Exhibit E-10
Initial Invalidity Claim Chart for U.S. Patent No. 10,984,911

All asserted claims of U.S. Patent No. 10,984,911 (the "'911 Patent") are anticipated and/or rendered obvious over the prior art references discussed in the following chart under at least the apparent construction of the claims by Masimo based on its Initial Infringement Contentions served on May 25, 2023 (the "Initial Infringement Contentions").

The following chart includes the below references. Apple expressly reserves the right to modify, amend, and/or supplement this list as additional information becomes available and as discovery proceeds.

- US. Patent No. 6,608,562 to Kimura et al. ("**Kimura**") (prior art at least as of August 19, 2003)
- "Pulse Oximetry" to John TB Moyle ("**Moyle**") (prior art at least as of 2002)
- "Design of Pulse Oximeters" to J G Webster ("**Webster**") (prior art at least as of 1997)
- U.S. Patent No. 7,620,212 to Allen et al. ("**Allen**") (prior art at least as of August 12, 2003)
- U.S. Patent No. 6,014,576 to Raley et al. ("**Raley**") (prior art at least as of August 19, 2003)
- U.S. Patent No. 6,278,889 to Robinson et al. ("**Robinson**") (prior art at least as of August 21, 2001)
- U.S. Patent No. 5,782,757 to Diab et al. ("**Diab**") (prior art at least as of July 21, 1998)
- U.S. Patent No. 7,190,986 to Hannula et al. ("**Hannula**") (prior art at least as of October 18, 2002)
- U.S. Patent No. 5,099,842 to Mannheimer et al. ("**Mannheimer 842**") (prior art at least as of March 31, 1992)
- U.S. Patent No. 3,638,640 to Shaw et al. ("**Shaw**") (prior art at least as of February 1, 1972)
- "New Hybrid Reflectance Optical Pulse Oximetry Sensor for Lower Oxygen Saturation Measurement and for Broader Clinical Application" to Nogawa et al.("**Nogawa**") (prior art at least as of 1997)
- U.S. Patent No. 5,720,284 to Aoyagi et al. ("**Aoyagi**") (prior art at least as of February 24, 1998)
- U.S. Patent 5,983,122 to Jarman et al. ("**Jarman**") (prior art at least as of November 9, 1999)
- U.S. Patent 5,413,100 to Barthelemy et al. ("**Barthelemy**") (prior art at least as of May 9, 1995)
- "Frequency-domain multichannel optical detector for noninvasive tissue spectroscopy and oximetry" to Fantini et al. ("**Fantini**") (prior art at least as of 1995)
- "Hamamatsu Lens for Side-on Type Photomultiplier Tubes" ("**Hamamatsu**") (prior art at least as of 1999)

The excerpts cited herein are exemplary. For any claim limitation, Apple may rely on excerpts cited for any other limitation and/or additional excerpts not set forth fully herein to the extent necessary to provide a more comprehensive explanation for a reference's disclosure of a limitation. Where an excerpt refers to or discusses a figure or figure items, that figure and any additional descriptions of that figure should be understood to be incorporated by reference as if set forth fully therein. Apple expressly reserves the right to use the entirety of any reference described and/or identified below, in the charts for the '911 Patent, and/or cited in Apple's Initial Invalidity

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Contentions for the ’911 Patent and otherwise to supplement these contentions to add additional information showing that any reference disclosed herein invalidates the asserted claims of the ’911 Patent.

One of ordinary skill in the art, as of the proper priority date of the ’911 Patent, would have known to combine the prior art elements disclosed by the references below, the references charted for the ’911 Patent, and/or the references cited in Apple’s Initial Invalidity Contentions for the ’911 Patent using known methods, and to use these elements according to their established functions in order to achieve a known and predictable result. Because these prior art references are within a common field of endeavor, and/or are directed to a related set of problems, it would have been obvious for one of ordinary skill in the art to look from one of the identified references to another in order to find any missing functionality. One of ordinary skill in the art would have been motivated to do so for the reasons identified by the references below, because there were only a finite number of predictable solutions and/or because known work in a common field of endeavor often prompts variations based on predictable design incentives and/or market forces in the same or a related field. Moreover, one of ordinary skill in the art would have found the combination obvious to try, due at least to the similarity and interrelatedness of the technical teachings of the art. As another example, one of ordinary skill in the art would have found that the teachings may have been predictably interchanged by, for example, simple substitution of parts, at least because of the predictability of the art and the known interchangeability of the various elements or process steps. In addition, combining the references identified below would have been obvious because the combinations represent known potential options with a reasonable expectation of success. Further, a POSITA would have been motivated to combine any of the references below, the references charted for the ’911 Patent, and/or the references cited in Apple’s Initial Invalidity Contentions for the ’911 Patent with one or more of the references below for the reasons set forth in Apple’s Initial Invalidity Contentions. A POSITA would have had a reasonable expectation of success in combining any of the references below, the references charted for the ’911 Patent, and/or the references cited in Apple’s Initial Invalidity Contentions for the ’911 Patent with one or more of those references for the reasons set forth in Apple’s Initial Invalidity Contentions.

These Initial Invalidity Contentions are based on Apple’s present understanding of the ’911 Patent claims and Masimo’s theories of infringement against Apple. Apple expressly does not agree that, under a correct construction or reading of the claims, that Apple’s accused products meet the limitations of the asserted claims of the ’911 Patent or that the claims satisfy the requirements of 35 U.S.C. § 112. Apple’s contentions herein are not, and should in no way be seen as, admissions as to or adoptions of any particular claim scope or construction, or as an admission that any particular element is met by any accused product in any particular way. Apple therefore objects to any attempt to imply claim construction from this chart. Apple’s Initial Invalidity Contentions do not represent Apple’s agreement or view as to the meaning, definiteness, written description support for, or enablement of any claim contained therein. However, at least under Masimo’s apparent application of the claims for the purposes of infringement (which Apple expressly disagrees with), the prior art disclosed herein would have rendered the asserted claims of the ’911 Patent invalid. Except where specifically noted otherwise, this chart applies the apparent constructions of claim terms as used by Masimo in its Initial Infringement Contentions; such use, however, does not imply that Apple adopt or agree with Masimo’s constructions in any way. Apple further reserves the right to supplement these contentions in response to any claim construction orders by the Court.

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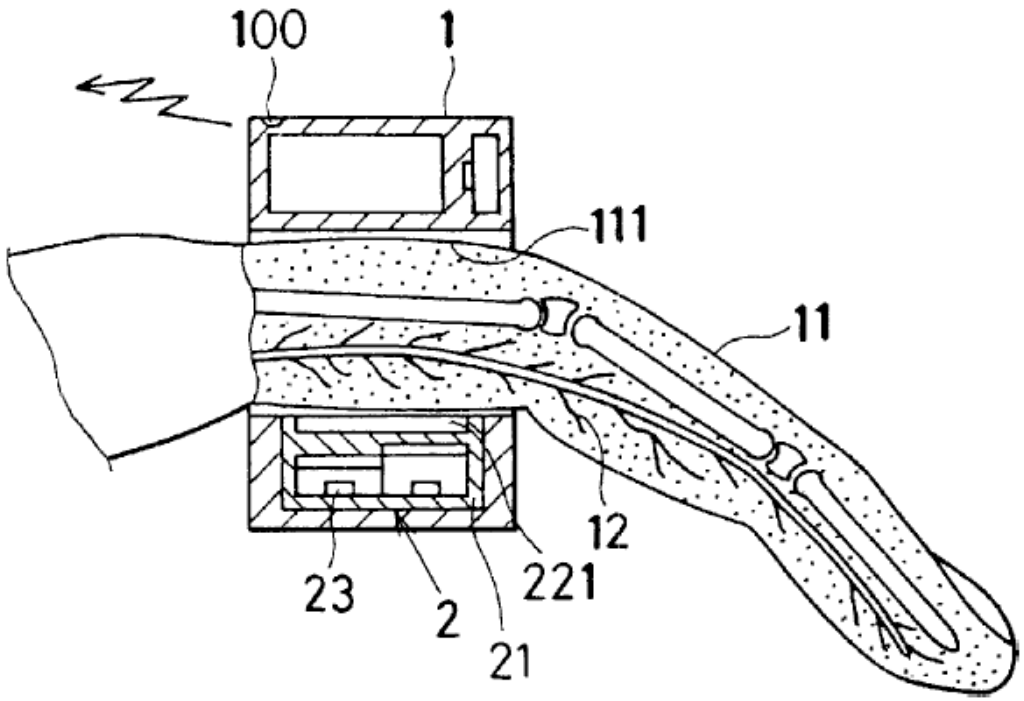
Apple is investigating this prior art and has not yet completed discovery from third parties who may have information concerning it. Pursuant to Federal Rule of Civil Procedure 26(e), the Local Rules of the District of Delaware, and the Orders of record in this matter Apple reserves the right to modify, amend, and/or supplement these contentions as information becomes available (*e.g.*, witness testimony and/or non-public documentation) and as discovery proceeds.

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Claim 1	Prior Art
1[pre] A physiological monitoring device comprising:	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, Kimura discloses and/or renders obvious a physiological monitoring device. For example, Kimura discloses and/or suggest a vital signs detecting apparatus that is capable measuring vital signals such as pulse: *See, e.g.*, Kimura at Abstract ("A vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. The pulse wave detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, Fig. 1A

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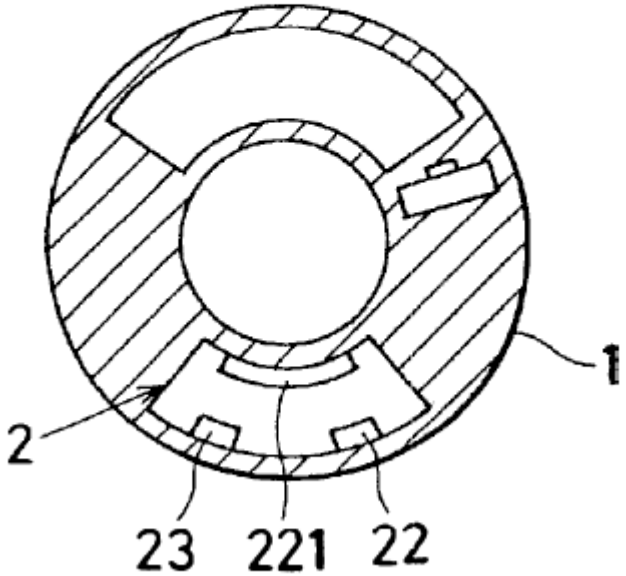
FIG. 1A



Kimura, Fig. 1B.

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FIG. 1B

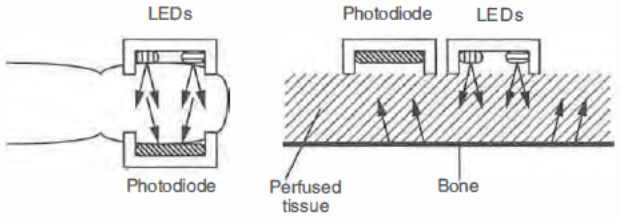


Kimura, 1:46-2:2 ("It is therefore an object of the present invention to provide a vital signal detecting apparatus which eliminates problems caused by abnormal vital signals detected when an attachable device is not attached.

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	According to the present invention, a vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. Preferably, the vital signal detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, Webster discloses and/or renders obvious a physiological monitoring device. For example, Webster discloses and/or suggests pulse oximeter technology relying on LEDs and detectors for measuring physiological parameters, where reflectance and transmittance oximeters rely on the same technology: *See, e.g.*, Webster at 36:

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	3.7.4 Probes Improved technology in photodiodes and LEDs has another benefit. They allow the probe to be small and attach to the pulse oximeter with conventional wires. The Hewlett-Packard eight wavelength oximeter was considered an accurate device, but because bulky fiber optic cables were needed to carry the light source to the patient and the transmitted light back to a light sensor, it was impractical (Rebuck *et al* 1983). Probes for the pulse oximeter are not only smaller, but can be disposable. Figure 3.10 shows a transmission pulse oximeter and a reflectance pulse oximeter. As the names indicate, a transmission pulse oximeter measures the amount of light that passes through the tissue as in a finger probe. A reflectance pulse oximeter measures the amount of light reflected back to the probe. Both types use the same technology differing only in positioning of the probes and calibration.  **Figure 3.10** On the left is a transmission pulse oximeter measuring the transmission of light by two LEDs through the finger of a patient. On the right is a reflectance pulse oximeter measuring the amount of light reflected back to the probe.
1[a] at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;	Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths. For example, Moyle discloses and/or suggests relying on different types of LEDs to emit light, where each type of LED emits light of a different wavelength, and where the LEDs relied upon for a pulse oximeter could include three or more LEDs: *See, e.g.*, Moyle at Pages 16-21, 17-18:

The early generations of pulse oximeters all used similar wavelengths, namely 660 nm (red) and 940 nm (near infrared). However, modern devices, including transmission, reflection and intrauterine pulse oximeters, often make use of other wavelengths. LEDs of 660 nm and 940 nm were originally chosen, as they were wavelengths that were easy to manufacture, but a much greater range of wavelengths is now available (see Box).

Gallium arsenide doping of the semiconductor material of light-emitting diodes to produce specific wavelengths

Ultraviolet	455–350 nm	GaN GaS2
Violet	455–390 nm	GaN
Blue	492–455 nm	GaAs-phosphor (ZnS, SiC)
Green	577–492 nm	GaP:N
Yellow	597–577 nm	GaAs.14P.86
Orange	622–597 nm	GaAs.35P.65
Red	780–622 nm	GaP:ZnO GaAs.6P.4
Near infrared	810 nm	GaAlAs
	880 nm	GaAlAs
	900 nm	GaAs
	940 nm	GaAsSi
	1100 nm	Ga.17In.83As.34P.66
Infrared	1250 nm	Ga.28In.72As.6P.4

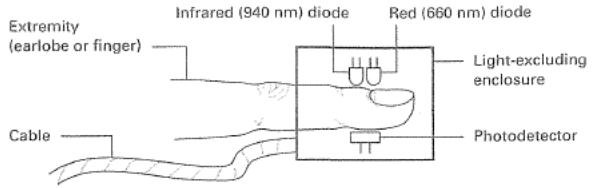


Figure 3.2 Components of transmission pulse oximeter probe.

very little difference to calibration. The advantage of 660 nm as the red wavelength chosen is that there is a comparatively large difference in the absorption between reduced and oxygenated haemoglobin at this point on the spectrum, yielding detectable changes in absorption with small changes in oxygen saturation. Although the curves are not horizontal at 660 nm, they are considerably flatter than at shorter wavelengths.

Moyle at Page 31:

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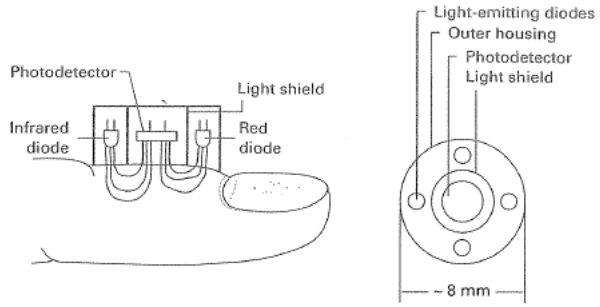


Figure 3.11 Section (left) and plan (right) of reflection oximeter probe.

Reflection pulse oximetry

There are certain advantages in using reflected rather than transmitted light. The design of the probe is simpler, with greater mechanical strength (Figure 3.11).

From a clinical point of view a reflection pulse oximeter has the advantage that it can be used at more sites than the transmission type, for example the forearm, thigh, chest, forehead and cheeks. This means that its saturation readings can be made in patients with poorer perfusion and in those who are hypothermic. The reflection pulse oximeter may prove useful after cardiac bypass surgery, where initially the periphery is very shut down and much cooler than normal. Palve[7] showed that saturation could be measured with a reflection-type probe from a patient's forehead when the fingertip temperature was only 28·8°C. Reflection pulse oximetry works well on ventilated patients who are unconscious, but difficulty with probe

Moyle at Page 36:

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Modern multiwavelength spectrophotometers can measure all four common species of haemoglobin (haemoglobin A, oxygenated haemoglobin, carboxyhaemoglobin, and methaemoglobin). The percentage oxygen saturation of the haemoglobin is now defined as a ratio of the amount of haemoglobin saturated with oxygen to all the four species. This is termed the fractional saturation:

$$\text{Fractional } SaO_2 = \frac{HbO_2}{HbO_2 + Hb + HbCO + MetHb} \times 100\%$$

Ideally, the pulse oximeter should measure either fractional or functional saturation, and the manufacturer should state whether a particular unit has been calibrated as fractional or functional. However, with current pulse oximeters using only two wavelengths, it must be said that pulse oximeters indicate neither functional nor fractional saturation.[4] The conventional two-wavelength pulse oximeter measures the absorption at two wavelengths and applies their ratio to look-up tables, which then indicate a value, SpO_2, which is best defined as *oxygen saturation as measured by a pulse oximeter*.

Moyle at Page 39-40:

variable over the range 500 nm to 700 nm, controlled by an electric (stepper) motor, so that the light emanating from the monochromator can be scanned. This variable wavelength light is passed through the cuvette containing the haemolysed blood. As the monochromator is controlled by a stepper motor, the wavelength is changed in discrete steps. As this CO-oximeter is designed to measure five components (see Box), only five wavelengths are necessary to make the calculations. However, the sample will contain other absorbents, including fetal haemoglobin, bilirubin, and fragments of the erythrocyte membranes, so the AVL 912 uses up to 17 wavelengths. The light emanating from the cuvette after passing through the blood is detected by a photodiode. The signal from the photodiode is amplified, converted from analogue

to digital, and passed to a microprocessor, which makes use of the Beer–Lambert law and simultaneous equations to calculate the values shown in the box.

Under at least the apparent construction based on Masimo's Infringement Contentions, Webster discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths.

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	For example, Webster discloses and/or suggests, for pulse oximetry systems, relying on three LEDs emitting light at three wavelengths in order to measure additional physiological parameters. *See, e.g.*, Webster at 37-38: *3.7.6 A three-wavelength pulse oximeter for COHb determination* Current pulse oximeters estimate the arterial oxygen saturation of the blood by measuring absorbances at two wavelengths of light. Because of this, the pulse oximeter is only able to account for Hb and HbO_2. Increased levels of COHb, for example, will cause an overestimation in S_aO_2 because the pulse oximeter cannot distinguish between HbO_2 and COHb. In cases of carbon-monoxide poisoning, this could have terrible consequences if the clinician is unaware. Buinevicius (1987) designed a three wavelength pulse oximeter to solve this problem. An additional LED at 810 nm was used in an attempt to determine the amount of COHb in the blood. Buinevicius also presented a method to calibrate the pulse oximeter for three wavelengths using three-dimensional solutions to Beer's law. Webster at 69-70:

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5.7 LED PACKAGING

Most LED packages are made of resin, offering superior mechanical strength and the ability to withstand vibration and shock. In some of today's pulse oximeter probes, the two LEDs can be found in one package, which has the distinct advantage of keeping costs down. In the Nellcor SCP–10 reusable and Oxisensor II D–25 disposable pulse oximeter probes, the two LEDs come encased in a transparent rectangular solid with approximate dimensions of 5 mm long by 4 mm wide by 2 mm thick. The LEDs themselves are flat squares with sides of approximately 0.25 mm.

Other probes have discrete LEDs inside, with the LEDs lying side by side and a mirror to reflect light at a 90° angle to the tissue. Some probes even have three or four LEDs in them to increase light output. The details of these and many other probes will be discussed in Chapter 7.

There is no wrong choice for LED packaging as long as the LEDs are small yet powerful enough to perform the task at hand. However, there is definitely a superior choice for packaging when trying to minimize costs, and that choice is almost always a package containing both LEDs.

Webster at 218-219:

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13.2.3 Dental pulp blood supply and viability

Pulse oximetry can also be used to diagnose dental pulp viability (Schmitt *et al* 1991). A tooth may be degenerating even though it appears normal to the naked eye or via x-ray images. Also, pulp inflammation can occasionally subside without intervention. Blood flow determines the viability of dental pulp and S_aO_2 determines the state of degeneration of a still viable tooth. Past techniques to determine dental pulp viability involved nerve stimulation. This was painful, often inaccurate, and gave no information about the state of degeneration. Nerves can sometimes function although blood flow is impaired.

To understand how monitoring oxygen saturation of dental pulp with pulse oximetry is accomplished, it is important to be familiar with the morphology of the tooth. The outer layers of the tooth consist of bone-like enamel and *dentin*. Collagen fibers connect the jaw bone to a layer of cementum at the base of the tooth, fixing the tooth in its socket. *Apical foramen*, small holes in the roots of the tooth, allow nerves and blood vessels to access the dental pulp. The blood provides oxygen, mineral salts, and nutrients to sustain the *odontoblasts* and neural tissues. Figure 13.2 shows that to measure the blood oxygen saturation, an adapted transmission probe in the shape of a U is applied over the tooth (Schmitt *et al* 1991). A black-foam insert conforms to the tooth and provides shielding from ambient light. It can be replaced and the probe reused on successive patients. The U-shaped probe is flat on top, providing a surface for the patient to bite down on to increase probe stability. The bone-like layers which surround the pulp create an optical shunt of sorts, allowing some light from the LEDs to be transmitted to the photodiode without passing through blood. Due to this extra variable, three wavelengths are needed to isolate the extinction coefficients of the blood. A wavelength in the range of 540 to 570 nm (green) is used because the extinction coefficients of enamel and dentin at this wavelength are similar to their extinction coefficients at 660 and 940 nm. Also, the extinction coefficients of oxygenated and deoxygenated blood at this wavelength greatly exceed their values at the red and IR wavelengths. The hardware of the pulse oximeter is similar to that of a two-wavelength pulse oximeter and the ratio of ratios computation of oxygen saturation is used. However, the denominator of each ratio is adjusted by subtracting off the detected DC value of the green wavelength (see equation (9.30)).

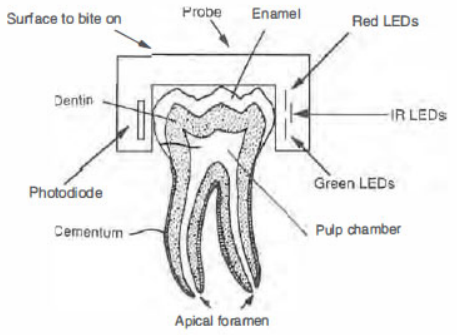


Figure 13.2 Morphology of the tooth and adapted pulse oximeter probe for determining the viability of dental pulp (adapted from Schmitt *et al* 1991).

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where the at least three LEDs configured to emit light of at least three different wavelengths, including as a non-limiting example four LEDs each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound: *See, e.g.*, Raley at Abstract ("A two piece probe having a universal probe end and an interconnect cable segment provides for the use of the universal probe end with a variety of different photoplethysmographic devices. The universal probe end includes a detector, a substrate for removably affixing the probe end to a patient, a window or aperture and a connector. The interconnect cable has a connector mated to the connector on the probe end for mechanical and electrical connection of the probe-end to the interconnect cable and the photoplethysmographic monitor. The connector end of the interconnect cable also houses a plurality of emitters which are directed through the window or aperture in the probe end in order to illuminate the patient. The interconnect cable also houses the resistors or other elements which identify the type of probe, monitor manufacturer or actual emitter wavelengths. Alternatively, the emitters may be housed in the main monitor and an optical fiber may be used to direct light to the patient. An electrical conductor transmits light received by the detector back to the photoplethysmographic monitor."). Fig. 1.

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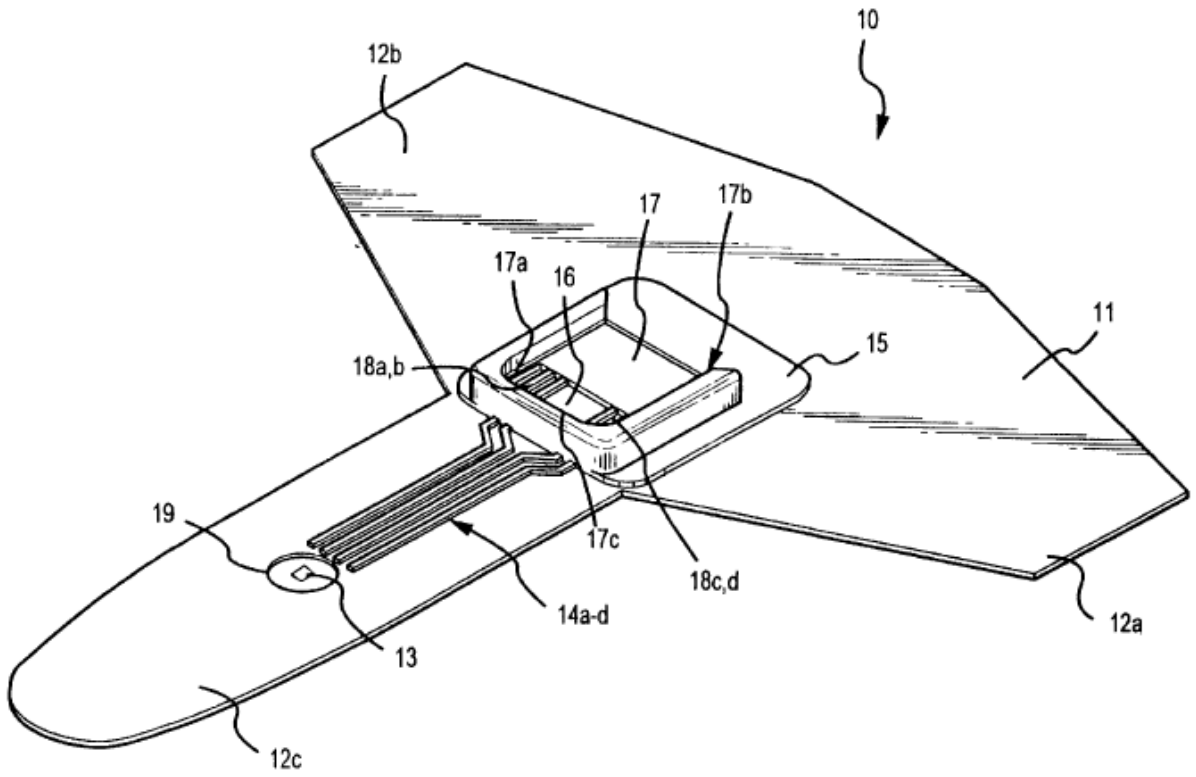


FIG.1

Fig. 3a.

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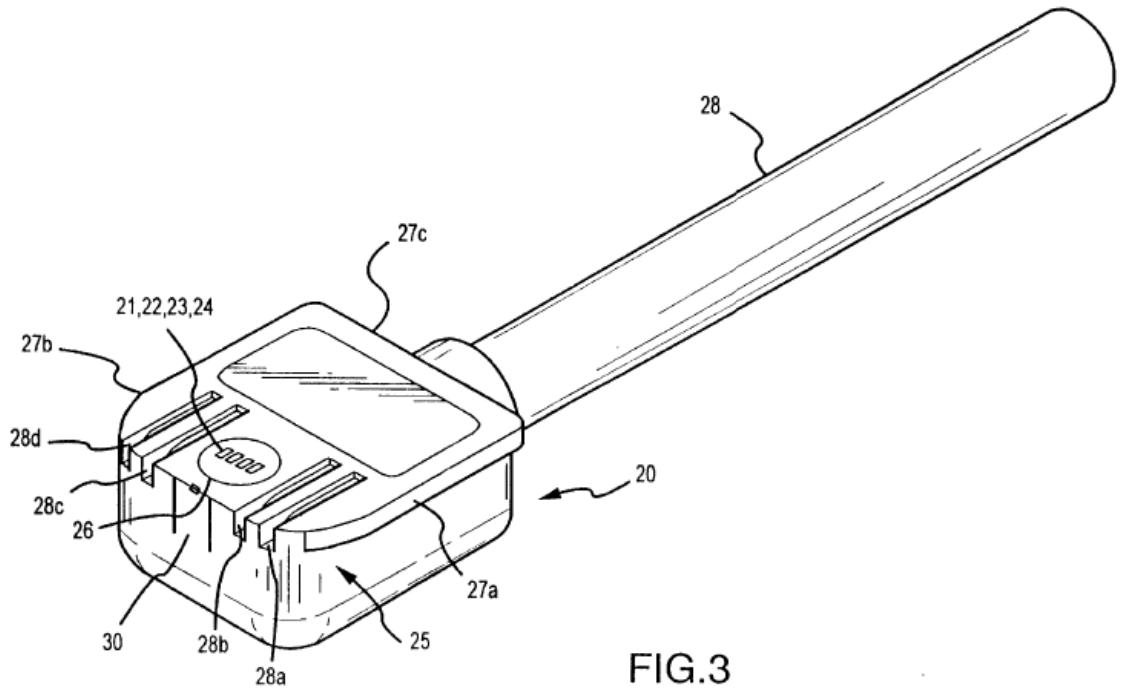


FIG.3

Fig. 3b.

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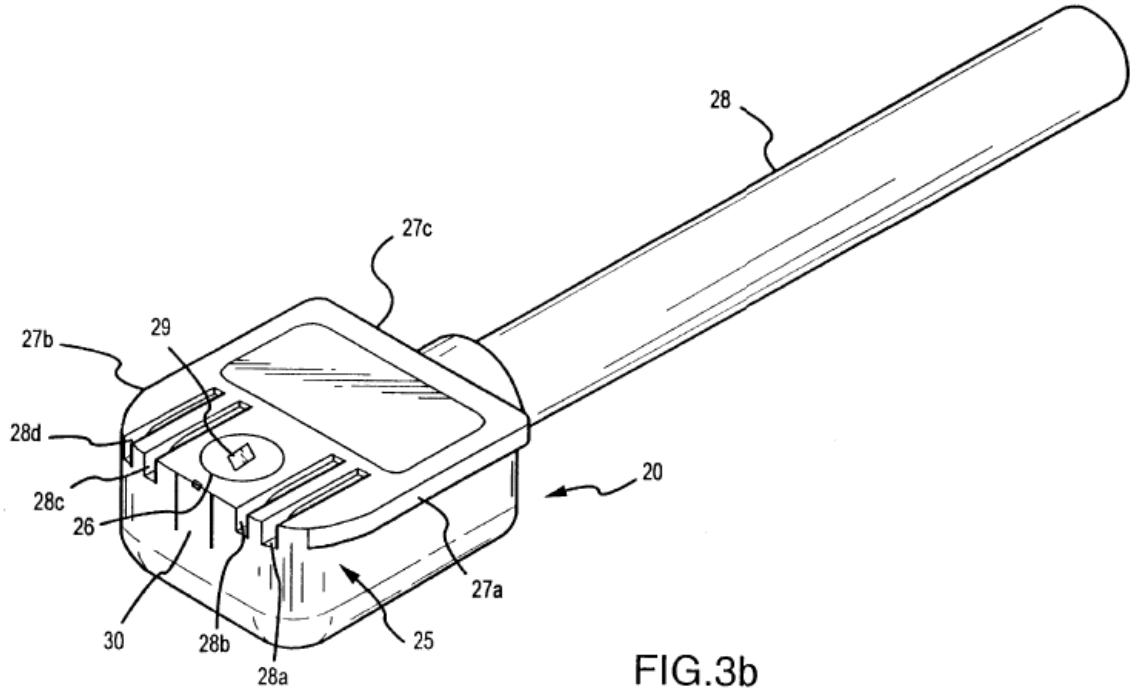


FIG.3b

Raley, 3:11-4:13 ("A pulse oximeter instrument operates by use of a probe that illuminates an appendage of the patient (such as a finger, earlobe, toe, neonatal appendages, or the nasal septum) that is rich in arterial blood and measures the differential absorption of the light by the pulsatile portion of the arterial blood flow to thereby determine oxygen saturation of the arterial blood. The pulse oximeter instrument makes use of a plurality of light-emitting devices, each of which transmits light at a predetermined wavelength, which wavelengths are selected such that at least one is highly absorbed by oxygenated hemoglobin in the arterial blood and at least one is highly absorbed by reduced hemoglobin in the arterial blood. The amount of absorption of the light beams generated by these light emitting devices that are located in the probe is a measure of the relative concentration of the various hemoglobin species contained in the arterial blood. The absorption of the light that illuminates the appendage of the patient includes a constant portion that is a result of skin, bone, steady-state (venous)

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	blood flow and light loss due to various other factors. The pulsatile component of absorption is due to the pulsatile arterial blood flow and is a small fraction of the received signal and is used by the pulse oximeter instrument to perform its measurements. It is also possible to measure additional analytes in the arterial blood, such as additional dyshemoglobins, with one additional wavelength of light for each component. The measurements are computed by sampling the output of the light detector located in the probe to determine the incremental change in absorption of the various wavelengths of light that are used to illuminate the appendage of the patient. These incremental changes in light absorption are then used to compute the oxygen saturation of the arterial blood as well as the patient's pulse rate. Since the pulsatile component of the signals received by the light detector represent only a small fraction of the incident light, it is important that the incident light be of significant magnitude to result in transmitted signals that have sufficient amplitude to provide accurate readings. In addition, the probe containing the light-emitting devices and the light detector must be placed in intimate contact with the skin of the patient to obtain the most accurate readings. Referring to FIGS. 1, 2, 3, 4, 5 and 6, the probe 40 of the present invention is designed for use with one of two basic photoplethysmographic monitor architectures depicted in FIGS. 5 and 6. FIG. 5 depicts one of the monitor architectures in which the monitor 100 communicates with probe 40 through socket 104 and mating interconnect cable plug 42. The configuration of plug 42 depends on the type and manufacturer of monitor 100. For example, if the monitor 100 is capable of measuring a plurality of blood analyte concentrations such as O2Hb, RHb, COHb and MetHB then plug 42 and interconnect 104 will contain sufficient electrical connectors 46 to interconnect probe interface 102 with a plurality of emitters 21, 22, 23 and 24 located in the connector-end 25 of interconnect cable segment 20. In a preferred embodiment, the plurality of emitters 21, 22, 23 and 24 each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ_1 λ_2 λ_3 and λ_4. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. In a photoplethysmographic instrument designed to generate four blood analyte levels, the preferred embodiment is to use at least four separate emitters each producing light with a distinct spectral content. If fewer blood analyte levels are desired then fewer emitters may be used either in the interconnect cable. For example, in a probe made according to the present invention for use with a standard pulse oximeter, only two emitters would be needed in the interconnect cable.”).

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	Raley, 4:47-6:12 (“An alternative method of implementing a photoplethysmographic monitor is depicted in FIG. 6 and operates in conjunction with the alternative probe embodiment in FIG. 3b. The emitters 21, 22, 23 and 24 (which may be LED's or laser diodes, but which are preferably laser diodes) are housed in the monitor 200. The emitters 21, 22, 23 and 24 are driven by emitter driver 230 which is controlled by the data processing circuit 107. The emitted light is then combined by an optical coupler 228 and transmitted to the probe 40 by internal optical fiber 260 which is coupled to an optical fiber or other such optically transmissive material (not shown) internal to interconnect cable segment 28. Thus, plug 42 and connector 204 now includes electrical conductors for connecting photodiode 13 back to the probe interface 102 and an optical connector for connecting optical fiber 260 to an optical fiber (not shown) located in cable 28. The light transmitted through the optical fiber 260 and transmitted through the optical fiber located in cable 28, reflects off mirror 29 of FIG. 3b in connector end 25 and passes through window or opening 26 and window 16 in probe-end 10 and impinges on the tissue of the patient. Transmitted light is received by photodetector 13 which send an electrical signal back to the probe interface 102 through the electrical conductors in cable 28 and electrical pathway 262 in monitor 200. The probe interface 102 converts the analog signal to a digital signal and transmits the signal to memory 106 and on to data processing circuit 107 for processing and display of blood analyte concentration values using graphic display 114 and numeric display 115 driven by display driver 109. The transmission of the emitted light can be controlled in a time division multiplexing manner and an optical coupler 228 can be used to provide a means for combining multiple emitters onto one strand of optical fiber 260. Alternatively, the plurality of emitters may be placed or abutted against optical fiber 260. The Probe Referring again to FIG. 4 the probe 40 consists of two releasable connected segments: the probe-end 10, separately depicted in FIG. 1 and interconnect cable segment 20, separately depicted in FIGS. 2, 3 and 3b. Universal probe-end 10 is designed to be disposable and to accommodate any type of interconnect cable segment 20, whether it contains LED's, laser diode, or an optical fiber/mirror for illuminating the tissue. Thus, the construction of probe-end 10 is simple and flexible consisting of a flexible substrate 11 having three portions 12a, 12b and 12c. Substrate portions 12a and 12b are designed to wrap around

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	an appendage of a patient. In FIG. 1 the substrate is designed to be wrapped around a finger. Substrate portions 12a and 12b have an adhesive layer applied to one or more surfaces to enable the portions to be removably attached to the finger. Substrate portions 12a and 12b may be configured differently for attachment of probe-end 10 to the feet of neonates, the smaller fingers of children, or to other appendages of adult, child or neonatal patients. Substrate portion 12c includes a photodetector 13 which is mounted in an optically transmissive window 19 in the substrate 11 and which is connected to connector 17 through flexible electrical circuits 14 a-d. Connector 17 has three lip portions 17a, 17b, and 17c which are designed to accommodate and hold the connector-end 25 of interconnect cable segment 20. Connector portion 15 provides a larger surface area for connector 17 to be either adhesively affixed to substrate 12 or, alternatively, to be retained between layers of substrate 12. Connector 17 also houses an optically transmissive window 16 and electrical contacts 18a, 18b, 18c, and 18d which connect flexible electrical circuits 14a,b,c and d with interconnect cable segment 20. Window 16 enables light to be passed from the emitters 21,22,23 and 24 or optical fiber and mirror 29 to the patient while protecting the patient from excess heat and also protecting the reusable interconnect cable segment 20. FIG. 2 depicts a top elevational view of the patient end of interconnect cable segment 20. Cable 28 consists of a bundle of one or more electrical conductors and, if the emitters are located in the monitor 200, an optical fiber. The electrical conductors and optical fiber are covered by a flexible insulating material to protect the internal components. Conductive grooves 28a, 28b, 28c and 28d provide for electrical interconnection of photodetector 13 through flexible conductors 14a, 14b, 14c and 14d and electrical contacts 18a, 18b, 18c and 18d. Ridge 27b is designed to fit under lip 17b to hold connector-end 25 onto probe-end 10. FIG. 3 depicts a bottom elevational view of one embodiment of the patient end of interconnect cable segment 20. The embodiments of FIG. 3 includes four emitters 21, 22, 23 and 24. Such an embodiment would be useful in a photoplethysmographic monitor for measuring three or four blood analytes such as oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin. Alternatively, the number of emitters could be two in a probe for use with standard pulse oximeters which typically use two emitters having spectral contents characterized by distinct center wavelengths, often 660 nm and

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	940 nm. Ridges 27a, 27b and 27c fit under lip portions 17a, 17b and 17c to hold connector-end 25 onto probe end 10. The end of latch 30 is designed to click into a hole near the base of lip portion 17c so that upon engagement of the connector-end 25 into connector 17 a releasable latching occurs. In order to disengage the latching mechanism latch 30 is simply depressed."). Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths. For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Nogawa at Abstract:

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	A new reflectance pulse oximeter sensor for lower arterial oxygen saturation (SaO_2) measurement has been designed and evaluated in animals prior to clinical trials. The new sensor incorporates ten light emitting diode chips for each wavelength of 730 and 880 nm mounted symmetrically and at the radial separation distance of 7 mm around a photodiode chip. The separation distance of 7 mm was chosen to maximize the ratio of the pulsatile to the average plethysmographic signal level at each wavelength. The 730 and 880 wavelength combination was determined to obtain a linear relationship between the reflectance ratio of the 730 and 880 nm wavelengths and SaO_2. In addition to these features of the sensor, the Fast Fourier Transform method was employed to compute the pulsatile and average signal level at each wavelength. The performance of the new reflectance pulse oximeter sensor was evaluated in dogs (N=5) in comparison to the 665/910 nm sensor. As predicted by the theoretical simulation based on a 3-dimensional photon diffusion theory, the 730/880 nm sensor demonstrated an excellent linearity over the SaO_2 range from 100 to 30%. For the SaO_2 range between 100 and 70%, the 665/910 and 730/880 sensors showed the standard error of around 3.5% and 2.1%, respectively, in comparison to the blood samples. For the range between 70 and 30%, the standard error of the 730/880 nm sensor was only 2.7%, while that of the 665/910 nm sensor was 9.5%. The 730/880 sensor showed improved accuracy for a wide range of SaO_2, particularly over the range between 70 and 30%. This new reflectance sensor can provide noninvasive measurement of SaO_2 accurately over the wide saturation range from 100 to 30%. *See, e.g.*, Nogawa at 80:

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The reflectance pulse oximeter, as reported by Mendelson et al, was the first monitor to measure SaO_2 from the finger-tip [7]. Although several reflectance pulse oximeters have been reported since then, they have not acquired the clinical acceptability yet [8,9]. The effectiveness of the reflectance pulse oximeters has been hindered by a poor signal to noise ratio and small pulsatile signals, particularly at the red wavelength. These weak signals preclude continuous measurement at the forehead or cheek. Mendelson et al used multiple photodiodes around the light emitting diode to increase the signal level. In 1992, Takatani et al [10] reported a multiple-light source hybrid reflection pulse oximeter sensor that incorporated a near-infrared heater to warm the skin and to increase the pulsatile signal level. The sensor was evaluated in animals and humans to show acceptable performance. However, the incorporation of the heater complicated the system and possible skin burn prevented long term continuous usage.

In this study, improvements in sensor design and signal processing method were proposed based on the theoretical simulation using a 3-dimensional photon diffusion theory to improve the performance of the reflectance pulse oximeter for lower SaO_2 measurement, possibly down to 40%, as well as wider clinical application without requiring vaso-dilating method. They are:

1) To improve the overall accuracy of the reflectance pulse oximeter, a new wavelength pair of 730/880 nm will be used, instead of the 660/910 nm pair. This combination can improve the overall linearity, with particular interest in its application to low SaO_2 measurement such as in fetal monitoring.

2) To increase the pulsatile signal level as well as to minimize tissue inhomogeneity, hence the variability among the subjects, ten light-emitting diode (LED) chips for each wavelength will be mounted around a photodiode (PD) chip at an equal radial distance of 7mm. The radial distance of 7 mm was decided through theoretical and experimental studies.

3) Furthermore, to improve the signal processing method, a Fast Fourier Transform (FFT) method will be used to compute the pulsatile (AC) and average (DC) components of the reflectance optical pulse signals at each wavelength. The DC and fundamental component of the Fourier transformed reflectance optical signal will correspond to the DC and AC component of the conventional method.

See, e.g., Nogawa at 83:

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The Hybrid Reflectance Optical Pulse Oximeter Sensor

The schematic diagram of the hybrid reflectance pulse oximeter sensor is shown in Fig. 4. A photodiode (PD) chip is located at the center and is surrounded by an optical barrier that blocks direct coupling between the light emitting diode (LED) and PD. Ten LED chips for each wavelength of 730 and 880 nm are placed symmetrically and at an equal radial distance of 7 mm around the PD to enhance pulsatile signal level and minimize the tissue inhomogeneity, hence the variability among the subjects. The diameter of the sensor is 23.0 mm with the thickness being 6.7 mm. Its weight is 7.2 gm. A four layered ceramic circuitry design allowed to accommodate twenty LED chips and a PD chip on a single substrate, resulting as a compact hybrid sensor design. After layout of LED and PD chips and wire bonding, the hybrid circuit was placed in a header and its surface was covered with an optical clear epoxy. After the epoxy cured, its surface was polished.

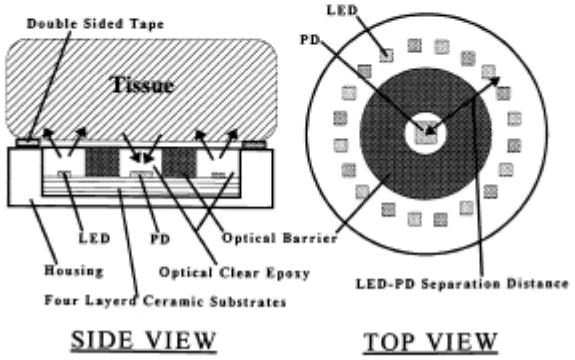


Fig. 4. A schematic drawing of the newly developed reflectance pulse oximeter sensor.

See, e.g., Nogawa at 85-86:

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DISCUSSION

In this study, a new hybrid reflectance pulse oximeter sensor has been evaluated in animals. The new sensor demonstrated significantly improved accuracy over a wide range of SaO_2, particularly at lower SaO_2 between 70 and 30%. The contributing factors for this improved performance are 1) sensor geometry, 2) wavelength selection, and 3) signal processing method [12].

Concerning the sensor geometry, the separation distance between the light source and detector was optimized to yield the largest AC/DC ratio. Although the theoretical study revealed that the AC/DC ratio increases with the radial separation distance, the reduction in the absolute signal level led us to choose the separation distance of 7 mm. For this separation distance, in order to enhance the signal level and average out the inhomogeneous effect of tissue, ten LED chips for each wavelength were placed symmetrically and at the equal radial distance around a photodiode chip. The changes in the reflectance signal that is specific to inhomogeneous effect and movement artifacts can be minimized to reduce abrupt changes in the signal level. This sensor geometry helped to minimize differences among individuals. To incorporate this layout into a final sensor design, a special

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hybrid circuit consisting of four layers of ceramic substrates were designed and fabricated. A total of twenty LED chips, one PD chip and an optical barrier were all together mounted on this header with its top covered with a clear epoxy, allowing a compact hybrid optical reflectance sensor.

As for wavelength selection, the 730/880 nm pair was used instead of the conventional 665/910 combination. The relationship between the R values computed using Equation (3) and SaO_2 was linear over a wide range of SaO_2; theoretical prediction based on the photon diffusion theory agreed well with the experimental results. Since the optical absorption due to deoxygenated hemoglobin at 730 nm is less than a half of that at 665 nm (Fig. 1), nonlinear relationship between the optical reflectance and the SaO_2 value was minimized at a wide range saturation. Moreover, since the optical penetration depth into tissue at 730 nm is deeper than that at 665 nm, and closer to that at 880 nm, measured reflectance signals at 730 and 880 nm wavelengths contain information come from similar depth inside the tissue.

In addition to the sensor geometry and wavelength selection, the new signal processing method utilizes the Fast Fourier Transformation of the reflectance pulse signal to derive AC and DC components. Approximately 10 second data was analyzed to compute the DC and fundamental spectral density from which the R value was derived. This method resulted in minimization of the errors involved with the detection of each pulse amplitude.

In conclusion, the new reflectance pulse oximeter sensor in combination with the new signal processing method demonstrated improved performance in noninvasive measurement of SaO_2 over its wide range. The new reflectance pulse oximeter sensor can broaden the clinical application of the reflectance pulse oximetry in caring patients in the operating room, ICU and fetuses during delivery. Currently, clinical evaluation of the sensor is under progress.

Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths.

For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments such as one including four emitters relying on different wavelengths, where relying on any number of additional wavelengths beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy:

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	See, e.g., Jarman at Abstract ("An improved method and apparatus for the photoplethysmographic monitoring of blood analyte parameters, specifically oxyhemoglobin, deoxyhemoglobin (reduced hemoglobin), carboxyhemoglobin and, in addition, in a four emitter apparatus, methemoglobin, uses a plurality of beams of light having different spectral contents to trans-illuminate the tissue of a patient. The apparatus and method require the application of an emitter set comprised of four emitters. The emitters may be LED's or laser diodes. In the three analyte system the center wavelength of the emitters must fall within three specific bands. In the four emitter system (capable of measuring methemoglobin) the center wavelength of the emitters in the emitter set must fall within four predetermined bands and the emitters having the two lowest center wavelengths must be at least 5 nanometers apart. The apparatus can use emitters which are located either in a probe, or, preferably, in the monitor, as well as a photodiode which can either be located in the patient probe or in the monitor."). Fig. 3

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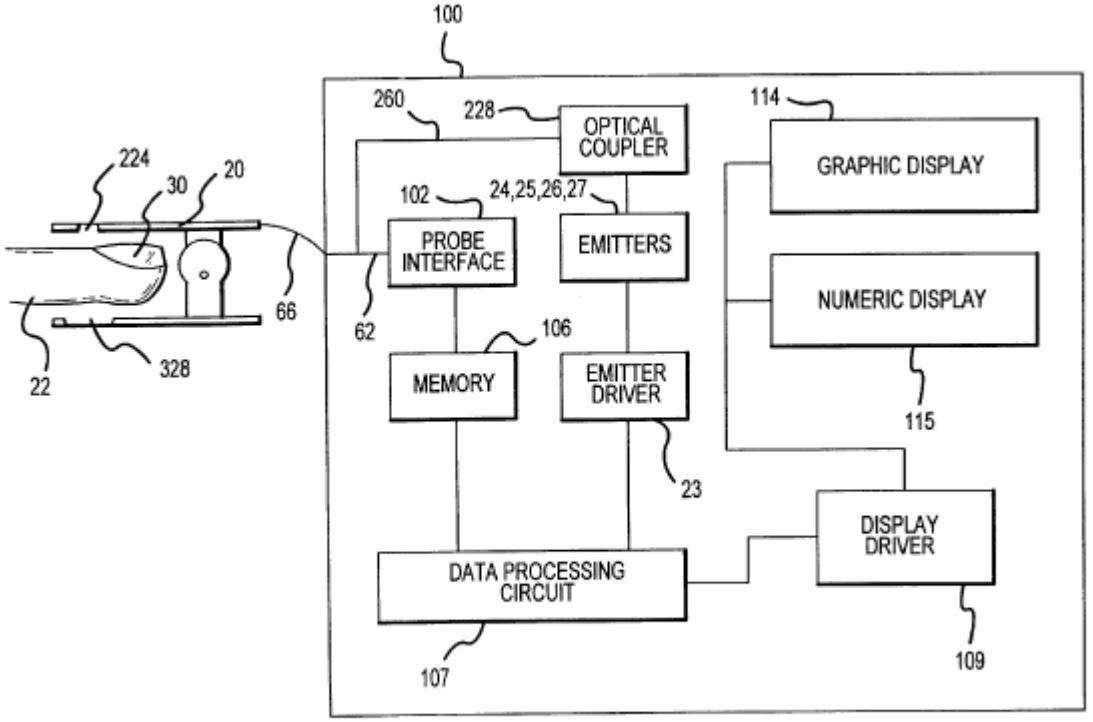


FIG.3

Jarman, 1:9-45 ("The present invention generally concerns the monitoring of a patient's tissue using a photoplethysmographic device to generate information related to the concentration of oxyhemoglobin (O2Hb), deoxyhemoglobin or reduced hemoglobin (RHb), carboxyhemoglobin (COHb) and, additionally, methemoglobin (MetHb) in the patient's blood. More specifically, the application relates to a device for the measurement of such blood analytes using a set of emitters having optimal spectral contents defined by a set of specific wavelength ranges.

During emergency evaluation, surgery and other medical procedures, clinicians often want to know the oxygen concentration of the blood, as well as other factors. In pulse oximetry the relative

	concentration of oxyhemoglobin and deoxyhemoglobin is displayed as a percentage of total hemoglobin in order to provide data on the oxygenation of the patient's blood. Blood oxygenation can be adversely affected by the generation of additional hemoglobin species, called dyshemoglobins. Most notably, carboxyhemoglobin is generated when carbon monoxide molecules bind to the hemoglobin in blood. An accurate measurement of carboxyhemoglobin concentration in the patient's blood may be needed when the patient is a smoker or if carbon monoxide poisoning is suspected. Additionally, elevated methemoglobin levels in the blood can be caused by various medications, illegal drugs and certain pathological conditions such as sickle cell anemia. Therefore measurement of the methemoglobin concentration is also useful during patient evaluation. Pulse-oximeters have been commercially available for measuring the oxygen saturation, or percent oxyhemoglobin, in arterial blood. These instruments rely on time-varying absorption of light by tissue supplied with pulsating arterial blood with a technique known generally as photoplethysmography. Conventional pulse oximeter instruments transmit light having spectral contents defined by two different center wavelengths through tissue."). Jarman, 1:63-2:10 ("The most obvious limitation of pulse oximetry derives from the fact that it is only a two channel (two wavelength bands) system and therefore can only solve for two components in the blood. Pulse oximetry makes the assumption that only oxyhemoglobin and reduced hemoglobin are present in the arterial blood. Any additional chromophores that are present in arterial blood and which absorb light in the wavelength bands used by the instrument will lead to erroneous readings. Two such chromophores are carboxyhemoglobin and methemoglobin. In particular, if carboxyhemoglobin or methemoglobin is present in above normal levels, a conventional pulse oximeter will give falsely high readings for the arterial oxygen saturation. This is one of the most serious and potentially dangerous limitations of current pulse oximetry."). Jarman, 2:45-3:42 ("This application discloses a photoplethysmographic apparatus and method for the accurate continuous, real-time, noninvasive measurement of a plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and, in additional embodiments, methemoglobin levels in blood. The apparatus uses three emitters for measuring oxyhemoglobin, deoxyhemoglobin and carboxyhemoglobin or four emitters for measuring methemoglobin in addition to the former three analytes. Each of the emitters has a spectral content characterized by a wavelength

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	that falls within a wavelength range which has been determined to be the optimal wavelength range for measuring the set of three or four blood analytes. The method of the invention is the optimization of the specific centerwavelengths necessary for accurate measurement of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and additionally methemoglobin. A photoplethysmographic method according to the present invention comprises the step of generating at least three monochromatic or essentially monochromatic beams of light having at least distinct first, second and third spectral contents denoted by center wavelengths λ1, λ2 and λ3. The terms "monochromatic beams of light" or "essentially monochromatic beams of light" are used to refer to light generated by emitters such as a laser diode or other relatively narrow band source, or light of narrow spectral bandwith, isolated by the use of gratings or interference filters, originating from a broadband source such as a tungsten lamp. A fourth emitter having a spectral content characterized by center wavelength λ4 is used in systems where methemoglobin levels are desired. The light from the emitters is then directed into a portion of the tissue of the patient in order to pass light through the tissue portion along an optical path. The method of the invention further comprises the use of means for detecting the received light transmitted from the tissue such as a photodiode or other appropriate detector. I.sub.λ1, I.sub.λ2 and I.sub.λ3 (and I.sub.λ4 in the four emitter apparatus) are the measurements of the light received from tissue after absorption and modulation by the various absorbers in the tissue and arterial blood under test. From the received light measurements, I.sub.λ1, I.sub.λ2, and I.sub.λ3 (and I.sub.λ4 in the four emitter case), the differential absorptions (dA's) of the transmitted light by various absorbers in the blood are calculated. These differential absorptions (dA's) are then used in the estimation of the blood analyte levels according to known techniques described or referenced herein. In the present invention, the emitters are chosen so that the spectral contents (denoted by center wavelengths λ1, λ2 and λ3 for the three emitter apparatus and λ1, λ2 λ3 and λ4 for the four emitter apparatus) are optimized for the detection of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and, additionally, in the four emitter case, methemoglobin. The center wavelength for the first, second and third emitters in the three emitter apparatus should be in the range of

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	approximately 610-640 nm, 680-770 nm and 850-1000 nm. The center wavelength for the fourth emitter, in the four emitter apparatus should be in the range of 635-650 nm with the additional constraint that the center wavelength of the first emitter must be at least 5 nm less than the center wavelength of the fourth emitter."). Jarman, 3:51-4:36 ("FIG. 3 is a diagram showing an additional embodiment of the claimed invention. FIG. 4 is a graph of the extinction curves of oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin and methemoglobin in terms of millimolar extinction, on a logarithmic scale, versus wavelength in nanometers. DETAILED DESCRIPTION OF THE INVENTION The photoplethysmographic monitor of the present invention measures the concentration of oxyhemoglobin (O2Hb), deoxyhemoglobin or reduced hemoglobin (RHb), carboxyhemoglobin (COHb) and, if four emitter are used, methemoglobin (MetHb) in a patient's blood. This is accomplished through the use of at least three emitters (or a filtered broadband emitter) emitting beams of light having a spectral content characterized by center wavelengths, λ1 λ2, and λ3 (and λ4 in the four emitter case). The spectral content of the light emitted by the three or four emitters (or filtered broadband emitter) must be distinct and it is preferable that the center wavelengths for each of the emitters also be distinct so that λ1 ≠λ2 ≠λ3 ≠λ4. FIG. 1 depicts an apparatus having four emitters made according to the present invention. The three emitter apparatus would be essentially identical except for the lack of one emitter and corresponding channel. Probe 20 is placed on the tissue under test 22 so that a plurality of emitters 24, 25, 26, 27 transmit light through the tissue which is then received by one or more photodetectors 28. Emitters 24, 25, 26, 27 (or a filtered broadband light source) each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ1 λ2, λ3 and λ4. In the case of a finger probe, the emitters are arranged to emit the light at or near the base of the fingernail 30. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. However, the preferred embodiment is to use at least four separate emitters preferably laser diodes each producing light with a distinct spectral content. It should be understood that four emitters could be used to measure three blood

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	analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin. Additionally, a number of emitters greater than the number of blood analytes being measured may be used in a photoplethysmographic system in order to create an overdetermined system. Through cable 60, an electrical signal indicative of the light emitted by emitters 24, 25, 26 and 27, transmitted through finger 22 and received by photodetector 28 is transmitted back to monitor 100. The internal components of monitor 100 are described in detail below."). Jarman, 4:7-36 ("FIG. 1 depicts an apparatus having four emitters made according to the present invention. The three emitter apparatus would be essentially identical except for the lack of one emitter and corresponding channel. Probe 20 is placed on the tissue under test 22 so that a plurality of emitters 24, 25, 26, 27 transmit light through the tissue which is then received by one or more photodetectors 28. Emitters 24, 25, 26, 27 (or a filtered broadband light source) each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ1 λ2, λ3 and λ4. In the case of a finger probe, the emitters are arranged to emit the light at or near the base of the fingernail 30. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. However, the preferred embodiment is to use at least four separate emitters preferably laser diodes each producing light with a distinct spectral content. It should be understood that four emitters could be used to measure three blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin. Additionally, a number of emitters greater than the number of blood analytes being measured may be used in a photoplethysmographic system in order to create an overdetermined system. Through cable 60, an electrical signal indicative of the light emitted by emitters 24, 25, 26 and 27, transmitted through finger 22 and received by photodetector 28 is transmitted back to monitor 100. The internal components of monitor 100 are described in detail below."). Jarman, 5:37-46 ("Where C is the concentration of the specific absorber, E is the extinction for that absorber at wavelength λ and ΔL is the differential change in effective path length the transmitted light has traveled. (Superscripts O, R, CO, and Met refer to O2Hb, RHb, COHb, and MetHb respectively.) Thus, after measuring the received light intensities and knowing the extinction coefficient E for each wavelength it is possible to determine the concentrations of the specific absorbers. In the three emitter system the same calculations are made according to the following equation:").

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	Jarman, 6:9-18 ("where xHb refers to one of O2 Hb, RHb, COHb, or MetHb, the constants a1, a2, a3, a4, b1, b2, b3, and b4 are calibration coefficients determined previously in a calibration experiment, and N21, N31, and N41 are normalized dAs for channels 2 and 1, 3 and 1, and 4 and 1, respectively. As one skilled in the art will understand, however, the calibration equation for each analyte is not limited to this form of equation, and may be, for example, a polynomial. In the three emitter system the calibration equation is given by:"). Jarman, 8:26-35 ("Thus, using emitter sets comprising four emitters having spectral contents characterized by a center wavelength within the four wavelength ranges (610-640 nm, 635-650 nm, 680-770 nm and 850-1000 nm) and subject to the one difference constraint, i.e., that the two lowest center wavelengths be 5 nanometers apart, provides an improved photoplethysmographic system for the measurement of oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin and methemoglobin."). Under at least the apparent construction based on Masimo's Infringement Contentions, Aoyagi discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths. For example, Aoyagi discloses and/or suggests a patient monitor relying on an optical sensor, where additional LEDs at additional wavelengths, such as six LEDs in one embodiment, are used to measure levels of additional unknowns (such as compounds) in blood, where the more number of wavelengths the more number of unknowns that can be measured: *See, e.g.*, Aoyagi at Abstract ("Light of various wavelengths emitted from light sources and transmitted through vital tissues is converted by light sensors and current/voltage transducers, into electric signals. The signals are converted into digital values by an A/D converter. The light source emits light of a wavelength which can be optically absorbed by water. A computer obtains a ratio of variations of the digital values for each wavelength, and calculates the values of tissue terms and the hemoglobin concentration on the basis of the ratios. In the calculation, since tissue terms of the wavelengths have mutual constant relationships, an equation which is prepared so that there exists only one unknown in the tissue terms is used.").

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Fig. 2.

FIG. 2

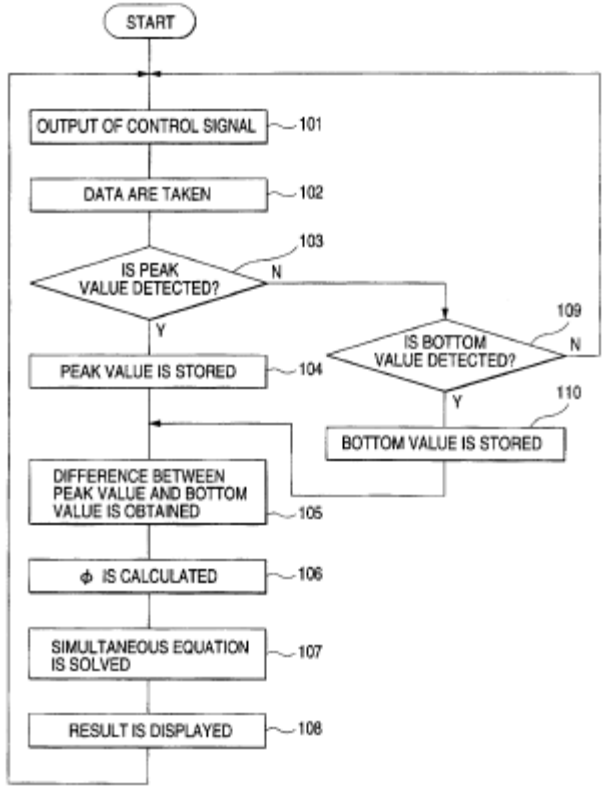
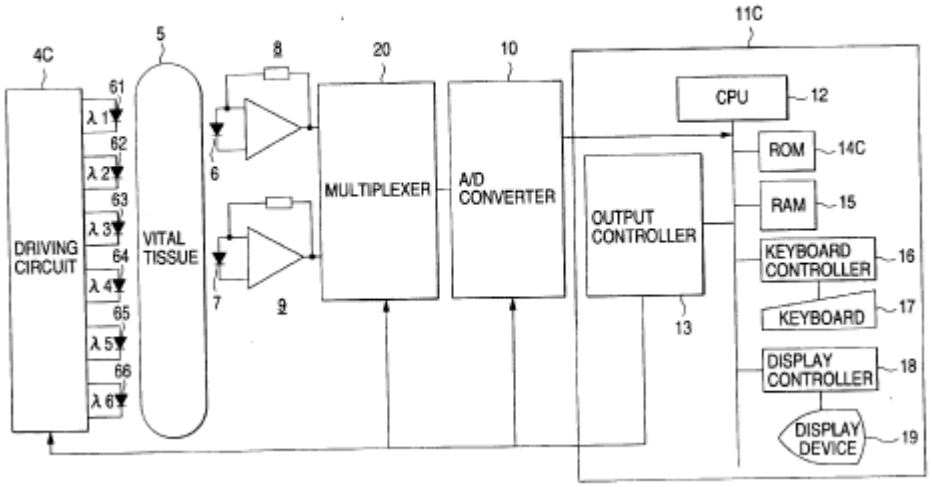


Fig. 5.

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FIG. 5



Aoyagi, 3:26-39 ("First, the principle common to all embodiments will be described. In the embodiments, the pulse method is used. In the pulse method, the phenomenon in which the effective thickness of the blood is caused to pulsate by blood pulsation in the vital tissues is used, and the optical absorptive characteristics of the blood in the tissues are measured while irradiating the vital tissues with light. Since the kinds of hemoglobin have different optical absorptive characteristics, the total hemoglobin can be obtained by obtaining respective hemoglobin concentrations in the blood and then calculating the total sum of the concentrations. Therefore, the number of light wavelengths required for the measurement depends on that of kinds of hemoglobin contained in the blood.").

Aoyagi, 4:16-25 ("IG. 6 shows optical absorptive characteristics of various kinds of hemoglobin, and FIG. 7 shows optical absorption of water with respect to that of oxyhemoglobin in the case where the hemoglobin concentration is 14 [g/dL].

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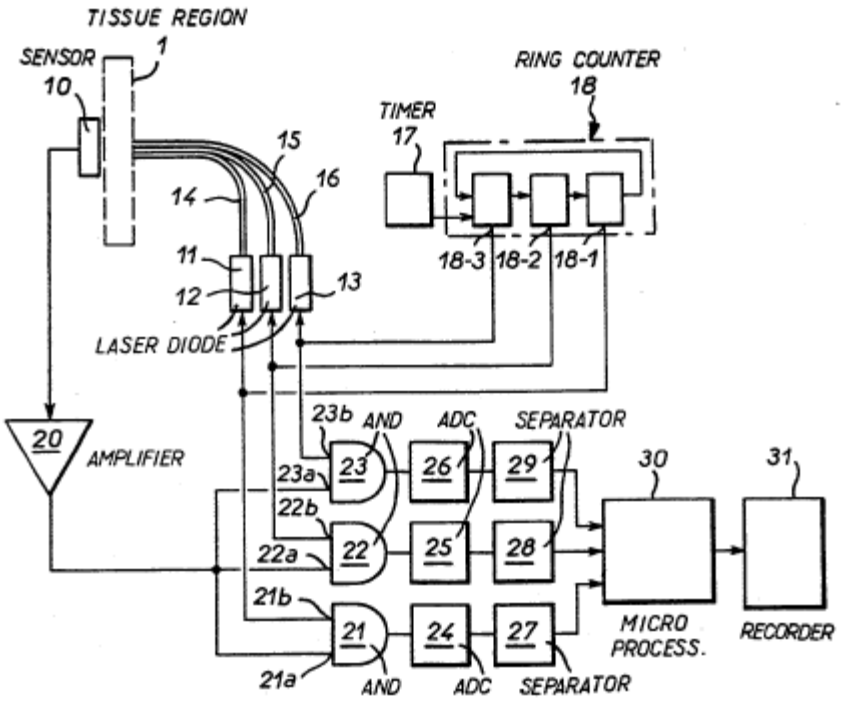
	The principle of a first embodiment will be described. The embodiment is directed to an apparatus which is to be used in the case where only oxyhemoglobin and reduced hemoglobin exist as hemoglobin in the blood. In this case, four light wavelengths are used and the following simultaneous equations with three unknowns are employed:"). Aoyagi, 6:21-28 ("This is set as a first embodiment (B). Next, the principle of a second embodiment will be described. The embodiment is directed to an apparatus which is to be used in the case where oxyhemoglobin, reduced hemoglobin, and carboxyhemoglobin exist as hemoglobin in the blood. In this case, five light wavelengths are used and the following simultaneous equations with four unknowns are employed."). Aoyagi, 7:28-40 ("By substituting equations (10) to (12), (18), and (19) into equations (14) to (17), simultaneous equations with four unknowns So, Sc, EX2, and Hb are obtained. When the simultaneous equations are solved, the values of So, Sc, Ex2, and Hb can be obtained. Next, a third embodiment will be described. When there exists methemoglobin in place of carboxyhemoglobin in the second embodiment, equations corresponding to equations (14) to (17) are as follows:"). Aoyagi, 8:18-25 ("By substituting equations (10) to (12), (18), (25), and (26) into equations (20) to (24), simultaneous equations with five unknowns So, Sc, Sm, Ex2, and Hb are obtained. When the simultaneous equations are solved, the values of So, Sc, Sm, Ex2, and Hb can be obtained. FIG. 6 shows optical absorptive characteristics of various kinds of hemoglobin. For example, light wavelengths used in the embodiments are as follows:"). Aoyagi, 8:47-51 ("In the fourth embodiment which measures four kinds of hemoglobin (O2 Hb, RHb, COHb, and MetHb) and six wavelengths are used Used wavelengths: λ1 =660 nm, λ2 =700 nm, λ3 =850 nm, λ4 =805 nm, λ5 =890 nm, and λ6 =1,250 nm").

