; RIB at 215-19. Accordingly, the evidence shows that the “disposed within the substrate” limitation is met by the Accused Products, but Complainants have not shown that the Accused Products have a “thermal mass.”

6. Element [7E]: “a temperature sensor thermally coupled to the thermal mass”

With respect to the “temperature sensor thermally coupled to the thermal mass” limitation, Mr. Goldberg identified a thermistor near the center of the sensor board of the Accused Products. Tr. (Goldberg) at 620:4-16; CDX-0013C.012 (citing CX-0057C; CX-0025C). He performed testing to show that the thermistor is thermally coupled to the [REDACTED] of the PCB. Tr. (Goldberg) at 620:17-621:15; CDX-0013C.013 (citing CX-0839C; CX-0840C). As discussed above, Complainants have not shown that the [REDACTED] of the PCB

comprise a “thermal mass,” although Apple does not dispute that the thermistor is thermally coupled to the [REDACTED]. See CIB at 261-62; RIB at 215-19. Accordingly, the evidence shows that the “temperature sensor” limitation is met by the Accused Products, but Complainants have not shown that the Accused Products have a “thermal mass.”

7. Element [7F]: the temperature sensor “capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature”

With respect to the “bulk temperature” limitation, Complainants identify the temperature measured by the thermistor in the Accused Products. CIB at 262-65. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Complainants argue that the [REDACTED]

measured by the thermistor is the claimed “bulk temperature,” because it is a single temperature

for the thermal mass that is used to estimate the wavelengths of the LEDs. CIB at 262-65; CRB at 149-54.

[REDACTED]

In consideration of the parties' arguments, the undersigned finds that Complainants have not shown, by a preponderance of the evidence, that the thermistor in the Accused Products determines a "bulk temperature for the thermal mass." As discussed above in the context of claim construction, the claimed "bulk temperature" must be a representative temperature for the thermal mass. Complainants have not shown, however, that the Accused Products have a "thermal mass" that stabilizes a bulk temperature. [REDACTED]

[REDACTED]

[REDACTED] Complainants disagree with Dr. Sarrafzadeh's conclusion, arguing that the observed temperature variation is "remarkably uniform" and "very stable." CRB at 145-46. But Complainants' contentions are only attorney argument, without any expert testimony. *See* RRB at 128-29. Apple documents contradict Complainants' contentions, [REDACTED]

[REDACTED] RX-0093C.0009-10.

Mr. Goldberg admitted that he did not perform any tests to show whether a thermal mass stabilizes or normalizes a bulk temperature in the Accused Products. Tr. (Goldberg) at 649:4-11. His infringement analysis instead relied on the fact that the "temperature as measured by the

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thermistor is meaningful, and that meaningfulness has to do with being able to use that bulk temperature to determine the operating wavelengths.” Tr. (Goldberg) at 624:7-25. This evidence may indicate that the temperature sensor in the Accused Products measures a representative temperature for the LEDs, but it does not show a representative temperature for the “thermal mass.” As discussed above in the context of the “thermal mass” limitation, the fact that a temperature is used to determine the operating wavelengths of LEDs is insufficient to prove that the temperature is “a bulk temperature for the thermal mass.” The determination of operating wavelengths is a separate requirement of this limitation,¹⁰⁶ and the examiner recognized that calculation of wavelengths using a representative temperature was known in the prior art. *See* JX-008 at 338 (MASITC_00077663), 363 (MASITC_00077988); RX-04.06 at 13:20-32. Accordingly, in addition to the failure to show that the Accused Products have a “thermal mass,” Complainants have failed to show by a preponderance of the evidence that the temperature measured by the thermistor is a “bulk temperature for the thermal mass.”¹⁰⁷

8. Element [7G]: “a detector capable of detecting light emitted by the light emitting sources after tissue attenuation”

With respect to the “detector” limitation, Mr. Goldberg identified four photodiodes in the Accused Products. Tr. (Goldberg) at 625:1-9; CDX-0013C.018 (citing CX-0057C; CX-0025C).

¹⁰⁶



¹⁰⁷ Apple separately argues in its post-hearing briefs that  and that Complainants were required to show that one of these measurements is the “bulk temperature.” RIB at 224; RRB at 129-30. This non-infringement argument was not raised in Apple’s pre-hearing brief, however, and accordingly, it has been waived pursuant to Ground Rule 9.2. *See* CRB at 153-54.

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Complainants further cite the testimony of Apple witnesses confirming that the photodiodes in the Accused Products detect light that is emitted by the LEDs and attenuated by the user's tissue. *See, e.g.*, CX-0281C (Block Dep. Tr.) at 86:17-87:14; CX-0289C (Mannheimer Dep. Tr.) at 133:2-134:12. There is no dispute with respect to this limitation. *See* CIB at 265; RIB at 215-19. Accordingly, the evidence shows that the "detector" limitation is met by the Accused Products.

9. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

With respect to the "outputting a signal" limitation, Mr. Goldberg identified "PPG signals" described in Apple documents corresponding to the output of the photodiodes, which are used to determine blood oxygen saturation in combination with the wavelength estimates for the LEDs. Tr. (Goldberg) at 625:10-25; CDX-0013C.019 (citing CX-0100C at 5-8; CX-0012C at 21). Complainants further cite the testimony of Apple witnesses confirming that signals from the photodiodes are used to determine blood oxygen saturation. *See, e.g.*, CX-0281C (Block Dep. Tr.) at 72:10-73:7; CX-0289C (Mannheimer Dep. Tr.) at 134:14-138:1. There is no dispute with respect to this limitation. *See* CIB at 266; RIB at 215-19. Accordingly, the evidence shows that the "outputting a signal" limitation is met by the Accused Products.

10. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 7 is a thermistor. As discussed above in the context of the "temperature sensor" limitation, there is no dispute that the Accused Products have a temperature sensor that is a thermistor. *See* Tr. (Goldberg) at 626:3-16; CDX-0013C.020 (citing CX-0057C at 1-2; CX-0025C at 31). Accordingly, the evidence shows that the "thermistor" limitation of claim 9 is met by the Accused Products.

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As discussed above, because Complainants have not shown by a preponderance of the evidence that the “thermal mass” and “bulk temperature for the thermal mass” limitations of claim 7 are met by the Accused Products, the undersigned finds that the Accused Products have not been shown to infringe claim 9 of the ’127 patent.

F. Domestic Industry—Technical Prong

Complainants allege that Masimo’s rainbow® sensors practice claim 9 of the ’127 patent, relying on the testimony of Mr. Diab and Mr. Goldberg. CIB at 266-74; CRB at 154-60; *see* Tr. (Diab) at 216:15-226:19; Tr. (Goldberg) at 627:3-635:11. Apple disputes whether the rainbow® sensors meet the limitations requiring a “thermal mass” and a temperature sensor “capable of determining a bulk temperature for the thermal mass,” relying on the testimony of Dr. Sarrafzadeh. RIB at 224-32; RRB at 130-36; Tr. (Sarrafzadeh) at 1084:6-1087:12. For the reasons discussed below, the undersigned finds that only some of Masimo’s rainbow® sensors have been shown to practice claim 9 of the ’127 patent.

1. Domestic Industry Products

Mr. Diab explained that there are two different LED assemblies used in Masimo’s rainbow® sensors —early rainbow® sensors dating back to 2005 used [REDACTED] in a substrate, and current rainbow® sensors use a [REDACTED]. Tr. (Diab) at 216:15-219:5; *see* Tr. (Goldberg) at 627:4-13; CDX-0013C.021. Apple argues that Complainants have failed to identify the Masimo rainbow® sensors by product number and have failed to specify which products are “early” or “current” rainbow® sensors. RIB at 224-24; RRB at 130-31. Complainants submit that the rainbow® sensors have been identified on a sales spreadsheet. CRB at 9; CX-0649C. Complainants contend that “pre-2009 sales are for early rainbow®

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sensors and later sales are for current rainbow® sensors,” citing the testimony of Mr. Diab. CRB at 10 (citing Tr. (Diab) at 216:15-218:1, 220:4-221:10). Mr. Diab testified at the hearing: “My understanding is that . . . we have switched to the [REDACTED] in around 2009.” Tr. (Diab) at 233:16-20. Masimo’s sales spreadsheet (CX-0649C) shows continuous sales of rainbow® sensors from 2008 through 2012, with no indication of distinct product numbers for early rainbow® sensors and current rainbow® sensors. *See* CX-0649C. The undersigned agrees with Apple that the record lacks any straightforward identification of Masimo’s rainbow® sensors, but the sales data, as explained by Mr. Diab’s testimony, is sufficient to infer that the design of Masimo’s rainbow® sensors was changed in 2009 such that “early” rainbow® sensors before 2009 were comprised of [REDACTED], but all of the rainbow® sensors made and sold after 2009 are “current” rainbow® sensors with a [REDACTED].

2. Element [7 preamble]: “physiological sensor”

There is no dispute that the early and current rainbow® sensors meet the limitations in the preamble of claim 7, describing “[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient.” *See* CIB at 266-67.¹⁰⁸ Mr. Goldberg identified evidence that the rainbow® sensors contain a photodetector that detects light emitted by LEDs and produces a signal that is used to determine “patient measurement values.” Tr. (Goldberg) at 627:14-22; CDX-0013C.022 (citing CX-0430C at 5). Accordingly, the evidence shows that the preamble limitations of claim 7 are met by each of the rainbow® sensors.

¹⁰⁸ The parties have stipulated that the preambles of the asserted patent claims are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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3. Element [7A]: “a thermal mass”

With respect to the “thermal mass” limitation, Complainants rely on different structures in the current rainbow® sensors and the early rainbow® sensors. CIB at 267-69. Mr. Diab described an [REDACTED] material that is used in the substrate of the current rainbow® sensors, “because it has very good heat conduction.” Tr. (Diab) at 220:4-222:1 (citing CX-0454C; CX-0589C). Mr. Goldberg identified this [REDACTED] as the claimed “thermal mass” in the current rainbow® sensors, relying on Masimo documents and Mr. Diab’s testimony. Tr. (Goldberg) at 627:23-628:24; CDX-0013C.023 (citing CX-0590C; CX-135C at 81, 98).

With respect to the early rainbow® sensors, Mr. Diab identified [REDACTED], which are “connected with . . . through-holes to make sure that there is a good heat conduction throughout the system.” Tr. (Diab) at 216:15-219:5 (citing CX-0397C; CX-0588C). Mr. Goldberg identified the [REDACTED] as the claimed “thermal mass” in the early rainbow® sensors. Tr. (Goldberg) at 628:25-629:18; CDX-0013C.024 (citing CX-0588C).

Apple argues that Complainants have failed to show that the rainbow® sensors have a “thermal mass.” RIB at 226-29, 230-32. Apple submits that Complainants failed to provide any analysis of the thermal properties of the substrate in the current rainbow® sensors or the early rainbow® sensors. *Id.* at 226-279, 230-32 *see* Tr. (Sarrafzadeh) at 1084:22-1085:11 (noting the Mr. Goldberg “did not do any simulation or any other analysis”). Apple contrasts the lack of analysis for the current rainbow® sensors with Mr. Diab’s extensive testing and simulation in the development of the early rainbow® sensors. RIB at 227-29. Apple further argues that Mr. Goldberg did not rely on any of Mr. Diab’s testing and simulation for his opinions. RRB at 131-35.

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In consideration of the parties’ arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that the early rainbow® sensors had a “thermal mass,” but Complainants have failed to show that the current rainbow® sensors meet this limitation. Although Mr. Goldberg’s testimony on this limitation did not rely on testing or detailed analysis of the substrates in the rainbow® sensors, his testimony is supported by other evidence in the record, including Masimo documents and Mr. Diab’s testimony. In particular, Mr. Diab testified at his deposition that the early rainbow® sensors were designed to have a relatively significant thermal mass. RX-1200C (Diab Dep. Tr.) at 110:7-11. Mr. Diab also described testing and simulations that he performed in the development of the early rainbow® sensors, where he modeled the temperature of the “thermal mass” to observe the relationship between the temperature of the thermistor and the temperature of the LEDs. *Id.* at 121:4-122:3; Tr. (Diab) at 200:17-203:6 (citing CX-0342C). He observed [REDACTED] [REDACTED] finding [REDACTED] [REDACTED] *Id.* at 201:19-203:6. Apple argues that these simulations were only performed with a prototype design and not an actual product, RIB at 232 n.32, but Mr. Diab’s description of the metal layers in his simulation matches his description of the structure of the early rainbow® sensors, and this is confirmed in the underlying documents. *Compare* Tr. (Diab) at 201:2-20 *to id.* at 216:15-218:21; CX-0342C at 6; CX-0588C. Apple argues that the rainbow® sensors have more LEDs than in Mr. Diab’s simulations, but Mr. Diab explained that the amount of [REDACTED] was designed to account for up to 16 LEDs. RX-1200C (Diab Dep. Tr.) at 110:7-112:1. Mr. Diab further described testing on the early rainbow® sensors where he verified that the wavelength of the LEDs could be accurately determined with an equation using the measured

temperature, confirming that the actual products work in accordance with his simulations. Tr. (Diab) at 203:7-204:11. Apple has offered no independent testing to refute Mr. Diab’s testimony regarding the thermal mass in the early rainbow® sensors. *See* CRB at 156. Accordingly, the undersigned finds that Complainants have shown by a preponderance of the evidence that this limitation is met by the early rainbow® sensors.

The evidence from Mr. Diab’s simulations is not applicable to the current rainbow® sensors, however. Mr. Goldberg and Mr. Diab described different structures for the alleged “thermal mass” in the current rainbow® sensors, which have a [REDACTED]. Tr. (Goldberg) at 627:3-13; Tr. (Diab) at 220:25-222:1. The [REDACTED] of the current rainbow® sensors is supplied by a [REDACTED]. *Id.* at 221:19-222:1; CX-0598C. Mr. Diab could not find any analysis of temperature stabilization for the [REDACTED]. Tr. (Diab) at 240:4-11. To show the presence of a “thermal mass,” Complainants merely rely on the undisputed fact that the substrate is composed of interconnected metal layers, *see* Tr. (Goldberg) at 627:23-628:13, and Mr. Diab’s testimony that the current rainbow® sensors are tested to verify the accuracy of the calculation of wavelengths for the LEDs. *See* Tr. (Diab) at 246:7-19. As discussed above in the context of infringement, this is insufficient to prove that this limitation is met. Accordingly, Complainants have failed to show by a preponderance of the evidence that the current rainbow® sensors have a “thermal mass.”

4. Element [7B]: “a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass”

There is no dispute that the early and current rainbow® sensors meet the “plurality of light emitting sources” limitation. *See* CIB at 269-70. Mr. Diab testified that all of Masimo’s rainbow® sensors have more than two LEDs. Tr. (Diab) at 211:17-23. He described the

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placement of the LEDs in the early rainbow® sensors, *id.* at 216:15-217:8 (citing CX-0397C), and the current rainbow® sensors. *Id.* at 220:4-24 (citing CX-0454C). Mr. Goldberg identified Masimo documents showing the LEDs attached to the substrate of the rainbow® sensors using “thermally and electrically conductive epoxy.” Tr. (Goldberg) at 629:19-630:12; CDX-0013C.025 (citing CX-0454C); CDX-0013C.026 (citing CX-0397C). Accordingly, the evidence shows that the “plurality of light emitting sources” limitation is met by each of the rainbow® sensors, except to the extent that the current rainbow® sensors have not been shown to have a “thermal mass.”

5. Element [7C]: “the sources having a corresponding plurality of operating wavelengths”

There is no dispute that the early and current rainbow® sensors meet the “plurality of operating wavelengths” limitation. *See* CIB at 271. Mr. Goldberg cites Masimo schematics showing the multiple wavelengths of light for the LEDs in the rainbow® sensors. Tr. (Goldberg) at 630:13-24; CDX-0013C.027 (citing CX-0454C); CDX-0013C.028 (citing CX-0397C). Accordingly, the evidence shows that the “plurality of operating wavelengths” limitation is met by each of the rainbow® sensors.

6. Element [7D]: “the thermal mass disposed within the substrate”

There is no dispute that the early and current rainbow® sensors meet the “disposed within the substrate” limitation. *See* CIB at 271. Mr. Goldberg identified the [REDACTED] [REDACTED] between the top and bottom of the substrate in the current rainbow® sensors. Tr. (Goldberg) at 630:25-31:6; CDX-0013C.029 (citing CX-0590C). He identified the [REDACTED] [REDACTED] between the top and bottom of the substrate in the early rainbow® sensors. Tr. (Goldberg) at 631:9-16; CDX-0013C.030 (citing CX-0588C). Accordingly, the evidence shows that the “thermal mass disposed within the substrate” limitation is met by the early rainbow® sensors,

and the [REDACTED] of the current rainbow® sensors are also “disposed within a substrate,” although they have not been shown to be a “thermal mass.”

7. Element [7E]: “a temperature sensor thermally coupled to the thermal mass”

There is no dispute that the early and current rainbow® sensors have “a temperature sensor thermally coupled to the thermal mass.” *See* CIB at 271. Mr. Goldberg identified a thermistor on the substrate in the current rainbow® sensors and the early rainbow® sensors. Tr. (Goldberg) at 631:17-632:16; CDX-0013C.031 (citing CX-0454C); CDX-0013C.032 (citing CX-0397C). Accordingly, the evidence shows that the “thermally coupled” limitation is met by each of the rainbow® sensors, except to the extent that the current rainbow® sensors have not been shown to have a “thermal mass.”

8. Element [7F]: the temperature sensor “capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature”

With respect to the “bulk temperature” limitation, Complainants identify the temperature measured by the thermistor in the rainbow® sensors. CIB at 271-73. Mr. Goldberg identifies Masimo documentation showing that the output from the thermistor in the rainbow® sensors is used “so that adjustments can be made to account for the temperature.” Tr. (Goldberg) at 632:17-633:12; CDX-0013C.033 (citing CX-0430C). He further relies on Masimo source code that shows a calculation of wavelengths for the LEDs using the thermistor temperature. Tr. (Goldberg) at 633:13-24; CDX-0013C.034 (citing CPX-0152C; CPX-0151C). His analysis is the same for the early rainbow® sensors and the current rainbow® sensors. Tr. (Goldberg) at 633:25-634:2. Mr. Diab explained that in the development of the early rainbow® sensors, Masimo engineers developed an equation for predicting the wavelength of LEDs using a temperature measurement from a thermistor. Tr. (Diab) at 198:12-200:13. They were able to

confirm that the equation correctly estimated the wavelengths using a spectrometer. *Id.* at 203:7-204:1. Mr. Diab explained that he wrote “[t]he original code for all of the rainbow [sensors] including the wavelength correction,” and the code on the current rainbow® sensors is a “modified version.” Tr. (Diab) at 212:21-213:6.

Apple argues that Complainants have not shown that the rainbow® sensors are capable of determining a “bulk temperature,” because Mr. Goldberg did not perform any testing on the thermistor or the “thermal mass” in these products. RIB at 229-30; RRB at 135-36. Dr. Sarrafzadeh offered his opinion that the thermistor in the rainbow® sensors measures a “local temperature” and not a “bulk temperature.” Tr. (Sarrafzadeh) at 1086:11-21. Apple further argues that Mr. Goldberg’s testimony regarding the determination of operating wavelengths was conclusory. RRB at 136.

In consideration of the parties’ arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that the thermistors in the early rainbow® sensors are capable of measuring a “bulk temperature” that is a representative temperature for the “thermal mass” in the substrate of these products. As discussed above in the context of the “thermal mass” limitation, Mr. Diab described “hundreds of experiments” in simulations for the design of the early rainbow® sensors. Tr. (Diab) at 199:17-200:13 (citing CX-0342C). In those simulations, he observed that [REDACTED]

[REDACTED] *Id.* at 201:19-203:6. Mr. Diab also described testing on the early rainbow® sensors where he verified that the wavelength of the LEDs could be accurately determined with an equation using the measured temperature. Tr. (Diab) at 203:7-204:11.

Apple’s arguments primarily rely on Complainants’ alleged failure of proof for this limitation—the only affirmative evidence that Apple cites is Dr. Sarrafzadeh’s opinion that the thermistor measures a “local temperature” rather than a “bulk temperature.” Tr. (Sarrafzadeh) at 1086:11-21. As discussed above in the context of infringement, however, Apple concedes that “a ‘bulk temperature’ could be measured by a properly positioned single thermistor if the thermal mass were stabilized at the bulk temperature,” RRB at 122, and the “bulk temperature” embodiment in the specification is based on a single thermistor. *See* JX-007 at 10:62-11:4, Fig. 16. Mr. Diab testified that Masimo’s design of the early rainbow® sensors was based on the use of a single thermistor after recognizing that it would be difficult [REDACTED] [REDACTED]. Tr. (Diab) at 198:12-199:16. Mr. Diab’s testimony further confirms that the bulk temperature from the thermistor in the early rainbow® sensors was used to determine the operating wavelengths of LEDs. *See* Tr. (Diab) at 203:7-204:11. Accordingly, a preponderance of the evidence shows that the early rainbow® sensors meet the limitation requiring a temperature sensor to determine a “bulk temperature” for the thermal mass, and the wavelengths of the LEDs are dependent on the bulk temperature.

As discussed above in the context of the “thermal mass” limitation, however, Complainants have not shown that the current rainbow® sensors have a “thermal mass” that stabilizes a “bulk temperature.” Complainants did not present any analysis of temperature stabilization on the [REDACTED] of the current rainbow® sensors, and accordingly, Complainants have not shown, by a preponderance of the evidence, that the current rainbow® sensors meet the “bulk temperature” limitation.

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9. Element [7G]: “a detector capable of detecting light emitted by the light emitting sources after tissue attenuation”

There is no dispute that the early and current rainbow® sensors have “a detector capable of detecting light emitted by the light emitting sources after tissue attenuation.” *See* CIB at 273-74. Mr. Goldberg identified detectors in the rainbow® sensors that detect “modulated LED light, which passes through the tissue.” *Tr.* (Goldberg) at 634:3-635:11; CDX-0013C.035 (citing CX-0440C); CDX-0013C.03 (citing CX-0430C at 2, 5). Accordingly, the evidence shows that the “detector” limitation is met by each of the rainbow® sensors.

10. Element [7H]: “wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths”

There is no dispute that the detector in the rainbow® sensors outputs a signal that is used to determine physiological parameters. *See* CIB at 273-74. Complainants identify a Masimo specification describing the signal from the detectors, stating that “[t]he OEM Board uses this signal to compute patient measurement values.” CX-0430C at 5; *see Tr.* (Goldberg) at 634:22-635:11; CDX-0013C.03 (citing CX-0430C at 2, 5). Accordingly, the evidence shows that the “signal usable to determine one or more physiological parameters” limitation is met by each of the rainbow® sensors.

11. Element [9]: “a thermistor”

Claim 9 further requires that the “temperature sensor” of claim 1 is a thermistor. As discussed above in the context of the “temperature sensor” limitation, and there is no dispute that the temperature sensor in the rainbow® sensors is a thermistor. *Tr.* (Goldberg) at 631:17-632:16; CDX-0013C.031 (citing CX-0454C); CDX-0013C.032 (citing CX-0397C). Accordingly, the evidence shows that the “thermistor” limitation of claim 9 is met by each of the rainbow® sensors.

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Accordingly, because each limitation of claims 1 and 9 is met, the undersigned finds that Complainants have shown by a preponderance of the evidence that the early rainbow® sensors practice claim 9 of the '127 patent. For the reasons discussed above in the context of the “thermal mass” and “bulk temperature” limitations, Complainants have not shown by a preponderance of the evidence that the current rainbow® sensors practice claim 9 of the '127 patent.

G. Invalidity

Apple contends that claim 9 of the '127 patent is obvious in view of several prior art references. RIB at 233-45; RRB at 136-50. Apple’s contentions primarily rely on two references: an article published in 1991 by Yitzhak Mendelson (RX-0458, “Mendelson”); and a Japanese patent application published in 2004 naming inventor Yukio Yamada (RX-0381, “Yamada”). Apple relies on the testimony of Dr. Sarrafzadeh to support its invalidity contentions. Tr. (Sarrafzadeh) at 1046:14-1064:7.

1. Mendelson

Apple contends that claim 9 of the '127 patent is obvious in view of an article entitled “Invasive and Noninvasive Blood Gas Monitoring” authored by Yitzhak Mendelson and published in *Bioinstrumentation and Biosensors* in 1991 (RX-0458 “Mendelson”), in combination with the textbook *Design of Pulse Oximeters* by J.G. Webster, published in 1997 (RX-0035, “Webster”). RIB at 233-39; RRB at 140-46. Mendelson and Webster are both prior art to the '127 patent pursuant to 35 U.S.C. § 102(b).¹⁰⁹

¹⁰⁹ The pre-AIA version of 35 U.S.C. § 102 is applicable to the '127 patent. *See* America Invents Act, 35 USCA § 100 Note, § 3(n)(1), 125 Stat. 284 (Sept. 16, 2011)

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Complainants argue that Apple has not shown claim 9 to be obvious in view of Mendelson and Webster because Mendelson does not disclose the claimed “thermal mass,” “thermal mass disposed within the substrate,” or a “temperature sensor.” CIB at 277-78; CRB at 161-62. Complainants further argue that the combination of Mendelson and Webster fails to meet the “thermal mass” limitations and the limitations requiring a temperature sensor “thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass.” CIB at 279-80; CRB at 162-64. Complainants argue that Webster’s disclosures are cumulative of U.S. Patent No. 5,259,381 to Cheung (RX-0406, “Cheung”), a prior art patent that was considered during the prosecution of the ’127 patent. CIB at 275-76.

a. Element [7 preamble]: “physiological sensor”

There is no dispute that Mendelson meets the limitations of the preamble of claim 7, describing “[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient.” *See* CIB at 277-80; CRB at 161-64. Dr. Sarrafzadeh identified a “noninvasive reflection SaO₂ sensor” disclosed in Mendelson. Tr. (Sarrafzadeh) at 1049:9-13; RX-0458 at 266-71, Fig. 10.16. He described the operation of a pulse oximeter as depicted in Mendelson, where LEDs emit light to the tissue, “and there are a collection of photodiodes that collect the light after it has been through the tissue, and they make a determination of physiological parameters based on the optical light received by the photodiodes.” Tr. (Sarrafzadeh) at 1049:14-23.

b. Element [7A]: “a thermal mass”

Apple identifies the ceramic substrate depicted in Mendelsohn as the claimed “thermal mass.” RIB at 234-35. Dr. Sarrafzadeh offers his opinion that the circuit board in Mendelsohn would provide thermal connectivity and that one of ordinary skill in the art would have known to

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add a “metal core or thermal core” to provide “thermal management.” Tr. (Sarrafzadeh) at 1049:24-1051:12. He references a textbook, *The Multilayer Printed Circuit Board Handbook* by J.A. Scarlett, which describes thermal cores that can be manufactured within substrates for heat conduction. RX-0397.0122 (recognizing that “the popular epoxy fiberglass substrates are notably poor heat conductors and therefore cannot provide a sufficient heat extraction,” and describing “an integral heat conductor, i.e., a metal core, within the structure, to alleviate this problem”). Apple also compares Mendelsohn’s disclosure of a printed circuit board with Complainants’ contentions that the metal layers in the printed circuit boards of the Accused Products and the rainbow® sensors meet the “thermal mass” limitation, arguing that Mendelsohn would meet this limitation for the same reasons. CIB at 234-35; *see* Tr. (Sarrafzadeh) at 1050:25-1051:12.

Complainants argue that Mendelsohn does not disclose a “thermal mass” because there is no disclosure of thermal properties or any description of thermal coupling. CIB at 277-78. Complainants submit that Dr. Sarrafzadeh failed to provide any testing or simulations of the ceramic substrate in Mendelsohn. *Id.* at 278. Complainants argue that Apple mischaracterizes Mr. Goldberg’s infringement and domestic industry analysis, which does not rely on an assumption that every multilayer circuit board contains a “thermal mass”—Complainants submit that Mr. Goldberg relied on evidence of the thermal coupling of components and the fact that the temperature of the board could be used to reliably estimate the operating wavelengths of the LEDs. *Id.* at 277-78. Complainants further argue that Apple should be precluded from relying on Scarlett as an obviousness ground, because it was not identified in Apple’s invalidity contentions. *Id.* at 283-84. Even if Scarlett’s disclosures were considered, Complainants submit that Apple failed to identify any reason to add a thermal core to Mendelsohn. CRB at 161.

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Dr. Goldberg testified that the problem of heat removal addressed in Scarlett is different from the use of a “thermal mass” to facilitate a bulk temperature measurement. Tr. (Goldberg) at 1398:9-1399:8.

In consideration of the parties’ arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Mendelsohn discloses a “thermal mass.” The pulse oximeter depicted in Mendelsohn has a “ceramic substrate,” but there is no description of the thermal characteristics of this substrate or any components thereon. See RX-0458 at 269-71. Dr. Sarrafzadeh’s analysis of this element also contains no description of the thermal characteristics of Mendelsohn’s substrate. See Tr. (Sarrafzadeh) at 1049:24-1052:2. Moreover, it is not clear that the addition of a metal core designed for heat removal in Scarlett would stabilize a bulk temperature, as required for the “thermal mass” limitation—neither Scarlett nor Mendelsohn describe such stabilization. See Tr. (Goldberg) at 1398:9-1399:8.

Apple has also failed to identify any clear reason for one of ordinary skill in the art to modify Mendelsohn to add a “thermal mass,” merely relying on Dr. Sarrafzadeh’s testimony that thermal cores were “known for many years,” pointing to a description of a thermal core in Scarlett.¹¹⁰ *Id.* (citing RX-0397 at 122). Dr. Sarrafzadeh suggests that adding a thermal core to Mendelsohn would provide “for better management,” relying on disclosures in Scarlett. Tr. (Sarrafzadeh) at 1051:1-12. In particular, Scarlett describes the problem of “heat removal from tightly packaged components” on “epoxy fiberglass substrates,” which can be addressed “[w]ith

¹¹⁰ Complainants argue that Apple should be precluded from relying on Scarlett because no such combination was identified in Apple’s invalidity contentions. CIB at 283-84. This argument was previously rejected in the context of Complainants’ motion *in limine* no. 2, however, where Apple was allowed to present evidence relying on Scarlett and other prior art references in accordance with the arguments in its prehearing brief. See Order No. 40 at 2 (Jun. 1, 2022). Accordingly, Apple will not be precluded from relying on Scarlett in the context of its obviousness arguments.

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an integral heat conductor, i.e., a metal core.” RX-0397 at 122. It is not clear that “heat removal” is the same as temperature stabilization, however, and it is not clear that one of ordinary skill in the art would have been motivated to add a metal core to Mendelsohn for the purpose of temperature stabilization or heat removal. Dr. Sarrafzadeh’s testimony that a metal core would be added for “better management” is the type of conclusory opinion that has been found to be insufficient to establish a motivation to combine. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (where expert testified that a motivation to combine would have been “to build something better,” the court found that “[t]his testimony is generic and . . . fails to explain why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does”).

Accordingly, Apple has failed to show by clear and convincing evidence that one of ordinary skill in the art would have modified the device in Mendelsohn to add a “thermal mass.”

c. Element [7B]: “a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass”

There is no dispute that Mendelsohn discloses a device with a plurality of LEDs thermally coupled to a circuit board. *See* RIB at 235; CIB at 277-79. Dr. Sarrafzadeh identified red and infrared LEDs shown on a circuit board in Mendelsohn. Tr. (Sarrafzadeh) at 1052:3-8; RDX-7.20.

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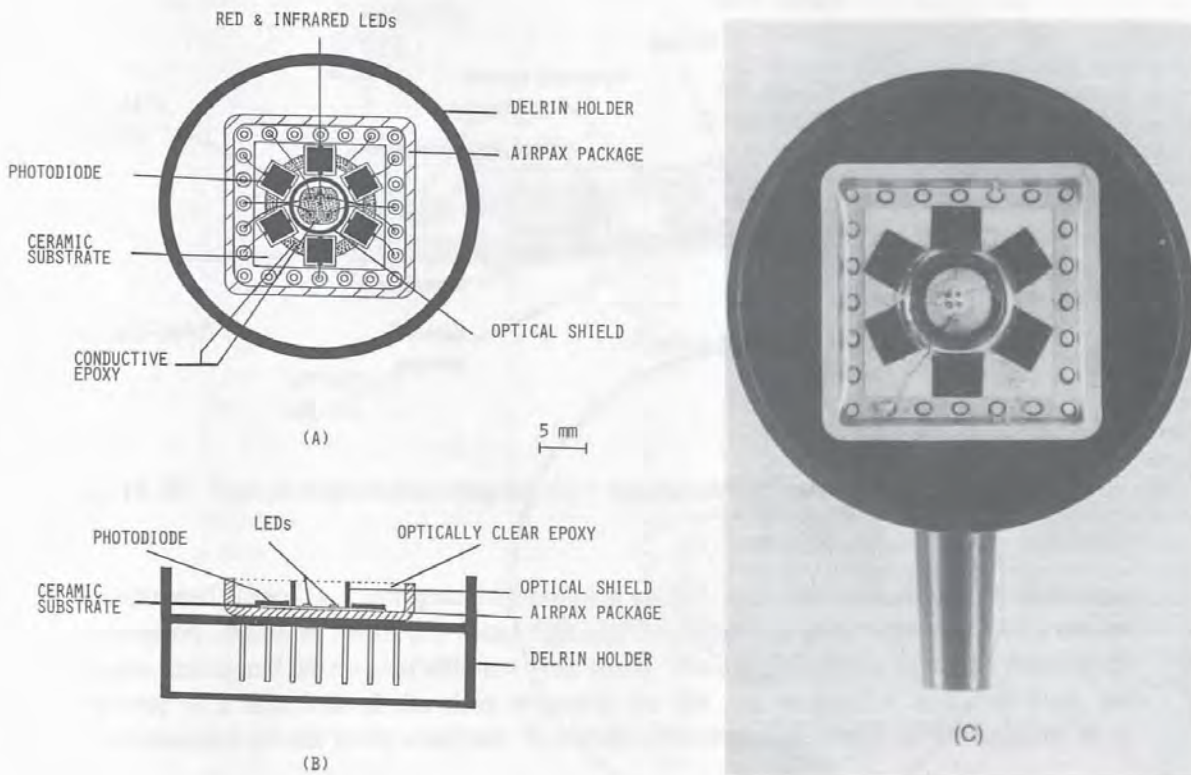


Fig. 10.16 Noninvasive reflection SaO₂ sensor.

RX-0458.0024 at Fig. 10.16; *see also* RX-0458.0022 (“The basic optical sensor of a noninvasive pulse oximeter consists of a light source (typically, a pair of red and infrared LEDs) and a photodetector mounted inside a spring-loaded clip.”). Dr. Sarrafzadeh explained that “[b]ecause of electrical connection, we know that the LEDs are connected by wires to the printed circuit board, and that’s the thermal connection.” Tr. (Sarrafzadeh) at 1052:9-13.

d. Element [7C]: “the sources having a corresponding plurality of operating wavelengths”

There is no dispute that the LEDs in Mendelsohn have two different wavelengths. *See* RIB at 236; CIB at 277-79. Dr. Sarrafzadeh explains that Mendelsohn describes “red and infrared LEDs.” Tr. (Sarrafzadeh) at 1052:18-22; RDX-7.21; RX-0458.0024 at Fig. 10.16; *see also* RX-0458.0022 (describing “a pair of red and infrared LEDs”).

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e. Element [7D]: “the thermal mass disposed within the substrate”

Apple argues that the “thermal mass disposed within the substrate” limitation is obvious in view of Mendelsohn for the same reasons that as the “thermal mass” limitation. *See* RIB at 236; Tr. (Sarrafzadeh) at 1053:1-7. For the reasons discussed above in the context of the “thermal mass” limitation, the undersigned finds that Apple has not shown that “the thermal mass disposed within the substrate” is disclosed in Mendelsohn or that one of ordinary skill in the art would have modified the device in Mendelsohn to add a “thermal mass.”

f. Element [7E]: “a temperature sensor thermally coupled to the thermal mass”

Mendelsohn does not disclose a temperature sensor in its pulse oximetry device, but Apple argues that it would have been obvious to incorporate a temperature sensor in this device based on disclosures in Webster. RIB at 236-37. Dr. Sarrafzadeh identifies Webster’s disclosure of a temperature sensor as a way to compensate for LED temperature changes that can affect pulse oximetry measurements. Tr. (Sarrafzadeh) at 1053:8-22; RDX-7.23. Webster explicitly states: “One way to compensate for LED temperature changes is to have a temperature sensor built into the probe along with the LEDs and photodiode.” RX-0035.085. Dr. Sarrafzadeh explains that such a temperature sensor would have been electrically connected and thus thermally coupled to the LEDs and the circuit board of the device in Mendelsohn. Tr. (Sarrafzadeh) at 1053:8-22. Complainants dispute the alleged obviousness of a “temperature sensor” as disclosed in Webster, but their arguments appear to be directed to the “thermal mass” limitation and the “bulk temperature” limitation. CIB at 280; CRB at 162. There does not appear to be any dispute that Webster explicitly discloses a reason for incorporating a

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temperature sensor in a pulse oximeter and that one of ordinary skill in the art would have expected success in doing so.

- g. Element [7F]: the temperature sensor “capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature”**

With respect to the “bulk temperature” limitation, Apple cites Webster’s recognition that “a shift in LED peak wavelength due to a change in temperature can cause erroneous SpO₂ readings.” RX-0035.085. Webster provides a solution to this problem: “One way to compensate for LED temperature changes is to have a temperature sensor built into the probe along with the LEDs and photodiode.” *Id.* Webster further explains that “[t]emperature information is fed back to the microprocessor, which then estimates how much the peak wavelength of each LED has changed from its rated value.” *Id.* Although Webster only describes one temperature sensor, Dr. Sarrafzadeh suggests that “one of ordinary skill in the art would know that . . . in order to get the bulk temperature in multiple locations, you would just add multiple temperature sensors of Webster.” Tr. (Sarrafzadeh) at 1053:23-1054:11. He further testifies that the relationship between wavelength and temperature described in Webster is “a fact of physics that has been known for many years.” *Id.* at 1054:20-1055:3. Apple argues that the single temperature sensor in Webster is similar to the single temperature sensor in the Accused Products, and if these products measure a “bulk temperature” then this limitation should also be met by Webster. RIB at 237; *see* Tr. (Sarrafzadeh) at 1054:14-19.

Complainants argue that Webster’s disclosure of a temperature sensor relies on Cheung (RX-0406), which was considered during the prosecution of the ’127 patent. CIB at 280, 275-76. Complainants further argue that Mendelson does not disclose a thermal mass, and that Apple does not rely on Webster as disclosing a thermal mass. *Id.* at 279-80.

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In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Webster discloses a temperature sensor capable of determining a "bulk temperature for the thermal mass." Webster does not describe a "thermal mass"—the temperature sensor is "built into the probe" and it is designed to estimate the temperature of the LEDs—not a "bulk temperature for the thermal mass." RX-0035.085.¹¹¹ Dr. Sarrafzadeh suggests that one of ordinary skill in the art would have added multiple sensors to obtain an average temperature, Tr. (Sarrafzadeh) at 1054:23-1054:7, but this opinion is not grounded in any prior art disclosure.¹¹² There is no clear disclosure of a measurement of a "bulk temperature for the thermal mass" in Webster.

h. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

There is no dispute that Mendelsohn discloses photodiodes that are capable of detecting light from its LEDs after being attenuating by the user's tissue. *See* RIB at 238; CIB at 277-79. These photodiodes are depicted on Figure 10.16 in Mendelsohn. RX-0458.0024; *see* Tr. (Sarrafzadeh) at 1055:4-8.

i. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

With respect to the "outputting a signal" limitation, Dr. Sarrafzadeh identified a block diagram (Fig. 10.12) in Mendelsohn depicting an ear oximeter that includes a processor and an output to a digital display. Tr. (Sarrafzadeh) at 1055:11-18; RX-0458.021. Complainants do not

¹¹¹ Webster notes the potential "difference between the sensed temperature and the actual temperature of the *p-n* junctions of the LEDs." RX-0035.085.

¹¹² Webster teaches away from the addition of multiple sensors or other components: "In addition, the sensor and additional wires needed will add cost to the probes, making a cost-benefit analysis of this method necessary before its inclusion in a pulse oximeter design." RX-0035.086.

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dispute that Mendelsohn discloses a detector meeting this limitation but argues that Dr. Sarrafzadeh incorrectly identified Mendelsohn's ear oximeter as a pulse oximeter. CIB at 278-79; CRB at 164.

j. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 1 is a thermistor. Complainants argue that a thermistor is not disclosed in Mendelsohn or in Webster. CIB at 278, 280. Apple relies on Dr. Sarrafzadeh's testimony that thermistors "have been known for many years as a resistive circuit." Tr. (Sarrafzadeh) at 1055:19-1056:1. Apple cites a 2003 technical dictionary describing a "thermistor," RX-0419, and a thermistor in a pulse oximeter disclosed in Yamada. RX-0381 at ¶ [0111]. As discussed below, Yamada's disclosure shows that thermistors were known in the prior art and could be used in pulse oximeters.

As discussed above, Apple has not shown by clear and convincing evidence that claim 9 of the '127 patent is obvious in view of Mendelsohn in combination with Webster, because these references fail to disclose a "thermal mass" or the measurement of a "bulk temperature for the thermal mass," and Apple has not shown that it would have been obvious for one of ordinary skill in the art to add these elements.

2. Yamada

Apple contends that claim 9 of the '127 patent is obvious in view of Japanese Patent Application Publication No. 2004-337605A, entitled "Light Probe, Measuring System Using the Same, and Reflected Light Detecting Method Using the Same," naming inventor Yukio Yamada (RX-0381, "Yamada"), in combination with U.S. Patent No. 5,334,916, entitled "Apparatus and Method for LED Mission Spectrum Control, naming inventor Masahiro Noguchi (RX-0353,

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“Noguchi”). RIB at 239-43; RRB at 146-48. Yamada was published on December 2, 2004, and Noguchi issued on August 2, 1994. RX-0381; RX-0353. Yamada and Noguchi are prior art to the '127 patent pursuant to 35 U.S.C. § 102(b).¹¹³

Complainants argue that Apple has not shown claim 9 to be obvious in view of Yamada and Noguchi because these references fail to disclose the claimed “thermal mass” and the limitations requiring a temperature sensor “thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass.” CIB at 280-83; CRB at 164-67.

a. Element [7 preamble]: “physiological sensor”

There is no dispute that Yamada meets the limitations of the preamble of claim 7 by describing a pulse oximeter, which is “[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient.” *See* RIB at 239; CIB at 280-82; Tr. (Sarrafzadeh) at 1058:2-7; RDX-7.33C; RX-0381 at ¶ 0041, Fig. 1, Fig. 5.

b. Element [7A]: “a thermal mass”

With respect to the “thermal mass” limitation, Dr. Sarrafzadeh identifies Yamada’s disclosure of LEDs and photodetectors mounted on a printed circuit board with electrical connections, wherein “the wires provide thermal connectivity.” Tr. (Sarrafzadeh) at 1058:8-19. Dr. Sarrafzadeh testified that a person of ordinary skill in the art “would know that you can readily implement this in a multilayer fashion, also add thermal cores in order to provide better thermal management in the circuit.” *Id.* Apple argues that Complainants have accused a similar multilayer printed circuit board of meeting this limitation in the context of infringement. RIB at 239-40; RRB at 146-47.

¹¹³ *See supra* n.109.

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Complainants argue that Yamada does not disclose a “thermal mass” because there is no description of the structure or thermal properties of Yamada’s substrate. CIB at 281.

Complainants submit that Dr. Sarrafzadeh’s testimony is insufficient to show that Yamada’s circuit board is a “thermal mass.” *Id.* Mr. Goldberg testified that Yamada does not disclose a thermal mass “which stabilizes and normalizes in a manner that allows the bulk temperature as measured by the temperature sensor.” Tr. (Goldberg) at 1396:22-1397:8. Complainants note that Yamada discloses a “thermal conductor” that “is able to adequately disperse heat from” Yamada’s LED to the exterior. RX-0381 at ¶¶ 101-102. Complainants argue that this heat dispersal is different from the use of a thermal mass to stabilize a bulk temperature for measurement. CRB at 165-166; *see* Tr. (Goldberg) at 1398:9-1399:8.

In consideration of the parties’ arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Yamada discloses a “thermal mass.” For the same reasons discussed above in the context of Mendelsohn, Apple has failed to show that the circuit board in Yamada is a “thermal mass” and has failed to show that one of ordinary skill in the art would have modified Yamada to incorporate a “thermal mass.” In particular, Apple has failed to identify any disclosure in Yamada that describes the stabilization of temperatures on its circuit board, and Dr. Sarrafzadeh’s testimony with respect to modifying Yamada was conclusory and unsupported by disclosures in the prior art. Apple failed to identify any clear evidence that one of ordinary skill in the art would have modified Yamada to provide temperature stabilization—Yamada discloses a “thermal conductor” that “is able to adequately disperse heat,” RX-0381 at ¶¶ 101-102, without any discussion of temperature stabilization and no identified need for additional thermal management.

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- c. Element [7B]: “a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass”**

There is no dispute that Yamada discloses a plurality of LEDs mounted on a substrate. *See* RIB at 240-41; CIB at 280-82. Dr. Sarrafzadeh identified two LEDs electrically and thermally connected to the circuit board in Yamada. Tr. (Sarrafzadeh) at 1058:20-1059:6; RDX-7.35C; RX-0381 at ¶ [0043], Fig. 5.

- d. Element [7C]: “the sources having a corresponding plurality of operating wavelengths”**

There is no dispute that the LEDs in Yamada have two different wavelengths. *See* RIB at 241; CIB at 280-82. Dr. Sarrafzadeh identifies disclosures in Yamada describing wavelengths of red light and infrared light. Tr. (Sarrafzadeh) at 1059:10-16; RDX-7.36C; RX-0381 at ¶ [0043] (“The light a first wavelength may be, for example, red light with a wavelength near 660 [nm]. . . The light of a second wavelength may be, for example, near infrared light with a wavelength near 880 [nm].”).

- e. Element [7D]: “the thermal mass disposed within the substrate”**

Apple argues that the “thermal mass disposed within the substrate” limitation is obvious in view of Yamada for the same reasons that as the “thermal mass” limitation. *See* RIB at 241; Tr. (Sarrafzadeh) at 1059:18-25. For the reasons discussed above in the context of the “thermal mass” limitation, the undersigned finds that Apple has not shown that “the thermal mass disposed within the substrate” is disclosed in Yamada or that one of ordinary skill in the art would have modified Yamada to add a “thermal mass.”

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f. Element [7E]: “a temperature sensor thermally coupled to the thermal mass”

With respect to the “temperature sensor” limitation, Apple points to Yamada’s disclosure that “a temperature sensor maybe be attached to the light probe . . . to the surface of the substrate.” RX-0381 at ¶ [0109]. Dr. Sarrafzadeh explains that this temperature sensor would be electrically attached and thus thermally coupled to the alleged “thermal mass.” Tr. (Sarrafzadeh) at 1060:1-7; RDX-7.38C. Complainants dispute Yamada’s disclosure of a “temperature sensor,” but their arguments appear to be directed to the “thermal mass” limitation and the “bulk temperature” limitation. CIB at 281-82; CRB at 165. There does not appear to any dispute that Yamada explicitly discloses that a temperature sensor may be attached to the substrate.

g. Element [7F]: the temperature sensor “capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature”

With respect to the “bulk temperature” limitation, Apple cites Yamada’s disclosure of a temperature sensor attached to the light probe on the surface of the LED substrate. RIB at 241; Tr. (Sarrafzadeh) at 1060:8-17. Apple argues that Yamada’s temperature sensor meets the “bulk temperature” limitation under the same theory that Complainants have asserted for infringement of this limitation. CIB at 242. Dr. Sarrafzadeh explains that the relationship between the temperature of an LED and its wavelength is a property of physics that would have been known to persons of ordinary skill in the art, and an equation defining this relationship is explicitly described in Noguchi. Tr. (Sarrafzadeh) at 1060:25-1061:9; RDX-7.40C; RX-0353 at 2:59-68. Noguchi describes “a temperature measurement means for measuring the temperature of an LED or for measuring the temperature in the environment in which the LED is disposed,” adding that “[a] plurality of LEDs and a plurality of temperature measurement means can be utilized in the present invention.” RX-0353 at 1:38-50. Dr. Sarrafzadeh testified that one of ordinary skill in

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the art would have known from the teaching in Noguchi that a temperature measurement could be used to provide better wavelength estimation for the pulse oximeter in Yamada. Tr. (Sarrafzadeh) at 1061:10-1062:8. He explains that using Noguchi's wavelength estimation would have improved the functioning of Yamada's pulse oximeter and that this functionality would have been "easily added" by one of ordinary skill in the art. *Id.*

Complainants argue that the temperature sensor in Yamada does not measure a "bulk temperature." CIB at 281-82. Mr. Goldberg testified that Yamada's temperature sensor is only configured to detect "when the temperature gets too high for safety reasons," and not to measure a bulk temperature that "can be used for reliably estimating LED operating wavelengths." Tr. (Goldberg) at 1396:22-1397:8 (citing RX-0381 at ¶ [111]). Complainants note that Yamada discloses a "thermal conductor" for heat dispersal rather than to stabilize a bulk temperature for measurement. CRB at 165-166 (citing RX-0381 at ¶¶ 101-102); *see* Tr. (Goldberg) at 1398:9-1399:8. Complainants argue that Noguchi does not measure a "bulk temperature" for estimating wavelengths for multiple LEDs but merely discloses measuring the temperature of an LED to measure the wavelength for that LED. CIB at 283; CRB at 166-67; Tr. (Goldberg) at 1397:9-21. Complainants argue that Apple has failed to show a motivation to combine Yamada and Noguchi with an expectation of success. CRB at 167.

In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Yamada in combination with Noguchi discloses a temperature sensor capable of determining a "bulk temperature for the thermal mass." Yamada does not disclose a measurement of temperature for a "thermal mass"—the temperature sensor is placed "to measure the temperature near the user" to "take action when the temperature gets too high, for example by sounding an alarm or halting light emission from the light-emitting

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component.” RX-0381 at ¶¶ 0901-0111. Noguchi similarly fails to disclose a measurement of temperature for a “thermal mass”—similar to Webster’s disclosures discussed above, Noguchi describes the relationship between an LED’s temperature and its operating wavelength, *see* RX-0353 at 1:38-50, 2:58-60, but Noguchi fails to disclose the measurement of a “bulk temperature for the thermal mass.” Noguchi does not describe the use of a single representative temperature for a “thermal mass” but instead suggests direct temperature measurements of individual LEDs, describing “[a] plurality of LEDs and a plurality of temperature means.” RX-0353 at 1:48-50. Dr. Sarrafzadeh’s suggestion to average the readings from multiple temperature sensors to generate a “bulk temperature” is conclusory and is not supported by disclosures in the prior art. *See* Tr. (Sarrafzadeh) at 1060:8-16. Apple has not shown that any measurement of a “bulk temperature” is disclosed in Yamada or Noguchi, or that such a measurement would have been known to persons of ordinary skill in the art.

h. Element [7G]: “a detector capable of detecting light emitted by the light emitting sources after tissue attenuation”

There is no dispute that Yamada discloses a detector that receives light from the LEDs after tissue attenuation. *See* RIB at 243; CIB at 280-82. Yamada explicitly discloses that “[a] portion of the light that traversed body tissue is received by the light-receiving component 12.” RX-0381 at ¶ 0062; *see* Tr. (Sarrafzadeh) at 1062:9-14.

i. Element [7H]: “wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths”

There is no dispute that the detector in Yamada is used to determine blood oxygen saturation based on the ratio of the fluctuation ranges of red and infrared light. *See* RIB at 243; CIB at 280-82. Yamada explicitly discloses that “a strength signal for the light is sent to the analysis component 2 in the form of an electrical signal,” and “analysis component 2 determines

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the range of fluctuation in the strength signal at each wavelength The CPU 23 then searches the memory component 25 for the numerical value of the oxygen concentration level corresponding to the ratio of the fluctuation ranges, and outputs the result of the search.” RX-0381 at ¶ 0062, 0065; *see* Tr. (Sarrafzadeh) at 1062:15-24.

j. Element [9]: “a thermistor”

Claim 9 further requires that the “temperature sensor” of claim 1 is a thermistor. There is no dispute that Yamada discloses the use of a thermistor as its temperature sensor. *See* RIB at 243; CIB at 280-82. Yamada explicitly provides examples of temperature sensors: “it is possible to use a thermistor, a metal resistance temperature detector, or a thermocouple as the temperature sensor.” RX-0381 at ¶ 0111; *see* Tr. (Sarrafzadeh) at 1062:21-25.

For the reasons discussed above, Apple has not shown by clear and convincing evidence that claim 9 of the ’127 patent is obvious in view of Yamada in combination with Noguchi , because these references fail to disclose a “thermal mass” or the measurement of a “bulk temperature for the thermal mass,” and Apple has not shown that it would have been obvious for one of ordinary skill in the art to add these elements.

3. Objective Indicia of Non-Obviousness

Complainants identify evidence of commercial success and industry praise for Masimo’s rainbow® sensors that support a finding of non-obviousness. CIB at 285-87. Masimo’s financial records show that Masimo has earned ██████████ in revenue from the sale of rainbow® sensors practicing claim 9 of the ’127 patent, with a growth rate of ██████████ from 2008 through 2014. Tr. (McGavock) at 1426:9-1427:7; CDX-0019C.0012 (citing CX-0649C). Complainants further cite evidence that the rainbow® sensors have won numerous awards,

including the 2006 Medical Design Excellence Gold Award, the 2007 LoneStar Award for Innovation and Support, and the 2006 American Electronics Association Innovative Medical Technology Award. CX-1378 at 62-68. In connection with a 2006 award from the Society for Technology in Anesthesia, a study of a rainbow® sensor product found that the “technology represents a major advance in the monitoring of oxygenation.” *Id.* at 69. Mr. Goldberg testified that the success of the rainbow® sensor products “obviously depended on them functioning to do what they were meant to do, which was to measure a variety of physiological parameters in a manner that hadn’t been done before,” and the patented features were [REDACTED]

[REDACTED] Tr. (Goldberg) at 1400:9-1401:18.¹¹⁴ Apple argues that Complainants failed to show a nexus between the invention of the ’127 patent and the alleged commercial success and industry praise, criticizing Mr. Goldberg’s testimony as conclusory. CRB at 149.

In consideration of the parties’ arguments, the undersigned finds that the evidence of commercial success and industry praise for the early rainbow® sensor products is consistent with the findings of nonobviousness with respect to claim 9 of the ’127 patent, although Complainants’ evidence for nexus is weak.¹¹⁵ There is no explicit praise for the temperature-based wavelength correction in the early rainbow® sensor products, but Complainants did present testimony from Mr. Diab that the [REDACTED]

¹¹⁴ Complainants also identify evidence of teaching away, CIB at 287, but this evidence has been considered in the context of the *prima facie* case for obviousness with respect to the “bulk temperature” limitation allegedly disclosed in Webster. *See supra*, n.111, n.112.

¹¹⁵ These secondary considerations are only relevant with respect to the early rainbow® sensors that have been found to practice claim 9 of the ’127 patent. Accordingly, any post-2009 commercial success is not relevant to obviousness.

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[REDACTED] Tr. (Diab) at 204:2-11. This evidence shows that there may be some nexus between the invention of the '127 patent and the commercial success and industry praise for the early rainbow® sensor products, although inventor testimony is not the type of “objective” evidence that is generally considered by the Federal Circuit. *Cf. Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) (“The so-called “secondary considerations” provide evidence of how the patented device is viewed by the interested public: not the inventor, but persons concerned with the product in the objective arena of the marketplace.”). Accordingly, the evidence of commercial success and industry praise for the early rainbow® sensor products is not entitled to significant weight, but it is consistent with the findings of nonobviousness above with respect to claim 9 of the '127 patent.

VII. DOMESTIC INDUSTRY – ECONOMIC PRONG (MASIMO WATCH)

With respect to the Poeze patents and the '745 patent, Masimo relies on “Masimo Watch” products to satisfy the domestic industry requirement, including certain prototypes that were developed between 2019 and 2021, and a final product that was manufactured in December 2021. *See* CIB at 26-35, 288-309.

A. The “Masimo Watch” Articles

The earliest “Masimo Watch” prototype identified in this investigation is the “Circle sensor” (CPX-0021C), which “would have been built in October 2019,” according to Masimo engineer Stephen Scruggs. Tr. (Scruggs) at 394:12-18. Masimo’s next domestic industry product is the “Wings sensor” (CPX-0029C), which “would have been built in January of 2020.” *Id.* at 395:7-15. Both the Circle sensor and Wings sensor relied on an external device to calculate oxygen saturation, but in November 2020, Masimo built the “RevA sensor” (CPX-

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0052C), “which included onboard processing.” *Id.* at 396:2-13. Then in April 2021, Masimo added a display for the “RevD sensor” (CPX-0058C). *Id.* at 397:7-24. Between May and September 2021, during the time the complaint was filed, Masimo developed the “RevE sensors” (CPX-0019C, CPX-0020C, CPX-0065C), which included certain changes to the emitters and photodiodes of the “RevD sensor.” Tr. (Scruggs) at 398:1-23.¹¹⁶

B. Disputed Background Issues Regarding Domestic Industry Investments

As preliminary issues, the parties dispute (1) whether the investments in “Masimo Watch” products can be aggregated for the economic prong analysis; and (2) whether Masimo’s pre-2018 investments regarding wrist-worn sensors should be considered. *See* RIB at 249-50, 256-57, 267-68; RRB at 155, 164; CIB at 301-05; CRB at 179-80. Each of these disputes is addressed below.

1. Aggregation of “Masimo Watch” Expenditures

Complainants have not separately accounted for domestic industry expenditures with respect to each Masimo Watch prototype, relying on Masimo’s aggregate investments because the prototypes were part of a continuous design and development effort towards a commercial product. CIB at 300-301 (citing Tr. (Muhsin) at 342:25-343:7 (describing “many iterations of wrist sensors”), 345:2-7 (describing “[m]any iterations on the watch through the design phases”); Tr. (Scruggs) at 393:12-20 (“we’ve designed, built, and tested many iterations of the Masimo Watch”), 402:2-12 (describing “the progression of the different sensor designs”).

¹¹⁶ Complainants also rely on the Masimo W1 as a domestic industry product, but for the reasons discussed *supra* in the context of the technical prong, evidence regarding this product will not be considered.

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Apple argues that it was improper for Complainants to aggregate the Masimo Watch expenditures. RIB at 256-57. Apple cites *Certain Electronic Stud Finders, Metal Detectors, And Electrical Scanners*, where the Commission held that “aggregating investments in different domestic products that practice different patents effectively precludes the Commission from quantifying the amounts of the investments in each statutory category and determining the significance” of such investments. Inv. No. 337-TA-1221, Comm’n Op. at 48, EDIS Doc. ID 765331 (Mar. 14, 2022) (“*Electronic Stud Finders*”).

In consideration of the parties’ arguments, the undersigned finds that Masimo’s investments in the development of Masimo Watch prototypes can be aggregated for the economic prong analysis. The record shows continuous development of such prototypes at Masimo—unlike the different products at issue in *Electronic Stud Finders*, the evidence indicates that the Masimo Watch prototypes are merely “iterations” of a product design that was continuously developed in the years leading up to the filing of the complaint. *See* Tr. (Muhsin) at 342:25-343:7, 345:2-7; Tr. (Scruggs) at 393:12-20, 402:2-12; Tr. (Al-Ali) at 275:13-276:11. The Circle sensor was built in October 2019, the Wings sensor in January 2020, the RevA sensor in November 2020, the RevD sensor in April 2021, and the RevE sensors between May and September 2021. *See* Tr. (Scruggs) at 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23. Within such a development timeline, there is no reasonable way to delineate between work on separate prototypes—research and development activities within the Masimo Watch project between January 2020 and November 2020 are likely to involve both improvements to the Wings sensor and development of new features for the RevA sensor. Masimo’s CFO, Micah Young, explained that Masimo’s financial records did not track expenditures at this level of detail. *See* Tr. (Young) at 48:22-25.

With respect to the '745 patent, aggregation of the domestic industry expenditures is clearly appropriate because each of the identified prototypes has been found to practice claim 18 of the '745 patent.¹¹⁷ Complainants have not asserted that the Circle sensor or the Wings sensor practice claims of the Poeze patents, but the record shows that the development of these prototypes led to the development of the RevA, RevD, and RevE prototypes that Complainants have asserted as domestic industry products for the Poeze patents. *See* Tr. (Scruggs) at 394:12-398:23. Accordingly, the undersigned finds that Masimo's pre-complaint investments in all of the identified prototype Masimo Watch products can also be considered as part of the domestic industry for the Poeze patents and the '745 patent. The evidence shows that Masimo's investment in the development of these prototypes occurred in the most relevant timeframe for determining whether the domestic industry requirement has been satisfied—*i.e.*, the time period leading up to the date the complaint was filed in July 2021.

2. Masimo's Pre-2018 Investments

Complainants have identified over [REDACTED] in investments in research and development related to “wrist-worn parameter monitoring” dating back to 2001 and continuing up to 2018. CIB at 305; CRB at 179-80. Complainants submit that these research and development activities were “foundational” to the development of the Masimo Watch. CRB at 179-80. Apple argues that these investments pre-date any of the identified Masimo Watch prototypes and cannot be reasonably attributed to the asserted domestic industry articles. RIB at 249-50, 267-68; RRB at 155, 164.

¹¹⁷ Although the record is not clear as to whether the Circle sensor and Wings sensor were connected to the identified Rad-97 monitor before the filing of the complaint for satisfaction of the technical prong, there is evidence that these sensors were used with some external monitors to measure blood oxygen, *see* Tr. (Scruggs) at 403:11-404:2, and investments in these prototypes are thus “with respect to articles protected by” the '745 patent.

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In consideration of the parties' arguments, Masimo's pre-2018 expenditures will be excluded from the domestic industry analysis. There is no specific evidence in the record describing Masimo's "wrist-worn" research and development activities, and Complainants have provided no clear explanation of the relationship between these activities and the identified Masimo Watch prototypes. *See* Tr. (Kiani) at 115:1-122:21.¹¹⁸ The Commission has held that merely identifying expenditures with respect to general product lines is not sufficient to account for expenditures "with respect to" domestic industry articles. *See Certain Digital Media Devices, Including Televisions, Blu-Ray Disc Players, Home Theater Systems, Tablets and Mobile Phones, Components Thereof and Associated Software*, Inv. No. 337-TA-882, Final Initial Determination at 449-51, EDIS Doc. ID 539707 (July 7, 2014) (finding that investments that "are linked to broad product categories rather than to specific products" do not "form an adequate basis for a determination that a domestic industry exists"), *not reviewed in relevant part* by Comm'n Notice, EDIS Doc. ID 541887 (Sept. 11, 2014). Accordingly, Masimo's pre-2018 expenditures will not be considered as part of the domestic industry analysis.

C. Domestic Industry Existing at the Time of the Complaint

As discussed above in the context of the technical prong of the domestic industry requirement for the Poeze patents and the '745 patent, *supra* Section IV.F.7, Section V.F.2, Complainants have shown that Masimo Watch prototypes practicing claim 12 of the '501 patent, claim 28 of the '502 patent, claims 12, 24, and 30 of the '648 patent, and claim 18 of the '745 patent existed at the time of the filing of the complaint. Complainants rely on investments with

¹¹⁸ There is evidence that there were separate concurrent projects in this timeframe related to wrist-based pulse oximetry at Masimo and Cercacor. *See* Tr. (Kiani) at 119:4-8 (describing a "friendly rivalry" with Cercacor in 2018). It is unclear whether some of these projects were related to product designs that are distinct from the asserted "Masimo Watch" prototypes.

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respect to the development of “Masimo Watch” prototypes to show that a domestic industry existed at the time of the complaint. CIB at 288-309. Complainants rely on Masimo financial information that was presented in appendices to the complaint that were extracted from Masimo’s records. Tr. (Young) at 485:10-488:17; CDX-0006C.002 (citing CX-0629C; CX-0635C; CX-0624C; CX-0623C; CX-0646C; CX-0632C; CX-0628C; CX-0638C); CDX-0006C.003 (citing CX-0641C; CX-0645C; CX-0644C; CX-0640C; CX-0648C; CX-0649C; CX-0642C). Complainants have separately identified investments with respect to plant and equipment and labor and capital. *See* CIB at 301-09.

1. Plant and Equipment Expenditures

Mr. Kiani described research and development on wrist-based pulse oximetry at Masimo and Cercacor in Irvine, California. Tr. (Kiani) at 119:9-12. Mr. Young, Masimo’s CFO and Executive Vice President, presented certain facility expenditures between the third quarter of 2019 and the first quarter of 2021 at Masimo’s Irvine headquarters and a nearby manufacturing facility. Tr. (Young) at 481:17-20, 488:18-490:16; CDX-0006C.004. Complainants do not rely on the amounts reported by Mr. Young, however, instead identifying adjusted (and lower) amounts for plant and equipment investment that were calculated by its expert, Mr. McGavock. CIB at 301-02; *see* Tr. (McGavock) at 539:16-23; CDX-0015C.006. For the 2018-2021 timeframe, Masimo identifies ██████████ in plant and equipment expenditures for Masimo Watch research and development at Masimo’s headquarters (52 Discovery), and ██████████ in plant and equipment expenditures for manufacturing at the Laguna Canyon Road facility. CIB at 301-02

Mr. McGavock testified that he “followed basically the same methodology as Mr. Young did.” Tr. (McGavock) at 538:4-15. Mr. Young explained that he allocated the operating expenses at Masimo headquarters using the portion of square footage of the facility that was

dedicated to R&D and then the percentage of employee time that was spent on the Masimo Watch. Tr. (Young) at 489:22-16. With respect to the Laguna Canyon Road facility, Mr. Young allocated operating expenses based on an estimate that “about [REDACTED] percent of the square footage of that facility is dedicated to the Masimo Watch project.” *Id.* at 489:10-16. Mr. Young explained that Masimo’s operating expenses include “maintenance and utilities, property taxes, and other facility-related costs.” *Id.* at 489:17-21.

Apple contends that Mr. McGavock’s analysis was unreliable, arguing that it was based on Masimo financial data that has not been verified and estimates from Masimo employees without sufficient explanation. RIB at 245-48; RRB at 152-54. With respect to the allocation of Masimo’s facility operating expenses, Apple argues that there is no documentary evidence to support the square footage allocations, such as floor plans. RRB at 157. Apple further identifies evidence that the portion of the Laguna Canyon Road facility designated for Masimo Watch manufacturing is shared by other projects. RIB at 251 (citing CX-0629C). A Masimo witness admitted that the allocation percentage was based on projections, without confirming that the space was used for the Masimo Watch. RX-1202C (Kaufman Dep. Tr.) at 71:12-19. With respect to allocations of employee time, Apple argues that there is no documentary evidence in the record, such as time sheets or calendar entries, to support these estimates, and the Masimo witness testimony is insufficient to explain the basis for the allocations. CRB at 152-54.

In consideration of the parties’ arguments, the undersigned finds that Complainants have provided a sufficiently reliable allocation of 2018-2021 facility operating expenses for research and development at Masimo’s headquarters for the Masimo Watch. The time allocations relied upon by Mr. McGavock appear to be reasonable, and the Commission has relied on similar allocations of square footage and employee time based on witness testimony. *See Certain Solid*

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State Storage Drives, Stacked Electronics Components, and Products Containing Same, Inv. No. 337-TA-1097, Comm'n Op. at 17-20, EDIS Doc. ID 649139 (June 29, 2018) (relying on a manager's estimates for allocations of square footage and employee time); *see also Certain Electrical Connectors and Cages, Components, And Products Containing the Same Thereof*, Inv. No. 337-TA-1241, Final ID at 362-66, EDIS Doc. ID 767918 (Mar. 11, 2022) (finding "good faith" estimates of employee time to be reliable), *not reviewed in relevant part by* Comm'n Notice, EDIS Doc. ID 779717 (Sept. 8, 2022). Mr. Young explained that the time allocations were prepared with Masimo's "executive team members as well as leaders of different functions and departments across the organization." Tr. (Young) at 486:16-18; *see* Tr. (Scruggs) at 436:8-12 (estimated of square footage); Tr. (Al-Ali) at 322:6-14 (estimated headcounts and percentages of time for Masimo Watch engineers); Tr. (Muhsin) at 359:12-360:5 (estimated time for executives). The allocation of manufacturing expenses at the Laguna Canyon Road facility does not appear to be reliable, however, because it is based on a projection without confirmation that any of the Masimo Watch prototypes were manufactured there. *See* RX-1202C (Kaufman Dep. Tr.) at 71:12-72:15 (explaining that the [REDACTED] percent allocation was based on a projection of the square footage that would be used for Masimo Watch manufacturing). Complainants cite testimony from the hearing that Masimo Watch prototypes were manufactured at Masimo's California facilities, *see* CRB at 175, but there is no evidence specifically placing any manufacturing at the Laguna Canyon Road facility. These manufacturing-related expenditures cannot be considered part of the alleged domestic industry without evidence that operations in the Laguna Canyon Road facility were "with respect to" the domestic industry articles.

Accordingly, the qualifying plant and equipment expenditures for the Masimo Watch are limited to the [REDACTED] in operating expenses at Masimo's headquarters for Masimo Watch research and development from 2018-2021.¹¹⁹

2. Labor and Capital Expenditures

Complainants further rely on Masimo's employment of labor and capital with respect to the Masimo Watch. CIB at 303-05. Using a timeframe from the third quarter of 2019 to the first quarter of 2021, Mr. Young identified several categories of Masimo's labor and capital expenditures with respect to the Masimo Watch. Tr. (Young) at 488:18-496:19; CDX-0006.004. Using the projections and allocation methods described above, Mr. Young calculated [REDACTED] in operating expenditures for the Laguna Canyon Road manufacturing facility for the Masimo Watch at. Tr. (Young) at 489:2-21; CDX-0006C.005. Relying on estimates of square footage and employee time, Mr. Young calculated [REDACTED] in operating expenditures for research and development at Masimo's headquarters. Tr. (Young) at 489:22-490:15; CDX-0006C.004-.008; CX-0635C. Mr. Young calculated [REDACTED] in capital items expenditures related to the Masimo Watch, based on purchases of "new machinery that we used in production of the watch, as well as existing machinery that was repurchased." Tr. (Young) at 490:19-492:10; CDX-0006C.009-.010; CX-0635C; CX-0611C; CX-0835C. He also identified [REDACTED] spent on equipment supplies for the Masimo Watch. Tr. (Young) at 492:11-15; CDX-0006C.011. Mr. Young calculated [REDACTED] in labor expenditures for research and development related to the Masimo Watch, explaining that this amount was determined by using estimated time

¹¹⁹ As discussed above, the most relevant timeframe for domestic industry expenditures is the period when the Masimo Watch prototypes were built between 2019 and 2021. Expenditures extending to 2018 may be less relevant, but the inclusion of this additional year in Masimo's plant and equipment investments does not affect the domestic industry analysis because, as discussed *infra*, Complainants have not identified any context for assessing the significance of these investments.

allocations for Masimo employees. Tr. (Young) at 492:20-493:7; CDX-0006C.012-.013; CX-0635C. He also identified [REDACTED] in labor expenditures for [REDACTED] executives who worked on Masimo Watch. Tr. (Young) at 493:8-494:17; CDX-0006C.014-.015; CX-0624C. Mr. Young further identified [REDACTED] for clinical labor, [REDACTED] for regulatory and quality assurance, and [REDACTED] for recruiting labor for the Masimo Watch project. Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Mr. Young calculated [REDACTED] in expenditures for external watch design, which were paid by Masimo to third parties [REDACTED]. Tr. (Young) at 495:8-496:19; CX-0617C; CX-0620C.

Complainants also identify an estimated [REDACTED] in investments in research and development for wrist-worn technology dating back to 2001, which was calculated by taking Masimo's total R&D investments in the United States and allocating the time of Masimo employees that was related to wrist-worn technology. CIB at 305; Tr. (Young) at 497:1-20.

Apple argues that Mr. Young's estimates are unreliable, contending that the amounts are based on Masimo financial data that has not been verified and estimates from Masimo employees without sufficient explanation. RIB at 245-48. Apple argues that there is no documentary evidence in the record, such as time sheets or calendar entries, to support Complainants' estimates of employee time, and that Masimo's witness testimony is insufficient to explain the basis for these allocations. CRB at 152-54. Apple further argues that Complainants improperly rely on expenditures related to early development of products that are not asserted to practice any claim of the Poeze patents or the '745 patent. RIB at 249-50; RRB at 155. With respect to the alleged manufacturing expenditures, Apple argues that the square footage allocation is unreliable and there is no evidence that prototypes were manufactured at that facility. RIB at 250-51; RRB at 156. With respect to Masimo's R&D expenditures, Apple argues that there is insufficient

evidence in the record describing the activities of Masimo employees or the use of Masimo facilities. RIB at 252-53, 271; RRB at 157. Apple argues that the alleged watch equipment supplies are not cognizable expenditures because there is no evidence in the record identifying the purchased supplies. RIB at 267. Apple contends that no consistent methodology was used to estimate the amount of executive labor, and it is not clear whether this includes non-cognizable expenditures, such as administrative overhead. *Id.* at 269-70. Apple further argues that there is insufficient evidence to substantiate Masimo's third-party payments for watch design or regulatory expenses. *Id.* at 271-72. Apple also argues that the estimate for recruiting labor expense is unreliable. *Id.* at 272.

In consideration of the parties' arguments, the undersigned finds that a majority of Complainants' asserted labor and capital expenditures have been reliably quantified for consideration as part of the alleged domestic industry in this investigation. As discussed above in the context of the plant and equipment expenditures, the time allocations for Masimo's employees are supported by the testimony of Masimo witnesses, which is similar to evidence that has been relied upon in other investigations. *See* Tr. (Young) at 492:20-493:7 ("We worked with our leaders of engineering, and they put together a listing of all the employees working on the watch. I think there's over [REDACTED] employees on the spreadsheet. They also provided the time allocation by month . . . And then we applied that to the compensation by each of those employees to come up with the allocation of R&D dollars."). Complainants have identified the names and salaries of each employee involved in the Masimo Watch project with monthly estimates of their time from 2019 to 2021. CX-0635C. Complainants provide a similar

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accounting for executive labor. CX-0624C.¹²⁰ Complainants further identify expenditures for recruiting engineers to work on the Masimo Watch. Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Apple argues that Complainants have provided insufficient detail regarding the staffing of particular Masimo Watch projects or the specific activities of Masimo executives and employees, RIB at 269-71, but Mr. Young explained that such detailed information is not tracked in Masimo's financial records. Tr. (Young) at 484:22-25. As discussed above, Masimo engineers explained that the asserted Masimo Watch prototypes were "iterations" of a product design that was continuously developed in the years leading up to the filing of the complaint. See Tr. (Muhsin) at 342:25-343:7, 345:2-7; Tr. (Scruggs) at 393:12-20, 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23, 402:2-12. Mr. Young further explained that with respect to the time allocations, he and other Masimo executives "were trying to also be conservative." Tr. (Young) at 493:14-494:6. With respect to Masimo's recruiting expenditures, the relevant human resources staff are identified in a spreadsheet, CX-0632C, and the allocations of time are supported by estimates made by Masimo employees. See RX-1202C (Kaufman Dep. Tr.) at 18:17-188:12. The Commission has held that with respect to domestic industry, "[a] precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation." *Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm'n Op., 2009 WL 5134139, at *17 (December 2009); see also *Certain Electronic Devices*, Inv. No. 337-TA-701, Order No. 58 at 5, EDIS Doc. ID 439031 (Nov. 18, 2010) ("[T]he Administrative Law

¹²⁰ Apple argues that the executive labor should be excluded because it may include "administrative overhead," RIB at 269-70, but the Commission's exclusion of "administrative overhead" concerns those activities "associated with importation of the domestic industry products." *Certain Bone Cements*, Inv. No. 337-TA-1153, Comm'n Op. at 22, EDIS Doc. ID 731649 (Jan. 25, 2021). Apple has not persuasively argued that administrative expenditures should be excluded for executives who are managing employees working on research and development in the United States.

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Judge declines as a matter of law to give credence to Apple's pro forma objections that Nokia has failed to give a precise accounting or failed to provide underlying documentation for sworn witness testimony."), *not reviewed by* Comm'n Notice, EDIS Doc. ID 440675 (Dec. 20, 2010). The allocations for employee and executive labor expenditures are thus reasonable, and these expenditures account for a majority of the asserted labor and capital, with [REDACTED] for employees engaged in Masimo Watch research and development, [REDACTED] for executives involved with the Masimo Watch project, and [REDACTED] in expenditures for recruiting. *See* CDX-0006C.012-.015, .016-.018.

With respect to the expenditures paid to outside firms for the design of the Masimo Watch, Apple argues that some of these may be foreign expenditures. RIB at 271-72. *See Certain Products Having Laminated Packaging, Laminated Packaging, and Components Thereof*, Inv. No. 337-TA-874, Comm'n Op. at 17, EDIS Doc. ID 517360 (Sept. 3, 2013) (finding that payments to vendors cannot be counted as part of the domestic industry where complainant "did not show that the . . . vendors manufacture the laminated packages in the United States"). Complainants submit that Masimo contracted with U.S.-based entities for these services, CRB at 176, but it is unclear whether the work will be conducted in the United States. The presentation from [REDACTED] identifies a U.S. address, but with additional addresses in Germany and China. CX-0620C at 23. The contract with [REDACTED] identifies a U.S. address, but the evidence is insufficient to show activities taking place in the United States before the time of the complaint. *See* CX-0617C (identifying [REDACTED]); CX-0618C (describing design milestones extending to the end of 2021).¹²¹ Based on this record, the

¹²¹ Apple contends that [REDACTED]. RIB at 271.

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undersigned agrees with Apple that these expenditures should not be counted as part of the alleged domestic industry. In any case, these expenditures are relatively small in comparison to Masimo's R&D expenditures, *see* CIB at 304-05, and whether these additional expenditures are counted as part of the domestic industry has no impact on the determination with respect to significance, *infra*, which is based on the number of Masimo employees engaged in R&D for the Masimo Watch in the United States.

Certain of Complainants' other claimed expenditures are also insufficiently supported by evidence in the record, and whether these additional expenditures are counted as part of the domestic industry has no impact on the determination with respect to significance, *infra*, which is based on Masimo's research and development activities. As discussed above in the context of plant and equipment, the operating expenses related to manufacturing are not supported by a reliable allocation or any evidence that the domestic industry articles were manufactured at the Laguna Canyon Road facility. In addition, Complainants have not identified evidence in the record cataloguing the capital items or the supplies that correspond to the asserted expenditures—Mr. Young's testimony only identifies one piece of machinery with a "picture of the piece of equipment being used in the production of the watch," Tr. (Young) at 491:14-23 (citing CX-0611C), but even for this piece of equipment, Complainants do not explain what it does or how it is related to any Masimo Watch prototypes. The claimed labor expenses related to clinical studies and regulatory and quality assurance appear to relate to the work of a small number of Masimo employees, but Complainants do not identify the employees or explain what they do. *See* CX-0623C; CX-0646C.

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As discussed above, Complainants have identified approximately [REDACTED] in qualifying plant and equipment expenditures based on operating expenses at Masimo’s headquarters, and approximately [REDACTED] in qualifying labor expenditures for employees, executives, and recruiting—each of these amounts relates to research and development of Masimo Watch prototype products.¹²²

Complainants argue that Masimo’s domestic investments are significant because 100% of the research and development activities for the Masimo Watch occur in the United States. CIB at 307; *see* Tr. (Kiani) at 321:23-322:5. Mr. McGavock testified that it was his understanding that the Masimo Watch was Masimo’s “[REDACTED]” Tr. (McGavock) at 543:1-544:14. Mr. Kiani described the Masimo Watch as [REDACTED] [REDACTED] Tr. (Kiani) at 126:19-23.

With respect to the labor expenditures, Complainants submit that the headcount of [REDACTED] employees ([REDACTED] full-time equivalent) in the first quarter of 2021 is significant. CIB at 307; *see* Tr. (Young) at 504:9-13; CX-0648C. Complainants submit that [REDACTED] percent of Masimo’s R&D engineers were working on the Masimo Watch at that time. CIB at 308; *see* Tr. (McGavock) at 544:21-545:25; CDX-0015C.012.¹²³ For the Masimo engineers working on the Masimo Watch,

¹²² Approximately [REDACTED] in operating expenses is also asserted as a capital expenditure, representing the same expenditures recognized as investments in plant and equipment. Regardless of whether this amount is added to the labor expenditures under subparagraph (B), it would not affect the significance analysis below.

¹²³ There is a discrepancy between Mr. McGavock’s testimony and his demonstrative regarding the “[REDACTED] percent” figure. He said: “The portion of the Masimo’s R&D engineering time dedicated to the watch was [REDACTED] percent at the first quarter of 2021.” Tr. (McGavock) at 545:12-14. His demonstrative reads: “Portion of Masimo R&D engineers dedicated to the Watch: [REDACTED] at Q1 2021.” CDX-0015C.012. Apple does not appear to dispute that the [REDACTED] refers to a percentage of Masimo R&D engineer headcount, as described in the demonstrative. *See* RIB at 274.

█ of their time was spent on the Masimo Watch. CIB at 308; *see* Tr. (McGavock) at 544:21-545:25; CDX-0015C.012. Mr. Al-Ali identified a specific team of engineers that █
█ for the Masimo Watch. Tr. (Al-Ali) at 323:18-342:21; *see also* Tr. (Muhsin) at 34:14-345:1. Mr. McGavock identified █, and
Complainants argue that their work was significant. CIB at 308; Tr. (McGavock) at 544:21-545:25; CDX-0015C.012. Complainants argue that Masimo’s investments are significant in absolute terms. CIB at 308-09.

Apple argues that Complainants have failed to demonstrate the significance of the claimed expenditures. RIB at 253-56, 272-74. With respect to plant and equipment, Apple argues that the facility operating expenditures related to research and development for the Masimo Watch only represent about █ of Masimo’s total facility operating expenditures. RIB at 255. Apple submits that Masimo’s R&D investments with respect to the Masimo Watch represent only █ of Masimo’s overall R&D investments. RIB at 273; Tr. (Thomas) at 1305:2-9. Apple argues that there is no significance to Complainants’ claim that the Masimo Watch represents Masimo’s █ because Masimo has historically focused on clinical products. RIB at 254-55 (citing Tr. (Kiani) at 140:8-11). Apple argues that Complainants’ reliance on allocation percentages to represent significance is unsupported and unreliable. RIB at 274; *see* Tr. (Thomas) at 1306:7-13 (“[U]sing percentages to arrive at a number and then circularly using those percentages to represent significance, I think, is misleading and inappropriate.”). Apple argues that the employment of █
█ does not demonstrate significance, and there is no evidence for what those engineers are doing after completion of the █. RIB at 274; Tr. (Thomas) at 1306:14-18.

In consideration of the parties' arguments, the undersigned finds that Complainants have shown significant employment of labor with respect to Masimo's investments in research and development for the Masimo Watch. The [REDACTED] in labor expenditures is quantitatively significant in the context of Masimo's broader research and development efforts, because it involves [REDACTED] employees ([REDACTED] full-time equivalent) representing over [REDACTED] percent of Masimo's research and development engineers. *See* Tr. (Young) at 504:9-13; Tr. (McGavock) at 545:12-14; CDX-0015C.012. Apple questions the reliability of Masimo's allocations of employee time, RIB at 274, but as discussed above, the allocations are supported by reliable witness testimony. *See* Tr. (Young) at 492:20-493:7. Apple argues that the investments in the Masimo Watch are a small fraction of Masimo's overall research and development budget, RIB at 273, but the fact that Masimo invests in other products does not diminish the significance of Masimo's investments in the Masimo Watch, because "[s]ignificance is based on the marketplace conditions regarding the articles protected by the Asserted Patents," and activities regarding "other products is not pertinent to this analysis." *Certain Carburetors and Products Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm'n Op. at 28, EDIS Doc. ID 692517 (Oct. 28, 2019). The significance of Masimo's investments in the Masimo Watch is corroborated by qualitative evidence that this was Masimo's [REDACTED] [REDACTED] *See* Tr. (Kiani) at 12:19-2; Tr. (McGavock) at 543:1-544:14. In addition, Masimo's investments are significant because all of the research and development for the Masimo Watch has occurred in the United States. CIB at 307; *see* Tr. (Kiani) at 321:23-322:5; *see Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83, EDIS Doc. ID 709073 (Apr. 28, 2020) (finding quantitative significance where "all, *i.e.*, 100 percent, of Kyocera's R&D and

engineering expenditures relating to complainant’s [DI products] occurs in the United States.”), *vacated and remanded on other grounds*, 22 F.4th 1369 (Fed. Cir. 2022); *Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing the Same*, Inv. No. 337-TA-1223, Initial Determination at 60, EDIS Doc. ID 756910 (Oct. 22, 2021) (finding quantitative significance where 100% of research and development activities were based in the United States), *not reviewed in relevant party by Comm’n Notice*, EDIS Doc. ID 762554 (Feb. 4, 2022).

Complainants also submit that Masimo’s investments in research and development for the Masimo Watch are qualitatively significant, because it represents [REDACTED]

[REDACTED] CIB at 307; Tr. (Kiani) at 121:11-123:16, 126:19-23; Tr. (McGavock) at 543:16-544:14. Complainants also point to the “custom designing and building tools and equipment” for the Masimo Watch. CIB at 307; Tr. (Scruggs) at 433:13-15; Tr. (McGavock) at 543:1-544:14. In particular, Complainants cite the design of a [REDACTED]. CIB at 307-08; Tr. (Al-Ali_ at 323:18-324:25; Tr. (Muhsin) at 344:14-345:1. These qualitative factors demonstrate the importance of the Masimo Watch development to Masimo, and this supports the finding of quantitative significance.

Complainants have not, however, persuasively shown that Masimo’s investments and plant and equipment are quantitatively significant. The floor space in Masimo’s headquarters that is attributable to work on the Masimo Watch only represents about [REDACTED] of the facility. *See* RIB at 255; Tr. (Young) at 489:22-490:13 (allocating [REDACTED] percent of the floor space to R&D and between [REDACTED] percent of R&D to the Masimo Watch); CX-0635C. In their briefing, Complainants have not placed their plant and equipment expenditures in any appropriate context that shows significance. *See Certain Earpiece Devices and Components Thereof*, Inv. No. 337-

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TA-1121, Comm'n Op. at 19, EDIS Doc. ID 693820 (Nov. 8, 2019) (remanding a summary determination on the economic prong because complainant did "not provide context of the company's operations, the marketplace, or the industry in question necessary to understand whether the relative value of its domestic activities and investments is significant or substantial."').¹²⁴

* * *

Accordingly, Complainants have met the economic prong of the domestic industry requirement based on the existence of a domestic industry at the time of the complaint with respect to significant investments in labor and capital for the research and development of the Masimo Watch. Complainants have thus satisfied the domestic industry requirement with respect to the Poeze patents and the '745 patent.

D. Domestic Industry in the Process of Being Established

Complainants further argue that there is a domestic industry in the process of being established based on Masimo's projected expenditures for the Masimo Watch. CIB at 305-09.¹²⁵ Mr. Young explained that at the time of the complaint, Masimo's financial department worked with engineering leaders and other Masimo employees to create a forecast of expected expenditures from the second quarter of 2021 to 2023. Tr. (Young) at 500:23-503:3; CDX-

¹²⁴ Complainants' other arguments for significance fail for the same reasons. It is unclear why the fact that engineers working on the Masimo Watch spend █████ of their time on the Masimo Watch should be evidence for significance. See CIB at 308; RIB at 274. There is evidence that the design of a █████ was qualitatively important to Masimo, but Complainants fail to explain why the work of these █████ engineers is quantitatively significant. See CIB at 308; RIB at 274.

¹²⁵ Masimo also relies on post-complaint evidence for the number of employees it has hired, a 2022 corporate acquisition, and a statement in Masimo's 2021 Earnings Presentation, CIB at 307-09, but this evidence will not be considered in the context of the economic prong, as discussed *supra*. Whether Complainants have shown a domestic industry in the process of being established will be determined based on the projections made by Masimo before the filing of the complaint.

000C.030-.031. Masimo projected an increase in headcount from [REDACTED] to [REDACTED] for research and development on the Masimo Watch during this timeframe. Tr. (Young) at 502:7-18; CDX-000C.032. Masimo also projected production costs for the Masimo Watch, estimating that there would be between [REDACTED] and [REDACTED] in US-based production costs in 2022 and between [REDACTED] and [REDACTED] in US-based production costs in 2023. Tr. (Young) at 502:19-503:3; CDX-000C.033. Mr. McGavock relied on these projections to estimate that [REDACTED] of the cost of goods for the Masimo Watch would be incurred in the United States. Tr. (McGavock) at 545:8-9; CDX-0015C.012. Complainants further argue that Masimo's growing number of Masimo Watch personnel and the expansion of the Laguna Canyon Road manufacturing facility shows that a domestic industry is in the process of being established. CRB at 176-77; *see* Tr. (McGavock) at 542:14-20, 563:8-13, 574:25-575:2.

Apple argues that Complainants have produced no definitive timeline for the completion of the Masimo Watch, citing the absence of business plans or other documentation in the evidentiary record. RIB at 258-60, 275; RRB at 158-59, 172. Apple further argues that Masimo's projected expenditures are unsupported and unreliable. RIB at 258-60; RRB at 151, 156, 169-70.¹²⁶ Apple argues that Complainants' projections for the share of domestic expenditures in the manufacturing of future Masimo Watch products is unreliable and notes that the [REDACTED] for later versions of the Masimo Watch. CIB at 273 (citing CX-0629C). Apple suggests that Masimo Watch manufacturing would likely be [REDACTED]

¹²⁶ Apple argues that Masimo's projections for Masimo Watch manufacturing was [REDACTED], RIB at 258-60, RRB at 169-70, but this post-complaint evidence will not be considered in the context of the economic prong analysis.

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██████████. *Id.* at 273-74; *see* RX-1211C (Young Dep. Tr.) at 84:14-17; Tr. (McGavock) at 570:7-10.

In consideration of the parties' arguments, the undersigned finds that Complainants have satisfied the economic prong of the domestic industry requirement with respect to a domestic industry in the process of being established for the Masimo Watch. The Commission has held that a domestic industry is in the process of being established when (1) a complainant takes "the necessary tangible steps to establish such an industry in the United States," and (2) there is a "significant likelihood that the industry requirement will be satisfied in the future." *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 16-17, EDIS Doc. ID 300615 (May 16, 2008). For the reasons discussed below, the evidentiary record shows that Masimo has met both requirements based on evidence of activities and investments before the filing of the complaint and projections that were made at the time of the filing of the complaint.

Masimo's design and production of Masimo Watch prototypes represent tangible steps toward the establishment of a domestic industry with respect to the Masimo Watch. As explained by Mr. Scruggs, these prototypes were designed and built from 2019 through 2021, incorporating features asserted in the claims of the Poeze patents and the '745 patent. *See* Tr. (Scruggs) at 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23. Mr. Kiani explained that these prototypes were part of the ongoing project to design and manufacture the Masimo Watch. Tr. (Kiani) at 121:7-122:8, 123:17-124:4; CX-0364C; CX-0783C. As discussed above in the context of Masimo's pre-complaint investments in labor, the research and development of the Masimo Watch prototypes involved up to ████████ Masimo employees (working the equivalent of ████████ full-time employees). *See* Tr. (Young) at 504:9-13. There is further evidence that at the time of the filing

of the complaint, Masimo planned to hire additional engineers to work on the Masimo Watch project, *see* Tr. (Young) at 502:7-18, CDX-000C.032, and in preparation for this expanding workforce, Masimo had taken the tangible step of hiring additional recruiting staff. *See* Tr. (Young) at 495:3-7; RX-1202C (Kaufman Dep. Tr.) at 18:17-188:12; CX-0632C. Masimo has also contracted with external design firms for work on future Masimo Watch products. *See* Tr. (Young) at 495:16-496:19; CX-0617C; CX-0618C; CX-0620C.¹²⁷ The record thus shows that Masimo was taking tangible steps towards the design and manufacture of the Masimo Watch at the time of the complaint.

As discussed above, Masimo invested ██████████ in labor expenditures in the years leading up to the complaint for research and development with respect to Masimo Watch prototypes, and this amount is both quantitatively and qualitatively significant in the context of Masimo's research and development activities. The record further shows that Masimo projected increased hiring for the Masimo Watch, and this further employment of labor would be significant for the same reasons as Masimo's past employment of labor. *See* Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Accordingly, there is a significant likelihood that the economic prong of the domestic industry requirement will be satisfied in the future with respect to the Masimo Watch based on Masimo's past and future investments in labor for research and development.

In addition, Masimo's projected expenditures for manufacturing of the Masimo Watch are further evidence for a significant likelihood that the domestic industry requirement will be satisfied in the future. Masimo has projected that about ██████ percent of its Laguna Canyon Road

¹²⁷ Even if this work is not conducted in the United States, *see* RIB at 271-72, the engagement of these design firms is evidence of Masimo's plans for the Masimo Watch.

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facility will be used for manufacturing the Masimo Watch. Tr. (Young) at 49:10-16; RX-1202C (Kaufman Dep. Tr.) at 71:12-72:15. Masimo has also projected that [REDACTED] of the manufacturing costs for the [REDACTED] Masimo Watch in 2021 would be domestic. Tr. (McGavock) at 545:8-9; CDX-000C.033; CX-0629C. The domestic share of manufacturing costs was projected to [REDACTED] to [REDACTED] for a [REDACTED] Masimo Watch in 2022 and to [REDACTED] for a [REDACTED] Masimo Watch in 2023. See RIB at 273; CX-0629C. Apple has identified reasons to be skeptical of the high projection for the [REDACTED] Masimo Watch, see RIB at 273-74, Tr. (Thomas) at 1305:10-19, but even the [REDACTED] figure would likely support a finding that the domestic industry requirement has been satisfied. Cf. *Certain Self-Anchoring Beverage Containers*, Inv. No. 337-TA-1092, Comm'n Op. at 13, EDIS Doc. ID 683010 (Jul. 4, 2019) (finding domestic investments representing 9 percent of the sales revenue for the domestic industry product to be significant). Moreover, even if Masimo's domestic contribution to manufacturing the Masimo Watch dropped in the future, the domestic industry requirement could still be satisfied based on Masimo's significant investments in research and development, as long as Masimo was continuing to make appropriate qualifying domestic investments. See *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm'n Op. at 68, 2015 WL 6755093, at *36 (Oct. 30, 2015) ("Past expenditures may be considered to support a domestic industry claim so long as those investments pertain to the complainant's industry with respect to the articles protected by the asserted IP rights and the complainant is continuing to make qualifying investments at the time the complaint is filed."); *Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1362 (Fed. Cir. 2019) (affirming Commission's "conclusion that a past investment may, by virtue of its connection to ongoing field service and assembly expenses, support a finding that the economic prong of the domestic industry requirement is met."). Although the level of

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investment can be disputed, the record unequivocally shows that Masimo expected to continue investing in the Masimo Watch in the United States with expenditures in research and development and manufacturing. *See* Tr. (Kiani) at 123:17-124:22 (describing 2020 presentation for Masimo Watch, CX-0783C); Tr. (Young) at 500:23-503:3 (describing projections for 2021-2023 spending).

* * *

Accordingly, Complainants have identified investments and projections for investments at the time of the complaint showing, by a preponderance of the evidence, a domestic industry in the process of being established with respect to the Masimo Watch. As discussed above, Complainants have also shown that Masimo Watch products meeting the limitations of certain claims of the Poeze patents and the '745 patent were in the process of being developed at the time of the complaint. Complainants have thus satisfied the economic prong of the domestic industry requirement for the Poeze patents and the '745 patent based on an industry in the process of being established.

VIII. DOMESTIC INDUSTRY – ECONOMIC PRONG ('127 PATENT)

For the '127 patent, Complainants rely on investments with respect to research and development and manufacturing of Masimo's rainbow® sensors to satisfy the economic prong of the domestic industry requirement. *Id.* at 302-03, 309-10.

A. Domestic Industry Existing at the Time of the Complaint

As discussed above in the context of the technical prong, the domestic industry products include “early” rainbow® sensors sold before 2009, which have been shown to practice claim 9 of the '127 patent, and “current” rainbow® sensors sold after 2009, which have not been shown

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to practice claim 9 of the '127 patent.^{128,129} Complainants have not allocated their domestic industry expenditures between early and current rainbow® sensors, however, and this precludes any reliable domestic industry analysis. *See Certain Subsea Telecomm. Sys. and Components Thereof*, Inv. No. 337-TA-1098, Comm'n Op. at 41, EDIS Doc. ID 691678 (Oct. 21, 2019) (“The Commission has found that complainants have not satisfied the domestic industry requirement where the complainant failed to allocate expenses to account for non-domestic industry products that do not practice the patent.”).

Even if Complainants had allocated their domestic industry expenditures between the early and current rainbow® sensors, Complainants cannot satisfy the domestic industry requirement based only on investments in the early rainbow® sensors, because the record indicates that these products were discontinued in favor of the current rainbow® sensors in 2009, more than a decade before the complaint in this investigation was filed. *See* CRB at 10; Tr. (Diab) at 233:16-20. In such circumstances, the Commission has required a showing of “ongoing qualifying activities under section 337(a)(3) at the time the complaint is filed.” *See Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm'n Op. at 68, 2015 WL 6755093, at *37 (Oct. 30, 2015); *see also*

¹²⁸ The parties dispute whether Complainants have sufficiently identified which products comprise the asserted Masimo rainbow® sensors. CIB at 36; RIB at 261; RRB at 160. As discussed above in the context of the technical prong, the undersigned finds that Complainants have sufficiently identified the asserted rainbow® sensors on a sales spreadsheet. CX-0649C.

¹²⁹ Apple argues that there are at least two models of rainbow® sensors that have not been asserted to practice the '127 patent, RRB at 160, but Complainants have acknowledged that the rainbow® sensors relevant to this investigation exclude these two models. *See* CIB at 36 n.4 (citing Tr. (Diab) at 210:13-19 (“All of rainbow sensors use wavelength correction except for a couple of them. One is an acoustic sensor, and the other one, it's called Light Set 1, but the rest of them all use temperature correction.”)). There is no indication that those two models are listed in the financial spreadsheet exhibit that lists the asserted rainbow® sensors. *See* CX-0649C.

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Certain Marine Sonar Imaging Devices, Including Downscan & Sidescan Devices, Prod. Containing the Same, & Components Thereof, Inv. No. 337-TA-921, Comm'n Op. at 55-57, EDIS Doc. ID 571940 (Jan. 6, 2016) (“The Commission, thus, has found, in various investigations, a domestic industry based on a complainant's past activities relating to a discontinued product where the complainant has shown continuing qualifying investments.”). There is no evidence in the record showing that Masimo has continued to invest in the early rainbow® sensors after their discontinuation. Complainants have not identified any continuing investments in warranty, customer service, or maintenance of early rainbow® sensors—the asserted domestic industry expenditures are related to research and development and manufacturing—these activities appear to have been directed to the current rainbow® sensors since 2009. CIB at 302-03, 309-10.

Accordingly, based on the present record, Complainants have failed to show that a domestic industry existed at the time of the complaint with respect to the early rainbow® sensors that have been shown to practice claim 9 of the '127 patent.

B. Domestic Industry in the Process of Being Established

Complainants also assert that there is a domestic industry in the process of being established for the rainbow® sensors, relying on projections of expenditures after the time the complaint was filed. CIB at 288, 299. These projected expenditures relate to research and development and manufacturing, CIB at 302-03, 309-10, and as discussed above, such expenditures appear to relate only to the current rainbow® sensors after 2009. Complainants have not attempted to explain how a domestic industry could be in the process of being established with respect to discontinued products. On this record, Complainants have failed to

show that a domestic industry was in the process of being established with respect to the early rainbow® sensors.

C. Asserted Domestic Industry Expenditures

As discussed above, Complainants have improperly aggregated their domestic industry expenditures for the early rainbow® sensors and the current rainbow® sensors, and there is insufficient evidence in the record to satisfy the economic prong of the domestic industry requirement with respect to the early rainbow® sensors alone. In the event the current rainbow® sensors were found to practice the '127 patent as well, however, the undersigned addresses certain of Complainants' domestic industry expenditures below to determine whether the asserted domestic industry expenditures are significant pursuant to subparagraphs (A) and (B) of section 337(a)(3). 19 U.S.C. § 1337(a)(3).

1. Plant and Equipment

Complainants identify Cercacor, which is headquartered in Irvine, California, as the developer of Masimo's rainbow® technology.¹³⁰ CIB at 299 (citing Tr. (Kiani) at 94:8-17, 119:9-12). Complainants further submit that Masimo manufactures the LEDs for the rainbow® sensors in a facility in Hudson, New Hampshire. CIB at 299; CX-0636C. Using allocations of square footage and employee time, Mr. McGavock calculated that Masimo invested ██████ in facility operating expenses at Masimo's headquarters for research and development of the rainbow® sensors between 2018 and the first quarter of 2021. Tr. (McGavock) at 547:6-13; CDX-0015C.014; *see* CIB at 302-03. He estimated ██████ in allocated research and development expenditures before 2018 at that facility and added an additional ██████ in

¹³⁰ Cercacor (formerly known as Masimo Laboratories) is a spinoff from Masimo that collaborates with Masimo on R&D for nonvital parameter monitoring. *See* Tr. (Kiani) at 93:12-94:7; *see also* CX-1612C.

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allocated research and development expenditures at an older Masimo facility. *Id.* He calculated ██████ in operating expenditures for manufacturing rainbow® sensors at Masimo’s Laguna Canyon Road facility between 2018 and the first quarter of 2021, and an additional ██████ in expenditures before 2018. *Id.* He further calculated ██████ in operating expenditures for manufacturing LEDs for rainbow® sensors at Masimo’s New Hampshire facility between 2018 and the first quarter of 2021, and an additional ██████ in expenditures before 2018. *Id.* As a measure of significance, Complainants submit that “█████ of Masimo’s facility investments for rainbow® are in the U.S.” CIB at 310; Tr. (McGavock) at 549:8-14; CDX-0015C.017.

Apple contends that Mr. McGavock’s analysis was unreliable, arguing that it was based on Masimo financial data that has not been verified with allocations that have not been explained. RIB at 262-64; RRB at 160-62. Apple argues that Complainants have failed to offer any documents or testimony explaining how employee time was estimated for rainbow® sensor R&D. RIB at 263; RRB at 161. With respect to manufacturing expenses, Apple argues that there is no explanation for how Complainants calculated the “standard cost” for the rainbow® sensor products. RIB at 263-64; RRB at 162. Apple argues that Complainants have failed to offer any evidence that explains how the LED manufacturing in New Hampshire relates to the rainbow® sensors and questions the accuracy of certain calculations of expenditures. RIB at 264; RRB at 162. Apple further argues that Mr. McGavock’s claim that Masimo’s facility expenses are ██████ domestic is not explained in the record, and it is contradicted by evidence that Masimo has significant manufacturing facilities in Mexico. RIB at 264-65; RRB at 163.

In consideration of the parties’ arguments, the undersigned finds that Complainants’ asserted expenditures are sufficiently reliable for the domestic industry analysis. With respect to these expenditures, Mr. McGavock explained that he “used the same methodology applied by

Mr. Young.” Tr. (McGavock) at 546:12-18. Mr. Young explained that for R&D expenditures on the rainbow® sensors, he relied on time allocations “received from our engineering leadership and teams,” explaining that these allocations were “ranges anywhere from [REDACTED] percent over time because that was a focus project for us.” Tr. (Young) at 500:8-22. For manufacturing costs, Mr. Young explained that he relied on “the U.S. standard costs,” which was pulled “from our financial data warehouse.” *Id.* at 498:2-10. Mr. Young confirmed that the semiconductor LEDs for the rainbow® sensors are manufactured in Hudson, New Hampshire. *Id.* at 505:12-16, 507:7-15. He further confirmed that Masimo’s engineering leads estimated that [REDACTED] percent of the Laguna Canyon Road facility and [REDACTED] percent of the Hudson facility was used to manufacture rainbow® sensors. *Id.* at 508:1-22. Although Masimo’s estimates may not be precise, the record shows that Mr. McGavock and Mr. Young relied upon reasonable allocations of Masimo’s expenditures to attribute the investments in plant and equipment to the rainbow® sensors.

There does not appear to be reliable support in the record, however, for Complainants’ assertion that [REDACTED] of Masimo’s facility investments for rainbow® are domestic. *See* CIB at 310; Tr. (McGavock) at 549:8-14; CDX-0015C.017; RIB at 264-65; RRB at 163.

Mr. McGavock’s testimony with respect to this figure is conclusory, with no explanation for how the percentage was calculated. *See* Tr. (McGavock) at 549:8-14; CDX-0015C.017.

Complainants cite two spreadsheets in their brief, *see* CIB at 310 (citing CX-0633C; CX-0636C), but it is not clear from these spreadsheets how the [REDACTED] figure was derived. This is Complainants’ only basis for significance that relies on investments in plant and equipment, and because this figure is unreliable, Complainants have failed to show significant investment in plant and equipment under subparagraph (A) of section 337(a)(3).

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With respect to employment of labor or capital, Complainants rely on investments by Cercacor in research and development for the rainbow® sensors. CIB at 309.¹³¹ Complainants claim that “Cercacor has employed the [REDACTED] to work on rainbow®.” CIB at 299 (citing CDX-0015C.015 (summarizing CX-0633C)). As such, Complainants assert that Cercacor’s expenditures in the employment of R&D labor or capital for the rainbow® sensors amounts to [REDACTED] pre-2018 and [REDACTED] from 2018-Q1 2021. *Id.* at 309 (citing CX-0633C at “R&D Spend History” tab; CX-0644C). In addition, Complainants state that “Cercacor has performed the [REDACTED] of its R&D on rainbow®, accounting for [REDACTED] in R&D through July of 2021.” *Id.* at 310 (citing Tr. (Hammarth) at 524:25-525:5).

Apple argues that Complainants offer no corroborating documentation for these R&D expenses or explain how their calculation provides a reliable basis for allocations necessary for the economic prong requirement. RIB at 276. In addition, Apple contends that Complainants fail to show that the R&D projects identified in Cercacor’s R&D expenditures are exclusively related to the rainbow® sensors, rather than to non-domestic industry products and projects. *Id.* For example, Apple asserts that Complainants’ expenditures include Ember, a commercialized product sold by Cercacor that is not a domestic industry product. *Id.* (citing Tr. (Hammarth) at 532:5-13). Similarly, Apple claims that Mr. Hammarth also identified [REDACTED] as a [REDACTED]

¹³¹ Complainants also set forth other labor or capital expenditures for the rainbow® sensors. *See* CIB at 309-10. However, because the other expenditures appear to be less reliable and are not as closely tied to Complainants’ asserted bases for significance, only Cercacor’s employment of R&D labor or capital is addressed herein.

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██████████ as an ██████████
██████████; and ██████████ as related, in part, to Ember. *Id.* (citing RX-1201C at 81:21-83:5; Tr. (Hammarth) at 527:12-528:22). Apple argues that Complainants allocate costs associated with each of these products and projects to the rainbow® sensors without any allocation for the non-domestic industry Ember product or any explanation for including R&D on ██████████ ██████████ in the absence of any showing that any of the rainbow® sensors use that technology. *Id.* at 276-77.

Contrary to Apple's assertions, the undersigned finds that a preponderance of the evidence demonstrates that these R&D expenditures are reliable. According to Mr. Kiani, the chairman and CEO of Masimo and Cercacor, Cercacor developed the rainbow® technology. Tr. (Kiani) at 94:8-17. Apple does not dispute this. Mr. Jeroen Hammarth, the CFO of Cercacor, testified that for the purposes of this investigation, Cercacor exported records from its ERP system and used Excel records from various tax analysis that it had performed over the years in the normal course of business. Tr. (Hammarth) at 523:22-524:2. He also testified that he prepared a financial spreadsheet showing Cercacor's R&D spend.¹³² *Id.* at 524:3-13; *see also* CX-0633C.¹³³ Mr. Hammarth testified that Cercacor's total R&D on the rainbow sensors though Q1 of 2021 was over ██████████. Tr. (Hammarth) at 525:3-5. This is consistent with the data in

¹³² The undersigned finds that such evidence is reasonable under the circumstances of this investigation. As the Commission has stated, "there is no need to define or quantify the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 26 (May 16, 2008) ("A precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation.")

¹³³ Apple refers to exhibit CX-0633C and states that it "concerns Cercacor R&D Labor, with no apparent relevance." RRB at 163. Sworn testimony demonstrates that Cercacor developed the rainbow® technology, making Cercacor's investment in R&D labor related to rainbow®, *i.e.*, the subject of CX-0633C, relevant. *See* Tr. (Kiani) at 94:8-17, 119:9-12; Tr. (Hammarth) at 524:3-13.

the financial spreadsheet prepared by Mr. Hammarth, as well as the financial spreadsheet prepared to support Mr. Young's declaration to the complaint.¹³⁴ See CX-0633C; CX-0644C at Tab "Rainbow Chart" (showing that Cercacor's rainbow® R&D spend from 2007-2020 is about [REDACTED]); Tr. (Young) at 488:2-17. And according to Mr. Hammarth all of that R&D "was done in the U.S." Tr. (Hammarth) at 525:6-8.

Moreover, the undersigned disagrees with Apple that certain R&D projects need to be excluded from Cercacor's R&D expenditures. The undersigned finds that a preponderance of the evidence shows that Cercacor specifically allocated certain of its projects to the rainbow® sensors. See, e.g., CX-0633 at Tab "Summary Calc" (showing subtotals for rainbow vs. non-rainbow). For example, Apple claims that the [REDACTED] project is outside the scope of the rainbow® sensors. However, Mr. Hammarth testified that the [REDACTED] [REDACTED] and the rainbow® sensor measures a collection of nonvital signs, including [REDACTED].¹³⁵ See Tr. (Hammarth) at 528:1-6; see also *id.* at 528:23-529:2. Similarly, Mr. Hammarth testified that Ember is a Cercacor product that "incorporates our technologies for hemoglobin measurement, carbon monoxide measurement, and some others."¹³⁶ Tr. (Hammarth) at 532:5-13; see also RX-1201C at 25:10-17 ("Ember is a small device that measures a number of blood constituents noninvasively."). The evidence, including documents

¹³⁴ As with the Masimo Watch, Complainants prepared several financial spreadsheets detailing their domestic expenditures for the rainbow® sensors. See CIB at 299-300. While Apple argues that these spreadsheets are unreliable as to the rainbow® sensors, Apple's arguments are unpersuasive for the same reasons as discussed above with respect to the Masimo Watch. See Part VII.C. *supra*.

¹³⁵ The [REDACTED]. See RX-1201C (Hammarth Dep.) at 82:2-4.

¹³⁶ [REDACTED] is the internal project name for the Ember product. See RX-1201C (Hammarth Dep.) at 82:8-10.

and sworn testimony, therefore shows that Cercacor accurately allocated certain R&D projects as related to the rainbow® sensors.

The evidence demonstrates that Cercacor's R&D investments in the rainbow® sensors are quantitatively and qualitatively significant.

Cercacor's largest project has been the rainbow® technology. For example, from 2005-2020, Cercacor spent a total net R&D expense of about [REDACTED], with about [REDACTED] of that dedicated to rainbow® technology. Tr. (Hammarth) at 524:16-525:5; CDX-0008C.002 (summarizing CX-0633C); CX-0633C. Moreover, as previously discussed, [REDACTED] of the investment in rainbow® technology was incurred in the U.S. Tr. (Hammarth) at 525:6-8; *see Gas Spring Nailer Prods. and Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83, EDIS Doc. ID 709073 (Apr. 28, 2020) (finding quantitative significance where "all, *i.e.*, 100 percent, of Kyocera's R&D and engineering expenditures relating to complainant's [DI products] occurs in the United States."), *vacated and remanded on other grounds*, 22 F.4th 1369 (Fed. Cir. 2022); *Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing the Same*, Inv. No. 337-TA-1223, Initial Determination at 60, EDIS Doc. ID 756910 (Oct. 22, 2021) (finding quantitative significance where 100% of research and development activities were based in the United States), *not reviewed in relevant party by Comm'n Notice*, EDIS Doc. ID 762554 (Feb. 4, 2022). Other than criticizing Complainants' other quantitative comparisons, or arguing that Complainants' expenditures are overstated and unreliable, Apple does not specifically rebut Complainants' contention that Cercacor's R&D investments are quantitatively

significant.¹³⁷ *See, e.g.* RIB at 278; RRB at 174-75. The evidence therefore demonstrates that Cercacor’s domestic investments in R&D labor for rainbow® are quantitatively significant.

Cercacor’s domestic R&D investments for the rainbow® sensors are also qualitatively significant. Cercacor’s R&D effort related to the rainbow technology has been a large part of its business, and again, was incurred entirely in the U.S. *See, e.g., Certain Percussive Massage Devices*, Inv. No. 337-TA-1206, Comm’n Op. at 10-15, EDIS Doc. ID 759545 (Jan. 4, 2022) (affirming finding that complainant satisfied the economic prong of the domestic industry requirement and finding qualitative significance, in part, because complainant’s domestic industry products “would not exist without [its] domestic operations and spending” because it “designed and developed the DI Products in the United States”). In addition, not only has it been Cercacor’s largest project in terms of R&D spend, as explained above, but over the years, Cercacor has employed the ██████ of its employees to work on rainbow®. *See* CDX-0015C.015 (summarizing CX-0633C) (showing that Cercacor has dedicated between ██████ and ██████ of its employees to rainbow®); CX-0633C. In addition to Cercacor’s domestic R&D labor investments, Masimo has also made domestic investments in R&D labor for rainbow®. *See* Tr. (Young) at 499:15-500:7; CX-0644C. Lastly, it is worth noting that Masimo also manufactures important components of the rainbow® sensors, semiconductor LEDs and optical packages of emitters and detectors, at its Hudson, New Hampshire facility in the U.S., distinguishing Complainants from a mere importer. *See* Tr. (Young) at 507:7-15; *see also* CX-0636C; CX-0638C; *see Certain Toner Supply Containers and Components Thereof (II)*, Inv. No. 337-TA-1260, Comm’n Op. at 11-12, EDIS Doc. ID 777011 (Aug. 3, 2022) (finding qualitative

¹³⁷ Apple’s arguments disputing quantitative significance focus on Complainant’s cost of goods (COGS) analysis. *See* RIB at 278. The undersigned, however, is not relying on that analysis in finding quantitative significance.

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significance where a domestic industry is based on “core manufacturing activities,” affirming an initial determination finding that “[s]uch activities have long been recognized as a domestic industry within the meaning of section 337.”).

In opposition, Apple argues that “Complainants ignore that rainbow® product revenues generally comprise only [REDACTED] of Masimo’s total product revenues in 2020.” *See* RIB at 278. Apple, however, fails to explain why this would be a more appropriate comparison under these circumstances. *See, e.g., Certain Carburetors and Prods. Containing Such Carburetors, Inv. No. 337-TA-1123, Comm’n Op. at 28 (Oct. 28, 2019)* (“Significance is based on the marketplace conditions regarding the articles protected by the Asserted Patents. The fact that a complainant may have substantial sales of other products is not pertinent to this analysis.”).

Accordingly, the undersigned finds that Complainants have demonstrated significant employment of labor or capital with respect to the rainbow® sensors. As discussed above, however, Complainants have not satisfied the domestic industry requirement with respect to the ’127 patent because the current rainbow® sensors have not been shown to practice any claim of the ’127 patent.

IX. CONCLUSIONS OF LAW

Based on the foregoing, and the record as a whole, it is the undersigned’s final initial determination that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof by reason of infringement of claims 24 and 30 of the ’648 patent. There has been no violation of the statute with respect to the asserted claims of the ’501 patent, the ’502 patent, the ’745 patent, or the ’127 patent.

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This determination is based on the following conclusions of law:

1. The Commission has subject matter jurisdiction over this investigation.
2. The Accused Products have been imported into the United States, sold for importation, and/or sold within the United States after importation.
3. The Commission has *in rem* jurisdiction over the Accused Products.
4. The Accused Products infringe claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.
5. The technical prong of the domestic industry requirement has been satisfied for claim 12 of the '501 patent, claim 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.
6. Claim 12 of the '501 patent, claim 28 of the '502 patent, and claim 12 of the '648 patent are invalid.
7. The '501 patent, '502 patent, and '648 patent have not been shown to be unenforceable.
8. The economic prong of the domestic industry requirement has been satisfied with respect to the '501 patent, the '502 patent, and the '648 patent.
9. The Accused Products have not been shown to infringe claims 9 or 27 of the '745 patent.
10. The technical prong of the domestic industry requirement has been satisfied for claim 18 of the '745 patent.
11. Claims 9, 18, and 27 of the '745 patent have not been shown to be invalid.
12. The '745 patent has not been shown to be unenforceable.
13. The economic prong of the domestic industry requirement has been satisfied with respect to the '745 patent.
14. The Accused Products have not been shown to infringe claim 9 of the '127 patent.
15. The technical prong of the domestic industry requirement has been satisfied for claim 9 of the '127 patent.
16. Claim 9 of the '127 patent has not been shown to be invalid.
17. The economic prong of the domestic industry requirement has not been satisfied with respect to the '127 patent.

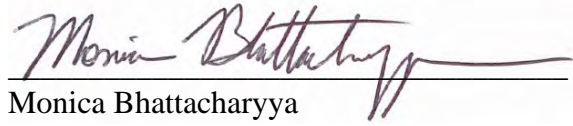
**CONTAINS CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO PROTECTIVE ORDER**

The undersigned hereby certifies the record in this investigation to the Commission with the undersigned's final initial determination. Pursuant to Commission Rule 210.38, the record further comprises the complaint and exhibits thereto, and the exhibits attached to the parties' summary determination motions and the responses thereto. 19 C.F.R. § 210.38(a).

Pursuant to Commission Rule 210.42(h)(2), this initial determination shall become the determination of the Commission 60 days after the service thereof, unless a party files a petition for review pursuant to Commission Rule 210.43(a), the Commission orders its own review pursuant to Commission Rule 210.44. 19 C.F.R. § 210.42(h)(2).

This initial determination is being issued with a confidential designation pursuant to Commission Rule 210.5 and the protective order in this investigation. Within 10 days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this final initial determination with any proposed redactions consistent with the manner specified by Ground Rule 1.9.¹³⁸ The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

SO ORDERED.



Monica Bhattacharyya
Administrative Law Judge

¹³⁸ Redactions should be limited to avoid obscuring the reasoning underlying the decision. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, explaining why each proposed redaction meets the definition for confidential business information in 19 C.F.R. § 201.6(a).

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

Certificate of Service – Page 1

CONFIDENTIAL CERTIFICATE OF SERVICE

I, Katherine M. Hiner, hereby certify that the attached **INITIAL DETERMINATION** has been served upon the following parties as indicated, on **January 24, 2023**.



Katherine M. Hiner, Acting Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

**On Behalf of Complainants Masimo Corporation and
Cercacor Laboratories, Inc.:**

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- Via Express Delivery
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- Other: Email Notification
of Availability for Download

On Behalf of Respondent Apple Inc.:

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- Via Express Delivery
- Via First Class Mail
- Other: Email Notification
of Availability for Download

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1276

LIMITED EXCLUSION ORDER

The United States International Trade Commission (“Commission”) has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by respondent Apple, Inc. of Cupertino, California (“Respondent”) of certain light-based physiological measurement devices and components thereof (as defined in paragraph 2 below) that infringe one or more of claims 22 and 28 of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648 (“Asserted Patents”).

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of infringing light-based physiological measurement devices and components thereof manufactured by or on behalf of Respondent or any of its affiliated companies, parents, subsidiaries, agents, or other related business entities, or its successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude the issuance of the limited exclusion order, and that the

bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the entered value of the articles subject to this Order.

Accordingly, the Commission hereby **ORDERS** that:

1. Light-based physiological measurement devices and components thereof that infringe one or more of claims 22 and 28 of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648 and are manufactured abroad by, or on behalf of, or imported by or on behalf of Respondent or any of its affiliated companies, parents, subsidiaries, agents, or other related business entities, or its successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the Asserted Patents, except under license from, or with the permission of, the patent owner or as provided by law; and except for parts necessary to service and repair covered products purchased by consumers prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4), and except for covered products that are replacements for covered products purchased by consumers prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4), provided that replacement is pursuant to a warranty for the replaced article.

2. The light-based physiological measurement devices and components thereof subject to this exclusion order (*i.e.*, “covered articles”) are as follows: wearable electronic devices with light-based pulse oximetry functionality and components thereof.

3. Notwithstanding paragraph 1 of this Order, covered articles are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of zero percent (0%, *i.e.*, no bond) of their entered value, pursuant to subsection (j) of section 337 (19 U.S.C.

§ 1337(j)) and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 Fed. Reg. 43,251), from the day after this Order is received by the United States Trade Representative until such time as the United States Trade Representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty (60) days after the receipt of this Order. All entries of covered articles made pursuant to this paragraph are to be reported to U.S. Customs and Border Protection (“CBP”), in advance of the date of the entry, pursuant to procedures CBP establishes.

4. At the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import articles may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate the certification.

5. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to covered articles that are imported by and for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

6. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission’s Rules of Practice and Procedure (19 C.F.R. § 210.76).

7. The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service and upon CBP.

8. Notice of this Order shall be published in the Federal Register.

By order of the Commission.

A handwritten signature in black ink, appearing to read "Lisa R. Barton". The signature is fluid and cursive, with a large loop at the end.

Lisa R. Barton
Secretary to the Commission

Issued: October 26, 2023

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1276

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT RESPONDENT Apple, Inc. of Cupertino, California cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of certain light-based physiological measurement devices and components thereof (as defined in Definition (G) below) that infringe one or more of claim 28 of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648 (“Asserted Patents”) in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

**I.
Definitions**

As used in this order:

- (A) “Commission” shall mean the United States International Trade Commission.
- (B) “Complainant” shall mean Masimo Corporation and Cercacor Laboratories, Inc., both of Irvine, California.
- (C) “Respondent” shall mean Apple, Inc. of Cupertino, California.

- (D) “Person” shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.
- (E) “United States” shall mean the fifty States, the District of Columbia, and Puerto Rico.
- (F) The terms “import” and “importation” refer to importation for entry for consumption under the Customs laws of the United States.
- (G) The term “covered products” shall mean light-based physiological measurement devices and components thereof that infringe one or more of claims 22 and 28 of U.S. Patent No. 10,912,502 and claims 12, 24, and 30 of U.S. Patent No. 10,945,648. The light-based physiological measurement devices and components thereof subject to this order are as follows: wearable electronic devices with light-based pulse oximetry functionality and components thereof. Covered products shall not include articles for which a provision of law or license avoids liability for infringement.

II. Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III. Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order.

For the remaining terms of the Asserted Patents, Respondent shall not:

- (A) import or sell for importation into the United States covered products;
- (B) market, distribute, sell, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered products;
- (C) advertise imported covered products;
- (D) solicit U.S. agents or distributors for imported covered products; or
- (E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of covered products.

IV. Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if:

- (A) in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct;
- (B) such specific conduct is related to the importation or sale of covered products by or for the United States; or
- (C) such specific conduct is limited to importation, sale, and provision of parts necessary to repair covered products purchased by consumers prior to the date this Order becomes final within the meaning of 19 U.S.C. § 1337(j)(4), or limited to importation and provision of covered products that are replacements for covered products purchased by consumers prior to the date this Order becomes final

within the meaning of 19 U.S.C. § 1337(j)(4), provided that replacement is pursuant to a warranty for the replaced article.

V. Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2023. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above. Submissions should refer to the investigation number (“Inv. No. 337-TA-1276”) in a prominent place on the cover pages and/or the first page. *See Handbook for Electronic Filing Procedures*, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf. Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the

original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.¹

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI. Record-Keeping and Inspection

- (A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.
- (B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

¹ Complainants must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

VII.
Service of Cease and Desist Order

The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service. While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 C.F.R. §§ 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant complete service of this Order for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

Respondent is ordered and directed to:

- (A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered products in the United States;
- (B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and
- (C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

VIII. Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX. Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X. Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI. Bonding

The conduct prohibited by section III of this order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 Fed. Reg. 43,251 (Jul. 21, 2005)), subject to Respondent's posting

of a bond in the amount of zero percent (0%, *i.e.*, no bond) of their entered value. This bond provision does not apply to conduct that is otherwise permitted by section IV of this Order.

Covered products imported on or after the date of issuance of this Order are subject to the entry bond as set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', enclosed within a large, loopy oval flourish.

Lisa R. Barton
Secretary to the Commission

Issued: October 26, 2023

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1276

**NOTICE OF THE COMMISSION'S FINAL DETERMINATION FINDING A
VIOLATION OF SECTION 337; ISSUANCE OF A LIMITED EXCLUSION ORDER
AND A CEASE AND DESIST ORDER; TERMINATION OF THE INVESTIGATION**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 in the above-captioned investigation. The Commission has determined to issue: (1) a limited exclusion order ("LEO") prohibiting the unlicensed entry of infringing wearable electronic devices with light-based pulse oximetry functionality and components thereof covered by certain claims of U.S. Patent Nos. 10,912,502 or 10,945,648 that are manufactured by or on behalf of, or imported by or on behalf of, respondent Apple, Inc. ("Apple") or any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns; and (2) a cease and desist order ("CDO") directed against Apple and any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 18, 2021, based on a complaint filed on behalf of Masimo Corporation and Cercacor Laboratories, Inc., both of Irvine, CA (collectively, "Complainants"). 86 FR 46275 (Aug. 18, 2021). The complaint, as amended, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for

importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,912,501 (“the ’501 patent”); U.S. Patent No. 10,912,502 (“the ’502 patent”); U.S. Patent No. 10,945,648 (“the ’648 patent”); U.S. Patent No. 10,687,745 (“the ’745 patent”); and U.S. Patent No. 7,761,127 (“the ’127 patent”). *Id.* The amended complaint further alleged that an industry in the United States exists and/or is in the process of being established as required by section 337. *Id.* The notice of investigation named Apple of Cupertino, California as the sole respondent. *Id.* at 46276. The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

Complainants previously withdrew certain asserted claims pursuant to Order No. 25 (Mar. 23, 2022), *unreviewed* by Comm’n Notice (Apr. 12, 2022), and Order No. 33 (May 20, 2022), *unreviewed* by Comm’n Notice (June 10, 2022). Only claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claims 12, 24, and 30 of the ’648 patent, claims 9, 18, and 27 of the ’745 patent, and claim 9 of the ’127 patent remain in the investigation. Claim 18 of the ’745 patent is still at issue for purposes of the domestic industry only.

On January 10, 2023, the presiding administrative law judge (“ALJ”) issued the final initial determination (“Final ID”), which found that Apple violated section 337 as to claims 24 and 30 of the ’648 patent, but not as to claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claim 12 of the ’648 patent, claims 9 and 27 of the ’745 patent, and claim 9 of the ’127 patent. *See* Final ID at 335–36. On January 24, 2023, the ALJ issued a Recommended Determination on remedy and bonding (“RD”) should a violation be found in the above-captioned investigation. The RD recommended that, if the Commission finds a violation, it should issue an LEO directed to certain wearable electronic devices with light-based pulse oximetry functionality and components thereof that are imported, sold for importation, and/or sold after importation by Apple; and a CDO directed to Apple. RD at 2, 5. The RD additionally recommended that the Commission set a zero percent (0%) bond (*i.e.*, no bond) during the sixty-day period of Presidential review. *Id.* at 6. In its notice instituting this investigation, the Commission did not instruct the ALJ to make findings and recommendations concerning the public interest. *See* 86 FR at 46275–76.

On January 23, 2023, Complainants and Apple each filed a petition for review. On January 31, 2023, Complainants and Apple each filed responses to the other party’s petitions.

On February 23, 2023, the parties filed their public interest statements pursuant to 19 CFR 210.50(a)(4). The Commission received numerous comments on the public interest from non-parties.

On May 15, 2023, after considering the parties’ petitions and responses thereto, the Commission determined to review the Final ID in part. *See* 88 FR 32243, 32243–46 (May 19, 2023). In particular, the Commission determined to review the following findings of the Final ID:

- (1) the domestic industry with regard to the '501 patent, the '502 patent, the '648 patent, and the '745 patent;
- (2) obviousness with regard to the '501 patent, the '502 patent, the '648 patent, and the '745 patent;
- (3) written description with regard to claim 28 of the '502 patent and claim 12 of the '648 patent;
- (4) claim construction and infringement with regard to the '745 patent; and
- (5) subject matter jurisdiction.

Id. The Commission requested briefing on certain issues under review and on remedy, the public interest, and bonding. *See id.*

On June 5, 2023, the parties filed their written submissions on the issues under review and on remedy, public interest, and bonding, and on June 12, 2023, the parties filed their reply submissions. The Commission also received numerous comments on the public interest from non-parties.

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission affirms with modifications the Final ID's domestic industry findings (both economic and technical prong) as to the '501, '502, '648, and '745 patents. The Commission additionally affirms with modifications the Final ID's conclusion that the asserted claims of the '501 patent are obvious, but the asserted claims of the '502, '648, and '745 patents are not obvious. The Commission has determined to reverse the Final ID's finding that Apple proved by clear and convincing evidence that claim 28 of the '502 patent and claim 12 of the '648 patent are invalid for lack of written description. Furthermore, the Commission affirms the Final ID's claim construction related to the recited term "first shape" and the related conclusion that the Accused Products do not satisfy elements [1B] and [20B] of the '745 patent. The Commission additionally vacates the Final ID's finding that the Commission has subject matter jurisdiction over the investigation and instead finds that the Commission has statutory authority over the investigation. The Commission affirms the remainder of the Final ID that is not inconsistent with the Commission's opinion issued concurrently herewith. As a result, the Commission finds that Apple has violated section 337 as to claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent.

The Commission has determined that the appropriate form of relief is an LEO prohibiting (1) the unlicensed entry of infringing wearable electronic devices with light-based pulse oximetry functionality and components thereof manufactured by or on behalf of Apple or any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns. The Commission has also determined to issue a CDO against Apple. The Commission has determined to include an exemption to the remedial orders for service or repair

or, under warranty terms, replacement of products purchased prior to the end of the period of Presidential review.

The Commission has further determined that the public interest factors enumerated in subsections (d)(1) and (f)(1) (19 U.S.C. 1337(d)(1), (f)(1)) do not preclude issuance of the above-referenced remedial orders. Additionally, the Commission has determined to impose a bond of zero (0%) (*i.e.*, no bond) of entered value of the covered products during the period of Presidential review (19 U.S.C. 1337(j)). This investigation is terminated.

The Commission vote for this determination took place on October 26, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: October 26, 2023

CONFIDENTIAL VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1276

COMMISSION OPINION

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CONFIDENTIAL VERSION**I. INTRODUCTION**

On May 15, 2023, the Commission determined to review in part the final initial determination (“ID”) issued by the presiding administrative law judge (“ALJ”) on January 10, 2023. 88 Fed. Reg. 32243 (May 19, 2023). On review, the Commission has determined that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to U.S. Patent Nos. 10,945,648 (“the ’648 patent”) and 10,912,502 (“the ’502 patent”), but not with respect to U.S. Patent Nos. 10,912,501 (“the ’501 patent”), 10,687,745 (“the ’745 patent”), and 7,761,127 (“the ’127 patent”). This opinion sets forth the Commission’s reasoning in support of that determination.

II. BACKGROUND**A. Procedural History**

The Commission instituted this investigation on August 18, 2021, based on an amended and supplemented complaint (“Complaint”) filed by complainants Masimo Corporation (“Masimo”) and Cercacor Laboratories, Inc. (“Cercacor,” collectively, “Complainants”).^{1, 2, 3} 86 Fed. Reg. 46275–76 (Aug. 18, 2021). The Complaint alleged violations of section 337 of the

¹ The original public complaint was filed on June 30, 2021. *See* EDIS Doc. ID 745713 (June 30, 2021). On July 7, 2021, Complainants filed an “Amendment to the Public Complaint, with Amended Exhibit 2 and Appendix C.” *See* EDIS Doc. ID 746186. And on July 12, 2021, Complainants filed a “Confidential Amendment to the Public Complaint and Exhibits.” *See* EDIS Doc. ID 746514. The Commission has determined that the filing date of the Complaint is July 12, 2021. *See, e.g.*, 86 Fed. Reg. at 46275; Final ID at 84 (including n.24).

² Supplement to the Confidential Amended Complaint and Exhibits, EDIS Doc. ID 747244 (July 19, 2021); Supplement to the Amended Public Complaint and Exhibits, EDIS Doc. ID 747240 (July 19, 2021).

³ Masimo is the owner of the ’501 patent (JX-0001), ’502 patent (JX-0002), ’648 patent (JX-0003), and ’745 patent (JX-0009). Compl. at ¶ 4. Cercacor is the owner of the ’127 patent (JX-0007). *Id.* Masimo and Cercacor have rights to each of the Asserted Patents through a cross-licensing agreement. *Id.* at ¶¶ 4, 77; CX-1612C.

CONFIDENTIAL VERSION

Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of the '501 patent; the '502 patent; the '648 patent; the '745 patent; and the '127 patent (collectively, the “Asserted Patents”). *Id.* The Complaint further alleged that an industry in the United States exists and/or is in the process of being established. *Id.* The notice of investigation named Apple Inc. of Cupertino, California as the sole respondent (“Apple”). *Id.* at 46276. The Office of Unfair Import Investigations is not participating in this investigation. *See id.*

Prior to the issuance of the Final ID, the investigation terminated as to several claims. Order No. 25 (Mar. 23, 2022), *unreviewed by* Comm’n Notice (Apr. 12, 2022); Order No. 33 (May 20, 2022), *unreviewed by* Comm’n Notice (June 10, 2022). At the time of the hearing on June 6–10, 2022, only the following claims remained at issue: claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, claims 12, 24, and 30 of the '648 patent, claims 9, 18,⁴ and 27 of the '745 patent, and claim 9 of the '127 patent.

⁴ Complainants proceeded at the hearing as to claim 18 of the '745 patent for domestic industry purposes only. *See, e.g.*, Final ID at 176. In other words, Complainants did not allege that Apple violated section 337 by infringing that claim.

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On May 13, 2022, Complainants and Apple filed their pre-hearing briefs.⁵ The parties filed initial post-hearing briefs on June 27, 2022,⁶ and the parties filed post-hearing reply briefs on July 11, 2022.⁷

On January 10, 2023, the ALJ issued the Final ID,⁸ which found that Apple violated section 337 as to only claims 24 and 30 of the '648 patent. *See* Final ID at 335–36. The Final ID found that Complainants did not establish a violation as to the other remaining asserted claims. *E.g., id.*

On January 24, 2023, the ALJ issued the Recommended Determination on Remedy and Bonding (“RD”).⁹ The RD recommended that, if the Commission finds a violation, it should

⁵ Complainants’ Pre-Hearing Brief, EDIS Doc. ID 770786 (May 13, 2022) (“CPreHBr.”); Respondent Apple Inc.’s Pre-Hearing Brief, EDIS Doc. ID 770790 (May 13, 2022). On May 16, 2022, Apple filed a corrected pre-hearing brief. Respondent Apple Inc.’s Corrected Pre-Hearing Brief, EDIS Doc. ID 770874 (May 16, 2022) (“RPreHBr.”).

⁶ Complainants’ Initial Post-Hearing Brief, EDIS Doc. ID 774000 (June 27, 2022); Respondent Apple Inc.’s Post-Hearing Brief, EDIS Doc. ID 774025 (June 27, 2022). On July 14, 2022, Complainant filed a corrected opening post-hearing brief. Complainants’ Corrected Initial Post-Hearing Brief, EDIS Doc. ID 775422 (July 14, 2022) (“CPHBr.”). On September 2, 2022, Apple filed a second corrected opening post-hearing brief. Respondent Apple Inc.’s Second Corrected Post-Hearing Brief, EDIS Doc. ID 779376 (Sept. 2, 2022) (“RPHBr.”).

⁷ Complainants’ Reply Post-Hearing Brief, EDIS Doc. ID 775058 (July 11, 2022) (“CPHBr. (Reply)”); Respondent Apple Inc.’s Reply Post-Hearing Brief, EDIS Doc. ID 775073 (July 11, 2022). On September 2, 2022, Apple filed a corrected post-hearing reply brief. Respondent Apple Inc.’s Corrected Post-Hearing Reply Brief, EDIS Doc. ID 779379 (Sept. 2, 2022) (“RPHBr. (Reply)”).

⁸ Final Initial Determination on Violation of Section 337, EDIS Doc. ID 787653 (Jan. 10, 2023); *see also* Final Initial Determination on Violation of Section 337, EDIS Doc. ID 789795 (Feb. 7, 2023) (Public Version).

