UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before the Honorable Monica Bhattacharyya
Administrative Law Judge

In the Matter of **CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF**	Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S OPENING *MARKMAN* BRIEF

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I. INTRODUCTION

For U.S. Patent No. 7,761,127 ("'127 patent") and U.S. Patent No. 10,687,745 ("'745 patent"), Complainants' terms for construction—"plurality of operating wavelengths" (from the '127 patent) and "second shape" (from the '745 patent)—are commonly understood, as demonstrated by Complainants' repetition of the terms "operating wavelength" and "shape" in their proposed constructions. They require no interpretation beyond their plain and ordinary meaning. Complainants' proposed addition of new phrases that are not found in the claims or specifications are unhelpful, add confusion, create redundancy, render meaningless express claim limitations, and lack basis in the intrinsic evidence.

As for U.S. Patent Nos. 10,912,501 (the "'501 Patent"), U.S. Patent No. 10,912,502 (the "'502 Patent") and U.S. Patent No. 10,945,648 (the "'648 Patent") (collectively, the "Asserted Poeze Patents"), the disputed term "bulk measurement" does not have a commonly understood meaning. The usage of "bulk measurement" in the asserted claims is irreconcilably inconsistent with the shared specification for the Asserted Poeze Patents, and therefore, the term is indefinite.

II. U.S. PATENT NO. 7,761,127

Claim Term	Proposed Constructions
"plurality of operating wavelengths" ('127 patent, cl. 7)	Complainants' Construction: "operating wavelength that varies with temperature"
	Apple's Construction: Plain and ordinary meaning (*i.e.*, two or more operating wavelengths)

A. Background

U.S. Patent No. 7,761,127 is entitled "Multiple Wavelength Sensor Substrate." The '127 patent states it is directed to a "physiological sensor [that] has emitters configured to transmit

optical radiation having multiple wavelengths in response to corresponding drive currents." '127 patent, Abstract.

The Summary of Invention observes that the plurality of "emission wavelengths [are] affected by one or more dynamic operating parameters," and describes "multiple operating wavelengths of the light emitting sources are determined dependent on a bulk temperature of the light emitting sources." '127 patent, 3:13-20. To perform that determination, "[a] thermal mass is disposed proximate the emitters so as to stabilize a bulk temperature for the emitters. … The temperature sensor provides a temperature sensor output responsive to the bulk temperature so that the wavelengths are determinable as a function of the drive currents and the bulk temperature." *Id*., Abstract. According to the specification, "[i]n one embodiment, an operating wavelength λ_a of each light emitter 710 is determined according to EQ. 3

$$\lambda_{a=f(}T_b, I_{drive}, \Sigma I_{drive})$$

where T_b is the bulk temperature, I_{drive} is the drive current for a particular light emitter … and ΣI_{drive} is the total drive current for all light emitters." '127 patent, 10:32-39; *see also, e.g.*, *id*., 3:2-8 (Light "sources have corresponding multiple operating wavelengths. A temperature sensor is thermally coupled to the thermal mass and is capable of determining a bulk temperature for the thermal mass, where the operating wavelengths are dependent on the bulk temperature.").

Asserted independent claim 7 requires, *inter alia*, "a plurality of light emitting sources … the sources having a corresponding ***plurality of operating wavelengths***":

> 7. [preamble] 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] a thermal mass;
>
> [b] 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;

[c] 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

[d] 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.

'127 patent, cl. 7.[1]

B. Parties' Claim Construction Dispute

The parties dispute whether the term "plurality of operating wavelengths" carries its plain and ordinary meaning, or whether the word "plurality" should be removed and replaced with the phrase "that varies with temperature." Complainants' construction should be rejected for numerous reasons, including because it is not necessary or helpful, injects confusing redundancy, renders meaningless an express claim limitation, and lacks any basis for adding a new limitation.

First, Complainants' proposed construction is unnecessary and unhelpful because "plurality," "operating," and "wavelengths" are all words in common parlance, and nothing in the intrinsic evidence imbues them with a special or unusual meaning. Complainants concede that the constituent term "operating wavelengths" would have been well-understood by skilled artisans and therefore requires no construction, because Complainants simply repeat the term "operating wavelengths" in their proposed construction. *See also supra* p. 2 (specification describing embodiment of how the "operating wavelength" of the light emitting sources can be "determined"). Because those words "are not technical terms of art, [they] do not require elaborate interpretation." *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001); *see also C.R. Bard, Inc. v.*

[1] Brackets added. All emphases added unless otherwise stated.

U.S. Surgical Corp., 388 F.3d 858, 863 (Fed. Cir. 2004) ("[C]ourts … regularly forgo detailed dictionary analyses if the term is as commonplace as 'conformable' or 'pliable'"); *Famosa, Corp. v. Gaiam, Inc*., 2012 WL 865687, at *2-3 (S.D.N.Y. Mar. 14, 2012) (explaining "courts should refrain from reading meaning into easily understandable terms" and declining to construe phrases because "their respective meanings are plain on their face").

Second, Complainants' proposed construction cannot be correct, and is unhelpful, because it would create confusing "redundan[cy]" in the claims. *Phillips v. AWH Corp*., 415 F.3d 1303, 1325 (Fed. Cir. 2005) (en banc) (rejecting construction that rendered dependent claim redundant); *see also Teashot LLC v. Green Mountain Coffee Roasters, Inc*., 2014 WL 485876, at *5 (D. Colo. Feb. 6, 2014) ("[P]atents are generally to be construed in a manner that avoids rendering superfluous any portion of a patent claim."), *aff'd,* 595 F. App'x 983 (Fed. Cir. 2015). Limitation 7[c] already requires a relationship between the operating wavelengths and bulk temperature, reciting, "the operating wavelengths dependent on the bulk temperature." '127 patent, cl. 7. There is no reason to add another requirement in limitation 7[b]—that each operating wavelength "varies with temperature"—because a temperature relationship is already expressly recited later in the claim.

Third, Complainants' construction is incorrect because it reads-out the word "plurality" and substitutes a new phrase—"that varies with temperature"—that appears nowhere in the specification. Complainants' attempt to excise the word "plurality" violates fundamental claim construction principles. *See Haemonetics Corp. v. Baxter Healthcare Corp*., 607 F.3d 776, 781 (Fed. Cir. 2010) (explaining courts should not "construe[] claims so as to render physical structures and characteristics specifically described in those claims superfluous"); *Bicon, Inc. v. Straumann Co*., 441 F.3d 945, 951 (Fed. Cir. 2006) (explaining that to read limitations out of a claim would

"be contrary to the principle that claim language should not be treated as meaningless"); *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1305-07 (Fed. Cir. 2000) (refusing to adopt construction which would render claim language "superfluous"). Likewise improper is Complainants' attempt to read-in a new claim limitation—the phrase "that varies with temperature." *Phillips*, 415 F.3d at 1323 (cautioning courts to "avoid the danger of reading limitations from the specification into the claim" and to avoid "importing limitations"); *see also Rothschild Connected Devices Innovations, LLC v. Coca-Cola Co*., 813 F. App'x 557, 561 (Fed. Cir. 2020) (non-precedential) ("[I]t is improper to import limitations from the specification into the claims."). Complainants' proposal finds no support in the intrinsic evidence. As previously explained, another claim limitation recites, "the operating wavelengths dependent on the bulk temperature"—*i.e.*, using different words than the proposed "varies with temperature." *See* '127 patent, cl. 7. The specification similarly does not use the phrase "varies with temperature." Instead, the specification states that, in certain embodiments, operating wavelengths "are determinable as a function of … the bulk temperature." *See* '127 patent, 2:62-65 (Summary of the Invention stating, "A temperature sensor provides a temperature sensor output responsive to the bulk temperature so that the wavelengths are determinable as a function of the drive currents and the bulk temperature."); 10:32-39 ("In one embodiment, an operating wavelength λ_a of each light emitter 710 is determined according to EQ. 3 $\lambda_{a=f(T_b, I_{drive}, \Sigma I_{drive})}$ where T_b is the bulk temperature, I_{drive} is the drive current for a particular light emitter … and ΣI_{drive} is the total drive current for all light emitters."). Complainants' attempt to change the language of the claim should be rejected.

Fourth, if the ALJ is inclined to give a construction, Apple's proposed elaboration should be accepted because it is consistent with the plain and ordinary meaning of the phrase. Dictionaries

define "plurality" as "the state of being plural … consisting of more than one." *See, e.g.*, Ex. 1 [Oxford English Dictionary] at 1. The Federal Circuit has similarly held that "plurality" means "two or more." *Dayco Prods., Inc. v. Total Containment, Inc*., 258 F.3d 1317, 1328 (Fed. Cir. 2001) (construing "'plurality … of projections'" to mean "'two or more'" projections); *see also York Prods., Inc. v. Cent. Tractor Farm & Family Ctr*., 99 F.3d 1568, 1575 (Fed. Cir. 1996) ("The term [plurality] means, simply, 'the state of being plural.'"). Thus, a "plurality of operating wavelengths" simply means "two or more operating wavelengths."

III. U.S. PATENT NO. 10,687,745

Claim Term	Proposed Constructions
"second shape" '745 patent, claims 1, 20	Complainants' Construction: "A shape that is different from the first shape beyond a change in size of the first shape"
	Apple's Construction: Plain and ordinary meaning (*i.e.*, a shape different than the first shape)

A. Background

U.S. Patent No. 10,687,745 is entitled "Physiological Monitoring Devices, Systems, and Methods" and is directed to "[a] non-invasive, optical-based physiological monitoring system." '745 patent, Abstract. Complainants assert infringement of claims 1-6, 8-9, 11, 14, 20-24, and 26-27, and Complainants rely on claims 15, 17, and 18 for domestic industry. Independent claims 1 and 20 require that a material positioned between the light-emitting diodes and tissue on a wrist of a user be 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," *e.g.*:

> 1. [1p] 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; and

[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**.**

'745 patent, cl. 1; *see also id*., cl. 20 (requiring "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").

The specification states that a "diffuser" can be "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." '745 patent, 3:5-14. In Figures 7A and 7B, the light emitter 702 transmits optical radiation and the "light diffuser receives the optical radiation emitted from the emitter 702 and homogenously spreads the optical radiation over a wide, donut-shaped area, such as the area outlined by the light diffuser 704 as

depicted in FIG. 7B." '745 patent, 10:52-11:2; *see id*. Fig. 7A & 7B (excerpted and with purple annotations below).

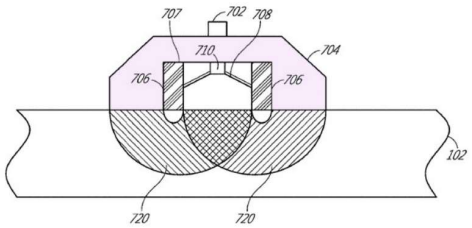

FIG. 7A

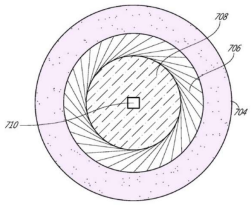

FIG. 7B

B. Parties' Claim Construction Dispute

The parties agree that the plain and ordinary meaning of the term "second shape" is "different than/from the first shape," but dispute whether a new phrase—"beyond a change in size of the first shape"—should also be added. Complainants' proposal should be rejected for multiple reasons, including because it is not necessary or helpful, adds a confusing new limitation, and lacks any basis.

First, Complainants' proposal is not helpful because it seeks to add new words and additional meaning to two elementary concepts—"second" and "shape"—that are already widely used and understood by both skilled artisans and laypersons. *See, e.g., Brown*, 265 F.3d at 1352 (simple, non-technical terms do not require construction); *Famosa*, 2012 WL 865687, at *2-3 ("courts should refrain from reading meaning into easily understandable terms" because "their respective meanings are plain on their face"). Complainants appear to agree that the word "shape"—which Complainants repeat in their proposed construction—is well-understood. The specification's usage of the word "shape" is consistent with that well-understood meaning. For example, the specification describes "shapes" that are "substantially rectangular, square, circular, oval, or annular, among others." '745 patent, 3:5-14; *see also id.* at 4:66-67 (describing a filter

that is "substantially rectangular in shape"); 6:24-50 (noting that the "irradiated surface area" can be "substantially rectangular in shape," "substantially square in shape," and "skilled artisan will appreciate that many other shapes and dimensions of irradiated surface area … can be used"); 8:9-14 (noting that "the diffuser 304 is capable of distributing the emitted light on the surface of a plane (e.g., the surface of the tissue measurement site 102) in a predefined geometry (e.g., a rectangle, square, or circle), and with a substantially uniform intensity profile and energy distribution").

Second, Complainants' proposal to add the words "beyond a change in size of the first shape" is also confusing for at least two reasons. To begin, Complainants' proposal seems to wrongfully imply that there must be ***at least*** a change in size for the second shape to be different from the first shape; in other words, if there is ***no*** change in area or size, Complainants' language implies there is no difference between the first shape and second shape. That cannot be correct because two images can have the same area but different shapes—e.g., rectangular, square, circular, annular. Moreover, Complainants' proposal places undue emphasis on changes in size not necessarily resulting in shape changes. Complainants seemingly seek to imply, in an *expressio unius* fashion, that any other changes necessarily result in a second shape that is different from the first shape. That, too, is misleading because two images can be different in ways other than size—*e.g.*, different color, different brightness, different polarization—but have the same shape. Where the claim language was clear, Complainants' attempt to add words injects ambiguity.[2]

[2] Complainants' expert, Dr. Madisetti, describes the prosecution history of a related patent application, U.S. Patent Application No. 16/532,065, wherein the examiner's non-final rejection "cited [prior art references] Fei and Scharf for the disclosure of lenses that could alter a light beam by changing its size." Ex. 2 [Expert Report of Vijay K. Madisetti, Ph.D. Regarding Claim Construction ("Opening Madisetti Rpt.")], ¶¶ 62-65. After an interview with the applicant, the examiner issued a Notice of Allowance amending the claim to recite "a material configured to alter the first shape into a second shape by which the light is emitted from one or more of the plurality of emitters is distributed onto a surface of the tissue measurement site." *Id.*, ¶ 68 (citing March 9,

Third, if the ALJ is inclined to give a construction, Apple's proposed elaboration should be adopted. Both parties agree that "second" means "different than/from the first." That construction consistent with the Federal Circuit's definition of "second" as identifying an element that is different than the "first." *See, e.g.*, *Gillette Co. v. Energizer Holdings, Inc*., 405 F.3d 1367, 1373 (Fed. Cir. 2005) (construing "'first,' 'second,' and 'third' blades" and holding "these ordinal terms designate different blades"); *Free Motion Fitness, Inc. v. Cybex Int'l, Inc*., 423 F.3d 1343, 1348 (Fed. Cir. 2005) (holding that the "'second pivot point'" "distinguishes the pivot point on the 'first extension arm'"). Thus, the "second shape" simply means "a shape different than the first shape."

IV. U.S. PATENT NOS. 10,912,501, 10,912,502, AND 10,945,648

A. Background

U.S. Patent Nos. 10,912,501 (the "'501 Patent"), U.S. Patent No. 10,912,502 (the "'502 Patent") and U.S. Patent No. 10,945,648 (the "'648 Patent") (collectively, the "Asserted Poeze Patents"), each entitled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," focus on user-worn devices for the non-invasive measurement of blood constituents, such as blood oxygen level.

As the Background section of the shared specification confirms, at the time of the original filing, the "standard of care" for patient monitoring included "spectroscopic analysis using, for

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2020 Notice of Allowance (MASITC_00267742)). The applicant then submitted an interview summary stating: "'Agreement was reached that Applicant's proposed claim amendments, which reflect a change in shape of emitted light beyond a change in size, defined over the Examiner's citation of judicial notice of emitted light passing through a lens.'" *Id*., ¶¶ 65-69 (quoting March 23, 2020 Summary of Interview at 1 (MASITC_00267717)). At most, that interview summary memorializes the applicant's disclaimer that a change in size is ***not sufficient*** to produce a change in shape. The context of the office actions, amendments, and interview summary does not suggest, however, that a change in size is necessary to produce a change in shape or that it could be the only change that does not produce a change in shape.

example, a pulse oximeter." '501 patent, 2:15-17; '502 patent, 2:15-17; '648 patent, 2:14-16; Ex. 3 [Initial Expert Claim Construction Report of Steven Warren Ph.D. ("Initial Warren Rpt.")] ¶ 34. These well-known devices typically included multiple light emitters for "transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood" and multiple photodetectors for "detect[ing] the attenuated light and output[ting] a detector signal(s) responsive to the detected attenuated light" after it passed through the tissue. '501 patent, 2:17-23; '502 patent, 2:17-23; '648 patent, 2:16-22; Ex. 3 [Initial Warren Rpt.] ¶¶ 34-35. A processor would then process the detected signals and output a "measurement indicative of a blood constituent of interest," such as blood oxygen level. '501 patent, 2:24-29; '502 patent, 2:24-29; '648 patent, 2:23-28; Ex. 3 [Initial Warren Rpt.] ¶ 36.

The specification discloses a variety of finger-worn devices for measuring a user's physiological conditions. Ex. 3 [Initial Warren Rpt.] ¶¶ 37-38. For example, Figures 3A, 3C, and 7B illustrate traditional clothespin-shaped user-worn pulse oximeters, with the light emitters (e.g., LEDs) located in the top portion of the device's housing and the light detectors (e.g., photodiodes) located in the bottom portion of the device's housing:

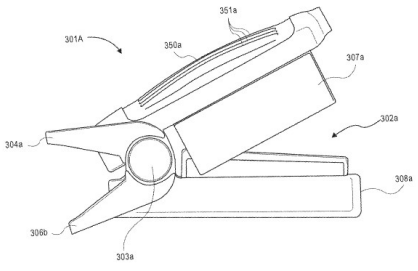

FIG. 3A

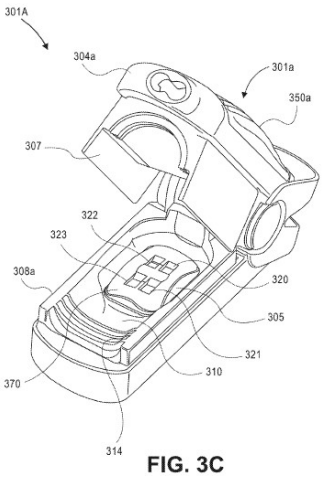

FIG. 3C

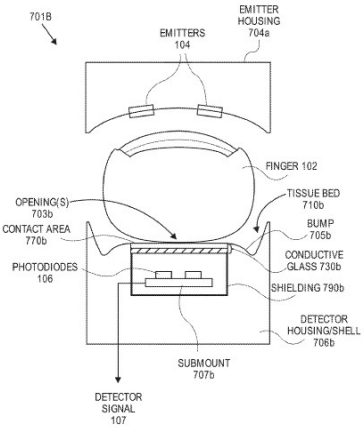

FIG. 7B

’501 patent, Figs. 3A, 3C, 7B; ’502 patent, Figs. 3A, 3C, 7B; ’648 patent, Figs. 3A, 3C, 7B; Ex. 3 [Initial Warren Rpt.] ¶ 40.

The specification does not identify the purported novelty of any of the exemplary devices described in the patents. Instead, it contends that the described devices can alternatively be used anywhere on a patient’s body (e.g., “finger, foot, ear lobe, or the like”) and can include any arrangement of light emitters (e.g., “one or more” “sets” of “LEDs, laser diodes, incandescent bulbs . . . or the like”), any arrangement of photodetectors (e.g., multiple “photodiodes, phototransistors, or the like” arranged in “any . . . spacing scheme”), and a “tissue shaper” or protrusion of any shape (e.g., “flat,” “substantially flat,” “convex,” “substantially convex,” or “concave”). ’501 patent, 10:65-68, 12:6-7, 14:18-19, 14:30-34; 11:4-23; ’502 patent, 10:65-68, 12:6-7, 14:18-19, 14:30-34; 11:4-23; ’648 patent, 10:59-61, 12:1-2, 14:13-14, 14:26-30; 10:66-11:18.

The asserted claims—added to Masimo’s applications twelve years after the original filing and a week after Apple introduced the accused Apple Watches—claim specific combinations and arrangements of these well-known elements that Complainants allege are used by the accused Apple Watches but that are not disclosed, together, in any of the examples in the shared specification.

The dependent claims also include various additional concepts that are mentioned only briefly in the specification. “Bulk measurement” is one such concept that is mentioned only briefly in the shared specification for the Asserted Poeze Patents. The shared specification states that “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." '501 patent, 34:49-54; '502 patent, 34:44-49; '648 patent, 34:32-37; Ex. 3 [Initial Warren Rpt.] ¶ 52. The shared specification further states that "***multiple detectors*** are employed and arranged in a spatial geometry" and that "[t]his 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." '501 patent, 9:18-22; '502 patent, 9:18-22; '648 patent, 9:13-17.[3]

Notably, the shared specification of the Asserted Poeze Patents does not mention a "bulk measurement" in the context of a single emitter (e.g., an LED) or single detector (*e.g.*, a photodiode). Although the specification describes a "bulk measurement" only in the context of multiple signals from multiple photodiodes, the claims recite a bulk measurement that can be taken from as few as ***one*** signal from ***one*** photodiode.

The term "bulk measurement" appears in dependent claim 13 of the '501 patent, dependent claim 12 of the '502 patent, and dependent claims 2 and 21 of the '648 patent. For example, claim 1 of the '648 patent requires the following:

> 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

[3] The path lengths referenced in the specification relate to the distances light travels between an emitter (or emitters) and the respective detectors. *See* Ex. 3 [Initial Warren Rpt.] ¶ 54. As the specification explains, a diversity of path lengths is achieved where there are multiple detectors in a spatial geometry. *Id.* A spatial arrangement of multiple detectors achieves a diversity of path lengths because the distance the light from each emitter travels to reach each detector will be different, and therefore reflected in the signal from each detector. *Id.* The specification always refers to the use of multiple detectors to achieve a diversity of path lengths and does not explain how a single signal from a single detector could reflect such a diversity.

> 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.

'648 patent, cl. 1. Dependent claim 2 of the '648 patent then recites determining a "bulk measurement" based upon the "one or more signals from at least one of the photodiodes" from independent claim 1 above:

> 2. 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*** indicating a positioning of the user-worn device.

'648 patent, cl. 2. Thus, the "bulk measurement" in dependent claim 2 of the '648 patent can be determined using as few as one signal from one photodiode, as expressed in independent claim 1. Likewise, dependent claim 13 of the '501 patent, dependent claim 12 of the '502 patent, and dependent claim 21 of the '648 patent similarly recite the determination or calculation of a "bulk measurement" responsive to, or indicating, a positioning of the device from the "one or more signals" from the photodiodes in their respective independent claims. *See* '501 patent at claim 1; '502 patent at claim 1; '648 patent at claim 20.

B. Parties' Claim Construction Dispute

Claim Term	Proposed Constructions
"bulk measurement" ('501 patent, cl. 13) ('502 patent, cl. 12) ('648 patent, cls. 2, 21)	Complainants' Construction: "baseline measurement" Apple's Construction: Indefinite

The parties dispute the meaning of the term "bulk measurement." Apple contends that the term "bulk measurement" as used in the claims is indefinite. Complainants argue that the term should be construed as a "baseline measurement." The ALJ should adopt Apple's proposal and find "bulk measurement" indefinite.

First, as confirmed by Apple's expert Dr. Steven Warren—who has over 30 years of experience in the field of physiological monitoring technologies—the term "bulk measurement" is not a term of art. The term does not—and did not as of the alleged priority date of the Asserted Patents—have a commonly understood meaning to a POSITA. Ex. 3 [Initial Warren Rpt.] ¶¶ 4-15, 50. Both sides agree a POSITA would thus have been required to examine the shared specification of the Asserted Poeze Patents to attempt to ascertain the meaning of "bulk measurement." *Id.* ¶ 50; *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.").

Second, the specification and claims are fatally inconsistent with each other on the meaning of the term "bulk measurement." The specification confirms that a "bulk measurement" is one obtained from ***multiple*** signals from ***multiple*** photodiodes. The claims, however, specifically recite a "bulk measurement" that can be obtained from as few as ***one*** signal from ***one*** photodiode. *See* '648 patent, cl. 2 (requiring "one or more signals to determine a bulk measurement" where the "one or more signals [are] from at least one of the photodiodes" in independent claim 1), cl. 21; '501 patent, cl. 13; '502 patent, cl. 12. As the Federal Circuit has confirmed, the claims in a patent must be construed so that their meaning is consistent with the full scope of the claim, which in the case of the Asserted Poeze Patents, is a "bulk measurement" obtained from as few as one signal. "To construe the claims otherwise would ignore the plain meaning of the words of the claims themselves." *Atl. Rsch. Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1354 (Fed. Cir. 2011) (quotation omitted).

Nowhere does the specification explain how a single signal (or output stream) from a single detector (e.g., single photodiode) could be used to determine a bulk measurement. Ex. 3 [Initial Warren Rpt.] ¶ 56. Rather, the specification explicitly states the opposite—that a bulk measurement is obtained using ***multiple*** detectors:

> [T]he ***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.

'501 patent, 34:49-54. As the specification further explains:

> 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.

'501 patent, 9:18-25; '502 patent, 9:18-25; '648 patent, 9:13-20; Ex. 3 [Initial Warren Rpt.] ¶ 57. As these disclosures confirm, each detector provides an output stream or signal. As the specification explains and Dr. Warren confirms, each of the multiple detectors provides its own output stream or signal. This accounts for a diversity of path lengths because the light from an emitter travels a different distance to each detector. Ex. 3 [Initial Warren Rpt.] ¶ 54. The signals from the detectors then reflect that diversity of path lengths. *Id*. The specification does not explain how an output stream, or signal, from a single detector (1) can achieve a diversity of path lengths or (2) can be used to determine a bulk measurement. *Id.* In sharp contrast to the specification, the claims recite a "bulk measurement" that can be taken from as few as ***one*** signal from ***one*** photodiode.

In this case, the specification's description of a "bulk measurement" cannot be reconciled with the scope of the claim language reciting the ability to determine a "bulk measurement" from a single signal. The claims are thus invalid because a POSITA would have no understanding of what the claims mean by a "bulk measurement." Ex. 3 [Initial Warren Rpt.] ¶¶ 49-62; *see Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014) ("[A] patent's claims, viewed in light of the specification and prosecution history, [must] inform those skilled in the art about the scope of the invention with reasonable certainty."); *Application of Cohn*, 438 F.2d 989, 993 (C.C.P.A. 1971) (affirming claims as indefinite where they were "inherently inconsistent" with the "description, definitions and examples" in the specification); *Smartmetric Inc. v. Am. Exp. Co.*, 476 F. App'x 742, 744 (Fed. Cir. 2012) (rejecting construction that "would deviate from the term's plain and ordinary meaning, conflict with the specification, and erroneously rewrite the claims"). Thus, claim 13 of the '501 patent, claim 12 of the '502 patent, and claims 2 and 21 of the '648 patent are invalid as indefinite.

Third, as Dr. Warren again confirms, a POSITA would not understand "bulk measurement" to mean "baseline measurement," as Complainants contend. Ex. 3 [Initial Warren Rpt.] ¶ 63. Complainants' expert Dr. Madisetti contends that a "bulk measurement" "is a non-pulsatile measurement, also known as the DC-component of a signal." Ex. 2 [Opening Madisetti Rpt.] ¶ 46. He further contends that a "baseline measurement" is "the non-pulsatile or DC component of a signal." *Id.* ¶ 50.[4] He therefore concludes that a "bulk measurement" is a "baseline measurement." This argument fails both as a matter of logic and because Dr. Madisetti's premises are inconsistent with the underlying technology and the specification. *See* Ex. 4 [Rebuttal Expert Claim Construction Report of Steven Warren, Ph.D. ("Rebuttal Warren Rpt.)] ¶¶ 13-31.

[4] Dr. Madisetti uses DC component and non-pulsatile component interchangeably.

To begin with, the specification does not support Dr. Madisetti's reasoning that a "bulk measurement" is a non-pulsatile or DC component. Dr. Madisetti focuses, for example, on the specification's statement that "[s]ome embodiments can employ a ***bulk, non-pulsatile measurement*** in order to confirm or validate a pulsatile measurement." '501 patent, 34:35-37; *see* Ex. 2 [Opening Madisetti Rpt.] ¶ 44. Contrary to Dr. Madisetti's argument, this statement simply confirms that the measurement has two characteristics: (1) a "bulk" characteristic; and (2) a "non-pulsatile" characteristic. Ex. 4 [Rebuttal Warren Rpt.] ¶¶ 18-22. As Dr. Warren explains, a POSITA would have understood that "bulk" and "non-pulsatile" are both used as adjectives to describe two separate characteristics of the measurement—that the measurement uses multiple signals from multiple detectors and that the measurement is non-pulsatile. Ex. 4 [Rebuttal Warren Rpt.] ¶ 17. This is like describing a car as a "red, convertible car." "Red" and "convertible" both describe the car but are not interchangeable or synonymous descriptions. The specification, in fact, describes the "bulk" characteristic of a "bulk, non-pulsatile measurement" as requiring signals from multiple detectors. The specification consistently explains that "the use of ***multiple-detectors in a spatial configuration allow for a bulk measurement*** to confirm or validate that the sensor is positioned correctly." '501 patent, 34:49-51, *see* 9:18-22. Accordingly, the non-pulsatile measurements referenced in the specification can have an additional "bulk" aspect when they are performed using multiple detectors. Ex. 4 [Rebuttal Warren Rpt.] ¶ 17. Again, the "bulk" characteristic of the measurement is different from the "non-pulsatile" characteristic for the measurement. A POSITA at the time of the alleged invention would not have understood a "bulk measurement" to be a DC component of a signal as Dr. Madisetti suggests.

Similarly flawed is Dr. Madisetti's opinion that a "baseline measurement" is a non-pulsatile, DC component of a signal. As an initial matter, the specification ***never*** references a

"baseline measurement" or a "DC component" of a signal. Because there is no mention of these concepts anywhere in the intrinsic record, Dr. Madisetti looks to two extrinsic references to try to explain the "baseline measurement" concept: (1) J. G. Webster's 1997 book Design of Pulse Oximeters ("Webster 1997") (Ex. 6); and (2) U.S. Patent No. 4,892,101 to Cheung et al. ("Cheung") (Ex. 7). Although these two references describe a "baseline" component, as Dr. Warren explains, both actually ***differentiate*** the "baseline component" from the "DC component" of a signal. Ex. 4 [Rebuttal Warren Rpt.] ¶¶ 23-29. Therefore, a POSITA would not have understood that a "baseline measurement" is a "DC component" of a signal. Moreover, neither reference uses the term "bulk measurement." Thus, despite Dr. Madisetti's best efforts, he was unable to identify any reference that defines the term "bulk measurement" as a "baseline measurement" or a DC component of a signal. Dr. Madisetti's rebuttal report also contends that "normalized" signals use a DC component, but this argument is unconnected to the meaning of a "bulk measurement." *See* Ex. 5 [Rebuttal Expert Report of Vijay K. Madisetti, Ph.D. Regarding Claim Construction] ¶ 10.

Finally, if the applicant for the Asserted Poeze Patents, Masimo, believed it was entitled to a claim to a "baseline," "non-pulsatile," or "DC" component (despite the paucity of any such disclosures), it should have specified that feature in the claims. The ALJ should not permit Complainants to rewrite the claims to substitute one indefinite term ("bulk measurement") with another ("baseline measurement"). *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008) ("Courts cannot rewrite claim language."); *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) ("[C]ourts can neither broaden nor narrow claims to give the patentee something different than what he has set forth.") (internal quotations omitted).

V. CONCLUSION

For the reasons set forth above, Apple's proposed constructions should be adopted.

Dated: January 27, 2022

Respectfully Submitted,

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EXHIBIT 1

plurality, *n.*

Pronunciation: Brit. /plʊəˈralɪti/, /plɔːˈralɪti/, /plɜːˈralɪti/, U.S. /plʊˈrælədi/, /pləˈrælədi/

Forms: Middle English **pluralite**, Middle English **pluralitte**, Middle English **pluralte** , Middle English–1500s **pluralyte**, 1500s **pluralytie**, 1500s–1600s **pluralitie**, 1500s–1600s **pluralitye**, 1500s– **plurality**, 1600s **plurallitie**, 1600s **plurallity**; *Scottish* pre-1700 **pluralite**, pre-1700 **pluralitee**, pre-1700 **pluraltie**, pre-1700 **prurality** (*rare*), pre-1700 1700s– **plurality**, pre-1700 1900s– **pluralitie**.

Frequency (in current use):

Origin: Of multiple origins. Partly a borrowing from French. Partly a borrowing from Latin. **Etymons:** French *pluralité*; Latin *pluralitas*.

Etymology: < Anglo-Norman *pluralité*, *pluralitee*, *pluralitie* and Middle French *pluralité* (French *pluralité*) state of being plural, multiplicity (second half of the 13th cent. in Old French), the plural number (*c*1320), great number, multitude (*c*1350), majority (1511) and their etymon post-classical Latin *pluralitas* the plural number, state of being more than one (4th cent.), great number, multitude (6th cent.), the holding of two or more benefices concurrently (from late 12th cent. in British sources), majority (*c*1343, *c*1450 in British sources) < classical Latin *plūrālis* PLURAL *adj.* + *-tās* (see -TY *suffix*[1]; compare -ITY *suffix*).

1.

a. The state of being plural; the fact or condition of denoting, comprising, or consisting of more than one; (also) an instance of this. Also: the fact of there being many or much; numerousness, plentifulness.

▸ *a*1398 J. TREVISA tr. Bartholomaeus Anglicus *De Proprietatibus Rerum* (BL Add.) f. 118ᵛ Plyades ben seuene sterris, and hauen þat name of..pluralite, for þey beoþ many.

?*a*1425 tr. Guy de Chauliac *Grande Chirurgie* (N.Y. Acad. Med.) f. 151 Þe byrþ is made hard for pluralite of birþez [?*c*1425 *Paris* for many children].

?*a*1475 (▸ ?*a*1425) tr. R. Higden *Polychron.* (Harl. 2261) (1865) I. 27 (*MED*) I haue studiede that hit schal be called Policronicon of the pluralite of tymes whom it dothe conteyne.

*a*1500 (▸ 1413) *Pilgrimage of Soul* (Egerton) (1953) v. ii. f. 90ᵛ (*MED*) So wold he than, be distribucion of many hundred yeres suyng be succession..schewe the pluralite of worldes.

1533 J. BELLENDEN tr. Livy *Hist. Rome* (1901) I. I. Prol. 7 In sic pluralite of writaris my fame is obscure and of litill estimatioun.

1563 *2nd Tome Homelyes* Cert. Places Holy Script. I, in J. Griffiths *Two Bks. Homilies* (1859) II. 374 The plurality of wives was by a special prerogative suffered to the fathers of the Old Testament.

1616 B. JONSON *Epicœne* IV. iii, in *Wks.* I. 571 Doe you count it lawfull to haue such pluralitie of seruants?

1624 T. GATAKER *Discuss. Transubstant.* 183 To shew how in one nature there may be a plurality of persons.

1659 J. PEARSON *Expos. Apostles Creed* ii. 271 The plurality of the verb, and the neutrality of the noun,..speak a perfect identity of their essence.