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	Aoyagi, 12:57-13:12 ("Next, a specific apparatus of the fourth embodiment will be described. FIG. 5 shows the whole configuration of the apparatus. The components which are identical with those of the apparatus of the first embodiment (A) are designated by the same reference numerals and their description is omitted. In the embodiment, the apparatus comprises six light sources 61 to 66. The light sources 61 to 66 emit light of wavelengths of λ1 =660 nm, λ2 =700 nm, λ3 =850 nm, λ4 =805 nm, λ5 =890 nm, and λ6 =1,250 nm, respectively. The wavelengths have features described above. A driving circuit 4C drives the six light sources 61 to 66. Light sensors 6 and 7 are placed so as to oppose the light sources 61 to 66, and converts light which is transmitted through the vital tissues 5 interposed between the light sources and the sensor, into an electric signal. A computer 11C conducts processing based on data supplied from the A/D converter 10 and outputs a control signal for controlling the operation timing to the driving circuit 4C and the multiplexer 20. A ROM 14C of the computer 11C stores a program which is slightly different from that stored in the ROM 14 of the computer 11 of the first embodiment (A) shown in FIG. 1. The other components of the computer 11C are the same as those of the computer 11A.").
	Under at least the apparent construction based on Masimo's Infringement Contentions, Barthelemy discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths.
	For example, Barthelemy discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs that emit light at more than two wavelengths, where relying on additional wavelengths allows for the measurement of the concentration of multiple compounds in the blood:
	See, e.g., Barthelemy, Abstract ("The apparatus comprises three laser diodes emitting at 660, 750 and 940 nm respectively, excited cyclically at the rate of a timer. The light emitted is channelled by three optical fibers to traverse a fully-vascularized tissue region of a subject along three virtually merged optical paths, and to terminate at an opto-electronic sensor, which generates overlapping signals representative of the molecular absorption. The pulsation of the arterial blood in the region induces variable components which are exclusively a function of the molecular absorptions due to oxyhemoglobin, deoxyhemoglobin and carboxyhemoglobin. The signals are switched by gates on three channels where the variable components are picked up and digitized, and then processed in a microprocessor to yield the oxygen saturation SaO_2 and the carbon monoxide fixation of the hemoglobin.").

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Fig. 1.



Barthelemy, 3:47-4:35 ("To achieve this, the invention proposes a method for determining the oxygen saturation rate of the arterial blood of a subject, in which the concentration of oxyhemoglobin or HbO2 is compared with the total concentration of hemoglobin, comprising the steps of providing first, second and third light sources emitting in respective wavelength bands including a near infrared wavelength band, a deep red wavelength band and a wavelength band therebetween, selectively directing light emitted from the respective light sources through an appropriate tissue region of the subject, acquiring representative signals of optical absorption through the tissue region, cyclicly exciting the light sources in succession and determining the frequency of the cyclic succession so as to

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	be large as compared with the arterial pulsation frequency of the subject, and calculating concentrations of HbO2, Hb and HbCO to determine the oxygen saturation rate. According to another aspect of the invention, there is provided a method for determining the oxygen saturation rate of the arterial blood of a subject, by comparison of the concentration of oxyhemoglobin, or HbO2, with the concentration of total hemoglobin, including providing two light sources each emitting in a different wavelength band, one in the near infrared and the second in the deep red, directing light emitted by the light sources along two paths through an appropriate tissue region of the subject, providing an opto-electronic sensor for acquiring representative signals of the optical absorption of the light, the representative signals comprising a variable component corresponding to the absorption by the pulsatile arterial blood, and a continuous component corresponding to absorption by the other tissues traversed, separating the variable component of each representative signal, calculating the respective concentrations of HbO2 and deoxyhemoglobin, and optionally Hb, from the variable components, determining the oxygen saturation rate, wherein the improvement comprises the steps of providing a third light source emitting a third wavelength band between the aforesaid two bands and a corresponding third optical path associated with said third light source, exciting the three light sources in cyclic succession, selecting the cyclic succession frequency so as to be large in comparison with the arterial pulsation frequency of the subject, whereby the representative signals overlap, and each representative signal is switched at the cyclic succession rate to a respective separate channel, and calculating HbO2, Hb and HbCO to determine the oxygen saturation rate therefrom. It goes without saying that the optical paths, as usual, will be taken on relatively small thicknesses of fully-vascularized tissues, such as the ear, or on the fingers. Operation with three wavelengths, λ1, λ2 and λ3, yields a system of linear equations with three unknowns:”). Barthelemy, 5:1-64 (“Preferentially, the wavelength bands are centered on 940, 660 and 750 nm respectively. By adopting an intermediate wavelength for the third optical path, a satisfactory separating power is obtained, thanks to the differences between the specific absorptions for the three hemoglobin species, and no absorption discontinuities are introduced for the non-blood tissues.

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	Preferably, the processing of the representative absorption signals, including the extraction of the variable components and the subsequent calculations, are carried out in a microprocessor under the control of a suitable software. From another standpoint, the invention proposes an apparatus for determining the oxygen saturation rate of the arterial blood of a subject, in which the concentration of oxyhemoglobin or HbO2 is compared with the total concentration of hemoglobin, comprising first, second and third light sources emitting in respective wavelength bands including a near infrared wavelength band, a deep red wavelength band and a wavelength band therebetween, the respective light sources being directed at an appropriate tissue region of the subject, an opto-electronic sensing means acquiring representative signals of optical absorption through the tissue region, means for cyclicly exciting the light sources in succession, the frequency of the cyclic succession being large as compared with the arterial pulsation frequency of the subject, and means for calculating HbO2, Hb and HbCO to determine the oxygen saturation rate. According to another aspect of the invention, there is provided an apparatus for determining the oxygen saturation rate of the arterial blood of a subject, comprising light sources emitting in respective wavelength bands, one of the wavelength bands being near infrared and another of the wavelength bands being deep red, opto-electronic sensing means for emitting respective signals responsive to optical absorption along respective optical paths through an appropriate tissue region of the subject, said signals including a variable component corresponding to absorptions by pulsatile arterial blood and a continuous component corresponding to absorption through other tissues traversed, means for separating the variable component of the respective absorption signals, calculating means for processing the variable components and determining the respective concentrations of oxyhemoglobin or HbO2 and deoxyhemoglobin, or Hb, and also determining the oxygen saturation rate, further comprising a third light source emitting a wavelength band intermediate the first two wavelength bands, a third optical path between the third light source and the tissue region, the three optical paths terminating in said optoelectronic sensing means, means for exciting the three light sources in cyclic succession at a cyclic succession frequency which is large in comparison with pulse frequency of the subject whereby the representative of signals overlap, means for switching each of the representative signals to a respective channel at the frequency cyclic succession, said last switching means comprising means for separating the variable component of the representative signal, said calculating means jointly

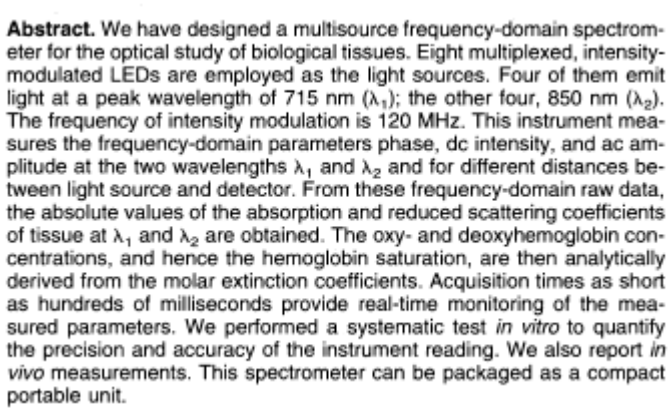
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processing the three variable components to identify HbO2, Hb and HbCO and determining the oxygen saturation rate therefrom.").

Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths.

For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased:

See, e.g., Fantini at Abstract:



Abstract. We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit.

See, e.g., Fantini at 33:

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	In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition. In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument. *See, e.g.*, Fantini at 34:	

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		Feature 2. The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. *Feature 3.* To implement the measurement of the slopes of the straight lines (as a function of the distance r between	

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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of

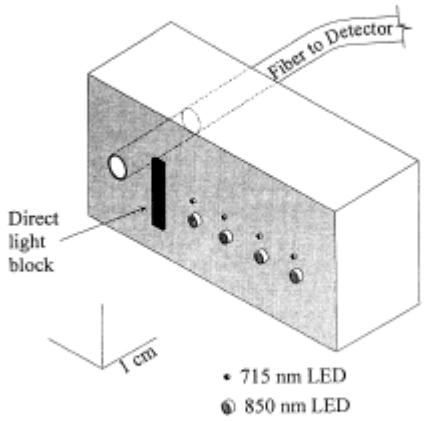
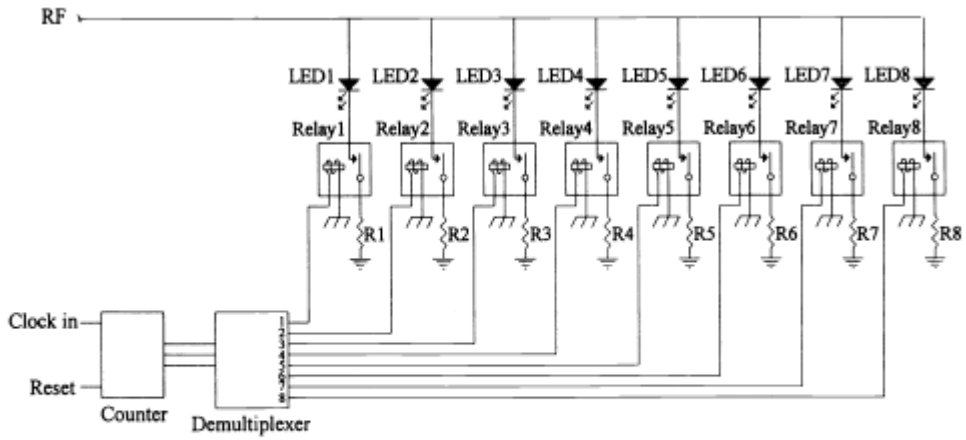


Fig. 2 Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium.

See, e.g., Fantini at 35:

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	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
1[b] at least one detector configured to detect at least a portion of the light	Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light.

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emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;	For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detector allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased, and where there is a detector implenmented as a Hamamatsu R928 detector which detects light from the LEDs after attenuation by teh tissue, where the detector then uses signals at least one signal to measure blood parameters such as hemogobin concentrations: *See, e.g.*, Fantini at Abstract: **Abstract.** We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit. *See, e.g.*, Fantini at 33:

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	In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition. In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument. *See, e.g.*, Fantini at 34:	

		Feature 2. The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. *Feature 3.* To implement the measurement of the slopes of the straight lines (as a function of the distance r between	

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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of

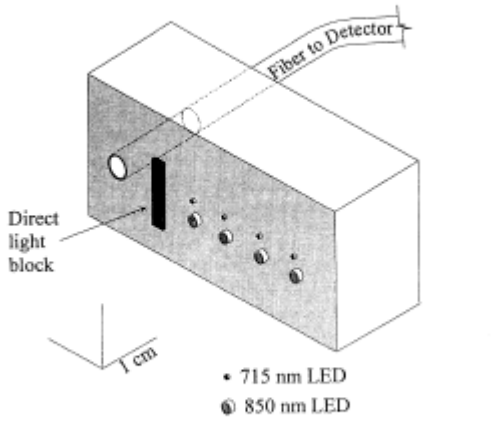
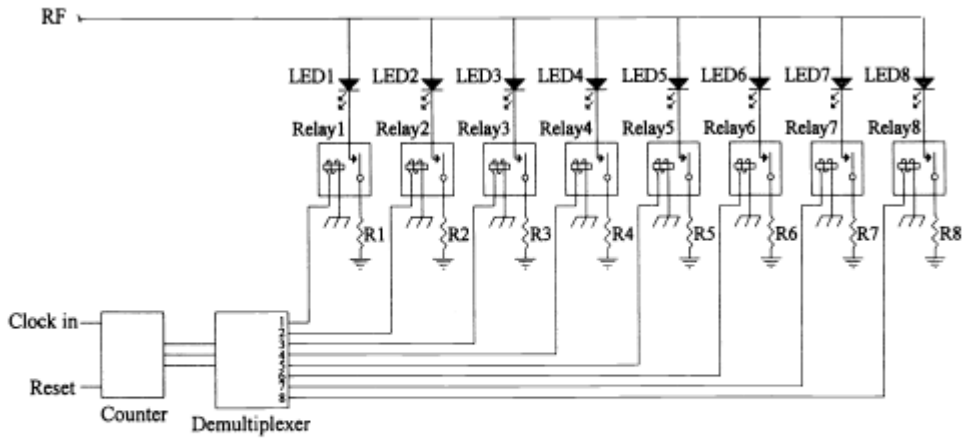


Fig. 2 Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium.

See, e.g., Fantini at 35:

	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
1[c-1] a light block surrounding the at least one detector, the light block	Under at least the apparent construction based on Masimo's Infringement Contentions, Webster discloses and/or renders obvious a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure

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comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass,	is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass. For example, Webster discloses and/or suggests a pulse oximeter for which there is a detector enclosed in a light block and for which a light absorbing coating is relied upon to reduce optical interference: *See, e.g.*, Webster at 77-78: 6.3 OPTICAL CONCERNS Since this is a system with an optical interface, it is important to minimize the effects from light other than the optical signals of interest. One way to minimize unwanted light incident upon the detector is to place some type of light filter over the detector. This allows light of wavelengths of interest to pass through the filter but does not allow light of other wavelengths to pass through the filter. For the pulse oximeter to work effectively, most of the light being transmitted from the LEDs must not reach the photodiode unless it has passed through tissue containing arterial blood. *6.3.1 Optical filtering* Optical filtering, placed between sources of light and the photodiode, is used to limit the spectral response of the photodiode. A number of optical filter types can be used. Cheung *et al* (1993) recommend a red Kodak No. 29 wratten gel filter to eliminate the flickering effect of fluorescent light. However, these external filters do not appear to be used much in actual pulse oximetry designs. In addition, the photodiode mounting package may contain filtering material. Many photodiodes are mounted in clear plastic which absorbs UV wavelengths (Burr-Brown 1994a,b,c). This is useful to filter out some of the unwanted effects of fluorescent lighting on the photodiode. Many photodiodes are available in a variety of packaging types each of which filters out selected wavelengths of light.

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6.3.2 Optical interference

To minimize errors, the pulse oximeter designer must attempt to limit the light reaching the photodiode to that which has traveled through tissue containing arterial blood (Nellcor 1993). This can be accomplished through thoughtful LED/photodiode placement. Light impervious barriers should be placed between LEDs and the photodiode in all areas where the emitted light could reach the photodiode without passing through tissue (New and Corenman 1987). Two additional measures can be taken to ensure this (figure 6.6). One is to decrease the angle of incidence to the photodiode. The second is to coat the housing around the photodiode with a material that does not scatter or reflect light.

There are two types of optical interference that may cause problems for the photodiode. The first is excessive ambient light. The source of this type of error may be surgical lamps, fluorescent lights, infrared heat lamps and direct sunlight. Usually this type of interference will saturate the photodiode so that no pulse can be distinguished, however some of these sources may result in apparently normal but inaccurate readings. The second source of interference is optical cross-talk. This type of interference typically may occur when multiple probes are used in close proximity. In this case, light from one LED probe is sensed by the photodiode of another probe.

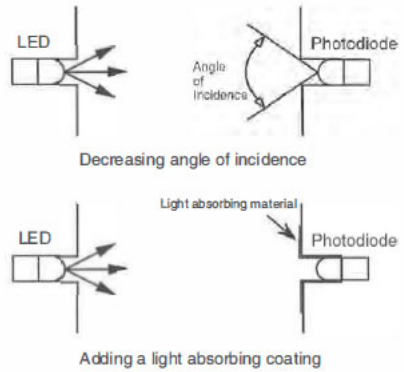


Figure 6.6 Minimizing photodiode optical interference (adapted from Marktech International 1993).

Under at least the apparent construction based on Masimo's Infringement Contentions, Hannula discloses and/or renders obvious a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass.

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For example, Hannula discloses and/or suggests a non-adhesive oximeter sensor that relies on LEDs in one cavity (for example, element 111) to emit light that is received by a detector in a separate enclosure (for example, element 116), where the detector such as a photodetector generates at least one signal that is decoded by an oximeter monitors to calculate a patient's blood oxygen saturation, where there is a light block comprising a shoebox structure surrounding the at least one photodetector, implemented in non-limiting examples as one or more of the reflective mask 117, layer 112, inner side 125 of layer 112, faraday shield 115, and/or polyurethane window 1118, where the light block comprising the shoebox structure recesses the at least one photodetector into the shoebox and provides only one opening through which light is configured to pass to the photodetector, such as through polyurethane window 118, and wherein the shoebox structure is at least partially formed of black materials, such as an black opaque film that comprises the inner side 125 of layer 112 and blocks ambient light that may interfere with photodetector 116:

> *See, e.g.*, Hannula at Abstract ("The present invention provides non-adhesive oximeter sensors for patients with sensitive skin. Sensors of the present invention include a light emitting diode (LED) and a photodetector. The LED and the photodetector may be covered by a reflective mask and a faraday shield. Sensors of the present invention have a non-adhesive laminated layer. The non-adhesive layer contacts, but does not stick to, the patient's skin. When the sensor is removed from the patient, the non-adhesive layer does not tear or irritate the patient's skin. The non-adhesive layer preferably has a large static coefficient of friction. Sensors of the present invention can also have hook-and-loop layers. The sensor can be attached to the patient's body by wrapping the sensor around the patient and engaging the hook layer to the loop layer.").
>
> Fig. 1B.

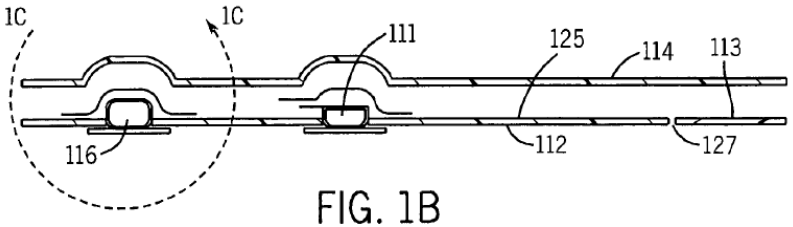


FIG. 1B

Fig. 1C.

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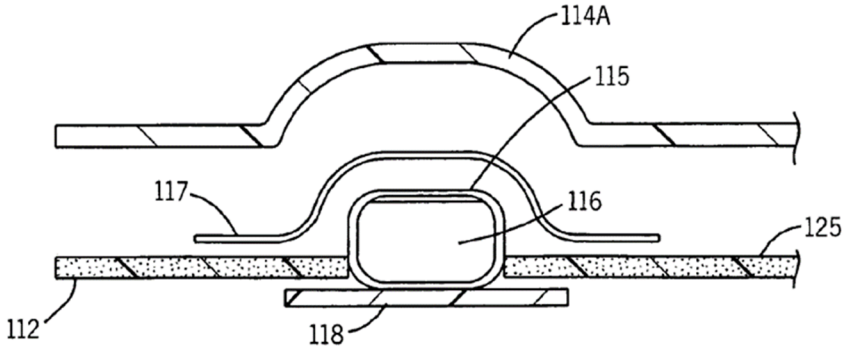


FIG. 1C

Fig. 2.

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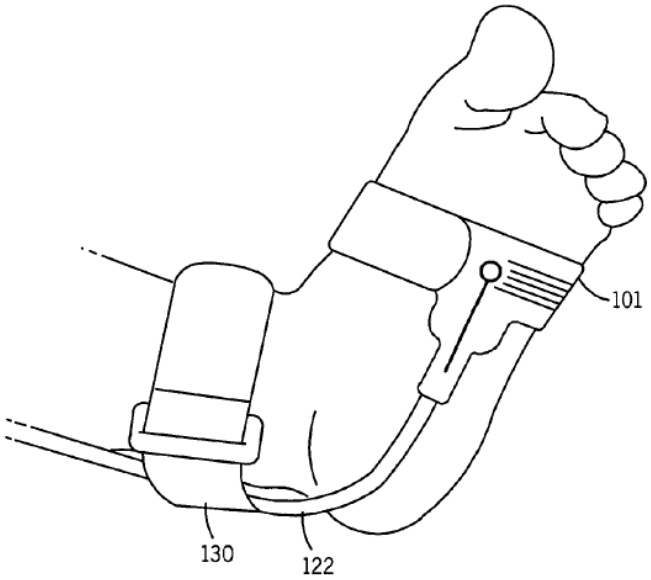


FIG. 2

Hannula, 1:55-2:19 ("The present invention provides non-adhesive oximeter sensors for patients with sensitive or fragile skin. Sensors of the present invention include a light emitting diode (LED) and a photodetector. The LED light shines light through a patient's tissue. The light from the LED is detected by the photodetector. The LED and photodetector may be covered by transparent windows. The LED and the photodetector may also be covered by a reflective mask and a Faraday electromagnetic shield. Sensors of the present invention have a laminated non-adhesive layer. The non-adhesive layer contacts, but does not stick to, the patient's skin. When the sensor is removed from the patient, the non-adhesive layer does not tear or irritate the patient's skin. Therefore, the non-adhesive layer protects sensitive skin. In one embodiment, the non-adhesive layer is a polyvinyl chloride foam material. The non-adhesive layer preferably has a large static coefficient of friction to help keep the sensor motionless relative to the patient.

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	Sensors of the present invention also include one or more laminated layers that hold the sensor unit on the patient's body. These layers may include hook and loop layers. The sensor can be attached to the patient's body by wrapping the sensor around the patient and engaging the hook layer to the loop layer. Sensors of the present invention may include a strengthening layer that lies between the other laminated layers. Furthermore, sensors of the present invention may include light-blocking features to minimize or eliminate ambient light interference and LED light from reaching the photodetector without passing through blood-perfused tissues (shunting)."). Hannula, 2:36-4:62 ("Oximeter sensor **101** shown in FIGS. 1A, B, and C is an embodiment of the present invention. A top down view of oximeter sensor **101** is shown in FIG. 1A. A cross sectional view of oximeter sensor **101** along a plane **105**A is shown in FIG. 1B. The cross sectional view shows the laminated layers of sensor **101**. FIG. 1C illustrates an expanded view of a portion of the cross sectional view. Oximeter sensor **101** has one or more light emitting diodes (LED) **111** and a photodetector **116** as shown in FIG. 1. LED **111** emits light that shines through a patient's tissue. The light from LED **111** is sensed by photodetector **116**. Photodetector **116** produces a signal in response to the detected light. The signal is decoded by an oximeter monitor (not shown) to calculate the patient's blood oxygen saturation. LED **111** and photodetector **116** are connected to the oximeter monitor through wires that feed through cable **122**. Sensor **101** has a polyurethane window **118** below photodetector **116**. Sensor **101** also has a polyurethane window below LED **111**. The polyurethane windows are transparent. Light from LED **111** can pass unobstructed through the polyurethane windows to photodetector **116**. As shown in exploded view in FIG. 1C, photodetector **116**, is surrounded by a reflective mask **117**. Reflective mask **117** reflects light from LED **111** (that has passed through patient tissue and exited near the photodetector) back toward photodetector **116** like a mirror. Reflective mask **117** increases the amount of LED light that the photodetector **116** receives from the patient's tissue, while assisting in blocking ambient light and LED light that may shunt through the laminated layers. LED **111** is also surrounded by a reflective mask that reflects light

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	from LED **111** toward the patient's tissue. The reflective masks may comprise polyester or polypropylene with a reflective metal surface. Photodetector **116** is also covered with a Faraday shield **115**. Faraday shield **115** protects photodetector **116** from electromagnetic fields in the environment. Shield **115** reduces electromagnetic interference that may introduce noise into the output signal of photodetector **116**. Sensor **101** has laminated layers including layer **112** and hook-and- loop layers **113** and **114** shown in FIG. 1. Loop layer **114** has, for example, small loops of threads. Hook layer **113** has, for example, small hooks that engage with the loops in loop layer **114**. Hook layer **113** and loop layer **114** are used to attach sensor **101** to a patient. Hooks in hook layer **113** engage with the loops in loop layer **114**. Once engaged, the hook-and-loop layers remain attached to each other, until they are pulled apart. The end user can engage and disengage hook layer **113** from loop layer **114** multiple times in order to open or close the fastener. One portion of layer **114** cannot attach to another portion of layer **114**. In one embodiment of the present invention, hook and loop layers **113** and **114** are VELCRO layers. In this embodiment, layer **114** comprises a VELCRO loop, and layer **113** comprises a VELCRO hook. Loop layer **114** has a first raised portion **114**A that provides room for the thickness of photodetector **116**. Loop **114** also has a second raised portion that provides room for LED **111**. Sensor **101** also has a bottom laminated layer **112** as shown in FIG. 1. Layer **112** is a non-adhesive layer. Layer **112** is preferably made of a material that has a soft, smooth, non-skid surface. Layer **112** may, for example, comprise polyvinyl chloride (PVC) foam. One type of PVC that may be used with the present invention is 3M-9777L PVC foam manufactured by 3M Co. Layer **112** may also comprise other types of soft, non-adhesive material. Bottom layer **112** is an outer layer of the sensor that contacts the patient's skin. Layer **112** comprises a non-adhesive material that does not adhere or stick to the patient's skin. Because layer **112** comprises

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	a soft, non-adhesive material, it does not tear or irritate sensitive or fragile skin when sensor **101** is removed from the patient. Layer **112** preferably comprises a material that has a relatively large static coefficient of friction. A material with a large static coefficient of friction helps to keep sensor **101** motionless relative to the skin as a patient moves. In sensors of the present invention, it is important to maximize the friction between the sensor and the skin, without the use of adhesives. Adhesives can damage fragile skin, and one objective of the present invention is to keep the sensor on the patient without slippage, but without the use of an adhesive. According to the present invention, the static coefficient of friction of a material is tested using the following procedure. Attach a protractor to a vertical wall with the center in line with the edge of a table. Set up a stop block at the edge of the table to act as a pivot point for a glass plate. Place the glass plate flat on the table with one edge along the edge of the table, up against the stop block. Place a test sample of the material on the glass plate (or other reference materials, such as skin). Lift the free edge of the glass plate until the test sample just starts to slip. Record angle at which slippage first occurred. This angle is the angle of repose. Then calculate the coefficient of friction, which is the tangent of the angle of repose. The coefficient of friction of polyvinyl chloride (PVC) foam is greater than the prior art foam wrap assembly found in the STAT-WRAP™ sensor. The 3M-9777L PVC foam measured using the above-described measuring technique resulted in a value of static coefficient of friction of infinity with respect to glass. The 3M-9777L PVC foam actually stayed on the glass test plate even after achieving a 90 degree angle of repose. The 3M-9777L PVC material almost exhibits slight adhesive properties, surface tension forces, or static cling forces. Therefore, PVC foam is a very good choice of material for layer **112** in consideration of the preferred non-slip characteristics. Using skin as a reference material instead of glass, the 3M-9777L PVC foam exhibits a static coefficient of friction of greater than 5, such as 5.7. The PVC material almost exhibits slight adhesive properties, surface tension forces, or static cling forces. Therefore, PVC foam is a very good choice of material for layer **112** in consideration of the preferred non-slip characteristics.

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	Materials other than PVC foam can be used for layer **112**. The static coefficient of friction for layer **112** is preferably greater than 10. Most preferably, layer **112** has a static coefficient of friction that is greater than 100. Layer **112** is preferably light in color to enhance the amplitude of the light signals received by photodetector **116**. For example, layer **112** may be white, off-white, or cream colored. Alternatively, layer **112** may be dark in color to decrease the amount of ambient and shunted light that reaches the photodetector, at an expense of the amount of detected LED light signals. Layer **112** is preferably a thin layer, as shown in the cross sectional views in FIG. 1. By selecting a narrow thickness for layer **112**, sensor **101** is less bulky. Because sensor **101** is thin, it is more flexible, and it can be easily conformed around a patient's body part. FIG. 2 illustrates an example of how sensor **101** can be placed around a patient's foot. Sensor **101** may include an additional laminated layer. The additional laminated layer is a strengthening film (not shown) that lies between laminated layers **114** and **112**. In one embodiment, hook layer **113** is attached to the strengthening film. In this embodiment, hook **113** is an integral part of one of the laminated layers that makes up the body of sensor **101**. Hook portion **113** is not attached to layer **112**. The foam layer **112** is discontinued at point **127** in FIG. 1, and hook portion **113** begins to the right of **127**. In other embodiments, hook layer **113** is an integral part of bottom layer **112** or top layer **114**. In one embodiment of the present invention, the inner side **125** of layer **112** is covered with a laminated opaque film. The opaque film blocks ambient light that may interfere with photodetector **116**. The opaque film may comprise polyethylene. The opaque film may be black or some other dark color that helps block ambient light and reduces shunted light. Dark in color is understood here to be of a nature with little reflectance of the wavelengths of light sensed by the sensor's photodetector. Non-adhesive layer **112** is preferably long enough to wrap all the way around the patient's finger, toe, ear, or other portion of the body. Non-adhesive layer **112** is the only portion of sensor **101** that directly

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	contacts the patient's skin. This feature of the present invention eliminates damage to the patient's skin that can be caused by adhesive portions of a sensor.”). Hannula, Claims 1, 8, 9, 10, 11, 16, 35, 42, 43, 44, 45, 50 (“1. An oximeter sensor comprising: a light emitting element; a light detecting element; a substrate adapted to support the light emitting element and the light detecting element, the substrate comprising a non-adhesive patient-contacting surface, the patient contacting-surface having a static coefficient of friction greater than 5 with respect to a patient's skin. 8. The oximeter sensor of claim 1 further comprising: faraday shields over one or both of the light emitting and light detecting elements. 9. The oximeter sensor of claim 1 further comprising: an opaque film that covers the inner surface of the first laminated layer. 10. The oximeter sensor of claim 9 wherein: the opaque film is dark in color. 11. A method for forming an oximeter sensor, the method comprising: providing a substrate having a surface that contacts a patient, the substrate comprising a non-adhesive material that has a static coefficient of friction greater than 5 with respect to the patient's skin, the non-adhesive material retaining the oximeter sensor on the patient without the use of an adhesive that contacts skin of the patient, the substrate having first and second receptacles; and

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	placing a light emitting element in the first receptacle; placing a light detecting element in the second receptacle. 16. The method of claim 11 wherein the light emitting and light detecting elements include faraday shields. 35. An oximeter sensor comprising: a light emitting element; a light detecting element; a substrate having a strap-like configuration configured encircle a portion of a patient and to attach to itself, the substrate being adapted to support the light emitting element and the light detecting element, the substrate comprising a non-adhesive patient-contacting surface, the patient contacting-surface having a static coefficient of friction greater than 5 with respect to the patient's skin. 42. The oximeter sensor of claim 35 comprising: faraday shields over one or both of the light emitting and light detecting elements. 43. The oximeter sensor of claim 35 comprising: an opaque film that covers the inner surface of the first laminated layer. 44. The oximeter sensor of claim 43 wherein: the opaque film is dark in color. 45. A method for forming an oximeter sensor, the method comprising:

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	providing a substrate having a predominant thickness of less than 0.1 inch and having a surface that contacts a patient, the substrate comprising a non-adhesive material that has a static coefficient of friction greater than 5 with respect to the patient's skin, the non-adhesive material retaining the oximeter sensor on the patient without the use of an adhesive that contacts skin of the patient, the substrate having first and second receptacles; and placing a light emitting element in the first receptacle; placing a light detecting element in the second receptacle. 50. The method of claim 45 wherein the light emitting and light detecting elements include faraday shields."). Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass. For example, Fantini discloses and/or suggests a light block surrounding the at least one detector comprising a Direct light block or measuring head, for example, and where the light block includes a shoebox structure comprising, under the apparent construction based on Masimo's Infringement Contentions, a measuring head for the detector including only one opening through which light is configured to pass, implemetned as a Fiber to Detector cable that is the only opening for light to the detector: *See, e.g.*, Fantini at Abstract:

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Abstract. We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit.

See, e.g., Fantini at 33:

In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition.

In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument.

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	See, e.g., Fantini at 34: ***Feature 2.*** The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. ***Feature 3.*** To implement the measurement of the slopes of the straight lines (as a function of the distance *r* between

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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of

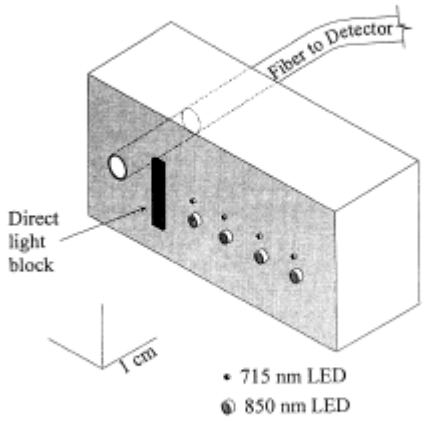
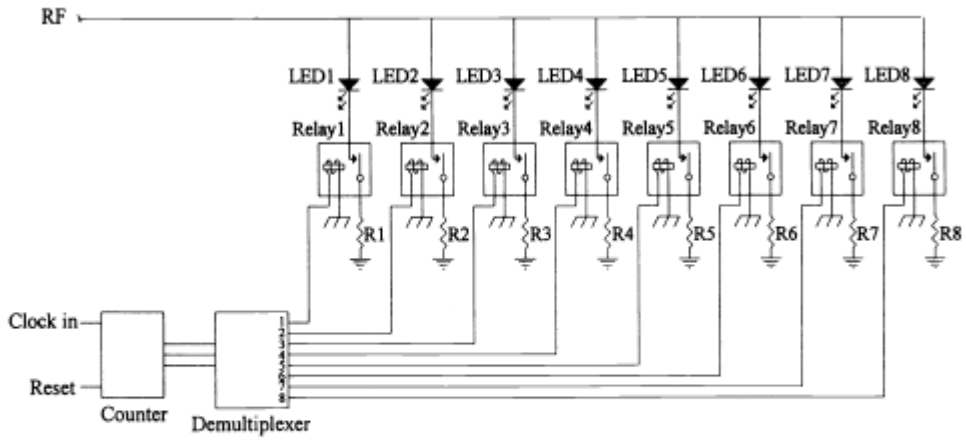


Fig. 2 Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium.

See, e.g., Fantini at 35:

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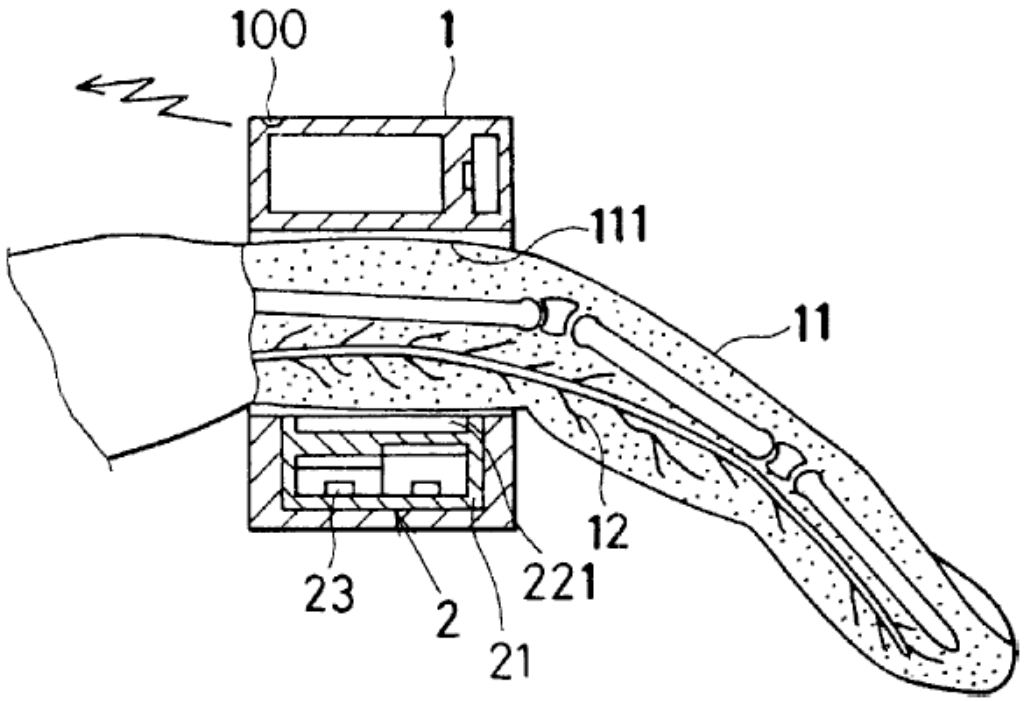
	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
1[c-2] the opening comprising an area smaller than a detection surface	Under at least the apparent construction based on Masimo's Infringement Contentions, Kimura discloses and/or renders obvious the opening comprising an area smaller than a detection surface area of the at least one detector.

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area of the at least one detector; and	For example, Kimura discloses and/or suggests a vital signs detecting apparatus that is capable measuring vital signals such as pulse by relying on a least three LEDs in a cavity and at least one detector in a different enclosure, where for an area of an only opening to the detector is smaller than a detection surface area of the at least one detector, implemented in a non-limiting example as a vital sign detecting apparatus for which there is a window above a light receiving device comprising a detector 404, where the window 412 is circular and has a surface area that is smaller than the surface area of the detector: *See, e.g.*, Kimura at Abstract ("A vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. The pulse wave detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, Fig. 1A

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FIG. 1A



Kimura, Fig. 1B.

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FIG. 1B

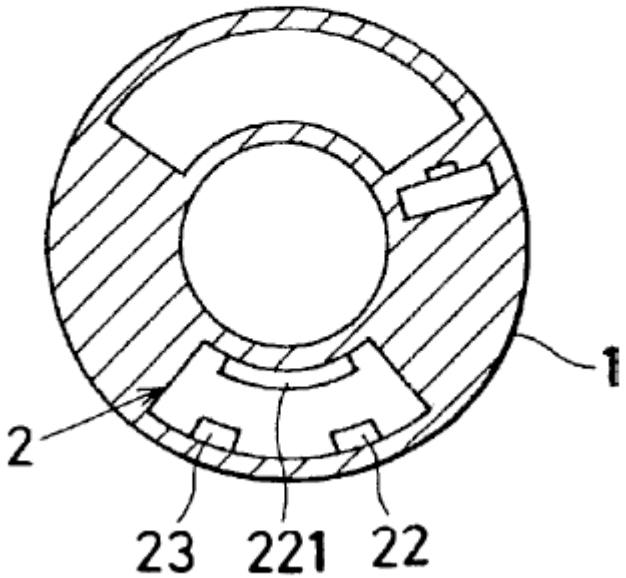


Fig. 2.

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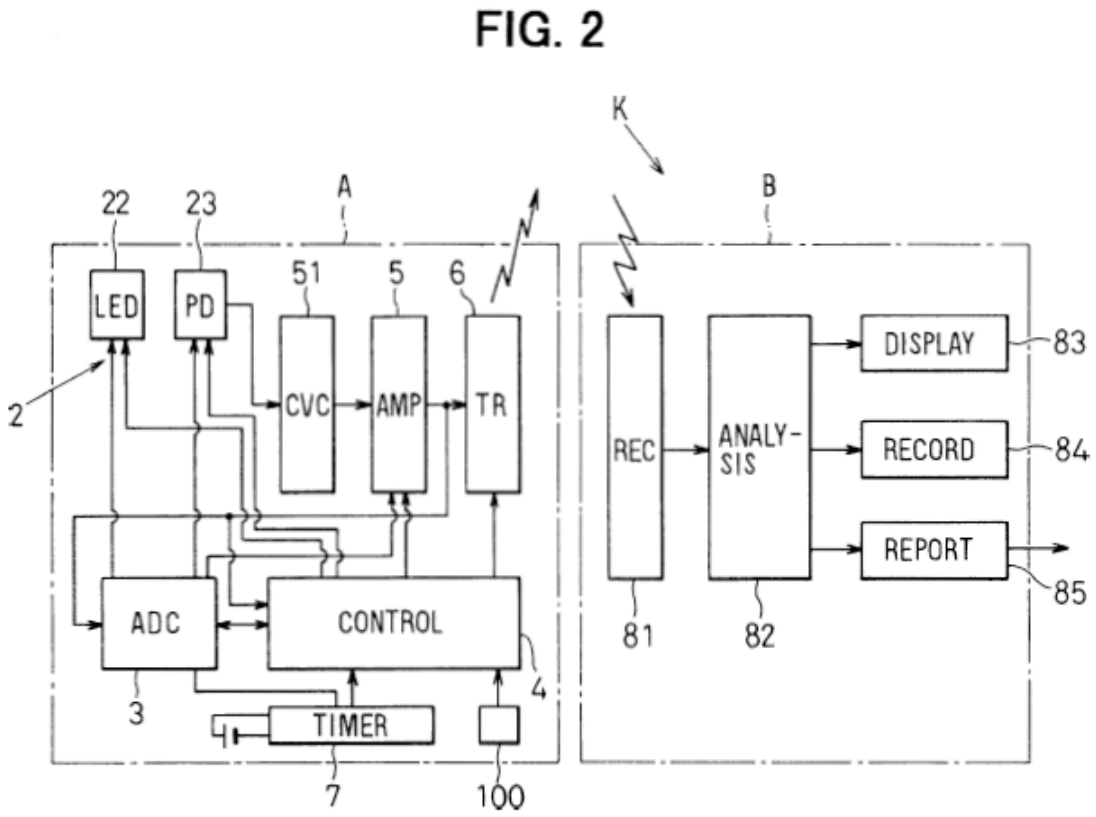


Fig. 22.

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FIG. 22

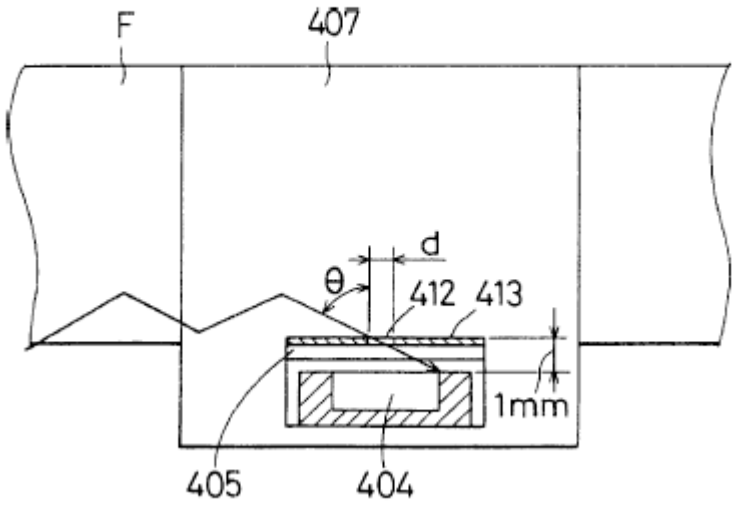
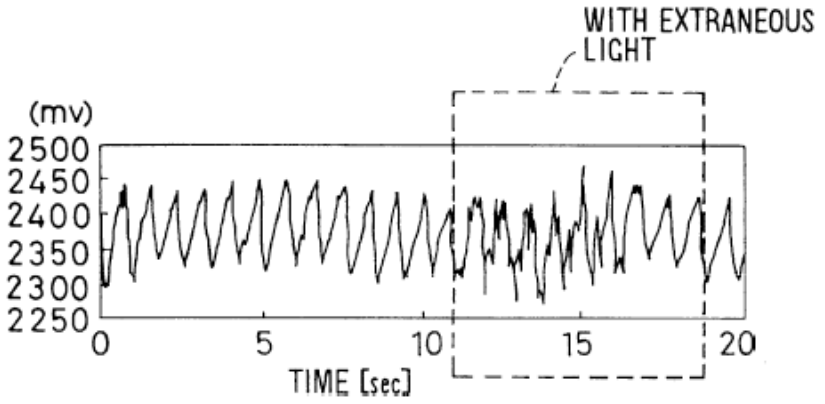


Fig. 23A.

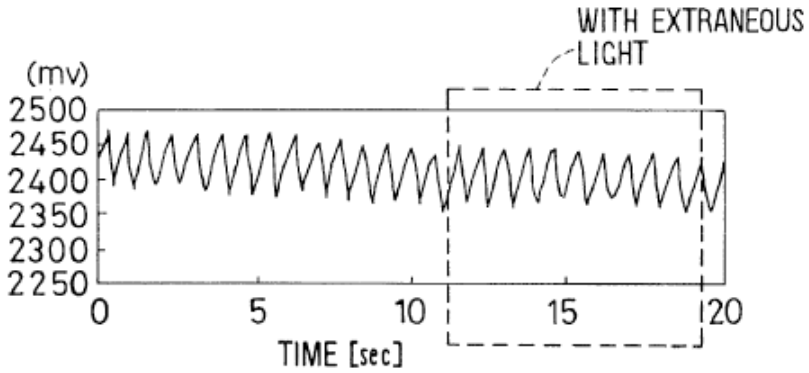
FIG. 23A



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Fig. 23B.

FIG. 23B



Kimura, 1:13-2:2 ("This invention relates to a vital signal detecting apparatus for detecting a vital signal, having an attachable device to be attached for example to a finger, an ear, an arm, a leg, torso or a neck of a human subject.

There have been vital signal detecting apparatuses, as disclosed, for instance, in JP-A-8-266493 or Electronic Data Communications Society, Technical Report 1995-06. To check a vital signal (such as a pulse wave), a human subject has to operate an on/off switch himself or herself. If the subject operates the on/off switch without inserting a finger into the attachable device, because a sensor picks up external noise and outputs an abnormal signal, the vital signal checking device erroneously determines that the subject is abnormal. Further, if a ring part of a pulse wave sensor fails even slightly to match the size (thickness) of the finger, it is difficult for a detecting part to be kept in contact with the surface of the finger. Thus, extraneous light, for example, sunlight or light from fluorescent lights, affect the measurement.

There have also been vital signal detecting apparatuses, used when a vital signal (such as the pulse wave) of for example an elderly or infirm subject is to be monitored over a long period, with which an attachable device is attached for instance to an arm or a leg of the subject and a vital signal detected by a sensor is transmitted to a vital signal checking device by radio waves or the like. If the elderly or

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	infirm subject removes the attachable device, because the sensor picks up external noise and transmits an abnormal signal to the vital signal checking device, again the vital signal checking device erroneously determines that the subject is abnormal. SUMMARY OF THE INVENTION It is therefore an object of the present invention to provide a vital signal detecting apparatus which eliminates problems caused by abnormal vital signals detected when an attachable device is not attached. According to the present invention, a vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. Preferably, the vital signal detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, 14:19-47 ("As shown in FIG. 22, in this preferred embodiment, a window **412** for limiting the angle of incidence at which light can enter the light-receiving device **404** is provided above the light-receiving device **404**. The window **412** above the light-receiving device **404** is formed by providing a blocking film **413** capable of blocking light on the surface of the light-transmitting plate **405** and then making a hole of a predetermined size in the center of this blocking film **413**.

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	By providing the window **412** above the light-receiving device **404**, for example as shown in FIG. 22, the light-receiving device **404** is disposed 1 mm below the interface between the light-transmitting plate **405** and the skin surface. If the window width d is made 0.5 mm, then it is possible to cut out light having an angle of incidence θ of over ±30°, as shown in FIG. **23**B. On the other hand, if the window width d is made 4 mm, then because only light whose angle of incidence θ is over ±60° is blocked, fluctuation arises in the detection result (voltage Value) of the pulse wave sensor **401** due to the influence of extraneous light, as shown in FIG. **23**A. As mentioned above with reference to the eleventh preferred embodiment, extraneous light guided in through the skin of the finger F can be considered to be incident on the light-receiving device **404** at a large angle of incidence (θ≧30°). Consequently, since extraneous light can be effectively cut out by limiting the window width d, it is possible to reduce erroneous detection caused by the influence of extraneous light."). Kimura, Claim 13 ("13. A vital signal detecting apparatus comprising: a light-emitting device; a light-receiving device; and a light-transmitting plate disposed above the light-emitting device and the light-receiving device to pass light therethrough, and used with the surface of the light-transmitting plate in contrast with the skin surface of a human body, wherein the light-receiving device is disposed in a position lowered by a predetermined distance with respect to the light-transmitting plate, and a window formed in a light-blocking layer that covers the surface of the light-transmitting plate and provided above the light-receiving device, the window for limiting the angle of incidence at which light can enter the light-receiving device.").

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Diab discloses and/or renders obvious the opening comprising an area smaller than a detection surface area of the at least one detector. For example, Diab discloses and/or suggests an optical prove that is particularly suited to reduce noise in measurements that relies on LEDs and a detector measure physiological parameters, where there is an opening to a detector 126 in a light blocking chamber 126 comprising the portion of a lens 132 through which light can pass to the detector, where light received by the detector must pass through the lens, and where the opening comprises an area smaller than a detection surface area of the detector because the opening is of a diameter that is less than the diameter of the detector by at least the thickness of an optical adhesive or lens retaining ring: *See, e.g.*, Diab at Abstract ("An optical probe, which is particularly suited to reduce noise in measurements taken on an easily compressible material, such as a finger, a toe, a forehead, an earlobe, or a lip, measures characteristics of the material. A neonatal and adult disposable embodiment of the probe include adhesive coated surfaces to securely affix the probe onto the patient. In addition, the surface of the probe is specially constructed to minimize light piping effects. Furthermore, a flex circuit acts as a spring to absorb shock which may misalign the emitter and detector. One embodiment of the adult probe includes a cushioning pocket formed for a fingertip to align the probe and to absorb motion of the probe due to contact. The neonatal probe is formed with a unique V-configuration which provides multiple advantages."). Fig. 5.

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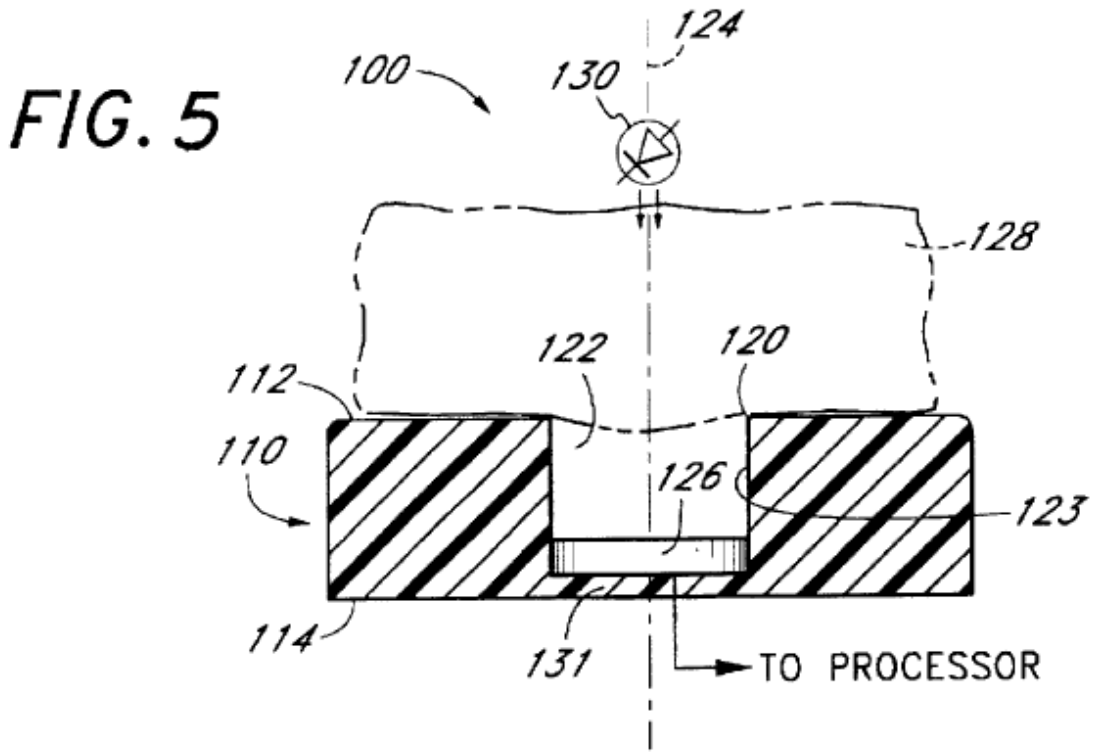


Fig. 6.

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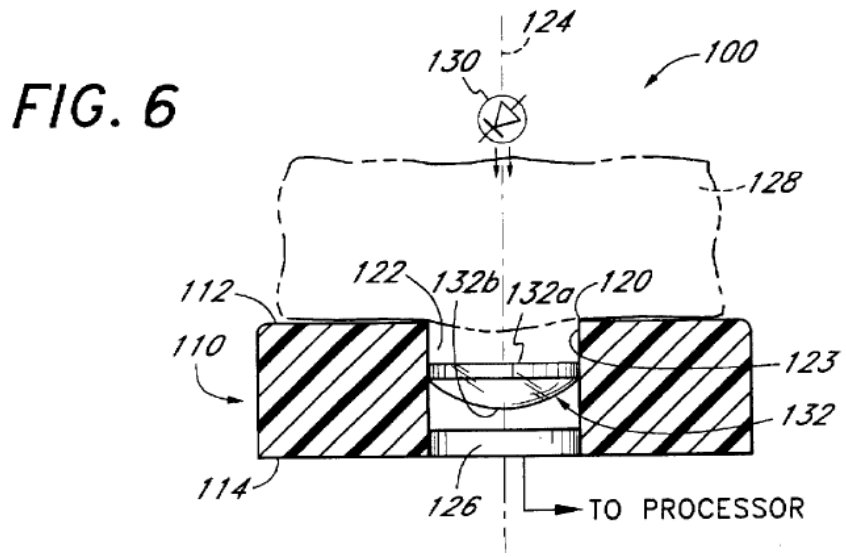


Fig. 12.

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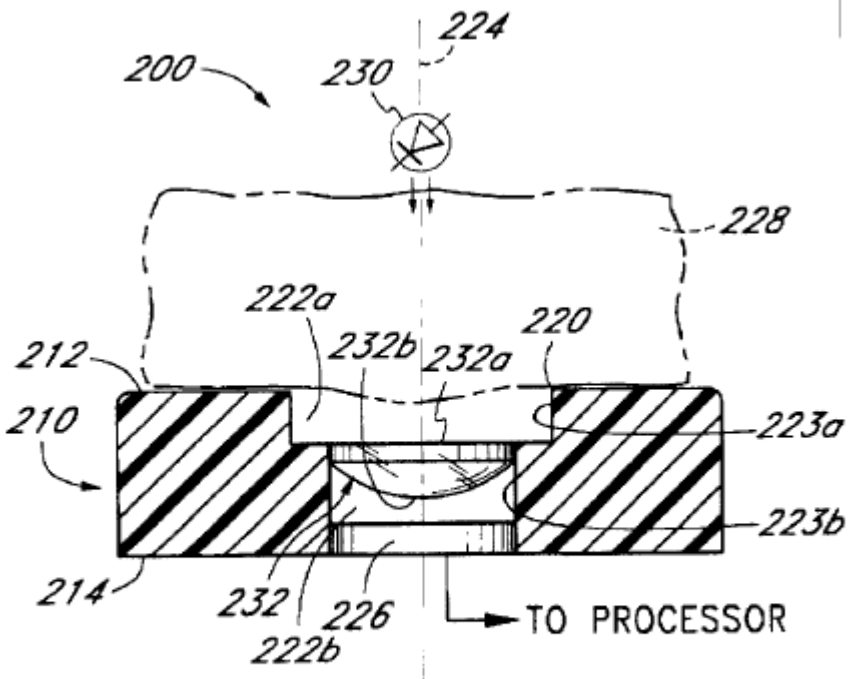


FIG. 12

Diab, 6:54-64 ("Examination of a material is often advantageous, especially when it is difficult or expensive to procure and test a sample of the material. For example, in physiological measurements, it is often desirable to monitor a patient without drawing of blood or tissue from the patient. The known properties of energy absorption as energy propagates through a material may be used to determine information about the material through which the energy has passed. Energy is made incident on a material, and a measurement is made of energy either transmitted by or reflected from the material.").

Diab, 7:36-9:43 ("FIG. 3 is a perspective view of one embodiment of an optical probe 100 of the present invention which greatly diminishes the effects of motion artifacts on the measured signal. FIG.

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	4 shows a cross-sectional view of the optical probe 100 of the present invention taken along line 4--4 in FIG. 3. For clarity in the perspective view of FIG. 3, a material 128 on which measurements are to be taken is not shown placed adjacent the probe 100. However, the material 128 on which measurements are to be made is shown in FIG. 4. As illustrated in FIGS. 3 and 4, a base 110, having a top 112, a bottom 114, a forward end 116, and a rear end 118, is made of a material which is preferably rigid and opaque. It will be understood, however, that the probe 100 may be made of materials which may be rigid, resilient, opaque, or transparent, for example. An aperture 120 is formed in the top 112 of the base 110. Typically, the aperture 120 is located at a point between one-quarter and one-half of the length of the base 100. The aperture 120 may be of any shape, including but not limited to circular, square, or triangular. The aperture 120 forms the opening to a chamber 122 which may also be of any shape. In one embodiment, a lateral cross-section (not shown) of the chamber 122 is the same shape as the aperture. A central axis 124 of the chamber 122 is defined by a line aligned perpendicular to the aperture 120 and extending generally through a central portion of the aperture 120. In the embodiment of FIG. 4, a light source 130, typically a light emitting diode (LED), is affixed adjacent the material 128, aligned along the central axis 124 of the chamber 122 opposite the chamber 122. Typically, an adhesive such as medical tape is used to affix the LED 130 to the material 128. A detector 126, such as a photodetector, is placed within the chamber 122. A central portion of the photodetector 126 is generally aligned with the central axis 124 of the chamber 122, typically at the bottom 114 of the chamber 122. The photodetector 126 may be fixed within the chamber 122 according to a number of different methods, including but not limited to adhesive, a press fit, or clear epoxy resin which transmits light over a range of wavelengths of interest. Typically, no matter how the photodetector 126 is held within the chamber 122, the bottom surface 114 of the chamber 122 is made opaque either via the press fit or via paint or tape, for example. It is often the case that materials 128 on which absorption measurements are performed are, at least in part, easily compressible. Easily compressible portions of the material 128 are placed directly adjacent (i.e., above) the chamber 122. The area surrounding the aperture 120 supports the material covering the chamber 122. The chamber 122 is wide enough that any compressible portion of the material 128 located above the aperture 120 may intrude into the chamber 122. Thus, the material 122 may rest

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	above or penetrate slightly into the chamber 122 and is thereby shielded from perturbations which compress the material 128, such as pressure caused when the material 128 is touched. In the present embodiment, the depth of the chamber 122 may range from 0.5 mm to 10 mm in depth, with 2-4 mm preferred, and 3-4 mm more preferred. Similarly, the diameter of the aperture 120 may, in the present embodiment, range from 3 mm to 20 mm, as required by the specific application. For instance, the aperture would be smaller for neonates than for adults. These sizes have been found to be effective in reducing perturbations and compression of the material 128, when the material is human skin. The chamber 122 is deep enough that the photodetector 126 and the bottom 114 of the chamber 122 do not come into contact with the easily compressible portion of the material 128, even when the material 128 is caused to move. Thus, along the central axis 124 of the chamber 122 nothing comes into physical contact with the easily compressible portion of the material 128 and causes it to compress With little or no compression of the material 128 in this region, the thickness of the material 128, or the optical path length of light energy propagating through the material 128, is substantially stabilized in the field of view of the photodetector. The movement of venous blood due to compression is also minimized in the field of view of the photodetector. The LED 130 emits light at a known wavelength. The light propagates through the material 128 and an attenuated signal is transmitted into the chamber 122 to be received by the photodetector 126. As light from the LED 130 propagates through the material 128, it is scattered by the material 128 and is thus transmitted into the chamber 122 over a broad range of angles in a very complex manner. Thus, some of the light is caused to be incident on the opaque walls 123 of the chamber 122 and is absorbed. Although the signal travels through a greater optical distance to reach the photodetector 126 at the bottom 114 of the chamber 122 than if the photodetector 126 were immediately adjacent the material 128, thus eliminating direct coupling between the photodetector 126 and the material 128, the resulting degradation to signal intensity is compensated for by the stabilization of the optical path length and the resultant reduction of noise in the measured signal. The photodetector 126 produces an electrical signal indicative of the intensity of light energy incident on the photodetector 126. The electrical signal is input to a processor which analyzes the signal to determine characteristics of the media 128 through which the light energy has passed.

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	The opaque quality of the base 110 absorbs ambient light which can interfere with the signal measured at the photodetector 126. This further improves signal quality. Further, the opaque bottom 114 of the chamber 122 protects the photodetector 126 from ambient light which can obscure the desired signal measured at the photodetector 126. Thus, an accurate measurement of the intensity of the attenuated signal may be made at the photodetector 126. An alternative embodiment of the chamber 122 is shown in frontal cross-section in FIG. 5. A shell 131 of base 110 material covers the bottom 114 of the chamber 122. The photodetector 126 is mounted on the shell 131, within the chamber 122, generally aligned with the LED 130. The photodetector 126 is electrically connected to a processor through a small hole (not shown) in the shell 131. The shell 131 shields the photodetector 126 from ambient light which can seriously degrade the signal-to-noise ratio of the signal measured at the photodetector 126. It will be understood that the bottom 114 of the chamber 122 may be formed with or without the shell in any embodiment of the probe of the present invention. FIG. 6 shows a frontal cross sectional view of another embodiment of the probe 100 of the present invention wherein a light collecting lens 132 is placed within the chamber 122, between the material 128 which rests above or enters into the chamber 122 and the photodetector 126. The lens 132 has one generally planar surface 132a aligned parallel to the aperture 120 in the top 112 of the base 110, located deep enough within the chamber 122 that any material 128 which intrudes into the chamber 122 does not contact the planar surface 132a of the lens 132. Another surface 132b of the lens 132 is generally convex having its apex directed toward the photodetector 126 in the bottom 114 of the chamber 122. The lens 132 may be held in the chamber 122 by a number of means, including but not limited to optical adhesive, a lens retaining ring, or a press fit. The chamber 122 functions in the same manner as described above to stabilize the optical path length and reduce motion artifacts. The light collecting lens 132 gathers much of the light which was scattered as it was transmitted through the material 128 and causes it to be incident on the photodetector 126. This produces a stronger measured signal."). Diab, 12:16-38 ("In another embodiment of the probe 200, a light collecting lens 232 is inserted within the chamber 222, as shown in cross-section in FIG. 12. The lens 232 is advantageously supported at the border 225 between the stabilizing segment 222a and the mounting segment 222b. The lens may be held in place by a number of means, including but not limited to an optical adhesive, a lens retaining ring, or a press fit. The lens 232 has a generally planar surface 232a aligned with the border 225

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	between the stabilizing segment 222a and the mounting segment 222b and a generally convex surface 223b extending into the mounting segment 222b of the chamber 222. The stabilizing segment 222a of the chamber 222 is deep enough that the lens 232 does not contact any of the compressible material 228 which may have intruded into the chamber 222. The lens 232 collects light which is incident on the planar surface 232a. Much of the light which is incident on this surface 232a at angles which would be absorbed by the walls 223a and 223b of the chamber 222 if the lens were not present is now directed toward the photodetector 226. Thus, a greater percentage of the light transmitted through the material 228 is caused to be incident on the photodetector 226, resulting in a stronger measured signal."). Under at least the apparent construction based on Masimo's Infringement Contentions, Mannheimer 842 discloses and/or renders obvious the opening comprising an area smaller than a detection surface area of the at least one detector. For example, Mannheimer 842 discloses and/or suggests a pulse oximetry probe where there is a detector 120 with an opaque surface cover with a hole to the detector that is smaller in width than the detector 120, thereby where the opening comprises an area smaller than a detection surface area of the detector: *See, e.g.*, Mannheimer 842 at Abstract ("A fetal pulse oximetry probe has clusters of light-transmissive bumps over the light source and the light detector on the surface of the probe. The probe is usually attached to the fetus' head. The clusters part the fetal hair and penetrate other light-attenuating organic materials on the head. The clusters thus transmit a more intense light signal. To reduce the amount of signal shunting between them, the clusters also may be separated by additional opaque (light-shielding) bumps."). Fig. 1a.

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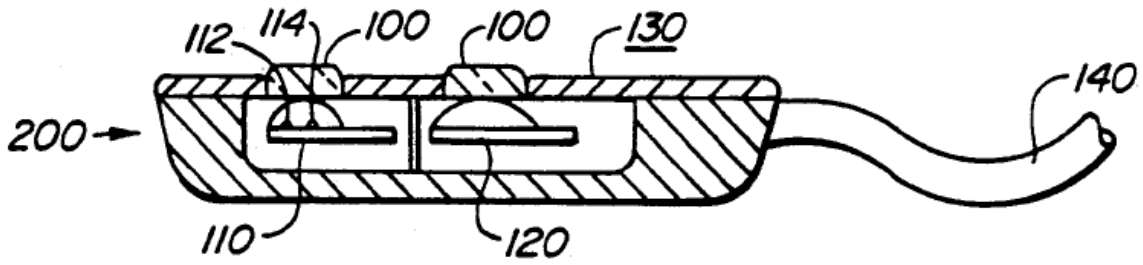


FIG. 1a.

Fig. 1b.

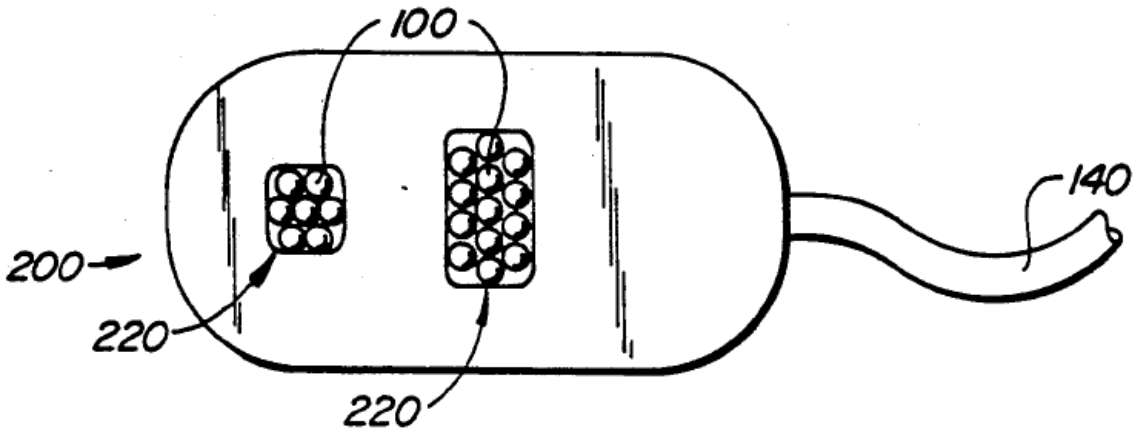


FIG. 1b.

Fig. 5a.

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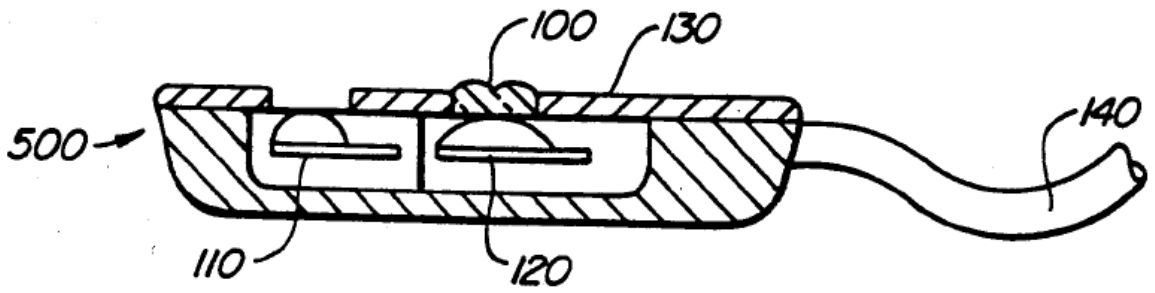


FIG. 5a.

