



US008838196B2

(12) **United States Patent**
Mannheimer

(10) **Patent No.:** **US 8,838,196 B2**
(45) **Date of Patent:** ***Sep. 16, 2014**

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

(71) Applicant: **Covidien LP**, Mansfield, MA (US)

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

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

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-
claimer.

(21) Appl. No.: **13/829,704**

(22) Filed: **Mar. 14, 2013**

(65) **Prior Publication Data**

US 2013/0201020 A1 Aug. 8, 2013

Related U.S. Application Data

(63) Continuation of application No. 12/080,139, filed on
Mar. 31, 2008, now Pat. No. 8,401,607, which is a
continuation of application No. 11/581,503, filed on
Oct. 16, 2006, now Pat. No. 8,401,606, which is a
continuation of application No. 10/850,513, filed on
May 19, 2004, now Pat. No. 7,123,950, which is a
continuation of application No. 09/910,700, filed on
Jul. 19, 2001, now Pat. No. 6,754,516.

(51) **Int. Cl.**

A61B 5/1455 (2006.01)

A61B 5/00 (2006.01)

A61B 5/0245 (2006.01)

G08B 21/02 (2006.01)

(52) **U.S. Cl.**

CPC **G08B 21/02** (2013.01); **A61B 5/14551**
(2013.01); **A61B 5/02455** (2013.01); **A61B**
2560/0276 (2013.01); **A61B 5/746** (2013.01)

USPC **600/323**; 600/300; 600/502

(58) **Field of Classification Search**

USPC 600/309, 310, 322, 323, 324, 325, 326,
600/500, 501, 502, 503, 504, 300

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,638,640 A 2/1972 Shaw
4,094,320 A 6/1978 Newton et al.

(Continued)

FOREIGN PATENT DOCUMENTS

EP 0909551 A1 4/1999
JP 2237544 9/1990

(Continued)

OTHER PUBLICATIONS

Bai et al. IEEE Transactions on Information Technology in Biomed-
icine 3(3):197-204 (1999).

(Continued)

Primary Examiner — Eric Winakur

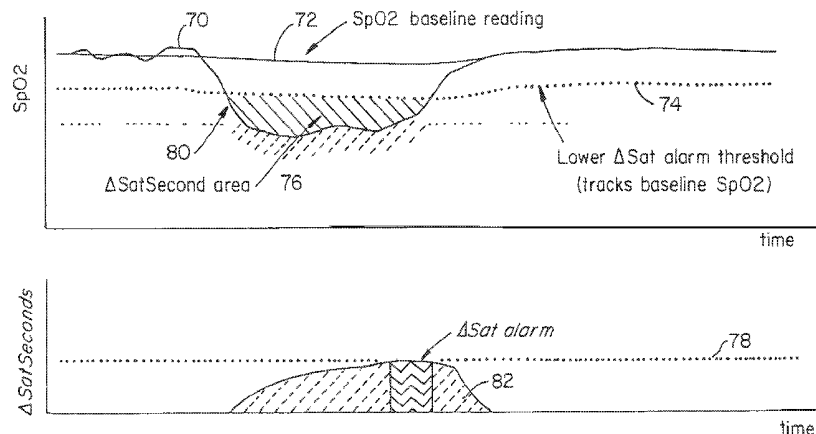
(74) *Attorney, Agent, or Firm* — Fletcher Yoder, P.C.

(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 base-
line 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.

