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(54) A PULSE OXIMETER AND A METHOD OF ITS OPERATION

PULSOXYMETER UND DEREN VERWENDUNGSVERFAHREN

SPHYGMO-OXYMETRE ET PROCEDE D'UTILISATION

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Description

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] This invention is generally in the field of pulse oximetry, and relates to a sensor for use in a pulse oximeter, and a method for the pulse oximeter operation.

Background of the Invention

[0002] Oximetry is based on spectrophotometric measurements of changes in the color of blood, enabling the non-invasive determination of oxygen saturation in the patient's blood. Generally, oximetry is based on the fact that the optical property of blood in the visible (between 500 and 700nm) and near-infrared (between 700 and 1000nm) spectra depends strongly on the amount of oxygen in blood.

[0003] Referring to Fig. 1, there is illustrated a hemoglobin spectra measured by oximetry based techniques. Graphs G1 and G2 correspond, respectively, to reduced hemoglobin, or deoxyhemoglobin (Hb), and oxygenated hemoglobin, or oxyhemoglobin (HbO_2), spectra. As shown, deoxyhemoglobin (Hb) has a higher optical extinction (i.e., absorbs more light) in the red region of spectrum around 660nm, as compared to that of oxyhemoglobin (HbO_2). On the other hand, in the near-infrared region of the spectrum around 940nm, the optical absorption by deoxyhemoglobin (Hb) is lower than the optical absorption of oxyhemoglobin (HbO_2).

[0004] Prior art non-invasive optical sensors for measuring arterial oxyhemoglobin saturation (SaO_2) by a pulse oximeter (termed SpO_2) are typically comprised of a pair of small and inexpensive light emitting diodes (LEDs), and a single highly sensitive silicon photodetector. A red (R) LED centered on a peak emission wavelength around 660nm and an infrared (IR) LED centered on a peak emission wavelength around 940nm are used as light sources.

[0005] Pulse oximetry relies on the detection of a photoplethysmographic signal caused by variations in the quantity of arterial blood associated with periodic contraction and relaxation of a patient's heart. The magnitude of this signal depends on the amount of blood ejected from the heart into the peripheral vascular bed with each systolic cycle, the optical absorption of the blood, absorption by skin and tissue components, and the specific wavelengths that are used to illuminate the tissue. SaO_2 is determined by computing the relative magnitudes of the R and IR photoplethysmograms. Electronic circuits inside the pulse oximeter separate the R and IR photoplethysmograms into their respective pulsatile (AC) and non-pulsatile (DC) signal components. An algorithm inside the pulse oximeter performs a mathematical normalization by which the time-varying AC signal at each wavelength is divided by the corresponding time-invariant DC component which results mainly from the light absorbed and scattered by the bloodless tissue, residual arterial blood when the heart is in diastole, venous blood and skin pigmentation.

[0006] Since it is assumed that the AC portion results only from the arterial blood component, this scaling process provides a normalized R/IR ratio (i.e., the ratio of AC/DC values corresponding to R- and IR-spectrum wavelengths, respectively), which is highly dependent on SaO_2, but is largely independent of the volume of arterial blood entering the tissue during systole, skin pigmentation, skin thickness and vascular structure. Hence, the instrument does not need to be re-calibrated for measurements on different patients. Typical calibration of a pulse oximeter is illustrated in Fig. 2 by presenting the empirical relationship between SaO_2 and the normalized R/IR ratio, which is programmed by the pulse oximeters' manufacturers.

[0007] Pulse oximeters are of two kinds operating, respectively, in transmission and reflection modes. In transmission-mode pulse oximetry, an optical sensor for measuring SaO_2 is usually attached across a fingertip, foot or earlobe, such that the tissue is sandwiched between the light source and the photodetector.

[0008] In reflection-mode or backscatter type pulse oximetry, as shown in Fig. 3, the LEDs and photodetector are both mounted side-by-side next to each other on the same planar substrate. This arrangement allows for measuring SaO_2 from multiple convenient locations on the body (e.g. the head, torso, or upper limbs), where conventional transmission-mode measurements are not feasible. For this reason, non-invasive reflectance pulse oximetry has recently become an important new clinical technique with potential benefits in fetal and neonatal monitoring. Using reflectance oximetry to monitor SaO_2 in the fetus during labor, where the only accessible location is the fetal scalp or cheeks, or on the chest in infants with low peripheral perfusion, provides several more convenient locations for sensor attachment.

[0009] Reflection pulse oximetry, while being based on similar spectrophotometric principles as the transmission one, is more challenging to perform and has unique problems that can not always be solved by solutions suitable for solving the problems associated with the transmission-mode pulse oximetry. Generally, comparing transmission and reflection pulse oximetry, the problems associated with reflection pulse oximetry consist of the following:

In reflection pulse oximetry, the pulsatile AC signals are generally very small and, depending on sensor configuration and placement, have larger DC components as compared to those of transmission pulse oximetry. As illustrated in Fig. 4, in addition to the optical absorption and reflection due to blood, the DC signal of the R and IR photoplethysmograms in reflection pulse oximetry can be adversely affected by strong reflections from a bone. This problem be-

comes more apparent when applying measurements at such body locations as the forehead and the scalp, or when the sensor is mounted on the chest over the ribcage. Similarly, variations in contact pressure between the sensor and the skin can cause larger errors in reflection pulse oximetry (as compared to transmission pulse oximetry) since some of the blood near the superficial layers of the skin may be normally displaced away from the sensor housing towards deeper subcutaneous structures. Consequently, the highly reflective bloodless tissue compartment near the surface of the skin can cause large errors even at body locations where the bone is located too far away to influence the incident light generated by the sensor.

[0010] Another problem with currently available reflectance sensors is the potential for specular reflection caused by the superficial layers of the skin, when an air gap exists between the sensor and the skin, or by direct shunting of light between the LEDs and the photodetector through a thin layer of fluid which may be due to excessive sweating or from amniotic fluid present during delivery.

[0011] It is important to keep in mind the two fundamental assumptions underlying the conventional dual-wavelength pulse oximetry, which are as follows:

(1) the path of light rays with different illuminating wavelengths in tissue are substantially equal and, therefore, cancel each other; and (2) each light source illuminates the same pulsatile change in arterial blood volume.

[0012] Furthermore, the correlation between optical measurements and tissue absorptions in pulse oximetry are based on the fundamental assumption that light propagation is determined primarily by absorbance due to Lambert-Beer's law neglecting multiple scattering effects in biological tissues. In practice, however, the optical paths of different wavelengths in biological tissues is known to vary more in reflectance oximetry compared to transmission oximetry, since it strongly depends on the light scattering properties of the illuminated tissue and sensor mounting.

[0013] Several human validation studies, backed by animal investigations, have suggested that uncontrollable physiological and physical parameters can cause large variations in the calibration curve of reflectance pulse oximeters primarily at low oxygen saturation values below 70%. It was observed that the accuracy of pulse oximeters in clinical use might be adversely affected by a number of physiological parameters when measurements are made from sensors attached to the forehead, chest, or the buttock area. While the exact sources of these variations are not fully understood, it is generally believed that there are a few physiological and anatomical factors that may be the major source of these errors. It is also well known for example that changes in the ratio of blood to bloodless tissue volumes may occur through venous congestion, vasoconstriction/vasodilatation, or through mechanical pressure exerted by the sensor on the skin.

[0014] Additionally, the empirically derived calibration curve of a pulse oximeter can be altered by the effects of contact pressure exerted by the probe on the skin. This is associated with the following. The light paths in reflectance oximetry are not well defined (as compared to transmission oximetry), and thus may differ between the red and infrared wavelengths. Furthermore, the forehead and scalp areas consist of a relatively thin subcutaneous layer with the cranium bone underneath, while the tissue of other anatomical structures, such as the buttock and limbs, consists of a much thicker layer of skin and subcutaneous tissues without a nearby bony support that acts as a strong light reflector.

[0015] Several in vivo and in vitro studies have confirmed that uncontrollable physiological and physical parameters (e.g., different amounts of contact pressure applied by the sensor on the skin, variation in the ratio of bloodless tissue-to-blood content, or site-to-site variations) can often cause large errors in the oxygen saturation readings of a pulse oximeter, which are normally derived based on a single internally-programmed calibration curve. The relevant in vivo studies are disclosed in the following publications:

1. Dassel, et al., "Effect of location of the sensor on reflectance pulse oximetry", British Journal of Obstetrics and Gynecology, vol. 104, pp. 910-916, (1997);
2. Dassel, et al., "Reflectance pulse oximetry at the forehead of newborns: The influence of varying pressure on the probe", Journal of Clinical Monitoring, vol. 12, pp. 421-428, (1996).]

The relevant in vitro studies are disclosed, for example in the following publication:

3. Edrich et al., "Fetal pulse oximetry: influence of tissue blood content and hemoglobin concentration in a new in-vitro model", European Journal of Obstetrics and Gynecology and Reproductive Biology, vol. 72, suppl. 1, pp. S29-S34, (1997).

[0016] Improved sensors for application in dual-wavelength reflectance pulse oximetry have been developed. As disclosed in the following publication: Mendelson, et al., "Noninvasive pulse oximetry utilizing skin reflectance photoplethysmography", IEEE Transactions on Biomedical Engineering, vol. 35, no. 10, pp. 798-805 (1988), the total amount of backscattered light that can be detected by a reflectance sensor is directly proportional to the number of photodetectors placed around the LEDs. Additional improvements in signal-to-noise ratio were achieved by increasing the active area of the photodetector and optimizing the separation distance between the light sources and photodetectors.

[0017] Another approach is based on the use of a sen-

sor having six photodiodes arranged symmetrically around the LEDs that is disclosed in the following publications:

4. Mendelson, et al., "Design and evaluation of a new reflectance pulse oximeter sensor", Medical Instrumentation, vol. 22, no. 4, pp. 167-173 (1988); and
5. Mendelson, et al., "Skin reflectance pulse oximetry: in vivo measurements from the forearm and calf", Journal of Clinical Monitoring, vol. 7, pp. 7-12, (1991).

[0018] According to this approach, in order to maximize the fraction of backscattered light collected by the sensor, the currents from all six photodiodes are summed electronically by internal circuitry in the pulse oximeter. This configuration essentially creates a large area photodetector made of six discrete photodiodes connected in parallel to produce a single current that is proportional to the amount of light backscattered from the skin. Several studies showed that this sensor configuration could be used successfully to accurately measure SaO_2 from the forehead, forearm and the calf on humans. However, this sensor requires a means for heating the skin in order to increase local blood flow, which has practical limitations since it could cause skin bums.

[0019] Yet another prototype reflectance sensor is based on eight dual-wavelength LEDs and a single photodiode, and is disclosed in the following publication: Takatani et al., "Experimental and clinical evaluation of a noninvasive reflectance pulse oximeter sensor", Journal of Clinical Monitoring, vol. 8, pp. 257-266 (1992). Here, four R and four IR LEDs are spaced at 90-degree intervals around the substrate and at an equal radial distance from the photodiode.

[0020] A similar sensor configuration based on six photodetectors mounted in the center of the sensor around the LEDs is disclosed in the following publication: Konig, et al., "Reflectance pulse oximetry - principles and obstetric application in the Zurich system", Journal of Clinical Monitoring, vol. 14, pp. 403-412 (1998).

[0021] According to the techniques disclosed in all of the above publications, only LEDs of two wavelengths, R and IR, are used as light sources, and the computation of SaO_2 is based on reflection photoplethysmograms measured by a single photodetector, regardless of whether one or multiple photodiodes chips are used to construct the sensor. This is because of the fact that the individual signals from the photodetector elements are all summed together electronically inside the pulse oximeter. Furthermore, while a radially-symmetric photodetector array can help to maximize the detection of backscattered light from the skin and minimize differences from local tissue inhomogeneity, human and animal studies confirmed that this configuration can not completely eliminate errors caused by pressure differences and site-to-site variations.