1728 E. CHAMBERS *Cycl.* (at cited word) A Plurality of Worlds is a thing which Mr. Huygens has endeavoured to prove in his Cosmotheoros.

1781 E. GIBBON *Decline & Fall* II. xviii. 103 Many of the Armenian nobles still refused to abandon the plurality of their gods and of their wives.

*a*1834 S. T. Coleridge *Specimens of Table Talk* (1835) II. 61 It is very natural to have a dual, duality being a conception quite distinct from plurality.

1898 J. R. Illingworth *Divine Immanence* (1904) vii. 86/2 The fact that there is plurality, triune plurality in God.

1932 *Mod. Lang. Notes* **47** 320 The first important association of the heliocentric hypothesis with the theory of a plurality of inhabited worlds seems to have been made by Giordano Bruno.

1991 S. Woolf *Napoleon's Integration of Europe* ii. 48 The very plurality of sources of power under the Directory..sometimes offered the possibility to local patriots to transform provisional administrations into new republics.

b. A large number or quantity *of*; a multitude, a profusion.

1657 E. Calamy *Evid. for Heaven* 160 The Position of the Apostle, is confirmed by a plurality of witnesses.

1701 T. D'Urfey *Bath* v. i. 46 It may be so where she is singly imploy'd, and where there are a plurality of Lovers.

1784 E. Allen *Reason* viii. §1. 286 There will be an uncertain plurality '*of last days*', which must be understood to be short of a month, or a year.

1839 C. Dickens *Nicholas Nickleby* ix. 75 Mrs Squeers, when excited, was accustomed..to make use of a plurality of epithets.

1866 J. E. T. Rogers *Hist. Agric. & Prices* I. xx. 512 The money-chest was also secured by a plurality of locks.

1931 *Official Gaz.* (U.S. Patent Office) 1 Dec. 270/2 Covering a plurality of laminations of the impregnated wood with a surface coating of powdered phenolic resin.

1994 *Lay Witness* Nov.–Dec. 3/2 Setting a table with a plurality of china, crystal, cutlery, and napery cannot be accomplished unless there is a table in the first place.

2.

a. The holding of two or more benefices or livings concurrently by one member of the clergy. Also: an instance of this practice; a benefice or living held concurrently with another or others (chiefly in *plural*).

*c*1400 (▸ *a*1376) W. Langland *Piers Plowman* (Trin. Cambr. R.3.14) (1960) A. xi. 200 Dewid he is also, And haþ possessions & pluralites [*v.r.* pluraltes] for pore menis sake.

*c*1450 *Jacob's Well* (1900) 18 Alle þey bene acursed þat receyvin & holdyn pluralyte of cherchys.

1551 R. Crowley *Pleasure & Payne* sig. Dii Geue ouer your pluralities..Betake you to one benifice.

1574 J. Studley tr. J. Bale *Pageant of Popes* f. 79ᵛ He..concluded many thinges against dualities, pluralityes, and totquots.

1642 J. Milton *Apol. Smectymnuus* 57 Who ingrosse many pluralities under a non-resident and slubbring dispatch of soules.

1680 R. Baxter *Church-hist. Govt. Bishops* xii. 400 The Legate was in danger for opposing Pluralities.

*a*1715 Bp. G. Burnet *Concl. Hist. Own Time* (1741) 24 I do not reckon the holding poor Livings that lie contiguous, a Plurality, where both are looked after, and both afford only a competent Maintenance.

1750 J. Mayhew *Disc. Submission* 25 A number of Reverend and Right Reverend Drones..who preached..not the gospel of Jesus Christ; but the divine right of tythes;—the dignity of their office as ambassadors of Christ,..a plurality of benefices, [etc.].

*a*1817 T. Dwight *Trav. New-Eng. & N.-Y.* (1821) II. 50 There are two congregations in North-Haven: a Presbyterian, and an Episcopal. The latter is a small plurality, under the care of a neighbouring minister.

1868 E. A. FREEMAN *Hist. Norman Conquest* II. vii. 82 With that double see he had held..the Bishoprick of Worcester in plurality.

1906 *Times* 12 Oct. 9/1 Plurality of livings, once the rule, has now become the exception.

1996 *Church Times* 19 July 4/1 They..decided to permit one person to hold two churchwardenships, only if they were in parishes already linked through plurality or having the same minister.

b. *gen.* The holding of two or more offices or positions concurrently; an instance of this.

1647 W. PRYNNE *Hypocrites Vnmasking* 7 He hath a plurallity of Offices of very great trust and profit.

1678 LADY CHAWORTH in *12th Rep. Royal Comm. Hist. MSS* (1890) App. v. 47 Some mention the laying sums upon all pluralities of qualities, dignities, and offices.

1757 W. SMITH *Hist. Province N.-Y.* v. 152 The Secretary enjoys a Plurality of Offices, conversant with the first Springs of our provincial Oeconomy.

1850 C. LYELL *2nd Visit U.S.* (ed. 2) II. 82 Some wealthy slave-owners of Alabama have estates in Mississippi. With a view of checking the increase of these 'pluralities', a tax has recently been imposed on absentees.

1893 *Law Times* **94** 452/1 There is a growing feeling that plurality in the matter of directorships is dangerous and to be deprecated.

1977 *Musical Times* Feb. 120/2 He criticized their neglect of duties and the plurality of appointments that was its cause.

2004 *Financial Times* (Nexis) 26 Oct. 21 One of the first advocates for plurality of directorships, Mr Leighton holds the chairmanships of the Royal Mail and the BHS retail business and is a non-executive director at British Sky Broadcasting.

3. Originally *Scottish*. More than half of the whole or of the total number (esp. in an election, referendum, etc.); = MAJORITY *n.*[1] 3a. In early use also: †the fact of there being a majority (*obsolete*).

*c*1570 *Art of Music* (BL Add. 4911) f. 9[v], in *Dict. Older Sc. Tongue* at *Pluralite(e* Guid it war to..follow the pluralitie of the nationis of all vther regionis.

1578 *38th Gen. Assembly* in A. Peterkin *Bk. Universall Kirk Scotl.* (1839) 178 For electioun of ane Moderatour, Mrs John Row, David Fargysone and John Duncansone, was proponit in leets, and be pluralitie of votes, Mr John Row was chosen Moderator.

1581 *Art of Music* 522 The said Mr Johne, be pluralitie of votes, was chosin Moderator hac vice.

1600 E. BLOUNT tr. G. F. di Conestaggio *Hist. Uniting Portugall to Castill* 228 The pluralitie of voices refusing to accept the armes.

1651 T. HOBBES *Leviathan* xlii. 290 To bring the people together, to elect them by plurality of Votes.

1683 J. EVELYN *Mem.* (1857) II. 187 The plurality of the younger judges and rising men judged it otherwise.

1703 DUKE OF QUEENSBERRY in H. Ellis *Orig. Lett. Eng. Hist.* (1827) 2nd Ser. IV. No. 394. 227 This was thrown out by a great plurality.

1786 *Daily Universal Reg.* 3 Oct. 2/1 The States of Holland and West Frisseland have determined, by a plurality of sixteen to three voices, to [etc.].

1794 *Hist.* in *Ann. Reg.* 91/1 The plurality..of their chiefs endeavoured in vain to stem the torrent of disobedience.

1823 *Niles' Reg.* **24** 217/2 At the late election..[in Maine], only three gentlemen were chosen... Neither of the others had a plurality of the whole number of votes.

1871 B. JOWETT in tr. Plato *Dialogues* I. 72 Socrates would rather not decide the question by a plurality of votes.

1928 H. W. SCHNEIDER *Making Fascist State* iii. 88 The bill provided that whichever party should get the plurality of votes in the nation as a whole, should be given two thirds of all the seats.

1991 *Internat. Jrnl. Law & Family* **5** 236 The court disagreed as to whether this shifting of the burden to the defendant was following precedent or taking a new turn. The plurality stated it was not a new interpretation.

4. Originally and chiefly *U.S.*

a. The fact of having the largest share of the votes cast, when this is less than an absolute majority.

1803 U. TRACY in *Deb. Congr. U.S.* (1852) 8th Congress 1 Sess.165 The public will is sometimes expressed by pluralities instead of majorities.

1846 J. E. WORCESTER *Universal Dict. Eng. Lang.* (at cited word) A candidate, in an election, receives a plurality of votes, when he receives more than any other candidate; and he receives a majority of votes, when he receives more than all others.

1885 *Pall Mall Gaz.* 31 Mar. 8/2 He ran again last fall, and had a plurality over the Republican candidate; but as it requires in that State [*sc.* Connecticut] a majority over all to elect, the Legislature elected his Republican competitor.

1907 *Polit. Sci. Q.* **22** 646 If, after two ballots have been taken, no candidate has secured a clear majority, a plurality is sufficient to elect.

1992 *New Republic* 27 July 42/1 Unfortunately, in a three-way race where the prevailing candidate gets only a plurality, not a majority, there is no easy way to say what the people's preference is.

b. The amount by which the vote of such a winning candidate, party, etc., exceeds that of the next (or another specified) candidate. Cf. MAJORITY *n.*[1] 4.

1832 *Workingman's Advocate* 1 Dec. 1 The Clay electoral ticket has succeeded by a plurality of about 600 votes over the Jackson ticket, and 2,000 over the Anti-Masonic ticket.

1859 *National Era* 14 Apr. 58 In the first district, Loomis, Republican, is elected by a plurality of 65 votes. Clark only received 216 votes.

1884 *Manch. Examiner* 8 Nov. 4/7 Governor Cleveland had a thousand plurality in New York State, and was elected President.

1906 U. SINCLAIR *Jungle* xxv. 314 On a day of Democratic landslides they elected 'Scotty' Doyle, the ex-ten-pin setter, by nearly a thousand plurality.

1948 *Chicago Daily News* 24 Feb. 1/6 The..primary resulted in a 120,000 plurality for Long over three other candidates. But that was not the clear majority needed for election.

1986 S. MAINWARING in D. H. Levine *Relig. & Polit. Conflict Lat. Amer.* vii. 137 Leonel Brizola won by a large plurality in Nova Iguaçu.

COMPOUNDS

C1. General *attributive.*

plurality hypothesis *n.*

1899 T. C. Allbutt et al. *Syst. Med.* VIII. 863 The differences on which the plurality hypothesis is founded.

1944 E. Schrödinger *What is Life?* 90 Such consequences, even if only tentative, must make us suspicious of the plurality hypothesis, which is common to all official Western creeds.

plurality system *n.*

1854 *N.-Y. Daily Times* 8 Feb. 1/3 In the House to-day, the amendment to the Constitution, by which the plurality system in elections is substituted for the majority system, was adopted by a vote of 226 Yeas to 46 Nays.

1907 *Proc. Amer. Polit. Sci. Assoc.* **4** 187 It seems likely that the public will accept the plurality system before it is reconciled to the complications of the preferential plan.

1991 *Parl. Affairs* **44** 553 Defenders of plurality systems do not take the view that fairness in the sense of proportionality is the prime virtue of an electoral system.

C2.

† plurality-gaping *adj. Obsolete rare*

1642 J. Milton *Apol. Smectymnuus* 43 The non-resident and plurality-gaping Prelats, the gulphs and whirle pooles of benefices.

This entry has been updated (OED Third Edition, September 2006; most recently modified version published online December 2021).

EXHIBIT 2

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before the Honorable Monica Bhattacharyya
Administrative Law Judge

In the Matter of **CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF**	Inv. No. 337-TA-1276

EXPERT REPORT OF VIJAY K. MADISETTI, PH.D. REGARDING CLAIM CONSTRUCTION

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I. INTRODUCTION

1. I am a tenured full professor in the Colleges of Computing and Engineering at the Georgia Institute of Technology ("Georgia Tech"), and I have worked in digital signal processing, wireless communications, computer engineering, integrated circuit design, and software engineering for over 25 years. Complainants Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Masimo") have retained me as an expert in this investigation. A copy of my *curriculum vitae* is attached to this report as Exhibit A.

2. I have been asked to evaluate and address the meaning, to a person of ordinary skill in the art ("POSA"), of certain claim phrases in four patents asserted in this litigation: United States Patent Nos. 10,912,501 ("the '501 patent"), 10,912,502 ("the '502 patent"), 10,945,648 ("the '648 patent"), and 10,687,745 ("the '745 patent") (collectively, "the asserted patents").

3. Specifically, I understand that the parties dispute, among other things, the meaning of the phrase "bulk measurement" in certain asserted claims of the '501, '502, and '648 patents and the phrase "second shape" in certain asserted claims of the '745 patent. I have been asked by Masimo to provide an expert report regarding the meaning of the above disputed terms as understood by a POSA, and to provide a background regarding the technology.

II. MATERIALS AND INFORMATION CONSIDERED

4. Exhibit B lists the documents and things I have considered in forming my opinions expressed in this report. I have also relied upon my educational and professional experience in reaching my opinions.

III. SUMMARY OF OPINIONS

5. I have been informed that the joint claim construction chart attached as Exhibit C to this report sets forth the positions of the parties regarding the proper interpretation of "bulk measurement" as used in the '501, '502, and '648 patents, and "second shape" as used in the '745

patent. I have reviewed Masimo's patents, the related file histories, the parties' positions regarding the level of ordinary skill in the art, and the proposed constructions of these phrases.

6. I agree with Masimo that a POSA would understand "bulk measurement" to mean "baseline measurement" in the context of the '501, '502, and '648 patents.

7. I agree with Masimo that a POSA would understand "second shape" to mean "a shape that is different from the first shape beyond a change in size of the first shape" in the context of the '745 patent.

IV. BACKGROUND AND QUALIFICATIONS

8. I obtained my Ph.D. in Electrical Engineering and Computer Science at the University of California, Berkeley, in 1989. While there, I received the Demetri Angelakos Outstanding Graduate Student Award and the IEEE/ACM Ira M. Kay Memorial Paper Prize.

9. I joined Georgia Tech in the Fall of 1989 and am now a tenured full professor in Electrical and Computer Engineering and more recently in the College of Computing. Among other things, I have been active in the areas of digital signal processing, wireless communications, integrated circuit design (analog & digital), system-level design methodologies and tools, and software engineering. I have been the principal investigator ("PI") or co-PI in several active research programs in these areas, including DARPA's Rapid Prototyping of Application Specific Signal Processors, the State of Georgia's Yamacraw Initiative, the United States Army's Federated Sensors Laboratory Program, and the United States Air Force Electronics Parts Obsolescence Initiative. I have received an IBM Faculty Award and NSF's Research Initiation Award. I have been awarded the 2006 Frederick Emmons Terman Medal by the American Society of Engineering Education for contributions to Electrical Engineering, including authoring a widely used textbook in the design of VLSI (very large scale implementation) digital signal processors.

10. During the past 30 years at Georgia Tech, I have created and taught undergraduate and graduate courses in hardware and software design for signal processing, computer engineering (software and hardware systems), computer engineering and wireless communication circuits.

11. I have been involved in research and technology in the area of digital signal processing since the late 1980s, and I am the Editor-in-Chief of the CRC Press's 3-volume Digital Signal Processing Handbook (1998, 2010).

12. I have founded three companies in the areas of signal processing, embedded software, military chipsets involving imaging technology, and software for computing and communications systems. I have supervised Ph.D. dissertations of over twenty engineers in the areas of computer engineering, signal processing, communications, rapid prototyping, and system-level design methodology.

13. I have designed several specialized computer and communication systems over the past two decades at Georgia Tech for such tasks as wireless audio and video processing and protocol processing for portable platforms, such as cell phones and PDAs. I have designed systems that are efficient in view of performance, size, weight, area, and thermal considerations. I have developed courses and classes for industry on these topics, and many of my lectures in advanced computer system design, developed under the sponsorship of the United States Department of Defense in the late 1990s, are available for educational use at http://www.eda.org/rassp and have been used by several U.S. and international universities as part of their course work. Some of my recent publications in the area of design of computer engineering and wireless communications systems and associated protocols are listed in Exhibit A.

14. In the mid-2006-2007 timeframe, I collaborated with Professor John Scharf and his colleagues at Emory Healthcare system in developing FFT-based pulse oximetry system

prototypes on FPGAs (field-programmable gate arrays), which extended technologies developed by Prof. Scharf and his colleagues from the 1996 time frame (*See* T. Rush, R. Sankar, J. Scharf, "Signal Processing Methods for Pulse Oximetry", Comput. Bio. Med, Vol. 26, No. 2, 1996). Some of my more recent publications in the area of biological signal processing and bioinformatics are listed in my CV and include, A. Bahga, V. Madisetti, "Healthcare Data Integration and Informatics in the Cloud", IEEE Computer, Vol. 48, Issue 2, 2015, and "Cloud-Based Information Integration Informatics Framework for Healthcare Applications", IEEE Computer, Issue 99, 2013. In addition to my signal processing experience specific to pulse oximetry, I also have experience in developing systems for other physiological signals. Beginning in the early 1990s, I worked, in particular, with ECG/EKG signals, and, in general, with biomedical signals and systems.

15. In addition to my signal processing experience specific to pulse oximetry, I also have experience in developing algorithms and systems for other physiological signals. I worked with ECG/EKG signals in particular, and biomedical signals and systems in general, beginning in the early 1990s. In particular, I worked with graduate student Dr. Shahram Famorzadeh, in 1990 and 1991, to analyze and apply pattern recognition (a category of signal processing algorithms that is based on correlation with a set of templates) to ECG/EKG waveforms to identify physiological conditions.

16. I have experience with biomedical signals and devices in the field of speech and image processing since the late 1980s. I developed deconvolution algorithms for use with physiological signals in the 1993-1998 timeframe. These signal processing techniques can be applied to pulse oximetry signals, and I have been working with these techniques since the mid-1980s.

17. I have studied, researched, and published in the area of adaptive filter signal processing for noise reduction and signal prediction, using correlation-based approaches since the mid-1980s, both in the time-domain and frequency domain, and also to ray-tracing applications, such as Seismic Migration for oil and shale gas exploration. *See*, for instance, V. Madisetti and D. Messerschmitt, Dynamically Reduced Complexity Implementation of Echo Cancellers, IEEE International Conference on Speech, Acoustics and Signal Processing, ICASSP 1986, Tokyo, Japan, and M. Romdhane and V. Madisetti, "All-Digital Oversampled Front-End Sensors" IEEE Signal Processing Letters, Vol. 3, Issue 2, 1996, and "LMSGEN: A Prototyping Environment for Programmable Adaptive Digital Filters in VLSI", VLSI Signal Processing, pp. 33-42, 1994.

18. Deconvolution of symmetric (seismic) and asymmetric (pulse oximetry) signals has gained much importance and some of my early work on "Homomorphic Deconvolution of Bandpass Signals" in IEEE Transactions on Signal Processing, October 1997, established several new methods for deconvolution of such signals that had several advantages of robustness, increased accuracy, and simplicity.

19. I have authored several peer-reviewed papers in the area of computer systems, instruments, and software design, and these include:

- Madisetti, et al., "The Georgia Tech Digital Signal Multiprocessor, IEEE Transactions on Signal Processing, Vol. 41, No. 7, July 1993.
- V. Madisetti et al., "Rapid Prototyping on the Georgia Tech Digital Signal Multiprocessor", IEEE Transactions on Signal Processing, Vol. 42, March 1994.
- V. Madisetti, "Reengineering legacy embedded systems", IEEE Design & Test of Computers, Vol. 16, Vol. 2, 1999.

- V. Madisetti et al., "Virtual Prototyping of Embedded Microcontroller-based DSP Systems", IEEE Micro, Vol. 15, Issue 5, 1995.
- V. Madisetti, et al., "Incorporating Cost Modeling in Embedded-System Design", IEEE Design & Test of Computers, Vol. 14, Issue 3, 1997
- V. Madisetti, et al., "Conceptual Prototyping of Scalable Embedded DSP Systems", IEEE Design & Test of Computers, Vol. 13, Issue 3, 1996.
- V. Madisetti, Electronic System, Platform & Package Codesign," IEEE Design & Test of Computers, Vol. 23, Issue 3, June 2006.
- V. Madisetti, et al., "A Dynamic Resource Management and Scheduling Environment for Embedded Multimedia and Communications Platforms", IEEE Embedded Systems Letters, Vol. 3, Issue 1, 2011.

V. COMPENSATION

20. I am being compensated at my usual and customary rate of $550 per hour for each hour of services that I spend working on this investigation. My compensation is not affected by the outcome of this investigation.

VI. LEGAL FRAMEWORK FOR MY OPINIONS

21. I am not an attorney and I will not offer opinions of law. However, I have been informed of several principles concerning patent claim construction and definiteness, which I apply in addressing the disputed claim phrases discussed herein. I understand that claim terms are generally given their ordinary and customary meaning they would have to a POSA as of the patent's earliest priority date. I understand that in determining the proper meaning of claim terms in a patent, consideration is first given to "intrinsic evidence," including the claim language, the patent specification, and the prosecution history. I also understand that, after reviewing the

intrinsic evidence, consideration may be given to "extrinsic evidence," such as technical references, dictionaries, and testimony of experts.

22. I understand that the claims and specification are the best guide to the meaning of a disputed claim term. I understand that absent a change by the inventors, a claim term is given its plain and ordinary meaning to a POSA. I also understand that an inventor can act as a lexicographer by clearly setting forth a special definition of a claim term that differs from the plain and ordinary meaning it would otherwise possess. I also understand that an inventor can define terms by implication, in other words, according to the usage of the term in the context of the specification. I understand that if a claim term has no plain or established meaning to a POSA, the term ordinarily should not be understood in a manner broader than the disclosure in the specification.

23. I understand that the prosecution history of a patent can inform the meaning of the claim language by demonstrating how the inventor and patent examiner understood the invention and whether the inventor limited the invention during prosecution. I further understand that the public has a right to rely on the inventor's statements made during prosecution, regardless of whether or how much the examiner relied on them. I understand that an inventor may surrender claim scope to which he otherwise would have been entitled through a clear and unmistakable disavowal or disclaimer in the prosecution history. I understand that such prosecution disavowal or disclaimer can arise from both claim amendments and arguments made by the inventor during prosecution.

24. I understand that multiple patents can be related when they claim priority to the same initial application. I further understand that the prosecution history regarding a claim

limitation in any related application can apply with equal force to subsequently issued patents that contain the same limitation.

25. I understand that the "definiteness" of claims is determined from the perspective of a POSA at the time the patent was filed, reading the claims in light of the patent's specification and prosecution history. I understand that the definiteness requirement mandates clarity, but recognizes that absolute precision is unattainable and that some modicum of uncertainty is the price of ensuring the appropriate incentives for innovation. I understand that a claim is indefinite only if, in view of the specification and prosecution history, it fails to inform a POSA about the scope of the claimed invention with reasonable certainty.

26. I understand that claim construction is assessed from the view of a hypothetical person of ordinary skill in the relevant art at the time of the invention. I understand there are multiple factors relevant to determining the level of ordinary skill in the art, including (1) the level of education and experience of persons working in the field at the time of the invention; (2) the sophistication of the technology; (3) the types of problems encountered in the field; and (4) the prior art solutions to those problems.

VII. PERSON OF ORDINARY SKILL IN THE ART

27. The relevant field of art is devices and sensors for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate.

28. I understand that the level of ordinary skill in the art for the '501, '502 and '648 patents is determined as of July 3, 2008.

29. I understand that the level of ordinary skill in the art for the '745 patent is determined at least as of July 2, 2015.

30. I understand that Apple has proposed the following definition of a POSA with respect to the asserted patents:

> A person of ordinary skill in the art would have been 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.

I apply this definition for the purposes of my analysis herein.

VIII. TECHNICAL BACKGROUND

31. The ’501, ’502, and ’648 patents are entitled “USER-WORN DEVICE FOR NONINVASIVELY MEASURING A PHYSIOLOGICAL PARAMETER OF A USER.” Pulse oximetry is one example of a noninvasive measurement of a physiological parameter (oxygen saturation of blood). *See, e.g.*, ’501 patent[1] at 2:25-29.

32. Pulse oximetry systems non-invasively determine the oxygen saturation levels of an individual’s arterial blood. During respiration, oxygen in the lungs binds with hemoglobin molecules within blood. *See generally* DESIGN OF PULSE OXIMETERS, Webster J.G (ed.) (1997) (“Webster”) at 6-10 (APL_MAS_ITC_00015640-44). The circulatory system transports that oxygen saturated blood through the human body through arteries. *Id.* The surge of blood flow entering the arteries causes a pulse (referred to as the pulsatile flow of blood), whereas venous blood returning from the capillaries is largely non-pulsatile. *Id.* Pulse oximetry technology relies on differences in light absorption of oxygen-bound and oxygen-unbound hemoglobin. *Id.* at 13-14 (APL_MAS_ITC_00015647-48).

33. A typical pulse oximeter includes red and infrared (IR) light-emitting diode (LED) emitters and one or more photodiode detectors. *Id*. at 34-36 (APL_MAS_ITC_00015668-70). The

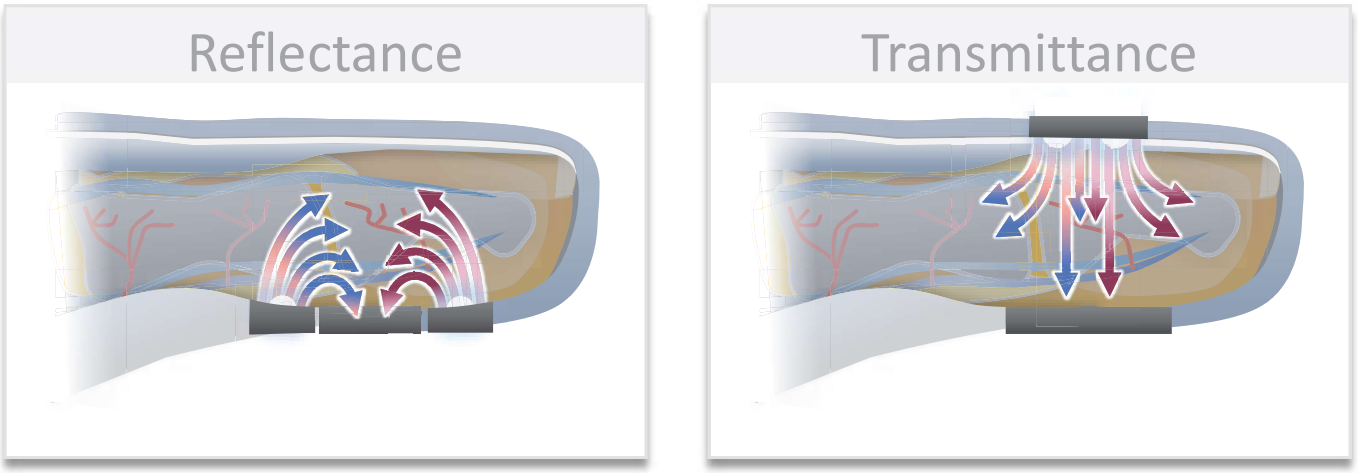
[1] I understand that the ’501, ’502, and ’648 patents share a specification (referred to herein as the “shared specification”). I cite to the specification of the ’501 patent in this report for convenience.

shared specification explains: "Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off of a measurement site, such as, body tissue carrying pulsing blood." '501 Patent at 2:17-20. "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." *Id*. at 2:20-23.

34. Pulse oximetry determines oxygen saturation by comparing the light absorbance of oxygenated hemoglobin and deoxygenated hemoglobin at two different wavelengths. Webster at 13-14 (APL_MAS_ITC_00015647-48). Bright red oxygenated blood absorbs light differently than dark red deoxygenated blood. *Id.* at 40-46 (APL_MAS_ITC_00015674-80). The ratio of light absorbed at red wavelengths compared to light absorbed at infrared wavelengths generally correlate to the percentage of hemoglobin carrying oxygen. *Id*. That is known as oxygen saturation.

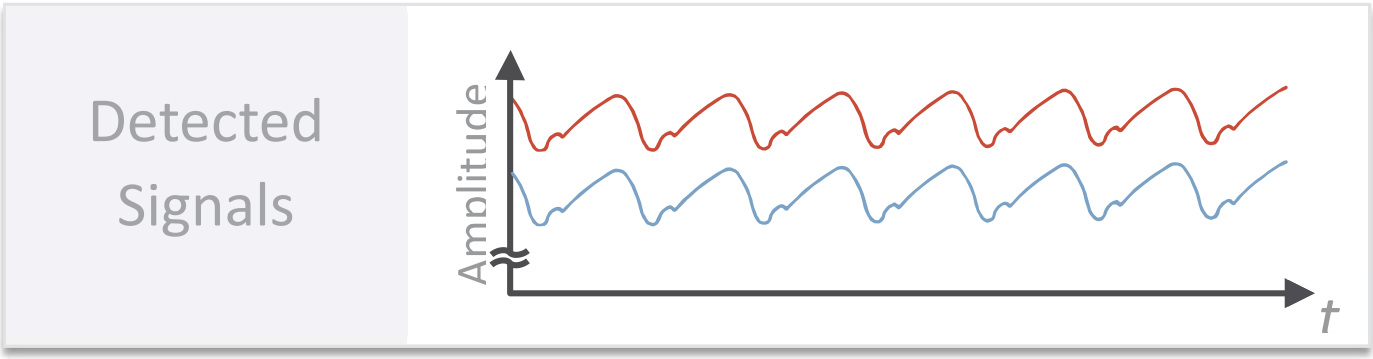
35. As the blood flow pulsates, it changes, or modulates, the light absorption. *Id*. at 14 (APL_MAS_ITC_00015648). The pulse oximeter tracks the changes in light absorbance as the blood pulsates. *Id*. at 34 (APL_MAS_ITC_00015668).

36. The shared specification describes two ways to track the changes in light absorbance as the blood pulsates: transmittance and reflectance. '501 patent 2:17-20. Because light both transmits through tissue and backscatters or reflects back after entering tissue, pulse oximeter sensors can operate either by transmittance or reflectance. That is, for pulse oximeter sensors operating by transmittance, the detector (sometimes referred to as a photodiode) and emitter are on opposite sides of the tissue at the measurement site. *See also* Webster at 36 (APL_MAS_ITC_00015670). For pulse oximeter sensors operating by reflectance, a detector is placed on the same side as the emitters. *Id*. Both methods are illustrated below.

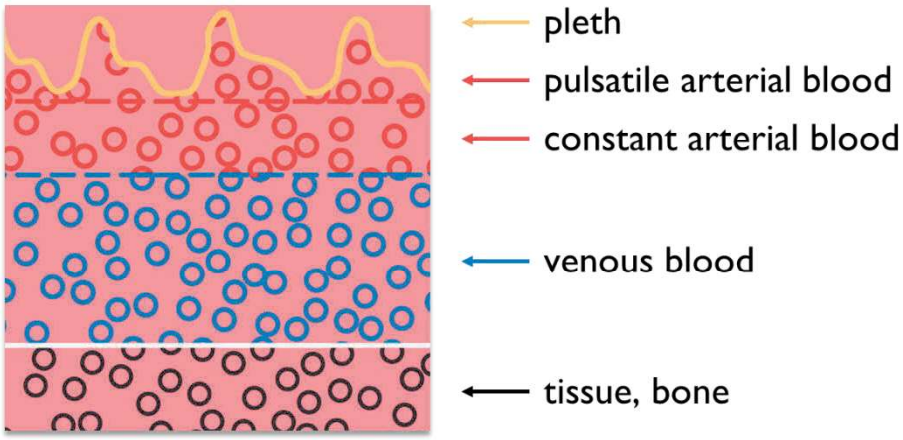


37. The shared specification also describes that the devices (*e.g.*, pulse oximeters) "may include multiple optical sources that emit light at a plurality of wavelengths" and may include "a plurality of photodetectors." '501 Patent at 2:57-64. When there are multiple optical sources (emitters), the pulse oximeter turns the light sources on and off in an alternating fashion. Thus, a pulse oximeter alternately activates each light source, one at a time. The pulse oximeter analyzes the signal from the photodetectors with knowledge of which light source was on at any time.

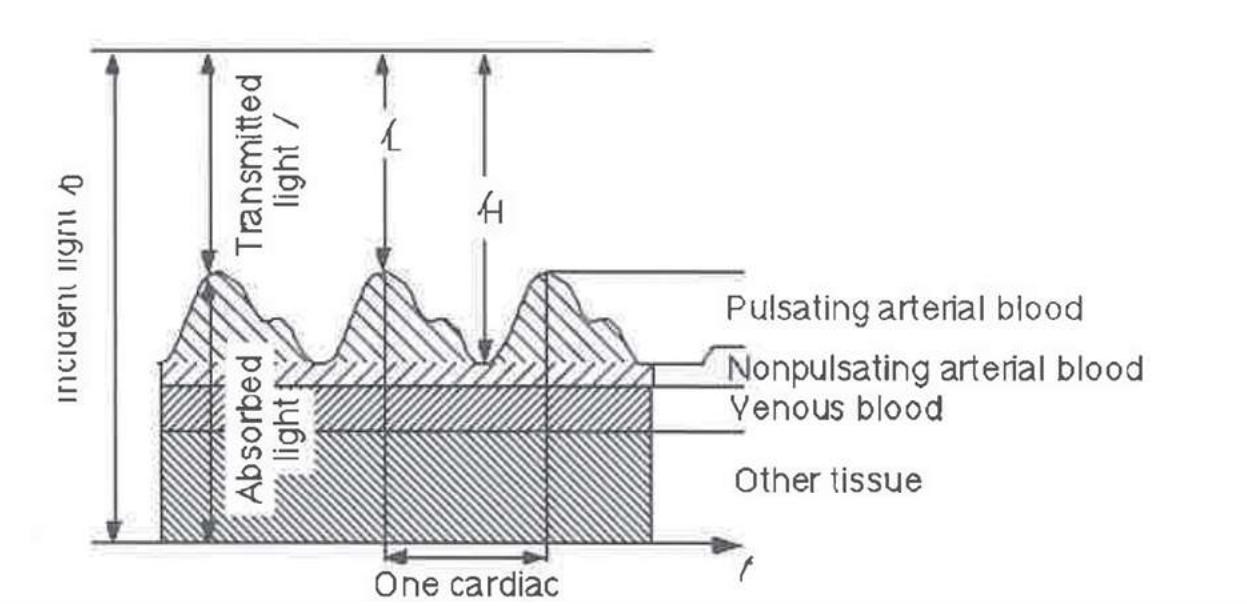
38. Light traveling through the measurement site is absorbed by various substances such as skin pigmentation, bones, tissue, and the arterial and venous blood. Webster at 46-47 (APL_MAS_ITC_00015680-81). The resulting light absorption at the detector also varies due to the blood volume change of arterial blood. The detector(s) generate an output signal proportional to the intensity of the detected light. The illustration below shows detected signals corresponding to two different light sources.



