24. The optical probe of Claim 23, wherein at least a portion of said first and second support surfaces comprises an absorptive material or has an absorbtive coating capable of absorbing at least a portion of the light energy incident thereon.

25. The optical probe of Claim 23, wherein said shield is formed within said first support surface.

26. The optical probe of Claim 23, further comprising a chamber having an entrance in the form of said second aperture, wherein at least a portion of said tissue material covers said second aperture and is supported by said second support surface around said aperture, said chamber isolating at least a portion of said tissue material during optical analysis thereof.

27. The optical probe of Claim 14, further comprising an optical scattering medium disposed within at least one of said first and second apertures.

28. The optical probe of Claim 14, wherein said at least a portion of said light energy directed onto said tissue and received by said light energy detector is transmitted through at least a portion of said tissue material.

29. The optical probe of Claim 14, wherein said at least a portion of said light energy directed onto said tissue and received by said light energy detector is reflected from at least a portion of the surface of said tissue material.

30. A method of measuring a physical property using an optical probe, comprising:

forming a housing element capable of receiving tissue material, said housing element having a first aperture and second aperture formed therein, said first and second apertures being located proximate to said tissue material;

generating light energy using a light energy source;

transmitting said light energy through said first aperture onto said tissue material;

detecting, via said second aperture, at least a portion of said light energy generated by said source and transmitted onto said tissue material, using a detector;

shielding said detector at least partly from light energy not generated by said light energy source and not transmitted through said first aperture; and

generating a signal based on said light energy detected by said detector.

31. The method of Claim 30, further comprising the act of isolating at least a portion of said tissue material using a chamber formed within said housing element in order to increase the accuracy of said signal.

32. The method of Claim 31, further comprising the act of scattering at least a portion of said light energy generated by said optical source and an optical scattering medium disposed within at least one of said first and second apertures.

33. The method of Claim 30, wherein the act of shielding said detector comprises the act of absorbing at least a portion of said light energy not generated by said light energy source and not transmitted through said first aperture.

34. The method of Claim 30, further comprising the act of shielding said detector from electromagnetic interference using a Faraday shield.

35. The method of Claim 30, wherein the act of detecting at least a portion of said light energy generated by said source and transmitted onto said tissue material comprises the act of detecting light energy transmitted through said tissue material.

36. The method of Claim 30, wherein the act of detecting at least a portion of said light energy generated by said source and transmitted onto said tissue material comprises the act of detecting light energy reflected from the surface of said tissue material.

37. The method of Claim 35, further comprising the act of isolating at least a portion of said tissue material using a chamber formed within said housing element in order to increase the accuracy of said signal.

38. The method of Claim 37, further comprising the act of scattering at least a portion of said light energy generated by said optical source and an optical scattering medium disposed within at least one of said first and second apertures.

39. The method of Claim 38, wherein the act of shielding said detector comprises the act of absorbing at least a portion of said light energy not generated by said light energy source and not transmitted through said first aperture.

40. The method of Claim 39, further comprising the act of shielding said detector from electromagnetic interference using a Faraday shield.

41. The method of Claim 30, further comprising the act of counting the number of pulses detected by said detector, and comparing said number to a predetermined value.

42. An optical probe comprising:

a housing capable of receiving at least a portion of the tissue material of a patient, said housing having first and second apertures formed therein, said first and second apertures being proximate to said tissue material when said tissue material is received by said housing, at least a portion of said housing comprising an absorptive material capable of absorbing at least a portion of the light energy incident thereon;

a light energy source disposed within said housing, said light energy source being positioned such that at least a portion of the light energy emitted thereby is transmitted through said first aperture onto said tissue material;

a light energy detector disposed within said housing, said light energy detector being positioned so as to receive, via said second aperture, at least a portion of said light energy transmitted onto said tissue; and

a light shield located proximate to said tissue material;

wherein said light shield and said absorptive material of said housing cooperate to attenuate at least a portion of any light energy both not generated by said light energy source and not transmitted through

said first aperture which is incident on said tissue material when said tissue material is received by said housing.

43. The optical probe of Claim 42, further comprising an optical scattering medium disposed at least partly with at least one of said first and second apertures.

44. The optical probe of Claim 42, further comprising an electromagnetic shield used to shield said detector from electromagnetic interference.

45. The optical probe of Claim 42, wherein said absorptive material is a substantially black coating deposited on at least a portion of said housing element.

46. Data indicative of the physical condition of a patient generated using the method comprising:

forming a housing element capable of receiving tissue material, said housing element having a first aperture and second aperture formed therein, said first and second apertures being located proximate to said tissue material;

generating light energy using a light energy source;

transmitting said light energy through said first aperture onto said tissue material;

detecting, via said second aperture, at least a portion of said light energy generated by said source and transmitted onto said tissue material, using a detector;

shielding said detector at least partly from light energy not generated by said light energy source and not transmitted through said first aperture;

generating a signal based on said light energy detected by said detector; and

analyzing said signal in order to produce said data.

47. The data of Claim 46, wherein the act of analyzing said signal comprises the act of processing at least a portion of said signal using a digital signal processor.

48. The data of Claim 47, wherein the act of processing said signal comprises performing a series of mathematical operations on said signal using said digital signal processor.

49. The data of Claim 48, further comprising the act of shielding said detector against electromagnetic interference using a Faraday shield.

50. A method of monitoring the age of an optical probe during use, comprising:

generating a plurality of optical pulses;

directing said plurality of optical pulses onto the tissue of a patient;

detecting at least a portion of said plurality of optical pulses directed onto said tissue using a detector;

generating a first signal representative of said patient's condition based on said detected optical pulses;

counting the number of said portion of said plurality of optical pulses;

comparing said number to a predetermined value;

generating a second signal indicative of the age of said probe when said number bears a given relationship to said predetermined value.

51. The method of Claim 50, wherein the act of directing comprises the act of transmitting said optical pulses through at least a portion of said tissue.

52. The method of Claim 50, wherein the act of generating a second signal comprises the act of illuminating a light-emitting diode when said number exceeds said predetermined value.

53. A method of monitoring the condition of an optical probe during use by an operator, comprising:

generating a plurality of optical pulses using a light energy source;

detecting said plurality of optical pulses using a detector;

measuring a parameter related to said optical pulses;

comparing said measured parameter to a predetermined value;

generating a signal indicative of said condition the when said parameter bears a given relationship to said predetermined value, said signal being perceivable by said operator.

54. The method of Claim 53, wherein the act of measuring a parameter related to said optical pulses comprises counting the number of optical pulses detected by said detector.

55. The method of Claim 53, wherein the act of measuring a parameter related to said optical pulses comprises counting the number of optical pulses generated by said light energy source.

56. The method of Claim 53, wherein the act of measuring a parameter related to said optical pulses comprises measuring the duration said light energy source is emitting light energy.

57. A system for monitoring the condition of an optical probe, comprising:

at least one light source capable of generating a plurality of optical pulses;

at least one photodetector capable of detecting at least a portion of said plurality of optical pulses directed onto the tissue of a patient;

a monitor circuit capable of monitoring at least one parameter relating to said optical pulses, comparing said at least one parameter to a predetermined value, and generating a signal when said at least one parameter and said predetermined value are in a given relationship to each other; and

an indicator, operatively connected to said monitoring circuit, said indicator generating an indication of the condition of said optical probe based on said signal.

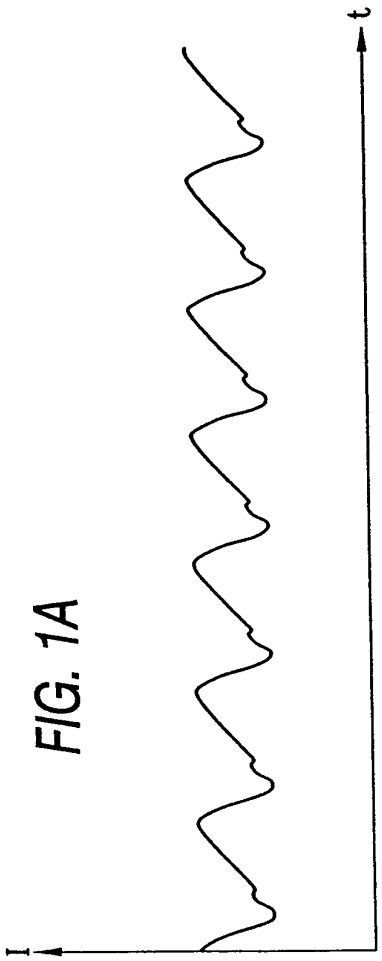


FIG. 1A

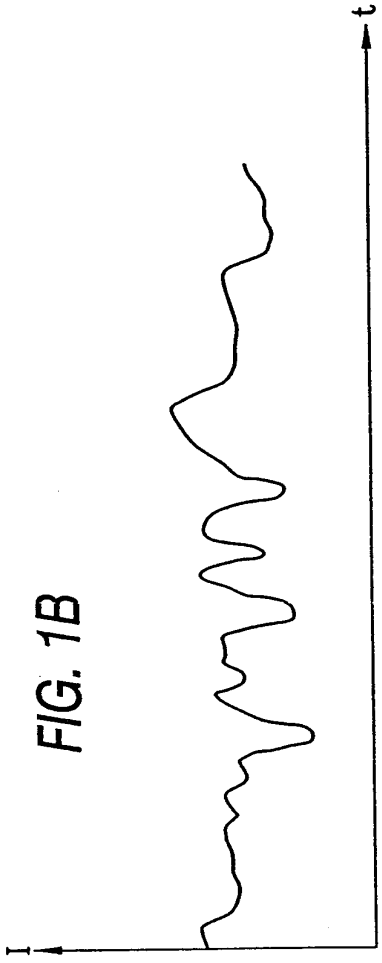


FIG. 1B

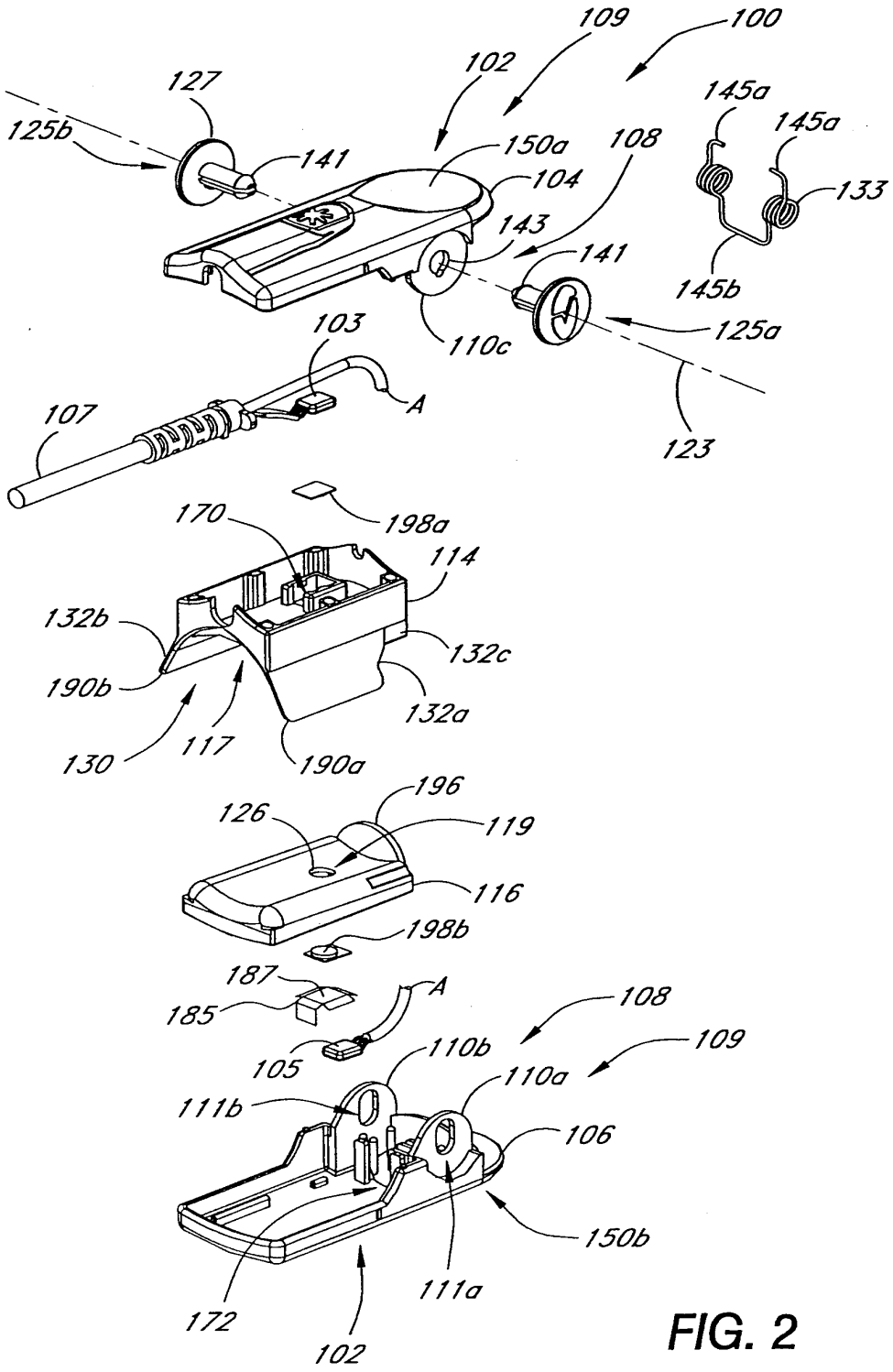

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FIG. 2

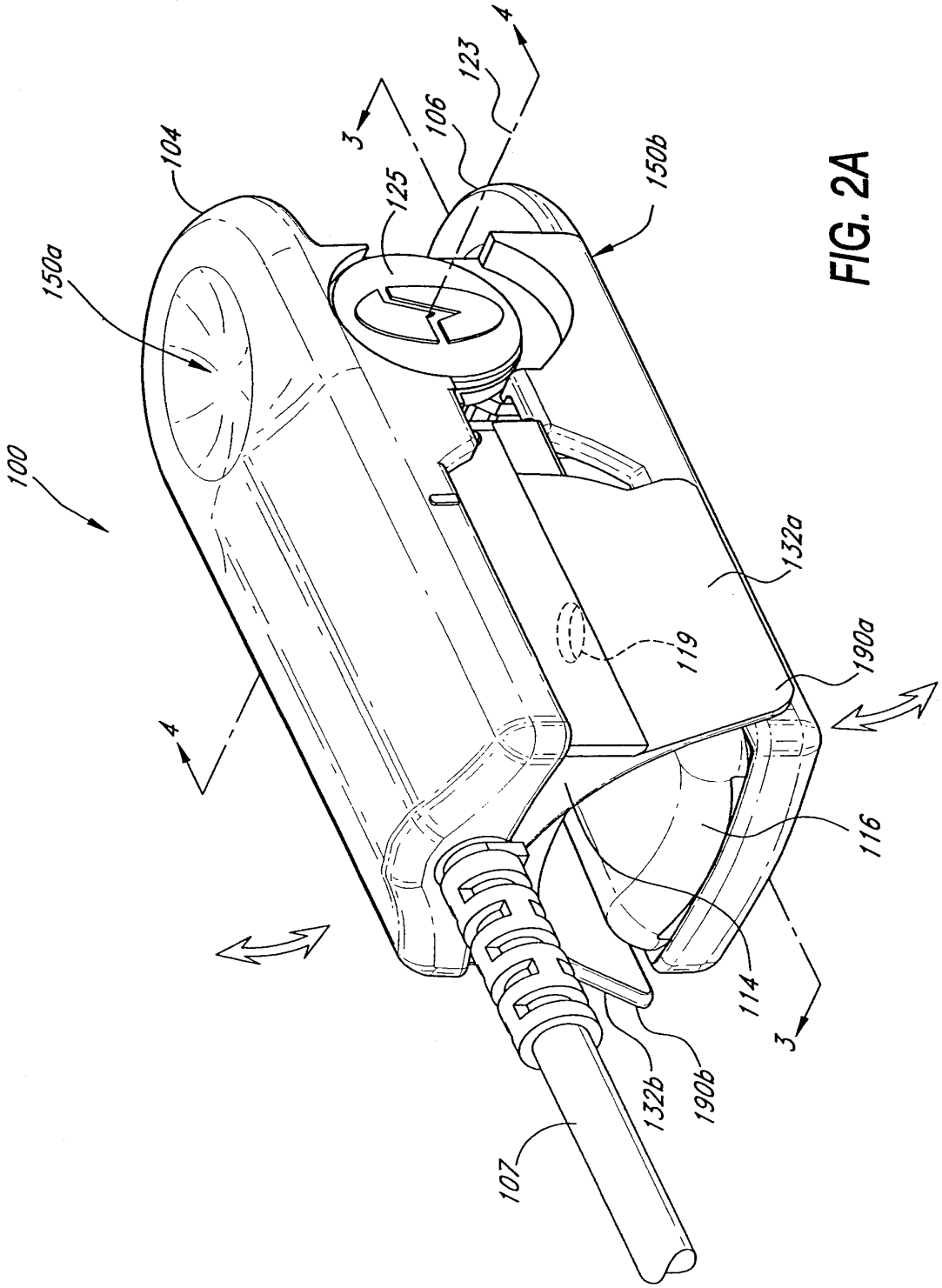

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FIG. 2A

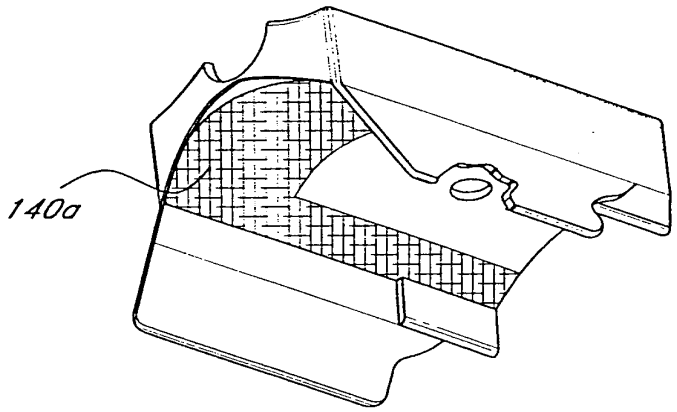


FIG. 2B

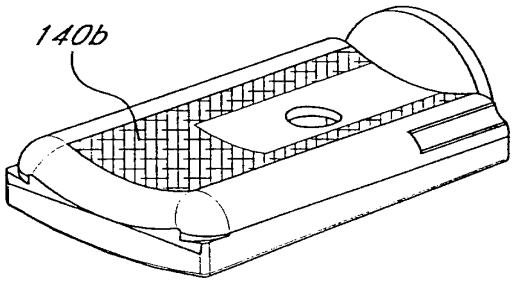


FIG. 2C

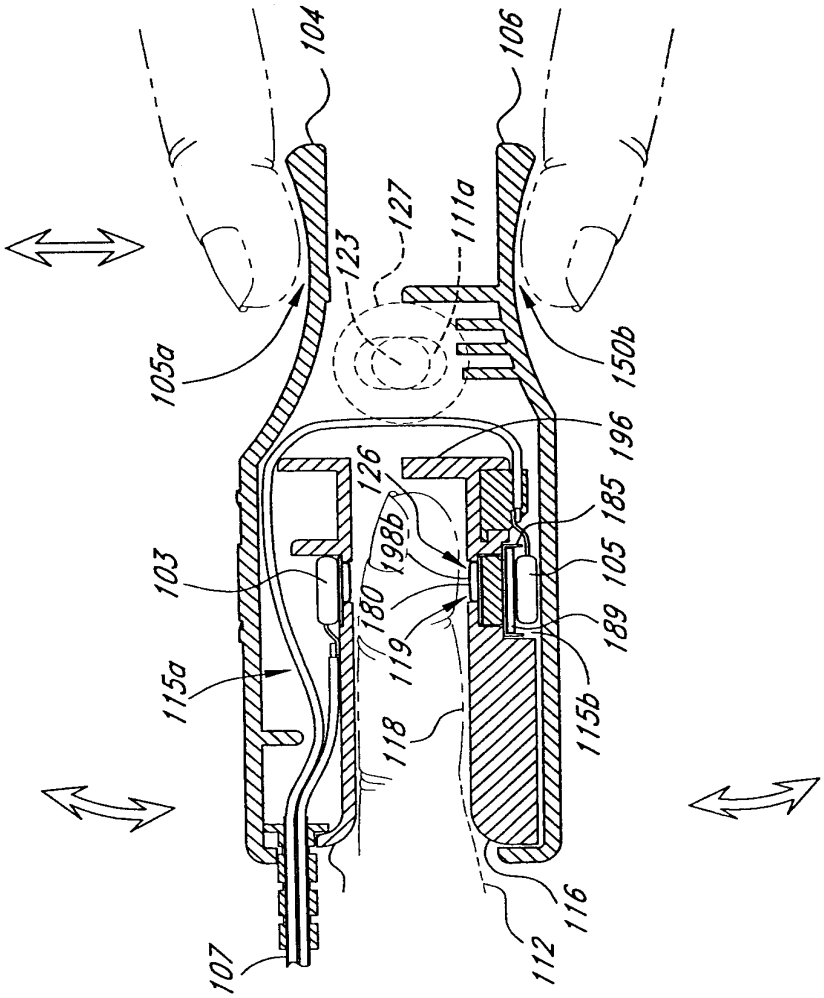

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FIG. 3

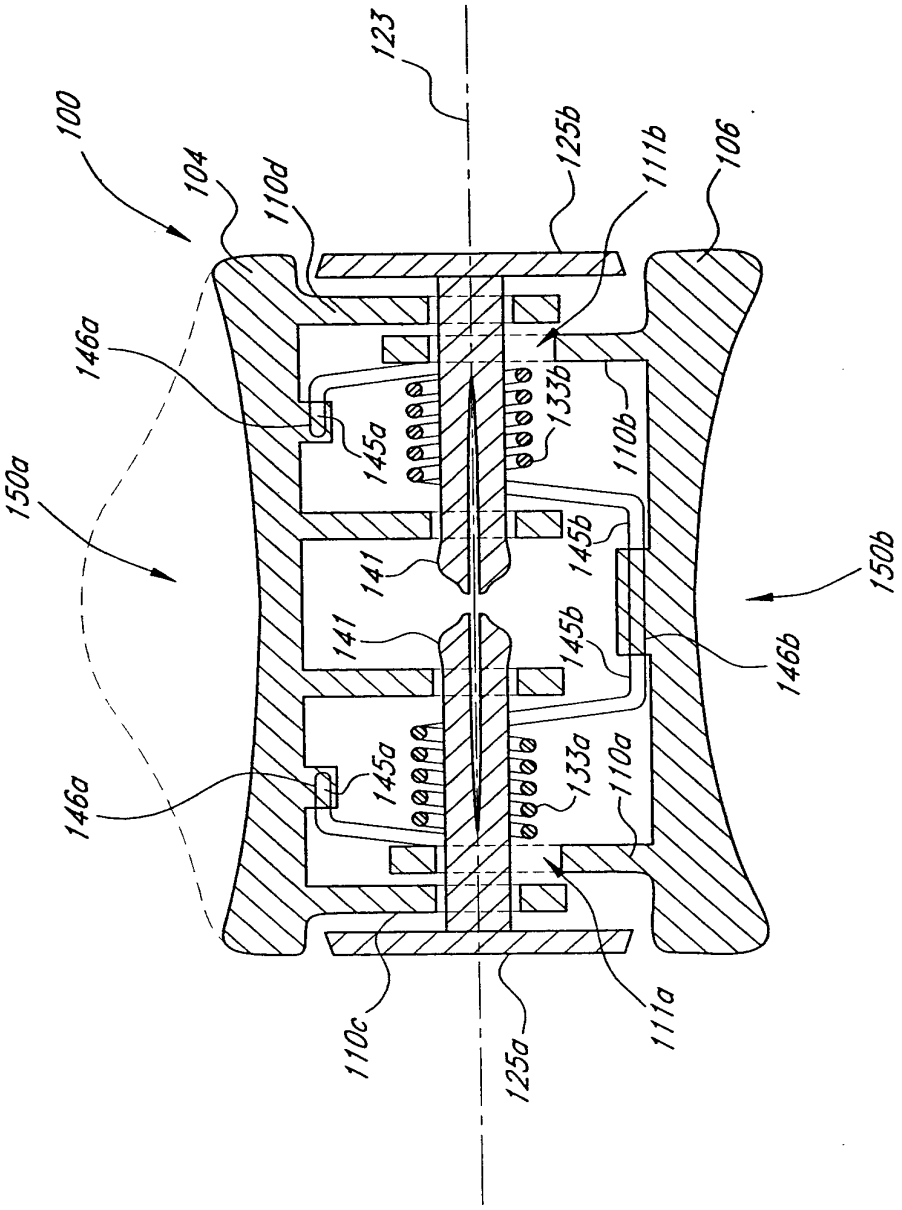

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FIG. 4

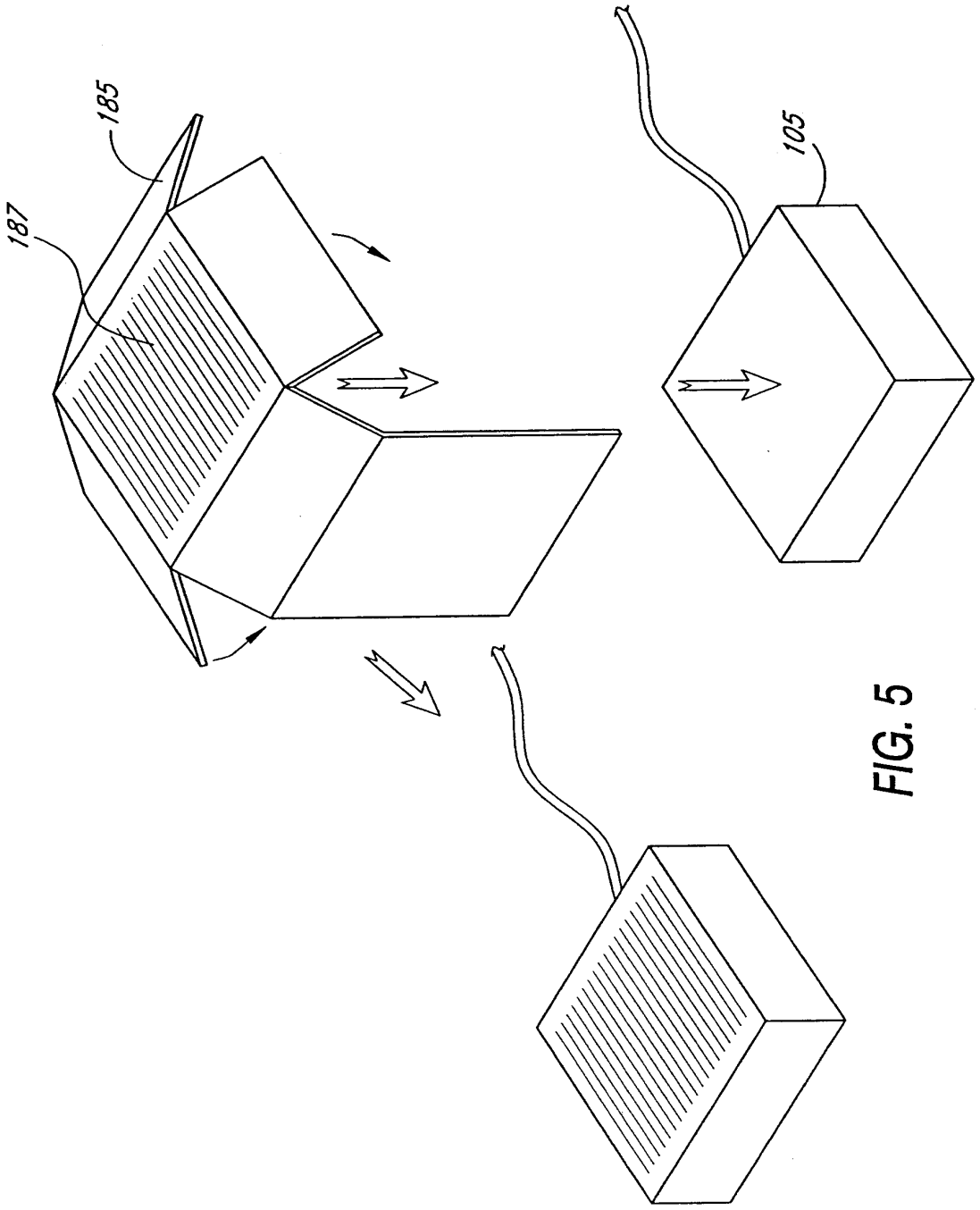


FIG. 5

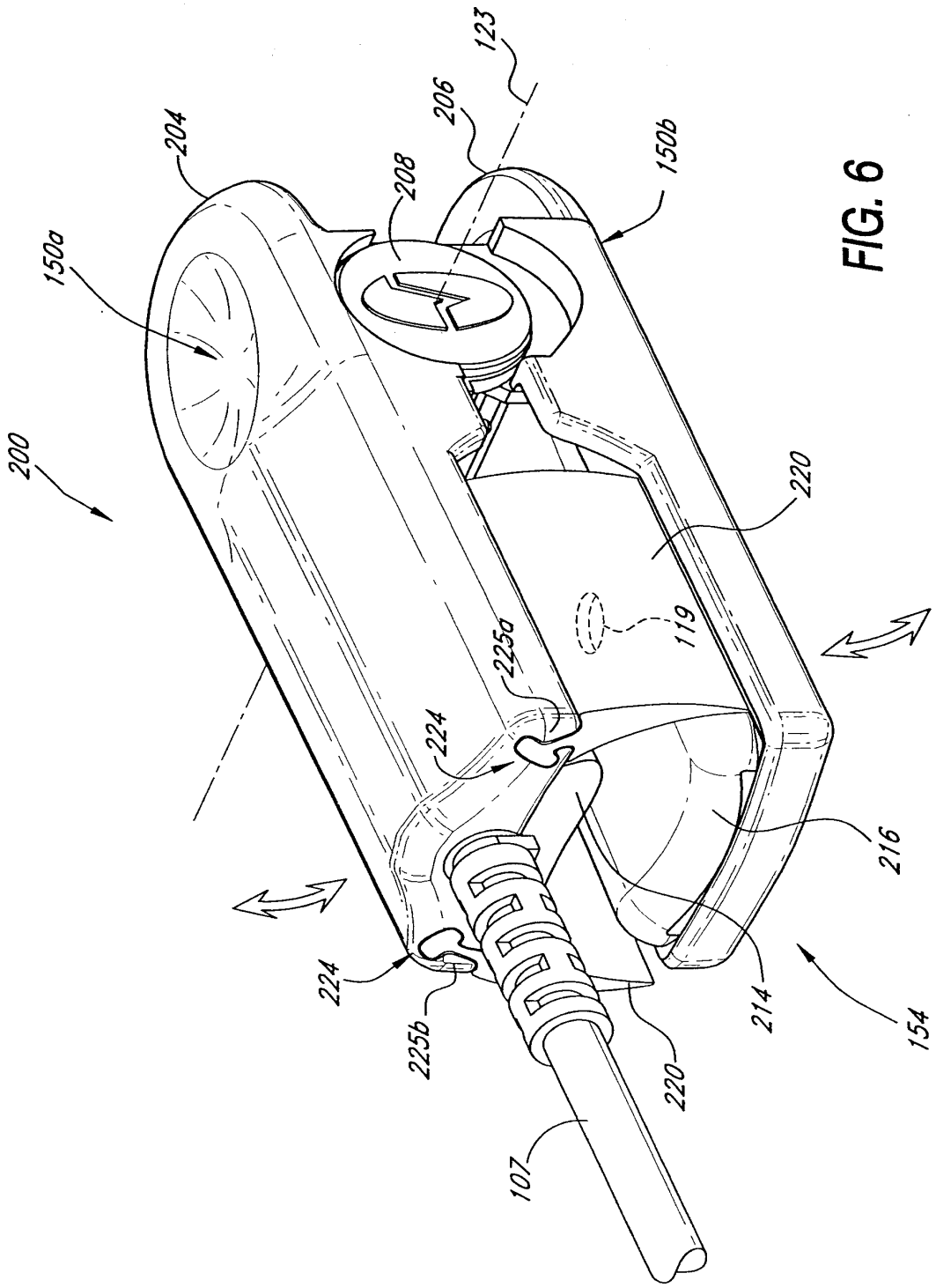

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FIG. 6

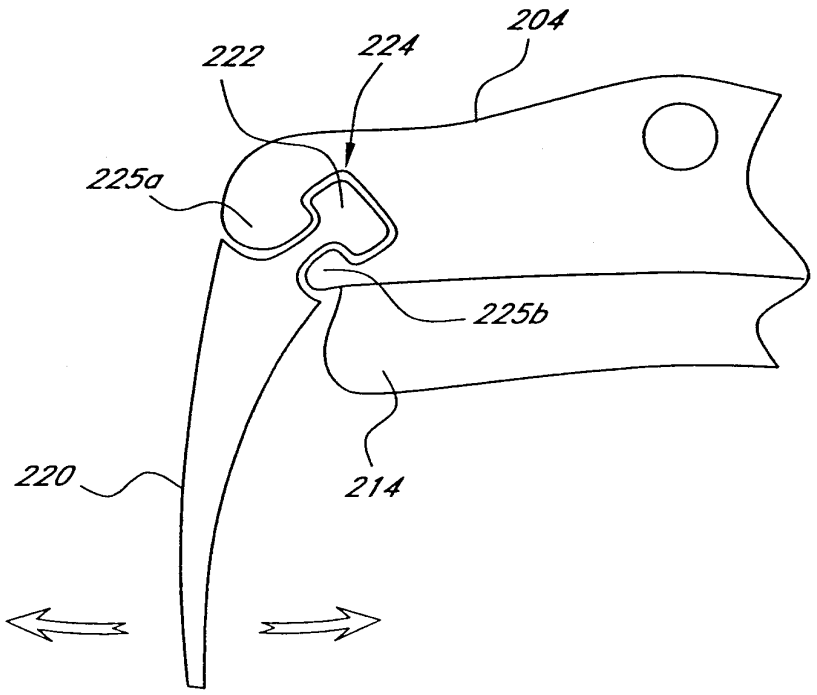


FIG. 6A

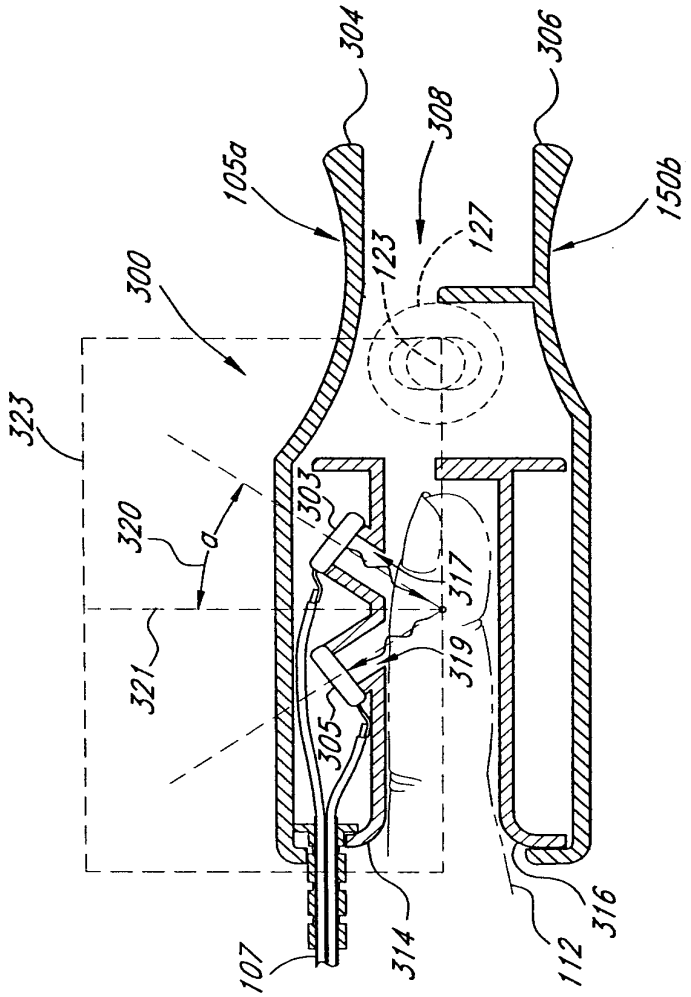
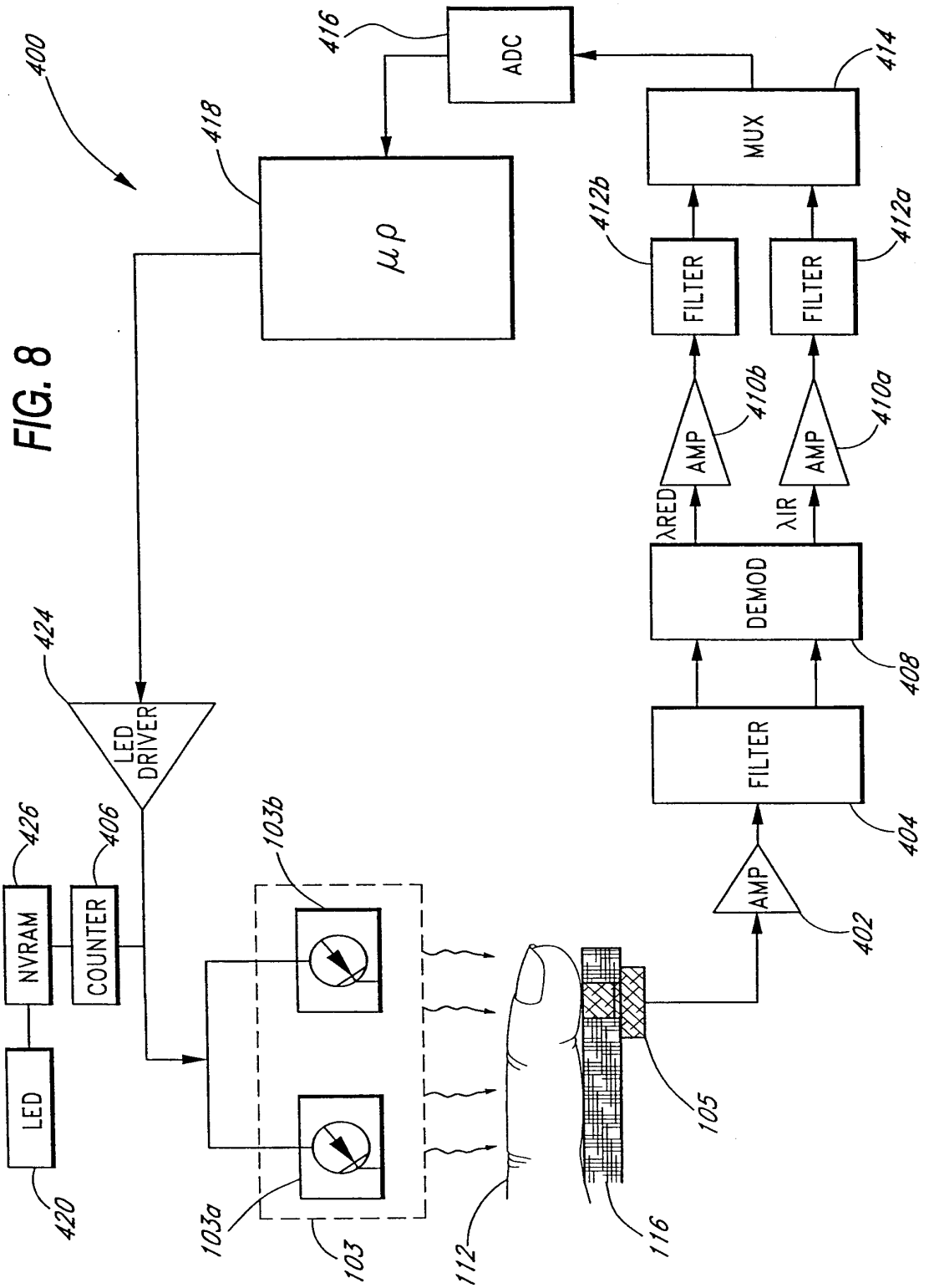

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FIG. 7

FIG. 8


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FILTER
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AMP
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INTERNATIONAL SEARCH REPORT

Inter ɔnal Application No
PCT/US 00/22849

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/024 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 685 464 A (GOLDBERGER DANIEL S ET AL) 11 August 1987 (1987-08-11) column 4; figures 2-4 column 8-10 ---	1-49
X	PATENT ABSTRACTS OF JAPAN vol. 1999, no. 03, 31 March 1999 (1999-03-31) & JP 10 314149 A (CASIO COMPUT CO LTD), 2 December 1998 (1998-12-02) abstract ---	50-57
A	EP 0 745 348 A (OHMEDA INC) 4 December 1996 (1996-12-04) figure 3 --- -/--	1-57

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
13 December 2000	21/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Mason, W

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INTERNATIONAL SEARCH REPORT

Inter ɔnal Application No
PCT/US 00/22849

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 481 612 A (NELLCOR INC) 22 April 1992 (1992-04-22) figure 1 ---	1-57
A	EP 0 262 779 A (PHYSIO CONTROL CORP) 6 April 1988 (1988-04-06) figure 11 ---	1-57
A	WO 97 23159 A (CME TELEMETRIX INC ;PAWLUCZYK ROMUALD (CA); YANG WEI (CA); HOCKLEY) 3 July 1997 (1997-07-03) figure 7 ---	1-57
A	US 5 313 940 A (FUSE MASAYOSHI ET AL) 24 May 1994 (1994-05-24) figures 3-5 ---	1-57
A	US 5 247 931 A (NORWOOD MARK D) 28 September 1993 (1993-09-28) figures 1,5 ---	1-57
A	US 5 438 986 A (DISCH DANIEL ET AL) 8 August 1995 (1995-08-08) figures 2,5 -----	1-57

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INTERNATIONAL SEARCH REPORT

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(19) World Intellectual Property Organization
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(51) International Patent Classification[7]: A61B 5/00, 6/00

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(22) International Filing Date:
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(71) Applicant: INSTRUMENTATION METRICS, INC. [US/US]; 7470 West Chandler Boulevard, Chandler, AZ 85226 (US).

(72) Inventor: GRUBISIC, Dragan; 16219 S. 12th Pl, Phoenix, AZ 85048 (US).

(74) Agents: GLENN, Michael et al.; Glenn Patent Group, 3475 Edison Way, Suite L., Menlo Park, CA 94025 (US).

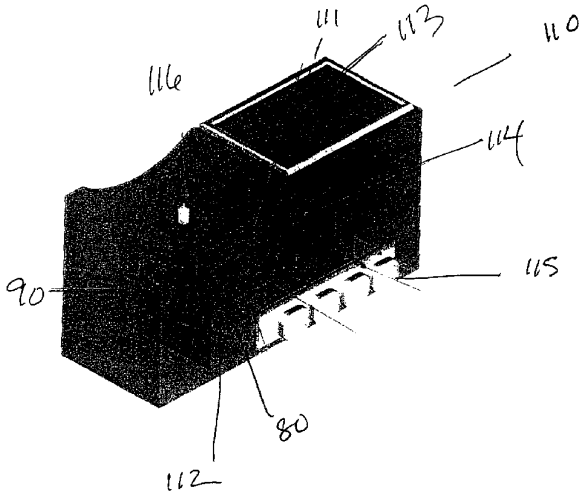
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(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *with amended claims*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LED LIGHT SOURCE-BASED INSTRUMENT FOR NON-INVASIVE BLOOD ANALYTE DETERMINATION



(57) Abstract: A compact, lightweight instrument (110) for non-invasive blood analyte determination employs a light source (60) incorporating an assembly of LEDs (10) interconnected within a thermally stable substrate (20). A large diameter mixer (61) couples the signal to a fiber optic probe for delivering the signal to a tissue measurement site. Back-diffused light is collected and dispersed across an array of photo detectors (90) in a miniature spectrometer (80) instrument. A high-speed DSP (112) executes an algorithm for predicting concentration of a target analyte, which is ouptput to a LCD display (113). Instrument control is by means of keypad or voice recognition.

WO 02/26123 A1

LED LIGHT SOURCE-BASED INSTRUMENT FOR NON-INVASIVE BLOOD ANALYTE DETERMINATION

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

The current invention relates to the field of non-invasive blood analyte measurement. More particularly, the current invention relates to a compact instrument for non-invasive blood analyte determination that employs light emitting diodes (LED's) supported on a thermally stable substrate as a source of light energy.

DESCRIPTION OF RELATED ART

Conventional methods of clinical testing have required the use of invasive procedures, such as biopsy and phlebotomy, to sample blood and tissue. Subsequently, the samples were transported to a central location, such as a laboratory, for examination and analysis. There is an increasing trend, however, toward point-of care testing, and even in-home testing. A benefit of this trend is to minimize the turnaround time from when a sample is taken to being able to take action based on test results. At the same time, sampling procedures are becoming less and less invasive. Since they minimize or eliminate the need to handle blood and tissue specimens, minimally invasive and non-invasive procedures drastically reduce biohazard risk, both to the subject and to the practitioner.

The goal of non-invasive blood analyte measurement is to determine the concentration of targeted blood analytes without penetrating the skin. Near infrared (NIR) diffuse reflectance spectroscopy is a promising technology for noninvasive blood analyte measurement and involves the illumination of a spot on the body with low energy near-infrared light (750 – 2500 nm). The light is partially absorbed and scattered, according to its interaction with chemical components within the tissue, prior to being reflected back to a detector. The detected light is used to create a graph of $-\log \mathbf{R}/\mathbf{R}_s$, where $\mathbf{R}$ is the reflectance spectrum of the skin and $\mathbf{R}_s$ is the reflectance of an instrument standard. In infrared spectroscopy, this graph is analogous to an absorbance spectrum containing quantitative information that is based on the known interaction of the incident light with components of the body.

Portable and handheld noninvasive blood glucose analyzers are being developed for point of care and in home use. The development of such devices has been hindered, in part, by the type of light source commonly used in spectrometer instruments. The conventional halogen tungsten lamp found in most spectrometer instruments is large and energy inefficient. It has a high power requirement, thus shortening battery life, generates excessive amounts of heat, requires a long time to stabilize and has a short life expectancy.

Furthermore, conventionally, light emitted from a light source is coupled into an optical probe, or otherwise directed toward a measurement site using space optics consisting of sets of mirrors and lenses. Such arrangements have high space requirements and they are highly vulnerable to mechanical shock.

The prior art provides a few examples of light source assemblies for non-invasive optical sampling. For example, F. Levinson, *Light mixing device with fiber optic output*, U.S. Patent No. 5,271,279 (December 14, 1993) describes a light-mixing device for a spectroscopic instrument in which a mixing rod couples light from a light source composed of LED's, die bonded into an electric header, with a plurality of optical fibers. The LED's have differing central wavelengths of emitted light and the mixing rod efficiently mixes the output of the several LED's into a single beam of light and then splits the beam in uniform fashion across the several optical fibers. The described device does not provide any means of collecting light energy emitted from a sample. It also doesn't provide any means of shaping light as it is emitted from the individual LED's. While the header of the LED assembly acts as a conduit for excess thermal energy produced by the LED's, it would be desirable to provide an active cooling element to provide an environment that maximizes energy efficiency of the LED's.

R. Rosenthal, *Light probe for a near infrared body chemistry measurement instrument*, U.S. Patent No. 6,134,458 (December 31, 1991) describes a light probe for a spectroscopic instrument that includes an illumination ring having external facets. LED s positioned about the facets emit light into the illumination ring; light is coupled to the measurement site by bringing the body part bearing the site into contact with the illumination ring. An optical detector is located coaxially with the illumination ring. While the Rosenthal device does provide a means of collecting light energy emitted from the site, it doesn t provide any means of mixing the light energy emitted from the several LED s. The light from the LED s is coupled directly with the probe, without the interposition of a mixer to thoroughly

blend the wavelength content of the light. The Rosenthal device also does not provide any means of shaping the light beams emitted from the LED s, nor does it provide a thermally stable substrate for the LED s. Furthermore, no active cooling system is provided to optimize operating temperature of the LED s.

Spectrometer instruments for measuring concentration of blood analystes such as glucose are known. Typically, such devices are not intended to be portable. For example, K. Kaffka, L. Gyarmati, I. V lyi-Nagy, I. G d lle, G. Domj n, J. J ko, *Method and apparatus for rapid non-invasive determination of blood composition parameters*, U.S. Patent No. 5,947,337 (October 26, 1999) describe an instrument for non-invasive glucose measurement. The described instrument irradiates the distal phalanx of a subject s finger with light in the near IR. The transmitted or reflected radiation is detected and analyzed and an estimate of blood glucose level made. There is no indication that the device described by Kaffka, *et al.* is portable or handheld. The signal is coupled with a fiber optic probe by means of a conventional arrangement of lenses and mirrors. The space requirements of such an arrangement are unsuited to a handheld device. Illumination fibers and collection fibers are provided in separate structures, also requiring excessive amounts of space.

M. Block, L. Sodickson, *Non-invasive, non-spectrophotometric infrared measurement of blood analyte concentrations,* U.S. Patent No. 5,424,545 (June 13, 1995) describe an instrument for noninvasive blood analyte determination that relies on colorimetric analysis to arrive at a blood analyte determination. The described device is not handheld or portable. As with the previous reference, a light beam is coupled with an illumination fiber by means of lenses and mirrors, with similar disadvantages.

T. Aldrich, *Non-invasive blood component analyzer*, U.S. Patent No. 6,064,898 (May 16, 2000) describe a non-invasive blood component analyzer that also provides built-in path length monitoring to allow use in subjects of varying finger size. The Aldrich device is not a handheld or otherwise portable device. It provides

a light source either from LED s or from a lamp. No structure is provided for coupling the light beam from the light source; the light is simply emitted in the vicinity of the sampling site and coupled through the atmosphere. The current device, plus all of the previously described devices for blood analyte determination, while they often employ several LED s as a light source, do not provide the LED s in structured arrays; and they do not provide substrates to lend the LED s mechanical support, thermal stability and electrical connectivity.

Handheld spectrometers are known in the prior art. K. Levin, S. Kerem, V. Madorsky, *Handheld infrared spectrometer*, U.S. Patent No. 6,031,233 (February 29, 2000) describe a handheld infrared spectrometer. Space is conserved by aligning the optics and eliminating fibers. Light is emitted from a conventional lamp and passed through an acousto-optical tuning filter (AOTF) for wavelength selection. The filtered light is focused through one or more lenses and directed toward the measurement site through a window. While the design is highly space-efficient, allowing for a truly handheld spectrometer, the use of an AOTF for wavelength selection requires a wavelength synthesizer and an RF amplifier. Furthermore, a conventional lamp for a light source is energy inefficient, shortening battery life and generating excessive amounts of thermal energy.

H. Van Aken, A. Kravetz, K. Garde, W. Weber, J. Corrado, *Handheld portable spectrometer,* U.S. Patent No. 5,319,437 (June 7, 1994) describe a handheld spectrometer. The Van Aken device employs a conventional lamp, with all of its attendant disadvantages.

An example of a portable noninvasive blood glucose analyzer is provided by R. Rosenthal, *Instrument for non-invasive measurement of blood glucose*, U.S. Patent No. 5,077,476 (October 17, 2000). Rosenthal describes a hand-held instrument for non-invasive measurement of glucose. One or more LED's are used to provide a point source of near IR energy of a predetermined bandwidth. The emitted energy is coupled with the sampling site by means of a focusing lens. The Rosenthal instrument does not provide a wide band signal from an array of LED's emitting in overlapping wavelength regions. The space requirements for the mirror arrangement and the detector arrangement are such that the overall size of the instrument would be unwieldy for a

handheld device. The Rosenthal device does not provide a spectrum analyzer or a linear detector array.

There exists, therefore, a need in the art for a long-lived, space efficient, energy-efficient light source assembly for non-invasive optical sampling. It would be desirable to provide a light source assembly that employs light-emitting diodes (LED's) as a light source. Furthermore, it would be desirable to combine the LED's into a compact sub-assembly by attaching LED's to a substrate that provided electrical connections, and mechanical and thermal stability. It would be a great advantage to provide a simple space-efficient means of coupling light from the light source with an optical probe that is resistant to mechanical shock and perturbation, while mixing wavelengths thoroughly and normalizing light intensity. It would be a further advantage to provide a means of optimizing the operating temperature to maximize LED efficiency. It would be a significant technological advance to incorporate such a light source assembly into a lightweight, compact instrument for non-invasive blood analyte determination.

SUMMARY OF THE INVENTION

In a first embodiment, the invention provides a LED-based light source assembly for non-invasive optical sampling. A wide band signal is achieved by combining LED's, singly or in groups, that emit in overlapping wavelength bands. LED's are combined into a LED/substrate sub-assembly, in which LED's, attached to reflectors mounted in a thermally stable substrate, are electrically connected by means of bonding wires. A LED light source assembly includes the LED/substrate sub-assembly; a mixer, consisting of a large diameter fiber optic having a hollow center to couple the signal to a probe; a collection fiber, threaded through the hollow center, for collecting light emitted from the sample under test; a printed circuit board, in which the LED/substrate sub-assembly is seated, and having electrical contacts for connecting the LED's to an LED driver; and a cooling system for stabilizing the substrate temperature.

In a second embodiment, the invention provides a compact, lightweight instrument for non-invasive blood analyte determination that incorporates the light source assembly provided by the first embodiment. The instrument includes the LED-based light source assembly; an optical module that includes a miniature spectrum analyzer having a grating to focus and disperse the light received from the collection fiber and a linear detector array for receiving the dispersed spectrum; an LED driver; a digital electronics module for processing the spectrum and estimating concentration of a target analyte; and a display, for outputting the target analyte concentration.

The high conversion efficiency of the light source results in extremely low power dissipation and virtually no heat generation, making incorporation of the light source and the spectrometer into a single unit practicable. High-speed pulsing of the signal allows application of high-sensitivity, synchronous detection techniques. Speed and flexibility in sequencing LED's allows simultaneous measurement and skin temperature control.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a typical light emitting diode (LED) in an upside down configuration, wherein the LED has a light emitting junction at the bottom of the chip and light is emitted through the top of the chip;

Figures 2a and 2b show top and bottom views, respectively, of a substrate for LED's according to the invention;

Figure 3 provides a detailed view of the substrate of Figure 2, showing parabolic reflectors in which LED's are to be mounted, according to the invention;

Figure 4 provides a close-up, detailed view of a substrate/LED subassembly, according to the invention;

Figure 5 provides a section view of the subassembly of Figure 4, according to the invention;

Figure 6 provides a three dimensional rendering of a LED light source assembly according to the invention;

Figure 7 provides a three dimensional rendering of a LED light source assembly printed circuit board (PCB) according to the invention;

Figure 8 provides an isometric view of a miniature spectrum analyzer, according to the invention;

Figure 9 provides a three dimensional rendering of a photo diode array (PDA) module,

according to the invention;

Figure 10 provides a three-dimensional rendering of an optical module including the miniature spectrometer of Figure 8 and the PDA module of Figure 9, according to the invention;

Figure 11 provides a three dimensional rendering of a LED light source-based instrument for non-invasive blood glucose measurement, according to the invention; and

Figure 12 shows an alternate version of a PDA module, according to the invention.

DETAILED DESCRIPTION

Spectrometer instruments have conventionally employed a light source consisting of a halogen-tungsten lamp. For portable and handheld applications, such light sources have several disadvantages: most notably that they are neither space nor energy efficient. In addition, these light sources generate excessive amounts of heat, take a long time to stabilize and have a short life expectancy.

In a first embodiment, the invention provides a light source assembly for non-invasive optical sampling that employs light emitting diodes (LED) as the light source. An LED-based light source offers a number of advantages. Among them are:

- Compact Size;
- LED's can be selected and combined to emit light only in a spectral region of interest;
- High light conversion efficiency / low heat generation;
- Light intensity is easily modulated;
- Provides the option of continuous wave and pulsed modes of operation; and
- Long Lifetime (> 100,000 hrs.).

Recent applications using superluminescence light emitting diodes (LED) as a replacement for incandescent lighting, as well as for billboards, show that LED's are well suited as light sources in spectrometry applications. While these applications have employed superluminescence LED's that emit in the visible wavelength region, it is apparent that future improvements offer even more promise regarding the light levels available from such light sources

LIGHT-EMITTING DIODES (LED)

LED's are solid-state components that emit a narrow wavelength band of peak intensity and spectral width, determined by construction. Construction may vary depending on performance requirements: single-junction, hetero-junction or super-luminescence. Also, chip size is highly variable, ranging from about 0.1 x 0.1 x 0.1 mm to about 1 x 1 x 0.1 mm. The wavelength band is determined by the material used to build the LED, thus it is not a consequence of the physical construction of the LED.

Since LED's emit a narrow wavelength band, to obtain a wide band light source, a combination of different LED's must be used. In the present embodiment of the invention, individual LED types that emit in different wavelength bands with overlaps at full-width half maximum (FWHM) spectral points or better are selected and combined in a single sub-assembly to provide a wide band light source. Furthermore, since individual LED's can be so small (i.e. 300 x 300 x 200 microns), the invented light source assembly is extremely compact, while generating very little heat due to high conversion efficiency. Referring now to Figure 1, a typical LED 10, in an upside down configuration, is shown. A light-emitting junction 11 produces light from an applied voltage. Back metallization 12 along the bottom reflects the generated light, greatly improving energy efficiency. A top contact 13 together with the back metallization enables electrical connections to and from the LED.

LED SUBSTRATE

As mentioned before, it is necessary to combine several different types of LED's in order to build a wide band light source. A novel substrate provides a housing and electrical interconnections for the selection of LED's that make up the light source. The substrate provides several features essential to the proper function of the invented light source assembly:

- Mechanical support and compactness;
- Electrical connections;
- Light beam shaping;
- Light intensity profile shaping; and
- Thermal stability.

Furthermore, the invented LED substrate advantageously provides a high degree of flexibility with respect to the interconnection of the LED's; for example, by allowing individual access to selected LED's, or grouping LED's by type to improve the power level to the selected type, or to intentionally increase the light power level at selected wavelength ranges of interest. By virtue of the flexibility of the LED substrate desing, other embodiments of the invention are possible in which other light sources are provided, in addition to the LED's, such as laser diodes, and/or sensors for monitoring

and controlling conditions at the measurement site, such as skin temperature or surface hydration.

Referring now to Figure 2a, the invented LED substrate 20 according to the invention is shown. The main body 21 of the substrate may be fabricated from any material that has sufficient mechanical strength, good thermal conductivity and that can be easily shaped into the required geometry. Examples of such materials are different types of ceramics and plastic resins. On the anterior face 22 of the substrate 20, an array of wells 23 is provided into which the LED's are mounted. A metallization pattern 24 on the sides and both faces of the substrate provides electrical contacts for electrically connecting the LED's to an LED driver, described in greater detail below. Viewing the posterior face 25 of the substrate, as shown in Figure 2b, a large well 26 receives a thermoelectric cooler, described in detail below. A conduit 27 communicates with the anterior face to provide passage for a collection fiber, also described below. Figure 3 shows a detailed view of the anterior face 22 of the substrate body 21. Each well 23 provides a parabolic reflector 30 within which the LED's 10 are to be mounted. Since the light emitted from the LED's 10 is Lambertian in nature and emanates from the junction area 11 on the sides as well as the top surface, the reflectors 30 are necessary to from a low divergence light beam from each LED 10. A well-behaved light beam improves light coupling efficiency, whether the light beam is coupled into a fiber or directly to a sample under test. Figure 3 also provides a detailed view of the metallization pattern 24. The metallization pattern can be designed to either allow electrical connections to every LED 10 singly, or LED's can be interconnected into groups, offering the advantage of built in redundancy. Subsequently, the single LED's, or the groups are connected to the LED driver. The electrical connection scheme within the groups, as well as the overall design of the connection scheme varies according to application and overall instrument design. The LED substrate is fabricated using conventional methods.

LED/SUBSTRATE SUBASSEMBLY

As Figures 4 and 5 show, the LED's and the substrate are fabricated into a subassembly 40. Each LED 10 is centered within its respective well 23 and fastened to the bottom of the reflector 30, preferably with electrically conductive epoxy. As shown in Figure 5, individual LED's 10 are bonded and electrically interconnected using bonding wires 50 of appropriate size. Preferably, the bonding wires 50 are gold; the size of the wire is dictated by the current drive requirement of the corresponding LED and the diameter of the top contact 13. The anterior face of the entire assembly, bearing the mounted and electrically interconnected LED's is covered with an appropriate optical epoxy or polymeric resin material (not shown) having favorable transmission

characteristics in the spectral range represented by the light emitting LED's of the light source assembly 60. This material provides two important functions:

- Mechanical protection for fragile bond wires; and
- Matching refreactive index of substrate medium, minimizing Fresnel's losses.

The filling material preferably has a refractive index approximately equal to:

$$\sqrt{n_{LED} * n_o}$$

where:

n_{LED} = Light emitting diode index of refraction; and

n_o = Surrounding medium index of refraction.

LED LIGHT SOURCE ASSEMBLY

Referring now to Figure 6, shown is the LED/substrate assembly integrated into a light source assembly 60. Emitted light must be coupled to a sample interface, or otherwise directed toward the measurement site. Conventionally, space optics, consisting of arrangements of mirrors and lenses are used for this purpose. However, the space requirements of these arrangements render them unsuitable for compact, space efficient applications. Furthermore, conventional optical arrangements are highly sensitive to mechanical shock and other perturbations, rendering them unsuitable for use in handheld devices. The invention utilizes an optical mixer 61, enjoying the advantages of simplicity and compactness, for this purpose. Preferably, the mixer 61 is a special, large diameter fiber, in which the size is determined by the optimal pathlength of the light through the skin, and having a hollow center 62 to accommodate a collection fiber 63. The preferred material for the mixer 61 is low $^-$OH silica fiber, however other materials having a high refractive index, such as sapphire or silicon, would also be suitable. The mixer provides a medium for thorough mixing of wavelength content and normalization of light intensity in the light beam emanating from the LED's without introducing an unacceptable level of light loss. Preferably, the mixer 61 is mounted onto the substrate 20 at the same time it is encapsulated with resin, however the mixer may also be mounted by means of a mechanical fixture.

Preferably, the collection fiber 63 is a low $^-$OH silica fiber having a core diameter of approximately 600 microns. As shown, the collection fiber is a short, straight piece of fiber, fixedly positioned in the hollow center 62 of the mixer, such that it passes through all the components of the light source assembly, in order to increase light collection efficiency. The collection fiber 63 may be held stationary by gluing it into position within the mixer 61. The end of the collection fiber is reinforced with a ferule 64 that is

dimensioned to fit the entrance of the spectrum analyzer, described below.

As Figure 6 shows, the subassembly consisting of LED's 10, substrate 20, mixer 61 and collection fiber 63 is mounted into a self-aligning indent 70 on the anterior face 71 of a printed circuit board (PCB) 65, shown in detail in Figure 7, that functions to facilitate electrical connections 72 between driving electronics and the rest of the light source while providing the substrate 20 additional mechanical support.

The self-aligning feature is provided by an aperture 73 that penetrates the PCB 65 from the floor of the indent 70 to the posterior face of the PCB, allowing placement of a thermoelectric cooler 66, the cold side of which fits into the well 26 on the posterior face 25 of the substrate 20. While the primary function of the thermo-electric cooler 66 is to stabilize the substrate temperature, it also provides a moderate cooling effect, since LED efficiency is dramatically improved at lower temperatures. A proportional heat sink 67 is attached to the "hot" side of thermoelectric cooler 66 for power efficient operation.

Due to its energy and space efficiency, the invented LED based light source assembly 60 is ideally suited for use in a portable instrument for non-invasive measurement of blood analytes such as glucose. A compact, lightweight instrument for non-invasive blood analyte determination incorporating the light source assembly 60 is described below.

INSTRUMENT FOR NON-INVASIVE BLOOD ANALYTE DETERMINATION

In overview, the instrument 110, shown in Figure 11, irradiates a sampling site on the skin of a subject with a beam of wideband light. The back-diffused light, transmitted or reflected by the skin, is collected. Spectral content is analyzed by dispersing the light beam against a grating within a spectrum analyzer. The dispersed spectrum is projected across a linear detector array sensitive in the wavelength range of interest. The detector array records the received signal and converts it to a voltage. After the signal is conditioned and digitized, a signal processor within a digital electronics module analyzes the signal according to a prediction algorithm to estimate blood level of the target analyte.

I. OPTICAL MODULE

As shown in Figure 10, the optical module 100 includes a miniature spectrum analyzer 80 and an associated linear detector array module 90.

SPECTRUM ANALYZER

As Figure 11 shows, the invented instrument 110 for non-invasive blood analyte determination incorporates a spectrum analyzer 80, wherein a signal is received from the collection fiber 63, and dispersed against a holographic grating (not shown). As Figure 8 shows, the spectrum analyzer has an input slit 81 and an output slit 82. In order to deliver a light beam to the detector array having a width equal to, or about equal to, the length of the detector array, the width of the input slit 81 duplicates that of an individual pixel of the detector array. The height of the array (*i.e.* 500 m) dictates the size of the collection fiber (*i.e.* 600 m). A light beam is emitted from the collection fiber 63 and received by the input slit of the spectrum analyzer 81. The spectrum analyzer further includes an angled mirror (not shown) and a concave holographic grating (not shown) in a conventional arrangement, well known to those skilled in the art. The mirror, at an angle of 45°, folds the light beam received from the collection fiber 63 and directs it toward the diffraction grating. The diffraction grating both disperses the light beam into spectral components and focuses it at the focal plane of the detector array. The output slit 82 of the spectrum analyzer is dimensioned to be slightly wider than the detector array in order to avoid clipping the dispersed spectrum as it is emitted toward the detector array through the output slit. A flat field region of the dispersed spectrum is created through the front slit at the plane where the surface of the linear detector array is positioned, in which the area of the flat field region is approximately equal to the total active area of the detector array. It should be noted that, while the described spectrum analyzer is preferred, other configurations may also be suitable, as long as they meet the functional requirements of small size and low stray light emission imposed by the instrument's use as a blood glucose analyzer, characteristics that are critical in the design of a hand-held instrument.

LINEAR DETECTOR ARRAY MODULE

A linear photo diode array (PDA), in which each photodiode is optimized for the wavelength range of interest, records the whole spectrum. Figure 9 shows an example of a PDA module 90. The PDA module 90 incorporates the detector in a conventional manner apparent to those skilled in the art of integrated circuit design and electronics packaging. As previously mentioned, the module 90 is positioned in such a way that a flat field image of the dispersed spectrum is projected toward the hybrid focal plane located behind the face 91 of the detector array module. Figure 12 provides an alternate version of a PDA module 120 that includes a linear array of photodiodes 121. Such linear arrays are commonly known in the art as focal plane arrays. The hybrid focal plane consists of a linear array of photodiodes and silicon multiplexer chips that are interconnected through wire-bonding and substrate metallization. The photodiodes are

manufactured from a material system suited to the wavelength range of interest, for example, InGaAs, Ge, or InAs. The linear photodiode array records signals by detecting light and converting the light to a signal, the voltage of which is representative of the intensity of the detected light. Each individual photodiode, representing a single pixel, simultaneously records a one-pixel portion of the projected spectrum, so that the entire spectrum is recorded. The signals are then read out through the silicon multiplexer chips. Subsequently, measured values are then clocked serially out through signal conditioning and Analog-to-Digital circuitry, described in greater detail, below. Preferably, the multiplexer chips have the following characteristics:

- Low system noise;
- Programmable gain;
- Offset voltage cancellation; and
- High readout speed.

Optimum acquisition speed in scans per second is determined by the available light level (integration time) and readout speed. The current embodiment of the invention provides readout speed in a range from approximately 100 scans per second to 1000 scans per second.

The linear detector array module 90 is incorporated into a single PCB 101 with the above-mentioned signal conditioning circuitry and ADC.

Signal conditioning is provided by conventional circuitry performing any of the following:

buffering;
impedance matching;
frequency smoothing; and
level-shifting.

Following signal conditioning, the signal is digitized by means of a conventional analog-to-digital converter (ADC).

II. ELECTRONICS

LED DRIVER

As shown in Figure 11, an LED driver circuit 111 supplies power to and controls illumination of the LED's 10 of the light source assembly 60. Preferably, the LED driver 110 provides the following capabilities:

- Addressability of each serially connected group of LED's/individual LED's, one at a time;

- Simultaneous addressability of all groups/individual LED's (LED) in the light source;
- Flexible sequencing of any group of/individual LED based on pre-programmed sequences stored in the memory; and
- Amplitude modulation of light intensity.

Additionally, the LED driver circuit sources very short pulses, 100 - 400 nanoseconds in duration, with programmable high peak current of up to 10 amps. Also, it provides means to drive the LED's in continuous wave mode at moderate current levels of 100 - 500 mA and the ability to drive the LED's under either AC or DC conditions. LED drivers having the capabilities described are well known to those skilled in the art, therefore a detailed illustration of the LED driver is not shown.

HIGH SPEED DIGITAL ELECTRONICS MODULE

A high-speed digital electronics module 112, incorporating a digital signal processor (DSP) provides the signal processing functionality necessary to execute the glucose measurement algorithm, recorded in a non-volatile memory such as ROM (read-only) or EPROM (electronically programmable read-only). Signal processing functionalities include:

- High level - performing all necessary sequencing and synchronization of events needed for accurate blood analyte determination; and
- Low Level - monitoring status of important instrument indicators, acquiring data.

Volatile memory (RAM) is provided for storage of digital values.

Measurement status indicators as well as results are displayed on the high resolution LCD 113, further described below.

POWER SUPPLY (114)

While various light, high efficiency batteries are suitable as a power supply, the instrument preferably uses a nickel-metal-hydride type battery 114, designed to support instrument power requirements, while being size- and weight-optimized, in order to meet instrument portability requirements.

III. CONTROLS AND DISPLAY

Control over the instrument is exercised through a panel of push buttons 115. In an alternate embodiment, hands-free control is provided by means of spoken prompts, recognized by a speech recognition chip on the digital module 112. Measurement status indicators, results and reports are displayed on the high resolution LCD screen

113, positioned on the top of the instrument for improved visibility.

The small size and compactness of the instrument 110, shown in Figure 11, are achieved primarily through the use of the LED light source and the unique scheme employed to illuminate the sample site and collect light from it. The light source is positioned very close to the sample site, at a distance dictated by the mixer length necessary to achieve sufficient spectral and intensity mixing. Light emitted by the LED's 10 is coupled to the sample interface 116 by the mixer 61. In the preferred embodiment of the invention, the sample interface 116 consists of a fiber optic probe that contacts the sample site, usually the skin of a live subject. The design of the light source assembly and the central position of the light collection fiber allow placement of the spectrum analyzer in close proximity to the light source itself. Since virtually no heat is generated by the light source, it is natural that the spectrum analyzer and the light source itself be combined into one module.

Although the invention has been described herein with reference to certain preferred embodiments, one skilled in the art will readily appreciate that other applications may be substituted without departing from the spirit and scope of the present invention. Accordingly, the invention should only be limited by the Claims included below.

CLAIMS

What is claimed is:

1. A light source assembly for non-invasive optical sampling, wherein LED's are combined to provide a wide band signal, comprising:

a plurality of LED's;

a LED substrate, said substrate providing mechanical support for said LED's, so that said LED's and said substrate form a LED/substrate subassembly;

means for electrically connecting said LED's;

means for shaping light beams emitted from said LED's;

means for controlling light intensity profile;

means for coupling said signal to a sample interface;

means for collecting light emitted from said sample; and

means for monitoring and controlling conditions at a measurement site.

2. The assembly of Claim 1, wherein said LED's are any of single junction, hetero-junction and super-luminescence LED's.

3. The assembly of Claim 1, wherein said LED's emit at different, overlapping wavelength regions, so that combining light beams encompassing said wavelength regions produces a single wide band signal.

4. The assembly of Claim 1, wherein said substrate has an anterior face, a posterior face and sides.

5. The assembly of Claim 4, wherein said means for shaping light beams emitted from said LED's comprises a plurality of parabolic reflectors, wherein each reflector is mounted within a well on the anterior face of said substrate, and wherein each of said LED's is fixedly attached within a corresponding reflector, so that divergence between light beams is minimized.

6. The assembly of Claim 5, wherein said sub-assembly is coated with one of optical epoxy and a polymeric resin to provide mechanical protection and minimize Fresnel's losses, said coating having favorable transmission characteristics in the wavelength range of the light source assembly.

7. The assembly of Claim 6, wherein said substrate is fabricated from one of a ceramic resin and a plastic resin.

8. The assembly of Claim 7, wherein said coating has a refractive index of:

$$\sqrt{n_{LED} * n_o}$$

where:

n_{LED} = LED index of refraction; and

n_o = substrate material index of refraction.

9. The assembly of Claim 4, wherein said means for coupling said signal to a sample interface comprises a mixer, said mixer comprising a large diameter fiber optic having a hollow center and having a high index of refraction, so that wavelength content and intensity of light beams emanating from said sub-assembly are thoroughly mixed without introducing additional light loss.

10. The assembly of Claim 9, wherein said mixer is fabricated from one of low OH^- silica, sapphire and silicon.

11. The assembly of Claim 9, wherein said mixer is fixedly mounted on said anterior face of said substrate.

12. The assembly of Claim 9, wherein said means for collecting light emitted from said sample comprises a collection fiber, said collection fiber comprising a second fiber optic threaded through said hollow center and passing through a conduit from said anterior face of said substrate to a well in said posterior face of said substrate, said well being dimensioned to receive a temperature regulation element.

13. The assembly of Claim 12, wherein said collection fiber has a core diameter of approximately 600 microns, and wherein said collection fiber is fabricated from low OH^- silica.

14. The assembly of Claim 12, wherein said means for electrically connecting said LED's comprises bonding wires for interconnecting said LED's.

15. The assembly of Claim 14, where said means for electrically connecting said LED's further comprises a metallization pattern on the anterior face and sides of said substrate, said metallization pattern forming electrical contacts for contacting said bonding wires.

16. The assembly of Claim 15, wherein said means for electrically connecting said LED's further comprises a metallization pattern on a printed circuit board (PCB), said PCB having an anterior face and a posterior face, said anterior face of said PCB defining a self-aligning indent adapted to receive said sub-assembly, said metallization providing electrical contacts that contact said electrical contacts on said substrate when said substrate is seated in said indent and that, in turn, contact a LED driver, so that said LED's are electrically connected to said LED driver.

17. The assembly of Claim 16, wherein said LED's are connected to a LED driver individually.

18. The assembly of Claim 16, wherein said LED's are connected to a LED driver in groups.

19. The assembly of Claim 16, wherein said PCB defines an aperture, so that said substrate conduit and said PCB aperture align when said sub-assembly is seated in said PCB.

20. The assembly of Claim 19, wherein said means for regulating temperature comprises a thermo-electric cooler, having a cold side and a hot side, that fits through said aperture to be received by said posterior well so that said cold side is in contact with said posterior face of said substrate; and

a heat sink, said heat sink in contact with said hot side of said cooler;

wherein said thermoelectric cooler and said heat sink together comprise a sub-assembly.

21. The assembly of Claim 20, further comprising a support ferrule, wherein said collection fiber passes through said PCB aperture and said thermoelectric cooler-heat sink sub-assembly to be received by said ferrule at the posterior face of said PCB.

22. A compact, lightweight instrument for non-invasive blood analyte determination, wherein a prediction algorithm estimates concentration of a target analyte based on spectroscopic analysis of light emitted from a sampling site, said instrument comprising:

a light source assembly for non-invasive optical sampling, wherein LED's are combined to provide a wide band signal coupled to a tissue measurement site and wherein light emitted from said sample is collected;

an optical module, for dispersing, focusing and detecting said emitted light;

a LED driver for powering said LED's;
processor means for executing said prediction algorithm; and
display means for outputting said analyte determination.

23. The instrument of Claim 22, wherein said light source assembly comprises:
a plurality of LED's;
a LED substrate; said substrate providing mechanical support for said LED's, so that said LED's and said substrate form a LED/substrate subassembly;
means for controlling light intensity profile;
means for electrically connecting said LED's;
means for shaping light beams emitted from said LED's;
means for coupling said signal to a sample interface;
means for collecting light emitted from said sample; and
means for controlling and monitoring conditions at said tissue measurement site.

24. The instrument of Claim 23, wherein said LED's emit at different, overlapping wavelength regions, so that combining light beams encompassing said wavelength regions produces a single wide band signal.

25. The instrument of Claim 23, wherein said substrate has an anterior face, a posterior face and sides.

26. The instrument of Claim 25, wherein said means for shaping light beams emitted from said LED's comprises a plurality of parabolic reflectors, wherein each reflector is mounted within a well on the anterior face of said substrate, and wherein each of said LED's is fixedly attached within a corresponding reflector, so that divergence between light beams is minimized.

27. The instrument of Claim 26, wherein said sub-assembly is coated with one of optical epoxy and a polymeric resin to provide mechanical protection and minimize Fresnel's losses, said coating having favorable transmission characteristics in the wavelength range of the light source assembly.

28. The instrument of Claim 26, wherein said means for coupling said signal to a sample interface comprises a mixer, said mixer comprising a large diameter fiber optic having a hollow center and having a high index of refraction, so that wavelength content and intensity of light beams emanating from said sub-assembly are thoroughly mixed without introducing additional light loss.

29. The instrument of Claim 28, wherein said mixer is fixedly mounted on said anterior face of said substrate.

30. The instrument of Claim 29, wherein said means for collecting light emitted from said sample comprises a collection fiber, said collection fiber comprising a second fiber optic threaded through said hollow center and passing through a conduit from said anterior face of said substrate to a well in said posterior face of said substrate, said well being dimensioned to receive a temperature regulation element.

31. The instrument of Claim 27, wherein said means for electrically connecting said LED's comprises bonding wires for interconnecting said LED's.

32. The instrument of Claim 31, where said means for electrically connecting said LED's further comprises a metallization pattern on the anterior face and sides of said substrate, said metallization pattern forming electrical contacts for contacting said bonding wires.

33. The instrument of Claim 32, wherein said means for electrically connecting said LED's further comprises a metallization pattern on a printed circuit board (PCB), said PCB having an anterior face and a posterior face, said anterior face of said PCB defining a self-aligning indent adapted to receive said sub-assembly, said metallization providing electrical contacts that contact said electrical contacts on said substrate when said substrate is seated in said indent; wherein said PCB that in turn contacts said LED driver, so that said LED's are electrically connected to said LED driver;

wherein said LED's are connected to said LED driver either individually or in groups.

34. The instrument of Claim 33, wherein said PCB defines an aperture, so that said substrate conduit and said PCB aperture align when said sub-assembly is seated in said PCB.

35. The instrument of Claim 34, wherein said temperature regulating element comprises a thermo-electric cooler, having a cold side and a hot side, that fits through said aperture to be received by said posterior well so that said cold side is in contact with said posterior face of said substrate; and

a heat sink, said heat sink in contact with said hot side of said cooler, wherein said thermo-electric cooler and said heat sink together comprise a thermoelectric cooler-heat sink subassembly.

36. The instrument of Claim 35, further comprising a support ferrule, wherein said collection fiber passes through said PCB aperture and said thermoelectric cooler-heat sink subassembly to be received by said ferrule at the posterior face of said PCB.

37. The instrument of Claim 30, wherein said optical module comprises:

a miniature spectrum analyzer having entry and output slits;

a linear detector array module, said spectrometer and said detector array module fixedly attached to each other such that said output slit and a face of said detector array module are facing.

38. The instrument of Claim 37, wherein width of said entry slit equals width of an individual pixel in a linear detector array within said linear detector array assembly.

39. The instrument of Claim 38, wherein said spectrum analyzer comprises:

a mirror, wherein a light beam emitted from said collection fiber and projected through said entry slit is folded by said mirror;

a concave holographic grating, wherein said folded light beam is projected from said mirror and dispersed and focused by said grating;

wherein a flat field section of said spectrum is projected toward said array through said output slit.

40. The instrument of Claim 40, wherein said linear detector array comprises a linear photodiode array, each photodiode comprising a detection element and an associated multiplexer element, each photodiode representing a pixel, wherein said photodiodes each simultaneously record a one pixel portion of said projected spectrum, so that the entire spectrum is recorded, and wherein said portions of said recorded spectrum are converted into a voltage by said detection elements.

41. The instrument of Claim 40, wherein said multiplexing elements read signals output from each of said detection elements in a serial fashion.

42. The instrument of Claim 41, wherein said linear detector array module further comprises a signal conditioning circuit, wherein said multiplexing elements transfer said signals to said signal conditioning circuit for conditioning though any of:

buffering;
impedance matching;
frequency smoothing; and
level-shifting.

43. The instrument of Claim 42, wherein said linear detector array assembly further comprises an analog-to-digital conversion circuit (ADC), wherein said signal conditioning circuit transfers said conditioned signal to said ADC;

wherein said ADC converts said conditioned signal to digital values and transfers said digital values to said processor means.

44. The instrument of Claim 43, wherein said processor means comprises a high speed digital electronics module, said module including:

a digital signal processor; and

at least one memory;

wherein said module receives said digital values form said optical module and processes said digital values according to said prediction algorithm to arrive at an estimate of target analyte concentration.

45. The instrument of Claim 44, wherein said memory comprises non-volatile memory, and wherein said algorithm is stored in said non-volatile memory.

46. The instrument of Claim 44, wherein said memory comprises volatile memory, and wherein said digital values are stored in said volatile memory.

47. The instrument of Claim 31, wherein said LED driver comprises:

a module for powering said LED's, so that said individual LED's and said groups of LED's are:

serially addressable, one LED or group of LED's at a time;

simultaneously addressable, all LED's or groups of LED's at a time; and

wherein selected groups or selected LED's are flexibly sequenceable according to one or more stored, pre-programmed sequences.

48. The instrument of Claim 47, wherein said module produces pulses of approximately 100 – 400 nanoseconds, with programmable high peak current of up to 10 amps, and wherein said module drives LED's or groups of LED's in continuous wave mode at current levels of approximately 100 – 500 mA, and wherein said LED module drives said LED's or groups of LED's under either of AC or DC conditions.

49. The instrument of Claim 22, wherein said display means comprises a high-resolution LCD.

50. The instrument of Claim 22, further comprising a power supply, said power

supply comprising a nickel-metal-hydride battery.

51. The instrument of Claim 22, further comprising a control means, said control means comprising one of a keypad and a speech recognition module.

52. The instrument of Claim 23, wherein said sample interface comprises a fiber optic probe.

AMENDED CLAIMS

[received by the International Bureau on 6 February 2002 (06.02.02));
original claims 1, 9, 12, 22 and 24 amended; remaining claims unchanged (4 pages)]

1. A light source assembly for non-invasive optical sampling, wherein LED's are combined to provide a wide band signal, comprising:

a plurality of LED's, wherein the LED's emit at different, overlapping wavelength regions, so that combining light beams encompassing said wavelength regions produces a single wide band signal;

a LED substrate, said substrate providing mechanical support for said LED's, so that said LED's and said substrate form a LED/substrate subassembly;

means for electrically connecting said LED's;

means for shaping light beams emitted from said LED's;

means for controlling light intensity profile;

a mixer, comprising a large diameter fiber optic for coupling said signal to a sample interface such that wavelength content and intensity of light beams emanating from said sub-assembly are thoroughly mixed, said mixer having a hollow center and;

a collection fiber threaded through said hollow center for collecting light emitted from said sample comprises; and

means for monitoring and controlling conditions at a measurement site.

2. The assembly of Claim 1, wherein said LED's are any of single junction, hetero-junction and super-luminescence LED's.

3. The assembly of Claim 1, wherein said

4. The assembly of Claim 1, wherein said substrate has an anterior face, a posterior face and sides.

5. The assembly of Claim 4, wherein said means for shaping light beams emitted from said LED's comprises a plurality of parabolic reflectors, wherein each reflector is mounted within a well on the anterior face of said substrate, and wherein each of said LED's is fixedly attached within a corresponding reflector, so that divergence between light beams is minimized.

6. The assembly of Claim 5, wherein said sub-assembly is coated with one of optical epoxy and a polymeric resin to provide mechanical protection and minimize Fresnel's losses, said coating having favorable transmission characteristics in the wavelength range of the light source assembly.

7. The assembly of Claim 6, wherein said substrate is fabricated from one of a ceramic resin and a plastic resin.

8. The assembly of Claim 7, wherein said coating has a refractive index of:

$$\sqrt{n_{LED} * n_o}$$

where:

n_{LED} = LED index of refraction; and
n_o = substrate material index of refraction.

9. The assembly of Claim 4, said mixer having a high index of refraction, so that wavelength content and intensity of light beams emanating from said sub-assembly are thoroughly mixed without introducing additional light loss.

10. The assembly of Claim 9, wherein said mixer is fabricated from one of low OH^- silica, sapphire and silicon.

11. The assembly of Claim 9, wherein said mixer is fixedly mounted on said anterior face of said substrate.

12. The assembly of Claim 9, wherein, said collection fiber passes through a conduit from said anterior face of said substrate to a well in said posterior face of said substrate, said well being dimensioned to receive a temperature regulation element.

13. The assembly of Claim 12, wherein said collection fiber has a core diameter of approximately 600 microns, and wherein said collection fiber is fabricated from low OH^- silica.

14. The assembly of Claim 12, wherein said means for electrically connecting said LED's comprises bonding wires for interconnecting said LED's.

15. The assembly of Claim 14, where said means for electrically connecting

said LED's further comprises a metallization pattern on the anterior face and sides of said substrate, said metallization pattern forming electrical contacts for contacting said bonding wires.

16. The assembly of Claim 15, wherein said means for electrically connecting said LED's further comprises a metallization pattern on a printed circuit board (PCB), said PCB having an anterior face and a posterior face, said anterior face of said PCB defining a self-aligning indent adapted to receive said sub-assembly, said metallization providing electrical contacts that contact said electrical contacts on said substrate when said substrate is seated in said indent and that, in turn, contact a LED driver, so that said LED's are electrically connected to said LED driver.

17. The assembly of Claim 16, wherein said LED's are connected to a LED driver individually.

18. The assembly of Claim 16, wherein said LED's are connected to a LED driver in groups.

19. The assembly of Claim 16, wherein said PCB defines an aperture, so that said substrate conduit and said PCB aperture align when said sub-assembly is seated in said PCB.

20. The assembly of Claim 19, wherein said means for regulating temperature comprises a thermo-electric cooler, having a cold side and a hot side, that fits through said aperture to be received by said posterior well so that said cold side is in contact with said posterior face of said substrate; and

a heat sink, said heat sink in contact with said hot side of said cooler;

wherein said thermoelectric cooler and said heat sink together comprise a sub-assembly.

21. The assembly of Claim 20, further comprising a support ferrule, wherein said collection fiber passes through said PCB aperture and said thermoelectric cooler-heat sink sub-assembly to be received by said ferrule at the posterior face of said PCB.

22. A compact, lightweight instrument for non-invasive blood analyte determination, wherein a prediction algorithm estimates concentration of a target

analyte based on spectroscopic analysis of light emitted from a sampling site, said instrument comprising:

a light source assembly for non-invasive optical sampling, wherein LED's emitting at different, overlapping wavelength regions are combined to provide a wide band signal coupled to a tissue measurement site and wherein light emitted from said sample is collected;

an optical module, for dispersing, focusing and detecting said emitted light;

a LED driver for powering said LED's;

processor means for executing said prediction algorithm; and

display means for outputting said analyte determination.

23. The instrument of Claim 22, wherein said light source assembly comprises:

a plurality of LED's;

a LED substrate; said substrate providing mechanical support for said LED's, so that said LED's and said substrate form a LED/substrate subassembly;

means for controlling light intensity profile;

means for electrically connecting said LED's;

means for shaping light beams emitted from said LED's;

means for coupling said signal to a sample interface;

means for collecting light emitted from said sample; and

means for controlling and monitoring conditions at said tissue measurement site.

24. The instrument of Claim 23, wherein combining light beams encompassing said wavelength regions produces a single wide band signal.

25. The instrument of Claim 23, wherein said substrate has an anterior face, a posterior face and sides.

26. The instrument of Claim 25, wherein said means for shaping light beams emitted from said LED's comprises a plurality of parabolic reflectors, wherein each reflector is mounted within a well on the anterior face of said substrate, and wherein each of said LED's is fixedly attached within a corresponding reflector, so that divergence between light beams is minimized.

27. The instrument of Claim 26, wherein said sub-assembly is coated with one of optical epoxy and a polymeric resin to provide mechanical protection and

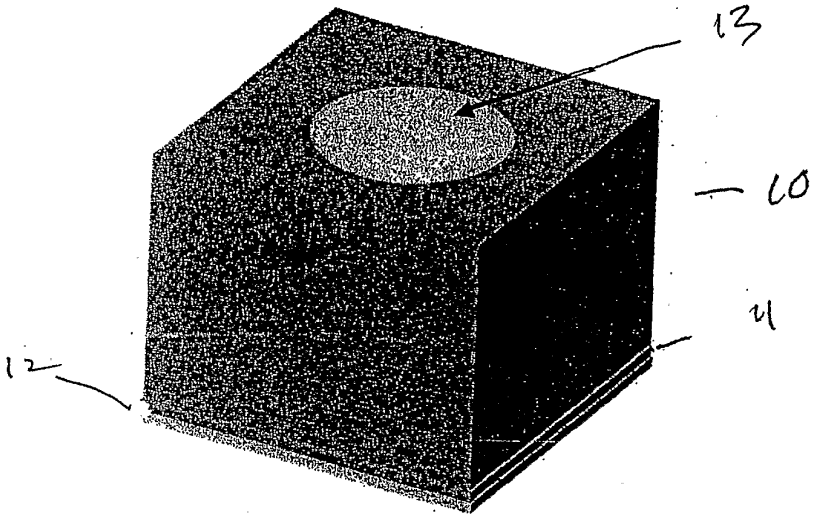


Figure 1

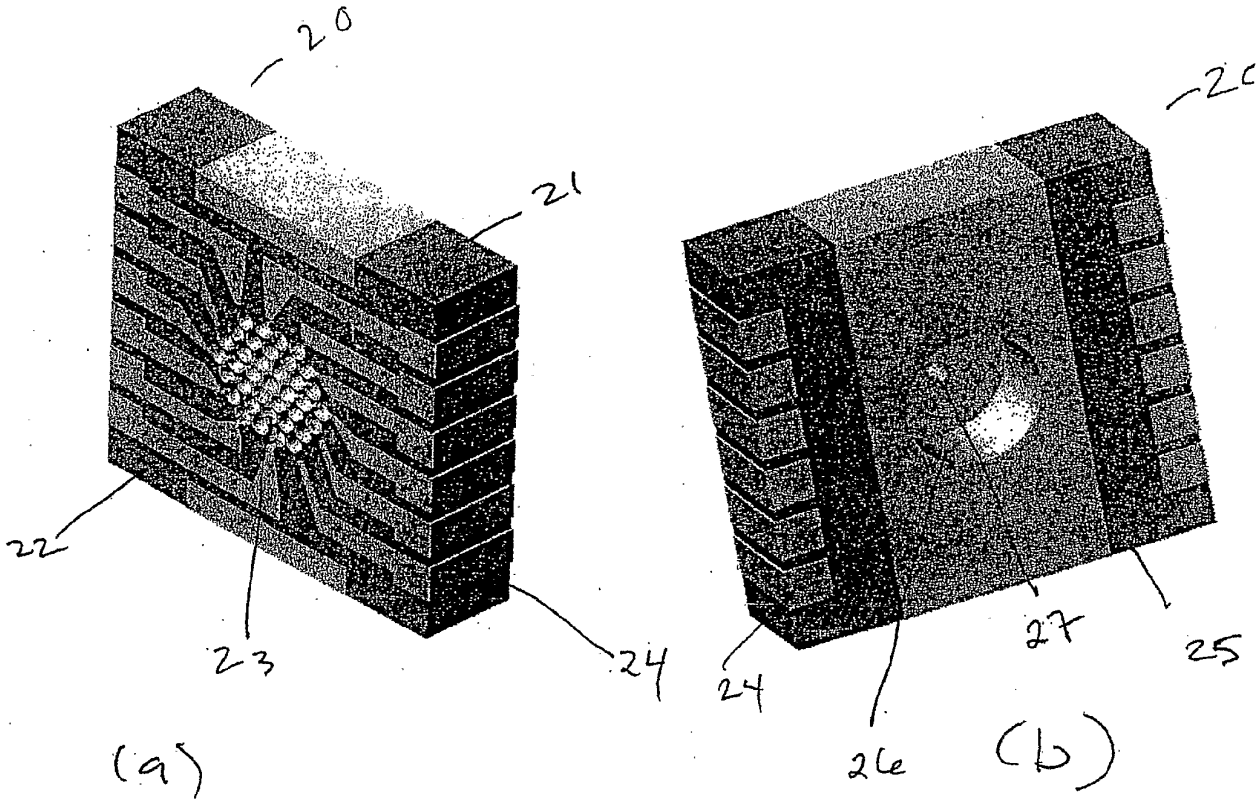


Figure 2

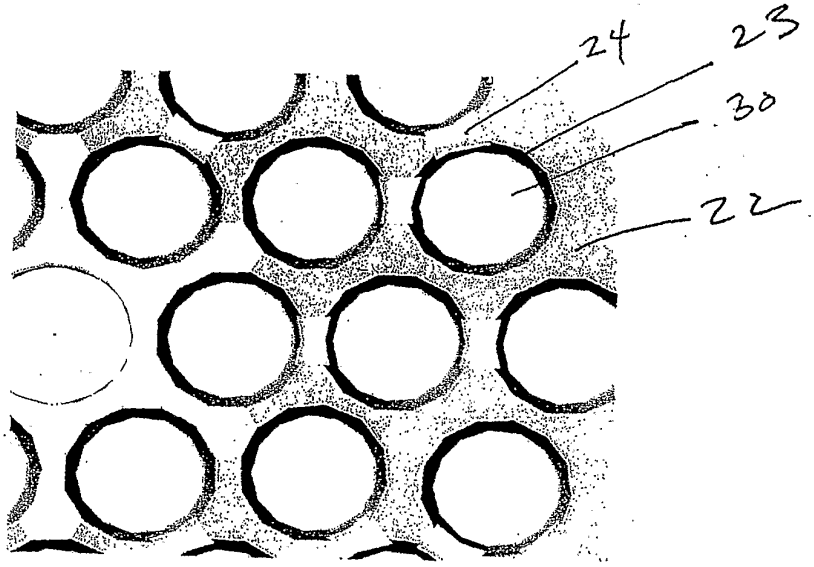


Figure 3

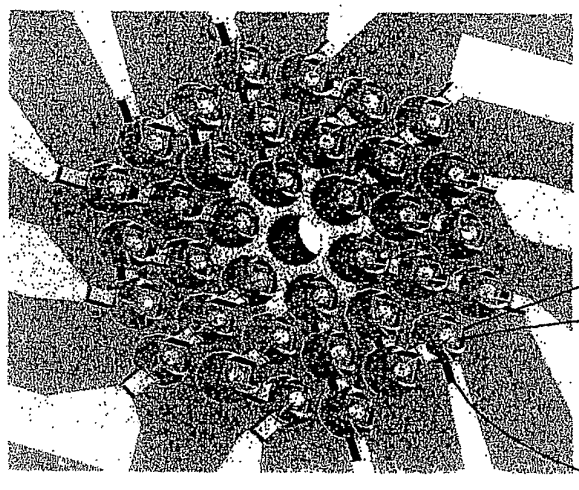


Figure 4

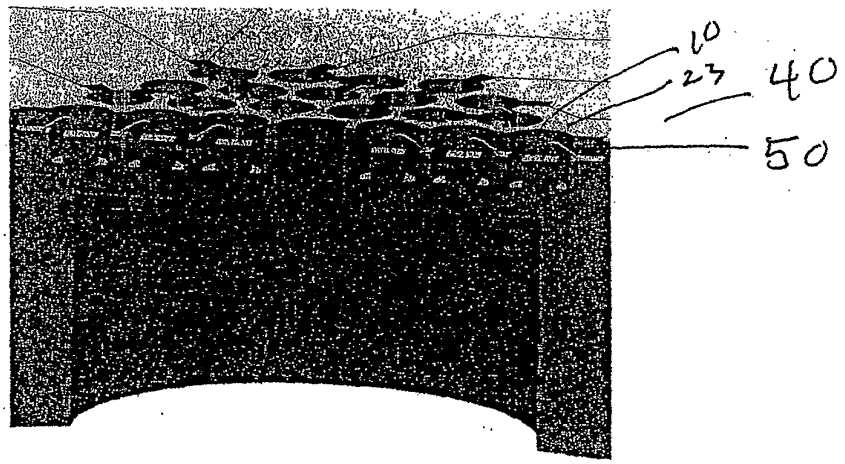


Figure 5

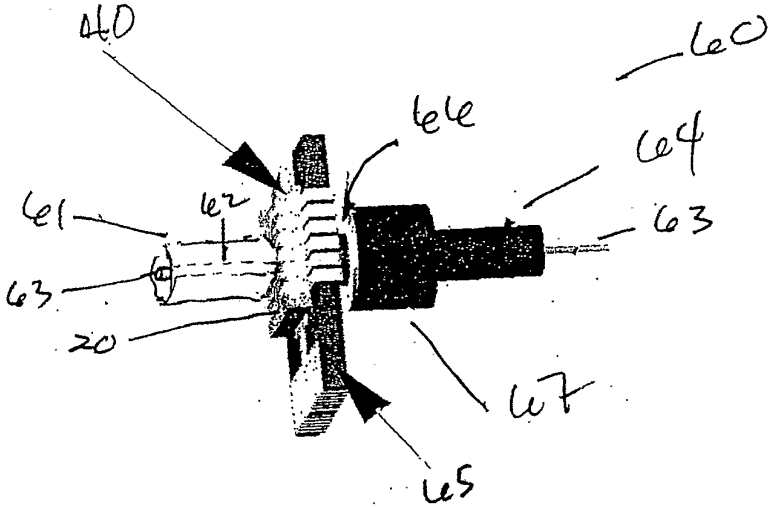


Figure 6.

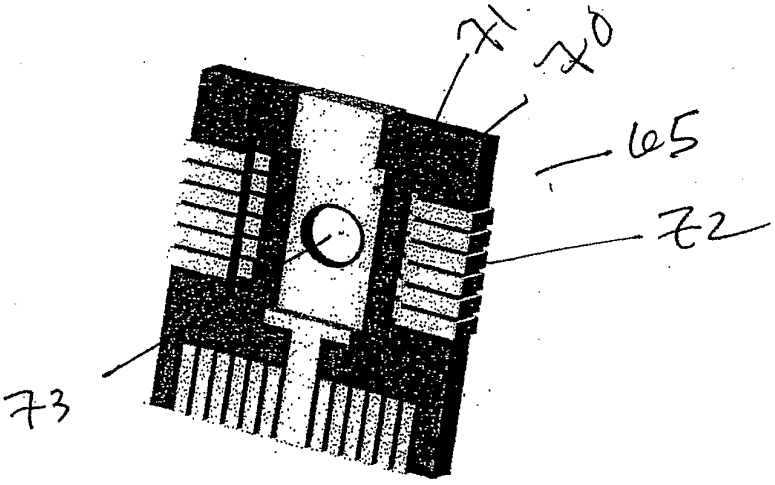


Figure 7

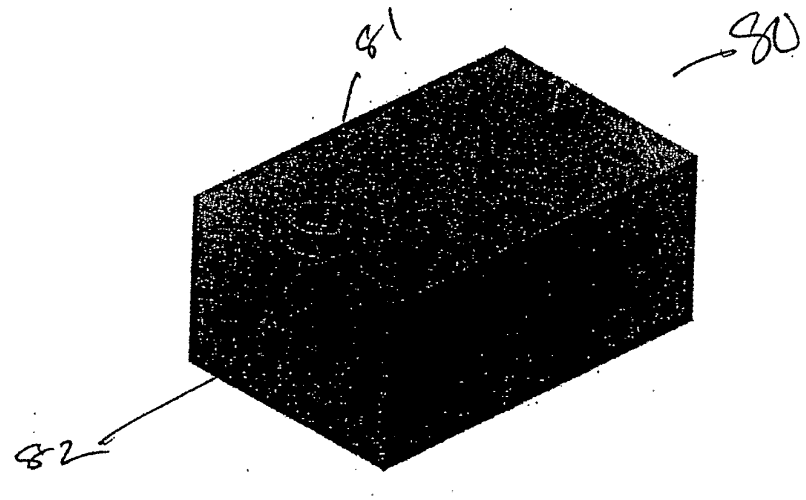


Figure 8

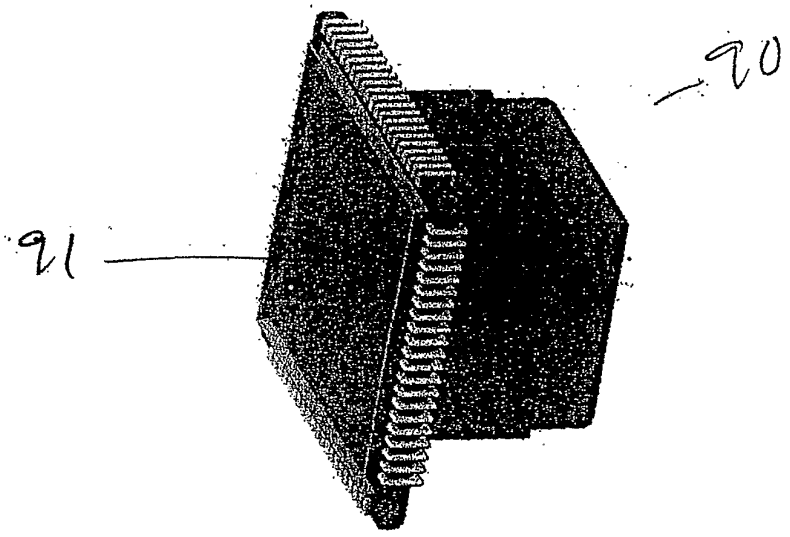


Figure 9

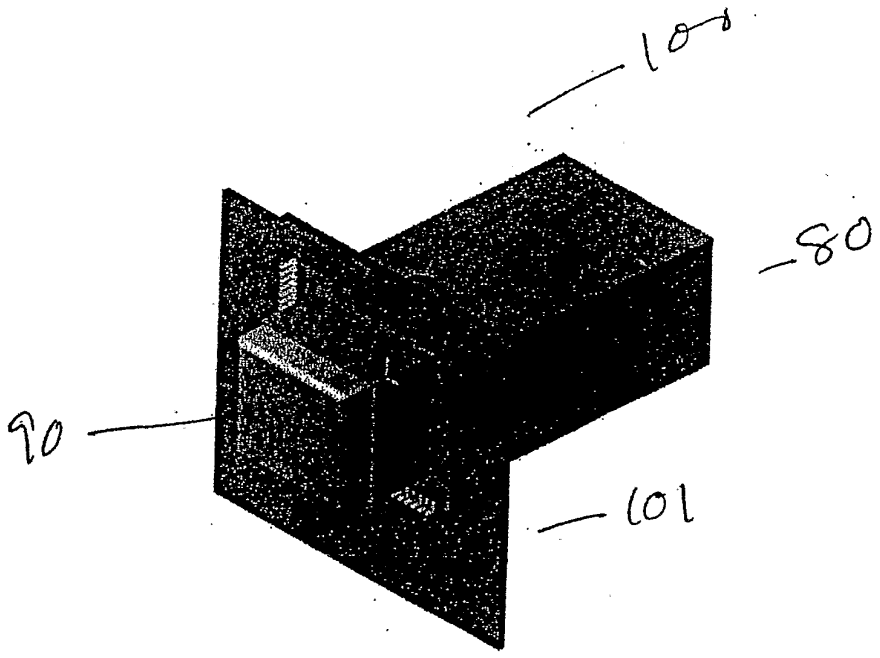


Figure 10.

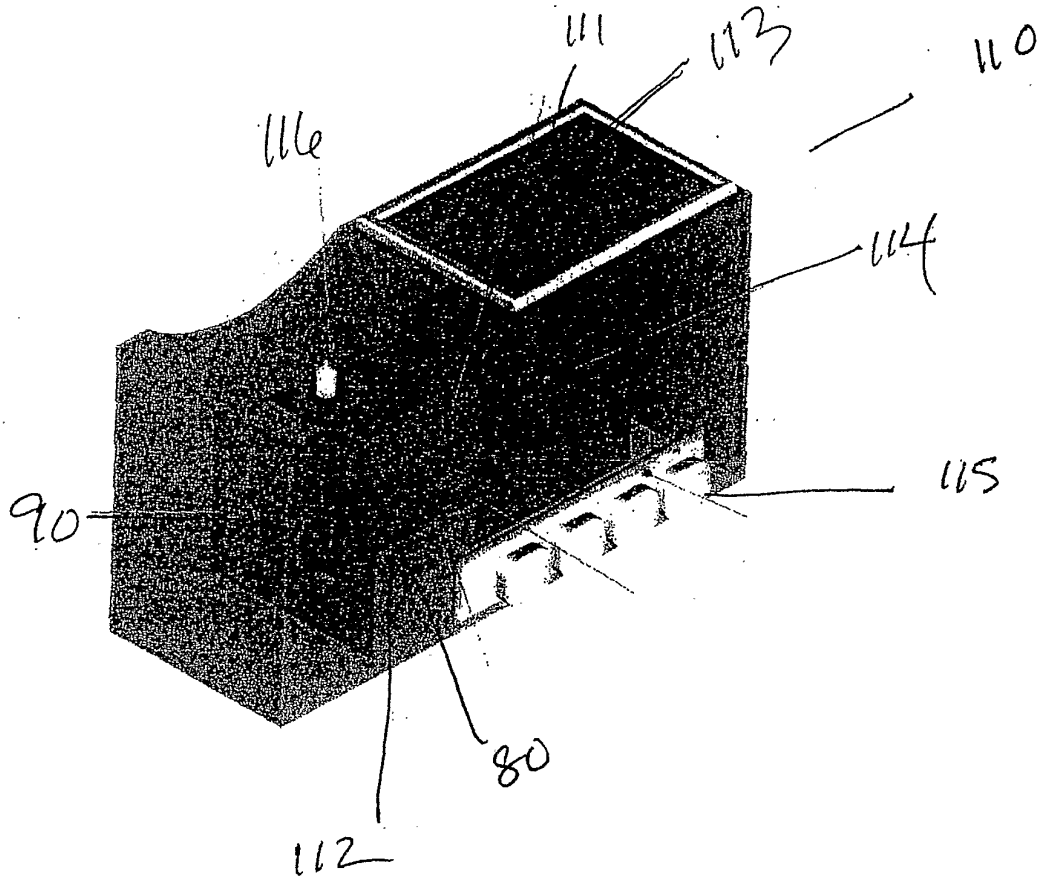


Figure 11

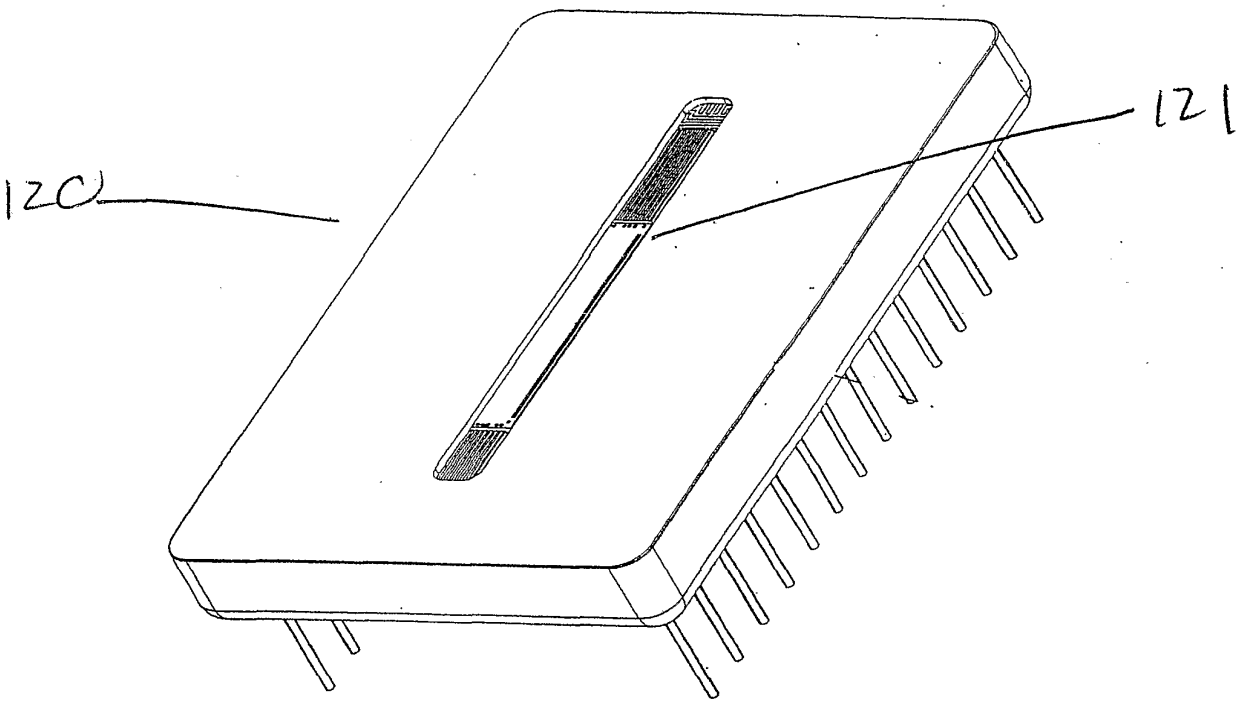


Figure 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/29189

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/00, 6/00
US CL :356/39; 600/476
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 356/39; 600/476

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,601,079 A (WONG et al.) 11 February 1997 (11.02.1997), see entire document.	1-52
Y	US 5,638,816 A (KIANI-AZARBAYJANY et al.) 17 June 1997 (17.06.1997), see entire document.	1-52

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
16 NOVEMBER 2001	**26 December 2001**
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Sharon D. Hoppe ROY M. PUNNOOSE
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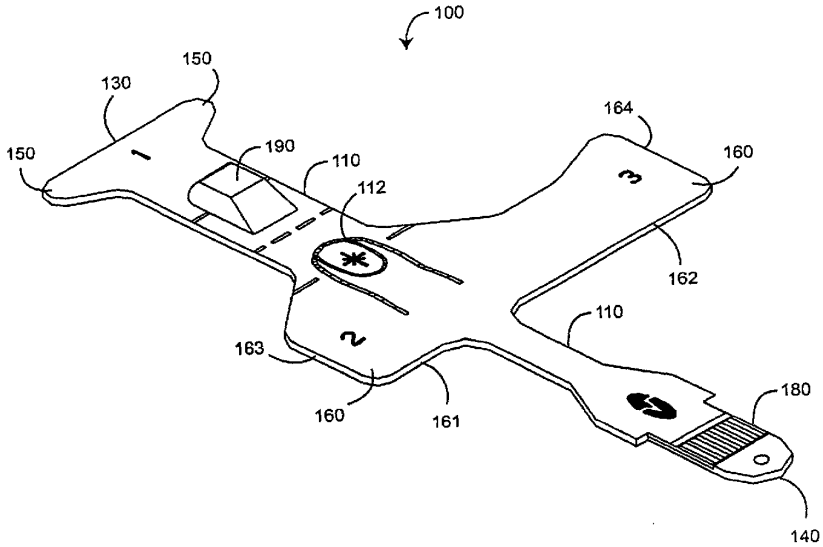
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: FLEX CIRCUIT SHIELDED OPTICAL SENSOR



(57) Abstract: A flex circuit optical sensor has an integrated Faraday shield. A conductive trace layer disposed on a substrate is used to form a conductive grid which shields the face of a photodetector. A conductive ink layer is formed on a substrate side opposite the trace layer. The back and sides of the detector are shielded by flex circuit flaps that have the conductive ink layer but substantially exclude the trace layer so as to fold over and closely adhere to the detector body. The shielded substrate flaps advantageously eliminate a separate detector shield, which is typically fabricated with an etched copper part that must be attached to a flex circuit before mounting the detector.

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FLEX CIRCUIT SHIELDED OPTICAL SENSOR

BACKGROUND OF THE INVENTION

Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of a person's oxygen supply. Early detection of low blood oxygen level is critical in the medical field, for example in critical care and surgical applications, because an insufficient supply of oxygen can result in brain damage and death in a matter of minutes. A pulse oximetry system consists of a sensor applied to a patient, a pulse oximeter, and a patient cable connecting the sensor and the pulse oximeter. The pulse oximeter may be a standalone device or may be incorporated as a module or built-in portion of a multiparameter patient monitoring system and typically provides a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each pulse. In addition, the pulse oximeter may display the patient's plethysmograph, which provides a visual display of the patient's pulse contour and pulse rate.

SUMMARY OF THE INVENTION

One aspect of a flex circuit shielded optical sensor is an emitter and detector mounted to a flex circuit. The emitter is configured to transmit optical radiation and the detector is configured to receive optical radiation from the emitter. A plurality of flap portions of the flex circuit each having an unfolded position extending from the flex circuit and a folded position at least partially enclosing the detector. In one embodiment, the flap portions comprise a back flap configured to fold over and adhere to a first portion of the detector and a side flap configured to fold over and adhere to a second portion of the detector. In another embodiment the flex circuit comprises a substrate layer having a first side and a second side and a conductive layer disposed on the second side substantially including the flap portions so that the flap portions in the folded position shield electromagnetic interference from the detector. The sensor may also comprise a trace layer disposed on the first side providing signal connections for the detector and the emitter. A conductive grid portion of the trace layer is proximate the flap portions and is configured to form a Faraday shield for the detector in conjunction with the flap portions. The trace layer may be substantially excluded from the flap portions.

Another aspect of a flex circuit shielded optical sensor is a flex circuit substrate having a first side and an opposite second side. A trace layer is disposed on the first side and has a pattern of conductors so as to electrically connect with an emitter and a detector. A conductive grid portion of the trace layer has at least one aperture so as to pass optical radiation from the emitter to the detector. The trace layer is configured to mount the detector proximate the grid portion. In one embodiment, the at least one aperture comprises at least one hole drilled through the substrate and the grid. In another embodiment, the substrate is adapted to transmit light and the at least one aperture comprises a pattern etched in the grid. In yet another embodiment, the optical sensor further comprising a shield layer disposed on the second side. The substrate

has a foldable portion including the shield layer and substantially excluding the trace layer. The foldable portion is configured to substantially enclose the detector so as to form a Faraday shield in conjunction with the conductive grid portion. The foldable portion may have a plurality of flaps adapted to adhere to the detector. In a further embodiment, the sensor further comprises a stock material retaining the substrate and having a first wrap with a first end and a second wrap with a second end, where each of the wraps is adapted for finger attachment of the substrate. The wraps are configured so that the first end is covered by the second end and the second end terminates away from a person's palm.

A further aspect of a flex circuit shielded optical sensor is an optical sensor assembly method comprising the steps of fabricating an elongated flex circuit having a component side, an opposite side and a foldable portion. Other steps are creating a plurality of traces on the component side substantially excluding the foldable portion and creating a conductive layer on the opposite side substantially including the foldable portion. Further steps are mounting a detector and an emitter to the component side, where the traces provide electrical connections for the detector and the emitter, and disposing the foldable portion around the detector so as to shield the detector from electromagnetic interference. In one embodiment, the fabricating step comprises the substep of forming a back flap and a plurality of side flaps on the foldable portion. In another embodiment, the disposing step comprises the substeps of adhering the side flaps to first portions of the detector and adhering the back flap to second portions of the detector. In a further embodiment, the assembly method also comprises the step of creating a conductive grid portion of at least one of the traces. The mounting step may comprise the substep of positioning the detector proximate the grid portion so as to shield the detector from electromagnetic interference.

Yet another aspect of a flex circuit shielded optical sensor is a substrate means for supporting a flex circuit, a trace means disposed on a first side of the substrate means for connecting to a detector and an emitter, a conductive ink means disposed on a second side of the substrate for shielding the flex circuit, and a shield means including the substrate means and the conductive ink means for folding onto and attaching to the detector. In one embodiment, the optical sensor further comprises a grid means portion of the trace means for forming a Faraday shield around the detector. The grid means may comprise an aperture means for transmitting light to the detector. In another embodiment, the optical sensor further comprises a wrap means for finger attachment without an exposed wrap end on the palm-side of a finger.

For purposes of summarizing the invention, certain aspects, advantages and novel features of the invention have been described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features will be embodied in any particular embodiment of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

A general architecture that implements the various features of the invention will now be described with reference to the drawings. The drawings and the associated descriptions are provided to illustrate embodiments of the invention and not to limit the scope of the invention. Throughout the drawings, reference

numbers are re-used to indicate correspondence between referenced elements. In addition, the first digit of each reference number indicates the figure in which the element first appears.

FIGS. **1A-B** are perspective views of a flex-circuit-shielded optical sensor;

FIGS. **2A-E** are perspective views of a flex circuit shield folded to enclose an optical sensor detector;

FIGS. **3A-B** are component side and non-component side views, respectively, of an optical sensor flex circuit;

FIG. **4** is a graphical depiction identifying the relative placement of various flex circuit layers;

FIGS. **5A-F** are views of the various flex circuit layers;

FIG. **6** is a functional flowchart of flex circuit shielded optical sensor construction;

FIG. **7** is a component-side perspective view of a flex circuit panel;

FIGS. **8A-B** are exploded and assembled perspective views, respectively, of a sensor core assembly;

FIG. **9A-E** are top, sectional, bottom, front and perspective views, respectively, of a detector cavity; and

FIGS. **10A-B** are an exploded view and a perspective view, respectively, of a sensor panel.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Sensor Configuration

FIG. **1A** illustrates one embodiment of a flex circuit shielded optical sensor. The sensor **100** has a central body **110**, a foldover end **130**, a connector end **140**, a pair of adhesive end attachment wraps **150**, a pair of adhesive middle attachment wraps **160**, a connector **180** and a detector housing **190**. The end wraps **150** and middle wraps **160** extend on either side of the central body **110** and are used to attach the sensor **100** to a patient's finger, in a manner similar to that described in US Patent No. 5,782,757 entitled "Low Noise Optical Probe," which is assigned to the assignee of the present invention and incorporated by reference herein. The central body **110** retains a flex circuit assembly **200** (FIGS. **2A-B**), described in detail below. The flex circuit assembly **200** is a portion of a sensor core assembly **800** (FIG. **8A-B**), which is sandwiched into a completed sensor **100**, as described in detail with respect to FIGS. **8-10**, below.

As shown in FIG. **1A**, an emitter **760** (FIG. **7**) is located proximate a printed target **112** that indicates finger placement. A detector **740** (FIG. **7**) is located in the detector housing **190**. The sensor **100** is configured so that, when attached to a finger, the emitter **760** (FIG. **7**) projects light through the fingernail, through the blood vessels and capillaries underneath and into the detector **740** (FIG. **7**), which is positioned at the finger tip opposite the fingernail. The sensor **100** may also have an identification (ID) component **780** (FIG. **7**) with multiple uses depending on the manufacturer, such as an indicator of LED wavelength, sensor type or manufacturer. The connector **180** electrically connects the sensor **100** to a pulse oximetry monitor (not shown) via an associated mating connector on a patient cable (not shown).

Also shown in FIG. **1A** in an unwrapped position, the middle wraps **160** include a short attachment wrap **161** and an extended attachment wrap **162**. To attach the sensor to a person's finger, the short attachment wrap **161** is wrapped around the finger first. The extended attachment wrap **162** is then wrapped around the short attachment wrap **161**, covering the short attachment wrap end **163**. The extended attachment wrap end **164** terminates away from the person's palm, such as on the side of the finger or, for small fingers, the back-of-the-hand. In this wrapped position, there are no wrap ends **163**, **164** exposed on the person's palm. As such, the wrap ends **163**, **164** of the middle attachment wraps **160** are not prone to snag, attract debris or delaminate. In one embodiment, the sensor **100** has an optional extension **110** to a connector **180**. Alternatively, the sensor **100** may have a connector **180** proximate the middle wraps **160** with no extension **110**, such as shown in FIG. **1B**, described below.

FIG. **1B** illustrates another embodiment of a flex circuit shielded optical sensor. The sensor **100** has a central body **110**, a printed target **112**, a foldover end **130**, a connector end **140**, an adhesive end attachment wrap **150**, a pair of adhesive middle attachment wraps **160**, a connector **180** and a detector housing **190** and retains a flex circuit assembly **200** (FIGS. **2A-B**), as described with respect to FIG. **1A**, above. As compared with the embodiment shown in FIG. **1A**, the end wrap **150** and middle wraps **160** have greater surface area to achieve better finger adhesion. In particular, the end wrap **150** is a generally rectangular, flared extension from the central body **110** having rounded corners. The middle wraps **160** include a short attachment wrap **161** and an extended attachment wrap **162**. The extended attachment wrap **162** is configured to wrap around the short attachment wrap **161** so that there are no wrap ends **163**, **164** exposed on the person's palm, as described with respect to FIG. **1A**, above.

FIGS. **2A-E** illustrate a flex circuit assembly **200**. As shown in FIG. **2A**, the flex circuit assembly **200** has a flex circuit **300**, a conductive detector shield **201**, a detector **740**, an emitter **760**, and an ID component **780**. Mounted on the flex circuit **300** are the emitter **760**, having both red and infrared LEDs encapsulated on a leaded carrier, the detector **740** having a photodiode encapsulated on a leaded carrier and the ID component **780** such as a resistor on a leadless carrier. The flex circuit **300** is described in detail with respect to FIGS. **3-5**, below. Mounting of the components **740**, **760**, **780** is described in further detail with respect to FIG. **7**, below.

FIGS. **2A-E** also illustrate the folding of the detector shield **201** around the detector **740**. As shown in FIG. **2A**, the detector shield **201** is an integral portion of the flex circuit **300** and is located at one end of the flex circuit **300** proximate the detector **740**. The shield **201** has a back flap **210** and a pair of side flaps **230**, which have an unfolded position and a folded position. In the unfolded position illustrated in FIG. **2A**, the flaps **210**, **230** extend from the flex circuit **300**. In the folded position illustrated in FIGS. **2D-E**, each of the flaps **210**, **230** at least partially enclose the detector **740**.

As shown in FIG. **2B**, the side flaps **230** are folded toward and adhere to the sides of the detector **740**. As shown in FIG. **2C**, the back flap **210** is also folded toward and adheres to the top of the detector **740**.

As shown in FIG. **2D**, the back flap **210** is also folded over the detector **740** and adheres to the back face of the detector **740** and the surface of the flex circuit **300**. As shown in FIG. **2E**, the detector shield **201** is configured to substantially enclose the detector **740** in conjunction with a conductive grid **310** (FIG. **3A**), acting as a Faraday shield to limit electromagnetic interference (EMI) reaching the detector **740**. The detector shield **201** and conductive grid **510** (FIG. **3A**) are described in further detail with respect to FIGS. **3A** and **5D-F**, below.

FIGS. **3A-B** illustrate one embodiment of the flex circuit **300**, which has an elongated body **302** widened at a connector end **304** and an opposite shield end **303**. The detector shield **201**, as described with respect to FIGS. **2A-E**, above, is located at the shield end **303**. Between the ends **303**, **304** is a widened body portion **305** having an emitter aperture **308**. The body **302** has a component side **301** (FIG. **3A**) and a non-component side **306** (FIG. **3B**). The flex circuit **300** is made up of multiple conducting and insulating layers, as described with respect to FIGS. **4-5**, below.

As shown in FIG. **3A**, the flex circuit component side **301** has a conductive grid **510**, a detector pad **520**, an emitter pad **530**, an ID pad **540** and connector traces **550**. The emitter pad **530** and ID pad **540** are exposed through coverlays **410**, **430** (FIG. **4**) at an emitter pad aperture **330** and an ID pad aperture **340**, respectively. The detector **740** (FIG. **7**), emitter **760** (FIG. **7**) and ID **780** (FIG. **7**) components are mounted to the flex circuit **300** at the detector **520**, emitter **530** and ID **540** pads, as described with respect to FIG. **7**, below. The detector shield **201** has a back flap pressure sensitive adhesive (PSA) **372** and a side flap PSA **374** that allow the shield **201** to adhere to the detector **740** (FIG. **7**), as described with respect to FIGS. **2A-E**, above.

As shown in FIG. **3B**, the non-component side **306** has a cover PSA **382** and a cavity PSA **384** that adhere inside the detector housing **190** (FIG. **1**) and also a tab PSA **388** that adheres to the connector tab **820** (FIG. **8A**), as described with respect to FIGS. **8A-B**, below. The conductive grid **510** (FIG. **3A**) has apertures **512** that allow light to reach the detector **740** (FIG. **7**). Specifically, light is transmitted from the emitter component **760** (FIG. **2A**), through the emitter aperture **308**, through a fingernail bed and exits from a fingertip, entering the detector housing **190** (FIG. **1**) and into the detector grid **510** to be received by the detector **740** (FIG. **7**). The flex circuit **300** has printed traces of deposited or etched conductive material, described with respect to FIG. **5D**, below.

FIG. **4** illustrates the layered structure of the flex circuit **300**, which includes a top coverlay **410**, a top ink layer **420**, an inner coverlay **430**, a trace layer **440** and a substrate layer **460**, a bottom ink layer **470**, a bottom coverlay **480**, a PSA layer **490** and a release liner **496**. The trace layer **440** consists of conductive material carried on an insulating substrate **460**. The trace layer **440** has a trace pattern that defines a conductive grid **510**, a detector pad **520**, an emitter pad **530**, an ID pad **540**, connector contacts **550** and associated interconnects. In a particular embodiment, the trace layer **440** and substrate layer **460** are constructed from a single sided 1 oz. rolled/annealed copper clad 1 mil. polyimide film, and a trace pattern is

etched from the copper accordingly. The bottom ink layer **470** is carried on the opposite side of the insulating substrate **460**, and, in a particular embodiment, is DUPONT CB028 silver-filled thermoplastic screenable ink. The inner coverlay **430** carries the top ink layer **420** and insulates it from the trace layer **440**. Thru-holes in the inner coverlay **430** and substrate **460** provide selective connections between trace layer **440**, the top ink layer **420**, and the bottom ink layer **470**. The top coverlay **410** and bottom coverlay **480** provide insulating protection for the top ink layer 420 and the bottom ink layer **470**. The PSA layer **490** and the release liner layer **496** provide the cover, cavity and tab PSA **382**, **384**, **388** (FIG. **3B**). Similar layers (not shown) on the top coverlay **410** provide the detector shield PSA **372**, **374** (FIG. **3A**). In a particular embodiment, the coverlays **410**, **430**, **480** are 1 mil polyimide and the PSA is 3M-467MP. These layers **410-470** are described in further detail with respect to FIGS. **5A-F**, below.

FIGS. **5A-F** illustrate the flex circuit layers identified with respect to FIG. **4**, above. FIG. **5A** illustrates the top coverlay **410** positioned relative to the substrate **460** (dashed outline). The top coverlay **410** is an insulating film having an emitter aperture **308**, an emitter pad aperture **330** and an ID pad aperture **340**. The emitter aperture **330** allows light from the emitter **760** (FIG. **7**) to pass through the coverlay **410** and other layers. The emitter pad aperture **330** and ID pad aperture **340** expose the emitter pad contacts **530** (FIG. **3A**) and ID pad contacts **540** (FIG. **3A**) for attachment of the emitter **760** (FIG. **7**) and ID component **780** (FIG. **7**). In one embodiment, the top coverlay **410** is 1 mil polyimide.

FIG. **5B** illustrates the top ink layer **420** positioned relative to the substrate **460** (dashed outline) and the inner coverlay **430** (solid outline). The top ink layer **420** (filled area) is applied to the inner coverlay **430** with a pull back **422** around the periphery of the inner coverlay **430**. Additional pullbacks **424** are around the peripheries of the emitter aperture **308** (FIG. **5C**), the emitter pad aperture **330** (FIG. **5C**) and the ID pad aperture **340** (FIG. **5C**). In one embodiment, the top ink layer is DUPONT CB028 silver-filled thermoplastic screenable ink and the pullbacks **422**, **424** are a minimum 25 mil.

FIG. **5C** illustrates the inner coverlay **430** positioned relative to the substrate **460** (dashed outline). The inner coverlay **430** is an insulating film having an emitter aperture **308**, an emitter pad aperture **330** and an ID pad aperture **340**, corresponding to those described with respect to the top coverlay **410** (FIG. **5A**), above. The inner coverlay **430** has thru-holes **432**, **434**, **436** that allow the top ink layer **420** (FIG. **5B**) to electrically connect with portions of the trace layer **440** (FIG. **5D**). In particular, an upper thru-hole **432** and a middle thru-hole **434** provide connections to a grid trace **590** (FIG. **5D**), and a lower thru-hole **436** provides a connection to a guard trace **580** (FIG. **5D**).

FIG. **5D** illustrates the trace layer **440** positioned relative to the substrate **460** (dashed outline). The trace layer **440** is advantageously substantially excluded from the flap portions **461**, **465** (FIG. **5E**) of the substrate layer **460**, allowing the flaps **210**, **230** (FIG. **2A-E**) to fold over and closely adhere to the detector **740** (FIGS. **2A-E**) without obstruction from circuit components, conductors and connectors. The trace layer **440** has a detector grid **510**, a detector pad **520**, an emitter pad **530**, an ID pad **540**, and connector contacts

550. The grid 510 has a grid conductor 512 that provides an EMI shield for the detector 740 (FIG. 7) in conjunction with the flex circuit shield 201 (FIG. 3A). The grid 510 also has grid apertures 514 that allow light to reach the detector 740 (FIG. 7). Detector traces 560 electrically connect a detector pinout portion 561 of the contacts 550 to the detector pad 520. Emitter traces 570 electrically connect an emitter pinout portion 571 of the contacts 550 to the ID pad 540 and the emitter pad 530. A guard trace 580 extends from a shield pinout portion 581 of the contacts 550 proximate the detector traces 560 to a stub proximate the detector pad 520. A grid trace 590 extends from the grid 510 to a stub proximate the connector contacts 550. Grid pads 592, 594 provide an electrical connection via thru-holes 432, 434 (FIG. 5C) and thru-holes 462, 464 (FIG. 5E) at either end of the grid trace 590 to the top ink layer 420 (FIG. 5B) and bottom ink layer 470 (FIG. 5F). A guard pad 582 provides for an electrical connection via a thru-hole 436 (FIG. 5C) and a thru-hole 466 (FIG. 5E) at one end of the guard trace 580 to the top ink layer 420 (FIG. 5B) and bottom ink layer 470 (FIG. 5F), respectively.

FIG. 5E illustrates the substrate layer 460, which has back flap 461 and side flaps 465 that are the substrate layer portions of the shield back flap 210 (FIGS. 2A-E) and side flaps 230 (FIGS. 2A-E), respectively. The substrate layer 460 also has indents 463 that narrow the substrate between the back flap 461 and the side flaps 463, allowing the back flap 461 to fold as described with respect to FIGS. 2A-E, above. Further, the substrate layer 460 has slots 467 on the opposite end of the side flaps 465 from the indents 463 that, in conjunction with the indents 463 allow the side flaps 465 to fold as described with respect to FIGS. 2A-E, above. In addition, the substrate layer 460 has grid apertures 514 and an emitter aperture 308, described with respect to FIGS. 3A-B, above. Substrate thru-holes 462, 464, 466 are drilled to allow the bottom ink 470 (FIG. 5F) to connect with portions of the trace layer 440 (FIG. 5D), as described above.

FIG. 5F illustrates the bottom ink layer 470 positioned relative to the substrate 460 (solid outline). The bottom ink layer 470 is advantageously substantially included on the flap portions 461, 465 (FIG. 5E) of the substrate layer 460, allowing the flaps 210, 230 (FIG. 2A-E) to shield the detector 740 (FIGS. 2A-E) from electromagnetic interference. The bottom ink layer 470 (filled area) is applied to the substrate 460 with a pull back 472 around the periphery of the substrate 460 except in a shield area 474 proximate the detector end of the substrate. The bottom ink layer 470 also has a pull back 476 around the emitter aperture 308. In one embodiment, the bottom ink layer is DUPONT CB028 silver-filled thermoplastic screenable ink and the pullback is a minimum 25 mil.

Sensor Fabrication

Flex Circuit Assembly

FIG. 6 illustrates general construction steps 600 for a flex-circuit-shielded optical sensor 100 (FIG. 1). As represented by a fabricate flex circuit panel activity block 610, multiple flex circuits 300 (FIGS. 3A-B) are formed on a panel constructed of multiple layers 400 (FIG. 4), as described above. In a particular

embodiment, a 7-up panel layout is used. Represented by an attach panel components activity block **620**, panel components are attached to each of the multiple flex circuits on a panel **700** (FIG. **7**).

FIG. **7** illustrates the flex-circuit panel fabrication and panel component attachment. Multiple flex circuits are formed by etching a pattern of conductors in the trace layer **440** (FIG. **4**), which creates a circuit as described with respect to FIG. **5D**, above. Thru-holes are drilled in the inner coverlay **430** (FIG. **4**) and substrate **460** (FIG. **4**), as described with respect to FIGS. **5C**, **5E**, above. The inner coverlay **430** (FIG. **4**) and substrate **460** (FIG. **4**) layers are laminated. Conductive ink is screened onto the inner coverlay **430** (FIG. **4**) and substrate **460** (FIG. **4**) as described with respect to FIGS. **5B** and **5F**, above. The remaining layers are laminated. The contacts **550** are selectively electroplated with gold. In a particular embodiment, the plating is 10 micro inches minimum of hard gold using a pulse plating method over 75 ± 25 micro inches of nickel. Grid aperture holes **514** are drilled. The detector **740**, emitter **760** and ID **780** components are electrically connected to the panel pads **520**, **530**, **540**.

As shown in FIG. **6**, represented by a die-cut panel activity block **630**, the flex circuit panel **700** (FIG. **7**), described above, is die-cut to separate individual flex circuits **200** (FIGS. **2A-E**). Represented by a fold shield over detector activity block **640** the shield **201** of each flex circuit assembly **200** is folded so as to enclose the detector **740** (FIG. **7**) and shield it from EMI, as described with respect to FIGS. **2A-E**, above.

Sensor Core Assembly

Also shown in FIG. **6**, a place cavity on base stock activity block **651**, a place connector tab on base stock activity block **655** and a place flex circuit on base stock activity block **660** represent attachment of the detector cavity **900** (FIG. **9**) and the connector tab **820** (FIG. **8A**) to the flex circuit assembly **200** (FIG. **8A**). A place disk and cover over cavity activity block **670** represents completing the detector housing **190** (FIG. **8B**) to finish a sensor core assembly **800** (FIG. **8A-B**) as described below.

FIGS. **8A-B** illustrate the sensor core assembly **800**, which has a flex circuit assembly **200**, including a folded over flex circuit detector shield **201**, as described with respect to FIGS. **2A-E** and **7**, above. The sensor core assembly **800** also has a connector tab **820**, a detector cavity **900**, an opaque optical disk **830** and a cover **840**. The connector tab **820** attaches with tab PSA **388** (FIG. **3B**) behind the connector contacts **550**, forming a connector plug **180** configured to engage and electrically connect with a patient cable connector socket (not shown) as described in US Patent No. 5,782,757, referenced above. The connector tab **820** has an aperture **821** that catches onto a latching portion of the mating socket. In a particular embodiment, the connector tab **820** is fabricated of an ABS polymer blend.

As shown in FIGS. **8A-B**, the cavity **900**, disk **830** and cover **840** form a detector housing **190** that retains the detector **740** (FIG. **7**) and corresponding flex circuit shield **201**. The cavity **900** provides a receptacle **920** for the shielded detector **740** (FIG. **7**) and secures the shield **201** against the detector **740** (FIG. **7**), as described with respect to FIGS. **9A-E**, below. Cavity PSA **384** (FIG. **3B**) adheres a portion of the flex circuit assembly **200** inside the cavity **900**. The cover **840** fits over the cavity **900** to physically retain the

detector **740** (FIG. **7**) and to seal out ambient light. An opaque disk **830** provides further ambient light protection and, in one embodiment, is a metal foil. Cover PSA **382** (FIG. **3B**) adheres the disk **830** and cover **840** to the flex circuit assembly **200**. The cover **840** has a flange **842** that serves as a bonding surface for base stock **1010** (FIG. **10A**) and face stock **1020** (FIG. **10A**) material. In one embodiment, the cover **840** is vacuum formed from polystyrene and has an opaque characteristic obtained from coating or from its construction material.

FIGS. **9A-E** illustrate a detector cavity **900**, which has a ramp **910**, a rectangular receptacle **920**, alignment guides comprising a back guide **932** and two side guides **934** and a cavity aperture **940**. The rectangular receptacle **920** is adapted to receive the detector end of the flex circuit assembly **200** (FIGS. **8A-B**). The ramp **910** is wedge-shaped and provides for a smooth transition for the flex circuit assembly **200** (FIGS. **8A-B**) between the surface of the base stock **1010** (FIG. **10A**) and the surface of the rectangular receptacle **920**. The alignment guides **932**, **934** hold the flex circuit assembly **200** (FIGS. **8A-B**) in position so that the detector **740** (FIG. **7**) aligns properly with the aperture **940**. Also, the back guide **932** secures the back flap **210** (FIGS. **2A-E**) and the side guides **934** secure the side flaps **230** (FIGS. **2A-E**) against the detector **740** (FIGS. **2A-E**). The aperture **940** stabilizes a finger within the sensor so as to reduce optical decoupling between the emitter and the detector, avoids compression of finger tissue so as to stabilize the optical path length through the finger, and reduces light-piping, i.e. direct coupling of light between the detector **740** (FIG. **7**) and emitter **760** (FIG. **7**), as described with respect to US Patent No. 5,782,757, referenced above. In one embodiment, the cavity **900** is made from an ABS polymer blend and has an opaque characteristic obtained from coating or from its construction material. In a particular embodiment, the aperture **940** is conical or cylindrical in shape.

Sensor Panel Assembly

Further shown in FIG. **6**, represented by a place face stock over base stock activity block **680**, the face stock **1020** (FIG. **10A**) placement over the base stock **1010** (FIG. **10A**) retains the sensor assembly **800** (FIG. **8B**) within the stock material, as described with respect to FIGS. **10A-B**, below. As represented by a die-cut sensor panel to final shape activity block **690**, individual sensors **100** (FIG. **10B**) are cut from the sensor panel **1000** (FIGS. **10A-B**), as described below. In a particular embodiment, the sensor panel **1000** (FIGS. **10A-B**) is configured for two sensors **100** (FIG. **10B**).

