OPTICAL SENSOR FOR MEASURING PHYSIOLOGICAL PROPERTIES

RELATED APPLICATIONS

[0001] The present application claims the benefit of priority to United States Provisional Application No. 61/444,320, filed February 18, 2011, which is hereby incorporated by reference, including the drawings.

BACKGROUND OF THE INVENTION

[0002] The following discussion of the background of the invention is merely provided to aid the reader in understanding the invention and is not admitted to describe or constitute prior art to the present invention.

[0003] The saturation of peripheral oxygen in the blood (SpO2) is sometimes referred to as the 'fifth vital sign'. Medical professionals can detect hypoxemia, i.e. a deficiency of oxygen, by monitoring a patient's SpO2. Values between about 95 – 100% are considered normal; those below this indicate hypoxemia, and will typically trigger an alarm in a hospital setting.

[0004] A technique called pulse oximetry measures SpO2. Technically this parameter is determined from a patient's arterial oxygen saturation, or SaO2, which is a percentage of oxygenated arterial hemoglobin present in their blood. Functional hemoglobin molecules can bind with up to four oxygen molecules to yield 'oxygenated' hemoglobin (HbO2). A hemoglobin molecule bound to less than four oxygen molecules is classified as 'reduced' hemoglobin (Hb). Conventional pulse oximeters feature algorithms that assume only HbO2 and Hb are present in the blood, and measure SpO2 from the ratio of oxygenated hemoglobin to the total amount of hemoglobin (both oxygenated and reduced) according to equation (1):

$$SpO2 = \frac{HbO2}{HbO2 + Hb} \quad (1)$$

[0005] HbO2 and Hb feature different absorption spectra in the visible and infrared regions, and can therefore be measured optically. Conventional pulse oximeters thus typically feature light sources (most typically light-emitting diodes, or LEDs) that radiate in the red (near 660nm) and infrared (typically between 900-950nm) spectral regions. A photodetector measures a portion of radiation at each wavelength that transmits through the patient's pulsating blood, but is not absorbed. At 660nm, for example, Hb absorbs about ten times as much radiation as HbO2, whereas at 905nm HbO2 absorbs about two times as much radiation as Hb. Detection of transmitted radiation at these wavelengths yields two time-dependent waveforms, each called a plethysmogram (PPG), that an oximeter analyzes to solve for SpO2 as defined in equation (1) above.

[0006] Specifically, the oximeter processes PPG waveforms measured with red (RED(PPG)) and infrared (IR(PPG)) wavelengths to determine time-dependent AC and DC signals. The term 'AC' signals, as used herein, refers to a portion of a PPG waveform that varies relatively rapidly with time, e.g. the portion of the signal modulated by pulsations in the patient's blood. 'DC' signals, in contrast, are portions of the PPG that are relatively invariant with time, e.g. the portion of the signal originating from scattering off of components such as bone, skin, and non-pulsating components of the patient's blood.

[0007] More specifically, AC signals are modulated by a heartbeat-induced pulse present in both waveforms. The pulse represents a pressure wave, launched by the heart, which propagates through the patient's vasculature and causes a time-dependent increase in volume in both arteries and capillaries. When the pressure pulse reaches vasculature irradiated by the oximeter's optical system, a temporary volumetric increase results in a relatively large optical absorption according to the Beer-Lambert Law. Typically only

about 0.5 - 1% of the total signal measured by the photodetector originates from the AC signal, with the remainder originating from the DC signal. Separation of AC and DC signals is typically done with both analog and digital filtering techniques that are well-known in the art.

[0008] During pulse oximetry a normalized 'r' value is typically calculated from AC and DC signals using equation (2), below:

$$r = \frac{660nm(AC)/660nm(DC)}{905nm(AC)/905nm(DC)} \quad (2)$$

r, which is sometimes called a 'ratio of ratios' (RoR), represents a ratio of Hb to HbO2. It equates an actual SpO2 value, which ranges from 0 – 100% O2, to an empirical relationship that resembles a non-linear equation. Above about 70% O2 this equation typically yields values that are accurate to a few percent. Measurements below this value, while not necessarily accurate, still indicate a hypoxic patient in need of medical attention.

[0009] Like SpO2, continuous noninvasive blood pressure ("cNIBP") monitoring relies on accurate measurement of PPG and ACC waveforms obtained from a pulse oximeter, together with an electrocardiogram waveform (ECG). cNIBP is typically measured with the 'Composite Technique', which is described in detail in the co-pending patent applications entitled: VITAL SIGN MONITOR FOR MEASURING BLOOD PRESSURE USING OPTICAL, ELECTRICAL, AND PRESSURE WAVEFORMS (U.S.S.N 12/138, 194; filed June 12, 2008 and published as 20090018453A1), and BODY-WORN SYSTEM FOR MEASURING CONTINUOUS NON-INVASIVE BLOOD PRESSURE (cNIBP) (U.S.S.N 12/650,354, filed November 15, 2009 and published as 20100168589A1), the contents of which are fully incorporated herein by reference.