[0022] The use of a nominal dual-wavelength pair of 735/890nm was suggested as providing the best choice for optimizing accuracy, as well as sensitivity in dual-wavelength reflectance pulse oximetry, in US 5,782,237 and 5,421,329. This approach minimizes the effects of tissue heterogeneity and enables to obtain a balance in path length changes arising from perturbations in tissue absorbance. This is disclosed in the following publications:

6. Mannheimer at al., "Physio-optical considerations in the design of fetal pulse oximetry sensors", European Journal of Obstetrics and Gynecology and Reproductive Biology, vol. 72, suppl. 1, pp. S9-S19, (1997); and
7. Mannheimer at al., "Wavelength selection for low-saturation pulse oximetry", IEEE Transactions on Biomedical Engineering, vol. 44, no. 3, pp. 48-158 (1997)].

[0023] However, replacing the conventional R wavelength at 660nm, which coincides with the region of the spectrum where the difference between the extinction coefficient of Hb and HbO_2 is maximal, with a wavelength emitting at 735nm, not only lowers considerably the overall sensitivity of a pulse oximeter, but does not completely eliminate errors due to sensor placement and varying contact pressures.

[0024] Pulse oximeter probes of a type comprising three or more LEDs for filtering noise and monitoring other functions, such as carboxyhemoglobin or various indicator dyes injected into the blood stream, have been developed and are disclosed, for, example, in WO 00/32099 and US 5,842,981. The techniques disclosed in these publications are aimed at providing an improved method for direct digital signal formation from input signals produced by the sensor and for filtering noise.

[0025] Further, US 5385143 describes a system for measuring oxygen saturation or haemoglobin levels by determining intensity levels of light transmitted through a living tissue from a three-wavelength source. In WO 96/41566, a blood oximetry sensor using two point-like light emitters and concentrical annular detectors for reflected signals in order to improve the signal-to-noise ratio of obtained values is disclosed. US 5413100 shows another pulse oximeter using three different wavelengths of illuminating light and a corresponding detector assembly.

[0026] None of the above prior art techniques provides a solution to overcome the most essential limitation in reflectance pulse oximetry, which requires the automatic correction of the internal calibration curve from which accurate and reproducible oxygen saturation values are derived, despite variations in contact pressure or site-to-site tissue heterogeneity.

[0027] In practice, most sensors used in reflection pulse oximetry rely on closely spaced LED wavelengths in order to minimize the differences in the optical path lengths of the different wavelengths. Nevertheless, within

the wavelength range required for oximetry, even closely spaced LEDs with closely spaced wavelengths mounted on the same substrate can lead to large random error in the final determination of SaO_2.

SUMMARY OF THE INVENTION AND ADVANTAGES

[0028] The object of the invention is to provide a novel sensor design and method that functions to correct the calibration relationship of a reflectance pulse oximeter, and reduce measurement inaccuracies in general. Another object of the invention is to provide a novel sensor and method that functions to correct the calibration relationship of a reflectance pulse oximeter, and reduce measurement inaccuracies in the lower range of oxygen saturation values (typically below 70%), which is the predominant range in neonatal and fetal applications.

[0029] Yet another object of the present invention is to provide automatic correction of the internal calibration curve from which oxygen saturation is derived inside the oximeter in situations where variations in contact pressure or site-to-site tissue heterogeneity may cause large measurement inaccuracies.

[0030] Another object of the invention is to eliminate or reduce the effect of variations in the calibration of a reflectance pulse oximeter between subjects, since perturbations caused by contact pressure remain one of the major sources of errors in reflectance pulse oximetry. In fetal pulse oximetry, there are additional factors, which must be properly compensated for in order to produce an accurate and reliable measurement of oxygen saturation. For example, the fetal head is usually the presenting part, and is a rather easily accessible location for application of reflectance pulse oximetry. However, uterine contractions can cause large and unpredictable variations in the pressure exerted on the head and by the sensor on the skin, which can lead to large errors in the measurement of oxygen saturation by a dual-wavelength reflectance pulse oximeter. Another object of the invention is to provide accurate measurement of oxygen saturation in the fetus during delivery.

[0031] The basis for the errors in the oxygen saturation readings of a dual-wavelength pulse oximeter is the fact that, in practical situations, the reflectance sensor applications affect the distribution of blood in the superficial layers of the skin. This is different from an ideal situation, when a reflectance sensor measures light backscattered from a homogenous mixture of blood and bloodless tissue components. Therefore, the R and IR DC signals practically measured by photodetectors contain a relatively larger proportion of light absorbed by and reflected from the bloodless tissue compartments. In these uncontrollable practical situations, the changes caused are normally not compensated for automatically by calculating the normalized R/IR ratio since the AC portions of each photoplethysmogram, and the corresponding DC components, are affected differently by pressure or site-to-site variations. Furthermore, these changes depend not only on wavelength, but depend also on the sensor geometry, and thus cannot be eliminated completely by computing the normalized R/IR ratio, as is typically the case in dual-wavelength pulse oximeters.

[0032] The inventor has found that the net result of this nonlinear effect is to cause large variations in the slope of the calibration curves. Consequently, if these variations are not compensated automatically, they will cause large errors in the final computation of SpO_2, particularly at low oxygen saturation levels normally found in fetal applications.

[0033] Another object of the present invention is to compensate for these variations and to provide accurate measurement of oxygen saturation. The invention consists of, in addition to two measurement sessions typically carried out in pulse oximetry based on measurements with two wavelengths centered around the peak emission values of 660nm (red spectrum) and 940nm $\pm$ 20nm (IR spectrum), one additional measurement session is carried out with an additional wavelength. At least one additional wavelength is preferably chosen to be substantially in the IR region of the electromagnetic spectrum, i.e., in the NIR-IR spectrum (having the peak emission value above 700nm).

[0034] The use of at least three wavelengths enables the calculation of an at least one additional ratio formed by the combination of the two IR wavelengths, which is mostly dependent on changes in contact pressure or site-to-site variations. Slight dependence of the ratio on variations in arterial oxygen saturation that may occur, is easily minimized or eliminated completely, by the proper selection and matching of the peak emission wavelengths and spectral characteristics of the at least two IR-light sources.

[0035] Preferably, the selection of the IR wavelengths is based on certain criteria. The IR wavelengths are selected to coincide with the region of the optical absorption curve where HbO_2 absorbs slightly more light than Hb. The IR wavelengths are in the spectral regions where the extinction coefficients of both Hb and HbO_2 are nearly equal and remain relatively constant as a function of wavelength, respectively.

[0036] Tracking changes in the ratio formed by the two IR wavelengths, in real-time, permits automatic correction of errors in the normalized ratio obtained from the R-wavelength and each of the IR-wavelengths. The term"ratio" signifies the ratio of two values of AC/DC corresponding to two different wavelengths. This is similar to adding another equation to solve a problem with at least three unknowns (i. e., the relative concentrations of HbO_2 and Hb, which are used to calculate SaO_2, and the unknown variable fraction of blood-to-tissue volumes that effects the accurate determination of SaO_2), which otherwise must rely on only two equations in the case of only two wavelengths used in conventional dual-wavelength pulse oximetry. A third wavelength provides the added ability to compute Saxo, based on the ratio formed from the R-wavelength and either of the IR-wavelengths.

Changes in these ratios are tracked and compared in real-time to determine which ratio produces a more stable or less noisy signal. That ratio is used predominantly for calculating SaO_2.

[0037] The present invention utilizes collection of light reflected from the measurement location at different detection locations arranged along a closed path around light emitting elements, which can be LEDs or laser sources. Preferably, these detection locations are arranged in two concentric rings, the so-called "near" and "far" rings, around the light emitting elements. This arrangement enables optimal positioning of the detectors for high quality measurements, and enables discrimination between photodetectors receiving "good" information (i. e., AC and DC values which would result in accurate calculations of SpO_2) and "bad" information (i. e., AC and DC values which would result in inaccurate calculations of SpO_2).

[0038] There is thus provided according to one aspect of the present invention, a pulse oximeter according to claim 8.

[0039] The term "closed path" used herein signifies a closed curve, like a ring, ellipse, or polygon, and the like.

[0040] The detector assembly is comprised of at least one array of discrete detectors (e. g., photodiodes) accommodated along at least one closed path, or at least one continuous photodetector defining the closed path.

[0041] The term "substantially IR spectrum" used herein signifies a spectrum range including near infrared and infrared regions.

[0042] According to yet another aspect of the present invention, there is provided a method for non-invasive determination of a blood parameter according to claim 1.

[0043] Preferred embodiments are defined by the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0044] Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Fig. 1 illustrates hemoglobin spectra as measured by oximetry based techniques;

Fig. 2 illustrates a calibration curve used in pulse oximetry as typically programmed by the pulse oximeters manufacturers;

Fig. 3 illustrates the relative disposition of light source and detector in reflection-mode or backscatter type pulse oximetry ;

Fig. 4 illustrates light propagation in reflection pulse oximetry;

Figs. 5A and 5B illustrate a pulse oximeter reflectance sensor operating under ideal and practical conditions, respectively;

Fig. 6 illustrates variations of the slopes of calibration curves in reflectance pulse oximetry measurements;

Fig. 7 illustrates an optical sensor according to the invention;

Fig. 8 is a block diagram of the main components of a pulse oximeter utilizing the sensor of Fig. 7 ;

Fig. 9 is a flow chart of a selection process used in the signal processing technique according to the invention ; and

Figs. 10A to 10C are flow charts of three main steps, respectively, of the signal processing method according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0045] Referring to the Figures, wherein like numerals indicate like or corresponding parts throughout the several views, Figs. 1 and 2 illustrate typical hemoglobin spectra and calibrations curve utilized in the pulse oximetry measurements.

[0046] The present invention provides a sensor for use in a reflection-mode or backscatter type pulse oximeter. The relative disposition of light source and detector in the reflection-mode pulse oximeter are illustrated in Fig. 3.

[0047] Fig. 4 shows light propagation in the reflection-mode pulse oximeter where, in addition to the optical absorption and reflection due to blood, the DC signal of the R and IR photoplethysmograms can be adversely affected by strong reflections from the bone.

[0048] Figs. 5A and 5B illustrate a pulse oximeter reflectance sensor operating under, respectively, ideal and practical conditions. Referring now to Fig. 5A, it is shown that, under ideal conditions, reflectance sensor measures light backscattered from a homogenous mixture of blood and bloodless tissue components. Accordingly, the normalized R/IR ratio in dual-wavelength reflection type pulse oximeters, which relies on proportional changes in the AC and DC components in the photoplethysmograms, only reflect changes in arterial oxygen saturation.

[0049] Referring now to Fig. 5B, in practical situations, the sensor applications affect the distribution of blood in the superficial layers of the skin. Accordingly, the R and IR DC signals measured by photodetectors contain a relatively larger proportion of light absorbed by and reflected from the bloodless tissue compartments. As such, the changes in DC signals depend not only on wavelength but also sensor geometry and thus cannot be eliminated completely by computing the normalized R/IR ratio, as is typically the case in dual-wavelength pulse oximeters. The result is large variations in the slope of the calibration curves, as illustrated in Fig. 6. Referring now to Fig. 6, graphs C1, C2 and C3 show three calibration curves, presenting the variation of the slope for oxygen saturation values between 50% and 100%.

[0050] Referring to Fig. 7, there is illustrated an optical sensor 10 designed according to the invention aimed at minimizing some of the measurement inaccuracies in a

reflectance pulse oximeter. The sensor 10 comprises such main constructional parts as a light source 12 composed of three closely spaced light emitting elements (e.g., LEDs or laser sources) 12a, 12b and 12c generating light of three different wavelengths, respectively; an array of discrete detectors (e.g., photodiodes), a "far" detector 16 and a "near" detector 18, arranged in two concentric ring-like arrangements (constituting closed paths) surrounding the light emitting elements; and a light shield 14. In the present example, six photodiodes form each ring. All these elements are accommodated in a sensor housing 17. The light shield 14 is positioned between the photodiodes and the light emitting elements, and prevents direct optical coupling between them, thereby maximizing the fraction of backscattered light passing through the arterially perfused vascular tissue in the detected light.

