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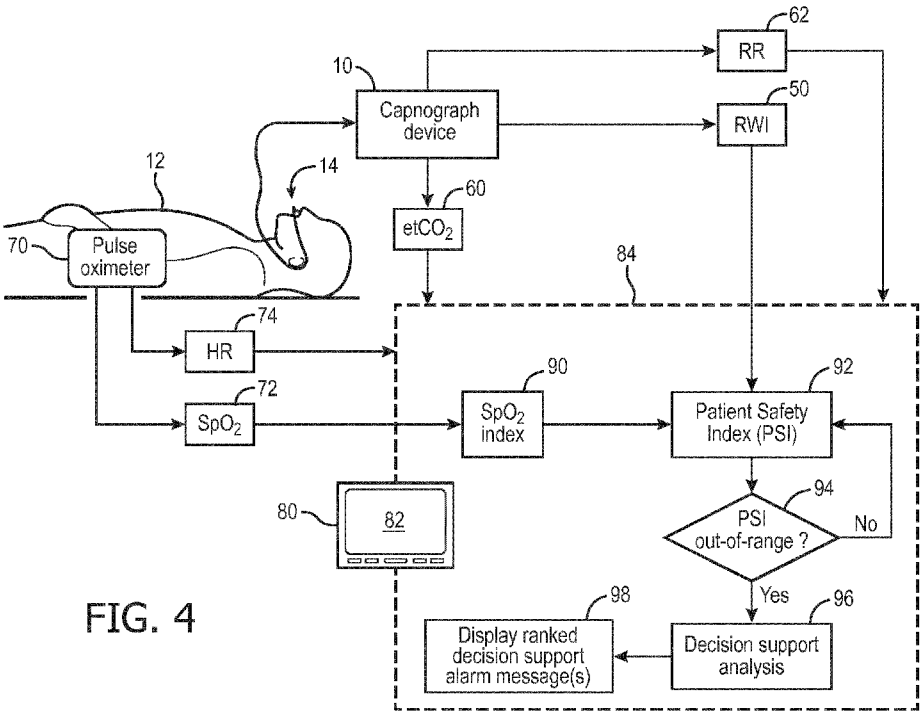

FIG. 4

(57) Abstract: A patient monitoring device includes a capnograph device (10) and a pulse oximeter (70). An electronic processor (84) is programmed to generate a capnography index (50) indicative of patient well-being from a capnogram measured by the capnograph device, and to generate an arterial blood oxygen saturation (SpO2) index (90) indicative of patient well-being from SpO2 (72) measured by the pulse oximeter. A patient safety index (92) is computed from the capnography index and the SpO2 index. One or more clinical warnings are determined based at least in part on the patient safety index. A display component (82) is configured to display at least one of the computed one or more clinical warnings.

[Continued on next page]

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PHYSIOLOGIC MONITORING DECISION SUPPORT SYSTEM COMBINING CAPNOMETRY AND OXYGEN SATURATION

FIELD

The following relates generally to the capnography arts, medical monitoring arts, and related arts.

BACKGROUND

A capnography device monitors the concentration or partial pressure of carbon dioxide (CO_2) in respiratory gases. Capnography is commonly used in conjunction with mechanically ventilated patients in order to assess respiratory system status. A skilled anesthesiologist can usually evaluate the capnogram (that is, the CO_2 trend line as measured by a capnograph device) to assess respiratory health.

Capnography is increasingly used as a more generic vital sign for assessing patient health. For example, capnography may be used to monitor a patient who is breathing spontaneously and not undergoing mechanical ventilation, using a side stream capnograph device configuration in which respired air is sampled via a nasal cannula in conjunction with a dedicated sampling pump. In these broader contexts, medical personnel with limited expertise in anesthesiology are required to assess respiratory health on the basis of capnograph data. To facilitate this, it is common for the capnograph device to be programmed to output standard derived parameters, particularly respiration rate (RR) and end-tidal CO_2 ($etCO_2$). The RR is the breathing rate, quantified as the (quasi-)periodicity of the capnogram waveform. The $etCO_2$ is the partial pressure at the end of the exhalation phase. However, since the expired CO_2 is usually highest at the end of the exhalation phase, $etCO_2$ is commonly defined as the maximum observed CO_2 partial pressure over the breathing cycle.

While RR and $etCO_2$ are useful parameters, they do not capture the rich informational content of the capnogram waveform. To this end, it is also known to perform automated capnogram waveform analyses, designed to mimic clinical analyses that might be performed by a skilled anesthesiologist. For example, Colman et al., U.S. Pat. No. 8,412,655 and Colman et al., U.S. Pat. No. 8,414,488 disclose capnogram waveform analyses such as correlating pauses with apnea events, correlating a long downward slope of the capnogram waveform with possible partial airway obstruction, correlating a low capnogram waveform with possible low cardiac output, correlating a rounded capnogram waveform with a possible problem with the nasal cannula, or so forth. Based on such waveform analyses, the capnograph

device may provide informational messages such as "open airway", "check airway", "possible low cardiac output", "check cannula interface", or so forth.

Capnogram waveform analyses provide richer information from the capnogram, but entail complex processing such as detecting the breath cycling, amplitude and period normalization, and segmenting regions of the capnogram waveform within each breath cycle. These complex analyses introduce numerous possible error mechanisms such as incorrect waveform segmentation or information loss during the normalization operations.