[0010] As described therein, the Composite Technique (or, alternatively, the 'Hybrid Technique' referred to therein) typically uses a single PPG waveform from the SpO2 measurement (typically the IR(PPG) waveform, as this typically has a better signal-to-noise ratio than the RED(PPG) waveform), along with the ECG waveform, to calculate a parameter called 'pulse transit time' (PTT) which strongly correlates to blood pressure. Specifically, the ECG waveform features a sharply peaked QRS complex that indicates depolarization of the heart's left ventricle, and, informally, provides a time-dependent marker of a heart beat. PTT is the time separating the peak of the QRS complex and the onset, or 'foot', of the RED/IR(PPG) waveforms; it is typically a few hundred milliseconds. The QRS complex, along with the foot of each pulse in the RED/IR(PPG), can be used to more accurately extract AC signals using a mathematical technique described in detail below. In certain embodiments, both the RED/IR(PPG) waveforms may be collectively processed to enhance the accuracy of the cNIBP measurement.

[0011] Typical pulse oximeters feature a probe encased in a clothespin-shaped housing that includes both red and infrared LEDs, and a photodetector that detects radiation from the LEDs after it passes through a portion of the patient's body. The probe typically clips to a patient's index finger. Most probes operate in a transmission-mode optical geometry, and relay analog waveforms measured by LEDs and the photodetector to an external processing unit. Because it is based on an optical measurement, pulse oximetry can be extremely sensitive to a patient's motion. Activities such as walking, finger tapping, falling, and convulsing can result in a number of artifacts that distort both the AC and DC components of waveforms measured with the oximeter's optical system. Motion-related activities, for example, can cause the oximeter probe to move relative to the patient's finger, change the amount of ambient light that irradiates the photodetector, and disrupt both arterial and venus blood flow in vasculature measured by the optical

system. Each of these events can generate artifacts that, in some cases, are similar to the AC and DC signals within the PPG waveforms. Ultimately this can cause the pulse oximeter to generate inaccurate values and false alarms.

[0012] International Patent Application No. PCT/US2010/039000, which is hereby incorporated by reference in its entirety, describes a physiological probe that comfortably clips to the base of the patient's thumb, thereby freeing up their fingers for conventional activities in a hospital, such as reading and eating. The probe reversibly secures to the thumb with, e.g., an easy-to-use Velcro strap, disposable tape, or similar closure, or may be provided in the form of a closed ring which slips over the thumb. It measures time-dependent waveforms (RED/IR(PPG)) corresponding to LEDs typically operating near 660 nm and 905 nm. Clinically accurate pulse oximetry measurements made at the base of the patient's thumb require a set of coefficients relating r (from Eq. 2) to SpO2 that are typically determined with a set of empirical experiments (e.g. a 'breathe down' study, described below). These coefficients differ from those used in conventional oximetry measurements because of the differences between vasculature in the base of the thumb and the tip of the index finger. Typically the base of the thumb features relatively fewer capillary beds, and thus the coefficients are preferably adjusted accordingly.

[0013] It is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components set forth in the following description or illustrated in the drawings. The invention is capable of embodiments in addition to those described and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein, as well as the abstract, are for the purpose of description and should not be regarded as limiting.

[0014] As such, those skilled in the art will appreciate that the conception upon which this disclosure is based may readily be utilized as a basis for the designing of other structures, methods and systems for carrying out the several purposes of the present invention. It is important, therefore, that the claims be regarded as including such equivalent constructions insofar as they do not depart from the spirit and scope of the present invention.

SUMMARY OF THE INVENTION

[0015] It is an object of the present invention to provide a physiological probe having at least one emitter and an associated detector configured to attach to a tissue site, where the detector is configured to measure a detector signal responsive to the intensity of energy from the emitter after it has interacted with a tissue site. These physiological probes, which are well suited to function as pulse oximeter probes as described hereinafter, are configured for securing to a digit of the subject, and most preferably to a subject's thumb at the level of a proximal phalanx.

[0016] In particular, the physiological probe of the present invention comprises a sensor module and a cradle module. In various aspects, the present invention relates to the individual components of the probe, to the probe itself, and to methods of its manufacture and use.

[0017] The sensor module comprises: (a) a electronic circuitry, which in certain embodiments takes the form of a flexible circuit board, which comprises (i) one or more, and preferably at least two sources of electromagnetic radiation, and (ii) a photodetector configured to detect the radiation from the source(s) which has passed through or been reflected by the subject's tissue, thereby acquiring data relating to at least the oxygen saturation level of blood of the subject, wherein the photodetector is operably connected to a connection cable for delivery of photodetector signals to an external processing unit;

and (b) a flexible enclosure providing a cover for the circuit board, wherein the flexible enclosure comprises (i) at least one aperture through which the source(s) emit radiation for irradiating the subject's tissue, (ii) at least one aperture through which the photodetector receives radiation which has interacted with (e.g., passed through and/or been reflected by) the subject's tissue, and (iii) an aperture through which the connection cable passes.