[0051] It should be noted that more than three wavelengths can be utilized in the sensor. The actual numbers of wavelengths used as a light source and the number of photodetectors in each ring are not limited and depend only on the electronic circuitry inside the oximeter. The array of discrete photodiodes can be replaced by one or more continuous photodetector rings.

[0052] In addition to the R and IR light emitting elements 12a and 12b as used in the conventional pulse oximeter sensors, the sensor 10 incorporates the third, reference, light emitting element 12c, which emits light in the NIR-IR spectrum. Wavelength $\lambda 1$ and $\lambda 2$ of the R and IR light emitting elements 12a and 12b are centered, respectively, around the peak emission values of 660nm and 940nm, and wavelength $\lambda 3$ of the third light emitting element 12c has the peak emission value above 700nm (typically ranging between 800nm and 900nm). In the description below, the light emitting elements 12b and 12c are referred to as two IR light emitting elements, and wavelengths $\lambda 2$ and $\lambda 3$ are referred to as two IR wavelengths.

[0053] During the operation of the sensor 10, different light emitting elements are selectively operated for illuminating a measurement location (not shown) with different wavelengths. Each of the photodetectors detects reflected light of different wavelengths and generates data indicative of the intensity I of the detected light of different wavelengths.

[0054] It should be noted that the sensor can be of a compact design utilizing an integrated circuit manufactured by CMOS technology. This technique is disclosed in a co-pending application assigned to the assignee of the present application. According to this technique, the sensor comprises a package including the light source, a block of two tubular optical waveguides of different diameters concentrically dislocated one inside the other and surrounding the light source, and an integrated circuit plate comprising two ring-like areas of photodiodes positioned concentrically one inside the other. The integrated circuit is also provided with a plurality of printed contact areas and electric conductors intended for mounting the light source thereon, controlling the light source, and transmitting electric signals produced by the photodiodes areas for further processing.

[0055] Fig. 8 illustrates a block diagram of a pulse oximeter 20 utilizing the above-described sensor 10. The pulse oximeter typically includes a control unit 21, which is composed of an electronic block 22 including A/D and D/A converters connectable to the sensor 10, a microprocessor 24 for analyzing measured data, and a display 26 for presenting measurement results. The measured data (i.e., electrical output of the sensor 10 indicative of the detected light) is directly processed in the block 22, and the converted signal is further processed by the microprocessor 24. The microprocessor 24 is operated by a suitable software model for analyzing the measured data and utilizing reference data (i.e., calibration curve stored in a memory) to compute the oxygen saturation value, which is then presented on the display 26. The analysis of the measured data utilizes the determination of AC- and DC-components in the detected light for each wavelength, $\lambda 1$, $\lambda 2$, and $\lambda 3$, respectively, i.e., $I_1^{(AC)}$, $I_1^{(DC)}$, $I_2^{(AC)}$, $I_2^{(DC)}$, $I_3^{(AC)}$, and $I_3^{(DC)}$, and the calculation of AC/DC ratio for each wavelength, namely, $W_1 = I_1^{(AC)}/I_1(DC)$ $W_2 = I_2^{(AC)}/I_2^{(DC)}$, and $W_3 = I_3^{(AC)}/ I_3^{(DC)}$, as will be described more specifically further below with reference to Figs. 9 and 10A-10C.

[0056] The pulse oximeter 20 with the sensor arrangement shown in Fig. 7 provides the following three possible ratio values: W_1/W_2, W_1/W_3 and W_2/W_3. It should be noted that W_1/W_2 and W_1/W_3 are the ratios that typically have the highest sensitivity to oxygen saturation. This is due to the fact that $\lambda 1$ is chosen in the red region of the electromagnetic spectrum, where the changes in the absorption between Hb and HbO_2 are the largest, as described above with reference to Fig. 1. Therefore, in principle, the absorption ratios formed by either wavelength pair $\lambda 1$ and $\lambda 2$ or wavelength pair $\lambda 1$ and $\lambda 3$ can be used to compute the value of SaO_2.

[0057] The inventor conducted extensive human and animal studies, and confirmed that either of the two ratios W_1/W_2 and W_1/W_3 can be affected not only by changes in arterial oxygen saturation, but also by sensor placement and by the amount of pressure applied by the sensor on the skin. Any calculation of SaO_2 based on either of the two ratios W_1/W_2 and W_1/W_3 alone (as normally done in commercially available dual-wavelength pulse oximeters) could result in significant errors. Furthermore, since at least two wavelengths are necessary for the calculation of arterial oxygen saturation, it is not feasible to self-correct the calibration curve for variations due to contact pressure or site-to-site variations utilizing the same two wavelengths used already to compute SaO_2.

[0058] The inventor has found that the third ratio W_2/W_3 formed by the combination of the two IR wavelengths is mostly dependent on changes in contact pressure or site-to-site variations. Furthermore, this ratio can depend, but to a much lesser degree, on variations in arterial oxygen saturation. The dependency on arterial

oxygen saturation, however, is easily minimized or eliminated completely, for example by selection and matching of the peak emission wavelengths and spectral characteristics of the two IR light emitting elements 12b and 12c.

[0059] Generally, the two IR wavelengths λ2 and λ3 are selected to coincide with the region of the optical absorption curve where HbO_2 absorbs slightly more light than Hb, but in the spectral region, respectively, where the extinction coefficients of both Hb and HbO_2 are nearly equal and remain relatively constant as a function of wavelength. For example, at 940nm and 880nm, the optical extinction coefficients of Hb and HbO_2 are approximately equal to 0.29 and 0.21, respectively. Therefore, ideally, the ratio of W2/W3 should be close to 1, except for situations when the AC/DC signals measured from λ2 and λ3 are affected unequally causing the ratio W2/W3 to deviate from 1.

[0060] Fortunately, variations in the ratio W2/W3 mimic changes in the ratios W_1/W_2 and W_1/W_3 since these ratios are all affected by similar variations in sensor positioning or other uncontrollable factors that normally can cause large errors in the calibration curve from which oxygen saturation is typically derived. Thus, by tracking in real-time changes in the ratio formed by wavelengths λ2 and λ3, it is possible to automatically correct for errors in the normalized ratios obtained from wavelengths λ1 and λ2, or from λ1 and λ3.

[0061] The use of an additional third wavelength in the sensor serves another important function (not available in conventional dual-wavelength pulse oximeters), which is associated with the following. Reflectance pulse oximeters have to be capable of detecting and relying on the processing of relatively low quality photoplethysmographic signals. Accordingly, electronic or optical noise can cause large inaccuracies in the final computation of SaO_2. Although the amount of electronic or optical noise pickup from the sensor can be minimized to some extent, it is impossible to render the signals measured by the pulse oximeter completely noise free. Therefore, pulse oximeters rely on the assumption that any noise picked up during the measurement would be cancelled by calculating the ratio between the R- and IR-light intensities measured by the photodetector. Practically, however, the amount of noise that is superimposed on the R- and IR-photoplethysmograms cannot be cancelled completely and, thus, can lead to significant errors in the final computation of SaO_2 which, in dual-wavelength pulse oximeters, is based only on the ratio between two wavelengths.

[0062] By utilizing a third wavelength, the invention has the added ability to compute SaO_2 based on the ratio formed from either W_1/W_2 or W_1/W_3. An algorithm utilized in the pulse oximeter according to the invention has the ability to track and compare in real-time changes between W_1/W_2 and $W_1/W_3$to determine which ratio produces a more stable or less noisy signal and selectively choose the best ratio for calculating SaO_2.

[0063] The method according to the invention utilizes the so-called "selection process" as part of the signal processing technique based on the measured data obtained with the multiple photodetectors. The main steps of the selection process are shown in Fig. 9 in a self-explanatory manner. Here, the symbol i corresponds to a single photodetector element in the array of multiple discrete photodetector elements, the term "1st" signifies the last photodetector element in the array, and the term "DATA" signify three ratios (AC/DC) computed separately for each of the three wavelengths, namely, W_1, W_2 and W_3.

[0064] The selection process is associated with the following: Practically, each time one of the light emitting elements is in its operative position (i.e., switched on), all of the photodetectors in the sensor receiving backscattered light from the skin. However, the intensity of the backscattered light measured by each photodetector may be different from that measured by the other photodetectors, depending on the anatomical structures underneath the sensor and its orientation relative to these structures.

[0065] Thus, the selection process is used to discriminate between photodetectors receiving "good" signals (i.e., "good" signal meaning that the calculation of SpO_2 from the pulsating portion of the electro-optic signal (AC) and the constant portion (DC) would result in accurate value) and "bad" signals (i.e., having AC and DC values which would result in inaccurate calculations of SpO_2). Accordingly, each data point (i.e., ratio W_{1i}, W_{2i} or W_{3i} detected at the corresponding i^{th} detector) is either accepted, if it meets a certain criteria based for example on a certain ratio of AC to DC values (e.g., such that the intensity of AC signal is about 0.05-2.0% of the intensity of DC signal), or rejected. All of the accepted data points (data from accepted detection locations) are then used to calculate the ratios W_1/W_2, W_1/W_3 and W_1/W_3, and to calculate the SpO_2 value, in conjunction with the signal processing technique, as will be described further below with reference to Figs. 10A-10C.

[0066] Besides the use of the third IR-wavelength to compensate for changes in the internal calibration curve of the pulse oximeter, the pulse oximeter utilizing the sensor according to the invention provides a unique new method to compensate for errors due to sensor positioning and pressure variability. This method is based on multiple photodetector elements, instead of the conventional approach that relies on a single photodetector.

[0067] While optical sensors with multiple photodetectors for application in reflectance pulse oximetry have been described before, their main limitation relates to the way the information derived from these photodetectors is processed. Although the primary purpose of utilizing multiple photodetectors is to collect a larger portion of the backscattered light from the skin, practically, summing the individual intensities of each photodetector and using the resulting value to compute SaO_2 can introduce large errors into the calculations. These errors can be caused, for example, by situations where the sensor is placed over inhomogeneous tissue structures such as

when the sensor is mounted on the chest. The case may be such that, when using a continuous photodetector ring to collect the backscattered light, a portion of the photodetector ring lies over a rib, which acts as a strongly reflecting structure that contributes to a strong DC component, and the remaining part of the photodetector is positioned over the intercostals space, where the DC signal is much smaller. In this case, the final calculation of SaO_2 would be inaccurate, if the current produced by this photodetector is used indiscriminately to compute the DC value before the final computation of SaO_2 is performed. Therefore, in addition to automatically correcting errors in the calibration curve as outlined above using three different LEDs (one R and two different IR wavelengths), the sensor 10 has the optional ability to track automatically and compare changes in the R/IR ratios obtained from each of the discrete photodiodes individually. For example, if some of either the near or the far photodetectors in the two concentrically arranged arrays detect larger than normal DC signals during the operation of one of the photodiodes compared to the other photodiodes in the sensor, it could be indicative of one of the following situations: the sensor is positioned unevenly, the sensor is partially covering a bony structure, or uneven pressure is exerted by the sensor on the skin causing partial skin "blanching" and therefore the blood-to-bloodless tissue ratio might be too high to allow accurate determination of SaO_2. If such a situation is detected, the oximeter has the ability to selectively disregard the readings obtained from the corresponding photodetectors. Otherwise, if the DC and AC signals measured from each photodetector in the array are similar in magnitude, which is an indication that the sensor is positioned over a homogeneous area on the skin, the final computation of SaO_2 can be based on equal contributions from every photodetector in the array.

[0068] Turning now to Figs. 10A, 10B and 10C, there are illustrated three main steps of the signal processing technique utilized in the present invention. Here, TH_1 and TH_2 are two different threshold values (determined experimentally) related respectively to W_2/W_3 and $(W_1/W_2\text{-}W_1/W_3)$.

[0069] During step 1 (Fig. 10A), measured data generated by the "near" and "far" photodetectors indicative of the detected (backscattered) light of wavelength $\lambda 2$ and $\lambda 3$ is analyzed to calculate the two ratios W_2/W_3 (far and near). If one of the calculated ratios (far or near) is not in the range of $1 \pm TH_1$ (TH_1 is for example 0.1), then this data point is rejected from the SpO_2 calculation, but if both of them are not in the mentioned range, a corresponding alarm is generated indicative of that the sensor position should be adjusted. Only if there are calculated ratios which are in the range of $1 \pm TH1$, they are accepted and the process (data analysis) proceeds by performing step 2.