FIGS. **10A-B** illustrate a sensor panel **1000**, which has a base stock **1010** and a face stock **1020** enclosing multiple sensor core assemblies **800**. As shown in FIG. **10A**, the base stock **1010** is a flexible material that is transparent to the wavelength of the emitter. In an alternative embodiment, the base stock **1010** has holes corresponding to the emitter apertures **308** (FIGS. **3A-B**) and grid apertures **514** (FIG. **5E**) of the sensor core assemblies **800**. The base stock **1010** has PSA on the base stock side **1012** to which the face stock **1020** is applied. In one embodiment, the face stock **1020** is a flexible woven material, such as Betham part no. 1107S. The face stock **1020** has housing apertures **1022** that allow portions of the detector

housing covers **840** to protrude through the face stock **1020**. In one embodiment, the face stock **1020** has PSA on the side (not visible) facing the base stock **1010**. A sensor panel **1000** is created by sandwiching the sensor core assemblies **800** between the base stock **1010** and the face stock **1020** and applying pressure so that the base stock **1010** and face stock **1020** bond together, retaining the sensor core assemblies **800**.

As shown in FIG. **10B**, the assembled sensor panel **1000** is cut and the excess material discarded to complete multiple sensors **100**. In one embodiment, a completed sensor panel assembly **1000** forms two sensors **100**.

The flex circuit shielded optical sensor has been disclosed above with respect to a polyimide substrate supporting a copper trace layer. A detector Faraday shield has a detector grid portion fabricated from the copper trace layer and aperture holes drilled through the substrate and the grid so as to allow light to be received by the detector. In an alternative embodiment, a polyester nitrile (PEN) substate supports the copper trace layer. The grid has an aperture pattern etched in the trace layer rather than drilled aperture holes. The PEN material is clear, allowing light to pass to the detector while maintaining mechanical strength in the grid area.

Although the flex circuit shielded optical sensor has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. Moreover, these embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

WHAT IS CLAIMED IS:

1. An optical sensor comprising:

a flex circuit;

an emitter configured to transmit optical radiation;

a detector configured to receive optical radiation from said emitter,

said detector and said emitter mounted to said flex circuit; and

a plurality of flap portions of said flex circuit each having an unfolded position extending from said flex circuit and a folded position at least partially enclosing said detector.

2. The optical sensor according to claim 1 wherein said flap portions comprise:

a back flap configured to fold over and adhere to a first portion of said detector; and

a side flap configured to fold over and adhere to a second portion of said detector.

3. The optical sensor according to claim 1 wherein said flex circuit comprises:

a substrate layer having a first side and a second side; and

a conductive layer disposed on said second side substantially including said flap portions so that said flap portions in said folded position shield electromagnetic interference from said detector.

4. The optical sensor according to claim 3 further comprising:

a trace layer disposed on said first side providing signal connections for said detector and said emitter; and

a conductive grid portion of said trace layer proximate said flap portions, said grid portion configured to form a Faraday shield for said detector in conjunction with said flap portions.

5. The optical sensor according to claim 4 wherein said trace layer is substantially excluded from said flap portions.

6. An optical sensor comprising:

a flex circuit substrate having a first side and an opposite second side;

a trace layer disposed on said first side having a pattern of conductors so as to electrically connect with an emitter and a detector; and

a conductive grid portion of said trace layer having at least one aperture so as to pass optical radiation from said emitter to said detector, said trace layer configured to mount said detector proximate said grid portion.

7. The optical sensor according to claim 6 wherein said at least one aperture comprises at least one hole drilled through said substrate and said grid.

8. The optical sensor according to claim 6 wherein said substrate is adapted to transmit light and said at least one aperture comprises a pattern etched in said grid.

9. The optical sensor according to claim 6 further comprising a shield layer disposed on said second side, said substrate having a foldable portion including said shield layer and substantially excluding said trace layer, said foldable portion configured to substantially enclose said detector so as to form a Faraday shield in conjunction with said conductive grid portion.

10. The optical sensor according to claim 9 wherein said foldable portion has a plurality of flaps adapted to adhere to said detector.

11. The optical sensor according to claim 6 further comprising:

a stock material retaining said substrate and having a first wrap with a first end and a second wrap with a second end,

each of said wraps adapted for finger attachment of said substrate,

said wraps configured so that, in a wrapped position, said first end covers said second end and said second end terminates distal a person's palm.

12. An optical sensor assembly method comprising the steps of:

fabricating an elongated flex circuit having a component side, an opposite side and a foldable portion;

creating a plurality of traces on said component side substantially excluding said foldable portion;

creating a conductive layer on said opposite side substantially including said foldable portion;

mounting a detector and an emitter to said component side, said traces providing electrical connections for said detector and said emitter; and

disposing said foldable portion around said detector so as to shield said detector from electromagnetic interference.

13. The optical sensor assembly method according to claim 12 wherein said fabricating step comprises the substep of forming a back flap and a plurality of side flaps on said foldable portion.

14. The optical sensor assembly method according to claim 12 wherein said disposing step comprises the substeps of adhering said side flaps to first portions of said detector and adhering said back flap to second portions of said detector.

15. The optical sensor assembly method according to claim 12 further comprising the step of creating a conductive grid portion of at least one of said traces.

16. The optical sensor assembly method according to claim 15 wherein said mounting step comprises the substep of positioning said detector proximate said grid portion so as to shield said detector from electromagnetic interference.

17. An optical sensor comprising:

a substrate means for supporting a flex circuit;

a trace means disposed on a first side of said substrate means for connecting to a detector and an emitter;

a conductive ink means disposed on a second side of said substrate for shielding said flex circuit; and

a shield means including said substrate means and said conductive ink means for folding onto and attaching to said detector.

18. The optical sensor according to claim 17 further comprising a grid means portion of said trace means for forming a Faraday shield around said detector.

19. The optical sensor according to claim 18 wherein said grid means comprises an aperture means for transmitting light to said detector.

20. The optical sensor according to claim 17 further comprising a wrap means for finger attachment without an exposed wrap end on the palm of a hand.

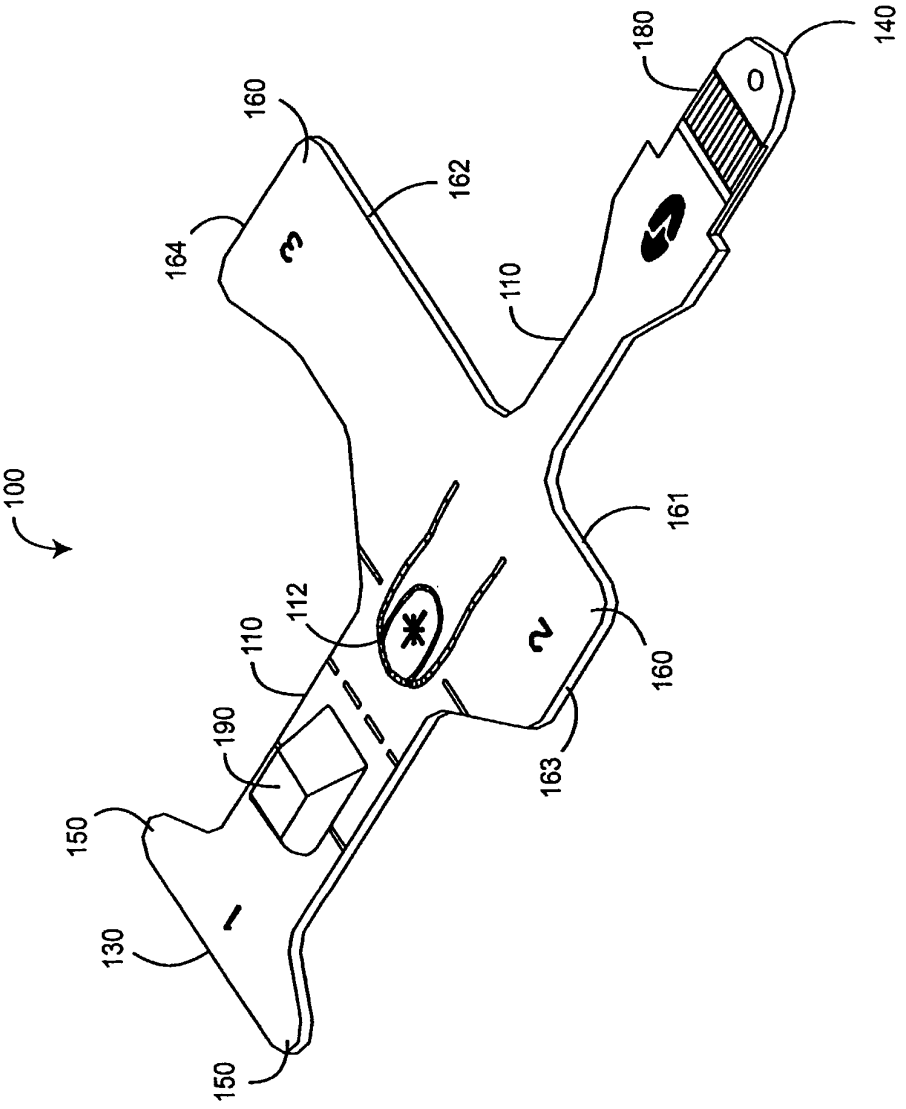


FIG. 1A

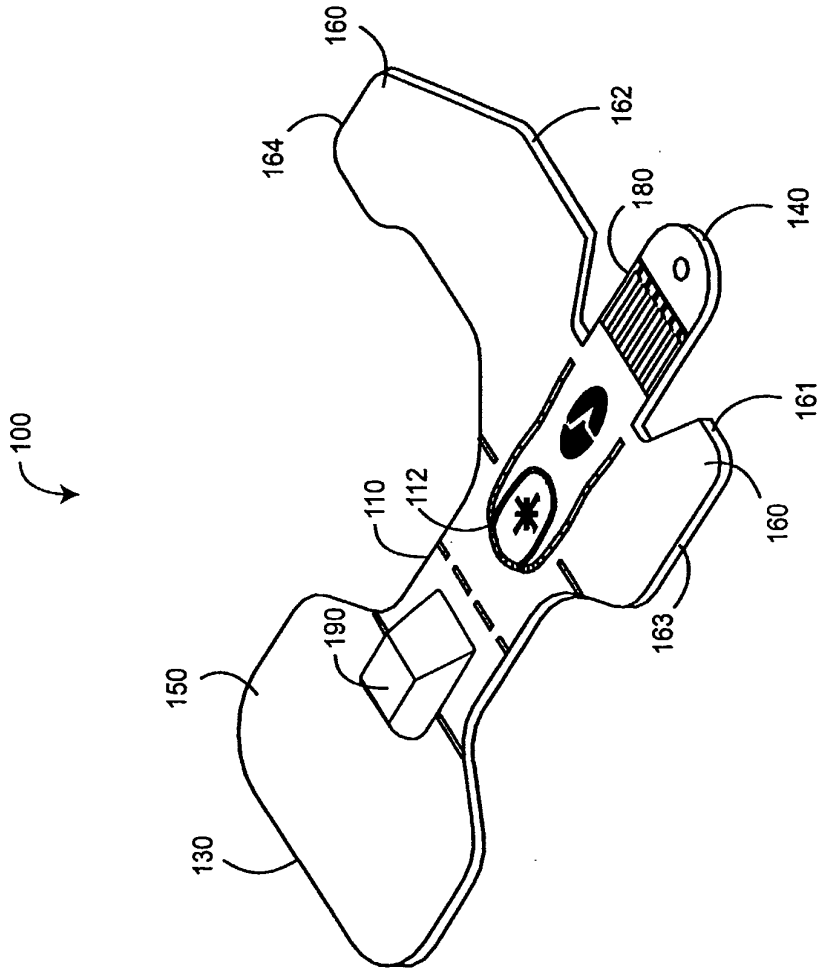


FIG. 1B

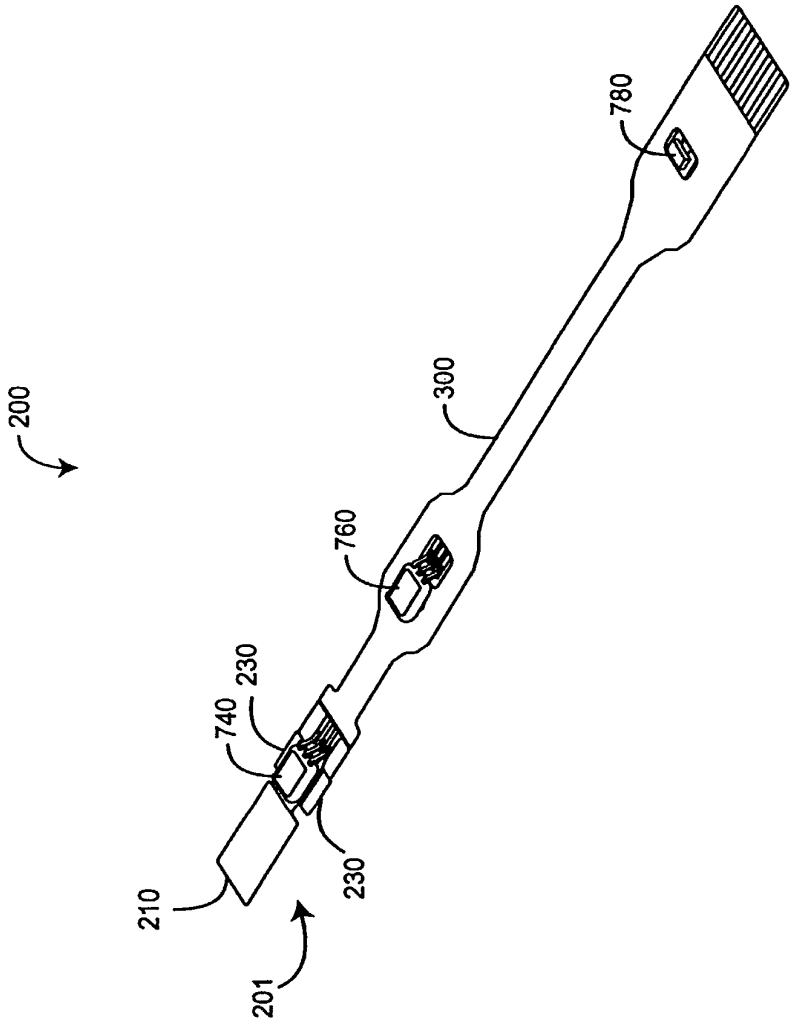


FIG. 2A

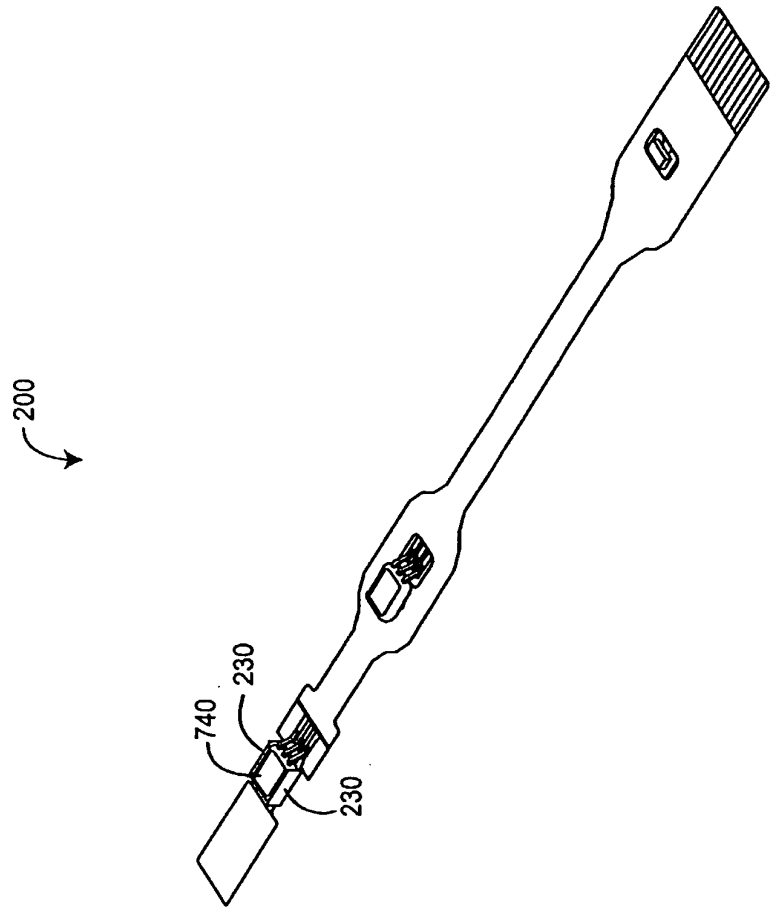


FIG. 2B

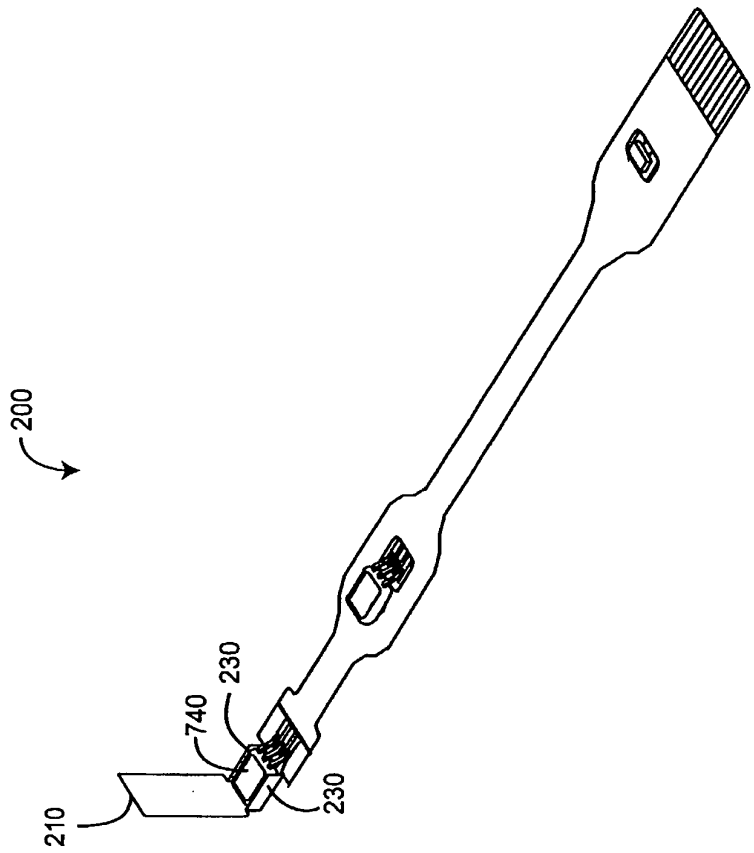


FIG. 2C

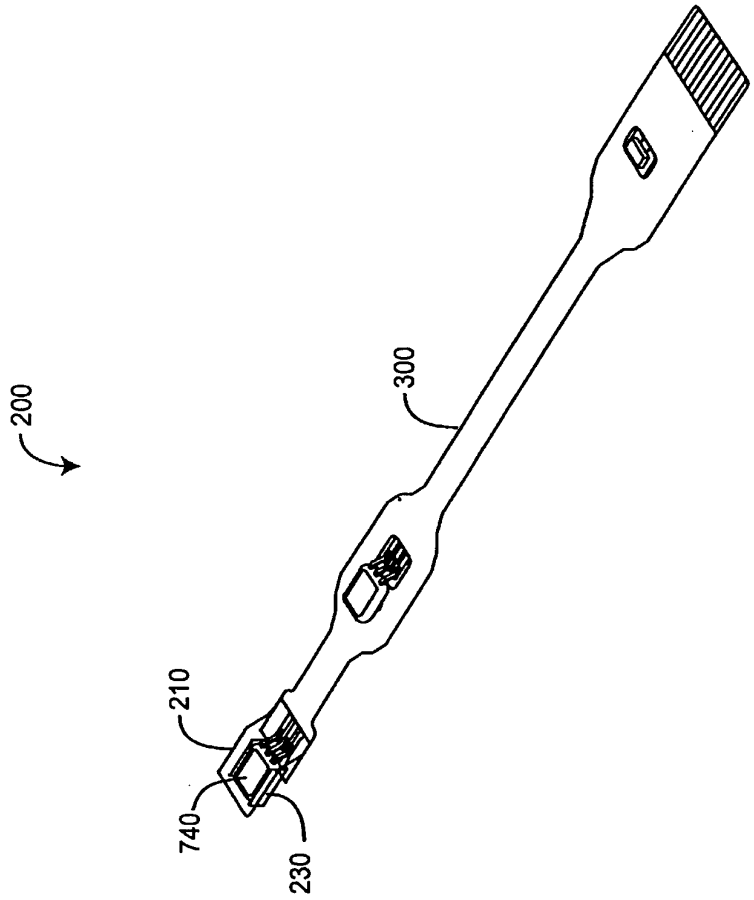


FIG. 2D

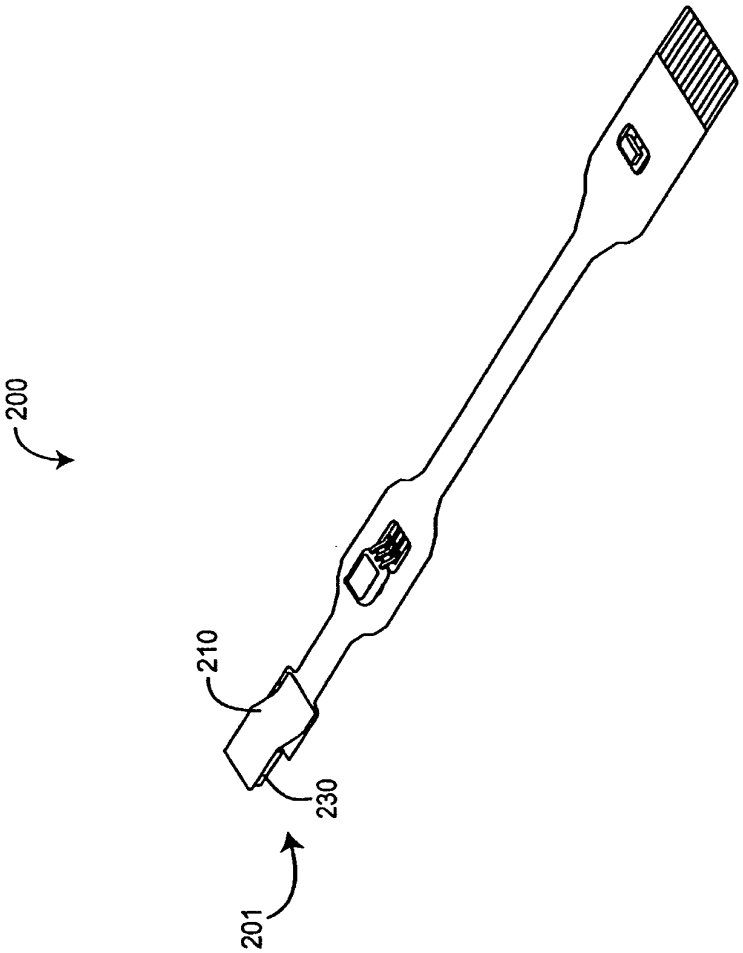


FIG. 2E

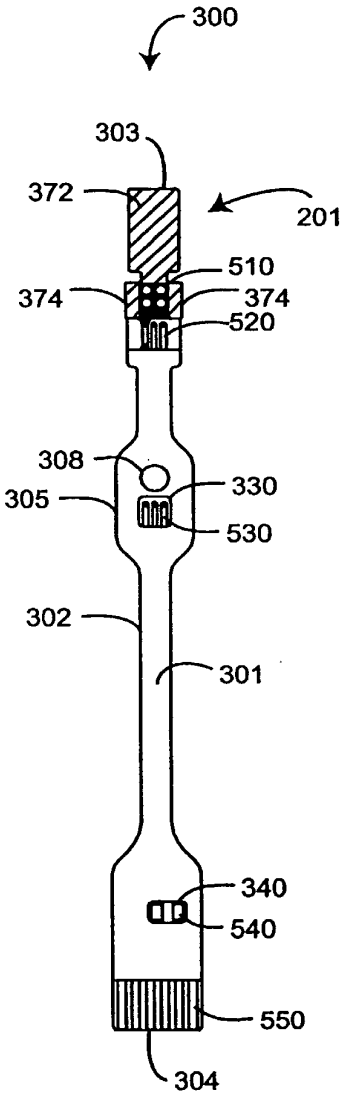

300
303
372
201
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374
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302
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304

FIG. 3A

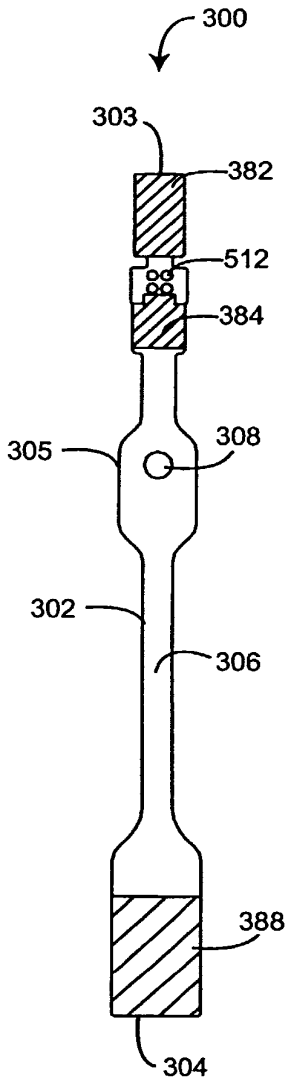


FIG. 3B

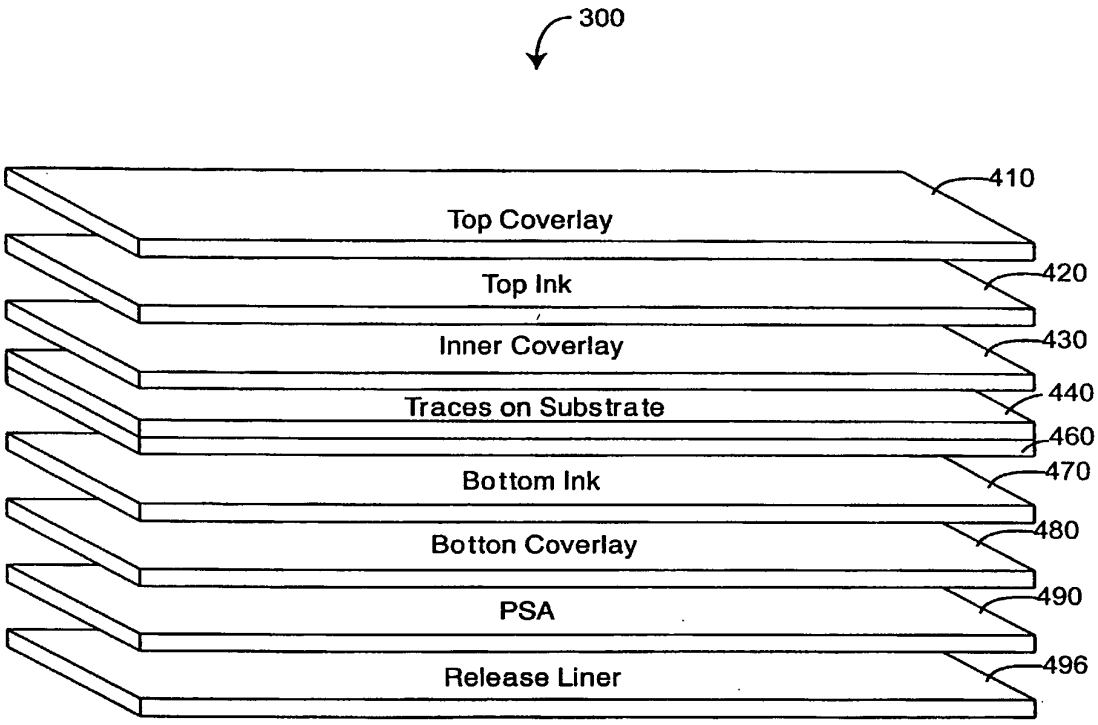

300
410
Top Coverlay
420
Top Ink
430
Inner Coverlay
440
Traces on Substrate
460
470
Bottom Ink
480
Botton Coverlay
490
PSA
496
Release Liner

FIG. 4

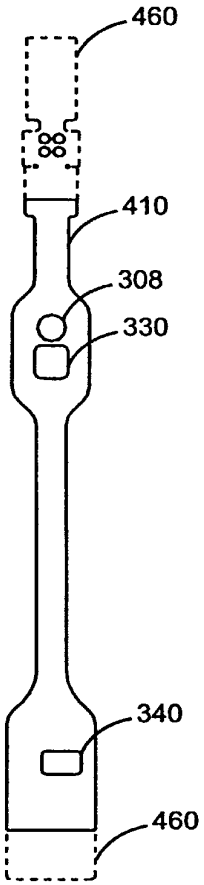


FIG. 5A

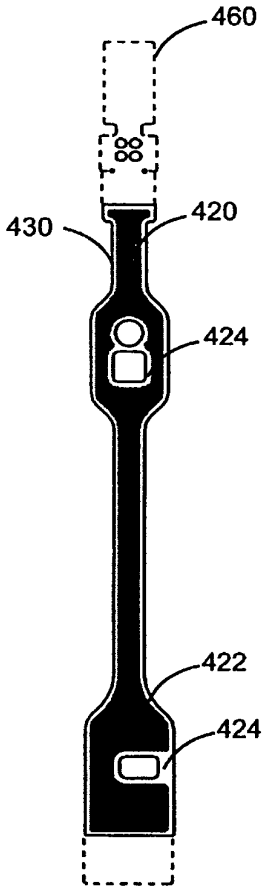


FIG. 5B

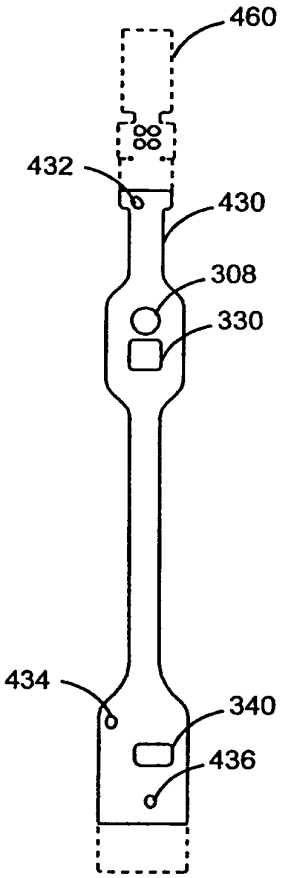


FIG. 5C

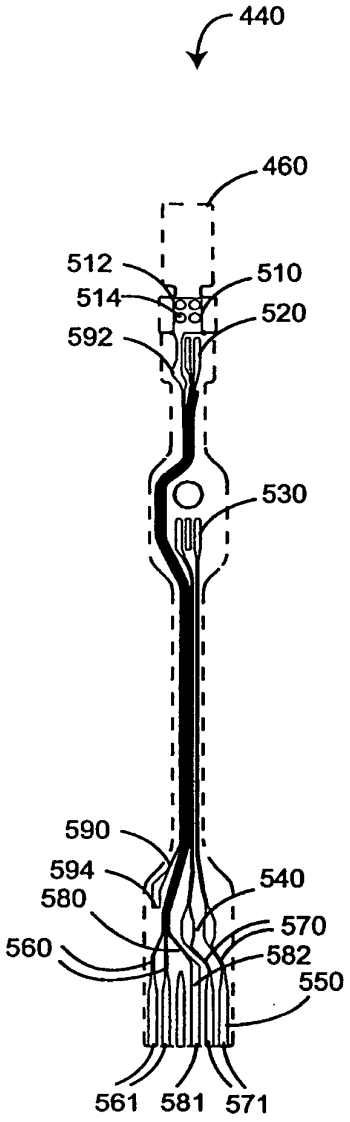

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FIG. 5D

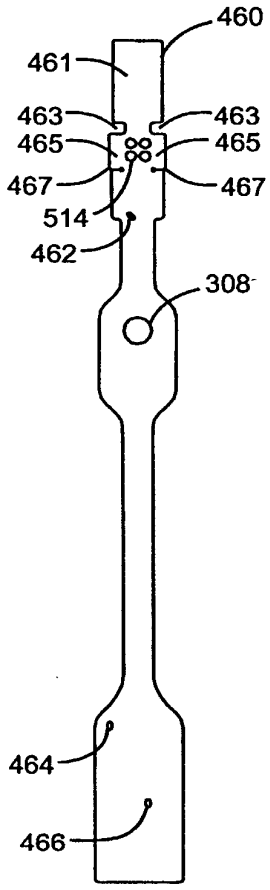


FIG. 5E

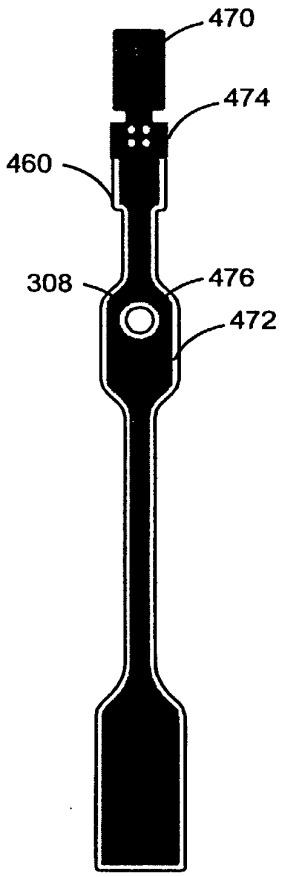


FIG. 5F

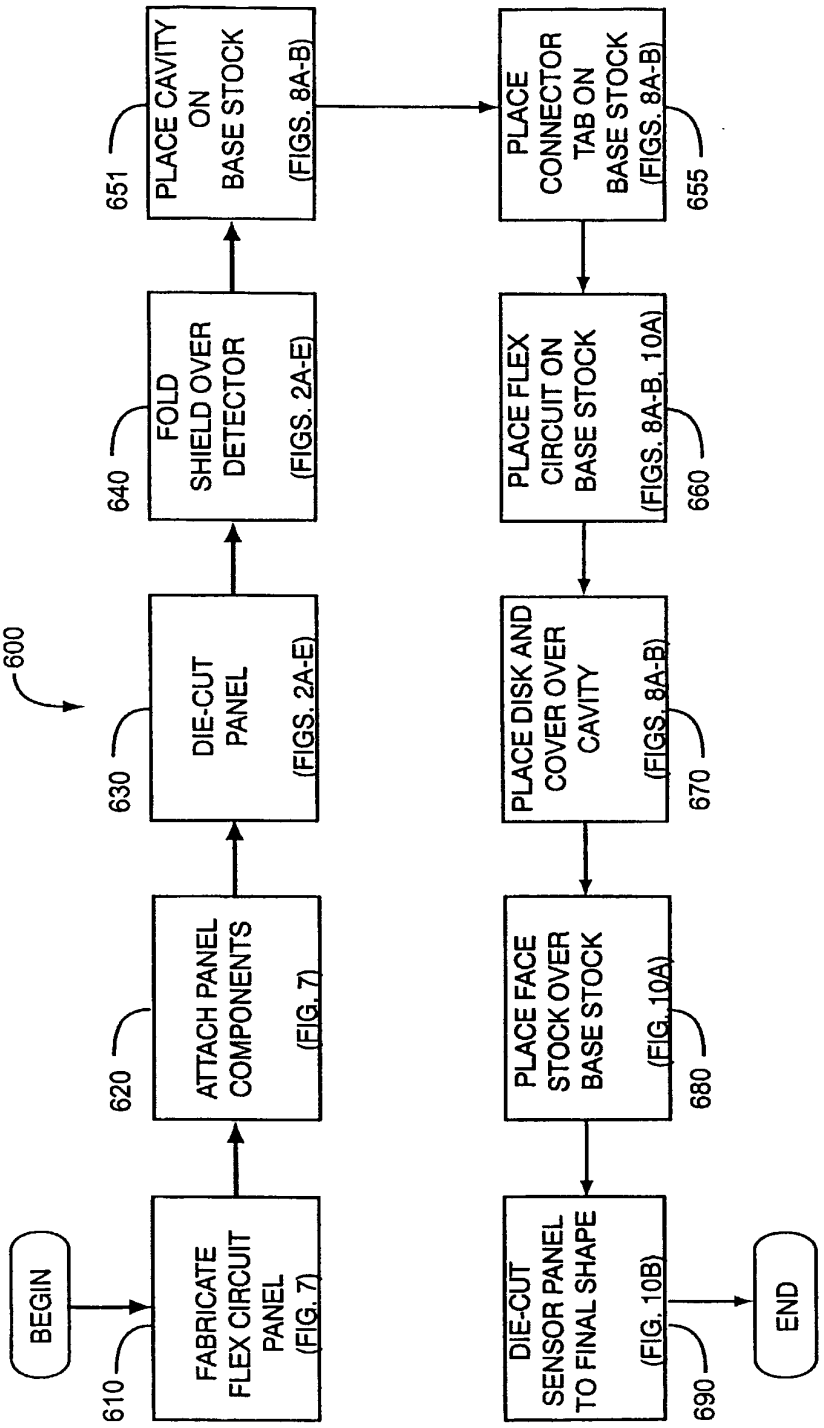

600
BEGIN
610
FABRICATE FLEX CIRCUIT PANEL (FIG. 7)
620
ATTACH PANEL COMPONENTS (FIG. 7)
630
DIE-CUT PANEL (FIGS. 2A-E)
640
FOLD SHIELD OVER DETECTOR (FIGS. 2A-E)
651
PLACE CAVITY ON BASE STOCK (FIGS. 8A-B)
655
PLACE CONNECTOR TAB ON BASE STOCK (FIGS. 8A-B)
660
PLACE FLEX CIRCUIT ON BASE STOCK (FIGS. 8A-B, 10A)
670
PLACE DISK AND COVER OVER CAVITY (FIGS. 8A-B)
680
PLACE FACE STOCK OVER BASE STOCK (FIG. 10A)
690
DIE-CUT SENSOR PANEL TO FINAL SHAPE (FIG. 10B)
END

FIG. 6

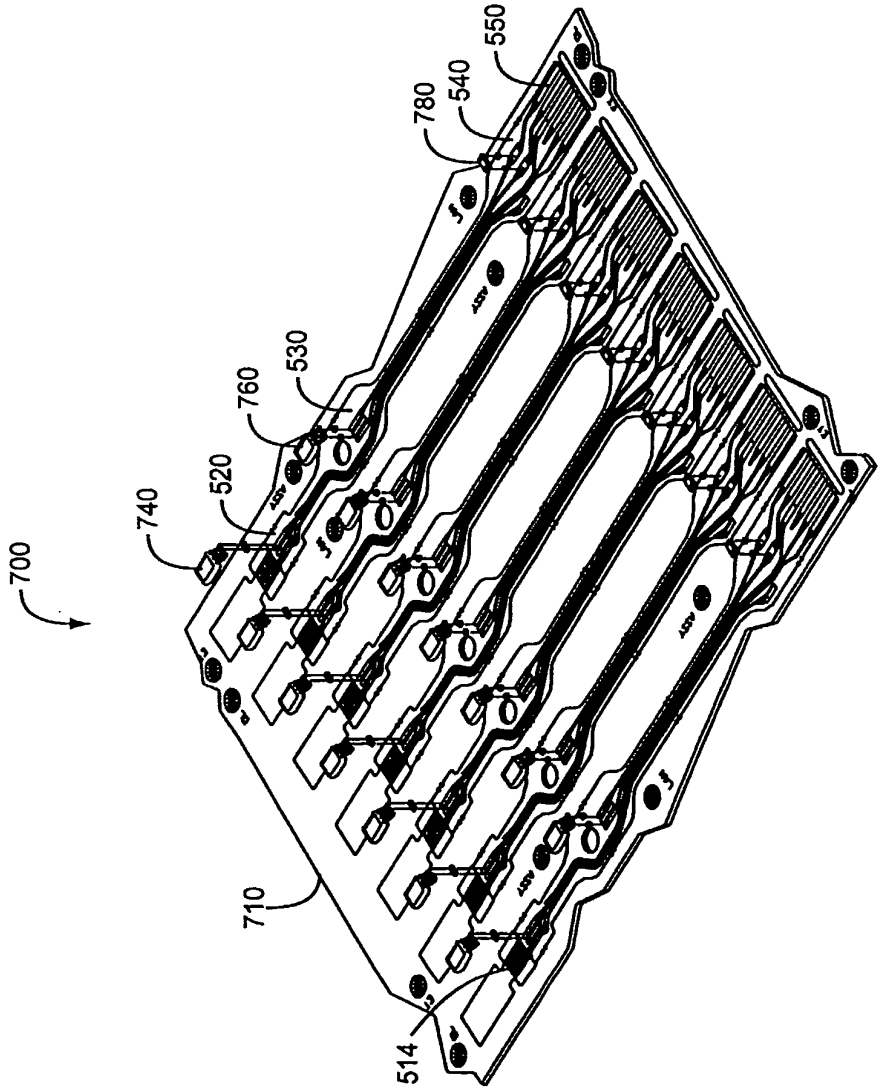


FIG. 7

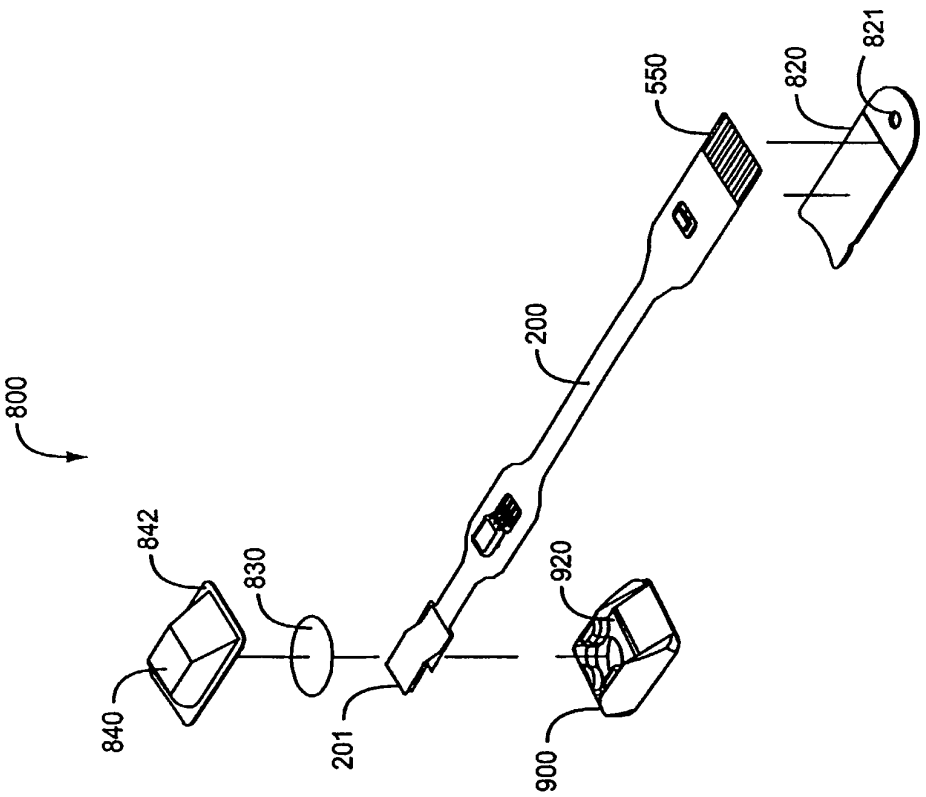


FIG. 8A

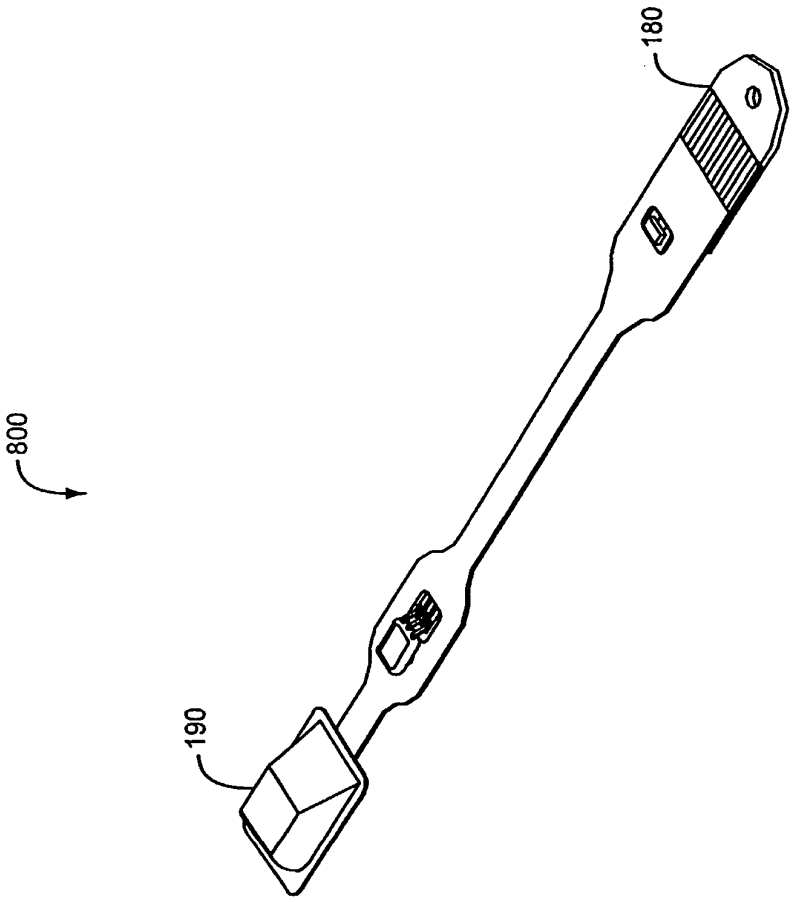


FIG. 8B

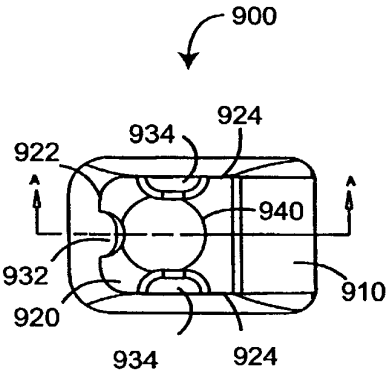


FIG. 9A

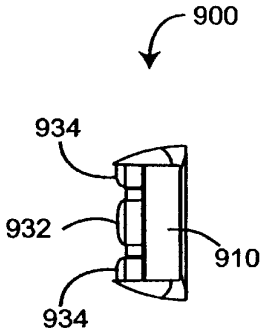
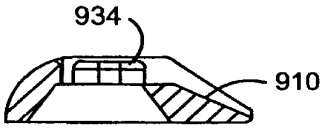


FIG. 9D



SECTION A-A

FIG. 9B

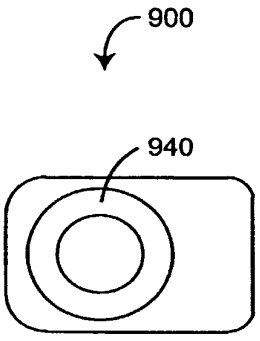


FIG. 9C

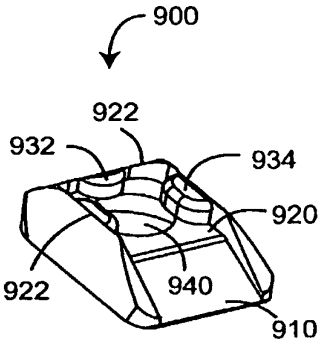


FIG. 9E

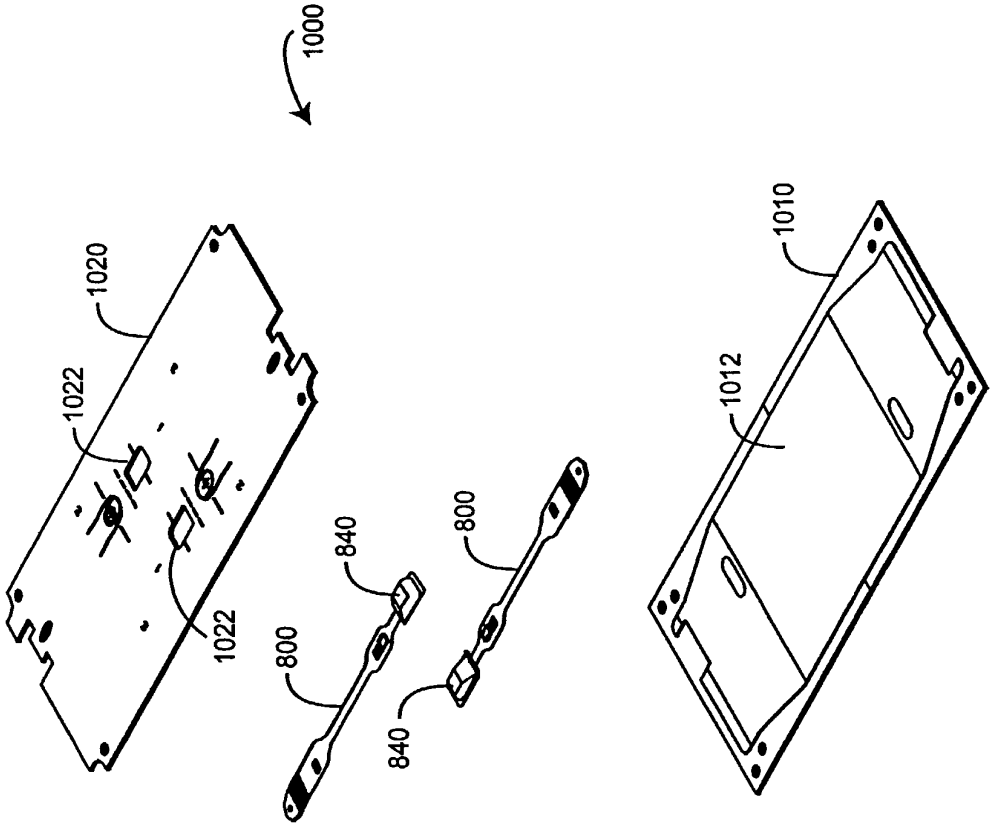


FIG. 10A

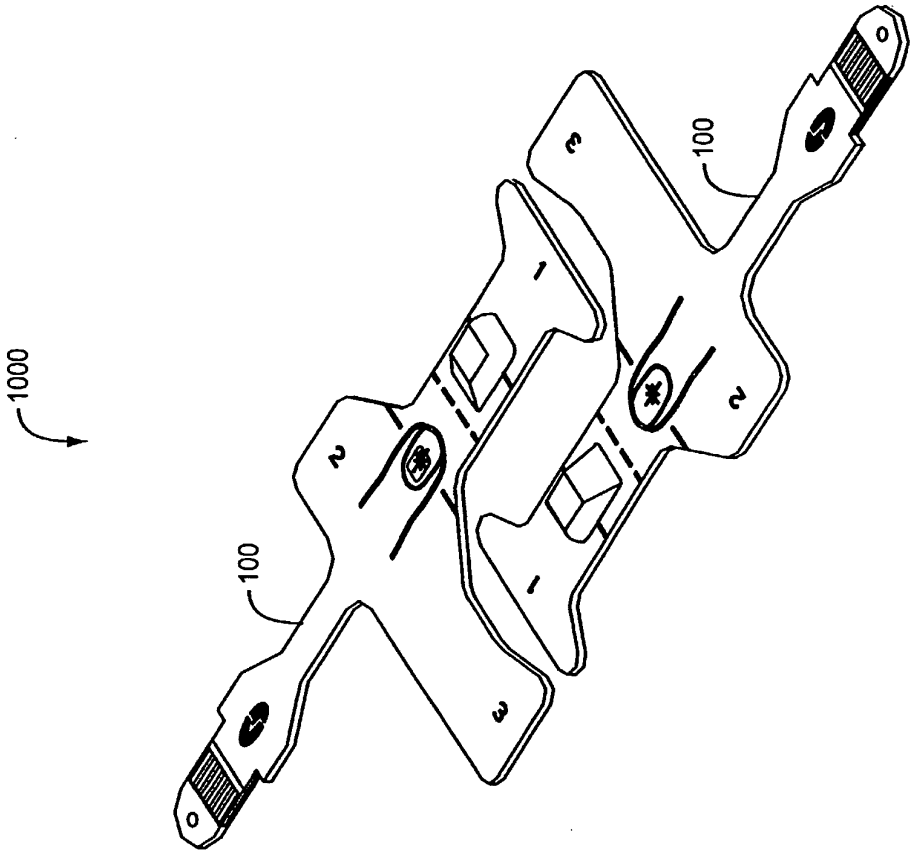


FIG. 10B

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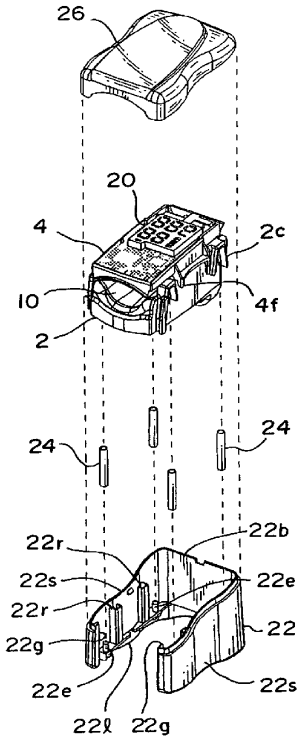
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[Continued on next page]

(54) Title: FINGER OXIMETER WITH FINGER GRIP SUSPENSION SYSTEM



(57) Abstract: A finger oximeter has a fixed first finger grip member (4) and a second finger grip member (2) that is movable relative to the first fixed finger grip member (4).The finger grip members are mounted to a casing (22), with the first grip member (4) being fixedly coupled to a top portion of the casing (22) and the second f inger grip member (2) being movable vertically within the casing (22). A force is continuously applied against the movable finger grip member (2) to bias it towards the fixed finger gripping member (4). This biasing force has sufficient yield so that when a finger is inserted between the two finger grip members (2,4),the movable finger grip member (2) would yield to the incoming finger.The biasing forse is evenly distributed to the movable finger grip portion (2) to effect a floating finger grip suspension system for the finger oximeter.

WO 03/020129 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

FINGER OXIMETER WITH FINGER GRIP SUSPENSION SYSTEM

Field of the Invention

The present invention relates to finger oximeters and more particularly to a finger oximeter having a suspension system that enables the finger gripping portions of the oximeter to firmly and evenly grasp a patient's finger.

Background of the Invention

There are a number of known finger oximeters. Generally, these finger oximeters are pulse oximetry units that utilize a sensor, and a coacting photodetector that detects the light emitted by the sensor, for determining the blood oxygen saturation of the arterial blood passing through the finger of a subject. To illuminate the finger of the subject, and to detect the light passing through the subject's finger, a prior art finger oximeter usually would have a finger gripping mechanism that has two finger gripping portions. The prior art teaches that these finger gripping portions hingedly coact with each other, usually by pivots. The following U.S. patents specifically disclose finger gripping portions that open to accept a finger via some hinge mechanism that enables the finger gripping portions of the finger oximeter to pivot about one end point of the finger oximeter: 4,685,464; 5,490,523; 5,792,052; 5,313,940; 5,676,139; 5,810,724; 5,957,840; and 6,041,247.

There are other methods of enclosing two finger gripping portions about a finger. One such method is the taping of a finger to a photodetector by means of a tape that has a light emitter, as disclosed in U.S. patent 5,209,230. Another method clamps two finger gripping portions together by means of coacting teeth at the respective sidewalls of the finger gripping portions. This is disclosed in U.S. patent 5,339,810. The use of a single piece U-shaped flexible holder that expands with the insertion of a finger is disclosed in U.S. patent 5,311,865.

For those finger oximeters that use two piece finger gripping portions which are tightened by coacting grasping teeth at their respective sidewalls, there is the disadvantage that it is difficult to remove the finger from the finger gripping portions since the finger gripping portions are locked at a given dimension. And for those finger oximeters that utilize a hinged pivoting mechanism, the force that the finger gripping portions applies to a finger tends to be uneven along the finger, and gets weaker the further the finger is away from the hinged location.

Summary of the Present Invention

The present invention finger oximeter has a floating suspension system that results from one of the finger gripping portions being movable vertically relative to the other finger gripping portion, which is fixed. A biasing force is applied against the movable finger gripping portion so that the movable finger gripping portion is constantly biased towards the fixed finger gripping portion. The two coacting finger gripping portions are configured such that their opposing surfaces are contoured to form an opening for accepting a finger inserted therebetween. The biasing force applied against the movable finger gripping portion is such that the movable finger portion is yieldable when a finger is inserted between the fixed and movable finger portions, and yet at the same time has a sufficient large biasing force to push the movable finger portion towards the fixed finger gripping portion with an even distribution of force along the length of the finger, to thereby cause the two finger gripping portions to firmly grasp the finger placed therebetween.

The force applied against the movable finger gripping portion to bias it towards the fixed finger gripping portion is supplied by a plurality of coiled springs interposed between the movable finger gripping portion and a casing along which sidewalls the movable finger gripping portion guidingly moves. The springs may be secured to ledges extending from the lower portion of the respective sidewalls of the casing so that the biasing force is applied against the movable finger

gripping portion in such a way that the movable finger gripping portion is movable vertically with respect to the fixed finger gripping portion.

The fixed finger gripping portion may be mounted to the upper part of the casing, and is configured such that its upper surface is adaptable to receive a printed circuit board that has mounted thereto or etched thereon a number of electronic components or circuits that effect the operation of the finger oximeter. A display, LED or otherwise, is also mounted to the PC circuit board for displaying values that represent the physical parameters of the patient measured via the patient's finger.

The finger gripping portions are further configured to have respective apertures through which light from a light emitter may be directed from one of the finger gripping portions to a corresponding aperture of the other finger gripping portion, which is equipped with a receptive photodetector.

To power the finger oximeter of the instant invention, a battery pack or module is mounted to the underside of the movable finger gripping portion so as to move in unison with the movable finger gripping portion. To operate, a user needs to manually activate a switch mounted to the casing. To conserve energy, the device is automatically turned off after a predetermined time period, if it no longer is in use.

It is therefore an objective of the present invention to provide a finger oximeter that has a floating suspension system.

The finger oximeter of the instant invention has the further objective of evenly distributing the gripping force applied by its finger gripping portions to the being gripped finger.

Brief Description of the Drawings

The above-mentioned objectives and advantages of the instant invention will become apparent and the invention itself will be best understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a perspective drawing that shows various components of the finger oximeter of the instant invention being in various superposed positions;

Fig. 2 is a perspective view illustrating the various components shown in Fig. 1 as well as the coil springs, the casing and the cover of the device being in alignment with each other;

Fig. 3A is a top view of an assembled device of the instant invention;

Fig. 3B is a front view of the finger oximeter of the instant invention that shows the opening through which a finger may be inserted between the two finger gripping portions of the device;

Fig. 3C is a back view of the finger oximeter of the instant invention;

Fig. 3D is a side view of the Fig. 3A device; and

Fig. 4 is an electrical schematic of the finger oximeter of the instant invention.

Detailed Description of the Invention

With reference to Fig. 1, the finger oximeter of the present invention is shown to include a lower finger grip portion 2 and an upper finger grip portion 4. Fitted to lower finger grip portion 2 and upper finger grip portion 4 are lower finger

pad 6 and upper finger pad 8, respectively. The lower and upper finger grip portions, as well as their finger pads, are configured to conform to the shape of a human digit, such as for example a finger. This is best illustrated by the lower surface of finger pad 6 and the upper surface of finger pad 8, which are opposed to each other. Thus, once the respective finger pads 6, 8 are attached to their corresponding finger grip portions 2, 4, an opening 10, best shown in Figs. 2 and 3B, is provided when finger grip portions 2 and 4 are positioned adjacent to each other.

As best shown in Fig. 1, lower grip finger portion 2 is an elongate member that has two sides 2s extending from a base 2b. A space or void 2v is provided at approximately the center of base 2b onto which a photodetector 18 (D1 in Fig. 4) may be positioned. The front end of base 2b is curved for forming one portion of opening 10. The back end of elongate member 2 has a backstop 2bs that is configured to receive, in a sliding engagement fashion, a battery module 10. Although not shown, battery module 10 is configured to enable the insertion of two batteries thereinto for providing power to the electronic components shown in Fig. 4 to thereby energy the finger oximeter, whose operation will be discussed later. A spring-like conductor 12 inserted to battery module 10 connects in series the batteries, thereby increasing the available voltage.

Each of sidewalls 2s of elongate member 2 further has extending therefrom at least two ears, or catches 2c1 (2c1') and 2c2 (2c2'). The purpose of catches 2c will be discussed with reference to Fig. 2.

Lower finger pad 6, which may be made of a rubbery material that is not compliant, is attached to base 2b of finger grip portion 2. In addition to finger pad 6, a conductive strip 14 is inserted to the back end of finger grip portion to provide an electrical path for the power supplied by battery module 10. Connected to conductive end 14 is a flexible strip 16 which has attached thereto photodetector

18. With photodetector 18 resting in space 2v of elongate member 2 and with finger pad 6 placed thereover, photodetector 18 is exposed, and is therefore adaptable to receive light directed thereto, per aperture 6a of finger pad 6. As can be seen, finger pad 6 is configured, per its arcuate interior surface, to conform partially to the shape of a human finger.

Upper finger grip portion 4, which is also configured in the form of an elongate member, has attached to its underside finger pad 8, which is curved in an opposing manner to finger pad 6 and contoured to partially conform to the shape of a finger. Finger pad 8, also made of a non-compliant rubber material, may be attached to the lower surface of elongate member 4 by glue or other adhesive means, which is similar to the way by which finger pad 6 is attached to elongate member 2. Once attached, aperture 8a of finger pad 8 is aligned with aperture 4a of elongate member 4.

Elongate member 4 has two sides 4s extending upwards from its base 4b to form a semi-closed enclosure at its upper surface for accepting a printed circuit board or module 18. Although not shown clearly, mounted to module 18 are a number of electronic components, the circuitries of which are shown in detail in Fig. 4. Extending from each side 4s of elongate member is an extension 4e that has two fingers 4f pointing downwards. The purpose of extensions 4e will be discussed with respect to Fig. 2. Also mounted to module 18 is a display 20 that includes a number of digits for displaying information that corresponds to the physical parameters of a patient, such as for example the blood oxygen saturation of arterial blood, as measured from the patient's finger being inserted between finger grip portions 2 and 4. To effect the measurement of the physical attribute of the patient, a light source, such as for example a light emitting diode, is mounted to the underside of module 18 to be in alignment with aperture 4a of elongate member 4. The power provided to module 18 comes from the flexible conductive strip 16.

With reference to Fig. 2, the various components illustrated in Fig. 1 of the finger oximeter of the instant invention are shown as having been assembled, with upper finger grip portion 4 being adjacent to lower finger grip portion 2. As was mentioned previously, when in such close contact, opening 10 is formed at the front of the two finger gripping members. It is through this opening that a finger is placed between the finger grip portions 2 and 4.

As further shown in Fig. 2, the in contact finger grip portions 2, 4 are superposed over a casing 22, which has the form of a U-shaped skirt. Casing 22 has a back wall 22b and two sidewalls 22s. Extending from the lower portion of sidewalls 22s are respective ledges 22l. In the inside of the respective sidewalls 22s are receptacles 22r, which are configured to receive fingers 4f of extension 4e of upper finger grip portion 4. Upon insertion of fingers 4f to receptacles 22r, finger grip portion 4 is fixedly coupled to the top or upper part of casing 22. An adhesive may be used to further ensure that upper finger grip portion 4 is fixedly coupled to casing 22.

At the two distal ends of sides 22s there are formed respective gripping edges or fingers 22g. Formed at the respective ledges 22l are a number of fingers or extensions 22e that provide the respective anchors each for securely receiving a corresponding spring 24. As shown, there are four springs 24, each securedly anchored by one of the extensions 22e at one corner of casing 22. Springs 24 may each be conventional compression coil springs.

As further shown in Fig. 2, once anchored to extensions 2e, when lower finger grip portion 2 is inserted to casing 22, each of catches 2c in the form of ears extending from sidewalls 2s of elongate member 2 catches and presses down on a corresponding spring 24. Springs 24 are chosen to have a given elasticity so that, in combination, those springs provide a biasing force against elongate member 2 in an upwards direction, with reference to upper finger grip

portion 4, which is fixedly attached to the upper part of casing 22. Thus, once elongate member 4 is fixedly coupled to casing 22, elongate member 2 nonetheless remains movable relative to elongate member 4, and is guidedly movable along the respective sidewalls 22s of casing 22.

Given the fact that elongate member 2 is supported by independent springs 24 at different locations along its sidewalls 2s, when a finger is inserted to opening 10, although giving way to the finger, the biasing force exerted by springs 24 would act against elongate member 2 vertically so as to firmly bias elongate member 2 against the inserted finger, to thereby firmly grip the inserted finger against fixed elongate member 4. Further, by providing springs 24 at the four corners of elongate member 2, a four point suspension system is effected to evenly distribute across elongate member 2 the biasing force. Accordingly, a finger gripped by elongate members 2 and 4 is gripped evenly along its length. Furthermore, by hiding the springs at the respective corners of casing 22 and elongate member 2 so that no support base is required for elongate member 2, the respective sizes of the case 22 and elongate member 2 could be reduced, thereby leading to a reduction in the size of the entire device. So, too, by hiding the springs between the respective sidewalls of casing 22 and elongate member 2, the springs are sealed from dirt and isolated from potential mechanical abuse.

Although only four springs are shown in the being discussed embodiment, it should be appreciated that a three spring configuration, with one spring at each sidewall and one spring at the back wall of casing 22 may also be used. Conversely, a greater number of springs, with more than two springs along each sidewall of casing 22, may also be used in other embodiments of the instant invention.

To complete the assembled device of the instant invention, a filtered cover 26 that allows the digits to be seen from display 20, is placed over elongate

member 4 so as to be fixedly coupled either to elongate member 4 or to the upper edges of casing 22.

With reference to Figs. 3A-3D, different views of the assembled finger oximeter of the instant invention is shown. Fig. 3A shows a plan view of the assembled device 28, with the digits displaying the blood oxygen saturation, and also the heart rate that may be obtained by measuring the physical attributes of a patient by means of her finger.

Fig. 3B is a front view of the device showing opening 10 through which the finger of a patient is inserted. As further shown, upper finger grip portion 4 is protected by cover 26 so that only a portion thereof, and a portion of finger pad 8, are shown. However, movable finger grip portion 2 is shown to be mounted within casing 22, with battery module 10 removably coupled to the underside thereof. Movable finger grip member 2, which, in response to the bias force suppled by springs 24, is movable bidirectionally as indicated by directional arrow 30.

Fig. 3C shows the back side of the finger oximeter of the instant invention. As shown, casing 22, or rather the back walls 22b thereof, has mounted thereto a switch 32, which enables a user to manually activate the device, i.e., by energizing the electronic components mounted to circuit board 18. The back side of battery module 10 is also shown in Fig. 3C.

Fig. 3D is a side view of device 28 of the instant invention which shows cover 26 attached to casing 22. Battery pack 10 is shown to form the bottom base of the device.

Fig. 4 is a schematic of the electronic circuitry representative of the electronic components mounted to circuit board 18 of the device. For ease of

discussion, the various major functions of the circuitry of the instant invention device are separately grouped together by dotted lines. In particular, as shown in dotted box 34, a photodiode D1 (18 in Fig. 1) is mounted onto a flexible circuit support strip that is fitted to space 2v of lower grip member 2. Switch SW1, also mounted to and in electrical connection to the flexible circuit strip 34, when turned on by the user, causes light from the LED in circuit 40 to be directed to the finger placed between the finger grip portions 2 and 4. Once the finger is removed from the finger grip portions, microprocessor U1 is programmed to turn off device 28 after a predetermined time period, for example 8 seconds, so as to conserve energy.

The photodetector and switch SW1 are connected to the main circuit by means of a conventional coupling. In particular, circuit 34 mounted on the flexible strip is connected to functional circuit 36, which is an analog detector pre-conditioning circuit. As shown, the input electrical current signal measured from the finger of the patient is sent to an op amp U2A, where the analog current signal is converted to an analog voltage signal. The analog voltage signal is amplified by op amp U2C to output an amplified analog voltage signal VSIG. The dynamic range of the signal is controlled by IC circuit U4, which in essence is an integrated digital potentiometer.

The amplified analog voltage signal VSIG is input to microprocessor U1 at input A2. This analog voltage signal is converted by microprocessor U1 to a corresponding digital signal and output to circuit 38, which is a LED driver circuit comprising driver IC circuits U8 and U9. The driver circuit 38 provides the signal to the various digits DIG1-DIG6 for displaying the information collected from the patient on display 20.

Another major functional component of the circuitry of Fig. 4 includes circuit 40, which is a variable LED driver circuit that drives the two LEDs that emit the

light directed to the finger of the patient through apertures 4a and 8a of the upper finger grip portion and the upper finger pad 8, respectively. The light, after diffusing through the finger of the patient, is sensed by photodetector D1 (18), which in turn outputs the resulting current signal to analog detector pre-conditioning circuit 36.

Sub-circuit 44 of the Fig. 4 circuitry is a switching power supply circuit that regulates the power to be supplied to the various components of the Fig. 4 circuitry.

Circuit 46 is a battery measurement voltage divider circuit that identifies when the voltage from battery pack 10 is low.

Circuit 48 is a timing circuit for the components of the finger oximeter of the instant invention. A clock pulse is generated from circuit 48 for microprocessor U1 by component U6A. Components U6B and U6C in combination ensure that there is enough voltage from battery pack 10 if the voltage output is less than 3 volts, so that the appropriate clocking signals are provided for the various components of the circuitry of Fig. 4.

The present invention is subject to many variations, modifications and changes in detail. For example, instead of springs 34 being anchored to extensions 22e of ledges 22l of casing 22, the biasing mechanism for lower grip portion 2 could be an elastic one piece spring mechanism such as a leaf spring that biases elongate member 2 against the sidewalls 22s, and/or back wall 22b of casing 22. To anchor such leaf spring to the casing, the ledges at the base of the casing may have to be expanded. So, too, could an elastic material such as rubber that has sufficient biasing characteristics be used to keep a force biasing movable elongate member 2 towards fixed elongate member 4. Thus, it is intended that all matter described throughout this specification and shown in the

accompanying drawings be interpreted as illustrative only and not in a limiting sense. Accordingly, it is intended that the invention be limited only by the spirit and scope of the hereto appended claims.

Claims

1. A finger oximeter, comprising:

a casing having a back wall and two sidewalls each extending from said back wall;

a first finger portion sandwiched by and movable vertically along said sidewalls;

a second finger portion in fixed relation with said casing to form an upper stop for the movement of said first finger portion;

wherein the respective surfaces of said first and second finger portions facing each other are configured to conform to a finger placed therebetween; and

spring means provided at said casing for applying a biasing force against said first finger portion so that a finger placed between said first and second finger portions is firmly gripped by said first and second finger portions due to said first finger portion being biased by said spring means towards said second finger portion.

2. Finger oximeter of claim 1, wherein each of said sidewalls of said casing comprises a ledge for forming a barrier to prevent said first finger portion from falling out of said casing, each of said sidewalls guiding the vertical movement of said first finger portion; and

wherein said spring means comprises a plurality of springs at least two of which being secured to opposite ends of the ledge of each of said sidewalls for supporting and applying said biasing force vertically against said first finger portion.

3. Finger oximeter of claim 1, further comprising:

a printed circuit board having mounted thereon a plurality of electronic circuit components coupled to the top of said second finger portion, said second finger portion having an aperture for enabling the light from a light emitting source

mounted to said circuit board to be directed toward said finger gripped by said first and second finger portions;

a display mounted on top of said circuit board for displaying at least readings of blood oxygen saturation of arterial blood measured from said finger; and

a cover positioned over said display and fixedly coupled to either said second finger portion or the top of said casing.

4. Finger oximeter of claim 3, further comprising:

a battery module removably coupled to the underside of said fist finger portion for supplying power to said electronic circuit components and said display.

5. Finger oximeter of claim 3, further comprising:

a switch mounted to said casing to enable a user to manually activate said electronic circuit components.

6. A pulse oximeter, comprising:

a fixed portion;

a non-fixed portion movable relative to said fixed portion, said fixed and non-fixed portions in combination providing an opening through which a finger is insertable; and

means biasing against said non-fixed portion so that when a finger is inserted between said fixed and non-fixed portions, said non-fixed portion is movable relative to said fixed portion to accommodate said finger but remains biased toward said fixed portion so that said finger is firmly gripped by said fixed and non-fixed portions.

7. Pulse oximeter of claim 6, further comprising:

a casing having two sidewalls extending from a back wall, said fixed portion being sandwiched by and in fixed relation with the upper parts of said sidewalls,

said non-fixed portion being sandwiched by said sidewalls and movable vertically along the opposing surfaces of said sidewalls, respective ledges extending from the respective lower parts of said sidewalls forming a base support said non-fixed portion.

8. Pulse oximeter of claim 7, wherein said biasing means comprises a plurality of springs, at least two of said springs being secured to each of the ledges at a given distance away from each other to provide an evenly distributed biasing upward support force for said non-fixed portion, so that when a finger is inserted between said fixed and non-fixed portions, said non-fixed portion is movable vertically relative to said fixed portion with said non-fixed portion continuously being forced upward against said finger to thereby maintain a firm grip on said finger.

9. Pulse oximeter of claim 8, wherein said springs are compression coil springs.

10. Pulse oximeter of claim 6, wherein said fixed portion and said non-fixed portions are respective elongate members with respective opposing surfaces positioned in alignment with each other, said pulse oximeter further comprising:

respective finger pads each attached to a corresponding opposing surface of said elongate members, said finger pads are configured to follow the contour of a finger so as to enhance the gripping of a finger placed between said finger pads.

11. Pulse oximeter of claim 6, further comprising a circuit board coupled to the upper surface of said fixed portion, electronic components and a display being mounted to said circuit board, said fixed portion having an aperture through which a light from a light emitting device electrically connected to said circuit board

passes for illuminating a finger placed below said fixed portion, a cover being placed over said circuit board and fixedly coupled to said casing.

12. Pulse oximeter of claim 11, further comprising a battery module removably coupled to the underside of said non-fixed portion for supplying power to said electronic circuit components and said display.

13. Pulse oximeter of claim 11, further comprising a switch mounted to said casing to enable a user to manually activate said electronic circuit components to measure the blood oxygen saturation of arterial blood from said finger gripped by said fixed and non-fixed portions.

14. Apparatus for gripping a finger, comprising:

first grip means;

second grip means opposing said first grip means, said first and second grip means having respective surfaces facing each other being contoured to enable the gripping of a finger placed therebetween;

wherein one of said first and second grip means is fixed while the other of said first and second grip means is movable relative to said one fixed grip means; and

bias means yieldingly forcing said movable grip means towards said fixed grip means so that a finger remains firmly gripped by said first and second grip means once it is placed therebetween.

15. Apparatus of claim 14, further comprising a casing having two sidewalls extending from a back wall, said fixed grip means being sandwiched by and in fixed relation with the upper parts of said sidewalls, said movable grip means being sandwiched by said sidewalls and movable vertically along the opposing surfaces of said sidewalls, respective ledges extending from the respective lower parts of said sidewalls;

wherein said bias means comprises a plurality of springs at least two of which being interposed between each of said ledges and a corresponding opposite side of said movable grip means, said springs providing a biasing force against said movable grip means.

16. Apparatus of claim 14, wherein said first and second grip means comprise respective one and other elongate members each having top and bottom surfaces, said elongate members being in alignment with each other so that the bottom surface of said one elongate member faces the top surface of said other elongate member, said elongate members having respective apertures, and respective finger pads each attached to a corresponding one of said bottom surface of said one elongate member and the top surface of said other elongate member, said finger pads being configured to conform to the contour of a finger, each of said finger pads having an aperture in alignment with the apertures of said one and other elongate members.

17. Apparatus of claim 16, further comprising a casing having two sidewalls extending from a back wall, said one elongate member being sandwiched by and fixedly coupled to the upper parts of said sidewalls, said other elongate member being sandwiched by said sidewalls and movable vertically along the opposing surfaces of said sidewalls, respective ledges extending from the respective lower parts of said sidewalls, said bias means comprising a plurality of springs at least two of which being interposed between each of said ledges and a corresponding one of respective ears extending from opposite sides of said other elongate member, said springs functioning as a suspension system for said other elongate member.

18. Apparatus of claim 16, further comprising electronic components and a display mounted on a circuit board coupled to the top surface of said one elongate member, a light emitting source outputting a light through the respective

apertures of said one elongate member and the finger pad attached to the bottom surface of said one elongate member, a light detector in alignment with the respective apertures of said other elongate member and the finger pad attached to the top surface of said other elongate member for receiving the light output from said light emitting source passing through the finger gripped by said finger pads.

19. Apparatus of claim 18, further comprising a battery module removably coupled to the bottom surface of said other elongate member so as to move in unison with said other elongate member, said battery module supplying power to said electronic components and said display.

20. Apparatus of claim 15, further comprising a switch mounted to said back wall to enable a user to manually activate electronic circuit components mounted to said one grip means.

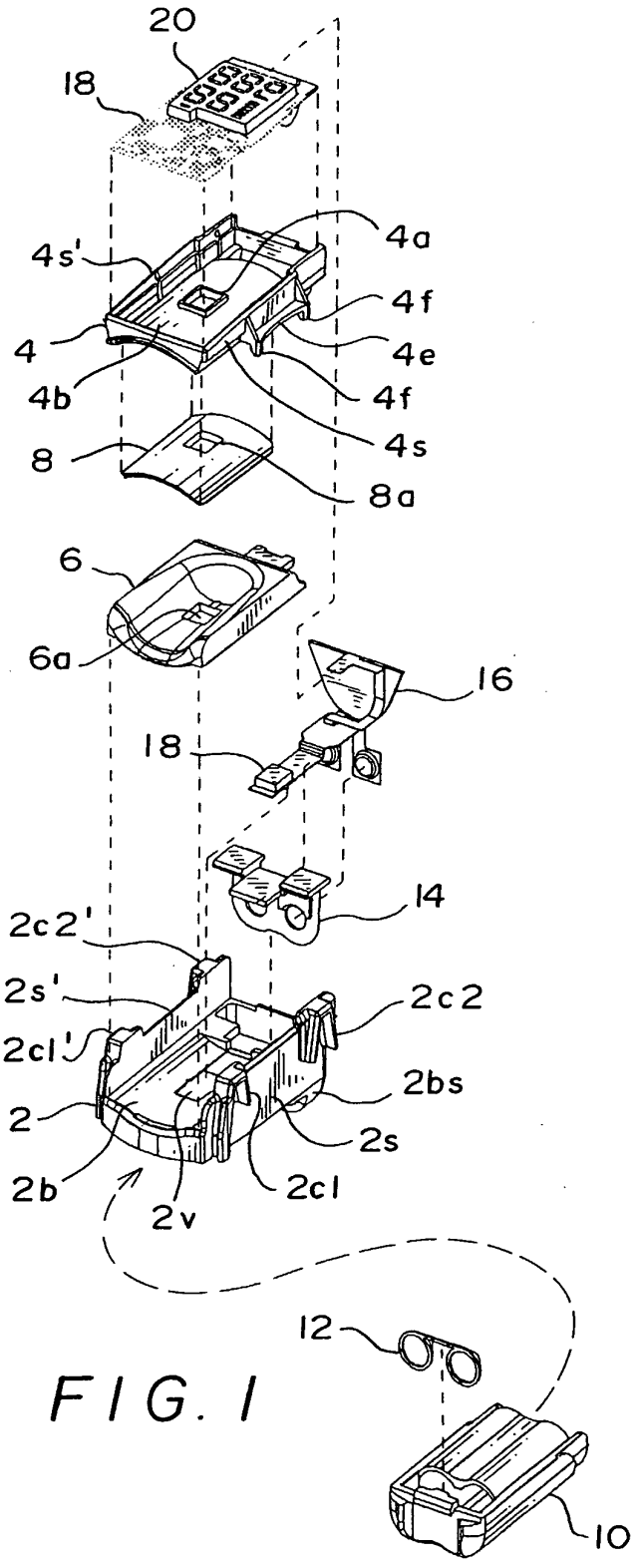

20
18
4a
4s'
4f
4
4e
4b
4f
4s
8
8a
6
6a
16
18
14
2c2'
2s'
2c2
2c1'
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2s
2b
2v
2c1
12
10

FIG. 1

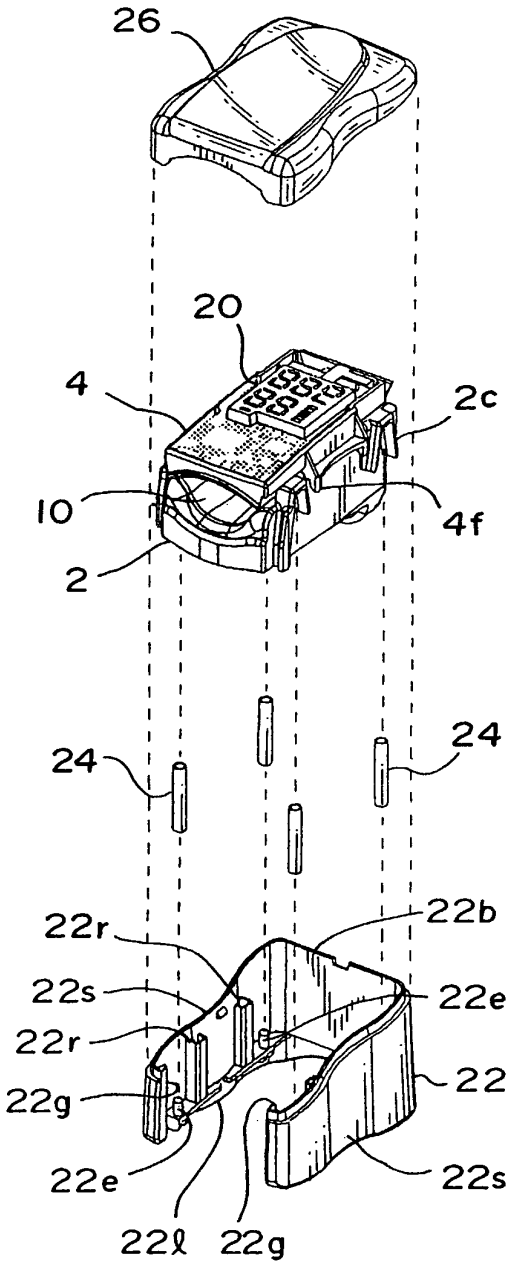

26
20
4
2c
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FIG. 2

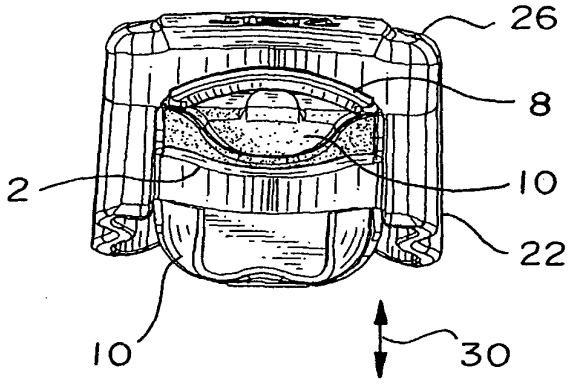


FIG. 3B

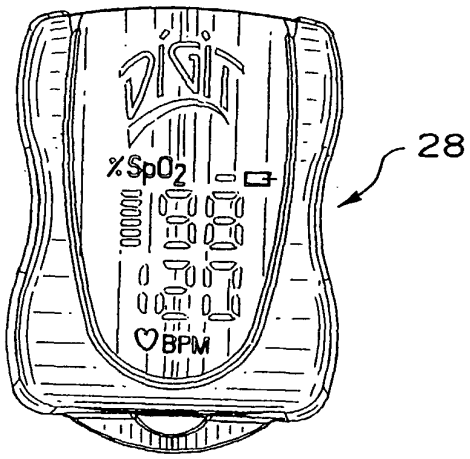


FIG. 3A

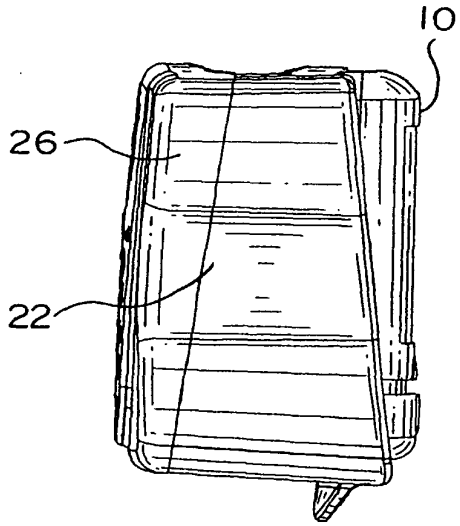


FIG. 3D

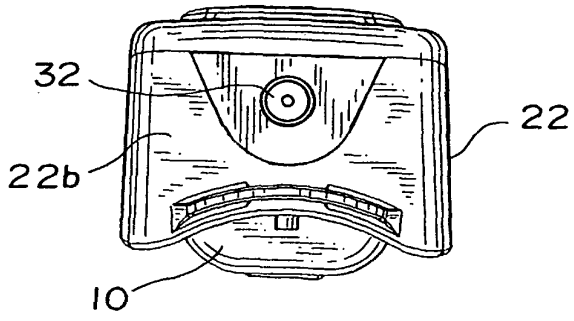


FIG. 3C

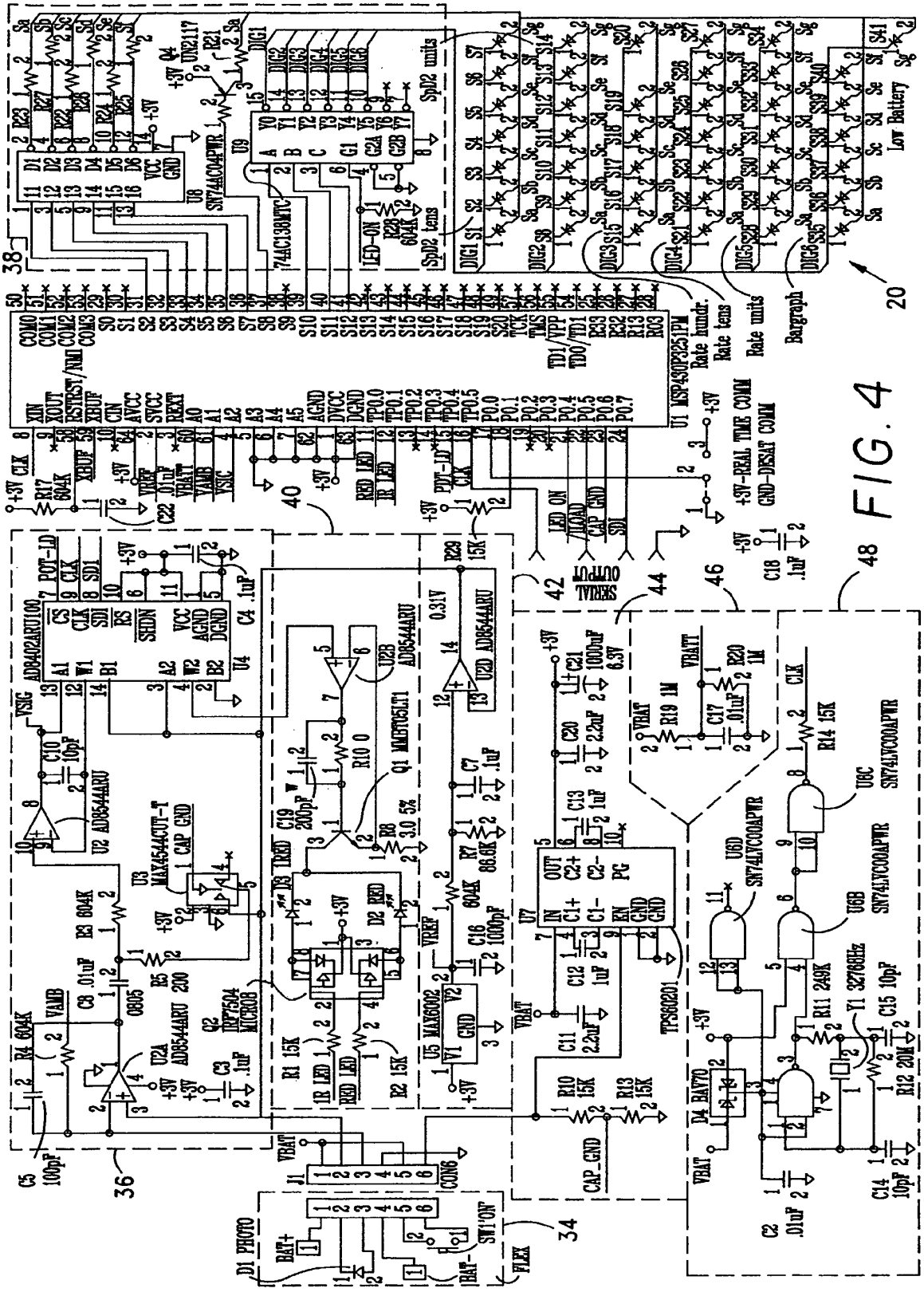


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/26979

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 5/00
US CL : 600/323, 340, 344
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/322, 323, 340, 344, 485, 490, 499

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,006,120 A (LEVIN) 21 DECEMBER 1999 (21.12.1999), cols. 2 and 3, abstract and Figure 3.	1, 3, 5-7, 10, 11, 13-16, 18 and 20 --- 4, 12 and 19
Y	US 5,490,523 A (ISAACSON et al) 13 FEBRUARY 1996 (13.02.1996), Abstract and Figure 7.	4, 12 and 19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search	Date of mailing of the international search report
10 October 2002 (10.10.2002)	11 DEC 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer David J. McCrosky Telephone No. 703-308-0858

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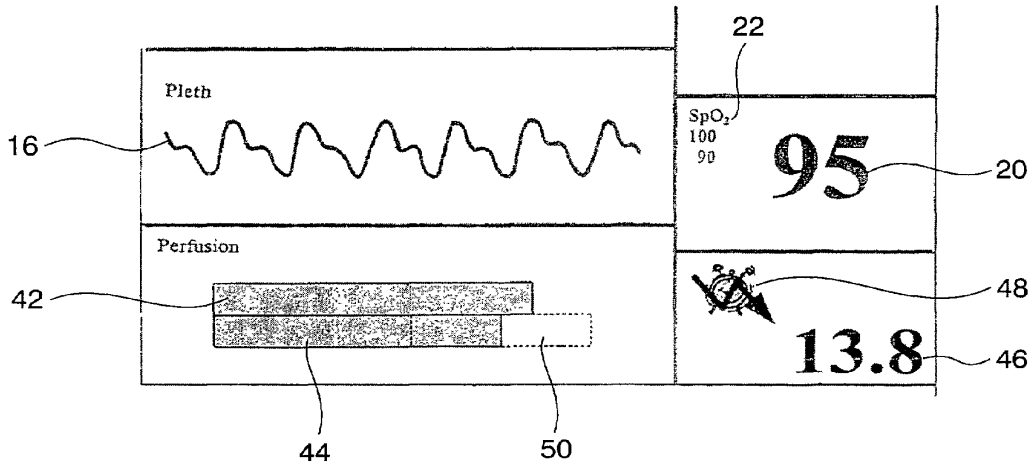
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[Continued on next page]

(54) **Title:** METHOD FOR THE PRESENTATION OF INFORMATION CONCERNING VARIATIONS OF THE PERFUSION



(57) **Abstract:** The invention relates to a method for the presentation of information concerning variations of the arterial filling with blood (perfusion) of organs of living beings on the user surface (10) of a display screen, in which method the data required for the presentation (perfusion index) is derived, using an algorithm, from measuring values of a non-invasive photometric measuring process for determining the arterial oxygen saturation of the blood. The invention is characterized in that a first perfusion index is defined as a reference value and the subsequent perfusion indices are determined as relative deviations with respect to the reference value, said relative deviations being presented in the form of analog, graphic elements (42, 44) on the user surface (10) as information concerning the 10 variations of the perfusion.

WO 2004/034898 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Method for the presentation of information concerning variations of the perfusion

The invention relates to a method for the presentation of information concerning variations of the perfusion as disclosed in claim 1, to a method for the presentation of the quality of the measuring values (signal quality) acquired during a photometric measuring process as claimed in the claims 16 to 18, and to a device for carrying out the method as disclosed in claim 21.

As is known, in the field of patient monitoring special patient data such as, for example, perfusion, oxygen saturation of the arterial blood (SPO_2 value), ECG curves and the like are important for the evaluation of the condition of a patient.

Information as regards the perfusion can be derived only indirectly in normal practice. To this end, the clinical staff can fall back on measuring values resulting from the measurement of the oxygen saturation of the arterial blood.

The measurement of the arterial oxygen saturation of the blood or the arterial hemoglobin is usually performed continuously in a non-invasive manner by means of a photometric measuring process, that is, the so-called pulsoximetry. A peripheral part of the body, usually a finger, is then irradiated by means of a sensor. The sensor usually comprises two light sources for the emission of light and a corresponding photodetector for the measurement of the light absorption.

Pulsoximetry is based on two principles. On the one hand, the oxygen-enriched hemoglobin (oxyhemoglobin) and the oxygen-reduced hemoglobin (desoxyhemoglobin) differ as regards their ability to absorb red and infrared light (spectrophotometry) and on the other hand the amount of arterial blood in the tissue changes, and hence also the absorption of light by this blood, during the pulse (plethysmography). A pulsoximeter determines the SPO_2 value by emitting red and infrared light and by measuring the variations of the light absorption during the pulse cycle.

Whereas the clinical staff is presented with the oxygen saturation of the blood, that is, the SPO_2 value, in the form of a numerical value, for information concerning the perfusion the staff has to take recourse to an interpretation of the plethysmography curve which is presented in the context of the pulsoximetry; this curve also shows inter alia the variation of the volume of a part of the body which is induced by the perfusion.

Because the perfusion is a clinically relevant parameter which is used, for example, to signal the changing of physiological factors, the effect of anesthesia or the like, this way of deriving information concerning the perfusion is found to be very detrimental.

On the one hand, the read-out accuracy is limited as the information has to be read from a curve which is not especially conceived for this purpose, meaning that this information has to be estimated, whereas on the other hand the amplification must be invariable for the presentation of the curve, making an evaluation of the shape of the curve practically impossible in the case of a very low perfusion. Moreover, a change of the curve amplitude in the plethysmogram is also dependent on the oxygen saturation and not only on the amount of blood flowing into the part of the body, for example, a finger.

US 4,867,165 A1 discloses a method for determining the perfusion whereby the perfusion can be quantified. To this end, a so-called perfusion index is determined from measuring values of the pulsoximetry process by means of an algorithm. It has been found to be a drawback of this method, however, that it yields absolute values only so that the detection of a variation of the perfusion by the clinical staff must take place by continuous observation and comparison of numerical values.

It is an object of the invention to mitigate this problem by way of a method for the presentation of information concerning variations of the perfusion, thus facilitating the reading out of this information while avoiding said drawbacks.

In respect of the method this object is achieved as disclosed in the characterizing part of claim 1 whereas in respect of the device it is achieved as disclosed in claim 21.

Further features of the invention are disclosed in the claims 16 to 18 and in the dependent claims.

The invention is based on the recognition of the fact that information represented by autonomous graphic elements can be observed faster and simpler than information that has to be derived by interpretation of curves or comparison of several numerical values.

In accordance with the invention, the numerical data (perfusion index) required for the graphic presentation of the variations of the perfusion is determined continuously from measuring values of the photometric measuring process while using an algorithm. A first perfusion index is defined as a reference value and the relative deviations of the subsequent perfusion indices are determined in relation to this reference value. These

relative deviations are represented by analog graphic elements on the user surface of the display screen as information concerning the variation of the perfusion.

Thus, it is simply possible to read out the relative variation of the perfusion, which is presented in the form of analog graphic elements. Such a representation is very advantageous, because the clinical staff is presented with significant and ready-for-use information concerning the variation of the perfusion. Interpretation on the basis of the plethysmography curve or by continuous observation and comparison of numerical values is no longer necessary. Moreover, the size of presentation of the plethysmography curve can now be automatically adapted to the signal, thus facilitating interpretation of the curve characteristic.

Preferably, the reference value is automatically determined at the beginning of the photometric measuring process.

The instant for determining the reference value, however, can also be chosen at will by the clinical staff. It is thus ensured that a negative effect on the reference value, for example, due to a temporary state of shock of the patient or the like, can be precluded by way of a suitable choice of the instant for determining the reference value.

For reasons of flexibility, for example, for the comparison of two reference values of a patient which have been determined at different instants, such values can be stored on a memory chip.

In order to enable adjustment of the size of the graphic element and hence of the presentation of the information concerning variations of the perfusion, the reference value as well as the subsequent perfusion indices can be normalized or scaled with a factor.

Preferably, this factor is individually adjustable. The individual adjustability offers the advantage that the representation can be readjusted in dependence on a relevant situation, for example, also during an operation, so that an optimum presentation of the information concerning variations of the perfusion is always ensured.

In order to ensure a clear, readily recognizable presentation of the information, the information concerning variations of the perfusion is presented in the form of bar elements.

The relative variations of the perfusion are preferably represented by way of different lengths of the bars. The use of different bar lengths for the representation of the relative variation has been found to be advantageous, because it ensures in a simple manner a fast optical and intuitive recognition of a change of information by the clinical staff.

In order to facilitate the recognition of critical variations of the perfusion there is provided an upper alarm limit and a lower alarm limit, each of which is individually adjustable. When a critical value is reached, that is, when the adjusted alarm limits are exceeded, such an event can then be accentuated by means of an optical and/or acoustic signal.

Preferably, the quality of the measuring values (signal quality) acquired during the photometric measuring process is presented on the user surface of the display screen by way of a different color of icons or background areas, that is, the color green for everything in order, yellow for dubious and red for poor. The estimation of the signal quality can be performed, for example, by evaluation of a combination of various parameters such as, for example, transmission level, interference level, artifact level, signal waveform, perfusion index or the like. The additional presentation of the signal quality is of major importance to the clinical staff, because it enables an evaluation of the measuring values derived from pulsoximetry as well as an evaluation of the information concerning the variations of the perfusion. Moreover, the coloring ensures intuitive observation, which in turn substantially simplifies the interpretation of the indicated signal quality.

Preferably, the same graphic elements are used for the presentation of the variations of the perfusion and for the presentation of the signal quality. Thus, a bar element provided for the presentation of the variation of the perfusion may at the same time be colored, that is, green for the signal quality o.k., yellow for a reduced signal quality, or red for a poor signal quality. This form of presentation, where the icons for the presentation of the signal quality are identical to the graphic elements for the presentation of the variations of the perfusion, has been found to be advantageous, because it results in a space-saving display format. A further space-saving possibility for presentation consists in that a background area, for example, the background of the bar elements, the plethysmography curve or also the background of the numerical display for the oxygen saturation, is characterized by a corresponding color. Coloring of other elements, for example, of the plethysmography curve itself, is also feasible.

However, it is also possible to present the icons as independent graphic elements, notably as a segment or bar representation, as color-encoded surface elements, or in the form of three circular elements arranged like a traffic light.

The device for carrying out the method includes a pulsoximeter for determining the arterial O_2 saturation and for calculating the perfusion index for the determination of the information concerning the variation of the perfusion, means for

detecting interference signals, notably motion artifacts, and for estimating the quality of the acquired measuring values and hence the information concerning a variation of the perfusion, and means for displaying the information.

Further advantages and feasible applications of the present invention are disclosed in the following description in conjunction with the embodiment which is shown in the drawing.

The invention is described more or less diagrammatically hereinafter on the basis of an embodiment as shown in the drawing. Therein:

Fig. 1 is a diagrammatic representation of a user surface of a display screen as used in the field of patient monitoring,

Fig. 2 shows a measuring cap which is fitted on the tip of a finger and comprises two light-emitting diodes and a photoreceiver,

Fig. 3 shows a part of a further user surface with graphic elements for the presentation of the perfusion,

Fig. 4 shows a part of a user surface with graphic elements for the presentation of the perfusion and independent graphic elements for the presentation of the signal quality, and

Fig. 5 shows a further part of a user surface with graphic elements for the presentation of the variation of the perfusion.

For a better understanding of the invention a brief description will first be given of the procedures used thus far for the determination of the perfusion of a patient.

Fig. 1 shows a typical user surface 10 as used in the field of patient monitoring. The Figure shows inter alia a plurality of dynamically varying patient data, such as an ECG (electrocardiography) curve (derivative I) 12, a further ECG curve (derivative II) 14, a plethysmography curve 16 as well as a CO_2 respiration curve 18. To the right of the real-time curves 12, 14, 16 and 18 the associated physiological values are displayed in numerical form. For example, to the right of the plethysmography curve 16 the current value of the oxygen saturation of the arterial blood (SPO_2 value) 20 is shown with associated alarm limits 22.

With regard to the perfusion to be monitored, thus far the plethysmography curve 16 was observed by the clinical staff in order to derive information as regards the current perfusion by interpretation of the varying curve amplitude.

As is known, the plethysmography curve 16 is determined by means of a photometric measuring process, that is, the so-called pulsoximetry.

Pulsoximetry is a spectrophotometric method for the non-invasive determination of the arterial oxygen saturation of the blood. To this end, use is made of a measuring cap 24 as shown in Fig. 2, which cap comprises two light-emitting diodes 26, 28 and a photoreceiver 30 and is fitted on the tip 32 of a finger of the patient to be monitored. The arteries 36 and veins 38 extending in the tissue 34 and the capillaries 40 present between the arteries 36 and veins 38 are denoted by dashed lines. The light-emitting diodes 26 and 28 emit light of different wavelength, for example, 660 nm and 950 nm, to the photoreceiver 30. The photoreceiver 30 measures the intensity variation of the light which is due to a variation of an arterial blood volume and converts this information into a current signal which serves inter alia to present the plethysmography curve 16 on the user surface 10. Since photometric measuring methods are well known, for the sake of simplicity the measuring method will not be shown or elaborated further.

In order to enable direct representation of the variations of the perfusion of a patient, a known algorithm is used to determine the so-called perfusion index from the measuring values continuously produced by pulsoximetry. After a first perfusion index has been defined as a reference value, the relative deviations of the subsequently calculated perfusion indices are determined relative to the reference value. Such relative deviations then serve as information concerning the variation of the perfusion and are presented on the user surface 10 in the form of graphic elements.

Because artifacts due to optical disturbances or motion of the patient are recognized prior to the calculation of the perfusion index and filtered by the algorithm, it is ensured that the information displayed in respect of the variation of the perfusion is highly accurate.

For reasons of simplicity, the algorithms necessary for the calculation of the perfusion indices and the presentation of the graphic elements on the user surface 10 will not be elaborated further herein.

Fig. 3 shows a part of a further user surface 10 as used in the field of patient monitoring. In addition to the plethysmography curve 16 and the current SPO_2 value 20 with associated alarm limits 22, information concerning the variation of the perfusion is also

shown. The information is represented by means of two bar elements 42, 44. The numerical value of the perfusion 46 is displayed to the right of the bar elements 42, 44. Moreover, a symbol 48 indicates that corresponding alarm limits for the perfusion have been deactivated.

Whereas the bar element 42 symbolizes the reference value so that the length of the bar element 42 is constant, the bar element 44 represents, by way of its variable length, the variation of the perfusion in relation to the reference value. The fact that the length of the bar element 44 is variable is denoted by the dashed line 50.

The variation of the perfusion can then be readily and intuitively read out by the clinical staff via the different bar length. In order to ensure optimum presentation, the bar elements 42, 44 can be scaled, that is, the length of the bar element 42 can be individually adjusted, causing a corresponding variation of the length of the bar element 44.

The additional display of the estimate of the signal quality as derived by evaluation of various parameters such as the transmission level, interference level, artifact level, signal waveform and perfusion index, is realized by way of corresponding coloring of the bar elements 42, 44 shown. For example, a green bar element indicates a good signal quality while a yellow element indicates a dubious signal quality and a red bar element indicates a poor signal quality.

Fig. 4 shows a further possibility for the representation of the signal quality. Fig. 4 again concerns a part of a user surface 10 as used in the field of patient monitoring. The user surface 10 again displays the plethysmography curve 16, the SPO_2 value 20 with alarm limits 22 and the bar elements 42, 44 for presenting the variation of the perfusion with the associated numerical value 46. Three circular elements 52 are arranged horizontally adjacent one another as graphic elements for the presentation of the signal quality, that is, underneath the numerical value 46 of the perfusion. The signal quality is indicated in known manner by way of corresponding coloring of the circular elements, that is, green = good signal quality, yellow = mediocre signal quality, and red = poor signal quality.

Fig. 5 shows a further version in which only the variation of the perfusion is represented via the element 44, 50 in addition to the numerical information 20, 22 and 46 so that more room is available for the display of the plethysmography curve 16. The reference value is indicated by way of a further graphic element 54, for example, the tip of an arrow or a line.

LIST OF REFERENCES:

10	user surface for patient monitoring
12	ECG curve, derivative I
14	ECG curve, derivative II
16	plethysmography curve
18	CO_2 respiration curve
20	SPO_2 value
22	alarm limits
24	measuring cap
26	first light-emitting diode
28	second light-emitting diode
30	photoreceiver
32	finger cap
34	tissue
36	arteries
38	veins
40	capillaries
42	first bar element
44	second bar element
46	numerical value of the perfusion
48	symbol for deactivated alarm limits
50	variation of the length of the second bar element
52	independent graphic elements for indicating the signal quality
54	marking of the reference value

CLAIMS:

1. A method for the presentation of information concerning variations of the arterial filling with blood (perfusion) of organs of living beings on the user surface (10) of a display unit, in which method the data required for the presentation (perfusion index) is determined, using an algorithm, from measuring values produced by a non-invasive photometric measuring process for determining the arterial oxygen saturation of the blood, characterized in that a first perfusion index is defined as a reference value and the subsequent perfusion indices are determined as relative deviations with respect to the reference value, said relative deviations being presented as information concerning the variations of the perfusion on the user surface (10).

2. A method as claimed in claim 1, characterized in that the determination of the reference value takes place automatically at the beginning of the photometric measuring process.

3. A method as claimed in claim 1, characterized in that the instant of determination of the reference value can be chosen at will.

4. A method as claimed in the claims 1 to 3, characterized in that the reference value is stored on a memory chip.

5. A method as claimed in one of the preceding claims, characterized in that the reference value as well as the subsequent perfusion indices are scaled by a factor.

6. A method as claimed in claim 5, characterized in that the factor is adjustable.

7. A method as claimed in one of the preceding claims, characterized in that the variation of the perfusion is presented in numerical form.

8. A method as claimed in one of the preceding claims, characterized in that analog graphic elements (42, 44) are used for the presentation.

9. A method as claimed in claim 8, characterized in that bar elements (42, 44) are used as the graphic elements.

10. A method as claimed in claim 9, characterized in that the relative variations of the perfusion are represented by different bar lengths.

11. A method as claimed in claim 8, characterized in that a representation in conformity with a tachometer display is used as the graphic element.

12. A method as claimed in claim 8, characterized in that the display is formed as a multidimensional type in conjunction with other physiological variables, notably as a spider diagram.

13. A method as claimed in one of the preceding claims, characterized in that an upper alarm limit and a lower alarm limit are provided.

14. A method as claimed in claim 13, characterized in that the alarm limit is adjustable.

15. A method as claimed in the claims 13 and 14, characterized in that an acoustic and/or optical alarm signal is triggered when the alarm limit is exceeded.

16. A method of determining the quality of the measuring values (signal quality) derived by means of a photometric measuring process, notably in combination with a method as claimed in one of the preceding claims, characterized in that the signal quality is determined by a single one or a combination of the following variables:

- saturation-independent perfusion index
- transmission factor
- extent of ambient disturbances, such as stray light, EM radiation and the like
- shape of the PLETH signal
- strength and/or duration of artifacts.

17. A method of determining the quality of the measuring values (signal quality) derived by means of a photometric measuring process, characterized in that the signal quality is determined by the modulation factor (AC/DC) of one or more wavelengths in combination with one or more of the following variables:

- saturation-independent perfusion index
- transmission factor
- extent of ambient disturbances, such as stray light, EM radiation, and the like
- shape of the PLETH signal
- strength and/or duration of artifacts.

18. A method of presenting the quality of the measuring values (signal quality) derived by means of the photometric measuring process, notably as claimed in claim 16 or 17, characterized in that this information is graphically presented on the user surface (10) by way of different coloring of icons and/or background areas, notably in green for everything o.k., yellow for dubious quality and red for a poor quality.

19. A method as claimed in claim 18, characterized in that the icons are identical to the graphic elements (42, 44) used for the presentation of the perfusion.

20. A method as claimed in claim 18 or 19, characterized in that the icons are independent graphic elements (52), notably segment-like or bar-like presentations, color-encoded surface elements or circular elements arranged in the form of a traffic light.

21. A device for carrying out the method, comprising
a pulsoximeter for determining the arterial O_2 saturation and for calculating the perfusion index in order to determine the information concerning the variation of the perfusion,
means for the detection of interference signals, notably motion artifacts, and for estimating the quality of the measuring values acquired and hence the information concerning a variation of the perfusion, and
means for presenting the information.

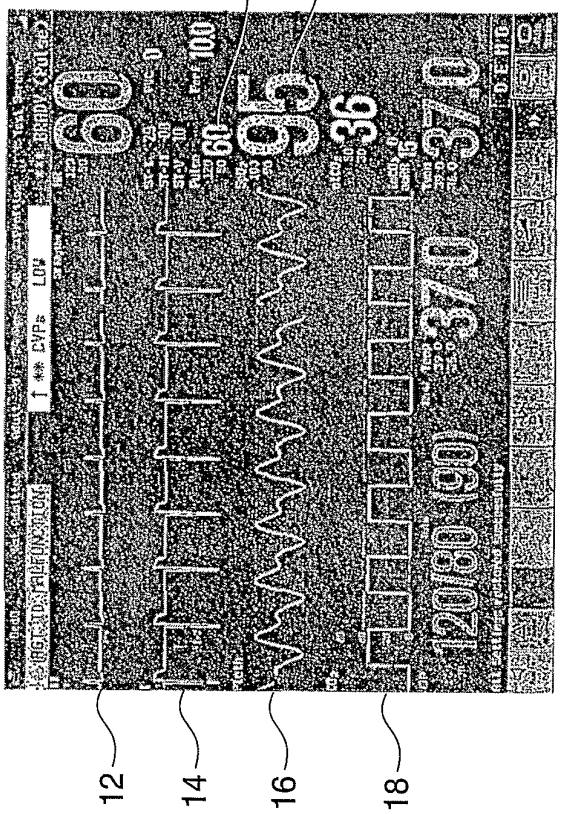


FIG.1

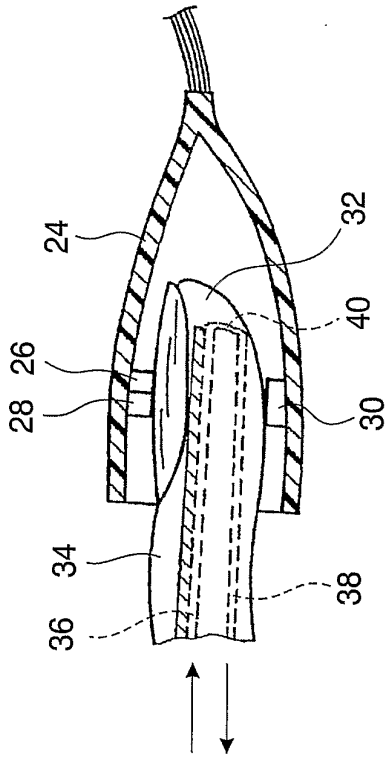


FIG.2

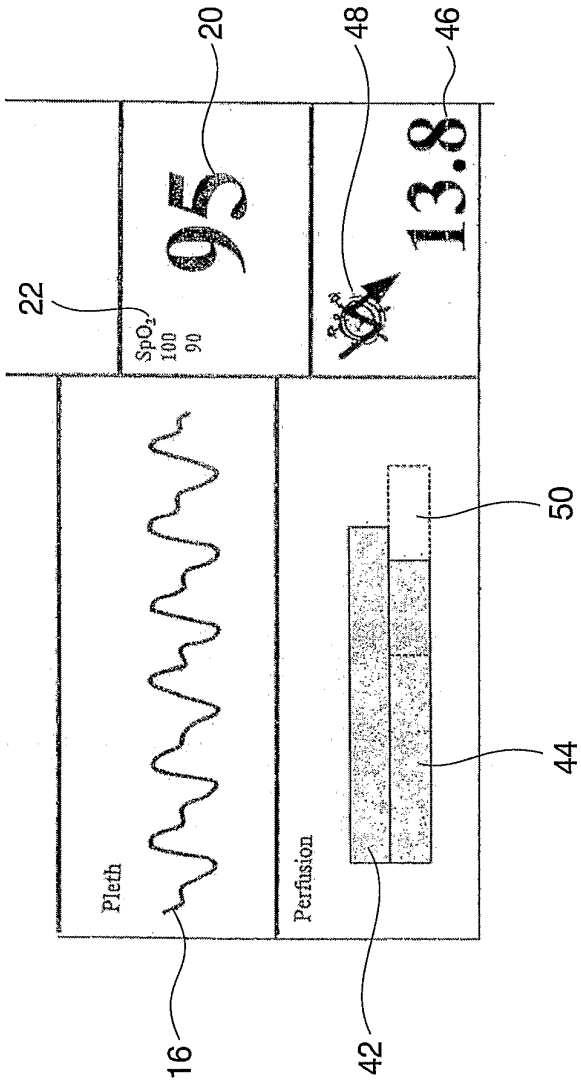


FIG.3

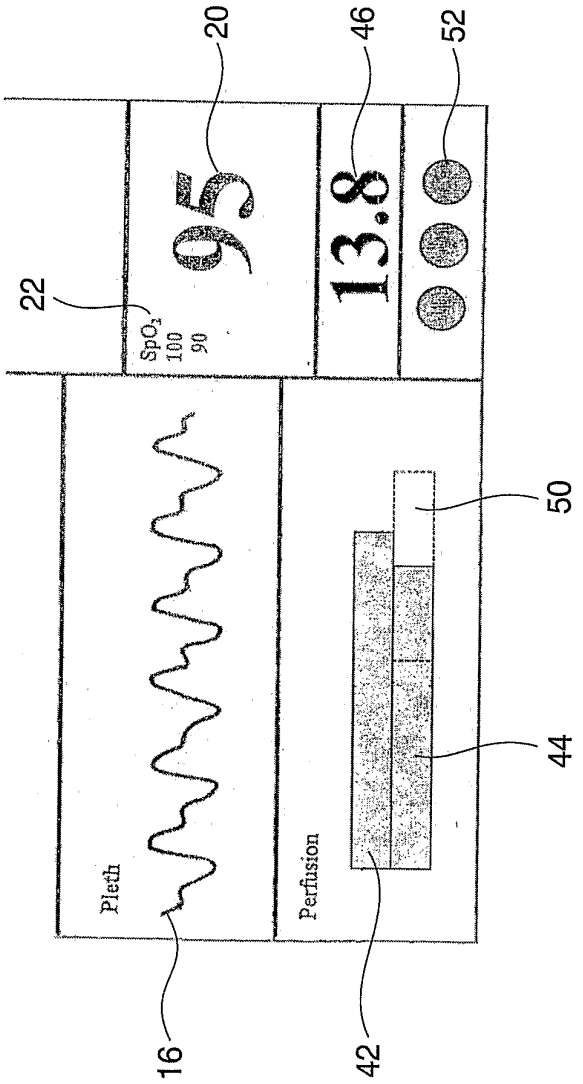


FIG.4

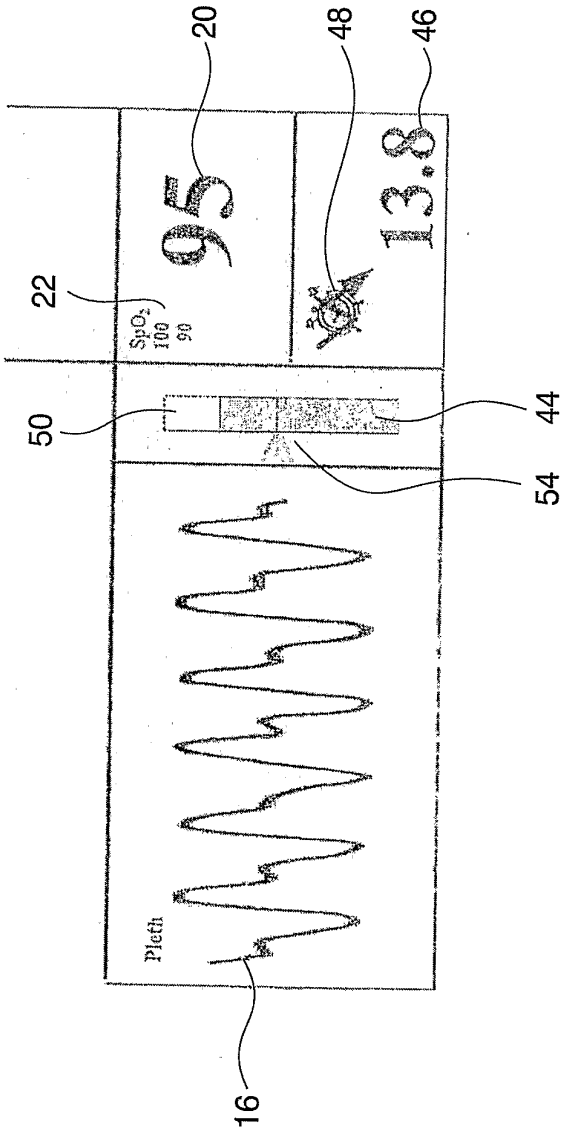


FIG.5

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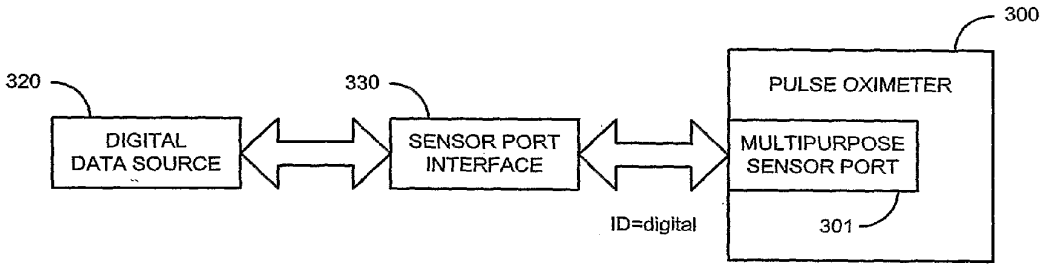
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(54) Title: MULTIPURPOSE SENSOR PORT



(57) Abstract: A sensor port is adapted to connect to either a sensor or a data source. A reader is configured to identify which of the sensor and the data source is connected to the sensor port. A data path is configured to communicate an analog signal associated with the sensor and digital data associated with the data source to a signal processor according to the identification made by the reader.

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MULTIPURPOSE SENSOR PORT

Background of the Invention

[0001] A pulse oximeter is a physiological instrument that provides noninvasive measurements of arterial oxygen saturation along with pulse rate. To make these measurements, a pulse oximeter performs a spectral analysis of the pulsatile component of arterial blood so as to determine the relative concentration of oxygenated hemoglobin, the major oxygen carrying constituent of blood. Pulse oximeters provide early detection of decreases in the arterial oxygen supply, reducing the risk of accidental death and injury. As a result, these instruments have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care units, general wards and home care.

[0002] FIG. **1** illustrates a pulse oximetry system **100** having a sensor **110** and a monitor **120**. The monitor **120** may be a multi-parameter patient monitor or a standalone, portable or handheld pulse oximeter. Further, the monitor **120** may be a pulse oximeter **200**, such as an OEM printed circuit board (PCB), integrated with a host instrument including a host processor **122**, as shown. The sensor **110** attaches to a patient and receives drive current from, and provides physiological signals to, the pulse oximeter **200**. An external computer (PC) **130** may be used to communicate with the pulse oximeter **200** via the host processor **122**. In particular, the PC **130** can be used to download firmware updates to the pulse oximeter **200** via the host processor **122**, as described below.

[0003] FIG. **2** illustrates further detail of the pulse oximetry system **100**. The sensor **110** has emitters **112** and a detector **114**. The emitters **112** typically consist of a red light emitting diode (LED) and an infrared LED that project light through blood vessels and capillaries underneath a tissue site, such as a fingernail bed. The detector **114** is typically a photodiode positioned opposite the LEDs so as to detect the emitted light as it emerges from the tissue site. A pulse oximetry sensor is described in U.S. Patent 6,088,607 entitled "Low Noise Optical Probe," which is assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0004] As shown in FIG. **2**, the pulse oximeter **200** has a preamp **220**, signal conditioning **230**, an analog-to-digital converter (ADC) **240**, a digital signal processor (DSP) **250**, a drive controller **260** and LED drivers **270**. The drivers **270** alternately activate the emitters **112** as determined by the controller **260**. The preamp **220**, signal

conditioning **230** and ADC **240** provide an analog front-end that amplifies, filters and digitizes the current generated by the detector **114**, which is proportional to the intensity of the light detected after tissue absorption in response to the emitters **112**. The DSP **250** inputs the digitized, conditioned detector signal **242** and determines oxygen saturation, which is based upon the differential absorption by arterial blood of the two wavelengths projected by the emitters **112**. Specifically, a ratio of detected red and infrared intensities is calculated by the DSP **250**, and arterial oxygen saturation values are empirically determined based upon the ratio obtained. Oxygen saturation and calculated pulse rate values are communicated to the host processor **122** for display by the monitor **120** (FIG. **1**). A pulse oximeter is described in U.S. Patent 6,236,872 entitled "Signal Processing Apparatus," which is assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0005] Further shown in FIG. **2**, the pulse oximeter **200** has a sensor port **210** and a communications port **280**. The sensor port **210** includes a connector and associated input and output signals and provides an analog connection to the sensor **110**. In particular, the sensor port **210** transmits a drive signal **212** to the LED emitters **112** from the LED drivers **270** and receives a physiological signal **214** from the photodiode detector **114** in response to the LED emitters **112**, as described above. The communication port **280** also includes a connector and associated input and output signals and provides a bi-directional communication path **282** between the pulse oximeter **200** and the host processor **122**. The communication path **282** allows the DSP **250** to transmit oxygen saturation and pulse rate values to the monitor **120** (FIG. **1**), as described above. The communication path **282** also allows the DSP firmware to be updated, as described below.

[0006] Additionally shown in FIG. **2**, the pulse oximeter **200** has a micro-controller **290** and a flash memory **255**. The flash memory **255** holds the stored program or firmware that executes on the DSP **250** to compute oxygen saturation and pulse rate. The micro-controller **290** controls data transfers between the DSP **250** and the host processor **122**. In particular, to update the DSP firmware, the firmware is uploaded into the PC **130** (FIG. **1**), which downloads the firmware to the host processor **122**. In turn, the host processor **122** downloads the firmware to the micro-controller **290**, which downloads it to the DSP **250**. Finally, the DSP **250** writes the firmware to the flash memory **255**.

Summary of the Invention

[0007] To update the firmware in a pulse oximeter, particularly firmware on an OEM PCB integrated into a host instrument, requires a circuitous path using multiple protocols and multiple processors developed by different companies. Some of the protocols and processor interfaces are non-standard, requiring custom programming for different instruments. This is particularly problematic when the instruments are part of an installed base at various medical facilities. Further, some pulse oximeter products, such as handheld products, may not have a communications port for connecting to an external computer, and firmware upgrades would typically require returning the instrument to the factory.

[0008] Every pulse oximeter has a sensor port, which provides access to a DSP via one or more signal paths. Therefore, it is desirable to utilize a sensor port for downloading pulse oximetry firmware to the DSP. It is also desirable to provide this sensor port capability in existing instruments without hardware modification. Utilizing a sensor port in this manner would alleviate an instrument manufacturer from having to provide download communication capability between a host processor and an OEM PCB and would allow easy field upgrades of all instruments, including handhelds.

[0009] One aspect of a multipurpose sensor port is a physiological measurement method comprising a sensor port adapted to connect with an analog sensor, and a digital data source connected to the sensor port. An identifier associated with said data source is read, where the identifier is indicative that the data source is connected to the sensor port in lieu of the analog sensor. Digital data is then received over the sensor port. In one embodiment, the digital data is compiled in a signal processor. Where the digital data are instructions executable by the signal processor, the data may then be written from the signal processor into a firmware memory. The instructions may be uploaded to a PC, which is attached to a PC interface that is attached to the sensor port. Alternatively, the instructions are stored into a nonvolatile memory that is in communications with the sensor port. In another embodiment, the digital data is processed as a physiological signal.

[0010] Another aspect of a multipurpose sensor port is a physiological measurement system having a sensor port adapted to connect to a sensor and a data source. A reader is configured to identify which of the sensor and the data source is connected to the sensor port. A data path is configured to communicate an analog signal associated with the sensor and digital data associated with the data source to a signal processor according to

the reader. In one embodiment, a firmware memory is configured to provide instructions to the signal processor. The signal processor is programmed to download the instructions from the data source and store the instructions in the memory. The instructions are executable by the signal processor so as to extract a physiological measurement from the analog signal. The data source may be a PC interfaced to the sensor port, where the instructions are uploaded to the PC. Alternatively, the data source is a nonvolatile memory adapted to communicate with the sensor port, where the instructions being stored in a nonvolatile memory.

[0011] In another embodiment, a first physiological measurement is derivable by the signal processor from the analog signal, and a second physiological measurement is derivable by the signal processor from the digital data. In yet another embodiment, a drive path is configured to communicate stored data associated with a physiological measurement to a digital device connected to the sensor port. The stored data may be trend data and/or log data maintained in memory that can be accessed by the signal processor. In a further embodiment, a drive path is configured to communicate acknowledgement data in conjunction with the communication of the digital data.

[0012] Yet another aspect of a multipurpose sensor port is a physiological measurement method where a drive path is provided that is adapted to activate emitters so as to transmit optical radiation through a fleshy medium having flowing blood. A signal path is provided that is adapted to communicate a detector response to the optical radiation after attenuation by the fleshy medium, where the response is indicative of optical characteristics of the flowing blood. Output digital data is transmitted over at least a portion of the drive path. In one embodiment, the output digital data is read from a memory having trend data and/or log data. In another embodiment, input digital data is received over at least a portion of the signal path, and receipt of that input digital data is acknowledged with the output digital data. In a particular embodiment, the input digital data is stored for use as signal processing instructions.

Brief Description of the Drawings

[0013] FIG. **1** is a general block diagram of a prior art pulse oximeter system utilizing an OEM printed circuit board (PCB);

[0014] FIG. **2** is a detailed block diagram of a prior art pulse oximeter system;

[0015] FIGS. **3A-D** are general block diagrams of a multipurpose sensor port connected to an analog sensor, a digital data source, or both;

[0016] FIG. **4** is a general block diagram of a multipurpose sensor port having various digital data source inputs;

[0017] FIG. **5** is a block diagram of a multipurpose sensor port configured to download pulse oximeter firmware;

[0018] FIG. **6** is a DSP firmware memory map;

[0019] FIG. **7** is a detailed block diagram of a multipurpose sensor port embodiment and associated signal and data paths;

[0020] FIG. **8** is a flowchart of a digital data receiver routine; and

[0021] FIG. **9** is a schematic of a RS232 interface for a multipurpose sensor port.

Detailed Description of the Preferred Embodiment

Overview

[0022] FIGS. **3A-B** illustrate a pulse oximeter **300** having a multipurpose sensor port **301** connected to an analog sensor **310** and a digital data source **320**, respectively. As shown in FIG. **3A**, if the pulse oximeter **300** determines that an analog sensor **310** is attached to the multipurpose sensor port **301**, the multipurpose sensor port **301** is operated in an analog mode and functions as a typical sensor port, described above. As shown in FIG. **3B**, if the pulse oximeter **300** determines that a digital data source **320** is attached to the multipurpose sensor port **301**, the multipurpose sensor port **301** is operated in a digital mode and functions as a digital communications device. The data source **320** may connect to a sensor port interface **330** which, in turn, connects to the sensor port **301**. The sensor port interface **330** may be used, for example, to present a standard communications interface, such as RS-232, to the data source **320**. In one embodiment, when the pulse oximeter **300** is powered up, it reads an information element or other means of identification (ID) for the device connected to the sensor port **301**. The ID identifies the device as either an analog sensor **310** or a data source **320**. A sensor information element is described in U.S. Patent 6,397,091 entitled "Manual and Automatic Probe Calibration," which is assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0023] FIG. **3C** illustrates a sensor port embodiment where a resistor value is a device ID. A resistor **303** is located in a device **302**, which includes a sensor **310** (FIG.

3A), data source **320** (FIG. **3B**) or interface **330** (FIG. **3B**). The sensor port **301** has a reader **304** that measures the resistor value. The reader **304** includes a voltage source **305** and a current measurement device **307**, such as a current-to-voltage converter. The voltage source **305** has a known voltage, which is applied to the resistor **303** when the device **302** is connected to the sensor port **301**. The current measurement device **307** senses the magnitude of the resulting current flowing through the resistor **303** so as to determine the resistor value and, hence, the device ID.

[0024] FIG. **3D** illustrates a pulse oximeter **300** having an analog sensor **310**, a digital data source **320** and a switch **360** connected to a multipurpose sensor port **301**. If the pulse oximeter **300** reads an ID that identifies mixed analog and digital, then the multipurpose sensor port **301** functions to transfer either an analog signal or digital data, as determined by the switch **360**. The state of the switch **360** may be determined by the data source **320**, the pulse oximeter **300** or both. In one embodiment, the pulse oximeter **300** transmits an identifiable waveform over an LED drive path **510** (FIG. **5**) that is recognized by the switch **360** as a change state command. In this manner, the pulse oximeter **300** may occasionally receive digital data from, or transmit digital data to, the data source **320**.

Applications

[0025] FIG. **4** illustrates various digital data source **320** and sensor port interfaces **330** that connect to a multipurpose sensor port **301**. In one application, a preprogrammed module **405** connects directly to the sensor port **301**. The module **405** has nonvolatile memory preprogrammed with, for example, upgrade firmware for the pulse oximeter **300**. The module **405** also has the associated electronics to readout the memory data and communicate that data to the sensor port **301**. In particular, the module **405** provides mechanical, signal level, and communication protocol compliance with the sensor port **301**.

[0026] As shown in FIG. **4**, in another application, a PC **410** connects to the sensor port **301** via a PC interface **450**. For example, the PC **410** can be used to download firmware to the pulse oximeter **300**, as described with respect to FIG. **5**, below. As another example, the PC **410** can be used to upload information from the pulse oximeter **300**, as described with respect to FIG. **6**, below. In one embodiment, the PC interface **450** provides mechanical and signal level compliance with RS-232 on the PC side and mechanical and

signal level compliance with the sensor port **301** on the pulse oximeter side, as described with respect to FIG. **9**, below.

[0027] Also shown in FIG. **4**, a physiological sensor **420** other than a conventional pulse oximeter sensor is attached to the multipurpose sensor port **301**. A physiological sensor interface **460** drives the physiological sensor **420** and generates raw digital data to the sensor port **301**. In this manner, a pulse oximeter **300** can be advantageously extended to provide physiological measurements in addition to oxygen saturation and pulse rate.

[0028] Further shown in FIG. **4**, a wireless data device **430** is attached to the multipurpose sensor port **301** via a wireless interface **470**. In this manner, the pulse oximeter can be advantageously extended to wireless data I/O and wireless networks. In one embodiment, the wireless interface **470** provides mechanical and signal level compliance with a wireless standard, such as IEEE-802.11, on one side and mechanical and signal level compliance with the sensor port **301** on the pulse oximeter side.

[0029] Additionally shown in FIG. **4**, networked digital I/O devices **440** are attached to the multipurpose sensor port **301** via a network interface **480**. In one embodiment, the network interface **480** provides mechanical and signal level compliance with a network standard, such as Ethernet, on one side and mechanical and signal level compliance with the sensor port **301** on the pulse oximeter side.

Firmware Upgrade Port

[0030] FIG. **5** illustrates a multipurpose sensor port **301** configured to download pulse oximeter firmware **501**. The firmware **501** is uploaded to a PC **410** and downloaded over a standard communications bus **503** to a target pulse oximeter **300**. The standard bus **503** may be, for example, RS-232, IEEE-488, SCSI, IEEE-1394 (FireWire), and USB, to name just a few. A PC interface **450** translates the signal levels on the sensor port **301** to the signal levels of the standard bus **503**, and vice-a-versa. In particular, an output signal on the standard bus **503** is translated to a sensor port input signal **522**, and a sensor port output signal **512** is translated to an input signal on the standard bus **503**.

[0031] As shown in FIG. **5**, the pulse oximeter **300** has a detector signal path **520**, a DSP **530**, a flash memory **540** or other nonvolatile memory and a LED drive path **510**, such as described with respect to FIG. **2**, above. Data transmitted from the PC **410** is

carried on the sensor port input **522**, over the detector signal path **520** to the DSP **530**, which loads the data into a flash memory **540**. Acknowledgement data is transmitted from the DSP **530**, over the LED drive path **510**, and is carried on the sensor port output **512**.

[0032] FIG. **6** illustrates a memory map **600** for the DSP flash memory **540** (FIG. **5**). The memory map **600** illustrates partitions for DSP executable instructions such as boot firmware **610**, signal processing firmware **620** and sensor port communications firmware **630** in addition to application data **640**. The boot firmware **610** executes upon DSP power-up. The boot firmware **610** initializes the DSP and loads either the signal processing firmware **620** or the communications firmware **630** into DSP program memory, depending on the device ID, as described with respect to FIGS. **3A-D**, above. The signal processing firmware **620** contains the oxygen saturation and pulse rate measurement algorithms, referred to with respect to FIGS. **1-2**, above. The communications firmware **630** contains communications protocol algorithms, such as described with respect to FIG. **8**, below. After completing its task of downloading firmware and/or uploading the applications data **640**, the communications firmware **630** loads the signal processing firmware **620** so that the DSP can perform pulse oximetry measurements.

[0033] Also shown in FIG. **6**, the application data **640** includes trend data **632**, operational logs **634** and manufacturer's logs **638**, which can be advantageously uploaded to a PC **410** (FIG. **5**) or other digital device connected to the sensor port **301** (FIG. **5**). Trend data **632** contains oxygen saturation and pulse rate measurement history. Operational logs **634** contain, for example, failure codes and event information. Failure codes indicate, for example, pulse oximeter board failures and host failures. Event information includes alarm data, such as the occurrence of probe off and low saturation events. Manufacturer's logs **638** contains, for example, service information.

[0034] FIG. **7** illustrates a multipurpose sensor port embodiment **301** incorporating an LED drive path **510**, a detector signal path **520** and a DSP **530**, which function generally as described with respect to FIG. **5**, above. The LED drive path **510** has a shift register **710**, a red LED drive **720** and an IR LED drive **730**. The shift register **710** has a data input **712**, a red control output **714** and an IR control output **718**. The DSP **530** provides serial control data on the shift register input **712** that is latched to the shift register outputs **714**, **718** so as to turn on and off the LED drives **720**, **730** according to a predetermined sequence of red on, IR on and dark periods. The detector signal path **520**

has a preamp **740**, signal conditioning **750** and an ADC **760** that perform amplification, filtering and digitization of the detector signal **522**. The detector signal path **520** also has a comparator **770** that compares the preamp output **742** to a fixed voltage level and provides an interrupt output **774** to the DSP **530** accordingly. The comparator **770** allows the DSP to control the preamp voltage as a function of the level of the preamp signal output **742**, as described in U.S. Patent Application No. 10/351,961 entitled "Power Supply Rail Controller," filed 01/24/2003, which is assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein. Advantageously, the comparator signal path also allows the DSP to accept serial digital data, as described with respect to FIG. **8**, below.

[0035] FIG. **8** illustrates a serial data receiver **800** embodiment of one aspect of the communications firmware **630** (FIG. **6**). The data receiver **800** utilizes the detector signal path **520** (FIG. **7**) described above. A DSP internal timer is initialized to generate an interrupt at the incoming data baud rate. The timer interrupt periodically starts the data receiver **800** to determine and store a single bit. The data receiver **800** polls the status of the DSP interrupt input **774** (FIG. **7**), which is initialized to be level-sensitive and disabled. Thus, whenever the comparator **770** (FIG. **7**) is triggered, it will latch into a DSP interrupt pending register but will not generate an interrupt event. The timer service routine **800** polls the interrupt pending register **820**. The pending register value is determined **830**. If the value is a "1," then a zero bit has been received **840**, else a one bit has been received **850**. The received bit is stored **860** and the timer reset **870**.

[0036] FIG. **9** illustrates an RS-232 PC interface embodiment **450** having an RS-232 connector **910**, a sensor connector **920**, a voltage regulator **930** and a transceiver **940**. The voltage regulator **930** draws power from either the RS-232 **910** RTS (request to send) or DTR (data terminal ready) signal lines and provides regulated VCC power to transceiver **940**. The transceiver **940** operates on either of the sensor **920** red or IR drive signal lines to generate an RS-232 **910** RXD (receive data) signal. The transceiver **940** further operates on the RS-**232** TXD (transmit data) signal line to generate a sensor **920** detector signal.

[0037] A multipurpose sensor port has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

WHAT IS CLAIMED IS:

1. A physiological measurement method comprising the steps of:

providing a sensor port adapted to connect with an analog sensor;

connecting a digital data source to said sensor port;

reading an identifier associated with said data source, said identifier indicative that said data source is connected to said sensor port in lieu of the analog sensor; and

receiving digital data over said sensor port.

2. The physiological measurement method according to claim 1 comprising the further step of compiling said digital data in a signal processor.

3. The physiological measurement method according to claim 2 comprising the further step of writing said digital data from said signal processor into a firmware memory, said digital data comprising a plurality of instructions executable by said signal processor.

4. The physiological measurement method according to claim 3 wherein said connecting step comprises the substeps of:

uploading said instructions to a PC;

attaching a PC interface to said sensor port;

attaching said PC to said PC interface.

5. The physiological measurement method according to claim 3 wherein said connecting step comprises the substeps of:

storing said instructions into a nonvolatile memory; and

providing communications between said nonvolatile memory and said sensor port.

6. The physiological measurement method according to claim 2 comprising the further step of processing said digital data as a physiological signal.