[0018] The cradle module comprises: at least first and second rigid housing members mated to one another via a hinge region to form an approximately semicircular ring which is configured to reversibly receive the sensor module; that is, in use the sensor module is releasably attached to the cradle module.

[0019] Optionally, the physiological probe of the present invention further comprises a retainer attached to the cradle module and configured to reversibly attach the physiological probe to the digit of the subject, for example by wrapping around the entire circumference of the digit.

[0020] As used herein, the term "releasably attached" refers to two separate modules which may be engaged with and disengaged from one another in the course of normal use. In certain embodiments, the hinge region is configured to provide a range of adjustment in the diameter of the ring while physically constraining the included angle measured between the sources and the photodetector within a predetermined range. As used herein, the term "semicircular ring" is not meant to refer to the geometric shape forming an arc of constant radius extending through 180 degrees. Rather, the term refers to a shape which fits circumferentially around a portion of, but not the complete circumference of, a digit as depicted, for example, in Fig. 4.

[0021] As noted, the hinge region provides a range of adjustment in the diameter of the semicircular ring formed by the cradle, thereby allowing the physiological probe to

adjust to a range of different digit girths. In certain embodiments meant to be compatible with the human thumb, the hinge of an adult-sized cradle is preferably designed to accommodate a girth of between about 6.2 cm and about 7.4 cm, with pediatric sizes or sizes for other (smaller) digits being made appropriately smaller. At the same time, it is important for proper functioning that the geometry of the radiation sources and the photodetector be maintained within an acceptable range for proper function of the sensor.

[0022] In one example, the hinge region may be a pivoting joint in which a pin on one rigid housing member fits into a corresponding hole on the other rigid housing member. Alternatively, the hinge region may simply be a flexible region which bridges the two rigid housing members. Other types of hinge arrangements will be apparent to the skilled artisan. When desired, the angular constraint can be accomplished by providing "stops" in one or both of the first and second rigid housing members which prevent opening or closing of the hinge past the predetermined range. Preferably, the predetermined range of the included angle measured between the sources and the photodetector are less than or equal to about 60°, and more preferably between about 60° and about 30°, and most preferably between about 55° and about 35°. The term "about" in the context of this patent application refers to +/- 10% of a given measurement.

[0023] The cradle module is preferably designed as a disposable component which receives a sensor module preferably designed for multiple uses. As used herein, the term "disposable" with regard to the cradle refers to the characteristic that the cradle module may be disengaged from sensor module in the course of normal use by the user of the physiological probe such that the sensor module may be easily separated from, and need not be discarded with, the cradle. This can serve to place the device components of the physiological probe most susceptible to wear and cleanability issues on a disposable unit, while retaining the more expensive electronic components on an easily cleanable and

reusable unit. In certain embodiments, the hinge is configured such that a force may be applied to move the hinge past one or more of its "stops," thereby separating the first and second rigid housing members and preventing improper reuse. This can also facilitate removal of the sensor module for its reuse. In certain embodiments, the sensor module can be rendered cleanable for reuse by sealing of the apertures positioned proximal to the radiation source(s) and the detector with a material providing sufficient transparency to the appropriate wavelengths being employed in the device.

[0024] When the sensor module is mated to the cradle, the sensor module substantially conforms to the semicircular ring shape created by the cradle. As used herein, the term "substantially conforms" refers to a module which fits into the designed shape of another module in a manner which permits the two modules to function as a unit in the intended fashion. To facilitate this conformal fit, the sensor module may comprise one or more flexible hinge regions, (e.g., one or more living hinges molded into the flexible enclosure).

[0025] In certain embodiments, the surface of the sensor module and the surface of the cradle module which come into contact when the two modules are mated comprise corresponding registration structures, e.g., a ridge structure on one module which inserts into a corresponding dimple structure on the other module; a tab on one module which fits into a corresponding slot on the other module. The term "registration" as used herein refers to the act of adjusting or aligning the parts of a device in relation to each other. These corresponding registration structures can help to ensure proper placement of the sensor module into the cradle module. The combination of a rigid cradle housing and careful registration of components helps to maintain a consistent orientation of the optical components in the probe and improves the consistency of the optical path through the

artery and capillary tissue, while maintaining comfort through the use of relatively soft and flexible materials on the sensor module.

[0026] In preferred embodiments, the sensor module comprises at least two flexible hinge points, such that mating of the sensor module to the cradle creates three substantially planar sensor module surfaces. A first planar surface comprises the radiation sources; a middle planar surface provides a flat base surface to engage the thumb tissue of the subject; and a third planar surface comprises the photodetector. These substantially planar surfaces can serve to improve pressure application to the underlying arteries, thereby helping to increase signal amplitudes and maintain a consistent light path.

[0027] In certain embodiments, the length of the cradle module is less than the average length of the desired proximal phalanx. In the case of an adult-sized thumb, the cradle may be about 1 cm to 1.5 cm in length, with pediatric sizes being made appropriately smaller. The term "about" in this context refers to +/- 10% of a given measurement.