[0070] Step 2 (Fig. 10B) consists of determining whether the quality of each photoplethysmogram is acceptable or not. The quality determination is based on the relative magnitude of each AC component compared to its corresponding DC component. If the quality is not acceptable (e.g., the signal shape detected by any detector varies within a time frame of the measurement session, which may for example be 3.5 sec), the data point is rejected and a corresponding alarm signal is generated. If the AC/DC ratio of W_1, W_2 and W_3 are within an acceptable range, the respective data point is accepted, and the process proceeds through performing step 3.

[0071] In step 3 (Fig. 10C), the measured data is analyzed to calculate ratios W_1/W_2 and W_1/W_3 from data generated by far and near photodetectors, and to calculate the differences $(W_1/ W_2\text{-} W_1/ W_3)$.

[0072] In a perfect situation, W_1/W_2 (far) is very close to W_1/W_3 (far), and W_1/W_2 (near) is very close to W_1/W_3 (near). In a practical situation, this condition is not precisely satisfied, but all the ratios are close to each other if the measurement situation is "good".

[0073] Then, the calculated differences are analyzed to determine the values (corresponding to far and near photodetectors) that are accepted and to use them in the SpO_2 calculation. For each detector that satisfied the condition $ABS(W_1/W_2 - W_1/W_3)<TH_2)$, where ABS signifies the absolute value, its respective data point is accepted and used to calculate the oxygen saturation value that will be displayed. If the condition is not satisfied, the data point is rejected. If all data points are rejected, another measurement session is carried out.

[0074] It should be noted that, although the steps 1-3 above are exemplified with respect to signal detection by both near and far photodetectors, each of these steps can be implemented by utilizing only one array of detection locations along the closed path. The provision of two such arrays, however, provides higher accuracy of measurements.

Claims

1. A method for non-invasive determination of a blood parameter, the method comprising the steps of:

(i) illuminating a measurement location with at least three different wavelengths, a first wavelength (B1) lying in a red (R) spectrum, and at least second and third wavelengths (B2 and B3) lying substantially in the infrared (IR) spectrum;
(ii) detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light, said generated data including first, second and third signals indicative of a value of the reflected radiation at the respective first, second and third wavelengths (B1, B2 and B3), and
(iii) analyzing the generated data and determining the blood parameter wherein
said different detection locations are arranged so as to define at least one closed path around

the measurement location; and
wherein
the determination of the blood parameters comprises the steps of:

calculating data indicative of an AC/DC ratio in the light detected at each of the detection locations for the at least three wavelengths;
analyzing the calculated data and determining accepted detection locations to select corresponding AC/DC ratios for each of the at least three wavelengths (B1, B2 and B3);
wherein for each location W1 is an AC/DC ratio for the first wavelength (B1), W2 is a AC/DC ratio for the second wavelength (B2), and W3 is a AC/DC ratio for the third wavelength (B3);
characterized by
calculating values of a third ratio W2/W3 for the accepted detection locations in at least one closed path;
analyzing each of the calculated values of the third ratio W2/W3 to determine whether it satisfies a first predetermined condition, so as to generate a signal indicative of that a sensor position is to be adjusted, if the condition is not satisfied;
if the condition is satisfied, determining whether the quality of a photoplethysmogram is acceptable;
if the quality is acceptable, analyzing the selected ratios for calculating a first ratio W1/W2 and a second ratio W1/W3 from the data detected in at least one closed path, and calculating the absolute differences ABS(W1/W2-W1/W3);
and, analyzing the calculated absolute differences for determining whether each of the differences satisfies a second predetermined condition and determining the blood parameter if the condition is satisfied;
wherein said first predetermined condition consists of that the calculated value of W2/W3 is inside a predetermined range around the value one, said predetermined range being defined by the first threshold value, and the second predetermined condition consists of that the calculated absolute difference ABS(W1/W2-W1/W3) is less than a certain, second threshold value.

2. The method according to claim 1, wherein the quality of a photoplethysmogram is acceptable if a ratio of the AC portion to the DC portion is within a predetermined range.

3. The method according to claim 2, wherein the predetermined range is 0.05 to 2.0 percent.

4. The method according to any of claims 2 to 3, wherein the parameter of the blood is determined as a function of the first ratio W1/W2 and second ratio W1/W3 and a calibration curve.

5. The method according to claim 4, including the step of adjusting the calibration curve as a function of the third ratio W2/W3.

6. The method according to any previous claim, wherein the first wavelength is in a red wavelength range, the second wavelength is in an infrared wavelength range, and the third wavelength is in a near infrared wavelength range.

7. The method according to claim 6, wherein the second wavelength (B2) is in the IR spectral region around 940nm+/-20nm, and the third wavelength (B3) is above 700nm.

8. A pulse oximeter for detecting a value of a parameter of blood, comprising:

a sensor housing;
a source of radiation coupled to the housing and being adapted to emit radiation at predetermined wavelengths;
a detector assembly coupled to the housing and being adapted to detect reflected radiation at first, second, and third wavelengths (B1, B2 and B3) and
to generate respective first, second, and third signals, wherein the first, second,
and third signals are indicative of a value of the reflected radiation at the respective first, second, and third wavelengths (B1, B2 and B3), wherein the first wavelength is in a red spectrum, and the second wavelength and the third wavelength are substantially in the infrared spectrum; and,
a control unit coupled to the detector assembly and adapted to receive the first, second, and third signals, to calculate first, second and third ratios of the first, second, and third signals and to responsively determine the parameter of the blood as a function of the first, second and third ratios,
the control unit is adapted to determine the blood parameters by:

calculating data indicative of an AC/DC ratio in the light detected at each of the detection locations for the at least three wavelengths;
analyzing the calculated data and determining accepted detection locations to select corresponding AC/DC ratios for each of the at least three wavelengths (B1, B2 and B3);
wherein for each location W1 is an AC/DC

ratio for the first wavelength (B1), W2 is a AC/DC ratio for the second wavelength (B2), and W3 is a AC/DC ratio for the third wavelength (B3);

characterized in that the control unit is adapted for

calculating values of the third ratio W2/W3 for the accepted detection locations in at least one closed path;
analyzing each of the calculated values of the third ratio W2/W3 to determine whether it satisfies a first predetermined condition, so as to generate a signal indicative of that a sensor position is to be adjusted, if the condition is not satisfied;
if the condition is satisfied, determining whether the quality of a photoplethysmogram is acceptable;
if the quality is acceptable, analyzing the selected ratios for calculating the first ratio W1/W2 and the second ratio W1/W3 from the data detected in at least one closed path, and calculating the absolute differences ABS(W1/W2-W1/W3);
and, analyzing the absolute calculated differences for determining whether each of the differences satisfies a second predetermined condition and determining the blood parameter if the condition is satisfied;
wherein said first predetermined condition consists of that the calculated value of the third ratio W2/W3 is inside a predetermined range around the value one, said predetermined range being defined by the first threshold value, and the second predetermined condition consists of that the calculated absolute difference ABS(W1/W2-W1/W3) is less than a certain, second threshold value.

9. A pulse oximeter, as set forth in claim 8, wherein the control unit is adapted to determine the parameter of the blood as a function of the first and second ratios W1/W2 and W1/W3 and a calibration curve.

10. A pulse oximeter, as set forth in claim 9, wherein the calibration curve is adjusted as a function of the third ratio W2/W3.

11. A pulse oximeter, as set forth in any of claims 8 to 10, wherein the first wavelength is in a red wavelength range, the second wavelength is in a near-infrared wavelength range, and the third wavelength is in an infrared wavelength range.

12. A pulse oximeter according to claim 11, wherein the second wavelength (B2) is in the IR spectral region around 940nm+/-20nm, and the third wavelength (B3) is above 700 nm.

13. A pulse oximeter, as set forth in claims 8, wherein the quality of a plethysmogram is acceptable if a ratio of the AC portion to the DC portion of the signal is within a predetermined range.

14. A pulse oximeter, as set forth in claim 13, wherein the predetermined range is 0.05 to 2.0 percent.

Patentansprüche

1. Verfahren zur nichtinvasiven Bestimmung eines Blutparameters, wobei das Verfahren die Schritte umfasst:

(i) Beleuchten eines Meßortes mit mindestens drei verschiedenen Wellenlängen, wobei eine erste Wellenlänge (B1) in einem roten Spektrum (R) liegt, und mindestens zweite und dritte Wellenlängen (132 und B3) im Wesentlichen im infraroten (IR) Spektrum liegen;
(ii) Erfassen von Licht, das von dem Meßort zurückgegeben wird, an verschiedenen Erfassungsorten, und Erzeugen von Daten, die das erfasste Licht anzeigen, wobei die erzeugten Daten erste, zweite und dritte Signale einschließen, die einen Wert der reflektierten Strahlung bei der jeweiligen ersten, zweiten und dritten Wellenlänge (B1, B2 und B3) anzeigen; und
(iii) Analysieren der erzeugten Daten und Bestimmen des Blutparameters, wobei
die verschiedenen Erfassungsorte so angeordnet sind, dass sie zumindest einen geschlossenen Pfad um den Messort herum definieren; und
wobei die Bestimmung der Blutparameter die folgenden Schritte umfasst:

Berechnen von Daten, die ein AC/DC-Verhältnis in dem erfassten Licht an jedem der Erfassungsorte für die mindestens drei Wellenlängen anzeigen;
Analysieren der berechneten Daten und Bestimmen von akzeptierten Erfassungsorten zum Wählen entsprechender AC/DC-Verhältnisse für jede der mindestens drei Wellenlängen (B1, B2 und B3); wobei für jeden Ort W1 ein AC/DC-Verhältnis für die erste Wellenlänge (B1) ist, W2 ein AC/DC-Verhältnis für die zweite Wellenlänge (B2) ist, und W3 ein AC/DC-Verhältnis für die dritte Wellenlänge (B3) ist;

gekennzeichnet durch

Berechnen von Werten eines dritten Verhältnisses W2/W3 für die akzeptierten Erfassungsorte in mindestens einem geschlossenen Pfad;
Analysieren jedes der berechneten Werte des dritten Verhältnisses W2/W3, um zu bestimmen, ob er eine erste vorbestimmte Bedingung erfüllt, um so ein Signal zu erzeugen, das anzeigt, dass eine Sensorposition angepasst werden muss, falls die Bedingung nicht erfüllt ist;
falls die Bedingung erfüllt ist, Bestimmen ob die Qualität eines Photoplethysmogramms akzeptabel ist;
falls die Qualität akzeptabel ist, Analysieren der gewählten Verhältnisse zum Berechnen eines ersten Verhältnisses W1/W2 und eines zweiten Verhältnisses W1/W3 aus den erfassten Daten in mindestens einem geschlossenen Pfad, und Berechnen der absoluten Differenzen ABS(W1/W2 - W1/W3);
und Analysieren der berechneten absoluten Differenzen zum Bestimmen, ob jede der Differenzen eine zweite vorbestimmte Bedingung erfüllt, und Bestimmen des Blutparameters, falls die Bedingung erfüllt ist;
wobei die erste vorbestimmte Bedingung darin besteht, dass der berechnete Wert von W2/W3 innerhalb eines vorbestimmten Bereichs um den Wert eins liegt, wobei der vorbestimmte Bereich **durch** den ersten Schwellwert festgelegt ist, und die zweite vorbestimmte Bedingung darin besteht, dass die berechnete absolute Differenz ABS(W1/W2-W1/W3) weniger als ein bestimmter zweiter Schwellwert ist.

2. Verfahren nach Anspruch 1, wobei die Qualität eines Photoplethysmogramms akzeptabel ist, falls ein Verhältnis des AC-Anteils zu dem DC-Anteil innerhalb eines vorbestimmten Bereichs liegt.

