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(54) **Title**: SYSTEM AND METHOD FOR FACILITATING OBSERVATION OF MONITORED PHYSIOLOGIC DATA

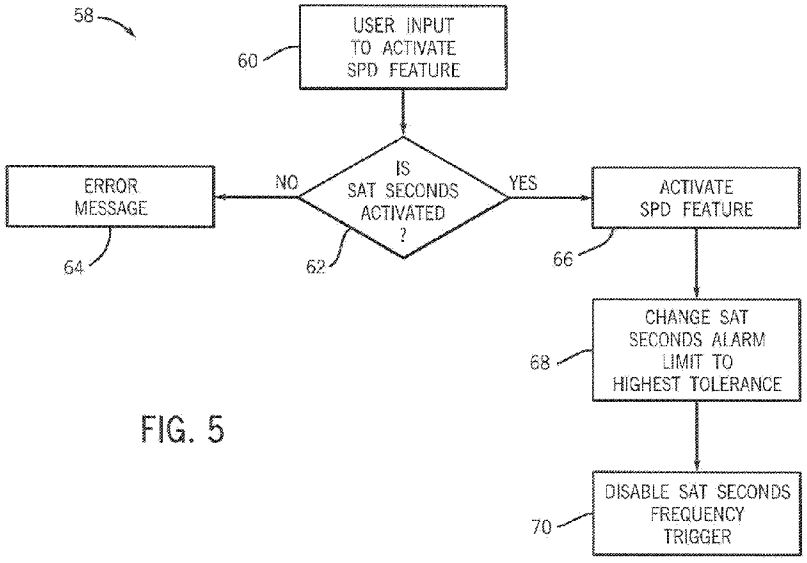


FIG. 5

(57) **Abstract**: Present embodiments are directed to a system and method capable of detecting and graphically indicating physiologic patterns in patient data. For example, present embodiments may include a monitoring system that includes a monitor capable of receiving input relating to patient physiological parameters and providing indications or alarms related to oxygen saturation declines and oxygen desaturation patterns associated with sleep apnea. Present embodiments may include methods and systems for mediating between alarms and other indicators associated with oxygen desaturation and ventilatory instability.

WO 2010/053845 A1

SYSTEM AND METHOD FOR FACILITATING OBSERVATION OF MONITORED PHYSIOLOGIC DATA

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 61/111620 filed November 5, 2008 and U.S. Non Provisional Application No. 12/609344 filed October 30, 2009, which application is hereby incorporated herein by reference.

BACKGROUND

The present disclosure relates generally to user-interface applications for patient monitoring devices. In particular, present embodiments relate to display features that facilitate observation of monitored physiological data with patient monitoring instruments.

This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present disclosure, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present disclosure. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

Patient monitors include medical devices that facilitate measurement and observation of patient physiological data. For example, pulse oximeters are a type of patient monitor. A typical patient monitor cooperates with a sensor to detect and display a patient's vital signs (*e.g.,* temperature, pulse rate, or respiratory rate) and/or other physiological measurements (*e.g.,* water content of tissue, or blood oxygen level) for observation by a

user (*e.g.*, clinician). For example, pulse oximeters are generally utilized with related sensors to detect and monitor a patient's functional oxygen saturation of arterial hemoglobin (*i.e.*, SpO_2) and pulse rate. Other types of patient monitors may be utilized to detect and monitor other physiological parameters. The use of patient monitors may improve patient care by facilitating supervision of a patient without continuous attendance by a human observer (*e.g.*, a nurse or physician).

A patient monitor may include a screen that displays information relating to operation and use of the patient monitor. A typical patient monitor screen may display patient data for further interpretation by a user. Such display information may include indications that relate to a patient's physiological conditions. In addition, a patient monitor may also be capable of generating alarms related to the patient's condition (*e.g.*, changes in a physiological parameter), as well as alarms related to certain operating characteristics of the monitor itself (*e.g.*, low battery alarms). These patient-related alarms may alert a caregiver to conditions that may benefit from medical intervention. However, because a monitor may display various patient information that may be associated with a number of alarms, a monitor may generate so many alarms that the patient's rest is disturbed, and the caregiver may not be able to quickly interpret an individual alarm, particularly if multiple alarms are triggered at once.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of present embodiments may become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. 1 is a perspective view of an exemplary patient monitor;

FIG. 2 is a perspective view of the exemplary patient monitor in a system with separate devices;

FIG. 3 is a block diagram of an exemplary electronic device;

FIG. 4 is a representation of an exemplary display with graphical indicators;

FIG. 5 is an exemplary flowchart depicting a method of mediating between ventilatory instability alarms and saturation alarm limit detection alarms;

FIG. 6 is a block diagram of an exemplary electronic device;

FIG. 7 is an exemplary graph of SpO_2 trend data with an upper band and lower band based on mean and standard deviation values; and

FIG. 8 is an exemplary graph including an SpO_2 trend that contains a ventilatory instability SpO_2 pattern and a trend of the resulting saturation pattern detection index.

DETAILED DESCRIPTION

One or more specific embodiments of the present disclosure will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

Present embodiments provide methods and systems for mediating between multiple alarms and indicators on a medical device such as a patient monitor. As provided, when an indicator related to a patient parameter, *e.g.,* oxygen saturation, is displayed with or without other related indicators, its alarm settings and/or display characteristics may be altered depending upon which other indicators and alarms are present. For example, to efficiently and effectively utilize alarms, it may be useful to limit alarm settings for metrics that may have overlapping effects. Specifically, certain aspects of sleep apnea monitoring may overlap the monitoring of oxygen saturation declines, and, thus, when both metrics are being monitored, it may be desirable to change the tolerance settings for oxygen saturation alarms to reduce redundant alarms. Accordingly, a monitor in accordance with present embodiments may impose certain tolerance settings for alarms related to a first metric, such has oxygen saturation declines, when alarms related to a second metric, such as sleep apnea detection, are eneabled. Because a user, or in certain embodiments a manufacturer, may enable or disable certain monitoring functionalities, for example a sleep apnea monitoring functionality, the present embodiments may provide a medical device with alarm management that mediates alarm settings and tolerance levels to reduce alarm redundancies.

Medical devices, in the course of monitoring a patient, may generate certain alerts that provide information to a caregiver about a patient's physiological condition. For example, a pulse oximetry device may include a graphical indicator or other display alert that notifies a caregiver when a patient's oxygen saturation dips below a certain range or threshold. A caregiver may wish to be alerted to such changes because declines in oxygen saturation may be associated with a range of clinical conditions.

In a patient care environment, a sleeping patient may awaken before a nurse has had the opportunity to acknowledge the alarm, investigate the patient's condition, and/or silence the alarm. To eliminate false alarms that may irritate the patient, the alarm may include certain limits that may reduce alarm notifications for short, sudden dips in oxygen saturation that may be associated with signal interference rather than a change in a patient's condition. For example, an alarm related to oxygen desaturation may only be triggered if an oxygen saturation decline lasts for a certain amount of time or happens with a certain frequency. Such limits may be part of a more complex algorithm or saturation decline detection feature for determining whether a user should be notified of a saturation decline. In addition, the alarm limits may further be determined by user input. For example, a user may decide that an alarm should be more tolerant, and, thus, trigger a notification when the saturation decline is of a greater magnitude lasts for a longer period of time, and/or occurs with a higher frequency. On the other hand, alarm limits that are less tolerant, *i.e.,* more stringent, may trigger a user notification when a relatively smaller decline in oxygen saturation occurs, or when the decline lasts for a relatively shorter duration, and/or occurs with a lower frequency.

In embodiments, a medical device may facilitate observation of a patient's oxygen saturation and may generate alarms associated with both saturation declines and certain patterns associated with saturation declines. For example, certain patterns in oxygen saturation data gathered by a medical monitoring system may be used to assess sleep apnea. Obstructive sleep apnea is a condition in which a patient's breathing is temporarily interrupted when sleeping, and may be assessed by looking for characteristic patterns of ventilatory instability in the oxygen saturation data. These patterns may be

detected by the monitor, and appropriate indicators of these patterns may be provided on a display with corresponding alerts and/or alarms.

In embodiments in which a medical monitor may assess both ventilatory instability and saturation declines, it may be advantageous to eliminate or reduce alarms that may be redundant between these two monitoring functions. For example, in certain embodiments, a saturation decline detection feature may trigger an alarm when a certain number of "dips" below threshold occur in a given time period, *i.e.,* an alarm limit may be associated with a certain frequency of desaturation events. Additionally, a ventilatory instability detection feature may also trigger an alarm when a cluster is detected, which may occur when these dips are part of a desaturation pattern. In such an exemplary case, the saturation decline alarm may be redundant, because the ventilatory instability detection feature may monitor such clusters of desaturation. In other words, while the pattern detection feature and the saturation decline detection feature are monitoring different metrics, their monitoring may overlap and, in embodiments, may trigger two different alarms in response to the same oxygen desaturation events. Accordingly, a medical monitor may adjust its alarm settings and tolerance limits for monitoring both saturation declines and ventilatory instability to reduce redundant alarms.

FIG. 1 is a perspective view of a patient monitor **10** in accordance with an exemplary embodiment of the present disclosure. Specifically, the patient monitor **10** illustrated by **FIG. 1** is a pulse oximeter that is configured to detect and monitor blood oxygen saturation levels, pulse rate, and so forth. It should be noted that while the illustrated embodiment includes a pulse oximeter, other embodiments may include different types of patient monitors **10**. For example, the patient monitor **10** may be representative of a vital signs monitor, a critical care monitor, an obstetrical care monitor, or the like.

The illustrated patient monitor **10** includes a front panel **12** coupled to a body **14** of the monitor **10**. The front panel **12** includes a display screen **16** and various indicators **18** (*e.g.,* indicator lights and display screen graphics) that facilitate operation of the monitor **10** and observation of a patient's physiological metrics (*e.g.,* pulse rate). Some of the indicators **18** are specifically provided to facilitate monitoring of a patient's physiological parameters. For example, the indicators **18** may include representations of the most recently measured values for SpO_2, pulse rate, index values, and pulse amplitude. In embodiments, the indicators **18** may include an indicator related to ventilatory instability and an indicator related to oxygen saturation declines. In an embodiment, one indicator **18** may be a triangular indicator that is related to an index of ventilatory instability determined by the monitor **10**. When the index increases, the triangle fills from bottom to top. In an embodiment, the indicators **18** may also include Sat Seconds indicator that provides an indication related to low oxygen saturation. Other indicators **18** may be specifically provided to facilitate operation of the monitor **10**. For example, the indicators **18** may include an A/C power indicator, a low battery indicator, an alarm silence indicator, a mode indicator, and so forth. The front panel **12** may also include a speaker **20** for emitting audible indications (*e.g.,* alarms), a sensor port **22** for coupling with a sensor **24** (*e.g.,* a temperature sensor, a pulse oximeter sensor) and other monitor features.

