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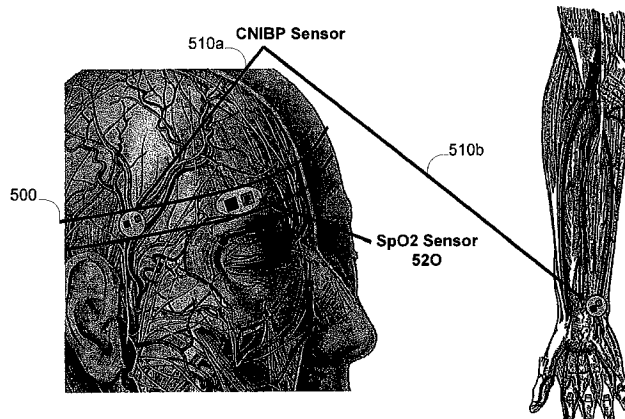


FIG. 4

(57) **Abstract:** The present disclosure relates to pulse oximetry measurements and, more particularly, relates to a combined sensor that includes a pulse oximetry (SpO₂) sensor component and a continuous non-invasive blood pressure (CNIBP) sensor component. The combined sensor can be positioned such that the SpO₂ sensor component is located over tissues where pulsatility is weak while the CNIBP sensor component may be located over tissues where pulsatility is strong. A second separate CNIBP sensor may be used to together with the CNIBP sensor component of the combined sensor in order to detect the differential pressure pulse transit time from the heart to two different locations on the body. A pulse signal detected by the CNIBP sensor component of the combined sensor can be used to trigger the SpO₂ measurement from the SpO₂ sensor component in order to improve SpO₂ measurement fidelity.



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SYSTEMS AND METHODS FOR COMBINED PULSE OXIMETRY AND BLOOD PRESSURE MEASUREMENT

Summary

The present disclosure relates to pulse oximetry measurements and, more particularly, relates to a combined sensor that includes a pulse oximetry (SpO₂) sensor component and a continuous non-invasive blood pressure (CNIBP) sensor component.

5 In an embodiment, a combined sensor that includes a support structure that is coupled to an SpO₂ sensor component and a CNIBP sensor component, is provided. The SpO₂ sensor component and the CNIBP sensor component both include at least one emitter and at least one detector. The SpO₂ sensor may be located over tissues where pulsatility is weak while the CNIBP sensor component may be located over tissues
10 where pulsatility is strong. In some embodiments, the combined sensor may be positioned on the head of a subject such that that the SpO₂ sensor component is located approximately over the subject's eyebrow while the CNIBP sensor component is located approximately over the subject's temple. A second separate CNIBP sensor may be used together with the CNIBP sensor component of the combined sensor in order to detect the
15 differential pressure pulse transit time from the heart to two different locations on the body. A pulse signal detected by the CNIBP sensor component of the combined sensor may be used to trigger the SpO₂ measurement from the SpO₂ sensor component in order to improve SpO₂ measurement fidelity.

Brief Description of the Drawings

20 The above and other features of the present disclosure, its nature and various advantages will be more apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings in which:

FIG. 1 shows a perspective view of an illustrative pulse oximetry system in accordance with an embodiment;

25 **FIG. 2** is a block diagram of the illustrative pulse oximetry system of **FIG. 1** coupled to a patient in accordance with an embodiment;

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FIG. 3 is a block diagram of an illustrative signal processing system in accordance with some embodiments;

FIG. 4 shows an illustrative combined sensor that includes a pulse oximetry (SpO₂) sensor component and a continuous non-invasive blood pressure (CNIBP) sensor component in accordance with some embodiments;

FIG. 5 shows an illustrative cross-section of a combined sensor that includes a SpO₂ sensor component, a CNIBP sensor component, and a support structure in accordance with some embodiments;

FIG. 6 shows illustrative signals detected by the CNIBP and SpO₂ sensors in accordance with some embodiments;

FIG. 7 shows another illustrative combined sensor that includes a SpO₂ sensor component and a CNIBP sensor component in accordance with some embodiments; and

FIG. 8 shows an illustrative diagram of a combined sensor that may be attached to an ear in accordance with some embodiments.

15 Detailed Description

An oximeter is a medical device that may determine the oxygen saturation of the blood. One common type of oximeter is a pulse oximeter, which may indirectly measure the oxygen saturation of a patient's blood (as opposed to measuring oxygen saturation directly by analyzing a blood sample taken from the patient) and changes in blood volume in the skin. Ancillary to the blood oxygen saturation measurement, pulse oximeters may also be used to measure the pulse rate of the patient. Pulse oximeters typically measure and display various blood flow characteristics including, but not limited to, the oxygen saturation of hemoglobin in arterial blood.

An oximeter may include a light sensor that is placed at a site on a patient, typically a fingertip, toe, forehead or earlobe, or in the case of a neonate, across a foot. The oximeter may pass light using a light source through blood perfused tissue and photoelectrically sense the absorption of light in the tissue. For example, the oximeter may measure the intensity of light that is received at the light sensor as a function of time. A signal representing light intensity versus time or a mathematical manipulation of this signal (*e.g.*, a scaled version thereof, a log taken thereof, a scaled version of a log taken thereof, etc.) may be referred to as the photoplethysmograph (PPG) signal. In

addition, the term "PPG signal," as used herein, may also refer to an absorption signal (*i.e.*, representing the amount of light absorbed by the tissue) or any suitable mathematical manipulation thereof. The light intensity or the amount of light absorbed may then be used to calculate the amount of the blood constituent (*e.g.*, oxyhemoglobin) being measured as well as the pulse rate and when each individual pulse occurs.

The light passed through the tissue is selected to be of one or more wavelengths that are absorbed by the blood in an amount representative of the amount of the blood constituent present in the blood. The amount of light passed through the tissue varies in accordance with the changing amount of blood constituent in the tissue and the related light absorption. Red and infrared wavelengths may be used because it has been observed that highly oxygenated blood will absorb relatively less red light and more infrared light than blood with a lower oxygen saturation. By comparing the intensities of two wavelengths at different points in the pulse cycle, it is possible to estimate the blood oxygen saturation of hemoglobin in arterial blood.

When the measured blood parameter is the oxygen saturation of hemoglobin, a convenient starting point assumes a saturation calculation based on Lambert-Beer's law. The following notation will be used herein:

$$I(\lambda, t) = I_o(\lambda) \exp(-(s\beta_o(\lambda) + (1-s)\beta_r(\lambda))l(t)) \quad (1)$$

where:

λ =wavelength;

t =time;

I =intensity of light detected;

I_o =intensity of light transmitted;

s =oxygen saturation;

β_o, β_r =empirically derived absorption coefficients; and

$l(t)$ =a combination of concentration and path length from emitter to detector as a function of time.

The traditional approach measures light absorption at two wavelengths (*e.g.*, red and infrared (IR)), and then calculates saturation by solving for the "ratio of ratios" as follows.

1. First, the natural logarithm of (1) is taken ("log" will be used to represent the natural logarithm) for IR and Red

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$$\log I = \log I_0 - (s\beta_o + (1-s)\beta_r)l \tag{2}$$

2. (2) is then differentiated with respect to time

$$\frac{d \log I}{dt} = -(s\beta_o + (1-s)\beta_r) \frac{dl}{dt} \tag{3}$$

3. Red (3) is divided by IR (3)

$$5 \quad \frac{d \log I(\lambda_R) / dt}{d \log I(\lambda_{IR}) / dt} = \frac{s\beta_o(\lambda_R) + (1-s)\beta_r(\lambda_R)}{s\beta_o(\lambda_{IR}) + (1-s)\beta_r(\lambda_{IR})} \tag{4}$$

4. Solving for s

$$s = \frac{\frac{d \log I(\lambda_{IR})}{dt} \beta_r(\lambda_R) - \frac{d \log I(\lambda_R)}{dt} \beta_r(\lambda_{IR})}{\frac{d \log I(\lambda_R)}{dt} (\beta_o(\lambda_{IR}) - \beta_r(\lambda_{IR})) - \frac{d \log I(\lambda_{IR})}{dt} (\beta_o(\lambda_R) - \beta_r(\lambda_R))}$$

