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(54) **NUISANCE ALARM REDUCTIONS IN A PHYSIOLOGICAL MONITOR**

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See application file for complete search history.

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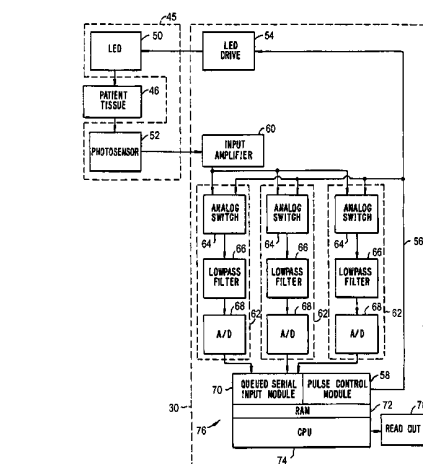
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(57)   **ABSTRACT**

A method and apparatus for controlling alarms in a medical diagnostic apparatus where an alarm is generated when a measured value for a physiological parameter is outside a specified range. The method continuously calculates a baseline value, and establishes dynamic thresholds that are related to and continuously track the baseline value. The method determines the amount of time the measured value is past the dynamic threshold, and the amount by which the threshold is passed. Alarms are triggered based upon a combination of the amount of time and the amount by which the threshold is passed. Preferably, the combination is an integral or some function of an integral.

