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MOTION COMPATIBLE SENSOR FOR (54)NON-INVASIVE OPTICAL BLOOD ANALYSIS

(75) Inventors: Rodney Chin, Oakland, CA (US); Paul Mannheimer, Danville, CA (US); Ross Flewelling, Oakland, CA (US)

Correspondence Address:

TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 (US)

(73) Assignee: Nellcor Puritan Bennett Incorporated,

4280 Hacienda Drive, Pleasanton, CA

94588 (US)

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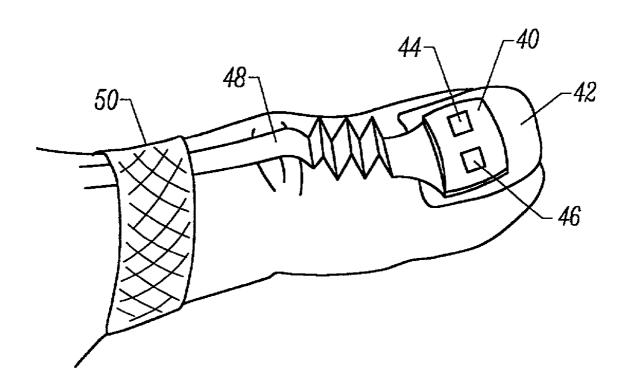
Division of application No. 09/348,437, filed on Jul. 7, 1999, now Pat. No. 6,374,129, which is a division of application No. 08/722,443, filed on Oct. 10, 1996, now Pat. No. 6,018,673.

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ABSTRACT (57)

A non-invasive optical sensor which uses the motion signal to calculate the physiological characteristic being measured. For pulse oximetry, a least squares or a ratio-of-ratios technique can be applied to the motion signal itself. This is made possible by selecting a site on the patient where variations in motion produce signals of two wavelengths which are sufficiently correlated. In particular, it has been determined that a sensor placed on a nail, in particular a thumbnail, exhibits the characteristics of having the and infrared signals correlated when used for pulse oximetry, and the resulting signals correlate to arterial oxygen satura-



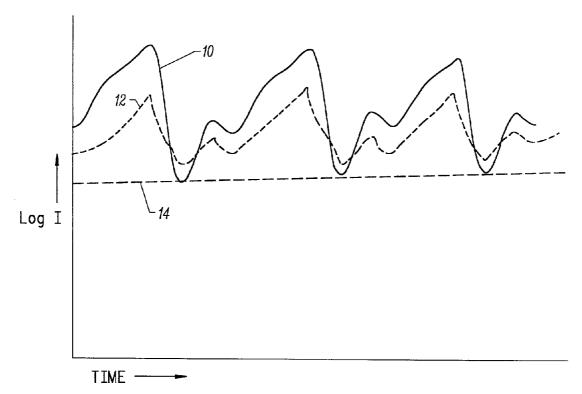


FIG. 1

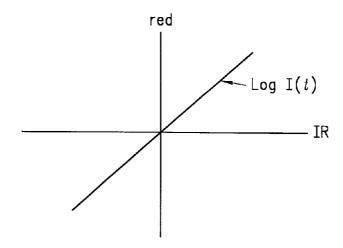
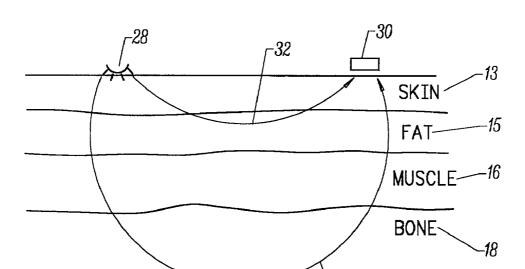


