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(54) **METHOD AND APPARATUS FOR DETECTING AND ANALYZING VARIATIONS IN A PHYSIOLOGIC PARAMETER**

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USPC **600/323**

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USPC 128/204.23, 204.18, 204.26, 205.24; 600/309, 310, 323, 338, 328, 330, 300, 301; 604/66; 709/201
See application file for complete search history.

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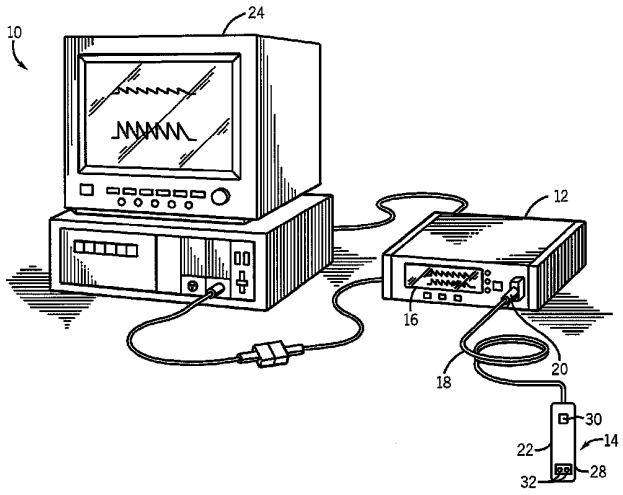
(57) **ABSTRACT**

The present disclosure is generally directed to identifying and/or analyzing high resolution variations in a measured physiologic parameter, such as blood oxygen saturation (SpO_2) measured using pulse oximetry. Present embodiments may include a system including a sensor comprising an emitter capable of emitting light at different wavelengths into a tissue bed, and a detector capable of detecting the light from the emitter after dispersion and/or reflection by the tissue bed. Further, the system may include a pulse oximeter capable of receiving signals from the sensor that are indicative of characteristics of the light detected by the detector, and utilizing the signals to estimate blood oxygen saturation values over time at a high resolution to facilitate detection of variations in the blood oxygen saturation values that are smaller in magnitude than an accuracy, display precision, and/or calibration of the blood oxygen saturation values.

17 Claims, 5 Drawing Sheets



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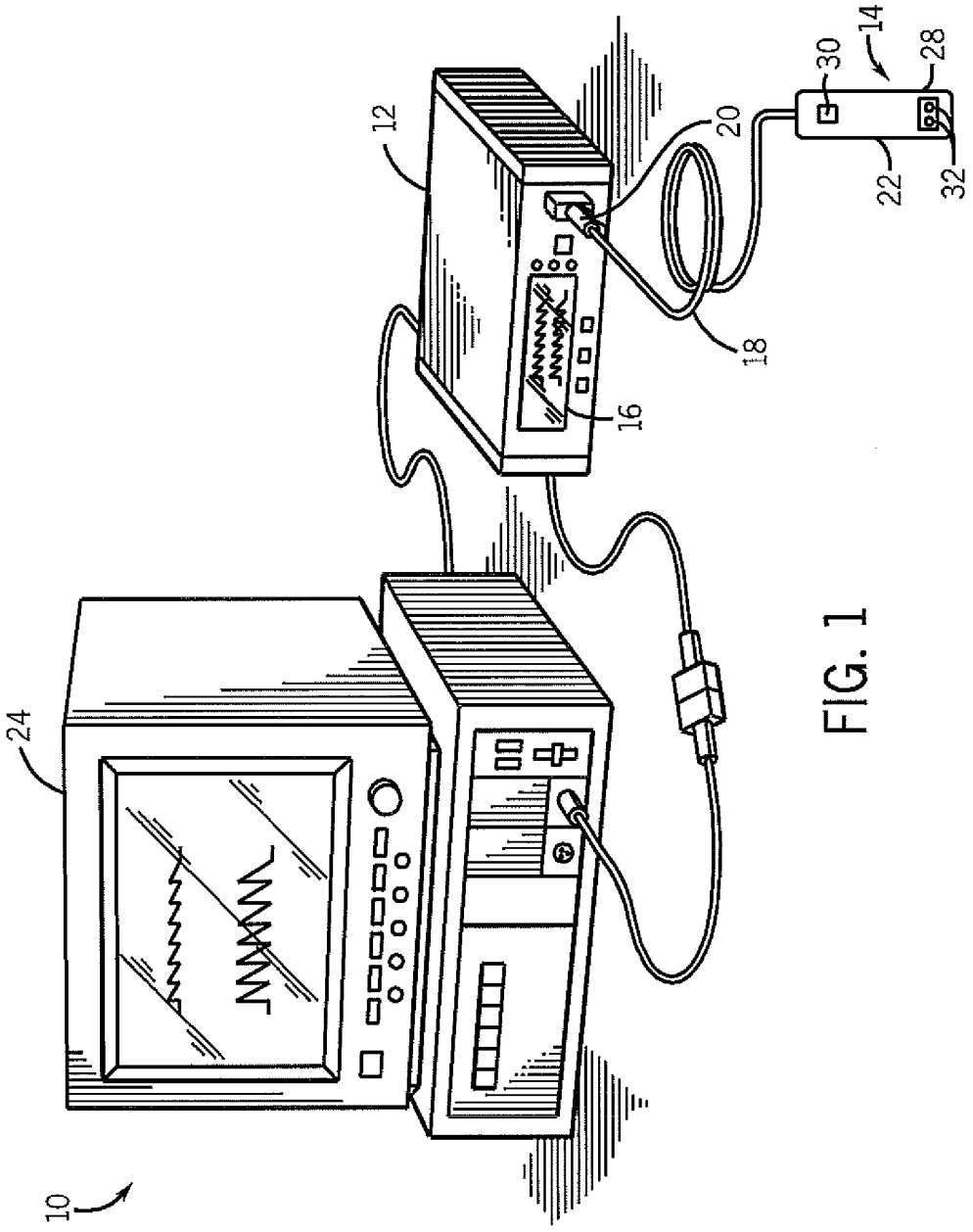

