



(19) **United States**
(12) **Patent Application Publication**
Baker, JR.

(10) **Pub. No.: US 2014/0309507 A1**
(43) **Pub. Date: Oct. 16, 2014**

(54) **REDUCING NUISANCE ALARMS**

Publication Classification

- (71) Applicant: **Covidien LP**, Boulder, CO (US)
- (72) Inventor: **Clark R. Baker, JR.**, Newman, CA (US)
- (73) Assignee: **Covidien LP**, Boulder, CO (US)
- (21) Appl. No.: **14/315,693**
- (22) Filed: **Jun. 26, 2014**

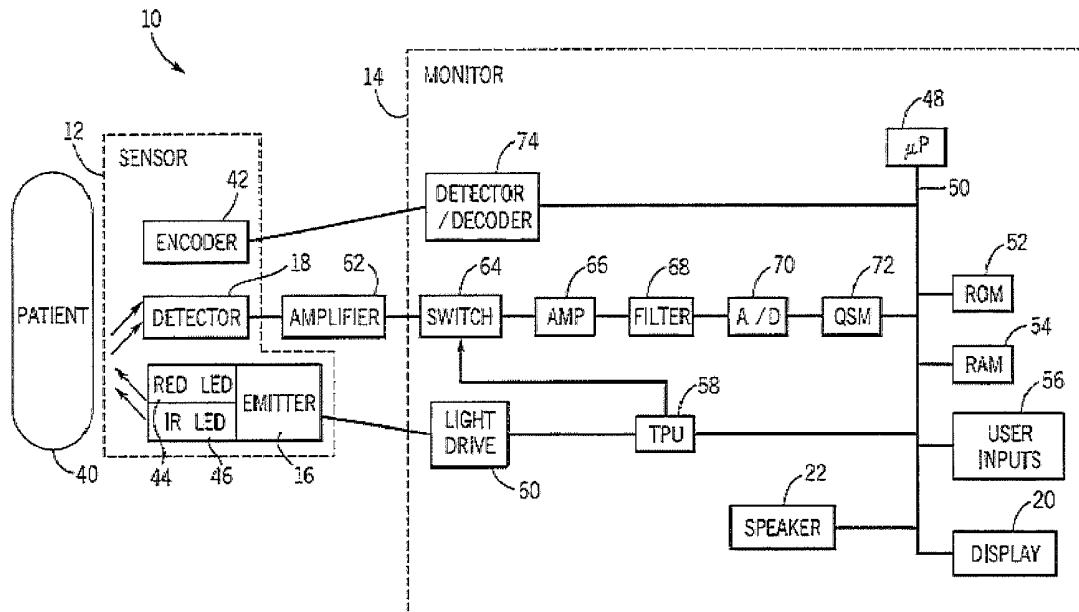
- (51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/00 (2006.01)
- (52) **U.S. Cl.**
CPC *A61B 5/1452* (2013.01); *A61B 5/7221* (2013.01)
USPC **600/323**

Related U.S. Application Data

- (63) Continuation of application No. 12/399,304, filed on Mar. 6, 2009, now Pat. No. 8,792,949.
- (60) Provisional application No. 61/041,042, filed on Mar. 31, 2008.

(57) **ABSTRACT**

Embodiments disclosed herein may describe systems and methods for reducing nuisance alarms using probability and/or accuracy of a measured physiological parameter, such as the pulse rate or SpO2 measurement generated by a pulse oximeter. Embodiments may include methods for adjusting a predetermined alarm threshold based on the probability distribution of the estimated pulse rate and/or oxygen saturation of a patient's blood.