34 Claims, 6 Drawing Sheets

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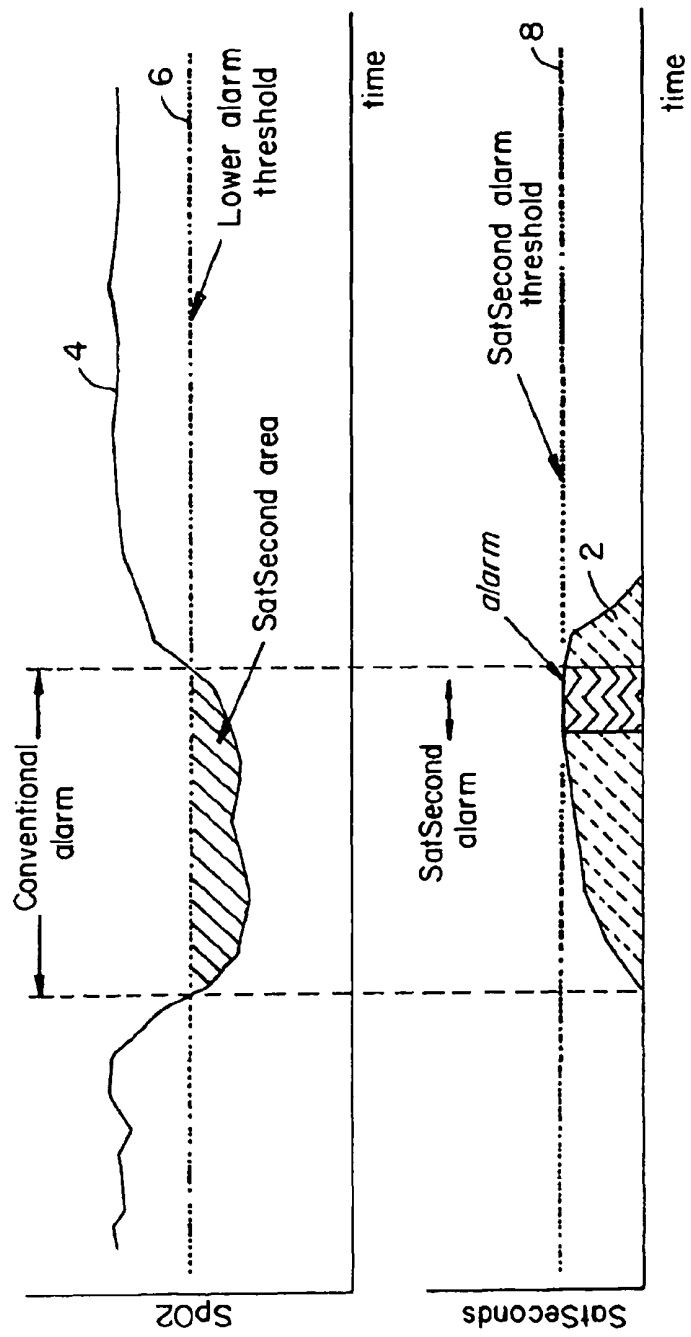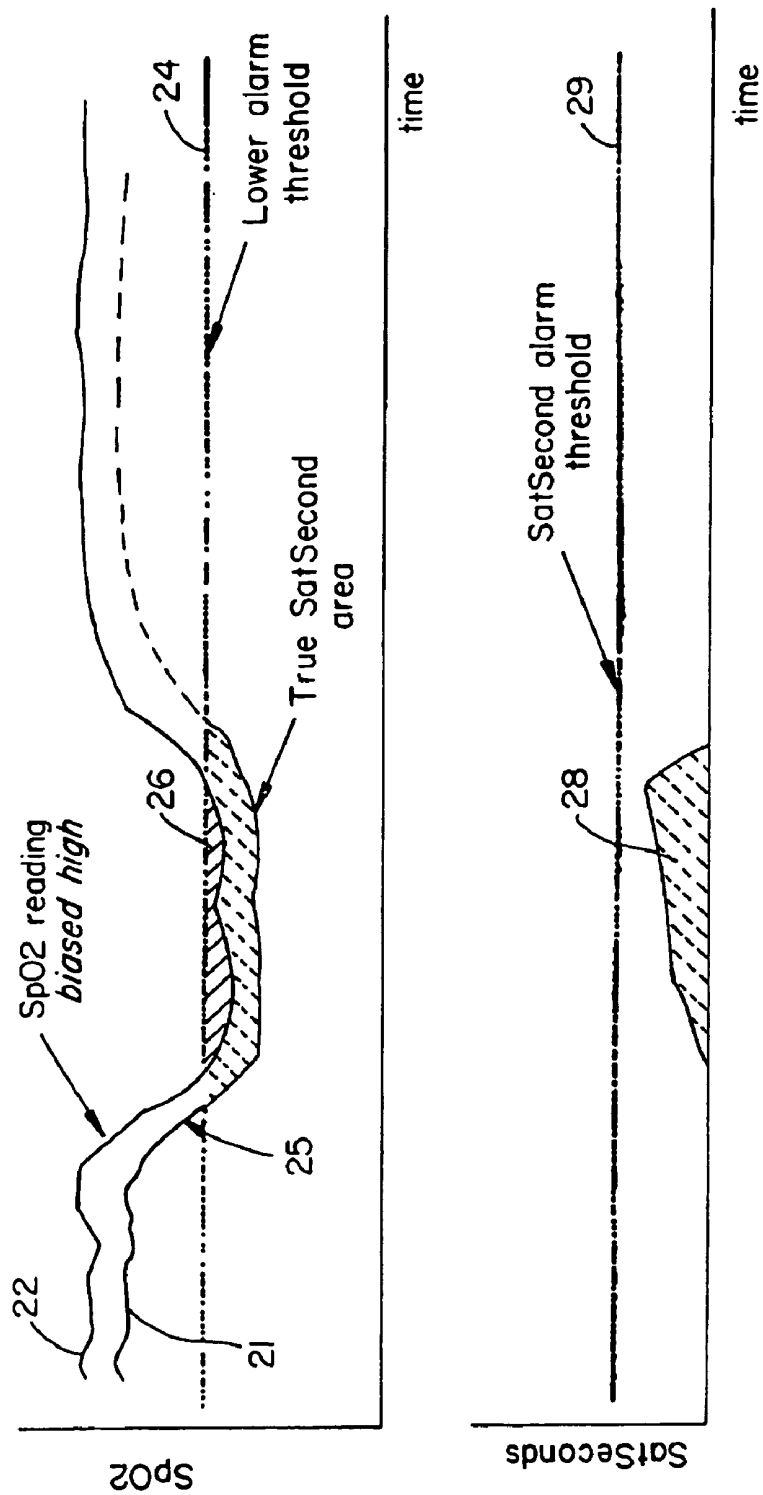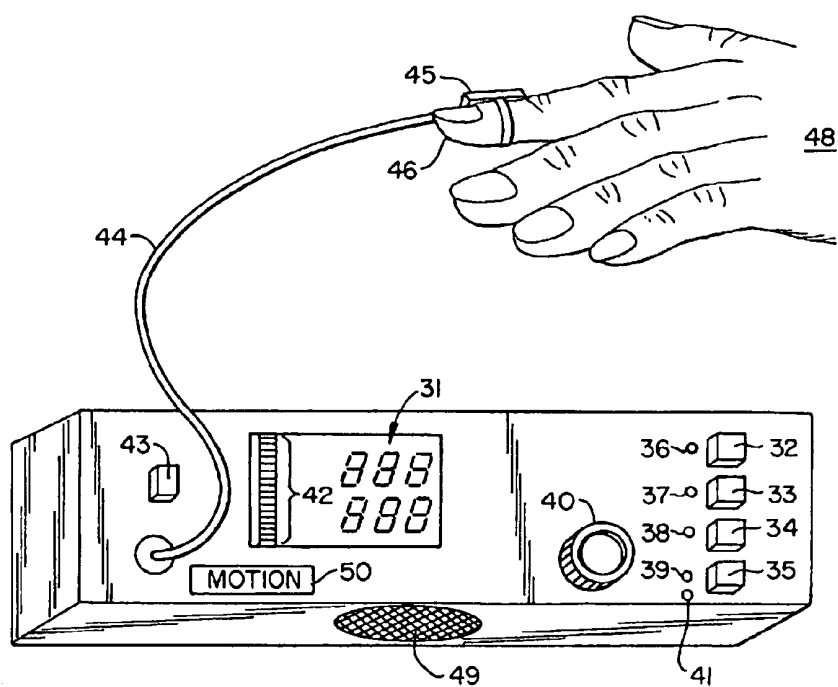
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FIG. 1
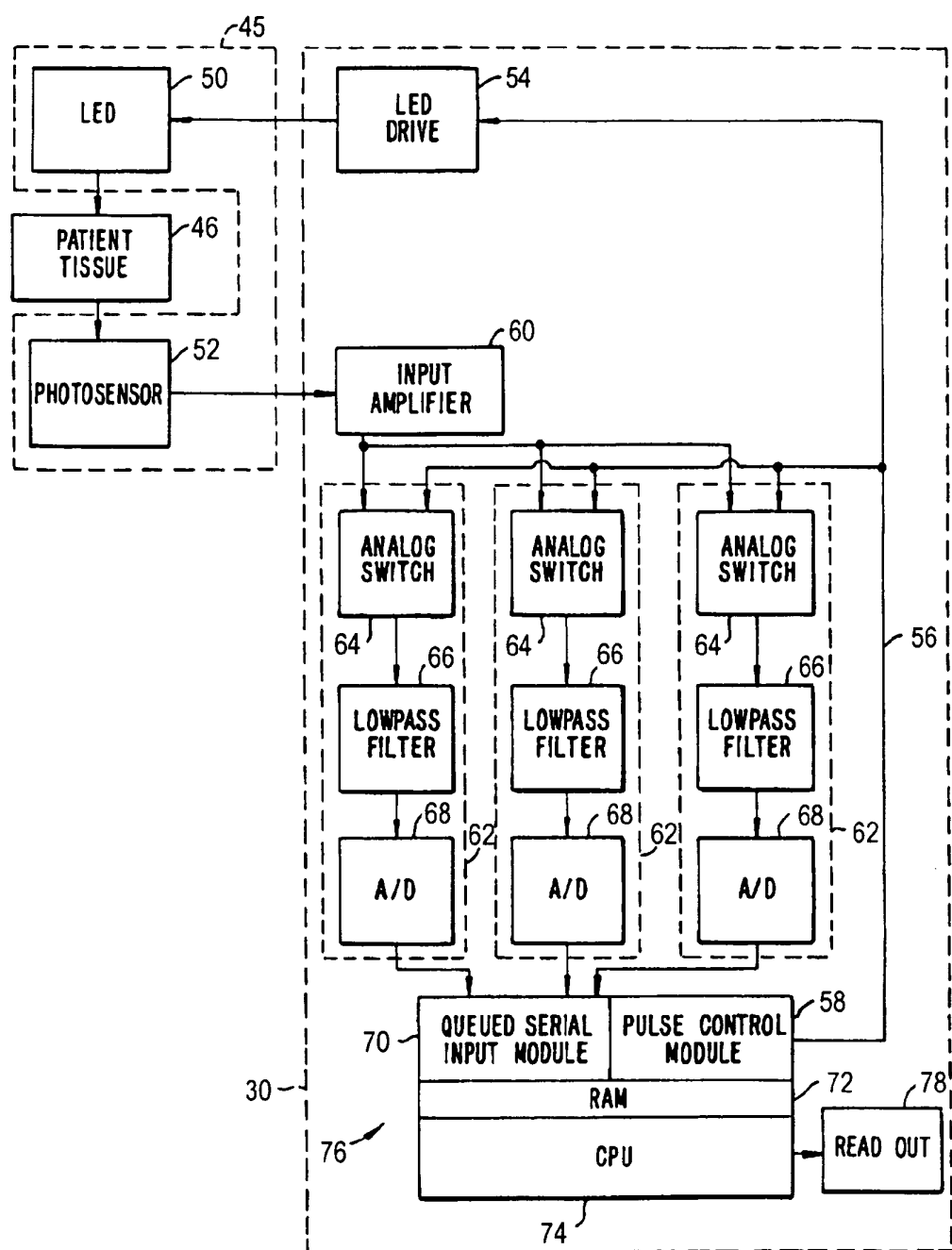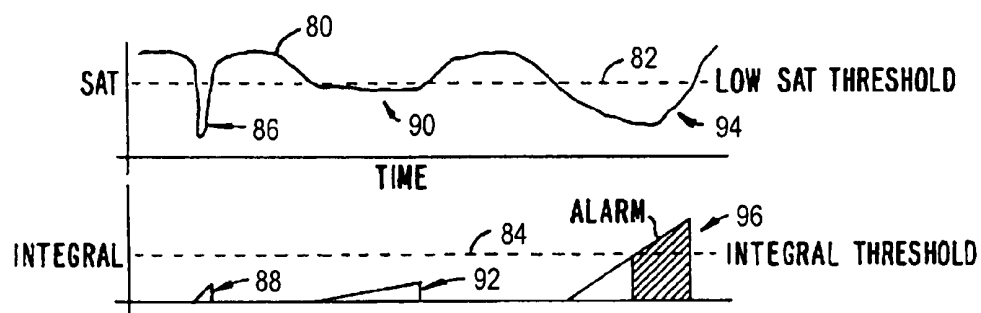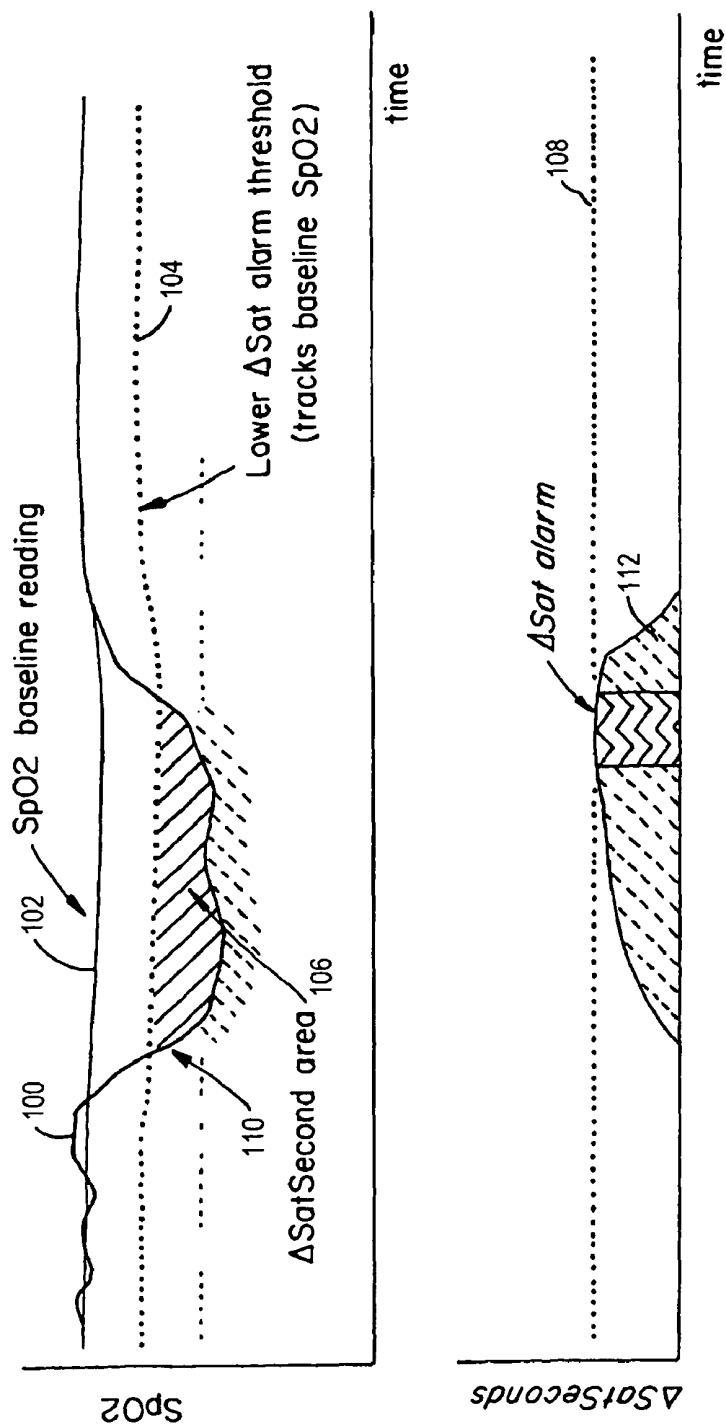(PRIOR ART)