Fig. 5b.

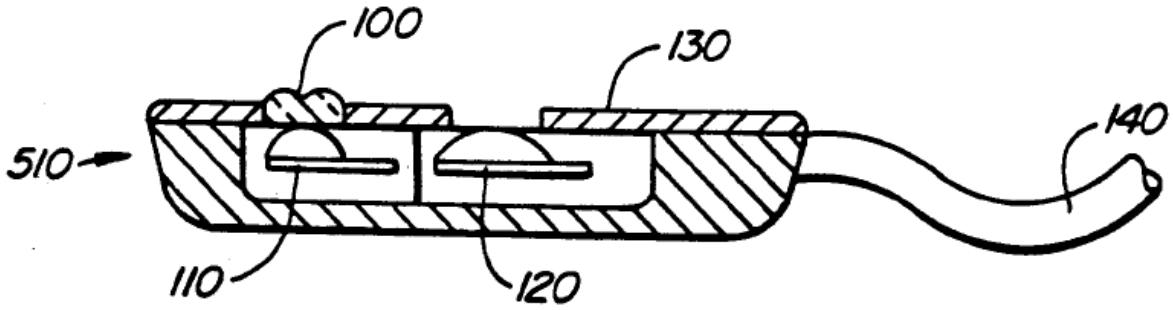


FIG. 5b.

Mannheimer 842, 1:45-2:14 ("The purpose of the present invention is to improve the accuracy and consistency of the readings, especially in the presence of substances, by increasing the optical signal levels.

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	Various methods may be used to increase signal levels by intensifying the emitted light from the probe and increasing the sensitivity of the detector. However, substances like hair may significantly lessen the amount of light passing between the probe and the skin and consequently decrease the signal-to-noise ratio. To overcome this problem, the invention reduces the amount of substances between the probe and the fetal tissue. In the probe of the prior application, the curved surface portions or bumps improve the signal. The apex of the bump pushes aside the substances and comes to rest on the scalp (or close to it). The clusters in the present invention more effectively penetrate the substances on the head. The clusters "scrub" aside the substances better than does the single bump of the prior invention. Clusters also are more effective when used over larger surface areas of the source and detector. A single bump, if too flat, would not effectively part the fetal hair and penetrate the other light-attenuating materials. But if too high, a single bump would hold the probe too far above the fetal tissue. The present invention therefore uses clusters of bumps over the source, the detector, or both. The bumps in the clusters are sufficiently pointed to penetrate the substances. The action of these bumps is much like combing. Like the teeth of a comb, the bumps penetrate a wad of hair or other material. When the probe, biased toward the head, is slid back and forth, the "comb" also moves aside substances caught underneath its "teeth" (i.e., the bumps). As the probe slides back and forth the substances are forced away from the apex of the bumps. The spaces between the bumps receive the substances that are pushed aside."). Mannheimer 842, 2:49-57 ("FIG. 1(a) shows a perinatal pulse oximetry probe 200 that includes light source 110, detector 120, and cord 140. The probe can be made of acrylonitrile-co-butadiene-co-styrene (ABS) plastic or any bio-compatible flexible or inflexible material. Source 110 and detector -20 are covered by light-transmissive bumps 100. Opaque surface 130 covers the probe 200. FIG. 1(b) shows the clusters 220 of bumps 100. Cord 140 connects probe 200 to a power source."). Mannheimer 842, 4:25-31 ("FIGS. 5a-b show another alternative embodiment where either only the light source 110 or the detector 120 is covered by light transmissive bumps 100. FIG. 5a shows the probe 500 with only detector 120 having light transmissive bumps 100 as a cover, while FIG. 5b shows the probe 510 with only light source 110 having light transmissive bumps 100 as a cover.").

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Shaw discloses and/or renders obvious the opening comprising an area smaller than a detection surface area of the at least one detector. For example, Shaw discloses and/or suggests an oximeter relying on at least three electroluminescent diodes (9, 11, 13) emitting light at at least three different wavelengths (600, 715, 805 nm), where the emitted light is received by a photoresponsive detector (Fig. 3a, 47, 49, 51) and the detected signals are processed to measure the blood oxygen saturation of a patient, where the photoresponsive detector is positioned in an enclosure, and the opening to the enclosure (aperture 95) has an area smaller than a detection surface area of the detector (47, 49, 51): *See, e.g.*, Shaw at Abstract ("Oximeter method and apparatus uses a test appliance that includes a source for directing radiation into skin tissue or other blood-confining container at three or more wavelengths and a detector for sensing the radiation intensity emanating from the skin tissue or other container at each wavelength. The oximeter method and apparatus also uses circuitry for combining the detector outputs in a predetermined manner to provide an indication of the oxygen saturation of the blood independently of position or movement of the test appliance on the patient and without first calibrating the indication on each patient."). Fig. 1.

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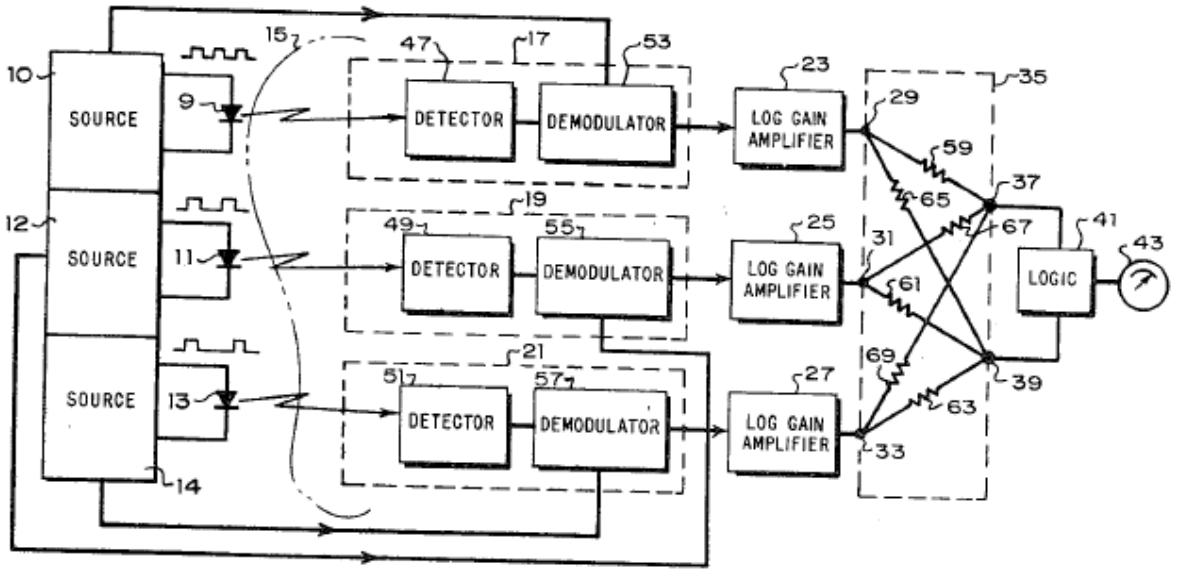


Figure 1

Fig. 2.

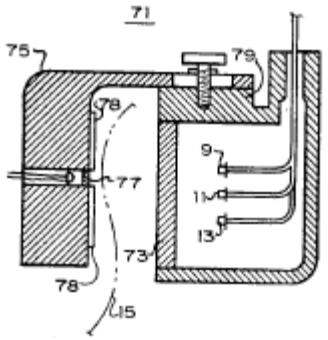


Figure 2

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Fig. 3a.

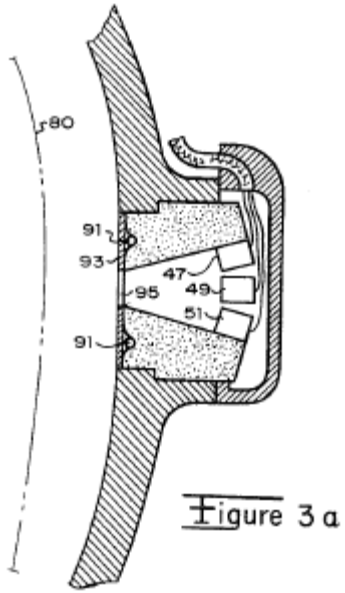


Figure 3a

Fig. 3b.

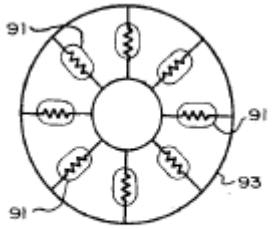


Figure 3b

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	Shaw, 1:63-2:14 ("Accordingly, the present invention provides spectrophotometer apparatus which measures oxygen saturation of blood in vivo and which obviates the need for making said reference measurements. The present apparatus operates at a number of different wavelengths equal to at least one plus the number of wavelength-dependent, radiation-absorptive substances present in the test sample and requires only a single intensity measurement at each of the wavelengths to provide an indication of oxygen saturation of blood in vivo. Changes in measurement conditions due to movement of the test appliance, changes in the geometry of illumination and detection, changes in thickness and geometry of neutral density sample containers, changes in the quantity of blood perfusing the skin tissue, and the like, are accounted for by making simultaneous intensity measurements at each of the selected wavelengths. This provides a continuous indication of oxygen saturation of blood in vivo as the measurement conditions change from patient to patient or even on a given patient. Thus, in the illustrated embodiment of the present invention, radiation sources and detectors are disposed about the ear of a patient to measure the intensity of radiation passing therethrough at each of at least three different radiation wavelengths. The logarithms of the detector responses are combined linearly to yield an indication of oxygen saturation as the ratio of the concentration of oxyhemoglobin to the concentration of total hemoglobin present in the patient's ear."). Shaw, 2:30-3:50 ("Referring to FIG. 1, there is shown a schematic diagram of one embodiment of the present oximeter apparatus which includes three semiconductor electroluminescent diodes 9, ll and 13 arranged to irradiate substantially the same area of the ear I5 of a patient at at least three different narrow-band portions of the electromagnetic radiation spectrum, for example, about the 660, 7 l 5, and 805 millimicron wavelengths. Each of the diodes is energized intermittently by its associated source l0, l2 and 14 at a selected repetition rate. The radiation transmitted through the ear I5 is detected within each of the different hands by the detector means l7, l9 and 21, each of which includes a photoresponsive detector 47, 49, or 51 such as a photodiode, phototransistor, photomultiplier tube, or the like. Each of these detectors is disposed to receive radiation from substantially the same area of the car 15 and is connected to a synchronous demodulator 53, 55, or 57 which in turn is connected to one of the sources for synchronous operation at the repetition rate of the associated source I0, 12, or 14. The resulting output from each demodulator S3, 55, or 57 is thus representative of the radiation which passed through the ear 15 only at the radiation wavelength produced by the diode that is energized in synchronism with the associated demodulator. A very narrow-band radiationselective optical system is thus provided at the three radiation wavelengths produced by each of the diodes 9, 11 and 13. Of course, a single detector means may be used and its responses to radiation at three different

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	wavelengths may be separated out by synchronous demodulation at each of the frequencies of excitation from sources l0, l2 and 14 or by time-shared sequential operation of each of the diodes 9, II and 13. Also, the diode light sources 9, II and 13 may be operated continuously to produce three selected radiation wavelengths or an incandescent light source may be used to provide a broad spectrum of radiation. In these cases, the synchronous demodulators 53, 55 and 57 would be eliminated, and in these cases, the detector means I7, 19 and 21 would include filters 52,54 and 56in the field of view of the detectors 47, 49 and S1 to provide the required response to radiation at at least three different wavelengths, as shown in FIG. 4. The signals from the demodulators 53, 55 and 57 are amplifled by amplifiers 23, 25 and 27 which have logarithmic output vs. input signal amplitude characteristics to provide signals at the output terminals 29, 31 and 33 which are representative of the logarithms of the total radiation received from the car 15 at each of the three different radiation wavelengths. These three signals contain the information necessary to determine within tolerable limits of accuracy the ratio of the concentrations of the two wavelength-dependent, radiation-absorbing substances oxyhemoglobin and reduced hemoglobin where these substances are substantially the only wavelength-dependent, radiation-absorbing substances present in the test sample of blood and its container. However, where other wavelength-dependent, radiation-absorbing substances are significantly present, such as skin pigments or colored materials in the blood, then as discussed above, the number of wavelengths required will increase to one plus the number of such significant wavelength-dependent, radiationabsorbing substances present. In order to determine oxygen saturation, it is not necessary to determine the concentrations of each of the significant wavelength-dependent, radiation-absorbing substances present, since it is only necessary to know the ratio of the concentration of oxyhemoglobin to the concentration of total hemoglobin present in the patients ear. Thus in the embodiment shown, the three logarithmic signals at the output terminals 29, 31 and 33 may be combined linearly using resistors 59, 67 and 69 to produce a signal at terminal 37 which is indicative of the concentration of oxyhemoglobin and, further, may be combined linearly using resistors 65, 61 and 63 to produce a signal at terminal 39 which is indicative of the concentration of total hemoglobin. Logic circuit 41 connected to the terminals 37 and 39 thus combines these signals as the ratio of the signal on terminal 37 to the signal on terminal 39 for producing an indication on meter 43 of the percent oxygen saturation of blood in the patients ear. The relative gain of the detectors and the values of the resistors 59-69 may be set initially by conducting

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	actual tests on ear tissue-containing blood at various known values of oxygen saturation and by computing the resistor values required to produce meter indications from the logarithmic outputs 29, 31 and 33 which correspond to the known values of oxygen saturation. Thereafter, the meter 43 provides an accurate indication of percent oxygen saturation of blood in the ear 15 of a patient simply upon attachment to the ear is of a test appliance which includes the radiation sources l0, l2 and 14 and the detectors 47, 49 and 51. Thus, by continuously combining the logarithms of the radiation transmissions through blood in the patients ear 15 at least three wavelengths, the Beer's law relationship between radiation absorption and the concentration of oxyhemoglobin present in the total concentration of hemoglobin is determined under all test conditions as they may vary from patient to patient or with movement of the test appliance on the ear of a particular patient."). Shaw, 4:20-59 ("In another embodiment of the test appliance, as shown in the sectional side view of FIG. 3(a) and the schematic front view of FIG. 3(1)), a selected body part 80, say, the forehead of a patient or other container of the blood sample is illuminated on the same side that the radiation is detected on. A wide-area diffused light source is provided by a plurality of light sources 91, either incandescent lamps or electroluminescent diodes, uniformly spaced behind an annular diffusing screen 93 surrounding a small-area detection aperture 95. Each of the three or more diode detector elements 47, 49 and 51 is disposed behind the aperture 95 to receive the radiation which emanates only from the selected body part 80 within a field of view that excludes both the radiation directly from the light source 91 and the reflected radiation from the surface of the selected body part 80. This assures that the diode detectors 47, 49 and 5] respond only to radiation which passed through the blood and skin tissue in the selected body part 80 of the patient. Thus, direct contact with the body part 80 by the radiation source and detector aperture is not essential as long as the field of view of the detectors 47, 49 and 51 does not include either the radiation directly from the light source or the mere reflected radiation from the surface of skin tissue or other container of the blood sample. The light sources 91 may thus be operated in the manner previously described in connection with the system of FIG. I to produce the three or more wavelength determination of percent oxygenation of blood. it should be noted that this arrangement of radiation sources and detectors does not provide true radiation transmission through the blood in skin tissue or other container, as required for the Beers law relationship between concentration of a substance in solution and the radiation transmission through the solution at a selected radiation wavelength. However, in practice the skin tissue of the selected body part 80 and the blood contained therein scatter the radiation so that a small portion of the incident radiation emanates from the part 80 in the region adjacent the radiation source. This scattered radiation

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	is suitably altered or modified by the radiation-absorbing substances in the skin tissue to permit detection and signal processing for producing an indication of percent oxygen saturation within tolerable limits of accuracy."). Shaw, 5:1-12 ("While the preferred embodiment is described above for use in making measurements of oxygen saturation of blood in vivo, it should be noted that the containers for the blood need not be restricted to the tissues of a subject, but may be cuvettes or other containers in which the blood may be present in either a hemolized or nonhemolized form. Also, it should be noted that the concentration of other wavelength-dependent, radiation-absorbing substances than oxyhemoglobin and total hemoglobin (for example, tracer dye) can be determined in accordance with the present invention. Further, the fluid containing the wavelength-dependent, radiation-absorbing substances need not be blood."). Shaw, Claims 1, 2 ("1. Apparatus for determining the oxygen saturation of blood in the tissues of animal bodies in which variations occur in the optical measurement geometry and from which the blood cannot be removed for the purpose of making reference radiation intensity measurements, the apparatus comprising: source means for producing electromagnetic radiation at at first, second and third radiation wavelengths and being disposed to supply incident radiation to the measurement site on the body at the plurality of wavelengths for producing output radiation from the body with intensities at the respective wavelengths that are altered from the incident intensities at such wavelengths by substantially the same conditions of the optical measurement geometry, the body and the blood present therein; detector means for receiving said output radiation at each of said plurality of wavelengths for producing at least three electrical outputs which are representative only of the intensities of the output radiation at the respective wavelengths as altered from the corresponding incident intensities by the condItions of the optical measurement geometry, the body and the blood present therein at the measurement site; and circuit means connected to the detector means to receive the electrical outputs produced thereby in response to said output radiation for simultaneously combining all of said electrical outputs to produce therefrom an indication of the oxygen saturation of the blood present in the body at the measurement site substantially independently of changes in the optical measurement geometry. 2. Apparatus as in claim 1 comprising: radiant-energy diffusing means interposed between said source means and the body for providing radiation thereto diffused over a given area of irradiation; and said

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	detector means includes an aperture of area substantially smaller than said given area of diffused irradiation for receiving said output radiation therethrough from said body.”). Under at least the apparent construction based on Masimo’s Infringement Contentions, Shaw Fantini and/or renders obvious the opening comprising an area smaller than a detection surface area of the at least one detector. For example, Fantini discloses and/or suggests the opening comprising an area smaller than a detection surface area of the at least one detector, implemented as the opening to the Fiber being 3 mm in diameter, and the surface area of the Hamamatsu R928 detector being 13 mm x 24 mm: *See, e.g.*, Fantini at Abstract: **Abstract.** We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit. *See, e.g.*, Fantini at 33:

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	In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition. In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument. *See, e.g.*, Fantini at 34:	

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		Feature 2. The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. *Feature 3.* To implement the measurement of the slopes of the straight lines (as a function of the distance *r* between	

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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of

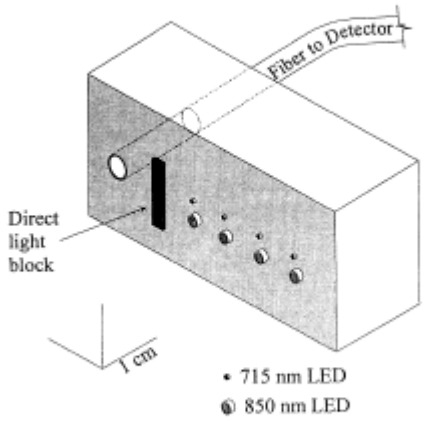


Fig. 2 Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium.

See, e.g., Fantini at 35:

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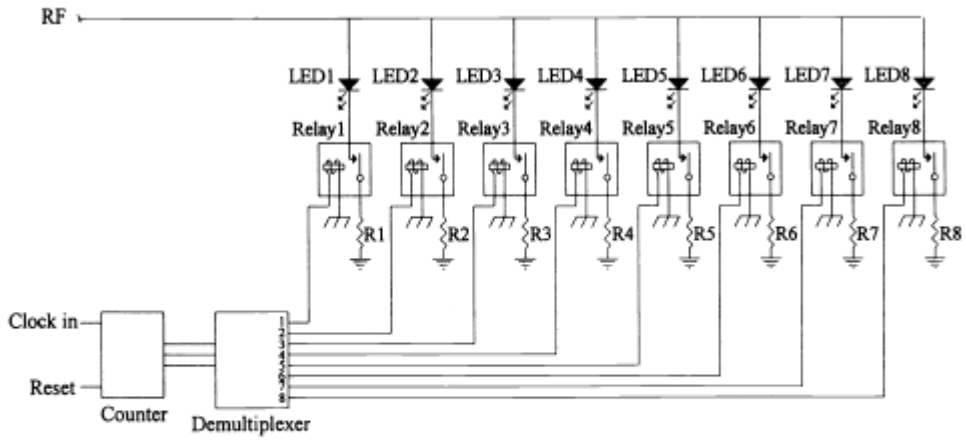


Fig. 3 Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED.

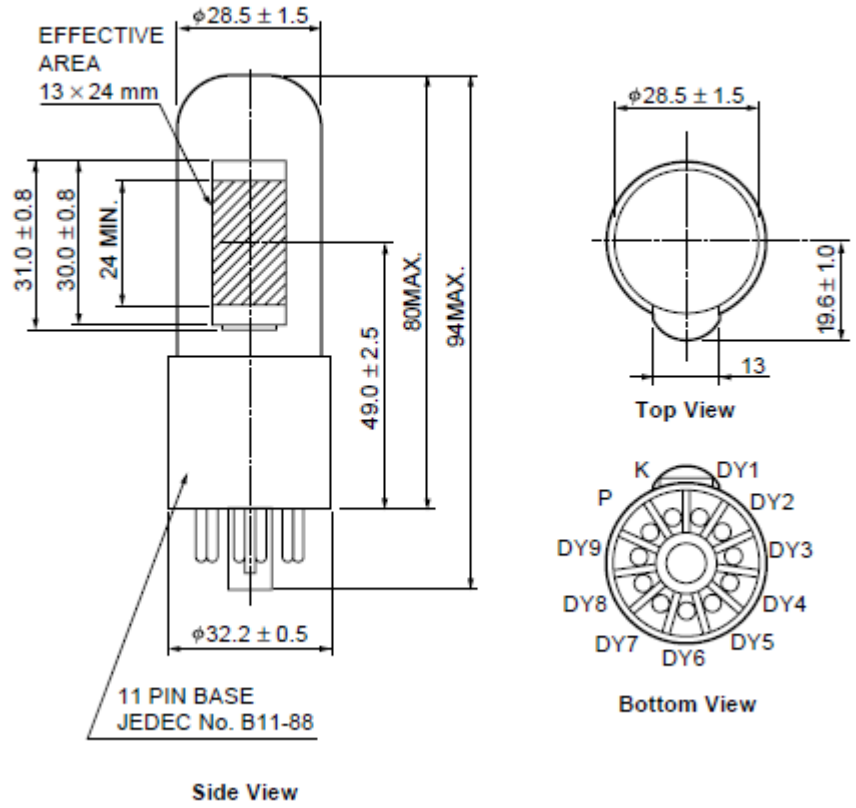
See, e.g., Fantini at 40:

There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas:

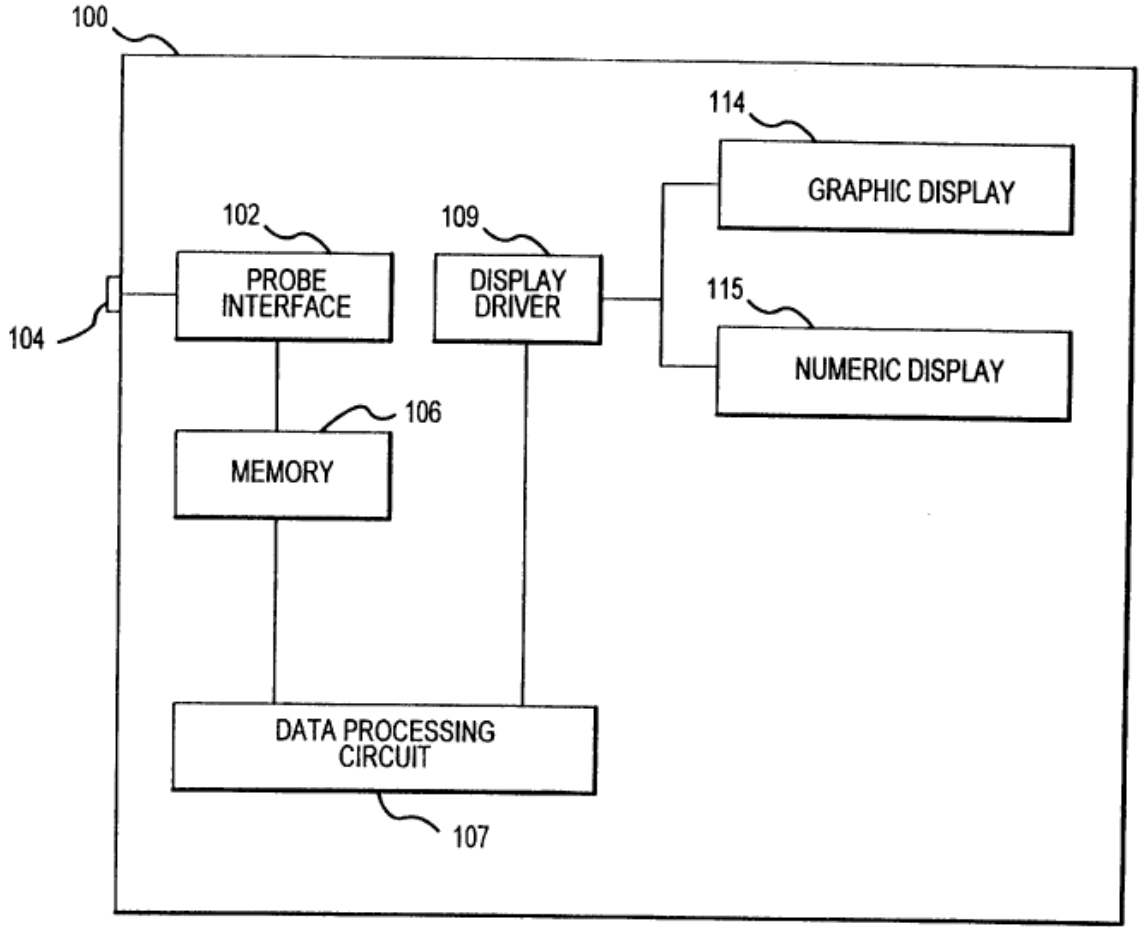
- The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.

See, e.g., Hamamatsu at 2:

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	Figure 4: Dimensional Outline (Unit: mm) 
1[d] a processor configured to receive and process one or more signals responsive to the outputted at least	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signal. For example, Raley discloses and/or suggests a processor such as a data processing circuit that is configured to receive and process one or more signals outputted from a detector that are corresponding to the intensity of

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one signal and determine a physiological parameter of a user responsive to the one or more signals.	light received and determine a physiological parameter of a user responsive such as a blood analyte to the one or more signals: *See, e.g.*, Raley at Fig. 5:  FIG.5

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Fig. 6.

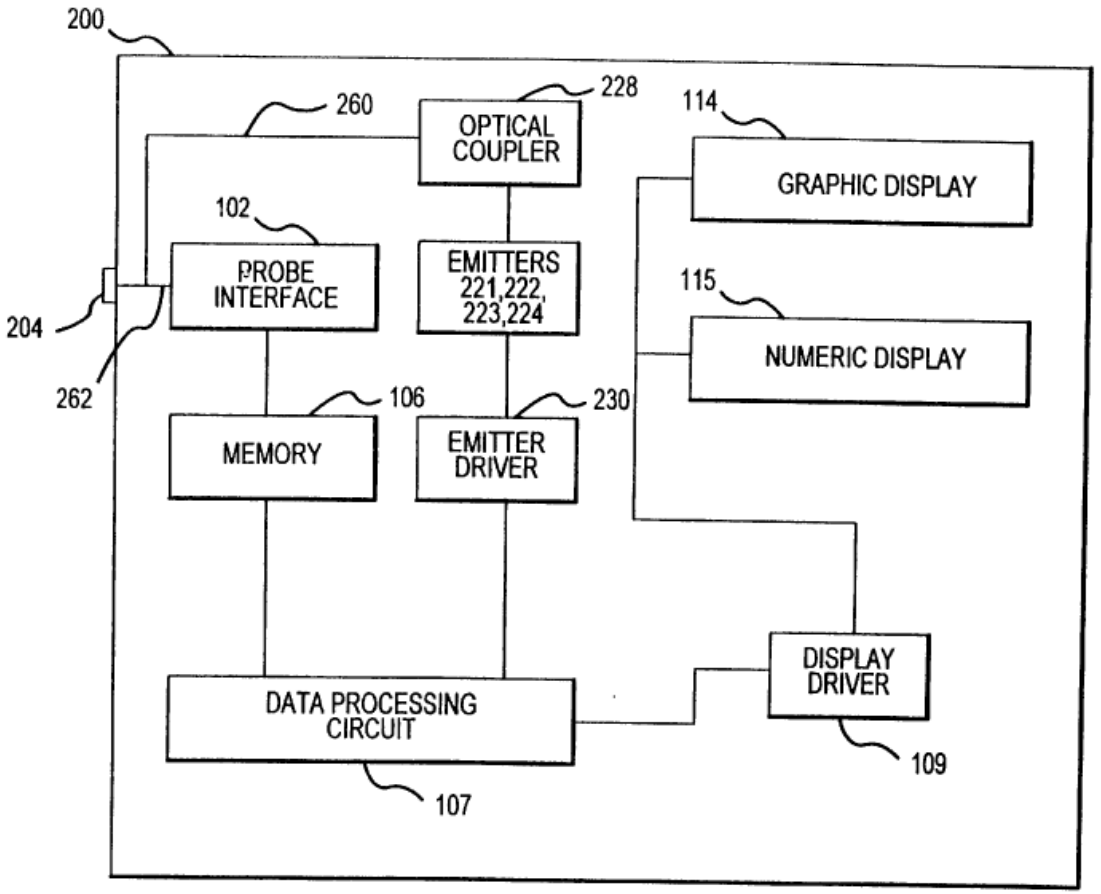


FIG.6

Raley, 4:29-5:15 ("The intensity of light transmitted through the tissue under test is measured by one or more photodetectors 13 which are located in the disposable probe-end 10. Photodetector 13 provides a signal corresponding to the intensity of light received denoted I.sub.λ1, I.sub.λ2, I.sub.λ3 and I.sub.λ4. This signal is then electrically routed back to the monitor 100 through cable 28, plug 42 and

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	socket 104 to the probe interface 102. In the monitor the analog received intensity signals, I.sub.λ1, I.sub.λ2, I.sub.λ3 and I.sub.λ4 are converted into digital signals through a well-known analog to digital (A/D) converter. The intensity signals are then stored in memory 106 and manipulated in data processing circuit 107 of the monitor 100 according to data processing instructions stored in memory 106 and executed by the data processing circuit 107 in order to determine an estimate of the blood analyte levels output as a percentage concentration. Blood analyte levels (output as percentages) may then be displayed via display driver 109 and graphic display 114 and/or numeric display 115. An alternative method of implementing a photoplethysmographic monitor is depicted in FIG. 6 and operates in conjunction with the alternative probe embodiment in FIG. 3b. The emitters 21, 22, 23 and 24 (which may be LED's or laser diodes, but which are preferably laser diodes) are housed in the monitor 200. The emitters 21, 22, 23 and 24 are driven by emitter driver 230 which is controlled by the data processing circuit 107. The emitted light is then combined by an optical coupler 228 and transmitted to the probe 40 by internal optical fiber 260 which is coupled to an optical fiber or other such optically transmissive material (not shown) internal to interconnect cable segment 28. Thus, plug 42 and connector 204 now includes electrical conductors for connecting photodiode 13 back to the probe interface 102 and an optical connector for connecting optical fiber 260 to an optical fiber (not shown) located in cable 28. The light transmitted through the optical fiber 260 and transmitted through the optical fiber located in cable 28, reflects off mirror 29 of FIG. 3b in connector end 25 and passes through window or opening 26 and window 16 in probe-end 10 and impinges on the tissue of the patient. Transmitted light is received by photodetector 13 which send an electrical signal back to the probe interface 102 through the electrical conductors in cable 28 and electrical pathway 262 in monitor 200. The probe interface 102 converts the analog signal to a digital signal and transmits the signal to memory 106 and on to data processing circuit 107 for processing and display of blood analyte concentration values using graphic display 114 and numeric display 115 driven by display driver 109. The transmission of the emitted light can be controlled in a time division multiplexing manner and an optical coupler 228 can be used to provide a means for combining multiple emitters onto one strand of optical fiber 260. Alternatively, the plurality of emitters may be placed or abutted against optical fiber 260.”).
Claim 2	**Prior Art**

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2. The device of claim 1, wherein the at least three LEDs comprises at least eight LEDs.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 1. *See, e.g.*, Claim 1. Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Moyle discloses and/or suggests where more wavelengths of light, and correspondingly more LEDs, may be used to measure more physiological parameters: *See, e.g.*, Disclosure for Moyle for claim limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood: *See, e.g.*, Allen at Abstract ("Methods and systems are provided that extend the functionality of electro-optical sensors. A device has a multiple light sources, a light detector, and a processor configured to operate the light sources and the light detector to perform distinct functions. At least one of the distinct functions includes a biometric identification function in which light is propagated from the plurality of light sources through presented material. The propagated light is received with the light detector, with the presented material being identified from the received light. Another of the distinct functions includes a nonidentification function performed with the light sources and the light detector."). Fig. 1.

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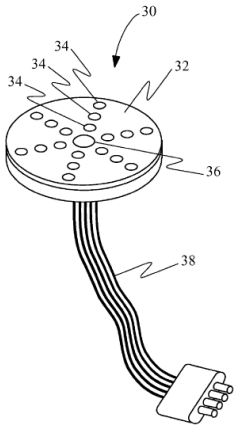


FIG. 1

Fig. 2.

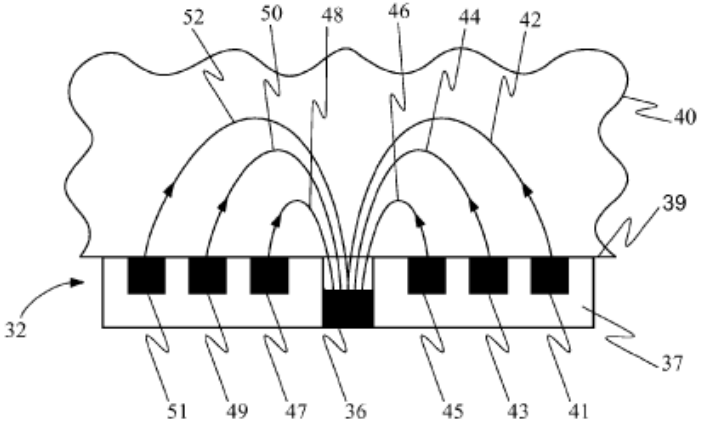
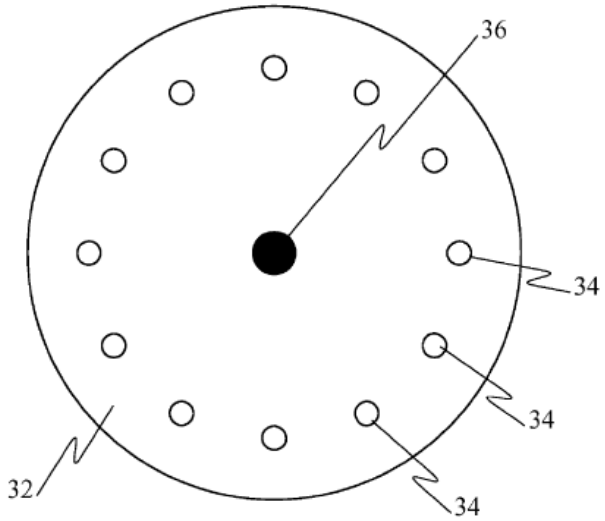


FIG. 2

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	Fig. 4.  **FIG. 4** Fig. 5.

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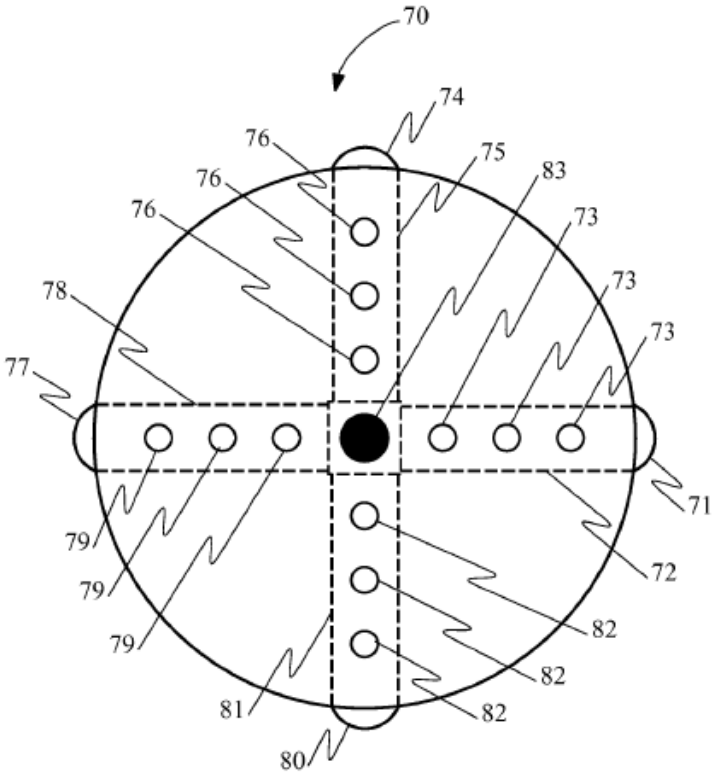


FIG. 5

Fig. 8A.

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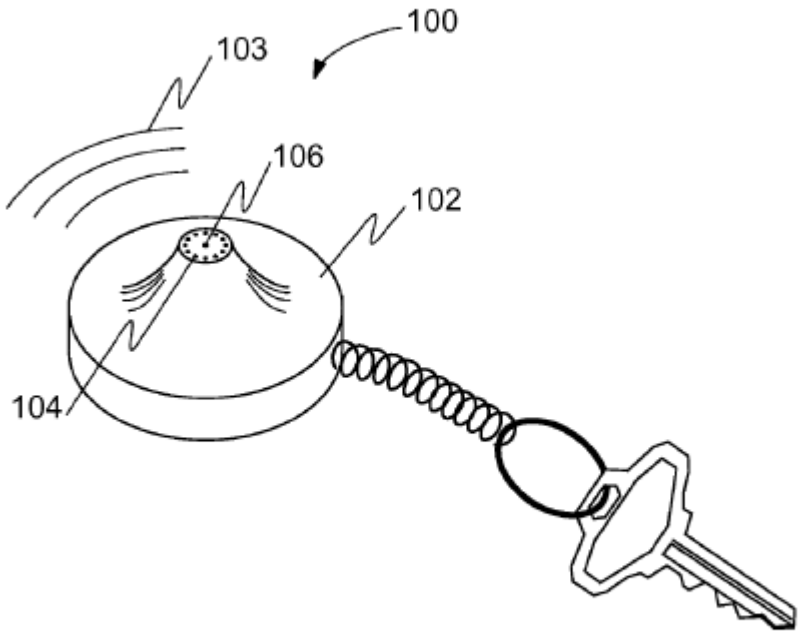


FIG. 8A

Fig. 8B.

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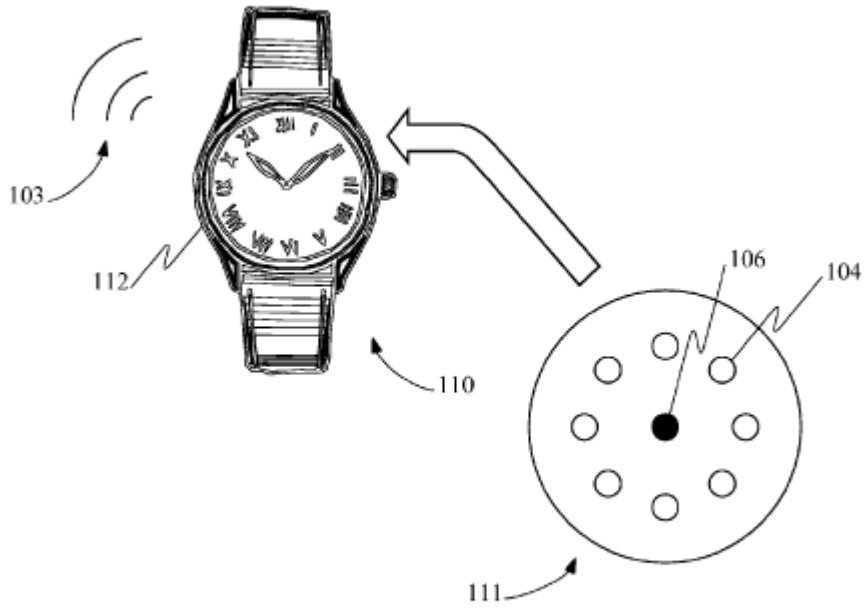


FIG. 8B

Allen, 5:30-6:5 (“Embodiments of the invention are based on the recognition that an accurate, precise, and repeatable tissue spectrum of an individual in certain electromagnetic wavelength ranges contain spectral features and combinations of spectral features that are unique to the individual. In some embodiments, the wavelength ranges comprise the ultraviolet, visible, very-near-infrared, or near-infrared ranges, or combinations of these ranges. In addition, embodiments of the invention recognize that analysis, such as with discriminant-analysis techniques, can identify these unique features or combinations, which may not be readily apparent in visual analysis of a spectral output, so that an individual's identity may be determined by comparison of tissue spectral data taken at the time of use and compared to stored tissue spectral data from prior measurement.

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	In addition, the tissue spectrum has been found not only to contain information that is unique to an individual, but also to contain numerous features and combinations of features that indicate whether such spectral samples were taken while the sample was alive or not. The physiological effects that give rise to spectral features that indicate the "liveness" state of a sample, i.e. whether it is alive or dead, include, but are not limited to blood perfusion, temperature, hydration status, glucose and other analyte levels, and overall state of tissue decay. Thus, the biometric identification and verification methods of the present invention may also be used in conjunction with, or separately from, the determination of the state of the liveness of the tissue. Tissue from other biological systems, such as organs, animals, etc., has also been found to have spectral characteristics that are distinctly different from human skin due to differences in the tissue composition and form. Thus, the biometric identification methods of the present invention may also be used in conjunction with or separately from the determination of whether the sample is human skin or some other tissue. In addition, it has been found that tissue-like substances such as collagen gelatin, latex, water solutions, or others that have been used to attempt to spoof various biometric sensors have spectral characteristics that are distinctly different that human tissue due to differences in composition and form. The biometric identification and verification methods of the present invention can thus be used with or separately from the determination whether the sample is actual tissue or some other substance."). Allen, 6:20-7:53 ("Referring now to FIG. 1, a perspective view of an embodiment of a typical optical sensor head in one embodiment is shown. The sensor assembly **30** comprises a plurality of light sources **34** arranged in a selected manner on a sensor head **32**, which also contains one or more detectors **36**. The sensor assembly **30** may also include power conditioning electronics (not shown) that supply power to the light sources **34** and may also include signal processing electronics (not shown) that amplify the resulting signal from the detector **36**. A multiconductor cable **38** provides a means to power the sensor head and to transmit the detected signal back to a microprocessor or computer (not shown) that processes the spectral data. Alternatively, the power and/or signals to and from the sensor head can be achieved by a direct connection to the supporting electronics or through a variety of electrical interconnects such as PC boards, backplanes, wirebonds, IC connectors, as well as a variety of wireless connections including RF and optical. The light sources **34** may comprise light emitting diodes ("LEDs"), laser diodes, vertical cavity surface emitting lasers ("VCSELs"), quartz tungsten halogen incandescent bulbs with optical pass-band filters

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	which may optionally include optical shutters, or any of a variety of other optical sources known in the art. The light sources **34** can each have the same wavelength characteristics or can be comprised of sources with different center wavelengths in a spectral range from about 300 nm to about 10,000 nm. In general, the collection of light sources **34** can include some sources that have the same wavelengths as others and some sources that are different. In one embodiment, the light sources **34** includes sets of LEDs, laser diodes, VCSELs, or other solid-state optoelectronic devices with differing wavelength characteristics that lie within the spectral range from about 350 nm to about 1100 nm. The detector **36** may comprise a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements. The detector type and material is chosen to be appropriate to the source wavelengths and the measurement signal and timing requirements. These detectors can include PbS, PbSe, InSb, InGaAs, MCT, bolometers and micro-bolometer arrays. In one embodiment where the light sources **34** are solid-state optoelectronic devices operating in the spectral range from about 350 nm to about 1100 nm, a suitable detector material is silicon. The light sources **34** can be sequentially illuminated and extinguished to measure the tissue properties for each source by turning power to each of them on and off. Alternatively, multiple light sources **34** can be electronically modulated using encoding methods that are known to one knowledgeable in the art. These encoding patterns include Fourier intensity modulation, Hadamard modulation, random modulation, and other modulation methods. FIG. 2 shows a cross-sectional view of the sensor head **32** of FIG. 1, for use in diffuse reflectance measurements. Also shown is tissue **40** in contact with the face **39** of the sensor head **32** and the mean optical paths **42**, **44**, **46**, **48**, **50**, **52** of the light traveling from each light source **41**, **43**, **45**, **47**, **49**, **51**, respectively, to the detector **36**. In acquiring tissue spectral data, measurements can be made in at least two different sampling modes. The optical geometry illustrated in FIG. 2 is known as diffuse reflectance sampling geometry where the light sources and detector lie on the same side of the tissue. An alternative method is known as transmission sampling, wherein light enters a thin tissue region such as an earlobe or a fingertip on one side and then is detected by a detector located on the other side of the tissue. Although light in such regions as the silicon-region can penetrate tissue to significant depths of one centimeter or more, depending upon the wavelength, transmission sampling of the tissue limits the region of the body that can be used. Thus, while either mode of

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	sampling is within the scope of the present invention, and especially to analysis utilizing light in the silicon-region, a more versatile sampling method is based upon reflected light. Referring to FIG. 2, when the tissue is illuminated by a particular light source **41**, the resulting signal detected by detector **36** contains information about the tissue optical properties along a path between the source **41** and detector **36**. The actual path of any given photon is highly erratic due to effects of optical scattering by the tissue, but the mean optical path **42** is a more regular and smooth curve, as shown in the figure. This mean optical path is, in general, different for different source-detector separation distances. If another light source **51** is located at the same distance from the detector **36** as light source **41** and the two light sources have the same wavelength characteristics, the resulting signals can be processed as separate elements or can be combined to increase the resulting signal-to-noise ratio of the measurement. If light source **51** has a different wavelength characteristic than light source **41** then, in general, the resulting signals provide unique and useful information about the tissue optical properties, especially as they relate to spectral biometric determinations and may be analyzed as distinct data points. In a similar manner, if two light sources have the same wavelength characteristics and are positioned at different distances from the detector **36** (for example light sources **41** and **43**) then the resulting information in the two signals is different and the measurements may be recorded and analyzed as distinct data points. Differences in both wavelength characteristics and source-detector separation provide useful information about the optical characteristics of the tissue **40**."). Allen, 19:14-50 ("In some instances, the physiological state of an individual may be defined by concentration of a substance in the individual's tissue. For instance, the extended functionality may comprise a hemoglobin monitor. Similar to the effects of stress, increased activity levels in individuals as well as certain medical conditions are manifested by changes in blood flow in the body. Such changes in blood flow cause spectroscopic changes that may be detected according to the methods described above. According to this embodiment, these spectroscopic changes are correlated with oxygenation and/or hemoglobin levels in the blood. In addition to medical uses, the ability to quantify oxygenation levels is useful for individuals in monitoring exercise levels. Spectroscopic changes associated with different physiological states in human tissue may also result from the release of certain pigments in response to pathological conditions. One example is provided

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	by bilirubin, which is a reddish bile pigment that is released when liver tissue is diseased. The presence of the pigment causes a jaundicing of the affected person's skin. Such changes in skin color may be identified using the methods described above. Accordingly, in one embodiment, an extended functionality of the biometric sensor allows it to function as a bilirubin monitor. In other embodiments, levels of other pigments may similarly be monitored. The presence of toxic substances in an individual's blood may also manifest itself spectroscopically because of the effect such toxins have on vascularity as well as a direct spectroscopic signature in certain cases. For example, increases in alcohol levels result in spectroscopic changes that may be observed, particularly in the infrared portion of the electromagnetic spectrum. Thus, a further extended functionality of the biometric sensor permits it to function as an alcohol monitor. In other embodiments, the levels of other toxins and/or drugs may be similarly monitored.”). Allen, Claims 1, 8, 12 (“1. A device comprising: a plurality of light sources, wherein at least two of the plurality of light sources provide light with distinct wavelengths; a light detector, wherein the distance between the light detector and at least one of the plurality of light sources is different than the distance between the light detector and another of the plurality of the light sources; and a processor configured to operate the light sources and the light detector to perform a plurality of distinct functions, wherein at least one of the distinct functions comprises a biometric identification function comprising: propagating light from the plurality of light sources into presented material, and diffusely reflecting the propagated light toward the light detector; receiving the diffusely reflected light with the light detector; and

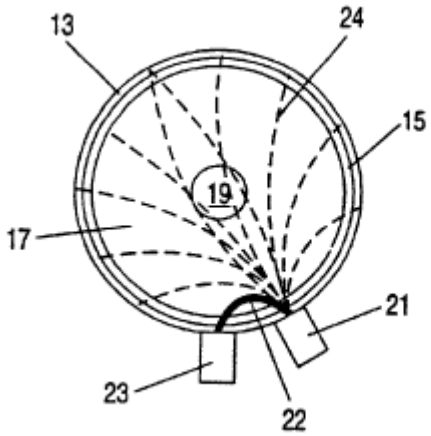
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	identifying the presented material from the received light based on the wavelength characteristics of the received light and the distance between the source and the detector; and wherein another of the distinct functions comprises a nonidentification function performed with the light sources and the light detector. 8. A portable electronic device comprising: an electronic arrangement for performing a standard function of the portable electronic device; a biometric sensor having: a plurality of light sources, wherein at least two of the plurality of light sources provide light at distinct wavelengths; and a light detector disposed relative to the light sources to detect light from the light sources that has propagated through tissue, wherein the distance between the light detector and at least one of the plurality of light sources is different than the distance between the light detector and another of the plurality of the light sources; and a processor configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor in accordance with the following: propagating light from the plurality of light sources into presented material, and diffusely reflecting the light toward the light detector; receiving the diffusely reflected light with the light detector; and identifying the presented material from the received light based on the wavelength characteristics of the received light and the distance between the source and the detector.

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	12. The portable electronic device recited in claim 11 wherein the spectrometer function is selected from the group consisting of a stress-detection function, a lie-detector function, a tanning-meter function, a complexion-monitor function, a toxicity-monitor function, an alcohol-monitor function, a bilirubin-monitor function, a hemoglobin-monitor function, a fruit-ripeness-monitor function, a counterfeit-document detection function, and a color-match function."). Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where LEDs are used each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound: *See, e.g.*, Disclosure for Raley for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs: For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths. *See, e.g.*, Robinson at Abstract ("An improved method and apparatus for determining noninvasively and in vivo one or more unknown values of a known characteristic, particularly the concentration of an analyte in human tissue. The method includes: (1) irradiating the tissue with infrared energy (400 nm-2400 nm) having at least several wavelengths in a given range of wavelengths so that there is differential absorption of at least some of the wavelengths by the tissue as a function of the wavelengths

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	and the known characteristic, the differential absorption causeing intensity variations of the wavelengths incident from the tissue; (2) providing a first path through the tissue; (3) optimizing the first path for a first sub-region of the range of wavelengths to maximize the differential absorption by at least some of the wavelengths in the first sub-region; (4) providing a second path through the tissue; and (5) optimizing the second path for a second sub-region of the range, to maximize the differential absorption by at least some of the wavelengths in the second sub-region. In the preferred embodiment a third path through the tissue is provided for, which path is optimized for a third sub-region of the range. With this arrangement, spectral variations which are the result of tissue differences (e.g., melanin and temperature) can be reduced. At least one of the paths represents a partial transmission path through the tissue. This partial transmission path may pass through the nail of a finger once and, preferably, twice. Also included are apparatus for: (1) reducing the arterial pulsations within the tissue; and (2) maximizing the blood content in the tissue."). Fig. 9A.  FIG 9A Fig. 9B.

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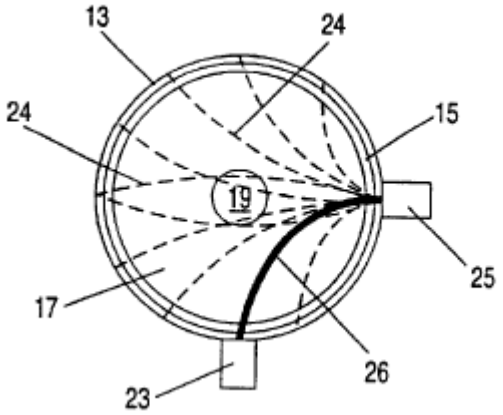


FIG 9B

Fig. 9C.

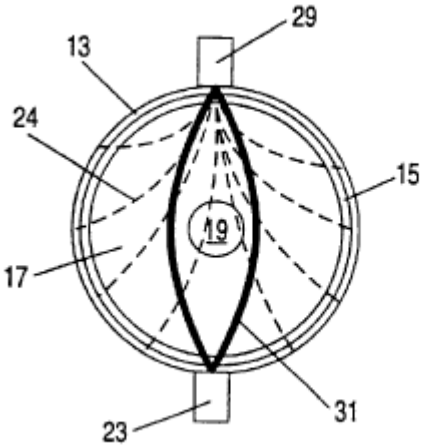


FIG 9C

Fig. 12.

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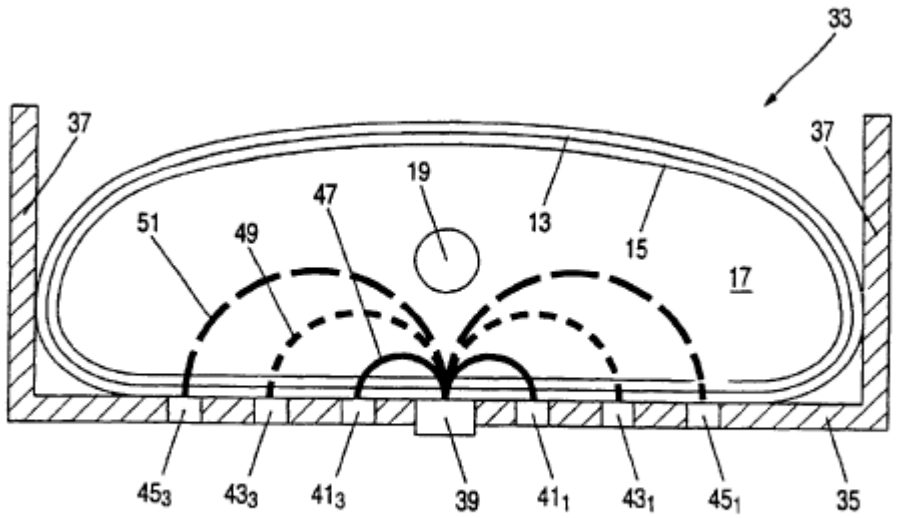


FIG 12

Fig. 13.

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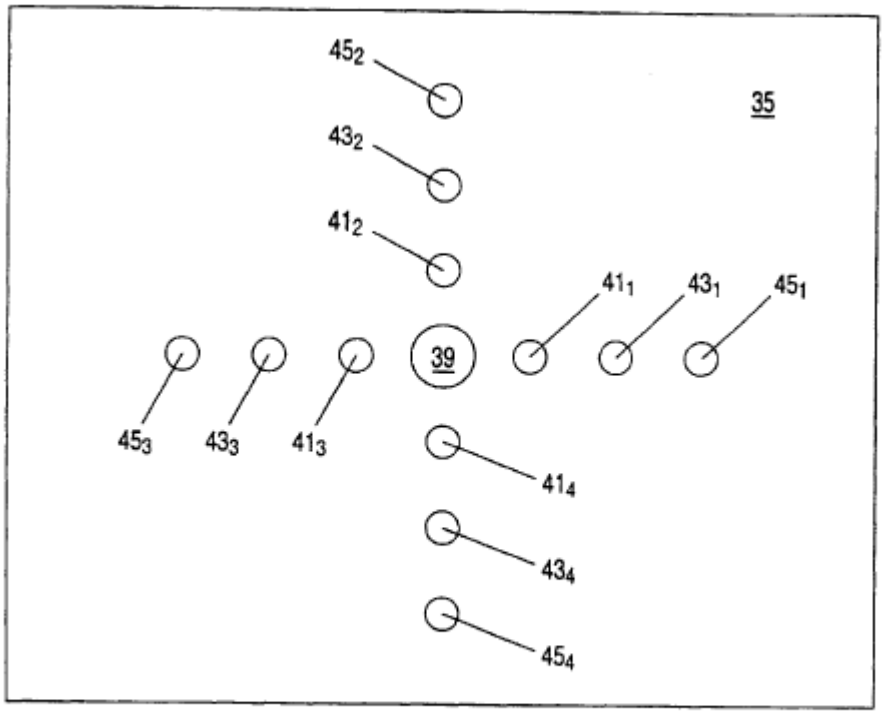


FIG 13

Fig. 34.

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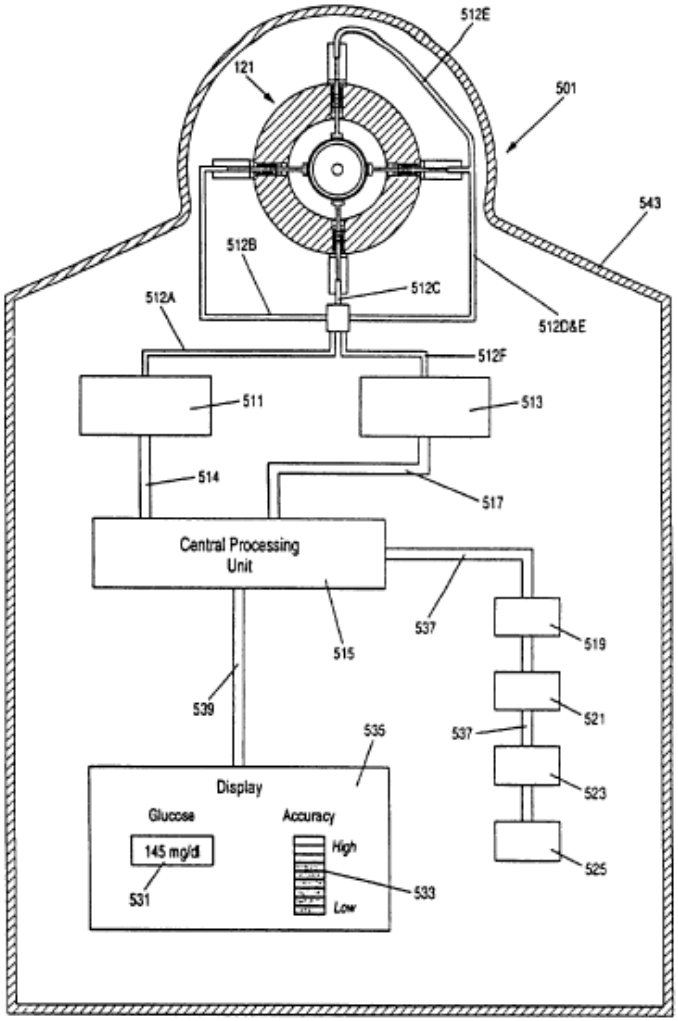


FIG 34

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	Robinson, 1:12-18 ("The present invention relates to a robust, accurate non-invasive analyte monitor, particularly to a reliable instrument (and associated methodology) for the measurement of glucose levels in a human in both clinical and at home situations. Other analytes which can also be measured include alcohol, BUN (blood urea nitrogen), bilirubin, hemoglobin, creatine, cholesterol, and electrolytes."). Robinson, 1:63-2:11 ("Although glucose absorbs at multiple frequencies in both the mid and near infrared, there are other infrared active analytes in the blood which also absorb at similar frequencies. Due to the overlapping nature of these absorption bands no single or specific frequency can be used for reliable noninvasive glucose measurement. Analysis of spectral data for glucose measurement thus requires evaluation of many spectral intensities over a wide spectral range to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination. This is also true for other blood analytes. In addition to overlapping absorption bands, measurement of glucose is further complicated by the fact that glucose is a minor component by weight in blood and that the resulting spectral data may exhibit a nonlinear response due to both the properties of the substance being examined and/or inherent nonlinearities in optical instrumentation."). Robinson, 4:22-34 ("To demonstrate the utility of using multiple wavelength regions a simple experiment was performed. A set of cuvette samples containing water, urea, and glucose were optically sampled over the entire wavelength region from 700 to 2400 nm. The optical pathlength used for data acquisition was 1 cm in the 700 to 1400 nm range and 1 mm in the 1400 to 2400 nm range. The change in pathlength was necessitated due to differences in the absorbance of water in given wavelength regions, the importance of which is discussed at length in the Description of the Preferred Embodiments. The resulting spectra was processed using four different wavelength ranges. The results are shown in Table I below."). Robinson, 4:48-55 ("Thus, it is clear that the inclusion of information from all wavelength regions containing glucose information improves the accuracy of the optical measurement. Therefore, it is an object of the present invention to provide for a tissue sampling device and associated instrumentation which enables use of spectral information from, in the case of glucose, the entire wavelength region from 700 to 2400 nm."). Robinson, Table 1:

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TABLE I

Wavelength Region	# of wavelengths used in 700–1100 nm	# of wavelengths used in 1100–1400 nm	# of wavelengths used in 1400–2000 nm	# of wavelengths used in 2000–2400 nm	Total number of wavelengths used	Standard error of prediction
700–1100 nm	7	N/A	N/A	N/A	7	18.1
700–1400 nm	6	2	N/A	N/A	8	12.2
700–2000 nm	4	4	6	N/A	14	10.4
700–2400 nm	3	7	8	5	23	5.83

Robinson, 10:36-47 ("In general the preceding instruments are based on dispersion of a broadband light source with subsequent detection of the separated wavelengths. The quantitative measurement of blood analytes can be performed by the use of a discrete number of wavelengths. Specifically, glucose has been measured in vitro solutions composed of glucose, urea, alcohol and water through the use of 20 discrete groups of contiguous wavelengths. Thus, the use of sources that emit in a narrow wavelength region could be used in combination for analyte measurement. Specifically light emitting diodes (LEDs), laser diodes, or tunable lasers could be used for the noninvasive measurement of blood analytes.").

Robinson, 14:6-15:19 ("As discussed in relation to in FIG. 6 supra, the relative pathlength varies considerably depending upon the wavelength of light used. FIGS. 9A, **9**B and **9**C illustrate three alternate sampling configurations which optimize the pathlength relative to the wavelength(s) selected. As those skilled in the art will appreciate, the relative positioning of the source and detector on finger/thumb **11** will influence the internal volume of tissue sampled spectrophotometrically. In FIG. 9A the source **21** and detector **23** are placed relatively close to one another. Thus, the average optical pathlength **22** travelled by the sampled light (via partial transmission) is quite short. Dashed lines (e.g., 24) represent some of the theoretical paths followed by light emitted by a point source placed against finger/thumb **11**. If, in the case of glucose, optical information is desired in the 2000 nm region or longer, then the average optical pathlength **22** should be in range of 0.5-3 mm. In addition to the 2000-2400 region, this optical sampling configuration enables measurement of spectral data over the entire wavelength region from 700 to 2400 nm. In FIG. 9A the internal volume sampled will be relatively small, consisting of the epidermis **13** and dermis **15** and the outermost portions of the subcutaneous tissue **17**.

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	Although the sampling configuration in FIG. 9A enables sampling of spectral data from 700 to 2400 nm, the spectral data acquired in the 700-1400 nm region is not acquired under optimal conditions. Given similar signal-to-noise ratios, spectral data in the 700-1400 nm range, obtained by the sampling geometries illustrated in FIGS. 9B and 9C, will contain more analyte information than spectra obtained from the geometry illustrated in FIG. **9**A. With similar intensity values at the detector, the information content of the spectra from FIG. 9A is less, due to the fact that a smaller portion of the internal volume of finger/thumb **11** is sampled by the light. In the configuration shown in FIG. 9A, 100% of the light is not forced to transverse the greater distances illustrated by FIGS. 9B and 9C and, thus, does not contain as much information from the deeper subcutaneous tissue. In FIG. 9B the detector **23** and source **25** are separated by a greater distance and the resulting average partial transmission pathlength **26** is longer. If the average pathlength **26** is assumed to be in the range of 3-7 mm, then the amount of light successfully transversing this distance with wavelengths longer than 2000 nm will be negligible in comparison to those which transverse a 0.5-3 mm pathlength. However, this pathlength represents a reasonable pathlength for light in the region from 1400 to 2000 nm, and also enables measurement of wavelengths below 1400 nm. FIG. 9C depicts a transmission measurement through finger/thumb **11**. The finger thickness of an average individual is, approximately, 1 cm. The influence of the bone in transmission is poorly understood and, thus, the ray tracings go around the bone for simplicity. The resulting optical information received by detector **23** from source **29** will be in the wavelength region from 700 to 1400 nm. The spectral information above 1400 nm will be negligible due to water absorbance at these longer wavelengths. The geometric configurations shown in FIGS. 9A, **9**B and **9**C enable procurement of optimal spectral data for glucose in each wavelength region (i.e. 700 to 1400, 1400 to 2000, and 2000 to 2400) in the best possible manner. For clarification the spectral range of interest is divided into 3 regions: Region **1** from 700-1400 nm; Region **2** from 1400-2000 nm; and Region **3** from 2000-2400 nm. FIGS. 10A, **10**B and **10**C are plots showing the spectral regions that can be recorded by each of the three source-detector configurations. FIG. 10A is the spectral data which can be recorded using the source-detector configuration shown in FIG. **9**A. As previously described, the configuration shown in FIG. 9A can sample all three regions as shown in FIG **10**A. FIG. 10B depicts the spectral data obtained

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	when using the optical configuration illustrated in FIG. 9B, which spectral data is in Regions **1** and **2**, but not in Region **3**. FIG. 10C shows the spectral data generated by using the optical configuration shown in FIG. **9**C. In this case, useful spectral information is available only in Region **1**. FIG. 11 is a plot of the resulting spectra from the source detector arrangements illustrated in FIGS. 9A, **9**B and **9**C. The resulting spectra contains the maximal amount of analyte information due to optimization of sampling path in each of the three wavelength regions."). Robinson, 16:15-34 ("With reference to FIGS. 12 and 13, finger/thumb holder **33** includes a bottom plate **35** and a pair of guide rails **37**. Positioned substantially in the center of plate **35** is a detector **39** and a plurality of sources **41** 1-4, **43** 1-4 and **45** 1-4. The average light path from sources **41** 1-4 to detector **39** is approximated by path **47**; from sources **43** 1-4 to detector **39**, by path **49**; and from sources **45** 1-4 to detector **39**, by path **51**. As was illustrated in FIGS. 9A, **9**B and **9**C, the optical sampling of the body part must maximize and compensate for the optical propagation characteristics of different wavelengths. In FIG. 12 light path **47** represents an optical pathlength of 0.5-3 mm, which is the same pathlength as illustrated in FIG. **9**A. Light path **49** is similar to that shown in FIG. 9B, and light path **51** is similar to that shown in FIG. **9**C. In either sampling geometry the relationship between the source and detector determines the length of the optical path and the depth of the internal volume sampled. For each distance a plurality of light sources is used to increase the intensity at detector **39**, and to reduce the total measurement time."). Robinson, 17:65-18:11 ("Due to the fact that not all wavelengths need to be recorded and the fact that relatively small number (e.g. 20) will produce good measurement results, a discrete set of light emitting diodes (LEDs) can be utilized instead of broadband sources such as 101 a of FIGS. 17 and 17A. Currently, LEDs are commercially manufactured in the wavelength region from 400 to approximately 1550. However, in the future, diodes will likely become commercially available over the entire spectral region from 400 to 2400 nm. As LEDs emit wavelengths with a narrow bandwidth (i.e., typically less than 10 nm) further dispersion of the spectra is not necessary. As further dispersion is not necessary a simple inexpensive detector or multiple detectors can be used to record the various wavelength intensities."). Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LED.