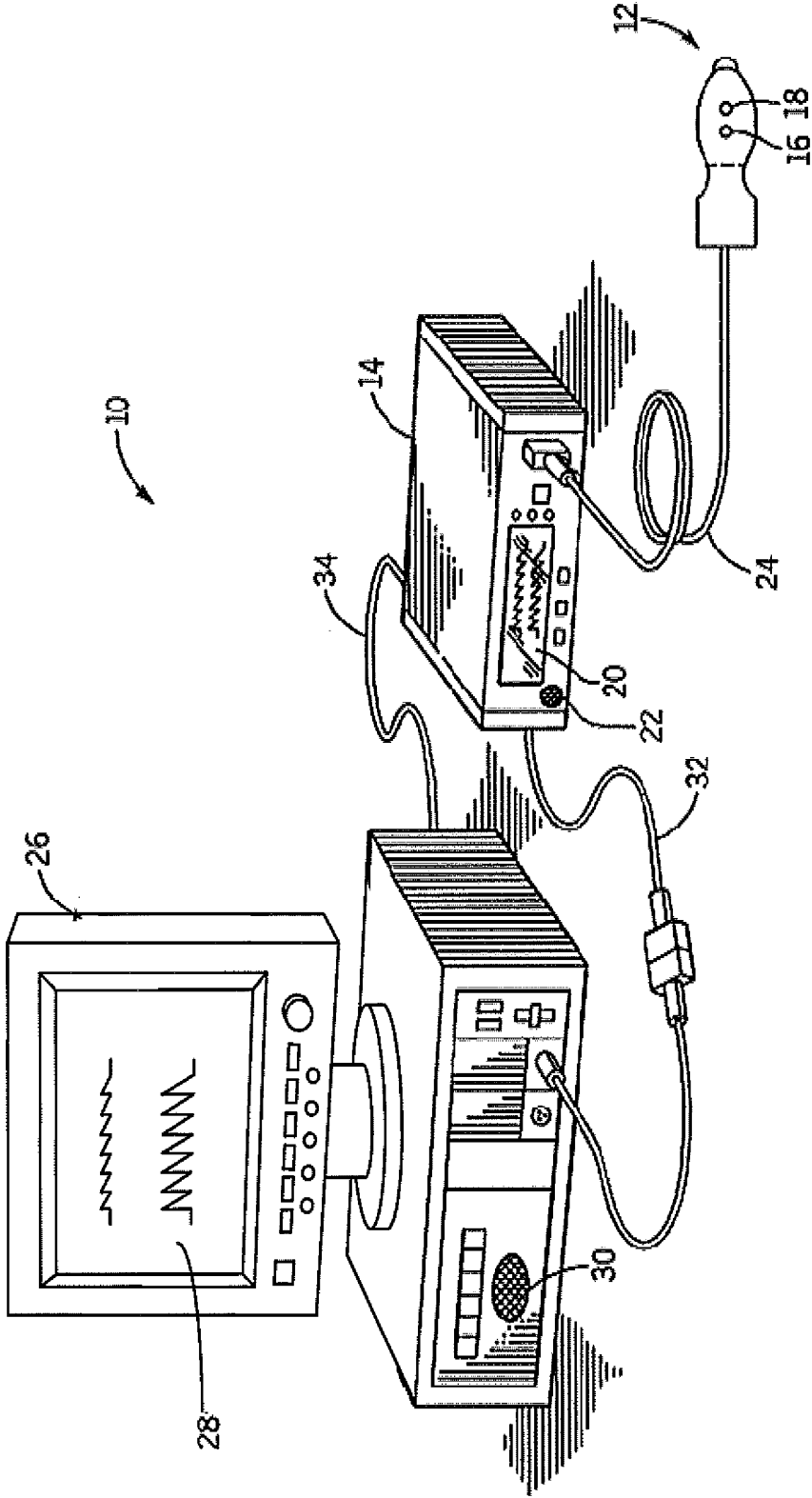


FIG.1

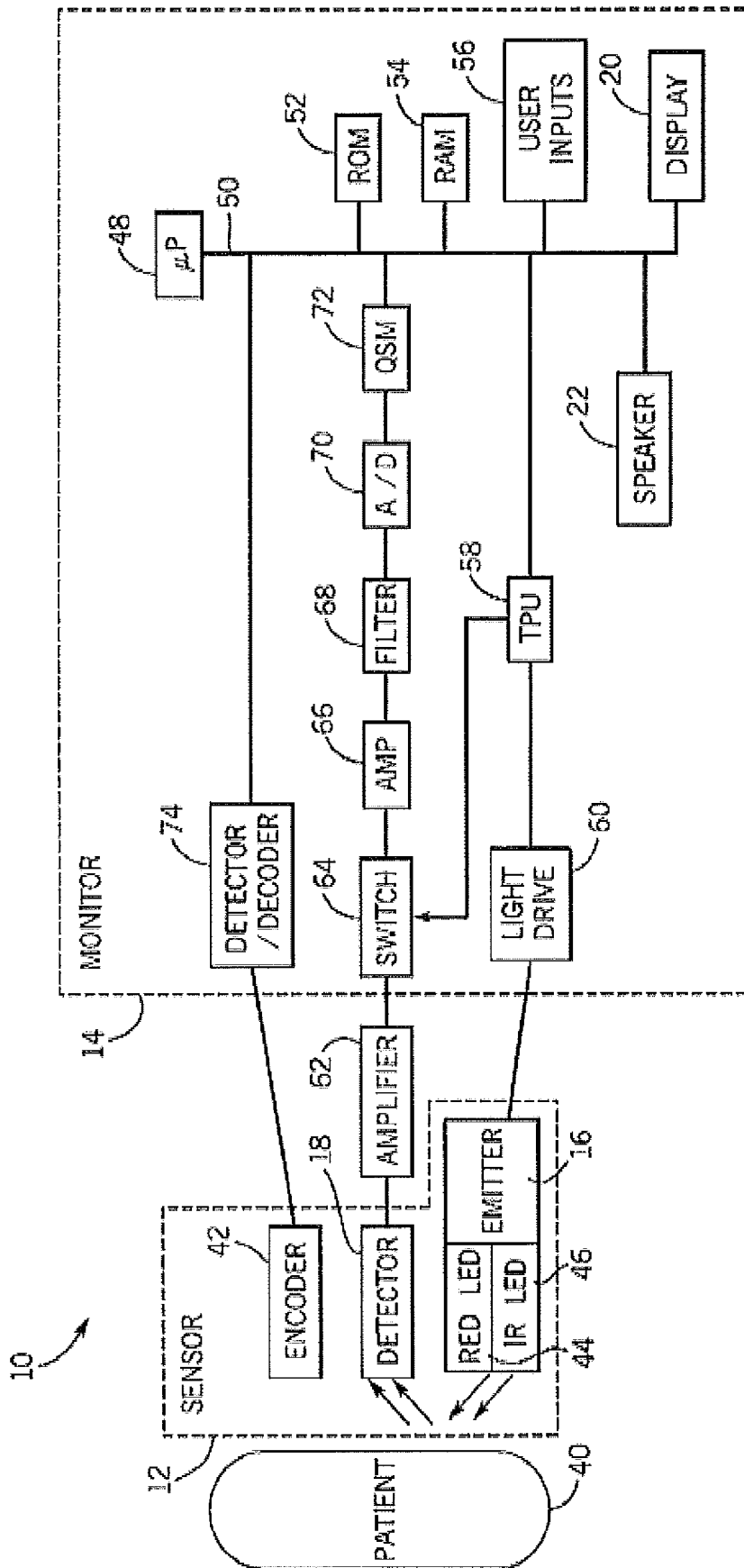


FIG. 2

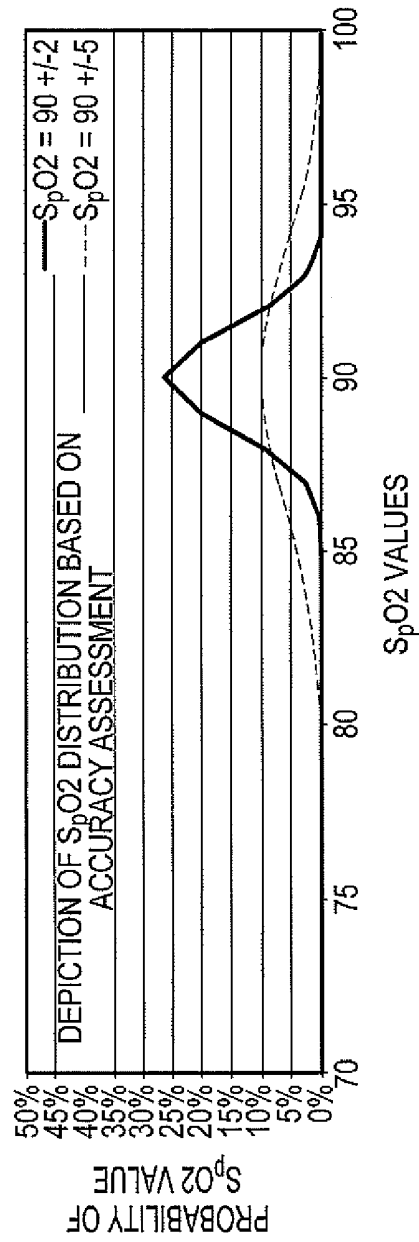


FIG. 3

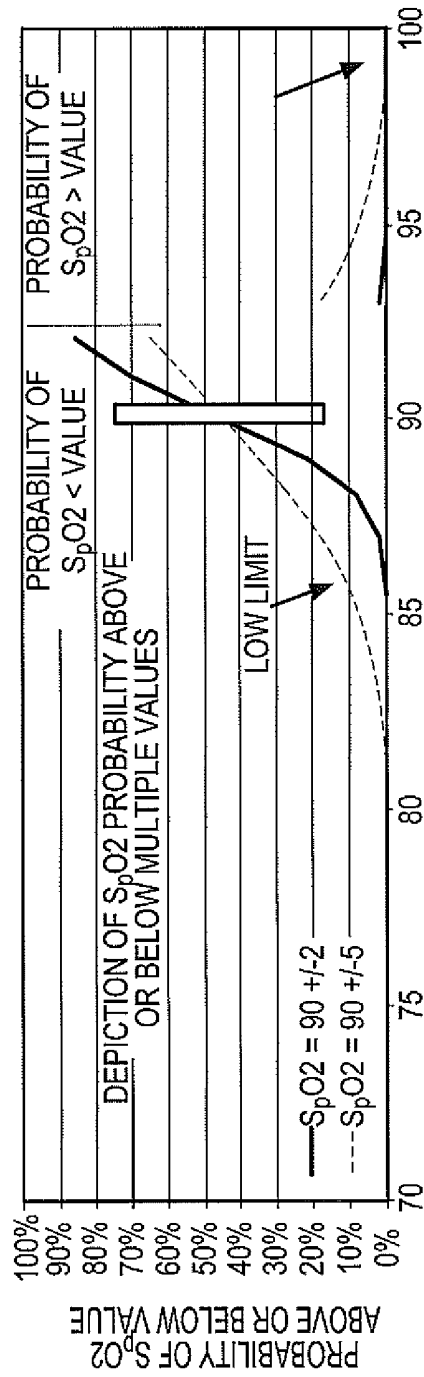


FIG. 4

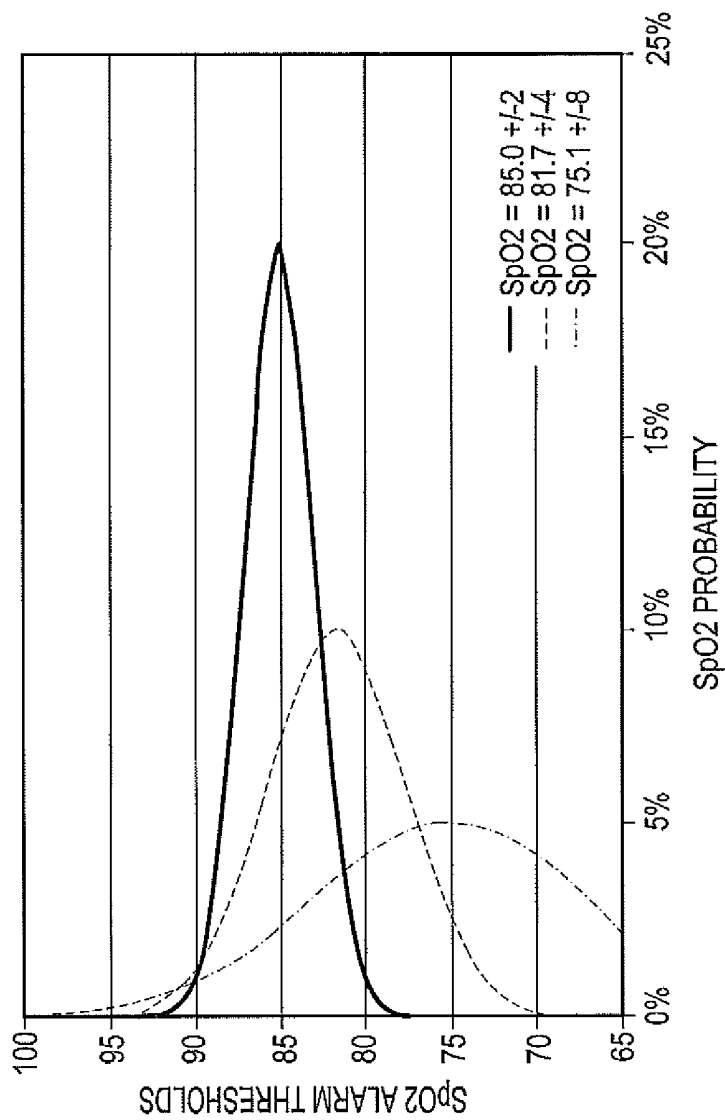


FIG. 5

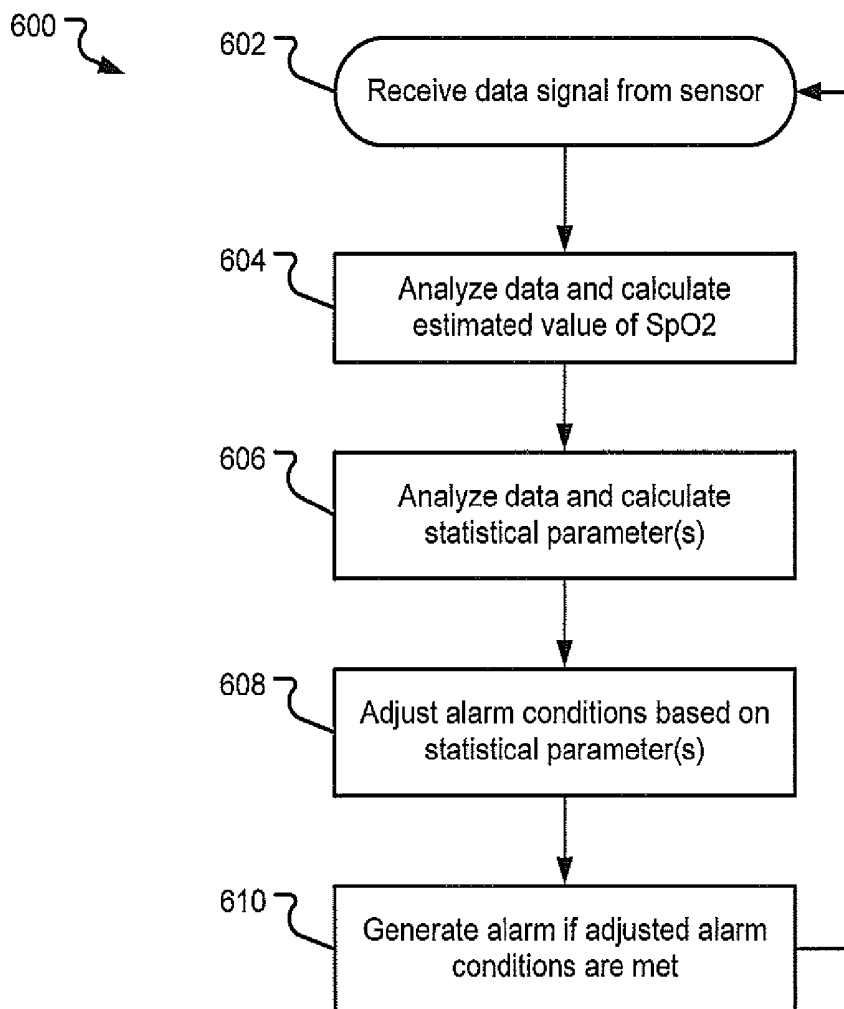


FIG. 6

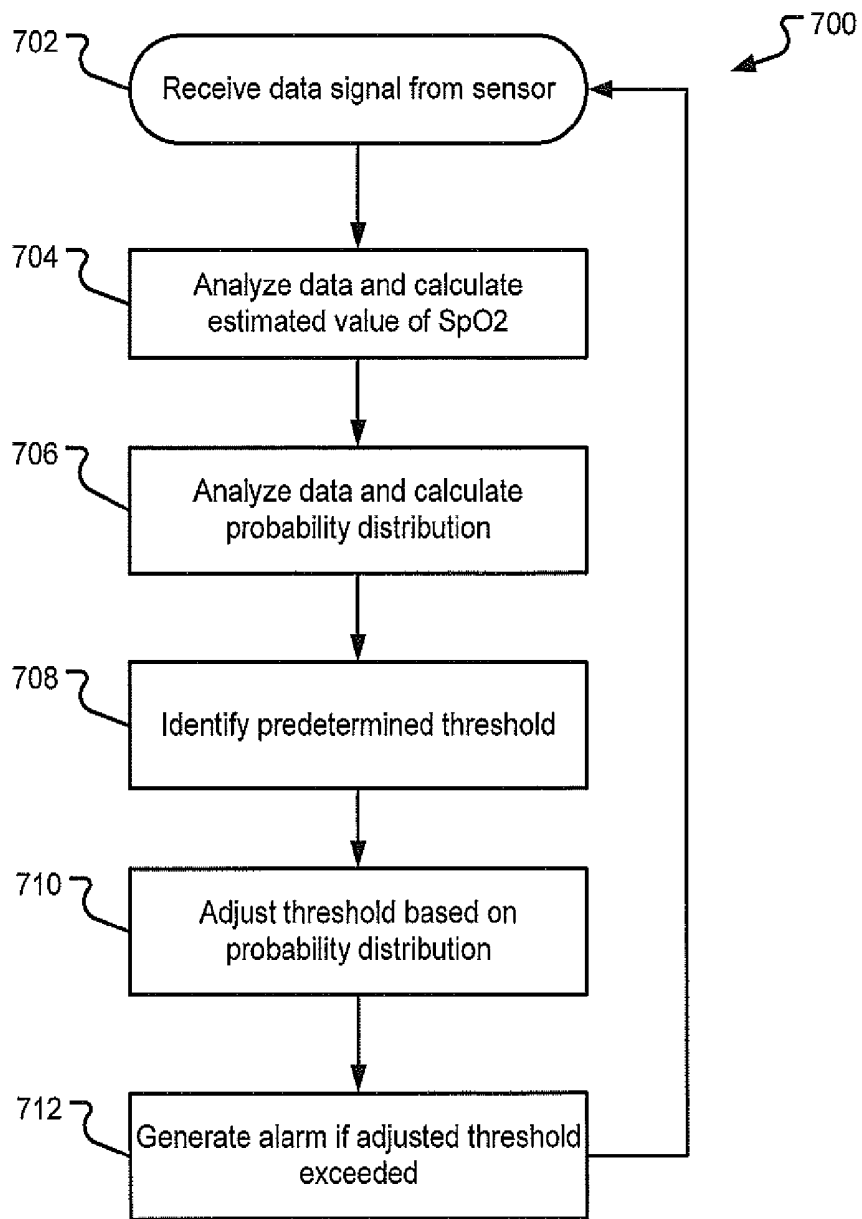


FIG. 7

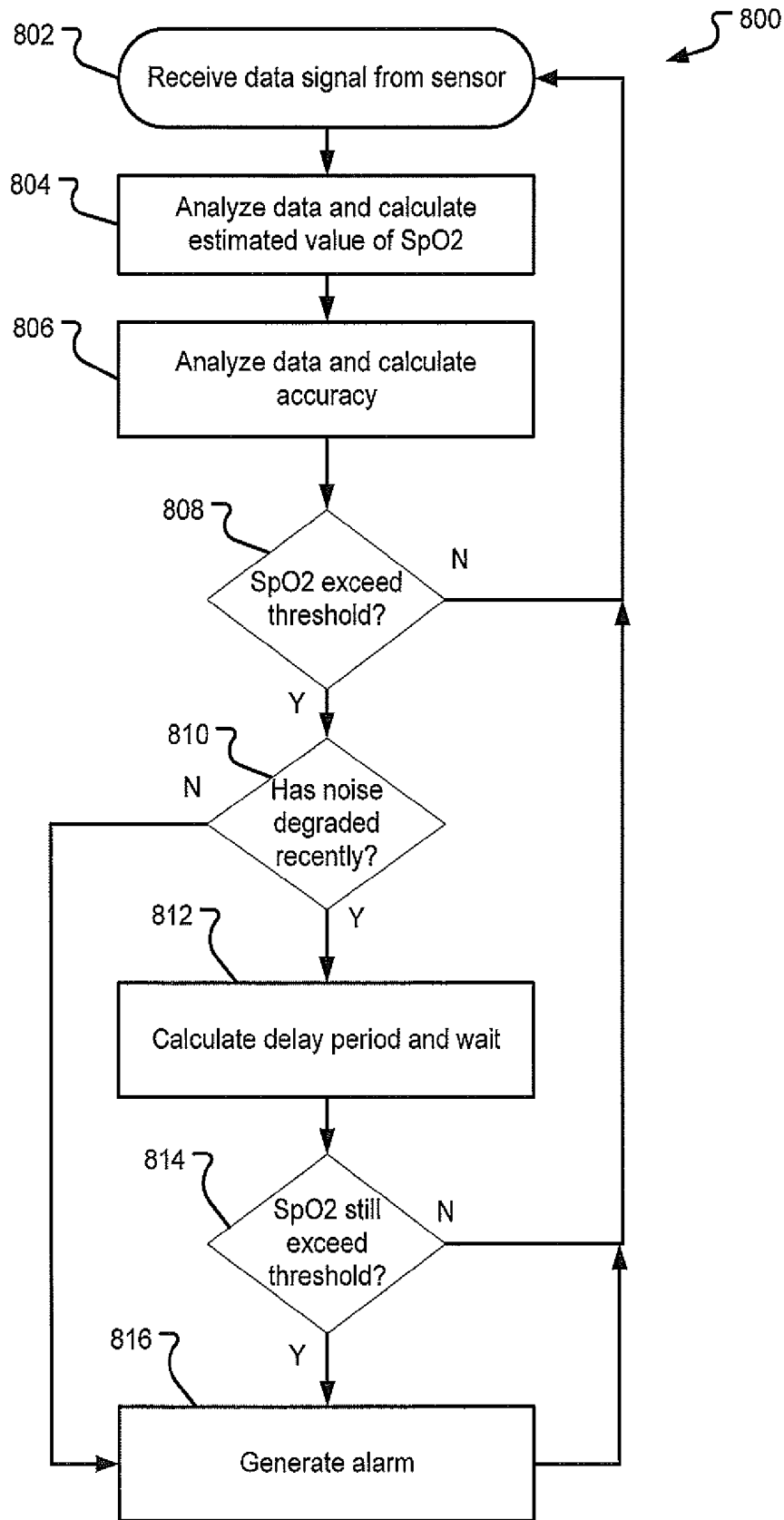


FIG. 8

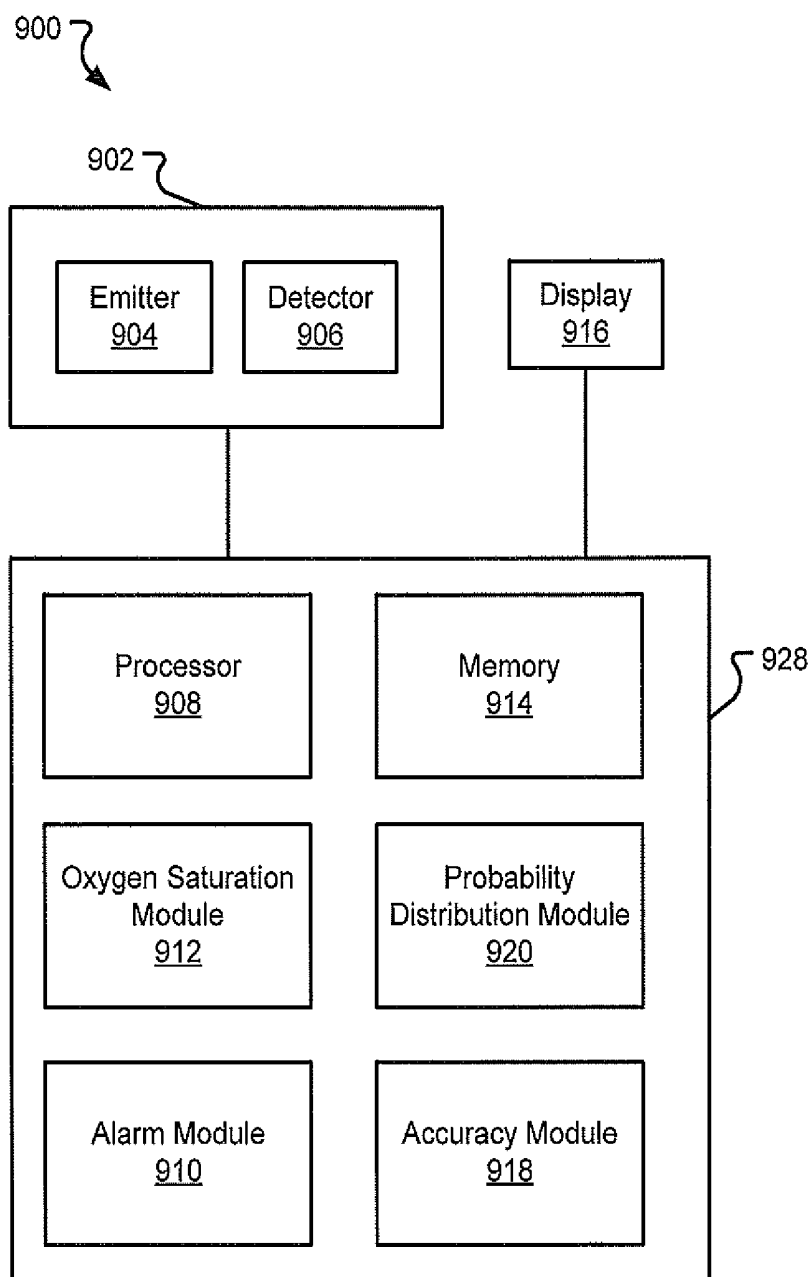


FIG. 9

REDUCING NUISANCE ALARMS

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 61/041,042, filed Mar. 31, 2008, and is incorporated herein by reference in its entirety.

BACKGROUND

[0002] In medicine, a plethysmograph is an instrument that measures physiological parameters, such as variations in the size of an organ or body part, through an analysis of the blood passing through or present in the targeted body part, or a depiction of these variations. An oximeter is an instrument that determines the oxygen saturation of the blood. One common type of oximeter is a pulse oximeter, which determines oxygen saturation by analysis of an optically sensed plethysmograph.

[0003] A pulse oximeter is a medical device that indirectly measures the oxygen saturation of a patient's blood (as opposed to measuring oxygen saturation directly by analyzing a blood sample taken from the patient) and changes in blood volume in the skin. Ancillary to the blood oxygen saturation measurement, pulse oximeters may also be used to measure the pulse rate of the patient.