20 Claims, 4 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

4,403,215 A	9/1983	Hofmann et al.	5,995,859 A	11/1999	Takahashi
4,603,700 A	8/1986	Nichols et al.	6,011,986 A	1/2000	Diab et al.
4,653,498 A	3/1987	New, Jr. et al.	6,047,201 A	4/2000	Jackson, III
4,714,341 A	12/1987	Hamaguri et al.	6,064,898 A	5/2000	Aldrich
4,776,339 A	10/1988	Schreiber	6,081,742 A	6/2000	Amano et al.
4,805,623 A	2/1989	Jöbssis	6,088,607 A	7/2000	Diab et al.
4,807,631 A	2/1989	Hersh et al.	6,120,460 A	9/2000	Abreu
4,911,167 A	3/1990	Corenman et al.	6,134,460 A	10/2000	Chance
4,913,150 A	4/1990	Cheung et al.	6,150,951 A	11/2000	Olejniczak
4,936,679 A	6/1990	Mersch	6,154,667 A	11/2000	Miura et al.
4,938,218 A	7/1990	Goodman et al.	6,163,715 A	12/2000	Larsen et al.
4,971,062 A	11/1990	Hasebe et al.	6,181,958 B1	1/2001	Steuer et al.
4,972,331 A	11/1990	Chance	6,181,959 B1	1/2001	Schöllermann et al.
4,974,591 A	12/1990	Awazu et al.	6,230,035 B1	5/2001	Aoyagi et al.
5,028,787 A	7/1991	Rosenthal et al.	6,241,661 B1	6/2001	Schluess et al.
5,065,749 A	11/1991	Hasebe et al.	6,266,546 B1	7/2001	Steuer et al.
5,084,327 A	1/1992	Stengel	6,266,565 B1	7/2001	Er et al.
5,119,815 A	6/1992	Chance	6,285,895 B1	9/2001	Ristolainen et al.
5,122,974 A	6/1992	Chance	6,312,393 B1	11/2001	Abreu
5,167,230 A	12/1992	Chance	6,353,750 B1	3/2002	Kimura et al.
5,190,038 A	3/1993	Polson et al.	6,354,991 B1	3/2002	Gross et al.
5,243,998 A	9/1993	Siulvman et al.	6,397,091 B2	5/2002	Diab et al.
5,246,003 A	9/1993	DeLonzor	6,397,100 B2	5/2002	Stadler et al.
5,247,931 A	9/1993	Norwood	6,398,727 B1	6/2002	Bui et al.
5,253,645 A	10/1993	Friedman et al.	6,415,236 B2	7/2002	Kobayashi et al.
5,263,244 A	11/1993	Centa et al.	6,419,671 B1	7/2002	Lemberg
5,275,159 A	1/1994	Griebel	6,438,399 B1	8/2002	Kurth
5,279,295 A	1/1994	Martens et al.	6,461,305 B1	10/2002	Schnall
5,297,548 A	3/1994	Pologe	6,466,809 B1	10/2002	Riley
5,309,908 A	5/1994	Friedman et al.	6,487,439 B1	11/2002	Skladnev et al.
5,348,004 A	9/1994	Hollub	6,501,974 B2	12/2002	Huiku
5,355,880 A	10/1994	Thomas et al.	6,501,975 B2	12/2002	Diab et al.
5,368,026 A	11/1994	Swedlow et al.	6,526,301 B2	2/2003	Larsen et al.
5,372,136 A	12/1994	Steuer et al.	6,544,193 B2	4/2003	Abreu
5,385,143 A	1/1995	Aoyagi	6,546,267 B1	4/2003	Sugiura et al.
5,390,670 A	2/1995	Centa et al.	6,549,795 B1	4/2003	Chance
5,413,099 A	5/1995	Schmidt et al.	6,579,242 B2	6/2003	Bui et al.
5,464,012 A	11/1995	Falcone	6,580,086 B1	6/2003	Schulz et al.
5,469,144 A	11/1995	Gradzki et al.	6,591,122 B2	7/2003	Schmitt
5,469,845 A	11/1995	DeLonzor et al.	6,594,513 B1	7/2003	Jobsis et al.
5,482,036 A	1/1996	Diab et al.	6,606,509 B2	8/2003	Schmitt
5,483,646 A	1/1996	Uchikoga	6,606,511 B1	8/2003	Ali et al.
5,517,988 A	5/1996	Gerhard	6,615,064 B1	9/2003	Aldrich
5,553,614 A	9/1996	Chance	6,618,042 B1	9/2003	Powell
5,564,417 A	10/1996	Chance	6,622,095 B2	9/2003	Kobayashi et al.
5,575,285 A	11/1996	Takanashi et al.	6,654,621 B2	11/2003	Palatnik et al.
5,611,337 A	3/1997	Bukta	6,654,624 B2 *	11/2003	Diab et al. 600/336
5,630,413 A	5/1997	Thomas et al.	6,658,276 B2	12/2003	Kianl et al.
5,632,272 A	5/1997	Diab et al.	6,658,277 B2	12/2003	Wasserman
5,638,818 A	6/1997	Diab et al.	6,662,030 B2	12/2003	Khalil et al.
5,645,059 A	7/1997	Fein et al.	6,668,183 B2	12/2003	Hicks et al.
5,645,060 A	7/1997	Yorkey	6,671,526 B1	12/2003	Aoyagi et al.
5,662,106 A	9/1997	Swedlow et al.	6,671,528 B2	12/2003	Steuer et al.
5,680,857 A	10/1997	Pelikan et al.	6,678,543 B2	1/2004	Diab et al.
5,692,503 A	12/1997	Kuenstner	6,684,090 B2	1/2004	Ali et al.
5,730,124 A	3/1998	Yamauchi	6,690,958 B1	2/2004	Walker et al.
5,758,644 A	6/1998	Diab et al.	6,697,658 B2	2/2004	Al-Ali
5,779,631 A	7/1998	Chance	6,708,048 B1	3/2004	Chance
5,782,757 A	7/1998	Diab et al.	6,711,424 B1	3/2004	Fine et al.
5,786,592 A	7/1998	Hök	6,711,425 B1	3/2004	Reuss
5,807,246 A	9/1998	Sakaguchi et al.	6,714,245 B1	3/2004	Ono
5,830,135 A	11/1998	Bosque et al.	6,731,274 B2	5/2004	Powell
5,830,136 A	11/1998	Delonzor et al.	6,754,516 B2	6/2004	Mannheimer
5,830,139 A	11/1998	Abreu	6,785,568 B2	8/2004	Chance
5,831,598 A	11/1998	Kauffert et al.	6,793,654 B2	9/2004	Lemberg
5,842,981 A	12/1998	Larsen et al.	6,801,797 B2	10/2004	Mannheimer et al.
5,846,190 A	12/1998	Woehrl	6,801,798 B2	10/2004	Geddes et al.
5,853,364 A	12/1998	Baker, Jr. et al.	6,801,799 B2	10/2004	Mendelson
5,865,736 A *	2/1999	Baker et al. 600/323	6,801,802 B2	10/2004	Sitzman et al.
5,871,442 A	2/1999	Madarasz et al.	6,807,494 B2 *	10/2004	Schutzbach et al. 702/45
5,873,821 A	2/1999	Chance et al.	6,829,496 B2	12/2004	Nagai et al.
5,920,263 A	7/1999	Huttenhoff et al.	6,830,549 B2	12/2004	Bui et al.
5,954,668 A	9/1999	Uber, III et al.	6,850,053 B2	2/2005	Daalmans et al.
5,995,855 A	11/1999	Kiani et al.	6,863,652 B2	3/2005	Huang et al.
5,995,856 A	11/1999	Mannheimer et al.	6,873,865 B2	3/2005	Steuer et al.
			6,889,153 B2	5/2005	Dietiker
			6,898,451 B2	5/2005	Wuori
			6,939,307 B1	9/2005	Dunlop
			6,947,780 B2	9/2005	Scharf