FIG. 1

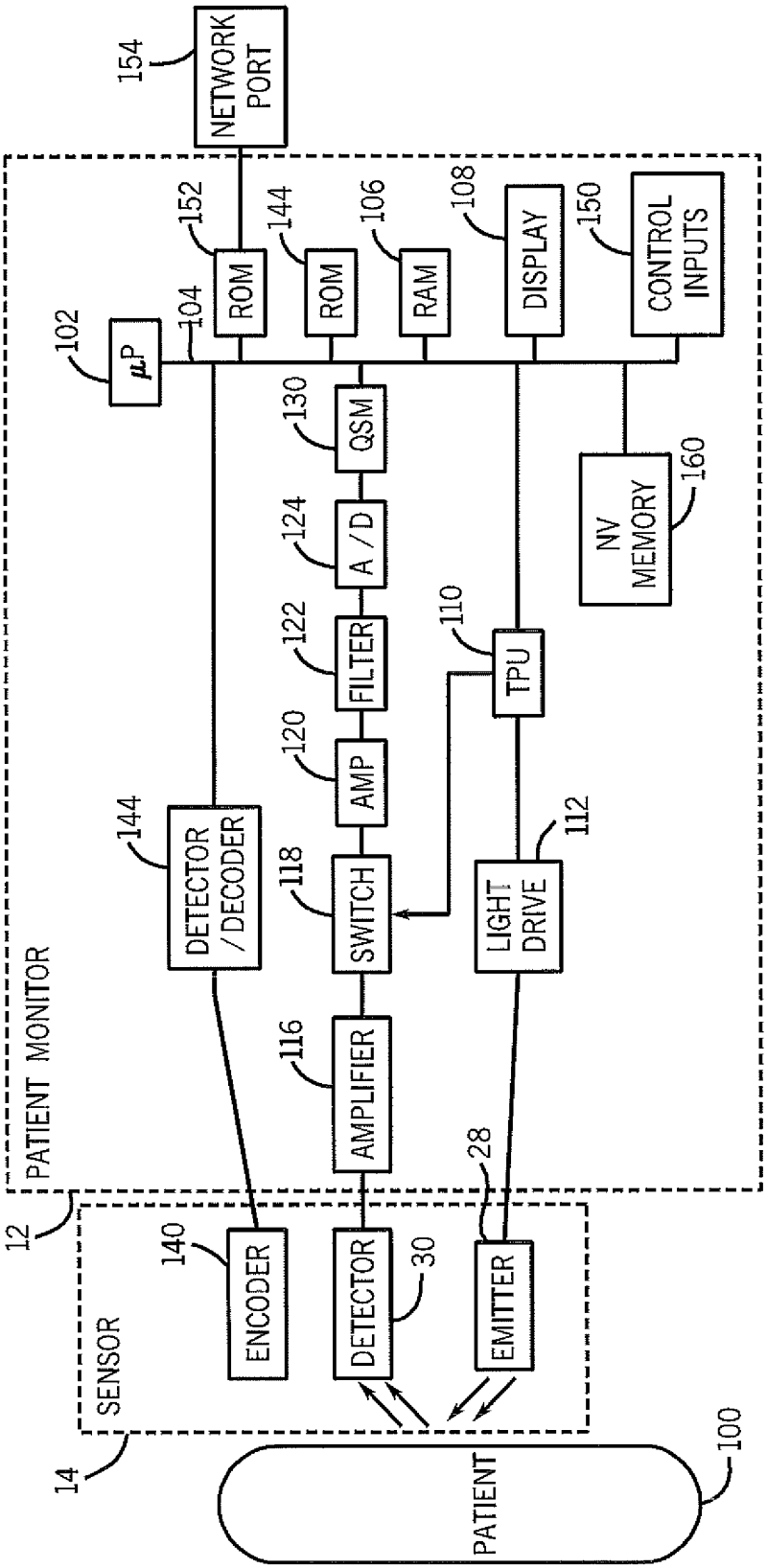
154
NETWORK PORT
152
ROM
144
ROM
106
RAM
108
DISPLAY
150
CONTROL INPUTS
102
μP
104
130
QSM
124
A / D
160
NV MEMORY
122
FILTER
110
TPU
120
AMP
144
DETECTOR / DECODER
118
SWITCH
112
LIGHT DRIVE
116
AMPLIFIER
PATIENT MONITOR
12
28
140
ENCODER
DETECTOR
30
EMITTER
SENSOR
14
PATIENT
100