[0004] A pulse oximeter typically includes a light sensor that is placed at a site on a patient, usually a fingertip, toe, forehead or earlobe, or in the case of a neonate, across a foot. Light, which may be produced by a light source integrated into the pulse oximeter, containing both red and infrared wavelengths is directed onto the skin of the patient and the light that passes through the skin is detected by the sensor. The intensity of light in each wavelength is measured by the sensor over time. The graph of light intensity versus time is referred to as the photoplethysmogram (PPG) or, more commonly, simply as the "pleth." From the waveform of the PPG, it is possible to identify the pulse rate of the patient and when each individual pulse occurs. In addition, by comparing the intensities of two wavelengths at different points in the pulse cycle, it is possible to estimate the blood oxygen saturation of hemoglobin in arterial blood. This relies on the observation that highly oxygenated blood will absorb relatively more red light and less infrared light than blood with lower oxygen saturation.

SUMMARY

[0005] This disclosure describes systems and methods for reducing nuisance alarms using probability and/or accuracy of a measured physiological parameter, such as the SpO₂ and/or pulse rate measurement generated by a pulse oximeter. As discussed in greater detail below, the disclosure describes methods for adjusting a predetermined alarm threshold based on the probability distribution of the estimated oxygen saturation of a patient's blood and further describes methods for delaying signaling an alarm based on the accuracy of the estimated oxygen saturation. In one aspect, the disclosure describes a method for generating an alarm indicating that a physiological parameter has exceeded a predetermined threshold. The method includes calculating a probability distribution of an actual value of the physiological parameter based on data received from a sensor or detector. The method then identifies the predetermined threshold associated with the physiological parameter and generates the alarm based on the predetermined threshold and the probability distribution.

[0006] In another aspect, the disclosure describes another method for generating an alarm indicating that a physiological parameter has exceeded a predetermined threshold. The method includes calculating a first estimated value of the physiological parameter and a first accuracy of the first estimated value from data. The method then determines that the first estimated value of the physiological parameter exceeds the predetermined threshold. However, instead of generating an alarm immediately, the method delays generating the alarm based on the first accuracy. The first accuracy is used to calculate a delay period after which, if the physiological parameter still exceeds the predetermined threshold, the alarm is generated.

[0007] In yet another aspect, the disclosure describes a pulse oximeter that includes an oxygen saturation module capable of calculating an estimated value of oxygen saturation of a patient's blood from information received from a sensor; an accuracy module capable of calculating the accuracy of the estimated value; and an alarm module capable of generating an alarm based on the estimated value and a predetermined alarm threshold, wherein the alarm module is capable of delaying the generation of an alarm based on the accuracy of the estimated value. The pulse oximeter may also include a probability distribution module capable of calculating a probability distribution of an actual value of the oxygen saturation of a patient's blood from information received from the sensor. In this embodiment, the alarm module is further capable of calculating an adjusted threshold based on the probability distribution and the predetermined threshold and generating an alarm based on the adjusted threshold.

[0008] The disclosure also describes a combined method for generating an alarm in which an adjusted threshold is calculated and if that threshold is exceeded, a delay period may be used to delay the generation of an alarm. For example, an embodiment of such a combined method includes the operations: a) receiving current data indicative of the physiological parameter; b) calculating an estimated value of the physiological parameter and an accuracy of the estimated value based on the current data; c) calculating a probability distribution of an actual value of the physiological parameter based on the current data; d) calculating an adjusted threshold based on the predetermined threshold and the probability distribution; e) determining that the estimated value of the physiological parameter exceeds the adjusted threshold; and f) delaying generating the alarm for at least a first time period based on a comparison of the accuracy with a predetermined accuracy range. After delaying generating the alarm for at least a first time period, operations a), b) and e) may be repeated and the alarm then generated. Alternatively, operations a)-e) may be repeated.

[0009] These and various other features as well as advantages which characterize the disclosed systems and methods will be apparent from a reading of the following detailed description and a review of the associated drawings. Additional features of the systems and methods described herein are set forth in the description which follows, and in part will be apparent from the description, or may be learned by practice of the technology. The benefits and features will be realized and attained by the structure particularly pointed out in the written description and claims as well as the appended drawings.

[0010] It is to be understood that both the foregoing general description and the following detailed description are exem-

plary and explanatory and are intended to provide further explanation of the disclosed technology as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The following drawing figures, which form a part of this application, are illustrative of disclosed technology and are not meant to limit the scope of the description in any manner, which scope shall be based on the claims appended hereto.

[0012] FIG. 1 is a perspective view of a pulse oximetry system, according to an embodiment.

[0013] FIG. 2 is a block diagram of the exemplary pulse oximetry system of FIG. 1 coupled to a patient, according to an embodiment.

[0014] FIG. 3 shows a depiction of two Gaussian bell-curves of the probability distribution in which the estimated SpO₂ value is 90%, but having accuracies of ± 2 (solid) and ± 5 (dashed) respectively, according to an embodiment.

[0015] FIG. 4 depicts the same distributions as shown in FIG. 4 plotted as the cumulative probability that the actual SpO₂ value is below or above each of the SpO₂ values on x-axis, according to an embodiment.

[0016] FIG. 5 illustrates the probability distributions of SpO₂ values equal to these alarm thresholds and associated SpO₂ accuracies (± 1 standard deviation), according to an embodiment.

[0017] FIG. 6 illustrates an embodiment of a method for generating an alarm based on the monitoring of a physiological parameter, according to an embodiment.

[0018] FIG. 7 illustrates an embodiment of a method for generating an alarm indicating that a physiological parameter has exceeded a predetermined threshold, according to an embodiment.

[0019] FIG. 8 illustrates an alternative embodiment of a method for generating an alarm indicating that a physiological parameter has exceeded a predetermined threshold, according to an embodiment.

[0020] FIG. 9 is a block diagram illustrating some of the components of a pulse oximetry system that generates an alarm based the accuracy and/or probability distribution of sensed data, according to an embodiment.

DETAILED DESCRIPTION

[0021] This disclosure describes systems and methods for reducing nuisance alarms using probability and/or accuracy of a measured physiological parameter, such as the SpO₂ and/or pulse rate measurements generated by a pulse oximeter. As discussed in greater detail below, the disclosure describes methods for adjusting a predetermined alarm threshold based on the probability distribution of the estimated oxygen saturation of a patient's blood and further describes methods for delaying signaling an alarm based on the accuracy of the estimated oxygen saturation.

[0022] Although the techniques for generating alarms based on an estimated physiological parameter introduced above and discussed in detail below may be implemented by a variety of medical devices and for a variety of physiological parameters, the present disclosure will discuss the implementation of these techniques in a pulse oximeter. Although described in detail in this context of a pulse oximeter displaying oxygen saturation measurements, the reader will understand that the systems and methods described herein may be equally adapted to the generation of alarms based on the

measurement of any physiological parameter of any patient (human or non-human) generated by any monitoring device.

[0023] FIG. 1 is a perspective view of an embodiment of a pulse oximetry system 10. The system 10 includes a sensor 12 and a pulse oximetry monitor 14. The sensor 12 includes an emitter 16 for emitting light at one or more wavelengths into a patient's tissue. A detector 18 is also provided in the sensor 12 for detecting the light originally from the emitter 16 that emanates from the patient's tissue after passing through the tissue. The emitter 16 and detector 18 may be on opposite sides of a digit such as a finger or toe, in which case the light that is emanating from the tissue has passed completely through the digit. In an alternative embodiment, the emitter 16 and detector 18 may be arranged so that light from the emitter 16 penetrates the tissue and is reflected by the tissue into the detector 18, such as a sensor designed to obtain pulse oximetry data from a patient's forehead.

[0024] The sensor may be connected to and draw its power from the monitor 14 as shown. Alternatively, the sensor may be wirelessly connected to the monitor 14 and include its own battery or similar power supply (not shown). The monitor 14 may be configured to calculate physiological parameters based on data received from the sensor 12 relating to light emission and detection. Further, the monitor 14 includes a display 20 configured to display the physiological parameters, other information about the system, and/or alarm indications. In the embodiment shown, the monitor 14 also includes a speaker 22 to provide an audible alarm in the event that the patient's physiological parameters are not within a normal range, as defined based on patient characteristics.

[0025] The sensor 12 is communicatively coupled to the monitor 14 via a cable 24. However, in other embodiments a wireless transmission device (not shown) or the like may be utilized instead of or in addition to the cable 24.

[0026] In the illustrated embodiment, the pulse oximetry system 10 also includes a multi-parameter patient monitor 26. The monitor may be cathode ray tube type, a flat panel display (as shown) such as a liquid crystal display (LCD) or a plasma display, or any other type of monitor now known or later developed. The multi-parameter patient monitor 26 may be configured to calculate physiological parameters and to provide a central display 28 for information from the monitor 14 and from other medical monitoring devices or systems (not shown). For example, the multiparameter patient monitor 26 may be configured to display an estimate of a patient's blood oxygen saturation generated by the pulse oximetry monitor 14 (referred to as an "SpO₂"), pulse rate information from the monitor 14 and blood pressure from a blood pressure monitor (not shown) on the display 28. Additionally, the multi-parameter patient monitor 26 may emit a visible or audible alarm via the display 28 or a speaker 30, respectively, if the patient's physiological parameters are found to be outside of the normal range. The monitor 14 may be communicatively coupled to the multi-parameter patient monitor 26 via a cable 32 or 34 coupled to a sensor input port or a digital communications port, respectively or may communicate wirelessly (not shown). In addition, the monitor 14 and/or the multi-parameter patient monitor 26 may be connected to a network to enable the sharing of information with servers or other workstations (not shown). The monitor 14 may be powered by a battery (not shown) or by a conventional power source such as a wall outlet.

[0027] FIG. 2 is a block diagram of the embodiment of a pulse oximetry system 10 of FIG. 1 coupled to a patient 40 in

accordance with present embodiments. Specifically, certain components of the sensor **12** and the monitor **14** are illustrated in FIG. 2. The sensor **12** includes the emitter **16**, the detector **18**, and an encoder **42**. In the embodiment shown, the emitter **16** is configured to emit at least two wavelengths of light, e.g., RED and IR, into a patient's tissue **40**. Hence, the emitter **16** may include a RED light emitting light source such as the RED light emitting diode (LED) **44** shown and an IR light emitting light source such as the IR LED **46** shown for emitting light into the patient's tissue **40** at the wavelengths used to calculate the patient's physiological parameters. In certain embodiments, the RED wavelength may be generally between about 600 nm and about 700 nm, and the IR wavelength may be between about 800 nm and about 1000 nm.

[0028] Alternative light sources may be used in other embodiments. For example, a single wide-spectrum light source may be used, and the detector **18** may be configured to detect light only at certain wavelengths. Alternatively, a third light source may be provided based on its ability to obtain an accurate signal when the starting oxygen saturation is known while consuming less power. In another example, the detector **18** may detect a wide spectrum of wavelengths of light, and the monitor **14** may process only those wavelengths which are of interest or which take the least power to detect.