FIG. 2

FIG. 3

FIG. 4

FIG. 5

FIG. 6

NUISANCE ALARM REDUCTIONS IN A PHYSIOLOGICAL MONITOR

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. application Ser. No. 10/850,513, filed May 19, 2004, now U.S. Pat. No. 7,123,950, which is a continuation of U.S. application Ser. No. 09/910/700, filed Jul. 19, 2001, now U.S. Pat. No. 6,754,516.

BACKGROUND OF THE INVENTION

The present invention relates to alarms in medical diagnostics apparatus, and in particular to improvements in reducing nuisance alarms for pulse oximeters.

A typical pulse oximeter measures two physiological parameters, percent oxygen saturation of arterial blood hemoglobin (SpO_2) and pulse rate. For alarm purposes, low and high thresholds are set for both SpO_2 and pulse rate, defining normal ranges within which it is desired to maintain the patient. For example, with a neonate it might be desired that sat should remain between 85 and 95 percent and pulse rate should remain between 120 and 170 beats per minute. From the two measured parameters, typically four alarm types can be generated, low sat, high sat, low rate, and high rate. In some pulse oximeters, an alarm begins immediately when either sat or rate goes outside the normal range and the alarm ends immediately when both sat and rate return within the normal range. Alarms are typically announced by audible and/or visual indicators. Alarms, which are dependent on the instantaneous excursions of a measured value outside a range, are commonly referred to as conventional alarms.

Each occurrence in which a measured parameter goes outside the normal range is referred to as an event. Thus, in a typical pulse oximeter, each event coincides with an alarm, and the alarm duration may be identical to the event duration. Some of the alarms produced by typical pulse oximeters are not generally considered to correspond to events that are clinically significant. The exact definition of clinical significance varies depending on the patient and circumstances, but is in general related to the severity and duration of the event of interest. For example, a very shallow desaturation might only be considered significant if sustained for a relatively long period of time. Likewise, a desaturation of very brief duration might only be considered significant if it falls very deep below the low sat threshold. In addition to clinically insignificant alarms, parameter measurement error due to noise, signal artifact or bias can also produce false events and trigger alarms. An alarm that does not correspond to a clinically significant event may be considered a nuisance alarm.

Several approaches are available which attempt to reduce the number of nuisance alarms. Some of these approaches have either looked at lowering the alarm threshold or waiting some fixed period of time after the threshold has been crossed before triggering an alarm. Lowering the threshold can be problematic because a patient's blood oxygen saturation can remain indefinitely below the original threshold, but above the new threshold, and an alarm will never be generated. Delaying alarm generation by a fixed amount of time is also problematic due to a potentially serious situation in which a patient's saturation abruptly falls to and remains at a very low level, requiring prompt medical attention.