FIG. 2



- 34

FIG. 3

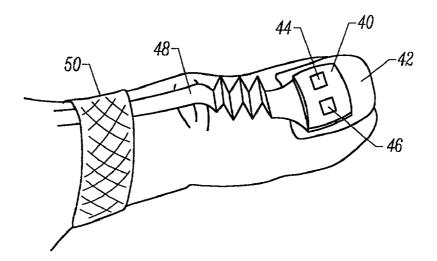


FIG. 4

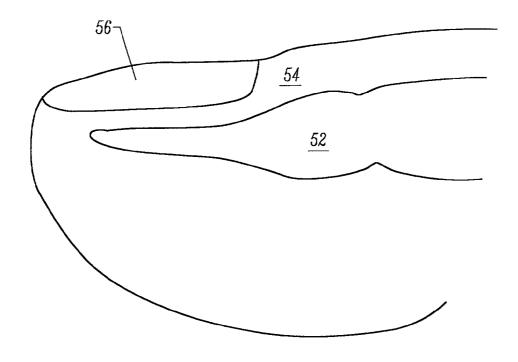


FIG. 5

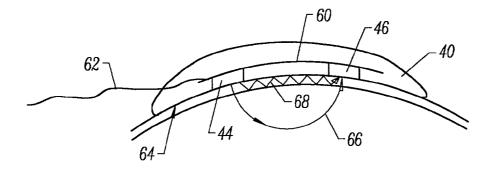


FIG. 6

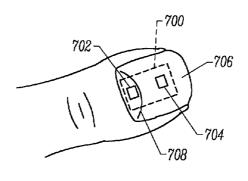
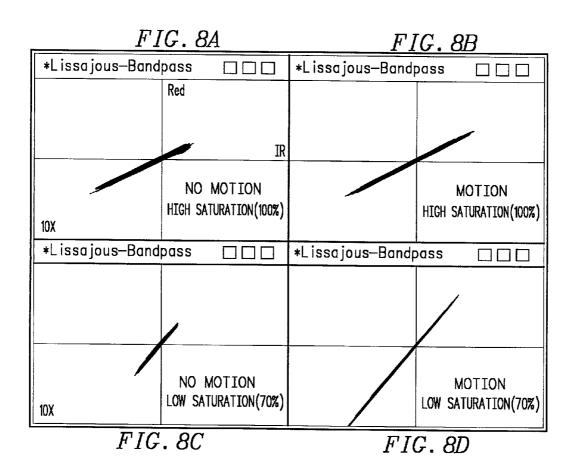
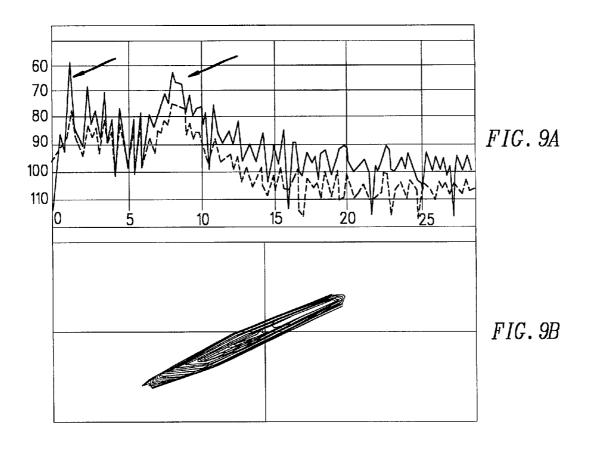
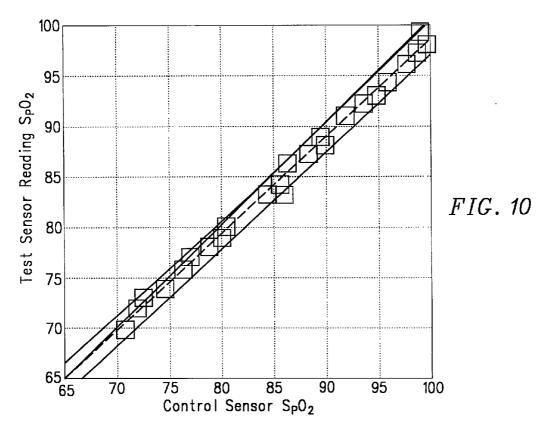


FIG. 7







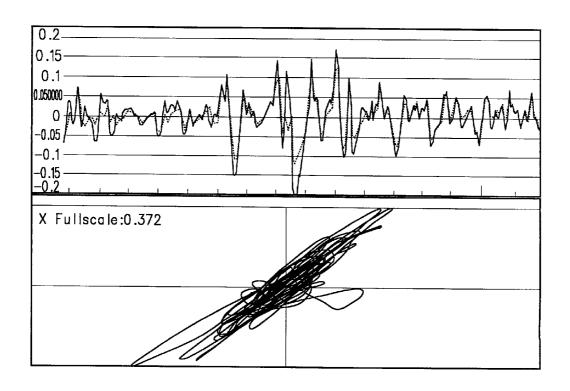


FIG. 11A (PRIOR ART)

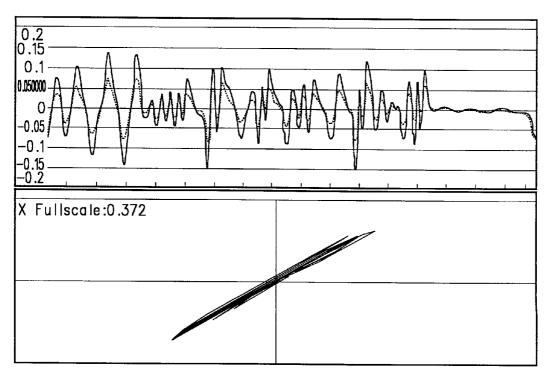
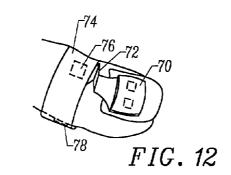
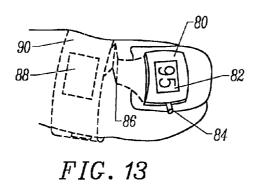
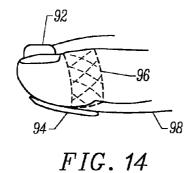
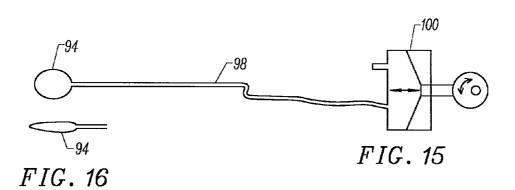


FIG. 11B









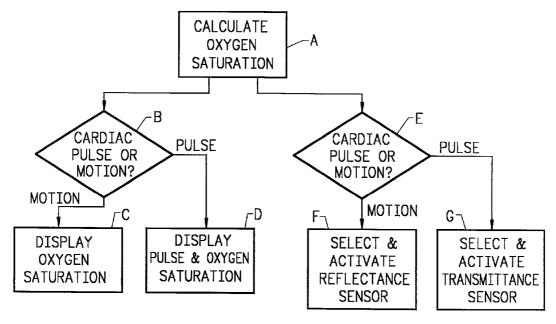
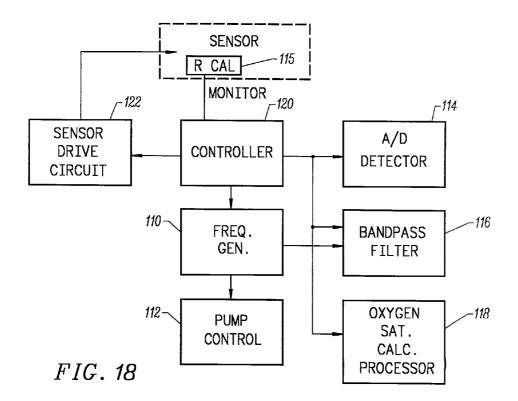


FIG. 17



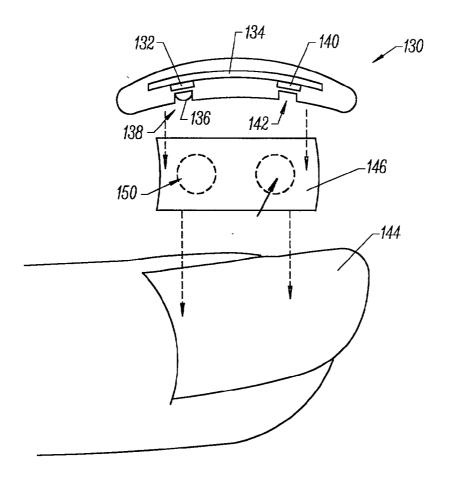


FIG. 19

MOTION COMPATIBLE SENSOR FOR NON-INVASIVE OPTICAL BLOOD ANALYSIS

BACKGROUND OF THE INVENTION

[0001] The present invention relates to optical sensors for non-invasive determination of physiological characteristics, and in particular to sensors for making such determinations in the presence of motion.