[0029] It should be understood that, as used herein, the term "light" may refer to one or more of ultrasound, radio, microwave, millimeter wave, infrared, visible, ultraviolet, gamma ray, X-ray and/or other electromagnetic radiation, and may also include any wavelength within the radio, microwave, infrared, visible, ultraviolet, or X-ray spectra, and that any suitable wavelength of light may be appropriate for use with the present techniques.

[0030] In an embodiment, the detector **18** may be configured to detect the intensity of light at the RED and IR wavelengths. In operation, light enters the detector **18** after passing through the patient's tissue **40**. The detector **18** converts the intensity of the received light into an electrical signal. The light intensity is directly related to the absorbance and/or reflectance of light in the tissue **40**. That is, when more light at a certain wavelength is absorbed or reflected, less light of that wavelength is received from the tissue by the detector **18**. After converting the received light to an electrical signal, the detector **18** sends the signal to the monitor **14**, where physiological parameters may be calculated based on the absorption of the RED and IR wavelengths in the patient's tissue **40**. An examples of devices configured to perform such calculations are the Model N600 and N600x pulse oximeters available from Nellcor Puritan Bennett LLC.

[0031] In an embodiment, the encoder **42** may contain information about the sensor **12**, such as what type of sensor it is (e.g., whether the sensor is intended for placement on a forehead or digit) and the wavelengths of light emitted by the emitter **16**. This information may be used by the monitor **14** to select appropriate algorithms, lookup tables and/or calibration coefficients stored in the monitor **14** for calculating the patient's physiological parameters. In addition the encoder **42** may include information such as coefficients utilized for the calculation of SpO₂. All information in the encoder **42** may be digitally encoded to insure accuracy, among other considerations.

[0032] In addition, the encoder **42** may contain information specific to the patient **40**, such as, for example, the patient's age, weight, and diagnosis. This information may allow the monitor **14** to determine patient-specific threshold ranges in

which the patient's physiological parameter measurements should fall and to enable or disable additional physiological parameter algorithms. The encoder **42** may, for instance, be a coded resistor which stores values corresponding to the type of the sensor **12**, the wavelengths of light emitted by the emitter **16**, and/or the patient's characteristics. These coded values may be communicated to the monitor **14**, which determines how to calculate the patient's physiological parameters and alarm threshold ranges. In another embodiment, the encoder **42** may include a memory on which one or more of the following information may be stored for communication to the monitor **14**: the type of the sensor **12**; the wavelengths of light emitted by the emitter **16**; the proper calibration coefficients and/or algorithms to be used for calculating the patient's physiological parameters and/or alarm threshold values; the patient characteristics to be used for calculating the alarm threshold values; and the patient-specific threshold values to be used for monitoring the physiological parameters.

[0033] Signals from the detector **18** and the encoder **42** may be transmitted to the monitor **14**. In the embodiment shown, the monitor **14** includes a general-purpose microprocessor **48** connected to an internal bus **50**. The microprocessor **48** is adapted to execute software, which may include an operating system and one or more applications, as part of performing the functions described herein. Also connected to the bus **50** are a read-only memory (ROM) **52**, a random access memory (RAM) **54**, user inputs **56**, the display **20**, and the speaker **22**.

[0034] The RAM **54** and ROM **52** are illustrated by way of example, and not limitation. Any computer-readable media may be used in the system for data storage. Computer-readable media are capable of storing information that can be interpreted by the microprocessor **48**. This information may be data or may take the form of computer-executable instructions, such as software applications, that cause the microprocessor to perform certain functions and/or computer-implemented methods. Depending on the embodiment, such computer-readable media may comprise computer storage media and communication media. Computer storage media includes volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage of information such as computer-readable instructions, data structures, program modules or other data. Computer storage media includes, but is not limited to, RAM, ROM, EPROM, EEPROM, flash memory or other solid state memory technology, CD-ROM, DVD, or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by components of the system.

[0035] In the embodiment shown, a time processing unit (TPU) **58** provides timing control signals to a light drive circuitry **60** which controls when the emitter **16** is illuminated and multiplexed timing for the RED LED **44** and the IR LED **46**. The TPU **58** also controls the gating-in of signals from detector **18** through an amplifier **62** and a switching circuit **64**. These signals are sampled at the proper time, depending upon which light source is illuminated. The received signal from the detector **18** may be passed through an amplifier **66**, a low pass filter **68**, and an analog-to-digital converter **70**. The digital data may then be stored in a queued serial module (QSM) **72** (or buffer) for later downloading to the RAM **54** as the QSM **72** fills up. In one embodiment, there may be mul-

tiple separate parallel paths having the amplifier **66**, the filter **68**, and the A/D converter **70** for multiple light wavelengths or spectra received.

[0036] The microprocessor **48** may determine the patient's physiological parameters, such as SpO₂ and pulse rate, using various algorithms and/or look-up tables based on the value of the received signals and/or data corresponding to the light received by the detector **18**. Signals corresponding to information about the patient **40**, and particularly about the intensity of light emanating from a patient's tissue over time, may be transmitted from the encoder **42** to a decoder **74**. These signals may include, for example, encoded information relating to patient characteristics. The decoder **74** may translate these signals to enable the microprocessor to determine the thresholds based on algorithms or look-up tables stored in the ROM **52**. The encoder **42** may also contain the patient-specific alarm thresholds, for example, if the alarm values are determined on a workstation separate from the monitor **14**. The user inputs **56** may also be used to enter information about the patient, such as age, weight, height, diagnosis, medications, treatments, and so forth. In certain embodiments, the display **20** may exhibit a list of values which may generally apply to the patient, such as, for example, age ranges or medication families, which the user may select using the user inputs **56**. The microprocessor **48** may then determine the proper thresholds using the user input data and algorithms stored in the ROM **52**. The patient-specific thresholds may be stored on the RAM **54** for comparison to measured physiological parameters.

[0037] The embodiments described herein relate to adjusting the conditions under which an alarm is generated based on one or more statistical parameters of an estimated physiological parameter value. Statistical parameters associated with the physiological parameter include parameters related to the accuracy of the estimated value such as error estimates and probability distributions of the data.

[0038] The following FIGS. **3** and **4** illustrate how different accuracies of estimates of SpO₂ values affect the probability distribution of the estimated values, according to various embodiments. FIG. **3** shows a depiction of two Gaussian bell-curves of the probability distribution in which the estimated SpO₂ value is 90%, but having accuracies of +/-2% (solid) and +/-5% (dashed) respectively. As shown in FIG. **3**, the difference in accuracy has a large effect on the probability distribution and the probability that the actual SpO₂ value is above or below any particular value. For example, if the accuracy is +/-2%, there is nearly a 100% chance that the actual value of the SpO₂ value is within the interval of 85% to 95%. The same can not be said of the data having an accuracy of +/-5%.

[0039] FIG. **4** depicts the same two contrasting examples, but shows the cumulative probability that the actual SpO₂ value is below or above each of the SpO₂ values on x-axis. For convenience, only a portion of two different sets of curves are displayed on FIG. **4**. Midway between the high saturation alarm threshold (100% saturation) and low saturation alarm threshold (85% saturation), the curves switch from "probability of SpO₂ below value" curves at each accuracy to "probability of SpO₂ above value" curves at each accuracy. If all of the "below value" curves were displayed, they would start to level off and end at the point 100% probability/100% saturation. The "probability of SpO₂ above value" curves would be seen to continue to rise and then level off, approaching 100% probability to end at the point 100% probability/0% saturation.

It should also be pointed out that at the SpO₂ value of 90% the probability curves converge.

[0040] This disclosure describes systems and methods for using accuracy and/or probability to reduce the number of nuisance alarms generated due to high noise in the data used to estimate physiological parameters. In an embodiment, the oximeter would adapt its alarm thresholds to assure that the probability of SpO₂ being outside the user-set limits was high before an alarm would be generated.

[0041] In order to illustrate this, consider the following three examples of estimated values of SpO₂ with different accuracies and probability distributions. The first example is a simple case in which no noise is measured and the sensor has a presumed accuracy (SpO₂-SaO₂) of +/-2% (1 standard deviation) due to physio-optics. Assuming that SpO₂-SaO₂ errors have a Gaussian zero-mean distribution, an SpO₂ of 85% really means that there is a 50% probability of SaO₂<85%, an 83% probability of SaO₂<87%, a 95% probability of SaO₂<88.3%, a 97.5% probability of SaO₂<89%, etc.

[0042] In the second example, there is noise in the data, perhaps due to motion artifact, and the current level of said noise corresponds to a somewhat degraded accuracy of +/-4% of oxygen saturation. In this situation, that same SpO₂ of 85% means that there is a 50% probability of SaO₂<85%, an 83% probability of SaO₂<89%, a 95% probability of SaO₂<91.6%, a 97.5% probability of SaO₂<93%, etc.

[0043] The third example is an extremely challenging case in which the accuracy is degraded to +/-8%, in which case an SpO₂ of 85% means that there is a 50% probability of SaO₂<85%, an 83% probability of SaO₂<93%, a 95% probability of SaO₂<98.2%, etc.

[0044] In embodiments described herein, different alarm thresholds are used to compensate for the different noise in order to reduce the instances of nuisance alarms due to noise. In an embodiment, this is done by designing the oximeter to alarm when the SpO₂, together with said noise metrics as indicated by the probability distribution, indicates a 95% probability that the SaO₂ is lower than 88.3% (set low saturation alarm threshold of 85 plus a 3.3% margin to reflect the probability distribution associated with a nominal 2% accuracy). In the first example above, the oximeter would alarm for estimated values of SpO₂<85%, but in the 2nd noisier example, it would alarm only for estimated values of SpO₂<81.7%, and in the third example this probability-enhanced oximeter would alarm only for estimated values of SpO₂<75.1%.

[0045] FIG. **5** illustrates the probability distributions of SpO₂ values equal to these alarm thresholds and associated SpO₂ accuracies (+/-1 standard deviation), according to an embodiment. In each case, the integral under the curve and above the SpO₂ alarm threshold of 88.3% (85%+3.3% margin) is 5%, although probability distributions differ substantially. This means that the probability that SaO₂ is NOT under this 88.3% threshold (probability of false alarm) is only 5% in each case. In contrast, if the low SpO₂ alarm limit were to remain fixed at 85%, then in the +/-8 case, an SpO₂ at this fixed limit of 85% would be associated with about a 40% probability of SaO₂>88.3%, with a corresponding likelihood of false alarms.