Another solution to the nuisance alarm problem is described in U.S. Pat. No. 5,865,736, entitled, "METHOD AND APPARATUS FOR NUISANCE ALARM REDUCTIONS," assigned to the assignee herein. The solution

described by the '736 patent is commercially known as the SatSeconds™ Alarm Management Technology ("SatSecond") feature. The SatSecond concept has been incorporated into some of assignee's pulse oximeters, such as the model N-395 pulse oximeter, for enhanced alarm management. FIG. 1 is a graph illustrating the alarm response according to this known SatSecond approach. This figure shows a conventional and the SatSeconds alarm management methods. This figure, for illustration purposes shows the methods applied to SpO_2 measurements. As described above and shown in FIG. 1, with conventional alarms, SpO_2 (4) or pulse rate (not shown) readings that fall below a specified fixed lower threshold 6 or above a specified fixed upper threshold (not shown) trigger an audible or visible alarm state. With the SatSecond methodology, an alarm state is entered only when the second-by-second accumulated product 2, of time and the degree to which the SpO_2 (4) exceeds the lower 6 or upper (not shown) specified threshold, equals or exceeds an integrated threshold 8. Both the conventional and SatSecond alarm management methods are equally applicable to pulse rate or other physiological measurements.

The motivation for the SatSecond method is to reduce the number of nuisance alarms in which a measured value such as SpO_2 is beyond an alarm threshold, but does not represent a clinically significant event. For example, if a caregiver feels that a desaturation of less than points below the lower alarm threshold for less than 5 seconds is not clinically meaningful, but rather constitutes a nuisance, the caregiver may set the SatSecond alarm threshold to "25" (5 points for 5 seconds). Then only a deeper desaturation of longer duration (i.e., a product that exceeds 25 SatSeconds) will initiate an alarm. In certain pulse oximeter models manufactured by the assignee herein, the product of saturation-below-the-threshold and time are accumulated once per second, and this product is compared to the SatSecond alarm threshold each time is it calculated. The effect of using the SatSecond alarm management method is to reduce the number of nuisance alarms and to alarm more specifically in response to events that are clinically meaningful as established previously by the caregiver.

A limitation in the use of the each of these prior art methods occurs when the SpO_2 value (or other measured value) is systematically in error, as in where there is a high or low bias in the measured value, even if the bias error is relatively small. Using the SatSecond method as an example, this limitation is illustrated in FIG. 2. The graph 22 shows a monitored value of SpO_2 having a bias of a few points high relative to the true saturation 21. As the desaturation event 25 occurs, the lower alarm threshold 24 is not reached until later in the event, if at all, and the SpO_2 value dips only slightly below the threshold 24. Accordingly, the SatSecond value 28 (which corresponds to the area of the dark hatched region 26 of the upper curve 22 below the lower alarm threshold 24) never achieves the necessary level 29 needed to initiate an alarm state. FIG. 2 provides an illustration of a "missed" SatSecond alarm due to a bias in the SpO_2 readings. The erroneously high SpO_2 value may interfere with the ability to accurately calculate the proper value of the SatSecond integral 28. The converse (i.e., false SatSecond alarm) would occur if the SpO_2 readings were too low due to a low bias. Hence, SpO_2 bias affects the reliability of measured values and alarms based on those values.

Ideally, the SpO_2 reading will be proper (i.e., unbiased from the true SaO_2). However, under some circumstances such a bias can and does occur. It is known that bias can be created, for example, by an improperly placed sensor that shunts light between the emitter and the detector, or by a sensor that has been applied too tightly, or a by patient with

significant edema. Additionally, sensor placement variations, as well as other factors introduce bias, such that even instrument specifications acknowledge the presence of bias. Specifically, the accuracy specification for pulse oximetry sensors readily allows a bias between two sensors placed on the same patient of 3 sat-points. Under such circumstances (i.e., two sensors placed on the same patient), one sensor may indicate an alarm state, while the other does not; resulting in ambiguity in not knowing which sensor is providing the more correct reading. Thus, although the SatSecond invention greatly reduces nuisance alarms in pulse oximeter readings, the measurements and hence alarm events may still be susceptible to bias-induced nuisance alarms. Moreover, the Sat-Second improvement is based on a product of saturation-below-a-fixed threshold (or above) and time. This fixed threshold can also be problematic, as is described below.

Alarm thresholds described thus far are based on fixed windows, where a window is defined by the region between a fixed lower and a fixed upper alarm threshold. The fixed lower and upper threshold values are based on typical default values used for patients in general, and which may be set by the caregiver irrespective of the current instrument readings. However, the fixed window approach may be problematic for patients having, for example, a chronically elevated pulse rate value. Some prior art pulse oximeters manufactured by the assignee herein offered a feature known as "Smart Alarms" to allow caregivers to quickly establish the lower and upper conventional alarm thresholds by manually pressing a button on the oximeter unit. The "Smart Alarm" is essentially a fixed relative threshold based on a current physiological value that is being monitored. Using this "Smart Alarm" feature, the conventional alarm thresholds could be established at a preset value above and below the current readings of pulse rate, as opposed to the fixed default values typically used for patients in general. Thus if a patient is chronically at an elevated pulse rate, a revised fixed threshold relative to the current readings could be easily set to a preset number below the current reading so as not to alarm unnecessarily. While the "Smart Alarm" approach allows for the setting of a new fixed threshold that is related to the then current readings, it is still a fixed threshold and hence suffers from the same shortcomings described thus far.

There is therefore a need for improvements in medical diagnostic devices, and in particular to improvements in both integrated or "product"-type and relative deviation threshold alarms for pulse oximeters.

SUMMARY OF THE INVENTION

The present invention provides a method and apparatus for controlling alarms in a medical diagnostic apparatus where an alarm is generated when a measured value for a physiological parameter is outside a specified range. The method continuously calculates a baseline value, and establishes dynamic thresholds that are related to and continuously track the baseline value, and triggers an alarm when a measured value exceeds the dynamic and continuously tracking threshold. In a preferred embodiment, the method determines the amount of time the measured value is beyond the dynamic threshold, and the amount by which the threshold is passed, and triggers an alarm based upon a combination of the amount of time and the amount by which the threshold is passed. Preferably, the combination is an integral or some function of an integral.

In one aspect directed to saturation alarms on a pulse oximeter, an alarm is generated when the measured saturation value falls above or below a baseline-tracking dynamically changing upper or lower threshold respectively.

In another aspect, the preferred embodiment of this invention calculates the integral of the amount by which a measured value of the oxygen saturation exceeds an upper baseline-tracking dynamically determined threshold, or falls below a lower baseline-tracking dynamically determined threshold. A saturation alarm is generated when the integral exceeds a predetermined value. Similarly, for a pulse rate alarm on a pulse oximeter, the preferred embodiment of this invention calculates the integral of the amount by which a measured value of the pulse rate exceeds an upper baseline-tracking dynamically-determined threshold, or falls below a lower baseline-tracking dynamically-determined threshold, and a pulse rate alarm is generated when the integral exceeds a predetermined value. The relative-threshold-based alarm management method of the present invention may also be combined with a fixed threshold alarm scheme.