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	For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nogawa for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments as four, five, and six separate emitters relying on different wavelengths, where relying on any number of additional wavelengths (and thereby LEDs) beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy: *See, e.g.*, Disclosure for Jarman for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under

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	the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].
Claim 3	**Prior Art**
3. The device of claim 2, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 2. *See, e.g.*, Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood, and where the at least eight LEDs comprise at least two LEDs of the same wavelength, including where the LEDs can include some LEDs that have the same wavelength and some sources that are different: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector,

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	where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths: *See, e.g.*, Disclosure for Robinson for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nagawa for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood

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	parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].
Claim 4	**Prior Art**
4. The device of claim 1, wherein the at least three LEDs comprises at least twelve LEDs.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 1. *See, e.g.*, Claim 1. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Moyle discloses and/or suggests where more wavelengths of light, and correspondingly more LEDs, may be used to measure more physiological parameters: *See, e.g.*, Disclosure for Moyle for claim limitation 1[a].

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where LEDs are used each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound: *See, e.g.*, Disclosure for Raley for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths: *See, e.g.*, Disclosure for Robinson for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs: For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement

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	artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nogawa for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments as four, five, and six separate emitters relying on different wavelengths, where relying on any number of additional wavelengths (and thereby LEDs) beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy: *See, e.g.*, Disclosure for Jarman for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].

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Claim 5	**Prior Art**
5. The device of claim 1, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 1. *See, e.g.*, Claim 1. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein at least two LEDs of the at least three LEDs are configured for concurrent activation. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood, and where the at least eight LEDs comprise at least two LEDs of the same wavelength, and where LEDs of the same wavelength can be activated concurrently in order to combine the strength of the signal at that wavelength so as to allow for those signals to be combined to increase the resulting signal-to-noise ratio of the measurement: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein at least two LEDs of the at least three LEDs are configured for concurrent activation. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision,

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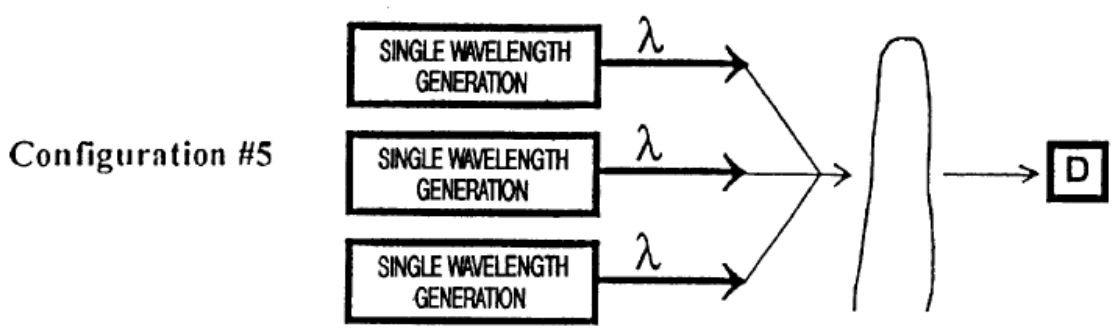
	accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths, and where at least two LEDs are configured for concurrent activation, including where half of the total number of single wavelength emitting devices are energized concurrently for a measurement observation: *See, e.g.*, Disclosure for Robinson for Claim 2. *See also* Robinson, 10:48-11:25 ("As the time required to make the measurement is an important parameter, any instrument recording wavelengths in a multiplex manner is desired. The recording of more than one wavelength during a given time period will result in a multiplex advantage. Optical multiplexing increases the effective signal-to-noise ratio that can be achieved for detector-noise-limited spectroscopic measurements. For example, consider the case of measuring each wavelength intensity one at a time versus measurement of multiple wavelengths on an array detector. Given the same measurement time the signal-to-noise ratio of the array detector will exceed that of the single wavelength measurement device. It is important to recognize that any device having either multiple detectors or sources can acquire data in a multiplex manner. When using LEDs or multiple single element detectors, they can be energized using Hadamard transform techniques. Through Hadamard transform optical coding techniques the (theoretical) signal-to-noise ratio gains at constant observing time when compared with conventional point-by-point image scanning, can be as high as $1/2N^{½}$, where N is the total number of image resolution elements. The principles of Hadamard transformation are explained in the following articles: "Fourier and Hadamard transform methods in Spectroscopy", by A. G. Marshall, et al., *The Journal of Analytical Chemistry* Vol. 47, No. 4, pp 491A-504A, April 1975 and "Hadamard Transform Image Scanning", by J. A. Decker, Jr., *The Journal of Applied Optics,* Vol. 9, No. 6, pp 1392-1395, June. 1970. With Hadamard transform methods, during operation approximately half of the total number of single wavelength emitting devices are energized for a measurement observation. During the second observation a different set of diodes will be energized. The process continues until N (the number of diodes) observations have been made. The end result is N different observations expressed as N linear equations. The solution of these equations yields the specific intensity value associated with each specific diode. Through the Hadamard approach an improvement of a factor of N/2 in signal-to-noise

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ratio over the conventional one-diode-at-a-time measurement is achieved because half the diodes are energized during each observation, rather than just one. Thus, in the preferred embodiment the diodes or detectors may be energized via Hadamard transform optical coding techniques to maximize signal-to-noise ratios for a given measurement time.").

Robinson, 22:25-35 ("FIG. 30 schematically illustrates Configurations **5** and **6**, where the light source is capable of emitting light of a narrow bandwidth and subsequent dispersion of the light is not necessary. Some light sources having these characteristics are light emitting diodes, lasers of all types, and tunable lasers. Although a tunable laser is a single unit, it is considered as multiple sources in this description. FIGS. 18 and 34 illustrate Configuration **6** and describe a noninvasive measurement device incorporating multiple sources and multiple detectors.").

Robinson, Fig. 30, Configuration 5:



Under at least the apparent construction based on Masimo's Infringement Contentions, Mannheimer 842 discloses and/or renders obvious wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.

For example, Mannheimer 842 discloses and/or suggests [relying on multiple LEDs of the same wavelength that are activated concurrently to intensify the signal at a desired wavelength and/or in order to increase the ratio of light transmitted at a desired wavelength to other wavelengths transmitted, and/or to overcome

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interference at the concurrently activated wavelength, such as interference caused by light attenuation by tissue:

See, e.g., Mannheimer 842 at Abstract ("A fetal pulse oximetry probe has clusters of light-transmissive bumps over the light source and the light detector on the surface of the probe. The probe is usually attached to the fetus' head. The clusters part the fetal hair and penetrate other light-attenuating organic materials on the head. The clusters thus transmit a more intense light signal. To reduce the amount of signal shunting between them, the clusters also may be separated by additional opaque (light-shielding) bumps.").

Fig. 1a.

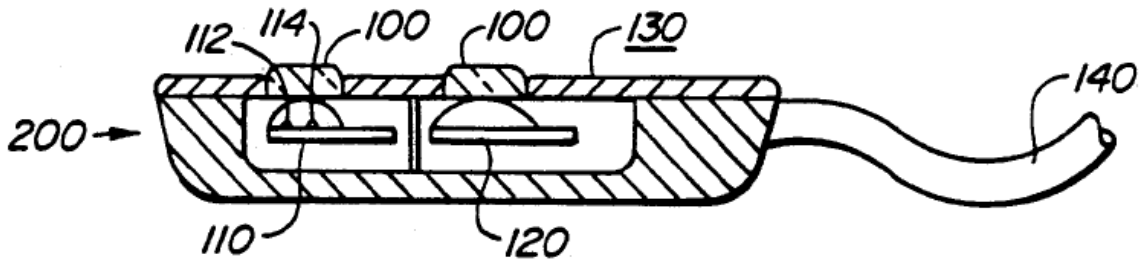


FIG. 1a.

Mannheimer, 842 at 3:4-20 ("As is conventional in pulse oximetry, source 110 provides light of two different wavelengths (red and infra-red). To further intensify the signal, this particular embodiment uses a light source having three light-emitting diodes or "LEDs" (two red LEDs 112, one infrared LED 114) that each generate the necessary red and infra-red wavelengths (660 and 900 nanometers, respectively).

The red wavelength especially is attenuated by darkly pigmented hair. The thickness of the hair also attenuates the signal. Such interference can cause too great a variation in the ratio of red to infra-red signals. The applicants have observed red-to-infrared transmission ratios of 1:4 for lightly pigmented

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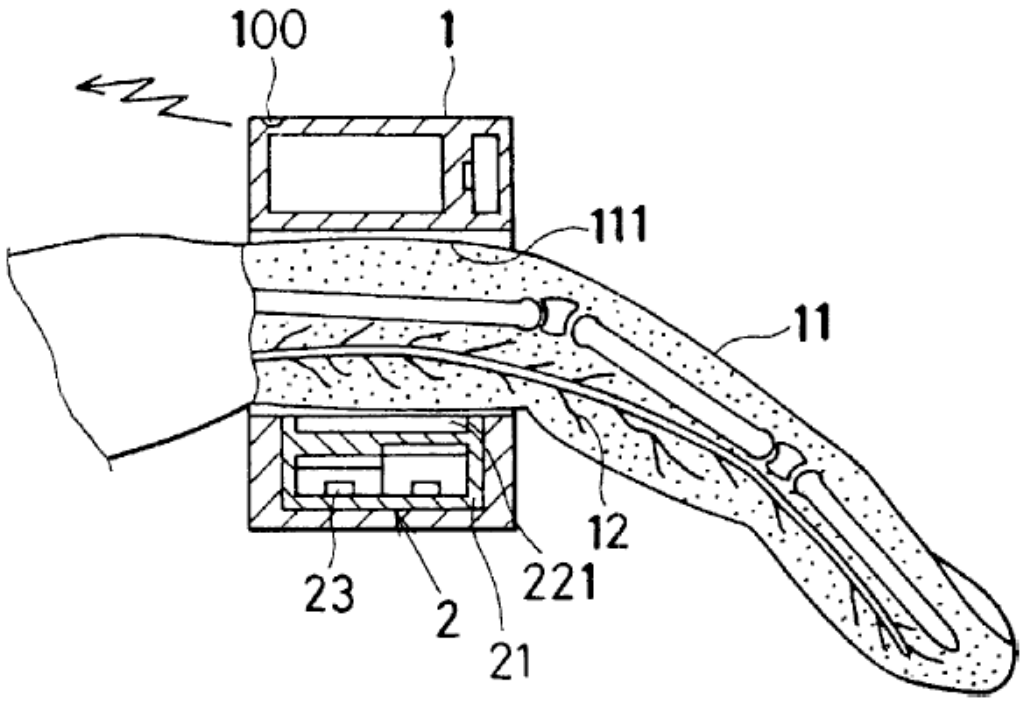
	hair, and as little as 1:150 for darker pigments. Using clusters of bumps to provide a relatively less obstructed path makes the ratio more consistent.”). Under at least the apparent construction based on Masimo’s Infringement Contentions, Nogawa discloses and/or renders obvious wherein at least two LEDs of the at least three LEDs are configured for concurrent activation: For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs that are fired concurrently for each wavelength enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nogawa for Limitation 1[a].
Claim 8	**Prior Art**
8. The device of claim 1, wherein the opening provides an optical path from the tissue to the at least one detector.	Under at least the apparent construction based on Masimo’s Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple’s Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 1. *See, e.g.*, Claim 1. Under at least the apparent construction based on Masimo’s Infringement Contentions, the primary references identified in Apple’s Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious wherein the opening provides an optical path from the tissue to the at least one detector. *See, e.g.*, Exhibits E-1 — E-10.

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Claim 10	**Prior Art**
10[pre] A physiological monitoring device comprising:	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, Kimura discloses and/or renders obvious a physiological monitoring device. For example, Kimura discloses and/or suggest a vital signs detecting apparatus that is capable measuring vital signals such as pulse: *See, e.g.*, Kimura at Abstract ("A vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. The pulse wave detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, Fig. 1A

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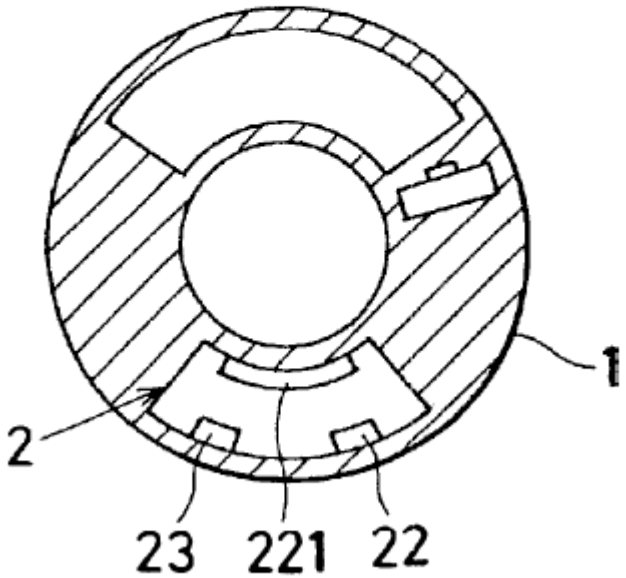
FIG. 1A



Kimura, Fig. 1B.

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FIG. 1B

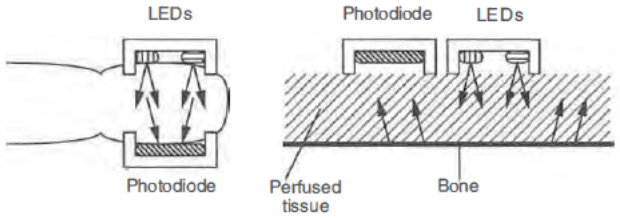


Kimura, 1:46-2:2 ("It is therefore an object of the present invention to provide a vital signal detecting apparatus which eliminates problems caused by abnormal vital signals detected when an attachable device is not attached.

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	According to the present invention, a vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. Preferably, the vital signal detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, Webster discloses and/or renders obvious a physiological monitoring device. For example, Webster discloses and/or suggests pulse oximeter technology relying on LED s and detectors for measuring physiological parameters, where reflectance and transmittance oximeters rely o the same technology: *See, e.g.*, Webster at 36:

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	3.7.4 Probes Improved technology in photodiodes and LEDs has another benefit. They allow the probe to be small and attach to the pulse oximeter with conventional wires. The Hewlett-Packard eight wavelength oximeter was considered an accurate device, but because bulky fiber optic cables were needed to carry the light source to the patient and the transmitted light back to a light sensor, it was impractical (Rebuck *et al* 1983). Probes for the pulse oximeter are not only smaller, but can be disposable. Figure 3.10 shows a transmission pulse oximeter and a reflectance pulse oximeter. As the names indicate, a transmission pulse oximeter measures the amount of light that passes through the tissue as in a finger probe. A reflectance pulse oximeter measures the amount of light reflected back to the probe. Both types use the same technology differing only in positioning of the probes and calibration.  **Figure 3.10** On the left is a transmission pulse oximeter measuring the transmission of light by two LEDs through the finger of a patient. On the right is a reflectance pulse oximeter measuring the amount of light reflected back to the probe.
10[a] at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;	Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths. For example, Moyle discloses and/or suggests relying on different types of LEDs to emit light, where each type of LED emits light of a different wavelength, and where the LEDs relied upon for a pulse oximeter could include three or more LEDs.: *See, e.g.*, Moyle at Pages 16-21, 17-18:

The early generations of pulse oximeters all used similar wavelengths, namely 660 nm (red) and 940 nm (near infrared). However, modern devices, including transmission, reflection and intrauterine pulse oximeters, often make use of other wavelengths. LEDs of 660 nm and 940 nm were originally chosen, as they were wavelengths that were easy to manufacture, but a much greater range of wavelengths is now available (see Box).

Gallium arsenide doping of the semiconductor material of light-emitting diodes to produce specific wavelengths

Ultraviolet	455–350 nm	GaN GaS2
Violet	455–390 nm	GaN
Blue	492–455 nm	GaAs-phosphor (ZnS, SiC)
Green	577–492 nm	GaP:N
Yellow	597–577 nm	GaAs.14P.86
Orange	622–597 nm	GaAs.35P.65
Red	780–622 nm	GaP:ZnO GaAs.6P.4
Near infrared	810 nm	GaAlAs
	880 nm	GaAlAs
	900 nm	GaAs
	940 nm	GaAsSi
	1100 nm	Ga.17In.83As.34P.66
Infrared	1250 nm	Ga.28In.72As.6P.4

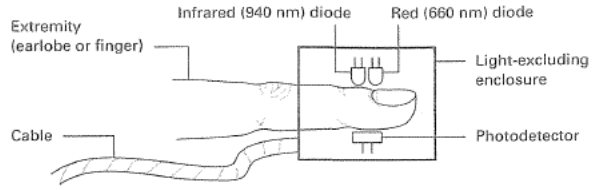


Figure 3.2 Components of transmission pulse oximeter probe.

very little difference to calibration. The advantage of 660 nm as the red wavelength chosen is that there is a comparatively large difference in the absorption between reduced and oxygenated haemoglobin at this point on the spectrum, yielding detectable changes in absorption with small changes in oxygen saturation. Although the curves are not horizontal at 660 nm, they are considerably flatter than at shorter wavelengths.

Moyle at Page 31:

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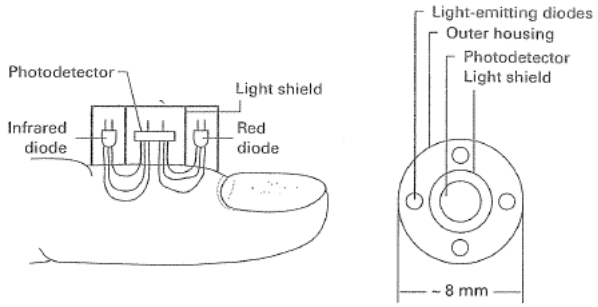


Figure 3.11 Section (left) and plan (right) of reflection oximeter probe.

Reflection pulse oximetry

There are certain advantages in using reflected rather than transmitted light. The design of the probe is simpler, with greater mechanical strength (Figure 3.11).

From a clinical point of view a reflection pulse oximeter has the advantage that it can be used at more sites than the transmission type, for example the forearm, thigh, chest, forehead and cheeks. This means that its saturation readings can be made in patients with poorer perfusion and in those who are hypothermic. The reflection pulse oximeter may prove useful after cardiac bypass surgery, where initially the periphery is very shut down and much cooler than normal. Palve[7] showed that saturation could be measured with a reflection-type probe from a patient's forehead when the fingertip temperature was only 28·8°C. Reflection pulse oximetry works well on ventilated patients who are unconscious, but difficulty with probe

Moyle at Page 36:

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Modern multiwavelength spectrophotometers can measure all four common species of haemoglobin (haemoglobin A, oxygenated haemoglobin, carboxyhaemoglobin, and methaemoglobin). The percentage oxygen saturation of the haemoglobin is now defined as a ratio of the amount of haemoglobin saturated with oxygen to all the four species. This is termed the fractional saturation:

$$\text{Fractional } SaO_2 = \frac{HbO_2}{HbO_2 + Hb + HbCO + MetHb} \times 100\%$$

Ideally, the pulse oximeter should measure either fractional or functional saturation, and the manufacturer should state whether a particular unit has been calibrated as fractional or functional. However, with current pulse oximeters using only two wavelengths, it must be said that pulse oximeters indicate neither functional nor fractional saturation.[4] The conventional two-wavelength pulse oximeter measures the absorption at two wavelengths and applies their ratio to look-up tables, which then indicate a value, SpO_2, which is best defined as *oxygen saturation as measured by a pulse oximeter*.

Moyle at Page 39-40:

variable over the range 500 nm to 700 nm, controlled by an electric (stepper) motor, so that the light emanating from the monochromator can be scanned. This variable wavelength light is passed through the cuvette containing the haemolysed blood. As the monochromator is controlled by a stepper motor, the wavelength is changed in discrete steps. As this CO-oximeter is designed to measure five components (see Box), only five wavelengths are necessary to make the calculations. However, the sample will contain other absorbents, including fetal haemoglobin, bilirubin, and fragments of the erythrocyte membranes, so the AVL 912 uses up to 17 wavelengths. The light emanating from the cuvette after passing through the blood is detected by a photodiode. The signal from the photodiode is amplified, converted from analogue

to digital, and passed to a microprocessor, which makes use of the Beer–Lambert law and simultaneous equations to calculate the values shown in the box.

Under at least the apparent construction based on Masimo's Infringement Contentions, Webster discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths.

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	For example, Webster discloses and/or suggests, for pulse oximetry systems, relying on three LEDs emitting light at three wavelengths in order to measure additional physiological parameters. *See, e.g.*, Webster at 37-38: *3.7.6 A three-wavelength pulse oximeter for COHb determination* Current pulse oximeters estimate the arterial oxygen saturation of the blood by measuring absorbances at two wavelengths of light. Because of this, the pulse oximeter is only able to account for Hb and HbO_2. Increased levels of COHb, for example, will cause an overestimation in S_aO_2 because the pulse oximeter cannot distinguish between HbO_2 and COHb. In cases of carbon-monoxide poisoning, this could have terrible consequences if the clinician is unaware. Buinevicius (1987) designed a three wavelength pulse oximeter to solve this problem. An additional LED at 810 nm was used in an attempt to determine the amount of COHb in the blood. Buinevicius also presented a method to calibrate the pulse oximeter for three wavelengths using three-dimensional solutions to Beer's law. Webster at 69-70:

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5.7 LED PACKAGING

Most LED packages are made of resin, offering superior mechanical strength and the ability to withstand vibration and shock. In some of today's pulse oximeter probes, the two LEDs can be found in one package, which has the distinct advantage of keeping costs down. In the Nellcor SCP–10 reusable and Oxisensor II D–25 disposable pulse oximeter probes, the two LEDs come encased in a transparent rectangular solid with approximate dimensions of 5 mm long by 4 mm wide by 2 mm thick. The LEDs themselves are flat squares with sides of approximately 0.25 mm.

Other probes have discrete LEDs inside, with the LEDs lying side by side and a mirror to reflect light at a 90° angle to the tissue. Some probes even have three or four LEDs in them to increase light output. The details of these and many other probes will be discussed in Chapter 7.

There is no wrong choice for LED packaging as long as the LEDs are small yet powerful enough to perform the task at hand. However, there is definitely a superior choice for packaging when trying to minimize costs, and that choice is almost always a package containing both LEDs.

Webster at 218-219:

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13.2.3 Dental pulp blood supply and viability

Pulse oximetry can also be used to diagnose dental pulp viability (Schmitt *et al* 1991). A tooth may be degenerating even though it appears normal to the naked eye or via x-ray images. Also, pulp inflammation can occasionally subside without intervention. Blood flow determines the viability of dental pulp and S_aO_2 determines the state of degeneration of a still viable tooth. Past techniques to determine dental pulp viability involved nerve stimulation. This was painful, often inaccurate, and gave no information about the state of degeneration. Nerves can sometimes function although blood flow is impaired.

To understand how monitoring oxygen saturation of dental pulp with pulse oximetry is accomplished, it is important to be familiar with the morphology of the tooth. The outer layers of the tooth consist of bone-like enamel and *dentin*. Collagen fibers connect the jaw bone to a layer of cementum at the base of the tooth, fixing the tooth in its socket. *Apical foramen*, small holes in the roots of the tooth, allow nerves and blood vessels to access the dental pulp. The blood provides oxygen, mineral salts, and nutrients to sustain the *odontoblasts* and neural tissues. Figure 13.2 shows that to measure the blood oxygen saturation, an adapted transmission probe in the shape of a U is applied over the tooth (Schmitt *et al* 1991). A black-foam insert conforms to the tooth and provides shielding from ambient light. It can be replaced and the probe reused on successive patients. The U-shaped probe is flat on top, providing a surface for the patient to bite down on to increase probe stability. The bone-like layers which surround the pulp create an optical shunt of sorts, allowing some light from the LEDs to be transmitted to the photodiode without passing through blood. Due to this extra variable, three wavelengths are needed to isolate the extinction coefficients of the blood. A wavelength in the range of 540 to 570 nm (green) is used because the extinction coefficients of enamel and dentin at this wavelength are similar to their extinction coefficients at 660 and 940 nm. Also, the extinction coefficients of oxygenated and deoxygenated blood at this wavelength greatly exceed their values at the red and IR wavelengths. The hardware of the pulse oximeter is similar to that of a two-wavelength pulse oximeter and the ratio of ratios computation of oxygen saturation is used. However, the denominator of each ratio is adjusted by subtracting off the detected DC value of the green wavelength (see equation (9.30)).

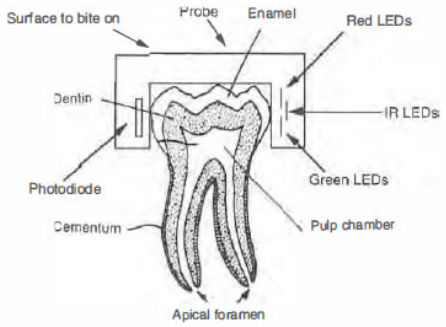


Figure 13.2 Morphology of the tooth and adapted pulse oximeter probe for determining the viability of dental pulp (adapted from Schmitt *et al* 1991).

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where the at least three LEDs configured to emit light of at least three different wavelengths, including as a non-limiting example four LEDs each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound: *See, e.g.*, Raley at Abstract ("A two piece probe having a universal probe end and an interconnect cable segment provides for the use of the universal probe end with a variety of different photoplethysmographic devices. The universal probe end includes a detector, a substrate for removably affixing the probe end to a patient, a window or aperture and a connector. The interconnect cable has a connector mated to the connector on the probe end for mechanical and electrical connection of the probe-end to the interconnect cable and the photoplethysmographic monitor. The connector end of the interconnect cable also houses a plurality of emitters which are directed through the window or aperture in the probe end in order to illuminate the patient. The interconnect cable also houses the resistors or other elements which identify the type of probe, monitor manufacturer or actual emitter wavelengths. Alternatively, the emitters may be housed in the main monitor and an optical fiber may be used to direct light to the patient. An electrical conductor transmits light received by the detector back to the photoplethysmographic monitor."). Fig. 1.

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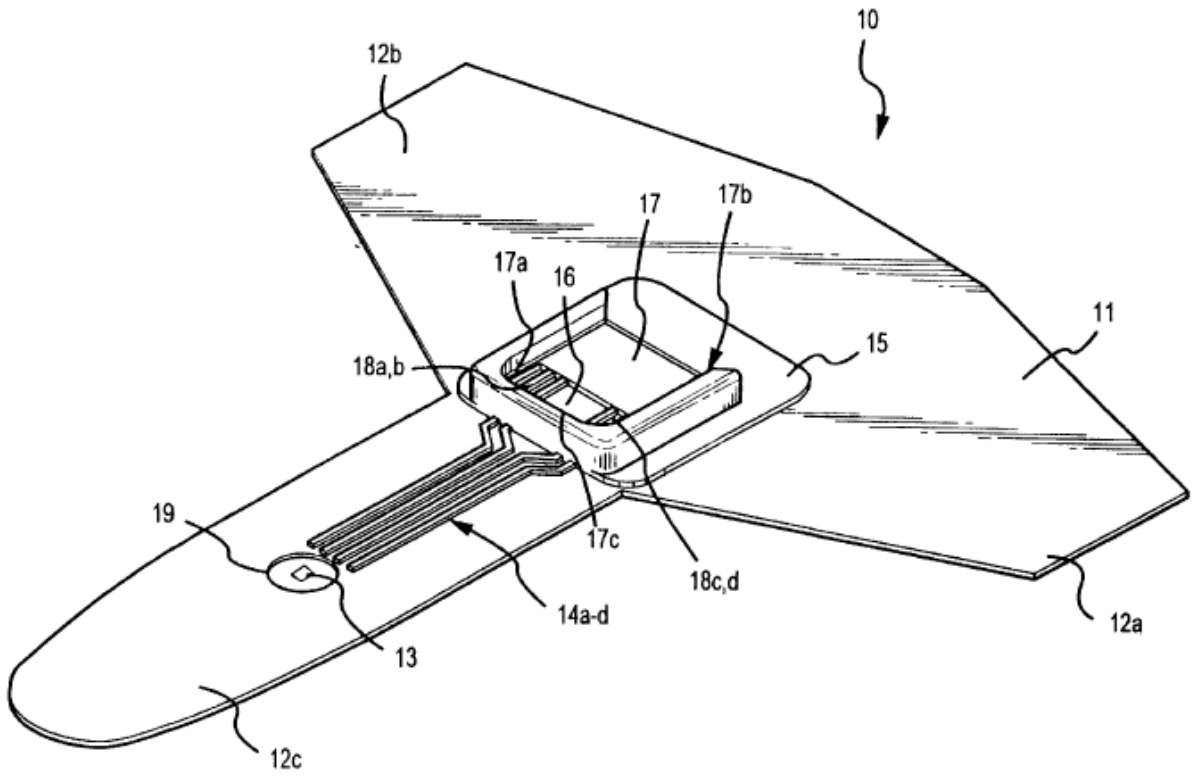


FIG.1

Fig. 3a.

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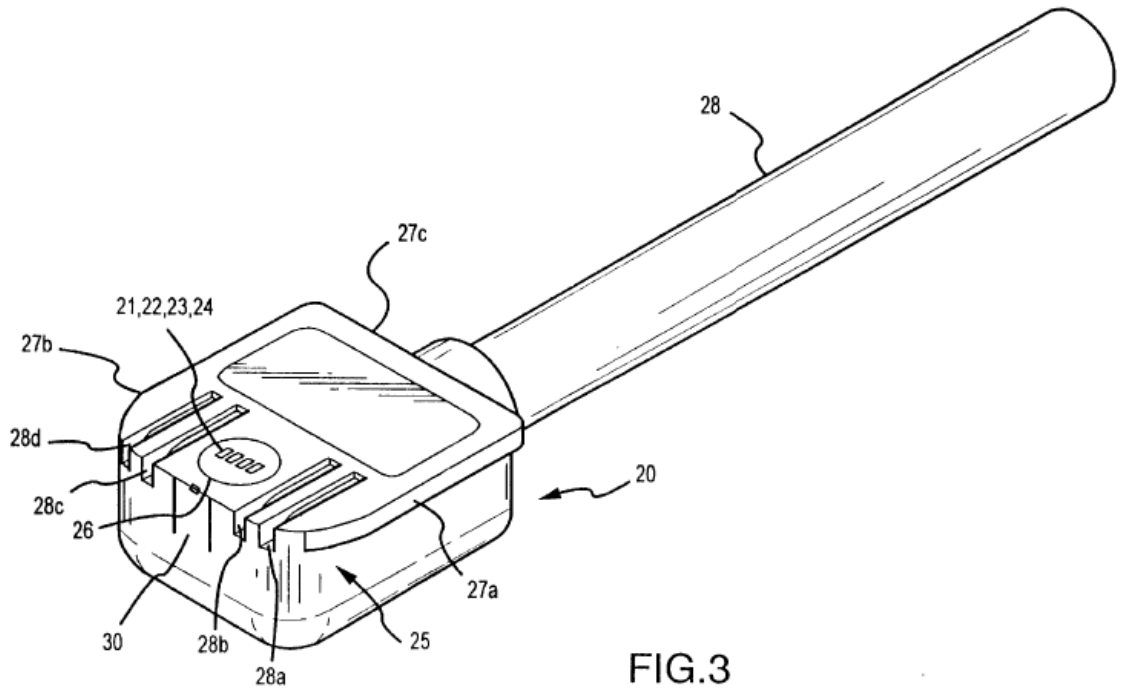


FIG.3

Fig. 3b.

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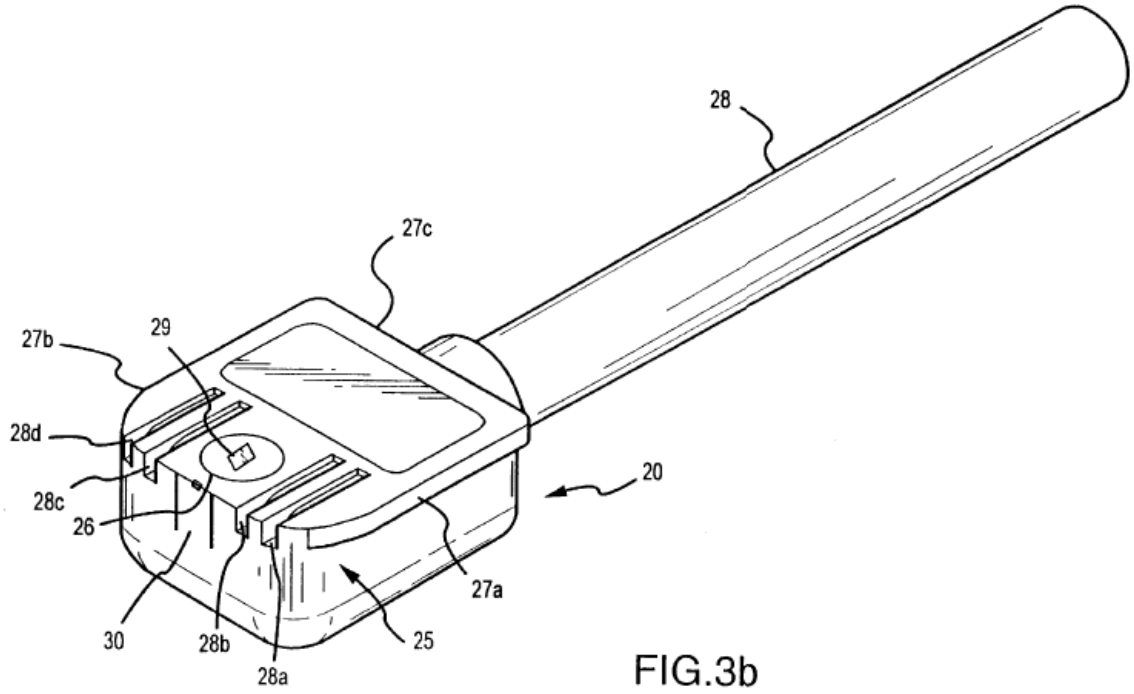


FIG.3b

Raley, 3:11-4:13 ("A pulse oximeter instrument operates by use of a probe that illuminates an appendage of the patient (such as a finger, earlobe, toe, neonatal appendages, or the nasal septum) that is rich in arterial blood and measures the differential absorption of the light by the pulsatile portion of the arterial blood flow to thereby determine oxygen saturation of the arterial blood. The pulse oximeter instrument makes use of a plurality of light-emitting devices, each of which transmits light at a predetermined wavelength, which wavelengths are selected such that at least one is highly absorbed by oxygenated hemoglobin in the arterial blood and at least one is highly absorbed by reduced hemoglobin in the arterial blood. The amount of absorption of the light beams generated by these light emitting devices that are located in the probe is a measure of the relative concentration of the various hemoglobin species contained in the arterial blood. The absorption of the light that illuminates the appendage of the patient includes a constant portion that is a result of skin, bone, steady-state (venous)

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	blood flow and light loss due to various other factors. The pulsatile component of absorption is due to the pulsatile arterial blood flow and is a small fraction of the received signal and is used by the pulse oximeter instrument to perform its measurements. It is also possible to measure additional analytes in the arterial blood, such as additional dyshemoglobins, with one additional wavelength of light for each component. The measurements are computed by sampling the output of the light detector located in the probe to determine the incremental change in absorption of the various wavelengths of light that are used to illuminate the appendage of the patient. These incremental changes in light absorption are then used to compute the oxygen saturation of the arterial blood as well as the patient's pulse rate. Since the pulsatile component of the signals received by the light detector represent only a small fraction of the incident light, it is important that the incident light be of significant magnitude to result in transmitted signals that have sufficient amplitude to provide accurate readings. In addition, the probe containing the light-emitting devices and the light detector must be placed in intimate contact with the skin of the patient to obtain the most accurate readings. Referring to FIGS. 1, 2, 3, 4, 5 and 6, the probe 40 of the present invention is designed for use with one of two basic photoplethysmographic monitor architectures depicted in FIGS. 5 and 6. FIG. 5 depicts one of the monitor architectures in which the monitor 100 communicates with probe 40 through socket 104 and mating interconnect cable plug 42. The configuration of plug 42 depends on the type and manufacturer of monitor 100. For example, if the monitor 100 is capable of measuring a plurality of blood analyte concentrations such as O2Hb, RHb, COHb and MetHB then plug 42 and interconnect 104 will contain sufficient electrical connectors 46 to interconnect probe interface 102 with a plurality of emitters 21, 22, 23 and 24 located in the connector-end 25 of interconnect cable segment 20. In a preferred embodiment, the plurality of emitters 21, 22, 23 and 24 each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ_1 λ_2 λ_3 and λ_4. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. In a photoplethysmographic instrument designed to generate four blood analyte levels, the preferred embodiment is to use at least four separate emitters each producing light with a distinct spectral content. If fewer blood analyte levels are desired then fewer emitters may be used either in the interconnect cable. For example, in a probe made according to the present invention for use with a standard pulse oximeter, only two emitters would be needed in the interconnect cable.”).

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	Raley, 4:47-6:12 (“An alternative method of implementing a photoplethysmographic monitor is depicted in FIG. 6 and operates in conjunction with the alternative probe embodiment in FIG. 3b. The emitters 21, 22, 23 and 24 (which may be LED's or laser diodes, but which are preferably laser diodes) are housed in the monitor 200. The emitters 21, 22, 23 and 24 are driven by emitter driver 230 which is controlled by the data processing circuit 107. The emitted light is then combined by an optical coupler 228 and transmitted to the probe 40 by internal optical fiber 260 which is coupled to an optical fiber or other such optically transmissive material (not shown) internal to interconnect cable segment 28. Thus, plug 42 and connector 204 now includes electrical conductors for connecting photodiode 13 back to the probe interface 102 and an optical connector for connecting optical fiber 260 to an optical fiber (not shown) located in cable 28. The light transmitted through the optical fiber 260 and transmitted through the optical fiber located in cable 28, reflects off mirror 29 of FIG. 3b in connector end 25 and passes through window or opening 26 and window 16 in probe-end 10 and impinges on the tissue of the patient. Transmitted light is received by photodetector 13 which send an electrical signal back to the probe interface 102 through the electrical conductors in cable 28 and electrical pathway 262 in monitor 200. The probe interface 102 converts the analog signal to a digital signal and transmits the signal to memory 106 and on to data processing circuit 107 for processing and display of blood analyte concentration values using graphic display 114 and numeric display 115 driven by display driver 109. The transmission of the emitted light can be controlled in a time division multiplexing manner and an optical coupler 228 can be used to provide a means for combining multiple emitters onto one strand of optical fiber 260. Alternatively, the plurality of emitters may be placed or abutted against optical fiber 260. The Probe Referring again to FIG. 4 the probe 40 consists of two releasable connected segments: the probe-end 10, separately depicted in FIG. 1 and interconnect cable segment 20, separately depicted in FIGS. 2, 3 and 3b. Universal probe-end 10 is designed to be disposable and to accommodate any type of interconnect cable segment 20, whether it contains LED's, laser diode, or an optical fiber/mirror for illuminating the tissue. Thus, the construction of probe-end 10 is simple and flexible consisting of a flexible substrate 11 having three portions 12a, 12b and 12c. Substrate portions 12a and 12b are designed to wrap around

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	an appendage of a patient. In FIG. 1 the substrate is designed to be wrapped around a finger. Substrate portions 12a and 12b have an adhesive layer applied to one or more surfaces to enable the portions to be removably attached to the finger. Substrate portions 12a and 12b may be configured differently for attachment of probe-end 10 to the feet of neonates, the smaller fingers of children, or to other appendages of adult, child or neonatal patients. Substrate portion 12c includes a photodetector 13 which is mounted in an optically transmissive window 19 in the substrate 11 and which is connected to connector 17 through flexible electrical circuits 14 a-d. Connector 17 has three lip portions 17a, 17b, and 17c which are designed to accommodate and hold the connector-end 25 of interconnect cable segment 20. Connector portion 15 provides a larger surface area for connector 17 to be either adhesively affixed to substrate 12 or, alternatively, to be retained between layers of substrate 12. Connector 17 also houses an optically transmissive window 16 and electrical contacts 18a, 18b, 18c, and 18d which connect flexible electrical circuits 14a,b,c and d with interconnect cable segment 20. Window 16 enables light to be passed from the emitters 21,22,23 and 24 or optical fiber and mirror 29 to the patient while protecting the patient from excess heat and also protecting the reusable interconnect cable segment 20. FIG. 2 depicts a top elevational view of the patient end of interconnect cable segment 20. Cable 28 consists of a bundle of one or more electrical conductors and, if the emitters are located in the monitor 200, an optical fiber. The electrical conductors and optical fiber are covered by a flexible insulating material to protect the internal components. Conductive grooves 28a, 28b, 28c and 28d provide for electrical interconnection of photodetector 13 through flexible conductors 14a, 14b, 14c and 14d and electrical contacts 18a, 18b, 18c and 18d. Ridge 27b is designed to fit under lip 17b to hold connector-end 25 onto probe-end 10. FIG. 3 depicts a bottom elevational view of one embodiment of the patient end of interconnect cable segment 20. The embodiments of FIG. 3 includes four emitters 21, 22, 23 and 24. Such an embodiment would be useful in a photoplethysmographic monitor for measuring three or four blood analytes such as oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin. Alternatively, the number of emitters could be two in a probe for use with standard pulse oximeters which typically use two emitters having spectral contents characterized by distinct center wavelengths, often 660 nm and

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	940 nm. Ridges 27a, 27b and 27c fit under lip portions 17a, 17b and 17c to hold connector-end 25 onto probe end 10. The end of latch 30 is designed to click into a hole near the base of lip portion 17c so that upon engagement of the connector-end 25 into connector 17 a releasable latching occurs. In order to disengage the latching mechanism latch 30 is simply depressed."). Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths. For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Nogawa at Abstract:

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	A new reflectance pulse oximeter sensor for lower arterial oxygen saturation (SaO_2) measurement has been designed and evaluated in animals prior to clinical trials. The new sensor incorporates ten light emitting diode chips for each wavelength of 730 and 880 nm mounted symmetrically and at the radial separation distance of 7 mm around a photodiode chip. The separation distance of 7 mm was chosen to maximize the ratio of the pulsatile to the average plethysmographic signal level at each wavelength. The 730 and 880 wavelength combination was determined to obtain a linear relationship between the reflectance ratio of the 730 and 880 nm wavelengths and SaO_2. In addition to these features of the sensor, the Fast Fourier Transform method was employed to compute the pulsatile and average signal level at each wavelength. The performance of the new reflectance pulse oximeter sensor was evaluated in dogs (N=5) in comparison to the 665/910 nm sensor. As predicted by the theoretical simulation based on a 3-dimensional photon diffusion theory, the 730/880 nm sensor demonstrated an excellent linearity over the SaO_2 range from 100 to 30%. For the SaO_2 range between 100 and 70%, the 665/910 and 730/880 sensors showed the standard error of around 3.5% and 2.1%, respectively, in comparison to the blood samples. For the range between 70 and 30%, the standard error of the 730/880 nm sensor was only 2.7%, while that of the 665/910 nm sensor was 9.5%. The 730/880 sensor showed improved accuracy for a wide range of SaO_2, particularly over the range between 70 and 30%. This new reflectance sensor can provide noninvasive measurement of SaO_2 accurately over the wide saturation range from 100 to 30%. *See, e.g.*, Nogawa at 80:

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The reflectance pulse oximeter, as reported by Mendelson et al, was the first monitor to measure SaO_2 from the finger-tip [7]. Although several reflectance pulse oximeters have been reported since then, they have not acquired the clinical acceptability yet [8,9]. The effectiveness of the reflectance pulse oximeters has been hindered by a poor signal to noise ratio and small pulsatile signals, particularly at the red wavelength. These weak signals preclude continuous measurement at the forehead or cheek. Mendelson et al used multiple photodiodes around the light emitting diode to increase the signal level. In 1992, Takatani et al [10] reported a multiple-light source hybrid reflection pulse oximeter sensor that incorporated a near-infrared heater to warm the skin and to increase the pulsatile signal level. The sensor was evaluated in animals and humans to show acceptable performance. However, the incorporation of the heater complicated the system and possible skin burn prevented long term continuous usage.

In this study, improvements in sensor design and signal processing method were proposed based on the theoretical simulation using a 3-dimensional photon diffusion theory to improve the performance of the reflectance pulse oximeter for lower SaO_2 measurement, possibly down to 40%, as well as wider clinical application without requiring vaso-dilating method. They are:

1) To improve the overall accuracy of the reflectance pulse oximeter, a new wavelength pair of 730/880 nm will be used, instead of the 660/910 nm pair. This combination can improve the overall linearity, with particular interest in its application to low SaO_2 measurement such as in fetal monitoring.

2) To increase the pulsatile signal level as well as to minimize tissue inhomogeneity, hence the variability among the subjects, ten light-emitting diode (LED) chips for each wavelength will be mounted around a photodiode (PD) chip at an equal radial distance of 7mm. The radial distance of 7 mm was decided through theoretical and experimental studies.

3) Furthermore, to improve the signal processing method, a Fast Fourier Transform (FFT) method will be used to compute the pulsatile (AC) and average (DC) components of the reflectance optical pulse signals at each wavelength. The DC and fundamental component of the Fourier transformed reflectance optical signal will correspond to the DC and AC component of the conventional method.

See, e.g., Nogawa at 83:

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The Hybrid Reflectance Optical Pulse Oximeter Sensor

The schematic diagram of the hybrid reflectance pulse oximeter sensor is shown in Fig. 4. A photodiode (PD) chip is located at the center and is surrounded by an optical barrier that blocks direct coupling between the light emitting diode (LED) and PD. Ten LED chips for each wavelength of 730 and 880 nm are placed symmetrically and at an equal radial distance of 7 mm around the PD to enhance pulsatile signal level and minimize the tissue inhomogeneity, hence the variability among the subjects. The diameter of the sensor is 23.0 mm with the thickness being 6.7 mm. Its weight is 7.2 gm. A four layered ceramic circuitry design allowed to accommodate twenty LED chips and a PD chip on a single substrate, resulting as a compact hybrid sensor design. After layout of LED and PD chips and wire bonding, the hybrid circuit was placed in a header and its surface was covered with an optical clear epoxy. After the epoxy cured, its surface was polished.

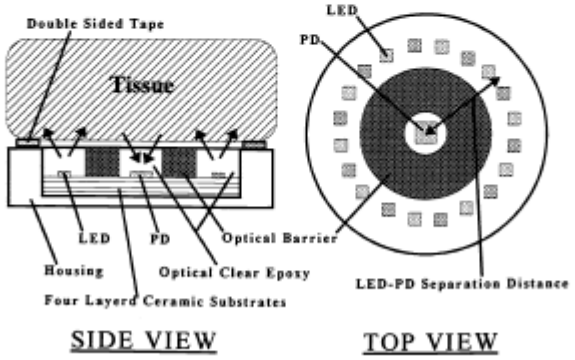


Fig. 4. A schematic drawing of the newly developed reflectance pulse oximeter sensor.

See, e.g., Nogawa at 85-86:

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DISCUSSION

In this study, a new hybrid reflectance pulse oximeter sensor has been evaluated in animals. The new sensor demonstrated significantly improved accuracy over a wide range of SaO_2, particularly at lower SaO_2 between 70 and 30%. The contributing factors for this improved performance are 1) sensor geometry, 2) wavelength selection, and 3) signal processing method [12].

Concerning the sensor geometry, the separation distance between the light source and detector was optimized to yield the largest AC/DC ratio. Although the theoretical study revealed that the AC/DC ratio increases with the radial separation distance, the reduction in the absolute signal level led us to choose the separation distance of 7 mm. For this separation distance, in order to enhance the signal level and average out the inhomogeneous effect of tissue, ten LED chips for each wavelength were placed symmetrically and at the equal radial distance around a photodiode chip. The changes in the reflectance signal that is specific to inhomogeneous effect and movement artifacts can be minimized to reduce abrupt changes in the signal level. This sensor geometry helped to minimize differences among individuals. To incorporate this layout into a final sensor design, a special

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hybrid circuit consisting of four layers of ceramic substrates were designed and fabricated. A total of twenty LED chips, one PD chip and an optical barrier were all together mounted on this header with its top covered with a clear epoxy, allowing a compact hybrid optical reflectance sensor.

As for wavelength selection, the 730/880 nm pair was used instead of the conventional 665/910 combination. The relationship between the R values computed using Equation (3) and SaO_2 was linear over a wide range of SaO_2; theoretical prediction based on the photon diffusion theory agreed well with the experimental results. Since the optical absorption due to deoxygenated hemoglobin at 730 nm is less than a half of that at 665 nm (Fig. 1), nonlinear relationship between the optical reflectance and the SaO_2 value was minimized at a wide range saturation. Moreover, since the optical penetration depth into tissue at 730 nm is deeper than that at 665 nm, and closer to that at 880 nm, measured reflectance signals at 730 and 880 nm wavelengths contain information come from similar depth inside the tissue.

In addition to the sensor geometry and wavelength selection, the new signal processing method utilizes the Fast Fourier Transformation of the reflectance pulse signal to derive AC and DC components. Approximately 10 second data was analyzed to compute the DC and fundamental spectral density from which the R value was derived. This method resulted in minimization of the errors involved with the detection of each pulse amplitude.

In conclusion, the new reflectance pulse oximeter sensor in combination with the new signal processing method demonstrated improved performance in noninvasive measurement of SaO_2 over its wide range. The new reflectance pulse oximeter sensor can broaden the clinical application of the reflectance pulse oximetry in caring patients in the operating room, ICU and fetuses during delivery. Currently, clinical evaluation of the sensor is under progress.

Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths.

For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments as four, five, and six separate emitters relying on different wavelengths, where relying on any number of additional wavelengths beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy:

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	See, e.g., Jarman at Abstract ("An improved method and apparatus for the photoplethysmographic monitoring of blood analyte parameters, specifically oxyhemoglobin, deoxyhemoglobin (reduced hemoglobin), carboxyhemoglobin and, in addition, in a four emitter apparatus, methemoglobin, uses a plurality of beams of light having different spectral contents to trans-illuminate the tissue of a patient. The apparatus and method require the application of an emitter set comprised of four emitters. The emitters may be LED's or laser diodes. In the three analyte system the center wavelength of the emitters must fall within three specific bands. In the four emitter system (capable of measuring methemoglobin) the center wavelength of the emitters in the emitter set must fall within four predetermined bands and the emitters having the two lowest center wavelengths must be at least 5 nanometers apart. The apparatus can use emitters which are located either in a probe, or, preferably, in the monitor, as well as a photodiode which can either be located in the patient probe or in the monitor."). Fig. 3.

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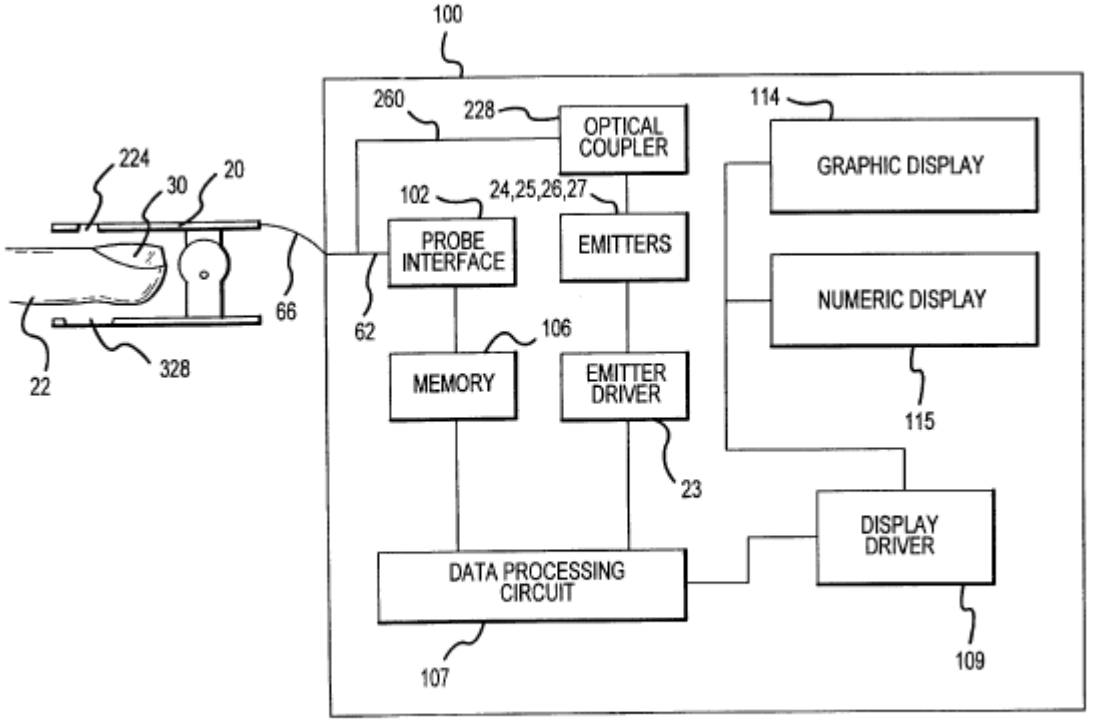


FIG.3

Jarman, 1:9-45 ("The present invention generally concerns the monitoring of a patient's tissue using a photoplethysmographic device to generate information related to the concentration of oxyhemoglobin (O2Hb), deoxyhemoglobin or reduced hemoglobin (RHb), carboxyhemoglobin (COHb) and, additionally, methemoglobin (MetHb) in the patient's blood. More specifically, the application relates to a device for the measurement of such blood analytes using a set of emitters having optimal spectral contents defined by a set of specific wavelength ranges.

During emergency evaluation, surgery and other medical procedures, clinicians often want to know the oxygen concentration of the blood, as well as other factors. In pulse oximetry the relative

	concentration of oxyhemoglobin and deoxyhemoglobin is displayed as a percentage of total hemoglobin in order to provide data on the oxygenation of the patient's blood. Blood oxygenation can be adversely affected by the generation of additional hemoglobin species, called dyshemoglobins. Most notably, carboxyhemoglobin is generated when carbon monoxide molecules bind to the hemoglobin in blood. An accurate measurement of carboxyhemoglobin concentration in the patient's blood may be needed when the patient is a smoker or if carbon monoxide poisoning is suspected. Additionally, elevated methemoglobin levels in the blood can be caused by various medications, illegal drugs and certain pathological conditions such as sickle cell anemia. Therefore measurement of the methemoglobin concentration is also useful during patient evaluation. Pulse-oximeters have been commercially available for measuring the oxygen saturation, or percent oxyhemoglobin, in arterial blood. These instruments rely on time-varying absorption of light by tissue supplied with pulsating arterial blood with a technique known generally as photoplethysmography. Conventional pulse oximeter instruments transmit light having spectral contents defined by two different center wavelengths through tissue."). Jarman, 1:63-2:10 ("The most obvious limitation of pulse oximetry derives from the fact that it is only a two channel (two wavelength bands) system and therefore can only solve for two components in the blood. Pulse oximetry makes the assumption that only oxyhemoglobin and reduced hemoglobin are present in the arterial blood. Any additional chromophores that are present in arterial blood and which absorb light in the wavelength bands used by the instrument will lead to erroneous readings. Two such chromophores are carboxyhemoglobin and methemoglobin. In particular, if carboxyhemoglobin or methemoglobin is present in above normal levels, a conventional pulse oximeter will give falsely high readings for the arterial oxygen saturation. This is one of the most serious and potentially dangerous limitations of current pulse oximetry."). Jarman, 2:45-3:42 ("This application discloses a photoplethysmographic apparatus and method for the accurate continuous, real-time, noninvasive measurement of a plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and, in additional embodiments, methemoglobin levels in blood. The apparatus uses three emitters for measuring oxyhemoglobin, deoxyhemoglobin and carboxyhemoglobin or four emitters for measuring methemoglobin in addition to the former three analytes. Each of the emitters has a spectral content characterized by a wavelength

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	that falls within a wavelength range which has been determined to be the optimal wavelength range for measuring the set of three or four blood analytes. The method of the invention is the optimization of the specific centerwavelengths necessary for accurate measurement of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and additionally methemoglobin. A photoplethysmographic method according to the present invention comprises the step of generating at least three monochromatic or essentially monochromatic beams of light having at least distinct first, second and third spectral contents denoted by center wavelengths λ1, λ2 and λ3. The terms "monochromatic beams of light" or "essentially monochromatic beams of light" are used to refer to light generated by emitters such as a laser diode or other relatively narrow band source, or light of narrow spectral bandwith, isolated by the use of gratings or interference filters, originating from a broadband source such as a tungsten lamp. A fourth emitter having a spectral content characterized by center wavelength λ4 is used in systems where methemoglobin levels are desired. The light from the emitters is then directed into a portion of the tissue of the patient in order to pass light through the tissue portion along an optical path. The method of the invention further comprises the use of means for detecting the received light transmitted from the tissue such as a photodiode or other appropriate detector. I.sub.λ1, I.sub.λ2 and I.sub.λ3 (and I.sub.λ4 in the four emitter apparatus) are the measurements of the light received from tissue after absorption and modulation by the various absorbers in the tissue and arterial blood under test. From the received light measurements, I.sub.λ1, I.sub.λ2, and I.sub.λ3 (and I.sub.λ4 in the four emitter case), the differential absorptions (dA's) of the transmitted light by various absorbers in the blood are calculated. These differential absorptions (dA's) are then used in the estimation of the blood analyte levels according to known techniques described or referenced herein. In the present invention, the emitters are chosen so that the spectral contents (denoted by center wavelengths λ1, λ2 and λ3 for the three emitter apparatus and λ1, λ2 λ3 and λ4 for the four emitter apparatus) are optimized for the detection of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and, additionally, in the four emitter case, methemoglobin. The center wavelength for the first, second and third emitters in the three emitter apparatus should be in the range of

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	approximately 610-640 nm, 680-770 nm and 850-1000 nm. The center wavelength for the fourth emitter, in the four emitter apparatus should be in the range of 635-650 nm with the additional constraint that the center wavelength of the first emitter must be at least 5 nm less than the center wavelength of the fourth emitter."). Jarman, 3:51-4:36 ("FIG. 3 is a diagram showing an additional embodiment of the claimed invention. FIG. 4 is a graph of the extinction curves of oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin and methemoglobin in terms of millimolar extinction, on a logarithmic scale, versus wavelength in nanometers. DETAILED DESCRIPTION OF THE INVENTION The photoplethysmographic monitor of the present invention measures the concentration of oxyhemoglobin (O2Hb), deoxyhemoglobin or reduced hemoglobin (RHb), carboxyhemoglobin (COHb) and, if four emitter are used, methemoglobin (MetHb) in a patient's blood. This is accomplished through the use of at least three emitters (or a filtered broadband emitter) emitting beams of light having a spectral content characterized by center wavelengths, λ1 λ2, and λ3 (and λ4 in the four emitter case). The spectral content of the light emitted by the three or four emitters (or filtered broadband emitter) must be distinct and it is preferable that the center wavelengths for each of the emitters also be distinct so that λ1 ≠λ2 ≠λ3 ≠λ4. FIG. 1 depicts an apparatus having four emitters made according to the present invention. The three emitter apparatus would be essentially identical except for the lack of one emitter and corresponding channel. Probe 20 is placed on the tissue under test 22 so that a plurality of emitters 24, 25, 26, 27 transmit light through the tissue which is then received by one or more photodetectors 28. Emitters 24, 25, 26, 27 (or a filtered broadband light source) each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ1 λ2, λ3 and λ4. In the case of a finger probe, the emitters are arranged to emit the light at or near the base of the fingernail 30. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. However, the preferred embodiment is to use at least four separate emitters preferably laser diodes each producing light with a distinct spectral content. It should be understood that four emitters could be used to measure three blood

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	analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin. Additionally, a number of emitters greater than the number of blood analytes being measured may be used in a photoplethysmographic system in order to create an overdetermined system. Through cable 60, an electrical signal indicative of the light emitted by emitters 24, 25, 26 and 27, transmitted through finger 22 and received by photodetector 28 is transmitted back to monitor 100. The internal components of monitor 100 are described in detail below."). Jarman, 4:7-36 ("FIG. 1 depicts an apparatus having four emitters made according to the present invention. The three emitter apparatus would be essentially identical except for the lack of one emitter and corresponding channel. Probe 20 is placed on the tissue under test 22 so that a plurality of emitters 24, 25, 26, 27 transmit light through the tissue which is then received by one or more photodetectors 28. Emitters 24, 25, 26, 27 (or a filtered broadband light source) each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ1 λ2, λ3 and λ4. In the case of a finger probe, the emitters are arranged to emit the light at or near the base of the fingernail 30. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. However, the preferred embodiment is to use at least four separate emitters preferably laser diodes each producing light with a distinct spectral content. It should be understood that four emitters could be used to measure three blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin. Additionally, a number of emitters greater than the number of blood analytes being measured may be used in a photoplethysmographic system in order to create an overdetermined system. Through cable 60, an electrical signal indicative of the light emitted by emitters 24, 25, 26 and 27, transmitted through finger 22 and received by photodetector 28 is transmitted back to monitor 100. The internal components of monitor 100 are described in detail below."). Jarman, 5:37-46 ("Where C is the concentration of the specific absorber, E is the extinction for that absorber at wavelength λ and ΔL is the differential change in effective path length the transmitted light has traveled. (Superscripts O, R, CO, and Met refer to O2Hb, RHb, COHb, and MetHb respectively.) Thus, after measuring the received light intensities and knowing the extinction coefficient E for each wavelength it is possible to determine the concentrations of the specific absorbers. In the three emitter system the same calculations are made according to the following equation:").

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	Jarman, 6:9-18 ("where xHb refers to one of O2 Hb, RHb, COHb, or MetHb, the constants a1, a2, a3, a4, b1, b2, b3, and b4 are calibration coefficients determined previously in a calibration experiment, and N21, N31, and N41 are normalized dAs for channels 2 and 1, 3 and 1, and 4 and 1, respectively. As one skilled in the art will understand, however, the calibration equation for each analyte is not limited to this form of equation, and may be, for example, a polynomial. In the three emitter system the calibration equation is given by:"). Jarman, 8:26-35 ("Thus, using emitter sets comprising four emitters having spectral contents characterized by a center wavelength within the four wavelength ranges (610-640 nm, 635-650 nm, 680-770 nm and 850-1000 nm) and subject to the one difference constraint, i.e., that the two lowest center wavelengths be 5 nanometers apart, provides an improved photoplethysmographic system for the measurement of oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin and methemoglobin."). Under at least the apparent construction based on Masimo's Infringement Contentions, Aoyagi discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths. For example, Aoyagi discloses and/or suggests a patient monitor relying on an optical sensor, where additional LEDs at additional wavelengths, such as six LEDs in one embodiment, are used to measure levels of additional unknowns (such as compounds) in blood, where the more number of wavelengths the more number of unknowns that can be measured: *See, e.g.*, Aoyagi at Abstract ("Light of various wavelengths emitted from light sources and transmitted through vital tissues is converted by light sensors and current/voltage transducers, into electric signals. The signals are converted into digital values by an A/D converter. The light source emits light of a wavelength which can be optically absorbed by water. A computer obtains a ratio of variations of the digital values for each wavelength, and calculates the values of tissue terms and the hemoglobin concentration on the basis of the ratios. In the calculation, since tissue terms of the wavelengths have

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mutual constant relationships, an equation which is prepared so that there exists only one unknown in the tissue terms is used.").

Fig. 2.

FIG. 2

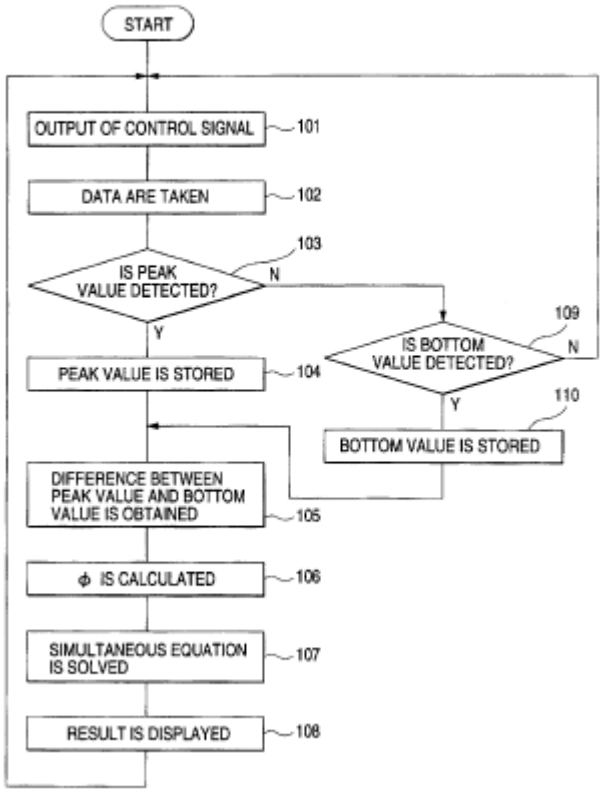
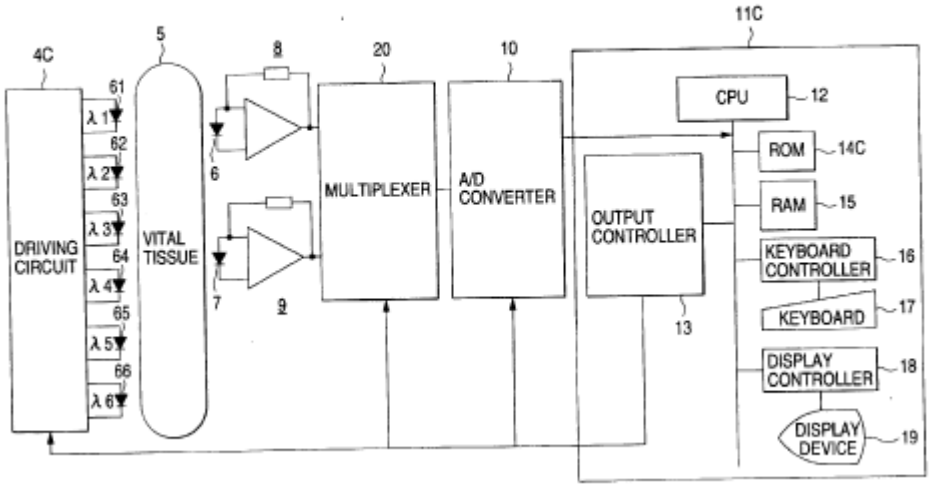


Fig. 5.

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FIG. 5



Aoyagi, 3:26-39 ("First, the principle common to all embodiments will be described. In the embodiments, the pulse method is used. In the pulse method, the phenomenon in which the effective thickness of the blood is caused to pulsate by blood pulsation in the vital tissues is used, and the optical absorptive characteristics of the blood in the tissues are measured while irradiating the vital tissues with light. Since the kinds of hemoglobin have different optical absorptive characteristics, the total hemoglobin can be obtained by obtaining respective hemoglobin concentrations in the blood and then calculating the total sum of the concentrations. Therefore, the number of light wavelengths required for the measurement depends on that of kinds of hemoglobin contained in the blood.").

Aoyagi, 4:16-25 ("IG. 6 shows optical absorptive characteristics of various kinds of hemoglobin, and FIG. 7 shows optical absorption of water with respect to that of oxyhemoglobin in the case where the hemoglobin concentration is 14 [g/dL].