[0046] In an alternative embodiment, at times when said noise metrics increase suddenly and dramatically, probability theory may be used to hold the older and presumably more accurate SpO₂ value, instead of displaying the newer but less

accurate value, for some period of time determined based on the noise. For example, if an increase in said noise metrics indicates that SpO₂ accuracy has just degraded from +/-2 points to +/-8 points, the oximeter might be designed to hold the old SpO₂ value unless the new SpO₂ value has changed by 8 points or until the noise metrics go back down. Alternatively, it could assume that the accuracy of the held SpO₂ value might degrade at some fixed rate, such as for example 0.5% per second, and therefore hold the old SpO₂ value for no longer than $8.0/0.5=16$ seconds.

[0047] Either the dynamic alarm threshold or holding scheme based on noise (signal quality) metrics in combination with probability significantly reduces nuisance alarms. Furthermore, a time-value integral may be used to reduce nuisance alarms. This method may integrate at a rate that was modified (reduced) by the probability that the estimated value exceeded the alarm threshold. It should be noted that, to the extent that the challenging conditions that degrade oximeter accuracy are brief in duration, modifying the oximeter's behavior to assure a higher probability that the alarms are real should preserve patient safety, as motion artifact generally biases SpO₂ low. Similarly, high SpO₂ alarms, to the extent that they are reduced or delayed in neonates, will be less urgent than low SpO₂ alarms, as they impact longer-term development rather than the body's ability to meet current metabolic demands.

[0048] FIG. 6 illustrates an embodiment of a method for generating an alarm based on the monitoring of a physiological parameter. In the embodiment shown, an alarm will be generated when the monitored physiological parameter is determined to meet an alarm condition. For the purposes of this disclosure, the alarm condition will be discussed in terms of a value of some parameter exceeding a threshold value. One skilled in the art will understand that when a value is said to "exceed a threshold" it means that the value is within a range of values for which an alarm should be generated; the range of values being separated by the threshold from an acceptable range of values for which an alarm will not be generated. Thus, the term "exceeding a threshold" covers both the instance in which a measured or calculated value is lower than a lower threshold of an acceptable range and the instance in which the measured or calculated value is higher than an upper threshold of the acceptable range.

[0049] In the method 600, information and/or data are received from a data source in a receive data operation 602. In the context of the pulse oximeter described above, the receive data operation 602 includes receiving an electronic signal from a sensor indicative of the light received by the detector and processing that signal to generate data that can be processed by the microprocessor. In an embodiment, the data, or samples thereof, may be temporarily stored in a buffer to allow multiple analyses of the same data. In addition, some or all of the data may be retained for some period of time for subsequent processing at a later time.

[0050] The received data are analyzed to generate an estimated value of the physiological parameter that is being measured in the generate estimate operation 604. In the context of a pulse oximeter, one physiological parameter estimated is the oxygen saturation of the blood of the patient. In an embodiment, the oxygen saturation of the patient's blood is calculated based on the most recent data received from the sensor in order to provide a current measurement of the oxygen saturation. The estimated value of the oxygen saturation may be generated by a sophisticated algorithm and may uti-

lize a significant amount of processor cycles and signal processing hardware (e.g., filters, amplifiers, high-resolution digital to analog converters, etc.). In an embodiment, generation of the estimated value of the oxygen saturation may use statistical information derived from data in the generation of the final estimate. An example of generating an estimated value for oxygen saturation is described in the commonly-assigned U.S. Pat. No. 6,836,679, titled "Method and apparatus for estimating physiological parameters using model-based adaptive filtering". Other methods for generating the estimated value are known in the art and any suitable method, now known or later developed, may be used.

[0051] In addition to the generation of the estimated value, one or more statistical parameters describing the data are calculated in a calculate statistical parameters operation 606. In the embodiment shown, the calculate statistical parameters operation 606 is performed after the generate estimate operation 604. In alternative embodiments, the statistical parameter (s) may be calculated before, concurrently with or as part of the generate estimate operation 604. In yet another embodiment, the calculate statistical parameters operation 606 may be performed only if the estimated value exceeds a predetermined (i.e., non-adjusted) alarm condition.

[0052] Furthermore, the statistical parameter(s) calculated may or may not be used in the calculation of the estimated value and may or may not be calculated by the same module, software application or component of the pulse oximeter that calculates the estimated value. For example, in an embodiment, a single software application may be utilized to calculate all parameters. In an alternative embodiment, separate and independent software modules or system components may be used to calculate each parameter described herein.

[0053] One statistical parameter that may be determined from the data is a single value representing the accuracy of the estimated value. Accuracy is a well known statistical term of art referring how close an estimated value is likely to be to the actual value based on the errors and limitations of the measurement process and the data obtained. Accuracy can be quantified by many different techniques, including reporting a single value that is a numerical representation of the accuracy of the estimated value. For example, the accuracy of an estimated value of oxygen saturation may be determined by calculating a standard deviation of the physiological data from which the estimated value is determined; the smaller the standard deviation, the greater the accuracy of the estimated value. Thus, the standard deviation itself may be displayed as a parameter representing the accuracy of the estimated value.

[0054] In an alternative embodiment, the accuracy an estimated value may be further determined by more complicated calculations involving a detailed analysis of data received from the sensor. A number of data characteristics potentially indicative of the accuracy of pulse oximetry calculations (i.e. oxygen saturation and pulse rate) are known to those skilled in the art. Examples include pulse amplitude, pulse shape, correlation of the IR and Red photoplethysmograph, as well as temporal variations in any of these characteristics. Those skilled in the art of pulse oximeter design will also recognize that multiple data characteristics may be combined empirically in order to more accurately reflect the accuracy of a pulse oximetry system under challenging conditions that may be created experimentally or encountered in clinical usage. Those skilled in the art will also recognize that in order to design such an empirical combination, the accuracy of oxygen saturation and pulse rate measurements under challeng-

ing conditions may be independently assessed by techniques such as arterial blood sampling, ECG monitoring, or use of a second pulse oximeter at a different tissue site. Such empirical combinations of data characteristics reflective of the accuracy of a physiological parameter may involve linear or non-linear combinations, together with one or more thresholds, limits, coefficients, exponents, etc. The process of defining such an empirical combination of data characteristics, including gathering oximetry data representative of a variety of challenging conditions, may be time-consuming and complex, but would nevertheless be a routine undertaking for one of ordinary skill in the art.

[0055] Statistical parameters calculated in the calculate statistical parameters operation **606** may also include parameters based on probability distribution of the data. This may include selecting a probability profile (e.g., Gaussian) and matching the data to the profile in order to determine the statistical parameters.

[0056] An example of one such probability distribution statistical parameter is a confidence interval. A confidence interval is an interval estimate of a parameter. The confidence interval represents a range of values within which the actual value of the parameter is expected to occur with a high probability, referred to as the confidence level. For example, a confidence interval may be a range within which the actual value is expected to be with a 95% certainty. An alternative way of stating this is that there is a 95% probability that the actual value will be within the confidence interval.

[0057] When calculating confidence intervals, the confidence level to be used is identified as part of the operation **606**. The confidence level may be predetermined by the system manufacturer, selected automatically by the system, or may be adjustable by the user of the system. For example, in an embodiment a system may use a 95% confidence level for all confidence interval calculations unless a user has specifically selected a different confidence level. The system may facilitate user selection of confidence levels by providing an interface, such as a confidence level selection menu, through which the user can select a confidence level (e.g., 90%, 95%, 97.5%, 98%, 99%, etc.) or enter a user-designated confidence level. Confidence levels received by the system from a user through such an interface may be stored in memory on the system and also may be displayed on the display GUI as described in greater detail below.

[0058] Confidence intervals may also be represented as confidence limits, such as an upper confidence limit and a lower confidence limit. A confidence limit is an interval estimate of a parameter indicating the probability that the actual value is above (or below) the limit. For the purposes of this disclosure, the terms “upper confidence limit” or “upper limit” refers to the upper limit of any confidence interval (including a confidence interval with no lower limit) and, likewise, the term “lower confidence limit” will be used when referring to the lower limit of any confidence interval with a lower limit. The relationship between the estimated value, its accuracy estimate, and its confidence interval depends on the probability distribution function of the measurement errors. Measurement errors are often presumed to have a Gaussian probability distribution, characterized by the “bell-curve” function $e^{-\frac{x^2}{2\sigma^2}}$, where σ denotes the standard deviation of the measurement errors (i.e. the accuracy). Assuming a Gaussian error distribution, an oxygen saturation estimate of 92% with an accuracy, σ , of 3% will have a 95% confidence interval of

92%±6%, or 86%-98%, because 95% of the area under the curve defined by a Gaussian error distribution falls within the range of $\pm 2\sigma$.

[0059] Confidence intervals, confidence limits and accuracy calculations are examples of statistical parameters that may be calculated by the method **600**. The reader will understand that any other statistical parameter related to any aspect of the data (e.g., signal strength, noise, harmonics, etc.) may be calculated as part of the calculate statistical parameter operation **606**.

[0060] After the calculations have been made, an alarm condition adjustment operation **608** is performed. In the alarm condition adjustment operation **608** an adjusted alarm condition is determined based on a predetermined alarm condition. In an embodiment, the predetermined alarm condition may be defined by a predetermined acceptable range that is defined by two predetermined thresholds. The predetermined thresholds may be user-selected thresholds or thresholds provided by the device manufacturer. The predetermined thresholds may be provided in terms of estimated value thresholds or in some other form, such as confidence limit thresholds.

[0061] The alarm condition adjustment operation **608** retrieves or otherwise accesses the predetermined alarm condition and then adjusts it, if necessary, based on the statistical parameters. In an embodiment, the predetermined alarm condition may be adjusted based on accuracy, probability distribution, or any other statistical parameter. The adjustment may include changing the value of a predetermined threshold (e.g., raising the threshold or lowering it), changing the type of threshold (e.g., changing a predetermined estimated value threshold to a threshold for a confidence limit) and/or changing a temporal condition (such as a delay period) that must be met in addition to some other condition such as the estimated value exceeding a threshold.

[0062] In the embodiment shown, the alarm condition adjustment operation **608** is illustrated as being performed after calculation of the estimated value and statistical parameters. In an alternative embodiment, the alarm condition adjustment operation **608** may be performed concurrently with or as part of the calculate statistical parameter(s) operation **606**. In yet another embodiment, the alarm condition adjustment operation **608** may be performed only if the estimated value exceeds the non-adjusted alarm condition.

[0063] The alarm condition adjustment operation **608** may be omitted in an embodiment in which the predetermined threshold is defined in terms of a confidence level rather than in terms of an estimated value. For example, in an embodiment a predetermined threshold may be defined as a 95% confidence limit threshold of $\text{SaO}_2 \geq 85\%$ oxygen saturation. In this example, if the data indicate that there is 95% probability that the actual $\text{SaO}_2 \geq 83\%$, the threshold is exceeded and the alarm should be generated. In this embodiment, the alarm is generated based on the predetermined threshold and the probability distribution without the need to adjust the alarm condition.