Note in discrete time

$$\frac{d \log I(\lambda, t)}{dt} \simeq \log I(\lambda, t_2) - \log I(\lambda, t_1)$$

10 Using $\log A - \log B = \log A/B$,

$$\frac{d \log I(\lambda, t)}{dt} \simeq \log \left(\frac{I(t_2, \lambda)}{I(t_1, \lambda)} \right)$$

So, (4) can be rewritten as

$$\frac{\frac{d \log I(\lambda_R)}{dt}}{\frac{d \log I(\lambda_{IR})}{dt}} \simeq \frac{\log \left(\frac{I(t_1, \lambda_R)}{I(t_2, \lambda_R)} \right)}{\log \left(\frac{I(t_1, \lambda_{IR})}{I(t_2, \lambda_{IR})} \right)} = R \tag{5}$$

where **R** represents the "ratio of ratios." Solving (4) for s using (5) gives

$$15 \quad s = \frac{\beta_r(\lambda_R) - R\beta_r(\lambda_{IR})}{R(\beta_o(\lambda_{IR}) - \beta_r(\lambda_{IR})) - \beta_o(\lambda_R) + \beta_r(\lambda_R)}$$

From (5), **R** can be calculated using two points (e.g., PPG maximum and minimum), or a family of points. One method using a family of points uses a modified version of (5).

Using the relationship

$$\frac{d \log I}{dt} = \frac{dI / dt}{I} \tag{6}$$

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now (5) becomes

$$\begin{aligned} \frac{\frac{d \log I(\lambda_R)}{dt}}{\frac{d \log I(\lambda_{IR})}{dt}} &\simeq \frac{\frac{I(t_2, \lambda_R) - I(t_1, \lambda_R)}{I(t_1, \lambda_R)}}{\frac{I(t_2, \lambda_{IR}) - I(t_1, \lambda_{IR})}{I(t_1, \lambda_{IR})}} \\ &= \frac{[I(t_2, \lambda_R) - I(t_1, \lambda_R)]I(t_1, \lambda_{IR})}{[I(t_2, \lambda_{IR}) - I(t_1, \lambda_{IR})]I(t_1, \lambda_R)} \\ &= R \end{aligned} \quad (7)$$

5 which defines a cluster of points whose slope of y versus x will give **R** where

$$\begin{aligned} x(t) &= [I(t_2, \lambda_{IR}) - I(t_1, \lambda_{IR})]I(t_1, \lambda_R) \\ y(t) &= [I(t_2, \lambda_R) - I(t_1, \lambda_R)]I(t_1, \lambda_{IR}) \\ y(t) &= Rx(t) \end{aligned} \quad (8)$$

FIG. 1 is a perspective view of an embodiment of a pulse oximetry system **10**. System **10** may include a sensor **12** and a pulse oximetry monitor **14**. Sensor **12** may include an emitter **16** for emitting light at two or more wavelengths into a patient's tissue. A detector **18** may also be provided in sensor **12** for detecting the light originally
10 from emitter **16** that emanates from the patient's tissue after passing through the tissue.

According to another embodiment and as will be described, system **10** may include a plurality of sensors forming a sensor array in lieu of single sensor **12**. Each of the sensors of the sensor array may be a complementary metal oxide semiconductor
15 (CMOS) sensor. Alternatively, each sensor of the array may be charged coupled device (CCD) sensor. In another embodiment, the sensor array may be made up of a combination of CMOS and CCD sensors. The CCD sensor may comprise a photoactive region and a transmission region for receiving and transmitting data whereas the CMOS sensor may be made up of an integrated circuit having an array of pixel sensors. Each
20 pixel may have a photodetector and an active amplifier.

According to an embodiment, emitter **16** and detector **18** may be on opposite sides of a digit such as a finger or toe, in which case the light that is emanating from the tissue has passed completely through the digit. In an embodiment, emitter **16** and detector **18** may be arranged so that light from emitter **16** penetrates the tissue and is
25 reflected by the tissue into detector **18**, such as a sensor designed to obtain pulse oximetry data from a patient's forehead.

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In an embodiment, the sensor or sensor array may be connected to and draw its power from monitor **14** as shown. In another embodiment, the sensor may be wirelessly connected to monitor **14** and include its own battery or similar power supply (not shown). Monitor **14** may be configured to calculate physiological parameters based at least in part on data received from sensor **12** relating to light emission and detection. In an alternative embodiment, the calculations may be performed on the monitoring device itself and the result of the oximetry reading may be passed to monitor **14**. Further, monitor **14** may include a display **20** configured to display the physiological parameters or other information about the system. In the embodiment shown, monitor **14** may also include a speaker **22** to provide an audible sound that may be used in various other embodiments, such as for example, sounding an audible alarm in the event that a patient's physiological parameters are not within a predefined normal range.

In an embodiment, sensor **12**, or the sensor array, may be communicatively coupled to monitor **14** via a cable **24**. However, in other embodiments, a wireless transmission device (not shown) or the like may be used instead of or in addition to cable **24**.

In the illustrated embodiment, pulse oximetry system **10** may also include a multi-parameter patient monitor **26**. The monitor may be cathode ray tube type, a flat panel display (as shown) such as a liquid crystal display (LCD) or a plasma display, or any other type of monitor now known or later developed. Multi-parameter patient monitor **26** may be configured to calculate physiological parameters and to provide a display **28** for information from monitor **14** and from other medical monitoring devices or systems (not shown). For example, multiparameter patient monitor **26** may be configured to display an estimate of a patient's blood oxygen saturation generated by pulse oximetry monitor **14** (referred to as an "SpO₂" measurement), pulse rate information from monitor **14** and blood pressure from a blood pressure monitor (not shown) on display **28**.

Monitor **14** may be communicatively coupled to multi-parameter patient monitor **26** via a cable **32** or **34** that is coupled to a sensor input port or a digital communications port, respectively and/or may communicate wirelessly (not shown). In addition, monitor **14** and/or multi-parameter patient monitor **26** may be coupled to a network to enable the sharing of information with servers or other workstations (not shown). Monitor **14** may

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be powered by a battery (not shown) or by a conventional power source such as a wall outlet.

FIG. 2 is a block diagram of a pulse oximetry system, such as pulse oximetry system **10** of **FIG. 1**, which may be coupled to a patient **40** in accordance with an embodiment. Certain illustrative components of sensor **12** and monitor **14** are illustrated in **FIG. 2**. Sensor **12** may include emitter **16**, detector **18**, and encoder **42**. In the embodiment shown, emitter **16** may be configured to emit at least two wavelengths of light (e.g., *RED* and *IR*) into a patient's tissue **40**. Hence, emitter **16** may include a *RED* light emitting light source such as *RED* light emitting diode (LED) **44** and an *IR* light emitting light source such as *IR* LED **46** for emitting light into the patient's tissue **40** at the wavelengths used to calculate the patient's physiological parameters. In one embodiment, the *RED* wavelength may be between about 600 nm and about 700 nm, and the *IR* wavelength may be between about 800 nm and about 1000 nm. In embodiments where a sensor array is used in place of single sensor, each sensor may be configured to emit a single wavelength. For example, a first sensor emits only a *RED* light while a second only emits an *IR* light.

It will be understood that, as used herein, the term "light" may refer to energy produced by radiative sources and may include one or more of ultrasound, radio, microwave, millimeter wave, infrared, visible, ultraviolet, gamma ray or X-ray electromagnetic radiation. As used herein, light may also include any wavelength within the radio, microwave, infrared, visible, ultraviolet, or X-ray spectra, and that any suitable wavelength of electromagnetic radiation may be appropriate for use with the present techniques. Detector **18** may be chosen to be specifically sensitive to the chosen targeted energy spectrum of the emitter **16**.

In an embodiment, detector **18** may be configured to detect the intensity of light at the *RED* and *IR* wavelengths. Alternatively, each sensor in the array may be configured to detect an intensity of a single wavelength. In operation, light may enter detector **18** after passing through the patient's tissue **40**. Detector **18** may convert the intensity of the received light into an electrical signal. The light intensity is directly related to the absorbance and/or reflectance of light in the tissue **40**. That is, when more light at a certain wavelength is absorbed or reflected, less light of that wavelength is received from the tissue by the detector **18**. After converting the received light to an

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electrical signal, detector **18** may send the signal to monitor **14**, where physiological parameters may be calculated based on the absorption of the *RED* and *IR* wavelengths in the patient's tissue **40**.