FIG. 2

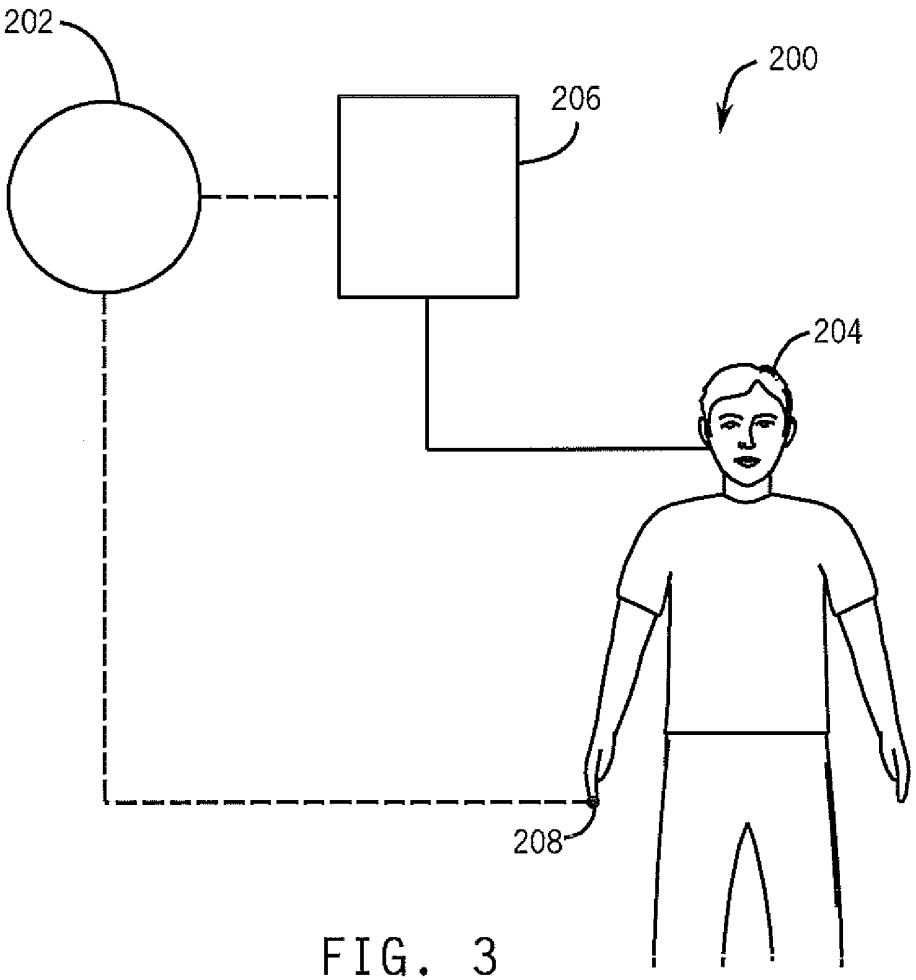

FIG. 3

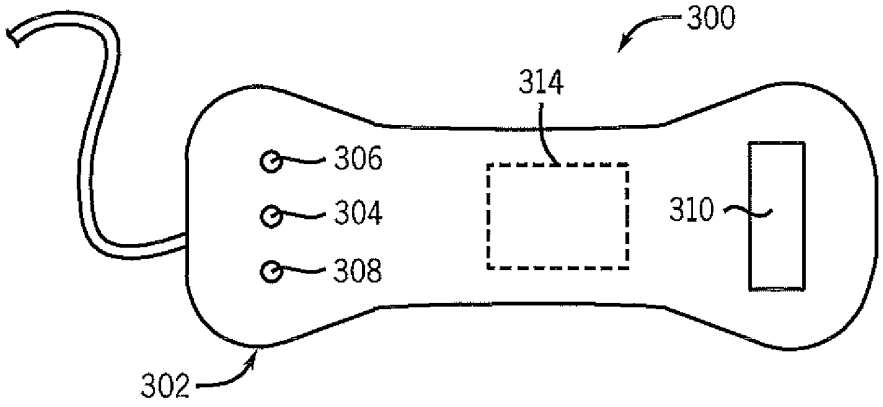

FIG. 4

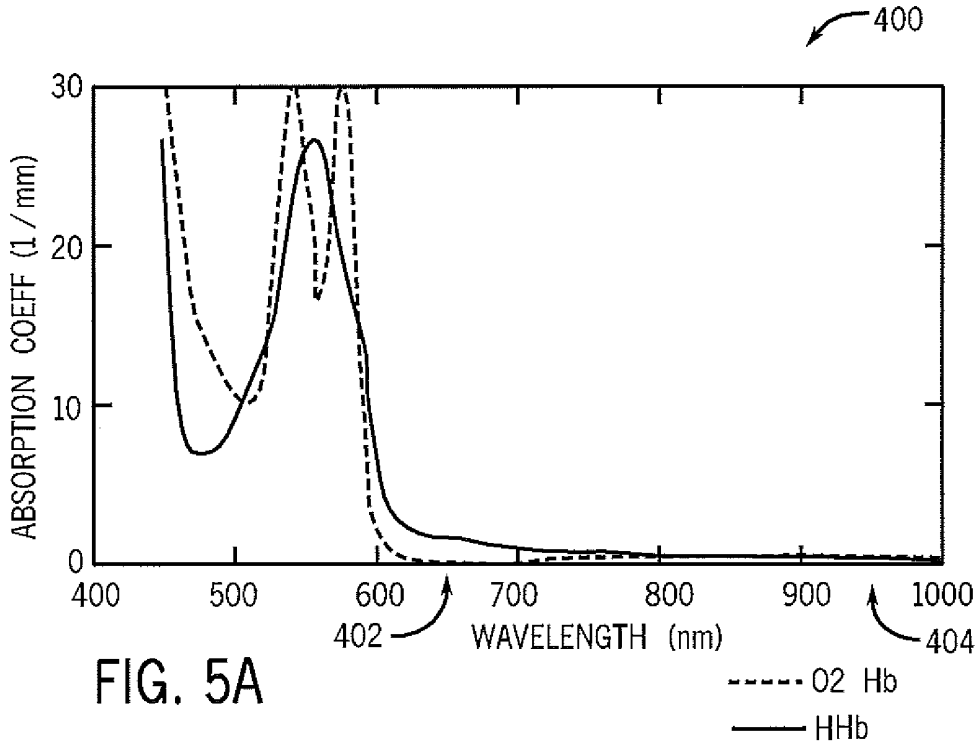
400
30
20
10
0
ABSORPTION COEFF (1/mm)
400
500
600
700
800
900
1000
402
404
WAVELENGTH (nm)
02 Hb
HHb

FIG. 5A

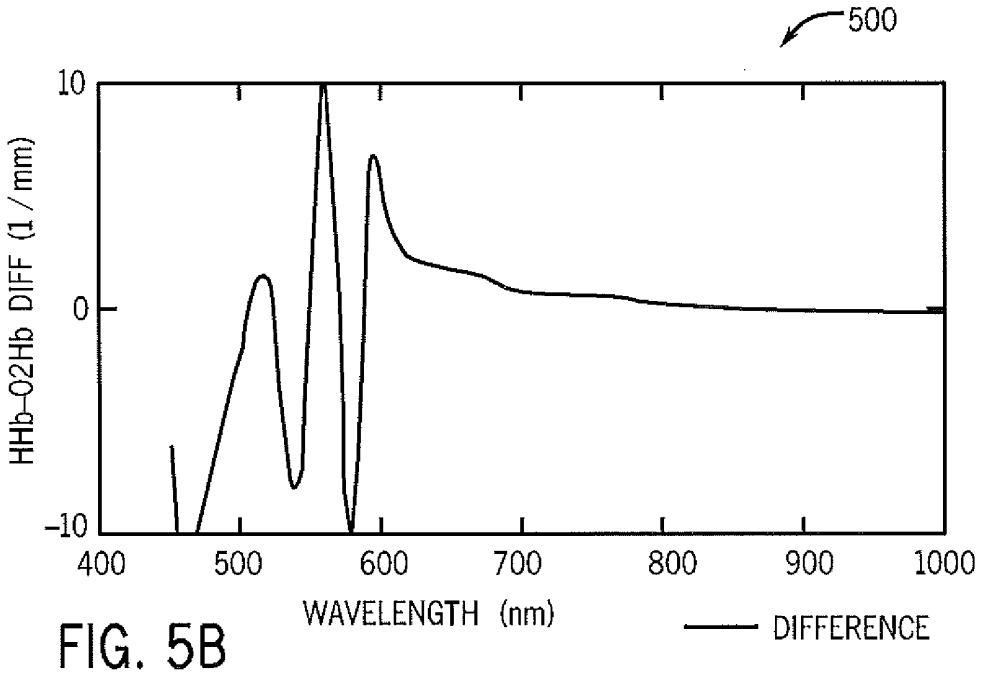
500
10
0
-10
HHb-02Hb DIFF (1/mm)
400
500
600
700
800
900
1000
WAVELENGTH (nm)
DIFFERENCE

FIG. 5B

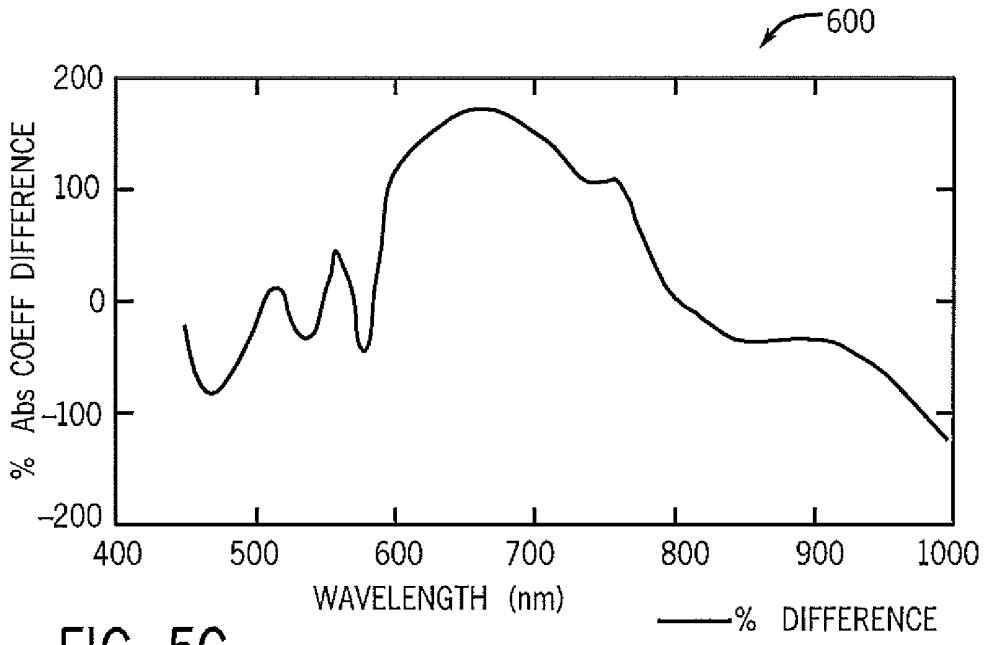
600
200
100
0
-100
-200
% Abs COEFF DIFFERENCE
400
500
600
700
800
900
1000
WAVELENGTH (nm)
% DIFFERENCE