(56)

References Cited**U.S. PATENT DOCUMENTS**

6,949,081 B1 9/2005 Chance
 6,961,598 B2 11/2005 Diab
 6,963,767 B2 11/2005 Rantala et al.
 6,983,178 B2 1/2006 Fine et al.
 6,993,371 B2 1/2006 Kiani et al.
 6,996,427 B2 2/2006 Ali et al.
 7,024,233 B2 4/2006 Ali et al.
 7,024,235 B2 4/2006 Melker et al.
 7,027,849 B2 4/2006 Al-Ali
 7,030,749 B2 4/2006 Al-Ali
 7,035,697 B1 4/2006 Brown
 7,047,056 B2 5/2006 Hannula et al.
 7,127,278 B2 10/2006 Melker et al.
 7,161,484 B2 1/2007 Tsoukalis
 7,162,306 B2 1/2007 Caby et al.
 7,209,775 B2 4/2007 Bae et al.
 7,220,220 B2 5/2007 Stubbs et al.
 7,236,811 B2 6/2007 Schmitt
 7,263,395 B2 8/2007 Chan et al.
 7,272,426 B2 9/2007 Schmid
 7,373,193 B2 5/2008 Al-Ali et al.
 2001/0005773 A1 6/2001 Larsen et al.
 2001/0020122 A1 9/2001 Steuer et al.
 2001/0039376 A1 11/2001 Steuer et al.
 2001/0044700 A1 11/2001 Kobayashi et al.
 2002/0026106 A1 2/2002 Khalil et al.
 2002/0035318 A1 3/2002 Mannheimer et al.
 2002/0038079 A1 3/2002 Steuer et al.
 2002/0042558 A1 4/2002 Mendelson
 2002/0049389 A1 4/2002 Abreu
 2002/0062071 A1 5/2002 Diab et al.
 2002/0111748 A1 8/2002 Kobayashi et al.
 2002/0133068 A1 9/2002 Huiku
 2002/0156354 A1 10/2002 Larson
 2002/0161287 A1 10/2002 Schmitt
 2002/0161290 A1 10/2002 Chance
 2002/0165439 A1 11/2002 Schmitt
 2002/0190863 A1 12/2002 Lynn
 2002/0198442 A1 12/2002 Rantala et al.
 2002/0198443 A1 12/2002 Ting
 2003/0023140 A1 1/2003 Chance
 2003/0055324 A1 3/2003 Wasserman
 2003/0060693 A1 3/2003 Monfre et al.
 2003/0139687 A1 7/2003 Abreu
 2003/0144584 A1 7/2003 Mendelson
 2003/0220548 A1 11/2003 Schmitt
 2003/0220576 A1 11/2003 Diab
 2004/0010188 A1 1/2004 Wasserman
 2004/0054270 A1 3/2004 Pewzner et al.
 2004/0087846 A1 5/2004 Wasserman