7. A physiological measurement system comprising:

a sensor port adapted to connect to a sensor and a data source;

a reader configured to identify which of said sensor and said data source is connected to said sensor port;

a signal processor; and

a data path configured to communicate an analog signal associated with said sensor and digital data associated with said data source to said signal processor according to said reader.

8. The physiological measurement system according to claim 7 further comprising:

a firmware memory configured to provide instructions to said signal processor,

said signal processor programmed to download said instructions from said data source and store said instructions in said memory, said instructions executable by said signal processor so as to extract a physiological measurement from said analog signal.

9. The physiological measurement system according to claim 8 wherein said data source is a PC interfaced to said sensor port, said instructions being uploaded to said PC.

10. The physiological measurement system according to claim 8 wherein said data source is a nonvolatile memory adapted to communicate with said sensor port, said instructions being stored in a nonvolatile memory.

11. The physiological measurement system according to claim 7 further comprising:

a first physiological measurement derivable by said signal processor from said analog signal; and

a second physiological measurement derivable by said signal processor from said digital data.

12. The physiological measurement system according to claim 7 further comprising a drive path configured to communicate stored data associated with a physiological measurement to a digital device connected to said sensor port.

13. The physiological measurement system according to claim 12 wherein said stored data is at least one of trend data and log data maintained in memory that can be accessed by said signal processor.

14. The physiological measurement system according to claim 7 further comprising a drive path configured to communicate acknowledgement data in conjunction with the communication of said digital data.

15. A physiological measurement method comprising the steps of:

providing a drive path adapted to activate emitters so as to transmit optical radiation through a fleshy medium having flowing blood;

providing a signal path adapted to communicate a detector response to said optical radiation after attenuation by said fleshy medium, said response indicative of optical characteristics of said flowing blood; and

transmitting output digital data over at least a portion of said drive path.

16. The physiological measurement method according to claim 15 comprising the further step of reading said output digital data from a memory having at least one of trend data and log data.

17. The physiological measurement method according to claim 15 comprising the further step of receiving input digital data over at least a portion of said signal path.

18. The physiological measurement method according to claim 17 comprising the further step of acknowledging receipt of said input digital data with said output digital data.

19. The physiological measurement method according to claim 18 comprising the further step of storing said input digital data for use as signal processing instructions.

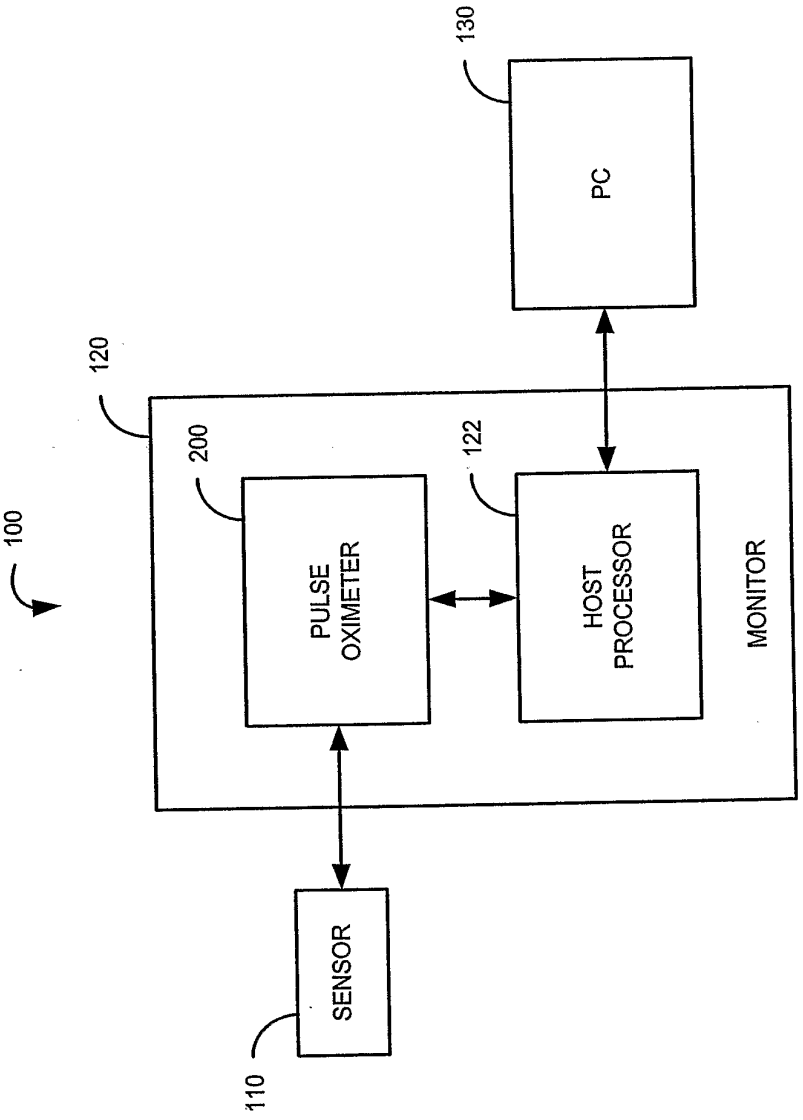


FIG. 1 (Prior Art)

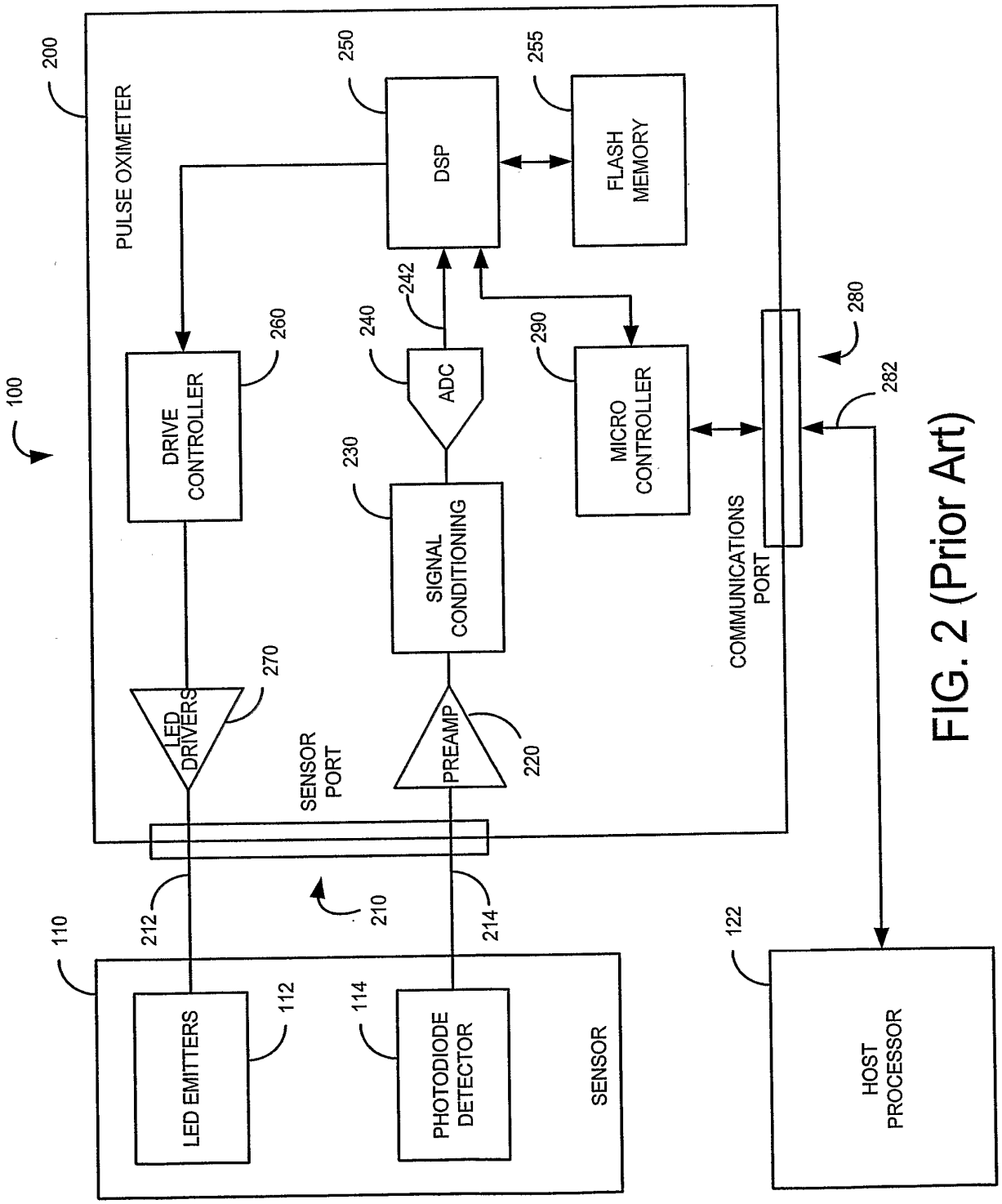


FIG. 2 (Prior Art)

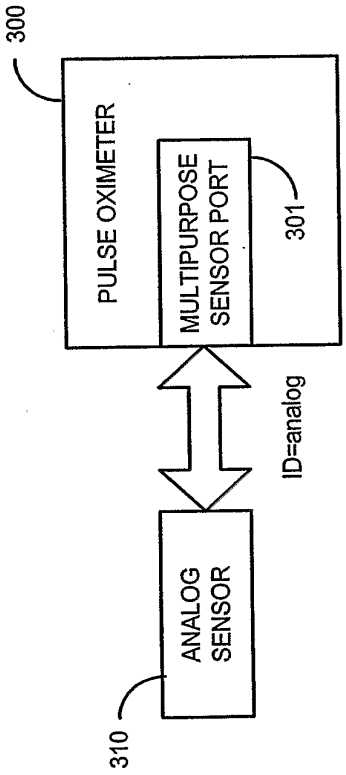

300
PULSE OXIMETER
MULTIPURPOSE SENSOR PORT
301
ID=analog
ANALOG SENSOR
310

FIG. 3A

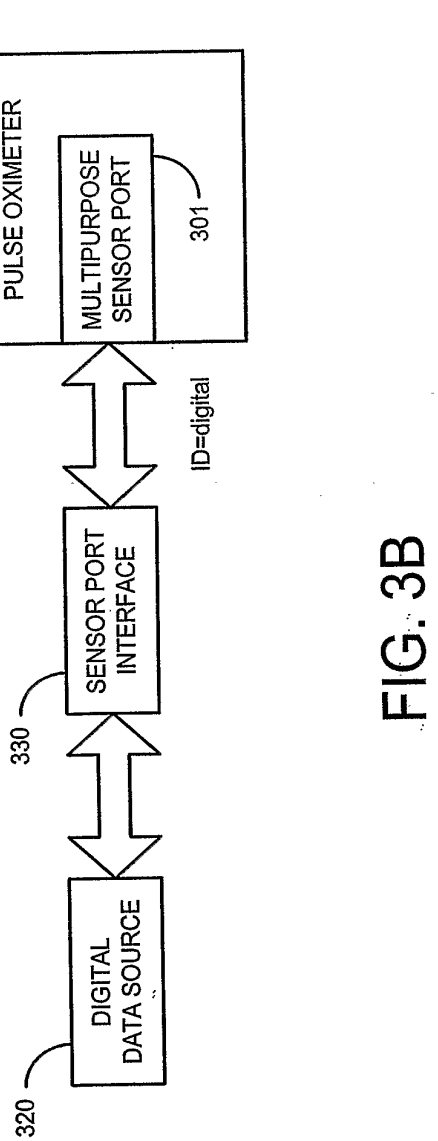

300
PULSE OXIMETER
MULTIPURPOSE SENSOR PORT
301
ID=digital
SENSOR PORT INTERFACE
330
DIGITAL DATA SOURCE
320

FIG. 3B

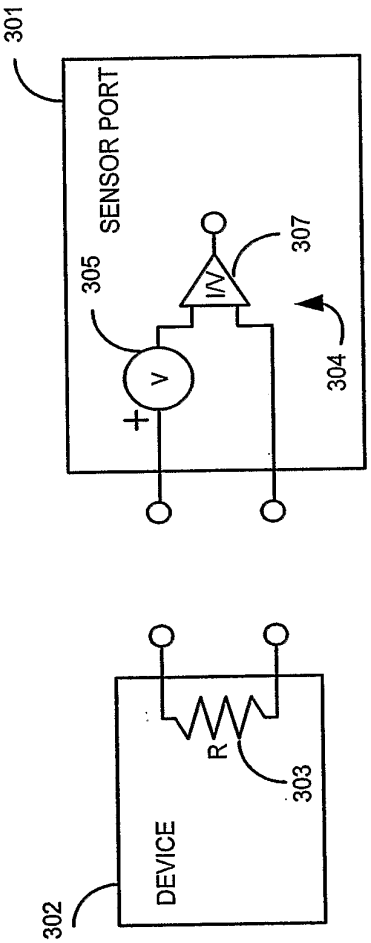

301
SENSOR PORT
305
V
+
I/V
307
304
R
303
DEVICE
302

FIG. 3C

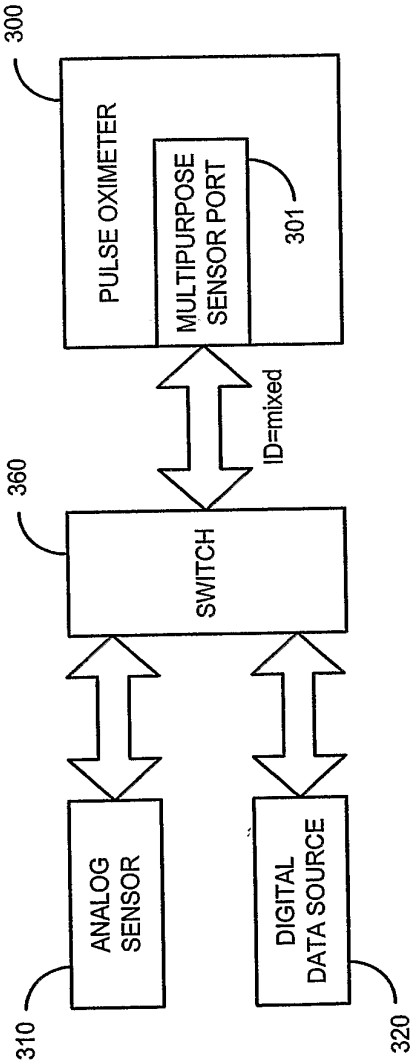

300
PULSE OXIMETER
MULTIPURPOSE SENSOR PORT
301
ID=mixed
360
SWITCH
ANALOG SENSOR
310
DIGITAL DATA SOURCE
320

FIG. 3D

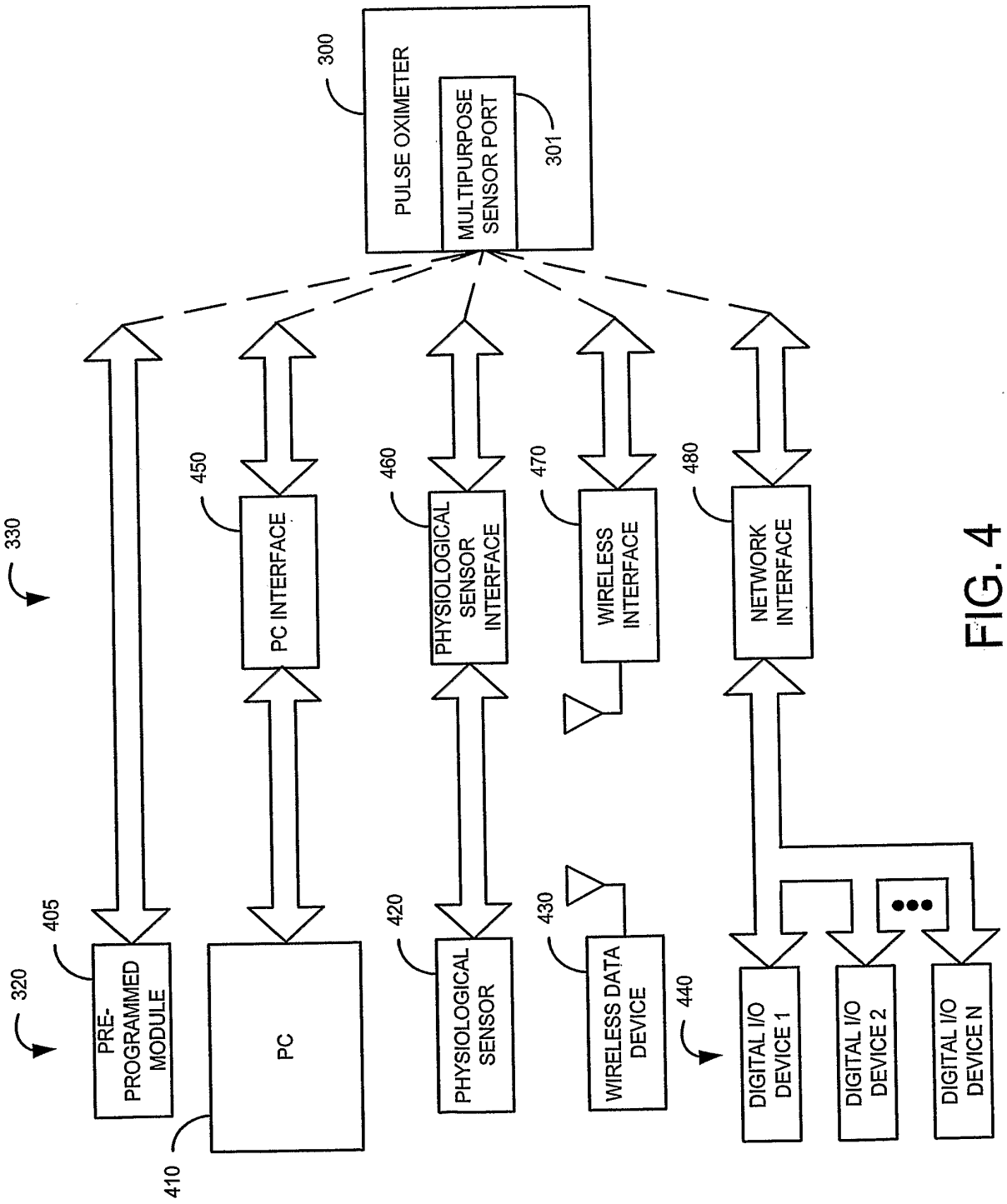

300
PULSE OXIMETER
MULTIPURPOSE SENSOR PORT
301
330
450
PC INTERFACE
460
PHYSIOLOGICAL SENSOR INTERFACE
470
WIRELESS INTERFACE
480
NETWORK INTERFACE
320
405
PRE-PROGRAMMED MODULE
410
PC
420
PHYSIOLOGICAL SENSOR
430
WIRELESS DATA DEVICE
440
DIGITAL I/O DEVICE 1
DIGITAL I/O DEVICE 2
DIGITAL I/O DEVICE N

FIG. 4

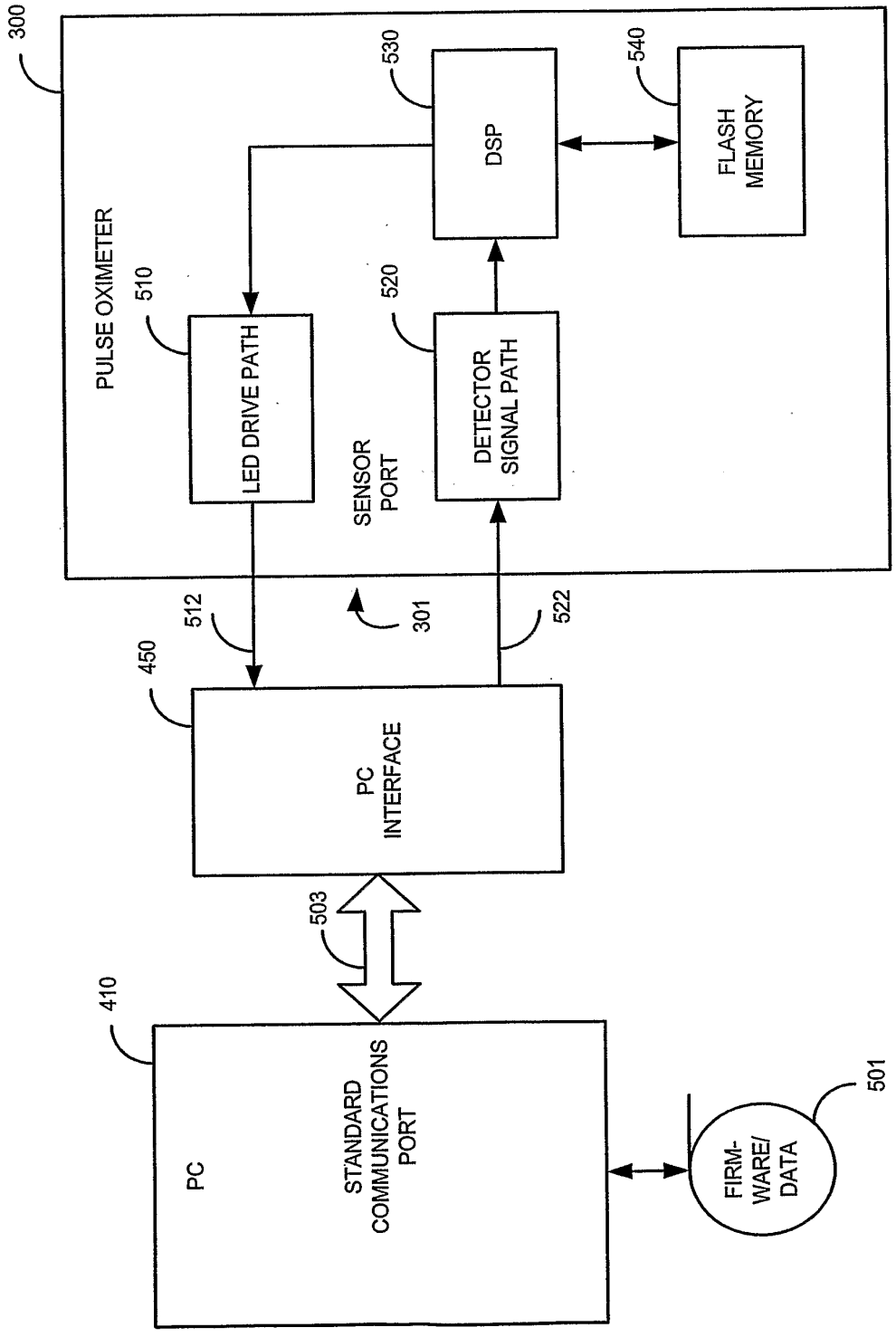

300
PULSE OXIMETER
530
DSP
540
FLASH MEMORY
510
LED DRIVE PATH
520
DETECTOR SIGNAL PATH
SENSOR PORT
301
512
522
450
PC INTERFACE
503
410
PC
STANDARD COMMUNICATIONS PORT
FIRM-WARE/ DATA
501

FIG. 5

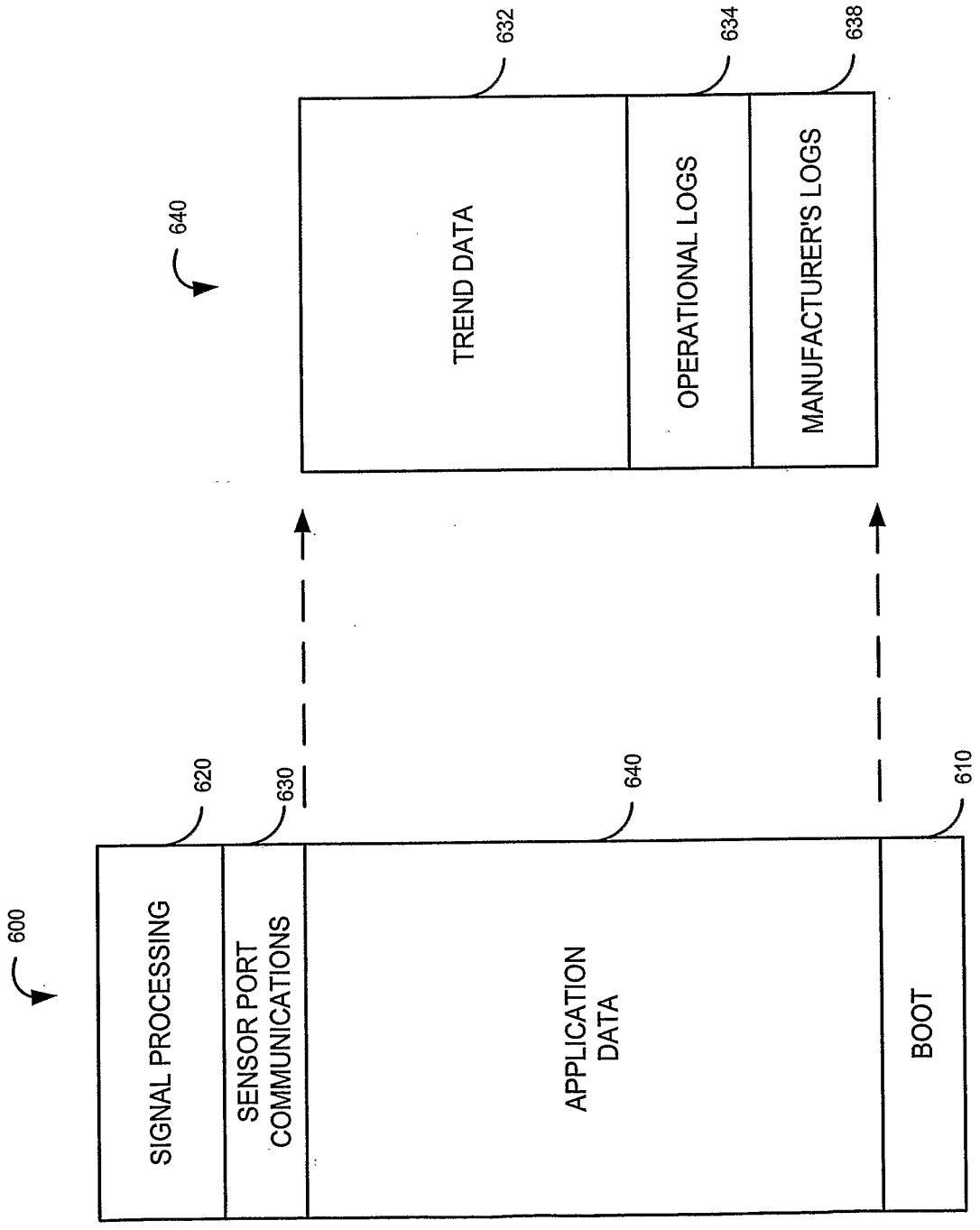

600
SIGNAL PROCESSING
SENSOR PORT COMMUNICATIONS
APPLICATION DATA
BOOT
620
630
640
610
640
TREND DATA
OPERATIONAL LOGS
MANUFACTURER'S LOGS
632
634
638

FIG. 6

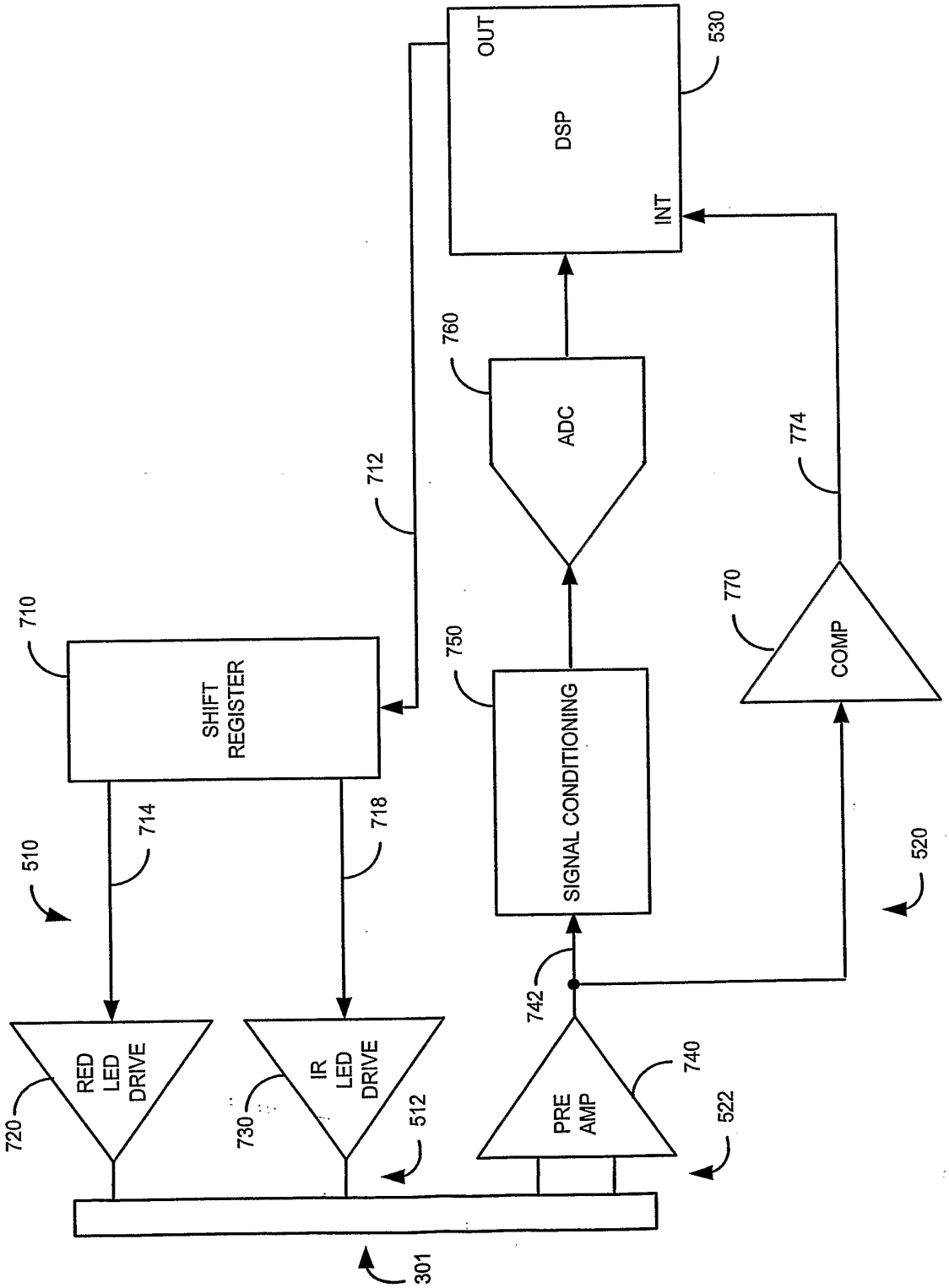

OUT
DSP
INT
530
760
ADC
712
774
710
SHIFT REGISTER
770
COMP
750
SIGNAL CONDITIONING
714
718
510
520
742
RED LED DRIVE
IR LED DRIVE
PRE AMP
740
720
730
512
522
301

FIG. 7

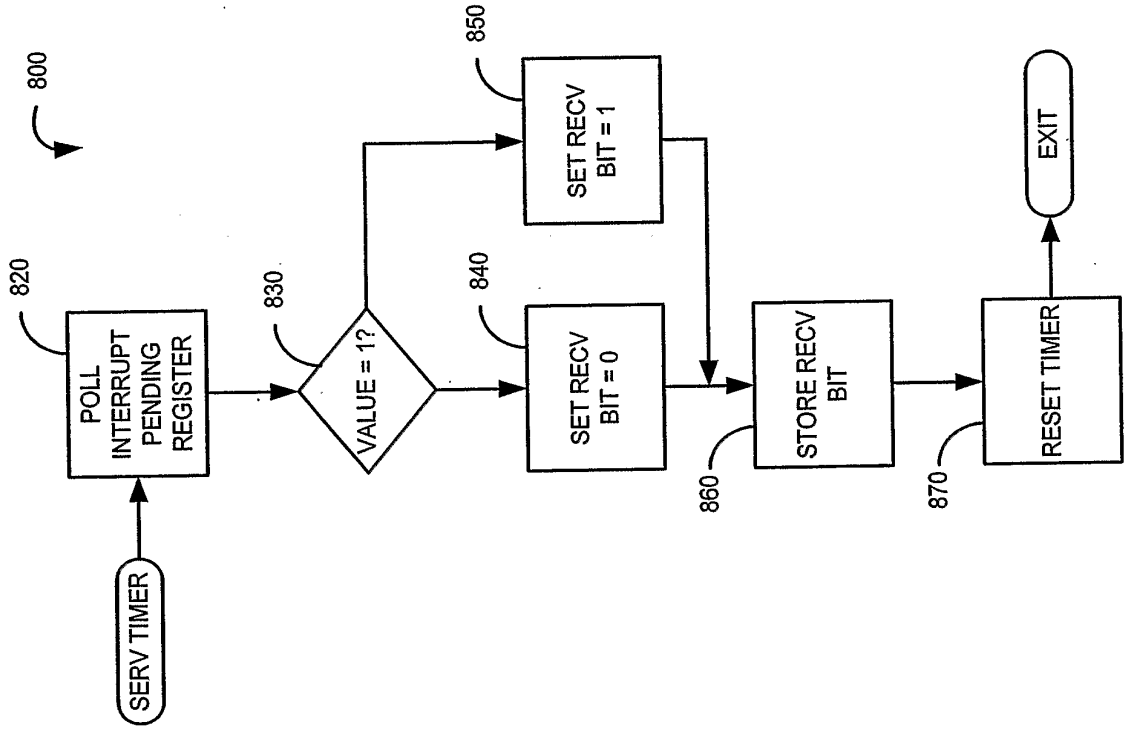

800
820
POLL INTERRUPT PENDING REGISTER
830
VALUE = 1?
840
SET RECV BIT = 0
850
SET RECV BIT = 1
860
STORE RECV BIT
870
RESET TIMER
EXIT
SERV TIMER

FIG. 8

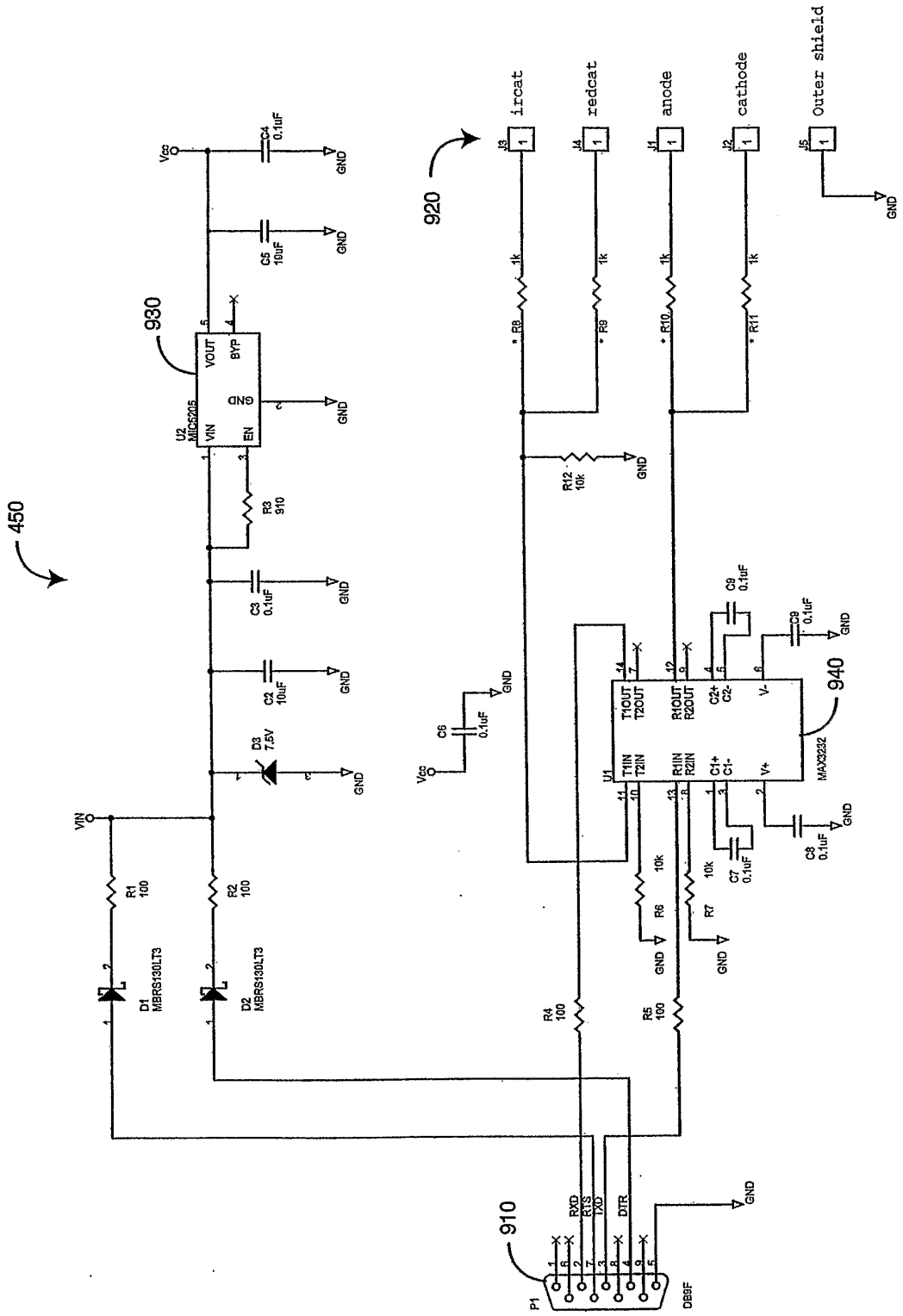

450
930
920
940
910
Vcc
VIN
GND
VOUT
BYP
VIN
EN
U2
MIC5205
C4 0.1uF
C5 10uF
C3 0.1uF
C2 10uF
D3 7.5V
R3 910
R1 100
R2 100
D1 MBRS130LT3
D2 MBRS130LT3
ircat
redcat
anode
cathode
Outer shield
J3
J4
J1
J2
J5
* R8 1k
* R9 1k
* R10 1k
* R11 1k
R12 10k
C6 0.1uF
C9 0.1uF
C8 0.1uF
C7 0.1uF
U1
T1IN
T2IN
R1OUT
R2OUT
C1+
C1-
C2+
C2-
V+
V-
MAX3232
R6 10k
R7 10k
R4 100
R5 100
P1
DB9F
RXD
RTS
TXD
DTR

FIG. 9

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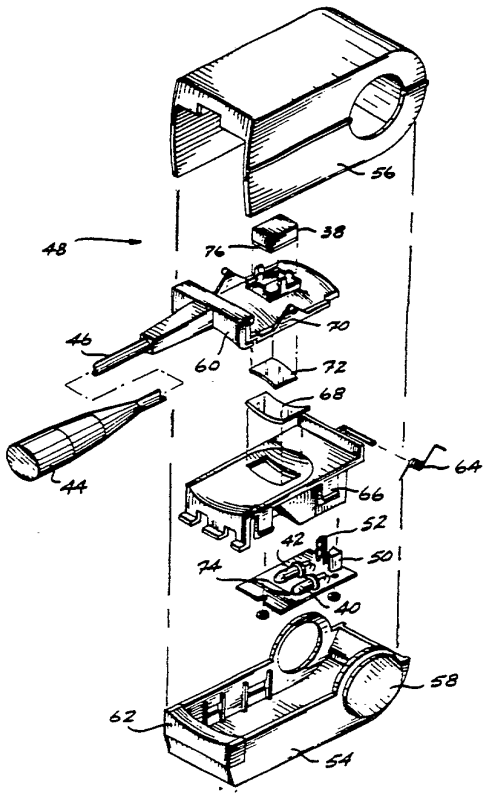
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(57) Abstract

Method and apparatus for compensating for the effect temperature variations have on the wavelength of light emitted by the oximeter sensor light sources (40, 42). In pulse oximetry, LEDs (40, 42) are typically employed to expose tissue to light at two different wavelengths. The light illuminating the tissue is received by a detector (38) where signals proportional to the intensity of light are produced. These signals are then processed by the oximeter circuitry to produce an indication of oxygen saturation. Because current oximetry techniques are dependent upon the wavelengths of light emitted by the LEDs (40, 42), the wavelengths must be known. Even when predetermined combinations of LEDs (40, 42) having relatively precise wavelengths are employed, variations in the wavelength of light emitted may result. Because the sensor (12) may be exposed to a significant range of temperatures while in use, the effect of temperature on the wavelengths may be significant. To compensate for this effect, a temperature sensor (50) is included in the sensor (12) to produce a signal indicative of sensor temperature. This signal is interpreted by the oximeter circuitry including, for example, a microcomputer (16), where the effect of temperature on wavelength is compensated for. In a preferred arrangement, this compensation takes the form of a computation of an alternative calibration curve from which the oxygen saturation is indicated, given a particular processing of signals from the detector (38).



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METHOD AND APPARATUS FOR THE AUTOMATIC CALIBRATION OF SIGNALS EMPLOYED IN OXIMETRY

Background of the Invention

This invention relates to oximetry and, more particularly, to automatic calibration techniques employed in oximetry.

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

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

As will be discussed in greater detail below, pulse transmittance oximetry basically involves measurement of the effect arterial blood in tissue has on the intensity of light passing therethrough. More particularly, the volume of blood in the tissue is a function of the arterial pulse, with a greater volume present at systole and a lesser volume present at diastole. Because blood absorbs some of the light passing through the tissue, the intensity of the light emerging

from the tissue is inversely proportional to the volume of blood in the tissue. Thus, the emergent light intensity will vary with the arterial pulse and can be used to indicate a patient's pulse rate. In addition, the absorption coefficient of oxyhemoglobin (hemoglobin combined with oxygen, HbO_2) is different from that of unoxygenated hemoglobin (Hb) for most wavelengths of light. For that reason, differences in the amount of light absorbed by the blood at two different wavelengths can be used to indicate the hemoglobin oxygen saturation, % SaO_2 (OS), which equals $([HbO_2]/([Hb] + [HbO_2])) \times 100\%$. Thus, measurement of the amount of light transmitted through, for example, a finger can be used to determine both the patient's pulse rate and hemoglobin oxygen saturation.

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

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

For a number of reasons, however, the Wood method fails to provide the necessary accuracy. For example, a true bloodless condition is not

practical to obtain. In addition, efforts to obtain a bloodless condition, such as by squeezing the tissue, may result in a different light transmission path for the two conditions. In addition to problems with accuracy, the Wood approach is both inconvenient and time consuming.

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

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

$$OS = \frac{X_1 R(\lambda_1) + X_2 R(\lambda_2)}{X_3 R(\lambda_1) + X_4 R(\lambda_2)}$$

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

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

In European Patent Application 83304940.6 (New et al.), a calibrated oximeter probe is disclosed. That probe includes a coding resistor or coding connector used to identify the particular combination of wavelengths of light emitted by the two LEDs contained thereon. Oximeter circuitry then senses the code of the resistor or connector to determine the wavelengths of light emitted by the LEDs. In this manner, the effect that different wavelengths have on the oxygen saturation computations can be compensated for. The basis upon which oxygen saturation is measured involves the determination of the quotient of the pulsatile component over the constant component of light transmitted at each wavelength. The ratio of the quotients for the two wavelengths is then fitted to a curve of independently derived oxygen saturations. Outputs include pulse rate and oxygen saturation.

Even with the calibration technique of New, Jr. et al. employed, however, the wavelengths of light emitted by the LEDs may change in a manner that the oximeter circuitry is unable to detect. As will be appreciated, such variations can significantly affect the accuracy of the oxygen saturation measurements. The disclosed invention is directed to the provision of more

complete information about the actual wavelengths of the light emitted and, hence, the production of more accurate oxygen saturation measurements.

Summary of the Invention

The present invention discloses a method of determining the oxygen saturation of arterial blood flowing in tissue. The method includes an initial step in which the tissue is exposed to light from two sources at separate temperature-dependent wavelengths. An indication of the temperature of the sources is produced, as are signals produced in response to the exposure of the tissue to the light at the separate temperature-dependent wavelengths. A preliminary indication of the oxygen saturation is then produced from the signals. A comparison of independently derived oxygen saturations with a continuum of such preliminary indications of oxygen saturation is then selected in accordance with the indication of the temperature of the sources earlier produced. From this comparison, the actual oxygen saturation corresponding to the preliminary indication previously obtained is produced.

In accordance with a particular aspect of the invention, an indication of the separate temperature-dependent wavelengths of light emitted by the sources at a reference temperature is produced. This indication is used to further aid in the selection of the appropriate comparison of independently derived oxygen saturations to the preliminary indications of oxygen saturation.

In accordance with a further aspect of the invention, an oximeter is disclosed that employs the foregoing method to determine the oxygen saturation of arterial blood flowing in tissue. The oximeter includes first and second light sources that illuminate the tissue with light at separate temperature-dependent wavelengths. The oximeter also includes a temperature detector that produces an indication of the temperature of the light sources. Signals that are proportional to the intensity of light received from the tissue at each of the temperature-dependent wavelengths are produced by a light detector and a processor analyzes the signals to produce a preliminary indication of the oxygen saturation of the blood. A selection circuit selects a particular comparison of oxygen saturations with the continuum of preliminary indications of the oxygen saturation in accordance with the indication of temperature received. Finally, a converter converts the preliminary indication of oxygen saturation into an oxygen saturation determination by reference to the comparison selected.

In accordance with additional aspects of the invention, a red optical filter filters the light received by the light detector. The signals produced by the light detector can, similarly, be amplified by a differential current-to-voltage amplifier before being analyzed by the processor. A sensor

housing, having first and second elements, is employed to receive the tissue being analyzed and to define a light path between the light sources and the detector. A mirror, attached to the housing, is positioned between the light sources and detector and breaks the lightpath up into first and second segments at a predetermined angle with respect to each other. The two elements of the housing may pivot and be closably biased. In another arrangement, an apparatus is constructed in accordance with this invention independently of the light sources and light detector.

In accordance with another aspect of the invention, a sensor is disclosed for use with an oximeter to determine the oxygen saturation of arterial blood flowing in tissue. The sensor includes first and second light sources for illuminating the tissue with light at separate temperature-dependent wavelengths. A temperature indicator is also included to produce an indication of the temperature of the light sources. Signals are produced in response to the illumination of the tissue at each of the temperature-dependent wavelengths by a light detector.

Brief Description of the Drawings

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

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

FIGURE 2 is a block diagram illustrating the transmission of light through an absorptive medium;

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

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

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

FIGURE 6 is a block diagram illustrating the transmission of light through a block model of the components of a finger;

FIGURE 7 is a graphical comparison of independently derived oxygen saturation measurements with a variable that is measured by the oximeter;

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

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

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

FIGURE 11 is an exploded view showing the sensor of FIGURE 1 in greater detail;

FIGURE 12 is a more detailed schematic of the I/O circuit illustrated in the system of FIGURE 1;

FIGURE 13 is a schematic diagram of a conventional current-to-voltage amplifier circuit;

FIGURE 14 is a schematic diagram of a differential current-to-voltage preamplifier circuit included in the I/O circuit of FIGURE 1;

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

FIGURE 16 is a more complete schematic diagram of the microcomputer illustrated in FIGURE 1; and

FIGURE 17 is a family of curves similar to the one illustrated in FIGURE 7.

Detailed Description

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

An understanding of the relevant theory begins with a discussion of the Beer-Lambert law. This law governs the absorption of optical radiation by homogeneous absorbing media and can best be understood with reference to FIGURES 2 and 3 in the following manner.

As shown in FIGURE 2, incident light having an intensity I_0 impinges upon an absorptive medium 26. Medium 26 has a characteristic absorbance factor A that indicates the attenuating affect medium 26 has on the incident light. Similarly, a transmission factor T for the medium is defined as the reciprocal of the absorbance factor, I/A. The intensity of the light I_1 emerging from medium 26 is less than I_0 & : can be expressed functionally as the product

TI_0. With medium 26 divided into a number of identical components, each of unit thickness (in the direction of light transmission) and the same transmission factor T, the effect of medium 26 on the incident light I_0 is as shown in FIGURE 3.

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

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

Given the preceding discussion, it will be appreciated that the intensity of the light I_n emerging from medium 26 can be expressed in base 10 as $I_0 10^{-\alpha_1 n}$, or in base e as $I_0 e^{-\alpha_2 n}$, where α_1 and α_2 are the appropriate relative extinction coefficients for base 10 and base e respectively. The effect that the thickness of medium 26 has on the emergent light intensity I_n is graphically depicted in FIGURE 4. If the light incident upon medium 26 is established as having unit intensity, FIGURE 4 also represents the transmission factor T of the entire medium as a function of thickness.

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

$$I_1 = I_0 e^{-\alpha d} \qquad (1)$$

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

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

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

The manner in which the Beer-Lambert law is refined to eliminate the incident intensity and path length as variables is as follows. With reference to FIGURE 6, a human finger is modeled by two components 34 and 36, in a

manner similar to that shown in FIGURE 3. Baseline component 34 models the unchanging absorptive elements of the finger. This component includes, for example, bone, tissue, skin, hair, and baseline venous and arterial blood and has a thickness designated d and an absorbance α.

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

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

$$I_1 = I_0 e^{-\alpha d} \tag{2}$$

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

$$I_2 = I_1 e^{-\alpha_A \Delta d} \tag{3}$$

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

$$I_2 = I_0 e^{-[\alpha d + \alpha_A \Delta d]} \tag{4}$$

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

$$T_{\Delta A} = \frac{I_2}{I_1} \tag{5}$$

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

$$T_{\Delta A} = \frac{I_0 e^{-[\alpha d + \alpha_A \Delta d]}}{I_0 e^{-\alpha d}} \tag{6}$$

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

$$T_{\Delta A} = e^{-\alpha_A \Delta d} \tag{7}$$

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

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

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

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

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

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

where α_{OA} is the oxygenated arterial absorbance, α_{DA} is the deoxygenated arterial absorbance, and OS is the hemoglobin oxygen saturation of the arterial blood volume. As will be appreciated from FIGURE 5, α_{OA} and α_{DA} are substantially unequal at all light wavelengths in the visible-red and near-infrared wavelength regions except for an isobestic wavelength occurring at approximately 805 nanometers. With an arterial oxygen saturation OS of approximately 90 percent, it will be appreciated from equation (9) that the arterial absor-

bance α_A is 90 percent attributable to the oxygenated arterial absorbance α_{OA} and 10 percent attributable to the deoxygenated arterial absorbance α_{DA}. At the isobestic wavelength, the relative contribution of these two coefficients to the arterial absorbance α_A is of minimal significance in that both α_{OA} and α_{DA} are equal. Thus, a wavelength roughly approximating the isobestic wavelength of the curves illustrated in FIGURE 5 is a convenient one for use in eliminating the change in finger thickness Δd attributable to arterial blood flow.

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

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

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

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

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

As will be appreciated, equation (11) is independent of both the incident light intensity I_0 and the change in finger thickness Δd attributable to arterial blood flow. The foregoing derivations form the theoretical basis of pulse oximetry measurement. Because of the complexity of the physiological process, however, the ratio indicated in equation (11) does not directly provide an accurate measurement of oxygen saturation. The correlation between the ratio

of equation (11) and actual arterial blood gas measurements is, therefore, relied on to produce an indication of the oxygen saturation. Thus, if the ratio of the arterial absorbance at the red and infrared wavelengths can be determined, the oxygen saturation of the arterial blood flow can be extracted from independently derived, empirical calibration curves in a manner independent of I_0 and Δd.

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

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

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

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

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

Similarly:

$$R_H = I_0 e^{-\alpha d} @ \lambda_R \tag{14}$$

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

$$\frac{R_L}{R_H} = \frac{I_0 e^{-[\alpha d + \alpha_A \Delta d]}}{I_0 e^{-\Delta d}} @ \lambda_R = e^{-\alpha_A \Delta d} @ \lambda_R \tag{15}$$

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

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

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

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

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

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

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

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

Use of logarithms simplifies equation (19) to:

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

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

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

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

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

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

as that disclosed by Wilber, by performing measurements based upon both the baseline and pulsatile components of the signals.

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

The details of the sensor 12, constructed to satisfy the foregoing requirements, are shown in FIGURE 11. Sensor 12 includes a connector 44, cable 46, and sensor optical component assembly 48 and, in the arrangement shown, is for use with the finger of a patient. Connector 44 is a male, 9-pin plug that engages a mating female receptacle provided on the oximeter housing (not shown), thereby providing attachment of sensor 12 to the oximeter 10. The connector 44 is preferably custom molded to cable 46 for durability.

Cable 46 is a six-conductor, shielded cable having one shielded, twisted-wire pair and four single wires. The twisted-wire pair conducts the signal from the detector 38 in sensor assembly 48 to I/O circuit 14. Two of the single wires conduct power to the LEDs 40 and 42. The remaining two wires, in conjunction with the common shield, are connected to a temperature sensor 50 and coding resistor 52 included in, for example, the sensor assembly 48.

Addressing now the detailed construction of sensor assembly 48, a sensor housing is defined by base 54 and cover 56. Base 54 and cover 56 are made of an opaque plastic that shields detector 38 from the influence of the ambient light that sensor assembly 48 is exposed to. The cover 56 is pivotal about hubs 58 provided on one end of the base 54. This hinged arrangement of

base 54 and cover 56 allows the housing to accommodate a range of adult finger sizes.

Upper and lower cushions 60 and 62 are provided near the open end of the housing on cover 56 and base 54, respectively, and form opposing, cup-shaped resilient surfaces for contacting the finger. A torsion spring 64 tends to close the hinged base 54 and cover 56, thereby applying a slight pressure to the patient's finger through the cushions 60 and 62. In this manner, a comfortable attachment of sensor assembly 48 to the finger is provided. In addition, sensor assembly 48 will not slip significantly with respect to the finger, thus reducing the likelihood that motion artifact will affect the oxygen saturation and pulse rate determined. Light from the open end of sensor assembly 48 is also substantially blocked by the engagement of upper and lower cushions 60 and 62 with the patient's finger.

LEDs 40 and 42 are mounted on a lower retainer 66 attached to base 54. A shallow depression is provided in the upper surface of retainer 66 for receiving the anterior side of the patient's finger. A lens 68 is provided in the lower retainer 66 and conforms to the shape of the depression therein. Lens 68 allows light from LEDs 40 and 42, when reflected off mirror 74, to impinge upon the patient's finger in a direction substantially perpendicular to the longitudinal axis of the finger when extended. An upper retainer 70 is affixed to the cover 56 and has a lower surface provided with a depression for receiving the dorsal side of the patient's finger. A lens 72 provided in the upper retainer 70 opposite the lower retainer lens 68, allows light passing through the finger to impinge upon detector 38 for conversion into an electrical signal. Mirror 74 is held in place by the lower retainer 66 at an angle, preferably 45 degrees, with respect to the lightpath. This arrangement allows sensor assembly 48 to be more compact when viewed in the direction of the lightpath through the finger. The detector 38 is held in place by the upper retainer 70. In a preferred arrangement, the temperature sensor 50 is also provided on the lower retainer 70.

As will be appreciated from the brief discussion of oximetry theory provided above, the wavelengths of light emitted by the particular LEDs 40 and 42 selected affect the measurement of oxygen saturation. Therefore, the wavelengths of light emitted by each LED must be known and the LEDs segregated by their peak emission wavelength prior to assembly into the sensor. More particularly, LEDs 40 and 42, which emit light at red and infrared wavelengths, respectively, are segregated by their peak wavelengths at a standard ambient temperature into appropriate predetermined incremental subsets of an appropriate predetermined given range of wavelengths. A two-

dimensional matrix is then formed, with, for example, the rows indicating the various visible-red wavelength incremental subsets and the columns indicating the various near-infrared wavelength incremental subsets. Each position in the matrix has a particular coding resistor value assigned thereto. In this manner, the particular wavelength combination of LEDs 40 and 42 used in the sensor is identified by a coding resistor 52 located, for example, adjacent the LEDs. With LEDs 40 and 42 each arranged into groups having defined wavelength ranges, different coding resistors 52 can be used to distinctly identify every possible combination of LEDs on sensor 12.

A current provided to the sensor 12 allows microcomputer 16 to determine the resistance of the coding resistor 38 by measuring the voltage drop across it. Thus, the particular combination of LEDs 40 and 42 employed in sensor 12 can be determined. Microcomputer 16 can then make the necessary adjustments to the determination of oxygen saturation, as discussed in greater detail below.

Because the wavelengths of light emitted by LEDs 40 and 42 influence the determination of oxygen saturation, accurate measurements require that the effect of temperature on the wavelengths also be compensated. As noted previously, a temperature sensor 50, for example, Thomson CSF LM335A, is employed to produce a signal that indicates the temperature of sensor assembly 48. As described in greater detail below, this signal, when combined with information about the coding resistor 52 value, allows microcomputer 16 to accurately determine the wavelengths of the light emitted by LEDs 40 and 42 and subsequently produce an accurate determination of oxygen saturation.

In a preferred embodiment of the invention, a red optical filter 76 interrupts the lightpath between the LEDs 40 and 42 and the detector 38. Preferably, red filter 76 is a Kodak No. 29 wratten gel filter. Its function is to minimize the influence of fluorescent light flicker on the oxygen saturation determination made. As will be appreciated, although the opaqueness of base 54 and cover 56 blocks a significant portion of the ambient light, some ambient light may still reach detector 38. Light from the sun and incandescent lamps is substantially continuous. Fluorescent lighting, on the other hand, includes alternating energized and deenergized intervals that form a visually imperceptible flicker. The frequency of the fluorescent light flicker is such that it might influence the signal produced by detector 38 in response to light received from LED 40 at the red wavelength. Thus, the red optical filter 76 is placed

over the detector 38 and filters out most fluorescent light present, eliminating the effect its flicker might have on the oxygen saturation determination made.

LEDs 40 and 42 are supplied with current by transistor drivers 78 located in the I/O circuit 14, as shown in FIGURE 12. Drivers 78 are controlled by microcomputer 16 to produce current pulses at a 960Hz repetition rate. The duration of each pulse is 70 microseconds and a pulse is supplied to the red wavelength LED 40 first and then to the infrared wavelength LED 42. The voltage drop across scaling resistors in the drivers 78 allows the magnitude of the current pulses to be determined and, thus, maintained in a manner described in greater detail below. LEDs 40 and 42 respond to the current pulses by producing corresponding light pulses transmitted through the finger to detector 38. Dectector 38, in turn, produces a signal that includes information about the pulsatile response of the finger to the red and infrared wavelength light, intermixed at the 960Hz LED pulse repetition rate.

At the I/O circuit 14, the signal from detector 38 is received by a preamplifier 80. In a preferred embodiment, preamplifier 80 includes a differential current-to-voltage amplifier 82 and a single-ended output amplifier 84. To understand the advantages of using the differential amplifier 80, it may first be helpful to consider the operation of a conventional current-to-voltage amplifier as shown in FIGURE 13. As shown, a current-to-voltage amplifier 86 is substantially comprised of an operational amplifier 88 and gain determination resistor R_F. With a detector 38 connected to the inputs of the amplifier as shown, a current I_D is input to the amplifier upon the detection of suitable wavelength light. The output of amplifier 88 is designated V_0 and, as will be appreciated, is equal to the product of the detector current I_D and the gain determination resistor R_F. The primary problem with such a construction is that it also amplifies the external interference noise produced, making the signal extracted less accurate.

Adoption of the differential current-to-voltage amplifier 82, when combined with the single-ended output amplifier 84 as shown in FIGURE 14, however, eliminates this problem. As shown, the differential amplifier 82 produces positive and negative versions of the output, the absolute value of each version being equal to the product of the gain determination resistance R_F and the detector current I_D. These outputs are then supplied to the single-ended output amplifier 84, which provides unity gain, thus producing an output signal having a magnitude that is twice that of the inputs. An advantage of this arrangement is that external interference noise is cancelled at the single-ended output amplifier 84 by the opposing signs of the two differential transimpedance amplifier

outputs. In addition, twice the signal is produced with the current noise only increasing by a magnitude of 1.414. Therefore, an improved signal-to-noise ratio results.

At this point, the mixed signal indicative of the red and infrared wavelength responses of detector 38 has been amplified and is input to a demodulator 90 to extract the red pulsatile and infrared pulsatile waveforms shown in FIGURES 9 and 10. In a preferred arrangement, the demodulator 90 includes a sample-and-hold (S/H) circuit 92 that responds to the detector signal produced in response to red wavelength light and a sample-and-hold (S/H) circuit 94 that responds to the infrared wavelength response of detector 38. The timing of circuits 92 and 94 is controlled so that each circuit samples the signal input to demodulator 90 during the portion of the signal corresponding to the wavelength to which it responds. In this manner, two signals are reconstructed from the single input to demodulator 90. As noted above, these signals correspond to the red pulsatile signal and infrared pulsatile signals shown in FIGURES 9 and 10.

To remove high-frequency noise from the outputs of circuits 92 and 94, they are input to lowpass filters 96 and 98. In a preferred embodiment, the "red" lowpass filter 96 and "infrared" lowpass filter 98 each include two stages. The first stage of each filter utilizes a fifth-order, monolithic integrated circuit switched capacitor filter because of its low cost, relatively small physical size, and accuracy. Since both the "red" and "infrared" signals pass through nearly identical first-stage filters due to monolithic integrated-circuit matching, their gain and phase frequency responses are matched. The second stage of each filter is a second-order Bessel filter having a slightly higher roll-off frequency than the first stage. This insures that the first-stage filter is the dominant filter of the two-stage combination, providing the desired filtering accuracy. The second stage then filters the switching noise from the first-stage output.

The filtered red and infrared pulsatile signals are next prepared for conversion and transmission to the microcomputer 16. As will be discussed in greater detail below, this process involves the use of a programmable DC subtractor or offset 100 followed by a programmable gain amplifier 102 having a gain range from approximately one to 256. The appropriately processed signals are combined at multiplexer 104, sampled and held, and converted to digital form by A/D converter 106 for transmission to microcomputer 16.

Before a more complete discussion of the operation of programmable subtractor 100, programmable gain amplifier 102, multiplexer 104, sample-and-hold circuit 105, and A/D converter 106 is provided, several details regarding

the signals to be transferred to microcomputer 16 should be noted. For example, as shown in FIGURES 9 and 10, the signal produced by detector 38 in response to light at each wavelength includes components that, for convenience, are termed baseline and pulsatile. The baseline component approximates the intensity of light received at detector 38 when only the "fixed" nonpulsatile absorptive component is present in the finger. This component of the signal is relatively constant over short intervals but does vary with nonpulsatile physiological changes or system changes, such as movement of sensor 12 on the finger. Over a relatively long interval this baseline component may vary significantly. As will be appreciated, the magnitude of the baseline component at a given point in time is substantially equal to the level identified in FIGURE 9 as R_H. For convenience, however, the baseline component may be thought of as the level indicated by R_L, with the pulsatile component varying between the values for R_H and R_L over a given pulse. That pulsatile component is attributable to light transmission changes through the finger resulting from blood volume changes in the finger during a cardiac pulse. Typically, the pulsatile component may be relatively small in comparison to the baseline component and is shown out of proportion in FIGURES 9 and 10.

The determination of R_{OS} in accordance with equation (22) requires accurately measured values for both the baseline and pulsatile signal components. Because the pulsatile components are smaller, however, greater care must be exercised with respect to the measurement of these components. As will be readily appreciated, if the entire signal shown in FIGURES 9 and 10, including the baseline and pulsatile components, was amplified and converted to a digital format for use by microcomputer 16, a great deal of the accuracy of the conversion would be wasted because a substantial portion of the resolution would be used to measure the baseline component. For example, with an A/D converter employed having an input range of between +10 and -10 volts, a signal having a baseline component referenced to -10 volts that is four times that of the pulsatile component can be amplified until the baseline component is represented by a 16-volt difference and the pulsatile signal represented by a 4-volt difference. With a 12-bit A/D converter 106, the total signal can be resolved into 4096 components. Therefore, the number of incremental levels representing the pulsatile signal would be approximately 819. If, on the other hand, the baseline component is removed prior to the conversion, the gained pulsatile signal could be resolved into 4096 intervals, substantially improving accuracy.

The disclosed invention employs this technique, as the first half of a construction-reconstruction process controlled by microcomputer 16. Accordingly, an input signal received from each filter 96 and 98 includes both the AC and DC components discussed above. The programmable subtractors 100 remove a substantial offset portion of the baseline component of each signal and the programmable gain amplifiers 102 gain-up the remaining signal for conversion by A/D converter 106. A digital reconstruction of the original signal is then produced by the microcomputer, which through the use of digital feedback information removes the gain and adds the offset voltages back to the signal.

Feedback from microcomputer 16 to I/O circuit 14 is also required to maintain the values for the offset subtraction voltage, gain, and driver currents at levels appropriate to produce optimal A/D converter 106 resolution. Proper control requires that the microcomputer continually analyze, and respond to, the offset subtraction voltage, gain, driver currents, and the output of A/D converter in a manner to be described next.

Briefly, with reference to FIGURE 15, thresholds L1 and L2 slightly below and above the maximum positive and negative excursions L3 and L4 allowable for the A/D converter 106 input, are established and monitored by microcomputer 16 at the A/D converter 106 output. When the magnitude of the signal input to, and output from, A/D converter 106 exceeds either of the thresholds L1 or L2, the driver currents I_D are readjusted to increase or decrease the intensity of light impinging upon the detector 38. In this manner, the A/D converter 106 is not overdriven and the margin between L1 and L3 and between L2 and L4 helps assure this even for rapidly varying signals. An operable voltage margin for A/D converter 106 exists outside of the thresholds, allowing A/D converter 106 to continue operating while the appropriate feedback adjustments to A and V_{OS} are made.

When the signal from A/D converter 106 exceeds positive and negative thresholds L5 or L6, microcomputer 16 responds by signaling the programmable subtractor 100 to increase or decrease the offset voltage being subtracted. This is done through the formation and transmission of an offset code whose magnitude is dependent upon the level of the signal received from converter 106.

The manner in which the various thresholds are established and the relationship of the offset codes to the signal received can be altered to produce substantially any form of control desired. Thus, the arrangement shown in FIGURE 15 is illustrative only and represents the currently preferred embodiment.

As will be appreciated from FIGURE 16, the instructions for the microcomputer program that controls the signal construction-reconstruction discussed above are stored in erasable, programmable, read-only memory (EPROM) 108 of microcomputer 16. Similarly, values for R_H, IR_H, R_L and IR_L are determined pursuant to peak-detection software contained in EPROM 108. These values are stored in random-access memory (RAM) 110 for operation upon by a central processing unit (CPU) 112 in accordance with further computational instructions stored in EPROM 108. Interfaces 114 act as input and output buffers for microcomputer 16.

The computational software in EPROM 108 initially causes CPU 112 to determine the present value for R_{OS} by substituting the measured values for R_H, IR_H, R_L, and IR_L into equation (22):

$$R_{OS} = \frac{\ln(R_L/R_H)}{\ln(IR_L/IR_H)} \qquad (23)$$

Then, the computational software instructs CPU 112 to determine the oxygen saturation from R_{OS} by use of a calibration curve selected from a family of curves in the following manner.

The calibration curve is a plot of the relationship between independently determined actual oxygen saturations, produced by the analysis of drawn blood samples, and the corresponding values of R_{OS}, produced by oximeter 10 in accordance with the technique described above. As shown in FIGURE 17, a family of such curves includes a zero-compensation reference curve designated by a code C_0. The calibration curve identified by code C_0 is the plot of R_{OS} versus oxygen saturation for the combination of LEDs 40 and 42 having predetermined reference wavelength light emissions, when those LEDs are operated at a predetermined reference temperature. If the response received by microcomputer 16 from coding resistor 52 and temperature sensor 50 indicates that sensor 12 does not have the predetermined reference wavelength LEDs or is not at the reference temperature, the calibration curve identified by code C_0 may no longer produce an accurate indication of the oxygen saturation from the value of R_{OS} computed. Thus, the difference in source light wavelength from the standards must be compensated for and is achieved in the following manner.

A code variable C_N is established to identify the various curves in the family shown in FIGURE 17. These curves are incrementally offset in each direction from the curve identified by code C_0. A sufficient number and arrangement of curves is included to accurately model the response produced by

using any set of sorted LEDs 40 and 42 at any temperature within an expected operating range of 0°C to 45°C. The appropriate curve is selected by determining the applicable code number C_N in the following manner.

As noted previously, microcomputer 16 responds to information received from temperature sensor 50 and coding resistor 52. More particularly, the voltage drop across resistor 52, when supplied with a current of known magnitude or as part of a precision voltage divider, can be used to identify the resistance of resistor 52 and, hence, the combination of LEDs 40 and 42 included on sensor 12. This voltage represents C_{CM}, the compensation code for sensor M, and can be considered to include a component identifying the wavelength of light emitted by each LED, $C_{\lambda 1M}$ and $C_{\lambda 2M}$ at a reference temperature T_0.

Temperature sensor 50 produces an output having a magnitude that is proportional to the temperature sensed, T, in degrees Kelvin (°K). A compensation code C_{CT} can be determined from this information by multiplying a temperature compensation coefficient C by the difference between T and the probe reference temperature T_0 in °K.

Together, the probe compensation code C_{CM} and temperature compensation code C_{CT}, indicate the adjustment to the zero-compensation reference curve C_0 needed to allow the oxygen saturation to be accurately determined from a given value for R_{OS}. Thus, a simple compensation code total, C_T, can be defined as:

$$C_T = C_{CM} + C_{CT} + C_0 \tag{24}$$

Allowing for nonlinearities as well as variable dependencies, equation (24) can be more completely expressed as:

$$C_T = F_a (C_{\lambda 2M}) \sum a_i C_{1M}^i + F_b (C_{\lambda 1M}) \sum b_i C_{2M}^i + F_c (C_{\lambda 1M}, C_{\lambda 2M}) \sum c_i (T-T_0)^i \tag{25}$$

where a_i, b_i, and c_i are scaling constants; F_a, F_b, and F_c are dependency correlating functions derived from modeled theory as well as empirical tests; and the summations are performed over a range of i extending from zero to n, with the summed terms being the power series approximation of the desired function.

Note that equation (25) can be placed in linear form, corresponding to equation (24), as:

$$C_T = a_1 C_{\lambda 1M} + b_1 C_{\lambda 2M} + C_1(T-T_0) + C_0 \quad (26)$$

With the compensation code total C_T determined, a compensated indication of oxygen saturation can be produced in accordance with the expression:

$$SaO_{2C} = \sum_{j=0}^{n} \left[R_{OS}^{j} \sum_{i=0}^{m} [a_{i+j(m+1)}] C_T^{i} \right] \quad (27)$$

where SaO_{2c} is the compensated nominal value of SaO_2; $a_{i+j(m+1)}$ is the scaling coefficient at i+n(m+1); the sum of R_{OS}^{j} from j=0 to j=n is the power series approximation to SaO_2 of degree n; the sum of $a_{i+j(m+1)}$ C_T^{i} from i=0 to i=m is the power series approximation of the compensating coefficient for R_{OS}^{j} of degree m; i and j are integer values; and m and n are degrees of approximation.

By appropriate establishment of the zero-compensation code and temperature compensation coefficient, as well as the proper conditioning of information received from temperature sensor 50 and coding resistor 52, the resultant value of C_T from equation (25) will indicate which of the curves in family C_F allows the oxygen saturation to be most accurately determined. When a limited number of curves have been independently determined, and interpolation between curves is not employed, the curve to be used, C_N, is determined from C_T by rounding C_T to the nearest integer.

As will be appreciated, the values for C_0, T_0, C, and the various values for C_{CM}, depend upon a variety of factors, including the temperature-dependency of the wavelengths of light produced by LEDs 40 and 42. Thus, the manner of identifying the various curves of family C_F shown in FIGURE 17, as well as the number and orientation of the curves, may be varied and a suitable arrangement may best be determined by empirical studies.

The software that processes information received from temperature sensor 50 and coding resistor 52 and determines the applicable calibration curve C_N is contained in EPROM 108. The software basically performs the computation set out in equation (25) and then rounds the resultant number to the nearest integer to determine C_N. The details of software capable of achieving such a result will be readily apparent to one of ordinary skill and, as such, are not presented here.

To generate a compensated curve, the coefficients and appropriate formulae for describing the nominal relationship between R_{OS} and SaO_2 are stored in EPROM 108. After CPU 112 process information from the wavelength coding resistor 52 and temperature sensor 50 in sensor 12, the software solves a series of equations determining both the minimum and maximum values of R_{OS} that can be produced for the spectrum of sensor codes and temperature range possible. As shown in FIGURE 17, these minimum and maximum values of R_{OS} producible by oximeter 10 correspond to oxygen saturation of 100 and 0 percent, respectively.

Next, the software instructs CPU 112 to compute the compensation formula given in equation (27). With this compensation value the nominal curve, or relationship between R_{OS} and SaO_2, is modified to generate a compensated conversion formula. This compensated relationship is then used to generate a look-up table of sufficient resolution to guarantee a mapping of R_{OS} with respect to SaO_2 such that the table includes every SaO_2 in one-percent increments from 0-100% SaO_2. When an actual SaO_2 prediction is to be made, a look-up algorithm transforms the ratio computed for equation (23) into a table index allowing the appropriate SaO_2 to be extracted from the table. This technique is employed to afford a run-time computational economy. The table need not be regenerated unless a different sensor with a new sensor code is used with the oximeter or when the temperature sensor 50 indicates a change in the ambient temperature that requires a curve shift to preserve predictive accuracy.

The peak-detection software in EPROM 108 also causes CPU 112 to determine the period of the signals received by microcomputer 16 from I/O circuit 14. Pursuant to the computational instructions in EPROM 108, CPU 112 then determines the pulse rate of the arterial blood flowing in the finger to be the inverse of the signal period. Displays 20 provide visible and audible outputs of the oxygen saturation and pulse rate in a manner conveniently used by the operator of oximeter 20.

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

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

1. An oximeter, comprising:

first and second light sources for illuminating tissue having arterial blood flowing therein, the light produced by each of said first and second sources being at a separate temperature-dependent wavelength;

temperature-indication means for producing an indication of the temperature of said first and second light sources;

light detection means responsive to the illumination of said tissue for producing signals that are proportional to the intensity of light received at each of said temperature-dependent wavelengths;

processing means for analyzing said detection means signals to produce a preliminary indication of the oxygen saturation of said arterial blood flowing in said tissue;

selection means for selecting a comparison of independently derived oxygen saturations with a continuum of said preliminary indications of oxygen saturation, said comparison selected in accordance with said indication of temperature; and

output means for converting said preliminary indication into an oxygen saturation determination by referring to said comparison selected.

2. The oximeter of Claim 1, further comprising a red optical filter for filtering said light received by said light detection means.

3. The oximeter of Claim 1, futher comprising a differential current-to-voltage amplifier for amplifying said signals produced by said light detection means before said signals are analyzed by said processing means.

4. The oximeter of Claim 1, further comprising a sensor housing to which said first and second light sources, said temperature indication means, and said light detection means are connected.

5. The oximeter of Claim 4, wherein said sensor housing comprises first and second elements, said first and second light sources being attached to said first element and said light detection means being attached to said second element, said first and second elements arranged to allow insertion

of said tissue therebetween and to define a lightpath between said first and second sources and said light detection means that includes said tissue.

6. The oximeter of Claim 5, further comprising a reflective member positioned between said light detection means and said first and second light sources, said lightpath including a first segment defined between said first and second sources and said reflective member and a second segment defined between said reflective member and said light detection means, said first and second segments of said lightpath being at a predetermined angle to each other.

7. The oximeter of Claim 6, wherein said first and second elements of said sensor housing are pivotally connected in a closably biased manner.

8. The oximeter of Claim 1, further comprising a substrate, said first and second light sources and said temperature indication means being mounted on said substrate.

9. The oximeter of Claim 1, further comprising wavelength-indication means for producing an indication of said separate temperature-dependent wavelengths of light produced by said first and second sources at a reference temperature, said selection means further selecting said comparison of said independently derived oxygen saturations with said continuum of preliminary indications in accordance with said indication of said wavelengths at said reference temperature.

10. The oximeter of Claim 9, wherein said wavelengths of said light produced by said first and second sources at said reference temperature are within a plurality of predetermined wavelength ranges.

11. The oximeter of Claim 10, wherein said plurality of predetermined wavelength ranges includes a first plurality of ranges substantially centered about a visible-red wavelength and a second plurality of ranges substantially centered about a near-infrared wavelength, said wavelength of said first source falling within one of said first plurality of ranges and said wavelength of said second source falling within one of said second plurality of ranges.

12. An oximeter sensor, comprising:

first and second light sources for illuminating tissue having arterial blood flowing therein, the light produced by each of said first and second sources being at a separate temperature-dependent wavelength;

temperature-indication means for producing an indication of the temperature of said first and second light sources;

light detection means, responsive to the illumination of said tissue, for producing signals that are proportional to the intensity of light received of each of said temperature-dependent wavelengths; and

a sensor housing to which said first and second light sources, said temperature-indication means, and said light detection means are connected.

13. The sensor of Claim 12, further comprising a red optical filter for filtering said light received by said light detection means.

14. The sensor of Claim 12, further comprising a substrate, said first and second light sources and said temperature indication means being mounted on said substrate.

15. The sensor of Claim 12, wherein said sensor housing comprises first and second elements, said first and second light sources being attached to said first element and said light detection means being attached to said second element, said first and second elements arranged to allow insertion of said tissue therebetween and to define a lightpath, between said first and second sources and said light detection means, that includes said tissue.

16. The sensor of Claim 15, further comprising a reflective member positioned between said light detection means and said first and second light sources, said lightpath including a first segment defined between said first and second sources and said reflective member, and a second segment defined between said reflective member and said light detection means, said first and second segments of said lightpath being at a predetermined angle to each other.

17. The sensor of Claim 16, wherein said first and second elements of said sensor housing are pivotally connected in a closably biased manner.

18. The sensor of Claim 12, further comprising wavelength indication means for producing an indication of said separate temperature-dependent wavelengths of light produced by said first and second light sources at a reference temperature.

19. The sensor of Claim 18, wherein said wavelengths of light produced by said first and second sources at said reference temperature are within separate ones of a plurality of predetermined wavelength ranges.

20. The sensor of Claim 19, wherein said plurality of predetermined wavelength ranges includes a first plurality of ranges substantially centered about a visible-red wavelength and a second plurality of ranges substantially centered about a near-infrared wavelength, said wavelength of said first source falling within one of said first plurality of ranges and said wavelength of said second source falling within one of said second plurality of ranges.

21. An apparatus for receiving and processing signals produced by light detection means in response to the illumination of tissue having arterial blood flowing therein by light from first and second sources at separate temperature-dependent wavelengths, said signals containing information about the oxygen saturation of said arterial blood, said apparatus comprising:

temperature indication means for producing an indication of the temperature of said first and second light sources;

processing means for analyzing said detection means signals to produce a preliminary indication of the oxygen saturation of said arterial blood flowing in said tissue;

selection means for selecting a comparison of independently derived oxygen saturations with a continuum of said preliminary indications of oxygen saturation, said comparison selected in accordance with said indication of temperature; and

output means for converting said preliminary indication into an oxygen saturation determination by referring to said comparison selected.

22. A method of determining the oxygen saturation of arterial blood flowing in tissue, comprising the steps of:

exposing the tissue to light from two sources at separate temperature-dependent wavelengths;

producing an indication of the temperature of said sources;

producing signals in response to the exposure of the tissue to said light at said separate temperature-dependent wavelengths;

producing a preliminary indication of said oxygen saturation from said signals;

selecting a comparison of independently derived oxygen saturations with a continuum of said preliminary indications of oxygen saturation, said comparison selected in accordance with said indication of temperature; and

converting said preliminary indication of oxygen saturation into an oxygen saturation measurement by determining the oxygen saturation associated with said preliminary indication in said comparison selected.

23. The method of Claim 22, further comprising the step of producing an indication of said separate temperature-dependent wavelengths at a reference temperature.

24. The method of Claim 23, wherein said comparison is further selected in accordance with said indication of said separate temperature-dependent wavelengths at said reference temperature.

25. The method of Claim 24, wherein said separate temperature-dependent wavelengths of light from said sources at said reference temperature are within a plurality of predetermined wavelength ranges.

26. The method of Claim 25, wherein said plurality of predetermined wavelength ranges includes a first plurality of ranges substantially centered about a visible-red wavelength and a second plurality of ranges substantially centered about a near-infrared wavelength, said wavelength of said first source at said reference temperature falling within one of said first plurality of ranges and said wavelength of said second source at said reference temperature falling within one of said second plurality of ranges.

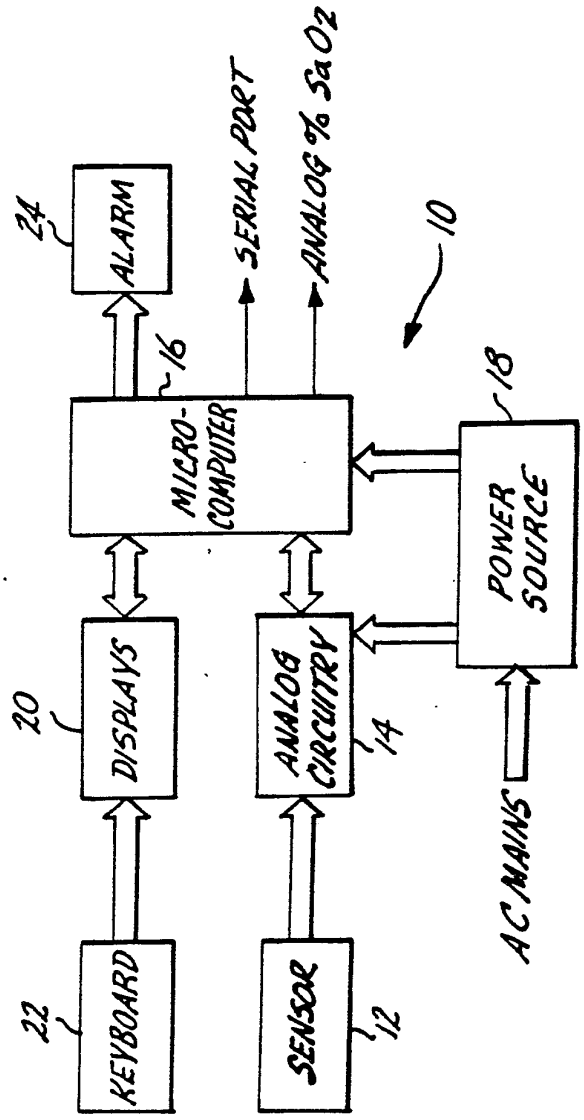

24
ALARM
16
MICRO-COMPUTER
SERIAL PORT
ANALOG % SaO2
10
18
POWER SOURCE
20
DISPLAYS
ANALOG CIRCUITRY
14
AC MAINS
22
KEYBOARD
SENSOR
12

Fig. 1.

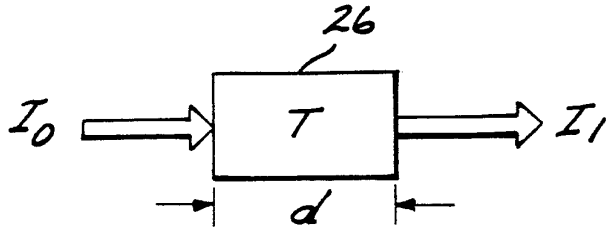


Fig. 2.

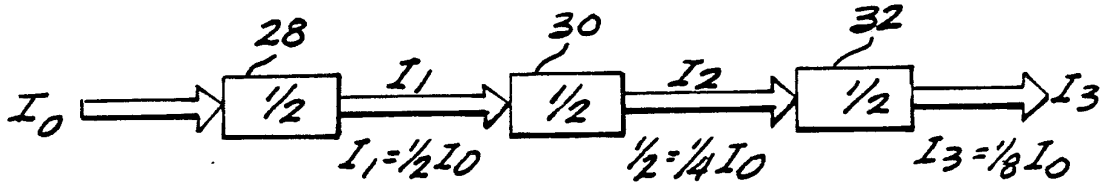


Fig. 3.

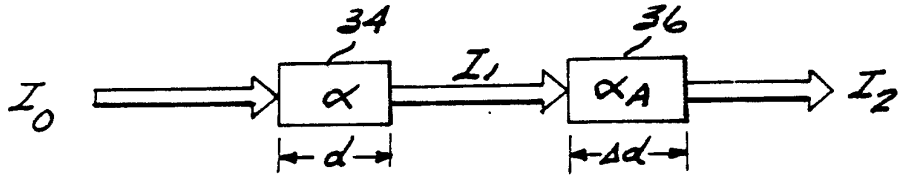


Fig. 6.

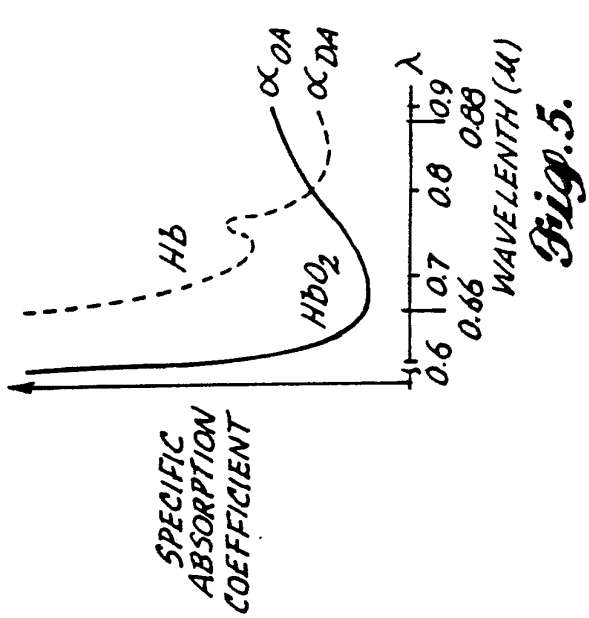


Fig. 5.

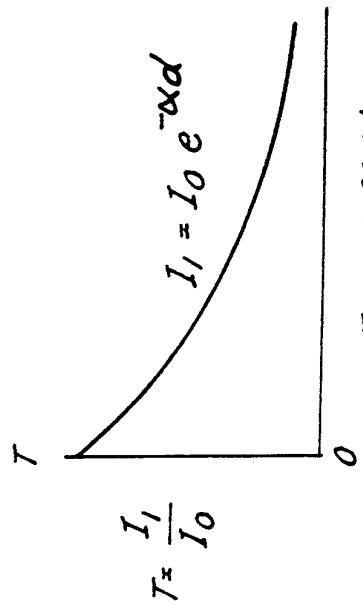


Fig. 4.

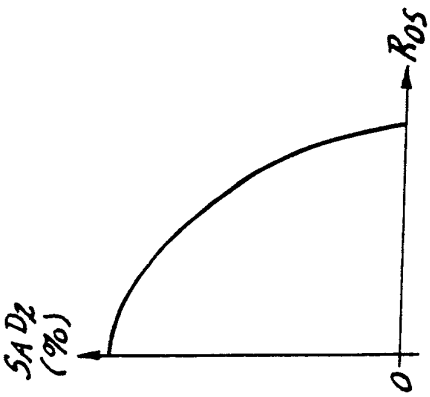


Fig. 7.

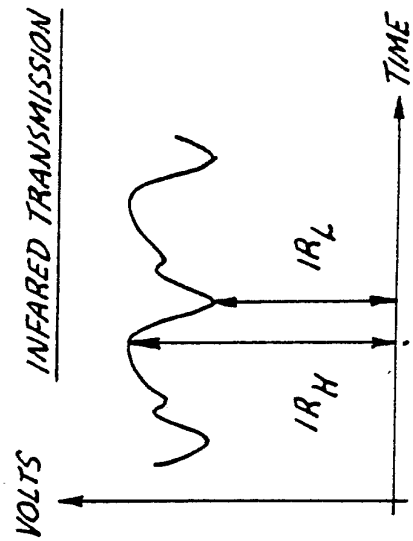


Fig. 10.

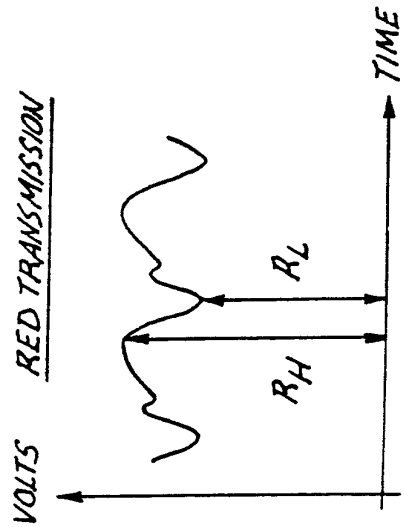


Fig. 9.

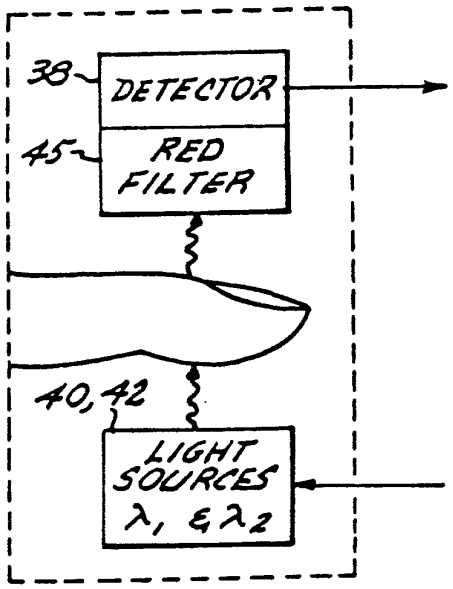


Fig. 8.

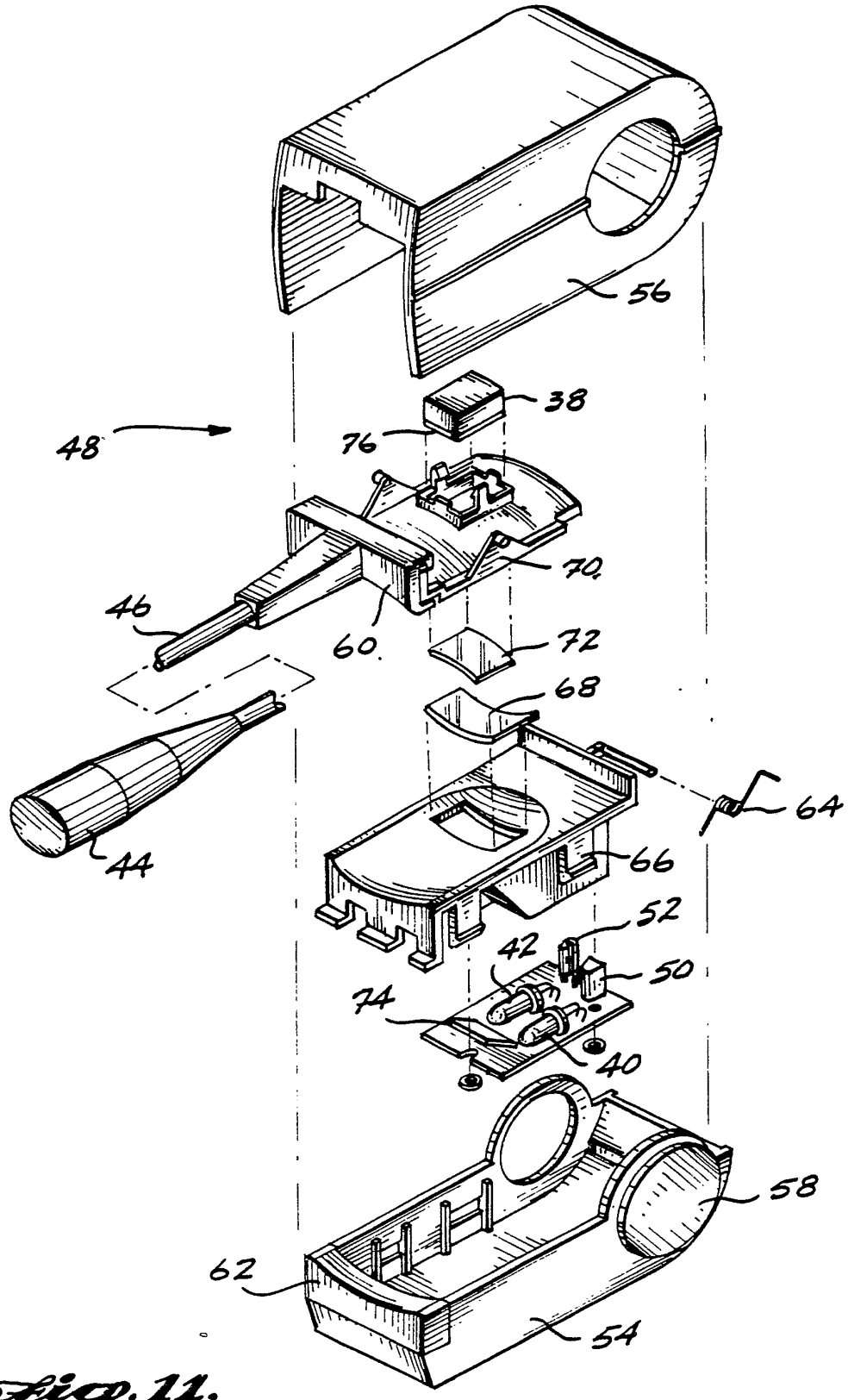


Fig. 11.

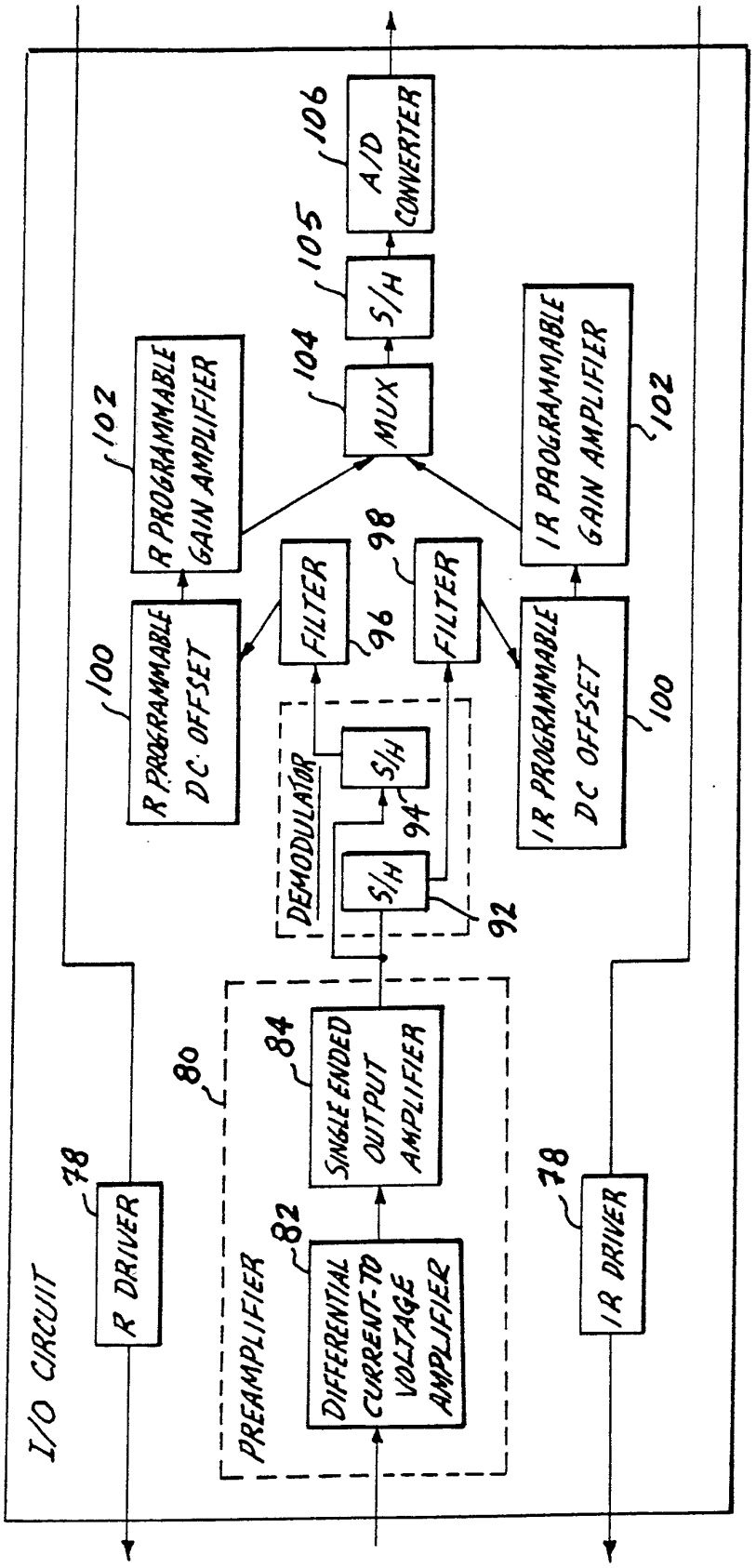

I/O CIRCUIT
R DRIVER
78
PREAMPLIFIER
80
DIFFERENTIAL CURRENT-TO VOLTAGE AMPLIFIER
82
SINGLE ENDED OUTPUT AMPLIFIER
84
DEMODULATOR
92
S/H
94
FILTER
96
FILTER
98
R PROGRAMMABLE DC OFFSET
100
R PROGRAMMABLE GAIN AMPLIFIER
102
MUX
104
S/H
105
A/D CONVERTER
106
IR DRIVER
78
IR PROGRAMMABLE DC OFFSET
100
IR PROGRAMMABLE GAIN AMPLIFIER
102

Fig. 12.

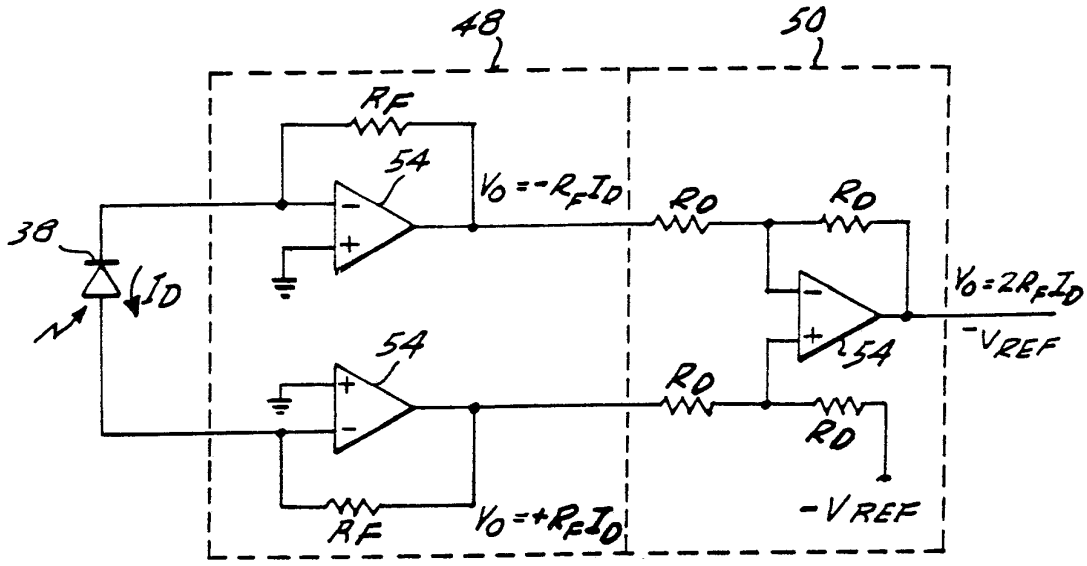

48
50
RF
54
$V_O = -R_F I_D$
RD
RD
38
I_D
$V_O = 2R_F I_D$
$-V_{REF}$
54
54
RD
RD
RF
$V_O = +R_F I_D$
$-V_{REF}$

Fig. 14.

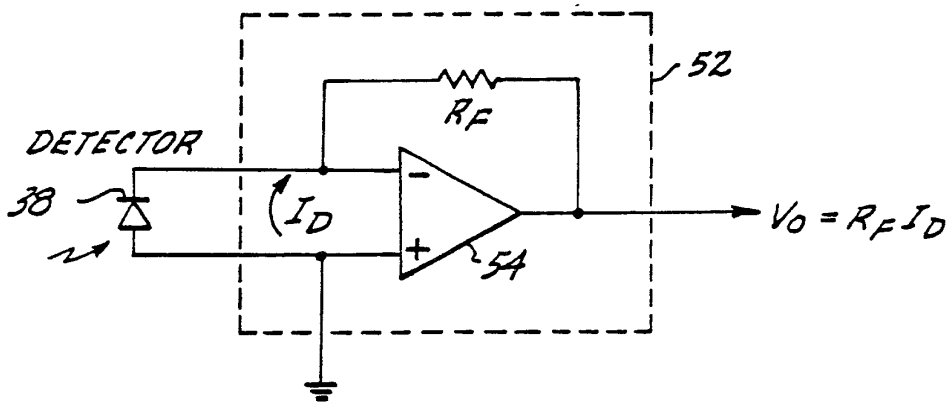

52
RF
DETECTOR
38
I_D
$V_O = R_F I_D$
54

Fig. 13.

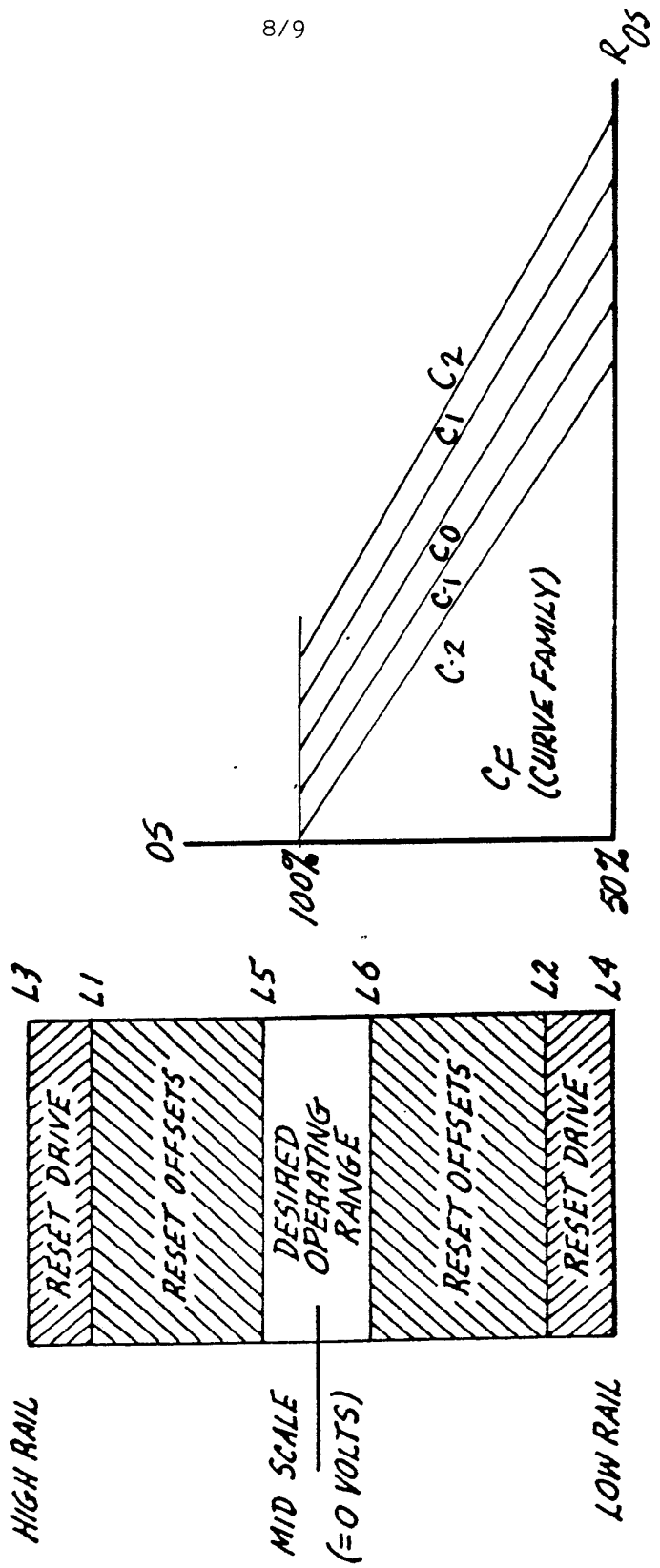

L3
L1
L5
L6
L2
L4
RESET DRIVE
RESET OFFSETS
DESIRED OPERATING RANGE
RESET OFFSETS
RESET DRIVE
HIGH RAIL
MID SCALE
(=0 VOLTS)
LOW RAIL

Fig. 15.

R05
C2
C1
C0
C-1
C-2
CF
(CURVE FAMILY)
05
100%
50%

Fig. 17.

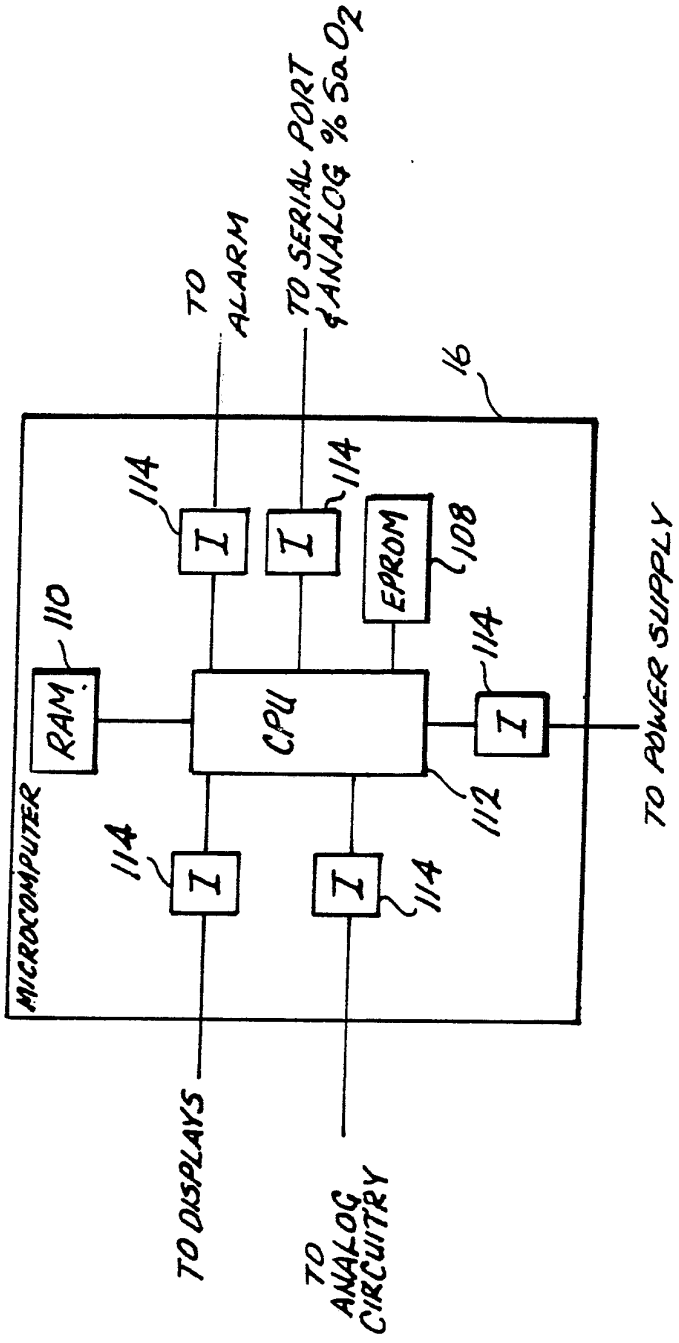

TO ALARM
TO SERIAL PORT & ANALOG % SaO_2
16
114
114
I
I
EPROM
108
110
RAM
CPU
114
I
MICROCOMPUTER
112
TO POWER SUPPLY
114
114
I
I
TO DISPLAYS
TO ANALOG CIRCUITRY

Fig. 16.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 87/02020

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 B 5/00; G 01 N 21/31

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 B 5/00; G 01 N 21/00

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 4447150 (HEINEMANN) 8 May 1984 see abstract; column 7, lines 30-45; column 5, lines 9-46; figures 1,2A	1,3,9,11,20
A	GB, A, 1538695 (BIOTRON MEDICAL PRODUCTS LTD.) 24 January 1979 see page 3, line 10 - page 5, line 11; figure 1	1,9
P,A	EP, A, 0204459 (THE BOC GROUP INC.) 10 December 1986 see page 4, line 5 - page 7, line 15; figures 1,2,4	4,5,7,15,17
A	EP, A, 0104772 (NELLCOR INC.) 4 April 1984 see page 9, line 31 - page 11, line 16; figure 4 cited in the application	1,3,9,11,20

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
20th November 1987	21 JAN 1988
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G. VAN DER PUTTEN

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. US 8702020
SA 18592

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 29/12/87
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4447150	08-05-84	US-A- 4444498	24-04-84
GB-A- 1538695	24-01-79	None	
EP-A- 0204459	10-12-86	JP-A- 61280845	11-12-86
EP-A- 0104772	04-04-84	JP-A- 59064031	11-04-84
		US-A- 4621643	11-11-86

EPO FORM P0479

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

PCT

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国際事務局

特許協力条約に基づいて公開された国際出願

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C10M 111/02 // C10N 40:04 C10N 40:08		(43) 国際公開日	1988年3月24日 (24.03.88)

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(81) 指定国
KR, US.
添付公開書類
国際調査報告書

(54) Title: LUBRICATING OIL COMPOSITION

(54) 発明の名称 潤滑油組成物

(57) Abstract

A lubricating oil composition which comprises 97 to 60 wt % of mineral oil having a dynamic viscosity at 100°C of 2 to 50 cSt, a flow point (according to JIS K-2269) of not higher than -30°C, and a viscosity index (according to JIS K-2283) of 70 or more and 3 to 40 wt % of a polyester. This composition is suitably used for lubrication of parts such as wet brakes or wet clutches of automatic transmissions, tractors, etc. This composition shows a proper viscosity at high temperatures and a low viscosity at low temperatures. Further, it has excellent friction properties, oxidation stability, and rubber seal resistance.

(57) 要約

本発明は100℃における動粘度が2～50センチストークス（cSt），流動点（JIS K-2269に準拠）が－30℃より低く、粘度指数（JIS K-2283に準拠）が70以上である鉱油97～60重量％およびポリエステル3～40重量％からなる潤滑油組成物であり、自動変速機，トラクター等湿式ブレーキや湿式クラッチを有する部分の潤滑に好適に用いられる。

本発明の潤滑油組成物は、高温での粘度が適正であり、しかも低温粘度が低い。

さらに本発明の潤滑油組成物は摩擦特性，酸化安定性に優れると共に耐ゴムシール性にも優れている。

情報としての用途のみ

PCTに基づいて公開される国際出願のパンフレット第1頁にPCT加盟国を同定するために使用されるコード

AT オーストリア
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BB バルバドス
BE ベルギー
BG ブルガリア
BJ ベナン
BR ブラジル
CF 中央アフリカ共和国
CG コンゴー
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GA ガボン
GB イギリス
HU ハンガリー
IT イタリー
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ML マリー
MR モーリタニア
MW マラウイ
NL オランダ
NO ノルウエー
RO ルーマニア
SD スーダン
SE スウエーデン
SN セネガル
SU ソビエト連邦
TD チャード
TG トーゴ
US 米国

明　　細　　書

潤滑油組成物

技術分野

本発明は潤滑油組成物に関し、詳しくは自動変速機，トラクター等湿式ブレーキや湿式クラッチを有する部分の潤滑に好適に用いられる潤滑油組成物に関する。

背景技術

湿式ブレーキや湿式クラッチを有する部分の潤滑に用いられる湿式ブレーキや湿式クラッチ用潤滑油は、始動性を考慮して低温粘度が低いことが要求される。一般に基油全体の粘度を低くすると、その目的を達しやすいが、逆に高温時に低粘度すぎて潤滑性能を低下させ、実用上使用できなくなるという問題がある。

そこで低粘度基油に、高分子化合物などの粘度指数向上剤を配合する方法が多用されているが、使用と共に高分子が剪断を受けて低粘度化するため本質的解決とならない。

本発明の第一の目的は基油自体の特性として、高温での粘度を一定に保ちつつ、しかも低温粘度が低い基油を提供することである。勿論、その基油は酸

化安定性に優れ、耐ゴムシール性にも優れたものであることが要求されている。

さらに本発明の第二の目的は、その基油自身で、湿式ブレーキや湿式クラッチに対する摩擦特性を向上させることのできる潤滑油組成物を提供することである。

発明の開示

すなわち本発明は、100℃における動粘度が2～50センチストークス（cSt），流動点（JIS K-2269に準拠）が－30℃より低く、粘度指数（JIS K-2283に準拠）が70以上である鉱油97～60重量％およびポリエステル3～40重量％からなる潤滑油組成物を提供するものである。

本発明の潤滑油組成物は、高温での粘度が適正であり、しかも低温粘度が低い。

しかも本発明の潤滑油組成物は、摩擦特性にも優れたものである。

さらに本発明の潤滑油組成物は、酸化安定性に優れると共に耐ゴムシール性にも優れたものである。

発明を実施するための最良の形態

本発明の潤滑油組成物の主成分をなす鉱油は、100℃における動粘度が2～50cSt、好ましくは5～30cSt であり、流動点が－30℃より低く、好ましく

は－35℃以下、より好ましくは－40℃以下であり、かつ粘度指数が70以上、好ましくは75～105のものである。上記範囲外のものであると、目的とする潤滑油組成物を得ることはできない。

上述の如き性状を有する鉱油は、パラフィン系または中間基系原油等を蒸留して得られた留出油（常圧換算で沸点およそ250～450℃）を常法に従って精製した後、深脱ろう処理を行なうことによって得ることができる。

なお、留出油とは原油を常圧蒸留するかあるいは常圧蒸留の残渣油を減圧蒸留して得られるものを意味する。精製法は特に制限はないが、次の①～⑤のいずれかの処理をすることによって得ることができる。

①留出油を水素化処理するか、または水素化処理したのち、アルカリ蒸留もしくは硫酸洗浄を行なう。②留出油を溶剤精製処理するか、または溶剤精製処理した後、アルカリ蒸留もしくは硫酸洗浄を行なう。③留出油を水素化処理したのち、続いて第2段目の水素化処理を行なう。④留出油を水素化処理したのち、第2段目の水素化処理、さらに第3段目の水素化処理を行なう。⑤留出油を水素化処理したのち、第2段目の水素化処理を行ない、さらにアルカリ蒸留もしくは硫酸洗浄を行なう。以下に処理法

の１例を示す。

パラフィン系原油や中間基原油から常法により、潤滑油粗原料を調製し、苛酷な水素化処理を行なう。この処理によって芳香族分などの潤滑油留分に好ましくない成分を除去したり、有効な成分に変えたりする反応が行なわれる。この際、硫黄分や窒素分も殆んど除去される。

次いで、減圧蒸留により必要な粘度を得るような分留を行なう。しかる後に、既知の溶剤脱ろうを行ない、通常のパラフィンベースオイルが有する流動点、すなわち－15～－10℃程度に脱ろうする。この脱ろう処理後、必要に応じてさらに水素化処理を行ない、芳香族分の大部分を水素化させて飽和分とし、ベースオイルの熱的，化学的な安定性を向上させる。しかし、流動点が未だ高いため、適当でない。そのために引続き深脱ろう処理が行なわれる。この処理は苛酷な条件での溶剤脱ろう法やゼオライト触媒を用い、該触媒の細孔に吸着されるパラフィン（主としてノルマルパラフィン）を選択的に水素雰囲気下で分解してろう分となるものを除去する接触水添脱ろう法が適用される。

水素化処理は原料油の性状等により異なるが、通常は反応温度200～480℃、好ましくは250～450℃，水素圧力５～300kg/cm^2、好ましくは30～250

kg／cm²，水素導入量（対供給留出油1kℓ当り）30～3000N m³、好ましくは100～2000N m³の条件で行なわれる。また、この際に用いられる触媒は担体としてアルミナ，シリカ，シリカ・アルミナ，ゼオライト，活性炭，ボーキサイトなどを用い、周期律表第Ⅵ族，第Ⅷ族などの金属、好ましくはコバルト，ニッケル，モリブデン，タングステンなどの触媒成分を既知の方法で担持させたものが使用される。なお、触媒は予め予備硫化したものが好ましい。

上記した如く、留出油は水素化処理した後、種々の処理が行なわれるが、第2段目あるいは第3段目の水素化処理を行なう場合、水素化処理条件は上記範囲内で設定すればよく、第1～3段目の各条件は同一であってもよく異なってもよい。しかし、通常は第1段目よりは第2段目、第2段目よりは第3段目の条件を厳しくして行なわれる。

次に、アルカリ蒸留は微量の酸性物質を除去して留出分の安定性を改良する工程として行なわれ、NaOH，KOH等のアルカリを加えて減圧蒸留することにより行なう。

また、硫酸洗浄は、一般に石油製品の仕上げ工程として行なわれているものであり、芳香族炭化水素、特に多環芳香族炭化水素やオレフィン類，硫黄化合物などを除去して留出油の性状を改善するため

に適用される。具体的には処理油に0.5～5重量%の濃硫酸を加えて室温～60℃の温度で処理することにより行ない、しかる後NaOHなどで中和する。

なお、留出油の処理は上記操作の組合せにより前記した如く①～⑤の具体的方法があるが、これら方法の中では特に①，③，④の方法が好適である。

上記の如き処理により、前記した性状を有する鉱油を得ることができるが、さらにこのものを白土処理することもできる。

次に本発明において、他方の成分とし用いられるポリエステルとしては、ヒンダードエステルまたはジカルボン酸エステルがある。

ここでヒンダードエステルとしては、流動点が－30℃以下、好ましくは－40℃以下のものが用いられる。流動点が－30℃を超えたものであると低温粘度が高くなるため好ましくない。ヒンダードエステルの化学構造は、動粘度，粘度指数，流動点の点から次のものが好ましい。

すなわち、ヒンダードエステルを形成するポリオールとしては、ネオペンチルグリコール，トリメチロールプロパン，トリメチロールエタン，ペンタエリスリトール等のアルコールβ炭素が第4級のものが用いられる。一方、上記ポリオールと共にヒンダードエステルを形成する脂肪酸としては、炭素数

3～18、好ましくは炭素数4～14の直鎖または分枝の脂肪酸が好ましく、特に分枝脂肪酸が好ましい。具体的にはヘキサン酸，ヘプタン酸，オクタン酸，ノナン酸，デカン酸などの直鎖脂肪酸や、2－エチルヘキサン酸，イソオクタン酸，イソノナン酸，イソデカン酸などの分枝脂肪酸が挙げられる。

また主成分が炭素数4～14の混合脂肪酸も好ましく使用できる。分枝脂肪酸，混合脂肪酸を用いたものは低温流動性を向上させるからである。

次に、ジカルボン酸エステルとしては、流動点が－30℃以下、好ましくは－40℃以下のものが用いられる。流動点が－30℃を超えたものであると低温粘度が高くなるため好ましくない。ジカルボン酸エステルの化学構造は、動粘度，粘度指数，流動点の点から次のものが好ましい。

すなわち、ジカルボン酸エステルを形成するアルコールとしては、炭素数が3～18、特に4～13であって、分岐アルコールが好ましい。具体的にはイソブチルアルコール，イソアミルアルコール，イソヘキシルアルコール，イソオクチルアルコール，イソノニルアルコール，イソデシルアルコール，イソトリデシルアルコールなどを挙げることができる。一方、上記アルコールと共にジカルボン酸エステルを形成する二塩基酸としては、炭素数4～16の二塩

基酸が使用でき、具体的にはアジピン酸，アゼライン酸，セバチン酸，ドデカン・2酸などを挙げることができる。

本発明の潤滑油組成物は、上述の如き鉱油とポリエステルからなるものである。ここで両者の配合割合は、前者97～60重量%に対し後者3～40重量%、好ましくは前者90～70重量%に対し後者10～30重量%である。後者の配合割合が3重量%未満であると、後者を配合したことによる効果がみられず、一方後者の配合割合が40重量%を超えるとゴム膨潤性および摩擦特性が低下するため好ましくない。

本発明の潤滑油組成物は上述の成分よりなるものであるが、目的等に応じて、酸化防止剤，清浄分散剤，粘度指数向上剤，消泡剤，極圧剤，流動点降下剤等を添加することができる。さらに、特に湿式ブレーキや湿式クラッチを有する潤滑部分の潤滑油としては脂肪酸とアミンの反応物などの摩擦調整剤を添加することもできる。なお、酸化防止剤としてはフェノール系化合物，アミン系化合物，ジチオリン酸亜鉛など一般的に使用されているものであればよい。具体的には2.6－ジ－t－ブチル－4－メチル－フェノール；2.6－ジ－t－ブチル－4－エチル－フェノール；4,4′－メチレンビス(2,6－ジ－t－ブチル－フェノール)；フェニル－α－ナフチルアミン；

ジアルキルジフェニルアミン；ジ－２－エチルヘキシルジチオリン酸亜鉛；ジアミルジチオカーバミン酸亜鉛；五硫化ピネンなどが挙げられる。

次に、清浄分散剤としては無灰系清浄剤，金属系清浄剤なども使用することができる。具体的にはアルケニルコハク酸イミド，スルホネート，フィネートなどが好ましく、例えばポリブテニルコハク酸イミド，カルシウムスルホネート，バリウムスルホネート，カルシウムフィネート，バリウムフィネート，カルシウムサリチレートなどが挙げられる。

粘度指数向上剤として特に制限はないが、ポリメタアクリレート，ポリブテンなどを用いることができる。

実施例１～６および比較例１～11

第１表に示す性状の鉱油に第２表に示す性状のポリエステルを、第３表に示す所定割合で配合して潤滑油組成物を調製し、その性能を評価した。結果を第３表に示す。なお、試験法は次の通りである。

試験法

(1) 動粘度：JIS K-2283に準拠

(2) ブルックフィールド(BF)粘度：ASTM D 2983－80に準拠

(3) ISOT（内燃機関用潤滑油酸化安定度試験）

JIS K 2514，３－１に準拠（165.5℃×48hr）

(4) SAE No. 2 摩擦試験

米国グリーニング社製，SAE No. 2 摩擦試験機を用い、下記の実験条件で摩擦特性を評価した。

〔実験条件〕

ディスク：国産自動変速機用ペーパー系ディスク（３枚）

プレート：国産自動変速機用鋼製プレート（４枚）

モーター回転数：3000rpm

油　　温：100℃

以上の実験条件で回転数1200rpmのときの動摩擦係数をμ_{1200}、停止するときの摩擦係数をμ_0として測定した。

(5) アニリン点：JIS K-2256に準拠

(6) ゴム浸漬試験

JIS K-6301に準拠し、次の条件で行なった。

ゴム：ニトリルゴム（日本オイルシール製A727）

油温：150℃

時間：170時間

比較例12

市販のパラフィン系溶剤精製油を用い、実施例1と同様にして性能を評価した。結果を第３表に示す。

第 1 表

		性状			備考
		動粘度 (@100 ℃ cSt)	粘度指数	流動点 (℃)	
本発明	鉱油 I	2.36	75	−47.5	*1
	〃 II	5.65	89	−45.0	*1
対照	〃 III	4.00	85	−17.5	*2
	〃 IV	5.15	103	−15.0	*3
	〃 V	4.08	−2	−37.5	*4
	〃 VI	9.00	43	−25.0	*5

*1：下記の如くして得られた鉱油を使用した。

クウェート原油を常圧蒸留後、減圧蒸留して得た留出分および残渣油を脱れきした留分を供給原料としてプロダクトの脱ろう油（最初の脱ろう処理したもの）の粘度指数が約100となるような苛酷な条件で水素化処理した。

上記の方法で得られたプロダクトを分留し、100℃の粘度でほぼ2.3cSt, 5.6cStとなるような2種の留出油を得た。

これら2種の留出油のそれぞれをさらに溶剤脱ろう処理した。この段階での処理条件は、脱ろう油の流動点が−15℃となるようにした。

次いで、上記脱ろう油で芳香族分（ゲルクロ

マトグラフ法による）が1.5重量％以下になるようさらに水素化処理を行なった。

さらに、上記の二段水素化処理油を脱ろう油の流動点が－35℃以下となるように溶剤脱ろう処理した。

*2：パラフィン系溶剤精製油

*3：パラフィン系溶剤精製油

*4：ナフテン油

*5：ナフテン油

第 2 表

	性状			備考
	粘度（@100℃，cSt）	粘度指数	流動点（℃）	
ポリエステル I	4.3	142	－ 50	*1
ポリエステル II	3.48	162	－ 70	*2

*1：日本油脂㈱製ユニスターH-334R，トリメチロールプロパンと炭素数6～12の混合脂肪酸とのエステル

*2：三建化工製DINA，アジピン酸ジイソノニルエステル

第 3 表

			実施例						比較例											
			1	2	3	4	5	6	1	2	3	4	5	6	7	8	9	10	11	12
配合組成（重量%）	鉱油 I		25	21	17	9	26	18	28	—	—	—	—	—	—	—	—	27	13	市販油
	鉱油 II		63	55	71	67	69	45	72	—	—	—	—	—	—	—	—	72	37	
	鉱油 III		—	—	—	—	—	—	—	68	60	40	—	—	—	—	—	—	—	
	鉱油 IV		—	—	—	—	—	—	—	32	28	48	—	—	—	—	—	—	—	
	鉱油 V		—	—	—	—	—	—	—	—	—	—	100	87	84	—	—	—	—	
	鉱油 VI		—	—	—	—	—	—	—	—	—	—	—	1	4	—	—	—	—	
	ポリエステル I		12	24	—	—	—	37	—	—	12	—	—	12	—	100	—	1	50	
	ポリエステル II		—	—	12	24	5	—	—	—	—	12	—	—	12	—	100	—	—	
添加剤 I *1（重量部）			10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	
添加剤 II *2（重量部）			5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
結果	動粘度（@100℃, cSt）		6.98	7.01	7.00	6.99	6.99	6.96	6.91	6.97	6.94	7.00	6.92	7.02	6.96	7.29	7.24	6.95	7.07	6.91
	BF粘度（@−40℃, cp）		14800	12900	14000	9800	19200	13800	23800	36900	23100	22500	78700	46300	40100	6460	1930	23300	9100	42000
	ISOT	動粘度比（@100℃）	1.15	1.12	1.17	1.08	1.19	1.11	1.27	1.52	1.31	1.27	1.93	1.91	1.81	1.09	1.05	1.25	1.08	1.32
		全酸価増加	0.53	0.58	0.49	0.44	0.50	0.62	0.48	7.37	5.39	4.31	6.70	6.45	6.21	0.49	0.71	0.48	0.65	1.20
	SAE No 2	μ1200	0.135	0.132	0.134	0.131	0.130	0.128	0.124	0.122	0.133	0.134	0.120	0.133	0.133	0.125	0.117	0.124	0.123	0.124
		μ0/μ1200	1.06	1.07	1.06	1.07	1.05	1.09	1.04	1.05	1.08	1.09	1.06	1.07	1.09	1.10	1.12	1.05	1.10	1.31
	アニリン点（℃）		92.2	84.0	93.0	84.0	97.3	80.0	101.3	95.0	86.9	89.0	76.3	70.6	73.8	室温以下	室温以下	100.5	71.0	95
	ゴム浸漬試験	重量変化率（%）	3.2	4.1	3.0	4.1	2.6	5.9	2.0	2.7	4.0	3.8	9.7	11.3	10.8	16.3	24.1	2.2	11.0	2.8
		体積変化率（%）	6.4	8.1	5.8	8.3	5.0	11.4	4.0	5.6	7.0	6.8	16.5	20.5	18.3	27.0	40.8	4.5	20.3	5.7

*1：清浄分散剤，酸化防止剤，摩擦調整剤，消泡剤等を含むパッケージ型添加剤

*2：ポリメタアクリレート型粘度指数向上剤

第３表より次のことが判る。すなわち、比較例１，２および５では、低温粘度（@－40℃）がそれぞれ23800，36900，78700cpであり、市場の要求値20000cp以下という条件を満足せず、しかも特に比較例２および５ではISOTの全酸価の上昇が大きく劣化が著しいことが判る。

また、比較例３～４および比較例６～７では、ISOTでの全酸価が大きく、しかも低温粘度は低くはなっているが、やはり市場の要求値20000cp以下という条件を満足しない。さらに比較例８～９ではアニリン点が低く、ゴムに対して重量および体積変化率が大きく、膨潤が大きいことが判る。

また比較例10，11は共に、配合割合を本発明の範囲外としたものである。比較例10の如くポリエステルの配合割合が少なすぎると低温粘度（@－40℃）が市場の要求値20000cp以下という条件を満足せず、一方比較例11の如くポリエステルの配合割合が多すぎるとアニリン点が低く、しかもゴムに対して重量および体積変比率が大きく、膨潤が大きいことが判る。

さらに比較例12の如く市販油を用いた場合、低温粘度(@ − 40℃)が42000cpであり、市場の要求値を満足せず、しかも摩擦特性も十分でないことが判る。

これに対して実施例1～6では低温粘度は20000cp以下であり、酸化安定性(ISOT)およびゴム膨潤性も良好であることが判る。さらに、摩擦特性にも優れていることが判る。

産業上の利用可能性

本発明の潤滑油組成物は、湿式ブレーキや湿式クラッチを有する部分の潤滑剤、例えば自動変速機用潤滑剤，トラクター油などに使用でき、さらに低温粘度が低く、酸化安定性，ゴム膨潤性が良いためパワーステアリング油，油圧油，内燃機関油などとしても使用することができる。

請　求　の　範　囲

1．100℃における動粘度が2～50センチストークス，流動点が－30℃より低く、粘度指数が70以上である鉱油97～60重量％およびポリエステル3～40重量％からなる潤滑油組成物。

2．鉱油が、100℃における動粘度が5～30センチストークスのものである特許請求の範囲第1項記載の組成物。

3．鉱油が、流動点－40℃以下のものである特許請求の範囲第1項記載の組成物。

4．鉱油が、粘度指数75～105のものである特許請求の範囲第1項記載の組成物。

5．鉱油が、100℃における動粘度が5～30センチストークス，流動点が－40℃以下，粘度指数75～105のものである特許請求の範囲第1項記載の組成物。

6．ポリエステルが、ヒンダードエステルまたはジカルボン酸エステルである特許請求の範囲第1項記載の組成物。

7．ポリエステルが、流動点－30℃以下のものである特許請求の範囲第1項記載の組成物。

INTERNATIONAL SEARCH REPORT

International Application No PCT/JP87/00657

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl[4] C10M111/02, C10N40:04, C10N40:08

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
IPC	C10M101/02, 105/32-105/40, C10N20:02, 40:04, 40:08, 60:02

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y	JP, A, 59-133297 (Idemitsu Kosan Co., Ltd.) 31 July 1984 (31. 07. 84) Column 1, line 5 to column 2, line 3, column 6, lines 16 to 19 & DE, A, 3401149 & FR, A, 2539755 & GB, A, 2134538	1-7
Y	JP, A, 60-161486 (Nippon Oil Co., Ltd.) 23 August 1985 (23. 08. 85) Column 1, lines 5 to 10, column 4, lines 5 to 11 (Family: none)	1-7
Y	JP, B2, 60-27711 (Toa Nenryo Kogyo Kabushiki Kaisha) 1 July 1985 (01. 07. 85) Column 1, lines 2 to 9, column 10, line 28 to column 11, line 26 & NL, A, 7406662 & DE, A, 2424296 & FR, A, 2229760 & US, A, 3962071 & GB, A, 1472655 & CA, A, 1030887	1-7

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
November 30, 1987 (30.11.87)	December 7, 1987 (07.12.87)
International Searching Authority [1]	**Signature of Authorized Officer [20]**
Japanese Patent Office	

Form PCT/ISA/210 (second sheet) (October 1977)

国 際 調 査 報 告

国際出願番号PCT/JP 87/ 00657

Ⅰ. 発明の属する分野の分類

国際特許分類(IPC) Int. Cl⁴
C10M111／02//C10N40：04, C10N40：08

Ⅱ. 国際調査を行った分野

調 査 を 行 っ た 最 小 限 資 料

分類体系	分類記号
IPC	C10M101／02, 105／32－105／40// C10N20：02, 40：04, 40：08, 60：02

最小限資料以外の資料で調査を行ったもの

Ⅲ. 関連する技術に関する文献

引用文献のカテゴリー*	引用文献名 及び一部の箇所が関連するときは、その関連する箇所の表示	請求の範囲の番号
Y	JP, A, 59－133297(出光興産株式会社) 31. 7月. 1984(31. 07. 84) 第1欄第5行－第2欄第3行, 第6欄第16－19行 &DE, A, 3401149 &FR, A, 2539755 &GB, A, 2134538	1－7
Y	JP, A, 60－161486(日本石油株式会社) 23. 8月. 1985(23. 08. 85) 第1欄第5－10行, 第4欄第5－11行 (ファミリーなし)	1－7
Y	JP, B2, 60－27711(東亜燃料工業株式会社) 1. 7月. 1985(01. 07. 85) 第1欄第2－9行, 第10欄第28行－第11欄 第26行 &NL, A, 7406662 &DE, A, 2424296 &FR, A, 2229760 &US, A, 3962071 &GB, A, 1472655	1－7

*引用文献のカテゴリー
「A」特に関連のある文献ではなく、一般的技術水準を示すもの
「E」先行文献ではあるが、国際出願日以後に公表されたもの
「L」優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献(理由を付す)
「O」口頭による開示、使用、展示等に言及する文献
「P」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献
「T」国際出願日又は優先日の後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの
「X」特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの
「Y」特に関連のある文献であって、当該文献と他の1以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの
「&」同一パテントファミリーの文献

Ⅳ. 認 証

国際調査を完了した日	国際調査報告の発送日
30. 11. 87	07.12.87
国際調査機関	権限のある職員
日本国特許庁(ISA/JP)	特許庁審査官 須藤政彦 4H 7162

様式PCT／ISA／210(第2ページ) (1981年10月)

第2ページから続く情報

（Ⅱ欄の続き）

&CA. A. 1030887

Ⅴ. ☐ 一部の請求の範囲について国際調査を行わないときの意見

次の請求の範囲については特許協力条約に基づく国際出願等に関する法律第8条第3項の規定によりこの国際調査報告を作成しない。その理由は、次のとおりである。

1. ☐ 請求の範囲＿＿＿＿＿は、国際調査をすることを要しない事項を内容とするものである。

2. ☐ 請求の範囲＿＿＿＿＿は、有効な国際調査をすることができる程度にまで所定の要件を満たしていない国際出願の部分に係るものである。

3. ☐ 請求の範囲＿＿＿＿＿は、従属請求の範囲でありかつPCT規則6.4(a)第2文の規定に従って起草されていない。

Ⅵ. ☐ 発明の単一性の要件を満たしていないときの意見

次に述べるようにこの国際出願には二以上の発明が含まれている。

1. ☐ 追加して納付すべき手数料が指定した期間内に納付されたので、この国際調査報告は、国際出願のすべての調査可能な請求の範囲について作成した。
2. ☐ 追加して納付すべき手数料が指定した期間内に一部分しか納付されなかったので、この国際調査報告は、手数料の納付があった発明に係る次の請求の範囲について作成した。
   請求の範囲＿＿＿＿＿
3. ☐ 追加して納付すべき手数料が指定した期間内に納付されなかったので、この国際調査報告は、請求の範囲に最初に記載された発明に係る次の請求の範囲について作成した。
   請求の範囲＿＿＿＿＿
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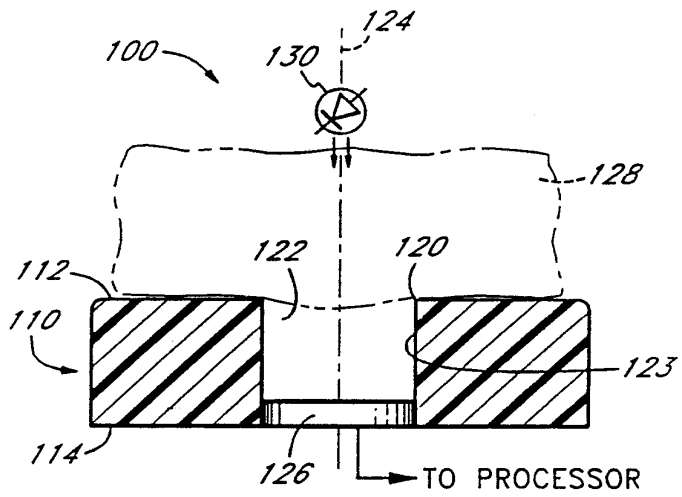
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(57) Abstract

An optical probe (100) which is particularly suited to reduce noise in measruements taken on an easily compressible material, such as a finger, a toe, a forehead, an earlobe, or a lip. The probe includes a base (110) having an aperture (120) which leads to a chamber (122). The base is placed adjacent a portion of the material, the chamber being placed directly adjacent any easily compressible portion of the material. A photodetector (126) is located within the chamber and does not contact the material. A light emitting diode (LED) (130) is affixed to the material, opposite the photodetector and above the chamber. The material which is supported by the aperture and therefore rests above or has intruded into the chamber is inhibited from compression since nothing comes in contact with this portion of the material, even when the material moves. Thus, light from the LED is directed through a stabilized portion of the material, such that the optical path length through which light travels is stabilized.

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LOW NOISE OPTICAL PROBE

TECHNICAL FIELD

The present invention relates to the sensing of energy. More specifically, the present invention relates to the reduction of noise in signals via an improved sensing mechanism.

BACKGROUND ART

Energy is often transmitted through or reflected from a medium to determine characteristics of the medium. For example, in the medical field, instead of extracting material from a patient's body for testing, light or sound energy may be caused to be incident on the patient's body and transmitted (or reflected) energy may be measured to determine information about the material through which the light has passed. This type of non-invasive measurement is more comfortable for the patient and can be performed more quickly.

Non-invasive physiological monitoring of bodily function is often required. For example, during surgery, blood pressure and the body's available supply of oxygen, or the blood oxygen saturation, are often monitored. Measurements such as these are often performed with non-invasive techniques where assessments are made by measuring the ratio of incident to transmitted (or reflected) light through a portion of the body, for example a digit such as a finger, or an earlobe, or a forehead.

Transmission of optical energy as it passes through the body is strongly dependent on the thickness of the material through which the light passes, or the optical path length. Many portions of a patient's body are typically soft and compressible. For example, a finger comprises skin, muscle, tissue, bone, blood, etc.

