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(72) Inventors: **BAKER, Clark, R., Jr.**; 18493 Magee Way, Castro Valley, CA 94546 (US). **RICHARDS, Edward, M.**; 6693 Hansen Drive, Pleasanton, CA 94566 (US).

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(74) Agents: **KUSHA, Babak** et al.; TOWNSEND AND TOWNSEND AND CREW LLP, Two Embarcadero Center, Eighth Floor, San Francisco, CA 94111-3834 (US).

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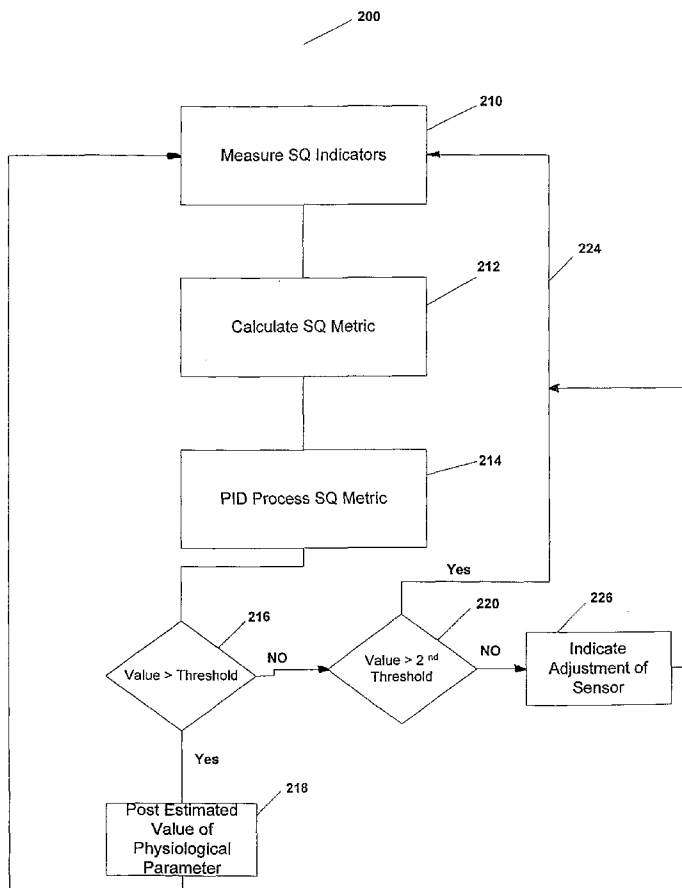
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(71) Applicant: **NELLCOR PURITAN BENNETT INCORPORATED** [US/US]; 4280 Hacienda Drive, Pleasanton, CA 94588 (US).

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(54) Title: SIGNAL QUALITY METRICS DESIGN FOR PHYSIOLOGICAL DATA



(57) Abstract: A method and a device for determining the quality of signal used for measuring a physiological parameter. One embodiment of the present invention is directed towards a pulse oximeter, where the measured physiological parameter includes a patient's pulse rate and blood oxygen saturation. The signal quality, which is indicative of the accuracy and reliability of the measured physiological parameter, is calculated by combining a plurality of signal quality indicators, each of which is an indicator of a quality of the measured signal. The value of the signal quality metric is compared to a threshold and based on this comparison various decisions are made by the medical device. One decision is directed towards deciding whether or not to display the measured physiological parameter, to ensure that only accurate measured values are displayed. Another decision is directed towards providing feedback to guide the clinician to adjust the location of the sensor to a more suitable tissue location.

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SIGNAL QUALITY METRICS DESIGN FOR PHYSIOLOGICAL DATA

BACKGROUND OF THE INVENTION

[0001] The present invention relates to physiological monitoring equipment and, in particular, monitoring equipment that include processes for quantitatively estimating the quality of the detected signals corresponding to physiological measurements and which
5 provide appropriate feedback to the clinician based on that estimate of signal quality.

[0002] Typically, for physiological monitoring instruments, the instrument is unable to accurately determine the accuracy and reliability, or a quality of a signal obtained from the sensor. An example of such physiological monitoring instrument is a pulse oximeter. Pulse oximetry is typically used to measure various blood characteristics including
10 the blood oxygen saturation of hemoglobin in arterial blood and the pulse rate of the patient. Measurement of these characteristics has been accomplished by use of a non-invasive sensor that passes light through a portion of a patient's blood perfused tissue and photo-electrically senses the absorption and scattering of light in such tissue. The amount of light absorbed and scattered is then used to estimate the amount of blood constituent in the tissue using various
15 algorithms known in the art. The "pulse" in pulse oximetry comes from the time varying amount of arterial blood in the tissue during a cardiac cycle. The signal processed from the sensed optical measurement is the familiar plethysmographic waveform due to cyclic light attenuation.

[0003] The accuracy of the estimates of the blood flow characteristics depends
20 on a number of factors. For example, the light absorption characteristics typically vary from patient to patient depending on their physiology. Moreover, the absorption characteristics vary depending on the location (e.g., the foot, finger, ear, and so on) where the sensor is applied, and whether there are objects interfering between the sensor and the tissue location (e.g., hair, nail polish, etc.). Further, the light absorption characteristics vary depending on
25 the design or model of the sensor. Also, the light absorption characteristics of any single sensor design vary from sensor to sensor (e.g., due to different characteristics of the light sources or photo-detector, or both). The clinician applying the sensor correctly or incorrectly may also have a large impact in the results, for example, by loosely or firmly applying the

sensor or by applying the sensor to a body part which is inappropriate for the particular sensor design being used.

[0004] The clinician needs to know how accurate or reliable of a reading is being provided by the instrument. Moreover, the instrument should ideally provide measurements that are accurate and reliable. A measure of the reliability and accuracy of a physiological measurement can be the quality of the signal. Although quality is a rather nebulous term, generally speaking, high quality signals are indicative of more reliable and more accurate physiological measurements and conversely, low quality signals are indicative of less reliable and accurate signals.

[0005] Some oximeters devices qualify measurements before displaying them on the monitor, by comparing the measured signals to various phenomenologically-derived criteria. These oximeters qualify the signal by making an assessment of its accuracy and only display values of estimated parameters when the signal quality meets certain criteria. The disadvantage of such approaches is that no feedback is provided to the clinician regarding what the clinician should do to improve the measurements. Worse yet, if the signal quality is deemed poor, and a decision is made by the device to not display the measured value, then the clinician is left with no more information than if the device was never used in the first place, which can be frustrating. Most typically, the clinician will end up removing the sensor from a particular tissue location to re-attach it to another location and heuristically repeats this process until more reliable measurements, deemed worthy of being displayed are provided by the instrument. The time duration where a measured value is displayed is known as the posting time. An ideal oximeter provides both accurate measurements and high posting times. While some instruments make estimates of signal quality, there still exists a need for improvements in this area; improvements that assess the quality of the signal while maintaining or increasing the posting times of the measured values. There is therefore a need for an improved and more quantitative assessment of signal quality. There is also a need for the monitoring equipment to guide the clinician to make necessary adjustments to improve the signal quality.