Additionally, the front panel **12** may include various activation mechanisms **26** (*e.g.,* buttons and switches) to facilitate management and operation of the monitor **10**. For example, the front panel **12** may include function keys (*e.g.,* keys with varying functions), a power switch, adjustment buttons, an alarm silence button, and so forth. It should be noted that in other embodiments, the indicators **18** and activation mechanisms

26 may be arranged on different parts of the monitor **10**. In other words, the indicators **18** and activation mechanisms **26** need not be located on the front panel **12**. Indeed, in some embodiments, activation mechanisms **26** are virtual representations in a display or actual components disposed on separate devices.

In some embodiments, as illustrated in **FIG. 2**, the monitor **10** may cooperate with separate devices, such as a separate screen **28**, a wireless remote **30**, and/or a keyboard **32**. These separate devices may include some of the indicators **18** and activation mechanisms **26** described above. For example, buttons **34** on the remote **30** and/or keyboard **32** may operate as activation mechanisms **26**. Specifically, for example, the buttons **34** may cause the monitor **10** to perform specific operations (*e.g.*, power up, adjust a setting, silence an alarm) when actuated on the separate device. Similarly, the indicators **18** and/or activation mechanisms **26** may not be directly disposed on the monitor **10**. For example, the indicators **18** may include icons, indicator lights, or graphics on the separate screen **28** (*e.g.*, a computer screen). Further, the activation mechanisms **26** may include programs or graphic features that can be selected and operated via a display. It should be noted that the separate screen **28** and/or the keyboard **32** may communicate directly or wirelessly with the monitor **10**.

FIG. 3 shows an exemplary block diagram of a monitor **10** including saturation pattern detection feature **38** and a saturation alarm limit detection feature **40**. Data **42** collected by a sensor **24** may be processed by the monitor **10** in any suitable manner and reported to both the saturation pattern detection feature **38** and the saturation alarm limit detection feature **40**. The sensor data **24** may be analyzed by one or both of the saturation pattern detection feature **38** and the saturation alarm limit detection feature **40** (both discussed

below) to provide an output to one or more notification features **44**. The notification features **44** may include an output for display on a display screen **28**, such as a graphical or text indicator, an output to drive indicator lights, and/or an output to audible alarm structures, such as speakers.

FIG. 4 is an exemplary display **50** including exemplary user notifications of graphical indicators for notifying a healthcare provider about patient ventilatory instability (via saturation pattern detection feature **38**) and oxygen desaturation (via saturation alarm limit detection feature **40**). In embodiments, a desaturation indicator **52** may be a Sat Seconds indicator that relates to oxygen saturation information. As shown, a SatSeconds indicator may be displayed as a dashed circle that may fill up in relation to the information provided by a calculation algorithm, such as one that may be stored in a memory (*e.g.,* a mass storage device, an EEPROM, an optical memory device, a RAM, a ROM, or any other device for storing machine-readable instructions) and executed by a processor as part of a saturation alarm limit detection feature **40**.

Sat Seconds indicator **52** may assist a healthcare provider in focusing on desaturations related to a patient condition rather than short desaturations that may be the result of measurement anomalies. The Sat Seconds indicator **52** may display results determined by the saturation alarm limit detection feature **40** (*i.e.,* a Sat Second analyzing function), which in an embodiment analyzes desaturation events by multiplying their duration (seconds) by the number of percentage points the patient exceeds the alarm limit.

In an embodiment, the saturation alarm limit detection feature **40** may determine if an oxygen desaturation event has occurred by analyzing a plot of oxygen saturation versus time. The Sat Seconds saturation alarm limit detection feature **40** may integrate the area

under the curve of time spent below a certain oxygen saturation threshold. Accordingly, sudden, short desaturation readings that may be measurement noise (*e.g.*, that otherwise may trigger nuisance alarms) may be eliminated from a Sat Seconds counter clock while more prolonged desaturations may be counted. In embodiments, a SatSeconds limit, or clock, shown as indicator may be set to 10, 25, 50 or 100 SatSeconds, with 100 SatSecond representing the highest tolerance (i.e. least stringent(and 10 SatSeconds representing the lowest tolerance (*i.e.*, most stringent) settings. In an embodiment, the clock may be set to 100, and therefore only events that equal or surpass the 100 SatSeconds limit may trigger an alarm. In addition, the Sat Seconds indicator **52** may fill up in relation to the Sat Seconds count. For example, the indicator **52** may be full when the count reaches 100. In embodiments, the saturation alarm limit detection feature **40** may incorporate techniques such as those provided in U.S. Patent No. 5,865,736 to Baker Jr. et al., U.S. Patent No. 6,754,516 to Mannheimer, and U.S. Patent No. 7,123,950 to Mannheimer, the specifications of which are incorporated by reference in their entireties herein for all purposes.

In embodiments, the display **50** may also include a Saturation Pattern Detection (SPD) graphical indicator **54** that may provide information to a user related to the occurrence, frequency, and/or magnitude of the patterns detected. The information may be based on a scoring metric, for example a Saturation Pattern Detection index (SPDi index), as provided herein, which is proportional to the magnitude and variability of qualified reciprocations. The SPD calculation feature may be capable of notifying a user of ventilatory instability that corresponds to a certain SPDi index value. In embodiments, when the SPDi is at or above a threshold setting, the user may be notified via a graphical indicator **54**.

As illustrated in **FIG. 4**, the graphical indicator **54** may be represented on display **50** as a dashed triangle that may graphically fill from top to bottom as a monitored and/or calculated value increases. For example, in one embodiment, the graphical indicator **54** may gradually fill as the SPDi index calculated by an SPDi calculation feature increases. Further, the graphical indicator **54** may include a tolerance level indicator **56** that displays an index, for example 1, 2, or 3, for tolerance or sensitivity settings of High, Medium, and Low, respectively, for the SPDi calculation feature. The tolerance settings may set the threshold for triggering a change in the graphical indicator **54** and/or for triggering SPD-associated alarms (*e.g.*, audible and/or visual alarms). As shown in **FIG. 4**, the graphical indicator **54** may be empty, indicating that an SPDi index is below a certain threshold.

The indicator **54** may have multiple possible display states, which may include: empty, 25% full, 50% full, 75% full, or 100% full. In embodiments, the indicator **54** may fill in any suitable manner. For example, a graphical indicator may have any number of fill states, *e.g.*, filling up in 10%, 20%, 25%, or 50% increments. A filled state of the graphical indicator **54** may trigger a primary or secondary alarm. In an embodiment, a primary alarm, such as a text alert, may be triggered when the graphical indicator **54** begins to fill. When the indicator **54** has reached a full state, a secondary alarm, such as an audio alarm, may then be triggered. The "filling up" may represent the addition of a fill (*e.g.*, any color pixels) to the area of the triangle. In one embodiment, the graphical indicator **54** may fill up when the calculated SPDi index is higher than a tolerance setting. As noted, the High Tolerance, Medium Tolerance, and Low Tolerance alarm limits may refer to certain default values of the SPDi index, such as 24, 15, and 6, respectively. When the SPDi index is higher than, for example, 24 (High Tolerance

setting), the graphical indicator **54** may begin to fill. In an embodiment, the graphical indicator **54** may begin to fill up when the SPDi index is lower than but near 24, whereby an SPDi index of 24 represents a "full" state. In such an embodiment, the approximately 25% full graphical indicator as shown may represent an SPDi index of, for example, 18.

In embodiments, a user may have the ability to change certain settings on the monitor **10** related to the graphical indicators and monitoring function. **FIG. 5** is a flow chart depicting a method **58** of mediating between SPD monitoring functions and indicators and saturation alarm limits (e.g. Sat Seconds limits) and indicators. In an embodiment, a user may be able to select an option in which the monitor **10** activates SPD calculation features **38** and associated indicators and alarms (step **60**).

In embodiments, the SPD feature **38** may be activated only when a Sat Seconds feature, such as saturation alarm limit feature **40**, is also active. In such embodiments, prior to activating the SPD feature **38**, the monitor may establish whether a Sat Seconds calculation and/or display feature is activated at step **62**. In embodiments in which Sat Seconds is not active and initiation of the SPD feature **38** is being requested, the monitor **10** may display an error message or other notification at step **64**. In embodiments in which Sat Seconds is active, the monitor **10** may activate the SPD feature **38** (step **66**) and adjust or mediate the Sat Seconds alarm and notification settings to account for the additional features provided in the SPD feature **38**. For example, at step **68**, a Sat Seconds alarm limit may be automatically raised to a higher tolerance upon activation of the SPD feature **38**. The monitor **10** may assess the setting of the Sat Seconds tolerance, and if the tolerance is not already set to a highest possible level, the monitor **10** may

automatically reset the Sat Seconds tolerance. In such an embodiment, with a Sat Seconds alarm limit set to a higher tolerance, alarms associated with oxygen desaturation may occur less frequently while SPD-associated alarms for ventilatory instability may be triggered. Because certain aspects of the SPD calculation feature **38** may overlap with the saturation alarm limit detection feature **40**, by setting a Sat Seconds limit to a higher tolerance, redundant alarm triggering may be reduced. In addition, the occurrence of redundant alarms may also be reduced if certain overlapping monitoring features of the saturation alarm limit detection feature **40** calculation or algorithm are disabled. For example, at step **70**, a frequency trigger portion of the algorithm may be disabled. For example, a portion of the saturation alarm limit detection feature **40** that triggers a Sat Seconds count when a certain number of oxygen saturation dips occurs within a certain time period, no matter their magnitude or duration, may be disabled. Because the SPD calculation feature **38** may monitor and assess the occurrence of desaturation clusters, it may be redundant to trigger an additional alarm with the saturation alarm limit detection feature **40** when clusters of desaturations occur in a short time period.

In an embodiment, a user may be able to change the default values on the limits to user-selected values and override the Sat Seconds alarm limit. In addition, a user may select between multiple SPD tolerance settings for High, Medium, or Low Tolerance of the SPD-associated alarms. In an embodiment, a monitor **10** may store certain default values associated with SPDi index values. These default values may be determined based on clinical observations of a test patient population or other input from healthcare providers. For example, the default High Tolerance value may be associated with an SPDi index value of 24. Accordingly, any SPD-associated alarms may not trigger until the SPDi index for a calculated window of time is at or near 24.

In another embodiment, a user may input specific values for High, Medium, and Low Tolerance limits. A user may select any value, so long as the High Tolerance limit is higher than the Medium Tolerance limit, and the Medium Tolerance limit is higher than the Low Tolerance limit. A monitor **10** may be able trigger an error message if a user attempts to set a limit of less than zero or if a user attempts to set a High Tolerance limit that is lower than a Medium Tolerance limit, and so on.