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

FIG. 1 is a graph illustrating prior art conventional and SatSeconds™ Alarm Management Technology alarm management methods.

FIG. 2 is a graph illustrating a missed SatSecond™ alarm due to SpO_2 bias.

FIG. 3 is a diagram of an example pulse oximeter.

FIG. 4 is a block diagram of an example of electronic circuitry for a pulse oximeter incorporating the present invention.

FIG. 5 is a graph illustrating the behavior of an integral algorithm in accordance with one embodiment.

FIG. 6 is a graph illustrating the alarm management method according to embodiments of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Embodiments of the present invention relate to increasing the reliability of alarms in medical diagnostic equipment measuring a physiological parameter by improving reductions in nuisance alarms. In order to illustrate the invention, the example of a pulse oximeter with thresholds for blood oxygen saturation (SpO_2) will be described. In particular, a low saturation event is described. Alternately, high saturation, low pulse rate, high pulse rate or other alarm parameters could be addressed by the present invention. In addition, the invention could be used for other types of medical diagnostic equipment.

FIG. 3 illustrates a typical pulse oximeter 30. FIG. 3 illustrates the oximeter housing which includes a digital display 31, select buttons 32 35, alarm status lights 36 39, and adjustment knob 40, synchronization status light 41, LED digital view meter 42, and power switch 43. A cable 44 to the sensor 45 is shown with the sensor attached to a finger 46 on a patient's hand 48.

An alarm in accordance with the embodiment of the present invention can be either produced audibly through a speaker 49, or produced on one of the displays described above. Also shown is a display 50 for providing an indication of motion distorting the signal, which could also generate an alarm condition. The display 50 and/or display 31 are also used to provide other information to the clinician as is deemed necessary. The pulse oximeter 30 shown in FIG. 3 is shown for exemplary purposes and is not meant to limit the embodi-

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ments of the present invention. For example, the sensor **45** can be replaced by other appropriate sensors for use at other tissue locations including but not limited to the ear, foot, forehead and nose of adult, infant, neonatal and perinatal patients.

An example of an electronic circuitry for a pulse oximeter which may be configured to incorporate the embodiment of the present invention is provided as FIG. 2 of U.S. Pat. No. 5,865,736, entitled: "METHOD AND APPARATUS FOR NUISANCE ALARM REDUCTIONS," assigned to the assignee herein, the disclosure of which is hereby incorporated herein in its entirety. U.S. Pat. No. 5,865,736 also describes algorithms used to calculate the integral of the difference between the current saturation and a saturation threshold whenever the current saturation is below the saturation threshold, as well as any necessary additional logic related to resetting and clearing the integral and the alarm.

FIG. **4** is a block diagram of an example of electronic circuitry for a pulse oximeter incorporating the present invention. Shown is sensor **45** which includes LEDs **50** which provide light through patient tissue **46** to a photosensor **52**. The LEDs are driven by a drive circuit **54** via a signal line **56** from a pulse control module **58**. The signal from photosensor **52** is provided through input amplifier **60** to three possible channels **62**. Each channel includes an analog switch **64**, low-pass filter **66**, and an A/D converter **68**. The signals are provided to a queued serial input module **70**, which provides data to a RAM **72** for reading and analysis by a CPU **74**. The control circuitry is generally referred to as a microcontroller/ processor unit (MPU) **76**. A readout circuit **78** is also shown for providing outputs to one of the displays shown in FIG. **3** or to another output.

An algorithm according to one embodiment of the invention calculates the integral of the difference between the current saturation and a saturation threshold whenever the current saturation is below the saturation threshold. Because we are working with a sampled data system, we used a simple summation to approximate the integral.

$$I_{sat}(n){=}I_{sat}(n{-}1){+}|T_{sat}{-}\text{sat}(n)| \qquad (1)$$

where $I_{sat}(n)$ is the saturation integral at time n, sat(n) is the saturation at time n, and T_{sat} is the saturation threshold. Those skilled in the art will recognize that an equivalent continuous-time form could also be used. An alarm is generated when I_{sat} exceeds an integral threshold.

FIG. **5** illustrates the behavior of the integral algorithm. A saturation signal **80** is compared to a low sat threshold **82**. Also illustrated is an integral threshold **84**. As can be seen, three separate incursions below the low sat threshold are shown. A deep but short incursion **86** produces an integral value **88** which does not exceed the integral threshold **84**, and thus does not produce an alarm. In prior devices, because the low sat threshold was passed, an alarm would have been generated even though the event is short lived and would thus be considered a nuisance-type alarm.

In a second example, an incursion **90** barely drops below the low sat threshold, but stays there for an amount of time. This would also cause a nuisance alarm in systems which immediately alarm on any incursion below the low sat threshold. In addition, prior art systems which produce an alarm after a fixed time for incursions below the low sat threshold will also produce an alarm when that time is exceeded. In the present invention, however, as illustrated by integral **92**, the integral threshold is not exceeded because, although a significant amount of time passes, the incursion is limited.

A final incursion **94** is both long enough and deep enough to cause the integral value **96** to exceed the integral threshold and generate an alarm.

In implementing the alarm reduction algorithm, additional logic must be provided to govern when the integral equation is applied, how the integral is reset (i.e., zeroed), the integral/ alarm relationship, and how the alarm is cleared. Upper and lower limits might be imposed on the integral. Integrals and/ or alarms might be held until the measured parameter has been within normal range for a specified time duration and/or amount. Alternatively, an alarm might be cleared immediately when the measured parameter returns to normal range, but be regenerated immediately upon a subsequent event unless the parameter has been in normal range for a sufficient time duration and/or amount. The way these issues are handled affects the sensitivity and hysteresis of the algorithm. The preferred embodiment depends on the patient population of interest and the expected uncertainty inherent in the parameter estimation. We have examined two particular embodiments, which we will call the basic embodiment and the fading embodiment.

The basic embodiment integrates according to equation (1) while sat is abnormal, resets the integral when sat transitions from abnormal to normal, alarms when the integral reaches the integral threshold, and clears the alarm when sat transitions from abnormal to normal. With the basic embodiment, each event is treated as being distinct from all others.

Some populations exhibit periodic desaturations in which it may not be appropriate to view each desaturation as a clinically separate event. For example, although a single incursion, similar to **86** or **90**, should not generate an alarm, a sequence of such incursions occurring close together in time perhaps should generate an alarm. The preferred embodiment for these populations uses an integral clearing method that we refer to as fading. Fading is not an alarm reduction enhancement, but rather a means of obtaining sensitivity to periodic events.

The fading embodiment, as it pertains to saturation, works as follows. The integral is bounded with a lower limit of zero and an upper limit equal to the integral threshold value. When sat is outside normal range, the integral increases according to (1). When sat is inside normal range, the integral is reduced by the weighted difference between the sat and the low sat threshold, as shown in equation (2).

$$I_{sat}(n){=}I_{sat}(n{-}1){-}|W{\times}(T_{sat}{-}\text{sat}(n))| \qquad (2)$$

The integral fading rate is controlled by w, which is typically a predetermined constant.