[0006] The issues related to obtaining high quality signals which are indicative of reliable and accurate measurements of critical physiological parameters, are further compounded when the sensor is "blindly" placed. A blindly placed sensor is one that is placed adjacent to a tissue location that is not readily observable by the clinician. An example of such a blind sensor placement is when a clinician uses a fetal pulse oximeter. The fetal pulse oximetry sensor is placed through the cervix during labor. The sensor, which is

supposed to lie between the cheek of the fetus and the wall of the uterus, measures the fetus' blood oxygen levels. The sensor is connected to a monitor that displays the fetus' current blood oxygen levels. During the course of monitoring the quality of the signal obtained can vary significantly and rapidly. This change in the quality of the signal can be caused by
5 sensor-to-fetus positioning irrespective of actual fetus physiological condition, resulting in spurious readings and interrupted posting times over relatively short time frames. Monitoring the heart rate of the fetus is an indirect way of assessing the amount of oxygen in the fetus' blood, which allows a clinician to determine whether the fetus is in distress during labor. Knowing the fetus' blood oxygen level during labor, and hence whether the fetus is in
10 distress or not, allows a clinician to better decide as to whether to perform a cesarean versus letting the labor progress. Therefore, with a blindly placed sensor, and especially one used in a fetal pulse oximetry, the need for an improved assessment of signal quality is heightened. Moreover, just as in non-blindly placed sensors, there is also a need for the medical device to provide guidance to a clinician to improve the quality of the signal when the signal quality is
15 so low as to indicate an inaccurate and/or unreliable estimate of a measured value.

BRIEF SUMMARY OF THE INVENTION

[0007] The present invention provides a method and a device for determining the quality of signal used for measuring a physiological parameter. One embodiment of the
20 present invention is directed towards a pulse oximeter, where the measured physiological parameter includes a patient's pulse rate and blood oxygen saturation. The signal quality, which is indicative of the accuracy and reliability of the measured physiological parameter, is calculated by combining a plurality of signal quality indicators, each of which is an indicator of a quality of the measured signal. The value of the signal quality metric is compared to a
25 threshold and based on this comparison various decisions are made by the medical device. One decision is directed towards deciding whether or not to display the measured physiological parameter, to ensure that only accurate measured values are displayed. Another decision is directed towards providing feedback to guide the clinician to adjust the location of the sensor to a more suitable tissue location.

30 [0008] In a pulse oximeter embodiment, the signal quality indicators of the present invention include: a signal measure indicative of the degree of similarity of an infrared and red waveforms; a signal measure indicative of a low light level; a signal measure indicative of an arterial pulse shape; a signal measure indicative of the high frequency signal component in the measure value; a signal measure indicative of a consistency of a pulse

shape; a signal measure indicative of an arterial pulse amplitude; a signal measure indicative of modulation ratios of red to infrared modulations and a signal measure indicative of a period of an arterial pulse. These various indicators provide for an indirect assessments of the presence of known error sources in pulse oximetry measurements, which include optical interference between the sensor and the tissue location; light modulation by other than the patient's pulsatile tissue bed; physical movement of the patient and improper tissue-to-sensor positioning.

[0009] The signal quality is calculated periodically, and hence can vary significantly and rapidly. In order to temper the decision making algorithm's response to changes in the calculated signal quality, certain embodiments of the present invention base the decisions to display a measured value and/or the decisions to guide the clinician, by comparing a PID-processed (proportional, integral and derivative) signal quality value to a threshold. PID processing is known in the controls arena and provides several advantages. In the context of a medical device and specifically a pulse oximeter device, the use of PID processing will ensure that a small magnitude, short time change in signal quality signal is reacted to quickly, preventing spurious responses, or delayed responses that could result in the display of inaccurate information. Further, a large magnitude signal quality change is responded to in a shorter period of time, and a slower long term change in signal quality is responded to in an adequate time frame to give the clinician sufficient timely information to work with.

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

[0010] Fig. 1 is a block diagram of an exemplary oximeter.

[0011] Fig. 2 is a flow chart showing an embodiment of the decision making algorithm of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0012] Embodiments of the present invention describe a physiological monitor and sensor incorporating methods and systems that quantitatively estimate signal quality, and based on that estimate of signal quality decide whether to display the measured physiologic parameter and/or provide feedback to guide the clinician to adjust the location of the sensor.

The signal quality estimate is based on the measurement of a plurality of signal quality indicators which when combined provide a quantitative measure of signal quality.

[0013] The invention is particularly applicable to and will be explained by reference to measurements of oxygen saturation of hemoglobin in arterial blood and patient hear rate, as in pulse oximeter monitors and pulse oximetry sensors. However, it should be realized the invention is equally applicable to any generalized patient monitor and associated patient sensor, such as ECG, blood pressure, temperature, etc., and is not limited to use only with oximetry or pulse oximetry. A brief description of pulse oximeters is provided below.

Pulse Oximeters

[0014] As described above, pulse oximeters are typically used to measure various blood flow characteristics including the blood oxygen saturation of hemoglobin in arterial blood and the heartbeat of a patient. Measurement of these characteristics has been accomplished by the use of a non-invasive sensor that passes light through a portion of a patient's blood perfused tissue and photo-electrically senses the absorption and scattering of light in such tissue.

[0015] The light passed through the tissue is typically selected to be of two or more wavelengths that are absorbed by the blood in an amount related to the amount of blood constituent present in the blood. The amount of transmitted light that passes through the tissue varies in accordance with the changing amount of blood constituent in the tissue and the related light absorption.

[0016] To estimate arterial blood oxygen saturation of a patient, conventional two-wavelength pulse oximeters emit light from two light emitting diodes (LEDs) into a pulsatile tissue bed and collect the transmitted light with a photo detector positioned on an opposite surface (i.e., for transmission pulse oximetry) or an adjacent surface (i.e., for reflectance pulse oximetry). The LEDs and photodetector are typically housed in a reusable or disposable oximeter sensor that couples to a pulse oximeter electronics and display unit. One of the two LEDs' primary wavelength is selected at a point in the electromagnetic spectrum where the absorption of oxyhemoglobin (HbO₂) differs from the absorption of reduced hemoglobin (Hb). The second of the two LEDs' wavelength is selected at a different point in the spectrum where the absorption of Hb and HbO₂ differs from those at the first wavelength. Commercial pulse oximeters typically utilize one wavelength in the near red part of the visible spectrum near 660 nanometers (nm) and one in the near infrared (IR) part of the spectrum in the range of 880-940 nm.