[0002] Many types of optical sensors are used to measure physiological characteristics of a patient. Typically, an optical sensor provides emitted light which is then scattered through tissue and detected. Various characteristics of a patient can be determined from analyzing such light, such as oxygen saturation, pulse rate, pH, etc.

[0003] Pulse oximetry is typically used to measure various blood characteristics including, but not limited to, the blood-oxygen saturation of hemoglobin in arterial blood, the volume of individual blood pulsations supplying the tissue, and the rate of blood pulsations corresponding to each heartbeat of a patient. Measurement of these characteristics has been accomplished by use of a non-invasive sensor which scatters light through a portion of the patient's tissue where blood perfuses the tissue, and photoelectrically senses the absorption of light in such tissue. The amount of light absorbed is then used to calculate the amount of blood constituent being measured.

[0004] The light scattered 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 transmitted light scattered through the tissue will vary in accordance with the changing amount of blood constituent in the tissue and the related light absorption. For measuring blood oxygen level, such sensors have typically been provided with a light source that is adapted to generate light of at least two different wavelengths, and with photodetectors sensitive to both of those wavelengths, in accordance with known techniques for measuring blood oxygen saturation.

[0005] Known non-invasive sensors include devices that are secured to a portion of the body, such as a finger, an ear or the scalp. In animals and humans, the tissue of these body portions is perfused with blood and the tissue surface is readily accessible to the sensor. A photoelectric pulse transducer from World Precision Instruments is described as even recording signals through the fingernail.

[0006] Optical sensors are typically either reflective or transmissive. Transmissive sensors have the emitter and detector on opposite sides of a finger, toe, nose or other tissue. They measure light transmitted through the tissue from one side to the other. Reflectance sensors, on the other hand, have the emitter and detector side-by-side, such as placement on the forehead, or on a fetus where it is difficult to position a sensor over a finger, etc. Reflectance sensors detect light which is scattered back to the same surface.

[0007] In pulse oximetry, the goal is to determine the amount of oxygen in arterial blood, as distinguished from venous blood or the tissue itself. The light emitted can be absorbed by all three, however, and they need to be distinguished among. FIG. 1 illustrates a plot of the logarithm of the detected intensity signal versus time. Solid line 10 is the detected infrared signal in a pulse oximeter, shown varying

with time. Dotted line 12 is the detected red wavelength signal. As can be seen, the value moves up and down with the heartbeat frequency, due to the pulsing of the blood through the arteries. The portion of the signal below line 14 is representative of light absorbed by the tissue, venous blood, and a baseline component of the arterial blood.

[0008] Using appropriate signal analysis, the DC portion can be eliminated, leaving an extracted AC portion which is due to absorption by arterial blood. As can be seen in FIG. 1, and more clearly in FIG. 2, the red and infrared signals, although varying by different amounts, are in phase. FIG. 2 illustrates a plot over an epoch of time of the red logarithmic signal versus the infrared logarithmic signal, and is commonly referred to as a Lissajous plot. As can be seen, a line is formed, indicating they are in phase.

[0009] This characteristic of the red and infrared signals allows the determination of oxygen saturation through two methods. In a first method, the "ratio of ratios" is calculated, which is the ratio, between red and infrared, of the logarithms of the quotients obtained by dividing the maximum signal intensity and the subsequent minimum signal intensity. This ratio-of-ratios is then used in a predetermined formula to calculate arterial oxygen saturation. This is described more fully in U.S. Pat. No. 4,653,498.

[0010] In a second method, referred to here as "least squares," a least squares regression analysis is performed on the above-mentioned Lissajous plot to determine the slope of the ensemble of data points taken during an epoch of time. This slope is then used in a predetermined formula to determine arterial oxygen saturation. Other techniques are set forth in a copending application entitled "Method and Apparatus for Estimating Physiological Parameters Using Model-Based Adaptive filtering," filed Jun. 7, 1996, serial no. 08/660,510, the disclosure of which is hereby incorporated by reference.

[0011] In some cases, it is desirable to measure the oxygen saturation of the venous blood in order to get an indication of how much oxygen is being used by the body. The arterial blood, on the other hand, gives an indication of how much oxygen is being delivered to the body. In Shiga U.S. Pat. No. 4,927,264, the oxygen saturation in venous blood is determined by inducing a venous pressure with a pressure cuff. This effectively varies line 14 of FIG. 1 at a frequency different from the heart rate, so that it can be separately filtered and isolated and compared to the arterial pulse. The nonvarying portion is then assumed to be the tissue absorption and can be distinguished from the slowly varying pressure induced venous blood absorption. An alternate approach can be used in extracorporeal monitoring where the blood is actually pumped out of the body and then back in. Such a technique is set forth in an article by Odell et al., entitled "Use of Pulse Oximetry to Monitor Venous Saturation During Extracorporeal Life Support" Critical Care Medicine, vol. 22, no. 4 (Apr. 4, 1994). In Odell, the venous blood being pumped out of the body passes the sensor, and the pumping mechanism provides an artificial pulse allowing the use of pulse oximetry techniques.

[0012] Motion artifact can degrade a pulse oximetry signal relied upon by a physician, without the physician's awareness. This is especially true if the 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. Thus, typically techniques are employed to reduce the effects of motion or compensate for motion.

[0013] In one oximeter system described in U.S. Pat. No. 5,025,791, an accelerometer is used to detect motion. When motion is detected, readings influenced by motion are either eliminated or indicated as being corrupted. In a typical oximeter, measurements taken at the peaks and valleys of the blood pulse signal are used to calculate the desired characteristic. Motion can cause a false signal peak and valley, resulting in a measurement having an inaccurate value and one which is recorded at the wrong time. In U.S. Pat. No. 4,802,486, assigned to Nellcor Puritan Bennett, the assignee of the present invention, an EKG signal is monitored and correlated to the oximeter reading to provide synchronization to limit the effect of noise and motion artifact pulses on the oximeter readings. This reduces the chances of the oximeter locking onto a periodic motion signal. Still other systems, such as the one described in U.S. Pat. No. 5,078, 136, assigned to Nellcor Puritan Bennett, use signal processing in an attempt to limit the effect of noise and motion artifact. The '136 patent, for instance, uses linear interpolation and rate of change techniques to analyze the oximeter signal. U.S. Pat. No. 5,337,744 sets forth sensor modifications used to improve the immunity of the signal from motion artifacts.