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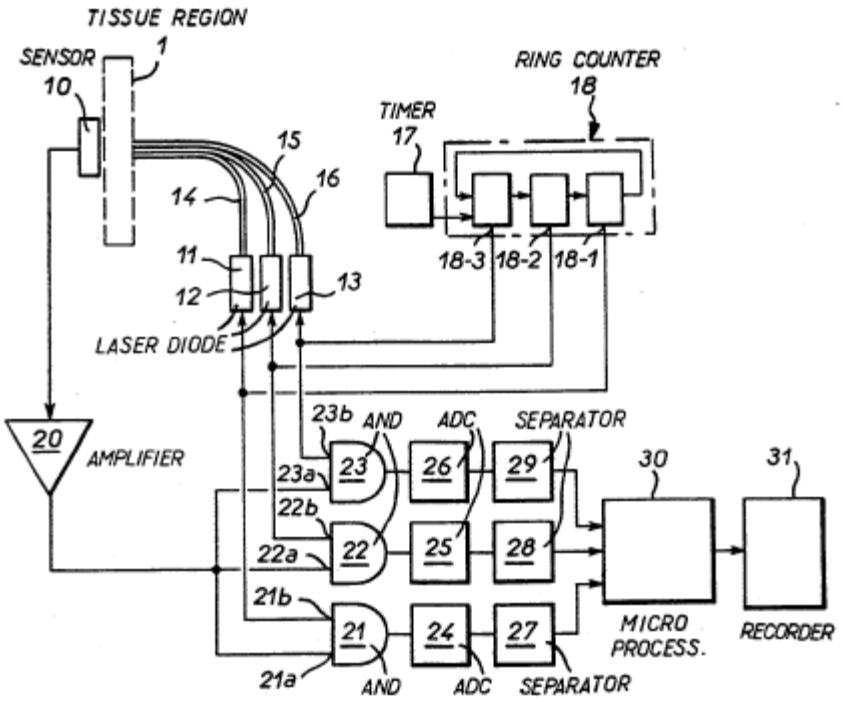
	The principle of a first embodiment will be described. The embodiment is directed to an apparatus which is to be used in the case where only oxyhemoglobin and reduced hemoglobin exist as hemoglobin in the blood. In this case, four light wavelengths are used and the following simultaneous equations with three unknowns are employed:"). Aoyagi, 6:21-28 ("This is set as a first embodiment (B). Next, the principle of a second embodiment will be described. The embodiment is directed to an apparatus which is to be used in the case where oxyhemoglobin, reduced hemoglobin, and carboxyhemoglobin exist as hemoglobin in the blood. In this case, five light wavelengths are used and the following simultaneous equations with four unknowns are employed."). Aoyagi, 7:28-40 ("By substituting equations (10) to (12), (18), and (19) into equations (14) to (17), simultaneous equations with four unknowns So, Sc, EX2, and Hb are obtained. When the simultaneous equations are solved, the values of So, Sc, Ex2, and Hb can be obtained. Next, a third embodiment will be described. When there exists methemoglobin in place of carboxyhemoglobin in the second embodiment, equations corresponding to equations (14) to (17) are as follows:"). Aoyagi, 8:18-25 ("By substituting equations (10) to (12), (18), (25), and (26) into equations (20) to (24), simultaneous equations with five unknowns So, Sc, Sm, Ex2, and Hb are obtained. When the simultaneous equations are solved, the values of So, Sc, Sm, Ex2, and Hb can be obtained. FIG. 6 shows optical absorptive characteristics of various kinds of hemoglobin. For example, light wavelengths used in the embodiments are as follows:"). Aoyagi, 8:47-51 ("In the fourth embodiment which measures four kinds of hemoglobin (O2 Hb, RHb, COHb, and MetHb) and six wavelengths are used Used wavelengths: λ1 =660 nm, λ2 =700 nm, λ3 =850 nm, λ4 =805 nm, λ5 =890 nm, and λ6 =1,250 nm").

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	Aoyagi, 12:57-13:12 ("Next, a specific apparatus of the fourth embodiment will be described. FIG. 5 shows the whole configuration of the apparatus. The components which are identical with those of the apparatus of the first embodiment (A) are designated by the same reference numerals and their description is omitted. In the embodiment, the apparatus comprises six light sources 61 to 66. The light sources 61 to 66 emit light of wavelengths of λ1 =660 nm, λ2 =700 nm, λ3 =850 nm, λ4 =805 nm, λ5 =890 nm, and λ6 =1,250 nm, respectively. The wavelengths have features described above. A driving circuit 4C drives the six light sources 61 to 66. Light sensors 6 and 7 are placed so as to oppose the light sources 61 to 66, and converts light which is transmitted through the vital tissues 5 interposed between the light sources and the sensor, into an electric signal. A computer 11C conducts processing based on data supplied from the A/D converter 10 and outputs a control signal for controlling the operation timing to the driving circuit 4C and the multiplexer 20. A ROM 14C of the computer 11C stores a program which is slightly different from that stored in the ROM 14 of the computer 11 of the first embodiment (A) shown in FIG. 1. The other components of the computer 11C are the same as those of the computer 11A.").
	Under at least the apparent construction based on Masimo's Infringement Contentions, Barthelemy discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths.
	For example, Barthelemy discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs that emit light at more than two wavelengths, where relying on additional wavelengths allows for the measurement of the concentration of multiple compounds in the blood:
	See, e.g., Barthelemy, Abstract ("The apparatus comprises three laser diodes emitting at 660, 750 and 940 nm respectively, excited cyclically at the rate of a timer. The light emitted is channelled by three optical fibers to traverse a fully-vascularized tissue region of a subject along three virtually merged optical paths, and to terminate at an opto-electronic sensor, which generates overlapping signals representative of the molecular absorption. The pulsation of the arterial blood in the region induces variable components which are exclusively a function of the molecular absorptions due to oxyhemoglobin, deoxyhemoglobin and carboxyhemoglobin. The signals are switched by gates on three channels where the variable components are picked up and digitized, and then processed in a microprocessor to yield the oxygen saturation SaO_2 and the carbon monoxide fixation of the hemoglobin.").

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Fig. 1.



Barthelemy, 3:47-4:35 ("To achieve this, the invention proposes a method for determining the oxygen saturation rate of the arterial blood of a subject, in which the concentration of oxyhemoglobin or HbO2 is compared with the total concentration of hemoglobin, comprising the steps of providing first, second and third light sources emitting in respective wavelength bands including a near infrared wavelength band, a deep red wavelength band and a wavelength band therebetween, selectively directing light emitted from the respective light sources through an appropriate tissue region of the subject, acquiring representative signals of optical absorption through the tissue region, cyclicly exciting the light sources in succession and determining the frequency of the cyclic succession so as to

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	be large as compared with the arterial pulsation frequency of the subject, and calculating concentrations of HbO2, Hb and HbCO to determine the oxygen saturation rate. According to another aspect of the invention, there is provided a method for determining the oxygen saturation rate of the arterial blood of a subject, by comparison of the concentration of oxyhemoglobin, or HbO2, with the concentration of total hemoglobin, including providing two light sources each emitting in a different wavelength band, one in the near infrared and the second in the deep red, directing light emitted by the light sources along two paths through an appropriate tissue region of the subject, providing an opto-electronic sensor for acquiring representative signals of the optical absorption of the light, the representative signals comprising a variable component corresponding to the absorption by the pulsatile arterial blood, and a continuous component corresponding to absorption by the other tissues traversed, separating the variable component of each representative signal, calculating the respective concentrations of HbO2 and deoxyhemoglobin, and optionally Hb, from the variable components, determining the oxygen saturation rate, wherein the improvement comprises the steps of providing a third light source emitting a third wavelength band between the aforesaid two bands and a corresponding third optical path associated with said third light source, exciting the three light sources in cyclic succession, selecting the cyclic succession frequency so as to be large in comparison with the arterial pulsation frequency of the subject, whereby the representative signals overlap, and each representative signal is switched at the cyclic succession rate to a respective separate channel, and calculating HbO2, Hb and HbCO to determine the oxygen saturation rate therefrom. It goes without saying that the optical paths, as usual, will be taken on relatively small thicknesses of fully-vascularized tissues, such as the ear, or on the fingers. Operation with three wavelengths, λ1, λ2 and λ3, yields a system of linear equations with three unknowns:”). Barthelemy, 5:1-64 (“Preferentially, the wavelength bands are centered on 940, 660 and 750 nm respectively. By adopting an intermediate wavelength for the third optical path, a satisfactory separating power is obtained, thanks to the differences between the specific absorptions for the three hemoglobin species, and no absorption discontinuities are introduced for the non-blood tissues.

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	Preferably, the processing of the representative absorption signals, including the extraction of the variable components and the subsequent calculations, are carried out in a microprocessor under the control of a suitable software. From another standpoint, the invention proposes an apparatus for determining the oxygen saturation rate of the arterial blood of a subject, in which the concentration of oxyhemoglobin or HbO2 is compared with the total concentration of hemoglobin, comprising first, second and third light sources emitting in respective wavelength bands including a near infrared wavelength band, a deep red wavelength band and a wavelength band therebetween, the respective light sources being directed at an appropriate tissue region of the subject, an opto-electronic sensing means acquiring representative signals of optical absorption through the tissue region, means for cyclicly exciting the light sources in succession, the frequency of the cyclic succession being large as compared with the arterial pulsation frequency of the subject, and means for calculating HbO2, Hb and HbCO to determine the oxygen saturation rate. According to another aspect of the invention, there is provided an apparatus for determining the oxygen saturation rate of the arterial blood of a subject, comprising light sources emitting in respective wavelength bands, one of the wavelength bands being near infrared and another of the wavelength bands being deep red, opto-electronic sensing means for emitting respective signals responsive to optical absorption along respective optical paths through an appropriate tissue region of the subject, said signals including a variable component corresponding to absorptions by pulsatile arterial blood and a continuous component corresponding to absorption through other tissues traversed, means for separating the variable component of the respective absorption signals, calculating means for processing the variable components and determining the respective concentrations of oxyhemoglobin or HbO2 and deoxyhemoglobin, or Hb, and also determining the oxygen saturation rate, further comprising a third light source emitting a wavelength band intermediate the first two wavelength bands, a third optical path between the third light source and the tissue region, the three optical paths terminating in said optoelectronic sensing means, means for exciting the three light sources in cyclic succession at a cyclic succession frequency which is large in comparison with pulse frequency of the subject whereby the representative of signals overlap, means for switching each of the representative signals to a respective channel at the frequency cyclic succession, said last switching means comprising means for separating the variable component of the representative signal, said calculating means jointly

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processing the three variable components to identify HbO2, Hb and HbCO and determining the oxygen saturation rate therefrom.").

Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths.

For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased:

See, e.g., Fantini at Abstract:

Abstract. We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit.

See, e.g., Fantini at 33:

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In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition.

In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument.

See, e.g., Fantini at 34:

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		Feature 2. The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. *Feature 3.* To implement the measurement of the slopes of the straight lines (as a function of the distance r between	

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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of

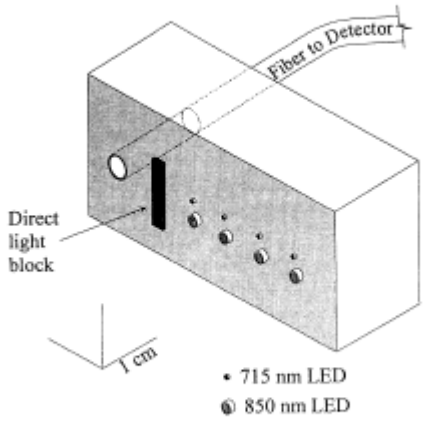
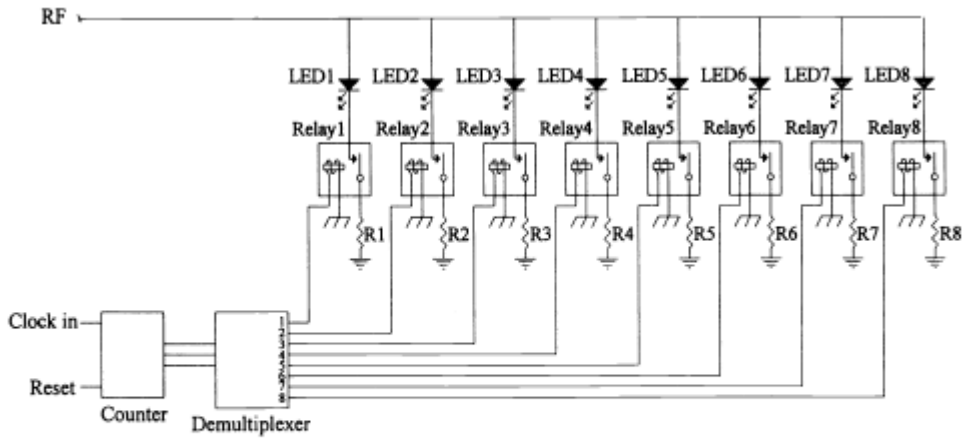


Fig. 2 Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium.

See, e.g., Fantini at 35:

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	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
10[b] at least one detector configured to detect at least a portion of the light	Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light.

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emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;	For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detector allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased, and where there is a detector implenmented as a Hamamatsu R928 detector which detects light from the LEDs after attenuation by teh tissue, where the detector then uses signals at least one signal to measure blood parameters such as hemogobin concentrations: *See, e.g.*, Fantini at Abstract: **Abstract.** We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit. *See, e.g.*, Fantini at 33:

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	In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition. In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument. *See, e.g.*, Fantini at 34:	

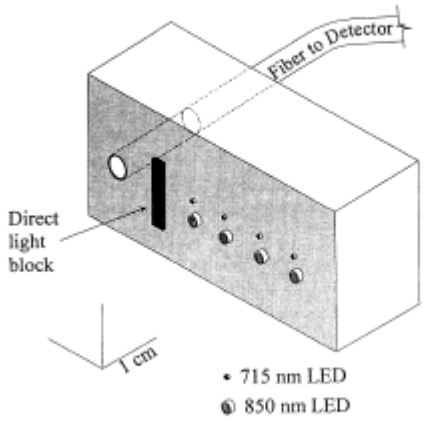
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		Feature 2. The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. *Feature 3.* To implement the measurement of the slopes of the straight lines (as a function of the distance *r* between	

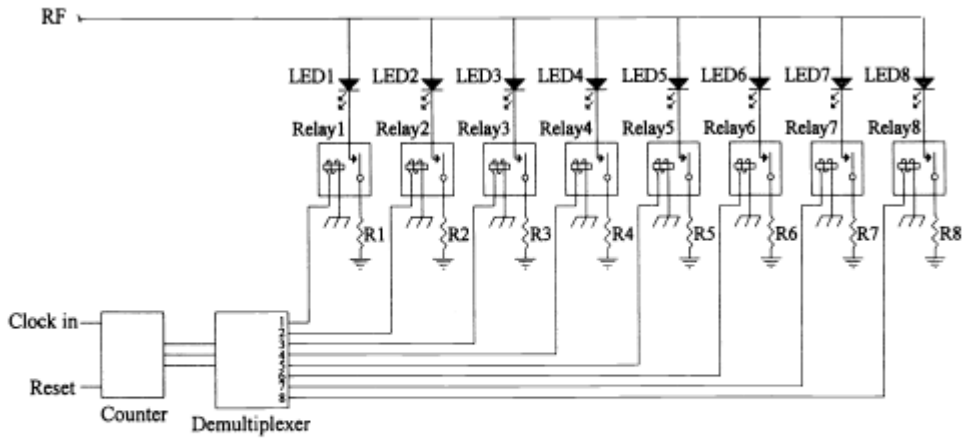
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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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	Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of  **Fig. 2** Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium. *See, e.g.*, Fantini at 35:

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	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
10[c] an electromagnetic interference shield positioned between	Under at least the apparent construction based on Masimo's Infringement Contentions, Kimura discloses and/or renders obvious an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector.

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the at least three LEDs and the at least one detector;	For example, Kimura discloses and/or suggests a vital signs detecting apparatus that is capable measuring vital signals such as pulse by relying on a least three LEDs in a cavity and at least one detector in a different enclosure, where for the at least one detector, there is an electromagnetic interference shield positioned between the at least three LEDs and the at least on detector, implemented in a non-limiting example as an IR-cut filter that is disposed above a light-receiving device (at least one detector) which filters out extraneous light: *See, e.g.*, Kimura at Abstract ("A vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. The pulse wave detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, Fig. 1A

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FIG. 1A

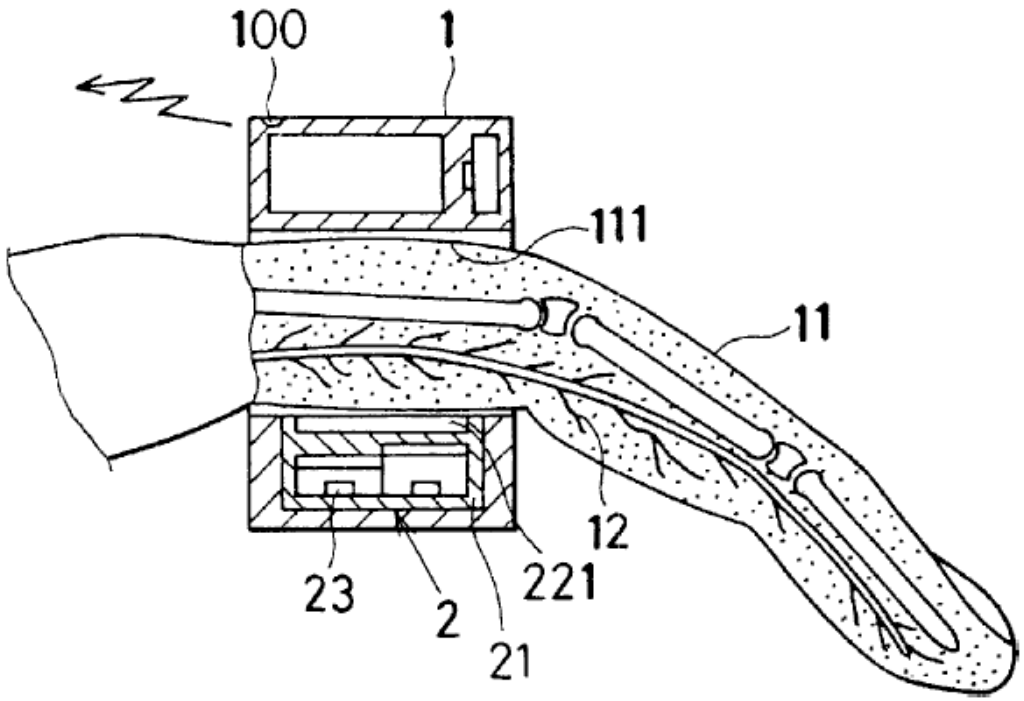


Fig. 2.

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FIG. 2

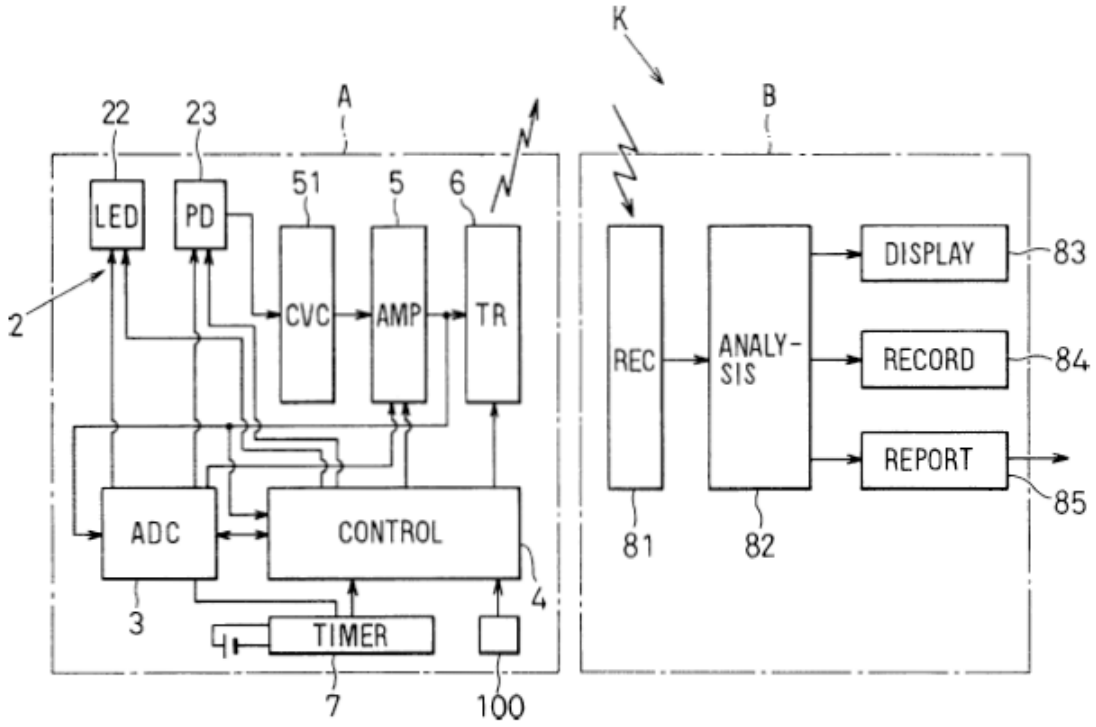
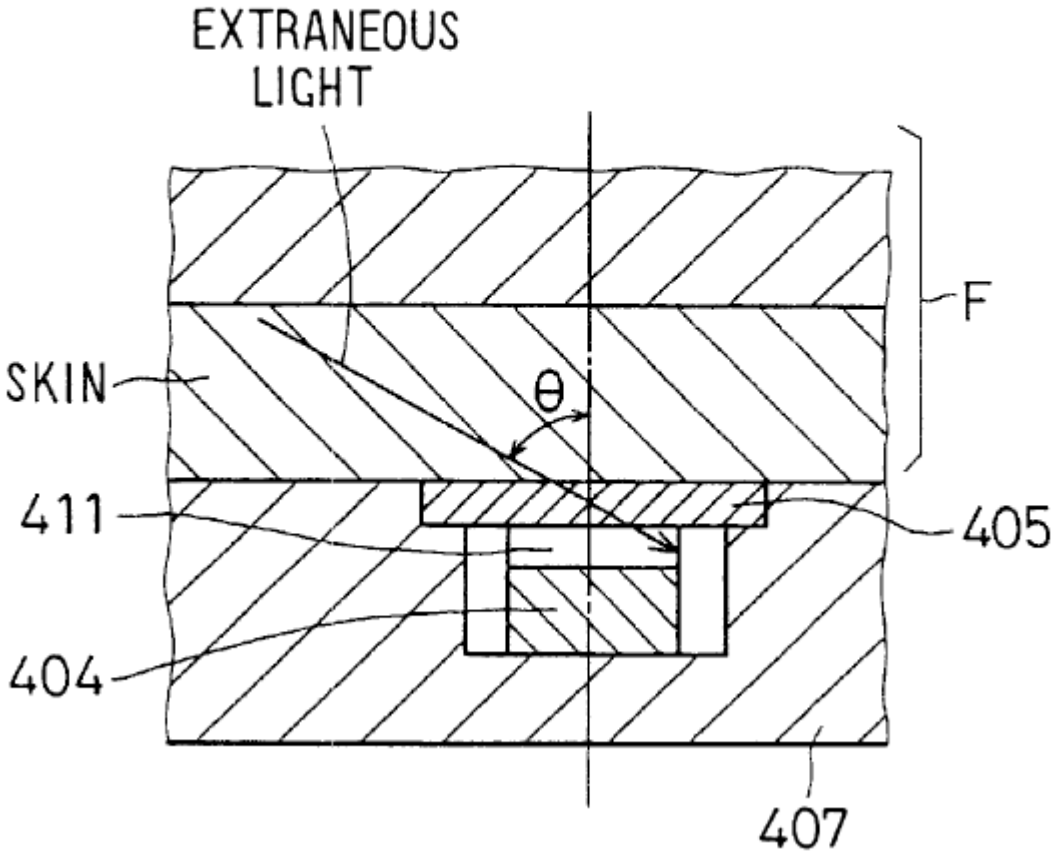


Fig. 21.

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FIG. 21



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	Kimura, 1:13-2:2 ("This invention relates to a vital signal detecting apparatus for detecting a vital signal, having an attachable device to be attached for example to a finger, an ear, an arm, a leg, torso or a neck of a human subject. There have been vital signal detecting apparatuses, as disclosed, for instance, in JP-A-8-266493 or Electronic Data Communications Society, Technical Report 1995-06. To check a vital signal (such as a pulse wave), a human subject has to operate an on/off switch himself or herself. If the subject operates the on/off switch without inserting a finger into the attachable device, because a sensor picks up external noise and outputs an abnormal signal, the vital signal checking device erroneously determines that the subject is abnormal. Further, if a ring part of a pulse wave sensor fails even slightly to match the size (thickness) of the finger, it is difficult for a detecting part to be kept in contact with the surface of the finger. Thus, extraneous light, for example, sunlight or light from fluorescent lights, affect the measurement. There have also been vital signal detecting apparatuses, used when a vital signal (such as the pulse wave) of for example an elderly or infirm subject is to be monitored over a long period, with which an attachable device is attached for instance to an arm or a leg of the subject and a vital signal detected by a sensor is transmitted to a vital signal checking device by radio waves or the like. If the elderly or infirm subject removes the attachable device, because the sensor picks up external noise and transmits an abnormal signal to the vital signal checking device, again the vital signal checking device erroneously determines that the subject is abnormal. SUMMARY OF THE INVENTION It is therefore an object of the present invention to provide a vital signal detecting apparatus which eliminates problems caused by abnormal vital signals detected when an attachable device is not attached. According to the present invention, a vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit.

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	Preferably, the vital signal detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, 13:53-14:17 ("In this embodiment, the pulse wave sensor **401** has an IR-cut filter **411** is disposed above the light-receiving device **404** as shown in FIG. **21**. When extraneous light enters the light-receiving device **404** through the finger F as a light guide, light whose wavelength is below 700 nm cannot reach the light-receiving device **404** through the finger F as a light guide. Thus, it is only necessary to block light whose wavelength is at least 700 nm. By providing the IR-cut filter **411** capable of blocking light of wavelengths greater than 700 nm above the light-receiving device **404**, extraneous light entering through the finger F as a light guide can be cut out, erroneous detection caused by the influence of extraneous light can be reduced, and thus the detection probability can be increased. In the case of this preferred embodiment, the IR-cut filter **411** can also be used as the light-transmitting plate **405**. For example when the IR-cut filter **411** is used superposed on the light-transmitting plate **405**, because the refractive indices of the two are different, reflection occurs at the interface between the light-transmitting plate **405** and the filter **411**. However, if the IR-cut filter **411** is used as the light-transmitting plate **405**, reflection at such an interface can be eliminated. When the IR-cut filter **411** is used superposed on the light-transmitting plate **405**, naturally the number of parts is greater, and also it becomes necessary for the refractive indices of the two to be adjusted with an adjusting liquid or the like. On the other hand, if the IR-cut filter **411** is used as the light-transmitting plate **405**, because there is no increase in the number of parts and no adjustment of refractive indices is necessary, costs can be kept down.").

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector. For example, Moyle discloses and/or suggests pulse oximetry devices where there is a photodetector in an assembly that is protected from extraneous light over the range of wavelengths to which the detector is sensitive, and where there can be a reduction in EMI for a detector by screening the detector, such as by using a Conductive Faraday screen connected to a screen braid: *See, e.g.*, Moyle at 18-19: Manufacturers are now paying more attention to electrical screening of the probe assembly and using differential amplifier techniques in the 18

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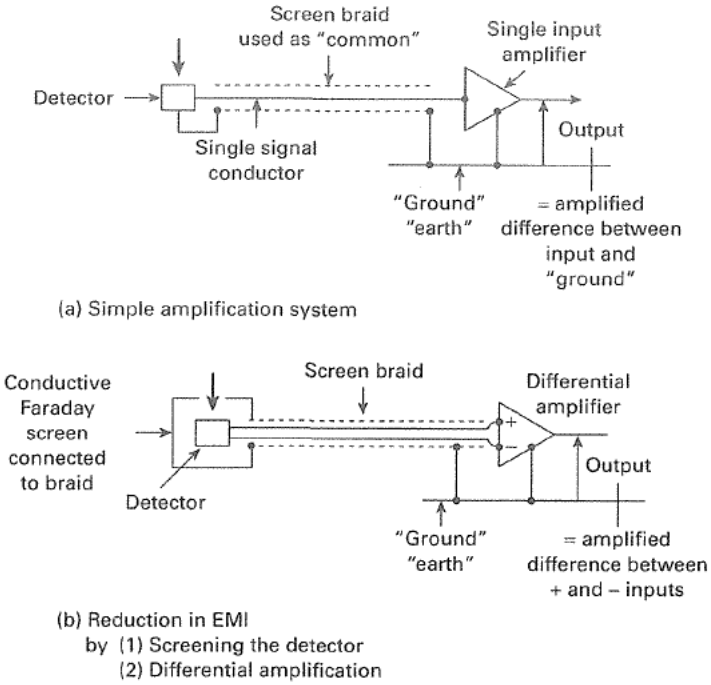


Figure 3.3 Electronic reduction in interference at the probe.

amplification of the plethysmograph signal to reduce the common-mode electrical and magnetic noise. The simplest way of amplifying a small signal is shown in Figure 3.3a, where there is one signal conductor and the other current pathway is the "common", which is often the screening braid of the flexible cable from the probe to the unit. If electromagnetic interference (EMI) affects the probe or the lead it will affect the signal conductor slightly differently from the "common". With the very small signal voltages involved, the voltage generated by the EMI may even be greater than the signal itself. Using a differential amplifier (Figure 3.3b), there are two identical conductors from the detector to an amplifier whose output is a function of the difference between these two conductors. Any EMI affecting these two signal leads will induce identical voltages, which therefore cancel each other out. This is an important technique used in any small-signal medical application (e.g. ECG, EEG, EMG, direct BP etc.).

See, e.g., Moyle at 21:

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Photodetector

A single photodetector is used to detect the energy alternately from both LEDs. In conventional transmission pulse oximetry, it is positioned perpendicular opposite the LEDs with the extremity snugly held between them (Figure 3.2). This assembly must be protected from extraneous light over the range of wavelengths to which the detector is sensitive.

In the case of transmission pulse oximetry, the photodetector is mounted a small but discrete distance away from and in the same plane as the LEDs. The photodetector is usually a silicon photodiode. Most semiconductors alter their electrical properties when exposed to outside energy; this is considered to be a disadvantage, and semiconductor manufacturers go to enormous lengths to avoid this problem. Semiconductor photodetectors, however, take advantage of this property. Photosensitivity is usually over a limited bandwidth, and this limits the selection of device and the range of wavelengths of LEDs in a particular case. The silicon photodiode has a large dynamic range, with a linear change in its output proportional to incident light level over a range of 10 decades of light energy. Phototransistors are more sensitive than photodiodes but have the disadvantage of being electrically more "noisy".[5] Furthermore, the sensitivity of all photodetectors varies with wavelength, and it is necessary to take this into account in the design of the electronics and in calibration.

See, e.g., Moyle at 142-144:

Electromagnetic interference

Electromagnetic interference includes several different sources of interference from the electromagnetic spectrum (Figure 10.1). It may be generated by many sources, mostly manmade, but also results from atmospheric events and cosmic noise: even nuclear explosions produce an enormous electromagnetic pulse. Electromagnetic interference is coupled to a piece of electronic equipment by galvanic, capacitive, inductive or electromagnetic (light) means, or by direct spark (static electricity).[12] In general, the more highly complex and

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miniaturised a piece of electronic equipment, the more likely it is that it will be susceptible to electromagnetic interference. Pulse oximeters contain much microelectronic circuitry and many microprocessors, and would be very sensitive to electromagnetic interference but for the requirement in their design for a high degree of electromagnetic compatibility – this is now required by statute, especially in equipment on which lives depend.

In pulse oximetry, visible light will interfere with SpO_2 unless the probe is well designed to eliminate its effect. The effects of visible light are far worse if the light source is pulsatile, even if the frequency

is as high as 50 or 60 Hz, which is not noticeable to the human eye. Thus problems may occur with fluorescent lighting and poorly designed probes.[13,14] In North America it is common to use xenon arc lighting in operating theatres, and the effect on pulse oximetry is especially severe if this energy is allowed to reach the photodetector.[15] This interference extends into the near infrared wavelengths, and may also include the wavelengths used for infrared diathermy. Infrared heating lamps are also reported to effect the accuracy of pulse oximetry.[16]

The most powerful source of electromagnetic interference that is likely to be encountered is the radiofrequency surgical diathermy unit, which may produce up to 400 W of radiofrequency energy at mixed frequencies. A sign of how well electromagnetic compatibility has been designed into the hardware and software of the pulse oximeter is how well it copes with electromagnetic interference in general, but especially with radiofrequency surgical diathermy.

Under at least the apparent construction based on Masimo's Infringement Contentions, Webster discloses and/or renders obvious an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector.

For example, Webster discloses and/or suggests a pulse oximeter for which optical filtering is used between sources of light such as LEDs and the photodiode, implemented in a non-limiting example as a clear plastic which absorbs unwanted wavelengths of light or some other type of light filter over the detector to minimum unwanted light incident upon the detector:

See, e.g., Webster at 77-78:

6.3 OPTICAL CONCERNS

Since this is a system with an optical interface, it is important to minimize the effects from light other than the optical signals of interest. One way to minimize unwanted light incident upon the detector is to place some type of light filter over the detector. This allows light of wavelengths of interest to pass through the filter but does not allow light of other wavelengths to pass through the filter. For the pulse oximeter to work effectively, most of the light being transmitted from the LEDs must not reach the photodiode unless it has passed through tissue containing arterial blood.

6.3.1 Optical filtering

Optical filtering, placed between sources of light and the photodiode, is used to limit the spectral response of the photodiode. A number of optical filter types can be used. Cheung *et al* (1993) recommend a red Kodak No. 29 wratten gel filter to eliminate the flickering effect of fluorescent light. However, these external filters do not appear to be used much in actual pulse oximetry designs. In addition, the photodiode mounting package may contain filtering material. Many photodiodes are mounted in clear plastic which absorbs UV wavelengths (Burr-Brown 1994a,b,c). This is useful to filter out some of the unwanted effects of fluorescent lighting on the photodiode. Many photodiodes are available in a variety of packaging types each of which filters out selected wavelengths of light.

6.3.2 Optical interference

To minimize errors, the pulse oximeter designer must attempt to limit the light reaching the photodiode to that which has traveled through tissue containing arterial blood (Nellcor 1993). This can be accomplished through thoughtful LED/photodiode placement. Light impervious barriers should be placed between LEDs and the photodiode in all areas where the emitted light could reach the photodiode without passing through tissue (New and Corenman 1987). Two additional measures can be taken to ensure this (figure 6.6). One is to decrease the angle of incidence to the photodiode. The second is to coat the housing around the photodiode with a material that does not scatter or reflect light.

There are two types of optical interference that may cause problems for the photodiode. The first is excessive ambient light. The source of this type of error may be surgical lamps, fluorescent lights, infrared heat lamps and direct sunlight. Usually this type of interference will saturate the photodiode so that no pulse can be distinguished, however some of these sources may result in apparently normal but inaccurate readings. The second source of interference is optical cross-talk. This type of interference typically may occur when multiple probes are used in close proximity. In this case, light from one LED probe is sensed by the photodiode of another probe.

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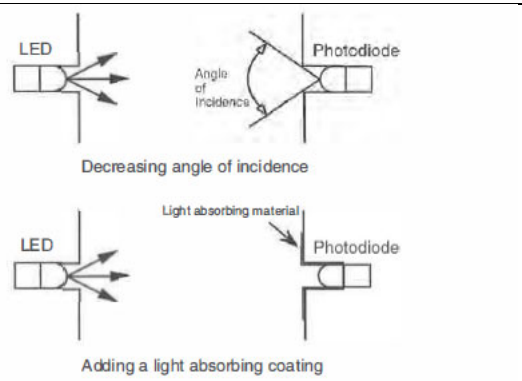


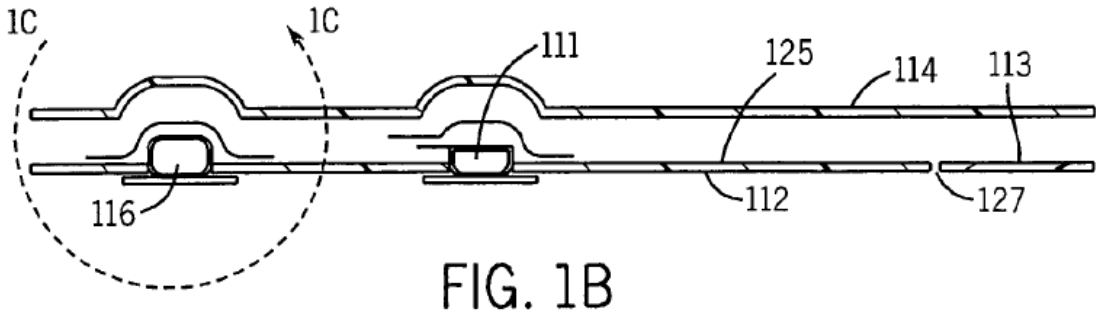
Figure 6.6 Minimizing photodiode optical interference (adapted from Marktech International 1993).

Under at least the apparent construction based on Masimo's Infringement Contentions, Hannula discloses and/or renders obvious an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector.

For example, Hannula discloses and/or suggests a non-adhesive oximeter sensor that relies on LEDs in one cavity (for example, element 111) to emit light that is received by a detector in a separate enclosure (for example, element 116), where the detector such as a photodetector generates at least one signal that is decoded by an oximeter monitors to calculate a patient's blood oxygen saturation, where the detector may be covered by a reflective mask and a Faraday electromagnetic shield, where the Faraday electromagnetic shield protects the photodetector from electromagnetic fields in the environment and reduces electromagnetic interference that may introduce noise into the output signal of photodetector 116:

> *See, e.g.*, Hannula at Abstract ("The present invention provides non-adhesive oximeter sensors for patients with sensitive skin. Sensors of the present invention include a light emitting diode (LED) and a photodetector. The LED and the photodetector may be covered by a reflective mask and a faraday shield. Sensors of the present invention have a non-adhesive laminated layer. The non-adhesive layer contacts, but does not stick to, the patient's skin. When the sensor is removed from the patient, the non-adhesive layer does not tear or irritate the patient's skin. The non-adhesive layer preferably has a large static coefficient of friction. Sensors of the present invention can also have hook-and-loop layers. The

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	sensor can be attached to the patient's body by wrapping the sensor around the patient and engaging the hook layer to the loop layer.”). Fig. 1B.  FIG. 1B Fig. 1C.

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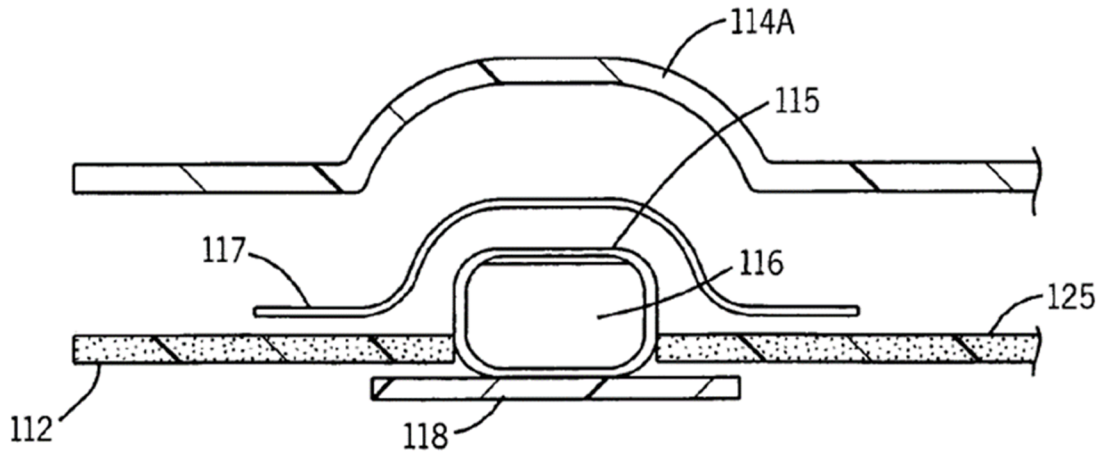


FIG. 1C

Fig. 2.

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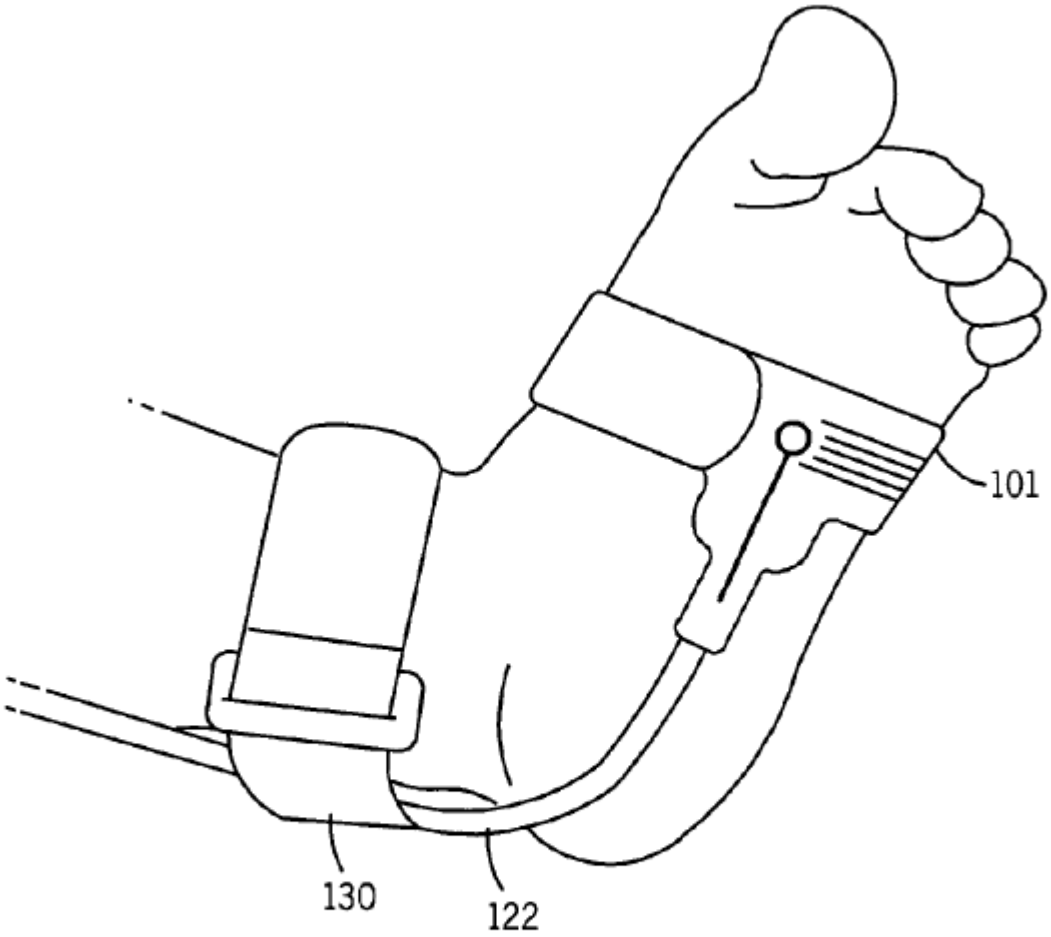


FIG. 2

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	Hannula, 1:55-2:19 (“(“The present invention provides non-adhesive oximeter sensors for patients with sensitive or fragile skin. Sensors of the present invention include a light emitting diode (LED) and a photodetector. The LED light shines light through a patient's tissue. The light from the LED is detected by the photodetector. The LED and photodetector may be covered by transparent windows. The LED and the photodetector may also be covered by a reflective mask and a Faraday electromagnetic shield. Sensors of the present invention have a laminated non-adhesive layer. The non-adhesive layer contacts, but does not stick to, the patient's skin. When the sensor is removed from the patient, the non-adhesive layer does not tear or irritate the patient's skin. Therefore, the non-adhesive layer protects sensitive skin. In one embodiment, the non-adhesive layer is a polyvinyl chloride foam material. The non-adhesive layer preferably has a large static coefficient of friction to help keep the sensor motionless relative to the patient. Sensors of the present invention also include one or more laminated layers that hold the sensor unit on the patient's body. These layers may include hook and loop layers. The sensor can be attached to the patient's body by wrapping the sensor around the patient and engaging the hook layer to the loop layer. Sensors of the present invention may include a strengthening layer that lies between the other laminated layers. Furthermore, sensors of the present invention may include light-blocking features to minimize or eliminate ambient light interference and LED light from reaching the photodetector without passing through blood-perfused tissues (shunting).”). Hannula, 2:36-3:42 (“Oximeter sensor **101** shown in FIGS. 1A, B, and C is an embodiment of the present invention. A top down view of oximeter sensor **101** is shown in FIG. 1A. A cross sectional view of oximeter sensor **101** along a plane **105**A is shown in FIG. 1B. The cross sectional view shows the laminated layers of sensor **101**. FIG. 1C illustrates an expanded view of a portion of the cross sectional view. Oximeter sensor **101** has one or more light emitting diodes (LED) **111** and a photodetector **116** as shown in FIG. 1. LED **111** emits light that shines through a patient's tissue. The light from LED **111** is sensed by photodetector **116**. Photodetector **116** produces a signal in response to the detected light. The signal is decoded by an oximeter monitor (not shown) to calculate the patient's blood oxygen saturation. LED **111** and photodetector **116** are connected to the oximeter monitor through wires that feed through cable **122**.

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	Sensor **101** has a polyurethane window **118** below photodetector **116**. Sensor **101** also has a polyurethane window below LED **111**. The polyurethane windows are transparent. Light from LED **111** can pass unobstructed through the polyurethane windows to photodetector **116**. As shown in exploded view in FIG. 1C, photodetector **116**, is surrounded by a reflective mask **117**. Reflective mask **117** reflects light from LED **111** (that has passed through patient tissue and exited near the photodetector) back toward photodetector **116** like a mirror. Reflective mask **117** increases the amount of LED light that the photodetector **116** receives from the patient's tissue, while assisting in blocking ambient light and LED light that may shunt through the laminated layers. LED **111** is also surrounded by a reflective mask that reflects light from LED **111** toward the patient's tissue. The reflective masks may comprise polyester or polypropylene with a reflective metal surface. Photodetector **116** is also covered with a Faraday shield **115**. Faraday shield **115** protects photodetector **116** from electromagnetic fields in the environment. Shield **115** reduces electromagnetic interference that may introduce noise into the output signal of photodetector **116**. Sensor **101** has laminated layers including layer **112** and hook-and- loop layers **113** and **114** shown in FIG. 1. Loop layer **114** has, for example, small loops of threads. Hook layer **113** has, for example, small hooks that engage with the loops in loop layer **114**. Hook layer **113** and loop layer **114** are used to attach sensor **101** to a patient. Hooks in hook layer **113** engage with the loops in loop layer **114**. Once engaged, the hook-and-loop layers remain attached to each other, until they are pulled apart. The end user can engage and disengage hook layer **113** from loop layer **114** multiple times in order to open or close the fastener. One portion of layer **114** cannot attach to another portion of layer **114**. In one embodiment of the present invention, hook and loop layers **113** and **114** are VELCRO layers. In this embodiment, layer **114** comprises a VELCRO loop, and layer **113** comprises a VELCRO hook.

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	Loop layer **114** has a first raised portion **114**A that provides room for the thickness of photodetector **116**. Loop **114** also has a second raised portion that provides room for LED **111**. Sensor **101** also has a bottom laminated layer **112** as shown in FIG. 1. Layer **112** is a non-adhesive layer. Layer **112** is preferably made of a material that has a soft, smooth, non-skid surface. Layer **112** may, for example, comprise polyvinyl chloride (PVC) foam. One type of PVC that may be used with the present invention is 3M-9777L PVC foam manufactured by 3M Co. Layer **112** may also comprise other types of soft, non-adhesive material. Bottom layer **112** is an outer layer of the sensor that contacts the patient's skin. Layer **112** comprises a non-adhesive material that does not adhere or stick to the patient's skin. Because layer **112** comprises a soft, non-adhesive material, it does not tear or irritate sensitive or fragile skin when sensor **101** is removed from the patient."). Hannula, Claims 1, 8, 11, 16, 35, 42, 45, 50 ("1. An oximeter sensor comprising: a light emitting element; a light detecting element; a substrate adapted to support the light emitting element and the light detecting element, the substrate comprising a non-adhesive patient-contacting surface, the patient contacting-surface having a static coefficient of friction greater than 5 with respect to a patient's skin. 8. The oximeter sensor of claim 1 further comprising: faraday shields over one or both of the light emitting and light detecting elements. 11. A method for forming an oximeter sensor, the method comprising: providing a substrate having a surface that contacts a patient, the substrate comprising a non-adhesive material that has a static coefficient of friction greater than 5 with respect to the patient's skin, the non-

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	adhesive material retaining the oximeter sensor on the patient without the use of an adhesive that contacts skin of the patient, the substrate having first and second receptacles; and placing a light emitting element in the first receptacle; placing a light detecting element in the second receptacle. 16. The method of claim 11 wherein the light emitting and light detecting elements include faraday shields. 35. An oximeter sensor comprising: a light emitting element; a light detecting element; a substrate having a strap-like configuration configured encircle a portion of a patient and to attach to itself, the substrate being adapted to support the light emitting element and the light detecting element, the substrate comprising a non-adhesive patient-contacting surface, the patient contacting-surface having a static coefficient of friction greater than 5 with respect to the patient's skin. 42. The oximeter sensor of claim 35 comprising: faraday shields over one or both of the light emitting and light detecting elements. 45. A method for forming an oximeter sensor, the method comprising: providing a substrate having a predominant thickness of less than 0.1 inch and having a surface that contacts a patient, the substrate comprising a non-adhesive material that has a static coefficient of friction greater than 5 with respect to the patient's skin, the non-adhesive material retaining the oximeter sensor on the patient without the use of an adhesive that contacts skin of the patient, the substrate having first and second receptacles; and

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	placing a light emitting element in the first receptacle; placing a light detecting element in the second receptacle. 50. The method of claim 45 wherein the light emitting and light detecting elements include faraday shields.”).
10[d-1] a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure,	Under at least the apparent construction based on Masimo’s Infringement Contentions, Webster discloses and/or renders obvious a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure. For example, Webster discloses and/or suggests a pulse oximeter for which there is a detector enclosed in a light block and for which a light absorbing coating is relied upon to reduce optical interference: *See, e.g.*, Webster at 77-78: 6.3 OPTICAL CONCERNS Since this is a system with an optical interface, it is important to minimize the effects from light other than the optical signals of interest. One way to minimize unwanted light incident upon the detector is to place some type of light filter over the detector. This allows light of wavelengths of interest to pass through the filter but does not allow light of other wavelengths to pass through the filter. For the pulse oximeter to work effectively, most of the light being transmitted from the LEDs must not reach the photodiode unless it has passed through tissue containing arterial blood. *6.3.1 Optical filtering* Optical filtering, placed between sources of light and the photodiode, is used to limit the spectral response of the photodiode. A number of optical filter types can be used. Cheung *et al* (1993) recommend a red Kodak No. 29 wratten gel filter to eliminate the flickering effect of fluorescent light. However, these external filters do not appear to be used much in actual pulse oximetry designs. In addition, the photodiode mounting package may contain filtering material. Many photodiodes are mounted in clear plastic which absorbs UV wavelengths (Burr-Brown 1994a,b,c). This is useful to filter out some of the unwanted effects of fluorescent lighting on the photodiode. Many photodiodes are available in a variety of packaging types each of which filters out selected wavelengths of light.

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6.3.2 Optical interference

To minimize errors, the pulse oximeter designer must attempt to limit the light reaching the photodiode to that which has traveled through tissue containing arterial blood (Nellcor 1993). This can be accomplished through thoughtful LED/photodiode placement. Light impervious barriers should be placed between LEDs and the photodiode in all areas where the emitted light could reach the photodiode without passing through tissue (New and Corenman 1987). Two additional measures can be taken to ensure this (figure 6.6). One is to decrease the angle of incidence to the photodiode. The second is to coat the housing around the photodiode with a material that does not scatter or reflect light.

There are two types of optical interference that may cause problems for the photodiode. The first is excessive ambient light. The source of this type of error may be surgical lamps, fluorescent lights, infrared heat lamps and direct sunlight. Usually this type of interference will saturate the photodiode so that no pulse can be distinguished, however some of these sources may result in apparently normal but inaccurate readings. The second source of interference is optical cross-talk. This type of interference typically may occur when multiple probes are used in close proximity. In this case, light from one LED probe is sensed by the photodiode of another probe.

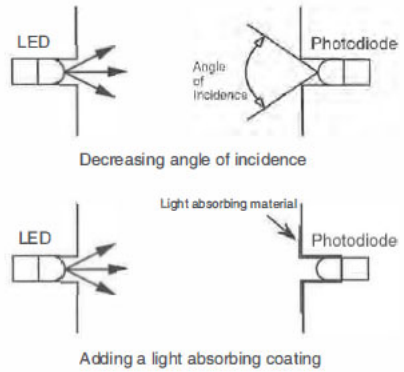
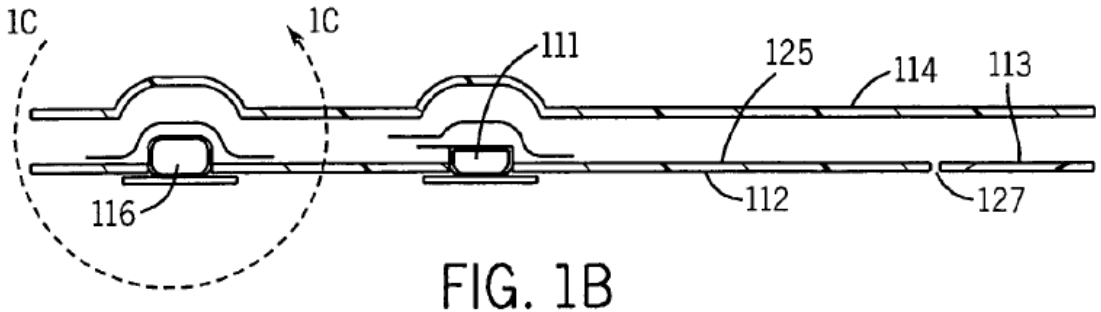


Figure 6.6 Minimizing photodiode optical interference (adapted from Marktech International 1993).

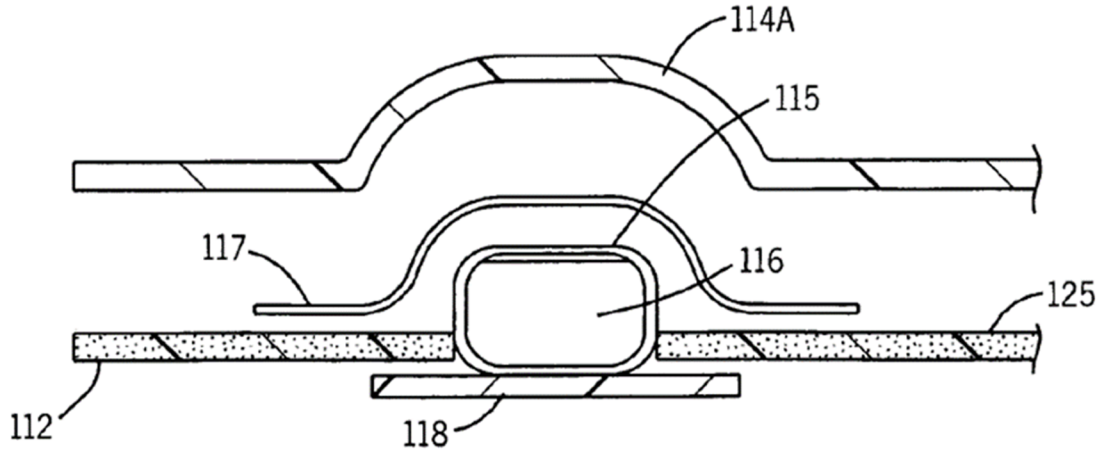
Under at least the apparent construction based on Masimo's Infringement Contentions, Hannula discloses and/or renders obvious obvious a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure.

For example, Hannula discloses and/or suggests a non-adhesive oximeter sensor that relies on LEDs in one cavity (for example, element 111) to emit light that is received by a detector in a separate enclosure (for example, element 116), where the detector such as a photodetector generates at least one signal that is decoded

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	by an oximeter monitors to calculate a patient's blood oxygen saturation, where there is a light block surrounding the at least one photodetector, implemented in non-limiting examples as one or more of the reflective mask 117, layer 112, inner side 125 of layer 112, faraday shield 115, and/or polyurethane window 1118, where the light block encloses the at least one photodetector into structure formed by a base (for example, 114A or 117 or 115), four side walls (the four side walls of 117 or 115) and a top (the patient-facing top of the detector 116, the patient-facing top of the faraday shield 115, or 118), and wherein the light block structure is at least partially formed of black materials, such as an black opaque film that comprises the inner side 125 of layer 112 and blocks ambient light that may interfere with photodetector 116: *See, e.g.*, Hannula at Abstract ("The present invention provides non-adhesive oximeter sensors for patients with sensitive skin. Sensors of the present invention include a light emitting diode (LED) and a photodetector. The LED and the photodetector may be covered by a reflective mask and a faraday shield. Sensors of the present invention have a non-adhesive laminated layer. The non-adhesive layer contacts, but does not stick to, the patient's skin. When the sensor is removed from the patient, the non-adhesive layer does not tear or irritate the patient's skin. The non-adhesive layer preferably has a large static coefficient of friction. Sensors of the present invention can also have hook-and-loop layers. The sensor can be attached to the patient's body by wrapping the sensor around the patient and engaging the hook layer to the loop layer."). Fig. 1B.  FIG. 1B

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	Fig. 1C.  FIG. 1C Fig. 2.

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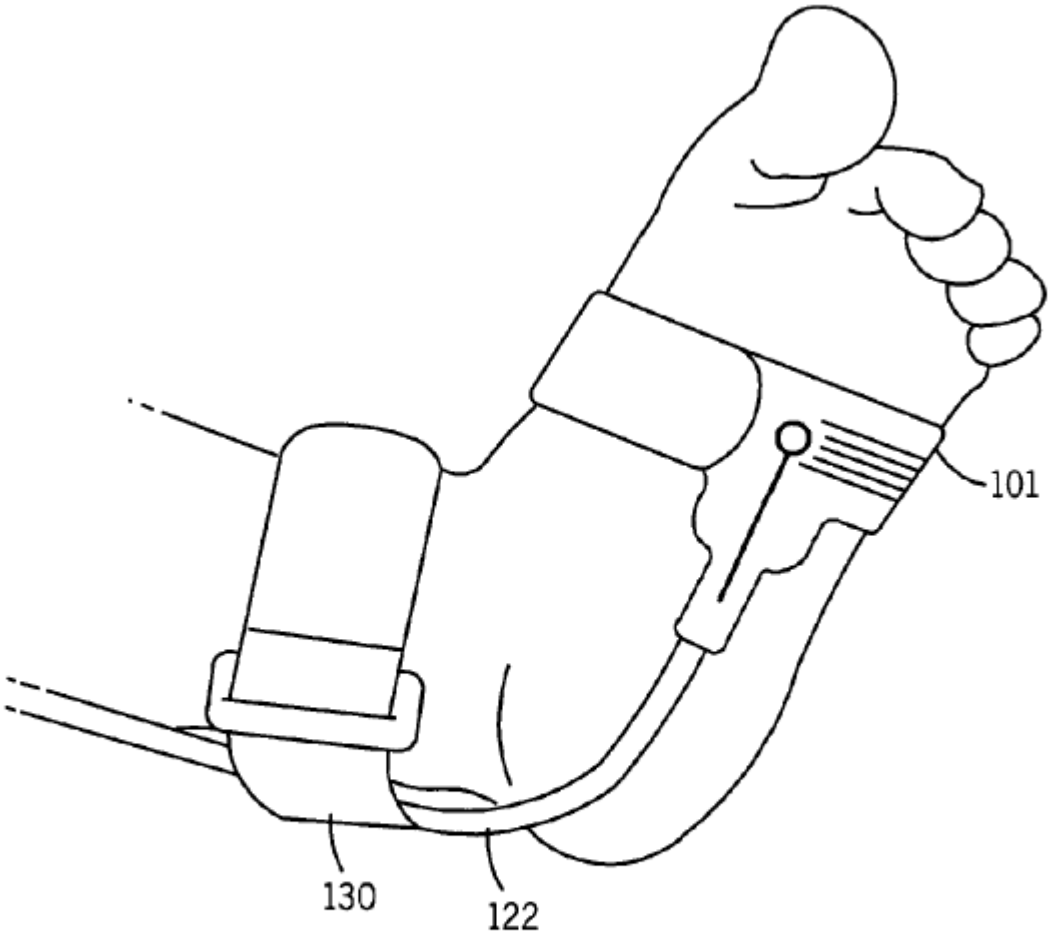


FIG. 2

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	Hannula, 1:55-2:19 ("The present invention provides non-adhesive oximeter sensors for patients with sensitive or fragile skin. Sensors of the present invention include a light emitting diode (LED) and a photodetector. The LED light shines light through a patient's tissue. The light from the LED is detected by the photodetector. The LED and photodetector may be covered by transparent windows. The LED and the photodetector may also be covered by a reflective mask and a Faraday electromagnetic shield. Sensors of the present invention have a laminated non-adhesive layer. The non-adhesive layer contacts, but does not stick to, the patient's skin. When the sensor is removed from the patient, the non-adhesive layer does not tear or irritate the patient's skin. Therefore, the non-adhesive layer protects sensitive skin. In one embodiment, the non-adhesive layer is a polyvinyl chloride foam material. The non-adhesive layer preferably has a large static coefficient of friction to help keep the sensor motionless relative to the patient. Sensors of the present invention also include one or more laminated layers that hold the sensor unit on the patient's body. These layers may include hook and loop layers. The sensor can be attached to the patient's body by wrapping the sensor around the patient and engaging the hook layer to the loop layer. Sensors of the present invention may include a strengthening layer that lies between the other laminated layers. Furthermore, sensors of the present invention may include light-blocking features to minimize or eliminate ambient light interference and LED light from reaching the photodetector without passing through blood-perfused tissues (shunting)."). Hannula, 2:36-4:62 ("Oximeter sensor **101** shown in FIGS. 1A, B, and C is an embodiment of the present invention. A top down view of oximeter sensor **101** is shown in FIG. 1A. A cross sectional view of oximeter sensor **101** along a plane **105**A is shown in FIG. 1B. The cross sectional view shows the laminated layers of sensor **101**. FIG. 1C illustrates an expanded view of a portion of the cross sectional view. Oximeter sensor **101** has one or more light emitting diodes (LED) **111** and a photodetector **116** as shown in FIG. 1. LED **111** emits light that shines through a patient's tissue. The light from LED **111** is sensed by photodetector **116**. Photodetector **116** produces a signal in response to the detected light. The signal is decoded by an oximeter monitor (not shown) to calculate the patient's blood oxygen saturation. LED **111** and photodetector **116** are connected to the oximeter monitor through wires that feed through cable **122**.

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	Sensor **101** has a polyurethane window **118** below photodetector **116**. Sensor **101** also has a polyurethane window below LED **111**. The polyurethane windows are transparent. Light from LED **111** can pass unobstructed through the polyurethane windows to photodetector **116**. As shown in exploded view in FIG. 1C, photodetector **116**, is surrounded by a reflective mask **117**. Reflective mask **117** reflects light from LED **111** (that has passed through patient tissue and exited near the photodetector) back toward photodetector **116** like a mirror. Reflective mask **117** increases the amount of LED light that the photodetector **116** receives from the patient's tissue, while assisting in blocking ambient light and LED light that may shunt through the laminated layers. LED **111** is also surrounded by a reflective mask that reflects light from LED **111** toward the patient's tissue. The reflective masks may comprise polyester or polypropylene with a reflective metal surface. Photodetector **116** is also covered with a Faraday shield **115**. Faraday shield **115** protects photodetector **116** from electromagnetic fields in the environment. Shield **115** reduces electromagnetic interference that may introduce noise into the output signal of photodetector **116**. Sensor **101** has laminated layers including layer **112** and hook-and- loop layers **113** and **114** shown in FIG. 1. Loop layer **114** has, for example, small loops of threads. Hook layer **113** has, for example, small hooks that engage with the loops in loop layer **114**. Hook layer **113** and loop layer **114** are used to attach sensor **101** to a patient. Hooks in hook layer **113** engage with the loops in loop layer **114**. Once engaged, the hook-and-loop layers remain attached to each other, until they are pulled apart. The end user can engage and disengage hook layer **113** from loop layer **114** multiple times in order to open or close the fastener. One portion of layer **114** cannot attach to another portion of layer **114**. In one embodiment of the present invention, hook and loop layers **113** and **114** are VELCRO layers. In this embodiment, layer **114** comprises a VELCRO loop, and layer **113** comprises a VELCRO hook.

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	Loop layer **114** has a first raised portion **114**A that provides room for the thickness of photodetector **116**. Loop **114** also has a second raised portion that provides room for LED **111**. Sensor **101** also has a bottom laminated layer **112** as shown in FIG. 1. Layer **112** is a non-adhesive layer. Layer **112** is preferably made of a material that has a soft, smooth, non-skid surface. Layer **112** may, for example, comprise polyvinyl chloride (PVC) foam. One type of PVC that may be used with the present invention is 3M-9777L PVC foam manufactured by 3M Co. Layer **112** may also comprise other types of soft, non-adhesive material. Bottom layer **112** is an outer layer of the sensor that contacts the patient's skin. Layer **112** comprises a non-adhesive material that does not adhere or stick to the patient's skin. Because layer **112** comprises a soft, non-adhesive material, it does not tear or irritate sensitive or fragile skin when sensor **101** is removed from the patient. Layer **112** preferably comprises a material that has a relatively large static coefficient of friction. A material with a large static coefficient of friction helps to keep sensor **101** motionless relative to the skin as a patient moves. In sensors of the present invention, it is important to maximize the friction between the sensor and the skin, without the use of adhesives. Adhesives can damage fragile skin, and one objective of the present invention is to keep the sensor on the patient without slippage, but without the use of an adhesive. According to the present invention, the static coefficient of friction of a material is tested using the following procedure. Attach a protractor to a vertical wall with the center in line with the edge of a table. Set up a stop block at the edge of the table to act as a pivot point for a glass plate. Place the glass plate flat on the table with one edge along the edge of the table, up against the stop block. Place a test sample of the material on the glass plate (or other reference materials, such as skin). Lift the free edge of the glass plate until the test sample just starts to slip. Record angle at which slippage first occurred. This angle is the angle of repose. Then calculate the coefficient of friction, which is the tangent of the angle of repose. The coefficient of friction of polyvinyl chloride (PVC) foam is greater than the prior art foam wrap assembly found in the STAT-WRAP™ sensor. The 3M-9777L PVC foam measured using the above-described measuring technique resulted in a value of static coefficient of friction of infinity with respect

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	to glass. The 3M-9777L PVC foam actually stayed on the glass test plate even after achieving a 90 degree angle of repose. The 3M-9777L PVC material almost exhibits slight adhesive properties, surface tension forces, or static cling forces. Therefore, PVC foam is a very good choice of material for layer **112** in consideration of the preferred non-slip characteristics. Using skin as a reference material instead of glass, the 3M-9777L PVC foam exhibits a static coefficient of friction of greater than 5, such as 5.7. The PVC material almost exhibits slight adhesive properties, surface tension forces, or static cling forces. Therefore, PVC foam is a very good choice of material for layer **112** in consideration of the preferred non-slip characteristics. Materials other than PVC foam can be used for layer **112**. The static coefficient of friction for layer **112** is preferably greater than 10. Most preferably, layer **112** has a static coefficient of friction that is greater than 100. Layer **112** is preferably light in color to enhance the amplitude of the light signals received by photodetector **116**. For example, layer **112** may be white, off-white, or cream colored. Alternatively, layer **112** may be dark in color to decrease the amount of ambient and shunted light that reaches the photodetector, at an expense of the amount of detected LED light signals. Layer **112** is preferably a thin layer, as shown in the cross sectional views in FIG. 1. By selecting a narrow thickness for layer **112**, sensor **101** is less bulky. Because sensor **101** is thin, it is more flexible, and it can be easily conformed around a patient's body part. FIG. 2 illustrates an example of how sensor **101** can be placed around a patient's foot. Sensor **101** may include an additional laminated layer. The additional laminated layer is a strengthening film (not shown) that lies between laminated layers **114** and **112**. In one embodiment, hook layer **113** is attached to the strengthening film. In this embodiment, hook **113** is an integral part of one of the laminated layers that makes up the body of sensor **101**. Hook portion **113** is not attached to layer **112**. The foam layer **112** is discontinued at point **127** in FIG. 1, and hook portion **113** begins to the right of **127**. In other embodiments, hook layer **113** is an integral part of bottom layer **112** or top layer **114**.

