US 20060211925A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2006/0211925 A1

Lamego et al. (43) Pub. Date: Sep. 21, 2006

(54) PHYSIOLOGICAL PARAMETER CONFIDENCE MEASURE

(76) Inventors: **Marcelo Lamego**, Rancho Santa Margarita, CA (US); **Mohamed Diab**, Mission Viejo, CA (US); **Ammar Al-Ali**, Tustin, CA (US)

Correspondence Address:
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614 (US)

(21) Appl. No.: **11/367,034**

(22) Filed: **Mar. 1, 2006**

Related U.S. Application Data

(60) Provisional application No. 60/657,596, filed on Mar. 1, 2005. Provisional application No. 60/657,281, filed on Mar. 1, 2005. Provisional application No. 60/657,268, filed on Mar. 1, 2005. Provisional application No. 60/657,759, filed on Mar. 1, 2005.

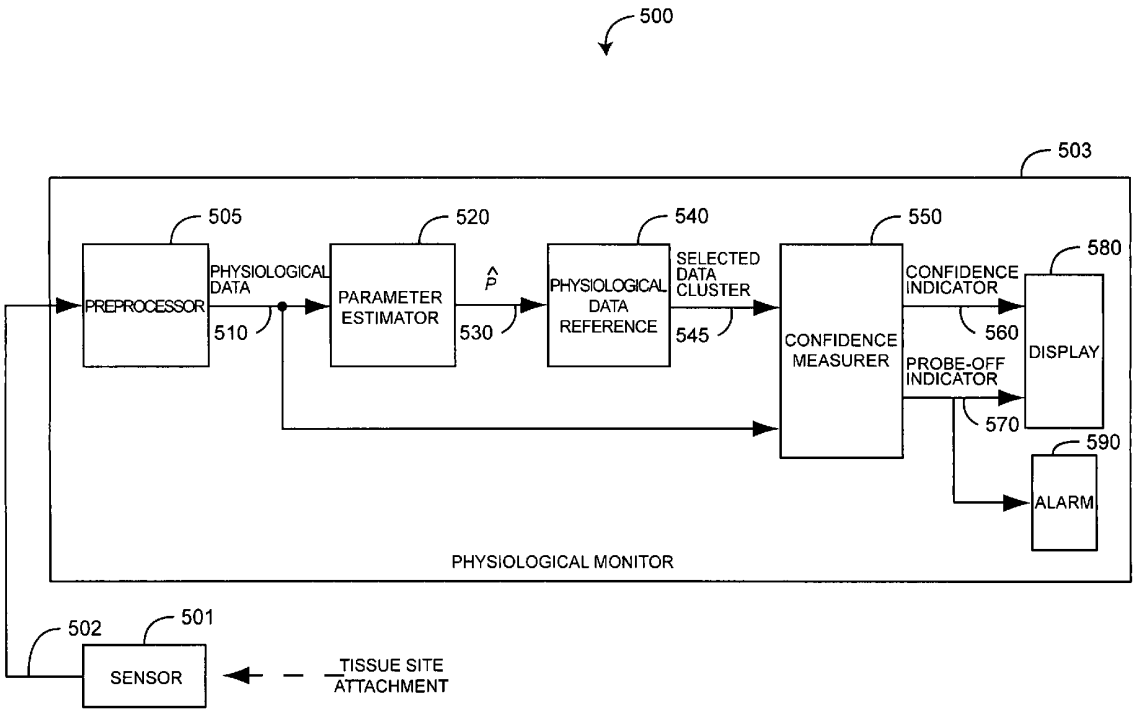
Publication Classification

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/310**; 600/322

(57) **ABSTRACT**

Confidence in a physiological parameter is measured from physiological data responsive to the intensity of multiple wavelengths of optical radiation after tissue attenuation. The physiological parameter is estimated based upon the physiological data. Reference data clusters are stored according to known values of the physiological parameter. At least one of the data clusters is selected according to the estimated physiological parameter. The confidence measure is determined from a comparison of the selected data clusters and the physiological data.



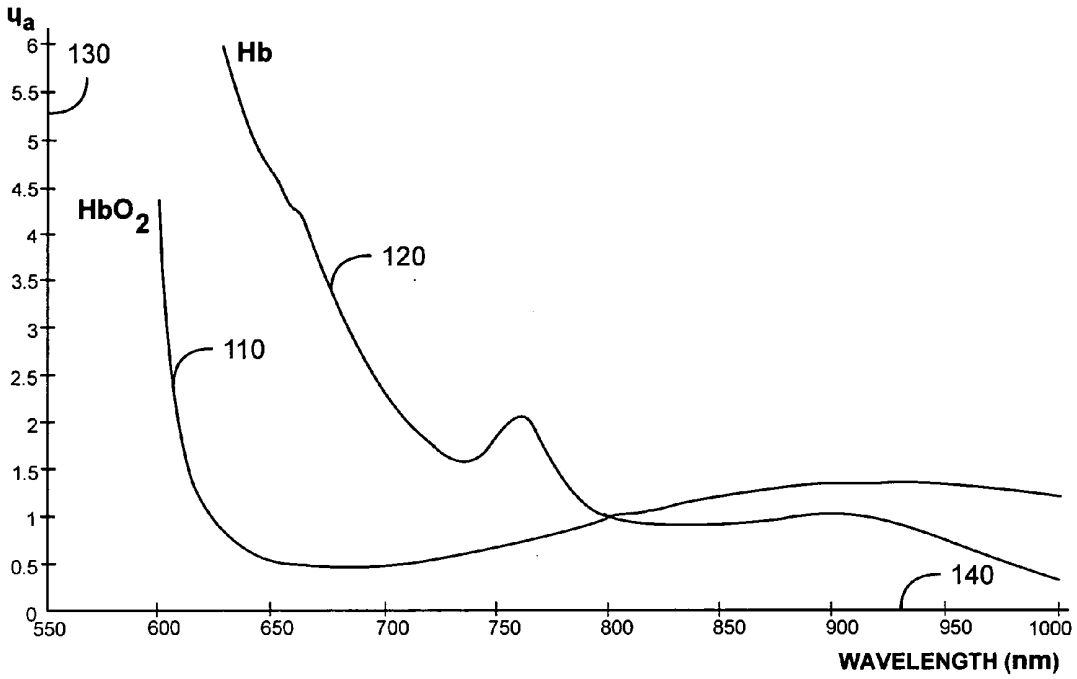

μ_a
130
Hb
HbO_2
120
110
140
6
5.5
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
550
600
650
700
750
800
850
900
950
1000
WAVELENGTH (nm)