⁹ Recommended Determination on Remedy and Bonding, EDIS Doc. ID 788506 (Jan. 24, 2023); *see also* Recommended Determination on Remedy and Bonding, EDIS Doc. ID 790079 (Feb. 10, 2023) (Public Version).

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issue a limited exclusion order (“LEO”) directed to certain wearable electronic devices with light-based pulse oximetry functionality and components thereof that are imported, sold for importation, and/or sold after importation by Apple; and a cease and desist order (“CDO”) directed to Apple. *See* RD at 2–5. The RD additionally recommended that the Commission set a 0% bond (*i.e.*, no bond) during the sixty-day period of Presidential review. *See id.* at 6–7. The Commission’s notice of investigation did not instruct the ALJ to make findings and recommendations concerning the public interest. *See* 86 Fed. Reg. at 46275–76.

On January 23, 2023, Complainants and Apple each filed a petition for review of the Final ID.¹⁰ On January 31, 2023, Complainants and Apple each filed responses to the other respective petition.¹¹

On January 24 and 30, 2023, (after the Final ID issued and petitions for review were filed), the United States Patent and Trademark Office (“USPTO”) denied Apple’s request for the institution of *inter partes* review proceedings (“IPRs”) as to the ’501, ’502, and ’648 patents based on a combination of references that included the same primary reference as one of the

¹⁰ Complainants’ Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 788456 (Jan. 23, 2023) (“CPet.”); Complainants’ Summary of Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 788457 (Jan. 23, 2023); Respondent Apple Inc.’s Petition for Review of the Initial Determination of Violation of Section 337, EDIS Doc. ID 788470 (Jan. 23, 2023) (“RPet.”); Respondent Apple Inc.’s Summary of Petition for Review of the Initial Determination of Violation of Section 337, EDIS Doc. ID 788474 (Jan. 23, 2023).

¹¹ Complainants’ Response to Apple Inc.’s Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 789044 (Jan. 31, 2023) (“CResp.”); Complainants’ Summary of Response to Apple Inc.’s Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 789045 (Jan. 31, 2023); Respondent Apple Inc.’s Response to Complainants’ Petition for Review, EDIS Doc. ID 789061 (Jan. 31, 2023) (“RResp.”); Respondent Apple Inc.’s Summary of Its Response to Complainants’ Petition for Review, EDIS Doc. ID 789067 (Jan. 31, 2023).

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combinations of references asserted against the asserted claims of those patents in this investigation. *See Apple Inc. v. Masimo Corp.*, IPR2022-01272 (USPTO Jan. 24, 2023) ('501 patent) (available at CResp. at Appx. B); *Apple Inc. v. Masimo Corp.*, IPR2022-01274 (USPTO Jan. 24, 2023) ('502 patent) (available at CResp. at Appx. C); *Apple Inc. v. Masimo Corp.*, IPR2022-01276 (USPTO Jan. 30, 2023) ('648 patent) (available at CResp. at Appx. A).

On February 23, 2023, the parties filed their public interest statements pursuant to 19 C.F.R. § 210.50(a)(4).¹² The Commission received numerous comments on the public interest from non-parties, discussed below in the public interest section of this Opinion.

On May 15, 2023, after considering the parties' petitions and responses thereto, the Commission determined to review the Final ID in part. *See* 88 Fed. Reg. at 32243–46. In particular, the Commission determined to review: (1) the domestic industry with regard to the '501 patent, the '502 patent, the '648 patent, and the '745 patent; (2) obviousness with regard to the '501 patent, the '502 patent, the '648 patent, and the '745 patent; (3) written description with regard to claim 28 of the '502 patent and claim 12 of the '648 patent; (4) claim construction and infringement with regard to the '745 patent; and (5) subject matter jurisdiction. *Id.* at 32244. The Commission determined not to review the remaining findings of the Final ID, including the finding of no violation as to the '127 patent. *Id.* The Commission requested briefing on certain issues under review and also on remedy, the public interest, and bonding. *See id.* at 32244-46. The Commission's public interest briefing request also solicited input from non-parties. *See id.*

¹² Complainants' Statement on the Public Interest, EDIS Doc. ID 791050 (Feb. 23, 2023) ("CStmt."); Respondent Apple Inc.'s Public Interest Statement, EDIS Doc. ID 791062 (Feb. 23, 2023) ("RStmt.").

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On June 5, 2023, the parties filed their written submissions on the issues under review and on remedy, public interest, and bonding,¹³ and on June 12, 2023, the parties filed their reply submissions.¹⁴ The Commission additionally received numerous comments on the public interest from non-parties, which are discussed below in the public interest section of this Opinion.

B. The Asserted Patents

The technology at issue in this investigation relates to user-worn devices for noninvasively measuring physiological parameters of a user.

1. U.S. Patent Nos. 10,912,501; 10,912,502; and 10,945,648: The “Poeze Patents”

The '501 patent (JX-0001), '502 patent (JX-0002), and '648 patent (JX-0003) share a common specification, claiming priority to an application filed on July 3, 2008. These patents are titled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User” and name as inventors Jeroen Poeze, *et al.* These patents are referred to herein as the “Poeze patents.”

¹³ Complainants’ Submission in Response to the Commission’s May 15, 2023 Notice of Commission Determination to Review in Part, EDIS Doc ID 797853 (June 5, 2023) (“CBr.”); Respondent Apple Inc.’s Response to the Commission’s Notice to Review in Part a Final Initial Determination and Request for Written Submissions, EDIS Doc ID 797870 (June 5, 2023) (“RBr.”).

¹⁴ Complainants’ Reply to Apple Inc.’s Response to the Commission’s Notice to Review in Part a Final Initial Determination and Request for Written Submissions, EDIS Doc ID 798353 (June 12, 2023) (“CBr. (Reply)”); Respondent Apple Inc.’s Reply to Complainants’ Response to the Commission’s Notice to Review in Part a Final Initial Determination and Request for Written Submissions, EDIS Doc ID 798383 (June 12, 2023) (“RBr. (Reply)”).

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Complainants assert claim 12 of the '501 patent, which depends from claim 1. *See* CPHBr. at 53–66. Claim 12 is reproduced below in a claim/element identifier chart that includes the element designations used by the parties and the Final ID.

| U.S. Patent No. 10,912,501 | |
|-----------------------------------|---|
| Identifier | Claim/Element |
| Claim 12 | |
| [1PRE] | A user-worn device configured to noninvasively measure a physiological parameter of a user, the user-worn device comprising: |
| [1A] | at least three light emitting diodes (LEDs); |
| [1B] | at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user; |
| [1C] | a protrusion arranged over the interior surface, the protrusion comprising a convex surface and |
| [1D] | a plurality of openings extending through the protrusion and positioned over the three photodiodes, |
| [1E] | the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion; and |
| [1F] | one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user. |
| [12] | The user-worn device of Claim 1, wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape. |

Complainants also assert claim 22 of the '502 patent, which depends from claims 19, 20, and 21, and claim 28, a separate independent claim. *See* CPHBr. at 66–77. These claims are reproduced below.

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| U.S. Patent No. 10,912,502 | |
|-----------------------------------|--|
| Identifier | Claim/Element |
| Claim 22 | |
| [19PRE] | A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising: |
| [19A] | a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs); |
| [19B] | four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user; |
| [19C] | a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue; |
| [19D] | optically transparent material within each of the openings; and |
| [19E] | one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user. |
| [20] | The user-worn device of claim 19 further comprising a thermistor. |
| [21] | The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal. |
| [22] | The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs. |

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| U.S. Patent No. 10,912,502 | |
|-----------------------------------|--|
| Identifier | Claim/Element |
| Claim 28 | |
| [28PRE] | A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising: |
| [28A] | a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength; |
| [28B] | a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength; |
| [28C] | four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user; |
| [28D] | a thermistor configured to provide a temperature signal; |
| [28E] | a protrusion arranged above the interior surface, the protrusion comprising: a convex surface; |
| [28F] | a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and |
| [28G] | a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings; |
| [28H] | at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities; |
| [28I] | one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal; |
| [28J] | a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network; |
| [28K] | a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user; |
| [28L] | a storage device configured to at least temporarily store at least the measurement; and |
| [28M] | a strap configured to position the user-worn device on the user. |

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Complainants further assert claim 12 of the '648 patent, which depends from claim 8, and claims 24 and 30, which depend from claim 20. *See* CPHBr. at 77–83. These claims are reproduced below.

| U.S. Patent No. 10,945,648 | |
|-----------------------------------|---|
| Identifier | Claim/Element |
| Claim 12 | |
| [8PRE] | A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising: |
| [8A] | a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength; |
| [8B] | a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength; |
| [8C] | four photodiodes; |
| [8D] | a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material; |
| [8E] | a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes; |
| [8F] | a separate optically transparent window extending across each of the openings; |
| [8G] | one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user; |
| [8H] | a housing; and |
| [8I] | a strap configured to position the housing proximate tissue of the user when the device is worn. |
| [12] | The user-worn device of Claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation. |

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| U.S. Patent No. 10,945,648 | |
|-----------------------------------|---|
| Identifier | Claim/Element |
| Claims 24 and 30 | |
| [20PRE] | A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising: |
| [20A] | a plurality of light emitting diodes (LEDs); |
| [20B] | at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user; |
| [20C] | a protrusion comprising a convex surface and |
| [20D] | a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and |
| [20E] | one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user. |
| [24] | The user-worn device of Claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping. |
| [30] | The user-worn device of Claim 20, wherein the protrusion further comprises one or more chamfered edges. |

2. U.S. Patent No. 10,687,745

The '745 patent (JX-0009) is titled "Physiological Monitoring Devices, Systems, and Methods," claims priority to an application filed on June 28, 2016, and names Ammar Al-Ali as the sole inventor. Complainants assert that Apple infringes claims 9 and 27, and they rely on claim 18 for domestic industry purposes only. Claim 9 is reproduced below as representative of the asserted claims of the '745 patent.

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| U.S. Patent No. 10,687,745 | |
|-----------------------------------|--|
| Identifier | Claim/Element |
| Claim 9 | |
| [1PRE] | A physiological monitoring device comprising: |
| [1A] | a plurality of light-emitting diodes configured to emit light in a first shape; |
| [1B] | a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue; |
| [1C] | a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light; |
| [1D] | a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface; |
| [1E] | a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue; |
| [1F] | and a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal. |
| [9] | The physiological monitoring device of claim 1, wherein the physiological parameter comprises oxygen saturation. |

3. U.S. Patent No. 7,761,127

The '127 patent (JX-0007) is titled "Multiple Wavelength Sensor Substrate," issued from an application filed on March 1, 2006, and names as inventors Ammar Al-Ali, *et al.*

Complainants assert claim 9 of the '127 patent, which depends from claim 7.

C. The Accused Products

Complainants accuse certain Apple Watches of infringing the Asserted Patents, including the Apple Watch Series 6, the Apple Watch Series 7, and certain prototype Apple Watch

products with project names [REDACTED] (collectively, the “Accused Products”). CPHBr. at 37–39. The parties have stipulated that the Accused Products are materially identical for the purposes of infringement in this investigation. *See* Joint Stipulation of Facts at ¶¶ 11–13, EDIS Doc. ID 770692 (May 13, 2022); CX-1259C at ¶¶ 7–8. Notably, the parties do not dispute that the currently-existing Apple Watch Series SE does not infringe the Asserted Patents because it is not equipped to measure the blood oxygen saturation of a user.

D. The Domestic Industry Products

With respect to the ’501, ’502, ’648, and ’745 patents, Complainants rely on their “Masimo Watch” products. CPHBr. at 26–35. These Masimo Watch products include certain prototypes identified as the “Circle Sensor” (CPX-0021C), the “Wings Sensor” (CPX-0029C), the “RevA Sensor” (CPX-0052C), the “RevD Sensor” (CPX-0058C), the “RevE Sensors” (CPX-0019C, CPX-0020C, CPX-0065C) (collectively, the “Masimo Watch Prototypes”), and a product identified as the “W1 Watch” (CPX-0146C). CPHBr. at 30–35. The Masimo Watch Prototypes were developed as part of an iterative design process that resulted in the W1 Watch, which was not completed until after the Complaint was filed. *Id.* at 62 n.16, 18.

With respect to the ’127 patent, Complainants rely on certain of Masimo’s “Rainbow[®] Sensors.” *Id.* at 36.

III. COMMISSION REVIEW OF THE FINAL ID

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Soft-Edged Trampolines & Components Thereof*, Inv. No. 337-TA-908, Comm’n Op. at 4 (May 1, 2015). Upon review, the “Commission has ‘all the powers which it would have in making the initial determination,’ except where the issues are limited on notice or by rule.” *Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm’n Op. at 9–10 (July 1997) (quoting *Certain Acid-Washed*

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Denim Garments & Accessories, Inv. No. 337-TA-324, Comm’n Op. at 5 (Nov. 1992)). With respect to the issues under review, “the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge.” 19 C.F.R. § 210.45(c). The Commission also “may take no position on specific issues or portions of the initial determination,” and “may make any findings or conclusions that in its judgment are proper based on the record in the proceeding.” *Id.*; *see also Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

IV. ANALYSIS OF THE ISSUES UNDER REVIEW

The Commission’s findings, conclusions, and supporting analysis follow. The Commission affirms and adopts the ID’s findings, conclusions, and supporting analysis that are not inconsistent with the Commission’s opinion.

A. Subject Matter Jurisdiction

The Final ID found that the Commission has “subject matter jurisdiction over this investigation.” Final ID at 336. The Commission reviewed this finding. 88 Fed. Reg. at 32244. On review, the Commission vacates the Final ID’s “subject matter jurisdiction” finding and instead finds that the Commission has statutory authority, rather than subject matter jurisdiction, over the present investigation. *See Certain Video Security Equipment & Sys., Related Software, Components Thereof, & Prods. Containing Same*, Inv. No. 337-TA-1281, Comm’n Op. at 9–10 (Apr. 19, 2023). The Commission and ALJs have used the term “jurisdiction” in the past as a shorthand for statutory authority. Executive agencies, of course, do not have jurisdiction, but rather are creatures of statute that cannot exceed their statutory authority.

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The Final ID found that claim 12 of the '501 patent would have been invalid as obvious over combinations of references primarily based on “Lumidigm,”¹⁵ but claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent would not have been invalid as obvious over those combinations. *E.g.*, Final ID at 88, 336. The Commission reviewed this finding. 88 Fed. Reg. at 32244. On review, the Commission affirms the Final ID’s conclusions as to obviousness with the modifications and supplements discussed herein.

1. The Applicable Law

A party cannot be held liable for infringement if the asserted patent claim is invalid. *See Pandrol USA, LP v. AirBoss Ry. Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003). Patent claims are presumed valid (35 U.S.C. § 282), so a respondent challenging validity must overcome this statutory presumption by “clear and convincing” evidence of invalidity. *Checkpoint Sys., Inc. v. Int’l Trade Comm’n*, 54 F.3d 756, 761 (Fed. Cir. 1995). One such ground for invalidity is that the claimed invention would have been obvious under 35 U.S.C. § 103.

Under 35 U.S.C. § 103(a), a patent is valid unless “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made” to a person having ordinary skill in the art. 35 U.S.C. § 103(a). The ultimate question of obviousness is a question of law, but “it is well understood that there are factual issues underlying the ultimate obviousness decision.”

¹⁵ U.S. Patent No. 7,620,212 (RX-0411), titled “Electro-Optical Sensor,” which issued from an application filed on August 12, 2003.

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Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

After claim construction:

The second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness.

Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1354 (Fed. Cir. 1999) (citing *Graham*, 383 U.S. at 17). The existence of secondary considerations, or objective indicia of non-obviousness, does not control the obviousness determination, because a court (and the Commission) must consider “the totality of the evidence” before reaching a decision on obviousness. *Richardson-Vicks*, 122 F.3d at 1483.

The Supreme Court clarified the obviousness inquiry in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 389 (2007). There, the Supreme Court said:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida*¹⁶ and *Anderson’s-Black Rock*¹⁷ are illustrative—a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple

¹⁶ *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976).

¹⁷ *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969).

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substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

...

The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

KSR, 550 U.S. at 417–19.

The Federal Circuit has since held that when a patent challenger contends that a patent is invalid for obviousness based on a combination of several prior art references, “the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so.”

PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

The TSM¹⁸ test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence—teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)—that arise before the

¹⁸ “TSM” is an acronym for “teaching, suggestion, or motivation.”

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time of invention as the statute requires. As *KSR* requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans.

Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1365 (Fed. Cir. 2008).

2. Introduction

a. Lumidigm

Lumidigm is titled “Electro-Optical Sensor.” See RX-0411 (Lumidigm). Lumidigm’s

Abstract is reproduced below:

Methods and systems are provided that extend the functionality of electro-optical sensors. A device has . . . multiple light sources, a light detector, and a processor configured to operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector.

RX-0411 (Lumidigm) at Abstract.

Figure 2 of Lumidigm is reproduced below:

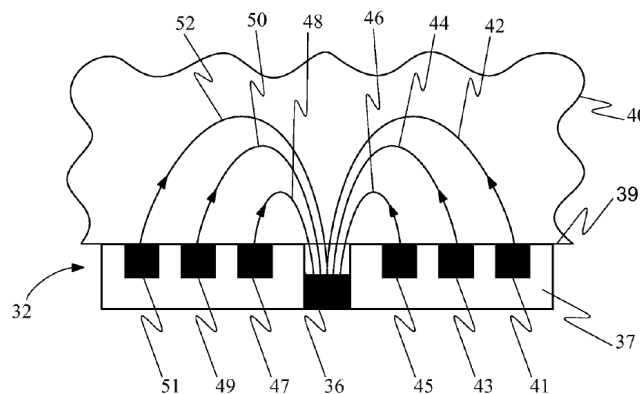


FIG. 2

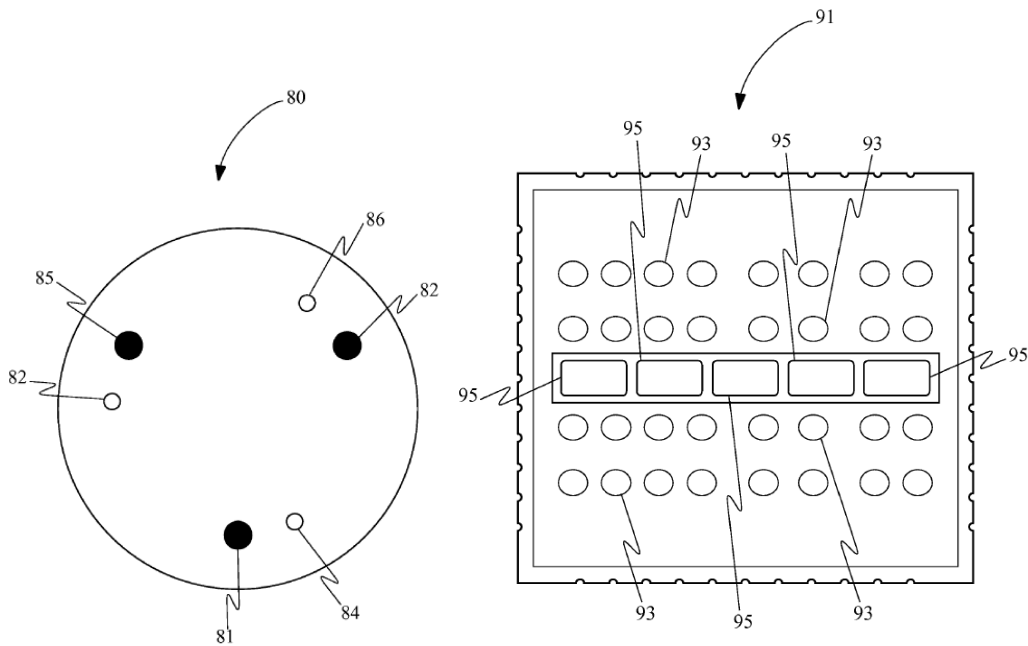
RX-0411 (Lumidigm) at Fig. 2. Figure 2 depicts a “cross-sectional view of a biometric sensor element couple[d] to a tissue surface showing multiple mean optical paths.” *Id.* at 4:45–47.

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Sensor head 32 includes light sources 41, 43, 45, 47, 49, and 51 and detector 36. *Id.* at 7: 5–10.

These light sources correspond to the claimed “LEDs,” and detector 36 corresponds to a claimed “photodiode.” Optical paths 42, 44, 46, 48, 50, and 52 show light passing through tissue 40 of a user. *Id.* Sensor head 32 is formed of optically opaque material 37, corresponding to the claimed “opaque material.”

Figures 6 and 7A of Lumidigm are reproduced below:

**FIG. 6****FIG. 7A**

RX-0411 (Lumidigm) at Figs. 6 and 7A. Figures 6 and 7A illustrate top-views of biometric sensors according to two embodiments of the invention. *Id.* at 4:60–67. In Figure 6, biometric sensor 80 includes light sources/LEDs 82, 84, and 86 positioned relative to detectors/photodiodes

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81, 83,¹⁹ and 85. *Id.* at 9:14–17. In Figure 7A, biometric sensor 91 includes four rows of light sources/LEDs 93 and one row of detectors/photodiodes 95. *Id.* at 9:27–30.

Figure 8B, reproduced below, depicts a wrist-watch embodiment:

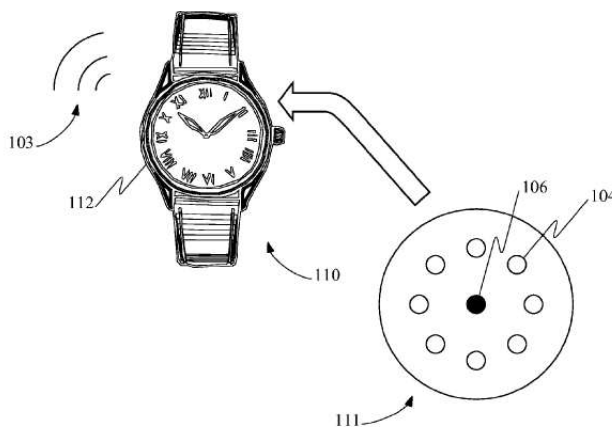


FIG. 8B

RX-0411 (Lumidigm) at Fig. 8B (depicting biometric system 110 including wristwatch 112, biometric reader 111, illumination system 104, and detection/diode system 106).

b. Summary of the Commission’s Conclusions

As noted above, the Final ID found that claim 12 of the ’501 patent would have been invalid as obvious over combinations of references primarily based on Lumidigm, but claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent would not have been invalid as obvious over those combinations. *E.g.*, Final ID at 88, 336. The Commission reviewed this finding. 88 Fed. Reg. at 32244.

On review, the Commission affirms the Final ID’s findings as to *prima facie* obviousness of claim 12 of the ’501 patent in its entirety. *See* Final ID at 89–113. Secondary considerations are discussed separately below.

¹⁹ The item number “82” for the dark circle at approximately 2 o’clock of Figure 6 is a typographical error. It is apparent that that item number was intended to be “83.”

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Regarding claim 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent, these claims recite, *inter alia*, a “user-worn device” comprising (1) “four photodiodes,” (2) a “protrusion,” (3) an “opening” or “through hole” “extending through” or “provided through” the protrusion and “aligned with” or “over” each of the four photodiodes, and (4) a separate “transmissive window” or “optically transparent material” “extending across” or “arranged over” each of the openings or through holes. *See* JX-0002 ('502 patent) at claim 28, elements [28C], [28E], [28F], and [28G]; JX-0003 ('648 patent) at claim 12, elements [8C], [8D], [8E], and [8F], and claims 24 and 30, elements [20B], [20C], and [20D]. Claim 22 of the '502 patent is similar, but more narrowly requires that an “optically transparent material” be included “*within* each of the openings.” *See* JX-0002 ('502 patent) at claim 22, elements [19B], [19C], and [19D].

The Commission concludes that Lumidigm and combinations of references therewith teach or suggest (1) the four photodiodes, and (2) the protrusion, but the combinations of references do not teach or suggest (4) a separate transmissive window or optically transparent material within, extending across, or over each of the openings or through holes. The Commission, however, takes no position on the Final ID's finding that the combinations of references do not teach or suggest (3) an opening or through hole extending through or provided through the protrusion and aligned with or over each of the four photodiodes. *See Beloit*, 742 F.2d at 1423. In doing so, the Commission slightly modifies the Final ID, as discussed below.

Regarding claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent, these claims also recite, *inter alia*, various limitations directed at the claimed user-worn devices being configured to measure the oxygen saturation of the user. JX-0002 ('502 patent) at claim 22, elements [19PRE] and [19E], and at claim 28, elements [28PRE], [28I], [28J], and

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[28K]; JX-0003 ('648 patent) at claim 12, elements [12], and claims 24 and 30, element [20E].²⁰

The Final ID found that neither Lumidigm nor combinations therewith teach or suggest these claim limitations. *See* Final ID at 113–18, 124, 128, 132–33, 140, 142. The Final ID also found that element [24] of claim 24 of the '648 patent was not taught or suggested by Lumidigm or combinations of references therewith. *See id.* at 142–44. The Commission affirms these findings for the reasons given in the Final ID.

Regarding the Final ID's analysis of objective indicia of non-obviousness, the Commission alters the Final ID's findings as to commercial success, and it does so by affirming those findings with the modifications discussed below.

Because the Commission modifies or supplements the Final ID's findings as to the *prima facie* obviousness and/or secondary considerations of these claims, the Commission evaluates anew (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness, to determine whether Apple has shown by clear and convincing evidence that these claims are invalid for obviousness. In doing so, the Commission concludes, as did the Final ID, that claim 12 of the '501 patent would have been invalid as obvious over combinations of references primarily based on Lumidigm, but claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent are not invalid as obvious over those combinations of references.

Below, the Commission provides its analysis regarding *prima facie* obviousness of the above-mentioned structural limitations, and then discusses the objective evidence of non-

²⁰ As the Final ID noted, the parties stipulated that the preambles of the asserted patents are limiting. *See* Final ID at 180 n.66.

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obviousness. Last, the Commission provides its analysis as to whether, in view of its underlying findings, Apple has shown by clear and convincing evidence that the asserted claims of the Poeze patents are invalid. In sum, the Commission concludes that Apple has not met its burden, except with respect to claim 12 of the '501 patent. The Commission affirms the Final ID as to *prima facie* obviousness and secondary considerations over Lumidigm and combinations of references therewith to the extent it is not modified or reversed herein.

3. Prima Facie Obviousness Over Lumidigm and Combinations Therewith**a. The “Openings” or “Through Holes” Limitations**

As noted above, the claims recite an “opening” or “through hole” “extending through” or “provided through” the protrusion and “aligned with” or “over” each of the photodiodes. More specifically, the claims recite (with added emphasis) as follows:

- Element [1D] of claim 12 of the '501 patent: “*a plurality of openings extending through the protrusion and positioned over the three photodiodes.*”
- Element [19C] of claim 22 of the '502 patent: “*a protrusion comprising a convex surface²¹ including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes.*”
- Element [28F] of claim 28 of the '502 patent: “*a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four*

²¹ The Commission affirms the Final ID’s finding that Lumidigm combined with prior art knowledge teaches or suggests a “protrusion” having a “convex surface.” *E.g.*, Final ID at 101–03. The Final ID found that known ergonomic and contact benefits would provide persons of ordinary skill in the art a reason to modify Lumidigm to include a convex surface, as argued by Apple. *See id.*

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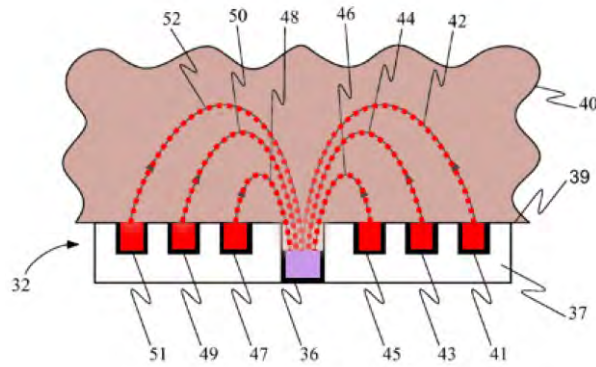
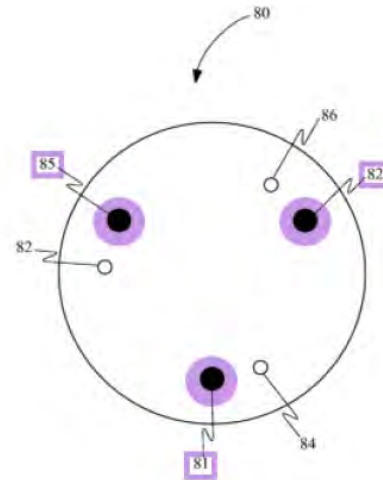
photodiodes, each opening defined by an opaque surface configured to reduce light piping.”

- Element [8E] of claim 12 of the ’648 patent: “a *plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes.*”
- Element [20D] of claims 24 and 30 of the ’648 patent: “a *plurality of through holes*, each through hole including a window and *arranged over a different one of the at least four photodiodes.*”

i. The “Openings” in the “Three Photodiode” Claim (Claim 12 of the ’501 Patent)

The Final ID first analyzed the “openings” limitations in its discussion of claim 12 of the ’501 patent, which claims a “user-worn device” that, unlike the other asserted claims of the Poeze patents, has “at least three photodiodes,” as opposed to “four photodiodes.” The “openings” limitation of that claim is included in element [1D], which recites “a plurality of openings extending through the protrusion and positioned over the three photodiodes.” *See* JX-0001 (’501 patent) at claim 12, element [1D]. The Final ID found that Lumidigm teaches or suggests this limitation, *see* Final ID at 104–06, contrary to its conclusions as to the four photodiode claims, *see id.* at 120–21, 130, 139, 142.

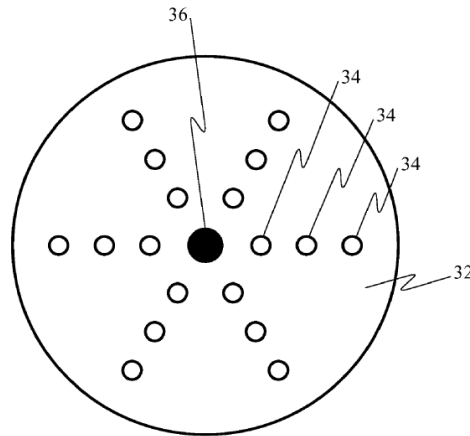
Before the ALJ, Apple argued that element [1D] of the ’501 patent was taught by Lumidigm because Lumidigm expressly states that photodiode/detector 36 in Figure 2 (annotated version provided below showing detector 36 in purple) “may comprise . . . a plurality of discrete elements” and Figure 6 (annotated version also provided below) illustrates an embodiment having three such detectors (also shown in purple). *See* RPHBr. at 76.

CONFIDENTIAL VERSION**FIG. 2****FIG. 6**

RX-0411 (Lumidigm) at Fig. 2 and Fig. 6 (identifying light sources/LEDs 82, 84, and 86 and detectors/photodiodes 81, 82 [sic],²² and 85). For their part, Complainants argued that element [1D] was not met because Figure 2, which undisputedly shows a side view “opening” over a single photodiode, is allegedly in no way linked to Figure 6, which shows a top-down view of three photodiodes. *See* CPHBr. (Reply) at 48.

The Final ID accepted Apple’s arguments, reasoning that “Figure 2 corresponds to the source-detector arrangement of Figure 3, and that . . . arrangement of three sources and three detectors in Figure 6 is a disclosed alternative to Figure 3.” *See* Final ID at 105–06. Figure 3 is reproduced below.

²² As noted above, item number 82 should be item number 83.

CONFIDENTIAL VERSION**FIG. 3**

RX-0411 (Lumidigm) at Fig. 3 (depicting photodiodes/detectors 36 and LEDs/light sources 34).

The Final ID therefore determined that element [1D] was met. *See id.*

No party petitioned for the Commission to review this finding, so the Commission has determined to affirm this finding.

ii. The Openings in the “Four Photodiode” Claims

The Final ID found that the openings or through holes limitations in elements [19C] and [28F] of the '502 patent and elements [8E] and [20D] of the '648 patent were not taught or suggested by the prior art.

Before the ALJ, Apple argued that Lumidigm explains that, for any of the “reflectance” type sensor heads shown in its figures, reflected light on the top surface of the tissue can be “detrimental” to optical measurements, and thus the detectors should be “recessed from the sensor surface” in “optically opaque material” to “minimize[] the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue” and to provide “optical blocking.” RPHBr. at 72–74, 82–83 (quoting and citing RX-0411 (Lumidigm) at 7:64–8:1). Apple further argued that a person of ordinary skill in the art would have understood that, for the

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embodiments with multiple photodiodes, the protrusion would include separate openings positioned over each of the photodiodes. RPHBr. at 75–77, 83.

The Final ID disagreed with Apple, finding that the evidence does not show that the “array”-type detectors in Lumidigm relied upon by Apple for element [19B] of the ’502 patent for identification of the “four photodiodes” would be formed with “separate openings” through the protrusion for individual photodiodes in the array, as required by element [19C] of the ’502 patent. Final ID at 120–21 (citing RPHBr. at 82; CPHBr. at 143; CPHBr. (Reply) at 55). The Final ID also rejected Apple’s argument that these limitations are obvious based on the combination of Lumidigm with Cramer. *E.g.*, Final ID at 121.

Apple petitioned for the Commission to review these findings. RPet. at 21–26.

The Commission has determined to take no position as to the openings or through holes limitations of the asserted claims of the ’502 patent and ’648 patent. *See Beloit*, 742 F.2d at 1423. Specifically, the Commission has determined to take no position on the Final ID’s findings as to the following “openings” and “through hole” limitations: (1) element [19C] of claim 22 of the ’502 patent: “a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, *each opening positioned over a different one of the four photodiodes*”; (2) element [28F] of claim 28 of the ’502 patent: “a plurality of openings in the convex surface, extending through the protrusion, and *aligned with the four photodiodes*, each opening defined by an opaque surface configured to reduce light piping”; (3) element [8E] of claim 12 of the ’648 patent: “a plurality of openings provided through the protrusion and the convex surface, *the openings aligned with the photodiodes*”; and (4) element [20D] of claims 24 and 30 of the ’648 patent: “a plurality of

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through holes, each through hole including a window and *arranged over a different one of the at least four photodiodes.*”

As explained below, the Commission affirms the Final ID’s findings that Lumidigm and combinations therewith fail to teach or suggest several other limitations in claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent. The Commission therefore takes no position on whether Lumidigm, or Lumidigm in combination with other prior art references, discloses the openings or through holes limitations of the ’502 and ’648 patents.

b. The “Transmissive Window” or “Optically Transparent Material” Limitations

The asserted claims of the ’502 and ’648 patents also recite a separate “transmissive window” or “optically transparent material” “within,” “extending across,” or “arranged over” each of the “openings” or “through holes.” More specifically, the claims recite as follows:

- Element [19D] of claim 22 of the ’502 patent: “optically transparent material within each of the openings.”
- Element [28G] of claim 28 of the ’502 patent: “a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings.”
- Element [8F] of claim 12 of the ’648 patent: “a separate optically transparent window extending across each of the openings.”
- Element [20D] of claims 24 and 30 of the ’648 patent: “each through hole including a window and arranged over a different one of the at least four photodiodes.”

The Final ID found that the “extending across” and “arranged over” limitations (element [28G] of claim 28 of the ’502 patent, element [8F] of claim 12 of the ’648 patent, and element

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[20D] of claims 24 and 30 of the '648 patent) were taught by Lumidigm or combinations therewith, but that the “within” limitation (element [19D] of claim 22 of the '502 patent) was not. *See* Final ID at 130 (element [28G] of claim 28 of the '502 patent), 139 (element [8F] of the '648 patent), 142 (element [20D] of claims 24 and 30 of the '648 patent), 121–24 (element [19D] of claim 22 of the '502 patent).

As discussed below, on review, the Commission finds that none of these limitations are taught by Lumidigm or combinations therewith.

i. Element [19D] of Claim 22 of the '502 Patent**a) The Final ID**

With respect to element [19D] of the '502 patent (an “optically transparent material within each of the openings”), Apple identified as the “optically transparent material” Lumidigm’s disclosure of an “optical relay” positioned “between the sensor surface 39 and the skin 40” that “transfers the light . . . from the skin back to the detector(s).” RPHBr. at 84–85; RX-0411 (Lumidigm) at 8:19–23; Final ID at 121. Lumidigm provides examples of “optical relays,” including “fiber-optic face plates and tapers, individual optical fibers and fiber bundles, light pipes and capillaries, and other mechanisms known to one of skill in the art.” RX-0411 (Lumidigm) at 8:23–26; *see also* Final ID at 121–22. Apple relied on Dr. Warren’s testimony that one of ordinary skill in the art would have understood an “optical relay” to be an optically transparent material. RPHBr. at 84–85; Final ID at 122; Tr. (Warren²³) at 1221:16–1222:25. Apple further argued that these limitations would be obvious because the use of optically transparent materials within openings

²³ Steven Warren was admitted as an Apple expert witness in biomedical engineering, medical monitoring systems, biomedical instrumentation, biomedical optics, light issue interaction, diagnostic systems, wearable sensors, and biomedical signal processing. *E.g.*, Final ID at 6–7.

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over photodiodes and the use of transmissive or transparent windows arranged over or extending across openings over photodiodes was well-known at the time of the Poeze patents. RPHBr. at 111–13; Tr. (Warren) at 1193:23–1194:14, 1221:16–1222:9; RDX-8C at .11 (citing, *inter alia*, RX-0670 (Cramer²⁴); RX-0665 (Nippon²⁵); RX-0666 (Seiko 131²⁶); RX-1221 (CLT 2160²⁷); *see also* Final ID at 122–23. According to Apple, a person of ordinary skill in the art would have been motivated to combine Lumidigm’s wristwatch with teachings from Seiko 131 and Cramer because “(1) Lumidigm expressly states that its sensor can include an optical relay; and (2) a [person of ordinary skill in the art] would have independently looked to literature like Seiko 131 and Cramer for this element as the benefits were well-known.” RPHBr. at 113. Those alleged benefits are protecting the photodiodes from dirt and helping to transfer light. *E.g.*, RResp. at 17–18 (citing Tr. (Warren) at 1193:24–1194:14, 1221:16–1222:9).

For their part, Complainants argued that Lumidigm’s disclosure of an “optical relay” does not meet the “optically transparent material” limitation and, in any event, is not disclosed in connection with Lumidigm’s wristwatch embodiment. CPHBr. at 138–39 (citing Tr.

²⁴ U.S. Patent No. 4,224,948, titled “Wrist Borne Pulse Meter/Chronometer,” issued to Frank B. Cramer, *et al.*, on September 30, 1980, from an application filed on November 24, 1978 (RX-0670).

²⁵ U.S. Patent No. 4,880,304, titled “Optical Sensor for Pulse Oximeter,” issued to Jonathan P. Jaeb, *et al.*, on November 14, 1989, from an application filed on April 1, 1987 (RX-0665). The face of the patent indicates that Nippon is assigned to Nippon Colin Co., Ltd.

²⁶ U.S. Patent No. 5,766,131, titled “Pulse-Wave Measuring Apparatus,” issued to Yutaka Kondo, *et al.*, on June 16, 1998, from an application filed on July 30, 1996 (RX-0666). The face of the patent indicates that Seiko 131 is assigned to Seiko Epson Corporation and Seiko Instruments, Inc.

²⁷ “CLT 2160” is a datasheet introduced by Apple. RX-1221. The Final ID found the datasheet to be reliable evidence. Final ID at 109 n.38.

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(Madiseti²⁸) at 1330:2–5); *see also* Final ID at 123. Complainants further argued that Seiko 131 fails to disclose multiple openings or optically transparent material within multiple openings. CPHBr. at 148–49; *see also* Final ID at 123. Complainants further argued that, with respect to Cramer, the alleged windows are between the annular rings and are not “within” the openings. CPHBr. at 146–47; *see also* Final ID at 123.

The Final ID found that Lumidigm clearly discloses “optically transparent material” over openings associated with photodiodes, but that the evidence does not clearly and convincingly show a reason to incorporate such material “within” each opening. Final ID at 123. According to the Final ID, Lumidigm describes an optical relay that is comprised of optically transparent material. *Id.* at 123 (citing RX-0411 (Lumidigm) at 8:19–26; Tr. (Warren) at 1221:16–1222:25). However, the Final ID found that the optical relay is not “within” the opening depicted in Figure 2, rather, it is located “between the sensor surface 39 and the skin 40.” *Id.* (quoting RX-0411 (Lumidigm) at 8:19–26) (citing RX-0411 (Lumidigm) at Fig. 2).

The Final ID likewise found that Seiko 131 similarly discloses a “light transmittance plate” that is positioned above its sensor, but that plate is not “within” any opening. *Id.* at 123 n.47 (citing RX-0666 (Seiko 131), at 10:30–32). And the Final ID also found that Cramer discloses annular windows, but those windows do not appear to be associated within “each” opening. *Id.* (citing Tr. (Warren) at 1234:22–1235:12; RDX-8C at .73; RX-0670 (Cramer) at Fig. 6). The Final ID added that “Apple appears to have identified transparent windows within an opening in Cramer’s preferred photodiode, the CLT 2160, but did not provide a clear and convincing reason to modify Lumidigm to include such material within the openings or to

²⁸ Vijay Madiseti is Complainants’ expert witness and was admitted as an expert in the field of physiological monitoring technologies. Final ID at 6.

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incorporate the CLT 2160 photodiode in Lumidigm.” *Id.* at 123–24 (citing RX-0670 (Cramer) at 5:33–35, Fig. 6; RX-1221 (CLT 2160); RPHBr. at 112–13).

Apple petitioned for review of the Final ID’s findings regarding Lumidigm alone and Lumidigm combined with Cramer. *See* RPet. at 96–97.

b) Apple’s Petition

Regarding Lumidigm alone, Apple’s petition argued that Lumidigm teaches an optical relay to “transfer[] the light from the light sources to the skin and from the skin back to the detector(s) while minimizing light loss and spreading.” RPet. at 96 (quoting RX-0411 (Lumidigm) at 8:19–26) (citing Tr. (Warren) at 1221:16–1222:25, 1235:14–1236:2). Apple further asserted that a person of ordinary skill in the art would have understood that an optical relay could be added to Lumidigm’s sensor. *Id.* (citing RX-0411 (Lumidigm) at 8:19–26, Fig. 2; Tr. (Warren) at 1221:16–1222:25). Apple further argued that a person of ordinary skill in the art would have further understood that the optical relay could be placed over or within the openings to “transfer light” from the tissue to the photodiodes and “protect the detector from dust and debris and dirt.” *Id.* (citing Tr. (Warren) at 1193:24–1194:7, 1221:16–1222:16).

Regarding Lumidigm in combination with Cramer, Apple argued that the “use of optically transparent materials extending across or within opening[s] associated with photodiodes was well known in the art prior to 2008 and taught by Lumidigm.” RPet. at 97 (citing Tr. (Warren) at 1221:16–1222:9, 1193:24–1194:14; RX-0411 (Lumidigm) at 8:19–26, Fig. 2).

Apple added that a person of ordinary skill in the art:

would have naturally looked to other references in the field to improve on Lumidigm’s teachings and would recognize the CLT 2160 taught by Cramer as a “can” detector and would understand that each can would include a lens at the top end of the can, that the detector would be positioned inside the can at the focal point of the lens, and that there would be a gap between the detector and the lens, creating an opening between the detector and the lens.

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Id. (citing RX-0670 (Cramer) at Fig 6; Tr. (Warren) at 1231:23–1232:9, 1234:3–8, 1234:22–1235:12). Thus, according to Apple, a person of ordinary skill in the art would have been motivated to combine Lumidigm with Cramer because “Lumidigm expressly teaches the benefits of transparent material within openings over photodiodes and, more generally, because the benefits were well known.” *Id.* (citing Tr. (Warren) at 1235:14–1236:2).

c) Complainants’ Response

In response, Complainants argued that the evidence refutes Apple’s argument that Lumidigm alone teaches or suggests that the optical relay would be *within* the opening. CResp. at 95 (citing RX-0411 (Lumidigm) at 8:19–26, Fig. 2; Tr. (Madisetti) at 1330:2–5, 1343:1–4; Tr. (Warren) at 1221:16–1221:25) (emphasis added); Final ID at 123–24. Complainants presented a similar argument regarding the combination of Lumidigm with Cramer. *See id.* (citing RX-0411 (Lumidigm) at 8:19–26, Fig. 2; RX-0670 (Cramer) at Fig. 6; Tr. (Madisetti) at 1330:2–5, 1334:15–1335:25, 1343:1–4; Tr. (Warren) at 1221:16–1221:25, 1235:24–1236:2); Final ID at 123–24 (including n.47). Complainants further pointed out that the USPTO, in denying institution of Apple’s IPR petitions, found that “none of the prior art on which [Apple] relies[, including Lumidigm,] discloses a convex protrusion with multiple openings or windows for multiple detectors.” *Id.* at 95–96 (citing CResp. Appx. A, at 17; Appx. B, at 16; Appx. C, at 16) (emphasis omitted).

Relatedly (but more specifically directed to element [28G] of claim 28 of the ’502 patent),²⁹ Complainants argue that Apple’s witness, Dr. Warren, testified only about what a

²⁹ Recall that that claim language recites: “a plurality of transmissive windows, each of the transmissive windows *extending across* a different one of the openings.” This language differs from that of element [19D] of claim 22 of the ’502 patent only in that it does not require the window or optically transparent material to be “*within*” the through holes or openings.

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person of ordinary skill in the art *could do*, and not what such a person would have been motivated to do or have a reason to do. *E.g.*, CPet. (Summary) at 3 (citing Final ID at 131); *see also* CPet. at 23–24. Complainants argued that Apple provided no evidence that a person of ordinary skill in the art “*would have* modified Lumidigm’s face plate into multiple windows with a reasonable expectation of success ([RPHBr.] at 84–85), and the [Final] ID made no findings regarding reasonable expectation of success for such a modification.” CPet. (Summary) at 3 (citing Final ID at 131) (emphasis added); *see also* CPet. at 23–24.

d) Analysis

The Commission has determined to affirm and adopt the Final ID’s findings and conclusion that neither Lumidigm nor a combination of Lumidigm and other prior art teaches or suggests an “optically transparent material *within* each of the openings.” Final ID at 121–24. The Commission has considered Apple’s arguments that the Final ID erred as to this limitation and finds them unpersuasive.

The Commission has further determined to supplement the Final ID. Beyond the prior art not teaching or suggesting the optically transparent material within each of the openings, Apple failed to show that the prior art provides a reason to use a separate optically transparent material or window for each of the separate openings or through holes. *See* CPet. at 23–24. First, none of the prior art cited by Apple teaches or suggests separate optically transparent materials (or windows), and Apple has not shown by clear and convincing evidence that a person of ordinary skill at the time of the claimed inventions would have arrived at these limitations, as claimed. Apple acknowledges that Lumidigm does not teach the separate optically transparent materials (or windows). *E.g.*, RResp. at 18–19 (relying on knowledge in the art to modify Lumidigm to arrive at separate windows). Moreover, neither Cramer nor Seiko 131 disclose the separate optically transparent materials (or windows). As the Final ID properly found, Apple has failed to

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clearly and convincingly show that Cramer teaches or suggests a protrusion with separate openings or through holes over separate photodiodes. *See* Final ID at 103 n.36; CPHBr. at 144–46; Tr. (Warren) at 1231:18–22; Tr. (Madisetti) at 1334:23–1335:2. Thus, Cramer cannot teach separate optically transparent materials (or windows) within (or over or extending across) the claimed separate openings or through holes. Additionally, Complainants correctly point out that Seiko 131 discloses only a singular phototransistor and light transmittance plate and thus does not teach the separate optically transparent materials (or windows) within (or over or extending across) the claimed separate openings or through holes. *See* CPHBr. at 148–50. CLT 2160 similarly discloses only a single window and photodiode. *See* RX-1221 (CLT 2160).

Second, Apple has not shown by clear and convincing evidence that, at the time of the claimed inventions, a person of ordinary skill in the art would have had a reason to use a separate optically transparent material (or window) within (or over or extending across) each of the separate openings (or through holes). As Complainants point out, Dr. Warren testified only about what a person of ordinary skill in the art *could* do, not what such a person *would* do. *See* CPet. (Summary) at 3; CPet. at 23–24; *see also* RPet. at 96–97 (discussing and citing Dr. Warren’s testimony); Tr. (Warren) at 1193:24–1194:14 (stating only that windows were well known); *id.* at 1221:16–1222:25 (stating only a person of ordinary skill in the art “*could use*” an individual faceplate for each of the individual openings (emphasis added)); *id.* at 1235:24–1236:2 (stating that a person of ordinary skill in the art “would have known that windows *could be used*” (emphasis added)). Apple’s asserted motivation for including the optical relay (allowing for the transfer of light and to protect the detector from dust and dirt), could be obtained with a single optically transparent material (or window) over the surface, as opposed to separate optically transparent materials (or windows). And, Apple’s “convoluted combination of

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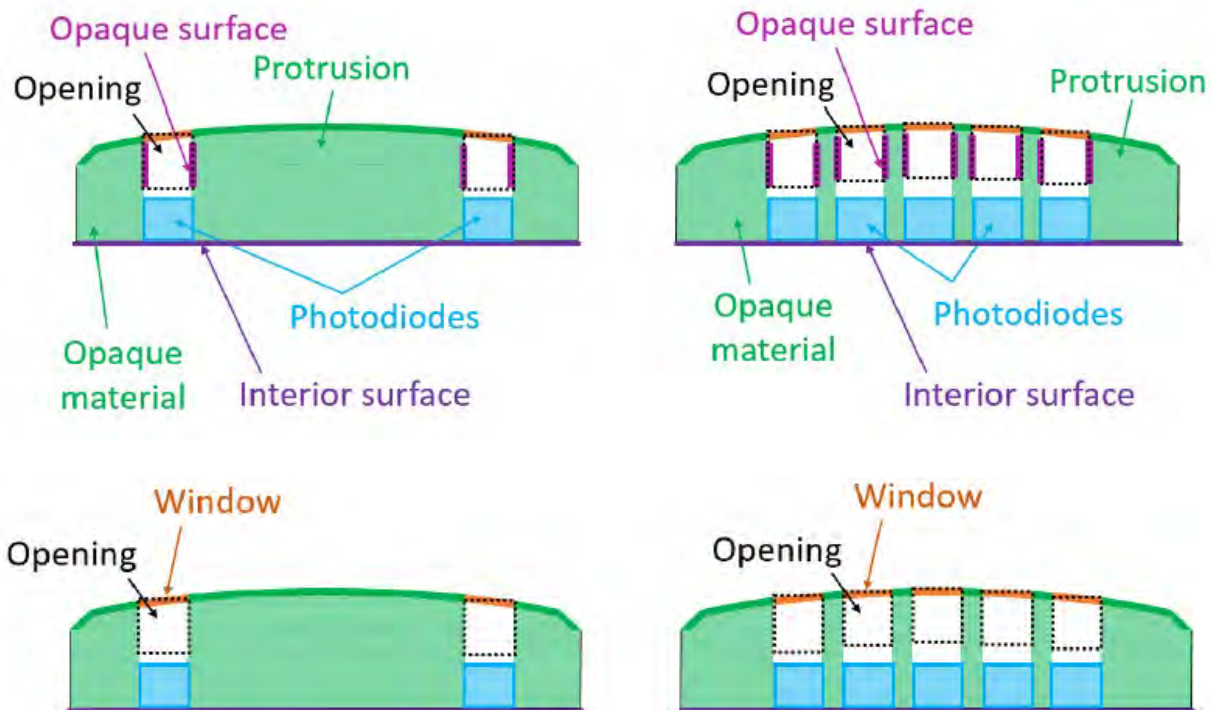
modifications” is driven by improved contact and comfort from the claimed “convex surface,” yet Apple has not shown why that improved contact and comfort would remain with the further modification to have multiple distinct openings and windows. *See Apple Inc. v. Masimo Corp.*, IPR2022-01274 (available at CResp. at Appx. C) (discussed below); Final ID at 101–03 (finding that a person of ordinary skill in the art would be motivated to implement a convex surface to obtain better contact and comfort). Moreover, as noted above, neither Cramer nor Seiko 131 teach the separate optically transparent material (or windows), and Apple points to no specific teachings of those references, or any other reference, that suggests using separate optically transparent materials (or windows). Apple has thus failed to present clear and convincing evidence that a person of ordinary skill in the art *would have* implemented Lumidigm’s “optical relay” as separate optically transparent materials (or windows) within (or over or extending across) each of the separate openings (or through holes), as opposed to a single optical relay covering the entire convex surface. *See, e.g.*, RResp. at 17–19; RPet. at 96–97; Final ID at 121–24.

Although not binding on the Commission,³⁰ the Commission notes that its decision herein is consistent with the USPTO’s denial of Apple’s petitions for an IPR to review claims 1–30 of the ’502 patent over combinations of references where Lumidigm serves as the primary reference. *See generally Apple Inc. v. Masimo Corp.*, IPR2022-01274 (available at CResp. at

³⁰ *See, e.g., Certain Hybrid Electric Vehicles & Components Thereof*, Inv. No. 337-1042, Notice of Investigation at 1 (Mar. 7, 2017) (Commission instituting investigation over proposed Respondents’ objection that asserted claims had been found unpatentable in IPR proceedings and were on appeal to Federal Circuit).

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Appx. C). There, Apple argued that based on the combined teachings of Lumidigm and “Kotanagi”³¹ the following figures emerge:



Id. at 15.

In this investigation, Apple’s Lumidigm-based theories of obviousness rely on the same modified version of Lumidigm. In denying institution, the USPTO agreed with Complainants that “none of the prior art on which [Apple] relies discloses a convex protrusion with multiple openings or windows for multiple detectors,” and that Apple “simply does not explain adequately why such configuration results from the actual teachings of the prior art.” *Id.* at 16; *see also id.* at 16–19. The USPTO reasoned that, “[w]ithout the guidance provided by the claims of the ’502 patent, it is difficult to conclude that [Apple’s] postulation as to a particular structure

³¹ PCT Application No. WO 2005/092182.

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that results from combining the teachings of Lumidigm [and the other prior art] is based on an objective assessment of what those teachings would have conveyed to a skilled artisan.” *Id.* at 16. In other words, Apple’s arguments there were “grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art.” *Id.* at 19. The same is true here.

While Apple alleges that both the evidentiary record and the obviousness theory before the USPTO and the Commission are different, *see* RResp. at 17 n.4, there are no notable differences. The above-shown modification of Lumidigm presented to the USPTO is based almost entirely on Lumidigm, *see Apple*, IPR2022-01274 at 16–19 (available at CResp. at Appx. C), as is Apple’s Lumidigm-based obviousness theory in this investigation. And while Apple relied on Kotanagi for the “convex surface” modification of Lumidigm before the USPTO (as opposed to other knowledge in the prior art, as it does before the Commission), Apple relied on the same reason for that modification of Lumidigm both before the USPTO and here—“better contact” and “comfort.” *Compare id.* at 16–17, *with* Final ID at 99, 101–02 (incorporating ergonomic features and optical and mechanical coupling). Accordingly, the Commission’s rejection of Apple’s Lumidigm-based theory for the obviousness of claim 22 of the ’502 patent is consistent with the USPTO’s denial of Apple’s petition to institute an IPR over combinations of references involving Lumidigm.³²

³² Complainants assert that the USPTO’s denial of the institution of Apple’s petition for an IPR over Lumidigm-based combinations of references as to the claims of the ’501 patent suggests that the Commission should also reverse the Final ID as to its obviousness finding as to claim 12 of the ’501 patent. CResp. at 3 n.2. However, in Apple’s petition related to the ’501 patent and Lumidigm, Apple’s theory was different than the Lumidigm-based theory that it presented in this investigation as to the ’501 patent. Significantly, in that petition, Apple presented a Lumidigm-based theory that is similar to the one it presents in this investigation as to the asserted claims of the ’502 and ’648 patents (*see Apple Inc. v. Masimo Corp.*, IPR 2022-01272 (USPTO Jan. 24, 2023) (available at CResp. at Appx. B)), which as discussed in this section, lacks a reason for a person of ordinary skill in the art to arrive at the claimed subject

CONFIDENTIAL VERSION**ii. Element [28G] of the '502 Patent—“Each of the Transmissive Windows Extending Across a Different One of the Openings”****a) The Final ID**

Regarding element [28G] of claim 28 of the '502 patent, which uses the phrase “extending across,” the Final ID found that Lumidigm discloses an “optical relay” that is transmissive and is positioned above an opening for a detector. Final ID at 131 (citing RX-0411 (Lumidigm) at 8:19–26; Tr. (Warren) at 1221:16–1222:25). The Final ID recognized that Lumidigm discloses a single window, but found, based on Dr. Warren’s testimony, that “a person of skill would know that you could do an individual faceplate for each of the individual openings as a means to provide light but still optimize the process.” *Id.* (citing, *inter alia*, Tr. (Warren) at 1221:1–1222:25, 1193:23–1194:14; RDX-8C at .11; RX-0670 (Cramer); RX-0666 (Seiko 131)).

Complainants petitioned for review the Final ID’s findings regarding Lumidigm. *See* CPet. at 23–24.

b) Complainants’ Petition

Complainants’ petition is largely the same as its argument discussed in the previous section. Complainants argued that the Final ID “legally erred by finding that Lumidigm satisfied the requirements of Element [28G] based on [Dr.] Warren’s testimony about what a [person of ordinary skill in the art] ‘could do.’” CPet. (Summary) at 3 (quoting Final ID at 131); *see also* CPet. at 23–24. Complainants further argued that the Final ID also legally erred because Apple

matter. In other words, while claim 12 of the '501 patent does not recite the separate windows, Apple’s IPR petition depended on proving that a person of ordinary skill in the art would arrive at a device that contained that limitation.

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provided no evidence that a person of ordinary skill in the art “would have modified Lumidigm’s face plate into multiple windows with a reasonable expectation of success ([RPHBr.] at 84–85), and the [Final] ID made no findings regarding reasonable expectation of success for such a modification.” CPet. (Summary) at 3 (citing Final ID at 131); *see also* CPet. at 23–24.

Complainants further argue that “[t]he Patent Office’s recent rejection of Apple’s IPR petitions challenging the Poeze Patents confirms that Apple’s obviousness theories are without merit and based in hindsight.” CResp. at 8.

c) Apple’s Response

Apple’s response is also largely the same argument as the one discussed in the previous section. According to Apple, Dr. Warren explained that this limitation was known in the prior art “both to help transfer light and to protect the photodiodes from dirt or debris.” RResp. at 17–18 (citing Tr. (Warren) at 1193:24–1194:14, 1221:16–1222:9; RX-0411 (Lumidigm) at 8:19–23). Apple also relied on Dr. Warren’s testimony that the listed examples were well known “and could be placed within or arranged over the openings to transfer light and to protect the photodiodes.” *Id.* at 18–19 (quoting Tr. (Warren) at 1221:16–1222:25). Apple further argued that a person of ordinary skill in the art would have “understood that the fiber optics face plates referenced in Lumidigm could be implemented as a single faceplate or as individual faceplates over each opening and would have been motivated to implement either alternative.” *Id.* at 19 (citing Tr. (Warren) at 1221:16–1222:25, 1193:24–1194:14).

d) Analysis

For the reasons discussed above as to element [19D] of the ’502 patent, the Commission finds that Apple has not shown, by clear and convincing evidence, that, at the time of the claimed invention, the prior art teaches separate transmissive windows for each of the openings or that a person of ordinary skill in the art would have had any reason or motivation to arrive at this

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limitation, as claimed. Additionally, for the same reasons noted above for element [19D] of the '502 patent, the Commission's determination is consistent with the USPTO's denial of Apple's petition requesting the institution of an IPR proceeding regarding the claims of the '502 patent. *See generally Apple Inc. v. Masimo Corp.*, IPR2022-01274 (available at CResp. at Appx. C).

iii. Element [8F] of Claim 12 of the '648 Patent—“A Separate Optically Transparent Window Extending Across Each of the Openings”; and Element [20D] of Claims 24 and 30 of the '648 Patent—“Each Through Hole Including a Window and Arranged Over a Different One of the at Least Four Photodiodes”

Regarding element [8F] of claim 12 of the '648 patent, which also uses the phrase “extending across,” the Final ID held:

For the same reasons discussed above in the context of the “plurality of openings” limitations of '502 patent claim 19 (Element [19C]), the evidence fails to show, clearly and convincingly, a “plurality of openings” with a “separate optically transparent window extending across each of the openings” in combination with the “four photodiodes” embodiments of Lumidigm relied upon by Apple.

Final ID at 139 (citing RPHBr. at 82, 91, 98). The Final ID made a similar conclusion regarding element [20D] of claims 24 and 30 of the '648 patent. *See* Final ID at 142. Thus, while the Final ID found that, *e.g.*, “a separate optically transparent window extending across each of the openings” limitation was taught (consistent with its finding as to element [28G] of the '502 patent, *see id.* at 131), the Final ID found that that limitation was not taught in a “four photodiode” embodiment having, *e.g.*, “openings aligned with the [four] photodiodes,” *see, e.g., id.* at 120–21.

As noted above, the Commission has determined to take no position as to the Final ID's underlying finding that the openings in these claims (elements [19C] and [28F] of the '502 patent

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and elements [8E] and [20D] of the '648 patent) were not taught or suggested by the prior art. However, the Commission has determined to affirm the Final ID for the alternative basis that because, for the reasons discussed above as to element [19D] of claim 22 of the '502 patent and element [28G] of claim 28 of the '502 patent, Apple did not present clear and convincing evidence that, at the time of the claimed invention, the prior art taught the claimed separate optically transparent windows extending across each of the openings, or that a person of ordinary skill in the art would have had any reason or motivation to arrive at this limitation. Additionally, for the same reasons noted above for element [19D] of the '502 patent and element [28G] of claim 28 of the '502 patent, the Commission's determination is consistent with the USPTO's denial of Apple's petition requesting the institution of an IPR proceeding regarding the claims of the '648 patent. *See generally Apple Inc. v. Masimo Corp.*, IPR2022-01276 (USPTO Jan. 30, 2023) (available at CResp. at Appx. A).

iv. Conclusions Regarding *Prima Facie* Obviousness and the Asserted Claims of the '501, '502, and '648 Patents

In sum, regarding *prima facie* obviousness and the asserted claims of the '502 and '648 patents, the Commission concludes that, although Lumidigm and combinations of references therewith teach or suggest (1) the four photodiodes and (2) the protrusion, the combinations of references do not teach or suggest (4) a separate "transmissive window" or "optically transparent material" "within," "extending across," or "arranged over" each of the openings or though holes. The Commission takes no position on whether Lumidigm and combinations of references therewith teach or suggest an opening or through hole extending through or provided through the protrusion and aligned with or over each of the four photodiodes. Thus, Apple has not shown by clear and convincing evidence that these claims are *prima facie* obvious.

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Regarding claim 12 of the '501 patent, the Commission affirms the Final ID's conclusion that Apple has shown by clear and convincing evidence that this claim is *prima facie* obvious.

4. Objective Evidence of Non-Obviousness**a. Introduction**

As noted above, the Commission must consider “the totality of the evidence” before reaching a decision on obviousness, and that totality of evidence includes the existence of secondary considerations, or objective indicia of non-obviousness. *E.g.*, *Richardson-Vicks*, 122 F.3d at 1483.

Also, as noted above, before the ALJ, Complainants presented evidence of objective indicia of non-obviousness that allegedly showed the following: (1) skepticism and unexpected results related to the “convex protrusion” claim limitations; (2) skepticism and failures of others related to measuring pulse oximetry at the wrist; (3) Apple's alleged copying of Masimo's technology; and (4) the commercial success of the Apple Watch products once Apple implemented that technology. *See, e.g.*, Final ID at 145–56, 240–241.

Regarding Complainants' evidence, the Final ID agreed with Apple that Complainants failed to show that there was skepticism in the industry regarding convex surfaces. *See* Final ID at 147. And regarding Complainants evidence of skepticism and failures of others related to measuring pulse oximetry at the wrist, the Final ID found that this evidence does not significantly show non-obviousness because the asserted claims apply to any “user-worn device,” including user-worn devices that are not worn on the wrist. *Id.* at 150–51. As for copying, the Final ID found that there was no significant credible evidence that Apple copied Masimo's patented technology. *Id.* at 153–54. Last, regarding commercial success, because the Final ID found that “there is little evidence of a significant nexus between Apple's commercial success and the allegedly non-obvious features of the asserted Poeze patent claims,” the Final ID

found that this evidence “does not meaningfully affect the obviousness analysis.” *Id.* at 156. Overall, the Final ID found that this evidence did not meaningfully alter the obviousness analysis. *See id.*

Complainants petitioned the Commission to review the Final ID’s findings related to commercial success, *see* CPet. at 25–29; skepticism regarding convex surfaces, *id.* at 30–32; and skepticism regarding pulse oximetry at the wrist, *id.* at 33. Complainants did not petition for review of the Final ID’s finding related to copying. *See generally id.* Accordingly, any such argument is waived. *Finnigan*, 180 F.3d at 1362–63.

The Commission has determined to affirm, without modifications, the Final ID as to (1) skepticism and unexpected results related to the “convex protrusion” claim limitations; (2) skepticism and failures of others related to measuring pulse oximetry at the wrist; and (3) Apple’s alleged copying of Masimo’s technology. Thus, the Commission adopts the Final ID’s findings as to that evidence. For the reasons discussed below, the Commission has determined to affirm, with modifications, the Final ID’s conclusion that Complainants’ evidence of commercial success provides at most minimal weight due to the lack of a nexus to the claimed and novel features. *See* Final ID at 153–56.

b. Commercial Success

i. The Final ID

Before the ALJ, Complainants argued that the commercial success of the Apple Watch Series 6 and 7 is objective evidence of non-obviousness. CPHBr. at 173–75; CPHBr. (Reply) at 95–96; Final ID at 154–56. According to Daniel McGavock, Complainants’ expert witness, sales of the Apple Watch Series 6 [REDACTED], and Apple advertised the blood oxygen feature as the key differentiator of the Series 6 over the previous series, Series 5. Tr. (McGavock) at 1416:10–21, 1422:8–1425:13; CX-0252; CX-1451; CX-

1532; CX-1289. Dr. Madisetti agreed with Mr. McGavock that there was a nexus between the blood oxygen feature of Apple Watch Series 6 and its commercial success. Tr. (Madisetti) at 1380:14–1381:4.

The Final ID found that the Apple Watch Series 6 was commercially successful and that “this may be due in some part to its blood oxygen monitoring features.” Final ID at 155. The Final ID also found that the evidence does not persuasively indicate that the [REDACTED] “sales of the Apple Watch Series 6 are largely attributable to the blood oxygen feature, as market analysts have recognized the Apple Watch’s ‘blend of sleek design, good usability on a small screen, and a growing portfolio of health and fitness apps.’” *Id.* (quoting CX-1644 (Strategy Analytics)). The Final ID added that it is not “clear that the Apple Watch Series 6 was significantly more successful than other smartwatches.” *Id.* (citing CX-1644 (Strategy Analytics)). According to the Final ID, the evidence “shows that much of the success of the Apple Watch Series 6 can be attributed to the growing market for smartwatches rather than the specific implementation of the pulse oximetry feature claimed in the patents-at issue.” *Id.* (citing, *inter alia*, CX-1644 (Strategy Analytics)). Thus, the Final ID discounted Complainants’ evidence of commercial success, finding that it does not “meaningfully affect the obviousness analysis.” *Id.* at 155–56 (citing *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1313 (Fed. Cir. 2006)).

Because the Final ID found that “there is little evidence of a *significant nexus* between Apple’s commercial success and the allegedly non-obvious features of the asserted Poeze patent claims, particularly for claim 12 of the ‘501 patent (which is not limited to blood oxygen measurements),” the Final ID found that this evidence “does not meaningfully affect the obviousness analysis above.” Final ID at 156 (emphasis added).

As noted above, Complainants petitioned for review of this finding. *See* CPet. at 25–29.

CONFIDENTIAL VERSION**ii. Complainants' Petition**

In their petition for review of the Final ID, Complainants argued that the Final ID erroneously required that “there be a ‘significant’ nexus in order to be objective evidence of non-obviousness.” CPet. at 25 (citing Final ID at 155, 156). According to Complainants, obviousness law does not require that “the patented invention be solely responsible for the commercial success[] in order for this factor to be given weight appropriate to the evidence.” *Id.* at 26 (citing *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.3d 1264, 1273 (Fed. Cir. 1991); *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1055–56 (Fed. Cir. 2016) (en banc)). Next, Complainants argued that the Final ID made clearly erroneous factual findings regarding commercial success. CPet. at 26–29.

iii. Analysis

On review, the Commission has determined to affirm the Final ID with modifications. The Commission agrees with Complainants that the standard for “commercial success” does not require a showing of “significant nexus.” *See* CPet. at 25. However, the Commission agrees with the Final ID that Complainants’ evidence is consistent with increased sales of smartwatches in general and was likely based on the Apple Watches’ “blend of sleek design, good usability on a small screen, and a growing portfolio of health and fitness apps.” *See, e.g.*, Final ID at 155–56. Accordingly, the Commission concludes that Complainants’ evidence of commercial success is entitled to minimal weight due to Complainants’ failure to show a nexus between the alleged commercial success and the alleged claimed and novel features.

5. Overall Conclusion as to Obviousness

Because the Commission modifies and/or supplements the Final ID’s findings as to the asserted claims of the Poeze patents regarding *prima facie* obviousness and/or secondary considerations, the Commission evaluates anew (1) the scope and content of the prior art, (2) the

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level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness, to determine whether Apple has shown by clear and convincing evidence that these claims are invalid for obviousness.

In doing so, the Commission concludes, as did the Final ID, that claim 12 of the '501 patent would have been invalid as obvious over combinations of references primarily based on Lumidigm, but that claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent are not invalid as obvious over those combinations of references.

Regarding claim 12 of the '501 patent, Apple has shown that this claim would have been *prima facie* obvious to a person of ordinary skill in the art. And, as discussed above, Complainants' objective evidence of non-obviousness has minimal weight. In view of these underlying findings, the Commission concludes that Apple has shown that this claim would have been invalid by clear and convincing evidence.

Regarding claim 28 of the '502 patent, Apple has not shown that this claim would have been *prima facie* obvious to a person of ordinary skill in the art. For example, Apple has failed to show that the prior art teaches or suggests elements [28PRE], [28G], [28I], [28J], and [28K]. Also, Complainants' evidence of secondary considerations has minimal weight. In view of these underlying findings, the Commission concludes that Apple has not shown that this claim would have been invalid by clear and convincing evidence.

Regarding claim 22 of the '502 patent, Apple has not shown that this claim would have been *prima facie* obvious to a person of ordinary skill in the art. Apple has failed to show that the prior art teaches or suggests elements [19PRE], [19D], and [19E]. Also, Complainants' evidence of secondary considerations has minimal weight. In view of these underlying findings,

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the Commission concludes that Apple has not shown that this claim would have been invalid by clear and convincing evidence.

Regarding claim 12 of the '648 patent, Apple has not shown that this claim would have been *prima facie* obvious to a person of ordinary skill in the art. Apple has failed to show that the prior art teaches or suggests elements [8F] and [12]. Also, Complainants' evidence of secondary considerations has minimal weight. In view of these underlying findings, the Commission concludes that Apple has not shown that this claim would have been invalid by clear and convincing evidence.

Regarding claims 24 and 30 of the '648 patent, Apple has not shown that these claims would have been *prima facie* obvious to a person of ordinary skill in the art. For example, Apple has failed to show that the prior art teaches or suggests elements [20D], [20E], and [24]. Also, Complainants' evidence of secondary considerations has minimal weight. In view of these underlying findings, the Commission concludes that Apple has not shown that these claims would have been invalid by clear and convincing evidence.

C. Non-Obviousness of the Asserted Claims of the '745 Patent**1. Introduction**

The Final ID found that claims 9, 18, and 27 of the '745 patent have not been shown to be invalid. Final ID at 336. The Commission reviewed this finding. 88 Fed. Reg. at 32244. On review, the Commission affirms this finding with modifications.

Before the ALJ, Apple argued that claims 9 and 27 of the '745 patent would have been obvious in view of the Apple Watch Series 0 and that claims 9, 18, and 27 of the '745 patent

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would have been obvious in view of U.S. Patent No. 8,670,819 to Iwamiya *et al.* (RX-0130³³) in combination with U.S. Patent No. 9,392,946 to Sarantos *et al.* (RX-0366³⁴) and U.S. Patent No. 8,998,815 to Venkatraman *et al.*, (RX-0368³⁵). *E.g.*, Final ID at 209.

Regarding claims 9 and 27 in view of the Apple Watch Series 0, the Final ID found that the prior art did not teach or suggest elements [1B], [1D], and [9] of claim 9 or elements [20B] and [20D] of claim 27. *See* Final ID at 212–14, 215–16, 218–20, 221, 222. Regarding claims 9, 18, and 27 and combinations based on Iwamiya, the Final ID found that the prior art did not teach or suggest element [9] of claim 9, element [18] of claim 18, and element [27] of claim 27. *See id.* at 228–31, 235–36, 239–40. Apple petitioned the Commission to review these findings. *See* RPet. at 62–70.

Complainants again presented objective evidence of non-obviousness. *See* CPHBr. at 233–34, CPHBr. (Reply) at 132–33. Complainants presented evidence allegedly showing Apple’s skepticism and failures in implementing wrist-based pulse oximetry, the commercial success of the Apple Watch Series 6, and Apple’s alleged copying of Masimo’s technology. *See* CPHBr. at 233–34, CPHBr. (Reply) at 132–33. The Final ID concluded that, “[f]or the reasons discussed above in the context of the Poeze patents, this evidence does not weigh significantly against a finding of obviousness.” Final ID at 241. The Final ID added that the “evidence of

³³ U.S. Patent No. 8,670,819, titled “Optical Biological Information Detecting Apparatus and Optical Biological Information Detecting Method,” issued to Hiroshi Iwamiya *et al.*, on March 11, 2014, from an application filed on June 29, 2010.

³⁴ U.S. Patent No. 9,392,946, titled “Heart Rate Sensor with High-Aspect-Ratio Photodetector,” issued to Chris H. Sarantos, *et al.*, on July 19, 2016, from an application filed on May 28, 2015.

³⁵ U.S. Patent No. 8,998,815, titled “Wearable Heart Rate Monitor,” issued to Subramaniam Venkatraman, *et al.*, on April 7, 2015, from an application filed on June 3, 2014.

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commercial success is not relevant because the Accused Products have not been shown to practice claims of the '745 patent.” *Id.* at 241 n. 87. Complainants petitioned for review of the Final ID’s findings as to Complainants’ objective evidence of non-obviousness. *See* CPet. at 45.

Based on the totality of the evidence, the Final ID found that Apple did not show by clear and convincing evidence that the asserted claims of the '745 patent are obvious. Final ID at 240. Apple petitioned for review of this finding. *See* RPet. at 62–70.

As noted above, the Commission determined to review the Final ID’s obviousness findings as to the '745 patent. 88 Fed. Reg. at 32244. On review, the Commission has determined to affirm the Final ID’s findings regarding *prima facie* obviousness of the asserted claims of the '745 patent. The Commission has considered Apple’s petition for review and found its arguments that the Final ID erred to be unpersuasive. As to Complainants’ evidence of secondary considerations, the Commission has determined to affirm in part and reverse in part the Final ID for the reasons discussed below. After considering the totality of the evidence, the Commission has further determined to affirm the Final ID’s finding that Apple has not shown that the asserted claims of the '745 patent are obvious.

2. Objective Evidence of Non-Obviousness

In their petition for review, Complainants point out that the Final ID rejected its arguments for the '745 patent “[f]or the reasons discussed above in the context of the Poeze patents.” CPet. at 45 (quoting Final ID at 150). Complainants argue that the Final ID’s reasoning for the Poeze patents as to skepticism and failures of others in implementing wrist-based pulse oximetry does not apply to claims 9 and 18 of the '745 patent. CPet. at 45 (quoting Final ID at 150). Complainants point out that the Final ID discounted Complainants’ evidence regarding the claims of the Poeze patents because the Poeze claims are not limited to pulse oximetry at “the wrist.” *Id.* (citing Final ID at 150). Complainants then argue that, on the other

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hand, claims 9 and 18 of the '745 patent are limited to pulse oximetry at the wrist. *See id.*; *see also* JX-0009 ('745 patent) at claim 9, element [1B] (“a material configured to be positioned between the plurality of light-emitting diodes and tissue on *a wrist of a user* when the physiological monitoring device is in use” (emphasis added)); *id.* at claim 18, elements [15A] and [15B] (“a plurality of light-emitting diodes configured to emit light proximate *a wrist of a user*; a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a tissue measurement site on *the wrist of the user* when the physiological monitoring device is in use” (emphasis added)). Thus, according to Complainants, the Final ID “erred by failing to properly weigh the objective evidence of skepticism and failure of others in evaluating Claims 9 and 18.” CPet. at 45.

The Commission agrees with Complainants. *See id.* Moreover, to the extent Apple disputes the Final ID’s finding that Complainants have shown evidence of skepticism of Apple engineers regarding pulse oximetry at the wrist and the relevance thereof, *see* RResp. at 41–43, the Commission finds Apple’s argument unpersuasive. The Final ID properly evaluated the evidence and arrived at its conclusion. In any event, this evidence does not meaningfully alter the obviousness analysis, as stated in the next sub-section.

The Commission affirms the Final ID’s findings as to Complainants’ other objective evidence of non-obviousness, including commercial success and Apple’s alleged copying of Masimo’s technology. *See* Final ID at 241. The Final ID found that this evidence does not support non-obviousness. *See id.*

3. Overall Conclusion as to Obviousness

Because the Commission alters the Final ID’s findings as to the asserted claims of the '745 patent regarding secondary considerations, the Commission evaluates anew (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between

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the claimed invention and the prior art, and (4) secondary considerations of non-obviousness, to determine whether Apple has shown by clear and convincing evidence that these claims are invalid for obviousness.

Like the Final ID, the Commission finds, regarding claims 9 and 27 in view of the Apple Watch Series 0, that the prior art does not teach or suggest elements [1B], [1D], and [9] of claim 9 or elements [20B] and [20D] of claim 27. *See* Final ID at 212–14, 215–16, 218–20, 221, 222. And like the Final ID, regarding claims 9, 18, and 27 and combinations based on Iwamiya, the Commission finds that the prior art does not teach or suggest element [9] of claim 9, element [18] of claim 18, and element [27] of claim 27. *See id.* at 228–31, 235–36, 239–40. Regarding claims 9 and 18, the objective evidence of skepticism and failure of others regarding implementing wrist-based pulse oximetry weighs in favor of a finding of non-obviousness. Thus, in view of these underlying findings, taken as a whole, the Commission concludes that Apple has not shown that any of these claims are invalid by clear and convincing evidence. Last, we note that the Commission’s conclusion would remain the same even if the objective evidence of skepticism and failure of others regarding implementing wrist-based pulse oximetry was not considered.

D. Written Description Support of Claim 28 of the ’502 Patent and Claim 12 of the ’648 Patent

The Final ID found that claim 28 of the ’502 patent is invalid for lacking written description support as to elements [28A] and [28B] and also found that claim 12 of the ’648 patent is invalid for lacking written description support as to elements [8A] and [8B], from which claim 12 depends. *E.g.*, Final ID at 336. The Commission reviewed this finding and requested briefing from the parties. *See* 88 Fed. Reg. at 32244. On review, the Commission reverses the Final ID for the reasoning provided below. In view of this conclusion and the Commission’s

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other conclusions herein, the Commission finds that Complainants have shown that Apple violated section 337 as to claims 22 and 28 of the '502 patent and claim 12 of the '648 patent, in addition to claims 24 and 30 of the '648 patent.

1. The Applicable Law

35 U.S.C. § 112 declares that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .” 35 U.S.C. § 112. “[T]his statutory language mandates satisfaction of two separate and independent requirements: an applicant must both describe the claimed invention adequately and enable its reproduction and use.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). The purpose of the written description requirement is to “ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.” *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004).

To comply with the written description requirement, a patent applicant must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the [claimed] invention.” *Vas-Cath*, 935 F.2d at 1563–64 (emphasis omitted). The test for written description “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). “[T]he applicant [for a patent] may employ ‘such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.’” *In re Skvorecz*, 580 F.3d 1262, 1269 (Fed. Cir. 2009) (citing *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996)); see also *Enzo Biochem*, 323 F.3d at

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964 (declaring that the written description may also be met by other “sufficiently detailed, relevant identifying characteristics,” such as “physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics”) (emphasis omitted)). Compliance with the written description requirement is a question of fact, and in order to overcome the presumption of validity, a party must set forth clear and convincing evidence. *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011).

2. The Final ID

As noted above, the Final ID concluded that claim 28 of the '502 patent is invalid for lacking written description support as to elements [28A] and [28B] and that claim 12 of the '648 patent is invalid for lacking written description support as to elements [8A] and [8B]. *See* Final ID at 156–70. As shown in the table below, these pairs of claim limitations require two separate sets of LEDs, each with an LED “configured to emit light at a first wavelength” and an LED “configured to emit light at a second wavelength.”

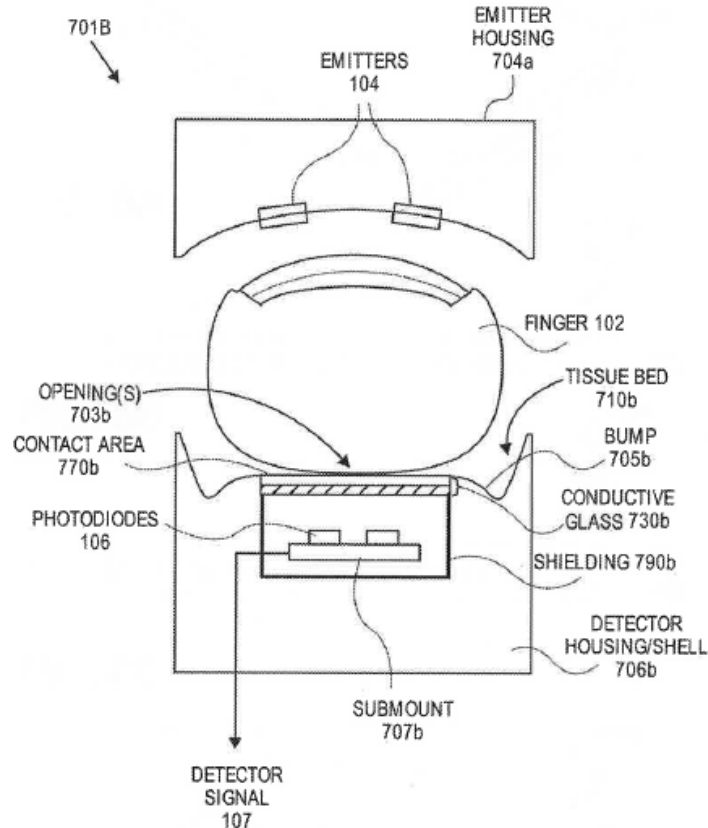
| Elements [28A] and [28B] of Claim 28 of the '502 Patent | |
|--|--|
| [28A] | a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength; |
| [28B] | a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength; |
| Elements [8A] and [8B] of Claim 12 of the '648 Patent | |
| [8A] | a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength; |
| [8B] | a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength; |

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Before the ALJ, Apple argued that the disputed limitations lack written description support because the specifications fail to disclose separate sets of LEDs emitting at the same “first wavelength” and the same “second wavelength.” *E.g.*, RPHBr. at 151–52; RPHBr. (Reply) at 75. Apple relied on the testimony of its expert witness, Dr. Warren, who testified that there was no support for these limitations. *See* Tr. (Warren) at 1247:13–17.

In reply, Complainants argued that Dr. Warren’s testimony was conclusory and therefore insufficient for Apple to show invalidity by clear and convincing evidence. *E.g.*, CPHBr. at 179. Complainants further argued that their expert, Dr. Madisetti, identified support for the disputed limitations. *See, e.g., id.* (citing Tr. (Madisetti) at 1349:7–1350:3); Final ID at 163. Complainants also relied on the specification, pointing to the two emitters (each having item number “104”) depicted in Figures 7A and 7B, as well as, for example, the related disclosure that “the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.” *See, e.g.*, CPHBr. at 179 (citing JX-0001 (’501 patent³⁶) at 12:9–12, Fig. 7A, Fig. 7B). Figure 7B is reproduced below:

³⁶ As noted above, the ’501, ’502, and ’648 patents share a common specification. The parties agree that citations to the ’501 patent are also applicable to the ’502 and ’648 patents.

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JX-0001 ('501 patent) at FIG. 7B. Figure 7A is largely identical to Figure 7B, with the most notable and relevant difference being that, in Figure 7A, the “emitters 104” are indicated as “LEDs 104.” Complainants also cited other portions of the specification. *See, e.g.*, CPHBr. at 179–80 (citing JX-0001 ('501 patent) at 9:60–63, 12:13–25, 13:16–21, 21:51–54, 33:30–38, 38:8–22); Final ID at 163.

The Final ID agreed with Apple, concluding that the claim language at issue requires two different matching pairs of wavelengths between the two sets of LEDs. *See* Final ID at 163–65. In other words, the first wavelength of an LED in the first set of LEDs must match the first wavelength of an LED in the second set of LEDs, and the second wavelength of an LED in the first set of LEDs must match the second wavelength of an LED in the second set of LEDs. *See*

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*id.*³⁷ The Final ID next found that there is no such disclosure in the specifications of the Poeze patents. *See id.* The Final ID acknowledged that, “[w]hen describing emitters that are capable of emitting visible and near-infrared optical radiation, the specification describes two different wavelengths, three different wavelengths, or up to eight different wavelengths,” but then found that the “specification does not describe any two LEDs having the same wavelength.” *Id.* at 164.

3. Complainants’ Petition

In their petition for review, Complainants argued that the Final ID “failed to acknowledge that the presumption of validity carries with it a presumption that the specification has an adequate written description as required by 35 U.S.C. § 112.” CPet. at 34. Complainants also argued that the Federal Circuit has repeatedly held that conclusory expert opinion testimony cannot overcome this presumption and the associated burden of “clear and convincing evidence.” *See id.* at 34–35 (citing, *inter alia*, *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1338–39 (Fed. Cir. 2016); *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004)). According to Complainants, the Final ID cited no evidence of what a person of ordinary skill in the art would understand from reading the specification, let alone any evidence supporting that a person of ordinary skill in the art would find no written description support for the disputed limitations. *Id.* at 37. Complainants added that the specification “discloses that emitter 104 can include ‘sets of optical sources that are capable of emitting visible and near-infrared [light]’—*i.e.*, emitting light at a first wavelength and a second wavelength,” and it teaches “exemplary LED sets.” *Id.* (citing JX-0001 (’501 patent) at 12:9–12, 4:55–57, 26:32). Complainants further argued that the “specification provides additional examples where the emitter 104 includes sets

³⁷ Neither party contests this interpretation of the claim language, either in their petitions for review of the Final ID or in their briefing in response to the Commission’s notice of review.

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of LEDs to emit light at two or more different wavelengths,” including that “emitter 104 can emit [light] at or about 1610 nm, about 1640 nm, *and* about 1665 nm.” *Id.* (citing JX-0001 (’501 patent) at 12:38–40, 12:64–13:1, 13:5–7) (emphasis added). Thus, according to Complainants, the specification “discloses an emitter 104 including a set of LEDs that emits light at a first wavelength and a second wavelength.” *Id.* (emphasis omitted).

Complainants further argued that Figure 7B shows two such emitters, each labeled 104, and that USPTO rules provide a presumption that each emitter set 104 is identical. CPet. at 38 (citing 37 C.F.R. § 1.84(p)(4)³⁸). Complainants then concluded that, by virtue of Figure 7B, the specification “discloses that the first and second wavelengths of the set of LEDs of one emitter 104 are the same as (*i.e.*, match) the first and second wavelengths of the corresponding set of LEDs of the other emitter 104.” *Id.* at 39.

4. Apple’s Response

In reply, Apple argued that the Final ID properly acknowledged the presumption of validity and properly found that the claim language “does not merely require that there be two sets of LEDs, each emitting light at two different wavelengths,” but instead also “requires matching wavelengths in each set of LEDs.” RResp. (Summary) at 4. Apple further argued that Dr. Warren’s testimony supports that the claims lack written description, and here, “no more elaboration was required.” *See* RResp. at 30–31. According to Apple, the only relevant issue was whether the specification disclosed the recited feature, and “there was nothing more that Dr. Warren could have said because, at the time he presented his testimony, Complainants had not

³⁸ 37 C.F.R. § 1.84(p)(4) recites: “The same part of an invention appearing in more than one view of the drawing must always be designated by the same reference character, and the same reference character must never be used to designate different parts.”

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even challenged the point that he confirmed in his testimony—namely, that there was no written description support for two sets of LEDs each with LEDs emitting at the same ‘first wavelength’ and ‘second wavelength.’” *Id.* at 30–32 (citing, *inter alia*, Tr. (Warren) at 1247:13–17; CPreHBr. at 126;³⁹ CPHBr. at 179–80).

Apple further argued that the Final ID relied on more than just Dr. Warren’s testimony by walking “through the portions of the specification that Complainants had identified in their post-hearing briefs” and confirming, based on that analysis, and “consistent with Dr. Warren’s testimony, that none [of those cited portions] discloses two sets of LEDs each with LEDs emitting at the same ‘first wavelength’ and ‘second wavelength.’” *Id.* at 32 (citing Final ID at 163–64); *see also id.* at 32–35. Apple also asserted that, in Complainants’ petition for review of the Final ID, Complainants “offer[ed a] lengthy, entirely new analysis of the Poeze specification,” but this new analysis was allegedly waived for not being presented to the ALJ. *Id.* at 32 (citing, *inter alia*, CPreHBr. at 123–27; CPHBr. at 175–80; Order No. 4 (Ground Rules), at Ground Rules 9.2 and 13.1; *In re Baxter Int’l, Inc.*, 678 F.3d 1357, 1362 (Fed. Cir. 2012)); *see also id.* at 32–35.

5. Analysis

The Commission has determined to reverse the Final ID and conclude that Apple did not carry its burden of proving, by clear and convincing evidence, that claim 28 of the ’502 patent and claim 12 of the ’648 patent are invalid for lacking written description support. As noted

³⁹ The Commission notes that, contrary to Apple’s argument, Complainants’ pre-hearing brief declared: “A [person of ordinary skill in the art] would . . . understand from the disclosure of emitter ‘sets’ that *corresponding LEDs in each set have the same wavelength* to allow the sensor to collect data from multiple measurement sites with multiple light paths.” CPreHBr. at 126 (emphasis added).

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above, because patent claims are presumed valid under 35 U.S.C. § 282, a party challenging the validity of a patent(s), including for lack of written description, must demonstrate by clear and convincing evidence that challenged patents are invalid. *See Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011) (“To overcome the presumption of validity of patents, the accused must show that the claims lack a written description by clear and convincing evidence.”). The Commission finds that Apple did not meet its burden of proof because it relied on conclusory expert witness testimony and then on attorney argument alone to explain why Complainants’ citations to the specification did not provide written description support, *see, e.g.*, RPHBr. (Reply) at 75, and Complainants’ citations to the specification and its expert witness’s testimony tend to show that the disputed limitations have written description support.

As an initial matter, the Commission agrees with Complainants that Apple’s expert’s testimony is conclusory. Dr. Warren simply stated:

Q. . . . Have you identified any discussion in the Poeze specification of the use of multiple sets of LEDs each with LEDs emitting at a first wavelength and a second wavelength?

A. I have not found one, no.

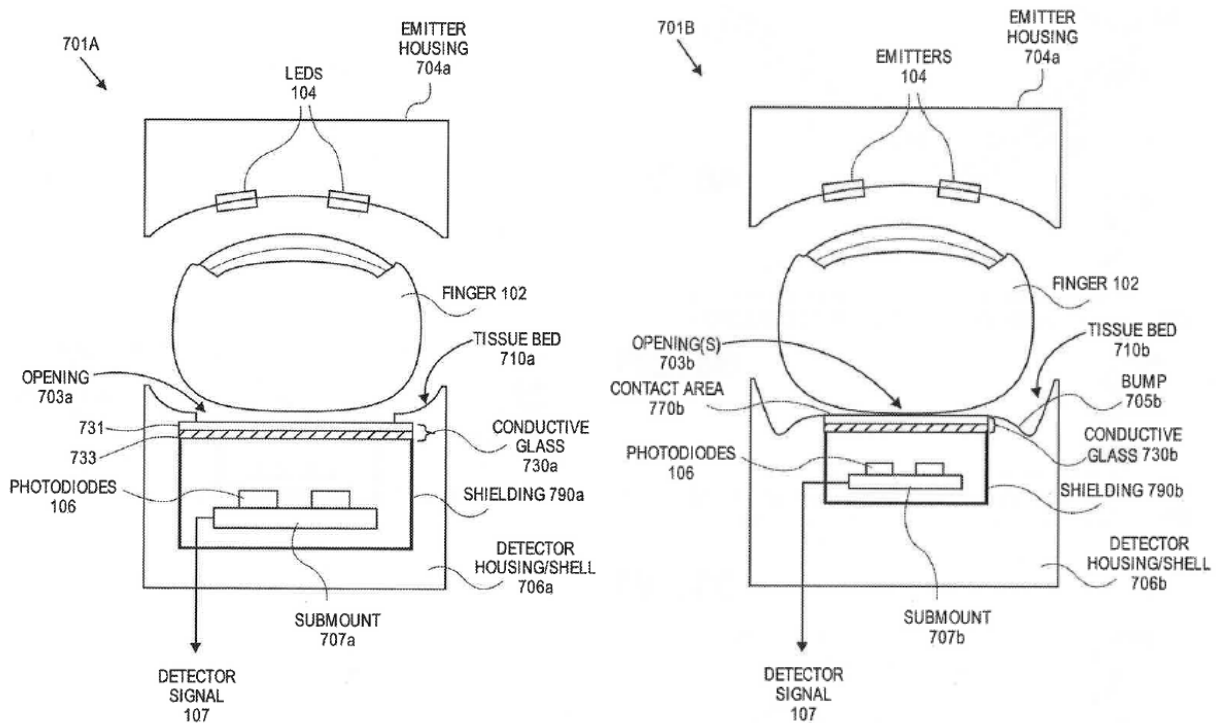
Tr. (Warren) at 1247:14–17. While, as Apple points out, reliance on expert testimony is not always necessary to find a claim invalid for written description,⁴⁰ in this case, Apple’s expert witness testimony is conclusory, and, as discussed below, it is not clear from the face of the patents that the disputed claims lack written description. Thus, the expert testimony here is

⁴⁰ *See* RBr. at 30–31 (citing, *inter alia*, *Centocor*, 636 F.3d 1341, 1347; *Certain Beverage Brewing Capsules, Components Thereof, & Prods. Containing the Same*, Inv. No. 337-TA-929, Comm’n Op., 2016 WL 9751230, at *18 (Apr. 5, 2016), *aff’d* by *Rivera v. Int’l Trade Comm’n*, 857 F.3d 1315 (Fed. Cir. 2017)).

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distinguishable from that in *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1325 (Fed. Cir. 2000), relied upon by the Final ID (*see* Final ID at 164–65), where the trial judge relied on extensive expert testimony and other prior art documents.

Turning to the evidence cited by Complainants to the ALJ, Figures 7A and 7B show two emitters or two LEDs, each labeled 104:

**FIG. 7A****FIG. 7B**

See CPHBr. at 179; *E.g.*, JX-0001 ('501 patent) at Figs. 7A, 7B. The fact that the LEDs and the emitters share the number (104) across the two figures, suggests that they are the same (*i.e.*, both can include sets of LEDs). *See, e.g.*, JX-0001 ('501 patent) at 13:16–21 (“[T]he emitter 104 can include sets of light-emitting diodes (LEDs) as its optical source.”). Even more than that, within Figure 7A, the two LEDs share the same label “LEDs 104,” and within Figure 7B, the two

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emitters share the same label “Emitters 104.” This suggests that the two LEDs in Figure 7A are the same, and the two emitters in Figure 7B are the same.⁴¹

The specifications further explain that: “In an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.” *E.g.*, JX-0001 (’501 patent) at 12:9–12; *see also, e.g., id.* at 9:60–63, 13:16–21; Tr. (Madisetti) at 1349:7–1350:3. If the two sets of LEDs or the two emitters having sets of optical sources are the same, then they must emit the same visible and near-infrared optical radiation, *i.e.*, at the same two respective wavelengths. At a minimum, the specifications do not clearly and convincingly show that these respective wavelengths of visible and near-infrared optical radiation are different between the identically-labelled LEDs or optical emitters.

Apple also responds that “‘visible and near-infrared light’ are not specific wavelengths,” and thus the sets of LEDs do not include matching pairs of wavelengths. *See* RBr. at 52–53. The Commission agrees with Apple that “visible light” and “near-infrared light” both refer to ranges of wavelengths. However, because Figures 7A and 7B each show two sets of the same LEDs or optical emitters, the Commission finds that the LEDs/optical emitters in the first set would emit the same light as the LEDs/optical emitters in the second set. The fact that this disclosure *could be* interpreted by a skilled artisan, as Apple suggests, to encompass situations where the first LED set emits visible light at one wavelength and near-infrared at a second wavelength, and the second LED set emits visible light at a third wavelength and near-infrared

⁴¹ The Commission’s conclusion is based on the specifications themselves, not on 37 C.F.R. § 1.84(p)(4), which Complainants cited for the first time in their petition for review of the ALJ’s Final ID. Thus, while the parties contest whether a waiver by Complainants prevents the Commission from relying on that rule, those arguments are moot because, in view of the specifications, the Commission need not and does not rely on that rule.

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light at a fourth wavelength, does not mean that this is how a skilled artisan would understand the disclosure, especially when there is no testimony to this effect. Again, at a minimum, the specifications do not clearly and convincingly show that these respective wavelengths of visible and near-infrared optical radiation are not the same between the sets of LEDs/optical emitters.

Thus, in view of Complainants' above-discussed citations to the specification and Apple's conclusory expert testimony, the Commission concludes that Apple has not met its burden of proof to show by clear and convincing evidence that Complainants did not convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the applicants were in possession of the claimed inventions.

In their petition for review and in their briefing to the Commission, Complainants cite additional passages from the specification that, although not necessary to sustain the Commission's conclusion, further support it. CBr. at 42–48 (citing JX-0001 ('501 patent) at 4:55–57, 9:4–6, 12:5–9, 12:26–32, 12:38–40, 12:64–13:6, 13:21–25, 29:19–22, 33:26–36). Apple alleges that Complainants waived reliance on these passages because Complainants cite these passages for the first time in their petition for review. The Commission notes, however, that these passages are intrinsic evidence within the four corners of the patent and they merely reinforce Complainants' general argument to the ALJ. *See, e.g.*, Order No. 4 (Ground Rules), EDIS Doc. ID 752396, at Ground Rule 13.1 (Initial Post-hearing Briefs; Filing and Content) (declaring only an *issue* is waived when that *issue* is not “included in the pre-hearing brief”). Thus, under these circumstances, the Commission declines to find Complainants' reliance on this evidence waived.

Complainants' newly-cited passages of the specification show that, in Figure 7B, each emitter 104 includes sets of LEDs that can emit light “at or about 1610 nm, about 1640 nm, *and*

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about 1665 nm.” JX-0001 (’501 patent) at 12:38–40 (emphasis added); *see also, e.g.*, CBr. at 42–48. Complainants additionally rely on JX-0001 (’501 patent) at 4:55–57, 9:4–6, 12:5–9, 12:26–32, 12:38–40, 12:64–13:6, 13:21–25, 29:19–22, 33:26–36. Complainants reason that Figure 7B shows two emitters, so each emitter 104 would have an LED with *each* of those three wavelengths, *i.e.*, at or about 1610 nm, at or about 1640 nm, *and* at or about 1665 nm, JX-0001 (’501 patent) at 12:5–9, 12:38–40, and thus the two emitters include at least matching pairs of wavelengths.⁴² *Id.* at 43–44. This evidence further confirms the Commission’s conclusion that Apple has not shown by clear and convincing evidence that the relevant claims are invalid for lacking written description support.⁴³

⁴² Regarding the wavelengths disclosed in these passages, Apple argues that the passages relate to measuring “analytes like glucose,” not “oxygen” or “oxygen saturation,” as the claims require, and thus those teachings cannot provide written description support here. *See* RBr. at 51–52 (citing JX-0001 (’501 patent) at 12:26–44). The Commission, however, agrees with Complainants that the specific wavelengths mentioned in the specification are “irrelevant because specific wavelengths are not claimed,” as the “claims merely recite that the two wavelengths used in the first set of LEDs—whatever they may be—are the same wavelengths used in the second set.” CBr. (Reply) at 26. Other portions of the specification, including those cited by Complainants, recite that the emitters 104 can have other matching wavelengths. JX-0001 (’501 patent) at 12:60–13:7 (“Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system 100 can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements.”).

⁴³ Chairman Johanson would not reverse the ALJ’s well-reasoned determination that claim 28 of the ’502 patent and claim 12 of the ’648 patent are invalid for lacking written description support.

The written description requirement “is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time.” *Ariad*, 598 F.3d at 1354. While the requirement does not demand any particular form of disclosure, “a description that merely renders the invention obvious does not satisfy the requirement.” *Id.* at 1352.

In finding support for disputed claims in the original specification, the majority relies heavily on the specification’s teaching that “[i]n an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation,” JX-0002 (’502 patent) at col. 12:9–12, and Figures 7A and 7B. The majority, noting that Figure 7B has two structures designated 104, concludes that “[i]f the two sets of LEDs or the two emitters

CONFIDENTIAL VERSION**E. Claim Construction and Infringement Regarding the '745 Patent**

The Final ID found that the Accused Products have not been shown to infringe claims 9 or 27 of the '745 patent. *E.g.*, Final ID at 336. The Commission determined to review this finding of the Final ID. *See* 88 Fed. Reg. at 32244. On review, the Commission has determined to affirm the Final ID without modification, thus adopting the Final ID's analysis.

F. The Domestic Industry Issues Under Review—The Poeze Patents and the '745 Patent

The Final ID found that the technical prong of the domestic industry requirement has been satisfied for claim 12 of the '501 patent, claim 28 of the '502 patent, claims 12, 24, and 30 of the '648 patent, and claim 18 of the '745 patent, and that the economic prong of the domestic industry requirement has been satisfied with respect to the '501, '502, '648, and '745 patents.

having sets of optical sources are the same, then they must emit the same visible and near-infrared optical radiation.” There is, however, no teaching that the emitters are the same. *See* Final ID at 164 (“there is no disclosure of two separate sets of LEDs using the same wavelengths in each set”). Rather, the specification and figures use “emitters” as a broad term for any light source of any frequency. Indeed, element 104 is used inconsistently in the figures relied upon by the majority. *Compare* Figure 7A with 7B.

Moreover, both Figures 7A and 7B depict embodiments that differ meaningfully from that of claim 28 of the '502 patent (which requires four photodiodes with aligned openings) or claim 12 of the '648 patent (similar limitations). This suggests a failure to describe each claim as an “integrated whole.” *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) (“Taking each claim—as we must—as an integrated whole rather than as a collection of independent limitations, one searches the 2000 application in vain for the disclosure of even a single species that falls within the claims.”).

The majority further relies on Respondents' expert testimony being “conclusory.” This is not persuasive. Caselaw is plain that no expert testimony is necessary to show a failure to comply with the written description requirement. *See, e.g., Centocor*, 636 F.3d at 1347. Further, Complainants' expert testimony lacks any discussion of the import of the disclosure found in column 12 relied on by the majority. *See* Tr. (Madisetti) at 1350:22–1352:4.

Considered as a whole, the evidence suggests that these late added claims (added by amendment years after the original priority date) reach beyond any disclosure fairly described by the specification and figures. Accordingly, Chairman Johanson would affirm the ALJ's determination that these claims are not fully supported by the original disclosure.

E.g., Final ID at 336. The Commission determined to review these findings of the Final ID. *See* 88 Fed. Reg. at 32244.

On review, the Commission has determined to take no position regarding the Final ID’s findings as to (1) whether post-Complaint evidence can be considered in satisfying the domestic industry requirement in this case with respect to the ’501, ’502, ’648, and ’745 patents; and (2) whether Complainants had shown a domestic industry in the process of being established. *See* 19 U.S.C. § 1337(a)(2); *Beloit*, 742 F.2d at 1423; *see also, e.g.*, Final ID at 56–59, , 62 n.16, 85–87, 209, 302 n.116, 319, 324.

The Commission affirms, however, the Final ID’s finding that Complainants have shown the existence of a domestic industry by way of significant employment of labor with respect to Masimo’s investments in research and development for the Masimo Watch, but with the following modified reasoning. Final ID at 317–18.

The Final ID found that Complainants’ employment of labor was significant, in part, because it involved 79 employees (█ full-time equivalents) representing over 17 percent of Masimo’s research and development engineers. Final ID at 317. The Commission additionally finds that Complainants’ employment of labor is quantitatively significant because the identified employment of labor is █ percent domestic. As the Final ID found, all the research and development of the Masimo Watch has occurred in the United States. *Id.* (citing CPHBr. at 307); *see also* Tr. (Kiani⁴⁴) at 321:23–322:5 (testifying that research and development occurred in Irvine, California).⁴⁵

⁴⁴ Joe Kiani is the chairman and chief executive officer of Masimo and Cercacor. *E.g.*, Final ID at 5.

⁴⁵ The Final ID recognized that Complainants presented evidence regarding approximately \$680,000 in payments to certain third-party firms for “design” work on the

The Commission finds that the fact that research and development of the Masimo Watch occurs [REDACTED] percent in the United States, combined with the qualitative significance of research and development to the Masimo Watch (Final ID at 318), shows that Complainants' employment of labor is significant. *See* Final ID at 317 (citing *Gas Spring Nailer Prods. & Components Thereof*, Inv. No. 337-TA-1082, Comm'n Op. at 83 (Apr. 28, 2020) (finding quantitative significance where "all, *i.e.*, 100 percent, of Kyocera's R&D and engineering expenditures relating to complainant's [domestic industry products] occurs in the United States"), *vacated and remanded on other grounds, Kyocera Senco Indus. Tools v. Int'l Trade Comm'n*, 22 F.4th 1369 (Fed. Cir. 2022)).

The Commission otherwise affirms the Final ID's domestic industry analysis as to the '501, '502, '648, and '745 patents, including the Final ID's finding that Complainants' plant and equipment investments were not significant. *See* Final ID at 315. Because the Final ID found that Complainants satisfied the domestic industry requirement as to these patents based only on pre-Complaint investments, the Commission determines that Complainants have satisfied the domestic industry requirement as to the '501, '502, '648, and '745 patents based on an "existing" domestic industry. *See* 19 U.S.C. § 1337(a)(3).

Masimo Watch (*see* CBr. at 26), but did not credit that evidence towards a domestic industry because it was unclear if those firms performed design work in the United States. Final ID at 313–14. However, even if these payments were directed to foreign labor, they are an order of magnitude smaller than the \$6.5 million employment of research and development labor at Masimo's U.S. facilities. *Id.* (finding that "these expenditures are relatively small in comparison to Masimo's R&D expenditures"). Thus, the overwhelming majority of Complainants' employment of labor is domestic and Complainants' domestic industry is therefore significant.

CONFIDENTIAL VERSION**V. REMEDY, THE PUBLIC INTEREST, AND BONDING**

The Commission has determined to issue an LEO and a CDO. Both remedial orders include a service, repair, and replacement exemption (discussed below in the context of the public interest), and will go into effect, without delay, at the end of the period of Presidential review. The Commission has concluded that the public interest does not counsel against providing Complainants this remedy. The Commission has also determined that the bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the articles subject to the LEO.

A. Remedy

The Commission has “broad discretion in selecting the form, scope, and extent of the remedy.” *Viscofan, S.A. v. US. Int’l Trade Comm’n*, 787 F.2d 544, 548 (Fed. Cir. 1986).

1. Limited Exclusion Order

As discussed below, the Commission has determined to issue an LEO directed to covered products that infringe any of claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent. The LEO includes the standard certification provision; includes a service, repair, and replacement exemption for infringing articles purchased prior to the expiration of the period of Presidential review; and is to go into effect without delay.

a. The Applicable Law

Section 337(d)(1) provides that “[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry.” 19 U.S.C. § 1337(d)(1).

CONFIDENTIAL VERSION**b. The RD**

Before the ALJ, Complainants requested that the Commission issue an LEO to remedy Apple's section 337 violation. *E.g.*, RD at 1; CPHBr. at 310–11. For its part, Apple argued that any LEO should include an exemption for “the continued service, repair, or replacement of previously purchased products, including software maintenance and updates.” *E.g.*, RD at 1; RPHBr. at 279. Apple further requested that any LEO include the standard certification provision and be no broader in scope than the scope of the investigation. *E.g.*, RD at 1–2; RPHBr. at 175, 279.

The RD recommended that any LEO be directed to Apple's importation of infringing wearable electronic devices with light-based pulse oximetry functionality and components thereof. RD at 2 (citing 86 Fed. Reg. at 46275 (defining scope of investigation)). The RD additionally declared that the record at the time did not include evidence to support an exemption for service, repair, or replacement. *Id.* at 2–3. The ALJ further recommended that any LEO include the standard certification provision. *Id.* at 3–4 (citing *Certain Composite Aerogel Insulation Materials & Methods for Manufacturing the Same*, Inv. No. 337-TA-1003, Comm'n Op. at 62–63, EDIS Doc. ID 637154 (Feb. 22, 2018); RPHBr. at 279). In doing so, the RD properly recognized that any non-adjudicated redesigns would not be subject to certification. *Id.* at 4 (citing *Certain Automated Teller Machines, ATM Modules, Components Thereof & Prods. Containing the Same*, Inv. No. 337-TA-972, Comm'n Op. at 26–27 and n.18, EDIS Doc. ID 613988 (June 12, 2017)).

c. The Parties' Arguments

In their briefing to the Commission, Complainants again request that the Commission issue an LEO. *See* CBr. at 87–88. Complainants accept the RD's recommendation that the LEO include a certification provision. *See id.* (citing RD at 4). Complainants further declare that the

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LEO should not include any exemption for a service, repair, or replacement for the reasons it discusses related to the public interest, discussed below. *See id.* at 88; *see also* CBr. (Reply) at 42–43. Complainants additionally argue that the LEO should state that no infringing articles should be allowed to be imported for any purpose, including the importation of any unreleased products for “engineering validation testing,” “design validation testing,” or “product validation testing” prior to commercial launch. CBr. at 88. Complainants further argue that the Commission should reject Apple’s request for an enforcement delay. *See* CBr. (Reply) at 40–41.

Apple argues that, for public interest reasons (discussed below), the Commission should decline to issue a remedy, or at least suspend enforcement of any remedy for twelve months and/or include an exemption allowing for the service, repair, and replacement of customers’ Apple Watches. *E.g.*, RBr. at 88–90, 67–72. Apple additionally declares that any LEO should contain the standard certification provision. *See id.* at 90–91. Apple further argues that Complainants’ “proposed LEO and CDO fail to conform the orders with the scope of the Investigation as defined in the Notice of Investigation: ‘wearable electronic devices with light-based pulse oximetry functionality and components thereof.’” *Id.* at RBr. (Reply) at 49 (quoting 86 Fed. Reg. at 46276) (citing *Certain Automated Mechanical Transmission Sys.*, Inv. No. 337-TA-503, Comm’n Op. at 4 (May 9, 2005)). Apple further points out Complainants’ requested remedial orders improperly seek to cover “hardware and *software* components thereof.” *Id.* (quoting CBr. at Appx. A, B) (Apple’s emphasis). Regarding “software components,” Apple argues that those, as “electronic transmissions,” are outside the scope of the Commission’s jurisdiction. *Id.* (citing *ClearCorrect Operating, LLC v. Int’l Trade Comm’n*, 810 F.3d 1283, 1286 (Fed. Cir. 2015)). Apple further addresses Complainants’ assertion that any LEO should provide “that no infringing articles should be imported for any purpose.” *Id.* at 50 (quoting CBr.

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at 88). Apple declares that it is “unaware of any instance in which the Commission has included such additional language in the past, and Complainants offer no proper basis to do so in this case.” *Id.*

d. Analysis

The Commission has determined to issue an LEO directed to covered products that infringe any of claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent. Consistent with standard practice, the Commission defines “covered products” in accordance with the plain language description of the accused products in the Complaint (*see* 19 C.F.R. § 210.10(b)(1)), which is “wearable electronic devices with light-based pulse oximetry functionality and components thereof.” 86 Fed. Reg. at 46276. The Commission also agrees with Apple that the LEO (and CDO) should not cover “software components.” *See* RBr. (Reply) at 49 (citing *ClearCorrect*, 810 F.3d at 1286 (Fed. Cir. 2015)); *see also, e.g., Certain Wearable Electronic Devices with ECG Functionality & Components Thereof*, Inv. No. 337-TA-1266, Comm’n Op. at 50 n.33 (Jan. 20, 2023) (“Commission exclusion orders, however, do not extend to electronic transmissions.”).

The issued LEO also includes the standard certification. Neither party has shown a valid basis for deviating from the Commission’s standard practice. Complainants argue that the LEO should include language that “clarifies that Apple cannot use the certification procedure for redesigns that have not been adjudicated as non-infringing.” *See* CBr. at 87. While the Commission declines to adopt that language as part of the Order itself, as the RD correctly recognized, the standard certification does not apply to redesigns that have not been adjudicated as non-infringing. *See* RD at 4 (citing *Automated Teller Machines*, Inv. No. 337-TA-972, Comm’n Op. at 26–27 (including n.18) (“The standard certification language does not apply to redesigns that have not been adjudicated as non-infringing.” (Internal quotations removed))).

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Should the Commission or U.S. Customs and Border Protection (“CBP”) later determine that a redesigned article presented for adjudication does not infringe, the certification provision can operate to exempt those articles.

Complainants argue that the LEO should explicitly state that no infringing articles should be allowed to be imported “for any purpose.” CBr. at 88. However, Complainants have shown no valid reason for why the Commission’s LEO should include this non-standard language. Moreover, Complainants’ request is inconsistent with section 337, which does not allow the Commission to bar, for example, products “imported by and for the use of the United States.” 19 U.S.C. § 1337(l).

For the reasons discussed below in the context of the public interest,⁴⁶ the LEO includes a service, repair, and replacement exemption. *See infra* section V.B.4.a.iii. However, also for the reasons discussed below in the context of the public interest, the Commission denies Apple’s request that the LEO be subject to a twelve-month delay.

2. Cease and Desist Order

As discussed below, the Commission has determined to issue a CDO directed to Apple and covered products that infringe any of claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent. The CDO includes a service, repair, and replacement exemption for

⁴⁶ Commissioner Kearns disagrees with the Commission majority’s position that public interest is the sole statutory ground for exemptions from the scope of remedial orders. As he explained in *Certain Cloud-Connected Wood-Pellet Grills & Components Thereof*, Inv. No. 337-TA-1237 (“*Grills*”) (joined by Commissioner Karpel), the Commission’s reviewing court has stated that the Commission has “broad discretion in selecting the form, scope, and extent of the remedy.” *Grills*, Comm’n Op. at 11–12 (including n.10) (May 24, 2022). Moreover, they observed that “the Commission has repeatedly indicated that it has granted warranty and repair exemptions ‘when unopposed, in view of the public interest, or upon some showing of a need for service and repair.’” *Grills*, Comm’n Op. at 11 n.10.

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infringing articles purchased prior to the expiration of the period of Presidential review, and the CDO is to go into effect without delay.

a. The Applicable Law

Section 337(f)(1) provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a CDO as a remedy for a violation of section 337. *See* 19 U.S.C. § 1337(f)(1). CDOs are generally issued when, with respect to the imported infringing products, the respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order.⁴⁷ *See, e.g., Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof*, Inv. No. 337-TA-965, Comm'n Op. at 4–6 (Feb. 1, 2017); *Certain Protective Cases & Components Thereof*, Inv. No. 337-TA-780, USITC Pub. No. 4405, Comm'n Op. at 28 (Nov. 19, 2012) (citing *Certain Laser Bar Code Scanners & Scan Engines, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-551, Comm'n Op. at 22 (June 24, 2007)). Complainants bear the burden on this issue: “[a] complainant seeking a [CDO] must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order.” *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 5 (citing *Certain Integrated Repeaters, Switches*,

⁴⁷ When the presence of infringing domestic inventory or domestic operations is asserted as the basis for a CDO under section 337(f)(1), Commissioner Schmidlein does not adopt the view that the inventory or domestic operations needs to be “commercially significant” in order to issue the CDO. *See, e.g., Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 65 n.24 (Apr. 9, 2019); *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 6 n.2 (Feb. 1, 2017). In Commissioner Schmidlein’s view, the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO. *Id.*

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Transceivers, & Prods. Containing Same, Inv. No. 337-TA-435, USITC Pub. No. 3547 (Oct. 2002), Comm'n Op. at 27 (Aug. 16, 2002); H.R. REP. No. 100-40, at 160 (1987)).

b. The RD

Before the ALJ, Complainants sought a CDO based on evidence of Apple's significant inventory of Accused Products. *E.g.*, RD at 4 (citing CPHBr. at 311). For its part, Apple argued that any CDO should include service, repair, and replacement exemption that permits "the continued service, repair, or replacement of previously purchased products, including software maintenance and updates." *Id.* (quoting RPHBr. at 279).

The RD found that "[t]here is no dispute that Apple maintains a significant commercial inventory of Accused Products." *Id.* at 5 (citing CPHBr. at 311; CX-0128C at ¶ 5). The RD further found that there is also "evidence that Apple has significant domestic operations, because Apple is headquartered in California and has over 75,000 U.S. employees." *Id.* (citing RStmt.). Thus, the RD recommended the issuance of a CDO against Apple. *Id.*

c. The Parties' Arguments

Complainants request that the Commission issue a CDO directed to Apple. *See* CBr. at 87–88. The parties make the same arguments as to the scope of the CDO that they made for the LEO. *See id.* at 88; RBr. at 88–90, 67–72. Apple does not dispute the RD's findings that it maintains a significant commercial inventory of Accused Products and has significant domestic operations. *See generally* RBr.; RBr. (Reply); *see also* RD at 5.

d. Analysis

The Commission has determined to issue a CDO directed to Apple and covered products that infringe any of claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648

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patent.⁴⁸ The Commission adopts the undisputed findings in the RD that Apple maintains a commercially significant inventory of Accused Products and has significant domestic operations. RD at 5; *see also generally* RBr. (not disputing that it maintains a commercially significant inventory or has significant domestic operations); RBr. (Reply) (same). The issued CDO directs Apple to cease and desist from conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of wearable electronic devices with light-based pulse oximetry functionality and components thereof that infringe claims 28 of the '502 patent or any of claims 12, 24, and 30 of the '648 patent. The language of the CDO is consistent with the Commission's standard practice of using the plain language description of the accused products in the Complaint as the definition of "covered products." *See* 19 C.F.R. § 210.10(b)(1). The scope of the CDO, like the LEO, is discussed below in the context of the public interest.

B. Public Interest

To prevent any harm from the remedial orders to the public health and welfare and to United States consumers, the Commission's LEO and CDO each include a service, repair, and replacement exemption. In view of this exemption, the public interest factors do not counsel against providing Complainants a remedy. Apple has not shown any reason why the Commission should delay the enforcement of its remedy.

⁴⁸ Commissioner Schmidlein agrees that a CDO should issue directed to Respondent Apple, but she differs from the majority with respect to the basis for that determination. *See supra* note 47 ("[T]he presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO.").

CONFIDENTIAL VERSION**1. The Applicable Law**

Section 337 requires that the Commission, upon finding a violation of section 337, issue an LEO “unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.” 19 U.S.C. § 1337(d)(1). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. § 1337(f)(1).

Under appropriate facts and circumstances, the Commission may determine that no remedy should issue because of the adverse impacts on the public interest. *See, e.g., Certain Fluidized Supporting Apparatus & Components Thereof*, Inv. Nos. 337-TA-182/188, USITC Pub. 1667, Comm’n Op. at 1–2, 23–25 (Oct. 1984) (finding that the public interest warranted denying complainant’s requested relief). Moreover, when the circumstances of a particular investigation require, the Commission has tailored its relief in light of the statutory public interest factors. For example, the Commission has allowed continued importation for ongoing medical research, exempted service parts, grandfathered certain infringing products, and delayed the imposition of remedies to allow affected third-party consumers to transition to non-infringing products. *E.g., Certain Microfluidic Devices*, Inv. No. 337-TA-1068 Comm’n Op. at 1, 22–48, 53–54 (analyzing the public interest, discussing applicable precedent, and ultimately issuing a tailored LEO and a tailored CDO); *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067, Comm’n Op. at 32–33 (July 18, 2019) (exempting service parts); *Certain Baseband Processor Chips & Chipsets, Transmitter, & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets*, 337-TA-543, USITC Pub. No. 4258, comm’n Op. at 150–51 (Oct. 2011) (grandfathering certain products); *Certain*

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Personal Data & Mobile Comm'n Devices & Related Software, 337-TA-710, USITC Pub. No. 4331, Comm'n Op., at 72–73, 80–81 (June 2012) (delaying imposition of remedy).

The statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found regardless of the quality or quantity of public interest information supplied by the parties. *See* 19 U.S.C. § 1337(d)(l), (f)(l). Thus, the Commission publishes a notice inviting the parties as well as interested members of the public and interested government agencies to gather and present evidence on the public interest at multiple junctures in the proceeding. *See* 19 U.S.C. § 1337(d)(l) & (f)(l).

2. Non-Party Comments on the Public Interest

The Commission's solicitation of public interest comments following the ALJ's RD (88 Fed. Reg. 6312, 6312–13 (Jan. 31, 2023)) resulted in numerous submissions on the public interest from non-parties, including:

- (1) Public Interest Comments of David Albert, EDIS Doc. ID 790883 (Feb. 22, 2023) (“Albert Stmt.”);
- (2) Public Interest Statement of the Alliance for U.S. Startups and Inventors for Jobs, EDIS Doc. ID 791674 (Mar. 3, 2023) (“Alliance for U.S. Startups Stmt.”);
- (3) Statement of Non-Party American Heart Association on the Public Interest of the Recommended Remedial Orders But Not in Support of Any Party, EDIS Doc. ID 791476 (Mar. 1, 2023) (“AHA Stmt.”);
- (4) Public Interest Letter from the Honorable Ken Buck, Henry C. Johnson, Jr., and Katie Porter, EDIS Doc. ID 791047 (Feb. 23, 2023) (“Buck Stmt.”);
- (5) Public Interest Comments from C4IP, EDIS Doc. ID 791567 (Mar. 2, 2023) (“C4IP Stmt.”);
- (6) Public Interest Comments of Bill Carpou from Octane, EDIS Doc. ID 790962 (Feb. 23, 2023) (“Carpou Stmt.”);
- (7) Statement of Third Party Computer and Communications Industry Association in Response to the Commission's January 31, 2023, Notice of Request for Statements on the Public Interest, EDIS Doc. ID 791054 (Feb. 23, 2023) (“CCIA Stmt.”);

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- (8) Public Interest Statement of Consumer Federation of America, EDIS Doc. ID 791163 (Feb. 27 2023) (“CFA Stmt.”);
- (9) Public Comments from California Life Sciences, EDIS Doc. ID 791012 (Feb. 23, 2023) (“CLS Stmt.”);
- (10) Letter of Support from Cure HHT, EDIS Doc. ID 790394 (Feb. 15, 2023) (“Cure HHT Stmt.”);
- (11) Public Interest Statement of David Dinielli and Michael Enseki-Frank, EDIS Doc. ID 791686 (Mar. 3, 2023) (“Dinielli Stmt.”);
- (12) Public Interest Statement of Ryan Drant from Questa Capital, EDIS Doc. ID 790991 (Feb. 23, 2023) (“Drant Stmt.”);
- (13) Public Interest Statement of Non-Party Mitchell Goldstein, M.D., EDIS Doc. ID 791179 (Feb. 27, 2023) (“Goldstein Stmt.”);
- (14) Public Interest Comments from Innovation Alliance, EDIS Doc. ID 791048 (Feb. 23, 2023) (“Innovation Alliance Stmt.”);
- (15) Public Interest Statement of Josh Malone, EDIS Doc. ID 790787 (Feb. 21, 2023) (“Malone Stmt.”);
- (16) Christopher McCarthy Public Interest Statement Points Supporting Masimo, EDIS Doc. ID 789080 (Feb. 1, 2023) (“McCarthy Stmt.”);
- (17) Public Interest Statement of Non-Party of Medical Device Manufacturers Association (MDMA), EDIS Doc. ID 791167 (Feb. 27, 2023) (“MDMA Stmt.”);
- (18) Public Interest Statement of Richard Milani, M.D., EDIS Doc. ID 791665 (Mar. 2, 2023) (“Milani Stmt.”);
- (19) Statement of Third Party Law Professors Adam Mossof and Kristen Osenga in Response to the Commission’s Notice of Request for Statements on the Public Interest and Reply to Respondent’s Statement of February 22, 2023, EDIS Doc. ID 791069 (Feb. 23, 2023) (“Mossof Stmt.”);
- (20) National Jewish Health Support for the Apple Watch for Use in Tracking Physiologic Features in Medical Patients, EDIS Doc. ID 790602 (Feb. 17, 2023) (“NJH Stmt.,” letter authored by Russell Bowler, M.D., Ph.D.);
- (21) Cynthia Persaud Comments for Inv. 337-1276, EDIS Doc. ID 789338 (Feb. 3, 2023) (“Persaud Stmt.”);
- (22) Public Interest Statement of Non-Party Peter Pronovost, M.D., EDIS Doc. ID 791162 (Feb. 27, 2023) (“Pronovost Stmt.”);

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- (23) Public Interest Statement of Non-Party Patient Safety Movement Foundation, EDIS Doc. ID 791175 (Feb. 27, 2023) (“PSMF Stmt.,” letter authored by Dr. Michael Ramsay);
- (24) Stanford University Medical Center Letter in Support of Apple Watch, EDIS Doc. ID 791060 (Feb. 23, 2023) (“Stanford Stmt.,” letter authored by Stephen Ruoss, MD);
- (25) StopAFib.org Letter of Support, EDIS Doc. ID 790642 (Feb. 21, 2023) (“StopAFib.org Stmt.”);
- (26) University of Michigan Health Letter of Support for Apple Watch, EDIS Doc. ID 790641 (Feb. 21, 2023) (“Univ. of Mich. Stmt.,” letter authored by Jessica R. Golbus MD, MS);
- (27) Public Interest Comments of US Inventor, Inc., EDIS Doc. ID 791041 (Feb. 23, 2023) (“US Inventor Stmt.”);
- (28) Dr. Robert M. Wachter Letter in Support of Apple and Public Interest, EDIS Doc. ID 790510 (Feb. 16, 2023) (“Wachter Stmt.”);
- (29) Public Interest Statement of Kevin R. Ward, MD, EDIS Doc. ID 790884 (Feb. 22, 2023) (“Ward Stmt.”);
- (30) Comments from Dr. Adam Waddell, MD, EDIS Doc. ID 789029 (Jan. 31, 2023) (“Waddell Stmt.”);
- (31) Public Interest Statement of Non-Party Bobby Yazdani, EDIS Doc. ID 791177 (Feb. 27, 2023) (“Yazdani Stmt.”).

The Commission’s notice of review (88 Fed. Reg. at 32243–46 (May 19, 2023)) also resulted in several submissions from third parties:

- (1) Public Interest Comments from Council for Innovation Promotion (C4IP), EDIS Doc. ID 797854 (June 5, 2023) (“C4IP Comments”);
- (2) Public Interest Comments from Hugh Calkins, M.D., EDIS Doc. ID 797827 (June 5, 2023) (“Calkins Comments”);
- (3) Public Interest Comments from Nelson Freimer, M.D., EDIS Doc. ID 797817 (June 5, 2023) (“Freimer Comments”);
- (4) Public Interest Comments from Calum A. MacRae, MD, PhD, EDIS Doc. ID 797826 (June 5, 2023) (“MacRae Comments”);
- (5) Public Interest Comments from Rod S. Passman, M.D., M.S.C.E., EDIS Doc. ID 797813 (June 5, 2023) (“Passman Comments”);

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- (6) Comments on Public Interest from Leslie A. Saxon, M.D., EDIS Doc. ID 797811 (June 5, 2023) (“Saxon Comments”);
- (7) Public Interest Comments from Professors Francisco J. Valero-Cuevas, PhD and Najmedin Meshkati, PhD, CPE, EDIS Doc. ID 798257 (June 12, 2023) (“Valero-Cuevas Comments”).

The Commission has considered all of these submissions in making its final determination.

3. Whether Apple is Collaterally Estopped from Arguing the Merits of the Public Interest

As a preliminary matter, Complainants allege that Apple is collaterally estopped from arguing the merits of its public interest arguments. *E.g.*, CBr. at 56–57. As discussed below, the Commission disagrees.

a. The Parties’ Arguments

Complainants argue that Apple should be estopped from arguing the merits of the public interest, reasoning that Apple already presented its arguments to the Commission in *Wearable Electronic Devices*, Inv. No. 337-TA-1266, where the Commission concluded that the public interest did not weigh against excluding the infringing Apple Watches.⁴⁹ *See* CBr. at 56–57. Complainants argue that the Commission has previously applied collateral estoppel when: (1) the issue decided in the prior litigation is identical to that before the tribunal; (2) the issue was actually litigated in the prior proceeding; (3) the resolution of the issue in the prior litigation was necessary to its resulting judgment; and (4) the party against whom collateral estoppel is

⁴⁹ In that investigation, the complainant (AliveCor, Inc.) accused the Apple Watch Series 4, 5, 6, and 7. *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 9. The Commission issued remedial orders with a service, repair, and replacement exemption, although the remedial orders remain suspended pending final resolution of the complainant’s appeal of the USPTO’s final written decisions finding the asserted claims invalid. *See id.* at 86–87.

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asserted had a full and fair opportunity to litigate its position. *Id.* at 56 (citing *Certain Three-Dimensional Cinema Sys. & Components Thereof*, Inv. No. 337-TA-939, EDIS Doc. ID 588763, Comm'n Op. at 53 (Aug. 23, 2016)). According to Complainants, all of those elements are satisfied here, and the Commission therefore should likewise conclude that no public interest concerns warrant denying their requested remedy. *See id.* at 56–57.

In reply, Apple asserts that collateral estoppel does not apply here. *See* RBr. (Reply) at 35–36. Apple reasons that the public interest issues now at issue are different from the ones in *Wearable Electronic Devices*, Inv. No. 337-TA-1266, where Commission briefing was completed months earlier and related to a different feature. *Id.* at 35. Apple further alleges that, in assessing the “propriety of remedial orders, the Commission should consider public interest issues on an ongoing basis, based on the present facts.” *Id.* Apple points out that the Commission has never applied collateral estoppel regarding the public interest, and Apple further asserts that the Commission has rejected the application of estoppel to the public interest in the past. *Id.* (citing, *inter alia*, *Certain Mobile Elec. Devices & Radio Frequency & Processing Components Thereof (II)*, Inv. No. 337-TA-1093, Final ID, 2019 WL 2058009, at *23 (Mar. 26, 2019)). Apple further argues that the particular public interest questions “posed in the Commission’s Notice of Review indicate that issues specific to this Investigation will bear on the Commission’s findings,” and the Commission should therefore consider that briefing. *Id.* at 36.

b. Analysis

The Commission concludes that collateral estoppel does not bar Apple from arguing the merits of the public interest. The statutory language of section 337 requires the Commission to consider the public interest in each investigation before issuing a remedy. *See, e.g.*, 19 U.S.C. § 1337(d)(1) (“If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned . . . be excluded

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from entry . . . *unless, after considering* the effect of such exclusion upon the [public interest factors], it finds that such articles should not be excluded from entry.” (Emphasis added)). Relying on the Commission’s decision in previous investigations alone does not satisfy the statutory mandate to consider the public interest. *See Microfluidic Devices*, Inv. No. 337-TA-1068, Comm’n Op at 28 (“[T]he statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found.”), 28 n.25 (“The Commission has a statutory duty to consider the public interest.”). While the Commission’s reasoning in *Wearable Electronic Devices* is in some instances applicable here (as discussed below), the Commission will consider Apple’s arguments anew. Furthermore, unlike the arguments in *Wearable Electronic Devices*, the public interest arguments here involve both the Apple Watches’ blood oxygen feature and electrocardiogram (“ECG”) recording feature. Moreover, any estoppel would be inapplicable to non-party comments.

4. The Public Interest Factors**a. Public Health and Welfare**

In general, Apple argues that Complainants’ requested remedy will adversely affect the public health and welfare because it will “prevent consumers and medical researchers from future access not only to the Blood Oxygen feature⁵⁰ that Complainants have accused of infringement, but also to a host of other health, wellness, and safety features—including ones known to be lifesaving.” RBr. at 83. Apple primarily points to the ECG recording feature that was at issue in *Wearable Electronic Devices*, Inv. No. 337-TA-1266. Apple further explains that, “[i]n addition to numerous consumer connectivity functions—including cellular capability,

⁵⁰ The “Blood Oxygen feature” refers to the infringing pulse oximetry feature.

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messaging, email, access to the Internet, and navigation,” the Apple Watches subject to exclusion “also offer the IRN⁵¹ feature and the ECG app, which provide notification of a potentially fatal cardiac condition (atrial fibrillation)⁵² and allow users to monitor their heart rhythm and share the data with their doctors.” *Id.* Apple further argues that Complainants’ proposed exclusion order would also be a “major setback for medical research, where Apple Watch plays a critical role.” *Id.* at 84.

Apple additionally argues that any remedial order should include a service, repair, and replacement exemption for consumers who have permissibly obtained an Apple Watch with the accused blood oxygen feature. *E.g., id.* at 74. Apple also argues that the enforcement of any remedial order should be delayed for twelve months to “allow other device manufacturers to scale up their production capacity and address supply chain constraints that will limit supply of alternatives” and to “allow Apple sufficient time to prepare and implement its proposed design-around, and to allow the design-around to go through the necessary approval process.” *E.g., id.* at 89.

As discussed below, the Commission has determined that any adverse effect on the public health and welfare from the Commission’s remedial orders can be mitigated by the provided service, repair, and replacement exemption. There are numerous reasonable substitutes for infringing Apple Watches available in the United States for both Apple Watch users who use the devices for personal, health-related use and for users who are using infringing Apple Watches to participate in medical studies. Additionally, the Commission’s remedial orders, in view of the

⁵¹ “IRN” stands for “irregular rhythm notification.” The Apple Watch SE, which is not subject to the Commission’s remedial order includes the IRN feature. *See* RBr. at 84 n.51.

⁵² “Atrial fibrillation” is sometimes abbreviated herein as “AFib.”

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service, repair, and replacement exemption, will have no meaningful effect on medical research. Last, Apple has not shown the need for any delay in the enforcement of the Commission's remedy.

i. Reasonable Substitutes**a) The Parties' Arguments*****Apple's Arguments***

Regarding the scope of reasonable substitutes, Apple asserts that the Accused Products “include numerous features pertinent to public health and public welfare, and relevant to the reasonable substitute inquiry,” such as: (1) they are smartwatches (*i.e.* they have “features similar to a smartphone,” including telecommunications and location-sharing capabilities and accessibility features that may assist the hearing or visually-impaired); (2) they are “fitness tracking devices”; and (3) they are “health and wellness devices” that include, for example, ECG, IRN, and HHRN⁵³ features, and have also been authorized by the FDA. RBr. at 64–66. Apple declares that, “[b]ecause the Accused Apple Watches are multi-featured devices intended to serve a wide spectrum of potential users, consumers purchase the Accused Apple Watches to obtain different combinations of the above-described features.” *Id.* at 66; *see also id.* at 66–67. And, according to Apple, while “[o]ther smartwatches . . . share some functionality with Apple Watches,” they “may lack crash-detection or AFib History, and many of them lack ECG, temperature tracking, and/or fall detection features.” *Id.* at 70. Apple further argues that Complainants erroneously “attempt to narrow the range of features relevant to the public interest inquiry to only ‘health, safety, and wellness features.’” RBr. (Reply) at 40 (citing

⁵³ “HHRN” stands for “high heart rate notification.” The non-infringing Apple Watch SE includes this feature. *See* CBr. (Reply) at Ex. 93 (McGavock Declaration) at ¶ 39 (Table 1).