Some additional background references include the following.

WO 2016/108121 Al published July 7, 2016 discloses, among other aspects, a gas concentration monitoring system that may include a processor configured to detect a concentration of a selected gas in a sample gas flow obtained from a physical interface to a patient. A dataset is formed, including a plurality of data points, each data point corresponding to the detected concentration of the selected gas within the sample gas flow during a sampling time. The data set may be variously employed. For example, the data points may be grouped according to a frequency of occurrence of the data points within the sampling time. A signal confidence and/or signal quality may be determined based on relative characteristics between the groups of data points. WO 2016/108121 Al claims priority to U.S. Serial No. 62/098,367 filed December 31, 2014. WO 2016/108121 Al and U.S. Serial No. 62/098,367 are each incorporated herein by reference in its entirety.

WO 2016/108127 Al published July 7, 2016 discloses, among other aspects, a capnography system. A controller is configured to obtain a sample gas flow from a physical interface for a patient. A change is determined in a characteristic of the sample gas flow during a sampling time interval. It is determined whether the change in the characteristic of the sample gas flow during the sampling time interval is equal to or greater than a corresponding threshold value. It is determined that supplemental oxygen is provided when it is determined that the change in the characteristic of the sample gas flow is equal to or greater than the threshold value. It is determined that supplemental oxygen is not provided when it is determined that the change in the characteristic of the sample gas flow is less than the threshold value. WO 2016/108127 Al claims priority to U.S. Serial No. 62/097,946 filed December 30, 2014. WO 2016/108127 Al and U.S. Serial No. 62/097,946 are each incorporated herein by reference in its entirety.

U.S. Serial No. 62/203,416 titled "Capnography with Decision Support System Architecture" filed August 11, 2015 is incorporated herein by reference in its entirety. U.S. Serial No. 62/203,416 discloses, among other aspects, a capnograph device that includes a

carbon dioxide measurement component and an electronic processor programmed to generate a capnogram comprising carbon dioxide level sample values measured as a function of time. End-tidal carbon dioxide ($etCO_2$) is determined from the capnogram, and an $etCO_2$ parameter quality index ($etCO_2$ PQI) is computed using one or more quantitative capnogram waveform metrics computed from the capnogram. A respiration rate (RR) value is also determined from the capnogram, and a RR PQI is computed using the RR value and the $etCO_2$ PQI. A respiratory well-being index (RWI) may be computed from the $etCO_2$ and RR values and the $etCO_2$ and RR PQI values. In some embodiments the one or more capnogram waveform metrics are computed from a capnogram histogram generated from the capnogram.

The following discloses a new and improved systems and methods that address the above referenced issues, and others.

SUMMARY

In one disclosed aspect, a patient monitoring device comprises a capnograph device, a pulse oximeter, and an electronic processor programmed to: generate a capnography index indicative of patient well-being from a capnogram measured by the capnograph device; generate an arterial blood oxygen saturation (SpO_2) index indicative of patient well-being from SpO_2 measured by the pulse oximeter; compute a patient safety index from the capnography index and the SpO_2 index; and compute one or more clinical warnings determined based at least in part on the patient safety index. A display component may be configured to display at least one of the computed one or more clinical warnings.

In another disclosed aspect, a non-transitory storage medium stores instructions readable and executable by an electronic processor to perform patient monitoring comprising: generating a capnography index indicative of patient well-being from a capnogram measured by a capnograph device; generating an arterial blood oxygen saturation (SpO_2) index indicative of patient well-being from SpO_2 (72) measured by a pulse oximeter; and computing a patient safety index from the capnography index and the SpO_2 index.

One advantage resides in providing a capnograph device whose output more effectively assesses patient respiratory health.

Another advantage resides in providing a capnograph device outputting derived parameters characterizing the detailed capnogram waveform without requiring breath detection or segmentation of the capnogram waveform.

Another advantage resides in more accurate respiratory system status information from capnogram data.

Another advantage resides in providing clinical decision support that synergistically combines capnography information with pulse oximetry information.

Another advantage resides in providing clinical decision support employing both capnography information with pulse oximetry information, which provides a ranked list of clinical warnings generated by each constituent monitoring modality.

A given embodiment may provide none, one, two, more, or all of the foregoing advantages, and/or may provide other advantages as will become apparent to one of ordinary skill in the art upon reading and understanding the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the invention.

FIGURE 1 diagrammatically illustrates a capnograph device.

FIGURE 2 diagrammatically illustrates an idealized capnogram and the corresponding capnogram histogram.

FIGURE 3 diagrammatically plots the CO_2 fall time for an idealized capnogram waveform (top plot) and a capnogram with supplemental oxygen washout (bottom plot).

FIGURE 4 diagrammatically illustrates a patient monitor that provides a Patient Safety Index (PSI) generated from a respiratory well-being index (RWI) generated by the capnography device of FIGURE 1 and a blood oxygenation level (e.g. SpO_2) generated by a pulse oximeter.

FIGURES 5 and 6 illustrate examples of an SpO_2 index-versus-SpO_2 value function suitably used in the patient monitor of FIGURE 4, for the case of no supplemental oxygen (FIGURE 5) and for the case of supplemental oxygen (FIGURE 6).