[0028] The radiation sources preferably emit radiation at about 660 nm and about 905 nm wavelengths. Preferably, the radiation sources are proximal to one another, and most preferably contained within the same electronic package. In proper use, the physiological probe is placed on the palmar aspect of the digit, preferably the thumb. The present invention can provide a consistent optical path from the radiation sources, through the princeps pollicis artery and soft tissue below the proximal phalanx, and subsequently to the photodetector.

[0029] Still other embodiments are found in the following detailed description of the invention, and in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] Fig. 1 shows a three-dimensional mechanical drawing of an exemplary cradle module for use as a component of a physiological probe, designed to function as a pulse oximeter probe, of the present invention.

[0031] Fig. 2 shows a three-dimensional mechanical drawing of an exemplary sensor module for use as a component of a physiological probe, designed to function as a pulse oximeter probe, of the present invention.

[0032] Fig. 3 shows a photograph of a distal end of the sensor module of Fig. 2 which includes a pair of light sources and a photodetector.

[0033] Figs. 4A-B show three-dimensional mechanical drawings of the cradle module of Fig. 1 attached to a flexible material configured to wrap around a patient's thumb and housing the sensor module of Fig. 2.

[0034] Fig. 4C shows a two-dimensional mechanical drawing of the cradle module of Fig. 1 housing the sensor module of Fig. 2.

[0035] Fig. 5 is a series of mechanical drawings depicting how the sensor module of Fig. 2 inserts into the cradle module of Fig. 1 to form an exemplary physiological probe.

[0036] Fig. 6 shows a graph depicting a relationship between SpO2 and a 'ratio of ratios' (RoR) for measurements from theoretical model in a medical textbook, made from the tip of a patient's index finger, and made from the base of a patient's thumb.

DETAILED DESCRIPTION OF THE INVENTION

[0037] Figs. 1-4 depict components of a semicircular physiologic probe 100 comprising a separate sensor module 101 and cradle module 102 which mate to one another. The probe is designed to be comfortably worn for extended periods (e.g. several days) while freeing up the patient's fingers for activities such as reading and eating that are commonplace in, e.g., a hospital. While described in detail as a pulse oximeter probe,

the physiological probes of the present invention are applicable to any similar device having at least one emitter and an associated detector configured to attach to a tissue site.

[0038] The cradle module 102 is shaped as a semicircular ring that wraps around a base of patient's digit to measure time-dependent waveforms (PPG) that can be used, e.g., in the determination of SpO2 and cNIBP. The cradle module 102 is comprised of two substantially rigid members 103, 104 connected by a hinge 105. The rigid members 103, 104 may be made out of a number of materials known in the art such as plastics, metals, and the like; for example, polypropylene, acrylates (PMMA, SMMA, etc.), styrenes (SAN, PS, ASA, ABS, etc.), polycarbonate, copolymers, ionomer resins (Surlyn), polyamides, polyesters, thermoplastic elastomers, aluminum, brass, nickel, etc. A preferred example is Eastman Tritan™ copolyester. The length of the cradle module is less than the average length of the proximal phalanx so as not to interfere with bending of the digit at the joint. An optimal length for an adult-sized cradle configured for attachment to a thumb is in the range of 1 cm to 1.5 cm.

[0039] A portion of each rigid member lying below the hinge location by providing points of interfering physical contact between the two rigid members which act as stops to constrain the opening and closing of the hinge within a predetermined range. This serves two purposes. First, the hinge 105 provides a range of adjustment in the diameter of the opening in the semicircular ring which fits over the digit, thereby allowing the physiological probe to adjust to a range of different finger sizes. In certain embodiments, the hinge of an adult-sized cradle is preferably designed to accommodate a thumb diameter of about 1.8-2.3 cm, or a girth of between about 6.2 cm and about 7.4 cm. Second, to increase the amount of radiation that passes through the artery and capillaries in the tissue, and thereby optimize signal quality, the cradle acts to maintain the LEDs 106, 107 and photodiode 108 at an included angle (θ) of approximately 35 - 55 degrees.

As shown in Fig. 4C, the 'included angle θ' refers to the angle formed between a first line drawn parallel to the planar surface comprising the radiation source and a second line drawn parallel to the planar surface comprising the photodetector. Optical components separated at this angle tend to increase the relative contribution of signal coming from the artery; ultimately this improves the accuracy of the cNIBP measurement, as PTT values measured from arterial components correlate better to blood pressure than those measured from capillary components.