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Thermoplastic-Encapsulated Motors, Inv. No. 337-TA-1073, RD, 2018 WL 10758211, at *5 (Nov. 27, 2018); *Elec. Digital Media Devices*, Inv. No. 337-TA-796, Comm’n Op., 2013 WL 10734395 at *80 (Nov. 27, 2018)). Apple explains that “[t]he protected interest is the public’s ability to access the numerous relevant features in the Accused Apple Watches, just as the public was interested in accessing the relevant active safety system functionality in *Certain Table Saws*.” *Id.* at 42.

Apple specifically argues that Masimo’s W1 Watch should not be considered a reasonable substitute because (1) it is not available to U.S. consumers in “any material quantity,” (2) it is not a “smartwatch,” (3) it allegedly has not been shown to “reliably measure physiological parameters,” and (4) it is allegedly not manufactured in sufficient quantity to meet the demand created by an exclusion order. RBr. at 63.

Complainants’ Arguments

Complainants argue that “reasonable substitutes” should be defined the same way as in *Wearable Electronic Devices*, *i.e.*, as watches with a “range of health, safety, and wellness features.” CBr. at 81 (citing *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 75). Complainants explain that, under *Table Saws*, a “reasonable substitute” is defined by the “protected interest” in the features benefitting the public health and welfare. *Id.* (citing *Table Saws*, Inv. No. 337-TA-965, Comm’n Op. at 3). Complainants then declare that the public health and welfare is not impacted by consumers’ inability to have smartwatches generally, and thus, “reasonable substitutes” should be defined as they were in *Wearable Electronic Devices*. See CBr. (Reply) at 37.

Regarding specific substitutes, Complainants rely in part on following chart from the Commission’s Opinion in *Wearable Electronic Devices*, Inv. No. 337-TA-1266:

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TABLE 1: SELECTED SMARTWATCH FEATURES PROMOTED BY DEVICE MANUFACTURERS

| | Apple | | Competitors | | | | |
|----------------------------------|------------------------|--------------------------|--------------------------|-----------------|----------------|----------------------|---------------------|
| | Apple Watch (Series 8) | Apple Watch (SE 2nd Gen) | Samsung Galaxy (Watch 5) | Fitbit (Sense2) | Fossil (Gen 6) | Garmin (Venu 2 Plus) | Zepp (Amazfit GTS4) |
| | [A] | [B] | [C] | [D] | [E] | [F] | [G] |
| GPS | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Emergency SOS Capability | ✓ | ✓ | ✓ | ✗ | ✗ | ✓ | ✗ |
| Water Resistant | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Speaker and Microphone | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| 24+ Hour Battery Life | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| iOS Compatibility | ✓ | ✓ | ✗ | ✓ | ✓ | ✓ | ✓ |
| Cellular Connectivity | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Personalizable Design | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Health Functions: | | | | | | | |
| ECG | ✓ | ✗ | ✓ | ✓ | ✗ | ✗ | ✗ |
| HHRN | ✓ | ✓ | ✓ | ✓ | - | ✓ | ✓ |
| IRN | ✓ | ✓ | - | ✓ | - | ✓ | ✓ |
| Low Cardio Fitness Notifications | ✓ | ✓ | - | ✓ | ✓ | ✓ | ✓ |
| Blood Oxygen | ✓ | ✗ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Fall Detection | ✓ | ✓ | ✓ | ✗ | ✗ | ✓ | ✓ |
| Crash Detection | ✓ | ✓ | ✓ | ✗ | ✗ | ✓ | ✓ |
| Wrist Temperature | ✓ | ✗ | ✓ | ✓ | ✗ | ✗ | ✗ |
| Sleep Monitoring | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

CBR. at 83; *Wearable Elec. Devices*, Inv. No 337-TA-1266, Comm'n Op. at 77. Complainants point out that most of these watches offer the blood oxygen feature and at least the Samsung Galaxy (Watch 5) and Fitbit (Sense 2) include an ECG recording feature. Complainants allege that “[a]ll of the wearables manufactured by third parties identified in the above chart would be reasonable substitutes for the infringing Apple Watches.” *Id.* Aside from reliance on *Wearable Electronic Devices*, Complainants argue:

Garmin’s vivoactive®, Fenix®, epix™, Venu®, and Forerunner® series all have watches that include a blood oxygen feature. Google’s Pixel watch[] includes a blood oxygen feature. Samsung’s Galaxy 5 watch contains a blood oxygen feature. The Fitbit Versa 4™, Sense 2™, and Charge 5™ also contain blood oxygen features. The Fossil Gen6 contains a blood oxygen feature as well. These smartwatches contain many of the features found in the Apple Watch and many sell at lower prices. Masimo’s W1, available directly to consumers, offers continuous clinical-grade pulse oximetry as well as other health features. It is currently used in hospitals as well, outside the United States. . . . Masimo’s Freedom smartwatch will also include pulse oximetry and other health features and is expected to launch in the Fall of this year. Moreover, Masimo offers its

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blood oxygen sensor as a module to third parties who can integrate the module in their own smartwatches.

Numerous other competitive products are reasonable substitutes for the ECG functionality of the infringing products. This includes the Garmin Venu 2 Plus, Google Pixel, Samsung Galaxy 5, Fitbit Sense 2, and Fitbit Charge 5. As the Commission held in [*Wearable Electronic Devices*], the public's interest in these health features of the Apple Watch is insufficient to overcome the statutory remedy given the availability of competing substitutes.

Id. at 64–65 (citations and footnotes omitted).

Complainants also specifically argue that Masimo's W1 Watch is a reasonable substitute for the infringing Apple Watches because it offers many of the same health features that the public would be interested in having access to, including blood oxygen measurements. *See* CBr. at 83–84. Complainants point out that the Final ID found that the W1 Watch can reliably measure physiological parameters, such as blood oxygen levels. *Id.* (citing, *inter alia*, Final ID at 60–63); *see also id.* at 38–39. Complainants further argue that the W1 Watch should not be outside the scope of reasonable alternatives for not being produced in a sufficient quantity alone to meet all consumer demand created by any exclusion order because the Commission does not require any alleged substitute to satisfy that demand alone. *See* CBr. (Reply) at 37.

Complainants further argue that there is no evidence that other manufacturers of suitable alternatives do not have capacity to meet consumer demands." CBr. (Reply) at 39; *see also id.* at 39–41. Complainants point out that Apple itself could manufacture its Apple Watch SE, "which contains virtually all the same features as the infringing products, or return to producing the Apple Watch Series 4 or 5, which also included ECG," but not blood oxygen measurements. *Id.* (citing CBr. Ex. 93 at ¶¶ 22–24).

b) Non-Party Comments

Some researchers stated that other devices can replace Apple Watches:

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Given our combined expertise in the theory, design, financing, execution, and dissemination of medical research, we see no reason why it is not possible to replace the Apple Watch in pending health applications with alternative wearable devices from *Fitbit*, *Withings*, *Garmin* and others that are able to provide human motion, heart function and oxygen saturation information. Several of these companies also readily provide the Application Programming Interface (API) code that allows connectivity and data transfer to the investigator's systems.

Valero-Cuevas Comments, EDIS Doc. ID 798257, at 2; *see also id.* at 2–3. Other researchers, medical professionals, and commenters submitted filings indicating a preference for Masimo's technology, with some going so far as discouraging reliance on Apple's blood oxygen saturation feature. *See, e.g.*, McCarthy Stmt., EDIS Doc. ID 789080; Waddell Stmt., EDIS Doc. ID 789029; Albert Stmt., EDIS Doc. ID 790883; Ward Stmt., EDIS Doc. ID 790884; Yazdani Stmt., EDIS Doc. ID 791177; Goldstein Stmt., EDIS Doc. ID 791179; MDMA Stmt., EDIS Doc. ID 791167; PSMF Stmt., EDIS Doc. ID 791175; Pronovost Stmt., EDIS Doc. ID 791162.

Still other researchers indicated a preference for the Apple Watch. *See, e.g.*, NJH Stmt., EDIS Doc. ID 790602, at 1; Passman Comments, EDIS Doc. ID 797813, at 1–2; Freimer Comments, EDIS Doc. ID 797817, at 1–2; Calkins Comments, EDIS Doc. ID at 797827, at 1–2; MacRae Comments, EDIS Doc. ID 797826, at 1–2; Saxon Comments, EDIS Doc. ID 797811, at 1–2; AHA Stmt., EDIS Doc. ID 791476, at 3.

c) Analysis

The Commission assesses the scope of reasonable alternatives from the perspective of public interest concerns raised in an investigation. *See Wearable Electronic Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 73–74 (assessing the scope of reasonable substitutes from the perspective of each of the three public interest concerns raised by Apple); *Table Saws*, Inv. No. 337-TA-965, Comm'n Op. at 9 (“The protected [public health and welfare] interest here is the public's ability to purchase table saws with [active injury management technology (‘AIMT’)]

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functionality, not the ability to purchase AIMT table saws with a specific feature set that is unrelated to the efficacy of the AIMT functionality.”). The Commission notes that Apple argues, regarding the public health and welfare, that the Apple Watches’ ECG feature should also be considered because all accused Apple Watches that have the blood oxygen feature also have the ECG feature, and thus an exclusion order affecting blood oxygen feature-containing Apple Watches would also result in the exclusion of ECG feature-containing Apple Watches. RBr. at 60. Therefore, for the purposes of the public health and welfare factor, because the ECG feature is a health related feature, the Commission considers the scope of “reasonable substitutes” to include substitutes that offer a wide range of health, safety, and wellness features, including those that allow consumers to measure blood oxygen levels and that can record ECGs, although a single device need not have the capability to measure both oxygen levels and record ECGs. *See Wearable Electronic Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 75. While it is not ideal for an individual or research participant to wear two wearable electronic devices to obtain all of the desired features, the inconvenience of doing so is not significant enough to rise to the level of a public interest concern, especially in view of the countervailing interest of protecting intellectual property rights. *See, e.g., Certain Two-Handle Centerset Faucets & Escutcheons & Components Thereof*, Inv. No. 337-TA-422, Comm’n Op. at 9 (July 21, 2000); *Microfluidic Devices*, Inv. No. 337-TA-1068, Comm’n Op. at 45–46.

Apple stretches the public health and welfare public interest factor too far by seeking to require reasonable substitutes for this factor to also have telecommunications features, location tracking features, “smart” wallet and keys features, and accessibility features. The connection to the public health and welfare with those features is too attenuated to rise to the level of a public interest concern, especially when some of those alleged Apple Watch features require a paired

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iPhone (which can independently perform many of those functions). *See* CBr. (Reply) at 37.

And again, “[t]he correct assessment . . . for ‘reasonable substitutes for the devices subject to the exclusion order,’ [is] not whether ‘every consumer cannot obtain the exact device desired.’”

Fitness Devices, Inv. No. 337-TA-1265, Comm’n Op., at 85 (quoting *Elec. Digital Media Devices*, Inv. No. 337-TA-796, Comm. Op. at 120, and citing *Table Saws*, Inv. No. 337-TA-965, Comm’n Op. at 9).⁵⁴

In view of the above, the scope of reasonable substitutes for the public health and wellness factor in this investigation include: Masimo’s W1 and Freedom Watches (blood oxygen feature), Google’s Pixel watch (blood oxygen and ECG features),⁵⁵ Samsung Galaxy Watch 5 (blood oxygen and ECG features),⁵⁶ Fitbit (Versa 4™ (blood oxygen feature), Sense 2™ (blood oxygen and ECG features), and Charge 5™ (blood oxygen and ECG features)),⁵⁷

⁵⁴ While “reasonable substitutes” also considers “price points,” *Table Saws*, Inv. No. 337-TA-965, Comm’n Op. at 8, Apple appears to allege that price point is an issue regarding only Masimo’s soon-to-be-released Freedom Watch. While the Freedom Watch will be priced higher than the base infringing Apple Watch models (*see* RBr. at Ex. 3 at ¶ 25 (\$999 for the Freedom Watch compared to the Apple Watch Series 8, which starts at \$399)), infringing Apple Watch models can be comparable in price (\$799) based on consumer choices (*see* RBr. at 77 (citing, *inter alia*, RBr. at Ex. 4 (Watkins Decl.) at ¶ 21; RX-0333 at .0011). Other reasonable substitutes are even more comparable in price. For example, the Garmin Venu® 2 Plus is available for \$449, *see* CBr. at Ex. 49 (<https://www.garmin.com/en-US/p/730659>), and the Garmin vivoactive® is available for \$349, *see* CBr. at Ex. 7 (<https://www.garmin.com/en-US/p/643399>).

⁵⁵ CBr. at Ex. 12 (https://store.google.com/product/google_pixel_watch_specs?hl=en-US); CBr. at Ex. 50 (<https://support.google.com/googlepixelwatch/answer/12759285?hl=en>).

⁵⁶ CBr. at Ex. 13 (<https://www.gadgetstowear.com/measure-blood-oxygen-on-galaxy-watch-5/>); CBr. at Ex. 51 (<https://www.androidcentral.com/wearables/measure-ecg-samsung-galaxy-watch-5>).

⁵⁷ CBr. at Ex. 14 (<https://www.fitbit.com/global/us/products/smartwatches/versa4?sku=523BKBK>); CBr. at Ex. 52 (https://help.fitbit.com/articles/en_US/Help_article/2457.htm).

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Fossil (Gen 6) (blood oxygen feature),⁵⁸ Garmin (vivoactive® (blood oxygen feature),⁵⁹ Fenix® (blood oxygen feature),⁶⁰ epix™ (blood oxygen feature),⁶¹ Venu® (blood oxygen feature),⁶² Venu® 2 Plus (ECG feature),⁶³ and Forerunner®⁶⁴ series (blood oxygen feature)), and Zepp (Amazefit GTS4). *See* CBr. at 64–66; CBr. (Reply) at 37 (citing *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 37). These watches (alone or combined with each) include one or both of the blood oxygen features and the ECG features (as well as the IRN, HHRN, or other features), and thus are reasonable substitutes.⁶⁵

The Commission agrees with Complainants that the W1 Watch can serve as a reasonable substitute for the infringing Apple Watches as to the public health and welfare factor. *See, e.g.*, CBr. (Reply) at 38–39. In protesting against the suitability of this product, Apple asserts that the W1 Watch “has not been shown to reliably measure physiological parameters.” RBr. at 68.

⁵⁸ CBr. at Ex. 15 (<https://www.fossil.com/en-us/watches/learn-more/gen-6-wellness/>).

⁵⁹ CBr. at Ex. 7 (<https://www.garmin.com/en-US/p/643399>).

⁶⁰ CBr. at Ex. 8 (<https://www.garmin.com/en-US/p/735542>).

⁶¹ CBr. at Ex. 9 (<https://www.garmin.com/en-US/p/760778>).

⁶² CBr. at Ex. 10 (<https://www.garmin.com/en-US/p/801643>).

⁶³ CBr. at Ex. 49 (<https://www.garmin.com/en-US/p/730659>).

⁶⁴ CBr. at Ex. 11 (<https://www.garmin.com/en-US/p/886785>).

⁶⁵ We note that Complainants argue, in response to Apple’s arguments regarding the ECG feature, that the Apple Watch SE should be considered a reasonable substitute for purposes of the public health and welfare factor because it was considered a substitute in *Wearable Electronic Devices*, Inv. No. 337-TA-1266. *E.g.*, CBr. at 66. However, in that investigation, the record included specific, reliable evidence that the Apple Watch SE, when combined with accessories, could be used to record ECGs and therefore was a reasonable substitute. *E.g.*, *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 75–76 (including n.39). Complainants point to no such evidence in the record in this investigation. Accordingly, the Commission rejects this argument.

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However, the Final ID properly found that “the variation in the measurements [of oxygen saturation by the W1 Watch] appears to be consistent with FDA guidance regarding pulse oximetry.” Final ID at 62 n.18. And, regarding Masimo’s Freedom Watch, Masimo’s Chief Operating Officer, Bilal Muhsin, stated in a declaration:

In Fall 2023, Masimo intends to launch the Masimo Freedom smartwatch. The Masimo Freedom grew out of the Masimo W1, and will also provide clinical-grade pulse oximetry, as well as unparalleled real-time health indicators such as pulse rate, and unique scores and indexes such as Hydration Index, and Stress Index. The Masimo Freedom will be capable of measuring all the same variables as the Masimo W1, but will also include other traditional smartwatch capabilities, and safety features such as fall detection.

CBr. at Ex. 53 at ¶ 5. Apple acknowledges that the Freedom Watch is a planned replacement for the W1 Watch. *See* RBr. at 87, 88 n.54 (noting a March 28, 2023 Masimo press release regarding pre-sale launch of the Freedom Watch). Thus, the Freedom Watch is also a reasonable substitute.

ii. The Remedial Orders Will Have at Most a Minimal Adverse Effect on Medical Research

In brief, the Commission finds that its remedial orders will have, at most, a minimal adverse effect on medical research.

a) The Parties’ Arguments

Apple’s Arguments

Apple argues that Complainants’ requested remedial orders will adversely affect medical studies using the infringing blood oxygen feature, as well as studies using the ECG recording feature, of the accused Apple Watches. *See* RBr. at 57–62. Apple reasons that studies using the Apple Watches’ ECG feature should also be considered in assessing impact on the public health and welfare because all accused Apple Watches that have the blood oxygen feature also have the ECG feature, and thus an exclusion order affecting blood oxygen feature-containing Apple

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Watches would also result in the exclusion of ECG feature-containing Apple Watches. *See id.* at 60. Apple further alleges that a “key benefit of [the] Apple Watch for . . . studies is that researchers can use the multiple health and wellness metrics available through the Accused Apple Watches (as opposed to a single data field), helping to advance scientific discovery by identifying how various metrics relate to certain conditions.” *Id.* at 58. Apple points to several specific studies. *See id.* at 57–61. Apple further points to certain research areas for which it believes the accused Apple Watches “could potentially be impactful,” including those related to racial disparities in pulse oximetry measurement accuracy. *Id.* at 59–60. Apple further argues that “the broad availability of [the] Apple Watch to consumers enables researchers more generally to conduct decentralized research, which helps promote higher enrollment and more diverse patient populations.” *Id.* at 61. Apple thus concludes that the Commission should find that Complainants’ requested remedial orders would undermine important medical studies, and because it would allegedly not be practical to tailor any remedial orders to permit the importation or sale of Apple Watch models for use in clinical trials and other medical research, the Commission should deny Complainants a remedy altogether. *See id.* at 62.

Complainants’ Arguments

Complainants acknowledge that ClinicalTrials.gov, a governmental database of clinical trials maintained by the U.S. National Library of Medicine, lists 109 studies that use or have used the Apple Watch, including 67 that remain ongoing. CBr. at 77 (citing CBr. at Ex. 24 and Ex. 25). However, Complainants state that most of these ongoing studies focus on heart rate features that are also available on the Apple Watch SE, which the parties agree would not be subject to exclusion. *Id.* Complainants declare that, while nine studies use the blood oxygen feature of the infringing Apple Watches, none of those studies will be affected by any exclusion

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order because they have already ended, are conducted outside of the United States, and/or do not require pulse oximetry measurements specifically from the infringing Apple Watches (as opposed to reasonable substitutes). *See id.* at 78–79; *see also* CBr. (Reply) at 30–35. As for studies using the ECG feature, Complainants argue that the Commission already rejected those arguments made by Apple in *Wearable Electronic Devices*, Inv. No. 337-TA-1266. *See* CBr. (Reply) at 30. Last, Complainants address Apple’s argument that the “broad availability of Apple Watch to consumers enables researchers more generally to conduct decentralized research.” *Id.* at 36 (quoting RBr. at 61). In response, Complainants assert that there are reasonable substitutes available, “including the Apple Watch SE and third-party devices from Samsung, Google, Fitbit, and others.” *Id.* (citing CBr. at 64–67, 82–84; CBr. at Ex. 93 at Table 1, ¶¶ 28–39).

b) Non-Party Comments

Some non-party researchers have stated that the Apple Watch is important to their studies. *See, e.g.*, NJH Stmt., EDIS Doc. ID 790602, at 1 (“[M]y research group has found the Apple Watch to be an exceptional device that accurately measures important parameters such as heart rate, physical activity, and oxygen saturation.”); Stanford Stmt., EDIS Doc. ID 791060, at 1 (“The oxygen saturation feature of the Apple Watch is a highly accurate device feature, with performance characteristics fully comparable to medical device standards for oximeters.”); Passman Comments, EDIS Doc. ID 797813, at 1–2 (“[I]f Apple Watch is excluded for an extended period of time, our REACT-AF study and other critical research that uses this technology will be altogether shut down.”); Freimer Comments, EDIS Doc. ID 797817, at 1–2; Calkins Comments, EDIS Doc. ID at 797827, at 1–2; MacRae Comments, EDIS Doc. ID 797826, at 1–2; Saxon Comments, EDIS Doc. ID 797811, at 1–2; AHA Stmt., EDIS Doc. ID 791476, at 3–4.

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On the other hand, some researchers have stated that other devices can replace infringing

Apple Watches:

Given our combined expertise in the theory, design, financing, execution, and dissemination of medical research, we see no reason why it is not possible to replace the Apple Watch in pending health applications with alternative wearable devices from *Fitbit*, *Withings*, *Garmin* and others that are able to provide human motion, heart function and oxygen saturation information. Several of these companies also readily provide the Application Programming Interface (API) code that allows connectivity and data transfer to the investigator's systems.

Valero-Cuevas Comments, EDIS Doc. ID 798257, at 2; *see also id.* at 2–3. Other researchers and commenters have expressed a preference for Masimo's technology and even discouraged the reliance on Apple's blood oxygen feature. *See Ward Stmt.*, EDIS Doc. ID 790884, at 2 (“I am . . . very concerned about the proliferation of ‘medical devices’ like the Apple Watch with pulse oximetry. These are not ‘medical devices’ as the FDA would use the term. Indeed, I understand only software associated with the ECG feature of certain Apple Watches is FDA cleared. . . . Despite this, it is my belief that confusion abounds in that many patients and medical professionals believe or at least use devices such as the Apple Watch as if they are FDA approved.”); *see also Goldstein Stmt.*, EDIS Doc. ID 791179.

c) Analysis

The Commission finds that the remedial orders will have only a minimal effect on formally planned or ongoing medical studies that will not rise to the level that warrants denying a remedy.⁶⁶

⁶⁶ Recall that Apple asserts that it “would not be practical to tailor any remedial orders to permit importation or sale of Apple Watch models for use in clinical trials and other medical research.” RBr. at 62.

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First, even without the service, repair and replacement exemption, any limited exclusion order would cover only new imports of infringing Apple Watches after the expiration of the period of Presidential review (estimated to be late 2023) until the earlier of Apple's clearance of a redesign or the expiration of the patents subject to the section 337 violation (August 2028). *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op at 70–71. Thus, the Commission's remedy will not prevent current study participants using infringing Apple Watches from continuing to participate in research studies. *See id.* Further, with this exemption, current research study participants who are using infringing Apple Watches who encounter a need for service, repair, or replacement of their device to continue participation in that study will be able to obtain such service, repair, or replacement. *See id.* Moreover, as Complainants point out, there is little evidence of ongoing studies that require infringing Apple Watches, as opposed to any of the many reasonable alternative devices (discussed above). *See CBr.* at 77–79; CBr. (Reply) at 31–35. Thus, ongoing research studies that are not enrolling new participants will not be affected by the Commission's remedial orders.

Second, the Commission's remedial orders will have at most a minimal adverse effect on ongoing studies that remain open to new participants. As just noted, the Commission's remedy will not prevent current study participants using infringing Apple Watches from continuing to participate in research studies using those infringing devices. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 70–71. Also as just noted, current owners of infringing Apple Watches will not lose their devices as a result of the Commission's remedial orders, and the Commission's remedial orders will also allow those owners to have their products serviced, repaired, or replaced. Moreover, potential new participants who already own or may own infringing Apple Watches as of the date the Commission's remedial orders become final within

the meaning of 19 U.S.C. § 1337(j)(4) will still be able to participate in those studies. *See id.*

And the record reflects that there are at least [REDACTED] such potential participants. *See* RBr. at

Ex. 6 (Dippon⁶⁷ Decl. a [REDACTED]
[REDACTED]

[REDACTED]. Furthermore, the [REDACTED] figure undercounts the number of potential participants because it does not capture approximately a year's-worth of imports of infringing Apple Watches. Thus, to the extent any study depends on having a large number of participants with infringing Apple Watches, a large number of potential participants is already present in the United States. Additionally, the record includes no specific evidence providing a reasoned basis why the already large number of infringing Apple Watches in the United States is insufficient for any such study. In any event, as Complainants point out, there is little evidence of ongoing studies that are accepting new participants who are located inside of the United States. *See* CBr. at 77–79; CBr. (Reply) at 31–35. In sum, the Commission's remedial orders will have at most a minimal adverse effect on ongoing studies that remain open to new participants.

Third, the Commission's remedial orders will also have, at most, a minimal adverse effect on formally planned but not yet started studies that are enrolling participants. As noted above, there are likely well over [REDACTED] potential participants in the United States, and the Commission's orders will also allow those owners to have their products serviced, repaired, or replaced. Thus, to the extent any studies depend on having a large number of participants with infringing Apple Watches, infringing Apple Watches have already been broadly sold in the United States such that there are already a large number of potential study participants. Neither

⁶⁷ Christian M. Dippon, PhD, is an Apple expert witness on the public interest. *See* RBr. at Ex. 5 (Dippon Decl.) at ¶¶ 1.

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Apple nor the non-party commenters have shown that the already large number of infringing Apple Watches in the United States is insufficient for any study. Additionally, as Complainants point out, there is little evidence of formally planned but not yet started studies that are enrolling participants and that require the infringing Apple Watches, as opposed to non-infringing Apple Watches or reasonable alternative devices. *See* CBr. at 77–79; CBr. (Reply) at 31–35. And again, the Commission’s remedial orders will have no effect on ongoing research studies that are accepting new participants when those participants use an Apple Watch that they owned prior to the date the Commission’s remedial orders becomes final within the meaning of 19 U.S.C. § 1337(j)(4), as discussed in more detail in the following subsection. In sum, the Commission’s remedial orders will also have, at most, a minimal adverse effect on formally planned, but not yet started, studies that are enrolling participants.

As for studies that have not yet been formally planned, the Commission finds that any alleged harm related to the public health and welfare is too speculative to rise a public interest concern.

iii. The Service, Repair, and Replacement Exemption

The Commission has determined that its remedial orders shall include a service, repair, and replacement exemption that allows for (1) providing infringing articles specifically for the service, repair, and/or replacement of Apple Watches purchased prior to the expiration of the period of Presidential review (*i.e.*, prior to the date the order becomes final within the meaning of 19 U.S.C. § 1337(j)(4)) and issuance of the orders when those imports are to service, repair, and/or replace Apple Watches pursuant to warranty obligations; and (2) providing infringing articles specifically for the service and/or repair of Apple Watches purchased prior to the expiration of the period for Presidential review when those imports are to service and/or repair

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Apple Watches outside of warranty obligations.⁶⁸ While the parties' arguments regarding the service, repair, and replacement exemption primarily relate to the United States consumers public interest factor, it is also relevant to the public health and welfare factor as the exemption allows research participants using infringing Apple Watches pursuant to a research study to have that device at least serviced and repaired, and replaced if it is under warranty, such that they may be able to continue the study using the same device they started with. That said, the parties' arguments and our analysis in this section primarily relate to the United States consumers public interest factor, which is discussed more fully below in section V.B.4.d.

a) The Parties' Arguments*Apple's Arguments*

Apple argues that “[a]ny remedial order should protect consumers who have permissibly obtained an Apple Watch with the accused Blood Oxygen feature by permitting Apple to provide technical support, service, repair, and replacement services, both with respect to units under warranty or other applicable service and repair obligations, and to units no longer under warranty.” RBr. at 74 (citing, *inter alia*, *Fitness Devices*, Inv. No. 337-TA-1265, Comm’n Op. at 88–92). Apple asserts that the “accused Apple Watches are subject to a manufacturer’s warranty that requires Apple to repair or replace products for one or two years, depending on the model.” *Id.* at 74–75 (citing RBr. at Ex. 4 (Watkins⁶⁹ Decl.) at ¶¶ 7–15; RX-0930 at .0003; RX-

⁶⁸ As explained *infra* at note 72, Commissioner Kearns does not join the majority’s determination to set the cutoff date for the exemption to the expiration of the period of Presidential review.

⁶⁹ Mr. Scott Watkins is an Apple employee. *See* RBr. at Ex. 4 (Watkins Decl.). He is “legal counsel for AppleCare at Apple Inc.” *Id.* at ¶ 2.

0926 at .0002; RX-0929 at .003; RX-0926 at .0003; RX-0927; Tr. (Land⁷⁰) at 968:11–18).

Apple explains that, under Apple’s warranties, “consumers expect that if Apple replaces their Watch having the Blood Oxygen feature with ‘the same model,’ the replacement Watch will also include the Blood Oxygen feature.” *Id.* at 75 (citing RBr. at Ex. 4 (Watkins Decl.) at ¶ 11).

Apple further argues that “[m]any consumers also purchase extended service and support coverage for their Watch devices through Apple’s AppleCare+ program.” *Id.* (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 16–24; RX-0926 at .0004)). Apple further declares that it “provides out-of-warranty repair and replacement for Watch devices that are beyond the warranty period,” for up to five years. *Id.* (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 25–27, 30–33; RX-0927 at .0002–0003; RX-0928C; Tr. (Land) at 968:19–969:1. While Apple’s warranties provide a refund option in place of repairing or replacing, Apple asserts that some U.S. states require product manufacturers to make available service parts for repair for five to seven years, regardless of warranty status, and a refund is also not a suitable option for consumers who purchased AppleCare+. *Id.* Apple further points out that “some consumers purchase warranties or insurance contracts through third party vendors, such as mobile device carriers and resellers,

[REDACTED]

[REDACTED] *Id.* at 77 (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 28–29).

Next, Apple argues that the repair and replacement exemption should cover both repair and replacement to protect consumers. *See* RBr. at 79–80. Apple asserts that the “[manufacturer’s suggested retail price] of Apple Watch devices with the accused Blood Oxygen

⁷⁰ Brian Land leads a health sensing hardware group at Apple. *See, e.g.*, Final ID at 6.

feature is not insignificant,” ranging from \$399 to \$799, which includes a price range consistent with previous Commission repair and replacement exemptions. *Id.* at 77 (citing, *inter alia*, RBr. at Ex. 4 (Watkins Decl.) at ¶ 21; RX-0333 at .0011; *Certain Robotic Floor Cleaning Devices & Components Thereof*, Inv. No. 337-TA-1252, Comm’n Op. at 77–78 (Apr. 13, 2023)). Apple adds that “[r]equiring Apple to refund the purchase price rather than repair or replace a consumer’s Watch could adversely impact consumers who may need a replacement Watch to allow them to continue ongoing monitoring and collection of health, wellness, and fitness data.” *Id.* at 78. Apple then declares that [REDACTED]

[REDACTED] *Id.* (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 31–33). According to Apple, “[e]xcluding replacement units from an exemption would be contrary to millions of consumers’ expectations.” *Id.* at 79 (citing RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 6, 15, 24, 27–29, 34; RX-0926; RX-0927; RX-0929; RX-0930).

Apple next argues that the cutoff date for a repair and replacement exemption should be the date that any remedial orders become final within the meaning of 19 U.S.C. § 1337(j)(4), in other words, the end of the period of Presidential review. RBr. at 80 (citing, *inter alia*, *Fitness Devices*, Inv. No. 337-TA-1265, Notice of Comm’n Determination to Reconsider the Original Remedial Orders and to Issue Orders Modifying Those Remedial Orders, 88 Fed. Reg. 30158, at 30158–59 (May 10, 2023)). According to Apple, “[t]his cutoff date protects consumers who—through no fault of their own—purchase an Accused Apple Watch between the date of any remedial order and when it becomes final.” *Id.*; *see also id.* at 80–81. Apple asserts that “[a]ny remedy should also include an exemption permitting continued sale of new AppleCare+ service

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and repair plans during and after the Presidential Review Period for any permissibly obtained Apple Watch devices.” *Id.* at 81.

Apple further argues that the exemption should apply to any products imported prior to the end of the period of Presidential review, regardless of whether they were purchased by users prior to that cutoff date. RBr. at 81–82. According to Apple, Apple Watches are sold by Apple directly to consumers and also through other retail channels such as retailers who may continue to receive shipments of imported Apple Watch devices up through the Presidential Review Period, subject to the posting of any required bond. *Id.* at 81. Apple declares that “[t]hese retailers, which were not named as respondents and will not be subject to any CDO, may then continue to sell the subject Watch devices,” and consumers “purchasing these Watch devices should also be protected by an exemption for repair or replacement” because “[t]hey will have the same legitimate expectation regarding the availability of repairs or replacements as consumers who purchased an article before the cutoff date.” *Id.* at 81–82.

Complainants’ Arguments

Complainants argue that “Apple presented no evidence of consumer harm that would justify an exemption for repair or replacement of infringing articles or parts.” CBr. at 85–86 (citing *Fitness Devices*, Inv. No. 337-TA-1265, Comm’n Op. at 88–92); *see also* CBr. (Reply) at 43 (citing *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 50). Complainants add that the Commission should not allow an exemption for repair or replacement of products under warranty because “Apple’s warranties provide an option for a refund, rather than a replacement.” CBr. (Reply) at 86 (quoting RX-0925 at .003 at (iii); RX-0929 at .003; RX-0930). Complainants further declare that “[t]here is no evidence in the record that consumers expect

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repair or replacement for products under warranty, and Apple’s refund provision gives consumers an alternative option.” *Id.*

Complainants further argue that, if the Commission were to provide a service, repair, and replacement exemption, the “cutoff date for any repair and replacement should follow Commission precedent and apply to products sold to an end user before the date of the remedial orders.” CBr. at 86 (citing *Fitness Devices*, Inv. No. 337-TA-1265, Comm’n Op. at 88–90). Complainants additionally assert that any “exemption should not apply broadly to all imported products and should be limited to products sold to an end user, because there is no consumer need for repair or replacement of products that have been imported, but not yet sold.” *Id.* In arguing that the exemption should not extend through the period of presidential review, Complainants point out that “Apple can inform customers by providing notice of the remedial order.” CBr. (Reply) at 43.

b) Analysis

The Commission has concluded that its remedial orders shall include a service, repair, and replacement exemption that allows for (1) providing infringing articles specifically for the service, repair, and/or replacement of Apple Watches purchased prior to the expiration of the period of Presidential review (*i.e.*, prior to the date the order becomes final within the meaning of 19 U.S.C. § 1337(j)(4)) when those imports are to service, repair, and/or replace Apple Watches pursuant to warranty obligations (regardless of whether the warranty was purchased through Apple or a third party vendor); and (2) providing infringing articles specifically for the service and/or repair of Apple Watches purchased prior to the expiration of the period for Presidential review when those imports are to service and/or repair Apple Watches outside of any warranty obligations. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 80–81; *Fitness Devices*, Inv. No. 337-TA-1265, Comm’n Op. at 89–92.

Here, also like in *Wearable Electronic Devices*, the service, repair, and replacement exemption is also justified as to the United States consumers public interest factor based on consumers' reasonable expectations. *See id.* at 80–81; *see also Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 89–92. Apple Watches are subject to a manufacturer's warranty that requires Apple to repair or replace products for one or two years, depending on the model. RBr. at Ex. 4 (Watkins⁷¹ Decl.) at ¶¶ 7–15; RX-0930 at .0003; RX-0926 at .0002; RX-0929 at .003; RX-0926 at .0003; RX-0927; Tr. (Land) at 968:11–18; *see also Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 80–81. Many consumers have also purchased extended service and support coverage (*i.e.*, warranty coverage) for their Apple Watch devices through Apple's AppleCare+ program. RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 16–24; RX-0926 at .0004). And some consumers have purchased warranties or insurance contracts through third party vendors, such as mobile device carriers and resellers, which Apple ultimately supports by [REDACTED].

RBr. at Ex. 4 (Watkins Decl.) at ¶¶ 28–29. Under these warranty programs (such as AppleCare+), consumers expect that, if Apple replaces their device, it will do so with the same model. RBr. at Ex. 4 (Watkins Decl.) at ¶ 11; *see also Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 80–81. Moreover, the cost of infringing Apple Watches is not insignificant, ranging from \$399 to \$799. RBr. at Ex. 4 (Watkins Decl.) at ¶ 21; RX-0333 at .0011. Accordingly, in view of these reasonable consumer expectations, the cost of the infringing Apple Watches, and the Commission's recent decision in *Wearable Electronic Devices*, the Commission has determined to provide a service, repair, and replacement

⁷¹ Mr. Scott Watkins is an Apple employee. *See* RBr. at Ex. 4 (Watkins Decl.). He is “legal counsel for AppleCare at Apple Inc.” *Id.* at ¶ 2.

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exemption. *E.g.*, *Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 80–81; *Robotic Floor Cleaning Devices*, Inv. No. 337-TA-1252, Comm'n Op. at 77–78.

However, the Commission declines to apply the replacement exemption to devices that are outside of warranty. Replacement for products outside of warranty, in view of the fee required by Apple's policies (*see* RBr. at Ex. 4 (Watkins Decl.) at ¶ 25), is tantamount to allowing consumers to purchase a new infringing article, which is outside of the scope of reasonable consumer expectations. *See Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Op. at 89–92.

Apple additionally requests that the exemption allow Apple to continue to sell “new AppleCare+ service and repair plans during and after the Presidential Review Period for any permissibly obtained Apple Watch devices.” RBr. at 81. The Commission declines Apple's request to permit the sale of AppleCare+ service and repair plans beyond the expiration of the period of Presidential review. If customers have not yet purchased the plans as of the expiration of that period, those customers have no reasonable expectation of those benefits, and Apple can simply stop selling those plans for infringing Apple Watches once the period of Presidential review expires. Moreover, customers will still receive the regular Apple warranty, and having the ability to encourage customers to purchase service and repair plans after this timeframe would give Apple a disproportionate benefit.

For their part, Complainants argue that a refund would suffice instead of a repair or replacement. *E.g.*, CBr. (Reply) at 86. However, the Commission has recently considered and rejected that same argument regarding the same warranties in *Wearable Electronic Devices*. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm'n Op. at 81. Here, like in that investigation, Complainants have failed to show that a refund will be adequate to compensate

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consumers who are seeking to maintain their Apple Watches or to participate in ongoing health-related studies using the Apple Watch. *See id.*

Next, the parties dispute the appropriate cutoff date for the Commission's service, repair, and replacement exemption. *E.g.*, RBr. at 80; CBr. at 86. In order to mitigate the impact of the remedial orders on United States consumers, the Commission has determined that the exemption shall apply to articles purchased prior to the expiration of the period for Presidential review (*i.e.*, prior to the date the order becomes final within the meaning of 19 U.S.C. § 1337(j)(4)). *See Fitness Devices*, Inv. No. 337-TA-1265, Comm'n Notice (May 5, 2023); 88 Fed. Reg. 30158–60 (Notice of a Commission Determination to Reconsider the Original Remedial Orders and to Issue Orders Modifying Those Remedial Orders) (May 10, 2023).⁷²

⁷² Commissioner Kearns does not join the majority in determining to set the cutoff date for the Commission's service, repair, and replacement exemption as the expiration of the period for Presidential review. He would instead use the date the Commission's orders issue. In his view, the Commission's service, repair, and replacement exemption is intended to mitigate the harm to U.S. consumers who—through no fault of their own—would lose access to repair components or replacement devices for articles they purchased at a time when those articles had not been found to have violated section 337. As of the date of the Commission's orders, however, the public is put on notice of a violation that must be remedied, *i.e.* by an exclusion order. He finds that extending the service, repair, and replacement exemption beyond the issuance of the Commission's orders undercuts that remedy to the detriment of the intellectual property holder. Thus, in order to balance the impact of the remedial orders on United States consumers with the public interest in protecting Complainants' intellectual property rights, he would determine that the exemption should only apply to articles purchased prior to the date of the Commission's determination of violation and issuance of the orders. He further notes that this approach is consistent with the Commission's recent approach to this issue. *See, e.g., Certain Variable Speed Wind Turbine Generators & Components Thereof*, Inv. No. 337-TA-1218, Limited Exclusion Order at 2 (Jan. 18, 2022); *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067 (Remand), Limited Exclusion Order at ¶ 1 (Nov. 4, 2021); *Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. (Revised) at 46 (Jan. 10, 2020); *Certain Magnetic Data Storage Tapes & Cartridges Containing the Same*, Inv. No. 337-TA-1012, Limited Exclusion Order at 2 (Mar. 8, 2018). In his view, the majority's approach here, and in *Fitness Devices*, Inv. No. 337-TA-1265, is thus a departure from the Commission's normal practice. *See Fitness Devices*, Notice of Comm'n Determination to Reconsider the

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Apple further requests that the exemption apply to infringing Apple Watches imported prior to the end of the period of Presidential review, but then purchased by customers after the end of the period of Presidential review. *See* RBr. at 81–82. The Commission denies Apple’s request for this extension to the exemption. The Commission notes that, after the Presidential review period has expired, if the orders are not disapproved, Apple will not be permitted to sell infringing articles that it imported during the Presidential review period.

Accordingly, as noted above, the Commission’s remedial orders include a service, repair, and replacement exemption that allows for (1) providing infringing articles specifically for the service, repair, and/or replacement of Apple Watches purchased prior to the expiration of the period of Presidential review (*i.e.*, prior to the date the order becomes final within the meaning of 19 U.S.C. § 1337(j)(4)) when those imports are to service, repair, and/or replace Apple Watches pursuant to warranty obligations; and (2) providing infringing articles specifically for the service and/or repair of Apple Watches purchased prior to the expiration of the period of Presidential review when those imports are to service and/or repair Apple Watches outside of warranty obligations. This exemption protects reasonable consumer expectations, and also mitigates potential harm to the public health and welfare by allowing research participants using infringing Apple Watches pursuant to a research study to have that device repaired or replaced such that they may be able to continue the study using the same device they started with.

iv. Apple Has Not Shown That a Delay Is Warranted

In brief, the Commission declines Apple’s request that enforcement of the Commission’s remedy be delayed for twelve months.

Original Remedial Orders and to Issue Orders Modifying Those Remedial Orders, 88 Fed. Reg. 30158, at 30160 n.2 (May 10, 2023) (dissenting views of Commissioner Kearns).

CONFIDENTIAL VERSION**a) The Parties' Arguments***Apple's Arguments*

Apple requests that the Commission delay the enforcement of its remedial order so that manufacturers of the reasonable alternatives to the infringing Apple Watches (discussed above) can ramp up supply of those alternatives such that they can fill any void created by the Commission's exclusion of the infringing Apple Watches. *See, e.g.*, RBr. at 70. According to Apple, "there simply will not be enough supply to fill the massive demand gap that will result from the supply shock of an exclusion order." RBr. at 70. Apple alleges that, in addition to any ordinary difficulty in meeting demand, "the well-documented global semiconductor shortage, after-effects from COVID-19 lockdowns in China, natural disasters (including severe weather events), and delays in procuring integrated circuits and other necessary components" will further complicate matters. *Id.* at 71. Apple further argues that "[t]here is no evidence that supply can be ramped up fast enough to meet anywhere close to the entirety of consumer demand in view of the enormity of the immediate shortfall the exclusion order would create." *Id.* Apple asserts that it will take years to ramp up production to compensate for the exclusion of the Accused Products. *Id.* at 71–72. Thus, Apple requests that the Commission delay the implementation of any remedy for at least twelve months. *E.g., id.* at 71–72, 89.

Complainants' Arguments

For their part, Complainants argue that the Commission should reject "Apple's unsubstantiated arguments regarding the capacity of third-party manufacturers to meet consumer demands." CBr. (Reply) at 39; *see also id.* at 39–41. Complainants further point out that Apple "fails to provide any reason it could not increase production of the Series SE, which contains virtually all the same features as the infringing products, or return to producing the Apple Watch Series 4 or 5, which also included ECG," but not blood oxygen measurements. *Id.* (citing CBr.

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Ex. 93 at ¶¶ 22–24). Regarding Apple’s argument related to a potential semiconductor shortage, Complainants allege that Apple overlooks that semiconductors no longer used by Apple will then become available to manufacturers of substitute products. *Id.*

b) Analysis

The Commission declines Apple’s request that the Commission’s remedy be delayed for twelve months. The Commission has recently considered and rejected Apple’s argument in *Wearable Electronic Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 74–75. Moreover, like in *Wearable Electronic Devices*, Apple failed to substantiate its position that manufacturers of suitable alternative products lack the manufacturing capability to ramp up production to meet any demand. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 74–75; RBr. at 69–72. Additionally, to the extent any global events have caused any component shortages, *see* RBr. at 71, those events would affect Apple as well as other manufacturers. Accordingly, Apple has not shown any basis for the Commission to delay the effect of its remedy.

v. Conclusion

To mitigate any public health and welfare concerns, the Commission provides within its remedial orders a service, repair, and replacement exemption. *See supra* section V.B.4.a.iii. In view of the provided exemption, the Commission finds that its remedial orders will not raise any public health or welfare concerns that warrant denying Complainants a remedy. There are numerous reasonable substitutes available to users and research participants in the United States, and there is at most scant evidence that the Commission’s remedial orders will have any meaningful adverse impact on medical studies in the United States. Furthermore, the public interest of supporting strong intellectual property rights further supports the Commission’s conclusion. *E.g., Centerset Faucets*, No. 337-TA-422, Comm’n Op. at 9; *Microfluidic Devices*,

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Inv. No. 337-TA-1068, Comm'n Op. at 45–46. Additionally, Apple has shown no reason for the Commission to delay the imposition of its remedy.

b. Competitive Conditions in the United States Economy

In brief, the Commission finds that the remedial orders in this investigation will not have an adverse impact on competitive conditions in the United States economy.

i. The Parties' Arguments

Apple argues that remedial orders would harm competitive conditions in the United States economy, asserting that the Apple Watch contributes to thousands of jobs across the United States. RBr. at 86; *see also id.* at 86–87. Apple argues that “excluding the Accused Apple Watches would distort market incentives, further harming competitive conditions.” *Id.* at 86 (citing RBr. at Ex. 5 (Dippon Decl.) at ¶¶ 22–56). According to Apple, “[r]emoving a product as popular as [the] Apple Watch would lessen competition, and a sudden shortfall of smartwatches would likely yield higher prices, which would impose further harm on US consumer.” *Id.* at 87 (citing RBr. at Ex. 5 (Dippon Decl.) at ¶¶ 22–24, 46–55) (internal quotations omitted).

For their part, Complainants argue that their requested remedy would not harm competitive conditions in the United States economy, but instead would benefit those conditions. *See* CBr. at 71–75. Complainants first allege that “major companies offer[] substitute smartwatches” and consumers who prefer the Apple ecosystem can still purchase the Apple Watch SE. *See id.* at 72. Complainants add that, in view of the impending remedial orders, Apple has had ample time to release non-infringing versions of its products, and “legitimate design-around efforts should always be encouraged as a path to spur further innovation.” *See id.* (quoting *Tivo, Inc. v. EchoStar Corp.*, 646 F.3d 869, 883 (Fed. Cir. 2011) (en banc); *see also id.* at 72–73 (citing, *inter alia*, Alliance for U.S. Startups Stmt., EDIS Doc. ID 791674, at 2

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(asserting that the Commission should not support Apple’s “efficient infringement”); Innovation Alliance Stmt., EDIS Doc. ID 791048, at 1 (same)). Complainants additionally assert that issuing their requested remedial orders would encourage companies to “re-shore manufacturing to the United States” and otherwise improve competitive conditions because “America’s innovation economy and global competitiveness are dependent on the continued robust enforcement of inventors’ intellectual property rights.” *Id.* at 73 (quoting Innovation Alliance Stmt., EDIS Doc. ID 791048, at 2). Complainants add that “[h]olding Apple accountable for its ‘efficient infringement’ would also curtail Apple’s exploitation of third parties who rely on the Apple platform.” *Id.* Complainants further argue that Apple’s violation of intellectual property rights “raises prices, denies consumers choice, lowers quality, and dampens the incentive of sellers of complementary, or competing products to innovate.” *Id.* at 74 (quoting CFA Stmt., EDIS Doc. ID 791163, at 3). Complainants allege that allowing the continued importation of infringing Apple Watches will “give Apple an unfair competitive advantage in the narrow market for smartwatches and in the adjacent market for device ecosystems.” CBr. at 74 (quoting Dinelli Stmt., EDIS Doc. ID 791686, at 4). As a result, according to Complainants, consumers are “likely to experience long term harm from reduced competition and innovation.” *Id.* (quoting Dinelli Stmt., EDIS Doc. ID 791686, at 4).

ii. Non-Party Comments

Non-parties have filed comments stating that issuing remedial orders would have a positive impact on competitive conditions in the United States. *See, e.g.,* Alliance for U.S. Startups Stmt., EDIS Doc. ID 791674, at 2 (asserting that the Commission should not support Apple’s “efficient infringement”); Buck Stmt., EDIS Doc. ID 791047 (“As members of Congress, it is our duty to ensure that patent laws are duly enforced, particularly when enforcement is against companies that engage in monopolistic and anti-competitive conduct.

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The American public ultimately bears the cost of the monopolistic behaviors of some of the largest technology firms that, as a business model, work to consolidate market power, stifle innovation, and crush competitors.”); Innovation Alliance Stmt., EDIS Doc. ID 791048, at 1 (“Vigorous enforcement and protection of intellectual property rights are essential to the competitive viability of innovative companies within the United States.”); CFA Stmt., EDIS Doc. ID 791163, at 3; Dinelli Stmt., EDIS Doc. ID 791686, at 4; US Inventor Stmt., EDIS Doc. ID 791041 (“A healthy and thriving innovation ecosystem in the United States is in the public interest.”).

iii. Analysis

The Commission finds, consistent with its holding in *Wearable Electronic Devices*, that its remedial orders in this investigation will not have any adverse impact on competitive conditions in the United States economy. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 79–80. As was the case in that investigation, here there are also numerous suitable alternatives to the excluded Apple Watches (as discussed above in relation to the public health and welfare public interest factor and below as to the United States consumers public interest factor).

Apple argues that the remedial orders will harm competitive conditions by jeopardizing United States jobs. *See RBr.* at 86. However, Apple does not specify how many jobs are particularly related to the infringing Apple Watches, as opposed to non-infringing Apple Watches (such as the Apple Watch SE) or researching and developing future non-infringing models, or supporting versions of the Apple Watch earlier than the Apple Watch Series 6), Apple Watch accessories (such as watch bands), or other Apple products beyond the Apple Watch altogether. *See id.* Moreover, Apple does not address whether any lost jobs due to the exclusion of the infringing Apple Watches will be counterbalanced by increased United States jobs for

manufacturers of reasonable substitutes. Apple further asserts that excluding Apple Watches would “lessen competition” and “likely yield higher prices.” *Id.* at 86–87. However, as noted above and below, there is ample competition and not all Apple Watches will be excluded, as at least the Apple Watch SE would not be subject to exclusion. Thus, the Commission finds that the remedial orders in this investigation will not have any adverse impact on competitive conditions in the United States economy.

c. The Production of Like or Directly Competitive Articles in the United States

The Commission finds that its remedial orders in this investigation will not have any adverse impact on the production of like or directly competitive articles in the United States.

i. The Parties’ Arguments

Apple does not contest that it does not manufacture any products in the United States.

See generally RBr.; RBr. (Reply). Instead, Apple argues:

The competitive harms will not be offset by substantial “production of like or directly competitive articles,” 19 U.S.C. § 1337(d)(1), because Apple’s primary smartwatch competitors, for example, do not manufacture their products in the United States. And while the Masimo W1 is manufactured in the United States, it is not a reasonable substitute.

RBr. at 73. Apple explains that, “[a]lthough Complainants claim that the Masimo W1 is made in the U.S., the W1 is not a smartwatch and not a reasonable substitute for smartwatch consumers who want the Accused Apple Watches.” RBr. (Reply) at 44. Apple adds that, regardless, “Complainants have not described how many [W1 Watch] units are manufactured in the U.S. or how many more units it would expect to manufacture in the U.S (as opposed to its [REDACTED]).” *Id.* Thus, according to Apple, “no evidence exists that an exclusion order would have any meaningful impact on U.S. production.” *Id.*

Complainants point out that neither the Apple Watches nor any smartwatches made by Samsung, Fitbit, or Garmin are produced in the United States, but that Masimo produces its W1 Watch in the United States and [REDACTED]. *Id.* (citing CBr. at Ex. 53 (Muhsin Decl.) at ¶ 5). Thus, according to Complainants, “the only impact an exclusion order would have on like or directly competitive articles made in the United States is that Masimo likely will be able to continue to build its domestic industry in its intellectual property because of the increased competition in the market caused by exclusion of Apple’s infringing products.” *Id.*

ii. Analysis

The Commission finds that the “production of like or directly competitive products in the United States” public interest factor does not weigh against the Commission’s remedy in this investigation. As the parties appear to agree, neither the Apple Watch nor smartwatches made by Samsung, Fitbit, or Garmin are produced in the United States. *See* CBr. at 75; RBr. at 73. Moreover, there is no evidence suggesting that any reasonable substitute for excluded Apple Watches, aside from Masimo’s W1 Watch or Freedom Watch, [REDACTED]. *See, e.g.,* CBr. at 75; RPHBr. at 251–52 (disputing only the extent that Masimo’s domestic facilities are used for production of the W1 Watch); RBr. (Reply) at 45 (asserting only that Complainants did not identify how many units it has produced or plans to produce in the United States).

And as for the W1 Watch and Freedom Watch, Complainants do not provide quantitative evidence regarding the extent of any United States production of these watches or the extent that potential customers would choose Masimo’s W1 Watch or Freedom Watch as a substitute for excluded Apple Watches. Therefore, the Commission cannot assess the extent to which Complainants’ requested remedial orders would result in increased domestic production of

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suitable substitutes to the excluded Apple Watches. However, based on the absence of domestic production of excluded products, the remedial orders in this investigation will not have an adverse impact on the production of like or directly competitive articles.

d. United States Consumers

In brief, in view of the exemption for service, repair, and replacement (discussed above), any effect of the Commission's remedial orders on United States consumers does not rise to the level of a public interest concern.

i. The Parties' Arguments

Apple argues, that “[b]eyond the potential effects on the health of U.S. consumers, an exclusion order would further harm those consumers by impeding access to the valuable, tightly integrated suite of features that drive demand for these devices.” RBr. at 85. According to Apple, “[m]illions of Americans rely on [the] Apple Watch to stay connected, and in addition to the Blood Oxygen feature at the heart of this Investigation and the health features described above, [the] Apple Watch also contains a complement of features consumers enjoy—including productivity, payment, navigation, safety, and accessibility functions.” *Id.* Apple then declares that “[a]n exclusion order would take those features out of the hands of American consumers.” *Id.* at 86.

For their part, Complainants argue that their requested remedy would benefit United States consumers by removing Apple's alleged poor-performing blood oxygen feature from the marketplace while not interfering with their access to non-infringing Apple Watches. *See* CBr. at 75. Complainants further argue that consumers would benefit “in the long run by encouraging investment in the next generation of healthcare innovation.” *Id.* Complainants additionally urge the Commission to reject any argument that remedial orders should be denied based on the widespread use of the Apple Watch. *Id.* at 75–76 (citing MDMA Stmt., EDIS Doc. ID 791167,

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at 4 (declaring that “[t]hat would be tantamount to arguing if you can infringe in a huge way, then you should escape the consequences”); C4IP Stmt., EDIS Doc. ID 791567, at 3–4 (similar)). Complainants then assert that “many consumers desire to have an Apple Watch only because of the benefits of having multiple devices within Apple’s device ecosystem,” and “[c]onsumers would benefit by expanding their choices to other device makers and those that choose to continue using Apple devices still would be able to select non-infringing Apple Watches like the SE.” *Id.* at 76 (citing Dinielli Stmt., EDIS Doc. ID 791686, at 3).

ii. Non-Party Comments

Non-parties filed submissions commenting on the United States consumers public interest factors both in support of Complainants and Apple. *See, e.g.,* Dinelli Stmt., EDIS Doc. ID 791686, at 4 (declaring that allowing Apple to import infringing Apple Watches would give Apple an unfair competitive advantage and will likely cause United States consumers “long term harm from reduced competition and innovation”); Saxon Comments, EDIS Doc. ID 797811 (asserting that consumers benefit from having “more accurate tools, not fewer . . . to help identify cardiac ailments”).

iii. Analysis

In view of the exemption for service, repair, and replacement (discussed above), any effect of the Commission’s remedial orders on United States consumers does not rise to the level of a public interest concern.

First, there are numerous reasonable substitutes for the infringing Apple Watches available to United States consumers. Looking beyond the public health and wellness aspects of the Apple Watch (as those are considered separately in the public health and welfare public interest factor, discussed above in section V.B.4.a.), the scope of reasonable substitutes includes general purpose smartwatches. *See Fitness Devices*, Inv. No. 337-TA-1265, Comm’n Op., at 85

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(“The correct assessment . . . for ‘reasonable substitutes for the devices subject to the exclusion order,’ [is] not whether ‘every consumer cannot obtain the exact device desired.’” (quoting *Elec. Digital Media Devices*, Inv. No. 337-TA-796, Comm. Op. at 120) (citing *Table Saws*, Inv. No. 337-TA-965, Comm’n Op. at 9)). Thus, United States consumers have as reasonable substitutes at least the Apple Watch SE, the Samsung Galaxy Watch, and the Google Pixel Watch. Second, to reduce the impact of the remedial orders on United States consumers, the Commission has provided a service, repair, and replacement exemption. *See supra* section V.B.4.a.iii. Accordingly, any impact of the Commission’s remedial orders on United States consumers will not rise to the level of a public interest concern.

5. Conclusion

In accordance with its statutory duty, the Commission has considered the effect of its remedial orders “upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, [and whether] it finds that such articles should not be excluded from entry.” 19 U.S.C. §§ 1337(d)(1), (f)(1). To prevent any harm from the remedial orders to the public health and welfare and to United States consumers, the Commission’s LEO and CDO each include an exemption for service, repair, and replacement. *See supra* section V.B.4.a.iii. As in *Wearable Electronic Devices*, this exemption mitigates potential harm to the public health and welfare by allowing research participants using infringing Apple Watches pursuant to a research study to have that device serviced and repaired or have it replaced, if it is under warranty, such that they may be able to continue the study using the same device they started with. *See Wearable Elec. Devices*, Inv. No. 337-TA-1266, Comm’n Op. at 70–71, 80–81. Additionally, Apple has not shown any reason why the Commission should delay the enforcement of its remedy.

CONFIDENTIAL VERSION**C. Bonding**

As discussed below, the Commission has determined that the bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the articles subject to the LEO.

1. The Applicable Law

If the Commission enters an exclusion order or a CDO, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be “sufficient to protect the complainant from any injury.” 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3). When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, & Prods. Containing Same, Including Self-stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. No. 2949, Comm’n Op. at 24 (Jan. 16, 1996). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., Certain Audio Digital-to-Analog Converters & Prods. Containing Same*, Inv. No. 337-TA-499, Comm’n Op. at 25 (Mar. 3, 2005). Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a one hundred percent (100%) bond. *See, e.g., Certain Liquid Crystal Display Modules, Prods. Containing Same, & Methods Using the Same*, Inv. No. 337-TA-634, Comm’n Op. at 6–7 (Nov. 24, 2009). The complainant, however, bears the burden of establishing the need for a bond. *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-533, USITC Pub. No. 3975, Comm’n Op. at 40 (July 21, 2006).

CONFIDENTIAL VERSION**2. The RD**

Before the ALJ, Complainants sought a bond in the amount of 100 percent of the entered value of the Accused Products because the accused Apple Watch products are allegedly “harming the public’s perception of pulse oximetry.” RD at 5 (quoting CPHBr. at 312 and citing CPHBr. (Reply) at 182–83). For its part, Apple argued that a zero percent bond is appropriate because Complainants have not identified any domestic industry products that compete with the Accused Products. *Id.* (citing RPHBr. at 280). Apple further argued that Complainants’ theory of harm to public perception is unsubstantiated and is, in any event, not an appropriate basis for requiring a bond. *Id.* (citing RPHBr. at 280–81; RPHBr. (Reply) at 175–76).

The RD found that Complainants did not meet their burden of establishing the need for a bond. RD at 6. The RD pointed out that Complainants did not argue that a bond is needed to protect any of its own competing products during the period of Presidential review. *Id.* (citing CPHBr. at 312). The RD further pointed out that Complainants did not present any evidence or argument regarding (1) the pricing (or expected pricing) of any such competing product; (2) the possibility (or impossibility) of performing a price differential analysis based on any such pricing; or (3) any reasonable royalty analysis. *Id.* at 6 n.5 (citing CPHBr. at 312; CPHBr. (Reply) at 182–83; *Certain Network Devices, Related Software & Components Thereof (II)*, Inv. No. 337-TA-945, Comm’n Op., 2017 WL 3614521, at *75 (“*Network Devices (II)*”). The RD further observed that, at the time of the hearing, the W1 Watch was not available for sale to consumers on the open market. *Id.* at 6 (citing, *inter alia*, Tr. (Kiani) at 179:17–22). The RD additionally declared that Complainants’ alleged harm to the “the public’s perception of pulse oximetry” based on the alleged inaccuracy of the Apple Watch’s pulse oximetry measurements is not an appropriate basis for setting a bond because the “purpose of bonding is to protect complainants from injury—not to remedy harms to public perception.” *Id.* The RD further

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added that “[i]t is not clear from the record that the alleged harm to public perception causes injury to Complainants.” *Id.* The RD additionally declared that “Complainants also have identified no clear evidence of current competition between the Apple Watch and Masimo rainbow[®] sensors.” *Id.* at 6 n.7 (citing, *inter alia*, CPHBr. at 312). Thus, the RD found that Complainants have failed to establish the need for a bond. *Id.* at 7.

3. The Parties’ Arguments

Before the Commission, Complainants again request that the Commission require bond to “protect Masimo from the detrimental impact of Apple’s continued importation of infringing Apple Watches that do not reliably measure oxygen saturation.” CBr. at 87 (citing CX-1616, CX-1293, CX-1606). Regarding an alleged competitive injury, Complainants rely on purported concessions by Apple that (1) it, like Complainants, sell “direct-to-consumer devices that measure wellness parameters (including blood oxygen)” and (2) it acknowledged that “Masimo plans to launch a product that competes directly with the Apple Watch later this year.” *Id.* (citing Respondent’s Motion to Preclude Stephen Jensen from Access to Apple’s Confidential Business Information under the Protective Order (Order No. 1), EDIS Doc. ID 750872, at 4, 11 (Sept. 2, 2021)). Complainants additionally assert that they will be injured by a lack of bond because of the “competitive status of the parties,” citing a Delaware litigation in which Apple’s financial expert described Masimo’s “ongoing and escalating sales of W1,” “Masimo’s serious and long-term intentions to pivot into the smartwatch segment,” and Masimo’s access to 20,000 points of distribution for the W1. CBr. (Reply) at 50 (citing CBr. (Reply) at Ex. 91 at 33, 36, 37).

For its part, Apple supports the RD’s recommendation that bond be set at zero percent. *See* RBr. at 91–92. Apple asserts that “Complainants have not met their burden of establishing the need for a bond,” *id.* at 91 (quoting RD at 6), reasoning that Complainants failed to identify

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any domestic industry products that “compete with the accused Apple Watch products” and to “present any argument concerning pricing of competing products or reasonable royalty analysis,” *id.* (citing RD at 6 & n.5; *Certain Elec. Devices, Including Wireless Comm’n. Devices, Portable Music & Data Processing Devices, and Tablet Computs.*, Inv. No. 337-TA-794, Comm’n Op. at 118–19 (July 5, 2013); *Network Devices (II)*, Inv. No. 337-TA-945, Comm’n Op. at 129–30).

Apple further agrees with the RD that the alleged harm to the public perception of pulse oximetry is not a proper basis for justifying bond. *Id.* (citing RD at 6–7). Apple adds that, at the time of the hearing, Complainants did not have a competing product available for sale to consumers in the United States on the open market. *Id.* at 92 (citing RD at 6). Apple further contests that the Apple Watches cause harm to the consumer perception of pulse oximetry. *See* RBr. (Reply) at 47–48. Apple asserts that Complainants’ assertion is based on “non-scientific news media articles” and “was addressed at the hearing and thoroughly debunked during the cross-examination of Complainants’ economic expert, who conceded that his opinion on ‘harm to consumer perception’ was not based on testing or technical expert testimony.” *Id.* (citing, *inter alia*, CX-1616, CX-1293, CX-1606; Tr. (McGavock⁷³) at 552:22–553:14). Apple adds that the “accuracy and reliability of the Blood Oxygen feature on Apple Watch is well documented.” *Id.*

4. Analysis

The Commission has determined that the bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the articles

⁷³ Daniel McGavock is Complainants’ expert witness, who was admitted as an expert in financial matters, offering testimony regarding economic domestic industry, bond, and commercial success. *E.g.*, Final ID at 6.

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subject to the LEO. The Commission agrees with the RD that the alleged harm to the public's perception of pulse oximetry is not a cognizable basis for establishing the need for bond and has nevertheless not been substantiated as causing any harm (quantifiable or otherwise) to Complainants. *See* RD at 6. The Commission additionally agrees with the RD that Complainants have not shown any basis for supporting any specific bond based on pricing information or reasonable royalty rates. *See, e.g.,* RD at 5; *Microsphere Adhesives*, Inv. No. 337-TA-366, Comm'n Op. at 24 (basing bond on price differential when such information is available); *Audio Digital-to-Analog Converters*, Inv. No. 337-TA-499, Comm'n Op. at 25 (relying on a reasonable royalty analysis when pricing information was not available). Complainants' vague assertions as to the "competitive status of the parties" (*see* CBr. (Reply) at 50) are insufficient to establish a bond amount sufficient to protect Complainants from any injury during the period of Presidential review. Accordingly, the Commission has determined that the bond during the period of Presidential review shall be in the amount of zero percent (0%, *i.e.*, no bond) of the entered value of the articles subject to the LEO.

VI. CONCLUSION

The Commission has considered all of the other arguments by the parties and does not find them persuasive. Therefore, for the reasons set forth herein, the Commission determines that Complainants have established a violation of section 337 by Apple with respect to claims 22 and 28 of the '502 patent and claims 12, 24, and 30 of the '648 patent, but not with respect to claim 12 of the '501 patent and claims 9 and 27 of the '745 patent. Accordingly, the investigation is terminated with a finding of a violation of section 337. The Commission determines that the appropriate remedy is an LEO and a CDO to Apple; that the public interest does not preclude that remedy; and the bond during the period of Presidential review is set at zero percent (*i.e.*, no bond) of the entered value.

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By order of the Commission.

A handwritten signature in black ink, appearing to read "Lisa R. Barton", enclosed within a large, loopy oval shape.

Lisa R. Barton
Secretary to the Commission

Issued: October 26, 2023

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

Certificate of Service – Page 1

CONFIDENTIAL CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served upon the following parties as indicated, on **October 27, 2023**.



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VOLUME II OF II (Addendum pages Appx485-817)

No. 2024-1285

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

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CONFIDENTIAL MATERIAL OMITTED

The material omitted from Addendum pages Appx9, Appx36, Appx41-44, Appx46-48, Appx108, Appx119, Appx121-122, Appx150-151, Appx153-154, Appx156-158, Appx187-190, Appx192-194, Appx196, Appx198, Appx218, Appx220-222, Appx265-276, and Appx373 contains confidential competitively sensitive product information subject to the Administrative Protective Order in effect in ITC Investigation No. 1276; the material omitted from Appx62, Appx67, Appx74, Appx176, Appx179, Appx205-206, Appx211, Appx278-286, Appx304-306, Appx309, Appx311-316, Appx318, Appx320-328, Appx332-340, Appx426-

427, and Appx473-474 contains information that complainants Masimo Corporation and Cercacor Laboratories, Inc. designated as Confidential Business Information under the Administrative Protective Order; and the material omitted from Appx404-405, Appx457, Appx460-461, and Appx464 contains confidential competitively sensitive financial and sales information subject to the Administrative Protective Order.

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THE UNITED STATES OF AMERICA

**TO ALL TO WHOM THESE PRESENTS SHALL COME;
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office**

May 18, 2021

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THIS OFFICE OF:**

U.S. PATENT: 10,912,501

ISSUE DATE: February 09, 2021

**By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office**



[Signature]
**R GLOVER
Certifying Officer**



US010912501B2

(12) **United States Patent**
Poeze et al.

(10) **Patent No.:** **US 10,912,501 B2**

(45) **Date of Patent:** ***Feb. 9, 2021**

(54) **USER-WORN DEVICE FOR NONINVASIVELY MEASURING A PHYSIOLOGICAL PARAMETER OF A USER**

(71) Applicant: **Masimo Corporation**, Irvine, CA (US)

(72) Inventors: **Jeroen Poeze**, Rancho Santa Margarita, CA (US); **Marcelo Lamego**, Cupertino, CA (US); **Sean Merritt**, Lake Forest, CA (US); **Cristiano Dalvi**, Lake Forest, CA (US); **Hung Vo**, Fountain Valley, CA (US); **Johannes Bruinsma**, Opeinde (NL); **Ferdyan Lesmana**, Irvine, CA (US); **Massi Joe E. Klani**, Laguna Niguel, CA (US); **Greg Olsen**, Lake Forest, CA (US)

(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/031,356**

(22) Filed: **Sep. 24, 2020**

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Related U.S. Application Data

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A61B 5/00 (2006.01)

(52) **U.S. Cl.**
CPC **A61B 5/1455** (2013.01); **A61B 5/14532** (2013.01); **A61B 5/14546** (2013.01); (Continued)

(58) **Field of Classification Search**
CPC . **A61B 5/1455**; **A61B 5/14546**; **A61B 5/6838**; **A61B 5/6816**; **A61B 5/6829**; (Continued)

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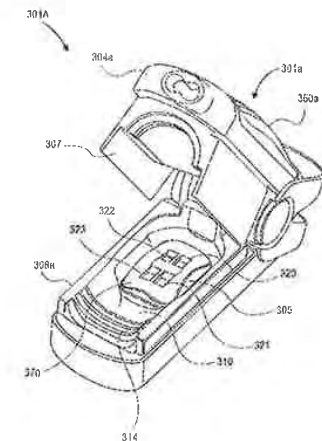
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(57) **ABSTRACT**

The present disclosure relates to noninvasive methods, devices, and systems for measuring various blood constituents or analytes, such as glucose. In an embodiment, a light source comprises LEDs and super-luminescent LEDs. The light source emits light at at least wavelengths of about 1610 nm, about 1640 nm, and about 1665 nm. In an embodiment, the detector comprises a plurality of photodetectors arranged in a special geometry comprising one of a substantially linear substantially equal spaced geometry, a substantially linear substantially non-equal spaced geometry, and a substantially grid geometry.

30 Claims, 65 Drawing Sheets



US 10,912,501 B2

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Related U.S. Application Data

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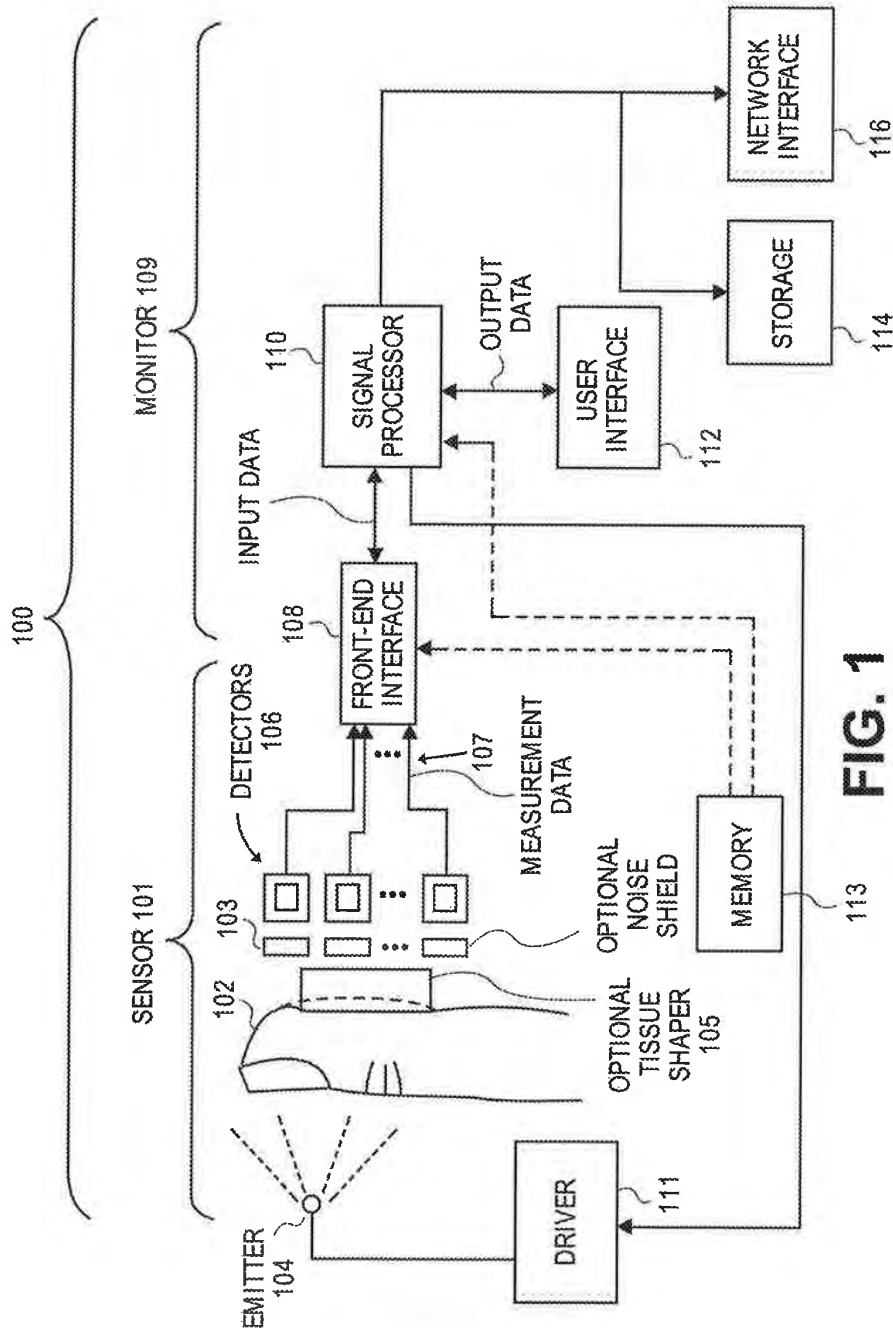


FIG. 1

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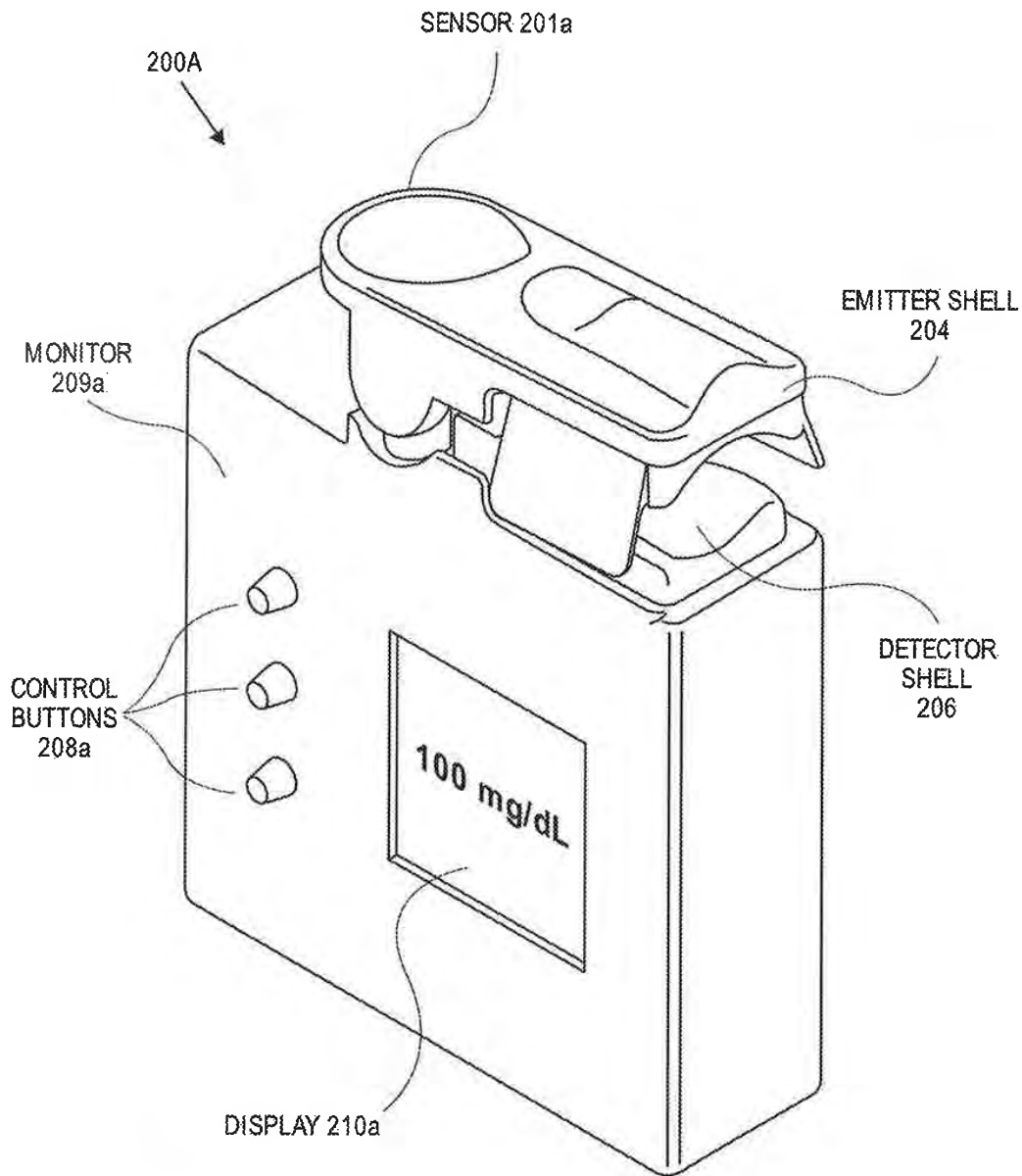


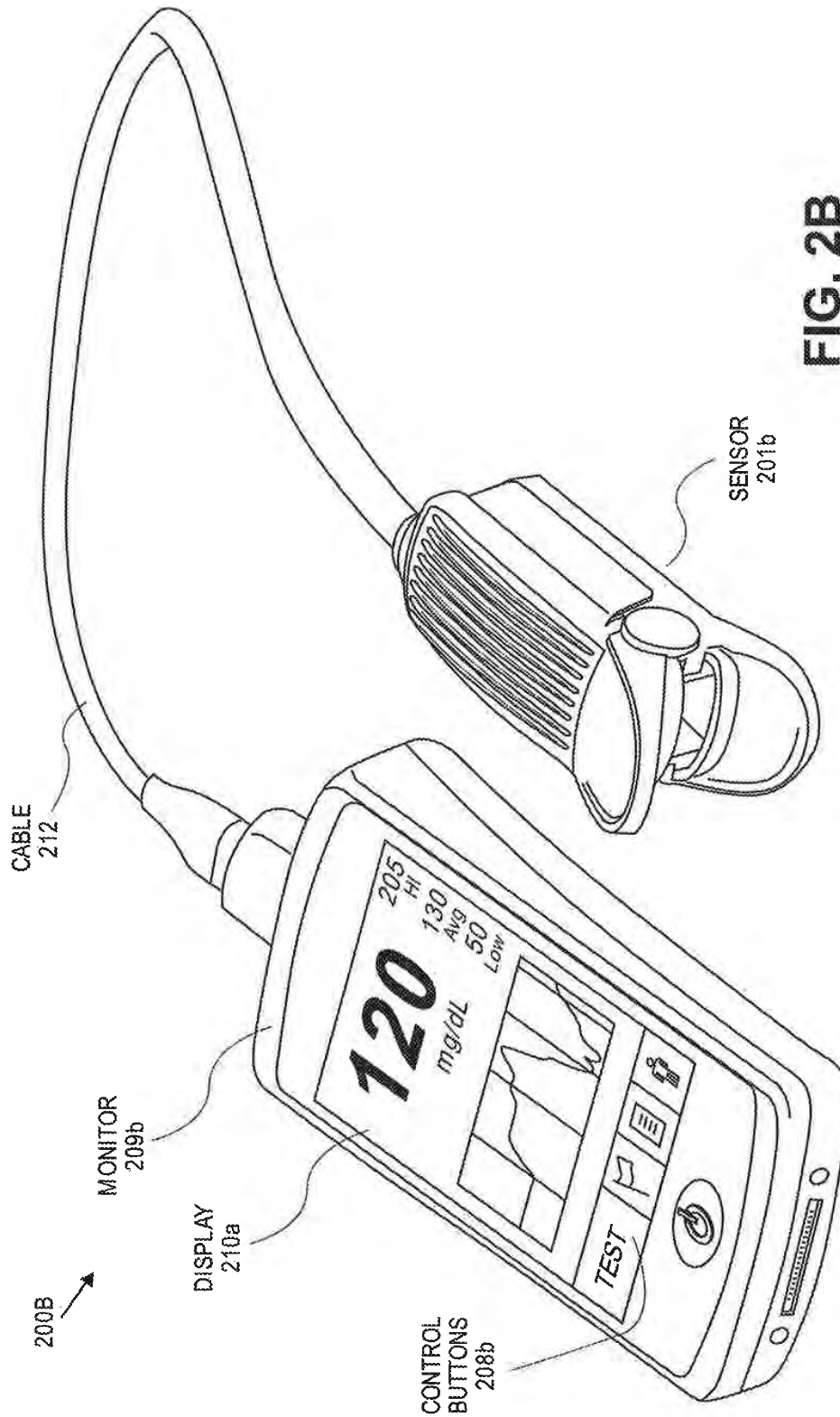
FIG. 2A

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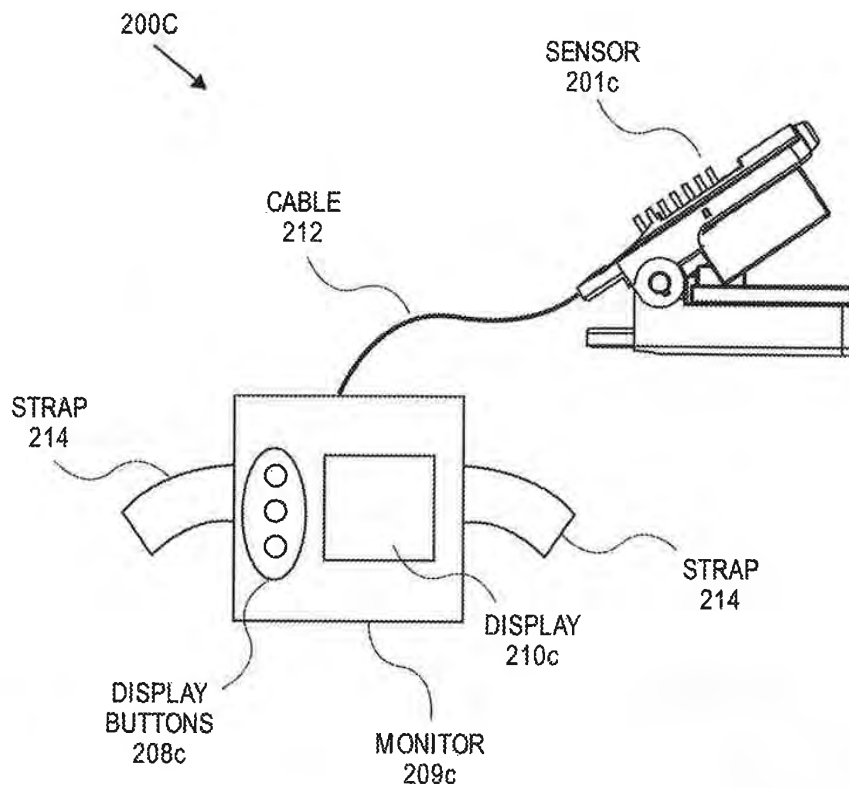


FIG. 2C

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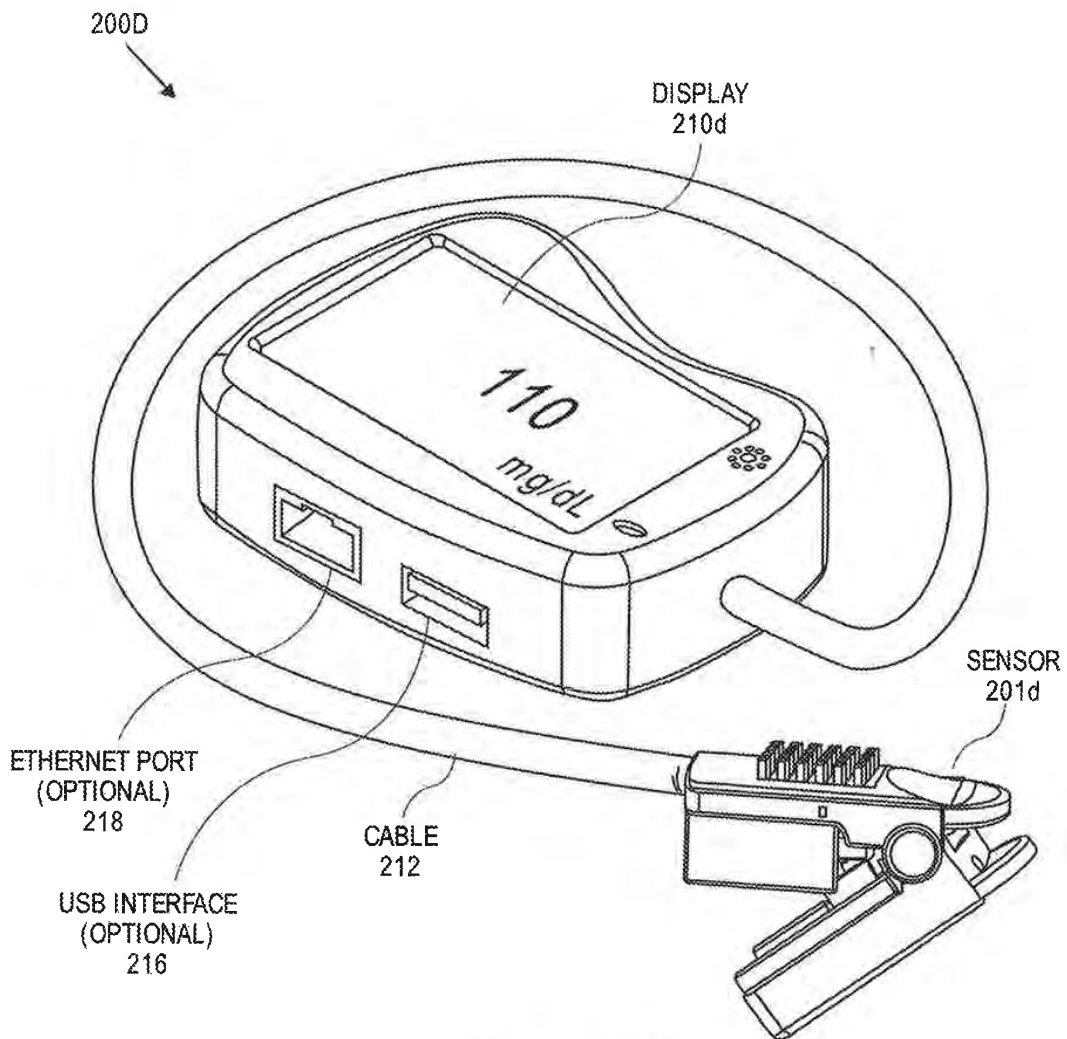


FIG. 2D

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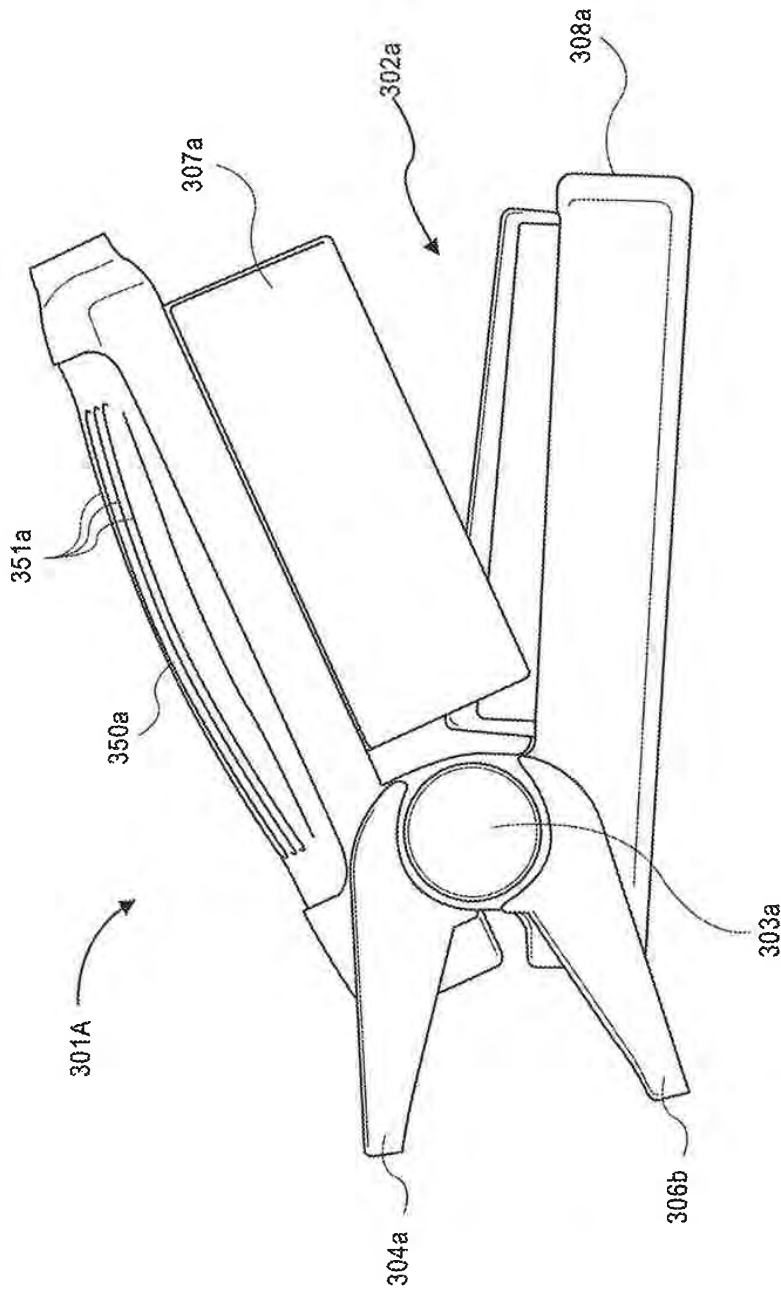


FIG. 3A

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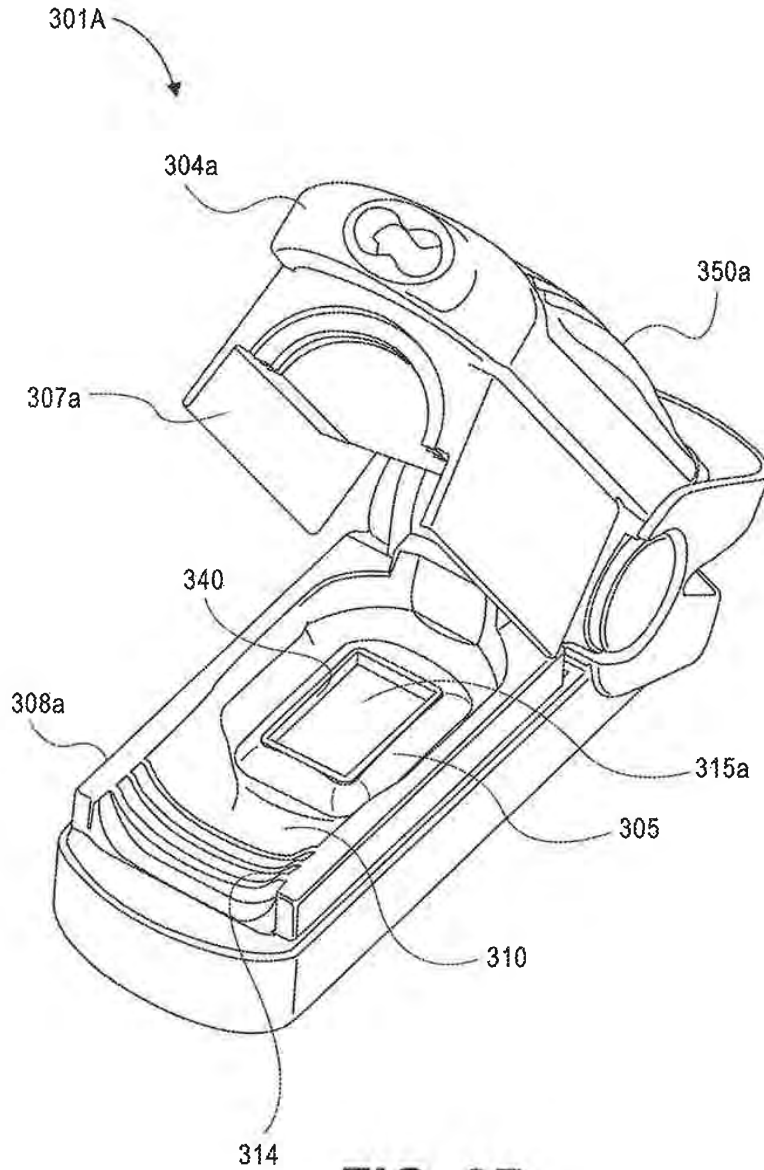


FIG. 3B

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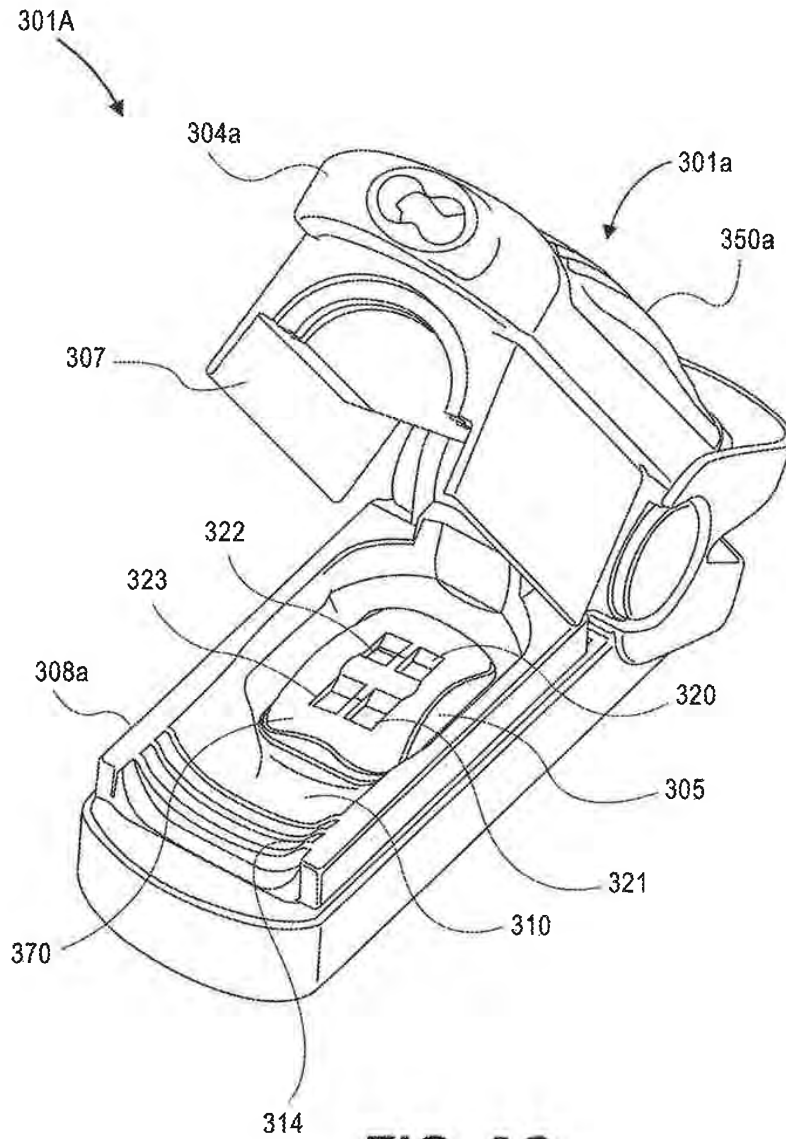


FIG. 3C

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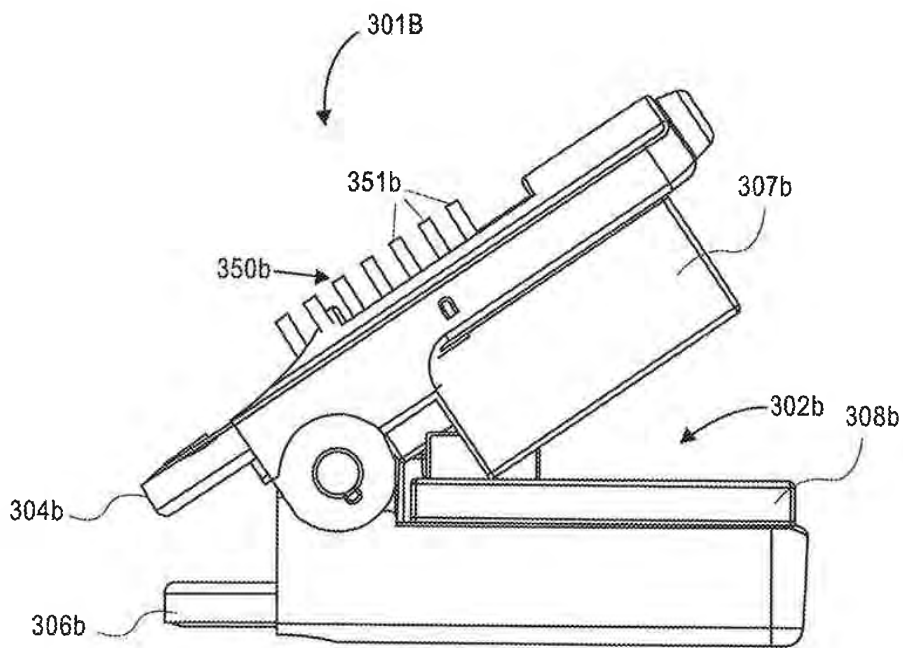


FIG. 3D

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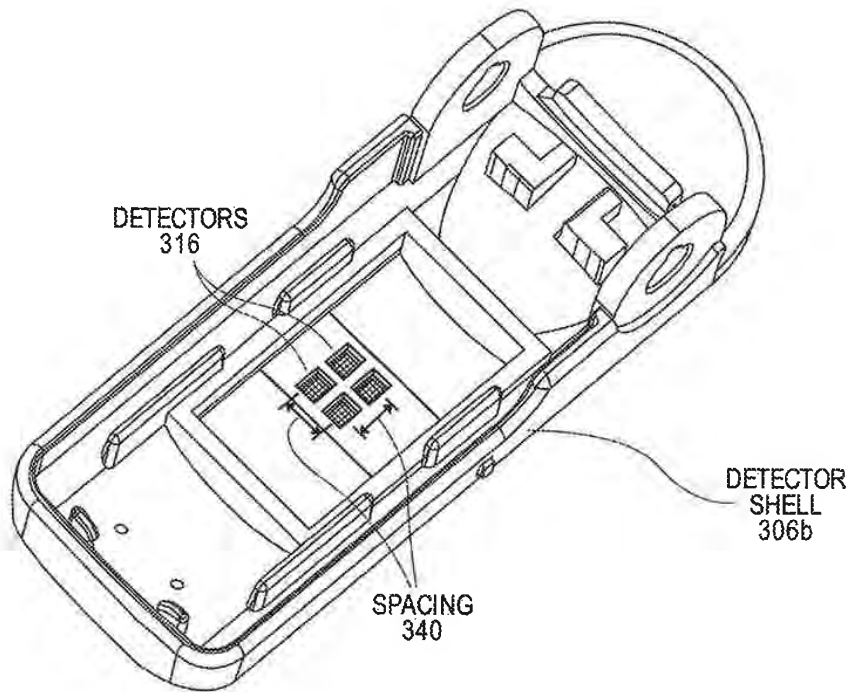


FIG. 3E

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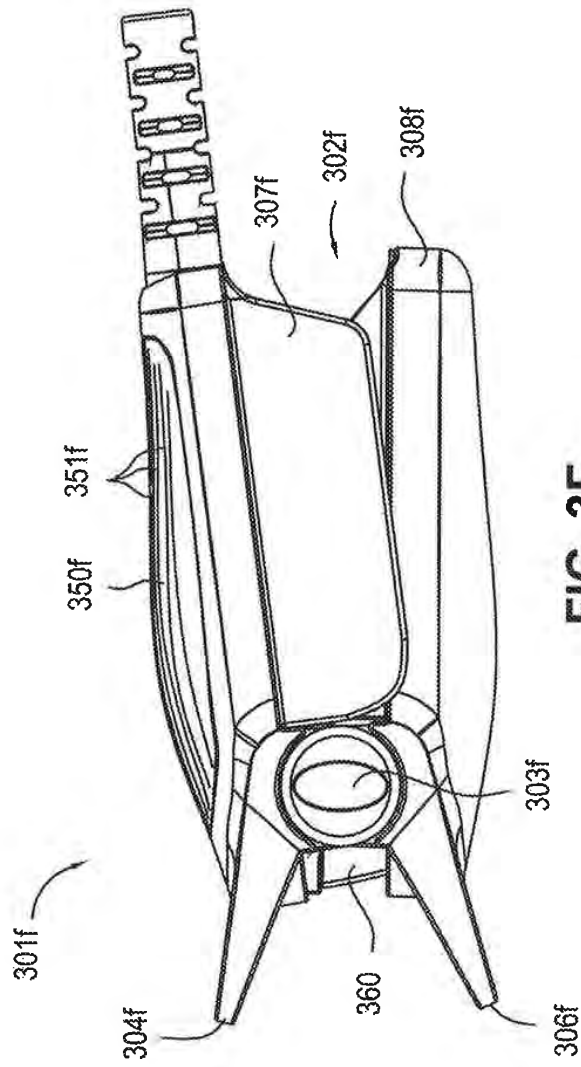


FIG. 3F

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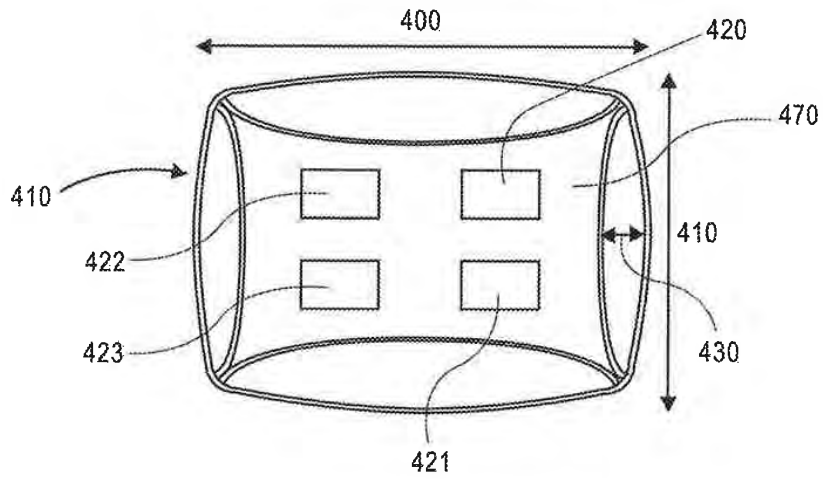


FIG. 4A

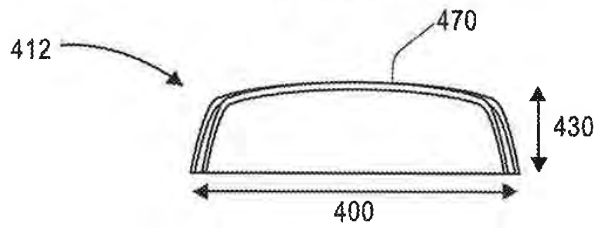


FIG. 4B

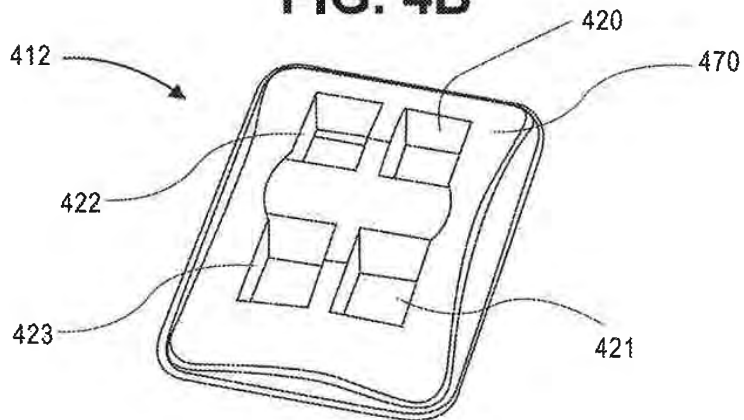


FIG. 4C

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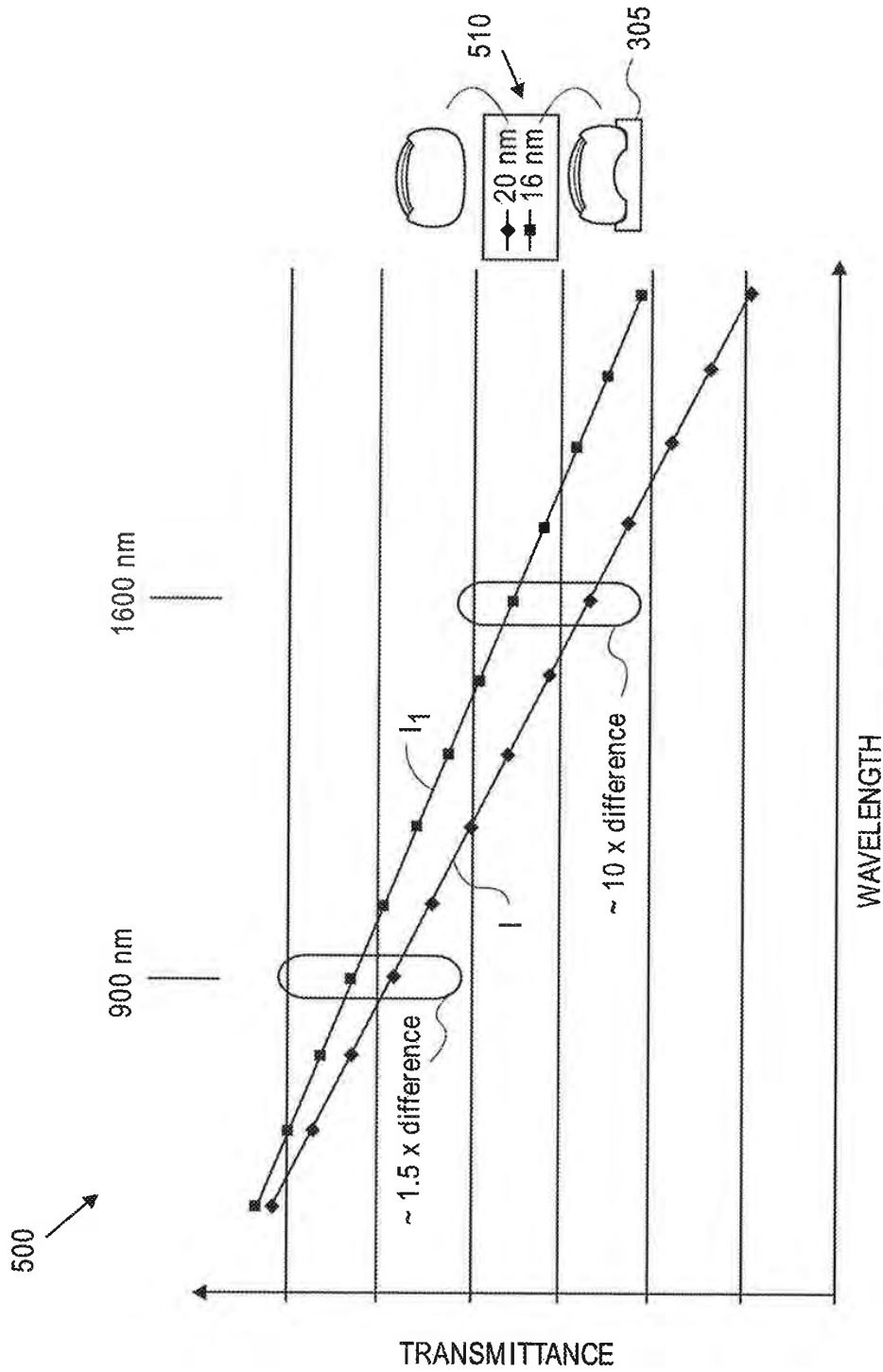


FIG. 5

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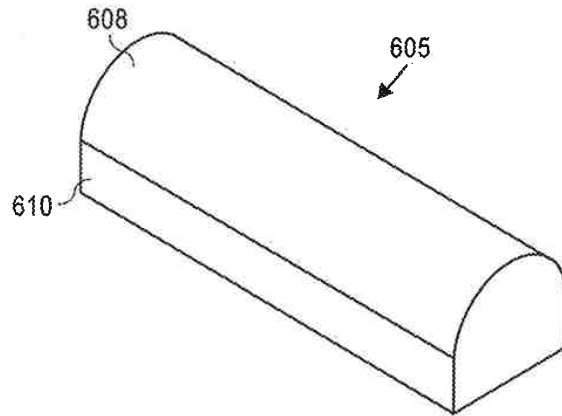


FIG. 6A

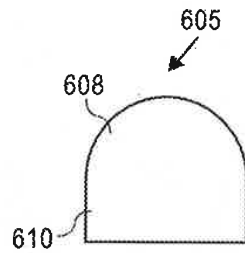


FIG. 6B

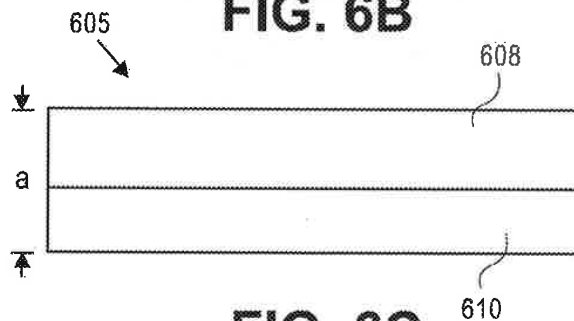


FIG. 6C



FIG. 6D

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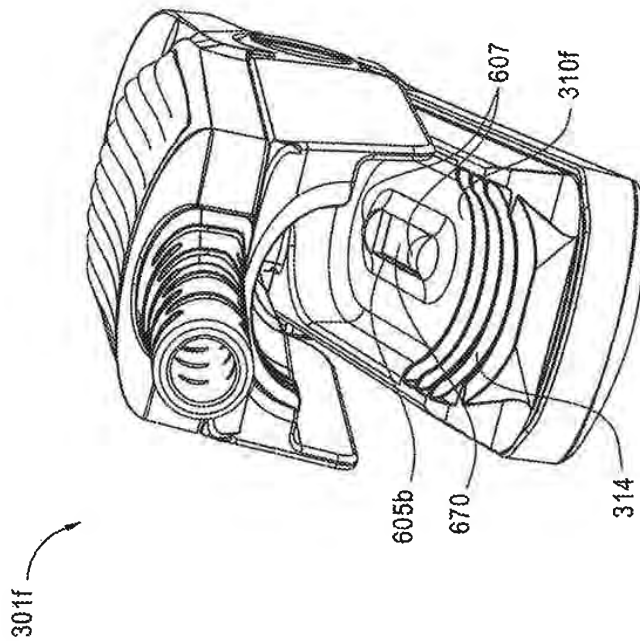


FIG. 6E

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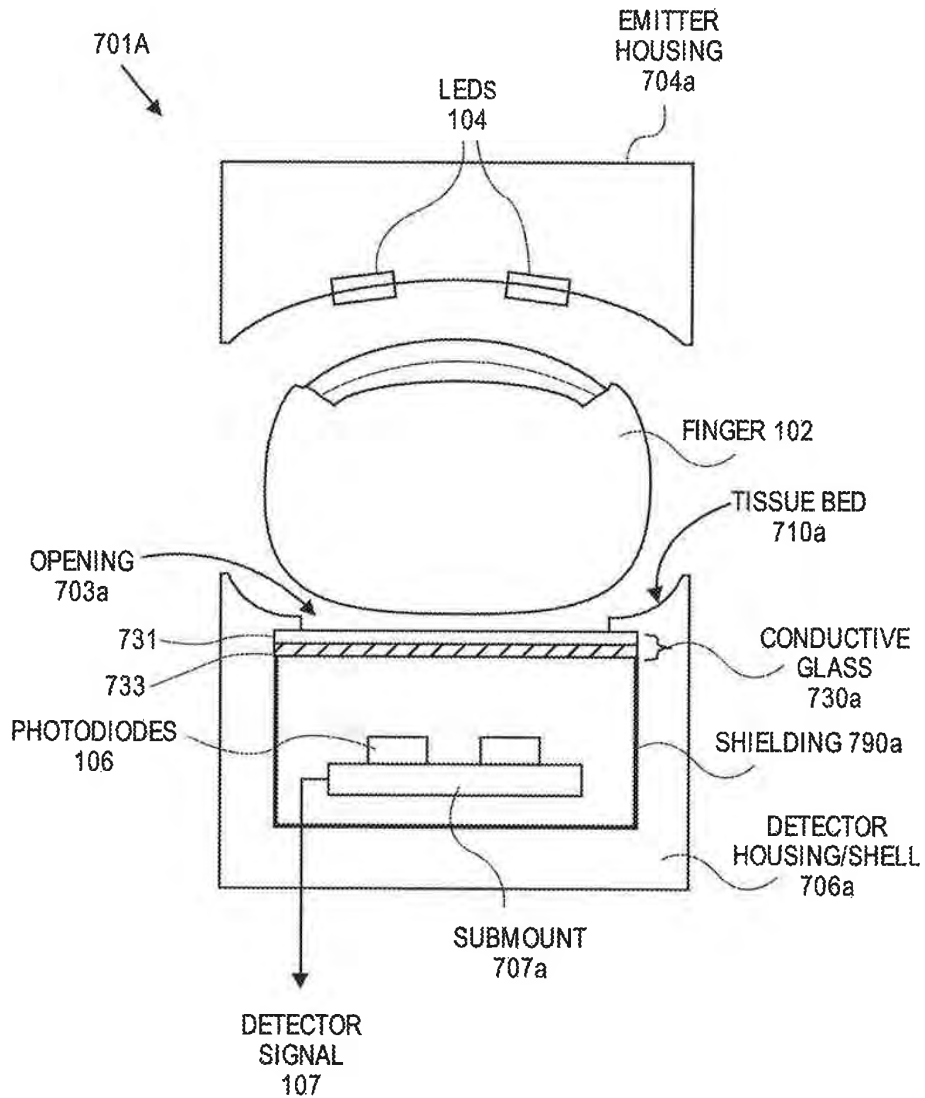


FIG. 7A

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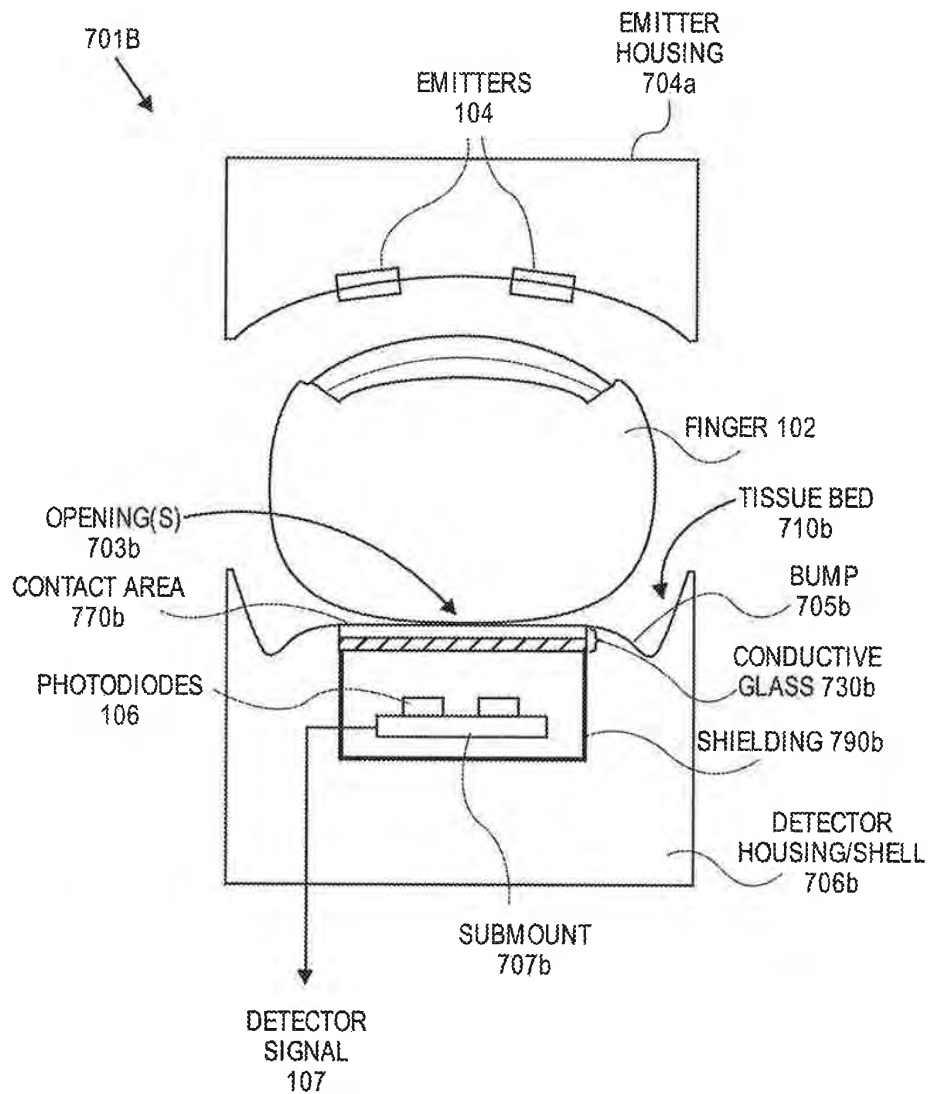


FIG. 7B

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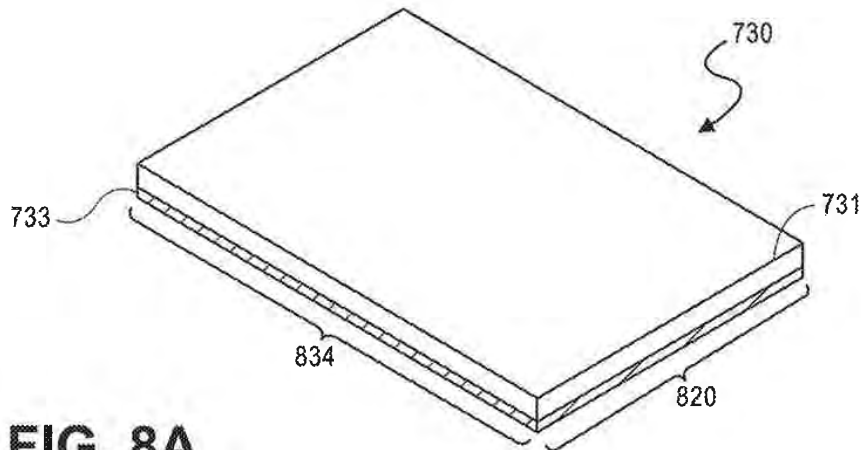


FIG. 8A

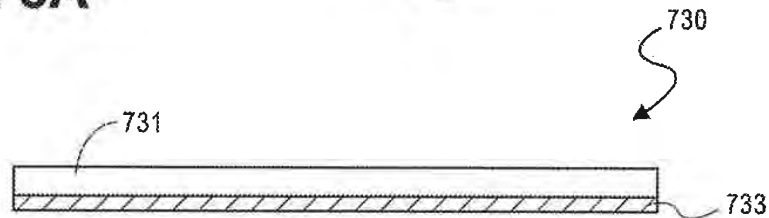


FIG. 8B

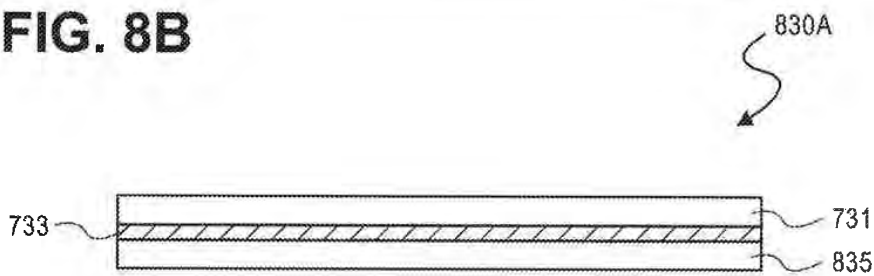


FIG. 8C

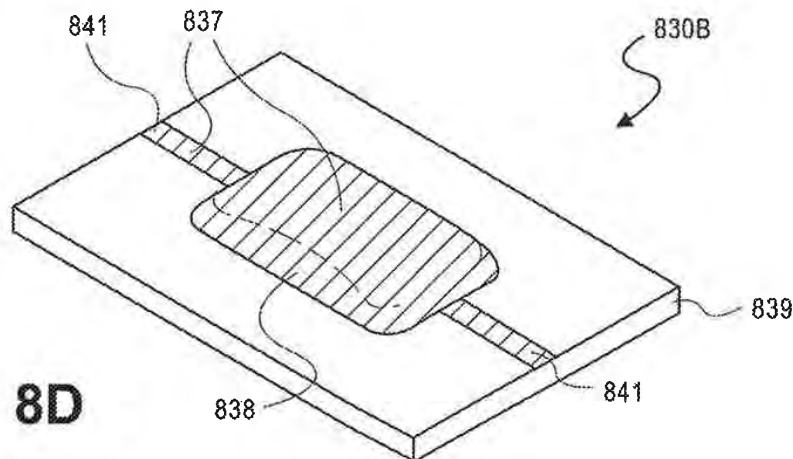


FIG. 8D

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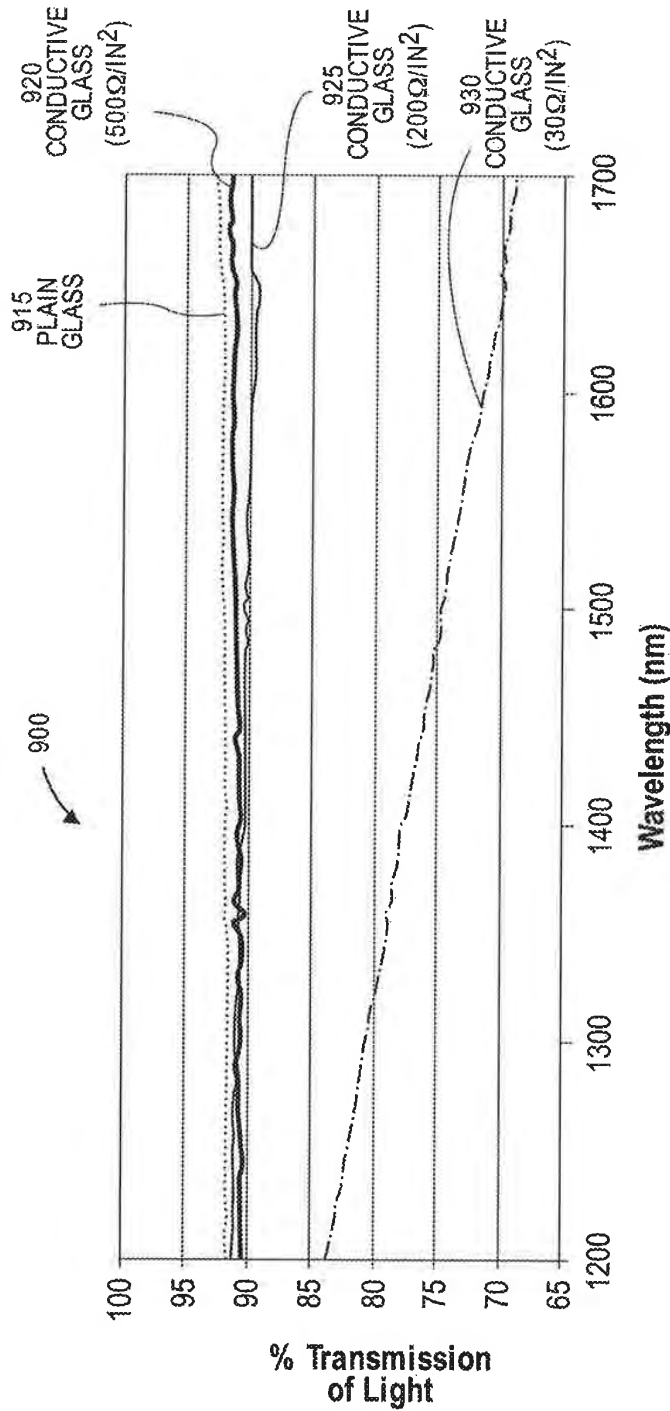


FIG. 9

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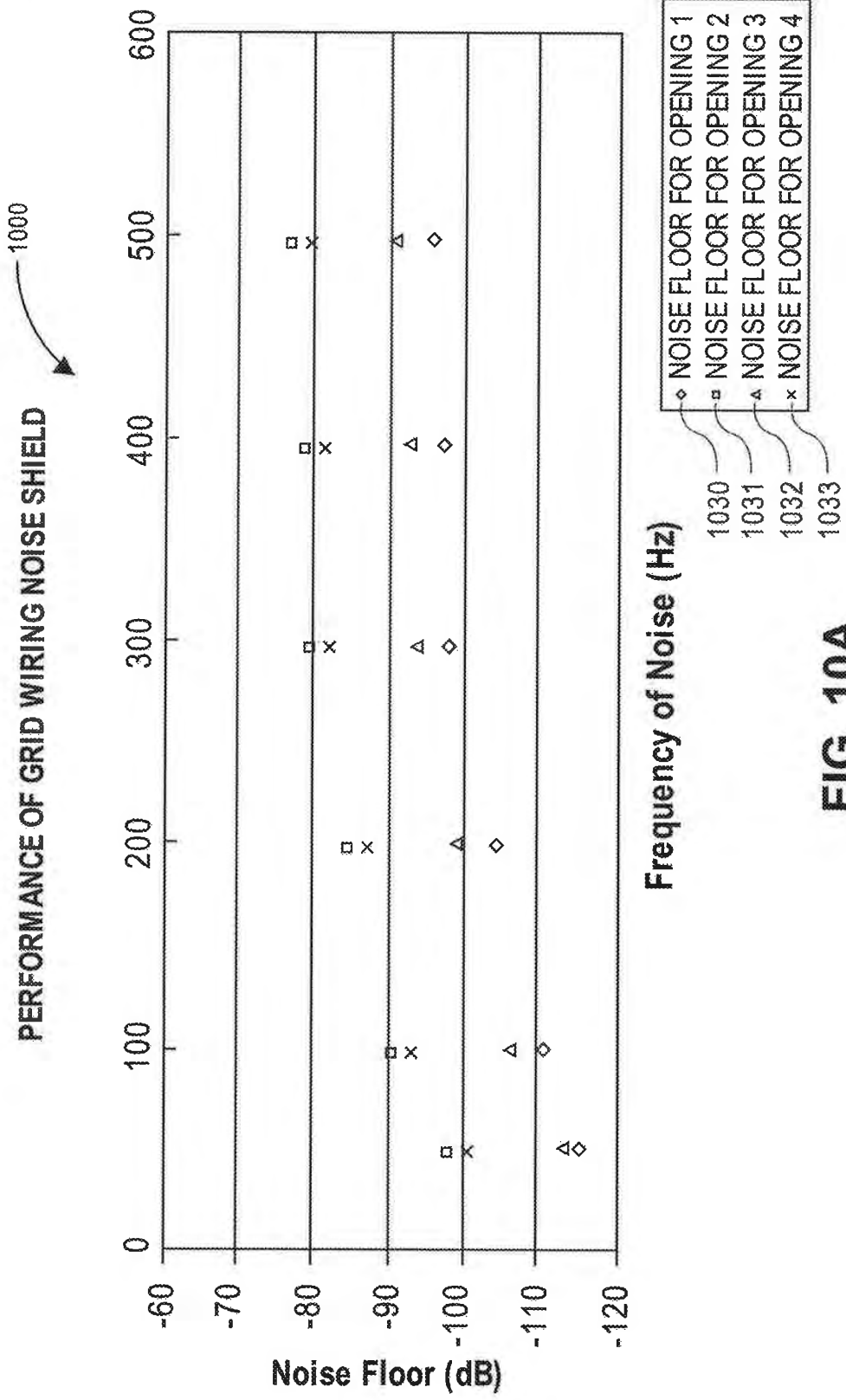


FIG. 10A

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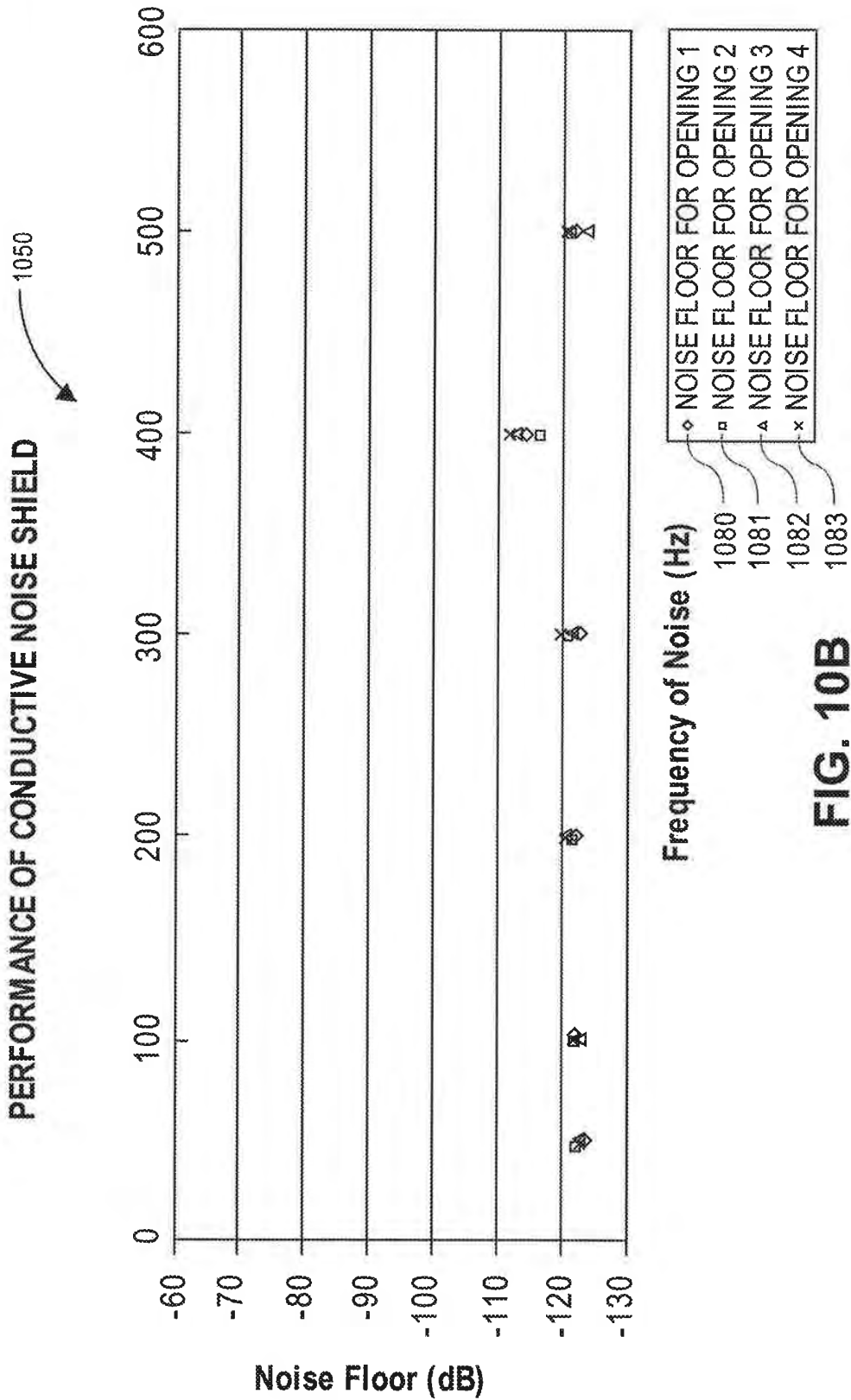


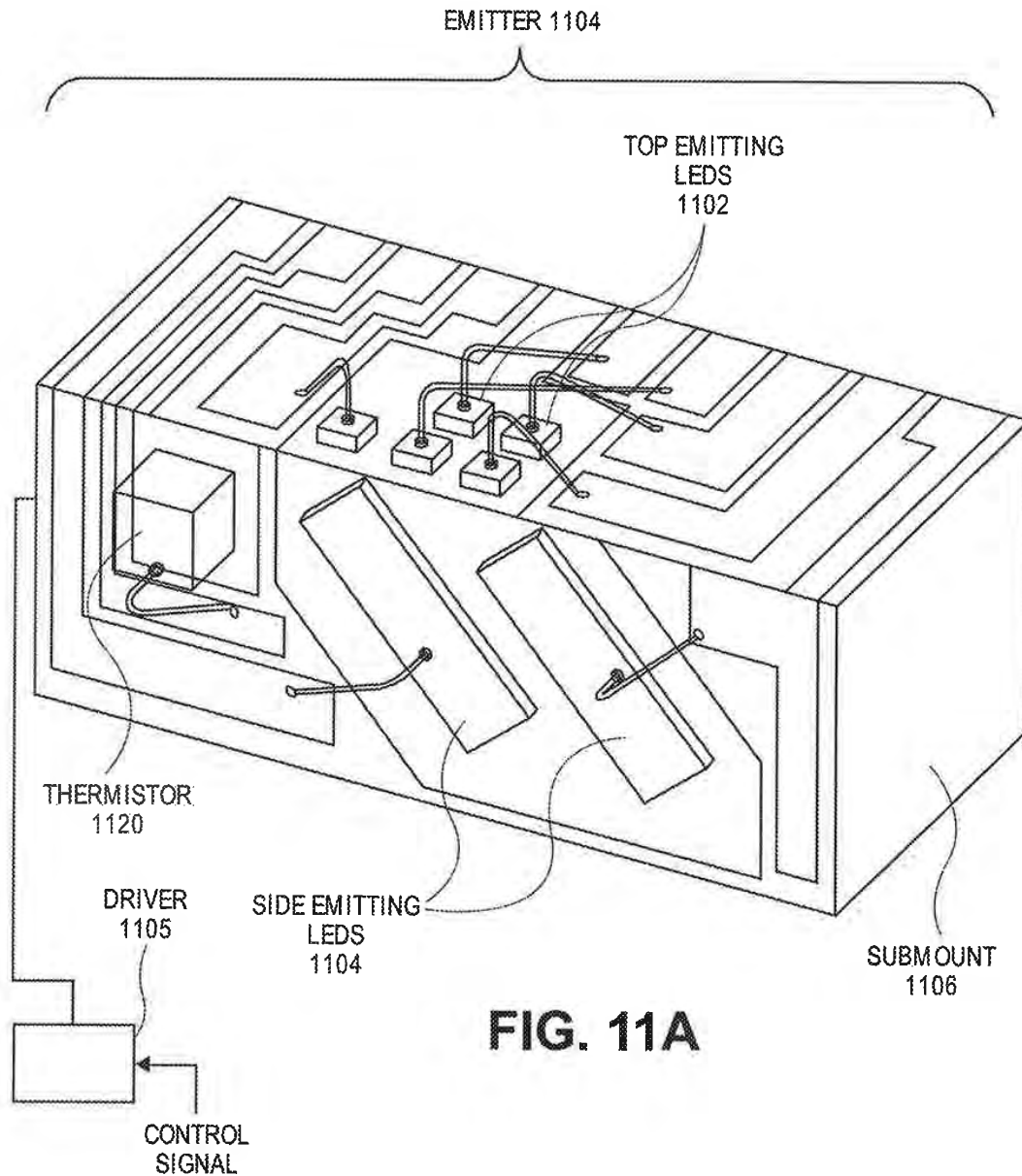
FIG. 10B

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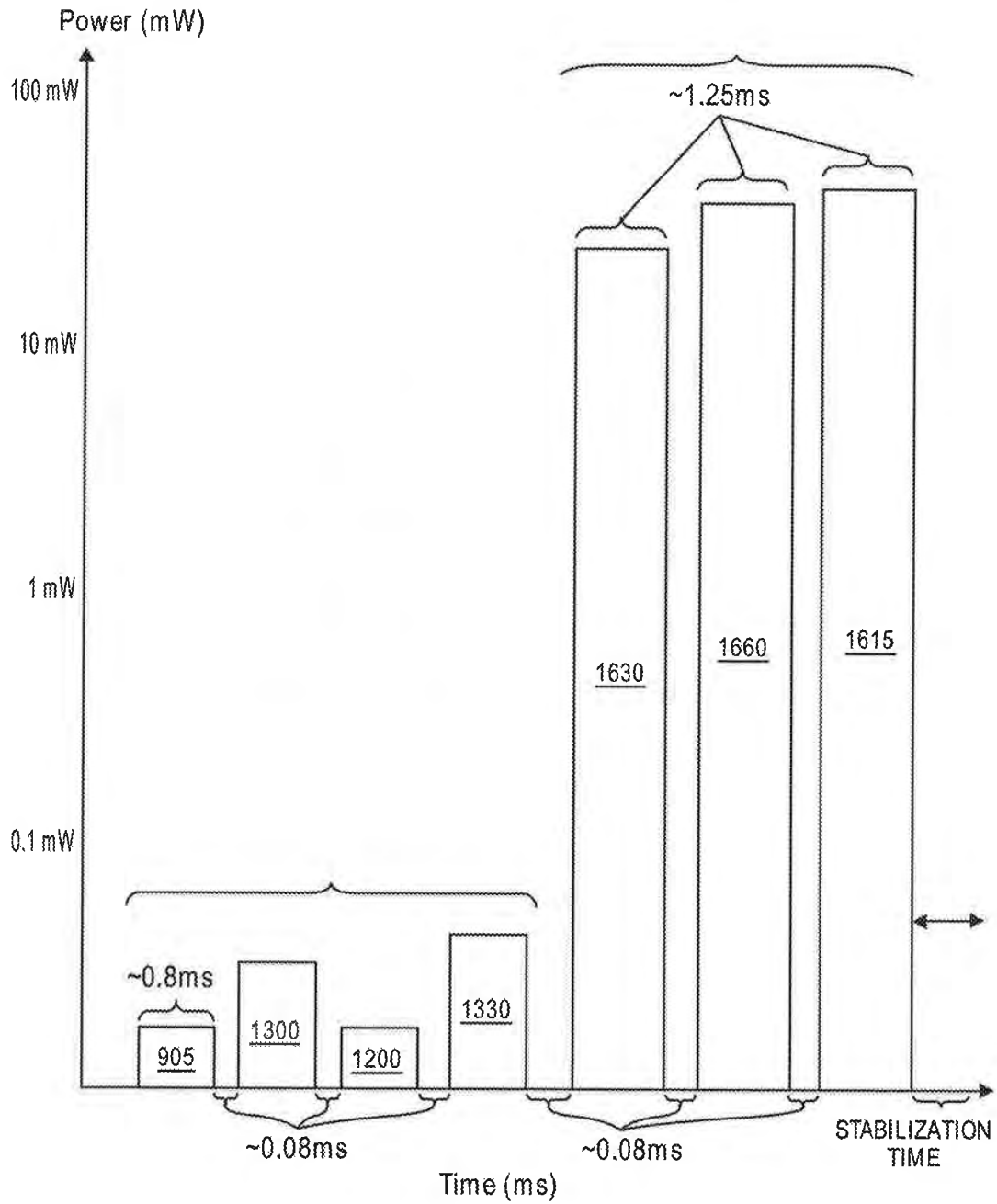