DETAILED DESCRIPTION

In some embodiments disclosed herein, parameter quality indices are computed to quantitatively assess the reliability of the respiratory rate (RR) and end-tidal CO_2 ($etCO_2$) evaluated from the capnogram. A respiratory well-being index (RWI) may also be computed, based in part on the $etCO_2$ parameter quality index ($etCO_2$ PQI) and the RR parameter quality index (RR PQI). These parameter quality indices enable medical personnel to interpret the

capnogram using conventional tools, especially the RR and $etCO_2$, but provide metrics (the quality control indices) to assist medical personnel in assessing whether the RR and $etCO_2$ are reliable data for making clinical decisions.

Further, in some embodiments the parameter quality indices are computed at least in part using a histogram of CO_2 value counts versus (binned) CO_2 level. This histogram is computed over a time interval encompassing several breaths. For example, the histogram is acquired over a 30 second time interval in one illustrative embodiment, which corresponds to about 6-10 breaths for a normal adult patient respiration interval of 3-5 seconds/breath (12-20 breaths per minute), up to 30 breaths for a rapidly respiring infant (respiration rate of 60 breaths per minute).

Advantageously, the capnogram histogram is computed without segmenting the waveform into different regions (e.g. inspiration, expiration) and without segmenting individual breath cycles (that is, without a breath detector). The capnogram histogram advantageously has a "standard" shape for a normally respiring patient, due to the typical capnogram pattern in which the CO_2 level is close to zero during the inspiration phase and close to its maximum (i.e. close to $etCO_2$ for the patient) during the expiration phase. These two phases define respective low and high regions of the disclosed capnogram histogram, with a third transitional histogram region in-between. Rich information about the capnogram waveform can be extracted from the capnogram histogram, without reliance upon the difficult and often imprecise task of segmenting the capnogram waveform into breath cycles which are then further segmented into inspiration and expiration time intervals.

In particular, the $etCO_2$ parameter quality index (PQI) is computed primarily or entirely using the histogram. In some embodiments the $etCO_2$ PQI is computed further based on capnogram characteristics that can be quantified without segmenting the capnogram into inspiration and expiration regions. Illustrative embodiments of the $etCO_2$ PQI do rely upon breath detection and capnogram waveform segmentation, as the RR is intimately associated with (indeed defined by) the breath cycle. However, the RR PQI is optionally further based on the $etCO_2$ PQI thereby incorporating waveform information from the capnogram histogram.

The RWI is computed based on the $etCO_2$ and RR values, and further based on the $etCO_2$ PQI and RR PQI. Incorporating the PQI values into the RWI captures the recognition herein that a poor capnogram waveform is often an indication of poor respiratory health, rather than being an indicator of a capnograph measurement problem.

With reference to FIGURE 1, an illustrative capnograph device **10** is connected with a patient **12** by a suitable patient accessory, such as a nasal cannula **14** in the illustrative

example, or by an airway adaptor or so forth. The patient accessory **14** may optionally include one or more ancillary components, such as an air filter, water trap, or the like (not shown). In the illustrative capnograph **10**, respired air is drawn from the patient accessory **14** into a capnograph air inlet **16** and through a carbon dioxide (CO_2) measurement component or cell **20** by an air pump **22**. The air is then discharged via an air outlet **24** of the capnograph **10** to atmosphere or, as in the illustrative embodiment, is discharged through the air outlet **24** into a scavenging system **26** to remove an inhaled anesthetic or other inhaled medicinal agent before discharge into the atmosphere. The CO_2 measurement component or cell **20** may, for example comprise an infrared optical absorption cell in which carbon dioxide in the respired air drawn from the patient accessory **14** produces absorption that is detected by an infrared light source/detector assembly.

The illustrative capnograph device **10** has a sidestream configuration in which respired air is drawn into the capnograph device **10** using the pump **22**, and the CO_2 measurement cell **20** is located inside the capnograph device **10**. That is, the sidestream capnograph device **10** includes, as a unit, the carbon dioxide measurement component **20**, the electronic processor **30**, and the pump **22** connected to draw respired air though the carbon dioxide measurement component **20**. The sidestream configuration is suitably used for a spontaneously breathing patient, i.e. a patient who is breathing on his or her own without assistance of a mechanical ventilator. In an alternative configuration, known as a mainstream configuration (not illustrated), the CO_2 measurement cell is located externally from the capnograph device housing, typically as a CO_2 measurement cell patient accessory that is inserted into the "mainstream" airway flow of the patient. Such a mainstream configuration may, for example, be employed in conjunction with a mechanically ventilated patient in which the CO_2 measurement cell patient accessory is designed to mate into an accessory receptacle of the ventilator unit, or is installed on an airway hose feeding into the ventilator. The disclosed approaches for quantitatively assessing parameter quality and patient respiratory well-being are readily applied either in conjunction with a sidestream capnograph device (as in the illustrative example of FIGURE 1) or in conjunction with a mainstream capnograph device.