Monitoring of ventilatory instability that may be associated with sleep apnea may be accomplished via saturation pattern detection feature 38. SPD feature 38 may be stored on a tangible, computer-readable medium (*e.g.,* a memory) and/or hardware capable of detecting the presence of a saturation pattern in a series of physiologic data. For example, **FIG. 6** is a block diagram of an electronic device or pattern detection feature 38 in accordance with present embodiments. The electronic device is generally indicated by the reference number **200**. The electronic device **200** (*e.g.,* an SpO_2 monitor and/or memory device) may comprise various subsystems represented as functional blocks in **FIG. 6**. Those of ordinary skill in the art will appreciate that the various functional blocks shown in **FIG. 6** may comprise hardware elements (*e.g.,* circuitry), software elements (*e.g.,* computer code stored on a hard drive) or a combination of both hardware and software elements. For example, each functional block may represent software code and/or hardware components that are configured to perform portions of an algorithm. Specifically, in the illustrated embodiment, the electronic device **200** includes a reciprocation detection (RD) feature **202**, a reciprocation qualification (RQ) feature **204**, a cluster determination (CD) feature **206**, SPD calculator feature **208**, and a user notification (UN) feature **210**. Each of these components and the coordination of their functions will be discussed in further detail below.

It should be noted that, in order to detect certain data patterns, embodiments of the present disclosure may utilize systems and methods such as those disclosed in U.S. Patent No. 6,760,608, U.S. Patent No. 6,223,064, U.S. Patent No. 5,398,682, U.S. Patent No. 5,605,151, U.S. Patent No. 6,748,252, U.S. Application No. 11/455,408 filed June 19, 2006, U.S. Application No. 11/369,379 filed March 7, 2006, and U.S. Application No. 11/351,787 filed February 10, 2006. Accordingly, U.S. Patent No. 6,760,608, U.S. Patent No. 6,223,064, U.S. Patent No. 5,398,682, U.S. Patent No. 5,605,151, U.S. Patent No. 6,748,252, U.S. Application No. 11/455,408 filed June 19, 2006, U.S. Application No. 11/369,379 filed March 7, 2006, and U.S. Application No. 11/351,787 filed February 10, 2006 are each incorporated herein by reference in their entirety for all purposes.

The RD feature **202** may be capable of performing an algorithm for detecting reciprocations in a data trend. Specifically, the algorithm of the RD feature **202** may perform a statistical method to find potential reciprocation peaks and nadirs in a trend of SpO_2 data. A nadir may be defined as a minimum SpO_2 value in a reciprocation. The peaks may include a rise peak (*e.g.*, a maximum SpO_2 value in a reciprocation that occurs after the nadir) and/or a fall peak (*e.g.*, a maximum SpO_2 value in a reciprocation that occurs before the nadir). Once per second, the RD feature **202** may calculate a **12** second rolling mean and standard deviation of the SpO_2 trend. Further, based on these mean and standard deviation values, an upper band **220** and lower band **222** with respect to an SpO_2 trend **224**, as illustrated by the graph **226** in **FIG. 7**, may be calculated as follows:

Upper Band = mean + standard deviation;

Lower Band = mean – standard deviation.

Once the upper band **220** and lower band **222** have been determined, potential reciprocation peaks and nadirs may be extracted from the SpO_2 trend **224** using the upper band **220** and the lower band **224**. Indeed, a potential peak may be identified as the highest SpO_2 point in a trend segment which is entirely above the upper band **220**. Similarly, a potential nadir may be identified as the lowest SpO_2 point in a trend segment that is entirely below the lower band **222**. In other words, peaks identified by the RD feature **202** may be at least one standard deviation above the rolling mean, and nadirs identified by the RD feature **202** may be at least one standard deviation below the mean. If there is more than one minimum value below the lower band **222**, the last (or most recent) trend point may be identified as a nadir. If more than one maximum value is above the upper band **220**, the point identified as a peak may depend on where it is in relation to the nadir. For example, regarding potential peaks that occur prior to a nadir (*e.g.,* fall peaks) the most recent maximum trend point may be used. In contrast, for peaks that occur subsequent to a nadir (*e.g.,* rise peaks), the first maximum point may be used. In the example trend data represented in **FIG. 7**, a peak and nadir is detected approximately every 30-60 seconds.

In one embodiment, a window size for calculating the mean and standard deviation may be set based on historical values (*e.g.,* average duration of a set number of previous reciprocations). For example, in one embodiment, a window size for calculating the mean and standard deviation may be set to the average duration of all qualified reciprocations in the last 6 minutes divided by 2. In another embodiment, an adaptive window method may be utilized wherein the window size may be initially set to 12

seconds and then increased as the length of qualified reciprocations increases. This may be done in anticipation of larger reciprocations because reciprocations that occur next to each other tend to be of similar shape and size. If the window remained at 12 seconds, it could potentially be too short for larger reciprocations and may prematurely detect peaks and nadirs. The following equation or calculation is representative of a window size determination, wherein the output of the filter is inclusively limited to 12-36 seconds, and the equation is executed each time a new reciprocation is qualified:

If no qualified reciprocations in the last 6 minutes:
Window Size = 12 (initial value)
else:
RecipDur = ½ * current qualified recip duration + ½ * previous RecipDur
Window Size = bound(RecipDur,12,36).

With regard to SpO_2 signals that are essentially flat, the dynamic window method may fail to find the three points (*i.e.*, a fall peak, a rise peak, and a nadir) utilized to identify a potential reciprocation. Therefore, the RD feature **202** may limit the amount of time that the dynamic window method can search for a potential reciprocation. For example, if no reciprocations are found in 240 seconds plus the current adaptive window size, the algorithm of the RD feature **202** may timeout and begin to look for potential reciprocations at the current SpO_2 trend point and later. The net effect of this may be that the RD feature **202** detects potential reciprocations less than 240 seconds long.

Once potential peaks and nadirs are found using the RD feature **202**, the RQ feature **204** may pass the potential reciprocations through one or more qualification stages to determine if a related event is caused by ventilatory instability. A first qualification stage may include checking reciprocation metrics against a set of limits (*e.g.*, predetermined hard limits). A second qualification stage may include a linear

qualification function. In accordance with present embodiments, a reciprocation may be required to pass through both stages in order to be qualified.

As an example, in a first qualification stage, which may include a limit-based qualification, four metrics may be calculated for each potential reciprocation and compared to a set of limits. Any reciprocation with a metric that falls outside of these limits may be disqualified. The limits may be based on empirical data. For example, in some embodiments, the limits may be selected by calculating the metrics for potential reciprocations from sleep lab data where ventilatory instability is known to be present, and then comparing the results to metrics from motion and breathe-down studies. The limits may then be refined to filter out true positives.

The metrics referred to above may include fall slope, magnitude, slope ratio, and path length ratio. With regard to fall slope, it may be desirable to limit the maximum fall slope to filter out high frequency artifact in the SpO_2 trend, and limit the minimum fall slope to ensure that slow SpO_2 changes are not qualified as reciprocations. Regarding magnitude, limits may be placed on the minimum magnitude because of difficulties associated with deciphering the difference between ventilatory instability reciprocations and artifact reciprocations as the reciprocation size decreases, and on the maximum magnitude to avoid false positives associated with sever artifact (*e.g.*, brief changes of more than 35% SpO_2 that are unrelated to actual ventilatory instability). The slope ratio may be limited to indirectly limit the rise slope for the same reasons as the fall slope is limited and because ventilatory instability patterns essentially always have a desaturation rate that is slower than the resaturation (or recovery) rate. The path length ratio may be

defined as Path Length/((Fall Peak – Nadir) + (Rise Peak – Nadir)), where Path Length = Σ|Current SpO_2 Value – Previous SpO_2 value| for all SpO_2 values in a reciprocation, and the maximum path length ratio may be limited to limit the maximum standard deviation of the reciprocation, which limits high frequency artifact. The following table (Table I) lists the above-identified metrics along with their associated equations and the limits used in accordance with one embodiment:

Metric	Equation	Minimum	Maximum
Fall Slope	(Nadir – Fall Peak)/Time between Fall Peak and Nadir	-1.6 (Fast Response Mode) -1 (Normal Response Mode)	-0.08 (Fast Response Mode) -0.05 (Normal Response Mode)
Magnitude	Max(Rise Peak, Fall Peak) – Nadir	3	35
Slope Ratio	|Fall Slope / Rise Slope |	0.05	1.75
Path Length Ratio	Path Length = ∑| Current SpO2 Value – Previous SpO2 Value| for all SpO2 values in a Reciprocation. Path Length Ratio = Path Length/ ((Fall Peak – Nadir) + (Rise Peak – Nadir))	N/A	2

Table I

As indicated in Table I above, an oximetry algorithm in accordance with present embodiments may operate in two response modes: Normal Response Mode or Fast Response Mode. The selected setting may change the SpO_2 filtering performed by the oximetry algorithm, which in turn can cause changes in SpO_2 patterns. Therefore a saturation pattern detection feature may also accept a response mode so that it can account for the different SpO_2 filtering. Table I indicates values associated with both types of response mode with regard to the Fall Slope values.

A second qualification stage of the RQ feature **204** may utilize a object reciprocation qualification feature. Specifically, the second qualification stage may utilize a linear qualification function based on ease of implementation, efficiency, and ease of optimization. The equation may be determined by performing a least squares analysis. For example, such an analysis may be performed with MATLAB®. The inputs to the equation may include the set of metrics described below. The output may be optimized to a maximum value for patterns where ventilatory instability is known to be present. The equation may be optimized to output smaller values (*e.g.*, 0) for other data sets where potential false positive reciprocations are abundant.

To simplify optimization, the equation may be factored into manageable sub-equations. For example, the equation may be factored into sub-equation 1, sub-equation D, and sub-equation 2, as will be discussed below. The output of each sub-equation may then be substituted into the qualification function to generate an output. The outputs from each of the sub-equations may not be utilized to determine whether a reciprocation is qualified in accordance with present embodiments. Rather, an output from a full qualification function may be utilized to qualify a reciprocation. It should be noted that the equations set forth in the following paragraphs describe one set of constants. However, separate sets of constants may be used based on the selected response mode. For example, a first set of constants may be used for the Normal Response Mode and a second set of constants may be used for the Fast Response Mode.

Preprocessing may be utilized in accordance with present embodiments to prevent overflow for each part of the qualification function. The tables (Tables II-VII) discussed

below, which relate to specific components of the qualification function may demonstrate this overflow prevention. Each row in a table contains the maximum value of term which is equal to the maximum value of the input variable multiplied by the constant, wherein the term "maximum" may refer to the largest possible absolute value of a given input. Each row in a table contains the maximum intermediate sum of the current term and all previous terms. For example, a second row may contain the maximum output for the second term calculated, as well as the maximum sum of terms 1 and 2. It should be noted that the order of the row may match the order that the terms are calculated by the RQ feature **204**. Further, it should be noted that in the tables for each sub-equation below, equations may be calculated using temporary signed 32-bit integers, and, thus, for each row in a table where the current term or intermediate term sum exceeds 2147483647 or is less than -2147483647 then an overflow/underflow condition may occur.