[0040] The probe makes a transmission-mode optical measurement along an inner portion of the digit with the pair of embedded LEDs 106, 107 operating at, respectively, 660 and 905 nm, and a single photodetector 108 that detects these wavelengths after they pass through vasculature and other tissue lying beneath the LEDs. Preferably, both LEDs and the photodetector are positioned to measure blood pulsing in portions of the princeps pollicis artery, which is the principal artery of the thumb and stems from the radial artery. Measuring blood flowing in this artery enhances the accuracy of a PTT-based measurements of blood pressure, as is described in more detail in VITAL SIGN MONITOR FOR MEASURING BLOOD PRESSURE USING OPTICAL, ELECTRICAL, AND PRESSURE WAVEFORMS (U.S.S.N 12/138, 194; filed June 12, 2008 and published as 20090018453A1), and BODY-WORN SYSTEM FOR MEASURING CONTINUOUS NON-INVASIVE BLOOD PRESSURE (cNIBP) (U.S.S.N 12/650,354, filed November 15, 2009 and published as 20100168589A1), the contents of which have been previously incorporated by reference.

[0041] Electronic circuitry providing the LEDs and photodetector may be provided in the form of a small flexible circuit board 109 in the sensor module, which may additionally include, for example, a trans-impedance amplifier for amplifying photocurrent from the photodetector and converting it into a corresponding voltage. The

electronic circuitry can also include a resistor that identifies specific wavelengths emitted by the LEDs; these wavelengths, in turn, influence values of correlation coefficients that relate RoR to SpO2, as described below. In other embodiments, the flexible circuit board 109 can be replaced with a series of insulated wires that connect the LEDs, photodetector, trans-impedance amplifier, and other components to form a circuit.

[0042] A flexible housing 110 covers and protects the flexible circuit board 109. The flexible housing 110 may preferably be formed from any water and alcohol-resistant material, with materials having a durometer (A) in the range of 25 to 60 (e.g., HTV, RTV, or LSR elastomers, etc.) providing an optimum combination of comfort and sufficient resistance to compression to allow the probe to apply pressure to the underlying arteries. A particularly preferred material has a durometer (A) of about 40, such as Nusil MED-4044 silicone elastomer. For purposes of manufacturing, the circuit board may be inserted into the housing through a slit-like opening 115 at the top, which may then be sealed, for example with a liquid silicone elastomeric material. A connection cable 116 extends through an opening 117 at the bottom of the housing.

[0043] The housing features rectangular openings 111 and 112 through which the LEDs emit, and the photodetector receives, radiation. In certain embodiments a filter may be provided over the photodetector in order to both seal the aperture and filter undesired ambient light frequencies. On the emission side, the opening 11 may be sealed using a silicone material which is sufficiently transparent at the emission wavelengths. Forming the housing in a white color allows the housing material to reflect more of the scattered radiation from the sources to the detector, thereby improving sensor efficiency. The size of openings 111 and 112 also affect the efficiency of the sensor, with the optimal size being windows that are somewhat larger than the active component areas. Preferred

window sizes are from about 3 to 5 mm, and may be of any shape including square, rectangular, or circular.

[0044] The housing also features two cut-out portions 113, 114, or 'living hinges', that make it easily bendable and able to accommodate to the shape of the cradle module. These living hinges serve to subdivide the cradle into three substantially planar sensor module surfaces. A first planar surface comprises the radiation sources; a middle planar surface provides a flat base surface to engage the thumb tissue of the subject; and a third planar surface comprises the photodetector. As shown in Fig. 4, when mated to the cradle, the housing substantially conforms to the shape of the cradle, while providing three relatively planar surfaces which contact the tissue. These surfaces provide for a more uniform pressure application to the underlying arteries, thereby helping to increase signal amplitudes and maintain a consistent light path. This also serves to improve sensor efficiency.

[0045] To ensure proper registration of the sensor module within the cradle module, the surfaces of each which come into contact when mated comprise corresponding registration structures, e.g., a ridge structure on the sensor module which inserts into a corresponding dimple or opening 118, 119 on the cradle module. The registration structures may take the form of a protruding ridge disposed on a surface of the sensor module housing which opposes the openings 111, 112. When the sensor module is properly positioned, the ridges insert into the openings 118, 119 in the cradle module to provide positive registration of the two modules. The skilled artisan will understand that other arrangements of registration structures may be probided. For example, the protruding ridge may be disposed on a surface of the cradle module, and a corresponding dimple may be disposed on the sensor module. The distal portions of the sensor module

may also insert into registration slots 121, 122 in the cradle module, thereby further ensuring proper positioning of the sensor module within this component..

[0046] The probe is held in place around the base of the digit with a reclosable retainer, such as a flexible nylon strap 120. The strap can be attached to the cradle in a number of methods known in the art, such as threading through two openings located the cradle's distal ends; or by bonding of the cradle to the strap via an adhesive, heat-staking or ultra-sonic welding as depicted in figure 4. A portion of the strap features a patch of Velcro (containing, e.g., 'hooks') that adheres to a mated patch (containing, e.g., 'loops') on the strap's main portion; the patches reversibly adhere to each other when the probe is placed on the patient's digit, and easily detach so that it can be removed. The strap allows the probe to be securely fastened, which in turn minimizes motion relative to the measurement site.