[0017] Fig. 1 is a block diagram of one embodiment of a pulse oximeter that may be configured to implement the embodiments of the present invention. The filter embodiments of the present invention can be a data processing algorithm that is executed by the microprocessor 122, described below. Light from light source 110 passes into patient tissue 112, and is scattered and detected by photodetector 114. A sensor 100 containing the light source and photodetector may also contain an encoder 116 which provides signals indicative of the wavelength of light source 110 to allow the oximeter to select appropriate calibration coefficients for calculating oxygen saturation. Encoder 116 may, for instance, be a resistor.

[0018] Sensor 100 is connected to a pulse oximeter 120. The oximeter includes a microprocessor 122 connected to an internal bus 124. Also connected to the bus is a RAM memory 126 and a display 128. A time processing unit (TPU) 130 provides timing control signals to light drive circuitry 132 which controls when light source 110 is illuminated, and if multiple light sources are used, the multiplexed timing for the different light sources. TPU 130 also controls the gating-in of signals from photodetector 114 through an amplifier 133 and a switching circuit 134. These signals are sampled at the proper time, depending upon which of multiple light sources is illuminated, if multiple light sources are used. The received signal is passed through an amplifier 136, a low pass filter 138, and an analog-to-digital converter 140. The digital data is then stored in a queued serial module (QSM) 142, for later downloading to RAM 126 as QSM 142 fills up. In one embodiment, there may be multiple parallel paths of separate amplifier filter and A/D converters for multiple light wavelengths or spectrums received.

[0019] Based on the value of the received signals corresponding to the light received by photodetector 114, microprocessor 122 will calculate the oxygen saturation using various algorithms. These algorithms require coefficients, which may be empirically determined, corresponding to, for example, the wavelengths of light used. These are stored in a ROM 146. The particular set of coefficients chosen for any pair of wavelength spectrums is determined by the value indicated by encoder 116 corresponding to a particular light source in a particular sensor 100. In one embodiment, multiple resistor values may be assigned to select different sets of coefficients. In another embodiment, the same resistors are used to select from among the coefficients appropriate for an infrared source paired with either a near red source or far red source. The selection between whether the near red or far red set will be chosen can be selected with a control input from control inputs 154. Control inputs 154 may be, for instance, a switch on the pulse oximeter, a keyboard, or a port providing instructions

from a remote host computer. Furthermore any number of methods or algorithms may be used to determine a patient's pulse rate, oxygen saturation or any other desired physiological parameter. The pulse oximeter shown in Fig. 1 is shown for exemplary purposes and is not meant to limit the embodiments of the present invention. For example, the sensor can be replaced by other appropriate sensors for use at other tissue locations including the ear, foot, forehead and nose of adult, infant, neonatal and perinatal patients.

[0020] Oxygen saturation can be estimated using various techniques. In one common technique, the photo-current generated by the photo-detector is conditioned and processed to determine the modulation ratio of the red to infrared signals. This modulation ratio has been observed to correlate well to arterial oxygen saturation. The pulse oximeters and sensors are empirically calibrated by measuring the modulation ratio over a range of in vivo measured arterial oxygen saturations (SaO_2) on a set of patients, healthy volunteers, or animals. The observed correlation is used in an inverse manner to estimate blood oxygen saturation (SpO_2) based on the measured value of modulation ratios of a patient. The estimation of oxygen saturation using modulation ratios or ratio of ratios is described in U.S. Patent No. 5,853,364, entitled "METHOD AND APPARATUS FOR ESTIMATING PHYSIOLOGICAL PARAMETERS USING MODEL-BASED ADAPTIVE FILTERING", issued December 29, 1998, and U.S. Patent No. 4,911,167, entitled "METHOD AND APPARATUS FOR DETECTING OPTICAL PULSES", issued March 27, 1990. The relationship between oxygen saturation and modulation ratio is further described in U.S. Patent No. 5,645,059, entitled "MEDICAL SENSOR WITH MODULATED ENCODING SCHEME," issued July 8, 1997. An electronic processor for calculating in vivo blood oxygenation levels using pulsed light is described in U.S. Patent No. 5,348,004, entitled "ELECTRONIC PROCESSOR FOR PULSE OXIMETER," issued September 20, 1994, and a display monitor for a pulse oximeter is described in U.S. Patent No. 4,653,498, entitled "PULSE OXIMETER MONITOR," issued March 31, 1987. All five patents are assigned to the assignee of the present invention and incorporated herein by reference.

[0021] The brief description of pulse oximeters, and associated electronic circuitry and algorithms described above serve as a contextual fabric for describing the method for estimating signal quality and the signal quality metrics design according to embodiments of the present invention, which are described below.

Signal Quality

[0022] While the methodologies described in the patents cited above are used to provide estimates of blood oxygen saturation and pulse rate, many intermediate signals are first obtained by the oximetry sensor which when finally processed through these circuits and algorithms conclude in determining these final estimates of blood oxygen saturation and pulse rate. A set of these intermediate signals is used for signal quality indicators. The signal quality indicators are then combined and processed to estimate a signal quality metric. The value of the signal quality metric is compared to a threshold and based on this comparison various decisions are made by the medical device. One decision is directed towards deciding whether or not to display the measured physiologic parameter. Another decision is directed towards providing feedback to guide the clinician to adjust the location of the sensor, when the signal quality metric is below a threshold.

A. Signal Quality Indicators

[0023] A signal quality indicator is a measured parameter that is capable of estimating the reliability and accuracy of a signal. For example, when measuring blood oxygen saturation using a pulse oximeter, a signal quality indicator is able to indirectly assess whether an estimate of a value of blood oxygen saturation is an accurate one. This determination of accuracy is made possible by a thorough and detailed study of volumes of measured values and various indicators to determine which indicators are indicative of signal quality and what, if any, is the correlation between the indicator and the accuracy of the estimated value. While a particular indicator may be highly correlated to the accuracy of a measured value, it is determined that a combination of several indicators correlates better to the accuracy of measured value over a wider range of clinical conditions. A few of these indicators are referred to as the "OVERLAP," "MIN-MAX-MIN," "PATH LENGTH" and "IR nAv" indicators. These, as well as other indicators and their utilities in determining the signal's quality and hence the accuracy of oxygen saturation estimates are each described below.

[0024] The "OVERLAP" indicator is a measure of the similarity of the pulse forms obtained from different wavelengths, such as for example, the infrared and red pulse forms. While many algorithms may be used to compute "OVERLAP," one equation that may be used to compute it is as follows:

$$R = \frac{\ln(Re d_{\max} / Re d_{\min})}{(IR_{\max} / IR_{\min})}$$

$$Overlap = \frac{\sum \min(IR_i - IR_{\min}, (Re d_i - Re d_{\min}) / R)}{\sum IR_i - IR_{\min}}$$

where IR_i and $Re d_i$ have been AC-coupled and normalized by their respective DC levels and the summations cover a timespan ranging from one to several seconds.