2004/0107065 A1 6/2004 Al-Ali
 2004/0127779 A1 7/2004 Steuer et al.
 2004/0133087 A1 7/2004 Ali et al.
 2004/0171920 A1 9/2004 Mannheimer et al.
 2004/0176670 A1 9/2004 Takamura et al.
 2004/0176671 A1 9/2004 Fine et al.
 2004/0230106 A1 11/2004 Schmitt et al.
 2005/0017864 A1 1/2005 Tsoukalis
 2005/0080323 A1 4/2005 Kato
 2005/0101850 A1 5/2005 Parker
 2005/0113651 A1 5/2005 Wood et al.
 2005/0113656 A1 5/2005 Chance
 2005/0168722 A1 8/2005 Forstner et al.
 2005/0177034 A1 8/2005 Beaumont
 2005/0192488 A1 9/2005 Bryenton et al.
 2005/0203357 A1 9/2005 Debreczeny et al.
 2005/0228248 A1 10/2005 Dietiker
 2005/0267346 A1 12/2005 Faber et al.
 2005/0283059 A1 12/2005 Iyer et al.
 2006/0009688 A1 1/2006 Lamego et al.
 2006/0015021 A1 1/2006 Cheng
 2006/0020181 A1 1/2006 Schmitt
 2006/0030763 A1 2/2006 Mannheimer et al.
 2006/0052680 A1 3/2006 Diab
 2006/0058683 A1 3/2006 Chance
 2006/0064024 A1 3/2006 Schnall
 2006/0161389 A1 7/2006 Weber et al.
 2006/0195025 A1 8/2006 Ali et al.
 2006/0195028 A1 8/2006 Hannula et al.
 2006/0224058 A1 10/2006 Mannheimer
 2006/0247501 A1 11/2006 Ali
 2006/0258921 A1 11/2006 Addison et al.

FOREIGN PATENT DOCUMENTS

JP 8256996 10/1996
 WO 9843071 1/1998

OTHER PUBLICATIONS

Barnum P.T. et al.; "Novel Pulse Oximetry Technology Capable of Reliable Bradycardia Monitoring in the Neonate" Respiratory Care vol. 42 No. 1 p. 1072 (Nov. 1997).
 Belal Suliman Yousef et al.; "A fuzzy system for detecting distorted plethysmogram pulses in neonates and paediatric patients" Physiol. Meas. vol. 22 pp. 397-412 (2001).
 Lutter Norbert O. et al.; "False Alarm Rates of Three Third-Generation Pulse Oximeters in PACU ICU and IABP Patients" Anesth Analg vol. 94 pp. S69-S75 (2002).
 Trang et al. "Masimo SetR Pulse Oximetry Improves Detection of Sleep Apnea-Related Hypoxemia" Abstract May 21, 2001.