FIG. 5C

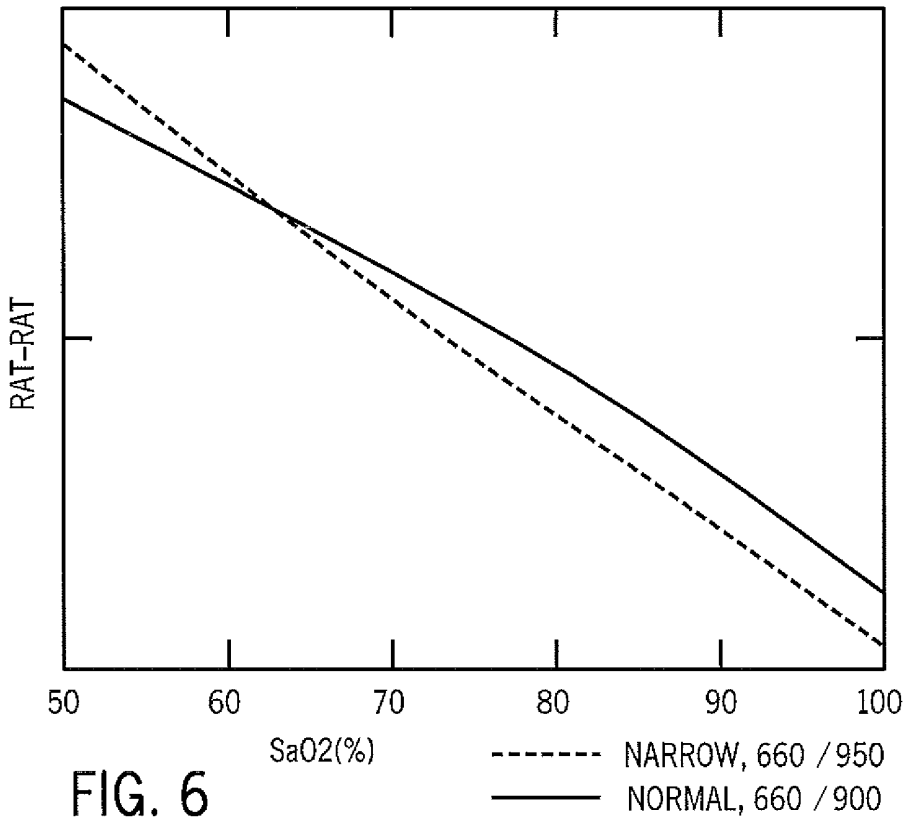
RAT-RAT
50
60
70
80
90
100
SaO2(%)
NARROW, 660 / 950
NORMAL, 660 / 900

FIG. 6

METHOD AND APPARATUS FOR DETECTING AND ANALYZING VARIATIONS IN A PHYSIOLOGIC PARAMETER

BACKGROUND

The present disclosure relates generally to identifying and/or analyzing variations in a measured physiologic parameter, such as blood oxygen saturation (SpO_2) measured using pulse oximetry. More particularly, the present disclosure includes embodiments directed to analyzing variations in SpO_2 values and/or variations in SpO_2 trend data that are smaller in magnitude than the accuracy, display precision, and/or calibration of the measurement.

This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present disclosure, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present disclosure. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

Pulse oximetry is used to continuously monitor the oxygen content of patients' blood in various settings (e.g., operating rooms, delivery rooms, and so forth). Specifically, pulse oximetry uses light waves to indirectly measure the arterial blood oxygen saturation of patients. For example, in operation, conventional two wavelength pulse oximeters emit light from two emitters (e.g., light emitting diodes (LEDs)) into a pulsatile tissue bed and collect the transmitted light with a detector (e.g., a photodiode). The detected light may then be utilized to estimate a level of oxygen saturation in the blood that is present in the tissue bed. The emitters and detector may be positioned in various orientations for different types of pulse oximetry. For example, in transmission pulse oximetry, the emitters and detector are positioned substantially opposite one another (e.g., on opposite sides of a patient's finger), while in reflectance pulse oximetry, the emitters and detector are placed adjacent to one another. The emitters and detector are typically housed in a sensor which connects to pulse oximeter electronics.

The "pulse" in pulse oximetry comes from the time varying amount of arterial blood in the tissue bed during the cardiac cycle. The processed signals from the photodetector create the familiar plethysmographic waveform due to the cycling light attenuation caused by the varying amount of arterial blood that the light from the emitters passes through. With regard to conventional two-wavelength pulse oximeters, at least one of two LEDs emits light at a wavelength at some point in the electromagnetic spectrum where the absorption of oxyhemoglobin (O_2Hb) differs from the absorption of reduced hemoglobin (HHb), and the other of the two LEDs emits light at a wavelength that is at a different point in the spectrum where the absorption differences between HHb and O_2Hb are different from those at the first wavelength. The use of these differing wavelengths facilitates estimation of blood oxygen saturation.

Typically, pulse oximeters utilize one wavelength in the red part of the visible spectrum near 660 nanometers (nm), and one in the near infrared part of the spectrum in the range of 880 nm-940 nm. Photocurrents generated within the detector are detected and processed for measuring the modulation ratio of the red to infrared signals. This modulation ratio has been observed to correlate well to arterial oxygen saturation. Pulse oximeters and pulse oximetry sensors are empirically calibrated by measuring the modulation ratio over a range of in vivo measured arterial oxygen saturations (SaO_2) on a set

of patients, healthy volunteers, or animals. The observed correlation is used in an inverse manner to determine SpO_2 based on the real-time measured value of modulation ratios. It should be noted that, as used herein, SaO_2 refers to the in vivo measured functional saturation, while SpO_2 refers to the estimated functional saturation using pulse oximetry.

Traditional uses of pulse oximetry are based on rounded values of SpO_2. Indeed, because SpO_2 values are generally only accurate to about 1 or 2%, the SpO_2 values are typically used after they have been rounded to the nearest 1%. Further, traditional uses of pulse oximetry may not typically benefit from more precise calculation. For example, pulse oximetry has traditionally been used on patient populations where arterial blood oxygen saturation is generally greater than 90%. In other words, pulse oximetry has traditionally been used in patient populations, wherein the functional hemoglobin in the arterial blood includes at least 90% oxyhemoglobin and 10% or less reduced hemoglobin. In such patient populations, oxygen saturation seldom falls below 80%, and such low values are generally indicative of an unhealthy condition that warrants intervention. Thus, in this and similar situations where pulse oximetry has typically been employed, a high degree of precision in the estimate of blood oxygen saturation based on traditional pulse oximetry has not generally been considered to be clinically relevant.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the present disclosure may become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. **1** is a perspective view of a pulse oximeter system in accordance with an embodiment;

FIG. **2** is a block diagram of a pulse oximeter system in accordance with an embodiment;

FIG. **3** is a block diagram of a physiologic parameter control system in accordance with an embodiment;

FIG. **4** is a perspective view of a sensor in accordance with an embodiment;

FIG. **5**A, FIG. **5**B, and FIG. **5**C is a set of charts illustrating various variables plotted against wavelength to demonstrate optimization of sensor sensitivity in accordance with an embodiment; and

FIG. **6** is a chart illustrating modulation ratio plotted against blood oxygen saturation at different emitter-detector spacing to demonstrate sensor optimization in accordance with an embodiment.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

One or more specific embodiments of the present disclosure will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover; it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

Present embodiments may be applied in the field of pulse oximetry. As indicated above, pulse oximetry may be defined

as a non-invasive technique that facilitates monitoring of a patient's blood characteristics. For example, pulse oximetry may be used to measure blood oxygen saturation of hemoglobin in a patient's arterial blood and/or the patient's heart rate. Specifically, these measurements may be acquired using a non-invasive sensor that passes light through a portion of a patient's tissue and photo-electrically senses the absorption and scattering of the light through the tissue. Typical pulse oximetry technology currently utilizes two LEDs and a single optical detector to measure pulse and oxygen saturation of a given tissue bed. Such measurements are largely based on absorption of emitted light by specific types of blood constituents. Once acquired, this measurement may be used with various algorithms to estimate a relative amount of blood constituent in the tissue. For example, such measurements may provide a ratio of oxygenated to the sum of oxygenated and deoxygenated hemoglobin (i.e., functional hemoglobin) in the volume being monitored.

