US 20080132771A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2008/0132771 A1

Parker et al. (43) Pub. Date: Jun. 5, 2008

(54) **MEASUREMENT OF BLOOD OXYGEN SATURATION**

(75) Inventors: **Dawood Parker**, Whitland (GB); **Michael J. Higgins**, Huntington Beach, CA (US)

Correspondence Address:
EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT, ONE EDWARDS WAY IRVINE, CA 92614

(73) Assignee: **Whitland Research Limited**, Whitland (GB)

(21) Appl. No.: **12/014,582**

(22) Filed: **Jan. 15, 2008**

Related U.S. Application Data

(60) Division of application No. 09/743,206, filed on Mar. 15, 2002, now Pat. No. 6,990,365, Continuation-in-part of application No. 10/950,257, filed on Sep. 24, 2004, said application No. 09/743,206 , said application No. PCT/GB99/02127 Continuation-in-part of application No. 09/762,923, filed on Apr. 16, 2001, now Pat. No. 6,842,635, filed as application No. PCT/GB99/02510 on Jul. 30, 1999.

(30) **Foreign Application Priority Data**

Jul. 4, 1998	(GB)	9814464.5
Aug. 13, 1998	(GB)	9817552.4
Nov. 13, 1998	(GB)	98224899.0
Feb. 25, 1999	(GB)	9904232.7
Jul. 2, 1999	(GB)	9825243.0
Sep. 26, 2003	(GB)	0322545.5

Publication Classification

(51) **Int. Cl.**
A61B 5/1455 (2006.01)

(52) **U.S. Cl.** **600/323**

(57) **ABSTRACT**

Oxygenation of a subject's blood is determined by sensing an absorption spectrum of light directed either invasively or non-invasively into the blood, and then calculating an oxygenation value by evaluating a cost function of the remitted spectrum relative to at least two pre-determined reference absorption spectra representing different, known levels of blood oxygenation. The source of light preferably uses stable, long-life, white LEDs, in which case white-balancing of the remitted spectrum can be accomplished by predetermining and storing the spectrum of the LEDs, one time for all, and then adjusting the remitted spectrum accordingly to compensate for deviations of the LED spectrum from the constant ideal.

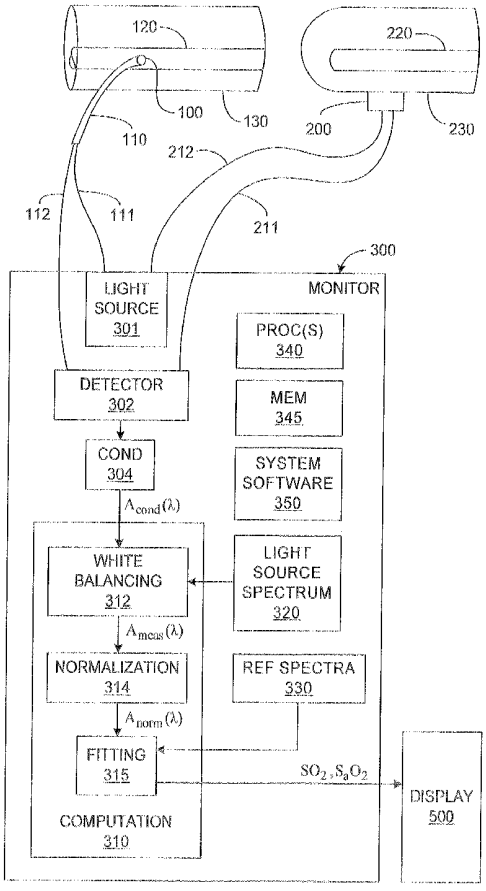


FIG. 1

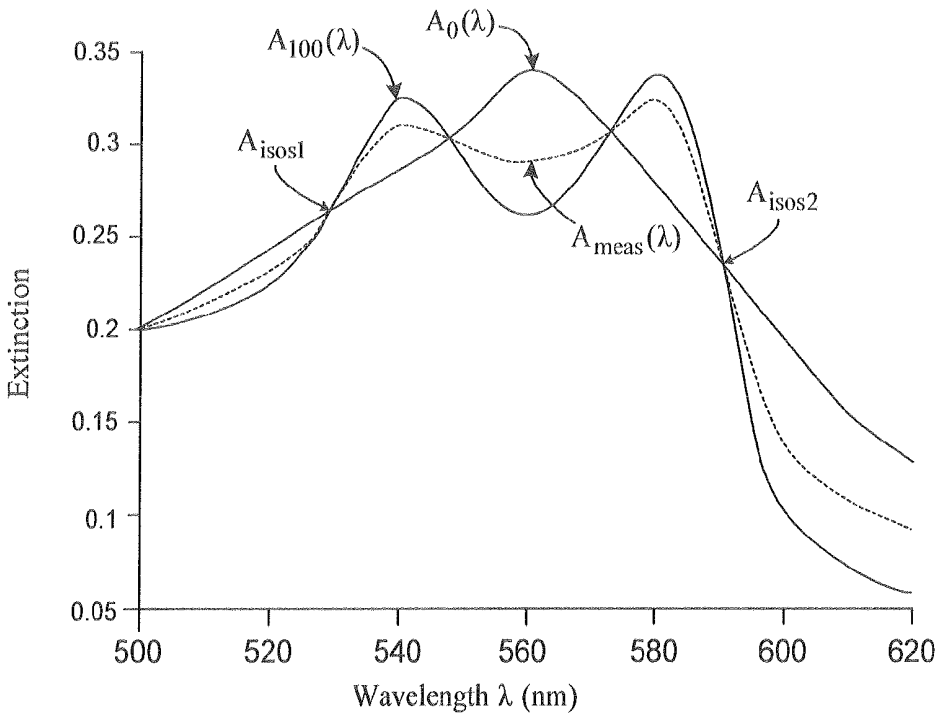

$A_{100}(\lambda)$
$A_0(\lambda)$
A_{isos1}
$A_{meas}(\lambda)$
A_{isos2}
Extinction
0.35
0.3
0.25
0.2
0.15
0.1
0.05
500
520
540
560
580
600
620
Wavelength λ (nm)