FIG. 11B

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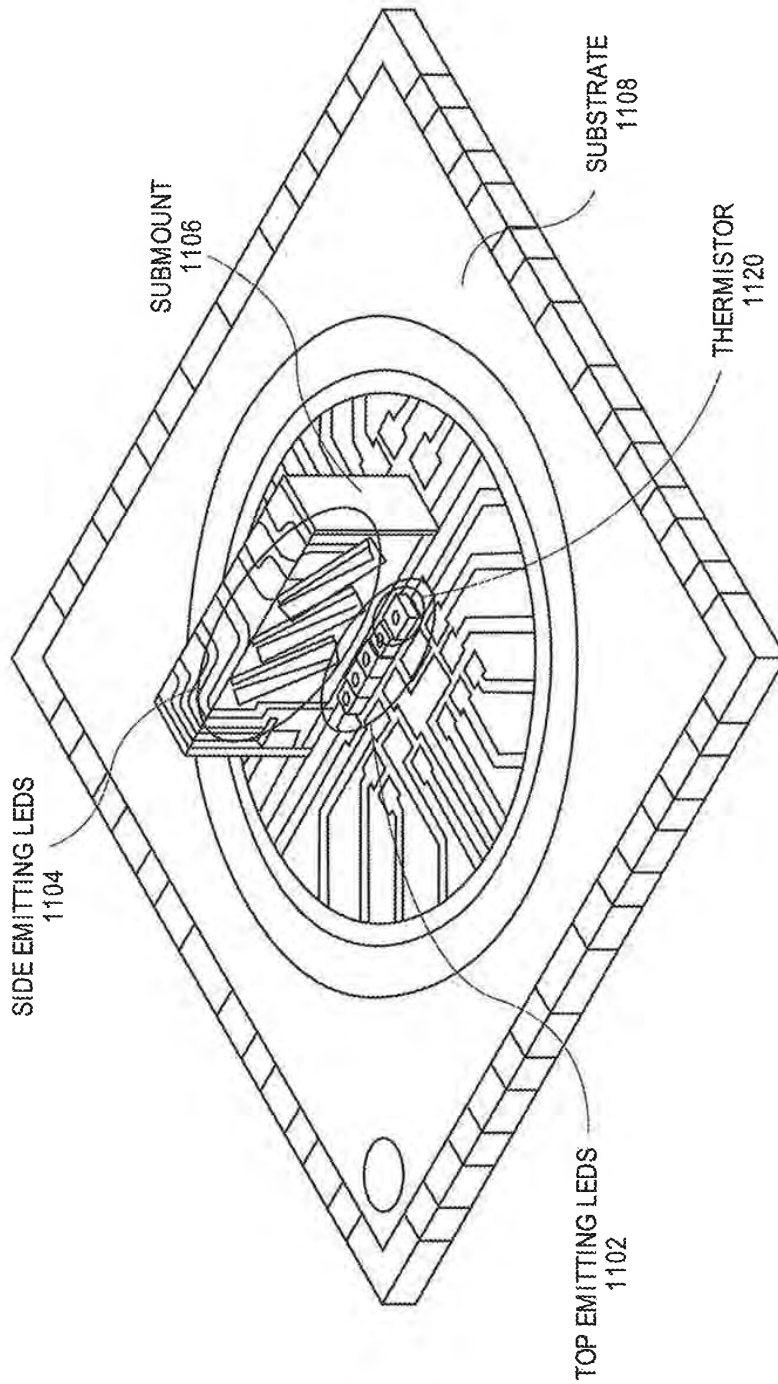


FIG. 11C

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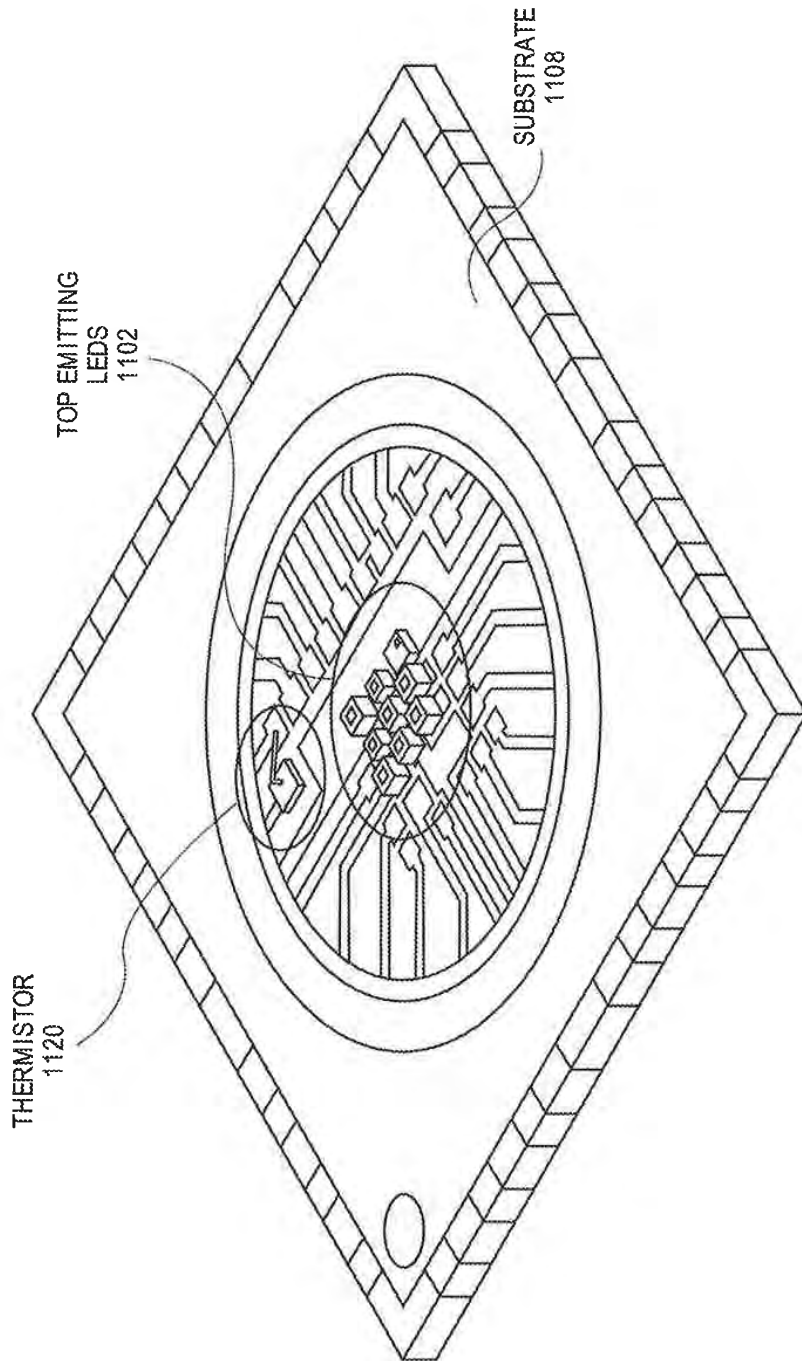


FIG. 11D

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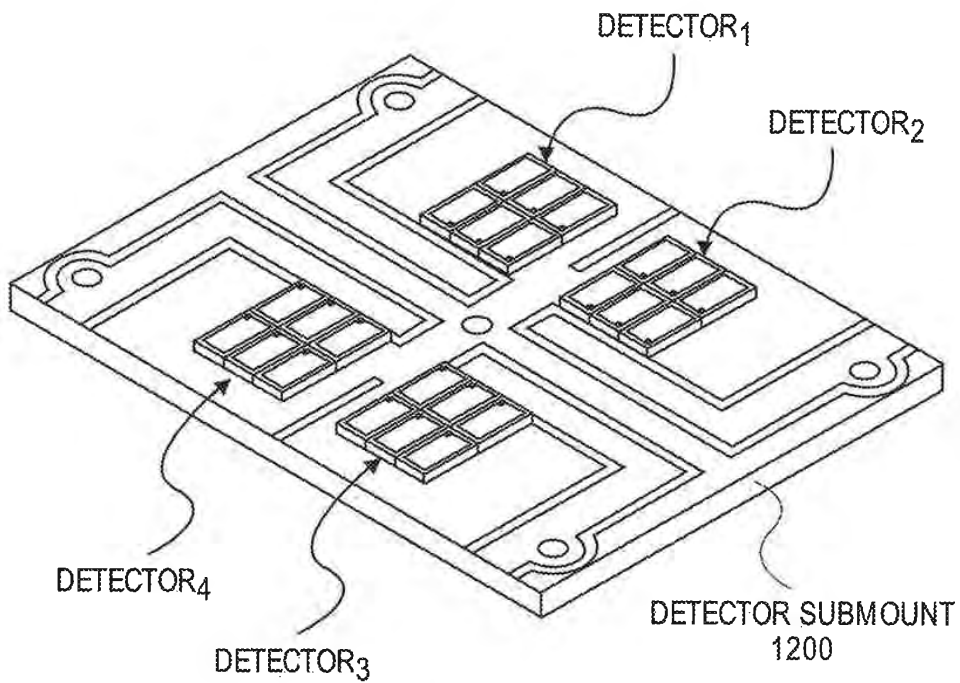


FIG. 12A

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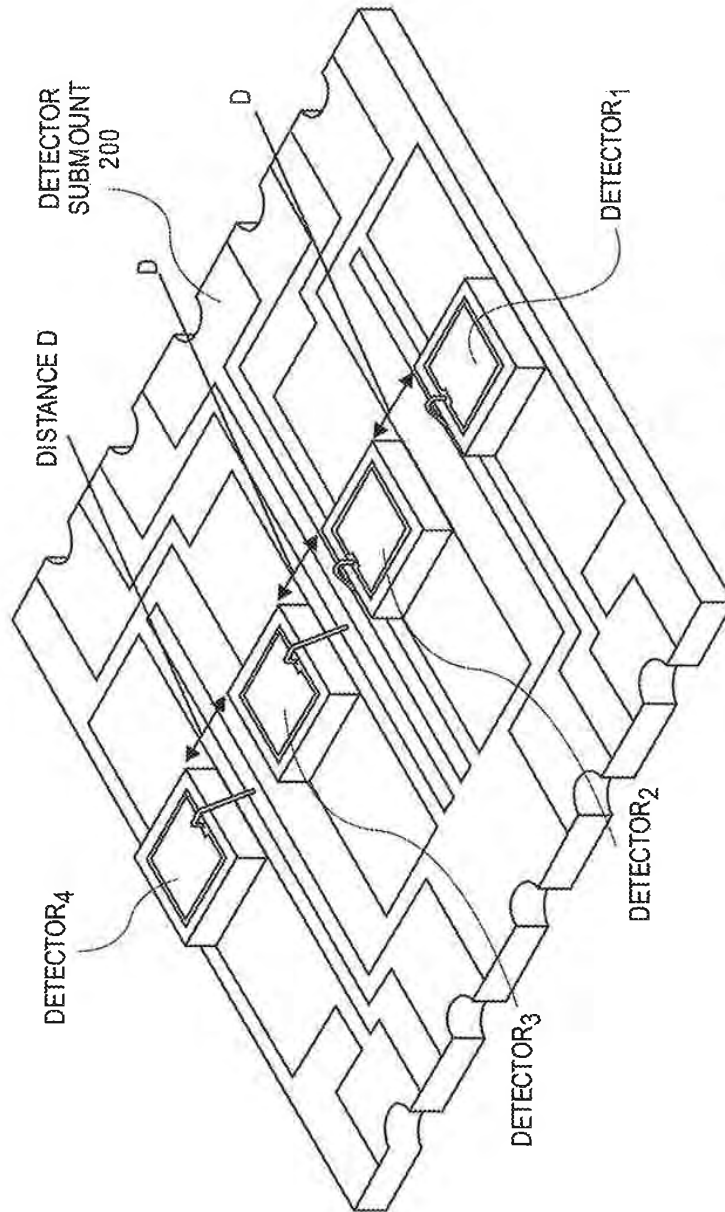


FIG. 12B

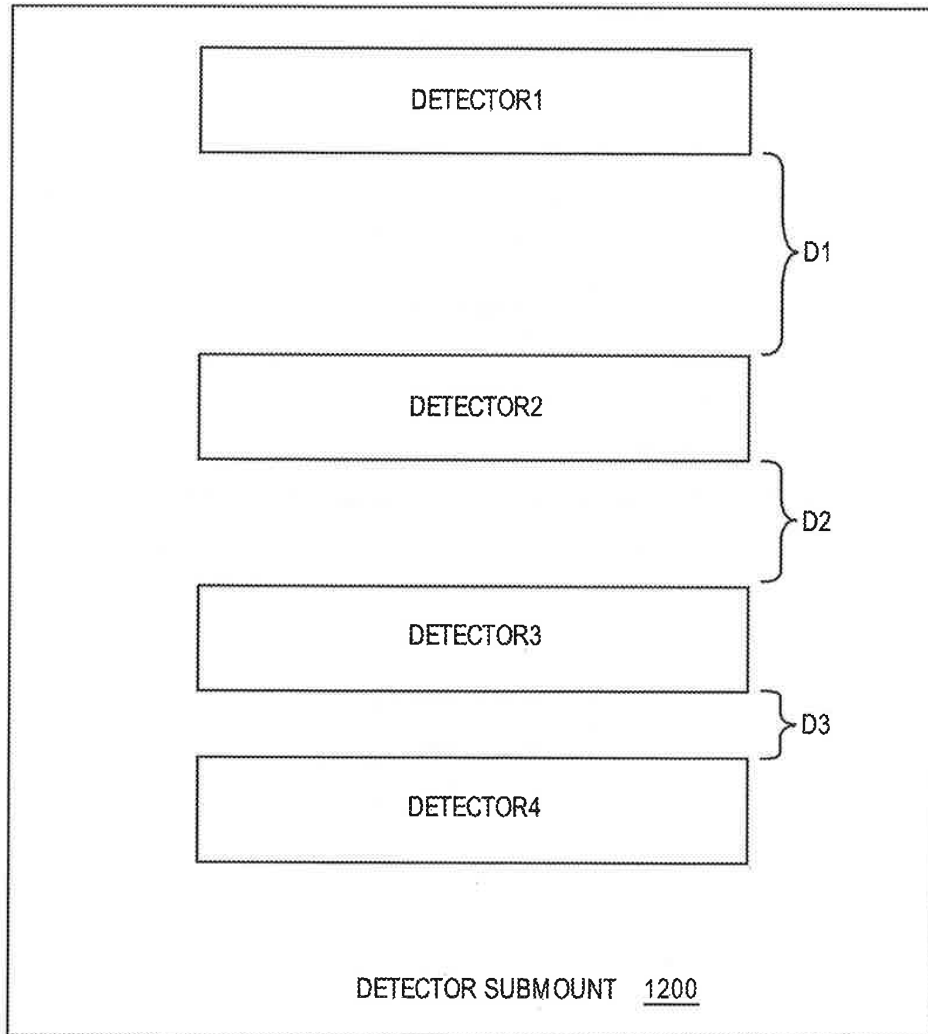


FIG. 12C

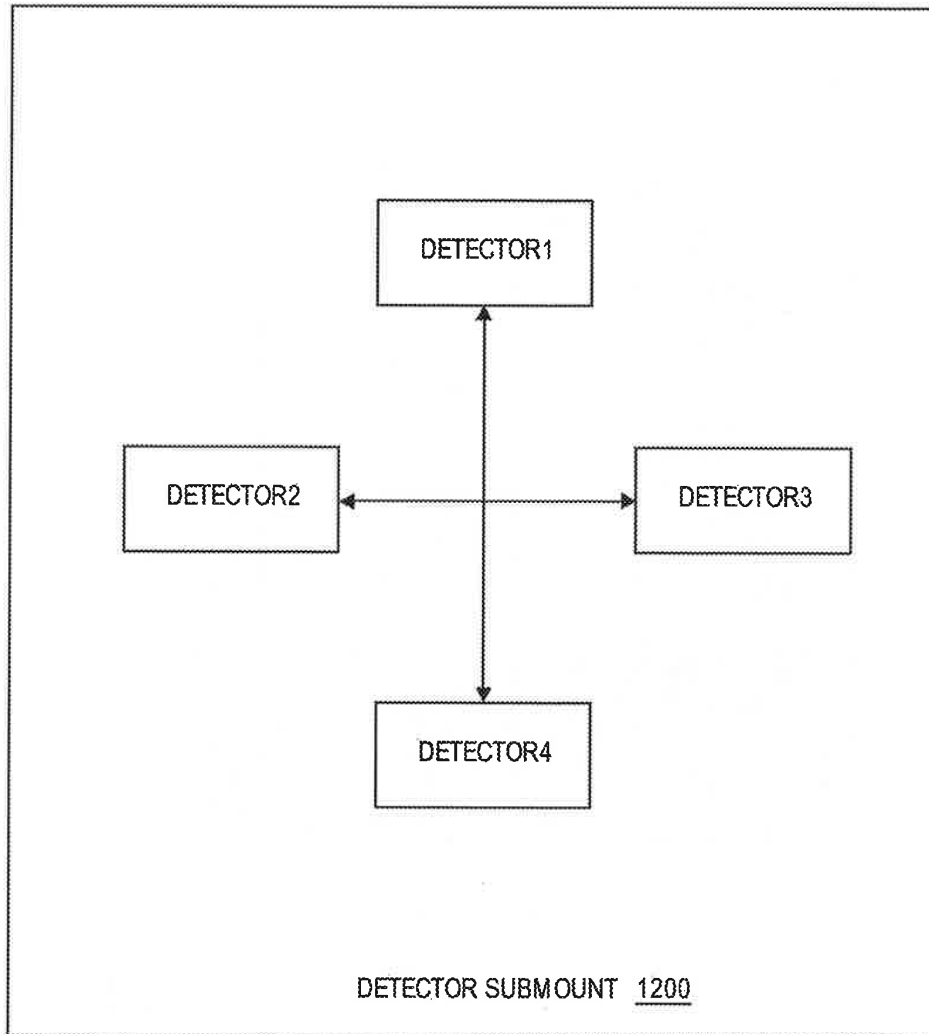


FIG. 12D

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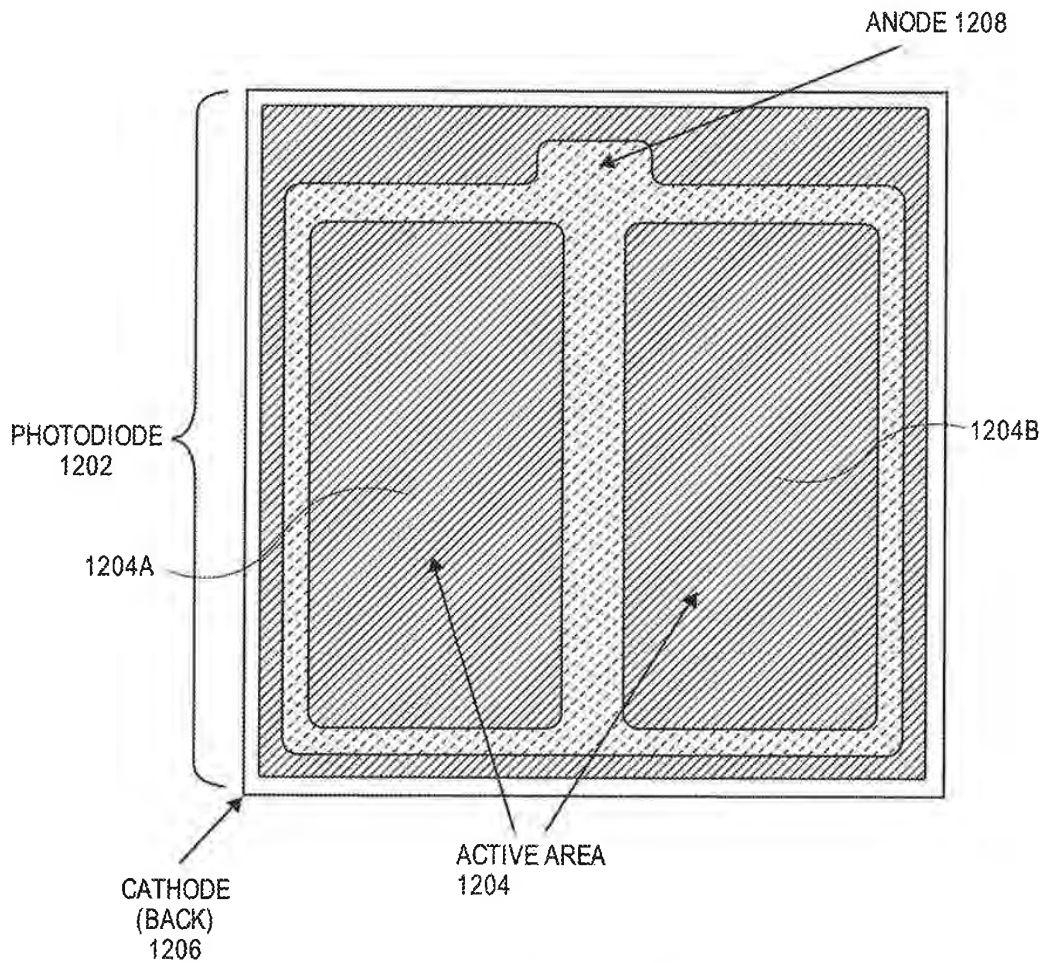


FIG. 12E

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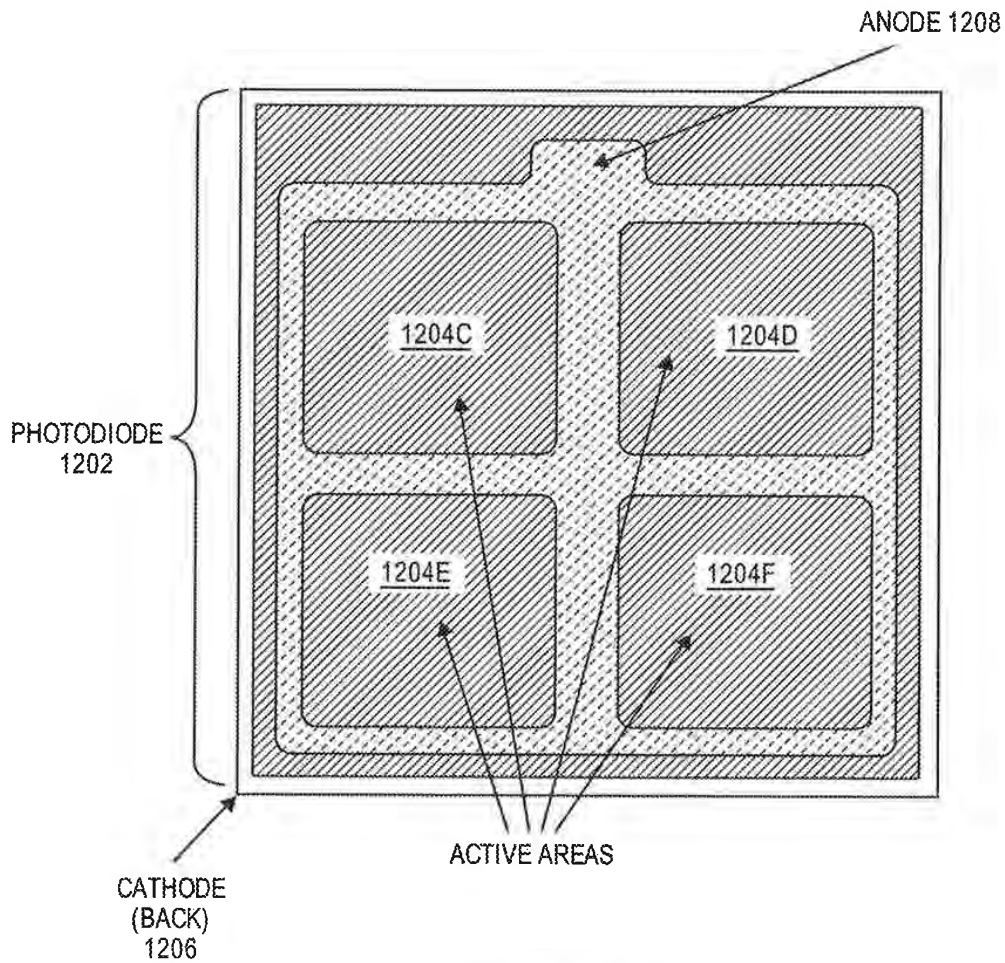


FIG. 12F

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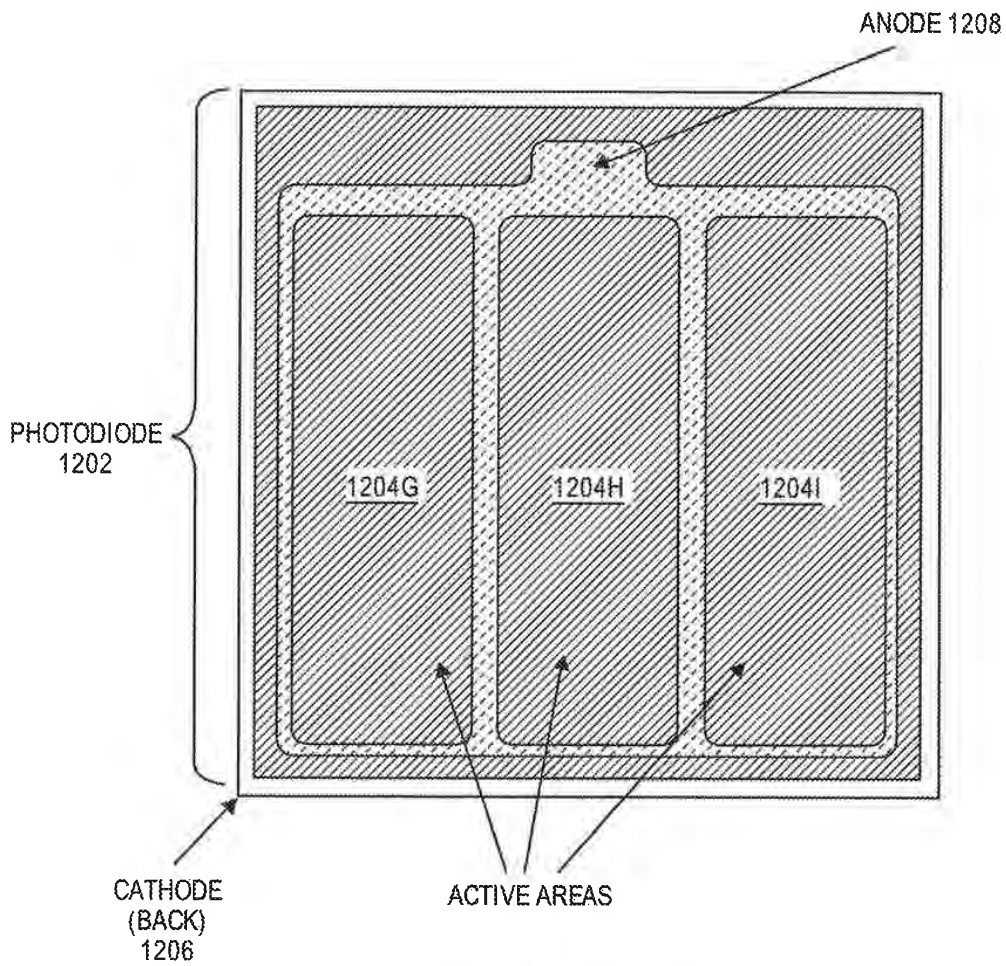


FIG. 12G

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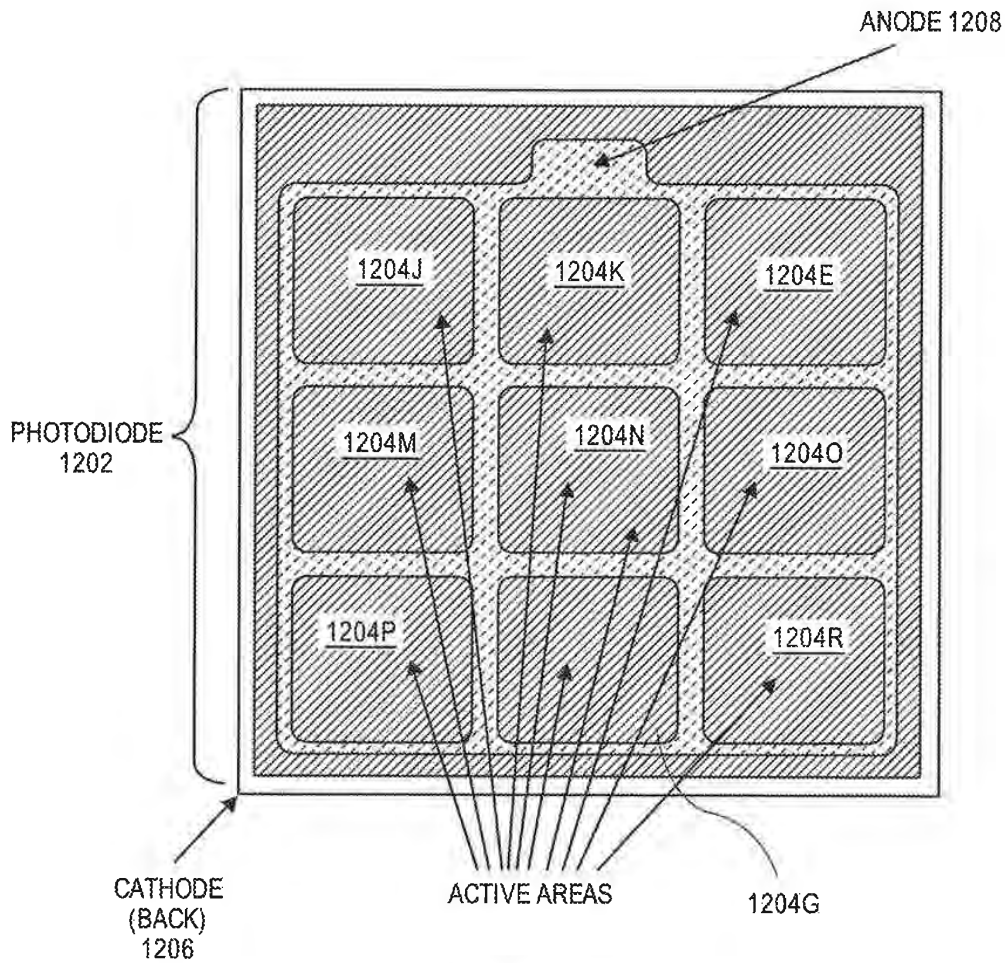


FIG. 12H

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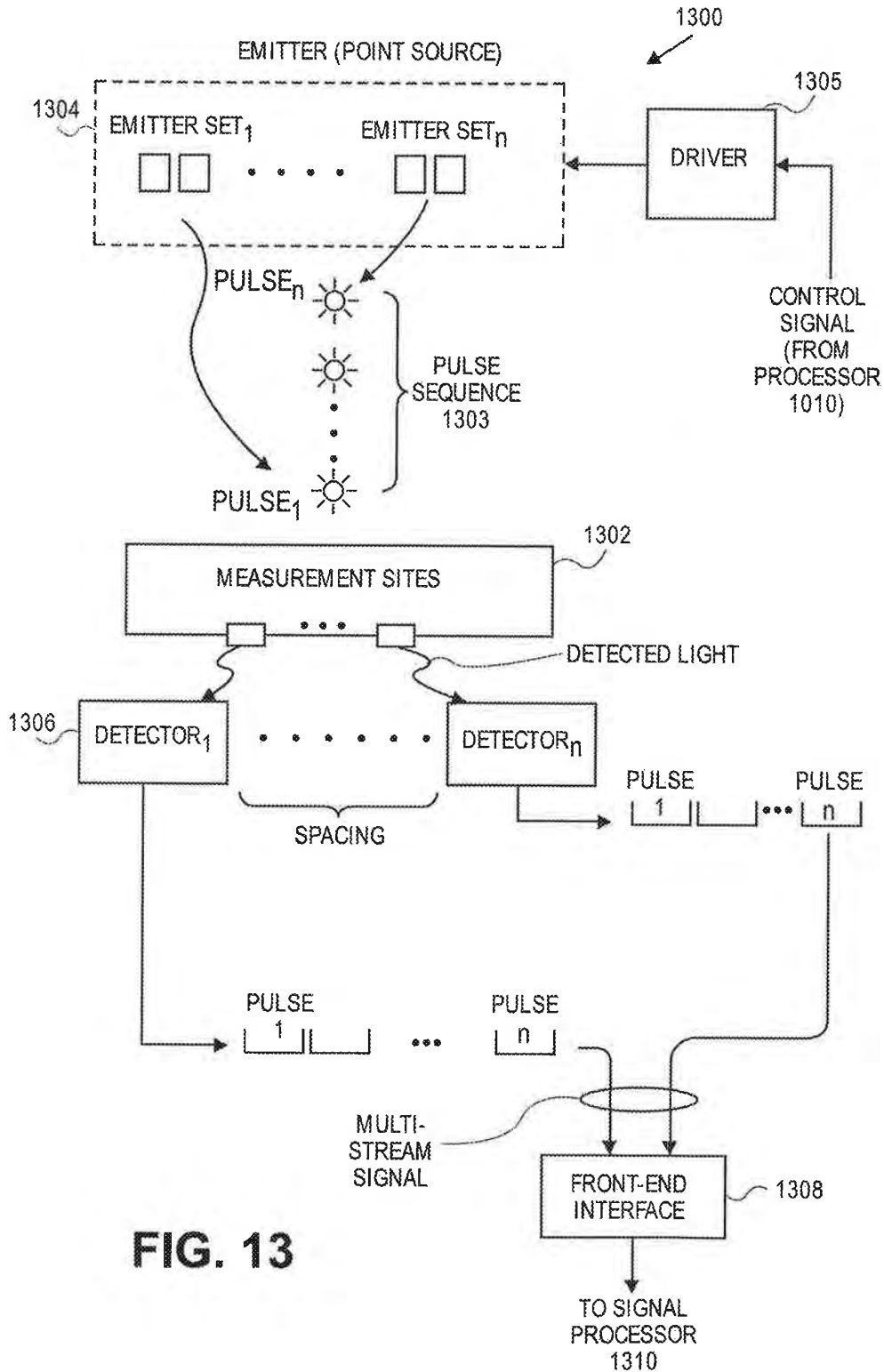


FIG. 13

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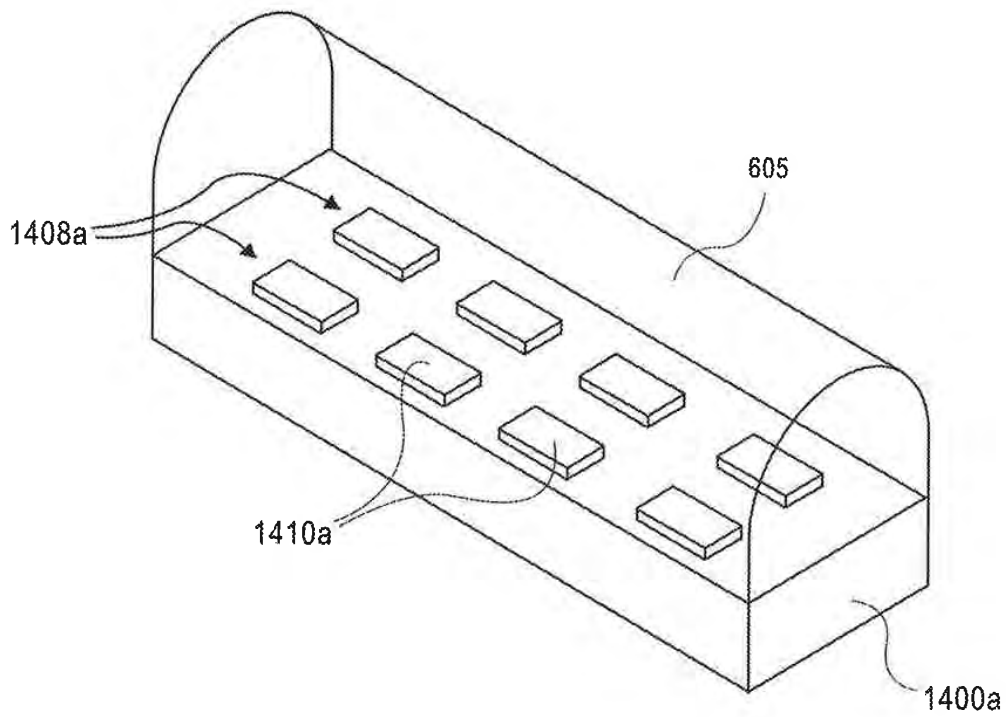


FIG. 14A

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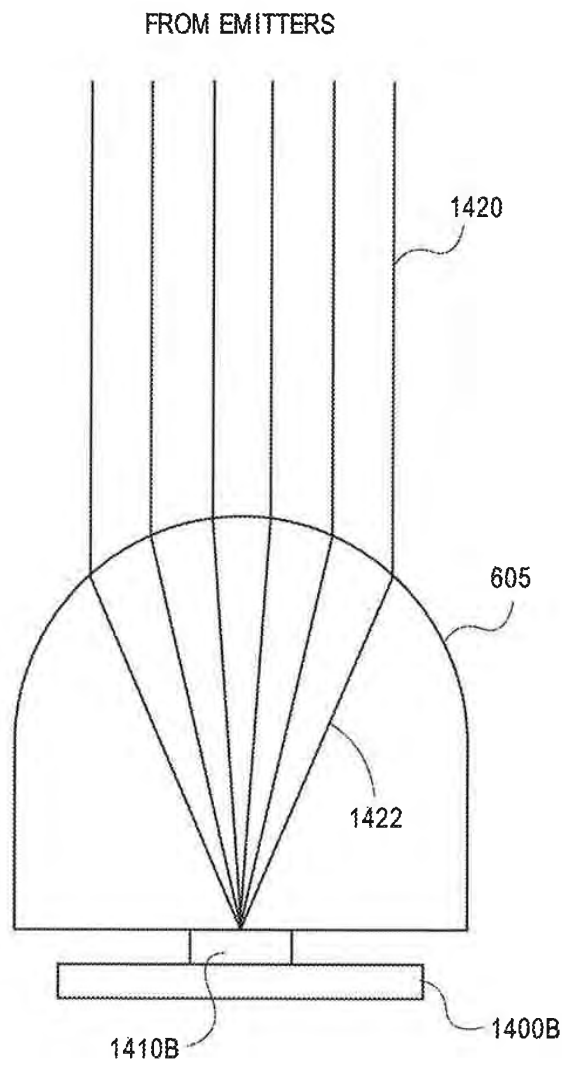


FIG. 14B

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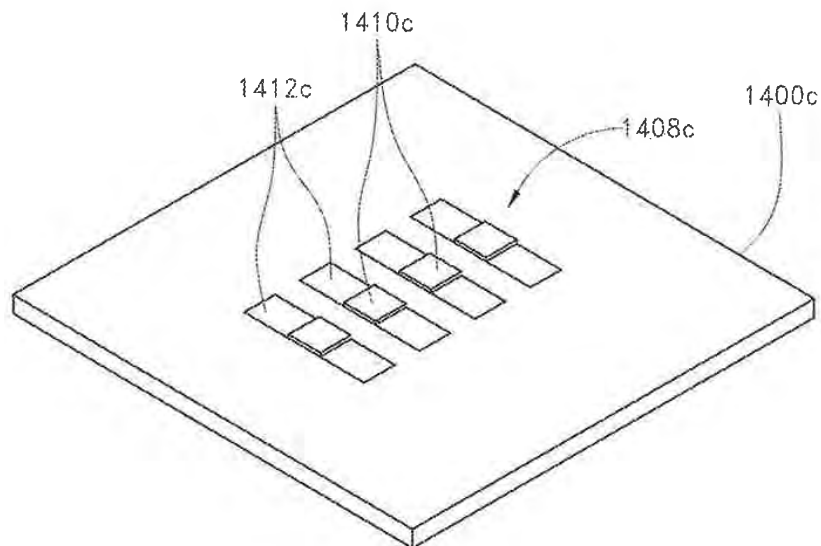


FIG. 14C

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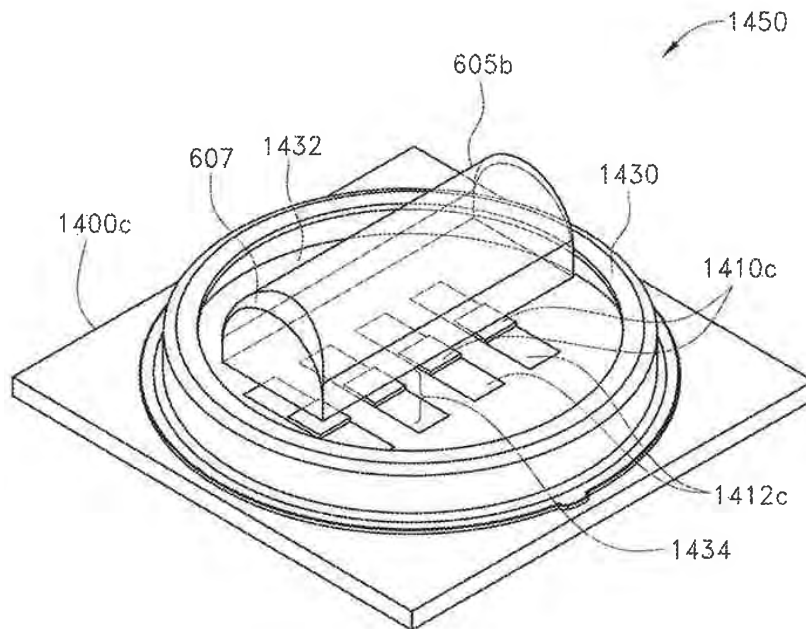


FIG. 14D

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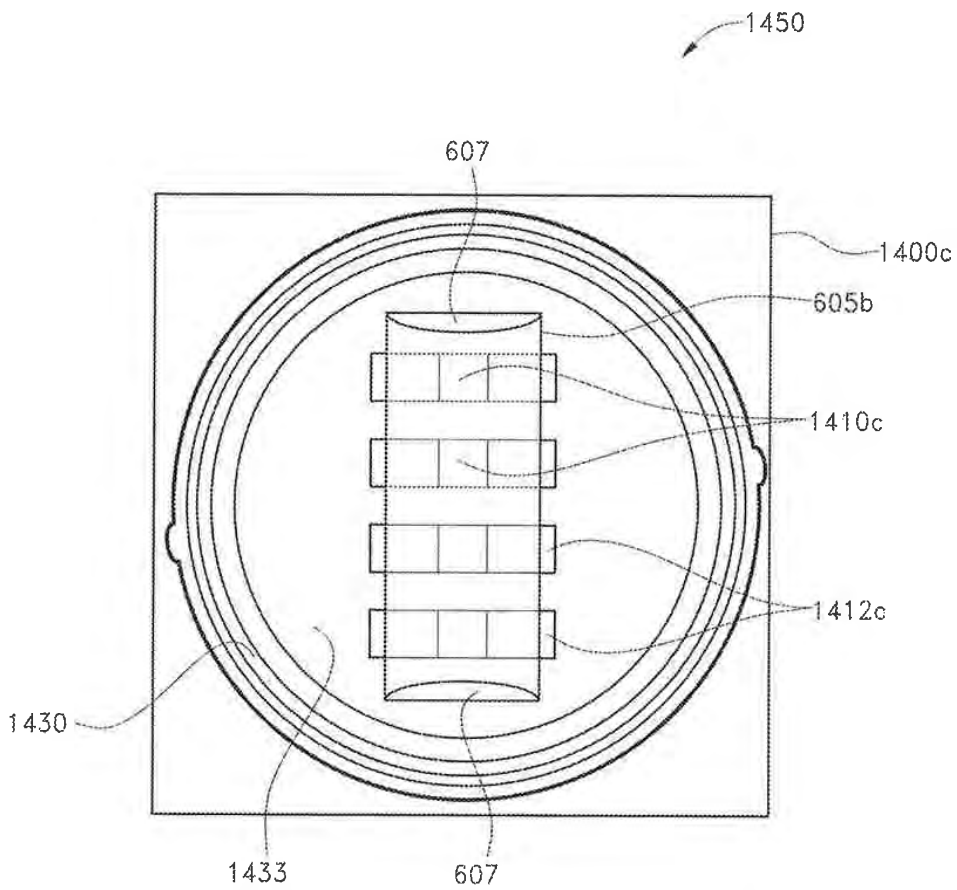


FIG. 14E

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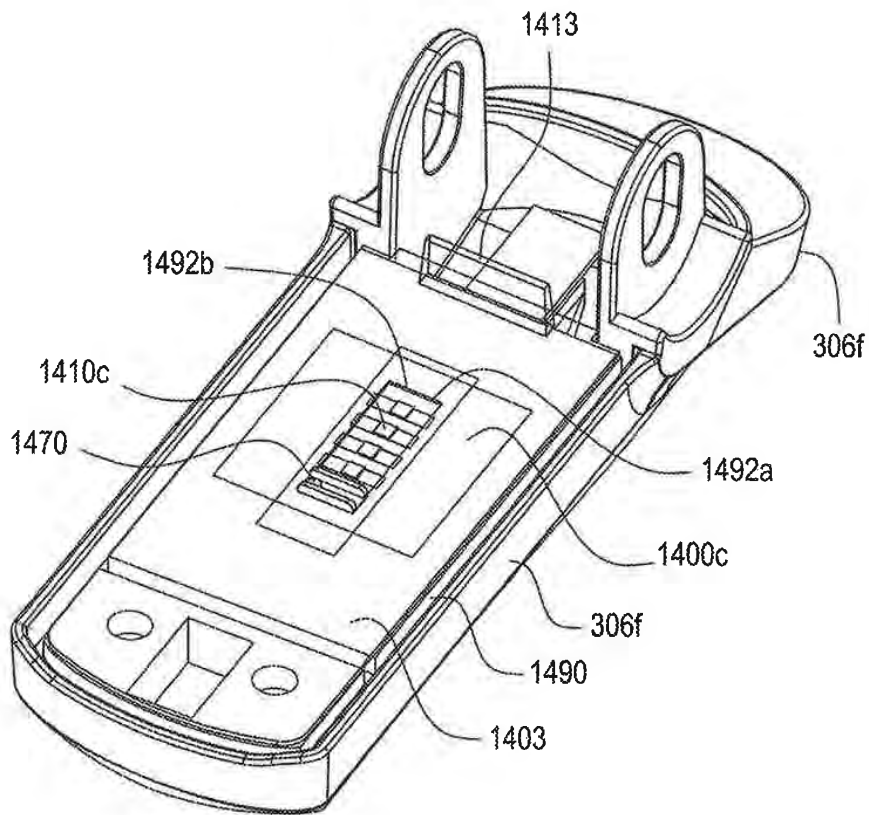


FIG. 14F

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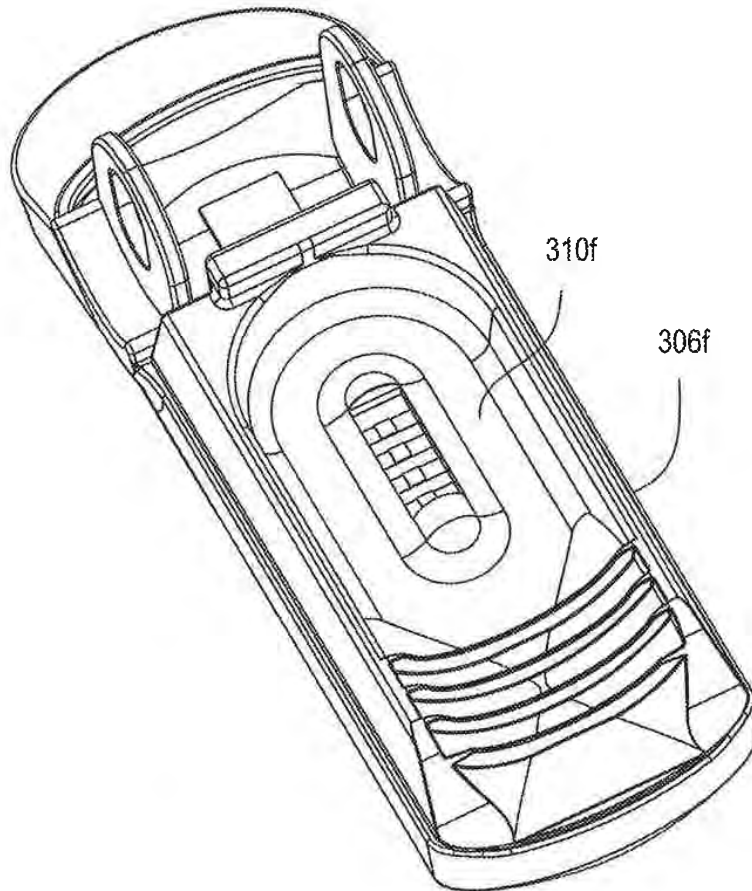


FIG. 14G

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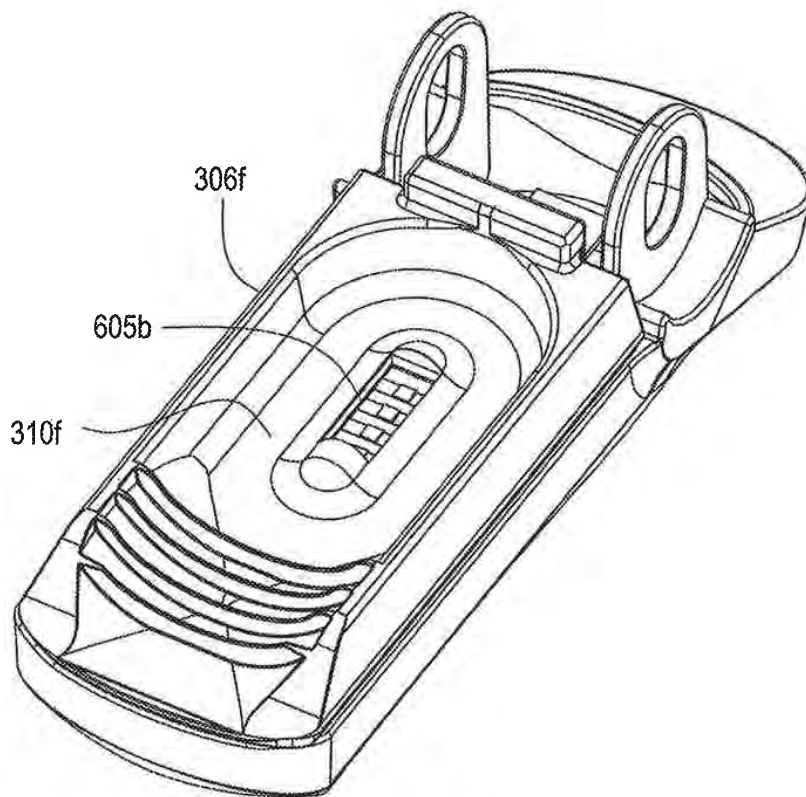


FIG. 14H

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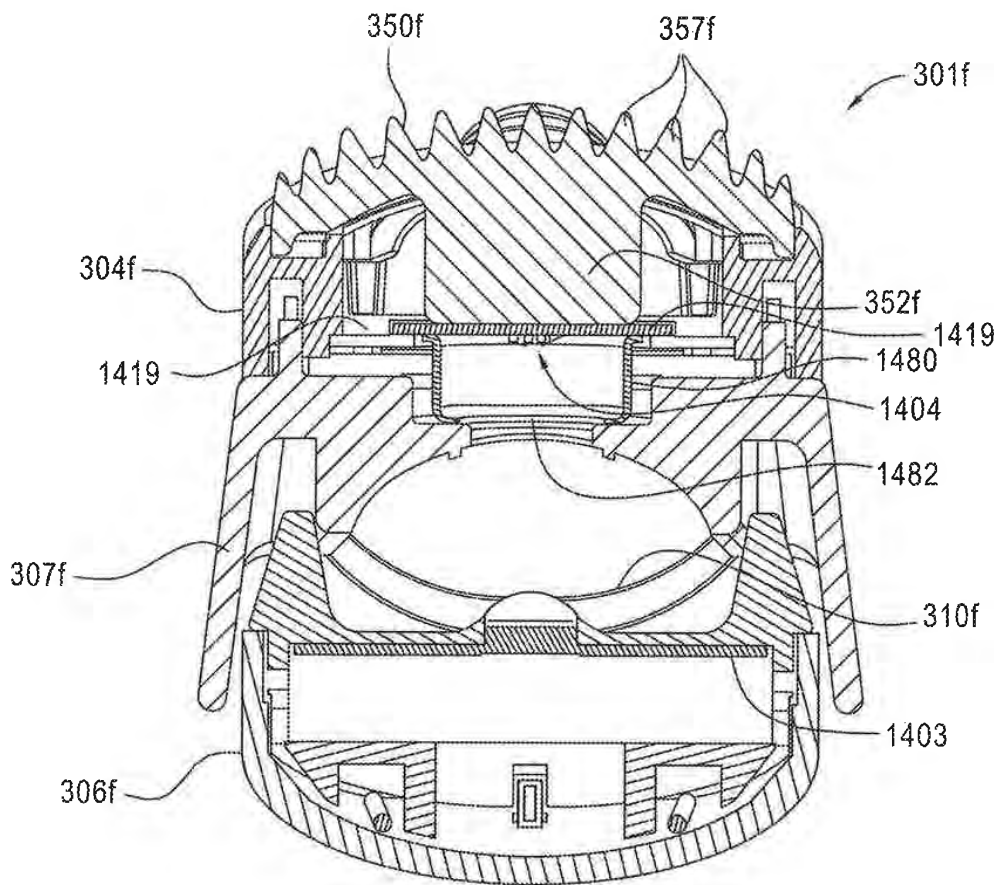


FIG. 14I

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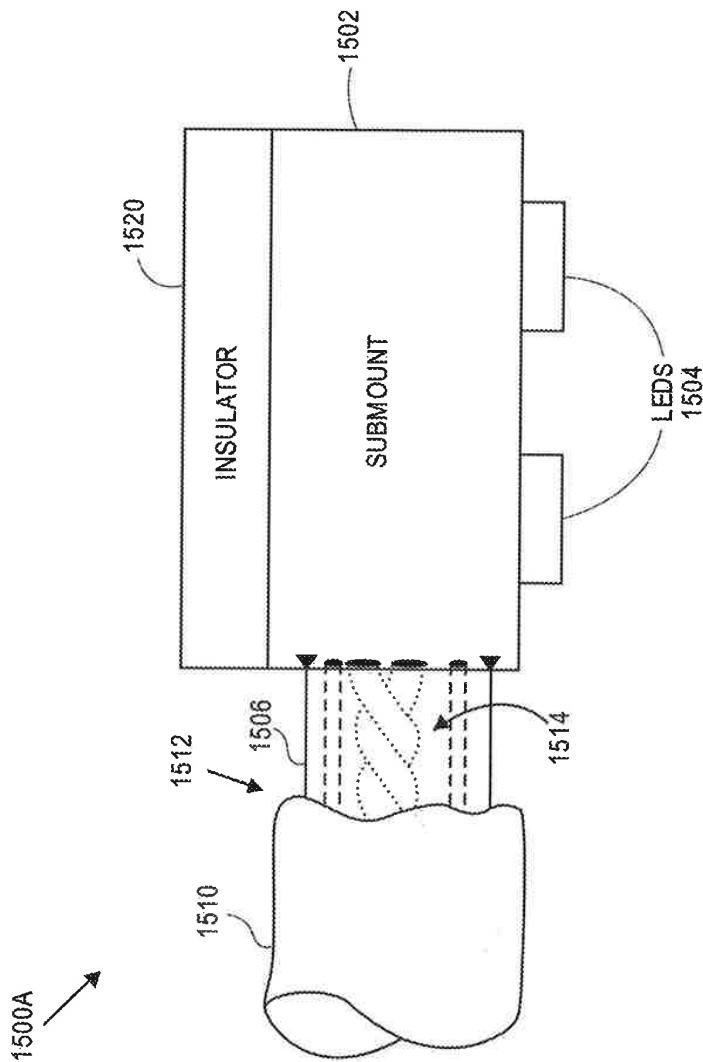


FIG. 15A

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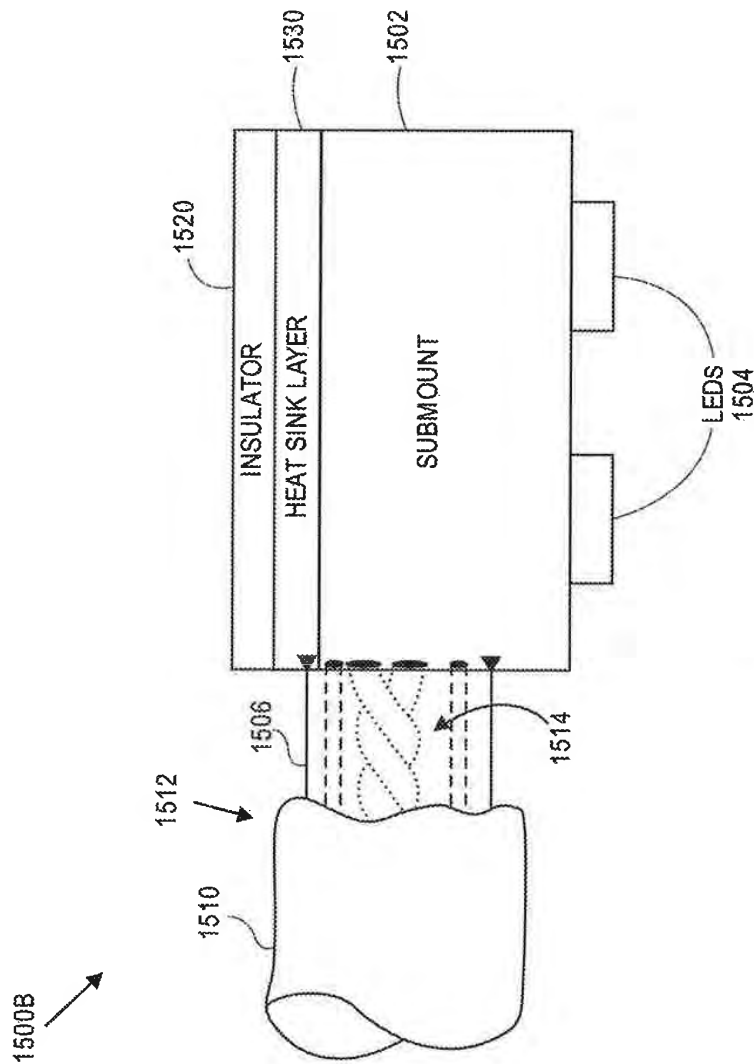


FIG. 15B

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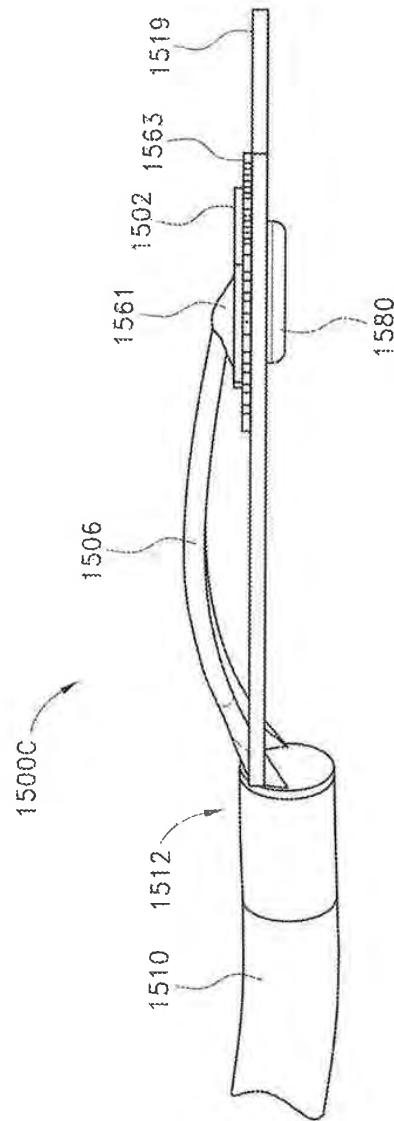


FIG. 1500C

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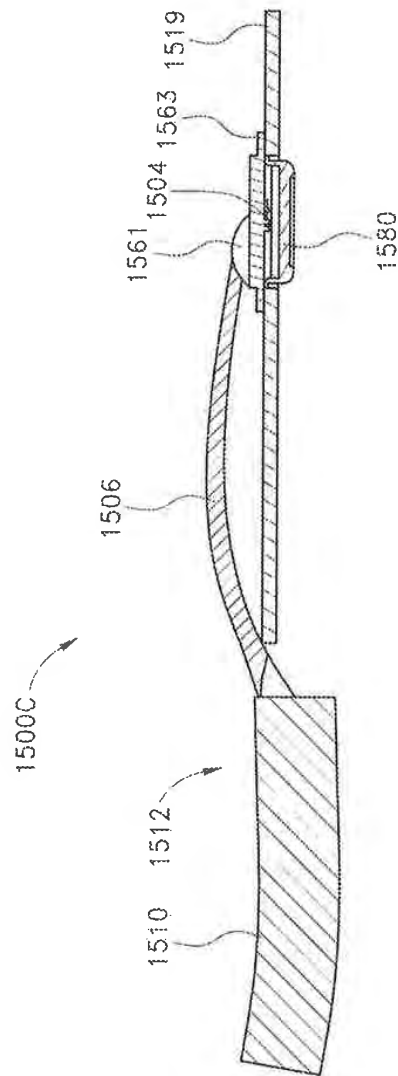


FIG. 15D

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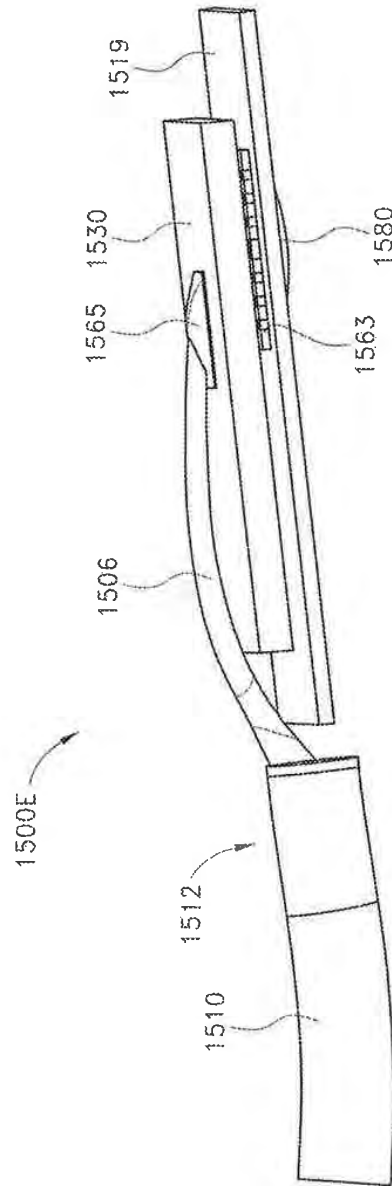


FIG. 15E

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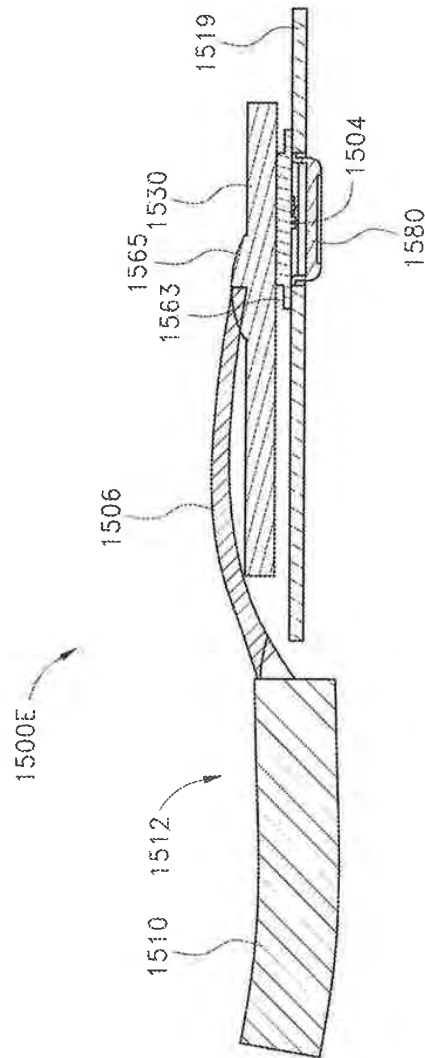


FIG. 15F

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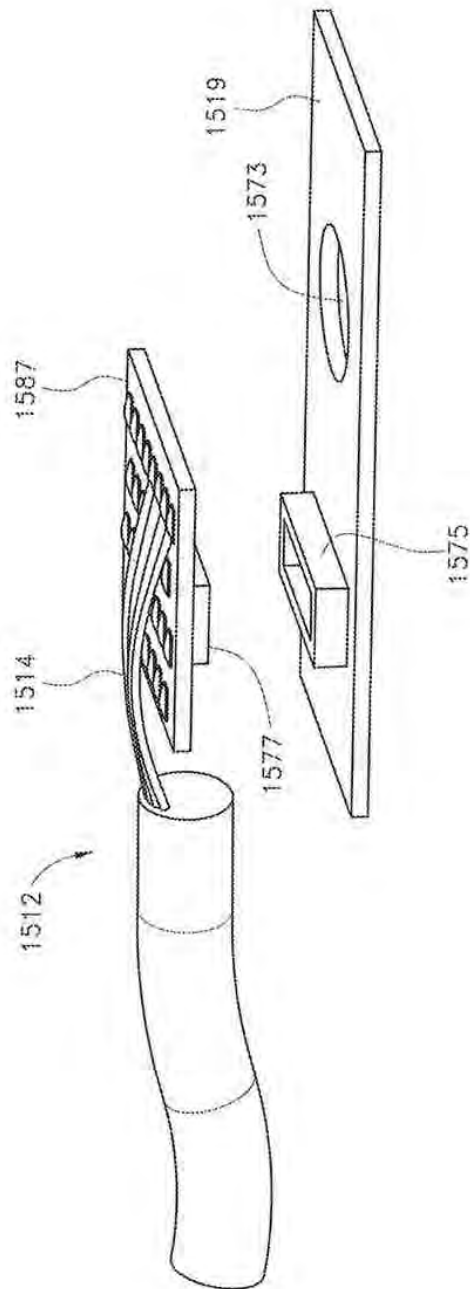


FIG. 15G

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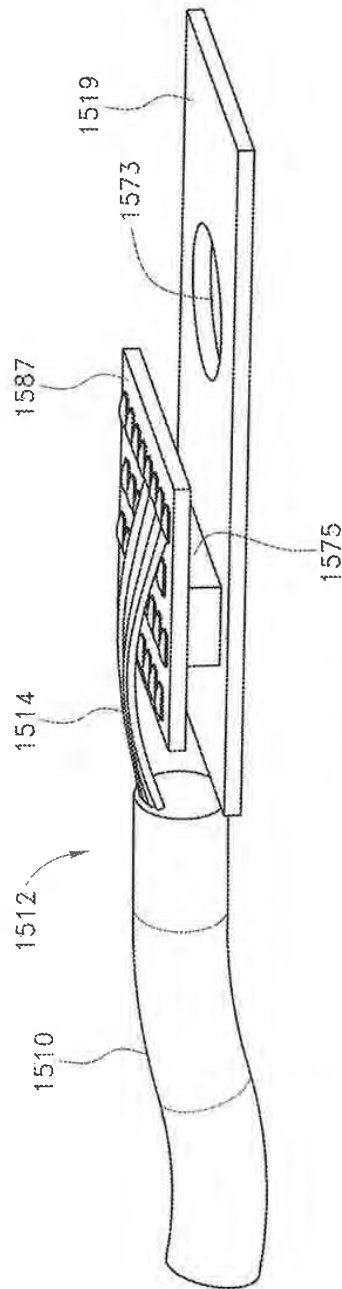


FIG. 15H

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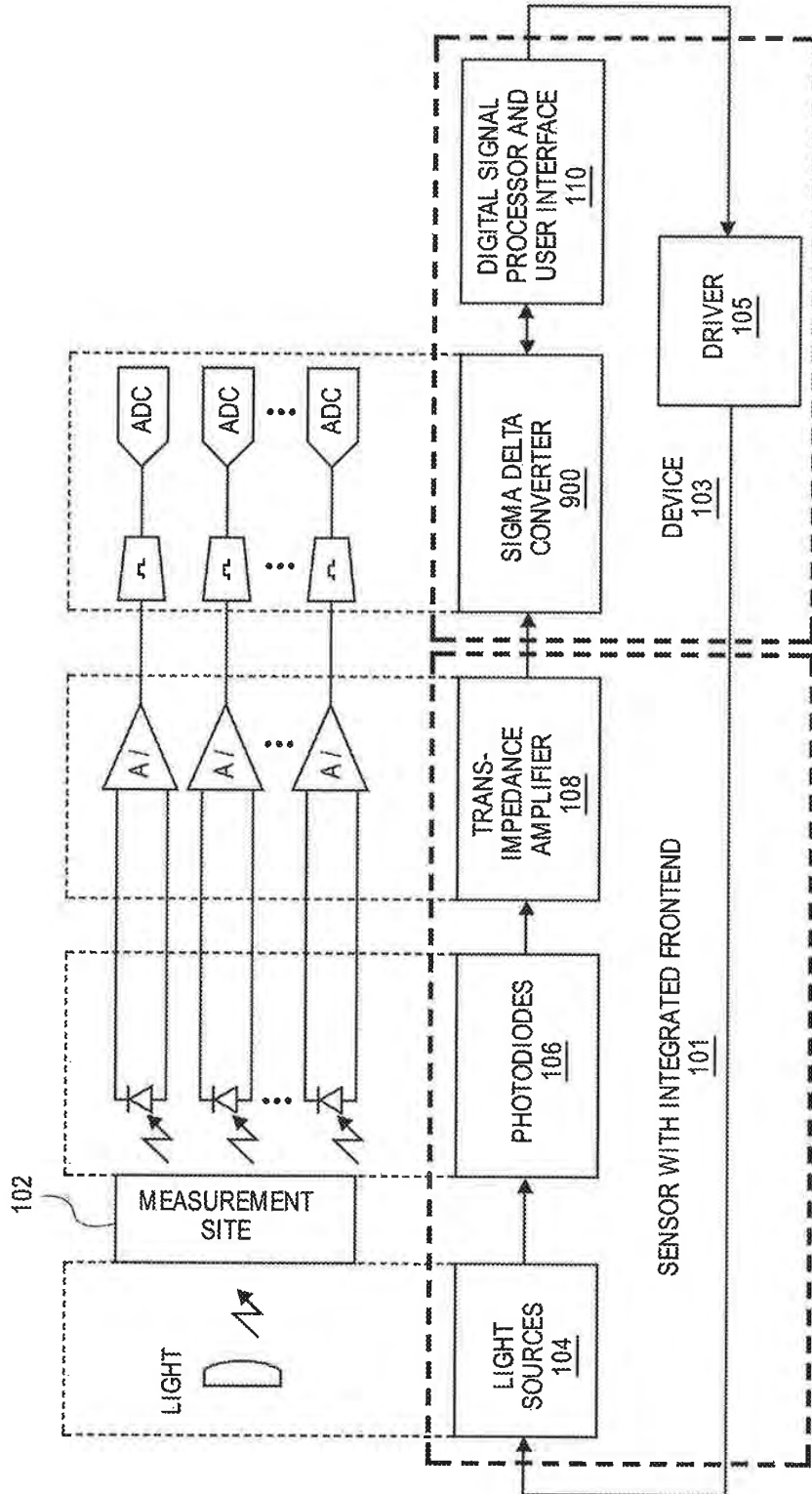


FIG. 151

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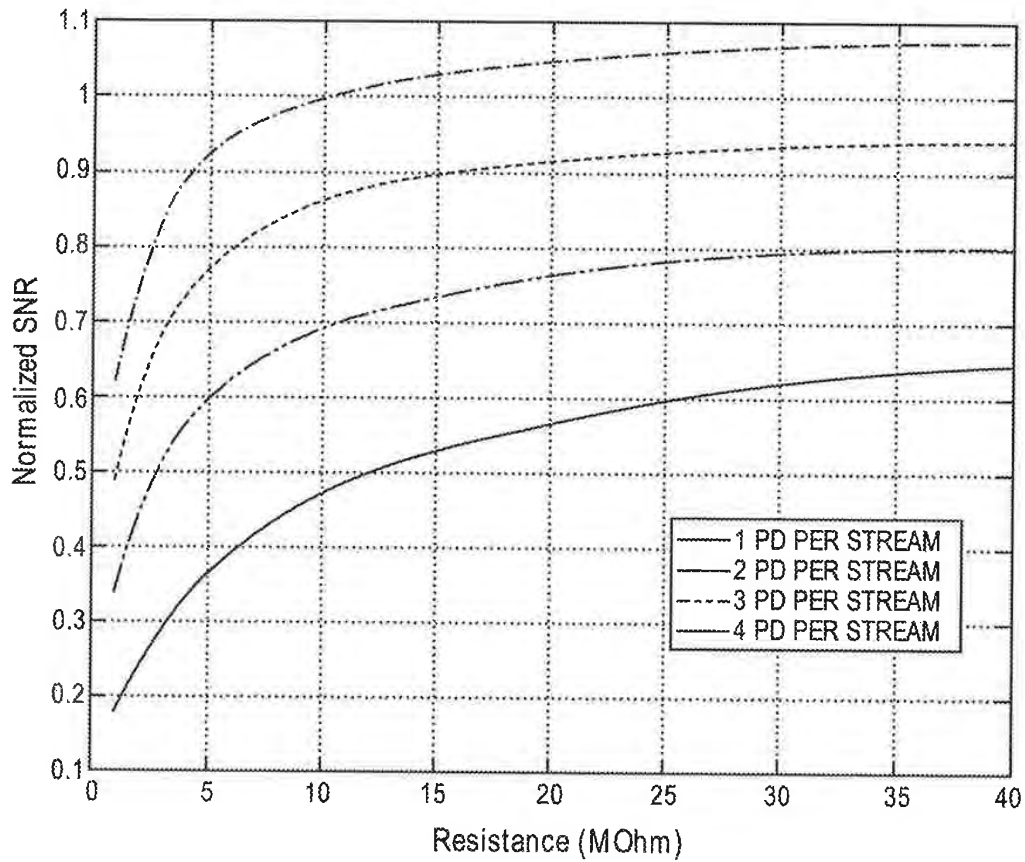


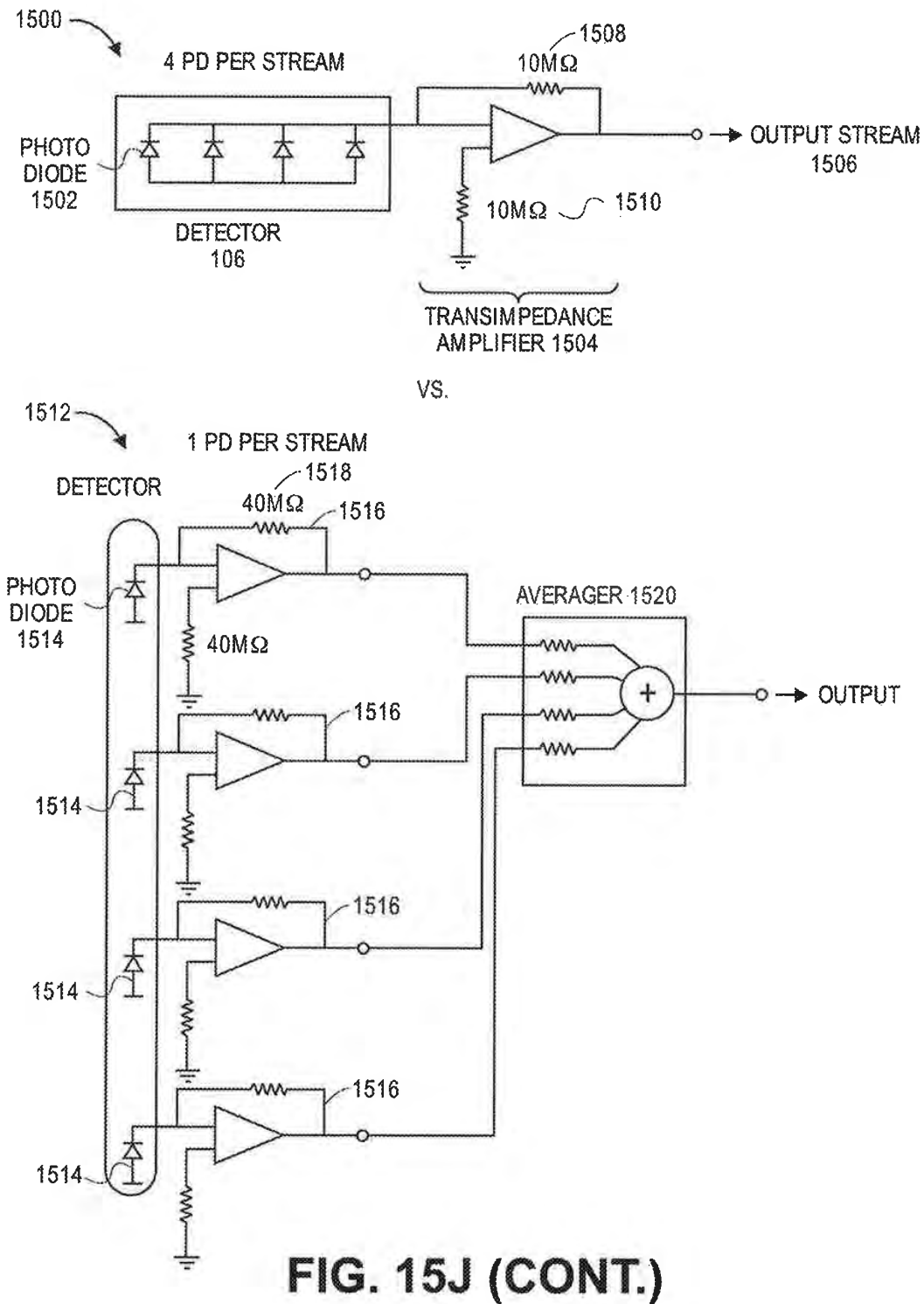
FIG. 15J

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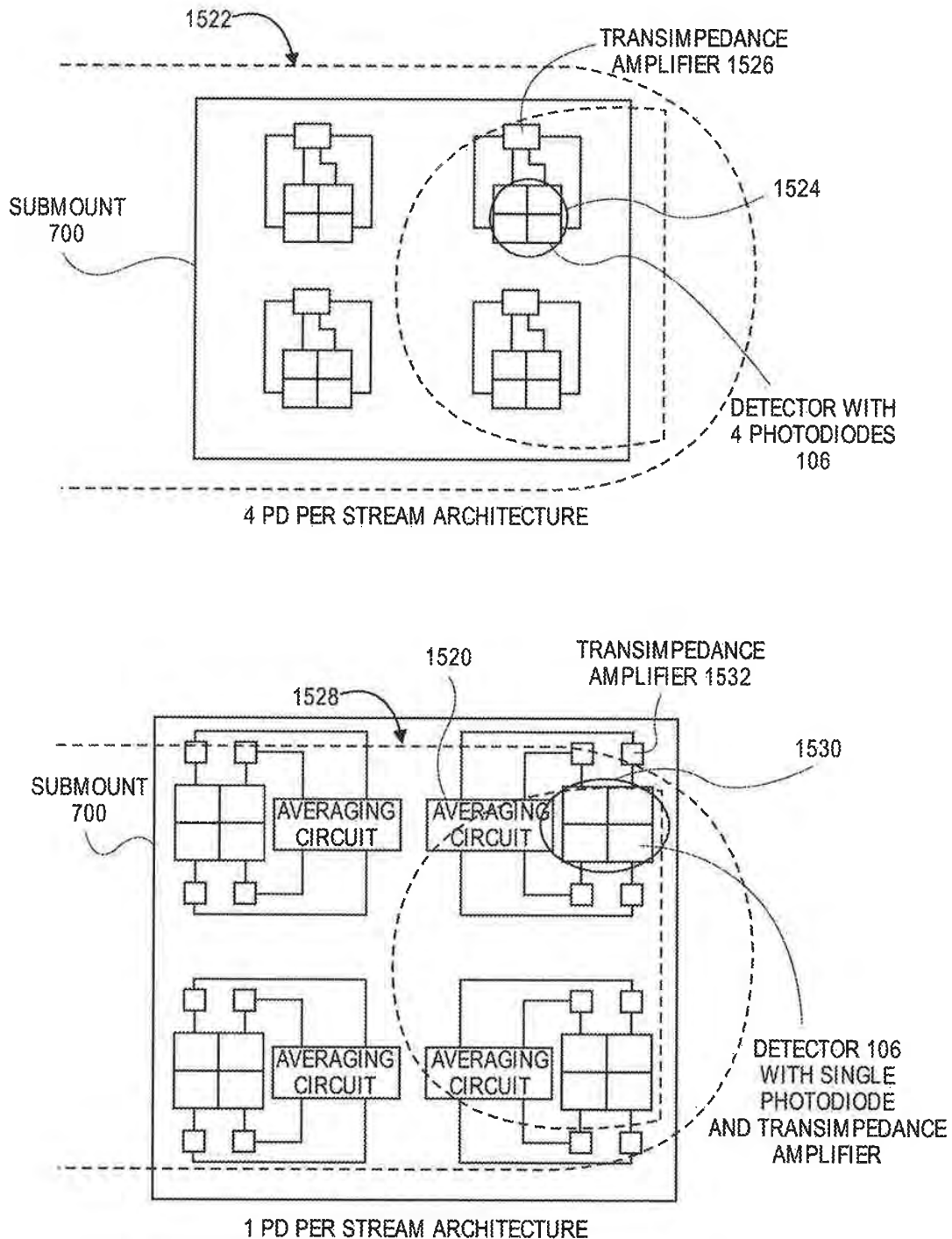


FIG. 15K

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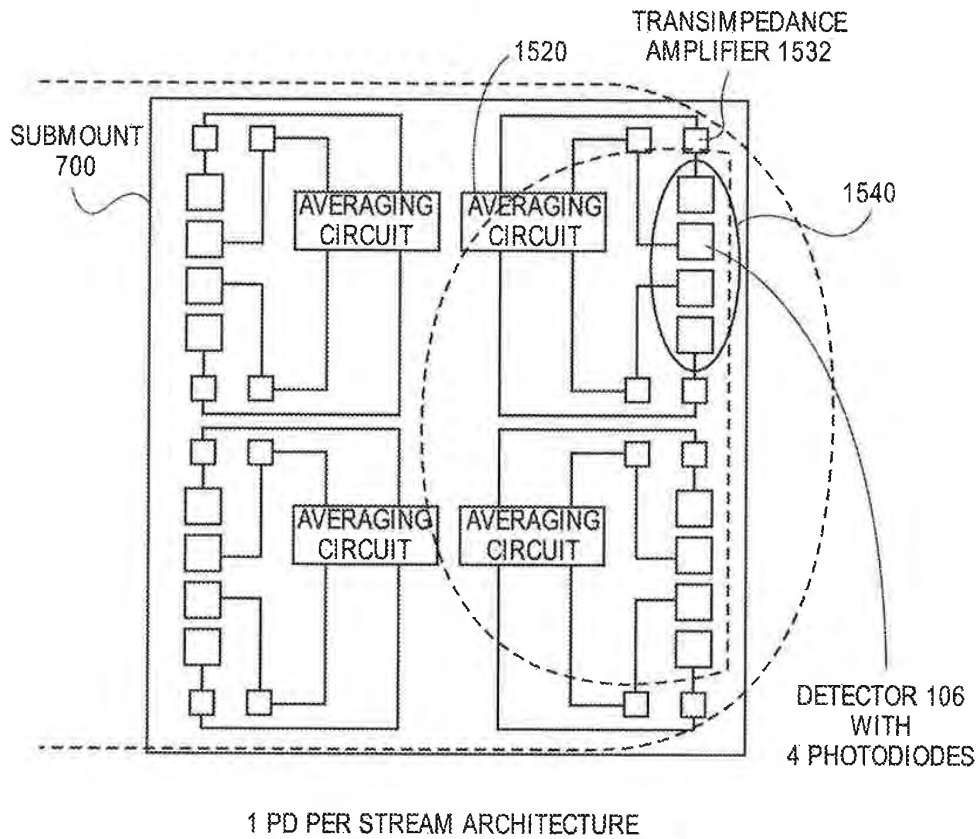
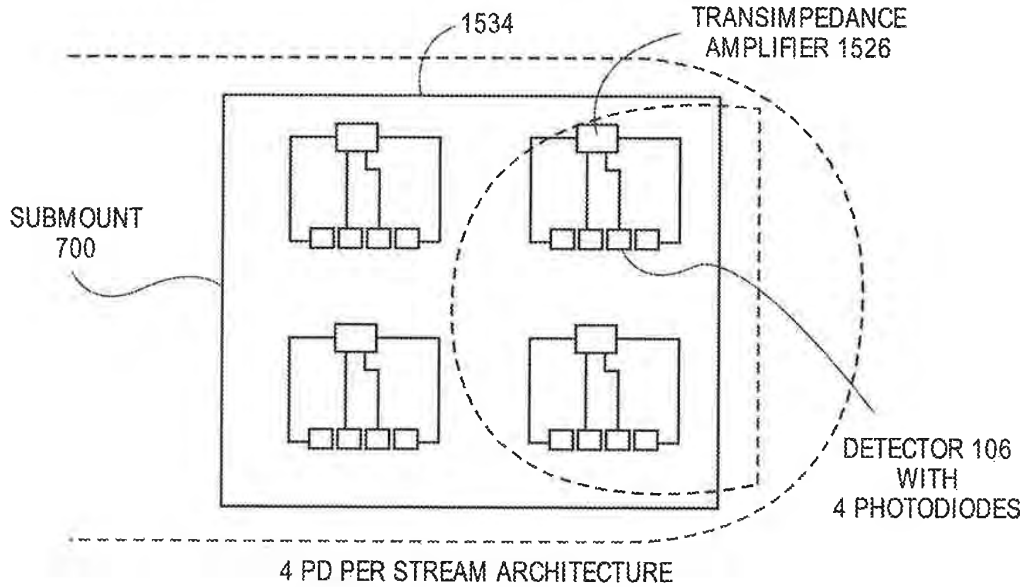


FIG. 15K (CONT.)

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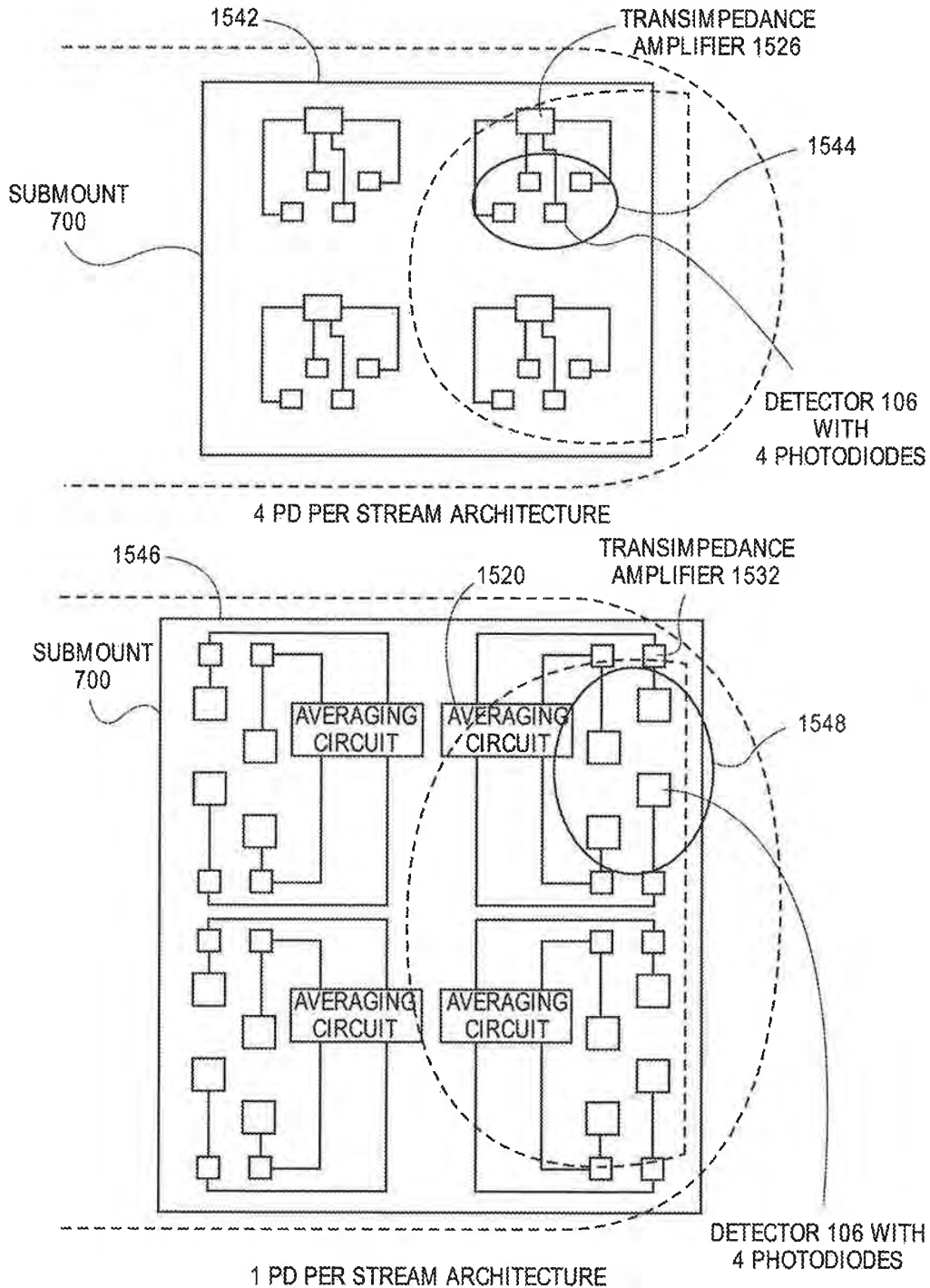


FIG. 15K (CONT.)

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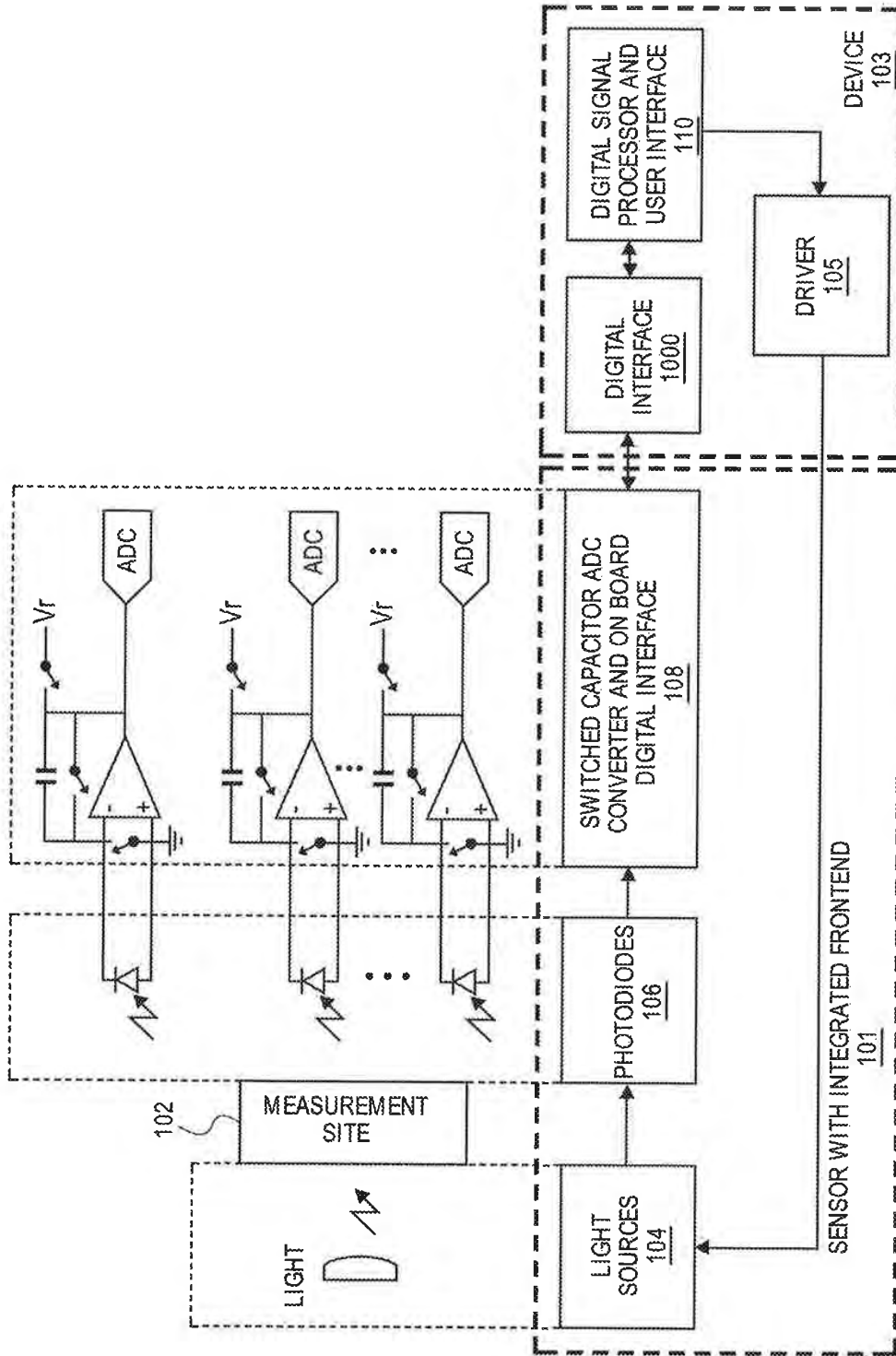


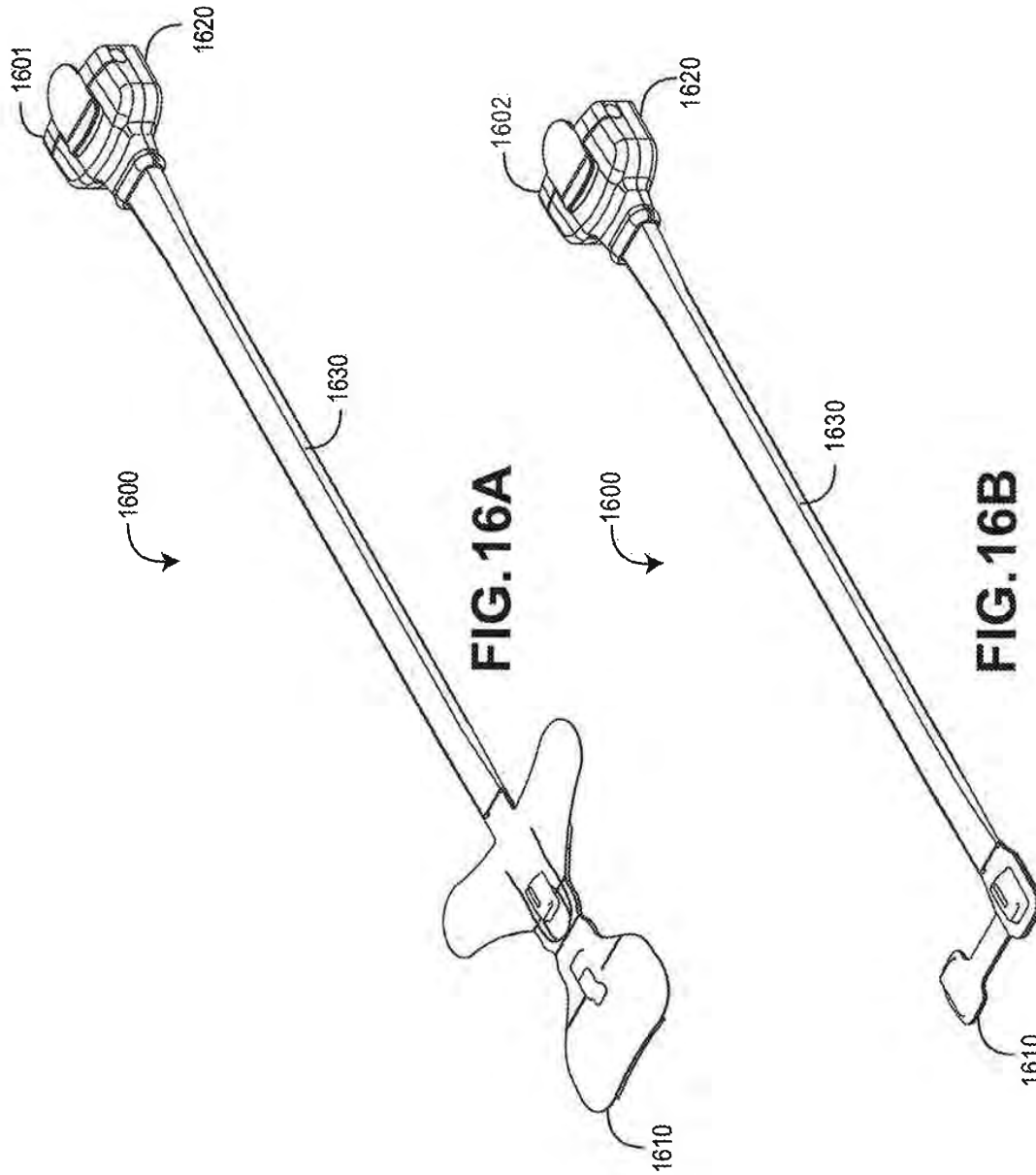
FIG. 15L

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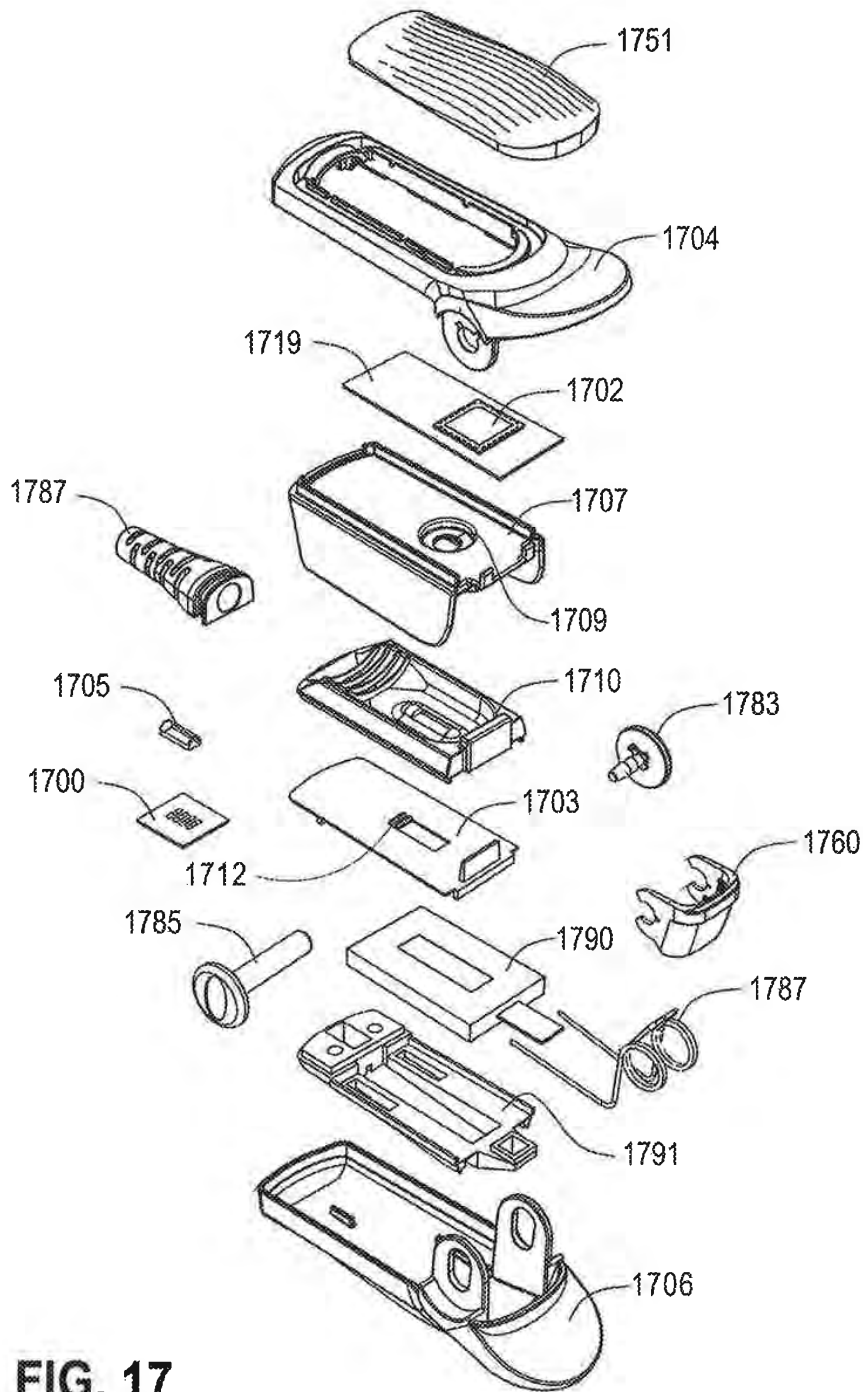


FIG. 17

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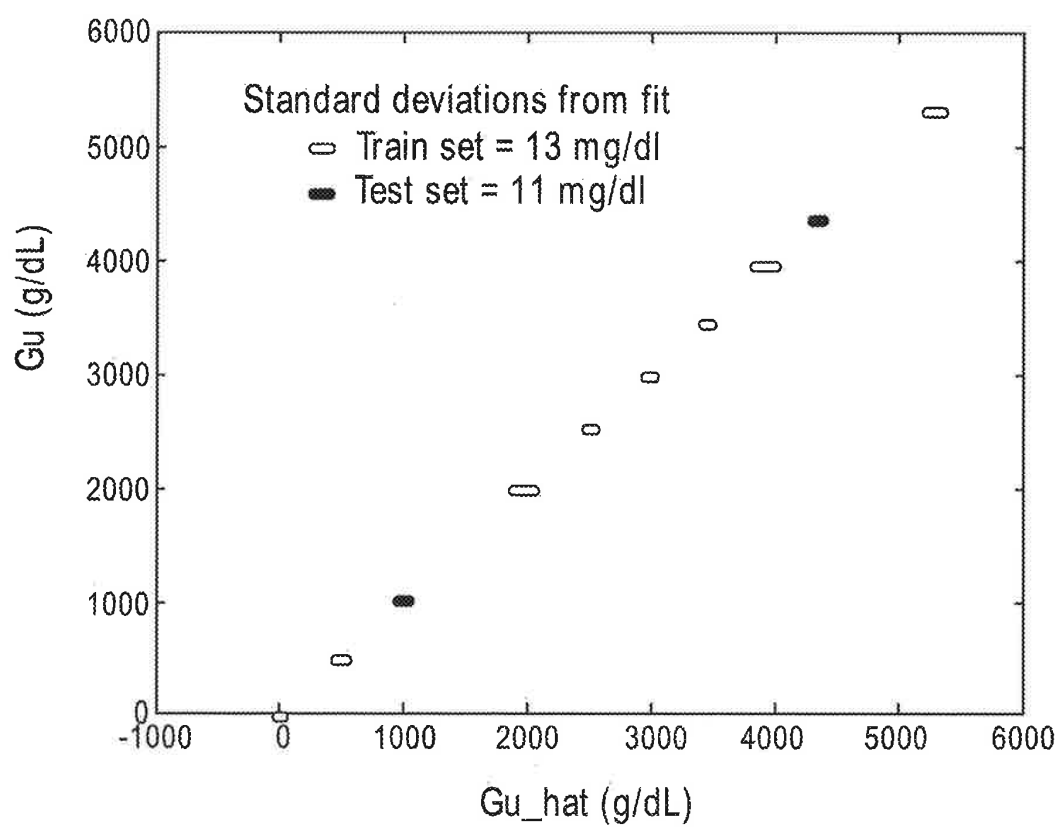


FIG. 18

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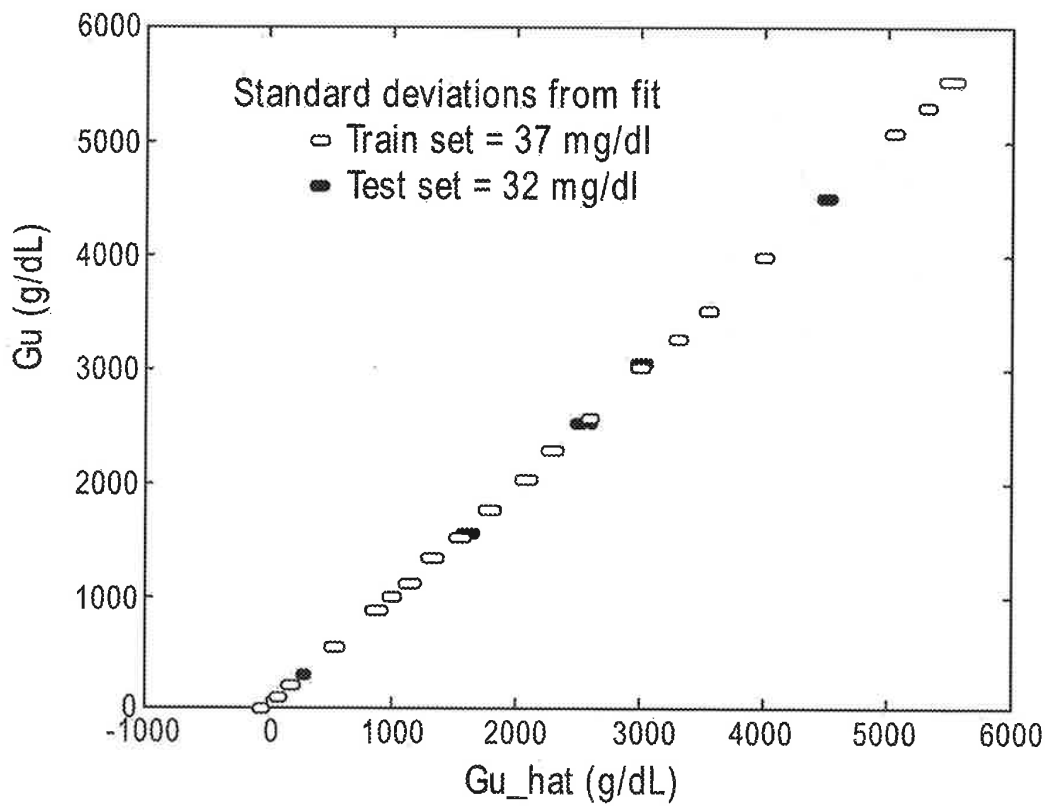


FIG. 19

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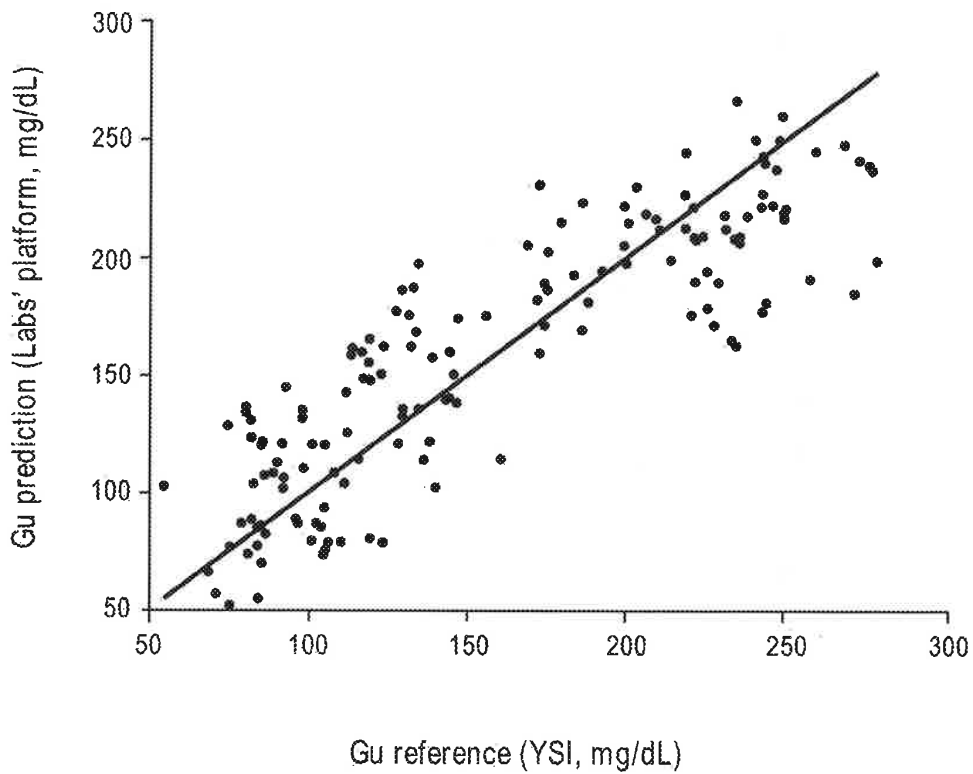


FIG. 20

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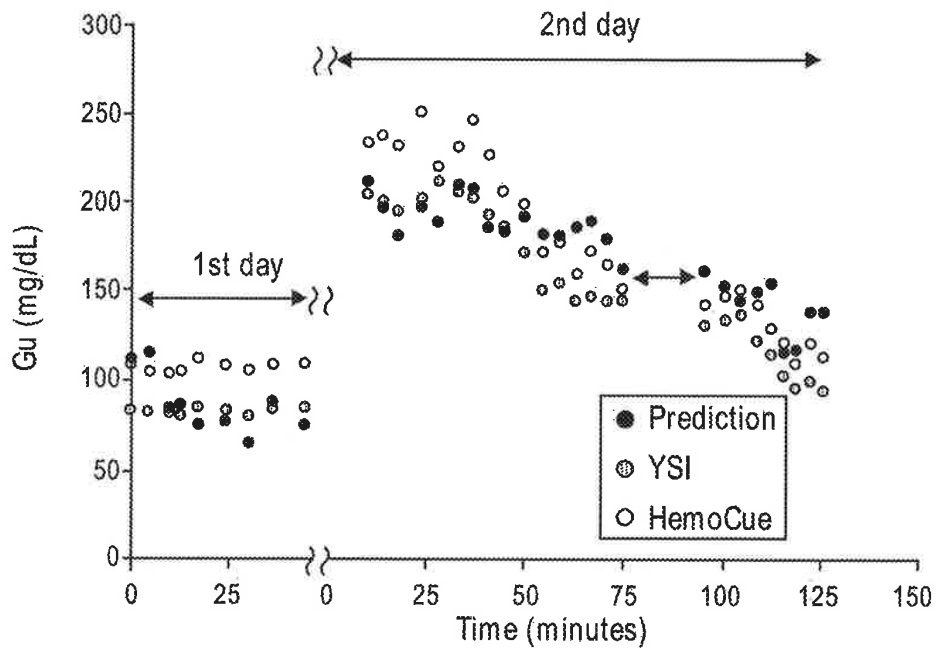


FIG. 21

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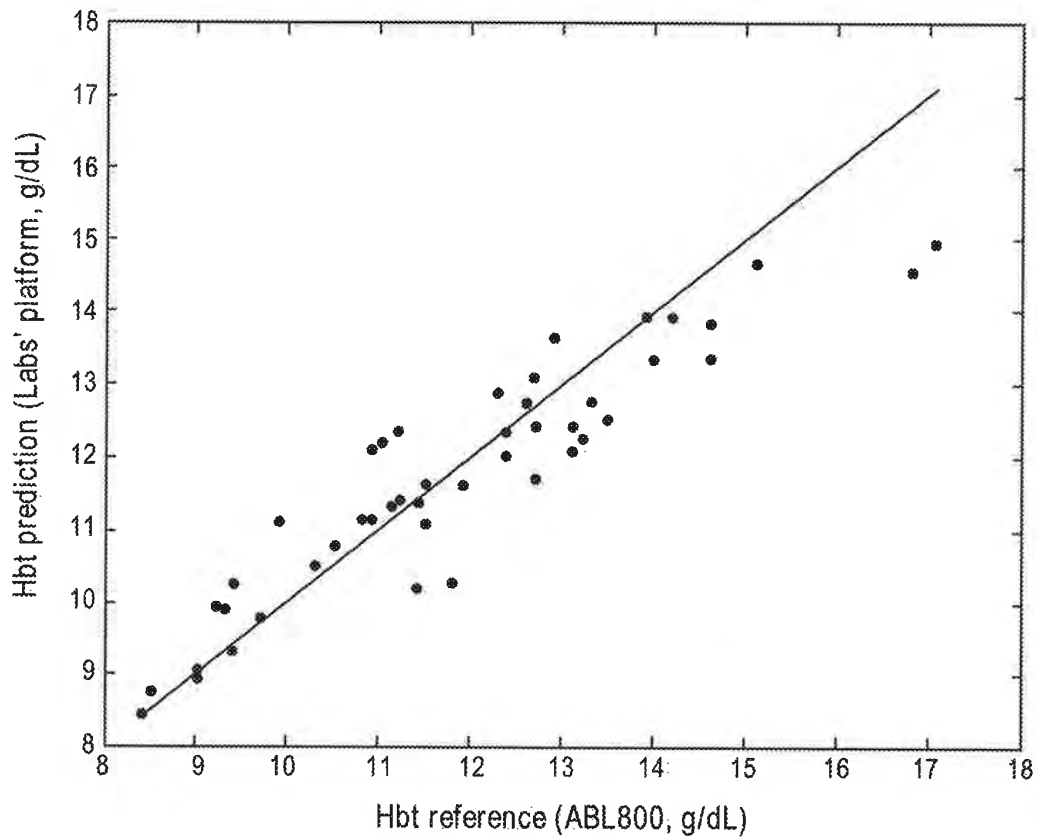


FIG. 22

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**USER-WORN DEVICE FOR
NONINVASIVELY MEASURING A
PHYSIOLOGICAL PARAMETER OF A USER**

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/834,538, filed Mar. 30, 2020, which is a continuation of U.S. patent application Ser. No. 16/725,292, filed Dec. 23, 2019, which is a continuation of U.S. patent application Ser. No. 16/534,949, filed Aug. 7, 2019, which is a continuation of U.S. patent application Ser. No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. patent application Ser. No. 16/261,326, filed Jan. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/212,537, filed Dec. 6, 2018, which is a continuation of U.S. patent application Ser. No. 14/981,290 filed Dec. 28, 2015, which is a continuation of U.S. patent application Ser. No. 12/829,352 filed Jul. 1, 2010, which is a continuation of U.S. patent application Ser. No. 12/534,827 filed Aug. 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,528 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Ser. No. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,523 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Ser. No. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008.

This application is related to the following U.S. Patent Applications:

| application Ser. No. | Filing Date | Title |
|----------------------|--------------|---|
| 12/497,528 | Jul. 2, 2009 | Noise Shielding for Noninvasive Device Contoured Protrusion for Improving Spectroscopic Measurement of Blood Constituents |
| 12/497,523 | Jul. 2, 2009 | Heat Sink for Noninvasive Medical Sensor |
| 12/497,506 | Jul. 2, 2009 | Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents |

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-continued

| application Ser. No. | Filing Date | Title |
|----------------------|--------------|---|
| 12/534,823 | Aug. 3, 2009 | Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents |
| 12/534,825 | Aug. 3, 2009 | Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents |

The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photo-detection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal (s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the non-invasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from

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said optical source after attenuation by the tissue of the measurement site and each output a respective signal stream responsive to the detected optical radiation.

In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the patient. The photodetectors are positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length.

In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the

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signals from the plurality of detectors into a digital output signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at

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sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. 1 illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

FIGS. 2A-2D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of FIG. 1, according to embodiments of the disclosure;

FIGS. 3A-3C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIG. 3D illustrates a side view of another example noninvasive sensor housing including a heat sink, according to an embodiment of the disclosure;

FIG. 3E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

FIG. 3F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIGS. 4A through 4C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

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FIG. 5 illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

FIGS. 6A through 6D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

FIG. 6E illustrates an example sensor incorporating the protrusion of FIGS. 6A through 6D, according to an embodiment of the disclosure;

FIGS. 7A through 7B illustrate example arrangements of conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIGS. 8A through 8D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIG. 9 shows example comparative results obtained by an embodiment of a sensor;

FIGS. 10A and 10B illustrate comparative noise floors of various embodiments of the present disclosure;

FIG. 11A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 12A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIGS. 12B through 12D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

FIGS. 12E through 12H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

FIG. 13 illustrates an example multi-stream operation of the system of FIG. 1, according to an embodiment of the disclosure;

FIG. 14A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion of FIG. 14A;

FIGS. 14C through 14E illustrate embodiments of a detector submount;

FIGS. 14F through 14H illustrate embodiment of portions of a detector shell;

FIG. 14I illustrates a cutaway view of an embodiment of a sensor;

FIGS. 15A through 15F illustrate embodiments of sensors that include heat sink features;

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described herein;

FIG. 15I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

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FIG. 15J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIG. 15I;

FIG. 15K shows different architectures and layouts for various embodiments of a sensor and its detectors;

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors;

FIG. 17 illustrates an exploded view of certain components of an example sensor; and

FIGS. 18 through 22 illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic,

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helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface.

The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of non-invasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metallicized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can

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be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that, in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modifications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter

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may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices. The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. 1 illustrates an example of a data collection system 100. In certain embodiments, the data collection system 100 noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system 100 can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The data collection system 100 can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system 100 can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm²-5 mm² (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase "at full scale" can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

The data collection system 100 can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system 100 can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired analytes. The data collection system 100 can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

The data collection system 100 can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a

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finger measurement site 102. However, the features of the embodiments disclosed herein can be used with other measurement sites 102.

In the depicted embodiment, the system 100 includes an optional tissue thickness adjuster or tissue shaper 105, which can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper 105 is a flat or substantially flat surface that can be positioned proximate the measurement site 102 and that can apply sufficient pressure to cause the tissue of the measurement site 102 to be flat or substantially flat. In other embodiments, the tissue shaper 105 is a convex or substantially convex surface with respect to the measurement site 102. Many other configurations of the tissue shaper 105 are possible. Advantageously, in certain embodiments, the tissue shaper 105 reduces thickness of the measurement site 102 while preventing or reducing occlusion at the measurement site 102. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

The embodiment of the data collection system 100 shown also includes an optional noise shield 103. In an embodiment, the noise shield 103 can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site 102 to one or more detectors 106 (described below). For example, the noise shield 103 can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor 101 or electrically grounded. In an embodiment where the noise shield 103 includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

In some embodiments, the measurement site 102 is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system 100 can be used on a person's non-dominant hand or arm.

The data collection system 100 can include a sensor 101 (or multiple sensors) that is coupled to a processing device or physiological monitor 109. In an embodiment, the sensor 101 and the monitor 109 are integrated together into a single unit. In another embodiment, the sensor 101 and the monitor 109 are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor 101 and monitor 109 can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor 101 and the monitor 109 will now be further described.

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In the depicted embodiment shown in FIG. 1, the sensor 101 includes an emitter 104, a tissue shaper 105, a set of detectors 106, and a front-end interface 108. The emitter 104 can serve as the source of optical radiation transmitted towards measurement site 102. As will be described in further detail below, the emitter 104 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

In some embodiments, the emitter 104 is used as a point optical source, and thus, the one or more optical sources of the emitter 104 can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters 104 can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sep. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters 104 can be arranged at least in part as described in paragraphs [0061] through [0068] of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters 104.

For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

In contrast, the emitter 104 of the data collection system 100 can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter 104 can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter 104 can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

In other embodiments, the emitter 104 can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better for analytes like glucose. Furthermore, in some embodiments, the emitter 104 can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

For example, the emitter 104 can emit optical radiation across other spectra for other analytes. In particular, the emitter 104 can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter 104 can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about

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1665 nm. In another embodiment, the emitter 104 can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, the emitter 104 can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system 100 can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

As briefly described above, the emitter 104 can include sets of light-emitting diodes (LEDs) as its optical source. The emitter 104 can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter 104 can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

The emitter 104 can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter 104 can employ SLEDs or side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter 104 can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO₂), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter 104 can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site 102.

In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter 104 can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter 104 to use LEDs with a higher output and/or to equalize intensity of LEDs.

The data collection system 100 also includes a driver 111 that drives the emitter 104. The driver 111 can be a circuit or the like that is controlled by the monitor 109. For example, the driver 111 can provide pulses of current to the emitter 104. In an embodiment, the driver 111 drives the emitter 104 in a progressive fashion, such as in an alternating manner. The driver 111 can drive the emitter 104 with a series of pulses of about 1 milliwatt (mW) for some wavelengths that can penetrate tissue relatively well and from

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about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

The driver 111 can be synchronized with other parts of the sensor 101 and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter 104. In some embodiments, the driver 111 is capable of driving the emitter 104 to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detectors 106 capture and measure light from the measurement site 102. For example, the detectors 106 can capture and measure light transmitted from the emitter 104 that has been attenuated or reflected from the tissue in the measurement site 102. The detectors 106 can output a detector signal 107 responsive to the light captured or measured. The detectors 106 can be implemented using one or more photodiodes, phototransistors, or the like.

In addition, the detectors 106 can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors 106. That is, some of the detectors 106 can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter 104. However, according to an embodiment, at least some of the detectors 106 can have a different path length from the emitter 104 relative to other of the detectors 106. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors 106. In some embodiments, the detectors 106 may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

The front end interface 108 provides an interface that adapts the output of the detectors 106, which is responsive to desired physiological parameters. For example, the front end interface 108 can adapt a signal 107 received from one or more of the detectors 106 into a form that can be processed by the monitor 109, for example, by a signal processor 110 in the monitor 109. The front end interface 108 can have its components assembled in the sensor 101, in the monitor 109, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface 108 can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front end interface 108 can be coupled to the detectors 106 and to the signal processor 110 using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface 108 can also be at least partially integrated with various components, such as the detectors 106. For example, the front end interface 108 can include one or more integrated circuits that are on the same circuit board as the detectors 106. Other configurations can also be used.

The front end interface 108 can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor 109), such as a sigma-delta ADC. A transimpedance-based front end interface 108 can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface 108 can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface 108

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can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter 104.

The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by the signal processor 110 of the monitor 109. Each channel can correspond to a signal output from a detector 106.

In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface 108. For example, the output of a transimpedance-based front end interface 108 can be output to a PGA that is coupled with an ADC in the monitor 109. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the detectors 106. Alternatively, the PGA and ADC components can be integrated with the transimpedance-based front end interface 108 in the sensor 101.

In another embodiment, the front end interface 108 can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface 108 can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface 108 can be useful because it can provide a digital signal to the signal processor 110 in the monitor 109.

As shown in FIG. 1, the monitor 109 can include the signal processor 110 and a user interface, such as a display 112. The monitor 109 can also include optional outputs alone or in combination with the display 112, such as a storage device 114 and a network interface 116. In an embodiment, the signal processor 110 includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors 106. The signal processor 110 can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor 110 can provide various signals that control the operation of the sensor 101. For example, the signal processor 110 can provide an emitter control signal to the driver 111. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter 104. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter 104 to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface 108 is used, the control signal from the signal processor 110 can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory 113 can be included in the front-end interface 108 and/or in the signal processor 110. This memory 113 can serve as a buffer or storage location for the front-end interface 108 and/or the signal processor 110, among other uses.

The user interface 112 can provide an output, e.g., on a display, for presentation to a user of the data collection system 100. The user interface 112 can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface 112 can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface 112 can include a flip screen, a screen that can be moved from one side to another on the monitor 109, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data

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collection system 100 can be provided without a user interface 112 and can simply provide an output signal to a separate display or system.

A storage device 114 and a network interface 116 represent other optional output connections that can be included in the monitor 109. The storage device 114 can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device 114, which can be executed by the signal processor 110 or another processor of the monitor 109. The network interface 116 can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor 109 to communicate and share data with other devices. The monitor 109 can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface 112, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the data collection system 100 can include various other components or can be configured in different ways. For example, the sensor 101 can have both the emitter 104 and detectors 106 on the same side of the measurement site 102 and use reflectance to measure analytes. The data collection system 100 can also include a sensor that measures the power of light emitted from the emitter 104.

FIGS. 2A through 2D illustrate example monitoring devices 200 in which the data collection system 100 can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices 200 shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system 100. In addition, certain of the features of the monitoring devices 200 shown in FIGS. 2A through 2D can be combined with features of the other monitoring devices 200 shown.

Referring specifically to FIG. 2A, an example monitoring device 200A is shown, in which a sensor 201a and a monitor 209a are integrated into a single unit. The monitoring device 200A shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor 201a includes an emitter shell 204a and a detector shell 206a. The depicted embodiment of the monitoring device 200A also includes various control buttons 208a and a display 210a.

The sensor 201a can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector 106 by forcing light back into the sensor 201a. Pads in the emitter shell 204a and the detector shell 206a can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell 204a and the detector shell 206a can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor 201a.

In some embodiments, some or all portions of the emitter shell 204a and/or detector shell 206a can be detachable and/or disposable. For example, some or all portions of the

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shells 204a and 206a can be removable pieces. The removability of the shells 204a and 206a can be useful for sanitary purposes or for sizing the sensor 201a to different patients. The monitor 209a can include a fitting, slot, magnet, or other connecting mechanism to allow the sensor 201c to be

removably attached to the monitor 209a. The monitoring device 200a also includes optional control buttons 208a and a display 210a that can allow the user to control the operation of the device. For example, a user can operate the control buttons 208a to view one or more measurements of various analytes, such as glucose. In addition, the user can operate the control buttons 208a to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many parameters, trends, alarms and parameter displays could be output to the display 210a, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo® Corporation of Irvine, Calif.

Furthermore, the controls 208a and/or display 210a can provide functionality for the user to manipulate settings of the monitoring device 200a, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device 200a can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

FIG. 2B illustrates another example of a monitoring device 200B. In the depicted embodiment, the monitoring device 200B includes a finger clip sensor 201b connected to a monitor 209b via a cable 212. In the embodiment shown, the monitor 209b includes a display 210b, control buttons 208b and a power button. Moreover, the monitor 209b can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor 201b, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

The cable 212 connecting the sensor 201b and the monitor 209b can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable 212 can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor 201b to the monitor 209b. Various lengths of the cable 212 can be employed to allow for separation between the sensor 201b and the monitor 209b. The cable 212 can be fitted with a connector (male or female) on either end of the cable 212 so that the sensor 201b and the monitor 209b can be connected and disconnected from each other. Alternatively, the sensor 201b and the monitor 209b can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

The monitor 209b can be attached to the patient. For example, the monitor 209b can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor 209b can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable 212 and sensor 201b to be attached to the monitor 209B.

The monitor 209b can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor 209b

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can include a display 210b that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor 209b.

In addition, although a single sensor 201b with a single monitor 209b is shown, different combinations of sensors and device pairings can be implemented. For example, multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

FIG. 2C illustrates yet another example of monitoring device 200C that can house the data collection system 100. Like the monitoring device 200B, the monitoring device 200C includes a finger clip sensor 201c connected to a monitor 209c via a cable 212. The cable 212 can have all of the features described above with respect to FIG. 2B. The monitor 209c can include all of the features of the monitor 200B described above. For example, the monitor 209c includes buttons 208c and a display 210c. The monitor 209c shown also includes straps 214c that allow the monitor 209c to be attached to a patient's limb or the like.

FIG. 2D illustrates yet another example of monitoring device 200D that can house the data collection system 100. Like the monitoring devices 200B and 200C, the monitoring device 200D includes a finger clip sensor 201d connected to a monitor 209d via a cable 212. The cable 212 can have all of the features described above with respect to FIG. 2B. In addition to having some or all of the features described above with respect to FIGS. 2B and 2C, the monitoring device 200D includes an optional universal serial bus (USB) port 216 and an Ethernet port 218. The USB port 216 and the Ethernet port 218 can be used, for example, to transfer information between the monitor 209d and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor 209b, and perform a variety of other functions. The USB port 216 and the Ethernet port 218 can be included with the other monitoring devices 200A, 200B, and 200C described above.

FIGS. 3A through 3C illustrate more detailed examples of embodiments of a sensor 301a. The sensor 301a shown can include all of the features of the sensors 100 and 200 described above.

Referring to FIG. 3A, the sensor 301a in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure 302a for receiving a patient's finger. The enclosure 302a is formed by an upper section or emitter shell 304a, which is pivotably connected with a lower section or detector shell 306a. The emitter shell 304a can be biased with the detector shell 306a to close together around a pivot point 303a and thereby sandwich finger tissue between the emitter and detector shells 304a, 306a.

In an embodiment, the pivot point 303a advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells 304a, 306a to effectively level the sections when applied to a tissue site. In another embodiment, the sensor 301a includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs [0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

The emitter shell 304a can position and house various emitter components of the sensor 301a. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metalized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell 304a can also include absorbing opaque mate-

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rial, such as, for example, black or grey colored material, at various areas, such as on one or more flaps 307a, to reduce ambient light entering the sensor 301a.

The detector shell 306a can position and house one or more detector portions of the sensor 301a. The detector shell 306a can be constructed of reflective material, such as white silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIG. 1). The detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308a, to reduce ambient light entering the sensor 301a.

Referring to FIGS. 3B and 3C, an example of finger bed 310 is shown in the sensor 301b. The finger bed 310 includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310 includes one or more ridges or channels 314. Each of the ridges 314 has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges 314 can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor 301a. The ridges 314 can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds 310.

Finger bed 310 can also include an embodiment of a tissue thickness adjuster or protrusion 305. The protrusion 305 includes a measurement site contact area 370 (see FIG. 3C) that can contact body tissue of a measurement site. The protrusion 305 can be removed from or integrated with the finger bed 310. Interchangeable, different shaped protrusions 305 can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

Referring specifically to FIG. 3C, the contact area 370 of the protrusion 305 can include openings or windows 320, 321, 322, and 323. When light from a measurement site passes through the windows 320, 321, 322, and 323, the light can reach one or more photodetectors (see FIG. 3E). In an embodiment, the windows 320, 321, 322, and 323 mirror specific detector placements layouts such that light can impinge through the protrusion 305 onto the photodetectors. Any number of windows 320, 321, 322, and 323 can be employed in the protrusion 305 to allow light to pass from the measurement site to the photodetectors.

The windows 320, 321, 322, and 323 can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows 320, 321, 322, and 323 can be made from materials, such as plastic or glass. In some embodiments, the windows 320, 321, 322, and 323 can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

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Turning to FIG. 3B, the sensor 301a can also include a shielding 315a, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding 315a is provided in the depicted embodiment below or embedded within the protrusion 305 to reduce noise. The shielding 315a can be constructed from a conductive material, such as copper. The shielding 315a can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the windows 320, 321, 322, and 323 on an external surface of the protrusion 305 (see FIG. 3C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIG. 3E).

In some embodiments, the shielding cage for shielding 315a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion 305 (see FIG. 3E). In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm² to about 60 mm² was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion 305 can be selected. In making such determinations, consideration can be made of protrusion's 305 effect on blood flow at the measurement site and mean path length for optical radiation passing through openings 320, 321, 322, and 323. Patient comfort can also be considered in determining the size and shape of the protrusion.

In an embodiment, the protrusion 305 can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and tactility by conforming the measurement site contact area 370 to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light. Alternatively, the protrusion 305 can be made from a rigid material, such as hard plastic or metal.

Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area 370. The contact area 370 can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion 305 can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion 305 and the contact area 370 can include a combination of materials with various characteristics.

The contact area 370 serves as a contact surface for the measurement site. For example, in some embodiments, the contact area 370 can be shaped for contact with a patient's finger. Accordingly, the contact area 370 can be sized and shaped for different sizes of fingers. The contact area 370 can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example,

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the contact area 370 can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

The formulas and analysis that follow with respect to FIG. 5 provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

Referring to FIG. 5, a plot 500 is shown that illustrates examples of effects of embodiments of the protrusion 305 on the SNR at various wavelengths of light. As described above, the protrusion 305 can assist in conforming the tissue and effectively reduce its mean path length. In some instances, this effect by the protrusion 305 can have significant impact on increasing the SNR.

According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I = I_0 * e^{-m * b * c}$, where I_0 is the initial power of light being transmitted, m is the path length traveled by the light, and the component "b*c" corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1} . Assuming a typical finger thickness of about 12 mm and a mean path length of 20 mm due to tissue scattering, then $I = I_0 * e^{(-20 * 0.7)}$.