In an embodiment, encoder **42** may contain information about sensor **12**, such as what type of sensor it is (*e.g.*, whether the sensor is intended for placement on a forehead or digit) and the wavelengths of light emitted by emitter **16**. This information may be used by monitor **14** to select appropriate algorithms, lookup tables and/or calibration coefficients stored in monitor **14** for calculating the patient's physiological parameters.

Encoder **42** may contain information specific to patient **40**, such as, for example, the patient's age, weight, and diagnosis. This information may allow monitor **14** to determine, for example, patient-specific threshold ranges in which the patient's physiological parameter measurements should fall and to enable or disable additional physiological parameter algorithms. Encoder **42** may, for instance, be a coded resistor which stores values corresponding to the type of sensor **12** or the type of each sensor in the sensor array, the wavelengths of light emitted by emitter **16** on each sensor of the sensor array, and/or the patient's characteristics. In another embodiment, encoder **42** may include a memory on which one or more of the following information may be stored for communication to monitor **14**: the type of the sensor **12**; the wavelengths of light emitted by emitter **16**; the particular wavelength each sensor in the sensor array is monitoring; a signal threshold for each sensor in the sensor array; any other suitable information; or any combination thereof.

In an embodiment, signals from detector **18** and encoder **42** may be transmitted to monitor **14**. In the embodiment shown, monitor **14** may include a general-purpose microprocessor **48** connected to an internal bus **50**. Microprocessor **48** may be adapted to execute software, which may include an operating system and one or more applications, as part of performing the functions described herein. Also connected to bus **50** may be a read-only memory (ROM) **52**, a random access memory (RAM) **54**, user inputs **56**, display **20**, and speaker **22**.

RAM **54** and ROM **52** are illustrated by way of example, and not limitation. Any suitable computer-readable media may be used in the system for data storage. Computer-readable media are capable of storing information that can be interpreted by microprocessor **48**. This information may be data or may take the form of computer-

executable instructions, such as software applications, that cause the microprocessor to perform certain functions and/or computer-implemented methods. Depending on the embodiment, such computer-readable media may include computer storage media and communication media. Computer storage media may include volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage of information such as computer-readable instructions, data structures, program modules or other data. Computer storage media may include, but is not limited to, RAM, ROM, EPROM, EEPROM, flash memory or other solid state memory technology, CD-ROM, DVD, or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by components of the system.

In the embodiment shown, a time processing unit (TPU) **58** may provide timing control signals to a light drive circuitry **60**, which may control when emitter **16** is illuminated and multiplexed timing for the *RED* LED **44** and the *IR* LED **46**. TPU **58** may also control the gating-in of signals from detector **18** through an amplifier **62** and a switching circuit **64**. These signals are sampled at the proper time, depending upon which light source is illuminated. The received signal from detector **18** may be passed through an amplifier **66**, a low pass filter **68**, and an analog-to-digital converter **70**. The digital data may then be stored in a queued serial module (QSM) **72** (or buffer) for later downloading to RAM **54** as QSM **72** fills up. In one embodiment, there may be multiple separate parallel paths having amplifier **66**, filter **68**, and A/D converter **70** for multiple light wavelengths or spectra received.

In an embodiment, microprocessor **48** may determine the patient's physiological parameters, such as SpO₂ and pulse rate, using various algorithms and/or look-up tables based on the value of the received signals and/or data corresponding to the light received by detector **18**. Signals corresponding to information about patient **40**, and particularly about the intensity of light emanating from a patient's tissue over time, may be transmitted from encoder **42** to a decoder **74**. These signals may include, for example, encoded information relating to patient characteristics. Decoder **74** may translate these signals to enable the microprocessor to determine the thresholds based on algorithms or look-up tables stored in ROM **52**. User inputs **56** may be used to enter information about the patient, such as age, weight, height, diagnosis, medications, treatments, and so forth.

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In an embodiment, display 20 may exhibit a list of values which may generally apply to the patient, such as, for example, age ranges or medication families, which the user may select using user inputs 56.

5 The optical signal through the tissue can be degraded by noise, among other sources. One source of noise is ambient light that reaches the light detector. Another source of noise is electromagnetic coupling from other electronic instruments. Movement of the patient also introduces noise and affects the signal. For example, the contact between the detector and the skin, or the emitter and the skin, can be temporarily disrupted when movement causes either to move away from the skin. In addition,
10 because blood is a fluid, it responds differently than the surrounding tissue to inertial effects, thus resulting in momentary changes in volume at the point to which the oximeter probe is attached.

Noise (*e.g.*, from patient movement) can degrade a pulse oximetry signal relied upon by a physician, without the physician's awareness. This is especially true if the
15 monitoring of the patient is remote, the motion is too small to be observed, or the doctor is watching the instrument or other parts of the patient, and not the sensor site. Processing pulse oximetry (*i.e.*, PPG) signals may involve operations that reduce the amount of noise present in the signals or otherwise identify noise components in order to prevent them from affecting measurements of physiological parameters derived from the
20 PPG signals.

It will be understood that the present disclosure is applicable to any suitable signals and that PPG signals are used merely for illustrative purposes. Those skilled in the art will recognize that the present disclosure has wide applicability to other signals including, but not limited to other biosignals (*e.g.*, electrocardiogram,
25 electroencephalogram, electrogastrogram, electromyogram, heart rate signals, pathological sounds, ultrasound, or any other suitable biosignal), dynamic signals, non-destructive testing signals, condition monitoring signals, fluid signals, geophysical signals, astronomical signals, electrical signals, financial signals including financial indices, sound and speech signals, chemical signals, meteorological signals including
30 climate signals, and/or any other suitable signal, and/or any combination thereof.

Various approaches have been used for monitoring the blood pressure of living subjects. One approach is to insert a pressure sensor directly into a suitable artery of the

subject. The sensor may be connected to a suitable monitoring device by a lead which passes through the subject's skin. This approach may provide highly accurate and instantaneous blood pressure measurements, but is very invasive. A surgical procedure is generally required to introduce the pressure sensor, and the fistula through which the lead exits the subject's body can provide a pathway for infection.

Another approach to measuring blood pressure uses a sphygmomanometer. A typical sphygmomanometer has an occluding cuff capable of being wrapped around a subject's arm. A pump is used to inflate the cuff, and an aneroid or mercury gravity sphygmomanometer is used to measure the pressure in the cuff. Such devices are widely used in hospitals, but are not well adapted for providing continuous blood pressure monitoring.

Some continuous non-invasive blood pressure monitoring (CNIBP) techniques have been developed that involve the use of two probes or sensors positioned at two different locations on a subject's body. The elapsed time, T , between the arrival of corresponding points of a pulse signal at the two locations may then be determined using the two probes or sensors. The estimated blood pressure, p , may then be related to the elapsed time, T , by

$$p = a + b \cdot \ln(T) \quad (9)$$

where a and b are constants that are dependent upon the nature of the subject and the signal detecting devices. Other blood pressure equations using elapsed time may also be used. These techniques may be referred to as differential pulse transit time (DPTT) based CNIBP.

In some embodiments, the constants a and b in equation (9) may be determined by performing a calibration. The calibration may involve taking a reference blood pressure reading to obtain a reference blood pressure P_0 , measuring the elapsed time T_0 corresponding to the reference blood pressure, and then determining values for both of the constants a and b from the reference blood pressure and elapsed time measurement. Calibration may be performed at any suitable time (*e.g.*, once initially after monitoring begins) or on any suitable schedule (*e.g.*, a periodic or event-driven schedule).

The calibration may include performing calculations mathematically equivalent to

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$$a = c_1 + \frac{c_2(P_0 - c_1)}{\ln(T_0) + c_2} \quad (10)$$

and

$$b = \frac{P_0 - c_1}{\ln(T_0) + c_2} \quad (11)$$

to obtain values for the constants a and b , where c_1 and c_2 are predetermined constants.