* cited by examiner

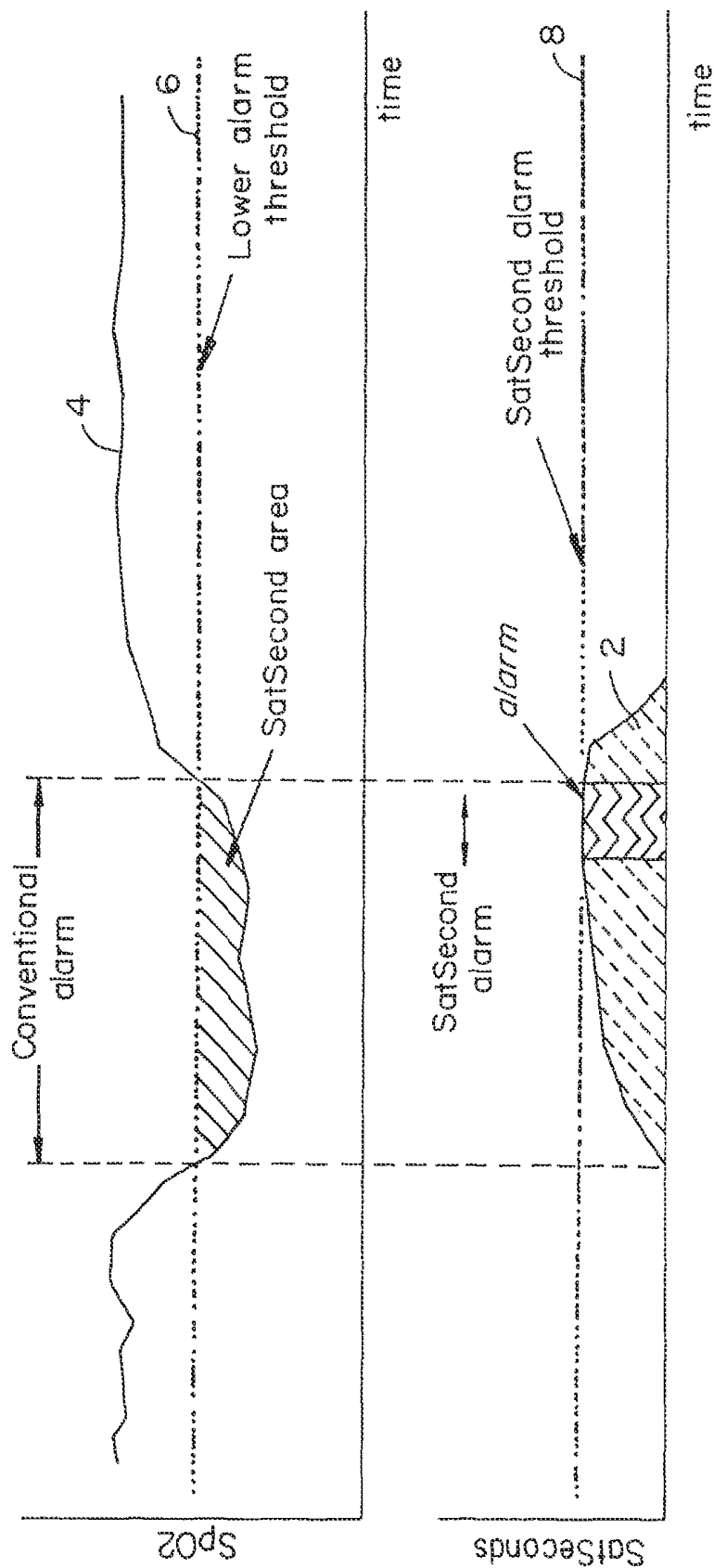


FIG. 1. (PRIOR ART)

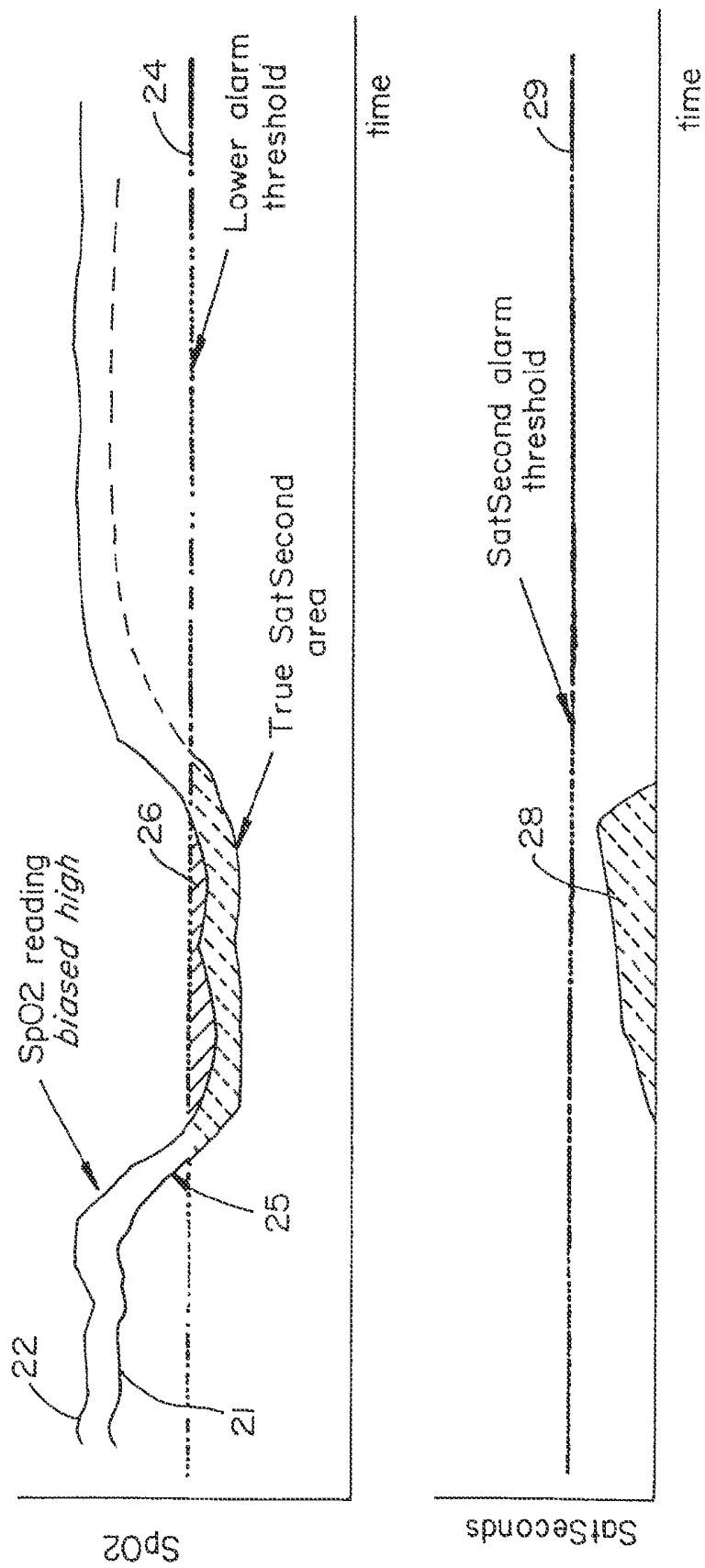


FIG. 2.