39. The pulse oximeter ultimately processes the detected intensities from the light sources. '501 patent at 2:15-34. As shown in the illustration above, the detected signal changes over time. One reason for that is the heart is moving blood through the body with each beat of the heart, or pulse. With each pulse, the volume of blood at different parts of the body changes. Therefore, the sensor signal in the pulse oximeter changes over time as blood flows into the measurement site. The resulting signal is called a plethysmograph or "pleth," for short. Pulsatile blood (referred to in the diagram below as "pulsatile arterial blood") causes variance in the absorbance of light.

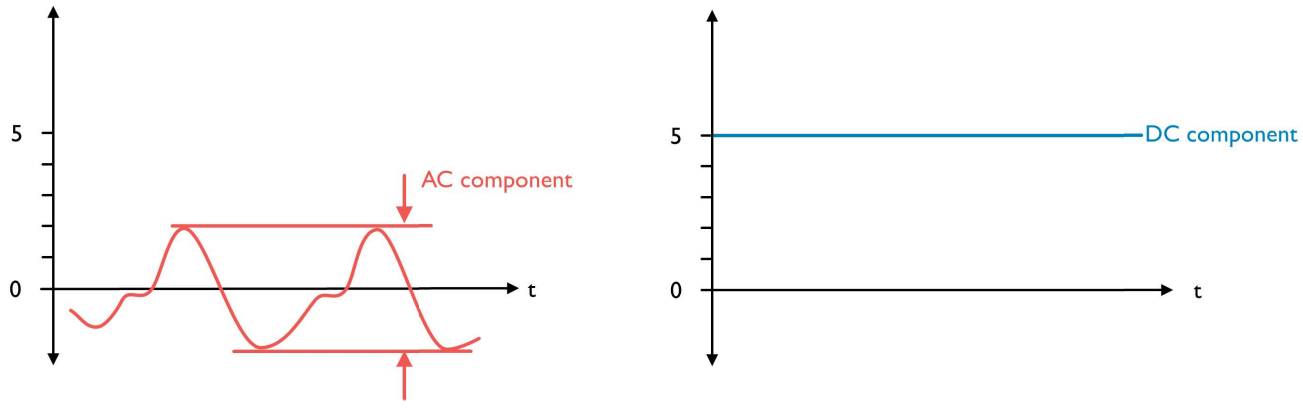


These concepts are also illustrated by Webster in the diagram below (with pulsatile blood referred to as "pulsating arterial blood"):

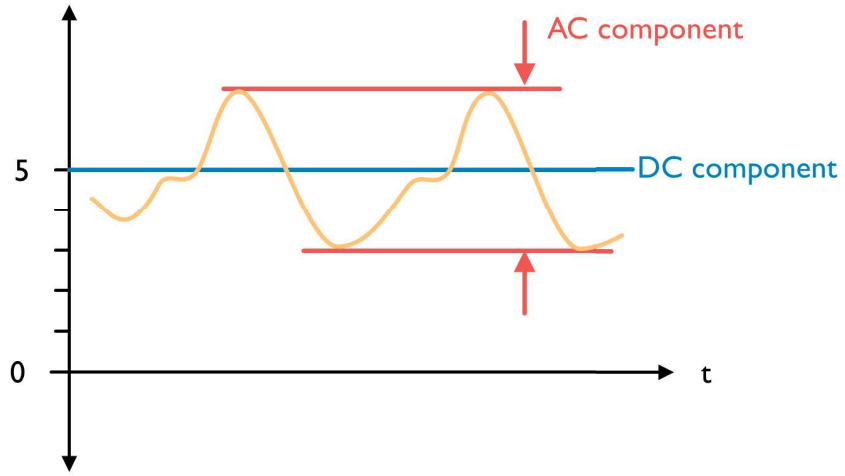


Webster at 47 (APL_MAS_ITC_00015681). The difference between the absorbed light and transmitted light depends on the amount of tissue, venous blood, nonpulsating arterial blood, and pulsating arterial blood. In the example depicted above, the amount of tissue, venous blood, and nonpulsating arterial blood are relatively constant. The pulsating arterial blood changes over time. Thus, the changes in the amount of absorbed light correlates with the pulsation of arterial blood.

40. POSAs often refer to the relatively constant, non-pulsating component of the pleth as "DC" (Direct Current). POSAs often refer to the pulsating arterial blood component of the pleth as "AC" (Alternating Current). The AC and DC components of a pleth waveform are illustrated below.



The pleth is the combination of the AC and DC components.



(Adapted from Webster at 131 (APL_MAS_ITC_00015765)).

41. These principles were well known to POSAs in this field when Masimo filed the asserted patents.

IX. A POSA'S UNDERSTANDING OF THE DISPUTED CLAIM TERMS

42. I understand that the parties set forth the following proposed constructions in the joint claim construction chart (Exhibit C):

Claim Phrase (Asserted Claims)	Masimo's Proposed Construction	Apple's Proposed Construction
"bulk measurement" ('501 patent, claim 13 '502 patent, claim 12 '648 patent, claims 2, 21)	"baseline measurement"	Indefinite as used in asserted claims
"second shape" (745 patent, claims 1, 20)	"a shape that is different from the first shape beyond a change in size of the first shape"	Plain and ordinary meaning (*i.e.*, a shape different than the first shape)

The full text of the claims containing the disputed claim phrases, as well as any claims from which the depend, are set forth in Exhibit D.

A. "Bulk Measurement"

43. In my opinion, a POSA would understand the phrase "bulk measurement" as used in claim 13 of the '501 patent, claim 12 of the '502 patent, and claims 2 and 21 of the '648 patent to mean "baseline measurement." The bulk or baseline measurement is the DC or non-pulsatile component of a signal for a given time window. Masimo's proposed construction would be evident to a POSA in view of the claim language and consistent usage of the phrase "bulk measurement" throughout the specification.

44. The specification repeatedly contrasts a "bulk" measurement with a "pulsatile" measurement and characterizes a "bulk" measurement as a "non-pulsatile" measurement. For example, the specification includes the following excerpts that clarify the meaning of "bulk measurement":

> 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.

'501 patent at 9:18-22 (emphasis added).

> 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.

Id. at 34:35-40 (emphasis added).

> 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.

Id. at 34:49-67 (emphasis added).

> 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.

Id. at 35:41-50.

45. These excerpts from the specification, which repeatedly contrast a bulk measurement with a pulsatile measurement and explain that a bulk measurement can be used to confirm or validate a pulsatile measurement, make clear that a bulk measurement is not a pulsatile measurement (typically what I explained as the AC-component of a signal).

46. My understanding is reinforced by the repeated usage of the term "non-pulsatile" in conjunction with "bulk measurement." Accordingly, a POSA would understand that a "bulk measurement" as used in the '501, '502, and '648 patents, is a non-pulsatile measurement, also known as the DC-component of a signal.

47. A POSA would further understand that this bulk, non-pulsatile measurement is a baseline measurement. The specification explains that the bulk measurement is employed to "confirm or validate a pulsatile measurement." '501 patent at 34:35-37. Similarly, the bulk measurement is described as "confirm[ing] or validat[ing] that the sensor is positioned correctly." *Id.* at 34:49-51. And again, the specification explains that the bulk measurement is 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." *Id.* at 35:43-47. The consistent description in the

specification that the bulk measurement functions to confirm or validate pulsatile measurements or sensor positioning would make clear to a POSA that a bulk measurement is a baseline measurement.

48. The specification further explains that "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." *Id.* at 34:55-59. And in another example, "[i]f 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." *Id.* at 34:59-64. The use of the bulk measurement to confirm proper positioning of the sensor, to determine that the sensor should be adjusted, or to set a calibration curve for processing pulsatile measurements further confirm that the bulk measurement is a baseline measurement.

49. The specification also refers to a "bulk measurement scheme" to explain how signal noise can be cancelled or reduced:

$$I_1/I_n = e^{-m(b_1 - b_n)c}$$

> 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.

Id. at 35:28-40. This scheme also accounts for variations from patient to patient and changes in measurement sites such as topological variations. The mean path length within the scheme allows for extension across multiple wavelengths. The use of the phrase "bulk-measurement scheme" in

this context refers to the process of reducing signal noise and accounting for such patient-to-patient variations. A POSA would find this use consistent with the understanding that a "bulk measurement" is a baseline measurement.

50. A POSA would understand that the bulk measurement is a baseline or non-pulsatile measurement or a value. A POSA would understand a measurement in the context of this specification to refer to a value that can be calculated from sensed data. Calculation of a baseline measurement—*i.e.*, the non-pulsatile or DC component of a signal—was well understood by a POSA by the priority date of the '501, '502, and '648 patents.

51. The context of the claim language containing the "bulk measurement" phrase further supports Masimo's proposed construction.

> **'501 patent, claim 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."
>
> **'502 patent, claim 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."
>
> **'648 patent, claim 2**: "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 indicating a positioning of the user-worn device."
>
> **'648 patent, claim 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."

52. In each of these claims, the bulk measurement is responsive to or indicative of the positioning of a user-worn device. This usage in the claims is consistent with description in the specification that the bulk measurement can be used to determine positioning of the sensor and supports that a bulk measurement is a baseline measurement that is calculated or measured.

53. I did not find any meaningful discussion of bulk measurement in the prosecution history.

54. Extrinsic evidence shows that POSAs would refer to the non-pulsatile component of the signal using other terms, such as a "baseline." For example, in Dr. Webster's book, the authors explain:

> The intensity of light transmitted through a finger is a function of the absorbance coefficient of both fixed components, such as bone, tissue, skin, and hair, as well as variable components, such as the volume of blood in the tissue. The intensity of light transmitted through the tissue, as a function of time is often said to include a **baseline component**, which varies slowly with time and represents the effect of the fixed components on the light, as well as a periodic pulsatile component, which varies more rapidly with time and represents the effect that changing tissue blood volume has on the light (Cheung *et al* 1989).

Webster at 126 (APL_MAS_ITC_00015760) (emphasis added). The authors also explain:

> The determination of the Ratio of Ratios *(ROS)* requires an accurate measure of both the **baseline** and pulsatile signal components (Frick *et al* 1989). The **baseline** component approximates the intensity of light received at the detector when only the fixed nonpulsatile absorptive component is present in the finger. This component of the signal is relatively constant over short intervals and does not vary with nonpulsatile physiological changes, such as movement of the probe. Over a relatively long time, this **baseline** component may vary significantly. The magnitude of the **baseline** component at a given point in time is approximately equal to the level identified as R_H (figure 9.2). However, for convenience, the **baseline** component may be thought of as the level indicated by R_L, with the pulsatile component varying between the values of R_H and R_L over a given pulse. Typically, the pulsatile component may be relatively small in comparison to the baseline component and is shown out of proportion in figure 9.3. Because the pulsatile components are smaller, greater care must be exercised with respect to the measurement of these components. If the entire signal, including the **baseline** and the pulsatile components, were amplified and converted to a digital format for use by microcomputer, a great deal of the accuracy of the conversion would be wasted because a substantial portion of the resolution would be used to measure the baseline component (Cheung *et al* 1989).
>
> In this process, a substantial portion of the **baseline** component termed offset voltage *VOS* is subtracted off the input signal *V1*. The remaining pulsatile component is amplified and digitized using an ADC. A digital reconstruction is then produced by reversing the process, wherein the digitally provided information allows the gain to be removed and the offset voltage added back. This step is necessary because the entire signal, including the baseline and pulsatile components is used in the oxygen saturation measurement process.

Webster at 133-134 (APL_MAS_ITC_00015767-78) (emphasis added).

55. Similarly, Cheung, referenced above in Webster, is U.S. Patent No. 4,892,101, entitled "Method and apparatus for offsetting baseline portion of pulse oximeter signal." It explains:

> As will be appreciated, the intensity of light transmitted through a finger is a function of the absorption coefficient of both "fixed" components, such as bone, tissue, skin, and hair, as well as "variable" components, such as the volume of blood in the tissue. The intensity of light transmitted through the tissue, when expressed as a function of time, is often said to include a **baseline component**, which varies slowly with time and represents the effect of the fixed components on the light, as well as a periodic pulsatile component, which varies more rapidly with time and represents the effect that changing tissue blood volume has on the light. Because the attenuation produced by the fixed tissue component does not contain information about pulse rate and arterial oxygen saturation, the pulsatile signal is of primary interest. In that regard, many of the prior art transmittance oximetry techniques eliminate **the so-called "DC" baseline component** from the signal analyzed.

U.S. Patent No. 4,892,101 at 1:64-2:14 (emphasis added).

56. I understand Apple asserts that "bulk measurement" in the phrase "wherein the one or more processors are further configured to process the one or more signals to determine a bulk measurement" as used in the asserted claims is indefinite. I understand that Apple argues:

> Claim 13 depends from claim 1, which confirms that the processors receive the "one or more signals" from the photodiodes. The specification does not disclose or explain how a bulk measurement responsive to the positioning of the device can be calculated from ***one*** signal from ***one*** photodiode or reasonably convey to those skilled in the art how such a measurement can be made. Instead, the specification indicates that ***multiple*** signals from ***multiple*** photodiodes would be required to take a bulk measurement. *See, e.g.*, '501 Patent at 34:49-54 ("the use of multiple-detectors in a spatial configuration allow for a bulk measurement . . . This is because the multiple locations of the spatial configuration can provide, for example, topology information . . . "). The specification accordingly fails to reasonably convey to those skilled in the art that the inventors possessed the claimed subject matter as of the time of the invention, and also fails to inform those skilled in the art, with reasonable certainty, about the scope of the alleged invention.

I disagree. As explained above, a POSA would already understand what is being referenced by the discussion of the "bulk measurement" in the specification. Apple's argument above does not articulate that a POSA would not understand the term. In fact, it appears that Apple understands

the term because Apple states that a "bulk measurement" can be taken from multiple photodiodes. Instead, Apple seems to address whether the specification teaches how to calculate a bulk measurement from one signal from one photodiode. As I explained, this baseline measurement is basic knowledge in the pulse oximetry field, as explained with reference to Webster above. I reserve the right to respond to any expert report or other evidence that Apple may rely on to support its position that "bulk measurement" as used in the asserted claims is indefinite.

B. <u>"Second Shape"</u>

57. In my opinion, a POSA would understand the phrase "second shape" as used in claims 1 and 20 of the '745 patent to mean "a shape that is different from the first shape beyond a change in size of the first shape." This construction would be evident to a POSA in view of the prosecution history of the '745 patent.

58. Claim 1 of the '745 patent recites, in relevant part:

> 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 by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue;
> . . .

59. Claim 20 recites, in relevant part:

> 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;
> . . .

60. The plain and ordinary meaning of "second shape" is a shape different than the "first shape." The '745 patent specification does not redefine the phrase "second shape." The specification uses the term "shape" to refer to patterns and geometry (such as rectangle, circle, or square). *See, e.g.*, '745 patent at 7:42-49, 8:9-14.

61. A POSA also would look to the prosecution history of the '745 patent for any guidance it provides on the meaning of "second shape" as used in claims 1 and 20 of the '745 patent.

62. I understand that the '745 patent claims priority to a series of related patent applications, including U.S. Patent Application No. 16/532,065 ("'065 application"). *See* '745 patent at 1: The claim phrase "second shape" was introduced during prosecution of the '065 application, as outlined below.

63. During prosecution of the '065 application, the Applicant submitted a preliminary amendment introducing, among others, independent claim 2. Independent claim 2 recited in part:

> A physiological monitoring device comprising:
> a plurality of emitters, wherein each of the plurality of emitters is configured to emit light proximate a wrist of a user;
> a material positioned between the plurality of emitters and the tissue measurement site, the material configured to alter a shape of the light emitted from one or more of the plurality of emitters before the light reaches the tissue measurement site;
> . . .

'065 patent Prosecution History, September 16, 2019 Preliminary Amendment at 4 (MASITC_0027940).

64. In a non-final rejection dated October 21, 2019, the Examiner rejected all pending claims. Among other reasons, pending claim 2 was rejected as unpatentable over U.S. Patent Application No. 2014/0361147 ("Fei") and U.S. Patent No. 5,830,137 ("Scharf"). With respect to claim 2, the Examiner stated:

> Fei discloses a physiological measurement device (figures 1-2, 5A) comprising: . . . a material positioned between the plurality of emitters and a tissue measurement site (lens 234 figure 5A, [0041]-[0042]), wherein the material is configured to alter a shape of the light emitted from the one or more of the plurality of emitters before the light reaches the tissue measurement site ([0041]-[0043]) . . . .

'065 Prosecution History, October 21, 2019 Non-Final Rejection at 3 (MASITC_00278280. The Examiner also stated:

> Scharf discloses a physiological measurement device (figures 3 and 6) comprising . . . a material positioned between the plurality of emitters and a tissue measurement site, wherein the material is configured to alter a shape of at least a portion of the light emitted from the one or more of the plurality of emitters before the light reaches the tissue measurement site (elements 16 and 18 figures 3 and 6, discrete lenses to focus radiant energy from LEDs onto the skin, Col.8 lines 51-64) . . . .

Id. at 13 (MASITC_00270838).

65. With respect to the claimed "material configured to alter a shape of light," the Examiner cited lens 234 in figure 5A and paragraphs [0041]-[0043] of Fei. These cited portions of Fei state, in part:

> [E]ach light source **230** includes one or more LEDs **232** that may be contained in a respective lens **234**. . . . In some embodiments, lenses **234** and **244** may comprise a mineral glass or plastic that exhibits a high degree of optical transmission at wavelengths of the optical energy emitted by LEDs **232**. In alternative embodiments, lenses **234** and **244** may comprise other suitable material.

Fei at [0041]-[0042]. Similarly, the Examiner cited elements 16 and 18 in figures 3 and 6 of Scharf, which are described as "green light optical filters." *See* Scharf at 1:23-24. The Examiner also relied on Scharf's disclosure of "discrete lenses to focus radiant energy from LEDs onto the skin, Col.8 lines 51-64." A POSA would understand that the Examiner cited Fei and Scharf for the disclosure of lenses that could alter a light beam by changing its size (or scale).

66. The Applicant submitted an amendment dated November 14, 2019, which amended claim 2 in relevant part as follows:

> . . . a material positioned between the plurality of emitters and a[[the]] tissue measurement site, the material configured to ~~alter a shape of~~distribute the light emitted from one or more of the plurality of emitters ~~before the light reaches the~~

~~tissue measurement site~~to form a customized shape on a surface of the tissue measurement site . . . .

'065 Patent Prosecution History, November 14, 2019 Amendment at 2 (MASITC_00270811).

67. Following a December 3, 2019 interview with the Examiner, the Applicant submitted another amendment to claim 2:

> . . . a material positioned between the plurality of emitters and a[[the]] tissue measurement site, the material configured to alter a shape [[of]]by which the light emitted from one or more of the plurality of emitters is distributed onto a surface of~~before the light reaches~~ the tissue measurement site . . . .

Id., January 7, 2020 Amendment at 2 (MASITC_00270005).

68. The Applicant submitted additional amendments to the pending claims on January 28, 2020 and February 5, 2020, but did not modify the relevant portion of claim 2 cited above. *See id.* at MASITC_00267793, 809. On March 9, 2020, the Examiner issued a Notice of Allowance, which included an Examiner's amendment to claim 2, amending the claim in relevant part as follows:

> . . . a material positioned between the plurality of emitters and a tissue measurement site on a wrist of a user, the material configured to alter the~~a~~ first shape into a second shape by which the light emitted from one or more of the plurality of emitters is distributed onto a surface of the tissue measurement site . . .

Id., March 9, 2020 Notice of Allowance at 2 (MASITC_00267742). This amendment introduced the term "second shape." The Notice of Allowance explained that the authorization for this Examiner's amendment was given in an interview on February 12, 2020. *Id.*

69. The Applicant submitted an interview summary dated March 23, 2020 stating: "Agreement was reached that Applicant's proposed claim amendments, which reflect a ***change in shape of emitted light beyond a change in size***, defined over the Examiner's citation of judicial notice of emitted light passing through a lens." *Id.*, March 23, 2020 Summary of Interview at 1 (MASITC_00267717) (emphasis added).

70. In view of the prosecution history as a whole, including the Applicant's March 23, 2020 interview summary, a POSA would understand that the Applicant excluded from the scope of "second shape" a change in shape of emitted light whereby the only change is a change in size. The Applicant's statement in the interview summary that the claim amendments—which introduced the phrase "second shape"—"reflect a change in shape of emitted light beyond a change in size," unambiguously conveys to a POSA that the second shape must be a shape different from the first shape beyond a change in size. In this statement, the Applicant distinguished the claimed alteration of the first shape into a "second shape" from changes in size or scale.

71. Accordingly, in view of the prosecution history of the '065 patent, a POSA would understand that "second shape" means "a shape that is different from the first shape beyond a change in size of the first shape."

72. I understand that the '745 patent is a continuation of U.S. Patent Application No. 16,791,963 ("the '963 application"), which is a continuation of the '065 application. I have reviewed the prosecution histories of the '745 patent and the '963 application, and nothing in them suggests a different meaning for the term "second shape. I further understand that pending claim 2 of the '065 application issued as claim 1 of U.S. Patent No. 10,646,146 ("the '146 patent"). The chart below compares the relevant portions of claim 1 of the '146 patent and claim 1 of the '745 patent.

'146 Patent, Claim 1	**'745 Patent, Claim 1**
. . . a material positioned between	. . . a material configured to be positioned between
the plurality of emitters and	the plurality of light-emitting diodes and
a tissue measurement site on a wrist of a user,	tissue on a wrist of a user when the physiological monitoring devices is in use,
the material configured to alter the first shape into a second shape	the material configured to change the first shape into a second shape

’146 Patent, Claim 1	’745 Patent, Claim 1
by which the light emitted from one or more of the plurality of emitters is distributed onto a surface of the tissue measurement site . . .	by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue . . .

The phrase “second shape” is used consistently in these claims. Thus, in view of the claim language and the prosecution history of the ’745 patent (including the prosecution history of its predecessor applications), a POSA would understand the phrase “second shape” as used in claims 1 and 20 of the ’745 patent to mean “a shape that is different from the first shape beyond a change in size of the first shape.”

73. I disagree with Apple’s purported “plain and ordinary meaning” construction, “i.e., a shape different than the first shape.” I presume based on Apple’s disagreement with Masimo’s proposal that Apple’s construction is intended to encompass not only differences in shape (such as a circle as opposed to a square), but also differences in size or scale (such as a larger circle as opposed to a smaller circle). Such a construction is inconsistent with both the plain meaning of “shape” and the prosecution history of the ’745 patent.

X. MISCELLANEOUS

74. I understand that Apple has not provided a detailed explanation of its proposed constructions. I reserve the right to modify and/or supplement my opinions should Apple serve an expert report related to its proposed constructions, including any indefiniteness positions, or otherwise provide additional explanation of its proposed constructions.

Dated: 1/18/22

Vijay K. Madisetti, Ph.D.

EXHIBIT 3

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

Before the Honorable Monica V. Bhattacharyya
Administrative Law Judge

In the Matter of CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF	Inv. No. 337-TA-1276

INITIAL EXPERT CLAIM CONSTRUCTION REPORT OF STEVEN WARREN, PH.D.

TABLE OF CONTENTS

I. INTRODUCTION

1. My name is Dr. Steven Warren. Counsel for Apple Inc. ("Apple") has retained me as an expert in this litigation. I submit this Initial Expert Claim Construction Report ("Report") to provide background regarding U.S. Patent No. 10,912,501 ("'501 patent"), U.S. Patent No. 10,912,502 ("'502 patent"), and U.S. Patent No. 10,945,648 ("'648 patent") (collectively, the "Asserted Patents"), and to explain how one of ordinary skill in the art would understand a disputed claim term.

2. This Report is based on the information available and known to me as of the date of this Report.

3. It may be necessary for me to supplement and/or amend this Report based on material or information that subsequently comes to light in this Investigation (including any claim construction declarations submitted on behalf of Complainants in this Investigation), and I reserve the right to do so.

II. QUALIFICATIONS

4. My educational background, career history, publications, and other relevant experience and qualifications provided here are only a summary. My complete curriculum vitae, which lists my educational preparation, professional appointments, publications and presentations, grant activity, courses I have taught, service endeavors, and cases in which I have previously given testimony is attached as Appendix A.

A. Education/Preparation

5. I received a B.S. in Electrical Engineering (Summa Cum Laude) from Kansas State University ("KSU") in 1989, an M.S. in Electrical Engineering from KSU in 1991 (graduate fellowship; high-frequency magnetic hysteresis), and a Ph.D. in Electrical Engineering from The University of Texas at Austin in 1994 (graduate fellowship; laser-induced fluorescence

of coronary artery and aorta; Monte Carlo simulation of light/tissue interaction; intravascular ultrasound). During the summers of 1989 and 1991, I was a research assistant at Lawrence Livermore National Laboratory, Livermore, CA, in the Nuclear Safety Systems Division (high-frequency magnetic hysteresis) and the Human Genome Flow Cytometry Unit (digitizer board programming; dyed chromosome measurement), respectively. Over this span from 1984 to 1994, I studied electronics, biomedical instrumentation (including device design), biomedical optics, light/tissue interaction, *in vitro* tissue analysis, computer programming, numerical computation, modeling/simulation, and engineering education.

B. Prior Professional Appointment at Sandia National Laboratories

6. From 1994 to 1999, I was employed by Sandia National Laboratories ("Sandia"), Albuquerque, NM, where I was initially hired as a Post-Doctoral Member of the Technical Staff ("MTS"). In March 1996, I was hired by Sandia as a Senior MTS and was then promoted to a Principal MTS in November 1998. In 1994, I became a member of the Personal Status Monitor project—the largest internally-funded biomedical project at Sandia up to that time. The goal of that effort was to develop wearable, wireless hardware and software suitable to acquire and track physiological data from an ambulatory individual in a civilian or military environment. As part of that work, I (1) conducted a broad pre-1997 literature search in the areas of ambulatory health monitoring, optical sensors, pulse oximetry, and optical signal processing; (2) built and tested custom transmittance- and reflectance-mode photoplethysmographic sensors; (3) performed Monte Carlo simulations of red and near-infrared light transport in tissue for reflectance-mode sensor configurations, using the C programming language; and (4) completed a comparative analysis of existing techniques to mitigate the effects of motion artifacts in photoplethysmograms, where I wrote MATLAB scripts to support these analyses.

7. During that time, I also led a $3.2M effort focused on (1) the economic viability of telemedicine as a new care modality and (2) a demonstration of a prototype CORBA-based telemedicine system that utilized plug-and-play interoperability standards. These biomedical projects required numerous industry interactions, workshops, and presentations. During that time, I also developed software using the C++ programming language to incorporate three-dimensional ACIS boundary representation solid models into the legacy Fortran *Integrated Tiger Series* of coupled photon/electron Monte Carlo radiation transport codes.

C. Current Professional Appointment at Kansas State University

i. Overview

8. From August 1999 to the present, I have been employed by the Kansas State University ("KSU") Department of Electrical & Computer Engineering, Manhattan, KS. I am a tenured full professor, and my academic appointment has three primary facets: research, teaching, and service. My over 30 years of research and development work has addressed the broader themes of biomedical engineering, physiological monitoring, wireless systems, embedded devices, signal processing, modeling/simulation, medical interoperability standards, and engineering education. I teach courses offered as part of the KSU Electrical Engineering, Computer Engineering, and Biomedical Engineering curricula. My service work involves engagements that benefit KSU, the local area, and the broader technical community. The following paragraphs summarize these research, teaching, and service endeavors.

ii. Research and Development

9. I direct the KSU Medical Component Design Laboratory, a National Science Foundation funded research and teaching facility that supports the development of distributed health monitoring technologies. My research relates thematically to (1) wireless wearable and nearby physiological sensors coupled with signal-processing and machine-learning techniques to

determine human and animal physiological status; (2) plug-and-play, point-of-care health monitoring systems that utilize interoperability standards; and (3) the creation and assessment of technologies and techniques to streamline engineering education and enhance learning. This work highlights vulnerable populations, including children with severe disabilities, the elderly, individuals with chronic conditions who require constant monitoring, and animals. These efforts include a personal investment of thousands of hours of programming in C/C++, MATLAB, Fortran, Pascal, and other languages.

10. While at KSU, I have been an investigator on 62 grant-funded efforts totaling $14.0M that have supported basic/applied research in the overlapping biomedical and educational research arenas. Primary funding has been provided by the National Science Foundation (CAREER, ITR, DUE, EEC, CRI, SIR, REESE, CCLI/TUES, CPS, and GARDE programs), with supplemental funding granted by NASA, the National Institutes of Health, the State of Kansas, private foundations, internal KSU awards, and corporate partners. This work has resulted in 151 peer-reviewed publications, three book chapters, various reports, and numerous workshops and presentations. I have been the major professor for 34 graduate students, supported 64 undergraduate researchers, and served on 57 graduate committees.

11. My research has addressed technical areas that include human/animal health monitoring, home care technology, human/animal telemedicine architectures, interoperability standards, assistive technology for children with severe cognitive/developmental disabilities, designs for the disabled/elderly, nighttime monitoring tools, sensor-laden beds, acceleration-based behavior analyses, biosignals as biometrics, biomedical instrumentation, biomedical optics, light/tissue interaction, pulse oximetry, ballistocardiography, accelerometry, actigraphy, ultrasonography, wearable ambulatory devices, wireless body area networks, wearable/wireless

pulse oximeters, time/frequency-domain signal processing algorithms, biosignal parameter extraction, motion artifact reduction, computational methods, and custom tools for engineering education.

iii. Teaching

12. I am a Robert and Becca Reichenberger Cornerstone Teaching Scholar in the KSU Carl R. Ice College of Engineering—an endowed position that recognizes consistent excellence in pursuit of improved teaching/learning toolsets and methods. I am also the program coordinator for the new undergraduate Biomedical Engineering degree program in the KSU College of Engineering, and I help to manage the Bioengineering Option within our undergraduate Electrical Engineering curriculum. Regarding coursework, I have taught the following semester-long courses and their associated subject areas:

- ***BME 001 – New Student Assembly*** (3 times): KSU Biomedical Engineering courses/curriculum, facilities/resources, student organizations, internship/job opportunities, and professional development;
- ***ECE 512 – Linear Systems*** (31 times): continuous/discrete signals/systems, time-domain representations, convolution, Fourier series/transforms, frequency-domain spectra, sampling/aliasing, analog/digital filters, and C/MATLAB programming;
- ***ECE 571 – Introduction to Biomedical Engineering*** (20 times): biomedical application domains, telemedicine, home care, assisted living, individuals with disabilities, exercise tracking, tissue engineering resource-limited environments, emergency response, reduced gravity, military medicine, veterinary applications, medical devices, biomedical instrumentation/optics, medical imaging, biosignal processing, biomaterials, biomechanics, wearable systems, body area networks, orthotics/prosthetics, cyberphysical systems, electronic patient records, and medical ethics;
- ***BME 200 – Introduction to Biomedical Engineering*** (3 times): biomedical engineering, biomedical instrumentation, wearable/implantable devices, medical imaging, benchtop systems, orthotics/prosthetics, laser-tissue interaction, biomaterials, tissue engineering, and biomechanics;
- ***ECE 690 – Independent Design*** (8 times): wearable/wireless devices, assistive technology, and biomedical signal processing;

- ***ECE 772/773 – Theory & Techniques of Biomedical Instrumentation*** (13 times): biomedical sensors, amplifiers, electrodes, biosignals, data acquisition, electrical safety, pulse oximetry, wearable devices, imaging, X-ray radiography, ultrasound, magnetic resonance imaging, fluorescence spectroscopy, and image processing; and

- ***ECE 840 – Computer Engineering Methods for Analysis, Simulation, and Design*** (4 times): computational limits, linear systems of equations, linear least squares, interpolation, fast Fourier transforms, random number generation, eigenvalues, optimization, and numerical integration/differentiation.

13. Recently, we procured funding from a private foundation that, when matched by the KSU Carl R. Ice College of Engineering, provided $1.5M for the construction and population of a new 2,000 square foot Biomedical Education and Innovation Laboratory that allows KSU faculty to teach facets of sterile techniques, tissue engineering, biomaterials, and biomedical instrumentation to students enrolled in the new KSU undergraduate Biomedical Engineering degree program and affiliated degree programs.

iv. Service

14. Service is a substantive component of my appointment, and I am honored to be the recipient of two recent service-related awards: a 2021-2022 Outstanding Faculty Award from the KSU XIX Chapter of Mortar Board, and the 2019 Larry E. and Laurel Erickson Public Service Award offered by the KSU Carl R. Ice College of Engineering. As noted above, I am the program coordinator for the undergraduate Biomedical Engineering degree program in the KSU College of Engineering. This program, which we proposed to the Kansas Board of Regents in 2016, was the first new undergraduate degree program in the KSU Carl R. Ice College of Engineering in almost 35 years. I have served on numerous internal KSU committees, including the KSU Internal Review Board, where I am the senior member after a 22-year commitment. I am a faculty senator for the KSU Carl R. Ice College of Engineering and serve on the Academic

Affairs committee. For several years, I occasionally traveled across Kansas to deliver lectures to high schools and community groups as part of the KSU Presidential Lecture Series.

15. Regarding service external to KSU, I am an active member of the Institute for Electrical and Electronics Engineers ("IEEE"). I act as an Associate Editor for the IEEE EMBC annual international conference, and since 2005 I have served as the founding faculty advisor for our college-wide KSU Student Chapter of the IEEE Engineering in Medicine and Biology Society. I am also the KSU college representative for the American Society for Engineering Education ("ASEE"), having recently served as the Chair of the ASEE Midwest Section and the Chair of the 2016 ASEE Midwest Section Conference. In 2017, I was honored to receive an Outstanding Service Award by the Midwest Section of the American Society for Engineering Education. I served two 3-year terms as a member of the Board of Trustees for Heartspring, Wichita, KS, and I have been engaged with a number of other industry workgroups and technical program committees. This service work has included many textbook, manuscript, and proposal reviews. Additional service as an expert witness is summarized in my CV.

III. COMPENSATION

16. I am being compensated at my normal consulting rate of $375 per hour. My compensation does not depend on the contents of this Report, any testimony I may provide, or the ultimate outcome of this Investigation or any other proceeding.

17. I have no financial interest in any party to this case.

IV. DOCUMENTS REVIEWED

18. In forming my opinions, I have considered and/or relied on the following materials and information: (1) the Asserted Patents and their corresponding file histories; (2) the parties' proposed constructions in the Joint Proposed Claim Construction Statement; and (3) any other documents cited within this Report. My opinions are further based upon my 30+ years of

knowledge, education, training, research, and personal and professional experience in the field of physiological monitoring technologies.

V. LEGAL STANDARDS

19. I have been instructed by counsel on the law regarding claim construction. My understanding based on those instructions is as follows.

A. Level of Ordinary Skill in the Art

20. I understand a patent is to be interpreted from the perspective of a person having ordinary skill in the art ("POSITA") as of the patent's priority date.

21. I have been informed that a POSITA is a hypothetical person who has full knowledge of all the pertinent prior art, and that courts may consider the following factors in determining the level of skill in the art:

- Type of problems encountered in art;
- Prior art solutions to those problems;
- Rapidity with which innovations are made;
- Sophistication of the technology; and
- Educational level of active workers in the field.