FIG. 3

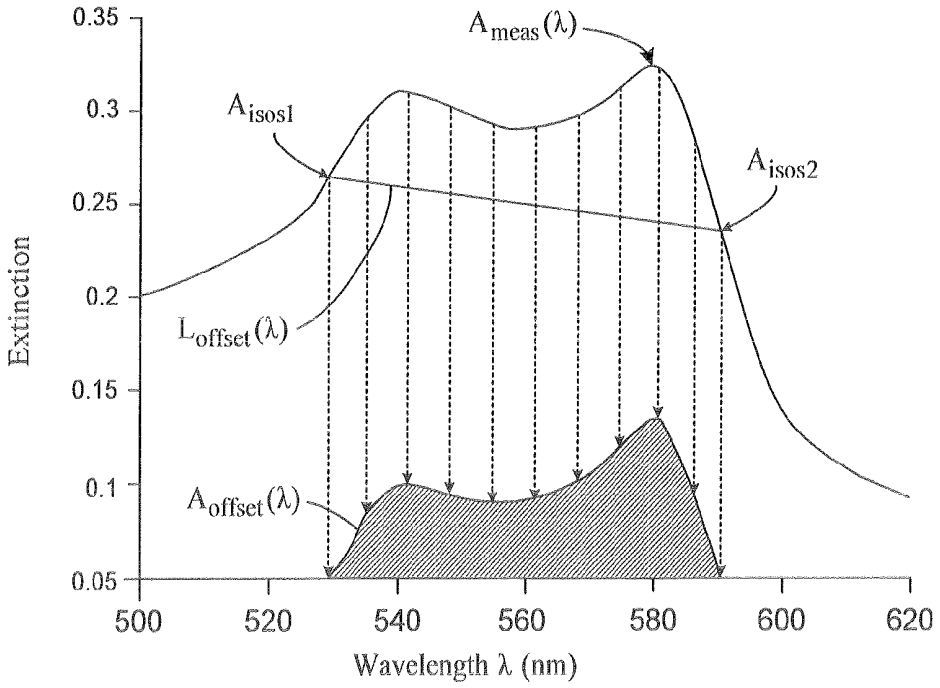
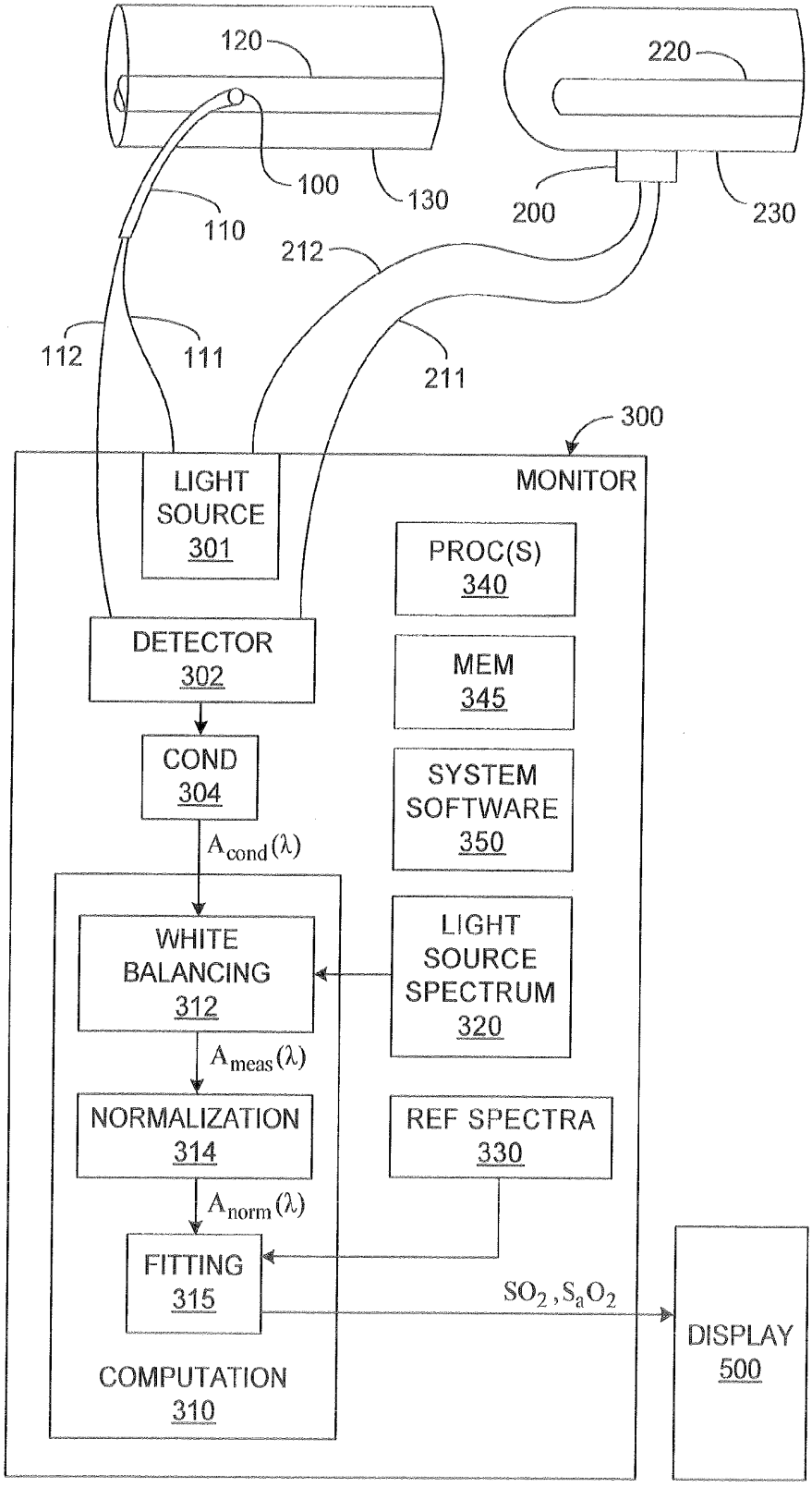