A first sub-equation, sub-equation 1, may use metrics from a single reciprocation. For example, sub-equation 1 may be represented as follows:

Eq1Score = SlopeRatio*SrCf + PeakDiff*PdCf + FallSlope*FsCf + PathRatio*PrCf + Eq1Offset,

where SrCf, PdCf, FsCf, PrCf, and Eq1Offset may be selected using least squares analysis (*e.g.*, using MATLAB®). PeakDiff may be defined as equal to |Recip Fall Peak – Recip Rise Peak|. It should be noted that PeakDiff is typically not considered in isolation but in combination with other metrics to facilitate separation. For example, a true positive reciprocation which meets other criteria but has a high peak difference could be an incomplete recovery. That is, a patient's SpO_2 may drop from a baseline to a certain nadir value, but then fail to subsequently recover to the baseline. However, when

used in combination with other metrics in the equation, PeakDiff may facilitate separation of two classifications, as large peak differences are more abundant in false positive data sets.

With regard to sub-equation 1, the tables (Tables II and III) set forth below demonstrate that the inputs may be preprocessed to prevent overflow. Further, the tables set forth below include exemplary limits that may be utilized in sub-equation 1 in accordance with present embodiments. It should be noted that Table II includes Fast Response Mode constants and Table III includes Normal Response Mode constants.

Term	Variable Type	Maximum Variable Value (a)	Variable Preprocessing	Constant Value (b) (Fast Mode)	Maximum Term Value (a * b)	Maximum Intermediate Sum (sum of all previous rows)	Overflow
PeakDiff*PdCf	U8	100	None. This value may not exceed 100 since the maximum SpO_2 value accepted is 100	-29282	-2928200	-2928200	NO
SlopeRatio*SrCf	U8	255	None	-1534	-391170	-3319370	NO
FallSlope*FsCf	S16	-32768	None	-19	622592	-2696778	NO
PathRatio*PrCf	U16	65535	None	-7982	-523100370	-525797148	NO
Eq1Offset	N/A	N/A	N/A	809250	809250	-524987898	NO

Table II.

Term	Variable Type	Maximum Variable Value (a)	Variable Preprocessing	Constant Value (b) (Normal Mode)	Maximum Term Value (a * b)	Maximum Intermediate Sum (sum of all previous rows)	Overflow
PeakDiff*PdCf	U8	100	None. This value may not exceed 100 since the maximum SpO2 value accepted is 100	-33311	-3331100	-3331100	NO
SlopeRatio*SrCf	U8	255	None	-2151	-548505	-3879605	NO
FallSlope*FsCf	S16	-32768	None	-706	23134208	19254603	NO
PathRatio*PrCf	U16	65535	None	-6178	-404875230	-385620627	NO
Eq1Offset	N/A	N/A	N/A	576330	576330	-385044297	NO

Table III.

A second sub-equation, sub-equation D, may correspond to a difference between two consecutive reciprocations which have passed the hard limit qualifications checks, wherein consecutive reciprocations include two reciprocations that are separated by less than a defined time span. For example, consecutive reciprocations may be defined as two reciprocations that are less than 120 seconds apart. The concept behind sub-equation D may be that ventilatory instability tends to be a relatively consistent event, with little change from one reciprocation to the next. Artifact generally has a different signature and tends to be more random with greater variation among reciprocations. For example, the following equation may represent sub-equation D:

EqD = SlopeRatioDiff*SrDCf + DurationDiff*DDCf + NadirDiff*NdCf + PathLengthRatioDiff*PrDCf _ EqDOffset,

where, SrDCf, DDCf, NdCf, PrDCf, and EqDOffset may be selected using least squares analysis (*e.g.,* using MATLAB®). With regard to other variables in sub-equation D, SlopeRatioDiff may be defined as |Current Recip Slope Ratio – Slope Ratio of last qualified Recip|; DurationDiff may be defined as |Current Recip Duration – Duration of last qualified Recip|; NadirDiff may be defined as |Current Recip Nadir – Nadir value of last qualified Recip|; and PathLengthRatioDiff may be defined as |Current Recip Path Length Ratio – Path Length Ratio of last qualified Recip|.

With regard to sub-equation D, the tables (Tables IV and V) set forth below demonstrate that the inputs may be preprocessed to prevent overflow. Further, the tables set forth below include exemplary limits that may be utilized in sub-equation D in accordance with present embodiments. It should be noted that Table IV includes Fast Response Mode constants and Table V includes Normal Response Mode constants.

Term	Variable Type	Maximum Variable Value (a)	Variable Preprocessing	Constant Value (b) (Fast Mode)	Maximum Term Value (a * b)	Maximum Intermediate Sum (sum of all previous rows)	Overflow
EqDOffset	N/A	N/A	N/A	885030	885030	885030	NO
SlopeRatioDiff * SrDCf	U8	255	None	-2809	-716295	168735	NO
DurationDiff * DDCf	U16	240	The Recip detection module may only detect recips less than or equal to 240 seconds long	-2960	-710400	-541665	NO
NadirDiff * NdCf	U8	100	This value may not exceed 100 since the maximum SpO2 value accepted is 100	-13237	-1323700	-1865365	NO
PathLengthRatioDiff * PrDCf	U16	65535	None	-7809	-511762815	-513628180	NO

Table IV.

Term	Variable Type	Maximum Variable Value (a)	Variable Preprocessing	Constant Value (b) (Normal Mode)	Maximum Term Value (a * b)	Maximum Intermediate Sum (sum of all previous rows)	Overflow
EqDOffset	N/A	N/A	N/A	847650	847650	847650	NO
SlopeRatioDiff * SrDCf	U8	255	None	-2629	-670395	177255	NO
DurationDiff * DDCf	U16	240	The Recip detection module may only detect recips less than or equal to 240 seconds long	-4282	-1027680	-850425	NO
NadirDiff * NdCf	U8	100	This value may not exceed 100 since the maximum SpO2 value accepted is 100	-11705	-1170500	-2020925	NO
PathLengthRatioDiff * PrDCf	U16	65535	None	-7844	-514056540	-516077465	NO

Table V.

A third sub-equation, sub-equation 2, may combine the output of sub-equation D with the output of sub-equation 1 for a reciprocation (*e.g.,* a current reciprocation) and a previous reciprocation. For example, the following equation may represent sub-equation 2:

Eq2Score = EqDScore*DCf + Eq1ScoreCurrent*CurrEq1Cf + Eq1ScorePrev*PrevEq1Cf,

where DCf, N1Cf, PrevEq1Cf, and Eq2Offset may be selected using least squares analysis (*e.g.,* using MATLAB®). With regard to other variables in sub-equation 2, EqDScore may be described as the output of sub-equation D; Eq1ScoreCurrent may be described as the output of sub-equation 1 for a current reciprocation; and Eq1ScorePrev may be described as the output of sub-equation 1 for the reciprocation previous to the current reciprocation.

With regard to sub-equation 2, the tables (Tables VI and VII) set forth below demonstrate that the inputs may be preprocessed to prevent overflow. Further, the tables set forth below include exemplary limits that may be utilized in sub-equation 2 in accordance with present embodiments. It should be noted that Table VI includes Fast Response Mode constants and Table VII includes Normal Response Mode constants.

Term	Variable Type	Maximum Variable Value (a)	Variable Preprocessing	Constant Value (b) (Fast Mode)	Maximum Term Value (a * b)	Maximum Intermediate Sum (sum of all previous rows)	Overflow
Eq2Offset	N/A	N/A	N/A	-203800	-203800	-203800	NO
*EqDScore * DCf*	S32	-501590	The largest output for sub-equation D may be -513628180 (see Table IV). The input value may be scaled by dividing the value by 1024. Therefore the largest input value may be -501590	529	-265341110	-265544910	NO
*Eq1ScorePrev * PrevEq1Cf*	S32	-512683	The largest output for sub-equation 1 may be -524987898 (see Table II). The input value may be scaled by dividing the value by 1024. Therefore the largest input value may be -512683	333	-170723439	-436268349	NO
*Eq1ScoreCurrent * CurrEq1Cf*	S32	-512683	Same as previous row	617	-316325411	-752593760	NO

Table VI.

Term	Variable Type	Maximum Variable Value (a)	Variable Preprocessing	Constant Value (b) (Normal Mode)	Maximum Term Value (a * b)	Maximum Intermediate Sum (sum of all previous rows)	Overflow
Eq2Offset	N/A	N/A	N/A	-194550	-194550	-194550	NO
*EqDScore * DCf*	S32	-503981	The largest output for sub- equation D may be -516077465 (see Table V). The input value may be scaled by dividing the value by 1024. Therefore the largest input value may be -503981	532	-268117892	-268312442	NO
*Eq1ScorePrev * PrevEq1Cf*	S32	-376000	The largest output for sub-equation 1 may be -385024297 (see Table III). The input value may be scaled by dividing the value by 1024. Therefore the largest input value may be -376000	496	-186496000	-454808442	NO
*Eq1ScoreCurrent * CurrEq1Cf*	S32	-376000	Same as previous row	406	-152656000	-607464442	NO

Table VII.

A qualification function may utilize the output of each of the equations discussed above (*i.e.,* sub-equation 1, sub-equation D, and sub-equation 2) to facilitate qualification and/or rejection of a potential reciprocation. For example, the output of the qualification function may be filtered with an IIR filter, and the filtered output of the qualification function may be used to qualify or reject a reciprocation. An equation for an unfiltered qualification function output in accordance with present embodiments is set forth below:

QFUnfiltered = Eq1Score*SingleRecipWt*Eq2Cf +
N2Score*MultipleRecipWt*Eq2Cf + NConsecRecip*ConsecCf +
RecipMax*MaxCf + Artifact%*ArtCf + QFOffset,

where Eq2Cf, ConsecCf, MaxCf, ArtCf, and QFOffset may be selected using least squares analysis (*e.g.,* using MATLAB®), and, as indicated above, Eq1Score may be defined as the output of sub-equation 1.

Other metrics in the unfiltered qualification function include SingleRecipWt, MultipleRecipWt, NConsecRecip, RecipMax, and Artifact%. With regard to SingleRecipWt and MultipleRecipWt, when there are two or more consecutive qualified reciprocations (*e.g.,* qualified reciprocations that are less than 120 seconds apart) present, SingleRecipWt may equal 0 and MultipleRecipWt may equal 1. However, when only a single reciprocation is present, SingleRecipWt may equal 1 and MultipleRecipWt may equal 0.

NConseRecip, which may be defined as equal to max(NConsecRecip',QFConsecMax), may include a count of the number of consecutive reciprocations (*e.g.,* reciprocations that are less than or equal to 120 seconds apart) that have passed the hard limit checks.