With continuing reference to FIGURE 1, the capnograph device **10** (in either the illustrative sidestream configuration or in the alternative mainstream configuration) includes capnograph electronics **30** which provide power and control for operating the CO_2 measurement cell **20** and (in the sidestream configuration) the pump **22**. Note that the power and control links are not illustrated in diagrammatic FIGURE 1. The capnograph electronics **30** additionally perform processing of the CO_2 signal output by the CO_2 measurement cell **20**,

as diagrammatically indicated in FIGURE 1 and as described herein. Clinical data output by the capnograph **10** are displayed on a display component **32**, stored in an electronic medical record (EMR) or the like, or otherwise utilized. The display component **32** may be a component of the capnograph or, as illustrated in FIGURE 1, the display component **32** may be an external display component connected to the capnograph **10**. For example, the external display component **32** may be a multi-function bedside patient monitor and/or a nurses' station patient monitor or so forth. It will be further appreciated that the capnograph may include numerous other components not illustrated in simplified diagrammatic FIGURE 1, such as a pressure gauge, flow meter, and so forth.

The capnograph electronics **30** may be variously implemented, such as by a suitably programmed electronic processor, e.g. a microprocessor or microcontroller of the capnograph **10**. While a single electronics unit **30** is illustrated, it is alternatively contemplated to employ various combinations of electronics, for example different electronic components may be operatively interconnected to implement a pump, power supply, infrared light source and detector, power supply (for the CO_2 measurement cell **20**), analog-to-digital conversion circuitry (to sample the infrared light detector of the CO_2 measurement cell **20**), and so forth. Still further, it is contemplated for the electronics that perform the capnograph data processing to be disposed outside of the capnograph device itself. For example, the capnograph data processing may be performed by electronics in another device (for example, the computer of a nurses' station that receives the CO_2 signal from the measurement cell **20**, or that receives a capnogram generated by the capnograph device and performs further processing). It will be still further appreciated that the capnograph data processing disclosed herein as being performed by the capnograph electronics **30** may be embodied by a non-transitory storage medium storing instructions that are readable and executable by the microprocessor, microcontroller, or other electronic processor to perform the disclosed capnograph data processing. Such non-transitory storage media may, by way of non-limiting illustration, include a hard disk drive or other magnetic storage medium, a flash memory, read-only memory (ROM) or other electronic storage medium, an optical disk or other optical storage medium, various combinations thereof, or so forth.

With continuing reference to FIGURE 1 and with further reference to FIGURE 2, an illustrative embodiment of the capnograph data processing performed by the capnograph electronics **30** (or alternatively in whole or in part by a nurses' station monitor, bedside patient monitor, or other device with a suitably programmed electronic data processor) is diagrammatically shown in FIGURE 1. The CO_2 signal is sampled and optionally corrected for

factors such as the presence of interfering gases (e.g. nitrous oxide), barometric pressure, and so forth in order to generate a capnogram **40**. The capnogram **40** is a signal representing the partial pressure or concentration of carbon dioxide, denoted in FIGURE 2 as $[CO_2]$, as a function of time. Diagrammatic FIGURE 2 illustrates the capnogram **40** as an idealized waveform for a healthy patient, in which every breath is identical and exhibits near-zero $[CO_2]$ during the inspiratory phase and a well-defined maximum $[CO_2]$ that rises gradually over the expiratory phase and terminates in a maximum $[CO_2]$ corresponding to end-tidal CO_2, and in which the $etCO_2$ is the same for every breath. In practice, it will be understood that the capnogram **40** for a real patient usually deviates significantly from this idealized curve due to numerous factors such as non-uniform breathing, talking, coughing, possible chronic lung problems in the case of an ill patient, or so forth. In the capnogram of a real patient, the $etCO_2$ may vary from breath to breath. The illustrative idealized example of FIGURE 2 further assumes a constant respiration rate. Again, in a real patient, the RR is generally not constant – the RR can increase significantly due to excitement or exertion, may slow during rest periods, may stop entirely during a sleep apnea episode, and/or may generally vary significantly due to various respiratory ailments or other medical conditions.

With continuing reference to FIGURES 1 and 2, the capnograph electronics **30** are programmed to compute a capnogram histogram **42** from the capnogram **40**. The capnogram histogram **42** is a histogram of CO_2 sample values (y-axis) versus CO_2 level (x-axis). The capnogram histogram **42** is computed for a sliding window of duration 30 seconds (for illustrative FIGURE 2; other window sizes are contemplated, preferably of a duration long enough to encompass several breaths). By way of illustrative example, if the CO_2 measurement cell **20** acquires samples at 10 msec intervals (100 samples per second) and the window is 30 seconds then, for each capnogram sample in the 30 second window (consisting of 3000 points) the bin corresponding to the CO_2 value for the point is incremented. In the capnogram histogram of a typical capnogram, there is a lower baseline region during inspiration and an elevated CO_2 region during expiration. Between these two regions, there are a set of points that make up the rising and falling edges of the capnogram. More particularly, as delineated in FIGURE 2, three regions **R1**, **R2**, **R3** can be defined. Region **R1** of the histogram **42** includes the points in the capnogram **40** measured by the CO_2 measurement cell **20** during the inspiratory phase of the breath. In the illustrative example of FIGURE 2, Region **R1** includes the bins from 0 to 3 mmHg. Region **R2** of the histogram **42** includes all the points from the capnogram **40** forming the rising and falling edges in the capnogram **40**. In the illustrative example of FIGURE 2, Region **R2** includes the bins from 4 to 30 mmHg. Finally, Region **R3**

of the histogram **42** includes the points in the capnogram **40** measured during the expiratory phase of the breath. In the illustrative example of FIGURE 2, Region **R3** includes all the bins from 31 to 39 mmHg.