FIG. 1

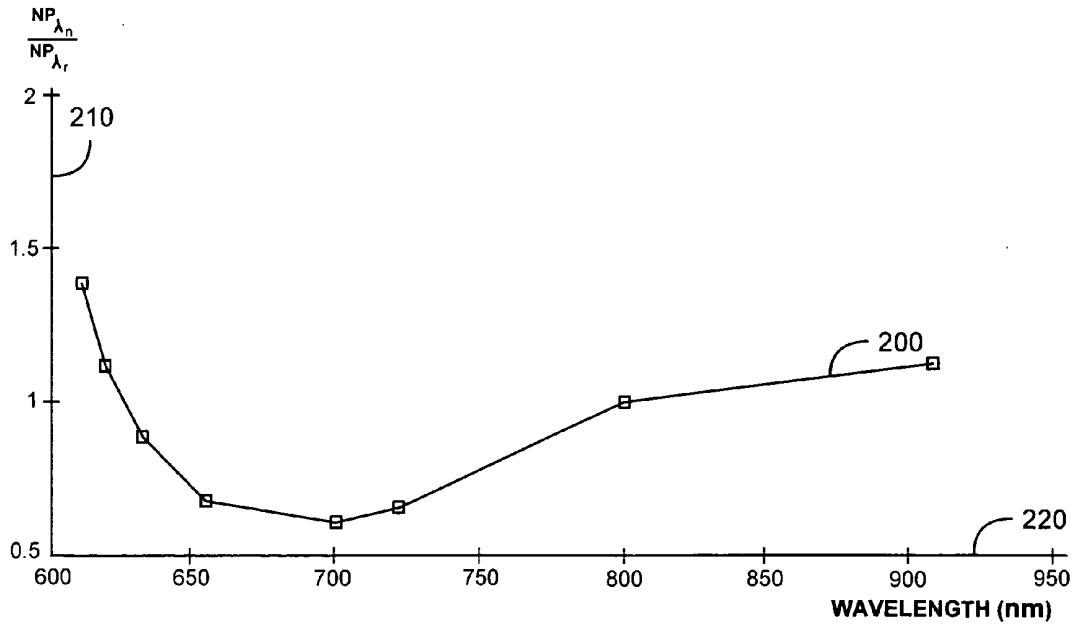

$\frac{NP_{\lambda_n}}{NP_{\lambda_r}}$
210
200
220
2
1.5
1
0.5
600
650
700
750
800
850
900
950
WAVELENGTH (nm)

FIG. 2

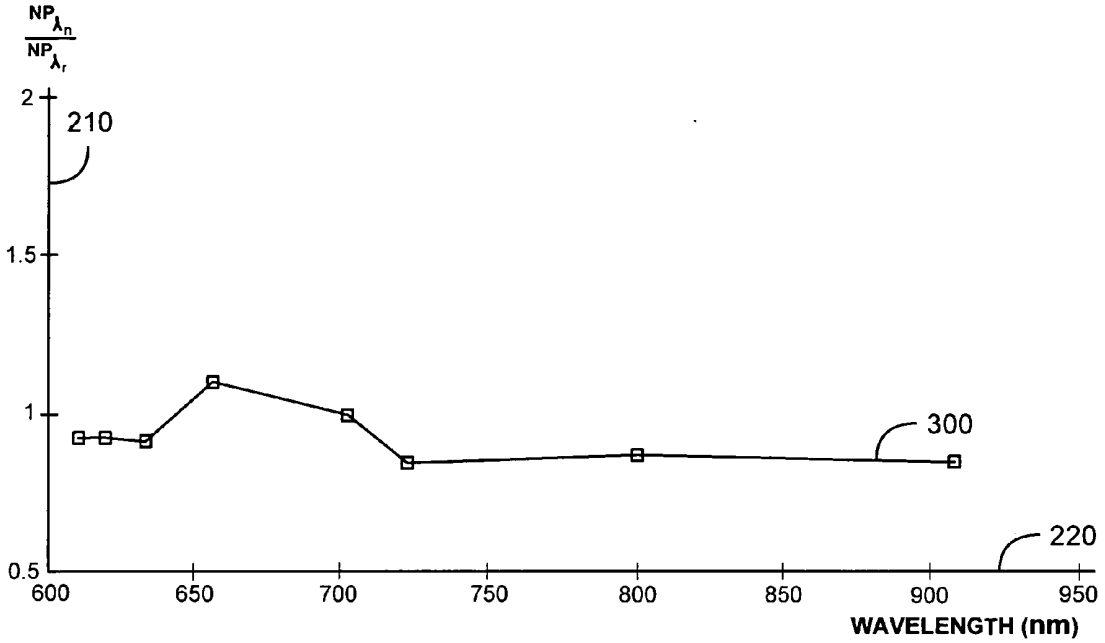

$\frac{NP_{\lambda_n}}{NP_{\lambda_r}}$
2
1.5
1
0.5
210
300
220
600
650
700
750
800
850
900
950
WAVELENGTH (nm)

FIG. 3

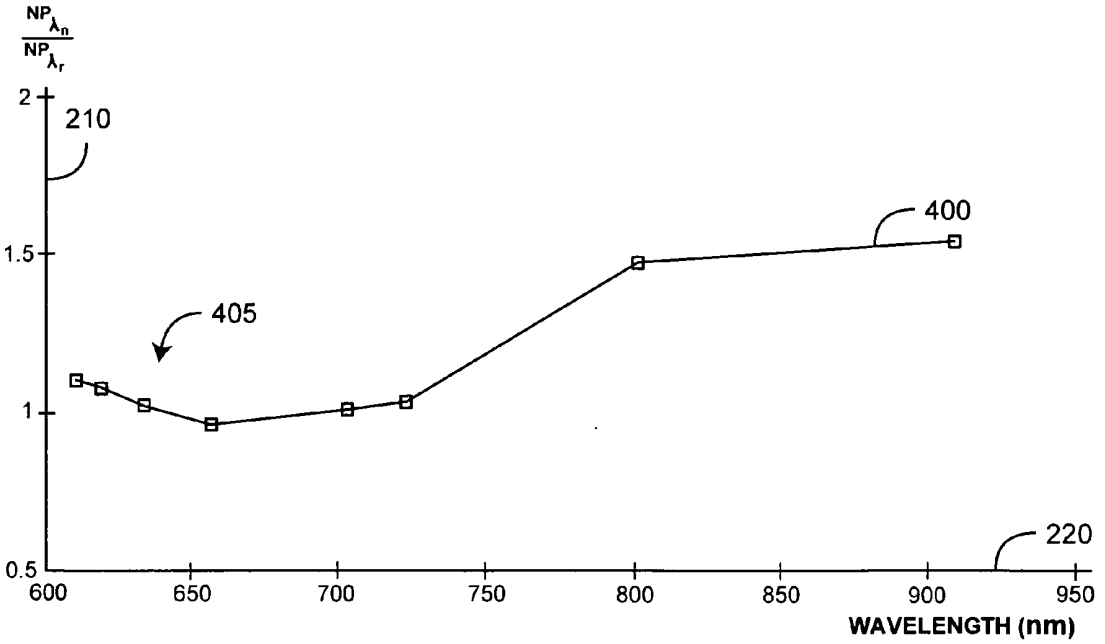

$\frac{NP_{\lambda_n}}{NP_{\lambda_r}}$
2
1.5
1
0.5
210
400
405
220
600
650
700
750
800
850
900
950
WAVELENGTH (nm)