[0064] A generate alarm operation **610** is then performed in which the adjusted alarm condition is used to determine if an alarm should be generated (i.e., an audio alarm should be sounded, a visual alarm should be displayed, an alarm notification should be sent, etc.). The generate alarm operation **610** includes testing the adjusted alarm condition against the current data and calculated values in order to determine if the adjusted alarm condition has been met. If the condition is met, an alarm is generated. An alarm may be generated until the

measured data indicate that the adjusted alarm condition is no longer met, until a user resets the device, or until some other interrupt occurs.

[0065] In an embodiment, the adjusted alarm condition may include an adjusted threshold for a specific parameter (e.g., an accuracy, confidence interval, estimated value, etc.). The generate alarm operation **610** compares the adjusted threshold to the appropriate parameter to determine if the parameter exceeds the adjusted threshold (i.e., is outside of the acceptable range). If so, the alarm is generated. In an alternative embodiment, an adjusted alarm condition may include a temporal requirement (e.g., the estimated value must exceed the threshold for some period of time determined based on a statistical parameter) before the adjusted alarm condition is considered to be met. These and other embodiments of the adjusted alarm condition are discussed in greater detail below.

[0066] In an embodiment, the method **600** is performed continuously, which is illustrated by the flow returning to the receive data operation **602**. That is, data is continually being received, calculations are made from the most recent data and the alarm conditions are continuously tested. Depending on the implementation, this can be done in a true continuous process or can be done by periodically repeating the operations in FIG. 6 for batches of data received and revising the displayed values after each repetition. For example, the method **600** may be performed twice every second.

[0067] FIG. 7 illustrates an embodiment of a method for generating an alarm indicating that a physiological parameter has exceeded a predetermined threshold. In the embodiment shown, the method starts with the collection of data indicative of the physiological parameter from the patient in a data collection operation **702**. In the context of a pulse oximeter, the data is received from a sensor and may take the form of a stream of data indicative of different light intensities measured by a detector as described above.

[0068] Next, a calculate estimated value operation **704** is performed. The estimated value of the physiological parameter being measured is calculated from the data received.

[0069] In addition, a calculate probability distribution operation **706** is performed. In an embodiment, this operation **706** calculates a probability distribution of the actual value of the physiological parameter based on the data received. As discussed above, the calculate distribution operation **706** may include calculating an accuracy of the estimated value. It may also include calculating a confidence interval or a confidence limit based on a predetermined confidence level, which may be retrieved from memory as part of the operation. The confidence level may be predetermined by the manufacturer (e.g., selected from 99%, 98%, 97.5%, 95%, 90%) or may be a user-selected value.

[0070] The calculate probability distribution operation **706** may be performed independently of the calculate estimated value operation **704** as illustrated. Alternatively, the two operations may be combined into a single operation. In addition, as discussed above the calculate probability distribution operation **706** may be performed automatically or only after a predetermined alarm condition has been met.

[0071] In the embodiment shown, a predetermined threshold is determined in an identify threshold operation **708**. In the operation **708**, a threshold may be retrieved from memory accessible by the system. This may include determining which predetermined threshold should be used based on other

information such as patient characteristics, physiological parameter being monitored, etc.

[0072] A calculate adjusted threshold operation **710** is then performed. In the calculate adjusted threshold operation **710** the predetermined threshold is modified based on the probability distribution. In the embodiment shown, the predetermined threshold may be provided in terms of an estimated value threshold and the adjustment operation **710** includes calculating an adjusted estimated value threshold based on the probability distribution.

[0073] For example, in an embodiment the predetermined threshold may be a lower threshold limit of $\text{SpO}_2=85\%$ oxygen saturation. Due to an increased amount of noise (e.g., resulting an accuracy of ± 4 as described above) that changes the probability distribution of the estimated SpO_2 values, the predetermined threshold may be lowered to generate an adjusted threshold of $\text{SpO}_2=81.7\%$. This results in an adjusted threshold for SpO_2 that maintains the $\leq 5\%$ probability of a false alarm at the decreased accuracy.

[0074] A generate alarm operation **712** is then performed in which the adjusted threshold is used to determine if an alarm should be generated (i.e., an audio alarm should be sounded, a visual alarm should be displayed, an alarm notification should be sent, etc.). The generate alarm operation **712** includes testing the adjusted threshold against the current data and calculated values in order to determine if the adjusted alarm condition has been met. If the threshold is exceeded, an alarm is generated.

[0075] As part of testing to determine if the adjusted alarm condition is met, the generate alarm operation **712** may compare the adjusted threshold to the appropriate parameter to determine if the parameter exceeds the adjusted threshold (i.e., is outside of the acceptable range). If so, the alarm is generated.

[0076] In an embodiment, the method **700** is performed continuously, which is illustrated by the flow returning to the receive data operation **702**. That is, data is continually being received, calculations are made from the most recent data and the displayed values are continuously updated. Depending on the implementation, this can be done in a true continuous process or can be done by periodically repeating the operations in FIG. 7 for batches of data received and revising the displayed values after each repetition.

[0077] FIG. 8 illustrates an alternative embodiment of a method for generating an alarm indicating that a physiological parameter has exceeded a predetermined threshold. In the embodiment shown, the method starts with the collection of data indicative of the physiological parameter from the patient in a data collection operation **802**. In the context of a pulse oximeter, the data are received from a sensor and may take the form of a stream of data indicative of different light intensities measured by a detector as described above.

[0078] Next, a calculate estimated value operation **804** is performed. The estimated value of the physiological parameter being measured is calculated from the data received.

[0079] In addition, a calculate accuracy operation **806** is performed. In an embodiment, this operation **806** calculates the accuracy of the estimated value of the SpO_2 based on the data received. The calculate accuracy operation **806** may be performed independently of the calculate estimated value operation **804** as illustrated. Alternatively, the two operations may be combined into a single operation. In addition, as

discussed above the calculate accuracy operation **806** may be performed automatically or only after a predetermined alarm condition has been met.

[**0080**] The method further performs a first determination operation **808** that determines if the predetermined alarm threshold has been exceeded. In the embodiment shown, this includes retrieving a predetermined SpO₂ threshold and comparing the threshold with the current estimated value of SpO₂. Alternatively, a different type of threshold (e.g., a confidence threshold or an adjusted threshold) may be retrieved as described above. If the threshold has not been exceeded, the normal monitoring and analysis continues as illustrated by the operational flow returning to the receive data operation **802**.

[**0081**] If the threshold has been exceeded, then the accuracy is evaluated in a second determination operation **810**. The purpose of the second determination operation **810** is to determine if the accuracy of the measurements and calculations being performed has recently degraded, thus indicating that the threshold may have been exceeded not because of a change in the physiological parameter but rather due to inaccurate estimation. In an embodiment, the second determination operation **810** compares the calculated accuracy of the current estimated value to one or more recently calculated accuracies. If there has not been a significant change between the current accuracy and the previous accuracy data (e.g., a difference of $>+/-1%$ oxygen saturation, $>+/-2%$, $>+/-3%$ or $>+/-4%$ between the current and recent accuracies, for example), then the method **800** causes the alarm to be generated in a generate alarm operation **816**. In order to facilitate this analysis, recent values of accuracies may be stored in temporary memory for the purpose of comparing them with accuracies calculated in the future. But if the accuracy has changed enough to meet the requirements of the second determination operation **810**, a generate delay period operation **812** is performed.

[**0082**] In an alternative embodiment, the significance of the current accuracy may be based on a comparison with a predetermined acceptable accuracy range. This range may be determined by the manufacturer or selected by the user. For example, an acceptable range of $+/-1%$, $+/-1.5%$ or $+/-2%$ may be used as the predetermined acceptable range for accuracy within which any exceeding of the threshold will be automatically considered to be a true alarm condition. Thus, if the accuracy of the current estimate is $+/-1.5%$ it would be considered to be within an acceptable range of, for example, $+/-2%$ and the alarm is generated. If the accuracy is greater than the acceptable range, the generate delay period operation **812** may be performed.

[**0083**] In yet another embodiment, the second determination operation **810** may be omitted altogether. In this embodiment, any time a threshold is exceeded the method proceeds directly to the generate delay period operation **812** regardless of the accuracy of the current estimated value of the physiological parameter.

[**0084**] The generate delay period operation **812** identifies a delay period which is used to delay the generation of the alarm. One purpose of the delay period is to allow for the noise to subside and the accuracy to improve, in the event that the alarm is being triggered by noise and not actual changes in the measured physiological parameter. In another embodiment, a time-value integral may be used to reduce nuisance alarms and may integrate at a rate that is modified (reduced)

by the probability that the estimated value exceeded the alarm threshold, such as described in U.S. Pat. No. 5,865,736.

[**0085**] In an embodiment, the delay period may be determined based on the calculated accuracy of the current estimate. Such a calculation may be based solely on the accuracy of the current estimate (as described above) or may be determined based on a comparison of the accuracy of the current estimate with the accuracy of one or more recent estimates. Alternatively, the delay period may be calculated based on a comparison of the accuracy of the current estimate with a predetermined accuracy or accuracy range, such as $+/-2%$. For example, in an embodiment a predetermined accuracy may be subtracted from the accuracy of the current estimate to determine an accuracy difference. This difference may then be used to calculate the delay period. For example, if the accuracy of the current estimate is $+/-8%$ and the acceptable range is $+/-2%$, the difference may be calculated to be $+/-6%$. The difference may then be multiplied by some factor such as 2 seconds/% to determine the delay period (in this example, 12 seconds). Other algorithms are also possible and any mathematical algorithm for calculating a delay period based on an accuracy or a difference between accuracies may be used.

[**0086**] Alternatively, the delay period may be selected from one or more predetermined delay periods based on the calculated accuracy. For example, if a calculated accuracy is between the range $+/-6%$ to $+/-8%$, then a predetermined delay period of 5 seconds may be used.

[**0087**] After waiting for the delay period, the method **800** illustrates a third determination operation **814** in which the alarm condition is tested again. The third determination operation **814** tests a newly estimated value and thus includes receiving additional data, calculating a new estimated value and, optionally, calculating a new accuracy. Thus, the third determination operation **814** could be considered to include repeating the receiving data operation **802**, the calculate estimated value operation **804** and the calculate accuracy operation **806** as well as any operations (such as those shown in FIG. 7) necessary to determine and/or adjust the threshold.