In an embodiment where the protrusion 305 is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box 510). This results in a new transmittance, $I_1 = I_0 * e^{(-16.6 * 0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot 500 of FIG. 5. The plot 500 illustrates potential effects of the protrusion 305 on the transmittance. As illustrated, comparing I and I_1 results in an intensity gain of $e^{(-16.6 * 0.7) / e^{(-20 * 0.7)}}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1} . The plot 500 also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

Turning again to FIGS. 3A through 3C, an example heat sink 350a is also shown. The heat sink 350a can be attached to, or protrude from an outer surface of, the sensor 301a, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor 301a in certain embodiments, the heat sink 350a can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see FIG. 1) generate sufficient heat that inclusion of the heat sink 350a can advantageously allow the sensor 301a to remain safely cooled. The heat sink 350a can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell 304a can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

In some embodiments, the heat sink 350a includes metallicized plastic. The metallicized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink 350a can include a thermally conductive liquid crystalline

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polymer, such as CoolPoly® D5506, commercially available from Cool Polymers®, Inc. of Warwick, R.I. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink 350a provides improved heat transfer properties when the sensor 301a is active for short intervals of less than a full day's use. In an embodiment, the heat sink 350a can advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink 350a can be selected that performs effectively in shorter or longer intervals.

Moreover, the heat sink 350a can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink 350a is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink 350a shown includes fins 351a (see FIG. 3A).

An alternative shape of a sensor 301b and heat sink 350b is shown in FIG. 3D. The sensor 301b can include some or all of the features of the sensor 301a. For example, the sensor 301b includes an enclosure 302b formed by an emitter shell 304b and a detector shell 306b, pivotably connected about a pivot 303a. The emitter shell 304b can also include absorbing opaque material on one or more flaps 307b, and the detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308b. However, the shape of the sensor 301b is different in this embodiment. In particular, the heat sink 350b includes comb protrusions 351b. The comb protrusions 351b are exposed to the air in a similar manner to the fins 351a of the heat sink 350a, thereby facilitating efficient cooling of the sensor 301b.

FIG. 3E illustrates a more detailed example of a detector shell 306b of the sensor 301b. The features described with respect to the detector shell 306b can also be used with the detector shell 306a of the sensor 301a.

As shown, the detector shell 306b includes detectors 316. The detectors 316 can have a predetermined spacing 340 from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors 316 and the emitter discussed above.

In the depicted embodiment, the detector shell 316 can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site 102). In the detector shell 316, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell 316 can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

As further illustrated by FIG. 3E, the detectors 316 can have a spatial configuration of a grid. However, the detectors 316 can be arranged in other configurations that vary the path length. For example, the detectors 316 can be arranged in a linear array, a logarithmic array, a two-dimensional

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array, a zig-zag pattern, or the like. Furthermore, any number of the detectors 316 can be employed in certain embodiments.

FIG. 3F illustrates another embodiment of a sensor 301f. The sensor 301f can include some or all of the features of the sensor 301a of FIG. 3A described above. For example, the sensor 301f includes an enclosure 302f formed by an upper section or emitter shell 304f, which is pivotably connected with a lower section or detector shell 306f around a pivot point 303f. The emitter shell 304f can also include absorbing opaque material on various areas, such as on one or more flaps 307f, to reduce ambient light entering the sensor 301f. The detector shell 306f can also include absorbing opaque material at various areas, such as a lower area 308f. The sensor 301f also includes a heat sink 350f, which includes fins 351f.

In addition to these features, the sensor 301f includes a flex circuit cover 360, which can be made of plastic or another suitable material. The flex circuit cover 360 can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell 304f to the detector shell 306f. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIG. 46 and associated description, which is hereby specifically incorporated by reference). The flex circuit cover 360 is shown in more detail below in FIG. 17.

In addition, sensors 301a-f has extra length—extends to second joint on finger—Easier to place, harder to move due to cable, better for light piping.

FIGS. 4A through 4C illustrate example arrangements of a protrusion 405, which is an embodiment of the protrusion 305 described above. In an embodiment, the protrusion 405 can include a measurement site contact area 470. The measurement site contact area 470 can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

The protrusion 405 can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion 405 can have a length 400, a width 410, and a height 430. The length 400 can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width 410 can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

The measurement site contact area 470 can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site. The measurement site contact area 470 can be other shapes that reduce or even minimize air between the protrusion 405 and/or the measurement site. Additionally, the surface pattern of the measurement site contact area 470 can vary from smooth to bumpy, e.g., to provide varying levels of grip.

In FIGS. 4A and 4C, openings or windows 420, 421, 422, and 423 can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows 420, 421, 422, and 423 can be of non-uniform shapes and sizes. As shown, the windows 420, 421, 422, and 423 can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of

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arranging the windows 420, 421, 422, and 423 are possible. For example, the windows 420, 421, 422, and 423 can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows 420, 421, 422, and 423 can be placed at different heights with respect to the finger bed 310 of FIG. 3. The windows 420, 421, 422, and 423 can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

FIGS. 6A through 6D illustrate another embodiment of a protrusion 605 that can be used as the tissue shaper 105 described above or in place of the protrusions 305, 405 described above. The depicted protrusion 605 is a partially cylindrical lens having a partial cylinder 608 and an extension 610. The partial cylinder 608 can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion 605 focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

FIG. 6A illustrates a perspective view of the partially cylindrical protrusion 605. FIG. 6B illustrates a front elevation view of the partially cylindrical protrusion 605. FIG. 6C illustrates a side view of the partially cylindrical protrusion 605. FIG. 6D illustrates a top view of the partially cylindrical protrusion 605.

Advantageously, in certain embodiments, placing the partially cylindrical protrusion 605 over the photodiodes in any of the sensors described above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion 605 penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

The partially cylindrical protrusion 605 can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion 605 can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIG. 14). If fewer or smaller photodiodes are used, the partially cylindrical protrusion 605 can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

The dimensions of the partially cylindrical protrusion 605 can vary based on, for instance, a number of photodiodes used with the sensor. Referring to FIG. 6C, the overall height of the partially cylindrical protrusion 605 (measurement "a") in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion 605 to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion 605 can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion 605 is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

Referring to FIG. 6D, the width of the partially cylindrical protrusion 605 (measurement "b") can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration

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of the partially cylindrical protrusion 605 into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the width of the partially cylindrical protrusion 605 can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion 605 could be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

In certain embodiments, the focal length (f) for the partially

$$f = \frac{R}{n-1},$$

cylindrical protrusion 605 can be expressed as: where R is the radius of curvature of the partial cylinder 608 and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion 605 can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

A partially cylindrical protrusion 605 having a material with a higher index of refraction such as nSF11 glass (e.g., $n=1.75$ at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion 605 can be chosen to improve or optimize the light focusing properties of the protrusion 605. A plastic partially cylindrical protrusion 605 could provide the cheap-est option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion 605.

Placing a photodiode at a given distance below the partially cylindrical protrusion 605 can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIG. 14). Different sizes of the partially cylindrical protrusion 605 can use different sizes of photodiodes. The extension 610 added onto the bottom of the partial cylinder 608 is used in certain embodiments to increase the height of the partially cylindrical protrusion 605. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion 605. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension 610 can also further facilitate the protrusion 605 increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension 610 can be omitted.

FIG. 6E illustrates another view of the sensor 301f of FIG. 3F, which includes an embodiment of a partially cylindrical protrusion 605b. Like the sensor 301A shown in FIGS. 3B and 3C, the sensor 301f includes a finger bed 310f. The finger bed 310f includes a generally curved surface shaped

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generally to receive tissue, such as a human digit. The finger bed 310f also includes the ridges or channels 314 described above with respect to FIGS. 3B and 3C.

The example of finger bed 310f shown also includes the protrusion 605b, which includes the features of the protrusion 605 described above. In addition, the protrusion 605b also includes chamfered edges 607 on each end to provide a more comfortable surface for a finger to slide across (see also FIG. 14D). In another embodiment, the protrusion 605b could instead include a single chamfered edge 607 proximal to the ridges 314. In another embodiment, one or both of the chamfered edges 607 could be rounded.

The protrusion 605b also includes a measurement site contact area 670 that can contact body tissue of a measurement site. The protrusion 605b can be removed from or integrated with the finger bed 310f. Interchangeable, differently shaped protrusions 605b can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

FIGS. 7A and 7B illustrate block diagrams of sensors 701 that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide increased SNR. The features of the sensors 701 can be implemented with any of the sensors 101, 201, 301 described above. Although not shown, the partially cylindrical protrusion 605 of FIG. 6 can also be used with the sensors 701 in certain embodiments.

For example, referring specifically to FIG. 7A, the sensor 701a includes an emitter housing 704a and a detector housing 706. The emitter housing 704a includes LEDs 104. The detector housing 706a includes a tissue bed 710a with an opening or window 703a, the conductive glass 730a, and one or more photodiodes for detectors 106 provided on a submount 707a.

During operation, a finger 102 can be placed on the tissue bed 710a and optical radiation can be emitted from the LEDs 104. Light can then be attenuated as it passes through or is reflected from the tissue of the finger 102. The attenuated light can then pass through the opening 703a in the tissue bed 710a. Based on the received light, the detectors 106 can provide a detector signal 107, for example, to the front end interface 108 (see FIG. 1).

In the depicted embodiment, the conductive glass 730 is provided in the opening 703. The conductive glass 730 can thus not only permit light from the finger to pass to the detectors 106, but it can also supplement the shielding of the detectors 106 from noise. The conductive glass 730 can include a stack or set of layers. In FIG. 7A, the conductive glass 730a is shown having a glass layer 731 proximate the finger 102 and a conductive layer 733 electrically coupled to the shielding 790a.

In an embodiment, the conductive glass 730a can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure 790a, the conductive glass 730a can be electrically coupled to the shielding enclosure 790a. The conductive glass 730a can be electrically coupled to the shielding 704a based on direct contact or via other connection devices, such as a wire or another component.

The shielding enclosure 790a can be provided to encompass the detectors 106 to reduce or prevent noise. For example, the shielding enclosure 790a can be constructed from a conductive material, such as copper, in the form of a

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metal cage. The shielding or enclosure can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

In some embodiments, the shielding enclosure 790a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure 790a can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

Referring to FIG. 7B, another block diagram of an example sensor 701b is shown. A tissue bed 710b of the sensor 701b includes a protrusion 705b, which is in the form of a convex bump. The protrusion 705b can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion 705b includes a contact area 370 that comes in contact with the finger 102 and which can include one or more openings 703b. One or more components of conductive glass 730b can be provided in the openings 703. For example, in an embodiment, each of the openings 703 can include a separate window of the conductive glass 730b. In an embodiment, a single piece of the conductive glass 730b can be used for some or all of the openings 703b. The conductive glass 730b is smaller than the conductive glass 730a in this particular embodiment.

A shielding enclosure 790b is also provided, which can have all the features of the shielding enclosure 790a. The shielding enclosure 790b is smaller than the shielding enclosure 790a; however, a variety of sizes can be selected for the shielding enclosures 790.

In some embodiments, the shielding enclosure 790b can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure 790b can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

FIGS. 8A through 8D illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors 701a, 701b. As shown in the perspective view of FIG. 8A and side view of FIG. 8B, the conductive glass 730 includes the electrically conductive material 733 described above as a coating on the glass layer 731 described above to form a stack. In an embodiment where the electrically conductive material 733 includes indium tin oxide, surface resistivity of the electrically conductive material 733 can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material 733.

Although the conductive material 733 is shown spread over the surface of the glass layer 731, the conductive material 733 can be patterned or provided on selected portions of the glass layer 731. Furthermore, the conductive material 733 can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

In FIG. 8C, a side view of a conductive glass 830a is shown to illustrate an embodiment where the electrically

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conductive material 733 is provided as an internal layer between two glass layers 731, 835. Various combinations of integrating electrically conductive material 733 with glass are possible. For example, the electrically conductive material 733 can be a layer within a stack of layers. This stack of layers can include one or more layers of glass 731, 835, as well as one or more layers of conductive material 733. The stack can include other layers of materials to achieve desired characteristics.

In FIG. 8D, a bottom perspective view is shown to illustrate an embodiment where a conductive glass 830b can include conductive material 837 that occupies or covers a portion of a glass layer 839. This embodiment can be useful, for example, to create individual, shielded windows for detectors 106, such as those shown in FIG. 3C. The conductive material 837 can be patterned to include an area 838 to allow light to pass to detectors 106 and one or more strips 841 to couple to the shielding 704 of FIG. 7.

Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

FIG. 9 depicts an example graph 900 that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGS. 7 and 8. The graph 900 depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

A line 915 on the graph 900 illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line 920 on the graph 900 demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line 925 on the graph 900 shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line 930 on the graph 900 shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring. Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

FIGS. 10A through 10B illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In FIG. 10A, a graph 1000 depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above

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included separate windows for four (4) detectors **106**. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols **1030-1033** illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

In FIG. **10B**, a graph **1050** depicts a noise floor for frequencies of noise **1070** for an embodiment in which the sensor included separate openings for four (4) detectors **106** and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols **1080-1083** illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodiment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of FIG. **10A**.

FIG. **11A** illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter **104** can include a driver **1105**, a thermistor **1120**, a set of top-emitting LEDs **1102** for emitting red and/or infrared light, a set of side-emitting LEDs **1104** for emitting near infrared light, and a submount **1106**.

The thermistor **1120** can be provided to compensate for temperature variations. For example, the thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** and **1104** due to heating. In addition, other thermistors can be employed, for example, to measure a temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement site. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

The driver **1105** can provide pulses of current to the emitter **1104**. In an embodiment, the driver **1105** drives the emitter **1104** in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor **110**). For example, the driver **1105** can drive the emitter **1104** with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver **1105** can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter **1104**. In some embodiments, the driver **1105** is capable of driving the emitter **1104** to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

The submount **1106** provides a support structure in certain embodiments for aligning the top-emitting LEDs **1102** and the side-emitting LEDs **1104** so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount **1106** is also constructed of aluminum nitride (AlN) or beryllium oxide (BEO) for heat

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dissipation, although other materials or combinations of materials suitable for the submount **1106** can be used.

FIG. **11B** illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter **104** may be driven in a progressive fashion to minimize noise and increase SNR of sensor **101**. For example, emitter **104** may be driven based on a progression of power/current delivered to LEDs **1102** and **1104**.

In some embodiments, emitter **104** may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter **104** may emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, emitter **104** may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

For purposes of illustration, FIG. **11B** shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs **1102**. FIG. **11B** also shows that emitter **104** may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs **1104**. Emitter **104** may be progressively driven at higher power/current. This progression may allow driver circuit **105** to stabilize in its operations, and thus, provide a more stable current/power to LEDs **1102** and **1104**.

For example, as shown in FIG. **11B**, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term "slots" includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs **1102** may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4 time slots in between. In addition, pulses from side emitting LEDs **1104** (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit **1105** to stabilize after operating at higher current/power.

As shown in FIG. **11B**, top emitting LEDs **1102** may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs **1102** may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs **502** for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter **104**.

Subsequently, side emitting LEDs **1104** may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site **102** to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment,

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the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the current needed to drive side emitting LEDs 1104. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter 104.

As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit 1105 to stabilize its power delivery to LEDs 1102 and 1104. Driver circuit 1105 may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a variable waiting period to allow for stabilization of driver circuit 1105. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system 100. That is, as the duty cycle is increased so may the signal to noise ratio.

Furthermore, as noted above, driver circuit 1105 may monitor temperatures of the LEDs 1102 and 1104 using the thermistor 1120 and adjust the output of LEDs 1102 and 1104 accordingly. Such a temperature may be to help sensor 101 correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter 104 can include components mounted on a substrate 1108 and on submount 1106. In particular, top-emitting LEDs 1102 for emitting red and/or infrared light may be mounted on substrate 1108. Side emitting LEDs 1104 may be mounted on submount 1106. As noted, side-emitting LEDs 1104 may be included in emitter 104 for emitting near infrared light.

As also shown, the sensor of FIG. 11C may include a thermistor 1120. As noted, the thermistor 1120 can be provided to compensate for temperature variations. The thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In some embodiments, the emitter 104 may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. In particular, an emitter 104 that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter 104 can include components mounted on a substrate 1108. In particular, top-emitting LEDs 1102 for emitting red and/or infrared light may be mounted on substrate 1108.

As also shown, the emitter of FIG. 11D may include a thermistor 1120. The thermistor 1120 can be provided to compensate for temperature variations. The thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 due to heating.

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FIG. 12A illustrates a detector submount 1200 having photodiode detectors that are arranged in a grid pattern on the detector submount 1200 to capture light at different quadrants from a measurement site. One detector submount 1200 can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount 1200. The detector submount 1200 can also be used with the partially cylindrical protrusion 605 described above with respect to FIG. 6.

The detectors include photodiode detectors 1-4 that are arranged in a grid pattern on the submount 1200 to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

As shown, the detectors 1-4 may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors 106 and the point light source discussed above.

Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site 102). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

FIGS. 12B through 12D illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors 106. As shown, detectors 106 may comprise photodiode detectors 1-4 that are arranged in a grid pattern on detector submount 1200 to capture light at different quadrants from measurement site 102.

As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors 106 may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors 106 may be employed by embodiments of the present disclosure.

For example, as shown in FIG. 12B, detectors 106 may comprise photodiode detectors 1-4 that are arranged in a substantially linear configuration on submount 1200. In this embodiment shown, photodiode detectors 1-4 are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors 1-4).

In FIG. 12C, photodiode detectors 1-4 may be arranged in a substantially linear configuration on submount 1200, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances $D_1 > D_2 > D_3$). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

In FIG. 12D, a different substantially grid pattern on submount 1200 of photodiode detectors 1-4 is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

FIGS. 12E through 12H illustrate several embodiments of photodiodes that may be used in detectors 106. As shown in

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these figures, a photodiode 1202 of detector 106 may comprise a plurality of active areas 1204. These active areas 204 may be coupled together via a common cathode 1206 or anode 1208 in order to provide a larger effective detection area.

In particular, as shown in FIG. 12E, photodiode 1202 may comprise two (2) active areas 1204a and 1204b. In FIG. 12F, photodiode 1202 may comprise four (4) active areas 1204c-f. In FIG. 12G, photodiode 1202 may comprise three (3) active areas 1204g-i. In FIG. 12H, photodiode 1202 may comprise nine (9) active areas 1204j-r. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode 1202.

FIG. 13 illustrates an example multi-stream process 1300. The multi-stream process 1300 can be implemented by the data collection system 100 and/or by any of the sensors described above. As shown, a control signal from a signal processor 1310 controls a driver 1305. In response, an emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302. As described above, in some embodiments, the pulse sequence 1303 is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence 1303 can be greater (or smaller).

In response to the pulse sequence 1300, detectors 1 to n (n being an integer) in a detector 1306 capture optical radiation from the measurement site 1302 and provide respective streams of output signals. Each signal from one of detectors 1-n can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets 1-n in the emitter 1304. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

A front end interface 1308 can accept these multiple streams from detectors 1-n and deliver one or more signals or composite signal(s) back to the signal processor 1310. A stream from the detectors 1-n can thus include measured light intensities corresponding to the light pulses emitted from the emitter 1304.

The signal processor 1310 can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor 1310 can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

The Beer-Lambert law is usually written as:

Absorbance $A = m * b * c$, where:

m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of $M^{-1} \text{ cm}^{-1}$);

b is the mean path length; and

c is the analyte concentration (e.g., the desired parameter).

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In spectroscopy, instruments attempt to obtain the analyte concentration (c) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

$T = I/I_0$, where:

I is the light intensity measured by the instrument from the measurement site; and

I_0 is the initial light intensity from the emitter.

Absorbance (A) can be equated to the transmittance (T) by the equation:

$$A = -\log T$$

Therefore, substituting equations from above:

$$A = -\log(I/I_0)$$

In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(I/I_0)$ and solving for analyte concentration (c).

Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (I_0), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude that what is achievable by currently available technology.

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In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$T = e^{-m \cdot b \cdot c}$$

In terms of light intensity, this equation can also be rewritten as:

$$I/I_o = e^{-m \cdot b \cdot c}$$

Or, at a detector, the measured light (I) can be expressed as:

$$I = I_o \cdot e^{-m \cdot b \cdot c}$$

As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in $I_1 \dots I_n$ streams of measurements. Assuming each of these detectors have their own path lengths, $b_1 \dots b_n$, from the light source, the measured light intensities can be expressed as:

$$I_n = I_o \cdot e^{-m \cdot b_n \cdot c}$$

The measured light intensities at any two different detectors can be referenced to each other. For example:

$$I_1/I_n = (I_o \cdot e^{-m \cdot b_1 \cdot c}) / (I_o \cdot e^{-m \cdot b_n \cdot c})$$

As can be seen, the terms, I_o , cancel out and, based on exponent algebra, the equation can be rewritten as:

$$I_1/I_n = e^{-m(b_1 - b_n)c}$$

From this equation, the analyte concentration (c) can now be derived from bulk signals $I_1 \dots I_n$ and knowing the respective mean path lengths b_1 and b_n . This scheme also allows for the cancelling out of I_o , and thus, noise generated by the emitter 1304 can be cancelled out or reduced. In addition, since the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) 1302. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

FIG. 14A illustrates an embodiment of a detector submount 1400a positioned beneath the partially cylindrical protrusion 605 of FIG. 6 (or alternatively, the protrusion 605b). The detector submount 1400a includes two rows 1408a of detectors 1410a. The partially cylindrical protrusion 605 can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion 605 can act as a lens that focuses light onto a smaller area.

To illustrate, in some sensors that do not include the partially cylindrical protrusion 605, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

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Applying the partially cylindrical protrusion 605 to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion 605 (see FIG. 14B). This is the example situation illustrated in FIG. 14—two rows 1408a of detectors 1410a are used instead of four. Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

In other embodiments, using the partially cylindrical protrusion 605 can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion 605 (or alternatively, the protrusion 605b) that illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors. The protrusion 605 is placed above a detector submount 1400b having one or more detectors 1410b disposed thereon. The submount 1400b can include any number of rows of detectors 1410, although one row is shown.

Light, represented by rays 1420, is emitted from the emitters onto the protrusion 605. These light rays 1420 can be attenuated by body tissue (not shown). When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion 605. The refraction causes the rays 1422 to be focused or substantially focused on the one or more detectors 1410b. Since the light is focused on a smaller area, a sensor including the protrusion 605 can include fewer detectors to capture the same amount of light compared with other sensors.

FIG. 14C illustrates another embodiment of a detector submount 1400c, which can be disposed under the protrusion 605b (or alternatively, the protrusion 605). The detector submount 1400c includes a single row 1408c of detectors 1410c. The detectors are electrically connected to conductors 1412c, which can be gold, silver, copper, or any other suitable conductive material.

The detector submount 1400c is shown positioned under the protrusion 605b in a detector subassembly 1450 illustrated in FIG. 14D. A top-down view of the detector subassembly 1450 is also shown in FIG. 14E. In the detector subassembly 1450, a cylindrical housing 1430 is disposed on the submount 1400c. The cylindrical housing 1430 includes a transparent cover 1432, upon which the protrusion 605b is disposed. Thus, as shown in FIG. 14D, a gap 1434 exists between the detectors 1410c and the protrusion 605b. The height of this gap 1434 can be chosen to increase or maximize the amount of light that impinges on the detectors 1410c.

The cylindrical housing 1430 can be made of metal, plastic, or another suitable material. The transparent cover 1432 can be fabricated from glass or plastic, among other materials. The cylindrical housing 1430 can be attached to the submount 1400c at the same time or substantially the same time as the detectors 1410c to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing 1430 in various embodiments.

In certain embodiments, the cylindrical housing 1430 (and transparent cover 1432) forms an airtight or substantially airtight or hermetic seal with the submount 1400c. As

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a result, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c more effectively than currently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

In embodiments where the cylindrical housing 1430 is at least partially made of metal, the cylindrical housing 1430 can provide noise shielding for the detectors 1410c. For example, the cylindrical housing 1430 can be soldered to a ground connection or ground plane on the submount 1400c, which allows the cylindrical housing 1430 to reduce noise. In another embodiment, the transparent cover 1432 can include a conductive material or conductive layer, such as conductive glass or plastic. The transparent cover 1432 can include any of the features of the noise shields 790 described above.

The protrusion 605b includes the chamfered edges 607 described above with respect to FIG. 6E. These chamfered edges 607 can allow a patient to more comfortably slide a finger over the protrusion 605b when inserting the finger into the sensor 301f.

FIG. 14F illustrates a portion of the detector shell 306f, which includes the detectors 1410c on the substrate 1400c. The substrate 1400c is enclosed by a shielding enclosure 1490, which can include the features of the shielding enclosures 790a, 790b described above (see also FIG. 17). The shielding enclosure 1490 can be made of metal. The shielding enclosure 1490 includes a window 1492a above the detectors 1410c, which allows light to be transmitted onto the detectors 1410c.

A noise shield 1403 is disposed above the shielding enclosure 1490. The noise shield 1403, in the depicted embodiment, includes a window 1492a corresponding to the window 1492a. Each of the windows 1492a, 1492b can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows 1492a, 1492b may be selected to have different sizes or shapes from each other.

The noise shield 1403 can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield 1403 extends about three-quarters of the length of the detector shell 306f. In other embodiments, the noise shield 1403 could be smaller or larger. The noise shield 1403 could, for instance, merely cover the detectors 1410c, the submount 1400c, or a portion thereof. The noise shield 1403 also includes a stop 1413 for positioning a measurement site within the sensor 301f. Advantageously, in certain embodiments, the noise shield 1403 can reduce noise caused by light piping.

A thermistor 1470 is also shown. The thermistor 1470 is attached to the submount 1400c and protrudes above the noise shield 1403. As described above, the thermistor 1470 can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In the depicted embodiment, the detectors 1410c are not enclosed in the cylindrical housing 1430. In an alternative embodiment, the cylindrical housing 1430 encloses the detectors 1410c and is disposed under the noise shield 1403. In another embodiment, the cylindrical housing 1430 encloses the detectors 1410c and the noise shield 1403 is not

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used. If both the cylindrical housing 1403 and the noise shield 1403 are used, either or both can have noise shielding features.

FIG. 14G illustrates the detector shell 306f of FIG. 14F, with the finger bed 310f disposed thereon. FIG. 14H illustrates the detector shell 306f of FIG. 14G, with the protrusion 605b disposed in the finger bed 310f.

FIG. 14I illustrates a cutaway view of the sensor 301f. Not all features of the sensor 301f are shown, such as the protrusion 605b. Features shown include the emitter and detector shells 304f, 306f; the flaps 307f; the heat sink 350f and fins 351f; the finger bed 310f; and the noise shield 1403.

In addition to these features, emitters 1404 are depicted in the emitter shell 304f. The emitters 1404 are disposed on a submount 1401, which is connected to a circuit board 1419. The emitters 1404 are also enclosed within a cylindrical housing 1480. The cylindrical housing 1480 can include all of the features of the cylindrical housing 1430 described above. For example, the cylindrical housing 1480 can be made of metal, can be connected to a ground plane of the submount 1401 to provide noise shielding, and can include a transparent cover 1482.

The cylindrical housing 1480 can also protect the emitters 1404 from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing 1480 can provide a gap between the emitters 1404 and the measurement site (not shown), which can allow light from the emitters 1404 to even out or average out before reaching the measurement site.

The heat sink 350f, in addition to including the fins 351f, includes a protuberance 352f that extends down from the fins 351f and contacts the submount 1401. The protuberance 352f can be connected to the submount 1401, for example, with thermal paste or the like. The protuberance 352f can sink heat from the emitters 1404 and dissipate the heat via the fins 351f.

FIGS. 15A and 15B illustrate embodiments of sensor portions 1500A, 1500B that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

The sensor portions 1500A, 1500B shown include LED emitters 1504; however, for ease of illustration, the detectors have been omitted. The sensor portions 1500A, 1500B shown can be included, for example, in any of the emitter shells described above.

The LEDs 1504 of the sensor portions 1500A, 1500B are connected to a substrate or submount 1502. The submount 1502 can be used in place of any of the submounts described above. The submount 1502 can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable 1512 is attached to the submount 1502 and includes electrical wiring 1514, such as twisted wires and the like, for communicating with the LEDs 1504. The cable 1512 can correspond to the cables 212 described above.

Although not shown, the cable 1512 can also include electrical connections to a detector. Only a portion of the cable 1512 is shown for clarity. The depicted embodiment of the cable 1512 includes an outer jacket 1510 and a conductive shield 1506 disposed within the outer jacket 1510. The conductive shield 1506 can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield 1506 or a portion of the conductive shield 1506 can be electrically connected to the submount

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1502 and can reduce noise in the signal generated by the sensor 1500A, 1500B by reducing RF coupling with the wires 1514. In alternative embodiments, the cable 1512 does not have a conductive shield. For example, the cable 1512 could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

Referring specifically to FIG. 15A, in certain embodiments, the conductive shield 1506 can act as a heat sink for the LEDs 1504 by absorbing thermal energy from the LEDs 1504 and/or the submount 1502. An optional heat insulator 1520 in communication with the submount 1502 can also assist with directing heat toward the conductive shield 1506. The heat insulator 1520 can be made of plastic or another suitable material. Advantageously, using the conductive shield 1506 in the cable 1512 as a heat sink can, in certain embodiments, reduce cost for the sensor.

Referring to FIG. 15B, the conductive shield 1506 can be attached to both the submount 1502 and to a heat sink layer 1530 sandwiched between the submount 1502 and the optional insulator 1520. Together, the heat sink layer 1530 and the conductive shield 1506 in the cable 1512 can absorb at least part of the thermal energy from the LEDs and/or the submount 1502.

FIGS. 15C and 15D illustrate implementations of a sensor portion 1500C that includes the heat sink features of the sensor portion 1500A described above with respect to FIG. 15A. The sensor portion 1500C includes the features of the sensor portion 1500A, except that the optional insulator 1520 is not shown. FIG. 15D is a side cutaway view of the sensor portion 1500C that shows the emitters 1504.

The cable 1512 includes the outer jacket 1510 and the conductive shield 1506. The conductive shield 1506 is soldered to the submount 1502, and the solder joint 1561 is shown. In some embodiments, a larger solder joint 1561 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, a cylindrical housing 1580, corresponding to the cylindrical housing 1480 of FIG. 14I, is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15E and 15F illustrate implementations of a sensor portion 1500E that includes the heat sink features of the sensor portion 1500B described above with respect to FIG. 15B. The sensor portion 1500E includes the heat sink layer 1530. The heat sink layer 1530 can be a metal plate, such as a copper plate or the like. The optional insulator 1520 is not shown. FIG. 15F is a side cutaway view of the sensor portion 1500E that shows the emitters 1504.

In the depicted embodiment, the conductive shield 1506 of the cable 1512 is soldered to the heat sink layer 1530 instead of the submount 1502. The solder joint 1565 is shown. In some embodiments, a larger solder joint 1565 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, the cylindrical housing 1580 is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described above with respect to FIGS. 1 through 15F. Referring to FIG. 15G, the circuit board 1519 includes a female connector 1575 that mates with a male connector 1577 connected to a daughter board 1587. The daughter board 1587 includes connections to the electrical wiring 1514 of the cable 1512. The connected boards 1519, 1587 are shown in FIG. 15H.

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Also shown is a hole 1573 that can receive the cylindrical housing 1580 described above.

Advantageously, in certain embodiments, using a daughter board 1587 to connect to the circuit board 1519 can enable connections to be made more easily to the circuit board 1519. In addition, using separate boards can be easier to manufacture than a single circuit board 1519 with all connections soldered to the circuit board 1519.

FIG. 15I illustrates an exemplary architecture for front-end interface 108 as a transimpedance-based front-end. As noted, front-end interfaces 108 provide an interface that adapts the output of detectors 106 into a form that can be handled by signal processor 110. As shown in this figure, sensor 101 and front-end interfaces 108 may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor 101 and front end interfaces 108 may comprise multiple components or circuits that are coupled together.

Front-end interfaces 108 may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors 106. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter 900 may be integrated with the transimpedance-based front-end in sensor 101.

Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector 106, the applicants developed a noise model to assist in configuring front-end 108. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

However, the following noise model was discovered by the applicants:

$$\text{Noise} = \sqrt{aR + bR^2}, \text{ where:}$$

aR is characteristic of the impedance of the transimpedance amplifier; and

bR^2 is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector 106.

The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors 1-4 (as shown, e.g., in FIG. 12A) may each comprise four photodiodes. In some embodiments, each detector of four

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photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in FIG. 15J.

Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors 1-4. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the transimpedance amplifiers in this setting may also be set according to the model shown in FIG. 15J.

As yet another alternative, as noted above with respect to FIGS. 12E through 12H, the photodiodes in detectors 106 may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

As noted, FIG. 15J illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

For example, an exemplary "4 PD per stream" sensor 1502 is shown where detector 106 comprises four photodiodes 1502. The photodiodes 1502 are coupled to a single transimpedance amplifier 1504 to produce an output stream 1506. In this example, the transimpedance amplifier comprises 10 M Ω resistors 1508 and 1510. Thus, output stream 1506 is produced from the four photodiodes (PD) 1502. As shown in the graph of FIG. 15J, the model indicates that resistance values of about 10 M Ω may provide an acceptable SNR for analytes like glucose.

However, as a comparison, an exemplary "1 PD per stream" sensor 1512 is also shown in FIG. 15J. In particular, sensor 1512 may comprise a plurality of detectors 106 that each comprises a single photodiode 1514. In addition, as shown for this example configuration, each of photodiodes 1514 may be coupled to respective transimpedance amplifiers 1516, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 M Ω resistors 1518. As also shown in the graph of FIG. 15J, the model illustrates that resistance values of 40 M Ω for resistors 1518 may serve as an alternative to the 4 photodiode per stream architecture of sensor 1502 described above and yet still provide an equivalent SNR.

Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor 1512 may provide enhanced performance because each of transimpedance amplifiers 1516 can be tuned or optimized to its respective photodiodes 1518. In some embodiments, an averaging component 1520 may also be used to help cancel or reduce noise across photodiodes 1518.

For purposes of illustration, FIG. 15K shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor 1522 may comprise a "4 PD per stream" architecture on a submount 700 in which each detector 106 comprises four (4) photodiodes 1524. As

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shown for sensor 1522, the output of each set of four photodiodes 1524 is then aggregated into a single transimpedance amplifier 1526 to produce a signal.

As another example, a sensor 1528 may comprise a "1 PD per stream" architecture on submount 700 in which each detector 106 comprises four (4) photodiodes 1530. In sensor 1528, each individual photodiode 1530 is coupled to a respective transimpedance amplifier 1532. The output of the amplifiers 1532 may then be aggregated into averaging circuit 1520 to produce a signal.

As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor 1534 illustrates an exemplary "4 PD per stream" sensor in which the detectors 106 comprise photodiodes 1536 arranged in a linear fashion. Likewise, sensor 1538 illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes 1540 arranged in a linear fashion.

Alternatively, sensor 1542 illustrates an exemplary "4 PD per stream" sensor in which the detectors 106 comprise photodiodes 1544 arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor 1546 illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes 1548 also arranged in a zig-zag pattern.

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces 108 may be implemented using switched capacitor circuits and any number of front-end interfaces 108 may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface 1000 and signal processor 110. Switched capacitor circuits may be useful in system 100 for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces 108 may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front end interfaces 108 may require less computational power by signal processor 110 to perform the same amount of decimation to obtain the same SNR.

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors 1600. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors 1600 shown. For instance, the sensors 1600 can be used as the sensors 101 in the system 100 described above with respect to FIG. 1. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

The sensors 1600 include an adult/pediatric sensor 1610 for finger placement and a disposable infant/neonate sensor 1602 configured for toe, foot or hand placement. Each sensor 1600 has a tape end 1610 and an opposite connector end 1620 electrically and mechanically interconnected via a flexible coupling 1630. The tape end 1610 attaches an emitter and detector to a tissue site. Although not shown, the tape end 1610 can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates

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a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

The sensor signal is communicated via the flexible coupling 1630 to the connector end 1620. The connector end 1620 can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGS. 2A through 2D. Alternatively, the connector end 1620 can mate directly with the monitor.

FIG. 17 illustrates an exploded view of certain of the components of the sensor 301 described above. A heat sink 1751 and a cable 1781 attach to an emitter shell 1704. The emitter shell attaches to a flap housing 1707. The flap housing 1707 includes a receptacle 1709 to receive a cylindrical housing 1480/1580 (not shown) attached to an emitter submount 1702, which is attached to a circuit board 1719.

A spring 1787 attaches to a detector shell 1706 via pins 1783, 1785, which hold the emitter and detector shells 1704, 1706 together. A support structure 1791 attaches to the detector shell 1706, which provides support for a shielding enclosure 1790. A noise shield 1713 attaches to the shielding enclosure 1790. A detector submount 1700 is disposed inside the shielding enclosure 1790. A finger bed 1710 provides a surface for placement of the patient's finger. Finger bed 1710 may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion 1705 may also be disposed in the finger bed 1710. As shown, finger bed 1710 attaches to the noise shield 1703. The noise shield 1703 may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield 1703 may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

Noise shield 1703 may also comprise a thermistor 1712. The thermistor 1712 may be helpful in measuring the temperature of a patient's finger. For example, the thermistor 1712 may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor 1712 may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

Moreover, a flex circuit cover 1706 attaches to the pins 1783, 1785. Although not shown, a flex circuit can also be provided that connects the circuit board 1719 with the submount 1700 (or a circuit board to which the submount 1700 is connected). A flex circuit protector 1760 may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector 1760 may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector 1760 may be constructed from well known materials, such as a plastic or rubber materials.

FIG. 18 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor 101 were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

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FIG. 19 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/Liposyn were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor 101 were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

FIGS. 20 through 22 shows other results that can be obtained by an embodiment of system 100. In FIG. 20, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs and four independent detector streams. As shown, the system 100 obtained a correlation of about 85% and Arms of about 31 mg/dL.

In FIG. 21, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106. As shown, the system 100 was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

The results shown in FIG. 22 relate to total hemoglobin testing with an exemplary sensor 101 of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector channels from detectors 106. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

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What is claimed is:

1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:

at least three light emitting diodes (LEDs);

at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;

a protrusion arranged over the interior surface, the protrusion comprising a convex surface and a plurality of openings extending through the protrusion and positioned over the three photodiodes, the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion; and

one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.

2. The user-worn device of claim 1, wherein glass covers each of the openings.

3. The user-worn device of claim 1 further comprising:

a network interface configured to wirelessly communicate the measurement of the physiological parameter to a mobile phone;

a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurement of the physiological parameter;

a memory configured to at least temporarily store at least the measurement; and

a strap configured to position the user-worn device on the user.

4. The user-worn device of claim 1 further comprising:

a network interface configured to wirelessly communicate the measurement of the physiological parameter to a computer network;

a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurement of the physiological parameter;

a memory configured to at least temporarily store at least the measurement; and

a strap configured to position the user-worn device on the user.

5. The user-worn device of claim 1 further comprising:

at least one wall extending between the interior surface and the protrusion, wherein at least the interior surface, the wall and the protrusion form one or more cavities, wherein the photodiodes are arranged within the cavities.

6. The user-worn device of claim 1, wherein the physiological parameter comprises oxygen or oxygen saturation.

7. The user-worn device of claim 1, wherein the physiological parameter comprises pulse rate.

8. The user-worn device of claim 1, wherein the physiological parameter comprises trending information.

9. The user-worn device of claim 1 further comprising:

a thermistor configured to output a temperature signal, wherein the one or more processors are further configured to:

receive the temperature signal; and

adjust operation of the user-worn device responsive to the temperature signal.

10. The user-worn device of claim 9, wherein the temperature signal is responsive to a temperature of the tissue of the user.

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11. The user-worn device of claim 1, wherein the LEDs and the photodiodes are arranged on a same side of the tissue of the user.

12. The user-worn device of claim 1, wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape.

13. The user-worn device of claim 1, wherein the one or more processors are further configured to process the one or more signals to determine a bulk measurement responsive to a positioning of the user-worn device.

14. The user-worn device of claim 1, wherein:

the at least three LEDs comprises at least six LEDs;

a first set of LEDs includes three of the six LEDs;

a second set of LEDs includes a different three of the six LEDs;

the second set is spaced apart from the first set;

a first of the three LEDs in the first set of LEDs is configured to emit light at a first wavelength and a second of the three LEDs in the first set of LEDs is configured to emit light at a second wavelength; and

a first of the three LEDs in the second set of LEDs is configured to emit light at the first wavelength and a second of the three LEDs in the second set of LEDs is configured to emit light at the second wavelength.

15. The user-worn device of claim 1, wherein the at least three photodiodes comprise four photodiodes arranged on the interior surface in a quadrant arrangement.

16. The user-worn device of claim 1, wherein the protrusion further comprises one or more extensions.

17. The user-worn device of claim 16, wherein the one or more extensions surround the convex surface.

18. The user-worn device of claim 1, wherein the protrusion further comprises one or more chamfered edges.

19. A user-worn device comprising:

a plurality of light emitting diodes (LEDs);

at least three photodiodes arranged within the user-worn device and configured to receive light attenuated by tissue of a user;

a protrusion extending over the three photodiodes and comprising a convex surface, the protrusion including a separate window associated with each of the three photodiodes, an opaque material lining a lateral surface of the windows and extending through the protrusion, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue; and

one or more processors configured to receive one or more signals from at least one of the photodiodes, the one or more processors configured to output measurements responsive to the one or more signals, the measurements indicative of a physiological parameter of the user.

20. The user-worn device of claim 19 further comprising a thermistor.

21. The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.

22. The user-worn device of claim 19, wherein the opaque material is configured to reduce an amount of noise caused by light piping in the one or more signals.

23. The user-worn device of claim 19 further comprising: a network interface configured to wirelessly communicate the measurements to another computing device;

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a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurements; and a memory configured to at least temporarily store at least the measurements.

24. The user-worn device of claim 19, wherein the physiological parameter comprises an oxygen saturation or oxygen measurement.

25. The user-worn device of claim 19, wherein the physiological parameter comprises a pulse rate.

26. A user-worn device configured to non-invasively measure a pulse rate of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;

a thermistor configured to provide a temperature signal;

a protrusion arranged over the interior surface, the protrusion comprising a convex surface extending over the three photodiodes, the protrusion further comprising one or more sidewalls extending at least partially around a perimeter of the convex surface;

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a plurality of openings extending through the protrusion and aligned with the three photodiodes, each opening defined by an opaque surface extending through the protrusion and configured to reduce light piping;

at least one wall extending between the interior surface and the protrusion, wherein at least the interior surface, the wall and the protrusion form one or more cavities, wherein the photodiodes are arranged within the cavities;

one or more processors configured to receive one or more signals from the photodiodes and calculate a pulse rate measurement of the user;

a user interface comprising a display, wherein the user interface is configured to display indicia responsive to the pulse rate measurement;

a memory configured to at least temporarily store at least the pulse rate measurement; and

a strap configured to position the user-worn device on the user.

27. The user-worn device of claim 26, further comprising a network interface configured to wirelessly communicate the pulse rate measurement to a mobile phone.

28. The user-worn device of claim 26, further comprising a network interface configured to wirelessly communicate the pulse rate measurement to a computer network without involving a mobile phone.

29. The user-worn device of claim 26, wherein the protrusion further comprises one or more extensions.

30. The user-worn device of claim 26, wherein the protrusion further comprises one or more chamfered edges.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 10,912,501 B2
APPLICATION NO. : 17/031356
DATED : February 9, 2021
INVENTOR(S) : Jeroen Poeze et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (63), Page 2, Column 1 at Line 10, Related U.S. Application Data, Change "which is a division"
to --which is a continuation--.

In the Specification

In Column 25 at Lines 10-18 (approx.), Change
"In certain embodiments, the focal length (f) for the partially

$$f = \frac{R}{n-1'}$$

cylindrical protrusion 605 can be expressed as:" to

--In certain embodiments, the focal length (f) for the partially cylindrical protrusion 605 can be
expressed as:

$$f = \frac{R}{n-1' \dots}$$

Signed and Sealed this
Sixth Day of April, 2021



Drew Hirshfeld
*Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office*



US010912502B2

(12) **United States Patent**
Poeze et al.

(10) **Patent No.:** **US 10,912,502 B2**

(45) **Date of Patent:** ***Feb. 9, 2021**

(54) **USER-WORN DEVICE FOR NONINVASIVELY MEASURING A PHYSIOLOGICAL PARAMETER OF A USER**

(52) **U.S. Cl.**
CPC **A61B 5/1455** (2013.01); **A61B 5/14532** (2013.01); **A61B 5/14546** (2013.01);
(Continued)

(71) Applicant: **Masimo Corporation**, Irvine, CA (US)

(58) **Field of Classification Search**
CPC . A61B 5/1455; A61B 5/14546; A61B 5/6838; A61B 5/6816; A61B 5/6829;
(Continued)

(72) Inventors: **Jeroen Poeze**, Rancho Santa Margarita, CA (US); **Marcelo Lamego**, Cupertino, CA (US); **Sean Merritt**, Lake Forest, CA (US); **Cristiano Dalvi**, Lake Forest, CA (US); **Hung Vo**, Fountain Valley, CA (US); **Johannes Bruinsma**, Opeinde (NL); **Ferdyan Lesmana**, Irvine, CA (US); **Massi Joe E. Kiani**, Laguna Niguel, CA (US); **Greg Olsen**, Lake Forest, CA (US)

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(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/031,407**

(22) Filed: **Sep. 24, 2020**

(65) **Prior Publication Data**

US 2021/0000392 A1 Jan. 7, 2021

Related U.S. Application Data

(60) Continuation of application No. 16/834,538, filed on Mar. 30, 2020, which is a continuation of application (Continued)

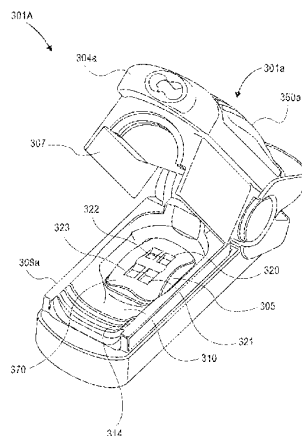
(51) **Int. Cl.**

A61B 5/1455 (2006.01)
A61B 5/145 (2006.01)
A61B 5/00 (2006.01)

(57) **ABSTRACT**

The present disclosure relates to noninvasive methods, devices, and systems for measuring various blood constituents or analytes, such as glucose. In an embodiment, a light source comprises LEDs and super-luminescent LEDs. The light source emits light at at least wavelengths of about 1610 nm, about 1640 nm, and about 1665 nm. In an embodiment, the detector comprises a plurality of photodetectors arranged in a special geometry comprising one of a substantially linear substantially equal spaced geometry, a substantially linear substantially non-equal spaced geometry, and a substantially grid geometry.

30 Claims, 65 Drawing Sheets



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Related U.S. Application Data

| | | | |
|--|--|--|---|
| No. 16/725,292, filed on Dec. 23, 2019, now Pat. No. 10,624,564, which is a continuation of application No. 16/534,949, filed on Aug. 7, 2019, now Pat. No. 10,588,553, which is a continuation of application No. 16/409,515, filed on May 10, 2019, now Pat. No. 10,376,191, which is a continuation of application No. 16/261,326, filed on Jan. 29, 2019, now Pat. No. 10,292,628, which is a continuation of application No. 16/212,537, filed on Dec. 6, 2018, now Pat. No. 10,258,266, which is a division of application No. 14/981,290, filed on Dec. 28, 2015, now Pat. No. 10,335,068, which is a continuation of application No. 12/829,352, filed on Jul. 1, 2010, now Pat. No. 9,277,880, which is a continuation of application No. 12/534,827, filed on Aug. 3, 2009, now abandoned, and a continuation-in-part of application No. 12/497,528, filed on Jul. 2, 2009, now Pat. No. 8,577,431, which is a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516, said application No. 12/829,352 is a continuation-in-part of application No. 12/497,523, filed on Jul. 2, 2009, now Pat. No. 8,437,825, and a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516. | 4,409,470 A 4,438,338 A 4,444,471 A 4,447,150 A 4,547,075 A 4,653,498 A 4,655,225 A 4,684,245 A 4,709,413 A 4,755,676 A 4,759,369 A 4,781,195 A 4,782,836 A 4,802,486 A 4,805,623 A 4,819,860 A 4,825,872 A 4,859,057 A 4,865,038 A 4,867,557 A 4,869,253 A 4,880,304 A 4,903,701 A 4,928,692 A 4,933,545 A 4,938,218 A 4,941,236 A 4,945,239 A 4,955,379 A 4,960,128 A 4,960,314 A 4,964,408 A 5,007,423 A 5,025,791 A 5,028,787 A 5,035,243 A 5,041,187 A 5,043,820 A 5,069,213 A 5,069,214 A 5,069,680 A 5,077,476 A 5,086,229 A 5,099,842 A 5,109,849 A D326,715 S 5,122,925 A 5,131,391 A 5,137,023 A 5,158,082 A 5,158,091 A 5,159,929 A 5,163,438 A 5,176,137 A 5,190,038 A 5,203,329 A 5,218,962 A 5,222,295 A 5,222,495 A 5,222,496 A 5,228,449 A 5,249,576 A 5,250,342 A 5,251,011 A 5,254,388 A 5,254,992 A 5,273,036 A 5,278,627 A 5,297,548 A 5,319,355 A 5,333,616 A 5,337,744 A 5,337,745 A 5,341,805 A 5,355,242 A 5,358,519 A 5,362,966 A D353,195 S D353,196 S | 10/1983 3/1984 4/1984 5/1984 10/1985 3/1987 4/1987 8/1987 11/1987 7/1988 7/1988 11/1988 11/1988 2/1989 2/1989 4/1989 5/1989 8/1989 9/1989 9/1989 9/1989 9/1989 11/1989 2/1990 5/1990 6/1990 7/1990 7/1990 7/1990 9/1990 10/1990 10/1990 10/1990 4/1991 6/1991 7/1991 7/1991 8/1991 8/1991 12/1991 12/1991 12/1991 12/1991 2/1992 3/1992 5/1992 6/1992 6/1992 7/1992 8/1992 10/1992 10/1992 11/1992 11/1992 1/1993 3/1993 4/1993 6/1993 6/1993 6/1993 7/1993 10/1993 10/1993 10/1993 10/1993 10/1993 12/1993 1/1994 3/1994 6/1994 8/1994 8/1994 8/1994 10/1994 10/1994 11/1994 12/1994 12/1994 | Shepard et al. Stitt Ford et al. Heinemann Fei New, Jr. et al. Dahne et al. Goldring Forrest Gaalema et al. Taylor Martin Alt Goodman et al. Jöbbsis Hargrove et al. Tan et al. Taylor et al. Rich et al. Takatani et al. Craig, Jr. et al. Jaeb et al. Moore et al. Goodman et al. Saaski et al. Goodman et al. Sherman et al. Wist et al. Hall Gordon et al. Smith et al. Hink et al. Branstetter et al. Niwa Rosenthal et al. Muz Hink et al. Wyles et al. Polczynski Samaras et al. Grandjean Rosenthal Rosenthal et al. Mannheimer et al. Goodman et al. Schmidt Inpyn Sakai et al. Mendelson et al. Jones Butterfiled et al. McMillen et al. Gordon et al. Erickson et al. Polson et al. Takatani et al. Mannheimer et al. Dorris, Jr. Clarke et al. Clarke et al. Christ et al. Goldberger et al. Lang Fujiwara et al. Melby et al. Keen et al. Kronberg et al. Aoyagi et al. Pologe Russek Mills et al. Branigan Benaron Stavridi et al. Eastmond et al. Grandjean Rosenthal et al. Savage et al. Savage et al. |
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| (52) U.S. Cl. CPC <i>A61B 5/14552</i> (2013.01); <i>A61B 5/6816</i> (2013.01); <i>A61B 5/6826</i> (2013.01); <i>A61B 5/6829</i> (2013.01); <i>A61B 5/6838</i> (2013.01); <i>A61B 5/6843</i> (2013.01); <i>A61B 2562/0233</i> (2013.01); <i>A61B 2562/04</i> (2013.01); <i>A61B 2562/046</i> (2013.01); <i>A61B 2562/146</i> (2013.01) | | | |
| (58) Field of Classification Search CPC . A61B 5/6843; A61B 5/6826; A61B 5/14551; A61B 5/14552; A61B 5/14532; A61B 2562/046; A61B 2562/04; A61B 2562/0233; A61B 2562/146 See application file for complete search history. | | | |
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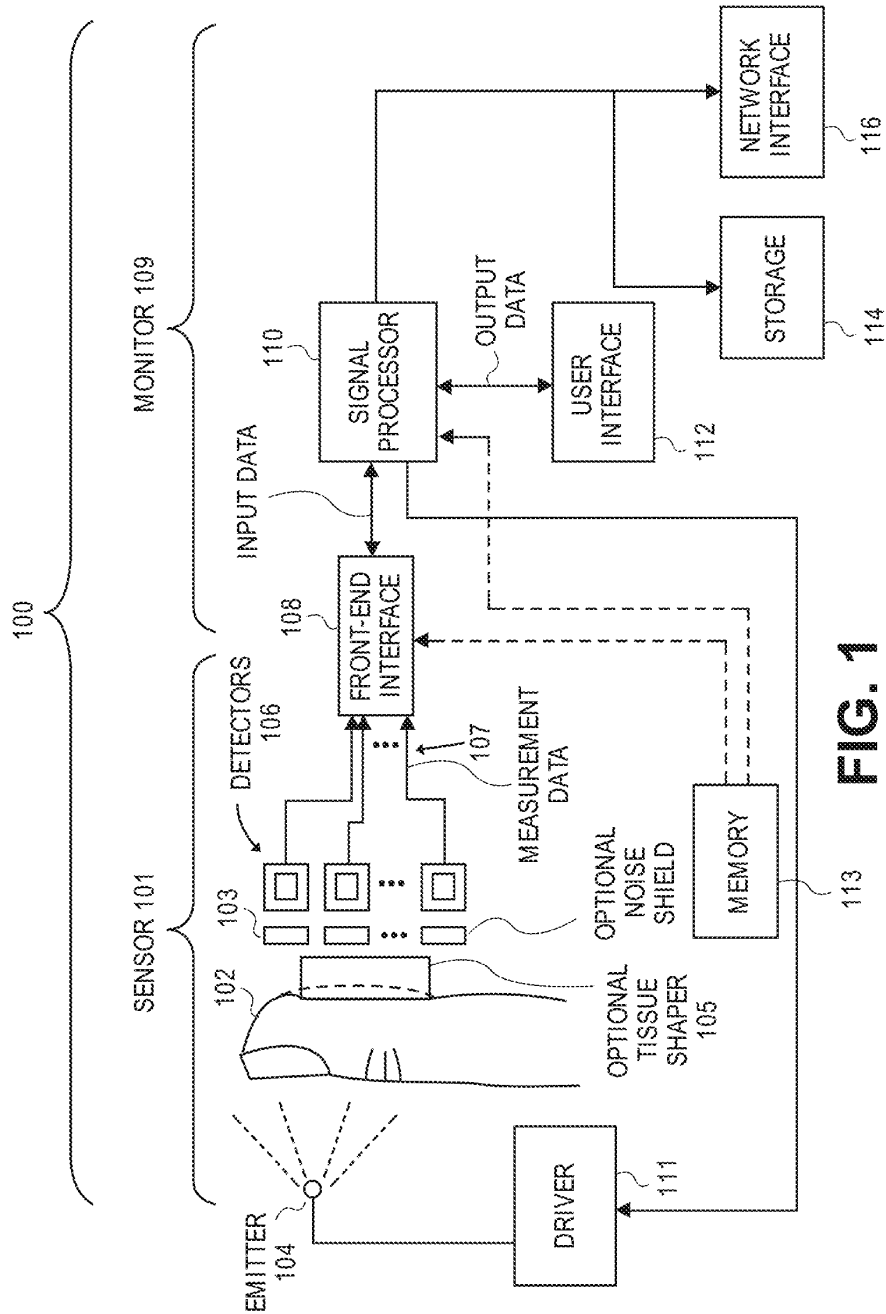


FIG. 1

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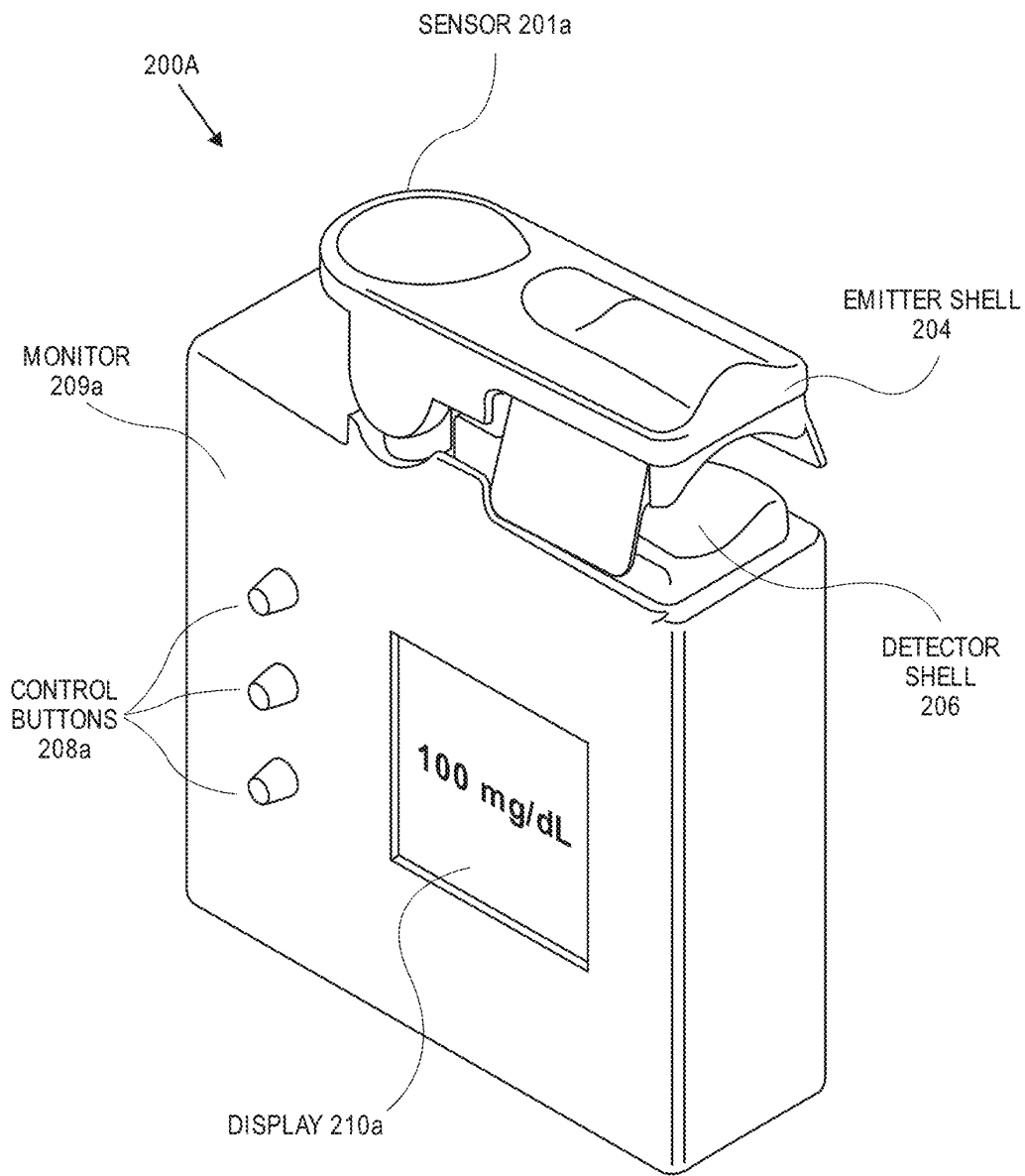


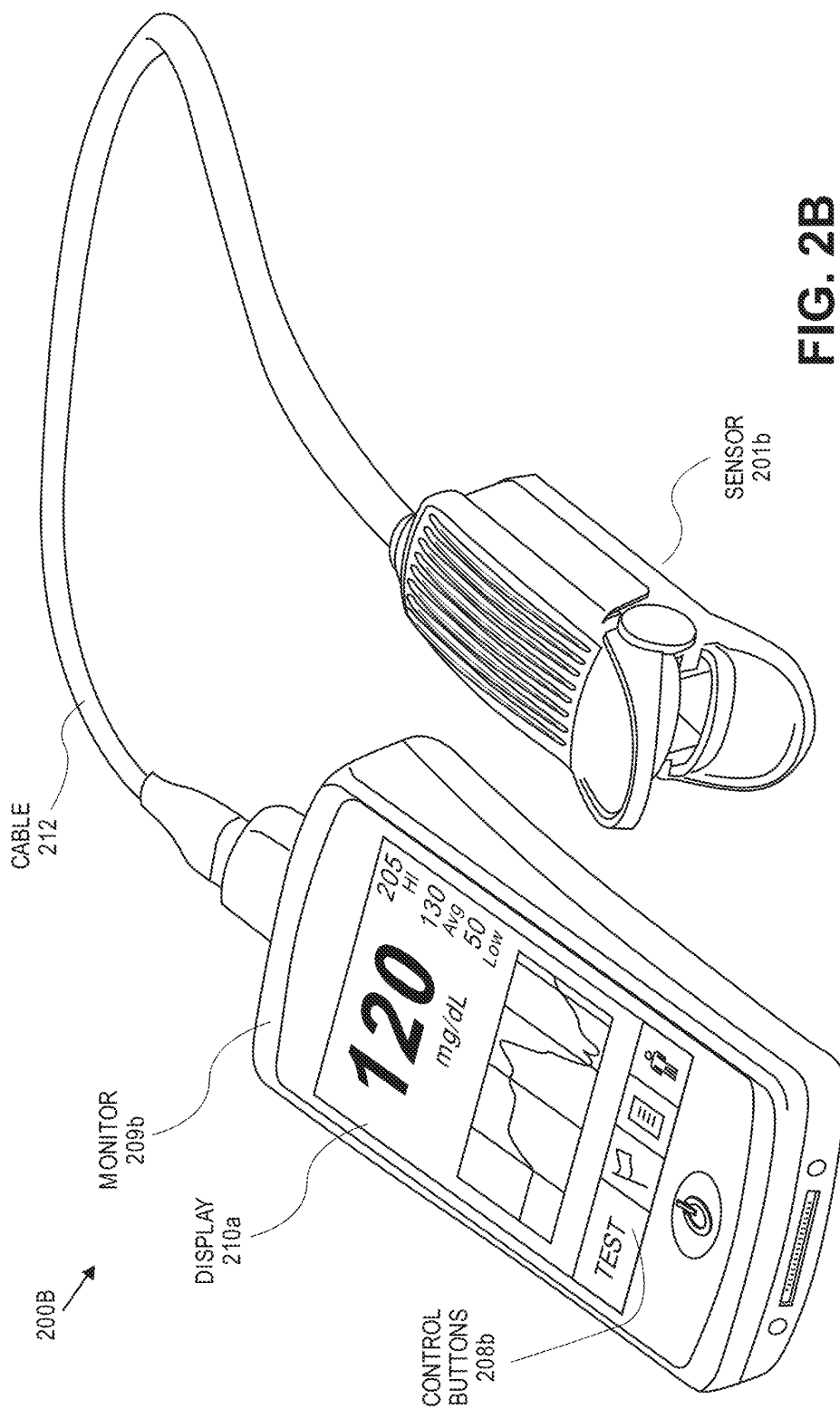
FIG. 2A

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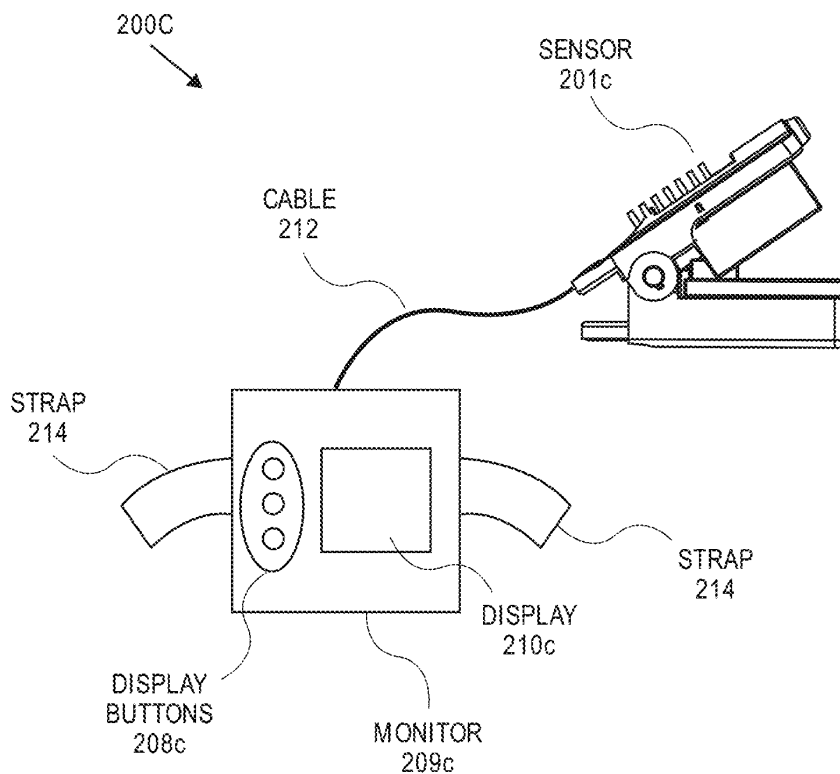


FIG. 2C

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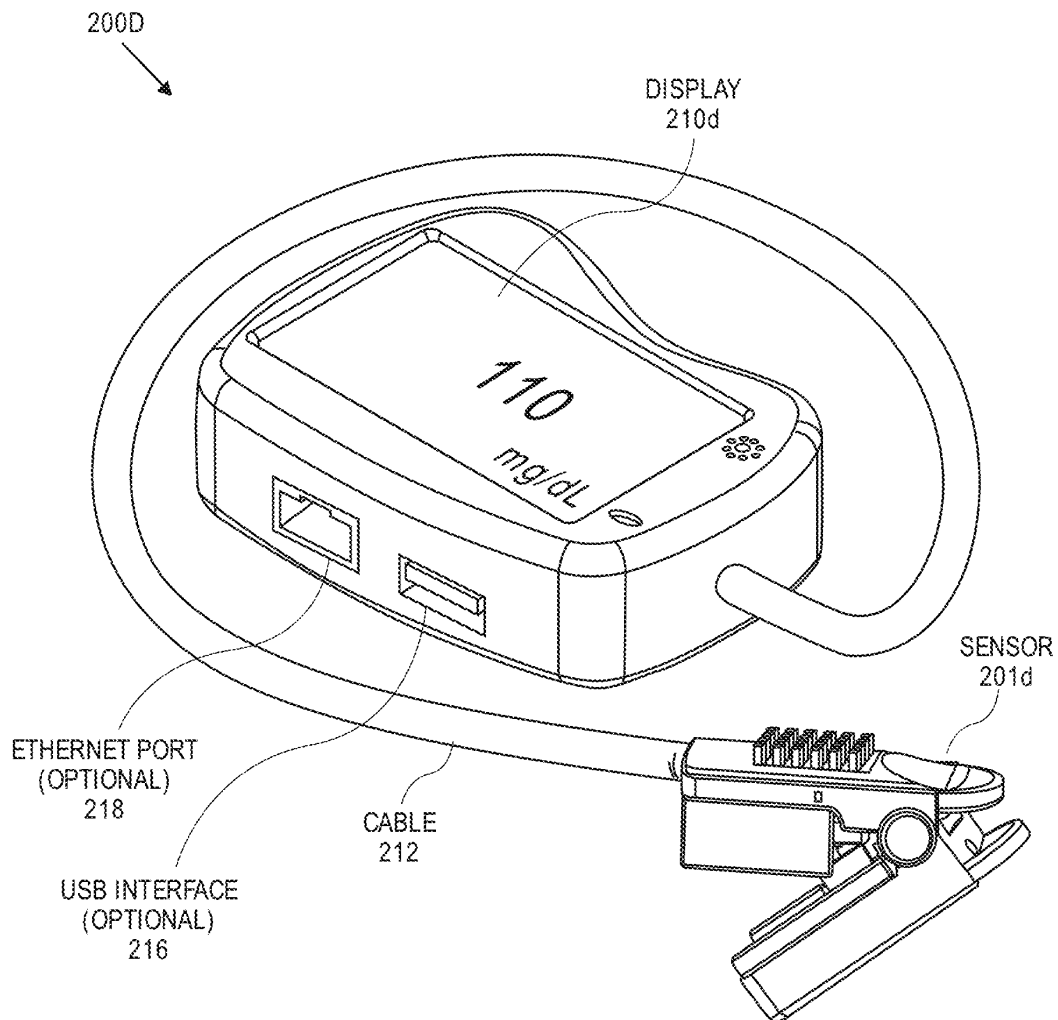


FIG. 2D

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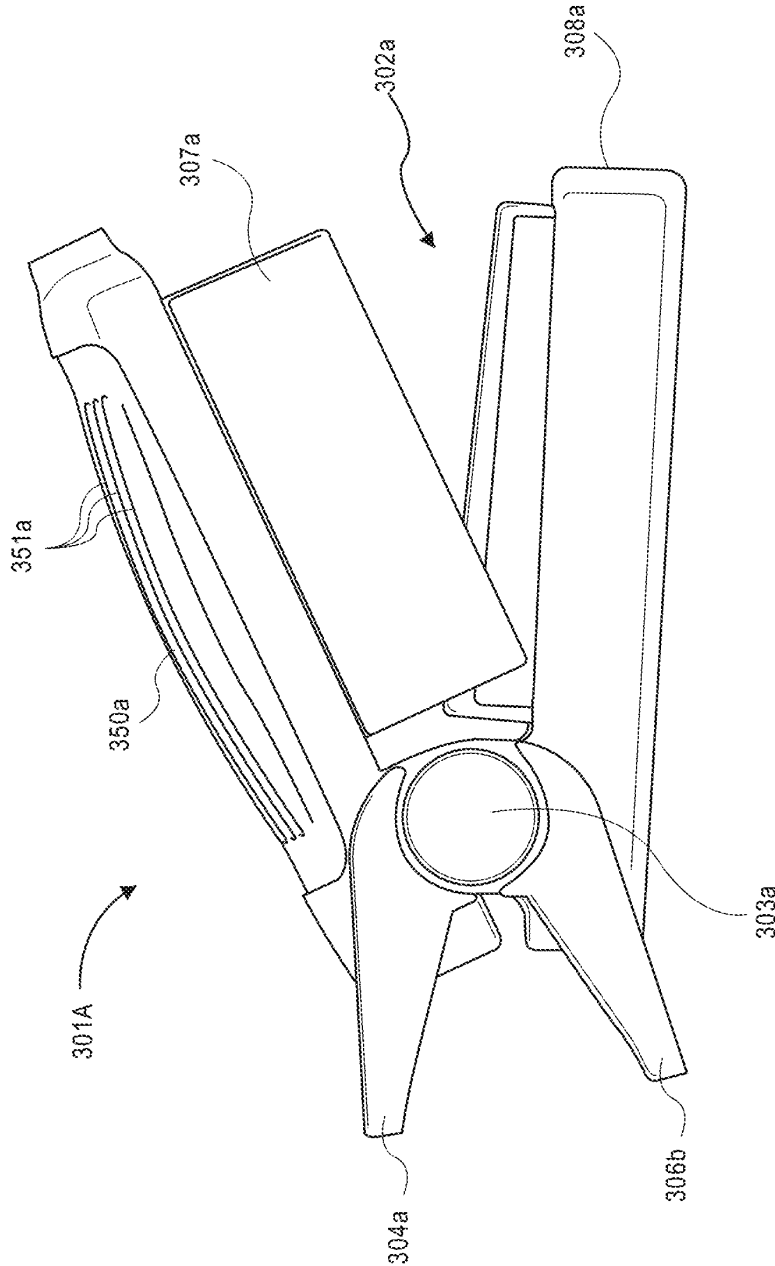


FIG. 3A

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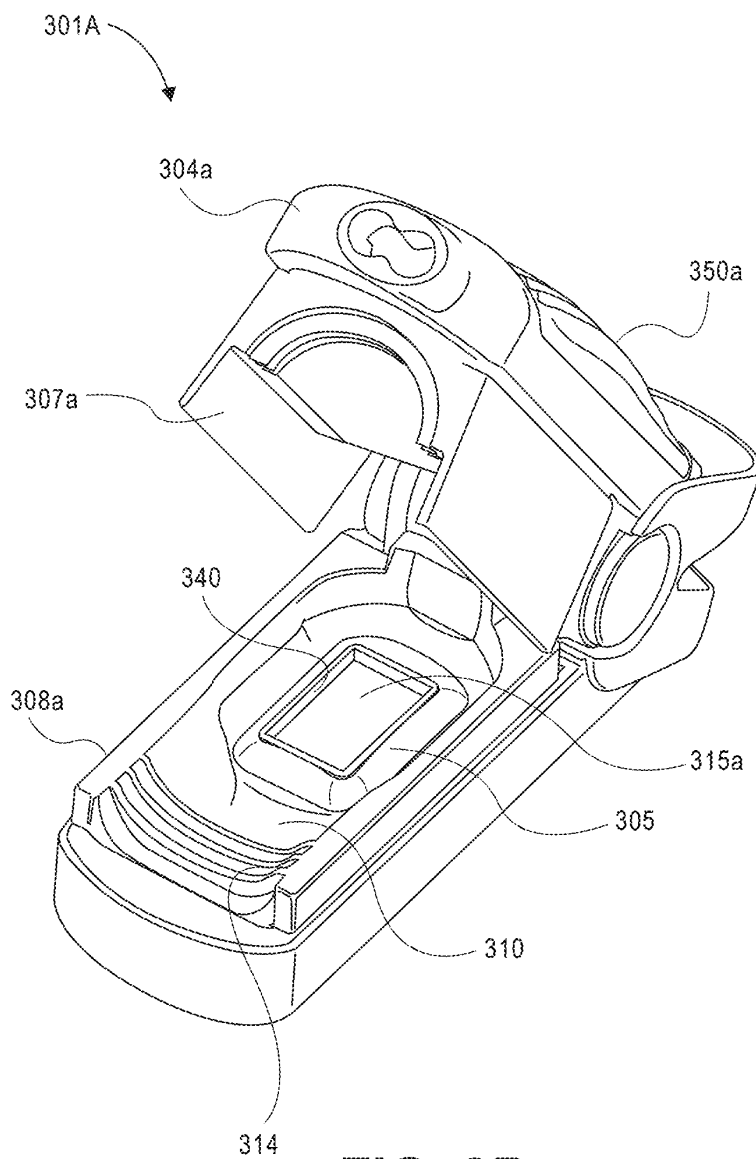


FIG. 3B

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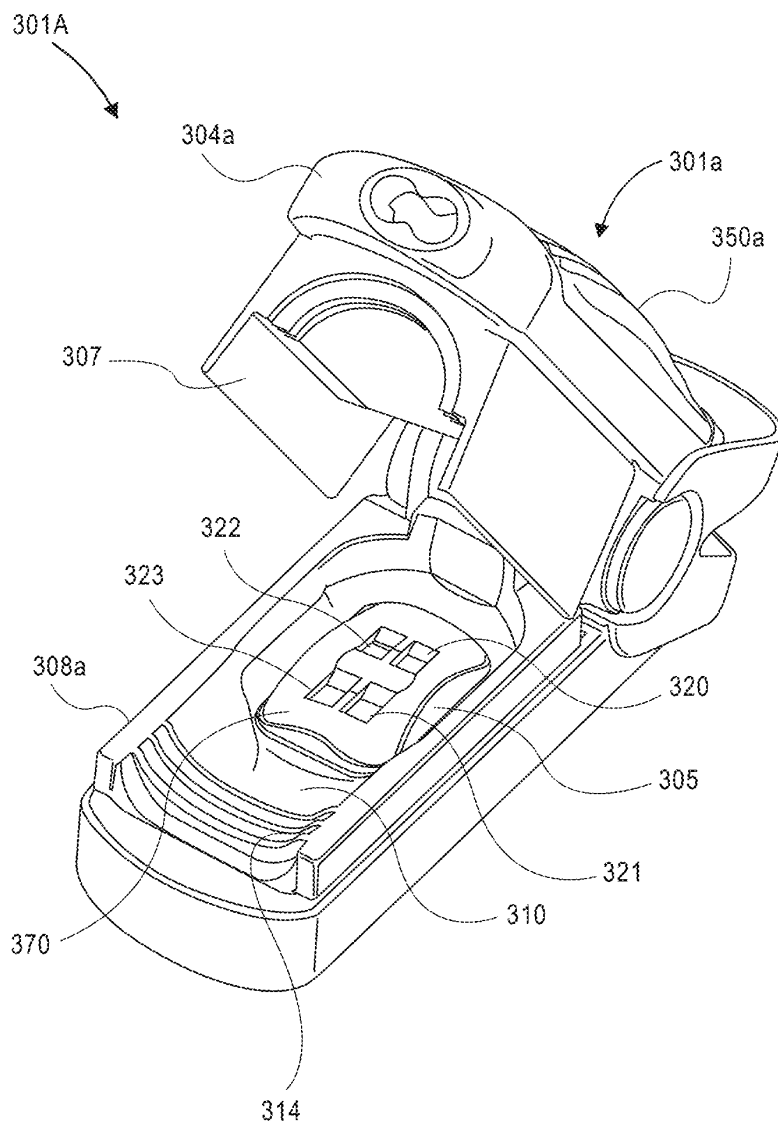


FIG. 3C

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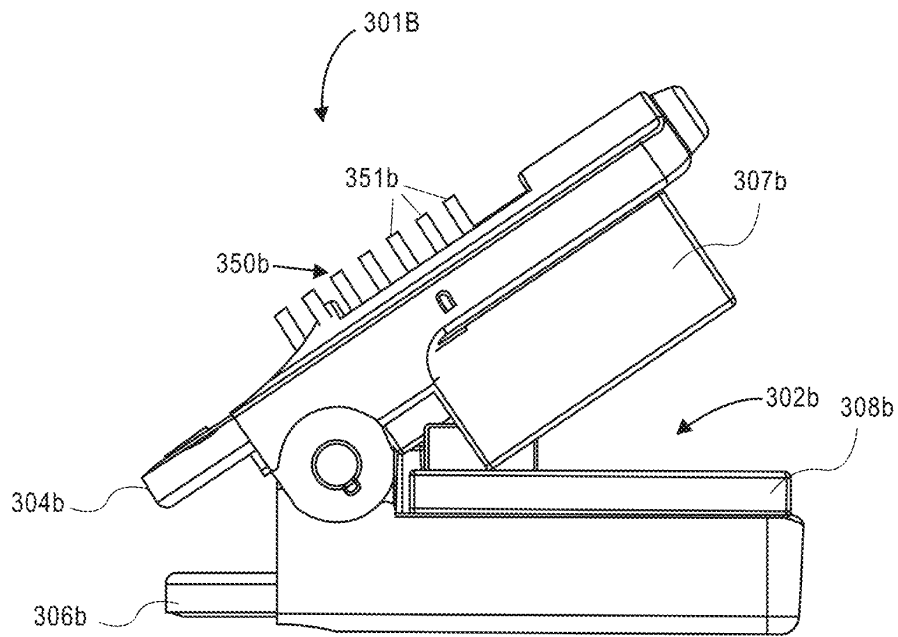


FIG. 3D

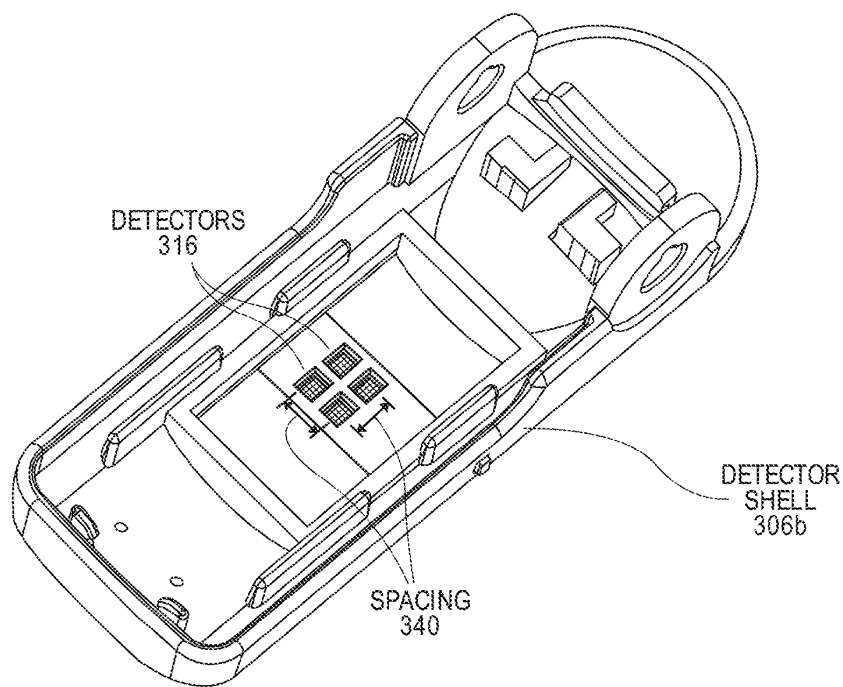


FIG. 3E

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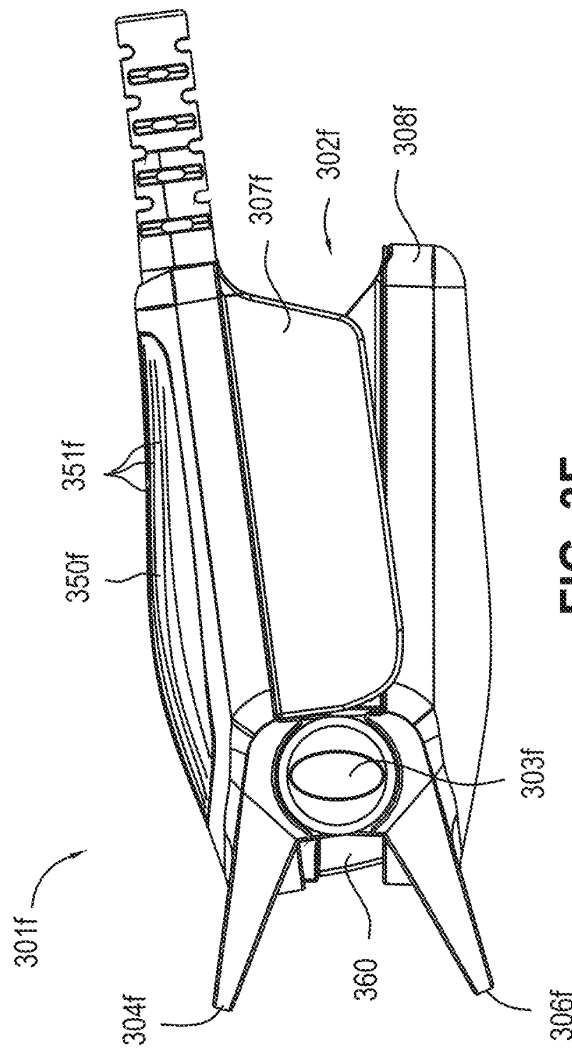


FIG. 3F

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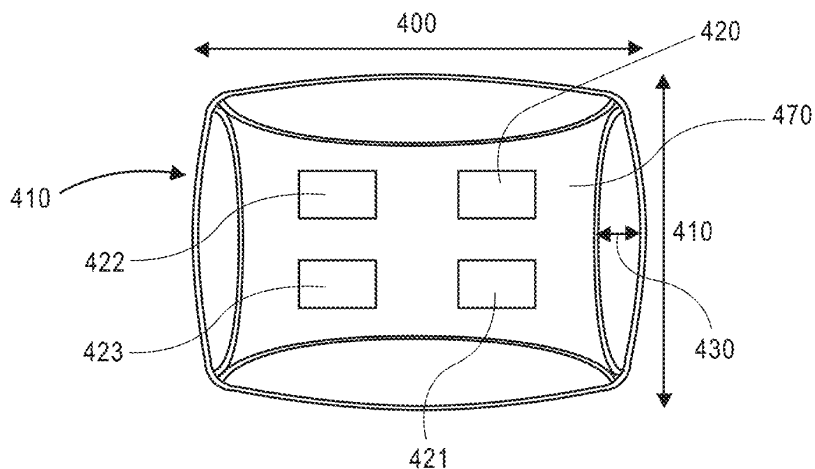


FIG. 4A

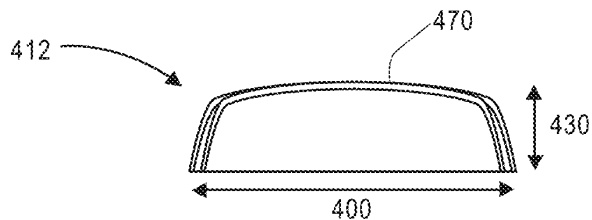


FIG. 4B

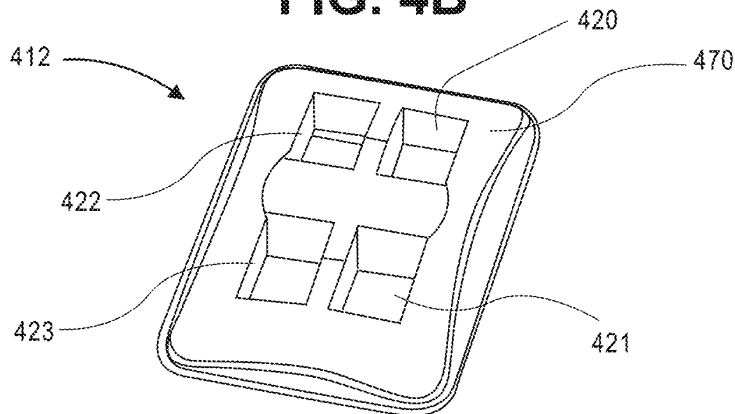


FIG. 4C

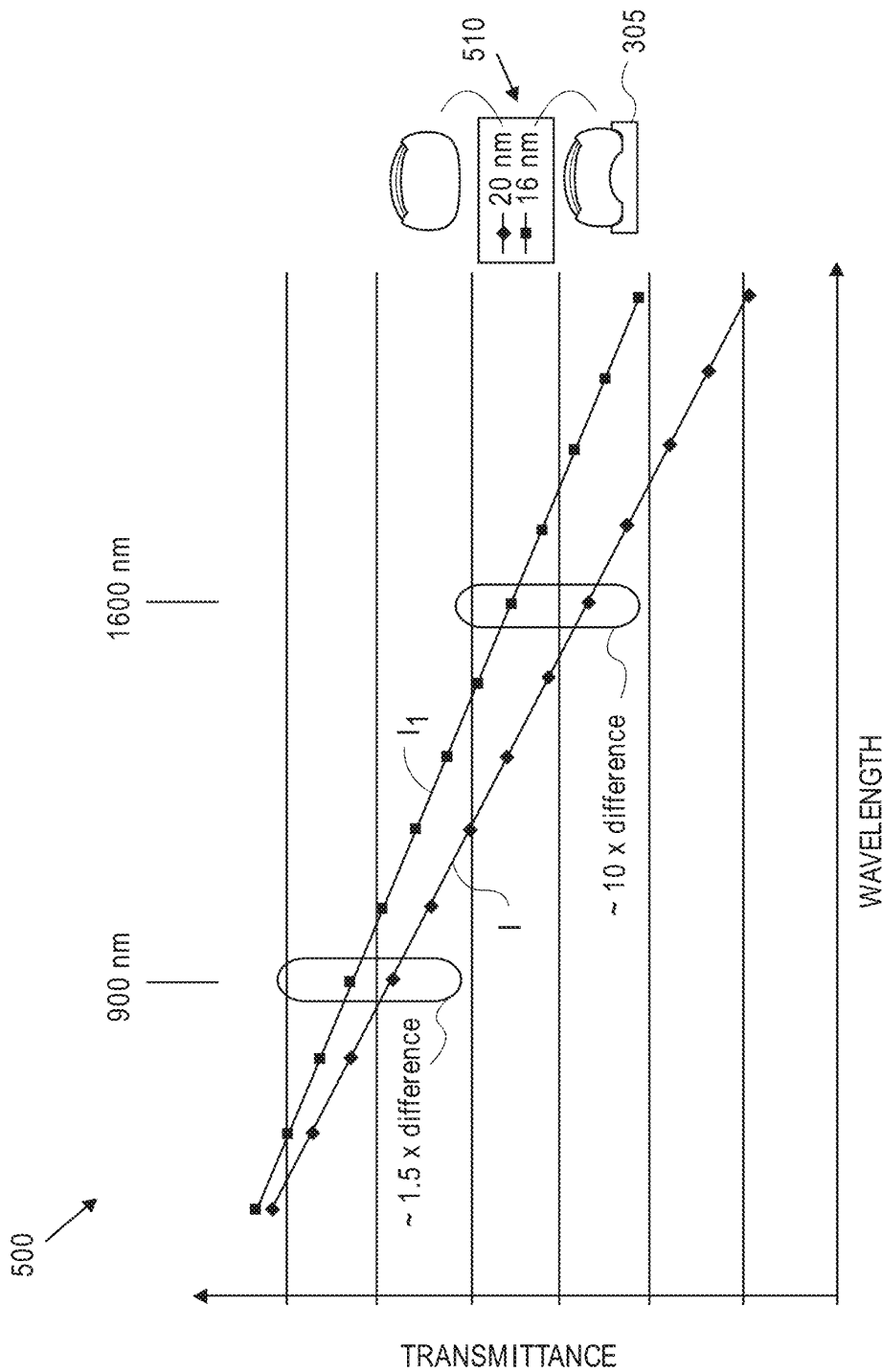


FIG. 5

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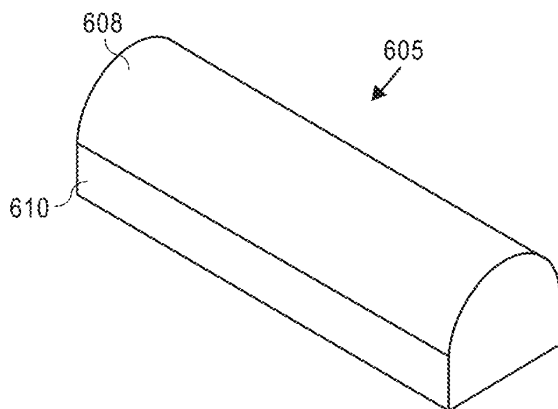


FIG. 6A

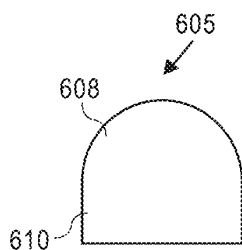


FIG. 6B

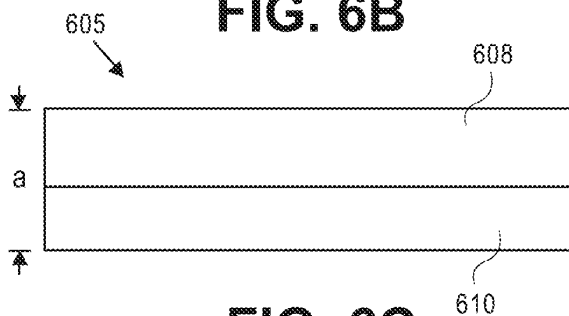


FIG. 6C



FIG. 6D

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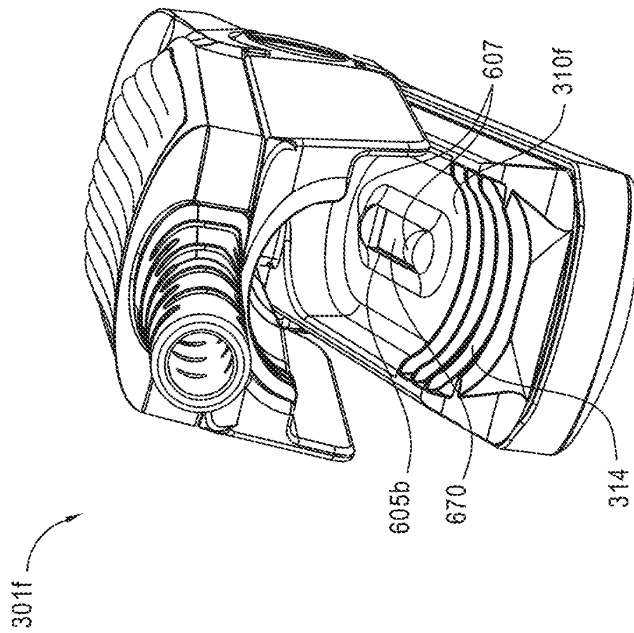


FIG. 6E

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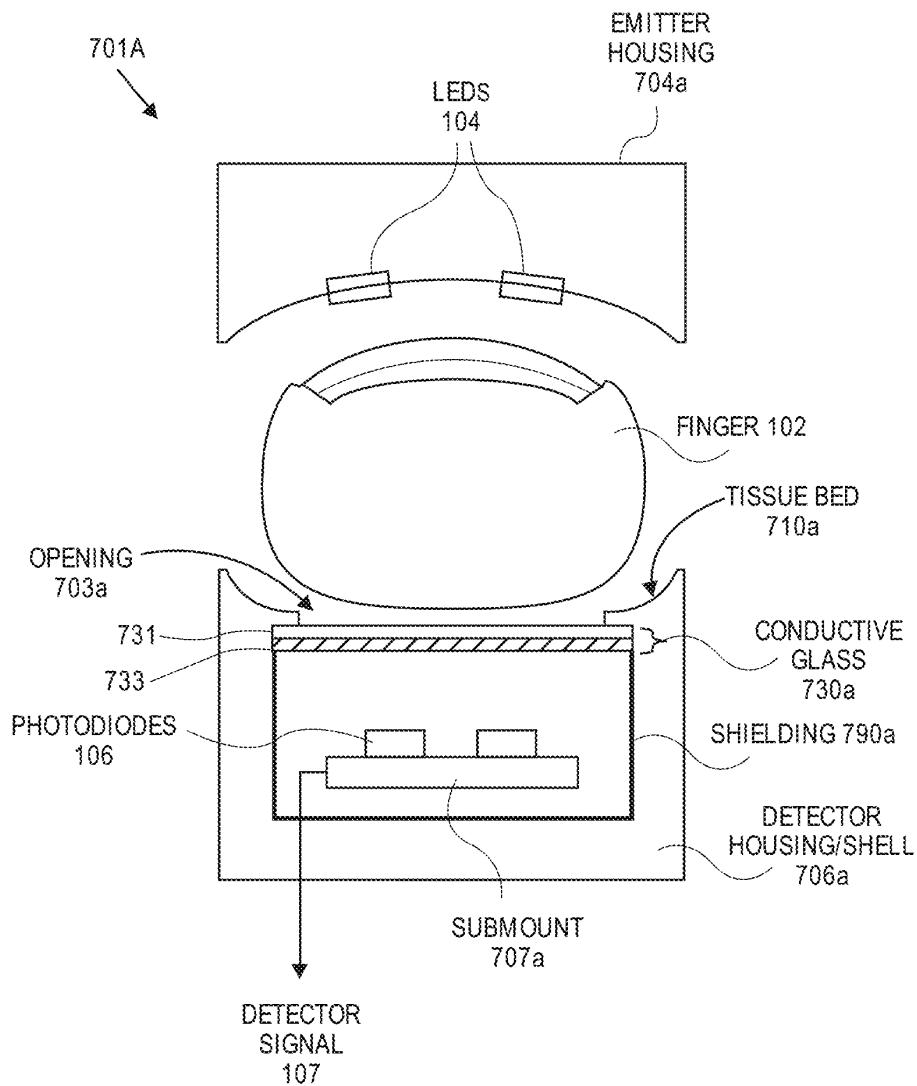


FIG. 7A

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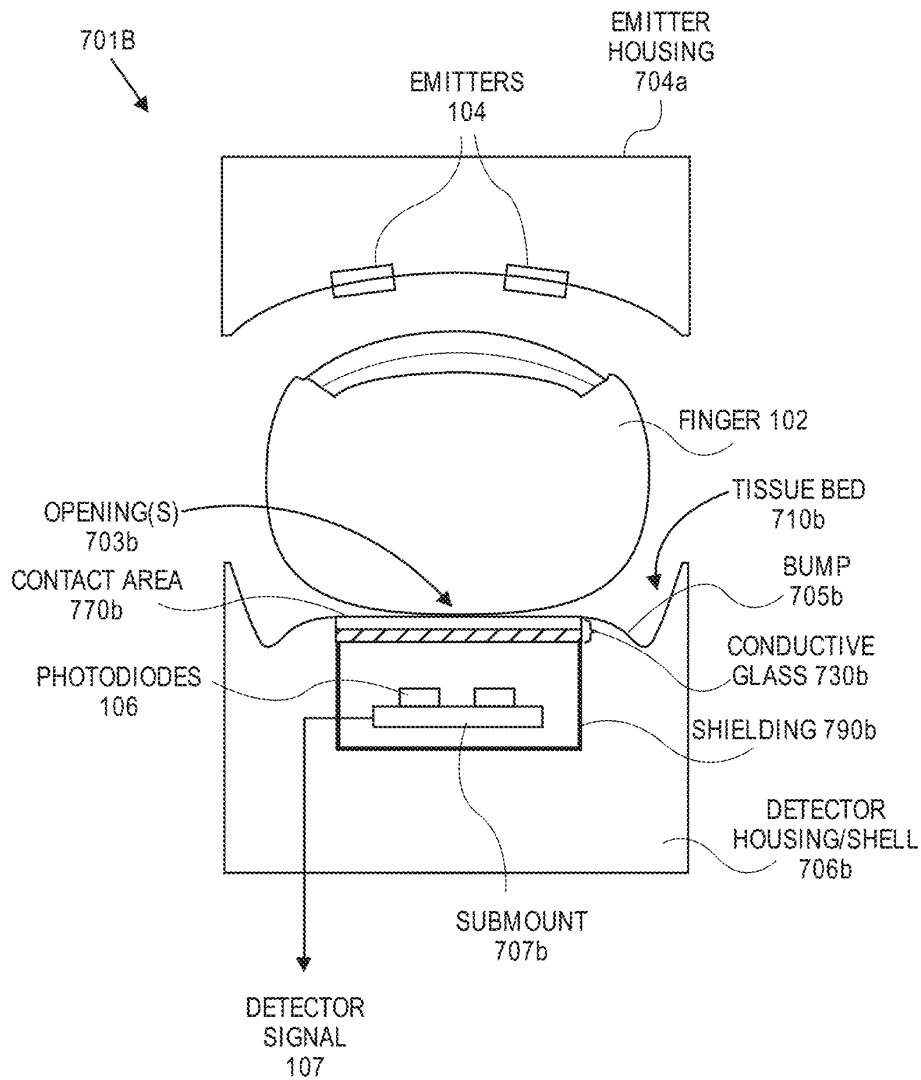


FIG. 7B

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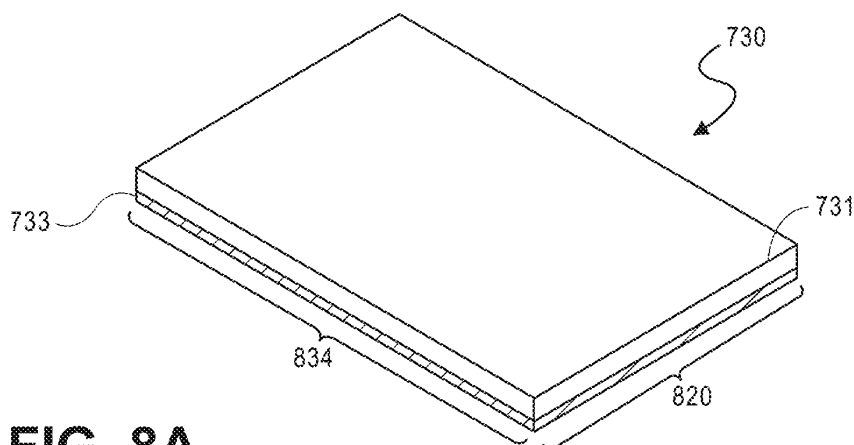


FIG. 8A

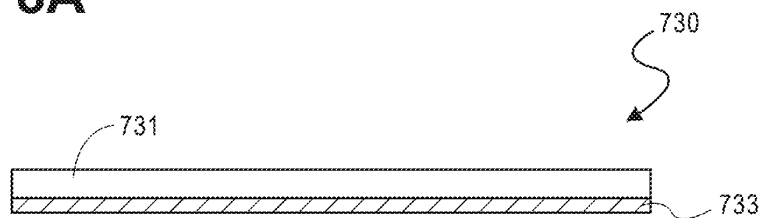


FIG. 8B

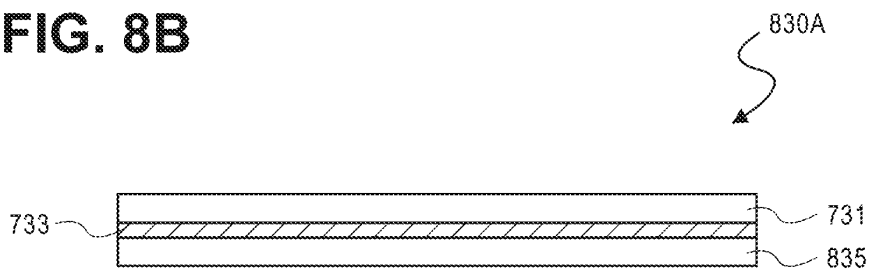


FIG. 8C

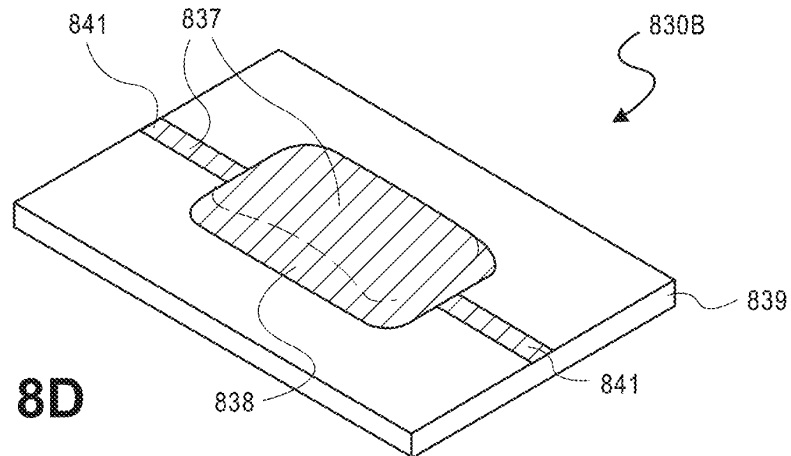


FIG. 8D

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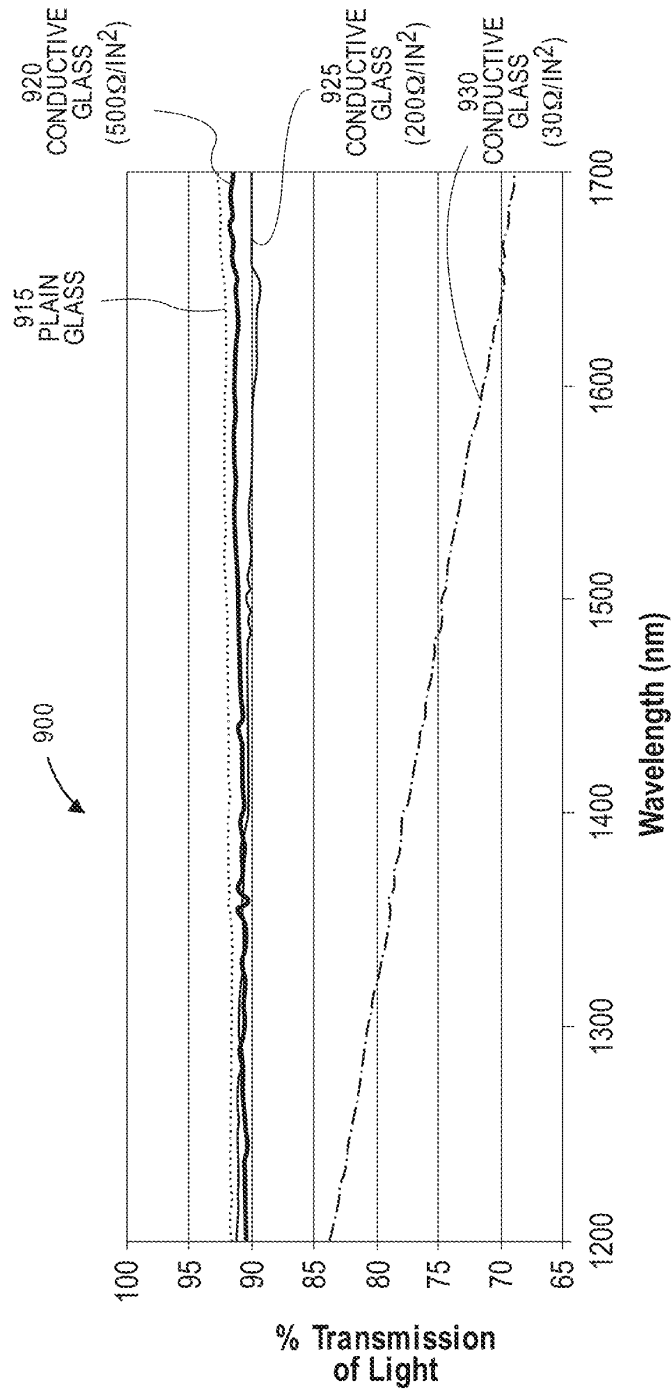


FIG. 9

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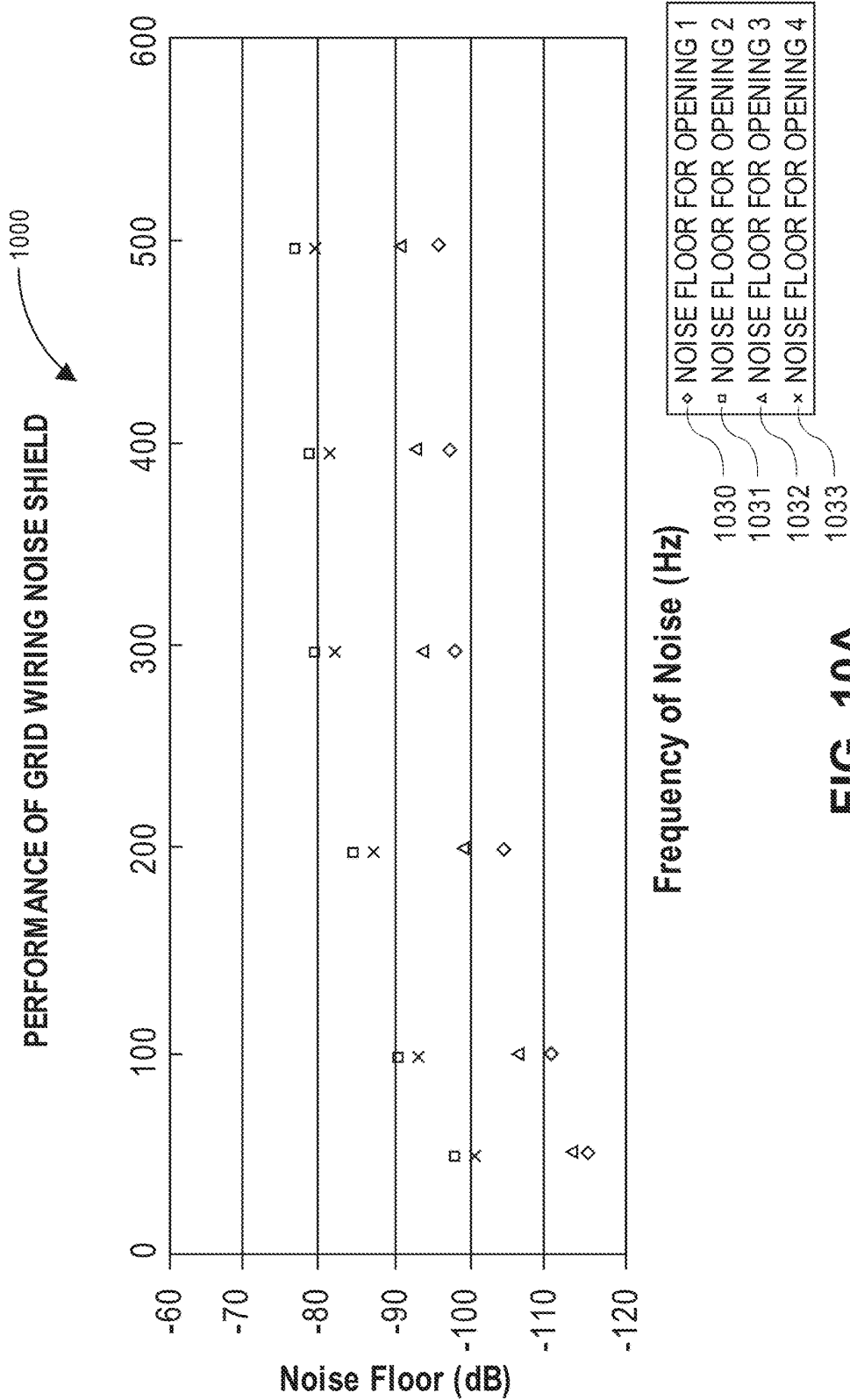


FIG. 10A

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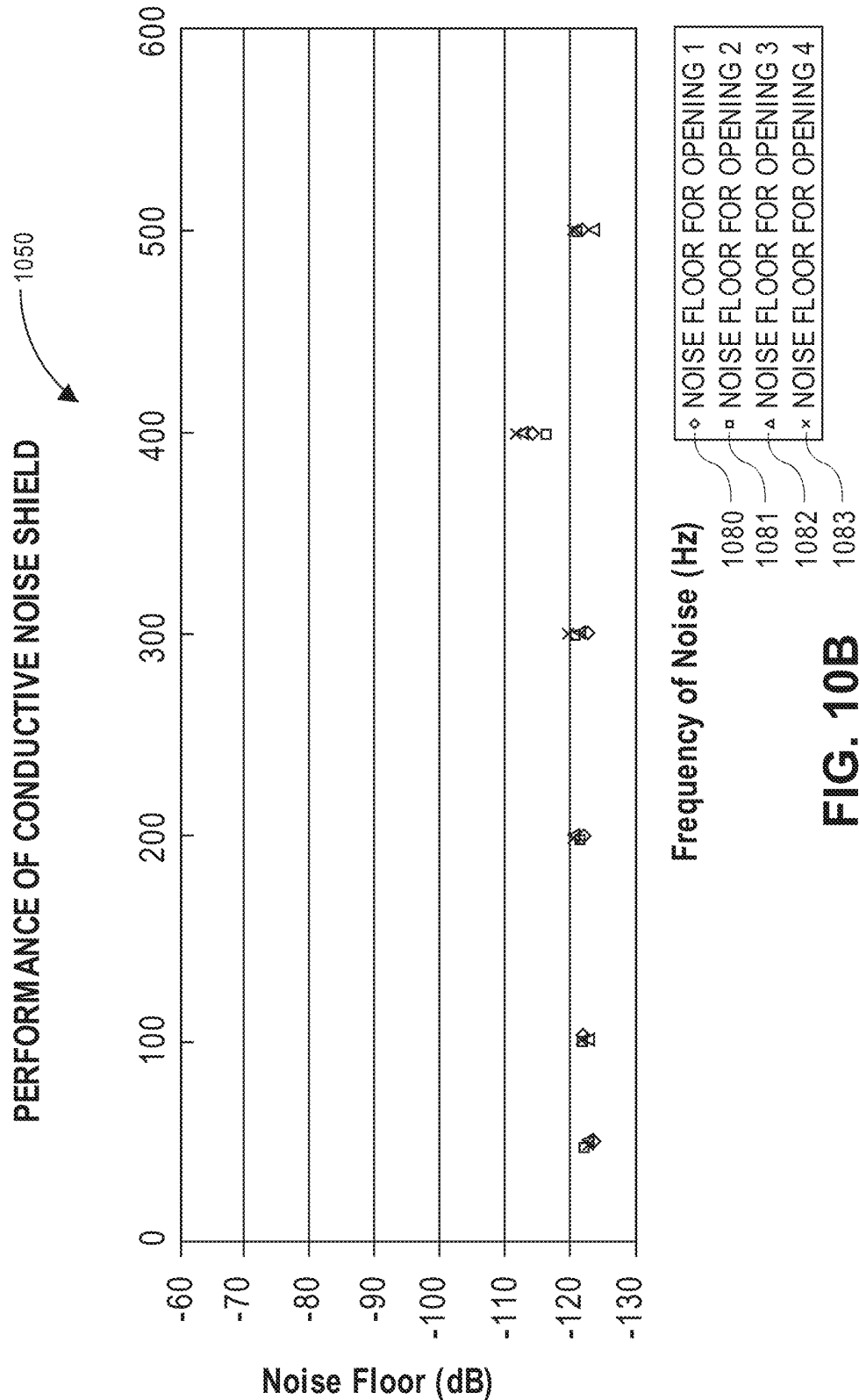


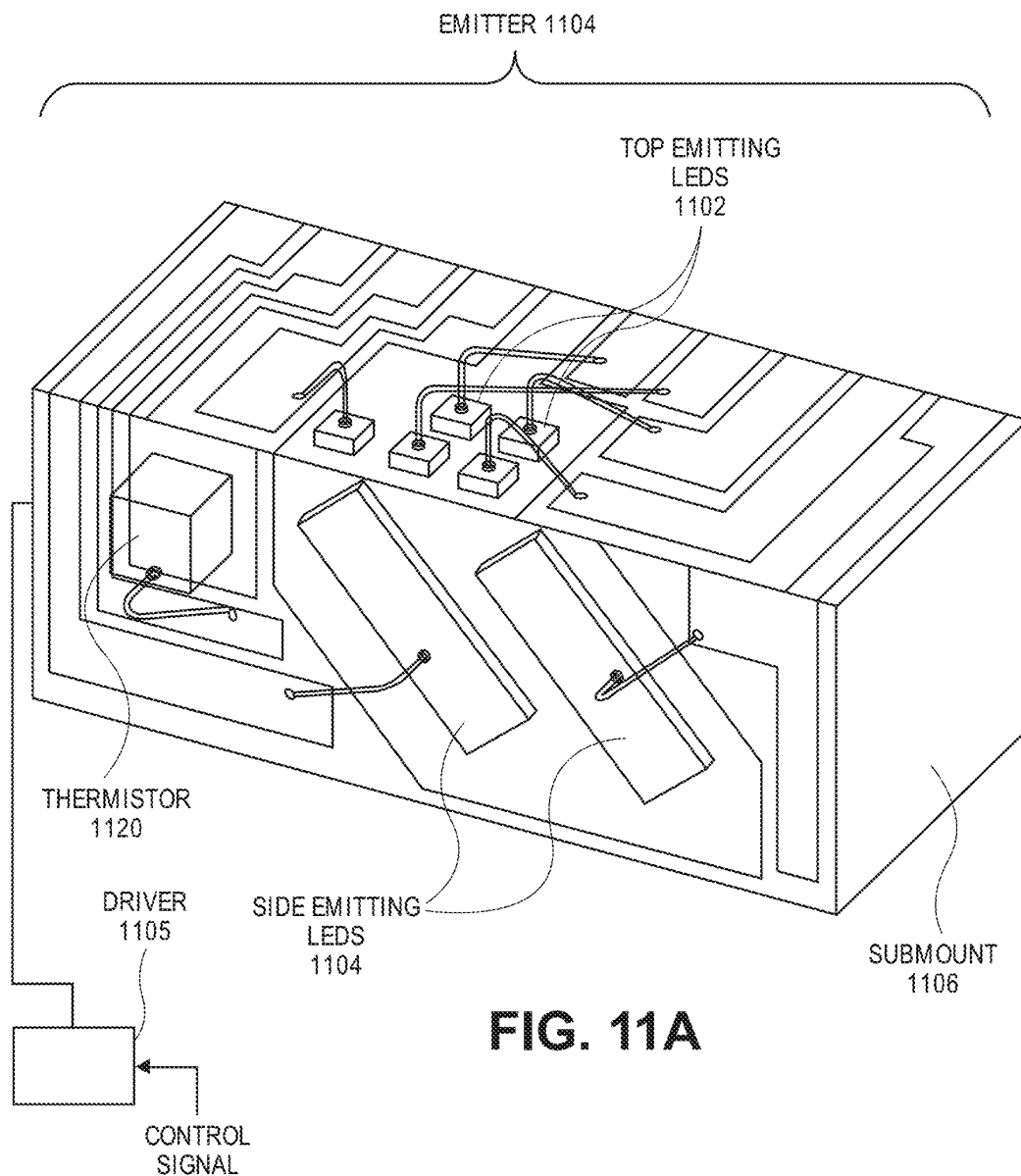
FIG. 10B

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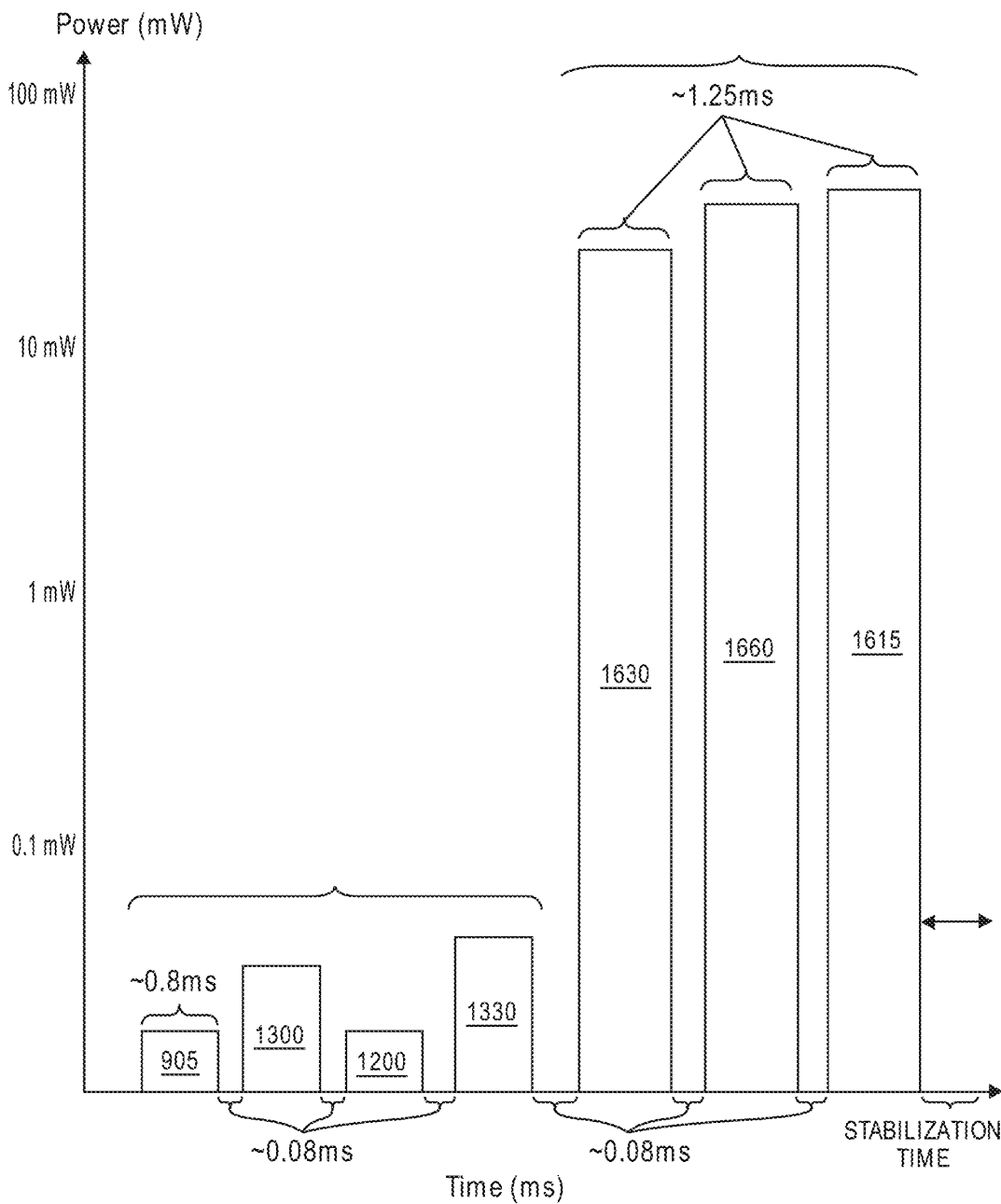


FIG. 11B

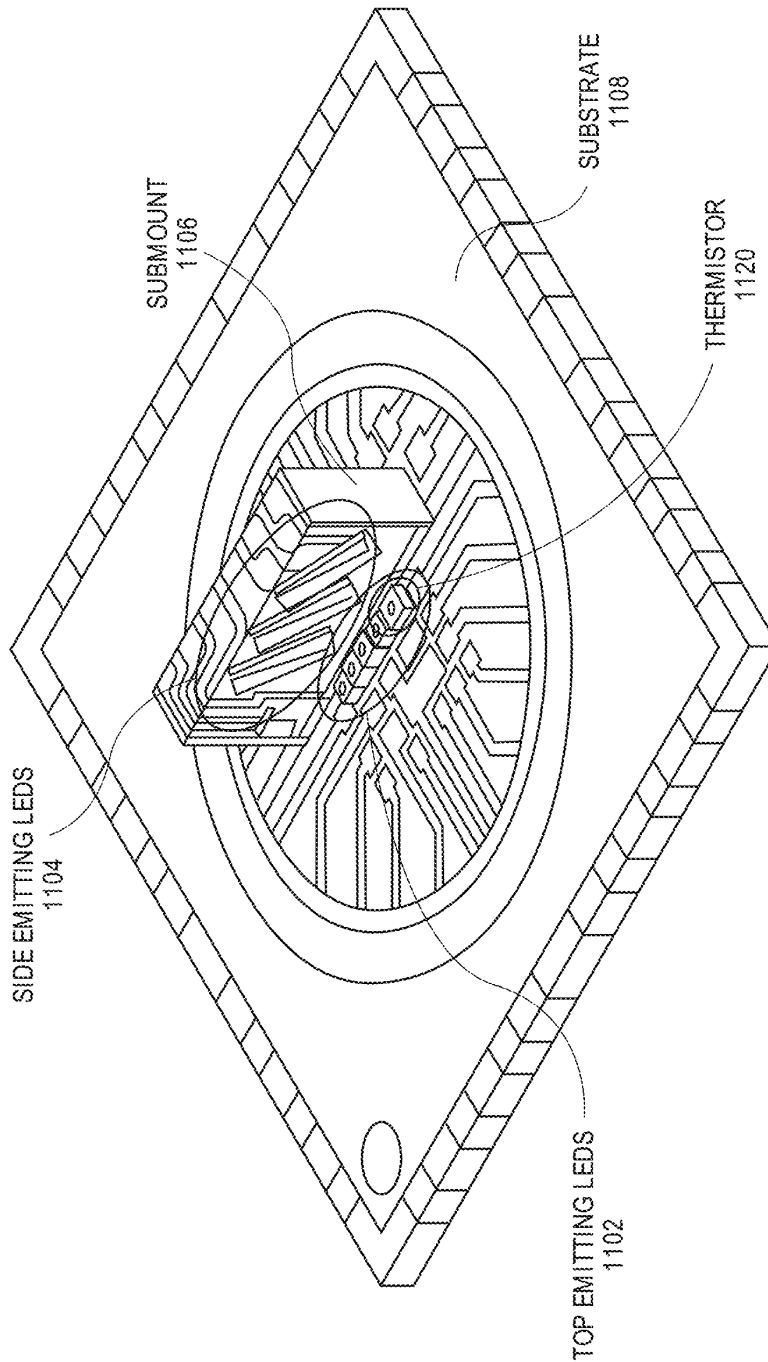


FIG. 11C

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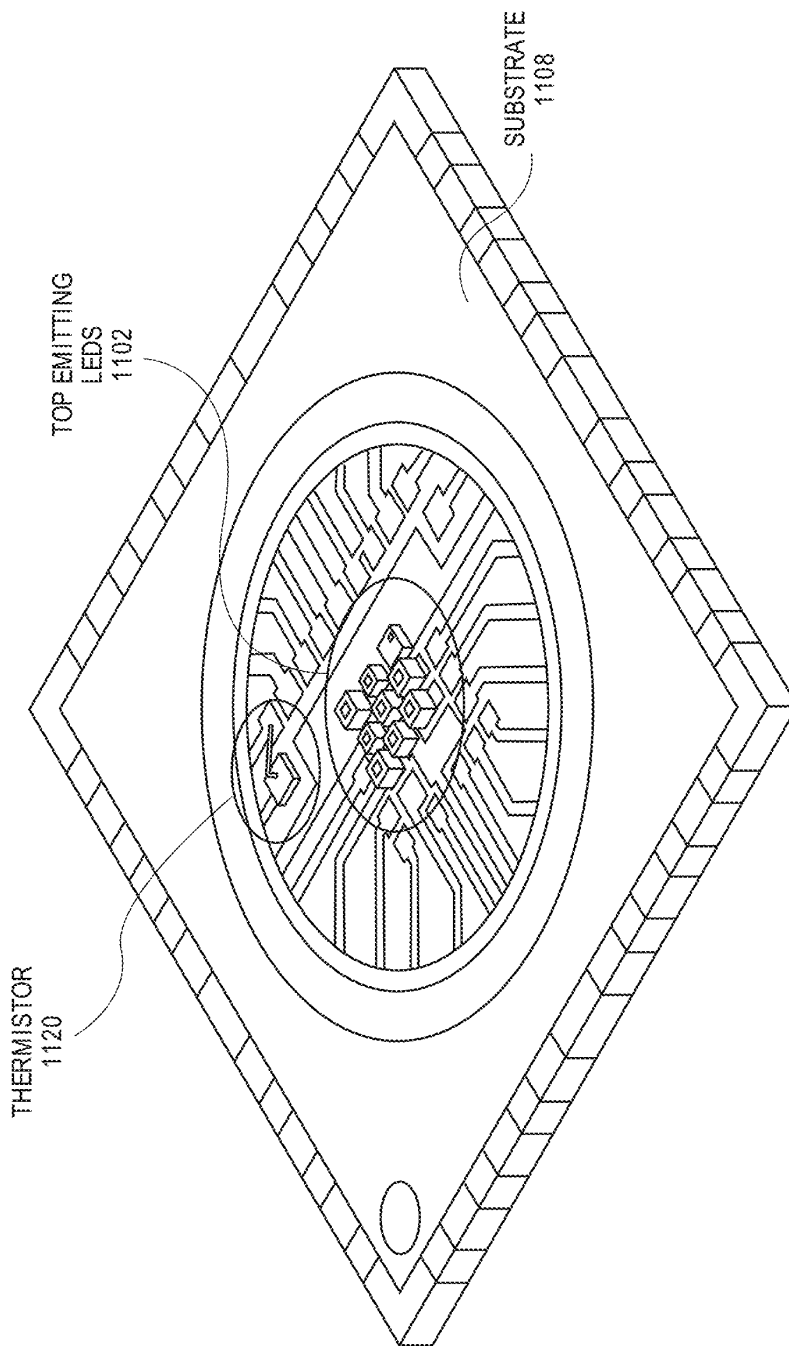


FIG. 11D

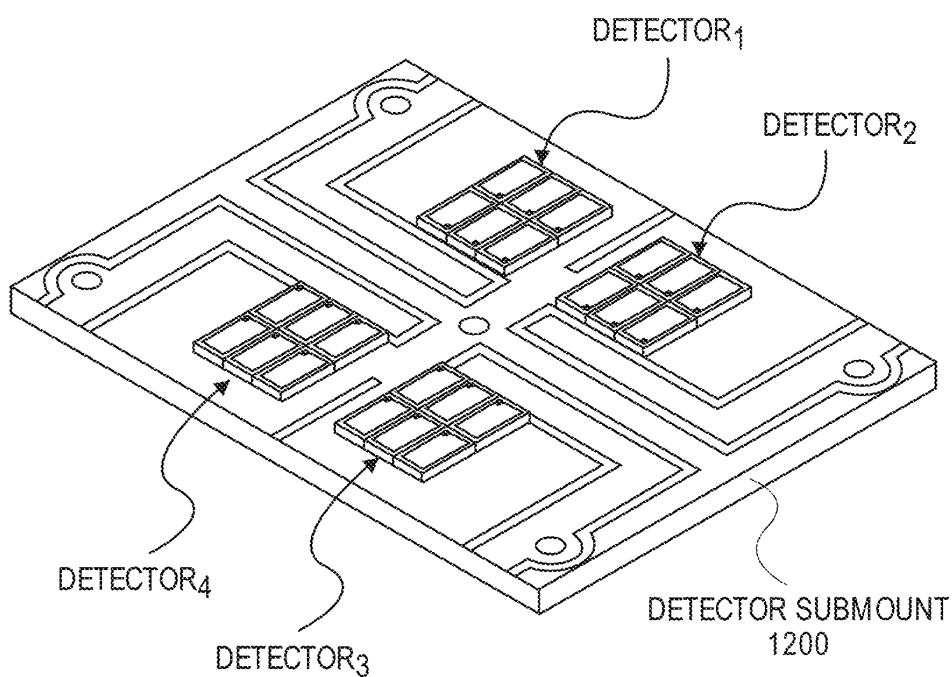


FIG. 12A

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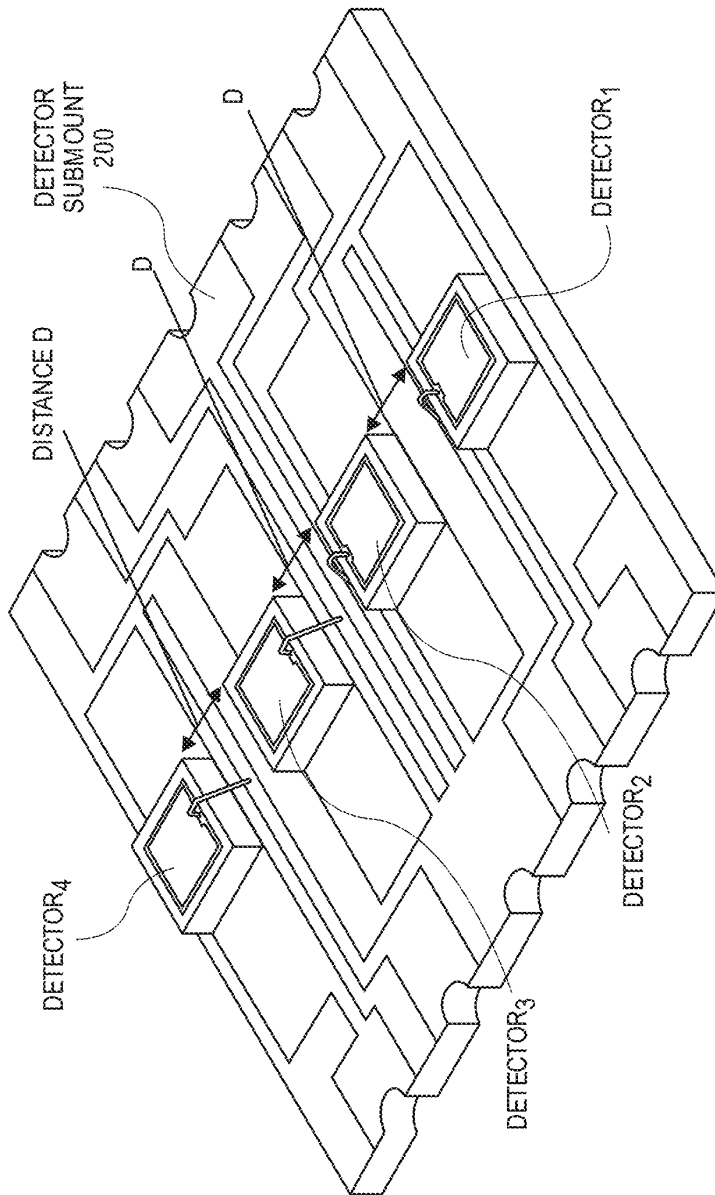