FIG. 4

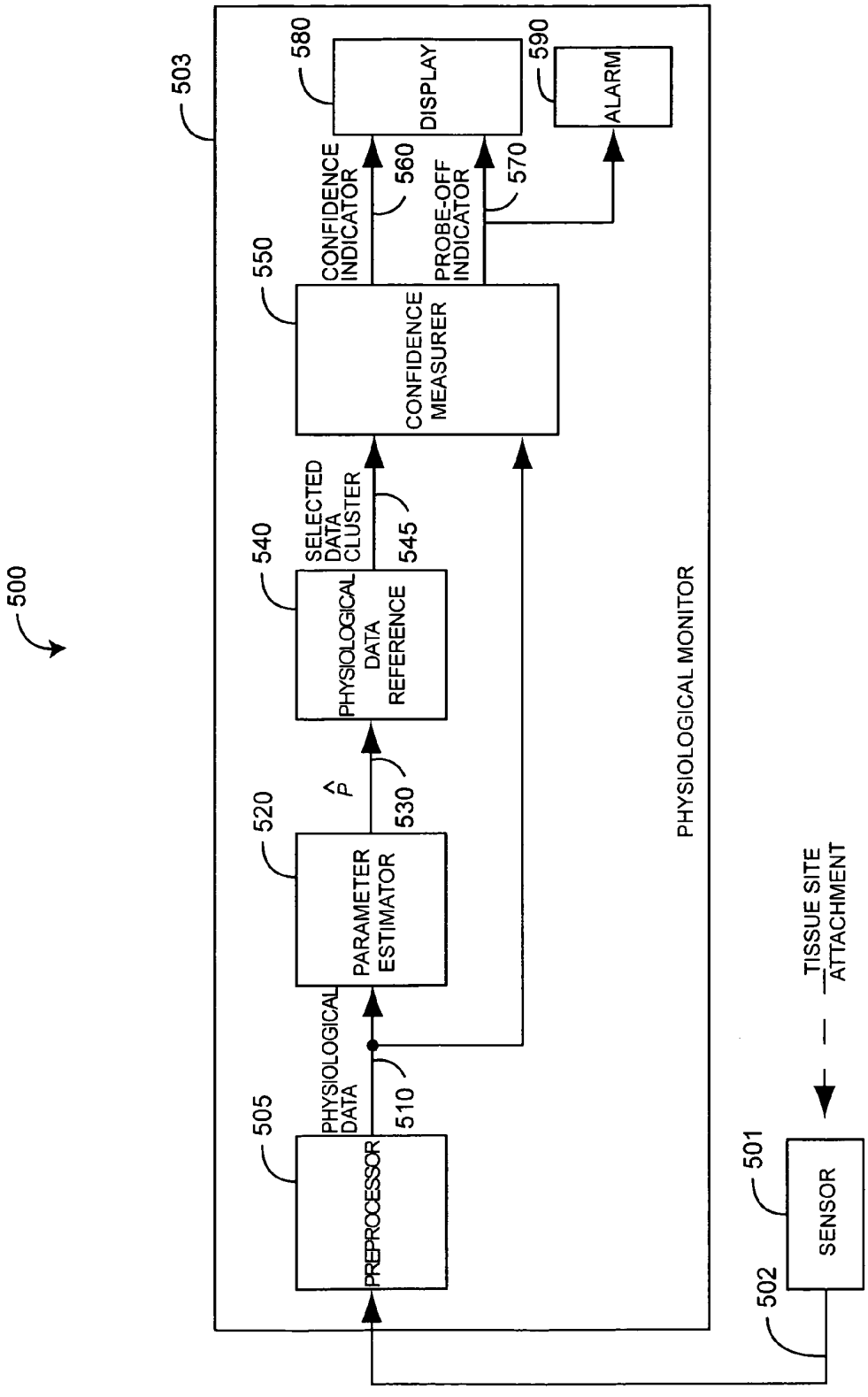

500
503
PHYSIOLOGICAL MONITOR
505
PREPROCESSOR
PHYSIOLOGICAL DATA
510
520
PARAMETER ESTIMATOR
$\hat{P}$
530
540
PHYSIOLOGICAL DATA REFERENCE
SELECTED DATA CLUSTER
545
550
CONFIDENCE MEASURER
CONFIDENCE INDICATOR
560
PROBE-OFF INDICATOR
570
580
DISPLAY
590
ALARM
501
SENSOR
502
TISSUE SITE ATTACHMENT

FIG. 5

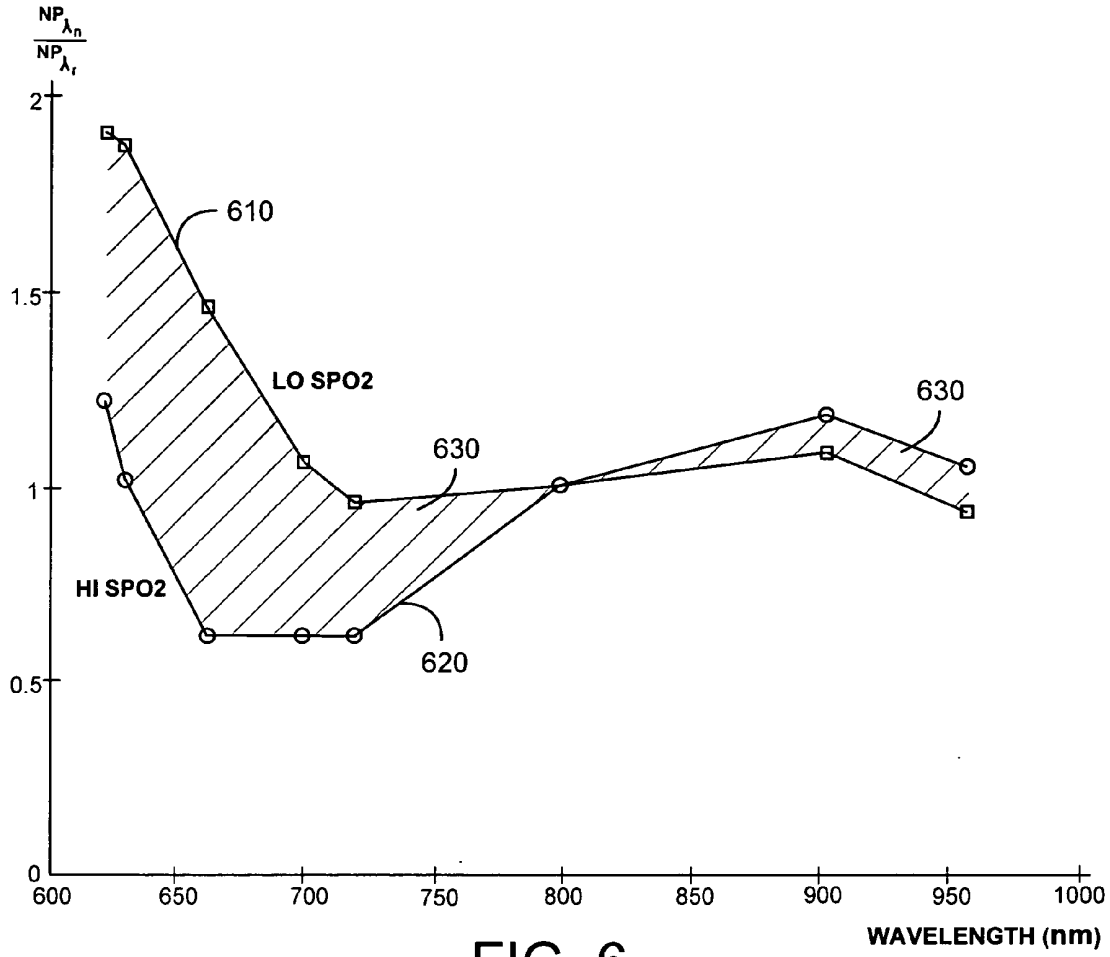

NP λn / NP λr
2
1.5
1
0.5
0
610
LO SPO2
630
630
HI SPO2
620
600
650
700
750
800
850
900
950
1000
WAVELENGTH (nm)