[0014] The motion signal impedes the measurement because it obscures the cardiac signal. The motion signal can have many components, such as, for example, the emitter or detector physically moving away from the body, or a volume of venous and arterial blood sloshing around in response to the motion, or the signal path being shortened or lengthened by expansion or compression of the tissue due to motion.

[0015] Contrary to conventional practice, signal analysis might be able to directly use the time-varying motion signal to calculate oxygen saturation. Under some conditions, the ratio-of-ratios (or least squares) resulting from a motioninduced signal has the same value as the ratio-of-ratios (or least squares) for the cardiac induced signal. The red and infrared intensity signals are often not in phase, and can limit the use of the motion signal for calculating oxygen saturation. One of the factors that may cause this is illustrated in FIG. 3. As FIG. 3 illustrates, light from emitter 28 can pass through skin 13, fat 15, muscle 16, and bone 18, on its way to a detector 30. Light of one wavelength may, on average, take path 32, while light of another wavelength may penetrate deeper and take path 34. Motion will cause disproportionate variances in the path lengths of the two wavelengths of light, resulting in out-of-phase signals of the detector.

SUMMARY OF THE INVENTION

[0016] The present invention provides a non-invasive optical sensor which uses the motion signal to calculate the physiological characteristic being measured. For pulse oximetry, a least squares or a ratio-of-ratios technique can be applied to the slope of the motion signal itself. This is made possible by selecting a site on the patient where motion produces signals at two wavelengths which are adequately correlated with each other. Adequately correlated signals have a "closed" or "nearly closed" Lissajous. In particular, it has been determined that a sensor placed on a nail, in

particular a thumbnail, exhibits the characteristics of having the red and infrared signals in phase when used for pulse oximetry.

[0017] The present invention also provides an optical sensor which fits entirely on a nail. No adhesive or other securing mechanism around the rest of the finger is necessary, resulting in the entire sensor moving with the nail. The use of the nail site reduces the likelihood of out-of-phase motion signals for red and infrared wavelengths, and takes advantage of the predominantly arterial blood saturation characteristic of the blood present beneath the nail. In addition, the nail is an advantageous surface for adhering the sensor to, and at this location the method of attachment allows a low profile, low mass sensor to be used which further limits differential phase errors due to motion.

[0018] Preferably, the sensor on a nail of the present invention is a reflectance-type sensor. In one embodiment, a closer spacing is used than in typical prior art sensors, preferably less than 5 mm., more preferably approximately 4 mm. It has been empirically determined that the physiological characteristics at a nail site produce an improved signal with closer spacing. In addition, the sensor preferably has a curvature which conforms to the shape of the nail, and is attached with an adhesive.

[0019] In alternate embodiments of the invention, artificial motion may be induced with an air bag or otherwise to produce a motion signal which can be used with the sensor of the invention. In particular, this could be used for patients with low perfusion, a weak heartbeat or no heartbeat such as is the case during heart bypass surgery.

[0020] For a further understanding of the nature and advantages of the invention, reference should be made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. 1 is a graph of the log of the infrared and red intensity signals for pulse oximeters.

[0022] FIG. 2 is a graph of the red and IR signals showing correlation.

[0023] FIG. 3 is a diagram of the different average paths of different wavelength light through a patient.

[0024] FIG. 4 is a perspective view of a nail sensor according to the present invention on a thumb.

[0025] FIG. 5 is a cross-sectional, cutaway view of a thumb showing its components.

[0026] FIG. 6 is a end, cutaway view of one embodiment of a conformable nail sensor according to the present invention.

[0027] FIG. 7 is a diagram of a sensor according to the present invention placed longitudinally to span the lunula of the nail.

[0028] FIGS. 8A-8D are Lissajous plots of the output of a sensor according to the invention with and without motion, and at low and high saturation.

[0029] FIG. 9A is a plot of the red and infrared frequency distribution (FFT of time signals) showing experimental results from a thumbnail sensor according to the invention.

[0030] FIG. 9B is a plot of the Lissajous for the results of FIG. 9A.

[0031] FIG. 10 is a graph showing a plot of oxygen saturation readings of a sensor according to the present invention compared to a standard prior art sensor.

[0032] FIGS. 11A and 11B compare the prior art sensor and the present invention. The output waveforms and Lissajous plot are shown for each.

[0033] FIG. 12 is a diagram of an alternate embodiment of the invention showing a combination reflective and transmissive sensor.

[0034] FIG. 13 is a diagram of an alternate embodiment of the invention showing a self-contained nail sensor with its own display.

[0035] FIG. 14 is a diagram of a nail sensor with a motion inducing mechanism according to the present invention.

[0036] FIGS. 15 and 16 are top and side views of the motion stimulating mechanism of FIG. 14.

[0037] FIG. 17 is a flowchart of one embodiment of a program for responding to whether motion or a cardiac pulse is used for calculating saturation.

[0038] FIG. 18 is a block diagram of one embodiment of portions of an oximeter using controlled generation of motion.

[0039] FIG. 19 is a diagram of an embodiment of the sensor using a cylindrical lens and a tinted adhesive.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0040] FIG. 4 illustrates a sensor 40 according to the present invention preferably mounted on a nail 42 (a thumbnail or any other digit may be used). The sensor is held on with adhesive, and has an emitter 44 and a detector 46. A flexible circuit 48 provides the electrical connections to the emitter and detector, and may be accordion-shaped between the sensor and a securing band 50 to provide additional strain relief. This isolates the sensor from tugging or pulling on the electrical connection cord from either the sensor side or the other direction. Band 50 may be, for instance, an elastic band, cloth wrap secured with VelcroTM, or another device. Flexible circuit 48 could be electrical wires or fiber optic cables. The different wavelength light could be premixed using the fiber optic cable.

[0041] The placement on the top of the nail allows the cable to extend along the top of the finger or other digit, without the sensor or the cable being on the palmar side of the digit where it would interfere with grasping or other functionality of the hand.

[0042] As can be seen, the emitter 44 and detector 46 are arranged laterally across the width of the nail. However, a longitudinal arrangement (discussed more fully below) or any other arrangement on a nail is possible. The spacing of the emitter and detector may be varied, but an optimum spacing was experimentally found to be less than 10 mm., preferably less than 5 mm., more preferably approximately 4 mm.