FIG. 12B

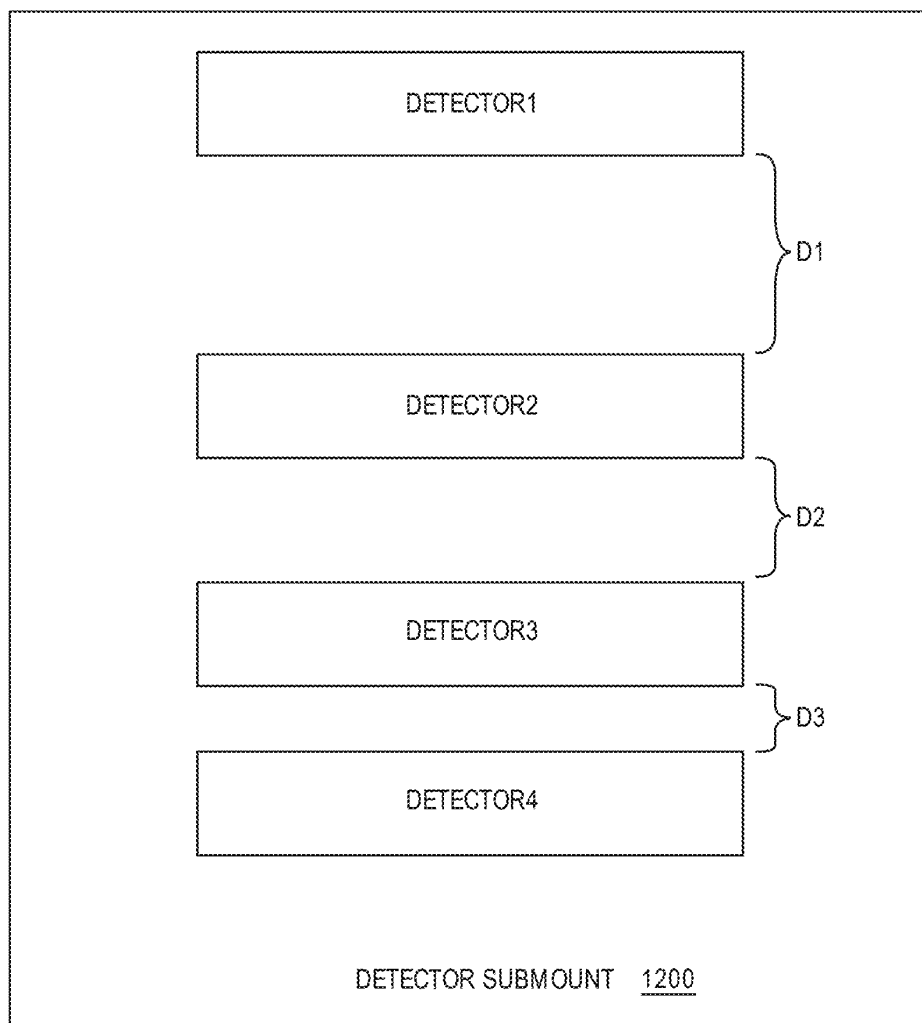


FIG. 12C

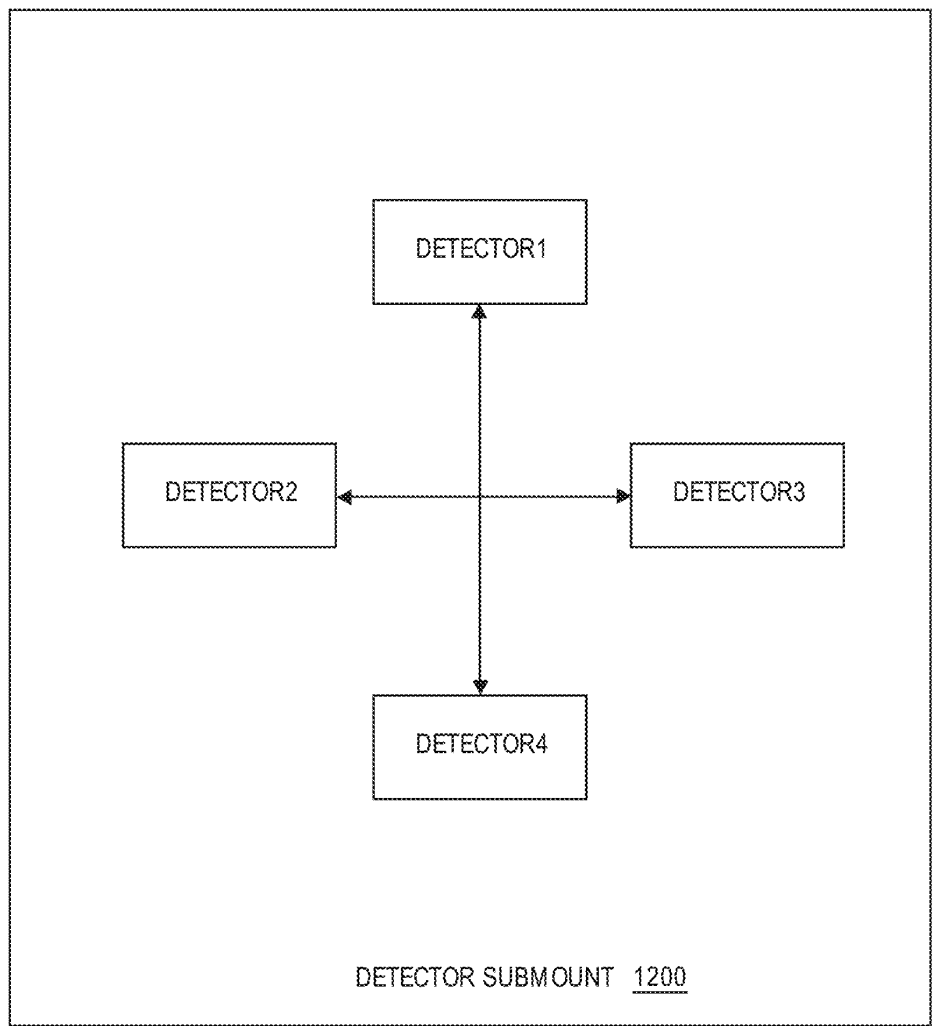


FIG. 12D

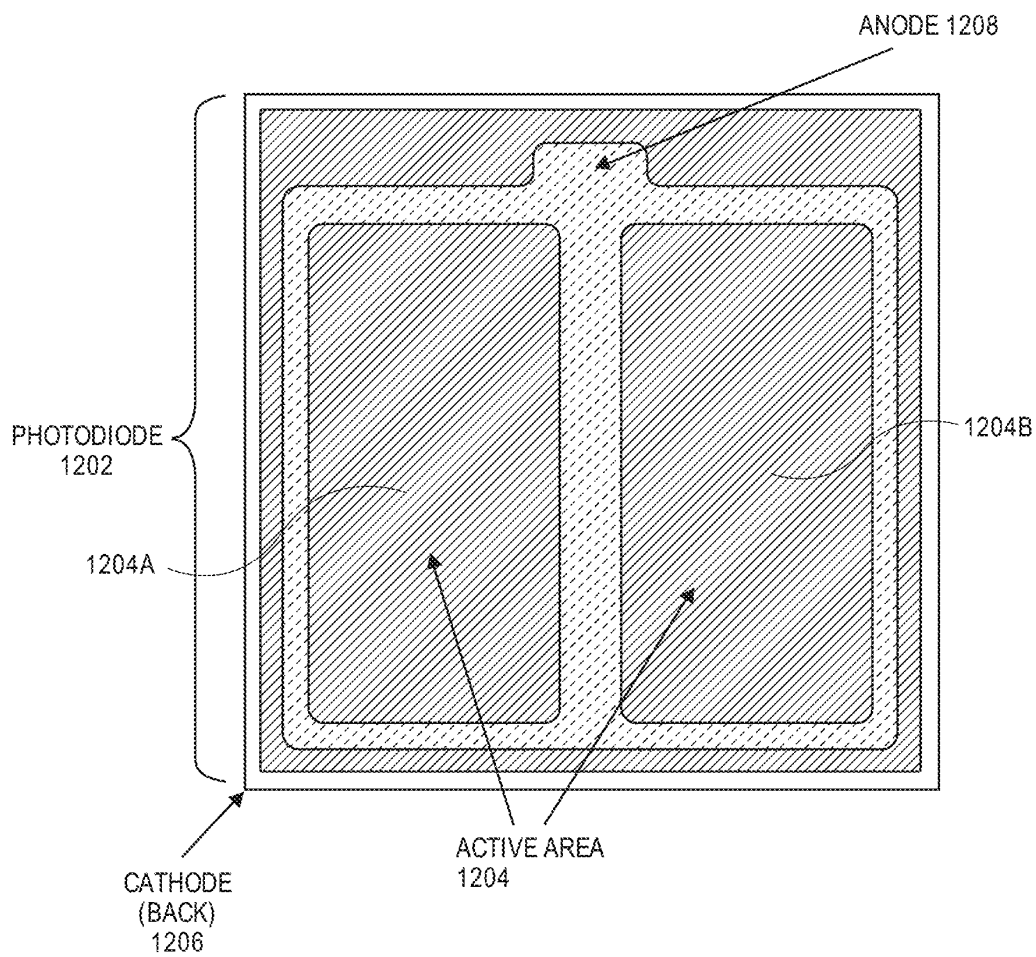


FIG. 12E

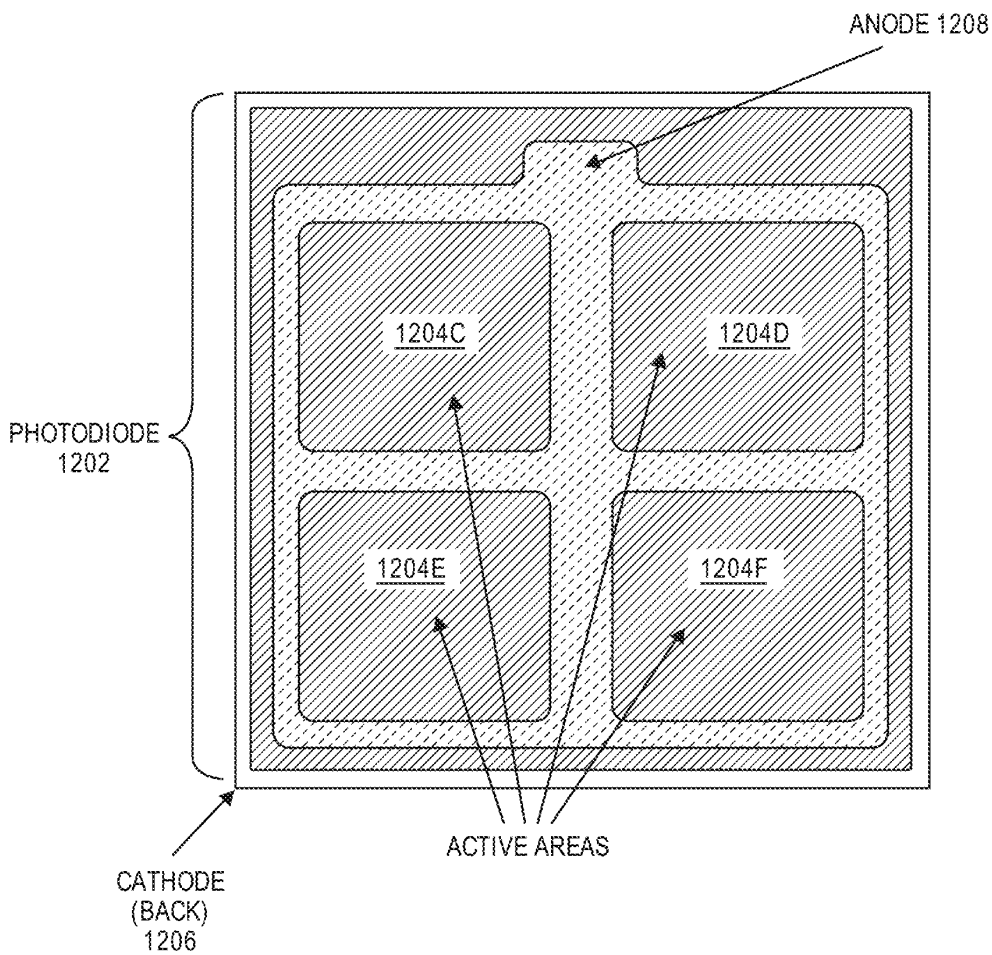


FIG. 12F

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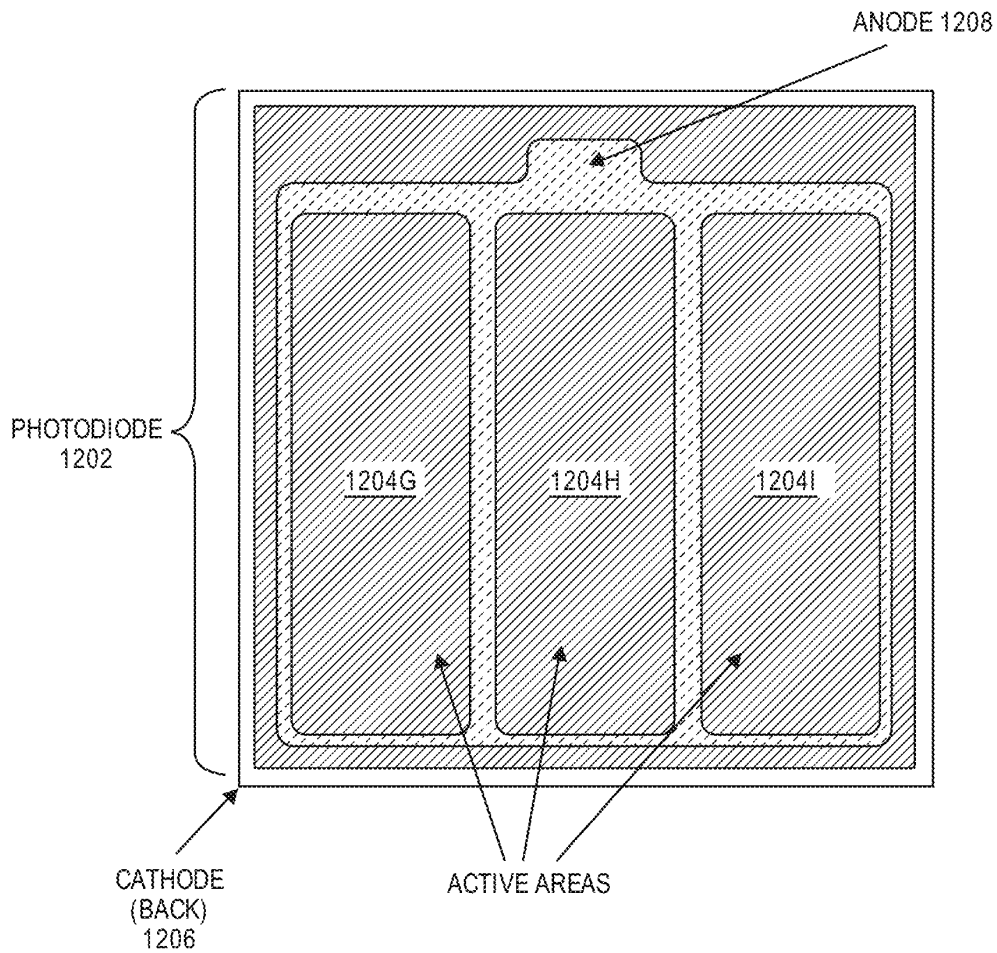


FIG. 12G

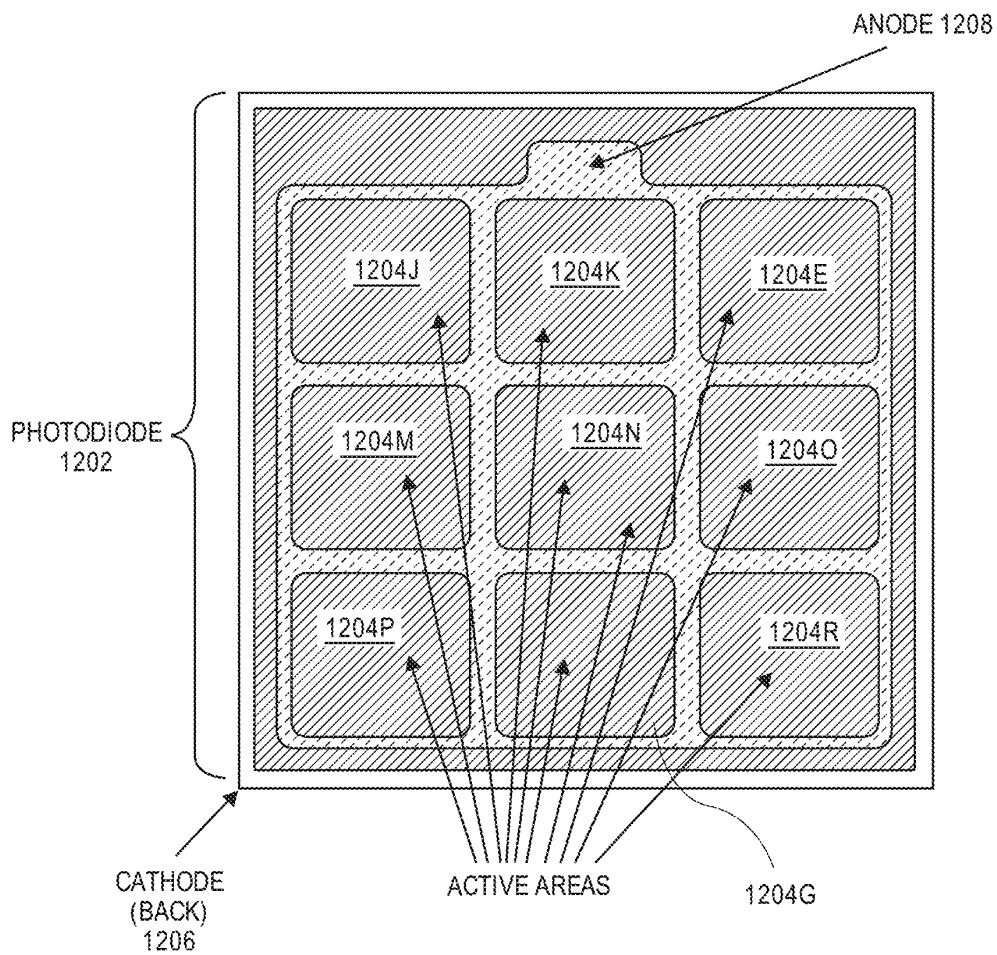


FIG. 12H

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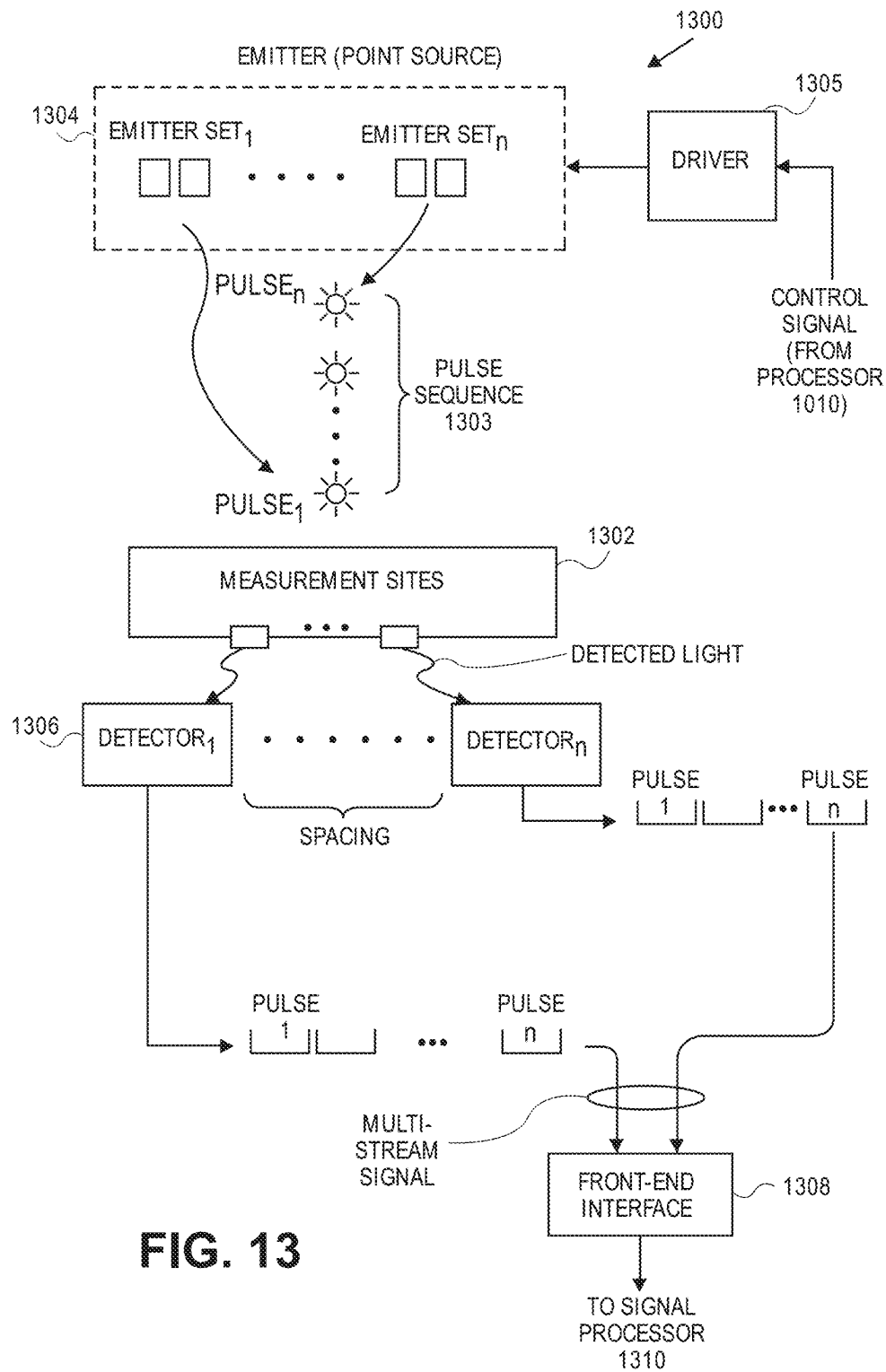


FIG. 13

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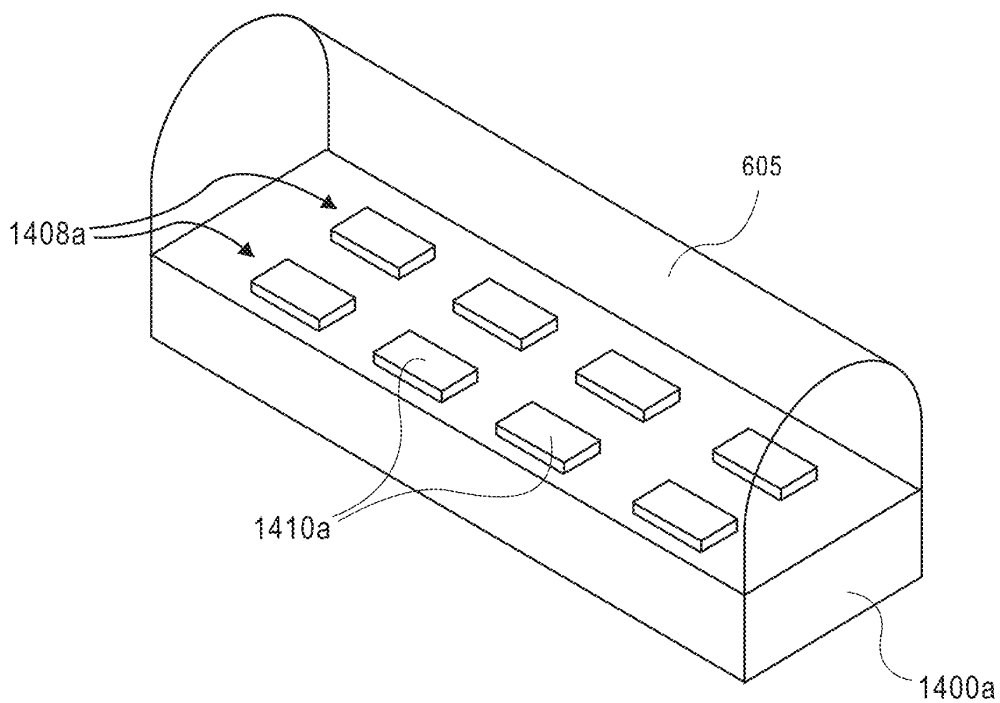


FIG. 14A

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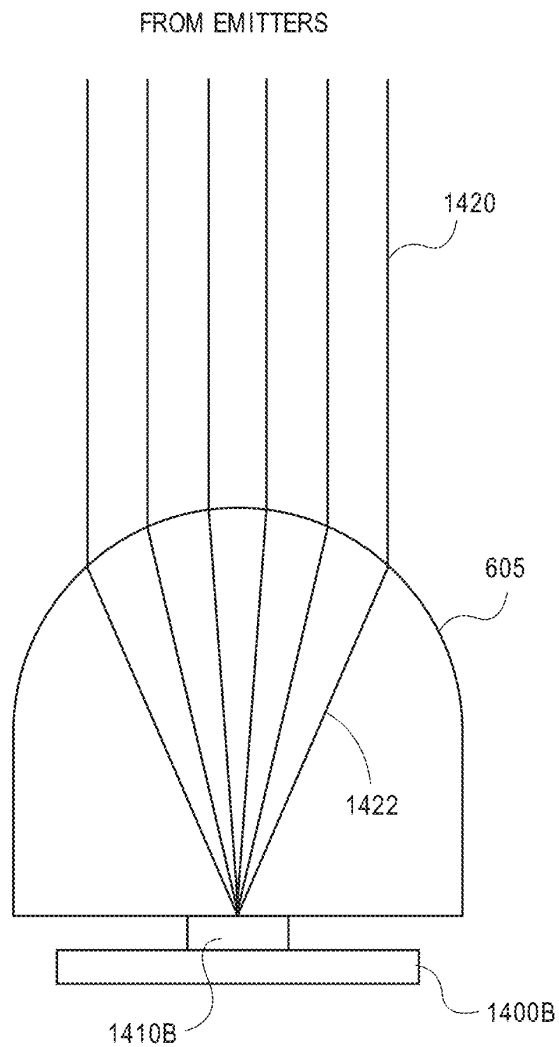


FIG. 14B

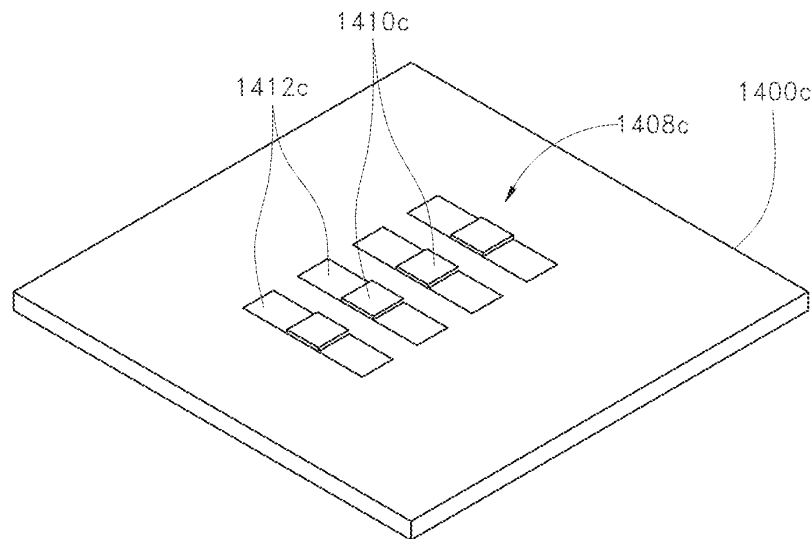


FIG. 14C

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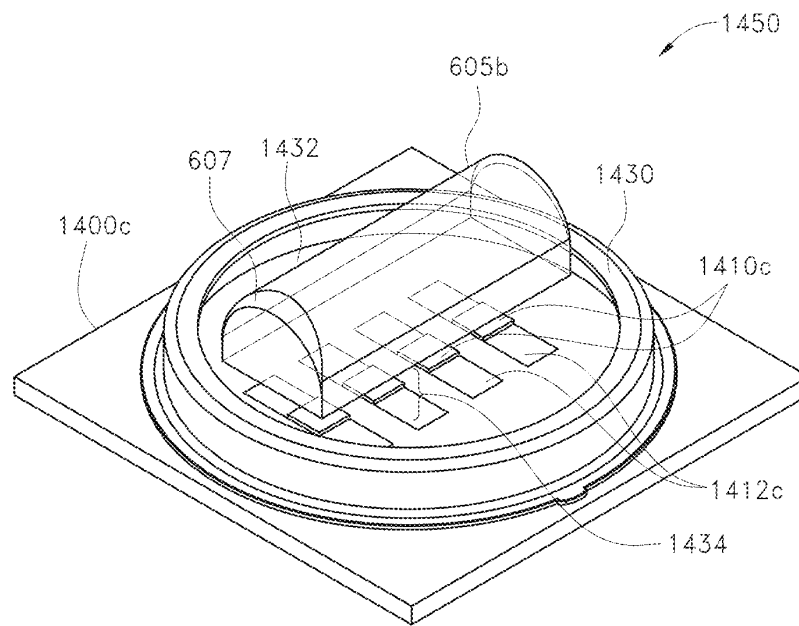


FIG. 14D

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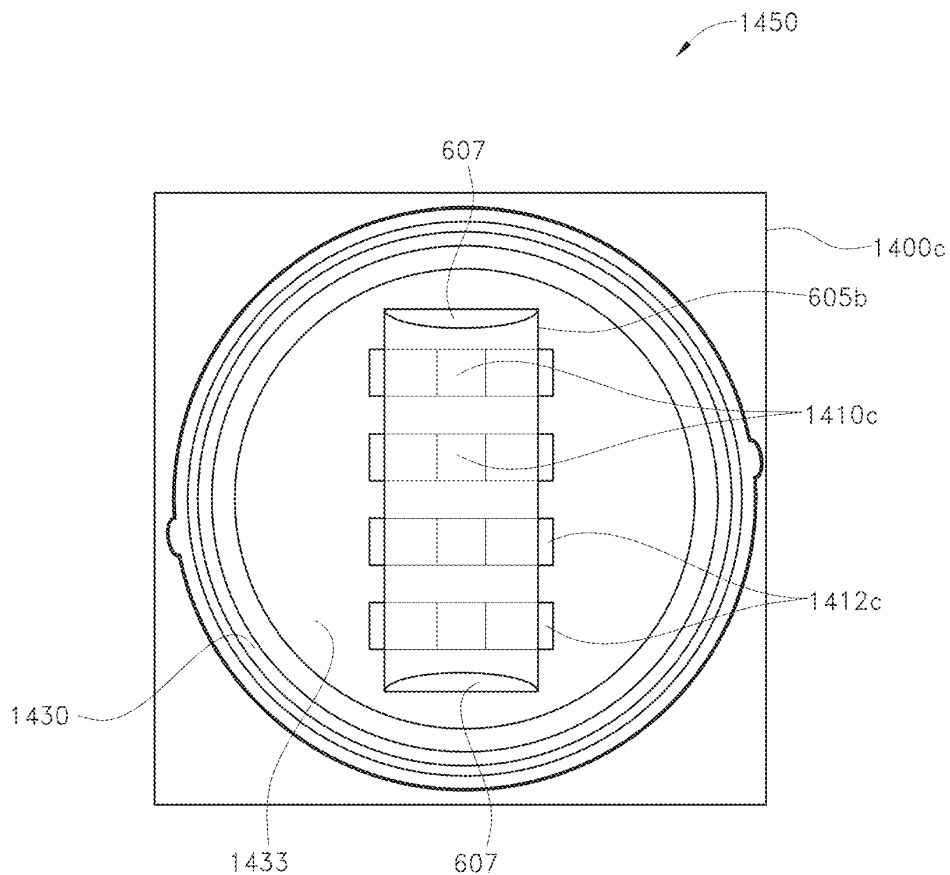


FIG. 14E

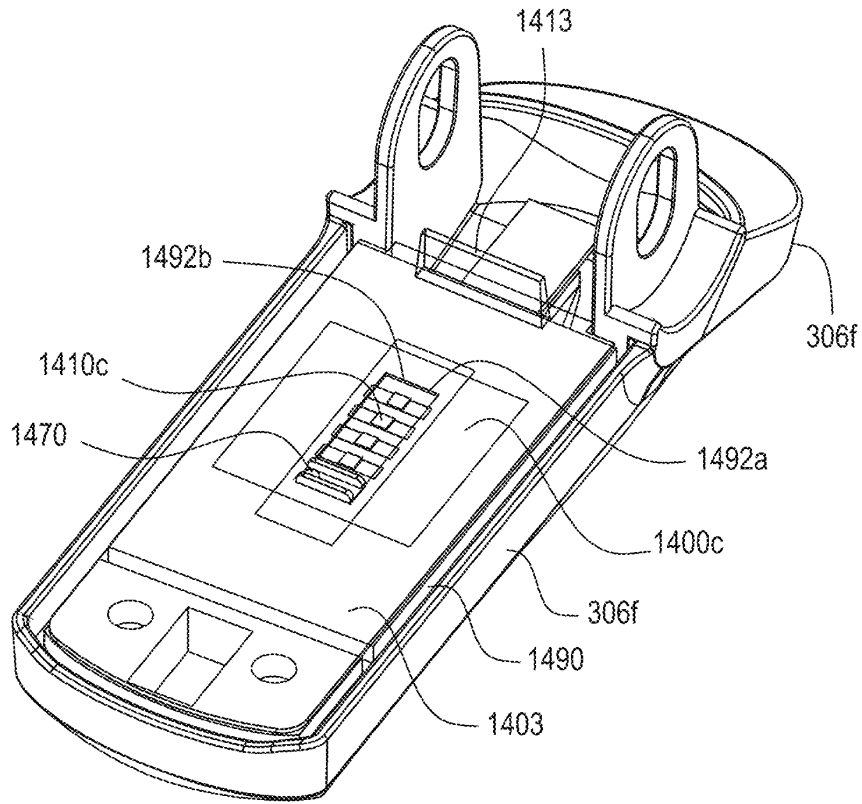


FIG. 14F

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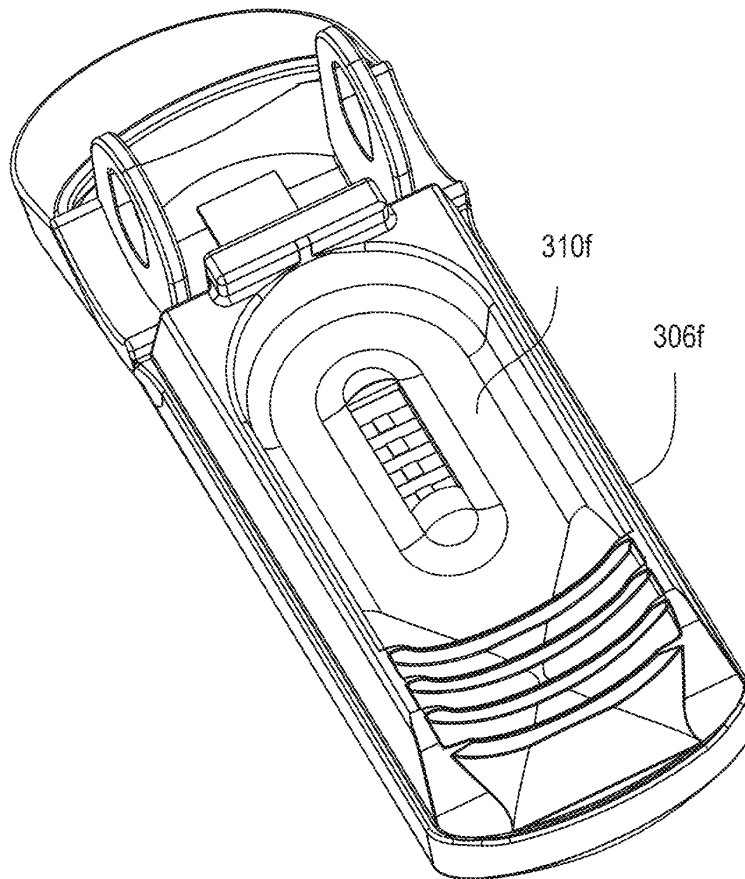


FIG. 14G

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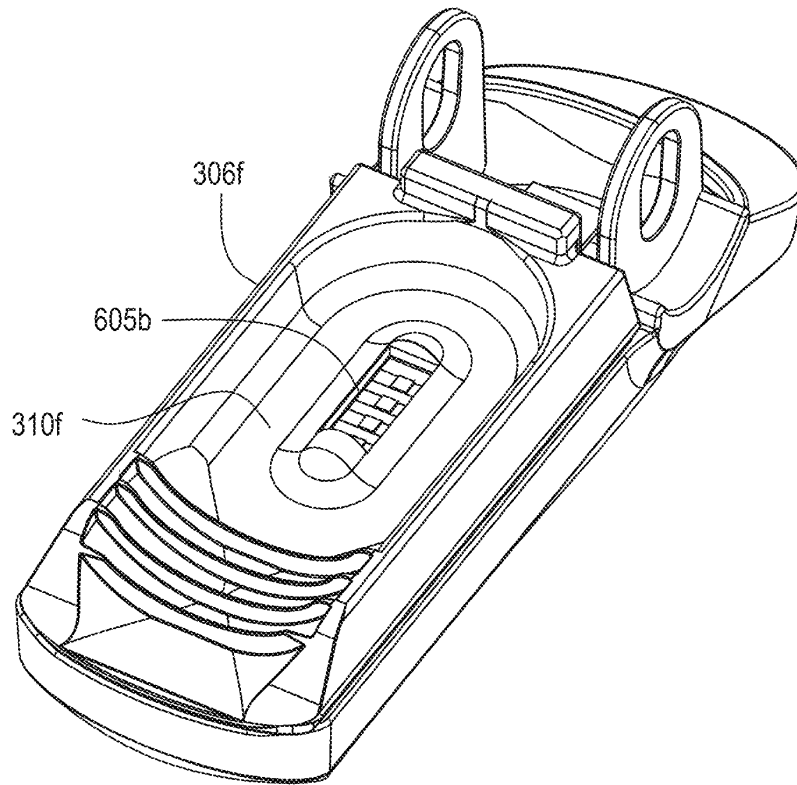


FIG. 14H

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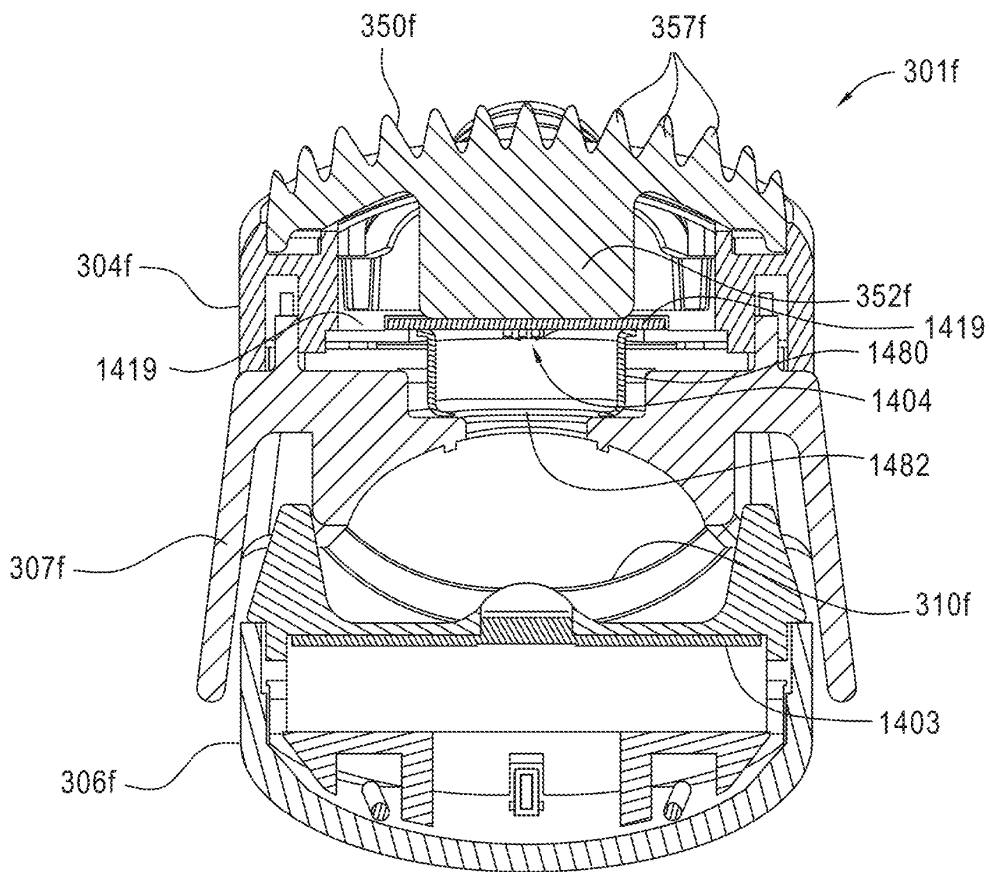


FIG. 14I

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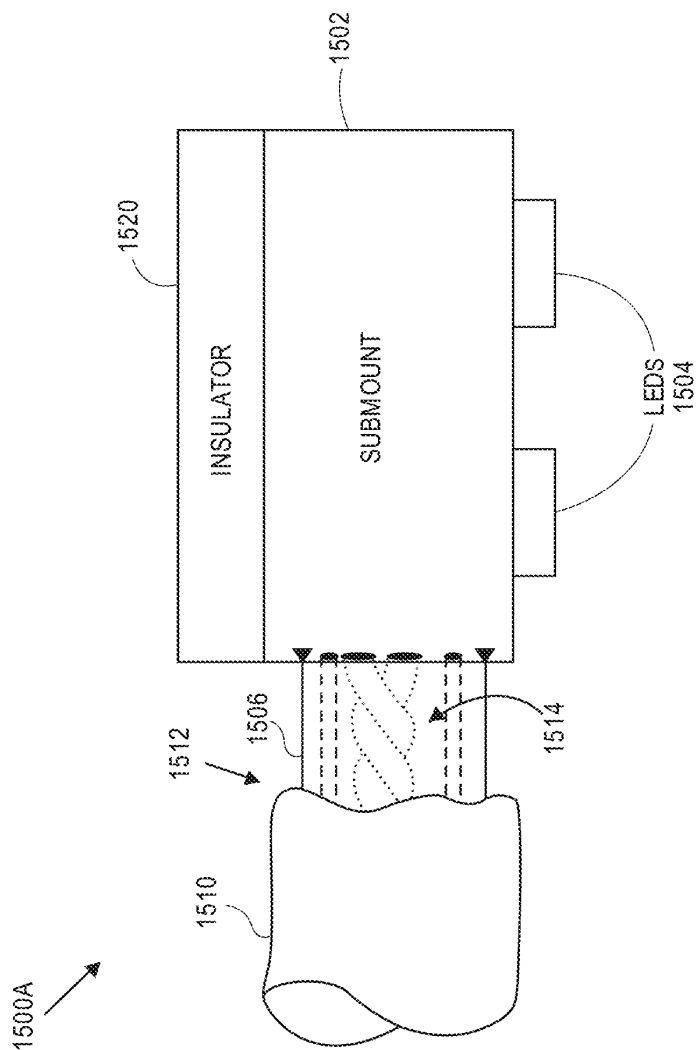


FIG. 15A

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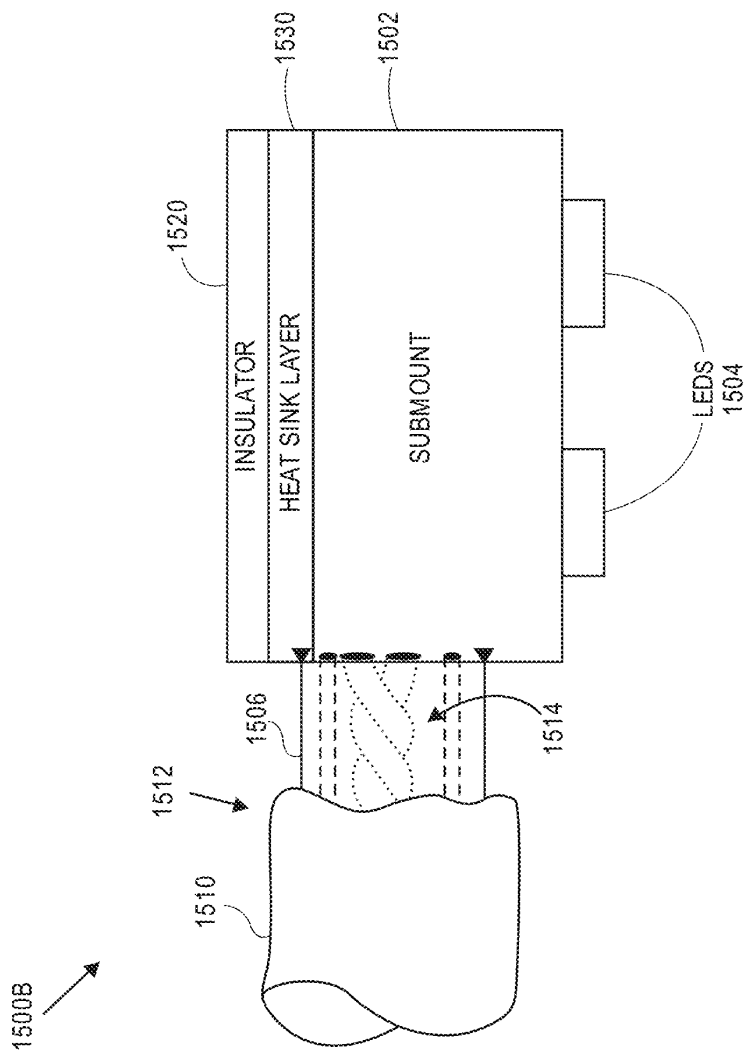


FIG. 15B

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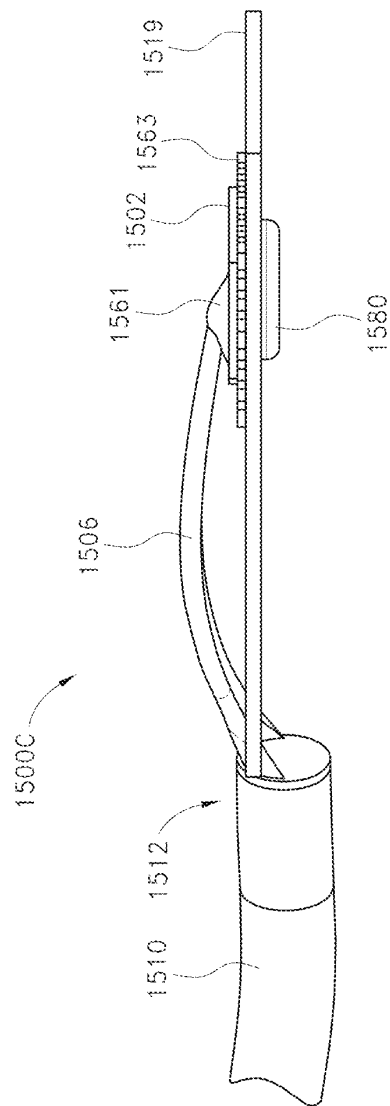


FIG. 15C

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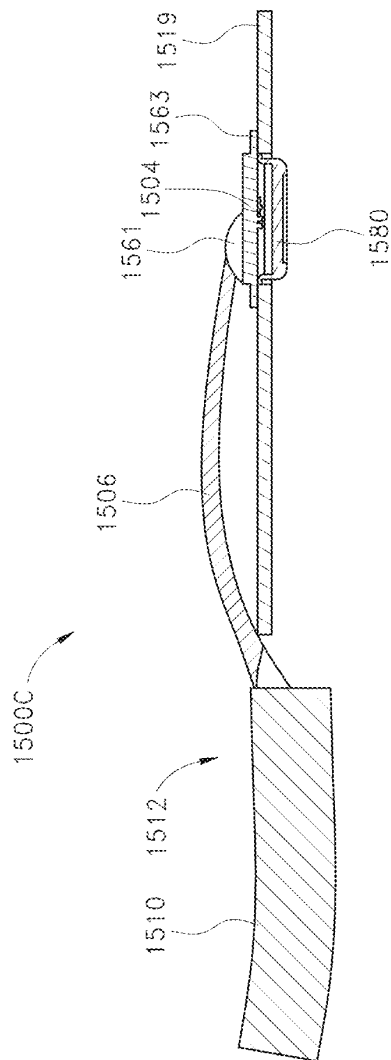


FIG. 15D

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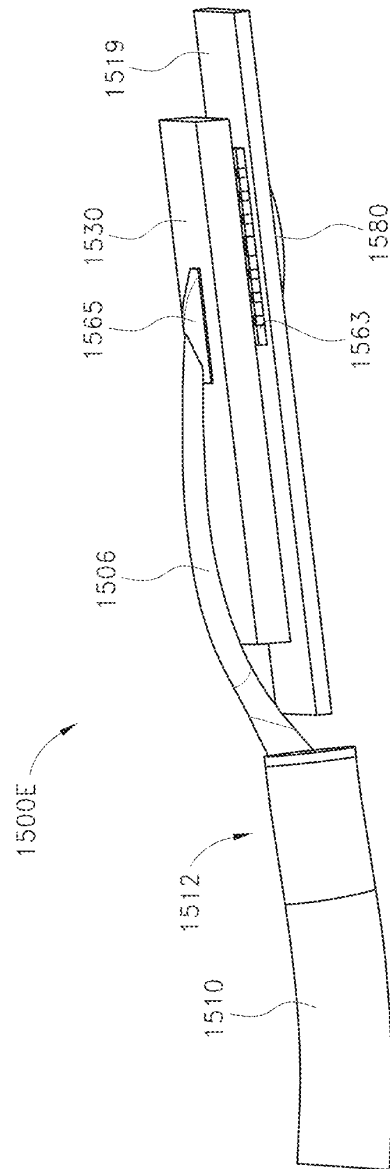


FIG. 15E

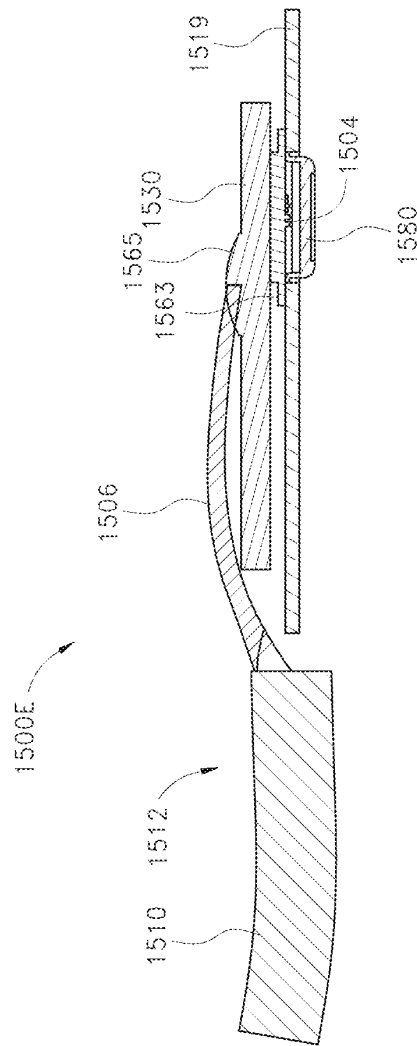


FIG. 15F

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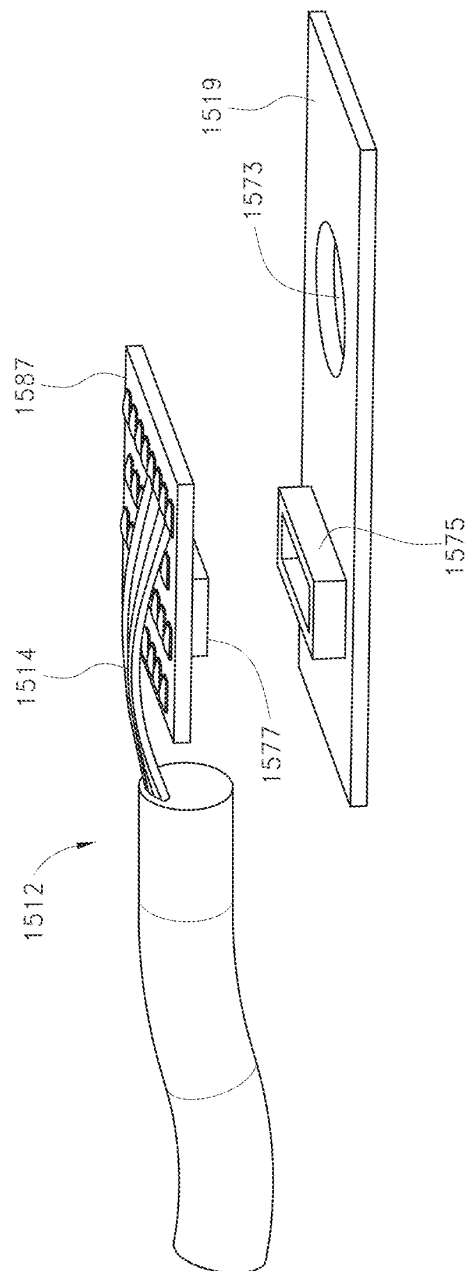


FIG. 15G

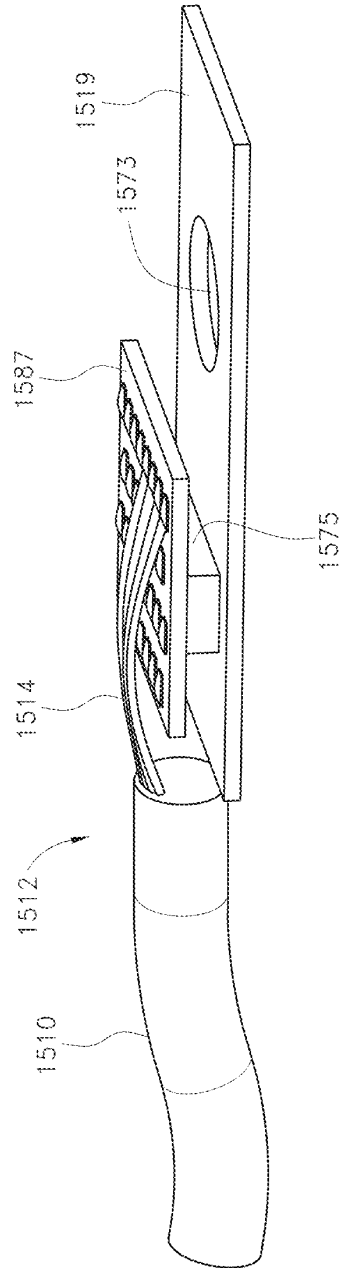


FIG. 15H

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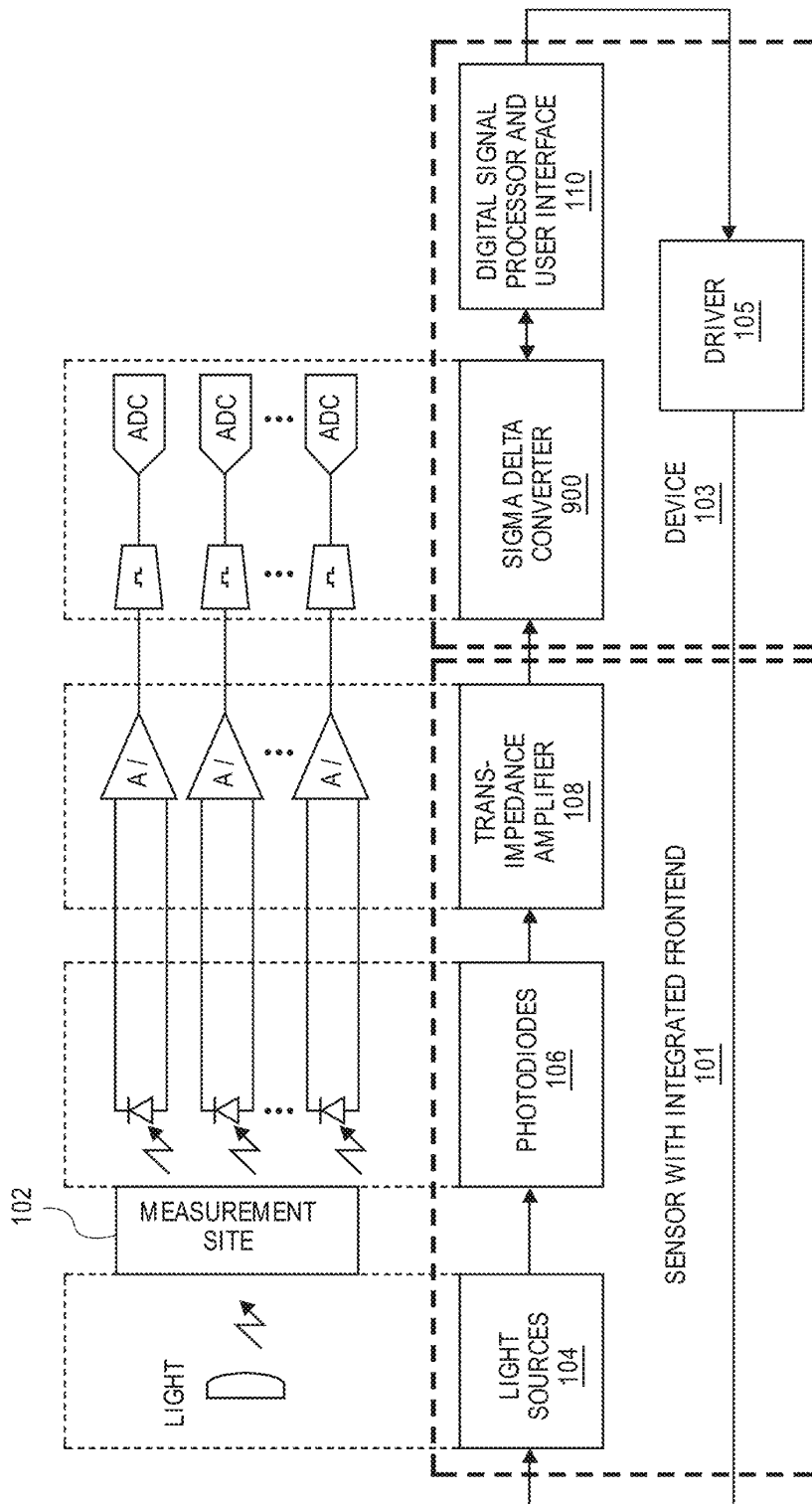


FIG. 15I

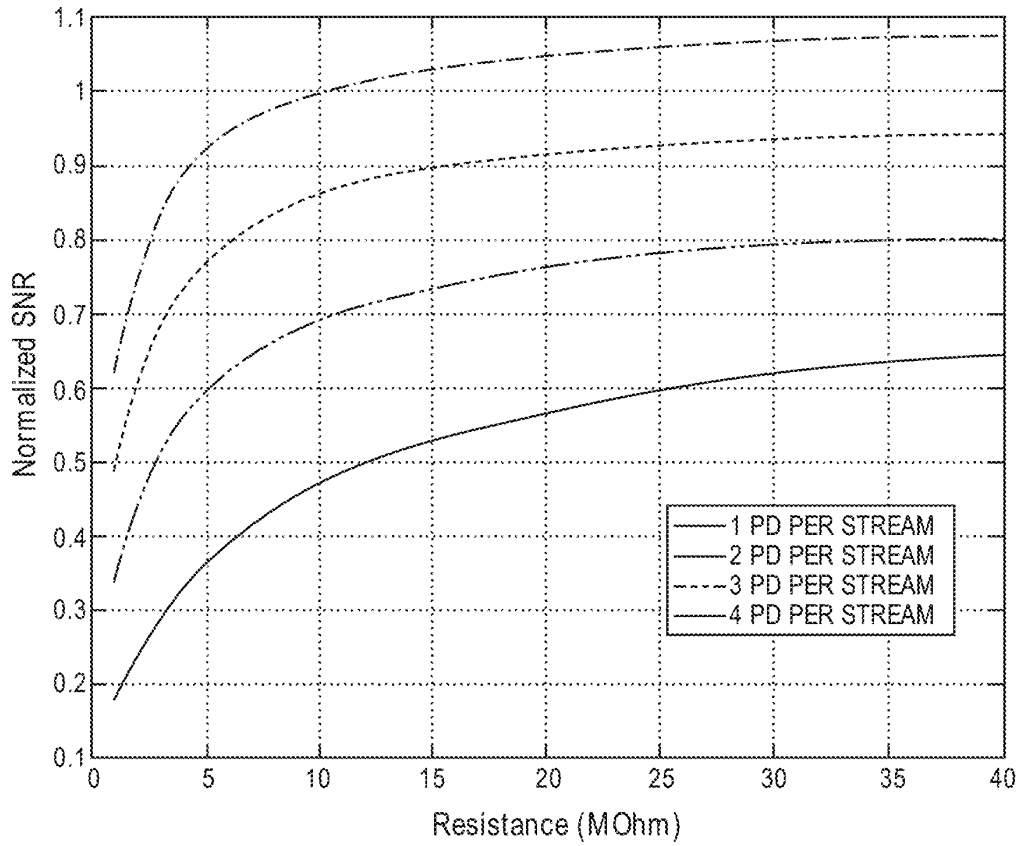


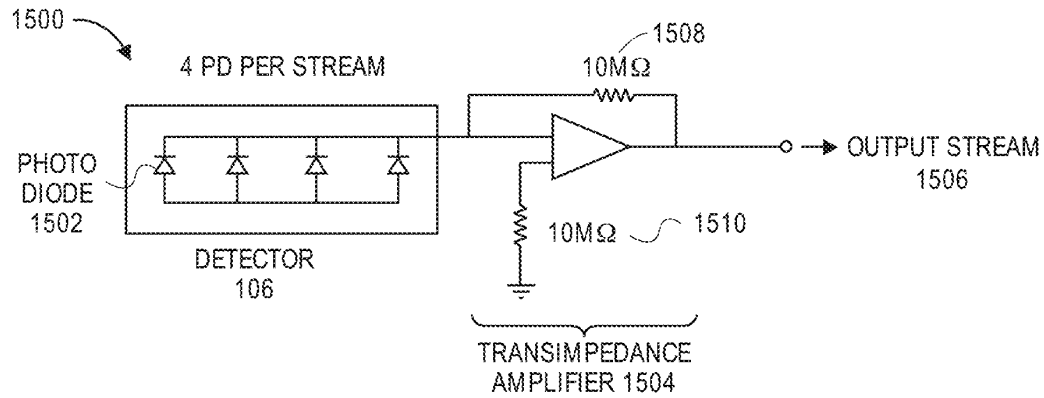
FIG. 15J

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VS.

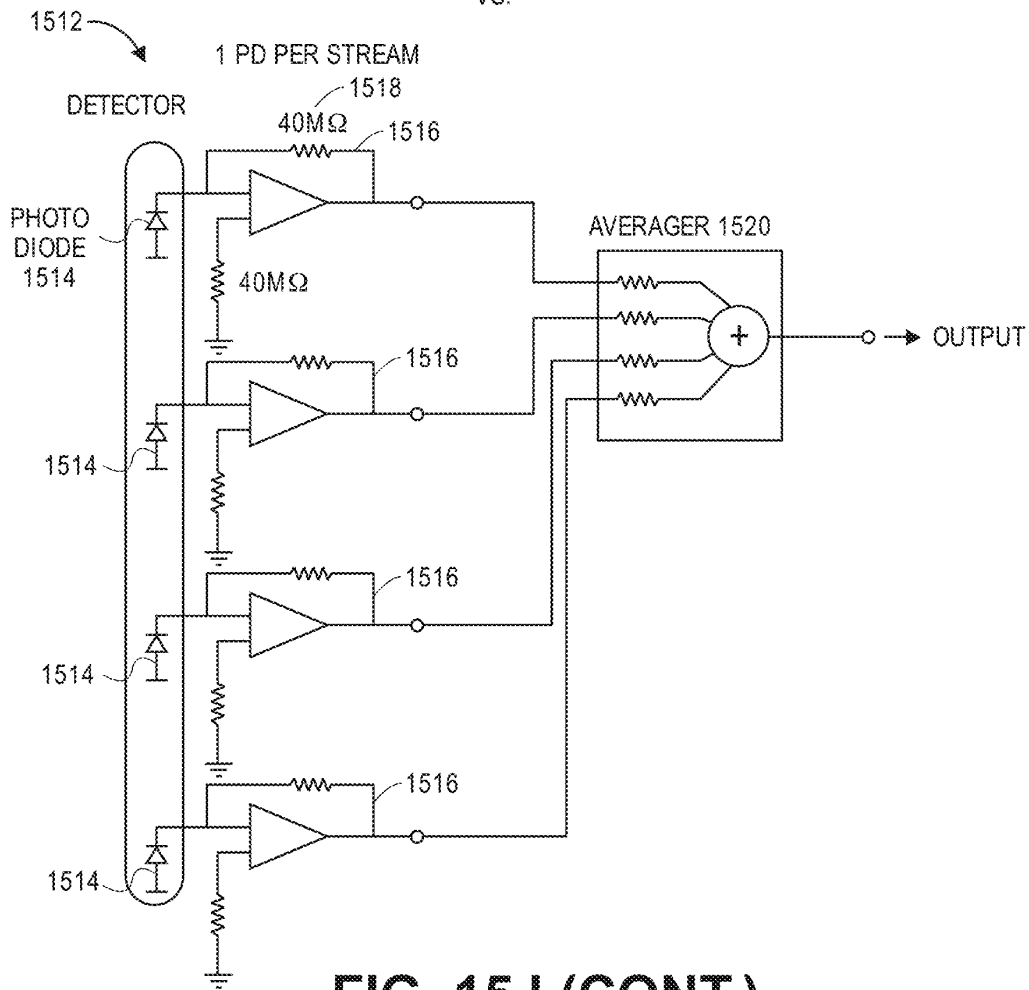


FIG. 15J (CONT.)

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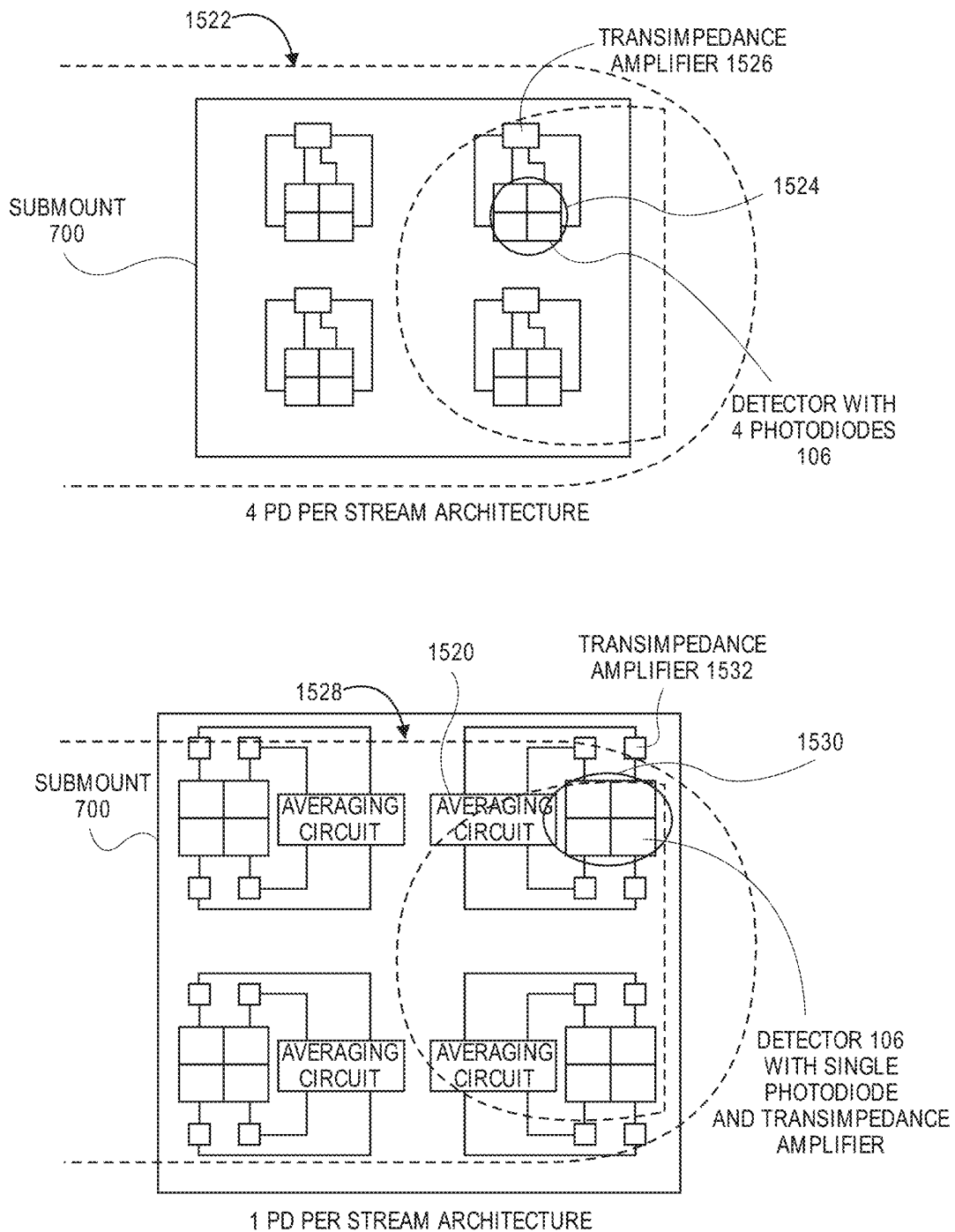


FIG. 15K

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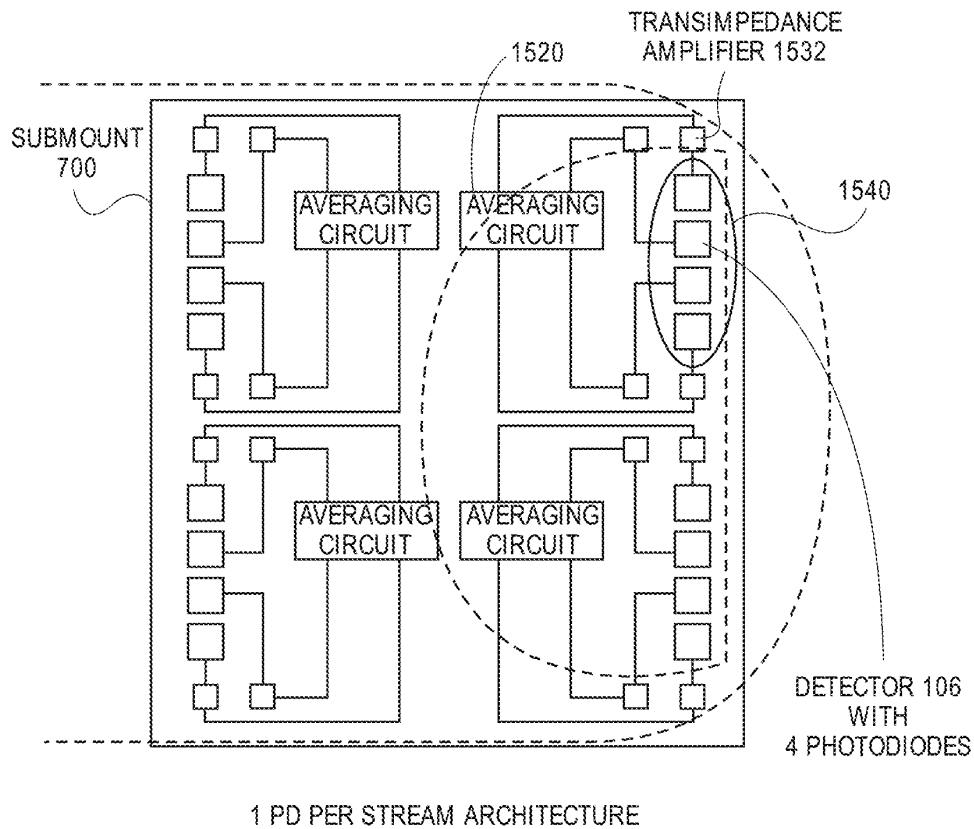
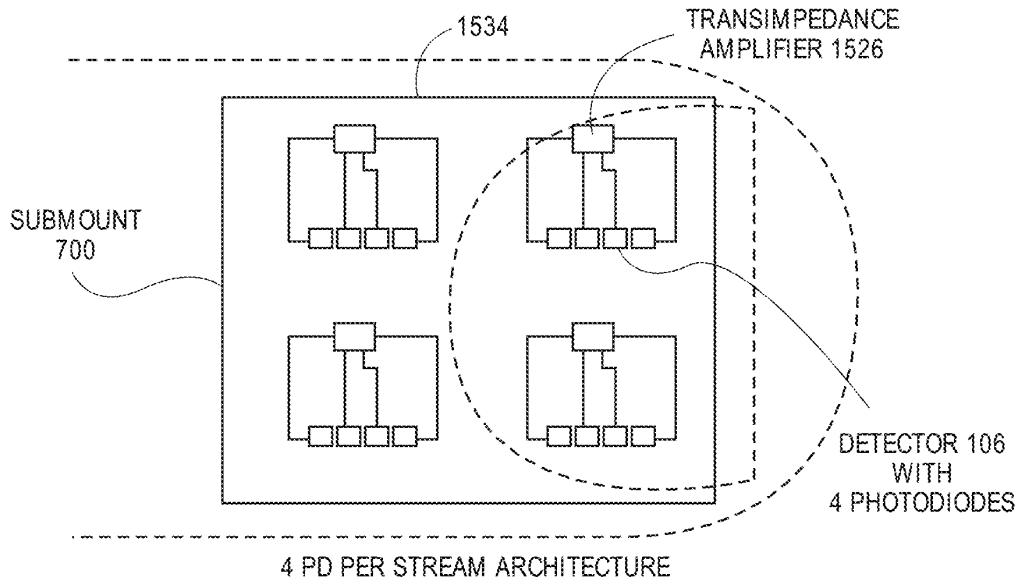


FIG. 15K (CONT.)

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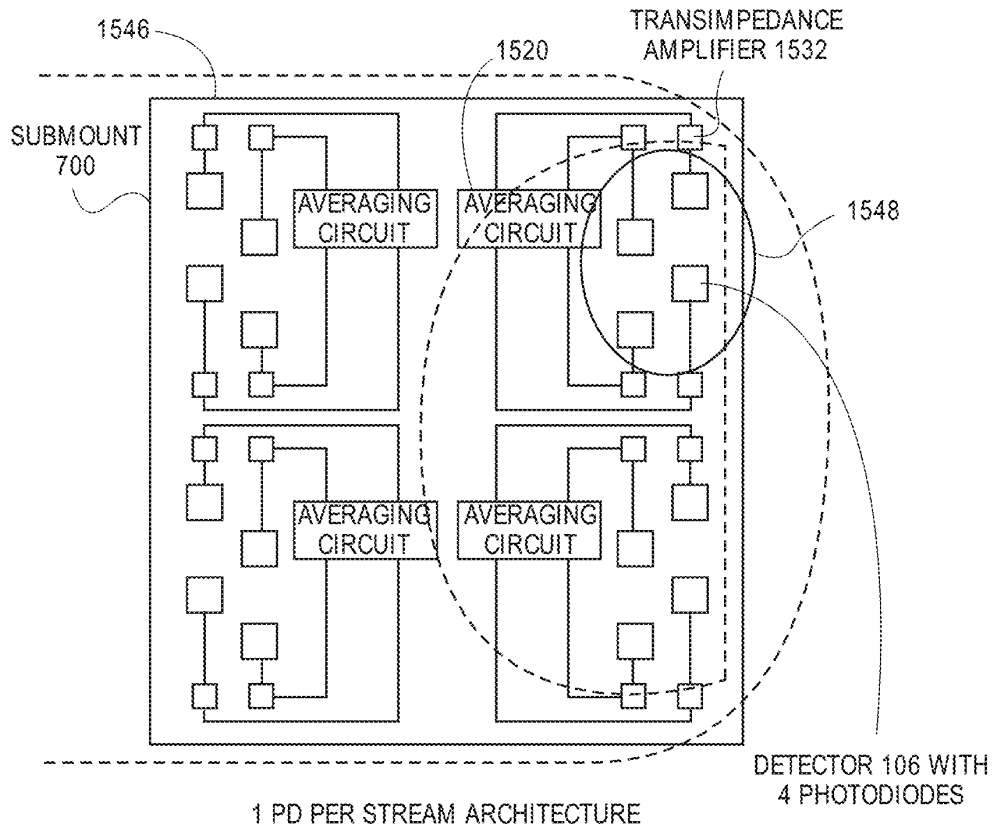
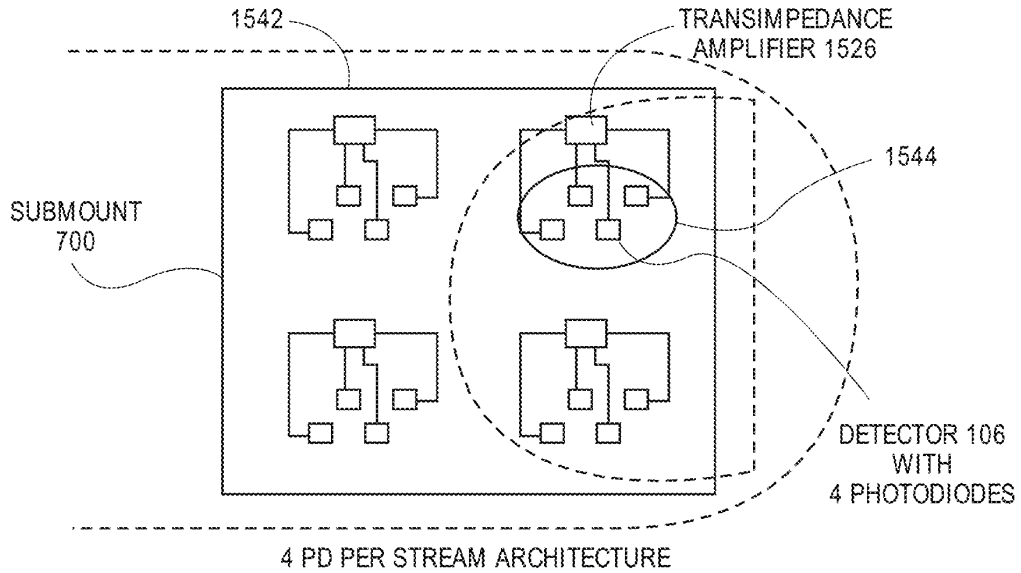


FIG. 15K (CONT.)

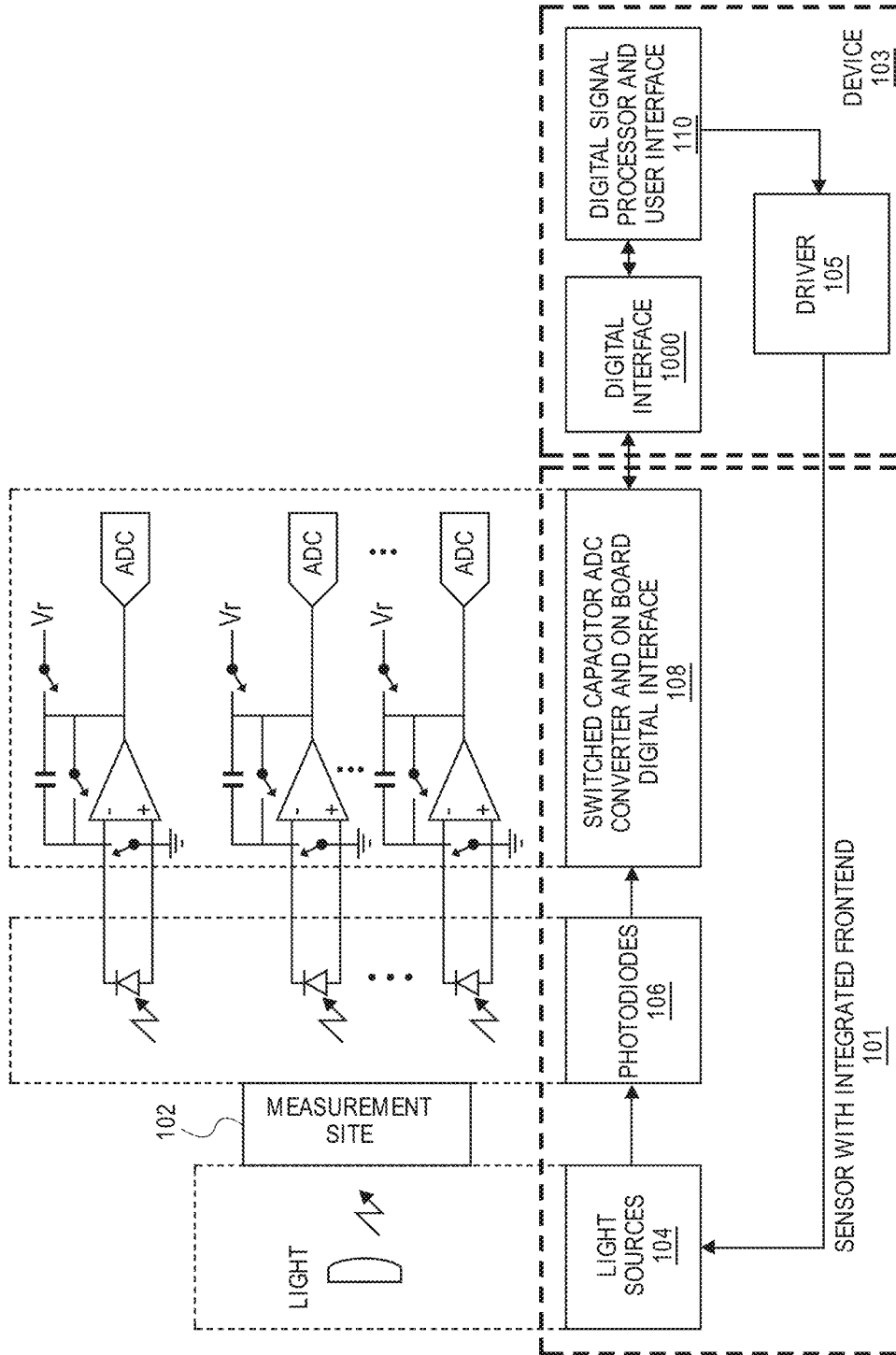


FIG. 15L

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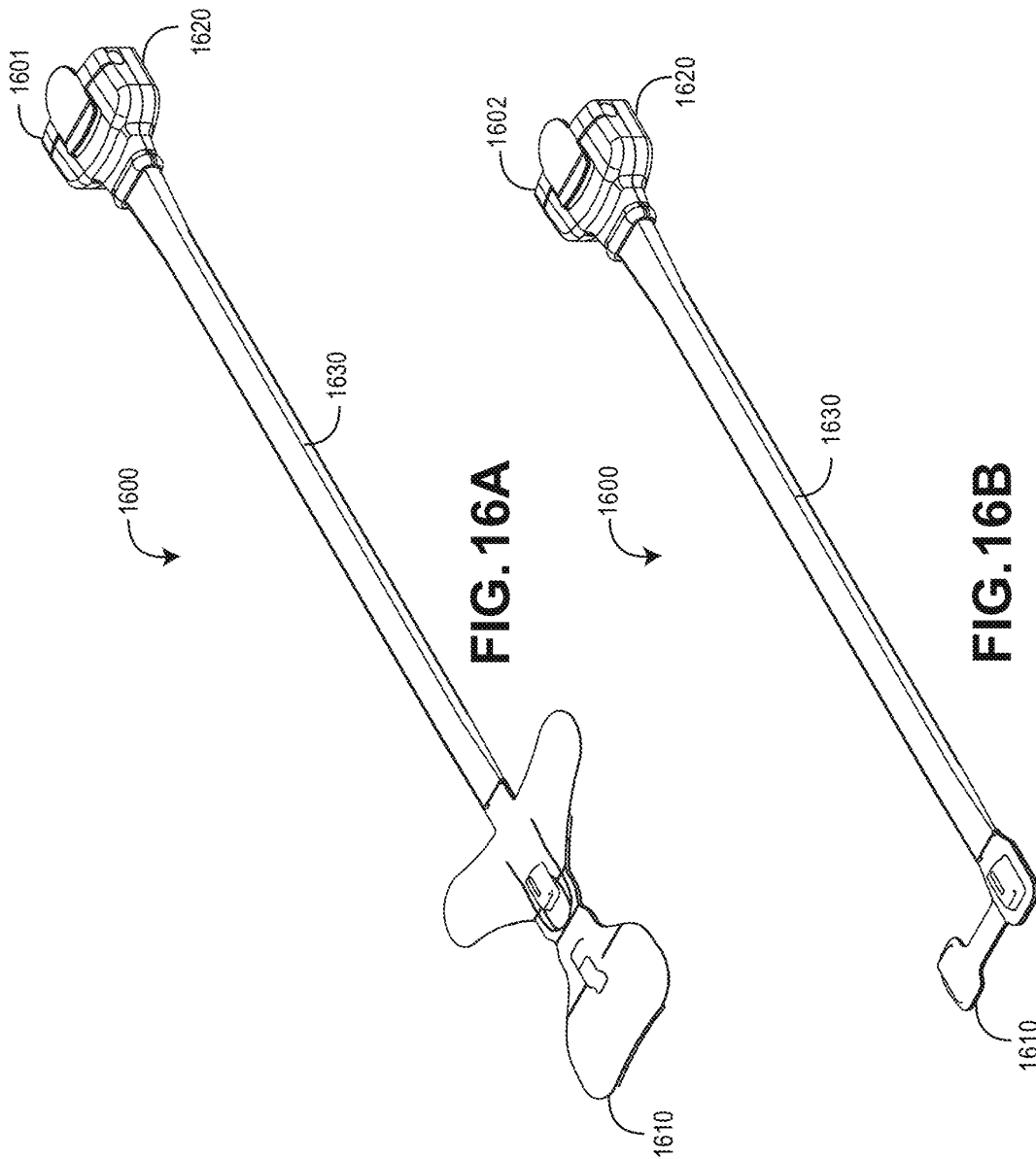


FIG. 16A

FIG. 16B

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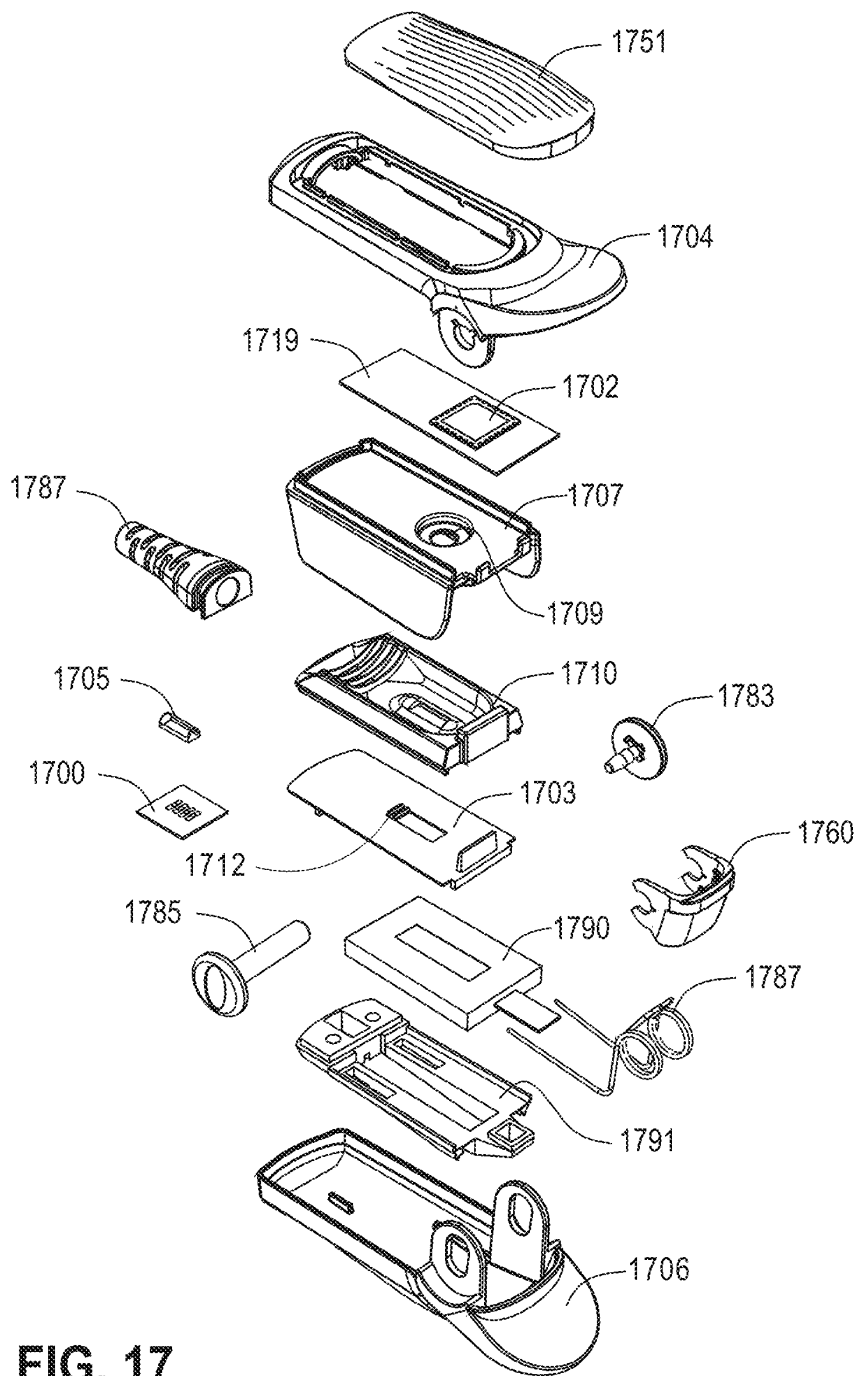


FIG. 17

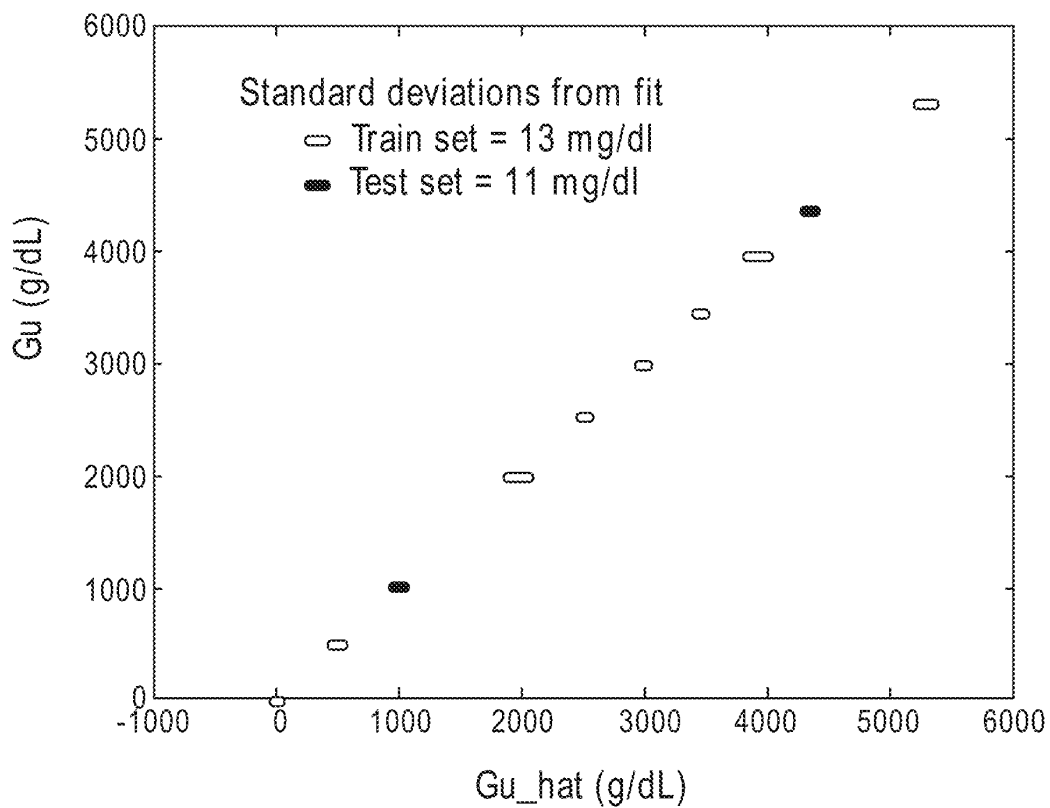


FIG. 18

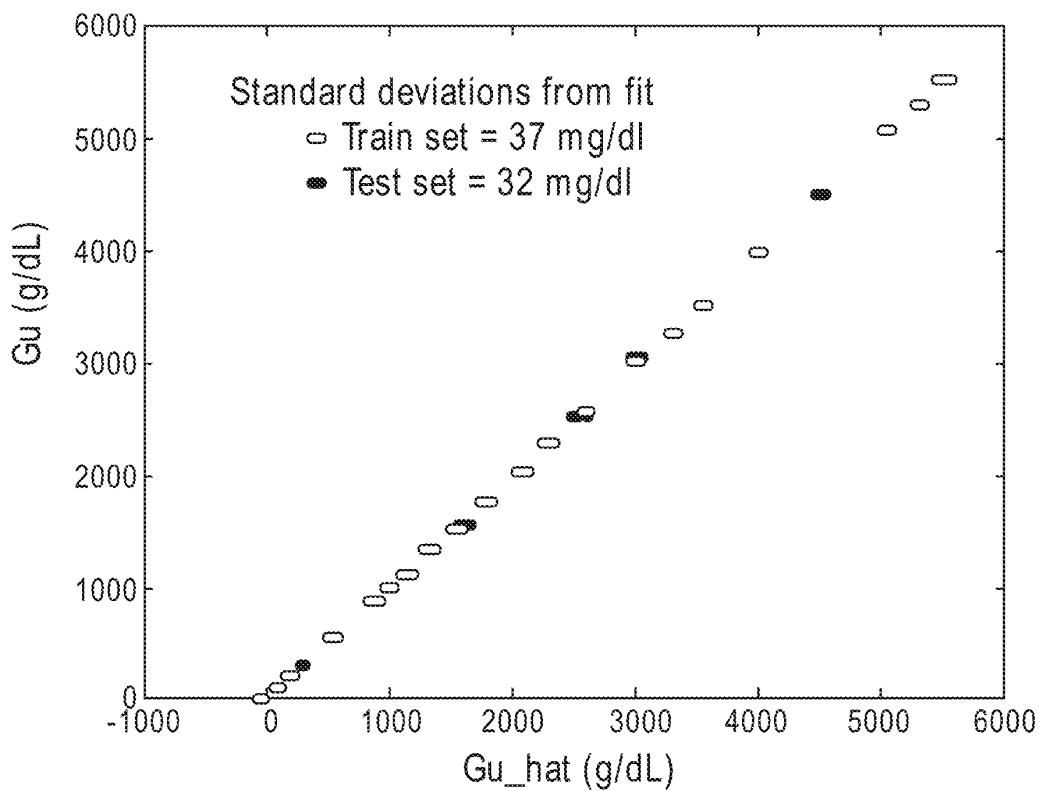


FIG. 19

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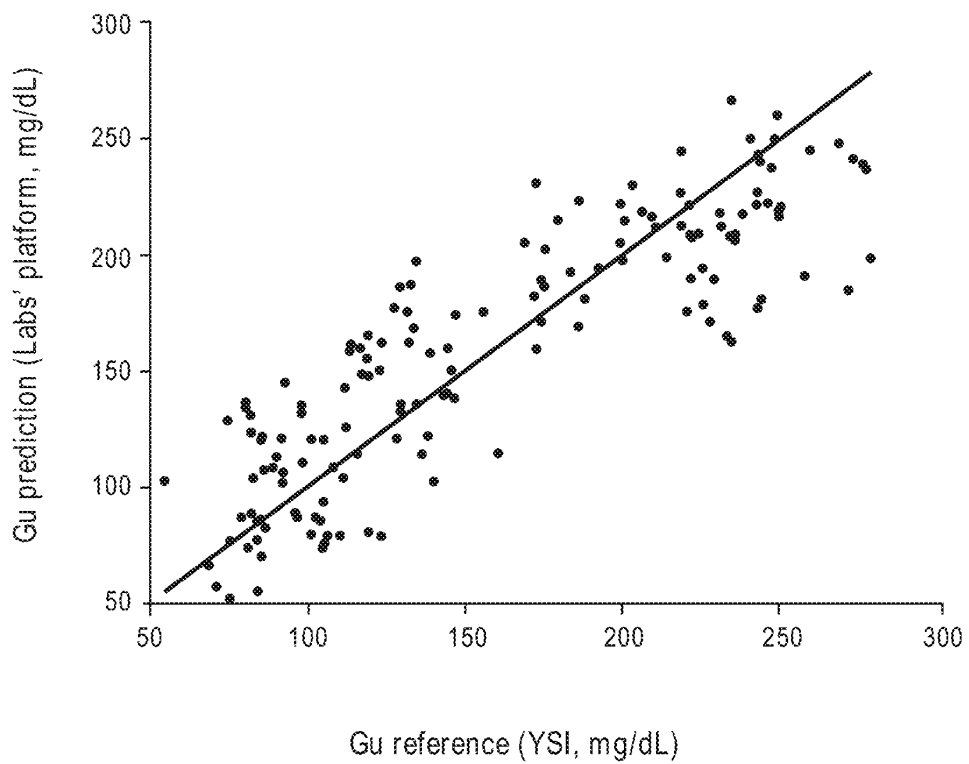


FIG. 20

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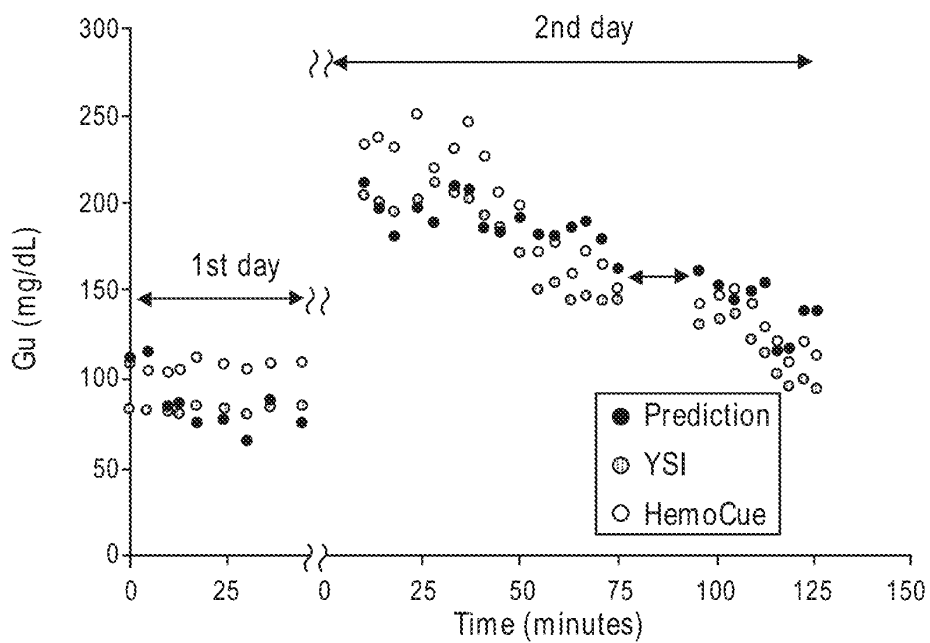


FIG. 21

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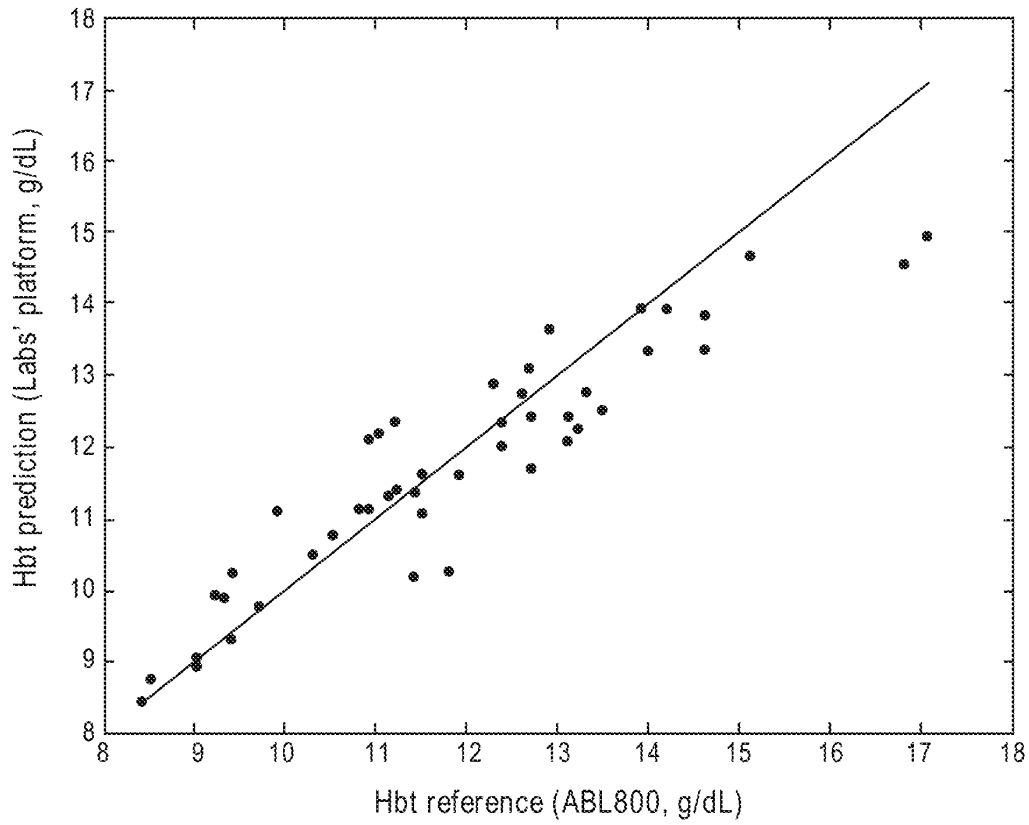


FIG. 22

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USER-WORN DEVICE FOR
NONINVASIVELY MEASURING A
PHYSIOLOGICAL PARAMETER OF A USER

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/834,538, filed Mar. 30, 2020, which is a continuation of U.S. patent application Ser. No. 16/725,292, filed Dec. 23, 2019, which is a continuation of U.S. patent application Ser. No. 16/534,949, filed Aug. 7, 2019, which is a continuation of U.S. patent application Ser. No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. patent application Ser. No. 16/261,326, filed Jan. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/212,537, filed Dec. 6, 2018, which is a continuation of U.S. patent application Ser. No. 14/981,290 filed Dec. 28, 2015, which is a continuation of U.S. patent application Ser. No. 12/829,352 filed Jul. 1, 2010, which is a continuation of U.S. patent application Ser. No. 12/534,827 filed Aug. 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,528 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Ser. No. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,523 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Ser. No. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008.

This application is related to the following U.S. patent applications:

| App. No. | Filing Date | Title |
|------------|--------------|--|
| 12/497,528 | Jul. 2, 2009 | Noise Shielding for Noninvasive Device |
| 12/497,523 | Jul. 2, 2009 | Contoured Protrusion for Improving Spectroscopic Measurement of Blood Constituents |
| 12/497,506 | Jul. 2, 2009 | Heat Sink for Noninvasive Medical Sensor |
| 12/534,812 | Aug. 3, 2009 | Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents |

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 -continued

| App. No. | Filing Date | Title |
|--------------|--------------|---|
| 5 12/534,823 | Aug. 3, 2009 | Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents |
| 12/534,825 | Aug. 3, 2009 | Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents |

10 The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

15 The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photo-detection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal (s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

30 In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

45 In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the non-invasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, 50 embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

65 In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from

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said optical source after attenuation by the tissue of the measurement site and each output a respective signal stream responsive to the detected optical radiation.

In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the patient. The photodetectors are positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length.

In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the

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signals from the plurality of detectors into a digital output signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose.

In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at

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sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be reused to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. 1 illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

FIGS. 2A-2D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of FIG. 1, according to embodiments of the disclosure;

FIGS. 3A-3C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIG. 3D illustrates a side view of another example noninvasive sensor housing including a heat sink, according to an embodiment of the disclosure;

FIG. 3E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

FIG. 3F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIGS. 4A through 4C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

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FIG. 5 illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

FIGS. 6A through 6D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

FIG. 6E illustrates an example sensor incorporating the protrusion of FIGS. 6A through 6D, according to an embodiment of the disclosure;

FIGS. 7A through 7B illustrate example arrangements of conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIGS. 8A through 8D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIG. 9 shows example comparative results obtained by an embodiment of a sensor;

FIGS. 10A and 10B illustrate comparative noise floors of various embodiments of the present disclosure;

FIG. 11A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 12A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIGS. 12B through 12D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

FIGS. 12E through 12H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

FIG. 13 illustrates an example multi-stream operation of the system of FIG. 1, according to an embodiment of the disclosure;

FIG. 14A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion of FIG. 14A;

FIGS. 14C through 14E illustrate embodiments of a detector submount;

FIGS. 14F through 14H illustrate embodiment of portions of a detector shell;

FIG. 14I illustrates a cutaway view of an embodiment of a sensor;

FIGS. 15A through 15F illustrate embodiments of sensors that include heat sink features;

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described herein;

FIG. 15I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

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FIG. 15J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIG. 15I;

FIG. 15K shows different architectures and layouts for various embodiments of a sensor and its detectors;

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors;

FIG. 17 illustrates an exploded view of certain components of an example sensor; and

FIGS. 18 through 22 illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic,

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helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of non-invasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metallicized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can

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be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that, in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modifications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter

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may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices. The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. 1 illustrates an example of a data collection system **100**. In certain embodiments, the data collection system **100** noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system **100** can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The data collection system **100** can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system **100** can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm²-5 mm² (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase "at full scale" can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

The data collection system **100** can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system **100** can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired analytes. The data collection system **100** can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

The data collection system **100** can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site **102**. The measurement site **102** can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a

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finger measurement site **102**. However, the features of the embodiments disclosed herein can be used with other measurement sites **102**.

In the depicted embodiment, the system **100** includes an optional tissue thickness adjuster or tissue shaper **105**, which can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper **105** is a flat or substantially flat surface that can be positioned proximate the measurement site **102** and that can apply sufficient pressure to cause the tissue of the measurement site **102** to be flat or substantially flat. In other embodiments, the tissue shaper **105** is a convex or substantially convex surface with respect to the measurement site **102**. Many other configurations of the tissue shaper **105** are possible. Advantageously, in certain embodiments, the tissue shaper **105** reduces thickness of the measurement site **102** while preventing or reducing occlusion at the measurement site **102**. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

The embodiment of the data collection system **100** shown also includes an optional noise shield **103**. In an embodiment, the noise shield **103** can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site **102** to one or more detectors **106** (described below). For example, the noise shield **103** can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor **101** or electrically grounded. In an embodiment where the noise shield **103** includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

In some embodiments, the measurement site **102** is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system **100** can be used on a person's non-dominant hand or arm.

The data collection system **100** can include a sensor **101** (or multiple sensors) that is coupled to a processing device or physiological monitor **109**. In an embodiment, the sensor **101** and the monitor **109** are integrated together into a single unit. In another embodiment, the sensor **101** and the monitor **109** are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor **101** and monitor **109** can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor **101** and the monitor **109** will now be further described.

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In the depicted embodiment shown in FIG. 1, the sensor **101** includes an emitter **104**, a tissue shaper **105**, a set of detectors **106**, and a front-end interface **108**. The emitter **104** can serve as the source of optical radiation transmitted towards measurement site **102**. As will be described in further detail below, the emitter **104** can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **104** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

In some embodiments, the emitter **104** is used as a point optical source, and thus, the one or more optical sources of the emitter **104** can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters **104** can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sep. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters **104** can be arranged at least in part as described in paragraphs [0061] through [0068] of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters **104**.

For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

In contrast, the emitter **104** of the data collection system **100** can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter **104** can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter **104** can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

In other embodiments, the emitter **104** can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better for analytes like glucose. Furthermore, in some embodiments, the emitter **104** can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

For example, the emitter **104** can emit optical radiation across other spectra for other analytes. In particular, the emitter **104** can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter **104** can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about

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1665 nm. In another embodiment, the emitter **104** can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, the emitter **104** can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system **100** can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

As briefly described above, the emitter **104** can include sets of light-emitting diodes (LEDs) as its optical source. The emitter **104** can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter **104** can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

The emitter **104** can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter **104** can employ SLEDs or side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter **104** can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO₂), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter **104** can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site **102**.

In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter **104** can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter **104** to use LEDs with a higher output and/or to equalize intensity of LEDs.

The data collection system **100** also includes a driver **111** that drives the emitter **104**. The driver **111** can be a circuit or the like that is controlled by the monitor **109**. For example, the driver **111** can provide pulses of current to the emitter **104**. In an embodiment, the driver **111** drives the emitter **104** in a progressive fashion, such as in an alternating manner. The driver **111** can drive the emitter **104** with a series of pulses of about 1 milliwatt (mW) for some wavelengths that can penetrate tissue relatively well and from

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about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

The driver **111** can be synchronized with other parts of the sensor **101** and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter **104**. In some embodiments, the driver **111** is capable of driving the emitter **104** to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detectors **106** capture and measure light from the measurement site **102**. For example, the detectors **106** can capture and measure light transmitted from the emitter **104** that has been attenuated or reflected from the tissue in the measurement site **102**. The detectors **106** can output a detector signal **107** responsive to the light captured or measured. The detectors **106** can be implemented using one or more photodiodes, phototransistors, or the like.

In addition, the detectors **106** can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors **106**. That is, some of the detectors **106** can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter **104**. However, according to an embodiment, at least some of the detectors **106** can have a different path length from the emitter **104** relative to other of the detectors **106**. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors **106**. In some embodiments, the detectors **106** may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

The front end interface **108** provides an interface that adapts the output of the detectors **106**, which is responsive to desired physiological parameters. For example, the front end interface **108** can adapt a signal **107** received from one or more of the detectors **106** into a form that can be processed by the monitor **109**, for example, by a signal processor **110** in the monitor **109**. The front end interface **108** can have its components assembled in the sensor **101**, in the monitor **109**, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface **108** can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front end interface **108** can be coupled to the detectors **106** and to the signal processor **110** using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface **108** can also be at least partially integrated with various components, such as the detectors **106**. For example, the front end interface **108** can include one or more integrated circuits that are on the same circuit board as the detectors **106**. Other configurations can also be used.

The front end interface **108** can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor **109**), such as a sigma-delta ADC. A transimpedance-based front end interface **108** can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface **108** can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface **108**

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can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter **104**.

The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by the signal processor **110** of the monitor **109**. Each channel can correspond to a signal output from a detector **106**.

In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface **108**. For example, the output of a transimpedance-based front end interface **108** can be output to a PGA that is coupled with an ADC in the monitor **109**. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the detectors **106**. Alternatively, the PGA and ADC components can be integrated with the transimpedance-based front end interface **108** in the sensor **101**.

In another embodiment, the front end interface **108** can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface **108** can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface **108** can be useful because it can provide a digital signal to the signal processor **110** in the monitor **109**.

As shown in FIG. 1, the monitor **109** can include the signal processor **110** and a user interface, such as a display **112**. The monitor **109** can also include optional outputs alone or in combination with the display **112**, such as a storage device **114** and a network interface **116**. In an embodiment, the signal processor **110** includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors **106**. The signal processor **110** can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor **110** can provide various signals that control the operation of the sensor **101**. For example, the signal processor **110** can provide an emitter control signal to the driver **111**. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter **104**. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter **104** to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface **108** is used, the control signal from the signal processor **110** can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory **113** can be included in the front-end interface **108** and/or in the signal processor **110**. This memory **113** can serve as a buffer or storage location for the front-end interface **108** and/or the signal processor **110**, among other uses.

The user interface **112** can provide an output, e.g., on a display, for presentation to a user of the data collection system **100**. The user interface **112** can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface **112** can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface **112** can include a flip screen, a screen that can be moved from one side to another on the monitor **109**, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data

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collection system **100** can be provided without a user interface **112** and can simply provide an output signal to a separate display or system.

A storage device **114** and a network interface **116** represent other optional output connections that can be included in the monitor **109**. The storage device **114** can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device **114**, which can be executed by the signal processor **110** or another processor of the monitor **109**. The network interface **116** can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor **109** to communicate and share data with other devices. The monitor **109** can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface **112**, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the data collection system **100** can include various other components or can be configured in different ways. For example, the sensor **101** can have both the emitter **104** and detectors **106** on the same side of the measurement site **102** and use reflectance to measure analytes. The data collection system **100** can also include a sensor that measures the power of light emitted from the emitter **104**.

FIGS. 2A through 2D illustrate example monitoring devices **200** in which the data collection system **100** can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices **200** shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system **100**. In addition, certain of the features of the monitoring devices **200** shown in FIGS. 2A through 2D can be combined with features of the other monitoring devices **200** shown.

Referring specifically to FIG. 2A, an example monitoring device **200A** is shown, in which a sensor **201a** and a monitor **209a** are integrated into a single unit. The monitoring device **200A** shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor **201a** includes an emitter shell **204a** and a detector shell **206a**. The depicted embodiment of the monitoring device **200A** also includes various control buttons **208a** and a display **210a**.

The sensor **201a** can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector **106** by forcing light back into the sensor **201a**. Pads in the emitter shell **204a** and the detector shell **206a** can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell **204a** and the detector shell **206a** can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor **201a**.

In some embodiments, some or all portions of the emitter shell **204a** and/or detector shell **206a** can be detachable and/or disposable. For example, some or all portions of the

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shells **204a** and **206a** can be removable pieces. The removability of the shells **204a** and **206a** can be useful for sanitary purposes or for sizing the sensor **201a** to different patients. The monitor **209a** can include a fitting, slot, magnet, or other connecting mechanism to allow the sensor **201c** to be

removably attached to the monitor **209a**.
The monitoring device **200a** also includes optional control buttons **208a** and a display **210a** that can allow the user to control the operation of the device. For example, a user can operate the control buttons **208a** to view one or more measurements of various analytes, such as glucose. In addition, the user can operate the control buttons **208a** to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many parameters, trends, alarms and parameter displays could be output to the display **210a**, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo® Corporation of Irvine, Calif.

Furthermore, the controls **208a** and/or display **210a** can provide functionality for the user to manipulate settings of the monitoring device **200a**, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device **200a** can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

FIG. 2B illustrates another example of a monitoring device **200B**. In the depicted embodiment, the monitoring device **200B** includes a finger clip sensor **201b** connected to a monitor **209b** via a cable **212**. In the embodiment shown, the monitor **209b** includes a display **210b**, control buttons **208b** and a power button. Moreover, the monitor **209b** can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor **201b**, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

The cable **212** connecting the sensor **201b** and the monitor **209b** can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable **212** can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor **201b** to the monitor **209b**. Various lengths of the cable **212** can be employed to allow for separation between the sensor **201b** and the monitor **209b**. The cable **212** can be fitted with a connector (male or female) on either end of the cable **212** so that the sensor **201b** and the monitor **209b** can be connected and disconnected from each other. Alternatively, the sensor **201b** and the monitor **209b** can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

The monitor **209b** can be attached to the patient. For example, the monitor **209b** can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor **209b** can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable **212** and sensor **201b** to be attached to the monitor **209B**.

The monitor **209b** can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor **209b**

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can include a display **210b** that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor **209b**.

In addition, although a single sensor **201b** with a single monitor **209b** is shown, different combinations of sensors and device pairings can be implemented. For example, multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

FIG. 2C illustrates yet another example of monitoring device **200C** that can house the data collection system **100**. Like the monitoring device **200B**, the monitoring device **200C** includes a finger clip sensor **201c** connected to a monitor **209c** via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. 2B. The monitor **209c** can include all of the features of the monitor **200B** described above. For example, the monitor **209c** includes buttons **208c** and a display **210c**. The monitor **209c** shown also includes straps **214c** that allow the monitor **209c** to be attached to a patient's limb or the like.

FIG. 2D illustrates yet another example of monitoring device **200D** that can house the data collection system **100**. Like the monitoring devices **200B** and **200C**, the monitoring device **200D** includes a finger clip sensor **201d** connected to a monitor **209d** via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. 2B. In addition to having some or all of the features described above with respect to FIGS. 2B and 2C, the monitoring device **200D** includes an optional universal serial bus (USB) port **216** and an Ethernet port **218**. The USB port **216** and the Ethernet port **218** can be used, for example, to transfer information between the monitor **209d** and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor **209b**, and perform a variety of other functions. The USB port **216** and the Ethernet port **218** can be included with the other monitoring devices **200A**, **200B**, and **200C** described above.

FIGS. 3A through 3C illustrate more detailed examples of embodiments of a sensor **301a**. The sensor **301a** shown can include all of the features of the sensors **100** and **200** described above.

Referring to FIG. 3A, the sensor **301a** in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure **302a** for receiving a patient's finger. The enclosure **302a** is formed by an upper section or emitter shell **304a**, which is pivotably connected with a lower section or detector shell **306a**. The emitter shell **304a** can be biased with the detector shell **306a** to close together around a pivot point **303a** and thereby sandwich finger tissue between the emitter and detector shells **304a**, **306a**.

In an embodiment, the pivot point **303a** advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells **304a**, **306a** to effectively level the sections when applied to a tissue site. In another embodiment, the sensor **301a** includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs [0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

The emitter shell **304a** can position and house various emitter components of the sensor **301a**. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metallicized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell **304a** can also include absorbing opaque mate-

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rial, such as, for example, black or grey colored material, at various areas, such as on one or more flaps 307a, to reduce ambient light entering the sensor 301a.

The detector shell 306a can position and house one or more detector portions of the sensor 301a. The detector shell 306a can be constructed of reflective material, such as white silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIG. 1). The detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308a, to reduce ambient light entering the sensor 301a.

Referring to FIGS. 3B and 3C, an example of finger bed 310 is shown in the sensor 301b. The finger bed 310 includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310 includes one or more ridges or channels 314. Each of the ridges 314 has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges 314 can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor 301a. The ridges 314 can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds 310.

Finger bed 310 can also include an embodiment of a tissue thickness adjuster or protrusion 305. The protrusion 305 includes a measurement site contact area 370 (see FIG. 3C) that can contact body tissue of a measurement site. The protrusion 305 can be removed from or integrated with the finger bed 310. Interchangeable, different shaped protrusions 305 can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

Referring specifically to FIG. 3C, the contact area 370 of the protrusion 305 can include openings or windows 320, 321, 322, and 323. When light from a measurement site passes through the windows 320, 321, 322, and 323, the light can reach one or more photodetectors (see FIG. 3E). In an embodiment, the windows 320, 321, 322, and 323 mirror specific detector placements layouts such that light can impinge through the protrusion 305 onto the photodetectors. Any number of windows 320, 321, 322, and 323 can be employed in the protrusion 305 to allow light to pass from the measurement site to the photodetectors.

The windows 320, 321, 322, and 323 can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows 320, 321, 322, and 323 can be made from materials, such as plastic or glass. In some embodiments, the windows 320, 321, 322, and 323 can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

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Turning to FIG. 3B, the sensor 301a can also include a shielding 315a, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding 315a is provided in the depicted embodiment below or embedded within the protrusion 305 to reduce noise. The shielding 315a can be constructed from a conductive material, such as copper. The shielding 315a can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the windows 320, 321, 322, and 323 on an external surface of the protrusion 305 (see FIG. 3C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIG. 3E).

In some embodiments, the shielding cage for shielding 315a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion 305 (see FIG. 3E). In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm² to about 60 mm² was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion 305 can be selected. In making such determinations, consideration can be made of protrusion's 305 effect on blood flow at the measurement site and mean path length for optical radiation passing through openings 320, 321, 322, and 323. Patient comfort can also be considered in determining the size and shape of the protrusion.

In an embodiment, the protrusion 305 can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and tactility by conforming the measurement site contact area 370 to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light. Alternatively, the protrusion 305 can be made from a rigid material, such as hard plastic or metal.

Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area 370. The contact area 370 can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion 305 can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion 305 and the contact area 370 can include a combination of materials with various characteristics.

The contact area 370 serves as a contact surface for the measurement site. For example, in some embodiments, the contact area 370 can be shaped for contact with a patient's finger. Accordingly, the contact area 370 can be sized and shaped for different sizes of fingers. The contact area 370 can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example,

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the contact area 370 can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

The formulas and analysis that follow with respect to FIG. 5 provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

Referring to FIG. 5, a plot 500 is shown that illustrates examples of effects of embodiments of the protrusion 305 on the SNR at various wavelengths of light. As described above, the protrusion 305 can assist in conforming the tissue and effectively reduce its mean path length. In some instances, this effect by the protrusion 305 can have significant impact on increasing the SNR.

According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I = I_0 * e^{-m * b * c}$, where I_0 is the initial power of light being transmitted, m is the path length traveled by the light, and the component "b*c" corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1} . Assuming a typical finger thickness of about 12 mm and a mean path length of 20 mm due to tissue scattering, then $I = I_0 * e^{(-20 * 0.7)}$.

In an embodiment where the protrusion 305 is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box 510). This results in a new transmittance, $I_1 = I_0 * e^{(-16.6 * 0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot 500 of FIG. 5. The plot 500 illustrates potential effects of the protrusion 305 on the transmittance. As illustrated, comparing I and I_1 results in an intensity gain of $e^{(-16.6 * 0.7)} / e^{(-20 * 0.7)}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1} . The plot 500 also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

Turning again to FIGS. 3A through 3C, an example heat sink 350a is also shown. The heat sink 350a can be attached to, or protrude from an outer surface of, the sensor 301a, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor 301a in certain embodiments, the heat sink 350a can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see FIG. 1) generate sufficient heat that inclusion of the heat sink 350a can advantageously allow the sensor 301a to remain safely cooled. The heat sink 350a can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell 304a can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

In some embodiments, the heat sink 350a includes metalized plastic. The metalized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink 350a can include a thermally conductive liquid crystalline

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polymer, such as CoolPoly® D5506, commercially available from Cool Polymers®, Inc. of Warwick, R.I. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink 350a provides improved heat transfer properties when the sensor 301a is active for short intervals of less than a full day's use. In an embodiment, the heat sink 350a can advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink 350a can be selected that performs effectively in shorter or longer intervals.

Moreover, the heat sink 350a can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink 350a is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink 350a shown includes fins 351a (see FIG. 3A).

An alternative shape of a sensor 301b and heat sink 350b is shown in FIG. 3D. The sensor 301b can include some or all of the features of the sensor 301a. For example, the sensor 301b includes an enclosure 302b formed by an emitter shell 304b and a detector shell 306b, pivotably connected about a pivot 303a. The emitter shell 304b can also include absorbing opaque material on one or more flaps 307b, and the detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308b.

However, the shape of the sensor 301b is different in this embodiment. In particular, the heat sink 350b includes comb protrusions 351b. The comb protrusions 351b are exposed to the air in a similar manner to the fins 351a of the heat sink 350a, thereby facilitating efficient cooling of the sensor 301b.

FIG. 3E illustrates a more detailed example of a detector shell 306b of the sensor 301b. The features described with respect to the detector shell 306b can also be used with the detector shell 306a of the sensor 301a.

As shown, the detector shell 306b includes detectors 316. The detectors 316 can have a predetermined spacing 340 from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors 316 and the emitter discussed above.

In the depicted embodiment, the detector shell 316 can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site 102). In the detector shell 316, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell 316 can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

As further illustrated by FIG. 3E, the detectors 316 can have a spatial configuration of a grid. However, the detectors 316 can be arranged in other configurations that vary the path length. For example, the detectors 316 can be arranged in a linear array, a logarithmic array, a two-dimensional

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array, a zig-zag pattern, or the like. Furthermore, any number of the detectors 316 can be employed in certain embodiments.

FIG. 3F illustrates another embodiment of a sensor 301f. The sensor 301f can include some or all of the features of the sensor 301a of FIG. 3A described above. For example, the sensor 301f includes an enclosure 302f formed by an upper section or emitter shell 304f, which is pivotably connected with a lower section or detector shell 306f around a pivot point 303f. The emitter shell 304f can also include absorbing opaque material on various areas, such as on one or more flaps 307f, to reduce ambient light entering the sensor 301f. The detector shell 306f can also include absorbing opaque material at various areas, such as a lower area 308f. The sensor 301f also includes a heat sink 350f, which includes fins 351f.

In addition to these features, the sensor 301f includes a flex circuit cover 360, which can be made of plastic or another suitable material. The flex circuit cover 360 can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell 304f to the detector shell 306f. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIG. 46 and associated description, which is hereby specifically incorporated by reference). The flex circuit cover 360 is shown in more detail below in FIG. 17.

In addition, sensors 301a-f has extra length—extends to second joint on finger—Easier to place, harder to move due to cable, better for light piping.

FIGS. 4A through 4C illustrate example arrangements of a protrusion 405, which is an embodiment of the protrusion 305 described above. In an embodiment, the protrusion 405 can include a measurement site contact area 470. The measurement site contact area 470 can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

The protrusion 405 can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion 405 can have a length 400, a width 410, and a height 430. The length 400 can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width 410 can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

The measurement site contact area 470 can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site. The measurement site contact area 470 can be other shapes that reduce or even minimize air between the protrusion 405 and/or the measurement site. Additionally, the surface pattern of the measurement site contact area 470 can vary from smooth to bumpy, e.g., to provide varying levels of grip.

In FIGS. 4A and 4C, openings or windows 420, 421, 422, and 423 can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows 420, 421, 422, and 423 can be of non-uniform shapes and sizes. As shown, the windows 420, 421, 422, and 423 can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of

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arranging the windows 420, 421, 422, and 423 are possible. For example, the windows 420, 421, 422, and 423 can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows 420, 421, 422, and 423 can be placed at different heights with respect to the finger bed 310 of FIG. 3. The windows 420, 421, 422, and 423 can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

FIGS. 6A through 6D illustrate another embodiment of a protrusion 605 that can be used as the tissue shaper 105 described above or in place of the protrusions 305, 405 described above. The depicted protrusion 605 is a partially cylindrical lens having a partial cylinder 608 and an extension 610. The partial cylinder 608 can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion 605 focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

FIG. 6A illustrates a perspective view of the partially cylindrical protrusion 605. FIG. 6B illustrates a front elevation view of the partially cylindrical protrusion 605. FIG. 6C illustrates a side view of the partially cylindrical protrusion 605. FIG. 6D illustrates a top view of the partially cylindrical protrusion 605.

Advantageously, in certain embodiments, placing the partially cylindrical protrusion 605 over the photodiodes in any of the sensors described above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion 605 penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

The partially cylindrical protrusion 605 can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion 605 can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIG. 14). If fewer or smaller photodiodes are used, the partially cylindrical protrusion 605 can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

The dimensions of the partially cylindrical protrusion 605 can vary based on, for instance, a number of photodiodes used with the sensor. Referring to FIG. 6C, the overall height of the partially cylindrical protrusion 605 (measurement "a") in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion 605 to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion 605 can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion 605 is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

Referring to FIG. 6D, the width of the partially cylindrical protrusion 605 (measurement "b") can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration

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of the partially cylindrical protrusion **605** into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical protrusion **605** can also accomplish this objective. For example, the width of the partially cylindrical protrusion **605** can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion **605** could be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

In certain embodiments, the focal length (f) for the partially cylindrical protrusion **605** can be expressed as:

$$f = \frac{R}{n-1},$$

where R is the radius of curvature of the partial cylinder **608** and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion **605** can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

A partially cylindrical protrusion **605** having a material with a higher index of refraction such as nSF11 glass (e.g., $n=1.75$ at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion **605** can be chosen to improve or optimize the light focusing properties of the protrusion **605**. A plastic partially cylindrical protrusion **605** could provide the cheapest option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion **605**.

Placing a photodiode at a given distance below the partially cylindrical protrusion **605** can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIG. 14). Different sizes of the partially cylindrical protrusion **605** can use different sizes of photodiodes. The extension **610** added onto the bottom of the partial cylinder **608** is used in certain embodiments to increase the height of the partially cylindrical protrusion **605**. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion **605**. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension **610** can also further facilitate the protrusion **605** increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension **610** can be omitted.

FIG. 6E illustrates another view of the sensor **301f** of FIG. 3F, which includes an embodiment of a partially cylindrical protrusion **605b**. Like the sensor **301A** shown in FIGS. 3B and 3C, the sensor **301f** includes a finger bed **310f**. The finger bed **310f** includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger

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bed **310f** also includes the ridges or channels **314** described above with respect to FIGS. 3B and 3C.

The example of finger bed **310f** shown also includes the protrusion **605b**, which includes the features of the protrusion **605** described above. In addition, the protrusion **605b** also includes chamfered edges **607** on each end to provide a more comfortable surface for a finger to slide across (see also FIG. 14D). In another embodiment, the protrusion **605b** could instead include a single chamfered edge **607** proximal to the ridges **314**. In another embodiment, one or both of the chamfered edges **607** could be rounded.

The protrusion **605b** also includes a measurement site contact area **670** that can contact body tissue of a measurement site. The protrusion **605b** can be removed from or integrated with the finger bed **310f**. Interchangeable, differently shaped protrusions **605b** can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

FIGS. 7A and 7B illustrate block diagrams of sensors **701** that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide increased SNR. The features of the sensors **701** can be implemented with any of the sensors **101**, **201**, **301** described above. Although not shown, the partially cylindrical protrusion **605** of FIG. 6 can also be used with the sensors **701** in certain embodiments.

For example, referring specifically to FIG. 7A, the sensor **701a** includes an emitter housing **704a** and a detector housing **706**. The emitter housing **704a** includes LEDs **104**. The detector housing **706a** includes a tissue bed **710a** with an opening or window **703a**, the conductive glass **730a**, and one or more photodiodes for detectors **106** provided on a submount **707a**.

During operation, a finger **102** can be placed on the tissue bed **710a** and optical radiation can be emitted from the LEDs **104**. Light can then be attenuated as it passes through or is reflected from the tissue of the finger **102**. The attenuated light can then pass through the opening **703a** in the tissue bed **710a**. Based on the received light, the detectors **106** can provide a detector signal **107**, for example, to the front end interface **108** (see FIG. 1).

In the depicted embodiment, the conductive glass **730** is provided in the opening **703**. The conductive glass **730** can thus not only permit light from the finger to pass to the detectors **106**, but it can also supplement the shielding of the detectors **106** from noise. The conductive glass **730** can include a stack or set of layers. In FIG. 7A, the conductive glass **730a** is shown having a glass layer **731** proximate the finger **102** and a conductive layer **733** electrically coupled to the shielding **790a**.

In an embodiment, the conductive glass **730a** can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure **790a**, the conductive glass **730a** can be electrically coupled to the shielding enclosure **790a**. The conductive glass **730a** can be electrically coupled to the shielding **704a** based on direct contact or via other connection devices, such as a wire or another component.

The shielding enclosure **790a** can be provided to encompass the detectors **106** to reduce or prevent noise. For example, the shielding enclosure **790a** can be constructed from a conductive material, such as copper, in the form of a metal cage. The shielding or enclosure can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

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In some embodiments, the shielding enclosure **790a** can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790a** can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

Referring to FIG. 7B, another block diagram of an example sensor **701b** is shown. A tissue bed **710b** of the sensor **701b** includes a protrusion **705b**, which is in the form of a convex bump. The protrusion **705b** can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion **705b** includes a contact area **370** that comes in contact with the finger **102** and which can include one or more openings **703b**. One or more components of conductive glass **730b** can be provided in the openings **703**. For example, in an embodiment, each of the openings **703** can include a separate window of the conductive glass **730b**. In an embodiment, a single piece of the conductive glass **730b** can be used for some or all of the openings **703b**. The conductive glass **730b** is smaller than the conductive glass **730a** in this particular embodiment.

A shielding enclosure **790b** is also provided, which can have all the features of the shielding enclosure **790a**. The shielding enclosure **790b** is smaller than the shielding enclosure **790a**; however, a variety of sizes can be selected for the shielding enclosures **790**.

In some embodiments, the shielding enclosure **790b** can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790b** can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

FIGS. 8A through 8D illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors **701a**, **701b**. As shown in the perspective view of FIG. 8A and side view of FIG. 8B, the conductive glass **730** includes the electrically conductive material **733** described above as a coating on the glass layer **731** described above to form a stack. In an embodiment where the electrically conductive material **733** includes indium tin oxide, surface resistivity of the electrically conductive material **733** can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material **733**.

Although the conductive material **733** is shown spread over the surface of the glass layer **731**, the conductive material **733** can be patterned or provided on selected portions of the glass layer **731**. Furthermore, the conductive material **733** can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

In FIG. 8C, a side view of a conductive glass **830a** is shown to illustrate an embodiment where the electrically conductive material **733** is provided as an internal layer between two glass layers **731**, **835**. Various combinations of integrating electrically conductive material **733** with glass

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are possible. For example, the electrically conductive material **733** can be a layer within a stack of layers. This stack of layers can include one or more layers of glass **731**, **835**, as well as one or more layers of conductive material **733**. The stack can include other layers of materials to achieve desired characteristics.

In FIG. 8D, a bottom perspective view is shown to illustrate an embodiment where a conductive glass **830b** can include conductive material **837** that occupies or covers a portion of a glass layer **839**. This embodiment can be useful, for example, to create individual, shielded windows for detectors **106**, such as those shown in FIG. 3C. The conductive material **837** can be patterned to include an area **838** to allow light to pass to detectors **106** and one or more strips **841** to couple to the shielding **704** of FIG. 7.

Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

FIG. 9 depicts an example graph **900** that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGS. 7 and 8. The graph **900** depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

A line **915** on the graph **900** illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line **920** on the graph **900** demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line **925** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line **930** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring. Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

FIGS. 10A through 10B illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In FIG. 10A, a graph **1000** depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above included separate windows for four (4) detectors **106**. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols **1030-1033** illustrate the

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noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

In FIG. 10B, a graph 1050 depicts a noise floor for frequencies of noise 1070 for an embodiment in which the sensor included separate openings for four (4) detectors 106 and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols 1080-1083 illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodiment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of FIG. 10A.

FIG. 11A illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter 104 can include a driver 1105, a thermistor 1120, a set of top-emitting LEDs 1102 for emitting red and/or infrared light, a set of side-emitting LEDs 1104 for emitting near infrared light, and a submount 1106.

The thermistor 1120 can be provided to compensate for temperature variations. For example, the thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors can be employed, for example, to measure a temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement site. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

The driver 1105 can provide pulses of current to the emitter 1104. In an embodiment, the driver 1105 drives the emitter 1104 in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor 110). For example, the driver 1105 can drive the emitter 1104 with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver 1105 can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter 1104. In some embodiments, the driver 1105 is capable of driving the emitter 1104 to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

The submount 1106 provides a support structure in certain embodiments for aligning the top-emitting LEDs 1102 and the side-emitting LEDs 1104 so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount 1106 is also constructed of aluminum nitride (AlN) or beryllium oxide (BEO) for heat dissipation, although other materials or combinations of materials suitable for the submount 1106 can be used.

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FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter 104 may be driven in a progressive fashion to minimize noise and increase SNR of sensor 101. For example, emitter 104 may be driven based on a progression of power/current delivered to LEDs 1102 and 1104.

In some embodiments, emitter 104 may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 may emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, emitter 104 may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

For purposes of illustration, FIG. 11B shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs 1102. FIG. 11B also shows that emitter 104 may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs 1104. Emitter 104 may be progressively driven at higher power/current. This progression may allow driver circuit 105 to stabilize in its operations, and thus, provide a more stable current/power to LEDs 1102 and 1104.

For example, as shown in FIG. 11B, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term "slots" includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs 1102 may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4 time slots in between. In addition, pulses from side emitting LEDs 1104 (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit 105 to stabilize after operating at higher current/power.

As shown in FIG. 11B, top emitting LEDs 1102 may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs 1102 may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs 502 for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter 104.

Subsequently, side emitting LEDs 1104 may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site 102 to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment, the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the

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current needed to drive side emitting LEDs **1104**. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter **104**.

As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit **1105** to stabilize its power delivery to LEDs **1102** and **1104**. Driver circuit **1105** may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a variable waiting period to allow for stabilization of driver circuit **1105**. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system **100**. That is, as the duty cycle is increased so may the signal to noise ratio.

Furthermore, as noted above, driver circuit **1105** may monitor temperatures of the LEDs **1102** and **1104** using the thermistor **1120** and adjust the output of LEDs **1102** and **1104** accordingly. Such a temperature may be used to help sensor **101** correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter **104** can include components mounted on a substrate **1108** and on submount **1106**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**. Side emitting LEDs **1104** may be mounted on submount **1106**. As noted, side-emitting LEDs **1104** may be included in emitter **104** for emitting near infrared light.

As also shown, the sensor of FIG. 11C may include a thermistor **1120**. As noted, the thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** and **1104** due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In some embodiments, the emitter **104** may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. In particular, an emitter **104** that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter **104** can include components mounted on a substrate **1108**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**.

As also shown, the emitter of FIG. 11D may include a thermistor **1120**. The thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** due to heating.

FIG. 12A illustrates a detector submount **1200** having photodiode detectors that are arranged in a grid pattern on the detector submount **1200** to capture light at different

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quadrants from a measurement site. One detector submount **1200** can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount **1200**. The detector submount **1200** can also be used with the partially cylindrical protrusion **605** described above with respect to FIG. 6.

The detectors include photodiode detectors 1-4 that are arranged in a grid pattern on the submount **1200** to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

As shown, the detectors 1-4 may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors **106** and the point light source discussed above.

Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site **102**). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

FIGS. 12B through 12D illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors **106**. As shown, detectors **106** may comprise photodiode detectors 1-4 that are arranged in a grid pattern on detector submount **1200** to capture light at different quadrants from measurement site **102**.

As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors **106** may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors **106** may be employed by embodiments of the present disclosure.

For example, as shown in FIG. 12B, detectors **106** may comprise photodiode detectors 1-4 that are arranged in a substantially linear configuration on submount **1200**. In this embodiment shown, photodiode detectors 1-4 are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors 1-4).

In FIG. 12C, photodiode detectors 1-4 may be arranged in a substantially linear configuration on submount **1200**, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances $D1 > D2 > D3$). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

In FIG. 12D, a different substantially grid pattern on submount **1200** of photodiode detectors 1-4 is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

FIGS. 12E through 12H illustrate several embodiments of photodiodes that may be used in detectors **106**. As shown in these figures, a photodiode **1202** of detector **106** may comprise a plurality of active areas **1204**. These active areas

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204 may be coupled together via a common cathode 1206 or anode 1208 in order to provide a larger effective detection area.

In particular, as shown in FIG. 12E, photodiode 1202 may comprise two (2) active areas 1204a and 1204b. In FIG. 12F, photodiode 1202 may comprise four (4) active areas 1204c-f. In FIG. 12G, photodiode 1202 may comprise three (3) active areas 1204g-i. In FIG. 12H, photodiode 1202 may comprise nine (9) active areas 1204j-r. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode 1202.

FIG. 13 illustrates an example multi-stream process 1300. The multi-stream process 1300 can be implemented by the data collection system 100 and/or by any of the sensors described above. As shown, a control signal from a signal processor 1310 controls a driver 1305. In response, an emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302. As described above, in some embodiments, the pulse sequence 1303 is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence 1303 can be greater (or smaller).

In response to the pulse sequence 1300, detectors 1 to n (n being an integer) in a detector 1306 capture optical radiation from the measurement site 1302 and provide respective streams of output signals. Each signal from one of detectors 1-n can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets 1-n in the emitter 1304. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

A front end interface 1308 can accept these multiple streams from detectors 1-n and deliver one or more signals or composite signal(s) back to the signal processor 1310. A stream from the detectors 1-n can thus include measured light intensities corresponding to the light pulses emitted from the emitter 1304.

The signal processor 1310 can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor 1310 can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

The Beer-Lambert law is usually written as:

Absorbance $A = m \cdot b \cdot c$, where:

m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of $M^{-1} \text{ cm}^{-1}$);

b is the mean path length; and

c is the analyte concentration (e.g., the desired parameter).

In spectroscopy, instruments attempt to obtain the analyte concentration (c) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

$$T = I/I_0, \text{ where:}$$

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I is the light intensity measured by the instrument from the measurement site; and

I_0 is the initial light intensity from the emitter.

Absorbance (A) can be equated to the transmittance (T) by the equation:

$$A = -\log T$$

Therefore, substituting equations from above:

$$A = -\log(I/I_0)$$

In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(I/I_0)$ and solving for analyte concentration (c).

Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (I_0), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude than what is achievable by currently available technology.