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	In one embodiment of the present invention, the inner side **125** of layer **112** is covered with a laminated opaque film. The opaque film blocks ambient light that may interfere with photodetector **116**. The opaque film may comprise polyethylene. The opaque film may be black or some other dark color that helps block ambient light and reduces shunted light. Dark in color is understood here to be of a nature with little reflectance of the wavelengths of light sensed by the sensor's photodetector. Non-adhesive layer **112** is preferably long enough to wrap all the way around the patient's finger, toe, ear, or other portion of the body. Non-adhesive layer **112** is the only portion of sensor **101** that directly contacts the patient's skin. This feature of the present invention eliminates damage to the patient's skin that can be caused by adhesive portions of a sensor."). Hannula, Claims 1, 8, 9, 10, 11, 16, 35, 42, 43, 44, 45, 50 ("1. An oximeter sensor comprising: a light emitting element; a light detecting element; a substrate adapted to support the light emitting element and the light detecting element, the substrate comprising a non-adhesive patient-contacting surface, the patient contacting-surface having a static coefficient of friction greater than 5 with respect to a patient's skin. 8. The oximeter sensor of claim 1 further comprising: faraday shields over one or both of the light emitting and light detecting elements. 9. The oximeter sensor of claim 1 further comprising: an opaque film that covers the inner surface of the first laminated layer. 10. The oximeter sensor of claim 9 wherein:

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	the opaque film is dark in color. 11. A method for forming an oximeter sensor, the method comprising: providing a substrate having a surface that contacts a patient, the substrate comprising a non-adhesive material that has a static coefficient of friction greater than 5 with respect to the patient's skin, the non-adhesive material retaining the oximeter sensor on the patient without the use of an adhesive that contacts skin of the patient, the substrate having first and second receptacles; and placing a light emitting element in the first receptacle; placing a light detecting element in the second receptacle. 16. The method of claim 11 wherein the light emitting and light detecting elements include faraday shields. 35. An oximeter sensor comprising: a light emitting element; a light detecting element; a substrate having a strap-like configuration configured encircle a portion of a patient and to attach to itself, the substrate being adapted to support the light emitting element and the light detecting element, the substrate comprising a non-adhesive patient-contacting surface, the patient contacting-surface having a static coefficient of friction greater than 5 with respect to the patient's skin. 42. The oximeter sensor of claim 35 comprising: faraday shields over one or both of the light emitting and light detecting elements.

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	43. The oximeter sensor of claim 35 comprising: an opaque film that covers the inner surface of the first laminated layer. 44. The oximeter sensor of claim 43 wherein: the opaque film is dark in color. 45. A method for forming an oximeter sensor, the method comprising: providing a substrate having a predominant thickness of less than 0.1 inch and having a surface that contacts a patient, the substrate comprising a non-adhesive material that has a static coefficient of friction greater than 5 with respect to the patient's skin, the non-adhesive material retaining the oximeter sensor on the patient without the use of an adhesive that contacts skin of the patient, the substrate having first and second receptacles; and placing a light emitting element in the first receptacle; placing a light detecting element in the second receptacle. 50. The method of claim 45 wherein the light emitting and light detecting elements include faraday shields.”). Under at least the apparent construction based on Masimo’s Infringement Contentions, Fantini discloses and/or renders obvious a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure. For example, Fantini discloses and/or suggests a light block surrounding the at least one detector comprising a Direct light block or measuring head: *See, e.g.*, Fantini at Abstract:

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Abstract. We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit.

See, e.g., Fantini at 33:

In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition.

In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument.

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	See, e.g., Fantini at 34: ***Feature 2.*** The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. ***Feature 3.*** To implement the measurement of the slopes of the straight lines (as a function of the distance *r* between

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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of

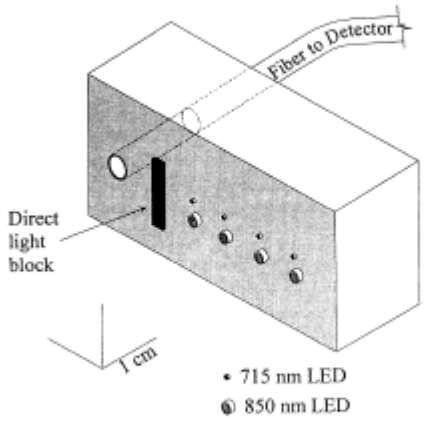
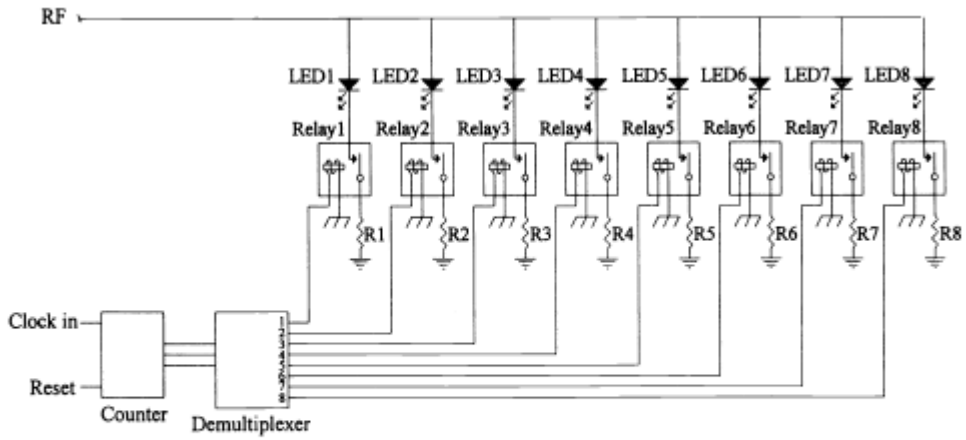


Fig. 2 Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium.

See, e.g., Fantini at 35:

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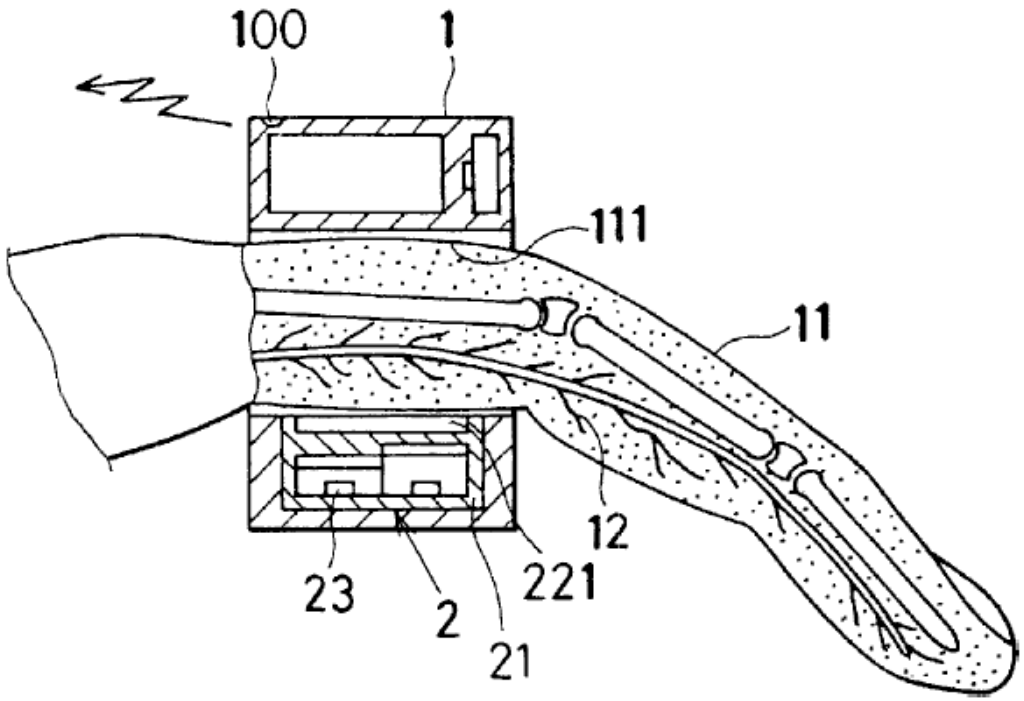
	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
10[d-2] wherein the light block comprises a window, the window	Under at least the apparent construction based on Masimo's Infringement Contentions, Kimura discloses and/or renders obvious wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector.

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having an area smaller than a detection surface area of the at least one detector; and	For example, Kimura discloses and/or suggests a vital signs detecting apparatus that is capable measuring vital signals such as pulse by relying on a least three LEDs in a cavity and at least one detector in a different enclosure, where for an area of an only opening to the detector is smaller than a detection surface area of the at least one detector, implemented in a non-limiting example as a vital sign detecting apparatus for which there is a window above a light receiving device comprising a detector 404, where the window 412 is circular and has a surface area that is smaller than the surface area of the detector: *See, e.g.*, Kimura at Abstract ("A vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. The pulse wave detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, Fig. 1A

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FIG. 1A



Kimura, Fig. 1B.

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FIG. 1B

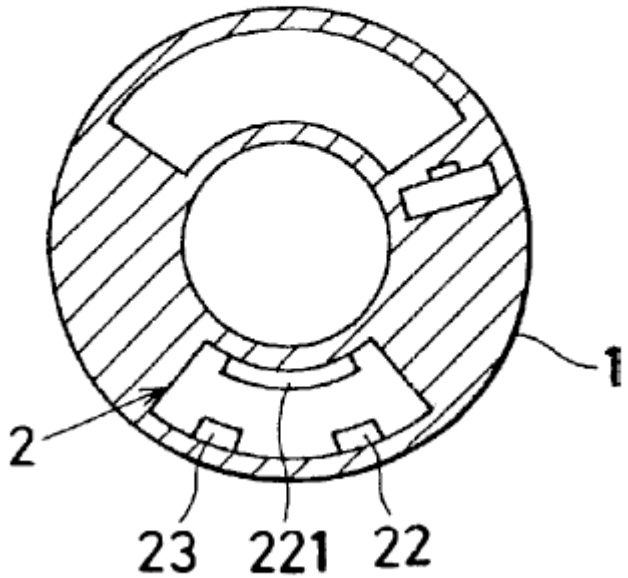


Fig. 2.

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FIG. 2

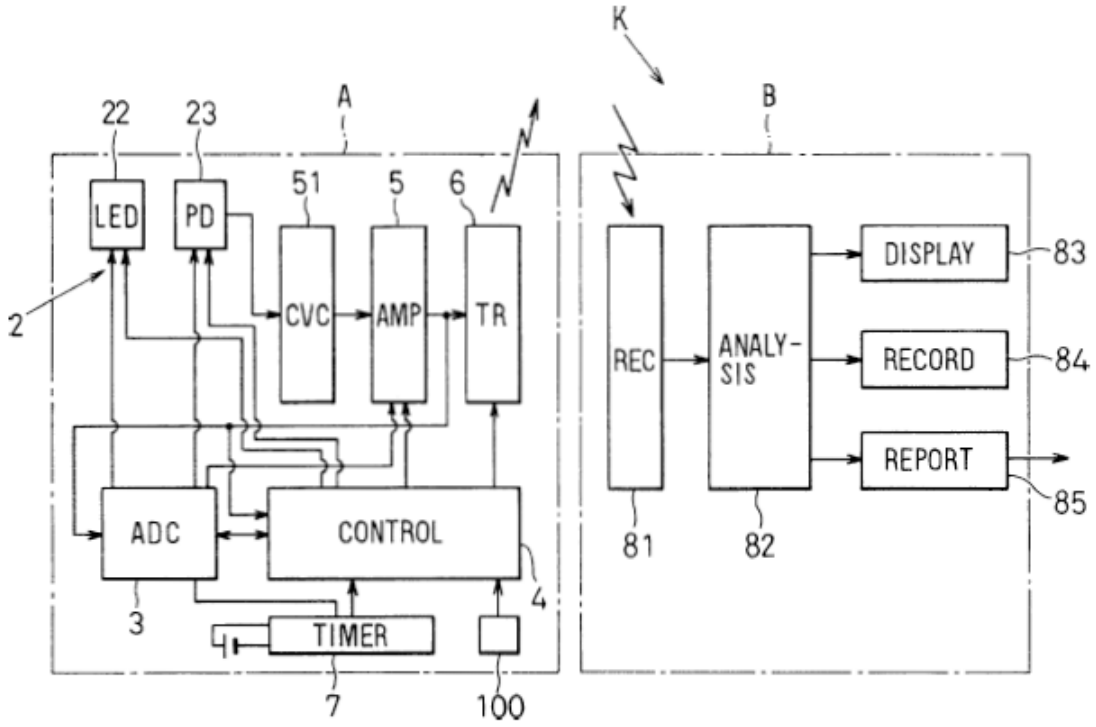


Fig. 22.

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FIG. 22

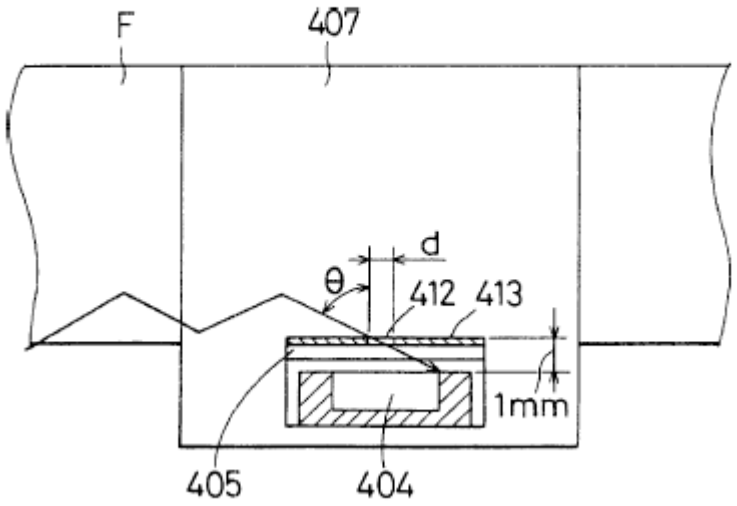
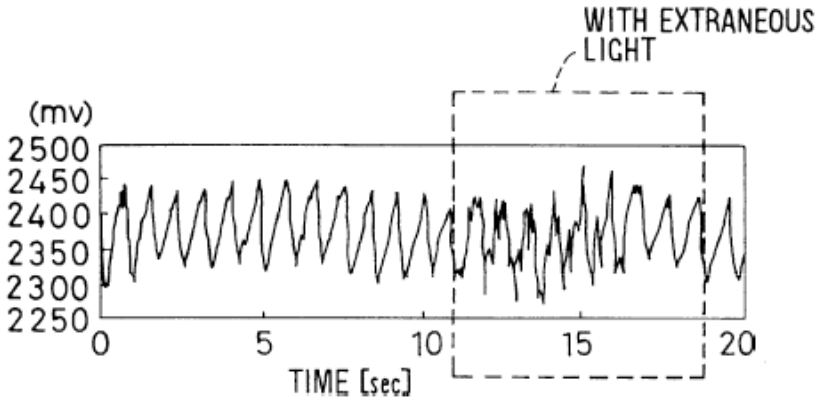


Fig. 23A.

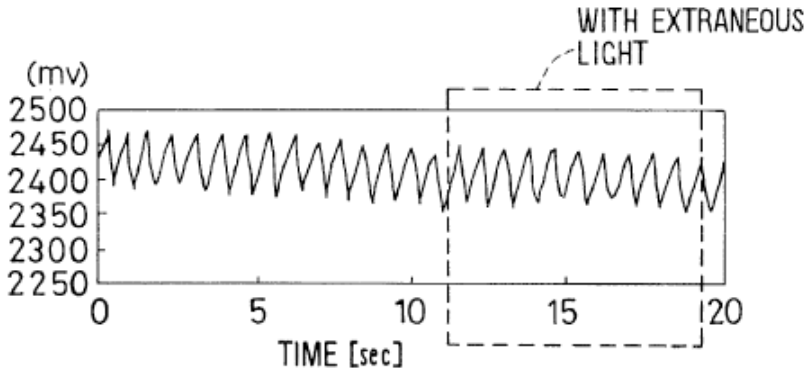
FIG. 23A



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Fig. 23B.

FIG. 23B



Kimura, 1:13-2:2 ("This invention relates to a vital signal detecting apparatus for detecting a vital signal, having an attachable device to be attached for example to a finger, an ear, an arm, a leg, torso or a neck of a human subject.

There have been vital signal detecting apparatuses, as disclosed, for instance, in JP-A-8-266493 or Electronic Data Communications Society, Technical Report 1995-06. To check a vital signal (such as a pulse wave), a human subject has to operate an on/off switch himself or herself. If the subject operates the on/off switch without inserting a finger into the attachable device, because a sensor picks up external noise and outputs an abnormal signal, the vital signal checking device erroneously determines that the subject is abnormal. Further, if a ring part of a pulse wave sensor fails even slightly to match the size (thickness) of the finger, it is difficult for a detecting part to be kept in contact with the surface of the finger. Thus, extraneous light, for example, sunlight or light from fluorescent lights, affect the measurement.

There have also been vital signal detecting apparatuses, used when a vital signal (such as the pulse wave) of for example an elderly or infirm subject is to be monitored over a long period, with which an attachable device is attached for instance to an arm or a leg of the subject and a vital signal detected by a sensor is transmitted to a vital signal checking device by radio waves or the like. If the elderly or

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	infirm subject removes the attachable device, because the sensor picks up external noise and transmits an abnormal signal to the vital signal checking device, again the vital signal checking device erroneously determines that the subject is abnormal. SUMMARY OF THE INVENTION It is therefore an object of the present invention to provide a vital signal detecting apparatus which eliminates problems caused by abnormal vital signals detected when an attachable device is not attached. According to the present invention, a vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. Preferably, the vital signal detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, 14:19-47 ("As shown in FIG. 22, in this preferred embodiment, a window **412** for limiting the angle of incidence at which light can enter the light-receiving device **404** is provided above the light-receiving device **404**. The window **412** above the light-receiving device **404** is formed by providing a blocking film **413** capable of blocking light on the surface of the light-transmitting plate **405** and then making a hole of a predetermined size in the center of this blocking film **413**.

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	By providing the window **412** above the light-receiving device **404**, for example as shown in FIG. 22, the light-receiving device **404** is disposed 1 mm below the interface between the light-transmitting plate **405** and the skin surface. If the window width d is made 0.5 mm, then it is possible to cut out light having an angle of incidence θ of over ±30°, as shown in FIG. **23**B. On the other hand, if the window width d is made 4 mm, then because only light whose angle of incidence θ is over ±60° is blocked, fluctuation arises in the detection result (voltage Value) of the pulse wave sensor **401** due to the influence of extraneous light, as shown in FIG. **23**A. As mentioned above with reference to the eleventh preferred embodiment, extraneous light guided in through the skin of the finger F can be considered to be incident on the light-receiving device **404** at a large angle of incidence (θ≧30°). Consequently, since extraneous light can be effectively cut out by limiting the window width d, it is possible to reduce erroneous detection caused by the influence of extraneous light."). Kimura, Claim 13 ("13. A vital signal detecting apparatus comprising: a light-emitting device; a light-receiving device; and a light-transmitting plate disposed above the light-emitting device and the light-receiving device to pass light therethrough, and used with the surface of the light-transmitting plate in contrast with the skin surface of a human body, wherein the light-receiving device is disposed in a position lowered by a predetermined distance with respect to the light-transmitting plate, and a window formed in a light-blocking layer that covers the surface of the light-transmitting plate and provided above the light-receiving device, the window for limiting the angle of incidence at which light can enter the light-receiving device.").

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Diab discloses and/or renders obvious wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector. For example, Diab discloses and/or suggests an optical prove that is particularly suited to reduce noise in measurements that relies on LEDs and a detector measure physiological parameters, where there is an opening to a detector 126 in a light blocking chamber 126 comprising the portion of a lens 132 through which light can pass to the detector, where light received by the detector must pass through the lens, and where the opening comprises an area smaller than a detection surface area of the detector because the opening is of a diameter that is less than the diameter of the detector by at least the thickness of an optical adhesive or lens retaining ring: *See, e.g.*, Diab at Abstract ("An optical probe, which is particularly suited to reduce noise in measurements taken on an easily compressible material, such as a finger, a toe, a forehead, an earlobe, or a lip, measures characteristics of the material. A neonatal and adult disposable embodiment of the probe include adhesive coated surfaces to securely affix the probe onto the patient. In addition, the surface of the probe is specially constructed to minimize light piping effects. Furthermore, a flex circuit acts as a spring to absorb shock which may misalign the emitter and detector. One embodiment of the adult probe includes a cushioning pocket formed for a fingertip to align the probe and to absorb motion of the probe due to contact. The neonatal probe is formed with a unique V-configuration which provides multiple advantages."). Fig. 5.

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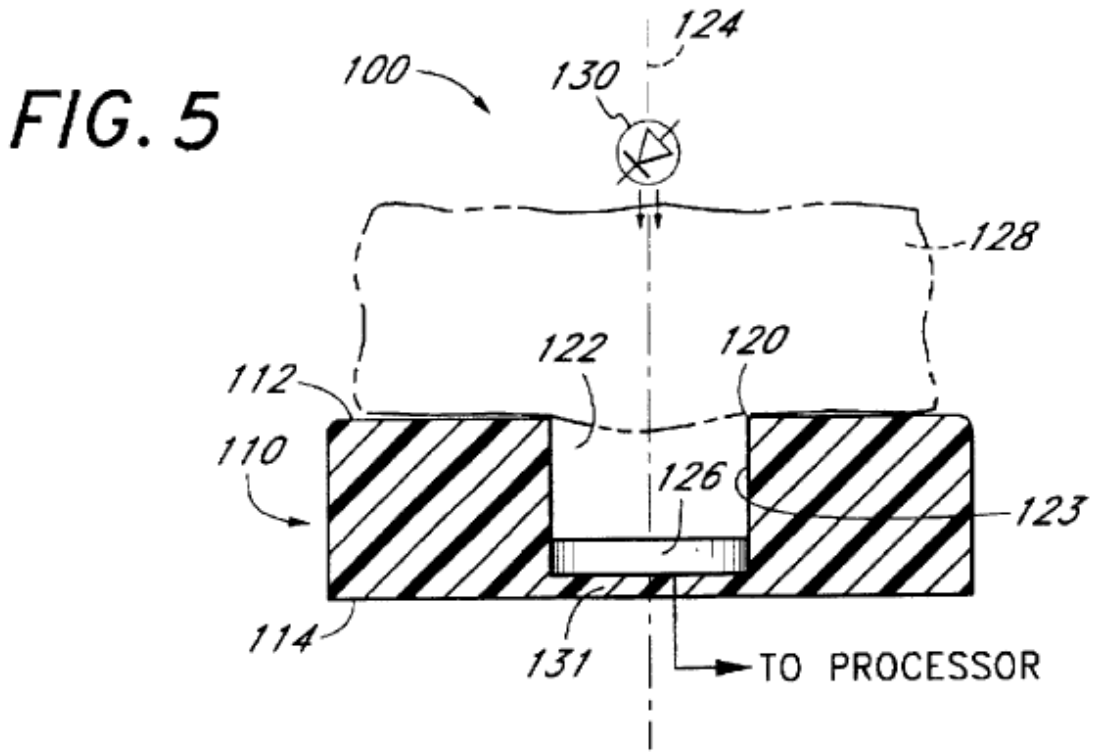


Fig. 6.

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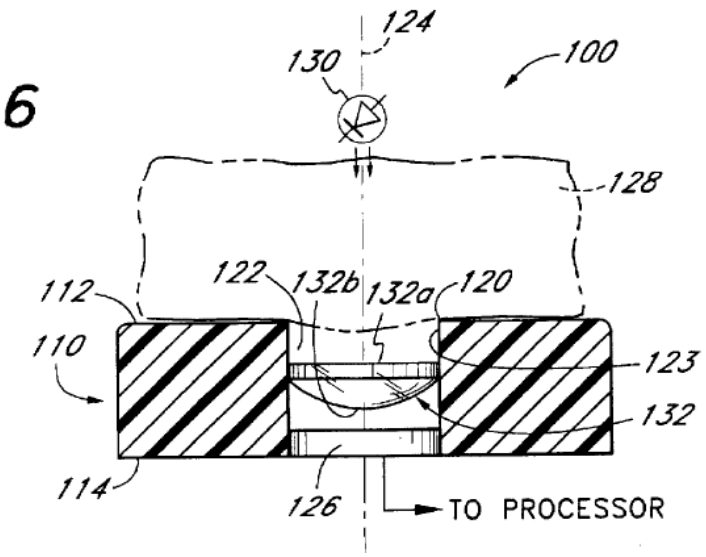


Fig. 12.

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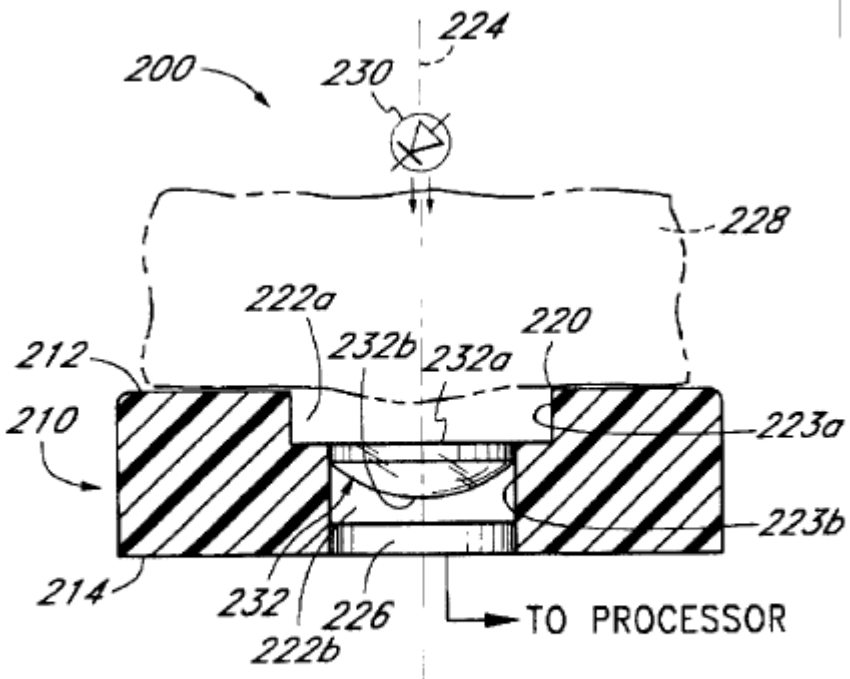


FIG. 12

Diab, 6:54-64 ("Examination of a material is often advantageous, especially when it is difficult or expensive to procure and test a sample of the material. For example, in physiological measurements, it is often desirable to monitor a patient without drawing of blood or tissue from the patient. The known properties of energy absorption as energy propagates through a material may be used to determine information about the material through which the energy has passed. Energy is made incident on a material, and a measurement is made of energy either transmitted by or reflected from the material.").

Diab, 7:36-9:43 ("FIG. 3 is a perspective view of one embodiment of an optical probe 100 of the present invention which greatly diminishes the effects of motion artifacts on the measured signal. FIG.

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	4 shows a cross-sectional view of the optical probe 100 of the present invention taken along line 4--4 in FIG. 3. For clarity in the perspective view of FIG. 3, a material 128 on which measurements are to be taken is not shown placed adjacent the probe 100. However, the material 128 on which measurements are to be made is shown in FIG. 4. As illustrated in FIGS. 3 and 4, a base 110, having a top 112, a bottom 114, a forward end 116, and a rear end 118, is made of a material which is preferably rigid and opaque. It will be understood, however, that the probe 100 may be made of materials which may be rigid, resilient, opaque, or transparent, for example. An aperture 120 is formed in the top 112 of the base 110. Typically, the aperture 120 is located at a point between one-quarter and one-half of the length of the base 100. The aperture 120 may be of any shape, including but not limited to circular, square, or triangular. The aperture 120 forms the opening to a chamber 122 which may also be of any shape. In one embodiment, a lateral cross-section (not shown) of the chamber 122 is the same shape as the aperture. A central axis 124 of the chamber 122 is defined by a line aligned perpendicular to the aperture 120 and extending generally through a central portion of the aperture 120. In the embodiment of FIG. 4, a light source 130, typically a light emitting diode (LED), is affixed adjacent the material 128, aligned along the central axis 124 of the chamber 122 opposite the chamber 122. Typically, an adhesive such as medical tape is used to affix the LED 130 to the material 128. A detector 126, such as a photodetector, is placed within the chamber 122. A central portion of the photodetector 126 is generally aligned with the central axis 124 of the chamber 122, typically at the bottom 114 of the chamber 122. The photodetector 126 may be fixed within the chamber 122 according to a number of different methods, including but not limited to adhesive, a press fit, or clear epoxy resin which transmits light over a range of wavelengths of interest. Typically, no matter how the photodetector 126 is held within the chamber 122, the bottom surface 114 of the chamber 122 is made opaque either via the press fit or via paint or tape, for example. It is often the case that materials 128 on which absorption measurements are performed are, at least in part, easily compressible. Easily compressible portions of the material 128 are placed directly adjacent (i.e., above) the chamber 122. The area surrounding the aperture 120 supports the material covering the chamber 122. The chamber 122 is wide enough that any compressible portion of the material 128 located above the aperture 120 may intrude into the chamber 122. Thus, the material 122 may rest

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	above or penetrate slightly into the chamber 122 and is thereby shielded from perturbations which compress the material 128, such as pressure caused when the material 128 is touched. In the present embodiment, the depth of the chamber 122 may range from 0.5 mm to 10 mm in depth, with 2-4 mm preferred, and 3-4 mm more preferred. Similarly, the diameter of the aperture 120 may, in the present embodiment, range from 3 mm to 20 mm, as required by the specific application. For instance, the aperture would be smaller for neonates than for adults. These sizes have been found to be effective in reducing perturbations and compression of the material 128, when the material is human skin. The chamber 122 is deep enough that the photodetector 126 and the bottom 114 of the chamber 122 do not come into contact with the easily compressible portion of the material 128, even when the material 128 is caused to move. Thus, along the central axis 124 of the chamber 122 nothing comes into physical contact with the easily compressible portion of the material 128 and causes it to compress With little or no compression of the material 128 in this region, the thickness of the material 128, or the optical path length of light energy propagating through the material 128, is substantially stabilized in the field of view of the photodetector. The movement of venous blood due to compression is also minimized in the field of view of the photodetector. The LED 130 emits light at a known wavelength. The light propagates through the material 128 and an attenuated signal is transmitted into the chamber 122 to be received by the photodetector 126. As light from the LED 130 propagates through the material 128, it is scattered by the material 128 and is thus transmitted into the chamber 122 over a broad range of angles in a very complex manner. Thus, some of the light is caused to be incident on the opaque walls 123 of the chamber 122 and is absorbed. Although the signal travels through a greater optical distance to reach the photodetector 126 at the bottom 114 of the chamber 122 than if the photodetector 126 were immediately adjacent the material 128, thus eliminating direct coupling between the photodetector 126 and the material 128, the resulting degradation to signal intensity is compensated for by the stabilization of the optical path length and the resultant reduction of noise in the measured signal. The photodetector 126 produces an electrical signal indicative of the intensity of light energy incident on the photodetector 126. The electrical signal is input to a processor which analyzes the signal to determine characteristics of the media 128 through which the light energy has passed.

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	The opaque quality of the base 110 absorbs ambient light which can interfere with the signal measured at the photodetector 126. This further improves signal quality. Further, the opaque bottom 114 of the chamber 122 protects the photodetector 126 from ambient light which can obscure the desired signal measured at the photodetector 126. Thus, an accurate measurement of the intensity of the attenuated signal may be made at the photodetector 126. An alternative embodiment of the chamber 122 is shown in frontal cross-section in FIG. 5. A shell 131 of base 110 material covers the bottom 114 of the chamber 122. The photodetector 126 is mounted on the shell 131, within the chamber 122, generally aligned with the LED 130. The photodetector 126 is electrically connected to a processor through a small hole (not shown) in the shell 131. The shell 131 shields the photodetector 126 from ambient light which can seriously degrade the signal-to-noise ratio of the signal measured at the photodetector 126. It will be understood that the bottom 114 of the chamber 122 may be formed with or without the shell in any embodiment of the probe of the present invention. FIG. 6 shows a frontal cross sectional view of another embodiment of the probe 100 of the present invention wherein a light collecting lens 132 is placed within the chamber 122, between the material 128 which rests above or enters into the chamber 122 and the photodetector 126. The lens 132 has one generally planar surface 132a aligned parallel to the aperture 120 in the top 112 of the base 110, located deep enough within the chamber 122 that any material 128 which intrudes into the chamber 122 does not contact the planar surface 132a of the lens 132. Another surface 132b of the lens 132 is generally convex having its apex directed toward the photodetector 126 in the bottom 114 of the chamber 122. The lens 132 may be held in the chamber 122 by a number of means, including but not limited to optical adhesive, a lens retaining ring, or a press fit. The chamber 122 functions in the same manner as described above to stabilize the optical path length and reduce motion artifacts. The light collecting lens 132 gathers much of the light which was scattered as it was transmitted through the material 128 and causes it to be incident on the photodetector 126. This produces a stronger measured signal."). Diab, 12:16-38 ("In another embodiment of the probe 200, a light collecting lens 232 is inserted within the chamber 222, as shown in cross-section in FIG. 12. The lens 232 is advantageously supported at the border 225 between the stabilizing segment 222a and the mounting segment 222b. The lens may be held in place by a number of means, including but not limited to an optical adhesive, a lens retaining ring, or a press fit. The lens 232 has a generally planar surface 232a aligned with the border 225

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	between the stabilizing segment 222a and the mounting segment 222b and a generally convex surface 223b extending into the mounting segment 222b of the chamber 222. The stabilizing segment 222a of the chamber 222 is deep enough that the lens 232 does not contact any of the compressible material 228 which may have intruded into the chamber 222. The lens 232 collects light which is incident on the planar surface 232a. Much of the light which is incident on this surface 232a at angles which would be absorbed by the walls 223a and 223b of the chamber 222 if the lens were not present is now directed toward the photodetector 226. Thus, a greater percentage of the light transmitted through the material 228 is caused to be incident on the photodetector 226, resulting in a stronger measured signal."). Under at least the apparent construction based on Masimo's Infringement Contentions, Mannheimer 842 discloses and/or renders obvious wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector. For example, Mannheimer 842 discloses and/or suggests a pulse oximetry probe where there is a detector 120 with an opaque surface cover with a hole to the detector that is smaller in width than the detector 120, thereby where the window comprising the hole comprises an area smaller than a detection surface area of the detector: *See, e.g.*, Mannheimer 842 at Abstract ("A fetal pulse oximetry probe has clusters of light-transmissive bumps over the light source and the light detector on the surface of the probe. The probe is usually attached to the fetus' head. The clusters part the fetal hair and penetrate other light-attenuating organic materials on the head. The clusters thus transmit a more intense light signal. To reduce the amount of signal shunting between them, the clusters also may be separated by additional opaque (light-shielding) bumps."). Fig. 1a.

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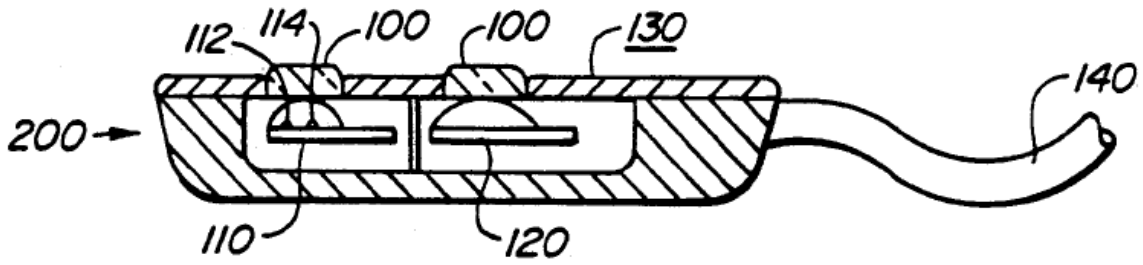


FIG. 1a.

Fig. 1b.

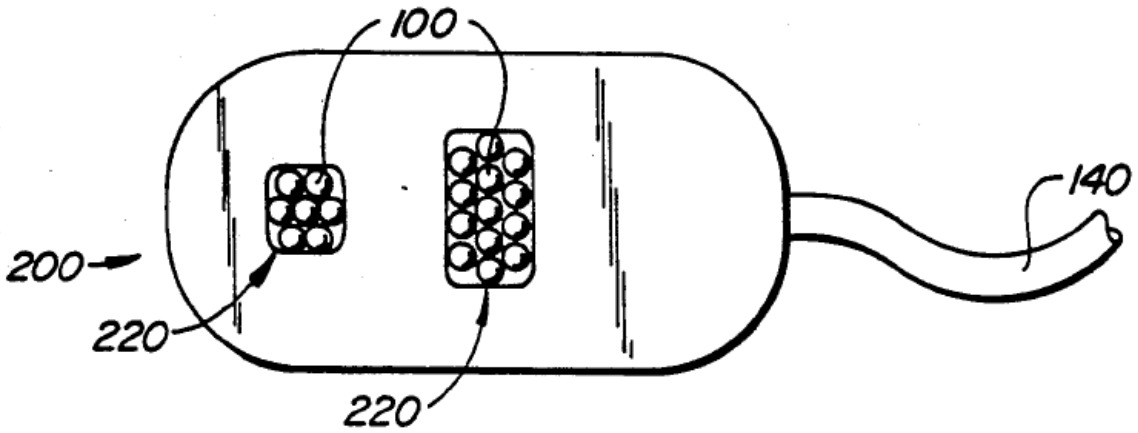


FIG. 1b.

Fig. 5a.

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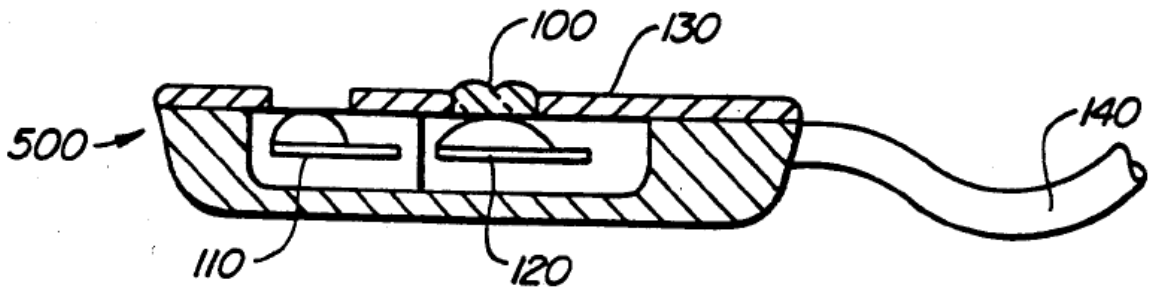


FIG. 5a.

Fig. 5b.

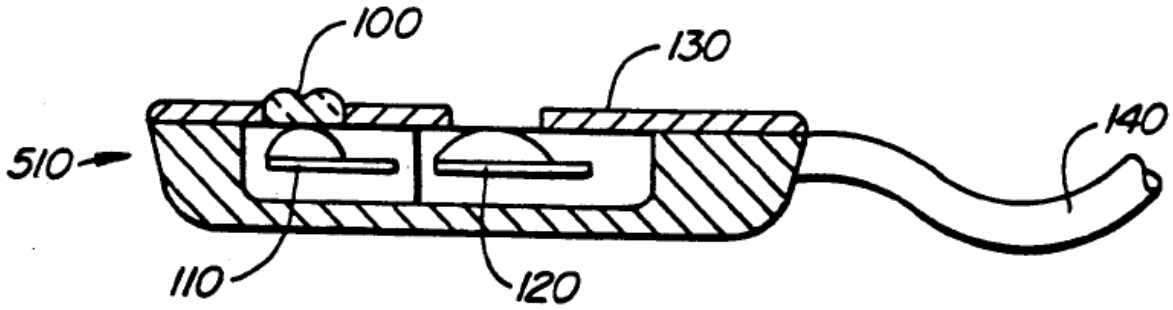


FIG. 5b.

Mannheimer 842, 1:45-2:14 ("The purpose of the present invention is to improve the accuracy and consistency of the readings, especially in the presence of substances, by increasing the optical signal levels.

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	Various methods may be used to increase signal levels by intensifying the emitted light from the probe and increasing the sensitivity of the detector. However, substances like hair may significantly lessen the amount of light passing between the probe and the skin and consequently decrease the signal-to-noise ratio. To overcome this problem, the invention reduces the amount of substances between the probe and the fetal tissue. In the probe of the prior application, the curved surface portions or bumps improve the signal. The apex of the bump pushes aside the substances and comes to rest on the scalp (or close to it). The clusters in the present invention more effectively penetrate the substances on the head. The clusters "scrub" aside the substances better than does the single bump of the prior invention. Clusters also are more effective when used over larger surface areas of the source and detector. A single bump, if too flat, would not effectively part the fetal hair and penetrate the other light-attenuating materials. But if too high, a single bump would hold the probe too far above the fetal tissue. The present invention therefore uses clusters of bumps over the source, the detector, or both. The bumps in the clusters are sufficiently pointed to penetrate the substances. The action of these bumps is much like combing. Like the teeth of a comb, the bumps penetrate a wad of hair or other material. When the probe, biased toward the head, is slid back and forth, the "comb" also moves aside substances caught underneath its "teeth" (i.e., the bumps). As the probe slides back and forth the substances are forced away from the apex of the bumps. The spaces between the bumps receive the substances that are pushed aside."). Mannheimer 842, 2:49-57 ("FIG. 1(a) shows a perinatal pulse oximetry probe 200 that includes light source 110, detector 120, and cord 140. The probe can be made of acrylonitrile-co-butadiene-co-styrene (ABS) plastic or any bio-compatible flexible or inflexible material. Source 110 and detector -20 are covered by light-transmissive bumps 100. Opaque surface 130 covers the probe 200. FIG. 1(b) shows the clusters 220 of bumps 100. Cord 140 connects probe 200 to a power source."). Mannheimer 842, 4:25-31 ("FIGS. 5a-b show another alternative embodiment where either only the light source 110 or the detector 120 is covered by light transmissive bumps 100. FIG. 5a shows the probe 500 with only detector 120 having light transmissive bumps 100 as a cover, while FIG. 5b shows the probe 510 with only light source 110 having light transmissive bumps 100 as a cover.").

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Shaw discloses and/or renders obvious the opening comprising an area smaller than a detection surface area of the at least one detector. For example, Shaw discloses and/or suggests an oximeter relying on at least three electroluminescent diodes (9, 11, 13) emitting light at at least three different wavelengths (600, 715, 805 nm), where the emitted light is received by a photoresponsive detector (Fig. 3a, 47, 49, 51) and the detected signals are processed to measure the blood oxygen saturation of a patient, where the photoresponsive detector is positioned in an enclosure, and the opening to the enclosure (aperture 95) has an area smaller than a detection surface area of the detector (47, 49, 51): *See, e.g.*, Shaw at Abstract ("Oximeter method and apparatus uses a test appliance that includes a source for directing radiation into skin tissue or other blood-confining container at three or more wavelengths and a detector for sensing the radiation intensity emanating from the skin tissue or other container at each wavelength. The oximeter method and apparatus also uses circuitry for combining the detector outputs in a predetermined manner to provide an indication of the oxygen saturation of the blood independently of position or movement of the test appliance on the patient and without first calibrating the indication on each patient."). Fig. 1.

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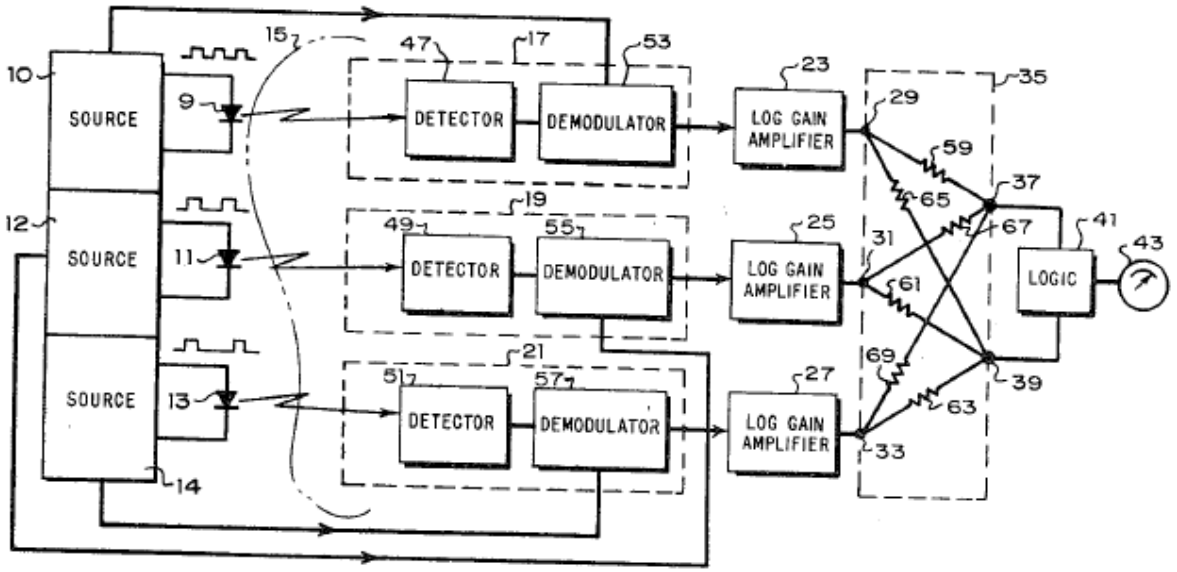


Figure 1

Fig. 2.

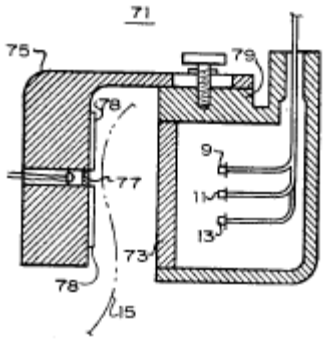


Figure 2

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Fig. 3a.

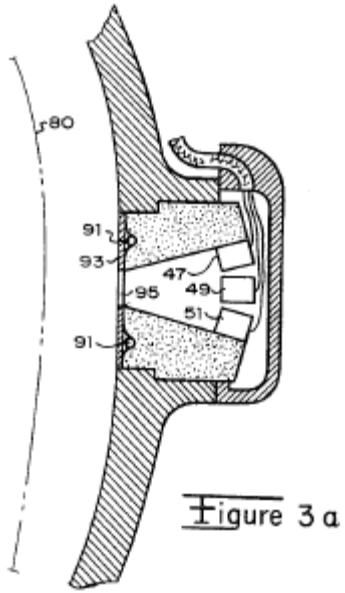


Figure 3a

Fig. 3b.

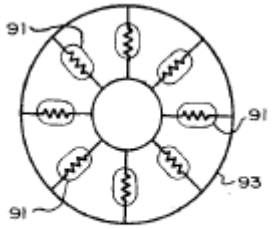


Figure 3b

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	Shaw, 1:63-2:14 ("Accordingly, the present invention provides spectrophotometer apparatus which measures oxygen saturation of blood in vivo and which obviates the need for making said reference measurements. The present apparatus operates at a number of different wavelengths equal to at least one plus the number of wavelength-dependent, radiation-absorptive substances present in the test sample and requires only a single intensity measurement at each of the wavelengths to provide an indication of oxygen saturation of blood in vivo. Changes in measurement conditions due to movement of the test appliance, changes in the geometry of illumination and detection, changes in thickness and geometry of neutral density sample containers, changes in the quantity of blood perfusing the skin tissue, and the like, are accounted for by making simultaneous intensity measurements at each of the selected wavelengths. This provides a continuous indication of oxygen saturation of blood in vivo as the measurement conditions change from patient to patient or even on a given patient. Thus, in the illustrated embodiment of the present invention, radiation sources and detectors are disposed about the ear of a patient to measure the intensity of radiation passing therethrough at each of at least three different radiation wavelengths. The logarithms of the detector responses are combined linearly to yield an indication of oxygen saturation as the ratio of the concentration of oxyhemoglobin to the concentration of total hemoglobin present in the patient's ear."). Shaw, 2:30-3:50 ("Referring to FIG. 1, there is shown a schematic diagram of one embodiment of the present oximeter apparatus which includes three semiconductor electroluminescent diodes 9, ll and 13 arranged to irradiate substantially the same area of the ear I5 of a patient at at least three different narrow-band portions of the electromagnetic radiation spectrum, for example, about the 660, 7 l 5, and 805 millimicron wavelengths. Each of the diodes is energized intermittently by its associated source l0, l2 and 14 at a selected repetition rate. The radiation transmitted through the ear I5 is detected within each of the different hands by the detector means l7, l9 and 21, each of which includes a photoresponsive detector 47, 49, or 51 such as a photodiode, phototransistor, photomultiplier tube, or the like. Each of these detectors is disposed to receive radiation from substantially the same area of the car 15 and is connected to a synchronous demodulator 53, 55, or 57 which in turn is connected to one of the sources for synchronous operation at the repetition rate of the associated source I0, 12, or 14. The resulting output from each demodulator S3, 55, or 57 is thus representative of the radiation which passed through the ear 15 only at the radiation wavelength produced by the diode that is energized in synchronism with the associated demodulator. A very narrow-band radiationselective optical system is thus provided at the three radiation wavelengths produced by each of the diodes 9, 11 and 13. Of course, a single detector means may be used and its responses to radiation at three different

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	wavelengths may be separated out by synchronous demodulation at each of the frequencies of excitation from sources l0, l2 and 14 or by time-shared sequential operation of each of the diodes 9, II and 13. Also, the diode light sources 9, II and 13 may be operated continuously to produce three selected radiation wavelengths or an incandescent light source may be used to provide a broad spectrum of radiation. In these cases, the synchronous demodulators 53, 55 and 57 would be eliminated, and in these cases, the detector means I7, 19 and 21 would include filters 52,54 and 56in the field of view of the detectors 47, 49 and S1 to provide the required response to radiation at at least three different wavelengths, as shown in FIG. 4. The signals from the demodulators 53, 55 and 57 are amplifled by amplifiers 23, 25 and 27 which have logarithmic output vs. input signal amplitude characteristics to provide signals at the output terminals 29, 31 and 33 which are representative of the logarithms of the total radiation received from the car 15 at each of the three different radiation wavelengths. These three signals contain the information necessary to determine within tolerable limits of accuracy the ratio of the concentrations of the two wavelength-dependent, radiation-absorbing substances oxyhemoglobin and reduced hemoglobin where these substances are substantially the only wavelength-dependent, radiation-absorbing substances present in the test sample of blood and its container. However, where other wavelength-dependent, radiation-absorbing substances are significantly present, such as skin pigments or colored materials in the blood, then as discussed above, the number of wavelengths required will increase to one plus the number of such significant wavelength-dependent, radiationabsorbing substances present. In order to determine oxygen saturation, it is not necessary to determine the concentrations of each of the significant wavelength-dependent, radiation-absorbing substances present, since it is only necessary to know the ratio of the concentration of oxyhemoglobin to the concentration of total hemoglobin present in the patients ear. Thus in the embodiment shown, the three logarithmic signals at the output terminals 29, 31 and 33 may be combined linearly using resistors 59, 67 and 69 to produce a signal at terminal 37 which is indicative of the concentration of oxyhemoglobin and, further, may be combined linearly using resistors 65, 61 and 63 to produce a signal at terminal 39 which is indicative of the concentration of total hemoglobin. Logic circuit 41 connected to the terminals 37 and 39 thus combines these signals as the ratio of the signal on terminal 37 to the signal on terminal 39 for producing an indication on meter 43 of the percent oxygen saturation of blood in the patients ear. The relative gain of the detectors and the values of the resistors 59-69 may be set initially by conducting

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	actual tests on ear tissue-containing blood at various known values of oxygen saturation and by computing the resistor values required to produce meter indications from the logarithmic outputs 29, 31 and 33 which correspond to the known values of oxygen saturation. Thereafter, the meter 43 provides an accurate indication of percent oxygen saturation of blood in the ear 15 of a patient simply upon attachment to the ear is of a test appliance which includes the radiation sources l0, l2 and 14 and the detectors 47, 49 and 51. Thus, by continuously combining the logarithms of the radiation transmissions through blood in the patients ear 15 at least three wavelengths, the Beer's law relationship between radiation absorption and the concentration of oxyhemoglobin present in the total concentration of hemoglobin is determined under all test conditions as they may vary from patient to patient or with movement of the test appliance on the ear of a particular patient."). Shaw, 4:20-59 ("In another embodiment of the test appliance, as shown in the sectional side view of FIG. 3(a) and the schematic front view of FIG. 3(1)), a selected body part 80, say, the forehead of a patient or other container of the blood sample is illuminated on the same side that the radiation is detected on. A wide-area diffused light source is provided by a plurality of light sources 91, either incandescent lamps or electroluminescent diodes, uniformly spaced behind an annular diffusing screen 93 surrounding a small-area detection aperture 95. Each of the three or more diode detector elements 47, 49 and 51 is disposed behind the aperture 95 to receive the radiation which emanates only from the selected body part 80 within a field of view that excludes both the radiation directly from the light source 91 and the reflected radiation from the surface of the selected body part 80. This assures that the diode detectors 47, 49 and 5] respond only to radiation which passed through the blood and skin tissue in the selected body part 80 of the patient. Thus, direct contact with the body part 80 by the radiation source and detector aperture is not essential as long as the field of view of the detectors 47, 49 and 51 does not include either the radiation directly from the light source or the mere reflected radiation from the surface of skin tissue or other container of the blood sample. The light sources 91 may thus be operated in the manner previously described in connection with the system of FIG. I to produce the three or more wavelength determination of percent oxygenation of blood. it should be noted that this arrangement of radiation sources and detectors does not provide true radiation transmission through the blood in skin tissue or other container, as required for the Beers law relationship between concentration of a substance in solution and the radiation transmission through the solution at a selected radiation wavelength. However, in practice the skin tissue of the selected body part 80 and the blood contained therein scatter the radiation so that a small portion of the incident radiation emanates from the part 80 in the region adjacent the radiation source. This scattered radiation

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	is suitably altered or modified by the radiation-absorbing substances in the skin tissue to permit detection and signal processing for producing an indication of percent oxygen saturation within tolerable limits of accuracy."). Shaw, 5:1-12 ("While the preferred embodiment is described above for use in making measurements of oxygen saturation of blood in vivo, it should be noted that the containers for the blood need not be restricted to the tissues of a subject, but may be cuvettes or other containers in which the blood may be present in either a hemolized or nonhemolized form. Also, it should be noted that the concentration of other wavelength-dependent, radiation-absorbing substances than oxyhemoglobin and total hemoglobin (for example, tracer dye) can be determined in accordance with the present invention. Further, the fluid containing the wavelength-dependent, radiation-absorbing substances need not be blood."). Shaw, Claims 1, 2 ("1. Apparatus for determining the oxygen saturation of blood in the tissues of animal bodies in which variations occur in the optical measurement geometry and from which the blood cannot be removed for the purpose of making reference radiation intensity measurements, the apparatus comprising: source means for producing electromagnetic radiation at at first, second and third radiation wavelengths and being disposed to supply incident radiation to the measurement site on the body at the plurality of wavelengths for producing output radiation from the body with intensities at the respective wavelengths that are altered from the incident intensities at such wavelengths by substantially the same conditions of the optical measurement geometry, the body and the blood present therein; detector means for receiving said output radiation at each of said plurality of wavelengths for producing at least three electrical outputs which are representative only of the intensities of the output radiation at the respective wavelengths as altered from the corresponding incident intensities by the condItions of the optical measurement geometry, the body and the blood present therein at the measurement site; and circuit means connected to the detector means to receive the electrical outputs produced thereby in response to said output radiation for simultaneously combining all of said electrical outputs to produce therefrom an indication of the oxygen saturation of the blood present in the body at the measurement site substantially independently of changes in the optical measurement geometry. 2. Apparatus as in claim 1 comprising: radiant-energy diffusing means interposed between said source means and the body for providing radiation thereto diffused over a given area of irradiation; and said

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	detector means includes an aperture of area substantially smaller than said given area of diffused irradiation for receiving said output radiation therethrough from said body.”). Under at least the apparent construction based on Masimo’s Infringement Contentions, Fantini discloses and/or renders obvious the opening comprising an area smaller than a detection surface area of the at least one detector. For example, Fantini discloses and/or suggests the opening comprising an area smaller than a detection surface area of the at least one detector, implemented as the opening to the Fiber being 3 mm in diameter, and the surface area of the Hamamatsu R928 detector being 13 mm x 24 mm: *See, e.g.*, Fantini at Abstract: **Abstract.** We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit. *See, e.g.*, Fantini at 33:

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	In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition. In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument. *See, e.g.*, Fantini at 34:	

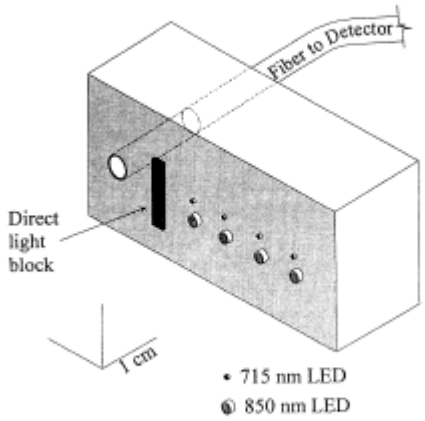
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		Feature 2. The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. *Feature 3.* To implement the measurement of the slopes of the straight lines (as a function of the distance *r* between	

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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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	Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of  **Fig. 2** Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium. *See, e.g.*, Fantini at 35:

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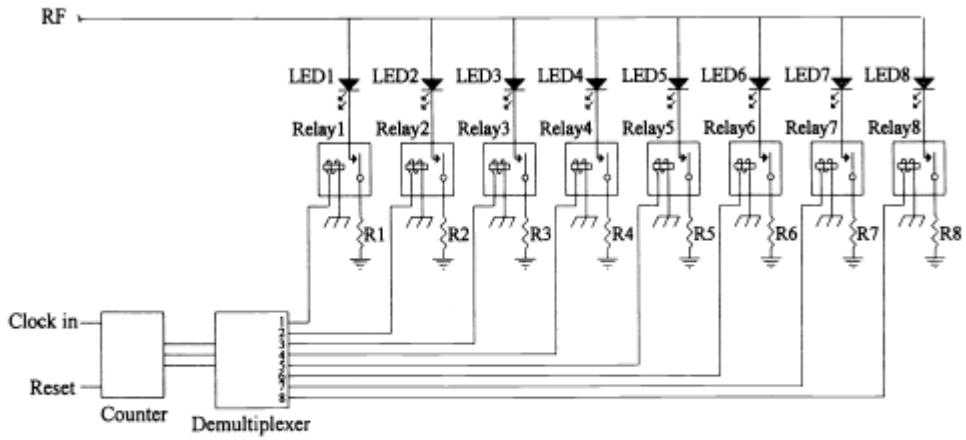


Fig. 3 Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED.

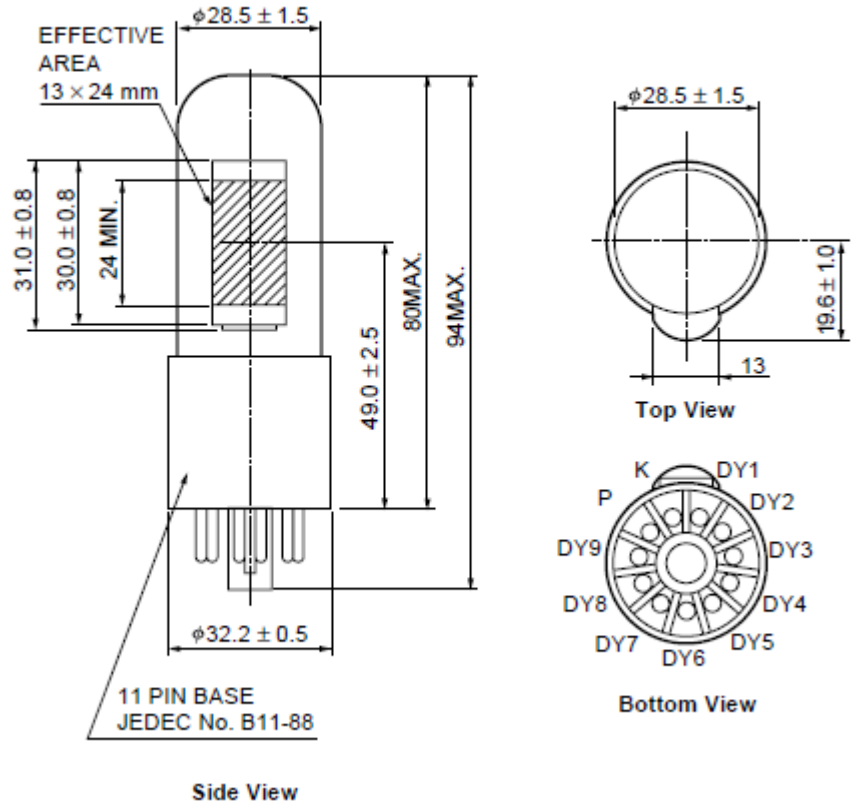
See, e.g., Fantini at 40:

There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas:

- The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.

See, e.g., Hamamatsu at 2:

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	Figure 4: Dimensional Outline (Unit: mm) 
10[e] a processor configured to receive and process one or more signals responsive to the	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

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outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.	For example, Raley discloses and/or suggests a processor such as a data processing circuit that is configured to receive and process one or more signals outputted from a detector that are corresponding to the intensity of light received and determine a physiological parameter of a user responsive such as a blood analyte to the one or more signals: *See, e.g.*, Raley at Fig. 5:

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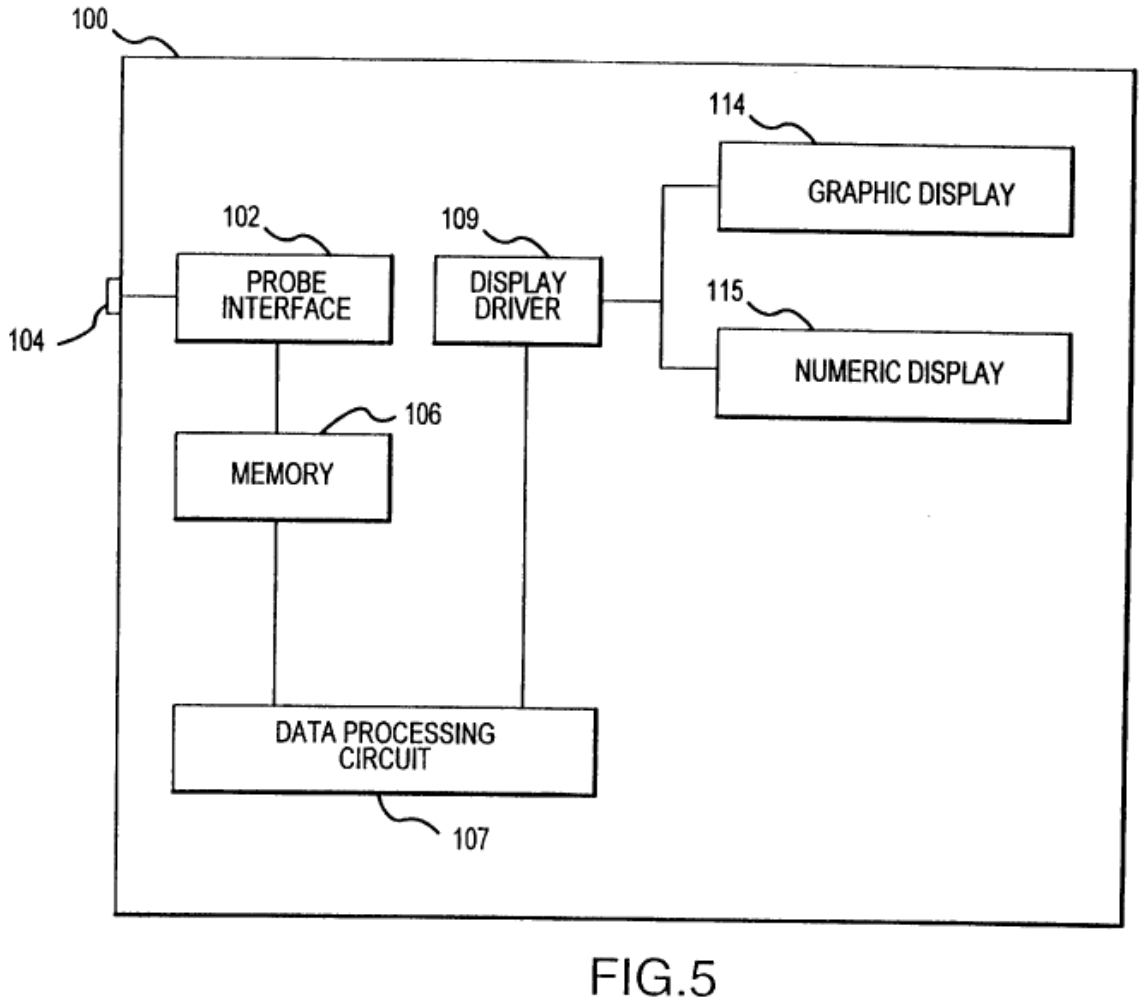


FIG.5

Fig. 6.