An SpO_2 value is generally considered to be limited in accuracy to within a few percentage points relative to invasively measured values of SaO_2. Thus, traditional pulse oximeters do not typically display SpO_2 values that have a greater precision than one percent. Likewise, traditional pulse oximeter systems do not perform control functions based on such precise values. It should be noted that the term "accurate" generally refers to a degree of correctness (i.e., closeness to a true value), while the term "precise" generally refers to a degree of exactness, that is, to the smallest change that can be detected in a value.

It has now been recognized that trending accuracy of high precision SpO_2 values is substantially more accurate than the individual values of SpO_2. In other words, the changes or differences between calculated SpO_2 values have been found to correspond closely with corresponding changes in values of SaO_2. Thus, changes in SpO_2 at high levels of precision are now recognized as accurate representations of changes in SaO_2. Accordingly, present embodiments are directed to systems and methods for analyzing variations in a measured physiologic parameter, such as SpO_2, where the variations are smaller in magnitude than the measurement's accuracy or display precision, or where the measurements are outside the displayed or calibrated range of the measured physiologic parameter. For example, SpO_2 values may only be accurate to within a range of +/−1 or 2% relative to an actual value of SaO_2. However, in present embodiments, SpO_2 values may be determined at a high resolution (e.g., a precision of 0.1%, 0.01%, or 0.001%) for use in pattern detection calculations, control algorithms, and so forth. Indeed, present embodiments may not round to the nearest 1%, which may increase the accuracy in detected changes in SpO_2. Similarly, while a pulse oxineter may only display SpO_2 values with limited precision (e.g., only whole number percentage values) and/or SpO_2 values within the range of 0-100%, present embodiments may utilize high resolution SpO_2 values and SpO_2 values outside the range of 0-100% to facilitate analysis, control, and treatment based on subtle changes in the high resolution SpO_2 values over time.

Specifically, present embodiments may utilize subtle variations in high resolution SpO_2 values, such as an incremental variation in the tenths, hundredths, or thousandths digit of an SpO_2 value, to detect or compensate for more significant variations in a related physiologic parameter. For example, small changes in an SpO_2 value may correspond to significant changes in minute ventilation, respiration rate, apnea, partial pressure of oxygen in the arterial blood and so forth. Thus, in accordance with present embodiments, subtle changes in high resolution SpO_2 values detected over time may be utilized to analyze and/or control variations in minute ventilation, respiration rate, partial pressure of oxygen in the arterial blood and/or apnea (e.g., obstructive sleep apnea or central sleep apnea). Further, present embodiments may include features for tracking subtle changes in SpO_2 and presenting them as changes in a related parameter based on the use of the SpO_2 values as a surrogate.

Further, present embodiments may facilitate detection, analysis, and/or control of physiologic parameters based on high resolution SpO_2 values by utilizing and/or including a sensor that is capable of enhancing measurement precision. For example, present embodiments may include an SpO_2 sensor with an emitter that functions to emit light at one or more wavelengths that facilitate increased sensitivity. Such sensitivity may further enable detection of high precision changes in SpO_2 values by a processor of the sensor, which can be utilized for control, detection, and so forth in accordance with present embodiments. It is now recognized based on calculations directed to increasing the slope of a modulation ratio versus SaO_2 curve, that the relative change or percentage difference in HHb to O_2Hb of a pair of signals facilitates high resolution determination of SpO_2 values. Specifically, for example, an SpO_2 sensor in accordance with present embodiments may include emitters with wavelengths near 660 nm (e.g., 650-670 nm) and near 950 nm (e.g., 940-1000 nm), as these two wavelengths may exhibit the greatest relative differences in absorbance from HHb and O_2Hb and, as a result, provide improved SpO_2 precision. It may be desirable to use a wavelength of 950 nm because silicon detectors generally roll off after around 950 nm. In some embodiments, green or yellow light may be utilized separately or in combination with the sensor's others LEDs. For example, a green LED that produces light with a wavelength in a range of about 500-570 nm or a yellow LED that produces light with a wavelength in a range of about 570-600 nm may be utilized in accordance with present embodiments because the wavelengths are typically more highly absorbed by hemoglobin, and may therefore enable the acquisition of a stronger pulsatile signal that facilicates detection of smaller changes in SpO_2.

Additionally, the spacing used between the emitter and detector in a reflectance sensor may be chosen to increase the precision of SpO_2 calculations. With a narrow spacing between the emitter and detector, the change in the pulse oximeter's modulation ratio for a given change in SaO_2 is larger than is found with a less narrow spacing. For example, a sensor with a 2-mm spacing between the LED light sources and the photodetector provides an improved precision in the SpO_2 estimate of SaO_2 relative to a sensor with a 10-mm spacing. Accordingly, present embodiments may utilize a spacing of approximately 2-3 mm between the LED light sources to generate high resolution values.

FIG. **1** illustrates a perspective view of a pulse oximetry system **10** in accordance with present embodiments. The system **10** may be utilized to observe the blood constituents of a patient's arterial blood to facilitate estimation of the state of oxygen exchange in the patient's body by emitting waves into tissue and detecting the waves after dispersion and/or reflection by the tissue. The system **10** may include a pulse oximeter or monitor **12** that communicatively couples to a sensor **14**. The monitor **12** may include a display **16**, a memory, a processor, and various monitoring and control features. The monitor **12** may be configured to perform pulse oximetry measurements, calculations, and control algorithms using high precision values in accordance with present embodiments. Further, the monitor **12** may be configured to display high resolution SpO_2 values based on the measurements, cal-

culations, and control algorithms. The sensor **14** may include a sensor cable **18**, a connector plug **20**, and a sensor assembly or body **22** configured to attach to a patient (e.g., a patient's finger, ear, forehead, or toe). Further, in the illustrated embodiment, the system **10** includes a separate display feature **24** that is communicatively coupled with the monitor **12** to facilitate presentation of pulse oximetry data and related data.

The sensor **14** includes an emitter **28** and a detector **30**. When attached to a patient's tissue and functioning, the emitter **28** transmits light at different wavelengths into the tissue and the detector **30** receives the light after it has passed through the tissue area. The amount of light that passes through the tissue and other characteristics of light waves may vary in accordance with the changing amount of certain blood constituents in the tissue and the related light absorption and/or scattering. For example, the system **10** may emit light from two or more LEDs **32**, or other suitable light sources such as lasers, into the pulsatile tissue and then detect the transmitted light with the detector **30**, such as a photodiode or photo-detector, after the light has passed through the pulsatile tissue. Such measurements may be utilized to estimate a percentage of blood oxygen saturation in the probed volume of blood. In other words, such measurements may be utilized to obtain an SpO_2 value. Further, such measurements may be utilized to track related parameters. For example, SpO_2 measurements may be utilized to track the partial pressure of oxygen (pO_2) in a patient's arterial blood by relating the pO_2 to the SpO_2 through the use of a selected or calculated oxygen dissociation curve. Indeed, SpO_2 may be utilized as a surrogate for pO_2.