This indicator is useful in determining the accuracy of the measured oxygen saturation value because it provides for an indirect method of sensing the extent to which the two wavelengths which are used by a sensor are probing the same tissue volume. It is known that errors in oxygen saturation measurements using pulse oximeters occur when the two light sources providing light at two wavelengths probe two different tissue locations. Thus when the two or more different pulse forms do not look the same, it is likely that photons are being modulated by different volumes of tissue, which is known to cause inaccurate measurements. On the other hand, when the two or more pulse forms (e.g., infrared and red) look the same, or "OVERLAP," then this indicates that it is likely that the same tissue volume is being probed by the two different wavelengths of light, thus avoiding a known source of error.

[0025] The "MIN-MAX-MIN" indicator provides for a measure of the arterial pulse shape. The arterial pulse referred to herein is caused by a cardiac cycle commonly referred to a heartbeat. During a typical cardiac cycle, blood pressure rises from a minimum value (MIN) at diastole to a maximum (MAX) at systole. The "MIN-MAX-MIN" indicator is a ratio represented by a fraction having the time it takes the pulse to go from a MAX to a MIN as the numerator and having the time it takes the pulse to go from a MIN to a MAX as the denominator. This indicator provides an indication of the ratio of fall to rise times of arterial pulse. A fundamental fact of human physiology is that in a typical arterial pulse, it takes a shorter time to go from the diastole to systole (MIN to MAX) than it does to go from systole to diastole (MAX to MIN). Recognizing this fundamental physiological aspect, then if the "MIN-MAX-MIN" indicator shows that for a pulse, the rise time is bigger than the fall time, then this indicates that the sensor's light is being modulated by other than an arterial pulse. The inventors have identified that when a pulse's rise time is bigger than its fall time, the light is not modulated by pulsation of evenly distributed arterial blood, but it is most likely that the observed pulse-like phenomenon is due to throbbing of underlying large blood vessels or physical movement of the sensor. It is known that either of these mechanisms may cause large errors in the calibration of the resulting oxygen saturation estimate. Therefore, by analyzing the shape of the arterial pulse, the "MIN-MAX-MIN" indicator determines whether

the light modulation is due to a pulsation, or evenly distributed arterial blood, or other phenomenon such as motion.

[0026] The "PATH LENGTH" indicator is also indicative of the pulse shape. This indicator provides for a measure of the frequency content of the pulse waveform relative to the pulse rate. While many algorithms may be used to compute "PATH LENGTH," one equation that may be used to compute it is as follows:

$$PathLength = \frac{\sum_{i=0}^{i=Samples_in_Pulse-1} |IR_{t-i} - IR_{t-i-1}|}{Pulse_Max - Pulse_Min}$$

High values of this metric indicate that a high proportion of the energy in the pulse is at frequencies higher than the pulse rate. High frequency components in the arterial pulse shape are an indication that light is being modulated by other than arterial pulsations. These high frequency components are also most likely to be caused by movement of the sensor. As described above, it is known that physical movement is a source of error when estimating blood oxygen saturation in pulse oximeters. Therefore, the "PATH LENGTH" indicator, is also a motion indicator, which is used to infer that signals that have high frequency components often lead to inaccurate estimates of pulse rate and/or blood oxygen saturation.

[0027] The "IR nAv" indicator provides for an infrared (IR) measure of the optical density of the tissue. This indicator represents a light level which has been normalized for the LED's brightness. In other words, the "IR nAv" indicator is a low light level measure. It is recognized that the cause of a low light level measure is sensor misplacement, as in when a sensor is placed over hair or other medium interfering with the light path between the sensor and the probed tissue volume. Therefore, the "IR nAv" indicator is used to infer that the measured value is potentially inaccurate because of sensor misplacement.

[0028] In addition to the indicators described above, many other indicators also provide for estimates of signal quality and hence a measure of the accuracy of the physiological measurements. These include indicators that qualify: pulse shape; pulse amplitude; modulation ratios of the red to infrared signals, known as ratio of ratios and pulse period. Moreover, other indicators that trend the consistency of pulse shapes relative to each of these additional indicators are also viable as measures of signal quality.

[0029] The signal quality indicators described above, may be derived from any wavelength used by an oximeter. Further, these indicators may be derived after a variety

of signal processing operations including filtering of the signal, such as low pass, high pass and comb filtering. Furthermore, although the indicators described above are based on time-domain analyses, similar indicators are derivable in the frequency domain as is apparent to those knowledgeable in signal processing.

5

B. Algorithms for Determining an Overall Signal Quality (SQ) Metric

[0030] As stated above, the signal quality indicators are processed and combined to provide an overall value for a lumped signal quality (SQ) metric. Many algorithms may be used to arrive at the lumped SQ value. An example of such an algorithm is shown below, which may be described as a combination of the "OVERLAP," "MIN-MAX-MIN" and "IR nAv" indicators.

$SQ = SQ1 * (SQ2/100) * (SQ3/100)$, where
 $SQ1 = 100 - 5*(96 - OVERLAP)$, clipped to between 0 and 100
 $SQ2 = 100 - (MIN-MAX-MIN - 16000) / 70$, clipped to between 0 and 100
 $SQ3 = 100 - 5 * (25 - IR\ nAv)$, clipped to between 50 and 100,

[0031] For example, for this particular algorithm, SQ is updated on each qualified pulse. Alternate algorithms update the calculation of SQ at other periodic rates, ranging from once every 5 seconds to once every one tenth of a second. The particular choice of algorithm which is used to compute an SQ, is very dependent on the choice of indicators and the target value for the lumped SQ parameter. As shown here, only three of the indicators are used, namely, "OVERLAP," "MIN-MAX-MIN" and "IR nAv." Using this particular algorithm, the SQ value is configured to have a range between 0 and 100. The algorithm shown above is for exemplary purposes only, since many other algorithms can be derived which would also combine various indicators to arrive at an overall signal quality metric. The advantage of this particular algorithm is that it is a relatively simple one, only using three signal quality indicators. Further, this particular algorithm processes the signal quality indicators by scaling and clipping the indicators to values to derive a signal quality metric which has a very ordinary range of between 0 and 100. Most, if not all practitioners in the technical and scientific communities can appreciate that a value of 100 represents a high quality value and that a value of 0 represents a low quality value. Depending on the choice of indicators and the desired range of values for the final SQ metric, many alternate algorithms can be contemplated, each having various different advantages and disadvantages as compared to the exemplary algorithm described above.