3. Verfahren nach Anspruch 2, wobei der vorbestimmte Bereich 0,05 bis 2,0 Prozent ist.

4. Verfahren nach Anspruch 2 oder 3, wobei der Blutparameter bestimmt wird als Funktion des ersten Verhältnisses W1/W2 und des zweiten Verhältnisses W1/W3 und einer Kalibrierkurve.

5. Verfahren nach Anspruch 4, umfassend den Schritt des Anpassens der Kalibrierkurve als Funktion des dritten Verhältnisses W2/W3.

6. Verfahren nach einem der vorhergehenden Ansprüche, wobei die erste Wellenlänge in einem roten Wellenlängenbereich liegt, die zweite Wellenlänge in einem infraroten Wellenlängenbereich liegt, und die dritte Wellenlänge in einem nah-infraroten Wellenlängenbereich liegt.

7. Verfahren nach Anspruch 6, wobei die zweite Wellenlänge (B2) im IR-Spektralbereich um etwa 940nm +/- 20nm liegt, und die dritte Wellenlänge (B3) oberhalb von 700nm liegt.

8. Pulsoximeter zum Erfassen eines Wertes eines Blutparameters, umfassend:

ein Sensorgehäuse;
eine Strahlungsquelle, die mit dem Gehäuse verbunden ist und angepasst ist,
Strahlung bei vorbestimmten Wellenlängen zu emittieren;
eine Detektoranordnung, die mit dem Gehäuse verbunden ist und angepasst ist,
reflektierte Strahlung bei einer ersten, zweiten und dritten Wellenlänge (B1, B2, und B3) zu erfassen und entsprechende erste, zweite und dritte Signale zu erzeugen, wobei die ersten, zweiten und dritten Signale einen Wert der reflektierten Strahlung bei den jeweiligen ersten, zweiten und dritten Wellenlängen (B1, B2 und B3) anzeigen, wobei die erste Wellenlänge in einem roten Spektrum liegt, und die zweite und die dritte Wellenlänge im Wesentlichen im infraroten Spektrum liegen; und
eine Steuereinheit, die mit der Detektoranordnung verbunden ist und angepasst ist, erste, zweite und dritte Signale zu empfangen, um erste, zweite und dritte Verhältnisse des ersten, zweiten und dritten Signals zu berechnen, und um daraufhin entsprechend die Blutparameter als eine Funktion der ersten, zweiten und dritten Verhältnisse zu bestimmen,
wobei die Steuereinheit angepasst ist, die Blutparameter zu bestimmen durch:

Berechnen von Daten, die ein AC/DC-Verhältnis in dem erfassten Licht an jedem der Erfassungsorte für die mindestens drei Wellenlängen anzeigen;
Analysieren der berechneten Daten und Bestimmen von akzeptierten Erfassungsorten zum Wählen entsprechender AC/DC-Verhältnisse für jede der mindestens drei Wellenlängen (B1, B2 und B3); wobei für jeden Ort W1 ein AC/DC-Verhältnis für die erste Wellenlänge (B1) ist, W2 ein AC/DC-Verhältnis für die zweite Wellenlänge (B2) ist, und W3 ein AC/DC-Verhältnis für die dritte Wellenlänge (B3) ist;
dadurch gekennzeichnet, dass die Steuereinheit angepasst ist zum
Berechnen von Werten des dritten Verhält-

nisses W2/W3 für die akzeptierten Erfassungsorte in mindestens einem geschlossenen Pfad;
Analysieren jedes der berechneten Werte des dritten Verhältnisses W2/W3, um zu bestimmen, ob er eine erste vorbestimmte Bedingung erfüllt, um so ein Signal zu erzeugen, das anzeigt, dass eine Sensorposition angepasst werden muss, falls die Bedingung nicht erfüllt ist;
falls die Bedingung erfüllt ist, Bestimmen ob die Qualität eines Photoplethysmogramms akzeptabel ist;
falls die Qualität akzeptabel ist, Analysieren der gewählten Verhältnisse zum Berechnen des ersten Verhältnisses W1/W2 und des zweiten Verhältnisses W1/W3 aus den erfassten Daten in mindestens einem geschlossenen Pfad, und Berechnen der absoluten Differenzen ABS(W1/W2 - W1/W3); und Analysieren der berechneten absoluten Differenzen zum Bestimmen, ob jede der Differenzen eine zweite vorbestimmte Bedingung erfüllt, und Bestimmen des Blutparameters, falls die Bedingung erfüllt ist;
wobei die erste vorbestimmte Bedingung darin besteht, dass der berechnete Wert des dritten Verhältnisses W2/W3 innerhalb eines vorbestimmten Bereichs um den Wert eins liegt, wobei der vorbestimmte Bereich durch den ersten Schwellwert festgelegt ist, und die zweite vorbestimmte Bedingung darin besteht, dass die berechnete absolute Differenz ABS(W1/W2-W1/W3) weniger als ein bestimmter zweiter Schwellwert ist.

9. Pulsoximeter nach Anspruch 8, wobei die Steuereinheit dazu angepasst ist, die Blutparameter als Funktion der ersten und zweiten Verhältnisse W1/W2 und W1/W3 und einer Kalibrierkurve zu bestimmen.

10. Pulsoximeter nach Anspruch 9, wobei die Kalibrierkurve als Funktion des dritten Verhältnisses W2/W3 angepasst wird.

11. Pulsoximeter nach einem der Ansprüche 8 bis 10, wobei die erste Wellenlänge in einem roten Wellenlängenbereich liegt, die zweite Wellenlänge in einem nah-infraroten Wellenlängenbereich liegt und die dritte Wellenlänge in einem infraroten Wellenlängenbereich liegt.

12. Pulsoximeter nach Anspruch 11, wobei die zweite Wellenlänge (B2) im IR-Spektralbereich um etwa 940nm+/-20nm liegt, und die dritte Wellenlänge (B3) über 700nm liegt.

13. Pulsoximeter nach Anspruch 8, wobei die Qualität eines Plethysmogramms akzeptabel ist, falls ein Verhältnis des AC-Anteils zum DC-Anteil des Signals innerhalb eines vorbestimmten Bereichs liegt.

14. Pulsoximeter nach Anspruch 13, wobei der vorbestimmte Bereich 0,05 bis 2,0 Prozent ist.

Revendications

1. Procédé de détermination non invasive d'un paramètre du sang, le procédé comprenant les étapes suivantes :

(i) éclairage d'un emplacement de mesure avec au moins trois longueurs d'onde différentes, une première longueur d'onde (B1) se trouvant dans un spectre rouge (R), et au moins des deuxième et troisième longueurs d'onde (B2 et B3) se trouvant sensiblement dans le spectre infrarouge (IR) ;
(ii) détection de la lumière renvoyée de l'emplacement de mesure au niveau de différents emplacements de détection et génération de données indiquant la lumière détectée, lesdites données générées comprenant des premier, deuxième et troisième signaux indiquant une valeur du rayonnement réfléchi aux première, deuxième et troisième longueurs d'onde respectives (B1, B2 et B3), et
(iii) analyse des données générées et détermination du paramètre du sang
dans lequel
lesdits différents emplacements de détection sont disposés pour définir au moins une trajectoire fermée autour de l'emplacement de mesure ; et
dans lequel
la détermination des paramètres du sang comprend les étapes suivantes :

calcul des données indiquant un rapport CA/CC dans la lumière détectée au niveau de chaque emplacement de détection pour les trois longueurs d'onde ou plus ;
analyse des données calculées et détermination des emplacements de détection acceptés pour sélectionner les rapports CA/CC correspondants pour chacune des trois longueurs d'onde ou plus (B1, B2 et B3) ; dans lequel pour chaque emplacement W1 est un rapport CA/CC pour la première longueur d'onde (B1), W2 est un rapport CA/CC pour la deuxième longueur d'onde (B2), et W3 est un rapport CA/CC pour la troisième longueur d'onde (B3) ;

caractérisé par :

le calcul des valeurs d'un troisième rapport W2/W3 pour les emplacements de détection acceptés dans au moins une trajectoire fermée ;
l'analyse de chacune des valeurs calculées du troisième rapport W2/W3 pour déterminer s'il satisfait à une première condition prédéterminée, pour générer un signal indiquant qu'une position de capteur doit être ajustée, si la condition n'est pas satisfaite ;
si la condition est satisfaite, la détermination du fait que la qualité d'un photopléthysmogramme est acceptable ou non ;
si la qualité est acceptable, l'analyse des rapports sélectionnés pour le calcul d'un premier rapport W1/W2 et d'un deuxième rapport W1/W3 à partir des données détectées dans au moins une trajectoire fermée, et le calcul des différences absolues ABS(W1/W2 - W1/W3) ;
et, l'analyse des différences absolues calculées pour déterminer si chacune des différences satisfait ou non à une deuxième condition prédéterminée et la détermination du paramètre du sang si la condition est satisfaite ;
dans lequel ladite première condition prédéterminée consiste en ce que la valeur calculée de W2/W3 est à l'intérieur d'une plage prédéterminée autour de la valeur un, ladite plage prédéterminée étant définie par la première valeur seuil, et la seconde condition prédéterminée consiste en ce que la différence absolue calculée ABS(W1/W2 - W1/W3) est inférieure à une certaine seconde valeur seuil.

2. Procédé selon la revendication 1, dans lequel la qualité d'un photoplétrysmogramme est acceptable si un rapport de la partie CA sur la partie CC se trouve dans une plage prédéterminée.

3. Procédé selon la revendication 2, dans lequel la plage prédéterminée est de 0,05 à 2,0 %.

4. Procédé selon l'une quelconque des revendications 2 à 3, dans lequel le paramètre du sang est déterminé en fonction du premier rapport W1/W2 et du deuxième rapport W1/W3 et d'une courbe d'étalonnage.

5. Procédé selon la revendication 4, comprenant l'étape d'ajustement de la courbe de d'étalonnage en fonction du troisième rapport W2/W3.

6. Procédé selon l'une quelconque des revendications précédentes, dans lequel la première longueur d'onde est dans une plage de longueurs d'onde rouge, la deuxième longueur d'onde est dans une plage de longueurs d'onde infrarouge, et la troisième longueur d'onde est dans une plage de longueurs d'onde proche infrarouge.

7. Procédé selon la revendication 6, dans lequel la deuxième longueur d'onde (B2) est dans la région spectrale IR autour de 940 nm $\pm$ 20 nm, et la troisième longueur d'onde (B3) est supérieure à 700 nm.

8. Sphygmo-oxymètre destiné à détecter une valeur d'un paramètre du sang, comprenant :

un logement pour capteur ;
une source de rayonnement couplée au logement et adaptée à émettre un rayonnement à des longueurs d'onde prédéterminées ;
un ensemble détecteur couplé au logement et adapté à détecter le rayonnement réfléchi à des première, deuxième, et troisième longueurs d'onde respectives (B1, B2 et B3) et à générer des premier, deuxième, et troisième signaux respectifs, dans lequel les premier, deuxième, et troisième signaux indiquent une valeur du rayonnement réfléchi aux première, deuxième, et troisième longueurs d'onde respectives (B1, B2 et B3), dans lequel la première longueur d'onde est dans un spectre rouge, et la deuxième longueur d'onde et la troisième longueur d'onde sont sensiblement dans le spectre infrarouge ; et
une unité de commande couplée à l'ensemble détecteur et adaptée à recevoir les premier, deuxième, et troisième signaux, pour calculer les premier, deuxième et troisième rapports des premier, deuxième, et troisième signaux et pour déterminer en réponse le paramètre du sang en fonction des premier, deuxième et troisième rapports,
l'unité de commande est adaptée à déterminer les paramètres du sang par :

calcul des données indiquant un rapport CA/CC dans la lumière détectée au niveau de chaque emplacement de détection pour les trois longueurs d'onde ou plus ;
analyse des données calculées et détermination des emplacements de détection acceptés pour sélectionner les rapports CA/CC correspondants pour chacune des trois longueurs d'onde ou plus (B1, B2 et B3) ; dans lequel pour chaque emplacement W1 est un rapport CA/CC pour la première longueur d'onde (B1), W2 est un rapport CA/CC pour la deuxième longueur d'onde (B2), et W3 est un rapport CA/CC

pour la troisième longueur d'onde (B3) ;
caractérisé en ce que l'unité de commande est adaptée à
calculer les valeurs du troisième rapport W2/W3 pour les emplacements de détection acceptés dans au moins une trajectoire fermée ;
analyser chacune des valeurs calculées du troisième rapport W2/W3 pour déterminer s'il satisfait à une première condition prédéterminée, pour générer un signal indiquant qu'une position de capteur doit être ajustée, si la condition n'est pas satisfaite ;
si la condition est satisfaite, déterminer si la qualité d'un photopléthysmogramme est acceptable ou non ;
si la qualité est acceptable, analyser les rapports sélectionnés pour le calcul du premier rapport W1/W2 et du deuxième rapport W1/W3 à partir des données détectées dans au moins une trajectoire fermée, et calculer les différences absolues ABS(W1/W2 - W1/W3) ;
et, analyser les différences absolues calculées pour déterminer si chacune des différences satisfait à une deuxième condition prédéterminée et déterminer le paramètre du sang si la condition est satisfaite ;
dans lequel ladite première condition prédéterminée consiste **en ce que** la valeur calculée du troisième rapport W2/W3 se trouve à l'intérieur d'une plage prédéterminée autour de la valeur un, ladite plage prédéterminée étant définie par la première valeur seuil, et la seconde condition prédéterminée consiste en ce que la différence absolue calculée ABS(W1/W2-W1/W3) est inférieure à une certaine seconde valeur seuil.