In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$T = e^{-m \cdot b \cdot c}$$

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In terms of light intensity, this equation can also be rewritten as:

I/I_o = e^{-m*b*c}

Or, at a detector, the measured light (I) can be expressed as:

I = I_o * e^{-m*b*c}

As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in I_1 . . . I_n streams of measurements. Assuming each of these detectors have their own path lengths, b_1 . . . b_n, from the light source, the measured light intensities can be expressed as:

I_n = I_o * e^{-m*b_n*c}

The measured light intensities at any two different detectors can be referenced to each other. For example:

I_1/I_n = (I_o * e^{-m*b_1*c}) / (I_o * e^{-m*b_n*c})

As can be seen, the terms, I_o, cancel out and, based on exponent algebra, the equation can be rewritten as:

I_1/I_n = e^{-m*(b_1-b_n)*c}

From this equation, the analyte concentration (c) can now be derived from bulk signals I_1 . . . I_n and knowing the respective mean path lengths b_1 and b_n. This scheme also allows for the cancelling out of I_o, and thus, noise generated by the emitter 1304 can be cancelled out or reduced. In addition, since the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) 1302. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

FIG. 14A illustrates an embodiment of a detector submount 1400a positioned beneath the partially cylindrical protrusion 605 of FIG. 6 (or alternatively, the protrusion 605b). The detector submount 1400a includes two rows 1408a of detectors 1410a. The partially cylindrical protrusion 605 can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion 605 can act as a lens that focuses light onto a smaller area.

To illustrate, in some sensors that do not include the partially cylindrical protrusion 605, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

Applying the partially cylindrical protrusion 605 to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion 605 (see FIG. 14B). This is the example situation illustrated in FIG. 14—two rows 1408a of detectors 1410a

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are used instead of four. Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

In other embodiments, using the partially cylindrical protrusion 605 can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion 605 (or alternatively, the protrusion 605b) that illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors. The protrusion 605 is placed above a detector submount 1400b having one or more detectors 1410b disposed thereon. The submount 1400b can include any number of rows of detectors 1410, although one row is shown.

Light, represented by rays 1420, is emitted from the emitters onto the protrusion 605. These light rays 1420 can be attenuated by body tissue (not shown). When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion 605. The refraction causes the rays 1422 to be focused or substantially focused on the one or more detectors 1410b. Since the light is focused on a smaller area, a sensor including the protrusion 605 can include fewer detectors to capture the same amount of light compared with other sensors.

FIG. 14C illustrates another embodiment of a detector submount 1400c, which can be disposed under the protrusion 605b (or alternatively, the protrusion 605). The detector submount 1400c includes a single row 1408c of detectors 1410c. The detectors are electrically connected to conductors 1412c, which can be gold, silver, copper, or any other suitable conductive material.

The detector submount 1400c is shown positioned under the protrusion 605b in a detector subassembly 1450 illustrated in FIG. 14D. A top-down view of the detector subassembly 1450 is also shown in FIG. 14E. In the detector subassembly 1450, a cylindrical housing 1430 is disposed on the submount 1400c. The cylindrical housing 1430 includes a transparent cover 1432, upon which the protrusion 605b is disposed. Thus, as shown in FIG. 14D, a gap 1434 exists between the detectors 1410c and the protrusion 605b. The height of this gap 1434 can be chosen to increase or maximize the amount of light that impinges on the detectors 1410c.

The cylindrical housing 1430 can be made of metal, plastic, or another suitable material. The transparent cover 1432 can be fabricated from glass or plastic, among other materials. The cylindrical housing 1430 can be attached to the submount 1400c at the same time or substantially the same time as the detectors 1410c to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing 1430 in various embodiments.

In certain embodiments, the cylindrical housing 1430 (and transparent cover 1432) forms an airtight or substantially airtight or hermetic seal with the submount 1400c. As a result, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c more effectively than cur-

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rently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

In embodiments where the cylindrical housing 1430 is at least partially made of metal, the cylindrical housing 1430 can provide noise shielding for the detectors 1410c. For example, the cylindrical housing 1430 can be soldered to a ground connection or ground plane on the submount 1400c, which allows the cylindrical housing 1430 to reduce noise. In another embodiment, the transparent cover 1432 can include a conductive material or conductive layer, such as conductive glass or plastic. The transparent cover 1432 can include any of the features of the noise shields 790 described above.

The protrusion 605b includes the chamfered edges 607 described above with respect to FIG. 6E. These chamfered edges 607 can allow a patient to more comfortably slide a finger over the protrusion 605b when inserting the finger into the sensor 301f.

FIG. 14F illustrates a portion of the detector shell 306f, which includes the detectors 1410c on the substrate 1400c. The substrate 1400c is enclosed by a shielding enclosure 1490, which can include the features of the shielding enclosures 790a, 790b described above (see also FIG. 17). The shielding enclosure 1490 can be made of metal. The shielding enclosure 1490 includes a window 1492a above the detectors 1410c, which allows light to be transmitted onto the detectors 1410c.

A noise shield 1403 is disposed above the shielding enclosure 1490. The noise shield 1403, in the depicted embodiment, includes a window 1492a corresponding to the window 1492a. Each of the windows 1492a, 1492b can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows 1492a, 1492b may be selected to have different sizes or shapes from each other.

The noise shield 1403 can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield 1403 extends about three-quarters of the length of the detector shell 306f. In other embodiments, the noise shield 1403 could be smaller or larger. The noise shield 1403 could, for instance, merely cover the detectors 1410c, the submount 1400c, or a portion thereof. The noise shield 1403 also includes a stop 1413 for positioning a measurement site within the sensor 301f. Advantageously, in certain embodiments, the noise shield 1403 can reduce noise caused by light piping.

A thermistor 1470 is also shown. The thermistor 1470 is attached to the submount 1400c and protrudes above the noise shield 1403. As described above, the thermistor 1470 can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In the depicted embodiment, the detectors 1410c are not enclosed in the cylindrical housing 1430. In an alternative embodiment, the cylindrical housing 1430 encloses the detectors 1410c and is disposed under the noise shield 1403. In another embodiment, the cylindrical housing 1430 encloses the detectors 1410c and the noise shield 1403 is not used. If both the cylindrical housing 1403 and the noise shield 1403 are used, either or both can have noise shielding features.

FIG. 14G illustrates the detector shell 306f of FIG. 14F, with the finger bed 310f disposed thereon. FIG. 14H illus-

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trates the detector shell 306f of FIG. 14G, with the protrusion 605b disposed in the finger bed 310f.

FIG. 14I illustrates a cutaway view of the sensor 301f. Not all features of the sensor 301f are shown, such as the protrusion 605b. Features shown include the emitter and detector shells 304f, 306f; the flaps 307f; the heat sink 350f and fins 351f; the finger bed 310f; and the noise shield 1403.

In addition to these features, emitters 1404 are depicted in the emitter shell 304f. The emitters 1404 are disposed on a submount 1401, which is connected to a circuit board 1419. The emitters 1404 are also enclosed within a cylindrical housing 1480. The cylindrical housing 1480 can include all of the features of the cylindrical housing 1430 described above. For example, the cylindrical housing 1480 can be made of metal, can be connected to a ground plane of the submount 1401 to provide noise shielding, and can include a transparent cover 1482.

The cylindrical housing 1480 can also protect the emitters 1404 from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing 1480 can provide a gap between the emitters 1404 and the measurement site (not shown), which can allow light from the emitters 1404 to even out or average out before reaching the measurement site.

The heat sink 350f, in addition to including the fins 351f, includes a protuberance 352f that extends down from the fins 351f and contacts the submount 1401. The protuberance 352f can be connected to the submount 1401, for example, with thermal paste or the like. The protuberance 352f can sink heat from the emitters 1404 and dissipate the heat via the fins 351f.

FIGS. 15A and 15B illustrate embodiments of sensor portions 1500A, 1500B that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

The sensor portions 1500A, 1500B shown include LED emitters 1504; however, for ease of illustration, the detectors have been omitted. The sensor portions 1500A, 1500B shown can be included, for example, in any of the emitter shells described above.

The LEDs 1504 of the sensor portions 1500A, 1500B are connected to a substrate or submount 1502. The submount 1502 can be used in place of any of the submounts described above. The submount 1502 can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable 1512 is attached to the submount 1502 and includes electrical wiring 1514, such as twisted wires and the like, for communicating with the LEDs 1504. The cable 1512 can correspond to the cables 212 described above.

Although not shown, the cable 1512 can also include electrical connections to a detector. Only a portion of the cable 1512 is shown for clarity. The depicted embodiment of the cable 1512 includes an outer jacket 1510 and a conductive shield 1506 disposed within the outer jacket 1510. The conductive shield 1506 can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield 1506 or a portion of the conductive shield 1506 can be electrically connected to the submount 1502 and can reduce noise in the signal generated by the sensor 1500A, 1500B by reducing RF coupling with the wires 1514. In alternative embodiments, the cable 1512 does not have a conductive shield. For example, the cable 1512

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could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

Referring specifically to FIG. 15A, in certain embodiments, the conductive shield 1506 can act as a heat sink for the LEDs 1504 by absorbing thermal energy from the LEDs 1504 and/or the submount 1502. An optional heat insulator 1520 in communication with the submount 1502 can also assist with directing heat toward the conductive shield 1506. The heat insulator 1520 can be made of plastic or another suitable material. Advantageously, using the conductive shield 1506 in the cable 1512 as a heat sink can, in certain embodiments, reduce cost for the sensor.

Referring to FIG. 15B, the conductive shield 1506 can be attached to both the submount 1502 and to a heat sink layer 1530 sandwiched between the submount 1502 and the optional insulator 1520. Together, the heat sink layer 1530 and the conductive shield 1506 in the cable 1512 can absorb at least part of the thermal energy from the LEDs and/or the submount 1502.

FIGS. 15C and 15D illustrate implementations of a sensor portion 1500C that includes the heat sink features of the sensor portion 1500A described above with respect to FIG. 15A. The sensor portion 1500C includes the features of the sensor portion 1500A, except that the optional insulator 1520 is not shown. FIG. 15D is a side cutaway view of the sensor portion 1500C that shows the emitters 1504.

The cable 1512 includes the outer jacket 1510 and the conductive shield 1506. The conductive shield 1506 is soldered to the submount 1502, and the solder joint 1561 is shown. In some embodiments, a larger solder joint 1561 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, a cylindrical housing 1580, corresponding to the cylindrical housing 1480 of FIG. 14I, is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15E and 15F illustrate implementations of a sensor portion 1500E that includes the heat sink features of the sensor portion 1500B described above with respect to FIG. 15B. The sensor portion 1500E includes the heat sink layer 1530. The heat sink layer 1530 can be a metal plate, such as a copper plate or the like. The optional insulator 1520 is not shown. FIG. 15F is a side cutaway view of the sensor portion 1500E that shows the emitters 1504.

In the depicted embodiment, the conductive shield 1506 of the cable 1512 is soldered to the heat sink layer 1530 instead of the submount 1502. The solder joint 1565 is shown. In some embodiments, a larger solder joint 1565 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, the cylindrical housing 1580 is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described above with respect to FIGS. 1 through 15F. Referring to FIG. 15G, the circuit board 1519 includes a female connector 1575 that mates with a male connector 1577 connected to a daughter board 1587. The daughter board 1587 includes connections to the electrical wiring 1514 of the cable 1512. The connected boards 1519, 1587 are shown in FIG. 15H. Also shown is a hole 1573 that can receive the cylindrical housing 1580 described above.

Advantageously, in certain embodiments, using a daughter board 1587 to connect to the circuit board 1519 can

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enable connections to be made more easily to the circuit board 1519. In addition, using separate boards can be easier to manufacture than a single circuit board 1519 with all connections soldered to the circuit board 1519.

FIG. 15I illustrates an exemplary architecture for front-end interface 108 as a transimpedance-based front-end. As noted, front-end interfaces 108 provide an interface that adapts the output of detectors 106 into a form that can be handled by signal processor 110. As shown in this figure, sensor 101 and front-end interfaces 108 may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor 101 and front end interfaces 108 may comprise multiple components or circuits that are coupled together.

Front-end interfaces 108 may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors 106. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter 900 may be integrated with the transimpedance-based front-end in sensor 101.

Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector 106, the applicants developed a noise model to assist in configuring front-end 108. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

However, the following noise model was discovered by the applicants:

$$\text{Noise} = \sqrt{aR + bR^2}, \text{ where:}$$

aR is characteristic of the impedance of the transimpedance amplifier; and
bR² is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector 106.

The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors 1-4 (as shown, e.g., in FIG. 12A) may each comprise four photodiodes. In some embodiments, each detector of four photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in FIG. 15J.

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Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors 1-4. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the transimpedance amplifiers in this setting may also be set according to the model shown in FIG. 15J.

As yet another alternative, as noted above with respect to FIGS. 12E through 12H, the photodiodes in detectors 106 may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

As noted, FIG. 15J illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

For example, an exemplary “4 PD per stream” sensor 1502 is shown where detector 106 comprises four photodiodes 1502. The photodiodes 1502 are coupled to a single transimpedance amplifier 1504 to produce an output stream 1506. In this example, the transimpedance amplifier comprises 10 MΩ resistors 1508 and 1510. Thus, output stream 1506 is produced from the four photodiodes (PD) 1502. As shown in the graph of FIG. 15J, the model indicates that resistance values of about 10 MΩ may provide an acceptable SNR for analytes like glucose.

However, as a comparison, an exemplary “1 PD per stream” sensor 1512 is also shown in FIG. 15J. In particular, sensor 1512 may comprise a plurality of detectors 106 that each comprises a single photodiode 1514. In addition, as shown for this example configuration, each of photodiodes 1514 may be coupled to respective transimpedance amplifiers 1516, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 MΩ resistors 1518. As also shown in the graph of FIG. 15J, the model illustrates that resistance values of 40 MΩ for resistors 1518 may serve as an alternative to the 4 photodiode per stream architecture of sensor 1502 described above and yet still provide an equivalent SNR.

Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor 1512 may provide enhanced performance because each of transimpedance amplifiers 1516 can be tuned or optimized to its respective photodiodes 1518. In some embodiments, an averaging component 1520 may also be used to help cancel or reduce noise across photodiodes 1518.

For purposes of illustration, FIG. 15K shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor 1522 may comprise a “4 PD per stream” architecture on a submount 700 in which each detector 106 comprises four (4) photodiodes 1524. As shown for sensor 1522, the output of each set of four photodiodes 1524 is then aggregated into a single transimpedance amplifier 1526 to produce a signal.

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As another example, a sensor 1528 may comprise a “1 PD per stream” architecture on submount 700 in which each detector 106 comprises four (4) photodiodes 1530. In sensor 1528, each individual photodiode 1530 is coupled to a respective transimpedance amplifier 1532. The output of the amplifiers 1532 may then be aggregated into averaging circuit 1520 to produce a signal.

As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor 1534 illustrates an exemplary “4 PD per stream” sensor in which the detectors 106 comprise photodiodes 1536 arranged in a linear fashion. Likewise, sensor 1538 illustrates an exemplary “1 PD per stream” sensor in which the detectors comprise photodiodes 1540 arranged in a linear fashion.

Alternatively, sensor 1542 illustrates an exemplary “4 PD per stream” sensor in which the detectors 106 comprise photodiodes 1544 arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor 1546 illustrates an exemplary “1 PD per stream” sensor in which the detectors comprise photodiodes 1548 also arranged in a zig-zag pattern.

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces 108 may be implemented using switched capacitor circuits and any number of front-end interfaces 108 may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface 1000 and signal processor 110. Switched capacitor circuits may be useful in system 100 for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces 108 may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front end interfaces 108 may require less computational power by signal processor 110 to perform the same amount of decimation to obtain the same SNR.

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors 1600. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors 1600 shown. For instance, the sensors 1600 can be used as the sensors 101 in the system 100 described above with respect to FIG. 1. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

The sensors 1600 include an adult/pediatric sensor 1610 for finger placement and a disposable infant/neonate sensor 1602 configured for toe, foot or hand placement. Each sensor 1600 has a tape end 1610 and an opposite connector end 1620 electrically and mechanically interconnected via a flexible coupling 1630. The tape end 1610 attaches an emitter and detector to a tissue site. Although not shown, the tape end 1610 can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

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The sensor signal is communicated via the flexible coupling 1630 to the connector end 1620. The connector end 1620 can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGS. 2A through 2D. Alternatively, the connector end 1620 can mate directly with the monitor.

FIG. 17 illustrates an exploded view of certain of the components of the sensor 301f described above. A heat sink 1751 and a cable 1781 attach to an emitter shell 1704. The emitter shell attaches to a flap housing 1707. The flap housing 1707 includes a receptacle 1709 to receive a cylindrical housing 1480/1580 (not shown) attached to an emitter submount 1702, which is attached to a circuit board 1719.

A spring 1787 attaches to a detector shell 1706 via pins 1783, 1785, which hold the emitter and detector shells 1704, 1706 together. A support structure 1791 attaches to the detector shell 1706, which provides support for a shielding enclosure 1790. A noise shield 1713 attaches to the shielding enclosure 1790. A detector submount 1700 is disposed inside the shielding enclosure 1790. A finger bed 1710 provides a surface for placement of the patient's finger. Finger bed 1710 may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion 1705 may also be disposed in the finger bed 1710. As shown, finger bed 1710 attaches to the noise shield 1703. The noise shield 1703 may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield 1703 may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

Noise shield 1703 may also comprise a thermistor 1712. The thermistor 1712 may be helpful in measuring the temperature of a patient's finger. For example, the thermistor 1712 may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor 1712 may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

Moreover, a flex circuit cover 1706 attaches to the pins 1783, 1785. Although not shown, a flex circuit can also be provided that connects the circuit board 1719 with the submount 1700 (or a circuit board to which the submount 1700 is connected). A flex circuit protector 1760 may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector 1760 may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector 1760 may be constructed from well known materials, such as a plastic or rubber materials.

FIG. 18 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor 101 were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

FIG. 19 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/

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Liposyn were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor 101 were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

FIGS. 20 through 22 shows other results that can be obtained by an embodiment of system 100. In FIG. 20, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs and four independent detector streams. As shown, the system 100 obtained a correlation of about 85% and Arms of about 31 mg/dL.

In FIG. 21, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106. As shown, the system 100 was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

The results shown in FIG. 22 relate to total hemoglobin testing with an exemplary sensor 101 of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector channels from detectors 106. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

What is claimed is:

1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit

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light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged on an interior surface of the user-worn device and configured to receive light after attenuation by tissue of the user;

a protrusion comprising:

- a convex surface extending over the interior surface, a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and
- a plurality of windows, each of the windows extending across a different one of the openings; and

one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate a measurement of the physiological parameter of the user.

2. The user-worn device of claim 1, wherein the windows comprise glass.

3. The user-worn device of claim 1, wherein the windows comprise plastic.

4. The user-worn device of claim 1 further comprising: a network interface configured to wirelessly communicate the measurement of the physiological parameter to at least one of: a mobile phone or a computer network; a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurement of the physiological parameter;

a storage device configured to at least temporarily store at least the measurement; and

a strap configured to position the user-worn device on the user.

5. The user-worn device of claim 1, wherein the opaque surface is configured to reduce light piping.

6. The user-worn device of claim 1 further comprising: at least one wall extending between the interior surface and the protrusion,

wherein at least the interior surface, the wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities.

7. The user-worn device of claim 1, wherein the physiological parameter comprises at least one of: methemoglobin, total hemoglobin, carboxyhemoglobin, or carbon monoxide.

8. The user-worn device of claim 1, wherein the physiological parameter comprises oxygen or oxygen saturation.

9. The user-worn device of claim 1, wherein the physiological parameter comprises trending information.

10. The user-worn device of claim 1 further comprising a thermistor.

11. The user-worn device of claim 1, wherein the LEDs and the photodiodes are arranged on a same side of the tissue of the user.

12. The user-worn device of claim 1, wherein the one or more processors are further configured to calculate a bulk measurement responsive to a positioning of the user-worn device.

13. The user-worn device of claim 1, wherein, within each of the first and second sets of LEDs, any one LED is positioned within 2 mm to 4 mm of another.

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14. The user-worn device of claim 1, further comprising a third set of LEDs, the third set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength.

15. The user-worn device of claim 1, wherein the four photodiodes comprise first, second, third and fourth photodiodes and wherein the first photodiode and the second photodiode are arranged on the interior surface across from each other on opposite sides of a central point along a first axis, and the third photodiode and the fourth photodiode are arranged across from each other on opposite sides of the central point along a second axis which is different from the first axis.

16. The user-worn device of claim 1, wherein the protrusion further comprises one or more extensions.

17. The user-worn device of claim 16, wherein the one or more extensions surround a perimeter of the convex surface of the protrusion.

18. The user-worn device of claim 1, wherein the protrusion further comprises one or more chamfered edges.

19. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

- a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);
- four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
- a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;
- optically transparent material within each of the openings; and
- one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.

20. The user-worn device of claim 19 further comprising a thermistor.

21. The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.

22. The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.

23. The user-worn device of claim 22, wherein, within each respective set of at least three LEDs, the LEDs of the set are positioned within 2 mm to 4 mm of each other.

24. The user-worn device of claim 19 further comprising: a network interface configured to wirelessly communicate at least the measurements of oxygen saturation to at least one of: a mobile phone or a computer network; a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurements of oxygen saturation; and

a memory device configured to at least temporarily store at least the measurements of oxygen saturation.

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25. The user-worn device of claim 19, wherein the photodiodes comprise first, second, third and fourth photodiodes and wherein the first photodiode and the second photodiode are arranged across from each other on opposite sides of a central point along a first axis, and the third photodiode and the fourth photodiode are arranged across from each other on opposite sides of the central point along a second axis which is different from the first axis.

26. The user-worn device of claim 19, wherein the optically transparent material is glass.

27. The user-worn device of claim 19, wherein the optically transparent material is plastic.

28. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;

a thermistor configured to provide a temperature signal;

a protrusion arranged above the interior surface, the protrusion comprising:

a convex surface;

a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and

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a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;

at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities;

one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal;

a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;

a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user;

a storage device configured to at least temporarily store at least the measurement; and

a strap configured to position the user-worn device on the user.

29. The user-worn device of claim 28, further comprising: a driver configured to energize the first and second sets of LEDs; and

a front-end interface comprising one or more amplifiers and one or more analog to digital converters (ADCs), wherein the front-end interface receives the signals from the photodiodes, the one or more amplifiers amplify the signals and the one or more ADCs convert the signals to digital information, and wherein the processors receive the converted signals.

30. The user-worn device of claim 28, wherein the protrusion further comprises one or more sidewalls extending at least partially around a perimeter of the convex surface.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 10,912,502 B2
APPLICATION NO. : 17/031407
DATED : February 9, 2021
INVENTOR(S) : Jeroen Poeze et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (63), Page 2, Column 1 at Line 10, Related U.S. Application Data, Change “which is a division” to --which is a continuation--.

Item (63), Page 2, Column 1 at Lines 24-25, Related U.S. Application Data, Change “and a continuation-in-part” to --which is a continuation-in-part--.

In the Specification

In Column 38 at Line 34, Change “15008” to --1500B--.

In Column 38 at Line 65, Change “15008” to --1500B--.

In Column 41 at Line 33, Change “10 MO” to --10 MΩ--.

In Column 41 at Line 36, Change “10 MO” to --10 MΩ--.

In the Claims

In Column 46 at Line 34, In Claim 19, change “one associated with each of” to --one of--.

Signed and Sealed this
Sixth Day of July, 2021



Drew Hirshfeld
*Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office*

U 8115196



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

June 02, 2021

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THIS OFFICE OF:**

U.S. PATENT: 10,945,648

ISSUE DATE: March 16, 2021

**By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office**



Sylvia Holley
SYLVIA HOLLEY
Certifying Officer



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(12) **United States Patent**
Poeze et al.

(10) **Patent No.:** **US 10,945,648 B2**

(45) **Date of Patent:** ***Mar. 16, 2021**

(54) **USER-WORN DEVICE FOR
NONINVASIVELY MEASURING A
PHYSIOLOGICAL PARAMETER OF A USER**

(52) **U.S. Cl.**
CPC *A61B 5/1455* (2013.01); *A61B 5/14532*
(2013.01); *A61B 5/14546* (2013.01);
(Continued)

(71) Applicant: **Masimo Corporation**, Irvine, CA (US)

(58) **Field of Classification Search**
CPC . *A61B 5/1455*; *A61B 5/14546*; *A61B 5/6838*;
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(Continued)

(72) Inventors: **Jeroen Poeze**, Rancho Santa Margarita,
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(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
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This patent is subject to a terminal dis-
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Related U.S. Application Data

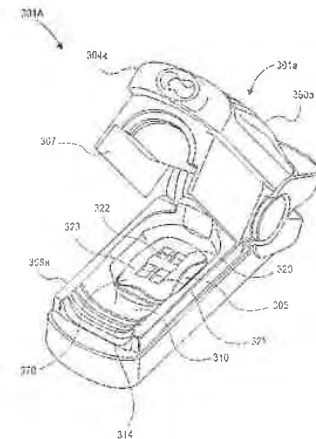
(60) Continuation of application No. 16/834,538, filed on
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(Continued)

(51) **Int. Cl.**
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(57) **ABSTRACT**

The present disclosure relates to noninvasive methods,
devices, and systems for measuring various blood constitu-
ents or analytes, such as glucose. In an embodiment, a light
source comprises LEDs and super-luminescent LEDs. The
light source emits light at least wavelengths of about 1610
nm, about 1640 nm, and about 1665 nm. In an embodiment,
the detector comprises a plurality of photodetectors arranged
in a special geometry comprising one of a substantially
linear substantially equal spaced geometry, a substantially
linear substantially non-equal spaced geometry, and a sub-
stantially grid geometry.

30 Claims, 65 Drawing Sheets



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Related U.S. Application Data

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| (52) U.S. Cl. CPC A61B 5/14552 (2013.01); A61B 5/6816 (2013.01); A61B 5/6826 (2013.01); A61B 5/6829 (2013.01); A61B 5/6838 (2013.01); A61B 5/6843 (2013.01); A61B 2562/0233 (2013.01); A61B 2562/04 (2013.01); A61B 2562/046 (2013.01); A61B 2562/146 (2013.01) | | | |
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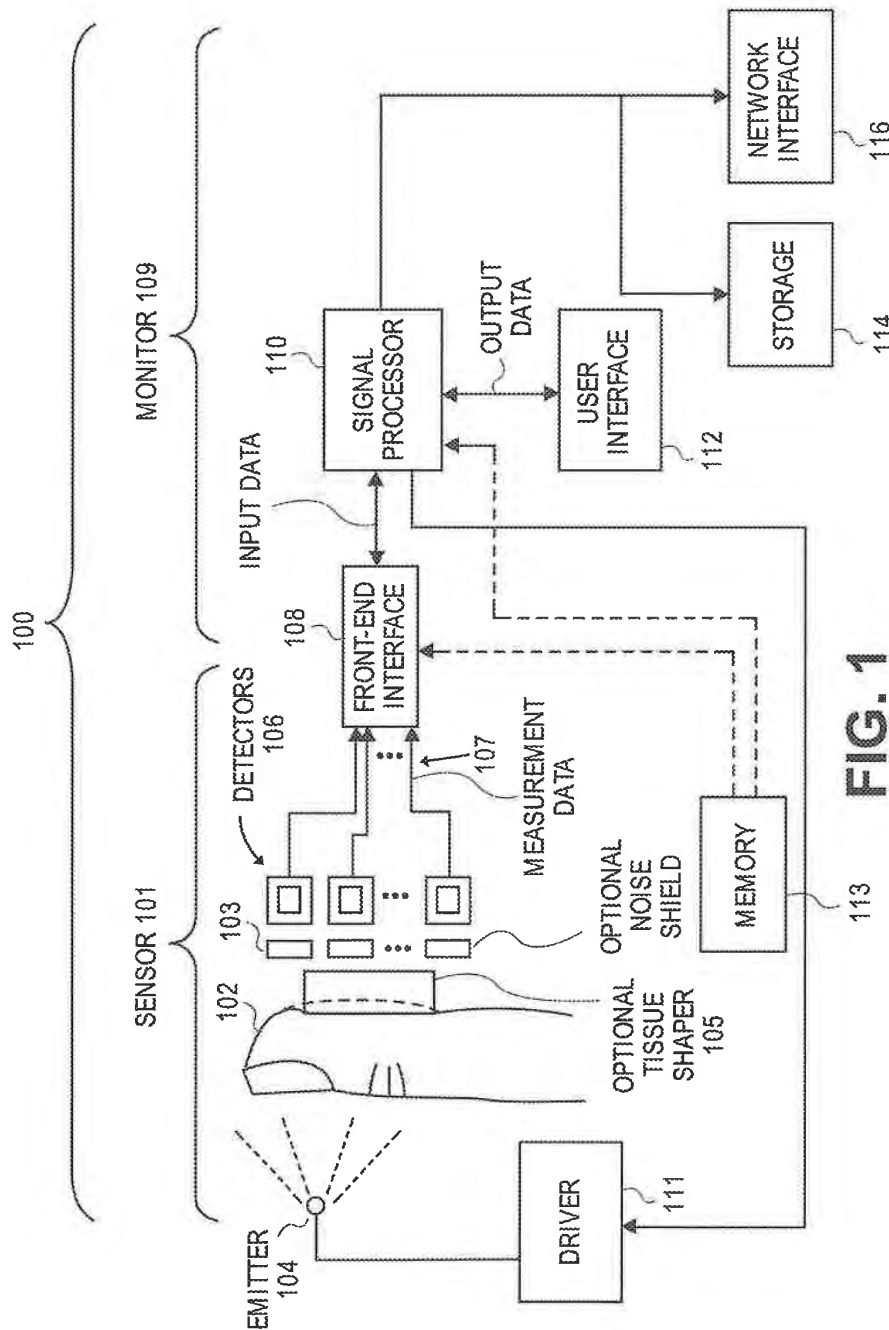


FIG. 1

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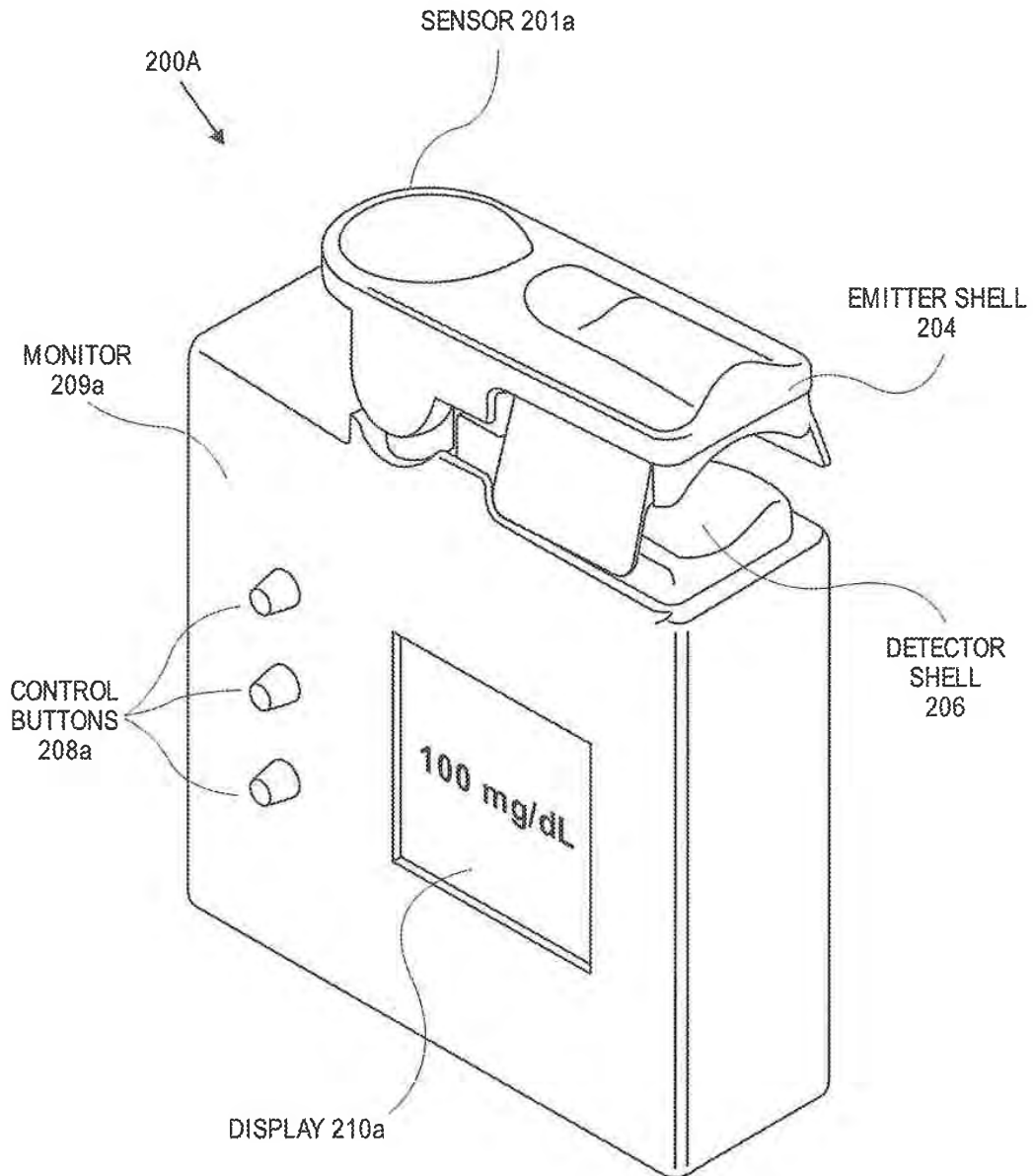


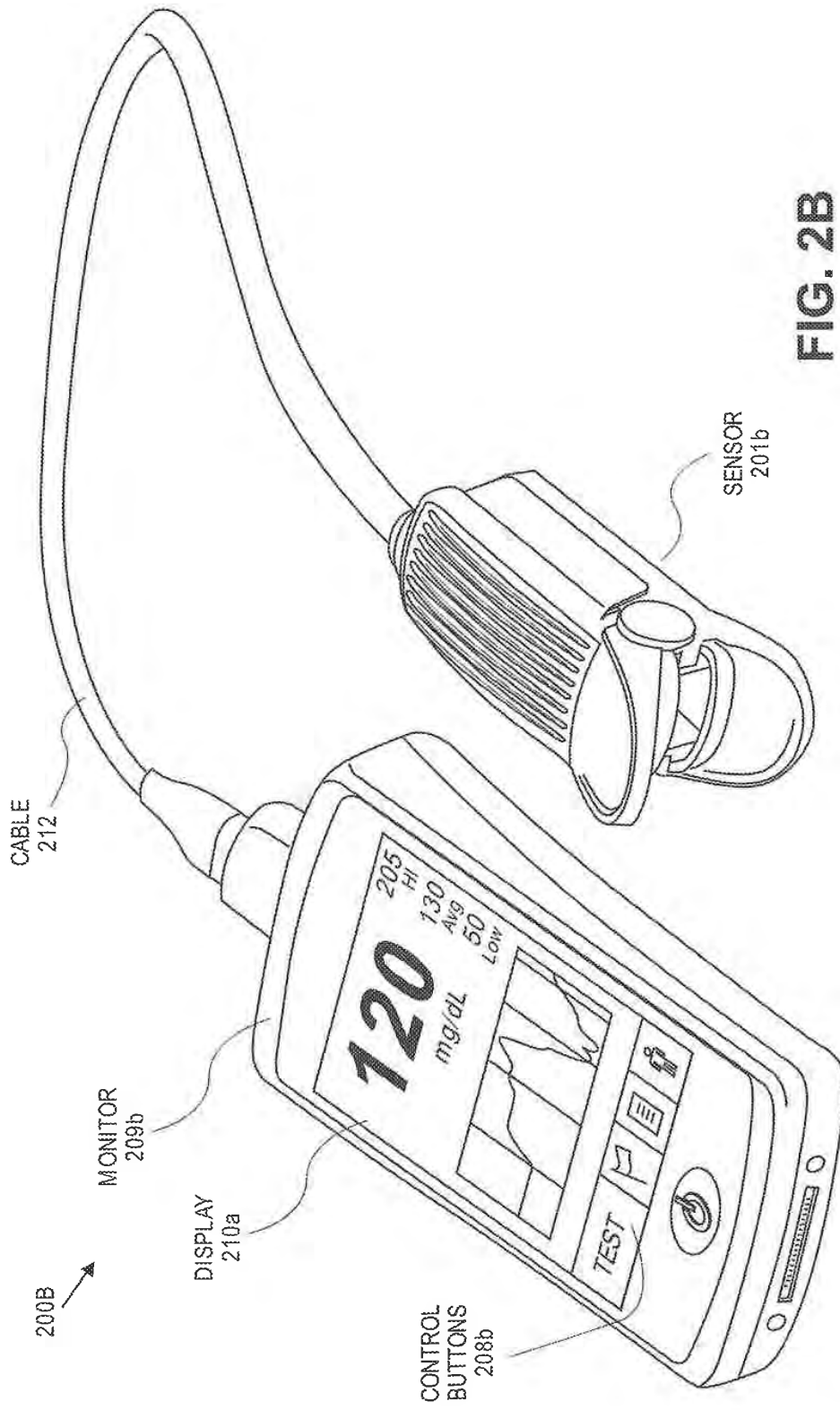
FIG. 2A

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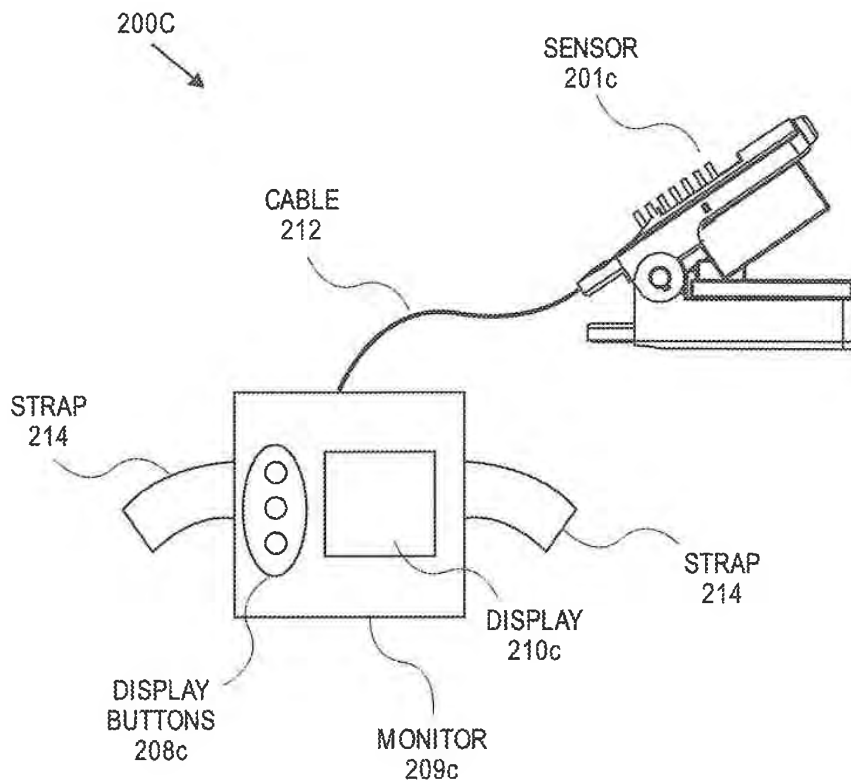


FIG. 2C

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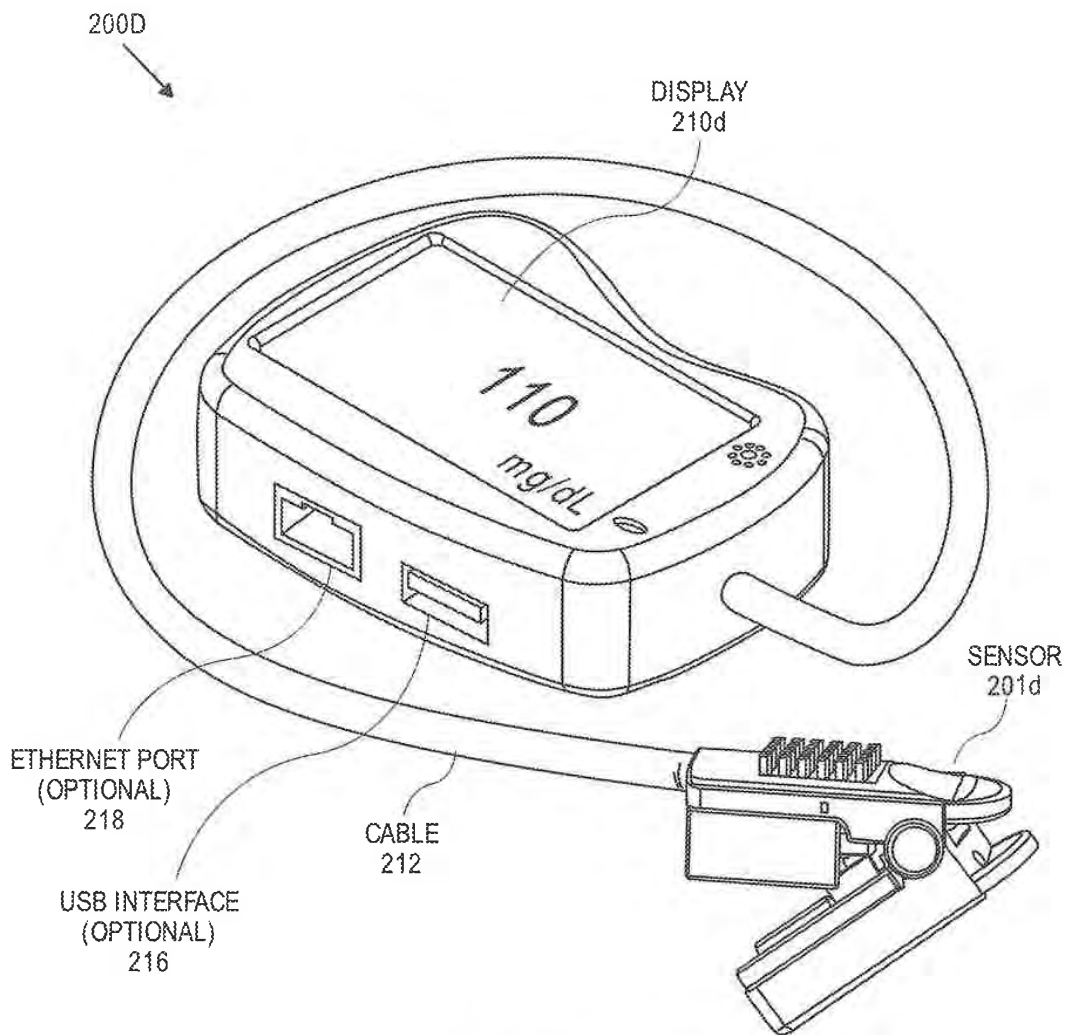


FIG. 2D

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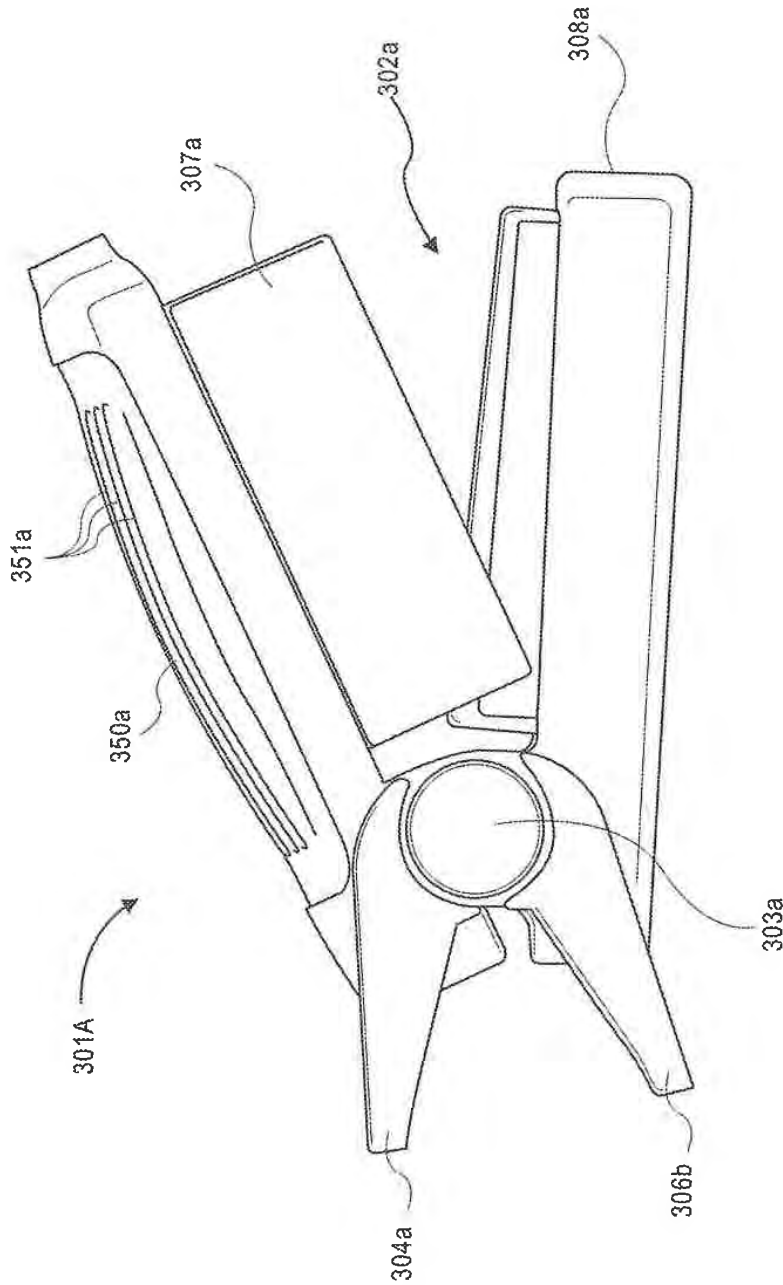


FIG. 3A

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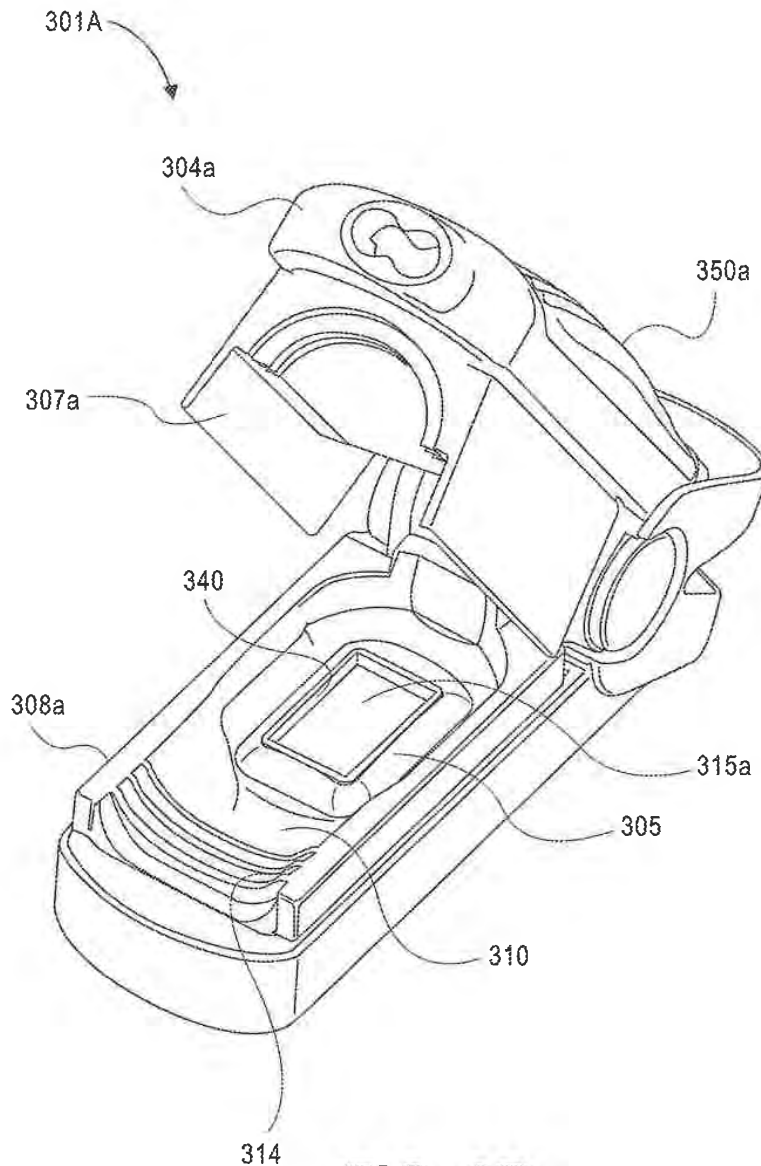


FIG. 3B

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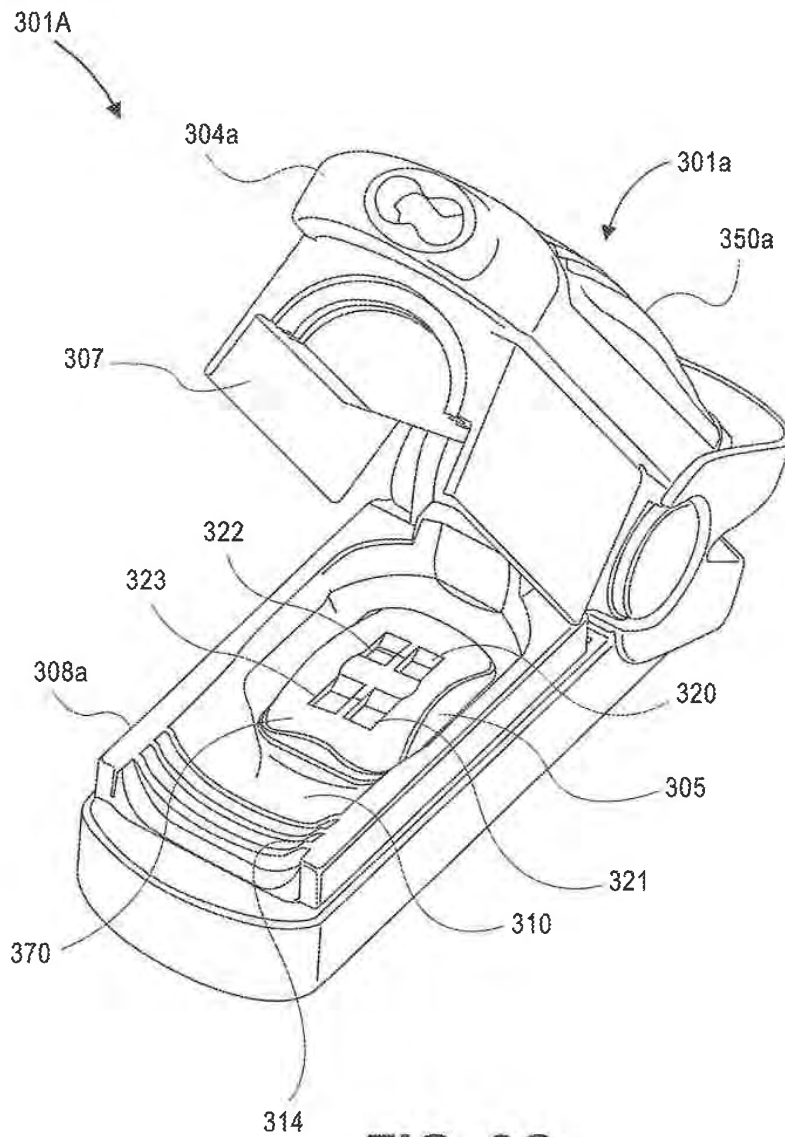


FIG. 3C

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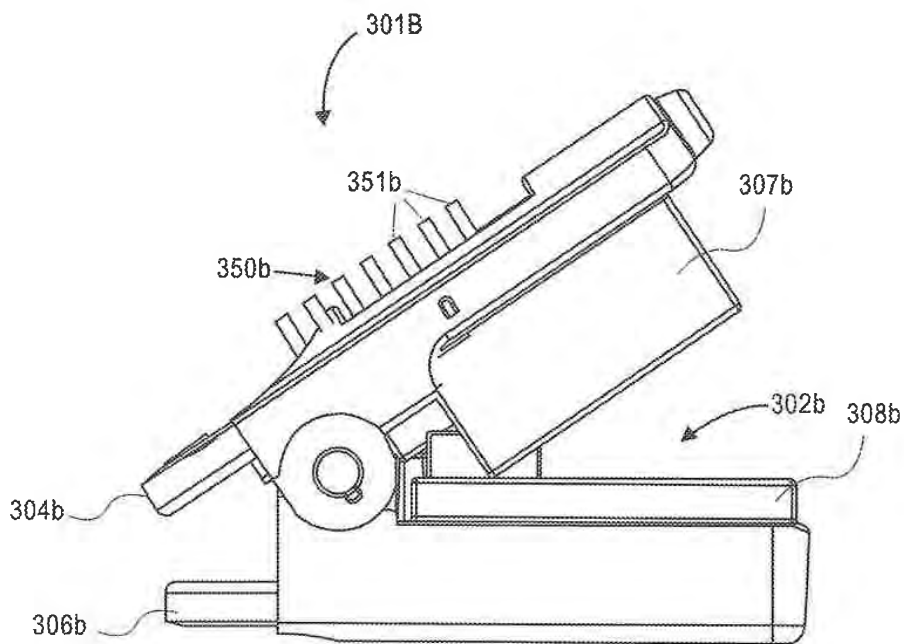


FIG. 3D

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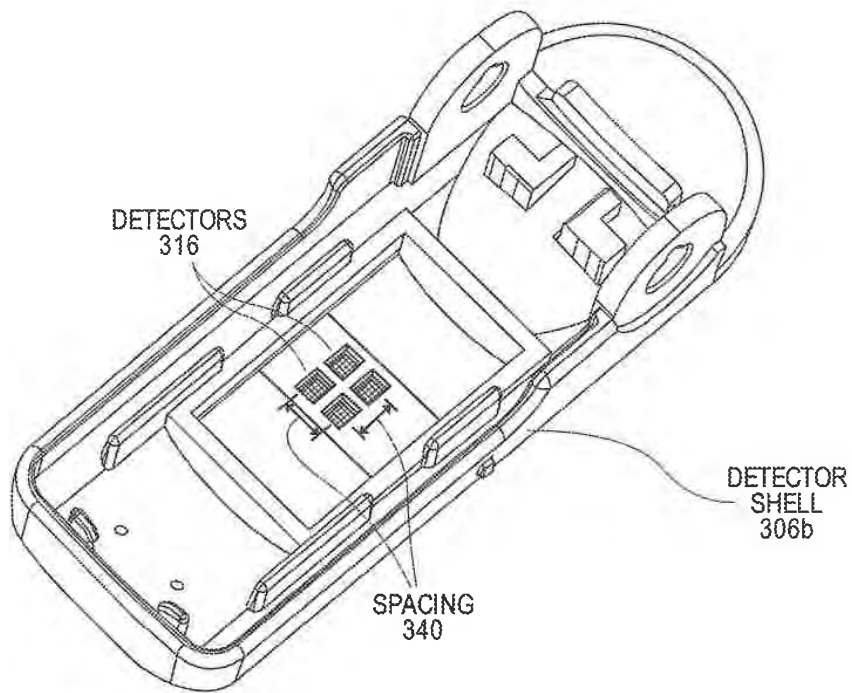


FIG. 3E

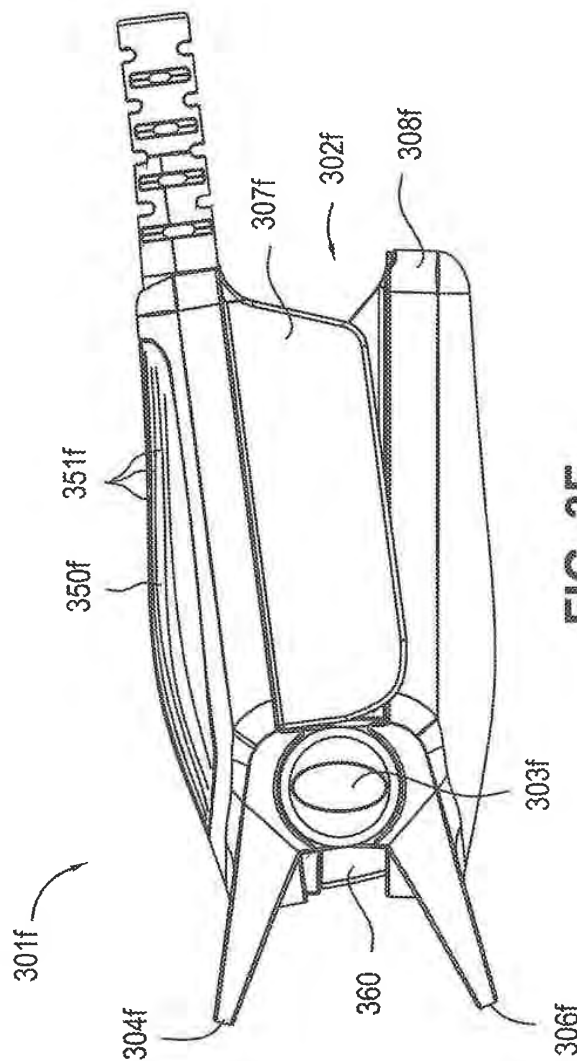


FIG. 3F

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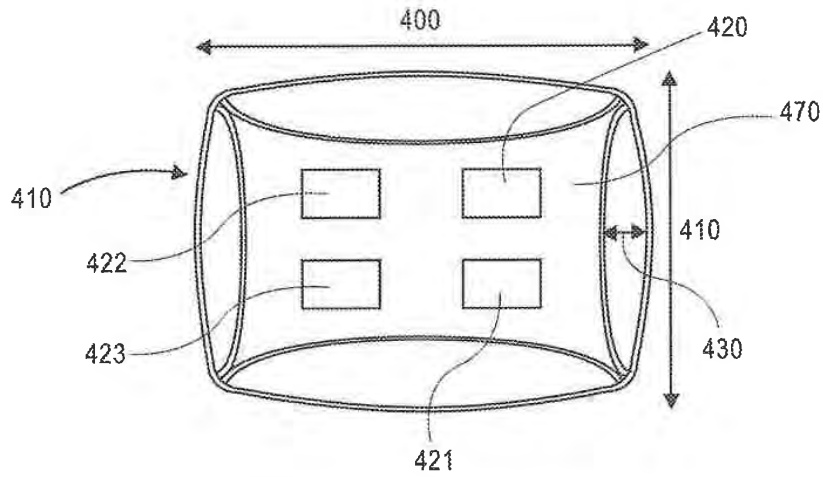


FIG. 4A

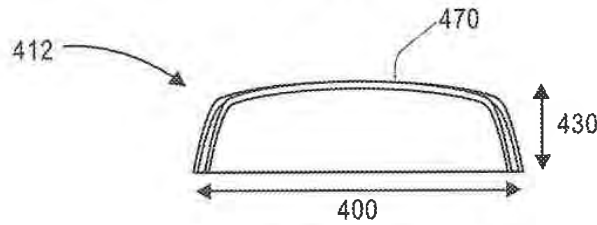


FIG. 4B

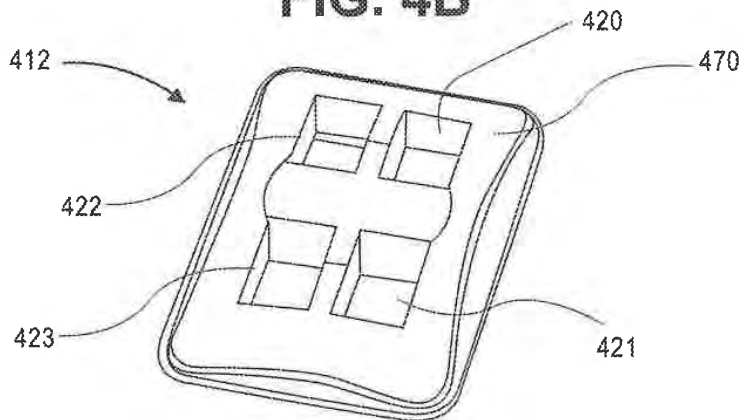


FIG. 4C

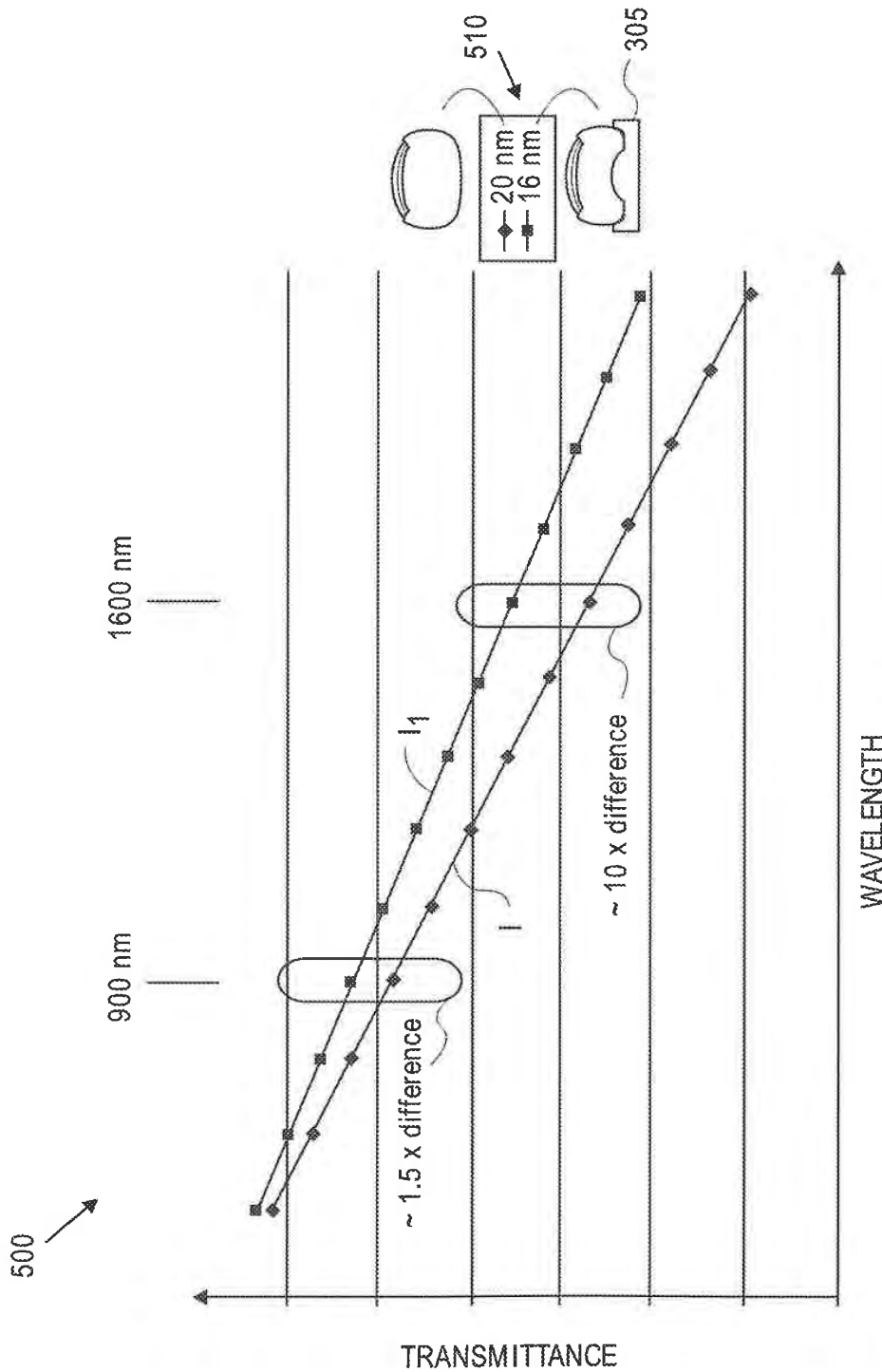


FIG. 5

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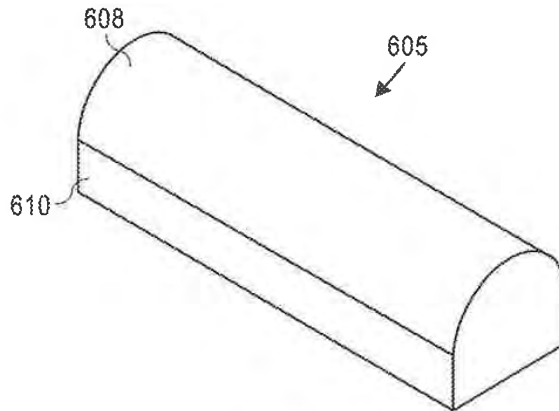


FIG. 6A

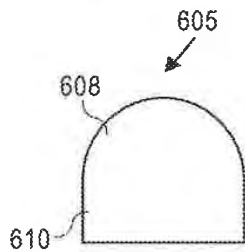


FIG. 6B

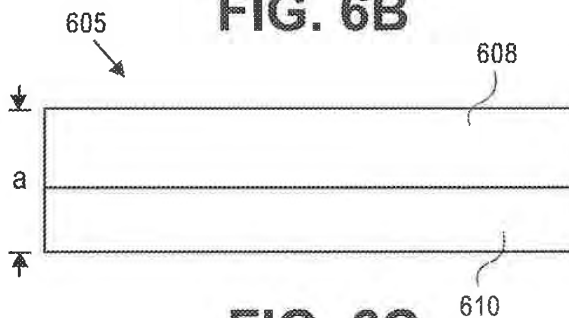


FIG. 6C

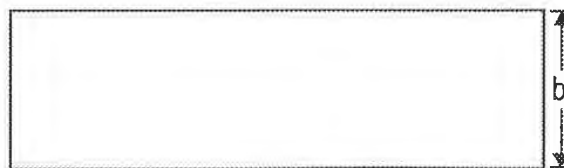


FIG. 6D

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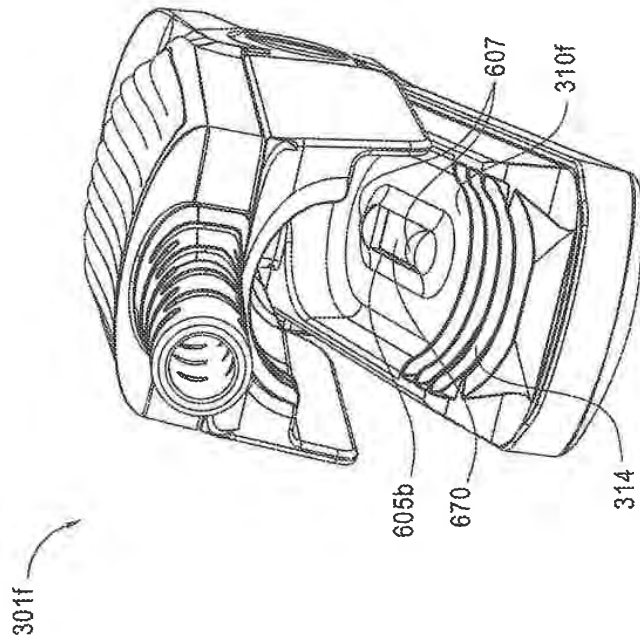


FIG. 6E

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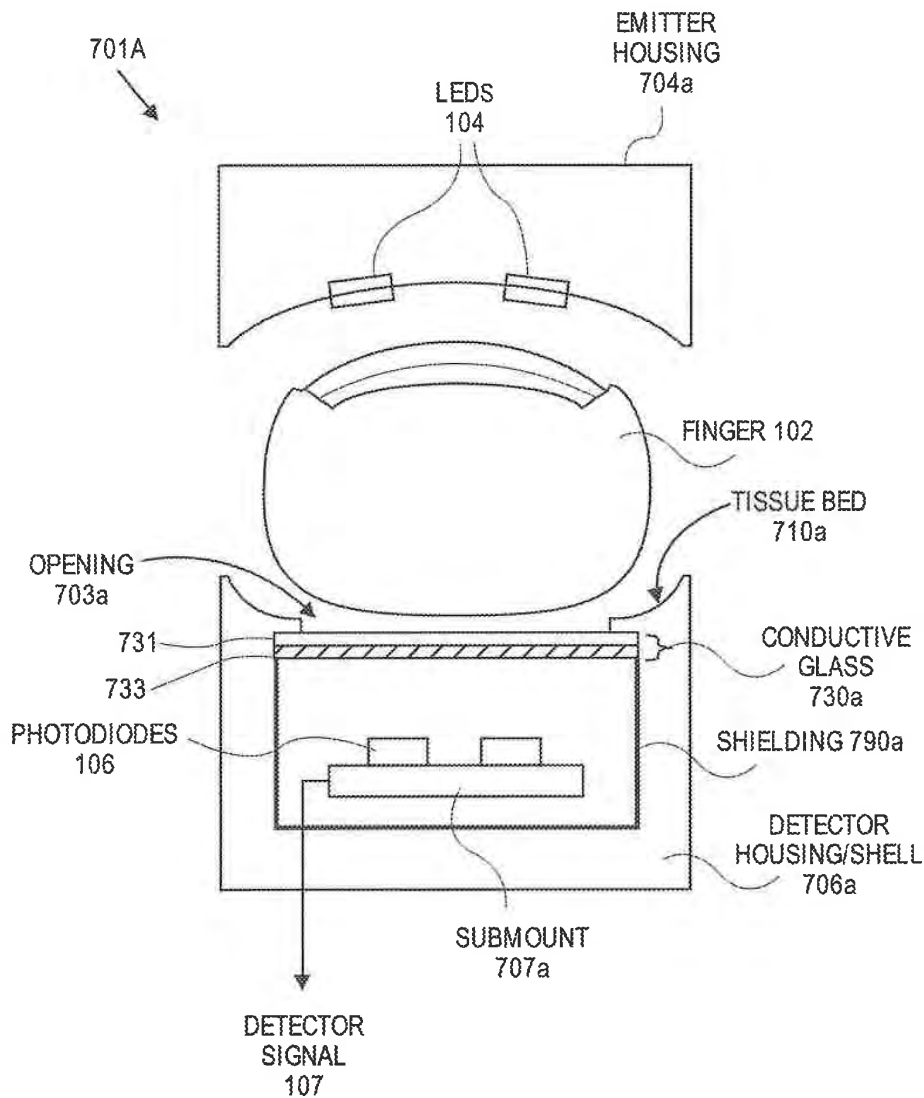


FIG. 7A

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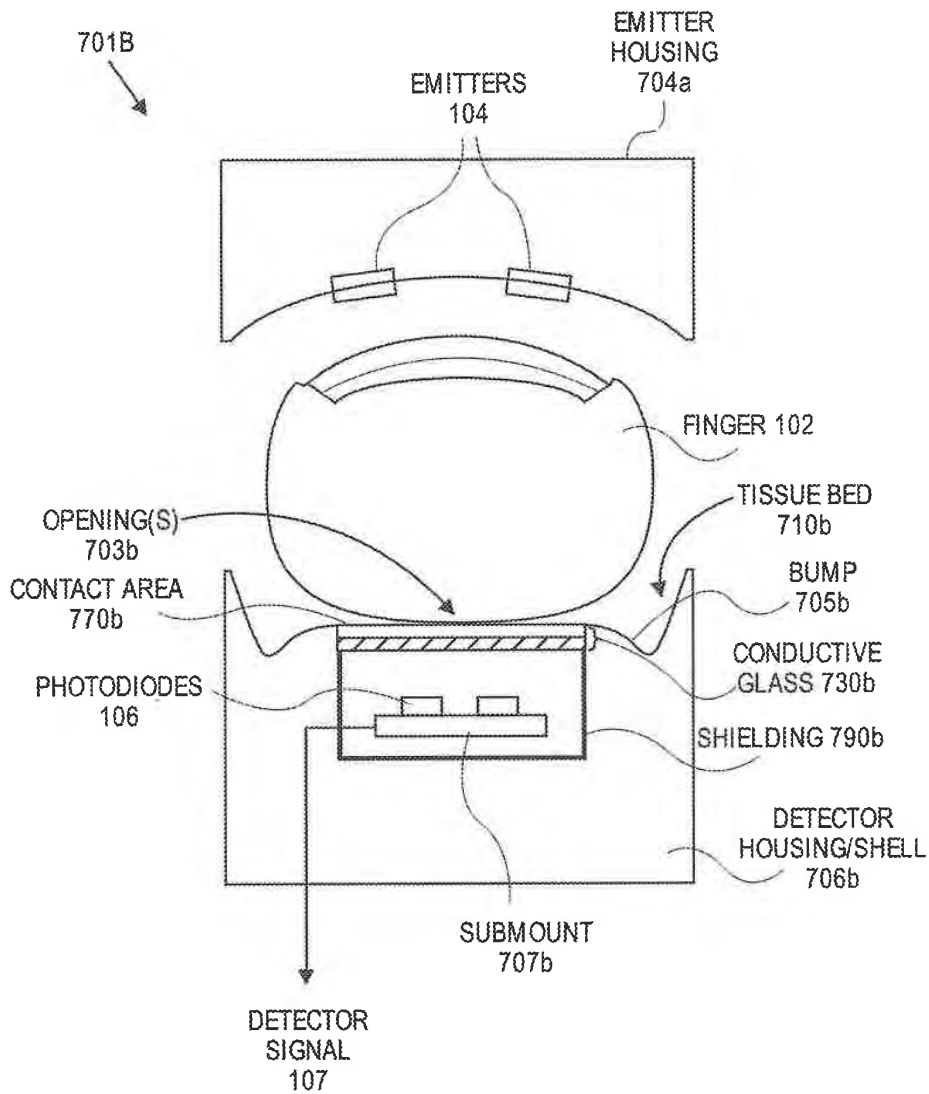


FIG. 7B

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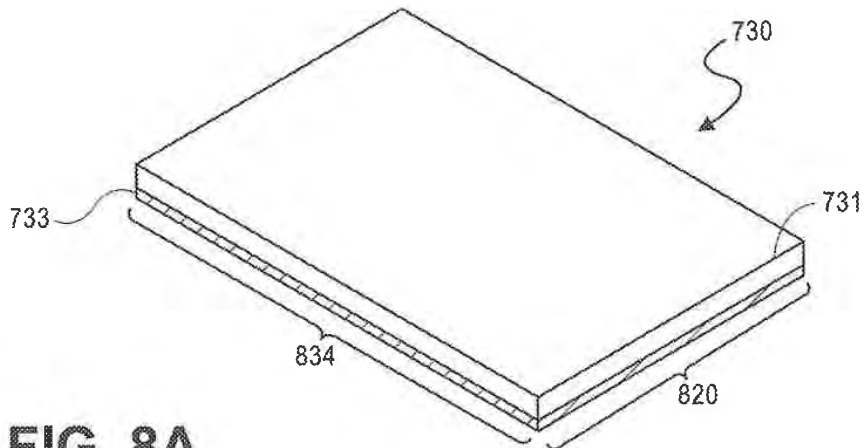


FIG. 8A

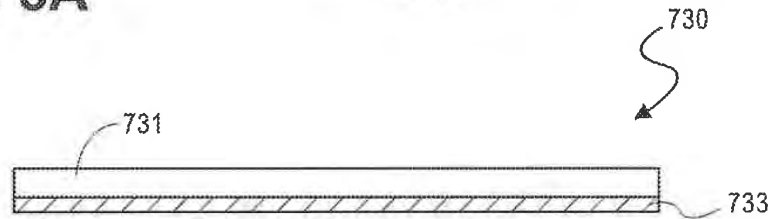


FIG. 8B

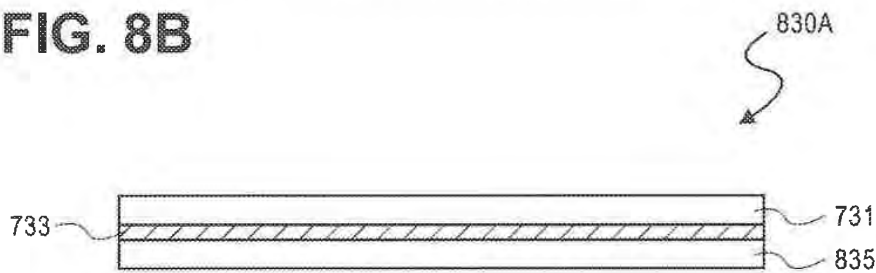


FIG. 8C

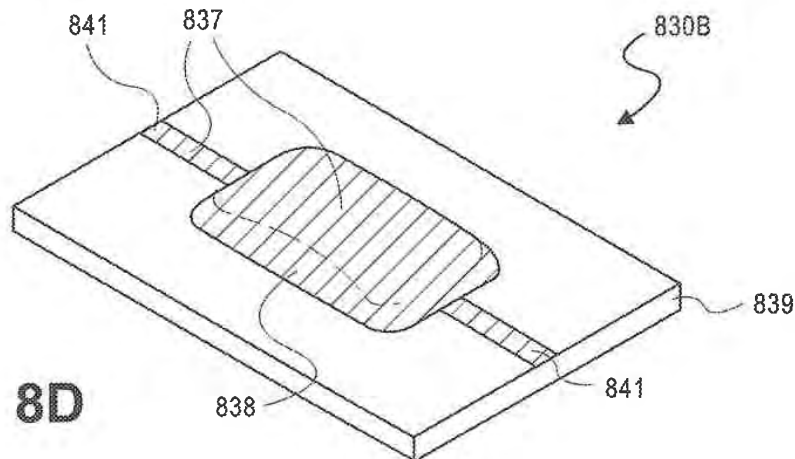


FIG. 8D

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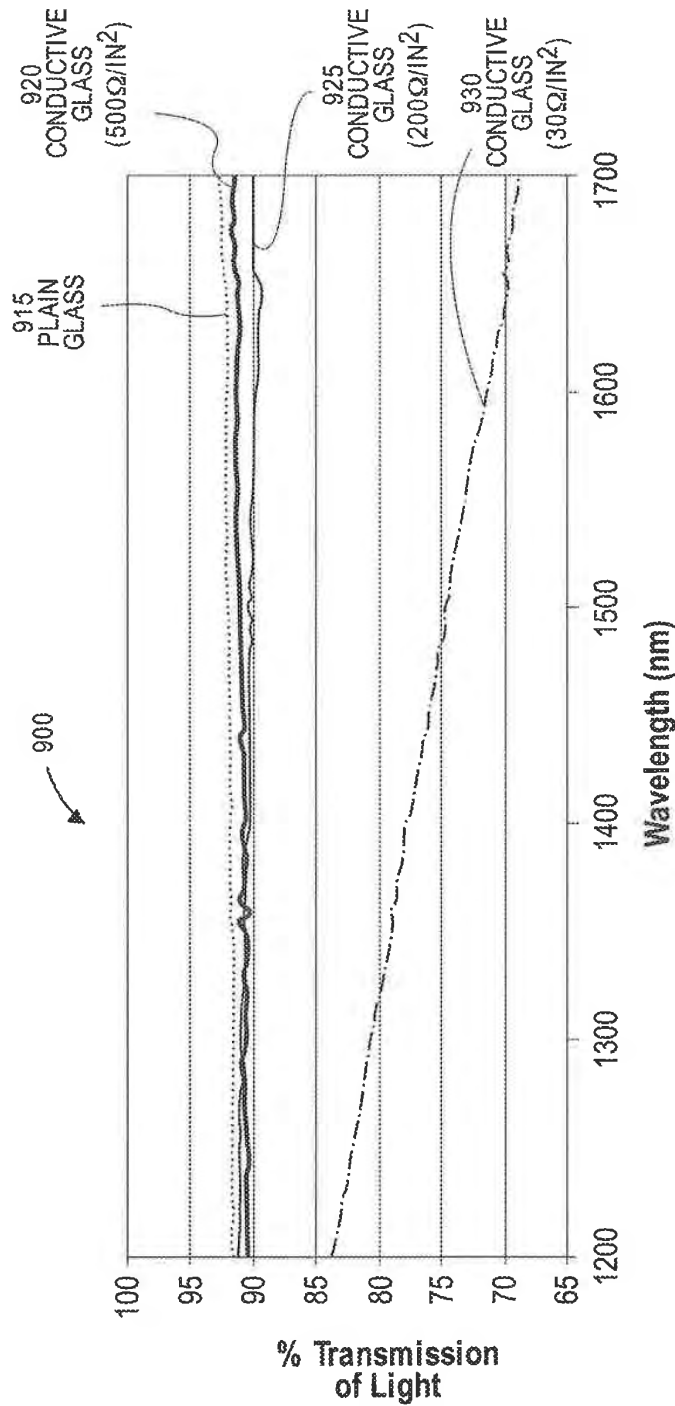


FIG. 9

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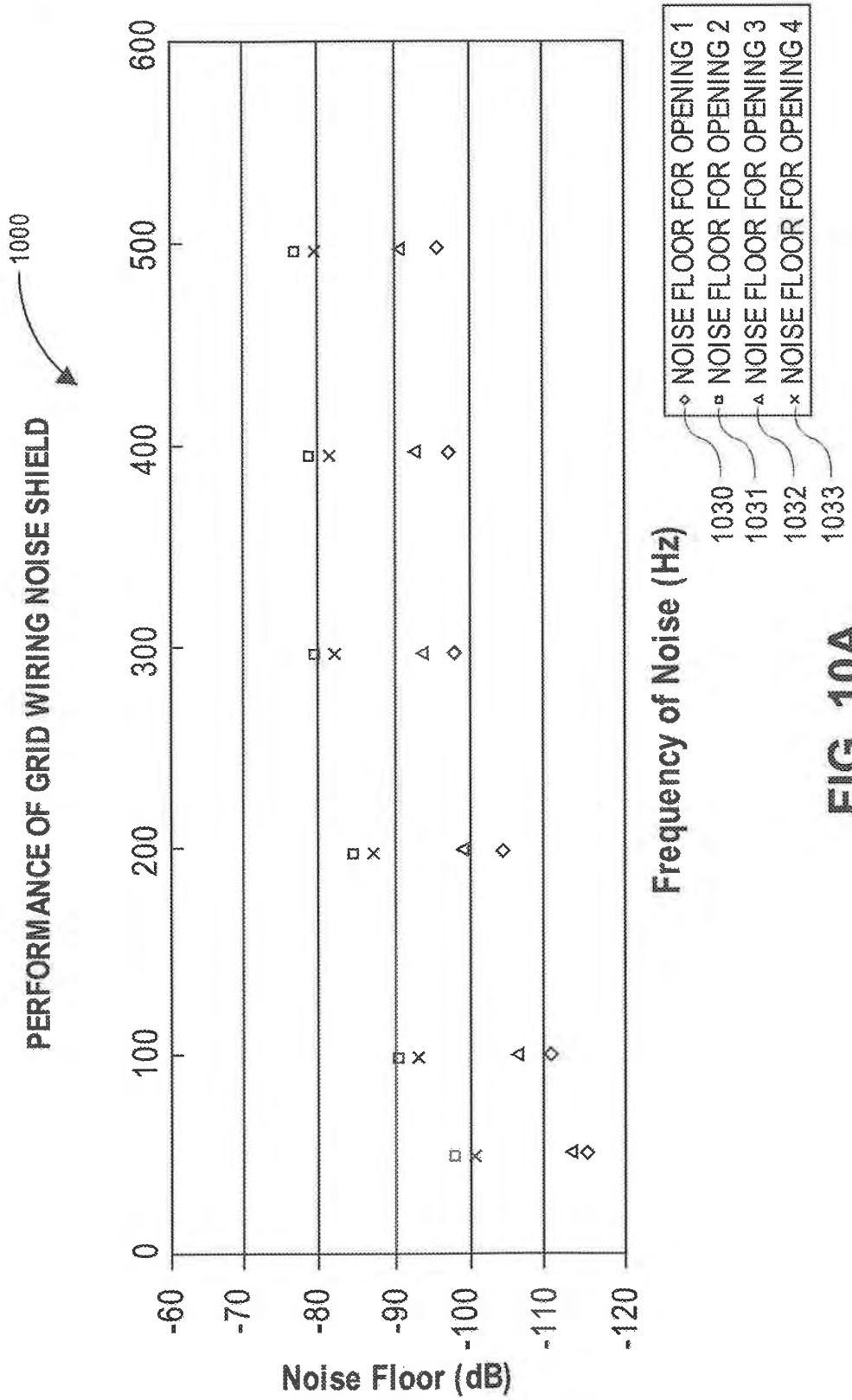


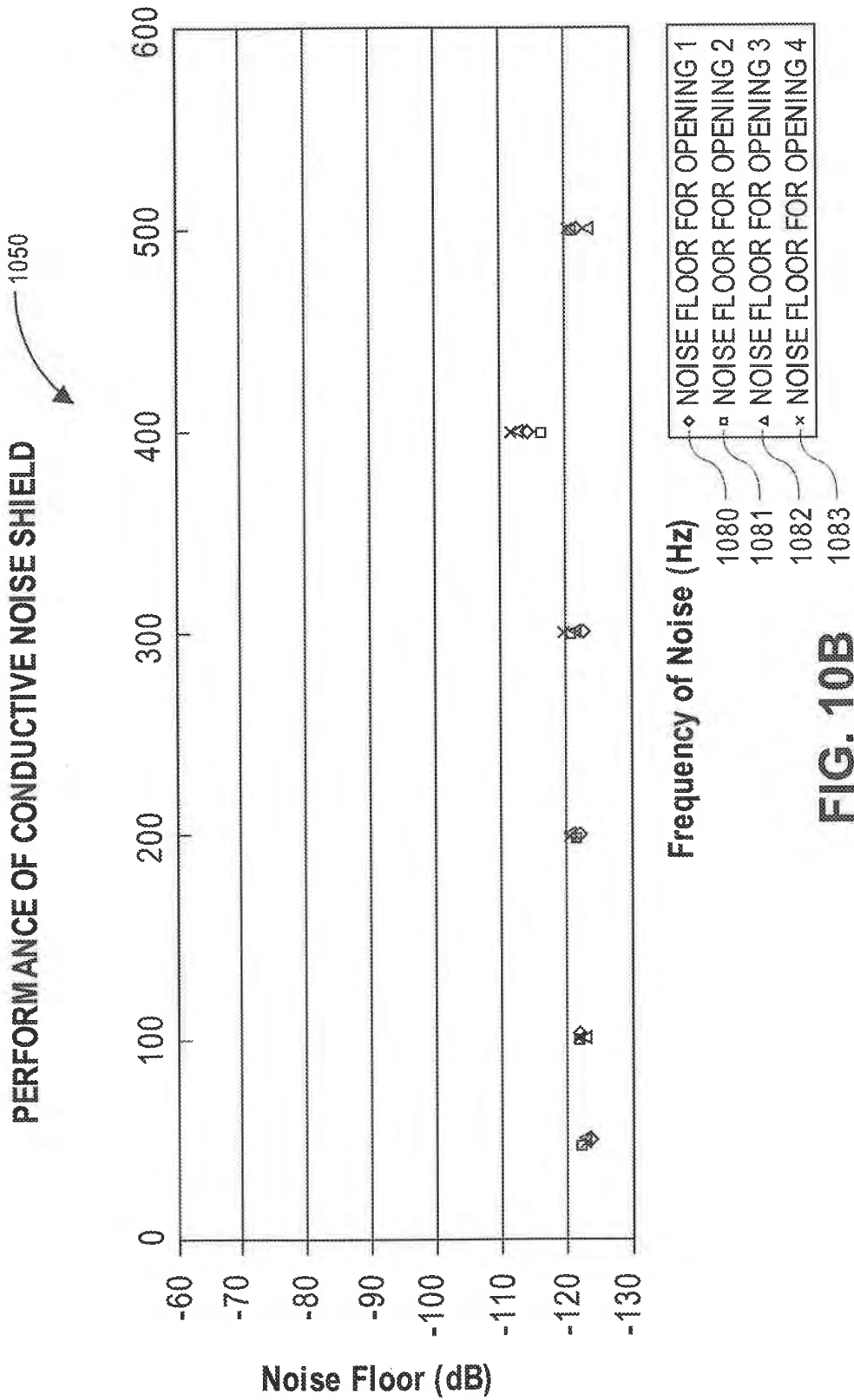
FIG. 10A

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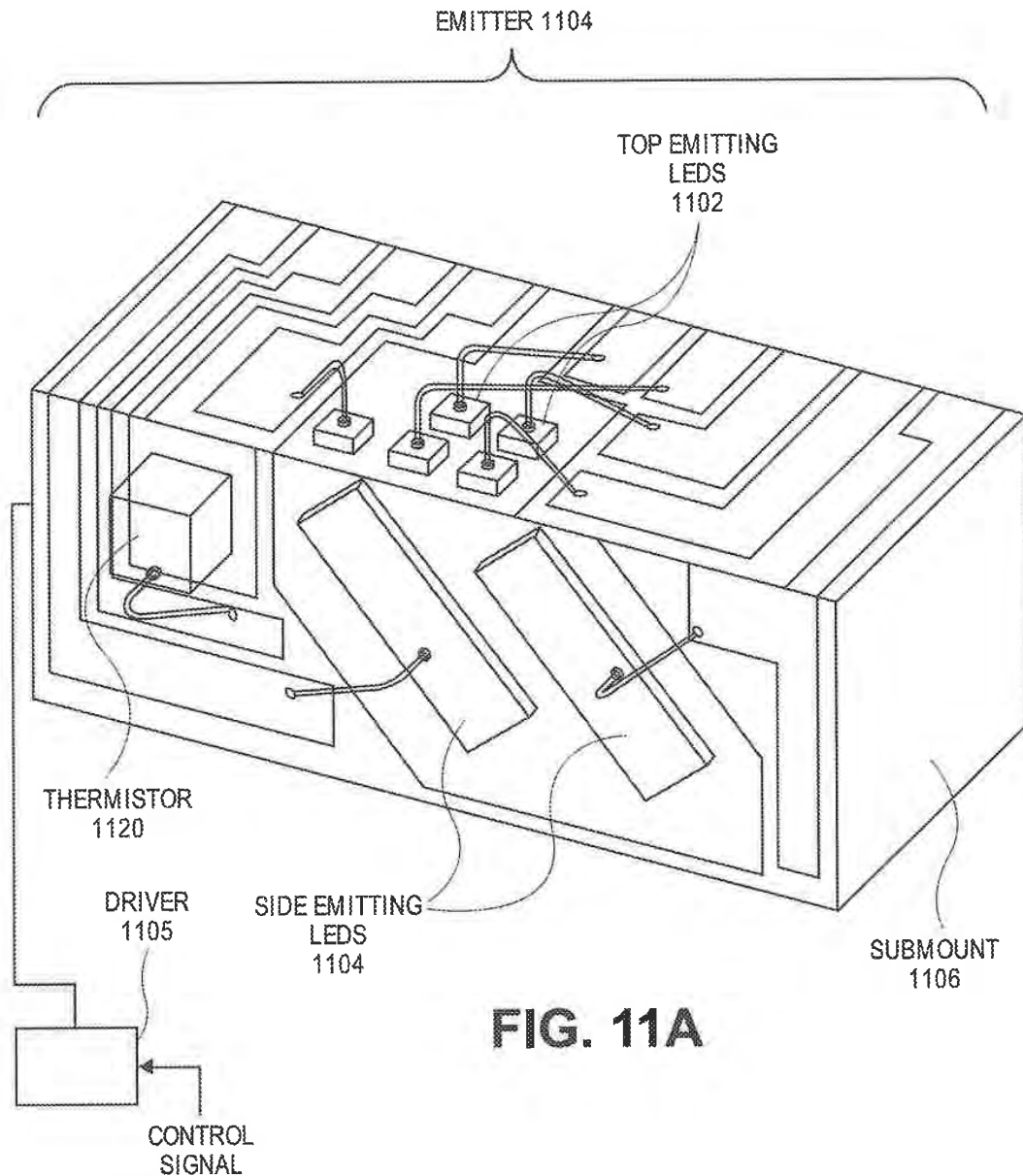


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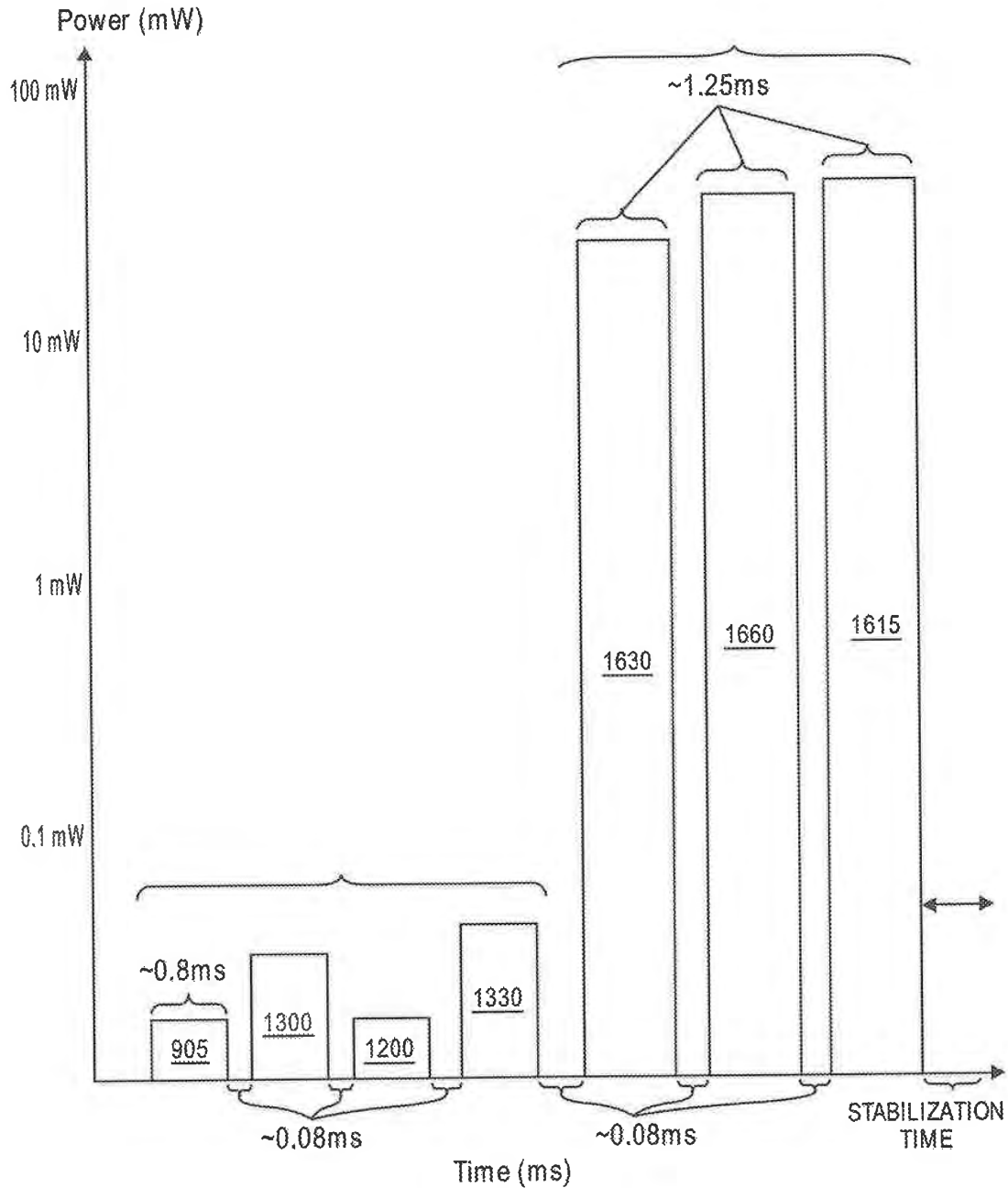


FIG. 11B

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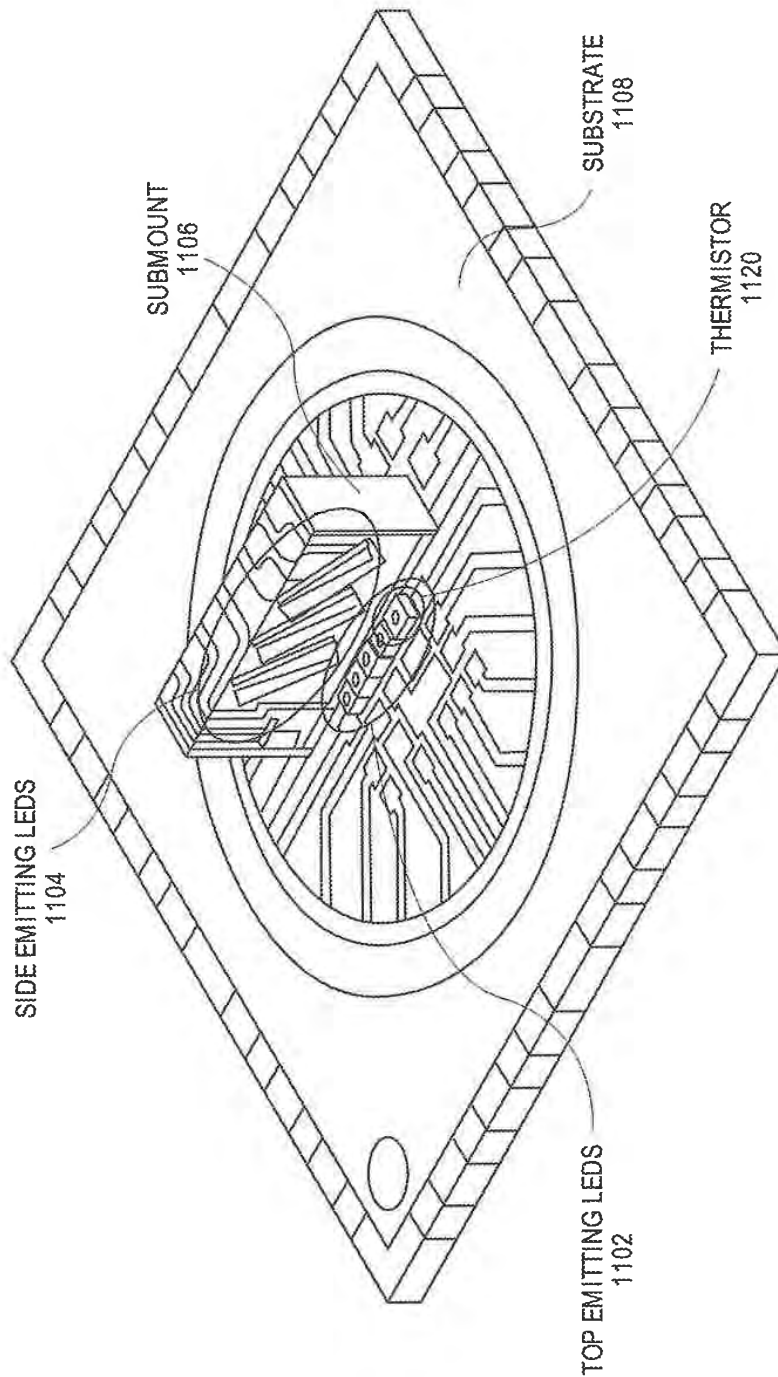


FIG. 11C

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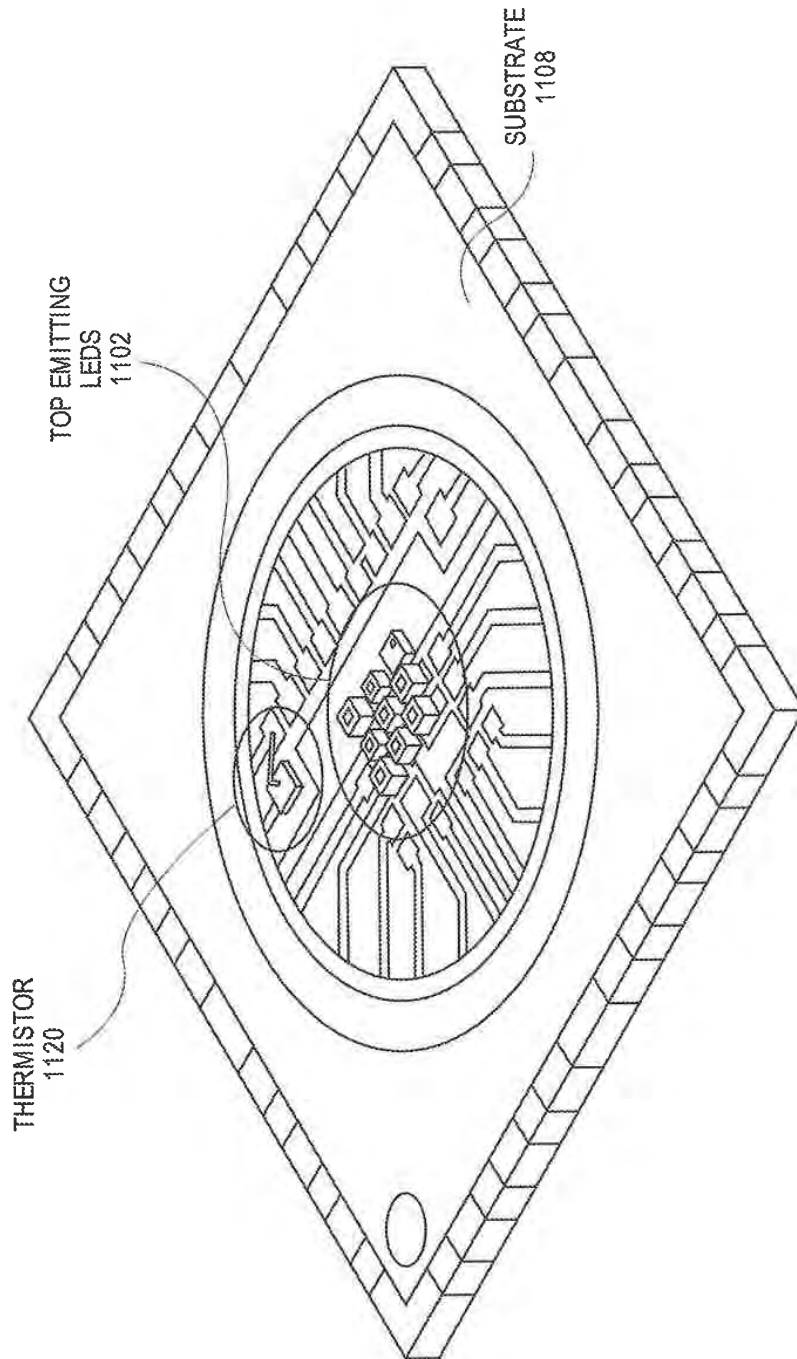


FIG. 11D

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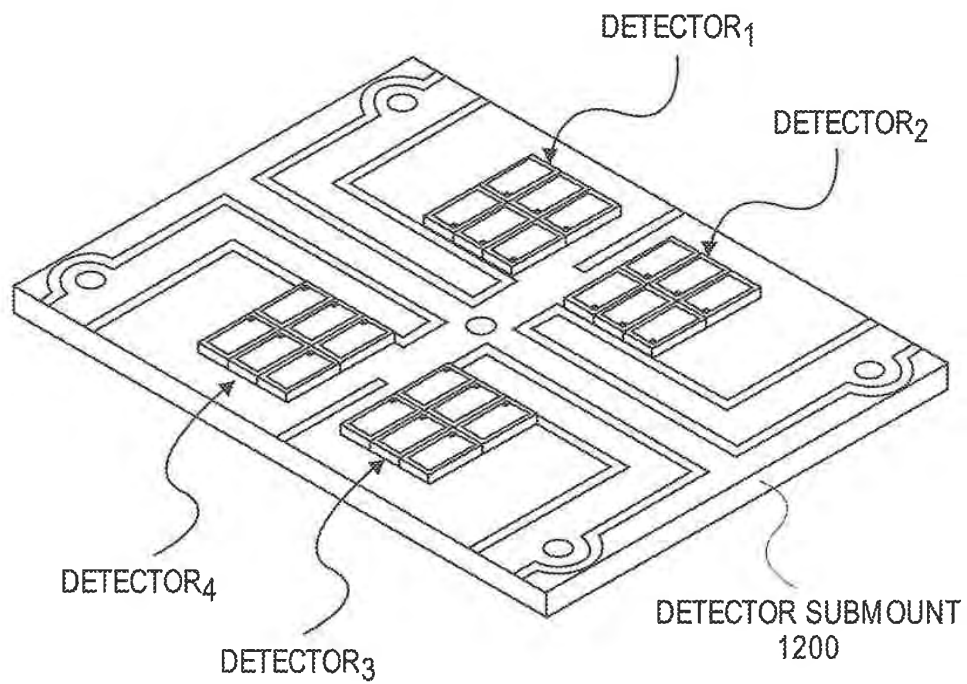


FIG. 12A

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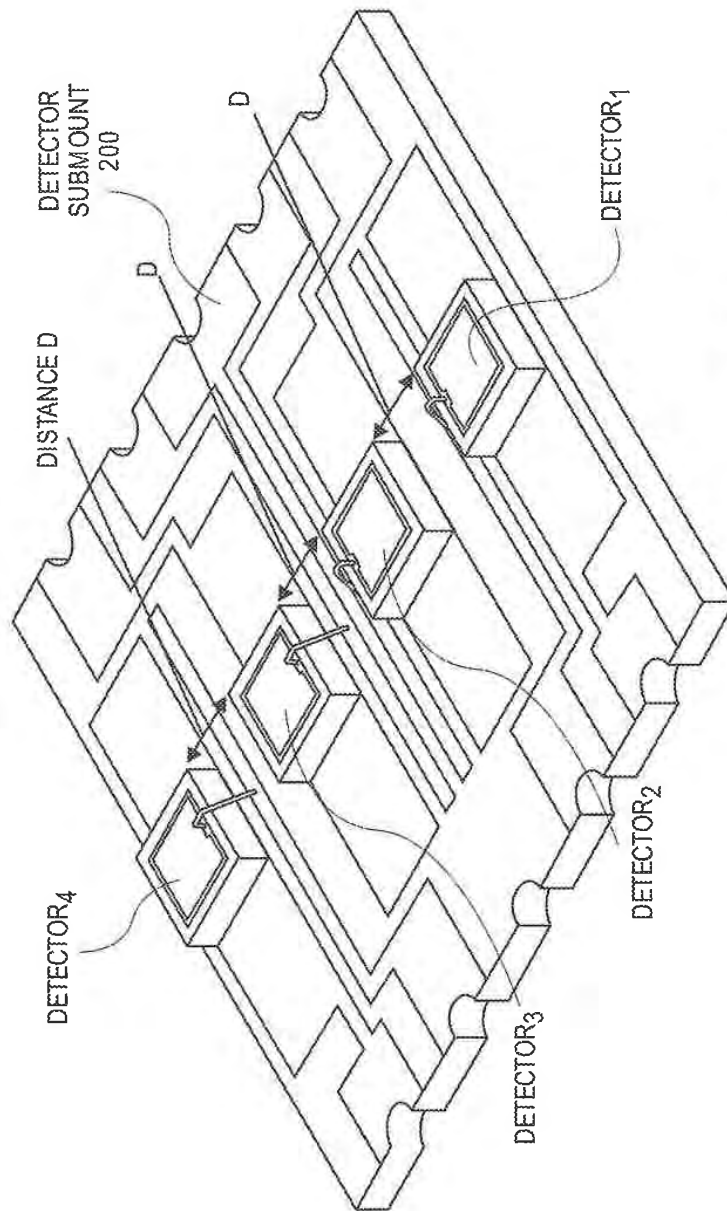


FIG. 12B

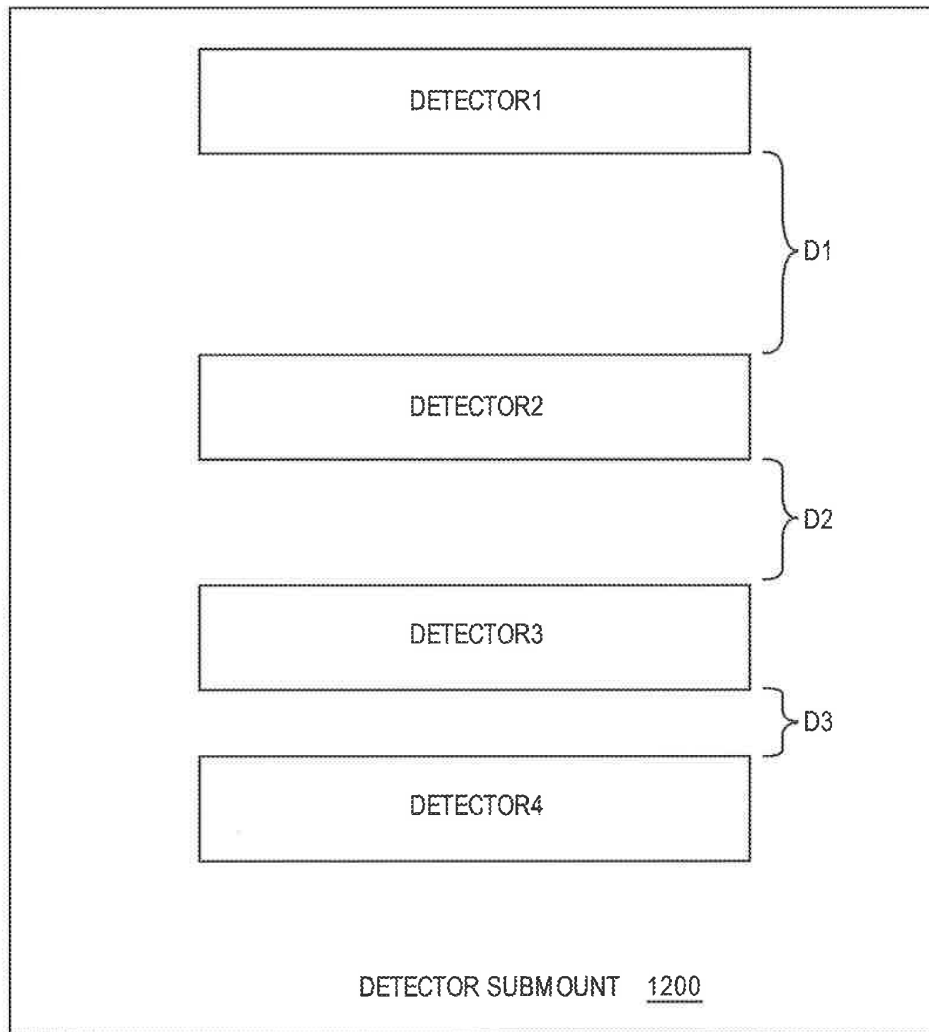


FIG. 12C

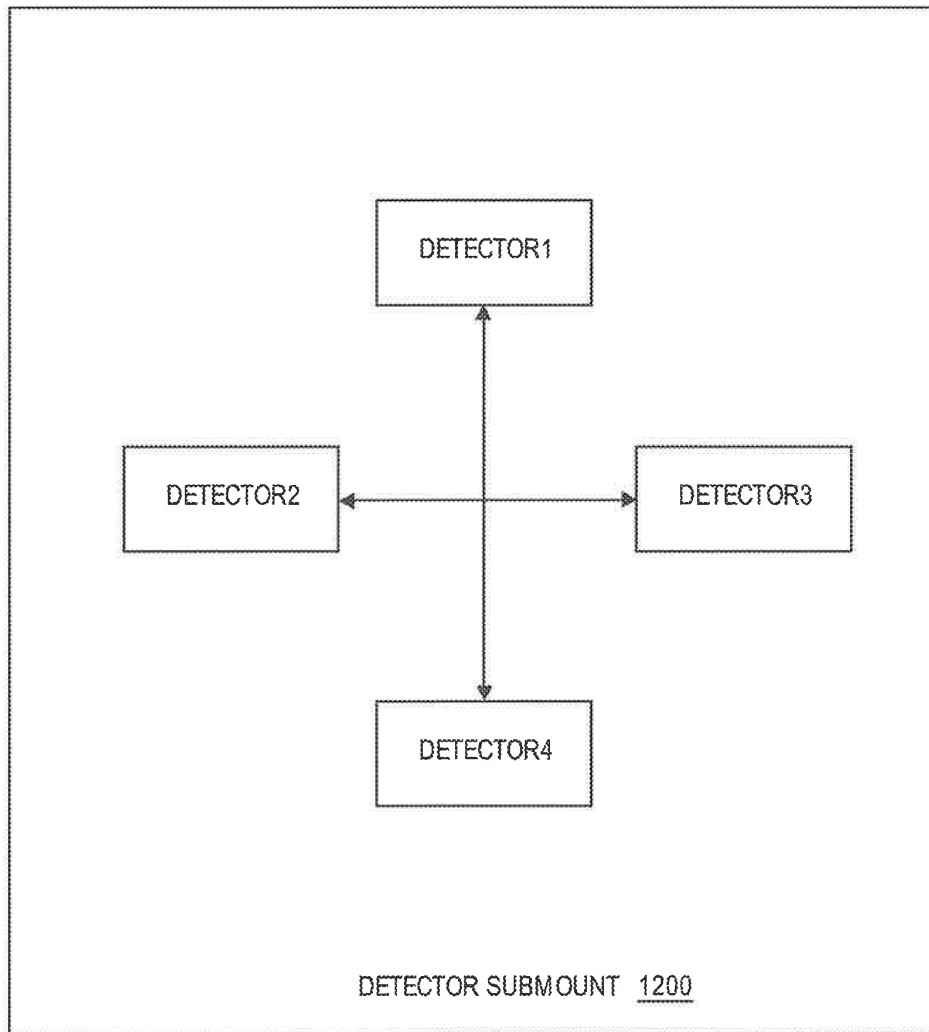


FIG. 12D

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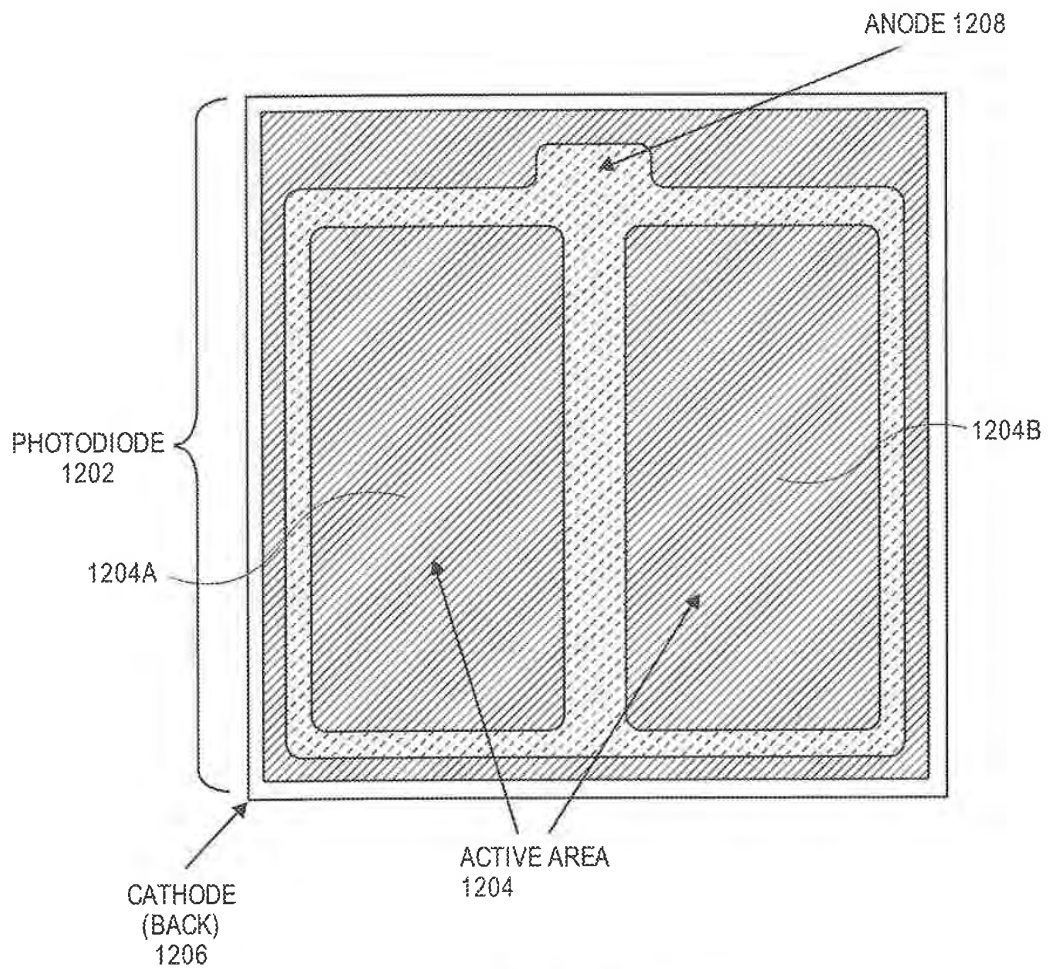


FIG. 12E

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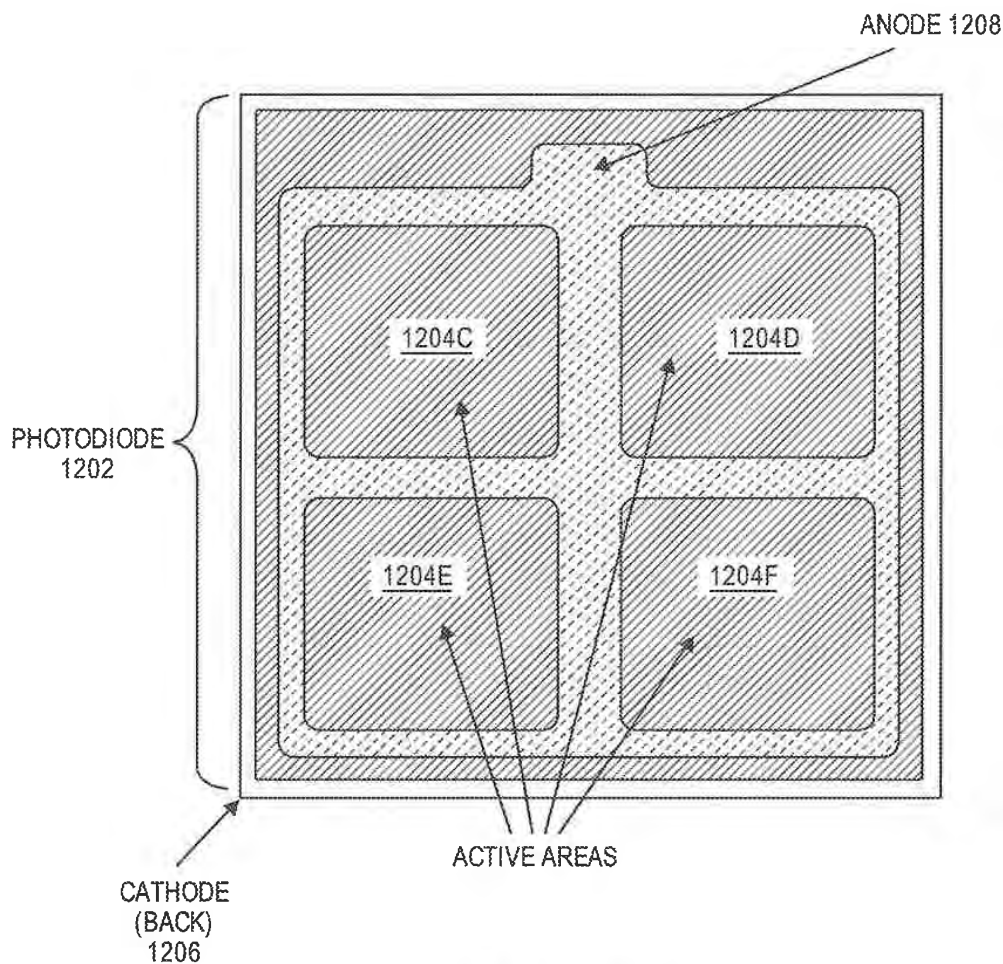


FIG. 12F

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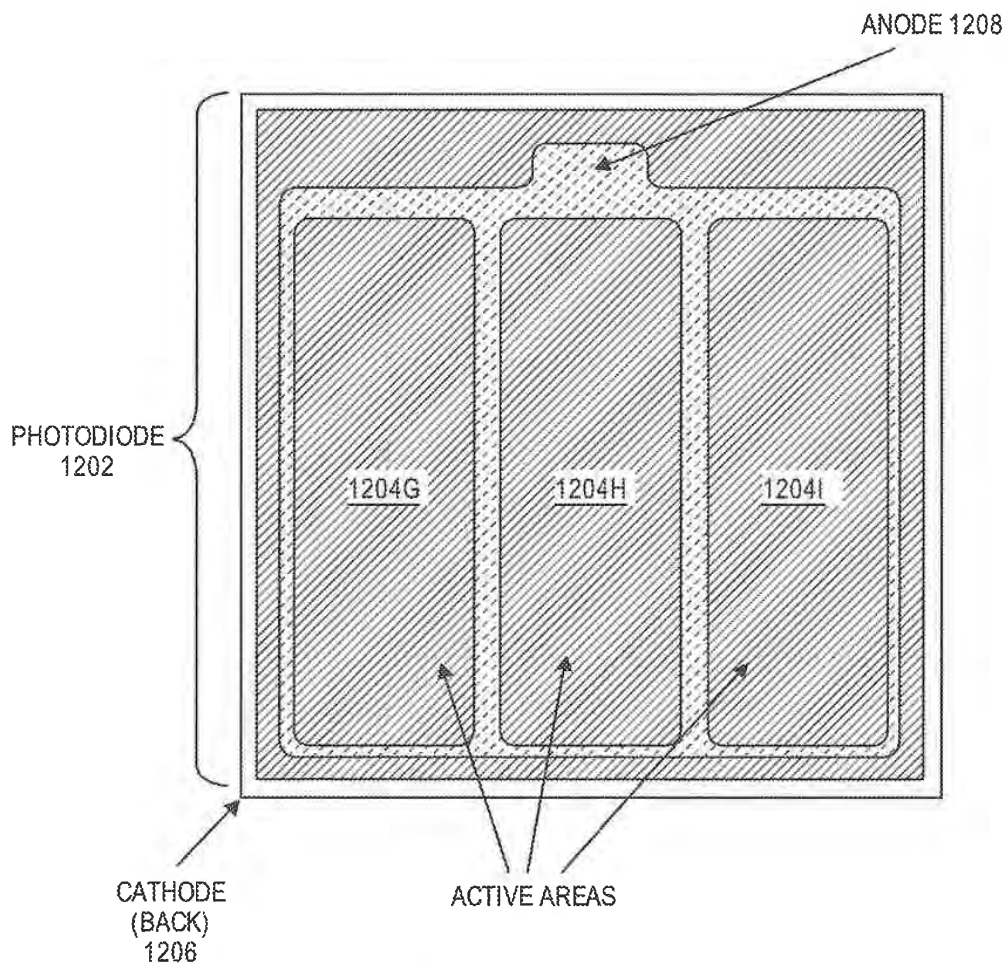


FIG. 12G

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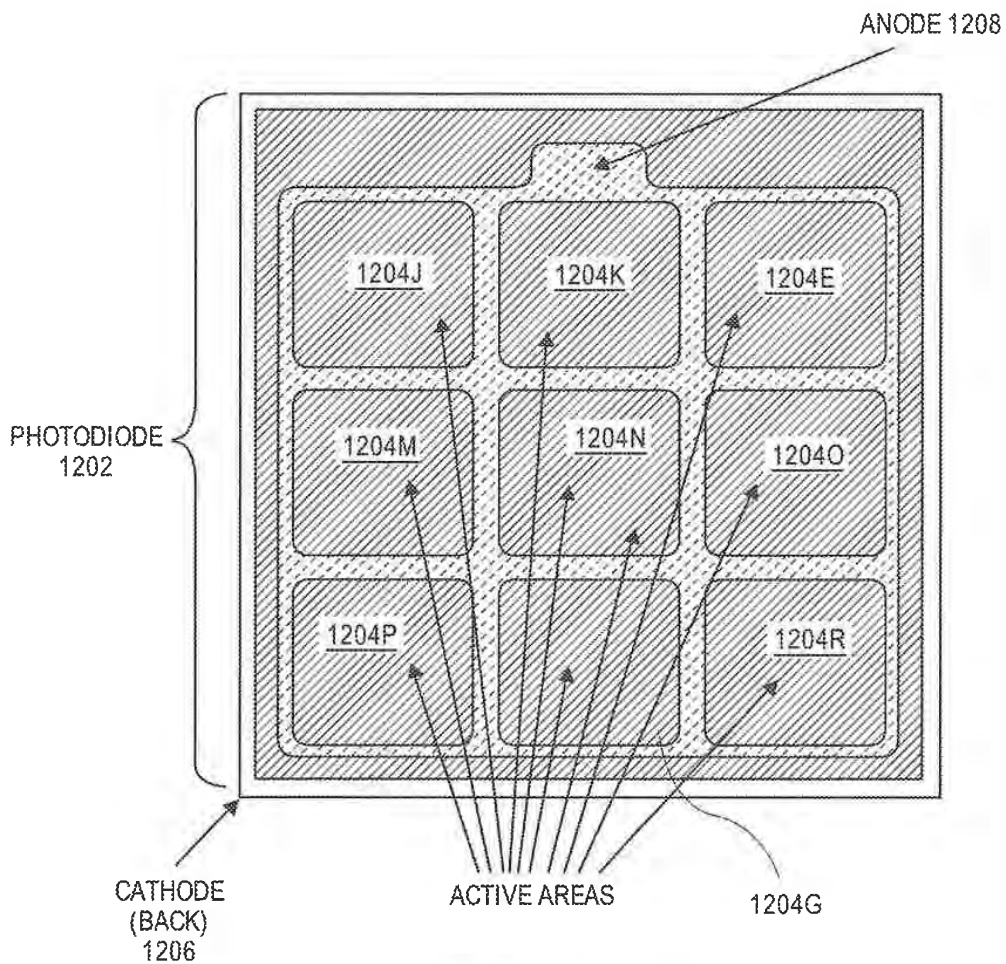


FIG. 12H

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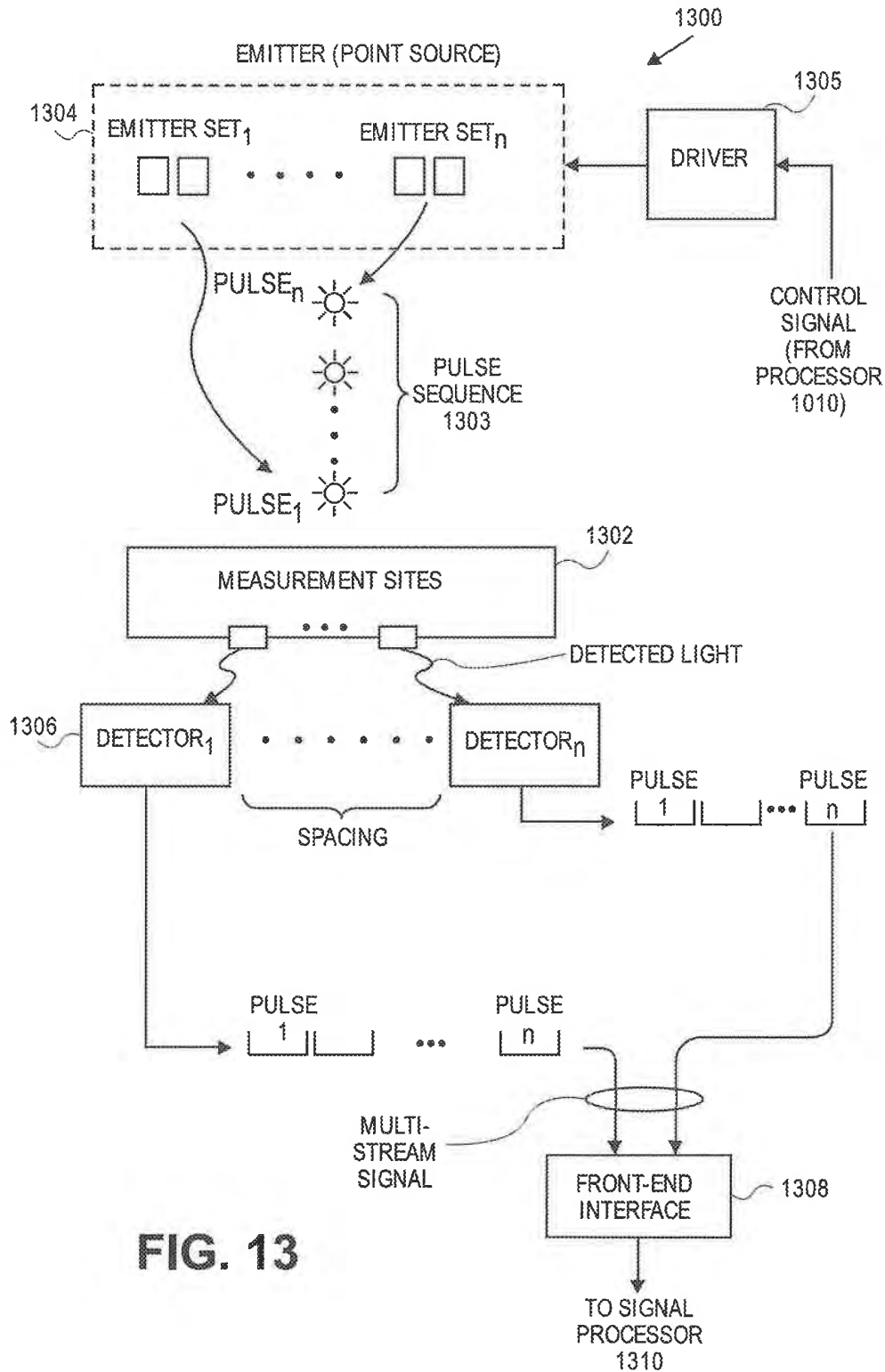


FIG. 13

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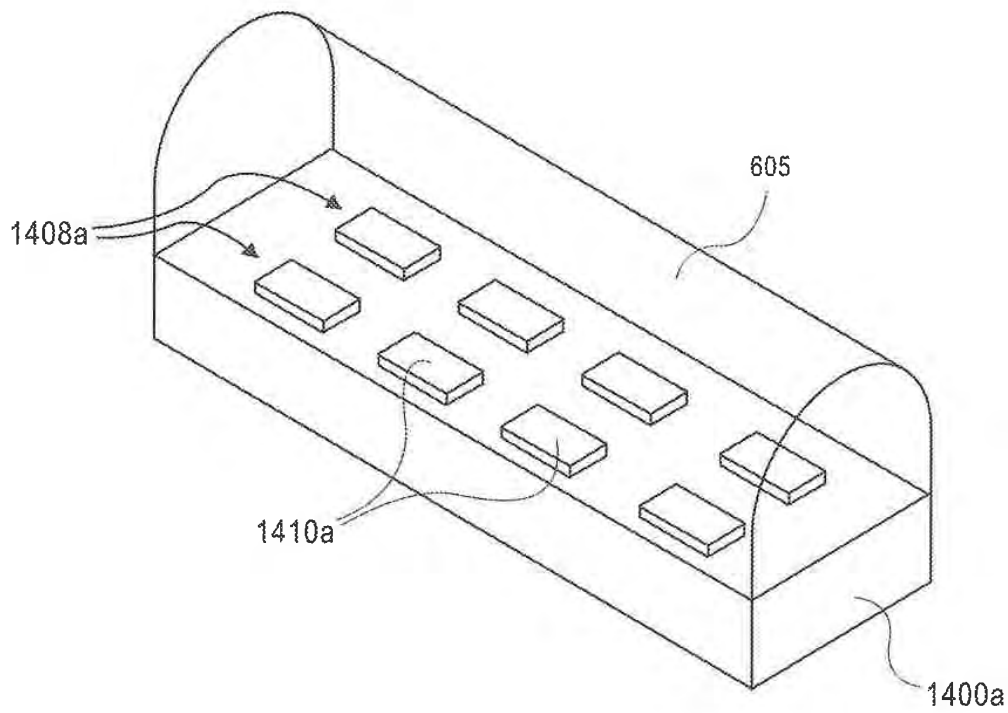


FIG. 14A

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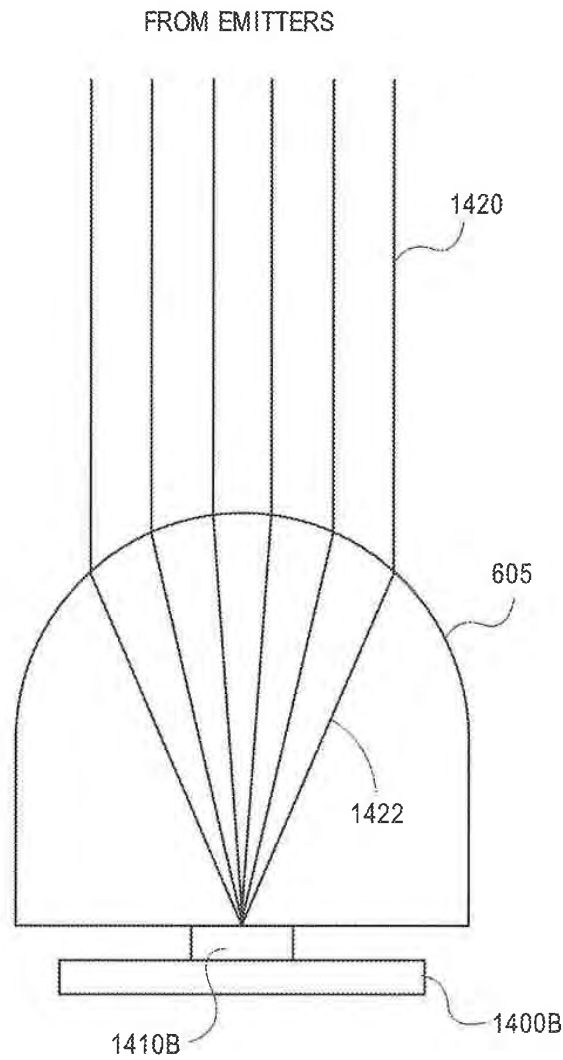


FIG. 14B

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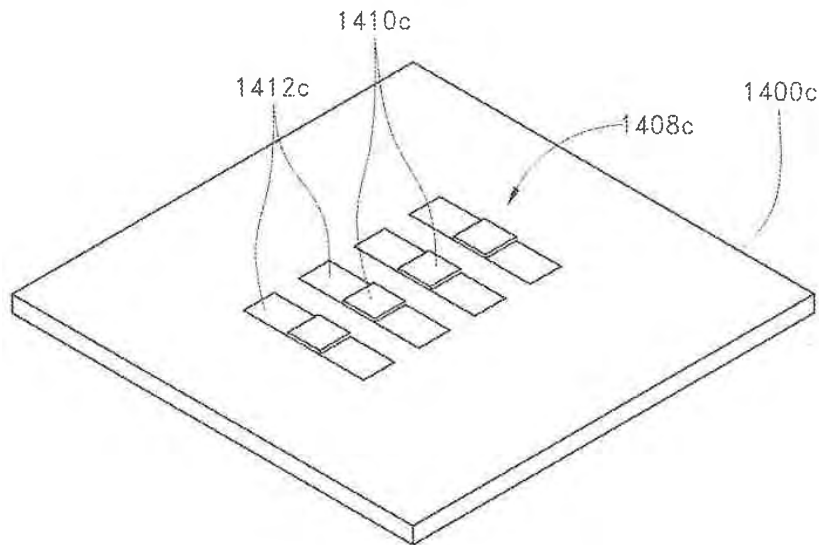


FIG. 14C

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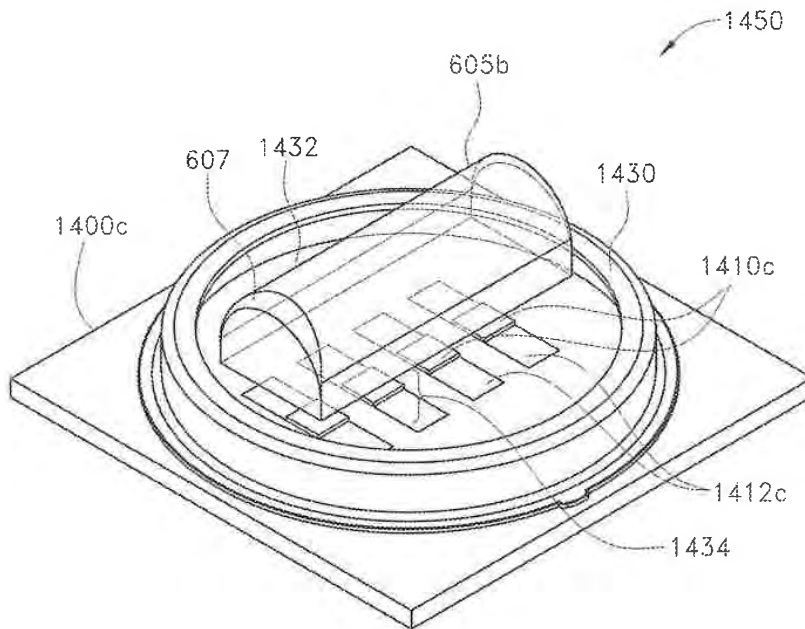