FIG. 6

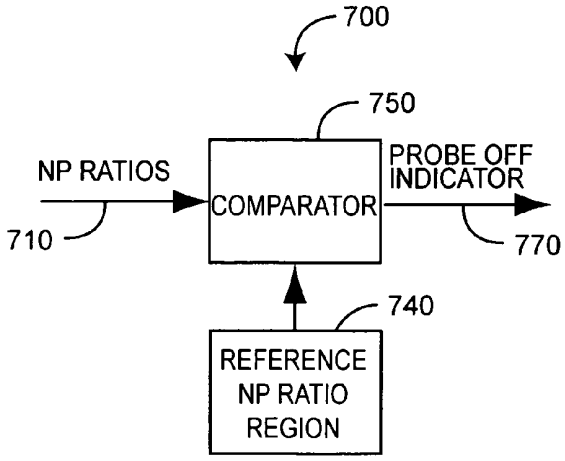

700
750
NP RATIOS
710
COMPARATOR
PROBE OFF INDICATOR
770
740
REFERENCE NP RATIO REGION

FIG. 7

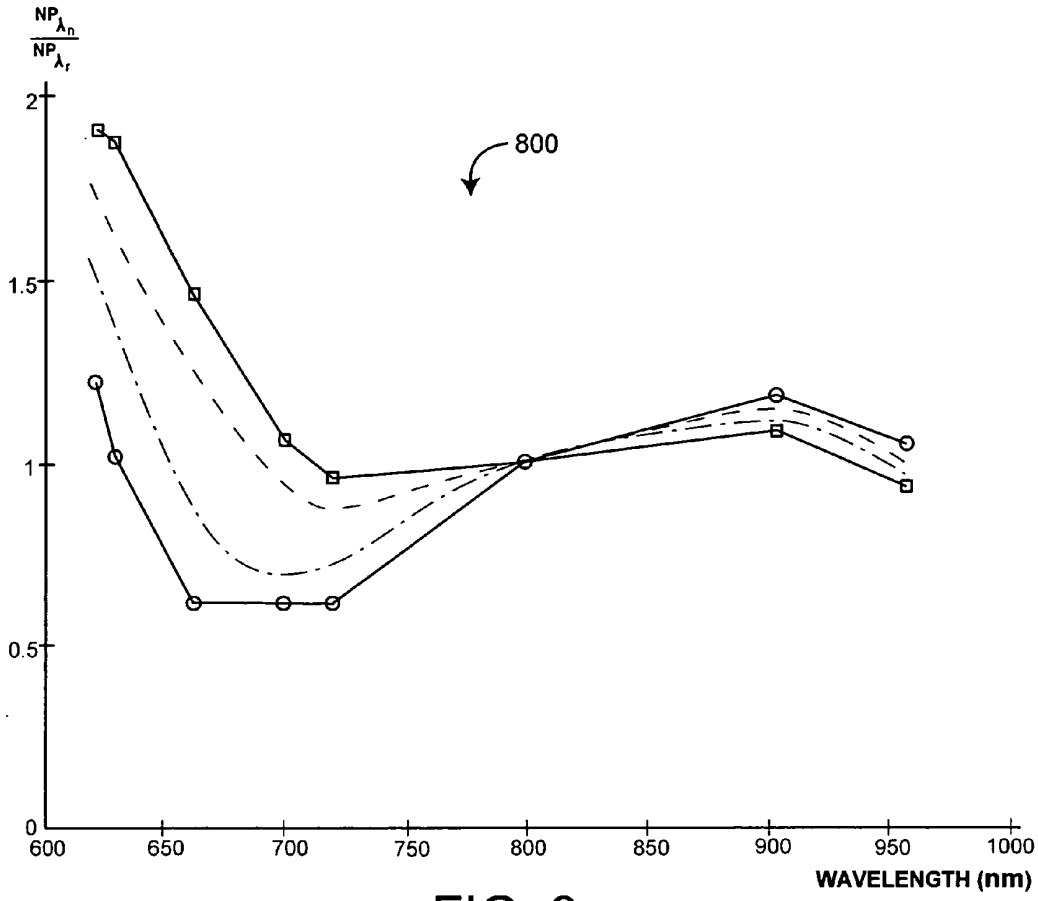

$\frac{NP_{\lambda_n}}{NP_{\lambda_r}}$
2
1.5
1
0.5
0
800
600
650
700
750
800
850
900
950
1000
WAVELENGTH (nm)

FIG. 8

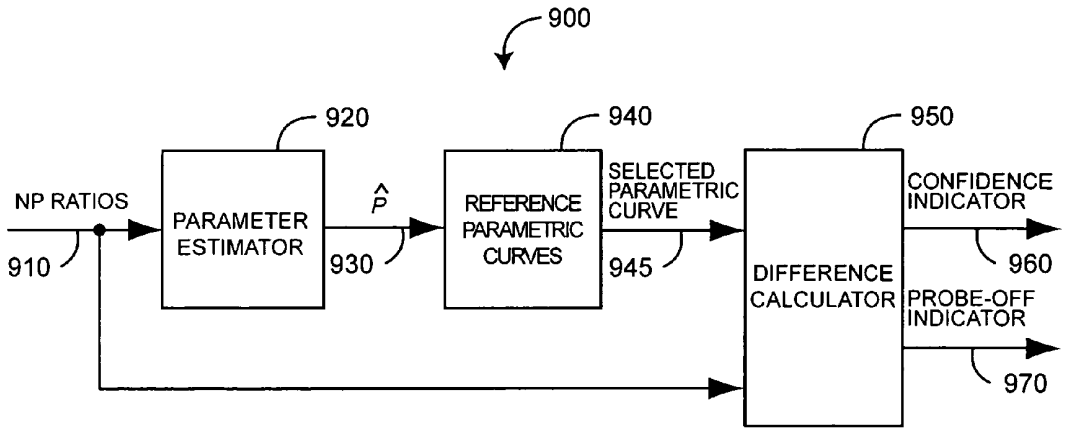

900
NP RATIOS
910
PARAMETER ESTIMATOR
920
$\hat{P}$
930
REFERENCE PARAMETRIC CURVES
940
SELECTED PARAMETRIC CURVE
945
DIFFERENCE CALCULATOR
950
CONFIDENCE INDICATOR
960
PROBE-OFF INDICATOR
970