$A_{meas}(\lambda)$
A_{isos1}
A_{isos2}
$L_{offset}(\lambda)$
$A_{offset}(\lambda)$
Extinction
0.35
0.3
0.25
0.2
0.15
0.1
0.05
500
520
540
560
580
600
620
Wavelength λ (nm)

FIG. 2


120
220
100
130
200
230
110
212
112
111
211
300
MONITOR
LIGHT SOURCE 301
PROC(S) 340
DETECTOR 302
MEM 345
COND 304
SYSTEM SOFTWARE 350
$A_{cond}(\lambda)$
WHITE BALANCING 312
LIGHT SOURCE SPECTRUM 320
$A_{meas}(\lambda)$
NORMALIZATION 314
REF SPECTRA 330
$A_{norm}(\lambda)$
FITTING 315
SO_2, S_aO_2
DISPLAY 500
COMPUTATION 310

MEASUREMENT OF BLOOD OXYGEN SATURATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority of and is a continuation-in-part (CIP) of co-pending U.S. patent application Ser. No. 09/743,206 filed 15 Mar. 2002, incorporated herein by reference and now U.S. Pat. No. 6,990,365, which is a national stage application claiming priority of international (PCT) patent application No. PCT/GB99/02127, filed 2 Jul. 1999, which in turn claims priority of Great Britain Patent Application No. 9825243.0, filed 19 Nov. 1998, Great Britain Patent Application No. 9824899.0, filed 13 Nov. 1998, and Great Britain Patent Application No. 9814464.5, filed 4 Jul. 1998 each of which are herein incorporated by reference. This application also claims priority of and is a CIP of co-pending U.S. patent application Ser. No. 09/762,923 filed 16 Apr. 2001, now U.S. Pat. No. 6,842,635, which is a national stage application claiming priority of international patent application No. PCT/GB99/02510, filed 30 Jul. 1999, which in turn claims priority of both Great Britain Patent Application No. 9817552.4, filed 13 Aug. 1998 and Great Britain Patent Application No. 9904232.7, filed 25 Feb. 1999, each of which are herein incorporated by reference.

[0002] This application also claims priority of Great Britain Patent Application No. 0322545.5, filed Sep. 26, 2003, herein incorporated by reference.

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention

[0004] This invention relates to a method and a system implementation for determining the oxygen saturation (SO_2) of blood in a blood vessel or body organ. The invention may employ invasive or noninvasive measurement techniques and is suitable for determining blood oxygen saturation in patients in any context, for example, central venous SO_2 monitoring, pulmonary artery SO_2 monitoring, extracorporeal SO_2 monitoring, amputation level assessment, free-flap SO_2 monitoring, etc.

[0005] 2. Description of the Related Art

[0006] The standard way to measure blood oxygen saturation in a patient is to direct light into or through the blood, to measure the intensity of the light at either discrete wavelengths or over a substantially continuous spectral range after transmission through or reflection by the blood, and then to calculate SO_2 as a function of the measured intensity values, Such devices are described, for example, in International Patent Application No WO94/03102.

[0007] Many factors reduce the accuracy of known SO_2 monitors. Beginning with the light source itself, it must be able to produce light at a well-defined wavelength, or over a well-defined wavelength range, and it should do so stably over the life of the measurement instrument—there is no point measuring light absorption at a, wavelength that is not produced with enough intensity to allow for a useful range of detection.

[0008] Getting the light to blood is also affected by various irregularities. When the light is directed into the blood using a non-invasive device such as a finger or ear lobe cuff, for example, inhomogeneities and irregularities in the body tissue between the light-generating device and the blood can influence light transmission in sometimes hard-to-estimate ways, which have nothing to do with the degree of blood oxygen saturation.

[0009] One irregularity that degrades the accuracy of most non-invasive monitors is patient motion, that is, motion artifact, which leads to a change in the path length of the light through the biological tissue and hence to a variation in the intensity of the detected transmitted or reflected light. This problem is in fact so great that it can render these devices inoperative for long periods of time. The problem is particularly severe in critical health care applications, were continuous monitoring is essential.

[0010] Generally, medical practitioners desire to measure arterial oxygen saturation (SaO_2). Accordingly, most conventionally used pulse oximeters measure SaO_2-The device described in WO 94/03102, for example, attempts to address the problem of motion artifact in measuring SaO_2 by transmitting into the blood not only n predetermined wavelengths of light, but also an additional wavelength that makes it possible to cancel the motion artifact. Although WO 94/03102 broadly describes the use of a plurality of wavelengths (including the n+1 motion artifact wavelength) the device exemplified uses three wavelengths. However, in practice, the three wavelengths proposed in WO 94/03102 are not sufficient to overcome motion sensitivity.

[0011] Yet another factor that reduces the accuracy of no-invasive SO_2 monitors is skin pigmentation: Many existing optical devices do not take into account the variations in transmitted light caused by with varying skin colors, which range from fair through brown to black as the concentration of melanin increases. The peak of melanin's absorption spectrum is at roughly 500 nm, decreasing almost linearly with increasing wavelength. Melanin is present in the epidermis; thus, in very high concentrations as is the case in black skin, it can mask the absorption of hemoglobin in the dermis. Even in brown skin, the absorption by melanin is superimposed on that of hemoglobin so that any algorithm which uses the shape of the absorption spectrum to produce an SO_2 estimate needs to compensate for this fact.