Although the bone is relatively incompressible, the tissue, muscle, etc. are easily compressible with pressure applied to the finger, as often occurs when the finger moves. Thus, if optical energy is made incident on a finger and the patient moves in a manner which distorts or compresses the finger, the optical path length changes. Since a patient generally moves in an erratic fashion, the compression of the finger is erratic. This causes the change in optical path length to be erratic, making the absorption erratic, resulting in a difficult to interpret measured signal.

Many types of non-invasive monitoring devices have been developed to try to produce a clear and discernable signal as energy is transmitted through a medium, such as a finger or other part of the body. In typical optical probes a light emitting diode (LED) is placed on one side of the medium while a photodetector is placed on an opposite side of the medium. Many prior art optical probes are designed for use only when a patient is relatively motionless since, as discussed above, motion induced noise can grossly corrupt the measured signal. Typically, probes are designed to maximize contact between the LED and the medium and the photodetector and the medium to promote strong optical coupling between the LED, the medium, and the photodetector, thereby generating a strong output signal intensity. In this way, a strong, clear signal can be transmitted through the medium when the patient is generally motionless.

For example, U.S. Patent No. 4,880,304 to Jaeb, et al. discloses an optical probe for a pulse oximeter, or blood oxygen saturation monitor, comprising a housing with a flat lower face containing a central protrusion in which a plurality of light emitting diodes (LED's) and an optical detector are mounted. When the probe is placed on the patient's tissue, the protrusion causes the LED's and the detector to press against the tissue to provide improved optical coupling of the sensor to the skin. In another embodiment (Figures 4a and 4b in the Jaeb patent), the LED's and the detector are arranged within a central chamber, generally horizontal with respect to the tissue on which the probe is placed. A set of mirrors or prisms causes light to be directed from the LED's onto the tissue through a polymer sealant within the chamber, the sealant providing a contact with the tissue for good optical coupling with the tissue.

U.S. Patent No. 4,825,879 to Tan, et al. discloses an optical probe wherein a T-shaped wrap, having a vertical stem and a horizontal cross bar, is utilized to secure a light source and an optical sensor in optical contact with a finger. The light source is located in a window on one side of the vertical stem while the sensor is located in a window on the other side of the vertical stem. The finger is aligned with the stem and the stem is bent such that the light source and the sensor lie on opposite sides of the finger. Then, the cross bar is wrapped around the finger to secure the wrap, thereby ensuring that the light

source and the sensor remain in contact with the finger to produce good optical coupling.

U.S. Patent No. 4,380,240 to Jöbsis, et al. discloses an optical probe wherein a light source and a light detector are incorporated into channels within a slightly deformable mounting structure which is adhered to a strap. Annular adhesive tapes are placed over the source and the detector. The light source and detector are firmly engaged with a bodily surface by the adhesive tapes and pressure induced by closing the strap around a portion of the body. An alternative embodiment provides a pressurized seal and a pumping mechanism to cause the body to be sucked into contact with the light source and detector.

U.S. Patent No. 4,865,038 to Rich, et al. discloses an optical probe having an extremely thin cross section such that it is flexible. A die LED and a die photodetector are located on a flexible printed circuit board and encapsulated by an epoxy bead. A spacer, having circular apertures positioned in alignment with the LED and photodetector, is placed over the exposed circuit board. A transparent top cover is placed over the spacer and is sealed with a bottom cover placed under the circuit board, thereby sealing the probe from contaminants. A spine may be added to strengthen the device. The flexibility of the device allows it to be pinched onto the body causing the epoxy beads over the LED and the photodetector to protrude through the apertures in the

spacer and press against the top cover such that good optical contact is made with the body.

U.S. Patent No. 4,907,594 to Muz discloses an optical probe wherein a dual wall rubberized sheath is fit over a finger. A pump is located at the tip of the finger such that a pressurized chamber may be formed between the two walls, thereby causing an LED and a photodetector located in the inner wall to be in contact with the finger.

Each of the above described optical probes attempts to cause a strong measured signal at the photodetector by optimizing contact between the LED, the patient, and the probe. However, this optimization forces compressible portions of the patient's body to be in contact with surfaces which compress these portions of the patient's body when the patient moves. This can cause extreme changes in the thickness of material through which optical energy passes, i.e., changes in the optical path length. Changes in the optical path length can produce enough distortion in the measured signal to make it difficult or impossible to determine desired information. Thus, a need exists for a probe which inhibits motion induced noise, or motion artifacts, during measurement of a signal while still generating a transmitted or reflected signal of sufficient intensity to be measured by a detector.

SUMMARY OF THE INVENTION

The present invention is a probe for use in both invasive and non-invasive energy absorption (or reflection) measurements. A base is formed in a shape generally corresponding to the material on which measurements are to be made, for example, a section of a patient's body such as a finger, an earlobe, a forehead, a toe, an organ, or a portion of tissue. The base has a forward end, a rear end, a top and a bottom. An aperture is formed in the top of the base. The aperture is the entrance to a chamber. A detector, such as a photodetector, is mounted within the chamber, typically in the bottom of the chamber. The material on which measurements are to be made is placed on the base such that any compressible portion of the material is located directly adjacent the chamber. Thus, the compressible portion of the material is caused to rest above or enter into the chamber. The chamber is deep enough that any material which intrudes into the chamber does not contact anything which might cause compression.

A light source, such as an LED, is affixed to the material, opposite the photodetector. The LED emits light energy which propagates through and is absorbed by the material along the optical path length, or thickness of material through which light propagates. An attenuated light energy signal emerges from the material, into the chamber. As light propagates through the material, it is

scattered by the material and is thus transmitted into the chamber over a broad range of angles. The photodetector produces an electrical signal indicative of the intensity of the signal transmitted by the material. The electrical signal is input to a processor which analyzes the signal to determine information about the medium through which light energy has been transmitted.

The probe of the present invention does not make direct physical contact between the photodetector and the material. Even though this results in less than optimal optical coupling, and thus generally lower output signal intensity, it enables an easily compressible portion of the material that light energy passes through to rest in the chamber and not be compressed. This results in less disturbance of the optical path between the light source and the detector. Since the LED is generally aligned with the chamber and the photodetector, the light energy signal propagates through the portion of the material which rests above or is accommodated within the chamber. The chamber allows the compressible portion of the material to remain substantially uncompressed, even during motion, since nothing within the chamber physically contacts the material through which light energy passes to cause compression. Thus, the thickness of the material, or the optical path length, is stabilized, thereby improving the signal-to-noise ratio of the measured signal. The intensity of the signal received at the photodetector may be improved by emission of higher intensity light by the

LED to compensate for losses caused in the chamber and by the poor optical coupling. Thus, the probe of the present invention produces a strong, clear signal wherein noise due to motion, or motion artifacts, is substantially reduced.

In another embodiment of the invention, an LED may be mounted within the chamber, typically at the bottom of the chamber. A material is placed over the probe, and a photodetector is affixed to the material, opposite the chamber. The chamber still functions to protect easily compressible portions of the material through which light energy will pass from being compressed, even during motion. Another embodiment having the LED within the chamber is one in which a collimating lens assembly is also incorporated into the chamber. The lens assembly is located deep enough within the chamber that any portion of the material on which measurements are being made that penetrates into the chamber does not contact the lens assembly. The collimating lens assembly causes light from the LED to be focused on the material above the chamber, thus providing a less scattered signal transmitted into the chamber and onto the photodetector surface, thereby utilizing the photodetector more effectively.

In yet another embodiment of the present invention, a photodetector is mounted within the chamber, typically at the bottom of the chamber. A material is placed adjacent the probe and an LED is affixed to the material, opposite the chamber. A light collecting lens is placed

within the chamber, above the photodetector, leaving enough space within the chamber for any easily compressible material to intrude into the chamber without contacting the lens and being compressed. The lens collects light which has been scattered by the material and directs this light onto the surface of the photodetector, resulting in a stronger measured signal.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a schematic medium comprising N different constituents.

FIG. 2a illustrates an ideal plethysmographic signal that would be measured by the optical probe of the present invention when utilized for pulse oximetry.

FIG. 2b illustrates a realistic signal measured by the optical probe of the present invention when utilized for pulse oximetry.

FIG. 3 is a perspective view of a probe of the present invention having a single segment chamber.

FIG. 4 is a cross-sectional view of an optical probe of the present invention illustrating a single segment chamber having a detector within it.

FIG. 5 is a cross-sectional view of a probe of the present invention having a detector resting on a shell of base material.

FIG. 6 is a cross-sectional view of a probe of the present invention incorporating a light collecting lens.

FIG. 7 is a cross-sectional view of a probe of the present invention illustrating a single segment chamber having an LED within it.

FIG. 8 is a cross-sectional view of a probe of the present invention incorporating a collimating lens assembly.

FIG. 9 is a cross-section view of a probe of the present invention wherein the LED and the detector are not aligned along the central axis of the chamber.

FIG. 10 is a perspective view of another embodiment of a probe of the present invention having a two segment chamber.

FIG. 11 is a cross-sectional view of another embodiment of the probe of FIG. 10 incorporating a two segment chamber having a detector within it.

FIG. 12 is a cross-sectional view of another embodiment of the probe of FIG. 10 incorporating a light collecting lens in a two segment chamber.

FIG. 13 is a perspective view of probe of the present invention having a three segment chamber.

FIG. 14 is a cross-sectional view of the probe of FIG. 13 incorporating a three segment chamber having a detector within it.

FIG. 15 is a cross-sectional view of another embodiment of the probe of FIG. 13 incorporating a light collimating lens.

FIG. 16 is a perspective view of a probe of the present invention specifically designed to be used with a digit.

FIG. 17 illustrates a schematic finger comprising fingernail, skin, bone, tissue, muscle, blood, etc.

FIG. 18 is a cross-section view of the probe of FIG. 16.

FIG. 19 is a longitudinal cross-sectional view of the probe of FIG. 16.

FIG. 20 is a cross-sectional view of another embodiment of the probe of FIG. 16 incorporating a light collecting lens.

FIG. 21 is a cross-sectional view of a probe of the present invention designed to be utilized for reflectance measurements.

FIG. 22 is a cross-sectional view of a probe which is advantageously used for non-invasive measurements when a material is compressible on more than one side. The probe has two bases, each with a chamber to house a detector or an energy source and thereby reduce motion artifacts.

FIG. 23 is a cross-sectional view of a probe having a generally cone-shaped chamber with a reflective surface which advantageously causes energy to be concentrated, or "funneled", onto the surface of a detector within the chamber, improving the measured signal.

FIG. 24 is a schematic of one system which may advantageously employ a probe of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

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 unnecessary extraction of blood or tissue. 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.

The amplitude of the measured signal is highly dependent on the thickness of the material through which the energy passes, or the optical path length. A schematic medium 20 comprising N different constituents A_1 through A_N is shown in Figure 1. Energy transmitted through the medium 20 is approximately attenuated according to the equation:

$$I = I_0 e^{-\sum_{i=1}^{N} \varepsilon_i c_i x_i} \qquad (1)$$

where ε_i is the absorption coefficient of the ith constituent; x_i is the thickness of the ith constituent through which light energy passes, or the optical path length of the ith; and c_i is the concentration of the ith constituent in thickness x_i.

Since energy absorption is strongly dependent on the thicknesses of the constituents A_1 through A_N which make up the medium 20 through which the energy passes, when the thickness of the medium 20 changes, due to motion for example, the thicknesses of the individual constituents A_1 through A_N change. This causes the absorption characteristics of the medium 20 to change.

Often a medium 20 is under random or erratic motion. For example, if the medium 20 is an easily compressible portion of a patient's body and the patient moves, the medium 20 compresses erratically causing the individual thicknesses X_1 through X_N of the constituents A_1 through A_N to vary erratically. This erratic variation may cause large excursions in the measured signal and can make it extremely difficult to discern a desired signal, as would be present without motion induced noise, or motion artifacts.

For example, Figure 2a illustrates an ideal desired signal waveform, labelled Y, measured in one application of the present invention, namely pulse oximetry. Figure 2b illustrates a more realistic measured waveform S, also measured in a pulse oximetry application, comprising the ideal desired signal waveform Y plus motion induced noise, n, i.e. S=Y+n. It is easily seen how motion artifacts obscure the desired signal portion Y.

Figure 3 is a perspective view of an optical probe 100 of the present invention which greatly diminishes the effects of motion artifacts on the measured signal.

Figure 4 shows a cross-sectional view of the optical probe 100 of the present invention taken along line 4-4 in Figure 3. For clarity in the perspective view of Figure 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 Figure 4. Referring to Figures 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. A lateral cross-section (not shown) of the chamber 122 is typically 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.

A light source 130, typically a light emitting diode (LED), is affixed to 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. Any easily compressible portion of the material 128 is placed directly adjacent the chamber 122. The area surrounding the aperture 120 supports the material adjacent 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 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.

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.

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. 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.

Additionally helping to improve signal quality, the opaque quality of the base 110 absorbs ambient light which can interfere with the signal measured at the photodetector 126. 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 Figure 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.

Figure 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.

Figure 7 shows another embodiment of the probe 100 of the present invention wherein the positions of the photodetector 126 and the LED 130 are interchanged. The LED 130 is placed within the chamber 122, typically at the bottom 114 of the chamber 122, generally aligned with the central axis 124 of the chamber 122. The LED 130 may be fixed within the chamber 122 according to a number of

different methods, including but not limited to a press fit, adhesive, or clear epoxy resin which transmits light over a range of wavelengths of interest, such as around the wavelength which the LED emits. Again, a material 128 is placed on the base 110 having any compressible portion of the material 128 located directly adjacent the chamber 122. The photodetector 126 is attached to the material 128, opposite the LED 130, such that the LED 130, the photodetector 126, and the chamber 122 are aligned along the central axis 124 of the chamber 122. The photodetector 126 is typically attached by an opaque material. For example, the photodetector 126 may be attached to the material 128 with opaque tape, thereby limiting signal degradation caused by ambient light. The photodetector 126 is, again, electrically connected to a processor.

The probe 100 of this embodiment functions substantially identically to the embodiment of the probe 100 having the photodetector 126 housed in the chamber 122. The chamber 122 stabilizes the optical path length by allowing easily compressible portions of the material 128 to rest above or intrude into the chamber 122, thereby stabilizing the optical path length and substantially reducing motion artifacts. This is true regardless of whether the photodetector 126 or the LED 130 is housed within the chamber 122.

Figure 8 shows a cross-sectional view of another embodiment of the probe 100 of the present invention

wherein the LED 130 is located within the chamber 122. A collimating lens assembly 140 is placed within the chamber 122, between the material 128 which rests above or enters into the chamber 122 and the LED 130. Collimating lens assemblies 140 are well known in the art and, thus, the lens assembly 140 is represented schematically in the Figure 8. The collimating lens assembly 140 is located deep enough within the chamber 122 that any material 128 which intrudes into the chamber 122 does not contact the lens assembly 140. The lens assembly 140 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 collimating lens assembly 140 causes light from the LED 130 to be focused on the material 128 above the chamber 122, thus providing a less scattered signal transmitted onto the photodetector 126 surface, thereby utilizing the photodetector 126 more effectively.

Figure 9 shows another embodiment of the probe 100 of the present invention wherein the LED 130 and the photodetector 126 are not aligned along the central axis 124 of the chamber 122. Light is scattered within the material 128, causing at least a portion of the light emitted by the LED 130 to reach the photodetector 126 for measurement. As long as light emitted by the LED 130 and scattered by the material 128 reaches the photodetector

126 with great enough intensity to be measured, the LED 130 and the photodetector 126 need not be aligned. While alignment of the LED 130 and the photodetector 126 along the same axis causes the light emitted by the LED 130 to reach the photodetector 126 more directly, it is not necessary for operation of the probe of the present invention. In some applications, misalignment may even be advantageous. It will be understood that this is true for any embodiment of the probe of the present invention. Additionally, it will be understood that a photodetector 126 which fills the width of the chamber 122 is advantageous in that more of the light directed into the chamber 122 will be incident on the surface of the photodetector 126, resulting in a stronger measured signal. However, any size photodetector 126 which acquires enough energy to produce an adequately strong measured signal is acceptable. It will be understood that this is true for any embodiment of the probe of the present invention.

A perspective view of another embodiment of the probe 200 of the present invention comprising a multi-segment chamber 222 is shown is Figure 10. Figure 11 shows a cross-sectional view of the probe 200 of the present invention taken along line 11-11 in Figure 10. For clarity in the perspective view of Figure 10, a material 228 on which measurements are to be taken is not shown placed adjacent the probe 200. However, the material 228 is shown adjacent the probe 200 in Figure 11.

Referring to Figures 10 and 11, a base 210, having a top 212, a bottom 214, a forward end 216, and a rear end 218, is made of a material which is preferably rigid and opaque. It will be understood, however, that the probe 200 may be made of materials which may be rigid, resilient, opaque, or transparent, for example. An aperture 220 of any shape is formed in the base 210, similar to the aperture 120 described above in conjunction with the probe 100 of Figures 3 through 9. The aperture 220 forms the opening to a stabilizing segment 222a of the multiple segment chamber 222. A lateral cross-section (not shown) of the stabilizing segment 222a of the chamber 222 is typically the same shape as the aperture 220. Walls 223a of the stabilizing segment 222a are generally perpendicular to the aperture 220. A central axis 224 of the chamber 222 is defined by a line aligned generally perpendicular to the aperture 220 and extending generally through a central portion of the aperture 220 and the chamber 222.

A mounting segment 222b is located directly adjacent and below the stabilizing segment 222b, connected to the stabilizing segment 222b by a border 225. The mounting segment 222b shares the central axis 224 of the stabilizing segment 222a and is typically of smaller width. Walls 223b of the mounting segment 222b are generally parallel to the central axis 224. The mounting segment 222b may extend through the bottom 214 of the base 210, as shown in Figure 11, or the mounting segment 222b

may extend to just above the bottom 214 of the base 210, leaving a shell (not shown) of base 210 material at the bottom 214 of the chamber 222.

A photodetector 226 is placed in the mounting segment 222b of the chamber 222, typically at the bottom 214 of the mounting segment 222b, having a central portion of the photodetector 226 generally aligned with the central axis 224 of the chamber 222. The mounting segment 222b of the chamber 222 is deep enough that the photodetector 226 does not penetrate into the stabilizing segment 222 of the chamber 222. The photodetector 226 may be fixed within the chamber 222 according to a number of different methods, including but not limited to adhesive, a press fit, or a clear epoxy resin which transmits light over a range of wavelengths of interest. Typically the bottom 214 of the chamber 222 is made opaque via paint or tape, for example, or by leaving a shell (not shown) of base 210 material at the bottom 214 of the chamber 222 when the chamber 222 is formed. The photodetector 226 is electrically connected to a processor, similarly to the photodetector 126 in the previous embodiment of the probe 100 of the present invention.

An energy absorbing material 228 is placed over the base 210 as shown in the cross section of Figure 11. A portion of the material 228 may rest above the chamber 222. Additionally, the stabilizing segment 222a of the chamber 222 is wide enough that any easily compressible portion of the material 228 may intrude into the

stabilizing segment 222a of the chamber 222. The stabilizing segment 222a of the chamber 222 is deep enough that the portion of the material 228 which enters into the stabilizing segment 222a does not contact matter within the stabilizing segment 222a which might cause compression, even when the material 228 is caused to move.

A light emitting diode (LED) 230 is affixed to the material 228, opposite the aperture 220. The LED 230 is advantageously aligned along the central axis 224 to optimize the amount of light incident directly through the material 228 onto the photodetector 226. However, it will be understood that the positions of the photodetector 226 and the LED 230 could be interchanged as discussed in conjunction with Figure 7. Additionally, a collimating lens assembly (not shown) could be added to the chamber 222 as discussed in conjunction with Figure 8. The collimating lens assembly may be held in the chamber 222 similarly to a light collecting lens 232 discussed hereinbelow. Further, it will be understood that the LED 230 and the photodetector 226 could be unaligned, as discussed in conjunction with Figure 9.

As light from the LED 230 propagates through the material 228, it is scattered by the material 228 and is thus transmitted into the chamber 222 over a broad range of angles. Thus, some of the light is caused to be incident on the opaque walls 223a and 223b of the chamber 222 and is absorbed. However, the advantageous alignment of the photodetector 226 and the LED 230 along the central

axis 224 causes a large percentage of the light to be incident on the surface of the photodetector 226. Since the material 228 remains substantially uncompressed above and within the stabilizing segment 222a, the thickness through which the light travels, or the optical path length, is substantially stabilized. Thus, the signal-to-noise ratio of the measured signal is improved by the suppression of motion artifacts due to the chamber 222.

In another embodiment of the probe 200, a light collecting lens 232 is inserted within the chamber 222, as shown in cross-section in Figure 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 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.

A perspective view of another embodiment of the probe 300 of the present invention which incorporates a chamber 322 having three segments 322a, 322b, and 322c is shown in Figure 13. The probe 300 has a base 310 with a top 312, a bottom 314, a forward end 316, and a rear end 318. The base 310 is typically made of rigid opaque material. However, it will be understood that the base 310 may be made of other materials which may be rigid, resilient, opaque, or transparent, for example. A cross-sectional view of the chamber 322 of this embodiment is shown in Figure 14. For clarity in the perspective view of Figure 13, a material 328 on which measurements are to be taken is not shown placed adjacent the probe 300. However, the material 328 is shown in the cross section of Figure 13. An aperture 320 of any shape is formed in the base 310, similar to the apertures 120 and 220 described above. The aperture 320 forms the opening to a stabilizing segment 322a of a three segment chamber 322. A lateral cross-section (not shown) of the stabilizing segment 322a of the chamber 322 is typically the same shape as the aperture 320. Walls 323a of the stabilizing segment 322a are generally perpendicular to the aperture 320. A central axis 324 of the chamber 322 is defined by a line aligned perpendicular to the aperture 320 and extending generally

through a central portion of the aperture 320 and the chamber 322.

A second, transitional segment 322b of the chamber 322 is adjacent the stabilizing segment 322a of the chamber 322. A top border 325a is formed between the transitional segment 322b and the stabilizing segment 322a of the chamber 322. The transitional segment 322b shares the same central axis 324 as the stabilizing segment 322a. Walls 323b of the transitional segment 322b are angled inwardly such that a bottom border 325b of the transitional segment 322b is of smaller dimension than the top border 325a of the transitional segment 322b.

The bottom border 325b of the transitional segment 322b leads into a mounting segment 322c of the chamber 322. The mounting segment 322c shares the same central axis 324 of the stabilizing and transitional segments 322a and 322b and is typically of smaller width than the stabilizing and transitional segments 322a and 322b. Walls 323c of the mounting segment 322c are generally parallel to the central axis 324. Thus, any cross-section of the mounting segment 322c cut perpendicular to the central axis 324 of the chamber 322 is typically of approximately the same shape as the bottom border 325b of the transitional segment 322b of the chamber 322. The mounting segment 322c may extend through the bottom 314 of the base 310, as shown. Alternatively, the mounting segment 322c may extend to just above the bottom 314 of the base 310, leaving a shell (not shown) of base 310

material at the bottom 314 of the three segment chamber 322.

A photodetector 326 is placed within the mounting segment 322c of the chamber 322, typically at the bottom 314 of the chamber 322. A central portion of the photodetector 326 is aligned with the central axis 324 of the chamber 322. The mounting segment 322c of the chamber 322 is deep enough that the photodetector 326 does not penetrate into the stabilizing segment 322 of the chamber 322. The photodetector 326 may be fixed within the chamber 322 according to a number of different methods, including but not limited to adhesive, a press fit, or a clear epoxy resin which transmits light over a range of wavelengths of interest. Typically, the bottom 314 of the chamber 322 is made opaque via the press fit, paint, or tape, for example. The photodetector 326 is electrically connected to a processor, similarly to the photodetectors 126 and 226 in the previous embodiments of the probe of the present invention.

When a portion of an energy absorbing material 328 is placed over the probe 300, as shown in the cross-section of Figure 14, it may rest above the chamber 322. Additionally, the stabilizing segment 322a of the chamber 322 is wide enough that easily compressible portions of the material 328 may enter into the stabilizing segment 322a of the chamber 322. The stabilizing segment 322a of the chamber 322 is deep enough that the easily compressible portion of the material 328 which intrudes

into the stabilizing segment 322a does not contact matter within the stabilizing segment 322a which might cause compression of the material 328, even when the material 328 is caused to move. The chamber 322 shields the compressible material 328 from contact which might cause compression of the material 328 and thereby change the optical path length through the material 328.

An LED 330 is affixed to the material 328, opposite the aperture 320. The LED 330 is advantageously aligned along the central axis 324 to optimize the amount of light incident directly through the material 328 onto the photodetector 326. It will be understood that the positions of the photodetector 326 and the LED 330 could be interchanged as discussed in conjunction with Figure 7. Additionally, a collimating lens assembly (not shown) could be added to the chamber 322 as discussed in conjunction with Figure 8. The collimating lens assembly may be held in the chamber 322 similarly to a light collecting lens 332 discussed hereinbelow. Further, it will be understood that the LED 330 and the photodetector 326 could be unaligned, as discussed in conjunction with Figure 9.

As light from the LED 330 propagates through the material 328, it is scattered by the material 328 and is thus transmitted into the chamber 322 over a broad range of angles. Thus, some of the light is caused to be incident on the opaque walls 323a, 323b, and 323c of the chamber 322 and is absorbed. However, the advantageous

alignment of the photodetector 326 and the LED 330 along the central axis 324 of the chamber 322 causes a large percentage of the light to be incident on the surface of the photodetector 326. Since the material 328 remains substantially uncompressed above and within the stabilizing segment 322a, the thickness through which the light travels, or the optical path length, is substantially stabilized. Thus, the signal-to-noise ratio of the measured signal is improved by the suppression of motion artifacts. Additionally helping to improve the signal to noise ratio of the measured signal is the opaque bottom 314 of the mounting segment 322c which shelters the photodetector 326 from ambient light.

In another embodiment of the probe 300 of the present invention, a light collecting lens 332 is added to the transitional segment 322b of the chamber 322, as shown in a cross sectional view in Figure 15. The lens 332 is supported in the transitional segment 322b and may be held in the transitional segment 322b by a number of means, including but not limited to optical adhesive, a lens retaining ring, or a press fit. The lens has a generally planar surface 332a aligned with the top border 325a of the transitional segment 322b of the chamber 322 and a generally convex surface 325b extending into the transitional segment 322b of the chamber 322. The stabilizing segment 322a of the chamber 322 is deep enough that the lens 332 does not contact the easily compressible

material 328 which rests above or has intruded into the chamber 322.

The lens 332 collects light which is incident on the planar surface 332a. Much of the light which is incident on this surface 332a at angles which would have been absorbed by the walls 323a, 323b and 323c of the chamber 322 if the lens 332 were not present is now directed toward the photodetector 326. Thus, a greater percentage of the light transmitted through the material 328 is caused to be incident on the photodetector 326, resulting in a stronger measured signal.

It will be understood that the walls 323b of the transitional segment 322b in each of the above described embodiments need not be sloped to achieve transition from larger width in the stabilizing segment 322a to smaller width in the mounting segment 322c. The walls 323b of the transitional segment 322b could be aligned generally parallel to the central axis 324, arranged at a distance which would cause the width of the transitional segment 322b to be less than the width of the stabilizing segment 322a and greater than the width of the mounting segment 322c.

Figure 16 shows a perspective view of another probe 400 of the present invention specifically designed for use with a digit, such as a finger or a toe. For ease of illustration, the present example will pertain to a finger, though it will be understood that the present example could equally well pertain to any digit. Figure

17 illustrates a schematic finger 428 comprising nail, skin, bone, tissue, muscle, blood, etc. Constituents in the finger's pad 404, such as fat and tissue, are easily compressible with motion of a patient. Even slight motion of the finger 428 can cause the thickness of constituents within the finger 428 to change greatly, thereby causing large motion induced excursions to occur in a measured signal, often obscuring a desired portion of the measured signal from which information about the patient can be determined.

Referring back to Figure 16, base 410 of the finger probe 400, called a saddle 410 in this embodiment, is generally semi-cylindrical and preferably is made of a rigid or semi-rigid, opaque material such as black plastic. It will be understood, however, that the saddle 410 may be made of other materials, including those which are rigid, resilient, opaque, and transparent, for example. The saddle 410 has a top 412, a bottom 414, a forward end 416, a rear end 418, a ridge 440, and sidewalls 450 which curve upwardly from the ridge 440 to form a U-shape in cross-section, as shown in Figure 18.

Referring to Figures 16 and 18, an aperture 420 forms the entrance to a chamber 422, located between one-quarter to one-half of the length of the saddle 410 from the forward end 416 of the saddle 410, as shown in the longitudinal cross-section of Figure 19. The aperture 420 can be of any shape, including but not limited to circular, square, or triangular. The aperture 420 is the

entrance to a chamber 422, as described previously in conjunction with other embodiments 100, 200, and 300 of the probe of the present invention. The chamber 422 may also be of any shape, including but not limited to circular, square, or triangular in cross-section.

The chamber 422 may have one or more segments, as described previously. Although the chamber 422 shown in this embodiment is a three segment chamber 422, having a stabilizing segment 422a, a sloped-wall transitional segment 422b, and a mounting segment 422c aligned on a common central axis 424, it will be understood that any chamber 422 which protects from compression, a compressible portion of the finger 428 through which light energy passes during absorption measurements, is a viable alternative. It will further be understood that a shell (not shown) of saddle 410 material could cover the bottom 414 of the chamber 422, as described previously with respect to the embodiment of the probe shown in Figure 5.

A photodetector 426 is placed within the chamber 422, typically at the bottom 414 of the mounting segment 422c of the chamber 422. The photodetector 426 may be in place by adhesive, a press fit, or a clear epoxy resin which transmits light over a range of wavelengths of interest, for example. Typically, the bottom 414 of the chamber 422 is made opaque via tape or paint, for example, such that ambient light does not affect the photodetector 426.

The finger 428 is placed on the saddle 410, the finger pad 404 directly adjacent the aperture 420 and

chamber 422. Additionally, the finger pad 404 may rest above the chamber 422. The aperture 420 and stabilizing segment 422a of the chamber 422 are wide enough that any easily compressible portion of the finger 428, such as a portion of the finger pad 404, may intrude into the chamber 422. The stabilizing segment 422a of the chamber 422 is deep enough that any portion of the finger 428 which does penetrate into the stabilizing segment 422a does not contact any matter within the stabilizing segment 422a which might cause compression of the finger 428, even when the finger 428 is caused to move.

An LED 430 is affixed to the finger 428, generally opposite the aperture 420. The LED 430 is typically attached to the finger 428 via adhesive, such as medical tape. The LED 430 is advantageously aligned along the central axis 424 to optimize the amount of light transmitted directly through the finger 428 onto the photodetector 426. However, it will be understood that the positions of the photodetector 426 and the LED 430 could be interchanged as discussed in conjunction with Figure 7. Additionally, a collimating lens assembly (not shown) could be added to the chamber 422 as discussed in conjunction with Figure 8. The collimating lens assembly may be held in the chamber 422 similarly to a light collecting lens 432 discussed hereinbelow. Further, it will be understood that the LED 430 and the photodetector 426 could be unaligned, as discussed in conjunction with Figure 9.

The LED 430 emits a light energy signal which propagates through the finger 428 and is transmitted into the chamber 422. The chamber 422 shields from compression the portion of the finger 428 through which light energy passes. Thus, the optical path length of the light through the finger 428 is substantially stabilized and motion artifacts are substantially reduced in the measured signal. It will be understood that a single segment chamber as described in conjunction with Figures 3 through 9 or a two segment chamber as described in conjunction with Figures 10 through 12 could equally well be used in the finger probe 400 of the present invention to shield the compressible portion of the finger 428 from compression and thereby reduce motion artifacts.

Figures 16, 18, and 19 illustrate a perspective view, a frontal cross-sectional view, and a longitudinal cross-sectional view, respectively, of one embodiment of the finger probe 400. The curvature of the saddle 410 is correlated to the average curvature of the finger 428 such that the sidewalls 450 form a semi-circular splint-type support for the finger 428. The saddle 410 is approximately 25 mm long between the forward end 416 and the rear end 418, such that a portion of the finger 428 between its tip 406 and approximately its first knuckle 408 (shown in Figure 17) fits between the front 416 and the rear 418 ends of the probe 400. The curvature of the saddle 410 is generally defined by a line 460 (shown in

Figure 18) which is tangent to a sidewall 450 at an angle between 30° and 50° from horizontal.

The placement of the aperture 420 at a point between one-third and one-half of the length of the saddle 410, causes the thickest section of the compressible portion of the finger 428, or the finger pad 404, to rest above and within the chamber 422. Thus, the portion of the finger 428 with the greatest amount of compressible material is safeguarded from compression by the chamber 422.

In the embodiment of the finger probe 400 shown in Figures 16, 18, 19, and 20, the aperture 420 is generally circular and the chamber 422 has three segments 422a, 422b, and 422c, as shown in the cross-sectional view of Figure 18. Advantageously employed dimensions for the finger probe 400 illustrated in Figures 16, 18, 19, and 20 include the stabilizing segment 422a of the chamber 422 being generally cylindrical and having a diameter of approximately seven millimeters. Additionally, the stabilizing segment 422a of the chamber 422 is deep enough that any portion of the finger 428 which penetrates into the chamber remains substantially free of perturbation, even when the finger 428 moves. An advantageous depth for the stabilizing segment 422a is thus approximately two millimeters deep. The mounting segment 422c of the chamber 422 is also cylindrical, having a diameter of approximately five millimeters. The transitional segment 422b of the chamber 422 is of varying diameter, having sloped walls 423b, such that a top border 425a is

approximately seven millimeters in diameter and a bottom border 425b is approximately five millimeters in diameter. A detector 426 having up to a 5 millimeter diameter in the bottom 416 of the mounting segment 422c of the chamber 422.

In another embodiment of the finger probe 400, a light collecting lens 432 may be added to the finger probe 400 of the present invention, as shown in Figure 20. The saddle 410 and the chamber 422 function as discussed above. The lens 432 functions as described above in conjunction with Figures 6, 12, and 15 to collect light incident on the lens 432 which would be absorbed by the walls 423a, 423b and 423c of the chamber 422 if the lens 432 were not present. Thus, a greater percentage of the light transmitted through the finger 428 is directed onto the photodetector 426, resulting in a stronger measured signal.

Other embodiments of the probe of the present invention may be specifically designed and manufactured for use with an earlobe or other thin section of the body, such as a nostril or a lip, using the principles described herein. Also, embodiments of the probe of the present invention utilizing the properties of attenuation as energy is reflected from a medium, rather than transmitted through a medium, may be made using similar principles.

A probe 700 specifically designed to measure reflected energy is shown in cross-section in Figure 21. A base 710 is placed adjacent a material 728 on which

reflectance measurements are to be made. A photodetector 726 and an LED 730 are located within the base 710. In the embodiment shown in Figure 21, the photodetector 726 is positioned within a chamber 722x and the LED 730 is positioned within a chamber 722y. Although single segment chambers 722x and 722y are illustrated, the chambers 722x and 722y may be of any suitable shape and size. The chambers 722x and 722y function to stabilize the optical path length, as discussed previously, by shielding from compression any compressible portion of a material which rests above or intrudes into the chambers 722x and 722y.

A light collecting lens (not shown) may be added to the chamber 722x having the photodetector 726 within it, as discussed previously in conjunction with Figures 6, 12 and 15. Additionally, a collimating lens assembly (not shown) may be added to the chamber 722y having the LED 730 in it, as discussed previously in conjunction with Figure 8. The chambers 722x and 722y may be formed with or without a shell (not shown) of base 710 material, as discussed previously in conjunction with Figure 5.

It will be understood that in other embodiments (not shown) of the reflectance probe 700, the photodetector 726 could protrude from the base 710 and the LED 730 be located within a chamber 722y or the LED 730 could be protrude from the base 710 and the photodetector 726 could be located within a chamber 722x. Additionally, the photodetector 726 and the LED 730 could be located within a single chamber 722. In any embodiment the chamber(s) 722 may have any number of segments of any suitable shape.

The type of probe 700 which relies on reflection may be advantageously utilized on materials where a photodetector 726 and an LED 730 cannot be placed on opposite sides of the material 728, such as with the forehead. However, a reflectance probe 700 can be used anywhere a non-invasive measurement needs to be taken, such as a lip, an earlobe, or a finger, for example.

Figure 22 shows a cross-sectional view of another probe 800 of the present invention wherein two bases 810x and 810y are placed adjacent to a material 828 on which measurements are to be made. The bases 810x and 810y are located on opposite sides of the material 828. A photodetector 826 is placed in a chamber 822x in the base 810x. An LED 830 is placed in a chamber 822y in the base 810y. The photodetector 826 and the LED 830 are aligned substantially along a central axis 824. Although two segment chambers 822x and 822y are illustrated, the chambers 822x and 822y may be of any suitable shape and size. Independent of which shape of chamber is utilized, the chambers 822x and 822y function to stabilize the optical path length and thereby reduce the effects of motion artifacts on the measured signals.

As discussed previously, the probe 800 may be modified slightly with a light collecting lens (not shown) added to the chamber 822x with the photodetector 826 in it. A collimating lens assembly (not shown) may be added to the chamber 822y with the LED 830 in it. Additionally, the chambers 822x and 822y may be formed with or without

a shell (not shown) of base 810x and 810y material. The probe 800 is particularly advantageous when a material 828 is compressible on more than one side since each chamber 822x and 822y supports and shields from compression any compressible portion of a material 828 which rests above or intrudes into the chambers 822x and 822y, respectively.

Figure 23 shows a cross-sectional view of another probe 900 of the present invention wherein a chamber 922 having walls 923 is formed to concentrate, or "funnel", energy onto the surface of a photodetector 926. An aperture 920 is formed in a base 910, the aperture 920 leading to a generally cone-shaped chamber 922. The base 910 is placed adjacent a material 928 on which measurements are to be made, the chamber 922 being placed directly adjacent any easily compressible portion of the material 928. The photodetector 926 is placed within the chamber 922, typically at the bottom of the chamber 928. A light emitting diode 930 is placed on the material 928, generally opposite and aligned with the photodetector 926.

As discussed previously, a portion of the material 928 is supported by the area surrounding the aperture 920. Additionally, the aperture 920 and chamber 922 are wide enough that any easily compressible portion of the material 928 may intrude into the chamber 922 without being compressed, thereby shielding this portion of the material 928 from compression, even during motion of the material 928. This substantially stabilizes the optical

path length and improves the signal to noise ratio of the signal measured at the photodetector 926.

Further improving the signal to noise ratio of measurements made with the probe 900, reflective material, such as a highly reflective metal, covers the walls 923 of the chamber 922. This causes light scattered by the material 928 and made incident on the walls of the chamber 922 to be reflected. The cone shape causes the light to be concentrated generally on the photodetector 926.

Depending upon the shape of the photodetector 926, the chamber 922 may be advantageously contoured to maximize the funneling of light onto the photodetector 926. If the photodetector 926 is flat, the chamber is most advantageously shaped having a generally hyperbolic cross-section. However, if the photodetector 926 is spherical or slightly curved, as is often the case due to manufacturing processes, the chamber is most advantageously shaped having a cone-shaped cross-section with uncurved walls 923.

As discussed previously in conjunction with other embodiments of the probe of the present invention, the probe 900 may be modified to include a light collecting lens (not shown). Alternatively, an LED 930 could be placed within the chamber 922 instead of the photodetector 926. With the LED in the chamber 922, a collimating lens assembly (not shown) could be placed within the chamber 922. Two bases 910 with two generally cone-shaped chambers could be utilized on one or either side of a

material 928. A single base 910 with two generally cone-shaped chambers 922 located side by side could also be used for reflective measurements. Additionally, the photodetector 926 and the LED 930 need not be aligned along the central axis 924.

Figure 24 shows a block diagram of one system which may utilize a probe of the present invention to make non-invasive optical measurements with reduced interference from motion artifacts. The system shown in Figure 24 is a pulse oximeter wherein the finger probe 400 is employed and two measured signals at different wavelengths, one of which is typically red and the other of which is typically infrared, are alternately passed through the finger 428. Signals measured at the photodetector 426 are then processed to determine the amount of oxygen available to the body. This is evaluated by finding the saturation of oxygenated hemoglobin in blood comprising both oxygenated and deoxygenated hemoglobin.

Two LED's 430a and 430b, one LED 430a emitting red wavelengths and another LED 430b emitting infrared wavelengths, are placed adjacent the finger 428. The finger probe 400 is placed underneath the finger 428, the aperture 420 and chamber 422 located directly adjacent the finger pad 404. The photodetector 426 in the bottom 414 of the chamber 422 is connected to a single channel of common processing circuitry including an amplifier 530 which is in turn connected to a band pass filter 540. The band pass filter 540 passes signal into a synchronized

demodulator 550 which has a plurality of output channels. One output channel is for signals corresponding to visible wavelengths and another output channel is for signals corresponding to infrared wavelengths.

The output channels of the synchronized demodulator 550 for signals corresponding to both the visible and infrared wavelengths are each connected to separate paths, each path comprising further processing circuitry. Each path includes a DC offset removal element 560 and 562, such as a differential amplifier, a programmable gain amplifier 570 and 572 and a low pass filter 580 and 582. The output of each low pass filter 580 and 582 is amplified in a second programmable gain amplifier 590 and 592 and then input to a multiplexer 600.

The multiplexer 600 is connected to an analog-to-digital converter 610 which is in turn connected to a microprocessor 620. Control lines between the microprocessor 620 and the multiplexer 600, the microprocessor 620 and the analog-to-digital converter 610, and the microprocessor 620 and each programmable gain amplifier 570, 572, 590, and 592 are formed. The microprocessor 620 has additional control lines, one of which leads to a display 630 and the other of which leads to an LED driver 640 situated in a feedback loop with the two LED's 430a and 430b.

Each of the LED's 430a and 430b alternately emits energy which is absorbed by the finger 428 and received by the photodetector 426. The photodetector 426 produces an

electrical signal which corresponds to the intensity of the light energy striking the photodetector 426 surface. The amplifier 530 amplifies this electrical signal for ease of processing. The band pass filter 540 then removes unwanted high and low frequencies. The synchronized demodulator 550 separates the electrical signal into electrical signals corresponding to the red and infrared light energy components. A predetermined reference voltage, V_{ref}, is subtracted by the DC offset removal element 560 and 562 from each of the separate signals to remove substantially constant absorption which corresponds to absorption when there are no motion artifacts. Then the first programmable gain amplifiers 570 and 572 amplify each signal for ease of manipulation. The low pass filters 580 and 582 integrate each signal to remove unwanted high frequency components and the second programmable gain amplifiers 590 and 592 amplify each signal for further ease of processing.

The multiplexer 600 acts as an analog switch between the electrical signals corresponding to the red and the infrared light energy, allowing first a signal corresponding to the red light to enter the analog-to-digital convertor 610 and then a signal corresponding to the infrared light to enter the analog-to-digital convertor 610. This eliminates the need for multiple analog-to-digital convertors 610. The analog-to-digital convertor 610 inputs the data into the microprocessor 620 for calculation of the saturation of oxygen according to

known methods, such as those described in U.S. Patent Application Serial No.660, 060 entitled "SIGNAL PROCESSING APPARATUS AND METHOD", filed March 7, 1991, assigned to VITAL SIGNALS, INC., the same assignee as the present patent, incorporated herein by reference. The microprocessor 620 centrally controls the multiplexer 600, the analog-to-digital convertor 610, and the first and second programmable gain amplifiers 570, 590, 572, and 592 for both the red and the infrared channels. Additionally, the microprocessor 620 controls the intensity of the LED's 430a and 430b through the LED driver 640 in a servo loop to keep the average intensity received at the photodetector 426 within an appropriate range.

One skilled in the art will realize that the light collecting lens, or other optical elements, may be added to the chamber in any optical probe of the present invention to more efficiently direct light onto the photodetector. One skilled in the art will further realize that the location of the photodetector and the LED may be interchanged in any of the above described probes. One skilled in the art will realize that the bottom of any chamber formed in a base of an optical probe of the present invention can remain exposed, be covered by a material such as opaque tape, or be covered by a shell of base material without affecting the reduction of motion artifacts brought about by the chamber. Additionally, one skilled in the art will realize that reflective measurements could be made with the probes of the present

invention by mounting both the photodetector and LED on the base of the probe. Also, one skilled in the art will realize that a plurality of LED's or photodetectors could be mounted in the chamber or affixed to the material such that more than one signal may be measured at a time. Furthermore, one skilled in the art will realize that any material having a chamber, with a detector or an LED mounted within the chamber, will reduce the effects of motion artifacts in non-invasive absorption (or reflection) measurements, according to the present invention.

It will be understood that the probe of the present invention may be employed in any circumstance where a measurement of transmitted or reflected energy is to be made, including but not limited to measurements taken on a finger, an earlobe, a lip, or a forehead. Thus, there are numerous other embodiments which will be obvious to one skilled in the art, including but not limited to changes in the shape of the probe, changes in the materials out of which the probe is made including rigid and resilient materials, and changes in the shape, dimensions, and location of the chamber. Moreover, the chamber(s) may be coated, in whole or in part, with reflective material to help direct energy onto the detector. Furthermore, the probe of the present invention may be employed in measurements of other types of energy. Depending upon the type of energy which is most advantageously utilized in a measurement, the type of

transmitter or receiver of energy may be changed. The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope. What is claimed is:

CLAIMS

1. An energy sensor comprising:

a housing having a support surface for a material which is to be analyzed;

a chamber having an entrance in the form of an aperture positioned on said housing support surface such that said material covers said aperture and is supported by said support surface around said aperture; and

a detector located in said chamber for detecting energy which has passed through a portion of said material and enters said chamber through said aperture, said detector positioned in said chamber in a manner such that said portion of said material which covers said aperture is isolated from contact with any surface which could cause compression of said portion of said material such that said portion of said material remains substantially uncompressed.

2. The energy sensor of Claim 1, further comprising an energy source for directing energy into said material, said energy source being located generally opposite said chamber.

3. The energy sensor of Claim 1, wherein walls of said chamber are formed such that said chamber is generally cone-shaped.

4. The energy sensor of Claim 3, wherein said chamber further comprises reflective walls.

5. The energy sensor of Claim 1, further comprising:

a second housing having a support surface for said material which is to be analyzed, said second housing located adjacent said material, generally opposite said first housing;

a second chamber having an entrance in the form of a second aperture on said second housing support surface such that said material covers said second aperture and is supported by said support surface around said aperture, said light source located in said second chamber.

6. The energy sensor of Claim 1, further comprising:

a second chamber having an entrance in the form of a second aperture positioned on said housing support surface, said material covering said second aperture and being supported by said support surface around said second aperture; and

an energy source located in said second chamber for causing energy to be incident on said material through said second aperture, said energy source located in said second chamber in a manner such that said portion of said material which covers said second aperture is isolated from contact with any surface which could cause compression of said portion of said material such that

said portion of said material remains substantially uncompressed.

7. An optical sensor comprising:

a housing having a support surface for a material which is to be analyzed;

a chamber having an entrance in the form of an aperture on said housing support surface such that said material covers said aperture and is supported by said support surface around said aperture; and

a detector located in said chamber for detecting light which has passed through a portion of said material and enters said chamber through said aperture, said detector positioned in said chamber in a manner such that said portion of said material which covers said aperture is isolated from contact with any surface which could cause compression of said portion of said material, such that said portion of said material remains substantially uncompressed.

8. The optical sensor of Claim 7, further comprising a light source for directing light into said material.

9. The optical sensor of Claim 7, wherein said chamber further comprises reflective walls.

10. In an apparatus for sensing light absorption through transillumination of flesh by a light source and

reception of light by an optical detector, a sensor comprising:

a base having a support surface for supporting a portion of a body member;

a chamber having an entrance in the form of an aperture on said base support surface such that said portion of a body member covers said aperture and is supported by said support surface around said aperture; and

a detector located in said chamber for detecting light which has passed through said portion of a body member and enters said chamber through said aperture, said detector positioned in said chamber in a manner such that said portion of a body member which covers said aperture is isolated from contact with any surface which could cause compression of said portion of said body member such that said portion of said body member remains substantially uncompressed.

11. The sensor of Claim 10, further comprising a light source for directing light into said body member.

12. A probe for measurements of a signal which has been attenuated by a compressible material, comprising:

a base;

an aperture formed in said base;

a chamber extending from said aperture into said base, said chamber being placed directly adjacent the compressible material, the chamber, base, and aperture

cooperating such that a portion of the compressible material adjacent said aperture remains generally uncompressed while a portion of the compressible material surrounding said aperture is supported by said base; and

a detector positioned within said chamber in said base, said detector being disposed to receive energy which has travelled through a portion of said material.

13. The probe of Claim 12, wherein said detector is a photodetector.

14. The probe of Claim 13, further comprising a light collecting lens located within said chamber between said material and said detector.

15. The probe of Claim 12, further comprising an energy source for transmitting energy into the material.

16. The probe of Claim 15, wherein said energy source emits optical energy.

17. The probe of Claim 12, wherein said chamber further comprises:

a stabilizing segment having walls located a first distance apart, said stabilizing segment having a central axis extending generally parallel to the walls of said stabilizing segment; and

a mounting segment located proximate to said stabilizing segment having walls located a second distance

apart, said second distance being less than said first distance, said mounting segment having a second central axis extending generally parallel to the walls of said second segment, said second central axis and said first central axis being generally aligned.

18. A probe for measurements of a signal which has been attenuated by a compressible material, comprising:

a base;

an aperture formed in said base;

a chamber extending from said aperture into said base, said chamber being placed directly adjacent the compressible material, the chamber, base, and aperture cooperating such that a portion of the compressible material adjacent said aperture remains generally uncompressed while a portion of the compressible material surrounding said aperture is supported by said base; and

an energy source positioned within said chamber in said base for transmitting energy into the material.

19. The probe of Claim 18, wherein said source is a light emitting diode.

20. The probe of Claim 18, further comprising a collimating lens assembly located within said chamber between said material and said source.

21. The probe of Claim 18, further comprising a detector positioned proximate said material, said detector

being disposed to receive energy which has travelled through a portion of said material.

22. An optical probe for measuring light energy transmitted through a material, comprising:

a base which is generally semi-cylindrical having curved sidewalls, said base having a thickness;

an aperture located within said base;

a chamber extending from said aperture into said base, through a substantial portion of the thickness of said base, said material being located adjacent said aperture and chamber; and

a photodetector located within said chamber.

23. The optical probe of Claim 22, further comprising a light collecting lens located within said chamber, between said material and said photodetector.

24. The optical probe of Claim 22, further comprising a light emitting diode located opposite said base, substantially aligned with said photodetector such that a substantial portion of light energy emitted from said light emitting diode is caused to be transmitted through the material and received at the photodetector.

25. An optical probe for measuring electromagnetic energy which has been attenuated by a material, comprising:

a base having a thickness, said base being positioned

adjacent said material;

an aperture in said base, said aperture leading to a chamber which extends substantially through the thickness of said base, said aperture and chamber being wide enough that a portion of said material may intrude into the chamber, thus minimizing perturbation of the material due to compression; and

a photodetector located within said chamber, separated from said portion of said material which may have intruded into said chamber, said photodetector receiving light energy transmitted through said material.

26. The optical probe of Claim 25, further comprising a light emitting diode located opposite said chamber, said diode causing light energy to be incident on said material.

27. An optical probe for use in non-invasive physiological measurements wherein energy is absorbed by a section of a patient's body, some portion of which is easily compressible comprising:

a base having curved sidewalls to form a semi-cylindrical shape, said body portion being placed adjacent said base such that said sidewalls curve generally around the body portion;

an aperture in said base, the aperture leading to a chamber, said chamber having a stabilizing segment directly adjacent said aperture, a transitional segment directly adjacent said stabilizing segment, and a mounting

segment directly adjacent said transitional segment, said stabilizing segment being generally cylindrical and having a stabilizing segment cross-sectional diameter, said mounting segment being generally cylindrical and having a mounting segment cross-sectional diameter, said mounting segment cross-sectional diameter being smaller than said stabilizing segment cross-sectional diameter, said transitional segment having a transitional segment cross-sectional diameter of varying length, varying between said stabilizing segment diameter and said mounting segment diameter; and

a photodetector located within said mounting segment.

28. The optical probe of Claim 27, further comprising a light emitting diode located generally opposite said photodetector, mounted proximate said body portion.

29. The optical probe of Claim 27, wherein a light collecting lens is held within said transitional segment of said chamber.

30. A method for acquiring a signal comprising the steps of:

transmitting energy into a material;

locating said material adjacent an aperture formed in a base wherein said aperture leads to a chamber, such that said base, aperture, and chamber cooperate to support said material in a manner that a portion of the material

immediately adjacent and covering said aperture remains substantially unperturbed; and

receiving an attenuated signal at a detector within said chamber, said detector being recessed from said material.

31. An energy sensor comprising:

a housing having a support surface for a material which is to be analyzed;

a first chamber having an entrance in the form of a first aperture positioned on said housing support surface such that a first portion of said material covers said aperture and is supported by said support surface around said aperture;

a second chamber having an entrance in the form of a second aperture positioned on said housing support surface such that a second portion of said material covers said second aperture and is supported by said support surface around said second aperture, said second aperture being located proximate said first aperture;

an energy source for transmitting energy through said first aperture into said material, said source being located in said first chamber positioned in a manner such that said first portion of said material which covers said first aperture is isolated from contact with any surface which could cause compression of said first portion of said material such that said first portion of said material remains substantially uncompressed; and

a detector for detecting energy through said second

aperture, said energy having been reflected from said material, said detector located in said second chamber positioned in a manner such that said second portion of said material which covers said second aperture is isolated from contact with any surface which could cause compression of said second portion of said material such that said second portion of said material remains substantially uncompressed.

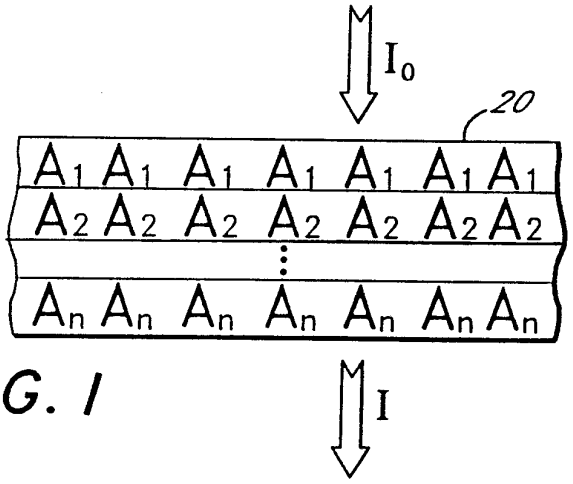


FIG. 1

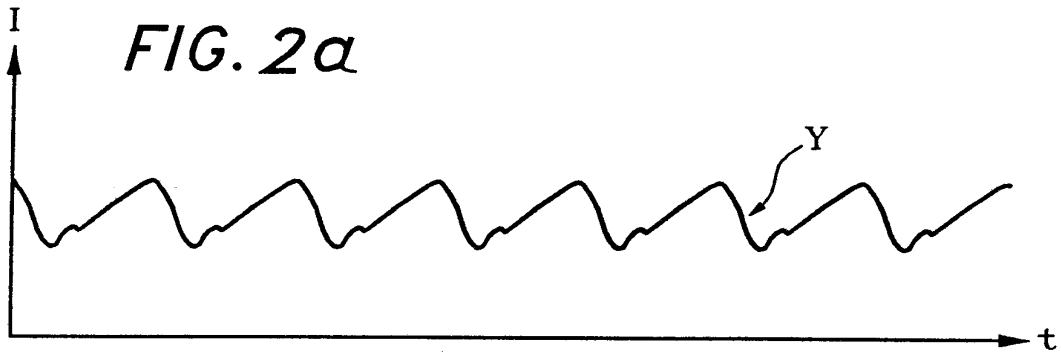


FIG. 2a

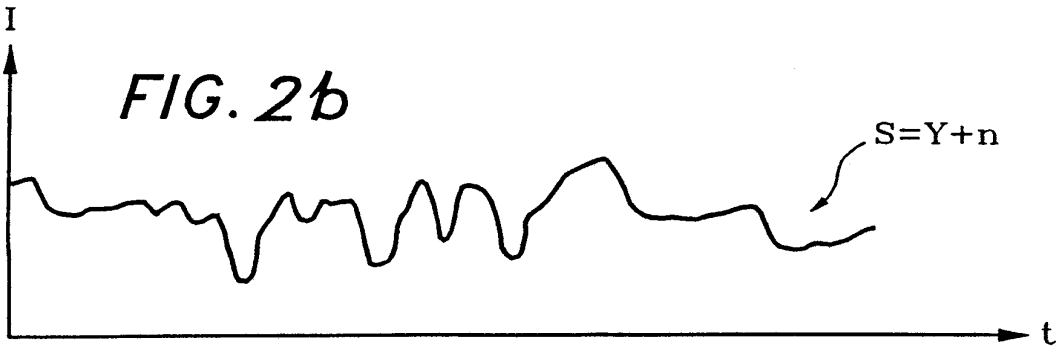


FIG. 2b

FIG. 3

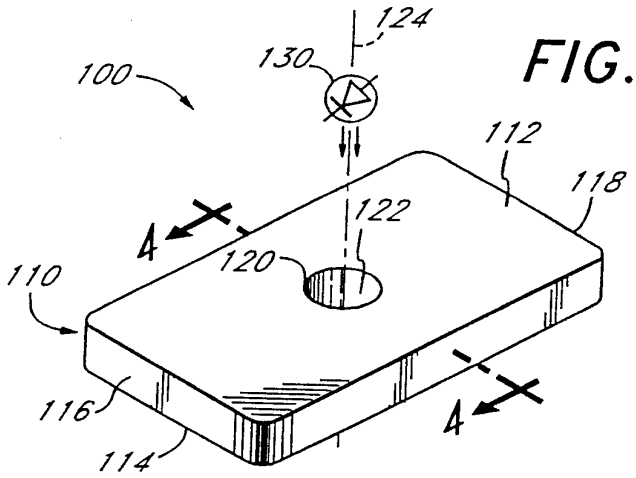


FIG. 4

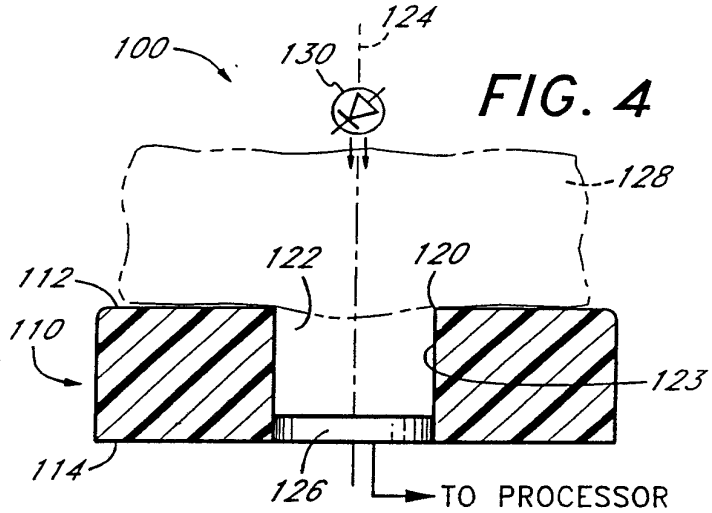
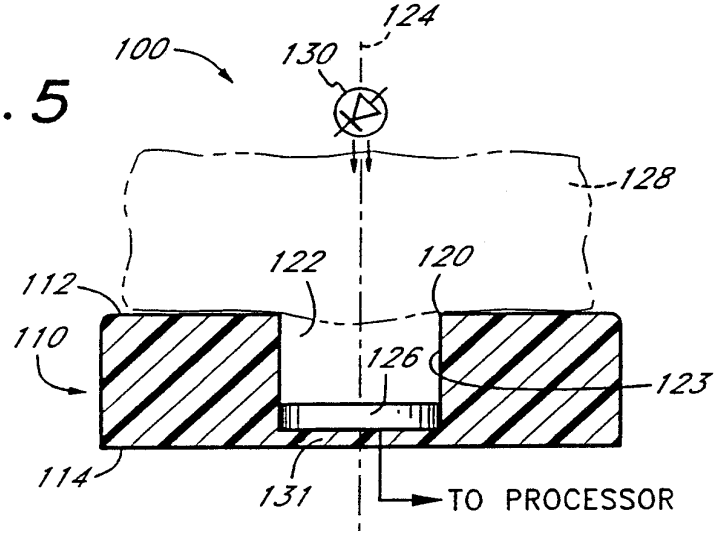


FIG. 5



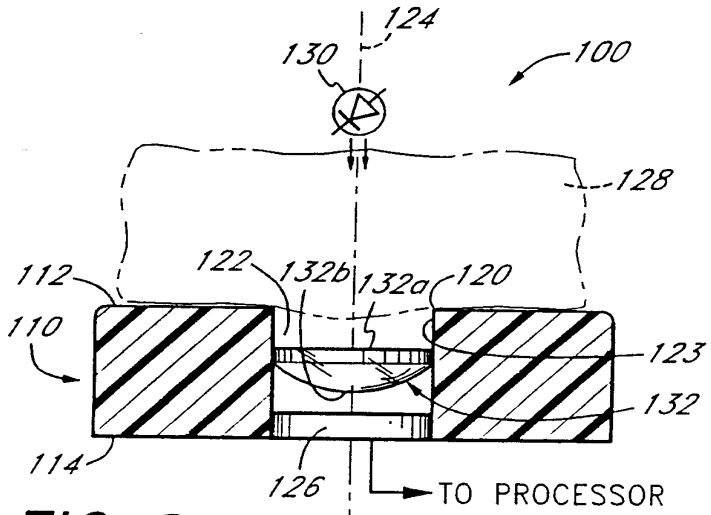


FIG. 6

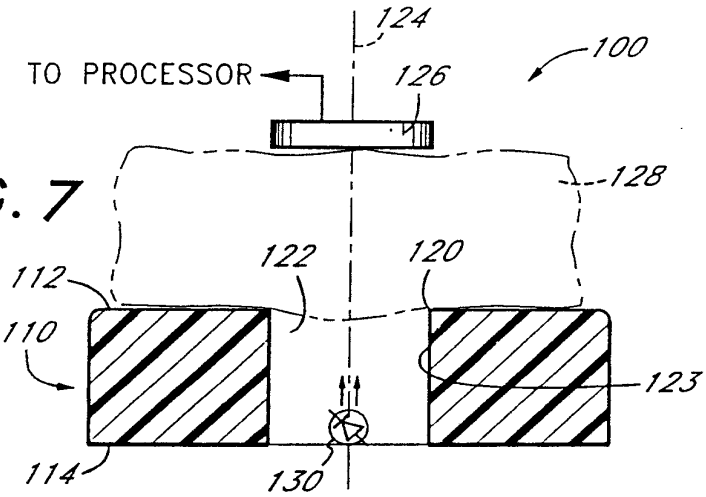


FIG. 7

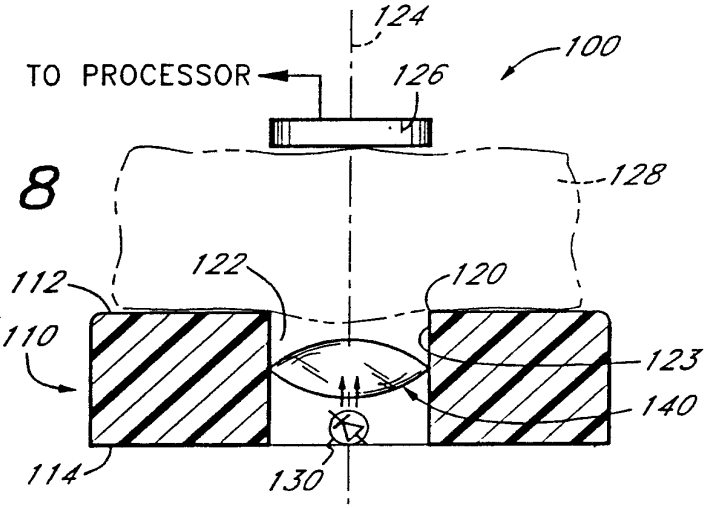


FIG. 8

FIG. 9

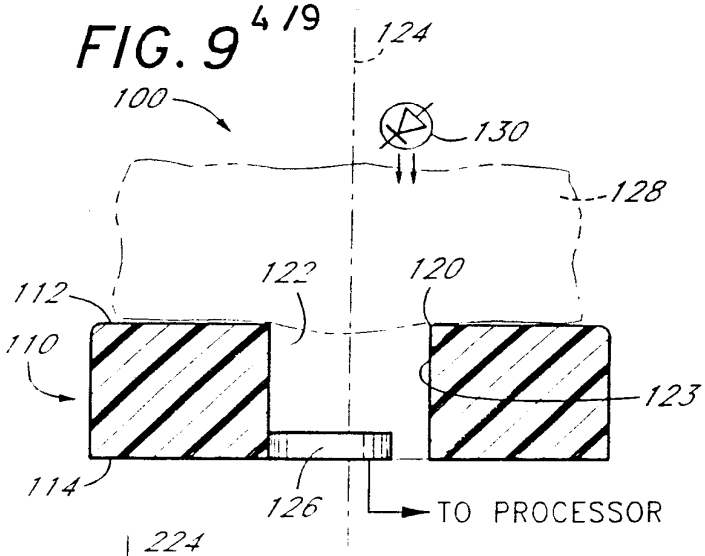


FIG. 10

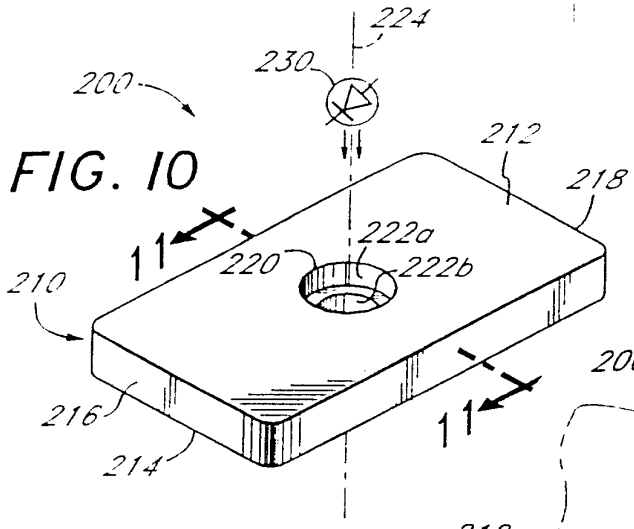


FIG. 11

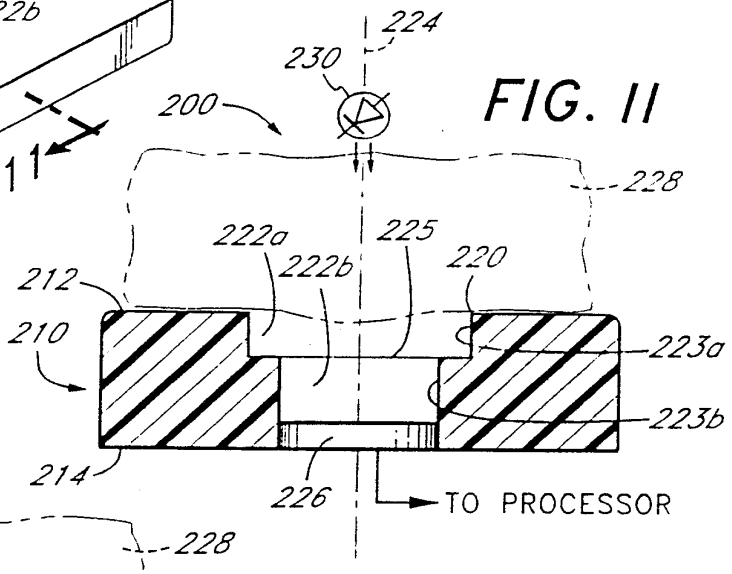


FIG. 12

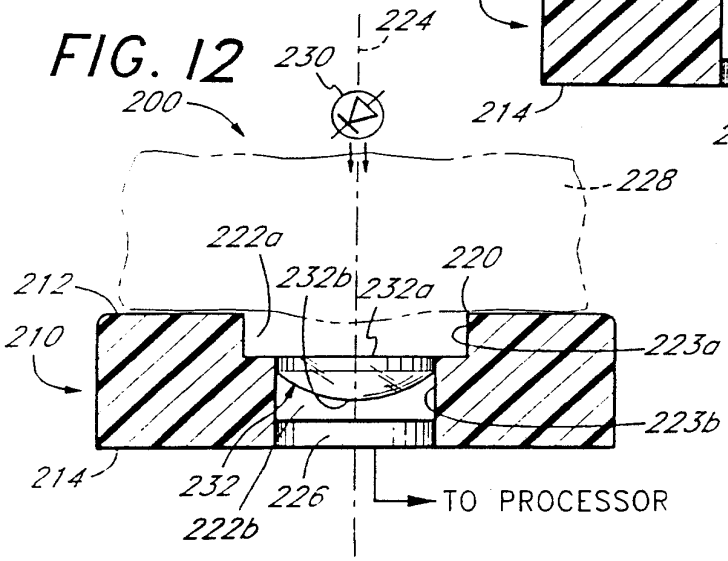


FIG. 13

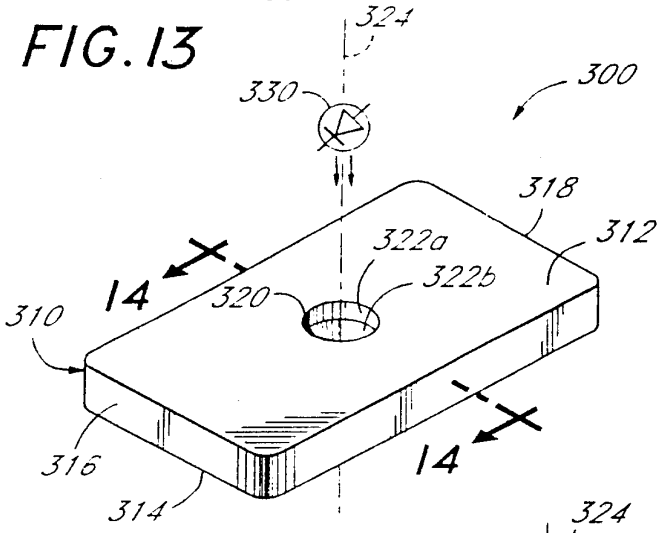


FIG. 14

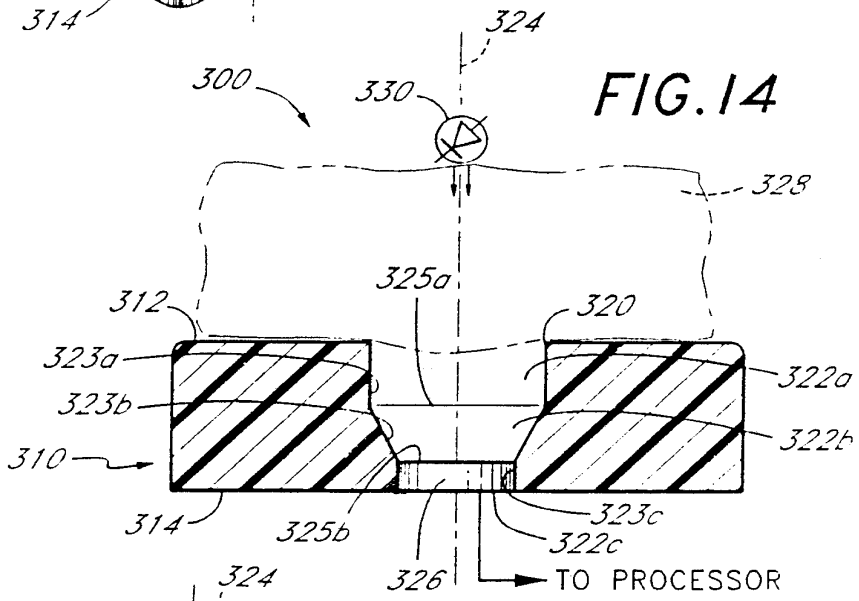


FIG. 15

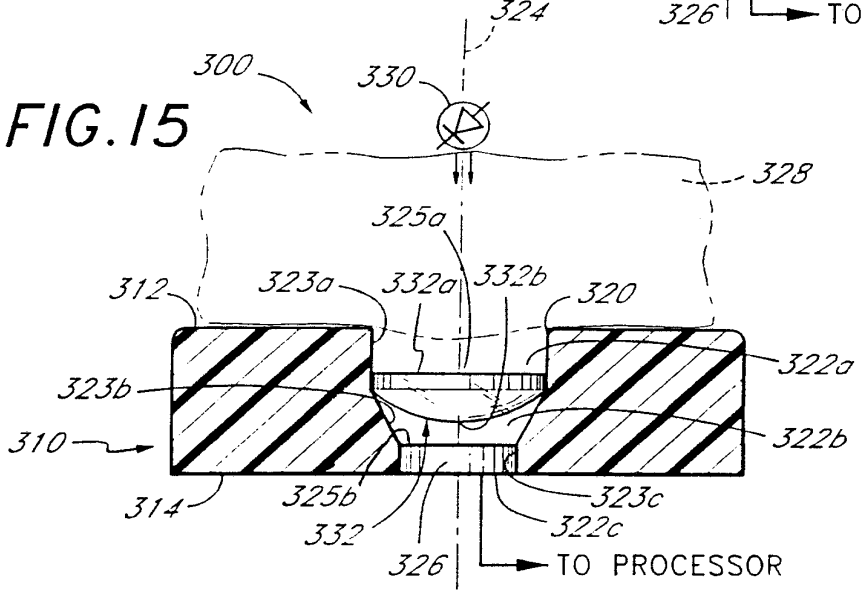
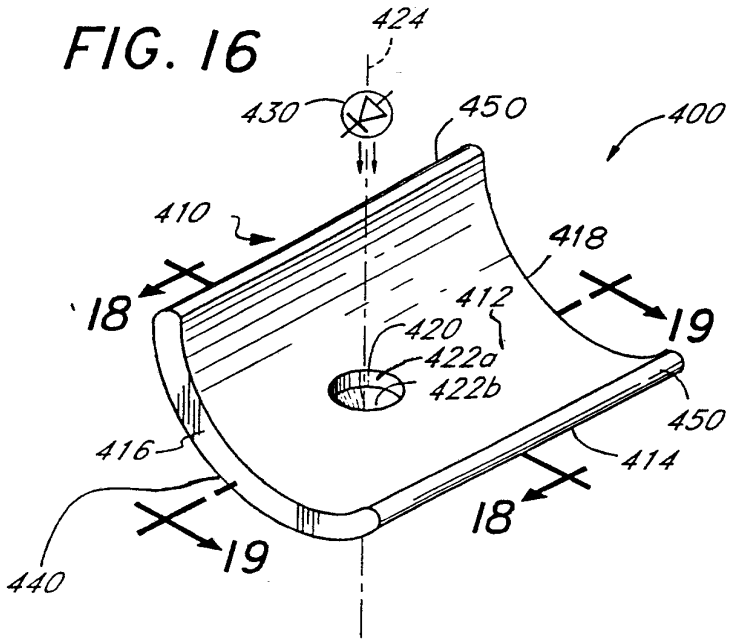


FIG. 16



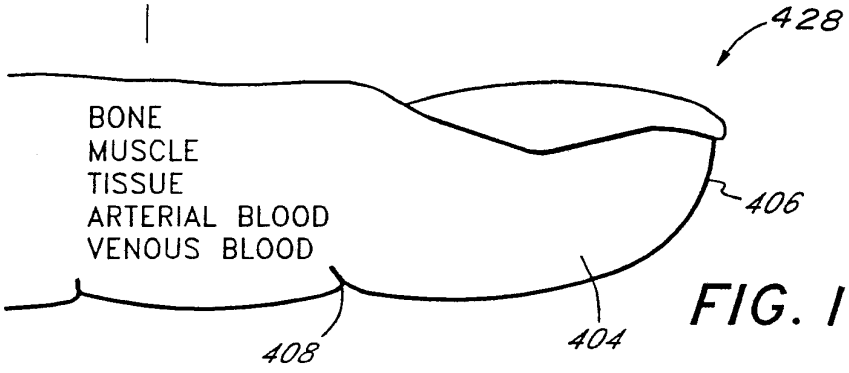


FIG. 17

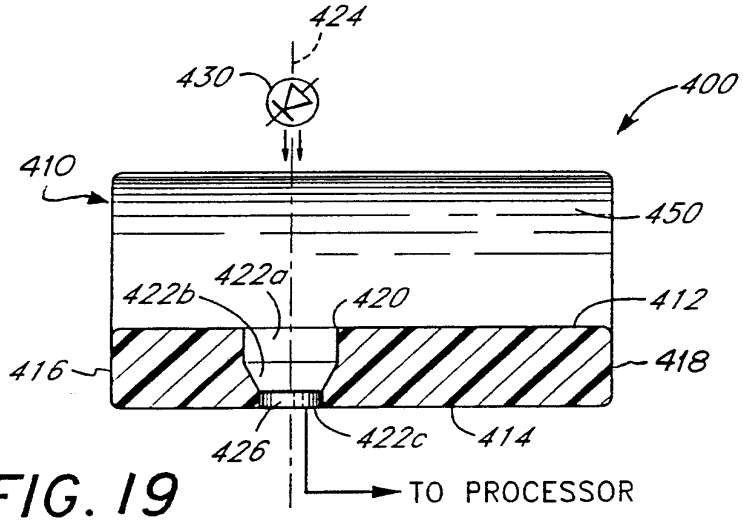


FIG. 19

FIG. 18

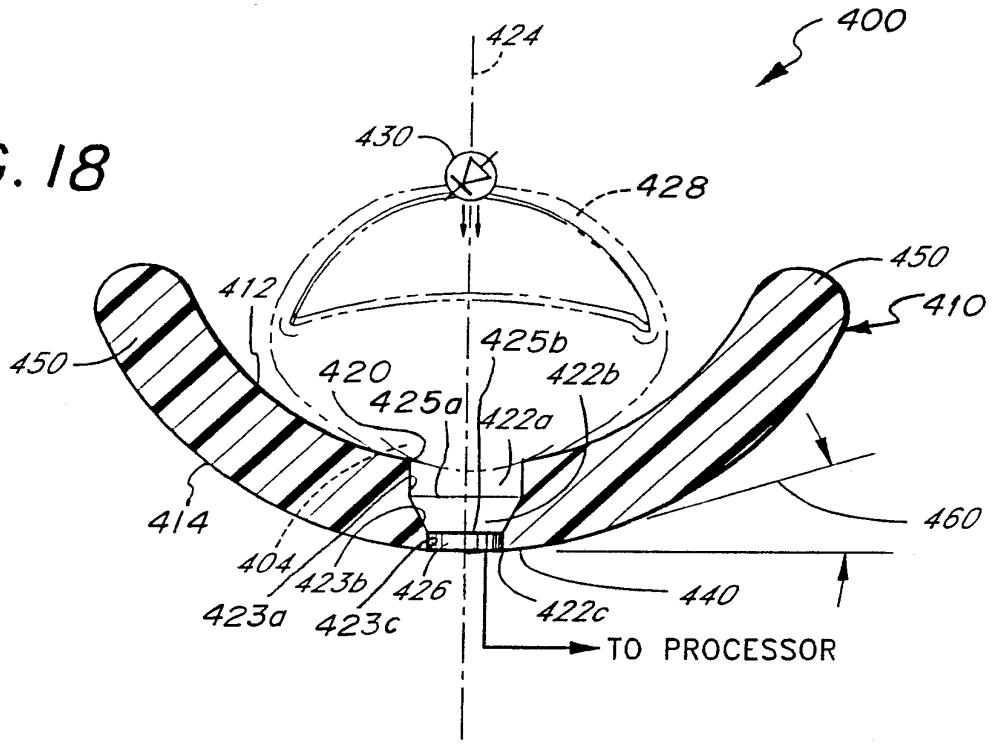
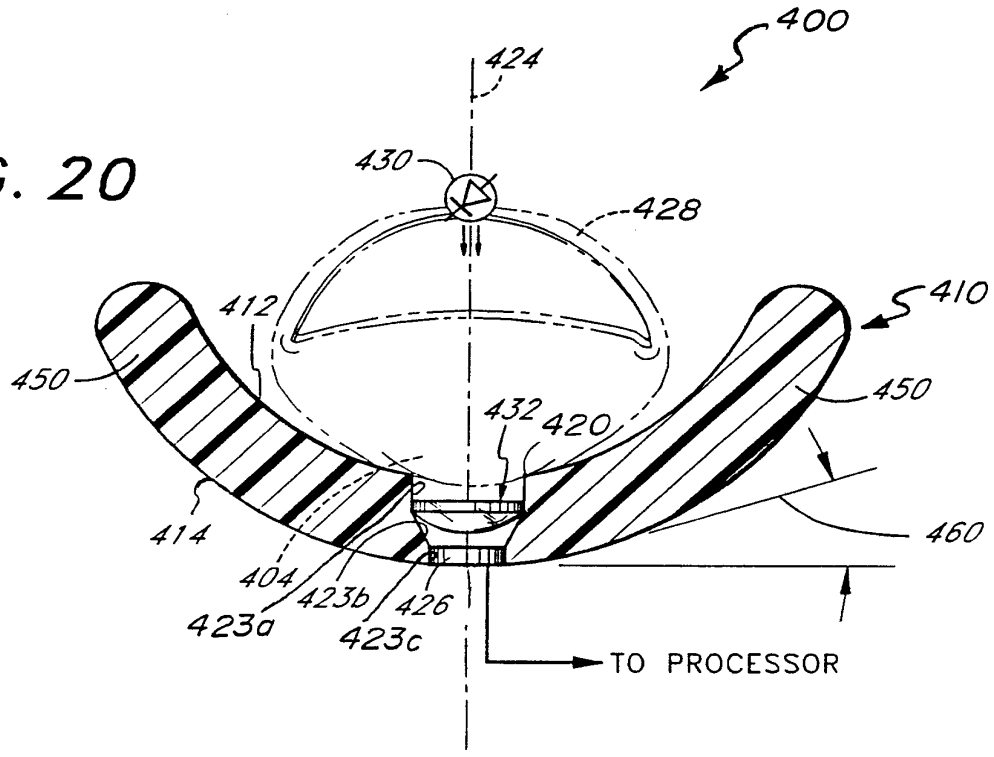

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TO PROCESSOR

FIG. 20


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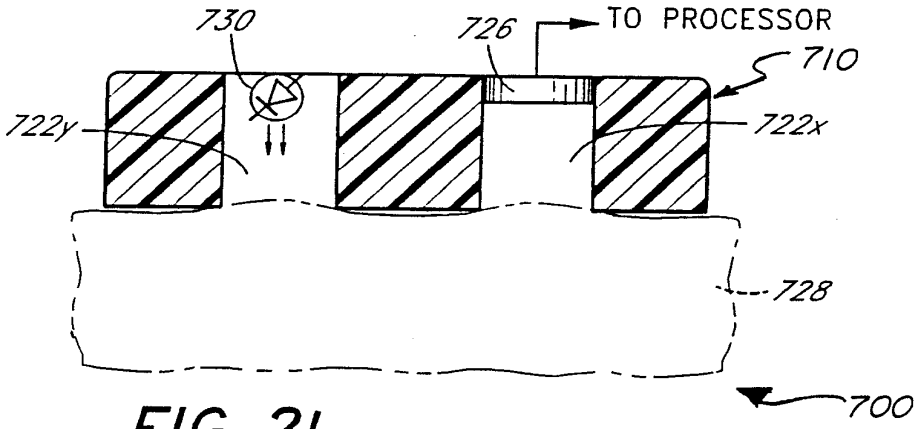


FIG. 21

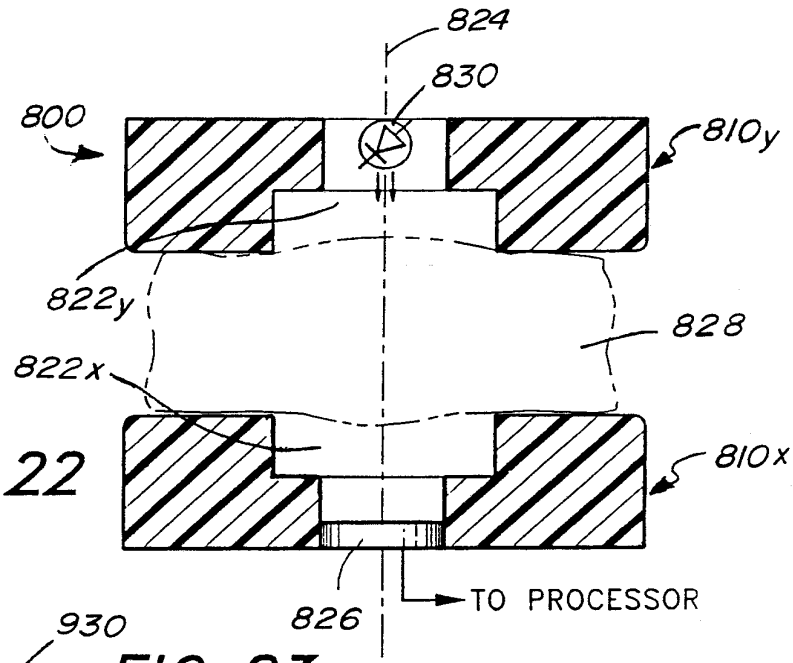


FIG. 22

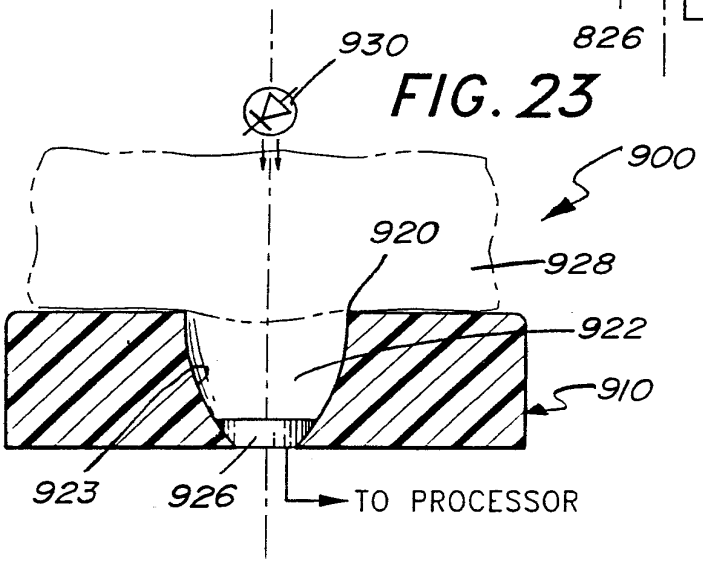


FIG. 23

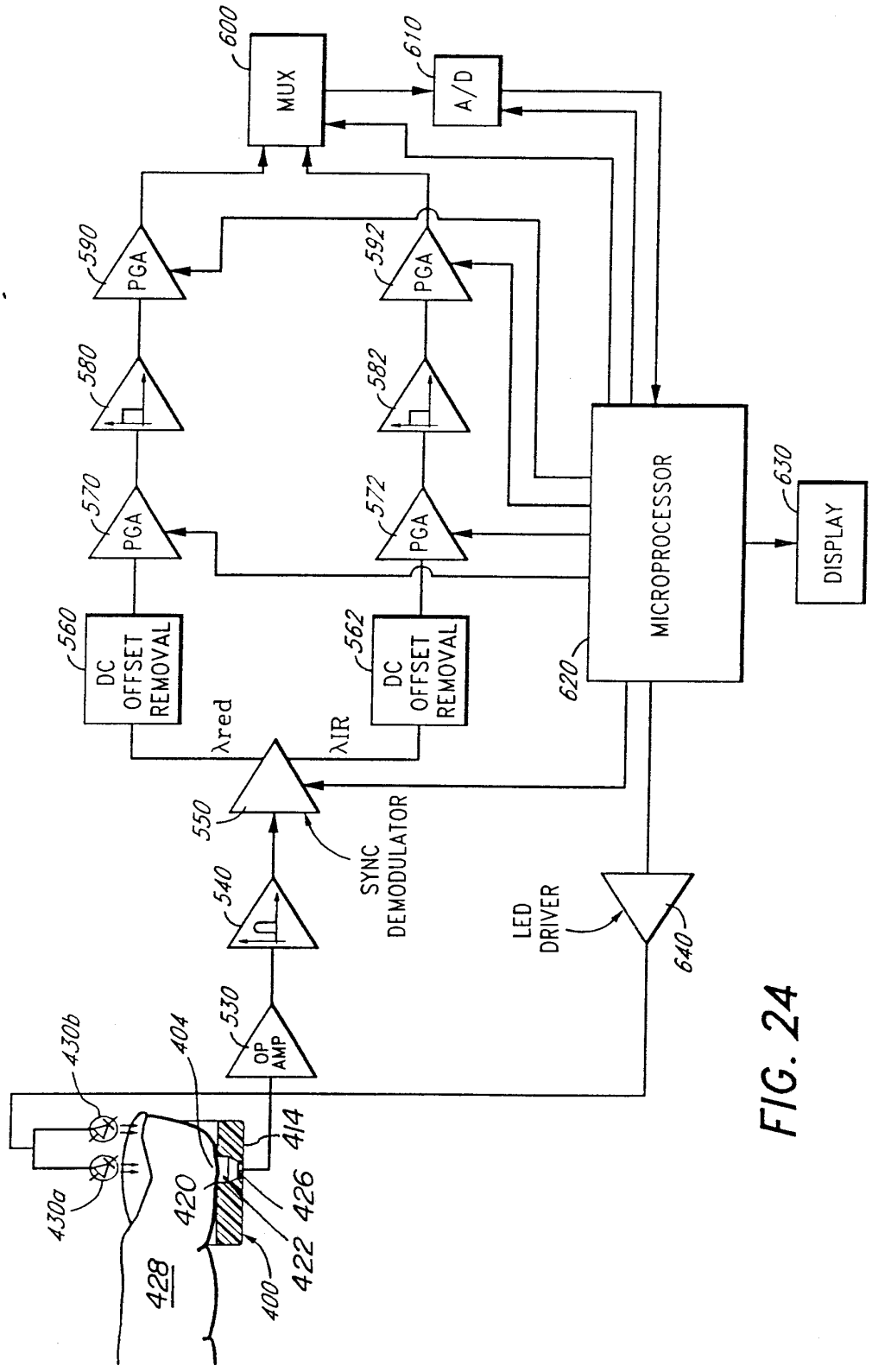

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SYNC DEMODULATOR
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LED DRIVER
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FIG. 24

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/01894

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61B 5/00 US Cl.: 128/633

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US Cl	633 665 634 666 128/664 356/41

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X Y	US,A, 4,621,643 (New Jr. et al) 11 November 1986 (See figure 3, col 5, lines 45-52.)	1,2,7-13,15, 16,25,26,30 14
X Y	US,A, 3,103,214 (Smith) 10 April 1962 (See entire document)	18,19,21 20,31
X Y	US,A, 4,334,544 ((Hill et al) 15 June 1982 (See figure 3)	1-5,7-13, 15-17, 25, 26 30 6,14,27-29,31
X Y	US,A, 4,528,986 (Arundel et al) 16 July 1985 (See entire document)	18,19 20,21
X Y	US,A, 4,685,464 (Goldberger et al) 11 August 1987 (See entire document)	22,24 23, 27-29
Y, P	US,A, 5,086,229 (Rosenthal et al) 4 February 1992 (See figure 2A)	14, 20,23,29
Y	US,A, 4,380,240 (Jobsis et al) 19 April 1983 (See entire document)	6

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
28 June 1992	17 JUL 1992
International Searching Authority	Signature of Authorized Officer
ISA/US	NGUYEN NGOC-HO INTERNATIONAL DIVISION Robert L. Nasser Jr.

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(21) International Application Number: PCT/US95/14785

(22) International Filing Date: 1 November 1995 (01.11.95)

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08/333,132 1 November 1994 (01.11.94) US

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(74) Agent: ALTMAN, Daniel, E.; Knobbe, Martens, Olson & Bear, Suite 1600, 620 Newport Center Drive, Newport Beach, CA 92660 (US).

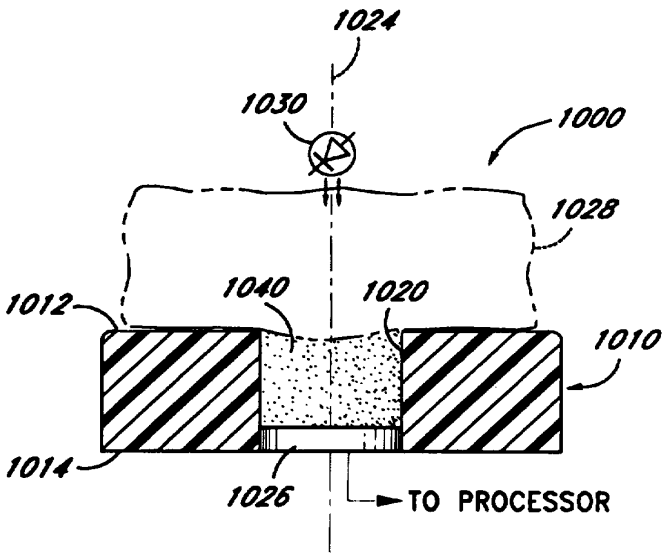
(81) Designated States: AL, AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, LS, MW, SD, SZ, UG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: LOW NOISE OPTICAL PROBE

(57) Abstract

An optical probe for measurements, 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. The probe includes a base having an aperture which leads to a chamber. The base is placed adjacent a portion of the material, the chamber being placed directly adjacent any easily compressible portion of the material. A photodetector is located within the chamber and does not contact the material. A light emitting diode (LED) is affixed to the material, opposite the photodetector and above the chamber. The material which is supported by the aperture and therefore rests above or has intruded into the chamber is inhibited from compression since nothing comes in contact with this portion of the material, even when the material moves. Thus, light from the LED is directly through a stabilized portion of the material, i.e., the optical path length through which light travels is stabilized, even during motion of the material. This reduces noise in the signal measured by the photodetector. A scattering medium is interposed between the LED and the material, between the material and the photodetector, or between the LED and the material as well as between the material and the photodetector. The scattering medium is used to improve the signal-to-noise ratio of the received optical signal.



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LOW NOISE OPTICAL PROBE

Background of the Invention

Field of the Invention

The present invention relates to the sensing of energy. More specifically, the present invention relates to the reduction of noise in signals via an improved sensing mechanism.

Description of the Related Art

Energy is often transmitted through or reflected from a medium to determine characteristics of the medium. For example, in the medical field, instead of extracting material from a patient's body for testing, light or sound energy may be caused to be incident on the patient's body and transmitted (or reflected) energy may be measured to determine information about the material through which the light has passed. This type of non-invasive measurement is more comfortable for the patient and can be performed more quickly.

Non-invasive physiological monitoring of bodily function is often required. For example, during surgery, blood pressure and the body's available supply of oxygen, or the blood oxygen saturation, are often monitored. Measurements such as these are often performed with non-invasive techniques where assessments are made by measuring the ratio of incident to transmitted (or reflected) light through a portion of the body, for example a digit such as a finger, or an earlobe, or a forehead.

Transmission of optical energy as it passes through the body is strongly dependent on the thickness of the material through which the light passes, or the optical path length. Many portions of a patient's body are typically soft and compressible. For example, a finger comprises skin, muscle, tissue, bone, blood, etc. Although the bone is relatively incompressible, the tissue, muscle, etc. are easily compressible with pressure applied to the finger, as often occurs when the finger moves. Thus, if optical energy is made incident on a finger and the patient moves in a manner which distorts or compresses the finger, the optical path length changes. Since a patient generally moves in an erratic fashion, the compression of the finger is erratic. This causes the change in optical path length to be erratic, making the absorbtion erratic, resulting in a difficult to interpret measured signal.

Many types of non-invasive monitoring devices have been developed to try to produce a clear and discernable signal as energy is transmitted through a medium, such as a finger or other part of the body. In typical optical probes a light emitting diode (LED) is placed on one side of the medium while a photodetector is placed on an opposite side of the medium. Many prior art optical probes are designed for use only when a patient is relatively motionless since, as discussed above, motion induced noise can grossly corrupt the measured signal. Typically, probes are designed to maximize contact between the LED and the medium and the photodetector and the medium to promote strong optical coupling between the LED, the medium, and the photodetector, thereby generating a strong output signal intensity. In this way, a strong, clear signal can be transmitted through the medium when the patient is generally motionless.

For example, U.S. Patent No. 4,880,304 to Jaeb, et al. discloses an optical probe for a pulse oximeter, or blood oxygen saturation monitor, comprising a housing with a flat lower face containing a central protrusion in which

a plurality of light emitting diodes (LEDs) and an optical detector are mounted. When the probe is placed on the patient's tissue, the protrusion causes the LEDs and the detector to press against the tissue to provide improved optical coupling of the sensor to the skin. In another embodiment (Figures 4a and 4b in the Jaeb patent), the LEDs and the detector are arranged within a central chamber, generally horizontal with respect to the tissue on which the probe is placed. A set of mirrors or prisms causes light to be directed from the LEDs onto the tissue through a polymer sealant within the chamber, the sealant providing a contact with the tissue for good optical coupling with the tissue.

U.S. Patent No. 4,825,879 to Tan, et al. discloses an optical probe wherein a T-shaped wrap, having a vertical stem and a horizontal cross bar, is utilized to secure a light source and an optical sensor in optical contact with a finger. The light source is located in a window on one side of the vertical stem while the sensor is located in a window on the other side of the vertical stem. The finger is aligned with the stem and the stem is bent such that the light source and the sensor lie on opposite sides of the finger. Then, the cross bar is wrapped around the finger to secure the wrap, thereby ensuring that the light source and the sensor remain in contact with the finger to produce good optical coupling.

U.S. Patent No. 4,380,240 to Jõbsis, et al. discloses an optical probe wherein a light source and a light detector are incorporated into channels within a slightly deformable mounting structure which is adhered to a strap. Annular adhesive tapes are placed over the source and the detector. The light source and detector are firmly engaged with a bodily surface by the adhesive tapes and pressure induced by closing the strap around a portion of the body. An alternative embodiment provides a pressurized seal and a pumping mechanism to cause the body to be sucked into contact with the light source and detector.

U.S. Patent No. 4,865,038 to Rich, et al. discloses an optical probe having an extremely thin cross section such that it is flexible. A die LED and a die photodetector are located on a flexible printed circuit board and encapsulated by an epoxy bead. A spacer, having circular apertures positioned in alignment with the LED and photodetector, is placed over the exposed circuit board. A transparent top cover is placed over the spacer and is sealed with a bottom cover placed under the circuit board, thereby sealing the probe from contaminants. A spine may be added to strengthen the device. The flexibility of the device allows it to be pinched onto the body causing the epoxy beads over the LED and the photodetector to protrude through the apertures in the spacer and press against the top cover such that good optical contact is made with the body.

U.S. Patent No. 4,907,594 to Muz discloses an optical probe wherein a dual wall rubberized sheath is fit over a finger. A pump is located at the tip of the finger such that a pressurized chamber may be formed between the two walls, thereby causing an LED and a photodetector located in the inner wall to be in contact with the finger.

Each of the above described optical probes is designed to cause a strong measured signal at the photodetector by optimizing contact between the LED, the patient, and the probe. However, this optimization forces compressible portions of the patient's body to be in contact with surfaces which compress these portions of the patient's body when the patient moves. This can cause extreme changes in the thickness of material through which optical energy passes, i.e., changes in the optical path length and changes due to scattering as a result of venous

blood movement during motion. Changes in the optical path length can produce enough distortion in the measured signal to make it difficult or impossible to determine desired information. Thus, a need exists for a probe which inhibits motion induced noise, or motion artifacts, during measurement of a signal while still generating a transmitted or reflected signal of sufficient intensity to be measured by a detector.

Summary of the Invention

The present invention involves a probe for use in both invasive and non-invasive energy absorption (or reflection) measurements. A base is formed in a shape generally corresponding to the material on which measurements are to be made, for example, a section of a patient's body such as a finger, an earlobe, a forehead, a toe, an organ, or a portion of tissue. The base has a forward end, a rear end, a top and a bottom. An aperture is formed in the top of the base. The aperture is the entrance to a chamber. A detector, such as a photodetector, is mounted within the chamber, typically in the bottom of the chamber. The material on which measurements are to be made is placed on the base such that any compressible portion of the material is located directly adjacent the chamber. Thus, the compressible portion of the material is caused to rest above or enter into the chamber. The chamber is deep enough that any material which intrudes into the chamber does not contact anything which might cause compression.

A light source, such as an LED, is affixed to the material, opposite the photodetector. The LED emits light energy which propagates through and is absorbed by the material along the optical path length, or thickness of material through which light propagates. An attenuated light energy signal emerges from the material, into the chamber. As light propagates through the material, it is scattered by the material and is thus transmitted into the chamber over a broad range of angles. The photodetector produces an electrical signal indicative of the intensity of the signal transmitted by the material. The electrical signal is input to a processor which analyzes the signal to determine information about the medium through which light energy has been transmitted.

The probe of the present invention has an aperture and chamber which enable an easily compressible portion of the material that light energy passes through to rest in the chamber and not be compressed. This results in less disturbance of the optical path between the light source and the detector. Since the LED is generally aligned with the chamber and the photodetector, the light energy signal propagates through the portion of the material which rests above or is accommodated within the chamber. The chamber allows the compressible portion of the material to remain substantially uncompressed, even during motion, since nothing within the chamber physically contacts the material through which light energy passes to cause compression. Thus, the thickness of the material, or the optical path length, is stabilized, and the movement of venous blood during motion is minimized, thereby improving the signal-to-noise ratio of the measured signal. Thus, the probe of the present invention produces a strong, clear signal wherein noise due to motion, or motion artifacts, is substantially reduced.

In one preferred embodiment of the present invention, the chamber is filled with a scattering medium. The scattering medium is advantageously formed of a conformable plastic or a highly compressible material so that the material on which measurements are to be made is not compressed upon contact with the scattering medium. The scattering medium helps to minimize the effects of local artifacts and perturbations within the material. Thus, an

increased optical signal-to-noise ratio is observed. The scattering medium also improves the optical coupling with the material.

In another preferred embodiment, the scattering medium is interposed between the light source and the material, and in yet another preferred embodiment, the scattering medium is interposed between the light source and the material as well as between the material and the photodetector. Each of these embodiments results in an improved optical signal-to-noise ratio.

In yet another preferred embodiment, an immersion lens is utilized in combination with the light source and/or the photodetector. In a particularly preferred embodiment, the immersion lens is formed by placing an epoxy bump forming a partial sphere over semiconductor diodes used as the light source and/or the photodetector to improve the signal-to-noise ratio.

Brief Description of the Drawings

Figure 1 illustrates a schematic medium comprising N different constituents.

Figure 2a illustrates an ideal plethysmographic signal that would be measured by the optical probe of the present invention when utilized for pulse oximetry.

Figure 2b illustrates a realistic signal measured by the optical probe of the present invention when utilized for pulse oximetry.

Figure 3 is a perspective view of a probe of the present invention having a single segment chamber.

Figure 4 is a cross-sectional view of an optical probe of the present invention illustrating a single segment chamber having a detector within it.

Figure 5 is a cross-sectional view of a probe of the present invention having a detector resting on a shell of base material.

Figure 6 is a cross-sectional view of a probe of the present invention incorporating a light collecting lens.

Figure 7 is a cross-sectional view of a probe of the present invention illustrating a single segment chamber having an LED within it.

Figure 8 is a cross-sectional view of a probe of the present invention incorporating a collimating lens assembly.

Figure 9 is a cross-section view of a probe of the present invention wherein the LED and the detector are not aligned along the central axis of the chamber.

Figure 10 is a perspective view of another embodiment of a probe of the present invention having a two segment chamber.

Figure 11 is a cross-sectional view of another embodiment of the probe of Figure 10 incorporating a two segment chamber having a detector within it.

Figure 12 is a cross-sectional view of another embodiment of the probe of Figure 10 incorporating a light collecting lens in a two segment chamber.

Figure 13 is a perspective view of probe of the present invention having a three segment chamber.

Figure 14 is a cross-sectional view of the probe of Figure 13 incorporating a three segment chamber having a detector within it.

Figure 15 is a cross-sectional view of another embodiment of the probe of Figure 13 incorporating a light collimating lens.

Figure 16 is a perspective view of a probe of the present invention specifically designed to be used with a digit.

Figure 17 illustrates a schematic finger comprising fingernail, skin, bone, tissue, muscle, blood, etc.

Figure 18 is a cross-section view of the probe of Figure 16.

Figure 19 is a longitudinal cross-sectional view of the probe of Figure 16.

Figure 20 is a cross-sectional view of another embodiment of the probe of Figure 16 incorporating a light collecting lens.

Figure 21 is a cross-sectional view of a probe of the present invention designed to be utilized for reflectance measurements.

Figure 22 is a cross-sectional view of a probe which is advantageously used for non-invasive measurements when a material is compressible on more than one side. The probe has two bases, each with a chamber to house a detector or an energy source and thereby reduce motion artifacts.

Figure 23 is a cross-sectional view of a probe having a generally cone-shaped chamber with a reflective surface which advantageously causes energy to be concentrated, or "funneled," onto the surface of a detector within the chamber, improving the measured signal.

Figure 24 is a schematic of one system which may advantageously employ a probe of the present invention.

Figure 25 is a cross-sectional view of a probe wherein the aperture is filled with a compressible scattering medium.

Figure 26 is a cross-sectional view of a probe wherein the LED is spaced from the material to be measured by a transmission assembly having a scattering medium interposed between the LED and the material.

Figure 27 is a cross-sectional view of a probe wherein a scattering medium is interposed between the LED and the material as well as between the material and the photodetector.

Figure 28 is a cross-sectional view of a preferred embodiment of a probe in accordance with the present invention having an immersion lens for the photodetector and for the LED and having scattering medium interposed between the LED and the test material as well as between the test material and the photodetector.

Detailed Description of the Invention

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 unnecessary 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.

The amplitude of the measured signal is highly dependent on the thickness of the material through which the energy passes, or the optical path length, as well as other properties such as the erratic movement of venous blood during motion. A schematic medium 20 comprising N different constituents A_1 through A_N is shown in Figure 1. Energy transmitted through the medium 20 is approximately attenuated according to the equation:

$$I \propto I_0 e^{-\Sigma_{i=1}^{N} \epsilon_i c_i x_i} \qquad (1)$$

where ϵ_i is the absorption coefficient of the ith constituent; x_i is the thickness of the ith constituent through which light energy passes, or the optical path length of the ith; and c_i is the concentration of the ith constituent in thickness x_i.

Since energy absorption is strongly dependent on the thicknesses of the constituents A_1 through A_N which make up the medium 20 through which the energy passes, when the thickness of the medium 20 changes, due to motion for example, the thicknesses of the individual constituents A_1 through A_N change. This causes the absorption characteristics of the medium 20 to change.

Often a medium 20 is under random or erratic motion. For example, if the medium 20 is an easily compressible portion of a patient's body, such as a digit, and the patient moves, the medium 20 compresses erratically causing the individual thicknesses X_1 through X_N of the constituents A_1 through A_N to vary erratically. This erratic variation may cause large excursions in the measured signal and can make it extremely difficult to discern a desired signal, as would be present without motion induced noise, or motion artifacts.

For example, Figure 2a illustrates an ideal desired signal waveform, labelled Y, measured in one application of the present invention, namely pulse oximetry. Figure 2b illustrates a more realistic measured waveform S, also measured in a pulse oximetry application, comprising the ideal desired signal waveform Y plus motion induced noise, n, i.e. S=Y+n. It is easily seen how motion artifacts obscure the desired signal portion Y.

Figure 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. Figure 4 shows a cross-sectional view of the optical probe 100 of the present invention taken along line 4-4 in Figure 3. For clarity in the perspective view of Figure 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 Figure 4. As illustrated in Figures 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 Figure 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 is 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 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.

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 Figure 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.

Figure 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.

Figure 7 shows another embodiment of the probe 100 of the present invention wherein the positions of the photodetector 126 and the LED 130 are interchanged. The LED 130 is placed within the chamber 122, typically at the bottom 114 of the chamber 122, generally aligned with the central axis 124 of the chamber 122. The LED 130 may be fixed within the chamber 122 according to a number of different methods, including but not limited to a press fit, adhesive, or clear epoxy resin which transmits light over a range of wavelengths of interest, such as around the wavelength which the LED emits. Again, a material 128 is placed on the base 110 having a compressible portion of the material 128 located directly above the chamber 122. The photodetector 126 is attached to the

material 128, opposite the LED 130, such that the LED 130, the photodetector 126, and the chamber 122 are aligned along the central axis 124 of the chamber 122. The photodetector 126 is typically attached by an opaque material. For example, the photodetector 126 may be attached to the material 128 with opaque tape, thereby limiting signal degradation caused by ambient light. The photodetector 126 is, again, electrically connected to a processor.

The probe 100 of this embodiment functions substantially identically to the embodiment of the probe 100 having the photodetector 126 housed in the chamber 122. The chamber 122 stabilizes the optical path length by allowing easily compressible portions of the material 128 to rest above or intrude into the chamber 122, thereby stabilizing the optical path length and substantially reducing motion artifacts. This is true regardless of whether the photodetector 126 or the LED 130 is housed within the chamber 122.

Figure 8 shows a cross-sectional view of another embodiment of the probe 100 of the present invention wherein the LED 130 is located within the chamber 122. A collimating lens assembly 140 is placed within the chamber 122, between the material 128 which rests above or enters into the chamber 122 and the LED 130. Collimating lens assemblies 140 are well known in the art and, thus, the lens assembly 140 is represented schematically in the Figure 8. The collimating lens assembly 140 is located deep enough within the chamber 122 that any material 128 which intrudes into the chamber 122 does not contact the lens assembly 140. The lens assembly 140 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 collimating lens assembly 140 causes light from the LED 130 to be focused on the material 128 above the chamber 122, thus providing a less scattered signal transmitted onto the photodetector 126 surface, thereby utilizing the photodetector 126 more effectively.

Figure 9 shows another embodiment of the probe 100 of the present invention wherein the LED 130 and the photodetector 126 are not aligned along the central axis 124 of the chamber 122. Light is scattered within the material 128, causing at least a portion of the light emitted by the LED 130 to reach the photodetector 126 for measurement. As long as light emitted by the LED 130 and scattered by the material 128 reaches the photodetector 126 with great enough intensity to be measured, the LED 130 and the photodetector 126 need not be aligned. While alignment of the LED 130 and the photodetector 126 along the same axis causes the light emitted by the LED 130 to reach the photodetector 126 more directly, it is not necessary for operation of the probe of the present invention. In some applications, misalignment may even be advantageous. It will be understood that this is true for any embodiment of the probe of the present invention. Additionally, it will be understood that a photodetector 126 which fills the width of the chamber 122 is advantageous in that more of the light directed into the chamber 122 will be incident on the surface of the photodetector 126, resulting in a stronger measured signal. However, any size photodetector 126 which acquires enough energy to produce an adequately strong measured signal is acceptable. It will be understood that this is true for any embodiment of the probe of the present invention.

A perspective view of another embodiment of a probe 200 of the present invention comprising a multi-segment chamber 222 is shown is Figure 10. Figure 11 shows a cross-sectional view of the probe 200 of the

present invention taken along line 11-11 in Figure 10. For clarity in the perspective view of Figure 10, a material 228 on which measurements are to be taken is not shown placed adjacent the probe 200. However, the material 228 is shown adjacent the probe 200 in Figure 11.

As illustrated in Figures 10 and 11, a base 210, having a top 212, a bottom 214, a forward end 216, and a rear end 218, is made of a material which is preferably rigid and opaque. It will be understood, however, that the probe 200 may be made of materials which may be rigid, resilient, opaque, or transparent, for example. An aperture 220 of any shape is formed in the base 210, similar to the aperture 120 described above in conjunction with the probe 100 of Figures 3 through 9. The aperture 220 forms the opening to a stabilizing segment 222a of the multiple segment chamber 222. A lateral cross-section (not shown) of the stabilizing segment 222a of the chamber 222 is typically the same shape as the aperture 220. Walls 223a of the stabilizing segment 222a are generally perpendicular to the aperture 220. A central axis 224 of the chamber 222 is defined by a line aligned generally perpendicular to the aperture 220 and extending generally through a central portion of the aperture 220 and the chamber 222.

A mounting segment 222b is located directly adjacent and below the stabilizing segment 222b, connected to the stabilizing segment 222b by a border 225. The mounting segment 222b shares the central axis 224 of the stabilizing segment 222a and is typically of smaller width. Walls 223b of the mounting segment 222b are generally parallel to the central axis 224. The mounting segment 222b may extend through the bottom 214 of the base 210, as shown in Figure 11, or the mounting segment 222b may extend to just above the bottom 214 of the base 210, leaving a shell (not shown) of base 210 material at the bottom 214 of the chamber 222.

A photodetector 226 is placed in the mounting segment 222b of the chamber 222, typically at the bottom 214 of the mounting segment 222b, having a central portion of the photodetector 226 generally aligned with the central axis 224 of the chamber 222. The mounting segment 222b of the chamber 222 is deep enough that the photodetector 226 does not penetrate into the stabilizing segment 222 of the chamber 222. The photodetector 226 may be fixed within the chamber 222 according to a number of different methods, including but not limited to adhesive, a press fit, or a clear epoxy resin which transmits light over a range of wavelengths of interest. In this embodiment, the bottom 214 of the chamber 222 is made opaque via paint or tape, for example, or by leaving a shell (not shown) of base 210 material at the bottom 214 of the chamber 222 when the chamber 222 is formed. The photodetector 226 is electrically connected to a processor, similarly to the photodetector 126 in the previous embodiment of the probe 100 of the present invention.

An energy absorbing material 228 (the material under test) is placed over the base 210 as shown in the cross section of Figure 11. A portion of the material 228 may rest above the chamber 222. Additionally, the stabilizing segment 222a of the chamber 222 is wide enough that any easily compressible portion of the material 228 may intrude into the stabilizing segment 222a of the chamber 222. The stabilizing segment 222a of the chamber 222 is deep enough that the portion of the material 228 which enters into the stabilizing segment 222a does not contact matter within the stabilizing segment 222a which might cause compression, even when the material 228 is caused to move.

A light emitting diode (LED) 230 is affixed adjacent to the material 228, opposite the aperture 220. The LED 230 is advantageously aligned along the central axis 224 to optimize the amount of light incident directly through the material 228 onto the photodetector 226. However, it will be understood that the positions of the photodetector 226 and the LED 230 could be interchanged as discussed in conjunction with Figure 7. Additionally, a collimating lens assembly (not shown) could be added to the chamber 222 as discussed in conjunction with Figure 8. The collimating lens assembly may be held in the chamber 222 similarly to a light collecting lens 232 discussed below. Further, it will be understood that the LED 230 and the photodetector 226 could be unaligned, as discussed in conjunction with Figure 9.

As light from the LED 230 propagates through the material 228, it is scattered by the material 228 and is thus transmitted into the chamber 222 over a broad range of angles. Thus, some of the light is caused to be incident on the opaque walls 223a and 223b of the chamber 222 and is absorbed. However, the advantageous alignment of the photodetector 226 and the LED 230 along the central axis 224 causes a large percentage of the light to be incident on the surface of the photodetector 226. Since the material 228 remains substantially uncompressed above and within the stabilizing segment 222a, the thickness through which the light travels, or the optical path length, is substantially stabilized. Thus, the signal-to-noise ratio of the measured signal is improved by the suppression of motion artifacts due to the chamber 222.

In another embodiment of the probe 200, a light collecting lens 232 is inserted within the chamber 222, as shown in cross-section in Figure 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 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.

A perspective view of another embodiment of the probe 300 of the present invention which incorporates a chamber 322 having three segments 322a, 322b, and 322c is shown in Figure 13. The probe 300 has a base 310 with a top 312, a bottom 314, a forward end 316, and a rear end 318. The base 310 is typically made of rigid opaque material. However, it will be understood that the base 310 may be made of other materials which may be rigid, resilient, opaque, or transparent, for example. A cross-sectional view of the chamber 322 of this embodiment is shown in Figure 14. For clarity in the perspective view of Figure 13, a material 328 on which measurements are to be taken is not shown placed adjacent the probe 300. However, the material 328 is shown

in the cross section of Figure 13. An aperture 320 of any shape is formed in the base 310, similar to the apertures 120 and 220 described above. The aperture 320 forms the opening to a stabilizing segment 322a of a three segment chamber 322. A lateral cross-section (not shown) of the stabilizing segment 322a of the chamber 322 is typically the same shape as the aperture 320. Walls 323a of the stabilizing segment 322a are generally perpendicular to the aperture 320. A central axis 324 of the chamber 322 is defined by a line aligned perpendicular to the aperture 320 and extending generally through a central portion of the aperture 320 and the chamber 322.

A second, transitional segment 322b of the chamber 322 is adjacent the stabilizing segment 322a of the chamber 322. A top border 325a is formed between the transitional segment 322b and the stabilizing segment 322a of the chamber 322. The transitional segment 322b shares the same central axis 324 as the stabilizing segment 322a. Walls 323b of the transitional segment 322b are angled inwardly such that a bottom border 325b of the transitional segment 322b is of smaller dimension than the top border 325a of the transitional segment 322b.

The bottom border 325b of the transitional segment 322b leads into a mounting segment 322c of the chamber 322. The mounting segment 322c shares the same central axis 324 of the stabilizing and transitional segments 322a and 322b and is typically of smaller width than the stabilizing and transitional segments 322a and 322b. Walls 323c of the mounting segment 322c are generally parallel to the central axis 324. Thus, any cross-section of the mounting segment 322c cut perpendicular to the central axis 324 of the chamber 322 is typically of approximately the same shape as the bottom border 325b of the transitional segment 322b of the chamber 322. The mounting segment 322c may extend through the bottom 314 of the base 310, as shown. Alternatively, the mounting segment 322c may extend to just above the bottom 314 of the base 310, leaving a shell (not shown) of base 310 material at the bottom 314 of the three segment chamber 322.

A photodetector 326 is placed within the mounting segment 322c of the chamber 322, at the bottom 314 of the chamber 322 in the present embodiment. A central portion of the photodetector 326 is aligned with the central axis 324 of the chamber 322. The mounting segment 322c of the chamber 322 is deep enough that the photodetector 326 does not penetrate into the stabilizing segment 322 of the chamber 322. The photodetector 326 may be fixed within the chamber 322 according to a number of different methods, including but not limited to adhesive, a press fit, or a clear epoxy resin which transmits light over a range of wavelengths of interest. In this embodiment, the bottom 314 of the chamber 322 is made opaque via the press fit, paint, or tape, for example. The photodetector 326 is electrically connected to a processor, similarly to the photodetectors 126 and 226 in the previous embodiments of the probe of the present invention.

When a portion of an energy absorbing material 328 is placed over the probe 300, as shown in the cross-section of Figure 14, it may rest above the chamber 322. Additionally, the stabilizing segment 322a of the chamber 322 is wide enough that easily compressible portions of the material 328 may enter into the stabilizing segment 322a of the chamber 322. The stabilizing segment 322a of the chamber 322 is deep enough that the easily compressible portion of the material 328 which intrudes into the stabilizing segment 322a does not contact matter within the stabilizing segment 322a which might cause compression of the material 328, even when the material

328 is caused to move. The chamber 322 shields the compressible material 328 from contact which might cause compression of the material 328 and thereby change the optical path length through the material 328.

An LED 330 is affixed to the material 328, opposite the aperture 320. The LED 330 is advantageously aligned along the central axis 324 to optimize the amount of light incident directly through the material 328 onto the photodetector 326. It will be understood that the positions of the photodetector 326 and the LED 330 could be interchanged as discussed in conjunction with Figure 7. Additionally, a collimating lens assembly (not shown) could be added to the chamber 322 as discussed in conjunction with Figure 8. The collimating lens assembly may be held in the chamber 322 similarly to a light collecting lens 332 discussed below. Further, it will be understood that the LED 330 and the photodetector 326 could be unaligned, as discussed in conjunction with Figure 9.

As light from the LED 330 propagates through the material 328, it is scattered by the material 328 and is thus transmitted into the chamber 322 over a broad range of angles. Thus, some of the light is caused to be incident on the opaque walls 323a, 323b, and 323c of the chamber 322 and is absorbed. However, the advantageous alignment of the photodetector 326 and the LED 330 along the central axis 324 of the chamber 322 causes a large percentage of the light to be incident on the surface of the photodetector 326. Since the material 328 remains substantially uncompressed above and within the stabilizing segment 322a, the thickness through which the light travels, or the optical path length, is substantially stabilized. Thus, the signal-to-noise ratio of the measured signal is improved by the suppression of motion artifacts. Additionally helping to improve the signal to noise ratio of the measured signal is the opaque bottom 314 of the mounting segment 322c which shelters the photodetector 326 from ambient light.

In another embodiment of the probe 300 of the present invention, a light collecting lens 332 is added to the transitional segment 322b of the chamber 322, as shown in a cross sectional view in Figure 15. The lens 332 is supported in the transitional segment 322b and may be held in the transitional segment 322b by a number of means, including but not limited to optical adhesive, a lens retaining ring, or a press fit. The lens has a generally planar surface 332a aligned with the top border 325a of the transitional segment 322b of the chamber 322 and a generally convex surface 325b extending into the transitional segment 322b of the chamber 322. The stabilizing segment 322a of the chamber 322 is deep enough that the lens 332 does not contact the easily compressible material 328 which rests above or has intruded into the chamber 322.

The lens 332 collects light which is incident on the planar surface 332a. Much of the light which is incident on this surface 332a at angles which would have been absorbed by the walls 323a, 323b and 323c of the chamber 322 if the lens 332 were not present is now directed toward the photodetector 326. Thus, a greater percentage of the light transmitted through the material 328 is caused to be incident on the photodetector 326, resulting in a stronger measured signal.

It will be understood that the walls 323b of the transitional segment 322b in each of the above described embodiments need not be sloped to achieve transition from larger width in the stabilizing segment 322a to smaller width in the mounting segment 322c. The walls 323b of the transitional segment 322b could be aligned generally parallel to the central axis 324, arranged at a distance which would cause the width of the transitional segment

322b to be less than the width of the stabilizing segment 322a and greater than the width of the mounting segment 322c.

Figure 16 shows a perspective view of another probe 400 of the present invention specifically designed for use with a digit, such as a finger or a toe. For ease of illustration, the present example will pertain to a finger, though it will be understood that the present example could equally well pertain to any digit. Figure 17 illustrates a schematic finger 428 comprising nail, skin, bone, tissue, muscle, blood, etc. Constituents in the finger's pad 404, such as fat and tissue, are easily compressible with motion of a patient. Even slight motion of the finger 428 can cause the thickness of constituents within the finger 428 to change greatly, thereby causing large motion induced excursions to occur in a measured signal, often obscuring a desired portion of the measured signal from which information about the patient can be determined.

As depicted in Figure 16, base 410 of the finger probe 400, called a saddle 410 in this embodiment, is generally semi-cylindrical and preferably is made of a rigid or semi-rigid, opaque material such as black plastic. It will be understood, however, that the saddle 410 may be made of other materials, including those which are rigid, resilient, opaque, and transparent, for example. The saddle 410 has a top 412, a bottom 414, a forward end 416, a rear end 418, a ridge 440, and sidewalls 450 which curve upwardly from the ridge 440 to form a U-shape in cross-section, as shown in Figure 18.

As illustrated in Figures 16 and 18, an aperture 420 forms the entrance to a chamber 422, located between one-quarter to one-half of the length of the saddle 410 from the forward end 416 of the saddle 410, as shown in the longitudinal cross-section of Figure 19. The aperture 420 can be of any shape, including but not limited to circular, square, or triangular. The aperture 420 is the entrance to a chamber 422, as described previously in conjunction with other embodiments 100, 200, and 300 of the probe of the present invention. The chamber 422 may also be of any shape, including but not limited to circular, square, or triangular in cross-section.

The chamber 422 may have one or more segments, as described previously. Although the chamber 422 shown in this embodiment is a three segment chamber 422, having a stabilizing segment 422a, a sloped-wall transitional segment 422b, and a mounting segment 422c aligned on a common central axis 424, it will be understood that any chamber 422 which protects from compression, a compressible portion of the finger 428 through which light energy passes during absorption measurements, is a viable alternative. It will further be understood that a shell (not shown) of saddle 410 material could cover the bottom 414 of the chamber 422, as described previously with respect to the embodiment of the probe shown in Figure 5.

A photodetector 426 is placed within the chamber 422, typically at the bottom 414 of the mounting segment 422c of the chamber 422. The photodetector 426 may be in place by adhesive, a press fit, or a clear epoxy resin which transmits light over a range of wavelengths of interest, for example. Typically, the bottom 414 of the chamber 422 is made opaque via tape or paint, for example, such that ambient light does not affect the photodetector 426.

The finger 428 is placed on the saddle 410, the finger pad 404 directly adjacent the aperture 420 and chamber 422. Additionally, the finger pad 404 may rest above the chamber 422. The aperture 420 and stabilizing

segment 422a of the chamber 422 are wide enough that any easily compressible portion of the finger 428, such as a portion of the finger pad 404, may intrude into the chamber 422. The stabilizing segment 422a of the chamber 422 is deep enough that any portion of the finger 428 which does penetrate into the stabilizing segment 422a does not contact any matter within the stabilizing segment 422a which might cause compression of the finger 428, even when the finger 428 is caused to move.

An LED 430 is affixed to the finger 428, generally opposite the aperture 420. The LED 430 is typically attached to the finger 428 via adhesive, such as medical tape. The LED 430 is advantageously aligned along the central axis 424 to optimize the amount of light transmitted directly through the finger 428 onto the photodetector 426. However, it will be understood that the positions of the photodetector 426 and the LED 430 could be interchanged as discussed in conjunction with Figure 7. Additionally, a collimating lens assembly (not shown) could be added to the chamber 422 as discussed in conjunction with Figure 8. The collimating lens assembly may be held in the chamber 422 similarly to a light collecting lens 432 discussed below. Further, it will be understood that the LED 430 and the photodetector 426 could be unaligned, as discussed in conjunction with Figure 9.

The LED 430 emits a light energy signal which propagates through the finger 428 and is transmitted into the chamber 422. The chamber 422 shields from compression the portion of the finger 428 through which light energy passes. Thus, the optical path length of the light through the finger 428 is substantially stabilized and motion artifacts are substantially reduced in the measured signal. It will be understood that a single segment chamber as described in conjunction with Figures 3 through 9 or a two segment chamber as described in conjunction with Figures 10 through 12 could equally well be used in the finger probe 400 of the present invention to shield the compressible portion of the finger 428 from compression and thereby reduce motion artifacts.

Figures 16, 18, and 19 illustrate a perspective view, a frontal cross-sectional view, and a longitudinal cross-sectional view, respectively, of one embodiment of the finger probe 400. The curvature of the saddle 410 is correlated to the average curvature of the finger 428 such that the sidewalls 450 form a semi-circular splint-type support for the finger 428. The saddle 410 is approximately 25 mm long between the forward end 416 and the rear end 418, such that a portion of the finger 428 between its tip 406 and approximately its first knuckle 408 (shown in Figure 17) fits between the front 416 and the rear 418 ends of the probe 400. The curvature of the saddle 410 is generally defined by a line 460 (shown in Figure 18) which is tangent to a sidewall 450 at an angle between 30° and 50° from horizontal.

The placement of the aperture 420 at a point between one-third and one-half of the length of the saddle 410, causes the thickest section of the compressible portion of the finger 428, or the finger pad 404, to rest above and within the chamber 422. Thus, the portion of the finger 428 with the greatest amount of compressible material is safeguarded from compression by the chamber 422.

In the embodiment of the finger probe 400 shown in Figures 16, 18, 19, and 20, the aperture 420 is generally circular and the chamber 422 has three segments 422a, 422b, and 422c, as shown in the cross-sectional view of Figure 18. Advantageously employed dimensions for the finger probe 400 illustrated in Figures 16, 18, 19, and 20 include the stabilizing segment 422a of the chamber 422 being generally cylindrical and having a diameter

of approximately seven millimeters. Additionally, the stabilizing segment 422a of the chamber 422 is deep enough that any portion of the finger 428 which penetrates into the chamber remains substantially free of perturbation, even when the finger 428 moves. An advantageous depth for the stabilizing segment 422a is thus approximately two millimeters deep. The mounting segment 422c of the chamber 422 is also cylindrical, having a diameter of approximately five millimeters. The transitional segment 422b of the chamber 422 is of varying diameter, having sloped walls 423b, such that a top border 425a is approximately seven millimeters in diameter and a bottom border 425b is approximately five millimeters in diameter. A detector 426 having up to a 5 millimeter diameter is positioned in the bottom 416 of the mounting segment 422c of the chamber 422.

In another embodiment of the finger probe 400, a light collecting lens 432 may be added to the finger probe 400 of the present invention, as shown in Figure 20. The saddle 410 and the chamber 422 function as discussed above. The lens 432 functions as described above in conjunction with Figures 6, 12, and 15 to collect light incident on the lens 432 which would be absorbed by the walls 423a, 423b and 423c of the chamber 422 if the lens 432 were not present. Thus, a greater percentage of the light transmitted through the finger 428 is directed onto the photodetector 426, resulting in a stronger measured signal.

Other embodiments of the probe of the present invention may be specifically designed and manufactured for use with an earlobe or other thin section of the body, such as a nostril or a lip, using the principles described herein. Also, embodiments of the probe of the present invention utilizing the properties of attenuation as energy is reflected from a medium, rather than transmitted through a medium, may be made using similar principles.

A probe 700 specifically designed to measure reflected energy is shown in cross-section in Figure 21. A base 710 is placed adjacent a material 728 on which reflectance measurements are to be made. A photodetector 726 and an LED 730 are located within the base 710. In the embodiment shown in Figure 21, the photodetector 726 is positioned within a chamber 722x and the LED 730 is positioned within a chamber 722y. Although single segment chambers 722x and 722y are illustrated, the chambers 722x and 722y may be of any suitable shape and size. The chambers 722x and 722y function to stabilize the optical path length, as discussed previously, by shielding from compression any compressible portion of a material which rests above or intrudes into the chambers 722x and 722y.

A light collecting lens (not shown) may be added to the chamber 722x having the photodetector 726 within it, as discussed previously in conjunction with Figures 6, 12 and 15. Additionally, a collimating lens assembly (not shown) may be added to the chamber 722y having the LED 730 in it, as discussed previously in conjunction with Figure 8. The chambers 722x and 722y may be formed with or without a shell (not shown) of base 710 material, as discussed previously in conjunction with Figure 5.

It will be understood that in other embodiments (not shown) of the reflectance probe 700, the photodetector 726 could protrude from the base 710 and the LED 730 be located within a chamber 722y or the LED 730 could be protrude from the base 710 and the photodetector 726 could be located within a chamber 722x. Additionally, the photodetector 726 and the LED 730 could be located within a single chamber 722. In any embodiment the chamber(s) 722 may have any number of segments of any suitable shape.

The type of probe 700 which relies on reflection may be advantageously utilized on materials where a photodetector 726 and an LED 730 cannot be placed on opposite sides of the material 728, such as with the forehead. However, a reflectance probe 700 can be used anywhere a non-invasive measurement needs to be taken, such as a lip, an earlobe, or a finger, for example.

Figure 22 shows a cross-sectional view of another probe 800 of the present invention wherein two bases 810x and 810y are placed adjacent to a material 828 on which measurements are to be made. The bases 810x and 810y are located on opposite sides of the material 828. A photodetector 826 is placed in a chamber 822x in the base 810x. An LED 830 is placed in a chamber 822y in the base 810y. The photodetector 826 and the LED 830 are aligned substantially along a central axis 824. Although two segment chambers 822x and 822y are illustrated, the chambers 822x and 822y may be of any suitable shape and size. Independent of which shape of chamber is utilized, the chambers 822x and 822y function to stabilize the optical path length and thereby reduce the effects of motion artifacts on the measured signals.

As discussed previously, the probe 800 may be modified slightly with a light collecting lens (not shown) added to the chamber 822x with the photodetector 826 in it. A collimating lens assembly (not shown) may be added to the chamber 822y with the LED 830 in it. Additionally, the chambers 822x and 822y may be formed with or without a shell (not shown) of base 810x and 810y material. The probe 800 is particularly advantageous when a material 828 is compressible on more than one side since each chamber 822x and 822y supports and shields from compression any compressible portion of a material 828 which rests above or intrudes into the chambers 822x and 822y, respectively.

Figure 23 shows a cross-sectional view of another probe 900 of the present invention wherein a chamber 922 having walls 923 is formed to concentrate, or "funnel," energy onto the surface of a photodetector 926. An aperture 920 is formed in a base 910, the aperture 920 leading to a generally cone-shaped chamber 922. The base 910 is placed adjacent a material 928 on which measurements are to be made, the chamber 922 being placed directly adjacent any easily compressible portion of the material 928. The photodetector 926 is placed within the chamber 922, typically at the bottom of the chamber 928. A light emitting diode 930 is placed on the material 928, generally opposite and aligned with the photodetector 926.

As discussed previously, a portion of the material 928 is supported by the area surrounding the aperture 920. Additionally, the aperture 920 and chamber 922 are wide enough that any easily compressible portion of the material 928 may intrude into the chamber 922 without being compressed, thereby shielding this portion of the material 928 from compression, even during motion of the material 928. This substantially stabilizes the optical path length and improves the signal to noise ratio of the signal measured at the photodetector 926.

Further improving the signal to noise ratio of measurements made with the probe 900, reflective material, such as a highly reflective metal, covers the walls 923 of the chamber 922. This causes light scattered by the material 928 and made incident on the walls of the chamber 922 to be reflected. The cone shape causes the light to be concentrated generally on the photodetector 926.

Depending upon the shape of the photodetector 926, the chamber 922 may be advantageously contoured to maximize the funneling of light onto the photodetector 926. If the photodetector 926 is flat, the chamber is most advantageously shaped having a generally hyperbolic cross-section. However, if the photodetector 926 is spherical or slightly curved, as is often the case due to manufacturing processes, the chamber is most advantageously shaped having a cone-shaped cross-section with uncurved walls 923.

As discussed previously in conjunction with other embodiments of the probe of the present invention, the probe 900 may be modified to include a light collecting lens (not shown). Alternatively, an LED 930 could be placed within the chamber 922 instead of the photodetector 926. With the LED in the chamber 922, a collimating lens assembly (not shown) could be placed within the chamber 922. Two bases 910 with two generally cone-shaped chambers could be utilized on one or either side of a material 928. A single base 910 with two generally cone-shaped chambers 922 located side by side could also be used for reflective measurements. Additionally, the photodetector 926 and the LED 930 need not be aligned along the central axis 924.

Figure 24 depicts one embodiment of a probe constructed in accordance with the present invention coupled to an oximeter. The oximeter could be any oximeter known in the art which utilizes light attenuation measurements. A block diagram of one possible oximeter is depicted in Figure 24. The oximeter shown in Figure 24 is a pulse oximeter wherein the finger probe 400 is employed and two measured signals at different wavelengths, one of which is typically red and the other of which is typically infrared, are alternately passed through the finger 428. Signals measured at the photodetector 426 are then processed to determine the amount of oxygen available to the body. This is evaluated by finding the saturation of oxygenated hemoglobin in blood comprising both oxygenated and deoxygenated hemoglobin.

Two LEDs 430a and 430b, one LED 430a emitting red wavelengths and another LED 430b emitting infrared wavelengths, are placed adjacent the finger 428. The finger probe 400 is placed underneath the finger 428, the aperture 420 and chamber 422 located directly adjacent the finger pad 404. The photodetector 426 in the bottom 414 of the chamber 422 is connected to a single channel of common processing circuitry including an amplifier 530 which is in turn connected to a band pass filter 540. The band pass filter 540 passes signal into a synchronized demodulator 550 which has a plurality of output channels. One output channel is for signals corresponding to visible wavelengths and another output channel is for signals corresponding to infrared wavelengths.

The output channels of the synchronized demodulator 550 for signals corresponding to both the visible and infrared wavelengths are each connected to separate paths, each path comprising further processing circuitry. Each path includes a DC offset removal element 560 and 562, such as a differential amplifier, a programmable gain amplifier 570 and 572 and a low pass filter 580 and 582. The output of each low pass filter 580 and 582 is amplified in a second programmable gain amplifier 590 and 592 and then input to a multiplexer 600.

The multiplexer 600 is connected to an analog-to-digital converter 610 which is in turn connected to a microprocessor 620. Control lines between the microprocessor 620 and the multiplexer 600, the microprocessor 620 and the analog-to-digital converter 610, and the microprocessor 620 and each programmable gain amplifier 570, 572,

590, and 592 are formed. The microprocessor 620 has additional control lines, one of which leads to a display 630 and the other of which leads to an LED driver 640 situated in a feedback loop with the two LEDs 430a and 430b.

Each of the LEDs 430a and 430b alternately emits energy which is absorbed by the finger 428 and received by the photodetector 426. The photodetector 426 produces an electrical signal which corresponds to the intensity of the light energy striking the photodetector 426 surface. The amplifier 530 amplifies this electrical signal for ease of processing. The band pass filter 540 then removes unwanted high and low frequencies. The synchronized demodulator 550 separates the electrical signal into electrical signals corresponding to the red and infrared light energy components. A predetermined reference voltage, V_{ref}, is subtracted by the DC offset removal element 560 and 562 from each of the separate signals to remove substantially constant absorption which corresponds to absorption when there are no motion artifacts. Then the first programmable gain amplifiers 570 and 572 amplify each signal for ease of manipulation. The low pass filters 580 and 582 integrate each signal to remove unwanted high frequency components and the second programmable gain amplifiers 590 and 592 amplify each signal for further ease of processing.

The multiplexer 600 acts as an analog switch between the electrical signals corresponding to the red and the infrared light energy, allowing first a signal corresponding to the red light to enter the analog-to-digital convertor 610 and then a signal corresponding to the infrared light to enter the analog-to-digital convertor 610. This eliminates the need for multiple analog-to-digital convertors 610. The analog-to-digital convertor 610 inputs the data into the microprocessor 620 for calculation of the saturation of oxygen according to known methods, such as those described in U.S. Patent Application Serial No. 07/666,060 filed March 7, 1991, and abandoned in favor of continuation U.S. Patent Application Serial No. 08/249,690, entitled "SIGNAL PROCESSING APPARATUS AND METHOD," filed May 26, 1994, both assigned to MASIMO CORPORATION, the same assignee as the present patent, and incorporated herein by reference. The microprocessor 620 centrally controls the multiplexer 600, the analog-to-digital convertor 610, and the first and second programmable gain amplifiers 570, 590, 572, and 592 for both the red and the infrared channels. Additionally, the microprocessor 620 controls the intensity of the LEDs 430a and 430b through the LED driver 640 in a servo loop to keep the average intensity received at the photodetector 426 within an appropriate range.

