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

(75) Inventor: **Paul D. Mannheimer**, Danville, CA (US)

(73) Assignee: **Covidien LP**, Mansfield, MA (US)

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This patent is subject to a terminal disclaimer.

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A61B 5/00 (2006.01)

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(58) **Field of Classification Search** 600/309, 600/310, 322, 323, 324, 325, 326, 500, 501, 600/502, 503, 504, 300
See application file for complete search history.

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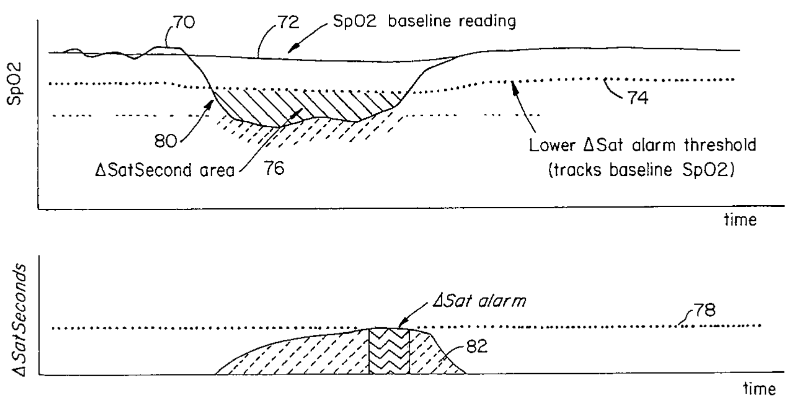
Primary Examiner — Eric Winakur

(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.

22 Claims, 4 Drawing Sheets



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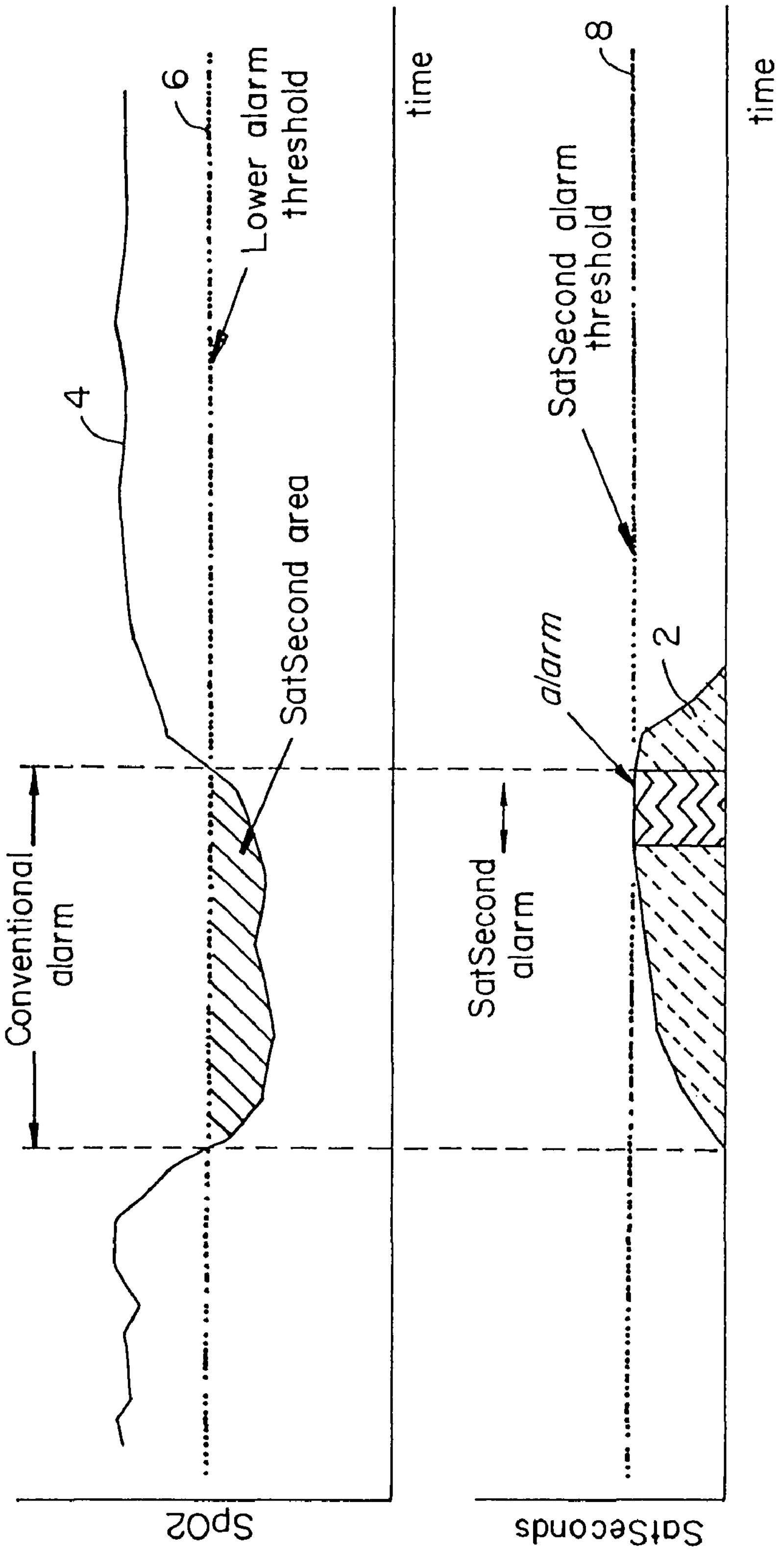