5 In other embodiments, determining the plurality of constant parameters in the multi-parameter equation (1) may include performing calculations mathematically equivalent to

$$a = P_0 - (c_3 T_0 + c_4) \ln(T_0) \quad (12)$$

and

$$10 \quad b = c_3 T_0 + c_4 \quad (13)$$

where a and b are first and second parameters and c_3 and c_4 are predetermined constants.

In some embodiments, the multi-parameter equation (9) includes a non-linear function which is monotonically decreasing and concave upward in a manner specified by the constant parameters.

15 Continuous and non-invasive blood pressure monitoring using these techniques is described in Chen et al. U.S. Patent No. 6,566,251, which is hereby incorporated by reference herein in its entirety. The technique described by Chen et al. may use two sensors (*e.g.*, ultrasound or photoelectric pulse wave sensors) positioned at any two locations on a subject's body where pulse signals are readily detected. For example,
20 sensors may be positioned on an earlobe and a finger, an earlobe and a toe, or a finger and a toe of a patient's body.

The use of multiple probes or sensors in non-invasive continuous blood pressure monitoring provides reliable results. However, in some instances, the use of multiple separate probes or sensors at different locations on the subject's body may be
25 cumbersome, especially for a mobile subject. Moreover, one of the multiple probes or sensors may become detached from the subject, resulting in a disruption in the continuous monitoring of the patient's blood pressure. Accordingly, some techniques for continuously monitoring a subject's blood pressure use only a single probe or sensor. In

some embodiments, the single probe or sensor may detect a photoplethysmograph (PPG) signal generated, for example, by a pulse oximeter. The PPG signal may then be analyzed and used to compute a time difference between two or more characteristic points in the PPG signal. From this time difference, reliable and accurate blood pressure measurements may be computed on a continuous or periodic basis. This technique is described in more detail in U.S. Provision Application No. 61/076,955, filed June 30, 2008, entitled (“SYSTEMS AND METHODS FOR NON-INVASIVE BLOOD PRESSURE MONITORING”), which is incorporated by reference herein in its entirety. In some embodiments, blood pressure measurements may be determined based on pulses in a PPG signal detected by a single sensor, for example, by measuring the area under a pulse or a portion of the pulse in the PPG signal. This technique is described in more detail in U.S. Provision Application No. 61/077,103, filed June 30, 2008, entitled (“SYSTEMS AND METHODS FOR NON-INVASIVE CONTINUOUS BLOOD PRESSURE DETERMINATION”), which is incorporated by reference herein in its entirety.

FIG. 3 is an illustrative signal processing system in accordance with an embodiment. In this embodiment, input signal generator **410** generates an input signal **416**. As illustrated, input signal generator **410** may include oximeter **420** coupled to sensor **418**, which may provide as input signal **416**, a PPG signal. It will be understood that input signal generator **410** may include any suitable signal source, signal generating data, signal generating equipment, or any combination thereof to produce signal **416**. Signal **416** may be any suitable signal or signals, such as, for example, biosignals (*e.g.*, electrocardiogram, electroencephalogram, electrogastrogram, electromyogram, heart rate signals, pathological sounds, ultrasound, or any other suitable biosignal), dynamic signals, non-destructive testing signals, condition monitoring signals, fluid signals, geophysical signals, astronomical signals, electrical signals, financial signals including financial indices, sound and speech signals, chemical signals, meteorological signals including climate signals, and/or any other suitable signal, and/or any combination thereof.

In this embodiment, signal **416** may be coupled to processor **412**. Processor **412** may be any suitable software, firmware, and/or hardware, and/or combinations thereof for processing signal **416**. For example, processor **412** may include one or more

hardware processors (*e.g.*, integrated circuits), one or more software modules, computer-readable media such as memory, firmware, or any combination thereof. Processor **412** may, for example, be a computer or may be one or more chips (*i.e.*, integrated circuits). Processor **412** may perform the calculations associated with the signal processing of the present disclosure as well as the calculations associated with any suitable interrogations of the transforms. Processor **412** may perform any suitable signal processing of signal **416** to filter signal **416**, such as any suitable band-pass filtering, adaptive filtering, closed-loop filtering, and/or any other suitable filtering, and/or any combination thereof.

Processor **412** may be coupled to one or more memory devices (not shown) or incorporate one or more memory devices such as any suitable volatile memory device (*e.g.*, RAM, registers, *etc.*), non-volatile memory device (*e.g.*, ROM, EPROM, magnetic storage device, optical storage device, flash memory, *etc.*), or both. The memory may be used by processor **412** to, for example, store data corresponding to signal **416**.

Processor **412** may be coupled to output **414**. Output **414** may be any suitable output device such as, for example, one or more medical devices (*e.g.*, a medical monitor that displays various physiological parameters, a medical alarm, or any other suitable medical device that either displays physiological parameters or uses the output of processor **412** as an input), one or more display devices (*e.g.*, monitor, PDA, mobile phone, any other suitable display device, or any combination thereof), one or more audio devices, one or more memory devices (*e.g.*, hard disk drive, flash memory, RAM, optical disk, any other suitable memory device, or any combination thereof), one or more printing devices, any other suitable output device, or any combination thereof.

It will be understood that system **400** may be incorporated into system **10** (FIGS. **1** and **2**) in which, for example, input signal generator **410** may be implemented as parts of sensor **12** and monitor **14** and processor **412** may be implemented as part of monitor **14**.

The present disclosure relates to a combined sensor that includes a SpO₂ sensor component and a CNIBP sensor component. Generally speaking, the location requirements for optimal detection of SpO₂ and DPTT based CNIBP may be different. As described above, CNIBP sensors can detect the differential pressure pulse transit time from the heart to two different locations on the body. These CNIBP sensors may be located over tissues where pulsatility is strong over a wide variety of perfusion

conditions. Major arteries are therefore typically good sites for these CNIBP sensors. For example, typical sites for CNIBP sensors are the radial artery on the forearm and the temporal artery on the head. In contrast, typical sites that are good for measuring SpO₂ are highly perfused tissues without the presence of large pulsating absorbers such as major arteries. For example, typically sites for measuring SpO₂ are a fingertip, toe, forehead or earlobe.

FIG. 4 shows an illustrative sensor **500** containing a first CNIBP sensor component **510a** positioned approximately over the temporal artery and SpO₂ sensor component **520** positioned approximately over the eyebrow. The area around the temporal artery is a strong pulsatility site which may be suitable for CNIBP measurement. The area around the eyebrow, in contrast, has low pulsatility which may be suitable for SpO₂ measurement. A second CNIBP sensor **510b** may be positioned over the radial artery on the wrist. As described above, DPTT based CNIBP techniques may use two sensors positioned at two different locations on a subject's body to estimate blood pressure by measuring an amount of time between the arrival of corresponding points of a pulse signal at the two locations. In some embodiments, single sensor CNIBP monitoring techniques, such as those described above, may be used. Using these techniques, only first CNIBP sensor component **510a** may be required for measuring blood pressure. In one single sensor CNIBP monitoring technique, an amount of time between two or more characteristic points of a pulse signal detected by the single sensor may be measured. In another single sensor CNIBP monitoring technique, an area under one or more portions of a pulse signal detected by the single sensor may be measured. In some embodiments, both sensor components may be used to measure CNIBP and SpO₂ signals at both sites, then one of the signals may be selected or the two signals may be combined.

CNIBP sensor components **510a** and **510b** may include a single wavelength emitter and detector for detecting pulsatility of the arteries. The emitter detector separation and wavelength selection of CNIBP sensors **510a** and **510b** may be optimized for detecting pulsatility. For example, the wavelength of the emitter and detector of the CNIBP sensors **510a** and **510b** may be an *IR* wavelength.

SpO₂ sensor component **520** may measure oxygen saturation using, for example, using the ratio of ratios technique described above or any other suitable technique. SpO₂

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sensor component **520** may include a dual wavelength emitter and a detector for measuring the absorption of light in the tissue. For example, SpO₂ sensor component **520** may include dual emitters for red and *IR* wavelengths. The emitter detector separation and wavelength selection of SpO₂ sensor component **520** may be optimized for measuring the intensity of light that is received at the sensor as a function of time.