FIG. **2** is a block diagram of an embodiment of the patient monitoring system **10** that may be configured to implement the techniques described herein. The system **10** may include the patient monitor **12** (e.g., a pulse oximeter) and the sensor **14**, which are configured to obtain and utilized high precision SpO_2 values. The sensor **14** is communicatively connected to the patient monitor **12** via a cable or wireless device. When the system **10** is operating, light from the emitter **28** may pass into a patient **100** and be scattered and detected by the detector **30**. The monitor **12** may include a microprocessor **102** connected to an internal bus **104**. Also connected to the bus **104** may be a RAM memory **106** and a display **108**. A time processing unit (TPU) **110** may provide timing control signals to light drive circuitry **112** which may control when the emitter **28** is illuminated, and if multiple light sources are used, the multiplexed timing for the different light sources. TPU **110** may also control the gating-in of signals from the detector **30** through an amplifier **116** and a switching circuit **118**. These signals may be sampled at the proper time, depending upon which of multiple light sources is illuminated, if multiple light sources are used. The received signal from the detector **30** may be passed through an amplifier **120**, a low pass filter **122**, and an analog-to-digital converter **124**. The digital data may then be stored in a queued serial module (QSM) **130**, for later downloading to the RAM **106** as the QSM **130** fills up. In one embodiment, there may be multiple parallel paths of separate amplifier, filter and A/D converters for multiple light wavelengths or spectra received. It should be noted that each of these features may be configured to facilitate the provision of SpO_2 values at a high level of precision in accordance with present embodiments. Present embodiments may be implemented on any suitable pulse oximeter, such as those available from Nellcor Puritan Bennett LLC.

In an embodiment, the sensor **14** may also contain an encoder **140** that provides signals indicative of the wavelength of one or more light sources of the emitter **28** to allow the monitor **12** to select appropriate calibration coefficients for calculating a physiological parameter such as blood oxygen saturation. The encoder **140** may, for instance, be a coded resistor, EEPROM or other coding devices (such as a capacitor, inductor, PROM, RFID, a barcode, parallel resonant circuits, or a colorimetric indicator) that may provide a signal to the processor **102** related to the characteristics of the sensor **14** that may allow the processor **102** to determine the appropriate calibration characteristics for the sensor **14**. Further, the encoder **140** may include encryption coding that prevents a disposable part of the sensor **14** from being recognized by a processor **102** that is not able to decode the encryption. For example, a detector/decoder **144** may be required to translate information from the encoder **140** before it can be properly handled by the processor **102**. Present embodiments may be implemented on any suitable sensor, such as those available from Nellcor Puritan Bennett LLC.

In various embodiments, based at least in part upon the value of the received signals corresponding to the light received by detector **30**, the microprocessor **102** may calculate a physiological parameter using various algorithms. These algorithms may utilize coefficients, which may be empirically determined, corresponding to, for example, the wavelengths of light used. These may be stored in a ROM **144**. In a two-wavelength system, the particular set of coefficients chosen for any pair of wavelength spectra may be determined by the value indicated by the encoder **140** corresponding to a particular light source in a particular sensor **14**. For example, the first wavelength may be a wavelength that is highly sensitive to small quantities of deoxyhemoglobin in blood, and the second wavelength may be a complimentary wavelength. Specifically, for example, such wavelengths may be produced by orange, red, infrared, green, and/or yellow LEDs. Different wavelengths may be selected with control inputs **150**. The control inputs **150** may be, for instance, a switch on the monitor, a keyboard, or a port providing instructions from a remote host computer.

In various embodiments, the monitor **12** may be connected to a network via a network interface **152**. The network interface **152** may implement any networking technology or protocol, such as Ethernet, wireless Ethernet, and so forth. The network interface **152** may be connected to a network port **154** via a network cable or via a wireless connection. Additionally, the monitor **12** may include a non-volatile memory **160** that may store caregiver preferences, patient information, or any other information useful for configuring the monitor **12**. The software for performing the configuration of the monitor **12** and retrieval of information over the network interface **152** may also be stored on the memory **160**, or may be stored on the ROM **144**.

The components of the monitor **12** may be configured to detect store, and utilize SpO_2 values at high resolution. In other words, the monitor **12** may estimate SpO_2 values at precisions of 0.1%, 0.01%, 0.001%, and so forth. Additionally, the monitor **12** may perform calculations and control algorithms based on these high resolution values. Further, the monitor **12** may be configured to correlate subtle changes in the SpO_2 values to large change in related parameters, such as pO_2, based on an inherent relationship between the parameters.

Pulse oximetry values of SpO_2 are generally only accurate to +/−1 or 2% precision with respect to invasively measured values of SaO_2. Accordingly, traditional pulse oximeters generally display values that are rounded to the nearest 1%. Further, inherent accuracy limitations in pulse oximetry may result in displaying an SpO_2 value that has been clipped at

100%. In other words, the displayed values of SpO_2 may be limited to 100% to address concerns that displaying a value greater than 100% may be misleading or confusing. For example, such clipping may occur in situations where supplemental oxygen is being utilized to treat a patient, and, due to inaccuracies, a calculated value of SpO_2 exceeds 100%. Specifically, for example, the SpO_2 value may be determined to be 102% and this value may be clipped to indicate a maximum value of 100% because an actual value of SaO_2 exceeding 100% would not be valid.

However, it is now recognized that the usual 1% SpO_2 reporting precision and the practice of clipping may limit the ability to detect subtle reentrant respiratory phenomena via SpO_2. Indeed, while pulse oximetry values of SpO_2 may be limited to +/−1 or 2% precision with respect to invasively measured values of SaO_2, it has now been recognized that the trending accuracy of SpO_2 is substantially more accurate. Indeed, once a pulse oximeter sensor is in place and not moved between observations, the changes in SpO_2 values have been determined to be quite accurate. In other words, the changes or differences between SpO_2 values correspond closely to the value of the actual changes or differences in the related SaO_2 values. Accordingly, present embodiments are directed to measuring and trending SpO_2 values that are measured with a precision in the tenths, hundredths, thousandths, and so forth. This facilitates detecting accurate and precise changes in SpO_2 and utilization of such detected changes in monitoring, control, and analysis.

Additionally, present embodiments may eliminate the artificial ceiling of 100% for calculated and/or displayed SpO_2 values. By eliminating such clipping, the changes that occur above an SpO_2 value of 100% may be utilized in accordance with present embodiments. For example, in one embodiment, a change in an SpO_2 value from 101.24% to 100.75% may be significant for control and/or monitoring. Specifically, for example, such a change may be significant with regard to monitoring and/or controlling pO_2, while remaining fairly insignificant with regard to monitoring SpO_2. Thus, by eliminating the ceiling of 100% and using changing high resolution SpO_2 values, present embodiments may include monitoring and control features that would be unavailable based on the use of less precise and/or clipped SpO_2 values.

Some embodiments in accordance with the present disclosure relate to systems and methods that use high-precision, unclipped SpO_2 values for the detection and/or characterization of subtle SpO_2 variations and/or patterns that may be indicative of clinically significant pathologies. For example, present embodiments may utilize trending or relative comparisons of small and precise SpO_2 values over time for detection and/or characterization of conditions relating to obstructive and/or central sleep apnea, hypopnea, hyperpnea, and/or Cheyne-Stokes syndrome.