For the fading embodiment, the alarm is controlled by the integral value. An alarm state is defined in which an alarm sounds (or is otherwise indicated) when the alarm state is true and the alarm is quiet when the alarm state is false. If the alarm state is false, the alarm state is set to true when the integral reaches the integral threshold. If the alarm state is true, the alarm state is set to false when the integral reaches zero. Thus, the condition for clearing the alarm is that the fading integral (2) has reached zero.

Additional embodiments can be envisioned in which (1) is modified in order to alter the time responsiveness or sensitivity of the algorithm. For example, to increase responsiveness to deep desaturations, the square of the distance from the low sat threshold could be used, as shown in (3).

$$I_{sat}(n){=}I_{sat}(n{-}1){+}(\Delta\text{sat}(n))^{2} \qquad (3)$$

where: $\Delta\text{sat}{=}|T_{sat}{-}\text{sat}(n)|$

Other embodiments can be envisioned that use the slope of the saturation to anticipate where the saturation is going. One way to achieve this effect is to integrate faster when the saturation is falling and integrate slower when the saturation is rising. An equation that provides this effect is given in (4).

$$I_{sat}(n)=I_{sat}(n-1)+\Delta sat(n)\times\alpha^{[sat(n-1)-sat(n)]} \quad (4)$$

where: $\alpha>1$

$$\Delta sat=|T_{sat}-sat(n)|$$

Another enhancement involves variable attack and decay rates. The idea here is to use one set of integration and fading rates before the alarm sounds and another set of rates after the alarm sounds.

We also used the integral method to screen pulse rate bradycardia and tachycardia alarms. The rate integral is calculated as a percentage in order to obtain a consistent alarm reduction effect, regardless of the rate threshold, T_{rate}.

$$I_{rate}(n) = I_{rate}(n-1) + 100 \times \left(\left|\frac{rate(n) - T_{rate}}{T_{rate}}\right|\right) \quad (5)$$

where $I_{rate}(n)$ is the rate integral at time n, rate(n) is the rate at time n, and T_{rate} is the rate threshold.

The alarm reduction method of this invention can be incorporated as an independent post-processing step that follows a saturation calculation algorithm. It is therefore suitable for use with existing pulse saturation algorithms.

Oxygen saturation can be estimated using various techniques. In one common technique, the photocurrent 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 is described in U.S. Pat. No. 5,853,364, entitled "METHOD AND APPARATUS FOR ESTIMATING PHYSIOLOGICAL PARAMETERS USING MODEL-BASED ADAPTIVE FILTERING", issued Dec. 29, 1998, and U.S. Pat. No. 4,911,167, entitled "METHOD AND APPARATUS FOR DETECTING OPTICAL PULSES", issued Mar. 27, 1990. The relationship between oxygen saturation and modulation ratio is further described in U.S. Pat. No. 5,645,059, entitled "MEDICAL SENSOR WITH MODULATED ENCODING SCHEME," issued Jul. 8, 1997. An electronic processor for calculating in vivo blood oxygenation levels using pulsed light is described in U.S. Pat. No. 5,348,004, entitled "ELECTRONIC PROCESSOR FOR PULSE OXIMETER," issued Sep. 20, 1994, and a display monitor for a pulse oximeter is described in U.S. Pat. No. 4,653,498, entitled "PULSE OXIMETER MONITOR," issued Mar. 31, 1987. All five patents are assigned to the assignee of the present invention and incorporated herein by reference.

The brief description of pulse oximeters, and associated electronic circuitry and algorithms described above serve as a contextual fabric for describing the alarm management method according to embodiments of the present invention, which are described below.

FIG. 6 illustrates the behavior of the alarm management method according to embodiments of this invention. In one embodiment of the present invention, an alarm is generated when saturation signal 100 falls below the baseline tracking saturation threshold 104.

In an alternate embodiment, the alarm management method is based on an integrated-relative-threshold algo-

rithm. A saturation signal 100 is compared to a low sat threshold 104. Also illustrated is an integral threshold 108. An excursion 110 produces an integral value 112 that can exceed the integral threshold 108. The value 112 is a product of the amount of time and the amount by which the measured value of oxygen saturation exceeds the threshold. The alarm management method according to embodiments of this invention include dynamically and continuously calculating a "baseline" value 102 for the SpO_2 readings, and establishing a continuously and dynamically tracking set of upper (not shown) and lower alarm threshold 104 that continuously and dynamically follow this baseline. Certain embodiments first calculate a baseline value for saturation or other physiological parameter of interest, and define the dynamic thresholds by offsetting from this baseline. As the instantaneous readings of SpO_2 (or other variable) wander beyond these thresholds, the product 112 of time and extent beyond the threshold is calculated. The low sat alarm threshold 104 tracks the baseline SpO_2 trend 102. The baseline trend 102 is an average of the measured SpO_2 signal 100, and which is obtained by low-pass filtering the measured SpO_2 signal 100. The area under the curve 106 where the instantaneous SpO_2 value drops below the lower threshold 104 is calculated (ASatSeconds) and an alarm state is entered when the value 112 of the integral equals or exceeds a user defined integral threshold 108. Alternately, a default value may be used in lieu of the user-defined threshold 108.

In one embodiment, the baseline value 102, which the upper (not shown) and lower thresholds 104 track, is computed by using a low-pass filter. Alternately, the baseline is calculated using a running median filter. Other alternate methods for calculating a baseline may also be used so long as the methodology results in a more slowly varying value for the baseline than the instantaneous readings 100. Examples of these alternate methods are described below.

In one alternate embodiment, an "Infinite Impulse Response" filter is used by continuously updating the baseline value using the most recent reading added to the running computation of the past, as shown in (6) below:

$$\text{Baseline Value}=1/N^* SpO_2+(N-1)/N^*\text{Last Baseline Value} \quad (6)$$

where N is a number that results in a "slow" response time (e.g. 15 minutes).

In another alternate embodiment, the baseline is tracked by using a running "Finite Impulse Response" filter, where readings taken over a past several minutes are stored and averaged. These baseline-tracking methods are examples of tracking algorithms, and are not meant to limit the embodiments of the present invention, as many methods are available for calculating the baseline SpO_2 value.

In the embodiments of the present invention, alarm thresholds are dynamic and determined relative to the tracked baseline. In the prior art integral-based methods referred to and described as the SatSecond concept, the (integral value) alarm threshold is calculated based on instantaneous readings wandering beyond fixed thresholds established by default values or user-specified upper and lower alarm thresholds. In the methods embodied by the present invention, the threshold dynamically follows a dynamically calculated baseline, trending up or down with the measured value, while the baseline dynamically smoothes out the short-lived excursions in the SpO_2 signal. In other words, a window is established by defining upper and lower threshold values that are offset from the baseline by a specified value above and below the baseline respectively, thus establishing a relative threshold. In this

way, any bias that exists between measured SpO_2 and true SaO_2 has minimal effect on the reliability of saturation alarms.