FIG. 9

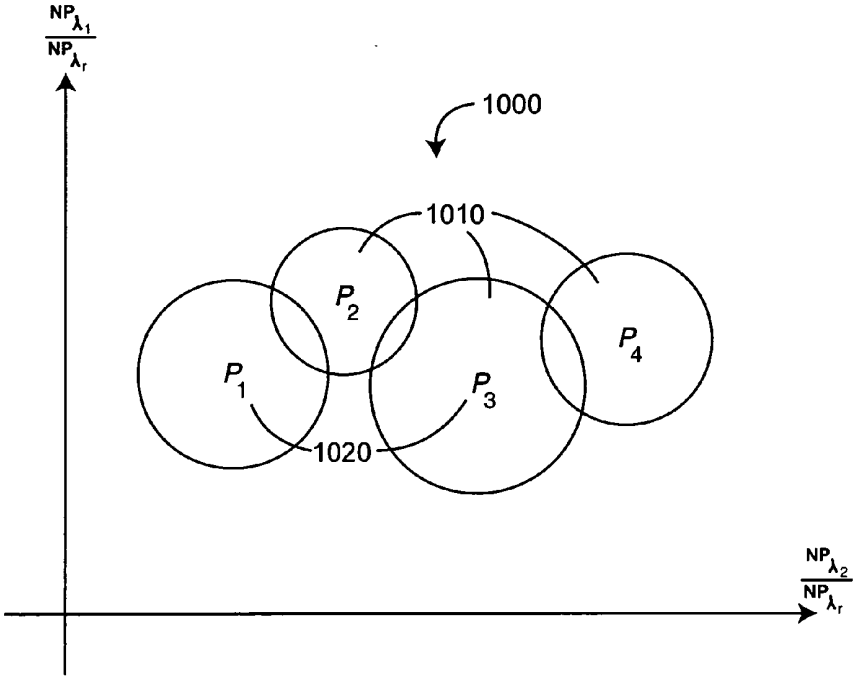

$\frac{NP_{\lambda_1}}{NP_{\lambda_r}}$
1000
1010
P_1
P_2
P_3
P_4
1020
$\frac{NP_{\lambda_2}}{NP_{\lambda_r}}$

FIG. 10

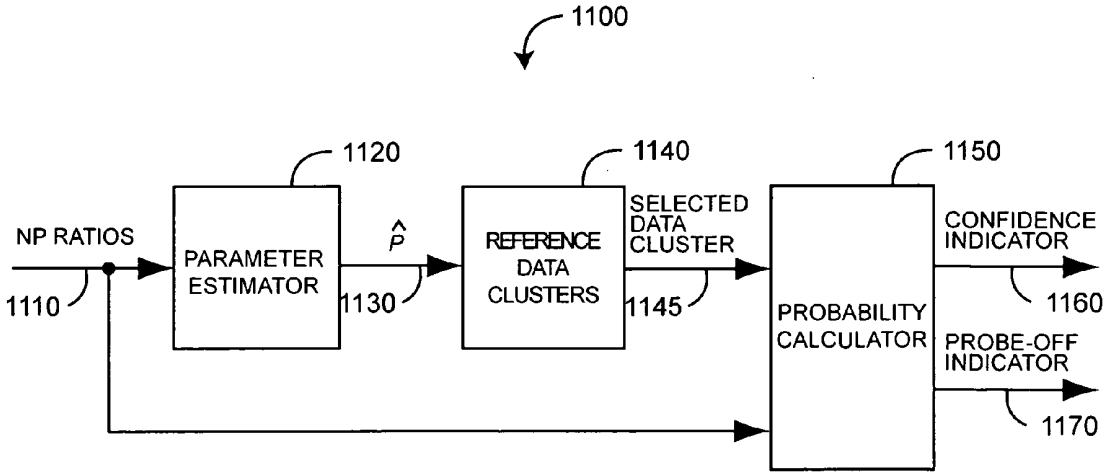

1100
1120
1140
1150
NP RATIOS
1110
PARAMETER ESTIMATOR
$\hat{P}$
1130
REFERENCE DATA CLUSTERS
SELECTED DATA CLUSTER
1145
PROBABILITY CALCULATOR
CONFIDENCE INDICATOR
1160
PROBE-OFF INDICATOR
1170

FIG. 11

PHYSIOLOGICAL PARAMETER CONFIDENCE MEASURE

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 Ser. No. 60/657,596, filed Mar. 1, 2005, entitled "Multiple Wavelength Sensor," No. 60/657,281, filed Mar. 1, 2005, entitled "Physiological Parameter Confidence Measure," No. 60/657,268, filed Mar. 1, 2005, entitled "Configurable Physiological Measurement System," and No. 60/657,759, filed Mar. 1, 2005, entitled "Noninvasive Multi-Parameter Patient Monitor." The present application incorporates the foregoing disclosures herein by reference.

CORPORATION BY REFERENCE OF COPENDING RELATED 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/###,###	Mar. 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
2	11/###,###	Mar. 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/###,###	Mar. 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/###,###	Mar. 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/###,###	Mar. 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/###,###	Mar. 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/###,###	Mar. 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/###,###	Mar. 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/###,###	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.012A
10	11/###,###	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
11	11/###,###	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

The present application incorporates the foregoing disclosures herein by reference.

BACKGROUND OF THE INVENTION

[0003] 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 $\epsilon_{i,\lambda}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{\alpha,\lambda}$ 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 EQS. 1-2 are the number of significant absorbers that are present in the solution.

[0004] 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.

[0005] Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. 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 5,769,785, and 5,758,644, 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.

[0006] **FIG. 1** illustrates HbO_2 and Hb absorption μ_α versus wavelength. At red and near IR wavelengths below 970 nm, where water has a significant peak, Hb and HbO_2 are the only significant absorbers normally present in the blood. Thus, typically only two wavelengths are needed to resolve the concentrations of Hb and HbO_2, e.g. a red (RD) wavelength at 660 nm and an infrared (IR) wavelength at 940 nm. In particular, SpO_2 is computed based upon a red ratio Red_{AC}/Red_{DC} and an IR ratio IR_{AC}/IR_{DC}, which are the AC detector response magnitude at a particular wavelength normalized by the DC detector response at that wavelength. The normalization by the DC detector response reduces measurement sensitivity to variations in tissue thickness, emitter intensity and detector sensitivity, for example. The AC detector response is a plethysmograph, as described above. Thus, the red and IR ratios can be denoted as NP_{RD} and NP_{IR} respectively, where NP stands for "normalized

plethysmograph." In pulse oximetry, oxygen saturation is calculated from the ratio NP_{RD}/NP_{IR}.