As explained above, the probe of the present invention could be used with a variety of oximeter systems. A recent embodiment of an oximeter by the assignee of the present application is described in detail in U.S. Patent Application Serial No. 08/320,154, entitled "Signal Processing Apparatus," and filed October 7, 1994, which patent application is also incorporated herein by reference.

Figures 25-28 depict alternative embodiments of the present invention wherein an improved signal to noise ratio is observed in the received signal due to optical scattering effects. A probe 1000, shown in cross-section in Figure 25, includes a base 1010, having a top 1012, a bottom 1014, and a forward and a rear end (not shown in Figure 25). The base 1010 is preferably rigid and opaque to the wavelengths used in the probe 1000. An aperture 1020 is formed in the top 1012 of the base 1010. The aperture 1020 may be cylindrical (as shown in Figure 25), conical, rectangular, or other shapes as called for by the specific application. The depth of the aperture 1020 may,

for example, range from 0.5 mm to 10 mm, and is preferably in the range of 2-4 mm in depth in one embodiment, and more preferably in the range of 3-4 mm. Furthermore, the diameter of the aperture 1020 may range from 3 mm to 20 mm, as called for by the specific application. It has been found by the inventors that an aperture less than .5 mm in diameter does not obtain the benefits of the present invention.

A light source 1030 (e.g., one or more light emitting diodes) is affixed adjacent to material 1028 (e.g., an earlobe, finger, or other fleshy material), aligned along a central axis 1024 which passes substantially through the center of a photodetector 1026. The aperture 1020 is filled wholly, or in part, by a scattering medium 1040, which may, for example, comprise 2.2 pound polyurethane reticulated foam (although conformable plastic or scattering gels may also be employed). In general, the scattering medium may comprise one of a number of fixotropic materials (i.e., materials having two or more mixed materials which are conducive to scattering). Ideally, the scattering medium 1040 scatters but does not significantly absorb optical radiation at the operational red (e.g., 660 nm) and infrared (e.g., 940 nm) wavelengths for the oximeter. In other words, the material is clear to optical absorption, but still scatters light.

In operation, the light source 1030 (e.g., two LEDs in the present embodiment) emits optical radiation (e.g., in the red or infra-red spectrum range) which passes through the material under test 1028. The optical radiation is received by the photodetector 1026 after passing through the scattering medium 1040. The received optical radiation is scattered by the scattering medium 1040.

The scattering of the optical radiation within the scattering medium 1040 has been found to increase the signal-to-noise ratio of the received signal. It is believed that the signal-to-noise ratio is improved because there appears to be a reduced effect on the signal from any particular local region of the material 1028 (e.g., flesh). That is, by scattering the signal either prior to or posterior to the material interface, the signal is effectively spread over a larger area of the material 1028. Thus, perturbations of a locality within the area of exposure will have less effect with a scattered beam over a large area than with a more concentrated signal passing through that same locality. In this way, the effect of perturbations on the average signal is reduced.

The scattering medium 1040 should be soft (i.e., highly compressible) so that the material 1028 does not significantly compress when the material 1028 presses against the scattering medium 1040. Compression of the scattering medium 1040 does not significantly alter the amplitude of the measured signal since the scattering medium is not highly absorbtive of the optical radiation. Furthermore, although conformable plastics may be used, reticulated foams are preferred since reticulated foams provide improved optical coupling with flesh. This is because the reticulated foam provides contact in spots rather than across large areas of the flesh. If contact is made across large areas of flesh, microscopic droplets of perspiration or oil can form a layer between the flesh and the scattering medium 1040. This layer creates an impedance mismatch interface which is absorbtive of the optical radiation. Of course, gels may also be used in accordance with the present invention. Such gels should not contain significant amounts of metal salts or silica because these materials absorb light.

The teachings of the present invention depart from conventional methods of improving optical signal-to-noise ratios. Commonly, lens assemblies which focus optical radiation are used to improve the signal-to-noise ratios of

optical signals. However, oximetry by means of transmission or reflection is a non-imaging method of optical detection. Thus, the form of the image is not important for detection purposes. For this reason, scattering may be used as a method of improving optical signal quality; whereas, since scattering was thought to degrade signal-to-noise ratios of optical signals, previous methods have not employed optical scattering techniques.

Figures 26 and 27 depict further alternative embodiments of the present invention wherein optical scattering is provided prior to the flesh interface, and both prior and posterior to the flesh interface, respectively. In Figure 26, an oximetry probe 1045 further has a transmission assembly 1050 which secures the LED 1030 in place within a backing 1055. A scattering medium 1060, having a face 1063, is interposed between the LED 1030 and the material 1028. In the embodiment depicted in Figure 26, the scattering medium 1060 does not contact the LED 1030; however, it should be understood that the scattering medium 1060 may contact one or both of the LED 1030 and the material 1028.

The scattering medium 1060 diffuses the optical radiation emitted by the LED 1030 over a wider area. Thus, the LED 1030, which is essentially a point source, is transformed into an evenly distributed source of light over the entire area of the face 1063 of the scattering medium 1060. The diffusion of the light over a wider area provides an improved signal-to-noise ratio.

As seen in Figures 26-28, the light is scattered. This is represented by the energy intensity contours rather than light path indicators. As recognized by the present inventors, the particular light path is not significant. The important aspect is the intensity of the light and the field of view of the photodetector and the light source. This will be explained further in connection with the embodiment of Figure 28 utilizing an immersion lens.

The operation of a probe 1065 shown in Figure 27 is essentially the same as that of the probe 1045, with the exception that the scattering medium 1040 is provided within the aperture 1020. It has been found that by providing a scattering medium on both sides of the material 1028, an improved signal-to-noise ratio is observed over the probes having a scattering medium on only one side of the material 1028.

Figure 28 depicts a preferred embodiment of a probe 1070 in accordance with the present invention. As depicted in Figure 28, the probe 1070 comprises a transmission assembly 1072, having a light source 1074, an immersion lens 1076, scattering medium 1078, a chamber 1080 defining an aperture 1082 along a support surface 1083 of the transmission assembly. A detector assembly 1084 is similarly configured with a support surface 1085, a chamber 1086 defining an aperture 1088 along the support surface 1085, a photodetector 1090, an immersion lens 1092 and scattering medium 1094. Figure 28 further depicts a test material 2000 such a human tissue (e.g., a finger or earlobe) interposed between the light source assembly 1072 and the detector assembly 1084.

Several advantages are obtained from the particular configuration shown in Figure 28. First, it should be understood that an economical way to fabricate the light source in the photodetector is to utilize small semiconductor LEDs and photodetectors. Such devices are very small, and therefore, have a very small field of view. The inventors have recognized that it is advantageous to improve the field of view of the photodetector and the LED because the surface of the tissue material 2000 at the aperture of the support surfaces is large compared to the surface of the semiconductor photodetector and LED. Thus, without enlarging the field of view of the photodetector and/or LED,

much of the tissue material interface at the apertures is not utilized. As explained above, scattering of the light improves the received signal quality. An immersion lens for the photodetector and/or LED increases the field of view of the semiconductor photodetector and LEDs such that a substantial portion of the tissue material covering the apertures is within the field of view of the photodetector and/or LED.

Because imaging optics are not required due to the advantages of scattering, a significantly advantageous configuration is to utilize epoxy placed directly over the photodetector and/or over the LED in the form of a partial sphere which performs suitably as an immersion lens in the present embodiment. In one embodiment, the index of refraction of the epoxy is advantageously 1.56. The epoxy also acts to protect the photodetector and/or LED. The immersion lens can be formed by placing a bump of epoxy over the photodetector and the LED.

The immersion lens formed by a bump of epoxy over the photodetector and/or LED expands the field of view for the photodetector and LED in order to disperse the transmitted light energy over the tissue surface area at the apertures which is large relative to the surface of the optical elements. This assists in minimizing the effects of the relatively small optical details of the test materials (e.g., pores, fingerprint lines, sweat glans).

In the advantageous embodiment of Figure 28, the scattering material 1080, 1086 is also placed in the chambers 1080, 1086 in order to enhance scattering of the light as explained above.

The cone shaped chambers 1080, 1086 depicted in Figure 28 are also advantageous when the walls of the chambers are coated with a highly reflective material which does not absorb the light from the LED. The cone shape assists in reflecting the light energy away from the LED and toward the photodetector. All of these elements in combination form a particularly advantageous probe which can maximize the signal-to-noise ratio of the probe and minimize the effects of motion artifact on the received signal.

It should be understood that in alternative embodiments of the probe 1070 depicted in Figure 28, elements could be removed and still obtain significant benefit. For instance, the detector assembly 1084 could remain the same with the light source assembly 1072 simply becoming an LED with no support surface and no chamber. Alternatively, the scattering media 1078, 1086 could be removed from either the chamber 1080 in the light source assembly 1072 or the chamber 1086 in the detector assembly 1082.

One skilled in the art will realize that the light collecting lens, or other optical elements, could also be added to the chamber in any optical probe of the present invention to direct light onto the photodetector. However, the immersion lens provides better performance. One skilled in the art will further realize that the location of the photodetector and the LED may be interchanged in any of the above described probes. One skilled in the art will realize that the bottom of any chamber formed in a base of an optical probe of the present invention can remain exposed, be covered by a material such as opaque tape, or be covered by a shell of base material without affecting the reduction of motion artifacts brought about by the chamber. Additionally, one skilled in the art will realize that reflective measurements could be made with the probes of the present invention by mounting both the photodetector and LED on the base of the probe. Also, one skilled in the art will realize that a plurality of LEDs or photodetectors could be mounted in the chamber or affixed to the material such that more than one signal may be measured at a time. Furthermore, one skilled in the art will realize that any material having a chamber, with a detector or an LED

mounted within the chamber, will reduce the effects of motion artifacts in non-invasive absorption (or reflection) measurements, according to the present invention.

It will be understood that the probe of the present invention may be employed in any circumstance where a measurement of transmitted or reflected energy is to be made, including but not limited to measurements taken on a finger, an earlobe, a lip, or a forehead. Thus, there are numerous other embodiments which will be obvious to one skilled in the art, including but not limited to changes in the shape of the probe, changes in the materials out of which the probe is made including rigid and resilient materials, and changes in the shape, dimensions, and location of the chamber. Moreover, the chamber(s) may be coated, in whole or in part, with reflective material to help direct energy onto the detector. Furthermore, the probe of the present invention may be employed in measurements of other types of energy. Depending upon the type of energy which is most advantageously utilized in a measurement, the type of transmitter or receiver of energy may be changed. The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED:

1. An energy sensor comprising:

a housing having a support surface for a tissue material which is to be analyzed;

a chamber having an entrance in the form of an aperture defined on said housing support surface such that, when said housing is positioned adjacent said tissue material, a first portion of said tissue material covers said aperture and is supported by said support surface around said aperture;

a first portion of optically scattering medium positioned within said chamber;

a light energy source; and

a detector located in said chamber, said detector positioned in said chamber in a manner such that said portion of said tissue material which covers said aperture is isolated from said detector by said optically scattering medium.

2. The energy sensor of Claim 1, wherein said light energy source is positioned generally opposite said chamber when said housing is positioned adjacent said first portion of tissue material.

3. The energy sensor of Claim 1, wherein walls of said chamber are formed such that said chamber is generally cone-shaped.

4. The energy sensor of Claim 3, wherein said chamber further comprises reflective walls.

5. The energy sensor of Claim 1, wherein said first portion of optically scattering medium is a conformable material which does not significantly perturb the tissue material when brought into contact with the first portion of tissue material.

6. The energy sensor of Claim 5, wherein said first portion of optically scattering medium is reticulated foam.

7. The energy sensor of Claim 6, wherein said first portion of optically scattering material is reticulated polyurethane foam.

8. The energy sensor of Claim 5, wherein said optically scattering medium is an optically scattering gel.

9. The energy sensor of Claim 1, further comprising:

a second housing having a second support surface for said material which is to be analyzed, said second housing located adjacent said material; and

a second chamber having an entrance in the form of a second aperture on said second housing support surface such that, when said housing is positioned adjacent said tissue material, a second portion of said tissue material covers said second aperture and is supported by said support surface around said aperture, said light energy source positioned in said second chamber a distance from said support surface, said distance sufficient that said tissue material does not contact said light energy source when said second housing is positioned adjacent said second portion of tissue material.

10. The energy sensor of Claim 9, further comprising a second portion of optically scattering medium positioned in said second chamber between said light energy source and said second aperture.

11. The energy sensor of Claim 1, further comprising:

a second chamber having an entrance in the form of a second aperture defined on said housing support surface, said light energy source located in said second chamber.

12. The energy sensor of Claim 11, further comprising a second portion of optically scattering medium positioned in said second chamber between said energy source and said aperture defined in said support surface

13. The energy sensor of Claim 12, wherein said second portion of optically scattering medium is compressible.

14. The energy sensor of Claim 12, wherein said second portion of optically scattering medium comprises reticulated foam.

15. The energy sensor of Claim 12, wherein said second portion of optically scattering medium comprises an optically scattering gel.

16. The energy sensor of Claim 12, wherein said scattering medium comprises a conformable plastic.

17. An optical sensor comprising:

a light energy source;

a housing having a support surface adapted to be placed adjacent tissue material to be analyzed, said housing having a chamber defining an aperture in said support surface;

a photodetector within said chamber and spaced away from said aperture in said support surface; and

an optically scattering medium positioned in said chamber between said photodetector and said aperture.

18. The optical sensor of Claim 17, wherein said optically scattering medium comprises reticulated foam.

19. The optical sensor of Claim 18, wherein said reticulated foam comprises 2.2 pound polyurethane reticulated foam.

20. The optical sensor of Claim 17, wherein said scattering medium comprises an optically scattering gel.

21. The optical sensor of Claim 17, wherein said scattering medium comprises a conformable plastic.

22. An optical sensor comprising:

a light energy source;

a photodetector;

a housing having a support surface adapted to be placed adjacent a material which is to be analyzed, said housing having a chamber defining an aperture in said support surface and extending from said support surface; and

an optically scattering medium positioned in said chamber;

23. The optical sensor of Claim 22, wherein said light energy source is positioned within said chamber such that said optically scattering medium is between said light energy source and said aperture.

24. The optical sensor of Claim 22, wherein said photodetector is positioned within said chamber such that said optically scattering medium is between said photodetector and said aperture.

25. The optical sensor of Claim 22, wherein said light energy source comprises a light emitting diode supported 3-4 millimeters from said top surface of said material.

26. The optical sensor of Claim 23, wherein said chamber is 3-4 millimeters deep as measured from said light energy source to said aperture.

27. The optical sensor of Claim 24, wherein said chamber is 3-4 millimeters deep as measured from said photodetector to said aperture.

28. The optical sensor of Claim 22, wherein said scattering medium comprises a reticulated foam.

29. An optical sensor as defined in Claim 28, wherein said reticulated foam comprises 2.2 pound polyurethane reticulated foam.

30. The optical sensor of Claim 22, wherein said scattering medium comprises an optically scattering gel.

31. The optical sensor of Claim 22, wherein said scattering medium comprises a conformable plastic.

32. An optical sensor comprising:

a light energy source;

a photodetector;

a housing having a support surface adapted to be placed adjacent a material which is to be analyzed, said housing having a chamber defining an aperture in said support surface and extending from said support surface; and

an immersion lens positioned within said chamber.

33. The optical sensor of Claim 32, wherein said light energy source is positioned within said chamber such that said immersion lens is between said light energy source and said aperture.

34. The optical sensor of Claim 33, wherein said light energy source is a semiconductor light emmitting diode and wherein said immersion lens is an epoxy bump covering said light energy source.

35. The optical sensor of Claim 32, wherein said photodetector is positioned within said chamber such that said immersion lens is adjacent said photodetector and between said photodetector and said aperture.

36. The optical sensor of Claim 32, wherein said light energy source comprises a light emitting diode supported 3-4 millimeters from said top surface of said material.

37. The optical sensor of Claim 33, wherein said chamber is 3-4 millimeters deep as measured from said light energy source to said aperture.

38. The optical sensor of Claim 35, wherein said chamber is 3-4 millimeters deep as measured from said photodetector to said aperture.

39. The optical sensor of Claim 32, further comprising an optically scattering medium positioned within said chamber.

40. An optical sensor as defined in Claim 39, wherein said reticulated foam comprises 2.2 pound polyurethane reticulated foam.

41. The optical sensor of Claim 39, wherein said scattering medium comprises an optically scattering gel.

42. The optical sensor of Claim 39, wherein said scattering medium comprises a conformable plastic.

43. A system for analyzing the blood in living tissue material comprising:

a housing having a support surface for receiving said tissue material which is to be analyzed;

a chamber having an entrance in the form of an aperture positioned on said housing support surface such that when said housing is positioned adjacent said tissue material, a portion of said tissue material covers said aperture and is supported by said support surface around said aperture, the opening of the aperture of said chamber being wide enough so that compressible tissue covering said aperture may enter said chamber such that said tissue material covering said aperture and tissue material that enters said chamber via said aperture will remain substantially uncompressed;

a detector located in said chamber for detecting energy which has passed through the portion of said material and enters said chamber through said aperture, said detector positioned in said chamber in a manner such that said tissue material entering said chamber via said aperture will be isolated from said detector and remain substantially uncompressed;

an energy source in communication with said detector and said chamber via said aperture, said energy source configured to transmit energy through said material to said detector; and

a monitor coupled to said detector, said monitor responsive to signals from said detector to calculate the concentration of blood constituents within said living tissue material depending upon the intensity of the energy which has passed through said material to said detector.

44. The system of Claim 43, wherein said energy source is located generally opposite said aperture and outside said chamber.

45. The system of Claim 43, wherein said monitor is a pulse oximeter adapted to indicate the saturation of oxygen within the blood in the tissue material being analyzed.

46. The system of Claim 45, wherein said energy source emits at least two output signals having different frequencies, said output signals being modulated prior to detection by said detector.

47. The system of Claim 46, wherein said two output signals are two optical signals having different wavelengths.

48. The system of Claim 47, wherein said two optical signals have wavelengths in the visible red and infrared spectrums, respectively.

49. The system of Claim 46, wherein said pulse oximeter includes:

a demodulator connected to said detector and configured to demodulate the modulated signals detected by said detector to form two demodulated signals which correspond to the two output signals of said energy source; and

a processor connected to said demodulator, said processor responsive to the intensity of said two demodulated signals to generate a value indicative of the saturation of oxygen within the blood of the living tissue.

50. The system of Claim 49, wherein said processor comprises:

an analog to digital converter interconnected with said demodulator and configured to receive said two demodulated signals; and

a digital computer connected to said analog to digital converter.

51. The system of Claim 50, said pulse oximeter further including a driver for said energy source, said driver having at least one input terminal connected to said digital computer and at least one output terminal connected to said energy source such that, via said driver, said digital computer controls the two output signals from said energy source.

52. The system of Claim 50, said processor further comprising a multiplexer connected between said demodulator and said analog to digital converter to control the application of said two demodulated signals to said analog to digital converter, one at a time.

53. An apparatus for sensing light absorption through transillumination of living flesh material by a light source and reception of light by an optical detector, said apparatus including a probe comprising:

a base having a support surface for supporting said flesh material;

a chamber having an entrance in the form of an aperture on said base support surface such that when said probe is in use said flesh material covers said aperture and is supported by said support surface around said aperture, said aperture having a diameter that is wide enough such that easily compressible flesh material covering the chamber may intrude through the aperture into the chamber, and remain substantially uncompressed such that movement between the flesh material and the chamber does not significantly disturb the flesh material in the area of the aperture;

A detector located in said chamber, said detector responsive to light which has passed through said flesh material and enters said chamber through said aperture, said detector positioned in said chamber in a manner such that said flesh material which covers said aperture is isolated from contact with said detector such that said flesh material remains substantially uncompressed, and said chamber having a particular width and depth such that any of said portion of flesh material which penetrates into the chamber via said aperture is not compressed; and

a light source for directing light into said portion of said flesh material.

54. The apparatus of Claim 53, also including a pulse oximeter connected to said detector, said pulse oximeter responsive to the intensity of the light which passes through said portion of said flesh material and is received by said detector to calculate the saturation of oxygen within the blood in the living flesh material.

55. A system for measuring electromagnetic energy which has been attenuated by a living flesh material, said system including an optical probe comprising:

a base having a thickness, said base being positioned adjacent said flesh material when said optical probe is positioned for use;

an aperture in said base, said aperture leading to a chamber which extends substantially through the thickness of said base, said aperture and chamber being wide enough that a portion of said flesh material may intrude into the chamber without significant perturbation of the flesh material due to compression, said chamber having a particular depth such that any portion of the flesh material which penetrates into the chamber via said aperture is not substantially compressed; and

a detector located within said chamber, separated from any of said portion of said flesh material which has penetrated into said chamber, said detector receiving electromagnetic energy transmitted through said flesh material.

56. The system of Claim 55, said optical probe further comprising a light emitting diode located opposite said chamber, said diode configured to transmit light energy through said flesh material to said detector.

57. The system of Claim 55, also including a pulse oximeter connected to said detector and responsive to the intensity of the electromagnetic energy transmitted through said flesh material and received by said detector to calculate the saturation of oxygen within the blood in the living flesh material.

58. A method for calculating the saturation of oxygen within the blood of living tissue material, said method comprising the steps of:

supporting said tissue material on a chamber having an aperture such that a portion of said tissue material covers said aperture, said chamber wide enough so that a compressible portion of said tissue material may enter said chamber without causing substantial compression in the tissue material covering the aperture;

locating a detector in said chamber for detecting electromagnetic energy which passes through the portion of tissue material covering the aperture of said chamber, said detector positioned so as not to contact said portion of tissue material and said chamber ;

locating an electromagnetic energy source outside said chamber in axial alignment with said detector and transmitting electromagnetic energy from said electromagnetic energy source through the portion of tissue material covering the aperture of said chamber to said detector;

detecting the magnitude of the electromagnetic energy which has passed through the portion of tissue material covering the aperture of said chamber to said detector;

computing the intensity of the electromagnetic energy detected by said detector; and

calculating the oxygen saturation in response to the intensity of the electromagnetic energy.

59. The method of claim 58, further comprising the step of transmitting electromagnetic energy from said energy source in the form of at least two light signals having different wavelengths.

60. The method of Claim 59, further comprising steps of transmitting one of said two light signals from said energy source having a wavelength in the visible spectrum and transmitting the other of said light signals having a wavelength in the infrared spectrum.

61. The method of Claim 60, further comprising the steps of:

modulating said two light signals transmitted from said energy source to said detector; and

demodulating the two modulated light signals detected by said detector to form two demodulated signals which correspond to the two light signals transmitted by said energy source.

62. The method of Claim 61, further comprising the steps of supplying said two demodulated signals from said detector to a digital computer and in response to the intensity of said two demodulated signals, calculating the saturation of oxygen within the blood of the tissue material.

63. The method of Claim 62, further comprising the steps of supplying said two demodulated signals, one at a time, from said detector to an analog to digital converter by way of a multiplexer and supplying the output of said analog to digital computer to said digital computer.

FIG. 1

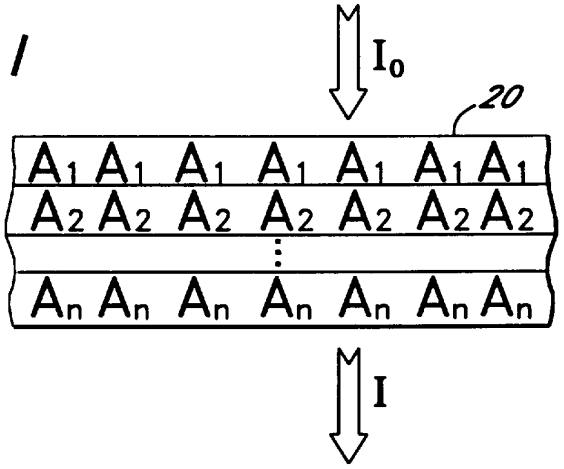


FIG. 2a

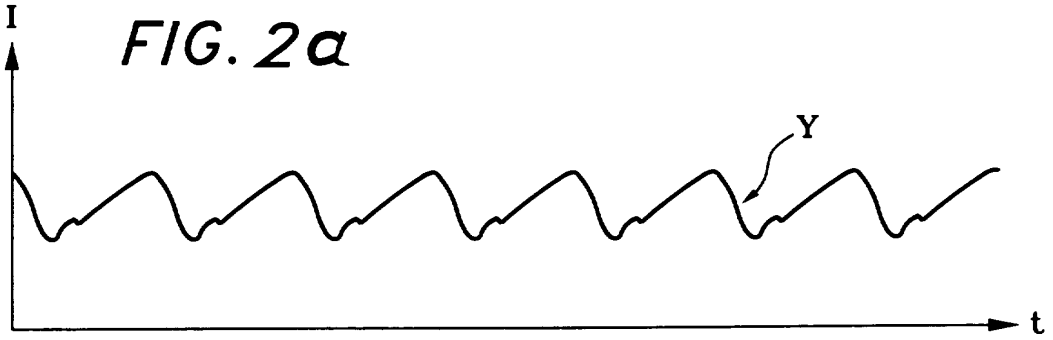


FIG. 2b

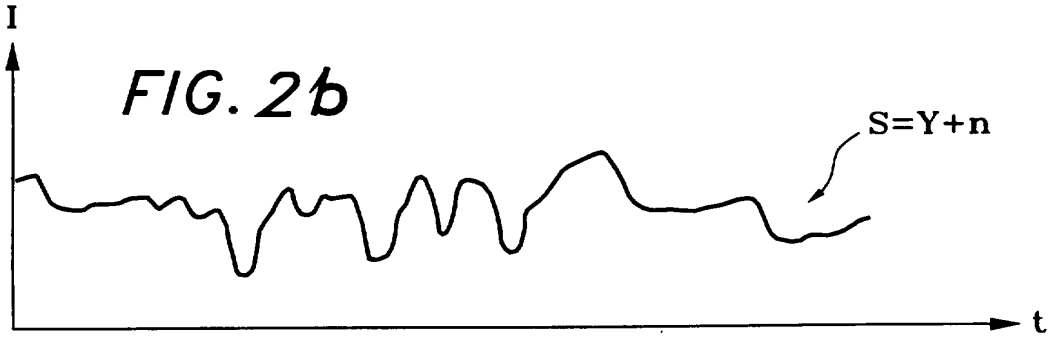


FIG. 3

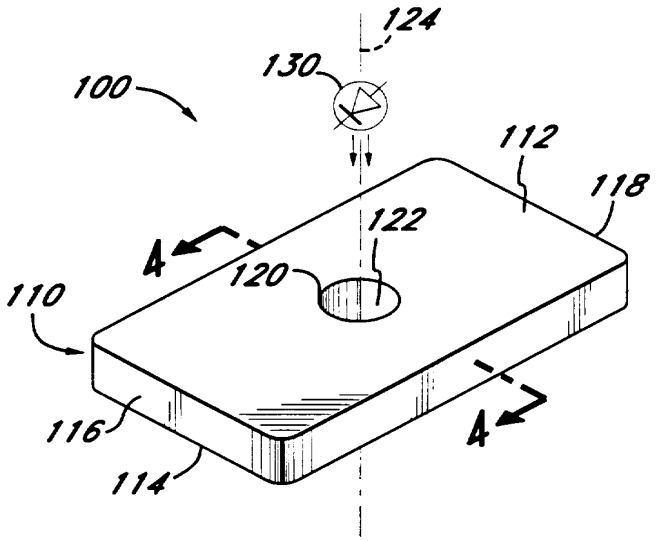

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FIG. 4

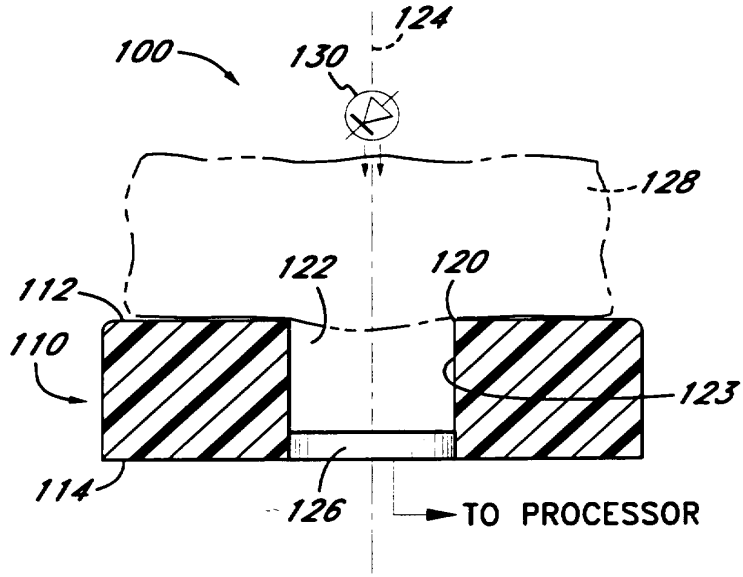

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TO PROCESSOR

FIG. 5

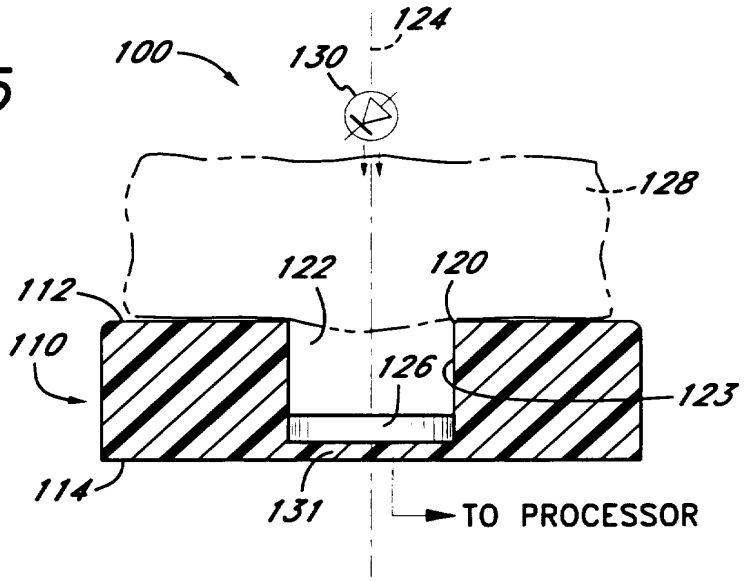
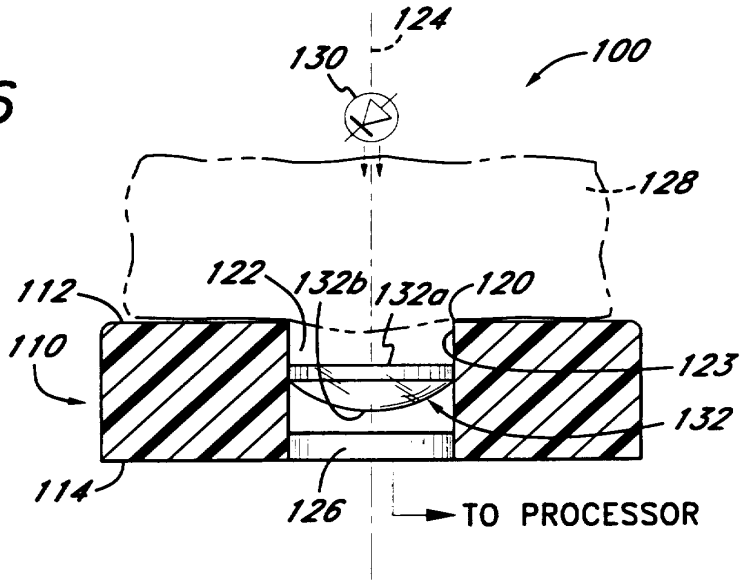

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TO PROCESSOR

FIG. 6


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TO PROCESSOR

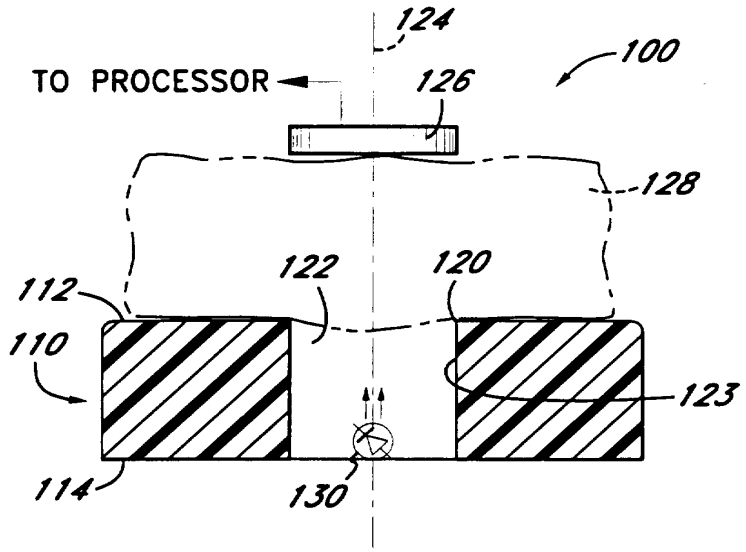


FIG. 7

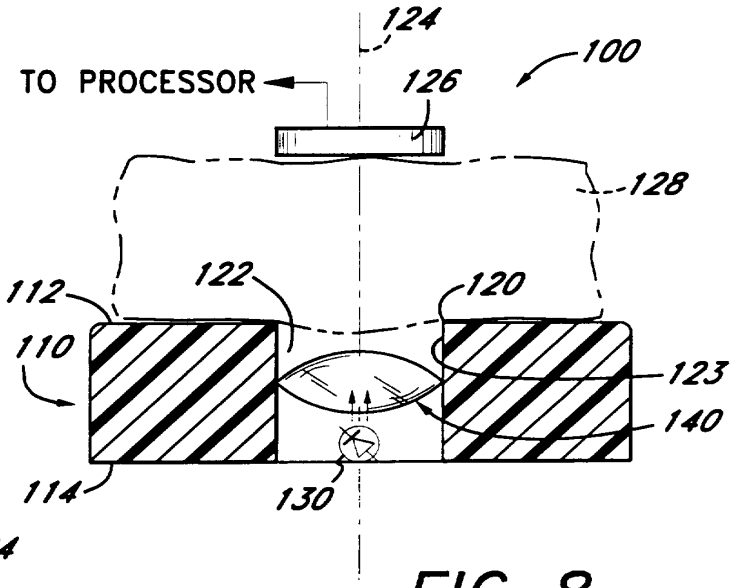


FIG. 8

FIG. 9

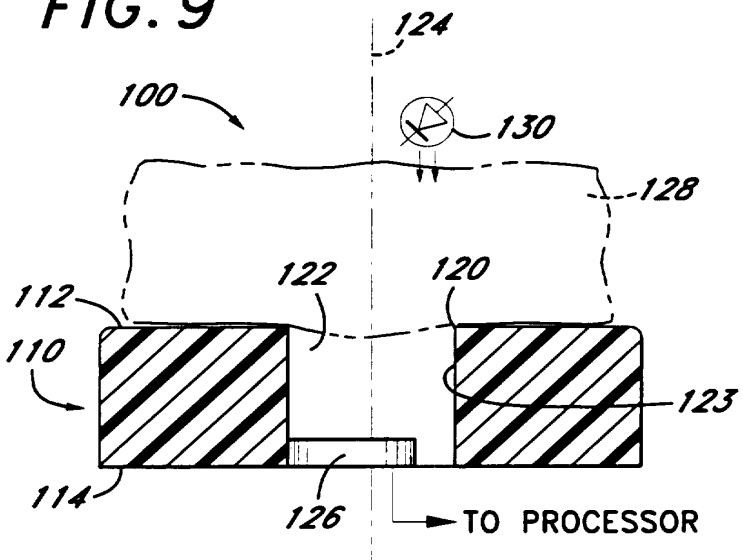


FIG. 10

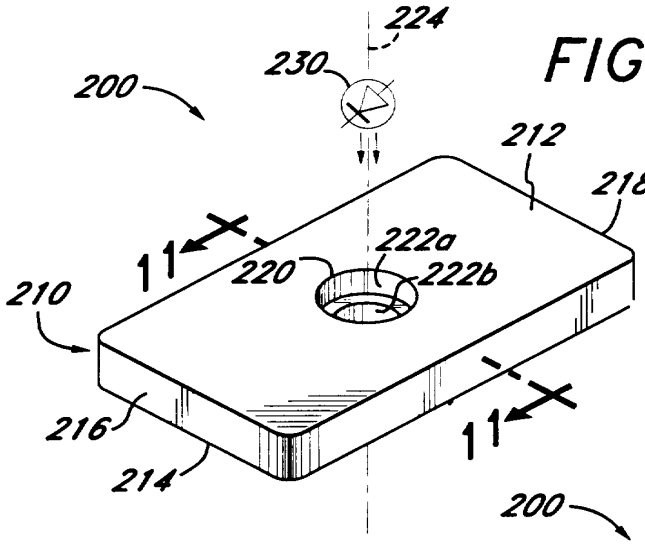
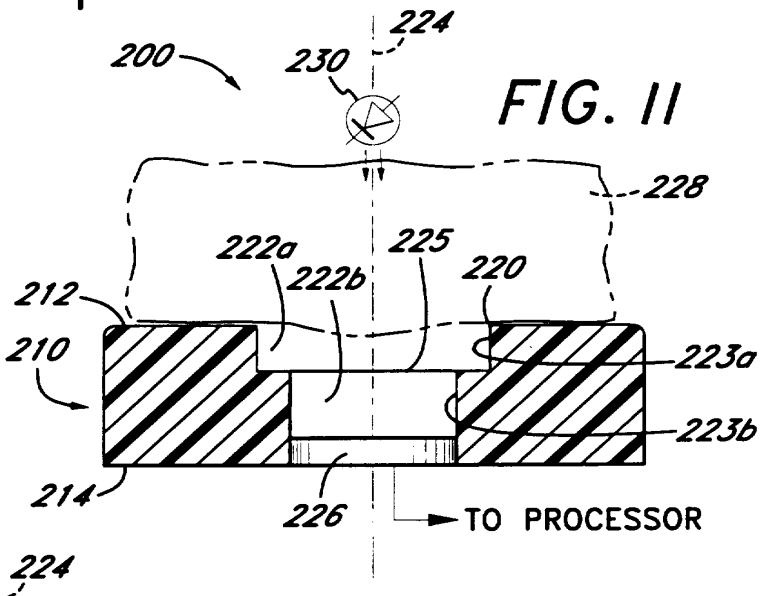


FIG. 11



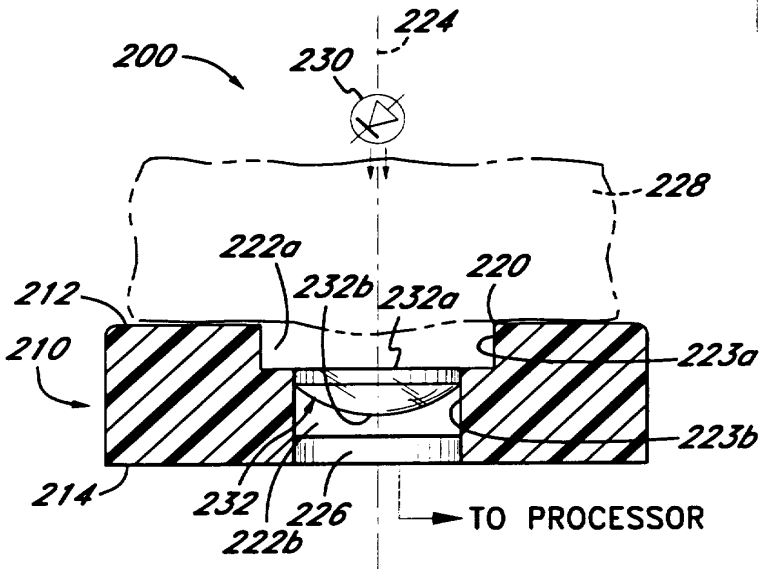


FIG. 12

FIG. 13

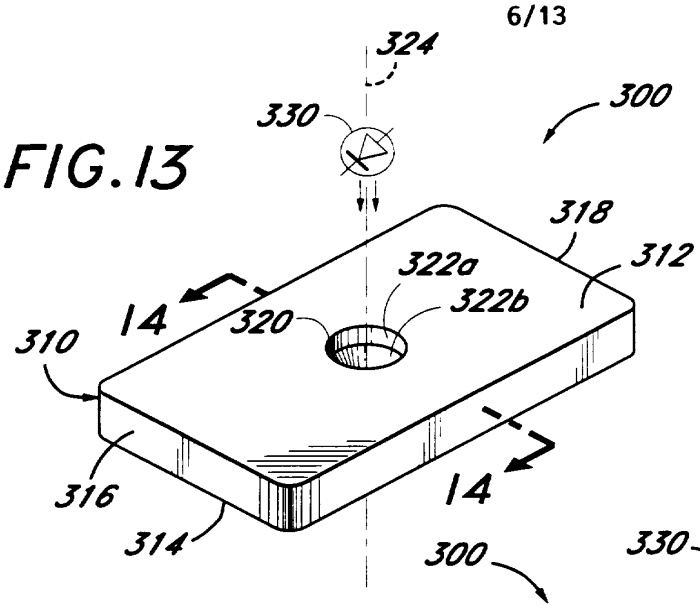


FIG. 14

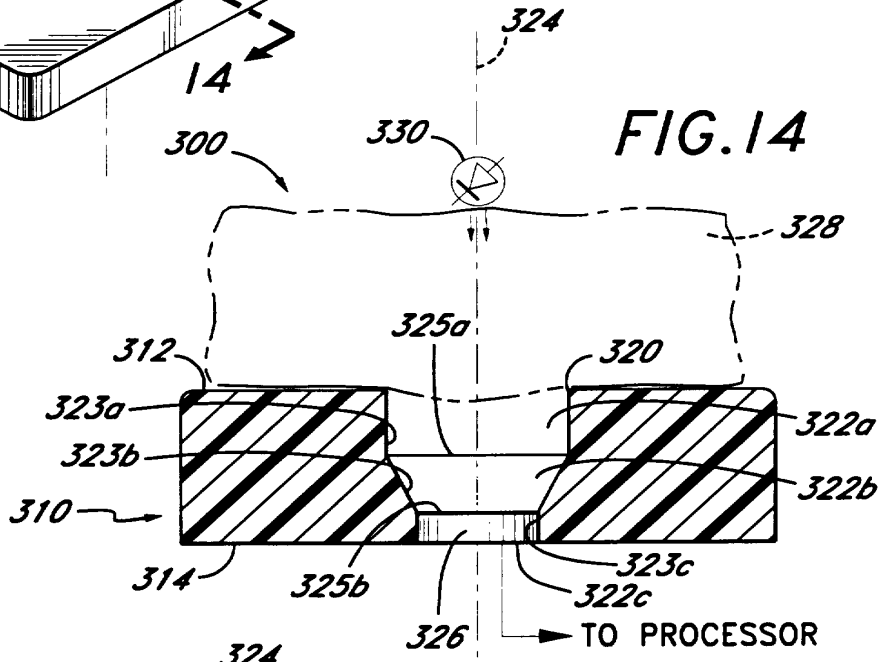


FIG. 15

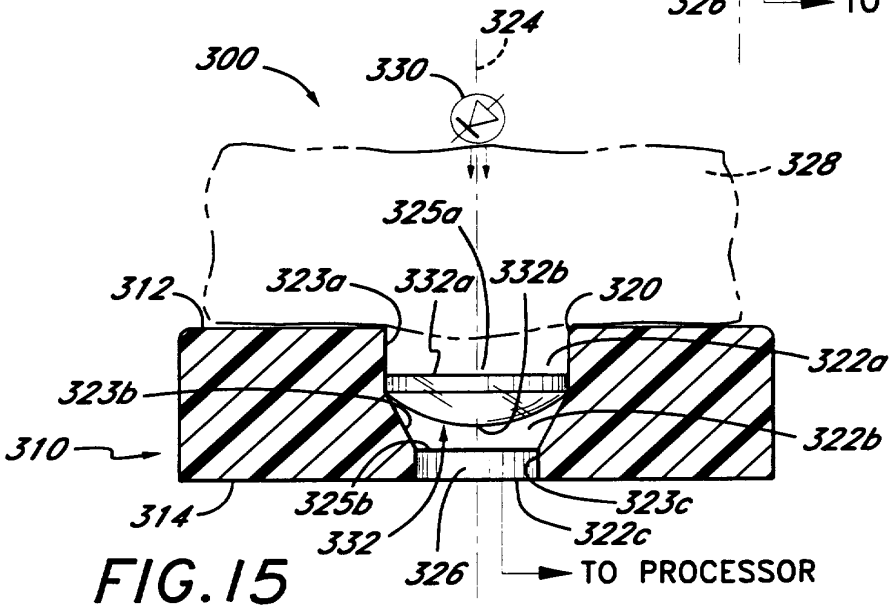
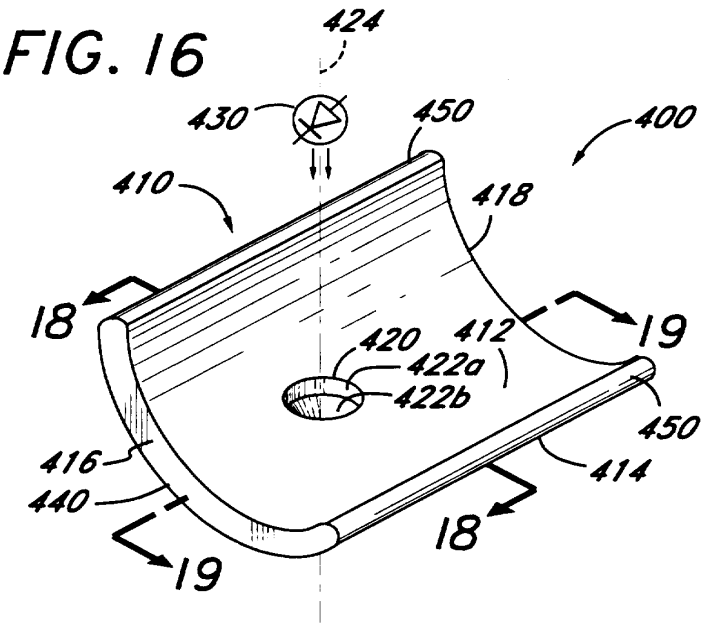


FIG. 16



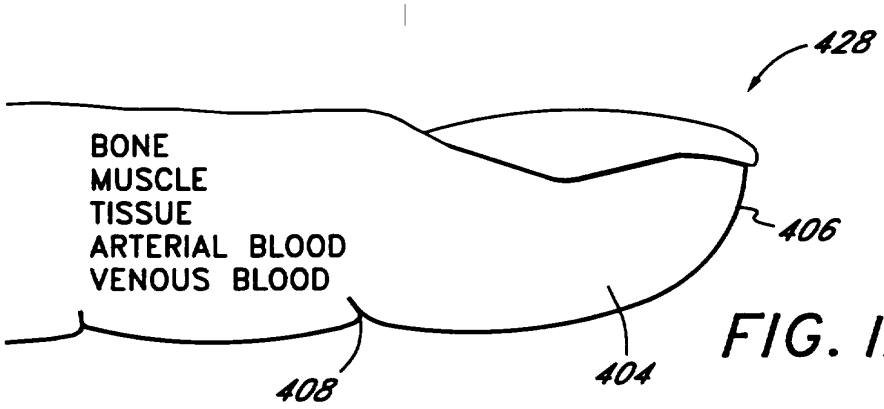


FIG. 17

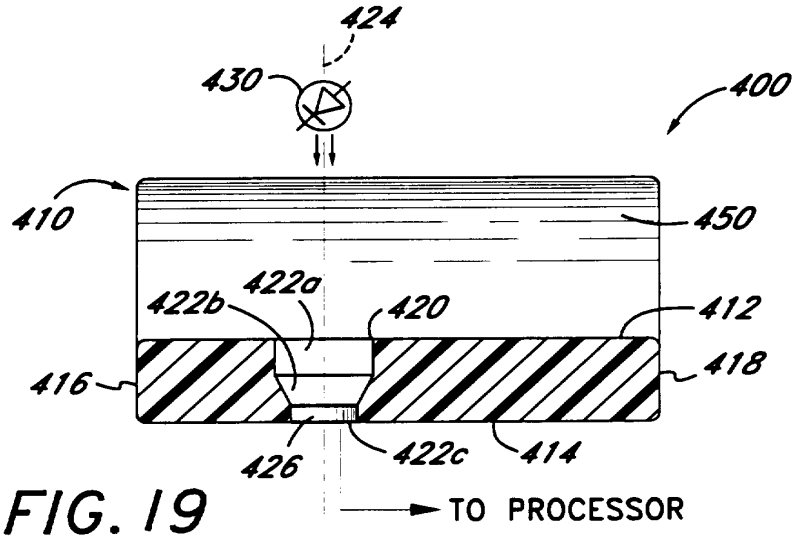


FIG. 19

FIG. 18

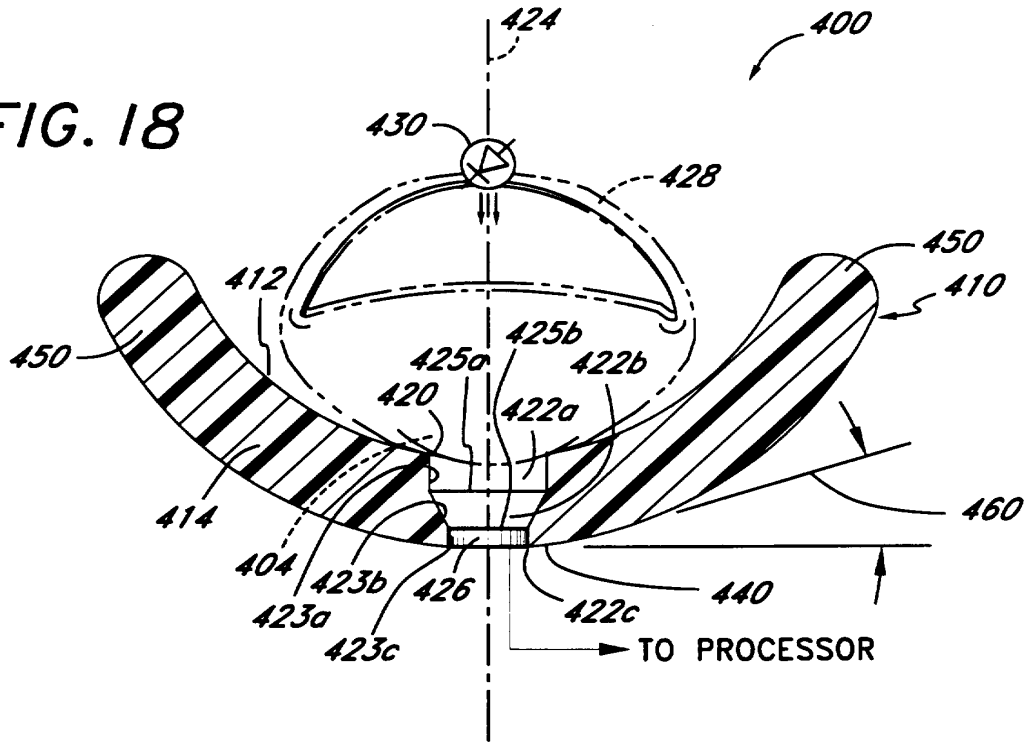

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TO PROCESSOR

FIG. 20

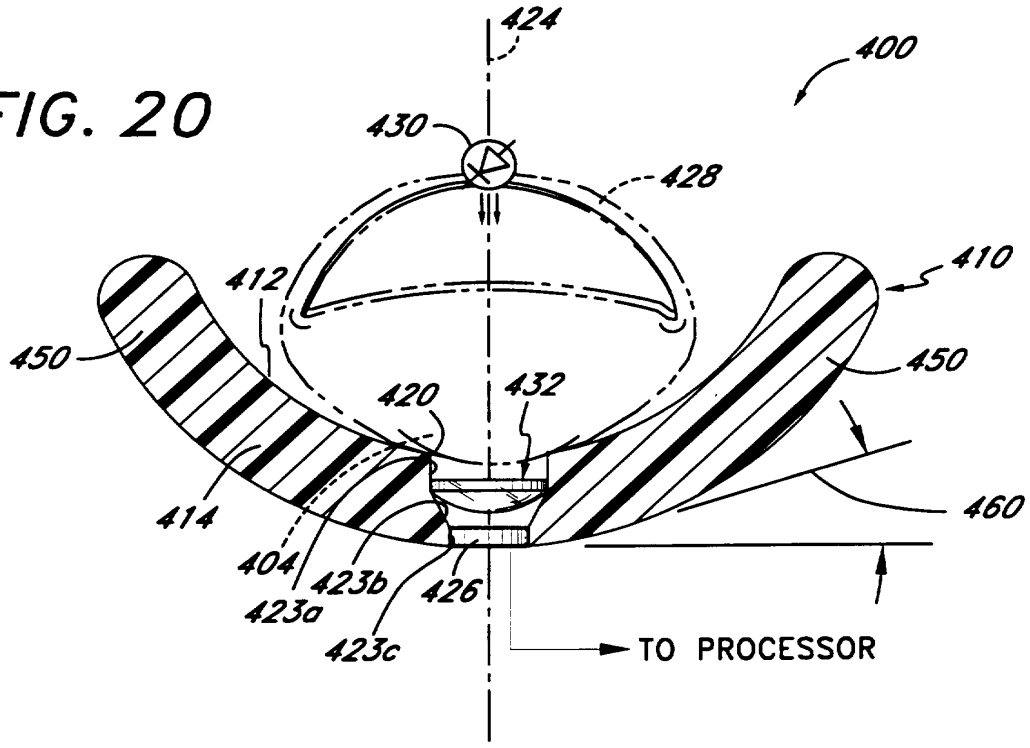

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450
450
420
432
460
414
404
423b
426
423a
423c
TO PROCESSOR

FIG. 21

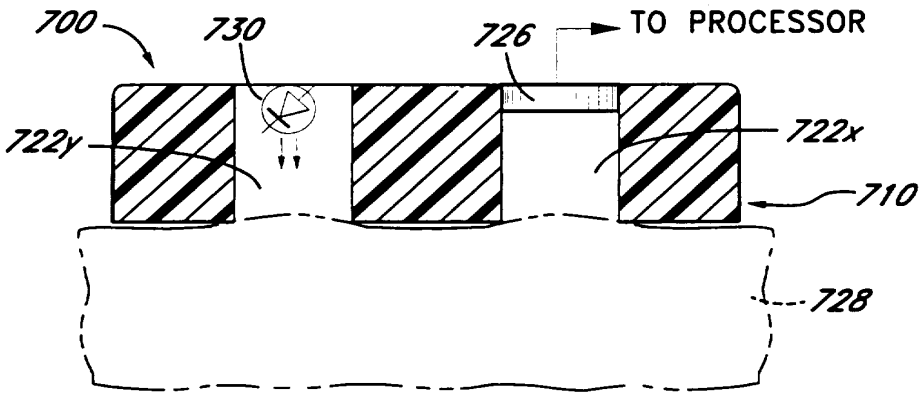


FIG. 22

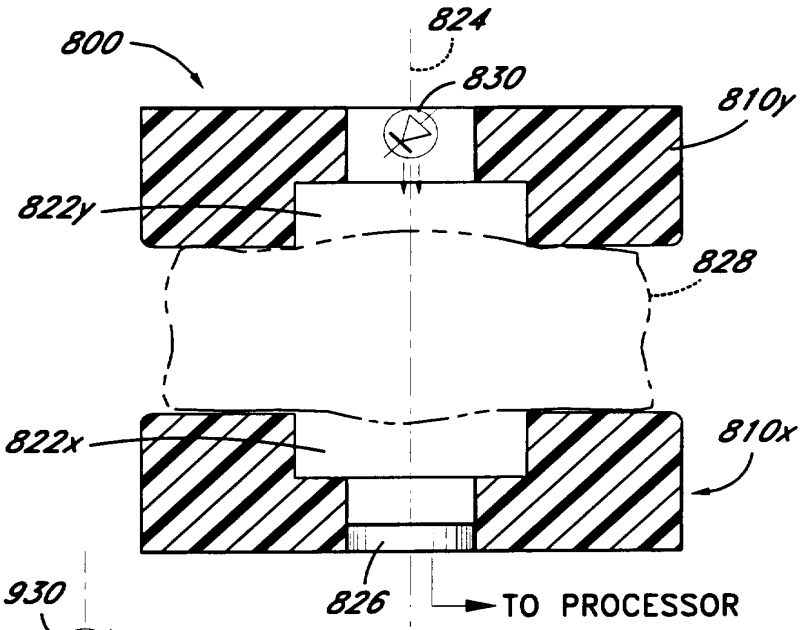
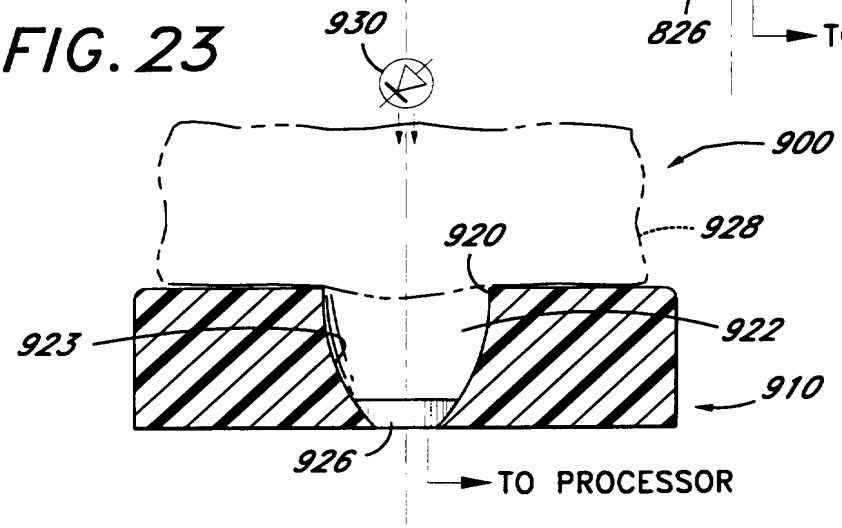


FIG. 23



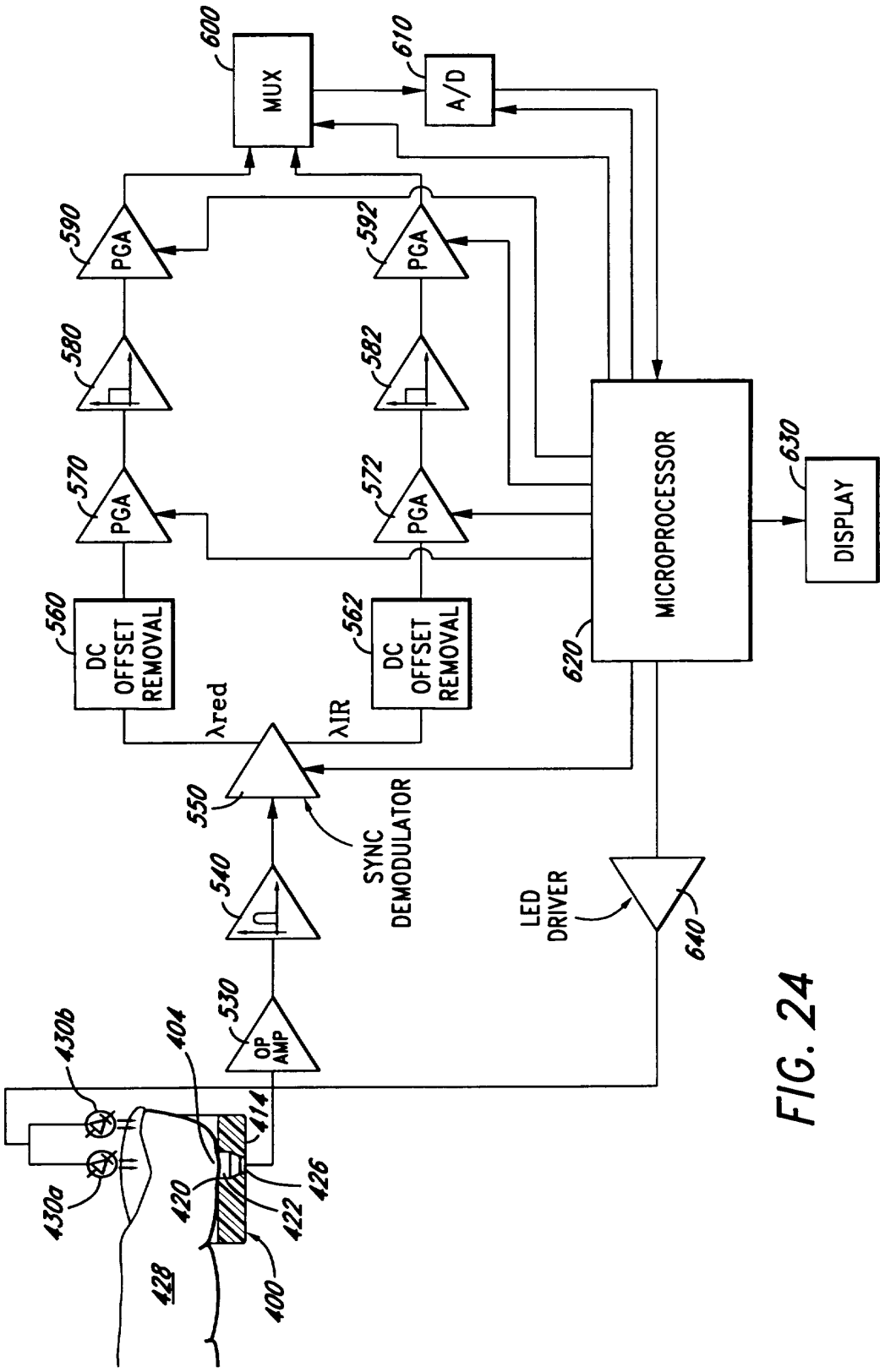

600
MUX
610
A/D
590
PGA
592
PGA
580
582
570
PGA
572
PGA
560
DC OFFSET REMOVAL
562
DC OFFSET REMOVAL
620
MICROPROCESSOR
630
DISPLAY
λred
λIR
550
SYNC DEMODULATOR
540
LED DRIVER
640
530
OP AMP
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406
414
426
420
422
428
400
430a

FIG. 24

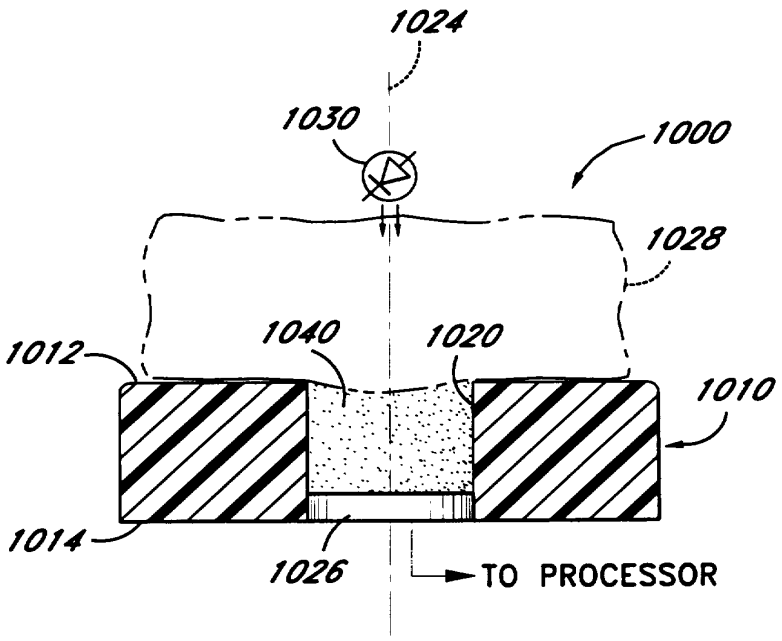

1024
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TO PROCESSOR

FIG. 25

FIG. 26

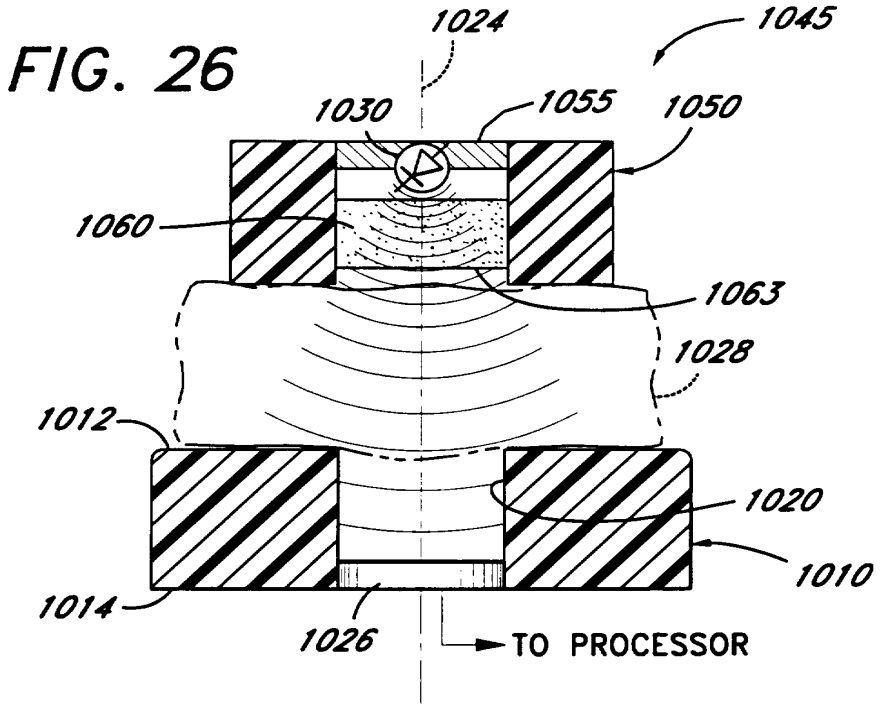
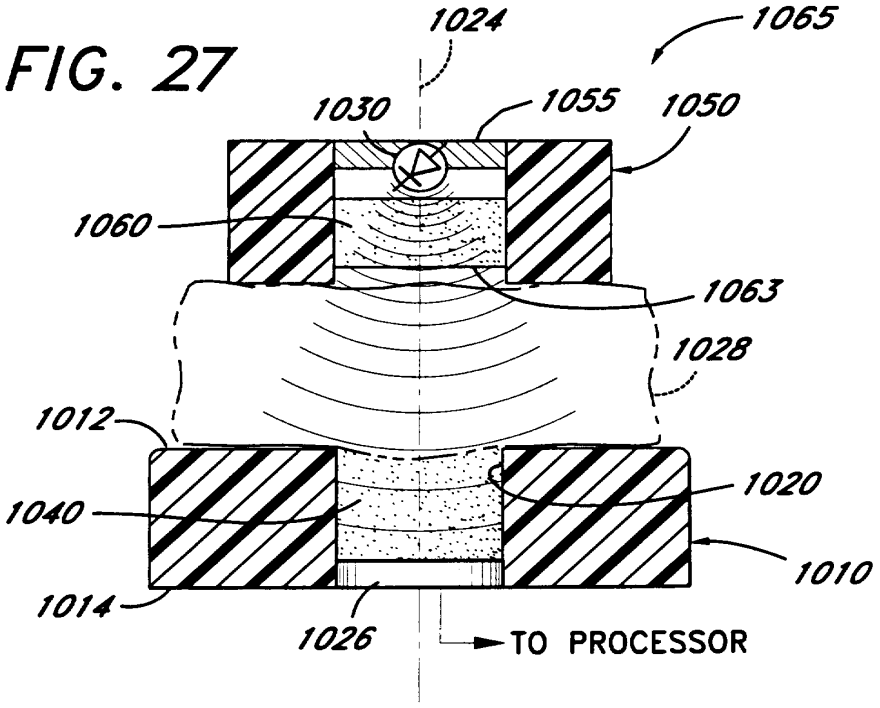

1024
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TO PROCESSOR

FIG. 27


1024
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TO PROCESSOR

13/13

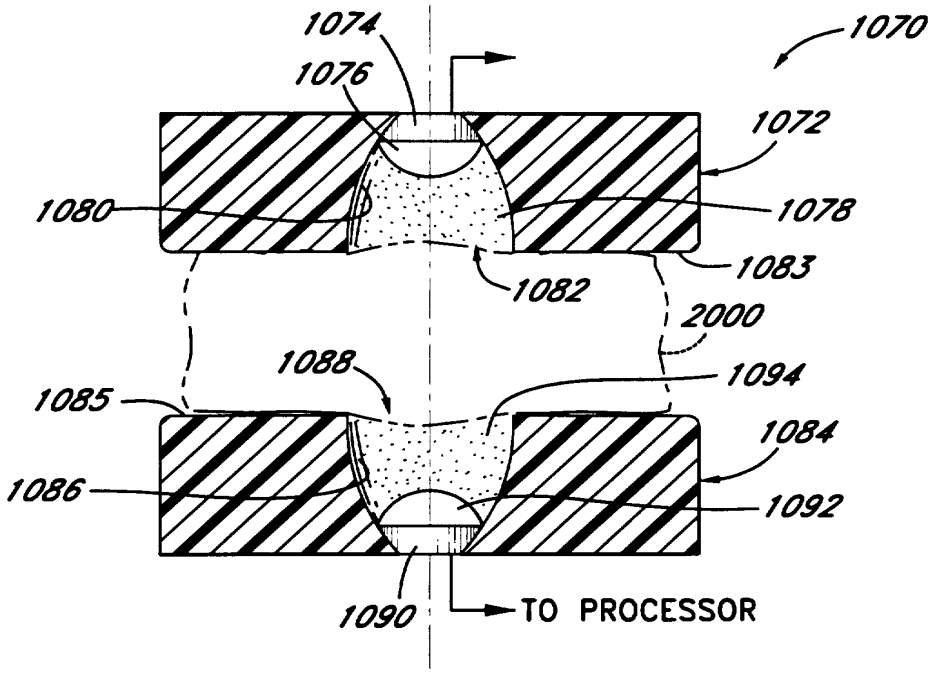

1074
1076
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1080
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1083
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2000
1088
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1085
1084
1086
1092
1090
TO PROCESSOR

FIG. 28

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 95/14785

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,92 16142 (VITAL SIGNALS) 1 October 1992 see the whole document	32-38, 43-63
Y		1-5, 8-13,15, 17,20, 22,24, 30,39-42

-/--

[X] Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search	Date of mailing of the international search report
5 March 1996	13.03.96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Thomas, R.M.

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INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 95/14785

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE,A,37 11 272 (HATSCHEK) 22 October 1987 see column 4, line 48 - line 55 see column 6, line 38 - line 41	1-5, 8-13,15, 17,20, 22,24, 30,39-42
A	see column 7, line 1 - line 9; figure 2	6,7,14, 18,19, 28,32, 43,53, 55,58

A	US,A,4 380 240 (JÖBSIS) 19 April 1983 cited in the application see column 6, line 27 - line 32; figure 1	6,7,14, 18,19,28

A	EP,A,0 329 196 (NELLCOR) 23 August 1989 see page 4, line 37 - line 40; figure 3	1,17,22, 32,43-63

A	US,A,5 224 478 (SAKAI) 6 July 1993 see column 3, line 10 - line 49; figure 1	1,17,22, 32,43-63

A	US,A,4 414 980 (MOTT) 15 November 1983 see column 2, line 65 - column 3, line 7 see figure 1	1,17,22, 32,43-63

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/US 95/14785

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9216142	01-10-92	AU-B-	664175	09-11-95
		AU-B-	1569192	21-10-92
		CA-A-	2105681	22-09-92
		EP-A-	0576560	05-01-94
		JP-T-	6505903	07-07-94
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		US-A-	4890619	02-01-90
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		EP-A,B	0104772	04-04-84
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		JP-C-	1790905	29-09-93
		JP-B-	3055129	22-08-91
		JP-A-	59064031	11-04-84
		US-A-	4770179	13-09-88
		US-A-	4621643	11-11-86
		US-A-	4700708	20-10-87
US-A-5224478	06-07-93	NONE		
US-A-4414980	15-11-83	NONE		

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(74) Agent: HAUFF, Charles, F., Jr.; Snell & Wilmer, One Arizona Center, 400 East Van Buren, Phoenix, AZ 85004-0001 (US).

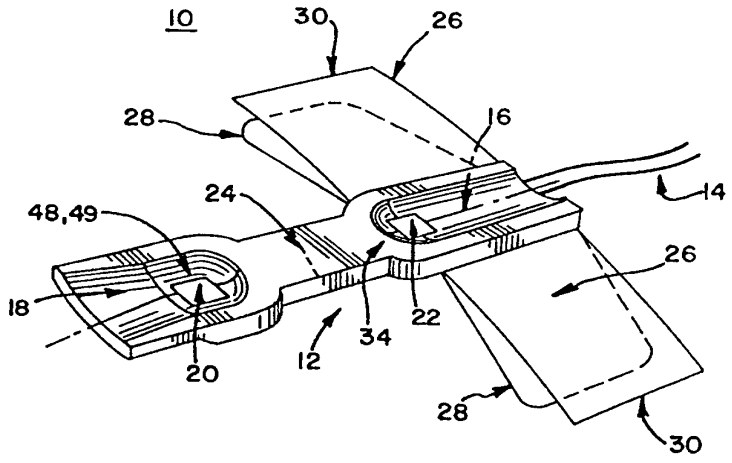
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TT, UA, UG, UZ, VN, ARIPO patent (KE, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
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(54) Title: APPARATUS FOR DETERMINING SPECTRAL ABSORPTION

(57) Abstract

An apparatus for determining spectral absorption by a specific substance in a fluid having an energy source (48, 49), a sensor (34), an interface device, a support structure, and a connector (14). The energy source (48, 49) directs energy having a predetermined wavelength into the fluid. The sensor (34) produces an electrical output reflecting the energy it senses and indicative of the sprectral absorption of the specific substance. The interface device generates a reference voltage to allow the apparatus to cooperate with prior art devices. A support structure secures the other elements in proximity to the fluid. The connector (14) communicates electrical signals to a remote display device.



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APPARATUS FOR DETERMINING SPECTRAL ABSORPTION

TECHNICAL FIELD OF THE INVENTION

The present invention is generally directed to an apparatus for determining spectral absorption by a particular substance in a fluid. Specifically, the present invention is directed to a probe apparatus for sensing arterial pulse and blood oxygen saturation in a patient.

BACKGROUND OF THE INVENTION

A system is needed for non-invasively monitoring pulse and arterial blood oxygen saturation in a patient. Along with blood pressure, pulse rate and blood oxygen saturation are routinely monitored in a patient undergoing surgery or receiving emergency medical treatment. Blood pressure and pulse rate provide essential information about the functioning of the patient's cardiovascular system. Blood oxygen saturation provides information about the patient's ventilation; thus, blood oxygen saturation is a key indicator of the patient's health, whether the patient is human or another animal.

The chemical composition of blood, including oxygen saturation, can be determined by drawing blood samples and employing well-known chemical analysis techniques. However, a non-invasive technique, in which no blood is drawn, is preferred, since drawing blood from a patient adds additional trauma to the patient. Also, analysis of the blood can be an expensive and time consuming procedure and may require elaborate chemical analysis equipment. Such time and equipment may not be readily available, particularly in the context of a medical emergency at a site remote from a hospital or other health care facility. A better technique uses a non-invasive probe which may be disposed after one or a few uses and is simple and inexpensive to manufacture and use. Using such a non-invasive probe yields routinely required information, such as pulse and blood oxygen saturation, by a simple, routine and portable measurement technique.

One method for non-invasively measuring the blood oxygen content of a patient involves monitoring the color of the blood, as disclosed in U.S. Patent No. 2,414,747 to Kirschbaum for "Method and Apparatus For Controlling the Oxygen Content of the Blood of Living Animals." However, Kirschbaum's sensing apparatus is linked to an additional oxygen administering apparatus which limits its portability. Kirschbaum makes no provision for a disposable probe. Additionally, Kirschbaum's probe must be recalibrated for each use to account for differences in each patient and differences in the lamps used in the probe.

Use of red and infrared light sources in an oximeter is disclosed in U.S. Patent No. 2,640,389 to Liston for "Oximeter." Liston's light sources are gas tubes containing neon and argon which emit light when excited electrically. Such tubes limit the portability and ruggedness of Liston's system. Also, Liston's probe is not practically disposable since the tubes are relatively expensive to produce.

A similar technique using red and infrared light in an oximeter is disclosed in U.S. Patent No. 3,412,729 to Smith for "Method and Apparatus for Continuously Monitoring Blood Oxygeneration, Blood Pressure, Pulse Rate and the Pressure Pulse Curve Utilizing an Ear Oximeter as Transducer." Smith also uses the data derived from the probe to provide blood pressure information. The oximeter of Smith uses a light bulb as a source of red and infrared energy. Use of an expensive, fragile element such as a light bulb limits the ruggedness and disposability of the Smith device and renders it unsuitable, for example, for emergency medical treatment at remote locations.

Infrared light has also been used to measure the concentration of blood analytes. As disclosed in U.S. Patent No. 4,882,492 to Schlager for "Non-invasive Near-infrared Measurement or of Blood Analyte Concentrations," near-infrared light having a wavelength greater than 1800

nanometers (nm) is directed into a body part of a patient and sensed to determine the concentration of analytes such as glucose in the blood. As is well known in the art, however, determination of oxygen saturation is preferably achieved using both red and infrared light energy at wavelengths less than 1000 nm.

The probes of Kirschbaum, Liston, Smith and Schlager are preferably attached to the ear of a patient. U.S. Patent No. 4,865,038 to Rich et al. for "Sensor Appliance for Non-invasive Monitoring" discloses a flexible probe which may be removably attached to a finger or other appendage. This probe has the advantage of providing the ability to conform to the appendage while maintaining secure attachment thereto. For medical procedures involving the head and neck, the ear probe could be inconvenient and create interference with access to the head and neck. The ability to attach the probe to a finger, toe or other appendage provides added flexibility and convenience, allowing the probe to be kept from interfering with other procedures. U.S. Patent No. 4,825,872 to Tan et al. for "Finger Sensor for Pulse Oximetry System" discloses a similar probe which is retained on the finger by means of expansive side panels which expand and contract appropriately to engage the finger.

Rich et al. also disclose the use of solid state devices to generate the red and infrared light energy directed into the patient's blood, and solid state optical sensors to detect light not absorbed by the blood. Specifically, semiconductor light emitting diodes (LEDs) are used because they provide such advantages as small size, ruggedness, ready interface with other solid state circuitry used in the oximeter, long life, and an output having a wavelength that is stable over time.

As is well known in the art, the transmission of light having a wavelength of approximately 660 nm (i.e., red light) through blood is strongly affected by the amount of

oxygenerated hemoglobin present in the blood. As also known in the art, the transmission of light having a wavelength of approximately 940 nm (i.e., infrared light) is not substantially affected by the amount of oxygenated hemoglobin present. By using these phenomena and shining red light and infrared light through the flesh of a patient, the percent saturation of oxygenation in the patient's blood can be determined.

An oximeter according to the present invention determines blood oxygen saturation based on the intensity of light received by an optical sensor and the known wavelength of an LED. The wavelength of the absorbed light defines an extinction coefficient which the oximeter uses in calculating blood oxygen concentration in a manner known in the art. Consequently, the oximeter must be calibrated to the wavelength of the LEDs employed in the probe. However, different wavelengths of LED light require coefficients having different values be employed for determining blood oxygen concentration. That is, if a probe with a first LED having a first wavelength is replaced by a probe with a second LED having a different second wavelength, the oximeter must use a different coefficient in calculating blood oxygen saturation. An oximeter using such a probe must be recalibrated, therefore, whenever a probe is changed, in order to maintain consistency of measurement and accuracy of results.

U.S. Patent No. 4,700,708 to New for "Calibrated Optical Oximeter Probe" addressed the need to recalibrate an oximeter when disposable probes are used. New discloses the technique of including in the probe an encoding means comprising a resistor; the value of the resistor corresponds in a predetermined manner to the wavelengths of the red and infrared LEDs used in the probe. When the probe is manufactured, the LEDs are tested to determine their wavelengths and the appropriate encoding resistor is chosen according to a table. When the probe is connected

to the oximeter, a constant current source contained in the oximeter passes current through the resistor thereby enabling the oximeter to read the resistor's value. The New oximeter then uses a corresponding look up table located in semiconductor memory in the oximeter to determine the appropriate wavelength of the LEDs in the probe and to select the requisite extinction coefficients. By using inexpensive components such as LEDs and a resistor, and by eliminating the need to recalibrate the oximeter when the probe is replaced, New provides a truly disposable probe.

The LEDs described by New are selected from batches having only generally known characteristics. Specifically, the wavelength tolerance of the LEDs is large relative to the range permitted by the oximeter. For example, the manufacturing tolerance of the LEDs might be ± 20 nm. That is, a LED specified by the manufacturer as having a wavelength of 660 nm actually has a wavelength somewhere in the range from 640 nm to 680 nm. To correctly determine the appropriate extinction coefficients and thereby yield correct measurements, the oximeter must effect calculations based on the actual LED wavelengths within a tolerance of less than 5 nm. Consequently, the use of the resistor to encode the wavelength value is a necessary step in providing a disposable probe. Without the resistor present to encode the LED wavelengths, the New oximeter does not function. To minimize the manufacturing cost of the oximeter probe, New provided for the use of low cost LEDs with a large manufacturing tolerance and a resistor to encode the exact values of the LED wavelengths within their tolerance ranges.

Many present oximeter systems typically do not rely on encoding the LED wavelength values. Manufacturing techniques for LEDs have improved so that LEDs having a tight tolerance--as low as ± 2 nm--are inexpensively available. Consequently, the encoding and look up table disclosed in New are not required in competing oximeter

systems. Competing systems specify a center value for the LED wavelengths, as for example, 660 nm and 940 nm, and each conforming probe is then supplied with LEDs having those wavelengths.

In addition, the oximeter probe disclosed by New has several shortcomings. To keep manufacturing cost low, the encoding resistor has a large tolerance and a large temperature coefficient of resistance. At extremes of temperature, the encoding resistor will vary considerably from its nominal value, creating the possibility that incorrect extinction coefficients will be read from the look up table by the oximeter. Oximeter systems are used not only in the controlled environments of operating rooms but, also, in the emergency medical treatment context, in situations of environmental temperature extremes. Consequently, the operating temperature of such a system may range from well below zero degrees Fahrenheit to well over one hundred degrees Fahrenheit. Under such extremes, a more precise means of interfacing the probe to the oximeter is needed.

Also, the probe disclosed by New is subject to noise which may cause incorrect readings. Low frequency noise may be misinterpreted by the oximeter to be pulsatile information. Such noise may have its source in radio frequency radiation propagated through the environment, as from other nearby test equipment, or as a motion artifact, due to movement of the bodily appendage to which the probe is attached.

A probe which avoids the encoding technique disclosed by New also provides manufacturing economies. The use of tight-tolerance LEDs eliminates the need to maintain multiple stocks of different wavelength LEDs. A single bin of devices can be used, reducing storage costs. The necessary step of testing LED wavelengths is eliminated. In addition, the step of matching a resistor to the LED wavelength is eliminated. Using precision LEDs and

eliminating the encoding resistor greatly reduces manufacturing cost and complexity.

Accordingly, there is a need for an oximeter probe which can accurately interface with multiple types of oximeter systems, including those which use an encoding resistor and those which specify a center wavelength value, as well as providing precise measurement characteristics in extreme as well as nominal environments, has reduced sensitivity to noise interference, and which is inexpensive enough to manufacture so as to be economically disposable after one or a few uses.

SUMMARY OF THE INVENTION

The present invention provides an apparatus for determining spectral absorption by a specific substance in a fluid and indicating the spectral absorption to a remote display device. The apparatus of the present invention comprises an energy source which emits energy having one or more characteristic wavelengths; a sensing device for sensing the energy emitted by the energy source and producing an electrical output which represents the spectral absorption of the energy by the substance; an interface device which generates a reference voltage which reference voltage interacts with the remote display device; a support structure for supporting the other elements in proximity to the fluid; and a connector for communicating the electrical output to the remote display device.

In its preferred embodiment, the energy source comprises at least one light emitting diode. Preferably, the energy source emits both red light and infra-red light. Also, in its preferred embodiment, the interface means comprises a voltage regulator.

The present invention further provides a pulse oximeter probe for non-invasively determining vascular oxygen saturation and pulse frequency in a patient. The pulse oximeter probe of the present invention comprises one or more light emitting diodes which direct light having a predetermined wavelength into tissue of the patient; a

sensor which senses the light directed by the light emitting diodes and produces an electrical signal which reflects the amount of energy sensed; a voltage source which generates a substantially constant output voltage, which voltage reflects the predetermined wavelength of the light emitting diodes; and an assembly structure which supports the other elements adjacent the tissue of the patient.

In its preferred embodiment, the light emitting diodes of the pulse oximeter probe of the present invention emit light having wavelengths corresponding to red and infrared light. The voltage source is preferably independent of variations in supply voltage and temperature. In addition, the pulse oximeter preferably includes a connector for communicating the electrical signal from the sensor and the output voltage from the voltage source to a remote display device.

The present invention still further provides a pulse oximeter probe for non-invasively sensing the arterial pulse frequency and percent oxygen saturation of the blood of a living patient and communicating with a display device. The pulse oximeter probe of the present invention comprises one or more light emitting diodes, which are responsive to the display device, which direct light energy into the tissue of the patient, the light energy being partly absorbed by the blood of the patient according to a known extinction coefficient corresponding to the predetermined wavelength and being partly reflected by the blood; a sensor which senses the intensity of light energy from the light emitting diodes and not absorbed by the blood and converts the intensity of the light energy to an electrical signal; a precision voltage regulator means which generates a voltage reflecting the predetermined wavelength and the extinction coefficient, which voltage is substantially independent of variations in temperature or supply voltage and electrical noise, and which voltage cooperates interactively with the display device; a support

structure for detachably supporting the one or more light emitting diodes, the sensor, and the precision voltage regulator adjacent the tissue of the patient; and a connector which communicates the electrical signal and the voltage to the display device.

In its preferred embodiment, the support structure of the pulse oximeter probe of the present invention comprises a structure for attaching the probe to the patient's finger. Preferably, the light emitting diodes are responsive to a control signal from the display device, which control signal is preferably communicated from the display device to the light emitting diodes by means of the connector.

Further objects and features of the present invention will be apparent from the following specification and claims when considered in connection with the accompanying drawings illustrating the preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a pulse oximeter probe employing the preferred embodiment of the present invention.

Fig. 2 is an exploded perspective view of a pulse oximeter probe employing the preferred embodiment of the present invention.

Fig. 3 is a top view of the chassis of a pulse oximeter probe employing the present invention.

Fig. 4 is a side view of the chassis of Fig. 3 taken at section AA of Fig. 3.

Fig. 5 is a top view of the printed circuit board of a pulse oximeter probe employing the preferred embodiment of present invention.

Fig. 6 is a top view of the interface module of a pulse oximeter probe employing the preferred embodiment of the present invention.

Fig. 7 is a schematic diagram of the circuit of a pulse oximeter probe employing the preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 is a perspective view of a pulse oximeter probe employing the preferred embodiment of the present invention. In Fig. 1, pulse oximeter probe 10 includes an assembly 12 and a connector 14. Connector 14 provides electrical connection to the remote pulse oximeter, not shown, as well as mechanical support and strain relief for assembly 12.

Assembly 12 includes first finger locator 16 and second finger locator 18. Finger locators 16 and 18 are depressions formed in assembly 12 which allow probe 10 to grippingly engage a patient's finger. Probe 10 may also engage the patient's toe or other bodily appendage. Assembly 12 is preferably formed of a flexible material which is impervious to dirt and grease and which may be readily wiped clean with water or alcohol, such as Alcryn, sold by DuPont Corp.

In Fig. 1, assembly 12 is shown in its stored, unflexed position. In use, assembly 12 preferably flexes along centerline 24. In this manner, first finger locator 16 engages the lower surface of the patient's finger and second finger locator 18 engages the upper surface of the patient's finger. Attached to assembly 12 are tie down tabs 28. The underside of tie down tabs 28 is coated with an adhesive material 30. When probe 10 is not in use, adhesive material 30 is protectively covered by paper strips 26. Paper strips 26 prevent dirt and other contaminants from contacting adhesive material 30. When probe 10 is placed on a patient's finger, assembly 12 is flexed along centerline 24 allowing finger locators 16, 18 to engage the patient's finger. Paper strips 26 are removed, exposing adhesive material 30. Tie down tabs 28 are then folded up so as to secure assembly 12 in place on the patient's finger. Tie down tabs 28 attach to assembly

12 and to one another by means of adhesive material 30. Preferably, probe 10 is held firmly in place on the patient's finger so as to ensure a fit which does not impede blood circulation in the patient's finger. Use of adhesive material 30 allows probe 10 to be reused multiple times on one or more patients before being discarded.

Assembly 12 includes LED mount 20 and sensor mount 22. One or more light emitting diodes 32 are mounted in LED mount 20. Preferably, two light emitting diodes 32, one having a wavelength corresponding to red light and one having a wavelength corresponding to infrared light, are mounted in LED mount 20. An optical sensor 34, sensitive to the wavelengths of light emitted by light emitting diodes 32 mounted in LED mount 20, is mounted in sensor mount 22. Optical sensor 34 preferably converts the intensity of light striking optical sensor 34 into an electrical signal, such as an electrical current.

In operation, probe 10 is fitted to a patient's finger. Light emitting diodes 48, 49 respond to signals communicated by connector 14 from a remote pulse oximeter. Light emitting diodes 48, 49 direct light of a predetermined wavelength into the patient's finger. For example, light emitting diodes 48, 49 might direct red light having a wavelength of 660 nm and infrared light having a wavelength of 2940 nm into the patient's finger. As is well known in the art, some of the light is absorbed by the oxygenerated hemoglobin in the patient's blood. Some of the light is reflected and diffused through the patient's finger and strikes optical sensor 34. Optical sensor 34 produces an electrical signal reflecting the intensity of the light striking optical sensor 34. The electrical signal is communicated by means of connector 14 to the remote pulse oximeter which determines the percent oxygen saturation of the patient's blood and produces an appropriate display.

Fig. 2 is an exploded perspective view of a pulse oximeter probe employing the preferred embodiment of the

present invention. In Fig. 2, chassis 40 forms the base for probe 10. Chassis 40 is preferably molded from a flexible material, such as Alcryn. Printed circuit board 38 is mounted on chassis 40. Printed circuit board 38 is preferably formed of a flexible material such as mylar. Connector 14 is attached to printed circuit board 38. Connector 14 is attached both electrically and mechanically to circuit board 38. Flexible laminate 36 is attached to chassis 40 so as to completely enclose printed circuit board 38. Printed circuit board 38 is thereby protected from contamination.

Fig. 3 is a top view of chassis 40. Fig.- 3 shows light emitting diode mount 20 in line with sensor mount 22 and voltage source mount 42. Light emitting diode mount 20 and sensor mount 22 preferably comprise perforations in chassis 40. Voltage source mount 42 preferably comprises a depression in chassis 40. These provide mechanical clearance for the active circuit components mounted on printed circuit board 38.

Fig. 4 is a side view of chassis 40 in partial section taken at section AA of Fig. 3. Fig. 4 shows curved faces 44, 46 in the upper surface of chassis 40. Curved face 44 is located at first finger locator 16. Curved face 46 is located at second finger locator 18. When probe 10 is in place on a patient's finger, curved faces 44, 46 engage the surface and edges of the finger to prevent lateral slippage.

Fig. 5 is a top view of printed circuit board 38 of a pulse oximeter probe employing the present invention. Fig. 5 shows preferred dimensions of printed circuit board 38. Traces 52 are located on the surface of printed circuit board 38 and are preferably formed of a flexible or malleable electrical conductor such as copper. When probe 10 is in use, traces 52 are in electrical contact with connector 14, not shown. Traces 52 carry electrical signals, power supply voltages and ground potential between the active components of probe 10 and connector 14. Fig. 5

also shows light emitting diodes 48, 49 mounted on printed circuit board 38. Light emitting diodes 48, 49 are fixedly attached to printed circuit board 38, for example, by eutectic bonding. Preferably, light emitting diodes 48, 49 emit light having a wavelength corresponding to red light and light having a wavelength corresponding infrared light. Also, Fig. 5 shows sensor mount 22 and module mount 50 on printed circuit board 38.

Fig. 6 is a top view of interface module 54 of a pulse oximeter probe employing the preferred embodiment of the present invention. Interface module 54 is rigidly attached to printed circuit board 38 at module mount 50, for example, by eutectic bonding. Voltage regulator 56 is mounted on interface module 54. Voltage regulator 56 is preferably configured as an integrated circuit.

Interface module 54 also includes resistor 58 and resistor 60. Resistors 58, 60 are preferably formed from conductive ink printed on the surface of interface module 54. When interface module 54 is assembled and tested, resistors 58, 60 may preferably be trimmed to a precise value. Laser trimming ensures that resistors 58, 60 have a manufacturing tolerance of ± 1%. Interconnect metal 62 is located on the surface of interface module 54 and connects resistors 58, 60 and voltage regulator 56.

In the embodiment illustrated in Fig. 6, interface module 54 includes IN terminal 64, OUT terminal 66, ADJUST terminal 68, SENSE terminal 70, VOUT terminal 72 and ground connection terminal 73. These terminals 64, 66, 68, 70, 72, 73 connect to printed circuit board 38. Voltage regulator 56 is connected to these terminals 64, 66, 68, 70, 72, 73 by wire bonds 74.

Fig. 7 is a schematic diagram of the circuit of a pulse oximeter probe employing the preferred embodiment of the present invention. In Fig. 7, terminals 78, 80, 82, 84, 86 are coupled to connector 14. Fig. 7 shows light emitting diodes 48, 49, optical sensor 34, voltage regulator 56, resistors 58, 60 and capacitor 76. Light

emitting diodes 48, 49 are coupled between terminals 78, 80 and terminal 86. Optical coupler 30 is coupled between terminal 82 and terminal 86. Terminal 88 is preferably coupled to IN terminal 64 of interface module 54 (see Fig. 6). Terminal 84 is preferably coupled to OUT terminal 66 of interface module 54 (Fig. 6). Terminal 84 is preferably coupled to ground connection 73 of interface module 54 (Fig. 6). Terminal 86 is preferably coupled to system ground. In the preferred embodiment illustrated in Fig. 7, terminal 88 is coupled to a system voltage (not shown) preferably in the range of 0 to 5 volts.

Capacitor 76 filters low and high frequency electrical noise from the output voltage generated at terminal 84. Such noise may have its source in radio frequency radiation caused by other nearby test equipment or as a motion artifact, as when probe 10 is attached to a moving patient, such as an infant, causing the probe to move in relation to the patient.

In the preferred embodiment, voltage regulator 56 is a precision adjustable voltage regulator which preferably provides an output voltage at terminal 84 which is substantially invariant with variations in temperature and supply voltage and maintains these characteristics over an operating range from approximately -55° to approximately +150°C.

In operation, light emitting diodes 48, 49 receive signals from the remote pulse oximeter (not shown in Fig. 7) by means of connector 14. In response, light emitting diodes 48, 49 direct red and infrared light into the tissue of the patient. A portion of the emitted light is absorbed by the oxygenated hemoglobin in the patient's blood. The balance of the light passes through the tissue and is incident on optical sensor 34. Optical sensor 34 senses the intensity of the incident light and generates an electrical signal representing that intensity. The electrical signal is communicated to the remote pulse oximeter via connector 14.

The remote pulse oximeter receives the electrical signals and calculates percent oxygen saturation in a manner known in the art. The calculation includes use of extinction coefficients which are dependent for their value on the wavelength of the incident light. Many commercially available pulse oximeter systems specify standard values for the wavelength of the light to be emitted by the light emitting diodes contained in conforming probes, for example, a red LED having a wavelength of 660 nm and an infrared LED having a wavelength of 904 nm. The oximeter system then uses extinction coefficients corresponding to the specified LED wavelengths to calculate percent oxygen saturation.

Other pulse oximeter systems do not specify a particular LED wavelength for conforming probes but rather specify a range of wavelengths. The probe must then additionally include an encoding means such as a resistor to communicate to the oximeter system the exact values of wavelength of the LEDs assembled with the probe. The pulse oximeter in such a system includes a constant current source which passes current through the encoding resistor, generating a reference voltage which can be read by the pulse oximeter system. The pulse oximeter system uses the reference voltage to determine, from a look up table located in semiconductor memory, the appropriate extinction coefficient. By using this technique, inexpensive LEDs having a wide tolerance, such as ± nm, are inexpensively available. For pulse oximeter systems that specify LED wavelengths, light emitting diodes 48, 49 can be chosen when probe 10 is assembled to correspond to the specified values. In applications in which probe 10 is used with such pulse oximeter systems, voltage regulator 56 does not interfere with the system.

In pulse oximeter systems which permit a range of LED wavelengths to be used and require a reference voltage from the probe to identify the wavelength of LEDs employed in the probe, voltage regulator 56 generates the required

reference voltage and configures probe 10 to interface with the pulse oximeter system. Thus, voltage regulator 56, with resistors 58, 60, generates a precisely regulated voltage at terminal 84 reflecting the wavelengths of light emitting diodes 48, 49. The pulse oximeter system uses the regulated voltage on terminal 84 to determine the appropriate extinction coefficients.

Use of voltage regulator 56 and resistors 58, 60 provides distinct advantages over prior art designs, such as oximeter probes using an encoding resistor. Except for precision resistors, the cost of which would be prohibitively high for manufacturing a competitively priced oximeter probe which could be economically discarded after one or a few uses, resistors generally exhibit great variation in their value with temperature and offer an inacceptably wide tolerance in their specified value.

A pulse oximeter system may be used in providing emergency medical treatment away from a controlled hospital environment, often at extremes of temperature. In such circumstance, the value of a resistor may vary too greatly to reliably accurately establish a reference voltage for an oximeter, thereby causing the wrong extinction coefficients to be employed by the oximeter so that incorrect conclusions may result from measurements taken.

In contrast to such unreliable operation by a resistor, voltage regulator 56 generates a temperature and voltage compensated reference voltage. Resistors 58, 60 may be laser trimmed during manufacturing ensuring accuracy within one percent of a specified value for a reference voltage. Thus, with the present invention, the proper reference voltage is always presented by the probe to the remote pulse oximeter system, thereby assuring correct values for extinction coefficients are employed by the oximeter system. In addition, capacitor 76 filters electrical noise which may appear as false pulsatile information and cause incorrect readings.

It is to be understood that, while the detailed drawings and specific examples given describe preferred embodiments of the invention, they are for the purpose of illustration only, that the apparatus of the invention is not limited to the precise details and conditions disclosed, and that various changes may be made therein without departing from the spirit of the invention which is defined by the following claims.

I claim:

1. An apparatus for determining spectral absorption by a specific substance in a fluid and indicating said spectral absorption to a remote display device, the apparatus comprising:

an energy source, said energy source emitting energy having one or more predetermined wavelengths, said energy being partly absorbed by said fluid in accordance with a known extinction coefficient corresponding to said one or more predetermined wavelengths;

a sensing means for sensing energy emitted by said energy source, said sensing means producing an electrical output representing said spectral absorption;

an interface means for supplying a predetermined reference voltage representing said one or more predetermined wavelengths and said extinction coefficient, said reference voltage cooperatively interacting with said remote display device;

a support means for supporting said energy source, said sensing means and said interface means in proximity to said fluid; and

connector means for communicating said electrical output and said reference voltage to said remote display device.

2. An apparatus for determining spectral absorption as recited in claim 1 wherein said energy source comprises at least one light emitting diode.

3. An apparatus for determining spectral absorption as recited in claim 2 wherein said energy source comprises a first light emitting diode emitting red light and a second light emitting diode emitting infrared light.

4. An apparatus for determining spectral absorption as recited in claim 1 wherein said interface means comprises a voltage regulator.

5. A pulse oximeter probe for non-invasively determining vascular oxygen saturation and pulse frequency in a patient, the pulse oximeter probe comprising:

one or more light emitting diode means for directing light into tissue of said patient, said light having a predetermined wavelength, said light being partly absorbed in accordance with a known extinction coefficient corresponding to said predetermined wavelength;

a sensing means for sensing light directed by said light emitting diode means, said sensing means producing an electrical signal representing the amount of energy sensed;

a voltage source means for supplying a predetermined, substantially constant output voltage, said voltage representing said predetermined wavelength and said extinction coefficient in a predetermined manner; and

an assembly means for cooperatively supporting said one or more light emitting diode means, said sensing means, and said voltage source means adjacent said tissue of said patient.

6. A pulse oximeter probe as recited in claim 5 wherein said one or more light emitting diode means directs light having a wavelength corresponding to red light and a wavelength corresponding to infrared light.

7. A pulse oximeter probe as recited in claim 5 wherein said voltage source means comprises a voltage regulator.

8. A pulse oximeter probe as recited in claim 7 wherein said output voltage is substantially independent of variations in supply voltage and temperature.

9. A pulse oximeter probe for non-invasively sensing the arterial pulse frequency and percent oxygen saturation of the blood of a living patient and communicating with a display device, the pulse oximeter probe comprising:

one or more light emitting diodes responsive to a control signal from said display device for directing light energy into the tissue of said patient, said light energy having a predetermined wavelength, said light energy being partly absorbed by the blood of the patient in accordance with a known extinction coefficient corresponding to said

predetermined wavelength and said light energy being partly reflected by said blood;

a sensor which senses the intensity of light energy directed by said one or more light emitting diodes and not absorbed by said blood, and converts said intensity of light energy to an electrical signal;

a precision voltage regulator cooperating interactively with said display device, said regulator supplies a predetermined voltage representing said predetermined wavelength and said extinction coefficient, said voltage being substantially independent of variations in temperature or supply voltage and electrical noise and said voltage;

a support which detachably supports said one or more light emitting diode means, said sensing means, and said precision voltage regulator means adjacent said tissue of said patient; and

connector means for communicating said electrical signal and said voltage to said display device.

10. A pulse oximeter probe as recited in claim 9 wherein said connector means further communicates said control signal from said display device to said light emitting diode means.

11. A pulse oximeter probe as recited in Claim 10 wherein said support comprises means for grippingly engaging a finger of said patient.

12. A pulse oximeter probe as recited in Claim 11 comprising a first light emitting diode directing energy having a first wavelength and a second light emitting diode directing energy having a second wavelength.

13. A pulse oximeter probe as recited in Claim 12 wherein said first wavelength corresponds to red light and said second wavelength corresponds to infrared light.

14. A pulse oximeter probe for use with a pulse oximeter, the pulse oximeter producing an indication of vascular oxygen saturation or pulse frequency, or both in a patient responsive to an electrical signal received from

the pulse oximeter probe, the pulse oximeter probe comprising:

an energy source adapted to be coupled with said pulse oximeter, said energy source directing light energy into tissue of the patient, said light energy having at least one predetermined wavelength, said light energy being partly absorbed by said tissue in accordance with at least one extinction coefficient, said at least one extinction coefficient corresponding to said at least one predetermined wavelength, said light energy being partly transmitted through said tissue;

a photodetector adapted to be coupled with said pulse oximeter, said photodetector sensing said transmitted light energy and producing said electrical signal, said electrical signal representing an amount of light energy sensed; and

an encoder adapted to be coupled with said pulse oximeter, said encoder supplying an encoded signal, said encoded signal encoding said at least one predetermined wavelength, said pulse oximeter decoding said encoded signal to determine said at least one extinction coefficient for producing said indication.

15. A pulse oximeter probe as recited in Claim 14 wherein the pulse oximeter probe further comprises a connector for communicating said electrical signal and said encoded signal to said pulse oximeter.

16. A pulse oximeter probe as recited in Claim 15 wherein said encoder comprises a voltage source generating a substantially constant voltage, said voltage having a magnitude corresponding to said at least one predetermined wavelength in accordance with a predetermined relationship.

17. A pulse oximeter probe as recited in Claim 16 wherein said voltage source comprises a voltage regulator, said voltage regulator establishing said magnitude substantially independent of variations in temperature or supply voltage.

18. A non-invasive pulse oximeter probe comprising:

an energy source coupled with said probe, energy source directing light energy into tissue of the patient to be interrogated, said light energy being partly absorbed by said tissue in accordance with at least one extinction coefficient and having at least one predetermined wavelength, said at least one extinction coefficient substantially corresponding to said at least one predetermined wavelength;

a sensor aligned to detect said directed light energy and producing an electrical signal representing the amount of energy detected;

a voltage regulator cooperating with said sensor and supplying a predetermined, substantially constant output voltage representing said predetermined wavelength and said extinction coefficient in a predetermined manner; and

an assembly to which said energy source, said sensor and said voltage regulator are attached.

19. The probe as recited in claim 18 wherein said energy source comprises one or more light emitting diodes.

20. The probe as recited in claim 19 wherein said voltage regulator comprises a precision voltage regulator which supplies a predetermined, substantially constant, voltage representing said predetermined wavelength and said extinction coefficient, said voltage being substantially independent of variations in temperature supply voltage or electrical noise.

FIG. 1

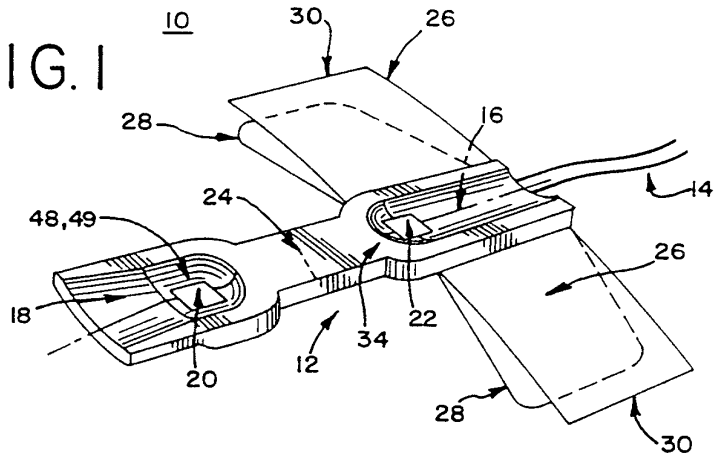
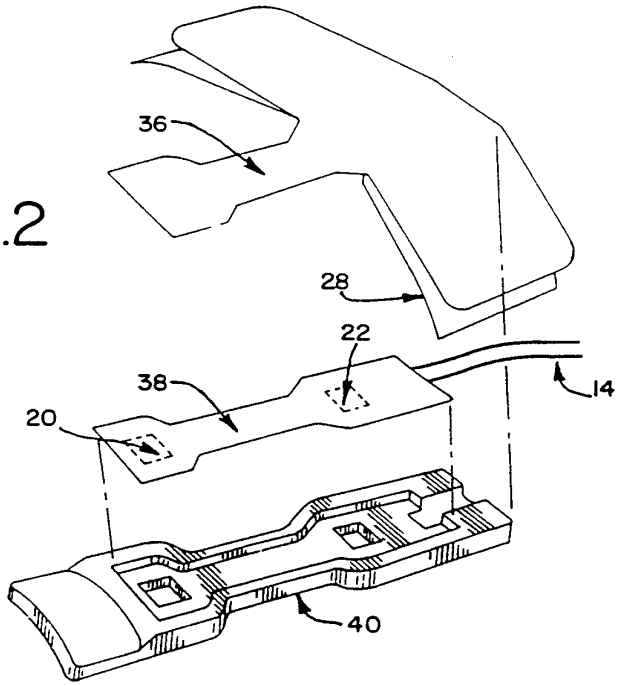


FIG. 2



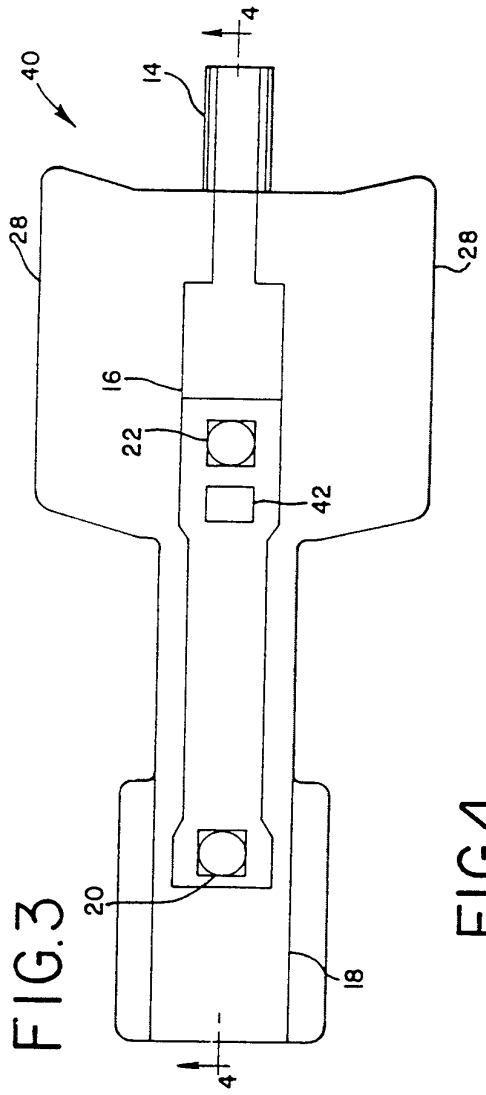


FIG.3

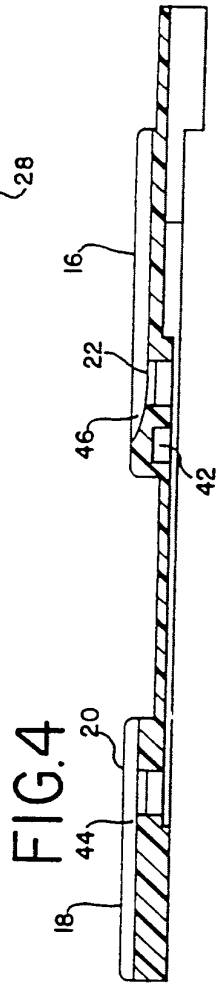


FIG.4

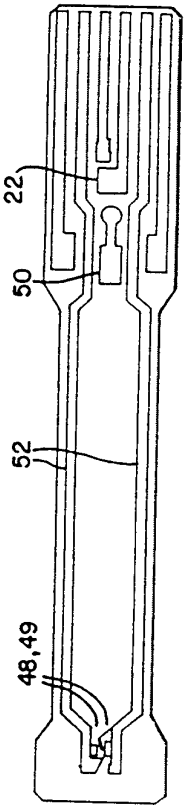


FIG.5

FIG.6

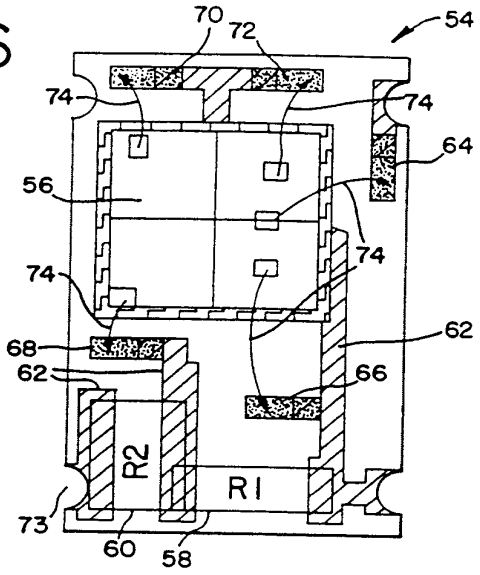
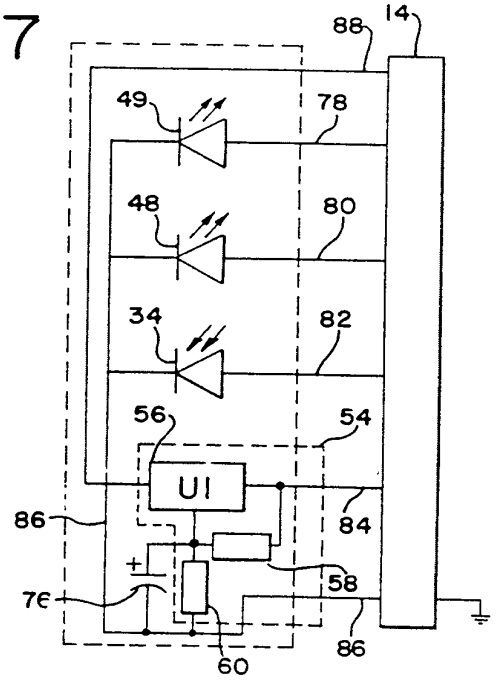

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R2
R1
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FIG.7


88
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/08343

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/00
US CL : 128/633
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/633, 634, 637, 664, 665, 666, 667; 356/39, 40, 41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, 5,058,588 (KAESTLE) 22 OCTOBER 1991, col. 3, line 62 - col. 7, line 38.	1-20
X --- Y	US, 5,069,213 (POLCZYNSKI) 03 DECEMBER 1991, see entire document.	1-7, 14-16 --- 8-13, 17-20
Y	US, 5,209,230 (SWEDLOW ET AL) 11 MAY 1993, col. 3, line 28 - col. 5, line 14.	1-7, 14-16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
11 OCTOBER 1995

Date of mailing of the international search report
13 NOV 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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Washington, D.C. 20231
Facsimile No. (703) 308-0131

Authorized officer
ERIC F. WINAKUR
Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)*

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

KNOBBE, MARTENS, OLSON & BEAR, LLP
Attn. Delaney, Karoline A.
2040 Main Street
Fourteenth Floor
Irvine, CA 92614
ETATS-UNIS D'AMERIQUE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference MLR.015VPC	Date of mailing *(day/month/year)* 12/08/2008 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2008/058327	International filing date *(day/month/year)* 26/03/2008
Applicant MASIMO LABORATORIES, INC.	

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

   For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Norbert Hiesch

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims,description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
MLR.015VPC		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2008/058327	26/03/2008	27/03/2007
Applicant		
MASIMO LABORATORIES, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   [X] the international application in the language in which it was filed

   [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   [X] the text is approved as submitted by the applicant

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 12A

   [X] as suggested by the applicant

   [ ] as selected by this Authority, because the applicant failed to suggest a figure

   [ ] as selected by this Authority, because this figure better characterizes the invention

   b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/058327

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96/13208 A (MASIMO CORP [US]) 9 May 1996 (1996-05-09) page 19, line 31 - page 23, line 15 figures 26-28	1,9,16, 17
Y		2,3, 10-13, 18-20
A		4-8,14, 15

Y	JP 2003 084108 A (KEIWA INC) 19 March 2003 (2003-03-19) paragraphs [0027], [0028], [0035], [0046] figures 1,2,3b	2,3, 10-13, 18-20

	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 July 2008	12/08/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Doyle, Aidan

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/058327

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 2005 253478 A (CITIZEN WATCH CO LTD) 22 September 2005 (2005-09-22) paragraph [0017] figure 4	1,16,17
Y		2,3, 18-20
A		4-15
A	WO 02/26123 A (INSTRUMENTATION METRICS INC [US] SENSYS MEDICAL INC [US]) 4 April 2002 (2002-04-04) the whole document	9,11,12, 17
A	US 2003/116769 A1 (SONG KYUNG SUB [KR] ET AL) 26 June 2003 (2003-06-26) the whole document	9,11,12, 17
A	US 6 861 641 B1 (ADAMS RICH [US]) 1 March 2005 (2005-03-01) the whole document	9,11,12, 17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/058327

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9613208	A	09-05-1996	AT	195409 T	15-09-2000
			AU	4236596 A	23-05-1996
			DE	69518434 D1	21-09-2000
			DE	69518434 T2	25-01-2001
			EP	0790800 A1	27-08-1997
			JP	3576168 B2	13-10-2004
			JP	10509352 T	14-09-1998
			JP	2004113814 A	15-04-2004
			US	5782757 A	21-07-1998
			US	6088607 A	11-07-2000
JP 2003084108	A	19-03-2003	NONE		
JP 2005253478	A	22-09-2005	WO	03077761 A1	25-09-2003
WO 0226123	A	04-04-2002	AU	9625901 A	08-04-2002
			US	2002041166 A1	11-04-2002
US 2003116769	A1	26-06-2003	DE	10227515 A1	10-07-2003
			JP	2003197974 A	11-07-2003
			KR	20030053853 A	02-07-2003
US 6861641	B1	01-03-2005	NONE		

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2008/058327	26.03.2008	27.03.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/00

Applicant
MASIMO LABORATORIES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Doyle, Aidan Telephone No. +49 89 2399-2342

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-15,17-20
	No:	Claims	1,16
Inventive step (IS)	Yes:	Claims	4-8,14-15
	No:	Claims	2,3,9-13,17-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1. Reference is made to the following documents:

D1: WO 96/13208 A (MASIMO CORP [US]) 9 May 1996 (1996-05-09)
D2: JP 2005 253478 A (CITIZEN WATCH CO LTD) 22 September 2005 (2005-09-22)
D3: WO 02/26123 A (INSTRUMENTATION METRICS INC [US] SENSYS MEDICAL INC [US]) 4 April 2002 (2002-04-04)
D4: US 2003/116769 A1 (SONG KYUNG SUB [KR] ET AL) 26 June 2003 (2003-06-26)
D5: US 6 861 641 B1 (ADAMS RICH [US]) 1 March 2005 (2005-03-01)
D6: JP 2003 084108 A (KEIWA INC) 19 March 2003 (2003-03-19)

2. LACK OF NOVELTY OF INDEPENDENT CLAIMS 1 AND 16

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claims 1 and 16 is not new in the sense of Article 33(2) PCT.

2.1 LACK OF NOVELTY OF INDEPENDENT CLAIM 1

The subject-matter of claim 1 is not novel (Article 33(2) PCT), because document D1 discloses (the references in parentheses applying to this document) a physiological sensor comprising an emitter that emits light having a plurality of wavelengths (see LED (1030) in lines 7 - 17, page 20, line 7, page 21, figs. 26, 27); a detector that generates an output signal responsive to the emitted light after absorption by tissue (see photodetector (1026) on line 7, page 20, figs. 26, 27); an attachment assembly that removably attaches the emitter and the detector to tissue (see transmission assembly (1050) and base (1010) on line 33, page 19, figs. 26, 27); a spacer that provides a predetermined gap between the emitter and tissue when the emitter is attached to the tissue (see transmission assembly (1050) in conjunction with backing (1055) on lines 7, 8, page 21, figs. 26, 27); a light scattering medium disposed in a

optical between the emitter and tissue (see scattering medium (1060) on line 8, page 21, figs. 26, 27); the spacer and the light scattering medium providing at least a substantially uniform illumination of tissue by the emitted light for each of the wavelengths (see lines 12 - 15, page 21). Therefore, D1 discloses the combination of features in claim 1, whose subject-matter is accordingly not new (Article 33(2) PCT).

2.2 LACK OF NOVELTY OF INDEPENDENT CLAIM 16

The subject-matter of claim 16 is not novel (Article 33(2) PCT), because document D1 discloses a physiological sensor comprising a light source that radiates light having a plurality of wavelengths (see LED (1030) in lines 7 - 17, page 20, line 7, page 21, figs. 26, 27); a diffuser that scatters the radiated light so that a tissue site is uniformly illuminated across all of the wavelengths (see scattering medium (1060) on line 8, page 21, lines 12 - 15, page 21, figs. 26, 27); and at least one detector that generates a sensor signal responsive to the radiated light after tissue attenuation (see photodetector (1026) on line 7, page 20, figs. 26, 27). Therefore, D1 discloses the combination of features in claim 16, whose subject-matter is accordingly not new (Article 33(2) PCT).

2.3 Document D2 also deprives the subject-matter of independent claims 1 and 16 of novelty (Article 33(2) PCT), because it too discloses emitters / light source (21 - 23), a detector (24), a spacer (27) and a light scattering medium / diffuser (25) in paragraph [0017], fig. 4.

3 LACK OF INVENTIVE STEP OF INDEPENDENT CLAIM 9

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 9 is not inventive in the sense of Article 33(3) PCT for the following reasons:

The document D1 is regarded as being the closest prior art to the subject-matter of claim 9 and discloses (the references in parentheses applying to this document) a physiological sensor comprising an emitter configured to radiate light having a

plurality of wavelengths into a tissue site; the emitter comprising a plurality of LEDs (see LED (1030) on line 7, page 21, plurality of LEDs in lines 34 - 36 on page 22, figs. 26, 27); a detector configured to receive the light after absorption by pulsatile blood flow within the tissue site (see photodetector (1026) on line 20, figs. 26, 27); the detector generates a sensor signal capable of being processed by a patient monitor so as to derive total hemoglobin (see lines 19, 20 on page 18); the detector comprises a plurality of photodiodes (see photodetector (1026) on line 20, plurality of photodetectors in lines 34 - 36 on page 22, figs. 26, 27) and a first set of the photodiodes is responsive to a first set of the wavelengths and a second set of the photodiodes is responsive to a second set of the wavelengths (all photodetectors are responsive to a plurality of wavelengths emitted by the source (1030) and therefore may be divided into any number of photodiode sets which are responsive to sets of wavelengths).

The subject-matter of claim 9 therefore differs from this known physiological sensor in that the plurality of LEDs and photodiodes are disposed within ceramic substrates. The problem to be solved by the present invention may therefore be regarded as how to choose an appropriate carrier material for the LED and photodiode arrays. The use of ceramic substrates for both LED and photodiodes arrays is well known in the art (see lines 4 - 9, on page 9, fig. 2a, claim 7 of D3, see paragraph [0049], fig. 8 of D4, see column 2, lines 8 - 12, fig. 1 of D5 for examples of LED and photodiode arrays using ceramic substrates). Consequently, their deployment here represents merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. Therefore, the subject-matter of claim 9 cannot be considered to involve an inventive step in view of the combination of D1 and the knowledge of a skilled person.

4. LACK OF INVENTIVE STEP OF DEPENDENT CLAIMS 2, 3, 10 - 13 AND 17 - 20

The subject-matter of claims 2, 3, 10 - 13 and 17 - 20 is not inventive within the meaning of Article 33(3) PCT.

- re claim 2: see binder (4) in paragraph [0027], silica light diffusion agent (5) in paragraph [0046], figs. 1, 2 of D6.
- re claim 3: see epoxy-based binder (4) in paragraph [0028], light diffusion agent microspheres (5) in paragraph [0035] of D6.
- re claim 10: see scattering medium (1060) on line 8, page 21, lines 12 - 15, page 21, figs. 26, 27 of D1.
- re claim 11: see figs 2, 3b of D6.
- re claim 12: The choice of the active material for a photodiode such that it matches the emitter is well known in the art. Therefore, using Si and InGaAs photodiodes, though not explicitly disclosed in document D1, is unable to confer an inventive step to the subject-matter of claim 12 (Article 33(3) PCT).
- re claim 13: see LED (1030) on line 7, page 21, plurality of LEDs in lines 34 - 36 on page 22, figs. 26, 27 of D1. Each of said LEDs radiate light generally centered around at least 12 unique wavelengths.
- re claim 17: see LED (1030) on line 7, page 21, plurality of LEDs in lines 34 - 36 on page 22, figs. 26, 27 of D1;
  or see source (21 - 23), diffuser (25), detector (24) in paragraph [0017], fig. 4. of D2;
  see argumentation regarding ceramic substrates in section 3.
- re claim 18: see binder (4), light diffusion agent (5) in paragraphs [0027], [0028], [0035], [0046] of D6.
- re claim 19: see transmission assembly (1050) and backing (1055) on lines 7, 8, page 21, figs. 26, 27 of D1;
  or see spacer (27) in paragraph [0017], fig. 4. of D2.
- re claim 20: The use of a connector and flexible coupling for communication between a sensor and a monitor is well known in the art. Therefore, this feature, though not explicitly disclosed in documents D1 and D2, does not confer an inventive step to the subject-matter of claim 20 (Article 33(3) PCT).

5. NOVELTY AND INVENTIVE STEP OF DEPENDENT CLAIMS 4 - 8 AND 14 - 15

5.1 DEPENDENT CLAIMS 4 - 8

The subject-matter of dependent claim 4 appears to meet the requirements of PCT with regards to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT) for the following reasons:

The document D2 is regarded as being the closest prior art to the subject-matter of claim 4, and discloses (the references in parentheses applying to this document) a physiological sensor for the calculation of hemoglobin concentration wherein the emitter comprises an array of three LEDs (see (21 - 23) in fig. 4). The subject-matter of claim 4 therefore differs from this known physiological sensor in that the emitter comprises at least eight LEDs emitting light generally centred around eight unique wavelengths. The problem to be solved by the present invention may therefore by regarded as how to further improve the detection performance of the sensor. When faced with this problem the skilled person would not consider it obvious to use at least eight LEDs emitting light generally centred around eight unique wavelengths. Although it is generally known that an increased sampling rate improves the detection of steep slopes in a curve, a negative assessment as to an inventive step of the choice of eight LEDs and eight wavelengths would benefit from hindsight. Accordingly, the subject-matter of claim 4 and its dependent claims 5 - 8 appears to meet the requirements of PCT with regards to both novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

5.2 DEPENDENT CLAIMS 14 - 15

The subject-matter of dependent claim 14 appears to meet the requirements of PCT with regards to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT) for the following reasons:

The document D1 is regarded as being the closest prior art to the subject-matter of claim 14, and discloses (the references in parentheses applying to this document) a physiological sensor for the calculation of hemoglobin concentration and discloses (the references in parentheses applying to this document) a physiological sensor for

the calculation of hemoglobin concentration wherein the emitter comprises an array of LEDs (see LED (1030) on line 7, page 21, plurality of LEDs in lines 34 - 36 on page 22, figs. 26, 27) wherein the LEDs radiate light generally centred around at least twelve unique wavelengths (see argumentation for claim 12 in section 4).

The subject-matter of claim 13 therefore differs from this known physiological sensor in that the LEDs are mounted in an array of at least thirteen LEDs connected within an electrical grid. The problem to be solved by the present invention may therefore by regarded as how to further improve the detection performance of the sensor. When faced with this problem the skilled person would not consider it obvious to use at least thirteen LEDs. Although it is generally known that an increased sampling rate improves the detection of steep slopes in a curve, a negative assessment as to an inventive step of the choice of thirteen LEDs and twelve wavelengths would benefit from hindsight. Therefore, the subject-matter of claim 14 and its dependent claim 15 appears to meet the requirements of PCT with regards to both novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street 14th Floor
Irvine, CA 92614
ETATS-UNIS D'AMERIQUE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	30.06.2009

Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
MLR. 015VPC	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2008/058327	26.03.2008	27.03.2007

Applicant
Masimo Laboratories, Inc.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the International preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	Acquaviva, Laure Tel. +49 89 2399-5656

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MLR. 015VPC	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US2008/058327	International filing date *(day/month/year)* 26.03.2008	Priority date *(day/month/year)* 27.03.2007
International Patent Classification (IPC) or national classification and IPC INV. A61B5/00		
Applicant Masimo Laboratories, Inc.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
2008-11-12	30.06.2009
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	Authorized officer Doyle, Aidan Telephone No. +49 89 2399-2342

Form PCT/IPEA/ 409 (Cover Sheet) (April 2005)

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-26 as originally filed

   Claims, Numbers

   1-19 filed with telefax on 12.11.2008

   Drawings, Sheets

   1/32-32/32 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

5. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2 (e)).

6. ☐ Supplementary international search report(s) from Authority(ies) have been received and taken into account in drawing up this report (Rule 45bis.8(b) and (c)).

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2,3,5,6,7,10,11,12,14,16,17,18,19
	No:	Claims	1,4,8,9,13,15
Inventive step (IS)	Yes:	Claims	14
	No:	Claims	2,3,5,6,7,10,11,12,16,17,18,19
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D3: WO 02/26123 A (INSTRUMENTATION METRICS INC [US] SENSYS MEDICAL INC [US]) 4 April 2002
   D6: JP 2003 084108 (KEIWA INC) 19 March 2003

2. INDEPENDENT CLAIM 1

   The subject-matter of claim 1 is not novel (Article 33(2) PCT), because document D3 discloses a physiological sensor comprising at least eight light emitting diodes (see **10**, lines 30 - 33, page 9, fig. 4) each generally centred around a wavelength unique from the remaining light emitting diodes (see lines 8 - 12, page 8); a detector (see **90**, lines 26 - 36, page 11, lines 2 - 4, page 13, figs. 10, 11) that generates an output signal responsive to the emitted light after absorption by tissue; an attachment assembly (see housing **110**, fig. 11) that removably positions the emitter and the detector with respect to the tissue to form an optical path from said emitter through said tissue to said detector; a spacer (see **23**, **63**, lines 8 - 9, page 9, lines 33 - 38, page 10 , figs. 4 - 6) that provides a predetermined gap disposed in an optical path between the emitter and the tissue wherein the attachment assembly removably positions the emitter and detector and a light scattering medium (see **61**, lines 21 - 31, page 10, fig. 6) disposed in said optical path between the emitter and tissue, wherein the spacer and the light scattering medium provide at least a substantially uniform illumination of tissue by the emitted light for each of the wavelengths (see lines 26 - 29, page 10). Therefore, D3 discloses the combination of features of claim 1, whose subject-matter is accordingly not novel (Article 33(2) PCT).

3. INDEPENDENT CLAIM 8

   The subject-matter of independent claim 8 is not novel (Article 33(2) PCT) in view of document D3, because said document discloses an emitter configured to radiate light having a plurality of wavelengths into a tissue site (see **10**, lines 8 -

12, page 8, lines 30 - 33, page 9, lines 3 - 10, page 15, fig. 4), the emitter including more than three LEDs disposed within an emitter substrate (see **10**, lines 30 - 33, page 9, fig. 4); a detector configured to receive the light after absorption by pulsatile blood flow within the tissue site (see **80**, **90**, **100**, lines 24 - 36, page 11, fig. 10); the detector generates a sensor signal capable of being processed by a patient monitor (see lines 28 - 32, page 11); the detector comprises a plurality of photodiodes (see **90**, lines 35 - 36, page 11, lines 27 - 29, page 12, figs. 9, 10); and a first set of the photodiodes is responsive to a first set of the wavelengths and a second set is responsive to a second set of the wavelengths (see **80**, **90**, line 23, page 11 - line 38, page 12, figs. 9 - 12) wherein the first and second set of photodiodes are all connected in parallel (see lines 28 - 38, page 12). Therefore, D3 discloses the combination of features of claim 8, whose subject-matter is accordingly not novel (Article 33(2) PCT).

4. INDEPENDENT CLAIM 15

The argumentation provided in section 2 applies mutatis mutandis to the subject-matter of independent claim 15, the subject-matter of which is accordingly not novel (Article 33(2) PCT).

5. DEPENDENT CLAIMS

5.1 The additional features defined in dependent claim 4, 9, and 13 are also known from document D3 (see **10**, **61**, lines 8 - 19, page 8, lines 31 - 35, page 9, lines 21 - 31, page 10, figs. 4, 6) so that said claim also does not meet the requirements of the PCT in respect of novelty (Article 33(2) PCT).

5.2 The additional features defined in dependent claims 2, 3, 10, 16 and 17 are also known from document D6 (see **4**, **5**, paragraphs [0027], [0028], [0035], figs. 1, 2) where said features have already been employed for their known purposes so that said claims also do not meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT). The further additional features defined in claim 18 are known from document D3 (see line 33, page 10 - line 15, page 11, fig. 6) so that said claim is also not inventive (Article 33(3) PCT).

5.3 The additional features defined in the dependent claims 5, 6, 7, 11, 12 and 19

relate to either minor procedural modifications routinely known and used by the skilled person for their already known purposes, or merely simple constructional modifications and are hinted at in document D3 (see lines 27 - 37, page 1, lines 20 - 22, page 5, lines 8 - 12, page 8, line 28, page 12 - line 6, page 13), so that said claims do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

5.4 The subject-matter of dependent claim 14 appears to meet the requirements of the PCT with regards to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT) for the following reason.

In addition to the distinguishing features of claims 11 and 12 (see argumentation provided in section 5.3), the subject-matter of claim 14 differs from the known physiological sensor disclosed in D3 in that the twelve unique wavelengths comprise eight wavelengths within a first range of about 620 - 905 nm and four wavelengths within a second range of about 1040 - 1270 nm.

The technical effect of this difference is that the subject is illuminated with radiation at a number of different wavelengths which are spectrally well-separated and reside in two different ranges. The technical problem solved is that such a configuration permits the simultaneous measurement of multiple physiological parameters which influence different regions of the illuminating spectrum.

Although it is generally known that multiple analytes / physiological parameters may be interrogated using multiple LED light sources, each emitting at different wavelengths, an assessment according to which the choice of twelve unique wavelengths comprising eight wavelengths within a first range of about 620 - 905 nm and four wavelengths within a second range of about 1040 - 1270nm is obvious would benefit from hindsight. Therefore, the subject-matter of claim 14 appears to meet the requirements of PCT with regards to both novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

6. CLARITY AND CONCISENESS

6.1 In view of three independent device claims, the present application lacks conciseness in the sense of Article 6 PCT.

6.2 The applicants attention is brought to the fact that the "ceramic substrate" of claims 16 and 17 lack antecedence (Article 6 PCT).

Replacement Sheet
WO 2008/118993 PCT/ US2008/058327

WHAT IS CLAIMED IS:

1. A physiological sensor comprising:

at least eight light emitting diodes each generally centered around a wavelength unique from the remaining light emitting diodes;

a detector that generates an output signal responsive to the emitted light after absorption by tissue;

an attachment assembly that removably positions the emitter and the detector with respect to the tissue to form an optical path from said emitter through said tissue to said detector;

a spacer that provides a predetermined gap disposed in an optical path between the emitter and the tissue wherein the attachment assembly removably positions the emitter and detector; and

a light scattering medium disposed in said optical path between the emitter and tissue, wherein the spacer and the light scattering medium provide at least a substantially uniform illumination of tissue by the emitted light for each of the wavelengths.

2. The physiological sensor according to claim 1 wherein the light scattering medium comprises glass beads mixed with an encapsulant disposed proximate the spacer.

3. The physiological sensor according to claim 2 wherein the light scattering medium further comprises microspheres mixed with an epoxy disposed proximate the emitter.

4. The physiological sensor according to claim 1 wherein the emitter comprises an array of at least thirteen light emitting diodes emitting light generally centered around at least twelve unique wavelengths.

5. The physiological sensor according to claim 1 wherein the detector comprises at least one Si photodiode and at least one InGaAs photodiode connected in parallel.

6. The physiological sensor according to claim 1 wherein the detector comprises two Si photodiodes and four InGaAs photodiodes all connected in parallel.

7. The physiological sensor according to claim 6 wherein the light emitting diodes emit light within a first range of about 620-905 nm. and within a second range of about 1040-1270 nm.

8. A physiological sensor comprising:

an emitter configured to radiate light having a plurality of wavelengths into a tissue site, the emitter including more than three LEDs disposed within an emitter substrate;

a detector configured to receive the light after absorption by pulsatile blood flow within the tissue site;

the detector generates a sensor signal capable of being processed by a patient monitor;

the detector comprises a plurality of photodiodes; and

a first set of the photodiodes is responsive to a first set of the wavelengths and a second set of the photodiodes is responsive to a second set of the wavelengths wherein the first and second set of photodiodes are all connected in parallel.

9. The physiological sensor according to claim 8 further comprising:

a diffuser that scatters the radiated light so that a tissue site is uniformly illuminated across all of the wavelengths.

10. The physiological sensor according to claim 9 wherein the diffuser comprises at least one of:

a first encapsulate containing glass beads mounted in a spacer proximate the emitter substrate; and

a second encapsulate mixed with micro spheres disposed on the LEDs within the emitter ceramic substrate.

11. The physiological sensor according to claim 8 wherein the photodiodes comprise at least one Si photodiode and at least one InGaAs photodiode connected in parallel.

12. The physiological sensor according to claim 11 wherein the at least three LEDs comprise at least 12 LEDs and wherein each LED radiates light generally centered around a wavelength unique from the other eleven wavelengths radiated by the other eleven LEDs.

13. The physiological sensor according to claim 8 wherein the LEDs are mounted in an array of at least thirteen LEDs connected within an electrical grid.

14. The physiological sensor according to claim 12 wherein the twelve unique wavelengths comprise eight wavelengths within a first range of about 620- 905 nm. and four wavelengths within a second range of about 1040-1270 nm.

15. A physiological sensor comprising:

a light source that radiates light having a plurality of wavelengths;

wherein the light source comprises a substrate having conductors arranged as an electrical grid;

at least eight LEDs mounted within the substrate in an array;

a diffuser that scatters the radiated light so that a tissue site is uniformly illuminated across all of the wavelengths; and

at least one detector that generates a sensor signal responsive to the radiated light after tissue attenuation.

16. The physiological sensor according to claim 15 wherein the diffuser comprises:

a first encapsulant having microspheres disposed over the LEDs; and

a second encapsulant having glass beads disposed proximate the ceramic substrate.

17. The physiological sensor according to claim 16 further comprising a spacer disposed proximate the ceramic substrate so as to form a gap between the LEDs and the tissue site.

18. The physiological sensor according to claim 17 further comprising:

a connector that connects to a patient cable so as to communicate the sensor signal to a monitor;

a flexible coupling having an optical end proximate the light source and the detector and a connector end proximate the connector; and

the flexible coupling having conductors that communicate the sensor signal from the optical end to the connector end.

19. The physiological sensor according to claim 15 wherein the at least one detector further comprises at least one Si photodiode and at least one InGaAs photodiode connected in parallel.

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INFORMATION DISCLOSURE STATEMENT

Applicant	:	Ammar Al-Ali, et al.
App. No	:	11/367033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Fardanesh, Marjan
Art Unit	:	3777
Conf No.	:	3334

CERTIFICATE OF EFS WEB TRANSMISSION

I hereby certify that this correspondence, and any other attachment noted on the automated Acknowledgement Receipt, is being transmitted from within the Pacific Time zone to the Commissioner for Patents via the EFS Web server on:

September 20, 2011
(Date)

/Jarom Kesler/
Jarom D. Kesler, Reg. No. 57,046

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 195 references, of which 56 are enclosed/submitted. An addition two (2) references are being enclosed/submitted along with a Continuing IDS Cover Letter submitted concurrently herewith.