In other embodiments, the dynamic alarm threshold is an offset of a continuously updated baseline, so that the alarm threshold is directly computed in one step, as opposed to calculating a baseline in a first step and then offsetting the baseline to determine the threshold in a second step. This is achieved by offsetting a slowly varying average of the measured value by a certain amount above and below the measured value to define upper and lower relative thresholds respectively.

The improved alarm management methodology, as embodied by the present invention can be used independently, or in conjunction with a fixed window method, with the combined alarm thresholds chosen to complement one another. The following examples, described below demonstrate the utility of the improvements as embodied by the present invention.

Examples of SpO_2 Monitoring Scenarios

The following assumptions apply to each of the following examples:

The baseline true value of SaO_2 is 95%,

The fixed alarm threshold is set to 85% and the SatSecond (SS) value needed to trigger an alarm is set to 25 sat-second,

the ΔSatSecond (ΔSS), relative-threshold is set to 25 based on a threshold of 10% less than a running baseline,

integrated products of deviation-from-threshold times time are calculated once every second.

Thus the thresholds are nominally equal (i.e., a drop in sat of 10%), but the Δ.SS alarm triggers based on the change from a baseline, while the SS alarm triggers based on crossing the fixed value of 85% SpO_2 (i.e., 10% drop from the 95% true baseline value).

Example 1

Correct SpO_2 Readings

This example involves a scenario where the SpO_2 readings are correct, or in other words, the SpO_2 and SaO_2 readings are equivalent, since no measurement bias is present. In this example, if the SaO_2 value drops 2 points below the fixed threshold (83% SaO_2 and SpO_2), the SS alarm will sounds in 13 seconds (13 sec*2 sat deviation=26 sat-seconds, which is greater than 25 sat seconds). The ΔSS level triggers at an equivalent point, but is redundant. Both trigger events represent True Positives (TP). A Positive event is an event where the diagnostic device triggers an alarm. A "True" condition refers to the real and actual data supporting the presence of an alarm condition. Thus a TP event is where the diagnostic device senses an event and triggers an alarm where a real clinically significant event was present. A TP event represents an event where the diagnostic device has correctly identified a clinically significant event and triggered an alarm.

If the SaO_2 drops to 2 points above the fixed threshold (87%), neither alarm will sound as SpO_2 does not cross either of the thresholds. Both non-trigger events will then represent True Negatives (TN). A Negative event is an event where the diagnostic device does not trigger an alarm. Thus a TN event is where the diagnostic device does not and should not trigger an alarm. A TN event represents an event where the diagnostic device has correctly identified a non-existent or clinically insignificant event and does not trigger an alarm.

Example 2

Positively Biased SpO_2 Readings

This example involves a scenario where the SpO_2 baseline reads 98%, 3 points high relative to the true SaO_2 value due to a reading with positive bias. In this example, if the SaO_2 value drops 12 points, that is 2 points below the threshold (83%), an alarm state should occur in 13 seconds (13 sec*2 sat deviation=26 sat-seconds, which is greater than 25 sat seconds), but does not due to the bias resulting in a SpO_2 reading of 86%. This results in a False Negative (FN) for the SatSecond (SS) threshold. A "False" event refers to a state sensed by the diagnostic device that is not supported by the real and actual data. Thus a FN event is where a diagnostic device should trigger an alarm but does not. A FN event represents an event where the diagnostic device has missed a clinically significant event and not triggered an alarm. In this example, the SS alarm would never occur since the SpO_2 value never drops below 85%. Further, a conventional SpO_2 set to less than 85% would also miss this event.

Since SpO_2 drops by 12 points, this will result in an ΔSS alarm in 13 seconds (2 points below the dynamic alarm threshold for 13 seconds=26 ΔSS). This event will then be a True Positive for ASS. This example clearly points out the improvement provided by the relative sat-second method over the fixed sat-second method for a case where the measurements are positively biased, since the fixed threshold alarm would miss the event, but a relative and dynamic alarm threshold would capture the event.

If SaO_2 drops 8 points, to two points above the threshold (87%), SpO_2 readings become 90% (98%-8%) and no SS alarm would sound, thus resulting in a True Negative event. The same result occurs with ASS, as the 8-point drop isn't sufficient to trigger the ΔSS integral. Recall that the ΔSS relative-threshold is set to 25 based on a threshold of 10% less than a running baseline.

Example 3

Negatively Biased SpO_2 Readings

This example involves a scenario where the SpO_2 baseline reads 92%, 3 points low relative to the true SaO_2 value due to a negatively biased reading. In this example, if the SaO_2 drops 12 points, 2 points below the fixed threshold (83%), with the SpO_2 reading 80% due to the negative bias, the SS alarm is triggered after 5 seconds (5 points below threshold* seconds=25 SS). The ΔSS alarm will trigger in 13 seconds (2 points below the 10 point allowable threshold takes 13 seconds to exceed 25 Δsat-seconds). Thus this scenario results in a TP for both alarm methods, though a little sooner than required for the fixed SS alarm.

If the SaO_2 drops 8 points, 2 points above the fixed threshold (87%), the SS alarm should never engage, but it does trigger a FP in 25 seconds due to the 3-point low bias (SpO_2=84%). The SpO_2 drop from 92% to 84% does not trigger an ΔSS alarm since it does not exceed the 10% necessary threshold drop. Here the advantage of the improved alarm management is illustrated since this clinically insignificant event (by definition) would trigger a FP SS alarm, and hence create an unnecessary or a nuisance alarm, while the dynamic threshold design (ΔSS) registers a TN.

As can be seen from these examples, the sensitivity and specificity for the dynamic and continuous baseline tracking approach is improved in the presence of bias over a fixed threshold approach. Particularly, the relative-dynamic thresh-

old method as embodied in this invention is especially adept at capturing clinically significant events in cases where the diagnostic device's readings are positively biased. When no bias is present, both the dynamic and fixed threshold approaches are equivalent in their sensitivity.

Alternate embodiments of this invention combine both the dynamic relative threshold methods as embodied by this invention and the known fixed threshold methods. This combined embodiment is especially useful where the diagnostic device is configured to prevent a slowly decaying baseline SaO_2 (and thus SpO_2) from falsely missing hypoxia. In such an embodiment, the fixed threshold is set at a lower value so as to avoid false positives; however, the lower fixed threshold is judiciously set to catch a potentially slowly deteriorating patient condition. This arrangement is useful because a dynamic and relative baseline tracking alarm management scheme would also slowly track the decaying baseline and thus not trigger a low saturation alarm.