SUMMARY OF THE INVENTION

[0007] A multiple wavelength sensor and a noninvasive multi-parameter patient monitor, such as referenced above, make blood absorption measurements at more than a red wavelength and an IR wavelength. In one embodiment, described below, blood absorption measurements are made at eight wavelengths. Advantageously, this rich wavelength data, compared with conventional pulse oximetry, allows a determination of a tissue profile or tissue characterization over a wavelength spectrum.

[0008] **FIG. 2** illustrates an example of a "tissue profile"**200** for SpO2=97%. For this example, including **FIGS. 3-4**, below, the sensor emits eight wavelengths (610, 620, 630, 655, 700, 720, 800 and 905 nm). The graph is a plot of NP ratios **210** versus wavelength **220**, where the NP ratios are of the form $NP_{\lambda 1}/NP_{\lambda 2}$. This is a generalization to multiple wavelengths of the ratio NP_{RD}/NP_{IR} described above for two (red and IR) wavelengths. In order to provide a common scale for these NP ratios, the ratios are calculated with respect to a reference wavelength, λr, which may be any of the available wavelengths. Thus, the plotted NP ratios are denoted $NP_{\lambda n}/NP_{\lambda r}$ over the n available wavelengths, including λr. Note that the NP ratio at the reference wavelength is $NP_{\lambda r}/NP_{\lambda r}=1$, which is 800 nm in **FIG. 2**.

[0009] As shown in **FIG. 2**, when a sensor is properly positioned on a tissue site, the detector only receives LED emitted light that has propagated through the tissue site after tissue scattering and absorption. Thus, a tissue profile **200** should reflect the blood constituent absorption characteristics illustrated in **FIG. 1**, above. For this high oxygen saturation (97%) example, HbO_2 is the only significantly absorbing blood constituent and, indeed, the resulting tissue profile **200** is shaped like the HbO_2 absorption curve **110** (**FIG. 1**).

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] **FIG. 1** is a graph of oxyhemoglobin and reduced hemoglobin light absorption versus wavelength across portions of the red and IR spectrum;

[0011] **FIG. 2** is a graph of NP ratios versus wavelength illustrating a tissue profile;

[0012] **FIG. 3** is a graph of NP ratios versus wavelength illustrating a probe-off profile;

[0013] **FIG. 4** is a graph of NP ratios versus wavelength illustrating a penumbra profile;

[0014] **FIG. 5** is a general block diagram of a confidence measurement system;

[0015] **FIG. 6** is a graph of normalized plethysmograph (NP) ratios versus wavelength for low and high SpO_2 illustrating a NP envelope;

[0016] **FIG. 7** is a block diagram of a multiple wavelength probe off detector utilizing an NP envelope;

[0017] **FIG. 8** is a graph of NP ratios versus wavelength illustrating a family of parametric NP curves;

[0018] **FIG. 9** is a block diagram of a multiple wavelength confidence measurement system utilizing parametric NP curves;

[0019] **FIG. 10** is an NP ratio graph illustrating a family of NP data clusters; and

[0020] **FIG. 11** is a block diagram of a multiple wavelength confidence measurement system utilizing NP data clusters.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0021] 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 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.

[0022] **FIG. 3** illustrates an example of a probe-off profile **300**. When a sensor is completely dislodged from a patient, a so-called "probe off" condition occurs. Despite a probe off condition, an optical sensor may continue to detect an AC signal, which can be induced at the detector by other than pulsatile arterial absorption of LED emitted light. For example, small patient movements, vibrations, air flow or other perturbations may cause the pathlength between the LEDs and the detector to vary, resulting in an AC detector signal that can be mistakenly interpreted by the monitor as due to pulsatile arterial blood. Further, ambient light may reach the detector, and any modulation of the ambient light due to AC power, power fluctuations, moving objects, such as a fan, among other perturbations can be also mistaken as a pulsatile arterial signal. Probe off errors are serious because a blood constituent monitor may display normal results, such as oxygen saturation, when, in fact, the sensor is not properly attached to the patient, potentially leading to missed severe desaturation events. As shown in **FIG. 3**, a probe-off profile **300** is readily apparent as it does not have a shape related to the absorption characteristics of hemoglobin constituents.

[0023] **FIG. 4** illustrates an example of a penumbra profile **400**. When a sensor is not properly positioned or becomes partially dislodged, a penumbra condition may occur, where the detector is "shadowed" by a tissue site, such as a finger, but also receives some light directly from the emitters or indirectly reflected off the sensor housing, or both. As a result, the DC signal at the detector rises significantly, which lowers the AC/DC ratio (NP). Because red wavelengths are more significantly absorbed by Hb and HbO_2, the penumbra condition is most noticeable at the red portion **405** of the $NP_{\lambda n}/ NP_{\lambda r}$. This effect is readily seen in the penumbra profile **400** as compared to a normal tissue profile **200** (**FIG. 2**).

[0024] Advantageously, a physiological parameter confidence measurement system, as described below, can distinguish a tissue profile **200** (**FIG. 2**) from a probe-off profile **300** (**FIG. 3**) or penumbra profile **400** (**FIG. 4**), as examples. Further, a physiological parameter confidence measurement system can provide indications that the detector signal is degraded as the result of various physiological and non-physiological phenomenon.

[0025] **FIG. 5** illustrates a physiological parameter confidence measurement system **500** having a physiological data **510** input, a confidence indicator **560** output and a probe-off indicator **570** output. In one embodiment, physiological data **510**, such as the NP ratios described above, is derived from a sensor **501** generating a sensor signal **502** responsive to multiple wavelengths of optical radiation transmitted into and attenuated by a tissue site. The confidence indicator **560** provides an observer with some measure of "goodness" for the physiological data **510**. That is, if confidence is high, it is likely the physiological data **510** is representative of a physiological condition or state. If confidence is low, the physiological data **510** may be less representative of a physiological condition or state. If the confidence is very low, a probe-off indicator **570** may be generated to alert an observer to the possibility that a sensor from which the physiological data **510** is derived is not properly positioned on a tissue site and may not be generating physiologically significant data. In one embodiment, a confidence measure may be provided as a percentage, such as 0-100%. In various embodiments, a confidence indicator **560** corresponding to a confidence measure may be visual or audible or both. For example, a confidence indicator **560** may be a number display, a display message, a bar display, a color indicator or display, such as green (high confidence), yellow (average confidence), red (low confidence). Also, a confidence indicator **560** may be any of various alarm sounds, tones or patterns of sounds or tones, such as a double beep at less than high confidence. In one embodiment, the physiological parameter confidence measurement system **500** is incorporated within a physiological monitor **503** having a display **580** or alarm **590** for outputting the confidence indicator **560** or probe-off indicator **570**.

