Description

~~A PULSE OXIMETER AND A METHOD OF ITS OPERATION~~

This application is a divisional application of U.S. patent application Ser. No. 09/939,391 filed Aug. 24, 2001, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

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.

2. Background of the Invention

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~~700 nm) and near-infrared (between 700 and ~~1000nm~~1000 nm) spectra depends strongly on the amount of oxygen in blood.

Referring to ~~Fig~~FIG. 1, there is illustrated a hemoglobin spectra measured by oximetry based techniques. Graphs ~~G1~~ 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~~660 nm, as compared to that of oxyhemoglobin (HbO_2). On the other hand, in the near-infrared region of the spectrum around ~~940nm~~940 nm, the optical absorption by deoxyhemoglobin (Hb) is lower than the optical absorption of oxyhemoglobin (HbO_2).

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~~660 nm and an infrared (IR) LED centered on a peak emission wavelength around ~~940nm~~940 nm are used as light sources.

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~~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.

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

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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~~FIG. 2 by presenting the empirical relationship between SaO_2 and the normalized R/IR ratio, which is programmed by the pulse oximeters' manufacturers.

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. ~~In reflection-mode or backscatter type pulse oximetry, as shown in Fig. 3, the~~ 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.

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~~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 becomes 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.

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

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.

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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~~absorbable due to ~~Lambert~~Lambent-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.

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.

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 ~~hmbs~~limbs, consists of a much thicker layer of skin and subcutaneous tissues without a nearby bony support that acts as a strong light reflector.

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~~"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).

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.

Another approach is based on the use of a sensor 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).

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 burns.

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.

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).

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.

The use of a nominal dual-wavelength pair of 735/~~890nm~~890 nm was suggested as providing the best choice for optimizing accuracy, as well as sensitivity in dual-wavelength reflectance pulse oximetry, in ~~US~~U.S. Pat. Nos. 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)].

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However, replacing the conventional R wavelength at ~~660nm~~660 nm, 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~~735 nm, 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.

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~~U.S. Pat. No. 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.

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.

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

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.

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.

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.

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

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