22. In determining the characteristics of a POSITA, I considered each of these factors. Additionally, I understand that the level of ordinary skill in the art must be assessed at the time of the invention, and I placed myself back at the priority date of the patents to determine the level of ordinary skill in the art.

B. Claim Construction

23. I am not a lawyer, and I do not intend to offer any opinion on the correct interpretation of the law. However, for the purposes of this Report, I have been informed about certain aspects of the law that are relevant to my opinions.

24. I have been informed that claim terms are generally given their ordinary and customary meaning as understood by a POSITA at the time of the alleged invention.

25. I have been informed that an applicant may define a claim term in a patent's specification in a manner that differs from the meaning it would otherwise possess. In such cases, the applicant's "lexicography" controls the definition of the claim term. In other cases, the specification may reveal a clear disavowal or intentional disclaimer of claim scope by the applicant. In such an instance, I have been informed that the inventor has dictated the correct claim scope, and the applicant's intention, as expressed in the specification, governs the scope of the claim term.

26. I have been informed that claim terms should be understood in the context of the claim as a whole. I have also been informed that a patent's specification is relevant to the meaning of a claim term. I have been informed that the claims must be read in light of a patent's specification.

27. I have been informed that the prosecution history should also be considered when interpreting the meaning of a patent's claims. The prosecution history may contain evidence of how the U.S. Patent and Trademark Office ("PTO") and the applicant understood the patent and the meaning of the patent's claim terms.

28. I have been informed that the claim language, specification, and prosecution history are all referred to as "intrinsic evidence." I also have been informed that proceedings before the PTO regarding an issued patent, such as *inter partes* reviews ("IPRs"), may also be considered as intrinsic evidence for the patent.

29. I have been informed that evidence from an expert in the field of the alleged invention can be relevant in determining how a person of ordinary skill in the art would

understand the claims. I have been informed that this evidence is a form of "extrinsic evidence," and that it must be considered in the context of the intrinsic evidence and cannot be used to change the meaning of a claim term to be inconsistent with the intrinsic evidence.

30. I have been informed and understand that the terms in the claims of patents are required by statute to be definite. I have been informed and understand that while terms do not need to be defined with absolute or mathematical precision, the terms of a claim must inform a POSITA about the scope of the terms and the scope of the invention with reasonable certainty. I have been informed and understand that a term is indefinite if it does not provide one of ordinary skill in the art with reasonable certainty about the scope of the term. I further understand that the specification and prosecution history should be consulted to determine whether a claim term is definite because the specification and prosecution history can inform the meaning and scope of a term.

VI. U.S. PATENT NO. 10,912,501, U.S. PATENT NO. 10,912,502, AND U.S. PATENT NO. 10,945,648

A. Level of Ordinary Skill in the Art

31. I have been informed and understand that the earliest alleged priority date for the Asserted Patents according to the Complainants is July 3, 2008.

32. A person of ordinary skill in the art relating to the subject matter of the '501 patent, '502 patent, and '648 patent as of July 3, 2008 would have been 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.

B. Overview of the Asserted Patents

33. The Asserted Patents all share a common specification, and therefore, descriptions of and citations to one patent are applicable to the other two patents.

34. The Asserted Patents are each titled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User." The Asserted Patents state, as background to the purported invention, that the long-standing "standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter." '501 patent at 2:15-17; '502 patent at 2:15-17; '648 patent at 2:14-16. Pulse oximeters and "[d]evices 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." '501 patent at 2:17-20; '502 patent at 2:17-20; '648 patent at 2:16-19.

35. The Asserted Patents further state that "[a]fter attenuation by tissue and fluids of the measurement site, a photodetection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light." '501 patent at 2:20-23; '502 patent at 2:20-23; '648 patent at 2:19-22.

36. Thereafter, according to the Asserted Patents, "[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." '501 patent at 2:24-29; '502 patent at 2:24-29; '648 patent at 2:23-28.

37. The Asserted Patents explain "[i]n 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." '501 patent at 2:30-34; '502 patent at 2:30-34; '648 patent at 2:29-33.

38. In light of this background, the Asserted Patents purport to disclose "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." '501 patent at 2:38-44; '502 patent at 2:38-44; '648 patent at 2:37-43.

39. The Asserted Patents include several examples of finger-worn devices for measuring a user's physiological characteristics.

40. For example, the following figures illustrate clothespin-shaped user-worn devices in the Asserted Patents, where the light sources (e.g., LEDs) are part of the top portion of the device's housing and the light detectors (e.g., photodiodes) are part of the bottom portion of the device's housing.

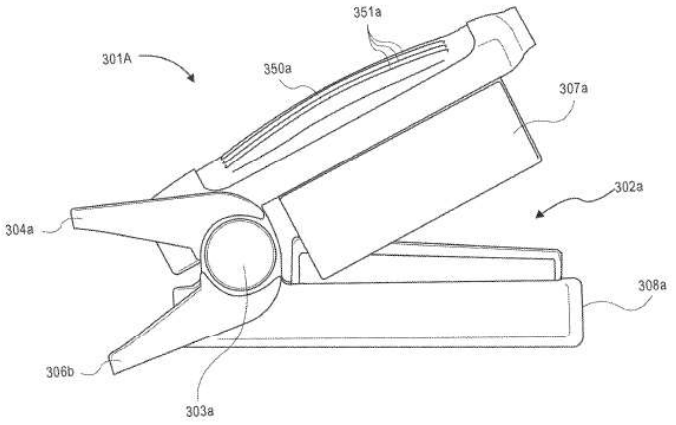


FIG. 3A

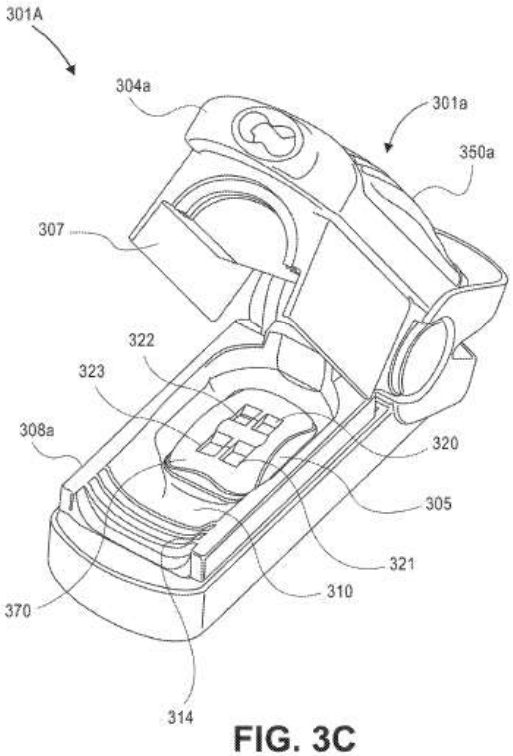


FIG. 3C

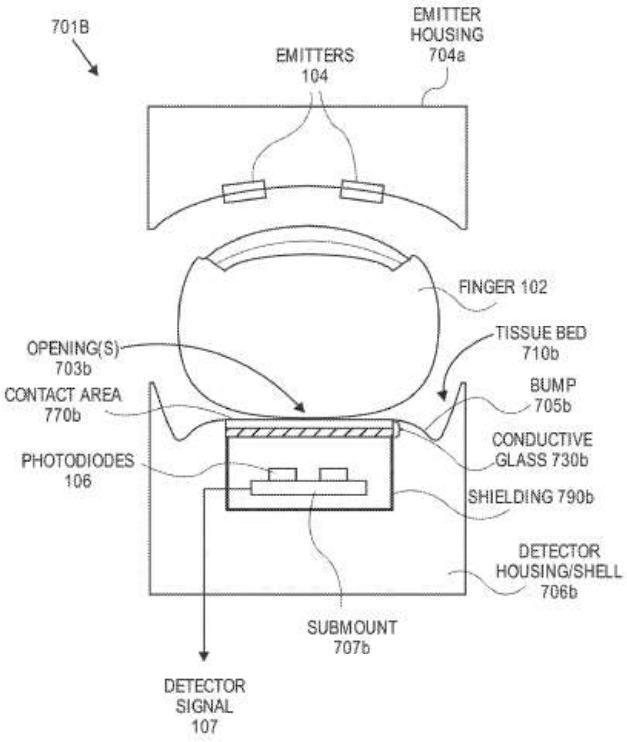


FIG. 7B

'501 patent at Figs. 3A, 3C, 7B; '502 patent at Figs. 3A, 3C, 7B; '648 patent at Figs. 3A, 3C, 7B.

C. The Asserted Claims

41. In this Investigation, I have been informed and understand that Complainants have asserted claims 1-9 and 11-30 of the ’501 patent, claims 1-6, 8-12, 14-22, and 24-30 of the ’502 patent, and claims 1-17 and 19-30 of the ’648 patent (collectively, “Asserted Claims”).

42. As an example, claim 1 of the ’501 patent requires the following:

> 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.

43. A number of the asserted dependent claims refer to a “bulk measurement.” For example, the term “bulk measurement” appears in claim 13 of the ’501 patent, claim 12 of the ’502 patent, and claims 2 and 21 of the ’648 patent.

44. Claim 13 of the ’501 patent recites the following:

> 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.

’501 patent at claim 13 (emphasis added).

45. Claim 12 of the ’502 patent recites the following:

> 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.

’502 patent at claim 12 (emphasis added).

46. Claim 2 of the ’648 patent recites the following:

> 2. 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*** indicating a positioning of the user-worn device.

’648 patent at claim 2 (emphasis added).

47. Claim 21 of the ’648 patent recites the following:

> 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.

’648 patent at claim 21 (emphasis added).

48. The determination of a “bulk measurement” in dependent claim 13 of the ’501 patent, dependent claim 12 of the ’502 patent, and dependent claims 2 and 21 of the ’648 patent relies upon the “one or more signals” from the photodiodes in the respective corresponding independent claims. *See* ’501 patent at claim 1; ’502 patent at claim 1; ’648 patent at claims 1, 20.

D. Claim Construction

i. “bulk measurement”

49. I understand the parties dispute the meaning of the term “bulk measurement” to a POSITA as used in the Asserted Claims of the Asserted Patents as of the alleged priority date (of July 3, 2008).

50. The term “bulk measurement” did not have a commonly understood meaning to a POSITA in the field of physiological monitoring technologies as of the alleged priority date of the Asserted Patents. Accordingly, a POSITA would have needed to look to the intrinsic

evidence, including the shared specification, for the Asserted Patents to understand how the term "bulk measurement" was used.

51. The specification for the Asserted Patents explains that the "bulk measurement" is acquired using multiple detectors in order to take advantage of the multiple-path-length information in the data streams acquired with these detectors.

52. The specification explains that "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." '501 patent at 34:49-54 (emphasis added); '502 patent at 44-49; '648 patent at 34:32-37. A POSITA would have understood from this disclosure that the bulk measurement is obtained from multiple detectors in a spatial configuration (i.e., at multiple locations), and that the use of multiple detectors in this manner can provide information about the positioning of the user-worn device.

53. The specification additionally explains that "[i]n 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." '501 patent at 9:18-25; '502 patent at 9:18-25; '648 patent at 9:13-20.

54. As affirmed in the specification, variations in path lengths—the light-propagation distances between an emitter (or emitters) and the detectors—result from the use of multiple detectors in a spatial geometry and are intended to create robustness in the resulting bulk measurement because (a) the associated photons propagate through a greater variety of sub-

tissues within the overall volumetric field of view of the optical sensing system and (b) the designer has flexibility in terms of the types of processing algorithms applied to the collection of output streams acquired from the multiple detectors. The desired benefits of such path length variations would be lost if the sensing system acquired only one signal from one detector. Instead, as the specification describes, multiple detectors in a spatial geometry are used to determine a bulk measurement.

55. Based on these disclosures in the specification of the Asserted Patents, a POSITA would have understood that a "bulk measurement" uses multiple detectors. This would be consistent with the idea of taking a measurement from a "bulk" (i.e., large) volume of the user's tissue, which the use of multiple detectors in a spatial configuration enables, as compared to the volume that can be 'seen' by a single detector.

56. Additionally, in the specification for the Asserted Patents, a bulk measurement is not mentioned in the context of a single emitter (e.g., LED) or in the context of a single detector (e.g., photodiode). Rather, as explained above, multiple detectors are required to create a diversity of path lengths. The specification, therefore, does not explain how the signal (or output stream) from an individual detector (e.g., one photodiode) could provide enough information to determine a bulk measurement responsive to a positioning of the user-worn device.

57. Further, the specification does not explain how to obtain a single signal from multiple detectors toward the acquisition of a bulk measurement. Rather, the specification explains as follows:

> 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***.

'501 patent at 9:18-25 (emphasis added); '502 patent at 9:18-25; '648 patent at 9:13-20. Each of the detectors has its own "respective output stream [or signal] based on the detected optical radiation." Even when the signals are summed, the process requires a plurality of "output streams" from each of multiple detectors, where each of the plurality of output streams would already be a signal. As the specification explains, each of the multiple detectors provides its own signal, which accounts for a diversity of path lengths. The specification does not explain how an output stream, or signal, from a single detector can be used to determine a bulk measurement.

58. As highlighted above, the term "bulk measurement" appears in claim 13 of the '501 patent, claim 12 of the '502 patent, and claims 2 and 21 of the '648 patent.

59. Claim 13 of the '501 patent depends from independent claim 1. Claim 1 of the '501 patent requires "one or more processors configured to receive ***one or more signals*** from the photodiodes." Thus, to implement the full scope of the claim, the one or more processors in claim 13 must be capable of determining the "bulk measurement" from as few as ***one*** signal from the photodiodes. Likewise, claim 12 of the '502 patent and claims 2 and 21 of the '648 patent also depend on independent claims that recite processors configured to calculate measurements from "***one or more signals***" from the photodiodes. *See* '502 patent at claim 12 (which depends from claim 1, which requires "one or more processors configured to receive one or more signals from at least one of the photodiodes"); '648 patent at claim 2 (which depends from claim 1, which requires "one or more processors configured to receive one or more signals from at least one of the photodiodes"), and claim 21 (which depends from claim 20, which requires "one or more processors configured to receive one or more signals from at least one of the

photodiodes"). The full scope of these claims thus also requires determining the "bulk measurement" from as few as ***one*** signal from the photodiodes.

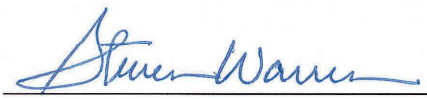
60. According to the claim language, the "one or more signals" from the photodiodes in independent claim 1 of the '501 patent are used by the one or more processors in dependent claim 13 to determine a bulk measurement responsive to a positioning of the user-worn device. *See* '501 patent at claim 13 ("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"). This understanding equally applies to claim 12 of the '502 patent and claims 2 and 21 of the '648 patent. In all cases, the claims describe the "bulk measurement" as something that can be determined from as few as one signal from the photodiodes.

61. Based upon the intrinsic evidence, a POSITA would not have understood that a "bulk measurement" could result from a single signal from the photodiodes.

62. Because a POSITA would have understood the specification to describe a "bulk measurement" as a measurement utilizing multiple signals from multiple photodiodes, whereas the claims which incorporate the term "bulk measurement" allow for the calculation or determination of a "bulk measurement" based on one signal, the meaning of "bulk measurement" as used in the Asserted Patents would have been unclear, and a POSITA would not have understood with reasonable certainty the scope of what is claimed by claim 13 of the '501 patent, claim 12 of the '502 patent, and claims 2 and 21 of the '648 patent.. As a result, it is my opinion that claim 13 of the '501 patent, claim 12 of the '502 patent, and claims 2 and 21 of the '648 patent are indefinite.

63. A POSITA that reviewed the intrinsic evidence for the Asserted Patents would not have understood a "bulk measurement" to mean a "baseline measurement," as Complainants contend.

Dated: January 18, 2022



Steven Warren, Ph.D.

EXHIBIT 4

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

Before the Honorable Monica V. Bhattacharyya
Administrative Law Judge

In the Matter of CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF	Inv. No. 337-TA-1276

REBUTTAL EXPERT CLAIM CONSTRUCTION REPORT OF STEVEN WARREN, PH.D.

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I. INTRODUCTION

1. My name is Dr. Steven Warren. Counsel for Apple Inc. ("Apple") has retained me as an expert in this litigation.

2. On January 18, 2022, I submitted a report titled "Initial Expert Claim Construction Report" ("Initial Report") to provide background regarding U.S. Patent No. 10,912,501 ("'501 patent"), U.S. Patent No. 10,912,502 ("'502 patent"), and U.S. Patent No. 10,945,648 ("'648 patent") (collectively, the "Asserted Patents"), and to explain how one of ordinary skill in the art would have understood the disputed claim term "bulk measurement," as of the earliest alleged priority date (July 3, 2008) for these Asserted patents, which share a specification. I incorporate by reference my Initial Report herein in its entirety.

3. I understand that on January 18, 2022, Complainants' expert Dr. Vijay Madisetti submitted a report titled "Expert Report of Vijay K. Madisetti, Ph.D. Regarding Claim Construction," which includes his opinions on the construction of "bulk measurement."

4. I have been asked to review and respond to Dr. Madisetti's report. I submit this Rebuttal Expert Claim Construction Report ("Rebuttal Report") to explain my disagreement with Dr. Madisetti's opinion that a POSITA at the time of the alleged invention of the Asserted Patents would have understood "bulk measurement" as used in the Asserted Patents to mean "baseline measurement."

5. This Rebuttal Report is based on the information available and known to me as of the date of this Rebuttal Report.

6. It may be necessary for me to supplement and/or amend this Rebuttal Report based on material or information that subsequently comes to light in this Investigation (including any additional claim construction reports submitted on behalf of Complainants in this Investigation), and I reserve the right to do so.

II. QUALIFICATIONS

7. My qualifications are set forth in my Initial Report, which includes my curriculum vitae attached as Appendix A to that report.

III. COMPENSATION

8. I am being compensated at my normal consulting rate of $375 per hour. My compensation does not depend on the contents of this Rebuttal Report, any testimony I may provide, or the ultimate outcome of this Investigation or any other proceeding.

9. I have no financial interest in any party to this case.

IV. DOCUMENTS REVIEWED

10. In forming my opinions, I have considered and/or relied on the following materials and information: (1) the Asserted Patents and their corresponding file histories; (2) the parties' proposed constructions in the Joint Proposed Claim Construction Statement; (3) Dr. Madisetti's report and the materials cited therein, including J. G. Webster's book Design of Pulse Oximeters and U.S. Patent No. 4,892,101 to Cheung *et al.* titled "Method and Apparatus for Offsetting Baseline Portion of Oximeter Signal;" and (4) any other documents cited within this Rebuttal Report. My opinions are further based upon my 30+ years of knowledge, education, training, research, and personal and professional experience in the field of physiological monitoring technologies.

V. LEGAL STANDARDS

11. I have been instructed by counsel on the law regarding claim construction. My understanding based on those instructions is summarized in the Legal Standards section of my Initial Report, which I herein incorporate by reference.

VI. U.S. PATENT NO. 10,912,501, U.S. PATENT NO. 10,912,502, AND U.S. PATENT NO. 10,945,648

A. Level of Ordinary Skill in the Art

12. I herein incorporate by reference the definition of a person having ordinary skill in the art ("POSITA") from my Initial Report. I note that Dr. Madisetti applied the same definition for purposes of his analysis and has not suggested an alternative definition. Accordingly, I use the same definition for purposes of responding to Dr. Madisetti's opinions.

B. Claim Construction

i. "bulk measurement"

13. Dr. Madisetti contends that a POSITA would have understood "bulk measurement" as used in the asserted claims to mean "baseline measurement." Madisetti Rpt. at ¶ 43. I disagree.

14. As an initial matter, as I explained in my prior declaration, the term "bulk measurement" did not have a commonly understood meaning to a POSITA in the field of physiological monitoring technologies as of the alleged priority date of the Asserted Patents.

15. Dr. Madisetti contends that a "bulk measurement" as used in the specification "is a non-pulsatile measurement, also known as the DC-component of a signal." Madisetti Rpt. at ¶ 46. Dr. Madisetti further contends that a "baseline measurement" is "the non-pulsatile or DC component of a signal." *Id*. at ¶ 50. Dr. Madisetti therefore equates a "bulk measurement" to a "baseline measurement." *Id.* at ¶ 43. Essentially, Dr. Madisetti attempts to apply the transitive property. According to Dr. Madisetti, a "bulk measurement," A, is a non-pulsatile measurement, B (i.e., A=B) and a "baseline measurement," C, is a non-pulsatile measurement, B (i.e., C=B), therefore, a "bulk measurement" must be a "baseline measurement" (i.e., A=C). This reasoning is flawed both as a matter of logic and because the underlying premise – that a "bulk

measurement" is the same as a "non-pulsatile measurement" – is inconsistent with how a POSITA would have understood the specification to use this term. A "bulk measurement" cannot mean either a DC component of a signal or a "baseline measurement" and still be consistent with the stated roles of a "bulk measurement" in the shared specification.[1]

16. First, a POSITA reviewing the intrinsic evidence would not have understood a "bulk measurement" to have the same meaning as a non-pulsatile measurement. Dr. Madisetti quotes various portions of the specification, including the following:

> 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.

'501 patent at 34:35-40 (emphasis added).

> [T]he 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.

[1] Dr. Madisetti sometimes refers to a "DC or non-pulsatile component of a signal." *See e.g.*, Madisetti Rpt. at ¶ 43. To the extent that Dr. Madisetti is using the DC component of a signal and a non-pulsatile component of a signal interchangeably, a POSITA would have had this same understanding. To the extent that Dr. Madisetti contends that the DC component of a signal and a non-pulsatile component of a signal are different, a POSITA would not have had that same understanding.

’501 patent at 34:49-67 (emphasis added);

> 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.

’501 patent at 35:41-50 (emphasis added).

17. These portions of the specification simply confirm that a “bulk measurement” can be made in concert with a non-pulsatile measurement. They do not suggest that a “bulk measurement” is itself a “non-pulsatile measurement.” Instead, a POSITA at the time of the alleged invention would have readily recognized that a non-pulsatile measurement can be used to help determine the correct positioning of a device. The “bulk” aspect of the “bulk, non-pulsatile measurement” or the “non-pulsatile, bulk measurement” in the above excerpts refers to the use of signals from multiple detectors, as described elsewhere in the specification, rather than a single detector. *See, e.g.*, ’501 patent at 34:49-51 (“[T]he use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly.”). Therefore, the non-pulsatile measurements noted in the above portions of the specification can have an additional “bulk” aspect when they are performed using multiple detectors. A POSITA would not have read the specification and understood that a “bulk measurement” is limited to only a non-pulsatile measurement.

18. Second, a POSITA reviewing the intrinsic evidence would not have understood a “bulk measurement” to be a DC component of a signal. Dr. Madisetti quotes several portions of the specification that allegedly “contrast[] a ‘bulk’ measurement with a ‘pulsatile’ measurement,

and he therefore characterizes a 'bulk' measurement as a 'non-pulsatile' measurement." Madisetti Rpt. at ¶ 44. However, nowhere in the specification is a "bulk measurement" identified as a DC signal component (average signal component) or as a non-pulsatile signal component: it is just referred to as a "bulk measurement."

19. For example, Dr. Madisetti relies on the following quote from the specification: "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." '501 patent at 9:18-22; *see* Madisetti Rpt. at ¶ 44. The specification distinguishes a "bulk" measurement from a pulsatile measurement, but the specification does not suggest that a bulk measurement is a non-pulsatile signal component.

20. Dr. Madisetti also quotes portions of the specification where a bulk measurement is actually distinguished from a non-pulsatile measurement:

> 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**.**

'501 patent at 34:35-40 (emphasis added); *see* Madisetti Rpt. at ¶ 44.

> 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.

’501 patent at 35:41-50 (emphasis added); *see* Madisetti Rpt. at ¶ 44. The excerpts above refer to either a “bulk, non-pulsatile measurement” or a “non-pulsatile, bulk measurement.” Each of these refers to a measurement having two characteristics: (1) a “bulk” characteristic ***and*** (2) a “non-pulsatile” characteristic. If “bulk” meant “non-pulsatile,” then there would not have been any reason for both words to describe the same measurement, especially since “bulk measurement” did not have a commonly understood meaning at the time of the alleged invention.

21. Another passage from the specification that Dr. Madisetti relies upon is as follows:

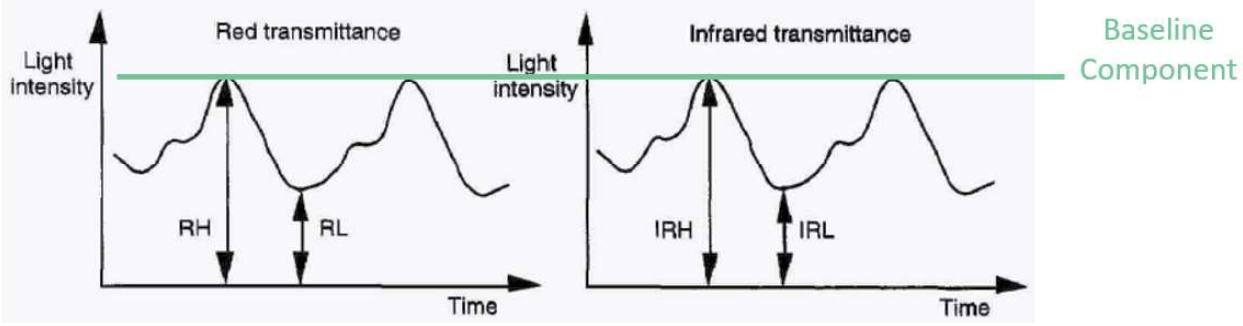
> Secondly, the use of multiple-detectors in a spatial configuration allow for a ***bulk measurement to confirm or validate that the sensor is positioned correctly***. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where 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.

’501 patent at 34:49-67 (emphasis added); *see* Madisetti Rpt. at ¶ 44. Here, the specification simply states that “the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly.” Nothing here equates a bulk measurement to a non-pulsatile measurement.

22. Likewise, nowhere does the intrinsic record for the Asserted Patents define or characterize a "bulk measurement" as a DC component of a signal.

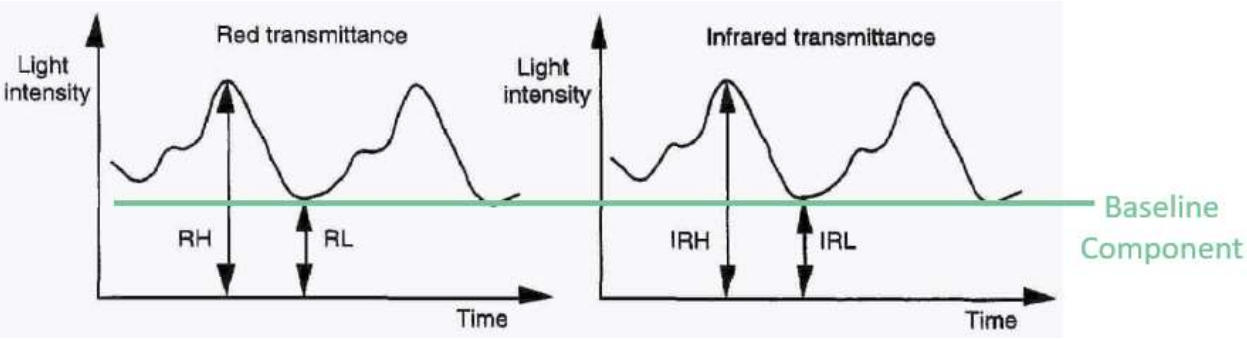
23. Third, the prior art literature that Dr. Madisetti identifies does not show that a "bulk measurement" is either a non-pulsatile measurement or a "baseline measurement." Dr. Madisetti relies upon Webster 1997 and U.S. Patent No. 4,892,101 ("Cheung") as examples of how he believes "the non-pulsatile component of the signal" has been referred to as a "baseline." Madisetti Rpt. at ¶¶ 54-55. Although these two prior art references discuss a "baseline component," neither mentions a "bulk measurement." Without any explanation or mention of a "bulk measurement," these two references would not have informed a POSITA as to the meaning of a "bulk measurement" in the context of the Asserted Patents.

24. Dr. Madisetti also cites both Webster 1997 and Cheung in support of his position that a "baseline" is the DC component of a signal. However, these references do not support that interpretation. For example, Webster 1997 states that "[t]he magnitude of the baseline component at a given point in time is approximately equal to the level identified as R_H (figure 9.2)." Webster 1997 at 147 (APL_MAS_ITC_00279651 at APL_MAS_ITC_00279797). Below, I have annotated Figure 9.2 from Webster 1997 to reflect the "baseline component" according to this disclosure:



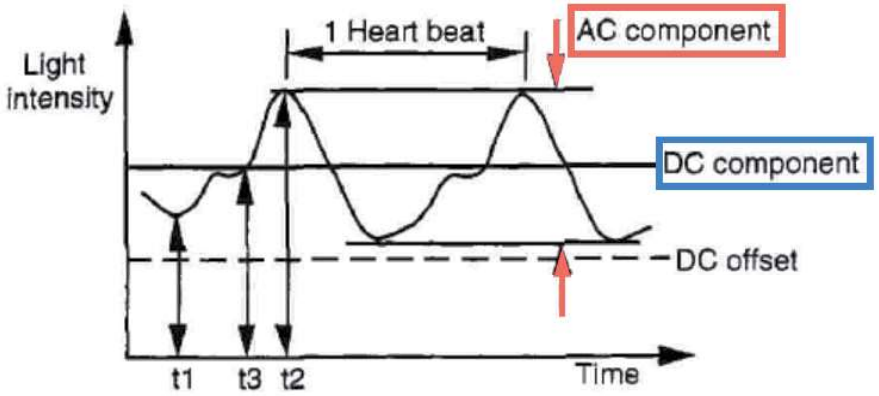
Webster 1997 at 144 (APL_MAS_ITC_00279651 at APL_MAS_ITC_00279794) (annotated). Webster 1997 goes on to explain that "for convenience, the baseline component may be thought

of as the level indicated by R_L, with the pulsatile component varying between the values of R_H and R_L over a given pulse." Webster 1997 at 147 (APL_MAS_ITC_00279651 at APL_MAS_ITC_00279797). Below, I have annotated Figure 9.2 from Webster 1997 to reflect the "baseline component" according to this disclosure:



Webster 1997 at 144 (APL_MAS_ITC_00279651 at APL_MAS_ITC_00279794) (annotated).

25. A POSITA reading Webster 1997, however, would have understood that the "baseline component" would be distinct from the DC component. Figure 9.3 in Webster 1997 illustrates the location of the DC component:



Webster 1997 at 145 (APL_MAS_ITC_00279651 at APL_MAS_ITC_00279795) (annotated).

26. In other words, a POSITA would have understood the "baseline component" in Webster 1997 to be mutually exclusive from the DC component, where the DC component exists

within the range of the pulsatile (AC) component. Accordingly, Webster 1997 does not equate a "baseline measurement" to a DC component, contrary to what Dr. Madisetti states.

27. Similarly, in Cheung, the "baseline component" is not the DC component. Cheung explains that "[a]s will be appreciated, the magnitude of the baseline component at a given point in time is substantially equal to the level identified in FIG. 9 as R_H." Cheung at 14:46-49. This disclosure is consistent with Webster 1997. I have annotated Figure 9 from Cheung to illustrate this disclosure:

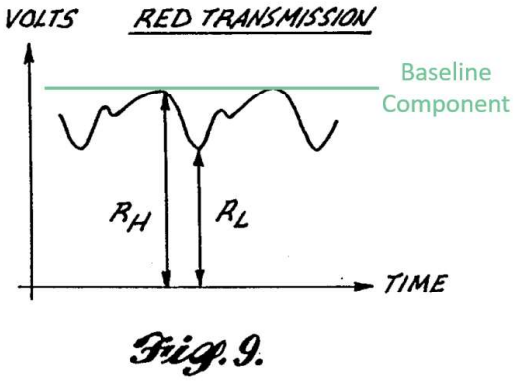


Fig. 9.

Cheung at Fig. 9 (annotated).

28. Cheung also explains that "[f]or convenience, however, the baseline component may be thought of as the level indicated by R_L, with the pulsatile component varying between the values for R_H and R_L over a given pulse." Cheung at 14:49-52. This disclosure is also consistent with Webster 1997. I have annotated below Figure 9 from Cheung to illustrate this disclosure:

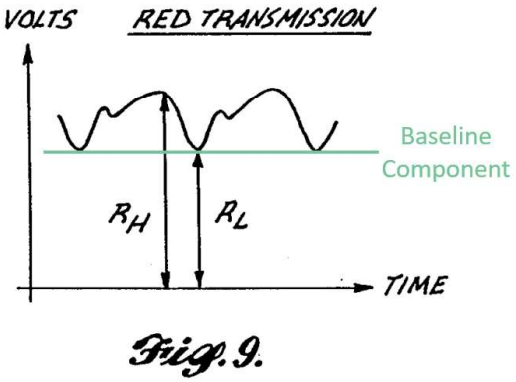


Fig. 9.

Cheung at Fig. 9 (annotated).

29. However, as explained above, a POSITA would have understood that the DC component is separate from the "baseline component," as illustrated below:

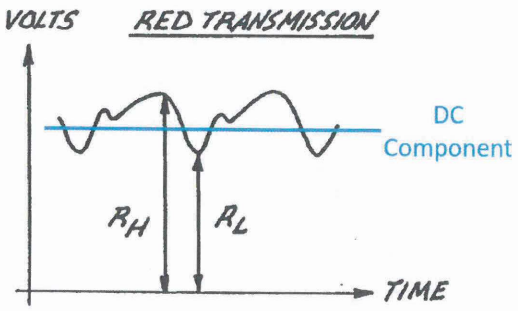


Fig. 9.

Cheung at Fig. 9 (annotated). Thus, Cheung does not equate a "baseline measurement" to a DC component, contrary to what Dr. Madisetti states.

30. Dr. Madisetti is incorrect that a "bulk measurement" is a DC component of a signal, and he is incorrect that a "baseline measurement" is a DC component of a signal. Therefore, Dr. Madisetti's conclusion, that a "bulk measurement" is a "baseline measurement," is incorrect.

31. Dr. Madisetti has failed to demonstrate that a POSITA would have understood at the time of the alleged invention that "bulk measurement," as used in the Asserted Patents, means a "baseline measurement."

Dated: January 25, 2022

Steven Warren, Ph.D.

EXHIBIT 5

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before the Honorable Monica Bhattacharyya
Administrative Law Judge

In the Matter of **CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF**	Inv. No. 337-TA-1276

REBUTTAL EXPERT REPORT OF VIJAY K. MADISETTI, PH.D. REGARDING CLAIM CONSTRUCTION

INTRODUCTION

1. I, Vijay K. Madisetti, Ph.D., submitted an expert report regarding claim construction, dated January 18, 2022 ("Initial Report"). I have been asked by Masimo to provide this rebuttal report to respond to opinions offered by Steven Warren, Ph.D. in his January 18, 2022 Initial Expert Claim Construction Report ("Warren Report").