[0012] International Patent Application No WO 00/09004 describes an optical device which is adapted to measure blood oxygen saturation. The device operates by passing light through biological tissue to monitor the transmitted or reflected output signal from a photodetector of this device continuously. However, one difficulty with the device of the prior art is the fact that the use of a limited number of wavelengths as in WO 00/09004 results in a poor signal-to-noise ratio in the detected signal. This reduces the accuracy of the SO_2 determination. Further, this limited-wavelength technique is also more prone to ambient interference e.g. fluorescent lighting, etc.

[0013] One way to reduce the impact of the factors mentioned above is to measure SO_2 invasively. In these applications, light is usually directed into blood by means of catheter-mounted or enclosed optical fibers. The light intensity measured to determine an absorption spectrum for the blood is then usually that of reflected rather than transmitted light. The obvious disadvantage of invasive monitors is the same as for any other invasive device: patient discomfort and the need for great care in positioning the sensor.

[0014] Regardless of whether the arrangement used to monitor SO_2 is invasive or non-invasive, there is still the problem of converting the measured light spectrum—which comprises intensity values measured at several and some-

times very many wavelengths—into a single, accurate SO_2 value, and to do so quickly enough to be useful in real-time, continuous patient monitoring. There is therefore a standing need to improve the accuracy and reliability of SO_2 monitors.

SUMMARY OF THE INVENTION

[0015] The invention provides a method for determining blood oxygen saturation, and a corresponding system implementation, according to which at least two blood absorption reference spectra are compiled, corresponding to two different levels of oxygenation, over a wavelength range. Light from a light source is then directed into blood of a subject, for example via one or more optical fibers, either invasively or non-invasively. A remitted light absorption spectrum from the blood is then sensed by a detection arrangement. After suitable signal conditioning to provide a digital representation of the remitted spectrum, computer-executable code in a computation software module then computes an oxygen saturation value as a function of the remitted light absorption spectrum relative to the blood absorption reference spectra.

[0016] The blood absorption reference spectra and the remitted light absorption spectrum are preferably normalized before the oxygen saturation value is computed. Normalization preferably comprises two main procedures: DC-offsetting of the spectra linearly between two isosbestic wavelengths that lie in the wavelength range; and scaling the DC-offsetted blood absorption reference spectra and the remitted light absorption spectrum by a function of the area under each respective DC-offsetted spectrum between the two isosbestic wavelengths.

[0017] The step of computing the oxygen saturation value advantageously comprises computing an optimal value of a cost function that indicates closeness of correspondence between the remitted light absorption spectrum relative to the blood absorption reference spectra. For example, the optimal value can be determined by interpolation of the remitted light absorption spectrum relative to at least two of the blood absorption reference spectra.

[0018] As for the reference spectra, at least one minimum blood absorption reference spectrum and one maximum blood absorption reference spectrum are preferably compiled, corresponding to minimum and maximum blood oxygenation values, as well as at least one intermediate blood absorption reference spectrum. Computation of the oxygen saturation value is then done as a function of the remitted light absorption spectrum relative to at least two of the blood absorption reference spectra. One way to do this is for the system to determine the two blood absorption reference spectra that are closest to but are respectively greater than and less than the remitted light absorption spectrum; the oxygen saturation value can then be computed by linear interpolation of the remitted light absorption spectrum relative to the closest blood absorption reference spectra. Another way comprises computing the oxygen saturation value by non-linear interpolation of the remitted light absorption spectrum relative to at least three of the blood absorption reference spectra.

[0019] Accuracy of the system may in many cases be improved by further white-balancing the remitted light absorption spectrum and then using the white-balanced remitted light absorption spectrum in the step of computing the an oxygen saturation value.

[0020] The light source preferably generates the light directed into the blood from a white-light LED). The spectrum of the white-light LED may then be predetermined and a representation of the white-light LED spectrum can be stored, for example in a non-volatile medium that can be delivered along with the LED. The remitted light absorption spectrum can then be adjusted as a function of the spectrum of the white-light LED. By storing the white-light LED spectrum permanently, that is, in a non-volatile medium, no further characterization of the light source is needed. This aspect of the invention may also be applied in other medical instruments that require a white-light source, even those that are not intended to measure blood oxygen saturation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. **1** illustrates different light absorption spectra of blood at different levels of oxygenation.

[0022] FIG. **2** is a block diagram of the main hardware and software components of a system that implements the method according to the invention.

[0023] FIG. **3** illustrates a preferred normalization method for absorption spectra.

DETAILED DESCRIPTION

[0024] FIG. **1** illustrates several characteristics of light absorption by blood over a range of wavelengths. In this discussion, $A_x(\lambda)$ represents an absorption spectrum of blood with x % oxygenation whereas A_y represents an absorption value at wavelength y. In FIG. **1**, three spectra are illustrated: $A_0(\lambda)$ and $A_{100}(\lambda)$, representing fully deoxygenated and fully oxygenated blood, respectively, and $A_{meas}(\lambda)$ representing an absorption spectrum that is measured in an actual subject using any invasive or non-invasive technique. For all patients, 0<meas<100. In words: the actual SO_2 (or S_aO_2) value for a patient will always be between 0% and 100%. Given an actual measured absorption spectrum $A_{meas}(\lambda)$, the question then becomes what S_aO_2 value the spectrum represents. The way in which the invention determines this is explained below and forms a key aspect of this invention.

[0025] As is well known, there are several wavelengths—isosbestic wavelengths—at which the light absorption of hemoglobin is independent of the degree of oxygenation. Five such isosbestic wavelengths are visible in FIG. **1**, two or which, at wavelengths 522.7 nm and 586.0 nm, are labeled A_{523} and A_{586}, respectively. Other isosbestic wavelengths are 505.9, 548.6, and 569.7 nm, and there are many more. These standard values are usually rounded, and are reported slightly differently in some literature, depending on the test methodology used.