[0026] As shown in **FIG. 5**, the physiological parameter confidence measurement system **500** also has a parameter estimator **520**, a physiological data reference **540** and a confidence measurer **550**. The parameter estimator **520** derives one or more physiological parameter estimates, $\hat{P}$, **530** based upon the physiological data **510**. The parameter estimate or estimates **530** are used to select one or more data clusters **545** from the physiological data reference **540**. In one embodiment, the physiological data reference **540** is a collection of predetermined physiological data organized in data clusters. For example the physiological data reference **540** may contain clinically-derived physiological data organized according to corresponding values of a physiological parameter determined by a "gold standard" instrument. In a particular embodiment, the physiological data are NP ratios obtained for various physiological parameters, such as SpO_2, HbCO, HbMet, Hbt, fractional oxygen saturation, bilirubin or glucose to name a few, as measured with a standardized cooximeter, for example. In one embodiment, the physiological data reference **540** is a non-volatile memory or other data storage device containing predetermined physiological data. The confidence measurer **550** uses the physiological data **510** and the selected data cluster or data clusters **545** to generate the confidence indicator **560**, the probe-off indicator **570** or both.

[0027] A confidence measurement and confidence indicator, as described herein, may be combined with other signal quality and data confidence measurements and indicators, such as those described in U.S. Pat. No. 6,996,427 titled Pulse Oximetry Data Confidence Indicator and U.S. Pat. No. 6,606,511 titled Pulse Oximetry Pulse Indicator, both patents assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. A probe off measurement and probe off indicator as described herein may be combined with other probe off measurements and indicators, such as those described in U.S. Pat. No. 6,654,624 titled Pulse Oximeter Probe-Off Detector and U.S. Pat. No. 6,771,994 titled Pulse Oximeter Probe-Off Detection System, both patents assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

[0028] **FIG. 6** illustrates NP ratio versus wavelength curves computed from a multiple wavelength sensor, such as described in the U.S. Patent Application titled Multiple Wavelength Sensor, referenced above. In this example, the sensor emits eight wavelengths (620, 630, 660, 700, 730, 805, 905 and 960 nm). Shown is a low oxygen saturation curve **610**, e.g. SpO^2=70% and a high oxygen saturation curve **620**, e.g. SpO^2≈100%. By comparison, a conventional two wavelength pulse oximetry sensor, as described above, results in a single point on a particular curve. Advantageously, the NP ratio curves **610**, **620** represent a tissue profile that can be compared to a particular sensor response to determine if a physiologically significant measurement has been made. In one embodiment, the NP ratio curves **610**, **620** delineate the boundaries of a physiologically significant NP ratio region **630**. Although described above with respect to SpO^2, such regions or boundaries can be derived for other physiological parameters such as HbCO, HbMet, Hbt, fractional oxygen saturation, bilirubin or glucose to name a few.

[0029] **FIG. 7** illustrates one embodiment of a physiological parameter confidence measurement system **700** utilizing a NP ratio region such as described with respect to **FIG. 6**, above. The confidence measurement system **700** has input NP ratios **710** measured in response to a multiple wavelength sensor, reference NP ratio region **740** that delineates physiologically significant NP ratios **630** (**FIG. 6**), and a comparator **750**. In one particular embodiment, the NP ratio region **740** is predetermined from clinically-derived data for one or more parameters of interest, such as SpO_2, HbCO, HbMet, Hbt, fractional oxygen saturation, bilirubin or glucose, to name a few. In another particular embodiment, the NP ratio region **740** is theoretically calculated. The comparator **750** compares the input NP ratios **710** with the NP ratio region **740** and generates a probe-off indicator **770** if any, or more than a predetermine number, of the input NP ratios **710** fall outside of an NP ratio region **740**.

[0030] **FIG. 8** illustrates a family of parametric NP ratio versus wavelength curves **800** computed from a multiple wavelength sensor, such as referenced above. Each curve represents a different value of a measured parameter, such as SpO_2. For example, there may be a curve for each of SpO_2=70%, 75%, 80%, . . . 100%. Advantageously, such curves more precisely indicate physiologically significant multiple wavelength sensor measurements as compared to a bounded NP ratio region **630** (**FIG. 6**) such as described with respect to **FIGS. 6-7**, above.

[0031] **FIG. 9** illustrates another embodiment of a physiological parameter confidence measurement system **900** utilizing parametric NP ratio curves, such as described with respect to **FIG. 8**, above. The confidence measurement system **900** has input NP ratios **910** measured in response to a multiple wavelength sensor, a parameter estimator **920**, reference parametric curves **940** and a difference calculator **950**. The parameter estimator **920** inputs the NP ratios **910** so as to generate a parameter estimate **930**, such as SpO_2, HbCO, HbMet, Hbt, fractional oxygen saturation, bilirubin or glucose, to name a few. The estimated parameter **930** selects one or more of the reference parametric curves **940**, which are predetermined from clinically-derived data that is stored in memory or data that is mathematically pre-calculated or calculated in real time and stored in memory. The difference calculator **950** measures the difference between the NP ratios **910** and the selected parametric curve **940**. For example, a mean-squared error calculation can be made between the input NP ratios **910** and the selected parametric curve **945**. The resulting difference calculation is used as a confidence measure or translated into a confidence measure and a confidence indicator output **960** is generated accordingly. Alternatively, or in addition to a confidence measure, a probe off condition can be indicated if the difference calculation is larger than a predetermined value or the confidence measure is less than a predetermined value. In another embodiment, a correlation calculator is used in place of the difference calculation.

[0032] **FIG. 10** illustrates a family of data clusters **1000** shown in two dimensions by way of example. Each data cluster **1000** represents NP ratios clinically measured across a population for specific values **1020** of a selected parameter P. such as P_1, P_2, P_3 and P_4 as shown. Each data cluster **1000** defines a region **1010** of NP ratios measured for a particular parameter value **1020** and has a probability distribution, such as a normal distribution, over the indicated region **1010**.

[0033] For example, the clinical data can be organized as a table of known values of P, corresponding NP ratios measured over a population, and the relative number of occurrences of particular NP ratio values for each value of P. The relative number of occurrences of particular NP ratio values for a particular value of P yields an NP ratio probability distribution for that value of P. Thus, each P value **1020** in the table has a corresponding data cluster **1000** of measured NP ratios and an associated probability distribution for those NP ratios.

[0034] **FIG. 11** illustrates yet another embodiment of a physiological parameter confidence measurement system **1100** utilizing NP data clusters and corresponding probability distributions, such as described with respect to **FIG. 10**, above. The confidence measurement system **1100** has input NP ratios **1110** measured in response to a multiple wavelength sensor, a parameter estimator **1120**, reference data clusters **1140** and a probability calculator **1150**. The parameter estimator **1120** inputs the NP ratios **1110** so as to generate a parameter estimate **1130**, such as described with respect to other embodiments, above. In one embodiment, the reference data clusters **1140**, such as described with respect to **FIG. 10**, are stored in a memory device, such as an EPROM. The estimated parameter **1130** is compared with the reference data clusters **1140** so as to determine the closest region **1010** (**FIG. 10**) or closest overlapping portion of two regions **1010** (**FIG. 10**). The probability calculator **1150** computes a probability based upon the distribution above the selected region **1010** (**FIG. 10**). A confidence measure is also derived based upon the calculated probability **1150**. In a particular embodiment, the confidence measure is the calculated probability. A confidence indicator **1160** is generated in response to the confidence measure. In one embodiment, if the confidence probability or the calculated confidence measure is below a predetermined threshold, a probe-off indicator **1170** is generated. In particular embodiments, the confidence indicator **1160** or probe-off indicator **1170** or both may be alphanumeric or digital displays, optical indicators or alarms or similar audible indicators, to name a few.