9. Sphygmo-oxymètre, selon la revendication 8, dans lequel l'unité de commande est adaptée à déterminer le paramètre du sang en fonction des premier et deuxième rapports W1/W2 et W1/W3 et d'une courbe d'étalonnage.

10. Sphygmo-oxymètre, selon la revendication 9, dans lequel la courbe d'étalonnage est ajustée en fonction du troisième rapport W2/W3.

11. Sphygmo-oxymètre, selon l'une quelconque des revendications 8 à 10, dans lequel la première longueur d'onde est dans une plage de longueurs d'onde rouge, la deuxième longueur d'onde est dans une plage de longueurs d'onde proche infrarouge, et la troisième longueur d'onde est dans une plage de longueurs d'onde infrarouge.

12. Sphygmo-oxymètre selon la revendication 11, dans lequel la deuxième longueur d'onde (B2) est dans la région spectrale IR autour de 940 nm $\pm$ 20 nm, et la troisième longueur d'onde (B3) est supérieure à 700 nm.

13. Sphygmo-oxymètre, selon la revendication 8, dans lequel la qualité d'un pléthysmogramme est acceptable si un rapport de la partie CA sur la partie CC du signal se trouve dans une plage prédéterminée.

14. Sphygmo-oxymètre, selon la revendication 13, dans lequel à plage prédéterminée est de 0,05 à 2,0 %.

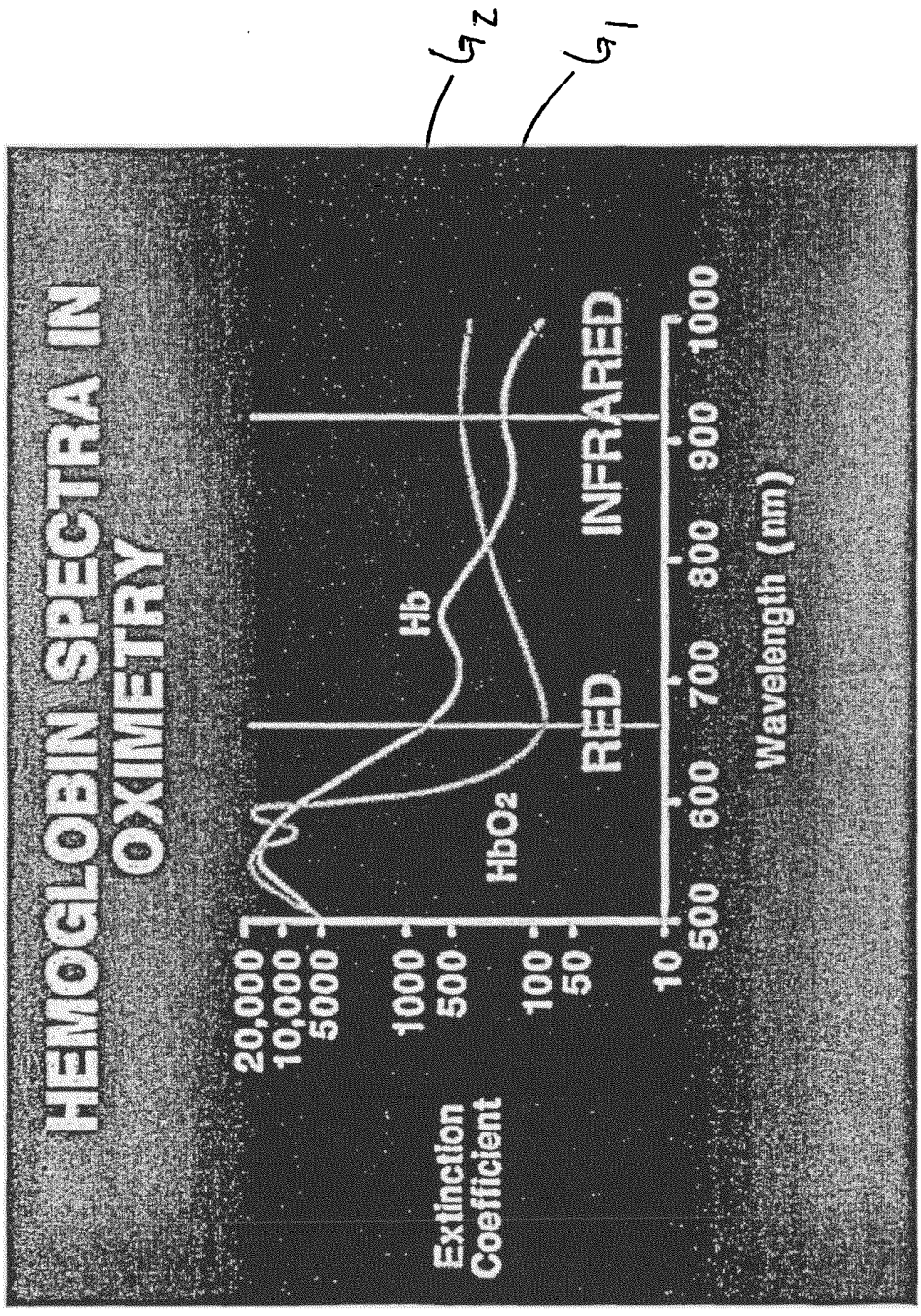
HEMOGLOBIN SPECTRA IN OXIMETRY
Extinction Coefficient
20,000
10,000
5000
1000
500
100
50
10
Hb
HbO2
RED
INFRARED
500
600
700
800
900
1000
Wavelength (nm)
λ2
λ1

Fig. 1

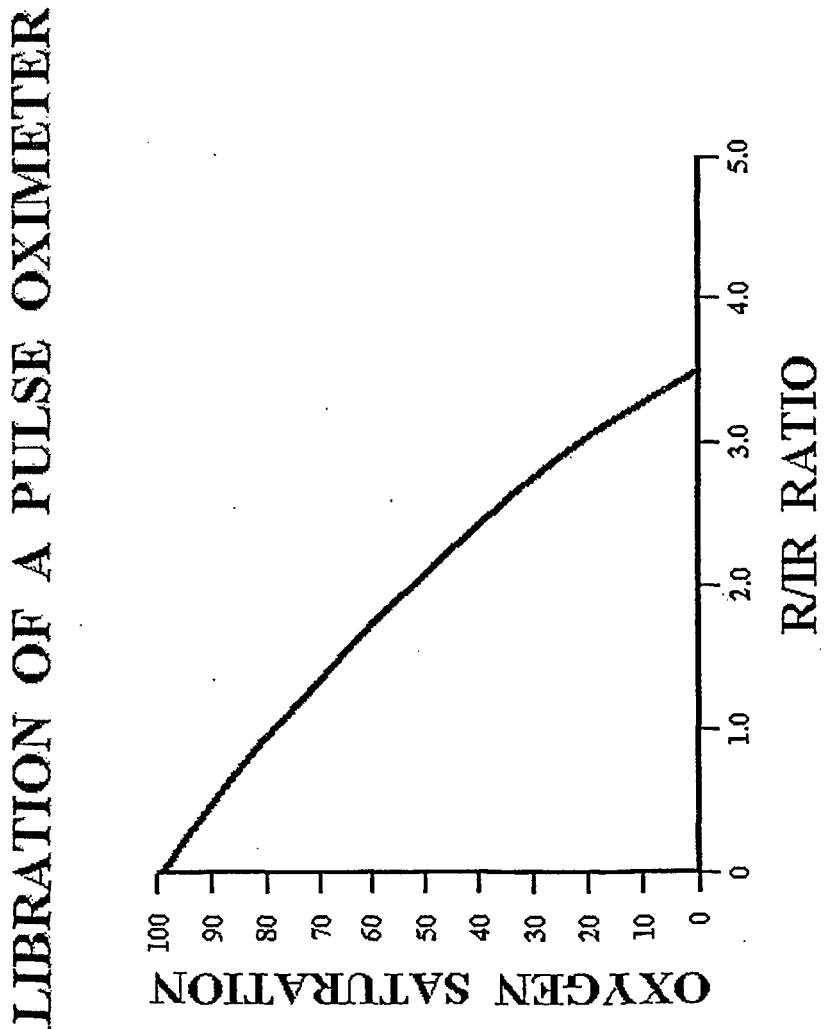
CALIBRATION OF A PULSE OXIMETER
OXYGEN SATURATION
100
90
80
70
60
50
40
30
20
10
0
0
1.0
2.0
3.0
4.0
5.0
R/IR RATIO

Fig. 2

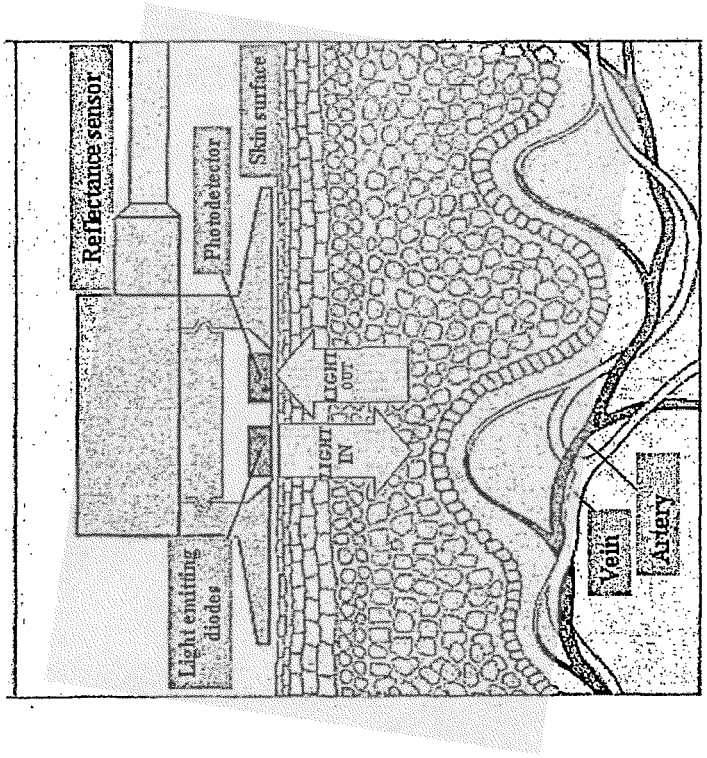
Reflectance sensor
Photodetector
Skin surface
LIGHT OUT
LIGHT IN
Light emitting diodes
Vein
Artery