A specific example in accordance with present embodiments may include a system that is configured to detect and/or assess issues relating to sleep apnea. Sleep apnea is generally described as a sleep disorder that is characterized by episodes of paused breathing during sleep. These episodes of paused breathing may occur repeatedly throughout sleep, and each episode may last long enough to cause one or more breaths to be missed. Such episodes may be referred to as apneas. A typical apnea may include an interval between breaths of at least 10 seconds, with a neurological arousal and/or a blood oxygen desaturation of 3% or greater. The actual duration and severity of each apnea may substantially vary between multiple patients. Further, duration and severity of apneas may vary throughout a period of sleep for a single patient. Indeed, sleep apnea may have a wide range of severity. Accordingly, it may be desirable to monitor precise SpO_2 levels, in accordance with present embodiments, to identify and/or assess potential indications of sleep apnea that could be overlooked by the less precise monitoring of traditional pulse oximetry systems. For example, small changes in SpO_2 levels over time may be utilized to ascertain subtle indications of sleep apnea.

Detection of subtle, yet pathological, SpO_2 variations may also be utilized in therapeutic systems and methods in accordance with present embodiments. In other words, changes occurring at high levels of precision, such as a change in the tenths or hundredths digit of a value of SpO_2, may be utilized to initiate therapy, control certain treatments (e.g., a rate of supplying supplemental oxygen), alert a caregiver to certain patient conditions, and so forth. For example, subtle changes in SpO_2 detected with high precision measurement may be utilized to reduce and/or block patient-controlled analgesia (PCA), recommend or titrate continuous positive air pressure (CPAP) therapy, or enable fine automatic adjustment of mechanical ventilation parameters (e.g., FiO_2, tidal volume, or respiratory rate). Indeed, such subtle changes may be utilized in a variety of different control algorithms to manage physiologic parameters and so forth.

One embodiment may include a system that is configured to control one or more physiologic parameters based on changes in the high precision component of the SpO_2 values or the like. Indeed, control of a patient's blood oxygen content with oxygen delivery is specifically discussed below as a particular example of present embodiments. However, one of ordinary skill in the art will recognize that this is merely one example and that different control parameters, delivery parameters, and the like may be utilized in accordance with present embodiments. For example, oxygen delivery may be adjusted based on a patient's estimated blood oxygen saturation level (SpO_2), oxygen delivery may be adjusted based on estimated pO_2 changes indicated by surrogate SpO_2 value changes, continuous positive airway pressure (CPAP) may be adjusted based on SpO_2, and/or patient-controlled analgesia may be inhibited during periods of low SpO_2. The small changes that are observable because of the added level of precision may facilitate such control mechanisms.

As indicated above, control of SpO_2 with oxygen delivery is presented herein as an example of a control feature in accordance with present embodiments. Specifically, FIG. **3** represents a system **200** including a controller **202** (e.g., a computer-based controller) that controls a composition and/or delivery amount of a gas mixture to a patient **204** to safely induce, maintain, and/or control the patient's SpO_2 level. Thus, in an example embodiment, a gas mixture supplied to the patient **204** may be considered the delivery parameter. For example, automatic adjustment of FiO_2 by the controller **202** may be utilized to control patient hypoxia or normoxia. FiO_2 may be defined as fractional inspired oxygen concentration or the percentage of oxygen in air inhaled by a patient through a ventilator. For example, in typical room air, the value for FiO_2 is approximately 21%.

In one embodiment a certain level of SpO_2 or pO_2 may be maintained within a narrow range by controlling based on the subtle changes in the high precision portion of the SpO_2 value (e.g., changes in a tenths, hundredths, or thousandths digit of an SpO_2 value). With regard to controlling pO_2, it should be noted that SpO_2 is a surrogate for pO_2 in blood. Precise ranges of control may be achieved in accordance with present embodiments by increasing and or decreasing FiO_2 based on the subtle changes in the SpO_2 value.

Indeed, as indicated above, changes illustrated by trending values have been found to be accurate. In other words, a change in the value of SpO_2 over time is an accurate reflection

of the change in SaO_2 over the same time period) while the individual SpO_2 values themselves are not necessarily accurate representations of the SaO_2 value at each time. Thus, a change in the tenths, hundredths, or thousandths place of an SpO_2 value, or a changes at a higher level of precision may be utilized to make adjustments and control a physiologic parameter. This can be especially useful for parameters that have large changes relative to smaller changes in SpO_2 levels, such as PO_2. Such levels of control may assist in the prevention of certain issues that can arise due to inappropriate oxygen levels, such as retinopathy in neonates. Indeed, with regard to certain patients (e.g., neonates), a controller in accordance with present embodiments may maintain a very narrow range of SpO_2 levels, and, thus, pO_2 levels, to facilitate the avoidance of low oxygen level conditions associated with a risk for retinopathy, while avoiding high oxygen level conditions associated with lung development issues and the like.

The controller **202** may include a closed-loop FiO_2 controller that cooperates with a ventilator **206** to control the patient's SpO_2 value. Indeed, the controller **102** may receive input from a sensor **208** (e.g., a pulse oximeter sensor) that measures the patient's SpO_2 value at a high level of precision, and, based on a comparison of the measured SpO_2 value with a target SpO_2 value, manipulates the ventilator's output (e.g., FiO_2). For example, the FiO_2 controller **202** may output a request for increased FiO_2 from the ventilator **206** when a measured SpO_2 value is below a predefined SpO_2 target, or output a request for decreased FiO_2 from the ventilator **206** when the measured SpO_2 value is above the SpO_2 target By increasing or decreasing FiO_2, the patient's lungs may receive more or less oxygen, respectively, and the value of SpO_2 obtained from the patient will typically change correspondingly.

In accordance with present embodiments, detection of subtle variations in SpO_2 may be enhanced relative to the performance of traditional detectors by using an oximetry sensor that comprises light emitters with wavelengths selected for enhanced sensitivity to small changes in SpO_2. For example, FIG. **4** illustrates a sensor **300** in accordance with present embodiments, wherein the sensor **300** includes a plurality of light emitters **302**. The plurality of light emitters **302** may include two or more emitters, wherein at least one of the light emitters **302** has a wavelength that facilitates detection of subtle variations in SpO_2. Indeed, the sensor **300** may include an emitter that is optimized for detection of small changes in SpO_2. Specifically, for example, the light emitters **302** may include a sensitivity optimized LED **304** that is capable of emitting light having a wavelength in the range of 600-680 nm. For example, in one embodiment, the LED **304** may emit light having a wavelength in the range of 600-620 nm. In another embodiment, the LED **304** may emit light having a wavelength near 660 nm. In the illustrated embodiment, the plurality of light emitters **302** includes the LED **304** and two other LEDs **306** and **308**. In some embodiments, only the LED **304** and a second LED may be utilized. For example, the LED **304**, which may be configured to emit light having a wavelength near 660 nm, may coordinate with the LED **306**, which may be configured to emit light having a wavelength near 950 nm, to detect subtle SpO_2 variations. In one embodiment, the two LEDs **306** and **308** illustrated in FIG. **4** may have wavelengths that are more traditional for pulse oximetry. In another embodiment the two LEDs **306** and **308** may be optimized to provide light at wavelengths that specifically compliment the sensitivity function of the LED **304**.

By including the LED **304**, the LED **306**, and/or the LED **308**, the sensor **300** may be highly sensitive to small quantities of deoxyhemoglobin in blood, and, therefore, highly sensitive to small changes in SpO_2 at values nears 100% SaO_2. In other words, the light detected by a detector **310** of the sensor **300** may be largely impacted by small fluctuations in deoxyhemogloin because of the nature of the light emitted by the LED **304**, the LED **306**, and/or the LED **308**. In the illustrated embodiment, the sensor **300** also includes a processor **314** that is capable of utilizing values related to detected light to calculate high resolution SpO_2 values and/or other blood characteristics.