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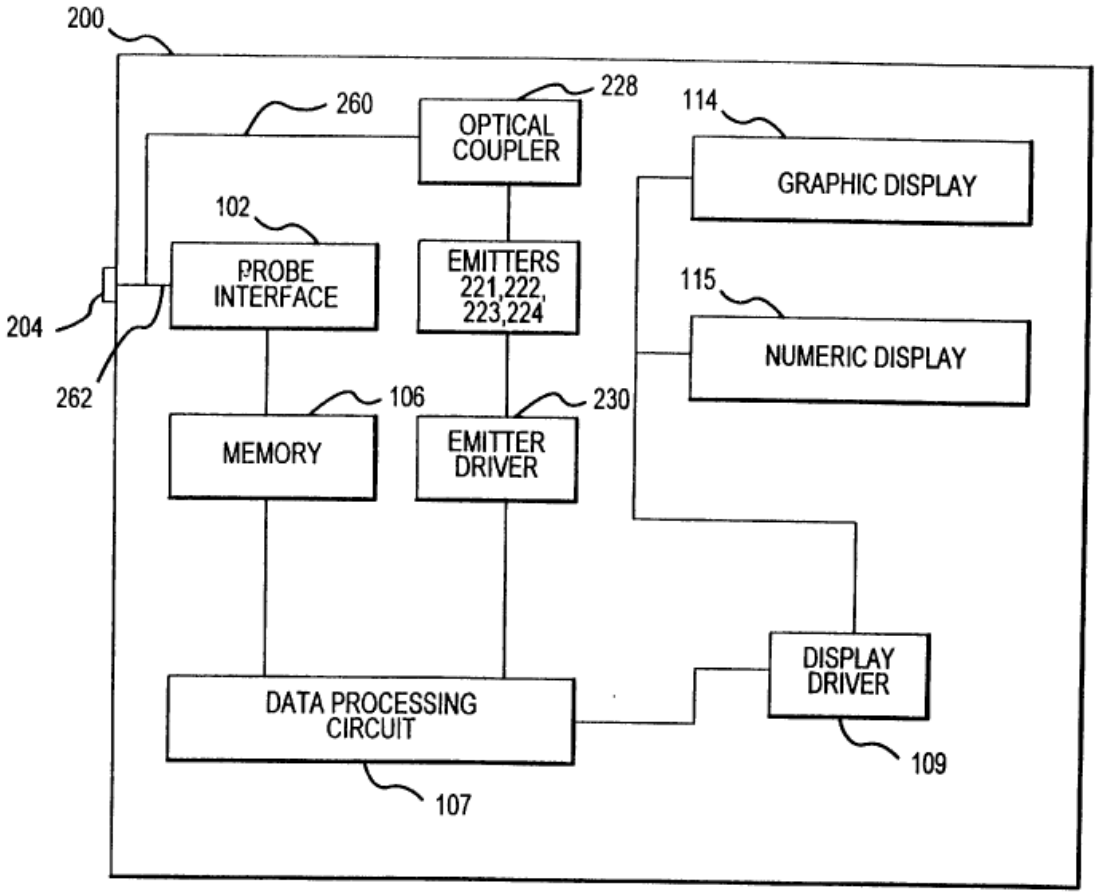


FIG.6

Raley, 4:29-5:15 ("The intensity of light transmitted through the tissue under test is measured by one or more photodetectors 13 which are located in the disposable probe-end 10. Photodetector 13 provides a signal corresponding to the intensity of light received denoted I.sub.λ1, I.sub.λ2, I.sub.λ3 and I.sub.λ4. This signal is then electrically routed back to the monitor 100 through cable 28, plug 42 and socket 104 to the probe interface 102. In the monitor the analog received intensity signals, I.sub.λ1,

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	I.sub.λ2, I.sub.λ3 and I.sub.λ4 are converted into digital signals through a well-known analog to digital (A/D) converter. The intensity signals are then stored in memory 106 and manipulated in data processing circuit 107 of the monitor 100 according to data processing instructions stored in memory 106 and executed by the data processing circuit 107 in order to determine an estimate of the blood analyte levels output as a percentage concentration. Blood analyte levels (output as percentages) may then be displayed via display driver 109 and graphic display 114 and/or numeric display 115. An alternative method of implementing a photoplethysmographic monitor is depicted in FIG. 6 and operates in conjunction with the alternative probe embodiment in FIG. 3b. The emitters 21, 22, 23 and 24 (which may be LED's or laser diodes, but which are preferably laser diodes) are housed in the monitor 200. The emitters 21, 22, 23 and 24 are driven by emitter driver 230 which is controlled by the data processing circuit 107. The emitted light is then combined by an optical coupler 228 and transmitted to the probe 40 by internal optical fiber 260 which is coupled to an optical fiber or other such optically transmissive material (not shown) internal to interconnect cable segment 28. Thus, plug 42 and connector 204 now includes electrical conductors for connecting photodiode 13 back to the probe interface 102 and an optical connector for connecting optical fiber 260 to an optical fiber (not shown) located in cable 28. The light transmitted through the optical fiber 260 and transmitted through the optical fiber located in cable 28, reflects off mirror 29 of FIG. 3b in connector end 25 and passes through window or opening 26 and window 16 in probe-end 10 and impinges on the tissue of the patient. Transmitted light is received by photodetector 13 which send an electrical signal back to the probe interface 102 through the electrical conductors in cable 28 and electrical pathway 262 in monitor 200. The probe interface 102 converts the analog signal to a digital signal and transmits the signal to memory 106 and on to data processing circuit 107 for processing and display of blood analyte concentration values using graphic display 114 and numeric display 115 driven by display driver 109. The transmission of the emitted light can be controlled in a time division multiplexing manner and an optical coupler 228 can be used to provide a means for combining multiple emitters onto one strand of optical fiber 260. Alternatively, the plurality of emitters may be placed or abutted against optical fiber 260.”).
Claim 11	**Prior Art**
11. The device of claim 10, wherein	Under at least the apparent construction based on Masimo’s Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple’s Initial Invalidity Contentions, alone or

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the at least three LEDs comprises at least eight LEDs.	in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 10. *See, e.g.*, Claim 10. Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Moyle discloses and/or suggests where more wavelengths of light, and correspondingly more LEDs, may be used to measure more physiological parameters: *See, e.g.*, Disclosure for Moyle for claim limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where LEDs are used each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound:

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	See, e.g., Disclosure for Raley for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths: *See, e.g.*, Disclosure for Robinson cited with Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs: For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nogawa with Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments as four, five, and six separate emitters relying on different wavelengths, where relying

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	on any number of additional wavelengths (and thereby LEDs) beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy: *See, e.g.*, Disclosure for Jarman with Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].
Claim 12	**Prior Art**
12. The device of claim 11, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 11. *See, e.g.*, Claim 11. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

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	For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood, and where the at least eight LEDs comprise at least two LEDs of the same wavelength, including where the LEDs can include some LEDs that have the same wavelength and some sources that are different: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths: *See, e.g.*, Disclosure for Robinson for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement

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	artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nagawa for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].
Claim 13	**Prior Art**
13. The device of claim 10, wherein the at least three LEDs comprises at least twelve LEDs.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 10. *See, e.g.*, Claim 10. Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Moyle discloses and/or suggests where more wavelengths of light, and correspondingly more LEDs, may be used to measure more physiological parameters:

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	See, e.g., Disclosure for Moyle for claim limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where LEDs are used each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound: *See, e.g.*, Disclosure for Raley for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision,

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	accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths: *See, e.g.*, Disclosure for Robinson for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs: For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nogawa for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments as four, five, and six separate emitters relying on different wavelengths, where relying on any number of additional wavelengths (and thereby LEDs) beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy: *See, e.g.*, Disclosure for Jarman for Limitation 1[a].

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].
Claim 14	**Prior Art**
14. The device of claim 10, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 10. *See, e.g.*, Claim 10. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein at least two LEDs of the at least three LEDs are configured for concurrent activation. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood, and where the at least eight LEDs comprise at least two LEDs of the same wavelength, and where LEDs of the same wavelength can be activated concurrently in order

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	to combine the strength of the signal at that wavelength so as to allow for those signals to be combined to increase the resulting signal-to-noise ratio of the measurement: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein at least two LEDs of the at least three LEDs are configured for concurrent activation. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths, and where at least two LEDs are configured for concurrent activation, including where half of the total number of single wavelength emitting devices are energized concurrently for a measurement observation: *See, e.g.*, Disclosure for Robinson for Claims 2 and 5. Under at least the apparent construction based on Masimo's Infringement Contentions, Mannheimer 842 discloses and/or renders obvious wherein at least two LEDs of the at least three LEDs are configured for concurrent activation. For example, Mannheimer 842 discloses and/or suggests [relying on multiple LEDs of the same wavelength that are activated concurrently to intensify the signal at a desired wavelength and/or in order to increase the ratio of light transmitted at a desired wavelength to other wavelengths transmitted, and/or to overcome interference at the concurrently activated wavelength, such as interference caused by light attenuation by tissue:

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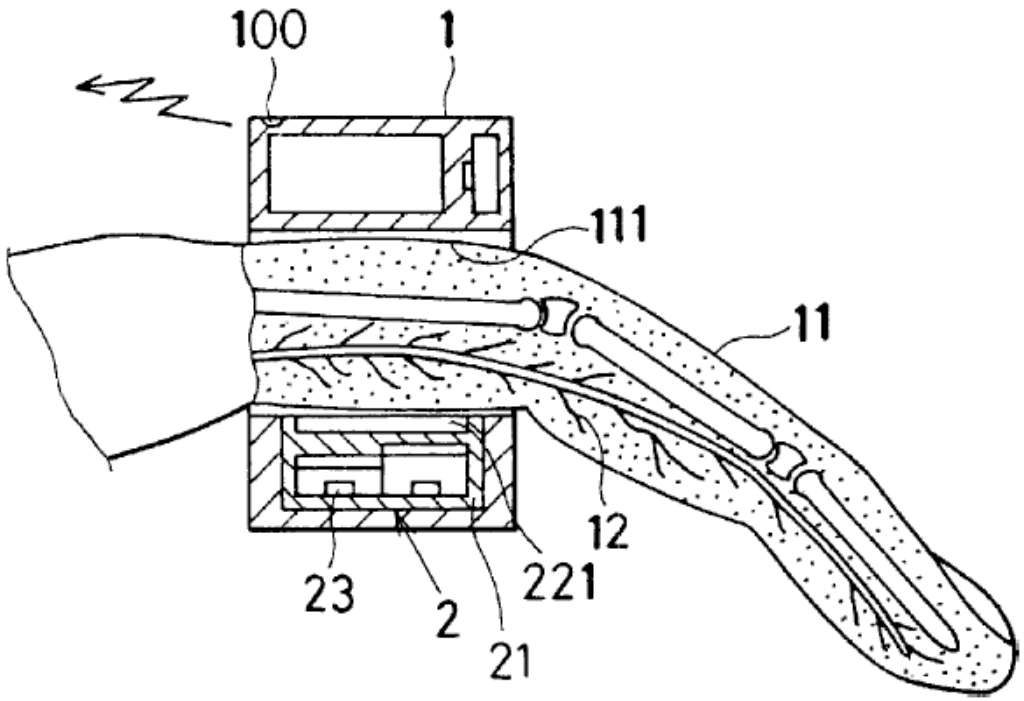
	See, e.g., Disclosure for Mannheimer 842 for Claim 5. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein at least two LEDs of the at least three LEDs are configured for concurrent activation: For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs that are fired concurrently for each wavelength enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing:same *See, e.g.*, Disclosure for Nogawa for Limitation 1[a].
Claim 17	**Prior Art**
17. The device of claim 10, wherein the window provides an optical path from the tissue to the at least one detector.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the device of claim 10. *See, e.g.*, Claim 10. Under at least the apparent construction based on Masimo's Infringement Contentions, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious wherein the window provides an optical path from the tissue to the at least one detector. *See, e.g.*, Exhibits E-1 — E-10.

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Claim 19	**Prior Art**
19[pre] A method for determining a physiological parameter of a living patient, the method comprising:	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, Kimura discloses and/or renders obvious a method for determining a physiological parameter of a living patient. For example, Kimura discloses and/or suggest a vital signs detecting apparatus that is capable measuring vital signals such as pulse: *See, e.g.*, Kimura at Abstract ("A vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. The pulse wave detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Kimura, Fig. 1A

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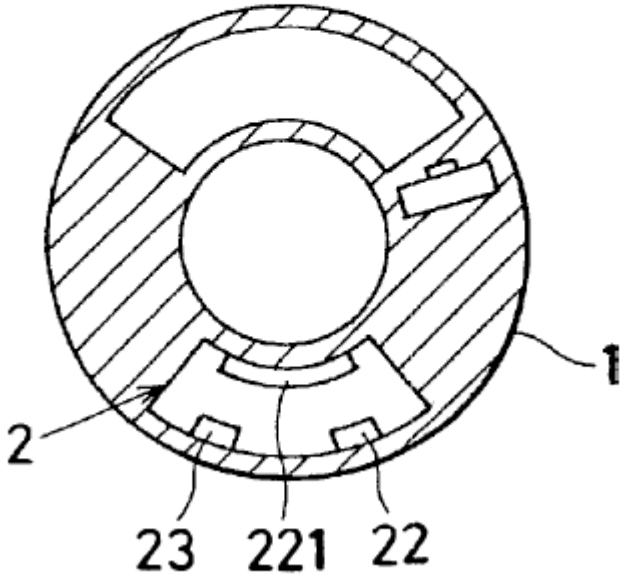
FIG. 1A



Kimura, Fig. 1B.

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FIG. 1B

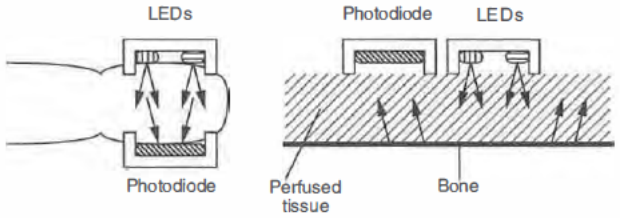


Kimura, 1:46-2:2 ("It is therefore an object of the present invention to provide a vital signal detecting apparatus which eliminates problems caused by abnormal vital signals detected when an attachable device is not attached.

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	According to the present invention, a vital signal detecting apparatus comprises an attachable device to be attached to a finger, a sensor having a light-emitting device and a light-receiving device, and a transmitting circuit for transmitting a signal waveform as a pulse wave from the sensor to a pulse wave monitoring unit. Preferably, the vital signal detecting unit also has an attachment detecting circuit for detecting whether or not the attachable device is in an attached state by comparing a signal waveform obtained when the light-emitting device is on with a signal waveform obtained when the light-emitting device is off and an operation control circuit for controlling the operation of the sensor, the transmitting circuit and the attachment detecting circuit. Preferably, the light-transmitting plate is disposed above the light-emitting device and the light-receiving device to pass light therethrough, and the light transmitting plate may be an IR-cut filter capable of blocking light of wavelengths greater than 700 nm."). Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, Webster discloses and/or renders obvious a method for determining a physiological parameter of a living patient. For example, Webster discloses and/or suggests pulse oximeter technology relying on LED s and detectors for measuring physiological parameters, where reflectance and transmittance oximeters rely o the same technology: *See, e.g.*, Webster at 36:

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	3.7.4 Probes Improved technology in photodiodes and LEDs has another benefit. They allow the probe to be small and attach to the pulse oximeter with conventional wires. The Hewlett-Packard eight wavelength oximeter was considered an accurate device, but because bulky fiber optic cables were needed to carry the light source to the patient and the transmitted light back to a light sensor, it was impractical (Rebuck *et al* 1983). Probes for the pulse oximeter are not only smaller, but can be disposable. Figure 3.10 shows a transmission pulse oximeter and a reflectance pulse oximeter. As the names indicate, a transmission pulse oximeter measures the amount of light that passes through the tissue as in a finger probe. A reflectance pulse oximeter measures the amount of light reflected back to the probe. Both types use the same technology differing only in positioning of the probes and calibration.  **Figure 3.10** On the left is a transmission pulse oximeter measuring the transmission of light by two LEDs through the finger of a patient. On the right is a reflectance pulse oximeter measuring the amount of light reflected back to the probe.
19[a] positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3): *See, e.g.*, Raley at Abstract ("A two piece probe having a universal probe end and an interconnect cable segment provides for the use of the universal probe end with a variety of different photoplethysmographic devices. The universal probe end includes a detector, a substrate for removably affixing the probe end to a patient, a window or aperture and a connector. The interconnect cable has a connector mated to the connector on the probe end for mechanical and electrical connection of the

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comprises only one opening through which light is configured to pass;	probe-end to the interconnect cable and the photoplethysmographic monitor. The connector end of the interconnect cable also houses a plurality of emitters which are directed through the window or aperture in the probe end in order to illuminate the patient. The interconnect cable also houses the resistors or other elements which identify the type of probe, monitor manufacturer or actual emitter wavelengths. Alternatively, the emitters may be housed in the main monitor and an optical fiber may be used to direct light to the patient. An electrical conductor transmits light received by the detector back to the photoplethysmographic monitor."). Fig. 1.

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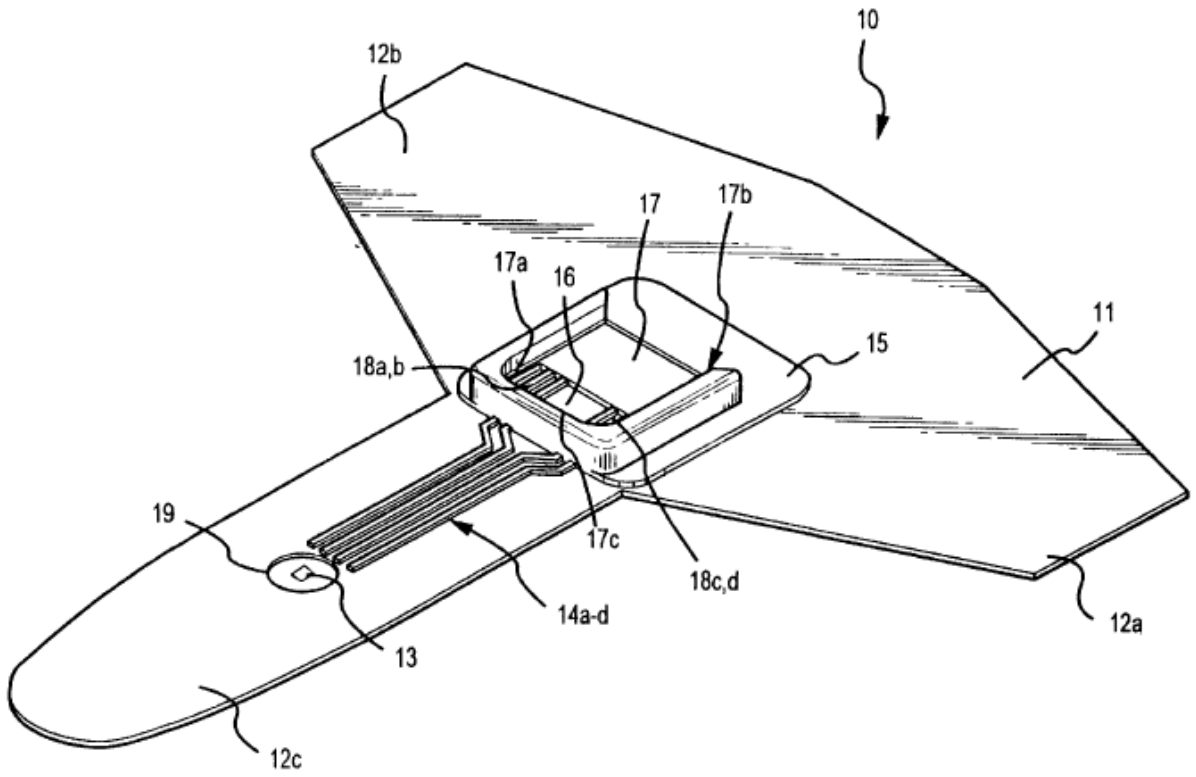


FIG.1

Fig. 3a.

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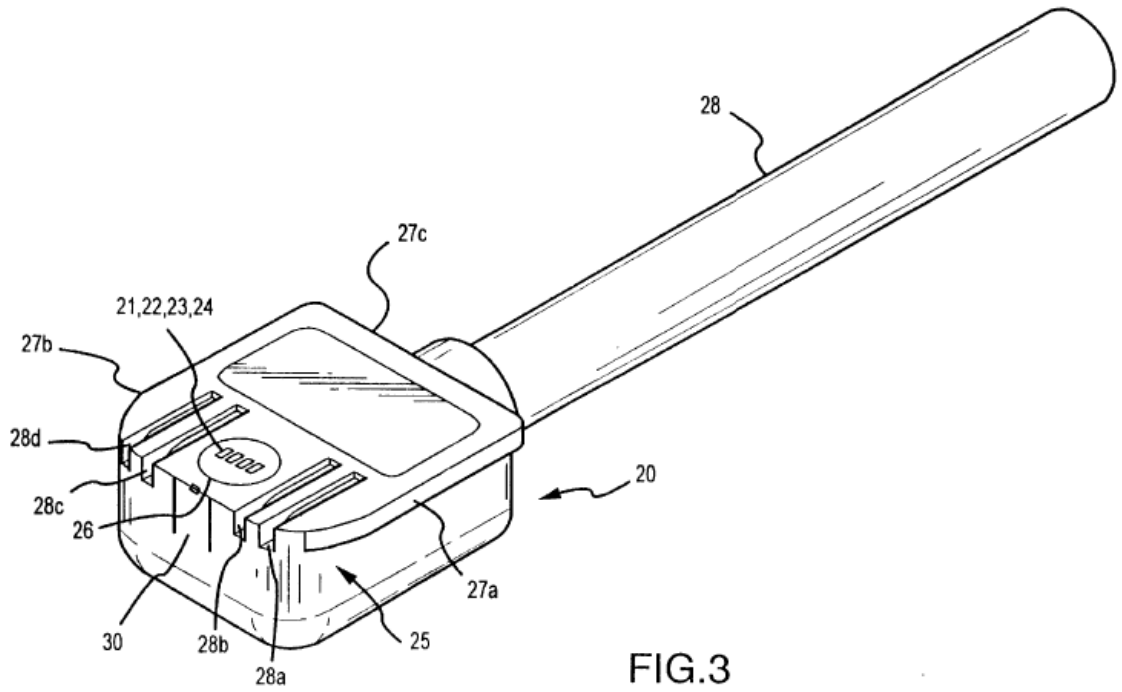


FIG.3

Fig. 3b.

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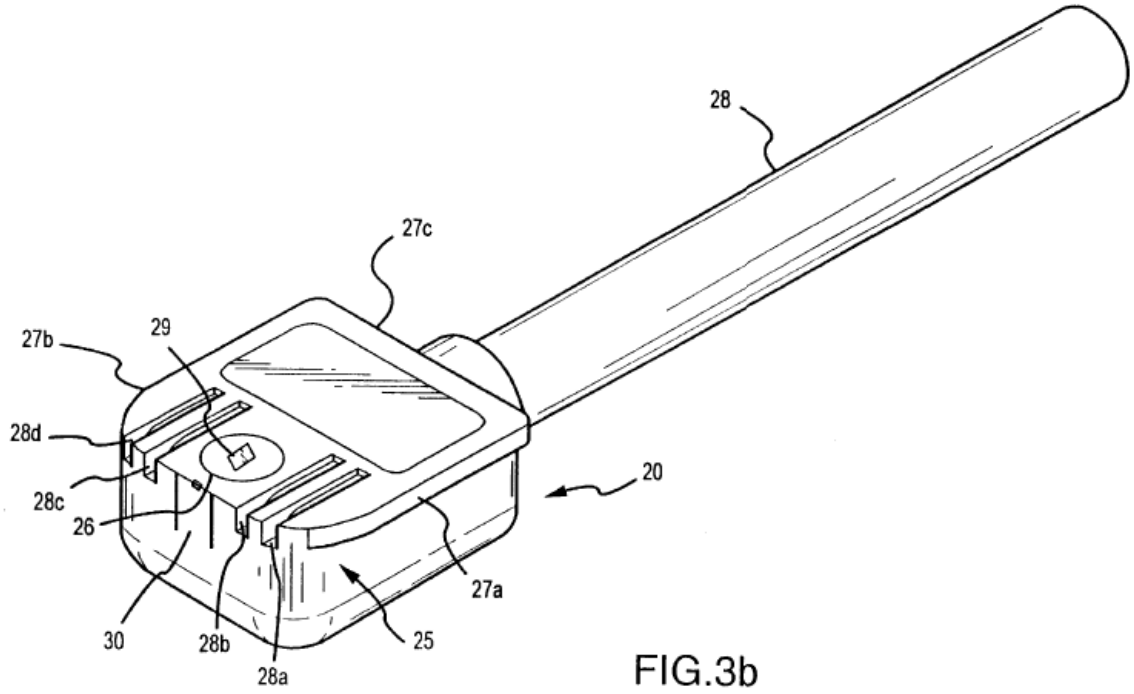


FIG.3b

Raley, 3:11-4:13 ("A pulse oximeter instrument operates by use of a probe that illuminates an appendage of the patient (such as a finger, earlobe, toe, neonatal appendages, or the nasal septum) that is rich in arterial blood and measures the differential absorption of the light by the pulsatile portion of the arterial blood flow to thereby determine oxygen saturation of the arterial blood. The pulse oximeter instrument makes use of a plurality of light-emitting devices, each of which transmits light at a predetermined wavelength, which wavelengths are selected such that at least one is highly absorbed by oxygenated hemoglobin in the arterial blood and at least one is highly absorbed by reduced hemoglobin in the arterial blood. The amount of absorption of the light beams generated by these light emitting devices that are located in the probe is a measure of the relative concentration of the various hemoglobin species contained in the arterial blood. The absorption of the light that illuminates the appendage of the patient includes a constant portion that is a result of skin, bone, steady-state (venous)

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	blood flow and light loss due to various other factors. The pulsatile component of absorption is due to the pulsatile arterial blood flow and is a small fraction of the received signal and is used by the pulse oximeter instrument to perform its measurements. It is also possible to measure additional analytes in the arterial blood, such as additional dyshemoglobins, with one additional wavelength of light for each component. The measurements are computed by sampling the output of the light detector located in the probe to determine the incremental change in absorption of the various wavelengths of light that are used to illuminate the appendage of the patient. These incremental changes in light absorption are then used to compute the oxygen saturation of the arterial blood as well as the patient's pulse rate. Since the pulsatile component of the signals received by the light detector represent only a small fraction of the incident light, it is important that the incident light be of significant magnitude to result in transmitted signals that have sufficient amplitude to provide accurate readings. In addition, the probe containing the light-emitting devices and the light detector must be placed in intimate contact with the skin of the patient to obtain the most accurate readings. Referring to FIGS. 1, 2, 3, 4, 5 and 6, the probe 40 of the present invention is designed for use with one of two basic photoplethysmographic monitor architectures depicted in FIGS. 5 and 6. FIG. 5 depicts one of the monitor architectures in which the monitor 100 communicates with probe 40 through socket 104 and mating interconnect cable plug 42. The configuration of plug 42 depends on the type and manufacturer of monitor 100. For example, if the monitor 100 is capable of measuring a plurality of blood analyte concentrations such as O2Hb, RHb, COHb and MetHB then plug 42 and interconnect 104 will contain sufficient electrical connectors 46 to interconnect probe interface 102 with a plurality of emitters 21, 22, 23 and 24 located in the connector-end 25 of interconnect cable segment 20. In a preferred embodiment, the plurality of emitters 21, 22, 23 and 24 each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ_1 λ_2 λ_3 and λ_4. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. In a photoplethysmographic instrument designed to generate four blood analyte levels, the preferred embodiment is to use at least four separate emitters each producing light with a distinct spectral content. If fewer blood analyte levels are desired then fewer emitters may be used either in the interconnect cable. For example, in a probe made according to the present invention for use with a standard pulse oximeter, only two emitters would be needed in the interconnect cable.”).

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	Raley, 4:47-6:12 (“An alternative method of implementing a photoplethysmographic monitor is depicted in FIG. 6 and operates in conjunction with the alternative probe embodiment in FIG. 3b. The emitters 21, 22, 23 and 24 (which may be LED's or laser diodes, but which are preferably laser diodes) are housed in the monitor 200. The emitters 21, 22, 23 and 24 are driven by emitter driver 230 which is controlled by the data processing circuit 107. The emitted light is then combined by an optical coupler 228 and transmitted to the probe 40 by internal optical fiber 260 which is coupled to an optical fiber or other such optically transmissive material (not shown) internal to interconnect cable segment 28. Thus, plug 42 and connector 204 now includes electrical conductors for connecting photodiode 13 back to the probe interface 102 and an optical connector for connecting optical fiber 260 to an optical fiber (not shown) located in cable 28. The light transmitted through the optical fiber 260 and transmitted through the optical fiber located in cable 28, reflects off mirror 29 of FIG. 3b in connector end 25 and passes through window or opening 26 and window 16 in probe-end 10 and impinges on the tissue of the patient. Transmitted light is received by photodetector 13 which send an electrical signal back to the probe interface 102 through the electrical conductors in cable 28 and electrical pathway 262 in monitor 200. The probe interface 102 converts the analog signal to a digital signal and transmits the signal to memory 106 and on to data processing circuit 107 for processing and display of blood analyte concentration values using graphic display 114 and numeric display 115 driven by display driver 109. The transmission of the emitted light can be controlled in a time division multiplexing manner and an optical coupler 228 can be used to provide a means for combining multiple emitters onto one strand of optical fiber 260. Alternatively, the plurality of emitters may be placed or abutted against optical fiber 260. The Probe Referring again to FIG. 4 the probe 40 consists of two releasable connected segments: the probe-end 10, separately depicted in FIG. 1 and interconnect cable segment 20, separately depicted in FIGS. 2, 3 and 3b. Universal probe-end 10 is designed to be disposable and to accommodate any type of interconnect cable segment 20, whether it contains LED's, laser diode, or an optical fiber/mirror for illuminating the tissue. Thus, the construction of probe-end 10 is simple and flexible consisting of a flexible substrate 11 having three portions 12a, 12b and 12c. Substrate portions 12a and 12b are designed to wrap around

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	an appendage of a patient. In FIG. 1 the substrate is designed to be wrapped around a finger. Substrate portions 12a and 12b have an adhesive layer applied to one or more surfaces to enable the portions to be removably attached to the finger. Substrate portions 12a and 12b may be configured differently for attachment of probe-end 10 to the feet of neonates, the smaller fingers of children, or to other appendages of adult, child or neonatal patients. Substrate portion 12c includes a photodetector 13 which is mounted in an optically transmissive window 19 in the substrate 11 and which is connected to connector 17 through flexible electrical circuits 14 a-d. Connector 17 has three lip portions 17a, 17b, and 17c which are designed to accommodate and hold the connector-end 25 of interconnect cable segment 20. Connector portion 15 provides a larger surface area for connector 17 to be either adhesively affixed to substrate 12 or, alternatively, to be retained between layers of substrate 12. Connector 17 also houses an optically transmissive window 16 and electrical contacts 18a, 18b, 18c, and 18d which connect flexible electrical circuits 14a,b,c and d with interconnect cable segment 20. Window 16 enables light to be passed from the emitters 21,22,23 and 24 or optical fiber and mirror 29 to the patient while protecting the patient from excess heat and also protecting the reusable interconnect cable segment 20. FIG. 2 depicts a top elevational view of the patient end of interconnect cable segment 20. Cable 28 consists of a bundle of one or more electrical conductors and, if the emitters are located in the monitor 200, an optical fiber. The electrical conductors and optical fiber are covered by a flexible insulating material to protect the internal components. Conductive grooves 28a, 28b, 28c and 28d provide for electrical interconnection of photodetector 13 through flexible conductors 14a, 14b, 14c and 14d and electrical contacts 18a, 18b, 18c and 18d. Ridge 27b is designed to fit under lip 17b to hold connector-end 25 onto probe-end 10. FIG. 3 depicts a bottom elevational view of one embodiment of the patient end of interconnect cable segment 20. The embodiments of FIG. 3 includes four emitters 21, 22, 23 and 24. Such an embodiment would be useful in a photoplethysmographic monitor for measuring three or four blood analytes such as oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin. Alternatively, the number of emitters could be two in a probe for use with standard pulse oximeters which typically use two emitters having spectral contents characterized by distinct center wavelengths, often 660 nm and

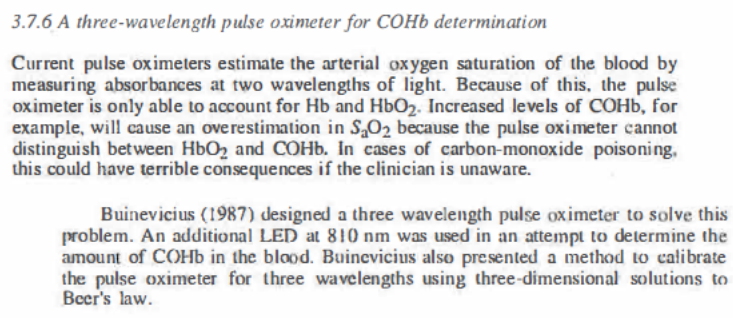
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940 nm. Ridges 27a, 27b and 27c fit under lip portions 17a, 17b and 17c to hold connector-end 25 onto probe end 10. The end of latch 30 is designed to click into a hole near the base of lip portion 17c so that upon engagement of the connector-end 25 into connector 17 a releasable latching occurs. In order to disengage the latching mechanism latch 30 is simply depressed.").

Under at least the apparent construction based on Masimo's Infringement Contentions, Webster discloses and/or renders obvious positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass.

For example, Webster discloses and/or suggests, for pulse oximetry systems, relying on three LEDs emitting light at three wavelengths to a detector in order to measure additional physiological parameters.

See, e.g., Webster at 37-38:



3.7.6 A three-wavelength pulse oximeter for COHb determination

Current pulse oximeters estimate the arterial oxygen saturation of the blood by measuring absorbances at two wavelengths of light. Because of this, the pulse oximeter is only able to account for Hb and HbO_2. Increased levels of COHb, for example, will cause an overestimation in S_aO_2 because the pulse oximeter cannot distinguish between HbO_2 and COHb. In cases of carbon-monoxide poisoning, this could have terrible consequences if the clinician is unaware.

Buinevicius (1987) designed a three wavelength pulse oximeter to solve this problem. An additional LED at 810 nm was used in an attempt to determine the amount of COHb in the blood. Buinevicius also presented a method to calibrate the pulse oximeter for three wavelengths using three-dimensional solutions to Beer's law.

Webster at 69-70:

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5.7 LED PACKAGING

Most LED packages are made of resin, offering superior mechanical strength and the ability to withstand vibration and shock. In some of today's pulse oximeter probes, the two LEDs can be found in one package, which has the distinct advantage of keeping costs down. In the Nellcor SCP–10 reusable and Oxisensor II D–25 disposable pulse oximeter probes, the two LEDs come encased in a transparent rectangular solid with approximate dimensions of 5 mm long by 4 mm wide by 2 mm thick. The LEDs themselves are flat squares with sides of approximately 0.25 mm.

Other probes have discrete LEDs inside, with the LEDs lying side by side and a mirror to reflect light at a 90° angle to the tissue. Some probes even have three or four LEDs in them to increase light output. The details of these and many other probes will be discussed in Chapter 7.

There is no wrong choice for LED packaging as long as the LEDs are small yet powerful enough to perform the task at hand. However, there is definitely a superior choice for packaging when trying to minimize costs, and that choice is almost always a package containing both LEDs.

Webster at 218-219:

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13.2.3 Dental pulp blood supply and viability

Pulse oximetry can also be used to diagnose dental pulp viability (Schmitt *et al* 1991). A tooth may be degenerating even though it appears normal to the naked eye or via x-ray images. Also, pulp inflammation can occasionally subside without intervention. Blood flow determines the viability of dental pulp and S_aO_2 determines the state of degeneration of a still viable tooth. Past techniques to determine dental pulp viability involved nerve stimulation. This was painful, often inaccurate, and gave no information about the state of degeneration. Nerves can sometimes function although blood flow is impaired.

To understand how monitoring oxygen saturation of dental pulp with pulse oximetry is accomplished, it is important to be familiar with the morphology of the tooth. The outer layers of the tooth consist of bone-like enamel and *dentin*. Collagen fibers connect the jaw bone to a layer of cementum at the base of the tooth, fixing the tooth in its socket. *Apical foramen*, small holes in the roots of the tooth, allow nerves and blood vessels to access the dental pulp. The blood provides oxygen, mineral salts, and nutrients to sustain the *odontoblasts* and neural tissues. Figure 13.2 shows that to measure the blood oxygen saturation, an adapted transmission probe in the shape of a U is applied over the tooth (Schmitt *et al* 1991). A black-foam insert conforms to the tooth and provides shielding from ambient light. It can be replaced and the probe reused on successive patients. The U-shaped probe is flat on top, providing a surface for the patient to bite down on to increase probe stability. The bone-like layers which surround the pulp create an optical shunt of sorts, allowing some light from the LEDs to be transmitted to the photodiode without passing through blood. Due to this extra variable, three wavelengths are needed to isolate the extinction coefficients of the blood. A wavelength in the range of 540 to 570 nm (green) is used because the extinction coefficients of enamel and dentin at this wavelength are similar to their extinction coefficients at 660 and 940 nm. Also, the extinction coefficients of oxygenated and deoxygenated blood at this wavelength greatly exceed their values at the red and IR wavelengths. The hardware of the pulse oximeter is similar to that of a two-wavelength pulse oximeter and the ratio of ratios computation of oxygen saturation is used. However, the denominator of each ratio is adjusted by subtracting off the detected DC value of the green wavelength (see equation (9.30)).

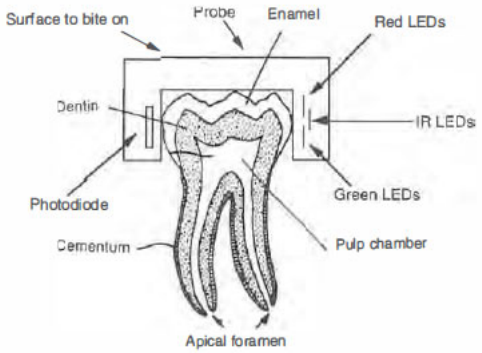


Figure 13.2 Morphology of the tooth and adapted pulse oximeter probe for determining the viability of dental pulp (adapted from Schmitt *et al* 1991).

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass. For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Nogawa at Abstract:

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	A new reflectance pulse oximeter sensor for lower arterial oxygen saturation (SaO_2) measurement has been designed and evaluated in animals prior to clinical trials. The new sensor incorporates ten light emitting diode chips for each wavelength of 730 and 880 nm mounted symmetrically and at the radial separation distance of 7 mm around a photodiode chip. The separation distance of 7 mm was chosen to maximize the ratio of the pulsatile to the average plethysmographic signal level at each wavelength. The 730 and 880 wavelength combination was determined to obtain a linear relationship between the reflectance ratio of the 730 and 880 nm wavelengths and SaO_2. In addition to these features of the sensor, the Fast Fourier Transform method was employed to compute the pulsatile and average signal level at each wavelength. The performance of the new reflectance pulse oximeter sensor was evaluated in dogs (N=5) in comparison to the 665/910 nm sensor. As predicted by the theoretical simulation based on a 3-dimensional photon diffusion theory, the 730/880 nm sensor demonstrated an excellent linearity over the SaO_2 range from 100 to 30%. For the SaO_2 range between 100 and 70%, the 665/910 and 730/880 sensors showed the standard error of around 3.5% and 2.1%, respectively, in comparison to the blood samples. For the range between 70 and 30%, the standard error of the 730/880 nm sensor was only 2.7%, while that of the 665/910 nm sensor was 9.5%. The 730/880 sensor showed improved accuracy for a wide range of SaO_2, particularly over the range between 70 and 30%. This new reflectance sensor can provide noninvasive measurement of SaO_2 accurately over the wide saturation range from 100 to 30%. *See, e.g.*, Nogawa at 80:

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The reflectance pulse oximeter, as reported by Mendelson et al, was the first monitor to measure SaO_2 from the finger-tip [7]. Although several reflectance pulse oximeters have been reported since then, they have not acquired the clinical acceptability yet [8,9]. The effectiveness of the reflectance pulse oximeters has been hindered by a poor signal to noise ratio and small pulsatile signals, particularly at the red wavelength. These weak signals preclude continuous measurement at the forehead or cheek. Mendelson et al used multiple photodiodes around the light emitting diode to increase the signal level. In 1992, Takatani et al [10] reported a multiple-light source hybrid reflection pulse oximeter sensor that incorporated a near-infrared heater to warm the skin and to increase the pulsatile signal level. The sensor was evaluated in animals and humans to show acceptable performance. However, the incorporation of the heater complicated the system and possible skin burn prevented long term continuous usage.

In this study, improvements in sensor design and signal processing method were proposed based on the theoretical simulation using a 3-dimensional photon diffusion theory to improve the performance of the reflectance pulse oximeter for lower SaO_2 measurement, possibly down to 40%, as well as wider clinical application without requiring vaso-dilating method. They are:

1) To improve the overall accuracy of the reflectance pulse oximeter, a new wavelength pair of 730/880 nm will be used, instead of the 660/910 nm pair. This combination can improve the overall linearity, with particular interest in its application to low SaO_2 measurement such as in fetal monitoring.

2) To increase the pulsatile signal level as well as to minimize tissue inhomogeneity, hence the variability among the subjects, ten light-emitting diode (LED) chips for each wavelength will be mounted around a photodiode (PD) chip at an equal radial distance of 7mm. The radial distance of 7 mm was decided through theoretical and experimental studies.

3) Furthermore, to improve the signal processing method, a Fast Fourier Transform (FFT) method will be used to compute the pulsatile (AC) and average (DC) components of the reflectance optical pulse signals at each wavelength. The DC and fundamental component of the Fourier transformed reflectance optical signal will correspond to the DC and AC component of the conventional method.

See, e.g., Nogawa at 83:

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The Hybrid Reflectance Optical Pulse Oximeter Sensor

The schematic diagram of the hybrid reflectance pulse oximeter sensor is shown in Fig. 4. A photodiode (PD) chip is located at the center and is surrounded by an optical barrier that blocks direct coupling between the light emitting diode (LED) and PD. Ten LED chips for each wavelength of 730 and 880 nm are placed symmetrically and at an equal radial distance of 7 mm around the PD to enhance pulsatile signal level and minimize the tissue inhomogeneity, hence the variability among the subjects. The diameter of the sensor is 23.0 mm with the thickness being 6.7 mm. Its weight is 7.2 gm. A four layered ceramic circuitry design allowed to accommodate twenty LED chips and a PD chip on a single substrate, resulting as a compact hybrid sensor design. After layout of LED and PD chips and wire bonding, the hybrid circuit was placed in a header and its surface was covered with an optical clear epoxy. After the epoxy cured, its surface was polished.

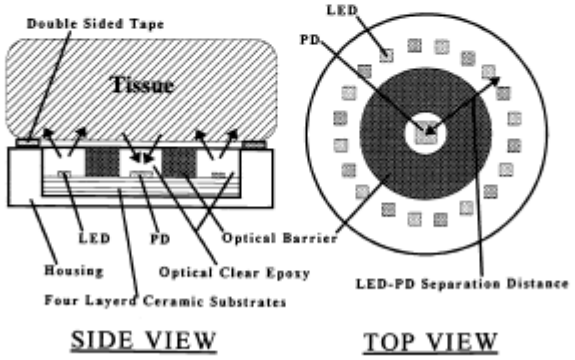


Fig. 4. A schematic drawing of the newly developed reflectance pulse oximeter sensor.

See, e.g., Nogawa at 85-86:

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DISCUSSION

In this study, a new hybrid reflectance pulse oximeter sensor has been evaluated in animals. The new sensor demonstrated significantly improved accuracy over a wide range of SaO_2, particularly at lower SaO_2 between 70 and 30%. The contributing factors for this improved performance are 1) sensor geometry, 2) wavelength selection, and 3) signal processing method [12].

Concerning the sensor geometry, the separation distance between the light source and detector was optimized to yield the largest AC/DC ratio. Although the theoretical study revealed that the AC/DC ratio increases with the radial separation distance, the reduction in the absolute signal level led us to choose the separation distance of 7 mm. For this separation distance, in order to enhance the signal level and average out the inhomogeneous effect of tissue, ten LED chips for each wavelength were placed symmetrically and at the equal radial distance around a photodiode chip. The changes in the reflectance signal that is specific to inhomogeneous effect and movement artifacts can be minimized to reduce abrupt changes in the signal level. This sensor geometry helped to minimize differences among individuals. To incorporate this layout into a final sensor design, a special

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hybrid circuit consisting of four layers of ceramic substrates were designed and fabricated. A total of twenty LED chips, one PD chip and an optical barrier were all together mounted on this header with its top covered with a clear epoxy, allowing a compact hybrid optical reflectance sensor.

As for wavelength selection, the 730/880 nm pair was used instead of the conventional 665/910 combination. The relationship between the R values computed using Equation (3) and SaO_2 was linear over a wide range of SaO_2; theoretical prediction based on the photon diffusion theory agreed well with the experimental results. Since the optical absorption due to deoxygenated hemoglobin at 730 nm is less than a half of that at 665 nm (Fig. 1), nonlinear relationship between the optical reflectance and the SaO_2 value was minimized at a wide range saturation. Moreover, since the optical penetration depth into tissue at 730 nm is deeper than that at 665 nm, and closer to that at 880 nm, measured reflectance signals at 730 and 880 nm wavelengths contain information come from similar depth inside the tissue.

In addition to the sensor geometry and wavelength selection, the new signal processing method utilizes the Fast Fourier Transformation of the reflectance pulse signal to derive AC and DC components. Approximately 10 second data was analyzed to compute the DC and fundamental spectral density from which the R value was derived. This method resulted in minimization of the errors involved with the detection of each pulse amplitude.

In conclusion, the new reflectance pulse oximeter sensor in combination with the new signal processing method demonstrated improved performance in noninvasive measurement of SaO_2 over its wide range. The new reflectance pulse oximeter sensor can broaden the clinical application of the reflectance pulse oximetry in caring patients in the operating room, ICU and fetuses during delivery. Currently, clinical evaluation of the sensor is under progress.

Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass.

For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments as four, five, and six separate emitters relying on different wavelengths, where relying on any number of additional wavelengths beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy:

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	See, e.g., Jarman at Abstract ("An improved method and apparatus for the photoplethysmographic monitoring of blood analyte parameters, specifically oxyhemoglobin, deoxyhemoglobin (reduced hemoglobin), carboxyhemoglobin and, in addition, in a four emitter apparatus, methemoglobin, uses a plurality of beams of light having different spectral contents to trans-illuminate the tissue of a patient. The apparatus and method require the application of an emitter set comprised of four emitters. The emitters may be LED's or laser diodes. In the three analyte system the center wavelength of the emitters must fall within three specific bands. In the four emitter system (capable of measuring methemoglobin) the center wavelength of the emitters in the emitter set must fall within four predetermined bands and the emitters having the two lowest center wavelengths must be at least 5 nanometers apart. The apparatus can use emitters which are located either in a probe, or, preferably, in the monitor, as well as a photodiode which can either be located in the patient probe or in the monitor."). Fig. 3.

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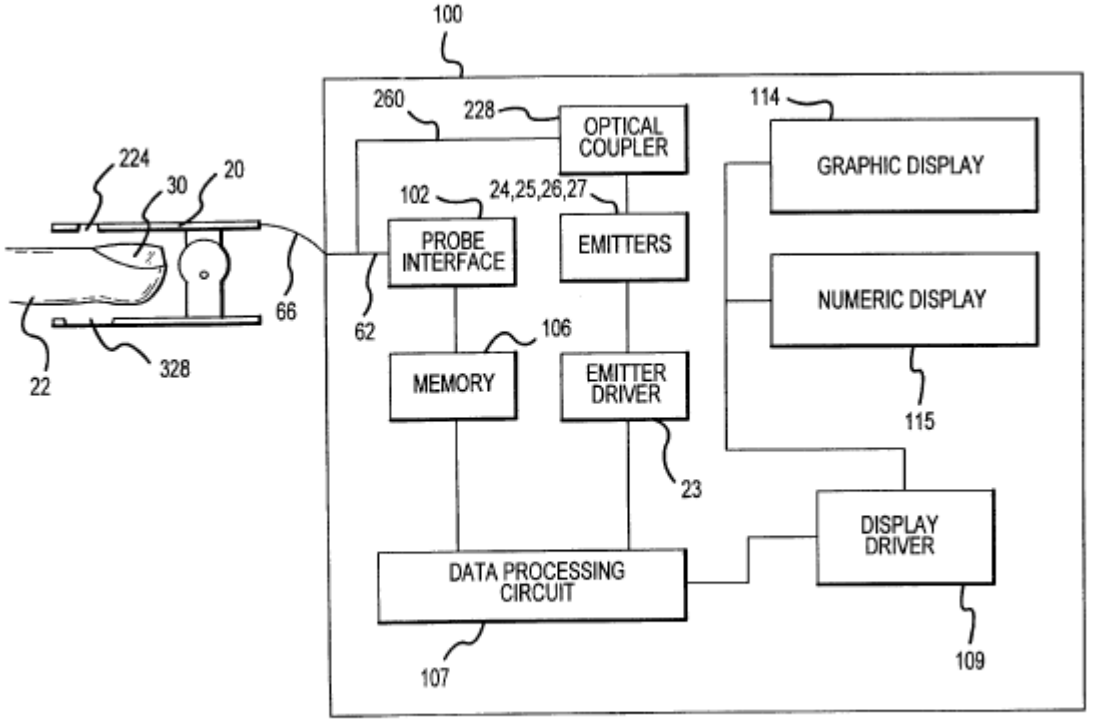


FIG.3

Jarman, 1:9-45 ("The present invention generally concerns the monitoring of a patient's tissue using a photoplethysmographic device to generate information related to the concentration of oxyhemoglobin (O2Hb), deoxyhemoglobin or reduced hemoglobin (RHb), carboxyhemoglobin (COHb) and, additionally, methemoglobin (MetHb) in the patient's blood. More specifically, the application relates to a device for the measurement of such blood analytes using a set of emitters having optimal spectral contents defined by a set of specific wavelength ranges.

During emergency evaluation, surgery and other medical procedures, clinicians often want to know the oxygen concentration of the blood, as well as other factors. In pulse oximetry the relative

	concentration of oxyhemoglobin and deoxyhemoglobin is displayed as a percentage of total hemoglobin in order to provide data on the oxygenation of the patient's blood. Blood oxygenation can be adversely affected by the generation of additional hemoglobin species, called dyshemoglobins. Most notably, carboxyhemoglobin is generated when carbon monoxide molecules bind to the hemoglobin in blood. An accurate measurement of carboxyhemoglobin concentration in the patient's blood may be needed when the patient is a smoker or if carbon monoxide poisoning is suspected. Additionally, elevated methemoglobin levels in the blood can be caused by various medications, illegal drugs and certain pathological conditions such as sickle cell anemia. Therefore measurement of the methemoglobin concentration is also useful during patient evaluation. Pulse-oximeters have been commercially available for measuring the oxygen saturation, or percent oxyhemoglobin, in arterial blood. These instruments rely on time-varying absorption of light by tissue supplied with pulsating arterial blood with a technique known generally as photoplethysmography. Conventional pulse oximeter instruments transmit light having spectral contents defined by two different center wavelengths through tissue."). Jarman, 1:63-2:10 ("The most obvious limitation of pulse oximetry derives from the fact that it is only a two channel (two wavelength bands) system and therefore can only solve for two components in the blood. Pulse oximetry makes the assumption that only oxyhemoglobin and reduced hemoglobin are present in the arterial blood. Any additional chromophores that are present in arterial blood and which absorb light in the wavelength bands used by the instrument will lead to erroneous readings. Two such chromophores are carboxyhemoglobin and methemoglobin. In particular, if carboxyhemoglobin or methemoglobin is present in above normal levels, a conventional pulse oximeter will give falsely high readings for the arterial oxygen saturation. This is one of the most serious and potentially dangerous limitations of current pulse oximetry."). Jarman, 2:45-3:42 ("This application discloses a photoplethysmographic apparatus and method for the accurate continuous, real-time, noninvasive measurement of a plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and, in additional embodiments, methemoglobin levels in blood. The apparatus uses three emitters for measuring oxyhemoglobin, deoxyhemoglobin and carboxyhemoglobin or four emitters for measuring methemoglobin in addition to the former three analytes. Each of the emitters has a spectral content characterized by a wavelength

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	that falls within a wavelength range which has been determined to be the optimal wavelength range for measuring the set of three or four blood analytes. The method of the invention is the optimization of the specific centerwavelengths necessary for accurate measurement of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and additionally methemoglobin. A photoplethysmographic method according to the present invention comprises the step of generating at least three monochromatic or essentially monochromatic beams of light having at least distinct first, second and third spectral contents denoted by center wavelengths λ1, λ2 and λ3. The terms "monochromatic beams of light" or "essentially monochromatic beams of light" are used to refer to light generated by emitters such as a laser diode or other relatively narrow band source, or light of narrow spectral bandwith, isolated by the use of gratings or interference filters, originating from a broadband source such as a tungsten lamp. A fourth emitter having a spectral content characterized by center wavelength λ4 is used in systems where methemoglobin levels are desired. The light from the emitters is then directed into a portion of the tissue of the patient in order to pass light through the tissue portion along an optical path. The method of the invention further comprises the use of means for detecting the received light transmitted from the tissue such as a photodiode or other appropriate detector. I.sub.λ1, I.sub.λ2 and I.sub.λ3 (and I.sub.λ4 in the four emitter apparatus) are the measurements of the light received from tissue after absorption and modulation by the various absorbers in the tissue and arterial blood under test. From the received light measurements, I.sub.λ1, I.sub.λ2, and I.sub.λ3 (and I.sub.λ4 in the four emitter case), the differential absorptions (dA's) of the transmitted light by various absorbers in the blood are calculated. These differential absorptions (dA's) are then used in the estimation of the blood analyte levels according to known techniques described or referenced herein. In the present invention, the emitters are chosen so that the spectral contents (denoted by center wavelengths λ1, λ2 and λ3 for the three emitter apparatus and λ1, λ2 λ3 and λ4 for the four emitter apparatus) are optimized for the detection of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and, additionally, in the four emitter case, methemoglobin. The center wavelength for the first, second and third emitters in the three emitter apparatus should be in the range of

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	approximately 610-640 nm, 680-770 nm and 850-1000 nm. The center wavelength for the fourth emitter, in the four emitter apparatus should be in the range of 635-650 nm with the additional constraint that the center wavelength of the first emitter must be at least 5 nm less than the center wavelength of the fourth emitter."). Jarman, 3:51-4:36 ("FIG. 3 is a diagram showing an additional embodiment of the claimed invention. FIG. 4 is a graph of the extinction curves of oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin and methemoglobin in terms of millimolar extinction, on a logarithmic scale, versus wavelength in nanometers. DETAILED DESCRIPTION OF THE INVENTION The photoplethysmographic monitor of the present invention measures the concentration of oxyhemoglobin (O2Hb), deoxyhemoglobin or reduced hemoglobin (RHb), carboxyhemoglobin (COHb) and, if four emitter are used, methemoglobin (MetHb) in a patient's blood. This is accomplished through the use of at least three emitters (or a filtered broadband emitter) emitting beams of light having a spectral content characterized by center wavelengths, λ1 λ2, and λ3 (and λ4 in the four emitter case). The spectral content of the light emitted by the three or four emitters (or filtered broadband emitter) must be distinct and it is preferable that the center wavelengths for each of the emitters also be distinct so that λ1 ≠λ2 ≠λ3 ≠λ4. FIG. 1 depicts an apparatus having four emitters made according to the present invention. The three emitter apparatus would be essentially identical except for the lack of one emitter and corresponding channel. Probe 20 is placed on the tissue under test 22 so that a plurality of emitters 24, 25, 26, 27 transmit light through the tissue which is then received by one or more photodetectors 28. Emitters 24, 25, 26, 27 (or a filtered broadband light source) each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ1 λ2, λ3 and λ4. In the case of a finger probe, the emitters are arranged to emit the light at or near the base of the fingernail 30. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. However, the preferred embodiment is to use at least four separate emitters preferably laser diodes each producing light with a distinct spectral content. It should be understood that four emitters could be used to measure three blood

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	analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin. Additionally, a number of emitters greater than the number of blood analytes being measured may be used in a photoplethysmographic system in order to create an overdetermined system. Through cable 60, an electrical signal indicative of the light emitted by emitters 24, 25, 26 and 27, transmitted through finger 22 and received by photodetector 28 is transmitted back to monitor 100. The internal components of monitor 100 are described in detail below."). Jarman, 4:7-36 ("FIG. 1 depicts an apparatus having four emitters made according to the present invention. The three emitter apparatus would be essentially identical except for the lack of one emitter and corresponding channel. Probe 20 is placed on the tissue under test 22 so that a plurality of emitters 24, 25, 26, 27 transmit light through the tissue which is then received by one or more photodetectors 28. Emitters 24, 25, 26, 27 (or a filtered broadband light source) each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ1 λ2, λ3 and λ4. In the case of a finger probe, the emitters are arranged to emit the light at or near the base of the fingernail 30. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. However, the preferred embodiment is to use at least four separate emitters preferably laser diodes each producing light with a distinct spectral content. It should be understood that four emitters could be used to measure three blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin. Additionally, a number of emitters greater than the number of blood analytes being measured may be used in a photoplethysmographic system in order to create an overdetermined system. Through cable 60, an electrical signal indicative of the light emitted by emitters 24, 25, 26 and 27, transmitted through finger 22 and received by photodetector 28 is transmitted back to monitor 100. The internal components of monitor 100 are described in detail below."). Jarman, 5:37-46 ("Where C is the concentration of the specific absorber, E is the extinction for that absorber at wavelength λ and ΔL is the differential change in effective path length the transmitted light has traveled. (Superscripts O, R, CO, and Met refer to O2Hb, RHb, COHb, and MetHb respectively.) Thus, after measuring the received light intensities and knowing the extinction coefficient E for each wavelength it is possible to determine the concentrations of the specific absorbers. In the three emitter system the same calculations are made according to the following equation:").

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	Jarman, 6:9-18 ("where xHb refers to one of O2 Hb, RHb, COHb, or MetHb, the constants a1, a2, a3, a4, b1, b2, b3, and b4 are calibration coefficients determined previously in a calibration experiment, and N21, N31, and N41 are normalized dAs for channels 2 and 1, 3 and 1, and 4 and 1, respectively. As one skilled in the art will understand, however, the calibration equation for each analyte is not limited to this form of equation, and may be, for example, a polynomial. In the three emitter system the calibration equation is given by:"). Jarman, 8:26-35 ("Thus, using emitter sets comprising four emitters having spectral contents characterized by a center wavelength within the four wavelength ranges (610-640 nm, 635-650 nm, 680-770 nm and 850-1000 nm) and subject to the one difference constraint, i.e., that the two lowest center wavelengths be 5 nanometers apart, provides an improved photoplethysmographic system for the measurement of oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin and methemoglobin."). Under at least the apparent construction based on Masimo's Infringement Contentions, Aoyagi discloses and/or renders obvious positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass. For example, Aoyagi discloses and/or suggests a patient monitor relying on an optical sensor, where additional LEDs at additional wavelengths, such as six LEDs in one embodiment, are used to measure levels of additional unknowns (such as compounds) in blood, where the more number of wavelengths the more number of unknowns that can be measured: *See, e.g.*, Aoyagi at Abstract ("Light of various wavelengths emitted from light sources and transmitted through vital tissues is converted by light sensors and current/voltage transducers, into electric signals. The signals are converted into digital values by an A/D converter. The light source emits light of a wavelength which can be optically absorbed by water. A computer obtains a ratio of variations of the digital values for each wavelength, and calculates the values of tissue terms and the hemoglobin concentration on the basis of the ratios. In the calculation, since tissue terms of the wavelengths have

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mutual constant relationships, an equation which is prepared so that there exists only one unknown in the tissue terms is used.").

Fig. 2.

FIG. 2

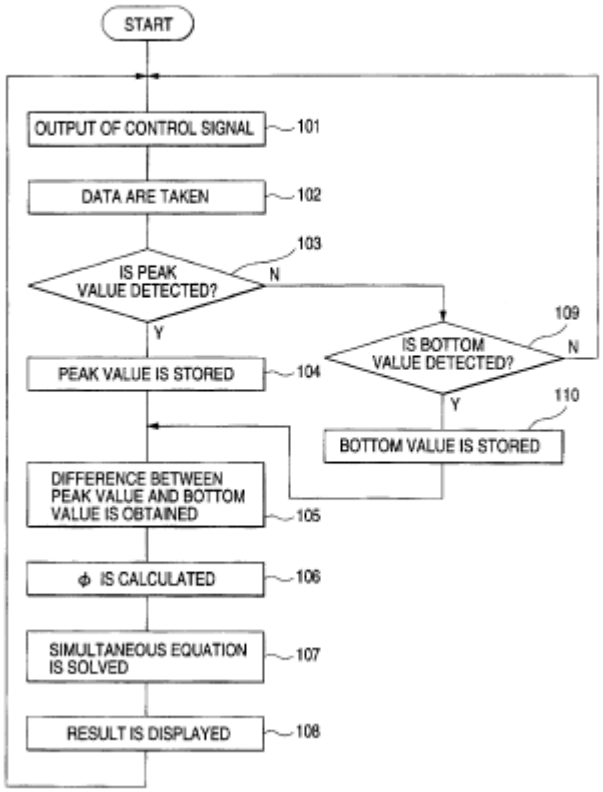
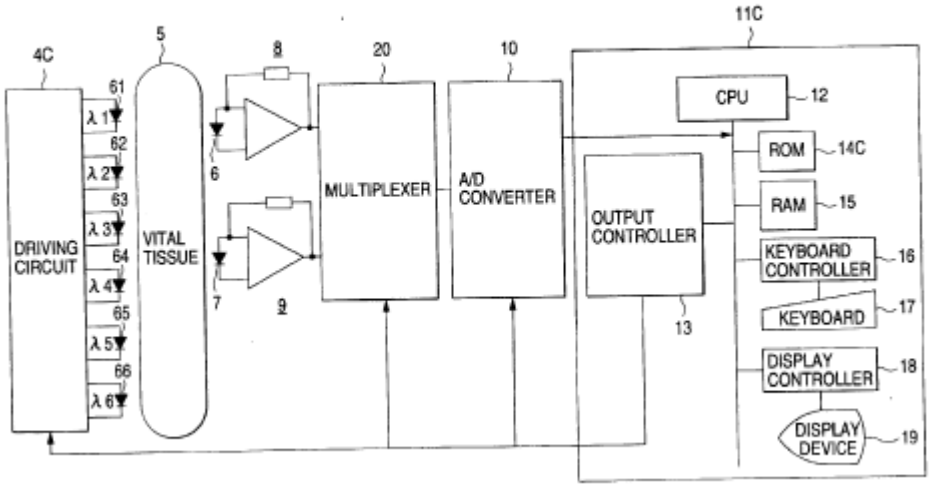


Fig. 5.

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FIG. 5



Aoyagi, 3:26-39 ("First, the principle common to all embodiments will be described. In the embodiments, the pulse method is used. In the pulse method, the phenomenon in which the effective thickness of the blood is caused to pulsate by blood pulsation in the vital tissues is used, and the optical absorptive characteristics of the blood in the tissues are measured while irradiating the vital tissues with light. Since the kinds of hemoglobin have different optical absorptive characteristics, the total hemoglobin can be obtained by obtaining respective hemoglobin concentrations in the blood and then calculating the total sum of the concentrations. Therefore, the number of light wavelengths required for the measurement depends on that of kinds of hemoglobin contained in the blood.").

Aoyagi, 4:16-25 ("Aoyagi, 4:16-25 ("IG. 6 shows optical absorptive characteristics of various kinds of hemoglobin, and FIG. 7 shows optical absorption of water with respect to that of oxyhemoglobin in the case where the hemoglobin concentration is 14 [g/dL].

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	The principle of a first embodiment will be described. The embodiment is directed to an apparatus which is to be used in the case where only oxyhemoglobin and reduced hemoglobin exist as hemoglobin in the blood. In this case, four light wavelengths are used and the following simultaneous equations with three unknowns are employed:"). Aoyagi, 6:21-28 ("This is set as a first embodiment (B). Next, the principle of a second embodiment will be described. The embodiment is directed to an apparatus which is to be used in the case where oxyhemoglobin, reduced hemoglobin, and carboxyhemoglobin exist as hemoglobin in the blood. In this case, five light wavelengths are used and the following simultaneous equations with four unknowns are employed."). Aoyagi, 7:28-40 ("By substituting equations (10) to (12), (18), and (19) into equations (14) to (17), simultaneous equations with four unknowns So, Sc, EX2, and Hb are obtained. When the simultaneous equations are solved, the values of So, Sc, Ex2, and Hb can be obtained. Next, a third embodiment will be described. When there exists methemoglobin in place of carboxyhemoglobin in the second embodiment, equations corresponding to equations (14) to (17) are as follows:"). Aoyagi, 8:18-25 ("By substituting equations (10) to (12), (18), (25), and (26) into equations (20) to (24), simultaneous equations with five unknowns So, Sc, Sm, Ex2, and Hb are obtained. When the simultaneous equations are solved, the values of So, Sc, Sm, Ex2, and Hb can be obtained. FIG. 6 shows optical absorptive characteristics of various kinds of hemoglobin. For example, light wavelengths used in the embodiments are as follows:"). Aoyagi, 8:47-51 ("In the fourth embodiment which measures four kinds of hemoglobin (O2 Hb, RHb, COHb, and MetHb) and six wavelengths are used Used wavelengths: λ1 =660 nm, λ2 =700 nm, λ3 =850 nm, λ4 =805 nm, λ5 =890 nm, and λ6 =1,250 nm").

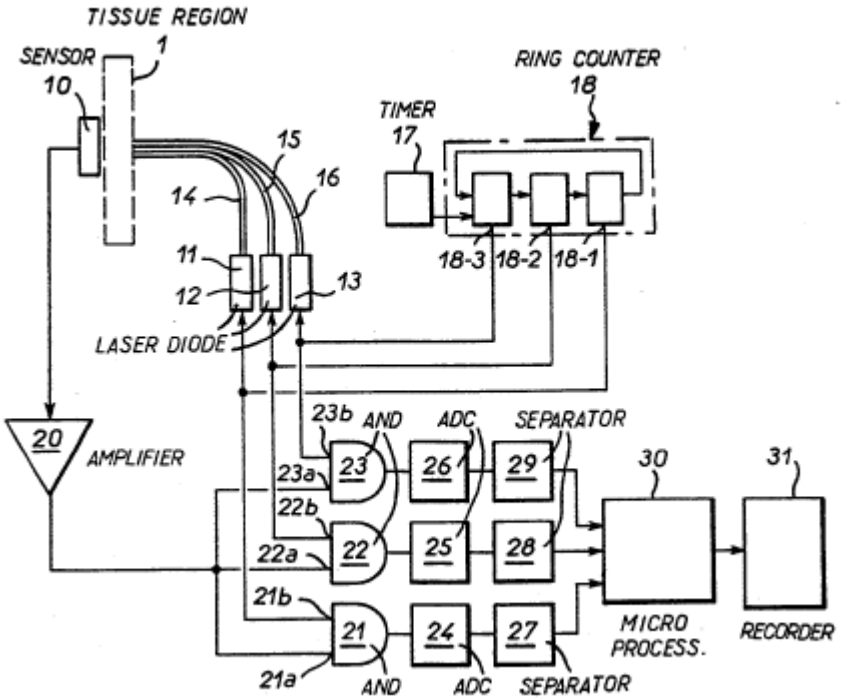
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	Aoyagi, 12:57-13:12 ("Next, a specific apparatus of the fourth embodiment will be described. FIG. 5 shows the whole configuration of the apparatus. The components which are identical with those of the apparatus of the first embodiment (A) are designated by the same reference numerals and their description is omitted. In the embodiment, the apparatus comprises six light sources 61 to 66. The light sources 61 to 66 emit light of wavelengths of λ1 =660 nm, λ2 =700 nm, λ3 =850 nm, λ4 =805 nm, λ5 =890 nm, and λ6 =1,250 nm, respectively. The wavelengths have features described above. A driving circuit 4C drives the six light sources 61 to 66. Light sensors 6 and 7 are placed so as to oppose the light sources 61 to 66, and converts light which is transmitted through the vital tissues 5 interposed between the light sources and the sensor, into an electric signal. A computer 11C conducts processing based on data supplied from the A/D converter 10 and outputs a control signal for controlling the operation timing to the driving circuit 4C and the multiplexer 20. A ROM 14C of the computer 11C stores a program which is slightly different from that stored in the ROM 14 of the computer 11 of the first embodiment (A) shown in FIG. 1. The other components of the computer 11C are the same as those of the computer 11A.").
	Under at least the apparent construction based on Masimo's Infringement Contentions, Barthelemy discloses and/or renders obvious positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass. For example, Barthelemy discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs that emit light at more than two wavelengths, where relying on additional wavelengths allows for the measurement of the concentration of multiple compounds in the blood: *See, e.g.*, Barthelemy, Abstract ("The apparatus comprises three laser diodes emitting at 660, 750 and 940 nm respectively, excited cyclically at the rate of a timer. The light emitted is channelled by three optical fibers to traverse a fully-vascularized tissue region of a subject along three virtually merged optical paths, and to terminate at an opto-electronic sensor, which generates overlapping signals representative of the molecular absorption. The pulsation of the arterial blood in the region induces variable components which are exclusively a function of the molecular absorptions due to oxyhemoglobin, deoxyhemoglobin and carboxyhemoglobin. The signals are switched by gates on three channels where the variable components are picked up and digitized, and then processed in a

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microprocessor to yield the oxygen saturation SaO_2 and the carbon monoxide fixation of the hemoglobin.").

Fig. 1.