FIG. 1. (PRIOR ART)

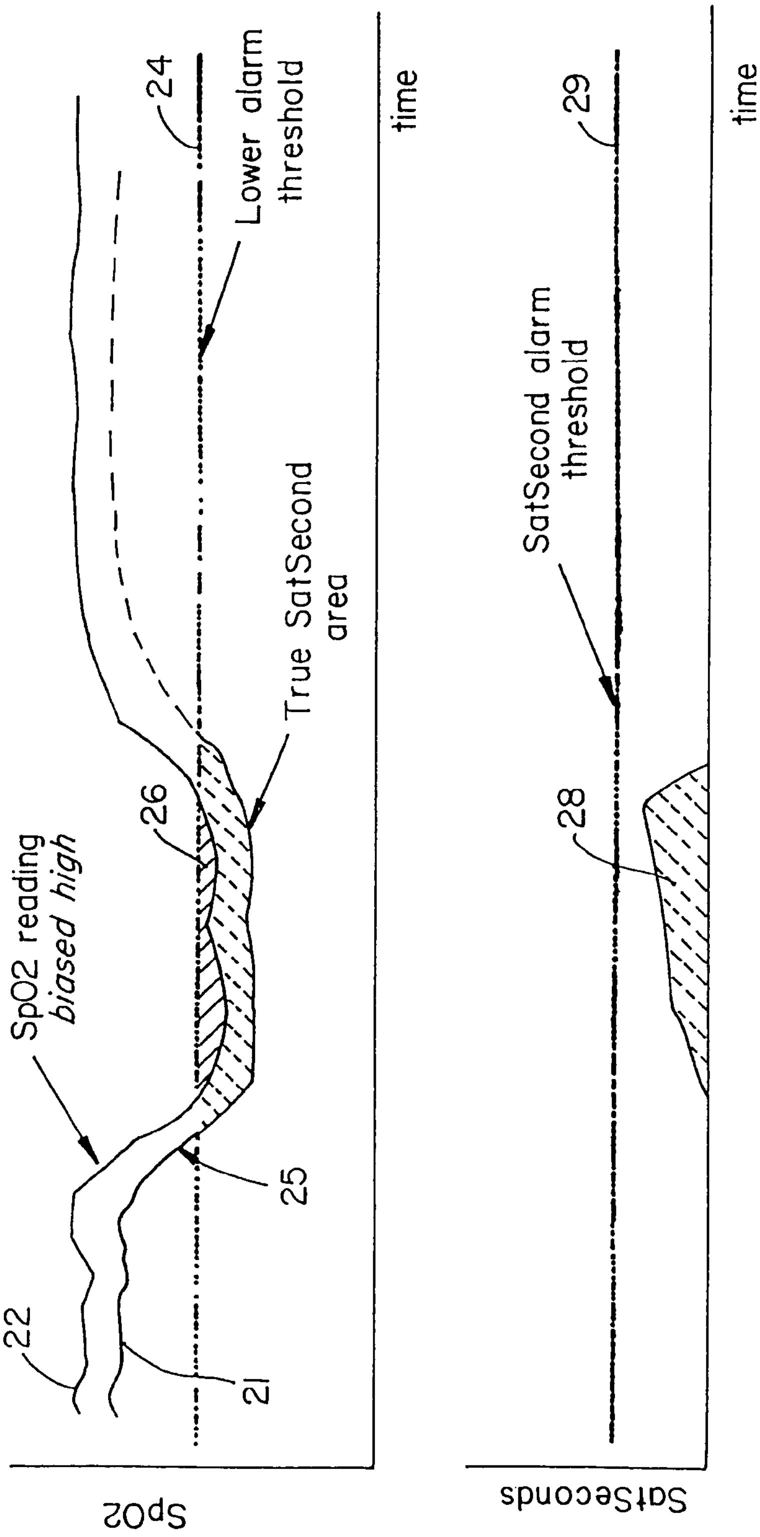
SpO2
SpO2 reading biased high
22
21
25
26
True SatSecond area
Lower alarm threshold
24
time
SatSeconds
SatSecond alarm threshold
28
29
time