Using the ratio of ratios SpO₂ measurement technique, the intensities of two wavelengths detected by SpO₂ sensor component **520** at different points in the pulse cycle may be compared to measure oxygen saturation levels. The upstroke portion of the detected PPG signal may provide the best results for using this measurement technique.

When SpO₂ sensor component **520** is in a relatively low perfusion site, such as around the eyebrow, it may be difficult to directly detect the upstroke portion of the PPG signal when, for example, noise or artifacts are present in the signal. In contrast, CNIBP sensor components **510a** and **510b**, located over major arteries, may more easily detect the location of upstrokes in the PPG signal. Thus, the pulse signal detected by one or both CNIBP sensor components **510a** and **510b** may be used to trigger the ratio of ratios calculation for SpO₂ measurement. For example finding the period of upstroke of the pressure pulse may involve taking the first derivative of the CNIBP signal and using the portions with a sustained value above a trigger threshold to identify suitable, upstroke, time periods. Using a pulse signal detected by CNIBP sensor components **510a** and **510b** to trigger the ratio of ratios calculation for SpO₂ measurement in this manner may improve the SpO₂ measurement fidelity and may minimize the affect of noise and artifacts.

Typically the signals detected by the CNIBP and SpO₂ sensors are similar. **FIG. 6** shows illustrative signals detected by the CNIBP and SpO₂ sensors. In an embodiment, the CNIBP and SpO₂ signals both include at least one transmission or reflection signal received from an optical emitter of common wavelength, for example both may use an IR emitting source. The main difference in signal morphology may be caused by the different site locations (*e.g.*, one capillary and one arterial) which may make the CNIBP signal more pulsatile, with increased high frequency components, and less affected by noise. A second difference between the two signals may be the sampling frequency. For example, the CNIBP sensor may sample at a much faster rate (*e.g.*, 1KHz or every 1 millisecond) that the SpO₂ sensor (*e.g.*, 75Hz or every 13.3

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milliseconds). The time difference between head sites (forehead/ear) from the finger is approximately 60 milliseconds, though it does vary from individual to individual. Therefore, if a CNIBP sensor were being used by the SpO₂ system (for example to identify characteristic points of the pleth or artifact) the pulse arrival times from finger to
5 head may differ by approximately 4 samples which may be considered irrelevant when detecting a pulse for SpO₂ calculation. However, where the CNIBP and SpO₂ sensors are proximal it is reasonable to assume that pulses may be observed at the same time by the two detectors.

As a processor (*e.g.*, processor **412** (**FIG. 4**)) receives both signals it may, in one
10 embodiment, use the CNIBP signal to improve the accuracy of a SpO₂ calculation through its application to the selection of useful data. In an alternative embodiment the CNIBP signal may be used to trigger a measurement from the SpO₂ sensor for use in the derivation of a saturation value, for example, during the upstroke of a pulse.

FIG. 5 shows an illustrative cross-section of sensor **500** containing a first CNIBP
15 sensor component **510a**, SpO₂ sensor component **520**, and support structure **600** coupled to both sensors. Sensor components **510a** and **520** may be secured to support structure **600** using adhesive **601** or any other suitable attachment technique. Further, while adhesive **601** is shown as securing the underside of sensor components **510a** and **520** to support structure **600**, it should be understood that sensor components **510a** and **520** may
20 be secured over support structure **600** (as shown), under support structure **600**, or at least partially embedded in support structure **600**. Similarly, adhesive **601** or an equivalent attachment medium may be located under the sensor components (as shown), around the sensor components, over the sensor components, or some combination thereof. In some
25 embodiments one or more of the sensor components may be integrated with or built directly onto support structure **600**. Support structure **600** may be made of any suitable material or combination of materials. Support structure **600** may be made of a flexible material that allows sensor components **510a** and **520** to achieve close contact with desired sensor site locations, even when those locations are across a curved surface such as a patient's head. As discussed above, positioning the two sensor components in close
30 proximity may reduce delays between the sensors. However, it should be noted that where CNIBP and SpO₂ sensors are close the issue of crosstalk must be minimized or compensated for.

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Sensor **500** may be attached to a patient using any suitable approach. For example, as shown in **FIG. 4**, sensor **500** may be attached to a patient's head using a headband. Such a headband may be directly attached to sensor components **510a** and **520** as a support structure or may be attached to a separate support structure **600**. In some embodiments, sensor **500** may attach directly to a patient using, for example, an integrated adhesive area or using any other suitable approach. Alternatively sprung clips may be used to measure capillary sites used for SpO₂ (e.g., ear lobe or fingertip) while adhesive sensors may be more suited for the arterial sites used for CNIBP measurements.

Another site that may be used for the combined sensor includes locations around and on the ear. **FIG. 7** shows an illustrative sensor **700** containing a CNIBP sensor component **710** and an SpO₂ sensor component **720**. CNIBP sensor component **710** may be positioned around the bottom of the ear, underneath the earlobe on the side of the face and neck. This sensor location exhibits strong pulsatility and may be a good site for measurement of strong pulsations suitable for CNIBP measurements. SpO₂ sensor component **720** positioned around the side of the face at the top of the ear over hard bone behind the "helix." Alternatively SpO₂ sensor component **720** may also be positioned on the ear lobe itself (not shown).

FIG. 8 shows an illustrative diagram of a combined sensor **800** that may be attached to an ear in the same manner as sensor **700** (**FIG. 7**). Sensor **800** includes deformable foam support structure **805** which may be used to attach two sensor components **810** and **820**, one optimized for SpO₂ and one optimized for CNIBP, around the ear. The foam support structure **805** may have adhesive at each end, at the sensor component sites and may be deformable in the middle part to allow the sensor **800** to be bent around the ear. In some embodiments, support structure **805** can loop around the ear to provide additional support.

It will be understood that sensor **500** or **700** may be used in place of sensor **12** in system **10** (**FIGS. 1** and **2**) or in place of input signal generator **410** in system **400** (**FIG. 3**)

The foregoing is merely illustrative of the principles of this disclosure and various modifications can be made by those skilled in the art without departing from the scope and spirit of the disclosure. The following claims may also describe various aspects of this disclosure.

What is Claimed is:

1. A sensor, comprising:
a support structure;
a pulse oximetry (SpO₂) sensor component comprising at least one
5 emitter and at least one detector, wherein the SpO₂ sensor component is coupled to the
support structure; and
a continuous non-invasive blood pressure (CNIPB) sensor
component comprising at least one emitter and at least one detector, wherein the CNIBP
sensor component is coupled to the support structure.
- 10 2. The sensor of claim 1, wherein the support structure is a flexible
support structure.
3. The sensor of claim 1, wherein the support structure is capable of
being attached to a subject such that the SpO₂ sensor component is positioned over tissue
having weak pulsatility and such that the CNIPB sensor component is simultaneously
15 positioned over tissue having strong pulsatility.
4. The sensor of claim 1, wherein the support structure is capable of
being attached to a head of a subject such that the SpO₂ sensor component is positioned
approximately over an eyebrow of the subject and such that the CNIPB sensor
component is simultaneously positioned approximately over a temporal artery of the
20 subject.
5. The sensor of claim 1, wherein the support structure is capable of
being attached to a head of a subject such that the SpO₂ sensor component is positioned
on the head of the subject near a top of an ear of the subject and such that the CNIPB
sensor component is simultaneously positioned on the head of the subject underneath an
25 earlobe of the subject.
6. The sensor of claim 1, wherein the CNIBP sensor component
coupled to the support structure is a first CNIBP sensor component, the sensor further

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comprising a second CNIBP sensor component that is not coupled to the support structure.

7. The sensor of claim 1, wherein the CNIBP sensor component is a single wavelength sensor component.

5 8. The sensor of claim 1, wherein the SpO₂ sensor component is a dual wavelength sensor component.

9. A pulse oximetry and blood pressure monitor, comprising:
a combined sensor comprising:

a support structure;

10 a pulse oximetry (SpO₂) sensor component comprising at least one emitter and at least one detector, wherein the SpO₂ sensor component is coupled to the support structure;

15 a continuous non-invasive blood pressure (CNIPB) sensor component comprising at least one emitter and at least one detector, wherein the CNIBP sensor component is coupled to the support structure; and

a processor capable of measuring pulse oximetry and blood pressure based at least in part on a pulse signal detected by CNIBP sensor component and a photoplethysmograph (PPG) signal detected by the SpO₂ sensor component.