[0047] The flexible cable 116 serves to connect the electronics of the oximeter probe to an external processor for processing signals necessary to determine SpO2 and/or blood pressure measurements. The cable can carry I/O signals to the probe electronics that drive the LEDs according to a timing diagram, and analog signals measured by the photodetector to an amplifying/filtering circuit. The cable preferably comprises a distal connector 123 that plugs into an external processing module to operably connect the probe to an external processor. There, the analog signals are amplified, filtered, digitized, and processed to measure SpO2 and/or blood pressure (e.g. cNIBP) values, as described in detail below.

[0048] A detailed description of a preferred embodiment for the circuitry to be incorporated into the oximeter probe, and interconnection of the oximeter probe to a wrist-worn external processing module may be found in International Patent Application

No. PCT/US2010/039000 entitled BODY-WORN PULSE OXIMETER, which is hereby incorporated by reference in its entirety.

[0049] Fig. 5 depicts in schematic form one example of the sensor module being inserted into the cradle module prior to use. For insertion, the sensor module is flexed at living hinges so that it may approximate the semicircular shape of the cradle module. As noted above with regard to Fig. 2, the sensor module contains the electronic components of the physiological probe, and is configured for multiple uses. In contrast, as depicted in Fig. 1, the cradle lacks electronic components and is intended for disposable use as it contains parts which may be more difficult to properly clean. Because of the rigid structure and constrained hinge of the cradle module, insertion of the sensor module into the cradle module serves to properly position the LEDs relative to the photodetector for an accurate pulse oximetry measurement.

[0050] During a pulse oximetry measurement the LEDs intermittently emit beams of radiation at 660 nm and 905nm at roughly 500 Hz according. Once emitted, the beams pass into the underlying tissue and rapidly diverge to scatter off tissue such as skin, bone, and capillaries near the tissue's outer surface. In the case of the thumb, a portion of the princeps pollicis artery is also sampled by the radiation before it illuminates the photodetector. Both the capillaries and the arteries carry blood that pulsates with each heartbeat and absorbs radiation emitted by the LEDs. This results in separate time-dependent optical waveforms (i.e. RED/IR(PPG), generated by the 660 and 905nm radiation. Both waveforms feature AC signals corresponding to the time-dependent pulsating blood, and DC signals corresponding to time-independent scattering off the skin, bone, and non-pulsating components of the capillaries and artery. Prior to any filtering the AC component typically represents about 0.5 - 1% of the total signal.

[0051] Collectively processing both the AC and DC signals of the RED/IR(PPG) waveforms yields a SpO2 value. The external processor can calculate these components using a number of signal-processing methodologies that are additionally important for determining PTT-based cNIBP. Ultimately the AC and DC components yield a RoR which then relates to a SpO2 using a series of empirically determined coefficients. In one embodiment, for example, the RoR is determined by first measuring RED/IR(PPG) waveforms, and then passing them through a low-pass filter characterized by a 20 Hz cutoff. The averaged baseline components of each waveform are sampled and stored in memory, and represent RED/IR(DC). Both waveforms are then additionally filtered with high-pass filter having a 0.1 Hz cutoff frequency, which is typically implemented with a finite impulse response function, and finally amplified with a variable gain amplifier. These steps can be done with either analog electronic or digital software filters. Once determined, the AC and DC signals are processed to yield a RoR value, described in equation (3), which relates to SpO2:

$$RoR = \frac{RED(AC)/RED(DC)}{IR(AC)/IR(DC)} \tag{3}$$

[0052] Fig. 6 shows an empirical relationship between RoR and SpO2 for measurements made at the base of the thumb with the oximeter probe, along with similar relationships for measurements made at the tip of the index finger with an off-the-shelf oximeter probe (small dashes), and the theoretical curve for measurements made from the tip of the index finger (large dashes). Curves corresponding to measurements made from the index finger and thumb are determined empirically from a group of patients measured under similar conditions. As is clear from the figure, the relationships between RoR and SpO2 are similar, but slightly offset due to differences in the measurement site. Without being bound to any theory, these differences may be due to the relatively low density of capillary beds near the base of the thumb as compared to those in the tip of the index

finger. The relationship for all curves in Fig. 6 is non-linear, particularly for SpO2 values ranging from about 70 – 100%. Values below 70% can be accounted for with a different non-linear model, such as one based on a second-order polynomial. Coefficients a, b, and c for this model are determined by fitting the empirical data to a corresponding mathematical function like the second-order polynomial shown in equation (4) below:

$$SpO2 = (a + b * RoR + c * RoR^2)\ x\ 100 \quad (4)$$

[0053] Optimized values for a, b, and c coefficients corresponding to measurements made at the base of the thumb are shown in Table 1, below:

Parameter	Value
A	107.3
B	-3.0
C	-20.0

Table 1 – coefficients for equation 4 relating RoR to SpO2 for measurements made at the base of the thumb

[0054] The exact values of parameters shown in Table 1 will depend of the specific wavelengths of the LEDs used in the pulse oximeter probe. This is because the SpO2 measurement is fundamentally determined by the relative optical absorption of Hb and HbO2 in the red and infrared spectral regions, and absorption, in turn, will depend on the wavelength emitted by the LEDs. The absorption spectra of Hb and HbO2 are relatively flat in the infrared spectral region, but strongly diverge in the red spectral region. The coefficients shown in Table 1 are thus relatively sensitive to the exact wavelength of the red LED. For this reason, a series of empirical studies need to be performed using pulse oximeter probes featuring LEDs of varying wavelengths surrounding the red emission wavelength (e.g. 600 - 610nm) prior to manufacturing. Such a study is typically classified as a 'breathe down' study because it involves lowering the SpO2 values of a series of patients (typically about 10-15) under medical supervision.