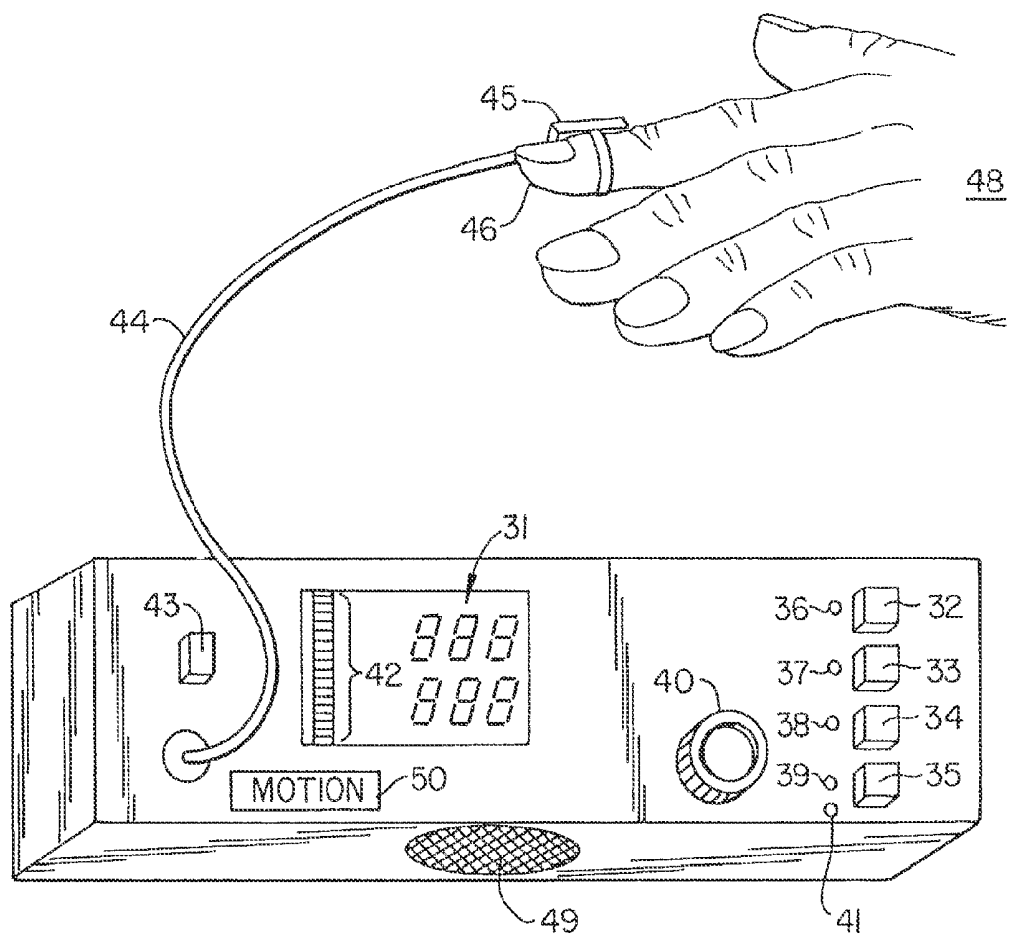


FIG. 3.