[0035] A physiological parameter confidence measurement system 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 art will appreciate many variations and modifications.

What is claimed is:

1. A method of determining a measure of confidence in a physiological parameter, the physiological parameter determined by transmitting multiple wavelengths of optical radiation into a tissue site and detecting the optical radiation after tissue attenuation, the method comprising:

deriving physiological data responsive to the intensity of multiple wavelengths of optical radiation transmitted into a tissue site and detected after tissue attenuation;

estimating a physiological parameter based upon the physiological data;

providing a physiological data reference;

obtaining at least one data cluster from the physiological data reference; and

determining a measure of confidence in the estimated physiological parameter based upon the at least one data cluster and the derived physiological data.

2. The method according to claim 1 wherein the providing step comprises:

predetermining the physiological data for known values of the physiological parameter across a sample population;

clustering the data according to the physiological parameter values; and

storing the data clusters so as to be retrievable according to the physiological parameter values.

3. The method according to claim 2 wherein the obtaining step comprises selecting the at least one data cluster according to the estimated physiological parameter.

4. The method according to claim 3 wherein the selecting step comprises:

determining at least one data cluster having a corresponding physiological parameter value closest to the estimated physiological parameter; and

reading the determined at least one data cluster from the memory.

5. The method according to claim 4 wherein the physiological data are ratios of normalized plethysmographs (NP ratios).

6. The method according to claim 5 wherein the physiological parameter is at least one of SpO_2, MetHb and HbCO.

7. The method according to claim 6 wherein the data clusters are a plurality of parameteric curves of NP ratio versus wavelength.

8. The method according to claim 6 wherein the data clusters are probability distributions of NP ratios.

9. A physiological parameter confidence measurement method comprising:

deriving physiological data responsive to the intensity of multiple wavelengths of optical radiation transmitted into a tissue site and detected after tissue attenuation;

estimating a physiological parameter based upon the physiological data;

providing a physiological data reference having a plurality of data clusters each corresponding to a particular value of the physiological parameter,;

comparing at least one of the data clusters to the physiological data; and

indicating confidence in the estimated physiological parameter based upon the comparison.

10. The physiological parameter confidence measurement method according to claim 9 further comprising associating a probability function with each of the data clusters.

11. The physiological parameter confidence measurement method according to claim 10 wherein the comparing step comprises determining a probability that the derived physiological data corresponds to the estimated physiological parameter.

12. The physiological parameter confidence measurement method according to claim 11 wherein the indicating step comprises generating at least one of a visual indication and an audible indication corresponding to the determined probability.

13. The physiological parameter confidence measurement method according to claim 12 further comprising triggering an alarm that a probe-off condition exists when the determined probability is below a predetermined threshold.

14. A confidence measurement system comprising:

a plurality of physiological data responsive to the intensity of multiple wavelengths of optical radiation transmitted into a tissue site and detected after tissue attenuation;

a parameter estimator configured to input the physiological data and output an estimate of a physiological parameter;

a physiological data reference having a plurality of data clusters corresponding to known values of the physiological parameter; and

a confidence measurer adapted to compare the physiological data with the data clusters so as to calculate a measure of confidence in the physiological parameter estimate.

15. The confidence measurement system according to claim 14 wherein the physiological data comprises a plurality of ratios of normalized plethysmographs corresponding to the multiple wavelengths of optical radiation.

16. The confidence measurement system according to claim 15 wherein the parameter estimator comprises a value calculation corresponding to at least one of SpO_2, HbCO, HbMet, Hbt, fractional oxygen saturation, bilirubin and glucose.

17. The confidence measurement system according to claim 16 wherein the physiological data reference comprises a plurality of known values of the physiological parameter, corresponding predetermined values of ratios of normalized plethysmographs and probabilities associated with the predetermined values.

18. The confidence measurement system according to claim 17 wherein the confidence measurer comprises a probability calculation that the input physiological data corresponds to the estimated physiological parameter.

19. The confidence measurement system according to claim 18 further comprising a confidence indicator responsive to the probability calculation.

20. The confidence measurement system according to claim 19 further comprising a probe-off indicator responsive to the probability calculation and a predetermined probability threshold.

21. A confidence measurement system comprising:

a plurality of physiological data responsive to the intensity of multiple wavelengths of optical radiation transmitted into a tissue site and detected after tissue attenuation;

a parameter estimator configured to input the physiological data and output a corresponding physiological parameter estimate;

a physiological data reference means for providing data clusters according to known values of the physiological parameter; and

a confidence measurement means for determining confidence in physiological parameter estimate based upon the physiological data and the data clusters.

22. The confidence measurement system according to claim 21 further comprising an output means for indicating confidence in the physiological parameter estimate.

23. The confidence measurement system according to claim 21 further comprising an alarm means for indicating a probe-off condition in response to low confidence in the physiological parameter estimate.

* * * * *

专利名称(译)	生理参数置信度测量		
公开(公告)号	US20060211925A1	公开(公告)日	2006-09-21
申请号	US11/367034	申请日	2006-03-01
[标]申请(专利权)人(译)	拉梅戈MARCELO 戴铂MOHAMED AL ALI AMMAR		
申请(专利权)人(译)	拉梅戈MARCELO 戴铂MOHAMED AL-ALI AMMAR		
当前申请(专利权)人(译)	拉梅戈MARCELO 戴铂MOHAMED AL-ALI AMMAR		
[标]发明人	LAMEGO MARCELO DIAB MOHAMED AL ALI AMMAR		
发明人	LAMEGO, MARCELO DIAB, MOHAMED AL-ALI, AMMAR		
IPC分类号	A61B5/00		
CPC分类号	A61B5/14552 A61B5/746 A61B2562/085 A61B2562/222 A61B5/1455 A61B5/0205 A61B5/14532 A61B5/14546 A61B5/6826 A61B5/742 Y10S439/909 G06F19/3418 A61B5/02427 A61B5/7221 A61B5/7405 A61B5/7475 A61B5/02416 A61B5/14551 A61B5/0261 A61B5/7246 A61B5/0295 A61B2562/08 A61B5/6832 G16H10/40 G16H40/67 A61B1/00 A61B5/0022 A61B5/1495 A61B5/6815 A61B5/6829 A61B5/6838 A61B5/7275 A61B5/7278 H05K999/99		
优先权	60/657596 2005-03-01 US 60/657281 2005-03-01 US 60/657268 2005-03-01 US 60/657759 2005-03-01 US		
其他公开文献	US7957780		
外部链接	Espacenet USPTO		

摘要(译)

生理参数的置信度是根据组织衰减后响应于多个波长的光辐射强度的生理数据来测量的。基于生理数据估计生理参数。根据生理参数的已知值存储参考数据簇。根据估计的生理参数选择至少一个数据簇。根据所选数据簇和生理数据的比较确定置信度量。