The capnogram histogram of a typical capnogram has certain characteristics. The histogram for a typical capnogram will have a higher number of occurrences of CO_2 sample values in the bins of Region **R1** and Region **R3**, and the number of occurrences in the bins of Region **R2** should be lower than the number of occurrences in Regions **R1** and **R3**. That is, the capnogram histogram **42** has a peak in lower Region **R1** and a peak in upper Region **R3**, and a valley in the intermediate Region **R2**. Further, the peak in upper Region **R3** is typically more spread-out than the peak in Region **R1**, as seen in the idealized capnogram histogram **42** of FIGURE 2. The spread in the peak in upper Region **R3** is caused by the slope of the capnogram **40** during the exhalation phase, with the highest CO_2 value typically occurring at the end of the breath (i.e. end-tidal point). This slope of the capnogram waveform **40** is reflected in spreading of the points making up the peak in upper Region **R3** of the capnogram histogram **42**. Such spreading may additionally or alternatively be caused by the usual situation in which every breath does not have the same peak CO_2 value (or, said another way, $etCO_2$ varies from breath to breath). The difference in $etCO_2$ value for each breath is reflected in spreading of the peak in upper Region **R3**. By contrast, during the inspiration phase of the capnogram the CO_2 level usually falls to a flat baseline level that is close to zero, and exhibits little variation from breath to breath, leading to a narrower peak in the lower Region **R1** of the histogram **42**.

The capnogram histogram **42** is computed from the capnogram **40** in the sliding window, with a new histogram computed every few seconds, e.g. every 5 seconds in one illustrative example employing a 30 second window. There is no attempt to synchronize the window with an integer number of breaths, but the window is preferably large enough to encompass several breaths (e.g. for a normal adult patient respiration interval of 3-5 seconds/breath the illustrative 30 sec window encompasses 6-10 breaths). By re-computing the histogram on a shorter time interval than the window size (e.g. every 5 sec using a 30 sec window) the successive histogram windows significantly overlap providing for a smoothing effect as a function of time. Since there is no synchronization with the breath cycling, there is no need to employ a breath detector in constructing the capnogram histogram **42**, and the determination of the histogram **42** is a very fast CO_2 sample binning process.

An end-tidal carbon dioxide ($etCO_2$) value and a respiratory rate (RR) value are determined from the capnogram signal **40**. Substantially any technique to detect a signal

maximum can be used to detect the $etCO_2$ value. For example, in some embodiments, the $etCO_2$ value is determined from the capnogram signal **40** by analysis of the histogram **42** derived from the capnogram signal **40**. In this approach, the CO_2 level of the highest CO_2 level bin having a non-zero sample count provides an $etCO_2$ value. Similarly, substantially any technique to determine periodicity of a signal can be used to detect the RR value. For example, the RR value can be determined by detecting breaths using the breath detector **48** and thereby determining breath intervals (the RR being the inverse of the average breath interval). Alternatively, a Fast Fourier Transform (FFT) can be applied to determine the RR value in the frequency domain.

With continuing reference to FIGURE 1, the capnogram histogram **42** is used to compute an end-tidal CO_2 parameter quality index ($etCO_2$ PQI) **44**. This index is computed as a weighted sum of parameters derived from the capnogram histogram **42**, and optionally also from the capnogram **40** itself. The parameters included in the weighted sum are suitably chosen as relevant criteria in determining the confidence in the $etCO_2$ measurement obtained from the capnogram **40**. In one illustrative embodiment, the $etCO_2$ PQI **44** is computed from parameters including (1) a metric of the portion of the histogram **42** that is above the baseline; (2) a metric of the difference between the maximum CO_2 in Region **R3** and the CO_2 level in Region **R3** having the highest histogram counts; (3) a metric comparing the Region **R3** count versus the Region **R2** count; (4) a metric of the fraction of the total counts in Region **R3**; and (5) a metric of the CO_2 fall time.

The metric of the portion of the histogram **42** that is above the baseline characterizes the portion of the histogram that is in Region **R3** as compared with Region **R1**. This metric is large for a normal capnogram, but may be low in the case of a poor capnogram waveform having an inconsistent expiratory plateau.

The metric of the difference between the maximum CO_2 in Region **R3** and the CO_2 level in Region **R3** having the highest histogram counts is expected to be small because the end-tidal point should have the largest CO_2 value and a CO_2 level bin at or close to $etCO_2$ should also have a large number of counts since the expiratory plateau usually flattens as it approaches the end-tidal point. This metric may be computed from the difference between the CO_2 level of the bin of Region **R3** having a non-zero count and the CO_2 level of the bin of Region **R3** storing the highest count.

The metric comparing the upper Region **R3** count versus the intermediate Region **R2** count quantifies the expectation that a sharp transition should be present from the inspiratory phase to the expiratory phase in the capnogram **40**. In such a case, the intermediate Region **R2** count is low and the upper Region **R3** count is high. However, since there are more

bins in intermediate Region **R2** than in upper Region **R3**, this metric may preferably be quantified using the average count over all bins of Region **R2**, and likewise using the average count over all bins of Region **R3**.