[0026] In broadest terms, this invention involves a method and system implementation that: 1) is invasive (inserted in the body, such as on catheters) or non-invasive (such as sensors placed against the skin, finger cuffs, ear lobe clips, etc.); 2) determines, measures, estimates, etc., blood oxygen saturation; 3) by directing multiple wavelengths of light from a light source, especially over the wavelength region of 500-600 nm; 4) into blood in an artery or any other blood vessel or body tissue; 5) to determine a measured absorption, reflectance, or transmission spectrum; 6) that is matched in any manner (least squares or other metric fits, neural networks, "pattern matching," table comparisons, etc.); 7) against two or more reference spectra representing different predetermined levels of blood oxygenation such that the match yields a measure of actual blood oxygen saturation SO_2 or S_aO_2.

[0027] FIG. **2** illustrates the main hardware and software components of the invention, which are explained below.

Shown without further explanation here are one or more processors **340**, system memory **345**, and system software (such as an operating system), which perform their well-known tasks, in particular, coordinating and controlling the various hardware devices within the monitor **300**, as well as executing the processor-executable code that implements the different software modules described below. Other hardware and software components of a conventional computer will of course also be included in the monitor **300** as needed.

[0028] In FIG. **2**, both an invasive and a non-invasive implementation is shown for the sake of simplicity; in practice, only the one or the other will normally be used, but FIG. **2** also illustrates the fact that the same monitor **300** according to the invention can be used in either case.

[0029] The source of light **301** is preferably broadband with sufficient spectral energy to allow for adequate discrimination and measurement resolution, at least over the wavelength range that includes the five isosbestic wavelengths that lie in the range of 500-600 nm. White light has, by definition, sufficient spectral energy within the visible spectrum in the range of 500-600 nm. Incandescent, fluorescent and halogen bulbs may be used to approximate white light. Greater thermal stability and longer life can usually be obtained by using white-light LEDs, however, and for that reason these solid-state devices are preferred.

[0030] Additional advantages of such long-life, white LEDs include: low power requirements, since it is a semiconductor, unlike an incandescent bulb, which generates heat to produce light; b) no ultraviolet (UV) light is generated (long exposure to high intensity UV can produce tissue problems (that is, sunburn); c) no infrared (IR) light is produced (a heat source)—the device stays cool, which contributes to its improved thermal stability; d) as a result of b) and c), all the power required to produce the spectral content of the LED is usable within the wavelength range of interest and, furthermore, no optical filtering is needed to remove unwanted spectral content; e) they are cheap; and f) the respond fast—since LEDs can be turned on and off very fast, they can be pulsed on and off so as to allow dark signal to be removed without the need for a mechanical shutter.

[0031] One problem with many conventional LEDs, however, is that their encapsulant yellows over time, which causes shift to longer wavelengths. Some newer LEDs use a silicone gel, however, as an encapsulant; these LEDs typically retain their original transmission spectrum much better over their exceptionally long normal lifespan, which is on the order of hundreds of thousands of hours of operation.

[0032] The light is led to the blood either directly and invasively, for example, through one or more optic fibers **111** mounted on or in a catheter **110** to a coupler or lens **100** (which may simply be the end of the transmission fiber), or indirectly and non-invasively, for example, by being conveyed from the source through one or more optic fibers **211** and then being directed against the skin of a patient's finger, etc., using a device **200** such as a finger cuff.

[0033] Light that is then remitted by the blood must be detected, and any conventional apparatus may be used to accomplish this. Either dedicated optical fibers **112**, **212** may be used to convey the remitted light to the monitor **300**, or the transmission fibers **111**, **211** may be used as long as suitable time-multiplexing is arranged.

[0034] Any known light-detector **302** may be used to measure the blood's absorption spectrum. Some conventional systems use an array of photodetectors, each tuned to the wavelength of a respective one of a plurality of substantially single-wavelength LEDs in the light source **301**. As mentioned above, though, the preferred light source is a broadband ("white" source). This avoids the need for separate optical transmission fibers (one per wavelength) and also provides sufficient spectral energy over the wavelength region of interest. In the preferred embodiment of the invention, the detector **302** is a conventional spectrometer that generates the measured spectrum using a diffraction grating and an array of photodetectors.

[0035] The signal from the detector **302** must normally be conditioned using known circuitry **304** before being processed digitally. Such conditioning will normally include various forms of filtering, scaling, analog-to-digital conversion, etc. The result of the conditioning will be a conditioned absorption spectrum $A_{cond}(\lambda)$

[0036] As mentioned above, the spectrum of the light source **301** will not be perfectly flat. This will affect the accuracy of the SO_2 (S_aO_2) calculations: a "dip" in the measured spectrum might have nothing to do with the blood absorption, for example, but rather with a lower-intensity spectral region in the transmitted light. The invention provides different methods for compensating for this deviation from pure "whiteness" in the light source so as to determine the measured absorption spectrum $A_{meas}(\lambda)$.

[0037] According to one method for white-balancing, a white-balancing software module **312** calculates $A_{meas}(\lambda.)$ according to the formula:

$$A_{Meas}(\lambda) = \log_{10} \frac{A_{cond}(\lambda) - D_\lambda}{R_\lambda - D_\lambda}$$

where D is a dark reference intensity at each wavelength .lambda. and R is a white reference intensity at each wavelength λ.

[0038] The white and dark reference spectra may be determined using known techniques: Before taking a measurement, the optical sensor (**100**, **200**) is exposed to a standard white reflective surface to give a white reference spectrum. A dark reference spectrum is then also obtained by excluding all excitation light from the optical sensor.