[**0088**] If the third determination operation **814** determines that the threshold is no longer exceeded, the method returns to its normal monitoring state as illustrated by the operational flow returning to the receive data operation **802**. On the other hand, if the third determination operation **814** determines that the threshold is still exceeded, a generate alarm operation **816** is performed.

[**0089**] In an alternative embodiment, the third determination operation **814** may be performed periodically during the delay period to determine if, during the delay period, the estimated value no longer exceeds the threshold or if the accuracy increases or decreases further. If in a determination operation **814** performed during the delay period it is determined that the estimated value no longer exceeds the threshold, then the method may return to its normal monitoring mode without generating an alarm. Alternatively, if the accuracy of the current estimates are determined to have degraded further, then the delay period may be recalculated in response.

[**0090**] The generate alarm operation **816** includes generating some form of notification, such as an audio alarm, a visual alarm, or an electronic message, that indicates that the threshold has been exceeded. As described above, an alarm may be generated until the measured data indicate that the adjusted alarm condition is no longer met, until a user resets the device, or until some other interrupt occurs.

[0091] As mentioned above, the methods described in FIGS. 7 and 8 could be combined to create yet another embodiment of a method for generating an alarm in which an adjusted threshold is calculated and if that threshold is exceeded, a delay period is used to delay the generation of an alarm.

[0092] FIG. 9 is a block diagram illustrating some of the components of a pulse oximetry system that generates an alarm based the accuracy and/or probability distribution of sensed data. In the embodiment shown, the system 900 includes a sensor 902 containing a light emitter 904 and a light detector 906; and, in a separate housing 918, a processor 908, an alarm module 910, a probability distribution module 920, an oxygen saturation module 912, an accuracy module 918 and a memory 914. A display 916 is also provided. The sensor 902 and its components operate as described previously with reference to FIG. 2.

[0093] The memory 914 may include RAM, flash memory or hard disk data storage devices. The memory stores data, which may be filtered or unfiltered data, received from the detector 906. The data may be decimated, compressed or otherwise modified prior to storing in the memory 914 in order to increase the time over which data may be retained. In addition, the memory 914 may also store one or more of the predetermined threshold, the adjusted threshold, at least one estimated value of oxygen saturation of a patient's blood, at least one accuracy associated with an estimated value, the probability distribution, and a delay time period calculated based on at least one accuracy of an estimated value.

[0094] The oxygen saturation module 912 generates a current oxygen saturation measurement from the data generated by the sensor. The probability distribution module 920 performs the analyses of the data received by the oximeter 918 and calculates the probability distribution for use in adjusting the alarm threshold. In an embodiment, the probability distribution module 920 is capable of calculating one or more parameters such as an upper confidence limit, a lower confidence limit, and a confidence interval based on information received from the sensor and a stored confidence level.

[0095] In the embodiment shown, a separate accuracy module 918 is illustrated. The accuracy module 918 is capable of calculating the accuracy of the estimated value of the oxygen saturation.

[0096] An alarm module 910 is further illustrated. The alarm module 910 tests the alarm condition and, if the conditions are met, generates an alarm as described above. The alarm module 910 is capable of generating an alarm based on the estimated value and a predetermined alarm threshold. In an embodiment, the alarm module is further capable of delaying the generation of an alarm based on the accuracy of the estimated value. In yet another embodiment, the alarm module is further capable of calculating an adjusted threshold based on the probability distribution and the predetermined threshold and then generating an alarm based on the adjusted threshold.

[0097] In an embodiment, the oxygen saturation module 912, alarm module 910, probability distribution module 920 and accuracy module 918 may each be a dedicated hardware circuit that may include filters, firmware comprising lookup tables or other data, and its own processor (not shown) that allow it to generate the current oxygen saturation measurement. In an alternative embodiment, they may be implemented as a single software application or separate software applications that are executed, in whole or in part, by the

system processor 908. In yet another embodiment, functions described herein as being performed by the oxygen saturation engine and modules may be distributed among hardware, software and firmware throughout the system 900 and its other components.

[0098] The display 916 may be any device that is capable of generating an audible or visual notification. The display need not be integrated into the other components of the system 900 and could be a wireless device or even a monitor on a general purpose computing device (not shown) that receives email or other transmitted notifications from the oximeter 918.

[0099] It will be clear that the described systems and methods are well adapted to attain the ends and advantages mentioned as well as those inherent therein. Those skilled in the art will recognize that the methods and systems described within this specification may be implemented in many different manners and as such is not to be limited by the foregoing exemplified embodiments and examples. In other words, functional elements being performed by a single or multiple components, in various combinations of hardware and software, and individual functions can be distributed among software applications and even different hardware platforms. In this regard, any number of the features of the different embodiments described herein may be combined into one single embodiment and alternate embodiments having fewer than or more than all of the features herein described are possible.

[0100] While various embodiments have been described for purposes of this disclosure, various changes and modifications may be made which are well within the scope of the described technology. Numerous other changes may be made which will readily suggest themselves to those skilled in the art and which are encompassed in the spirit of the invention disclosed and as defined in the appended claims.

What is claimed is:

1. A method for generating an alarm indicating that a physiological parameter has exceeded a predetermined threshold, the method comprising:

calculating a probability distribution of an actual value of the physiological parameter based at least in part upon data;

identifying the predetermined threshold associated with the physiological parameter; and

generating the alarm based at least in part upon the predetermined threshold and the probability distribution.

2. The method of claim 1 further comprising:

calculating an estimated value of the physiological parameter based at least in part upon data;

calculating an adjusted threshold based at least in part upon the predetermined threshold and the probability distribution; and

comparing the estimated value of the physiological parameter to the adjusted threshold.

3. The method of claim 1 further comprising:

calculating, based at least in part upon the probability distribution, a confidence interval for the actual value of the physiological parameter; and

comparing the confidence interval to the predetermined threshold.

4. The method of claim 3 further comprising:

retrieving a confidence level; and

calculating, based at least in part upon the probability distribution, the confidence interval for the physiological parameter using the retrieved confidence level.

5. The method of claim 4, wherein the retrieved confidence level is selected from 99%, 98%, 97.5%, 95%, 90% and a user-selected value.

6. The method of claim 2, wherein calculating the probability distribution further comprising:
calculating an accuracy of the estimated value based at least in part upon the data.

7. The method of claim 6, wherein calculating the probability distribution further comprising:
calculating the probability distribution of the actual value of the physiological parameter based at least in part upon the accuracy and the estimated value.

8. The method of claim 7, wherein calculating the probability distribution further comprising:
retrieving, based at least in part upon the accuracy and the estimated value, a confidence limit value from a set of predetermined confidence limit values; and
comparing the confidence limit value to the predetermined threshold.

9. A method for generating an alarm indicating that a physiological parameter has exceeded a predetermined threshold, the method comprising:

calculating a first estimated value of the physiological parameter and a first accuracy of the first estimated value based at least in part upon data;

determining that the first estimated value of the physiological parameter exceeds the predetermined threshold; and
delaying generating the alarm based on the first accuracy.

10. The method of claim 9 further comprising:
calculating a delay time period based at least in part upon a comparison of the first accuracy to a previously determined accuracy associated with a previously estimated value of the physiological parameter.

11. The method of claim 10 further comprising:
after the delay time period, calculating a second estimated value of the physiological parameter based at least in part upon new data; and
if the second estimated value of the physiological parameter still exceeds the predetermined threshold, generating the alarm.

12. The method of claim 9 further comprising:
determining that the first accuracy exceeds a predetermined accuracy range.

13. The method of claim 9 further comprising:
after a predetermined time period, calculating a second estimated value of the physiological parameter and a second accuracy of the second estimated value based at least in part upon new data;

determining that the second accuracy does not exceed the predetermined accuracy range and the second estimated

value of the physiological parameter exceeds the predetermined threshold, generating the alarm.

14. The method of claim 12, further comprising:
prior to calculating the first estimated value,
calculating a third estimated value of the physiological parameter and a third accuracy of the current estimated value from data;
determining that the third estimated value of the physiological parameter does not exceed the predetermined threshold; and
setting the third accuracy as the predetermined accuracy range.

15. A pulse oximeter comprising:
an oxygen saturation module capable of calculating an estimated value of pulse rate or oxygen saturation of a patient's blood from information received from a sensor;
an accuracy module capable of calculating the accuracy of the estimated value;
an alarm module capable of generating an alarm based at least in part upon the estimated value and a predetermined alarm threshold; and

wherein the alarm module is capable of delaying the generation of an alarm based at least in part upon the accuracy of the estimated value.

16. The pulse oximeter of claim 15, further comprising:
a probability distribution module capable of calculating a probability distribution of an actual value of the oxygen saturation of a patient's blood based at least in part upon information received from the sensor; and

wherein the alarm module is further capable of calculating an adjusted threshold based at least in part upon the probability distribution and the predetermined threshold and generating an alarm based at least in part upon the adjusted threshold.

17. The pulse oximeter of claim 16, further comprising:
a processor capable of executing software applications; and

wherein at least one of the modules is a software application capable of being executed by the processor.

18. The pulse oximeter of claim 16, further comprising:
a memory capable of storing one or more of the predetermined threshold, the adjusted threshold, at least one estimated value of oxygen saturation of a patient's blood; at least one accuracy associated with an estimated value, the probability distribution, and a delay time period calculated based on at least one accuracy of an estimated value.

* * * * *

| | | | |
|----------------|--|---------|------------|
| 专利名称(译) | 减少滋扰警报 | | |
| 公开(公告)号 | US20140309507A1 | 公开(公告)日 | 2014-10-16 |
| 申请号 | US14/315693 | 申请日 | 2014-06-26 |
| [标]申请(专利权)人(译) | 柯惠有限合伙公司 | | |
| 申请(专利权)人(译) | COVIDIEN LP | | |
| 当前申请(专利权)人(译) | COVIDIEN LP | | |
| [标]发明人 | BAKER JR CLARK R | | |
| 发明人 | BAKER, JR., CLARK R. | | |
| IPC分类号 | A61B5/1455 A61B5/00 | | |
| CPC分类号 | A61B5/7221 A61B5/14552 A61B5/14551 A61B5/746 G06F19/3418 G16H40/63 G16H40/67 | | |
| 优先权 | 61/041042 2008-03-31 US | | |
| 其他公开文献 | US9820681 | | |
| 外部链接 | Espacenet USPTO | | |

摘要(译)

本文公开的实施例可以描述用于使用测量的生理参数的概率和/或准确度来减少烦扰警报的系统和方法，例如由脉冲血氧计生成的脉搏率或SpO2测量值。实施例可以包括用于基于患者血液的估计脉搏率和/或氧饱和度的概率分布来调整预定警报阈值的方法。