The metric of the fraction of the total counts in upper Region **R3** should be high since a large portion of the capnogram waveform consists of the expiratory phase. This metric may be computed using the ratio of the total counts in upper Region **R3** to the total counts in the capnogram histogram **42**.

With brief reference to FIGURE 3, the metric of the CO_2 fall time differs from the previous four metrics contributing to the illustrative $etCO_2$ PQI in that the metric of the CO_2 fall time is computed from the capnogram **40** rather than from the capnogram histogram **42**. The metric of the CO_2 fall time is useful for detecting when the capnogram waveform is washed out due to the effect of supplemental oxygen. This is illustrated in FIGURE 3. The top plot of FIGURE 3 shows the expiratory plateau for the same idealized capnogram **40** as is shown in FIGURE 2. The CO_2 fall time is computed as the time interval from when a high CO_2 level falls below an upper threshold T_{upper} until the CO_2 level decreases below a lower threshold T_{lower}. This CO_2 fall time is indicated as t_{fall} in the top plot of FIGURE 3 showing the idealized capnogram **40**. It is seen that t_{fall} is relatively short. By contrast, FIGURE 3 bottom plot shows a capnogram $\mathbf{40_{O2}}$ which exhibits supplemental oxygen washout. In this case, the transition from T_{upper} to T_{lower} is much longer.

It will be noted that the CO_2 fall time can be determined without performing breath detection, and without segmenting the capnogram waveform into inspiratory and expiratory phases. For example, in the illustrative example the CO_2 fall time is computed by identifying when a high CO_2 level falls below T_{upper} and then when it falls below T_{lower}.

With returning reference to FIGURE 1, the $etCO_2$ PQI **44** is suitably computed as a weighted sum of these metrics (and/or other metric that correlate with the reliability of the $etCO_2$ measurement by capnography). That is:

$$etCO_2\ PQI = \sum_i W_i * S_i$$

where the index i ranges over the metrics contributing to $etCO_2$ PQI **44**, S_i is the score (i.e. value) of the ith metric, and W_i is a weight for the ith metric. The weights may be generated manually (e.g. based on assessment by a skilled pulmonologist, anesthesiologist, respiratory therapist or other expert of the relative importance of the various metrics) or by performing

machine learning using a training set of representative capnograms each labeled by a skilled pulmonologist, anesthesiologist, or other expert as to reliability of the $etCO_2$ value obtained from the training capnogram.

The five metrics contributing $etCO_2$ PQI in the example are merely illustrative. More generally, it will be appreciated that the capnogram histogram **42** is expected to exhibit a large narrow peak in a lower Region **R1** corresponding to the inspiration phase of the respiratory cycle, a large slightly broader peak in an upper Region **R3** corresponding to the expiratory phase, and a deep valley in an intermediate Region **R2** corresponding to transitions from inspiration-to-expiration and from expiration-to-inspiration. Deviations from this basic histogram shape are expected when the capnogram waveform is degraded, and consequently $etCO_2$ values are expected to be less reliable. Various metrics can be constructed and optimized using histograms constructed for training capnograms in order to quantitatively characterize metrics to assess the histogram shape and hence the capnogram waveform. The optimal choice of metrics, and their weights, depends on the capnograph device and its connection to the patient, the demographic being monitored, the desired sensitivity (e.g. how "bad" should the capnogram waveform be before the $etCO_2$ PQI starts to significantly decrease), and so forth. In some embodiments the metrics may be optimized for different patient connections (e.g. nasal cannula versus airway adaptor), different patient breathing conditions (e.g. spontaneous breathing versus various mechanical ventilation modes), or so forth. The capnogram histogram shape reflects the capnogram waveform, so quantitative metrics of the histogram provide assessment of the capnogram waveform quality without the need to detect breath intervals in the capnogram and without the need to segment the capnogram into inspiration and expiration phases. In the illustrative example, one metric (CO_2 fall time) is extracted directly from the capnogram **40** rather than from the capnogram histogram **42**, but this is still done without performing breath detection or segmenting the capnogram into breathing phases. The computations are fast, and can be performed in real-time (that is, with a delay of a few tens of seconds, a few seconds, or less).

With continuing reference to FIGURE 1, a respiratory rate parameter quality index (RR PQI) **46** is also determined. The RR, and the RR PQI, both depend on detecting breaths, and hence receive as input the breath intervals detected in the capnogram **40** by a breath detector **48**. The RR PQI **46** is suitably determined as a weighted sum of metrics including, by way of illustrative example: respiratory rate (RR), a metric of expiration time/inspiration time ratio (IE ratio), a metric quantifying invalid peak counts in the capnogram of a breath, a capnogram carbon dioxide level dynamic range metric, and a metric of how close

the inspiratory CO_2 level is to zero. The RR and IE ratio values should be in reasonable ranges (e.g. RR around 12-20 breaths per minute for an adult) so values falling significantly outside the reasonable reduce the RR PQI **46**. Extra (invalid) peaks can result in erroneous breath detections, hence more invalid peaks reduces the RR PQI. The capnogram dynamic range (maximum CO_2 level minus minimum CO_2 level) impacts the signal strength, so a low dynamic range reduces RR PQI. Similarly, the CO_2 level should be close to zero during inspiration; whereas, a higher CO_2 level during inspiration makes breath detection more difficult leading to a lower value for the RR PQI **46**.