20 10. The monitor of claim 9, wherein the combined sensor support structure is a flexible support structure.

11. The monitor of claim 9, wherein the combined sensor support structure is capable of being attached to a subject such that the SpO₂ sensor component is positioned over tissue having weak pulsatility and such that the CNIPB sensor component is simultaneously positioned over tissue having strong pulsatility.

25 12. The monitor of claim 9, wherein the combined sensor support structure is capable of being attached to a head of a subject such that the SpO₂ sensor component is positioned approximately over an eyebrow of the subject and such that the CNIPB sensor component is simultaneously positioned approximately over a temporal artery of the subject.

13. The monitor of claim 9, wherein the combined sensor support structure is capable of being attached to a head of a subject such that the SpO₂ sensor component is positioned on the head of the subject near a top of an ear of the subject and such that the CNIBP sensor component is simultaneously positioned on the head of the subject underneath an earlobe of the subject

14. The monitor of claim 9, wherein the CNIBP sensor component coupled to the support structure is a first CNIBP sensor component, the monitor further comprising a second CNIBP sensor component that is not coupled to the support structure.

15. The monitor of claim 14, wherein the processor is capable of measuring blood pressure based at least in part on a calculated differential pulse transit time (DPTT) between a portion of a pulse signal detected by the first and the second CNIBP sensor components.

16. The monitor of claim 9, wherein the processor is capable of measuring blood pressure based at least in part on a calculated amount of time between two or more portions of a pulse signal detected by the CNIBP sensor component.

17. The monitor of claim 9, wherein the processor is capable of measuring blood pressure based at least in part on a calculated amount of area underneath a portion of a pulse signal detected by the CNIBP sensor component.

18. The monitor of claim 9, wherein the processor is capable of measuring pulse oximetry levels using a photoplethysmograph (PPG) signal detected by the SpO₂ sensor component.

19. The monitor of claim 18, wherein the measuring of pulse oximetry levels relies, at least in part, on the signal detected by the CNIBP sensor component.

20. A method for measuring blood oxygen saturation and blood pressure, comprising:

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detecting a photoplethysmograph (PPG) signal with a pulse oximetry (SpO₂) sensor component of a combined sensor comprising at least one emitter and at least one detector;

5 detecting a pulse signal with a continuous non-invasive blood pressure (CNIPB) sensor component of the combined sensor comprising at least one emitter and at least one detector; and

measuring pulse oximetry and blood pressure based at least in part on the detected PPG signal and the detected pulse signal.

10 21. The method of claim 20, further comprising positioning the SpO₂ sensor component over tissue having weak pulsatility and simultaneously positioning the CNIPB sensor component over tissue having strong pulsatility.

22. The method of claim 20, further comprising positioning the SpO₂ sensor component over an eyebrow of a subject and simultaneously positioning the CNIPB sensor component over a temporal artery of the subject.

15 23. The method of claim 20, further comprising positioning the SpO₂ sensor component near a top of an ear of a subject and simultaneously positioning the CNIPB sensor component underneath an earlobe of the subject.

20 24. The method of claim 20, wherein measuring blood pressure comprises calculating a differential pulse transit time (DPTT) between a portion of a pulse signal detected by the CNIBP sensor component and a second CNIBP sensor component.

25 25. The method of claim 20, wherein measuring blood pressure comprises calculating an amount of time between two or more portions of a pulse signal detected by the CNIBP sensor component.

26. The method of claim 20, wherein measuring blood pressure comprises calculating an area underneath a portion of a pulse signal detected by the CNIBP sensor component.

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27. The method of claim 20, wherein measuring pulse oximetry levels comprises using a photoplethysmograph (PPG) signal detected by the SpO₂ sensor component.

28. The method of claim 20, wherein measuring of pulse oximetry
5 levels relies, at least in part, on the signal detected by the CNIBP sensor component.