The value for NConsecRecip may be reset to 0 whenever a gap between any two partially qualified reciprocations exceeds 120 seconds. This may be based on the fact that ventilatory instability is a relatively long lasting event as compared to artifact. Therefore, as more reciprocations pass the hard limit checks, the qualification function may begin qualifying reciprocations that were previously considered marginal. However, to guard against a situation where something is causing a longer term artifact event (*e.g.,* interference from nearby equipment), the value may be clipped to a maximum value to limit the metrics influence on the qualification function output.

RecipMax, which may be defined as equal to max(Fall Peak, Rise Peak), may facilitate making decisions about marginal reciprocations. Indeed, marginal reciprocations with higher maximum SpO_2 values may be more likely to get qualified than marginal reciprocations with lower SpO_2 values. It should be noted that this metric works in tandem with the NConsecRecip metric, and multiple marginal reciprocations with lower maximum SpO_2 values may eventually, over a long period of time, get qualified due to the NConsecRecip metric.

The metric Artifact% may be defined as an artifact percentage that is equal to 100*Total Artifact Count / Recip Duration, where Total Artifact Count is the number of times and artifact flag was set during the reciprocation. Present embodiments may include many metrics and equations that are used to set the artifact flag. Because of this it is a generally reliable indication of the amount of artifact present in the oximetry system as a whole. Marginal reciprocations with a high Artifact% are less likely to be qualified than marginal reciprocations with a low (or 0) artifact percentage.

A last component of the qualification function may include an infinite impulse response (IIR) filter that includes coefficients that may be tuned manually using a tool (*e.g.,* a spreadsheet) that models algorithm performance. The filtered qualification function may be represented by the following equation, which includes different constants for different modes (*e.g.,* Fast Response Mode and Normal Response Mode):

QFFiltered =SingleRecipWt * QFUnfiltered + ((1-a)*QFUnfiltered + a*PrevQFFiltered)*MultipleRecipWt,

where QFUnfiltered may be defined as the current unfiltered qualification function output; PrevQFFiltered may be defined as the previous filtered qualification function output; and where the constat "a" may be set to 0.34 for Fast Response Mode and 0.5 for Normal Response Mode.

The filtered output of the qualification function may be compared to a threshold to determine if the current reciprocation is the result of RAF or artifact. The optimum threshold may theoretically be 0.5. However, an implemented threshold may be set slightly lower to bias the output of the qualification function towards qualifying more reciprocations, which may result in additional qualification of false positives. The threshold may be lowered because, in accordance with present embodiments, a cluster determination portion of the algorithm, such as may be performed by the CD feature **206**, may require a certain number (*e.g.,* 5) of fully qualified reciprocations before an index may be calculated, and a certain number (*e.g.,* at least 2) of consecutive qualified reciprocations (with no intervening disqualified reciprocations) within the set of fully qualified reciprocations. Since multiple reciprocations may be required, the clustering detection method may be biased toward filtering out false positives. Accordingly, the

reciprocation qualification function threshold may be lowered to balance the two processes.

The CD feature **206** may be capable of performing an algorithm that maintains an internal reciprocation counter that keeps track of a number of qualified reciprocations that are currently present. When the reciprocation counter is greater than or equal to a certain value, such as 5, the clustering state may be set to "active" and the algorithm may begin calculating and reporting the SPDi. When clustering is not active (*e.g.*, reciprocation count < 5) the algorithm may not calculate the SPDi. The SPDi may be defined as a scoring metric associated with the identification of a saturation trend pattern generated in accordance with present embodiment and may correlate to ventilatory instability in a population of sleep lab patients.

The CD feature **206** may utilize various rules to determine the reciprocation count. For example, when the clustering state is inactive, the following rules may be observed:

If the distance between qualified reciprocation exceeds 120 seconds, then the reciprocation count = 0;

If the current reciprocation is qualified, and the time from the start of the current reciprocation to the end of the last qualified reciprocation is <= 120 seconds, then the reciprocation count = reciprocation count + 1;

If the current reciprocation is not qualified, then the reciprocation count = max(reciprocation count – 2, 0).

Once clustering is active, it may remain active until the time between two qualified reciprocations exceeds **120** seconds. The following table (Table II) illustrates an example of how the reciprocation count rules may be applied to determine a clustering state.

Current Reciprocation Qualified	Time Since Last Qualified Reciprocation (seconds)	Reciprocation Count	Clustering State
TRUE	N/A	1	INACTIVE
FALSE	60	0	INACTIVE
TRUE	N/A	1	INACTIVE
FALSE	60	0	INACTIVE
TRUE	N/A	1	INACTIVE
TRUE	30	2	INACTIVE
TRUE	120	3	INACTIVE
FALSE	60	1	INACTIVE
TRUE	10	2	INACTIVE
TRUE	20	3	INACTIVE
TRUE	40	4	INACTIVE
FALSE	30	2	INACTIVE
FALSE	60	0	INACTIVE
TRUE	N/A	1	INACTIVE
TRUE	20	2	INACTIVE
TRUE	120	3	INACTIVE
TRUE	10	4	INACTIVE
FALSE	90	2	INACTIVE
TRUE	120	3	INACTIVE
TRUE	60	4	INACTIVE
TRUE	20	5	ACTIVE
TRUE	30	6	ACTIVE
FALSE	50	6	ACTIVE
FALSE	100	6	ACTIVE
TRUE	121	1	INACTIVE
FALSE	50	0	INACTIVE
TRUE	N/A	1	INACTIVE
TRUE	30	2	INACTIVE
TRUE	121	1	INACTIVE
TRUE	10	2	INACTIVE
TRUE	20	3	INACTIVE
TRUE	40	4	INACTIVE
TRUE	40	5	ACTIVE

Table VIII

When the clustering state is active, the SPDi calculation feature **208** may calculate an unfiltered SPDi for each new qualified reciprocation. The following formula may be used by the SPDi calculation feature **208**:

Unfiltered SPDi = a*Magnitude + b*PeakDelta + c*NadirDelta;

wherein a = 1.4, b = 2.0, c = 0.2;

wherein Magnitude = average magnitude of all reciprocations in the last 6 minutes;

wherein PeakDelta = average of the three highest qualified reciprocation rise peaks in the last 6 minutes minus the average of the three lowest qualified reciprocation rise peaks in the last 6 minutes; and

wherein NadirDelta = average of the three highest qualified reciprocation nadirs in the last 6 minutes minus the average of the three lowest qualified reciprocation nadirs in the last 6 minutes.

Wherein SPDi <= 31

The above formula may be utilized to quantify the severity of a ventilatory instability pattern. The constants and metrics used may be based on input from clinical team members. It should be noted that the PeakDelta parameter may be assigned the largest weighting constant since the most severe patterns generally have peak reciprocation values that do not recover to the same baseline.

The unfiltered SPDi may be updated whenever clustering is active and a new qualified reciprocation is detected. Non-zero SPDi values may be latched for a period of time (*e.g.,* 6 minutes). The unfiltered SPDi may then be low pass filtered to produce the final output SPDi value. The following IIR filter with a response time of approximately 40 seconds may be used:

SPDi = Unfiltered SPDi / a + Previous Filtered SPDi * (a-1) / a;

wherein a = 40.

FIG. 8 is an exemplary graph **260** including an SpO_2 trend **262** that contains a ventilatory instability SpO_2 pattern and a trend of the resulting SPDi **264**. In the illustrated example, it should be noted that the SPDi is sensitive to the decreasing peaks (incomplete recoveries) starting at approximately t=6000.

The UN feature **210** may be capable of determining if a user notification function should be employed to notify a user (*e.g.,* via a graphical or audible indicator) of the presence of a detected patterns such as ventilatory instability. The determination of the UN feature **210** may be based on a user configurable tolerance setting and the current value of the SPDi. For example, the user may have four choices for the sensitivity or tolerance setting: Off, Low, Medium, and High. When the sensitivity or tolerance setting is set to Off, an alarm based on detection of a saturation pattern may never be reported to the user. The other three tolerance settings (*i.e.,* Low, Medium, and High) may each map to an SPDi threshold value. For example, Low may map to an SPDi threshold of 6, Medium may map to an SPDi threshold of 15, and High may map to an SPDi threshold of 24. The thresholds may be based on input from users. When the SPDi is at or above the threshold for a given tolerance setting, the user may be notified that ventilatory instability is present. As discussed below, the indication to the user may include a graphical designation of the trend data corresponding to the detected pattern. For example, the trend data utilized to identify a ventilatory instability pattern may be highlighted, flashing, or otherwise indicated on a user interface of a monitor in accordance with present embodiments. Similarly, parameters such as the SPDi value and the tolerance settings may be graphically presented on a display.

While the embodiments of the present disclosure may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. However, it should be understood that the present embodiments are not intended to be limited to the particular forms disclosed. Rather, present embodiments are to cover all modifications, equivalents and alternatives falling within the spirit and scope of present embodiments as defined by the following appended claims.

CLAIMS

What is claimed is:

1. A method of evaluating a condition of a patient, the method comprising:

receiving data from a sensor related to one or more physiological parameters of the patient;

receiving instructions for activating a pattern monitoring function, wherein the pattern monitoring function is capable of determining a presence of patterns in the data indicative of ventilatory instability and triggering a ventilatory instability alarm based on the presence of the patterns; and

increasing an alarm tolerance of a desaturation monitoring function, wherein the desaturation monitoring function is capable of analyzing the data and triggering a desaturation alarm based on one or more of a magnitude, frequency, or duration of an oxygen desaturation.

2. The method of claim 1, comprising displaying a first graphical indicator comprising a graphical representation based at least in part on the pattern indicative of ventilatory instability and a second graphical indicator comprising a graphical representation based at least in part on the oxygen desaturation.

3. The method of claim 1, comprising determining a scoring metric associated with the patterns indicative of ventilatory instability.

4. The method of claim 3, wherein triggering the ventilatory instability alarm comprising triggering the ventilatory instability alarm when the scoring metric reaches a predetermined threshold.

5. The method of claim 3, comprising receiving input to set the predetermined threshold.

6. The method of claim 3, wherein the predetermined threshold comprises a high tolerance threshold, a medium tolerance threshold, or a low tolerance threshold.

7. The method of claim 1, comprising determining a scoring metric associated with one or more of the magnitude, frequency, or duration of the oxygen desaturation.

8. The method of claim 7, wherein determining the scoring metric comprises calculating an integral of oxygen desaturation over a period of time.

9. The method of claim 7, wherein triggering the desaturation alarm comprises triggering the desaturation alarm when the scoring metric reaches a predetermined threshold.

10. The method of claim 9, comprising receiving input to set the predetermined threshold.

11. The method of claim 9, wherein the predetermined threshold comprises a high tolerance threshold, a medium tolerance threshold, or a low tolerance threshold.

12. The method of claim 9, wherein increasing the alarm tolerance comprises increasing the predetermined threshold to a highest possible tolerance.