As will be understood by those of skill in the art, the present invention which is related to calculating an integral of the time and depth product of a monitored variable, using a dynamically tracking threshold for initiating and calculating an integral, may be embodied in other specific forms without departing from the essential characteristics thereof. For example, variables other than SpO_2 such as pulse rate, blood pressure, temperature, or any other physiological variable could be continuously or periodically tracked. 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. A method of operating a medical device, comprising:
acquiring measurements of a physiological parameter;
establishing at least one dynamic alarm threshold based on a dynamically calculated baseline of the measurements; and
triggering an alarm when the measurements exceed the dynamic alarm threshold.

2. The method of claim **1**, comprising establishing a dynamic high alarm threshold and a dynamic low alarm threshold based on the dynamically calculated baseline of the measurements.

3. The method of claim **1**, wherein establishing the at least one dynamic alarm threshold comprises:
calculating a dynamic baseline value; and
adding a specified value to or subtracting a specified value from the dynamic baseline value.

4. The method of claim **1**, wherein establishing the at least one alarm threshold comprises offsetting the dynamically calculated baseline.

5. A method of operating a medical device, comprising:
acquiring measurements of a physiological parameter;
determining a dynamic baseline of the measurements;
establishing at least one dynamic alarm threshold based on the dynamic baseline;
calculating an integral of a difference between a current measurement and the dynamic alarm threshold when the current measurement exceeds the dynamic alarm threshold; and
triggering an alarm when the integral exceeds an integral threshold.

6. The method of claim **5**, wherein determining the dynamic baseline of the measurements comprises calculating a baseline value that varies slower than the measurements.

7. The method of claim **5**, wherein determining the dynamic baseline of the measurements comprises low-pass

filtering, running median filtering, infinite impulse response filtering, or finite impulse response filtering, or a combination thereof.

8. The method of claim **5**, comprising establishing a dynamic high alarm threshold and a dynamic low alarm threshold based on the dynamic baseline of the measurements.

9. The method of claim **5**, wherein establishing the at least one dynamic alarm threshold comprises at least one of adding a specified value to or subtracting a specified value from the dynamic baseline.

10. The method of claim **5**, wherein establishing the at least one alarm threshold comprises calculating an offset dynamic baseline.

11. The method of claim **5**, wherein the integral threshold comprises at least one of a default value or a user defined value.

12. The method of claim **5**, comprising clearing the alarm when the current measurement no longer exceeds the alarm threshold.

13. The method of claim **12**, wherein clearing the alarm comprises clearing the alarm at a fading rate greater than a build-up rate.

14. The method of claim **5**, wherein the measurements of a physiological parameter comprise at least one of a pulse rate measurement and an oxygen saturation measurement.

15. The method of claim **5**, wherein triggering an alarm comprises at least one of sounding an audible alarm or displaying a visual alarm.

16. One or more tangible, machine readable media, comprising code executable to perform the acts of:
determining a dynamic baseline of measurements of a physiological parameter;
establishing at least one dynamic alarm threshold based on the dynamic baseline;
calculating an integral of a difference between a current measurement and the dynamic alarm threshold when the current measurement exceeds the dynamic alarm threshold; and
triggering an alarm when the integral exceeds an integral threshold.

17. The tangible, machine readable media of claim **16**, wherein determining the dynamic baseline of the measurements comprises calculating a baseline value that varies slower than the measurements.

18. The tangible, machine readable media of claim **16**, wherein determining the dynamic baseline of the measurements comprises low-pass filtering, running median filtering, infinite impulse response filtering, or finite impulse response filtering.

19. The tangible, machine readable media of claim **16**, comprising establishing a dynamic high alarm threshold and a dynamic low alarm threshold based on the dynamic baseline of the measurements.

20. The tangible, machine readable media of claim **16**, wherein establishing the at least one dynamic alarm threshold comprises at least one of adding a specified value to or subtracting a specified value from the dynamic baseline.

21. The tangible, machine readable media of claim **16**, wherein establishing the at least one alarm threshold comprises calculating an offset dynamic baseline.

22. The tangible, machine readable media of claim **16**, wherein the integral threshold comprises at least one of a default value or a user defined value.

23. The tangible, machine readable media of claim **16**, comprising clearing the alarm when the current measurement no longer exceeds the alarm threshold.

24. The tangible, machine readable media of claim **23**, wherein clearing the alarm comprises clearing the alarm at a fading rate greater than a build-up rate.

25. The tangible, machine readable media of claim **16**, wherein the measurements of a physiological parameter comprise at least one of a pulse rate measurement and an oxygen saturation measurement.

26. The tangible, machine readable media of claim **16**, wherein triggering an alarm comprises at least one of sounding an audible alarm and displaying a visual alarm.

27. A patient monitoring system comprising:
  at least one channel configured to acquire measurements of a physiological parameter;
  a processor configured to determine a dynamic baseline of the measurements, to establish at least one dynamic alarm threshold based on the dynamic baseline, and to calculate an integral of a difference between a current measurement and the dynamic alarm threshold when the current measurement exceeds the dynamic alarm threshold; and
  an alarm configured to be triggered when the integral exceeds an integral threshold.

28. The system of claim **27**, wherein the alarm comprises at least one of an audible or visual alarm.

29. A method of operating a medical diagnostic device, comprising:
  acquiring measurements of a physiological parameter;
  determining a dynamic baseline of the measurements;
  establishing at least one dynamic alarm threshold based on the dynamic baseline;

  calculating an integral of a difference between a current measurement and the dynamic alarm threshold when the current measurement exceeds the dynamic alarm threshold;
  establishing at least one fixed alarm threshold; and
  triggering an alarm when the integral exceeds an integral threshold or when the current measurement exceeds the fixed alarm threshold.

30. The method of claim **29**, wherein determining the dynamic baseline of the measurements comprises at least one of low-pass filtering, running median filtering, infinite impulse response filtering, or finite impulse response filtering.

31. The method of claim **29**, comprising:
  establishing a dynamic high alarm threshold and a dynamic low alarm threshold based on the dynamic baseline of the measurements; and
  establishing a high fixed alarm threshold and a low alarm threshold based on default values or user input.

32. The method of claim **29**, comprising clearing the alarm when the current measurement no longer exceeds either of the dynamic alarm threshold or the fixed alarm threshold.

33. The method of claim **32**, wherein clearing the alarm comprises clearing the alarm at a fading rate greater than a build-up rate.

34. The method of claim **29**, wherein the measurements of a physiological parameter comprise at least one of a pulse rate measurement and an oxygen saturation measurement.

*   *   *   *   *

专利名称(译)	生理监测中的滋扰警报减少		
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[标]申请(专利权)人(译)	内尔科尔普里坦贝内特公司		
申请(专利权)人(译)	NELLCOR PURITAN BENNETT INC.		
当前申请(专利权)人(译)	COVIDIEN LP		
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摘要(译)

一种用于控制医疗诊断设备中的警报的方法和设备，其中当生理参数的测量值在指定范围之外时产生警报。该方法连续计算基线值，并建立与基线值相关并连续跟踪基线值的动态阈值。该方法确定测量值超过动态阈值的时间量以及阈值通过的量。基于时间量和阈值通过量的组合来触发警报。优选地，该组合是积分的整体或某种函数。