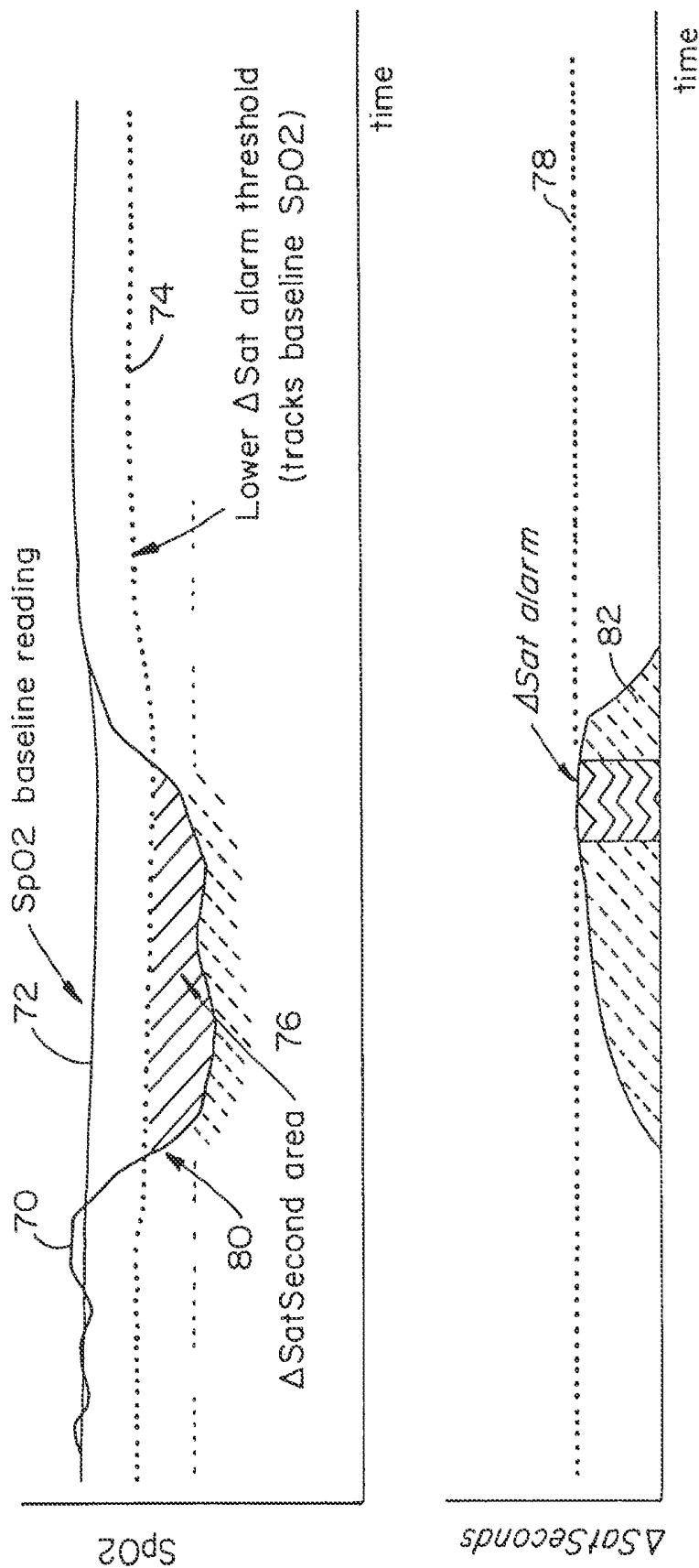


FIG. 4.

NUISANCE ALARM REDUCTIONS IN A PHYSIOLOGICAL MONITOR

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/080,139, filed Mar. 31, 2008, which 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 (SpO₂) and pulse rate. For alarm purposes, low and high thresholds are set for both SpO₂ 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 SpO₂ measurements. As described above and shown in FIG. 1, with conventional alarms, SpO₂ (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 SpO₂ (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 SpO₂ 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 it is 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 each of these prior art methods occurs when the SpO₂ 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 SpO₂ 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 SpO₂ 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 SpO₂ readings. The erroneously high SpO₂ 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 SpO₂ readings were too low due to a low bias. Hence, SpO₂ bias affects the reliability of measured values and alarms based on those values.

Ideally, the SpO₂ reading will be proper (i.e., unbiased from the true SaO₂). 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 by a 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 SpO₂ 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 (SpO₂) 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 alai in 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 ($\Delta\text{SatSeconds}$) 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:

$$\text{Baseline Value} = 1/N * \text{SpO}_2 + (N-1)/N * \text{Last Baseline Value}, \quad \text{Eqn. 1}$$

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 mea-

sured 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 SpO₂ Monitoring Scenarios

The following assumptions apply to each of the following examples:

The baseline true value of SaO₂ 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 (ASS), 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 ASS alarm triggers based on the change from a baseline, while the SS alarm triggers based on crossing the fixed value of 85% SpO₂ (i.e., 10% drop from the 95% true baseline value).

EXAMPLE 1

Correct SpO₂ Readings

This example involves a scenario where the SpO₂ readings are correct, or in other words, the SpO₂ and SaO₂ readings are equivalent, since no measurement bias is present. In this example, if the SaO₂ value drops 2 points below the fixed threshold (83% SaO₂ and SpO₂), the SS alarm will sound 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 SaO₂ drops to 2 points above the fixed threshold (87%), neither alarm will sound as SpO₂ 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 SpO₂ Readings

This example involves a scenario where the SpO₂ baseline reads 98%, 3 points high relative to the true SaO₂ value due to a reading with positive bias. In this example, if the SaO₂ 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 SpO₂ 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 SpO₂ value never drops below 85%. Further, a conventional SpO₂ set to less than 85% would also miss this event.

Since SpO₂ drops by 12 points, this will result in an ASS alarm in 13 seconds (2 points below the dynamic alarm threshold for 13 seconds=26 ASS). 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 SaO₂ drops 8 points, to two points above the threshold (87%), SpO₂ 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 ASS relative-threshold is set to 25 based on a threshold of 10% less than a running baseline.