2. In addition to the materials listed in Exhibit B to my Initial Report, I have reviewed the Warren Report and materials cited therein.

3. To the extent I have not addressed a particular point in the Warren Report, that does not mean that I agree with Dr. Warren's opinions.

BULK MEASUREMENT

4. I disagree with Dr. Warren regarding the meaning of the term "bulk measurement." Dr. Warren focuses on only one particular use of a bulk measurement disclosed in the specification—to confirm or validate that a sensor is positioned correctly. *See, e.g.*, Warren Report ¶ 52 (citing '501 patent at 34:49-54; '502 patent at 34:44-49; '648 patent at 34:32-37). In doing so, Dr. Warren limits the use of a "bulk measurement" to determining sensor position using multiple detectors. *Id*. ¶¶ 52, 55. In my opinion, a POSA would not limit the definition of the term "bulk measurement" to the use of a particular "bulk measurement" in a single embodiment when the term is used more broadly throughout the specification. This is analogous to limiting the definition of a car based on the description of the car being used as a taxi. As described below, the specification does not limit bulk measurement in this manner.

5. As explained in my Initial Report, a bulk measurement refers to a baseline measurement or the non-pulsatile or DC-component of the measurement. The specification discloses multiple uses of a "bulk measurement." For example, the specification describes the use of a bulk measurement to confirm or validate a pulsatile measurement and to "attain sufficient

SNR" (or Signal-to-Noise Ratio). *See* '501 patent at 34:35-41. The specification also describes a "bulk measurement to confirm or validate that the sensor is positioned correctly." *Id.* at 34:50-51. And the specification describes a "bulk-measurement scheme" to cancel or reduce noise. *See id.* at 35:28-40.

6. A POSA would understand these portions of the specification explain how a system may use a bulk measurement. But these uses do not limit the definition of a bulk measurement. Instead, as explained in my Initial Report, a POSA would understand that a bulk measurement is a baseline measurement.

7. Furthermore, the claims do not limit "bulk measurement" to only one of those uses. Instead, the claims recite a measurement "responsive to" or "indicating" a positioning of the user-worn device. A POSA would understand a baseline measurement, the non-pulsatile or DC-component, to be responsive to or indicating positioning. That is because the baseline measurement would change based on the amount of tissue and bone at the measurement site. For example, the difference in the amount of bone at a knuckle as compared to the tip of the finger will result in different baseline measurements.

8. I also disagree with Dr. Warren that "bulk measurement" is somehow indefinite. Dr. Warren focuses on the scope of certain asserted claims covering a bulk measurement determined from one emitter and one detector. *See* Warren Report ¶¶ 59-62. A POSA would have understood that the baseline (non-pulsatile or DC) measurement could be calculated for a single emitter and a single detector. Such a calculation would have been routine for a POSA.

9. For example, a comprehensive textbook on pulse oximetry describes differences between individual DC components for each LED. *See* DESIGN OF PULSE OXIMETERS, Webster

J.G. (ed.) (1997) ("Webster") at 49-50 (APL_MAS_ITC_00015683-84). Figure 4.6 in Webster depicts differences in detected signals from a red LED and an infrared LED:

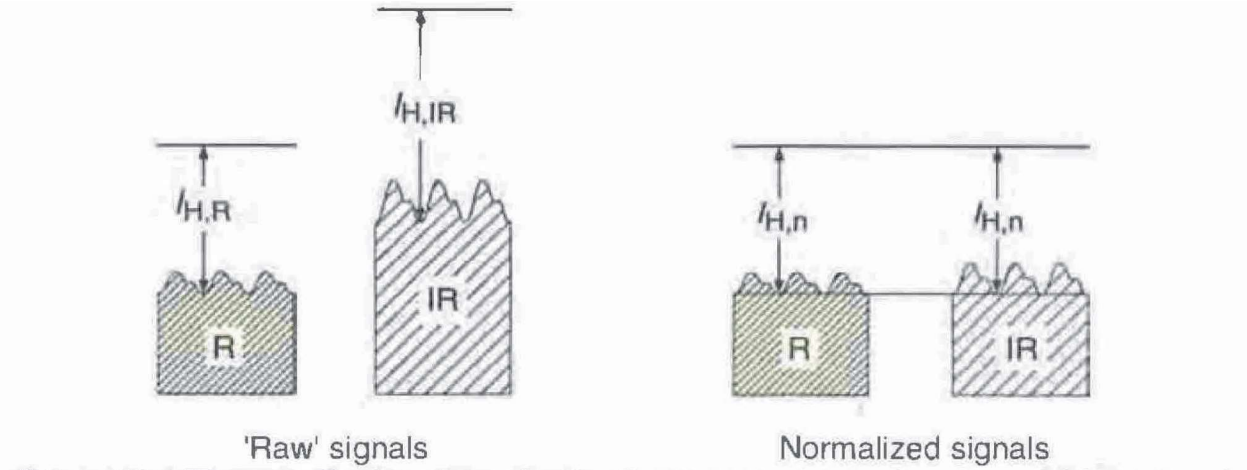


Figure 4.6 The normalization of the signals. The transmitted light from the red LED (R) and from the infrared LED (IR) is divided by its individual DC component. Thus, both normalized light intensities have the same magnitude during diastole. The normalized signals determine the basis for the calculation of the arterial oxygen saturation.

Id. at 50 (APL_MAS_ITC_00015684).

10. Because of the differences in detected signals from different LEDs, pulse oximeters can normalize signals before they are compared with each other. *See* Webster at 49 (APL_MAS_ITC_00015683). "[N]ormalized signals of the transmitted red and infrared light are independent of incident light levels and photodetector nonlinearities." *Id.* After normalization, the AC components of the signals "represent only changes of transmitted light caused by the pulsation of blood in the arteries," permitting comparison to each other. *Id.* Webster explains that such normalization of a signal is calculated by dividing the transmitted light from each LED by its individual DC component. *Id.* at 50. Normalization of signals, an important step in a pulse oximetry system, therefore involves use of the baseline component of a single signal from a single light source and single detector. Accordingly, Dr. Warren is incorrect to the extent he contends

that a POSA would not have known how to determine a "bulk measurement" (*i.e.*, a baseline or DC-value) of a single signal from a single emitter.

11. I also note that Dr. Warren uses "bulk" to refer to a "volume of the user's tissue." *See* Warren Report ¶ 55. This use is consistent with a POSA's understanding that a bulk measurement is the DC value or baseline measurement. In other words, the baseline measurement is responsive to the baseline volume of the user's tissue. Just like Dr. Warren, a POSA would have understood the meaning of the term "bulk" in the context of the '501, '502, and '648 patents.

MISCELLANEOUS

12. I understand that Apple has not provided a detailed explanation of its proposed constructions. I reserve the right to modify and/or supplement my opinions should Apple or Dr. Warren serve a rebuttal expert report related to the disputed claim construction issues.

Dated: 1/25/22

Vijay K. Madisetti, Ph.D.

EXHIBIT 6

Medical Science Series

Design of Pulse Oximeters

Edited by

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Department of Electrical and Computer Engineering
University of Wisconsin-Madison

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9.3 RATIO OF RATIOS

The Ratio of Ratios (R_{OS}) is a variable used in calculating the oxygen saturation level. It is typically calculated by taking the natural logarithm of the ratio of the peak value of the red signal divided by the valley measurement of the red signal. The ratio is then divided by the natural logarithm of the ratio of the peak value of the infrared signal divided by the valley measurement of the infrared signal (Cheung *et al* 1989).

9.3.1 Peak and valley method

A photodiode placed on the side of a finger opposite the red and infrared LEDs receives light at both wavelengths transmitted through the finger. The received red wavelength light intensity varies with each pulse and has high and low values R_H and R_L, respectively. R_L occurs during systole when arterial blood volume is at its greatest, while R_H occurs during diastole when the arterial blood volume is lowest (figure 9.2). Considering the exponential light decay through homogeneous media, it is observed that

$$R_L = I_0 e^{-[\alpha(\lambda_R)d + \alpha_A(\lambda_R)\Delta d]}. \tag{9.14}$$

Similarly,

$$R_H = I_0 e^{-\alpha(\lambda_R)d}. \tag{9.15}$$

Taking the ratio of equations (9.14) and (9.15) and simplifying, we have

$$\frac{R_L}{R_H} = e^{-\alpha_A(\lambda_R)\Delta d}. \tag{9.16}$$

Taking the logarithm of both sides of equation (9.16) yields

$$\ln\left(\frac{R_L}{R_H}\right) = -\alpha_A(\lambda_R)\Delta d. \tag{9.17}$$

Similar expressions can be produced for the infrared signal.

$$\ln\left(\frac{IR_L}{IR_H}\right) = -\alpha_A(\lambda_{IR})\Delta d. \tag{9.18}$$

The ratiometric combination of equations (9.17) and (9.18) yields

$$\frac{\ln\left(\frac{R_L}{R_H}\right)}{\ln\left(\frac{IR_L}{IR_H}\right)} = \frac{-\alpha_A(\lambda_R)\Delta d}{-\alpha_A(\lambda_{IR})\Delta d}. \tag{9.19}$$

Because the Δd terms in the numerator and denominator of the right side of the equation (9.19) cancel, as do the negative signs before each term, equation (9.19) when combined with equation (9.13) yields

$$\text{Ratio} = R_{OS} = \frac{\alpha_A(\lambda_R)}{\alpha_A(\lambda_{IR})} = \frac{\ln\left(\dfrac{R_L}{R_H}\right)}{\ln\left(\dfrac{IR_L}{IR_H}\right)}. \tag{9.20}$$

Thus, by measuring the minimum and the maximum emergent light intensities of both the red and infrared wavelengths (R_L, R_H, IR_L, IR_H), a value for the term R_{OS} can be computed. Empirically derived calibration curves are then used to determine the oxygen saturation based on R_{OS}.

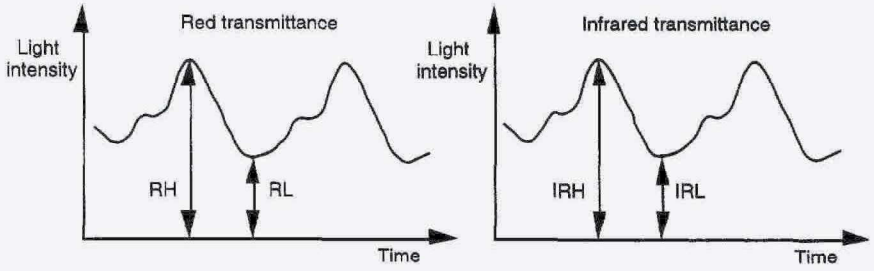

Figure 9.2. A graphical plot of transmitted light intensity converted into voltage. High (H) and low (L) signals are shown as a function of time of the transmittance of red (R) and infrared (IR) light through the finger.

9.3.2 Derivative method: noise reduction software

Yorkey (1996) derives the Ratio of Ratios by calculating using the separated AC and DC components of the measured signal. This mathematical derivation of the ratio of ratios is performed using the Beer–Lambert equation.

$$I_1 = I_0 e^{-\alpha L} \tag{9.21}$$

where I_1 is the emerging light intensity, I_0 is the incident light intensity, α is the relative extinction coefficient of the material and L is the path length. In this method, the Ratio of Ratios is determined using the derivatives. Assuming the change in path length is the same for both wavelengths during the same time interval between samples, the instantaneous change in path length (dL/dt) must also be the same for both wavelengths.

We can extend the general case of taking the derivative of e^u to our case

$$\frac{de^u}{dt} = e^u \frac{du}{dt} \tag{9.22}$$

$$\frac{dI_1}{dt} = I_0 e^{-\alpha L}\left(-\alpha \frac{dL}{dt}\right) \tag{9.23}$$

Therefore,

$$\frac{(dI_1/dt)}{I_1} = -\alpha \frac{dL}{dt}. \tag{9.24}$$

Here, I_1 is equal to the combined AC and DC component of the waveform and dI_1/dt is equal to the derivative of the AC component of the waveform. Using two wavelengths we have

$$\text{R of R} = \frac{(dI_R/dt)/I_R}{(dI_{IR}/dt)/I_{IR}} = \frac{-\alpha(\lambda_R)}{-\alpha(\lambda_{IR})}. \tag{9.25}$$

Instead of using the previous method of calculating the Ratio of Ratios based on the natural logarithm of the peak and valley values of the red and infrared signals, the value of the R of R can be calculated based on the derivative value of the AC component of the waveform.

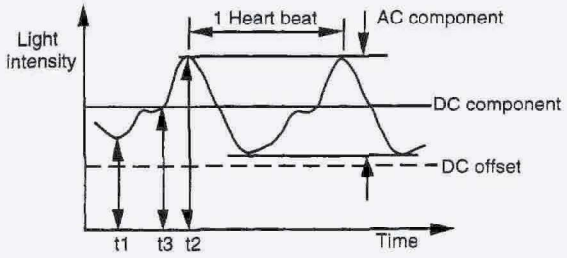

Figure 9.3. A waveform of the transmitted light intensity through a finger showing the AC component, the DC component and the DC offset.

Note in discrete time

$$\frac{dI_R(t)}{dt} \approx I_R(t_2) - I_R(t_1). \tag{9.26}$$

If we choose t_2 and t_1 to be the maximum and minimum of the waveform, we can refer to this difference as the AC value, and the denominator above evaluated at some point in time t_3 in between t_2 and t_1 as the DC value. So,

$$\frac{\dfrac{dI_R(t)/dt}{I_R}}{\dfrac{dI_{IR}(t)/dt}{I_{IR}}} \approx \frac{\dfrac{I_R(t_2) - I_R(t_1)}{I_R(t_3)}}{\dfrac{I_{IR}(t_2) - I_{IR}(t_1)}{I_{IR}(t_3)}} = \frac{\dfrac{AC_R}{DC_R}}{\dfrac{AC_{IR}}{DC_{IR}}} = R. \tag{9.27}$$

Potratz (1994) implemented another improved method for noise reduction called the derivative method of calculating the Ratio of Ratios. To calculate the Ratio of Ratios based on the derivative formula, a large number of sampled points along the waveform are used instead of merely the peak and valley measurements. A series of sample points from the digitized AC and AC + DC values for the infrared and red signals are used to form each data point. A digital FIR filtering step essentially averages these samples to give a data point. A large number of data points are determined in each period. The period is determined after the fact by noting where the peak and valley figure (Figure 9.3).

From the AC signal, a derivative is then calculated for each pair of data points and used to determine the ratio of the derivatives for R and IR. A plot of these ratios over a period will ideally result in a straight line. Noise from the motion artifact and other sources will vary some values. But by doing the linear regression, a best line through a period can be determined, and used to calculate the Ratio of Ratios.

A problem with other systems was DC drift. Therefore, a linear extrapolation was performed between two consecutive negative peaks of the waveform. This adjusts the negative peak of the waveform as if the shift due to the system noise did not occur. A similar correction can be calculated using the derivative form of the waveform. In performing the correction of the DC component of the waveform, it is assumed that the drift caused by noise in the system is much slower than the waveform pulses and the drift is linear. The linear change on top of the waveform can be described by the function

$$g(t) = f(t) + mt + b \tag{9.28}$$

where m is equal to the slope of the waveform and b is equal to a constant.

The linear change added to the waveform does not affect the instantaneous DC component of the waveform. However, the derivative of the linear change will have an offset due to the slope of the interfering signal:

$$\mathrm{d}(f(t) + mt + b)/\mathrm{d}t = \mathrm{d}f(t)/\mathrm{d}t + m. \tag{9.29}$$

if we assume that the offset is constant over the period of time interval, then the Ratio of Ratios may be calculated by subtracting the offsets and dividing:

$$\text{R of R} = \frac{Y}{X} = \frac{(y - m_y)}{(x - m_x)} \tag{9.30}$$

where y and x are the original values and m_x and m_y are the offsets.

Since the Ratio of Ratios is constant over this short time interval the above formula can be written as

$$\frac{(y - m_y)}{(x - m_x)} = R. \tag{9.31}$$

Therefore,

$$y = Rx - Rm_x + m_y. \tag{9.32}$$

Since it was assumed that m_1, m_2, and R are constant over the time interval, we have an equation in the form of $y = mx + b$ where m is the Ratio of Ratios. Thus,

we do a large number of calculations of the Ratio of Ratios for each period, and then do the best fit calculation to the line $y = Rx + b$ to fit the optimum value of R for that period, taking into account the constant b which is caused by DC drift.

To determine the Ratio of Ratios exclusive of the DC offset we do a linear regression. It is preferred to take points along the curve having a large differential component, for example, from peak to valley. This will cause the mx term to dominate the constant b:

$$R = \frac{n\sum x_j y_j - \sum x_j \sum y_j}{n\sum x_j^2 - (\sum x_j)^2} \tag{9.33}$$

where n = # of samples, j = sample #, $x = I_R \, dI_{IR} / dt$, $y = I_{IR} \, dI_R / dt$.

Prior sampling methods typically calculate the Ratio of Ratios by sampling the combined AC and DC components of the waveform at the peak and valley measurements of the waveform. Sampling a large number of points on the waveform, using the derivative and performing a linear regression increases the accuracy of the Ratio of Ratios, since noise is averaged out. The derivative form eliminates the need to calculate the logarithm. Furthermore doing a linear regression over the sample points not only eliminates the noise caused by patient movement of the oximeter, it also decreases waveform noise caused by other sources.

9.4 GENERAL PROCESSING STEPS OF OXIMETRY SIGNALS

The determination of the Ratio of Ratios (R_{OS}) requires an accurate measure of both the baseline and pulsatile signal components (Frick *et al* 1989). The baseline component approximates the intensity of light received at the detector when only the fixed nonpulsatile absorptive component is present in the finger. This component of the signal is relatively constant over short intervals and does not vary with nonpulsatile physiological changes, such as movement of the probe. Over a relatively long time, this baseline component may vary significantly. The magnitude of the baseline component at a given point in time is approximately equal to the level identified as R_H (figure 9.2). However, for convenience, the baseline component may be thought of as the level indicated by R_L, with the pulsatile component varying between the values of R_H and R_L over a given pulse. Typically, the pulsatile component may be relatively small in comparison to the baseline component and is shown out of proportion in figure 9.3. Because the pulsatile components are smaller, greater care must be exercised with respect to the measurement of these components. If the entire signal, including the baseline and the pulsatile components, were amplified and converted to a digital format for use by microcomputer, a great deal of the accuracy of the conversion would be wasted because a substantial portion of the resolution would be used to measure the baseline component (Cheung *et al* 1989).

In this process, a substantial portion of the baseline component termed offset voltage V_{OS} is subtracted off the input signal V_1. The remaining pulsatile component is amplified and digitized using an ADC. A digital reconstruction is then produced by reversing the process, wherein the digitally provided information allows the gain to be removed and the offset voltage added back.

EXHIBIT 7

United States Patent [19]

Cheung et al.

[11] **Patent Number: 4,892,101**

[45] **Date of Patent: * Jan. 9, 1990**

[54] **METHOD AND APPARATUS FOR OFFSETTING BASELINE PORTION OF OXIMETER SIGNAL**

[75] Inventors: **Peter W. Cheung**, Mercer Island; **Karl F. Gauglitz**, Kirkland; **Lee R. Mason**, Issaquah; **Stephen J. Prosser**, Lynnwood; **Robert E. Smith**, Edmonds; **Darrell O. Wagner**, Monroe; **Scott W. Hunsaker**, Seattle, all of Wash.

[73] Assignee: **Physio-Control Corporation**, Redmond, Wash.

[*] Notice: The portion of the term of this patent subsequent to Apr. 11, 2006 has been disclaimed.

[21] Appl. No.: **315,330**

[22] Filed: **Feb. 24, 1989**

Related U.S. Application Data

[63] Continuation of Ser. No. 897,664, Aug. 18, 1986, Pat. No. 4,819,646.

[51] **Int. Cl.**[4] **A61B 5/00**; A61B 6/00

[52] **U.S. Cl.** **128/633**; 128/664; 128/666; 356/41

[58] **Field of Search** 128/633, 634, 664–667; 356/41

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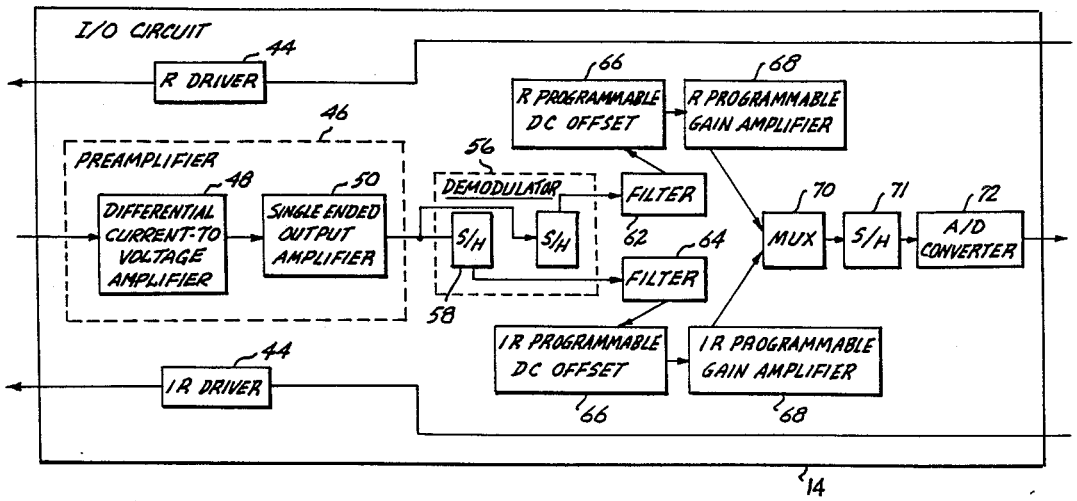
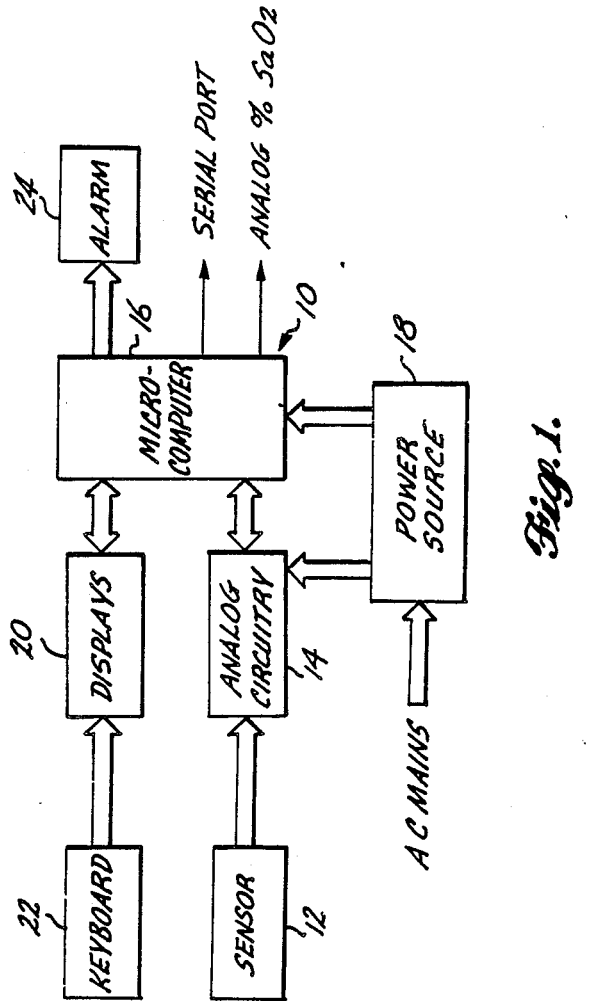
Primary Examiner—Max Hindenburg
Assistant Examiner—John C. Hanley
Attorney, Agent, or Firm—Christensen, O'Connor, Johnson & Kindness

[57] **ABSTRACT**

A feedback control system is disclosed for use in processing signals employed in pulse transmittance oximetry. The signals are produced in response to light transmitted through, for example, a finger at two different wavelengths. Each signal includes a slowly varying baseline component representing the relatively fixed attenuation of light produced by bone, tissue, skin, and hair. The signals also include pulsatile components representing the attenuation produced by the changing blood volume and oxygen saturation within the finger. The signals are processed by the feedback control system before being converted by an analog-to-digital (A/D) converter (**72**) for subsequent analysis by a microcomputer (**16**). The feedback control system includes a controllable offset subtractor (**66**), a programmable gain amplifier (**68**), controllable drivers (**44**) for the light sources (**40, 42**), and the microcomputer (**16**). The microcomputer (**16**) receives signals from the offset subtractor (**66**), gain amplifier (**68**), drivers (**44**) and A/D converter (**72**) to produce signals that control the function of the subtractor (**66**) and drivers (**44**) in the following manner. Normally, the drivers (**44**) are maintained within a predetermined current range. In the event the microcomputer (**16**) senses an output from the converter (**72**) that is not within a predetermined range, the drive signal is adjusted to produce an acceptable signal. The magnitude of the offset removed by the subtractor (**66**), as controlled by the microcomputer (**16**), is maintained at a constant level when the converter (**72**) output is within a first predetermined range and is a predetermined function of the converter (**72**) output when that output falls within a second predetermined range.

9 Claims, 17 Drawing Sheets

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ALARM
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16
10
18
MICRO-COMPUTER
POWER SOURCE
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DISPLAYS
ANALOG CIRCUITRY
14
A C MAINS
22
KEYBOARD
SENSOR
12

Fig. 1.

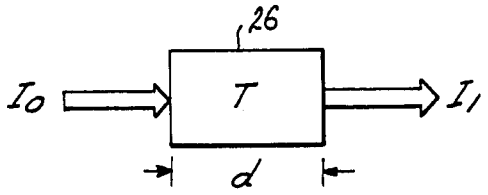


Fig. 2.

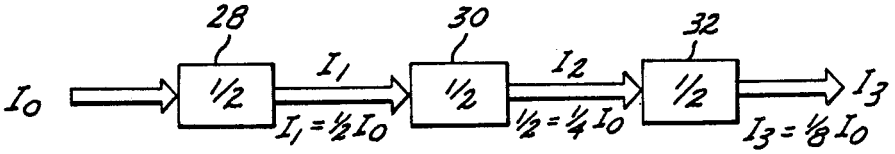


Fig. 3.

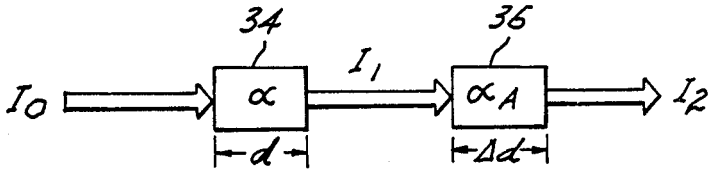


Fig. 6.

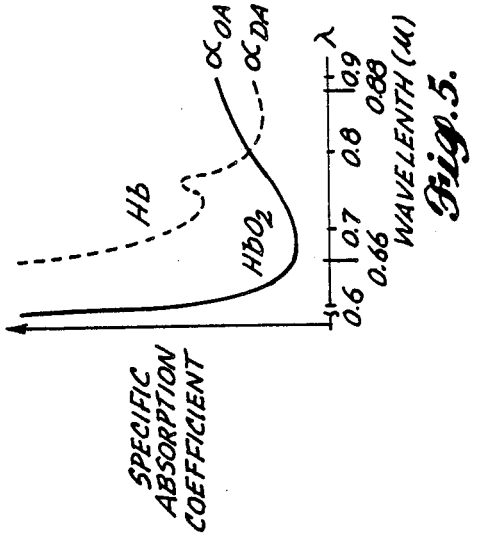


Fig. 5.

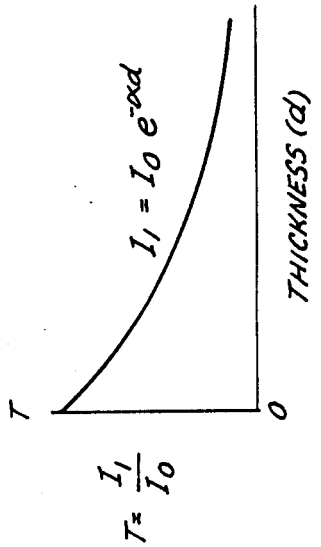


Fig. 4.

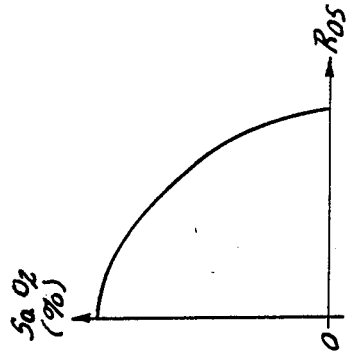


Fig. 7.

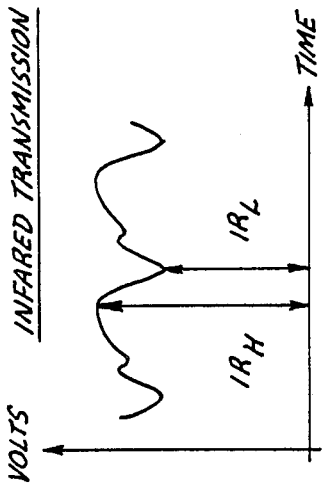


Fig. 10.

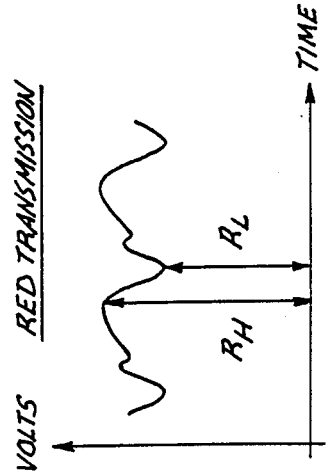


Fig. 9.

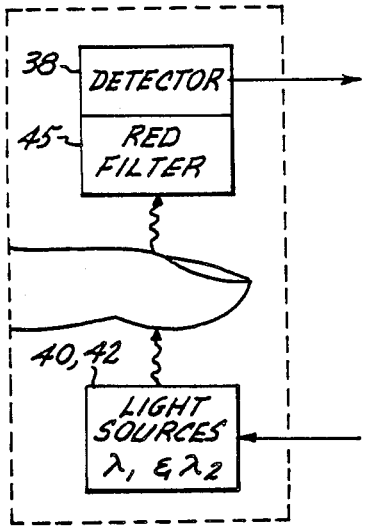


Fig. 8.

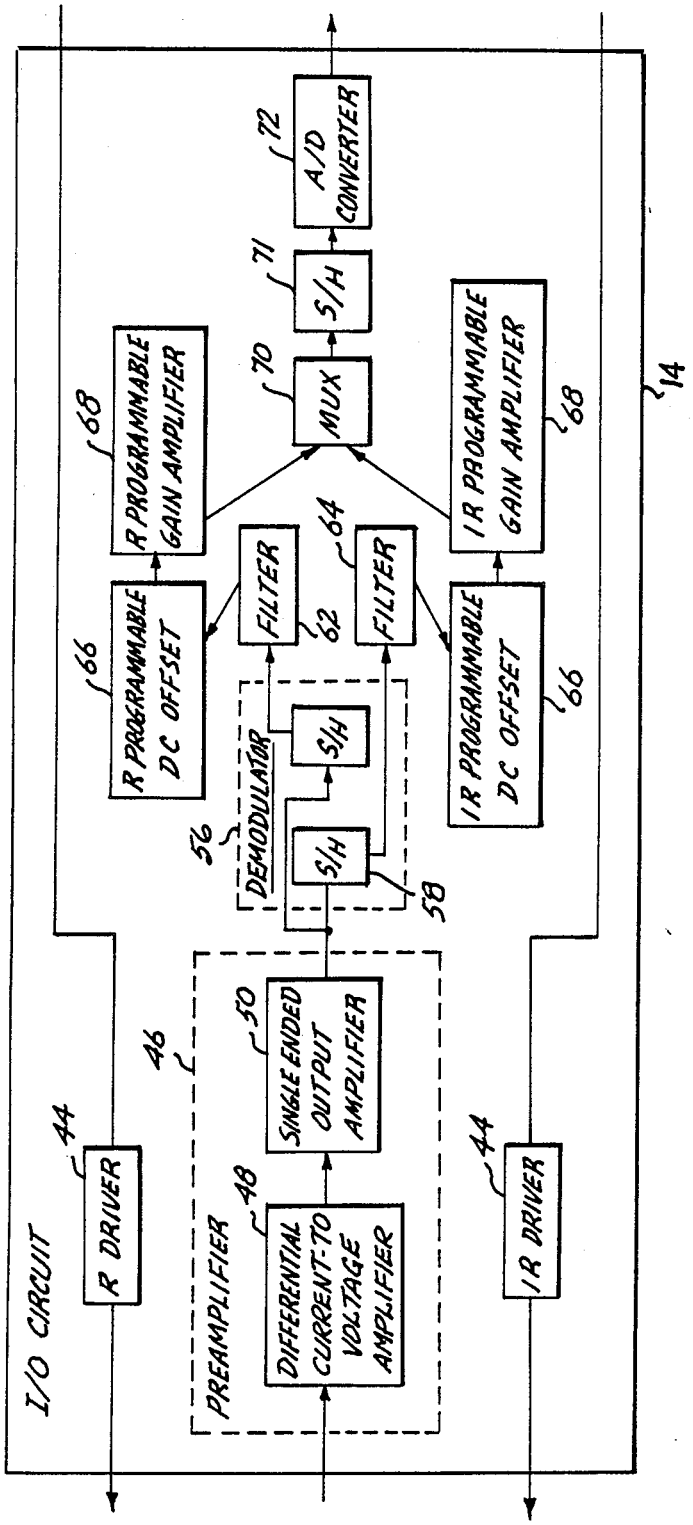

I/O CIRCUIT
R DRIVER
44
PREAMPLIFIER
46
DIFFERENTIAL CURRENT-TO VOLTAGE AMPLIFIER
48
SINGLE ENDED OUTPUT AMPLIFIER
50
DEMODULATOR
56
S/H
58
R PROGRAMMABLE DC OFFSET
66
FILTER
62
FILTER
64
R PROGRAMMABLE GAIN AMPLIFIER
68
MUX
70
S/H
71
A/D CONVERTER
72
IR PROGRAMMABLE DC OFFSET
66
IR PROGRAMMABLE GAIN AMPLIFIER
68
IR DRIVER
44
14

Fig. 11.