In the illustrative embodiment of FIGURE 1, the RR PQI **46** is also determined based on the $etCO_2$ PQI **44** which serves as an additional metric in the weighted sum. The $etCO_2$ PQI **44** is a metric of "normalcy" of the capnogram waveform. Since a highly abnormal capnogram waveform makes breath detection more difficult, a lower value for the $etCO_2$ PQI **44** results in a lower RR PQI value as well. Employing the $etCO_2$ PQI **44** as an input metric to the RR PQI **46** advantageously re-uses the $etCO_2$ PQI **44** in assessing reliability of the RR.

The RR PQI **46** is again suitably computed as a weighted sum of the contributing metrics:

$$RR\ PQI = \sum_i W_i * S_i$$

where the index i ranges over the metrics contributing to RR PQI **46**, S_i is the score (i.e. value) of the ith metric, and W_i is a weight for the ith metric. The weights again may be generated manually or by performing machine learning using a training set of representative capnograms labeled as to RR reliability. The metrics contributing RR PQI in the example are again merely illustrative, and additional or other metrics are contemplated.

In some embodiments, a respiratory well-being index (RWI) **50** is also computed, which represents a quality score to assess the respiratory well-being of a patient using the capnogram **40**. The RWI **50** is designed to help medical personnel evaluate the overall respiratory well-being of the patient. RWI **50** may also be used to identify non-intubated patients who are at risk for hypoventilation due to central or obstructive apnea, such as during procedural sedation. In a suitable embodiment, metrics that serve as weighted inputs to the RWI **50** include the measured RR and $etCO_2$ and the corresponding RR PQI **44** and $etCO_2$ PQI **46**. In general, if either the RR or $etCO_2$ are outside their respective normal ranges then this lowers the RWI **50**. A lower RR PQI **44** or lower $etCO_2$ PQI **46** also lowers the RWI **50**. In

some embodiments, a time-since-last-breath metric is also incorporated into the RWI **50** in order to facilitate its use in detecting airway obstruction or apnea episodes. For example, the time-since-last-breath may be quantified from the capnogram **40** by a block **52** assessing the time since last elevated CO_2 level.

The indices **44**, **46**, **50** are suitably re-calculated each time the capnogram histogram **42** is updated, e.g. every 5 seconds in the illustrative example. Since the illustrative histogram calculation window is 30 seconds, the first calculation of the indices **44**, **46**, **50** is performed after 30 seconds of the capnogram **40** are acquired.

If the capnograph device **10** is programmed to provide informational messages based on the RR and $etCO_2$ values, then the indices **44**, **46**, **50** may optionally be used to suppress these informational messages when the underlying RR or $etCO_2$ is unreliable as indicated by the corresponding PQI. By way of non-limiting illustration, in one contemplated embodiment the messaging scheme of Table 1 is employed, with the outputs only being displayed when RWI is lower than some threshold value.

Table 1

Parameter	**Message when the parameter is above the "Normal" range**	**Message when the parameter is below the "Normal" range**
$etCO_2$	"Hypo-ventilation"	"Shallow breaths" "try chin lift"
$etCO_2$ PQI Score	N/A	"Shallow breaths" "try chin lift"
RR	"Patient anxious" (do not show message if RR PQI is low)	"Low resp rate", "prompt patient to breathe"
RR PQI score	N/A	"Unstable breathing"
Time since high CO_2 signal	"Long time since breath", "prompt patient to breathe"	N/A

In this illustrative messaging scheme, the "patient anxious" message is suppressed if the RR PQI **46** is below a threshold value.

In addition to (or in place of) computing and displaying (on the display component **32**) values of probative parameters such as $etCO_2$, RR, $etCO_2$ PQI **44**, RR PQI **46**, and/or RWI **50**, it is contemplated to display on the display component **32** the capnogram histogram **42** itself. As previously discussed, the capnogram histogram **42** embodies substantial information about the capnogram waveform in a format that may be more readily perceived by medical personnel as compared with reading a display of the capnogram **40** (which may

optionally also be displayed on the display **32**, e.g. as a trend line). One advantage of displaying the capnogram histogram **42** as compared with displaying a trend line of the capnogram **40** is that the trend line is typically scrolled horizontally, whereas the capnogram histogram **42** does not scroll and is updated, e.g. every 5 seconds with substantial overlap between successive updates due to the large window overlap between successive updates (e.g. with a 30 second window and 5 sec updates, each successive histogram is derived from 25 seconds of the same capnogram data that was used to generate the immediately previous histogram and only 5 seconds of new capnogram data).

The foregoing embodiments advantageously provide capnography monitoring with output that is more readily comprehended and acted upon by medical personnel. In some embodiments which follow, the capnography monitoring is synergistically combined with blood hemoglobin oxygen saturation information, for example arterial blood oxygen saturation (SpO_2) measured by a pulse oximeter which measures the pulsatile part of blood in the finger or other tissue at which the SpO_2 measurement is made. While venous blood is the majority of the blood in the finger, venous blood does not pulse significantly, and hence is not considered in the SpO_2 measurement. Only the arterial blood pulsates strongly, and hence the pulse oximeter measures the arterial blood oxygen saturation. The term "arterial" refers to blood that has not yet participated in gas exchange (causing loss of O_2 captured in the lungs and collection of CO_2 from the tissues). It may be noted that the arterial blood may be located in arteries or in capillaries (including small capillaries) – such blood is nonetheless arterial blood even if located in the capillaries, so long as it has not yet participated in gas exchange. The SpO_2 measurement thus measures oxygenation of arterial blood in the fingertip or other tissue being measured, whether that arterial blood is in arteries, capillaries, or is in both blood vessel types.