C. Processing SQ

[0032] Having determined a signal quality (SQ) value by combining various signal quality indicators, the next task in determining whether a measured value is accurate and worthy of being displayed on a pulse oximeter's monitor is to compare the SQ value to a threshold. As described above, the SQ value is calculated periodically, and therefore it can also change periodically. This change in signal quality can occur due to both changes in physiological conditions of the patient as well as non-physiologically induced changes. Non-physiological changes in signal quality can be caused by such factors as motion of the sensor, changes in the sensor to tissue positioning and optical interference between the sensor and the tissue location such as those caused by hair being placed in between the sensor and the tissue location. These non-physiological-based changes occur to a higher extent in perinatal pulse oximeters, where the sensor-to-fetus positioning can change rapidly as the fetus moves in the womb during the course of labor and delivery.

[0033] Algorithms that make the decision regarding whether or not to display a measured value of a physiological parameter on a display monitor of a pulse oximeter, must account for the potential rapid changes in signal quality. Thus, a small-magnitude, short-time change in signal quality should not be reacted to quickly, thus preventing annoying and spurious responses. On the other hand, small magnitude changes in signal quality should not cause a delayed response that could result in the display of inaccurate measurements. Therefore, to avoid erratic changes in the response of the diagnostic device, algorithms that decide whether or not a measured value is of a high enough quality, and algorithms that decide whether or not the value should be displayed preferably should act on a processed form of the SQ value.

[0034] The concept of tempering a system's response to on an input is known in the automatic controls arena. This concept is related to various operations, including the proportional (P), integral (I) and derivative (D) control operations, with each operation having different attributes. A control operation using a combination of proportional, integral and derivative operations in response to an input is referred to as a PID control system. The embodiments of the present invention enhance the algorithms which are used to make decisions regarding whether or not to display a measured value on a display monitor by incorporating PID operations with these algorithms. Each of the proportional, integral and derivative operations as applied to the SQ-based algorithms is described below.

[0035] With proportional control, a change in response is made which is proportional to the change in input. For example, with proportional control, if the decision to display a measured value depends on the SQ being equal to or above a threshold value, the instant the SQ value exceeds the threshold, the measured value is displayed, and the very instant the SQ value drops below the threshold, the measured value is removed from the display. While a proportional control operation may be instantly responsive, it will also respond erratically to erratic changes in input. This potential of an erratic response is not ideal because short-lived excursions in SQ will cause short-lived responses which are, as described above, not desired.

[0036] With integral control, the input change is integrated over time and a change in response occurs when an integrated threshold value is met. Consider, for example if the integral threshold for removing a measured value from a display is set to a value of 10 SQ-seconds, beyond a threshold of SQ of 80. Under this scenario, a drop in SQ from 81 to 79 would cause the displayed value to be removed in 5 seconds, since the deviation of 2 SQ (81-79 = 2 SQ) times 5 seconds would equal 10 SQ-seconds. A bigger drop in SQ beyond the threshold value would remove the displayed value sooner, and conversely a smaller drop in the SQ beyond the threshold would remove the displayed value later. Thus, an integral control operation delays the decision by waiting for an integrated threshold to be met. In this manner, an integral-based control operation is able to ride out short lived excursions and result in an overall smoother display operation for a pulse oximeter device.

[0037] Lastly, a derivative control system responds to the rate of change of the input parameter as opposed to the parameter itself, as in proportional control, or an integrated change in the parameter, as in integral control. A derivative-based system anticipates the change in the input parameter and is thus able to foresee when an increasing SQ value is nearing the SQ threshold. In other words, derivative control will cause a transition to display a measured value on the display monitor faster if SQ has improved over the last few sensing periods.

[0038] Thus, the diagnostic device's decision making directed to determining whether a measured value has a high enough SQ to be worthy of being displayed on an oximeter's monitor is based on comparing a PID processed SQ to a threshold value. The PID processed SQ value is achieved by operating on the SQ value using a combination of proportional, derivative and integral operations. For example, the decision to post may be made when the combination of the proportional, integral and derivative processed SQ value

exceeds a threshold, as is shown below (i.e., display the measured value if P+I+D is greater than a threshold):

$$P + I + D > \text{Threshold, where}$$

5

$$P = P_0 * (SQ - 75) / 25, \text{ where}$$

P_0 is a proportional component scalar;

SQ is signal quality

10

$$I = \int (SQ - 50) dt, \text{ where}$$

the integral is updated each second; and

$$D = D_0 * (SQ_1 - SQ_0) / 14, \text{ where}$$

SQ_1 is the current signal quality

15

SQ_0 is the signal quality one second before

D_0 is the derivative component scalar

[0039] Thus, various algorithms are used to compute a signal quality metric for comparison to a threshold. Further, before comparing the calculated SQ value, an alternate embodiment processes the SQ value using PID operations. Once the PID processed or non-processed SQ value is compared to a threshold, various decisions are made by the medical device. As stated above, one decision is directed towards deciding whether or not to display the measured physiologic parameter. Another decision is directed towards providing feedback to guide the clinician to adjust the location of the sensor, when the signal quality metric is below a threshold.

D. Decision Algorithm

[0040] Fig. 2 is a flow chart 200 showing an embodiment of the above described decision making algorithm in accordance with the present invention. First a plurality of signal quality indicators are measured (step 210). Next, the signal quality indicators are processed and combined to calculate an SQ metric (step 212). As described above, the SQ value changes periodically, and may also change rapidly. To smooth out potential changes in the time-varying SQ value, it is PID processed (step 214). Next, the

value of the PID processed SQ metric is compared to a threshold (step 216). If the value is at least equal to the threshold, the measured physiological value is sent to be displayed by the device's monitor (step 218). For example, when the medical device is a pulse oximeter with a display monitor and the device is measuring oxygen saturation, once the PID processed SQ value exceeds the threshold, indicating that the measured value is reliable and accurate, the device makes the decision to display the oxygen saturation value on its display monitor. The measured value (i.e., oxygen saturation) remains displayed until the PID processed SQ value drops below a threshold.

[0041] On the other hand, if the PID processed value is below the threshold (step 216), the measured physiologic value is not displayed. Next, the PID processed SQ value is compared to another threshold (step 220). The threshold at step 220 may be equal to the threshold at step 216. Alternately the threshold at step 220 may be set to a different value. if the PID processed SQ value exceeds the second threshold value, the decision loop is ended (step 224) and the process begins all over again (step 210). On the other hand, if the PID processed SQ value is lower than the second threshold, a diagnostic message is displayed (step 226) on the medical devices display monitor to appropriately guide the clinician. For example, a text message such as "ADJUST SENSOR" is posted on the display monitor to guide the clinician to adjust the sensor's positioning. Once the "ADJUST SENSOR" text message is displayed, it remains displayed until the sensor's location is adjusted. Alternately, the diagnostic message may be an audible or visual alarm indicating that the sensor location must be adjusted.