SpO2 is typically lowered by decreasing the amount of oxygen each patient inhales through a specialized ventilator mask; this is often done in a room with a reduced temperature. Blood from the patients is extracted from an arterial line and analyzed with a blood gas analyzer to determine its oxygen content. Simultaneously, a pulse oximeter probe with known LED wavelengths is attached to each patient (in this case at the base of the thumb) and used to measure the RoR described in equation (3). SpO2 values for this experiment, as measured with the blood gas analyzer, typically range from 70 – 100%. Simultaneous studies are typically done using pulse oximeter probes having LEDs with different red emission spectra. Upon completion of the studies, the wavelength-dependent values of RoR are related to SpO2, as determined by the blood gas analyzer, to calculate coefficients a, b, c as described in Table 1. In general, a different set of coefficients will result for the different LED wavelengths. These coefficients and the optical wavelengths they correspond to, along with a resistor value described below, are stored in a database in memory on the wrist-worn transceiver.

[0055] Measurements made at the base of the thumb provide improvements to the measurement of SpO2 values because the circulatory anatomy at this location yields a more predictable arterial signal; this location also increases patient comfort by freeing up the tips of the fingers for use. The IR(PPG) measured from this site, when processed in combination to the ECG waveform, yields a PTT value that can be processed with the Composite Technique to yield an accurate cNIBP measurement. As described above, an IR(PPG) waveform measured from primarily from the princeps pollicis artery increases the accuracy of the cNIBP measurement. With an initial pressure-based calibration systolic (SYS) and diastolic (DIA) blood pressure can be explicitly determined for each heartbeat using an algorithm described in the above-mentioned patent applications, the contents of which have been previously incorporated herein by reference. Typically, PTT

values are processed over a 20-40 second time period (often implemented as a 'rolling average') using statistical filtering to improve accuracy. To better define the onset of the PPG waveform, and thus improve the accuracy to which SYS and DIA are determined, times corresponding to RED(foot) and IR(foot) are typically averaged together. When compared to SYS and DIA values measured under clinical conditions with a femoral arterial line, cNIBP measurements made from this particular location were well within the FDA's standards for accuracy (+/- 5mmHg) and standard deviation (8 mmHg). For this and other reasons the base of the thumb appears to be a uniquely good location for measuring both SpO2 and cNIBP.

[0056] One skilled in the art readily appreciates that the present invention is well adapted to carry out the objects and obtain the ends and advantages mentioned, as well as those inherent therein. The examples provided herein are representative of preferred embodiments, are exemplary, and are not intended as limitations on the scope of the invention.

[0057] It will be readily apparent to a person skilled in the art that varying substitutions and modifications may be made to the invention disclosed herein without departing from the scope and spirit of the invention.

[0058] All patents and publications mentioned in the specification are indicative of the levels of those of ordinary skill in the art to which the invention pertains. All patents and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

[0059] The invention illustratively described herein suitably may be practiced in the absence of any element or elements, limitation or limitations which is not specifically disclosed herein. Thus, for example, in each instance herein any of the terms

"comprising", "consisting essentially of" and "consisting of" may be replaced with either of the other two terms. The terms and expressions which have been employed are used as terms of description and not of limitation, and there is no intention that in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof, but it is recognized that various modifications are possible within the scope of the invention claimed. Thus, it should be understood that although the present invention has been specifically disclosed by preferred embodiments and optional features, modification and variation of the concepts herein disclosed may be resorted to by those skilled in the art, and that such modifications and variations are considered to be within the scope of this invention as defined by the appended claims.

[0060] Other embodiments are set forth within the following claims.

What is claimed is:

1. A physiological probe configured for securing to a subject's digit, comprising:

a sensor module comprising

(a) electronic circuitry which comprises (i) at least one source of electromagnetic radiation, and (ii) a photodetector configured to detect radiation from the at least one source of electromagnetic radiation after it has interacted with the subject's tissue, thereby acquiring data relating to at least one physiologic property of the subject, wherein the photodetector is operably connected to a connection cable for delivery of photodetector signals to an external processing unit, and

(b) a flexible enclosure providing a cover for the electronic circuitry, wherein the flexible enclosure comprises (i) at least one aperture through which the at least one source of electromagnetic radiation emits radiation for irradiating the subject's tissue, (ii) at least one aperture through which the photodetector receives radiation after it has interacted with the subject's tissue, and (iii) an aperture through which the connection cable passes; and

a cradle module comprising

(a) at least first and second rigid housing members mated to one another via a hinge region to form an approximately semicircular ring which is configured to releasably receive the sensor module, wherein the hinge region is configured to provide a range of adjustment in a diameter of the ring while physically constraining an included angle measured between the at least one source of electromagnetic radiation and the photodetector within a predetermined range.