Fig. 3

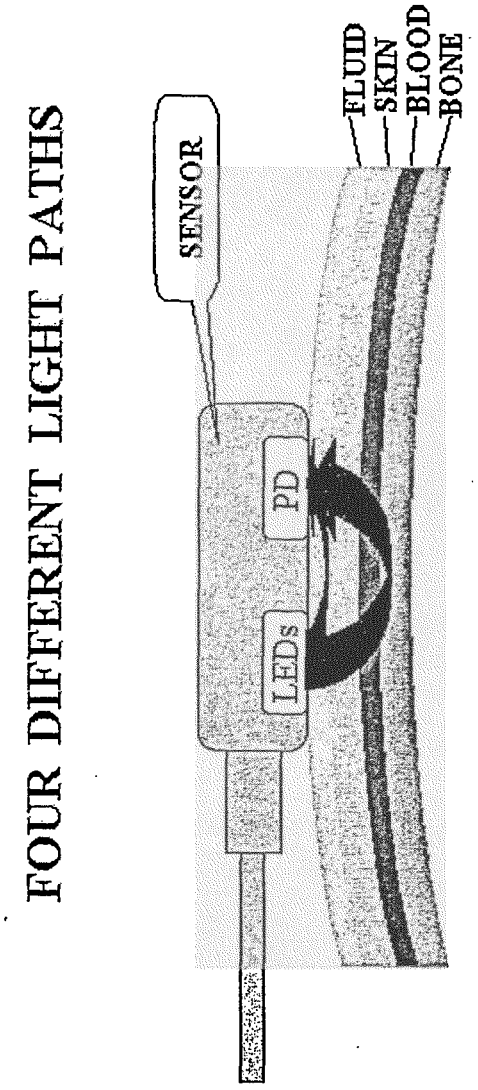
FOUR DIFFERENT LIGHT PATHS
SENSOR
PD
LEDs
FLUID
SKIN
BLOOD
BONE

Fig. 4

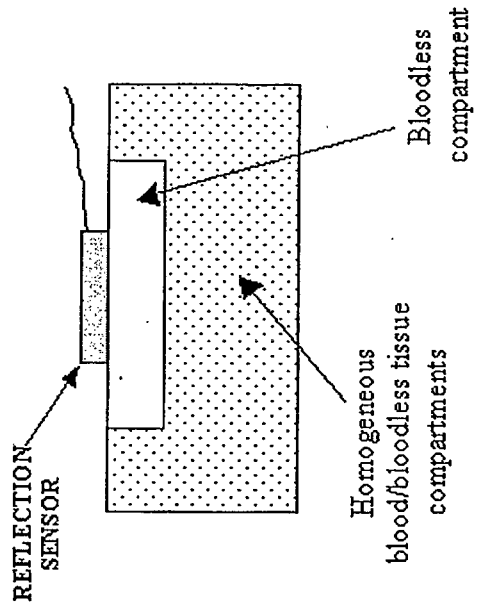
REFLECTION SENSOR
Homogeneous blood/bloodless tissue compartments
Bloodless compartment
(b)

Fig. 5b

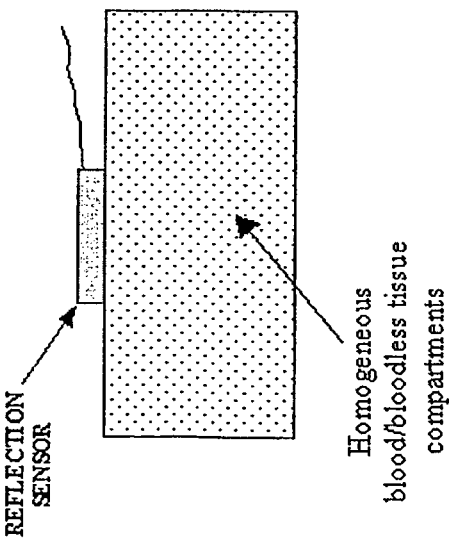
REFLECTION SENSOR
Homogeneous blood/bloodless tissue compartments
(a)

Fig. 5a

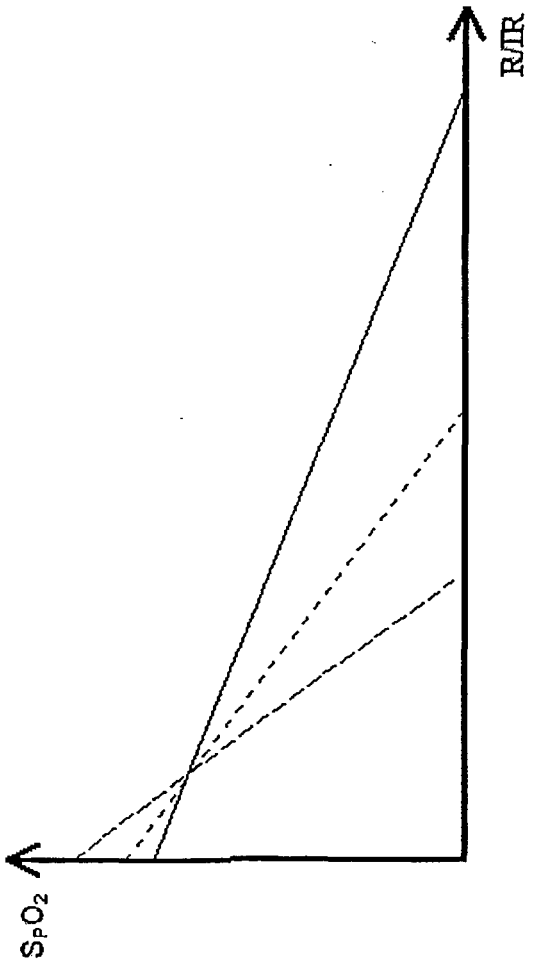

Fig. 6

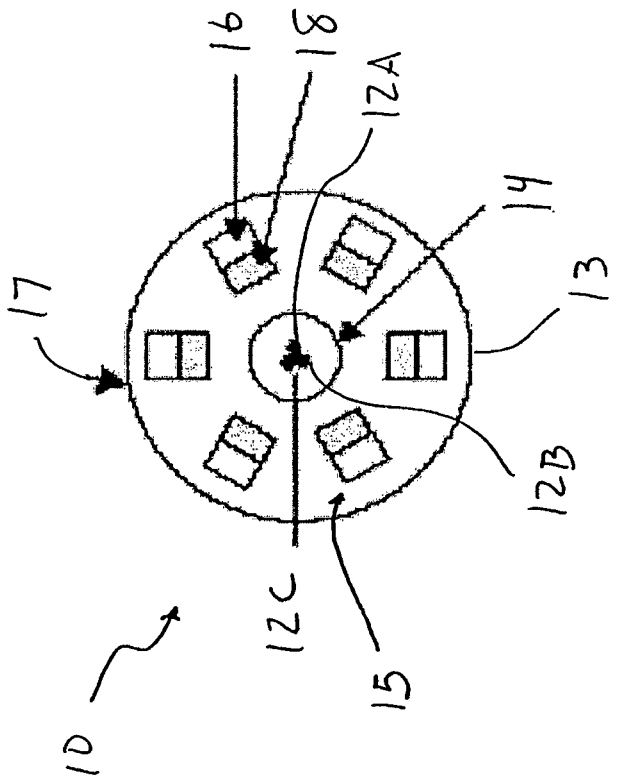

Fig. 7

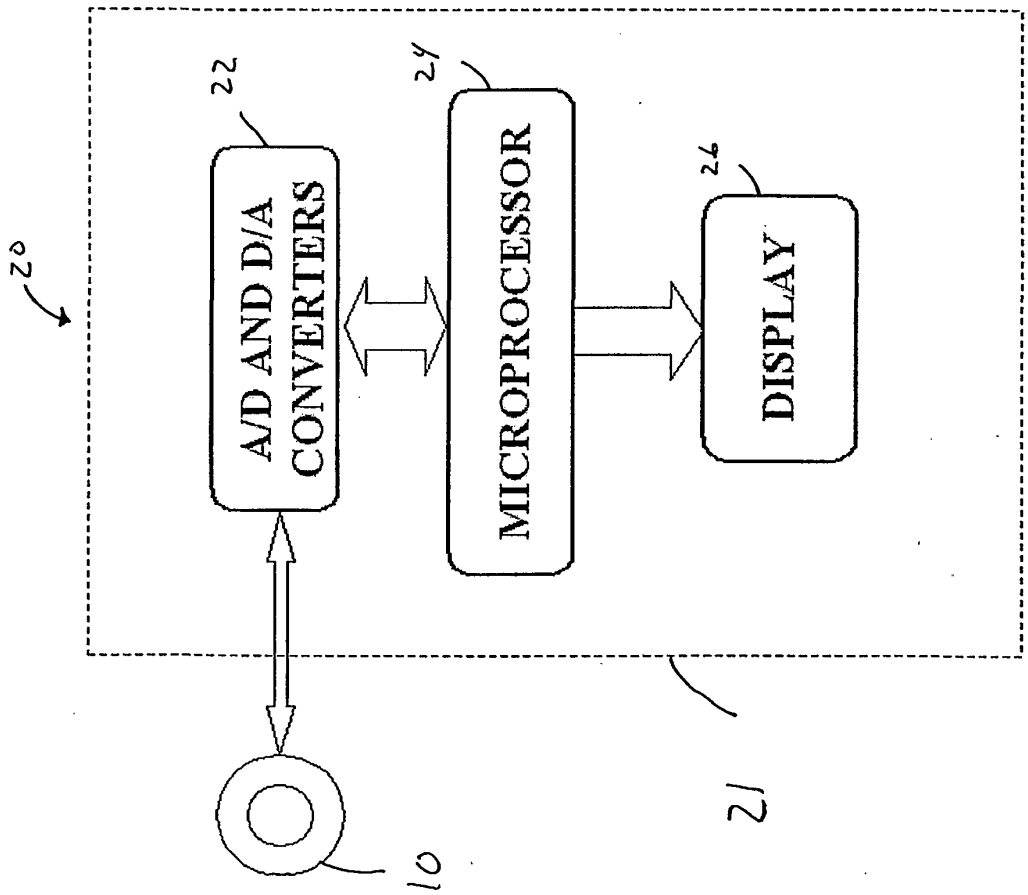
20
22
A/D AND D/A CONVERTERS
24
MICROPROCESSOR
26
DISPLAY
21
10