EXAMPLE 3

Negatively Biased SpO₂ Readings

This example involves a scenario where the SpO₂ baseline reads 92%, 3 points low relative to the true SaO₂ value due to a negatively biased reading. In this example, if the SaO₂ drops 12 points, 2 points below the fixed threshold (83%), with the SpO₂ reading 80% due to the negative bias, the SS alarm is triggered after 5 seconds (5 points below threshold* seconds=25 SS). The ASS 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 SaO₂ 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 (SpO₂=84%). The SpO₂ 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 (ASS) 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 SaO₂ (and thus SpO₂) 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 medical diagnostic apparatus, comprising:
a sensor configured to deliver a signal based at least in part on a physiological parameter; and
a processor configured to determine measurements of the physiological parameter based at least in part on the signal, to establish at least one dynamic alarm threshold based on a dynamically calculated baseline of the measurements, and to trigger an alarm when the measurements exceed the dynamic alarm threshold.
2. The apparatus of claim 1, wherein the processor is configured to establish a dynamic high alarm threshold and a dynamic low alarm threshold based on the dynamically calculated baseline of the measurements.
3. The apparatus of claim 1, wherein the processor is configured to establish the at least one dynamic alarm threshold by calculating a dynamic baseline value and adding a specified value to or subtracting a specified value from the dynamic baseline value.
4. The apparatus of claim 1, wherein the processor is configured to establish the at least one alarm threshold by offsetting the dynamically calculated baseline.
5. The apparatus of claim 1, wherein the physiological parameter comprises at least one of a pulse rate measurement, an oxygen saturation measurement, a blood pressure measurement, and a temperature measurement.
6. 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;
determining an amount of time the measurements are beyond the dynamic alarm threshold and an amount by which the measurements pass the dynamic alarm threshold; and
triggering an alarm based on a combination of the amount of time and the amount by which the dynamic alarm threshold is passed.
7. The method of claim 6, comprising establishing a dynamic high alarm threshold and a dynamic low alarm threshold based on the dynamically calculated baseline of the measurements.

8. The method of claim 6, 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.

9. The method of claim 6, wherein establishing the at least one dynamic alarm threshold comprises calculating an offset dynamic baseline.

10. The method of claim 6, wherein the combination of the amount of time and the amount by which the dynamic alarm threshold is passed comprises an integral or a function of an integral.

11. The method of claim 6, wherein the measurements of the physiological parameter comprise at least one of a pulse rate measurement, an oxygen saturation measurement, a blood pressure measurement, and a temperature measurement.

12. The method of claim 6, wherein triggering the alarm comprises at least one of sounding an audible alarm or displaying a visual alarm.

13. A patient monitoring system, comprising:

at least one channel configured to acquire measurements of a physiological parameter; and

a processor configured to determine a dynamic baseline of the measurements, to establish at least one dynamic alarm threshold based on the dynamic baseline, to determine an amount of time the measurements are beyond the dynamic alarm threshold and an amount by which the measurements pass the dynamic alarm threshold, and to trigger an alarm based on a combination of the amount of time and the amount by which the dynamic alarm threshold is passed.

14. The system of claim 13, wherein the combination of the amount of time and the amount by which the dynamic alarm threshold is passed comprises an integral or a function of an integral.

15. The system of claim 14, wherein the integral comprises an integral of a difference between a current measurement and the dynamic alarm threshold when the current measurement exceeds the dynamic alarm threshold.

16. The system of claim 13, wherein the processor is configured to determine the dynamic baseline of the measurements by calculating a baseline value that varies slower than the measurements.

17. The system of claim 13, wherein the measurements of the physiological parameter comprise at least one of a pulse rate measurement, an oxygen saturation measurement, a blood pressure measurement, and a temperature measurement.

18. The system of claim 13, wherein the processor is configured to determine the dynamic baseline of the measurements by low-pass filtering, running median filtering, infinite impulse response filtering, or finite impulse response filtering.

19. The system of claim 13, wherein the processor is configured to establish the at least one dynamic alarm threshold by adding a specified value to or subtracting a specified value from the dynamic baseline.

20. The system of claim 13, wherein the processor is configured to trigger the alarm by sounding an audible alarm, displaying a visual alarm, or both.

* * * * *

专利名称(译)	生理监测中的滋扰警报减少		
公开(公告)号	US8838196	公开(公告)日	2014-09-16
申请号	US13/829704	申请日	2013-03-14
[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	MANNHEIMER PAUL D		
发明人	MANNHEIMER, PAUL, D.		
IPC分类号	A61B5/1455 A61B5/00 A61B5/0245 A61B5/145 G08B21/02		
CPC分类号	G08B21/02 A61B5/14551 A61B5/02455 A61B5/746 A61B2560/0276		
其他公开文献	US20130201020A1		
外部链接	Espacenet USPTO		

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。

