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

(57) Abstract: A sensor for use in an optical measurement device and a method for non-invasive measurement of a blood parameter. The sensor includes sensor housing, a source of radiation coupled to the housing, and a detector assembly coupled to the housing. The source of radiation is adapted to emit radiation at predetermined frequencies. The detector assembly is adapted to detect reflected radiation at least one predetermined frequency and to generate respective signals. The signals are use to determine the parameter of the blood.

A PULSE OXIMETER AND A METHOD OF ITS OPERATION

BACKGROUND OF THE INVENTION

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.

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

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).

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.

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.

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.

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 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. 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:

(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.

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.

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

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