[0039] An alternative white-balancing method according to the invention takes advantage of the known spectral stability of modern long-life LEDs: Given one or more such LEDs as the light source, in particular, those with silicone encapsulation, the spectrum of the light source can be measured once, in an initial characterization step, and the parameters of this characterization (after normalization, as described below) can be stored in a non-volatile medium **320** such as an EPROM chip. This chip, or at least the parameters, can be created or determined once, for example by the LED manufacturer as a factory characterization, such that the parameters can be stored with the LED and can be recalled for later use. No further white measurements would then be needed at all. The values of $A_{cond}(\lambda.)$ can then be adjusted according to any known balancing algorithm to account for variations in the spectrum of the white-light LED and thus to form $A_{meas}(\lambda)$.

[0040] Note that this procedure of pre-characterizing the stable LED, storing its characterizing parameters in a non-volatile, computer-readable medium, and then including this medium along with the product (the LEDs) will also be ben-

eficial in any other medical instrument (that is, even those not related to determining blood oxygenation) that needs a well-defined source of white light for proper or accurate operation: Eliminating the need for continuing characterization will not only simplify the operation of such instruments but will also improve long-term reliability by eliminating the requirement for potentially error-prone re-characterizations.

[0041] In the preferred embodiment of the invention, the next step toward estimation of oxygen saturation is normalization of the measured absorption spectrum $A_{meas}(\lambda)$. This preferably involves two different procedures: DC-off-setting and area normalization. See FIG. **3**: Assume that one were to draw a line $L_{offset}(\lambda)$ through two of the isosbestic points A_{isos1} and A_{isos2} on the "curve" of the measured absorption spectrum $A_{meas}(\lambda)$. One suitable, but not necessary, choice would be isos1=523 and isos2'586, because they bracket almost the entire wavelength region of interest, Now, for each point on the $A_{meas}(\lambda)$ curve subtract $L_{offset}(\lambda)$ to form a new absorption curve $A_{offset}(\lambda)$. In essence, this brings down the A_{isos1} and A_{isos2} points to the 0-extinction axis, linearly adjusts every value in between and effectively removes the DC offset inherent in the $A_{meas}(\lambda)$ curve

[0042] As a second normalization step, a final normalized measured absorption spectrum $A_{norm}(\lambda)$ is then created by scaling each value of $A_{offset}(\lambda)$ by a function of (and preferably simply by division by) the area under the $A_{offset}(\lambda)$ curve from A=isos1to A=isos2. This is the shaded region in FIG. **3**. In short, $A_{offset}(\lambda)$ is normalized with respect to its area to give $A_{norm}(\lambda)$. Well known numerical methods may be used to calculate $A_{norm}(\lambda)$ given $A_{meas}(\lambda)$, A_{isos1} and A_{isos2}.

[0043] Finally, the normalized measured absorption spectrum $A_{norm}(\lambda)$ is compared in a fitting software module **315** with a plurality of reference absorption spectra (stored in numerical form in a memory region or non-volatile storage device **330**) to determine a value of SO_2 or S_{a2}, which may be displayed in any known manner by a display device **500**.

[0044] As a simple case of how oxygen saturation is determined according to the invention, assume that one uses any technique to determine a minimum and a maximum possible absorption spectrum $A_{min}(\lambda)$ and $A_{max}(\lambda)$. As an extreme example, $A_{min}(\lambda)$ and $A_{max}(\lambda)$ could be $A_0(\lambda)$ and $A_{100}(\lambda)$, respectively. Assume also that $A_{min}(\lambda)$ and $A_{max}(\lambda)$ are normalized in the same manner as was just described. For example, these spectra may be compiled from whole blood samples (measured in a cuvette), or spectra recorded in skin, or the mean spectra recorded from several individuals. As one example of.

[0045] As just one simple example, $A_{min}(\lambda)$ and $A_{max}(\lambda)$ may be chosen to be $A_0(\lambda)$ and $A_{100}(\lambda)$, respectively. The fully oxygenated spectrum $A_{100}(\lambda)$ can be obtained by equilibration of whole blood in a cuvette at 37° C., or in the skin of the forefinger heated to 44° C. at maximal reactive hyperemia following release of an inflatable cuff after six minutes of brachial artery occlusion. The fully deoxygenated spectrum $A_0(\lambda)$ can be obtained, for example, by equilibration of whole blood in the cuvette with 95% N, and 5% CO_2 at 37° C. or, in skin of the forefinger heated to 44° C. at the end of a six minute period of brachial artery occlusion prior to release of the inflatable cuff. The reference absorption spectra for a given light source can then be compiled using any known spectrometric technique. Of course, any other known laboratory procedure may be followed to determine $A_{min}(\lambda)$ and $A_{max}(\lambda)$ for any given choice of min and max.

[0046] Because some form of interpolation between reference spectra is used in the preferred embodiment of the invention for determining what level of oxygenation a given measured absorption spectrum corresponds to, $A_{min}(\lambda)$ and $A_{max}(\lambda)$ are preferably chosen to be less than and greater than, respectively, than all expected measured absorption spectra. The most obvious way to do this, of course, is to choose min=0 and max=100. This choice is not mandatory, however: as long as min and max are neither too great nor too small, respectively, then $A_0(\lambda)$ and $A_{100}(\lambda)$ could be determined by extrapolation from the $A_{min}(\lambda)$ and $A_{max}(\lambda)$ spectra actually measured in vitro. For greater accuracy, such extrapolation should preferably include at least one intermediate reference spectrum (see below).