This Information Disclosure Statement is being filed before the mailing date of a final action and before the mailing of a Notice of Allowance. This Statement is accompanied by the fees set forth in 37 C.F.R. § 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 20, 2011

By: /Jarom Kesler/
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20995
(949) 760-0404

11947083

EFS WEB CONTINUING IDS COVER LETTER

Applicant	:	Ammar Al-Ali, et al.
App. No	:	11/367033
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September 20, 2011
(Date)

/Jarom Kesler/
Jarom D. Kesler, Reg. No. 57,046

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Submitted herewith are two (2) references (citation numbers 194 and 195) as listed on the PTO/SB/08 Equivalent filed under EFS ID# 10994309.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 20, 2011

By: /Jarom Kesler/
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20995
(949) 760-0404

11947126

Electronic Acknowledgement Receipt

EFS ID:	10994714
Application Number:	11367033
International Application Number:	
Confirmation Number:	3334
Title of Invention:	Noninvasive multi-parameter patient monitor
First Named Inventor/Applicant Name:	Ammar Al-Ali
Customer Number:	20995
Filer:	Jarom D. Kesler/Jessica Egigian
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	MLR.012A
Receipt Date:	20-SEP-2011
Filing Date:	01-MAR-2006
Time Stamp:	19:54:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	Continuation.pdf	30329 43555b01dcd31be143437c336e2dec9f1e9af98b	no	1
Warnings:					
Information:					

2	Non Patent Literature	Schmitt_Simple.pdf	2081329 289330fcf3ff32621dfc2c46dfde7a72197d24be	no	10
Warnings:					
Information:					
3	Non Patent Literature	Schnapp.pdf	795484 77fa9d4b023948ee69c2919ec4d38cea40b4c65a	no	9
Warnings:					
Information:					
			Total Files Size (in bytes):	2907142	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Ammar Al-Ali, et al.
App. No.	:	11/367033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Marjan Fardanesh
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Conf No.	:	3334

CERTIFICATE OF EFS WEB TRANSMISSION

I hereby certify that this correspondence, and any other attachment noted on the automated Acknowledgement Receipt, is being transmitted from within the Pacific Time zone to the Commissioner for Patents via the EFS Web server on:

September 15, 2011
(Date)

/Jarom Kesler/
Jarom D. Kesler, Reg. No. 57,046

AMENDMENT AND RESPONSE TO OFFICE ACTION DATED APRIL 15, 2011

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the pending Office Action, please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 8 of this paper.

Summary of Interview begins on page 15 of this paper. .

Remarks/Arguments begin on page 16 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please amend the Specification as follows:

1. Please amend paragraph [0048] of the Specification as follows:

[0048] The monitor ~~202~~ 200 also comprises a HbCO indicator **204** advantageously providing a visual queue that a HbCO capable sensor is properly connected through the connector **202**. For example, the HbCO indicator **204** may advantageously activate when a sensor is connected that communicates sufficient information to determine HbCO, such as, for example, a sensor capable of emitting sufficient different wavelengths of light, a sensor storing sufficient data on the memory **122**, a sensor having appropriate encryption data or key, combinations of the same, or the like. For example, in an embodiment, the processor 112 may receive information from a memory 122 indicating a number of available LED wavelengths for the attached sensor. Based on the number of wavelengths, or other information stored on the memory 122, the processor 112 may determine whether an HbCO-ready sensor has been attached to the monitor 200. An artisan will also recognize from the disclosure herein that the HbCO indicator 204 may advantageously comprise a HbMet indicator, Hbt indicator, or the like, which activates to a predetermined color associated with a parameter, or any color, or deactivates the same, to convey a type of attached sensor. Moreover, the artisan will recognize from the disclosure herein other parameters that may use other sensor components and the monitor **200** may include indicators capable of indicating communication with those types of sensors.

2. Please amend paragraph [0050]-[0052] of the Specification as follows:

[0050] An artisan will also recognize from the disclosure herein that other mechanical (such as keys), electrical, or combination devices may inform the monitor ~~202~~ 200 of the type of attached sensor. In an embodiment, the processor

112 also may select to drive less emitters that are currently available, such as, for example, in the presence of low noise and when power consumption is an issue.

[0051] The monitor ~~202~~ 200 also comprises a multi-mode display **206** capable of displaying, for example, measurements of SpO_2 and HbCO (or alternatively, HbMet). In an embodiment, the display **206** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **200**. Thus, the multi-mode display **206** may advantageously cycle through two or more measured parameters in an area common to both parameters even when shifted. In such embodiments, the monitor **200** may also advantageously include parameter indicators **208**, **210**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **206** displays measured values of SpO_2 that are normal, the numbers may advantageously appear in green, while normal measured values of HbCO may advantageously appear in orange, and normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **206** flashes at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

[0052] The monitor ~~202~~ 200 also comprises a HbCO bar **212** where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. For example, the bar **212** is lowest when the dangers from carbon monoxide poisoning are the least, and highest when the dangers are the greatest. The bar **212** includes indicia **214** that provide an indication of the severity of carbon monoxide saturation in a patient's blood. As shown in **Fig. 2**, the bar **212** and the indicia **214** continuously indicate the concentration of HbCO in about 5% increments. The indicia **214** indicate a measurement of HbCO saturation percentage between about 0 and about 50% with a granularity of about 5%. However, an artisan will also recognize from the disclosure herein a wide variety of ranges and granularities could be used, the

indicia **214** could be electronically displayed in order to straightforwardly increase or decrease resolution, or the like. For example, HbCO may advantageously be displayed with greater resolution than ± about %5 in a lower portion of the scale. For example, an HbCO bar may advantageously include a scale of about <3%,. about 6%, about 9%, about 12%, about 15%, about 20%, about 25%, about 30%, about 35%, and about >40%.

3. Please amend paragraphs [0064]-[0066] of the Specification as follows:

[0064] The monitor ~~202~~ 200 also includes a battery level indicator **234** indicating remaining battery life. In the illustrated embodiment, four LED's indicate the status of the battery by incrementally deactivating to indicate proportionally decreasing battery life. In an embodiment, the four LED's may also change color as the battery charge decreases, and the final LED may begin to flash to indicate that the caregiver should replace the batteries.

[0065] Fig. 2 also shows the monitor ~~202~~ 200 including an audio transducer or speaker **236**. The speaker **236** advantageously provides audible indications of alarm conditions, pulse tone and feedback for key-presses, or the like. Moreover, the monitor ~~202~~ 200 includes a low signal quality indicator ("SQ" or "SIQ™") **238**. The signal IQ indicator **238** activates to inform a caregiver that a measured value of the quality of the incoming signal is below predetermined threshold values. For example, in an embodiment, the measured value for signal IQ is at least partially based on an evaluation of the plethysmograph data's correspondence to predetermined models or characteristics of physiological signals. In an embodiment, the signal IQ indicator **238** output may be associated with the displayed parameter. For example, the output may be associated with one threshold for the display of SpO_2 and another for the display of other parameter data.

[0066] The monitor ~~202~~ 200 also comprises a perfusion quality index ("PI™") bar **240** (which quantifies the measure of perfusion of the patient) where

in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. In one embodiment, the PI™ bar **240** shows a static value of perfusion for a given time period, such as, for example, one or more pulses. In another embodiment, or functional setting, the PI™ bar **240** may advantageously pulse with a pulse rate, may hold the last reading and optionally fade until the next reading, may indicate historical readings through colors or fades, or the like. Additionally, the PI™ bar **240** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

4. Please amend paragraph [0093]-[0096] of the Specification as follows:

[0093] Thus, the $SpaO_2$ graph **1172** provides the caregiver with the ability to recognize that even though the measured value of SpO_2 may be within acceptable ranges, there are potentially an unacceptable number of hemoglobin carriers unavailable for carrying oxygen, and that other potential problems may exist, such as, for example, harmful carbon monoxide levels, or the like. In an embodiment, various alarm conditions may cause the graph **1172** to change color, flash, or any combination of alarm indications discussed in the forgoing. Moreover, **Fig. ~~11I~~** 11Hillustrates yet an additional display of the foregoing parameters.

[0094] An embodiment may also include the monitor ~~**1100**~~ **1000** advantageously defining regions of wellness/severity of the monitored patient. For example, because the graph **1172** comprises two dimensions, the monitor ~~**1100**~~ **1000** may advantageously define regions where the patient's measured physiological parameters are considered acceptable, regions where the patient is considered at risk, regions where the patient is critical, and the like. For example, one region of acceptability may include a high SpO_2 and a low 1-$SpaO_2$, another region of risk may include a high SpO_2 and a high 1-$SpaO_2$, and another critical region may include a low SpO_2 and a high 1-$SpaO_2$. Moreover, an artisan will

recognize from the disclosure herein that different parameters may also be combined to provide readily identifiable indications of patient wellness.

[0095] In addition to or as an alternative to the two dimensional $SpaO_2$ graph **1172**, the monitor ~~1100~~ **1000** may also include a three dimensional graph, such as, for example, extending the graph **1172** along the variable of time. In this embodiment, the forgoing regions advantageously become three dimensional surfaces of wellness. Moreover, trend data may also be advantageously added to the surface to provide a history of when particular monitored parameters dipped in and out of various surfaces of wellness, risk, criticality, or the like. Such trend data could be color-coded, text identified, or the like. An artisan will also recognize that such surfaces may be dynamic. For example, measurements of HbCO > about 5 may dictate that trend data showing SpO_2 < about 90% should be considered critical; however, measurements of HbCO < about 5 may dictate only SpO_2 < about 85% would be critical. Again, an artisan will recognize from the disclosure herein other parameter combinations to create a wide variety of wellness/critical regions or surfaces that provide readily available visual or audio indications of patient well being, trigger specific alarms, or the like.

[0096] Moreover, the monitor ~~1100~~ **1000** may advantageously employ enlargement or reorganization of parameter data based on, for example, the severity of the measurement. For example, the monitor ~~1100~~ **1000** may display values for HbCO in a small portion of the screen or in the background, and when HbCO begins to approach abnormal levels, the small portion may advantageously grown as severity increases, even in some embodiments to dominate the display. Such visual alarming can be combined with audio alarms such as announcements, alarms, rising frequencies, or the like, and other visual alarms such as flashing, coloration, or the like to assist a caregiver in noticing the increasing severity of a monitored parameter. In an embodiment, a location of the display of an alarming value is changed to be displayed in a larger display area, such as 1102, so as to be readily noticeable and its display values readily ascertainable.

AMENDMENTS TO THE CLAIMS

The listing of claims replaces all prior versions and listings of claims. Only those claims being amended herein show their changes in highlighted form, where insertions appear as underlined text (e.g., insertions) while deletions appear as strikethrough text (e.g., ~~deletions~~).

1. **(Currently Amended)** A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

2. **(Currently Amended)** The patient monitor of Claim 1, wherein the first display area and the second display area ~~substantially~~ comprise the common display area.

3. **(Currently Amended)** The patient monitor of Claim 1, wherein activation of a user input causes the common display area to change from displaying one of the ~~first and second~~ measured value[[s]] of the first or second physiological parameter to displaying the other of the measured value of the first ~~and~~ or second ~~measured values~~physiological parameter.

4. **(Cancelled)**

5. **(Cancelled)**

6. **(Cancelled)**

7. **(Currently Amended)** ~~The patient monitor of Claim 4,~~ A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first

or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters based on an occurrence of an event, ~~wherein~~ the event ~~comprises~~ being one of the measured values of the first or second physiological parameters ~~first and second measured parameters~~ alarming.

8. **(Cancelled)**

9. **(Currently Amended)** The patient monitor of Claim 1, wherein the common display area is configured to default[[s]] to displaying one of the measured values of the first or second physiological parameters~~first and second measured values~~.

10. **(Currently Amended)** ~~The patient monitor of Claim 9,~~ A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters ~~wherein the common display area changes from defaulting to said one of the first and second measured values, to~~ automatically ~~displaying a~~based on which is a more critical one of the measured values of the first or second physiological parameters~~first and second measured value~~.

11. **(Currently Amended)** The patient monitor of Claim 1, wherein the measured value of the first physiological parameter~~first measured value~~ comprises an invasively measured value.

12. **(Currently Amended)** The patient monitor of Claim 1, wherein the measured value of the first physiological parameter ~~first measured value~~ comprises a non-invasively measured value.

13. **(Currently Amended)** The patient monitor of Claim 1, wherein the measured value of the first physiological parameter ~~first measured value~~ comprises glucose.

14. **(Cancelled)**

15. **(Currently Amended)** The patient monitor of Claim 1, wherein the measured value of the first physiological parameter ~~first measured value~~ comprises an indication of oxygen saturation and the measured value of the second physiological parameter ~~second measured value~~ comprises an indication of carbon monoxide saturation.

16. **(Currently Amended)** The patient monitor of Claim 1, wherein the measured value of the first physiological parameter ~~first measured value~~ comprises an indication of oxygen saturation and the measured value of the second physiological parameter ~~second measured value~~ comprises an indication of methemoglobin saturation.

17. **(Currently Amended)** The patient monitor of Claim 1, wherein the measured value of the first physiological parameter ~~first measured value~~ comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter ~~second measured value~~ comprises an indication of methemoglobin saturation.

18. **(Currently Amended)** The patient monitor of Claim [[~~1~~]]7, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters~~first and second measured values~~.

19. **(Currently Amended)** The patient monitor of Claim ~~17~~18, wherein the aspect that changes comprises a display color.

20. **(Currently Amended)** The patient monitor of Claim 1, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters~~first and second measured values~~.

21. **(Currently Amended)** The patient monitor of Claim 20, wherein the aspect that changes comprises a display color.

22. **(Currently Amended)** The patient monitor of Claim 20, wherein the aspect that changes comprises a display size.

23. **(Currently Amended)** The patient monitor of Claim 20, wherein the aspect that changes comprises a display intensity.

24. **(Currently Amended)** A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

displaying a ~~measurement~~ measured value of a first physiological parameter in a display location of an electronic display; and

replacing the display of the ~~measurement~~ measured value of the first physiological parameter with a display of a ~~measurement~~ measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.

25. **(Currently Amended)** The method of Claim 24, wherein ~~at least one aspect of the display changes when the display changes from the measurement of the first physiological parameter to the display of the measurement of the second physiological parameter~~the indication of the worsening state comprises an alarm condition.

26. **(Currently Amended)** The method of Claim 24, wherein the measured value of the first physiological parameter ~~first measured value~~ comprises an invasively measured value.

27. **(Currently Amended)** The method of Claim 24, wherein the measured value of the first physiological parameter ~~first measured value~~ comprises an indication of oxygen saturation and the measured value of the second physiological parameter ~~second measured value~~ comprises an indication of carbon monoxide saturation.

28. **(Currently Amended)** The method of Claim 24, wherein the measured value of the first physiological parameter ~~first measured value~~ comprises an indication of oxygen saturation and the measured value of the second physiological parameter ~~second measured value~~ comprises an indication of methemoglobin saturation.

29. **(Currently Amended)** The method of Claim 24, wherein wherein the measured value of the first physiological parameter ~~first measured value~~ comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter~~second measured value~~ comprises an indication of methemoglobin saturation.

30. **(Cancelled)**

31. **(Cancelled)**

32. **(Cancelled)**

33. **(Cancelled)**

34. **(Cancelled)**

35. **(Cancelled)**

36. **(Cancelled)**

37. **(Cancelled)**

38. **(Cancelled)**

39. **(Cancelled)**

40. **(Cancelled)**

41. **(Currently Amended)** The ~~physiological~~ patent monitor of Claim ~~30~~10, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.

42. **(Currently Amended)** The ~~physiological~~ patient monitor of Claim ~~30~~10, wherein at least one of measured physiological parameters is determined noninvasively.

43. **(Currently Amended)** A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

44. **(Original)** The patient monitor of Claim 43, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.

45. **(Original)** The patient monitor of Claim 44, comprising an additional display capable of indicating the percent carbon monoxide saturation.

46. **(Original)** The patient monitor of Claim 44, comprising an additional display capable of indicating the percent methemoglobin saturation.

47. **(Original)** The patient monitor of Claim 43, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate.

48. **(Original)** The patient monitor of Claim 47, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.

49. **(Original)** The patient monitor of Claim 47, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

50. **(Original)** The patient monitor of Claim 43, wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

51. **(Original)** The patient monitor of Claim 43, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.

52. **(Original)** The patient monitor of Claim 43, wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

53. **(Original)** The patient monitor of Claim 52, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.

54. **(Original)** The patient monitor of Claim 52, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button.

55. **(Original)** The patient monitor of Claim 43, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.

56. **(Original)** The patient monitor of Claim 43, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.

57. **(Original)** The patient monitor of Claim 43, wherein the attached sensor can provide data through the output signal and through a memory device.

58. **(Original)** The patient monitor of Claim 43, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.

59. **(Original)** The patient monitor of Claim 43, further comprising a memory for storing trend data on one or more of the first and second blood parameters.

60. **(Original)** The patient monitor of Claim 43, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.

61. **(Original)** The patient monitor of Claim 43, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.

62. **(Original)** The patient monitor of Claim 61, wherein the alarm comprises at least one of an audio or visual alarm.

63. **(Original)** The patient monitor of Claim 43, further comprising an additional display indicating perfusion through the body tissue.

SUMMARY OF THE INTERVIEW

On August 17, 2011, an in-person interview was held between Examiners Eric Winakur and Marjan Fardanesh and Applicant's counsel of record John M. Grover, reg. no. 42,610. Applicants presented distinctions between the claimed language and the cited prior art. Applicants agreed to include amendments along the lines discussed in the interview in the present amendment.

REMARKS

The Applicants thank the Examiner for their examination of the present application. By way of summary, Claims 1-63 were pending in this application. In the present amendment, the Applicants have amended the specification, canceled Claims 4-6, 8, 14 and 30-40, without prejudice or disclaimer and amended Claims 1-3, 7, 9-13, 15-29 and 41-43. Accordingly, Claims 1-3, 7, 9-13, 15-29 and 41-63 remain pending for consideration.

Objections to the Drawings

The Office Action objected to the drawings for failing to include reference signs referred to in the description and for including reference signs not referred to in the specification. Applicants have corrected minor typographical errors in the description that led to this objection. Specifically, Fig. 11I in paragraph [0093] was been amended to read FIG. 11H. Sign 1100 in paragraphs [0094]-[0095] has been amended to be sign 1000. Applications submit that no new matter is being introduced by way of these amendments. Accordingly, the Applicants respectfully request withdrawal of the objection to the drawings.

Objections to the Specification

The Office Action objected to the specification for minor typographical errors, suggesting that reference signs to "202" be changed to "200." Applicants have amended the specification along the lines suggested in the Office Action. Accordingly, the Applicants respectfully request withdrawal of the objection to the specification.

Objections To Claims and 11, 14 and 19

The Office Action objected to Claims 11, 14 and 19 for minor informalities. In particular, the Office Action suggested that Claim 19 be amended to depend from Claim 18 instead of claim 17. The Office Action also preliminarily objected to Claims11 and 14 as being substantially duplicate. In response, the Applicants have amended Claim 19 along the lines suggested in the Office Action and cancelled Claim 14 without prejudice or disclaimer. Accordingly, the Applicants respectfully request withdrawal of the objection to the claims.

Rejection Of Claims 2, 7, 9-23, 26-29, 31, 36-37, 39-42, 44 and 55 Under 35 U.S.C. § 112, ¶ 2

Claims 2, 7, 9-23, 26-29, 31, 36-37, 39-42, 44 and 55 are rejected under 35 U.S.C. § 112, ¶ 2, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2

Claim 2 is rejected because the Office Action alleges that "substantially" is a relative term that renders the claim indefinite. Applicants vigorisly disagree and traverse this rejection because "substantially" does not render the claim indefinite and a person of skill in the art would understand the limitations of the claim including the "substantially" language. However, in order to advance prosecution of this application, Applications have amended Claim 2 to delete the word "substantially". Accordingly, Applicants request that the rejection of Claim 2 be withdrawn.

Claim 19

Claim 19 is rejected because the Office Action alleges that "the aspect comprises a color" is an abstract idea. Applications traverse this rejection because "color" does provides structure to "the aspect". Although Applicants believe it is unnecessary for patentability purposes, Applicants have amended Claim 19 to clarify the claimed subject matter.

Claims 12-17, and 26-29

Claims 12-17 and 26-29 are rejected for having insufficient antecedent basis for "the first measured value" and "the second measured value." Again, Applicants traverse this rejection because antecedent basis can be found in each claims respective base claims. However, Applicants have amended these claims to clarify the claimed subject matter.

Claims 7, 9-23, 26-29, 31, 36-37, 39-42, 44 and 55

Claims 7, 9-23, 26-29, 31, 36-37, 39-42, 44 and 55 are rejected as allegedly failing to cite further structure. Applicants respectfully traverse this rejection because each of these rejected claims does cite further structure. The Office Action has failed to set forth its basis for indicating that each of these rejected claims does not cite further structure. Applicants urge the Office to reconsider this rejection. Accordingly, Applicants respectfully request the withdrawal of all of the Office Actions rejections under 35 U.S.C. § 112, ¶ 2

Rejection Of Claims 1-7, 9-12, 14, 24-26, 30-32, 36-43, 50, 57, 59 and 63 Under 35 U.S.C. § 102(b)

The Office Action rejected Claims 1-7, 9-12, 14, 24-26, 30-32, 36-43, 50, 57, 59 and 63 under 35 U.S.C. § 102(b) as being anticipated by U.S. Publication No. 2003/0120164, issued to Nielsen, et al., (the Nielsen publication). The Applicants respectfully traverse this rejection for the same reasons discussed in the interview and because the Nielsen publication fails to identically teach every element of each of the pending claims. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

Rejection Of Claim 13 Under 35 U.S.C. § 103

The Office Action rejected Claim 13 under 35 U.S.C. § 103 as being unpatentable over the Nielsen publication, in view of U.S. patent no. 4,014,321 issued to March (the March patent). The Applicants respectfully traverse this rejection for the same reasons discussed in the interview and because the cited alone or in combination fail to teach every element of each of the pending claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Request For Telephone Interview

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Applicants' undersigned attorney of record hereby formally requests a telephone interview with the Examiner. The Applicants' attorney can be reached at (949) 721-2923 or at the number listed below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 15, 2011

By: /Jarom Kesler/
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20995
(949) 760-0404

11527432

Electronic Patent Application Fee Transmittal

Application Number:	11367033
Filing Date:	01-Mar-2006
Title of Invention:	Noninvasive multi-parameter patient monitor
First Named Inventor/Applicant Name:	Ammar Al-Ali
Filer:	Jarom D. Kesler/Nadin Hamoui
Attorney Docket Number:	MLR.012A

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Independent claims in excess of 3	1201	1	220	220
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 2 months with $0 paid	1252	1	490	490
Miscellaneous:				
		Total in USD ($)		**710**

Electronic Acknowledgement Receipt	
EFS ID:	10961287
Application Number:	11367033
International Application Number:	
Confirmation Number:	3334
Title of Invention:	Noninvasive multi-parameter patient monitor
First Named Inventor/Applicant Name:	Ammar Al-Ali
Customer Number:	20995
Filer:	Jarom D. Kesler/ThuyQuyen Nguyen
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	MLR.012A
Receipt Date:	15-SEP-2011
Filing Date:	01-MAR-2006
Time Stamp:	19:36:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$710
RAM confirmation Number	6098
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		response-012a.pdf	926936 1ab3afb73470f9b9d9ddc635b09a5fce43a9ce70	yes	18

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Specification	2	6
Claims	7	13
Applicant summary of interview with examiner	14	14
Applicant Arguments/Remarks Made in an Amendment	15	18

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	31622 e24d9f606f45859aa6270a4a0729c5e2f06ec584	no	2

Warnings:

Information:

Total Files Size (in bytes):	958558

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/367,033	03/01/2006	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	09/15/2011	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 47	Minus	** 63	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 5	Minus	***4	= 1	X $ =		OR	X $220=	220
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	220

AMENDMENT		(Column 1)		(Column 2)	(Column 3)					
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/MARQUITA JONES/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/367,033	03/01/2006	Ammar Al-Ali	MLR.012A	3334

20995 7590 09/09/2011

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2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
FARDANESH, MARJAN	
ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
09/09/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
eOAPilot@kmob.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	11/367,033	AL-ALI ET AL.	
	Examiner	Art Unit	
	MARJAN FARDANESH	3777	

All participants (applicant, applicant's representative, PTO personnel):

(1) *MARJAN FARDANESH*. (3)*John Grover*.

(2) *Eric Winakur*. (4)_____.

Date of Interview: *17 August 2011*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☒102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1-10,30-37 and 40*.

Identification of prior art discussed: *Nielsen et al.*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicant presented an overview of the invention and how the claimed subject matter of dependent claims 6, 7, and 10 differs from subject matter disclosed by Nielsen et al. since Nielsen et al. do not teach changing output based on alarm threshold or an evaluation of the relative criticality of measured parameters. Examiners generally agreed that these details were not found in Nielsen et al. and further suggeted that Applicant amend the claim language to clarify certain details. Wtih regard to claim 30, Applicant discussed the claimed subject matter in relation to Figure 11G, element 1172. Examiner indicated that as claimed, the language was broader than what Applicant described with regard to the figure. Applicant indicated that they will take the discussion into consideration when filing their formal response..

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Eric F Winakur/ Primary Examiner, Art Unit 3777	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/367,033	03/01/2006	Ammar Al-Ali	MLR.012A	3334

20995 7590 04/15/2011

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EXAMINER	
FARDANESH, MARJAN	
ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
04/15/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	11/367,033	AL-ALI ET AL.	
	Examiner	Art Unit	
	MARJAN FARDANESH	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/21/2007,08/28/2006,06/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Fig.11l in page 30,[0093] line 8, sign 1100 in page 30, [0094],line 1, sign 1100 in page 30 [0095], line 2, [0096], lines 1-2 . Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: fig.11A, 1000. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing

date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: page 20,

Page 20, [0064], [0065], line 1—change “202” to “200”.

Page 20, [0065], line 4—change “202” to “200”.

Page 20, [0066], line 1—change “202” to “200”.

Page 20, [0064], line 1—change “202” to “200”.

Page 20, [0065], line 1—change “202” to “200”.

Page 20, [0066], line 1—change “202” to “200”.

Claim Objections

4. Claim 19, line 1, it is suggested that applicant amend the claim to depend on claim 18, instead of claim 17. For the examination purposes, the claim dependency is changed.

5. Applicant is advised that should claims 3 and 11 be found allowable, claims 14 and 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after

allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 7, 9-23, 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 2, the term "substantially" in claim 2 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

With respect to claim 19, it is not clear what applicant means by stating that “the aspect comprises a color”, Applicant should note that "comprises a color" is more of abstract ideas than structure.

With respect to claims 7, 9-23, 26-29, 31, 36-37, 39-42, 44 and 55, Applicant is not properly citing further structures. Appropriate correction is required.

With respect to claims 12-17, 26-29 recites the limitation "the first measured value” and “the second measured value". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-7,9-12, 14, 24-26, 30-32, 36-43, 50, 57,59, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Nielsen et al. (USPN 2003/0120164).

With respect to claims 1-5, Nielsen discloses a patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, the first display area and the second display area substantially comprise the common display area, activation of a user input causes the common display area to change from displaying one of the first and second measured values to displaying the other of the first and second measured values, the common display area changes from displaying one of the first and second measured values to

displaying the other of the first and second measured values based on occurrence of an event such as receipt of user input, ([figure 1,3, [0046]-[0053], [0056]). Examiner interprets the common display area as shown in figures 3-19, the display unit of Nielsen is configured to generate a first display mode wherein the waveforms of the data are displayed in a portion of a screen (i.e. fig.3) and a second display mode wherein the actual measured values are displayed in a same portion of the screen (i.e. fig. 6) therefore, the common display area of the screen can display information based on user input.

With respect to claims 6, 7, the event comprises one of the first and second measured parameters approaching one or more threshold values indicative of a worsening state of a patient, and one of the first and second measured parameters alarming ([0057]).

With respect to claims 9-10, the common display area defaults to displaying one of the first and second measured values, and the common display area changes from defaulting to said one of the first and second measured values, to automatically displaying a more critical (primary) one of the first and second measured value ([0046]-[0053], [0056]).

With respect to claims 11-12, 14, the first measured value comprises an invasively measured value, and a non-invasively measured value ([0047]).

With respect to claims 24-26, a method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the display comprising displaying a measurement of a first physiological

parameter in a display location of an electronic display, and replacing the display of the measurement of the first physiological parameter with a display of a measurement of a second physiological parameter in the display location, at least one aspect of the display changes when the display changes from the measurement of the first physiological parameter to the display of the measurement of the second physiological parameter, and the first measured value comprises an invasively measured value (figure 1,3, [0046]-[0053]).

With respect to claims 30-32, a physiological monitor comprising a processor capable of outputting values for at least two physiological parameters, and a display including a graphical representation which at a point in time indicates a first state of one of the at least two measured physiological parameters and a second state of another of the at least two measured physiological parameters, first and second states reflect substantially a same period of time, and an indicator capable of alerting a user that one or more of the at least two measured physiological parameters is approaching a predetermined threshold ([0036],[0046]-[0053],[0057]).

With respect to claim 36-37, the graphical representation associates a default color with each of the display of the first and second measured parameters, and the graphical representation associates a default line weight with each of the display of the first and second measured parameters (figure 3, see entire description of figure 3).

With respect to claim 38, the display comprises a first designated area for displaying information related to normal physiological conditions and a second designated area for displaying information related to non- normal physiological parameters ([0055]-[0056]).

With respect to claims 39-40, the display of one of the at least two measured physiological parameters comprises a function of the other of the at least two measured physiological parameters, and the display comprises a parametric graph (figure 3, [0044]-[0048]).

With respect to claim 41, measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue ([0046]-[0053], [0056]).

With respect to claim 42, at least one of measured physiological parameters is determined noninvasively ([0047]).

With respect to claim 43, the patient monitor comprising a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue, and a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue ([0046]-[0053], [0056]).

With respect to claim 50, the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter [0047].

With respect to claim 57, the attached sensor can provide data through the output signal and through a memory device [0078].

With respect to claim 59, a memory for storing trend data on one or more of the first and second blood parameters ([0036]-[0039], [0078]).

With respect to claim 63, an additional display indicating perfusion through the body tissue [0039].

10. Claims 1-5, 8, are rejected under 35 U.S.C. 102(e) as being anticipated by Simond et al. (USPN 2004/0262046).

With respect to claims 1-5,8, Simond et al. discloses a patient monitor capable of measuring at least two physiological parameters ([0023]), the patient monitor comprising a display (10) capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area (figure 4) or displaying a measured value of a second physiological parameter of the body tissue in a second display area ([0025]) where the first display area and the second display area comprise at least some common display area capable of displaying information (figure 4), the first display area and the second display area substantially comprise the common display area, activation of a user input causes the common display area to change from displaying one of the first and second measured values to displaying the other of the first and second measured values, the common display area changes from displaying one of the first and second measured values to displaying the other of the first and second measured values based on an occurrence of an event, the event

comprises receipt of a user input, and the event comprises expiration of a predetermined time ([0001], [0011],[0023]-[0031], [0042],[0064] and see entire description of figure 4).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (USPN 2003/0120164) in view of March (USPN 4,014,321).

While Nielsen et al. discloses displaying the measured values by the sensors connected to the monitoring system and may receive data from additional sensors ([0032]) Nielsen et al. does not disclose a sensor capable of measuring glucose, and does not particularly teach the type of data received.

March teaches a unique glucose sensor that determines the glucose level in patients. The result is transmitted to a remote receiver that is coupled to a readout device to thereby provide non-invasive glucose determinations of high specificity and reliability, therefore, March teaches measuring glucose, a known physiological value of interest, that one of skill would recognize as suitable as input as the additional data. (Abstract, Col.2 lines 34-56, Col.3 lines 21-41).

It would have been obvious to one having ordinary skills in art at the time invention was made to modify the monitoring system of Nielsen et al. to receive measurements from the glucose sensor of March, since such modification would have provided glucose measured values to the monitoring system of Nielsen in order to be displayed on the display unit, since Nielsen indicates that data from additional sensors may be input to the system.

13. Claims 15-17,27-29,44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (USPN 2003/0120164) in view of Jarman (USPN 5,842,979).

While Nielsen et al. discloses displaying the measured values by the sensors connected to the monitoring system, and the output devices further include one or more monitors for displaying the measured values such as pulse rate and oxygen saturation, also the device may receive data from additional sensors ([0032]), Nielsen et al. does not disclose a sensor capable of measuring methemoglobin saturation and carbon monoxide saturation and does not particularly teach the type of data received..

Jarman teaches a photoplethysmographic method and apparatus 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 methemoglobin levels in blood, which are known physiological values of interest, and one of skill would recognize as suitable as input as the additional data (Abstract, Col.3 line 63- Col. 4 line 62).

It would have been obvious to one having ordinary skills in art at the time invention was made to modify the monitoring system of Nielsen et al. to receive measurements from the sensor of Jarman, since such modification would have provided the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin levels in blood to the monitoring system of Nielsen in order to be displayed on the display unit Nielsen indicates that data from additional sensors may be input to the system.

14. Claims 18-23,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (USPN 2003/0120164) in view of Athan et al. (USPN 5,575,284).

While Nielsen et al. discloses a monitor for displaying a first and second physiological parameters, and the common display area capable of changing from displaying one of the first and second measured values to displaying the other of the first and second measured values, and changing the size of the display layout depending on the measured values, Nielsen does not disclose changing the color and the intensity of the display to illustrate a change in severity of one of the first and second measured values.

Athan et al. teaches a display unit that is capable of displaying one or more measured values, and having different color LEDs to represent the severity of the measured values (Col.9 lines 16-26).

It would have been obvious to one having ordinary skills in art at the time invention was made to modify the display unit of Nielsen et al. with changing color feature of Athan et

al., since such modification would have changed the color of display based on the severity of the measured values.

15. Claims 33-34, 51-54, 56, 58, 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (USPN 2003/0120164) in view of Kianl et al. (USPN 2002/0161291).

With respect to claims 33-34,61,62 , while Nielsen et al. discloses an indicator capable of alerting a user that one or more of the at least two measured physiological parameters is approaching a predetermined threshold, Nielsen et al. does not disclose audible and visual indicators.

Kianl et al. teaches a display unit having LED indicators, visual alarm indicator, and audible alarm indicator ([0049]-[0051], [0056]-[0059]).

It would have been obvious to one having ordinary skills in art at the time invention was made to modify the display unit of Nielsen et al. with alarm indicators of Kianl et al., since such modification would have provided an audible and visual alerting system, in order to alert the user if the measured physiological parameters is approaching a predetermined threshold.

With respect to claims 51-54, Nielsen et al. discloses monitoring system which permits the operator to adjust the display settings and all the components of claim 43; While Nielsen et al. allows the user to select which parameters to be displayed, Nielsen et al. does not disclose changing the displayed parameter after expiration of a predetermined duration which can be adjusted by the user.

Kianl et al. teaches display unit that by default after a certain period of time is capable of automatically refreshing and displaying another set of measurements, also allowing the user to adjust this time period ([0085]-[0090]).

It would have been obvious to one having ordinary skills in art at the time invention was made to modify the user interface within the display unit of Nielsen et al. with trend view settings of Kianl et al., since such modification would have refreshed the screen, displayed another set of measurements after expiration of a predetermined duration, and allowed the user to adjust the predetermined duration.

With respect to claims 56, 58, 60, Nielsen et al. discloses display unit that displays the parameters of the sensors attached to it, and all the components of claim 43; While Nielsen display the parameters on the display unit, Nielsen et al. does not include a sensor indicator capable of indicating the sensor's quality and received signal's quality. Kianl et al. teaches a display unit capable of indicating whether the attached sensor can provide sufficient data to determine the measured values and indicating the signal quality of the signals used to determine the measured values ([0062]-[0066]).

It would have been obvious to one having ordinary skills in art at the time invention was made to modify the he display unit of Nielsen et al. to include indicating feature of Kianl et al. and displaying messages according to the indication results, since such modification would have provided the user with information on whether or not the sensor is functioning and the quality of the received signals.

16. Claims 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (USPN 2003/0120164) in view of Yamashita et al. (USPN 6,542,763).

While Nielsen et al. discloses a display unit including a graphical representation of the measured values, Nielsen does not disclose a three dimensional graphical representation.

Yamashita et al. teaches displaying an image on the display unit, and the image displayed can be a contour map or a gray-scale image, a color identifying image, or a three-dimensional perspective image (Col.12 lines 10-15).

It would have been obvious to one having ordinary skills in art at the time invention was made to modify the display unit of Nielsen et al. with the three dimensional graphical representation of Yamashita et al., since such modification would have provided a three dimensional graphical representation of the image.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:30-18:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TSE Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3777

/MARJAN FARDANESH/
Examiner, Art Unit 3777

Notice of References Cited	Application/Control No. 11/367,033	Applicant(s)/Patent Under Reexamination AL-ALI ET AL.	
	Examiner MARJAN FARDANESH	Art Unit 3777	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2003/0120164	06-2003	Nielsen et al.	600/513
*	B	US-6,397,093	05-2002	Aldrich, Thomas K.	600/330
*	C	US-2004/0262046	12-2004	Simond et al.	177/025.13
*	D	US-4,014,321	03-1977	March, Wayne F.	600/319
*	E	US-5,842,979	12-1998	Jarman, Kristin Hoyer	600/322
*	F	US-5,575,284	11-1996	Athan et al.	600/323
*	G	US-2002/0161291	10-2002	Kianl et al.	600/324
*	H	US-6,542,763	04-2003	Yamashita et al.	600/310
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11367033	AL-ALI ET AL.
	Examiner	**Art Unit**
	MARJAN FARDANESH	3777

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	04/07/2011								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
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	30	✓								
	31	✓								
	32	✓								
	33	✓								
	34	✓								
	35	✓								
	36	✓								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11367033	AL-ALI ET AL.
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CLAIM		DATE								
Final	Original	04/07/2011								
	37	✓								
	38	✓								
	39	✓								
	40	✓								
	41	✓								
	42	✓								
	43	✓								
	44	✓								
	45	✓								
	46	✓								
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	59	✓								
	60	✓								
	61	✓								
	62	✓								
	63	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11367033	AL-ALI ET AL.
	Examiner	**Art Unit**
	MARJAN FARDANESH	3777

SEARCHED			
Class	**Subclass**	**Date**	**Examiner**
600	309-344	4/7/2011	/MF/

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
Eric Winakur was consulted	4/7/2011	/MF/
EAST(USPAT;USPGPub)-see search history	4/7/2011	/MF/
"PALM inventor name search"	4/7/2011	/MF/
Janet Baxter was consulted	4/8/2011	/MF/

INTERFERENCE SEARCH			
Class	**Subclass**	**Date**	**Examiner**

/MARJAN FARDANESH/ Examiner.Art Unit 3777	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	2	"6829501".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 10:25
S2	2	"20030120164".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 10:25
S3	2	"20030120164".pn. and display	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 10:27
S4	1	"20030120164".pn. and display and (user operator)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 10:53
S5	1	"20030120164".pn. and display and (user operator) and limit	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 11:07
S6	1	"20030120164".pn. and display and (user operator) and limit$1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 11:07
S7	1	"20030120164".pn. and display and (user operator) and limit$1 and primary	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 11:09

S8	2	"6397093".pn. and carbon and monoxide	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 11:21
S9	1	"6397093".pn. and carbon and monoxide and oxygen and saturation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 11:21
S10	0	"20020111748".pn. and glucose	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 13:48
S11	0	"20020111748".pn. and met and hemoglobin	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 13:48
S12	2	"20020111748".pn. and hemoglobin	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 13:48
S13	0	"2002156353".pn. and (diplay monitor) and alarm	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:26
S14	0	"2002156353".pn. and (diplay monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:26
S15	2	"2002156353".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:26
S16	2	"20020156353".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:26

S17	0	"20020156353".pn. and (display monitor) and alarm	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:27
S18	2	"20020156353".pn. and (display monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:27
S19	0	"2001045532".pn. and (display monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:38
S20	2	"20010045532".pn. and (display monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:38
S21	1	"6285895".pn. and (display monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:39
S22	12	("6611698" | "6743172" | "6253097" | "6184521" | "6122042" | "5800348" | "5645059" | "5331549" | "5259381" | "5058588"). pn. and (display monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:44
S23	7	("6611698" | "6743172" | "6253097" | "6184521" | "6122042" | "5800348" | "5645059" | "5331549" | "5259381" | "5058588"). pn. and (display monitor) and (warn$4 alarm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 14:51
S24	1	("6611698" | "6743172" | "6253097" | "6184521" | "6122042" | "5800348" | "5645059" | "5331549" | "5259381" | "5058588"). pn. and (display monitor) and glucose	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:05

S25	0	("4986665" | "4907876" | "20050011488" | "20040267103" | "20040262046" | "20040158134" | "20040147823" | "20040133087" | "20040081621" | "20040059209").pn. and (display monitor) and glucose	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:09
S26	11	("4986665" | "4907876" | "20050011488" | "20040267103" | "20040262046" | "20040158134" | "20040147823" | "20040133087" | "20040081621" | "20040059209").pn. and (display monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:09
S27	804	(600/300-350).ccls. and (display monitor) same critical	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:26
S28	5880197	(600/300-350).ccls. and (display monitor) same critical value$1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:26
S29	162	(600/300-350).ccls. and (display monitor) same critical same value$1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:26
S30	82	(600/309-344).ccls. and (display monitor) same critical same value$1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:27
S31	13	(600/309-344).ccls. and (display monitor) same critical same value$1 and size and color	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:52

S32	69	(600/309-344).ccls. and (display monitor) same value$1 and change same size and color	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 15:59
S33	34	(600/309-344).ccls. and (display monitor) same value$1 and change with size and color	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 16:00
S34	57	(600/309-344).ccls. and (display monitor) and (alarm indicat$4) and change with size and color	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 16:06
S35	1	"20030120164".pn. and alarm	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 16:41
S36	1	"11367033" and three same dimensional	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:02
S37	1	"11367033" and line same weight	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:05
S38	1	("4986665" | "4907876" | "20050011488" | "20040267103" | "20040262046" | "20040158134" | "20040147823" | "20040133087" | "20040081621" | "20040059209").pn. and (display monitor) and three same dimension$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:08
S39	1	("6611698" | "6743172" | "6253097" | "6184521" | "6122042" | "5800348" | "5645059" | "5331549" | "5259381" | "5058588"). pn. and (display monitor) and three same dimension $4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:10

S40	1	("20040034898" | "20020183819" | "20020161291" | "20020038081" | "20020021269" | "20010044700" | "5645059" | "5331549" | "5259381" | "5058588"). pn. and (display monitor) and three same dimension $4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:12
S41	0	("7006856" | "7001337" | "6987994" | "6975891" | "6944487" | "6931269" | "6928311" | "6922645" | "6921367" | "6919566"). pn. and (display monitor) and three same dimension $4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:15
S42	2	("6917422" | "6912049" | "6882874" | "6869402" | "6847835" | "6845256" | "6842702" | "6839582" | "6839580" | "6839579"). pn. and (display monitor) and three same dimension $4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:18
S43	0	("6836679" | "6829496" | "6825619" | "6819950" | "6810277" | "6801799" | "6801797" | "6788849" | "6780158" | "6778923"). pn. and (display monitor) and three same dimension $4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:21
S44	252	(600/309-310).ccls. and (display monitor) and three same dimension$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:22
S45	227	(600/309-310).ccls. and (display monitor) and three with dimension$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:22
S46	41	(600/309-310).ccls. and (display monitor) same three with dimension$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:22

S47	2	("6836679" | "6829496" | "6825619" | "6819950" | "6810277" | "6801799" | "6801797" | "6788849" | "6780158" | "6778923"). pn. and (display monitor) and glucose	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:36
S48	2	("6917422" | "6912049" | "6882874" | "6869402" | "6847835" | "6845256" | "6842702" | "6839582" | "6839580" | "6839579"). pn. and (display monitor) and glucose	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:56
S49	1	"20030176776".pn. and $hemoglobin and glucose and oxygen and saturation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/31 17:59
S50	256	(600/309-344).ccls. and (glucose with sensor) and probe and (monitor display)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 09:21
S51	760	(600/309-344).ccls. and (glucose with sensor) and (monitor display)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 09:26
S52	0	(600/309-344).ccls. and ((glucose with sensor) same $inavsive) and (monitor display)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 09:27
S53	264	(600/309-344).ccls. and ((glucose with sensor) same $invasive) and (monitor display)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 09:27
S54	3	"4,014,321".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 09:28

S55	2	"4,014,321".pn. and (sensor with glucose)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 09:32
S56	36	(600/300-350).ccls. and (carbon near1 monoxide) same oxygen same methemoglobin	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 09:39
S57	3	"11367033"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 10:03
S58	2	"11367033" and alarm	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 10:04
S59	1	"11367033" and normal	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 10:43
S60	1	"20030120164".pn. and storage	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/01 11:09
S61	8	"11768845"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/05 17:03
S62	28	"5189609"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/05 17:03
S63	2	"5189609".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/05 17:03

S64	1	"5189609".pn. and time	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/05 17:04
S65	2	"6829501".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/05 17:07
S66	5	("5309917" | "5319363" | "5456261" | "5956013" | "6221012").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:07
S67	5	("5309917" | "5319363" | "5456261" | "5956013" | "6221012").PN. and display and time	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:14
S68	899	predetermined same duration same monitor same (value measurement)	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:31
S69	117	predetermined same duration same monitor same (value measurement) same user	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:32
S70	94	("600"/$).ccls. and predetermined same duration same monitor same (value measurement)	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:32
S71	70	("600"/$).ccls. and predetermined with duration same (monitor display) same (value measurement)	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:33
S72	24	("600"/$).ccls. and predetermined with duration with (monitor display) same (value measurement)	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:35
S73	1343	("600"/309-310,513,324).ccls. and (monitor display) same (value measurement)	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:45
S74	695	("600"/309-310,513,324).ccls. and (monitor display) same (value measurement) same time	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:45

S75	185	("600"/309-310,513,324).ccls. and (monitor display) same (value measurement) same time same user	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:45
S76	26	("600"/309-310,513,324).ccls. and (monitor display) same (value measurement) same time same user same (switch change)	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:47
S77	26	("600"/309-310,513,324).ccls. and (monitor display) same (value measurement) same time same user same (switch change) and (display monitor)	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:48
S78	1	"10076860"	US-PGPUB; USPAT; USOCR	OR	OFF	2011/04/05 17:59
S79	12	("2002/0161291").URPN.	USPAT	OR	OFF	2011/04/05 18:00
S80	9	("2002/0161291").URPN. and change	USPAT	OR	OFF	2011/04/05 18:01
S81	155	(600/309-520).ccls. and (monitor display) same (time with set$4 with user $4)	USPAT	OR	OFF	2011/04/05 18:06

4/7/2011 10:57:08 AM
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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali
	Art Unit	3736
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 1 OF 1	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	US 2002/0156353 A1	10-24-2002	Eric Russell Larson	
	2	US 2001/0045532 A1	11-29-2001	Charles E. Schulz, et al.	
	3	US 6,285,895 B1	09-04-2001	Kimmo Juhani Ristolainen, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	4	International Search Report for PCT/US2006/007516, mailed on 01-11-2007, in 4 pages.	
	5	SCHMITT, JOSEPH M.; ZHOU, GUAN-XIONG; MILLER, JUSTIN, Measurement of Blood Hematocrit by Dual-wavelength Near-IR Photoplethysmography, published May 1992, Proc. SPIE Vol.1641, p.150-161, Physiological Monitoring and Early Detection Diagnostic Methods, Thomas S. Mang; Ed. (SPIE homepage), in 12 pages.	

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Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.F./

OIPE IAP11 JUN 23 2006 PATENT & TRADEMARK OFFICE

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Multiple sheets used when necessary)

SHEET 1 OF 13

Application No.	11/367,033
Filing Date	March 1, 2006
First Named Inventor	Ammar Al-Ali et al.
Art Unit	Unknown
Examiner	Unknown
Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	7,006,856	02-28-2006	Baker, Jr. et al.	
	2	7,001,337	02-21-2006	Dekker	
	3	6,987,994	01-17-2006	Mortz	
	4	6,975,891	12-13-2005	Pawluczyk	
	5	6,944,487	09-13-2005	Maynard, et al.	
	6	6,931,269	08-16-2005	Terry	
	7	6,928,311	08-09-2005	Pawluczyk et al.	
	8	6,922,645	07-26-2005	Haaland et al.	
	9	6,921,367	07-26-2005	Mills	
	10	6,919,566	07-19-2005	Cadell	
	11	6,917,422	07-12-2005	Samsoondar et al.	
	12	6,912,049	06-28-2005	Pawluczyk et al.	
	13	6,882,874	04-19-2005	Huiku	
	14	6,869,402	03-22-2005	Arnold	
	15	6,847,835	01-25-2005	Yamanishi	
	16	6,845,256	01-18-2005	Chin et al.	
	17	6,842,702	01-11-2005	Haaland et al.	
	18	6,839,582	01-04-2005	Heckel	
	19	6,839,580	01-04-2005	Zonios, et al.	
	20	6,839,579	01-04-2005	Chin	
	21	6,836,679	12-28-2004	Baker JR. et al.	
	22	6,829,496	12-07-2004	Nagai, et al.	
	23	6,825,619	11-30-2004	Norris	
	24	6,819,950	11-16-2004	Mills	
	25	6,810,277	10-26-2004	Edgar, Jr, et al.	
	26	6,801,799	10-05-2004	Mendelson	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 2 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	27	6,801,797	10-05-2004	Mannheimer et al.	
	28	6,788,849	09-07-2004	Pawluczyk	
	29	6,780,158	08-24-2004	Yarita	
	30	6,780,158	08-24-2004	Yarita	
	31	6,778,923	08-17-2004	Norris et al.	
	32	6,773,397	08-10-2004	Kelly	
	33	6,760,609	07-06-2004	Jacques	
	34	6,754,516	06-22-2004	Mannheimer	
	35	6,754,515	06-22-2004	Pologe	
	36	6,748,254	06-08-2004	O'Neil et al.	
	37	6,748,253	06-08-2004	Norris et al.	
	38	6,745,061	06-01-2004	Hicks et al.	
	39	6,741,876	05-25-2004	Scecina et al.	
	40	6,741,875	05-25-2004	Pawluczyk et al.	
	41	6,726,634	04-27-2004	Freeman	
	42	6,725,074	04-20-2004	Kastle	
	43	6,721,584	04-13-2004	Baker JR. et al.	
	44	6,720,734	04-13-2004	Norris	
	45	6,719,705	04-13-2004	Mills	
	46	6,714,805	03-30-2004	Jeon, et al.	
	47	6,714,803	03-30-2004	Mortz	
	48	6,711,503	03-23-2004	Haaland	
	49	6,708,049	03-16-2004	Berson et al.	
	50	6,701,170	03-02-2004	Stetson	
	51	6,697,655	02-24-2004	Sueppel, et al.	
	52	6,694,157	02-17-2004	Stone et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 3 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	53	6,687,620	02-03-2004	Haaland et al.	
	54	6,681,126	01-20-2004	Solenberger	
	55	6,675,106	01-06-2004	Keenan et al.	
	56	6,675,031	01-06-2004	Porges, et al.	
	57	6,671,526	12-30-2003	Aoyagi et al.	
	58	6,668,183	12-23-2003	Hicks et al.	
	59	6,665,551	12-16-2003	Suzuki	
	60	6,662,033	12-09-2003	Casciani et al.	
	61	6,658,277	12-02-2003	Wasserman	
	62	6,657,717	12-02-2003	Cadell et al.	
	63	6,654,623	11-25-2003	Kastle	
	64	6,631,281	10-07-2003	Kastle	
	65	6,628,975	09-30-2003	Fein et al.	
	66	6,622,095	09-16-2003	Kobayashi et al.	
	67	6,618,602	09-09-2003	Levin	
	68	6,615,151	09-02-2003	Scecina et al.	
	69	6,615,064	09-02-2003	Aldrich	
	70	6,614,521	09-02-2003	Samsoondar et al.	
	71	6,606,510	08-12-2003	Swedlow, et al.	
	72	6,606,509	08-12-2003	Schmitt	
	73	6,600,940	07-29-2003	Fein, et al.	
	74	6,594,511	07-15-2003	Stone et al.	
	75	6,591,123	07-08-2003	Fein et al.	
	76	6,584,413	06-24-2003	Keenan et al.	
	77	6,582,964	06-24-2003	Samsoondar et al.	
	78	6,571,113	05-27-2003	Fein, et al.	
	79	6,564,077	05-13-2003	Mortara	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 4 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	80	6,553,241	04-22-2003	Mannheimer, et al.	
	81	6,546,267	04-08-2003	Sugiura	
	82	6,537,225	03-25-2003	Mills	
	83	6,528,809	03-04-2003	Thomas et al.	
	84	6,526,301	02-25-2003	Larsen et al.	
	85	6,522,398	02-18-2003	Cadell et al.	
	86	6,519,486	02-11-2003	Edgar, Jr., et al.	
	87	6,510,329	01-21-2003	Heckel	
	88	6,505,133	01-07-2003	Hanna	
	89	6,505,061	01-07-2003	Larson	
	90	6,505,060	01-07-2003	Norris	
	91	6,504,943	01-07-2003	Sweatt et al.	
	92	6,501,974	12-31-2002	Huiku	
	93	6,497,659	12-24-2002	Rafert	
	94	6,490,466	12-03-2002	Fein et al.	
	95	6,480,729	11-12-2002	Stone	
	96	6,463,310	10-08-2002	Swedlow et al.	
	97	6,453,184	09-17-2002	Hyogo et al.	
	98	6,441,388	08-27-2002	Thomas et al.	
	99	6,434,408	08-13-2002	Heckel	
	100	6,415,236	07-02-2002	Kobayashi et al.	
	101	6,415,233	07-02-2002	Haaland	
	102	6,415,166	07-02-2002	Van Hoy et al.	
	103	6,411,833	06-25-2002	Baker, Jr. et al.	
	104	6,408,198	06-18-2002	Hanna et al.	
	105	6,397,093	05-28-2002	Aldrich	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 5 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	106	6,397,092	05-28-2002	Norris et al.	
	107	6,393,310	05-21-2002	Kuenstner	
	108	6,377,828	04-23-2002	Chaiken, et al.	
	109	6,374,129	04-16-2002	Chin, et al.	
	110	6,363,269	03-26-2002	Hanna et al.	
	111	6,356,774	01-12-2002	Bernstein et al.	
	112	6,351,658	02-26-2002	Middleman et al.	
	113	6,341,257	01-22-2002	Haaland	
	114	6,330,468	12-11-2001	Scharf	
	115	6,304,767	10-16-2001	Soller et al.	
	116	6,304,675	10-16-2001	Osbourn et al.	
	117	6,298,252	10-02-2001	Kovach et al.	
	118	6,272,363	08-07-2001	Casciani et al.	
	119	6,230,035	05-08-2001	Aoyagi et al.	
	120	6,226,539	05-01-2001	Potratz	
	121	6,157,041	12-05-2000	Thomas et al.	
	122	6,154,667	11-28-2000	Miura et al.	
	123	6,151,518	11-21-2000	Hayashi	
	124	6,112,107	08-29-2000	Hannula	
	125	6,104,938	08-15-2000	Huiku	
	126	6,094,592	07-25-2000	Yorkey et al.	
	127	6,083,172	07-04-2000	Baker JR. et al.	
	128	6,073,037	06-06-2000	Alam et al.	
	129	6,068,594	05-30-2000	Schloemer et al.	
	130	6,064,898	05-16-2000	Aldrich	
	131	6,023,541	02-08-2000	Merchant et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 6 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	132	6,018,674	01-25-2000	Aronow	
	133	6,018,673	01-25-2000	Chin et al.	
	134	6,014,576	01-11-2000	Raley	
	135	6,006,119	12-21-1999	Soller et al.	
	136	5,999,841	12-07-1999	Aoyagi et al.	
	137	5,995,859	11-30-1999	Takahashi	
	138	5,995,856	11-30-1999	Mannheimer et al.	
	139	5,983,122	11-09-1999	Jarman et al.	
	140	5,978,691	11-02-1999	Mills	
	141	5,954,644	09-21-1999	Dettling	
	142	5,934,277	08-10-1999	Mortz	
	143	5,921,921	07-13-1999	Potratz et al.	
	144	5,919,133	07-06-1999	Taylor	
	145	5,916,154	06-29-1999	Hobbs et al.	
	146	5,910,108	06-08-1999	Solenberger	
	147	5,891,024	04-06-1999	Jarman et al.	
	148	5,885,213	03-23-1999	Richardson et al.	
	149	5,876,348	03-02-1999	Sugo	
	150	5,865,736	02-02-1999	Baker JR. et al.	
	151	5,857,462	01-12-1999	Thomas et al.	
	152	5,853,364	12-29-1998	Baker, Jr., et al.	
	153	5,851,179	12-22-1998	Ritson et al.	
	154	5,851,178	12-22-1998	Aronow	
	155	5,842,979	12-01-1998	Jarman	
	156	5,839,439	11-24-1998	Nierlich et al.	
	157	5,830,137	11-03-1998	Sharf	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 7 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	158	5,827,182	10-27-1998	Raley	
	159	5,823,952	10-20-1998	Levinson et al.	
	160	5,818,985	10-06-1998	Merchant et al.	
	161	5,817,010	10-06-1998	Hibl	
	162	5,810,724	09-22-1998	Gronvall	
	163	5,810,723	09-22-1998	Aldrich	
	164	5,807,247	09-15-1998	Merchant et al.	
	165	5,807,246	09-15-1998	Sakaguchi et al.	
	166	5,803,910	09-08-1998	Potratz	
	167	5,800,349	09-01-1998	Isaacson et al.	
	168	5,793,485	08-11-1998	Gourley	
	169	5,792,052	08-11-1998	Isaacson et al.	
	170	5,790,729	08-04-1998	Pologe et al.	
	171	5,782,756	07-21-1998	Mannheimer	
	172	5,782,237	07-21-1998	Casciani et al.	
	173	5,779,630	07-14-1998	Fein et al.	
	174	5,772,587	06-30-1998	Gratton, et. al	
	175	5,755,226	05-26-1998	Carim et al.	
	176	5,752,914	05-19-1998	Delonzor et al.	
	177	5,746,697	05-05-1998	Swedlow et al.	
	178	5,746,206	05-05-1998	Mannheimer	
	179	5,743,263	04-28-1998	Baker, Jr.	
	180	5,713,355	02-03-1998	Richardson et al.	
	181	5,697,371	12-16-1997	Aoyagi	
	182	5,692,503	12-02-1997	Kuenstner	
	183	5,690,104	11-25-1997	Kanemoto, et al.	
	184	5,687,722	11-18-1997	Tien et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 8 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	185	5,687,719	11-18-1997	Sato, et al.	
	186	5,685,301	11-11-1997	Klomhaus	
	187	5,678,544	10-21-1997	Delonzor et al.	
	188	5,676,141	10-14-1997	Hollub	
	189	5,676,139	10-14-1997	Goldberger et al.	
	190	5,662,106	09-02-1997	Swedlow et al.	
	191	5,660,567	08-26-1997	Nierlich et al.	
	192	5,645,060	07-08-1997	Yorkey	
	193	5,630,413	05-20-1997	Thomas et al.	
	194	5,603,623	02-18-1997	Nishikawa et al.	
	195	5,596,992	01-28-1997	Haaland et al.	
	196	5,595,176	01-21-1997	Yamaura	
	197	5,590,652	01-07-1997	Inai	
	198	5,588,427	12-31-1996	Tien	
	199	5,584,299	12-17-1996	Sakai et al.	
	200	5,577,500	11-26-1996	Potratz	
	201	5,555,882	09-17-1996	Richardson et al.	
	202	5,553,615	09-10-1996	Carim, et al.	
	203	5,551,423	09-03-1996	Sugiura	
	204	5,533,507	07-09-1996	Potratz	
	205	5,520,177	05-28-1996	Ogawa	
	206	5,503,148	04-02-1996	Pologe et al.	
	207	5,494,032	02-27-1996	Robinson et al.	
	208	5,490,523	02-13-1996	Isaacson et al.	
	209	5,435,309	07-25-1995	Thomas et al.	
	210	5,429,128	07-04-1995	Cadell et al.	
	211	5,427,093	06-27-1995	Ogawa et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 9 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	212	5,421,329	06-06-1995	Casciani et al.	
	213	5,413,101	05-09-1995	Sugiura	
	214	5,392,777	02-28-1995	Swedlow et al.	
	215	5,387,122	02-07-1995	Goldberger et al.	
	216	5,385,143	01-31-1995	Aoyagi	
	217	5,368,224	11-29-1994	Richardson et al.	
	218	5,361,758	11-08-1994	Hall et al.	
	219	5,355,882	10-18-1994	Ukawa et al.	
	220	5,355,880	10-18-1994	Thomas et al.	
	221	5,351,685	10-04-1994	Potratz	
	222	5,348,004	09-20-1994	Hollub	
	223	5,335,659	08-09-1994	Pologe et al.	
	224	5,313,940	5-24-1994	Fuse et al.	
	225	5,297,548	03-29-1994	Pologe	
	226	5,278,627	01-11-1994	Aoyagi	
	227	5,267,563	12-07-1993	Swedlow et al.	
	228	5,267,562	12-07-1993	Ukawa et al.	
	229	5,209,230	05-11-1993	Swedlow et al.	
	230	5,190,040	03-02-1993	Aoyagi	
	231	5,078,136	01-07-1992	Stone et al.	
	232	5,054,495	10-08-1991	Uemura, et al.	
	233	5,033,472	07-23-1991	Sato, et al.	
	234	4,997,769	03-05-1991	Lundsgaard	
	235	4,975,581	12-04-1990	Robinson et al.	
	236	4,967,571	11-06-1990	Sporri	
	237	4,964,010	10-16-1990	Miyasaka et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 10 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	238	4,960,126	10-02-1990	Conlon et al.	
	239	4,955,379	09-11-1990	Hall	
	240	4,942,877	07-24-1990	Sakai et al.	
	241	4,934,372	06-19-1990	Corenman et al.	
	242	4,911,167	03-27-1990	Corenman et al.	
	243	4,869,254	09-26-1989	Stone et al.	
	244	4,867,571	09-19-1989	Frick et al.	
	245	4,863,265	09-05-1989	Flower, et al.	
	246	4,846,183	07-11-1989	Martin	
	247	4,832,484	05-23-1989	Aoyagi, et al.	
	248	4,800,885	01-31-1989	Johnson	
	249	4,781,195	11-01-1988	Martin	
	250	4,773,422	09-27-1988	Isaacson et al.	
	251	4,770,179	09-13-1988	New et al.	
	252	4,714,341	12-22-1987	Hamaguri et al.	
	253	4,700,708	10-20-1987	New et al.	
	254	4,694,833	09-22-1987	Hamaguri	
	255	4,685,464	08-11-1987	Goldberger	
	256	4,653,498	03-31-1987	New et al.	
	257	4,621,643	11-11-1986	New et al.	
	258	4,586,513	05-06-1986	Hamaguri	
	259	4,446,871	05-08-1984	Imura	
	260	4,266,554	05-12-1981	Hamaguri	
	261	4,167,331	09-11-1979	Nielsen	
	262	4,157,708	06-12-1979	Imura	
	263	3,998,550	12-21-1976	Konishi, et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.F./

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 11 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	264	RE35,122	12-19-1995	Corenman et al.	
	265	2004/0006261	01-08-2004	Swedlow et al.	
	266	2006/0030764	02-09-2006	Porges et al.	
	267	2004/0033618	02-19-2004	Haass, et al.	
	268	2002/0038078	03-28-2002	Ito	
	269	2005/0043902	02-24-2005	Haaland et al.	
	270	2005/0049469	03-03-2005	Aoyagi et al.	
	271	2002/0059047	05-16-2002	Haaland	
	272	2004/0064259	04-01-2004	Haaland et al.	
	273	2005/0070773	03-31-2005	Chin et al.	
	274	2005/0070775	03-31-2005	Chin et al.	
	275	2005/0075546	04-07-2005	Samsoondar et al.	
	276	2005/0085735	04/21-2005	Baker JR. et al.	
	277	2004/0092805	05-13-2004	Yarita	
	278	2003/0109775	06-12-2003	O'Neil, et al.	
	279	2002/0111748	08-15-2002	Kobayashi et al.	
	280	2003/0120160	06-26-2003	Yarita	
	281	2005/0124871	06/09-2005	Baker JR. et al.	
	282	2004/0138538	07-15-2004	Stetson	
	283	2004/0138540	07-15-2004	Baker JR. et al.	
	284	2003/0139657	07-24-2003	Solenberger	
	285	2005/143634	06-30-2005	Baker JR. et al.	
	286	2005/0143943	06-30-2005	Brown	
	287	2005/0148834	07-07-2005	Hull, et al.	
	288	2004/0158135	08-12-2004	Baker JR. et al.	
	289	2004/0162472	08-19-2004	Berson et al.	
	290	2004/0167382	08-26-2004	Gardner, et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 12 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	291	2004/0167382	08-26-2004	Gardner et al.	
	292	2004/0176670	09-09-2004	Takamura et al.	
	293	2004/0181134	09-16-2004	Baker JR. et al.	
	294	2005/0184895	08-25-2005	Petersen et al.	
	295	2005/0187447	08-25-2005	Chew et al.	
	296	2005/0187448	08-25-2005	Petersen et al.	
	297	2005/0187449	08-25-2005	Chew et al.	
	298	2005/0187450	08-25-2005	Chew et al.	
	299	2005/0187452	08-25-2005	Petersen et al.	
	300	2005/0187453	08-25-2005	Petersen et al.	
	301	2003/0195402	10-16-2003	Fein et al.	
	302	2005/0197549	09-08-2005	Baker JR.	
	303	2005/0197579	09-08-2005	Baker JR.	
	304	2005/0197793	09-08-2005	Baker JR.	
	305	2004/0199063	10-07-2004	O'Neil et al.	
	306	2005/0203357	09-15-2005	Debreczeny et al.	
	307	2004/0204639	10-14-2004	Casciani et al.	
	308	2004/0204868	10-14-2004	Maynard, et al.	
	309	2005/0228253	10-13-2005	Debreczeny	
	310	2005/0250997	11-10-2005	Takedo et al.	
	311	2004/0267140	12-30-2004	Ito et al.	
	312	RE36,000	12-22-1998	Swedlow et al.	
	313	RE33,643	07-23-1991	Isaacson et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	314					
	315					

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 13 OF 13	Attorney Docket No.	MLR.012A

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	316					
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	318					

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	319		
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	322		
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Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 1 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	7,044,918	05/2006	Diab	
	2	7,041,060	05/2006	Flaherty, et al	
	3	7,039,449	05/2006	Al-Ali	
	4	7,030,749	04/2006	Al-Ali	
	5	7,027,849	04/2006	Al-Ali	
	6	7,024,233	04/2006	Al, et al.	
	7	7,015,451	02/2006	Dalke, et al.	
	8	7,003,339	02/2006	Diab, et al.	
	9	7,003,338	02/2006	Weber, et al.	
	10	6,999,904	02/2006	Weber, et al.	
	11	6,996,427	02/2006	Ali, et al.	
	12	6,993,371	01/2006	Kiani, et al.	
	13	6,985,764	01/2006	Mason, et al.	
	14	6,979,812	12/2005	Al-Ali	
	15	6,970,792	11/2005	Diab	
	16	6,961,598	11/2005	Diab	
	17	6,950,687	09/2005	Al-Ali	
	18	6,943,348	09/2005	Coffin, IV	
	19	6,939,305	09/2005	Flaherty, et al.	
	20	6,934,570	08/2005	Kiani, et al.	
	21	6,931,268	08/2005	Kiani-Azarbayjany, et al.	
	22	6,920,345	07/2005	Al-Ali, et al.	
	23	6,898,452	05/2005	Al-Ali, et al.	
	24	6,861,639	03/2005	Al-Ali	
	25	6,852,083	02/2005	Caro, et al.	
	26	6,850,788	02/2005	Al-Ali	
	27	6,850,787	02/2005	Weber, et al.	
	28	6,830,711	12/2004	Mills, et al.	
	29	6,826,419	11/2004	Diab, et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 2 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	6,822,564	11/2004	Al-Ali	
	31	6,816,741	11/2004	Diab	
	32	6,813,511	11/2004	Diab, et al.	
	33	6,792,300	09/2004	Diab, et al.	
	34	6,771,994	08/2004	Kiani, et al.	
	35	6,770,028	08/2004	Ali, et al.	
	36	6,760,607	07/2004	Al-Ali	
	37	6,745,060	06/2004	Diab, et al.	
	38	6,735,459	05/2004	Parker	
	39	6,725,075	04/2004	Al-Ali	
	40	6,721,585	04/2004	Parker	
	41	RE38,492	04/2004	Diab, et al.	
	42	6,714,804	03/2004	Al-Ali, et al.	
	43	RE38,476	03/2004	Diab, et al.	
	44	6,699,194	03/2004	Diab, et al.	
	45	6,697,658	02/2004	Al-Ali	
	46	6,697,656	02/2004	Al-Ali	
	47	6,684,091	01/2004	Parker	
	48	6,684,090	01/2004	Ali, et al.	
	49	6,678,543	01/2004	Diab, et al.	
	50	6,671,531	12/2003	Al-Ali, et al.	
	51	6,661,161	12/2003	Lanzo, et al.	
	52	6,658,276	12/2003	Diab, et al.	
	53	6,654,624	11/2003	Diab, et al.	
	54	6,650,917	11/2003	Diab, et al.	
	55	6,643,530	11/2003	Diab, et al.	
	56	6,640,116	10/2003	Diab	
	57	6,632,181	10/2003	Flaherty, et al.	
	58	6,606,511	08/2003	Ali, et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 3 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	6,597,933	07/2003	Kiani, et al.	
	60	6,595,316	07/2003	Cybulski, et al.	
	61	6,584,336	06/2003	Ali, et al.	
	62	6,580,086	06/2003	Schulz, et al.	
	63	6,542,764	04/2003	Al-Ali, et al.	
	64	6,541,756	04/2003	Schulz, et al.	
	65	6,526,300	02/2003	Kiani, et al.	
	66	6,525,386	02/2003	Mills, et al.	
	67	6,519,487	02/2003	Parker	
	68	6,515,273	02/2003	Al-Ali	
	69	6,501,975	12/2002	Diab, et al.	
	70	6,470,199	10/2002	Kopotic, et al.	
	71	6,463,311	10/2002	Diab	
	72	6,430,525	08/2002	Weber, et al.	
	73	6,397,091	05/2002	Diab, et al.	
	74	6,388,240	05/2002	Schulz, et al.	
	75	6,377,829	04/2002	Al-Ali	
	76	6,371,921	04/2002	Caro, et al.	
	77	6,360,114	03/2002	Diab, et al.	
	78	6,349,228	02/2002	Kiani, et al.	
	79	6,343,224	01/2002	Parker	
	80	6,334,065	12/2001	Al-Ali, et al.	
	81	6,321,100	11/2001	Parker	
	82	6,285,896	09/2001	Tobler, et al.	
	83	6,280,213	08/2001	Tobler, et al.	
	84	6,278,522	08/2001	Lepper, Jr., et al.	
	85	6,263,222	07/2001	Diab, et al.	
	86	6,256,523	07/2001	Diab, et al.	
	87	6,236,872	05/2001	Diab, et al.	

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 4 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	88	6,229,856	05/2001	Diab, et al.	
	89	6,206,830	03/2001	Diab, et al.	
	90	6,184,521	02/2001	Coffin, IV, et al.	
	91	6,165,005	12/2000	Mills, et al.	
	92	6,157,850	12/2000	Diab, et al.	
	93	6,152,754	11/2000	Gerhardt, et al.	
	94	6,151,516	11/2000	Kiani-Azarbayjany, et al.	
	95	6,144,868	11/2000	Parker	
	96	6,110,522	08/2000	Lepper, Jr., et al.	
	97	6,088,607	07/2000	Diab, et al.	
	98	6,081,735	06/2000	Diab, et al.	
	99	6,067,462	05/2000	Diab, et al.	
	100	6,045,509	04/2000	Caro, et al.	
	101	6,036,642	03/2000	Diab, et al.	
	102	6,027,452	02/2000	Flaherty, et al.	
	103	6,011,986	01/2000	Diab, et al.	
	104	6,002,952	12/1999	Diab, et al.	
	105	5,997,343	12/1999	Mills, et al.	
	106	5,995,855	11/1999	Kiani, et al.	
	107	5,940,182	08/1999	Lepper, Jr., et al.	
	108	5,934,925	08/1999	Tobler, et al.	
	109	5,919,134	07/1999	Diab	
	110	5,904,654	05/1999	Wohltmann, et al.	
	111	5,890,929	04/1999	Mills, et al.	
	112	5,860,919	01/1999	Kiani-Azarbayjany, et al.	
	113	5,833,618	11/1998	Caro, et al.	
	114	5,830,131	11/1998	Caro, et al.	
	115	5,823,950	10/1998	Diab, et al.	
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Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 5 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	117	5,791,347	08/1998	Flaherty, et al.	
	118	5,785,659	07/1998	Caro, et al.	
	119	5,782,757	07/1998	Diab, et al.	
	120	5,769,785	06/1998	Diab, et al.	
	121	5,760,910	06/1998	Lepper, Jr., et al.	
	122	5,758,644	06/1998	Diab, et al.	
	123	5,743,262	04/1998	Lepper, Jr., et al.	
	124	Des. 393,830	04/1998	Tobler, et al.	
	125	5,685,299	11/1997	Diab, et al.	
	126	5,645,440	07/1997	Tobler, et al.	
	127	5,638,818	06/1997	Diab, et al.	
	128	5,638,816	06/1997	Kiani-Azarbayjany, et al.	
	129	5,632,272	05/1997	Diab, et al.	
	130	5,602,924	02/1997	Durand, et al.	
	131	5,590,649	01/1997	Caro, et al.	
	132	5,562,002	10/1986	Lalin	
	133	5,533,511	07/1996	Kaspari, et al.	
	134	5,494,043	02/1996	O'Sullivan, et al.	
	135	5,490,505	02/1996	Diab, et al.	
	136	5,482,036	01/1996	Diab, et al.	
	137	D363,120	10/1995	Savage, et al.	
	138	5,452,717	09/1995	Branigan, et al.	
	139	D362,063	09/1995	Savage, et al.	
	140	D361,840	08/1995	Savage, et al.	
	141	5,431,170	07/1995	Mathews	
	142	D353,196	12/1994	Savage, et al.	
	143	D353,195	12/1994	Savage, et al.	
	144	5,337,744	08/1994	Branigan	
	145	5,163,438	11/1992	Gordon, et al.	

Examiner Signature /Marjan Fardanesh/	Date Considered 03/31/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 6 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	146	5,069,213	12/1991	Polczynski	
	147	5,041,187	08/1991	Hink, et al.	
	148	4,964,408	10/1990	Hink, et al.	
	149	4,960,128	10/1990	Gordon, et al.	

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Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.F./

OIPE IAP84 AUG 29 2006 PATENT & TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Multiple sheets used when necessary)

SHEET 1 OF 2

Application No.	11/367,033
Filing Date	March 1, 2006
First Named Inventor	Al-Ali, et al.
Art Unit	Unknown
Examiner	Unknown
Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	6,743,172	6/1/04	Blike	
	2	6,611,698	8/26/03	Yamashita et al.	
	3	6,253,097	6/26/01	Aronow et al.	
	4	6,184,521	2/6/01	Coffin IV et al.	
	5	6,122,042	9/19/00	Wunderman et al.	
	6	5,800,348	1/9/98	Kaestle et al.	
	7	5,645,059	7/8/97	Fein et al.	
	8	5,331,549	7/19/94	Crawford Jr.	
	9	5,259,381	11/9/93	Cheung et al.	
	10	5,058,588	10/22/91	Kaestle et al.	
	11	4,986,665	1/22/91	Yamanishi et al.	
	12	4,907,876	3/13/90	Suzuki et al.	
	13	2005/0011488	2/10/05	Al Ali et al.	
	14	2004/0267103	12/30/04	Li Luya et al.	
	15	2004/0262046	12/30/04	Simon et al.	
	16	2004/0158134	8/12/04	Diab et al.	
	17	2004/0147823	7/29/04	Kiani et al.	
	18	2004/0133087	7/8/04	Al Ali et al.	
	19	2004/0081621	4/29/04	Arndt et al.	
	20	2004/0059209	3/25/04	Al Ali et al.	
	21	2004/0034898	2/10/05	Al Ali et al.	
	22	2002/0183819	12/5/02	Struble	
	23	2002/0161291	10/31/02	Kiani et al.	
	24	2002/0038081	3/28/02	Fein et al.	
	25	2002/0021269	2/21/00	Rast	
	26	2001/0044700	11/22/01	Koboyashi et al.	

FOREIGN PATENT DOCUMENTS

Examiner Signature	Date Considered

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T[1] - Place a check mark in this area when an English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.F./

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Al-Ali, et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 2 OF 2	Attorney Docket No.	MLR.012A

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	27	WO 00/59374	10/12/00	Scheuing et al.		
	28	WO 98/43071	10/1/98	Baker et al.		
	29	WO 03/068060	8/21/03	Huiku		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	30	Patent Cooperation Treaty (PCT) International Search Report; PCT/US 2006/007389; Date of Mailing 7/17/06; Pages 1-9	
	31	PCT International Search Report; PCT/US2006/007537; Date of Mailing 7/17/06; Pages 1-10	
	32	PCT International Search Report; PCT/US2006/007388; Date of Mailing 7/17/06; Pages 1-9	
	33	PCT International Search Report; PCT/US2006/007538; Date of Mailing 7/17/06; Pages 1-9	
	34	PCT International Search Report; PCT/US2006/007958; Date of Mailing 7/17/06; Pages 1-8	
	35	PCT International Search Report; PCT/US2006/007506; Date of Mailing 7/17/06; Pages 1-10	
	36	PCT International Search Report; PCT/US2006/007536; Date of Mailing 7/17/06; Pages 1-9	
	37	PCT International Search Report; PCT/US2006/007540; Date of Mailing 7/17/06; Pages 1-9	
	38	PCT International Search Report; PCT/US2006/007539; Date of Mailing 7/17/06; Pages 1-9	
	39	PCT International Search Report; PCT/US2006/007387; Date of Mailing 7/17/06; Pages 1-9	

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081706

Examiner Signature	/Marjan Fardanesh/	Date Considered	03/31/2011

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T[1] - Place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.F./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Ammar Al-Ali, et al.
App. No	:	11/367,033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Winakur, Eric Frank
Art Unit	:	3768
Conf No.	:	3334

CERTIFICATE OF EFS WEB TRANSMISSION

I hereby certify that this correspondence, and any other attachment noted on the automated Acknowledgement Receipt, is being transmitted from within the Pacific Time zone to the Commissioner for Patents via the EFS Web server on:

April 15, 2010
(Date)

Jarom D. Kesler, Reg. No. 57,046

PRELIMINARY AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph [0002] of the Specification with the following:

[0002] The present application is related to the following copending U.S. utility applications:

	App. Sr. No.	Filing Date	Title	Atty Dock.
1	11/367,013	March 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
2	11/366,995	March 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/366,209	March 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/366,210	March 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/366,833	March 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/366,997	March 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/367,034	March 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/367,036	March 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/367,014	March 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
10	11/366,208	March 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

REMARKS

In this amendment, Applicants have amended the Specification to include the serial numbers of the related applications incorporated by reference and filed on the same day as the present Application. Applicant submits that no new matter has been added through the amendments.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 15, 2010

By: _____
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20995
(949) 760-0404

8890764

Electronic Acknowledgement Receipt

EFS ID:	7422321
Application Number:	11367033
International Application Number:	
Confirmation Number:	3334
Title of Invention:	Noninvasive multi-parameter patient monitor
First Named Inventor/Applicant Name:	Ammar Al-Ali
Customer Number:	20995
Filer:	Jarom D. Kesler/Valerie Jones
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	MLR.012A
Receipt Date:	15-APR-2010
Filing Date:	01-MAR-2006
Time Stamp:	18:49:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		012A.pdf	77698 41b3373ac7b7101e72735ed01dbcb22e0b28fc63	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Specification	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3
Warnings:			
Information:			
	Total Files Size (in bytes):	77698	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

INFORMATION DISCLOSURE STATEMENT

Applicant	:	Ammar Al-Ali, et al.
App. No	:	11/367,033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Unknown
Art Unit	:	3736

Confirmation No.: 3334

EFS Web Transmission Certification

I hereby certify that this correspondence and all marked attachments are being transmitted via EFS

Jarom D. Kesler, Reg. No. 57,046

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 5 references to be considered by the Examiner. Also enclosed are 2 foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2/21/07

By:
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20,995
(949) 760-0404

3431973:cy
021507

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali
	Art Unit	3736
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 1 OF 1	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	US 2002/156353 A1	10-24-2002	Eric Russell Larson	
	2	US 2001/045532 A1	11-29-2001	Charles E. Schulz, et al.	
	3	US 6,285,895 B1	09-04-2001	Kimmo Juhani Ristolainen, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	4	International Search Report for PCT/US2006/007516, mailed on 01-11-2007, in 4 pages.	
	5	SCHMITT, JOSEPH M.; ZHOU, GUAN-XIONG; MILLER, JUSTIN, Measurement of Blood Hematocrit by Dual-wavelength Near-IR Photoplethysmography, published May 1992, Proc. SPIE Vol.1641, p.150-161, Physiological Monitoring and Early Detection Diagnostic Methods, Thomas S. Mang; Ed. (SPIE homepage), in 12 pages.	

3431979:cy
021507

Examiner Signature	Date Considered

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

Electronic Acknowledgement Receipt

EFS ID:	1534090
Application Number:	11367033
International Application Number:	
Confirmation Number:	3334
Title of Invention:	Noninvasive multi-parameter patient monitor
First Named Inventor/Applicant Name:	Ammar Al-Ali
Customer Number:	20995
Filer:	Jarom D. Kesler/Vanessa Langer
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	MLR.012A
Receipt Date:	21-FEB-2007
Filing Date:	01-MAR-2006
Time Stamp:	18:05:17
Application Type:	Utility

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed	MLR012aIDS.pdf	92550	no	2
Warnings:					

Information:					
This is not an USPTO supplied IDS fillable form					
2	NPL Documents	MLR012aNonPatRef1.pdf	762049	no	12
Warnings:					
Information:					
3	NPL Documents	MLR012aNonPatentRef2.pdf	172348	no	4
Warnings:					
Information:					
		Total Files Size (in bytes):	1026947		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number: 11/367033

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	63	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	63 minus 20=	* 43
INDEPENDENT CLAIMS	4 minus 3 =	* 1
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	$375	OR	BASIC FEE	$750
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL		OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

IFW

Docket No.: MLR.012A

August 25, 2006



Please Direct All Correspondence to Customer Number **20995**

TRANSMITTAL LETTER
INFORMATION DISCLOSURE STATEMENT

Applicant	:	Al-Ali, et al.
App. No	:	11/367,033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Unknown
Art Unit	:	Unknown

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

August 25, 2006
(Date)

Jarom D. Kesler, Reg. No. 57,046

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

(X) An Information Disclosure Statement and PTO/SB/08 equivalent listing references for consideration:

- (X) Listing 39 references.
- (X) Enclosing 13 references.

(X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

(X) Return prepaid postcard.

Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20,995
(949) 760-0404

2849697
081706

OIPE IAP64 AUG 28 2006 PATENT & TRADEMARK OFFICE

Docket No.: MLR.012A **Customer No. 20,995**

INFORMATION DISCLOSURE STATEMENT

Applicant	:	Al-Ali, et al.
App. No	:	11/367,033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Unknown
Art Unit	:	Unknown

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

August 25, 2006
(Date)

Jarom Kesler, Reg. No. 57,046

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 39 references to be considered by the Examiner. Also enclosed are 13 foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

This Information Disclosure Statement is being filed before the mailing date of a final action and before the mailing date of a Notice of Allowance.

CERTIFICATION UNDER 37 C.F.R. § 1.97(e)(1)

I hereby certify that each item of information contained in this Statement was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

Thus, no fee is required as set forth in 37 C.F.R. § 1.97(c).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 8/25/06

By: _____
Jarom Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20,995
(949) 760-0404

2849702/081706

OIPE IAP84 AUG 28 2006 PATENT & TRADEMARK OFFICE

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Multiple sheets used when necessary)

SHEET 1 OF 2

Application No.	11/367,033
Filing Date	March 1, 2006
First Named Inventor	Al-Ali, et al.
Art Unit	Unknown
Examiner	Unknown
Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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	2	6,611,698	8/26/03	Yamashita et al.	
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	4	6,184,521	2/6/01	Coffin IV et al.	
	5	6,122,042	9/19/00	Wunderman et al.	
	6	5,800,348	1/9/98	Kaestle et al.	
	7	5,645,059	7/8/97	Fein et al.	
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	11	4,986,665	1/22/91	Yamanishi et al.	
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	13	2005/0011488	2/10/05	Al Ali et al.	
	14	2004/0267103	12/30/04	Li Luya et al.	
	15	2004/0262046	12/30/04	Simon et al.	
	16	2004/0158134	8/12/04	Diab et al.	
	17	2004/0147823	7/29/04	Kiani et al.	
	18	2004/0133087	7/8/04	Al Ali et al.	
	19	2004/0081621	4/29/04	Arndt et al.	
	20	2004/0059209	3/25/04	Al Ali et al.	
	21	2004/0034898	2/10/05	Al Ali et al.	
	22	2002/0183819	12/5/02	Struble	
	23	2002/0161291	10/31/02	Kiani et al.	
	24	2002/0038081	3/28/02	Fein et al.	
	25	2002/0021269	2/21/00	Rast	
	26	2001/0044700	11/22/01	Koboyashi et al.	

FOREIGN PATENT DOCUMENTS

Examiner Signature	Date Considered

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Al-Ali, et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 2 OF 2	Attorney Docket No.	MLR.012A

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	27	WO 00/59374	10/12/00	Scheuing et al.		
	28	WO 98/43071	10/1/98	Baker et al.		
	29	WO 03/068060	8/21/03	Huiku		

NON PATENT LITERATURE DOCUMENTS			
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	32	PCT International Search Report; PCT/US2006/007388; Date of Mailing 7/17/06; Pages 1-9	
	33	PCT International Search Report; PCT/US2006/007538; Date of Mailing 7/17/06; Pages 1-9	
	34	PCT International Search Report; PCT/US2006/007958; Date of Mailing 7/17/06; Pages 1-8	
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	36	PCT International Search Report; PCT/US2006/007536; Date of Mailing 7/17/06; Pages 1-9	
	37	PCT International Search Report; PCT/US2006/007540; Date of Mailing 7/17/06; Pages 1-9	
	38	PCT International Search Report; PCT/US2006/007539; Date of Mailing 7/17/06; Pages 1-9	
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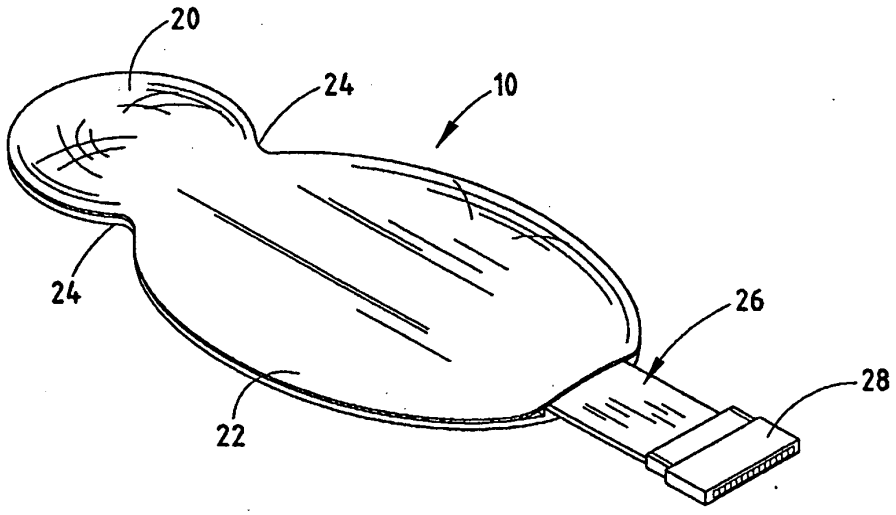
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(54) Title: PATIENT SENSOR FOR CLINICAL SPECTROPHOTOMETRIC APPARATUS



(57) Abstract

This invention is a small, and lightweight spectrophotometric sensor which is particularly, but not necessarily exclusively, useful in cerebral oximetry incorporates a flex circuit (26) having surface mounted electro–optical components that are electrically coupled to conductive traces carried on the flex circuit. At least some such components have an integrally attached rigid, and opaque light passage defining structure which may include a collar–like member, and is preferably a molded element that is "overmolded" upon the electro–optical component. The flex circuit includes a thin elongated member which includes alternate coatings of conductive, and non–conductive material over the conductive traces to provide electrical insulation, and electromagnetic shielding. The conductive traces are connected to short electrical leads extending outwardly from the sensor for only a brief distance, terminated by a manually connectable, and disconnected connector member. The flex circuit is mounted on a soft, thin, opaque, foam body (12), and covered by a thin protective layer (16).

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PATIENT SENSOR FOR CLINICAL SPECTROPHOTOMETRIC APPARATUS

BACKGROUND OF THE INVENTION

This invention relates generally to spectrophotometric devices and apparatus, particularly those used for medical purposes, for non-invasively monitoring or otherwise obtaining data from patients or other test subjects by passing selected light spectra through portions of the patient anatomy and monitoring the resulting light to obtain data based on spectrally related absorption by particular biologic substances which reveal internal physiological conditions.

More particularly, the invention relates to the sensors which are used to produce and administer the selected light spectra, and to detect the resultant light emanating from the test subject after it has transmissed the anatomical portion under test. Still more particularly, the invention pertains to sensors of this basic nature which comprise soft, light-weight, compliant members which carry the necessary electro-optical components (*e.g.*, emitters, detectors, and the like) and which are applied to a selected area or location on the patient/test subject in a manner which holds the electro-optical components in their desired positions relative to the patient/test subject, *e.g.*, normally in direct light-tight contact with the skin.

Many different versions and types of such sensors have been developed over the past decade or thereabouts, during which medically-related spectrophotometric devices have been developed and have gained increasing usage in hospitals and other such clinical locations. Many or most such previously developed sensors pertain to pulse oximeters, which are used to obtain a measure of arterial hemoglobin oxygen saturation on an ongoing, in vivo basis, most typically by attaching the sensor to the patient's finger, ear lobe, or the like. Other types of such sensors for using the broad underlying spectrophotometric principals to accomplish various other novel results have also been developed or proposed previously, particularly by Somanetics Corporation of Troy Michigan, the Applicant herein, which has developed a non-invasive spectrophotometric cerebral oximeter. That device operates on a non-pulsatile basis to compute oxygen saturation in the brain by mounting one or more sensors on the forehead and using selected light wavelengths in the near infrared/red bandwidth to transmiss brain tissue underlying the forehead and detect spectral absorption of the selected light wavelengths by the blood present in that area. In this regard, reference is made to Applicant's prior

U.S. Patent Nos. 5,795,292, 5,697,367, 5,584,296, 5,482,034, 5,465,714, and 5,217,013, relating to various aspects of this development and its associated apparatus.

Due to the emphasis on sanitation rigorously followed in hospitals and other such health facilities, the standard operating protocol is the utilization of single-use devices and equipment which comes in a sterilized container and is thrown away after use, or even after the container is opened. That same protocol has been followed in the use of spectrophotometric devices such as pulse oximeters and the like, as well as in cerebral oximeters, *i.e.*, the sensors are thrown away after a single use. This of course introduces a significant cost factor, and with the increasing emphasis on cost reduction in medical procedures there is a corresponding emphasis on the design and manufacture of equipment which is more economical to produce and correspondingly less wasteful when discarded after only a single use. At the same time, there is also an increased emphasis on the design and manufacture of better and more capable as well as more reliable componentry, which is usually contradictory to the economy paradigm.

SUMMARY OF THE INVENTION

The present invention satisfies both of the above-stated objectives by the provision of an improved spectrophotometric sensor which is particularly (but not necessarily exclusively) useful in cerebral oximetry. In satisfying these dual objectives of economy and performance, the improved sensor provided herewith comprises a less expensive but equally or even more reliable device, which is lighter in weight than predecessor devices yet nonetheless produces the same high level of operating efficiency and accuracy possessed by previous such devices; in fact, the present invention provides improvements in both such areas due to the novel and highly effective structure and method of manufacture made possible by and in accordance with the invention.

More particularly, the present invention provides an optimally small and lightweight spectrophotometric sensor which incorporates a flex circuit having surface-mounted electro-optical components that are electrically coupled to conductive traces carried on the flex circuit, wherein at least some such components have an integrally attached rigid and opaque light passage-defining structure which may comprise a collar-like member preferably a molded element that is "overmolded" upon the electro-optical component. In this aspect, the invention provides a spectrophotometric sensor of the type just noted having an electro-optical component which is embedded in a generally rigid and opaque light-passage structure comprising an aperture that is formed in place

upon the embedded electro-optical component. Preferably, the conductive traces of the flex circuit are connected to short electrical leads extending outwardly from the sensor for only a brief distance and terminated there by a manually connectable and disconnectable connector member.

Furthermore, the invention provides a method of conducting spectrophotometric procedures by use of an electro-optical sensor and a signal processing unit, in which the sensor is applied to the test subject and electrically connected to the processing unit by a coupling carried by and located close to the sensor, said coupling being releasably connectable to a reusable high-quality electrical cable having conductors extending to and connected to the processing unit, to reduce sensor cost, weight, and motion artifact effects. Also provided is a method of manufacturing a spectrophotometric sensor by automated machine operation, including the steps of using a thin flexible substrate which carries thin conductive traces on at least one side, placing electro-optical components in precise predetermined positions on said substrate by using robotic apparatus, and establishing secure electrical connections between said components and said conductive traces by automated means, *e.g.*, by conveying the substrate and placed components through a solder reflow oven, and by using conductive adhesive between said traces and said components.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view showing the basic appearance and nature of a preferred embodiment of the invention;

Fig. 2 is an exploded perspective view showing the components making up the structure of Fig. 1;

Fig. 3 is an overhead plan view showing some of the assembled components of the sensor in place, with others removed;

Fig. 4 is an overhead plan view showing one preferred embodiment of the flex circuit used in the sensor;

Fig. 5 is an overhead plan view showing the main body component of the sensor alone, prior to assembly;

Fig. 6 is an enlarged side elevational view showing a preferred embodiment of the flex circuit and assembled components;

Fig. 7 is a longitudinal central sectional view of the assembled sensor;

Fig. 8 is an enlarged fragmentary sectional view of the portion circled in Fig. 7 and label "VIII";

Fig. 9 is a enlarged perspective view showing a preferred embodiment of an electro-optical component as utilized in the sensor;

Fig. 10 is a further enlarged cross-sectional side elevation taken along the plane X-X of Fig. 9; and

Fig. 11 is a further enlarged cross-sectional side elevation taken along the plane XI-XI of Fig. 9.

DESCRIPTION OF PREFERRED EMBODIMENTS

The basic appearance and nature of a preferred embodiment 10 of the invention is illustrated in an overall manner in Fig. 1 and in further detail in Figs. 2, 7, and 8, from which it will be seen that this preferred embodiment is a composite device comprising a plurality of superimposed layers which are stacked one upon the other and adhesively or otherwise secured together into a composite, laminated structure. As best illustrated in Figs. 1 and 2, the sensor 10 preferably has an overall shape analogous to a "figure 8" or "snowman," having a first, smaller rounded portion 20 at one end and a second, larger rounded portion 22 at the other end, with a narrow waist portion 24 therebetween. A flat "flex circuit" 26 which protrudes from the larger end 22 carries a plurality of electrical traces (noted further below) that are terminated by an electrical connector 28 of a generally conventional nature, by which the sensor 10 may be connected to and disconnected from a spectrophotometric device such as an oximeter, by means of an electrical cable extending therefrom and having a corresponding and cooperating plug or other such connector part at its end (not specifically illustrated).

As illustrated in Figs. 2, 7, and 8 the various layers making up sensor 10 include a principal body portion 12, which preferably comprises a softly resilient but firm molded foam member having certain transverse apertures 56, recesses 58, and other shaped configurations, and preferably made of a conductive polymeric material such as polyethylene. In a specific preferred embodiment, body 12 may be approximately one-tenth to two-tenths inches thick at its thickest point. Immediately atop the main body portion 12 is a layer of adhesive (or thin "double-sided" adhesive tape film) 13, and a shielding layer 14, which preferably comprises copper-impregnated ripstop nylon approximately .005-.010 inches thick, both of which have substantially the same arrangement of apertures and recesses as those formed in the adjacent side of the foam

body 12 so as to register directly therewith when the adhesive layer 13 and shielding layer 14 are in place upon body 12. Atop the shielding layer 14 is the aforementioned flex circuit 26, whose surface-mounted electo-optical components fit closely inside the aforementioned registering apertures in the shielding layer 14, adhesive layer 13 and main body 12. Over the entire upper surface of main body 12, and covering it as well as shielding layer 14 and the flex circuit 26, is a relatively thin outer cover layer 16, which is preferably of polymeric foam or the like, preferably opaque or substantially opaque, and preferably adhesively secured in place on body 12 to hold the component layers under it securely together as well as provide a finished appearance. Fig. 3 is a top plan view of this layered structure with cover layer 16 removed, showing flex circuit 26 in place atop shielding layer 14 (which covers adhesive layer 13).

On the opposite side of the body 12 from the component layers noted above is one or more layers of electrically conductive adhesive 18a (Figs. 2, 7, and 8) and, directly adjacent and upon that, a protective outer liner layer 18b which should have a readily releasable surface characteristic, *e.g.*, silicone-coated polymeric sheet, so that it may be easily and quickly removed from the adhesive layer 18a for use of the sensor 10 by adhesively securing the latter to the forehead or other selected surface area of the patient or test subject by means of the conductive adhesive 18a. Adhesive layer(s) 18a may advantageously be conductive PSA such as "Arclad 8006," by Adhesives Research, Inc.

The overall nature and certain details or features of the flex circuit 26 are best seen in Figs. 4 and 6. Basically, this component comprises a flexible substrate 30 which carries a plurality of electrically conductive traces 32, a light-emitter component grouping 34, light-detectors 36 (preferably, at least two, carried at different spacings from the emitter 34), a programmed calibration memory chip 38, and the aforementioned connector 28. More particularly considered, the flexible substrate 30 preferably includes, in addition to the traces 32, a plurality of additional layers 40, 42, and 44 superimposed over one another on each side of the substrate. These layers may be and preferably are very thin (on the order of one mil thick each) coatings which are screen-printed or otherwise applied atop one another. The layers 40 applied directly to each side of the flexible substrate 30 (and atop the conductive traces 32) are of a non-conductive, electrically insulative material, and they are also preferably of an opaque white coloration, so as to be optically shielding as well as electrically insulative. The

layers 42 applied atop the insulating layers 40 preferably comprise screen-printed conductive silver or the like, to function as an electromagnetic shield, and the outer layers 44, applied over the shielding layers 42, preferably comprise another insulating layer of non-conductive, opaque white material.

In what is at least one of the most preferred embodiments, the flexible substrate 30 may comprise the polyimide sheet material known commercially as "Kapton®" (trademark of Dupont Company), on the order of about .005 -- .015 inches thick in this embodiment; however, other synthetic sheet materials may also be utilized, including more flexible materials such as polyester compounds (including the polyester derivative known as "PEN" (Pentech), which will withstand higher temperatures than many other polyesters), such materials all being electrically non-conductive. The conductive traces 32 applied on at least one side of substrate 30 are preferably copper in the case of Kapton® substrates, (which are somewhat stronger and more heavy-duty than the polyesters), on the order of .0003 inches thick, and covered by tin plate in exposed areas. Particularly located open (uncoated) "window" areas are left in the insulating and conductive shielding layers 40, 42, and 44 in the immediate area where the emitters 34, detectors 36, and memory chip 38 are to be located, to permit the desired electrical connections to be made between the terminals 48 of the components 34, 36, and 38 and the conductive traces 32.

Where the sensor configuration described above is utilized, these electrical connections may be made by silk-screening or otherwise applying solder paste to the specific area on the traces 32 where each such connection is to be made, placing the components 34, 36, 38 precisely in the desired position (by "pick and place", automated robotic apparatus) and using a contact adhesive to temporarily hold the components in this desired placement while the substrate 30 and attached components are conveyed through an oven that is sufficiently hot to melt the solder paste and establish the desired electrical connection without damaging the components, conductive strips or substrate (*i.e.*, about 175°C or less). Where other less rugged materials are used for the substrate 30 (such as polyester), this manufacturing method may be too demanding, but the conductive traces 32 may then be of silver or other conductive ink, printed in place, and the connections between these printed traces and the component terminals may be accomplished by use of conductive adhesives, thereby avoiding the use of hot solder reflow ovens and the like.

The components referred to above as the "emitter" 34 and "detectors" 36 are shown in more detail in Figs. 8, 9, and 10, as well as in Fig. 6, which illustrates the same mounted upon the substrate 30. As noted above, the emitter 34 comprises a selected grouping of wavelength-specific light-emitting components such as LEDs, and the detectors 36 comprise light-sensors such as photodiodes, which provide an electrical output whose magnitude is representative of the light intensity received by them on a real-time basis. In and of themselves, such electro-optical components (now often referred to as "optodes") are very small cubically-shaped solid-state components (indicated at 46 in Fig. 10), with laterally extending electrical terminals 48 protruding therefrom. In accordance with the present invention, each of the electro-optical components 46 is initially encapsulated in a clear epoxy which is preferably applied by the process known as transfer molding, at temperatures of about 150°C or less (to protect the components), to protectively cover each electro-optical component and seal it from moisture, *etc.*, with the electrical connection terminals 48 extending outwardly from the encapsulated component. (The electro-optical component 46 may be supplied in a form by which the component itself is mounted on a metal "lead frame" having integral strip-like projections which form the terminals 48, in which event the component and lead frame are both encapsulated except for the terminals.)

The epoxy-embedded optode 46 thus forms a protected assembly 50 which lends itself well to mechanical handling and other assembly techniques. In accordance with the invention, assembly 50 is overmolded to provide a rigid, windowed outer portion 52 (Fig. 10), for example by using the synthetic compound known as "GE/Ultem" no. 1000F-7101 (available from General Electric Corporation) or other opaque plastic which should be moldable at a sufficiently low temperature to avoid damage to the optode and its embedding material and also capable of withstanding the aforementioned subsequent solder reflow process without damage. Thus, the overmolded component assembly 50, 52 is the actual component which is mounted in place upon the flexible substrate 30 in the particular preferred embodiment under discussion, and it lends itself well to this process due to its size and regulated shape as well as its capability off being handled without damage by mechanical means. The overmolded exterior 52 is preferably opaque and essentially rigid, and it has a window-like opening on one side defined by walls 54, through which light may pass to or from the electro-optical component 46.

The window walls 54 of overmolded cover 52 provide an essentially non-distortable light passage of uniform and consistent shape and dimensions which is not subject to deformation or other such shape changes during use of the sensor, as for example when the sensor is applied to the patient or test subject and pressed firmly into place in a manner which bends or compresses portions of the compliant foam body 12. Also, the walls 54 block ambient light from reaching the sensors, particularly where their outer ends lie in direct contact with the subject to be tested, and the overmolded assembly lends itself well to the automated pick and place manufacturing procedure referred to above, which involves robotic machinery whose use contributes significantly to accurate and consistent component placement at reduced cost. Of course, the bottom extremity of the overmolded electro-optical assembly is the surface applied to the flexible substrate 30 and which carries the adhesive which secures the component in place for soldering, and the connection terminals 48 are offset and configured so that their end extremities basically lie in the same plane as the bottom of the overmolding 52, which is directly adjacent and contiguous to, and substantially the same plane as that occupied by the conductive traces 32, on which the solder paste mentioned previously is applied. It should be pointed out that (as shown in Figs. 9, 10, and 11) the window 54 defined by the overmolding 52 preferably corresponds to and has the same shape as those formed by the molded light guides and optode receptacles disclosed in Applicant's prior U.S. Patent No. 5,465,714, to provide the benefits described therein and broadly disclosed in Applicant's U.S. Patent No. 5,584,296.

Fig. 6 illustrates the assembly produced by mounting the overmolded electro-optical units 34, 36 on the flexible substrate 30, as discussed above, and also shows the calibration memory chip 38 mounted on substrate 30 in essentially this same manner. That is, while memory chip 38 does not necessarily embody the embedded or overmolded structures discussed above in connection with Figs. 9, 10, and 11, it does have projecting electrical terminals which are soldered (or otherwise connected) to the conductive traces 32 in the same manner. It should be noted that, in accordance with the most preferred embodiment of the invention, the mounted and soldered components 34, 36, and 38 are preferably "potted" after they have been so mounted, by applying a small quantity (*e.g.*, a drop or two) of silicone adhesive or the like around at least their edges, to settle around and cover at least side portions of each such component and in particular its soldered or otherwise connected electrical terminals, to thereby further protect them

from undesired direct contact with external objects, and seal them from moisture, dirt, *etc.* This final potting step will or may cover the entire memory chip 38 (as seen at 64 in Fig. 6), as well as the perimeter of the "window" openings left in the shielding and insulating layers 40, 42, and 44, mentioned above, which are provided for the purpose of mounting the electro-optical components. As shown in Fig. 8, the adhesive layer 13 may have somewhat smaller apertures for the components 34, 36, and 38 than the shielding layer 14 and body 12, such that the edges of the adhesive (which may be a thin film) overlie the ends of terminals 48 connected to the traces 32 on the substrate 26 (or overlie the potting compound 64).

It should be pointed out that the calibration chip 38 preferably comprises a miniaturized digital read-only memory device that is programmed at the factory in accordance with the overall performance parameters of the particular optodes used on a given substrate, *i.e.*, the detection response of the particular detectors involved in relation to the particular light emissions produced by the particular emitters (LEDs) being used, regardless of whatever the actual output wavelength of the latter may be (actual center wavelengths of LEDs and the like being subject to a certain amount of variance even though generally within a specified band, and affecting the wavelength-related measurement performance during spectrophotometric procedures). In this manner, the actual performance characteristics of each individual sensor may be instantly and automatically "read" from the sensor by the spectrophotometric device upon being connected thereto, and appropriate calibration of the device for that particular sensor being automatically implemented by the device using its own internal computer or controller.

The completely assembled flex circuit 26, as described above, is placed atop the foam main body 12, with the shielding layer 14 and adhesive layer 13 disposed therebetween, and with the electro-optical components in direct registry with, and disposed within, the corresponding apertures 56 provided in body 12, at which time the memory chip 38 and covered (potted) terminals 48 are preferably received into their corresponding recesses 58 in the foam body 12. This surface configuration of the foam body 12 is illustrated in Fig. 5, in which the openings for the overmolded electro-optical assemblies are designated by the numeral 56 and the recesses for the terminals 48 (as potted, or otherwise) are designated by the numeral 58. As further illustrated in Fig. 5, the top of the main body 12 preferably has a generally flat longitudinal plateau-like

section 60 having the same basic shape as the adhesive layer 13, shielding layer 14 and flex circuit 26, for receiving the latter in flush relationship, and the side portions 62 of main body 12 outboard of plateau area 60 (Figs. 3 and 5) preferably taper downwardly toward the edges of the body, whose flat underside carries the adhesive layer 18a that contacts the skin of the patient/test subject, together with the removable protective outer liner layer 18b.

The narrowed waist portion 24 of main body 12, and the adjacent smaller and larger rounded end portions 20, 22 are provided at least in part in order to reduce the overall size (footprint) of the sensor while nonetheless ensuring optimal shielding of both light and electromagnetic effects for the emitter 34 and detectors 36 and their associated circuitry. In this regard, it should be noted that the conductive body 12 and even the conductive adhesive layer 18a comprise part of the electromagnetic shielding for the sensor, along with the various conductive layers noted above, all of which should be interconnected and coupled to a system ground or other such circuit point (preferably, in accordance with the commonly owned prior patents identified above and incorporated by reference). At the same time, the illustrated sensor configuration also enhances the conformability of sensor 10 to various patient/test subject surface configurations without wrinkling or otherwise distorting the surface of the sensor in the area directly adjacent the patient/test subject, which is an important factor. Of course, the size and shape of the sensor must also be sufficient to ensure reliable adhesion to the forehead of the patient, but this obviously also involves the relative adhesiveness of the substance used in the adhesive layer 18a. Notwithstanding these utilitarian considerations, the "figure 8" or "snowman" shape, as generally illustrated, is also very distinctive and esthetic in appearance, and also helps to differentiate this sensor from all others.

It should be pointed out that there are significant advantages in terminating the electrical conductors for the electro-optical components (*i.e.*, the flex circuit 26 in the preferred embodiment described above) at a point closely adjacent the sensor 10 itself, and using a disconnectable connector at that point to couple the sensor to the spectrophotometric instrument, rather than equipping the sensor with a relatively long length electrical cable or the like whose end extremity carries a plug that is connectable to the instrument itself or some other point intermediate the two. By so doing, the cost of the sensor-connected cable may be eliminated from the cost of each sensor, and perhaps even more importantly the incentive to use inexpensive and hence inefficient

cable for this purpose is eliminated. At the same time, the use of high-grade and relatively expensive cable permanently connected to the oximeter instrument is actually made attractive since it need only be provided once, performs better, and is usable a great many times. In addition, the sensor itself is made lighter in weight and less susceptible to motion artifact, *etc.*, and, the automated and hence less expensive manufacture of the sensor is facilitated, since the practice of using lengthy connection cable attached permanently to the sensor required a manual soldering operation at the point of attachment. At the same time, use of a flex circuit such as that described above not only facilitates automated sensor manufacture but also eliminates other hand wiring, soldering, *etc.* No doubt, other significant advantages will be perceived by those skilled in the art upon further consideration of the foregoing specification.

It should be understood that the foregoing disclosure and attached drawings are directed to one or more particular preferred embodiments of the invention for purposes of illustration, and that variations and modifications of such particular embodiments may well occur to those skilled in the art after considering this disclosure. All such variations *etc.*, should therefore be considered an integral part of the underlying invention, especially in regard to particular shapes, configurations, component choices and variations in structural and system features.

The invention claimed is:

1. A compact, lightweight and flexible spectrophotometric sensor for clinical applications comprising:

a flexible body which is compliantly comformable to the shape of a subject to be examined;

a thin and flexible substrate mounted on said body, said substrate having electrically conductive traces on at least portions of a surface;

a plurality of electro-optical components mounted on said substrate and electrically coupled to said conductive traces, said components including at least one light source and at least one light detector;

said light source and said light detector components each having at least one side and an integrally attached generally opaque member having a generally annular collar-like portion on at least said side thereof to provide a light-guiding passage to and from said side, said generally opaque members and their respective electro-optical components each comprising an integral assembly adapted to facilitate robotic handling and precise placement thereof upon said substrate.

2. A spectrophotometric sensor as set forth in claim 1, wherein said light source and light detector components further include an optically clear light-transmissive covering on at least said side thereof.

3. A spectrophotometric sensor as set forth in claim 2, wherein said collar-like portion is disposed over said light-transmissive covering.

4. A spectrophotometric sensor as set forth in claim 1, wherein said collar-like portion comprises an overmolded structure which is molded in place on said electro-optical components.

5. A spectrophotometric sensor as set forth in claim 4, wherein said light source and light detector components further include an optically clear light-transmissive covering on at least said side thereof.

6. A spectrophotometric sensor as set forth in claim 5, wherein said collar-like portion is disposed over said light-transmissive covering.

7. A spectrophotometric sensor as set forth in claim 1, further including at least one shielding layer disposed between said substrate and said body.

8. A spectrophotometric sensor as set forth in claim 7, wherein said at least one shielding layer comprises a metal-carrying fabric.

9. A spectrophotometric sensor as set forth in claim 8, wherein said at least one layer comprises a metal-impregnated fabric.

10. A spectrophotometric sensor as set forth in claim 2, wherein said light-transmissive covering substantially encapsulates its related component.

11. A spectrophotometric sensor as set forth in claim 4, wherein said over-molded structure substantially encapsulates the component on which it is formed.

12. A spectrophotometric sensor as set forth in claim 11, wherein said overmolded structure is disposed over the light-transmissive covering on the associated component.

13. A spectrophotometric sensor as set forth in claim 1, wherein said body has a thickness greater than that of said integral assembly comprising an electro-optical component and it associated generally opaque member, and wherein said body has a recess for receiving each of said integral assemblies.

14. A spectrophotometric sensor as set forth in claim 13, wherein said body recesses comprise passages extending through said body and opening outwardly thereof through each of two opposite sides, whereby said integral assemblies are receivable into said passages from a first of said sides and face toward the passage opening on the other of said sides, to send or receive light therethrough.

15. A spectrophotometric sensor as set forth in claim 14, further including at least one shielding layer disposed between said substrate and said body, said shielding layer having an aperture therethrough positioned to register with said body recesses and sized to receive and pass said integral assemblies therethrough.

16. A spectrophotometric sensor as set forth in claim 15, wherein said electrically conductive traces are located on a side surface of said substrate and said side is disposed adjacent said body and said shielding layer is disposed between said side surface and a surface of said body.

17. A compact, lightweight and flexible spectrophotometric sensor for clinical applications comprising:

a flexible body which is compliantly comformable to the shape of a subject to be examined;

a thin and flexible substrate mounted on said body, said substrate having electrically conductive traces on at least portions of a surface;

a plurality of electro-optical components mounted on said substrate and electrically coupled to said conductive traces, said components including at least one light source and at least one light detector;

said substrate and said electrically conductive traces extending outwardly of said body only a short distance and terminating at an electrical connector;

said connector having a plurality of separate electrical terminals and certain of said traces being electrically coupled to certain of said terminals;

whereby said electro-optical components on said substrate are electrically connectable to a clinical device located at a distance from the sensor by means of a reusable intermediate cable connected to said clinical device and single use of said sensor results in minimal economic loss.

18. A spectrophotometric sensor as set forth in claim 17, wherein said short distance comprises only a few inches.

19. A compact, lightweight and flexible spectrophotometric sensor for clinical applications comprising:

a flexible body which is compliantly comformable to the shape of a subject to be examined;

a thin and flexible substrate mounted on said body, said substrate having electrically conductive traces on at least portions of a surface;

a plurality of electro-optical components mounted on said substrate and electrically coupled to said conductive traces, said components including at least one light source and at least one light detector;

said body having an overall shape which is thin when viewed from the side or end and which is rounded on the ends and narrows into a necked-down region between said ends when viewed in plan, said substrate extending across said necked-down region and into each of a first and second area located on opposite sides of said region, said at least one light source being disposed at said first area of said body located on one side of said necked-down region and said at least one light detector being disposed at said second area of said body located on the other side of said necked-down region.

20. A spectrophotometric sensor as set forth in claim 19, wherein both said first and said second areas of said body are rounded over most of their surface when viewed in plan.

21. A spectrophotometric sensor as set forth in claim 21, wherein each of said rounded ends of said body are substantially wider than said substrate.

22. A compact, lightweight and flexible spectrophotometric sensor for clinical applications comprising:

a flexible body which is compliantly comformable to the shape of a subject to be examined;

a thin and flexible substrate mounted on said body, said substrate having electrically conductive traces on at least portions of a surface;

a plurality of electro-optical components mounted on said substrate and electrically coupled to said conductive traces, said components including at least one light source and at least one light detector;

a data memory chip mounted on said substrate and having electrical terminals connected to said conductive traces thereon, to store and read out data representative of

the overall intensity response of the particular light detector mounted on said substrate to light from the particular light source mounted thereon, thereby facilitating calibration of a clinical analytic device coupled to said sensor for operation therewith.

23. A spectrophotometric sensor as set forth in claim 22, wherein said memory chip has a protective covering over its exterior.

24. A spectrophotometric sensor as set forth in claim 23, wherein said protective covering extends over the electrical terminals of said memory chip.

25. A spectrophotometric sensor as set forth in claim 24, wherein said memory chip comprises a miniature digital read-only memory.

26. A spectrophotometric sensor as set forth in claim 1, further including a data memory chip mounted on said substrate and having electrical terminals connected to said conductive traces thereon, to store and read out data representative of the overall intensity response of the particular light detector mounted on said substrate to light from the particular light source mounted thereon, thereby facilitating calibration of a clinical analytic device coupled to said sensor for operation therewith.

27. An electro-optical component assembly for use in a spectrophotometric sensor, comprising in combination:

an electrically actuated and optically responsive component to emit or receive light when electrically connected; and

an encasement covering at least the edges and part of an optically responsive side of said component, said encasement defining a light-transmissive path for light impinging upon or emitted from said optically responsive side of said component, and said encasement being formed in place upon said component.

28. An electro-optical component assembly for use in a spectrophotometric sensor as set forth in claim 27, wherein said encasement defines an aperture disposed in alignment with said optically responsive side of said component, said aperture forming at least part of said light transmissive path.

29. An electro-optical component assembly for use in a spectrophotometric sensor as set forth in claim 27, wherein said encasement comprises optically transmissive material which covers at least said edges and said side of said component, said optically transmissive material comprising at least part of said light transmissive path.

30. An electro-optical component assembly for use in a spectrophotometric sensor as set forth in claim 29, wherein said encasement further includes an outer covering extending over the outside of at least portions of said optically transmissive material, said outer cover being generally opaque and defining an aperture disposed in alignment with said optically responsive side of said component, and with said optically transmissive path, said aperture forming an extension of said path.

31. An electro-optical component assembly for use in a spectrophotometric sensor as set forth in claim 30, wherein said outer covering comprising an overmolding which is formed in place upon said component and optically transmissive covering.

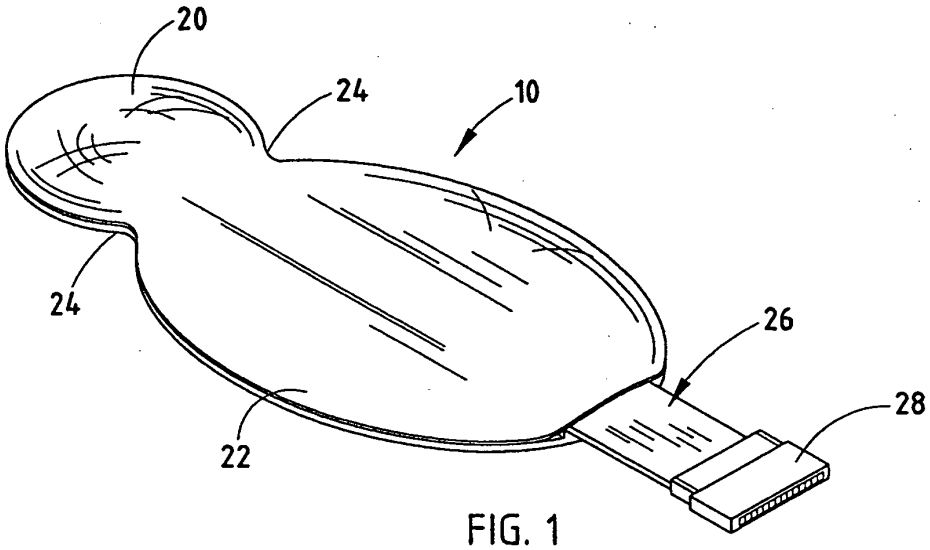


FIG. 1

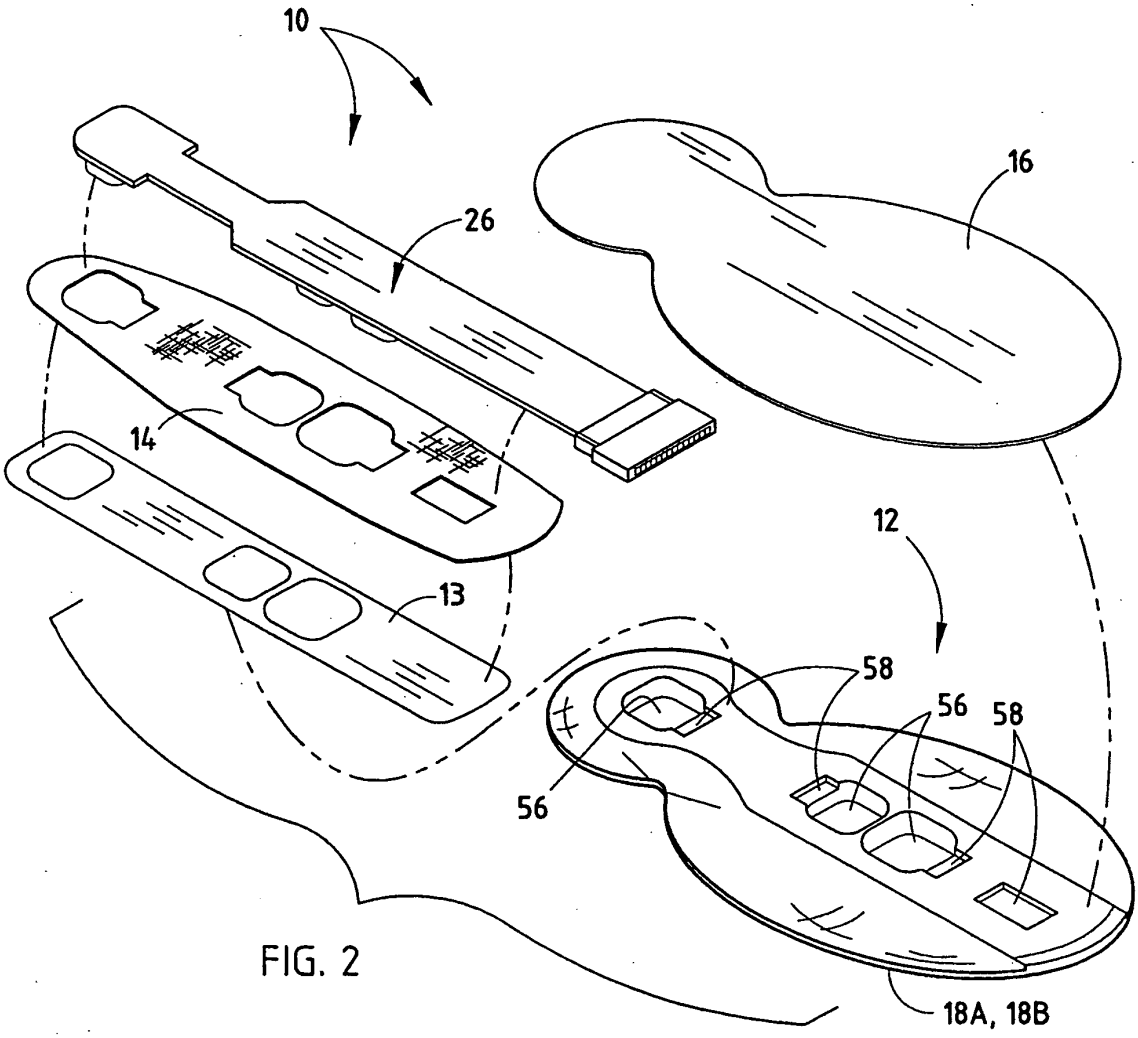


FIG. 2

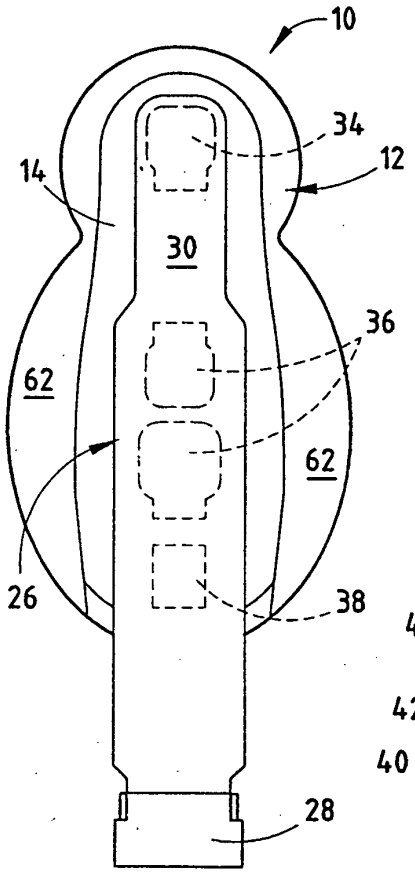


FIG. 3

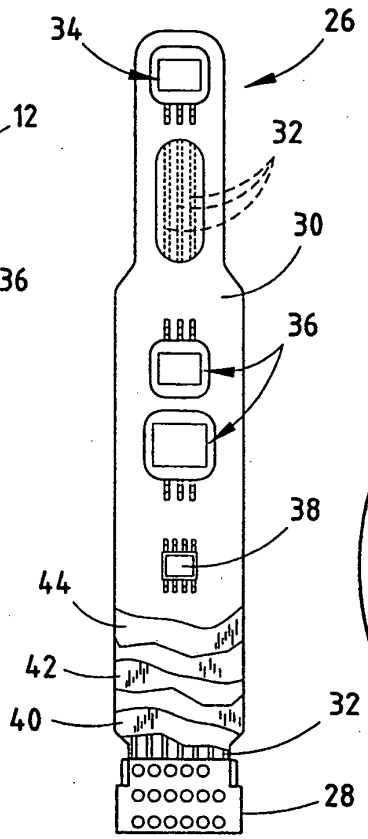


FIG. 4

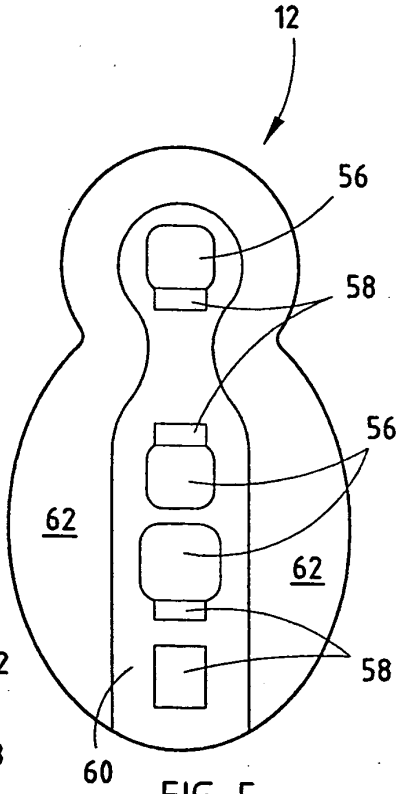


FIG. 5

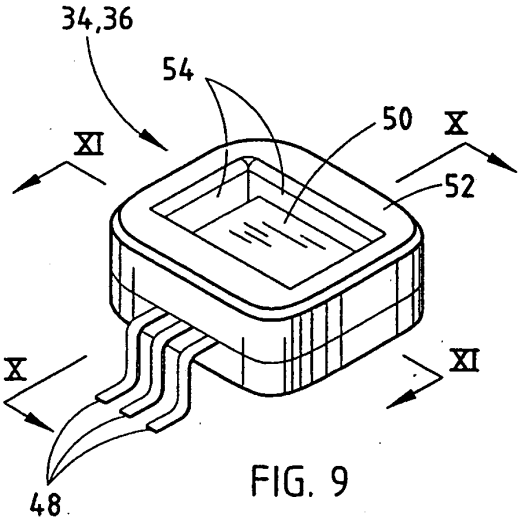


FIG. 9

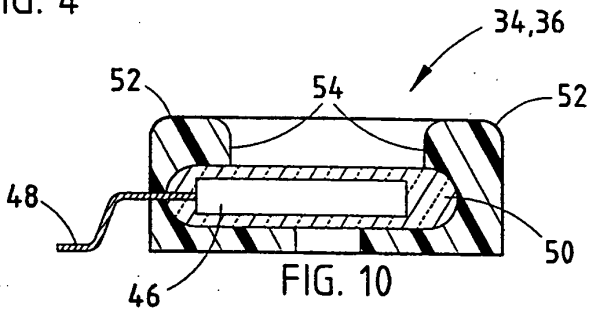


FIG. 10

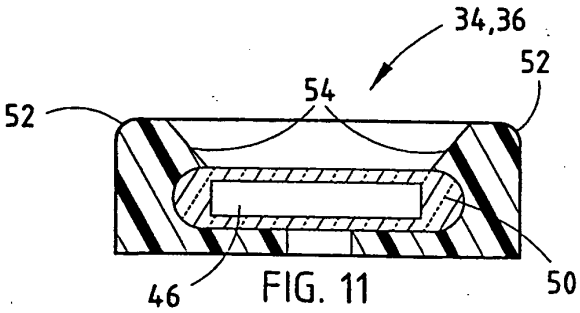


FIG. 11

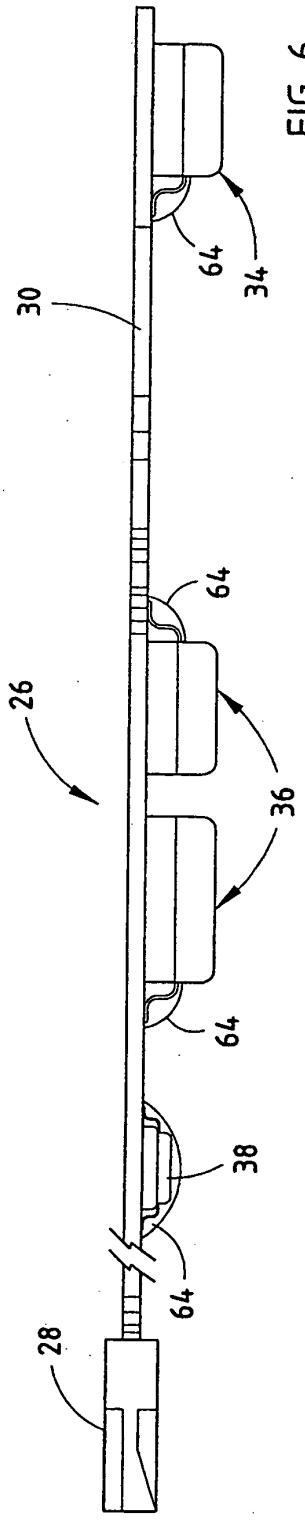


FIG. 6

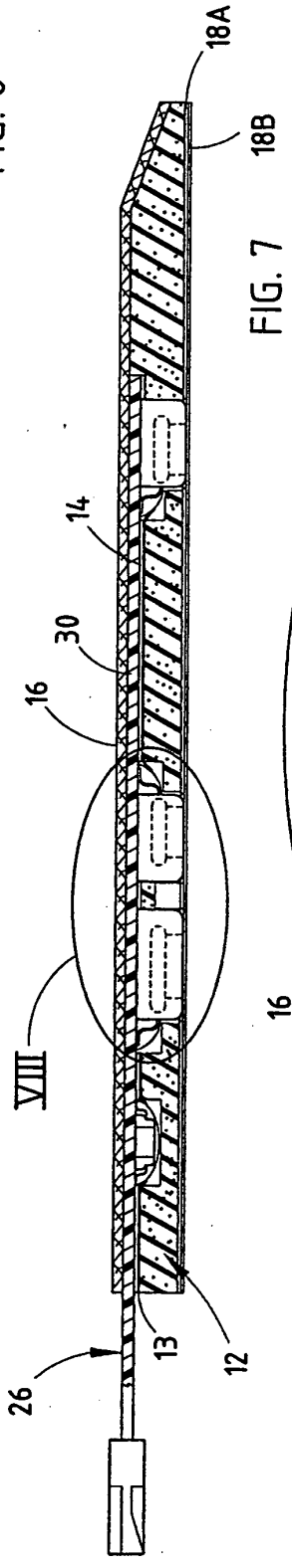


FIG. 7

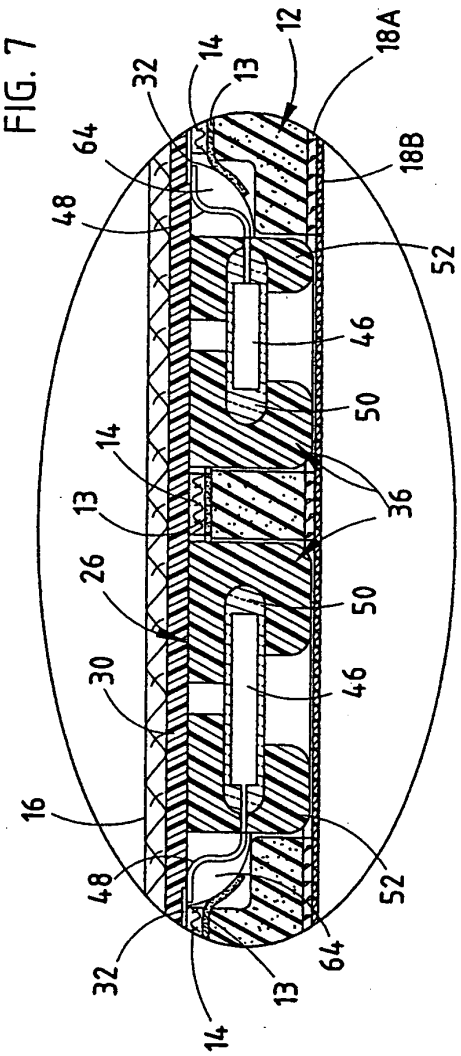


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/09502

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/00
US CL :600/323, 344

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/310, 322, 323, 340, 344

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,584,296 A (CUI et al.) 17 December 1996, col. 8 line 43 to col. 10 line 61.	1-12 --- 26
X --- Y	US 5,249,576 A (GOLDBERGER et al,) 05 October 1993, entire document.	17-25 --- 26
X	US 5,465,714 A (SCHEUING) 14 November 1995, col. 5 line 56 to col. 6 line 34.	27, 29

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 AUGUST 2000	06 SEP 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ERIC F. WINAKUR Telephone No. (703) 308-3940

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Published
With international search report.

(54) Title: METHOD AND APPARATUS FOR ARBITRATING TO OBTAIN BEST ESTIMATES FOR BLOOD CONSTITUENT VALUES AND REJECTING HARMONICS

(57) Abstract

A method of measuring a blood constituent value using data comprising a single data set comprises: (a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and (b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

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METHOD AND APPARATUS FOR ARBITRATING TO OBTAIN BEST ESTIMATES FOR BLOOD CONSTITUENT VALUES & REJECTING HARMONICS

This invention relates to a method and apparatus for measuring physiological parameters, in particular for processing data so that its reliability can be assessed. It relates in particular to a method and apparatus for arbitrating to obtain best estimates for blood constituent values and rejecting harmonics.

Pulse oximeters typically measure and display various blood flow characteristics including the oxygen saturation of haemoglobin in arterial blood and pulse rate. Oximeters pass light through blood perfused tissue such as a finger or an ear, and photoelectrically sense the absorption of light in the tissue. The amount of light absorbed is then used to calculate the amount of the blood constituent (for example oxyhaemoglobin) being measured.

Techniques for calculating blood oxygen saturation levels in haemoglobin are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR ADAPTIVELY AVERAGING DATA SIGNALS, which bears the reference P21977A. Information concerning these features of the present invention that is disclosed in those documents is incorporated in the specification of the present application by this reference. The disclosed technique involves assigning varying weights to different measurements, the weighted measurements being averaged to obtain a filtered measurement. It employs Kalman filtering techniques to calculate blood oxygen saturation. Kalman filtering allows one to fit parameters in a least squares sense when the parameters are varying in time.

Other techniques for calculating blood oxygen saturation levels in haemoglobin, in which a harmonic filter is used to reduce noise effects, are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR HARMONICALLY FILTERING DATA,

entitled METHOD AND APPARATUS FOR HARMONICALLY FILTERING DATA, which bears the reference P21977D. Information concerning these features of the present invention that is disclosed in that document is incorporated in the specification of the present application by this reference.

Techniques for determining pulse rates are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR MEASURING PULSE RATE AND SATURATION, which bears the reference P21977B. Information concerning these features of the present invention that is disclosed in this document is incorporated in the specification of the present application by this reference. A technique disclosed in the document involves use of a comb filter to isolate signal energy which corresponds to fundamental and related frequencies.

The present invention provides a technique for assessing signals relating to physiological parameters, in particular blood oxygen saturation and pulse rate, to determine whether and how they are to be displayed. The signals can be derived using techniques of the type that are disclosed in the specifications of the three applications referred to above. The technique of the invention involves arbitrating between possible values of the parameter in question according to a confidence level associated with each value based in a quality metric.

Accordingly, in one aspect, the invention provides a method of measuring a blood constituent value (for example, oxygenated haemoglobin in blood) using data comprising a single data set, which comprises:

(a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the

possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

In another aspect, the invention provides apparatus for measuring a blood constituent using a single data set, by applying the method referred to above.

In a further aspect, the invention provides a method of determining a patient's pulse rate using data comprising a single data set corresponding to electromagnetic energy transmitted through the tissue of a patient, the method comprising the steps of:

(a) determining a plurality of possible pulse rates using a plurality of pulse rate estimators, each of the pulse rate estimators using the single data set, each of the possible pulse rates having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible pulse rates with regard to the confidence levels to determine the patient's pulse rate.

In yet another aspect, the invention provides apparatus for determining a patient's pulse rate using a single data set, by applying the method referred to above.

Preferably, the arbitrating step comprises:

(a) comparing the confidence levels for each of the values with the confidence levels for other values; and

(b) selecting as the measure of the blood constituent or of the pulse rate (as the case may be) one of the plurality of possible values having a confidence level greater than all other confidence levels by at least a first amount.

Preferably, the arbitrating step comprises linearly interpolating between the plurality of possible values to generate the measure of the blood constituent or the patient's pulse rate (as the case may be) where none of the confidence levels is greater than all other confidence levels by more than a first amount.

When the method is measuring a blood constituent value, it is preferred that the quality metric is selected from the group comprising age of the possible blood constituent value and variance of the possible blood constituent value.

Preferably, in the second method aspect of the invention, the pulse rate estimator determines its corresponding possible pulse rate by:

(a) defining a comb filter to remove signal energy from the data corresponding to a fundamental frequency and harmonics thereof;
(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency; and
(c) generating the possible pulse rate corresponding to the particular harmonic frequency.

Preferably, the step of determining the harmonic frequency comprises:

(a) calculating squared noise for the data;

(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and

(c) performing a Newton-Raphson search to determine the particular harmonic frequency.

The determination of the pulse rate by the pulse rate estimator can include the steps of:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and

(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

When the method is determining a patient's pulse rate, it is preferred that the quality metric is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, arrhythmia probability, and, when there are two wavelengths of electromagnetic energy, a correlation between the data corresponding to the two wavelengths.

The pulse rate estimator in the second method aspect of the invention can determine its corresponding possible pulse rate by:

(a) comparing the data to a predetermined waveform template;

(b) identifying a sequence of waveform characteristics indicative of a waveform period;

(c) averaging a number of successive waveform periods to determine an average waveform period; and

(d) determining the corresponding possible pulse rate from the average waveform period.