[0043] The nailbed makes a good site for the sensor because it has been observed that motion generates artifact

signals for the red and infrared wavelengths that are largely correlated to one another. The inventors have observed that this results in a ratio-of-ratios (or least squares) which correlates well with the arterial oxygen saturation.

[0044] Referring to FIG. 5, a cross-sectional view of the thumb is shown. As can be seen, the thumb includes a bone 52 with a thin layer of connective tissue 54 between the bone and thumbnail 56. A number of characteristics may contribute to the improved signal and the motion induced artifact being in phase. The different wavelength paths illustrated in FIG. 3 may be limited by the presence of bone 52, preventing one of the wavelengths from going deeper into tissue and having a different distance to travel. This effect is provided by the selection of the thumbnail as a site, and the use of reflectance oximeter sensor as opposed to a transmissive sensor. In a transmissive sensor, light would have to travel around the bone deep through the tissue, and the red and infrared may travel different lengths and be affected differently by motion.

[0045] Connective tissue layer 54 is thin and apparently strongly connective. Thus, the expansion and compression of tissues, particularly fatty tissues, which may cause out of phase motion artifacts for other sites and types of sensors, is apparently greatly reduced here. Because the thumbnail 56 itself provides a strong mounting platform, the sensor can be securely attached to it with adhesive, avoiding the emitter and detector from separating from the patient and causing gaps that may cause corrupt ratio-of-ratio values.

[0046] The region beneath nail 56 also provides a region which appears to be concentrated with oxygen saturated blood similar to the saturation of arterial blood. Oxygen consumption beneath the nail appears to be small relative to the circulation there, or the relative volume of venous blood may be negligibly small.

[0047] The presence of many small capillaries, rather than large vessels, makes the region more homogeneous, and thus lessens the likelihood that two different light wavelengths would be affected differently by passing through differing regions. In the absence of motion, the high perfusion allows a normal pulse oximetry reading to be made. During the occurrence of motion, the large amount of blood present allows a strong motion signal to be obtained, since a lot of blood is moved around by the motion. In experiments conducted by the inventors, motion artifact signals greater than 50 times that of a normal pulsatile plethysmogram signal have been observed. The nail site also appears to have a nailbed-tissue boundary that is optically phase-matched for the wavelengths of the sensor.

[0048] In addition to measuring oxygen saturation, the nailbed is a good site for other optical sensors. For example, glucose detection which requires the use of a near infrared wavelength could be used. Among the blood properties or constituents that can be measured are blood gases (CO₂, O₂) pH, glucose, drug concentrations, or other analytes (THb, Hct, lactate, K⁺, Na⁺, Ca²⁺, etc.).

[0049] FIG. 6 is an end, cutaway view of one embodiment of a sensor 40 according to the present invention. Emitter 44 and detector 46 are shown mounted on a flexible circuit board 60. An electrical cord 62 provides the connection to the electrical components of circuit board 60. The body of the sensor is preferably a semi-rigid piece of black poron

foam. A metal strip could be imbedded to give extra rigidity. An adhesive is attached to underside **64** of the sensor to attach it securely to the nail. The underside is also curved to conform to the shape of the nail, but is slightly flexible to allow adaptation to differing nail shapes. Different curvature sensors could be provided for different sizes and shapes of nails to provide optimum fit, or the bottom surface could be fabricated from a softer, more conforming material.

[0050] One characteristic of the nail as a site is that the nail itself could act as a light pipe, shunting light between the emitter and the detector. Preferably, the light travels through the tissue beneath the nail along a path 66. However, some light could bounce back and forth through the nail itself on a path 68 between the emitter and detector in a manner not unlike a waveguide. To limit this shunting, the sensor body is made to absorb light, or at least the region between the emitter and detector is made at least partially absorbing to the wavelengths of interest. In this way, each time light strikes the side of the nail adjacent the absorbing layer, it will be absorbed, rather than propagating along the nail.

[0051] Shunting can also be limited by recessing the emitter and detector and providing a narrow numerical aperture. Because of the rigidity of the sensor body, recessing will not produce variations in distance during motion. By limiting the numerical aperture of the emitter and detector to values less than 0.9., preferably to values less than 0.5, the emitter will not directly launch light into the nail "waveguide," and light which does potentially travel path 68 will be outside the acceptance angle of the detector.

[0052] The nail also provides advantages for adhering the sensor to the patient since the nail does not have the quantity of oils or sweat as present on the skin.

[0053] FIG. 7 is a diagram of a sensor 700 arranged longitudinally along a nail 706. The sensor has an emitter 702 and a detector 704 which are not both on the lunula of the nail. The lunula is the light colored area of the nail below line 708 in FIG. 7. It is believed that if both the emitter and detector are located on the lunula, more undesirable shunting of light will occur.

[0054] FIG. 8 has FIGS. 8A-8D which show the Lissajous plots and calculated saturations for a sensor according to the present invention during four conditions: motion and no motion at high and low saturation. As can be seen in FIGS. 8A and 8B at high saturation, the calculated saturation 100% is equivalent with or without motion. In FIG. 8B, the motion signal is seen to be more than 10 times larger than the cardiac signal of FIG. 8A (FIGS. 8A and 8C are magnified by 10). Similar results occur at low saturation as seen in FIGS. 8C and 8D where the saturation values are calculated to be 70% under both conditions.

[0055] FIG. 9A is a graph of the frequency distribution of the detected red and infrared signals for a sensor of the present invention in an experiment with an 8 Hz artificial motion pulse applied. The cardiac signature can be seen at the lower frequencies below 5 Hz, while the 8 Hz driven motion signal is also visible. FIG. 9B is a graph of the red versus infrared intensity signals for the experiment illustrating that both signals are correlated and representative of the same saturation.

[0056] FIG. 10 illustrates the oxygen saturation readings of a sensor according to the present invention in experimen-

tal tests without motion comparing it with a standard prior art transmissive sensor at another site. A close agreement was noted, indicating the calibration of this sensor on the nailbed site is similar to a conventional transmission sensor.

[0057] FIGS. 11A and 11B show a comparison of the output waveform and Lissajous, in the presence of motion, of a sensor according to the present invention (FIG. 11B) with a standard prior art transmissive sensor at another site (Fig. 11A).