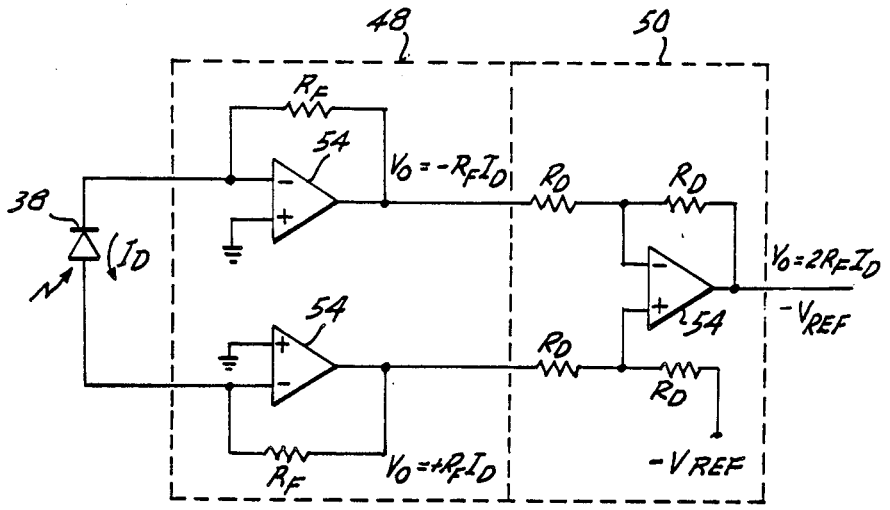

48
50
R_F
54
$V_O = -R_F I_D$
R_D
R_D
38
I_D
$V_O = 2R_F I_D$
$-V_{REF}$
54
54
R_D
R_D
R_F
$V_O = +R_F I_D$
$-V_{REF}$

Fig. 13.

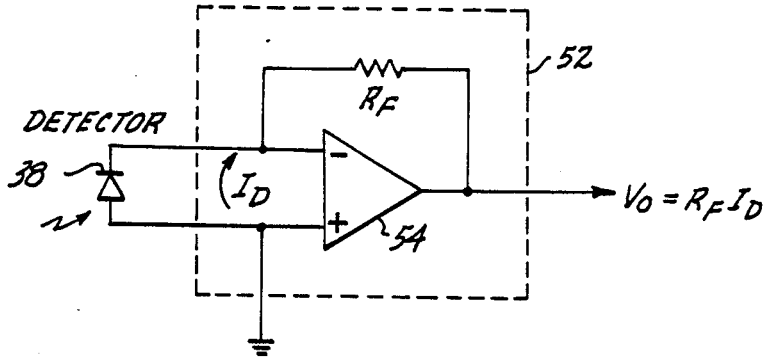
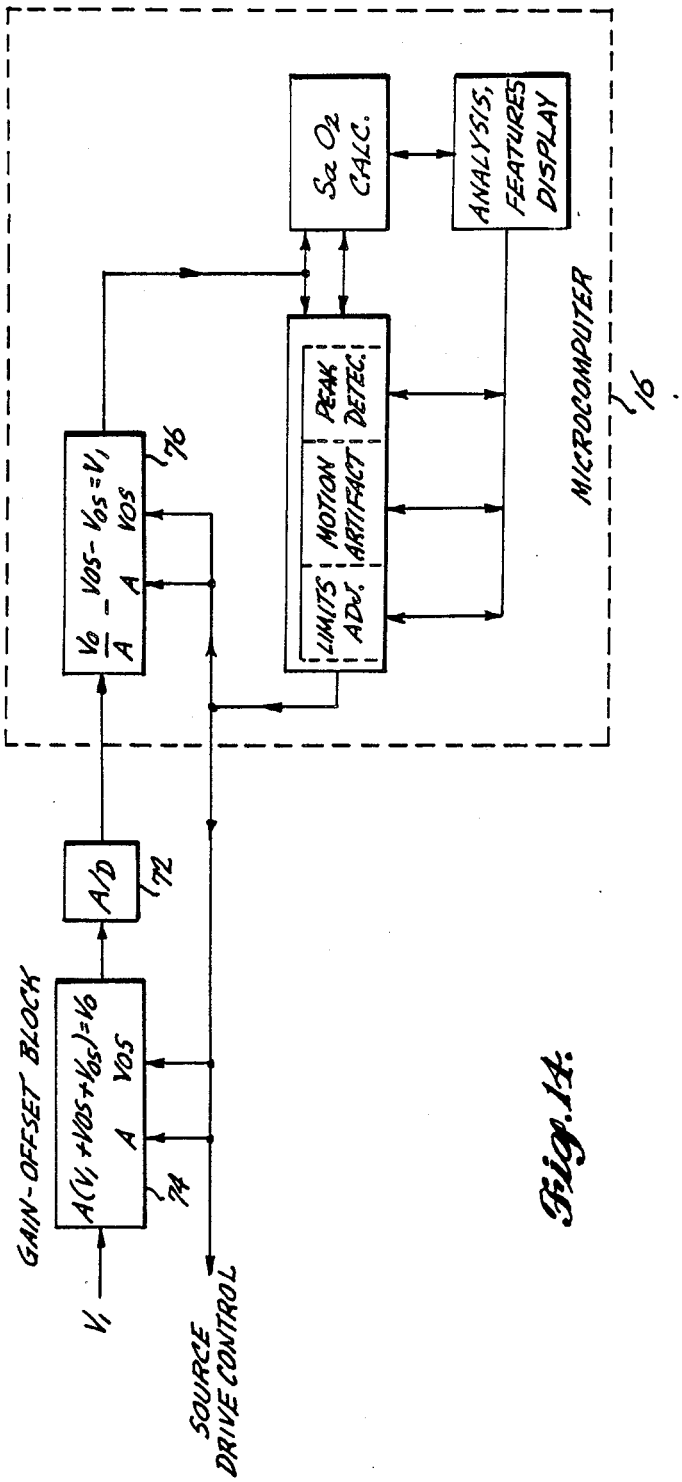

52
R_F
DETECTOR
38
I_D
54
$V_O = R_F I_D$

Fig. 12.


Sa O2 CALC.
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LIMITS ADJ.
MICROCOMPUTER
16
Vo/A - Vos = V1/A Vos
76
A/D
72
GAIN-OFFSET BLOCK
A(V1 + Vos + Vos) = Vo/A Vos
74
V1
SOURCE DRIVE CONTROL

Fig. 1A.

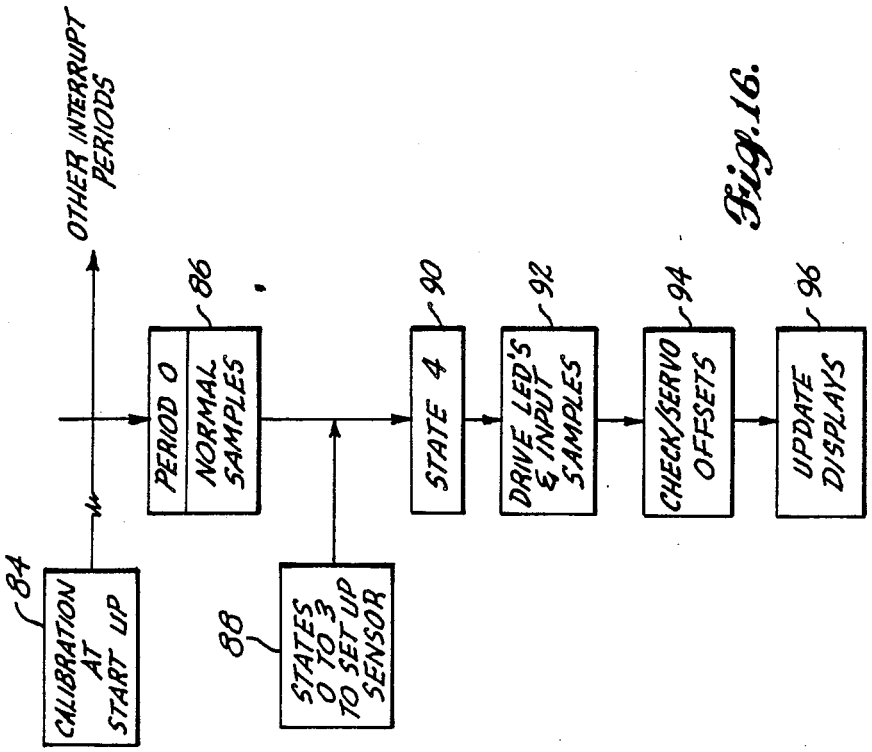
OTHER INTERRUPT PERIODS
84
CALIBRATION AT START UP
88
STATES 0 TO 3 TO SET UP SENSOR
86
PERIOD 0
NORMAL SAMPLES
90
STATE 4
92
DRIVE LED'S & INPUT SAMPLES
94
CHECK/SERVO OFFSETS
96
UPDATE DISPLAYS

Fig. 16.

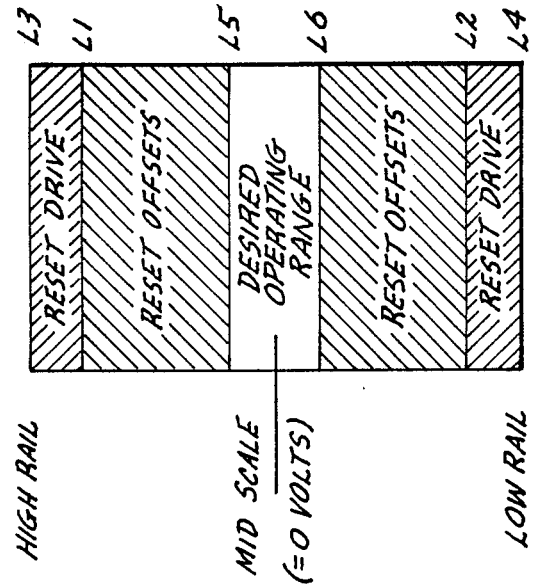
L3
L1
L5
L6
L2
L4
RESET DRIVE
RESET OFFSETS
DESIRED OPERATING RANGE
RESET OFFSETS
RESET DRIVE
HIGH RAIL
MID SCALE
(=0 VOLTS)
LOW RAIL

Fig. 15.

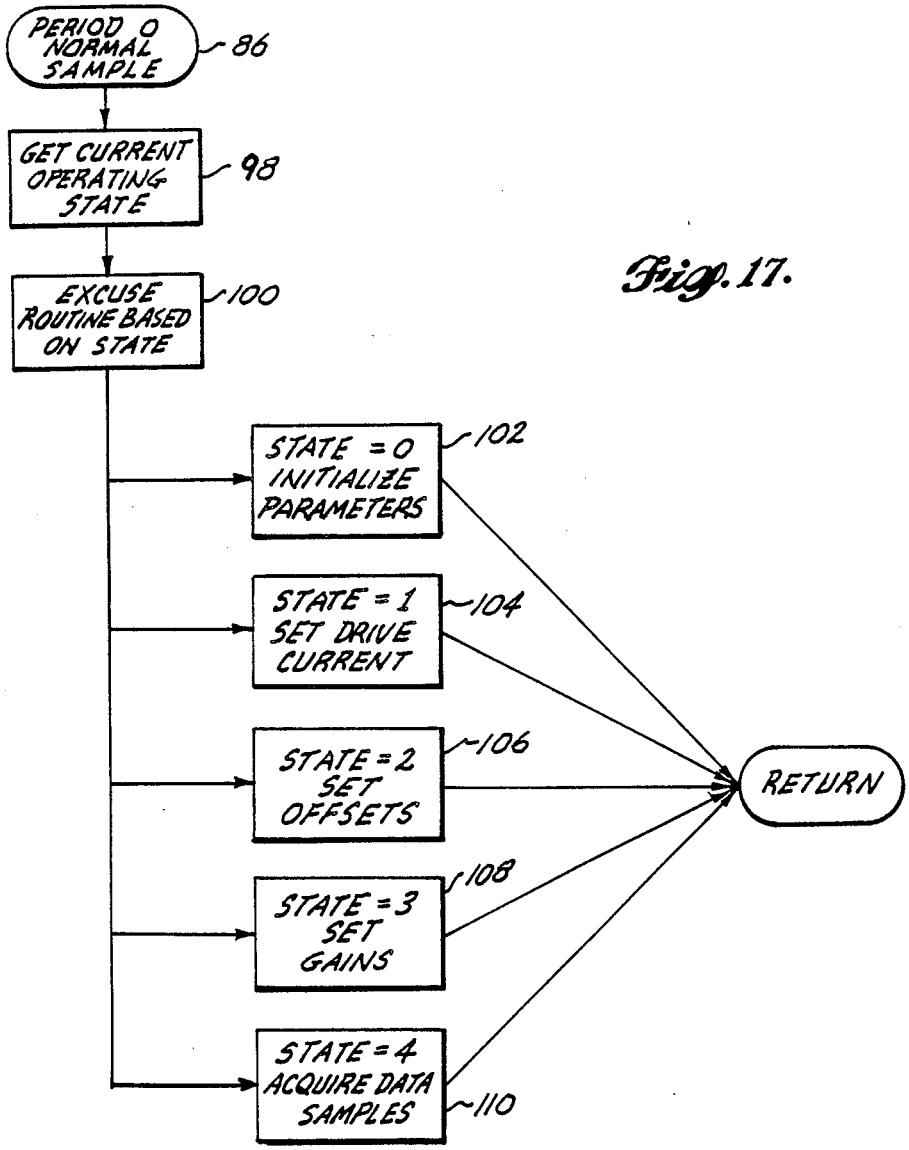
PERIOD 0 NORMAL SAMPLE
86
GET CURRENT OPERATING STATE
98
EXCUSE ROUTINE BASED ON STATE
100
STATE = 0 INITIALIZE PARAMETERS
102
STATE = 1 SET DRIVE CURRENT
104
STATE = 2 SET OFFSETS
106
STATE = 3 SET GAINS
108
STATE = 4 ACQUIRE DATA SAMPLES
110
RETURN

Fig. 17.

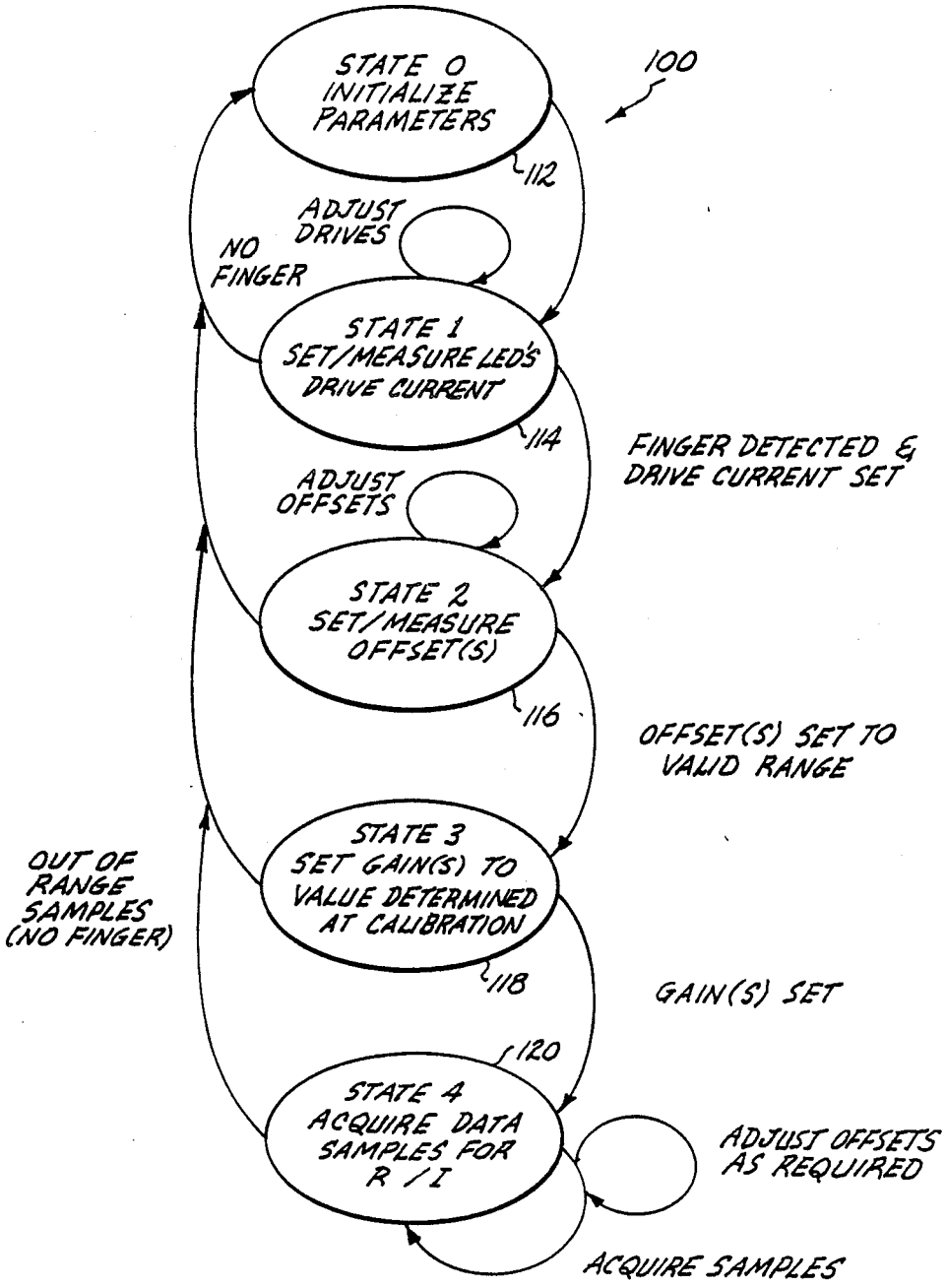
STATE 0
INITIALIZE
PARAMETERS
100
112
ADJUST
DRIVES
NO
FINGER
STATE 1
SET/MEASURE LED'S
DRIVE CURRENT
114
FINGER DETECTED &
DRIVE CURRENT SET
ADJUST
OFFSETS
STATE 2
SET/MEASURE
OFFSET(S)
116
OFFSET(S) SET TO
VALID RANGE
STATE 3
SET GAIN(S) TO
VALUE DETERMINED
AT CALIBRATION
OUT OF
RANGE
SAMPLES
(NO FINGER)
118
GAIN(S) SET
120
STATE 4
ACQUIRE DATA
SAMPLES FOR
R / I
ADJUST OFFSETS
AS REQUIRED
ACQUIRE SAMPLES

Fig. 18.

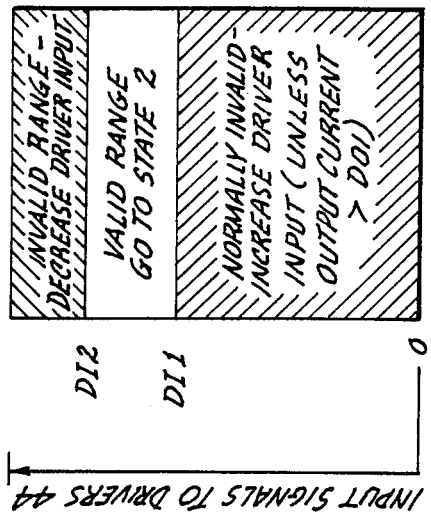
INVALID RANGE - DECREASE DRIVER INPUT
VALID RANGE GO TO STATE 2
NORMALLY INVALID - INCREASE DRIVER INPUT (UNLESS OUTPUT CURRENT > DOI)
DI2
DI1
0
INPUT SIGNALS TO DRIVERS 44

Fig. 21.

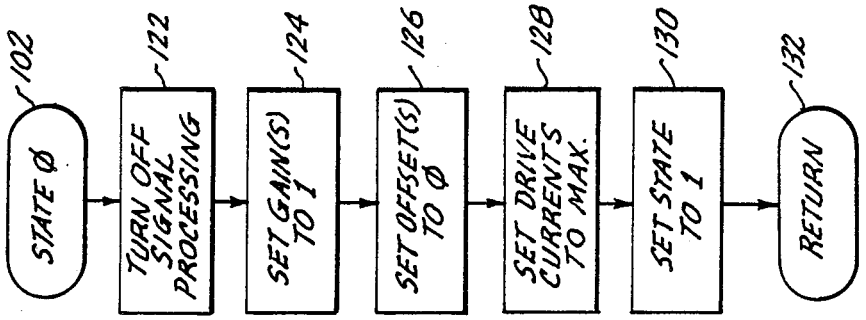
102
STATE Ø
122
TURN OFF SIGNAL PROCESSING
124
SET GAIN(S) TO 1
126
SET OFFSET(S) TO Ø
128
SET DRIVE CURRENTS TO MAX.
130
SET STATE TO 1
132
RETURN

Fig. 19.

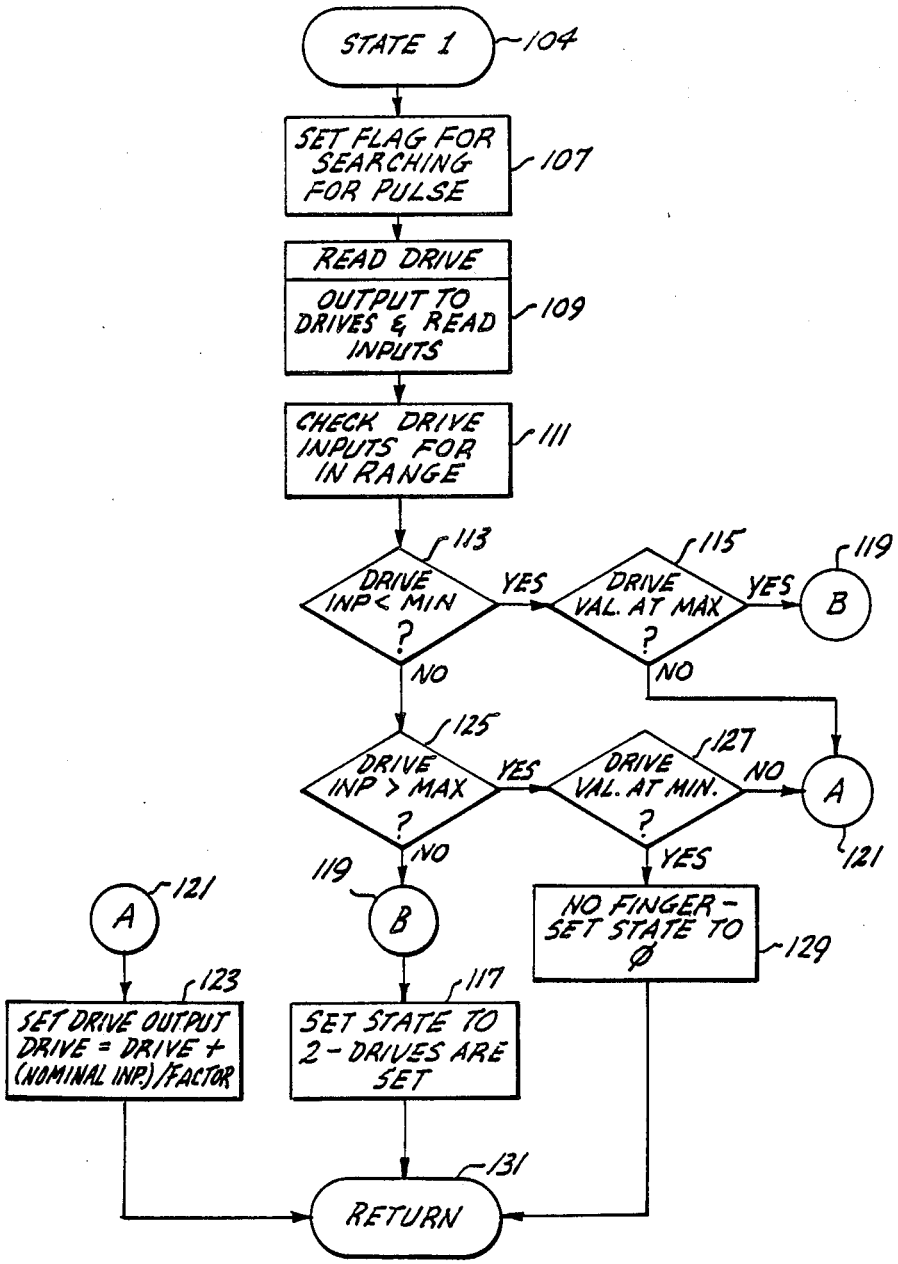
STATE 1
104
SET FLAG FOR SEARCHING FOR PULSE
107
READ DRIVE OUTPUT TO DRIVES & READ INPUTS
109
CHECK DRIVE INPUTS FOR IN RANGE
111
DRIVE INP < MIN ?
113
YES
DRIVE VAL. AT MAX ?
115
YES
B
119
NO
NO
DRIVE INP > MAX ?
125
YES
DRIVE VAL. AT MIN. ?
127
NO
A
121
NO
YES
119
B
A
121
NO FINGER - SET STATE TO Ø
129
123
SET DRIVE OUTPUT DRIVE = DRIVE + (NOMINAL INP.)/FACTOR
117
SET STATE TO 2 - DRIVES ARE SET
131
RETURN

Fig. 20.

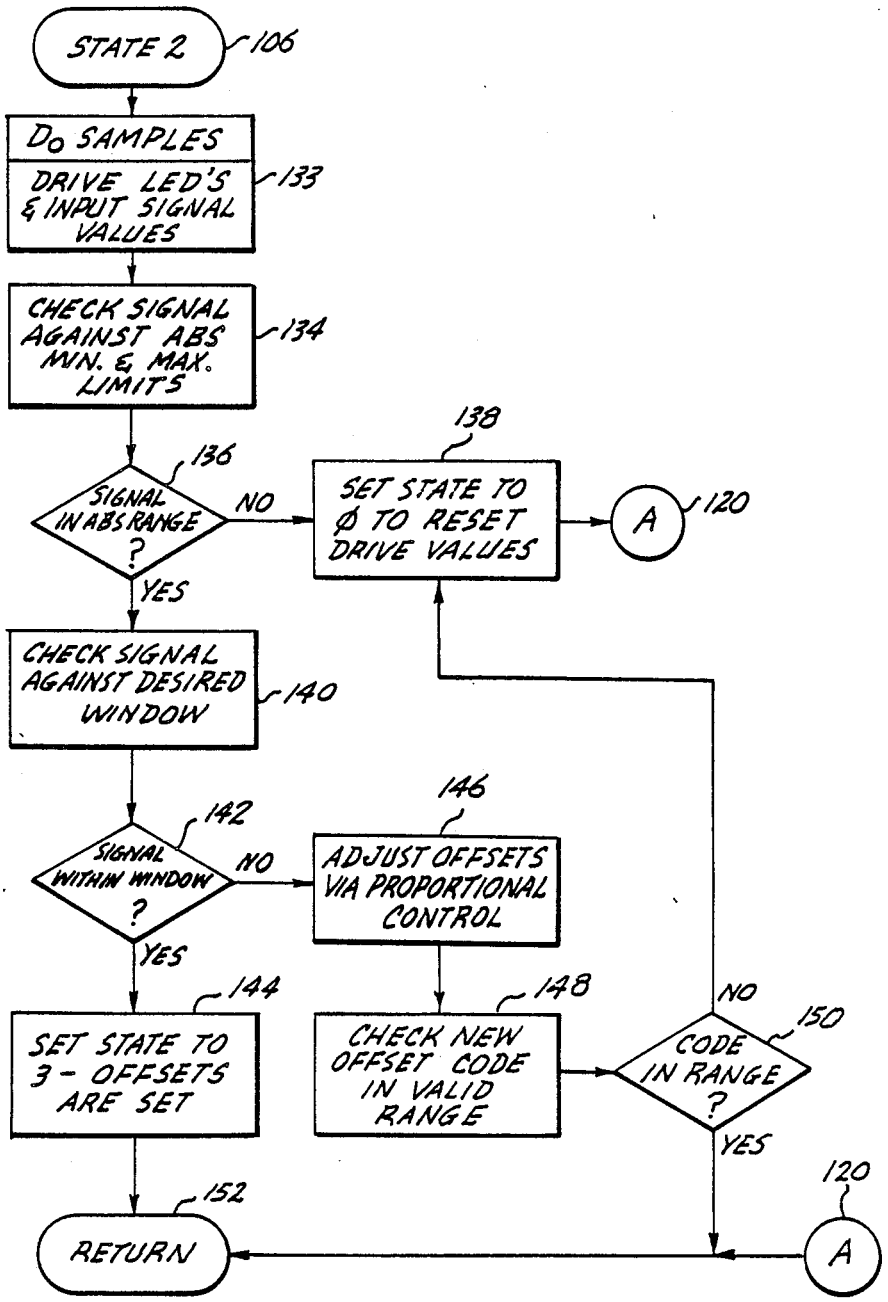
STATE 2
106
Do SAMPLES
DRIVE LED'S & INPUT SIGNAL VALUES
133
CHECK SIGNAL AGAINST ABS MIN. & MAX. LIMITS
134
136
SIGNAL IN ABS RANGE ?
NO
138
SET STATE TO Ø TO RESET DRIVE VALUES
A
120
YES
CHECK SIGNAL AGAINST DESIRED WINDOW
140
142
SIGNAL WITHIN WINDOW ?
NO
146
ADJUST OFFSETS VIA PROPORTIONAL CONTROL
YES
144
SET STATE TO 3 - OFFSETS ARE SET
148
CHECK NEW OFFSET CODE IN VALID RANGE
NO
150
CODE IN RANGE ?
YES
120
A
152
RETURN

Fig. 22.

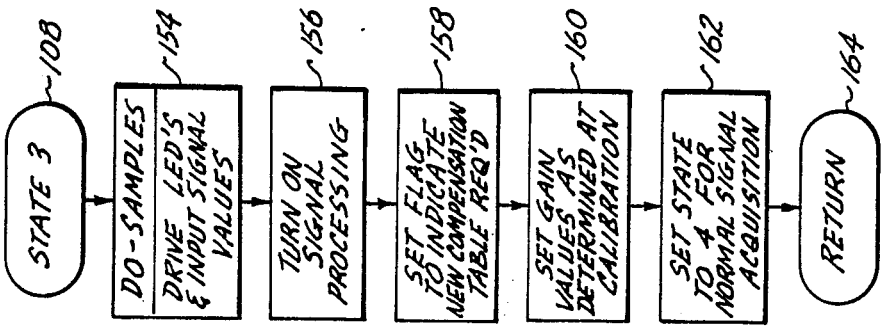

Fig. 23.

CALIBRATED OFFSET TABLE

OFFSET CODE/INCR.

CAL'D OFFSET VALUE FOR 8	+ 0/4
FOR CODE OF 8	+ 8/4
FOR CODE OF 16	+ 16/4
FOR CODE OF 24	+ 24/4
" " 32	+ 32/4
" " 40	+ 40/4
	+ 248/4

Fig. 26.

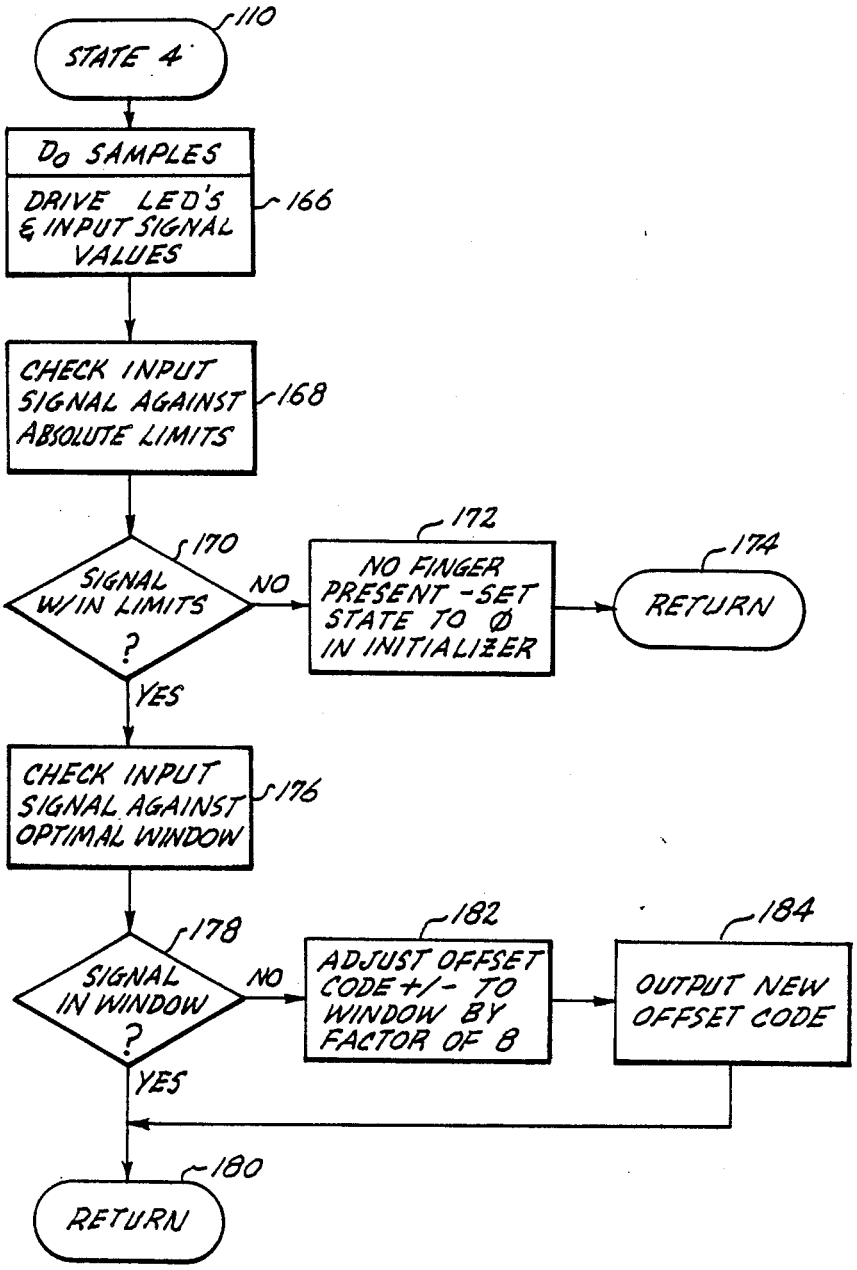
110
STATE 4
Do SAMPLES
DRIVE LED'S & INPUT SIGNAL VALUES
166
CHECK INPUT SIGNAL AGAINST ABSOLUTE LIMITS
168
170
SIGNAL W/IN LIMITS ?
NO
172
NO FINGER PRESENT - SET STATE TO Ø IN INITIALIZER
174
RETURN
YES
CHECK INPUT SIGNAL AGAINST OPTIMAL WINDOW
176
178
SIGNAL IN WINDOW ?
NO
182
ADJUST OFFSET CODE +/- TO WINDOW BY FACTOR OF 8
184
OUTPUT NEW OFFSET CODE
YES
180
RETURN

Fig. 24.