[0042] While the PID processing of the SQ value provides the advantages described above, it may lead to a delayed response, for example a PID processed SQ value with a large integral component- due to the required integration times. To avoid a potential delayed response, the PID algorithm is adjusted to reduce the significance of the integral component. Alternately, the algorithms are configured to base the decision making on a non-PID processed SQ signal.

[0043] Experiments conducted by the inventors show that pulse oximeter devices configured to use embodiments of the present invention described above, provide an increase in the overall posting time of the measures physiological values. Further, the improvements related to implementation of the embodiments of the present invention, provide for improvements in the accuracy of the displayed saturation values. Additionally, the "ADJUST SENSOR" feature leads to improved sensor placement. And lastly, with improved sensor placement, posting of the displayed signal begins sooner.

As will be understood by those of skill in the art, the present invention which is related to estimating the reliability and accuracy of a monitored value, and diagnostics algorithms based on that estimate, may be embodied in other specific forms without departing from the essential characteristics thereof. For example, variables other than oxygen saturation such as pulse rate, blood pressure, temperature, or any other physiological variable could be continuously or periodically tracked. Further, while the present embodiments have been described in the time-domain, frequency-based methods are equally relevant to the embodiments of the present invention. Accordingly, the foregoing disclosure is intended to be illustrative, but not limiting, of the scope of the invention which is set forth in the following claims.

WHAT IS CLAIMED IS:

1 1. A method of controlling a display of a measured value for a
2 physiological parameter in a medical diagnostic apparatus, comprising:
3 measuring a plurality of signal quality indicators;
4 processing said plurality of signal quality indicators, to form a plurality of
5 processed signal quality indicators;
6 combining said plurality of processed signal quality indicators to form a
7 combination of said plurality of processed signal quality indicators;
8 calculating a signal quality metric, wherein said signal quality metric
9 comprises said combination of said plurality of processed signal quality indicators;
10 establishing a signal quality threshold;
11 comparing said signal quality metric to said signal quality threshold; and
12 displaying said measured value only if said signal quality metric exceeds said
13 signal quality threshold.

1 2. The method of claim 1 wherein said measured value is an oxygen
2 saturation.

1 3. The method of claim 1 wherein said measured value is a pulse rate.

1 4. The method of claim 1 wherein said apparatus comprises a pulse
2 oximeter.

1 5. The method of claim 1 wherein said apparatus comprises a perinatal
2 pulse oximeter.

1 6. The method of claim 1 wherein said apparatus comprises a perinatal
2 pulse oximeter having a sensor configured to be placed at a tissue location which is not
3 observable during said measuring.

1 7. The method of claim 1 wherein said plurality of signal quality
2 indicators are selected from a group consisting of:
3 a signal measure indicative of the degree of similarity of an infrared and red
4 waveforms,
5 a signal measure indicative of a low light level,

6 a signal measure indicative of an arterial pulse shape,
7 a signal measure indicative of the high frequency signal component in said
8 measure value,
9 a signal measure indicative of infrared light modulation,
10 a signal measure indicative of red light modulation,
11 a signal measure indicative of a consistency of a pulse shape,
12 a signal measure indicative of an arterial pulse amplitude,
13 signal measure indicative of modulation ratios of red to infrared modulations
14 and
15 a signal measure indicative of a period of an arterial pulse.

1 8. The method of claim 1 wherein said plurality of signal quality
2 indicators comprise:
3 a signal measure indicative of the degree of similarity of an infrared and red
4 waveforms,
5 a signal measure indicative of a low light level,
6 a signal measure indicative of an arterial pulse shape and
7 a signal measure indicative of the high frequency signal component in said
8 measure value.

1 9. The method of claim 7 or 8 wherein said plurality of signal quality
2 indicators are derived after a signal processing, wherein said signal processing is one of low
3 pass filtering, high pass filtering, comb filtering, or a combination thereof.

1 10. The method of claim 7 or 8 wherein said plurality of signal quality
2 indicators are derived from a frequency domain analysis.

1 11. The method of claim 1 wherein said processing comprises scaling and
2 clipping.

1 12. The method of claim 1 wherein said calculating further comprises
2 averaging said signal quality over a period of time.

1 13. The method of claim 1 wherein said calculating further comprises
2 conditioning said signal quality metric by operating on said signal metric using a combination
3 of proportional, integral and derivative control operations.

1 14. The method of claim 1 wherein said signal quality metric is calculated
2 periodically at a rate between 0.1 and 5 seconds.

1 15. The method of claim 1 wherein said signal quality metric is calculated
2 periodically at a rate between 0.1 and 1.0 seconds.

1 16. The method of claim 1 wherein said signal quality metric is calculated
2 at a fixed time interval, said time interval being similar to one to several typical pulse periods.

1 17. The method of claim 1 wherein said signal quality metric is calculated
2 once for each qualified pulse.

1 18. A method of guiding a user of a pulse oximeter apparatus to properly
2 place the pulse oximeter sensor at a sensing location, comprising:
3 initially placing said sensor at a sensing location;
4 measuring a plurality of signal quality indicators;
5 processing said plurality of signal quality indicators, to form a plurality of
6 processed signal quality indicators;
7 combining said plurality of processed signal quality indicators to form a
8 combination of said plurality of processed signal quality indicators;
9 calculating a signal quality metric, wherein said signal quality metric
10 comprises said combination of said plurality of processed signal quality indicators;
11 establishing a signal quality threshold;
12 comparing said signal quality metric to said signal quality threshold; and
13 informing said user to adjust the location of said sensor when said signal
14 quality metric is lower than said signal quality threshold.

1 19. The method of claim 18 wherein said apparatus comprises a perinatal
2 pulse oximeter.

1 20. The method of claim 18 wherein said sensor is configured to be placed
2 at a tissue location which is not observable during said measuring.

1 21. The method of claim 18 wherein said plurality of signal quality
2 indicators are selected from a group consisting of:

3 a signal measure indicative of the degree of similarity of an infrared and red
4 waveforms,
5 a signal measure indicative of a low light level,
6 a signal measure indicative of an arterial pulse shape,
7 a signal measure indicative of the high frequency signal component in said
8 measure value,
9 a signal measure indicative of infrared light modulation,
10 a signal measure indicative of red light modulation,
11 a signal measure indicative of a consistency of a pulse shape,
12 a signal measure indicative of an arterial pulse amplitude,
13 signal measure indicative of modulation ratios of red to infrared modulations
14 and
15 a signal measure indicative of a period of an arterial pulse.

1 22. The method of claim 18 wherein said plurality of signal quality
2 indicators comprise:

3 a signal measure indicative of the degree of similarity of an infrared and red
4 waveforms,
5 a signal measure indicative of a low light level,
6 a signal measure indicative of an arterial pulse shape and
7 a signal measure indicative of the high frequency signal component in said
8 measure value.