Barthelemy, 3:47-4:35 ("To achieve this, the invention proposes a method for determining the oxygen saturation rate of the arterial blood of a subject, in which the concentration of oxyhemoglobin or HbO2 is compared with the total concentration of hemoglobin, comprising the steps of providing first, second and third light sources emitting in respective wavelength bands including a near infrared wavelength band, a deep red wavelength band and a wavelength band therebetween, selectively directing light emitted from the respective light sources through an appropriate tissue region of the subject, acquiring representative signals of optical absorption through the tissue region, cyclicly

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	exciting the light sources in succession and determining the frequency of the cyclic succession so as to be large as compared with the arterial pulsation frequency of the subject, and calculating concentrations of HbO2, Hb and HbCO to determine the oxygen saturation rate. According to another aspect of the invention, there is provided a method for determining the oxygen saturation rate of the arterial blood of a subject, by comparison of the concentration of oxyhemoglobin, or HbO2, with the concentration of total hemoglobin, including providing two light sources each emitting in a different wavelength band, one in the near infrared and the second in the deep red, directing light emitted by the light sources along two paths through an appropriate tissue region of the subject, providing an opto-electronic sensor for acquiring representative signals of the optical absorption of the light, the representative signals comprising a variable component corresponding to the absorption by the pulsatile arterial blood, and a continuous component corresponding to absorption by the other tissues traversed, separating the variable component of each representative signal, calculating the respective concentrations of HbO2 and deoxyhemoglobin, and optionally Hb, from the variable components, determining the oxygen saturation rate, wherein the improvement comprises the steps of providing a third light source emitting a third wavelength band between the aforesaid two bands and a corresponding third optical path associated with said third light source, exciting the three light sources in cyclic succession, selecting the cyclic succession frequency so as to be large in comparison with the arterial pulsation frequency of the subject, whereby the representative signals overlap, and each representative signal is switched at the cyclic succession rate to a respective separate channel, and calculating HbO2, Hb and HbCO to determine the oxygen saturation rate therefrom. It goes without saying that the optical paths, as usual, will be taken on relatively small thicknesses of fully-vascularized tissues, such as the ear, or on the fingers. Operation with three wavelengths, λ1, λ2 and λ3, yields a system of linear equations with three unknowns:”). Barthelemy, 5:1-64 (“Preferentially, the wavelength bands are centered on 940, 660 and 750 nm respectively.

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	By adopting an intermediate wavelength for the third optical path, a satisfactory separating power is obtained, thanks to the differences between the specific absorptions for the three hemoglobin species, and no absorption discontinuities are introduced for the non-blood tissues. Preferably, the processing of the representative absorption signals, including the extraction of the variable components and the subsequent calculations, are carried out in a microprocessor under the control of a suitable software. From another standpoint, the invention proposes an apparatus for determining the oxygen saturation rate of the arterial blood of a subject, in which the concentration of oxyhemoglobin or HbO2 is compared with the total concentration of hemoglobin, comprising first, second and third light sources emitting in respective wavelength bands including a near infrared wavelength band, a deep red wavelength band and a wavelength band therebetween, the respective light sources being directed at an appropriate tissue region of the subject, an opto-electronic sensing means acquiring representative signals of optical absorption through the tissue region, means for cyclicly exciting the light sources in succession, the frequency of the cyclic succession being large as compared with the arterial pulsation frequency of the subject, and means for calculating HbO2, Hb and HbCO to determine the oxygen saturation rate. According to another aspect of the invention, there is provided an apparatus for determining the oxygen saturation rate of the arterial blood of a subject, comprising light sources emitting in respective wavelength bands, one of the wavelength bands being near infrared and another of the wavelength bands being deep red, opto-electronic sensing means for emitting respective signals responsive to optical absorption along respective optical paths through an appropriate tissue region of the subject, said signals including a variable component corresponding to absorptions by pulsatile arterial blood and a continuous component corresponding to absorption through other tissues traversed, means for separating the variable component of the respective absorption signals, calculating means for processing the variable components and determining the respective concentrations of oxyhemoglobin or HbO2 and deoxyhemoglobin, or Hb, and also determining the oxygen saturation rate, further comprising a third light source emitting a wavelength band intermediate the first two wavelength bands, a third optical path between the third light source and the tissue region, the three optical paths terminating in said optoelectronic sensing means, means for exciting the three light sources in cyclic succession at a cyclic succession frequency which is large in comparison with pulse frequency of the

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	subject whereby the representative of signals overlap, means for switching each of the representative signals to a respective channel at the frequency cyclic succession, said last switching means comprising means for separating the variable component of the representative signal, said calculating means jointly processing the three variable components to identify HbO2, Hb and HbCO and determining the oxygen saturation rate therefrom."). Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detector allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased, further comprising a light block surrounding the at least one detector comprising a Direct light block or measuring head, the measuring head for the detector including only one opening through which light is configured to pass, implemented as a Fiber to Detector cable that is the only opening for light to the detector, further comprising a light block surrounding the at least one detector comprising a Direct light block or measuring head, for example, and where measuring head for the detector including only one opening through which light is configured to pass, implemetned as a Fiber to Detector cable that is the only opening for light to the detector: *See, e.g.*, Fantini at Abstract:

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Abstract. We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit.

See, e.g., Fantini at 33:

In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition.

In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument.

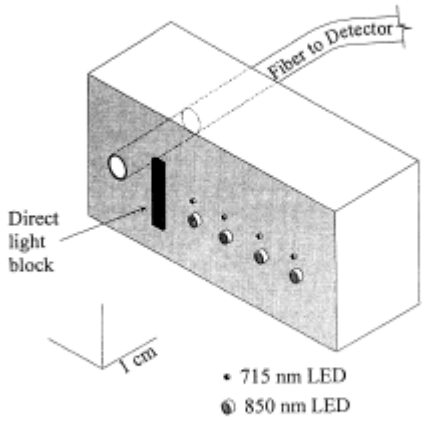
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	See, e.g., Fantini at 34: ***Feature 2.*** The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. ***Feature 3.*** To implement the measurement of the slopes of the straight lines (as a function of the distance *r* between

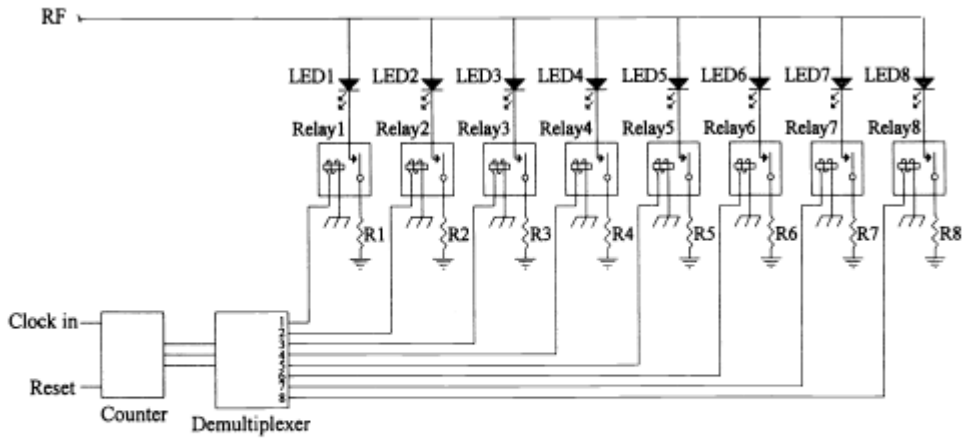
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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

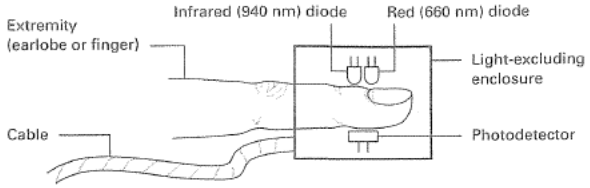
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	Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of  **Fig. 2** Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium. *See, e.g.*, Fantini at 35:

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	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
19[b] activating the at least three LEDs such that at least three wavelengths of	Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs.

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light are emitted from the at least three LEDs;	For example, Moyle discloses and/or suggests relying on different types of LEDs to emit light, where each type of LED emits light of a different wavelength, and where the LEDs relied upon for a pulse oximeter could include three or more LEDs.: *See, e.g.*, Moyle at Pages 16-21, 17-18: The early generations of pulse oximeters all used similar wavelengths, namely 660 nm (red) and 940 nm (near infrared). However, modern devices, including transmission, reflection and intrauterine pulse oximeters, often make use of other wavelengths. LEDs of 660 nm and 940 nm were originally chosen, as they were wavelengths that were easy to manufacture, but a much greater range of wavelengths is now available (see Box). **Gallium arsenide doping of the semiconductor material of light-emitting diodes to produce specific wavelengths** Ultraviolet 455–350 nm GaN GaS2 Violet 455–390 nm GaN Blue 492–455 nm GaAs-phosphor (ZnS, SiC) Green 577–492 nm GaP:N Yellow 597–577 nm GaAs.14P.86 Orange 622–597 nm GaAs.35P.65 Red 780–622 nm GaP:ZnO GaAs.6P.4 Near infrared 810 nm GaAlAs 880 nm GaAlAs 900 nm GaAs 940 nm GaAsSi 1100 nm Ga.17In.83As.34P.66 Infrared 1250 nm Ga.28In.72As.6P.4  Figure 3.2 Components of transmission pulse oximeter probe. very little difference to calibration. The advantage of 660 nm as the red wavelength chosen is that there is a comparatively large difference in the absorption between reduced and oxygenated haemoglobin at this point on the spectrum, yielding detectable changes in absorption with small changes in oxygen saturation. Although the curves are not horizontal at 660 nm, they are considerably flatter than at shorter wavelengths.

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Moyle at Page 31:

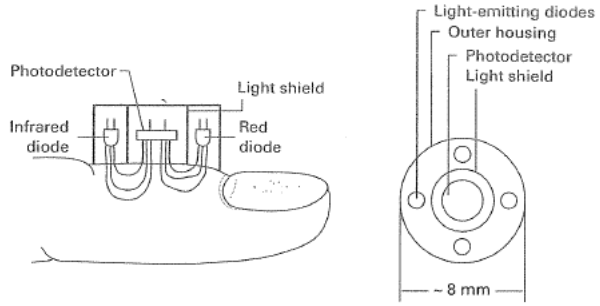


Figure 3.11 Section (left) and plan (right) of reflection oximeter probe.

Reflection pulse oximetry

There are certain advantages in using reflected rather than transmitted light. The design of the probe is simpler, with greater mechanical strength (Figure 3.11).

From a clinical point of view a reflection pulse oximeter has the advantage that it can be used at more sites than the transmission type, for example the forearm, thigh, chest, forehead and cheeks. This means that its saturation readings can be made in patients with poorer perfusion and in those who are hypothermic. The reflection pulse oximeter may prove useful after cardiac bypass surgery, where initially the periphery is very shut down and much cooler than normal. Palve[7] showed that saturation could be measured with a reflection-type probe from a patient's forehead when the fingertip temperature was only 28·8°C. Reflection pulse oximetry works well on ventilated patients who are unconscious, but difficulty with probe

Moyle at Page 36:

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Modern multiwavelength spectrophotometers can measure all four common species of haemoglobin (haemoglobin A, oxygenated haemoglobin, carboxyhaemoglobin, and methaemoglobin). The percentage oxygen saturation of the haemoglobin is now defined as a ratio of the amount of haemoglobin saturated with oxygen to all the four species. This is termed the fractional saturation:

$$\text{Fractional } SaO_2 = \frac{HbO_2}{HbO_2 + Hb + HbCO + MetHb} \times 100\%$$

Ideally, the pulse oximeter should measure either fractional or functional saturation, and the manufacturer should state whether a particular unit has been calibrated as fractional or functional. However, with current pulse oximeters using only two wavelengths, it must be said that pulse oximeters indicate neither functional nor fractional saturation.[4] The conventional two-wavelength pulse oximeter measures the absorption at two wavelengths and applies their ratio to look-up tables, which then indicate a value, SpO_2, which is best defined as *oxygen saturation as measured by a pulse oximeter*.

Moyle at Page 39-40:

variable over the range 500 nm to 700 nm, controlled by an electric (stepper) motor, so that the light emanating from the monochromator can be scanned. This variable wavelength light is passed through the cuvette containing the haemolysed blood. As the monochromator is controlled by a stepper motor, the wavelength is changed in discrete steps. As this CO-oximeter is designed to measure five components (see Box), only five wavelengths are necessary to make the calculations. However, the sample will contain other absorbents, including fetal haemoglobin, bilirubin, and fragments of the erythrocyte membranes, so the AVL 912 uses up to 17 wavelengths. The light emanating from the cuvette after passing through the blood is detected by a photodiode. The signal from the photodiode is amplified, converted from analogue

to digital, and passed to a microprocessor, which makes use of the Beer–Lambert law and simultaneous equations to calculate the values shown in the box.

Under at least the apparent construction based on Masimo's Infringement Contentions, Webster discloses and/or renders obvious activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs.

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	For example, Webster discloses and/or suggests, for pulse oximetry systems, relying on three LEDs emitting light at three wavelengths in order to measure additional physiological parameters. *See, e.g.*, Webster at 37-38: *3.7.6 A three-wavelength pulse oximeter for COHb determination* Current pulse oximeters estimate the arterial oxygen saturation of the blood by measuring absorbances at two wavelengths of light. Because of this, the pulse oximeter is only able to account for Hb and HbO_2. Increased levels of COHb, for example, will cause an overestimation in S_aO_2 because the pulse oximeter cannot distinguish between HbO_2 and COHb. In cases of carbon-monoxide poisoning, this could have terrible consequences if the clinician is unaware. Buinevicius (1987) designed a three wavelength pulse oximeter to solve this problem. An additional LED at 810 nm was used in an attempt to determine the amount of COHb in the blood. Buinevicius also presented a method to calibrate the pulse oximeter for three wavelengths using three-dimensional solutions to Beer's law. Webster at 69-70:

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5.7 LED PACKAGING

Most LED packages are made of resin, offering superior mechanical strength and the ability to withstand vibration and shock. In some of today's pulse oximeter probes, the two LEDs can be found in one package, which has the distinct advantage of keeping costs down. In the Nellcor SCP–10 reusable and Oxisensor II D–25 disposable pulse oximeter probes, the two LEDs come encased in a transparent rectangular solid with approximate dimensions of 5 mm long by 4 mm wide by 2 mm thick. The LEDs themselves are flat squares with sides of approximately 0.25 mm.

Other probes have discrete LEDs inside, with the LEDs lying side by side and a mirror to reflect light at a 90° angle to the tissue. Some probes even have three or four LEDs in them to increase light output. The details of these and many other probes will be discussed in Chapter 7.

There is no wrong choice for LED packaging as long as the LEDs are small yet powerful enough to perform the task at hand. However, there is definitely a superior choice for packaging when trying to minimize costs, and that choice is almost always a package containing both LEDs.

Webster at 218-219:

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13.2.3 Dental pulp blood supply and viability

Pulse oximetry can also be used to diagnose dental pulp viability (Schmitt *et al* 1991). A tooth may be degenerating even though it appears normal to the naked eye or via x-ray images. Also, pulp inflammation can occasionally subside without intervention. Blood flow determines the viability of dental pulp and S_aO_2 determines the state of degeneration of a still viable tooth. Past techniques to determine dental pulp viability involved nerve stimulation. This was painful, often inaccurate, and gave no information about the state of degeneration. Nerves can sometimes function although blood flow is impaired.

To understand how monitoring oxygen saturation of dental pulp with pulse oximetry is accomplished, it is important to be familiar with the morphology of the tooth. The outer layers of the tooth consist of bone-like enamel and *dentin*. Collagen fibers connect the jaw bone to a layer of cementum at the base of the tooth, fixing the tooth in its socket. *Apical foramen*, small holes in the roots of the tooth, allow nerves and blood vessels to access the dental pulp. The blood provides oxygen, mineral salts, and nutrients to sustain the *odontoblasts* and neural tissues. Figure 13.2 shows that to measure the blood oxygen saturation, an adapted transmission probe in the shape of a U is applied over the tooth (Schmitt *et al* 1991). A black-foam insert conforms to the tooth and provides shielding from ambient light. It can be replaced and the probe reused on successive patients. The U-shaped probe is flat on top, providing a surface for the patient to bite down on to increase probe stability. The bone-like layers which surround the pulp create an optical shunt of sorts, allowing some light from the LEDs to be transmitted to the photodiode without passing through blood. Due to this extra variable, three wavelengths are needed to isolate the extinction coefficients of the blood. A wavelength in the range of 540 to 570 nm (green) is used because the extinction coefficients of enamel and dentin at this wavelength are similar to their extinction coefficients at 660 and 940 nm. Also, the extinction coefficients of oxygenated and deoxygenated blood at this wavelength greatly exceed their values at the red and IR wavelengths. The hardware of the pulse oximeter is similar to that of a two-wavelength pulse oximeter and the ratio of ratios computation of oxygen saturation is used. However, the denominator of each ratio is adjusted by subtracting off the detected DC value of the green wavelength (see equation (9.30)).

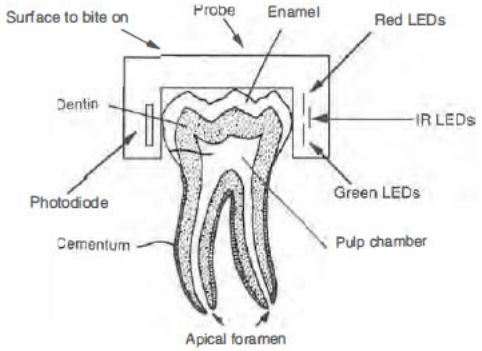


Figure 13.2 Morphology of the tooth and adapted pulse oximeter probe for determining the viability of dental pulp (adapted from Schmitt *et al* 1991).

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where the at least three LEDs configured to emit light of at least three different wavelengths, including as a non-limiting example four LEDs each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound: *See, e.g.*, Raley at Abstract ("A two piece probe having a universal probe end and an interconnect cable segment provides for the use of the universal probe end with a variety of different photoplethysmographic devices. The universal probe end includes a detector, a substrate for removably affixing the probe end to a patient, a window or aperture and a connector. The interconnect cable has a connector mated to the connector on the probe end for mechanical and electrical connection of the probe-end to the interconnect cable and the photoplethysmographic monitor. The connector end of the interconnect cable also houses a plurality of emitters which are directed through the window or aperture in the probe end in order to illuminate the patient. The interconnect cable also houses the resistors or other elements which identify the type of probe, monitor manufacturer or actual emitter wavelengths. Alternatively, the emitters may be housed in the main monitor and an optical fiber may be used to direct light to the patient. An electrical conductor transmits light received by the detector back to the photoplethysmographic monitor."). Fig. 1.

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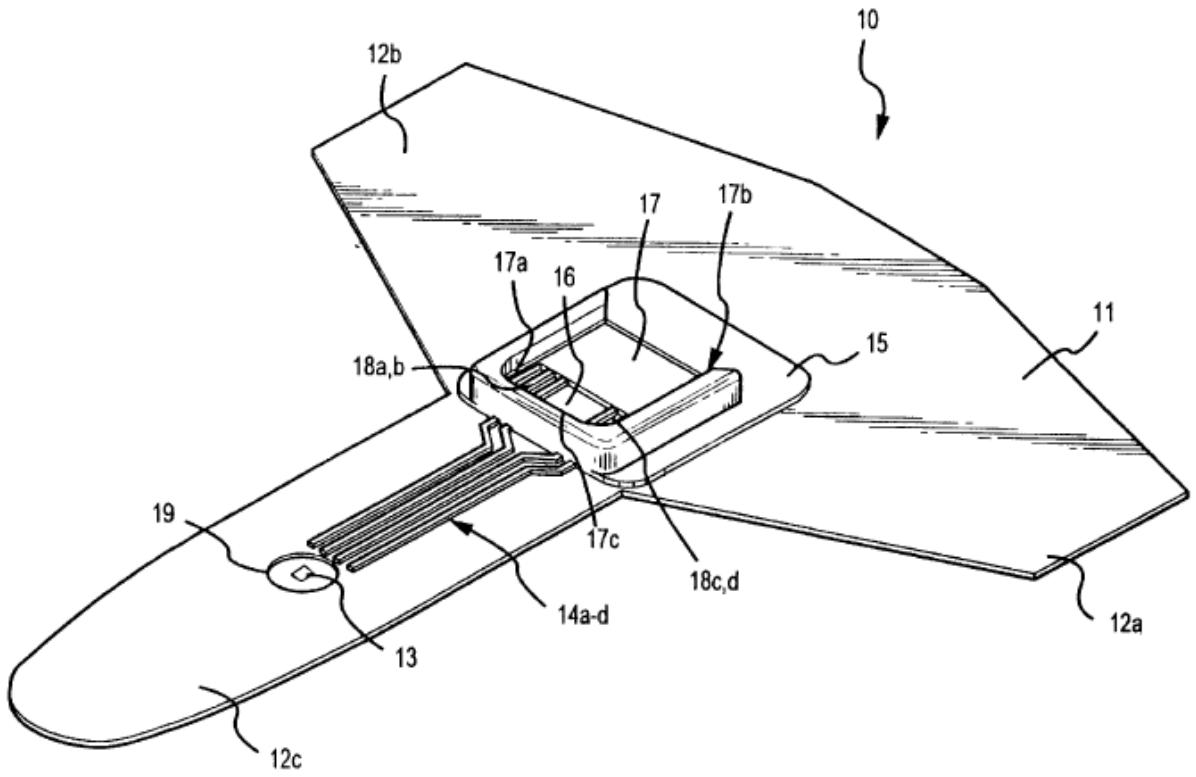


FIG.1

Fig. 3a.

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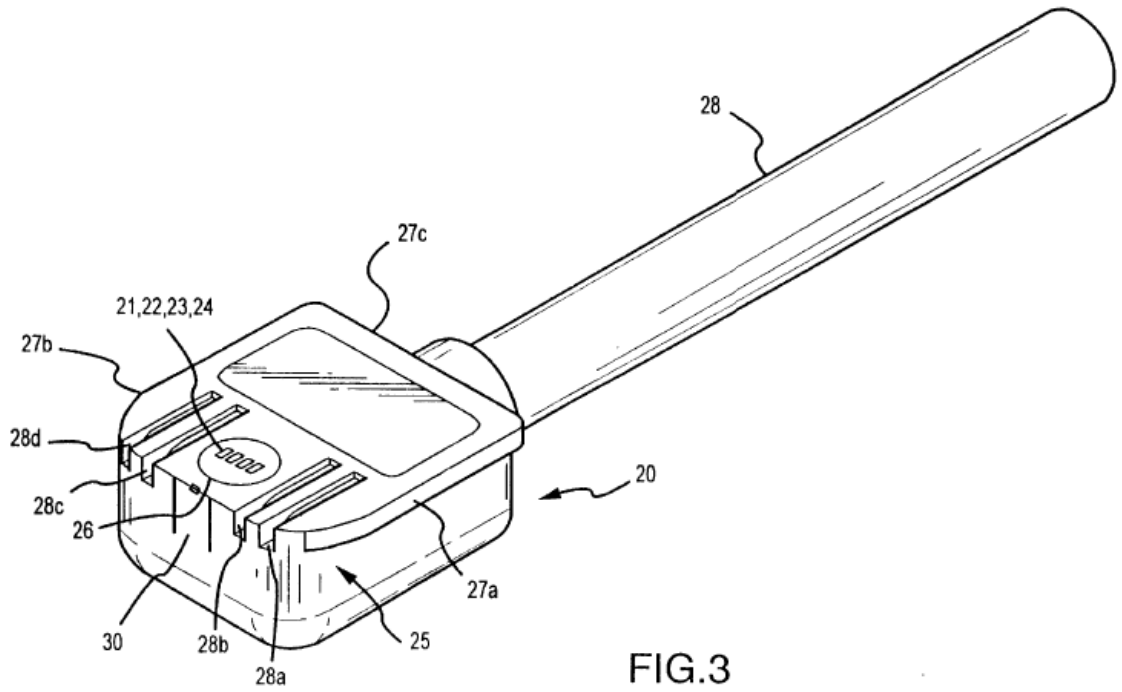


FIG.3

Fig. 3b.

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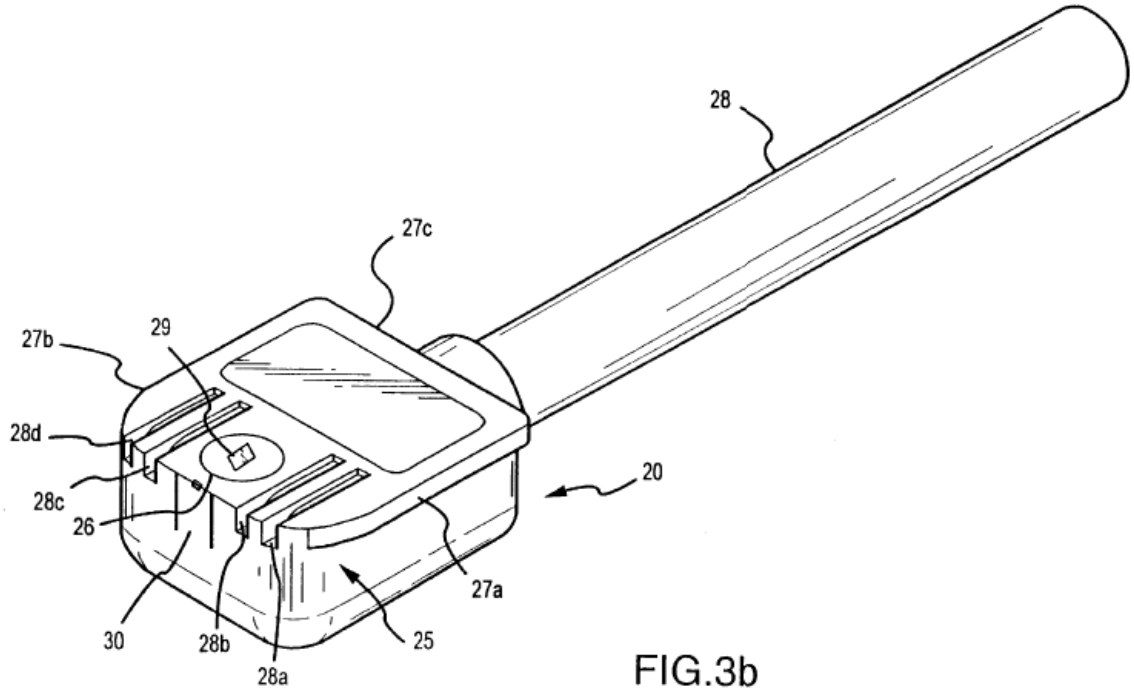


FIG.3b

Raley, 3:11-4:13 ("A pulse oximeter instrument operates by use of a probe that illuminates an appendage of the patient (such as a finger, earlobe, toe, neonatal appendages, or the nasal septum) that is rich in arterial blood and measures the differential absorption of the light by the pulsatile portion of the arterial blood flow to thereby determine oxygen saturation of the arterial blood. The pulse oximeter instrument makes use of a plurality of light-emitting devices, each of which transmits light at a predetermined wavelength, which wavelengths are selected such that at least one is highly absorbed by oxygenated hemoglobin in the arterial blood and at least one is highly absorbed by reduced hemoglobin in the arterial blood. The amount of absorption of the light beams generated by these light emitting devices that are located in the probe is a measure of the relative concentration of the various hemoglobin species contained in the arterial blood. The absorption of the light that illuminates the appendage of the patient includes a constant portion that is a result of skin, bone, steady-state (venous)

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	blood flow and light loss due to various other factors. The pulsatile component of absorption is due to the pulsatile arterial blood flow and is a small fraction of the received signal and is used by the pulse oximeter instrument to perform its measurements. It is also possible to measure additional analytes in the arterial blood, such as additional dyshemoglobins, with one additional wavelength of light for each component. The measurements are computed by sampling the output of the light detector located in the probe to determine the incremental change in absorption of the various wavelengths of light that are used to illuminate the appendage of the patient. These incremental changes in light absorption are then used to compute the oxygen saturation of the arterial blood as well as the patient's pulse rate. Since the pulsatile component of the signals received by the light detector represent only a small fraction of the incident light, it is important that the incident light be of significant magnitude to result in transmitted signals that have sufficient amplitude to provide accurate readings. In addition, the probe containing the light-emitting devices and the light detector must be placed in intimate contact with the skin of the patient to obtain the most accurate readings. Referring to FIGS. 1, 2, 3, 4, 5 and 6, the probe 40 of the present invention is designed for use with one of two basic photoplethysmographic monitor architectures depicted in FIGS. 5 and 6. FIG. 5 depicts one of the monitor architectures in which the monitor 100 communicates with probe 40 through socket 104 and mating interconnect cable plug 42. The configuration of plug 42 depends on the type and manufacturer of monitor 100. For example, if the monitor 100 is capable of measuring a plurality of blood analyte concentrations such as O2Hb, RHb, COHb and MetHB then plug 42 and interconnect 104 will contain sufficient electrical connectors 46 to interconnect probe interface 102 with a plurality of emitters 21, 22, 23 and 24 located in the connector-end 25 of interconnect cable segment 20. In a preferred embodiment, the plurality of emitters 21, 22, 23 and 24 each emit light having a distinct spectral content characterized by a distinct center wavelength denoted by λ_1 λ_2 λ_3 and λ_4. These emitters may be light-emitting-diodes (LED's) or laser diodes. It is also possible to filter a broadband light source to produce light having four spectral peaks of differing wavelengths. In a photoplethysmographic instrument designed to generate four blood analyte levels, the preferred embodiment is to use at least four separate emitters each producing light with a distinct spectral content. If fewer blood analyte levels are desired then fewer emitters may be used either in the interconnect cable. For example, in a probe made according to the present invention for use with a standard pulse oximeter, only two emitters would be needed in the interconnect cable.”).

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	Raley, 4:47-6:12 (“An alternative method of implementing a photoplethysmographic monitor is depicted in FIG. 6 and operates in conjunction with the alternative probe embodiment in FIG. 3b. The emitters 21, 22, 23 and 24 (which may be LED's or laser diodes, but which are preferably laser diodes) are housed in the monitor 200. The emitters 21, 22, 23 and 24 are driven by emitter driver 230 which is controlled by the data processing circuit 107. The emitted light is then combined by an optical coupler 228 and transmitted to the probe 40 by internal optical fiber 260 which is coupled to an optical fiber or other such optically transmissive material (not shown) internal to interconnect cable segment 28. Thus, plug 42 and connector 204 now includes electrical conductors for connecting photodiode 13 back to the probe interface 102 and an optical connector for connecting optical fiber 260 to an optical fiber (not shown) located in cable 28. The light transmitted through the optical fiber 260 and transmitted through the optical fiber located in cable 28, reflects off mirror 29 of FIG. 3b in connector end 25 and passes through window or opening 26 and window 16 in probe-end 10 and impinges on the tissue of the patient. Transmitted light is received by photodetector 13 which send an electrical signal back to the probe interface 102 through the electrical conductors in cable 28 and electrical pathway 262 in monitor 200. The probe interface 102 converts the analog signal to a digital signal and transmits the signal to memory 106 and on to data processing circuit 107 for processing and display of blood analyte concentration values using graphic display 114 and numeric display 115 driven by display driver 109. The transmission of the emitted light can be controlled in a time division multiplexing manner and an optical coupler 228 can be used to provide a means for combining multiple emitters onto one strand of optical fiber 260. Alternatively, the plurality of emitters may be placed or abutted against optical fiber 260. The Probe Referring again to FIG. 4 the probe 40 consists of two releasable connected segments: the probe-end 10, separately depicted in FIG. 1 and interconnect cable segment 20, separately depicted in FIGS. 2, 3 and 3b. Universal probe-end 10 is designed to be disposable and to accommodate any type of interconnect cable segment 20, whether it contains LED's, laser diode, or an optical fiber/mirror for illuminating the tissue. Thus, the construction of probe-end 10 is simple and flexible consisting of a flexible substrate 11 having three portions 12a, 12b and 12c. Substrate portions 12a and 12b are designed to wrap around

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	an appendage of a patient. In FIG. 1 the substrate is designed to be wrapped around a finger. Substrate portions 12a and 12b have an adhesive layer applied to one or more surfaces to enable the portions to be removably attached to the finger. Substrate portions 12a and 12b may be configured differently for attachment of probe-end 10 to the feet of neonates, the smaller fingers of children, or to other appendages of adult, child or neonatal patients. Substrate portion 12c includes a photodetector 13 which is mounted in an optically transmissive window 19 in the substrate 11 and which is connected to connector 17 through flexible electrical circuits 14 a-d. Connector 17 has three lip portions 17a, 17b, and 17c which are designed to accommodate and hold the connector-end 25 of interconnect cable segment 20. Connector portion 15 provides a larger surface area for connector 17 to be either adhesively affixed to substrate 12 or, alternatively, to be retained between layers of substrate 12. Connector 17 also houses an optically transmissive window 16 and electrical contacts 18a, 18b, 18c, and 18d which connect flexible electrical circuits 14a,b,c and d with interconnect cable segment 20. Window 16 enables light to be passed from the emitters 21,22,23 and 24 or optical fiber and mirror 29 to the patient while protecting the patient from excess heat and also protecting the reusable interconnect cable segment 20. FIG. 2 depicts a top elevational view of the patient end of interconnect cable segment 20. Cable 28 consists of a bundle of one or more electrical conductors and, if the emitters are located in the monitor 200, an optical fiber. The electrical conductors and optical fiber are covered by a flexible insulating material to protect the internal components. Conductive grooves 28a, 28b, 28c and 28d provide for electrical interconnection of photodetector 13 through flexible conductors 14a, 14b, 14c and 14d and electrical contacts 18a, 18b, 18c and 18d. Ridge 27b is designed to fit under lip 17b to hold connector-end 25 onto probe-end 10. FIG. 3 depicts a bottom elevational view of one embodiment of the patient end of interconnect cable segment 20. The embodiments of FIG. 3 includes four emitters 21, 22, 23 and 24. Such an embodiment would be useful in a photoplethysmographic monitor for measuring three or four blood analytes such as oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin. Alternatively, the number of emitters could be two in a probe for use with standard pulse oximeters which typically use two emitters having spectral contents characterized by distinct center wavelengths, often 660 nm and

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940 nm. Ridges 27a, 27b and 27c fit under lip portions 17a, 17b and 17c to hold connector-end 25 onto probe end 10. The end of latch 30 is designed to click into a hole near the base of lip portion 17c so that upon engagement of the connector-end 25 into connector 17 a releasable latching occurs. In order to disengage the latching mechanism latch 30 is simply depressed.").

Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs.

For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters):

See, e.g., Fantini at Abstract:

Abstract. We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit.

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See, e.g., Fantini at 33:

In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition.

In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument.

See, e.g., Fantini at 34:

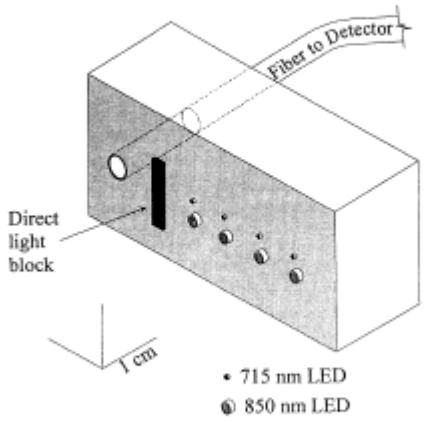
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		Feature 2. The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. *Feature 3.* To implement the measurement of the slopes of the straight lines (as a function of the distance r between	

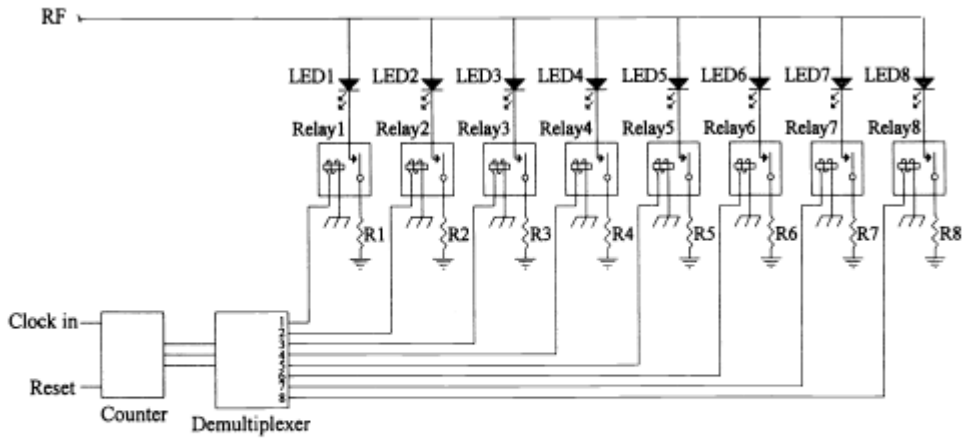
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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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	Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of  **Fig. 2** Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium. *See, e.g.*, Fantini at 35:

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	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
19[c] detecting, at the at least one detector, at least a portion of the light	Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious detecting, at the at least one detector, at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by the body tissue and passed through the

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emitted from the at least three LEDs after at least a portion of the light has been attenuated by the body tissue and passed through the opening of the top of the light block, wherein the at least one detector outputs at least one signal responsive to the detected light; and	opening of the top of the light block, wherein the at least one detector outputs at least one signal responsive to the detected light. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detector allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased, and where there is a detector implenmented as a Hamamatsu R928 detector which detects light from the LEDs after attenuation by the tissue, where the detector then uses signals at least one signal to measure blood parameters such as hemogobin concentrations: *See, e.g.*, Fantini at Abstract: **Abstract.** We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit. *See, e.g.*, Fantini at 33:

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In the near infrared, low-cost sources such as light-emitting diodes can be modulated at frequencies high enough to realiably measure the optical parameters of tissues.[13] Using the frequency-domain method and the diffusion theory, the absorption spectrum of a chromophore was quantitatively recovered even in the presence of a concentration of scattering particles similar to those found in tissues.[14] Furthermore, we have shown that the accuracy of a measurement is increased if several source-detector separations are employed.[14] The case of a semi-infinite geometry, which is a model of the noninvasive *in vivo* configuration, has been studied both in the time domain[5] and in the frequency domain.[15] As a result, the relationships between the phase and attenuation of the photon density wave on one hand and the optical properties of the medium on the other have been determined for such a boundary condition.

In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument.

See, e.g., Fantini at 34:

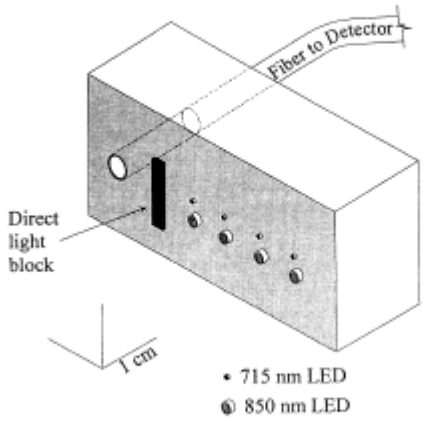
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		Feature 2. The feasibility of using LEDs as light sources in frequency-domain tissue spectroscopy has already been shown.[13] Commercially available LEDs cover the optical window from 700 to 900 nm almost continuously. We chose two emission wavelengths that maximize the precision of the measurement of [HbO_2] and [Hb]. The LEDs used were the following: 1. LED Hewlett Packard HEMT-6000 ($\lambda_1^{peak} = 715$ nm), 2. LED Motorola MFOE1203 ($\lambda_2^{peak} = 850$ nm). These LEDs can be efficiently modulated up to about 120 MHz by driving them with a low-voltage oscillating signal. We emphasize that the average optical power emitted by LEDs is usually less than a few milliwatts and is distributed over a wide solid angle. These properties make LEDs particularly safe in medical applications. The emission from LEDs has different ANSI standards than the emission from lasers. *Feature 3.* To implement the measurement of the slopes of the straight lines (as a function of the distance r between	

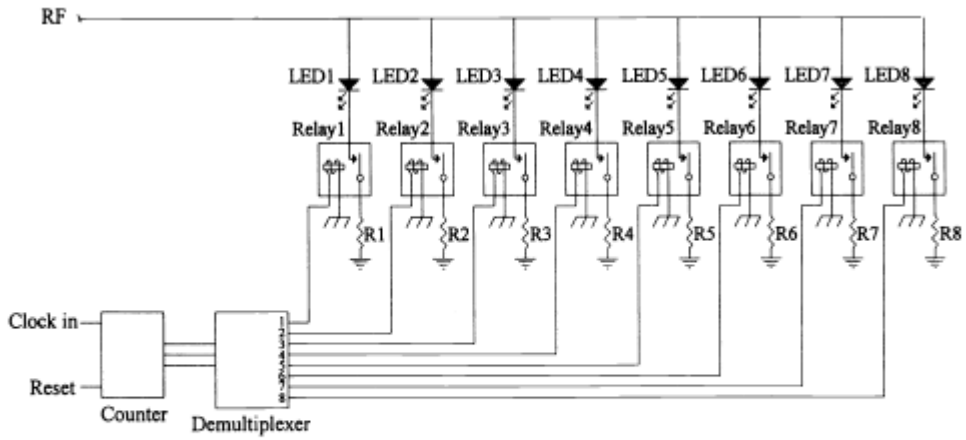
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source and detector) associated with dc, ac, and phase, we have designed a spectrometer that employs eight different light sources placed at different distances from the detector fiber bundle, as shown in Fig. 2. The detector fiber bundle (3 mm in diameter, 0.56 numerical aperture) is connected to a photomultiplier tube. The eight sources are arranged in two parallel rows of four LEDs: in the first (second) row we placed the 715-nm (850-nm) LEDs, so that each row implements the measurement of the slopes at one wavelength. The source-detector distances in each row range from 1.5 to 3.5 cm, and a light shield is placed between sources and detector to prevent reflected light from being detected. The two rows are placed as close as possible to each other in order to explore essentially the same region of the sample. The eight sources are turned on one at a time in rapid succession, using the multiplexer circuit shown in Fig. 3. The clock signal from the computer (whose frequency can be selected by software and is synchronous with the cross-correlation frequency introduced in the following paragraph) is the input of a counter (RCA CD4024), which drives a demultiplexer (RCA 74HCT238) with eight outputs connected to eight relays (Magnecraft W171DIP-2). The relays, which are closed one at a time, are in series with each LED. The result is that the LEDs are turned on in sequence at the frequency of the clock. In order to start the sequence always with the same LED, the counter is reset by a pulse sent by the computer at the beginning of the measurement. Resistors R_1 to R_8 in Fig. 3 are added to decrease the current in some of the light sources in order to have comparable light intensities at the detector fiber from each LED. This procedure of light-source equilibration allowed us to use the entire dynamic range of the analog-to-digital converter.

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	Feature 4. The light sources are sinusoidally modulated at a frequency of 120 MHz. This frequency provides the best compromise among the three requirements of high modulation of the source, high sensitivity of our detector (photomultiplier tube, Hamamatsu R928), and high sensitivity of  **Fig. 2** Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium. *See, e.g.*, Fantini at 35:

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	 **Fig. 3** Schematic diagram of the measuring head circuit. The inputs are the radio-frequency oscillating signal (from a frequency synthesizer), a clock signal, and a reset pulse (both from the computer). The counter (RCA CD4024) counts the waves of the clock signal and continuously transmits the number (mod 8) to the demultiplexer (74HCT238). The enabled line of the demultiplexer, which closes the corresponding relay (Magnecraft W171 DIP-2), is then changed at the frequency of the clock. The reset pulse is sent at the beginning of the measurement to start the sequence always with the same LED. *See, e.g.*, Fantini at 40: There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas: • The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.
19[d] determining a physiological parameter of the living patient	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious determining a physiological parameter of the living patient responsive to the outputted at least one signal.

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responsive to the outputted at least one signal.	For example, Raley discloses and/or suggests a processor such as a data processing circuit that is configured to receive and process one or more signals outputted from a detector that are corresponding to the intensity of light received and determine a physiological parameter of a user responsive such as a blood analyte to the one or more signals: *See, e.g.*, Raley at Fig. 5:

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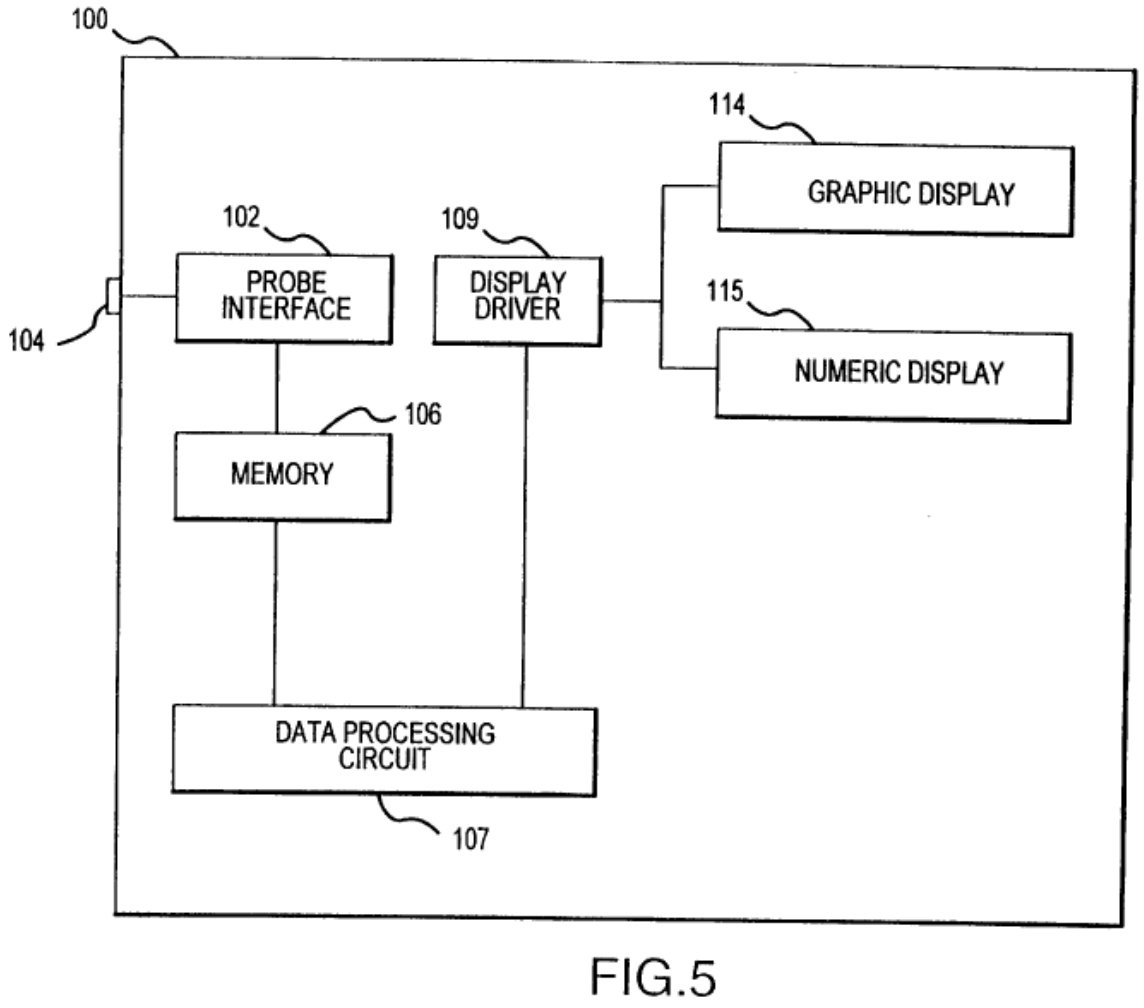


FIG.5

Fig. 6.

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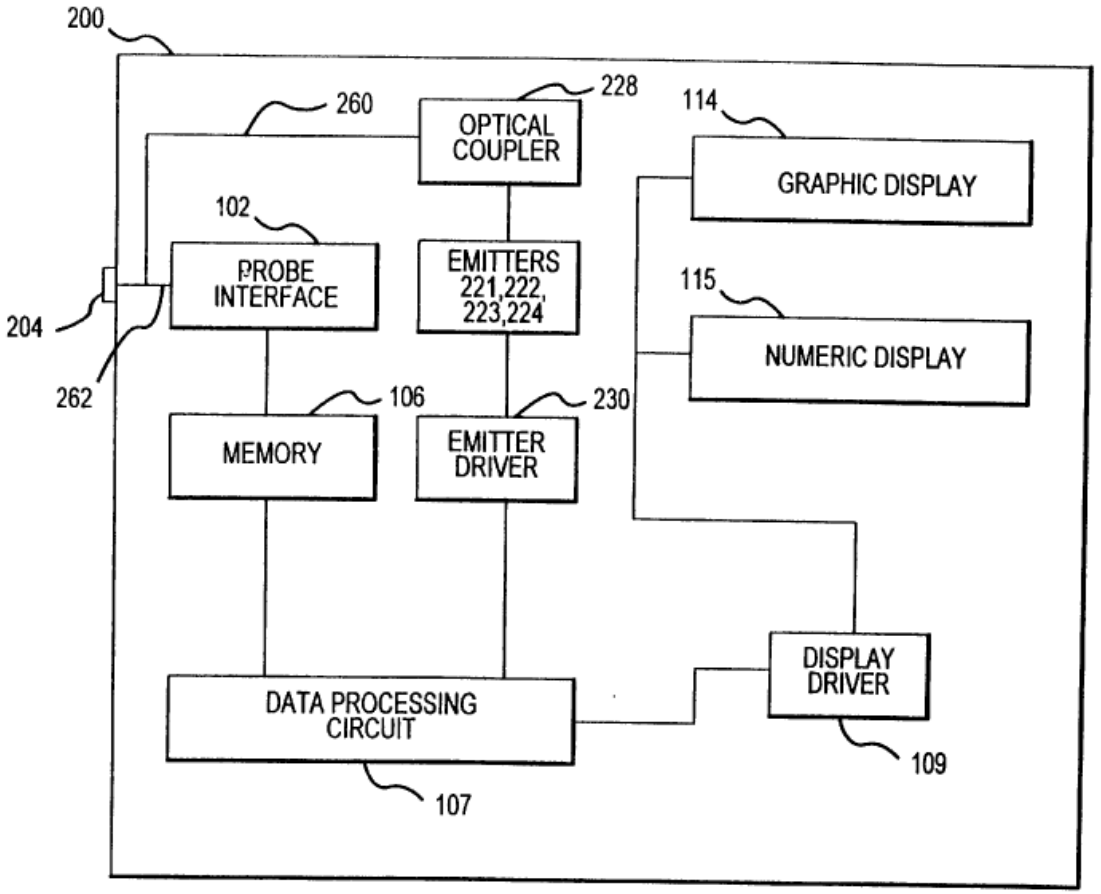


FIG.6

Raley, 4:29-5:15 ("The intensity of light transmitted through the tissue under test is measured by one or more photodetectors 13 which are located in the disposable probe-end 10. Photodetector 13 provides a signal corresponding to the intensity of light received denoted I.sub.λ1, I.sub.λ2, I.sub.λ3 and I.sub.λ4. This signal is then electrically routed back to the monitor 100 through cable 28, plug 42 and socket 104 to the probe interface 102. In the monitor the analog received intensity signals, I.sub.λ1,

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	I.sub.λ2, I.sub.λ3 and I.sub.λ4 are converted into digital signals through a well-known analog to digital (A/D) converter. The intensity signals are then stored in memory 106 and manipulated in data processing circuit 107 of the monitor 100 according to data processing instructions stored in memory 106 and executed by the data processing circuit 107 in order to determine an estimate of the blood analyte levels output as a percentage concentration. Blood analyte levels (output as percentages) may then be displayed via display driver 109 and graphic display 114 and/or numeric display 115. An alternative method of implementing a photoplethysmographic monitor is depicted in FIG. 6 and operates in conjunction with the alternative probe embodiment in FIG. 3b. The emitters 21, 22, 23 and 24 (which may be LED's or laser diodes, but which are preferably laser diodes) are housed in the monitor 200. The emitters 21, 22, 23 and 24 are driven by emitter driver 230 which is controlled by the data processing circuit 107. The emitted light is then combined by an optical coupler 228 and transmitted to the probe 40 by internal optical fiber 260 which is coupled to an optical fiber or other such optically transmissive material (not shown) internal to interconnect cable segment 28. Thus, plug 42 and connector 204 now includes electrical conductors for connecting photodiode 13 back to the probe interface 102 and an optical connector for connecting optical fiber 260 to an optical fiber (not shown) located in cable 28. The light transmitted through the optical fiber 260 and transmitted through the optical fiber located in cable 28, reflects off mirror 29 of FIG. 3b in connector end 25 and passes through window or opening 26 and window 16 in probe-end 10 and impinges on the tissue of the patient. Transmitted light is received by photodetector 13 which send an electrical signal back to the probe interface 102 through the electrical conductors in cable 28 and electrical pathway 262 in monitor 200. The probe interface 102 converts the analog signal to a digital signal and transmits the signal to memory 106 and on to data processing circuit 107 for processing and display of blood analyte concentration values using graphic display 114 and numeric display 115 driven by display driver 109. The transmission of the emitted light can be controlled in a time division multiplexing manner and an optical coupler 228 can be used to provide a means for combining multiple emitters onto one strand of optical fiber 260. Alternatively, the plurality of emitters may be placed or abutted against optical fiber 260."). Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious determining a physiological parameter of the living patient responsive to the outputted at least one signal.

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	For example, Fantini discloses and/or suggests where the detector then uses signals at least one signal to measure blood parameters such as hemogobin concentrations: *See, e.g.*, Fantini at Abstract: **Abstract.** We have designed a multisource frequency-domain spectrometer for the optical study of biological tissues. Eight multiplexed, intensity-modulated LEDs are employed as the light sources. Four of them emit light at a peak wavelength of 715 nm (λ_1); the other four, 850 nm (λ_2). The frequency of intensity modulation is 120 MHz. This instrument measures the frequency-domain parameters phase, dc intensity, and ac amplitude at the two wavelengths λ_1 and λ_2 and for different distances between light source and detector. From these frequency-domain raw data, the absolute values of the absorption and reduced scattering coefficients of tissue at λ_1 and λ_2 are obtained. The oxy- and deoxyhemoglobin concentrations, and hence the hemoglobin saturation, are then analytically derived from the molar extinction coefficients. Acquisition times as short as hundreds of milliseconds provide real-time monitoring of the measured parameters. We performed a systematic test *in vitro* to quantify the precision and accuracy of the instrument reading. We also report *in vivo* measurements. This spectrometer can be packaged as a compact portable unit. *See, e.g.*, Fantini at 33:

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In the present paper, we describe an LED-based frequency-domain spectrometer for the direct determination of the oxy- and deoxyhemoglobin content in tissues. Once the concentrations of these two chemical species are separately known, the amount of hemoglobin saturation and tissue hemoglobin content can be determined. The principle presented here is not limited to the measurement of these two substances, but can be extended to the measurement of other chromophores by properly choosing the wavelengths of the light sources. We also conducted an experimental test to study precision and accuracy of the instrument.

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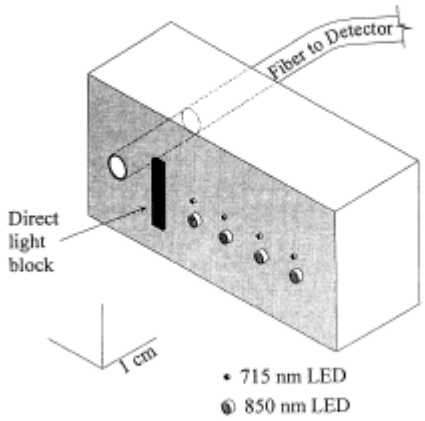


Fig. 2 Design of the measuring head of the tissue spectrometer. In a measurement, the shaded surface, on which the eight LEDs and the tip of the detector optical fiber are located, is placed in contact with the sampled medium. The light shield between sources and detector is used to block the light reflected at the surface of the medium.

See, e.g., Fantini at 40:

There are several characteristics of our instrument that can be changed without affecting the underlying principle ideas:

- The number of light sources can be augmented or decreased according to the application. For hemoglobin saturation measurement, eight sources are adequate. However, the same multiplexing principle can be applied to a much larger number of sources for the simultaneous determination of the concentration of more chromophores, for adding another wavelength, or for imaging applications.

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Claim 20	Prior Art
20. The method of claim 19, wherein an area of the opening is smaller than a detection surface area of the at least one detector.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the method of claim 19. *See, e.g.*, Claim 19. Under at least the apparent construction based on Masimo's Infringement Contentions, Kimura discloses and/or renders obvious wherein an area of the opening is smaller than a detection surface area of the at least one detector. For example, Kimura discloses and/or suggests a vital signs detecting apparatus that is capable measuring vital signals such as pulse by relying on a least three LEDs in a cavity and at least one detector in a different enclosure, where for an area of an only opening to the detector is smaller than a detection surface area of the at least one detector, implemented in a non-limiting example as a vital sign detecting apparatus for which there is a window above a light receiving device comprising a detector 404, where the window 412 is circular and has a surface area that is smaller than the surface area of the detector: *See, e.g.*, Disclosure for Kimura for Limitation 1[c-2]. Under at least the apparent construction based on Masimo's Infringement Contentions, Diab discloses and/or renders obvious wherein an area of the opening is smaller than a detection surface area of the at least one detector. For example, Diab discloses and/or suggests an optical prove that is particularly suited to reduce noise in measurements that relies on LEDs and a detector measure physiological parameters, where there is an opening to a detector 126 in a light blocking chamber 126 comprising the portion of a lens 132 through which light can pass to the detector, where light received by the detector must pass through the lens, and where the opening comprises an area smaller than a detection surface area of the detector because the opening is of a diameter that is less than the diameter of the detector by at least the thickness of an optical adhesive or lens retaining ring:

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	See, e.g., Disclosure for Diab for Limitation 1[c-2]. Under at least the apparent construction based on Masimo's Infringement Contentions, Mannheimer 842 discloses and/or renders obvious wherein an area of the opening is smaller than a detection surface area of the at least one detector. For example, Mannheimer 842 discloses and/or suggests a pulse oximetry probe where there is a detector 120 with a opaque surface cover with a hole to the detector that is smaller in width than the detector 120, thereby where the opening comprises an area smaller than a detection surface area of the detector: *See, e.g.*, Disclosure for Mannheimer 842 for Limitation 1[c-2]. Under at least the apparent construction based on Masimo's Infringement Contentions, Shaw discloses and/or renders obvious wherein an area of the opening is smaller than a detection surface area of the at least one detector. For example, Shaw discloses and/or suggests an oximeter relying on at least three electroluminescent diodes (9, 11, 13) emitting light at at least three different wavelengths (600, 715, 805 nm), where the emitted light is received by a photoresponsive detector (Fig. 3a, 47, 49, 51) and the detected signals are processed to measure the blood oxygen saturation of a patient, where the photoresponsive detector is positioned in an enclosure, and the opening to the enclosure (aperture 95) has an area smaller than a detection surface area of the detector (47, 49, 51): *See, e.g.*, Disclosure for Shaw for Limitation 1[c-2]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein an area of the opening is smaller than a detection surface area of the at least one detector. For example, Fantini discloses and/or suggests the opening comprising an area smaller than a detection surface area of the at least one detector, implemented as the opening to the Fiber being 3 mm in diameter, and the surface area of the Hamamatsu R928 detector being 13 mm x 24 mm:

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	See, e.g., Disclosure for Fantini for limitation 1[c-2].
Claim 21	**Prior Art**
21. The method of claim 19, wherein the light block is formed of black materials and further comprises a base, side walls, and a top forming an enclosure, and wherein the at least one detector is positioned in the enclosure.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the method of claim 19. *See, e.g.*, Claim 19. Under at least the apparent construction based on Masimo's Infringement Contentions, Webster discloses and/or renders obvious wherein the light block is formed of black materials and further comprises a base, side walls, and a top forming an enclosure, and wherein the at least one detector is positioned in the enclosure. For example, Webster discloses and/or suggests a pulse oximeter for which there is a detector enclosed in a light block and for which a light absorbing coating is relied upon to reduce optical interference: *See, e.g.*, Disclosure for Webster for Limitation 1[c-1]. For example, Hannula discloses and/or suggests a non-adhesive oximeter sensor that relies on LEDs in one cavity (for example, element 111) to emit light that is received by a detector in a separate enclosure (for example, element 116), where the detector such as a photodetector generates at least one signal that is decoded by an oximeter monitors to calculate a patient's blood oxygen saturation, where there is a light block surrounding the at least one photodetector, implemented in non-limiting examples as one or more of the reflective mask 117, layer 112, inner side 125 of layer 112, faraday shield 115, and/or polyurethane window 1118, where the light block encloses the at least one photodetector into structure formed by a base (for example, 114A or 117 or 115), four side walls (the four side walls of 117 or 115) and a top (the patient-facing top of the detector 116, the patient-facing top of the faraday shield 115, or 118), and wherein the light block structure is at least partially formed of black materials, such as an black opaque film that comprises the inner side 125 of layer 112 and blocks ambient light that may interfere with photodetector 116: *See, e.g.*, Disclosure for Hannula for limitation 10[d-1].

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Claim 22	**Prior Art**
22. The method of claim 19, wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the method of claim 19. *See, e.g.*, Claim 19. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood, and where the at least eight LEDs comprise at least two LEDs of the same wavelength, and where LEDs of the same wavelength can be activated concurrently in order to combine the strength of the signal at that wavelength so as to allow for those signals to be combined to increase the resulting signal-to-noise ratio of the measurement: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision,

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	accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths, and where at least two LEDs are configured for concurrent activation, including where half of the total number of single wavelength emitting devices are energized concurrently for a measurement observation: *See, e.g.*, Disclosure for Robinson for Claims 2 and 5. Under at least the apparent construction based on Masimo's Infringement Contentions, Mannheimer 842 discloses and/or renders obvious wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs. For example, Mannheimer 842 discloses and/or suggests [relying on multiple LEDs of the same wavelength that are activated concurrently to intensify the signal at a desired wavelength and/or in order to increase the ratio of light transmitted at a desired wavelength to other wavelengths transmitted, and/or to overcome interference at the concurrently activated wavelength, such as interference caused by light attenuation by tissue: *See, e.g.*, Disclosure for Mannheimer 842 for Claim 5. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs: For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs that are fired concurrently for each wavelength enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing:

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	See, e.g., Disclosure for Nogawa for Limitation 1[a].
Claim 23	**Prior Art**
23. The method of claim 19, wherein the at least three LEDs comprises at least eight LEDs.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the method of claim 19. *See, e.g.*, Claim 19. Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Moyle discloses and/or suggests where more wavelengths of light, and correspondingly more LEDs, may be used to measure more physiological parameters: *See, e.g.*, Disclosure for Moyle for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood: *See, e.g.*, Disclosure for Allen for Claim 2.

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where LEDs are used each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound: *See, e.g.*, Disclosure for Raley for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths: *See, e.g.*, Disclosure for Robinson for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs: For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement

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	artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nogawa for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments as four, five, and six separate emitters relying on different wavelengths, where relying on any number of additional wavelengths (and thereby LEDs) beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy: *See, e.g.*, Disclosure for Jarman for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least three LEDs comprises at least eight LEDs. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].

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Claim 24	**Prior Art**
24. The method of claim 23, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the method of claim 23. *See, e.g.*, Claim 23. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood, and where the at least eight LEDs comprise at least two LEDs of the same wavelength, including where the LEDs can include some LEDs that have the same wavelength and some sources that are different: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision,

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	accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths: *See, e.g.*, Disclosure for Robinson for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nagawa for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least eight LEDs comprises at least two LEDs of the same wavelength. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].

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Claim 25	Prior Art
25. The method of claim 19, wherein the at least three LEDs comprises at least twelve LEDs.	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the method of claim 19. *See, e.g.*, Claim 19. Under at least the apparent construction based on Masimo's Infringement Contentions, Moyle discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Moyle discloses and/or suggests where more wavelengths of light, and correspondingly more LEDs, may be used to measure more physiological parameters: *See, e.g.*, Disclosure for Moyle for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Allen discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Allen discloses and/or suggests an electro-optical sensor implemented in a system that relies on light emitted from at least eight LEDs, such as 18 LEDs, and where the emitted light is detected by a detector, and where at least one signal from the detector is relied on to measure physiological parameters such as hemoglobin, blood oxygenation, and toxins in blood: *See, e.g.*, Disclosure for Allen for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Raley discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Raley discloses and/or suggests a pulse oximeter instrument that relies on at least three LEDs that are recessed into a cavity (for example, cavity 26 in Fig. 3), where LEDs are used each emitting light having a distinct spectral content or wavelength and where relying on additional wavelengths allows the pulse

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	oximeter instrument to measure additional analytes of arterial blood, with one additional wavelength for each compound: *See, e.g.*, Disclosure for Raley for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Robinson discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Robinson discloses and/or suggests a method and apparatus for determining noninvasively blood analytes such as glucose that relies on light emitted from at least three LEDs that is received by a detector, where signals from the detector are relied upon to measure the blood analyte, and where the device may rely on 12 LEDs, where relying on multiple LEDs and multiple wavelengths may be preferred because measuring blood analytes requires analysis across multiple intensities and wavelength to achieve the sensitivity, precision, accuracy, and reliability necessary for quantitative determination, and where, as an example, measuring glucose can be done through the use of 20 discrete groups of contiguous wavelengths: *See, e.g.*, Disclosure for Robinson for Claim 2. Under at least the apparent construction based on Masimo's Infringement Contentions, Nogawa discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs: For example, Nogawa discloses and/or suggests an optical sensor using additional LEDs at each emission wavelength, such as 10 LEDs at each wavelength placed symmetrically around a detector, for a total of 20 LEDs, where relying on these additional LEDs enhances the sensor by enhancing the signal level at each wavelength so as to average out the inhomogeneous effect of tissue and movement artifacts, thereby minimizing abrupt changes in the signal level cause by the inhomogeneous effect of tissue and movement artifacts, and where the LEDs are recessed into a cavity that is separated from the detector by an optical barrier, where the detector is also enclosed by the optical barrier and the base of the housing: *See, e.g.*, Disclosure for Nogawa for Limitation 1[a].

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	Under at least the apparent construction based on Masimo's Infringement Contentions, Jarman discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Jarman discloses and/or suggests a patient monitor relying on an optical sensor, implemented in various embodiments as four, five, and six separate emitters relying on different wavelengths, where relying on any number of additional wavelengths (and thereby LEDs) beyond two wavelengths allows for the measurement of additional blood analytes, such as carboxyhemoglobin, oxyhemoglobin and deoxyhemoglobin or methemoglobin, oxyhemoglobin and deoxyhemoglobin, and where a number of emitters greater than the number of blood analytes being measured may also be used in a photoplethysmographic system in order to create an overdetermined system, thereby improving accuracy: *See, e.g.*, Disclosure for Jarman for Limitation 1[a]. Under at least the apparent construction based on Masimo's Infringement Contentions, Fantini discloses and/or renders obvious wherein the at least three LEDs comprises at least twelve LEDs. For example, Fantini discloses and/or suggests a patient monitor relying on an optical sensor that uses more than two LEDs and more than two wavelengths, implemented in an embodiment as four LEDs operating at a wavelength of 715 nm and four LEDs operating at a wavelength of 850 nm, where, further, the number of light sources can be augmented to the application such as where a much larger number of sources can be used (more than eight LEDs), and another wavelength (totaling three or more wavelengths) can be used with the purpose of simultaneous determinations of the concentration of more chromophores (corresponding to, under the apparent construction based on Masimo's Infringement Contentions, physiological parameters or blood parameters), and where using several LEDs in different positions relative to the detecotr allows for using several source-detector separations thatallows for the accuracy of a measurement to be increased: *See, e.g.*, Disclosure for Fantini for Limitation 1[a].
Claim 28	**Prior Art**
28. The method of claim 19, wherein the at least a portion of the light passes	Under at least the apparent construction based on Masimo's Infringement Contentions, and to the extent that the preamble is limiting, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious the method of claim 19.

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through the opening after it interacts with the body tissue.	*See, e.g.*, Claim 19. Under at least the apparent construction based on Masimo's Infringement Contentions, the primary references identified in Apple's Initial Invalidity Contentions, alone or in combination with each other or the secondary references identified herein, disclose and/or renders obvious wherein the at least a portion of the light passes through the opening after it interacts with the body tissue. *See, e.g.*, Exhibits E-1 — E-10.

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