[0047] $A_{norm}(\lambda)$ will fall between the two "extreme" absorption profiles, (either the experimentally determined $A_{min}(\lambda)$ and $A_{max}(\lambda)$, or $A_0(\lambda)$ and $A_{100}(\lambda)$, and in almost all cases, both) as shown in FIG. **1** (in non-offset and unnormalized form). The question is then how oxygenated the actual blood is. It is somewhere between min % and max %,

[0048] but where ? One way to answer this question is to use a simple table look-up with $A_x(\lambda)$ entries for a range of values of x, for example, every 1%, which may be computed using normal interpolation and stored in advance. Another procedure is to use well-known numerical methods to find the linear combination of the minimum and maximum oxygenation reference spectra $A_{min}(\lambda)$ and $A_{max}(\lambda)$ that "best" matches $A_{norm}(\lambda)$ in some sense, such as least-squares. In short, which value .α(0≦.α.≦1) gives the best match between $A_{norm}(\lambda)$ and [α.$A_{min}(\lambda)$+(1−α) $A_{max}(\lambda)$] over the range of wavelengths? This can be determined, again using known numerical techniques, by finding the value .alpha. that minimizes the cost function:

$$\underset{\lambda}{SUM}\{A_{norm} - [\alpha.A_{\min} + (1-\alpha)A_{\max}]\}^2 \ldots$$

[0049] Of course, other measures of closeness (other cost functions) of match could be used instead of least squares, and any of the many available numerical optimization methods maybe used to optimize a (just a couple examples: gradient descent, Newton-Raphson). The optimum value of α also yields the degree (percentage) of oxygenation, which will be=[α.max+(1−α)min].

[0050] One disadvantage of this simple method, which amounts to linear interpolation between $A_{min}(\lambda)$ and $A_{max}(\lambda)$, is that it is known that actual absorption profiles do not vary linearly between the extremes. This nonlinearity introduces inaccuracy in the estimate of oxygenation.

[0051] In the preferred embodiment of the invention, more than two reference spectra are compiled, that is, not only $A_{min}(\lambda)$ and $A_{max}(\lambda)$, but also at least one intermediate reference spectrum $A_{inter}(\lambda)$, whose (preferably normalized) parameters are stored in the component **330** along with the (also preferably normalized) parameters for $A_{min}(\lambda)$ and $A_{max}(\lambda)$ Such an intermediate spectrum can be determined in vitro in the same way as described above. There are different ways to determine the percentage of oxygenation given at least one intermediate reference spectrum. The simplest way is to determine whether $A_{norm}(\lambda)$ lies (wholly or at least mostly) between $A_{min}(\lambda)$ and $A_{inter}(\lambda)$, or between $A_{inter}(\lambda)$ and $A_{max}(\lambda)$ and then to apply the linear interpolation technique described above, but just within the bracketed range.

[0052] This method of bracketing followed by linear interpolation may be applied quickly even where many intermediate reference spectra are compiled. Note that it is not necessary for the reference spectra to be evenly spaced (in terms of degree of oxygenation). It is thus also not necessary to ensure that the degree of oxygenation of the reference spectra are whole numbers. Rather, a possibly large set of blood samples can be obtained; their degrees of oxygenation can be determined in vitro; and the samples' absorption spectra, possibly grouped according to other factors than oxygenation alone, call then be stored and used for actual SO_2 determination.

[0053] As an alternative, given two extreme reference spectra and one intermediate reference spectrum, a best-fit approximation of the normalized measured absorption spectrum $A_{norm}(\lambda)$ can be computed to the second-order (quadratic) surface (polynomial) that passes through all three reference spectra. In essence, determination of SO_2 then becomes, mathematically, equivalent to determining where on the second-order surface $A_{norm}(\lambda)$ most closely lies. Of course, given even more reference spectra, higher-order reference surfaces can be computed, with the cost function used to determine SO_2 being evaluated for a best-fit (in any chosen sense) with respect to $A_{norm}(\lambda)$.

[0054] Two of the advantages of the invention are: There is no requirement for the user to calibrate the system; and since the SO_2 determination is made by spectral recognition and spectral comparison with the reference spectra, the method is not prone to interference from patient movement. In the technique according to the invention, interference from patient movement will affect only certain wavelengths in the 500 to 600 nm range. These movement artifacts at particular wavelengths affect the quality of the fit between the measured spectrum and the stored reference spectrum, but otherwise have little influence on the spectral recognition and comparison processes which ultimately determine the SO_2. The technique is, therefore, insensitive to patient movement.

[0055] Although the light source preferably generates white light—for reasons explained—the invention's method of computing the oxygenation value by evaluating a cost function of the remitted absorption spectrum relative to at least two reference spectra could also be used in implementations that transmit discrete wavelengths of light, for example from an array of single-wavelength LEDs, as long as enough wavelengths are included to allow for compilation of a reasonable representation of the remitted spectrum, and at least two of the wavelengths are isosbestic such that they can be used in the spectral normalization procedure.

What is claimed is:

1. A sensor device comprising a light source for emitting a light beam, a photodetector for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelength of light received by the photodetector wherein the sensor device is configured to measure blood oxygen saturation.

2. A sensor device according to Claim I, wherein the sensor is configured to measure a plurality of wavelengths.

3. A sensor device according to claim **2**, wherein the sensor uses a spectral wavelength of from 500 to 600 mn.

4. A sensor device according to claim **3**, wherein the sensor uses a special wavelength of from 526 to 586 nm.

5. A sensor device according to claim **2**, wherein the different wavelengths bear a predetermined relationship with each other.

6. A sensor device according to claim **2**, wherein the sensor uses **3** or more different wavelengths.

7. A sensor device according to claim **6**, wherein the number of wavelengths used is 5 or 6.

8. A sensor device according to claim **2**, wherein at least one of the wavelengths is all isobestic wavelength.

9. A sensor device according to claim **8**, wherein most of the wavelengths are isobestic wavelengths.

10. A sensor device according to claim **9**, wherein the rive wavelengths are isobestic and one wavelength provides the maximum absorption difference between oxygenated haemoglobin and deoxygenated haemoglobin.

11 A sensor device according to claim **7**, wherein the number of wavelengths used are selected from 500, 528, 550, 560, 572 and 586 nm.

12. A sensor device according to claim **7**, wherein the scattered light is transmitted along 6 separate fibres to 6 photodetectors via narrow-band optical filtera all in the range 500 to 600 nm.