The method can include a step of identifying pulse data that is corrupted by motion, and rejecting that data.

The quality metric can then be selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

In a yet further aspect, the invention provides a method of determining a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, which comprises:

(a) tracking a fundamental frequency using an adaptive comb filter to filter the data and to thereby generate a first pulse rate, the first pulse rate having a first confidence level associated therewith based on at least one quality metric;

(b) comparing the data to a predetermined waveform template to generate a second pulse rate, the second pulse rate having a second confidence level associated therewith based on the at least one quality metric; and

(c) arbitrating between the first and second pulse rates with regard to the first and second confidence levels to determine the patient's pulse rate.

Preferably, the tracking step comprises:

(a) defining a comb filter to remove signal energy from the data corresponding to the fundamental frequency and harmonics thereof; and
(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency.

Preferably, the step of determining the harmonic frequency then comprises:

(a) calculating squared noise for the data;
(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and
(c) performing a Newton-Raphson search to determine the fundamental frequency.

The tracking step can comprise:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and
(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

It might also include a step of filtering the first pulse rate to determine a filtered first pulse rate, for example by a filtering technique such as Kalman filtering.

Preferably, the comparing step of the method comprises:

(a) identifying a sequence of waveform characteristics indicative of a waveform period;
(b) averaging a number of successive waveform periods to determine an average waveform period; and
(c) determining the second pulse rate from the average waveform period.

Preferably, the arbitrating step of the method comprises:

(a) comparing the first and second confidence levels; and

(b) selecting as the patient's pulse rate one of the first and second confidence levels which is greater than the other of the first and second confidence levels by at least a first amount.

The arbitrating step can comprise linearly interpolating between the first and second pulse rates to generate the patient's pulse rate where neither of the first and second confidence levels is greater than the other of the first and second confidence levels by more than a first amount.

Preferably, the at least one quality metric corresponding to the first confidence level is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

Preferably, there are two wavelengths of electromagnetic energy, and the at least one quality metric corresponding to the first confidence level comprises a correlation between the data corresponding to the two wavelengths.

Preferably, the at least one quality metric corresponding to the second confidence level is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

Preferably, prior to the processing step, the method includes the steps of:

(a) taking the logarithm of a signal representative of the at least one wavelength of electromagnetic energy, thereby generating a first signal;
(b) band pass filtering the first signal, thereby generating a second signal; and
(c) normalizing the second signal, thereby generating the data;

the tracking step comprising taking the derivative of the data.

The invention can involve reduction of noise effects when measuring a physiological parameter. It can include apparatus for reducing the noise effects which comprises:

means for generating a plurality of measurements derived from at least one wavelength of electromagnetic energy transmitted through living tissue;

means for providing a signal indicative of the at least one wavelength of electromagnetic energy;

means for comparing selected measurements with at least one expected measurement characteristic;

means for assigning one of a plurality of variable weights to each selected measurement based on the comparing step thereby generating a plurality of differently weighted measurements for each wavelength, the variable weights being assigned, in part, in response to a similarity between each selected measurement and a corresponding previous measurement, the variable weights comprising a plurality of different non-zero numbers;

means for averaging a plurality of the differently weighted measurements to obtain a filtered measurement for use in estimating the physiological parameter; and

means for calibrating the system to measure the physiological parameter in response to the signal indicative of the at least one wavelength of electromagnetic energy.

The invention also includes a monitor for measuring a physiological parameter, the monitor being for use with a sensor having emitting means for emitting at least one wavelength of electromagnetic energy, sensing means for sensing the electromagnetic energy and for generating a first signal representative thereof, means for detachably coupling the sensor to the oximeter and for providing communication of signals between the sensor and the oximeter, and means for providing a second signal indicative of the at least one wavelength of electromagnetic energy, the monitor comprising:

means for generating a plurality of measurements derived from the first signal;

means for comparing selected measurements with at least one expected measurement characteristic;

means for assigning one of a plurality of variable weights to each selected measurement based on the comparing step thereby generating a plurality of differently weighted measurements, the variable weights being assigned, in part, in response to a similarity between each selected measurement and a corresponding previous measurement, the variable weights comprising a plurality of different non-zero numbers;

means for averaging a plurality of the differently weighted measurements to obtain a filtered measurement for use in estimating the physiological parameter; and

means for calibrating the monitor to measure the physiological parameter in response to the second signal.

There now follows a discussion of preferred methods of processing and displaying the blood oxygen saturation and pulse rate for use on a hospital floor. With metrics that are available from algorithms for measuring oxygen saturation levels and pulse rates, confidence levels for the saturation and the pulse rate values that are calculated can be estimated, thus determining which saturation and which pulse rate of the multiple pulse rates and multiple saturations can be considered reliable, and how long the saturation or pulse rate previously selected should be held when a current estimate is not considered sufficiently reliable.

The present invention can be applied to blood oxygen saturation values calculated using Kalman filtering techniques (with or without cardiac gated averaging) as disclosed in the International patent application no. IB96/ (P21977A) referred to above. Metrics that can be calculated from these algorithms include:

Age: effective averaging period is double this; and

Deviation: standard deviation of saturation estimate in saturation points.

The present invention can be applied to pulse rate values calculated using a comb filter as disclosed in the International patent application no. [] referred to above. Metrics that can be calculated from these algorithms include:

Validity:	a heuristic metric based on the strength of harmonics in the pulse, i.e., the shape of the pulse;
S/N:	signal-to-noise ratio;
Arrhythmia probability:	a function of S/N vs. Uncorrelation averaged over time; and
Uncorrelation (IR & red)	$\sqrt{1-crosscorrelation\ (IR,red)^2}$ where crosscorrelation is over an appropriate number of sample points.
Motion flag:	set when motion is detected; and
Motion Percent:	percentage of motion corrupted patterns detected in the last ten seconds.

The confidence interval for a pulse rate measured using an adaptive comb filter is a function of the validity metric and the arrhythmia probability metric. This space divides into several regions in which one or both metrics are the determining factor in how likely the adaptive comb filter is to be tracking the correct rate.

The Age and Deviation metrics can be used to determine saturation. A general algorithm for calculating the age of the output of an IIR filter having the form

$$Filtered(n+1) = (1 + W) * Filtered(n) - W * Raw,$$

where the age of Filtered and Raw are known, and Filtered(n) is the value at sample number n, is described by the following steps:

1) Increment the age of Filtered by the amount of time elapsed since it was last calculated; and
2) Age of Filtered(n + 1) = (1 + W) * Age of Filtered(n) + W * Age of Raw

Preferably, the technique of the invention involves evaluation of several properties of the incoming oximetry signal, independent of the confidence metrics for the parameter in question (for example oxygen saturation and pulse rate) to determine whether the signal is actually due to a human pulse and what should appear on the display that is provided. Possible states include:

Disconnect:	when the sensor is unplugged;
No Contact:	when the sensor does not make sufficient contact with the patient;
Pulse lost:	when the pulse disappears and the sensor is still on the patient;
Non-pulse:	when the oximetry signal comes from a signal other than a human pulse because the sensor has fallen off or is seeing an enormous amount of interference;
Pulse Present:	when the oximetry signal comes from a human pulse; and
Not Sure:	a waiting period before declaring a Disconnect or Non-pulse state.

The possible actions in response to the occurrence of these various states are to update the display, hold the current values, or clear the display, for example blanks, dashes, zeroes, etc.

The criteria for the various states are evaluated in the following order:

Pulse lost:	The % IR modulation is below a threshold for period of seconds, or the criteria for Non-pulse are met and the previous state had been Pulse lost.
Non-pulse:	The uncorrelation is high and the percentage of energy above 5 Hz is high, OR the percent IR modulation is low. This criterion has been true for ten seconds continuously. If this criterion has been true for less than ten seconds, the Not Sure state is declared.
Pulse present:	The state is not one of the above states.

The criteria for the various display actions are UPDATE when the state is Pulse present, HOLD when the state is Not Sure or No contact, and CLEAR when the state is Disconnect, Pulse lost, or Non-pulse.

The best saturation is displayed when 1) the signal state action is UPDATE, and 2) the best saturation is sufficiently recent. Saturation is held when 1) the conditions for displaying the best saturation are not met, 2) the displayed saturation is less than sufficiently recent, and 3) the signal state action is not CLEAR. Saturation is blanked when 1) the conditions for displaying the best saturation are not met, and 2) the conditions for holding the saturation are not met.

The best heart rate is displayed when 1) the best calculated heart rate has a high confidence, and 2) the signal state action is UPDATE. The heart rate is held when 1) the conditions for displaying the current heart rate are not met, 2) the displayed heart rate is sufficiently recent, and 3) the signal state action is not CLEAR. The heart rate is blanked when 1) the conditions for displaying the current heart rate are not met, and 2) the conditions for holding the heart rate are not met.

CLAIMS:

1. A method of measuring a blood constituent value using data comprising a single data set, which comprises:

(a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

2. A method as claimed in claim 1, in which the arbitrating step comprises:

(a) comparing the confidence levels for each of the possible blood constituent values with the confidence levels for other blood constituent values; and

(b) selecting as the measure of the blood constituent one of the plurality of possible blood constituent values having a confidence level greater than all other confidence levels by at least a first amount.

3. A method as claimed in claim 1, in which the arbitrating step comprises linearly interpolating between the plurality of possible blood constituent values to generate the measure of the blood constituent where none of the confidence levels is greater than all other confidence levels by more than a first amount.

4. A method as claimed in claim 1, in which the at least one quality metric is selected from the group comprising age of the possible blood constituent value and variance of the possible blood constituent value.

5. A method as claimed in claim 1, in which the blood constituent comprises oxygenated haemoglobin in arterial blood.

6. Apparatus for measuring a blood constituent using a single data set, comprising:

(a) means for determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) means for arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

7. A method of determining a patient's pulse rate using data comprising a single data set corresponding to energy transmitted through the tissue of a patient, the method comprising the steps of:

(a) determining a plurality of possible pulse rates using a plurality of pulse rate estimators, each of the pulse rate estimators using the single data set, each of the possible pulse rates having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible pulse rates with regard to the confidence levels to determine the patient's pulse rate.

8. A method as claimed in claim 7, in which the arbitrating step comprises:

(a) comparing the confidence levels for each of the possible pulse rates with the confidence levels for other possible pulse rates; and

(b) selecting as the patient's pulse rate one of the plurality of possible pulse rates having a confidence level greater than all other confidence levels by at least a first amount.

9. A method as claimed in claim 7, in which the arbitrating step comprises linearly interpolating between the plurality of possible pulse rates to generate the patient's pulse rate where none of the confidence levels is greater than all other confidence levels by more than a first amount.

10. A method as claimed in claim 7, in which one pulse rate estimator determines its corresponding possible pulse rate by:

(a) defining a comb filter to remove signal energy from the data corresponding to a fundamental frequency and harmonics thereof;

(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency; and

(c) generating the possible pulse rate corresponding to the particular harmonic frequency.

11. A method as claimed in claim 10, in which the determining step comprises:

(a) calculating squared noise for the data;

(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and

(c) performing a Newton-Raphson search to determine the particular harmonic frequency.

12. A method as claimed in claim 10 further comprising the steps of:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and

(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

13. A method as claimed in claim 10, in which the at least one quality metric is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

14. A method as claimed in claim 10, in which there are two wavelengths of electromagnetic energy, and the at least one quality metric comprises a correlation between the data corresponding to the two wavelengths.

15. A method as claimed in claim 7, in which one pulse rate estimator determines its corresponding possible pulse rate by:

(a) comparing the data to a predetermined waveform template;

(b) identifying a sequence of waveform characteristics indicative of a waveform period;

(c) averaging a number of successive waveform periods to determine an average waveform period; and

(d) determining the corresponding possible pulse rate from the average waveform period.

16. A method as claimed in claim 15, in which the at least one quality metric is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

17. A method of determining a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, which comprises:

(a) tracking a fundamental frequency using an adaptive comb filter to filter the data and to thereby generate a first pulse rate, the first pulse rate having a first confidence level associated therewith based on at least one quality metric;

(b) comparing the data to a predetermined waveform template to generate a second pulse rate, the second pulse rate having a second confidence level associated therewith based on the at least one quality metric; and

(c) arbitrating between the first and second pulse rates with regard to the first and second confidence levels to determine the patient's pulse rate.

18. A method as claimed in claim 17, in which the tracking step comprises:

(a) defining a comb filter to remove signal energy from the data corresponding to the fundamental frequency and harmonics thereof; and

(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency.

19. A method as claimed in claim 18, in which the determining step comprises:

(a) calculating squared noise for the data;

(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and

(c) performing a Newton-Raphson search to determine the fundamental frequency.

20. A method as claimed in claim 18, in which the tracking step comprises:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and

(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

21. A method as claimed in claim 17, in which the tracking step comprises Kalman filtering the first pulse rate to determine a filtered first pulse rate.

22. A method as claimed in claim 17, in which the comparing step comprises:

(a) identifying a sequence of waveform characteristics indicative of a waveform period;

(b) averaging a number of successive waveform periods to determine an average waveform period; and

(c) determining the second pulse rate from the average waveform period.

23. A method as claimed in claim 17, in which the arbitrating step comprises:

(a) comparing the first and second confidence levels; and

(b) selecting as the patient's pulse rate one of the first and second confidence levels which is greater than the other of the first and second confidence levels by at least a first amount.

24. A method as claimed in claim 17, in which the arbitrating step comprises linearly interpolating between the first and second pulse rates to generate the patient's pulse rate where neither of the first and second confidence levels is greater than the other of the first and second confidence levels by more than a first amount.

25. A method as claimed in claim 17, in which the at least one quality metric corresponding to the first confidence level is selected from the group comprising pulse signal shape,

signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

26. A method as claimed in claim 17, in which there are two wavelengths of electromagnetic energy, and the at least one quality metric corresponding to the first confidence level comprises a correlation between the data corresponding to the two wavelengths.

27. A method as claimed in claim 17, in which the at least one quality metric corresponding to the second confidence level is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

28. A method as claimed in claim 17, which includes, before the processing step, the steps of:

(a) taking the logarithm of a signal representative of the at least one wavelength of electromagnetic energy, thereby generating a first signal;

(b) band pass filtering the first signal, thereby generating a second signal; and

(c) normalizing the second signal, thereby generating the data;

and in which the tracking step comprises taking the derivative of the data.

INTERNATIONAL SEARCH REPORT

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 5 355 880 A (THOMAS ET AL.) 18 October 1994	1,7
A	see the whole document	17
A	EP 0 522 674 A (UNIVERSITY OF NEW MEXICO & SANDIA NATIONAL LABORATORIES) 13 January 1993 see the whole document	1-28
A	WO 96 30742 A (CIBA CORNING DIAGNOSTICS CORP.) 3 October 1996 see the whole document	1-28
A	US 5 435 309 A (THOMAS ET AL.) 25 July 1995 see the whole document	1-28

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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A	DE 43 39 067 A (JENOPTIK GMBH) 18 May 1995 see the whole document	1-6

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 97/00292

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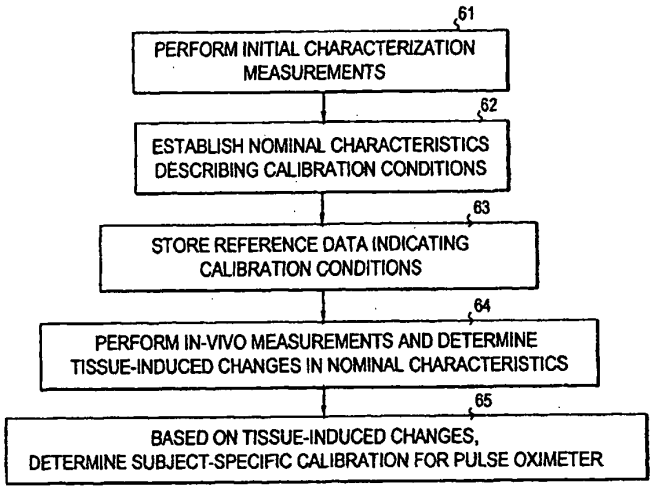
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMPENSATION OF HUMAN VARIABILITY IN PULSE OXIMETRY



(57) **Abstract:** The invention relates to the calibration of a pulse oximeter intended for non-invasively determining the amount of at least two light-absorbing substances in the blood of a subject. In order to bring about a solution by means of which the effects caused by the tissue of the subject can be taken into account in connection with the calibration of a pulse oximeter, initial characterization measurements are carried out for a pulse oximeter calibrated under nominal conditions. Based on the characterization measurements, nominal characteristics are established describing the conditions under which nominal calibration has been defined, and reference data indicating the nominal characteristics are stored. In-vivo measurements are then performed on living tissue and based on the in-vivo measurements and the reference data stored, tissue-induced changes in the nominal characteristics are determined. Subject-specific variation in the in-vivo measurements is compensated for by correcting the nominal calibration on the basis of the tissue-induced changes.

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COMPENSATION OF HUMAN VARIABILITY IN PULSE OXIMETRY

Field of the Invention

The invention relates generally to pulse oximeters used to detect blood oxygenation. More specifically, the invention relates to a method for taking into account human variability in pulse oximeters. The invention further relates to a sensor allowing compensation for the inaccuracies caused by human variability, the sensor being an integral part of the pulse oximeter.

Background of the Invention

Pulse oximetry is at present the standard of care for continuous monitoring of arterial oxygen saturation (SpO_2). Pulse oximeters provide instantaneous in-vivo measurements of arterial oxygenation, and thereby an early warning of arterial hypoxemia, for example.

A pulse oximeter comprises a computerized measuring unit and a probe attached to the patient, typically to a finger or ear lobe. The probe includes a light source for sending an optical signal through the tissue and a photo detector for receiving the signal after transmission through the tissue. On the basis of the transmitted and received signals, light absorption by the tissue can be determined. During each cardiac cycle, light absorption by the tissue varies cyclically. During the diastolic phase, absorption is caused by venous blood, tissue, bone, and pigments, whereas during the systolic phase there is an increase in absorption, which is caused by the influx of arterial blood into the tissue. Pulse oximeters focus the measurement on this arterial blood portion by determining the difference between the peak absorption during the systolic phase and the constant absorption during the diastolic phase. Pulse oximetry is thus based on the assumption that the pulsatile component of the absorption is due to arterial blood only.

Light transmission through an ideal absorbing sample is determined by the known Lambert-Beer equation as follows:

$$I_{out} = I_{in} e^{-\varepsilon DC}, \quad (1)$$

where I_{in} is the light intensity entering the sample, I_{out} is the light intensity received from the sample, D is the path length through the sample, ε is the extinction coefficient of the analyte in the sample at a specific wavelength, and C is the concentration of the analyte. When I_{in}, D, and ε are known, and I_{out} is measured, the concentration C can be calculated.

In pulse oximetry, in order to distinguish between two species of hemoglobin, oxyhemoglobin (HbO_2), and deoxyhemoglobin (RHb), absorption must be measured at two different wavelengths, i.e. the probe includes two different light emitting diodes (LEDs). The wavelength values widely used are 660 nm (red) and 940 nm (infrared), since the said two species of hemoglobin have substantially different absorption values at these wavelengths. Each LED is illuminated in turn at a frequency which is typically several hundred Hz.

The accuracy of a pulse oximeter is affected by several factors. This is discussed briefly in the following.

Firstly, the dyshemoglobins which do not participate in oxygen transport, i.e. methemoglobin (MetHb) and carboxyhemoglobin (COHb), absorb light at the wavelengths used in the measurement. Pulse oximeters are set up to measure oxygen saturation on the assumption that the patient's blood composition is the same as that of a healthy, non-smoking individual. Therefore, if these species of hemoglobin are present in higher concentrations than normal, a pulse oximeter may display erroneous data.

Secondly, intravenous dyes used for diagnostic purposes may cause considerable deviation in pulse oximeter readings. However, the effect of these dyes is short-lived since the liver purifies blood efficiently.

Thirdly, coatings like nail polish may in practice impair the accuracy of a pulse oximeter, even though the absorption caused by them is constant, not pulsatile, and thus in theory it should not have an effect on the accuracy.

Fourthly, the optical signal may be degraded by both noise and motion artifacts. One source of noise is the ambient light received by the photodetector. Many solutions have been devised with the aim of minimizing or eliminating the effect of the movement of the patient on the signal, and the ability of a pulse oximeter to function correctly in the presence of patient motion depends on the design of the pulse oximeter. One way of canceling out the motion artefact is to use an extra wavelength for this purpose.

A further factor affecting the accuracy of a pulse oximeter is the method used to calibrate the pulse oximeter. Usually the calibration is based on extensive empirical studies in which an average calibration curve is determined based on a high number of persons. By means of this calibration curve, which relates the oxygen saturation of blood to pulse oximeter signals, the average difference between the theory and practice (i.e. in-vivo

measurements) is taken into account. The calibration curve typically maps the measured in-vivo signal to a corresponding SpO_2 value.

Pulse oximeters, however, can also utilize the Lambert-Beer model for calculating the concentrations of the different Hb species. In this method of calibration, the measurement signals must first be transformed into signals applicable to the Lambert-Beer model for calculation. This transformation constitutes the calibration of the pulse oximeter, since it is the step which adapts the in-vivo signals to the Lambert-Beer theory, according to which the pulse oximeter is designed to operate. Thus, the calibration curves can also be in the form of transformations used to adapt the actual in-vivo measurements to the Lambert-Beer model.

Transformations are discussed for example in U.S. Patent 6,104,938, which discloses a calibration method based on the absorption properties of each hemoglobin component, i.e. on the extinction coefficients of blood. In this method, the effective extinction coefficients are determined for each light signal via a mathematical transformation from the extinction coefficients according to the Lambert-Beer theory.

However, each patient (i.e. subject of the measurement) has a calibration curve of his or her own, which deviates from the average calibration curve calculated on the basis of a high number of patients. This is due to the fact that for each patient the characteristics of the tissue through which light is transmitted deviate from those of an average patient. One drawback of the current pulse oximeters is that they are incapable of taking this human variability into account. Human variability here refers to any and all factors causing patient-specific variation in the calibration curve, including time-dependent changes in the calibration curve of a single patient. As discussed in the above-mentioned U.S. Patent, subject-dependent variation can also be seen as an effect of a third substance, such as a third hemoglobin species in the blood. However, the variation can also be interpreted as a subject-dependent change in the calibration curve of the pulse oximeter.

Without compensation for human variability, the accuracy of current pulse oximeters is about ±2%SpO2. However, in multi-wavelength applications in general, and especially if weak absorbers, such as COHb, are to be measured, the human variability represents a much more serious problem. Therefore, techniques of compensation for these inaccuracies are called for.

It is an objective of the invention to bring about a solution by means of which the effects caused by the tissue of the subject can be taken into account when a pulse oximeter is calibrated. In other words, it is an objective of the present invention to create a pulse oximeter which can take into account the differences caused by an individual subject as compared to the average calibration or transformation curve which the current pulse oximeter relies on.

A further objective of the invention is to bring about a general-purpose solution for the compensation of inaccuracies caused by human variability in pulse oximetry, a solution which is not limited to the particular general calibration method employed in the pulse oximeter, but which can be applied to any pulse oximeter regardless of its current built-in calibration method.

Summary of the Invention

These and other objectives of the invention are accomplished in accordance with the principles of the present invention by providing a mechanism by means of which the subject-specific deviation in the tissue-induced effects on the accuracy of the pulse oximeter can be taken into account.

In the method of the invention, the effect of tissue is taken into account and the inaccuracies caused by subject-specific variation in that effect are compensated for. This is implemented by defining a nominal calibration for the apparatus and making off-line measurements, also termed "initial characterization measurements", in order to define the characteristics which describe the conditions under which the nominal calibration has been defined. Reference data indicating the characteristics are stored for subsequent on-line measurements in which light transmission through the actual tissue is measured. (Off-line here refers to measurements performed before the apparatus is taken into use, whereas on-line refers to the actual in-vivo measurements.) Subject-specific calibration is then defined based on the nominal calibration, the on-line measurements, and the reference data created in connection with the off-line measurements. Thus, the inaccuracies are eliminated by means of on-line measurements, which indicate the effect of the tissue. Off-line measurements are used to create the reference data so that light transmission measured subsequently through the tissue of a subject can be used to correct the nominal calibration for that particular subject.

Thus in one aspect the invention provides a method for compensating for subject-specific variability in an apparatus intended for non-invasively determining the amount of at least two light absorbing substances in the blood of a subject and being provided with emitter means for emitting radiation at a minimum of two different wavelengths and with detector means for receiving the radiation emitted, the method comprising the steps of

- calibrating the apparatus using a nominal calibration,
- carrying out initial characterization measurements, said measurements to include the measuring of radiation received by the detector,
- based on the characterization measurements, establishing nominal characteristics describing conditions under which the nominal calibration is used,
- storing reference data indicating the nominal characteristics established,
- performing in-vivo measurements on a living tissue, wherein radiation emitted through the tissue and received by the detector means is measured,
- based on the in-vivo measurements and the reference data stored, determining tissue-induced changes in the nominal characteristics, and
- compensating for subject-specific variation in the in-vivo measurements by correcting the nominal calibration on the basis of the tissue-induced changes.

In a preferred embodiment of the invention the method is divided in two steps so that the first step compensates for the inaccuracies caused by tissue-induced wavelength shift and the second step compensates for the inaccuracies caused by internal effects occurring in the tissue. The first step is then used to correct the extinction coefficients of the blood analytes to be measured, and the second step is used to correct the average transformation stored in the pulse oximeter.

In a further preferred embodiment of the invention the effect of the temperature is also compensated for in connection with the first step.

The method is not limited to pulse oximeters explicitly using the transformations, but can be applied to any pulse oximeter. However, the method is preferably applied to a pulse oximeter based on a transformation, since in a preferred embodiment the method is implemented by carrying out changes separately in the transformation and in the extinction coefficients.

In another aspect, the invention provides an apparatus for non-invasively determining the amount of at least two light absorbing substances in the blood of a subject, the apparatus comprising

- emitter means for emitting radiation at a minimum of two different wavelengths,
- detector means for receiving said radiation at each of said wavelengths and producing at least two electrical output signals,
- first signal processing means for processing said output signals and producing a modulation signal for each wavelength, whereby each modulation signal represents the pulsating absorption caused by the arterialized blood of the subject,
- second signal processing means for applying a predetermined calibration on said modulation signals, whereby transformed modulation signals applicable in the Lambert-Beer model are obtained,
- memory means for storing reference data indicating nominal characteristics under which said predetermined calibration has been applied,
- first compensation means, operatively connected to the memory means, for determining tissue-induced changes in the nominal characteristics,
- second compensation means, operatively connected to the first compensation means, for defining a subject-specific calibration by correcting the predetermined calibration on the basis of the tissue-induced changes, and
- calculation means, responsive to the second compensation means, for determining said amounts.

In a still further aspect, the invention provides a sensor for collecting measurement data for a pulse oximeter intended for non-invasively determining the amount of at least two light absorbing substances in the blood of a subject, the sensor comprising

- emitter means for emitting radiation at a minimum of two different wavelengths,
- detector means for receiving said radiation at each of said wavelengths and for producing at least two electrical output signals,
- storage means including reference data indicating nominal characteristics describing calibration conditions of the pulse oximeter, said data allowing apparatus connected to the sensor to determine tissue-induced changes in the nominal characteristics when radiation is emitted through said tissue.

Preferred embodiments of the invention are discussed in more detail below.

Brief Description of the Drawings

In the following, the invention and its preferred embodiments are described more closely by referring to the examples shown in FIG. **1** to **12** in the appended drawings, wherein:

FIG. **1** illustrates the basic embodiment of a pulse oximeter according to the present invention,

FIG. **2** illustrates the signals utilized in the pulse oximeter of FIG. **1**,

FIG. **3** shows the extinction coefficients of two different species of hemoglobin as a function of wavelength,

FIG. **4a** to **4f** illustrate the average transformation curves for two different pulse oximeters,

FIG. **5** is a flow diagram illustrating the prior art calibration method,

FIG. **6** is a flow diagram illustrating the general principle according to the present invention,

FIG. **7** is a flow diagram illustrating compensation for the inaccuracies caused by tissue-induced wavelength shift,

FIG. **8** illustrates an example of the transmission curve of human tissue, the curve being employed in the compensation of the inaccuracies caused by tissue-induced wavelength shift,

FIG. **9** illustrates the emitter characteristics determined for the compensation,

FIG. **10** is a flow diagram illustrating the compensation of the inaccuracies caused by internal effects occurring in the tissue,

FIG. **11** illustrates the low frequency baseline fluctuation utilized in a preferred embodiment of the invention, and

FIG. **12** illustrates an embodiment of a sensor according to the invention.

Detailed Description of the Invention

Below, the solution according to the invention is discussed with reference to a pulse oximeter utilizing the above-mentioned transformations and four different wavelengths. As mentioned above, U.S. Patent 6,104,938 discloses a pulse oximeter utilizing the transformations.

FIG. **1** is a block diagram of a pulse oximeter utilizing four different wavelengths. Light from four different LEDs **10a**, **10b**, **10c**, and **10d**, each operating at a respective wavelength, passes into patient tissue, such as a finger **11**. The light propagated through or reflected from the tissue is received by a photodetector **12**, which converts the optical signal received into an electrical signal and feeds it to an input amplifier **13**. The amplified signal is then supplied to a control unit **14**, which carries out calculation of the amount of the Hb-derivatives in the blood. The control unit further controls the LED drive **15** to alternately activate the LEDs. As mentioned above, each LED is typically illuminated several hundred times per second.

When each LED is illuminated at such a high rate as compared to the pulse rate of the patient, the control unit obtains a high number of samples at each wavelength for each cardiac cycle of the patient. The value of these samples (i.e. the amplitude of the received signal) varies according to the cardiac cycle of the patient, the variation being caused by the arterial blood, as mentioned above. The control unit **14** therefore utilizes four measurement signals, as shown in FIG. **2**, each being received at one of the wavelengths.

In order for variations in extrinsic factors, such as the brightness of the LEDs, sensitivity of the detector, or thickness of the finger, to have no effect on the measurement, each signal received is normalized by extracting the AC component oscillating at the cardiac rhythm of the patient, and then dividing the AC component by the DC component of the light transmission or reflection. The signal thus obtained is independent of the above-mentioned extrinsic factors. Thus in this case the control unit utilizes four normalized signals, which are in the following denoted with $dA_i = \frac{AC_i}{DC_i}$, where i is the wavelength in question (in this basic embodiment of the multi-wavelength pulse oximeter i=1,2,3, 4), AC_i is the AC component at wavelength *i*, and DC_i is the DC component at wavelength *i*. The signals dA_i are also referred to below as modulation signals. The modulation signals thus indicate how absorption is affected by the arterial blood of the patient.

The above-described measurement arrangement corresponds to a conventional four-wavelength pulse oximeter. The method of the present invention is implemented in the control unit of the pulse oximeter on the basis of the four modulation signals described above, i.e. the novelty of the system resides within the control unit itself. However, to be able to perform the self-

calibration in conjunction with each patient, the control unit requires some pre-calculated data, which is stored in the memory (**M1**) of the pulse oximeter. Instead of being stored in conjunction with the control unit, this data, or at least part of it, can also be stored in the sensor part of the pulse oximeter. The sensor part, including at least the LEDs and the photo detector, is connected to the signal processing part, which includes the control unit. Consequently, depending on the overall configuration, the novelty can also reside partly in the sensor. The operation of the pulse oximeter is discussed in more detail below.

The theory of pulse oximetry is generally presented as being based on the Lambert–Beer Law. According to this theory, light transmission through the tissue at each wavelength is exponentially dependent on the absorbance of the tissue (Eq. **1**). This theory is generally accepted and established as a good model for pulse oximetry.

Next to be discussed is the theory and formalism on which the method of the invention is based.

According to the Lambert-Beer theory and for a system of two analytes, the signals described above can be presented as follows:

$$dA_1 = dA \times (\varepsilon_1^{HbO_2} \times HbO_2 + \varepsilon_1^{RHb} \times RHb)$$
$$dA_2 = dA \times (\varepsilon_2^{HbO_2} \times HbO_2 + \varepsilon_2^{RHb} \times RHb)$$
$$dA_3 = dA \times (\varepsilon_3^{HbO_2} \times HbO_2 + \varepsilon_3^{RHb} \times RHb)$$
$$dA_4 = dA \times (\varepsilon_4^{HbO_2} \times HbO_2 + \varepsilon_4^{RHb} \times RHb)$$
$$RHb = 1 - HbO_2$$

where *dA* is a common factor which depends on the absolute values, i.e. *inter alia* on the total amount of hemoglobin, $\varepsilon_i^{HbO_2}$ is the extinction coefficient of oxyhemoglobin at wavelength i (i=1-4), ε_i^{RHb} is the extinction coefficient of deoxyhemoglobin at wavelength i, HbO_2 is the concentration fraction of oxyhemoglobin, and *RHb* is the concentration fraction of deoxyhemoglobin.

Using a matrix notation, the above dependencies can be expressed for a system of n wavelengths and n analytes as follows:

$$\begin{pmatrix} dA_1 \\ dA_2 \\ \dots \\ dA_n \end{pmatrix} = C * \begin{pmatrix} \varepsilon_{11} \dots \varepsilon_{1n} \\ \varepsilon_{21} \dots \varepsilon_{2n} \\ \dots \\ \varepsilon_{n1} \dots \varepsilon_{nn} \end{pmatrix} \bullet \begin{pmatrix} HbX_1 \\ HbX_2 \\ \dots \\ HbX_n \end{pmatrix} \quad (2),$$

where dA_i is the differential change in absorption (i.e. the modulation signal) at wavelength λ_i, ε_{ij} is the extinction coefficient of the hemoglobin

derivative HbX_j at wavelength λ_l, and the constant C accounts for the change of units to fractional percentages of the concentrations of the analytes HbX_j.

FIG. **3** shows the extinction coefficients (ε^{HbO_2} and ε^{RHb}) of oxyhemoglobin (HbO_2) and deoxyhemoglobin (RHb) as a function of the wavelength. Point **P** shown in the figure is the isobestic point of oxyhemoglobin (HbO_2) and deoxyhemoglobin (RHb). The point has the special property that the modulation signal at the wavelength in question does not depend on the respective proportions (relative concentrations) of the hemoglobin species. Thus at the wavelength of point **P** the effect of the relative concentrations of oxyhemoglobin and deoxyhemoglobin on the result of the measurement is nil. It should be noted, however, that the modulation signal is independent of the relative concentrations only, not of the absolute concentrations. Thus, the absolute amount of the hemoglobin species has an effect on the result of the measurement.

As is known, there is a difference between the Lambert-Beer theory and the practical measurements. The difference is due to the fact that the Lambert-Beer theory does not take into account the scattering and non-homogeneity of the tissue, whereas the actual extinction coefficients are also dependent on the scattering of light caused by the tissue and blood, and on the combined effect of absorption and scattering. The larger the proportion of the attenuation caused by absorption and scattering, the larger is the correction needed between the actual and the theoretical (non-scatter) domains. This correction between these two domains can be represented by the transformation curves discussed above, by means of which the actual in-vivo measurements are mapped to the Lambert-Beer model.

The transformation can be expressed, for example, as follows:

$$N_{kl}^{L-B} = g_{kl}^{-1}\left(N_{kl}^{in-vivo}\right) \qquad (3),$$

where $N_{kl} = \frac{dA_k}{dA_l}$ is the modulation ratio (the superscript indicating the domain) in the form of a polynomial function (the subscripts *k* and *l* indicating the wavelengths in question), and *g* is the transformation (the subscript "-1" denoting the inverse function).

Figures **4a** to **4f** illustrate the average transformation curves measured for a pulse oximeter, where the two wavelengths for measuring the two species of hemoglobin are 660 nm and 900 nm and the third wavelength is

either 725 nm or 805 nm. Figures **4a** to **4c** illustrate the transformation curves for a pulse oximeter with the third wavelength being 725 nm, and Figures **4d** to **4f** illustrate the transformation curves for a pulse oximeter with the third wavelength being 805 nm. Each curve shows the Lambert-Beer $N_{k,l}$ as a function of the in-vivo N_{kl} at wavelengths k and l.

FIG. **5** is a flow diagram describing the general measurement principle described in U.S. Patent 6,104,938. In this method, the above-mentioned $N_{kl}^{in-vivo}$ values are first determined from the dA_l values measured (step **51**). The average transformations g_{kl} are then used to convert the measured in-vivo values to values N_{kl}^{L-B}, which can be used in the ideal Lambert-Beer model (step **52**). Other input values needed for the Lambert-Beer model are also determined (step **53**). In practice these input values are the ideal (nominal) extinction coefficients of the analytes to be measured, the extinction coefficients being given for the center wavelengths used in the measurement. The converted transformation values and the nominal input values (i.e. nominal extinction coefficients) are then used according to the Lambert-Beer model to calculate the concentrations of the desired analytes (step **54**). Thus in this approach the in-vivo values $N_{kl}^{in-vivo}$ measured from the tissue are converted to the ideal in-vitro (cuvette) environment, where the ideal oximetry model (i.e. the Lambert-Beer model) is applied to yield the desired concentrations.

In the standard two wavelength pulse oximetry the prior art technique is to map the modulation ratio $N_{kl}^{in-vivo}$ directly to the SpO2 percentage measured. In this simple case the transformation is not necessary, though the transformation technique together with the solution in the Lambert-Beer domain can be utilized as well.

There are two basic ways to determine the average transformation, a theoretical approach and an empirical approach. In the empirical approach the measurements are made in the tissue by taking blood samples and measuring the actual proportions of the hemoglobin species and then determining the value of N_{kl}^{L-B} on the basis of the measured proportions. The transformation is then obtained as the relationship between the values based on the blood samples and the values given by empirical measurements as measured by the pulse oximeter. The theoretical approach, in turn, is based on a known tissue model, which takes into account the characteristics of the tissue as referred to above, which are ignored in the Lambert-Beer model. A first value is

determined for in-vivo N_{kl} by means of the tissue model and a second value on the basis of the Lambert-Beer model. The tissue parameters of the model are determined so that the known 2-wavelength calibration (so-called R-curve) is reproduced. Then using these tissue parameters and the wavelength dependence of the tissue model, the relation of the in-vivo N_{kl} and the Lambert-Beer N_{kl} is extrapolated to other wavelengths in order to obtain the transformations at these new wavelengths. Thus in the theoretical approach no new empirical measurements are made.

In practice the transformation can be a quadratic equation yielding a correction of the order of 20 percent to the measured $N_{kl}^{in\text{-}vivo}$ value, for example. As discussed below, the transformation data (i.e. the transformation curves) are preferably stored in numeric form in the pulse oximeter or the sensor. The number of transformation curves stored in the pulse oximeter can vary, depending on the number of wavelengths used, for example. Typically there is a transformation curve for each wavelength pair.

As mentioned above, the accuracy of a pulse oximeter utilizing an average transformation is not necessarily sufficient, especially if analytes which are weak absorbers are to be measured or if two analytes absorb similarly, whereby it is difficult to distinguish the said analytes from each other.

In the present invention the accuracy of the pulse oximeter is improved by taking into account the subject-specific light transmission through the tissue, and changing the values input to the ideal model, i.e. the nominal transformation and the nominal extinction coefficients, on the basis of the measurement to compensate for the subject-specific changes.

FIG. **6** is a flow diagram illustrating the general principle of the present invention. In the method of the invention, initial characterization measurements are first made off-line, preferably at the calibration stage of the pulse oximeter with a nominal wavelength pulse oximeter sensor (step **61**). Based on the measurements, nominal characteristics are established describing the conditions under which the pulse oximeter has been calibrated (steps **62**). As a result of these steps, reference data are stored (step **63**), which describe the calibration conditions of the pulse oximeter. In connection with subsequent in-vivo measurements, the same characteristics are again estimated and tissue-induced changes in the characteristics are determined based on the measured characteristics and the reference data stored (step **64**). In in-vivo measurement, the $N_{kl}^{in-vivo}$ values are determined from the dA_l values

measured. On the basis of the changes determined, the subject-specific calibration is then determined (step **65**) for the in-vivo measurements to be performed by the pulse oximeter on the subject.

It is to be noted here that steps **61-63** are off-line steps performed either when the pulse oximeter has been calibrated in a known manner or at the manufacturing stage of the pulse oximeter sensor when the sensor characteristics are determined. After these steps, the nominal transformation and the nominal extinction coefficients are known to the pulse oximeter.

Human tissue can influence the accuracy of a pulse oximeter by two different mechanisms. First a direct wavelength shift is caused in the LED emission due to the filtering effect of the tissue. Namely, on one side of the LED center wavelength the absorbtion may be larger than on the other, whereby the center wavelength is effectively shifted towards the region with smaller absorption. The second mechanism is a subtle one. It arises from the fact that the arterial blood is in interaction with the surrounding tissue, which can either increase or decrease the effective path length through the arterial blood layer. The first mechanism is in this context termed the external mechanism, since it affects factors external to the tissue (wavelength). The second mechanism is called the internal mechanism, as it is caused by internal factors in the tissue itself.

Therefore, the subject-specific variations in the influence of tissue are preferably compensated for by adding two compensating processes to the above-described prior art mechanism; the first process attends to the subject-specific variation in the external mechanism, and the second one to the subject-specific variation in the internal mechanism. The first process preferably controls the extinction coefficients to be input to the Lambert-Beer model, while the second process preferably controls the value of the transformation used to transform the modulation ratios $N_{kl}^{in\text{-}vivo}$ to the Lambert-Beer model $N_{kl}^{L\text{-}B}$. The linear equations with the unknown analyte concentrations are then solved in the Lambert-Beer model, as in the prior art method. The degree of these compensations is determined by DC light transmission through the tissue (the measured DC signal), measured both in off-line and on-line conditions.

The first process is illustrated in the flow diagram of FIG. **7**. Initial off-line measurements are again made in order to determine the nominal characteristics under which the pulse oximeter has been calibrated (steps **71**

and **72**). As a result of these steps, reference data is created and stored, the data indicating the nominal characteristics (step **73**). On the basis of the data and the in-vivo measurements made, the tissue-induced changes in the extinction coefficients are then determined in connection with the in-vivo measurements (step **74**). The new coefficients are then used in the Lambert-Beer model to solve the concentrations of the analytes (step **75**). Thus in this embodiment the extinction coefficients are changed in a subject-specific manner in order to improve the accuracy of the pulse oximeter.

In one preferred embodiment of the invention the compensation for any other wavelength shift type interference than tissue-induced interference, such as a shift caused by high LED temperature, spectral absorption, or reflection properties of the sensor cushion or adhesive, is also implemented in connection with compensation for the filtering effect of the tissue.

In the following the compensations are discussed in more detail by disclosing a practical implementation for both compensation steps. The compensation of subject-variability causing wavelength shift type interference (i.e. external mechanism) is discussed first.

In the Lambert-Beer model (see Eq. **2**) the effective extinctions $\varepsilon_{ij}^{effective}$ for broadband emitters, such as LEDs, can be calculated as follows:

$$\varepsilon_{ij}^{effective} = \frac{1}{W}\int_{\Delta\lambda}\varepsilon_j(\lambda) * LED_i(\lambda(T)) * DET(\lambda) * tissue(\lambda)\partial\lambda \qquad (4),$$

where the integration is over the LED emission spectrum $LED_i(\lambda(T))$, $DET(\lambda)$ represents the spectral sensitivity of the detector, $tissue(\lambda)$ is the spectral transmission of light through the tissue, $\varepsilon_j(\lambda)$ is the spectral extinction of the analyte in question, T is the temperature, and $W=\int LED*DET*tissue*\partial\lambda$ represents a normalization factor.

In a preferred embodiment of the invention, the radiation emitting means are Light Emitting Diodes (LED), but lasers emitting at one single wavelength are also possible. For lasers the effective extinction values are the extinction values at the laser wavelength, which can depend, however, on the temperature of the emitter component. In the case of a laser, Eq. **4** is thus not needed to calculate the effective extinction value. In the preferred embodiment of the invention the emitter and detector means are located at the tissue site at which the radiation is transmitted through the tissue, but the radiation can also be conducted to and from the tissue site in a light conducting fiber or in

equivalent conduction means. In this case Eq. **4** shall also include a term for the spectral transmission of the radiation conductor. A sensor utilizing light conducting fibers can be as shown in FIG. **5** of the above–mentioned U.S. Patent 6,104,938.

The extinction coefficients can thus be calculated according to this equation by determining all the above factors, which depend on the actual wavelength values. However, as the task of determining the exact value of Eq. **4** is not possible in connection with a real-time pulse oximeter measurement using only a few discrete wavelength bands, in practice the result of Eq. **4** has to be approximated. The compensation is based on determining nominal extinction coefficients and approximating their wavelength dependence in advance at the factory and using this information in the real measurement situation to approximate the final subject-specific extinction coefficients.

The compensation algorithm will now be presented for a 4-wavelength pulse oximeter according to FIG. **1**, having four LEDs at nominal wavelengths of 627nm, 645nm, 670nm, and 870nm. The extinction matrix for RHb (first column), HbO_2, HbCO, and metHb (last column) and for the above four wavelengths (627nm on top) is then nominally in L/(mmol*cm).

$$E_{kl}^{0} = \begin{pmatrix} 1.132 & 0.1799 & 0.2734 & 3.575 \\ 0.9182 & 0.1124 & 0.1337 & 2.411 \\ 0.7353 & 0.0885 & 0.0550 & 0.5796 \\ 0.2071 & 0.2772 & 0.010 & 0.5754 \end{pmatrix} \qquad (5)$$

The above extinction coefficients have been calculated applying Eq. **4** at nominal LED drive temperature without the tissue filtering term *tissue*(λ). It then represents a nominal extinction matrix for a SpO2 sensor before its attachment on the tissue site. This extinction matrix is then altered on the basis of the measured filtering effect caused by the tissue, when the sensor is attached on the site.

We next introduce a parameter called the Functional Light Transmission $(FLT)_i$ at a wavelength i, since it is used below in order to make all DC_i values (measured at varying LED emission powers at the four discrete wavelengths *i*) comparable to each other. Using DC values comparable to each other is in practice a prerequisite for unveiling the real effect of the tissue on the measurements and the characteristics of the tissue. In order to obtain the comparable units, the DC light transmission for each LED channel

(wavelength) is first measured at a certain emitter drive current, and the measured DC value is then reduced in the preamplifier to a detector current, which is normalized to an emitter current value of 1 mA. When measured without the tissue in the probe, this result is called the Current Transfer Ratio (CTR) of the probe. CTR characterizes the sensor design and the efficiency of the light transmission from the emitters to the detector. It is usually of the order of a few microAmps (of detector current) per one milliAmp (of LED current). Now the tissue (e.g. a finger) is inserted into the probe and the CTR is again measured. This result is now called the Functional Current Transfer Ratio (FCTR) because it is the CTR measured under conditions of the function of the pulse oximeter, i.e. when the tissue is in place in the probe. The FLT_i is then calculated for each emitter (wavelength) as follows:

$$FLT(emitter\#k) = FCTR(1mA - emitter - current) / CTR(1mA - emitter - current).$$

Next the CTR and the FCTR concepts will be linked to the Lambert-Beer absorption model and to the actual measured intensities in the pulse oximeter. The CTR obviously describes how the external probe design factors, such as the color and geometry of the probe, affect the light transmission to the detector. On the other hand, the FLT can be associated with the true transmission through the tissue in units which are normalized to the emitter efficiency. Therefore, Eq. **1** can be written in a slightly different form, as it is often written in transport theory:

$$I = I_0 \exp(-\alpha * d) = I_0 \exp(-\alpha_{int} * d)\exp(-\alpha_{ext} * d') \qquad (6),$$

where d is the tissue thickness and α is an effective absorption coefficient. The above equation has been divided into two components. The attenuation factor with α_{int} accounts for all internal absorption effects, such as blood and can be associated to the FLT-value as the FLT equals one when no tissue (no internal attenuation) is in the probe, and the factor with α_{ext} accounts for all external attenuations, such as geometrical factors and multiple surface reflections without light penetration into the tissue, and can be associated with the CTR of the probe. (The term d' denotes the 'phantom' absorption thickness parameter for the external effects.) The term α_{ext} is mainly a SpO2 probe design issue which does not influence the measurement accuracy as such, and thus it need not to be compensated for by any means. The FLT at wavelength k can now be defined as:

$$FLT_k = \frac{I}{I_0 \exp(-\alpha_{ext} * d')} = \exp(-\alpha_{int} * d) = FCTR_k/CTR_k \quad (7).$$

The FLT thus describes light attenuation caused by the tissue, and it can be related to the DC light transmission in the pulse oximeter.

It is now assumed that the spectral tissue transmission is as presented in FIG. 8, which shows spectral characteristics of tissue in the same units for each wavelength, i.e. FLT as a function of the wavelength, based on an empirical measurement. In a continuous real-time SpO2 measurement, the transmission is known at 4 distinct wavelength values (the FLT values derived from the DC values in the pulse oximeter) marked in the figure. At each wavelength the slope of the tissue transmission curve can be determined or approximated using the four transmission values. The slope then determines the change in the tissue transmission in a band of a predetermined width (100 nm in this example) around the center of the LED band. We denote the slopes between 627 to 645nm and 645 to 670nm by A and B, respectively. This definition of the slopes is expressed as:

$$A = \frac{FLT(\lambda_2) - FLT(\lambda_1)}{(\lambda_2 - \lambda_1) * (FLT(\lambda_1) + FLT(\lambda_2))/2} * 100$$

and

$$B = \frac{FLT(\lambda_3) - FLT(\lambda_2)}{(\lambda_3 - \lambda_2) * (FLT(\lambda_2) + FLT(\lambda_3))/2} * 100 \ ,$$

where $FLT(\lambda_i)$ is the measured FLT value determined at wavelength λ_i. The estimation of these slopes can be improved by calculating the curvature at the center LED (645nm). This curvature (change of the slope/nm) is

$$curv = \frac{B - A}{(\lambda_3 - \lambda_1)/2}.$$

Finally the expressions are obtained for the slopes s at the three red wavelengths using A and B as parameters:

$$\begin{pmatrix} s_{\lambda_1} \\ s_{\lambda_2} \\ s_{\lambda_3} \\ s_{\lambda_4} \end{pmatrix} = \begin{pmatrix} A - curv * (\lambda_2 - \lambda_1)/2 \\ (A+B)/2 \\ B + curv * (\lambda_3 - \lambda_2)/2 \\ -0.5 \end{pmatrix} \quad (8),$$

where the slope at the IR wavelength has been estimated to be constant as it cannot be determined by the other LEDs. If we had had another LED, at about 800-1000nm range, for example, it could have been used for the estimation of the IR slope. Because the extinction curves are very flat at 870nm and the transmission is usually rather high, the tissue prefilter cannot alter the effective extinction coefficient from its nominal value significantly. The approximation of a constant transmission slope is thus considered sufficient.

In principle these slopes could be inserted in Eq. **4** in order to integrate the new true values for the extinction coefficients. However, this is impractical to do in real-time, so a simpler algorithm is presented below. We first calculate off-line the relative changes of extinction coefficients for each analyte of the system using Eq. **4** and assuming that the value of the slope equals a predetermined value, which is one in this example. This calculation results in a shift matrix of Eq. **9**:

$$Tissue_{SHIFT}^{SLOPE=1} = \begin{pmatrix} 0.975 & 0.942 & 0.940 & 0.999 \\ 0.984 & 0.966 & 0.920 & 0.916 \\ 0.963 & 0.986 & 0.896 & 0.789 \\ 1.01 & 1.03 & 0.903 & 1.05 \end{pmatrix} \quad (9),$$

where the effective extinction of HbO_2 at 645nm is 0.966 times the original value, and the effective extinction of HbCO at 670nm is 0.896 times the original value, for example. Thus, the matrix of Eq. **9** defines the relative changes caused by the tissue, assuming that the slope of the tissue transmission curve equals one. During in-vivo measurement, the slope is estimated using the DC values. The ratio of the slopes then indicates the relative change of a coefficient. In other words, if the relative change determined off-line for a slope value of *X1* is *r*, the relative change for a measured slope value of *X2* is then $r_{X(X2/X1)}$. The relative changes are different for different analytes since the extinction coefficients of the different analytes behave differently as a function of wavelength.

In real-time the effective extinction coefficients can thus be calculated as follows:

$$E^{Eff} = E_{kl}^{0} \otimes (1 + S \bullet (Tissue_{SHIFT}^{SLOPE=1} - 1)) \quad (10),$$

where *S* denotes the column array in Eq. **8** and the matrix multiplications are performed element by element ($\otimes$) or element by row ($\bullet$), respectively.

If the LEDs are not driven at the nominal drive currents, their effective wavelength may also be shifted by the temperature change at the LED p-n junction. The wavelength shift induced by temperature is typically about 0.1-0.2 nm/°C which is significant if the drive currents are high, as is usually the case at wavelengths shorter than 660 nm. Thus, the extinction matrix of Eq. **10** must also be compensated for in varying LED drive conditions.

There are many ways to find out the temperature of the LED p-n junction. One alternative is to add a temperature sensor on the LED substrate and use the reading of the sensor for the compensation of all LED emission wavelengths. Though the junction temperature follows the substrate temperature according to some empirical heat conduction model, the method may be unreliable because the LED chip contact to the substrate and the internal heat conductivity may vary considerably. A better way is therefore to determine the junction temperature directly from the forward voltage drop of the LED junction. The junction has typical diode characteristics, which can be determined off-line for each LED separately after assembling the LEDs on the substrate. It is even possible to measure, with an optical spectrometer the shift of the emission as a function of the LED forward voltage. Relating the wavelength shift to the forward voltage assumes that the forward voltage is measured during the operation of the pulse oximeter. The circuit board of the pulse oximeter should thus preferably have means for performing the forward voltage measurement. But if it does not, the LED emission shift can be calibrated against the temperature sensor at the substrate. The LED manufacturer specifications for the temperature shift can then be used to calculate the corresponding wavelength shift. Still another practical compensation for the emitter temperature changes is to map empirically the relationship of the emitter drive current to the observed wavelength shift and to use this information to adjust the on-line extinction coefficients for the sensor.

A method for temperature compensation of the LED emission is now presented, assuming that the LED forward voltage is measured on the circuit board. The wavelength shifts can then be calculated as follows

$$\begin{pmatrix} \Delta\lambda_1 \\ \Delta\lambda_2 \\ \Delta\lambda_3 \\ \Delta\lambda_4 \end{pmatrix} = \begin{pmatrix} k_1 \\ k_2 \\ k_3 \\ k_4 \end{pmatrix} \bullet \begin{pmatrix} \Delta V_1 \\ \Delta V_2 \\ \Delta V_3 \\ \Delta V_4 \end{pmatrix} \qquad (11),$$

where the shift coefficients k_i are values determined empirically in advance and ΔV_i are the measured changes of the forward voltage drops. For the 627-645-670-870nm LEDs of the sensor, the k-values are 0.06 nm/mV, 0.06nm/mV, 0.09nm/mV, and 0.1nm/mV, respectively.

As in the compensation discussed above relating to tissue filtering, it is practical to first calculate the change in the extinction coefficients off-line for a certain fixed wavelength shift. In this example the relative changes of the extinction coefficients are calculated, as in Eq. **9**, for a 5 nm wavelength shift for each of the four hemoglobin derivatives. The following shift matrix is then obtained:

$$Temp_{SHIFT}^{\Delta\lambda=5nm} = \begin{pmatrix} 0.919 & 0.820 & 0.798 & 0.974 \\ 0.963 & 0.926 & 0.823 & 0.794 \\ 0.941 & 0.983 & 0.855 & 0.725 \\ 1.0 & 1.01 & 0.963 & 1.02 \end{pmatrix} \quad (12).$$

During in-vivo measurement the relative changes are then calculated based on the measured wavelength shift. The ratio of the wavelength shifts then indicates the relative change of a coefficient caused by temperature. In other words, if the relative change calculated for a wavelength shift of *Y1* is *r*, the relative change for the measured (on-line) wavelength shift of *Y2* is *r×(Y2/Y1)*. The relative changes are different for different analytes, since the extinction coefficients of the different analytes behave differently as a function of wavelength.

The temperature compensated extinction coefficients are thus:

$$E_{TEMP}^{EFF} = E_{kl}^{0} \otimes (1 + (\Delta\lambda / 5nm) \bullet (Temp_{SHIFT}^{\Delta\lambda=5nm} - 1)) \quad (13),$$

where $\Delta\lambda$ is the array in Eq. **11**. As mentioned earlier, $\Delta\lambda$ can also be estimated by reading the temperature indicated by the temperature sensor on the LED substrate or by measuring the LED drive current and using the mapping of the current to the wavelength shift.

The compensation of the variability causing wavelength shift type interference can now be summed up as follows:

$$E^{Eff} = E_{kl}^{0} \otimes (1 + S \bullet (Tissue_{SHIFT}^{SLOPE=1} - 1)) \otimes (1 + (\Delta\lambda / 5nm) \bullet (Temp_{SHIFT}^{\Delta\lambda=5nm} - 1)) \quad (14).$$

As mentioned above, the practical compensations can be divided into steps performed off-line prior to the actual measurements, for example in the factory at the manufacturing stage of the pulse oximeter sensor, and to steps

performed on-line, i.e. in connection with the actual in-vivo measurements. Using the above practical example, the off-line compensation steps are as follows.

1. The spectral characteristics of the emitter/detector system is established. In other words, the LEDs are characterized for their light emission (the emission as a function of wavelength) and the detector for its spectral sensitivity. This step thus includes determination of the characteristics of the curve shown in FIG. **9**, i.e. the received intensity as a function of wavelength (at least around the wavelengths used). The light transmission from the light emitter to the light detector is measured without human tissue, i.e. the CTR is determined in the sensor in a fixed setup mimicking the actual use of the sensor. For clip-type sensors this is usually the Probe Off position of the sensor. The step also includes determination of the center wavelength of each LED.

2. The effective extinction coefficients are determined without the tissue term. Thus in this step Eq. **4** is used without the tissue term (*tissue*(λ)) to form a matrix E_{kl}^{0} according to Eq. **5**.

3. The relative changes in the effective extinction coefficients due to tissue filter effect are determined. Here Eq. **4** is used assuming that the slope of *tissue*(λ) equals a predetermined fixed value at each wavelength. In other words, the shift matrix of Eq. **9** is determined.

4. The relative changes in the effective extinction coefficients due to wavelength shift caused by changes in temperature are determined. In other words, the matrix of Eq. **12** is determined, which indicates the relative changes for a wavelength shift of a predetermined value.

5. If the LED forward voltage method is used, the LED forward voltages are characterized at a typical drive current for small ambient temperature changes. The temperature coefficients k_l in Eq. **11** and the nominal forward voltage drops at nominal temperature are determined for each LED.

6. The information obtained is saved in a memory unit in the sensor or in the control unit, or the corresponding information is otherwise made available to the pulse oximeter, for example, by using codes, such as sensor identification numbers, which indicate the values of the information.

As is obvious from the above, steps 1 to 6 include performing initial measurements for the compensation, said measurements to include

measuring the light transmission of the apparatus, establishing nominal DC transmission characteristics of the apparatus on the basis of the measurements, and for subsequent in-vivo measurements storing reference data which indicate the transmission characteristics established.

Thus in the off-line measurements, the value of Eq. **4** is determined using nominal values, and the nominal extinction matrix is formed. The apparatus is also provided with the data needed in the subsequent on-line compensation steps for calculating the changes in the factors included in Eq. **4**. In the on-line steps the said changes are determined and a new extinction matrix is formed, whereby the new extinction values are such that the external effects are compensated for.

To sum up, after the off-line steps the pulse oximeter stores the matrices according to equations **5**, **9**, and **12** and the values of the shift coefficients k_i . In addition to this, the oximeter stores the CTR values and the center wavelengths corresponding to these values.

Following the above practical algorithm, the on-line compensation steps utilizing the information stored during the off-line steps are as follows:

1. The forward voltage drops (ΔV) are determined for each LED. In this step, the change in the forward voltage relative to the sensor nominal values are calculated, the nominal values having been stored in the sensor memory unit or in the control unit memory. If the pulse oximeter does not have forward voltage measuring means, the temperature of each LED is estimated by reading the temperature indicated by a sensor on the LED substrate, and either the manufacturer specifications or empirical data for corresponding wavelength changes or a look-up table mapping the emitter drive current to the center wavelength shift is used.

2. The effective extinction matrix for the temperature compensation is determined. This is calculated as illustrated in Eq. **11-13**, i.e. using the wavelength shifts determined according to Eq. **11** and calculating the matrix of Eq. **13** using the matrices of Eq. **5** and **12** stored earlier.

3. The DC light transmission for each LED channel (wavelength) is measured, and the value measured is normalized to an emitter current value of 1 mA. The result is the FCTR of the sensor. An estimate for the FLT is then calculated for each emitter (wavelength). In this connection, the FLT values are for calculating the slopes (A and B). In other words, all DC values are

normalized in relation to the 1 mA emitter current in order to make all values comparable to one another.

5. The effective Lambert-Beer extinction coefficients are determined using Eq. **14**.

6. The extinction coefficients obtained in step **5** are used for solving the analyte concentrations in the Lambert-Beer model.

During the above on-line steps **1-6** in-vivo measurements are performed, wherein the DC component of the radiation emitted through the tissue and received by the detector is measured, tissue-induced changes in the transmission characteristics are determined based on the in-vivo DC component and the transmission characteristics stored, and on the basis of the tissue-induced changes the subject-specific variation in the in-vivo measurement is compensated for.

The above off-line and on-line steps compensate for the non-ideal characteristics of the broadband emitters or for external effects on the light source emission spectra. However, they do not compensate for the variation in the absorption and scattering interplay in the tissue, i.e. the internal effects, which equally influence a single line laser emitter and a broadband LED emitter. Lasers also show shifts in the emission line wavelength as a function of the temperature. Therefore, the lasers are compensated for the temperature and internal tissue effects, but not for the pre-filter tissue-induced spectral shifts.

The compensation step attending to the variations in the internal effects is illustrated in the flow diagram of FIG. **10**. Initial measurements are again made in order to determine the nominal DC transmission characteristics of the pulse oximeter (steps **101** and **102**). As a result of these steps, reference data are created and stored, and the data indicating the transmission characteristics are determined (step **103**). On the basis of the data and the in-vivo measurements made, the tissue-induced change in the average transformation is then determined in connection with the in-vivo measurements (step **104**). The new transformation is determined, and finally the concentrations of the analytes are solved in the Lambert-Beer model (step **105**). Thus in this embodiment the average transformation stored in the pulse oximeter is changed in a subject-specific manner in order to improve the accuracy of the pulse oximeter. As shown below, in this case during the off-line steps **101-103** partly different data is to be created and stored as compared to

the first compensation step, since in this case the DC light transmission characteristics are used to create a subject-specific transformation.

A practical implementation of the second compensating step is now discussed by introducing a new variable called "path length multiplier", since this will provide an easy way of understanding the technique in accordance with the invention.

As mentioned above, the purpose of the invention is to improve the accuracy of a pulse oximeter in situations in which the blood volume, the red blood cell density or the hematocrit, the total hemoglobin (g/dl), the division between the arterial and venous blood compartment volumes, and the arterial-venous saturation difference vary and produce human variability, which worsens the accuracy of the SpO2 measurement. It is also the purpose of the invention to compensate for the effect of skin pigmentation (dark skin), which in part can be considered to belong to the tissue prefilter category of compensations, but which also influences via modifying the path length multiplier. This modification is especially important for SpO2 ear sensors, which are attached to a very thin tissue part (of about the same thickness corresponding to the diffusion constant in human tissue).

The interdependence of the above-described transformation and the path length multiplier is first illustrated by considering the photon path lengths through a single layer of artery blood and examining how the scattering and absorption affect it. It is postulated here that multiple scattering effectively increases the photon path length through the artery and that the absorption of the surrounding tissue effectively decreases it. In this way the artery and tissue are in interaction with each other. To derive a mathematical formulation of this relationship, the known Kubelka-Munk two-flux model can be used. This model defines an absorption probability K as follows:

$$K = \left\langle \frac{dl}{dz} \right\rangle * \Sigma_a \qquad (15),$$

where Σ_a is the macroscopic absorption cross-section of the media and dl is the true average photon path length through the scattering and absorbing medium of infinitesimal layer thickness dz. The term $\langle dl/dz \rangle = K/\Sigma_a$ is a path length multiplier (*plm*) which enhances the arterial blood absorption from that of the Lambert-Beer non-scatter value because of the multiple scattering in the surrounding medium.

The idea of the path length multiplier is applied to the Lambert-Beer formulation of 2-λ pulse oximetry. The ratio of the change in absorption at the two probe wavelengths is defined as:

$$\frac{dA_k}{dA_l} = N_{kl}^{in-vivo} = \frac{\mu_a^k * d_k}{\mu_a^l * d_l} \qquad (16),$$

where μa^l is the arterial (non-scatter) absorption coefficient at wavelength *i* and d_i is the effective true optical path length. The transformation is defined by substituting equation **15** with $dl = d_i$ in equation **16**:

$$N_{kl}^{in-vivo} = \frac{\mu_a^k * \left(\frac{K}{\Sigma_a}\right)_k * dz}{\mu_a^l * \left(\frac{K}{\Sigma_a}\right)_l * dz} = \frac{\left(\frac{K}{\Sigma_a}\right)_k}{\left(\frac{K}{\Sigma_a}\right)_l} * N_{kl}^{ideal} \qquad (17),$$

where the ideal Lambert-Beer model is used for $N_{kl}^{ideal} \equiv \mu a^k / \mu a^l$, and where the layer thickness *dz* is the same for all wavelengths (*k, l*). Equation **17** now represents the transformation $(g_{kl})^{-1}$ from $N_{kl}^{in-vivo}$, i.e. from the measured value, to N_{kl}^{L-B}, which is the ratio of differential absorptions that would be measured if the measurement system were the ideal cuvette system of the Lambert-Beer model. For the transformation the equation below is obtained:

$$g_{kl} = \frac{\left(\frac{K}{\Sigma_a}\right)_k}{\left(\frac{K}{\Sigma_a}\right)_l} = \frac{plm_k}{plm_l} \qquad (18).$$

Thus the transforming quantity is a ratio of path length multipliers measured at two different wavelengths (*k* and *l*). The dependence of the function g_{kl} thus refers to the absorption density of the scattering tissue in the surrounding of the infinitesimal arterial layer *dz* including the layer itself. This essentially means that the transformation does not require knowledge of the analyte composition in the arterial blood, but refers rather to the macroscopic light absorption, i.e. transmission through the tissue part under the sensor. That is in the language of pulse oximetry the DC component of the light transmission. This is utilized in the compensation of the invention.

Modifying Eq.**1** and leaving the attenuation of the probe design factors (i.e. CTR values) out of consideration, the relationship of the DC light

transmission through the tissue and the path length multiplier can be presented as follows:

$$I_{out} = I_{in} e^{-\varepsilon DC} = I_{in} e^{-\varepsilon\, plm\, D1\, C} \qquad (19),$$

where D is the actual path length through the sample, $D1$ is the shortest path length through the sample (i.e. the thickness of the sample), and ε is the ideal extinction coefficient of the analyte. Here the I_{out}/I_{in} can be associated with the FLT at the wavelength in question. *Plm* thus describes the internal attenuation factors in the tissue and, in particular, the enhancement of the absorbancy relative to the ideal cuvette absorption.

In nominal conditions, the path length multiplier has a certain nominal value plm^0 (where the superscript '0' refers to the nominal value). This nominal value can be determined in the factory at the manufacturing stage of the pulse oximeter. When the DC component is measured again in connection with in-vivo measurement, the change in the *plm* from the nominal value can be used to determine the change in the average transformation.

The term α_{int} in Eq. **6** can be expressed with the help of the path length multiplier in the Lambert-Beer model as

$$\alpha_{\text{int}} = plm * \Sigma_a ,$$

where Σ_a accounts for all internal absorption sources and is defined in the non-scatter Lambert-Beer domain. The FLT at wavelength k can then be written as follows:

$$FLT_k = \exp(-\alpha_{\text{int}} * d) = \exp(-plm * \Sigma_a * d) \qquad (20).$$

We then ratio the logarithms of the FLTs at two wavelengths k and l, which results in Eq. **21**:

$$\frac{\log(FLT_k)}{\log(FLT_l)} = \frac{plm_k * \Sigma_a^k}{plm_l * \Sigma_a^l} = g_{kl} * \frac{f_a * \mu_a^k + f_v * \mu_v^k}{f_a * \mu_a^l + f_v * \mu_v^l} = g_{kl} * \frac{f_a(\mu_a^k - \mu_v^k) + \mu_v^k}{f_a(\mu_a^l - \mu_v^l) + \mu_v^l} \qquad (21),$$

where $g_{kl} = plm_k / plm_l$ is the transformation between the Lambert-Beer and in-vivo modulation ratios according to Eq. **18**, and in which the internal absorbing tissue compartments are venous and arterial blood with volume fractions f_v and f_a and with absorption coefficients μ_v and μ_a determined in the Lambert-Beer domain, respectively. In the last expression we have used for the venous volume fraction the relationship $f_v = 1 - f_a$. As the arterial volume fraction is always smaller than the venous volume fraction and as the arterial-

venous absorption difference is always smaller than the venous absorption, the dominating factor in the last term is μ_v^k/μ_v^l , i.e. the venous saturation SvO2.

Thus the changes in the FLT and SvO2 from their nominal values provide the compensation needed for estimating the correct transformation function g_{kl}. We can then finally write for the relative change of the transformation function g_{kl}:

$$\frac{g_{kl}}{g_{kl}^0} = \frac{\dfrac{\log(FLT_k)}{\log(FLT_l)} \Big/ \dfrac{\log(FLT_k)^0}{\log(FLT_l)^0}}{F_{kl}(SvO2, SaO2, f_a) \Big/ F_{kl}(SvO2, SaO2, f_a)^0} \quad (22),$$

where the function F_{kl} represents the ratio term $\dfrac{f_a(\mu_a^k - \mu_v^k) + \mu_v^k}{f_a(\mu_a^l - \mu_v^l) + \mu_v^l}$ in Eq. **21** and the superscript 0 represents the nominal values of the nominal calibration function g_{kl}^0 , which is on average true for a large patient population. In fact, the *log(FLT)* and the F_{kl} compensation terms account for quite different human variability factors in the tissue: whereas F_{kl} mainly tracks the changes of the arterial venous saturation difference, in particular SvO2, the *log(FLT)* reflects the changes in the total absorption of the tissue, i.e. in the total blood volume and the total hemoglobin or hematocrit, which are not seen in F_{kl} at all. In practice, the largest corrections to the transformation function are due to the *log(FLT)* and F_{kl} is less important.

The FLT in Eq. **22** is easily obtained at the two wavelengths *k* and *l*, as has been described earlier in Eq. **7**. The function F_{kl} represents the ratio of the absorption coefficients (in the Lambert-Beer non-scatter model) of the whole tissue at these same two wavelengths, i.e. it represents the internal color of the tissue. This internal absorption ratio can be measured by examining the low frequency baseline fluctuations of the plethysmographic wave signal. These fluctuations are caused by the low frequency changes (usually of respiration origin) in the blood volume or in the blood volume distribution of the tissue. Similarly, since the arterial color (= R-ratio) is defined as the ratio of the arterial absorption coefficients, function F_{kl} can be calculated as:

$$F_{kl} = \frac{f_a(\mu_a^k - \mu_v^k) + \mu_v^k}{f_a(\mu_a^l - \mu_v^l) + \mu_v^l} = g_{kl}^{-1}\left(\frac{(AC/DC)_k}{(AC/DC)_l}\right) = g_{kl}^{-1}(N_{kl}^{baseline}) \qquad (23),$$

where *AC* is the amplitude (or the instantaneous slope) of the low frequency baseline fluctuation, instead of the heart pulse amplitude of the plethysmographic wave, and DC is the DC light transmission at that particular wavelength. Because the effective tissue color is mainly determined by the venous blood, function F_{kl} can be approximated as the arterial modulation ratio calculated for the venous saturation, which is usually about SaO2-10% i.e. $F_{kl}=R(SvO2=SaO2-10\%)$.

If the venous saturation is determined by venous blood samples and the arterial saturation by the arterial blood samples, the function F_{kl} can be calculated using the real blood values (with the assumption that the corresponding blood compartment volumes are $f_a=0.25$ and $f_v=0.75$).

The second compensation step for human variability can then be performed in the following way:

1. The nominal light transmission through a finger or ear lobe or its approximation at the distinct nominal wavelengths of the sensor, is determined for a population of patients or volunteers or even for only one single volunteer, on whom the nominal calibration (the original standard pulse oximeter calibration or the actual multi wavelength measurements using this calibration directly or indirectly) was performed; this gives $\frac{\log(FLT_k)^0}{\log(FLT_l)^0}$ as a function of $N_{kl}^{in\text{-}vivo}$ at these wavelengths (*k, l*), i.e. as a function of the correct SpO2 in practice. Thus, the FLT^0 values are obtained for each wavelength. This information is stored in the sensor memory unit (or in the control unit).

2. Function F^0 can be determined in two alternative ways:

2.1 In the above measurement using the baseline fluctuations, $N_{kl}^{baseline}$ is calculated and transformed to the Lambert-Beer model by the nominal transformation $(g^0_{kl})^{-1}$ for the population of patients or volunteers or even for only one single volunteer, on whom the nominal calibration (the original standard pulse oximeter calibration or the actual multi-wavelength measurements using this calibration directly or indirectly) was performed; this is tabulated as a function of $N_{kl}^{in\text{-}vivo}$ at these wavelengths (*k, l*). These data are stored in the sensor memory unit (or in the control unit).

2.2. In the above measurement venous and arterial blood samples are taken from a position close to the sensor site and analyzed for RHb, HbO_2, HbCO, and metHb. The absorption coefficients μ_a and μ_v are then calculated using the measured analyte fractions. The arterial volume fraction f_a is then estimated. Usually it is sufficient to approximate that f_a is equal to 0.25. The functions F_{kl} are calculated in the Lambert-Beer Model using the venous and arterial volume fractions and

$$\mu_{a,v} = RHb * \mu_{a,v}^{RHb} + HbO2 * \mu_{a,v}^{HbO2} * HbCO * \mu_{a,v}^{HbCO} + metHb * \mu_{a,v}^{metHb}.$$

3. As a result of steps 1 and 2, we have an off-line determined look-up table for each wavelength pair, in which the following nominal information is tabulated:

k	l	$N_{kl}^{in\text{-}vivo}$	g_{kl}^{0}	$Log(FLT_k)/log(FLT_l)$	$g_{kl}^{-1} \times (N_{kl}^{baseline})$	F_{kl}

Table 1.

and where also the nominal transformation g^0 is presented and $N_{kl}^{baseline} \cong g_{kl}^{0} \times (F_{kl})$. Only one of the two last columns is necessary, depending on the way the values of function F are determined. It is also to be noted that the ratio is not necessary in column 5, but that it is enough to store the FLT values from which the ratio of their logarithms can be calculated.

As is obvious from the above, steps 1-3 again include measuring the DC light transmission of the apparatus, establishing nominal DC transmission characteristics for the apparatus on the basis of the measurements, and storing reference data for subsequent in-vivo measurements, the data indicating the transmission characteristics established.

After the above off-line steps, which can be performed at the manufacturing stage of the pulse oximeter, the following steps are performed in connection with the on-line (i.e. in-vivo) measurement.

4. The actual spectral shape of the light transmission through a finger or ear lobe at the distinct wavelengths of the sensor is determined, and $\frac{\log(FLT_k)}{\log(FLT_l)}$ is calculated for each wavelength pair similarly as in the off-line stage.

5. In Table 1 in the row where the measured modulation ratio at the wavelengths *k* and *l* equals $N_{kl}^{in\text{-}vivo}$, the nominal $\frac{\log(FLT_k)^0}{\log(FLT_l)^0}$ is read. The correction factor $\frac{\log(FLT_k)}{\log(FLT_l)} \Big/ \frac{\log(FLT_k)^0}{\log(FLT_l)^0}$ is then calculated.

6. In Table 1 in the row, where the measured modulation ratio at the wavelengths *k* and *l* equals $N_{kl}^{in\text{-}vivo}$, the nominal F_{kl}^0 is read from either of the last two columns.

7. The correction factor F_{kl}/F_{kl}^0 is determined in one of the following two ways:

7.1 Column $g^{-1}x(N^{baseline})$: By using the baseline fluctuations of the measured plethysmographic wave and by using Eq. **23** with g^{-1}, the function F_{kl} is determined. The correction factor F_{kl}/F_{kl}^0 is then calculated. For determining $N^{baseline}$ and its changes, the amplitudes of the signal can be used, as is normally done for a modulation ratio *N*.

7.2 Column F_{kl}: The blood analytes RHb, HbO_2, HbCO, and metHb are solved in the Lambert-Beer model using the nominal transformation g^0. This is the first approximation for the analytes. The absorption coefficients μ_a and μ_v are calculated using the measured analyte fractions in the arterial absorption and approximating the absorption coefficient in the venous blood by using the measured dyshemoglobin fractions and setting $HbO2^{vena}$=HbO2-10% and RHb^{vena}=RHb+10%, where $f_a = 0.25$ is assumed. The functions F_{kl} are calculated in the Lambert-Beer Model using the equation:

$$\mu_{a,v} = RHb * \mu_{a,v}^{RHb} + HbO2 * \mu_{a,v}^{HbO2} * HbCO * \mu_{a,v}^{HbCO} + metHb * \mu_{a,v}^{metHb}.$$

A more accurate estimate of F_{kl} can be obtained by iteration of new analyte fractions for the new corrected transformation after step 8.

8. A new transformation g_{kl} is calculated using Eq. **22,** and the new transformation is used for solving the analyte concentrations in the Lambert-Beer model.

The pre-calculated data utilized by the pulse oximeter can be stored in the sensor part of the pulse oximeter, whereby the same sensor can be attached to different pulse oximeter housings. FIG. **12** illustrates the general structure of a sensor according to the invention, the detailed configuration of the sensor being dependent on which information is stored in the sensor and

which in the signal processing part, and also on the amount of the calculation appropriate in the signal processing part.

Nevertheless, a sensor according to the invention includes the light sources (**10a-10c**) and the photo detector (**12**), the light sources being adapted to emit at two or more wavelengths. In addition, the sensor includes a data storage unit **M2** for storing the data on the basis of which the signal processing part can perform the above-described calibration. The information necessary for the above compensations is shown in the figure. For the first compensation process the pulse oximeter needs the k-values, the above-mentioned three matrices, i.e. the nominal extinction matrix (Eq. **5**), the shift matrices (Eqs. **9** and **12**), and the CTR/wavelength pairs. For the second compensation process, in turn, the pulse oximeter needs the information stored in Table 1 and the CTR/wavelength pairs. As mentioned above, at least part of this data determined prior to the use of the device for in-vivo measurements can also be stored in the control unit part of the pulse oximeter. The apparatus further preferably includes means **120** for measuring the forward voltage of the p-n junction of each LED, as discussed above.

As can be seen from the above, the method of the invention is based on the DC transmission of light. By means of the off-line DC measurements, reference data is first created. During subsequent in-vivo DC measurements, the reference data is then utilized to filter out human variability from the in-vivo measurement.

Although the method in accordance with the invention has been discussed in connection with a four wavelength pulse oximeter, it can also be employed in a basic two wavelength pulse oximeter. However, the method is more beneficial in a multi-wavelength pulse oximeter where the number of analytes to be measured is greater than two.

In the case of a two-wavelength pulse oximeter, the simplest way to apply the compensation is first to formulate the calibration of the two-wavelength oximeter as a first step using only one transformation function g^{-1} (e.g. at wavelengths 660nm and 900 nm) and a second step using a two-times-two extinction matrix ε for these wavelengths and for the two analytes RHb and HbO2. The compensation procedures are then identical to the ones presented in the above multi-wavelength method. If the calibration of the two-wavelength pulse oximeter is done in the normal way using a direct mapping of the in-vivo measured R-ratio (= $N_{660\text{-}900}$) to the SpO2 percentage, the

compensation steps could for example, be as follows: The wavelength shifts from the nominal LED center wavelength values to a change in the SpO2 value can first be coded. The wavelength shifts are determined for the temperature component as described in the above multi-wavelength method and for the tissue component by mapping at the two wavelengths the change in the FLT ratio from its nominal value in the calibration conditions to a change in the SpO2 value from the nominal calibration SpO2. The tissue wavelength shift cannot be estimated as accurately as in the multi-wavelength oximeter, but sufficient compensation to the tissue prefilter can still be obtained and the accuracy of the pulse oximeter can be improved. The last compensation step also includes the compensation for the internal tissue variability, which is summed with the prefilter effect.

Although the invention has been described above with reference to the examples shown in the appended drawings, it is obvious that the invention is not limited to these, but may be modified by those skilled in the art without departing from the scope and spirit of the invention. For example, instead of transformation, any other quantity by which the pulse oximeter can correct the average calibration known to it can be used to eliminate human variability.

The invention has also been described with reference to pulse oximeters for analytes which are in the blood of a subject. The invention, however, can also be applied at different wavelength ranges, e.g. at around 1.5 μm for glucose, at which similar compensation means are called for. The other substances in the tissue modify the effective extinction of the glucose because they alter the path length multiplier at this wavelength. Similarly, the tissue prefilter and temperature effects are taken into account.

Claims

1. A method for compensating for subject-specific variability in an apparatus intended for non-invasively determining the amount of at least two light-absorbing substances in the blood of a subject and provided with emitter means for emitting radiation at a minimum of two different wavelengths and with detector means for receiving the radiation emitted, characterized by the steps of:

- calibrating the apparatus using a nominal calibration,
- carrying out initial characterization measurements, said measurements to include measuring radiation received by the detector,
- based on the characterization measurements, establishing nominal characteristics describing conditions under which the nominal calibration is used,
- storing reference data indicating the nominal characteristics established,
- performing in-vivo measurements on a living tissue, wherein radiation emitted through the tissue and received by the detector means is measured,
- based on the in-vivo measurements and the reference data stored, determining tissue-induced changes in the nominal characteristics, and
- compensating for subject-specific variation in the in-vivo measurements by correcting the nominal calibration on the basis of the tissue-induced changes.

2. A method according to claim 1, including compensation for effects causing wavelength shift.

3. A method according to claim 1, including compensation for effects internal to the tissue.

4. A method according to claim 1, including both compensation for effects causing wavelength shift and for effects internal to the tissue.

5. A method according to claim 2, wherein the compensation for effects causing wavelength shift includes defining subject-specific extinction coefficients for the substances.

6. A method according to claim 3, wherein the compensation for effects internal to the tissue includes defining a subject-specific transformation used to transform in-vivo measurement results to the Lambert-Beer model.

7. A method according to claim 4, wherein the compensation for effects causing wavelength shift includes defining subject-specific extinction coefficients for the substances, and the compensation for effects internal to the tissue includes defining a subject-specific transformation used to transform in-vivo measurement results to the Lambert-Beer model.

8. A method according to claim 5, wherein said establishing step includes determining DC transmission characteristics of the emitter and detector means, spectral characteristics of the emitter and detector means and nominal transmission characteristics for the tissue.

9. A method according to claim 8, wherein said establishing step further includes determining the temperature in which the nominal calibration is used.

10. A method according to claim 9, wherein the extinction coefficients $\varepsilon_{i,j}$ are determined according to the following formula:

$$\varepsilon_{ij}^{effective} = \frac{1}{W}\int_{\Delta\lambda}\varepsilon_j(\lambda) * LED_i(\lambda(T)) * DET(\lambda) * tissue(\lambda)\partial\lambda,$$

where the integration is over the emission spectrum $LED_i(\lambda)$ of the emitter means, $DET(\lambda)$ represents the spectral sensitivity of the detector means, $tissue(\lambda)$ is the spectral transmission of radiation through the tissue, ε_j is the extinction coefficient of the substance, T is the temperature, and i and j are matrix indices.

11. A method according to claim 10, wherein

- the step of establishing nominal characteristics includes defining a nominal extinction matrix with a nominal extinction coefficient for each substance/wavelength pair, and
- the step of determining tissue-induced changes includes updating the nominal extinction matrix, whereby the updated matrix includes the subject-specific extinction coefficients to be used in the Lambert-Beer model.

12. A method according to claim 11, wherein the nominal extinction matrix is determined according to the following formula

$$\varepsilon_{ij}^{effective} = \frac{1}{W}\int_{\Delta\lambda}\varepsilon_j(\lambda) * LED_i(\lambda(T)) * DET(\lambda)\partial\lambda$$

where the integration is over the emission spectrum $LED_i(\lambda)$ of the emitter means, $DET(\lambda)$ represents the spectral sensitivity of the detector

means; ε is the extinction coefficient of the substance, T is the temperature, and i and j are matrix indices.

13. A method according to claim **11**, wherein the step of establishing nominal characteristics further includes determining a first shift matrix, the elements of which indicate a relative change in each extinction coefficient, assuming that the slope of the term *tissue*(λ) has a fixed value deviating from zero.

14. A method according to claim **13**, wherein the step of determining tissue-induced changes in the nominal characteristics includes defining (1) the slope of the term *tissue*(λ) and (2) the subject-specific extinction coefficients based on the shift matrix and the slope defined.

15. A method according to claim **6**, wherein the method further includes the steps of

- storing an average transformation measured for a great number of subjects and

- based on the tissue-induced changes, updating the average transformation, whereby the updated transformation represents the subject-specific transformation.

16. A method according to claim **10**, wherein

- the step of establishing nominal characteristics further includes defining temperature dependence of the emitter and detector means, and

- said compensating step includes temperature compensation for the emitter and detector means.

17. A method according to claim **16**, wherein the step of establishing nominal characteristics further includes determining a second shift matrix the elements of which indicate a relative change of each extinction coefficient for a predetermined wavelength shift.

18. A method according to claim **17**, wherein the step of determining tissue-induced changes in the nominal characteristics includes

- defining a wavelength shift caused by temperature and

- defining subject-specific coefficients based on the shift matrix and the wavelength shift defined.

19. A method according to claim **7**, wherein

- the step of defining nominal characteristics includes calculating nominal values for the Functional Light Transmission (FLT) of the apparatus,

- the step of determining tissue-induced changes includes calculating new values for the Functional Light Transmission (FLT) of the apparatus, and

the step of compensating includes determining the subject-specific transformation on the basis of the nominal and new values.

20. A method according to claim **7**, wherein

- the step of defining nominal characteristics includes calculating nominal values for function F_{kl} of the apparatus,

- the step of determining tissue-induced changes includes calculating new values for the function F_{kl} of the apparatus, and

- the step of compensating includes determining the subject-specific transformation on the basis of the nominal and new values,

wherein the function F_{kl} corresponds to the ratio $\frac{f_a(\mu_a^k - \mu_v^k) + \mu_v^k}{f_a(\mu_a^l - \mu_v^l) + \mu_v^l}$,

where μ_v and μ_a are the absorption coefficients of venous and arterial blood, respectively, as determined in the Lambert-Beer domain, f_a is the volume fraction of arterial blood, and the superscripts *k* and *l* indicate the wavelength.

21. A method according to claim **20**, wherein the nominal and new values for the Function F_{kl} are calculated on the basis of measured fluctuation of the DC component of the radiation received by the detector means.

22. A method according to claim 20, wherein

- the step of determining tissue-induced changes includes calculating a first approximation for the amount of the substances, and

- the step of compensating includes utilizing the first approximation for determining the subject-specific transformation.

23. A method according to claim **1**, wherein the at least two light absorbing substances include oxyhemoglobin (HbO2) and reduced hemoglobin (RHb).

24. An apparatus for non-invasively determining the amount of at least two light absorbing substances in the blood of a subject, c h a r a c t e r i z e d in that the apparatus comprises:

- emitter means for emitting radiation at a minimum of two different wavelengths,

- detector means for receiving said radiation at each of said wavelengths and producing at least two electrical output signals,

- first signal processing means for processing said output signals and producing a modulation signal for each wavelength, each modulation signal

representing the pulsating absorption caused by the arterialized blood of the subject,

- second signal processing means for applying a predetermined calibration on said modulation signals, whereby transformed modulation signals applicable in the Lambert-Beer model are obtained,

- memory means for storing reference data indicating nominal characteristics under which said predetermined calibration has been applied,

- first compensation means, operatively connected to the memory means, for determining tissue-induced changes in the nominal characteristics,

- second compensation means, operatively connected to the first compensation means, for defining a subject-specific calibration by correcting the predetermined calibration on the basis of the tissue-induced changes, and

- calculation means, responsive to the second compensation means, for determining said amounts.

25. A sensor for collecting measurement data for a pulse oximeter intended for non-invasively determining the amount of at least two light absorbing substances in the blood of a subject, characterized in that the sensor comprises:

- means for emitting radiation at a minimum of two different wavelengths,

- means for receiving said radiation at each of said wavelengths and producing at least two electrical output signals,

- storage means including reference data indicating nominal characteristics describing calibration conditions of the pulse oximeter, said data allowing an apparatus connected to the sensor to determine tissue-induced changes in the nominal characteristics when radiation is emitted through said tissue.

26. A sensor according to claim **25**, wherein the means for emitting radiation are Light Emitting Diodes.

27. A sensor according to claim **25**, wherein the means for emitting radiation are lasers.

28. A sensor according to claim **25**, wherein the means for emitting radiation include radiation conduction means for conducting radiation from the emitting component to the tissue site, at which the measurement is performed.

29. A sensor according to claim **25,** wherein the means for receiving radiation include radiation conduction means for conducting radiation from the tissue site to the detector component.

30. A sensor according to claim **25,** wherein the reference data includes the Functional Light Transmission (FLT) of the apparatus.

31. A sensor according to claim **25,** wherein the reference data includes function F_{kl} of the apparatus in nominal conditions,

wherein the function F_{kl} corresponds to the ratio $\frac{f_a(\mu_a^k - \mu_v^k) + \mu_v^k}{f_a(\mu_a^l - \mu_v^l) + \mu_v^l}$,

where μ_v and μ_a are the absorption coefficients of venous and arterial blood, respectively, as determined in the Lambert-Beer domain, f_a is the volume fraction of arterial blood, and the superscripts *k* and *l* indicate the wavelength.

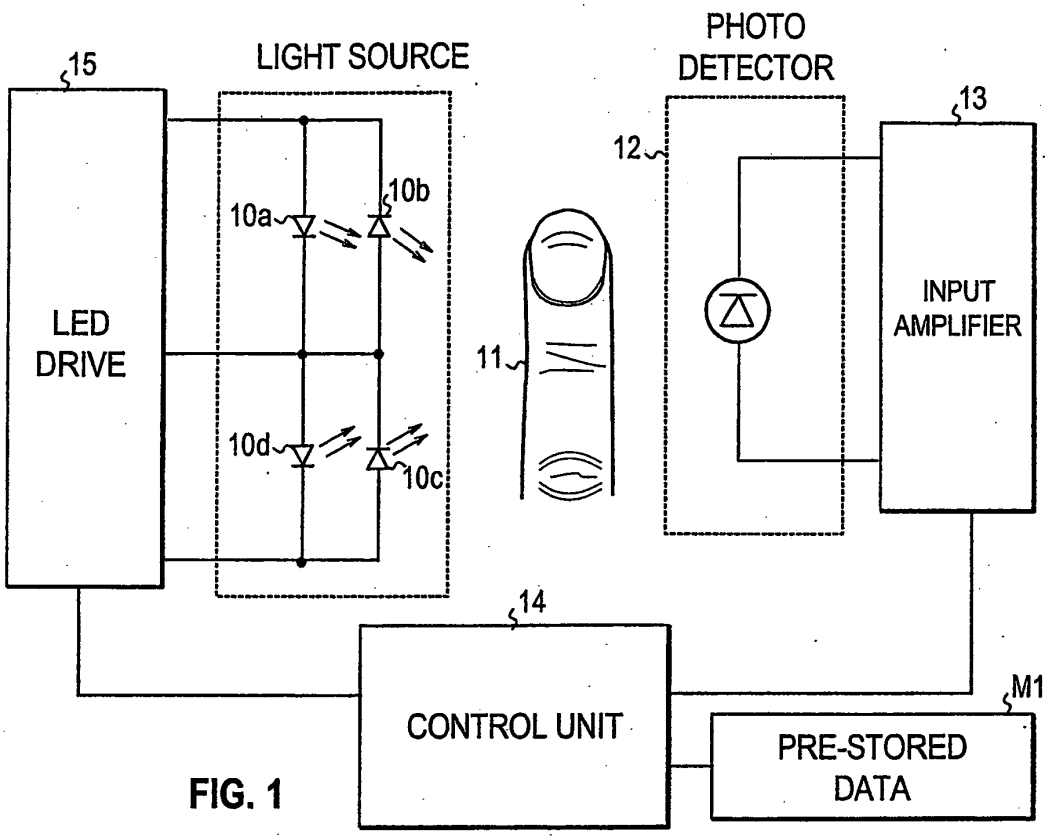


FIG. 1

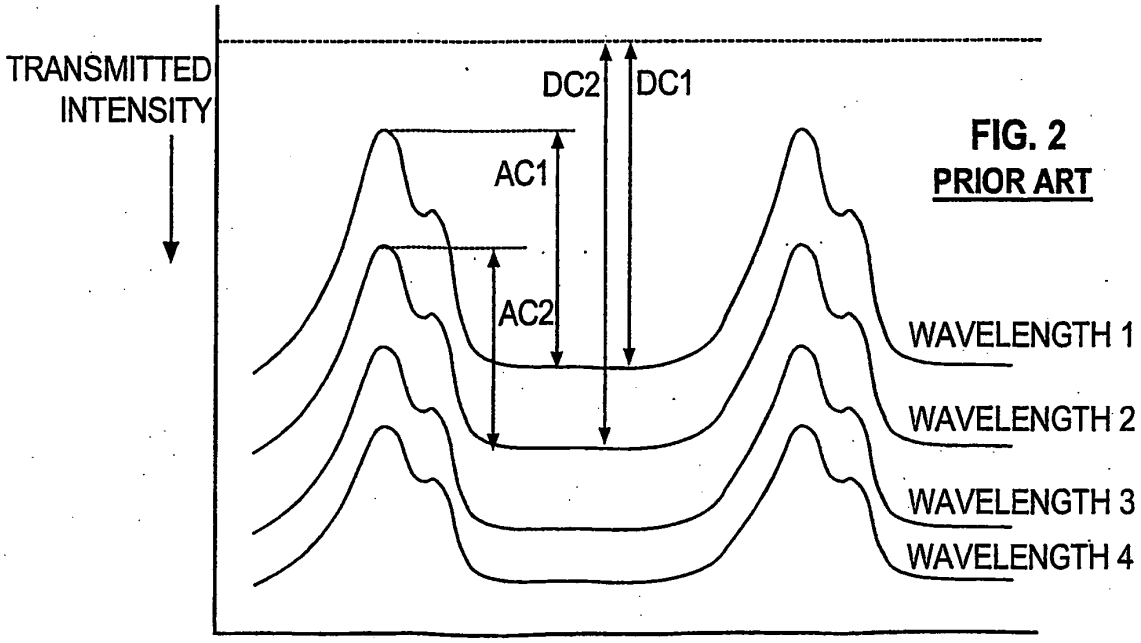


FIG. 2
PRIOR ART

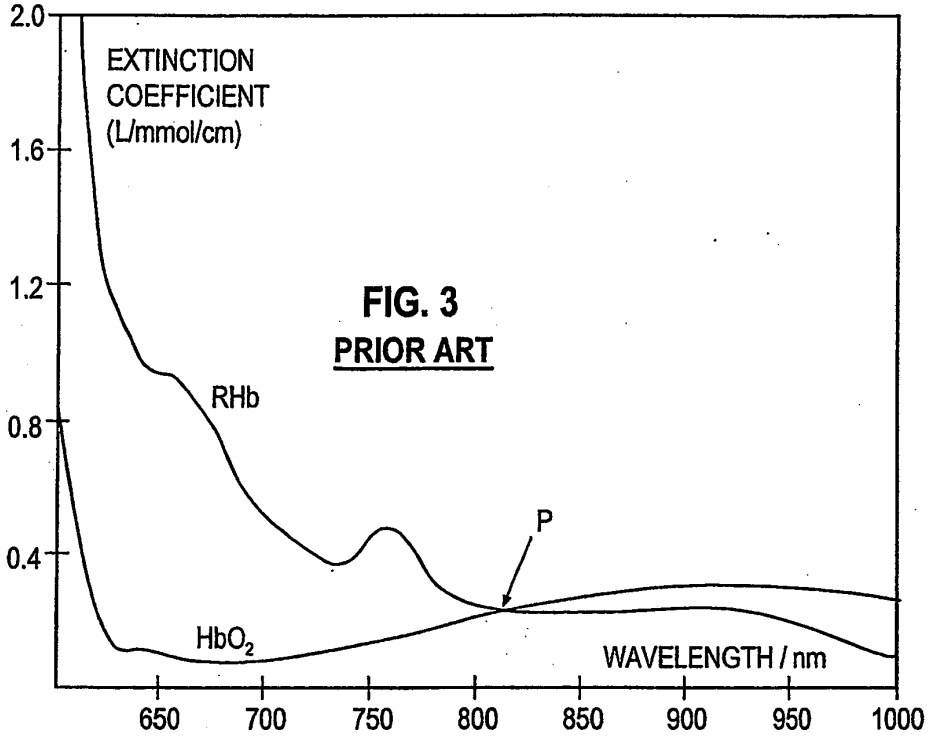


FIG. 3
PRIOR ART

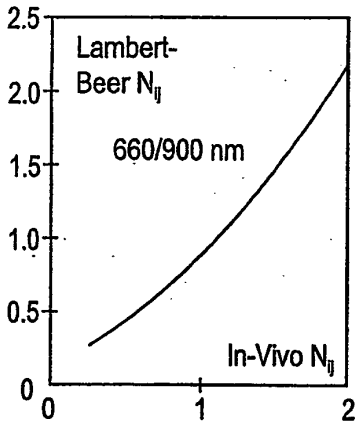


FIG. 4a PRIOR ART

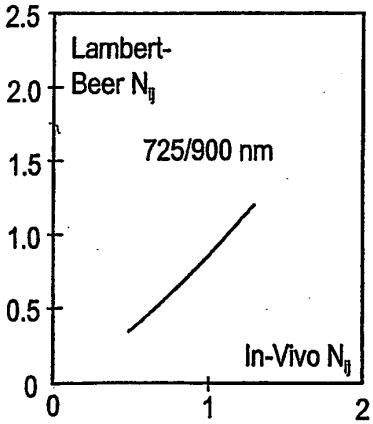


FIG. 4b PRIOR ART

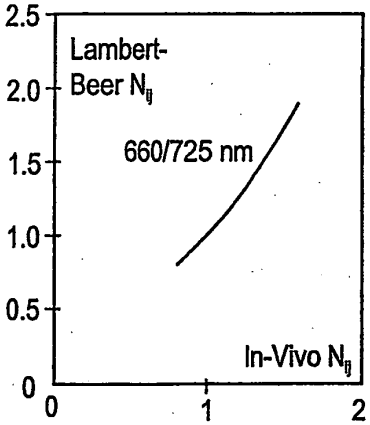


FIG. 4c PRIOR ART

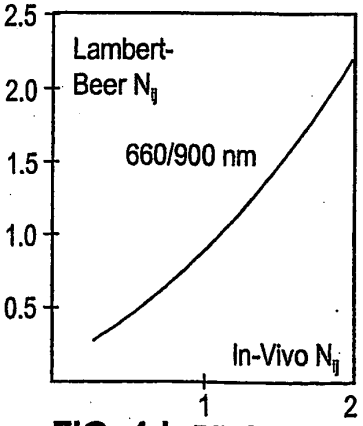


FIG. 4d PRIOR ART

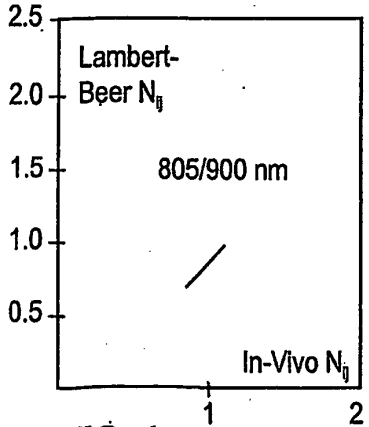


FIG. 4e PRIOR ART

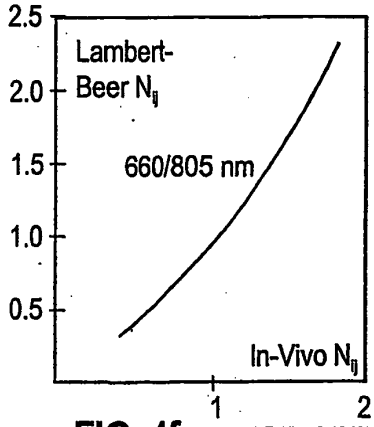


FIG. 4f PRIOR ART

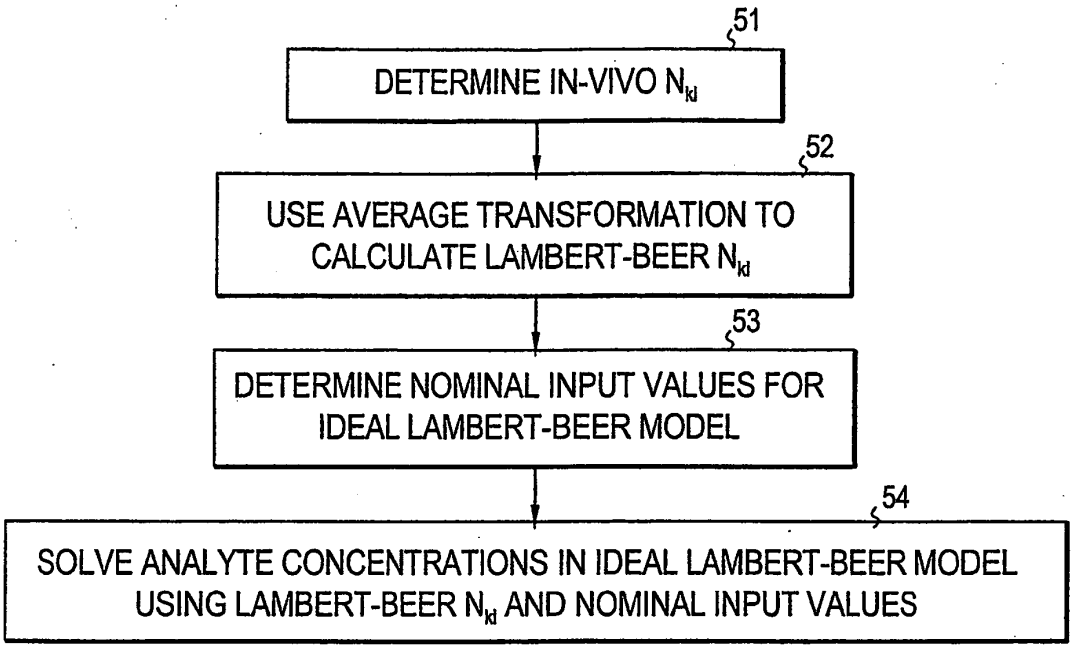


FIG. 5 PRIOR ART

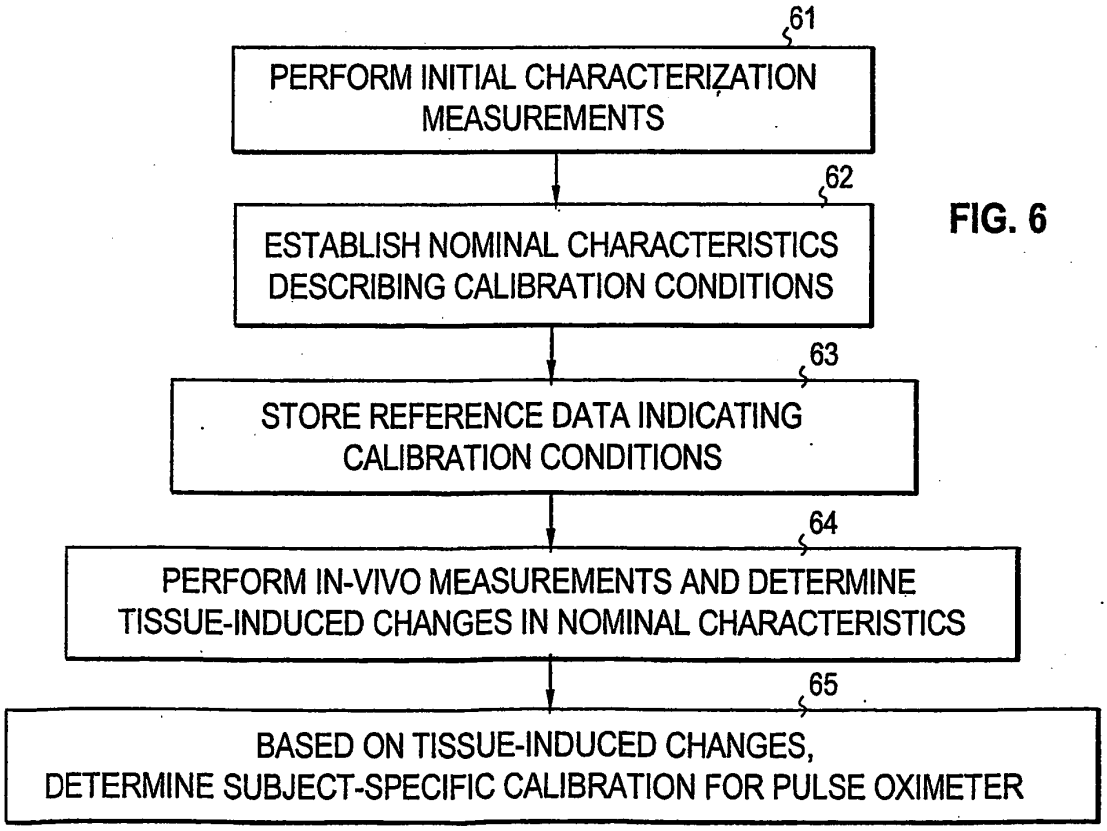


FIG. 6

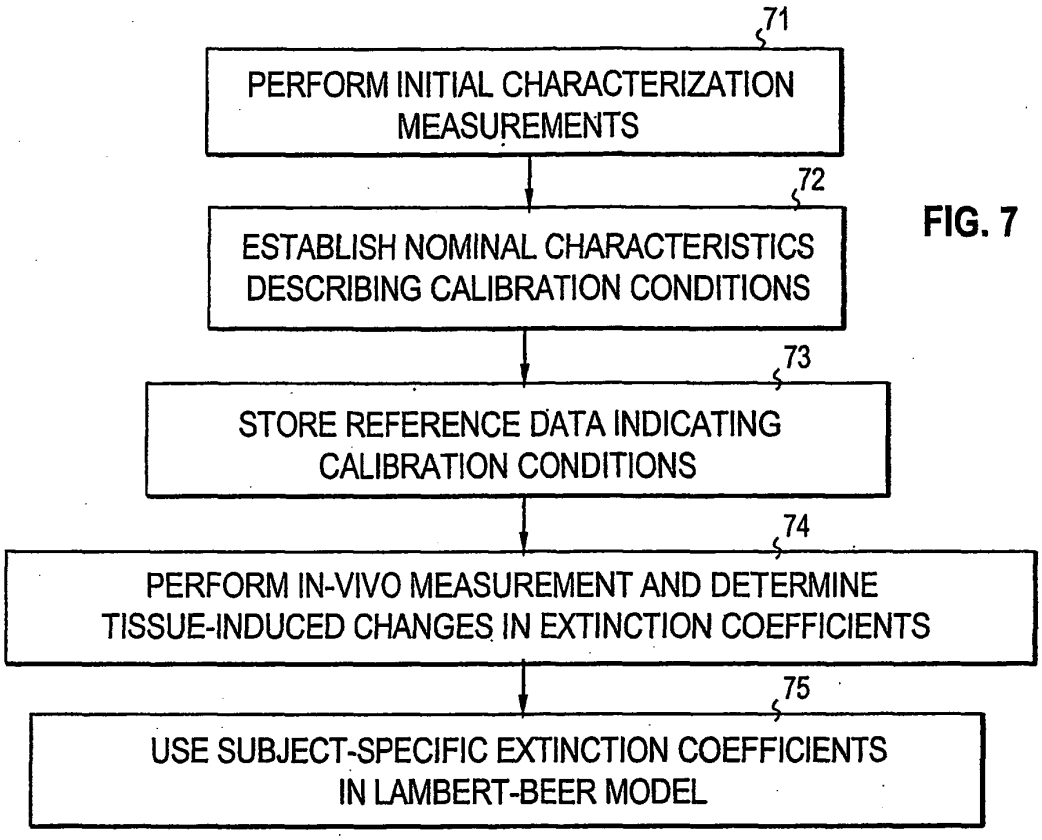

71
PERFORM INITIAL CHARACTERIZATION MEASUREMENTS
72
ESTABLISH NOMINAL CHARACTERISTICS DESCRIBING CALIBRATION CONDITIONS
73
STORE REFERENCE DATA INDICATING CALIBRATION CONDITIONS
74
PERFORM IN-VIVO MEASUREMENT AND DETERMINE TISSUE-INDUCED CHANGES IN EXTINCTION COEFFICIENTS
75
USE SUBJECT-SPECIFIC EXTINCTION COEFFICIENTS IN LAMBERT-BEER MODEL

FIG. 7

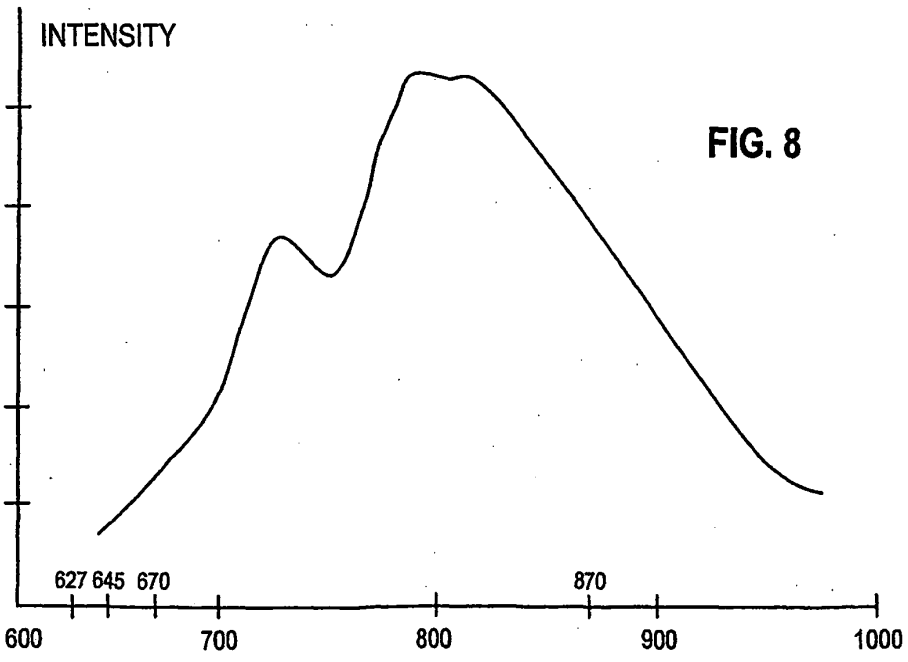

INTENSITY
627 645 670
870
600
700
800
900
1000

FIG. 8

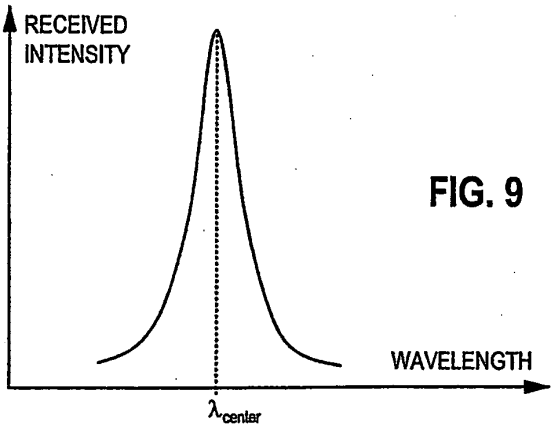

RECEIVED
INTENSITY
WAVELENGTH
λ_{center}

FIG. 9

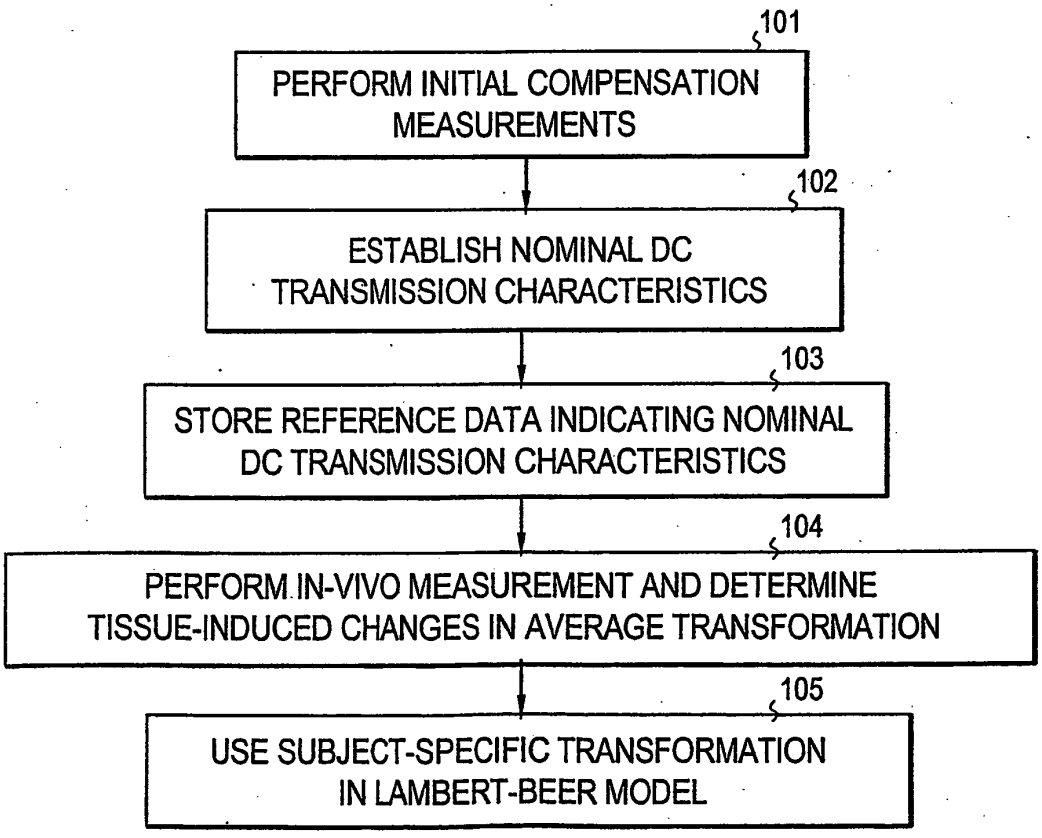

101
PERFORM INITIAL COMPENSATION MEASUREMENTS
102
ESTABLISH NOMINAL DC TRANSMISSION CHARACTERISTICS
103
STORE REFERENCE DATA INDICATING NOMINAL DC TRANSMISSION CHARACTERISTICS
104
PERFORM IN-VIVO MEASUREMENT AND DETERMINE TISSUE-INDUCED CHANGES IN AVERAGE TRANSFORMATION
105
USE SUBJECT-SPECIFIC TRANSFORMATION IN LAMBERT-BEER MODEL

FIG. 10

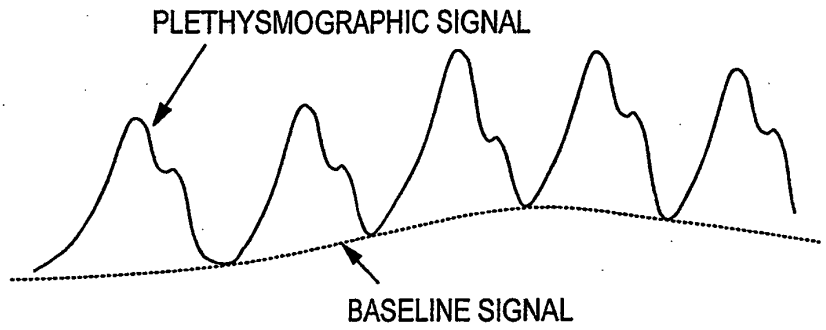

PLETHYSMOGRAPHIC SIGNAL
BASELINE SIGNAL

FIG. 11

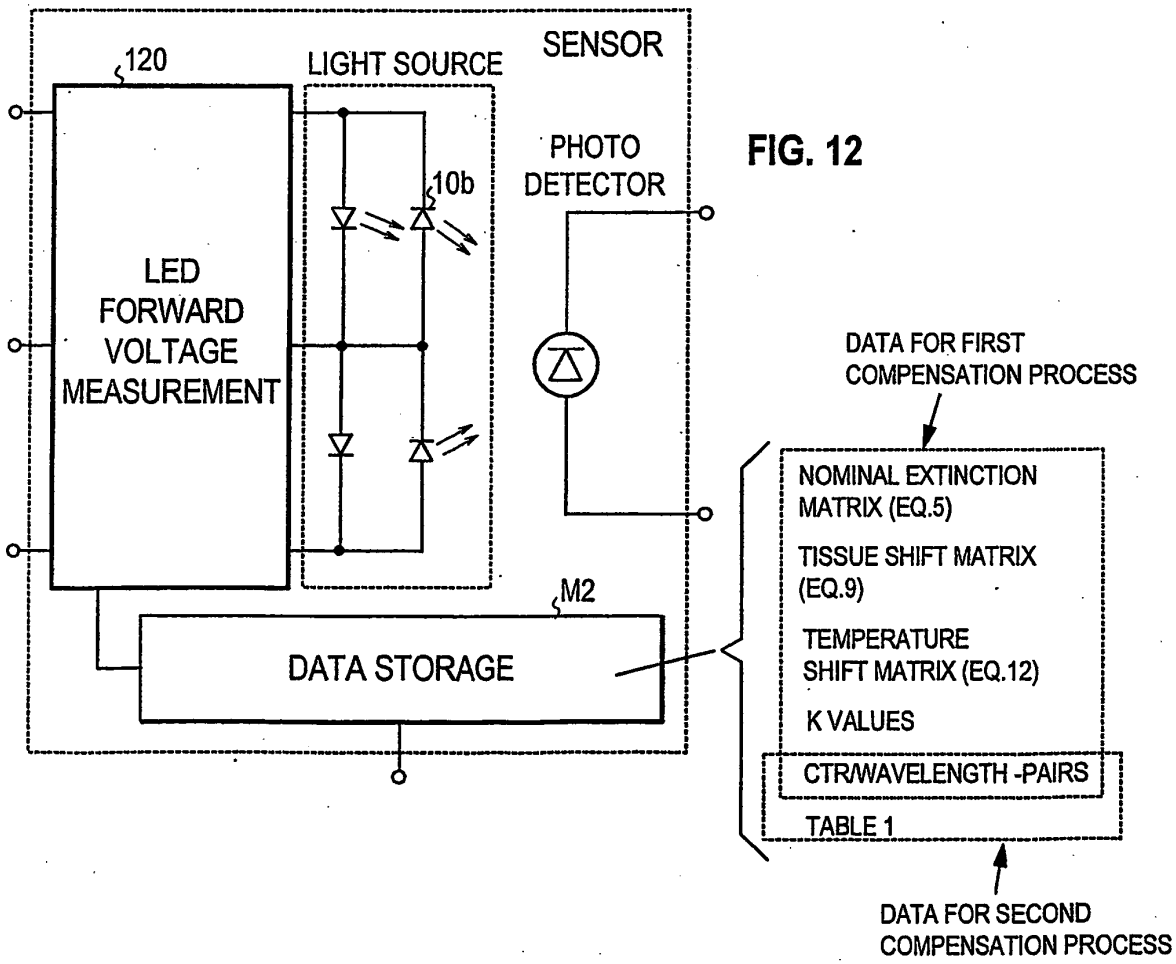

SENSOR
120
LIGHT SOURCE
10b
PHOTO DETECTOR
LED FORWARD VOLTAGE MEASUREMENT
M2
DATA STORAGE
DATA FOR FIRST COMPENSATION PROCESS
NOMINAL EXTINCTION MATRIX (EQ.5)
TISSUE SHIFT MATRIX (EQ.9)
TEMPERATURE SHIFT MATRIX (EQ.12)
K VALUES
CTR/WAVELENGTH -PAIRS
TABLE 1
DATA FOR SECOND COMPENSATION PROCESS

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 03/00089

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, G01J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	US 6501974 B2 (HUIKU, M.), 31 December 2002 (31.12.02), the whole document	1-31
	--	
A	WO 0178593 A1 (NELLCOR PURITAN BENNETT INCORPORATED), 25 October 2001 (25.10.01), summary of invention	1-31
	--	
A	US 6216021 B1 (FRANCESCHINI, M.A. ET AL), 10 April 2001 (10.04.01), summary of invention	1-31
	--	
A	US 6151107 A (SCHÖLLERMANN, H. ET AL), 21 November 2000 (21.11.00), summary of invention	1-31
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 May 2003	15-05-2003
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Pär Moritz /OGU Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 03/00089

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0800066 A2 (THE PERKIN-ELMER CORPORATION), 8 October 1997 (08.10.97), abstract ---	1-3,24-27
A	EP 0748609 A1 (OHMEDA INC.), 18 December 1996 (18.12.96), figures 2,3, abstract --- --------	1-31

Form PCT/ISA/210 (continuation of second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

29/04/03

International application No.
PCT/FI 03/00089

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6501974 B2	31/12/02	US 2002133068 A	19/09/02
		WO 02056759 A	25/07/02
WO 0178593 A1	25/10/01	AU 5165401 A	30/10/01
		EP 1274343 A	15/01/03
		US 2002035318 A	21/03/02
US 6216021 B1	10/04/01	NONE	
US 6151107 A	21/11/00	DE 59707228 D	00/00/00
		EP 0914601 A,B	12/05/99
		ES 2173457 T	16/10/02
		JP 2000515972 T	28/11/00
		WO 9804903 A	05/02/98
EP 0800066 A2	08/10/97	CA 2087360 A	13/08/93
		DE 69315607 D,T	30/04/98
		EP 0560006 A,B	15/09/93
		JP 6082307 A	22/03/94
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		KR 264163 B	16/08/00
		KR 273009 B	15/11/00
		US 5303165 A	12/04/94
EP 0748609 A1	18/12/96	US 5685301 A	11/11/97

IFW

Docket No.: ' MLR.012A

June 21, 2006
Page 1 of 1

Please Direct All Correspondence to Customer Number **20995**



TRANSMITTAL LETTER

INFORMATION DISCLOSURE STATEMENT

Applicant	:	Ammar Al-Ali, et al.
App. No	:	11/367,033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Unknown
Art Unit	:	Unknown

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June 21, 2006
(Date)

Jarom D. Kesler, Reg. No. 57,046

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

(X) Two Information Disclosure Statements and PTO/SB/08 Equivalents listing references for consideration:

- (X) Listing 313 references; and
- (X) Listing 149 references.

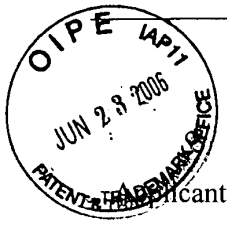
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(X) Return prepaid postcard.

Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20,995
(949) 760-0404

2697809
062006

Docket No.: MLR.012A **Customer No. 20,995**



INFORMATION DISCLOSURE STATEMENT

Applicant	:	Ammar Al-Ali, et al.
App. No	:	11/367,033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Unknown
Art Unit	:	Unknown

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June 21, 2006
(Date)

Jarom D. Kesler, Reg. No. 57,046

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are two PTO/SB/08 Equivalents listing 313 references and 149 references to be considered by the Examiner. Also enclosed are 0 foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 6/21/06

By:
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20,995
(949) 760-0404

2697781
062006

OIPE IAP11 JUN 23 2006 PATENT & TRADEMARK OFFICE

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 1 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	7,006,856	02-28-2006	Baker, Jr. et al.	
	2	7,001,337	02-21-2006	Dekker	
	3	6,987,994	01-17-2006	Mortz	
	4	6,975,891	12-13-2005	Pawluczyk	
	5	6,944,487	09-13-2005	Maynard, et al.	
	6	6,931,269	08-16-2005	Terry	
	7	6,928,311	08-09-2005	Pawluczyk et al.	
	8	6,922,645	07-26-2005	Haaland et al.	
	9	6,921,367	07-26-2005	Mills	
	10	6,919,566	07-19-2005	Cadell	
	11	6,917,422	07-12-2005	Samsoondar et al.	
	12	6,912,049	06-28-2005	Pawluczyk et al.	
	13	6,882,874	04-19-2005	Huiku	
	14	6,869,402	03-22-2005	Arnold	
	15	6,847,835	01-25-2005	Yamanishi	
	16	6,845,256	01-18-2005	Chin et al.	
	17	6,842,702	01-11-2005	Haaland et al.	
	18	6,839,582	01-04-2005	Heckel	
	19	6,839,580	01-04-2005	Zonios, et al.	
	20	6,839,579	01-04-2005	Chin	
	21	6,836,679	12-28-2004	Baker JR. et al.	
	22	6,829,496	12-07-2004	Nagai, et al.	
	23	6,825,619	11-30-2004	Norris	
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	25	6,810,277	10-26-2004	Edgar, Jr, et al.	
	26	6,801,799	10-05-2004	Mendelson	

Examiner Signature	Date Considered

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 2 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	27	6,801,797	10-05-2004	Mannheimer et al.	
	28	6,788,849	09-07-2004	Pawluczyk	
	29	6,780,158	08-24-2004	Yarita	
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	31	6,778,923	08-17-2004	Norris et al.	
	32	6,773,397	08-10-2004	Kelly	
	33	6,760,609	07-06-2004	Jacques	
	34	6,754,516	06-22-2004	Mannheimer	
	35	6,754,515	06-22-2004	Pologe	
	36	6,748,254	06-08-2004	O'Neil et al.	
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	38	6,745,061	06-01-2004	Hicks et al.	
	39	6,741,876	05-25-2004	Scecina et al.	
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	41	6,726,634	04-27-2004	Freeman	
	42	6,725,074	04-20-2004	Kastle	
	43	6,721,584	04-13-2004	Baker JR. et al.	
	44	6,720,734	04-13-2004	Norris	
	45	6,719,705	04-13-2004	Mills	
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	51	6,697,655	02-24-2004	Sueppel, et al.	
	52	6,694,157	02-17-2004	Stone et al.	

Examiner Signature	Date Considered
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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 3 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	53	6,687,620	02-03-2004	Haaland et al.	
	54	6,681,126	01-20-2004	Solenberger	
	55	6,675,106	01-06-2004	Keenan et al.	
	56	6,675,031	01-06-2004	Porges, et al.	
	57	6,671,526	12-30-2003	Aoyagi et al.	
	58	6,668,183	12-23-2003	Hicks et al.	
	59	6,665,551	12-16-2003	Suzuki	
	60	6,662,033	12-09-2003	Casciani et al.	
	61	6,658,277	12-02-2003	Wasserman	
	62	6,657,717	12-02-2003	Cadell et al.	
	63	6,654,623	11-25-2003	Kastle	
	64	6,631,281	10-07-2003	Kastle	
	65	6,628,975	09-30-2003	Fein et al.	
	66	6,622,095	09-16-2003	Kobayashi et al.	
	67	6,618,602	09-09-2003	Levin	
	68	6,615,151	09-02-2003	Scecina et al.	
	69	6,615,064	09-02-2003	Aldrich	
	70	6,614,521	09-02-2003	Samsoondar et al.	
	71	6,606,510	08-12-2003	Swedlow, et al.	
	72	6,606,509	08-12-2003	Schmitt	
	73	6,600,940	07-29-2003	Fein, et al.	
	74	6,594,511	07-15-2003	Stone et al.	
	75	6,591,123	07-08-2003	Fein et al.	
	76	6,584,413	06-24-2003	Keenan et al.	
	77	6,582,964	06-24-2003	Samsoondar et al.	
	78	6,571,113	05-27-2003	Fein, et al.	
	79	6,564,077	05-13-2003	Mortara	

Examiner Signature	Date Considered
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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 4 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	80	6,553,241	04-22-2003	Mannheimer, et al.	
	81	6,546,267	04-08-2003	Sugiura	
	82	6,537,225	03-25-2003	Mills	
	83	6,528,809	03-04-2003	Thomas et al.	
	84	6,526,301	02-25-2003	Larsen et al.	
	85	6,522,398	02-18-2003	Cadell et al.	
	86	6,519,486	02-11-2003	Edgar, Jr., et al.	
	87	6,510,329	01-21-2003	Heckel	
	88	6,505,133	01-07-2003	Hanna	
	89	6,505,061	01-07-2003	Larson	
	90	6,505,060	01-07-2003	Norris	
	91	6,504,943	01-07-2003	Sweatt et al.	
	92	6,501,974	12-31-2002	Huiku	
	93	6,497,659	12-24-2002	Rafert	
	94	6,490,466	12-03-2002	Fein et al.	
	95	6,480,729	11-12-2002	Stone	
	96	6,463,310	10-08-2002	Swedlow et al.	
	97	6,453,184	09-17-2002	Hyogo et al.	
	98	6,441,388	08-27-2002	Thomas et al.	
	99	6,434,408	08-13-2002	Heckel	
	100	6,415,236	07-02-2002	Kobayashi et al.	
	101	6,415,233	07-02-2002	Haaland	
	102	6,415,166	07-02-2002	Van Hoy et al.	
	103	6,411,833	06-25-2002	Baker, Jr. et al.	
	104	6,408,198	06-18-2002	Hanna et al.	
	105	6,397,093	05-28-2002	Aldrich	

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	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
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SHEET 5 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
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	106	6,397,092	05-28-2002	Norris et al.	
	107	6,393,310	05-21-2002	Kuenstner	
	108	6,377,828	04-23-2002	Chaiken, et al.	
	109	6,374,129	04-16-2002	Chin, et al.	
	110	6,363,269	03-26-2002	Hanna et al.	
	111	6,356,774	01-12-2002	Bernstein et al.	
	112	6,351,658	02-26-2002	Middleman et al.	
	113	6,341,257	01-22-2002	Haaland	
	114	6,330,468	12-11-2001	Scharf	
	115	6,304,767	10-16-2001	Soller et al.	
	116	6,304,675	10-16-2001	Osbourn et al.	
	117	6,298,252	10-02-2001	Kovach et al.	
	118	6,272,363	08-07-2001	Casciani et al.	
	119	6,230,035	05-08-2001	Aoyagi et al.	
	120	6,226,539	05-01-2001	Potratz	
	121	6,157,041	12-05-2000	Thomas et al.	
	122	6,154,667	11-28-2000	Miura et al.	
	123	6,151,518	11-21-2000	Hayashi	
	124	6,112,107	08-29-2000	Hannula	
	125	6,104,938	08-15-2000	Huiku	
	126	6,094,592	07-25-2000	Yorkey et al.	
	127	6,083,172	07-04-2000	Baker JR. et al.	
	128	6,073,037	06-06-2000	Alam et al.	
	129	6,068,594	05-30-2000	Schloemer et al.	
	130	6,064,898	05-16-2000	Aldrich	
	131	6,023,541	02-08-2000	Merchant et al.	

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	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
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U.S. PATENT DOCUMENTS					
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	132	6,018,674	01-25-2000	Aronow	
	133	6,018,673	01-25-2000	Chin et al.	
	134	6,014,576	01-11-2000	Raley	
	135	6,006,119	12-21-1999	Soller et al.	
	136	5,999,841	12-07-1999	Aoyagi et al.	
	137	5,995,859	11-30-1999	Takahashi	
	138	5,995,856	11-30-1999	Mannheimer et al.	
	139	5,983,122	11-09-1999	Jarman et al.	
	140	5,978,691	11-02-1999	Mills	
	141	5,954,644	09-21-1999	Dettling	
	142	5,934,277	08-10-1999	Mortz	
	143	5,921,921	07-13-1999	Potratz et al.	
	144	5,919,133	07-06-1999	Taylor	
	145	5,916,154	06-29-1999	Hobbs et al.	
	146	5,910,108	06-08-1999	Solenberger	
	147	5,891,024	04-06-1999	Jarman et al.	
	148	5,885,213	03-23-1999	Richardson et al.	
	149	5,876,348	03-02-1999	Sugo	
	150	5,865,736	02-02-1999	Baker JR. et al.	
	151	5,857,462	01-12-1999	Thomas et al.	
	152	5,853,364	12-29-1998	Baker, Jr., et al.	
	153	5,851,179	12-22-1998	Ritson et al.	
	154	5,851,178	12-22-1998	Aronow	
	155	5,842,979	12-01-1998	Jarman	
	156	5,839,439	11-24-1998	Nierlich et al.	
	157	5,830,137	11-03-1998	Sharf	

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	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
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U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	158	5,827,182	10-27-1998	Raley	
	159	5,823,952	10-20-1998	Levinson et al.	
	160	5,818,985	10-06-1998	Merchant et al.	
	161	5,817,010	10-06-1998	Hibl	
	162	5,810,724	09-22-1998	Gronvall	
	163	5,810,723	09-22-1998	Aldrich	
	164	5,807,247	09-15-1998	Merchant et al.	
	165	5,807,246	09-15-1998	Sakaguchi et al.	
	166	5,803,910	09-08-1998	Potratz	
	167	5,800,349	09-01-1998	Isaacson et al.	
	168	5,793,485	08-11-1998	Gourley	
	169	5,792,052	08-11-1998	Isaacson et al.	
	170	5,790,729	08-04-1998	Pologe et al.	
	171	5,782,756	07-21-1998	Mannheimer	
	172	5,782,237	07-21-1998	Casciani et al.	
	173	5,779,630	07-14-1998	Fein et al.	
	174	5,772,587	06-30-1998	Gratton, et. al	
	175	5,755,226	05-26-1998	Carim et al.	
	176	5,752,914	05-19-1998	Delonzor et al.	
	177	5,746,697	05-05-1998	Swedlow et al.	
	178	5,746,206	05-05-1998	Mannheimer	
	179	5,743,263	04-28-1998	Baker, Jr.	
	180	5,713,355	02-03-1998	Richardson et al.	
	181	5,697,371	12-16-1997	Aoyagi	
	182	5,692,503	12-02-1997	Kuenstner	
	183	5,690,104	11-25-1997	Kanemoto, et al.	
	184	5,687,722	11-18-1997	Tien et al.	

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	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 8 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	185	5,687,719	11-18-1997	Sato, et al.	
	186	5,685,301	11-11-1997	Klomhaus	
	187	5,678,544	10-21-1997	Delonzor et al.	
	188	5,676,141	10-14-1997	Hollub	
	189	5,676,139	10-14-1997	Goldberger et al.	
	190	5,662,106	09-02-1997	Swedlow et al.	
	191	5,660,567	08-26-1997	Nierlich et al.	
	192	5,645,060	07-08-1997	Yorkey	
	193	5,630,413	05-20-1997	Thomas et al.	
	194	5,603,623	02-18-1997	Nishikawa et al.	
	195	5,596,992	01-28-1997	Haaland et al.	
	196	5,595,176	01-21-1997	Yamaura	
	197	5,590,652	01-07-1997	Inai	
	198	5,588,427	12-31-1996	Tien	
	199	5,584,299	12-17-1996	Sakai et al.	
	200	5,577,500	11-26-1996	Potratz	
	201	5,555,882	09-17-1996	Richardson et al.	
	202	5,553,615	09-10-1996	Carim, et al.	
	203	5,551,423	09-03-1996	Sugiura	
	204	5,533,507	07-09-1996	Potratz	
	205	5,520,177	05-28-1996	Ogawa	
	206	5,503,148	04-02-1996	Pologe et al.	
	207	5,494,032	02-27-1996	Robinson et al.	
	208	5,490,523	02-13-1996	Isaacson et al.	
	209	5,435,309	07-25-1995	Thomas et al.	
	210	5,429,128	07-04-1995	Cadell et al.	
	211	5,427,093	06-27-1995	Ogawa et al.	

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	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 9 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	212	5,421,329	06-06-1995	Casciani et al.	
	213	5,413,101	05-09-1995	Sugiura	
	214	5,392,777	02-28-1995	Swedlow et al.	
	215	5,387,122	02-07-1995	Goldberger et al.	
	216	5,385,143	01-31-1995	Aoyagi	
	217	5,368,224	11-29-1994	Richardson et al.	
	218	5,361,758	11-08-1994	Hall et al.	
	219	5,355,882	10-18-1994	Ukawa et al.	
	220	5,355,880	10-18-1994	Thomas et al.	
	221	5,351,685	10-04-1994	Potratz	
	222	5,348,004	09-20-1994	Hollub	
	223	5,335,659	08-09-1994	Pologe et al.	
	224	5,313,940	5-24-1994	Fuse et al.	
	225	5,297,548	03-29-1994	Pologe	
	226	5,278,627	01-11-1994	Aoyagi	
	227	5,267,563	12-07-1993	Swedlow et al.	
	228	5,267,562	12-07-1993	Ukawa et al.	
	229	5,209,230	05-11-1993	Swedlow et al.	
	230	5,190,040	03-02-1993	Aoyagi	
	231	5,078,136	01-07-1992	Stone et al.	
	232	5,054,495	10-08-1991	Uemura, et al.	
	233	5,033,472	07-23-1991	Sato, et al.	
	234	4,997,769	03-05-1991	Lundsgaard	
	235	4,975,581	12-04-1990	Robinson et al.	
	236	4,967,571	11-06-1990	Sporri	
	237	4,964,010	10-16-1990	Miyasaka et al.	

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	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 10 OF 13	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
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	238	4,960,126	10-02-1990	Conlon et al.	
	239	4,955,379	09-11-1990	Hall	
	240	4,942,877	07-24-1990	Sakai et al.	
	241	4,934,372	06-19-1990	Corenman et al.	
	242	4,911,167	03-27-1990	Corenman et al.	
	243	4,869,254	09-26-1989	Stone et al.	
	244	4,867,571	09-19-1989	Frick et al.	
	245	4,863,265	09-05-1989	Flower, et al.	
	246	4,846,183	07-11-1989	Martin	
	247	4,832,484	05-23-1989	Aoyagi, et al.	
	248	4,800,885	01-31-1989	Johnson	
	249	4,781,195	11-01-1988	Martin	
	250	4,773,422	09-27-1988	Isaacson et al.	
	251	4,770,179	09-13-1988	New et al.	
	252	4,714,341	12-22-1987	Hamaguri et al.	
	253	4,700,708	10-20-1987	New et al.	
	254	4,694,833	09-22-1987	Hamaguri	
	255	4,685,464	08-11-1987	Goldberger	
	256	4,653,498	03-31-1987	New et al.	
	257	4,621,643	11-11-1986	New et al.	
	258	4,586,513	05-06-1986	Hamaguri	
	259	4,446,871	05-08-1984	Imura	
	260	4,266,554	05-12-1981	Hamaguri	
	261	4,167,331	09-11-1979	Nielsen	
	262	4,157,708	06-12-1979	Imura	
	263	3,998,550	12-21-1976	Konishi, et al.	