1 23. The method of claim 21 or 22 wherein said plurality of signal quality
2 indicators are derived after a signal processing, wherein said signal processing is one of low
3 pass filtering, high pass filtering, comb filtering or comb filtering with boxcar filtering.

1 24. The method of claim 21 or 22 wherein said plurality of signal quality
2 indicators are derived from a frequency domain analysis.

1 25. The method of claim 18 wherein said processing comprises scaling and
2 clipping.

1 26. The method of claim 18 wherein said calculating further comprises
2 averaging said signal quality over a period of time.

1 27. The method of claim 18 wherein said calculating further comprises
2 conditioning said signal quality metric by operating on said signal metric using a combination
3 of proportional, integral and derivative control operations.

1 28. The method of claim 18 wherein said signal quality metric is
2 calculated periodically at a rate between 0.1 and 5 seconds.

1 29. The method of claim 18 wherein said signal quality metric is
2 calculated periodically at a rate between 0.1 and 1.0 seconds.

1 30. The method of claim 18 wherein said signal quality metric is
2 calculated at a fixed time interval, said time interval being similar to one to several typical
3 pulse periods.

1 31. The method of claim 18 wherein said signal quality metric is
2 calculated once for each qualified pulse.

1 32. The method of claim 18 wherein said informing comprises visually
2 indicating on a display monitor a command indicative of a need to adjust said sensor location.

1 33. The method of claim 18 wherein said informing comprises an audible
2 notification indicative of a need to adjust said sensor location.

1 34. A pulse oximeter, comprising:
2 a display monitor for displaying a measured value;
3 means for measuring a plurality of signal quality indicators;
4 means for processing said plurality of signal quality indicators, to form a
5 plurality of processed signal quality indicators;
6 means for combining said plurality of processed signal quality indicators to
7 form a combination of said plurality of processed signal quality indicators;
8 means for calculating a signal quality metric, wherein said signal quality
9 metric comprises said combination of said plurality of processed signal quality indicators;
10 means for establishing a signal quality threshold;
11 means for comparing said signal quality metric to said signal quality
12 threshold; and

13 means for displaying said measured value on said monitor, only if said signal
14 quality metric exceeds said signal quality threshold.

1 35. The pulse oximeter of claim 34 wherein said sensor is configured to be
2 placed at a tissue location which is not observable during said measuring.

1 36. The pulse oximeter of claim 34 wherein said plurality of signal quality
2 indicators are selected from a group consisting of:

3 a signal measure indicative of the degree of similarity of an infrared and red
4 waveforms,

5 a signal measure indicative of a low light level,

6 a signal measure indicative of an arterial pulse shape,

7 a signal measure indicative of the high frequency signal component in said
8 measure value,

9 a signal measure indicative of infrared light modulation,

10 a signal measure indicative of red light modulation,

11 a signal measure indicative of a consistency of a pulse shape,

12 a signal measure indicative of an arterial pulse amplitude,

13 signal measure indicative of modulation ratios of red to infrared modulations

14 and

15 a signal measure indicative of a period of an arterial pulse.

1 37. The pulse oximeter of claim 34 further comprising means for guiding a
2 user of said oximeter to adjust the location of said sensor when said signal quality metric is
3 lower than said signal quality threshold.

1 38. The pulse oximeter of claim 37 wherein said means for guiding
2 comprises visually indicating on said display monitor a command indicative of a need to
3 adjust said sensor location.

1 39. The pulse oximeter of claim 37 wherein said means for guiding
2 comprises an audible notification indicative of a need to adjust said sensor location.