FIG. 2.

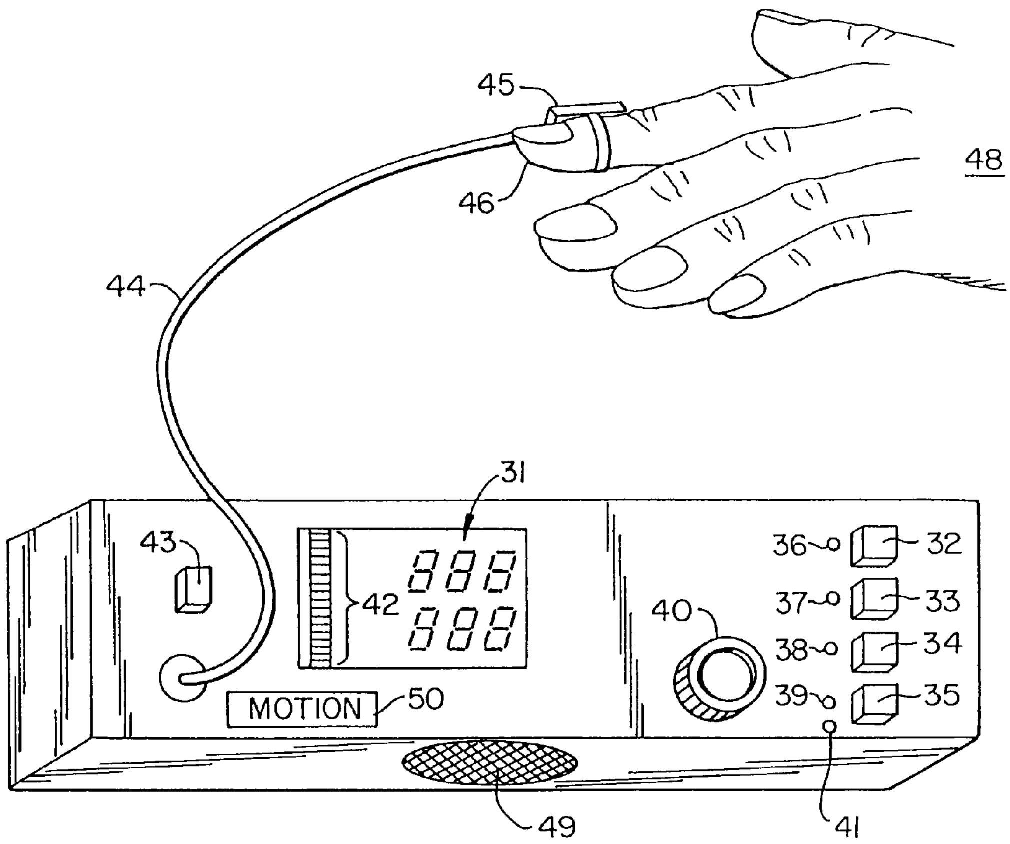
45
46
44
48
31
43
42
888
888
40
36
32
37
33
38
34
39
35
MOTION
50
49
41

FIG. 3.