13. The method of claim 7, wherein increasing the alarm tolerance comprises decreasing or eliminating an effect of the frequency of the oxygen desaturation on the scoring metric.

14. A medical device, comprising:

a microprocessor; and

a memory configured to store machine-readable instructions, wherein the contents of the memory comprises machine-readable instructions capable of directing the microprocessor to:

receive data from a sensor related to one or more physiological parameters of the patient;

receive instructions for activating a pattern monitoring function, wherein the pattern monitoring function is capable of determining a presence of patterns in the data indicative of ventilatory instability and triggering a ventilatory instability alarm based on the presence of the patterns; and

increase an alarm tolerance of a desaturation monitoring function, wherein the desaturation monitoring function is capable of analyzing the data and triggering a desaturation alarm based on one or more of a magnitude, frequency, or duration of an oxygen desaturation.

15. The medical device of claim 14, comprising a network interface unit configured to send a signal related to the desaturation alarm or the ventilatory instability alarm to a device located on a local area network.

16. The medical device of claim 14, wherein the desaturation monitoring function is capable of determining a value of an integral of the oxygen desaturation over a period of time by accumulating a product of time and a difference between the oxygen desaturation data and a threshold value.

17. The medical device of claim 14, wherein determining a presence of patterns in the data indicative of ventilatory instability comprises determinining the presence of one or more clusters.

18. The medical device of claim 14, comprising a display, and wherein the device is capable of displaying a first graphical indicator comprising a graphical representation based at least in part on the pattern indicative of ventilatory instability and a second

graphical indicator comprising a graphical representation based at least in part on the oxygen desaturation

19. A system, comprising:

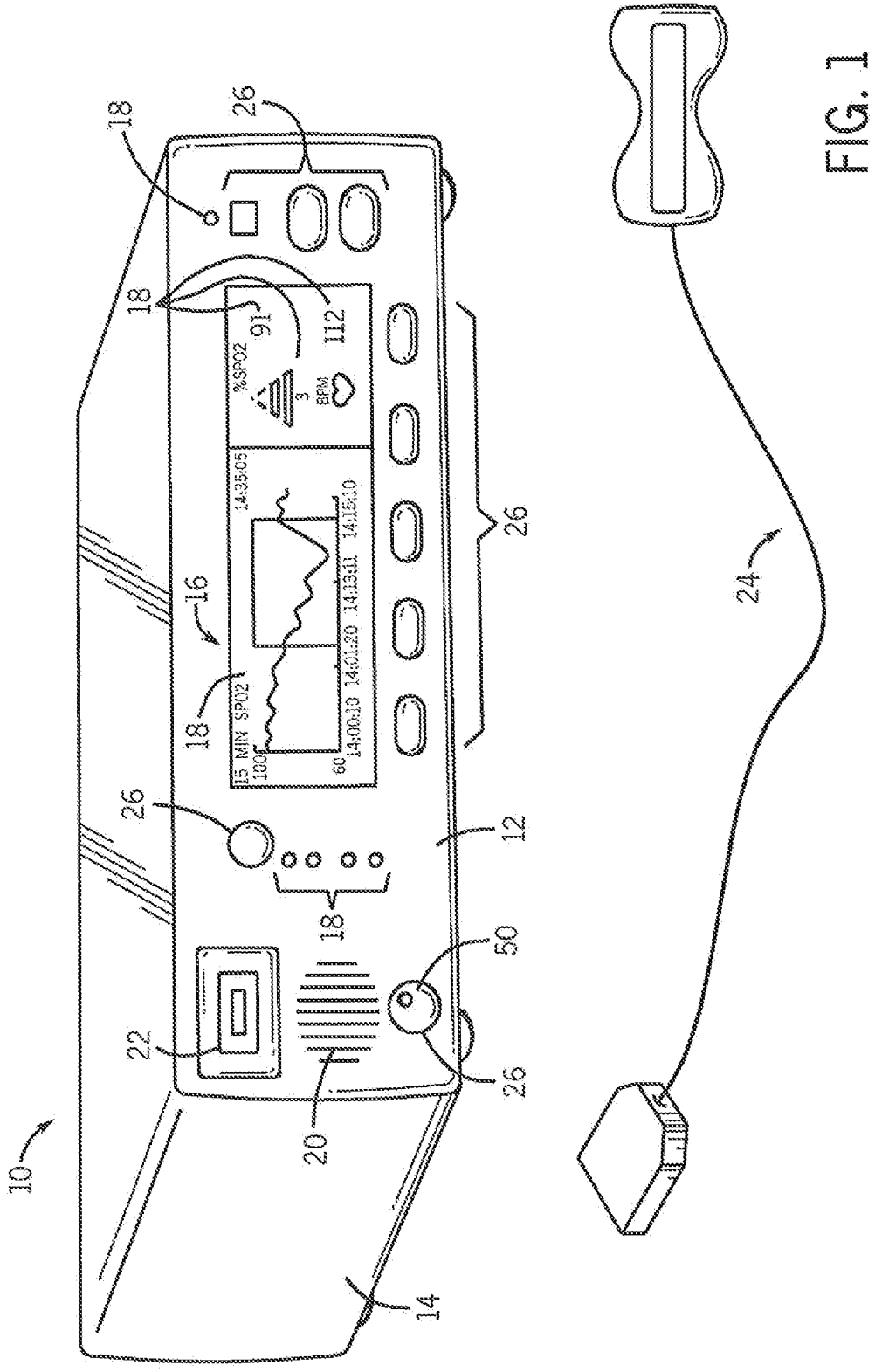
a sensor capable of sensing patient physiological parameters;

a monitor capable of receiving data from the sensor related to the patient physiological parameters and storing the data related to the parameters, the monitor comprising;

a pattern detection feature capable of analyzing the data to detect an pattern in the data indicative of ventilatory instability and triggering a ventilatory instability alarm based on the presence of the patterns; and

a desaturation detection feature capable of analyzing the data and triggering a desaturation alarm based on one or more of a magnitude, frequency, or duration of an oxygen desaturation, wherein when the pattern detection feature is activated, the desaturation alarm is configured to automatically increase an alarm tolerance of the desaturation alarm if the tolerance is below a certain default value.

20. The system of claim 19, wherein the sensor comprises a pulse oximetry sensor.


10
12
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16
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26
50
91
112
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14:16:10
14:35:05