1/2

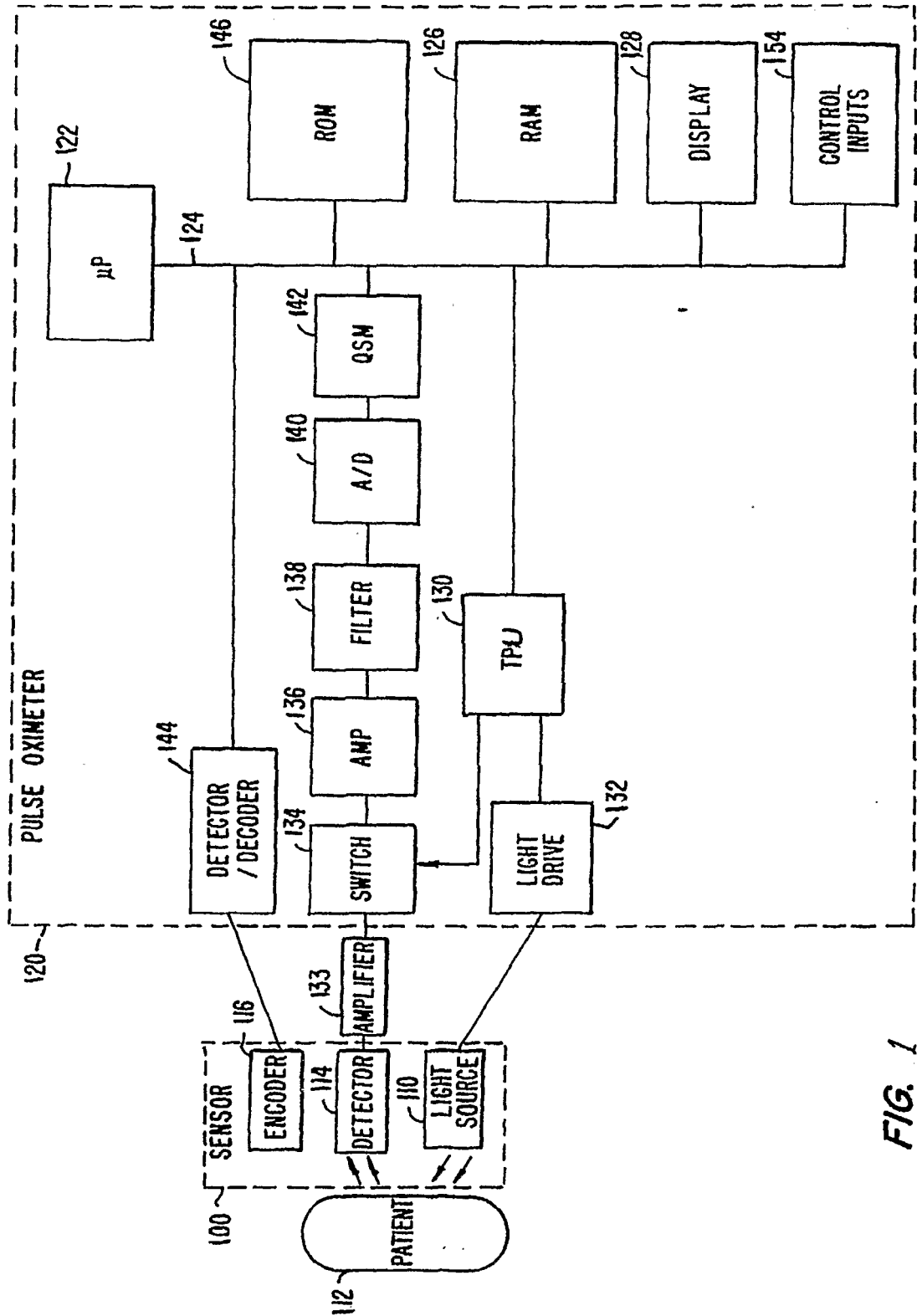


FIG. 1

2/2

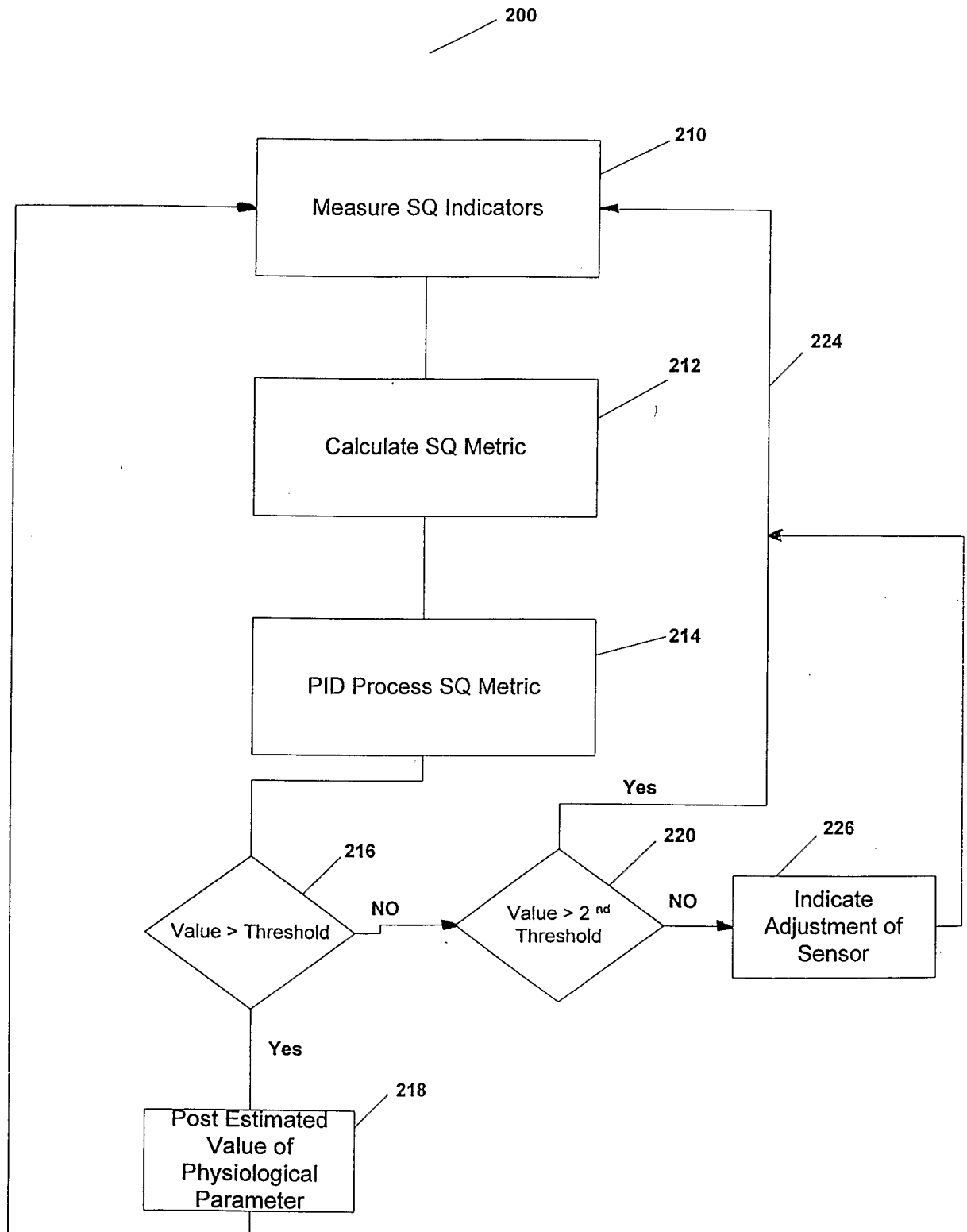


FIG. 2.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/41468

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 A61B5/024

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 035 223 A (BAKER JR CLARK R) 7 March 2000 (2000-03-07) the whole document	1-39
X	US 6 449 501 B1 (REUSS JAMES L) 10 September 2002 (2002-09-10)	18-39
A	column 3, line 43 - column 4, line 54 column 5, line 13 - column 10, line 52; claim 1; figure 1	1-17
X	WO 00/61000 A (MALLINCKRODT INC) 19 October 2000 (2000-10-19) page 3, lines 11-14 page 6, line 7 - page 15, line 28; figures 5-7	1,2,4-7, 17-21, 31-38
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Artikis, T

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/41468

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 846 190 A (WOEHRLE DIETER) 8 December 1998 (1998-12-08) column 2, line 66 - column 10, line 40; claim 1</p> <p style="text-align: center;">-----</p>	1-39

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/41468

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6035223	A	07-03-2000	CA 2310000 A1	27-05-1999
			EP 1032301 A1	06-09-2000
			JP 2001522680 T	20-11-2001
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			JP 9108203 A	28-04-1997

专利名称(译)	生理数据的信号质量度量设计		
公开(公告)号	EP1587416A1	公开(公告)日	2005-10-26
申请号	EP2003810083	申请日	2003-12-29
[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	BAKER CLARK R JR RICHARDS EDWARD M		
发明人	BAKER, CLARK, R., JR. RICHARDS, EDWARD, M.		
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代理机构(译)	GRUBERT , ANDREAS		
优先权	10/341318 2003-01-10 US		
外部链接	Espacenet		

摘要(译)

一种用于确定用于测量生理参数的信号质量的方法和设备。本发明的一个实施例涉及脉搏血氧计，其中测量的生理参数包括患者的脉搏率和血氧饱和度。通过组合多个信号质量指示符来计算指示所测量的生理参数的准确性和可靠性的信号质量，每个信号质量指示符是测量信号的质量的指示符。将信号质量度量的值与阈值进行比较，并且基于该比较，由医疗设备做出各种决定。一个决定是针对决定是否显示测量的生理参数，以确保仅显示准确的测量值。另一个决定旨在提供反馈以指导临床医生将传感器的位置调整到更合适的组织位置。