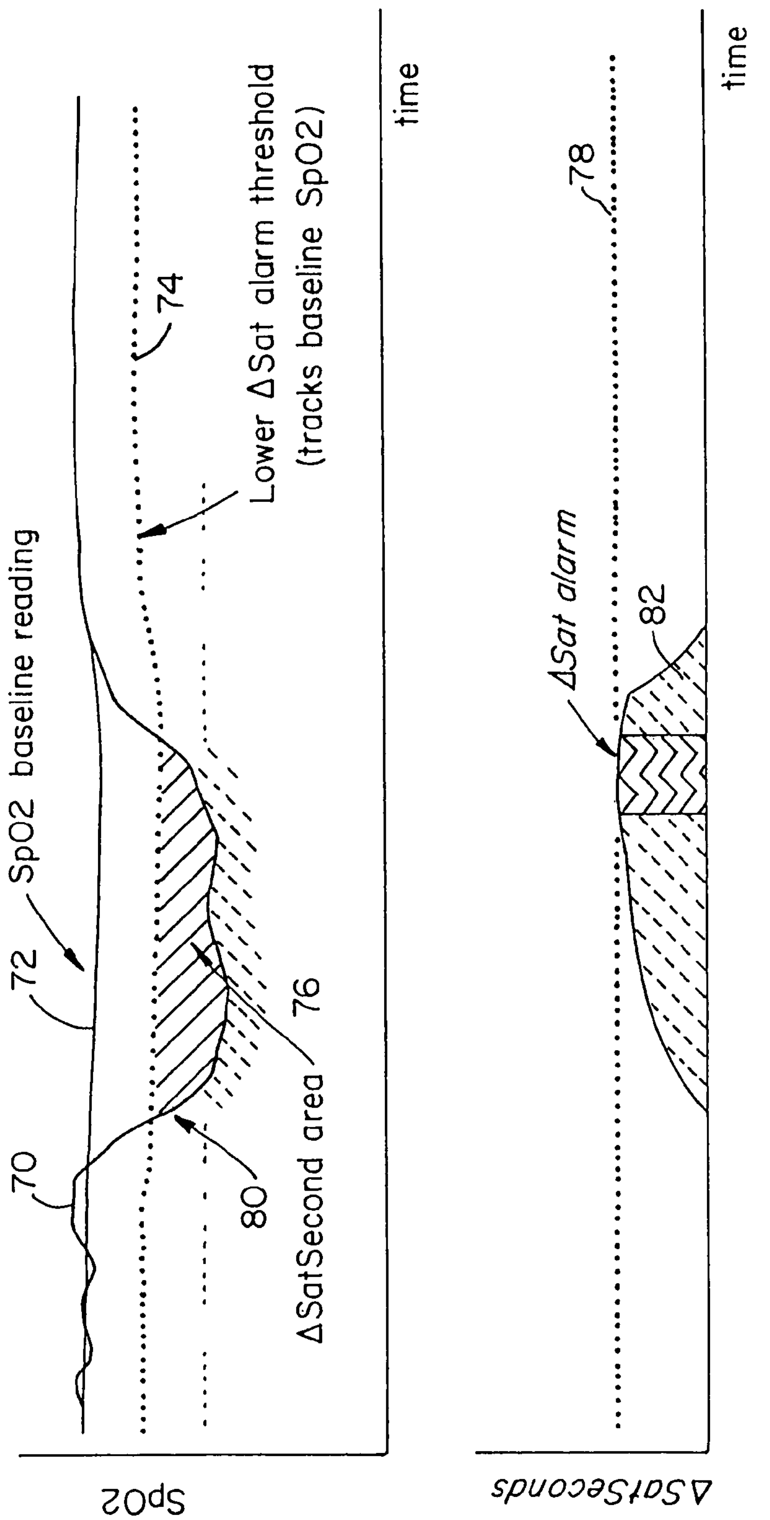
SpO2 baseline reading
72
70
74
Lower ΔSat alarm threshold
(tracks baseline SpO2)
time
76
80
ΔSatSecond area
SpO2
78
ΔSat alarm
82
time
ΔSatSeconds

FIG. 4.

NUISANCE ALARM REDUCTIONS IN A PHYSIOLOGICAL MONITOR

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 11/581,503, filed Oct. 16, 2006, which 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 5 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 SatSecond 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 provide 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 alarms 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** 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 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. 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 shown in FIG. **3** is shown for exemplary purposes and is not meant to limit the embodiments 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.

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. **4** 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 **70** falls below the baseline tracking saturation threshold **74**.

In an alternate embodiment, the alarm management method is based on an integrated-relative-threshold algorithm. A saturation signal **70** is compared to a low sat threshold **74**. Also illustrated is an integral threshold **78**. An excursion **80** produces an integral value **82** that can exceed the integral threshold **78**. The value **82** 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 **72** for the SpO_2 readings, and establishing a continuously and dynamically tracking set of upper (not shown) and lower alarm threshold **74** 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 **82** of time and extent beyond the threshold is calculated. The low sat alarm threshold **74** tracks the baseline SpO_2 trend **72**. The baseline trend **72** is an average of the measured SpO_2 signal **70**, and which is obtained by low-pass filtering the measured SpO_2 signal **70**. The area under the curve **76** where the instantaneous SpO_2 value drops below the lower threshold **74** is calculated (ΔSatSeconds) and an alarm state is entered when the value **82** of the integral equals or exceeds a user defined integral threshold **78**. Alternately, a default value may be used in lieu of the user-defined threshold **78**.