[0058] FIG. 12 illustrates an alternate embodiment of the present invention in which a nail sensor 70 according to the present invention is attached via a flexible circuit 72 to a transmissive sensor 74 which wraps around the finger and has an emitter 76 and detector 78 positioned on top and on the bottom of the finger. Such a combination sensor could allow the oximeter monitor with its program to choose between the sensors depending upon motion conditions. When motion is present, nail sensor 70 could be used, and when motion is not present, sensor 74, which may be more sensitive to the cardiac pulse signal, could be used. Alternately, a single pair of red and infrared emitters could be used, with a reflectance detector on the nail, and a transmissive detector off the nail. Depending on the mode, a switch in the sensor, or in an intermediate amplifier module, or in the oximeter monitor could select between the detectors. In another embodiment, a single detector is used, with one pair of emitters on the nail, and another pair of emitters off the nail. Alternately, a completely separate transmissive sensor could be used.

[0059] In some patients, in particular those with low blood perfusion, it may be difficult to lock onto a pulse waveform. The additional transmissive sensor could be used to enable locking on for such patients. In addition, a transmissive sensor could be used to calibrate the nail sensor "on-the-fly." Because of shunting and other unique aspects of the nail site, a predetermined calibration may be off. A measurement of saturation using the transmissive and the nail reflectance sensors could be done in the absence of motion, with a correction factor applied to the reflectance sensor. The correction could be a constant which is added or a multiplicative factor, or both. If measurements are done at different saturations, a calibration line or curve could be determined by the oximeter to allow adjustments anywhere along the calculated curve. Subsequently, in the presence of motion, the nail sensor will be more accurately calibrated.

[0060] FIG. 13 illustrates an alternate embodiment of the invention in which a self-contained sensor 80 according to the present invention includes the processing circuitry on one or more semiconductor chips inside, and has its own display 82, which may be a liquid crystal display, for instance. In one embodiment, a button 84 allows switching between modes, such as between displaying a pulse and oxygen saturation. In an alternate embodiment, a flex connection 86 to a module 88 attached on a band 90 may be used. Module 88 might contain the battery, or alternately the processing circuitry, or the display. Additionally, either embodiment could be used for a wireless transmission to an oximeter, with the transmitting circuit either being in module 88 or sensor body 80.

[0061] FIG. 14 illustrates another embodiment of the present invention in which a stimulator is used to generate an artificial pulse. A stimulator could electrically stimulate

the nerves to cause motion of an appendage, or could use a pneumatic pressure cuff to stimulate an artificial pulse, or use electromechanical stimulation or any other mechanism which generates a pulse characteristically different (e.g., amplitude, frequency, shape, etc.) than the cardiac pulse so that the cardiac pulse need not be used. Such an apparatus would be particularly advantageous for patients with low blood perfusion or a weak heartbeat. FIG. 14 is one embodiment showing a sensor 92 mounted on a thumbnail, with an airbag 94 mounted to the bottom of the thumb and held in place with a band 96. A hose 98 to the airbag periodically inflates and deflates it, causing a pressure wave through the thumb, giving artificially induced motion. This pressure induced motion provides the variation needed for sensor 92 to measure the oxygen saturation using either the ratio-ofratios or a least squares technique. If the motion is in the frequency range of a heartbeat, the sensor can be backward compatible with existing oximeter monitors, even those that look for a cardiac signal.

[0062] FIG. 15 illustrates airbag 94 in a top view, showing hose 98 connected to a diaphragm pump 100. FIG. 16 shows a side view of the airbag 94 of FIG. 15, showing that it is wide but flat.

[0063] FIG. 17 is a flowchart of one embodiment of a portion of a program for operating an oximeter so that either cardiac pulses or motion pulses can be used to calculate oxygen saturation. The oxygen saturation is calculated in a known manner (step A). In a first alternative, the signal is analyzed to determine if it is a cardiac pulse or a motion pulse (step B). This can be done using any of the pulse qualification or motion detection techniques known to those of skill in the art. If a motion signal is present and used for the oxygen saturation calculation, then in step C only the oxygen saturation signal is displayed, and not a pulse rate (which would be a motion pulse rate, and not the patient's heart rate). If a cardiac pulse is used, the pulse rate is also displayed (step D).

[0064] Alternately, a pulse determination step E could be used where the sensor includes both a reflectance sensor and a transmittance sensor. If motion is present above a predetermined threshold (such as at least twice the arterial pulse signal), the reflectance sensor is used, which uses the motion signal, and alters any motion filtering or motion reduction techniques (step F). If the motion signal is below the threshold, the transmittance sensor is used (step G), with standard motion reduction techniques being employed (either hardware or software or both).

[0065] Both sensors could be energized in an ongoing manner, and the saturation and rate could be chosen to come from the sensor considered most reliable, depending on the instrument's assessment of motion. Simultaneous computation may further allow improved processed signal estimates of cardiac rate in the presence of motion given knowledge of estimated saturation.

[0066] FIG. 18 is a block diagram of a portion of a pulse oximeter monitor used in conjunction with an artificial pulse generator, such as shown in FIGS. 14-16. A frequency generator 110 produces a desired frequency for the motion pulse. This could be varied to give a frequency which is not interfered with by other noise, or frequency hopping could be used to isolate the signal from other sources of motion or noise. A pump controller 112 activates a pump or motor 100

(Fig. 12) at the generated frequency. Since the driven frequency is known, optionally other frequencies could be filtered out to reduce noise. After a signal is captured and converted to digital form by a circuit 114, a bandpass filter 116 is used to reduce other frequency signals. A control signal from frequency generator 110 could vary the bandpass frequency. A circuit or processor 118 then calculates the oxygen saturation. A central controller 120 controls the rest of the circuitry, including a sensor driver circuit 122, which could selectively activate different reflectance and transmittance emitters in one embodiment. Controller 120 could also analyze the signals for the presence of motion to alternate between motion and cardiac pulse modes in one embodiment. Alternately, a separate motion sensor could provide an input to controller 120. Note that other physical implementations are possible, such as using a single processor to do the filtering, the frequency generation and the oxygen saturation calculation.