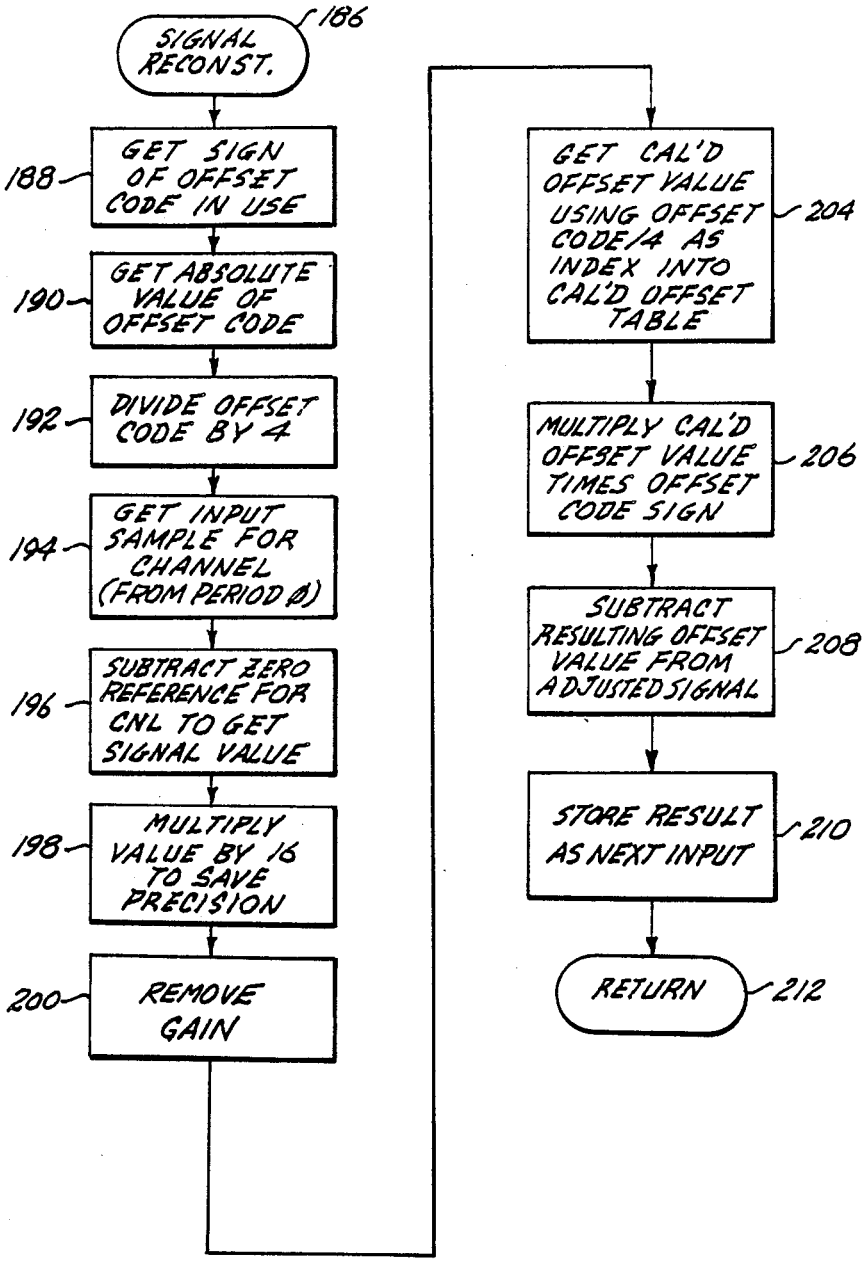
SIGNAL RECONST.
186
GET SIGN OF OFFSET CODE IN USE
188
GET ABSOLUTE VALUE OF OFFSET CODE
190
DIVIDE OFFSET CODE BY 4
192
GET INPUT SAMPLE FOR CHANNEL (FROM PERIOD Ø)
194
SUBTRACT ZERO REFERENCE FOR CNL TO GET SIGNAL VALUE
196
MULTIPLY VALUE BY 16 TO SAVE PRECISION
198
REMOVE GAIN
200
GET CAL'D OFFSET VALUE USING OFFSET CODE/4 AS INDEX INTO CAL'D OFFSET TABLE
204
MULTIPLY CAL'D OFFSET VALUE TIMES OFFSET CODE SIGN
206
SUBTRACT RESULTING OFFSET VALUE FROM ADJUSTED SIGNAL
208
STORE RESULT AS NEXT INPUT
210
RETURN
212

Fig. 25.

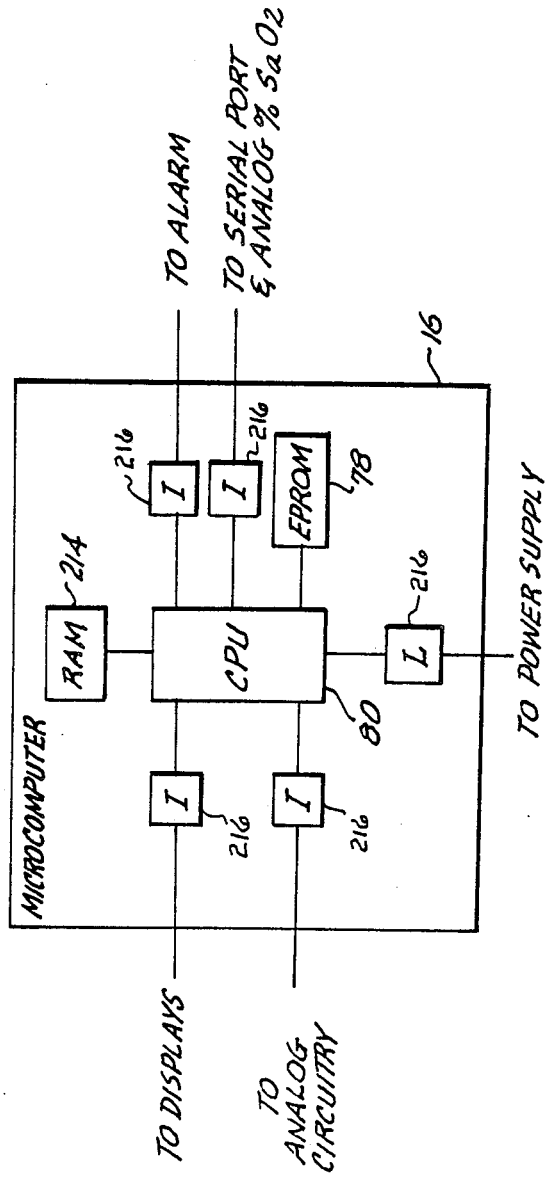
TO ALARM
TO SERIAL PORT & ANALOG % Sa O2
16
216
216
EPROM
78
214
RAM
CPU
216
80
MICROCOMPUTER
TO POWER SUPPLY
216
216
TO DISPLAYS
TO ANALOG CIRCUITRY

Fig. 27.

METHOD AND APPARATUS FOR OFFSETTING BASELINE PORTION OF OXIMETER SIGNAL

This is a continuation of the prior application Ser. No. 897,664, filed Aug. 18, 1986, now U.S. Pat. No. 4,819,646, the benefit of the filing date of which is hereby claimed under 35U.S.C.120.

BACKGROUND OF THE INVENTION

This invention relates to oximetry and, more particularly, to signal-processing techniques employed in oximetry.

The arterial oxygen saturation and pulse rate of an individual may be of interest for a variety of reasons. For example, in the operating room up-to-date information regarding oxygen saturation can be used to signal changing physiological factors, the malfunction of anaesthesia equipment, or physician error. Similarly, in the intensive care unit, oxygen saturation information can be used to confirm the provision of proper patient ventilation and allow the patient to be withdrawn from a ventilator at an optimal rate.

In many applications, particularly including the operating room and intensive care unit, continual information regarding pulse rate and oxygen saturation is important if the presence of harmful physiological conditions is to be detected before a substantial risk to the patient is presented. A noninvasive technique is also desirable in many applications, for example, when a home health care nurse is performing a routine checkup, because it increases both operator convenience and patient comfort. Pulse transmittance oximetry is addressed to these problems and provides noninvasive, continual information about pulse rate and oxygen saturation. The information produced, however, is only useful when the operator can depend on its accuracy. The method and apparatus of the present invention are, therefore, directed to the improved accuracy of such information without undue cost.

As will be discussed in greater detail below, pulse transmittance oximetry basically involves measurement of the effect arterial blood in tissue has on the intensity of light passing therethrough. More particularly, the volume of blood in the tissue is a function of the arterial pulse, with a greater volume present at systole and a lesser volume present at diastole. Because blood absorbs some of the light passing through the tissue, the intensity of the light emerging from the tissue is inversely proportional to the volume of blood in the tissue. Thus, the emergent light intensity will vary with the arterial pulse and can be used to indicate a patient's pulse rate. In addition, the absorption coefficient of oxyhemoglobin (hemoglobin combined with oxygen, HbO_2) is different from that of deoxygenated hemoglobin (Hb) for most wavelengths of light. For that reason, differences in the amount of light absorbed by the blood at two different wavelengths can be used to indicate the hemoglobin oxygen saturation, % SaO_2 (OS), which equals $([HBO_2]/([Hb]+[HbO_2]))\times 100\%$. Thus, measurement of the amount of light transmitted through, for example, a finger can be used to determine both the patient's pulse rate and hemoglobin oxygen saturation.

As will be appreciated, the intensity of light transmitted through a finger is a function of the absorption coefficient of both "fixed" components, such as bone, tissue, skin, and hair, as well as "variable" components, such as the volume of blood in the tissue. The intensity of light transmitted through the tissue, when expressed as a function of time, is often said to include a baseline component, which varies slowly with time and represents the effect of the fixed components on the light, as well as a periodic pulsatile component, which varies more rapidly with time and represents the effect that changing tissue blood volume has on the light. Because the attenuation produced by the fixed tissue components does not contain information about pulse rate and arterial oxygen saturation, the pulsatile signal is of primary interest. In that regard, many of the prior art transmittance oximetry techniques eliminate the so-called "DC" baseline component from the signal analyzed.

For example, in U.S. Pat. No. 2,706,927 (Wood) measurements of light absorption at two wavelengths are taken under a "bloodless" condition and a "normal" condition. In the bloodless condition, as much blood as possible is squeezed from the tissue being analyzed. Then, light at both wavelengths is transmitted through the tissue and absorption measurements made. These measurements indicate the effect that all nonblood tissue components have on the light. When normal blood flow has been restored to the tissue, a second set of measurements is made that indicates the influence of both the blood and nonblood components. The difference in light absorption between the two conditions is then used to determine the average oxygen saturation of the tissue, including the effects of both arterial and venous blood. As will be readily apparent, this process basically eliminates the DC, nonblood component from the signal that the oxygen saturation is extracted from.

For a number of reasons, however, the Wood method fails to provide the necessary accuracy. For example, a true bloodless condition is not practical to obtain. In addition, efforts to obtain a bloodless condition, such as by squeezing the tissue, may result in a different light transmission path for the two conditions. In addition to problems with accuracy, the Wood approach is both inconvenient and time consuming.

A more refined approach to pulse transmittance oximetry is disclosed in U.S. Pat. No. 4,086,915 (Kofsky et al.). The Kofsky et al. reference is of interest for two reasons. First, the technique employed automatically eliminates the effect that fixed components in the tissue have on the light transmitted therethrough, avoiding the need to produce bloodless tissue. More particularly, as developed in the Kofsky et al. reference from the Beer-Lambert law of absorption, the derivatives of the intensity of the light transmitted through the tissue at two different wavelengths, when multiplied by predetermined pseudocoefficients, can be used to determine oxygen saturation. Basic mathematics indicate that such derivatives are substantially independent of the DC component of the intensity. The pseudocoefficients are determined through measurements taken during a calibration procedure in which a patient first respires air having a normal oxygen content and, later, respires air of a reduced oxygen content. As will be appreciated, this calibration process is at best cumbersome.

The second feature of the Kofsky et al. arrangement that is of interest is its removal of the DC component of the signal prior to being amplified for subsequent processing. More particularly, the signal is amplified to allow its slope (i.e., the derivative) to be more accurately determined. To avoid amplifier saturation, a portion of the relatively large DC component of the signal is removed prior to amplification. To accomplish this

removal, the signal from the light detector is applied to the two inputs of a differential amplifier as follows. The signal is directly input to the positive terminal of the amplifier. The signal is also passed through a low-resolution A/D converter, followed by a D/A converter, before being input to the negative terminal of the amplifier. The A/D converter has a resolution of approximately 1/10 that of the input signal. For example, if the signal is at 6.3 volts, the output of the A/D converter would be 6 volts. Therefore, the output of the converter represents a substantial portion of the signal, which typically can be used to approximate the DC signal level. Combination of that signal with the directly applied detector signal at the amplifier produces an output that can be used to approximate the AC signal. As will be readily appreciated, however, the process may be relatively inaccurate because the output of the A/D converter is often a poor indicator of the DC signal.

U.S. Pat. No. 4,167,331 (Nielson) discloses another pulse transmittance oximeter. The disclosed oximeter is based upon the principle that the absorption of light by a material is directly proportional to the logarithm of the light intensity after having been attenuated by the absorber, as derived from the Beer-Lambert law. The oximeter employs light-emitting diodes (LEDs) to produce light at red and infrared wavelengths for transmission through tissue. A photosensitive device responds to the light produced by the LEDs and attenuated by the tissue, producing an output current. That output current is amplified by a logarithmic amplifier to produce a signal having AC and DC components and containing information about the intensity of light transmitted at both wavelengths. Sample-and-hold circuits demodulate the red and infrared wavelength signals. The DC components of each signal are then blocked by a series bandpass amplifier and capacitors, eliminating the effect of the fixed absorptive components from the signal. The resultant AC signal components are unaffected by fixed absorption components, such as hair, bone, tissue, skin. An average value of each AC signal is then produced. The ratio of the two averages is then used to determine the oxygen saturation from empirically determined values associated with the ratio. The AC components are also used to determine the pulse rate.

Another reference addressed to pulse transmittance oximetry is U.S. Pat. No. 4,407,290 (Wilber). In that reference, light pulses produced by LEDs at two different wavelengths are applied to, for example, an earlobe. A sensor responds to the light transmitted through the earlobe, producing a signal for each wavelength having a DC and AC component resulting from the presence of constant and pulsatile absorptive components in the earlobe. A normalization circuit employs feedback to scale both signals so that the DC nonpulsatile components of each are equal and the offset voltages removed. Decoders separate the two signals, so controlled, into channels A and B where the DC component from each is removed. The remaining AC components of the signals are amplified and combined at a multiplexer prior to analog-to-digital (A/D) conversion. Oxygen saturation is determined by a digital processor in accordance with the following relationship:

$$OS = \frac{X_1R(\lambda_1) + X_2R(\lambda_2)}{X_3R(\lambda_1) + X_4R(\lambda_2)}$$

wherein empirically derived data for the constants X_1, X_2, X_3 and X_4 is stored in the processor.

European patent application No. 83304939.8 (New, Jr. et al.) discloses an additional pulse transmittance oximeter. Two LEDs expose a body member, for example, a finger, to light having red and infrared wavelengths, with each LED having a one-in-four duty cycle. A detector produces a signal in response that is then split into two channels. The one-in-four duty cycle allows negatively amplified noise signals to be integrated with positively amplified signals including the detector response and noise, thereby eliminating the effect of noise on the signal produced. The resultant signals include a substantially constant DC component and a pulsatile AC component. To improve the accuracy of a subsequent analog-to-digital (A/D) conversion, a fixed DC value is subtracted from the signal prior to the conversion. This level is then added back in by a microprocessor after the conversion. Logarithmic analysis is avoided by the microprocessor in the following manner. For each wavelength of light transmitted through the finger, a quotient of the pulsatile component over the constant component is determined. The ratio of the two quotients is then determined and fitted to a curve of independently derived oxygen saturations. To compensate for the different transmission characteristics of different patients' fingers, an adjustable drive source for the LEDs is provided. In addition, an apparatus for automatically caibrating the device is disclosed.

Prior art oximeters have, however, not always employed signal-processing techniques that are adequate to provide maximum resolution of the signal received for analysis. As a result, the accuracy of oxygen saturation and pulse rate determinations made by the oximeter may suffer. The disclosed invention addresses this problem and improves the accuracy previously attainable in the art of oximetry.

SUMMARY OF THE INVENTION

The present invention discloses an apparatus for processing signals produced by a sensor that contain information about the oxygen saturation of arterial blood flowing in tissue. The apparatus includes an offset subtractor for subtracting a controlled portion of the sensor signal from that signal. The offset subtractor produces an output substantially equal to the portion of the sensor signal remaining after the controlled portion has been subtracted therefrom. The system also includes a controller, coupled to the offset subtractor, which receives the output of the offset subtractor and produces a subtraction control signal dependent upon that output. The subtraction control signal is transferred to the offset subtractor and determines the magnitude of the controlled portion of the signal subtracted thereby. An analyzer receives the output of the offset subtractor and produces an indication of the oxygen saturation of the arterial blood.

In accordance with a particular aspect of the invention, the controlled portion of the detector signal subtracted is held constant when the absolute value of the offset subtractor output is less than a first predetermined level. When the absolute value of the offset subtractor output falls within a predetermined range above that level, however, a subtraction control signal is produced indicating that the offset subtractor is to adjust the magnitude of the controlled portion by an amount proportional to the magnitude of the offset subtractor ouput.

When the absolute value of the offset subtractor output exceeds a second predetermined level, a subtraction control signal is produced indicating that the offset subtractor is no longer able to adjust the controlled portion of the signal to be subtracted. Preferably, the controlled portion subtracted from the detector signal by the offset subtractor is initialized at a predetermined value.

In accordance with another aspect of the invention, the system further includes a controllable gain amplifier for amplifying the output of the offset subtractor by a controlled gain. The amplifier produces an output that is substantially equal to the product of the offset subtractor output and the gain. The controller produces an amplifier control signal that is received by the amplifier, which adjusts the controlled gain in response thereto.

In accordance with a further aspect of the invention, the controller produces a sensor control signal to which said sensor responds. The controller establishes the sensor control signal at a level sufficient to cause the sensor signal to fall within a predetrmined sensor signal range.

In accordance with further aspects of this invention, a differential current-to-voltage amplifier amplifies the sensor signal before it is received by the offset subtractor. An analog-to-digital converter also converts the output of the controllable-gain amplifier into a digital format for analysis. The analyzer removes the gain and adds the controlled portion back to the amplifier output before producing the indication of oxygen saturation.

As will be appreciated, the disclosed invention also includes an oximeter employing the apparatus described above in conjunction with a sensor. The sensor includes a light source that responds to a control signal from the controller and illuminates the tissue. The intensity of the illumination is determined by the control signal. A detector included in the sensor responds to the illumination of the tissue by producing a signal that contains information about the oxygen saturation of the arterial blood. A red optical filter may be included to filter the light received by the detector.

As will also be appreciated, the disclosed invention includes the method of processing signals employed by the apparatus discussed above to determine the oxygen saturation of arterial blood flowing in tissue. In a basic form, the method includes the steps of subtracting from the sensor signal a controlled portion of the signal in response to a subtraction control signal. A subtraction output is produced that substantially equals the portion of the sensor signal remaining after the controlled portion has been subtracted therefrom. A subtraction control signal is also produced, dependent on the subtraction output in a manner indicating the desired adjustment in the controlled portion subtracted from the sensor signal.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can best be understood by reference to the following portion of the specification, taken in conjunction with the accompanying drawings in which:

FIG. **1** is a block diagram of an oximeter including a sensor, input/output (I/O) circuit, microcomputer, alarm, displays, power supply, and keyboard;

FIG. **2** is a block diagram illustrating the transmission of light through an absorptive medium;

FIG. **3** is a block diagram illustrating the transmission of light through the absorptive medium of FIG. **2**, wherein the medium is broken up into elemental components;

FIG. **4** is a graphical comparison of the incident light intensity to the emergent light intensity as modeled in FIG. **2**;

FIG. **5** is a graphical comparison of the specific absorption coefficients for oxygenated hemoglobin and deoxygenated hemoglobin as a function of the wavelength of light transmitted therethrough;

FIG. **6** is a block diagram illustrating the transmission of light through a block model of the components of a finger;

FIG. **7** is a graphical comparison of empirically derived oxygen saturation measurement with a variable that is measurable by the oximeter;

FIG. **8** is a schematic illustration of the transmission of light at two wavelengths through a finger in accordance with the invention;

FIG. **9** is a graphical plot as a function of time of the transmittance of light at the red wavelength through the finger;

FIG. **10** is a graphical plot as a function of time of the transmission of infrared light through the finger;

FIG. **11** is a more detailed schematic of the I/O circuit illustrated in the system of FIG. **1**;

FIG. **12** is a schematic diagram of a conventional current-to-voltage amplifier circuit;

FIG. **13** is a schematic diagram of a differential current-to-voltage preamplifier circuit included in the I/O circuit of FIG. **1**;

FIG. **14** is a functional block diagram illustrating the basic operation of the feedback control system constructed in accordance with this invention;

FIG. **15** is a graphical representation of the possible ranges of I/O circuit output, showing the desired response to the I/O ciruit and microcomputer at each of the various possible ranges;

FIG. **16** is a block diagram of a portion of an interrupt level software routine included in the microcomputer illustrated in FIG. **1**;

FIGS. **17** through **20** are more detailed block diagrams of the interrupt level routine depicted in FIG. **16**;

FIG. **21** is a graphical representation of the possible ranges of current supplied to the sensor, showing the desired response of the I/O circuit and microcomputer at each of the various possible ranges as a function of sensor output;

FIGS. **22** through **24** are further detailed block diagrams of the interrupt level routine depicted in FIG. **16**;

FIG. **25** is a block diagram of reconstruction software included in the microcomputer illustrated in FIG. **1**;

FIG. **26** illustrates a calibrated offset table stored in the microcomputer for use in adjusting the operation of the I/O circuit; and

FIG. **27** is a more complete schematic diagram of the microcomputer illustrated in FIG. **1**.

DETAILED DESCRIPTION

Referring to the overall system block diagram shown in FIG. **1**, a pulse transmittance oximeter **10** employing this invention includes a sensor **12**, input/output (I/O) circuit **14**, microcomputer **16**, power source **18**, display **20**, keyboard **22** and alarm **24**. Before discussing these elements in detail, however, an outline of the theoretical basis of pulse transmittance oximetry as practiced by the oximeter of FIG. **1** is provided.

An understanding of the relevant theory begins with a discussion of the Beer-Lambert law. This law governs

the absorption of optical radiation by homogeneous absorbing media and can best be understood with reference to FIGS. **2** and **3** in the following manner.

As shown in FIG. **2**, incident light having an intensity I_0 impinges upon an absorptive medium **26**. Medium **26** has a characteristic absorbance factor A that indicates the attenuating affect medium **26** has on the incident light. Similarly, a transmission factor T for the medium is defined as the reciprocal of the absorbance factor, I/A. The intensity of the light I_1 emerging from medium **26** is less than I_0 and can be expressed functionally as the product TI_0. With medium **26** divided into a number of identical components, each of unit thickness (in the direction of light transmission) and the same transmission factor T, the effect of medium **26** on the incident light I_0 is as shown in FIG. **3**.

There, medium **26** is illustrated as consisting of three components **28**, **30**, and **32**. As will be appreciated, the intensity I_1 of the light emerging from component **28** is equal to the incident light intensity I_0 multiplied by the transmission factor T. Component **30** has a similar effect on light passing therethrough. Thus, because the light incident upon component **30** is equal to the product TI_0, the emergent light intensity I_2 is equal to the product TI_1 or T^2I_0. Component **32** has the same effect on light and, as shown in FIG. **3**, the intensity of the emergent light I_3 for the entire medium **26** so modeled is equal to the product TI_2 or T^3I_0. If the thickness d of medium **26** is n unit lengths, it can be modeled as including n identical components of unit thickness. It will then be appreciated that the intensity of light emerging from medium **26** can be designated I_n and the product is equal to T^nI_0. Expressed as a function of the absorbance constant A, I_n can also be written as the product $(1/A^n)I_0$.

From the preceding discussion, it will be readily appreciated that the absorptive effect of medium **26** on the intensity of the incident light I_0 is one of exponential decay. Because A may be an inconvenient base to work with, I_n can be rewritten as a function of a more convenient base, b, by recognizing that A^n is equal to $b^{\alpha n}$, where α is the absorbance of medium **26** per unit length. The term α is frequently referred to as the relative extinction coefficient and is equal to $\log_b A$.

Given the preceding discussion, it will be appreciated that the intensity of the light I_n emerging from medium **26** can be expressed in base 10 (where $\alpha=\alpha_1$) as $I_0 1\text{-}0^{-\alpha 1 n}$, or in base e (where $\alpha=\alpha_2$) as $I_0e^{-\alpha 2 n}$. The effect that the thickness of medium **26** has on the emergent light intensity I_n is graphically depicted in FIG. **4**. If the light incident upon medium **26** is established as having unit intensity, FIG. **4** also represents the transmission factor T of the entire medium as a function of thickness.

The discussion above can be applied generally to the medium **26** shown in FIG. **2** to produce:

$$I_1=I_0e^{-\alpha d} \quad (1)$$

where I_1 is the emergent light intensity, I_0 is the incident light intensity, α is the absorbance coefficient of the medium, d is the thickness of the medium per unit length in unit lengths, and the exponential nature of the relationship has arbitrarily been expressed in terms of base e. Equation (1) is commonly referred to as the Beer-Lambert law of exponential light decay through a homogeneous absorbing medium.

With this basic understanding of the Beer-Lambert law, a discussion of its application to the problems of pulse rate and hemoglobin oxygen saturation measurement is now presented. As shown in FIG. **5**, the absorption coefficients for oxygenated and deoxygenated hemoglobin are different at every wavelength, except an isobestic wavelength. Thus, it will be appreciated that if a person's finger is exposed to incident light and the emergent light intensity measured, the difference in intensity between the two, which is the amount of light absorbed, contains information relating to the oxygenated hemoglobin content of the blood in the finger. The manner in which this information is extracted from the Beer-Lambert law is discussed below. In addition, it will be appreciated that the volume of blood contained within an individual's finger varies with the individual's pulse. Thus, the thickness of the finger also varies slightly with each pulse, creating a changing path length for light transmitted through the finger. Because a longer lightpath allows additional light to be absorbed, time-dependent information relating to the difference between the incident and emergent light intensities can be used to determine the individual's pulse. The manner in which this information is extracted from the Beer-Lambert law is also discussed below.

As noted in the preceding paragraph, information about the incident and emergent intensities of light transmitted through a finger can be used to determine oxygen saturation and pulse rate. The theoretical basis for extracting the required information, however, is complicated by several problems. For example, the precise intensity of the incident light applied to the finger is not easily determined. Thus, it may be necessary to extract the required information independently of the intensity of the incident light. Further, because the changing volume of blood in the finger and, hence, thickness of the lightpath therethrough, are not exclusively dependent upon the individual's pulse, it is desirable to eliminate the changing path length as a variable from the computations.

The manner in which the Beer-Lambert law is refined to eliminate the incident intensity and path length as variables is as follows. With reference to FIG. **6**, a human finger is modeled by two components **34** and **36**, in a manner similar to that shown in FIG. **3**. Baseline component **34** models the unchanging absorptive elements of the finger. This component includes, for example, bone, tissue, skin, hair, and baseline venous and arterial blood and has a thickness designated d and an absorbance α.

Pulsatile component **36** represents the changing absorptive portion of the finger, the arterial blood volume. As shown, the thickness of this component is designated Δd, representing the variable nature of the thickness, and the absorbance of this arterial blood component is designated α_A representing the arterial blood absorbance.

As will be appreciated from the earlier analysis with respect to FIG. **3**, the light I_1 emerging from component **34** can be written as a function of the incident light intensity I_0 as follows:

$$I_1=I_0e^{-\alpha d} \quad (2)$$

Likewise, the intensity of light I_2 emerging from component **36** is a function of its incident light intensity I_1, and:

$$I_2=I_1e^{-\alpha_A\Delta d} \quad (3)$$

Substitution of the expression for I_1 developed in equation (2) for that used in equation (3), when simplified, results in the following expression for the intensity I_2 of light emerging from the finger as a function of the intensity of light I_0 incident upon the finger;

$$I_2=I_0e^{-[ad+\alpha_A\Delta d]} \quad (4)$$

Because our interest lies in the effect on the light produced by the arterial blood volume, the relationship between I_2 and I_1 is of particular interest. Defining the change in transmission produced by the arterial component **36** as $T_{\Delta A}$, we have:

$$T_{\Delta A}=I_2/I_1 \quad (5)$$

Substituting the expressions for I_1 and I_2 obtained in equations (2) and (3), respectively, equation (5) becomes:

$$T_{\Delta A}=\frac{I_0e^{-[ad+\alpha_A\Delta d]}}{I_0e^{-ad}} \quad (6)$$

It will be appreciated that the I_0 term can be cancelled from both the numerator and denominator of equation (6), thereby eliminating the input light intensity as a variable in the equation. With equation (6) fully simplified, the change in arterial transmission can be expressed as:

$$T_{\Delta A}=e^{-\alpha_A\Delta d} \quad (7)$$

A device employing this principle of operation is effectively self-calibrating, being independent of the incident light intensity I_0.

At this point, a consideration of equation (7) reveals that the changing thickness of the finger, Δd, produced by the changing arterial blood volume still remains as a variable. The Δd variable is eliminated in the following manner. For convenience of expression, the logarithms of the terms in equation (7) are produced with respect to the same base originally employed in equation (1). Thus, equation (7) becomes:

$$\ln T_{\Delta A}=\ln (e^{-\alpha_A\Delta d})=-\alpha_A\Delta d \quad (8)$$

A preferred technique for eliminating the Δd variable utilizes information drawn from the change in arterial transmission experienced at two wavelenths.

The particular wavelengths selected are determined in part by consideration of a more complete expression of the arterial absorbance α_A:

$$\alpha_A=(\alpha_{OA})(OS)-(\alpha_{DA})(1-OS) \quad (9)$$

where α_{OA} is the oxygenated arterial absorbance, α_{DA} is the deoxygenated arterial absorbance, and OS is the hemoglobin oxygen saturation of the arterial blood volume. As will be appreciated from FIG. **5**, α_{OA} and α_{DA} are substantially unequal at all light wavelengths in the red and near-infrared wavelength regions except for an isobestic wavelength occurring at approximately 805 nanometers. With an arterial oxygen saturation OS of approximately 90 percent, it will be appareciated from equation (9) that the arterial absorbance α_A is 90 percent attributable to the oxygenated arterial absorbance α_{OA} and 10 percent attributable to the deoxygenated arterial absorbance α_{DA}. At the isobestic wavelength, the relative contribution of these two coefficients to the arterial absorbance α_A is of minimal significance in that both α_{OA} and α_{DA} are equal. Thus, a wavelength roughly approximating the isobestic wavelength of the curves illustrated in FIG. **5** is a convenient one for use in eliminating the change in finger thickness Δd attributable to arterial blood flow.

A second wavelength is selected at a distance from the approximately isobestic wavelength that is sufficient to allow the two signals to be easily distinguished. In addition, the relative difference of the oxygenated and deoxygenated arterial absorbances at this wavelength is more pronounced. In light of the foregoing considerations, it is generally preferred that the two wavelengths selected fall within the red and infrared regions of the electromagnetic spectrum.

The foregoing information, when combined with equation (8) is used to produce the following ratio:

$$\frac{\ln T_{\Delta AR}}{\ln T_{\Delta AIR}}=\frac{-\alpha_A\,\Delta d@\lambda_R}{-\alpha_A\,\Delta d@\lambda_{IR}} \quad (10)$$

where $T_{\Delta AR}$ equals the change in arterial transmission of light at the red wavelength λ_R and $T_{\Delta AIR}$ is the change in arterial transmission at the infrared wavelength λ_{IR}. It will be appreciated that if two sources are positioned at substantially the same location on the finger, the length of the lightpath through the finger is substantially the same for the light emitted by each. Thus, the change in the lightpath resulting from arterial blood flow, Δd, is substantially the same for both the red and infrared wavelength sources. For that reason, the Δd term in the numerator and denominator of the right-hand side of equation (10) cancel, producing:

$$\frac{\ln T_{\Delta AR}}{\ln T_{\Delta AIR}}=\frac{\alpha_A@\,\lambda_R}{\alpha_A@\,\lambda_{IR}} \quad (11)$$

As will be appreciated, equation (11) is independent of both the incident light intensity I_0 and the change in finger thickness Δd attributable to arterial blood flow. The foregoing derivations form the theoretical basis of pulse oximetry measurement. Because of the complexity of the physiological process, however, the ratio indicated in equation (11) does not directly provide an accurate measurement of oxygen saturation. The correlation between the ratio of equation (11) and actual arterial blood gas measurements is, therefore, relied on to produce an indication of the oxygen saturation. Thus, if the ratio of the arterial absorbance at the red and infrared wavelengths can be determined, the oxygen saturation of the arterial blood flow can be extracted from independently derived, empirical calibration curves in a manner independent of I_0 and Δd.

For simplicity, a measured ratio R_{OS} is defined from equation (11) as:

$$\text{Ratio} = R_{OS}=\frac{\alpha_A@\lambda_R}{\alpha_A@\lambda_{IR}} \quad (12)$$

It is this measured value for R_{OS} that is plotted on the x-axis of independently derived oxygen saturation curves, as shown in FIG. 7 and discussed in greater detail below, with the hemoglobin oxygen saturation being referenced on the y-axis.

Measurement of the arterial absorbances at both wavelengths is performed in the following manner. As

shown in FIG. 8, a detector 38 placed on the side of a finger opposite red and infrared wavelength light sources 40 and 42 receives light at both wavelengths transmitted through the finger. As shown in FIG. 9, the received red wavelength light intensity, plotted as a function of time, varies with each pulse, and has high and low values R_H and R_L, respectively. R_L occurs substantially at systole, when arterial blood volume is at its greatest; while R_H occurs substantially at diastole, when the arterial blood volume is lowest. From the earlier discussion of the exponential light decay through homogeneous media, it will be appreciated that:

$$R_L = I_0 e^{-[\alpha d + \alpha_A \Delta d]@\lambda_R} \quad (13)$$

Similarly:

$$R_H = I_0 e^{-\alpha d}@\lambda_R \quad (14)$$

Taking the ratio of equations (13) and (14) and simplifying, we have:

$$\frac{R_L}{R_H} = I_0 \frac{e^{-[\alpha d + \alpha_A \Delta d]}}{I_0 e^{-\Delta d}}@\lambda_R = e^{-\alpha_A \Delta d@\lambda R} \quad (15)$$

Taking the logarithm of both sides of equation (15) produces:

$$\ln (R_L/R_H) = \ln (e^{-\alpha_A \Delta d})@\lambda_R = -\alpha_A \Delta d@\lambda_R \quad (16)$$

As will be readily appreciated, similar expression can be produced for the signals representative of the infrared wavelength light received by detector 38. Thus, the minimum light intensity passing through the finger at the infrared wavelengtcan be written:

$$IR_L = I_0 e_{-}^{-[\alpha d + \alpha_A \Delta d]}@\lambda_{IR} \quad (17)$$

Similarly, the maximum light intensity emerging from the finger at the infrared wavelength can be expressed as:

$$IR_H = I_0 e^{-\alpha d}@\lambda IR \quad (18)$$

The ratio of the terms in equations (17) and (18) can be expressed as:

$$\frac{IR_L}{IR_H} = \frac{I_0 e^{-[\alpha d + \alpha_A \Delta d]}}{I_0 e^{-\alpha d}}@\lambda_{IR} = e^{-\alpha_A \Delta d@\lambda IR} \quad (19)$$

Use of logarithms simplifies equation (19) to:

$$\ln (IR_L/IR_H) = \ln (e^{-\alpha_A \Delta d})@\lambda_{IR} = -\alpha_A \Delta d@\lambda_{IR} \quad (20)$$

The ratiometric combination of equations (16) and (20) yields:

$$\frac{\ln (R_L/R_H)}{\ln (IR_L/IR_H)} = \frac{-\alpha_A \Delta d@\lambda_R}{-\alpha_A \Delta d@\lambda_{IR}} \quad (21)$$

Because the Δd term in the numerator and denominator of the right-hand side of equation (21) cancel, as do the negative signs before each term, it will be appreciated that equation (21) when combined with equation (12) yields:

$$\text{Ratio} = R_{OS} = \frac{\alpha_A@\lambda_R}{\alpha_A@\lambda_{IR}} = \frac{\ln(R_L/R_H)}{\ln(IR_L/IR_H)} = \frac{\ln(R_H/R_L)}{\ln(IR_H/IR_L)} \quad (22)$$

Thus, by measuring the minimum and maximum emergent light intensities at both the red and infrared wavelengths (R_L, R_H, IR_L, IR_H), a value for the term R_{OS} can be computed. From this, empirically derived calibration curves similar to that shown in FIG. 7 can be used to determine the oxygen saturation as described in greater detail in conjunction with the discussion of the various components of oximeter 10 that follows. As will be appreciated, the determination of oxygen saturation in this manner differs from prior art techniques, such as that disclosed by Wilber, by performing measurements based upon both the baseline and pulsatile components of the signals.