FIG. 14D

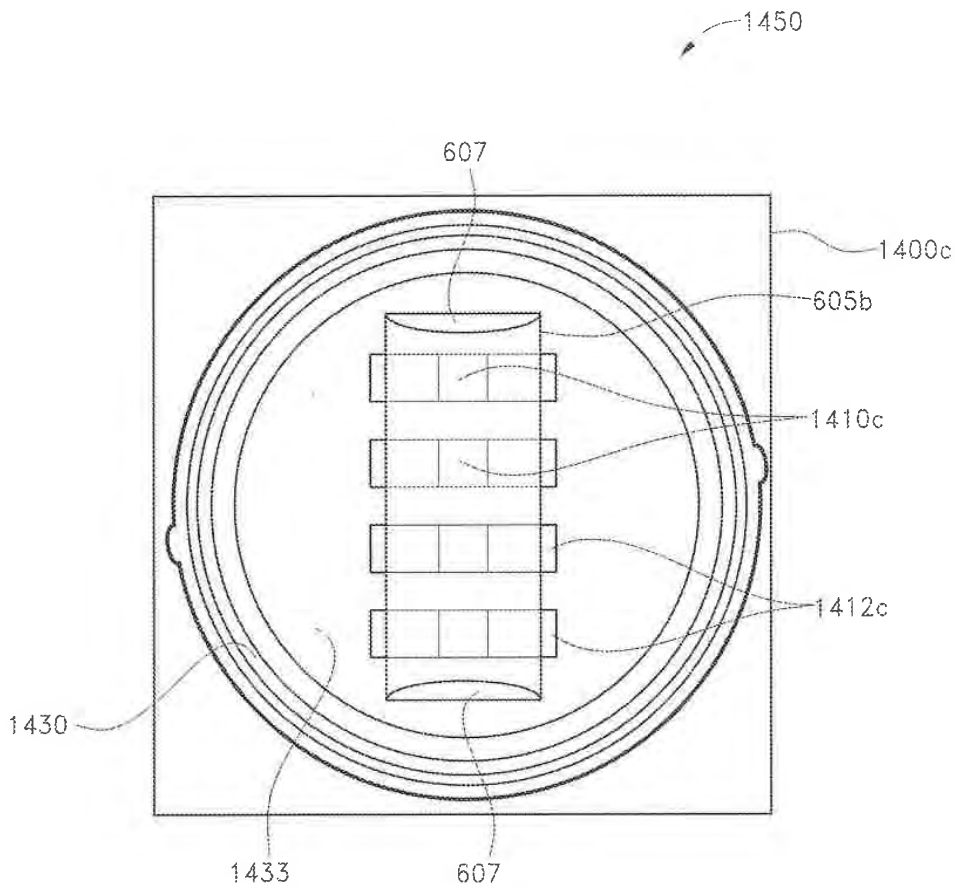


FIG. 14E

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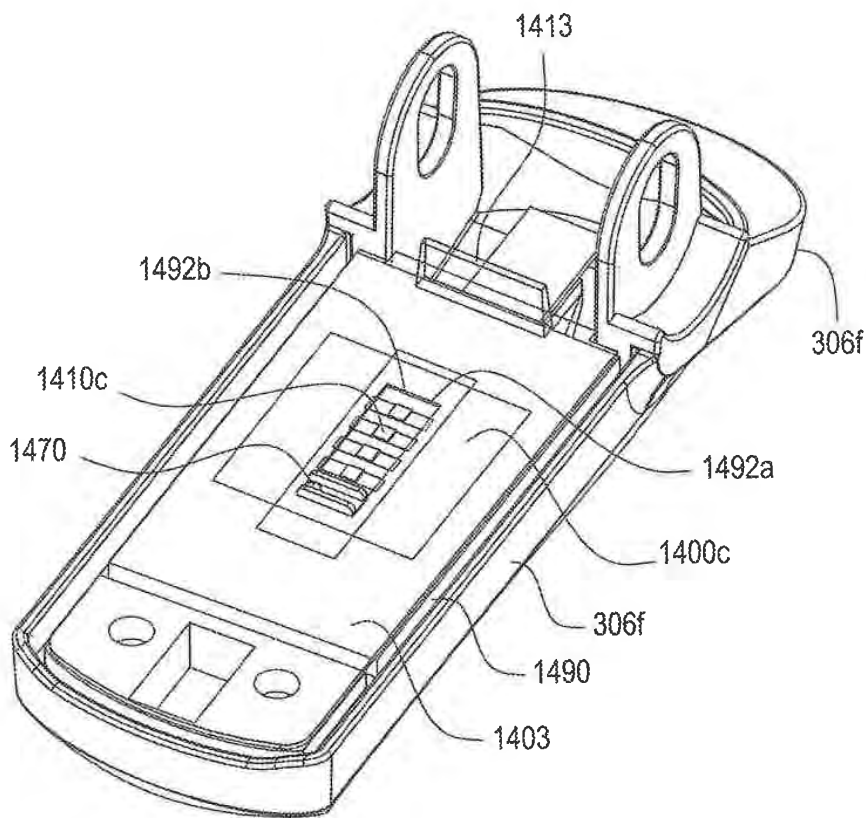


FIG. 14F

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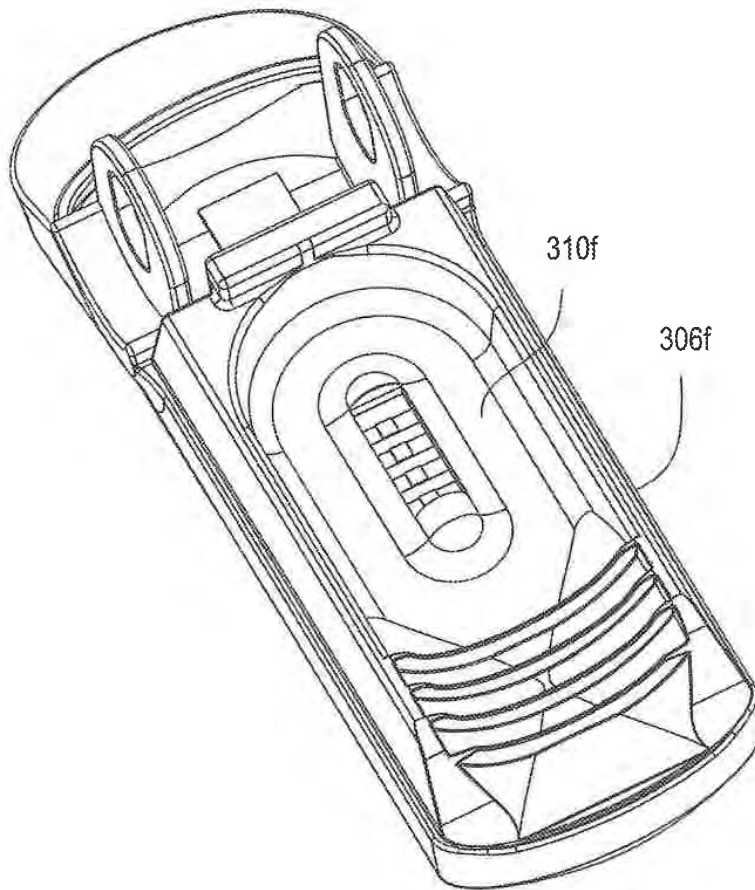


FIG. 14G

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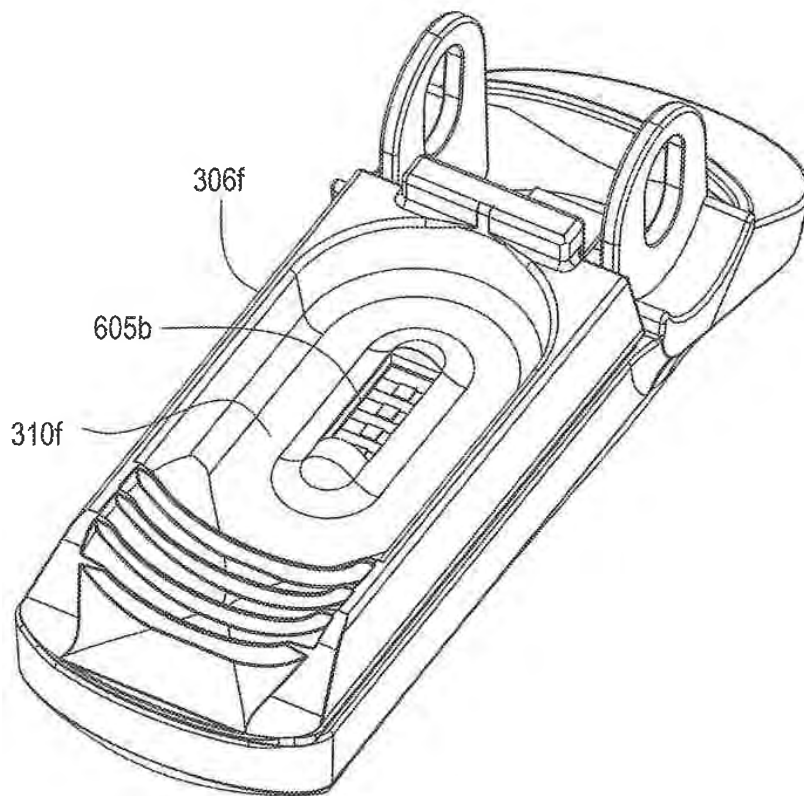


FIG. 14H

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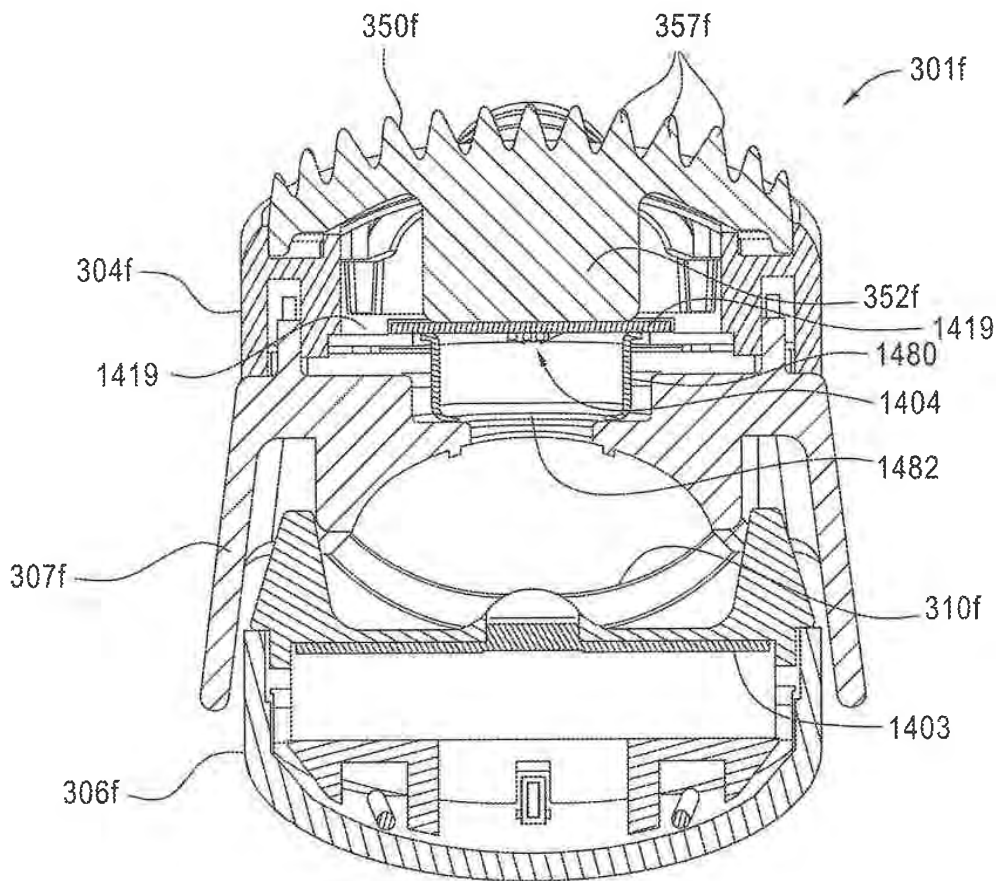


FIG. 14

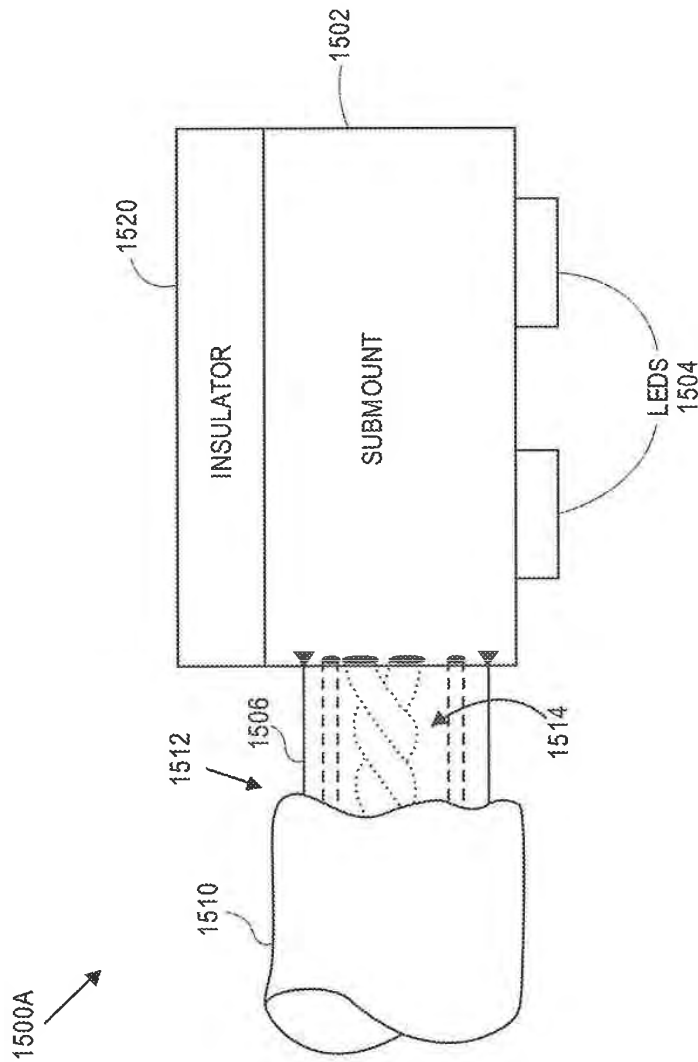


FIG. 15A

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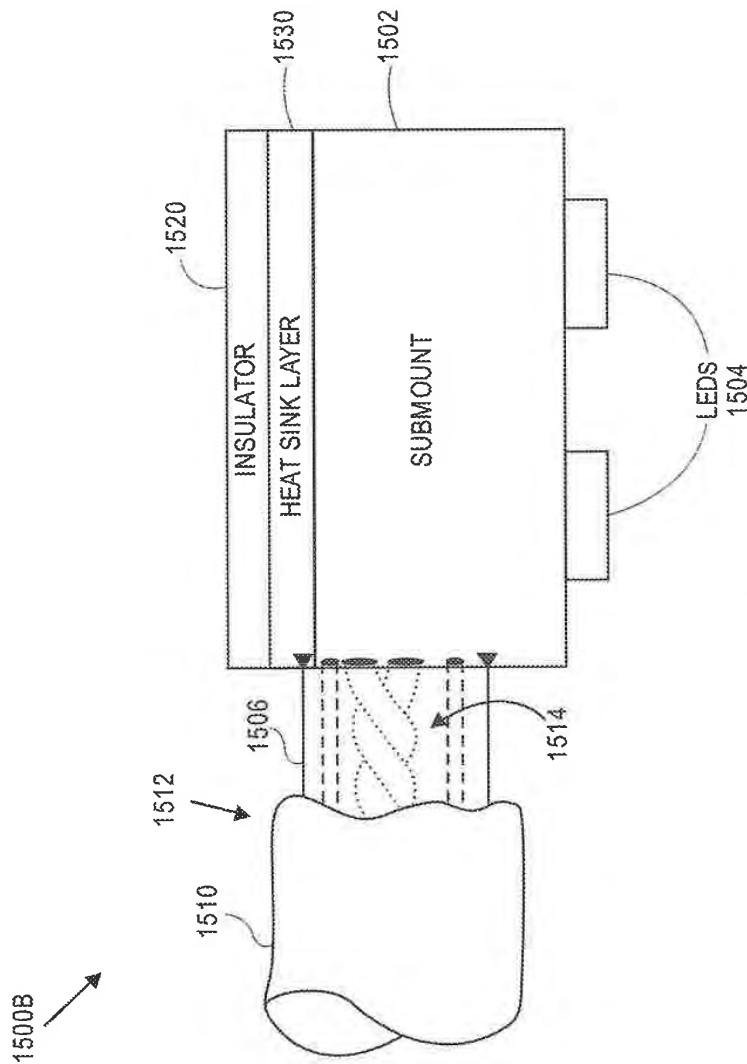


FIG. 15B

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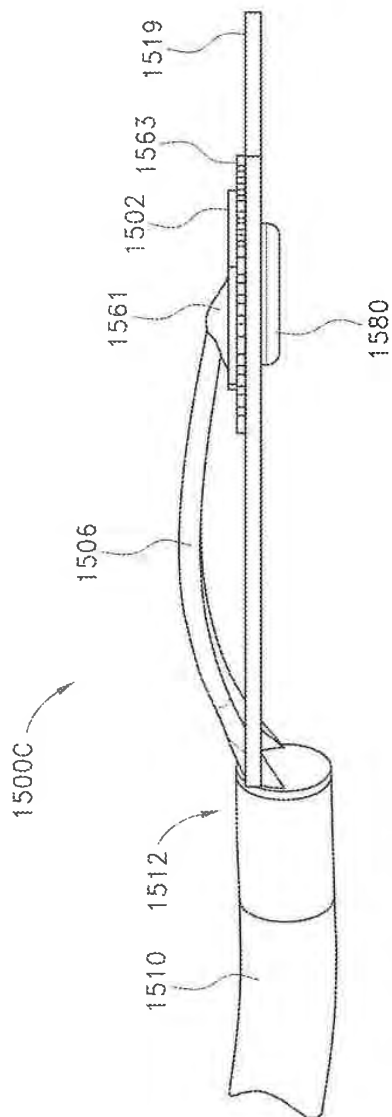


FIG. 1500C

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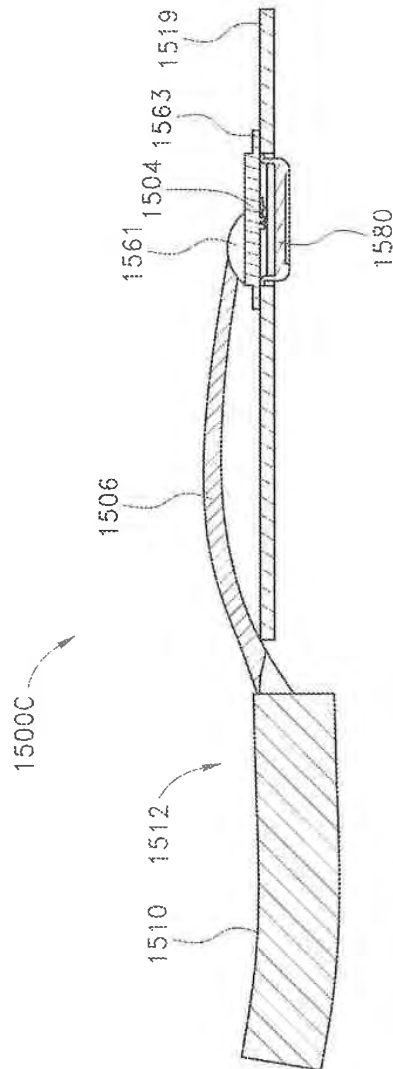


FIG. 15D

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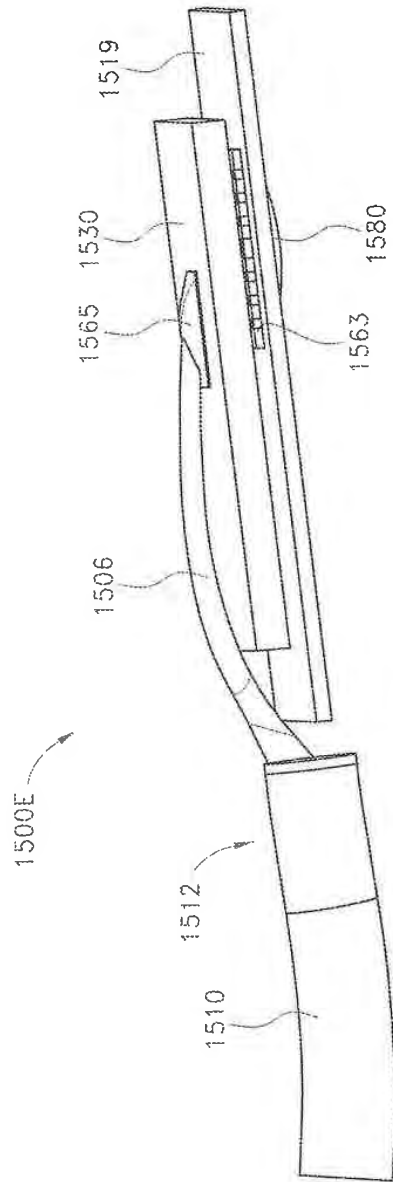


FIG. 15E

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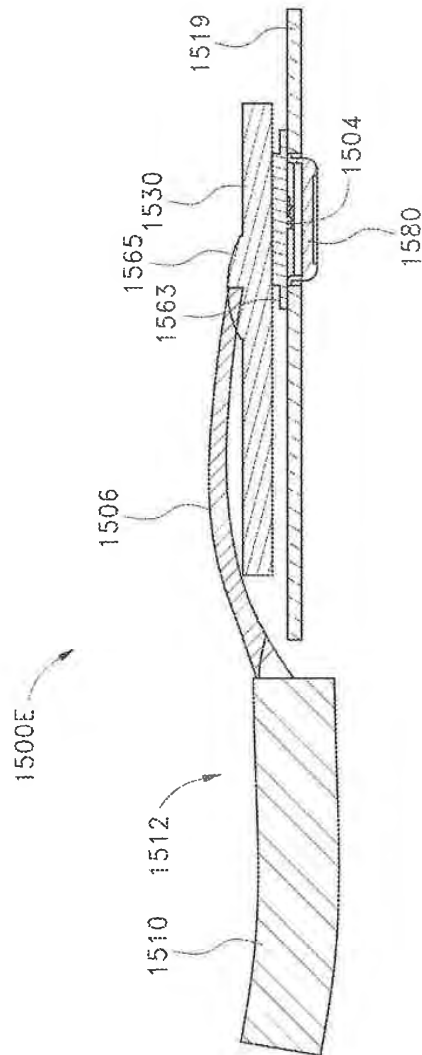


FIG. 1500E

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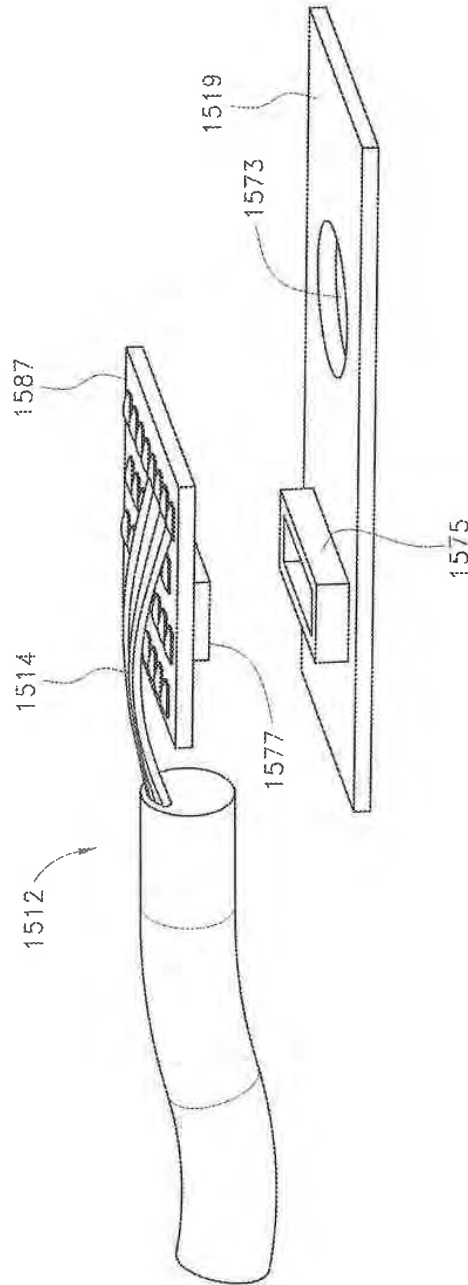


FIG. 15G

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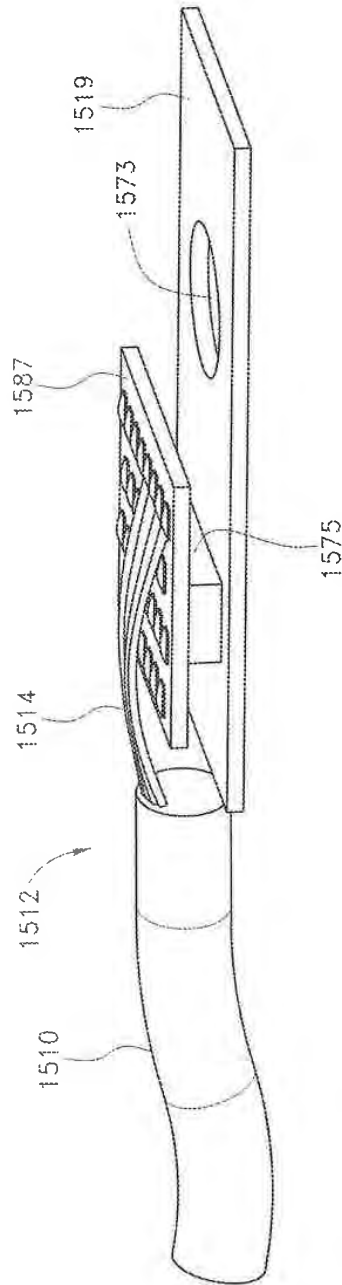


FIG. 15H

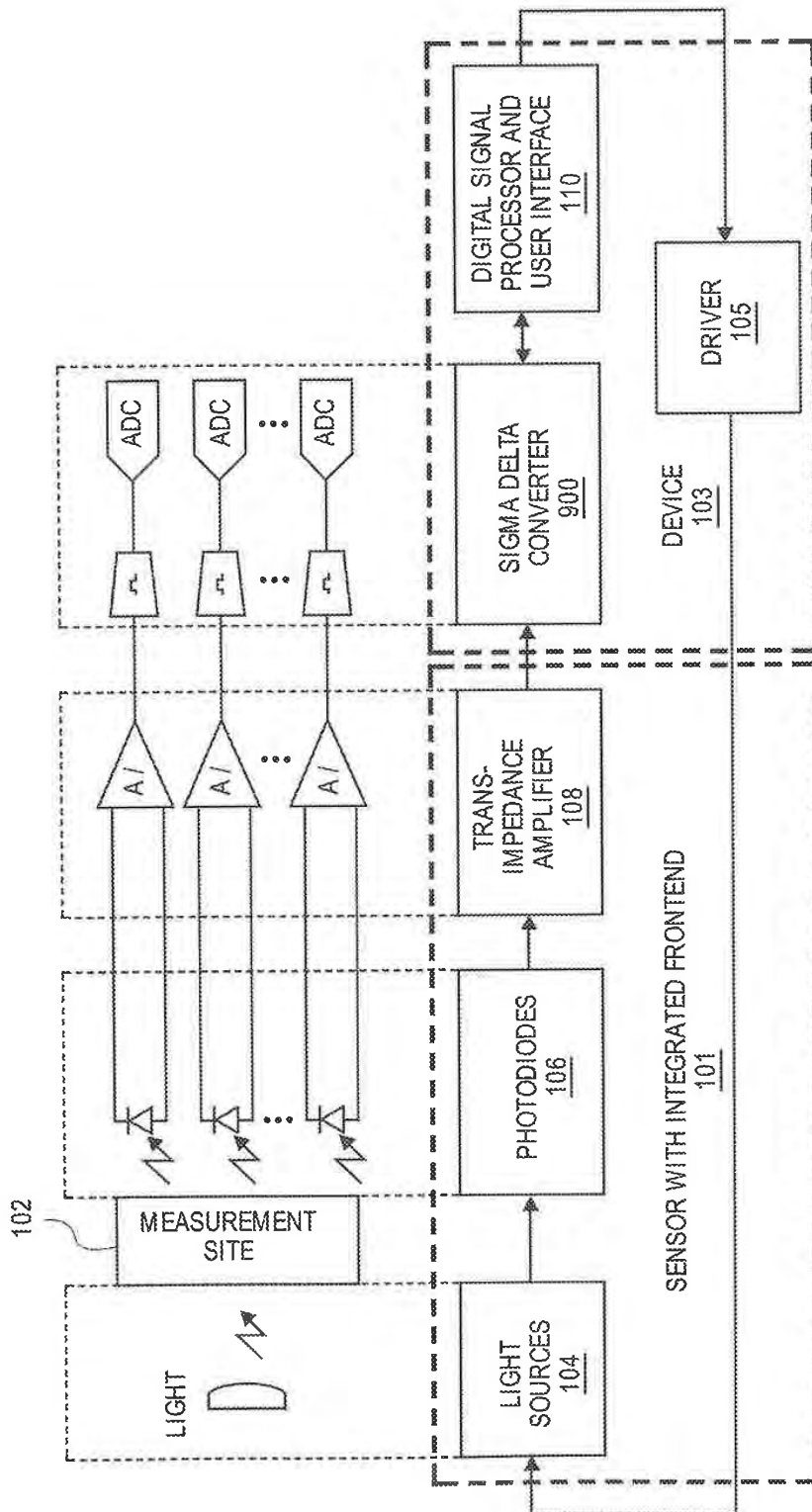


FIG. 151

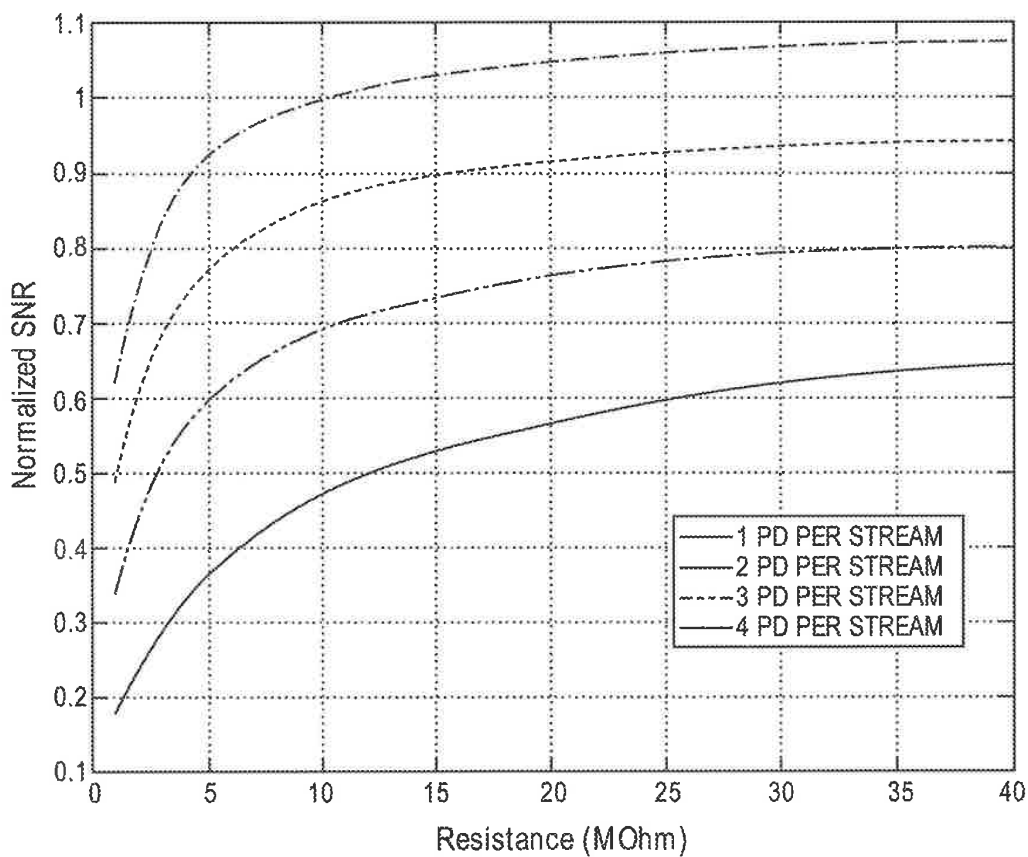


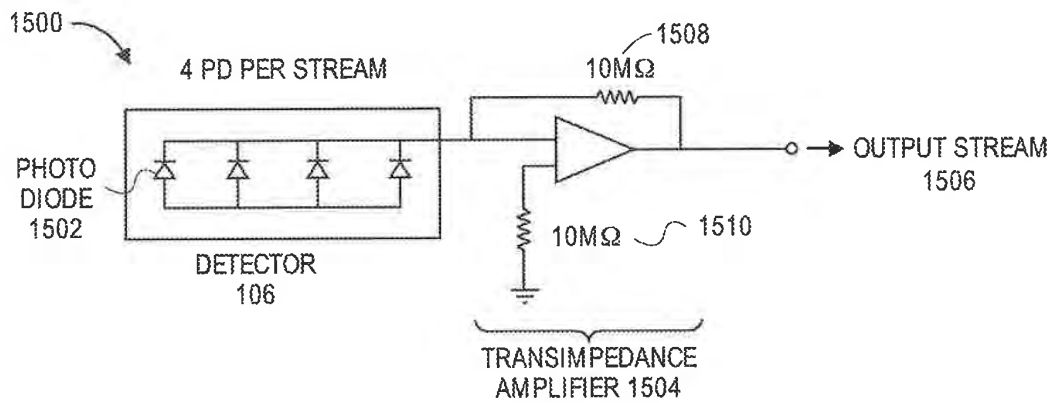
FIG. 15J

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VS.

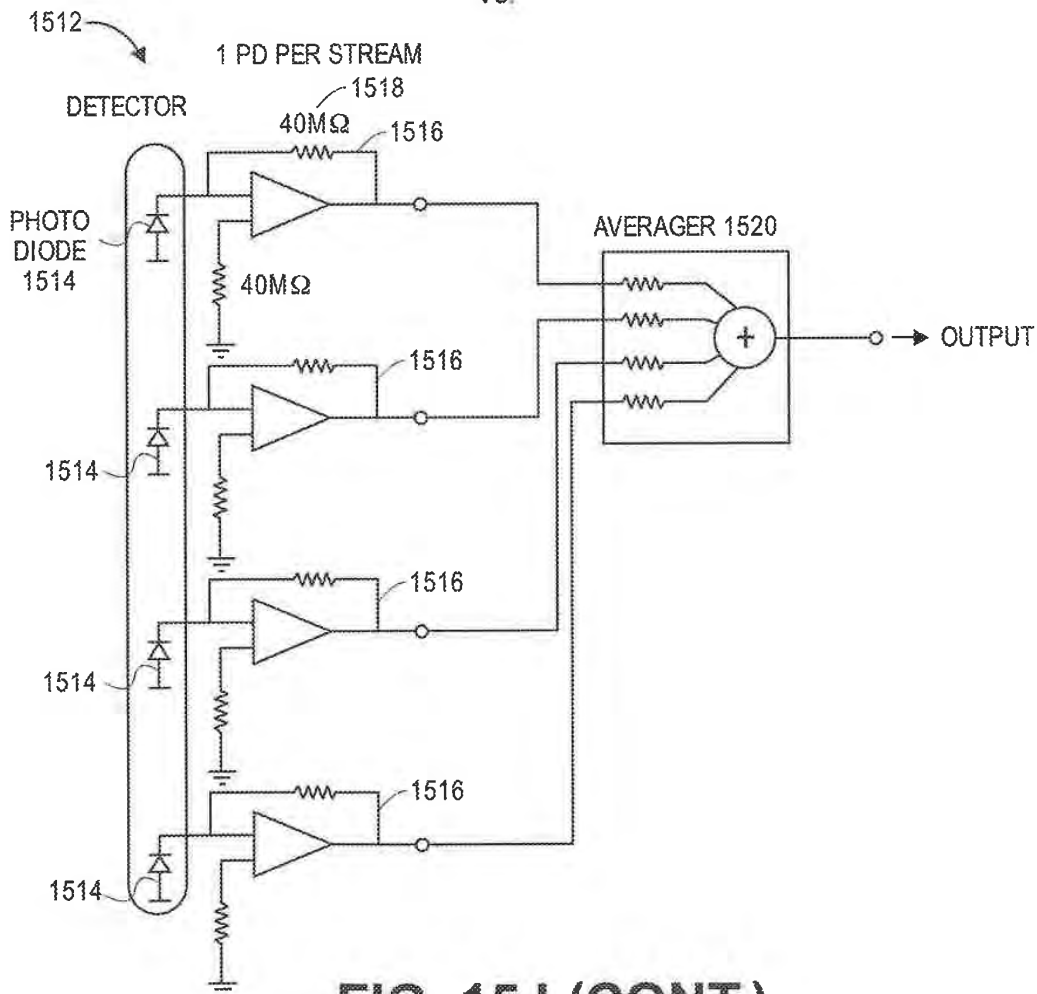


FIG. 15J (CONT.)

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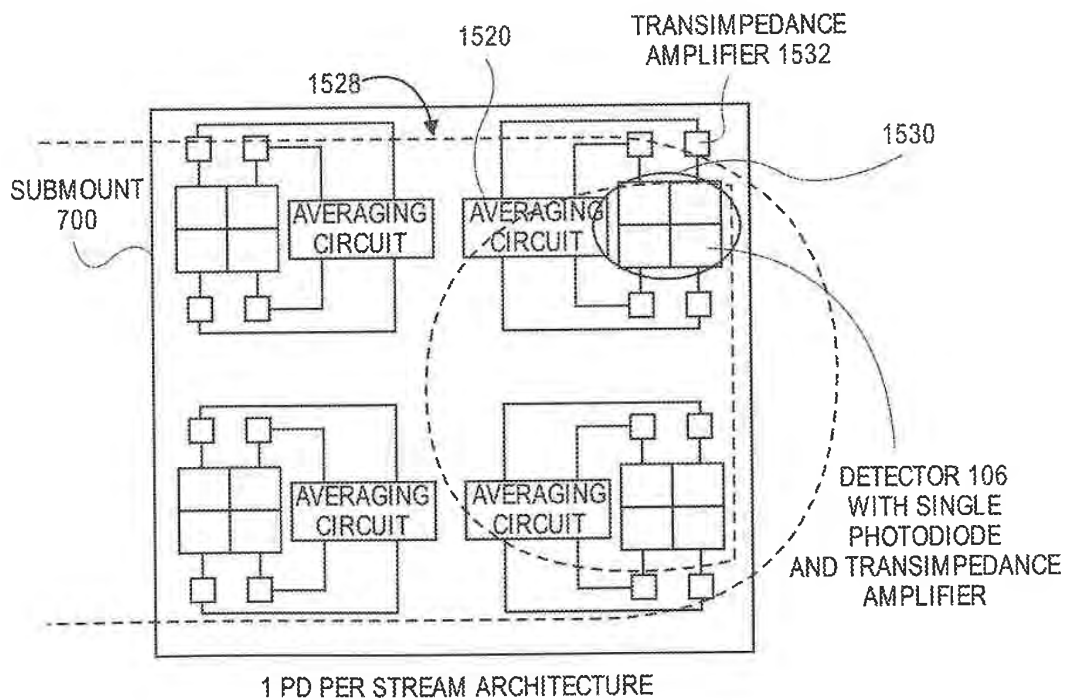
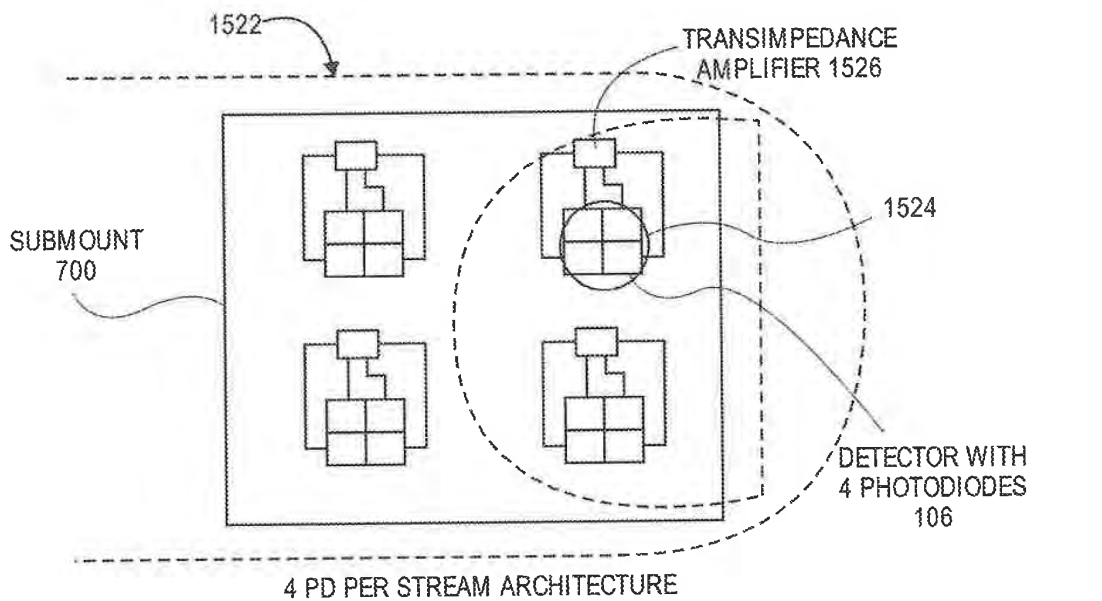


FIG. 15K

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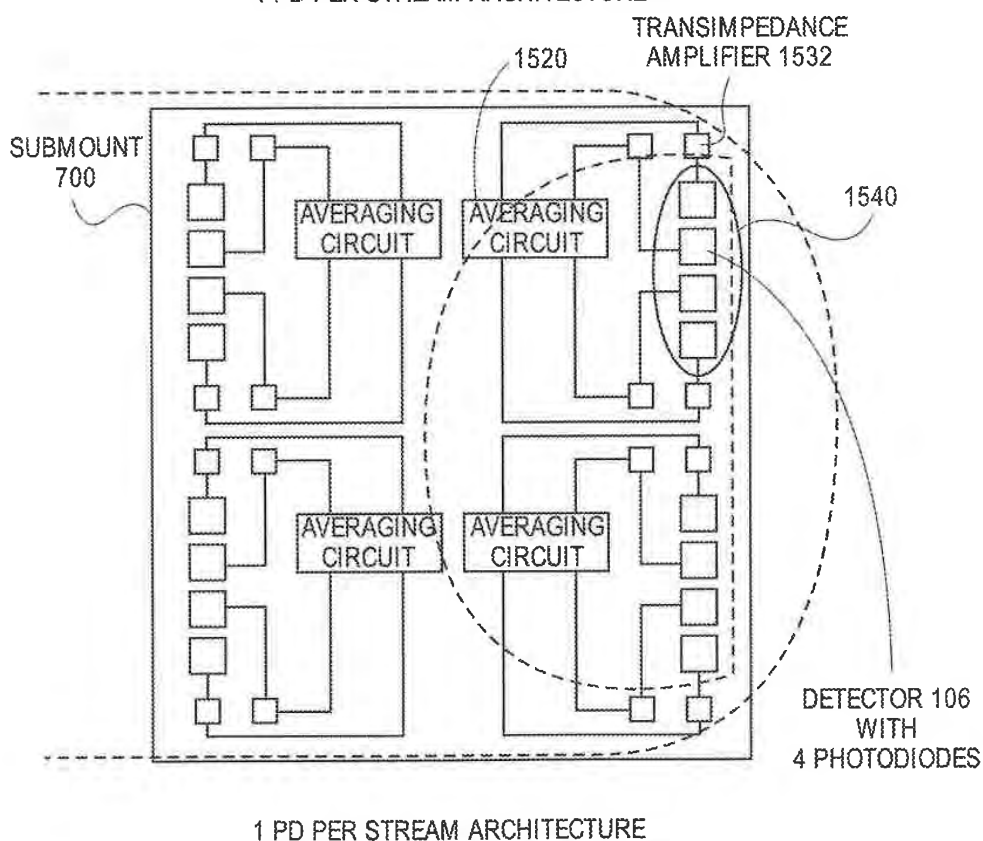
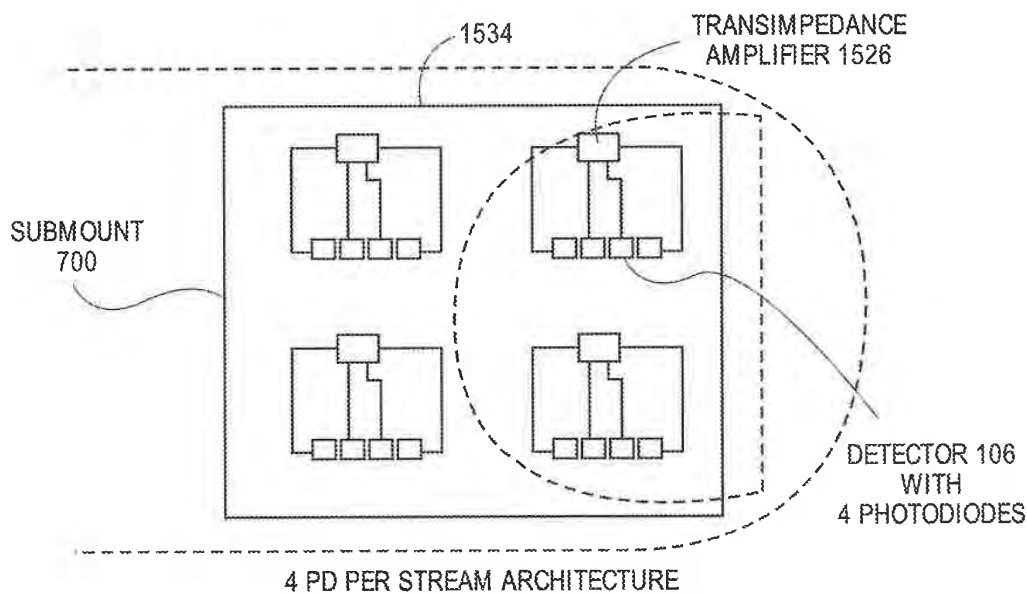


FIG. 15K (CONT.)

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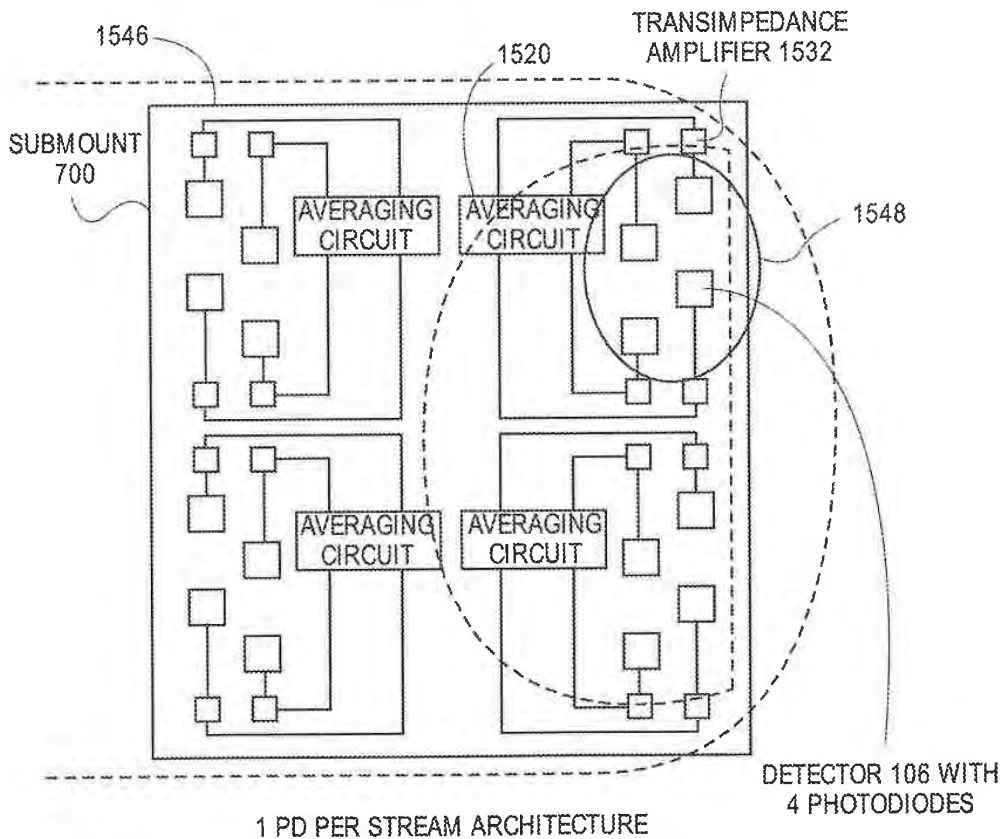
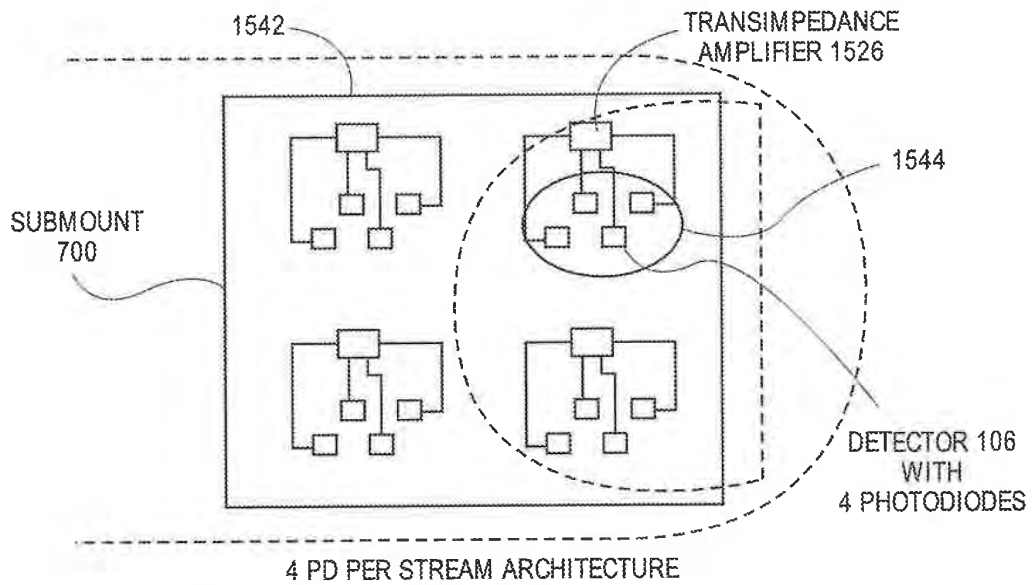


FIG. 15K (CONT.)

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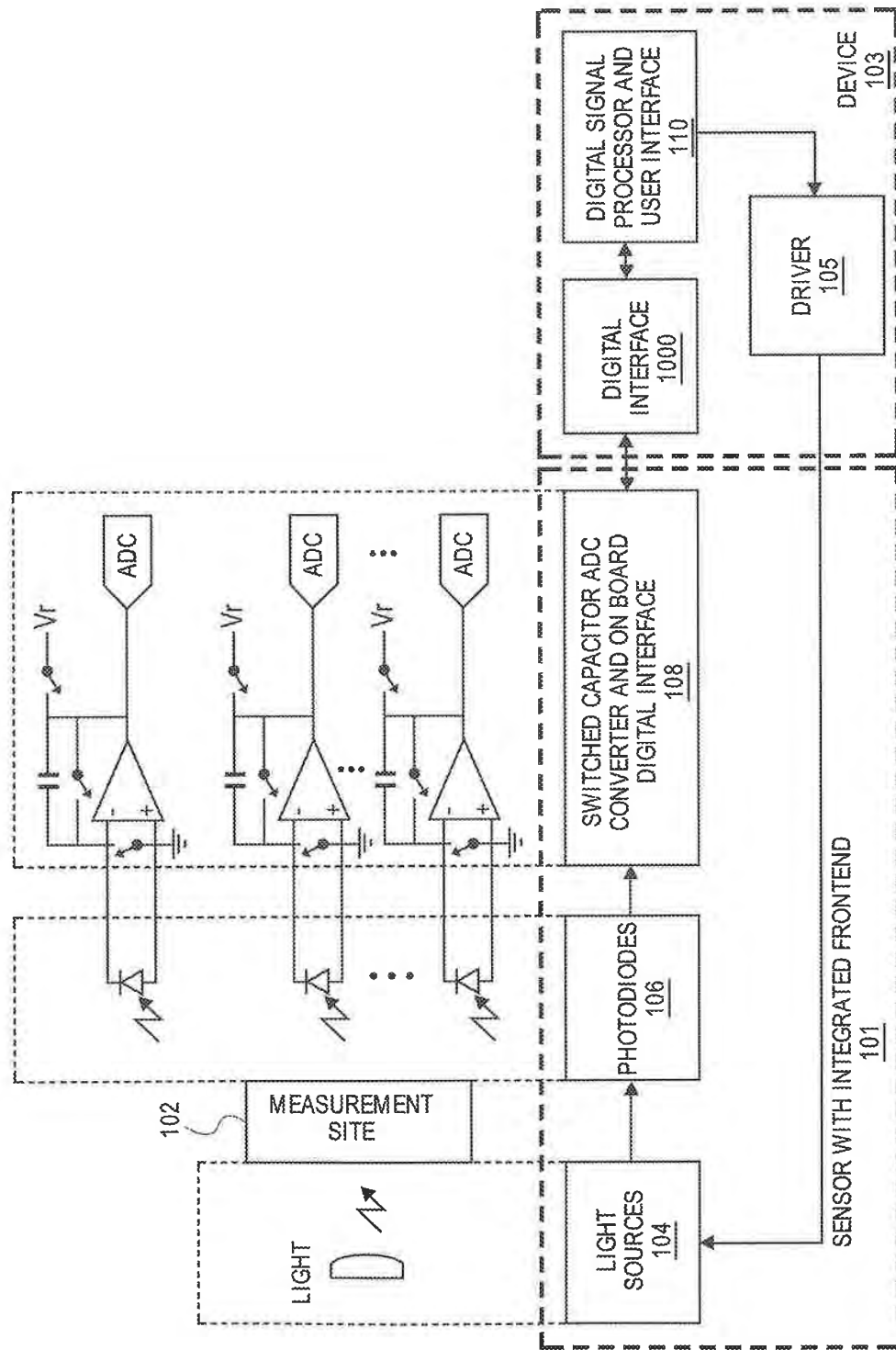


FIG. 15L

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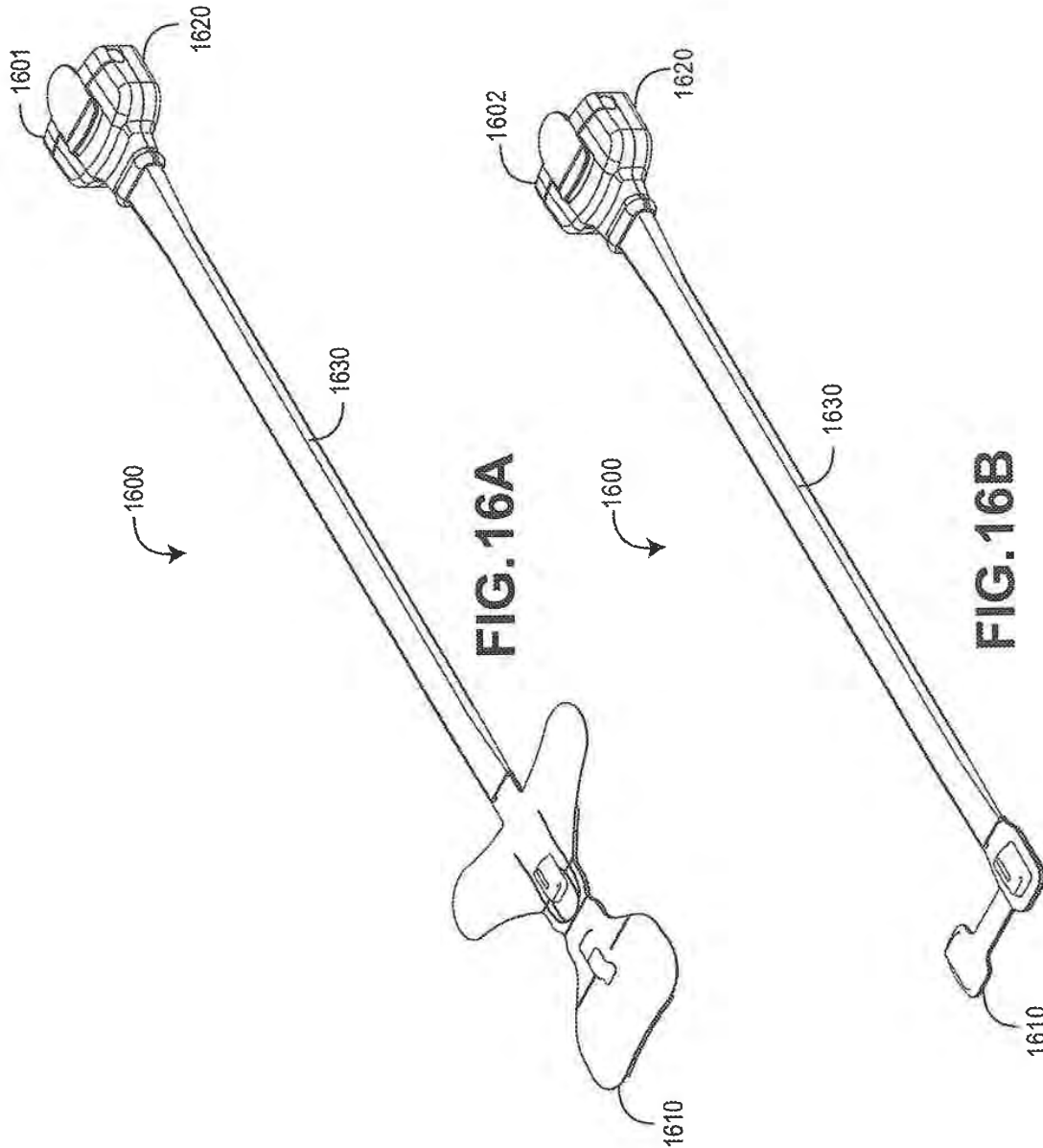


FIG. 16A

FIG. 16B

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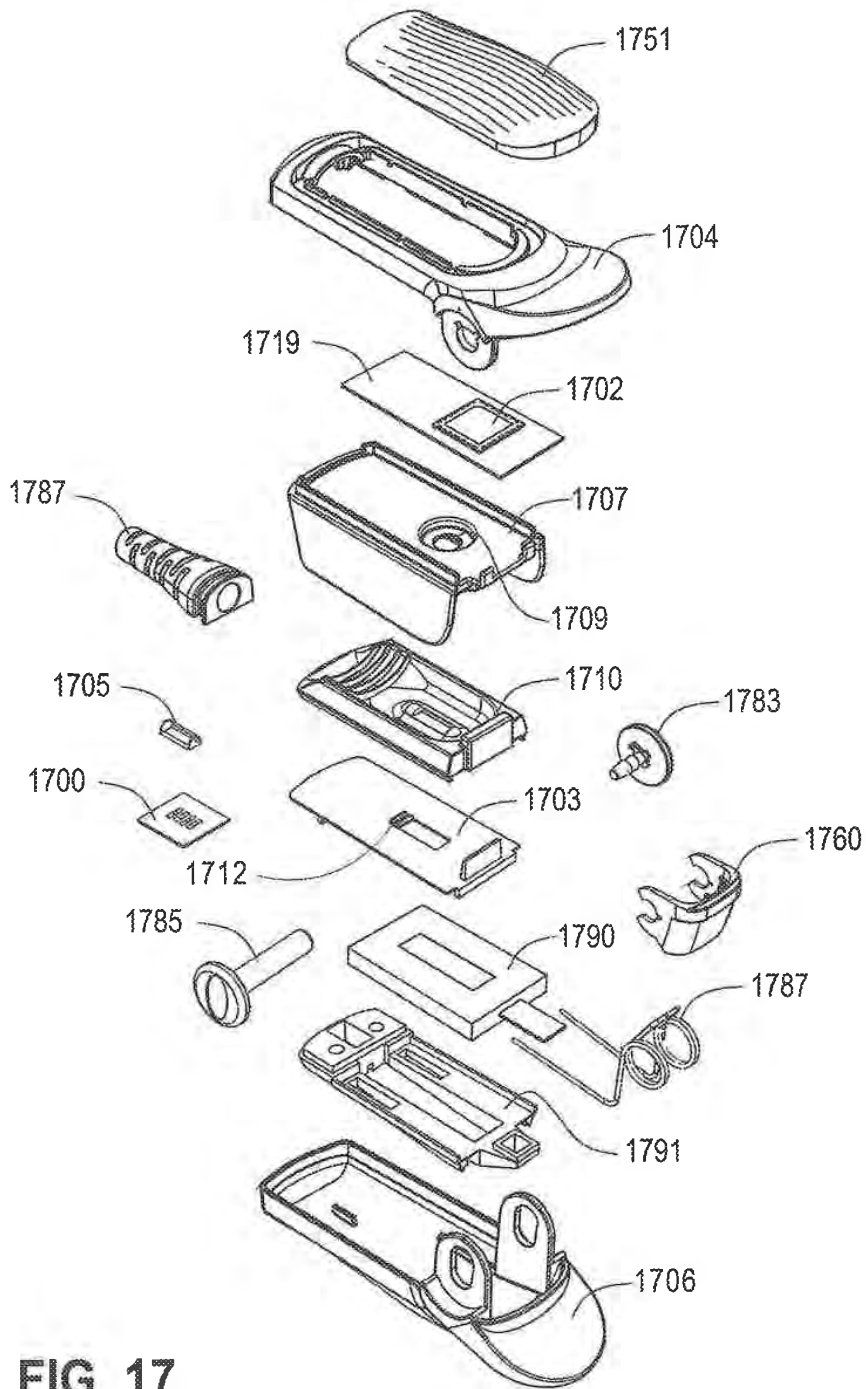


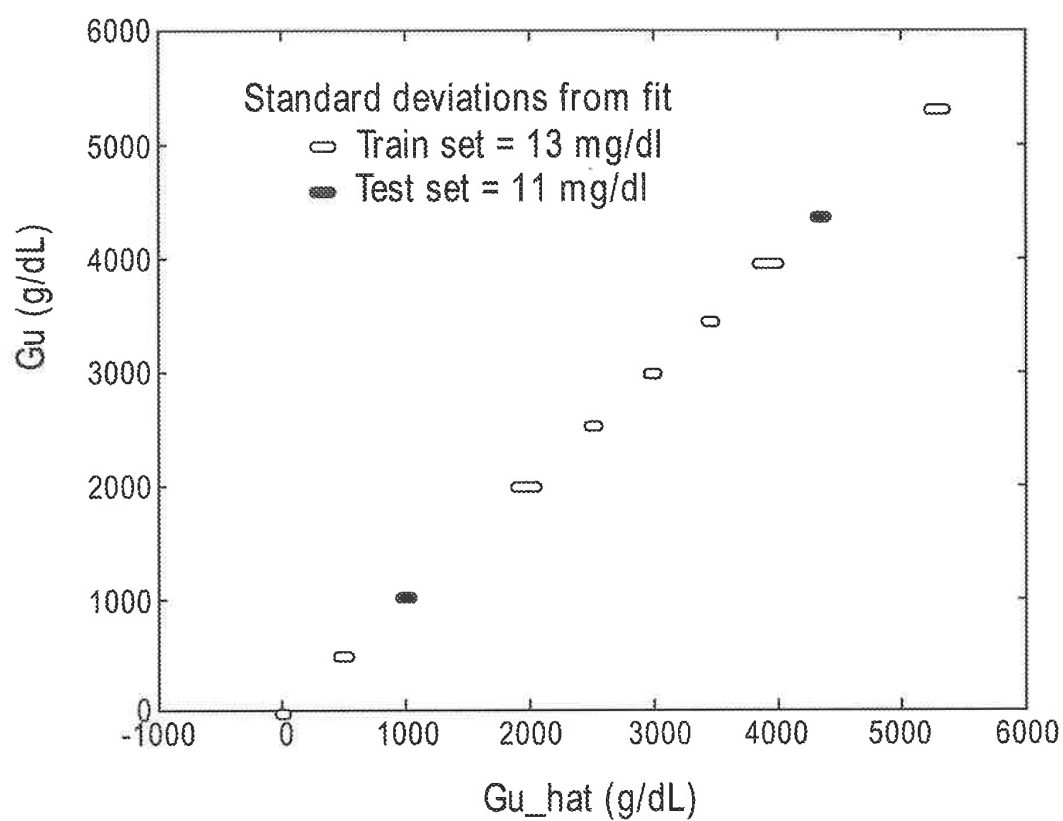
FIG. 17

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**FIG. 18**

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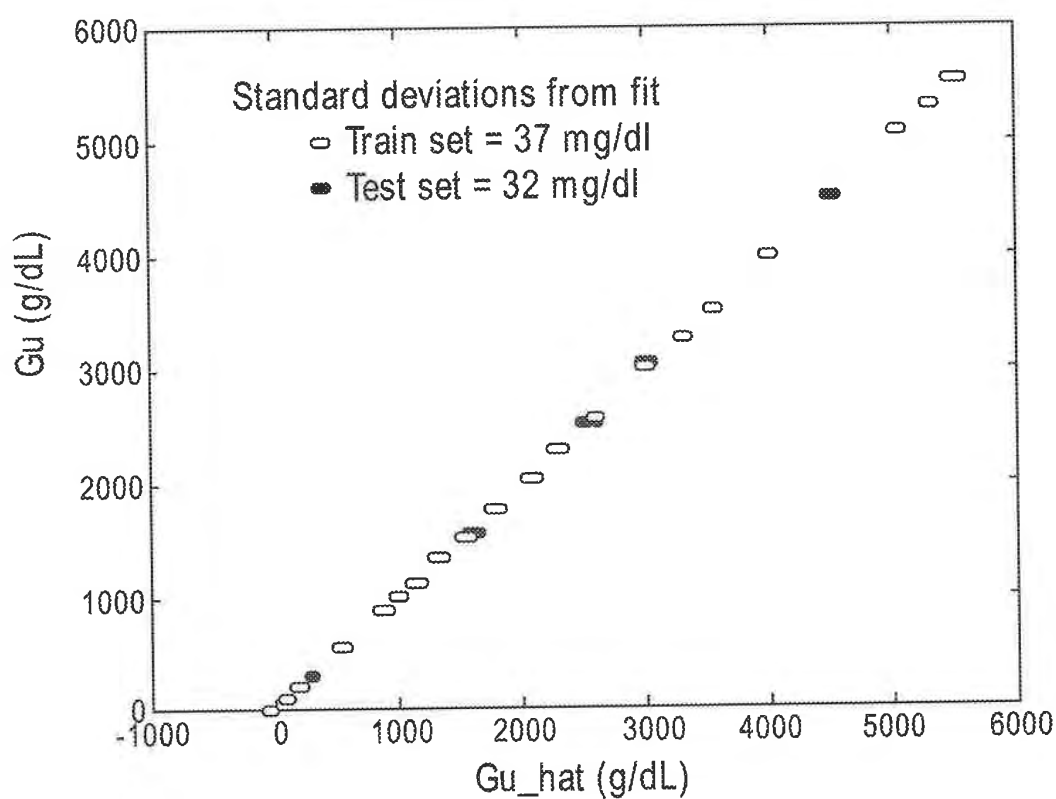


FIG. 19

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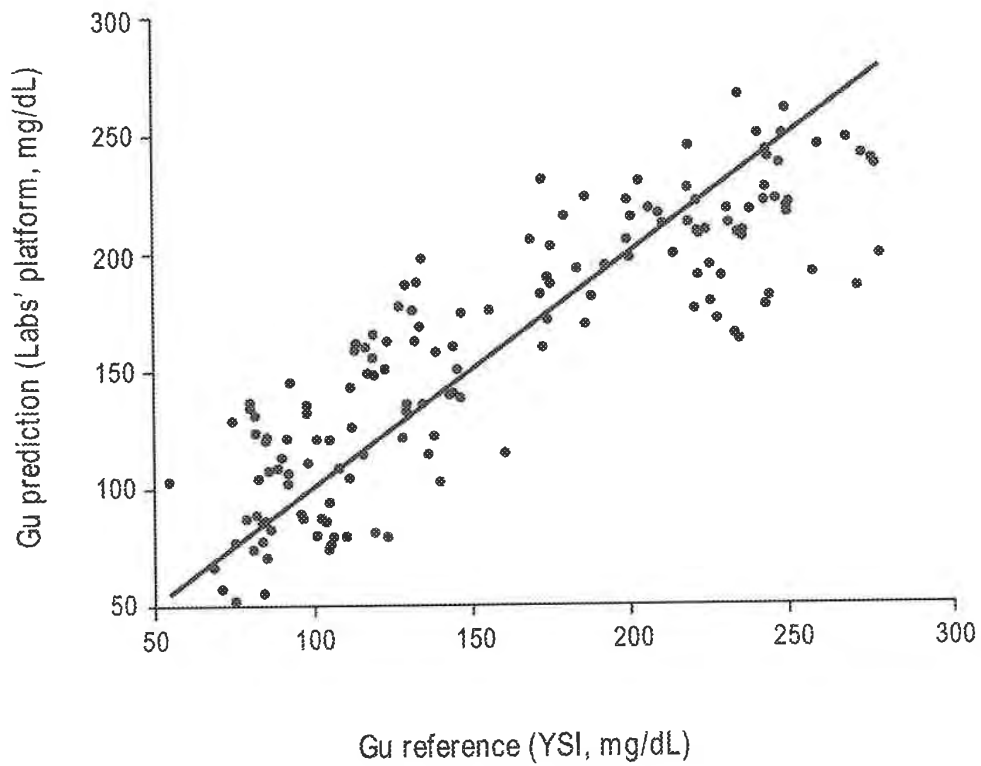


FIG. 20

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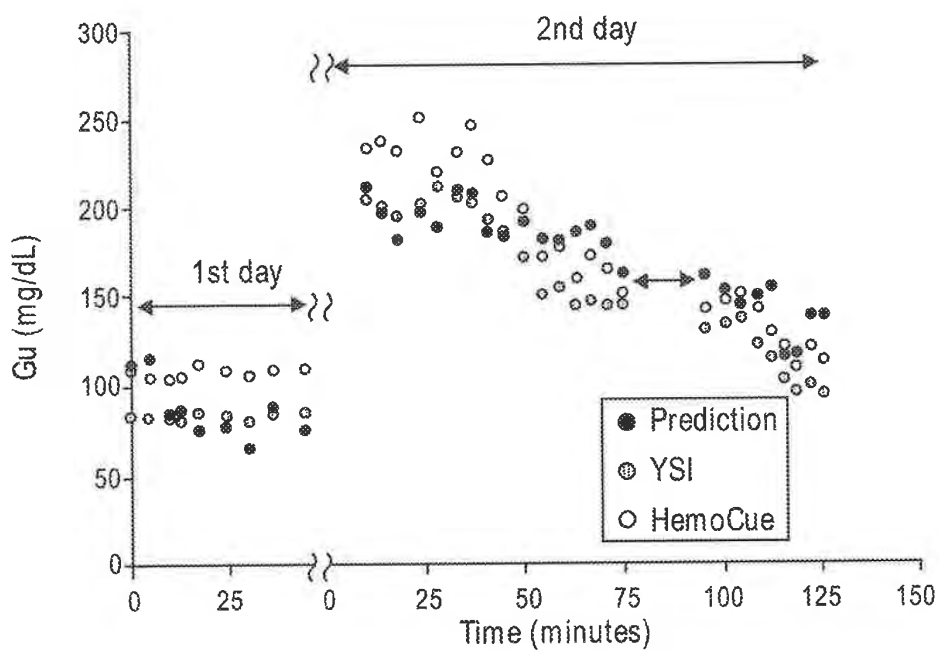


FIG. 21

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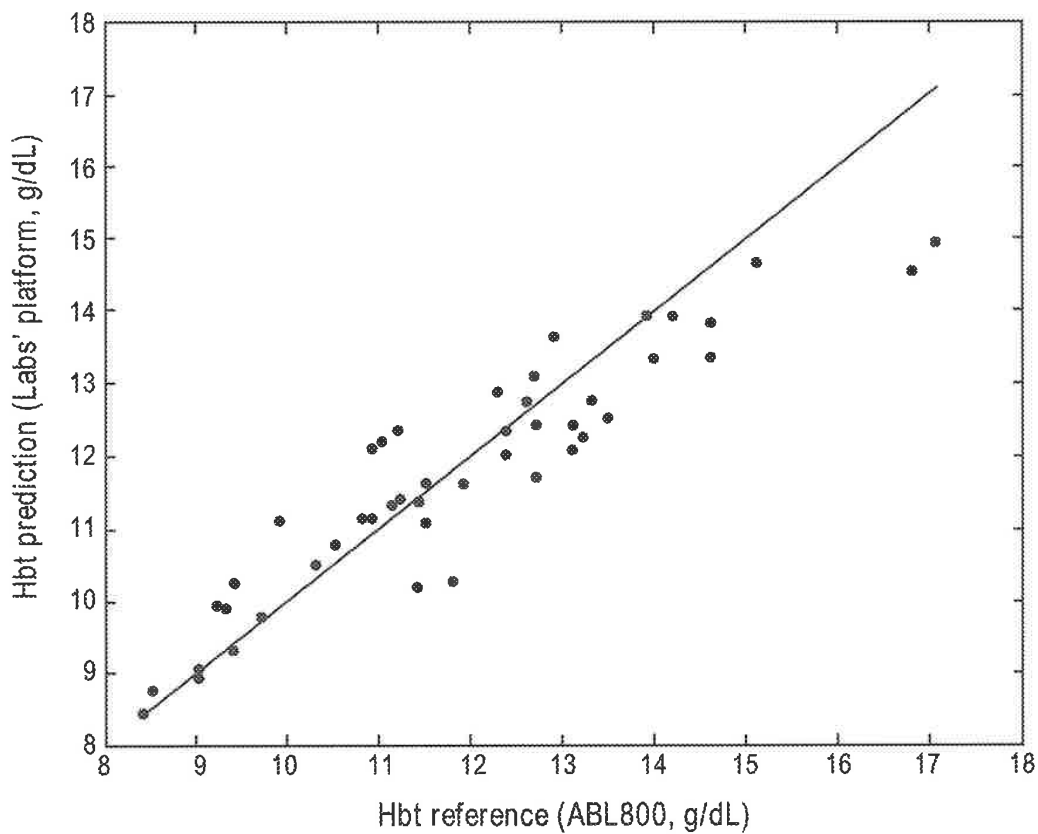


FIG. 22

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**USER-WORN DEVICE FOR
NONINVASIVELY MEASURING A
PHYSIOLOGICAL PARAMETER OF A USER**

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/834,538, filed Mar. 30, 2020, which is a continuation of U.S. patent application Ser. No. 16/725,292, filed Dec. 23, 2019, which is a continuation of U.S. patent application Ser. No. 16/534,949, filed Aug. 7, 2019, which is a continuation of U.S. patent application Ser. No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. patent application Ser. No. 16/261,326, filed Jan. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/212,537, filed Dec. 6, 2018, which is a continuation of U.S. patent application Ser. No. 14/981,290 filed Dec. 28, 2015, which is a continuation of U.S. patent application Ser. No. 12/829,352 filed Jul. 1, 2010, which is a continuation of U.S. patent application Ser. No. 12/534,827 filed Aug. 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,528 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed Aug. 25, 2008 and 29/323,408 filed Aug. 25, 2008. U.S. patent application No. 12/829,352 is also a continuation-in-part of U.S. patent application No. 12/497,523 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed Aug. 25, 2008 and 29/323,408 filed Aug. 25, 2008.

This application is related to the following U.S. patent applications:

| application No. | Filing Date | Title |
|-----------------|--------------|--|
| 12/497,528 | Jul. 2, 2009 | Noise Shielding for Noninvasive Device Contoured Protusion for Improving Spectroscopic Measurement of Blood Constituents |
| 12/497,523 | Jul. 2, 2009 | Heat Sink for Noninvasive Medical Sensor |
| 12/534,812 | Aug. 3, 2009 | Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents |
| 12/534,823 | Aug. 3, 2009 | Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents |

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-continued

| application No. | Filing Date | Title |
|-----------------|--------------|---|
| 5 12/534,825 | Aug. 3, 2009 | Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents |

The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photo-detection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal(s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the non-invasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from said optical source after attenuation by the tissue of the

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measurement site and each output a respective signal stream responsive to the detected optical radiation.

In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the patient. The photodetectors are positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length.

In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the signals from the plurality of detectors into a digital output

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signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

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In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. 1 illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

FIGS. 2A-2D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of FIG. 1, according to embodiments of the disclosure;

FIGS. 3A-3C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIG. 3D illustrates a side view of another example noninvasive sensor housing including a heat sink, according to an embodiment of the disclosure;

FIG. 3E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

FIG. 3F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIGS. 4A through 4C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

FIG. 5 illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

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FIGS. 6A through 6D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

FIG. 6E illustrates an example sensor incorporating the protrusion of FIGS. 6A through 6D, according to an embodiment of the disclosure;

FIGS. 7A through 7B illustrate example arrangements of conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIGS. 8A through 8D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIG. 9 shows example comparative results obtained by an embodiment of a sensor;

FIGS. 10A and 10B illustrate comparative noise floors of various embodiments of the present disclosure;

FIG. 11A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 12A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIGS. 12B through 12D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

FIGS. 12E through 12H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

FIG. 13 illustrates an example multi-stream operation of the system of FIG. 1, according to an embodiment of the disclosure;

FIG. 14A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion of FIG. 14A;

FIGS. 14C through 14E illustrate embodiments of a detector submount;

FIGS. 14F through 14H illustrate embodiment of portions of a detector shell;

FIG. 14I illustrates a cutaway view of an embodiment of a sensor;

FIGS. 15A through 15F illustrate embodiments of sensors that include heat sink features;

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described herein;

FIG. 15I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

FIG. 15J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIG. 15I;

FIG. 15K shows different architectures and layouts for various embodiments of a sensor and its detectors;

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FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors;

FIG. 17 illustrates an exploded view of certain components of an example sensor; and

FIGS. 18 through 22 illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to

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adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of non-invasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metallicized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that,

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in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modifications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in

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heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices. The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. 1 illustrates an example of a data collection system 100. In certain embodiments, the data collection system 100 noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system 100 can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The data collection system 100 can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system 100 can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm²-5 mm² (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase "at full scale" can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

The data collection system 100 can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system 100 can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired analytes. The data collection system 100 can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

The data collection system 100 can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a finger measurement site 102. However, the features of the embodiments disclosed herein can be used with other measurement sites 102.

In the depicted embodiment, the system 100 includes an optional tissue thickness adjuster or tissue shaper 105, which

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can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper 105 is a flat or substantially flat surface that can be positioned proximate the measurement site 102 and that can apply sufficient pressure to cause the tissue of the measurement site 102 to be flat or substantially flat. In other embodiments, the tissue shaper 105 is a convex or substantially convex surface with respect to the measurement site 102. Many other configurations of the tissue shaper 105 are possible. Advantageously, in certain embodiments, the tissue shaper 105 reduces thickness of the measurement site 102 while preventing or reducing occlusion at the measurement site 102. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

The embodiment of the data collection system 100 shown also includes an optional noise shield 103. In an embodiment, the noise shield 103 can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site 102 to one or more detectors 106 (described below). For example, the noise shield 103 can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor 101 or electrically grounded. In an embodiment where the noise shield 103 includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

In some embodiments, the measurement site 102 is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system 100 can be used on a person's non-dominant hand or arm.

The data collection system 100 can include a sensor 101 (or multiple sensors) that is coupled to a processing device or physiological monitor 109. In an embodiment, the sensor 101 and the monitor 109 are integrated together into a single unit. In another embodiment, the sensor 101 and the monitor 109 are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor 101 and monitor 109 can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor 101 and the monitor 109 will now be further described.

In the depicted embodiment shown in FIG. 1, the sensor 101 includes an emitter 104, a tissue shaper 105, a set of detectors 106, and a front-end interface 108. The emitter 104 can serve as the source of optical radiation transmitted towards measurement site 102. As will be described in

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further detail below, the emitter 104 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

In some embodiments, the emitter 104 is used as a point optical source, and thus, the one or more optical sources of the emitter 104 can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters 104 can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sep. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters 104 can be arranged at least in part as described in paragraphs [0061] through [0068] of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters 104.

For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

In contrast, the emitter 104 of the data collection system 100 can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter 104 can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter 104 can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

In other embodiments, the emitter 104 can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better for analytes like glucose. Furthermore, in some embodiments, the emitter 104 can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

For example, the emitter 104 can emit optical radiation across other spectra for other analytes. In particular, the emitter 104 can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter 104 can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of

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course, the emitter 104 can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system 100 can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

As briefly described above, the emitter 104 can include sets of light-emitting diodes (LEDs) as its optical source. The emitter 104 can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter 104 can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

The emitter 104 can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter 104 can employ SLEDs or side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter 104 can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO₂), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter 104 can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site 102.

In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter 104 can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter 104 to use LEDs with a higher output and/or to equalize intensity of LEDs.

The data collection system 100 also includes a driver 111 that drives the emitter 104. The driver 111 can be a circuit or the like that is controlled by the monitor 109. For example, the driver 111 can provide pulses of current to the emitter 104. In an embodiment, the driver 111 drives the emitter 104 in a progressive fashion, such as in an alternating manner. The driver 111 can drive the emitter 104 with a series of pulses of about 1 milliwatt (mW) for some wavelengths that can penetrate tissue relatively well and from about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

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The driver 111 can be synchronized with other parts of the sensor 101 and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter 104. In some embodiments, the driver 111 is capable of driving the emitter 104 to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detectors 106 capture and measure light from the measurement site 102. For example, the detectors 106 can capture and measure light transmitted from the emitter 104 that has been attenuated or reflected from the tissue in the measurement site 102. The detectors 106 can output a detector signal 107 responsive to the light captured or measured. The detectors 106 can be implemented using one or more photodiodes, phototransistors, or the like.

In addition, the detectors 106 can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors 106. That is, some of the detectors 106 can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter 104. However, according to an embodiment, at least some of the detectors 106 can have a different path length from the emitter 104 relative to other of the detectors 106. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors 106. In some embodiments, the detectors 106 may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

The front end interface 108 provides an interface that adapts the output of the detectors 106, which is responsive to desired physiological parameters. For example, the front end interface 108 can adapt a signal 107 received from one or more of the detectors 106 into a form that can be processed by the monitor 109, for example, by a signal processor 110 in the monitor 109. The front end interface 108 can have its components assembled in the sensor 101, in the monitor 109, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface 108 can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front end interface 108 can be coupled to the detectors 106 and to the signal processor 110 using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface 108 can also be at least partially integrated with various components, such as the detectors 106. For example, the front end interface 108 can include one or more integrated circuits that are on the same circuit board as the detectors 106. Other configurations can also be used.

The front end interface 108 can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor 109), such as a sigma-delta ADC. A transimpedance-based front end interface 108 can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface 108 can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface 108 can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter 104.

The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by

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the signal processor 110 of the monitor 109. Each channel can correspond to a signal output from a detector 106.

In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface 108. For example, the output of a transimpedance-based front end interface 108 can be output to a PGA that is coupled with an ADC in the monitor 109. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the detectors 106. Alternatively, the PGA and ADC components can be integrated with the transimpedance-based front end interface 108 in the sensor 101.

In another embodiment, the front end interface 108 can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface 108 can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface 108 can be useful because it can provide a digital signal to the signal processor 110 in the monitor 109.

As shown in FIG. 1, the monitor 109 can include the signal processor 110 and a user interface, such as a display 112. The monitor 109 can also include optional outputs alone or in combination with the display 112, such as a storage device 114 and a network interface 116. In an embodiment, the signal processor 110 includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors 106. The signal processor 110 can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor 110 can provide various signals that control the operation of the sensor 101. For example, the signal processor 110 can provide an emitter control signal to the driver 111. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter 104. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter 104 to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface 108 is used, the control signal from the signal processor 110 can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory 113 can be included in the front-end interface 108 and/or in the signal processor 110. This memory 113 can serve as a buffer or storage location for the front-end interface 108 and/or the signal processor 110, among other uses.

The user interface 112 can provide an output, e.g., on a display, for presentation to a user of the data collection system 100. The user interface 112 can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface 112 can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface 112 can include a flip screen, a screen that can be moved from one side to another on the monitor 109, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data collection system 100 can be provided without a user interface 112 and can simply provide an output signal to a separate display or system.

A storage device 114 and a network interface 116 represent other optional output connections that can be included in the monitor 109. The storage device 114 can include any

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computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device 114, which can be executed by the signal processor 110 or another processor of the monitor 109. The network interface 116 can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor 109 to communicate and share data with other devices. The monitor 109 can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface 112, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the data collection system 100 can include various other components or can be configured in different ways. For example, the sensor 101 can have both the emitter 104 and detectors 106 on the same side of the measurement site 102 and use reflectance to measure analytes. The data collection system 100 can also include a sensor that measures the power of light emitted from the emitter 104.

FIGS. 2A through 2D illustrate example monitoring devices 200 in which the data collection system 100 can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices 200 shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system 100. In addition, certain of the features of the monitoring devices 200 shown in FIGS. 2A through 2D can be combined with features of the other monitoring devices 200 shown.

Referring specifically to FIG. 2A, an example monitoring device 200A is shown, in which a sensor 201a and a monitor 209a are integrated into a single unit. The monitoring device 200A shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor 201a includes an emitter shell 204a and a detector shell 206a. The depicted embodiment of the monitoring device 200A also includes various control buttons 208a and a display 210a.

The sensor 201a can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector 106 by forcing light back into the sensor 201a. Pads in the emitter shell 204a and the detector shell 206a can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell 204a and the detector shell 206a can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor 201a.

In some embodiments, some or all portions of the emitter shell 204a and/or detector shell 206a can be detachable and/or disposable. For example, some or all portions of the shells 204a and 206a can be removable pieces. The removability of the shells 204a and 206a can be useful for sanitary purposes or for sizing the sensor 201a to different patients. The monitor 209a can include a fitting, slot, magnet, or other connecting mechanism to allow the sensor 201c to be removably attached to the monitor 209a.

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The monitoring device 200a also includes optional control buttons 208a and a display 210a that can allow the user to control the operation of the device. For example, a user can operate the control buttons 208a to view one or more measurements of various analytes, such as glucose. In addition, the user can operate the control buttons 208a to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many parameters, trends, alarms and parameter displays could be output to the display 210a, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo® Corporation of Irvine, Calif.

Furthermore, the controls 208a and/or display 210a can provide functionality for the user to manipulate settings of the monitoring device 200a, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device 200a can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

FIG. 2B illustrates another example of a monitoring device 200B. In the depicted embodiment, the monitoring device 200B includes a finger clip sensor 201b connected to a monitor 209b via a cable 212. In the embodiment shown, the monitor 209b includes a display 210b, control buttons 208b and a power button. Moreover, the monitor 209b can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor 201b, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

The cable 212 connecting the sensor 201b and the monitor 209b can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable 212 can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor 201b to the monitor 209b. Various lengths of the cable 212 can be employed to allow for separation between the sensor 201b and the monitor 209b. The cable 212 can be fitted with a connector (male or female) on either end of the cable 212 so that the sensor 201b and the monitor 209b can be connected and disconnected from each other. Alternatively, the sensor 201b and the monitor 209b can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

The monitor 209b can be attached to the patient. For example, the monitor 209b can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor 209b can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable 212 and sensor 201b to be attached to the monitor 209B.

The monitor 209b can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor 209b can include a display 210b that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor 209b.

In addition, although a single sensor 201b with a single monitor 209b is shown, different combinations of sensors and device pairings can be implemented. For example,

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multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

FIG. 2C illustrates yet another example of monitoring device 200C that can house the data collection system 100. Like the monitoring device 200B, the monitoring device 200C includes a finger clip sensor 201c connected to a monitor 209c via a cable 212. The cable 212 can have all of the features described above with respect to FIG. 2B. The monitor 209c can include all of the features of the monitor 200B described above. For example, the monitor 209c includes buttons 208c and a display 210c. The monitor 209c shown also includes straps 214c that allow the monitor 209c to be attached to a patient's limb or the like.

FIG. 2D illustrates yet another example of monitoring device 200D that can house the data collection system 100. Like the monitoring devices 200B and 200C, the monitoring device 200D includes a finger clip sensor 201d connected to a monitor 209d via a cable 212. The cable 212 can have all of the features described above with respect to FIG. 2B. In addition to having some or all of the features described above with respect to FIGS. 2B and 2C, the monitoring device 200D includes an optional universal serial bus (USB) port 216 and an Ethernet port 218. The USB port 216 and the Ethernet port 218 can be used, for example, to transfer information between the monitor 209d and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor 209b, and perform a variety of other functions. The USB port 216 and the Ethernet port 218 can be included with the other monitoring devices 200A, 200B, and 200C described above.

FIGS. 3A through 3C illustrate more detailed examples of embodiments of a sensor 301a. The sensor 301a shown can include all of the features of the sensors 100 and 200 described above.

Referring to FIG. 3A, the sensor 301a in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure 302a for receiving a patient's finger. The enclosure 302a is formed by an upper section or emitter shell 304a, which is pivotably connected with a lower section or detector shell 306a. The emitter shell 304a can be biased with the detector shell 306a to close together around a pivot point 303a and thereby sandwich finger tissue between the emitter and detector shells 304a, 306a.

In an embodiment, the pivot point 303a advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells 304a, 306a to effectively level the sections when applied to a tissue site. In another embodiment, the sensor 301a includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs [0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

The emitter shell 304a can position and house various emitter components of the sensor 301a. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metalicized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell 304a can also include absorbing opaque material, such as, for example, black or grey colored material, at various areas, such as on one or more flaps 307a, to reduce ambient light entering the sensor 301a.

The detector shell 306a can position and house one or more detector portions of the sensor 301a. The detector shell 306a can be constructed of reflective material, such as white

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silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIG. 1). The detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308a, to reduce ambient light entering the sensor 301a.

Referring to FIGS. 3B and 3C, an example of finger bed 310 is shown in the sensor 301b. The finger bed 310 includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310 includes one or more ridges or channels 314. Each of the ridges 314 has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges 314 can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor 301a. The ridges 314 can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds 310.

Finger bed 310 can also include an embodiment of a tissue thickness adjuster or protrusion 305. The protrusion 305 includes a measurement site contact area 370 (see FIG. 3C) that can contact body tissue of a measurement site. The protrusion 305 can be removed from or integrated with the finger bed 310. Interchangeable, different shaped protrusions 305 can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

Referring specifically to FIG. 3C, the contact area 370 of the protrusion 305 can include openings or windows 320, 321, 322, and 323. When light from a measurement site passes through the windows 320, 321, 322, and 323, the light can reach one or more photodetectors (see FIG. 3E). In an embodiment, the windows 320, 321, 322, and 323 mirror specific detector placements layouts such that light can impinge through the protrusion 305 onto the photodetectors. Any number of windows 320, 321, 322, and 323 can be employed in the protrusion 305 to allow light to pass from the measurement site to the photodetectors.

The windows 320, 321, 322, and 323 can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows 320, 321, 322, and 323 can be made from materials, such as plastic or glass. In some embodiments, the windows 320, 321, 322, and 323 can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

Turning to FIG. 3B, the sensor 301a can also include a shielding 315a, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding 315a is provided in the depicted embodiment below or embedded within the protrusion 305 to reduce noise. The shielding 315a can be constructed from a conductive material, such as copper. The

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shielding 315a can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the windows 320, 321, 322, and 323 on an external surface of the protrusion 305 (see FIG. 3C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIG. 3E).

In some embodiments, the shielding cage for shielding 315a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion 305 (see FIG. 3E).

In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm² to about 60 mm² was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion 305 can be selected. In making such determinations, consideration can be made of protrusion's 305 effect on blood flow at the measurement site and mean path length for optical radiation passing through openings 320, 321, 322, and 323. Patient comfort can also be considered in determining the size and shape of the protrusion.

In an embodiment, the protrusion 305 can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and facility by conforming the measurement site contact area 370 to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light. Alternatively, the protrusion 305 can be made from a rigid material, such as hard plastic or metal.

Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area 370. The contact area 370 can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion 305 can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion 305 and the contact area 370 can include a combination of materials with various characteristics.

The contact area 370 serves as a contact surface for the measurement site. For example, in some embodiments, the contact area 370 can be shaped for contact with a patient's finger. Accordingly, the contact area 370 can be sized and shaped for different sizes of fingers. The contact area 370 can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example, the contact area 370 can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

The formulas and analysis that follow with respect to FIG. 5 provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

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Referring to FIG. 5, a plot 500 is shown that illustrates examples of effects of embodiments of the protrusion 305 on the SNR at various wavelengths of light. As described above, the protrusion 305 can assist in conforming the tissue and effectively reduce its mean path length. In some instances, this effect by the protrusion 305 can have significant impact on increasing the SNR.

According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I=I_0 * e^{-m * b * c}$, where I_0 is the initial power of light being transmitted, m is the path length traveled by the light, and the component " $b * c$ " corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1} . Assuming a typical finger thickness of about 12 mm and a mean path length of 20 mm due to tissue scattering, then $I=I_0 * e^{(-20 * 0.7)}$.

In an embodiment where the protrusion 305 is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box 510). This results in a new transmittance, $I_1=I_0 * e^{(-16.6 * 0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot 500 of FIG. 5. The plot 500 illustrates potential effects of the protrusion 305 on the transmittance. As illustrated, comparing I and I_1 results in an intensity gain of $e^{(-16.6 * 0.7)} / e^{(-20 * 0.7)}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1} . The plot 500 also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

Turning again to FIGS. 3A through 3C, an example heat sink 350a is also shown. The heat sink 350a can be attached to, or protrude from an outer surface of, the sensor 301a, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor 301a in certain embodiments, the heat sink 350a can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see FIG. 1) generate sufficient heat that inclusion of the heat sink 350a can advantageously allow the sensor 301a to remain safely cooled. The heat sink 350a can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell 304a can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

In some embodiments, the heat sink 350a includes metalized plastic. The metalized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink 350a can include a thermally conductive liquid crystalline polymer, such as CoolPoly® D5506, commercially available from Cool Polymers®, Inc. of Warwick, Rhode Island. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink 350a provides improved heat transfer properties when the sensor 301a is active for short intervals of less than a full day's use. In an embodiment, the heat sink 350a can

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advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink 350a can be selected that performs effectively in shorter or longer intervals.

Moreover, the heat sink 350a can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink 350a is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink 350a shown includes fins 351a (see FIG. 3A).

An alternative shape of a sensor 301b and heat sink 350b is shown in FIG. 3D. The sensor 301b can include some or all of the features of the sensor 301a. For example, the sensor 301b includes an enclosure 302b formed by an emitter shell 304b and a detector shell 306b, pivotably connected about a pivot 303a. The emitter shell 304b can also include absorbing opaque material on one or more flaps 307b, and the detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308b.

However, the shape of the sensor 301b is different in this embodiment. In particular, the heat sink 350b includes comb protrusions 351b. The comb protrusions 351b are exposed to the air in a similar manner to the fins 351a of the heat sink 350a, thereby facilitating efficient cooling of the sensor 301b.

FIG. 3E illustrates a more detailed example of a detector shell 306b of the sensor 301b. The features described with respect to the detector shell 306b can also be used with the detector shell 306a of the sensor 301a.

As shown, the detector shell 306b includes detectors 316. The detectors 316 can have a predetermined spacing 340 from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors 316 and the emitter discussed above.

In the depicted embodiment, the detector shell 316 can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site 102). In the detector shell 316, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell 316 can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

As further illustrated by FIG. 3E, the detectors 316 can have a spatial configuration of a grid. However, the detectors 316 can be arranged in other configurations that vary the path length. For example, the detectors 316 can be arranged in a linear array, a logarithmic array, a two-dimensional array, a zig-zag pattern, or the like. Furthermore, any number of the detectors 316 can be employed in certain embodiments.

FIG. 3F illustrates another embodiment of a sensor 301f. The sensor 301f can include some or all of the features of the sensor 301a of FIG. 3A described above. For example, the sensor 301f includes an enclosure 302f formed by an upper section or emitter shell 304f, which is pivotably connected

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with a lower section or detector shell 306f around a pivot point 303f. The emitter shell 304f can also include absorbing opaque material on various areas, such as on one or more flaps 307f, to reduce ambient light entering the sensor 301f. The detector shell 306f can also include absorbing opaque material at various areas, such as a lower area 308f. The sensor 301f also includes a heat sink 350f, which includes fins 351f.

In addition to these features, the sensor 301f includes a flex circuit cover 360, which can be made of plastic or another suitable material. The flex circuit cover 360 can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell 304f to the detector shell 306f. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIG. 46 and associated description, which is hereby specifically incorporated by reference). The flex circuit cover 360 is shown in more detail below in FIG. 17.

In addition, sensors 301a-f has extra length—extends to second joint on finger—Easier to place, harder to move due to cable, better for light piping.

FIGS. 4A through 4C illustrate example arrangements of a protrusion 405, which is an embodiment of the protrusion 305 described above. In an embodiment, the protrusion 405 can include a measurement site contact area 470. The measurement site contact area 470 can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

The protrusion 405 can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion 405 can have a length 400, a width 410, and a height 430. The length 400 can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width 410 can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

The measurement site contact area 470 can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site. The measurement site contact area 470 can be other shapes that reduce or even minimize air between the protrusion 405 and/or the measurement site. Additionally, the surface pattern of the measurement site contact area 470 can vary from smooth to bumpy, e.g., to provide varying levels of grip.

In FIGS. 4A and 4C, openings or windows 420, 421, 422, and 423 can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows 420, 421, 422, and 423 can be of non-uniform shapes and sizes. As shown, the windows 420, 421, 422, and 423 can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of arranging the windows 420, 421, 422, and 423 are possible. For example, the windows 420, 421, 422, and 423 can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows 420, 421, 422, and 423 can be placed at different heights with respect to the finger bed 310 of FIG. 3. The windows 420, 421, 422, and 423 can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

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FIGS. 6A through 6D illustrate another embodiment of a protrusion 605 that can be used as the tissue shaper 105 described above or in place of the protrusions 305, 405 described above. The depicted protrusion 605 is a partially cylindrical lens having a partial cylinder 608 and an extension 610. The partial cylinder 608 can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion 605 focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

FIG. 6A illustrates a perspective view of the partially cylindrical protrusion 605. FIG. 6B illustrates a front elevation view of the partially cylindrical protrusion 605. FIG. 6C illustrates a side view of the partially cylindrical protrusion 605. FIG. 6D illustrates a top view of the partially cylindrical protrusion 605.

Advantageously, in certain embodiments, placing the partially cylindrical protrusion 605 over the photodiodes in any of the sensors described above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion 605 penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

The partially cylindrical protrusion 605 can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion 605 can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIG. 14). If fewer or smaller photodiodes are used, the partially cylindrical protrusion 605 can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

The dimensions of the partially cylindrical protrusion 605 can vary based on, for instance, a number of photodiodes used with the sensor. Referring to FIG. 6C, the overall height of the partially cylindrical protrusion 605 (measurement "a") in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion 605 to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion 605 can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion 605 is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

Referring to FIG. 6D, the width of the partially cylindrical protrusion 605 (measurement "b") can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration of the partially cylindrical protrusion 605 into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the width of the partially cylindrical protrusion 605 can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion 605 could

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be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

In certain embodiments, the focal length (f) for the partially cylindrical protrusion 605 can be expressed as:

$$f = \frac{R}{n-1},$$

where R is the radius of curvature of the partial cylinder 608 and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion 605 can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

A partially cylindrical protrusion 605 having a material with a higher index of refraction such as nSF11 glass (e.g., $n=1.75$ at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion 605 can be chosen to improve or optimize the light focusing properties of the protrusion 605. A plastic partially cylindrical protrusion 605 could provide the cheapest option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion 605.

Placing a photodiode at a given distance below the partially cylindrical protrusion 605 can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIG. 14). Different sizes of the partially cylindrical protrusion 605 can use different sizes of photodiodes. The extension 610 added onto the bottom of the partial cylinder 608 is used in certain embodiments to increase the height of the partially cylindrical protrusion 605. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion 605. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension 610 can also further facilitate the protrusion 605 increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension 610 can be omitted.

FIG. 6E illustrates another view of the sensor 301f of FIG. 3F, which includes an embodiment of a partially cylindrical protrusion 605b. Like the sensor 301A shown in FIGS. 3B and 3C, the sensor 301f includes a finger bed 310f. The finger bed 310f includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310f also includes the ridges or channels 314 described above with respect to FIGS. 3B and 3C.

The example of finger bed 310f shown also includes the protrusion 605b, which includes the features of the protrusion 605 described above. In addition, the protrusion 605b also includes chamfered edges 607 on each end to provide a more comfortable surface for a finger to slide across (see

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also FIG. 14D). In another embodiment, the protrusion 605b could instead include a single chamfered edge 607 proximal to the ridges 314. In another embodiment, one or both of the chamfered edges 607 could be rounded.

The protrusion 605b also includes a measurement site contact area 670 that can contact body tissue of a measurement site. The protrusion 605b can be removed from or integrated with the finger bed 310f. Interchangeable, differently shaped protrusions 605b can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

FIGS. 7A and 7B illustrate block diagrams of sensors 701 that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide increased SNR. The features of the sensors 701 can be implemented with any of the sensors 101, 201, 301 described above. Although not shown, the partially cylindrical protrusion 605 of FIG. 6 can also be used with the sensors 701 in certain embodiments.

For example, referring specifically to FIG. 7A, the sensor 701a includes an emitter housing 704a and a detector housing 706. The emitter housing 704a includes LEDs 104. The detector housing 706a includes a tissue bed 710a with an opening or window 703a, the conductive glass 730a, and one or more photodiodes for detectors 106 provided on a submount 707a.

During operation, a finger 102 can be placed on the tissue bed 710a and optical radiation can be emitted from the LEDs 104. Light can then be attenuated as it passes through or is reflected from the tissue of the finger 102. The attenuated light can then pass through the opening 703a in the tissue bed 710a. Based on the received light, the detectors 106 can provide a detector signal 107, for example, to the front end interface 108 (see FIG. 1).

In the depicted embodiment, the conductive glass 730 is provided in the opening 703. The conductive glass 730 can thus not only permit light from the finger to pass to the detectors 106, but it can also supplement the shielding of the detectors 106 from noise. The conductive glass 730 can include a stack or set of layers. In FIG. 7A, the conductive glass 730a is shown having a glass layer 731 proximate the finger 102 and a conductive layer 733 electrically coupled to the shielding 790a.

In an embodiment, the conductive glass 730a can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure 790a, the conductive glass 730a can be electrically coupled to the shielding enclosure 790a. The conductive glass 730a can be electrically coupled to the shielding 704a based on direct contact or via other connection devices, such as a wire or another component.

The shielding enclosure 790a can be provided to encompass the detectors 106 to reduce or prevent noise. For example, the shielding enclosure 790a can be constructed from a conductive material, such as copper, in the form of a metal cage. The shielding or enclosure a can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

In some embodiments, the shielding enclosure 790a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure 790a can also be used

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to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

Referring to FIG. 7B, another block diagram of an example sensor 701b is shown. A tissue bed 710b of the sensor 701b includes a protrusion 705b, which is in the form of a convex bump. The protrusion 705b can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion 705b includes a contact area 370 that comes in contact with the finger 102 and which can include one or more openings 703b. One or more components of conductive glass 730b can be provided in the openings 703. For example, in an embodiment, each of the openings 703 can include a separate window of the conductive glass 730b. In an embodiment, a single piece of the conductive glass 730b can be used for some or all of the openings 703b. The conductive glass 730b is smaller than the conductive glass 730a in this particular embodiment.

A shielding enclosure 790b is also provided, which can have all the features of the shielding enclosure 790a. The shielding enclosure 790b is smaller than the shielding enclosure 790a; however, a variety of sizes can be selected for the shielding enclosures 790.

In some embodiments, the shielding enclosure 790b can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure 790b can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

FIGS. 8A through 8D illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors 701a, 701b. As shown in the perspective view of FIG. 8A and side view of FIG. 8B, the conductive glass 730 includes the electrically conductive material 733 described above as a coating on the glass layer 731 described above to form a stack. In an embodiment where the electrically conductive material 733 includes indium tin oxide, surface resistivity of the electrically conductive material 733 can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material 733.

Although the conductive material 733 is shown spread over the surface of the glass layer 731, the conductive material 733 can be patterned or provided on selected portions of the glass layer 731. Furthermore, the conductive material 733 can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

In FIG. 8C, a side view of a conductive glass 830a is shown to illustrate an embodiment where the electrically conductive material 733 is provided as an internal layer between two glass layers 731, 835. Various combinations of integrating electrically conductive material 733 with glass are possible. For example, the electrically conductive material 733 can be a layer within a stack of layers. This stack of layers can include one or more layers of glass 731, 835, as well as one or more layers of conductive material 733. The stack can include other layers of materials to achieve desired characteristics.

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In FIG. 8D, a bottom perspective view is shown to illustrate an embodiment where a conductive glass 830b can include conductive material 837 that occupies or covers a portion of a glass layer 839. This embodiment can be useful, for example, to create individual, shielded windows for detectors 106, such as those shown in FIG. 3C. The conductive material 837 can be patterned to include an area 838 to allow light to pass to detectors 106 and one or more strips 841 to couple to the shielding 704 of FIG. 7.

Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

FIG. 9 depicts an example graph 900 that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGS. 7 and 8. The graph 900 depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

A line 915 on the graph 900 illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line 920 on the graph 900 demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line 925 on the graph 900 shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line 930 on the graph 900 shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring. Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

FIGS. 10A through 10B illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In FIG. 10A, a graph 1000 depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above included separate windows for four (4) detectors 106. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols 1030-1033 illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

In FIG. 10B, a graph 1050 depicts a noise floor for frequencies of noise 1070 for an embodiment in which the sensor included separate openings for four (4) detectors 106

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and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols 1080-1083 illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodiment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of FIG. 10A.

FIG. 11A illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter 104 can include a driver 1105, a thermistor 1120, a set of top-emitting LEDs 1102 for emitting red and/or infrared light, a set of side-emitting LEDs 1104 for emitting near infrared light, and a submount 1106.

The thermistor 1120 can be provided to compensate for temperature variations. For example, the thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors can be employed, for example, to measure a temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement site. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

The driver 1105 can provide pulses of current to the emitter 1104. In an embodiment, the driver 1105 drives the emitter 1104 in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor 110). For example, the driver 1105 can drive the emitter 1104 with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver 1105 can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter 1104. In some embodiments, the driver 1105 is capable of driving the emitter 1104 to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

The submount 1106 provides a support structure in certain embodiments for aligning the top-emitting LEDs 1102 and the side-emitting LEDs 1104 so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount 1106 is also constructed of aluminum nitride (AlN) or beryllium oxide (BeO) for heat dissipation, although other materials or combinations of materials suitable for the submount 1106 can be used.

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter 104 may be driven in a progressive fashion to minimize noise and increase SNR of sensor 101. For example, emitter 104 may be driven based on a progression of power/current delivered to LEDs 1102 and 1104.

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In some embodiments, emitter 104 may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 may emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, emitter 104 may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

For purposes of illustration, FIG. 11B shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs 1102. FIG. 11B also shows that emitter 104 may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs 1104. Emitter 104 may be progressively driven at higher power/current. This progression may allow driver circuit 105 to stabilize in its operations, and thus, provide a more stable current/power to LEDs 1102 and 1104.

For example, as shown in FIG. 11B, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term "slots" includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs 1102 may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4 time slots in between. In addition, pulses from side emitting LEDs 1104 (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit 1105 to stabilize after operating at higher current/power.

As shown in FIG. 11B, top emitting LEDs 1102 may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs 1102 may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs 502 for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter 104.

Subsequently, side emitting LEDs 1104 may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site 102 to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment, the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the current needed to drive side emitting LEDs 1104. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter 104.

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As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit 1105 to stabilize its power delivery to LEDs 1102 and 1104. Driver circuit 1105 may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a variable waiting period to allow for stabilization of driver circuit 1105. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system 100. That is, as the duty cycle is increased so may the signal to noise ratio.

Furthermore, as noted above, driver circuit 1105 may monitor temperatures of the LEDs 1102 and 1104 using the thermistor 1120 and adjust the output of LEDs 1102 and 1104 accordingly. Such a temperature may be to help sensor 101 correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter 104 can include components mounted on a substrate 1108 and on submount 1106. In particular, top-emitting LEDs 1102 for emitting red and/or infrared light may be mounted on substrate 1108. Side emitting LEDs 1104 may be mounted on submount 1106. As noted, side-emitting LEDs 1104 may be included in emitter 104 for emitting near infrared light.

As also shown, the sensor of FIG. 11C may include a thermistor 1120. As noted, the thermistor 1120 can be provided to compensate for temperature variations. The thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In some embodiments, the emitter 104 may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. In particular, an emitter 104 that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter 104 can include components mounted on a substrate 1108. In particular, top-emitting LEDs 1102 for emitting red and/or infrared light may be mounted on substrate 1108.

As also shown, the emitter of FIG. 11D may include a thermistor 1120. The thermistor 1120 can be provided to compensate for temperature variations. The thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 due to heating.

FIG. 12A illustrates a detector submount 1200 having photodiode detectors that are arranged in a grid pattern on the detector submount 1200 to capture light at different quadrants from a measurement site. One detector submount 1200 can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount 1200. The detector submount 1200 can also be used with the partially cylindrical protrusion 605 described above with respect to FIG. 6.

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The detectors include photodiode detectors 1-4 that are arranged in a grid pattern on the submount 1200 to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

As shown, the detectors 1-4 may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors 106 and the point light source discussed above.

Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site 102). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

FIGS. 12B through 12D illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors 106. As shown, detectors 106 may comprise photodiode detectors 1-4 that are arranged in a grid pattern on detector submount 1200 to capture light at different quadrants from measurement site 102.

As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors 106 may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors 106 may be employed by embodiments of the present disclosure.

For example, as shown in FIG. 12B, detectors 106 may comprise photodiode detectors 1-4 that are arranged in a substantially linear configuration on submount 1200. In this embodiment shown, photodiode detectors 1-4 are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors 1-4).

In FIG. 12C, photodiode detectors 1-4 may be arranged in a substantially linear configuration on submount 1200, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances $D1 > D2 > D3$). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

In FIG. 12D, a different substantially grid pattern on submount 1200 of photodiode detectors 1-4 is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

FIGS. 12E through 12H illustrate several embodiments of photodiodes that may be used in detectors 106. As shown in these figures, a photodiode 1202 of detector 106 may comprise a plurality of active areas 1204. These active areas 1204 may be coupled together via a common cathode 1206 or anode 1208 in order to provide a larger effective detection area.

In particular, as shown in FIG. 12E, photodiode 1202 may comprise two (2) active areas 1204a and 1204b. In FIG. 12F, photodiode 1202 may comprise four (4) active areas 1204c-f. In FIG. 12G, photodiode 1202 may comprise three (3)

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active areas 1204g-i. In FIG. 12H, photodiode 1202 may comprise nine (9) active areas 1204j-r. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode 1202.

FIG. 13 illustrates an example multi-stream process 1300. The multi-stream process 1300 can be implemented by the data collection system 100 and/or by any of the sensors described above. As shown, a control signal from a signal processor 1310 controls a driver 1305. In response, an emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302. As described above, in some embodiments, the pulse sequence 1303 is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence 1303 can be greater (or smaller).

In response to the pulse sequence 1300, detectors 1 to n (n being an integer) in a detector 1306 capture optical radiation from the measurement site 1302 and provide respective streams of output signals. Each signal from one of detectors 1-n can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets 1-n in the emitter 1304. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

A front end interface 1308 can accept these multiple streams from detectors 1-n and deliver one or more signals or composite signal(s) back to the signal processor 1310. A stream from the detectors 1-n can thus include measured light intensities corresponding to the light pulses emitted from the emitter 1304.

The signal processor 1310 can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor 1310 can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

The Beer-Lambert law is usually written as:

Absorbance $A = m * b * c$, where:

m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of $M^{-1} \text{ cm}^{-1}$);

b is the mean path length; and

c is the analyte concentration (e.g., the desired parameter).

In spectroscopy, instruments attempt to obtain the analyte concentration (c) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

$T = I/I_0$, where:

I is the light intensity measured by the instrument from the measurement site; and

I_0 is the initial light intensity from the emitter.

Absorbance (A) can be equated to the transmittance (T) by the equation:

$$A = -\log T$$

Therefore, substituting equations from above:

$$A = -\log (I/I_0)$$

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In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(I/I_0)$ and solving for analyte concentration (c).

Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (I_0), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude than what is achievable by currently available technology.

In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$T = e^{-m * b * c}$$

In terms of light intensity, this equation can also be rewritten as:

$$I/I_0 = e^{-m * b * c}$$

Or, at a detector, the measured light (I) can be expressed as:

$$I = I_0 * e^{-m * b * c}$$

As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in $I_1 \dots I_n$ streams of measurements. Assuming each of these detectors have their

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own path lengths, $b_1 \dots b_n$, from the light source, the measured light intensities can be expressed as:

$$I_n = I_o * e^{-m * b_n * c}$$

The measured light intensities at any two different detectors can be referenced to each other. For example:

$$I_1/I_n = (I_o * e^{-m * b_1 * c}) / (I_o * e^{-m * b_n * c})$$

As can be seen, the terms, I_o , cancel out and, based on exponent algebra, the equation can be rewritten as:

$$I_1/I_n = e^{-m(b_1 - b_n)c}$$

From this equation, the analyte concentration (c) can now be derived from bulk signals $I_1 \dots I_n$ and knowing the respective mean path lengths b_1 and b_n . This scheme also allows for the cancelling out of I_o , and thus, noise generated by the emitter 1304 can be cancelled out or reduced. In addition, since the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) 1302. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

FIG. 14A illustrates an embodiment of a detector submount 1400a positioned beneath the partially cylindrical protrusion 605 of FIG. 6 (or alternatively, the protrusion 605b). The detector submount 1400a includes two rows 1408a of detectors 1410a. The partially cylindrical protrusion 605 can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion 605 can act as a lens that focuses light onto a smaller area.

To illustrate, in some sensors that do not include the partially cylindrical protrusion 605, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

Applying the partially cylindrical protrusion 605 to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion 605 (see FIG. 14B). This is the example situation illustrated in FIG. 14—two rows 1408a of detectors 1410a are used instead of four. Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

In other embodiments, using the partially cylindrical protrusion 605 can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the

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detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion 605 (or alternatively, the protrusion 605b) that illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors. The protrusion 605 is placed above a detector submount 1400b having one or more detectors 1410b disposed thereon. The submount 1400b can include any number of rows of detectors 1410, although one row is shown.

Light, represented by rays 1420, is emitted from the emitters onto the protrusion 605. These light rays 1420 can be attenuated by body tissue (not shown). When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion 605. The refraction causes the rays 1422 to be focused or substantially focused on the one or more detectors 1410b. Since the light is focused on a smaller area, a sensor including the protrusion 605 can include fewer detectors to capture the same amount of light compared with other sensors.

FIG. 14C illustrates another embodiment of a detector submount 1400c, which can be disposed under the protrusion 605b (or alternatively, the protrusion 605). The detector submount 1400c includes a single row 1408c of detectors 1410c. The detectors are electrically connected to conductors 1412c, which can be gold, silver, copper, or any other suitable conductive material.

The detector submount 1400c is shown positioned under the protrusion 605b in a detector subassembly 1450 illustrated in FIG. 14D. A top-down view of the detector subassembly 1450 is also shown in FIG. 14E. In the detector subassembly 1450, a cylindrical housing 1430 is disposed on the submount 1400c. The cylindrical housing 1430 includes a transparent cover 1432, upon which the protrusion 605b is disposed. Thus, as shown in FIG. 14D, a gap 1434 exists between the detectors 1410c and the protrusion 605b. The height of this gap 1434 can be chosen to increase or maximize the amount of light that impinges on the detectors 1410c.

The cylindrical housing 1430 can be made of metal, plastic, or another suitable material. The transparent cover 1432 can be fabricated from glass or plastic, among other materials. The cylindrical housing 1430 can be attached to the submount 1400c at the same time or substantially the same time as the detectors 1410c to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing 1430 in various embodiments.

In certain embodiments, the cylindrical housing 1430 (and transparent cover 1432) forms an airtight or substantially airtight or hermetic seal with the submount 1400c. As a result, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c more effectively than currently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

In embodiments where the cylindrical housing 1430 is at least partially made of metal, the cylindrical housing 1430 can provide noise shielding for the detectors 1410c. For example, the cylindrical housing 1430 can be soldered to a ground connection or ground plane on the submount 1400c, which allows the cylindrical housing 1430 to reduce noise. In another embodiment, the transparent cover 1432 can include a conductive material or conductive layer, such as

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conductive glass or plastic. The transparent cover 1432 can include any of the features of the noise shields 790 described above.

The protrusion 605*b* includes the chamfered edges 607 described above with respect to FIG. 6E. These chamfered edges 607 can allow a patient to more comfortably slide a finger over the protrusion 605*b* when inserting the finger into the sensor 301*f*.

FIG. 14F illustrates a portion of the detector shell 306*f*, which includes the detectors 1410*c* on the substrate 1400*c*. The substrate 1400*c* is enclosed by a shielding enclosure 1490, which can include the features of the shielding enclosures 790*a*, 790*b* described above (see also FIG. 17). The shielding enclosure 1490 can be made of metal. The shielding enclosure 1490 includes a window 1492*a* above the detectors 1410*c*, which allows light to be transmitted onto the detectors 1410*c*.

A noise shield 1403 is disposed above the shielding enclosure 1490. The noise shield 1403, in the depicted embodiment, includes a window 1492*a* corresponding to the window 1492*a*. Each of the windows 1492*a*, 1492*b* can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows 1492*a*, 1492*b* may be selected to have different sizes or shapes from each other.

The noise shield 1403 can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield 1403 extends about three-quarters of the length of the detector shell 306*f*. In other embodiments, the noise shield 1403 could be smaller or larger. The noise shield 1403 could, for instance, merely cover the detectors 1410*c*, the submount 1400*c*, or a portion thereof. The noise shield 1403 also includes a stop 1413 for positioning a measurement site within the sensor 301*f*. Advantageously, in certain embodiments, the noise shield 1403 can reduce noise caused by light piping.

A thermistor 1470 is also shown. The thermistor 1470 is attached to the submount 1400*c* and protrudes above the noise shield 1403. As described above, the thermistor 1470 can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In the depicted embodiment, the detectors 1410*c* are not enclosed in the cylindrical housing 1430. In an alternative embodiment, the cylindrical housing 1430 encloses the detectors 1410*c* and is disposed under the noise shield 1403. In another embodiment, the cylindrical housing 1430 encloses the detectors 1410*c* and the noise shield 1403 is not used. If both the cylindrical housing 1403 and the noise shield 1403 are used, either or both can have noise shielding features.

FIG. 14G illustrates the detector shell 306*f* of FIG. 14F, with the finger bed 310*f* disposed thereon. FIG. 14H illustrates the detector shell 306*f* of FIG. 14G, with the protrusion 605*b* disposed in the finger bed 310*f*.

FIG. 14I illustrates a cutaway view of the sensor 301*f*. Not all features of the sensor 301*f* are shown, such as the protrusion 605*b*. Features shown include the emitter and detector shells 304*f*, 306*f*, the flaps 307*f*, the heat sink 350*f* and fins 351*f*, the finger bed 310*f*, and the noise shield 1403.

In addition to these features, emitters 1404 are depicted in the emitter shell 304*f*. The emitters 1404 are disposed on a submount 1401, which is connected to a circuit board 1419. The emitters 1404 are also enclosed within a cylindrical

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housing 1480. The cylindrical housing 1480 can include all of the features of the cylindrical housing 1430 described above. For example, the cylindrical housing 1480 can be made of metal, can be connected to a ground plane of the submount 1401 to provide noise shielding, and can include a transparent cover 1482.

The cylindrical housing 1480 can also protect the emitters 1404 from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing 1480 can provide a gap between the emitters 1404 and the measurement site (not shown), which can allow light from the emitters 1404 to even out or average out before reaching the measurement site.

The heat sink 350*f*, in addition to including the fins 351*f*, includes a protuberance 352*f* that extends down from the fins 351*f* and contacts the submount 1401. The protuberance 352*f* can be connected to the submount 1401, for example, with thermal paste or the like. The protuberance 352*f* can sink heat from the emitters 1404 and dissipate the heat via the fins 351*f*.

FIGS. 15A and 15B illustrate embodiments of sensor portions 1500A, 1500B that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

The sensor portions 1500A, 1500B shown include LED emitters 1504; however, for ease of illustration, the detectors have been omitted. The sensor portions 1500A, 1500B shown can be included, for example, in any of the emitter shells described above.

The LEDs 1504 of the sensor portions 1500A, 1500B are connected to a substrate or submount 1502. The submount 1502 can be used in place of any of the submounts described above. The submount 1502 can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable 1512 is attached to the submount 1502 and includes electrical wiring 1514, such as twisted wires and the like, for communicating with the LEDs 1504. The cable 1512 can correspond to the cables 212 described above.

Although not shown, the cable 1512 can also include electrical connections to a detector. Only a portion of the cable 1512 is shown for clarity. The depicted embodiment of the cable 1512 includes an outer jacket 1510 and a conductive shield 1506 disposed within the outer jacket 1510. The conductive shield 1506 can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield 1506 or a portion of the conductive shield 1506 can be electrically connected to the submount 1502 and can reduce noise in the signal generated by the sensor 1500A, 1500B by reducing RF coupling with the wires 1514. In alternative embodiments, the cable 1512 does not have a conductive shield. For example, the cable 1512 could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

Referring specifically to FIG. 15A, in certain embodiments, the conductive shield 1506 can act as a heat sink for the LEDs 1504 by absorbing thermal energy from the LEDs 1504 and/or the submount 1502. An optional heat insulator 1520 in communication with the submount 1502 can also assist with directing heat toward the conductive shield 1506. The heat insulator 1520 can be made of plastic or another suitable material. Advantageously, using the conductive shield 1506 in the cable 1512 as a heat sink can, in certain embodiments, reduce cost for the sensor.

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Referring to FIG. 15B, the conductive shield 1506 can be attached to both the submount 1502 and to a heat sink layer 1530 sandwiched between the submount 1502 and the optional insulator 1520. Together, the heat sink layer 1530 and the conductive shield 1506 in the cable 1512 can absorb at least part of the thermal energy from the LEDs and/or the submount 1502.

FIGS. 15C and 15D illustrate implementations of a sensor portion 1500C that includes the heat sink features of the sensor portion 1500A described above with respect to FIG. 15A. The sensor portion 1500C includes the features of the sensor portion 1500A, except that the optional insulator 1520 is not shown. FIG. 15D is a side cutaway view of the sensor portion 1500C that shows the emitters 1504.

The cable 1512 includes the outer jacket 1510 and the conductive shield 1506. The conductive shield 1506 is soldered to the submount 1502, and the solder joint 1561 is shown. In some embodiments, a larger solder joint 1561 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, a cylindrical housing 1580, corresponding to the cylindrical housing 1480 of FIG. 14I, is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15E and 15F illustrate implementations of a sensor portion 1500E that includes the heat sink features of the sensor portion 1500B described above with respect to FIG. 15B. The sensor portion 1500E includes the heat sink layer 1530. The heat sink layer 1530 can be a metal plate, such as a copper plate or the like. The optional insulator 1520 is not shown. FIG. 15F is a side cutaway view of the sensor portion 1500E that shows the emitters 1504.

In the depicted embodiment, the conductive shield 1506 of the cable 1512 is soldered to the heat sink layer 1530 instead of the submount 1502. The solder joint 1565 is shown. In some embodiments, a larger solder joint 1565 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, the cylindrical housing 1580 is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described above with respect to FIGS. 1 through 15F. Referring to FIG. 15G, the circuit board 1519 includes a female connector 1575 that mates with a male connector 1577 connected to a daughter board 1587. The daughter board 1587 includes connections to the electrical wiring 1514 of the cable 1512. The connected boards 1519, 1587 are shown in FIG. 15H. Also shown is a hole 1573 that can receive the cylindrical housing 1580 described above.

Advantageously, in certain embodiments, using a daughter board 1587 to connect to the circuit board 1519 can enable connections to be made more easily to the circuit board 1519. In addition, using separate boards can be easier to manufacture than a single circuit board 1519 with all connections soldered to the circuit board 1519.

FIG. 15I illustrates an exemplary architecture for front-end interface 108 as a transimpedance-based front-end. As noted, front-end interfaces 108 provide an interface that adapts the output of detectors 106 into a form that can be handled by signal processor 110. As shown in this figure, sensor 101 and front-end interfaces 108 may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor

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101 and front end interfaces 108 may comprise multiple components or circuits that are coupled together.

Front-end interfaces 108 may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors 106. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter 900 may be integrated with the transimpedance-based front-end in sensor 101.

Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector 106, the applicants developed a noise model to assist in configuring front-end 108. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

However, the following noise model was discovered by the applicants:

$$\text{Noise} = \sqrt{aR + bR^2}, \text{ where:}$$

aR is characteristic of the impedance of the transimpedance amplifier; and

bR^2 is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector 106.

The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors 1-4 (as shown, e.g., in FIG. 12A) may each comprise four photodiodes. In some embodiments, each detector of four photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in FIG. 15J.

Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors 1-4. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the

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transimpedance amplifiers in this setting may also be set according to the model shown in FIG. 15J.

As yet another alternative, as noted above with respect to FIGS. 12E through 12H, the photodiodes in detectors 106 may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

As noted, FIG. 15J illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

For example, an exemplary "4 PD per stream" sensor 1502 is shown where detector 106 comprises four photodiodes 1502. The photodiodes 1502 are coupled to a single transimpedance amplifier 1504 to produce an output stream 1506. In this example, the transimpedance amplifier comprises 10 M Ω resistors 1508 and 1510. Thus, output stream 1506 is produced from the four photodiodes (PD) 1502. As shown in the graph of FIG. 15J, the model indicates that resistance values of about 10 M Ω may provide an acceptable SNR for analytes like glucose.

However, as a comparison, an exemplary "1 PD per stream" sensor 1512 is also shown in FIG. 15J. In particular, sensor 1512 may comprise a plurality of detectors 106 that each comprises a single photodiode 1514. In addition, as shown for this example configuration, each of photodiodes 1514 may be coupled to respective transimpedance amplifiers 1516, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 M Ω resistors 1518. As also shown in the graph of FIG. 15J, the model illustrates that resistance values of 40 M Ω for resistors 1518 may serve as an alternative to the 4 photodiode per stream architecture of sensor 1502 described above and yet still provide an equivalent SNR.

Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor 1512 may provide enhanced performance because each of transimpedance amplifiers 1516 can be tuned or optimized to its respective photodiodes 1518. In some embodiments, an averaging component 1520 may also be used to help cancel or reduce noise across photodiodes 1518.

For purposes of illustration, FIG. 15K shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor 1522 may comprise a "4 PD per stream" architecture on a submount 700 in which each detector 106 comprises four (4) photodiodes 1524. As shown for sensor 1522, the output of each set of four photodiodes 1524 is then aggregated into a single transimpedance amplifier 1526 to produce a signal.

As another example, a sensor 1528 may comprise a "1 PD per stream" architecture on submount 700 in which each detector 106 comprises four (4) photodiodes 1530. In sensor 1528, each individual photodiode 1530 is coupled to a respective transimpedance amplifier 1532. The output of the amplifiers 1532 may then be aggregated into averaging circuit 1520 to produce a signal.

As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor 1534 illustrates an exemplary "4 PD per stream" sensor in which the detectors 106 comprise photo-

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diodes 1536 arranged in a linear fashion. Likewise, sensor 1538 illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes 1540 arranged in a linear fashion.

Alternatively, sensor 1542 illustrates an exemplary "4 PD per stream" sensor in which the detectors 106 comprise photodiodes 1544 arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor 1546 illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes 1548 also arranged in a zig-zag pattern.

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces 108 may be implemented using switched capacitor circuits and any number of front-end interfaces 108 may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface 1000 and signal processor 110. Switched capacitor circuits may be useful in system 100 for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces 108 may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front end interfaces 108 may require less computational power by signal processor 110 to perform the same amount of decimation to obtain the same SNR.

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors 1600. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors 1600 shown. For instance, the sensors 1600 can be used as the sensors 101 in the system 100 described above with respect to FIG. 1. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

The sensors 1600 include an adult/pediatric sensor 1610 for finger placement and a disposable infant/neonate sensor 1602 configured for toe, foot or hand placement. Each sensor 1600 has a tape end 1610 and an opposite connector end 1620 electrically and mechanically interconnected via a flexible coupling 1630. The tape end 1610 attaches an emitter and detector to a tissue site. Although not shown, the tape end 1610 can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

The sensor signal is communicated via the flexible coupling 1630 to the connector end 1620. The connector end 1620 can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGS. 2A through 2D. Alternatively, the connector end 1620 can mate directly with the monitor.

FIG. 17 illustrates an exploded view of certain of the components of the sensor 301/ described above. A heat sink 1751 and a cable 1781 attach to an emitter shell 1704. The emitter shell attaches to a flap housing 1707. The flap housing 1707 includes a receptacle 1709 to receive a cylin-

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dricial housing 1480/1580 (not shown) attached to an emitter submount 1702, which is attached to a circuit board 1719.

A spring 1787 attaches to a detector shell 1706 via pins 1783, 1785, which hold the emitter and detector shells 1704, 1706 together. A support structure 1791 attaches to the detector shell 1706, which provides support for a shielding enclosure 1790. A noise shield 1713 attaches to the shielding enclosure 1790. A detector submount 1700 is disposed inside the shielding enclosure 1790. A finger bed 1710 provides a surface for placement of the patient's finger. Finger bed 1710 may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion 1705 may also be disposed in the finger bed 1710. As shown, finger bed 1710 attaches to the noise shield 1703. The noise shield 1703 may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield 1703 may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

Noise shield 1703 may also comprise a thermistor 1712. The thermistor 1712 may be helpful in measuring the temperature of a patient's finger. For example, the thermistor 1712 may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor 1712 may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

Moreover, a flex circuit cover 1706 attaches to the pins 1783, 1785. Although not shown, a flex circuit can also be provided that connects the circuit board 1719 with the submount 1700 (or a circuit board to which the submount 1700 is connected). A flex circuit protector 1760 may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector 1760 may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector 1760 may be constructed from well known materials, such as a plastic or rubber materials.

FIG. 18 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor 101 were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

FIG. 19 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/Liposyn were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor 101 were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

FIGS. 20 through 22 shows other results that can be obtained by an embodiment of system 100. In FIG. 20, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with

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an embodiment of system 100 that comprised four LEDs and four independent detector streams. As shown, the system 100 obtained a correlation of about 85% and Arms of about 31 mg/dL.

In FIG. 21, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106. As shown, the system 100 was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

The results shown in FIG. 22 relate to total hemoglobin testing with an exemplary sensor 101 of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector channels from detectors 106. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

What is claimed is:

1. A user-worn device configured to non-invasively determine measurements of physiological parameter of a user, the user-worn device comprising:

a plurality of light emitting diodes (LEDs);

four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user; a protrusion comprising a convex surface and a plurality of openings extending through the protrusion, the openings arranged over the photodiodes and configured to allow light to pass through the protrusion to the photodiodes; and

one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

2. The user-worn device of claim 1, wherein the one or more processors are further configured to process the one or

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more signals to determine a bulk measurement indicating a positioning of the user-worn device.

3. The user-worn device of claim 1 further comprising optically transparent glass windows, each window extending across a different one of the openings.

4. The user-worn device of claim 1, wherein the plurality of LEDs and the photodiodes are positioned on a same side of tissue of the user.

5. The user-worn device of claim 1, wherein the protrusion further comprises an opaque material, and wherein the one or more signals are substantially free of noise caused by light piping.

6. A user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged on a surface and configured to receive light after at least a portion of the light has been attenuated by tissue of a user;

a protrusion arranged above the surface, the protrusion comprising a convex surface including windows, the windows extending across the four photodiodes, wherein light passes through the protrusion to the four photodiodes via at least the windows;

a thermistor configured to provide a temperature signal; and

one or more processors configured to:

receive one or more signals from at least one of the photodiodes;

receive the temperature signal; and

adjust operation of the user-worn device responsive to the temperature signal.

7. The user-worn device of claim 6, wherein the protrusion further comprises an opaque material, the opaque material extending from the convex surface of the protrusion to an interior surface of the protrusion opposite the convex surface.

8. A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes;

a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;

a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;

a separate optically transparent window extending across each of the openings;

one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;

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a housing; and

a strap configured to position the housing proximate tissue of the user when the device is worn.

9. The user-worn device of claim 8 further comprising a network interface configured to wirelessly communicate the measurements of the physiological parameter to at least one of a mobile phone or a computer network.

10. The user-worn device of claim 9 further comprising a user interface including a touch-screen display configured to display indicia responsive to the measurements of the physiological parameter.

11. The user-worn device of claim 10, wherein an orientation of the user interface is configurable responsive to a user input.

12. The user-worn device of claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation.

13. The user-worn device of claim 8 further comprising a storage device configured to at least temporarily store at least the measurements of the physiological parameter.

14. The user-worn device of claim 8, wherein the physiological parameter comprises pulse rate.

15. The user-worn device of claim 8 further comprising a thermistor.

16. The user-worn device of claim 8, wherein the openings are configured to prevent light piping.

17. The user-worn device of claim 8, wherein the housing hermetically seals at least a portion of an interior of the user-worn device.

18. The user-worn device of claim 8, wherein the windows comprise a conductive material.

19. The user-worn device of claim 8, wherein the windows are arranged on the protrusion configured to be in contact with tissue of the user.

20. A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:

a plurality of light emitting diodes (LEDs);

at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;

a protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and

one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

21. The user-worn device of claim 20, wherein the one or more processors are further configured to process the one or more signals to determine a bulk measurement indicating a positioning of the user-worn device.

22. The user-worn device of claim 20, wherein the plurality of LEDs and the photodiodes are positioned on a same side of the user's tissue.

23. The user-worn device of claim 20, wherein the one or more signals are substantially free of noise caused by light piping.

24. The user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping.

25. The user-worn device of claim 20, further comprising gaps between the photodiodes and the windows.

26. The user-worn device of claim 20, wherein the photodiodes are arranged in a quadrant configuration.

27. The user-worn device of claim 26, further comprising opaque walls surrounding the photodiodes.

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28. The user-worn device of claim 27, wherein the walls are configured to reduce mixing of light from distinct quadrants of the tissue.

29. The user-worn device of claim 20, wherein the protrusion further comprises one or more extensions.

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30. The user-worn device of claim 20, wherein the protrusion further comprises one or more chamfered edges.

* * * * *

JX-003

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 10,945,648 B2
APPLICATION NO. : 17/031316
DATED : March 16, 2021
INVENTOR(S) : Jeroen Poeze

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (60), Page 2, Column 1 at Line 10, Related U.S. Application Data, Change "which is a division" to --which is a continuation--.

Item (60), Page 2, Column 1 at Line 22, Related U.S. Application Data, Change "and a continuation-in-part" to --said application No. 12/829,352 is a continuation-in-part--.

In the Specification

In Column 35 at Line 8 (approx.), Change " $l_1/l_n = (l_o * e^{-mb_1c}) / (l_{oiL} * e^{-mb_n c})$ " to
-- $l_1/l_n = (l_o * e^{-mb_1c}) / (l_o * e^{-mb_n c})$ --.

In Column 38 at Line 22, Change "15008" to --1500B--.

In Column 38 at Line 53, Change "15008" to --1500B--.

Signed and Sealed this
Twentieth Day of April, 2021



Drew Hirshfeld
*Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office*

CERTIFICATE OF SERVICE

I hereby certify that, on this 5th day of April, 2024, I filed the Non-Confidential Brief for Appellant Apple Inc. with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Mark D. Selwyn

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**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME
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The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because:

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April 5, 2024