FIG. **5**A includes a chart **400**, which depicts absorption of oxyhemoglobin and deoxyhemoglobin plotted against wavelength. FIG. **5**B includes a chart **500**, which depicts an absorption coefficient difference plotted against wavelength. FIG. **5**C includes a chart **600**, which depicts a percent absolute coefficient difference plotted against wavelength. In the chart **400**, in accordance with one embodiment, a selected range for the LED **304** is indicated by arrow **402** and a selected range for a second LED, such as LED **306**, is indicated by arrow **404**. The greatest slope in the modulation ratio versus saturation (normalized to the modulation ratio at 95% SaO_2) may be achieved by pairing the largest and smallest values in the chart **600** (e.g., wavelengths of 660 and 1000 nm or greater). However, since the photo-response of silicon detectors decreases significantly beyond approximately 950 nm, a wavelength near 950 nm may be a practical value to use. Thus, the sensor **300** may be utilized with other features in accordance with present embodiments to facilitate detection, analysis, and control based on high resolution changes in SpO_2 values.

It should be noted that in other embodiments, the LED **304** may include and/or be coordinated with a green or yellow LED. For example, a green LED may have a wavelength of 500-570 nm and a yellow LED may have a wavelength of 570-600 nm. These wavelengths may be beneficial because their greater absorption of hemoglobin may enable the detection of a stronger pulsatile signal that facilitates resolution of smaller changes in SpO_2. The encoder **140** should provide calibration information appropriate to whichever two or more wavelengths are used for calculation of SpO_2 or changes therein. Further, it should be noted adjusting the emitter-detector spacing may increase detection resolution. Indeed, moving the optics closer together in a reflectance design (though not so close as to create an optical shunt) may increase the slope of the modulation ratio relative to SaO_2, as shown in FIG. **6**, wherein a 2-mm spacing (instead of 10 mm) at 660/950 results in −6.6% change in the modulation ratio per % SaO_2 (versus −5.6% per % SaO_2)

While the embodiments set forth in the present disclosure may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the disclosure is not intended to be limited to the particular forms disclosed. Indeed, the present techniques may not only be applied to measurements of blood oxygen saturation, but these techniques may also be utilized for the measurement and/or analysis of other blood constituents. For example, using the same, different, or additional wavelengths, the present techniques may be utilized in conjunction with the measurement and/or analysis of carboxyhemoglobin, met-hemoglobin, total hemoglobin, intravascular dyes, and/or water content. The disclosure is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure as defined by the following appended claims.

What is claimed is:

1. A pulse oximetry system, comprising:

a sensor comprising: an emitter configured to emit light at different wavelengths into a tissue bed; and a detector configured to detect the light from the emitter after dispersion and/or reflection by the tissue bed; and

a pulse oximeter configured to:

receive signals from the sensor that are indicative of characteristics of the light detected by the detector;

utilize the signals to estimate blood oxygen saturation values over time at a high resolution;

detect variations in the blood oxygen saturation values that are smaller in magnitude than an accuracy, display precision, and/or calibration of the blood oxygen saturation values; and

perform control and/or pattern detection functions based on the variations.

2. The pulse oximetry system of claim 1, wherein the pulse oximeter is configured to estimate the blood oxygen saturation values with a precision of 0.1%, 0.01% or 0.001%.

3. The pulse oximetry system of claim 1, wherein the pulse oximeter is configured to report changes in a value of partial pressure of oxygen in blood based on the detection of variations in the blood oxygen saturation values.

4. The pulse oximetry system of claim 1, wherein the emitter is configured to emit light having a wavelength in a bounded range of 600-660 nm.

5. The pulse oximetry system of claim 4, wherein the emitter comprises at least two light emitting diodes, wherein one of the at least two light emitting diodes is configured to emit light in the bounded range of 600-620 nm.

6. A method of performing pulse oximetry, comprising:

emitting light from an emitter component of a pulse oximeter sensor at first and second wavelengths useful for measuring oxygen saturation;

detecting the light with a detector component of the pulse oximeter sensor;

transmitting signals indicative of characteristics of the detected light to a pulse oximeter;

estimating blood oxygen saturation values over time at a high resolution based on the signals with the pulse oximeter;

detecting variations in the blood oxygen saturation values that are smaller in magnitude than an accuracy, display precision, and/or calibration of the blood oxygen saturation values; and

detecting a patient condition and/or controlling a physiologic parameter based on the variations.

7. The method of claim 6, wherein the first wavelength is between 650-670 nm.

8. The method of claim 6, wherein the first wavelength is within a range of 600-620 nm and the second wavelength is within a range of 800-940 nm.

9. The method of claim 6, comprising controlling a partial pressure of oxygen in a patient's blood based on the variations in the blood oxygen saturation values.

10. The method of claim 9, wherein controlling the partial pressure of oxygen comprises controlling delivery of oxygen to the patient based on the variations in the blood oxygen saturation values.

11. The method of claim 6, comprising identifying a pattern indicative of sleep apnea based on the variations in the blood oxygen saturation values.

12. The method of claim 6, comprising displaying the blood oxygen saturation values at the high resolution on a display screen.

13. A pulse oximeter sensor configured to facilitate detection of high precision changes in blood oxygen saturation estimates obtained via pulse oximetry, comprising:

a sensor body;

a plurality of emitters positioned within the sensor body, wherein each of the plurality of emitters is configured to emit light at a different wavelength, and wherein at least one of the plurality of emitters is selected for sensitivity to small changes in blood oxygen saturation by emitting light within a bounded range of wavelengths;

a detector configured to detect the light emitted by the plurality of emitters; and

a processor configured to calculate a value of blood oxygen saturation based on the detected light with a precision of 0.1, 0.01, or 0.001.

14. The pulse oximeter sensor of claim 13, wherein one of the plurality of emitters is configured to emit light having a wavelength in a bounded range of 600-620 nm.

15. The pulse oximeter sensor of claim 13, wherein one of the plurality of emitters is configured to emit light having a wavelength between 650-670 nm and another one of the plurality of emitters is configured to emit light having a wavelength between 940-1000 nm.

16. The pulse oximeter sensor of claim 14, wherein the plurality of emitters comprise an orange LED configured to emit light having a wavelength in a bounded range of 600-620 nm, and an infrared LED configured to emit light having a wavelength in a bounded range of 800-940 nm.

17. The pulse oximeter sensor of claim 14, wherein the plurality of emitters comprise an orange LED configured to emit light having a wavelength in a bounded range of 600-620 nm, and a red LED configured to emit light having a wavelength in a bounded range of 640-740 nm.

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专利名称(译)	用于检测和分析生理参数变化的方法和设备		
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申请(专利权)人(译)	NELLCOR PURITAN BENNETT LLC		
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摘要(译)

本公开一般涉及识别和/或分析测量的生理参数中的高分辨率变化，例如使用脉搏血氧测量法测量的血氧饱和度（SpO2）。本实施例可以包括一种系统，该系统包括传感器，该传感器包括能够将不同波长的光发射到组织床中的发射器，以及能够在组织床分散和/或反射之后检测来自发射器的光的检测器。此外，该系统可以包括脉冲血氧计，其能够接收来自传感器的信号，该信号指示由检测器检测到的光的特性，并且利用该信号以高分辨率随时间估计血氧饱和度值以便于检测变化。在血氧饱和度值中，血氧饱和度值的大小小于精确度，显示精度和/或血氧饱和度值的校准。