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	Art Unit	Unknown
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SHEET 11 OF 13	Attorney Docket No.	MLR.012A

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	264	RE35,122	12-19-1995	Corenman et al.	
	265	2004/0006261	01-08-2004	Swedlow et al.	
	266	2006/0030764	02-09-2006	Porges et al.	
	267	2004/0033618	02-19-2004	Haass, et al.	
	268	2002/0038078	03-28-2002	Ito	
	269	2005/0043902	02-24-2005	Haaland et al.	
	270	2005/0049469	03-03-2005	Aoyagi et al.	
	271	2002/0059047	05-16-2002	Haaland	
	272	2004/0064259	04-01-2004	Haaland et al.	
	273	2005/0070773	03-31-2005	Chin et al.	
	274	2005/0070775	03-31-2005	Chin et al.	
	275	2005/0075546	04-07-2005	Samsoondar et al.	
	276	2005/0085735	04/21-2005	Baker JR. et al.	
	277	2004/0092805	05-13-2004	Yarita	
	278	2003/0109775	06-12-2003	O'Neil, et al.	
	279	2002/0111748	08-15-2002	Kobayashi et al.	
	280	2003/0120160	06-26-2003	Yarita	
	281	2005/0124871	06/09-2005	Baker JR. et al.	
	282	2004/0138538	07-15-2004	Stetson	
	283	2004/0138540	07-15-2004	Baker JR. et al.	
	284	2003/0139657	07-24-2003	Solenberger	
	285	2005/143634	06-30-2005	Baker JR. et al.	
	286	2005/0143943	06-30-2005	Brown	
	287	2005/0148834	07-07-2005	Hull, et al.	
	288	2004/0158135	08-12-2004	Baker JR. et al.	
	289	2004/0162472	08-19-2004	Berson et al.	
	290	2004/0167382	08-26-2004	Gardner, et al.	

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	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
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U.S. PATENT DOCUMENTS

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	291	2004/0167382	08-26-2004	Gardner et al.	
	292	2004/0176670	09-09-2004	Takamura et al.	
	293	2004/0181134	09-16-2004	Baker JR. et al.	
	294	2005/0184895	08-25-2005	Petersen et al.	
	295	2005/0187447	08-25-2005	Chew et al.	
	296	2005/0187448	08-25-2005	Petersen et al.	
	297	2005/0187449	08-25-2005	Chew et al.	
	298	2005/0187450	08-25-2005	Chew et al.	
	299	2005/0187452	08-25-2005	Petersen et al.	
	300	2005/0187453	08-25-2005	Petersen et al.	
	301	2003/0195402	10-16-2003	Fein et al.	
	302	2005/0197549	09-08-2005	Baker JR.	
	303	2005/0197579	09-08-2005	Baker JR.	
	304	2005/0197793	09-08-2005	Baker JR.	
	305	2004/0199063	10-07-2004	O'Neil et al.	
	306	2005/0203357	09-15-2005	Debreczeny et al.	
	307	2004/0204639	10-14-2004	Casciani et al.	
	308	2004/0204868	10-14-2004	Maynard, et al.	
	309	2005/0228253	10-13-2005	Debreczeny	
	310	2005/0250997	11-10-2005	Takedo et al.	
	311	2004/0267140	12-30-2004	Ito et al.	
	312	RE36,000	12-22-1998	Swedlow et al.	
	313	RE33,643	07-23-1991	Isaacson et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T^1
	314					
	315					

Examiner Signature	Date Considered

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T^1 - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 13 OF 13	Attorney Docket No.	MLR.012A

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	316					
	317					
	318					

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	319		
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	322		
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Examiner Signature	Date Considered

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T[1] - Place a check mark in this area when an English language Translation is attached.

OIPE JUN 23 2006 PATENT & TRADEMARK OFFICE

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 1 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	7,044,918	05/2006	Diab	
	2	7,041,060	05/2006	Flaherty, et al	
	3	7,039,449	05/2006	Al-Ali	
	4	7,030,749	04/2006	Al-Ali	
	5	7,027,849	04/2006	Al-Ali	
	6	7,024,233	04/2006	Al, et al.	
	7	7,015,451	02/2006	Dalke, et al.	
	8	7,003,339	02/2006	Diab, et al.	
	9	7,003,338	02/2006	Weber, et al.	
	10	6,999,904	02/2006	Weber, et al.	
	11	6,996,427	02/2006	Ali, et al.	
	12	6,993,371	01/2006	Kiani, et al.	
	13	6,985,764	01/2006	Mason, et al.	
	14	6,979,812	12/2005	Al-Ali	
	15	6,970,792	11/2005	Diab	
	16	6,961,598	11/2005	Diab	
	17	6,950,687	09/2005	Al-Ali	
	18	6,943,348	09/2005	Coffin, IV	
	19	6,939,305	09/2005	Flaherty, et al.	
	20	6,934,570	08/2005	Kiani, et al.	
	21	6,931,268	08/2005	Kiani-Azarbayjany, et al.	
	22	6,920,345	07/2005	Al-Ali, et al.	
	23	6,898,452	05/2005	Al-Ali, et al.	
	24	6,861,639	03/2005	Al-Ali	
	25	6,852,083	02/2005	Caro, et al.	
	26	6,850,788	02/2005	Al-Ali	
	27	6,850,787	02/2005	Weber, et al.	
	28	6,830,711	12/2004	Mills, et al.	
	29	6,826,419	11/2004	Diab, et al.	

Examiner Signature	Date Considered
***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T[1] - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 2 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	6,822,564	11/2004	Al-Ali	
	31	6,816,741	11/2004	Diab	
	32	6,813,511	11/2004	Diab, et al.	
	33	6,792,300	09/2004	Diab, et al.	
	34	6,771,994	08/2004	Kiani, et al.	
	35	6,770,028	08/2004	Ali, et al.	
	36	6,760,607	07/2004	Al-Ali	
	37	6,745,060	06/2004	Diab, et al.	
	38	6,735,459	05/2004	Parker	
	39	6,725,075	04/2004	Al-Ali	
	40	6,721,585	04/2004	Parker	
	41	RE38,492	04/2004	Diab, et al.	
	42	6,714,804	03/2004	Al-Ali, et al.	
	43	RE38,476	03/2004	Diab, et al.	
	44	6,699,194	03/2004	Diab, et al.	
	45	6,697,658	02/2004	Al-Ali	
	46	6,697,656	02/2004	Al-Ali	
	47	6,684,091	01/2004	Parker	
	48	6,684,090	01/2004	Ali, et al.	
	49	6,678,543	01/2004	Diab, et al.	
	50	6,671,531	12/2003	Al-Ali, et al.	
	51	6,661,161	12/2003	Lanzo, et al.	
	52	6,658,276	12/2003	Diab, et al.	
	53	6,654,624	11/2003	Diab, et al.	
	54	6,650,917	11/2003	Diab, et al.	
	55	6,643,530	11/2003	Diab, et al.	
	56	6,640,116	10/2003	Diab	
	57	6,632,181	10/2003	Flaherty, et al.	
	58	6,606,511	08/2003	Ali, et al.	

Examiner Signature	Date Considered

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 3 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	6,597,933	07/2003	Kiani, et al.	
	60	6,595,316	07/2003	Cybulski, et al.	
	61	6,584,336	06/2003	Ali, et al.	
	62	6,580,086	06/2003	Schulz, et al.	
	63	6,542,764	04/2003	Al-Ali, et al.	
	64	6,541,756	04/2003	Schulz, et al.	
	65	6,526,300	02/2003	Kiani, et al.	
	66	6,525,386	02/2003	Mills, et al.	
	67	6,519,487	02/2003	Parker	
	68	6,515,273	02/2003	Al-Ali	
	69	6,501,975	12/2002	Diab, et al.	
	70	6,470,199	10/2002	Kopotic, et al.	
	71	6,463,311	10/2002	Diab	
	72	6,430,525	08/2002	Weber, et al.	
	73	6,397,091	05/2002	Diab, et al.	
	74	6,388,240	05/2002	Schulz, et al.	
	75	6,377,829	04/2002	Al-Ali	
	76	6,371,921	04/2002	Caro, et al.	
	77	6,360,114	03/2002	Diab, et al.	
	78	6,349,228	02/2002	Kiani, et al.	
	79	6,343,224	01/2002	Parker	
	80	6,334,065	12/2001	Al-Ali, et al.	
	81	6,321,100	11/2001	Parker	
	82	6,285,896	09/2001	Tobler, et al.	
	83	6,280,213	08/2001	Tobler, et al.	
	84	6,278,522	08/2001	Lepper, Jr., et al.	
	85	6,263,222	07/2001	Diab, et al.	
	86	6,256,523	07/2001	Diab, et al.	
	87	6,236,872	05/2001	Diab, et al.	

Examiner Signature	Date Considered
***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 4 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	88	6,229,856	05/2001	Diab, et al.	
	89	6,206,830	03/2001	Diab, et al.	
	90	6,184,521	02/2001	Coffin, IV, et al.	
	91	6,165,005	12/2000	Mills, et al.	
	92	6,157,850	12/2000	Diab, et al.	
	93	6,152,754	11/2000	Gerhardt, et al.	
	94	6,151,516	11/2000	Kiani-Azarbayjany, et al.	
	95	6,144,868	11/2000	Parker	
	96	6,110,522	08/2000	Lepper, Jr., et al.	
	97	6,088,607	07/2000	Diab, et al.	
	98	6,081,735	06/2000	Diab, et al.	
	99	6,067,462	05/2000	Diab, et al.	
	100	6,045,509	04/2000	Caro, et al.	
	101	6,036,642	03/2000	Diab, et al.	
	102	6,027,452	02/2000	Flaherty, et al.	
	103	6,011,986	01/2000	Diab, et al.	
	104	6,002,952	12/1999	Diab, et al.	
	105	5,997,343	12/1999	Mills, et al.	
	106	5,995,855	11/1999	Kiani, et al.	
	107	5,940,182	08/1999	Lepper, Jr., et al.	
	108	5,934,925	08/1999	Tobler, et al.	
	109	5,919,134	07/1999	Diab	
	110	5,904,654	05/1999	Wohltmann, et al.	
	111	5,890,929	04/1999	Mills, et al.	
	112	5,860,919	01/1999	Kiani-Azarbayjany, et al.	
	113	5,833,618	11/1998	Caro, et al.	
	114	5,830,131	11/1998	Caro, et al.	
	115	5,823,950	10/1998	Diab, et al.	
	116	5,810,734	09/1998	Caro, et al.	

Examiner Signature	Date Considered

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 5 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	117	5,791,347	08/1998	Flaherty, et al.	
	118	5,785,659	07/1998	Caro, et al.	
	119	5,782,757	07/1998	Diab, et al.	
	120	5,769,785	06/1998	Diab, et al.	
	121	5,760,910	06/1998	Lepper, Jr., et al.	
	122	5,758,644	06/1998	Diab, et al.	
	123	5,743,262	04/1998	Lepper, Jr., et al.	
	124	Des. 393,830	04/1998	Tobler, et al.	
	125	5,685,299	11/1997	Diab, et al.	
	126	5,645,440	07/1997	Tobler, et al.	
	127	5,638,818	06/1997	Diab, et al.	
	128	5,638,816	06/1997	Kiani-Azarbayjany, et al.	
	129	5,632,272	05/1997	Diab, et al.	
	130	5,602,924	02/1997	Durand, et al.	
	131	5,590,649	01/1997	Caro, et al.	
	132	5,562,002	10/1986	Lalin	
	133	5,533,511	07/1996	Kaspari, et al.	
	134	5,494,043	02/1996	O'Sullivan, et al.	
	135	5,490,505	02/1996	Diab, et al.	
	136	5,482,036	01/1996	Diab, et al.	
	137	D363,120	10/1995	Savage, et al.	
	138	5,452,717	09/1995	Branigan, et al.	
	139	D362,063	09/1995	Savage, et al.	
	140	D361,840	08/1995	Savage, et al.	
	141	5,431,170	07/1995	Mathews	
	142	D353,196	12/1994	Savage, et al.	
	143	D353,195	12/1994	Savage, et al.	
	144	5,337,744	08/1994	Branigan	
	145	5,163,438	11/1992	Gordon, et al.	

Examiner Signature	Date Considered

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	11/367,033
	Filing Date	March 1, 2006
	First Named Inventor	Ammar Al-Ali et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 6 OF 6	Attorney Docket No.	MLR.012A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	146	5,069,213	12/1991	Polczynski	
	147	5,041,187	08/1991	Hink, et al.	
	148	4,964,408	10/1990	Hink, et al.	
	149	4,960,128	10/1990	Gordon, et al.	

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Examiner Signature	Date Considered

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T[1] - Place a check mark in this area when an English language Translation is attached.

OIPE IAP64 JUN 15 2006 PATENT & TRADEMARK OFFICE

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/367,033	03/01/2006	Ammar Al-Ali	MLR.012A

CONFIRMATION NO. 3334

20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

06/16/2006 CCHAU1 00000019 11367033

01 FC:1011	300.00 OP
02 FC:1111	500.00 OP
03 FC:1311	200.00 OP
04 FC:1051	130.00 OP
05 FC:1201	200.00 OP
06 FC:1202	2150.00 OP

FORMALITIES LETTER

Date Mailed: 03/28/2006

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  Applicant must submit $ **300** *to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).*
- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **$2350** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$3480** for a Large Entity

- **$300** Statutory basic filing fee.
- **$130** Surcharge.

- The application search fee has not been paid. Applicant must submit **$500** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$200** to complete the examination fee for a large entity

- Total additional claim fee(s) for this application is **$2350**

  - **$200** for **1** independent claims over 3.
  - **$2150** for **43** total claims over 20.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
PART 2 - COPY TO BE RETURNED WITH RESPONSE



PATENT

Case Docket No. MLR.012A
Date: June 12, 2006

TRANSMITTAL LETTER

RESPONSE TO MISSING PARTS

Applicant	:	Ammar Al-Ali et al.
App. No	:	11/367,033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Art Unit	:	Unknown

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

June 12, 2006
(Date)

Jarom D. Kesler, Reg. No. 57,046

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice to File Missing Parts of Application Under 37 CFR 1.53(f), which was mailed by the Office on March 28, 2006, enclosed are:

(X) A Declaration in 3 pages.

(X) Statement Under 37 CFR 3.73(b), Power of Attorney and copy of Assignment.

(X) A Notice to File Missing Parts.

(X) Return prepaid postcard.

06/16/2006 CCHAU1 00000019 11367033
07 FC:1251 120.00 OP

The fee has been calculated as shown below:

FEE CALCULATION				
FEE TYPE		**FEE CODE**	**CALCULATION**	**TOTAL**
Basic Utility	*1.16(a)(1)*	1011 ($300)		$300
Search Fee	*1.16(k)*	1111 ($500)		$500
Examination Fee	*1.16(o)*	1311 ($200)		$200
Excess Claims > 20	63 - 20 = 43	1202 ($50)	43 x 50 =	$2150
Independent > 3	4 - 3 = 1	1201 ($200)	1 x 200 =	$200
Multiple Claim	*1.16(j)*	1203 ($360)		$0
Application Size Fee	58 - 100 = 0	1081 ($250)±	0 x 250 =	$0
Recordation Fee	*1.21(h)*	8021 ($40)	0 x 40 =	$0
Non-English Spec.	*1.17(i)*	1053 ($130)		$0
1 Month Extension	*1.17(a)(1)*	1251 ($120)		$120
Surcharge	*1.16(f)*	1051 ($130)		$130
			TOTAL FEE DUE	$3,480

(X) A check in the amount of $3,600 to cover the above fees is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required, now or in the future, or credit any overpayment, to Account No. 11-1410.

Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20,995
(949) 760-0404

2626779
061206

OIPE IAP84 JUN 15 2006 PATENT & TRADEMARK OFFICE

DECLARATION - USA PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled NONINVASIVE MULTI-PARAMETER PATIENT MONITOR; the specification of which was filed on March 1, 2006 as Application Serial No. 11/367,033.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56;

I hereby claim the benefit under Title 35, United States Codes § 119(e) of any United States provisional application(s) listed below.

Application No.: 60/657,596	Filing Date: March 1, 2005
Application No.: 60/657,281	Filing Date: March 1, 2005
Application No.: 60/657,268	Filing Date: March 1, 2005
Application No.: 60/657,759	Filing Date: March 1, 2005

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Ammar Al-Ali

Inventor's signature _____

Date 5/22/06

Residence: 10880 Phillips Street, Tustin, CA 92782

Citizenship: United States

Mailing Address: Same as above

Full name of second inventor: Joe Kiani

Inventor's signature _____

Date 5/22/06

Residence: 35 Brindisi, Laguna Niguel, CA 92677

Citizenship: United States

Mailing Address: Same as above

Full name of third inventor: Mohamed Diab

Inventor's signature _____

Date 5/22/06

Residence: 25075 White Spring, Mission Viejo, CA 92692

Citizenship: United States

Mailing Address: Same as above

Full name of fourth inventor: Greg Olsen

Inventor's signature _____

Date May 18, 2006

Residence: 96 Smokestone, Irvine, CA 92614

Citizenship: United States

Mailing Address: Same as above

Full name of fifth inventor: Roger Wu

Inventor's signature _____

Date 5.18.06

Residence: 34 Duet, Irvine, CA 92603

Citizenship: United States

Mailing Address: Same as above

Full name of sixth inventor: Rick Fishel

Inventor's signature _____

Date 6/7/2006

Residence: 6315 Cedarbrooks Road, Orange, CA 92867

Citizenship: United States

Mailing Address: Same as above

Send Correspondence To:
KNOBBE, MARTENS, OLSON & BEAR, LLP
Customer No. 20,995

2601802
051506

Docket No.: MLR.012A **Customer No. 20,995**



STATEMENT UNDER 37 CFR § 3.73(b)
and
CHANGE OF CORRESPONDENCE ADDRESS

Applicant	:	Ammar Al-Ali et al.
App. No.	:	11/367,033
Filed	:	March 1, 2006
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Unknown
Group Art Unit	:	Unknown

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This document is being filed with a copy of a "Revocation and General Power of Attorney" signed by the Assignee and sets forth the chain of title of the above-identified application.

Please recognize or change the correspondence address for the above-identified application to **Customer No. 20,995.**

MASIMO LABORATORIES, INC., a Corporation, is the Assignee of the entire right, title, and interest of the above-referenced application by virtue of:

The attached copy of the Assignment being forwarded to the Recordation Branch concurrently under separate cover.

The undersigned is an agent of Customer Number 20995 and is authorized to act on behalf of the assignee as provided in the attached copy of the "Revocation and Power of Attorney." All correspondence is to be directed to **Customer No. 20,995.**

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 6/12/06

By
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20,995
(949) 760-0404

2626867
052406

Docket No.: MLABS..000GEN **Customer No. 20,995**



REVOCATION
AND
GENERAL POWER OF ATTORNEY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned is an empowered representative of the Assignee and hereby appoints the registrants of Knobbe, Martens, Olson & Bear, LLP, **Customer No. 20,995**, as attorneys and agents to represent the Assignee before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned to the Assignee according to the USPTO assignment records or assignment documents supplied with an accompanying Statement Under 37 CFR § 3.73(b). This appointment is to be to the exclusion of the inventor(s) and his attorney(s) in accordance with the provisions of 37 CFR § 3.71.

All previous powers of attorney for the below named Assignee are hereby revoked.

A Statement Under 37 CFR § 3.73(b), signed by a registrant of Knobbe, Martens, Olson & Bear, LLP, is attached setting forth a full chain of title for the subject application owned by the Assignee named below.

Please recognize or change the correspondence address for the above-identified application to **Customer No. 20,995.**

By: _____ Date: 9-8-04

Name: Joe E. Kiani Title: President and CEO

Assignee: MASIMO LABORATORIES, INC.

Address: 40 Parker, Irvine, CA 92618

H:\DOCS\JMG\JMG-6382.DOC
072804

ASSIGNMENT

WHEREAS, We, Ammar Al-Ali, a United States citizen, residing at 10880 Phillips Street, Tustin, CA 92782; Joe E. Kiani, a United States citizen, residing at 35 Brindisi, Laguna Niguel, CA 92667; Mohamed Diab, a United States citizen, 25075 White Spring, Mission Viejo, CA 92692; Greg Olsen, a United States citizen, residing at 96 Smokestone, Irvine, CA 92614; Roger Wu, a United States citizen, residing at 34 Duet, Irvine, CA 92603 and Rick Fishel, a United States citizen, residing at 6315 Cedarbrooks Road, Orange, CA 92867, have invented certain new and useful improvements in a NONINVASIVE MULTI-PARAMETER PATIENT MONITOR for which we have filed an application for Letters Patent in the United States, Application No. 11/367,033, Filed on March 1, 2006;

AND WHEREAS, MASIMO LABORATORIES, INC. (hereinafter "ASSIGNEE"), a Corporation, with its principal place of business at 40 Parker, Irvine, CA 92618, desires to acquire the entire right, title, and interest in and to the said improvements and the said Application:

NOW, THEREFORE, in consideration of the sum of One Dollar ($1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, we, the said inventors, do hereby acknowledge that we have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over, unto the said ASSIGNEE, its successors, legal representatives and assigns, the entire right, title, and interest throughout the world in, to and under the said improvements, and the said application and all provisional applications relating thereto, and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all rights of priority under International Conventions and applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States, and all Letters Patent which may be granted for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and we hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said ASSIGNEE, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND WE DO HEREBY sell, assign, transfer, and convey to ASSIGNEE, his successors, legal representatives, and assigns all claims for damages and all remedies arising out of any violation of the rights assigned hereby that may have accrued prior to the date of assignment to ASSIGNEE, or may accrue hereafter, including, but not limited to, the right to sue for, collect, and retain damages for past infringements of the said Letters Patent before or after issuance.

AND WE HEREBY covenant and agree that we will communicate to the said ASSIGNEE, its successors, legal representatives and assigns, any facts known to us respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths and generally do everything possible to aid the said ASSIGNEE, its successors, legal representatives and assigns, to obtain and enforce proper patent protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 22 day of May, 2006

Ammar Al-Ali

STATE OF Ca.
COUNTY OF Orange } ss.

On 5/22/06, before me, Sasha Z. Paez, personally appeared Ammar Al-Ali personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity(ies), and that by his signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

[SEAL]

SASHA Z. PAEZ
COMM. #1527279
Notary Public-California
ORANGE COUNTY
My Comm. Exp. Nov 16, 2008

Notary Signature

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 22 day of May, 2006

Joe E. Kiani

STATE OF Ca.
COUNTY OF Orange } ss.

On 5/22/06, before me, Sasha Z. Paez, personally appeared Joe E. Kiani personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity(ies), and that by his signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

[SEAL]

SASHA Z. PAEZ
COMM. #1527279
Notary Public-California
ORANGE COUNTY
My Comm. Exp. Nov 16, 2008

Notary Signature

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 22 day of May, 2006

Mohamed Diab

STATE OF Ca
COUNTY OF Orange } ss.

On 5/22/06, before me, Sasha Z. Paez, personally appeared Mohamed Diab personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity(ies), and that by his signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

[SEAL] SASHA Z. PAEZ COMM. #1527279 Notary Public-California ORANGE COUNTY My Comm. Exp. Nov 16, 2008

Notary Signature

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 22 day of May, 2006

Greg Olsen

STATE OF Ca.
COUNTY OF Orange } ss.

On 5/22/06, before me, Sasha Z. Paez, personally appeared Greg Olsen personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity(ies), and that by his signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

[SEAL] SASHA Z. PAEZ COMM. #1527279 Notary Public-California ORANGE COUNTY My Comm. Exp. Nov 16, 2008

Notary Signature

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 22 day of May, 2006

Roger Wu

STATE OF Ca
COUNTY OF Orange } ss.

On 5/22/06, before me, Sasha Z. Paez, personally appeared Roger Wu personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity(ies), and that by his signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

[SEAL]

SASHA Z. PAEZ
COMM. #1527279
Notary Public-California
ORANGE COUNTY
My Comm. Exp. Nov 16, 2008

Notary Signature

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 22 day of May, 2006

Rick Fishel

STATE OF CA
COUNTY OF Orange } ss.

On 6/7/06, before me, Elisa M. Mulet, personally appeared Rick Fishel personally known to me ~~(or proved to me on the basis of satisfactory evidence)~~ to be the person~~(s)~~ whose name~~(s)~~ is/~~are~~ subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity~~(ies)~~, and that by his signature~~(s)~~ on the instrument the person~~(s)~~, or the entity upon behalf of which the person~~(s)~~ acted, executed the instrument.

WITNESS my hand and official seal.

[SEAL]

SASHA Z. PAEZ
COMM. #1527279
Notary Public-California
ORANGE COUNTY
My Comm. Exp. Nov 16, 2008

Notary Signature

ELISA M. MULET
COMM. # 1532892
NOTARY PUBLIC-CALIFORNIA
ORANGE COUNTY
My Comm. Expires DEC. 9, 2008

2601857
051506

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/367,033	03/01/2006	Ammar Al-Ali	MLR.012A

CONFIRMATION NO. 3334

20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

FORMALITIES LETTER

Date Mailed: 03/28/2006

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  Applicant must submit $ **300** *to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).*
- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **$2350** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$3480** for a Large Entity

- **$300** Statutory basic filing fee.
- **$130** Surcharge.

- The application search fee has not been paid. Applicant must submit **$500** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$200** to complete the examination fee for a large entity

- Total additional claim fee(s) for this application is **$2350**

  - **$200** for **1** independent claims over 3.
  - **$2150** for **43** total claims over 20.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
PART 3 - OFFICE COPY

030106

17224 U.S.PTO

UTILITY APPLICATION	Attorney Docket No.: MLR.012A First Named Inventor: Ammar Al-Ali Title: NONINVASIVE MULTI-PARAMETER PATIENT MONITOR Express Mail Label No.: EV 307965144 US
Direct all correspondence to Customer No.: 20995	Date: March 1, 2006 Page 1

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

112935 U.S.PTO
11/367033
030106

The following enclosures are transmitted herewith to be filed in the patent application of:

INVENTORS LIST:

1. Ammar Al-Ali
2. Joe E. Kiani
3. Mohamed Diab
4. Greg Olsen
5. Roger Wu
6. Rick Fishel

DOMESTIC PRIORITY INFORMATION:

The present application claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 60/657,596, filed March 1, 2005, entitled "*Multiple Wavelength Sensor,*" No. 60/657,281, filed March 1, 2005, entitled "*Physiological Parameter Confidence Measure,*" No. 60/657,268, filed March 1, 2005, entitled "*Configurable Physiological Measurement System,*" and No. 60/657,759, filed March 1, 2005, entitled "*Noninvasive Multi-Parameter Patient Monitor.*" The present application incorporates the foregoing disclosures herein by reference.

UTILITY APPLICATION	Attorney Docket No.: MLR.012A First Named Inventor: Ammar Al-Ali Title: NONINVASIVE MULTI-PARAMETER PATIENT MONITOR Express Mail Label No.: EV 307965144 US
Direct all correspondence to Customer No.: 20995	Date: March 1, 2006 Page 2

FILING FEES:

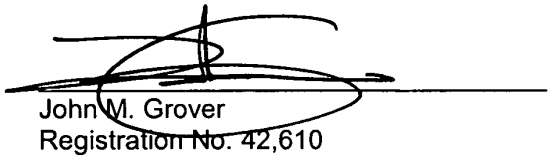
FEE CALCULATION					
FEE TYPE		**FEE CODE**		**CALCULATION**	**TOTAL**
Basic Utility	*1.16(a)(1)*	1011	($300)		$300
Search Fee	*1.16(k)*	1111	($500)		$500
Examination Fee	*1.16(o)*	1311	($200)		$200
Excess Claims > 20	63 - 20 = 43	1202	($50)	43 x 50 =	$2150
Independent > 3	4 - 3 = 1	1201	($200)	1 x 200 =	$200
Multiple Claim	*1.16(j)*	1203	($360)		$0
Application Size Fee	58 - 100 = 0	1081	($250)[±]	0 x 250 =	$0
Recordation Fee	*1.21(h)*	8021	($40)	0 x 40 =	$0
Non-English Spec.	*1.17(i)*	1053	($130)		$0
				TOTAL FEE DUE	$3,350

[±]Each additional group of 0-50 pages requires this fee. For example, a 101 page application requires this fee once, a 157 page application requires two times this fee, and a 211 page application requires three times this fee.

ENCLOSED APPLICATION ELEMENTS:

1. Specification in 40 pages.
2. Drawings in 18 sheets.
3. Return prepaid postcard.

The total fees calculated above will be paid at a later date.



John M. Grover
Registration No. 42,610
Attorney of Record
Customer No. 20,995
(949) 760-0404

2408994
030106

Knobbe Martens Olson & Bear LLP
Intellectual Property Law

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John M. Grover
jgrover@kmob.com

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Attorney Docket No.	:	MLR.012A
Applicants	:	Ammar Al-Ali et al.
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Attorney	:	John M. Grover
"Express Mail" Mailing Label No.	:	EV 307965144 US
Date of Deposit	:	March 1, 2006

I hereby certify that the accompanying

Transmittal Letter; Specification in 40 pages; 18 sheets of Drawings; Return Prepaid Postcard

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and are addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

John M. Grover

2408996
030106

Noninvasive Multi-Parameter Patient Monitor

Priority Claim to Related Provisional Applications

[0001] The present application claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 60/657,596, filed March 1, 2005, entitled "*Multiple Wavelength Sensor,*" No. 60/657,281, filed March 1, 2005, entitled "*Physiological Parameter Confidence Measure,*" No. 60/657,268, filed March 1, 2005, entitled "*Configurable Physiological Measurement System,*" and No. 60/657,759, filed March 1, 2005, entitled "*Noninvasive Multi-Parameter Patient Monitor.*" The present application incorporates the foregoing disclosures herein by reference.

Incorporation by Reference of Related Utility Applications

[0002] The present application is related to the following copending U.S. utility applications:

	App. Sr. No.	Filing Date	Title	Atty Dock.
1	11/###,###	March 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
2	11/###,###	March 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/###,###	March 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/###,###	March 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/###,###	March 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/###,###	March 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/###,###	March 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/###,###	March 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/###,###	March 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.012A
10	11/###,###	March 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
11	11/###,###	March 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

[0003] The present application incorporates the foregoing disclosures herein by reference.

Field of the Disclosure

[0004] The present disclosure relates to the field of noninvasive patient monitors. More specifically, the disclosure relates to monitors displaying measurements derived using signals from optical sensors.

Background

[0005] Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_λ, the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\varepsilon_{i,\lambda}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{0,\lambda}} \quad (1)$$

$$\mu_{0,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

[0006] where $\mu_{0,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve Equations 1-2 are the number of significant absorbers that are present in the solution.

[0007] A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2, pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used

herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

[0008] Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, California. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785. Read which are owned by Masimo, and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

Summary of the Disclosure

[0009] Despite the success of read through motion oximeter systems, there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to SpO_2, plethysmograph waveforms, or pulse rates. For example, in accessing a patient's condition, caregivers often desire knowledge of other blood constituents, including for example, a percent value for arterial carbon monoxide saturation ("HbCO") or a percent value for methemogobin saturation ("HbMet") or the like. For example, in an embodiment, the display advantageously displays one or more of the following: pulse rate, plethysmograph waveform data, perfusion index, values of blood constituents in body tissue, including for example, HbCO, HbMet, total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In other embodiments, the monitor may advantageously and accurately determine values for one or more of HbO_2, Hb, blood glucose, water, the

presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide ("CO_2") or oxygen ("O"), ph levels, bilirubin, perfusion quality, signal quality or the like. Accordingly, the present disclosure includes a multi-parameter patient monitor capable of determining one or more of the foregoing parameters, other than or in addition to, SpO_2, plethysmograph waveforms, or perfusion quality index.

[0010] In an embodiment, the display of a noninvasive multi-parameter patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display area or real estate. In an embodiment, a user may cycle different parameter values through an area of the display common to both parameters even when one parameter is shifted, through, for example, actuation of a user input key. The patient monitor may also display different parameters as color-coded. For example, when the following measured parameters are within "normal" ranges, SpO_2 may be displayed red, pulse rate (BPM) may be displayed green, HbCO may be displayed orange, HbMet may be displayed blue, or the like. In an embodiment, measured values of SpO_2 may be displayed in white, BPM may be displayed in yellow green or aquamarine, PITM may be displayed in violet, Hbt may be displayed in grass green, HbMet may be displayed in blue or light blue, HbCO may be displayed in orange, and $SpaO_2$ may be displayed in electric blue.

[0011] Moreover, parameter trend data may also be displayed using the same or similar color coding, especially when multiple trends are displayed on one or more display graphs. In addition, more coarse or gross parameter indications may be displayed for quick reference to indicate to a caregiver whether any of a variety of monitored parameters, such as, for example, SpO_2, HbCO or HbMet is within acceptable ranges. The monitor may advantageously include additional display information, such as, for example, parametric displays where one parameter is displayed as a function of another, three dimensional displays (for example, extending a parametric display along time or an additional parameter), directional

indicators predicting where a parameter is likely heading or reporting a general direction a parameters has been trending, or the like.

[0012] In addition to the foregoing, caregivers often desire to more closely monitor parameters that are close to, approaching, or beyond normal safe thresholds. In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical monitored parameters. In alternative embodiments, the patient monitor automatically changes display modes to show parameters moving closer to or beyond normal thresholds.

[0013] In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the monitor may determine how many wavelengths a particular attached sensor will emit through communication with memory devices associated with the attached sensor or cable.

[0014] Additional embodiments include audio or visual alarms for each of multiple monitored parameters, combinations of parameters, an indication of perfusion in the tissue of the measurement site, an indication of the confidence the signal processing has in its output measurements, or the like.

[0015] For purposes of summarization, certain aspects, advantages and novel features are described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features need to be present in any particular embodiment.

Brief Description of the Drawings

[0016] The drawings and the associated descriptions are provided to illustrate embodiments of the disclosure and not to limit the scope of the claims.

[0017] **Fig. 1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system including a sensor and a multi-parameter patient monitor.

[0018] **Fig. 2** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO, such as, for example, the patient monitor of **Fig. 1**.

[0019] **Fig. 3** illustrates an exemplary display of the patient monitor of **Fig. 2**.

[0020] **Fig. 4** illustrates the display of **Fig. 3** showing measured values of SpO_2, BPM, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0021] **Fig. 5** illustrates the display of **Fig. 3** showing measured values of HbCO, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0022] **Fig. 6** illustrates the display of **Fig. 3** showing measured values of SpO_2, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0023] **Fig. 7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of **Fig. 1**.

[0024] **Fig. 8** illustrates an exemplary display of the patient monitor of **Fig. 7**.

[0025] **Fig. 9** illustrates the display of **Fig. 8** showing measured values of SpO_2, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0026] **Fig. 10** illustrates the display of **Fig. 8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**.

[0027] **Fig. 11A** illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor such as, for example, the patient monitor of **Fig. 1**.

[0028] **Figs. 11B – 11H** illustrate display screens of the patient monitor of **Fig. 11A**.

Detailed Description of Preferred and Alternative Embodiments

[0029] Embodiments of the present disclosure include a portable or other multi-parameter patient monitor capable of determining multiple physiological parameters from one or more signals output from one or more light sensitive

detectors capable of detecting light attenuated by body tissue carrying pulsing blood. For example, in an embodiment, the monitor advantageously and accurately determines a wide variety of physiological parameters or other calculations as discussed above.

[0030] In an embodiment, the display of patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate. For example, the patient monitor may include one or more user input keys capable of toggling through measurement data. In an embodiment, the displays include mode indicators providing caregivers easily identifiable visual queues, such as LED's, text, icons, or other indicia providing readily identifiable queues as to which parameter is being displayed. In an embodiment, the display may shift, may be parameter color-coded, or the like to further ensure quick comprehension of which measured parameter is the displayed parameter. For example, in an embodiment, the monitor displays SpO_2 in white, pulse rate (BPM) in green, HbCO in orange, and HbMet in blue when the respective measured parameter is within a "normal" range.

[0031] In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical or time sensitive measured parameters, specific caregiver selected parameters, or the like. For example, the patient monitor may advantageously sound audio or visual alarms that alert the caregiver to particular one or more of worsening parameters, parameters changing in a predetermined pattern or rate, parameters stabilizing below user defined or safe thresholds, caregiver selected parameters, or the like. The monitor may also use alerts that provide audio or visual indications of the severity of the condition, severity of the change, or the like. In alternative embodiments, the patient monitor may automatically change display modes when a particular parameter crosses one or more thresholds. For example, a patient monitor may be displaying a first parameter, such as a plethysmograph, and upon determining measurements indicating that HBMet is trending toward an alarm condition, the monitor may automatically switch from displaying the first parameter to the alarming parameter, or in this case, a trend of the alarming parameter.

[0032] In an embodiment, a switch is provided to allow a user to switch displays to view an alarming measurement. In an embodiment, during an alarm condition, a parameter display may switch to a trend graph in the same or different color, line weight, flash, flash rate, intensity, size, or the like.

[0033] The patient monitor may also include one or more displays capable of displaying trend data for any one or more of the monitored or derived patient parameters. For example, the trend data may be displayed in graph form, may include multiple trend lines, each representing a different monitored or derived patient parameter. Moreover, each trend line may be color-coded to facilitate quick comprehension of which trend line represents which measured parameter. However, an artisan will recognize from the disclosure herein a large number of identification techniques including color-coding, identifying text, or the like. Additionally, user input may toggle displayed trend data, may select which parameters to display simultaneously, or the like.

[0034] In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the patient monitor may provide a particular audio or visual indication, such as a beep, LED activation, graphic activation, text messages, voice messages, or the like, to indicate communication with or connection to an approved sensor, patient cable, combination, or the like. In an embodiment, the indication may change based on the manufacturer, type of sensor recognized or not recognized, type of patient, type of physiological parameters measurable with the attached sensor, or the like. Additional embodiments include an indication of perfusion in the tissue of the measurement site and an indication of the confidence the signal processing has in its output measurements or input signal quality.

[0035] To facilitate an understanding of the disclosure, the remainder of the description references exemplary embodiments illustrated in the drawings. Moreover, in this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total

hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported herein in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

[0036] **Fig. 1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system **100**. As shown in **Fig. 1**, the system **100** includes a patient monitor **102** comprising a processing board **104** and a host instrument **108**. The processing board **104** communicates with a sensor **106** to receive one or more intensity signal(s) indicative of one or more parameters of tissue of a patient. The processing board **104** also communicates with a host instrument **108** to display determined values calculated using the one or more intensity signals. According to an embodiment, the board **104** comprises processing circuitry arranged on one or more printed circuit boards capable of installation into the monitor **102**, or capable of being distributed as some or all of one or more OEM components for a wide variety of host instruments monitoring a wide variety of patient information. In an embodiment, the processing board **102** comprises a sensor interface **110**, a digital signal processor and signal extractor ("DSP" or "processor") **112**, and an instrument manager **114**. In general, the sensor interface **110** converts digital control signals into analog drive signals capable of driving sensor emitters, and converts composite analog intensity signal(s) from light sensitive detectors into digital data.

[0037] In an embodiment, the sensor interface **110** manages communication with external computing devices. For example, in an embodiment, a multipurpose sensor port (or input/output port) is capable of connecting to the sensor **106** or alternatively connecting to a computing device, such as a personal computer, a PDA, additional monitoring equipment or networks, or the like. When connected to the computing device, the processing board **104** may upload various stored data for, for example, off-line analysis and diagnosis. The stored data may comprise trend data for any one or more of the measured parameter data,

plethysmograph waveform data acoustic sound waveform, or the like. Moreover, the processing board **104** may advantageously download from the computing device various upgrades or executable programs, may perform diagnosis on the hardware or software of the monitor **102**. In addition, the processing board **104** may advantageously be used to view and examine patient data, including raw data, at or away from a monitoring site, through data uploads/downloads, or network connections, combinations, or the like, such as for customer support purposes including software maintenance, customer technical support, and the like. Upgradable sensor ports are disclosed in copending U.S. App. No. 10/898,680, filed on July 23, 2004, titled "*Multipurpose Sensor Port*," incorporated by reference herein.

[0038] As shown in **Fig. 1**, the digital data is output to the DSP **112**. According to an embodiment, the DSP **112** comprises a processing device based on the Super Harvard ARChitecture ("SHARC"), such as those commercially available from Analog Devices. However, a skilled artisan will recognize from the disclosure herein that the DSP **112** can comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In particular, the DSP **112** includes program instructions capable of receiving multiple channels of data related to one or more intensity signals representative of the absorption (from transmissive or reflective sensor systems) of a plurality of wavelengths of emitted light by body tissue. In an embodiment, the DSP **112** accepts data related to the absorption of eight (8) wavelengths of light, although an artisan will recognize from the disclosure herein that the data can be related to the absorption of two (2) to sixteen (16) or more wavelengths.

[0039] **Fig. 1** also shows the processing board **104** including the instrument manager **114**. According to an embodiment, the instrument manager **114** may comprise one or more microcontrollers controlling system management, including, for example, communications of calculated parameter data and the like to the host instrument **108**. The instrument manager **114** may also act as a watchdog circuit by, for example, monitoring the activity of the DSP **112** and resetting it when appropriate.

[0040] The sensor **106** may comprise a reusable clip-type sensor, a disposable adhesive-type sensor, a combination sensor having reusable and disposable components, or the like. Moreover, an artisan will recognize from the disclosure herein that the sensor **106** can also comprise mechanical structures, adhesive or other tape structures, Velcro wraps or combination structures specialized for the type of patient, type of monitoring, type of monitor, or the like. In an embodiment, the sensor **106** provides data to the board **104** and vice versa through, for example, a patient cable. An artisan will also recognize from the disclosure herein that such communication can be wireless, over public or private networks or computing systems or devices, or the like.

[0041] As shown in **Fig.1**, the sensor **106** includes a plurality of emitters **116** irradiating the body tissue **118** with differing wavelengths of light, and one or more detectors **120** capable of detecting the light after attenuation by the tissue **118**. In an embodiment, the emitters **116** comprise a matrix of eight (8) emission devices mounted on a flexible substrate, the emission devices being capable of emitting eight (8) differing wavelengths of light. In other embodiments, the emitters **116** may comprise twelve (12) or sixteen (16) emitters, although other numbers of emitters are contemplated, including two (2) or more emitters. As shown in **Fig. 1**, the sensor **106** may include other electrical components such as, for example, a memory device **122** comprising an EPROM, EEPROM, ROM, RAM, microcontroller, combinations of the same, or the like. In an embodiment, other sensor components may include a temperature determination device **123** or other mechanisms for, for example, determining real-time emission wavelengths of the emitters **116**.

[0042] The memory **122** may advantageous store some or all of a wide variety data and information, including, for example, information on the type or operation of the sensor **106**; type or identification of sensor buyer or distributor or groups of buyer or distributors, sensor manufacturer information, sensor characteristics including the number of emitting devices, the number of emission wavelengths, data relating to emission centroids, data relating to a change in emission characteristics based on varying temperature, history of the sensor temperature, current, or voltage, emitter specifications, emitter drive requirements,

demodulation data, calculation mode data, the parameters for which the sensor is capable of supplying sufficient measurement data (*e.g.*, HpCO, HpMet, HbT, or the like), calibration or parameter coefficient data, software such as scripts, executable code, or the like, sensor electronic elements, whether the sensor is a disposable, reusable, multi-site, partially reusable, partially disposable sensor, whether it is an adhesive or non-adhesive sensor, whether the sensor is a reflectance, transmittance, or transreflectance sensor, whether the sensor is a finger, hand, foot, forehead, or ear sensor, whether the sensor is a stereo sensor or a two-headed sensor, sensor life data indicating whether some or all sensor components have expired and should be replaced, encryption information, keys, indexes to keys or hash functions, or the like, monitor or algorithm upgrade instructions or data, some or all of parameter equations, information about the patient, age, sex, medications, and other information that may be useful for the accuracy or alarm settings and sensitivities, trend history, alarm history, or the like. In an embodiment, the monitor may advantageously store data on the memory device, including, for example, measured trending data for any number of parameters for any number of patients, or the like, sensor use or expiration calculations, sensor history, or the like.

[0043] **Fig. 1** also shows the patient monitor **102** including the host instrument **108**. In an embodiment, the host instrument **108** communicates with the board **104** to receive signals indicative of the physiological parameter information calculated by the DSP **112**. The host instrument **108** preferably includes one or more display devices **124** capable of displaying indicia representative of the calculated physiological parameters of the tissue **118** at the measurement site. In an embodiment, the host instrument **108** may advantageously comprise a handheld housing capable of displaying one or more of a pulse rate, plethysmograph data, perfusion quality such as a perfusion quality index ("PI^{TM}"), signal or measurement quality ("SQ"), values of blood constituents in body tissue, including for example, SpO_2, HbCO, HbMet, Hbt, or the like. In other embodiments, the host instrument **108** is capable of displaying values for one or more of Hbt, Hb, blood glucose, bilirubin, or the like. The host instrument **108** may be capable of storing or displaying historical or trending data related to one or more of the measured values,

combinations of the measured values, plethysmograph data, or the like. The host instrument **108** also includes an audio indicator **126** and user input device **128**, such as, for example, a keypad, touch screen, pointing device, voice recognition device, or the like.

[0044] In still additional embodiments, the host instrument **108** includes audio or visual alarms that alert caregivers that one or more physiological parameters are falling below predetermined safe thresholds. The host instrument **108** may include indications of the confidence a caregiver should have in the displayed data. In a further embodiment, the host instrument **108** may advantageously include circuitry capable of determining the expiration or overuse of components of the sensor **106**, including, for example, reusable elements, disposable elements, or combinations of the same.

[0045] Although described in terms of certain embodiments, other embodiments or combination of embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **102** may comprise one or more monitoring systems monitoring parameters, such as, for example, vital signs, blood pressure, ECG or EKG, respiration, glucose, bilirubin, or the like. Such systems may combine other information with intensity-derived information to influence diagnosis or device operation. Moreover, the monitor **102** may advantageously include an audio system, preferably comprising a high quality audio processor and high quality speakers to provide for voiced alarms, messaging, or the like. In an embodiment, the monitor **102** may advantageously include an audio out jack, conventional audio jacks, headphone jacks, or the like, such that any of the display information disclosed herein may be audiblized for a listener. For example, the monitor **102** may include an audible transducer input (such as a microphone, piezoelectric sensor, or the like) for collecting one or more of heart sounds, lung sounds, trachea sounds, or other body sounds and such sounds may be reproduced through the audio system and output from the monitor **102**. Also, wired or wireless communications (such as Bluetooth or WiFi, including IEEE 801.11a, b, or g), mobile communications, combinations of the same, or the like,

may be used to transmit the audio output to other audio transducers separate from the monitor **102**.

[0046] For example, patterns or changes in the continuous noninvasive monitoring of intensity-derived information may cause the activation of other vital sign measurement devices, such as, for example, blood pressure cuffs.

[0047] **Fig. 2** illustrates a perspective view of an exemplary handheld noninvasive multi-parameter patient monitor **200**, such as, for example, the patient monitor **102** of **Fig. 2**. Patient monitors **200** exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57c." As shown in **Fig. 1**, the monitor **200** includes a patient cable connector **202** capable of mechanical mating with a patient cable to establish communication between the board **104** and the sensor **106**. In an embodiment, the connector **202** comprises a multipurpose cable connector such as that disclosed in the incorporated U.S. App. No. 10/898,680, titled "*Multipurpose Sensor Port*," disclosing communication between the board **104** and an external computing device.

[0048] The monitor **202** also comprises a HbCO indicator **204** advantageously providing a visual queue that a HbCO capable sensor is properly connected through the connector **202**. For example, the HbCO indicator **204** may advantageously activate when a sensor is connected that communicates sufficient information to determine HbCO, such as, for example, a sensor capable of emitting sufficient different wavelengths of light, a sensor storing sufficient data on the memory **122**, a sensor having appropriate encryption data or key, combinations of the same, or the like. For example, in an embodiment, the processor 112 may receive information from a memory 122 indicating a number of available LED wavelengths for the attached sensor. Based on the number of wavelengths, or other information stored on the memory 122, the processor 112 may determine whether an HbCO-ready sensor has been attached to the monitor 200. An artisan will also recognize from the disclosure herein that the HbCO indicator 204 may advantageously comprise a HbMet indicator, Hbt indicator, or the like, which activates to a predetermined color associated with a parameter, or any color, or

deactivates the same, to convey a type of attached sensor. Moreover, the artisan will recognize from the disclosure herein other parameters that may use other sensor components and the monitor **200** may include indicators capable of indicating communication with those types of sensors.

[0049] In an embodiment, the monitor **200** may also audibly indicate the type of sensor connected. For example, the monitor **200** may emit predetermined number or frequency of beeps associated with recognition of a particular sensor, a particular manufacturer, failure to recognize the sensor, or the like. Moreover, the sensor type may be indicative of the componentry, such as, for example, whether the sensor produces sufficient data for the determination of HbCO, HbMet, Hbt and SpO_2, SpO_2 only, SpO_2 and HbMet, any combination of the foregoing or other parameters, or the like. Additionally, the sensor type may be indicative of specific sensors designed for a type of patient, type of patient tissue, or the like. In other embodiments, the monitor **200** may announce the type of connector through speaker **236**.

[0050] An artisan will also recognize from the disclosure herein that other mechanical (such as keys), electrical, or combination devices may inform the monitor **202** of the type of attached sensor. In an embodiment, the processor **112** also may select to drive less emitters that are currently available, such as, for example, in the presence of low noise and when power consumption is an issue.

[0051] The monitor **202** also comprises a multi-mode display **206** capable of displaying, for example, measurements of SpO_2 and HbCO (or alternatively, HbMet). In an embodiment, the display **206** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **200**. Thus, the multi-mode display **206** may advantageously cycle through two or more measured parameters in an area common to both parameters even when shifted. In such embodiments, the monitor **200** may also advantageously include parameter indicators **208**, **210**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the

multi-mode display **206** displays measured values of SpO_2 that are normal, the numbers may advantageously appear in green, while normal measured values of HbCO may advantageously appear in orange, and normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **206** flashes at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

[0052] The monitor **202** also comprises a HbCO bar **212** where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. For example, the bar **212** is lowest when the dangers from carbon monoxide poisoning are the least, and highest when the dangers are the greatest. The bar **212** includes indicia **214** that provide an indication of the severity of carbon monoxide saturation in a patient's blood. As shown in **Fig. 2**, the bar **212** and the indicia **214** continuously indicate the concentration of HbCO in about 5% increments. The indicia **214** indicate a measurement of HbCO saturation percentage between about 0 and about 50% with a granularity of about 5%. However, an artisan will also recognize from the disclosure herein a wide variety of ranges and granularities could be used, the indicia **214** could be electronically displayed in order to straightforwardly increase or decrease resolution, or the like. For example, HbCO may advantageously be displayed with greater resolution than ± about %5 in a lower portion of the scale. For example, an HbCO bar may advantageously include a scale of about <3%,. about 6%, about 9%, about 12%, about 15%, about 20%, about 25%, about 30%, about 35%, and about >40%.

[0053] As is known in the art, carbon monoxide in the blood can lead to serious medical issues. For example and depending upon the particular physiology of a patient, about 10% carbon monoxide saturation can lead to headaches, about 20% can lead to throbbing headaches, or dyspnea on exertion, about 30% can lead to impaired judgment, nausea, dizziness and/or vomiting, visual disturbance, or fatigue, about 40% can lead to confusion and syncope, and about 50% and above can lead to comas, seizures, respiratory failure and even death.

[0054] In an embodiment, the bar **212** is the same or similar color as the multi-mode display **206** when displaying HbCO. In other embodiments, the bar **212** is lowest and green when the dangers from carbon monoxide poisoning are the least, and highest and red when the dangers are the greatest. In an embodiment, as HbCO increases, the entire bar **212** may advantageously change color, such as, for example, from green to red, to provide a clear indication of deepening severity of the condition. In other embodiments, the bar **212** may advantageously blink or flash, an audio alarm may beep or provide a continuation or rise in pitch or volume, or the like to alert a caregiver of deepening severity. Moreover, straightforward to complex alarm rules may be implemented to reduce false alarms based on, for example, knowledge of the physiological limitations on the rate of change in HbCO or the like.

[0055] Additionally, the monitor **200** may be capable of storing and outputting historical parameter data, display trend traces or data, or the like. Although the foregoing bar **212** has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

[0056] **Fig. 2** also shows the monitor **200** including a pulse display **216** displaying measured pulse rate in beats per minute ("BPM"). In an embodiment, the display **212** flashes when searching for a pulse. The pulse display **216** advantageously displays measured pulse rates from about zero (0) to about two hundred and forty (240) BPM. Moreover, when the measured pulse rates are considered normal, the pulse display **216** is advantageously green. Similar to other displays associated with the monitor **200**, the pulse display **216** may employ a variety of color changes, audio alarms, or combinations of the same to indicate measured BPM below predetermined safe thresholds. In an embodiment, the pulse rate display **216** displays the measured pulse rate during the display of SpO_2 and displays message data during the display of other parameters. For example, during the display of HbCO, the display **216** may advantageously display the term "CO." In an embodiment, the display of the message data may be in the same or similar color as the other displays. For example, in an embodiment, the multi-mode display

206, the bar **212**, and the pulse display **216** may all display data or messages in orange when the multi-mode display **206** displays measured HbCO values.

[0057] **Fig. 2** also illustrates the monitor **200** comprising user input keys **218**, including a HbCO button **220**, mode/enter button **222**, next button **224**, power on/off button **226**, up/down button **228**, and alarm silence button **230**. In an embodiment, activation of the HbCO button **220** toggles the measured value displayed in the multi-mode display **206**. For example, activation of the HbCO button **220** toggles the multi-mode display **206** from displaying measured values of SpO_2 to HbCO for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **206** back to SpO_2. A skilled artisan will also recognize that activation of the HbCO button **220** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO_2, may remain displayed until further activation of the button **220**, or the like.

[0058] Activation of the mode/enter button **222** cycles through various setup menus allowing a caregiver to select or activate certain entries within the menu setup system, including alarm threshold customizations, or the like. Activation of the next button **224** can move through setup options within the menu setup system and in an embodiment is not active during normal patient monitoring. For example, a caregiver may activate the mode/enter button **222** and the next button **224** to specify high and low alarm thresholds for one or more of the measured parameters, to specify device sensitivity, trend settings, display customizations, color code parameters, or the like. In an embodiment, the high alarm setting for SpO_2 can range from about two percent (2%) to about one hundred percent (100%) with a granularity of about one percent (1%). The low alarm setting for SpO_2 can range from about one percent (1%) to about one hundred percent (100%) with a granularity of about one percent (1%). Moreover, the high alarm setting for pulse rate can range from about thirty (30) BPM to about two hundred and forty (240) BPM with a granularity of about five (5) BPM. The low alarm setting for pulse rate can range from about twenty five (25) BPM to about two hundred and thirty five (235) BPM with a granularity of about five (5) BPM. Other high and low ranges for other

measured parameters will be apparent to one of ordinary skill in the art from the disclosure herein.

[0059] In a further embodiment, a caregiver may activate the mode/enter button **222** and the next button **224** to specify device sensitivity, such as, for example, device averaging times, probe off detection, whether to enable fast saturation calculations, or the like. Various embodiments of fast saturation calculations are disclosed in U.S. Pat. App. Ser. No. 10/213,270, filed August 5, 2002, titled "*Variable Indication Estimator*" and incorporated by reference herein. Using the menus, a caregiver may also advantageously enter appropriate information governing trend collection on one or more of the measured parameters, input signals, or the like.

[0060] **Fig. 2** also shows the power on/off button **226**. Activation of the power on/off button **226** activates and deactivates the monitor **200**. In an embodiment, press-and-hold activation for about two (2) seconds shuts the monitor **200** off. In an additional embodiment, activation of the on/off button **226** advantageously initiates detection of a type of attached sensor. For example, activation of the on/off button **226** may advantageously cause the monitor **200** to read information from a memory on an attached sensor and determine whether sufficient wavelengths exist on the sensor to determine one or more the physiological parameters discussed in the foregoing.

[0061] An artisan will recognize from the disclosure herein that the on/off button **226** may advantageously cause an electronic determination of whether to operate in at powers consisted with the U.S. (60 Hz) or another nationality (50 Hz). In an embodiment, such automatic determination and switching is removed from the monitor **200** in order to reduce a likelihood of problematic interfering crosstalk caused by such power switching devices.

[0062] Activation of the up/down button **228** may advantageously adjust the volume of the pulse beep tone. Additionally, activation of the up/down button **228** within the menu setup system, causes the selection of values with various menu options.

[0063] Moreover, activation of the alarm silence button **230** temporarily silences audio alarms for a predetermined period, such as, for example, about one hundred and twenty (120) seconds. A second activation of the alarm silence button **230** mutes (suspends) the alarm indefinitely, while a third activation returns the monitor **200** to standard alarm monitoring. **Fig. 2** also shows the alarm silence button **230** includes an alarm silenced indicator **232**. The alarm silenced indicator **232** may advantageously flash to indicate one or more alarms are temporarily silenced, may illuminate solid to indicate the alarms have been muted, or the like. Moreover, an artisan will recognize from the disclosure herein a wide variety of alarm silencing methodologies.

[0064] The monitor **202** also includes a battery level indicator **234** indicating remaining battery life. In the illustrated embodiment, four LED's indicate the status of the battery by incrementally deactivating to indicate proportionally decreasing battery life. In an embodiment, the four LED's may also change color as the battery charge decreases, and the final LED may begin to flash to indicate that the caregiver should replace the batteries.

[0065] **Fig. 2** also shows the monitor **202** including an audio transducer or speaker **236**. The speaker **236** advantageously provides audible indications of alarm conditions, pulse tone and feedback for key-presses, or the like. Moreover, the monitor **202** includes a low signal quality indicator ("SQ" or "SIQ™") **238**. The signal IQ indicator **238** activates to inform a caregiver that a measured value of the quality of the incoming signal is below predetermined threshold values. For example, in an embodiment, the measured value for signal IQ is at least partially based on an evaluation of the plethysmograph data's correspondence to predetermined models or characteristics of physiological signals. In an embodiment, the signal IQ indicator **238** output may be associated with the displayed parameter. For example, the output may be associated with one threshold for the display of SpO_2 and another for the display of other parameter data.

[0066] The monitor **202** also comprises a perfusion quality index ("PI™") bar **240** (which quantifies the measure of perfusion of the patient) where in an

embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. In one embodiment, the PI™ bar **240** shows a static value of perfusion for a given time period, such as, for example, one or more pulses. In another embodiment, or functional setting, the PI™ bar **240** may advantageously pulse with a pulse rate, may hold the last reading and optionally fade until the next reading, may indicate historical readings through colors or fades, or the like. Additionally, the PI™ bar **240** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

[0067] The PI™ bar **240** can be used to simply indicate inappropriate occlusion due, for example, to improper attachment of the sensor **106**. The PI™ bar **240** can also be used as a diagnostic tool during low perfusion for the accurate prediction of illness severity, especially in neonates. Moreover, the rate of change in the PI™ bar **240** can be indicative of blood loss, sleep arousal, sever hypertension, pain management, the presence or absence of drugs, or the like. According to one embodiment, the PI™ bar **240** values may comprise a measurement of the signal strength of the arterial pulse as a percentage of the total signal received. For example, in one preferred embodiment, the alternating portion of at least one intensity signal from the sensor **106** may advantageously be divided by the static portion of the signal. For example, an infrared intensity signal may advantageously be used as it is less subjective to noise.

[0068] In an embodiment, a measurement below about 1.25% may indicate medical situations in need of caregiver attention, specifically in monitored neonates. Because of the relevance of about 1.25%, the PI™ bar **240** may advantageously include level indicia **242** where the indicia **242** swap sides of the PI™ bar **240**, thus highlighting any readings below about that threshold. Moreover, behavior of the PI™ bar **240**, as discussed above, may advantageously draw attention to monitored values below such a threshold.

[0069] As discussed above, the monitor **200** may include output functionality that outputs, for example, trend perfusion data, such that a caregiver can monitor measured values of perfusion over time. Alternatively or additionally,

the monitor **200** may display historical trace data on an appropriate display indicating the measured values of perfusion over time. In an embodiment, the trend data is uploaded to an external computing device through, for example, the multipurpose sensor connector **202** or other input output systems such as USB, serial or parallel ports or the like.

[0070] The monitor **200** also includes an alarm indicator **244** capable of providing visual queues of the status of one or more of the measured parameters. For example, the alarm indicator **244** may advantageously be green when all of the measured parameters are within normal conditions, may gradually fade to red, may flash, increasing flash, or the like, as one or more of the measured values approaches or passes predetermined thresholds. In an embodiment, the alarm indicator **244** activates when any parameter falls below an associated threshold, thereby advantageously informing a caregiver that perhaps a nondisplayed parameters is at an alarm condition. In another embodiment, the alarm indicator **244** may indicate the status of the parameter displayed on the multi-mode display **206**. In an embodiment, the speaker **236** may sound in conjunction with and/or in addition to the indicator **244**. Moreover, in an embodiment, an alarming parameter may automatically be displayed, may be emphasized, flashed, colored, combinations of the same or the like to draw a user's attention to the alarming parameter.

[0071] Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

[0072] **Fig. 3** illustrates an exemplary display of the patient monitor **200**. As shown in **Fig. 3**, the display includes the multi-mode display **206**, the pulse rate display **216**, parameter indicators **208**, **210**, the HbCO bar **212** and indicator **204**, the PI™ bar **240**, and the alarm indicator **244**. In an embodiment, the multi-mode display **206** and the pulse rate display **216** each comprise a plurality of seven segment displays **302** capable of displaying alpha-numeric information. As disclosed in the foregoing, the exemplary display may advantageously include color-coded parameter displays. Moreover, the exemplary display may include color

progressions, flashing, flashing progressions, audible alarms, audible progressions, or the like, indicating worsening measured values of physiological data. In addition, in an embodiment, some or all of the displays may flash at a first rate to indicate attempts to acquire data when actual measured values are unavailable. Moreover, some or all of the display may flash at a second rate to indicate low signal quality where confidence is decreasing that the measured values reflect actual physiological conditions.

[0073] **Fig. 4** illustrates the display of **Fig. 3** showing measured values of SpO_2, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of **Fig. 1**. As shown in **Fig. 4**, the multi-mode display **206** is displaying a percentage value of SpO_2, and the pulse rate display **216** is displaying a pulse rate in beats per minute. Accordingly, the parameter indicator **210** is activated to confirm the display of measured values of SpO_2. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** is red, indicating blood oxygen measurements while the pulse rate display **216** is green, indicating normal values of a patient's pulse.

[0074] **Fig. 4** also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the HbCO indicator **204** is showing communication with a sensor producing insufficient data to determine measured values of additional parameters, such as, HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about two (2) different wavelengths, may comprise sensors with insufficient data stored on a memory associated therewith, or the like.

[0075] **Fig. 5** illustrates the display of **Fig. 3** showing measured values of HbCO, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of **Fig. 1**. As shown in **Fig. 5**, the multi-mode display **206** is displaying a percentage value of HbCO, and the pulse rate display **216** is displaying an appropriate message indicating the HbCO measurement, such as, for example, "CO". Also, the multi-mode display **206** has shifted the data to the left to quickly and efficiently indicate that the displayed parameter is other than SpO_2. Accordingly, the parameter indicator **208** is also activated to confirm the display of measured values

of HbCO. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** and pulse rate display message **216** are orange.

[0076] **Fig. 5** also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about eight (8) or more different wavelengths; however, such sensors may comprise about two (2) or more different wavelengths. Moreover, such sensors may have appropriate data stored on a memory associated therewith, or the like. **Fig. 5** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

[0077] **Fig. 6** illustrates the display of **Fig. 3** showing measured values of SpO_2, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of **Fig. 1**. In contrast to **Fig. 4**, **Fig. 6** shows that the monitor **200** is communicating with a sensor capable of producing sufficient data to determine measured values of HbCO, even though the displayed values are that of SpO_2 and BPM. Thus, **Fig. 6** shows the activation of the HbCO indicator **204**, and the continuous monitoring of HbCO by the HbCO bar **212**. **Fig. 6** also shows a high value of HbCO, and therefore, the indication of an alarm condition by activation of the alarm indicator **244**. In an embodiment, upon determination of an alarm condition on a nondisplayed parameter, the monitor **200** may advantageously provide an alarm indication through speaker and alarm indicator activation, automatic toggle to the nondisplayed parameter on the multi-mode display **206** for a defined or undefined time, or the like.

[0078] **Fig. 7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor **700** capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of **Fig. 1**. Patient monitors exhibiting combinations of many of the features described herein are

advantageously commercially available from Masimo under the brand name "Rad 57cm." As shown in **Fig. 7**, the monitor **700** comprises a monitor similar to monitor **200** disclosed with reference to **Fig. 2**. Moreover, monitor **700** further includes a multi-mode display **706** capable of displaying, for example, measurements of HbMet and BPM. In an embodiment, the display **706** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **700**. Thus, the multi-mode display **706** may advantageously cycle through two or more measured parameters. In such embodiments, the monitor **700** may also advantageously include parameter indicators **708**, **710**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display **706** may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display 706 displays measured values of BPM that are normal, the numbers may advantageously appear in green, while normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **706** may flash at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

[0079] **Fig. 7** also illustrates the monitor **700** comprising user input keys **718**, including an HbCO/HbMet button **220**. In an embodiment, activation of the HbCO/HbMet button **720** toggles the measured value displayed in the multi-mode display **706**. For example, activation of the HbCO/HbMet button **720** toggles the multi-mode display **206** from displaying measured values of SpO_2 and BPM, to HbCO and HbMet for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **706** back to SpO_2 and BPM. A skilled artisan will also recognize that activation of the HbCO/HbMet button **720** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO_2 and BPM, may remain displayed until further activation of the button **720**, or the like.

[0080] The monitor **700** also comprises a coarser indication of HbMet through an HbMet bar **740**. In an embodiment, a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value, with increments at about 0.5%, about 1%, about 2%, about 3%, about 4%, about 5%, about 7.5%, about 10%, about 15% and greater than about 20%, although an artisan will recognize from the disclosure herein other useful delineations. Additionally, the HbMet bar **740** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

[0081] Although disclosed with reference to the HbMet bar **740**, and artisan will recognize from the disclosure herein other coarse or even gross indications of HbMet, or any measured parameter. For example, a single LED may advantageously show green, yellow, and red, to indicate worsening coarse values of HbMet. Alternatively, a single LED may simply light to indicate an alarm or approaching alarm condition.

[0082] **Fig. 8** illustrates an exemplary display of the patient monitor **700** of **Fig. 7**. As shown in **Fig. 8**, the display includes the multi-mode displays **206**, **706**, parameter indicators **208**, **210**, **708**, **710**, the HbCO bar **212** and indicator **204**, the HbMet bar **740**, and the alarm indicator **244**. In an embodiment, the multi-mode display **706** is similar to multi-mode display **206**, comprising a plurality of seven segment displays **302** capable of displaying alpha-numeric information, and capable of altering its display characteristics or aspects in a wide variety of configurations discussed with reference to the display **206**.

[0083] **Fig. 9** illustrates the display of **Fig. 8** showing measured values of SpO_2, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**. **Fig. 9** also shows the HbMet bar **740** near the bottom and corresponding to about 1%, representing acceptable HbMet, while the HbCO bar **212** hovers at a dangerous near 20%. In addition, the HbCO indicator **204** is showing communication with a sensor producing sufficient data to determine measured values of additional parameters, such as, HbMet, HbCO or the like. In an embodiment, such sensors may comprise sensors capable of emitting

light of more than two (2) different wavelengths, preferably more than four (4) different wavelengths, and more preferably eight (8) or more different wavelengths.

[0084] **Fig. 10** illustrates the display of **Fig. 8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of **Fig. 1**. As shown in **Fig. 10**, the multi-mode display **706** is displaying a percentage value of HbMet that is shifted using the parameter indicator **708**. The data has been advantageously shifted to the left to quickly and efficiently indicate that the displayed parameter is other than BPM. Accordingly, the parameter indicator **708** is also activated to confirm the display of measured values of HbMet. As disclosed in the foregoing, in an embodiment, the multi-mode display **706** is blue.

[0085] **Fig. 10** also shows the HbMet bar **740** nearly empty, representing acceptable HbMet. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may have appropriate data stored on a memory associated therewith, or the like. **Fig. 10** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

[0086] **Fig. 11A** illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor **1100**, such as, for example, the patient monitor of **Fig. 1**. Moreover, **Figs. 11B – 11E** illustrate exemplary display screens of the patient monitor of **Fig. 11A**. As shown in **Figs. 11A – 11B**, an embodiment of the monitor **1100** includes a display **1101** showing a plurality of parameter data. For example, the display may advantageously comprise a CRT or an LCD display including circuitry similar to that available on oximeters commercially available from Masimo Corporation of Irvine, California sold under the name Radical™, and disclosed in the U.S. patents referenced above and incorporated above. However, an artisan will recognize from the disclosure herein many commercially available

display components capable of displaying multiple parameter data along with the ability to display graphical data such as plethysmographs, trend traces, and the like.

[0087] In an embodiment, the display includes a measured value of SpO_2 **1102**, a measured value of pulse rate **1104** in BPM, a plethysmograph **1106**, a measured value of HbCO **1108**, a measured value of HbMet **1110**, a measured value of a perfusion quality **1112**, a measured value of Hbt **1114**, and a derived value of fractional saturation "$SpaO_2$" **116**. In an embodiment, $SpaO_2$ comprises HbO_2 expressed as a percentage of the four main hemoglobin species, i.e., HbO_2, Hb, HbCO, and HbMet.

[0088] In an embodiment, one or more of the foregoing parameter includes trending or prediction indicators **1118** showing the current trend or prediction for that corresponding parameter. In an embodiment, the indicators **1118** may advantageously comprise an up arrow, a down arrow, and a hyphen bar to indicate up trending/prediction, down trending/prediction, or neutral trending/prediction.

[0089] **Fig. 11C** illustrates an exemplary display screen showing trend graph **1140** including trend line **1142** for HbMet. In an embodiment, the trend line **1142** may be advantageously colored for quick straightforward recognition of the trending parameter, may be associated with any one or more of the foregoing alarm attributes, may include trending lines for other parameters, or the like. The display screen also shows trending directional indicators **1142**, **1144** for many of the displayed physiological parameters. In an embodiment, the directional indicators **1142**, **1144** may advantageously comprises arrows showing the recent trend, predicted trend, user-customizable trend, combinations thereof, or the like for the associated parameters. In an embodiment, the directional indicators **1142**, **1144** comprises an up arrow indicating a rising trend/predicted trend, a middle bar indicating a somewhat stable trend/predicted trend, and a down arrow indicating a lowering trend/predicted trend. An artisan will recognize a wide variety of other directional indicators **1142**, **1144** from the disclosure herein.

[0090] **Fig. 11D** shows an exemplary display screen in vertical format. Such vertical format could be user actuated or based on a gravity switch. **Figs. 11E**

– **11F** illustrate additional displays of various physiological parameters similar to those discussed in the foregoing. being As shown in **Fig. 11G**, the display includes a measured value of SpO_2 **1162**, a measured value of pulse rate **1164** in BPM, a plethysmograph **1166**, a HbCO bar **1168**, and a HbMet bar **1170**. In an embodiment, the HbCO bar **1168** and HbMet bar **1170** may advantageously behave the same or similarly to the HbCO bar **212** and HbMet bar **712**. Moreover, similar bars may advantageously display any of the physiological parameters discussed herein using display indicia appropriate to that parameter. For example, a SpO_2 or $SpaO_2$ bar may advantageously range from about 0% to about 100%, and more preferably range from about 50% to about 100%, while a Hbt bar may advantageously range from about 0 to about 30.

[0091] Moreover, similar to the disclosure above, the measured value of SpO_2 **1162** may advantageously toggle to measured values of HbCO, HbMet, Hbt, or the like based on, for example, actuation of user input keys, or the like.

[0092] In addition to the foregoing, the display may also include graphical data showing one or more color-coded or other identifying indicia for traces of trend data. Moreover, other graphical presentations may advantageously provide readily identifiable indications of monitored parameters or combinations of monitored parameters of the patient. For example, in an embodiment, the display includes a $SpaO_2$ graph **1172**. The $SpaO_2$ graph **1172** plots SpO_2 as a function of other blood analytes (1-$SpaO_2$), where $SpaO_2$ comprises HbO_2 expressed as a percentage of the four main hemoglobin species, i.e., HbO_2, Hb, HbCO, and HbMet. Thus, as shown in **Fig. 11C**, as the slope of the displayed line or arrow increases, the caregiver can readily note that the majority of hemoglobin carriers are being used to carry oxygen, and not, for example, harmful carbon monoxide. On the other hand, as the slope decreases, the caregiver can readily and advantageously note that the number of hemoglobin species available to carry oxygen is decreasing, regardless of the current value of SpO_2. Moreover, the length of the arrow or line also provides an indication of wellness, e.g., the higher the line the more oxygen saturation, the lower the line, the more likely there may be desaturation event, or the like.

[0093] Thus, the $SpaO_2$ graph **1172** provides the caregiver with the ability to recognize that even though the measured value of SpO_2 may be within acceptable ranges, there are potentially an unacceptable number of hemoglobin carriers unavailable for carrying oxygen, and that other potential problems may exist, such as, for example, harmful carbon monoxide levels, or the like. In an embodiment, various alarm conditions may cause the graph **1172** to change color, flash, or any combination of alarm indications discussed in the forgoing. Moreover, **Fig. 11I** illustrates yet an additional display of the foregoing parameters.

[0094] An embodiment may also include the monitor **1100** advantageously defining regions of wellness/severity of the monitored patient. For example, because the graph **1172** comprises two dimensions, the monitor **1100** may advantageously define regions where the patient's measured physiological parameters are considered acceptable, regions where the patient is considered at risk, regions where the patient is critical, and the like. For example, one region of acceptability may include a high SpO_2 and a low 1-$SpaO_2$, another region of risk may include a high SpO_2 and a high 1-$SpaO_2$, and another critical region may include a low SpO_2 and a high 1-$SpaO_2$. Moreover, an artisan will recognize from the disclosure herein that different parameters may also be combined to provide readily identifiable indications of patient wellness.

[0095] In addition to or as an alternative to the two dimensional $SpaO_2$ graph **1172**, the monitor **1100** may also include a three dimensional graph, such as, for example, extending the graph **1172** along the variable of time. In this embodiment, the forgoing regions advantageously become three dimensional surfaces of wellness. Moreover, trend data may also be advantageously added to the surface to provide a history of when particular monitored parameters dipped in and out of various surfaces of wellness, risk, criticality, or the like. Such trend data could be color-coded, text identified, or the like. An artisan will also recognize that such surfaces may be dynamic. For example, measurements of HbCO > about 5 may dictate that trend data showing SpO_2 < about 90% should be considered critical; however, measurements of HbCO < about 5 may dictate only SpO_2 < about 85% would be critical. Again, an artisan will recognize from the disclosure herein

other parameter combinations to create a wide variety of wellness/critical regions or surfaces that provide readily available visual or audio indications of patient well being, trigger specific alarms, or the like.

[0096] Moreover, the monitor **1100** may advantageously employ enlargement or reorganization of parameter data based on, for example, the severity of the measurement. For example, the monitor **1100** may display values for HbCO in a small portion of the screen or in the background, and when HbCO begins to approach abnormal levels, the small portion may advantageously grown as severity increases, even in some embodiments to dominate the display. Such visual alarming can be combined with audio alarms such as announcements, alarms, rising frequencies, or the like, and other visual alarms such as flashing, coloration, or the like to assist a caregiver in noticing the increasing severity of a monitored parameter. In an embodiment, a location of the display of an alarming value is changed to be displayed in a larger display area, such as 1102, so as to be readily noticeable and its display values readily ascertainable.

[0097] Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **100** may advantageously be adapted to monitor or be included in a monitor capable of measuring physiological parameters other than those determined through absorption spectroscopy, such as, for example, blood pressure, ECG, EKG, respiratory rates, volumes, inputs for blood pressure sensors, acoustical sensors, and the like. Moreover, the monitor **100** may be adapted for wireless communication to and from the sensor **106**, and/or to and from other monitoring devices, such as, for example, multi-parameter or legacy monitoring devices.

[0098] Also, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

[0099] Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same

extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

WHAT IS CLAIMED IS:

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information.

2. The patient monitor of Claim 1, wherein the first display area and the second display area substantially comprise the common display area.

3. The patient monitor of Claim 1, wherein activation of a user input causes the common display area to change from displaying one of the first and second measured values to displaying the other of the first and second measured values.

4. The patient monitor of Claim 1, wherein the common display area changes from displaying one of the first and second measured values to displaying the other of the first and second measured values based on an occurrence of an event.

5. The patient monitor of Claim 4, wherein the event comprises receipt of a user input.

6. The patient monitor of Claim 4, wherein the event comprises one of the first and second measured parameters approaching one or more threshold values indicative of a worsening state of a patient.

7. The patient monitor of Claim 4, wherein the event comprises one of the first and second measured parameters alarming.

8. The patient monitor of Claim 4, wherein the event comprises expiration of a predetermined time.

9. The patient monitor of Claim 1, wherein the common display area defaults to displaying one of the first and second measured values.

10. The patient monitor of Claim 9, wherein the common display area changes from defaulting to said one of the first and second measured values, to automatically displaying a more critical one of the first and second measured value.

11. The patient monitor of Claim 1, wherein the first measured value comprises an invasively measured value.

12. The patient monitor of Claim 1, wherein the first measured value comprises a non-invasively measured value.

13. The patient monitor of Claim 1, wherein the first measured value comprises glucose.

14. The patient monitor of Claim 1, wherein the first measured value comprises an invasively measured value.

15. The patient monitor of Claim 1, wherein the first measured value comprises an indication of oxygen saturation and the second measured value comprises an indication of carbon monoxide saturation.

16. The patient monitor of Claim 1, wherein the first measured value comprises an indication of oxygen saturation and the second measured value comprises an indication of methemoglobin saturation.

17. The patient monitor of Claim 1, wherein the first measured value comprises an indication of carbon monoxide saturation and the second measured value comprises an indication of methemoglobin saturation.

18. The patient monitor of Claim 1, wherein an aspect of an alarm changes when the common display area changes from displaying one of the first and second measured values.

19. The patient monitor of Claim 17, wherein the aspect comprises a color.

20. The patient monitor of Claim 1, wherein an aspect of the display changes to illustrate a change in the severity of one of the first and second measured values.

21. The patient monitor of Claim 20, wherein the aspect comprises a display color.

22. The patient monitor of Claim 20, wherein the aspect comprises a display size.

23. The patient monitor of Claim 20, wherein the aspect comprises a display intensity.

24. A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

displaying a measurement of a first physiological parameter in a display location of an electronic display; and

replacing the display of the measurement of the first physiological parameter with a display of a measurement of a second physiological parameter in the display location.

25. The method of Claim 24, wherein at least one aspect of the display changes when the display changes from the measurement of the first physiological parameter to the display of the measurement of the second physiological parameter.

26. The method of Claim 24, wherein the first measured value comprises an invasively measured value.

27. The method of Claim 24, wherein the first measured value comprises an indication of oxygen saturation and the second measured value comprises an indication of carbon monoxide saturation.

28. The method of Claim 24, wherein the first measured value comprises an indication of oxygen saturation and the second measured value comprises an indication of methemoglobin saturation.

29. The method of Claim 24, wherein wherein the first measured value comprises an indication of carbon monoxide saturation and the second measured value comprises an indication of methemoglobin saturation.

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30. A physiological monitor comprising:

a processor capable of outputting values for at least two physiological parameters; and

a display including a graphical representation which at a point in time indicates a first state of one of the at least two measured physiological parameters and a second state of another of the at least two measured physiological parameters.

31. The physiological monitor of Claim 30, wherein first and second states reflect substantially a same period of time.

32. The physiological monitor of Claim 30, comprising an indicator capable of alerting a user that one or more of the at least two measured physiological parameters is approaching a predetermined threshold.

33. The physiological monitor of Claim 32, wherein the indicator comprises an audible indicator.

34. The physiological monitor of Claim 32, wherein the indicator comprises an graphical indicator.

35. The physiological monitor of Claim 30, wherein the graphical representation comprises a three dimensional graphical representation.

36. The physiological monitor of Claim 30, wherein the graphical representation associates a default color with each of the display of the first and second measured parameters.

37. The physiological monitor of Claim 30, wherein the graphical representation associates a default line weight with each of the display of the first and second measured parameters.

38. The physiological monitor of Claim 30, wherein the display comprises a first designated area for displaying information related to normal physiological conditions and a second designated area for displaying information related to non-normal physiological parameters.

39. The physiological monitor of Claim 30, wherein the display of one of the at least two measured physiological parameters comprises a function of the other of the at least two measured physiological parameters.

40. The physiological monitor of Claim 39, wherein the display comprises a parametric graph.

41. The physiological monitor of Claim 30, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.

42. The physiological monitor of Claim 30, wherein at least one of measured physiological parameters is determined noninvasively.

43. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

44. The patient monitor of Claim 43, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.

45. The patient monitor of Claim 44, comprising an additional display capable of indicating the percent carbon monoxide saturation.

46. The patient monitor of Claim 44, comprising an additional display capable of indicating the percent methemoglobin saturation.

47. The patient monitor of Claim 43, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate.

48. The patient monitor of Claim 47, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.

49. The patient monitor of Claim 47, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

50. The patient monitor of Claim 43, wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

51. The patient monitor of Claim 43, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.

52. The patient monitor of Claim 43, wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

53. The patient monitor of Claim 52, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.

54. The patient monitor of Claim 52, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button.

55. The patient monitor of Claim 43, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.

56. The patient monitor of Claim 43, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.

57. The patient monitor of Claim 43, wherein the attached sensor can provide data through the output signal and through a memory device.

58. The patient monitor of Claim 43, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.

59. The patient monitor of Claim 43, further comprising a memory for storing trend data on one or more of the first and second blood parameters.

60. The patient monitor of Claim 43, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.

61. The patient monitor of Claim 43, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.

62. The patient monitor of Claim 61, wherein the alarm comprises at least one of an audio or visual alarm.

63. The patient monitor of Claim 43, further comprising an additional display indicating perfusion through the body tissue.

Noninvasive Multi-Parameter Patient Monitor

Abstract of the Disclosure

[0100] Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.

PATENT

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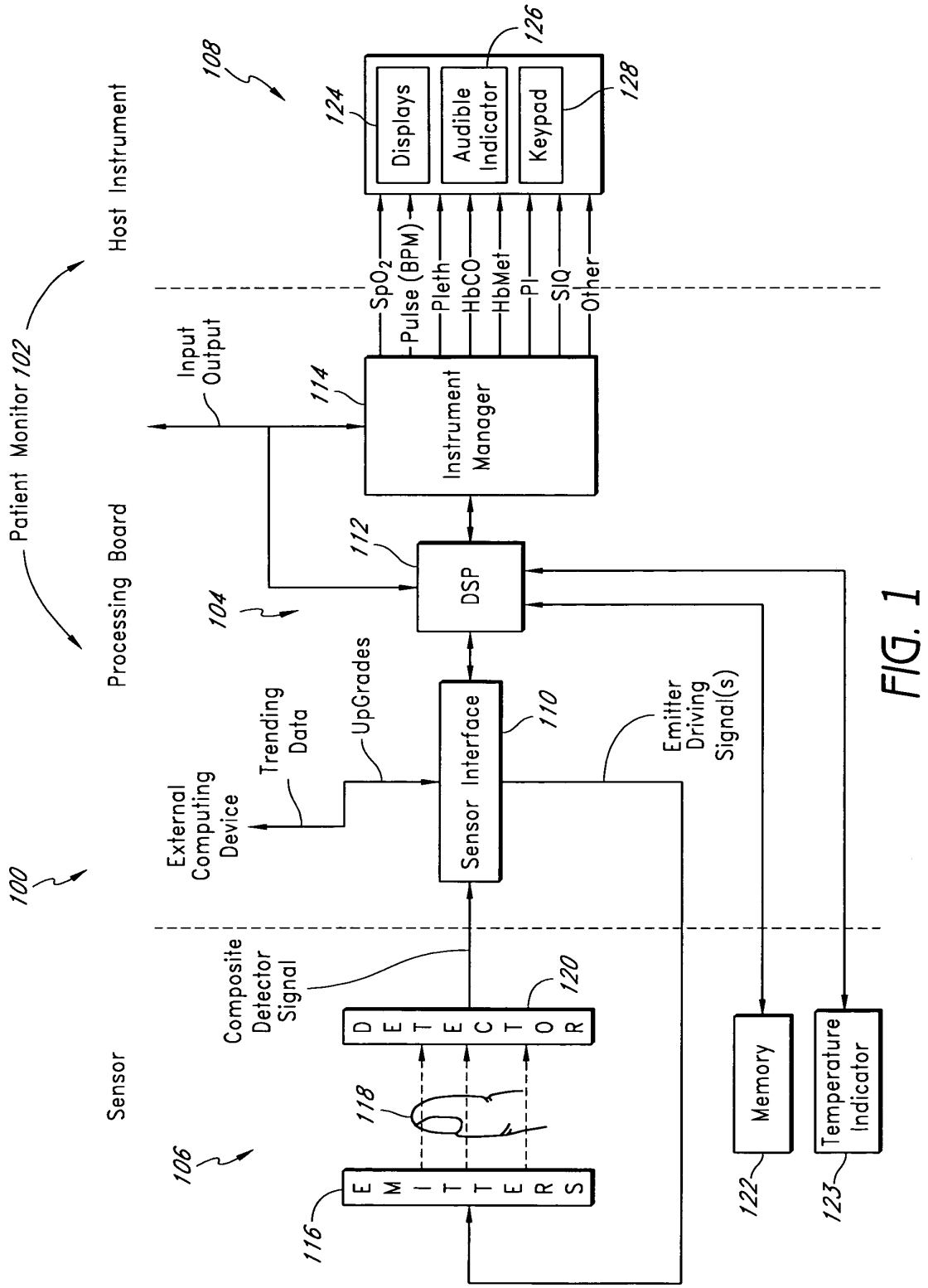

Patient Monitor 102
Host Instrument
Processing Board
Sensor
100
108
124
Displays
126
Audible Indicator
128
Keypad
SpO2
Pulse (BPM)
Pleth
HbCO
HbMet
PI
SIQ
Other
Input
Output
114
Instrument Manager
112
DSP
104
Trending Data
UpGrades
Sensor Interface
110
Emitter Driving Signal(s)
External Computing Device
Composite Detector Signal
DETECTOR
120
118
EMITTERS
116
Memory
122
Temperature Indicator
123
106

FIG. 1

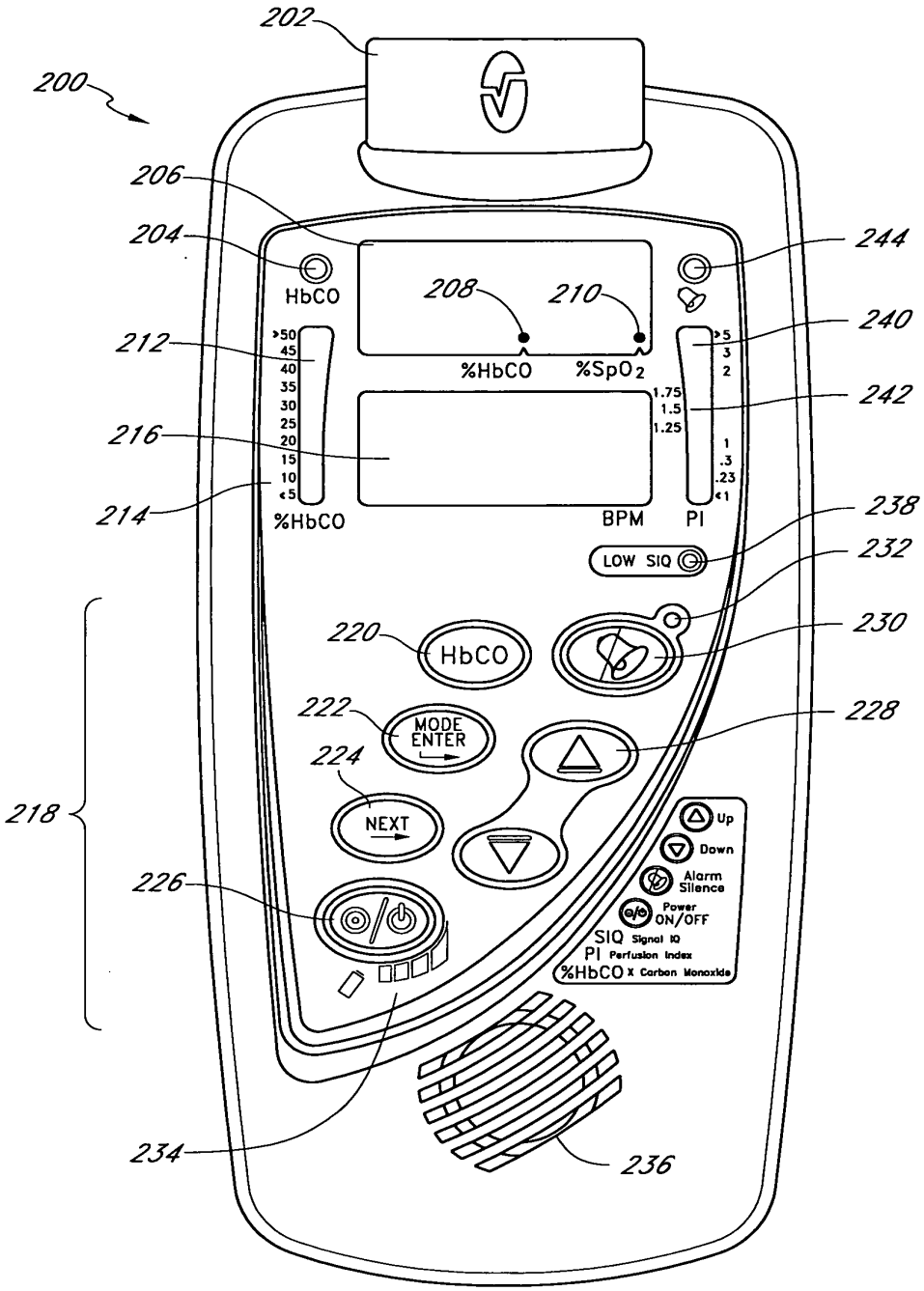

202
200
206
204
244
HbCO
208
210
240
212
%HbCO
%SpO2
242
216
214
%HbCO
BPM
PI
238
LOW SIQ
232
220
HbCO
230
222
MODE ENTER
228
224
218
NEXT
Up
Down
Alarm Silence
Power ON/OFF
SIQ Signal IQ
PI Perfusion Index
%HbCO x Carbon Monoxide
226
234
236

FIG. 2

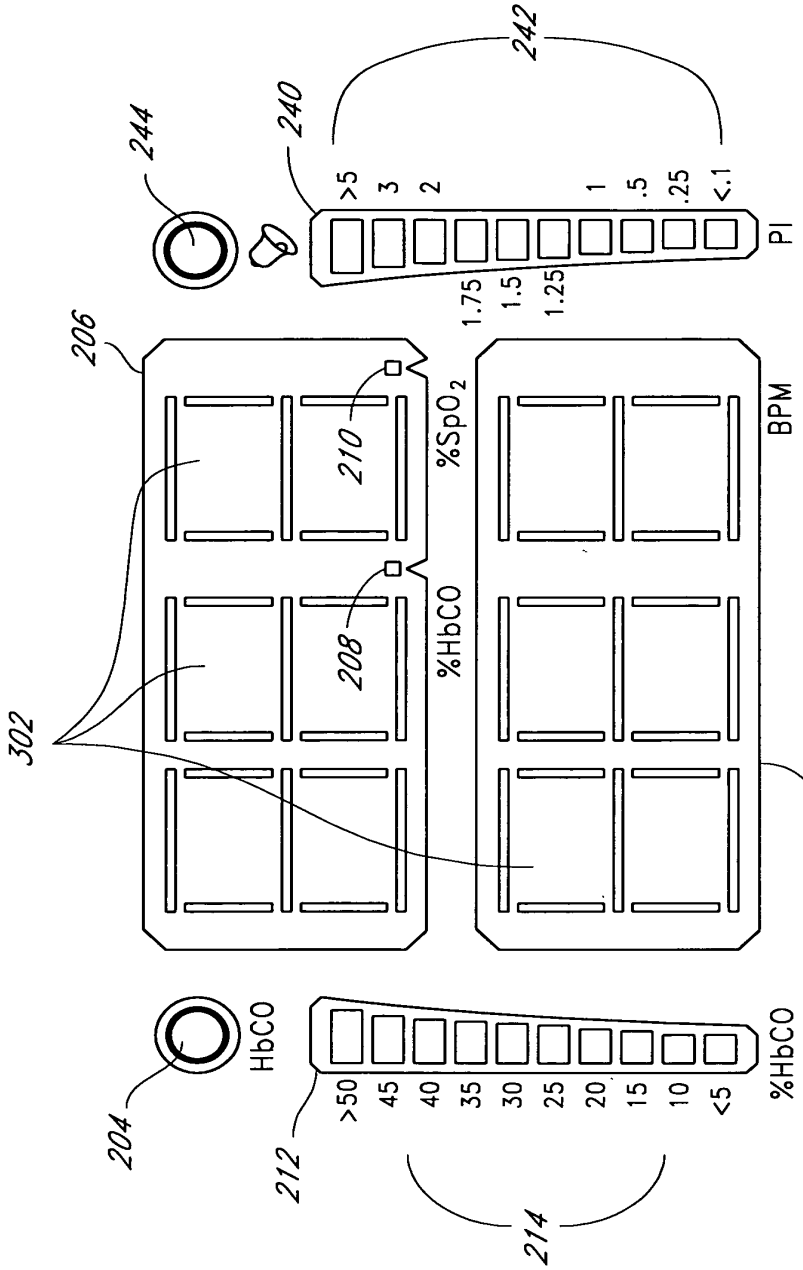

242
240
244
>5
3
2
1
.5
.25
<.1
PI
1.75
1.5
1.25
206
210
%SpO2
BPM
208
%HbCO
302
216
HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO
214

FIG. 3

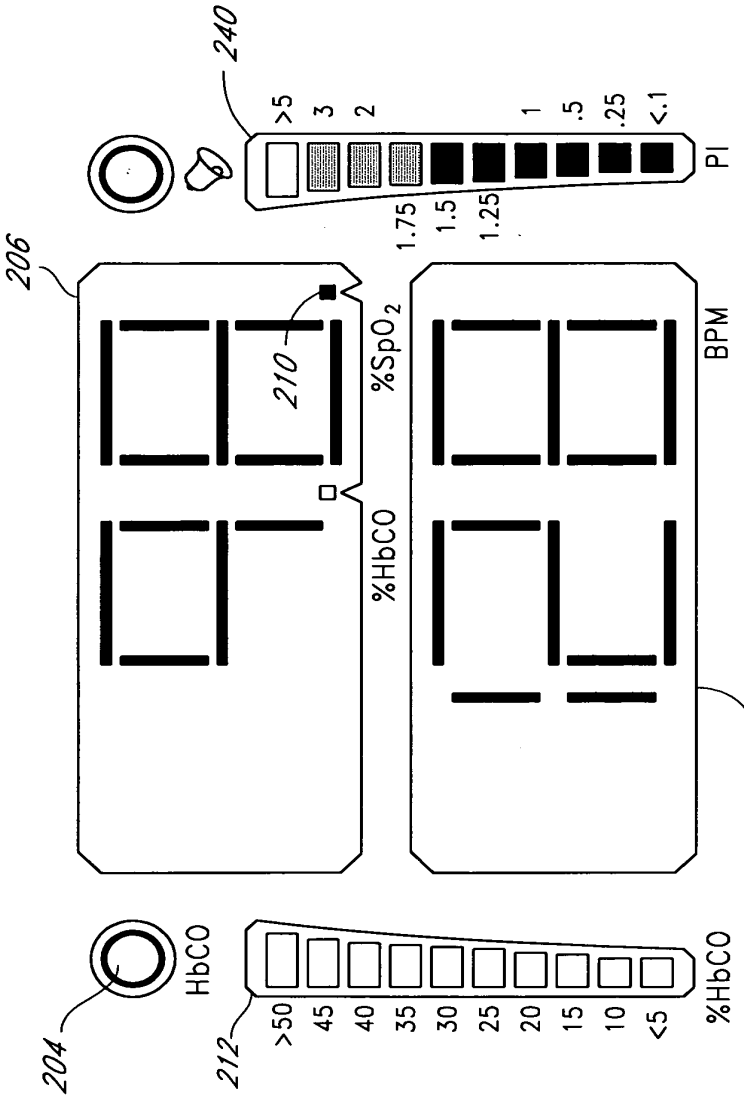

240
>5
3
2
1
.5
.25
<.1
PI
1.75
1.5
1.25
206
210
%SpO2
BPM
%HbCO
216
HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 4

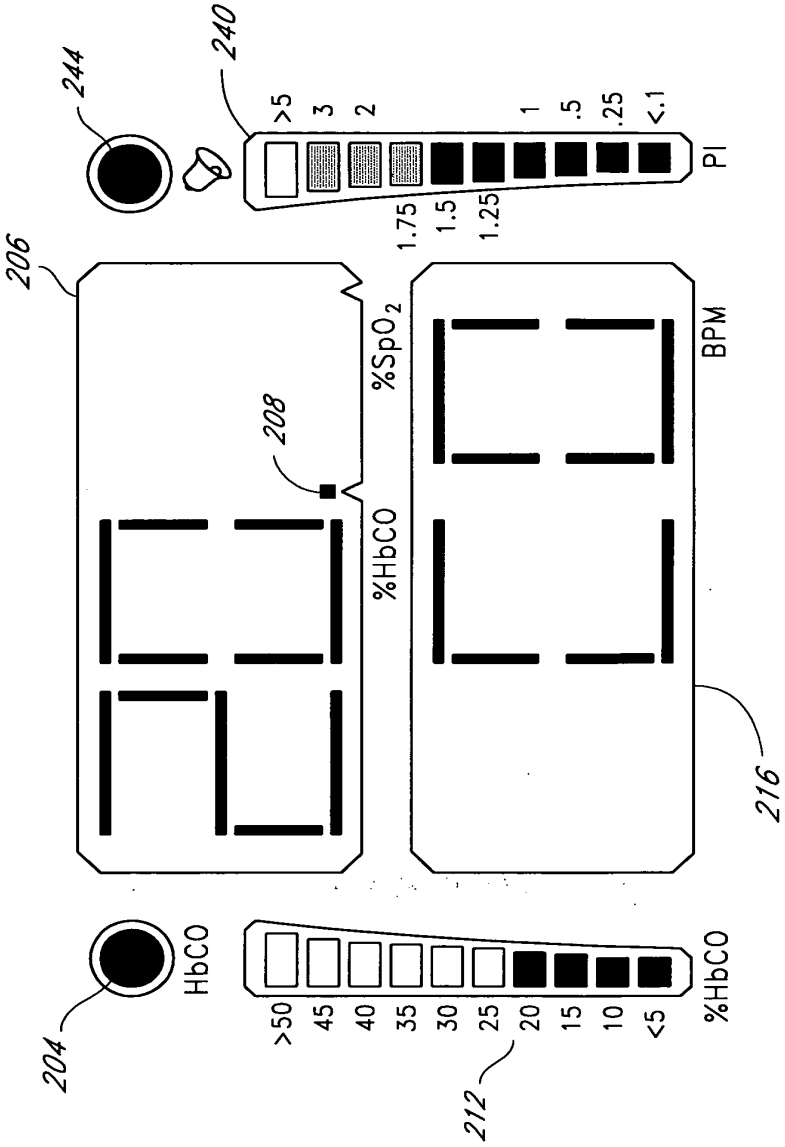

244
240
>5
3
2
1
.5
.25
<.1
PI
1.75
1.5
1.25
206
%SpO2
BPM
208
%HbCO
216
HbCO
204
>50
45
40
35
30
25
20
15
10
<5
%HbCO
212

FIG. 5

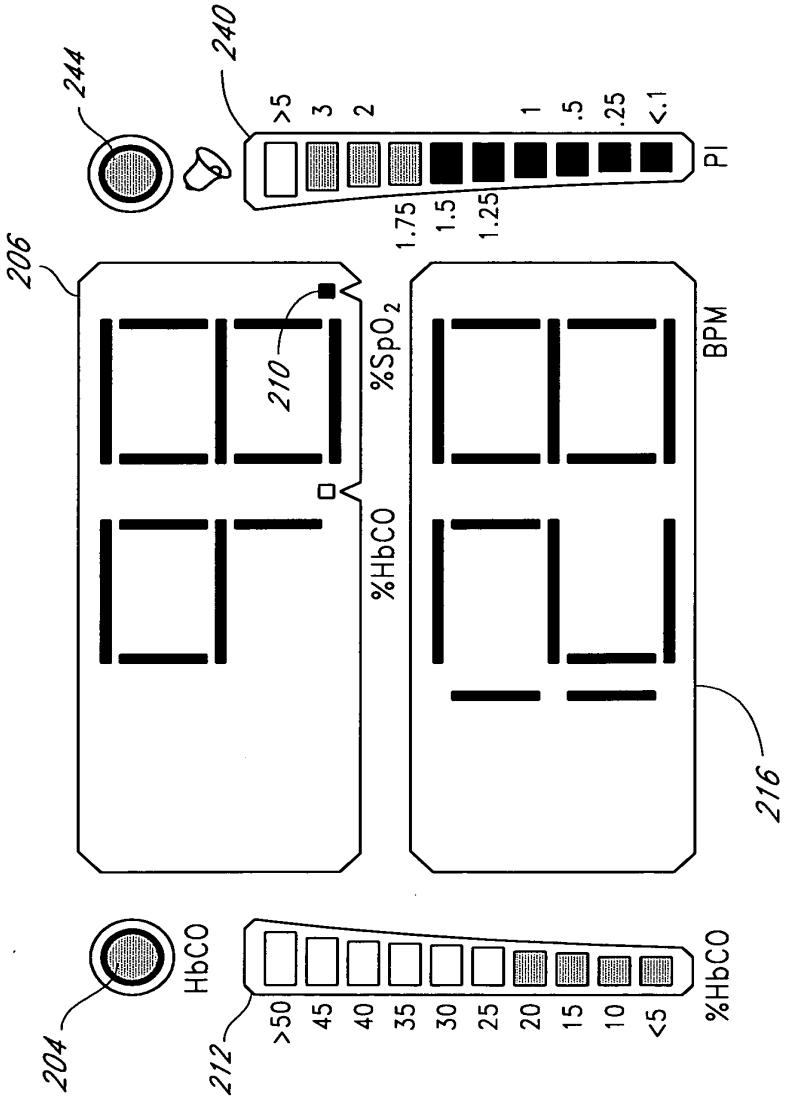

240
244
>5
3
2
1
.5
.25
<.1
PI
1.75
1.5
1.25
206
210
%SpO2
BPM
%HbCO
216
HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 6

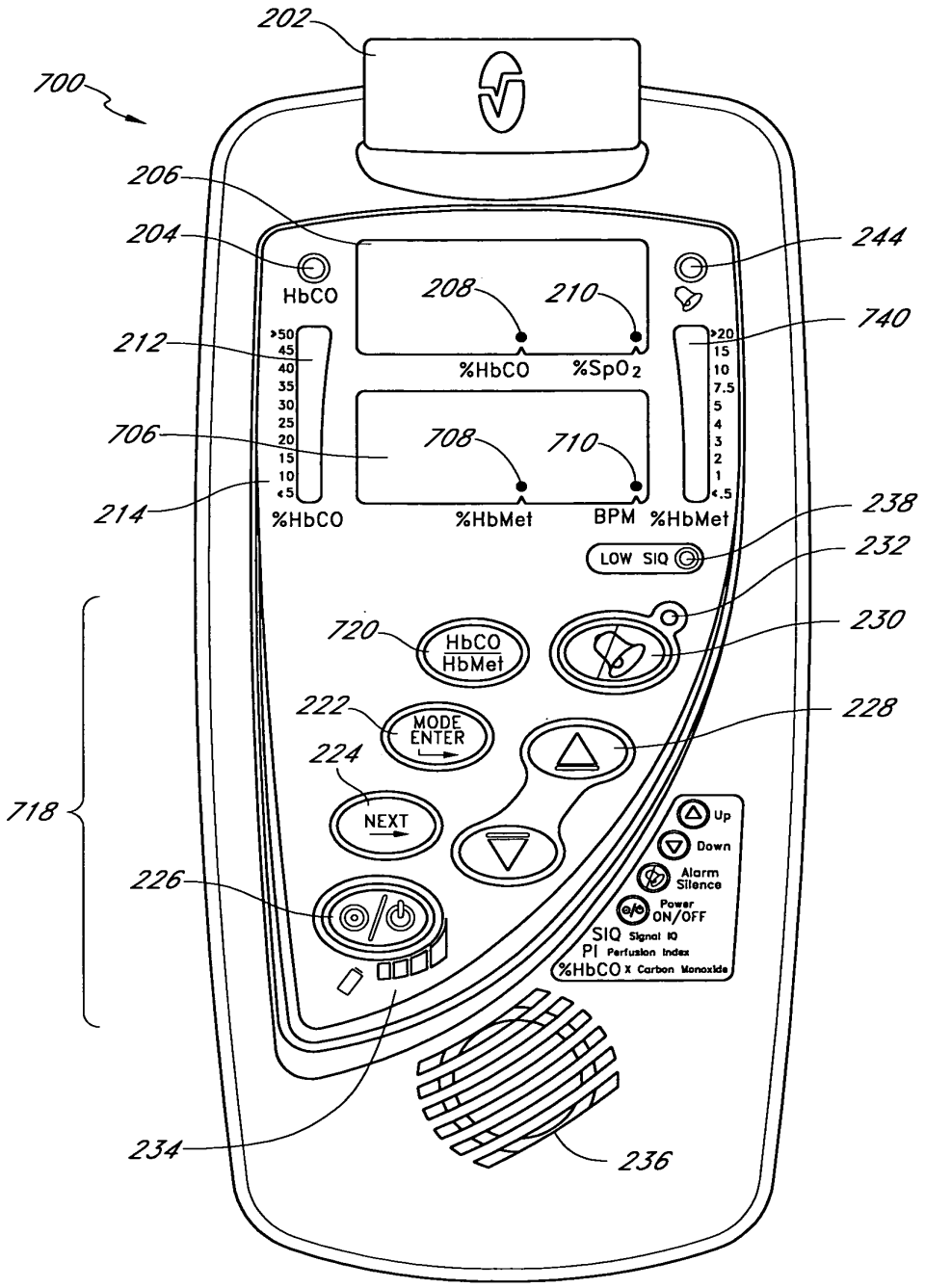

202
700
206
204
244
HbCO
208
210
740
212
%HbCO
%SpO2
706
708
710
214
%HbCO
%HbMet
BPM
%HbMet
238
LOW SIQ
232
720
HbCO
HbMet
230
222
MODE
ENTER
228
224
718
NEXT
Up
Down
Alarm
Silence
Power
ON/OFF
SIQ Signal IQ
PI Perfusion Index
%HbCO x Carbon Monoxide
226
234
236

FIG. 7

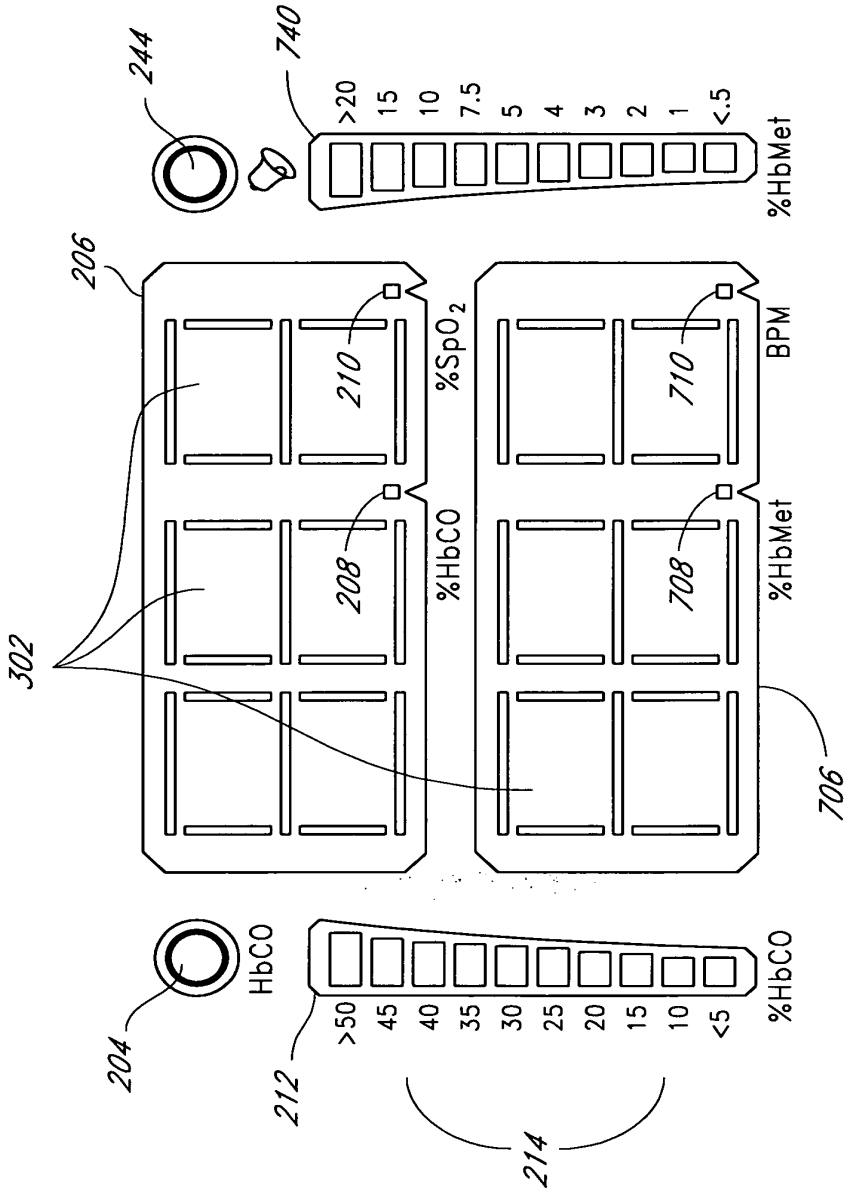

244
740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
710
BPM
208
%HbCO
708
%HbMet
302
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO
214

FIG. 8

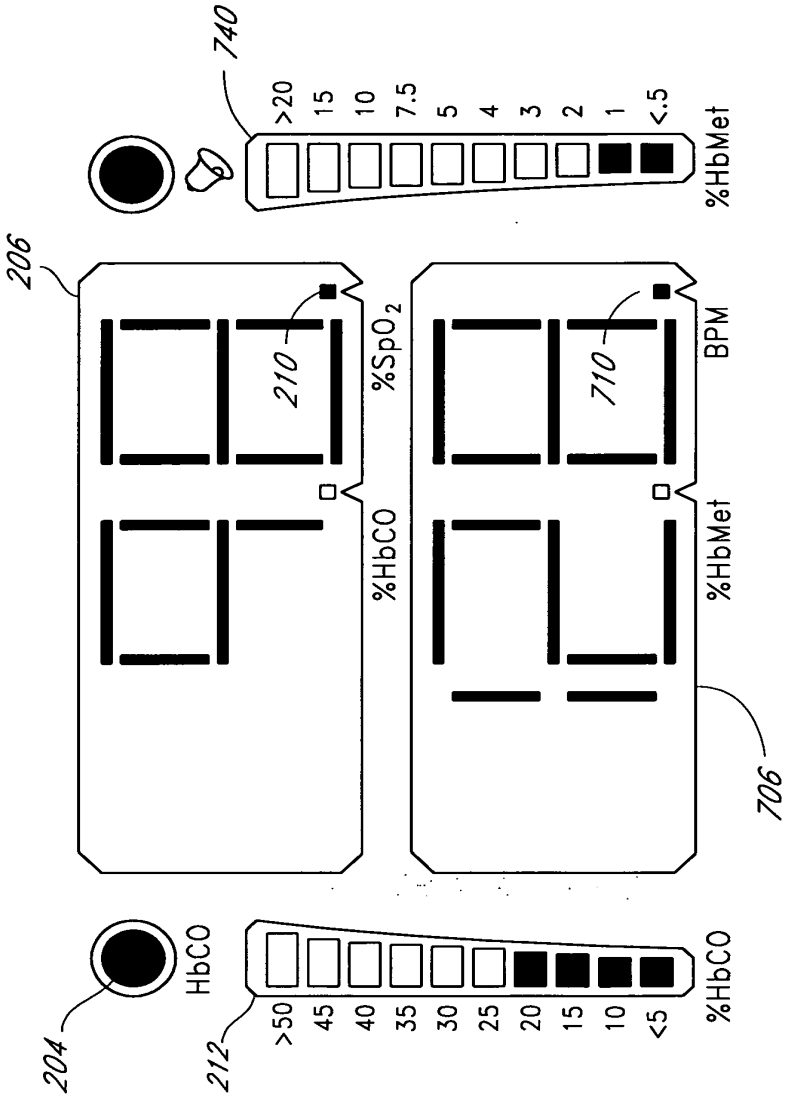

740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
%HbCO
710
BPM
%HbMet
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 9

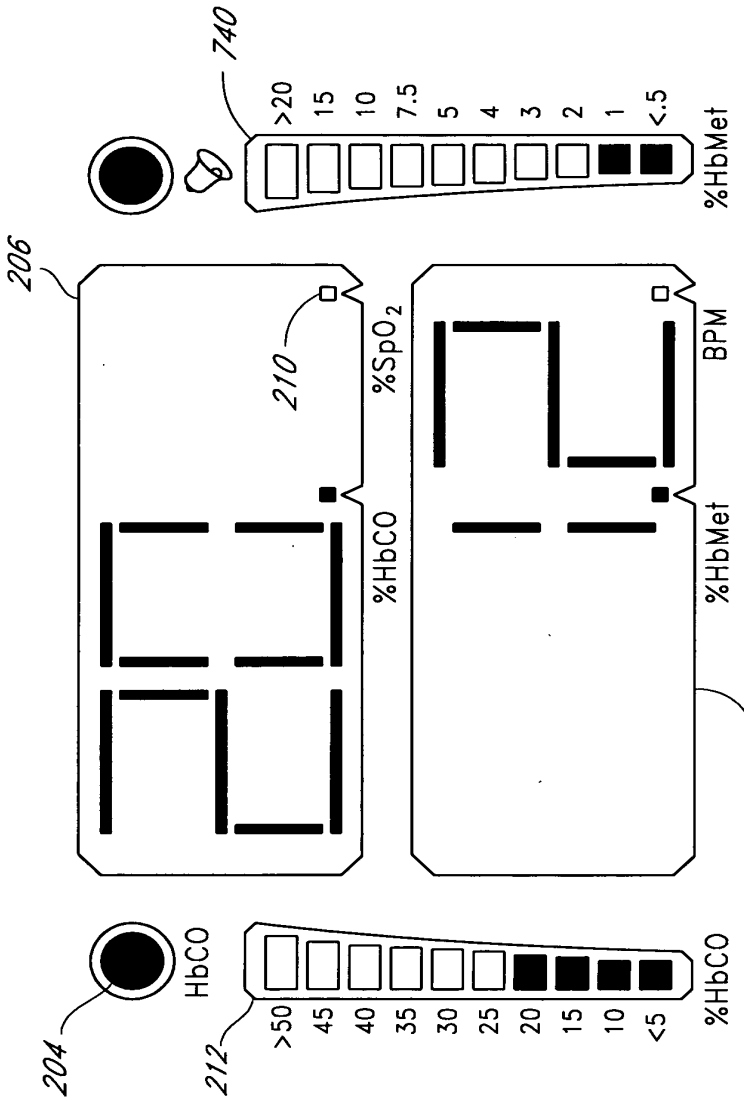

740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
%HbCO
BPM
%HbMet
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 10

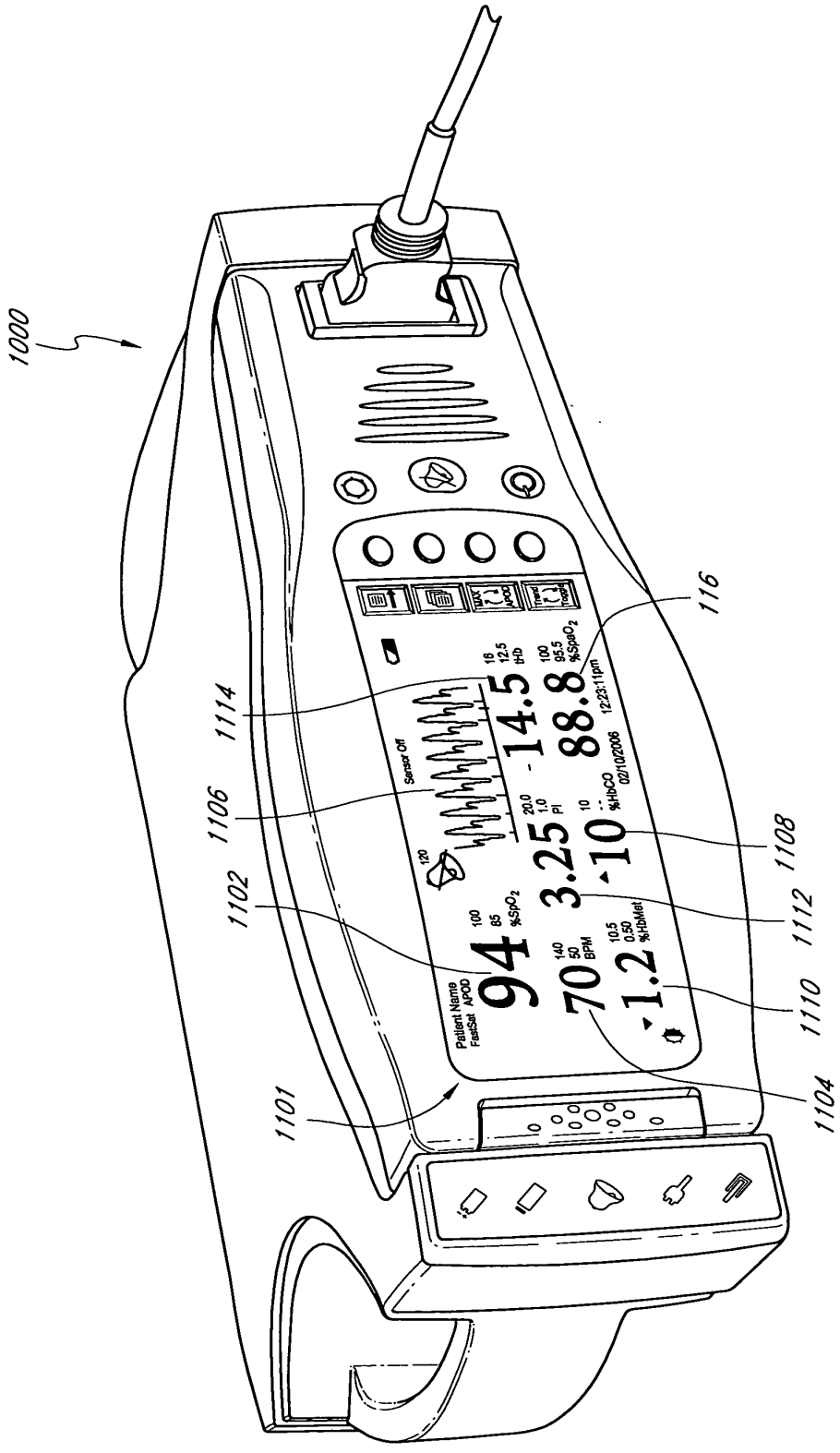

1000
1114
116
1106
1102
1108
1112
1110
1104
1101
Sensor Off
Patient Name
FastSat APOD
94
70
3.25
14.5
88.8
10
1.2
%SpO2
BPM
%HbCO
%HbMet
%SpO2
Hb
PI
02/10/2006
12:23:11pm

FIG. 11A

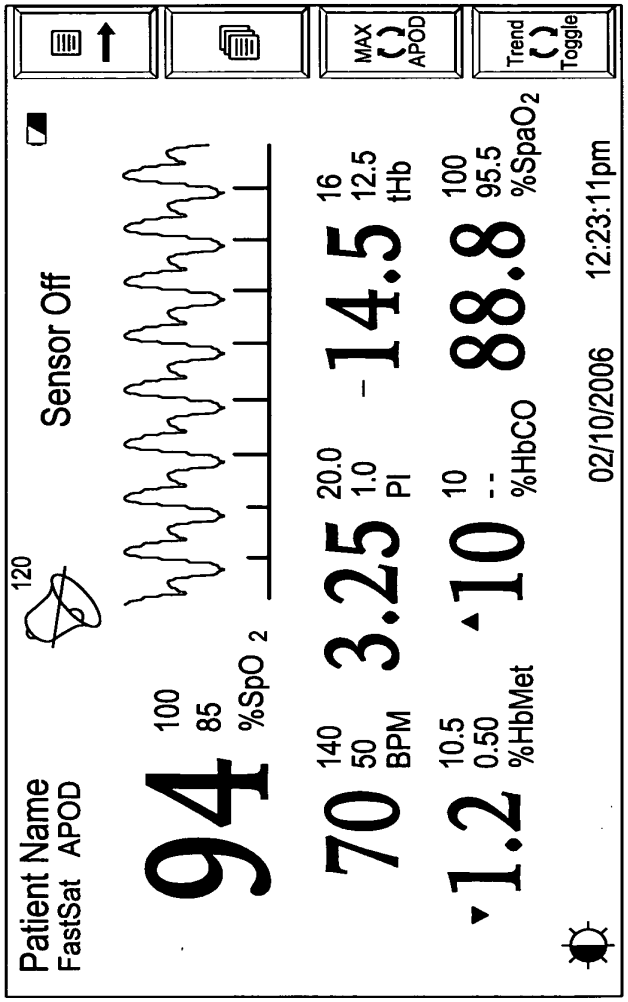

MAX APOD
Trend Toggle
Patient Name
FastSat APOD
Sensor Off
120
100
85
%SpO 2
94
140
50
BPM
70
10.5
0.50
%HbMet
1.2
3.25
20.0
1.0
PI
10
--
%HbCO
10
14.5
16
12.5
tHb
88.8
100
95.5
%SpaO2
02/10/2006
12:23:11pm

FIG. 11B

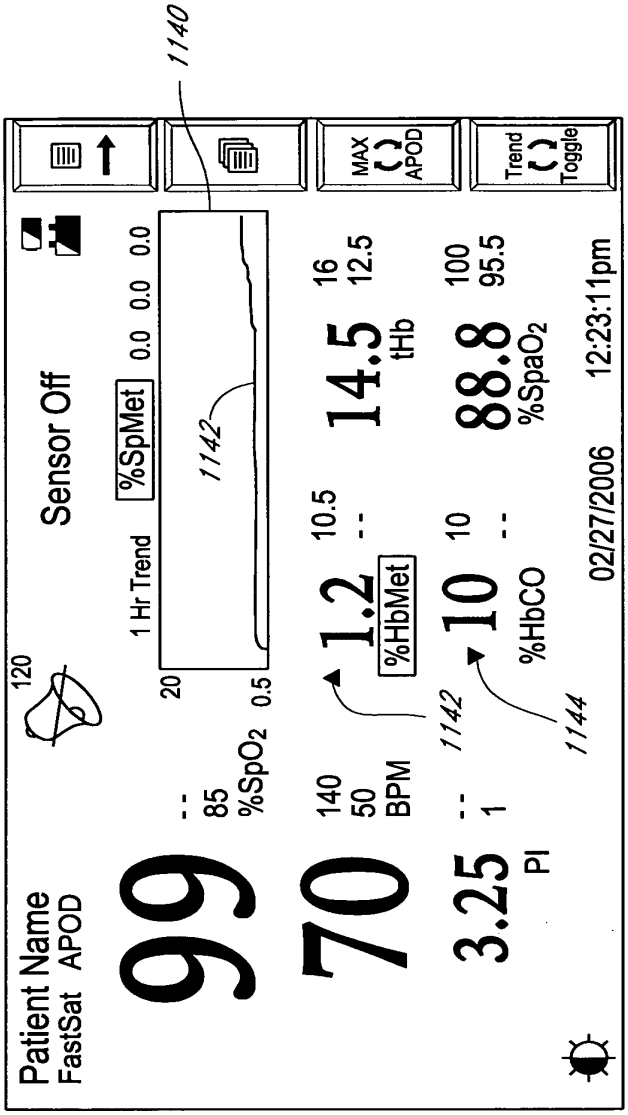

1140
MAX APOD
Trend Toggle
Patient Name
FastSat APOD
Sensor Off
120
1 Hr Trend
%SpMet
0.0 0.0 0.0
1142
20
0.5
99
-- 85 %SpO2
70
140 50 BPM
1.2
10.5 -- %HbMet
14.5
16 12.5 tHb
88.8
100 95.5 %SpaO2
3.25
-- 1 PI
10
10 -- %HbCO
1142
1144
02/27/2006
12:23:11pm

FIG. 11C

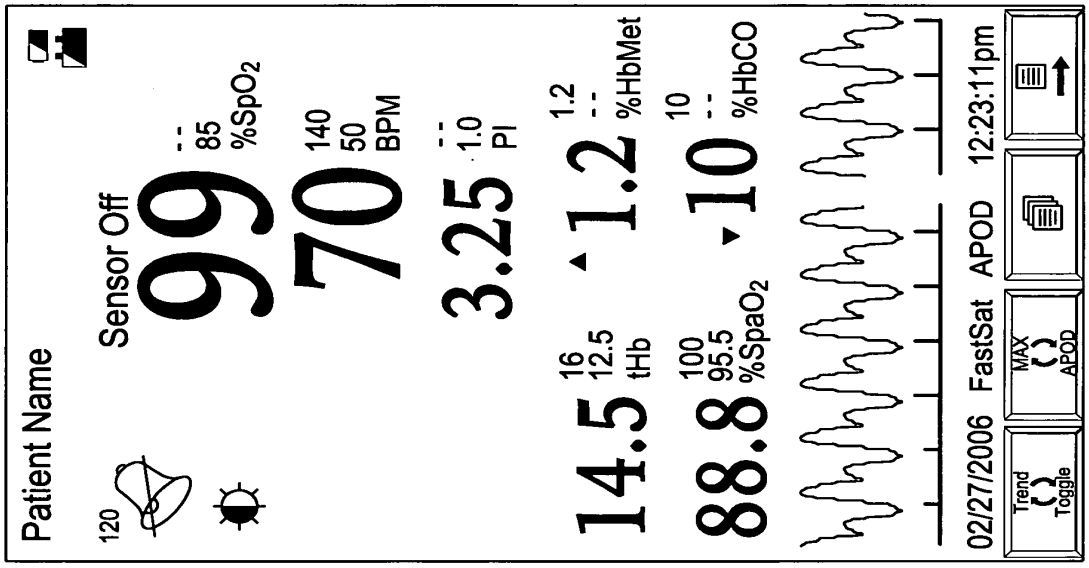

Patient Name
Sensor Off
99
85
%SpO2
70
140
50
BPM
3.25
1.0
PI
14.5
16
12.5
tHb
1.2
1.2
%HbMet
88.8
100
95.5
%SpaO2
10
10
%HbCO
120
02/27/2006
FastSat
APOD
12:23:11pm
Trend
Toggle
MAX
APOD

FIG. 11D

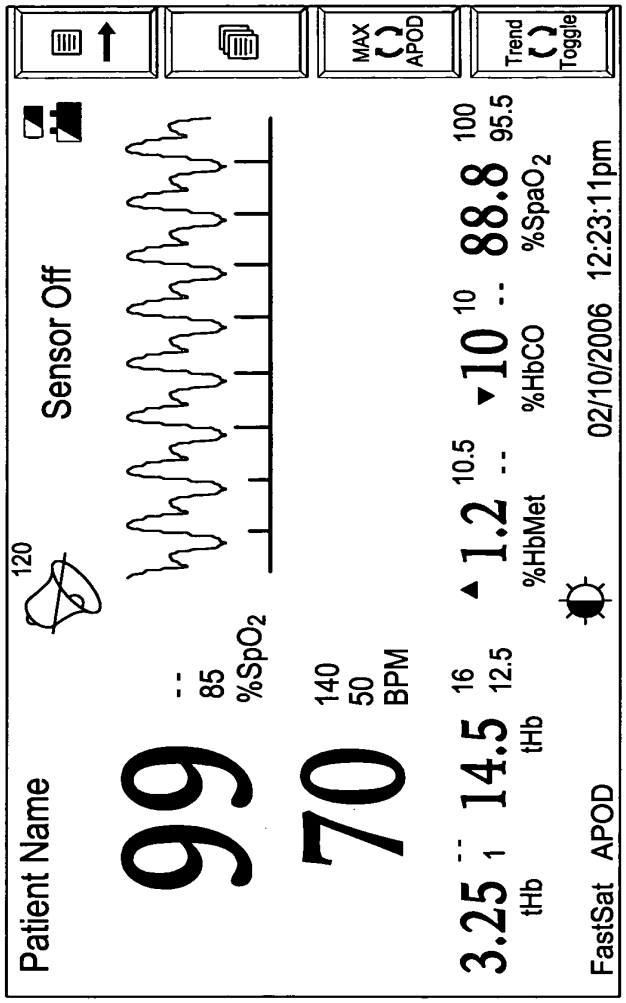

MAX APOD
Trend Toggle
Patient Name
Sensor Off
120
99
%SpO2
85
70
140
50
BPM
3.25
tHb
14.5
tHb
16
12.5
1.2
%HbMet
10.5
10
%HbCO
88.8
%SpaO2
100
95.5
FastSat APOD
02/10/2006 12:23:11pm

FIG. 11E

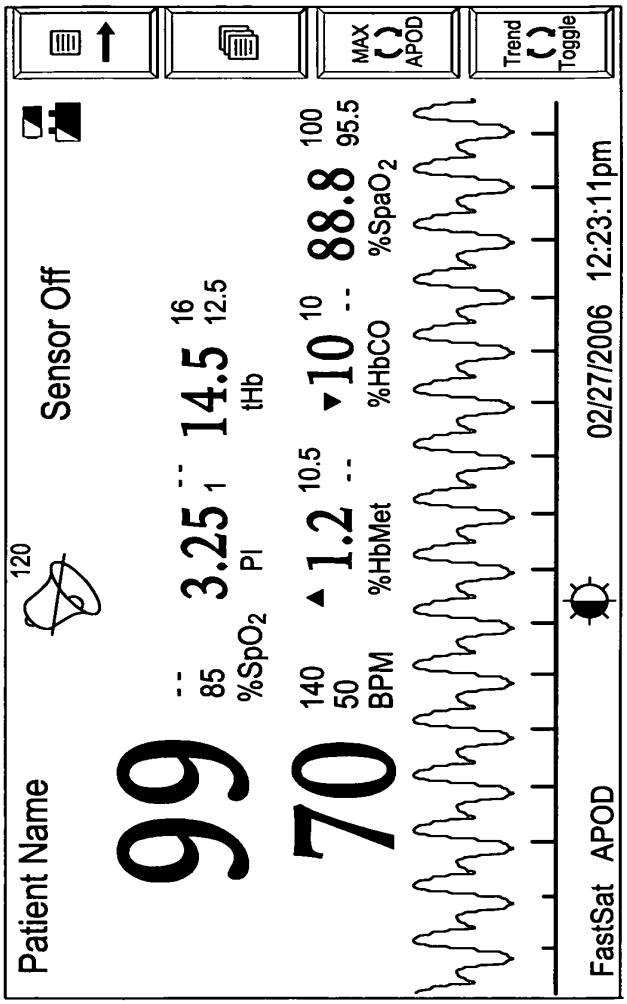

Patient Name
120
Sensor Off
MAX APOD
Trend Toggle
99
-- 85
%SpO2
3.25
-- 1
PI
14.5
16 12.5
tHb
70
140 50
BPM
1.2
10.5 --
%HbMet
10
10 --
%HbCO
88.8
100 95.5
%SpaO2
FastSat APOD
02/27/2006 12:23:11pm

FIG. 11F

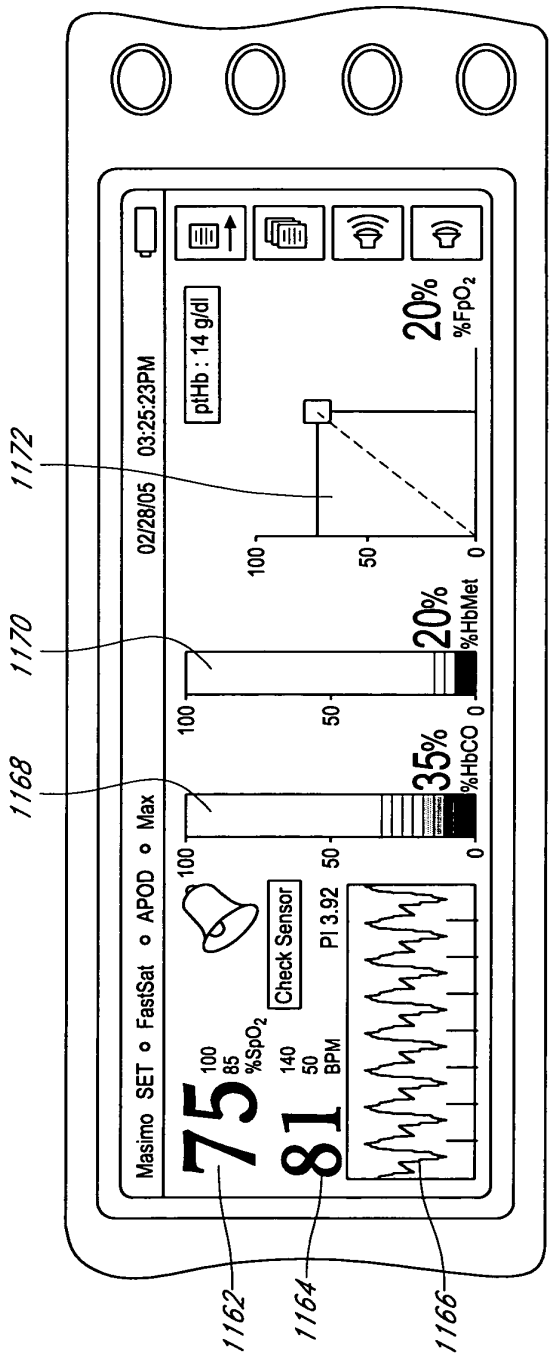

1172
1170
1168
1162
1164
1166
Masimo SET ○ FastSat ○ APOD ○ Max
02/28/05
03:25:23PM
ptHb : 14 g/dl
20% %FpO2
20% %HbMet
35% %HbCO
100
50
0
Check Sensor
PI 3.92
75
81
100
85
%SpO2
140
50
BPM

FIG. 11G

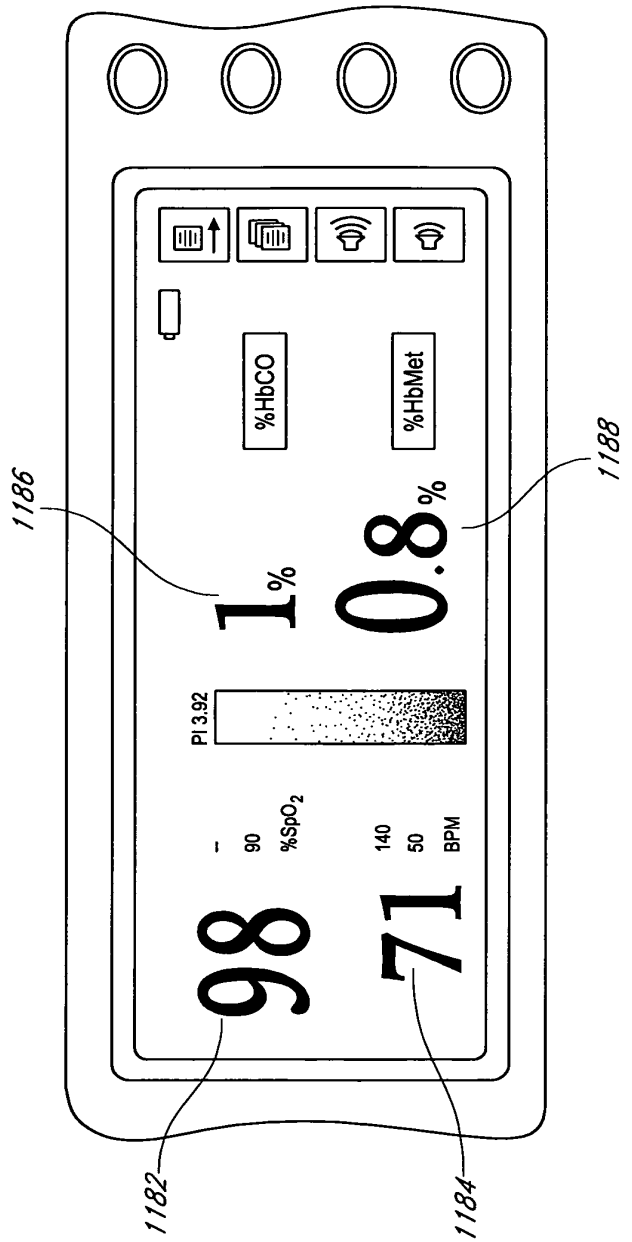

%HbCO
%HbMet
1%
0.8%
PI 3.92
90
%SpO2
140
50
BPM
98
71
1186
1188
1182
1184

FIG. 11H

PTO/SB/06 (12-04)
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PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number: 11367033

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))				150			300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))				250			500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))				100			200
TOTAL CLAIMS (37 CFR 1.16(i))	63 minus 20 =	* 43	X$ 25=		OR	X$50=	2150
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1	X$100=			X$200=	200
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			180			360	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	3350

APPLICATION AS AMENDED – PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDI-TIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDI-TIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					180		OR	360	
					TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDI-TIONAL FEE ($)	OR	RATE ($)	ADDI-TIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
					TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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