The first component of oximeter 10 to be discussed is sensor 12. The function of sensor 12 is substantially to provide the desired orientation of light sources 40 and 42, for example, light-emitting diodes (LEDs), and light detector 38 with respect to a suitable portion of a patient's body. For example, the sensor must align LEDs 40 and 42 with detector 38 in a manner such that the path of light from each LED to the detector 38 is substantially the same distance. In addition, the path must traverse a portion of the patient's body through which a usable amount of light is passed, for example, a finger, toe, earlobe, or the nasal septum. Because changes in the lightpath can significantly affect the readings taken, as noted above, the sensor must maintain the position of LEDs 40 and 42 and detector 38 with respect to the transmission path through the patient's skin at all times. Otherwise, signal fluctuations known as motion-artifact may be produced. In addition, the sensor should apply only insubstantial pressure to the patient's skin and underlying tissue. Otherwise, normal arterial blood flow upon which the pulse oximeter relies for accurate operation, may be disrupted. Finally, the sensor should be quickly attachable to the patient and should cause no discomfort.

LEDs 40 and 42 are supplied with current by transistor drivers 44 located in the I/O circuit 14, as shown in FIG. 11. Drivers 44 are controlled by microcomputer 16 to produce current pulses at a 960 Hz repetition rate. The duration of each pulse is 70 microseconds and a pulse is supplied to the red wavelength LED 40 first and then to the infrared wavelength LED 42. The voltage drop across scaling resistors in the drivers 44 allows the magnitude of the current pulses to be determined and, thus, maintained in a manner described in greater detail below. LEDs 40 and 42 respond to the current pulses by producing corresponding light pulses transmitted through the finger to detector 38. Detector 38, in turn, produces a signal that includes information about the pulsatile response of the finger to the red and infrared wavelength light, intermixed at the 960 Hz LED pulse repetition rate.

In a preferred embodiment of the invention, a red optical filter 45 interrupts the lightpath between the LEDs 40 and 42 and the detector 38, as shown in FIG. 8. Preferably, filter 45 is a Kodak No. 29 wratten gel filter. Its function is to eliminate the influence of fluorescent light flicker on the oxygen saturation determination made. As will be appreciated, although the body of

sensor **12** may be made of an opaque material that blocks a significant portion of the ambient light, some ambient light may still reach detector **38**. Light from the sun and incandescent lamps is substantially continuous. Fluorescent lighting, on the other hand, includes alternating energized and deenergized intervals that form a visually imperceptible flicker. The frequency of the fluorescent light flicker is such that it might influence the signal produced by detector **38** in response to light received from LED **40** at the red wavelength. Thus, the red optical filter **45** is placed over the detector **38** and filters out any fluorescent light present, eliminating the effect its flicker might have on the oxygen saturation determination made.

At the I/O circuit **14**, the signal from detector **38** is received by a preamplifier **46**. In a preferred embodiment, preamplifier **46** includes a differential current-to-voltage amplifier **48** and a single-ended output amplifier **50**. To understand the advantages of using the differential amplifier **48**, it may first be helpful to consider the operation of a conventional current-to-voltage amplifier as shown in FIG. **12**. As shown, a current-to-voltage amplifier **52** is substantially comprised of an operational amplifier **54** and gain determination resistor R_F. With a detector **38** connected to the inputs of the amplifier as shown, a current I_D is input to the amplifier upon the detection of suitable wavelength light. The output of amplifier **52** is designated V_0 and, as will be appreciated, is equal to the product of the detector current I_D and the gain determination resistor R_F. The primary problem with such a construction is that it also amplifies the external interference noise produced, making the signal extracted less accurate.

Adoption of the differential current-to-voltage amplifier **48**, when combined with the single-ended output amplifier **50** as shown in FIG. **13**, however, eliminates this problem. As shown, the differential amplifier **48** produces positive and negative versions of the output, the absolute value of each version being equal to the product of the gain determination resistance R_F and the detector current I_D. These outputs are then supplied to the single-ended output amp **50**, which provides unity gain, thus producing an output signal having a magnitude that is twice that of the inputs. An advantage of this arrangement is that external interference noise is cancelled at the single-ended output amplifier **50** by the opposing signs of the two transimpedance amplifier outputs. In addition, twice the signal is produced with the current noise only increasing by a magnitude of 1.414. Therefore, an improved signal-to-noise ratio results.

At this point, the mixed signal indicative of the red and infrared wavelength responses of detector **38** has been amplified and is input to a demodulator **56** to extract the red pulsatile and infrared pulsatile waveforms shown in FIGS. **9** and **10**. In a preferred arrangement, the demodulator **56** includes a sample-and-hold (S/H) circuit **60** that responds to the detector signal produced in response to red wavelength light and a sample-and-hold (S/H) circuit **58** that responds to the infrared wavelength response of detector **38**. The timing of circuits **58** and **60** is controlled so that each circuit samples the signal input to demodulator **56** during the portion of the signal corresponding to the wavelength to which it responds. In this manner, two signals are reconstructed from the single input to demodulator **56**. As noted above, these signals correspond to the red pulsatile signal and infrared pulsatile signals shown in FIGS. **9** and **10**.

To remove high-frequency noise from the outputs of circuits **58** and **60**, they are input to lowpass filters **64** and **62**. In a preferred embodiment, the "red" lowpass filter **62** and "infrared" lowpass filter **64** each include two stages. The first stage of each filter utilizes a fifth-order, monolithic integrated circuit switched capacitor filter because of its low cost, relatively small physical size and accuracy. Since both the "red" and "infrared" signals pass through nearly identical first-stage filters due to monolithic IC matching, their gain and phase frequency responses are matched. The second stage of each filter is a second-order Bessel filter having a slightly higher roll-off frequency than the first stage. This ensures that the first-stage filter is the dominant filter of the two-stage combination, producing the desired filtering accuracy. The second stage then filters the switching noise from the first-stage output.

The filtered red and infrared pulsatile signals are next prepared for conversion and transmission to the microcomputer **16**. As will be discussed in greater detail below, this process involves the use of a programmable DC subtractor or offset **66** followed by a programmable gain amplifier **68** having a gain range from approximately one to 256. The appropriately processed signals are combined at multiplexer **70**, sampled and held at **71**, and converted to digital form by A/D converter **72** for transmission to microcomputer **16**.

Before a more complete discussion of the operation of programmable subtractor **66**, programmable gain amplifier **68**, multiplexer **70**, S/H **71**, and A/D converter **72** is provided, several details regarding the signals to be transferred to microcomputer **16** should be noted. For example, as shown in FIGS. **9** and **10**, the signal produced by detector **30** in response to light at each wavelength includes components that, for convenience, are termed baseline and pulsatile. The baseline component approximates the intensity of light received at detector **38** when only the "fixed" nonpulsatile absorptive component is present in the finger. This component of the signal is relatively constant over short intervals but does vary with nonpulsatile physiological changes or system changes, such as movement of sensor **12** on the finger. Over a relatively long interval this baseline component may vary significantly. As will be appreciated, the magnitude of the baseline component at a given point in time is substantially equal to the level identified in FIG. **9** as R_H. For convenience, however, the baseline component may be thought of as the level indicated by R_L, with the pulsatile component varying between the values for R_H and R_L over a given pulse. That pulsatile component is attributable to light transmission changes through the finger resulting from blood volume changes in the finger during a cardiac pulse. Typically, the pulsatile component may be relatively small in comparison to the baseline component and is shown out of proportion in FIGS. **9** and **10**.

The determination of R_{OS} in accordance with equation (22) requires accurately measured values for both the baseline and pulsatile signal components. Because the pulsatile components are smaller, however, greater care must be exercised with respect to the measurement of these components. As will be readily appreciated, if the entire signal shown in FIGS. **9** and **10**, including the baseline and pulsatile components, was amplified and converted to a digital format for use by microcomputer **16**, a great deal of the accuracy of the conversion would

be wasted because a substantial portion of the resolution would be used to measure the baseline component. For example, with an A/D converter employed having an input range of between +10 and −10 volts, a signal having a baseline component referenced to −10 volts that is four times that of the pulsatile component can be amplified until the baseline component is represented by a 16-volt difference and the pulsatile signal represented by a 4-volt difference. With a 12-bit A/D converter **72**, the total signal can be resolved into 4096 components. Therefore, the number of incremental levels representing the pulsatile signal would be approximately 819. If, on the other hand, the baseline component is removed prior to the conversion, the gained pulsatile signal could be resolved into 4096 intervals, substantially improving accuracy.

The disclosed invention employs this technique, as the first half of a construction-reconstruction process, in the manner schematically outlined in FIG. **14**. As shown, an input signal V_1 (corresponding to the signals shown in FIGS. **9** and **10**) is received from each filter **62** and **64**. V_1 includes both the baseline and pulsatile components discussed above. As will be described, subsequent operations upon V_1 subtract off a substantial "offset voltage" portion of the baseline component, then gain up the remaining substantially pulsatile signal for conversion by A/D converter **72**. A digital reconstruction of the original signal is then produced by reversing the process, wherein digitally provided information allows the gain to be removed and the offset voltage added back. This step is necessary because the entire signal, including both the baseline and pulsatile components, is used in the oxygen saturation measurement process.

For purposes of the following discussion, an offset voltage V_{OS} (computed in a manner discussed in greater detail in conjunction with the description of microcomputer software provided below) is defined to be the negative value of the portion of the baseline component to be subtracted. Because some offset error voltage is introduced by the various components of the system, the portion of the signal ultimately attributable to these components V_{OS} is also preferably accounted for because it represents an error. As shown in FIG. **14**, a signal construction block **74**, corresponding to programmable subtractor **66** and programmable amplifier **68**, initially processes the input signal V_1 by adding to it the negatively defined offset voltage V_{OS}. The output of construction block **74**, V_O, is defined as follows:

$$V_O=(V_1+V_{OS}+V_{os})A \tag{23}$$

As will be readily appreciated, V_O is substantially proportional to the pulsatile component V_1, which contains the pulsatile information desired. Without gain A, this pulsatile signal may be relatively small in comparison to the maximum input range of A/D converter **72**. To provide good resolution, therefore, the signal is amplified by gain A, which is sufficient to produce a signal occupying a predetermined portion of the A/D converter **72** input range. In this manner, the resolution of the digital conversion is improved by providing a large pulsatile signal for measurement.

If R_H, R_L, IR_H and IR_L, as discussed previously, are to be measured and the oxygen saturation determined, however, the foregoing process must be reversed. As will be appreciated, dividing both sides of the equation (23) by the gain A produces:

$$V_1+V_{OS}+V_{os}=V_0/A \tag{24}$$

Restructuring of equation (24) results in:

$$V_1=V_0/A-V_{OS}-V_{os} \tag{25}$$

Thus, the original input signal V_1 containing the baseline and pulsatile components can be reconstructed at block **76** by dividing the output of the A/D converter **72**, V_0, by the gain A and the subtracting the offset voltages V_{OS} and V_{os}. The reconstruction is preferably performed at microcomputer **16** before oxygen saturation computations are initiated, allowing measurements based on the full signal to be performed. As will be appreciated, to accomplish this, values for V_{OS}, V_{os} and A must be supplied to microcomputer **16**.

Feedback from microcomputer **16** is also required to maintain the values for V_{OS}, V_{os} and gain A at levels appropriate to produce optimal A/D converter **72** resolution. Likewise, as shown in the FIG. **14**, feedback to the source drivers **44** may be used to help optimize the conversion. Proper control requires that the microcomputer continually analyze, and respond to, the offset voltages V_{OS} and V_{os}, gain A, driver currents I_0 and the output of A/D converter in a manner to be described next.

Briefly, with reference to FIG. **15**, thresholds L1 and L2 slightly below and above the maximum positive and negative excursions L3 and L4 allowable for the A/D converter **72** input are established and monitored by microcomputer **16** at the A/D converter output. When the magnitude of the signal input to, and output from, A/D converter **72** exceeds either of the thresholds L1 or L2, the drive currents I_D are readjusted to increase or decrease the intensity of light impinging upon the detector **38**. In this manner, the A/D converter **72** is not overdriven and the margin between L1 and L3 and between L2 and L4 helps assure this even for rapidly varying signals. An operable voltage margin for A/D converter **72** exists outside of the thresholds, allowing A/D converter **72** to continue operating while the appropriate feedback adjustments to A and V_{OS} are made.

When the signal from A/D converter **72** exceeds positive and negative thresholds L5 or L6, microcomputer **16** responds by signaling the programmable subtractor **66** to increase or decrease the voltage V_{OS} being subtracted. This is done through the formation and transmission of an offset code whose magnitude is dependent upon the level of the signal received from converter **72**.

The manner in which the various thresholds are established and the relationship of the offset codes to the signal received can be altered to produce substantially any form of control desired. In addition, gain control codes could be established by microcomputer **16** in response to the output of A/D converter **72** to vary the gain of amplifier **68** as a function of converter output. Thus, the arrangement shown in FIG. **15** is illustrative only and represents the currently preferred embodiment. This embodiment of the construction-reconstruction process will now be discussed in greater detail in conjunction with a portion of the oximeter software stored in the erasable, programmable read-only memory (EPROM) **78** of microcomputer **16**. The software defines a program of instructions to be executed by the central processing unit (CPU) **80** of microcomputer **16** and governs the manner in which microcomputer **16**

provides servosensor control as well as produces measurement outputs of display.

The first segment of the software to be considered is an interrupt level routine **82**, shown in part in FIG. **16**. Interrupts are events generated by a programmable timer, which is included in CPU **80** and is initialized at the power-up of microcomputer **16**. An interrupt event "interrupts" the part of the program currently being executed by CPU **80** and transfers control to a new instruction sequence associated with the particular interrupt. When processing associated with the interrupt is completed, the program may be resumed at the point of interruption, or elsewhere, depending on any status changes that may have resulted from processing of the interrupt.

Normal interrupt processing in accordance with routine **82** begins once CPU **80** has completed a number of preliminary routines, including power-up reset, calibration, and miscellaneous test code routines. Microcomputer **16** and the software stored in EPROM **78** are organized to provide real-time processing at the interrupt level routine **82**, as well as at the other, prioritized task levels noted below. Processing at the various task levels is prioritized such that the highest priority task ready and waiting to run is given control, in the absence of an interrupt. Thus, a task may be interrupted to execute a higher priority task and then resumed when processing at the higher priority level is completed. Interrupt processing occurs at a priority level above all other tasks.

While the interrupt routine **82** employed may have a number of subroutines controlling various portions of oximeter **10** operation, such as the filtering performed by lowpass filters **62** and **64**, only the details of the interrupt period subroutine directly pertinent to servosensor control are shown in FIG. **16**.

As shown at block **84**, processing of the interrupt level routine **82** does not begin until calibration is complete. After calibration, a nominal interrupt period zero subroutine **86** may be reached. This subroutine is responsible for normal sampling and includes five states, zero through four. Briefly, at block **88**, a sensor set-up subroutine is represented as including states zero to three of the period zero subroutine **86**. As will be discussed in greater detail below, during these states sensor parameters including amplifier gain A and offset voltages V_{OS} are initialized, provided that a finger is present in the sensor. State four of the interrupt period zero subroutine **86** is the normal data acquisition state and is shown at block **90**. This state is reached when, for example, a finger is present in sensor **12**, the amplifier gain, offset voltages, and driver currents are within their appropriate ranges, and the software is not performing a test task. As shown in FIG. **16**, state four of the period zero subroutine **86** includes a number of instructions. At block **92** drive currents are applied to LEDs **40** and **42** and the resulting signal produced by detector **38** is sampled. The signals produced in response to light at each wavelength are then compared against the desired operating ranges to determine whether modifications of the driver currents and voltage offsets are required. This step is shown at block **94**. The exact manner in which these control variables are tested and modified is discussed above and in greater detail below. Finally, as shown in block **96**, state four of the period zero subroutine **86** updates the displays **20** of oximeter **10**.

The operation of the period zero subroutine **86** of the interrupt routine **82** is now discussed in greater detail in conjunction with FIG. **17**. As shown at block **98**, the current state of sensor set-up is determined, including the levels of LED drive current, amplifier gain, and offset voltages. At block **100**, these sensor set-up states are analyzed to determine which of the five period zero interrupt state subroutines, indicated by blocks **102**, **104**, **106**, **108**, and **110**, are to be executed. The manner in which the various state subroutines are sequenced for execution by block **100** is shown in greater detail in FIG. **18**. Generally, states are entered in ascending order. Thus, the state zero subroutine **102** forms an initial block **112** in the sequencing performed by block **100**. In this state, as noted above and discussed in greater detail below, the various parameters and variables employed by oximeter **10** are initialized. As shown, the sequential processing returns to state zero whenever the conditions required for a particular state routine are violated. Given the general processing of state routines in ascending order, with the parameters initialized at block **112**, the state one subroutine **104** is reached at block **114**. This routine sets the drive currents applied to LEDs **40** and **42**. The state one subroutine **104** is maintained until the drive currents are set, at which time sequential processing moves to the state two subroutine **106** shown at block **116**. In the event that the state one subroutine **104** determines that the LED drive currents cannot be set, processing is returned to the state zero subroutine at block **112**.

Once the state two subroutine **106** of the interrupt period zero subroutine **86** is reached at block **116**, the offset voltages are adjusted. The state two subroutine **106** is maintained until the offsets are properly adjusted or it is determined that they cannot be so adjusted given the current drive settings. With the offsets properly adjusted, sequential processing continues to the state three subroutine at block **118**. If they cannot be properly adjusted, however, the interrupt period zero subroutine **86** is reset to state zero.

The amplifier gain levels determined during calibration are set in the state three subroutine shown at block **118**. Once properly set, sequencing continues to the state four subroutine at block **120**, where the normal analog signal processing is performed.

With this basic understanding of the various states of the period zero normal sample subroutine **86** and the sequential order in which those states are processed, a more detailed discussion of the various states of the period zero subroutine is now provided. FIG. **19** is a detailed flow chart of the processing included in the state zero subroutine **102** of FIG. **17**. As shown in block **122**, the first instruction in the state zero subroutine **102** calls for normal signal processing to be halted. At block **124**, the gain for each channed is reset to one and the offset voltage for each channel is reset to zero at block **126**. Similarly, the LED drive currents for each channel are initialized to their maximum values at block **128**. With these conditions performed, the sequential processing of the various state routines of the period zero interrupt subroutine **86** cause the state one subroutine **104** to be reached at block **130**. A return is provided at block **132** and the processing associated with the state one subroutine will occur at the time of the next period zero interrupt.

The state one subroutine **104** of FIG. **17** is shown in greater detail in FIG. **20**. When the state one subroutine **104** is executed, a pulse search flag is set at block **107** to indicate that no pulse is available. At block **109**, the presently established drive currents are output to LEDs

40 and 42 and the resulting signals produced from detector 38 are read. The signals input to the drivers 44 are then checked to determine whether they are in a valid operating range at block 111. More particularly, a test is performed at block 113 to determine whether the driver inputs are below some predetermined acceptable minimum value. If either input is below the acceptable minimum, the output of the corresponding driver 44 is then tested at block 115 to determine whether it is at some predetermined maximum value. With the output at a maximum, it is assumed that no greater drive current can be provided and the interrupt period zero subroutine 86 is advanced to state two at block 117 via block 119.

If, on the other hand, the input to either driver 44 is determined to be less than the predetermined minimum at block 113, but block 115 indicates that the drive current is not at its maximum value, the routine progresses via block 121 to block 123 where the drive is increased in proportion to the drive current read. In this manner, an attempt is made to adjust the drive current to a nominally desired level. More particularly, the input to driver 44 is increased by an amount equal to some nominal value minus the present input, all divided by a predetermined constant. The validity of the drive setting is then checked the next time that interrupt period zero routine 86 is performed.

If block 113 determines, for each channel, that the input to driver 44 is not below the predetermined minimum, a test is performed at block 125 to determine whether the input is above some predetermined maximum. If an input signal is above the desired range, the output of the corresponding driver 44 is checked at block 127 to determine whether it is at some predetermined minimum value. A driver output at its minimum value is interpreted at block 129 to indicate that no finger is present in the sensor and the routine is returned to state zero. If, on the other hand, block 127 indicates that the output of driver 44 is not at its minimum value, block 123 is reached via block 121, allowing the drive output to be adjusted in an attempt to bring the drive input back below the maximum predetermined value exceeded at block 125. More particularly, the drive output is adjusted at block 123 by decreasing the input to driver 44 by an amount equal to a nominal input minus the present input divided by some predetermined factor.

Finally, if the driver input falls within a predetermined desired operating range, the tests at block 113 and 125 will both be failed and the subroutine will progress to block 117 via block 119. This indicates that the drives are properly set and block 117 allows the subroutine to progress to state two at the next period zero interrupt via block 131. Although not shown in FIG. 20, such valid drive input values must exist multiple concurrent times before the state two subroutine 106 is reached.

FIG. 21 is a pictorial illustration of the response of the state one subroutine 104 to the various input and output levels of the drivers 44. As shown, if the input current to driver 44 is below a predetermined minimum, DI1, an invalid condition is indicated unless the output current of driver 44 is greater than some predetermined maximum DO1. If DO1 is not exceeded, the driver inputs are adjusted upward before the state two subroutine 106 is reached. Similarly, if the input signal to drivers 44 exceeds some predetermined maximum DI2, an invalid condition is indicated and the input to the drive is adjusted downward. When the input signal to drivers 44 falls between the levels DI1 and DI2, however, the signal is within a valid range and the state two subroutine 106 is directly accessed.

FIG. 22 is a more detailed flow chart of the state two routine 106 of the period zero interrupt subroutine 86. As shown, at step 133, the drive currents previously established at the state one subroutine 104 are provided to LEDs 40 and 42 and the response of detector 38 as processed by I/O circuit 14 is read. Thus, a signal is received corresponding to each wavelength of light and the signals of both channels are processed in the following manner. At block 134, the signal at each channel is checked to determine whether it is within an absolute range extending between limits L1 and L2 as shown in FIG. 15. As indicated at block 136, if the signal is outside this predetermined range, the state is reset to zero at step 138 and the input signal to drivers 44 is adjusted in the manner described above to produce an acceptable drive current for LEDs 40 and 42.

When the test performed at block 136 indicates that the signals from A/D converter 72 are within the range between L1 and L2, the state two subroutine 106 progresses to block 140. There, the signal for each channel is checked against a window defined between an upper limit L5 and a lower limit L6. If the signal falls within those limits, block 142 of the subroutine causes the program to be advanced to state three of the period zero interrupt subroutine 86 at block 144 without further adjustments being made. This indicates that the offset voltages are properly set. If, on the other hand, block 142 indicates that the signal is not within the window defined between L5 and L6, block 146 adjusts the offset voltage employed by subtractor 66 in proportion to the level of the signal received. For example, the offset may be either increased or decreased by an amount equal to the signal level divided by some predetermined factor. The adjustment of the offset voltage is accomplished by establishing a new offset code to be transmitted to subtractor 66. This new code is checked at block 148 to determine whether it is within a range of valid codes. The test is performed at block 150 and if the new code is not valid, the state is reset to zero via block 138 so that the drive currents for LEDs 40 and 42 can be reinitialized. If the code is in range, a return is accessed at block 152.

The operation of the state three subroutine 108 of the period zero interrupt subroutine 86 is shown in greater detail in FIG. 23. At block 154, the present drive current signals are provided to drivers 44 to drive LEDs 40 and 42. No samples of the input channels from I/O circuit 14 are made in this state. At block 156, a flag is set to initiate signal processing. In addition, a flag is set at step 158 to cause the generation of an appropriate independently derived calibration curve based upon information received from sensor 12. A gain code established during calibration is then set at block 160 to determine the gain of amplifier 68 and the period zero interrupt routine 86 is progressed to the state four subroutine 110 at block 162 via return 164.

The details of the state four subroutine 110 are shown in FIG. 24. Processing begins with the output of signals to drivers 44 for the production of drive currents at LEDs 40 and 42. Signals from each channel as processed by the subtractor 66 and amplifier 68 are then sampled and stored at block 166. These samples are then checked at block 168 against the maximum and minimum range limits L3 and L4 shown in FIG. 15. If the

signal is not within those limits, block **170** causes the subroutine to progress to block **172** where an indication is produced that a finger is no longer present in sensor **12** and the state is reset to zero via step **174**.

If, on the other hand, the signal is within the absolute maximum range, the samples are again checked at block **176** to determine whether they are within the desired operating range, shown in FIG. **15** as lying between limits **L5** and **L6**. If they are, block **178** directs the program to a return at block **180**. This indicates that the samples received are acceptable and allows computational software to produce a value of R_{OS}. If block **178** indicates that the signal is not within the desired operating range, however, the program is directed to step **182** where the offset voltage is adjusted upward or downward by a factor of eight to bring it within the desired range. At block **184**, the code for this new offset voltage is output.

As noted previously, before the signal samples produced in the state four subroutine **110** can be used in computations, they must be converted back to valid signals that do not include the effects of gain and offset. The instructions **186** for this reconstruction process are shown in FIG. **25**. This routine is executed during an interrupt event period not shown in FIG. **16**. Signal reconstruction is performed for each channel and begins at a first block **188** where the sign of the offset code currently in use is determined. Then, at block **190**, the absolute value of the offset code is extracted and divided by four at block **192**. This divided offset code is used as an index for a calibrated offset table shown in FIG. **26**. This table is generated during calibration and contains the calibrated offset voltage corresponding to each offset code.

From block **192**, the signal reconstruction routine **186** progresses to block **194** where the present signal sample for the channel involved, as produced by the period zero interrupt subroutine **86**, is retrieved. At block **196**, the equivalent zero reference value, determined at calibration, is subtracted from the input sample to produce a signed value. To allow subsequent arithmetic operations to be performed with the retention of a greater number of bits, the 12-bit input signal is scaled to a 16-bit number at block **198**.

At block **200**, the gain previously applied to the signal by amplifier **68** is removed. The effect of the offset voltages is then removed from the signal in the following manner. The calibrated offset value equivalent to the offset code is extracted from the table shown in FIG. **26** at block **204**. This calibrated offset value is converted to its signed equivalent at block **206** and is subtracted from the previously processed signal at block **208**. This value is then stored at block **210** for subsequent processing accomplished via a return at block **212**.

In addition to the analog sample processing task discussed above, the software may include a time task, display drive task, keyboard operation task and test routine task. The analog sample processing task has the highest priority of these various tasks.

As noted, the instructions for the software that controls the signal construction-reconstruction process discussed above are stored in EPROM **78** of microputer **16**. Simlarly, values for R_H, R_L, IR_H, IR_L, and signal period are determined pursuant to peak-detection software contained in EPROM **78**. These values are stored in random-access memory (RAM) **214** for operation upon by CPU **80** in accordance with further computational instructions stored in EPROM **78**. Interfaces **216** act as input and output buffers for microcomputer **16**.

The computational software in EPROM **78** initially causes CPU **80** to determine the present value for R_{OS} by substituting the measured values for R_H, R_L, IR_H, and IR_L into equation (22):

$$R_{OS} = \frac{\ln(R_L/R_H)}{\ln(IR_L/IR_H)} \tag{26}$$

Then, the computational software instructs CPU **80** to determine the oxygen saturation from R_{OS} by use of a calibration curve, such as the one depicted in FIG. **7**. The calibration curve is a plot of the relationship between independently determined oxygen saturations corresponding to values of R_{OS} produced by oximeter **10** in accordance with the technique described above.

With sufficiently large space in EPROM **78**, enough points along the calibration curve can be stored in a look-up table to allow CPU **80** to extract an accuate indication of oxygen saturation from the value of R_{OS} input to EPROM **78**. The storage of a sufficient number of calibration curve data points may, however, necessitate the use of an undesirably large-capacity EPROM **78**. For that reason, a second method of storing the calibration curve information is preferred.

Pursuant to that method, once independently derived data associating R_{OS} with the oxygen saturation is obtained, a mathematical expression between the two can be derived from a plot of the curve. The basic formula and the coefficients of the formula's variables are then stored in EPROM **78**. When a value for R_{OS} is measured, CPU **80** extracts the coefficients from EPROM **78** and computes a value for the oxygen saturation. This technique allows information completely identifying the entire calibration curve, or a family of such curves, to be stored within a relatively small amount of EPROM **78** space.

The computational software in EPROM **78** also instructs CPU **80** to determine the pulse rate from the signal period. Displays **20** then provide visible and audible outputs of the oxygen saturation and pulse rate in a manner conveniently used by the operator of oximeter **10**.

While the references have been described with reference to a preferred embodiment, it is to be clearly understood by those skilled in the art that the invention is not limited thereto, and that the scope of the invention is to be interpreted only in conjunction with the following claims.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An apparatus for receiving and processing signals, produced by a sensor, that contain information about the oxygen saturation of arterial blood flowing in tissue, said apparatus comprising:

offset subtraction means for subtracting from said sensor signal a controlled portion of said signal, said offset subtraction means having an output that is substantially equal to the portion of said sensor signal remaining after said controlled portion is subtracted therefrom;

control means for receiving said output of said offset subtraction means and providing a subtraction control signal, which is dependent on said output, to

said subtraction means to control the magnitude of said portion of said sensor signal; and

analyzing means for receiving said output of said subtraction means and said controlled portion of said signal and producing an indication of the oxygen saturation of said arterial blood flowing in said tissue.

2. The apparatus of claim 1, wherein said subtraction means subtracts the same said portion from said sensor signal when said subtraction means output is within a first predetermined range.

3. The apparatus of claim 2, wherein said subtraction means subtracts an adjusted said portion from said sensor signal when said subtraction means output falls within a second predetermined range, said magnitude of said adjusted portion being a function of the magnitude of said subtraction means output.

4. An apparatus for receiving and processing signals, produced by a sensor, that contain information about the oxygen saturation of arterial blood flowing in tissue, said signals including a relatively periodic pulsatile component superimposed upon a slowly varying baseline component, said apparatus comprising:

offset subtraction means for subtracting from said sensor signal a controlled portion of said signal, said offset subtraction means having an output that roughly approximates said periodic pulsatile component;

control means for receiving said output of said offset subtraction means and providing a subtraction control signal, which is dependent on said output, to said subtraction means to maintain the magnitude of said controlled portion of said sensor signal roughly approximate to said baseline component; and

analyzing means for receiving said output of said subtraction means and producing an indication of the oxygen saturation of said arterial blood flowing in said tissue.

5. The apparatus of claim 4, wherein said subtraction means subtracts the same said portion from said sensor signal when said subtraction means output is with a first predetermined range.

6. The apparatus of claim 5, wherein said subtraction means subtracts an adjusted said portion from said sensor signal when said subtraction means output falls within a second predetermined range, said magnitude of said adjusted portion being a function of the magnitude of said subtraction means output.

7. The apparatus of claim 4, wherein said analyzing means is further for receiving said controlled portion of said signal.

8. A method of processing signals that contain information about the oxygen saturation of arterial blood flowing in tissue, said signals including a relatively periodic pulsatile component superimposed upon a slowly varying baseline component, said method comprising the steps of:

subtracting from said information signal a controlled portion of said information signal, the magnitude of said controlled portion being approximately equal to said baseline component and being determined by a subtraction control signal;

producing a subtraction output that is approximately equal to the periodic pulsatile component of the information signal remaining after said controlled portion is subtracted from said information signal; and

producing said subtraction control signal, the magnitude of said subtraction control signal produced being a function of said subtraction output and indicating any adjustment to be made in said controlled portion subtracted from said information signal.

9. A method of processing signals, produced by a sensor, that contain information about the oxygen saturation of arterial blood flowing in tissue, said method comprising the steps of:

subtracting from said sensor signal a controlled portion of said signal to provide a remaining portion of said signal;

controlling the magnitude of said controlled portion of said signal based upon the magnitude of said remaining portion of said signal; and

processing information about said controlled portion and said remaining portion of said signal to produce an indication of the oxygen saturation of said arterial blood flowing in said tissue.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,892,101

DATED : January 9, 1990

INVENTOR(S) : Cheung et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column	Line	
5	21	"predetrmined" should be --predetermined--
6	36	"ciruit" should be --circuit--
9	63	"appareciated" should be --appreciated--
11	36	"wavelengtcan" should be --wavelength can--
16	11	"the" (second occurrence) should be --then--
21	63	"Microputer" should be --microcomputer--
22	21	"accuate" should be --accurate--
22	46	"references" should be --Figures--
23	42	"with" should be --within--

Signed and Sealed this

Fifteenth Day of December, 1992

Attest:

Attesting Officer

DOUGLAS B. COMER

Acting Commissioner of Patents and Trademarks

CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

CERTIFICATE OF SERVICE

I, Lanta M. Chase, hereby certify that true and correct copies of the foregoing, **RESPONDENT APPLE INC.'S OPENING MARKMAN BRIEF**, have been filed and served on this 27th day of January 2022, on the following in the manner indicated:

The Honorable Lisa R. Barton Secretary U.S. International Trade Commission 500 E Street, S.W. Washington, DC 20436	☒ Via Electronic Filing ☐ Via Hand Delivery (2 Copies) ☐ Via Overnight Delivery ☐ Via Facsimile
The Honorable Monica Bhattacharyya Administrative Law Judge U.S. International Trade Commission 500 E Street, S.W., Room 317 Washington, DC 20436	☐ Via Hand Delivery (2 Copies) ☐ Via Overnight Delivery ☐ Via Facsimile ☒ Via Electronic Mail edward.jou@usitc.gov michael.maas@usitc.gov
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