[0067] A calibration resistor (or other active or passive element) 115 encodes the mean wavelength of at least one LED, and provides it to a calibration reader circuit or CPU 120. The wavelength indicated is used to select coefficients stored in the monitor. Such a calibration technique is described in more detail in U.S. Pat. No. 4,621,643, the disclosure of which is incorporated herein by reference.

[0068] FIG. 19 is a cut-away view of an embodiment of a sensor 130 according to the invention. An emitter 132 is mounted on a circuit 134 inside the sensor housing. A cylindrical lens 136 is mounted in an aperture 138. The lens directs the light down through the nail, minimizing the light which hits the nail at an angle and can be shunted to the detector. An aperture itself can perform the same function, but the lens insures that more of the light is used, maintaining a higher intensity at a given power, or allowing less power to be used. Detector 140 is recessed in a aperture 142 to avoid shunted light on the receiving end.

[0069] The sensor is secured to a nail 144 using an adhesive layer 146. The adhesive layer can act as a shunt path itself. Accordingly, the adhesive layer may be tinted to be opaque to the wavelengths used, with preferably transparent windows 148 and 150 for the detector and emitter apertures.

[0070] As will be understood by those of skill in the art, the present invention could be embodied in other specific forms without departing from the spirit or essential characteristics thereof. For example, a sensor could be placed on a fingernail other than the thumb nail, and could be placed on toenails. Alternately, a sensor could be placed on the cuticle or the live nail fold skin extending over the beginning of the nail. The sensor could be attached with a clip-type sensor, or an elastic wrap, bandage or adhesive which encircles the appendage could be used. The sensor could be placed at locations other than the nailbed where signals at the multiple wavelengths in the presence of motion are still adequately correlated. The emitter in the sensor could be fabricated using an optical fiber to carry the light from a source remotely located, and equivalently the detector could be an optical light guide to pipe the light to a remote detector. Accordingly, reference should be made to the following claims which set forth the scope of the invention.

What is claimed is:

- 1. A system for determining an arterial blood constituent of a patient, comprising:
 - a processing device in communication with a detector to process a detector signal from said detector representing a noncardiac produced blood pulse for determination of said blood constituent.
- 2. The system of claim 1 wherein at least two points on said detector signal are used.
 - 3. The system of claim 1 further comprising:
 - a sensor for attaching to said patient, including a radiation emitter and a radiation detector.
- 4. The system of claim 3 wherein said sensor comprises a sensor body containing said emitter and said detector configured to fit entirely on a nail of a patient
- **5**. The system of claim 3 further comprising a stimulator configured to create an artificial pulse in said patient.
- 6. The system of claim 3 wherein said sensor is a reflectance sensor.
- 7. The system of claim 6 wherein said emitter and said detector are separated by less than 10 millimeters.
- **8**. The system of claim 3 wherein said sensor includes a sensor body preformed to conform to the curvature of a nail.
- 9. The system of claim 3 wherein said detector detects reflectance signals from said sensor, and further comprising at least one additional optical element mounted in said sensor body to facilitate transmittance signals.
- **10**. The system of claim 9 wherein said additional optical element is an additional radiation detector.
- 11. The system of claim 9 wherein said additional optical element is an additional radiation emitter.
- 12. The system of claim 9 further comprising means for cross-reference calibration of said reflectance and transmittance signals during periods of minimal motion.
- 13. The system of claim 1 wherein said processing device further comprises:
 - a first processing unit configured to determine a physiological parameter from a cardiac derived plethysmogram from said detector; and
 - a second processing unit configured to determine said physiological parameter from a motion artifact waveform from said detector.
- 14. The system of claim 13 further comprising a control unit configured to utilize said first and second processing units responsive to a motion artifact content of said detector signals.
- 15. The system of claim 14 wherein said control unit is configured to switch between said first and second processing units.
- 16. The system of claim 14 wherein said control unit is configured to combine signals from said first and second processing units.
- 17. The system of claim 3 wherein said sensor is an oximeter sensor.
 - 18. A reflectance optical sensor comprising:
 - a sensor body configured to attach to a patient's digit over a nail;
 - a radiation emitter mounted in said sensor body adjacent said nail; and
 - a radiation detector mounted in said sensor body spaced from said emitter and adjacent said nail.

- 19. The sensor of claim 18 further comprising an adhesive for attaching said sensor body to said nail, and wherein said sensor body is configured to fit entirely on said nail.
- **20**. The sensor of claim 18 further comprising a portion of said sensor off said nail.
- 21. The sensor of claim 18 wherein said emitter comprises a fiber optic light guide.
- 22. The sensor of claim 18 wherein said detector comprises a fiber optic light guide.
- 23. The sensor of claim 18 wherein said sensor body is rigid and preformed to the curvature of a nail.
- 24. The sensor of claim 18 wherein said sensor body is deformable to adapt to the exact curvature of a nail.
- 25. The sensor of claim 18 wherein said emitter and said detector are recessed within said sensor body.
- 26. The sensor of claim 18 wherein said sensor body provides a numerical aperture of less than 0.9 for radiation emitted from said emitter and detected by said detector.
- 27. The sensor of claim 18 wherein said sensor body provides a numerical aperture of less than 0.5 for radiation emitted from said emitter and detected by said detector.
- 28. The sensor of claim 18 further comprising a cylindrical lens mounted adjacent said emitter.
- 29. The sensor of claim 18 wherein said sensor body is at least partially absorbing for at least one wavelength of said emitter for at least a portion of a region of said sensor body between said emitter and said detector.
 - **30**. The sensor of claim 18 further comprising:
 - a cable attached to said sensor providing a connection to said emitter and said detector; and
 - a strap configured to attach said cable to a digit adjacent said sensor for strain relief of said cable.
- **31**. The sensor of claim 30 wherein said cable includes a fiber optic cable connected to at least one of said emitter and said detector.
- 32. The sensor of claim 30 wherein said cable includes a flexible circuit connected to at least one of said emitter and said detector.
- **33**. The sensor of claim 18 wherein said detector is mounted within 10 millimeters of said emitter.
- **34**. The sensor of claim 33 wherein said detector is mounted approximately 4 millimeters from said emitter.
- 35. The sensor of claim 18 wherein said emitter and detector are mounted more orthogonal than parallel to an axis of said digit.
- **36**. The sensor of claim 18 wherein said emitter and detector are mounted more parallel than orthogonal to an axis of said digit.
- 37. The sensor of claim 18 wherein said emitter and detector are spaced and positioned so that both will not be over the lunula of a nail when attached.
- **38**. The sensor of claim 18 wherein said sensor body includes a portion for contacting a portion of said digit off said nail.
- **39**. The sensor of claim 18 wherein said sensor is a pulse oximeter sensor.
 - **40**. An optical sensor comprising:
 - a sensor configured to attach to a patient;
 - an emitter connected to said sensor;
 - a detector connected to said sensor and spaced from said emitter to detect reflectance signals; and
 - at least one optical element connected to said sensor to facilitate transmittance signals.