FIG. 1

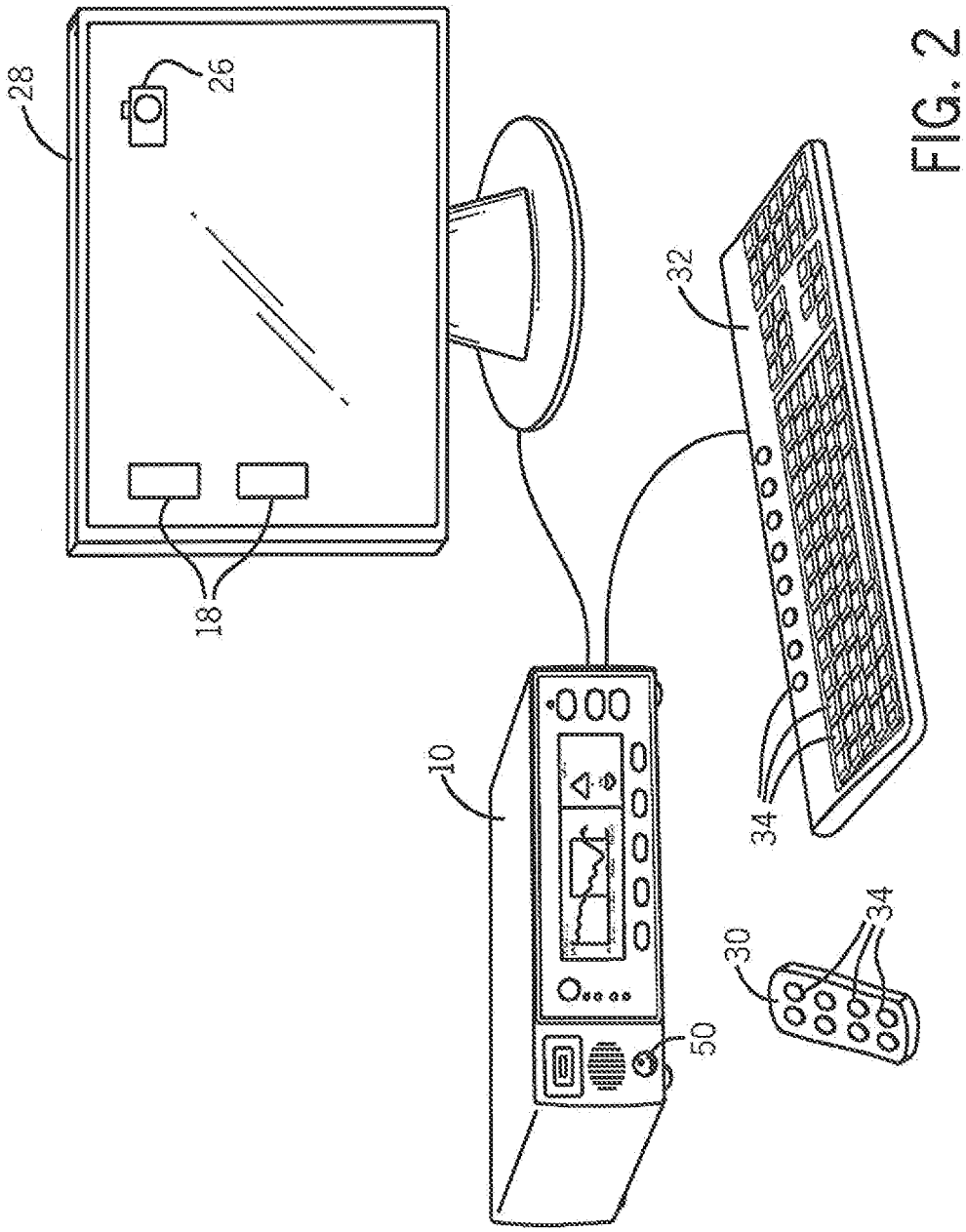

FIG. 2

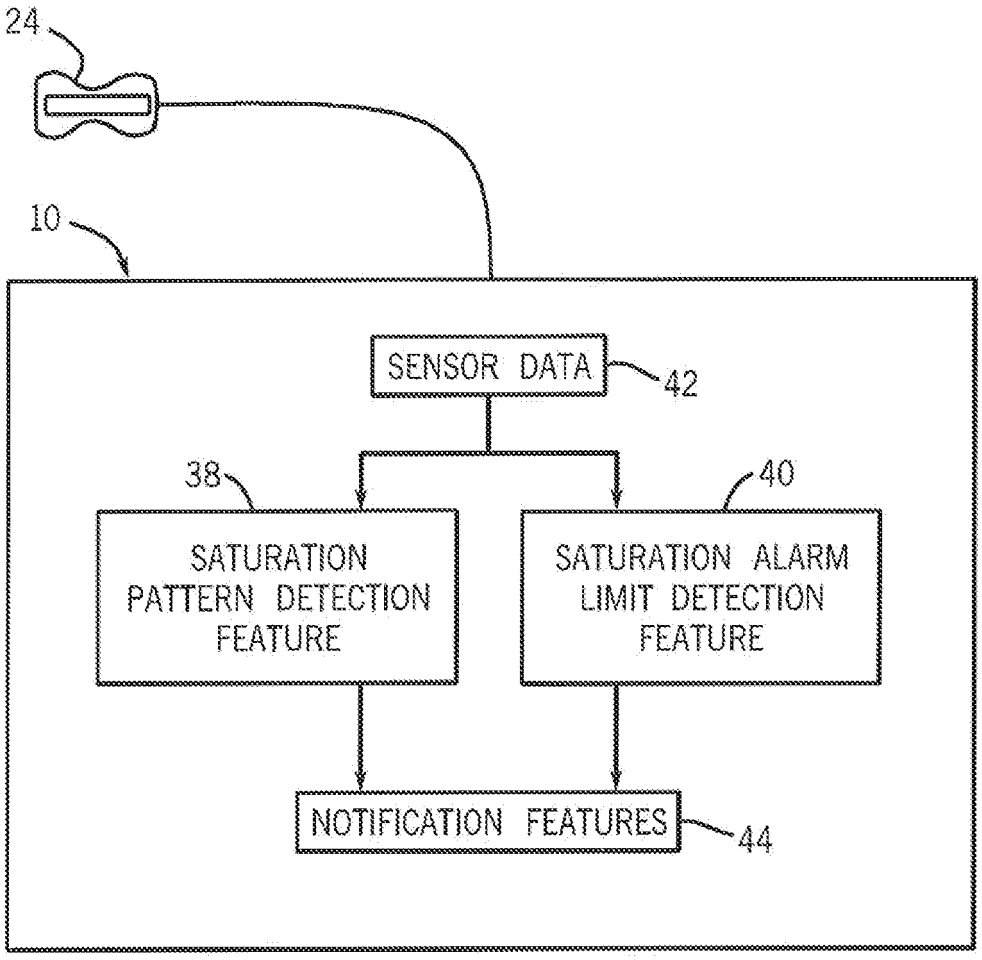
24
10
SENSOR DATA
42
38
40
SATURATION PATTERN DETECTION FEATURE
SATURATION ALARM LIMIT DETECTION FEATURE
NOTIFICATION FEATURES
44

FIG. 3

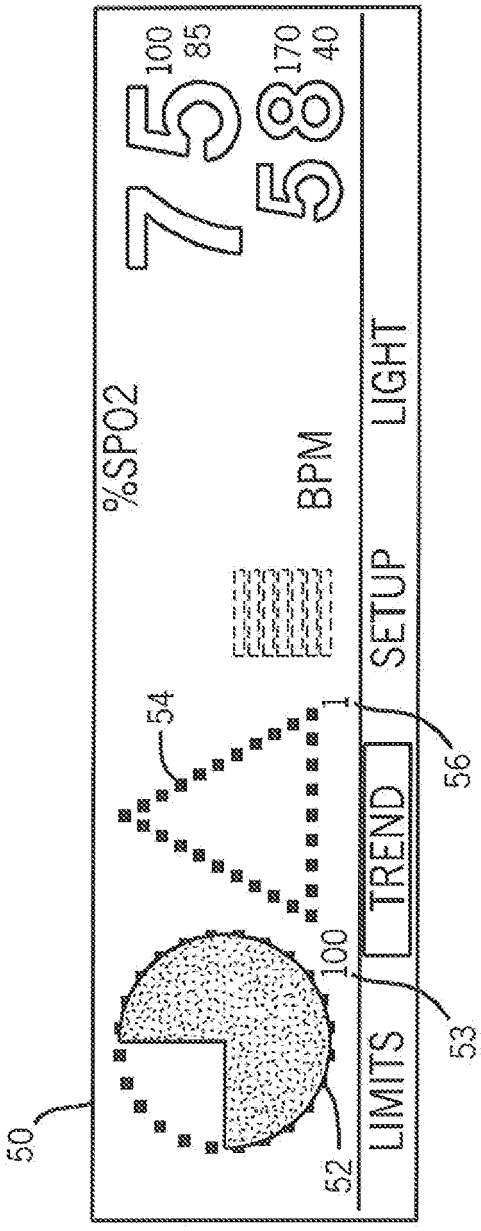
100
85
75
170
40
58
%SPO2
BPM
LIGHT
SETUP
TREND
LIMITS
50
52
53
54
56
100
1

FIG. 4

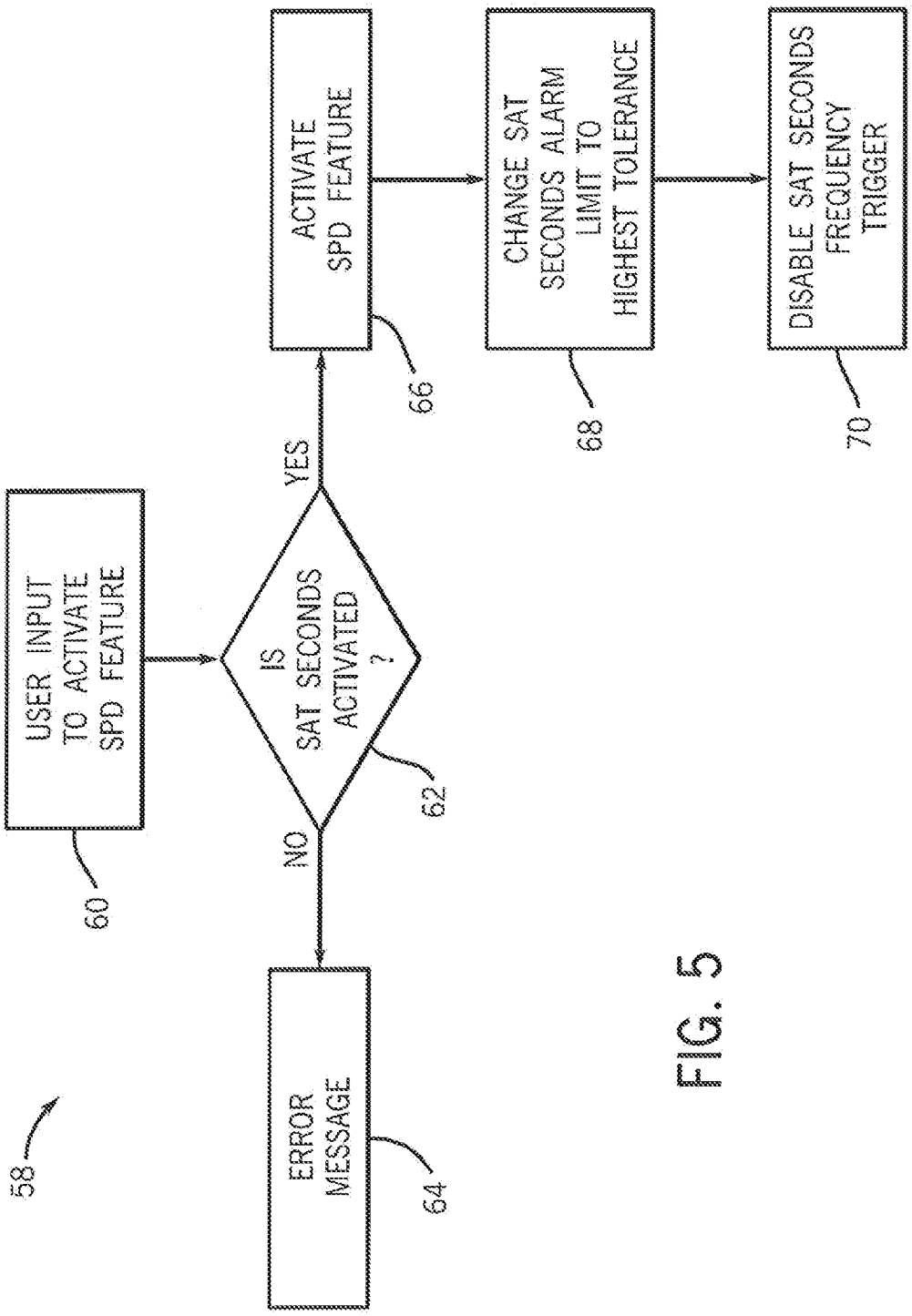
58
USER INPUT TO ACTIVATE SPD FEATURE
60
IS SAT SECONDS ACTIVATED ?
62
YES
NO
ACTIVATE SPD FEATURE
66
CHANGE SAT SECONDS ALARM LIMIT TO HIGHEST TOLERANCE
68
DISABLE SAT SECONDS FREQUENCY TRIGGER
70
ERROR MESSAGE
64

FIG. 5

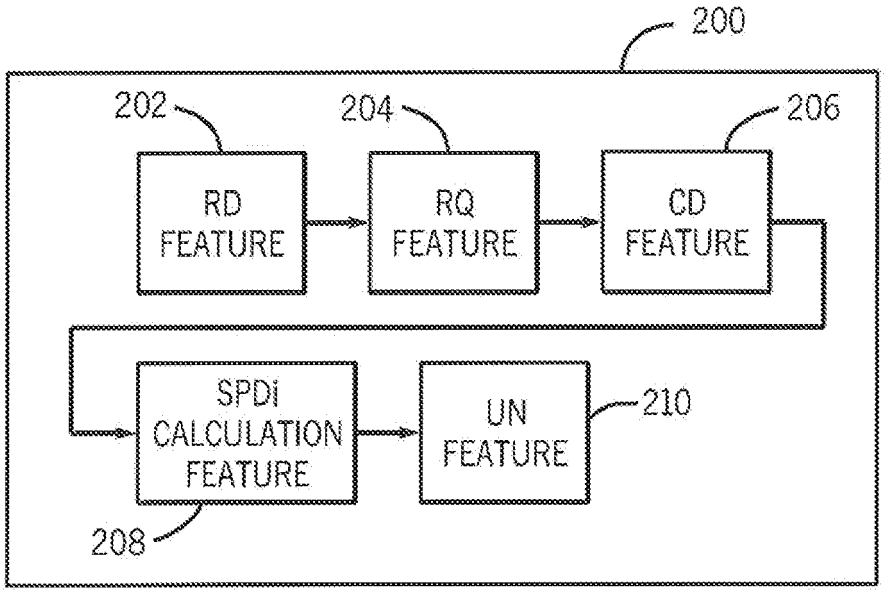
200
202
204
206
RD FEATURE
RQ FEATURE
CD FEATURE
SPDi CALCULATION FEATURE
UN FEATURE
210
208