In one embodiment, the baseline value **72**, which the upper (not shown) and lower thresholds **74** 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 **70**. 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 Eqn. 1 below:

$$\text{Baseline Value} = 1/N * SpO_2 + (N-1)/N * \text{Last Baseline Value,} \qquad \text{Eqn. 1}$$

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 ΔSS 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 SpO2 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 ΔSS. 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 ΔSS, 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*5 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 threshold 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 for controlling an alarm in a medical diagnostic apparatus, the method comprising:

measuring a value of a physiological parameter to obtain a measured value;

determining a dynamic threshold value correlative to the measured value;

establishing a condition value based at least in part on an integrated product of the extent by which the dynamic threshold value is passed by the measured value over a period of time; and

triggering an alarm when the condition value exceeds a threshold level.

2. The method of claim **1** wherein the dynamic threshold value comprises a lower alarm limit for the measured value.

3. The method of claim **1** wherein the dynamic threshold value comprises an upper alarm limit for the measured value.

4. The method of claim **1** wherein the measured value is an oxygen saturation, and the dynamic threshold value is at least one of a high oxygen saturation threshold value or a low oxygen saturation threshold value.

5. The method of claim **1** wherein the measured value is a pulse rate, and the dynamic threshold value is at least one of a high pulse rate threshold value or a low pulse rate threshold value.

6. The method of claim **1** wherein determining the dynamic threshold value comprises:

determining a baseline value correlative to the measured value; and

determining the dynamic threshold value correlative to the baseline value.

7. The method of claim **6** wherein the baseline value changes in time in response to the measured value changing in time.

8. The method of claim **6** wherein the baseline value is determined using a low-pass filter.

9. The method of claim **6** wherein the baseline value is determined using a running median filter.

10. The method of claim **6** wherein the baseline value is determined using an infinite impulse filter.

11. The method of claim **6** wherein the baseline value is determined using a finite impulse filter.

12. The method of claim **6** wherein the dynamic threshold value is determined by offsetting from the baseline value by a fixed value.

13. A medical diagnostic apparatus, comprising:

a sensor configured to deliver a signal based at least in part on a physiological parameter;

a processor configured to determine a measured value of the physiological parameter based at least in part on the signal, to determine a dynamic threshold value correlative to the measured value and a condition value based at least in part on an integrated product of the extent by which the dynamic threshold value is passed by the measured value over a period of time, and to trigger an alarm when the condition value exceeds a threshold level.

14. The apparatus of claim **13** wherein the measured value is an oxygen saturation, and the dynamic threshold value is at least one of a high oxygen saturation threshold value or a low oxygen-saturation threshold value.

15. The apparatus of claim **13** wherein the measured value is a pulse rate, and the dynamic threshold value is at least one of a high pulse rate threshold value or a low pulse rate threshold value.

16. The apparatus of claim **13** wherein the processor is configured to determine the dynamic threshold value:

by determining a baseline value correlative to the measured value, and

by determining the dynamic threshold value correlative to the baseline value.

17. The apparatus of claim **16** wherein the baseline value changes in time in response to the measured value changing in time.

18. The apparatus of claim **16** wherein the baseline value is determined using a low-pass filter.

19. The apparatus of claim **16** wherein the baseline value is determined using a running median filter.

20. The apparatus of claim **16** wherein the baseline value is determined using an infinite impulse filter.

21. The apparatus of claim **16** wherein the baseline value is determined using a finite impulse filter.

22. The apparatus of claim **16** wherein the dynamic threshold value is determined by offsetting from the baseline value by a fixed value.

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专利名称(译)	生理监测中的滋扰警报减少		
公开(公告)号	US8401607	公开(公告)日	2013-03-19
申请号	US12/080139	申请日	2008-03-31
[标]申请(专利权)人(译)	内尔科尔普里坦贝内特公司		
申请(专利权)人(译)	NELLCOR PURITAN BENNETT INCORPORATED		
[标]发明人	MANNHEIMER PAUL D		
发明人	MANNHEIMER, PAUL D.		
IPC分类号	A61B5/1455 A61B5/00 A61B5/0245 A61B5/145		
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其他公开文献	US20080183058A1		
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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。