2. A physiological probe according to claim 1, wherein the hinge is configured to accommodate a subject's thumb at the level of the proximal phalanx for purposes of acquiring the data relating to at least one physiologic property of the subject.

3. A physiological probe according to claim 1, wherein the hinge is configured to accommodate a girth of between about 6.2 cm and about 7.4 cm.

4. A physiological probe according to claim 1, wherein the hinge region is a pivoting hinge formed by mating the first and second rigid housing members, and wherein the structure of the first and second rigid housing members constrains opening or closing of the hinge beyond the predetermined range when mated to one another via the pivoting hinge.

5. A physiological probe according to claim 1, wherein the predetermined range of the included angle measured between the source(s) of electromagnetic radiation and the photodetector is less than or equal to about 60°.

6. A physiological probe according to claim 5, wherein the predetermined range of the included angle measured between the source(s) of electromagnetic radiation and the photodetector is between about 60° and about 30°.

7. A physiological probe according to claim 6, wherein the predetermined range of the included angle measured between the source(s) of electromagnetic radiation and the photodetector is between about 55° and about 35°.

8. A physiological probe according to claim 4, wherein, the hinge is configured such that a force applied to move the hinge beyond the predetermined range separates the first and second rigid housing members.

9. A physiological probe according to claim 1, wherein the sensor module comprises one or more hinge points in the flexible enclosure.

10. A physiological probe according to claim 9, wherein the sensor module comprises at least two hinge points in the flexible enclosure configured to provide three substantially planar sensor module surfaces when the sensor module is mated to the cradle module.

11. A physiological probe according to claim 1, wherein the surface of the sensor module and the surface of the cradle module which come into contact when the two modules are mated comprise corresponding registration structures configured to register the position of the sensor module in the cradle module.

12. A physiological probe according to claim 1, wherein the length of the cradle module is between about 1 cm and about 1.5 cm.

13. A physiological prove according to claim 1, wherein the cradle module is disposable.

14. A method of obtaining pulse oximetry signals from a subject, comprising:

affixing a physiological probe according to claim 1 to the palmar aspect of a digit of the subject at the level of the proximal phalanx, wherein the probe is positioned on the subject's digit such that the source(s) of electromagnetic radiation, when energized, provide irradiation of tissues of the subject through the capillary, arterial, and soft tissue of the digit, and subsequently to the photodetector;

energizing the sources to irradiate the tissues of the subject; and

detecting photodetector signals at an external processing unit operably connected via the connection cable.

15. A method according to claim 14, further comprising calculating one or more of a blood pressure value, an SpO2 value, a pulse rate, a respiration cycle, and a photoplethysmograph waveform for the subject using the photodetector signals.

16. A method according to claim 14, comprising determining a blood pressure value for the subject using the photodetector signals.

17. A cradle module adapted for use in a physiological probe, comprising:

at least first and second rigid housing members mated to one another via a pivoting hinge to form an approximately semicircular ring which is configured to releasably attach to a sensor module, the sensor module comprising (i) one or more sources of electromagnetic radiation , and (ii) a photodetector configured to detect the radiation from the sources which has passed through or been reflected by the subject's tissue,

wherein the hinge is configured to provide a range of adjustment in the diameter of the ring while physically constraining the included angle measured between the source(s) of electromagnetic radiation and the photodetector within a predetermined range.

18. A cradle module according to claim 17, wherein the hinge is configured to accommodate a subject's thumb at the level of the proximal phalanx for purposes of acquiring the data relating to at least one physiologic property of the subject.

19. A cradle module according to claim 17, wherein the hinge is configured to accommodate a girth of between about 6.2 cm and about 7.4 cm.

20. A cradle module according to claim 17, wherein the hinge region is a pivoting hinge formed by mating the first and second rigid housing members, and wherein the structure of the first and second rigid housing members constrains opening or closing of the hinge beyond the predetermined range when mated to one another via the pivoting hinge.

21. A cradle module according to claim 17, wherein the predetermined range of the included angle measured between the sources and the photodetector is less than or equal to about 60°

22. A cradle module according to claim 21, wherein the predetermined range of the included angle measured between the sources and the photodetector is between about 60° and about 30°.

23. A cradle module according to claim 22, wherein the predetermined range of the included angle measured between the sources and the photodetector is between about 55° and about 35°.

24. A cradle module according to claim 17, wherein, the hinge is configured such that a force applied to move the hinge beyond the predetermined range separates the first and second rigid housing members.

25. A cradle module according to claim 17, wherein the surface of the cradle module which comes into contact with the sensor module when the two modules are mated comprises registration structures configured to register the position of the sensor module in the cradle module.

26. A cradle module according to claim 17, wherein the length of the cradle module is between about 1 cm and about 1.5 cm.