- 41. The sensor of claim 40 further comprising:
- processing means for utilizing said transmittance signals to process signals produced predominantly by cardiac pulses, and utilizing said reflectance signals to process signals produced predominantly by non-cardiac blood pulses.
- **42**. The sensor of claim 40 further comprising:
- means for allowing the selective activation of said detector to use said reflectance signals in the presence of motion
- 43. A photometric device for processing detector signals representative of a blood property of a patient from a sensor attached to said patient, said sensor including a radiation emitter and a radiation detector, said monitor comprising:
 - a control unit configured to generate an activation signal to selectively activate said emitter; and
 - a processing unit configured to receive said detector signals and to process said detector signals utilizing at least two points on a detector signal waveform produced by motion of said patient for measurement of said blood property.
- 44. A photometric processing device for processing detector signals from a radiation detector in a patient sensor also having a radiation emitter, comprising:
 - a first processing unit configured to determine a blood parameter from a cardiac derived plethysmogram from said detector;
 - a second processing unit configured to determine said blood parameter from a motion artifact waveform from said detector; and
 - a control unit configured to utilize said first and second processing units responsive to a motion artifact content of said detector signals.
- **45**. The photometric processing device of claim 44 further comprising a processor and a memory, wherein said first and second processing units and said control unit are first, second and third programs stored in said memory.
- **46**. A photometric processing device for processing detector signals from a detector in a patient sensor having an emitter and a detector, comprising:
 - a stimulator configured to generate an artificial pulse in said patient, said artificial pulse being distinct from a cardiac derived arterial pulse; and
 - a processing unit configured to determine a physiological parameter of arterial blood from a signal from said detector representative of said artificial pulse.
- **47**. The device of claim 46 wherein said physiological parameter is arterial oxygen saturation.
- **48**. The device of claim 46 wherein said stimulator induces movement of an appendage of said patient.
- 49. The device of claim 46 wherein said stimulator comprises an inflatable bag and an attachment mechanism configured to attach said bag to one side of an appendage of said patient.
- **50**. The device of claim 46 further comprising a bandpass filter coupled to receive a signal from said detector, said bandpass filter passing one of an amplitude, phase and frequency of said stimulator, wherein said distinction is one of an amplitude, phase and frequency.

- **51**. The device of claim 50 wherein said frequency can be changed.
- **52**. The device of claim 46 further comprising a frequency generator coupled to said stimulator.
- **53**. The device of claim 52 wherein said frequency generator is configured to vary an output frequency.
- **54.** A photometric processing device for processing detector signals from a detector in at least one patient sensor having an emitter and a detector, comprising:
 - a selector configured to select between a reflectance signal and a transmittance signal from said at least one sensor; and
 - a processing unit configured to determine a physiological parameter from a plethysmogram from said at least one sensor.
 - 55. The device of claim 54 further comprising:
 - a first processing unit configured to determine a physiological parameter from a cardiac derived plethysmogram from said detector;
 - a second processing unit configured to determine said physiological parameter from a motion artifact waveform from said detector; and
 - a control unit configured to switch between said first and second processing units in accordance with a selection of said selector.
- **56**. The device of claim 55 wherein said selector is responsive to a motion artifact content of a detector signal from said at least one sensor.
- 57. A method of measuring arterial oxygen saturation, comprising the steps of:
 - selecting a site on a patient wherein detected light signals from at least two wavelengths are sufficiently correlated in the presence of motion;
 - placing a pulse oximeter sensor on said site; and
 - measuring arterial oxygen saturation using said sensor.
- **58**. The method of claim 57 wherein said light signals produce a closed Lissajous.
- **59**. The method of claim 57 wherein said sufficiently correlated signals produce an arterial oxygen saturation that is accurate within 15 saturation points.
- **60**. The method of claim 57 wherein said sufficiently correlated signals produce an arterial oxygen saturation that is accurate within 10 saturation points.
- 61. The method of claim 57 wherein said oxygen saturation is measured by analyzing at least two points on a waveform generated by motion of said patient.
- **62**. A method for measuring a property of blood, comprising the steps of:
 - selecting a site on a patient wherein propagated light of at least two wavelengths will have sufficiently correlated waveforms in the presence of non-cardiac pulses;
 - placing a light emitter and light detector on said site; and using signals derived from said light detector to measure said blood property.
- **63**. The method of claim **62** wherein said signals include predominately motion-induced variations and said site is a nail on a digit.

* * * * *



专利名称(译)	运动兼容传感器,用于非侵入式光学血液分析		
公开(公告)号	<u>US20020103423A1</u>	公开(公告)日	2002-08-01
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[标]申请(专利权)人(译)	内尔科尔普里坦贝内特公司		
申请(专利权)人(译)	NELLCOR PURITAN BENNETT INCORPORATED		
当前申请(专利权)人(译)	NELLCOR PURITAN BENNETT INCORPORATED		
[标]发明人	CHIN RODNEY MANNHEIMER PAUL FLEWELLING ROSS		
发明人	CHIN, RODNEY MANNHEIMER, PAUL FLEWELLING, ROSS		
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其他公开文献	US6845256		
外部链接	Espacenet USPTO		

摘要(译)

一种非侵入式光学传感器,它使用运动信号来计算被测量的生理特征。 对于脉搏血氧测定法,可以将最小二乘法或比率比技术应用于运动信号 本身。这可以通过选择患者的位置来实现,其中运动的变化产生两个充 分相关的波长的信号。特别地,已经确定放置在指甲上的传感器,特别 是缩略图,表现出当用于脉搏血氧测定时具有相关的红外信号的特性, 并且所得到的信号与动脉血氧饱和度相关。