FIG. 6

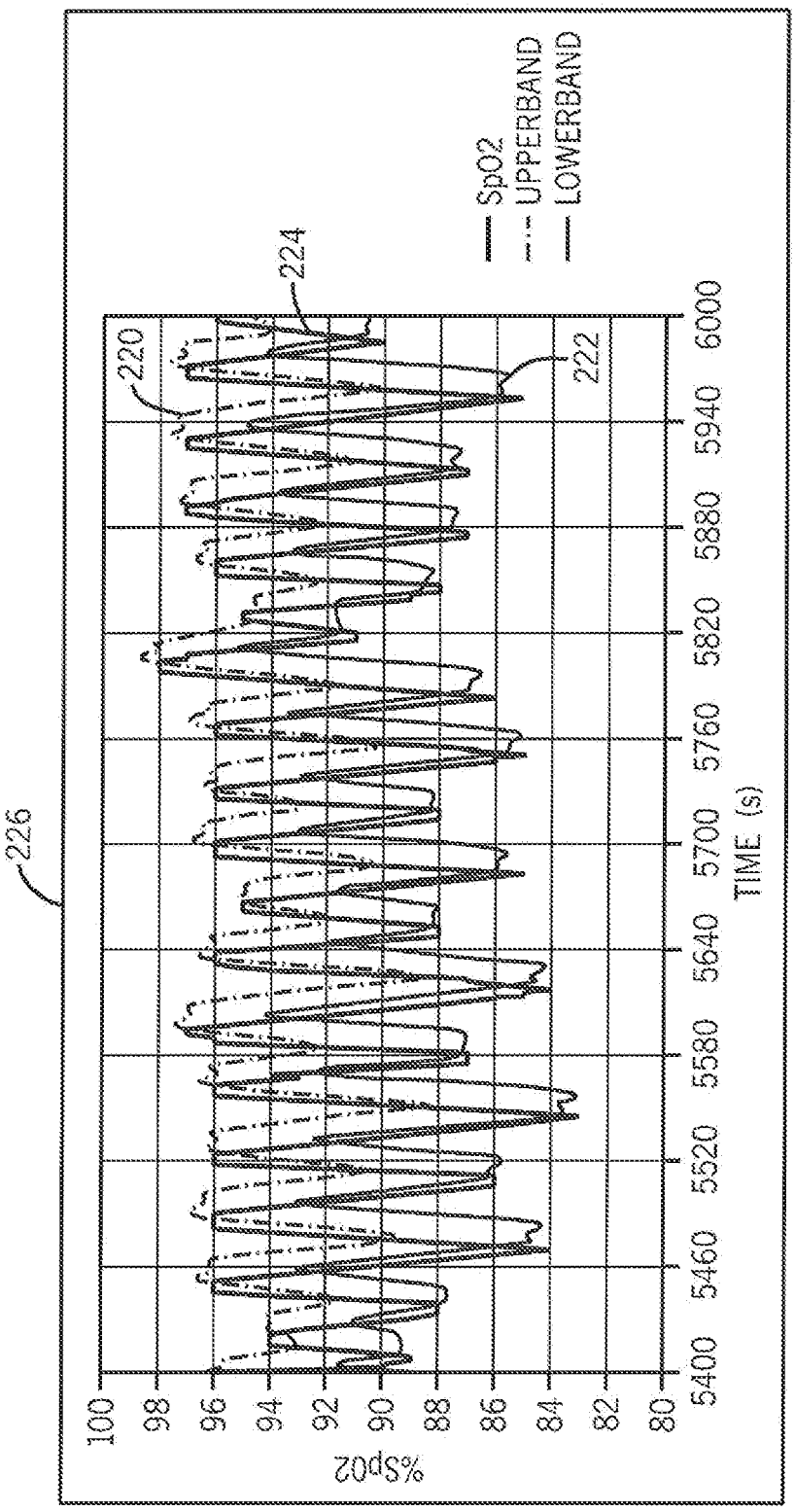
SpO2
UPPERBAND
LOWERBAND
220
222
224
226
%SpO2
100
98
96
94
92
90
88
86
84
82
80
5400
5460
5520
5580
5640
5700
5760
5820
5880
5940
6000
TIME (s)

FIG. 7

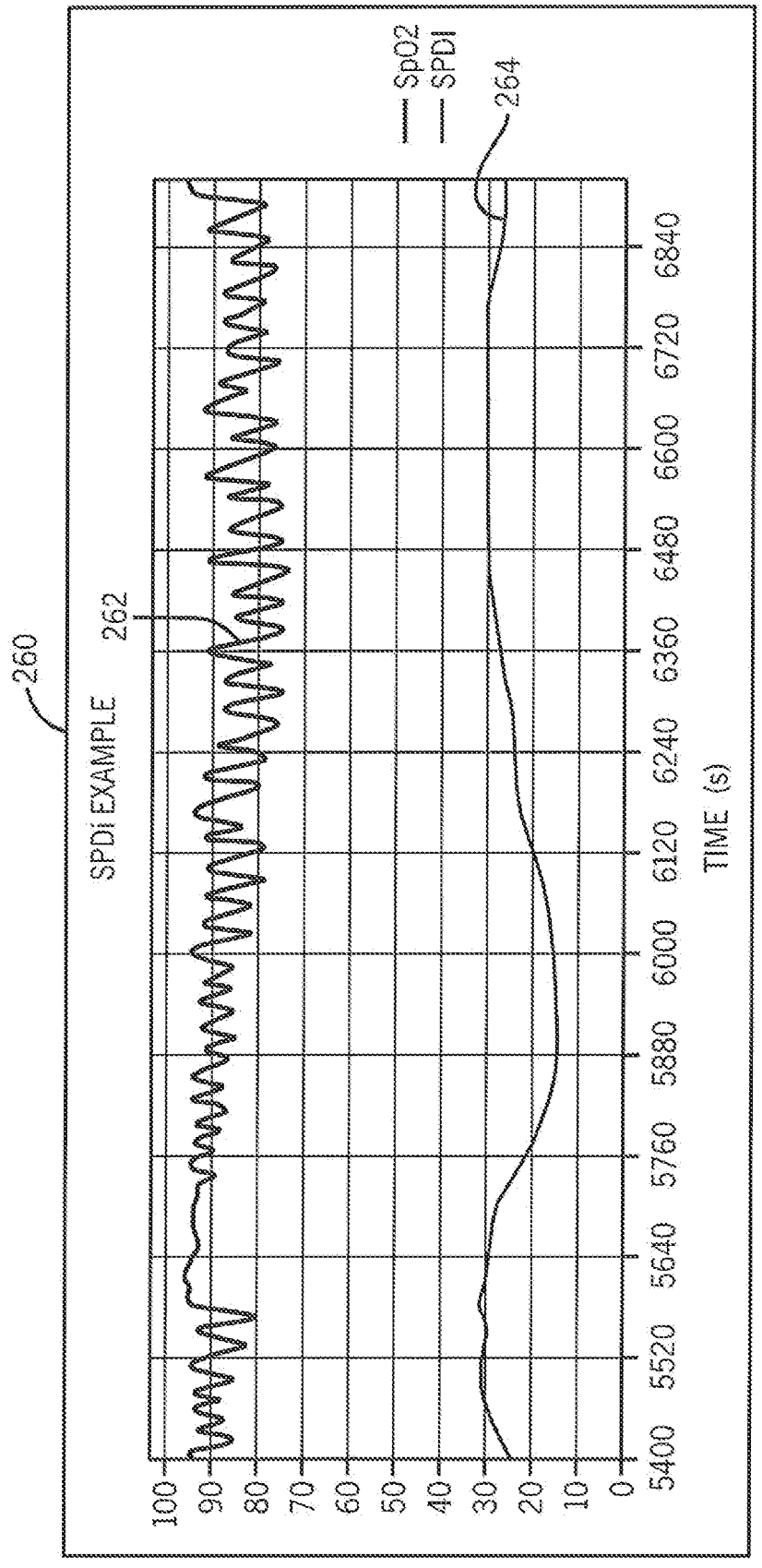
260
SPDi EXAMPLE
262
SpO2
SPDI
264
100
90
80
70
60
50
40
30
20
10
0
5400
5520
5640
5760
5880
6000
6120
6240
6360
6480
6600
6720
6840
TIME (s)

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/062834

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/192667 A1 (AL-ALI AMMAR [US]) 31 August 2006 (2006-08-31) paragraph [0020]; figures 3-8	14,16-20
X	US 2005/222503 A1 (DUNLOP DAVID A [US] ET AL DUNLOP DAVID A [US] ET AL) 6 October 2005 (2005-10-06) paragraphs [0036], [0039]; figures 1,2	14-15, 18-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 January 2010	18/01/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Worms, Georg

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/062834

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-13
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 1-13

The present application does not meet the criteria of Article 17(2)(a)(i) and Rule 39.1(iv) PCT, because the subject-matter of independent claim 1 discloses a diagnostic method (see also PCT Guidelines 9.10). Furthermore, the following phases can be found in claim 1 (i) the examination phase involving the collection of data, which has a technical character and is performed on a patient by "receiving data from a sensor", (iv) "triggering a ventilatory instability alarm": contains implicitly the decision phase. Furthermore, in order to being able to trigger an alarm, the actual value has to be compared with a standard (phase (ii)) and a significant deviation from this standard (phase (iii)) has to be found. Hence, phases (ii) and (iii) are included implicitly. These phases are required by the European procedure for a method to be considered as a diagnostic method and are, at least implicitly, included in the subject-matter of independent claim 1.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/062834

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006192667 A1	31-08-2006	NONE	
US 2005222503 A1	06-10-2005	NONE	

专利名称(译)	便于观察监测的生理数据的系统和方法		
公开(公告)号	EP2348960A1	公开(公告)日	2011-08-03
申请号	EP2009756083	申请日	2009-10-30
[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 LLC		
当前申请(专利权)人(译)	COVIDIEN LP		
[标]发明人	BATCHELDER KEITH AMUNDSON SCOTT OCHS JAMES MANNHEIMER PAUL		
发明人	BATCHELDER, KEITH AMUNDSON, SCOTT OCHS, JAMES MANNHEIMER, PAUL		
IPC分类号	A61B5/00		
CPC分类号	A61B5/14552 A61B5/14551 A61B5/4818 A61B5/743		
优先权	12/609344 2009-10-30 US 61/111620 2008-11-05 US		
外部链接	Espacenet		

摘要(译)

本实施例涉及能够检测和图形指示患者数据中的生理模式的系统和方法。例如，本实施例可以包括监视系统，该监视系统包括监视器，该监视器能够接收与患者生理参数有关的输入并提供与氧饱和度下降和与睡眠呼吸暂停相关的氧饱和度降低模式相关的指示或警报。本实施例可以包括用于在警报和与氧饱和度下降和通气不稳定性相关的其他指示之间进行调节的方法和系统。