Fig. 8

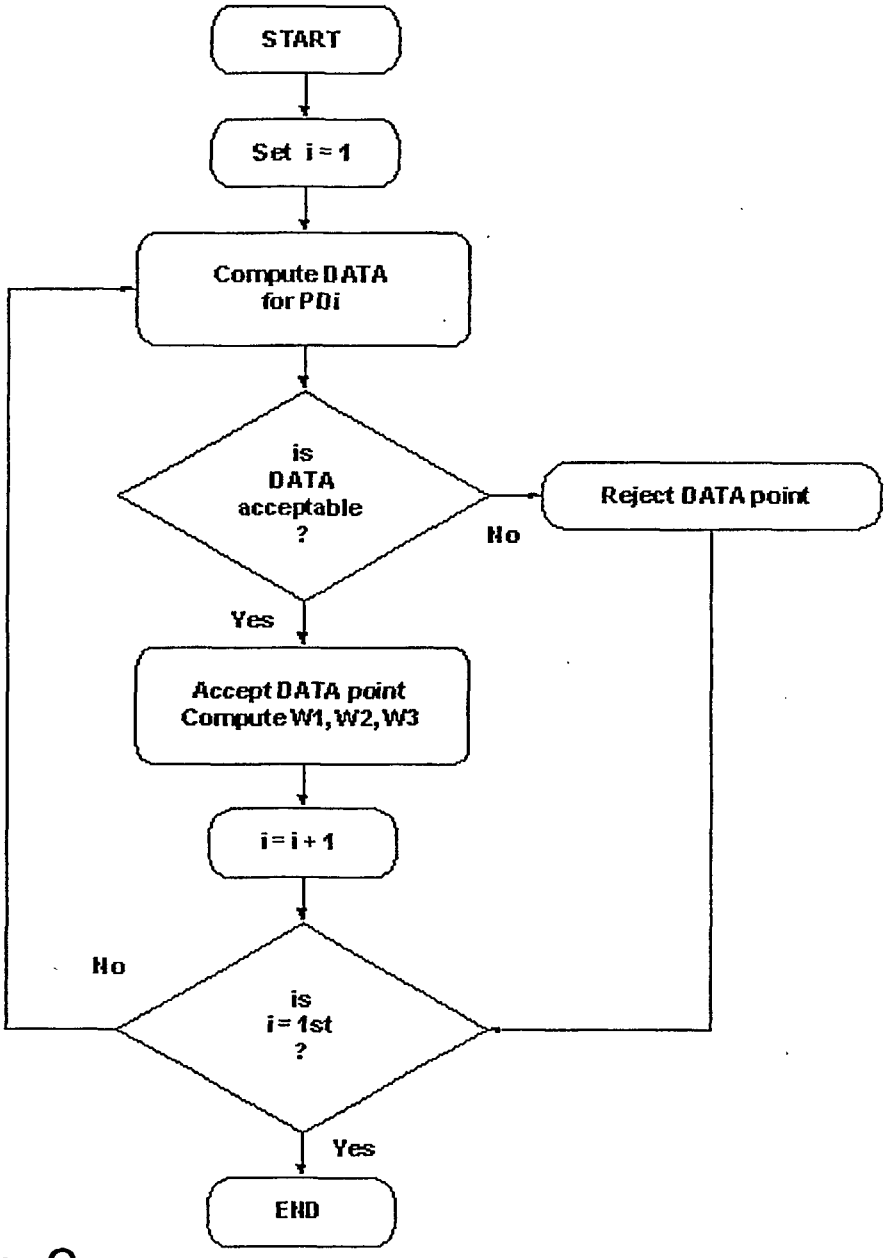
START
Set i = 1
Compute DATA for PDi
is DATA acceptable ?
No
Reject DATA point
Yes
Accept DATA point Compute W1, W2, W3
i = i + 1
No
is i = 1st ?
Yes
END

Fig. 9

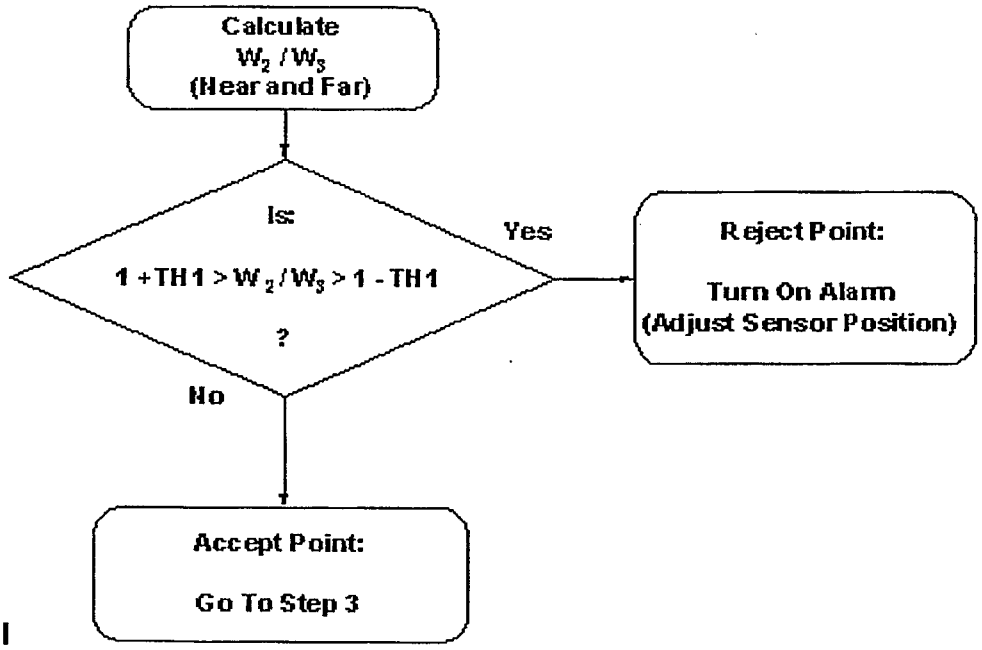
Calculate
W_2 / W_S
(Hear and Far)
Is:
$1 + TH1 > W_2 / W_S > 1 - TH1$
?
Yes
Reject Point:
Turn On Alarm
(Adjust Sensor Position)
No
Accept Point:
Go To Step 3

Fig. 10A

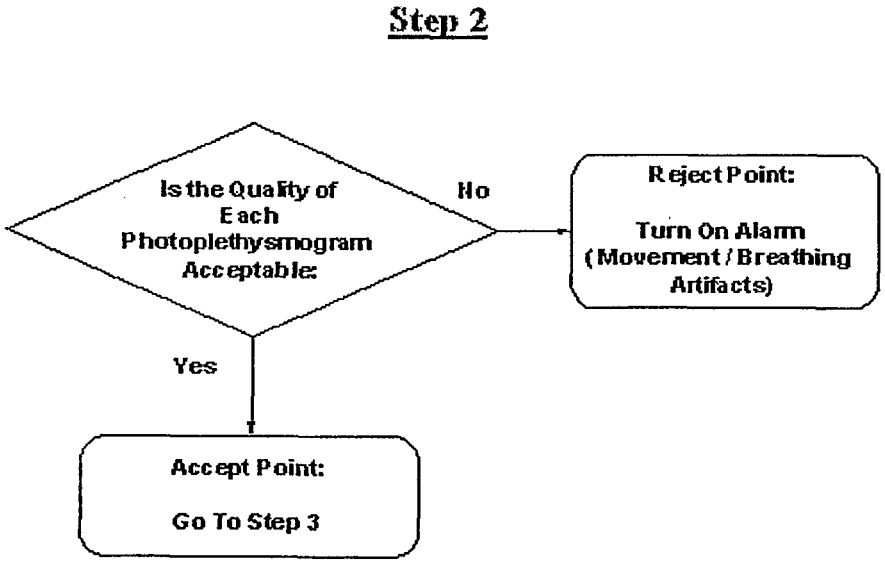
Step 2
Is the Quality of Each Photoplethysmogram Acceptable:
No
Reject Point:
Turn On Alarm (Movement / Breathing Artifacts)
Yes
Accept Point:
Go To Step 3

Fig. 10B

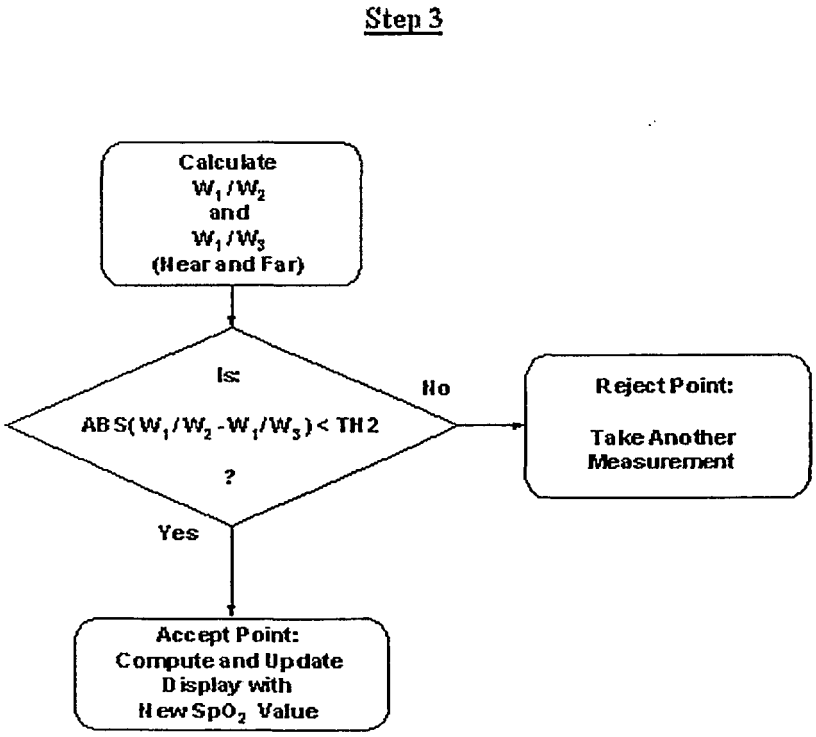
Step 3
Calculate
W_1/W_2
and
W_1/W_3
(Near and Far)
Is:
$ABS(W_1/W_2 - W_1/W_3) < TH2$
?
No
Reject Point:
Take Another
Measurement
Yes
Accept Point:
Compute and Update
Display with
New SpO_2 Value

Fig. 10C

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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- US 5842981 A **[0024]**
- US 5385143 A **[0025]**
- WO 9641566 A **[0025]**
- US 5413100 A **[0025]**

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- **DASSEL et al.** Reflectance pulse oximetry at the forehead of newborns: The influence of varying pressure on the probe. *Journal of Clinical Monitoring,* 1996, vol. 12, 421-428 **[0015]**
- **EDRICH et al.** Fetal pulse oximetry: influence of tissue blood content and hemoglobin concentration in a new in-vitro model. *European Journal of Obstetrics and Gynecology and Reproductive Biology,* 1997, vol. 72 (1), S29-S34 **[0015]**
- **MENDELSON et al.** Noninvasive pulse oximetry utilizing skin reflectance photoplethysmography. *IEEE Transactions on Biomedical Engineering,* 1988, vol. 35 (10), 798-805 **[0016]**
- **MENDELSON et al.** Design and evaluation of a new reflectance pulse oximeter sensor. *Medical Instrumentation,* 1988, vol. 22 (4), 167-173 **[0017]**
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- **KONIG et al.** Reflectance pulse oximetry - principles and obstetric application in the Zurich system. *Journal of Clinical Monitoring,* 1998, vol. 14, 403-412 **[0020]**
- **MANNHEIMER.** Physio-optical considerations in the design of fetal pulse oximetry sensors. *European Journal of Obstetrics and Gynecology and Reproductive Biology,* 1997, vol. 72 (1), S9-S19 **[0022]**
- **MANNHEIMER.** Wavelength selection for low-saturation pulse oximetry. *IEEE Transactions on Biomedical Engineering,* 1997, vol. 44 (3), 48-158 **[0022]**

专利名称(译)	脉冲血氧计及其操作方法		
公开(公告)号	EP1322216B1	公开(公告)日	2015-01-28
申请号	EP2001968151	申请日	2001-08-27
申请(专利权)人(译)	CYBRO MEDICAL LTD.		
当前申请(专利权)人(译)	CONMED CORPORATION		
[标]发明人	MENDELSON YIZHAK		
发明人	MENDELSON, YIZHAK		
IPC分类号	A61B5/1455 G01N21/35 A61B5/00 A61B5/145 A61B5/1464 G01N21/27		
CPC分类号	A61B5/14552 A61B5/1455		
优先权	138884 2000-10-05 IL		
其他公开文献	EP1322216A1		
外部链接	Espacenet		

摘要(译)

一种用于光学测量装置的传感器和一种用于血液参数的非侵入式测量的方法。传感器包括传感器壳体，耦合到壳体的辐射源，以及耦合到壳体的检测器组件。辐射源适于以预定频率发射辐射。检测器组件适于检测至少一个预定频率的反射辐射并产生相应的信号。信号用于确定血液的参数。

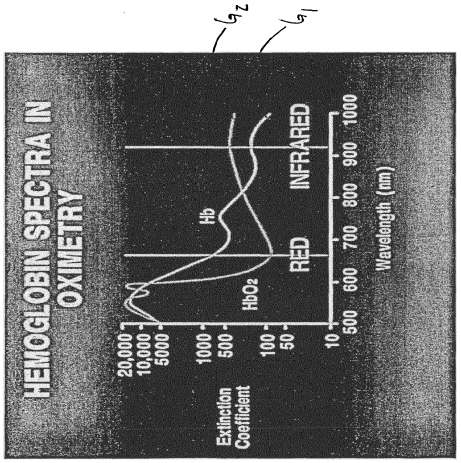

Fig. 1