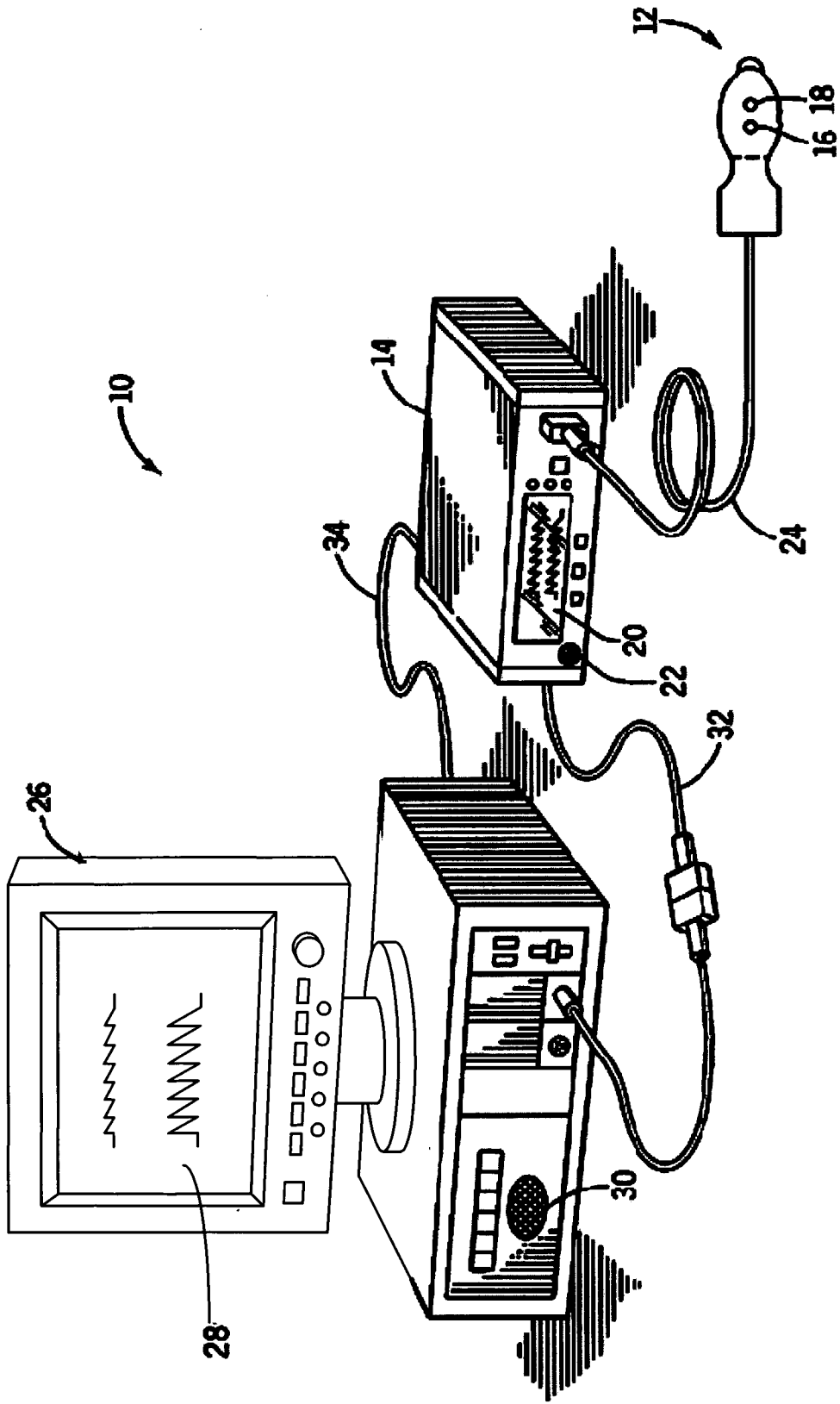


FIG.1

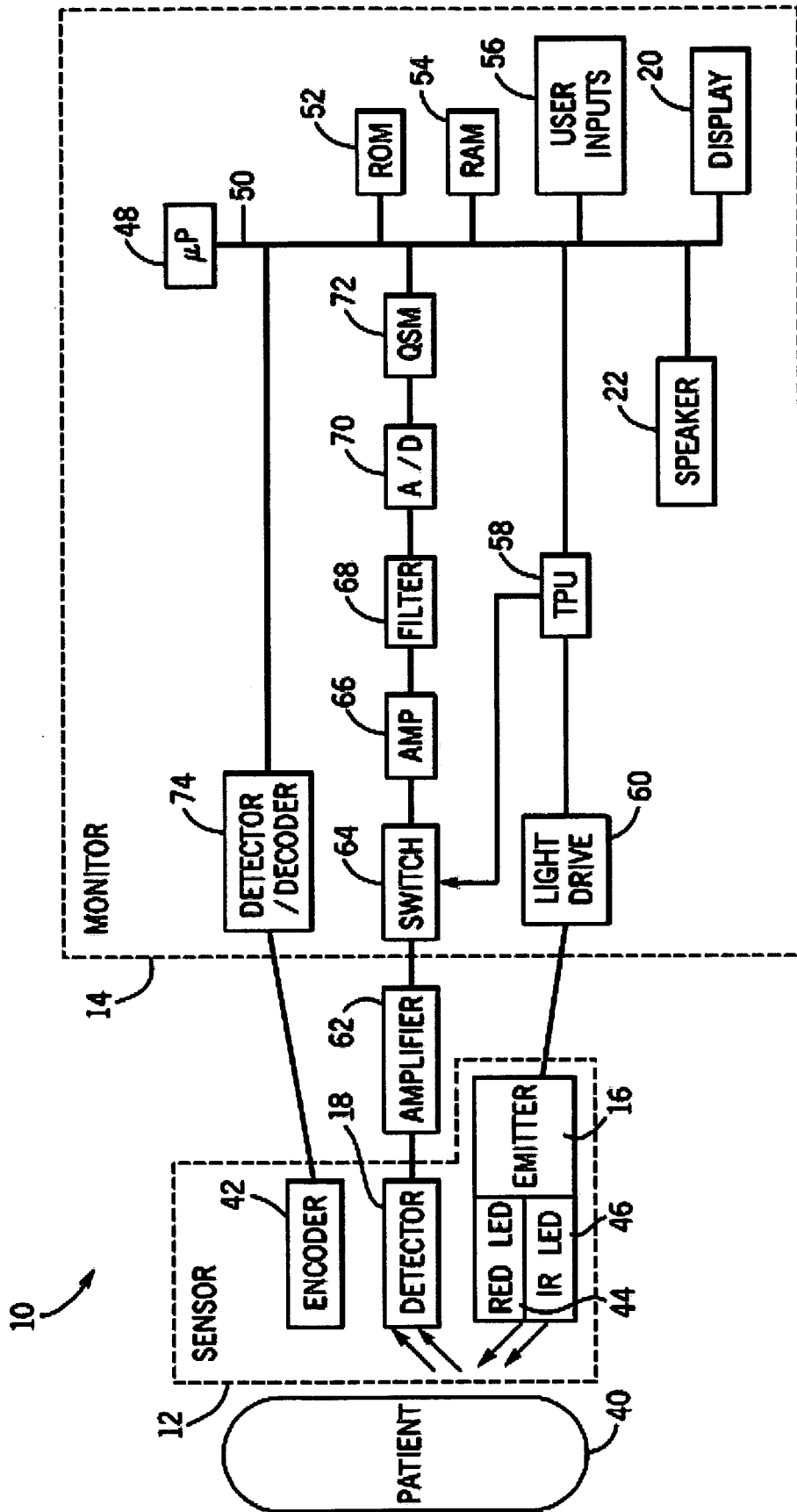


FIG. 2

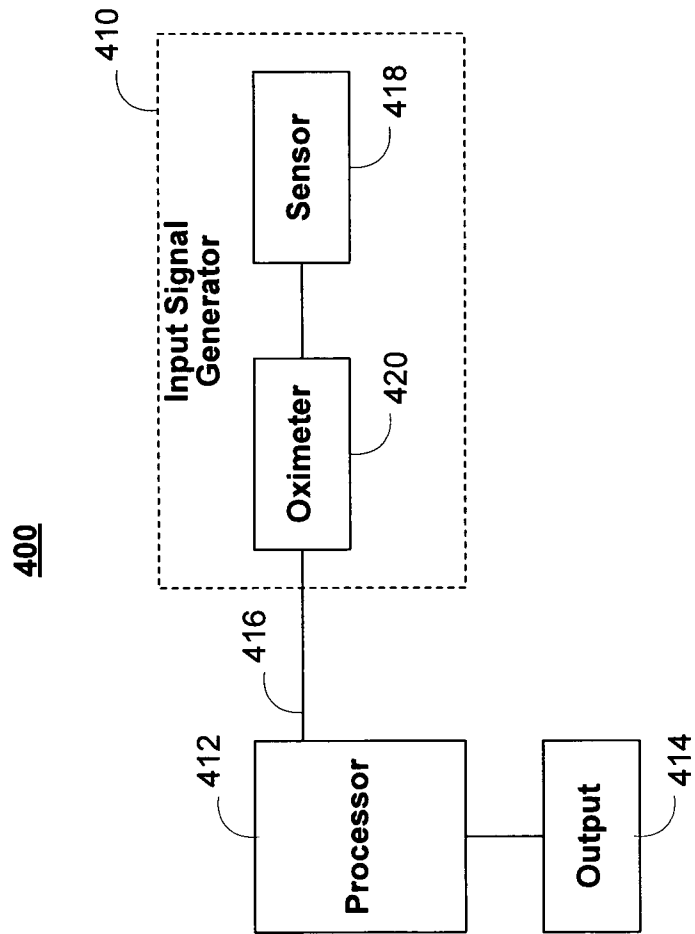


FIG. 3

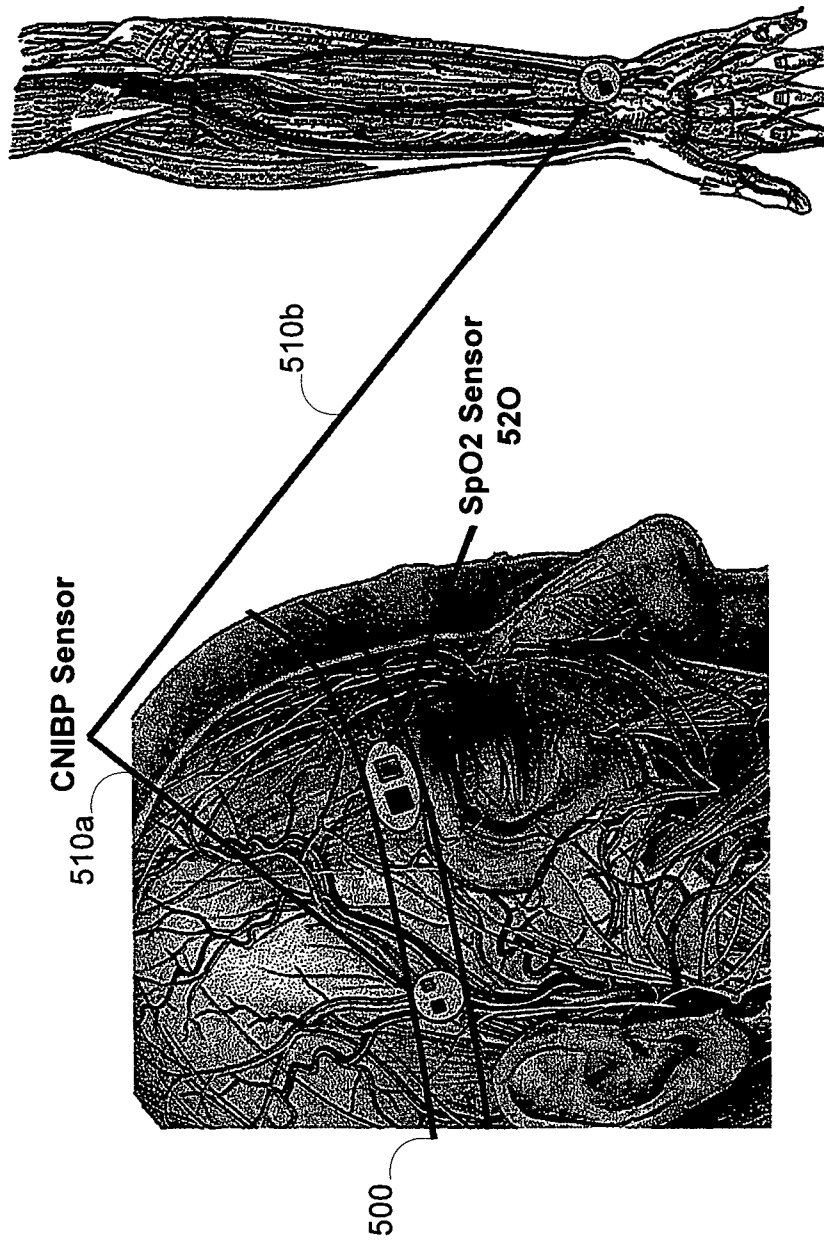


FIG. 4

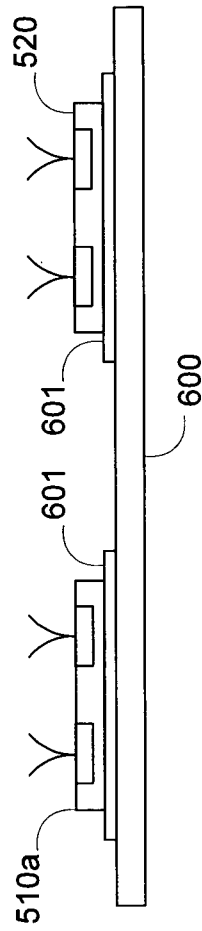


FIG. 5

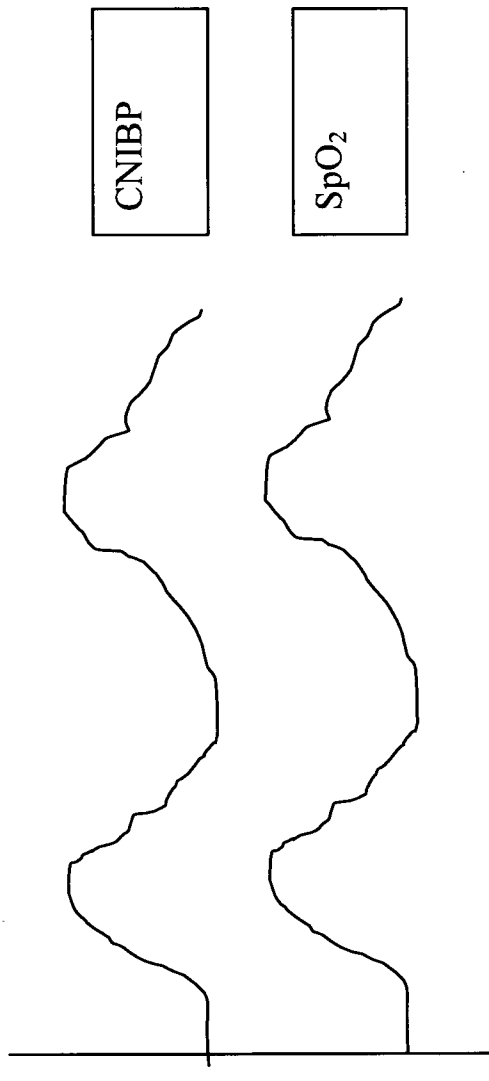


FIG. 6

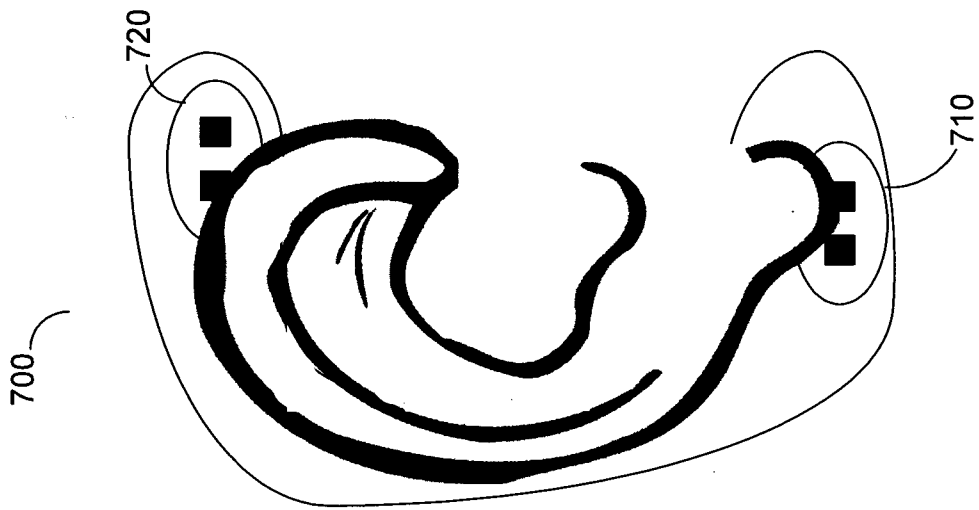


FIG. 7

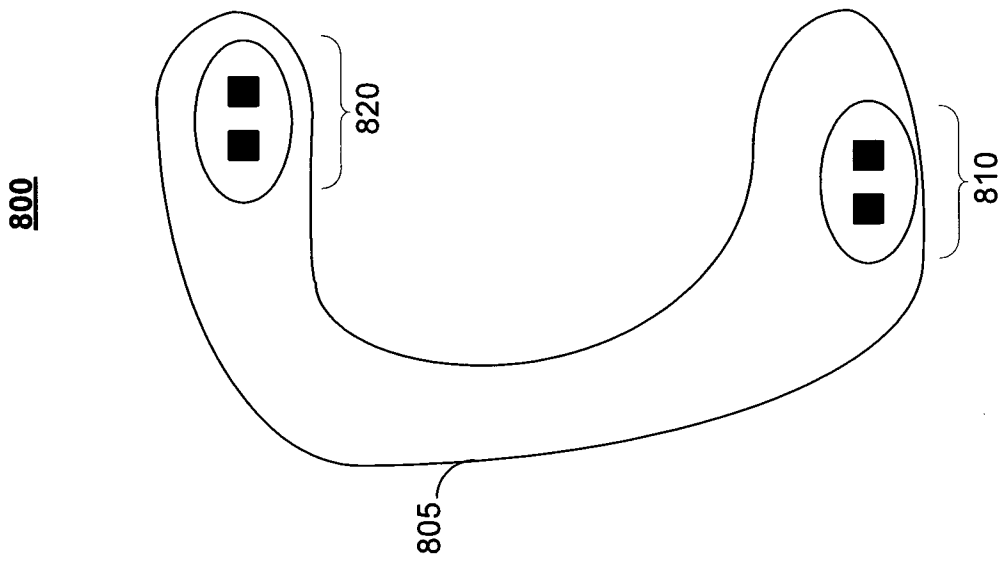


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2009/006896

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

International application No

PCT/IB2009/006896

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			WO 2004016170 A1 26-02-2004

专利名称(译)	用于组合脉搏血氧测量和血压测量的系统和方法		
公开(公告)号	EP2330972A1	公开(公告)日	2011-06-15
申请号	EP2009786265	申请日	2009-09-17
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IPC分类号	A61B5/00 A61B5/024		
CPC分类号	A61B5/6838 A61B5/0205 A61B5/02427 A61B5/02438 A61B5/14552 A61B5/6814 A61B5/6815		
优先权	12/242446 2008-09-30 US		
外部链接	Espacenet		

摘要(译)

本公开涉及脉搏血氧测量测量，并且更具体地，涉及包括脉搏血氧测定 (SpO₂) 传感器组件和连续无创血压 (CNIBP) 传感器组件的组合传感器。组合的传感器可以定位成使得SpO₂传感器组件位于脉动弱的组织上，而CNIBP传感器组件可以位于脉动强的组织上。第二单独的CNIBP传感器可以与组合传感器的CNIBP传感器组件一起使用，以便检测从心脏到身体上的两个不同位置的压差脉冲传输时间。由组合传感器的CNIBP传感器组件检测到的脉冲信号可用于触发SpO₂传感器组件的SpO₂测量，以提高SpO₂测量保真度。