13. A sensor device according to claim **12**, wherein the optical filters are all in the range 526 and 586 nm.

14. A sensor device according to claim **7**, wherein the scattered light is transmitted along a single fibre of from 50 to 150 nm in diameter used with one to three white LEDs.

15. A sensor device according to claim **1**, wherein the sensor device operates on reflectance.

16. A sensor device according to claim **1**, wherein the sensor device is coupled to an oximeter.

17. A blood oxygenation monitoring system comprising:

a sensor configured to transmit light containing a plurality of wavelengths into blood and to measure a remitted spectrum over the plurality of wavelengths; and

a monitoring device connected in communication with the sensor, said processor configured to:

calculate a measured blood absorption spectrum from the remitted spectrum;

estimate local rates of change in the measured blood absorption spectrum at a plurality of the wavelengths, including at least one isobestic wavelength; and,

calculate an estimate of SO_2 as a function of absolute values of the local rates of change of the measured blood absorption spectrum.

18. A monitoring system of claim **17**, wherein the plurality of wavelengths include at least five isobestic wavelengths.

19. A monitoring system of claim **17**, wherein the plurality of wavelengths lie in a range of 500 to 600 nm.

20. A monitoring system of claim **17**, wherein the processor is further configured to apply a Kubelka Monk transformation to the measured blood absorption spectrum.

21. All SO_2 monitoring system, comprising:

a sensor configured to transmit light containing a plurality of wavelengths into the blood and measure a remitted spectrum over the plurality of wavelengths; and

a monitoring device connected in communication with the sensor and configured to:

calculate an estimate of SO_2 in blood to be monitored;

correct said estimate of SO_2 in blood by a scaling factor;

calculate a measured blood absorption spectrum from the remitted spectrum;

estimate local rates of change in the measured blood absorption spectrum at a plurality of the wavelengths, including at least one isobestic wavelength; and,

calculate the estimate of SO_2 as a function of absolute values of the local rates of change of the measured blood absorption spectrum.

22. A monitoring system of claim **21**, wherein the monitoring device is configured to, before calculating the estimate of SO_2, remove effects of light scattering from the measured blood absorption spectrum; calculate an area under the measured blood absorption spectrum after removing effects of light scattering; and, normalize the measured blood absorption spectrum by the area under the measured blood absorption spectrum.

23. A monitoring system of claim **21**, wherein the monitoring device is configured to apply a Kubelka Monk transformation to the measured blood absorption spectrum.

24. A monitoring system of claim **21**, wherein the monitoring device is, when calculating the estimate of SO_2, configured to compute a hemoglobin index value as a function of absolute values of the local rates of change of the measured blood absorption spectrum between a plurality of pairs of isobestic points, whereby the hemoglobin index value is independent of blood oxygenation; compute an oxygenation parameter as a function of absolute values of the local rates of change of the measured blood absorption spectrum between a plurality of isobestic points and at least one non-isobestic point, whereby the oxygenation parameter is dependent on blood oxygenation; normalize the oxygenation parameter by the hemoglobin index value; and, estimate SO_2 as a measure of the level of the normalized oxygenation parameter relative to a predetermined fully deoxygenated reference value and a fully oxygenated reference value.

25. A blood oxygenation monitoring system comprising:

a sensor configured to transmit light containing the plurality of wavelengths into blood and measure a remitted spectrum over the plurality of wavelengths; and

a monitoring device configured to:

determine a first reference spectrum over a plurality of wavelengths;

determine a second reference spectrum over the plurality of wavelengths;

calculate a measured blood absorption spectrum as a function of the remitted spectrum, the first reference spectrum and the second reference spectrum; and,

remove effects of light scattering from the measured blood absorption spectrum by calculating a correction function that is a function of a plurality of isobestic points of the measured blood absorption spectrum by correcting the measured blood absorption spectrum by the correction function, normalizing the measured blood absorption spectrum following the correcting step, calculating an optimal spectrum as a function of a substantially oxygenated reference absorption spectrum and a substantially deoxygenated reference absorption spectrum, so that the optimal spectrum best matches the measured blood absorption spectrum in a determined sense and, calculating an estimate of SO_2 as a function of the optimal spectrum.

26. A monitoring system of claim **25**, wherein the first reference spectrum is a spectrally neutral "white" spectrum and the second reference spectrum represents an ambient "dark" spectrum.

* * * * *

专利名称(译)	测量血氧饱和度		
公开(公告)号	US20080132771A1	公开(公告)日	2008-06-05
申请号	US12/014582	申请日	2008-01-15
[标]申请(专利权)人(译)	怀特兰RES		
申请(专利权)人(译)	怀特兰研究有限公司		
当前申请(专利权)人(译)	怀特兰研究有限公司		
[标]发明人	PARKER DAWOOD HIGGINS MICHAEL J		
发明人	PARKER, DAWOOD HIGGINS, MICHAEL J.		
IPC分类号	A61B5/1455 A61B5/00 B65H23/18		
CPC分类号	A61B5/14532 B65H23/18 A61B5/14551 A61B5/1455		
优先权	1998024899 1998-11-13 GB 1998025243 1998-11-19 GB 2003022545 2003-09-26 GB 1998014464 1998-07-04 GB 1998017552 1998-08-13 GB 1999004232 1999-02-25 GB PCT/GB1999/002510 1999-07-30 WO		
外部链接	Espacenet USPTO		

摘要(译)

通过感测有创或无创地引导到血液中的光的吸收光谱来确定受试者血液的氧合，然后通过评估相对于至少两个预定参考吸收的所发射光谱的成本函数来计算氧合值。表示不同的已知血液氧合水平的光谱。光源优选使用稳定的，长寿命的白光LED，在这种情况下，可以通过预先确定和存储LED的光谱，一次性完成，然后相应地调整汇出的光谱来实现光谱的白平衡。补偿LED光谱与恒定理想值的偏差。