It is recognized herein that medical professionals often have a tendency to rely primarily on the SpO_2 vital sign to the exclusion of capnography data. This is due both to greater familiarity of many clinicians with SpO_2 as compared with capnography, and the recognition by clinicians that a low SpO_2 level is a direct clinical measure of an urgent medical problem, namely that the patient is not being sufficiently oxygenated. By contrast, interpretation of the capnography data, such as the $etCO_2$, is more complex, and may be more difficult for some medical professionals.

However, it is recognized herein that capnography is complementary to SpO_2 monitoring because capnometry can serve as a leading indicator by detecting a respiration problem before it manifests as reduced SpO_2 level. The capnography measures a direct product of blood-gas exchange in the lungs; whereas, SpO_2 measures a lagging metric of this blood-

gas exchange and provides a clinical warning only after an insufficiency in transfer of oxygen to blood in the lungs occurring over an extended period of time produces a cumulative reduction in blood oxygenation.

Another way that capnography can be complementary to SpO_2 monitoring is in the case of a patient who is receiving supplemental oxygen. Here, the supplemental oxygen facilitates a high SpO_2 level, but in so doing may mask an underlying blood-gas exchange problem in the lungs or respiration rate and/or volume is low. Capnography, by directly measuring the CO_2 product of this blood-gas exchange in the lungs, can detect respiratory problems that may be masked in the SpO_2 measurement by the additional oxygenation provided by the supplemental oxygen.

In approaches disclosed herein, SpO_2 and capnography are synergistically combined to provide patient monitoring that more rapidly detects respiratory problems, and can detect respiratory problems that may otherwise be masked by supplemental oxygen, while still providing life-critical blood oxygenation monitoring via SpO_2 monitoring. In some embodiments, the disclosed approaches further provide synergistic clinical decision support. The SpO_2 and capnography information are analyzed separately to identify one or more clinical warnings, and these warnings are displayed in a ranked fashion based on urgency.

The RWI, by itself, does not consider blood oxygenation (or, more generally, the cardiac condition of the patient). In the following illustrative embodiments, the arterial oxygen saturation level (SpO_2) of the patient is combined with the RWI to calculate an index of the overall patient safety, referred to herein as a patient safety index (PSI). The illustrative PSI is a value in the range of 1 to 10, where 1 is the lowest score (patient needs immediate attention) and 10 is the highest score (healthy ventilation and oxygenation). It is possible for a patient to simultaneously have both inadequate oxygen saturation in the blood, indicated by low hemoglobin oxygen saturation, and adequate respiration, indicated by normal respiration rate and end-tidal CO2 concentration.

With reference to FIGURE 4, an illustrative embodiment generating the PSI by combining the RWI and SpO_2 level is diagrammatically shown. The patient **12**, patient accessory **14** (nasal cannula in this instance), and capnograph device **10** are as already described for the embodiment of FIGURE 1. The capnograph device **10** outputs the respiratory well-being index (RWI) **50**, an end-tidal carbon dioxide ($etCO_2$) value **60** and a respiratory rate (RR) value **62** determined from the capnogram signal **40**, as also previously described with reference to FIGURE 1. The illustrative embodiment of FIGURE 4 does not output the capnogram signal waveform, the capnogram histogram, or the PQI (parameter quality index)

values of the embodiment of FIGURE 1, although any of these could also be outputs in variants of the embodiment of FIGURE 4 if desired.

The illustrative embodiment of FIGURE 4 further includes or has access to a pulse oximeter **70**, which may for example be a fingertip pulse oximeter or the like. In a typical pulse oximeter design, light emitting diodes (LEDs) or other light sources transmit red light and infrared light through tissue (e.g. a fingertip) of the patient, and the transmission in these wavelengths is measured. As is known in the art, differential absorption at these different spectral locations enables extraction of arterial blood oxygen saturation (SpO_2) **72**. Heart rate (HR) **74** may also be output by the pulse oximeter **70**, obtained from fluctuations in the optical signals as blood volume in the monitored tissue (e.g. fingertip) fluctuates cyclically with each successive heartbeat. (The heart rate may additionally or alternatively be obtained from another sensor, e.g. an electrocardiogram or so forth).

A multi-parameter patient monitor **80** receives as inputs the RWI **50** and the $etCO_2$ value **60**, and also optionally receives other physiological parameters such as RR **62** from the capnograph device **10**, HR **74** from the pulse oximeter **70**, blood pressure from a blood pressure monitor (components not shown), and/or so forth. The illustrative patient monitor **80** includes a display **82** and an electronic processor **84**. As is conventional in patient monitoring, the electronic processor **84** is optionally programmed to display one or more of the received physiological parameters **60**, **62**, **72**, **74** on the display **82**, e.g. as a trend line and/or as numerical values, optionally averaged over an averaging time window. Physically, the patient monitor **80** may be variously embodied, e.g. as a bedside patient monitor, a nurses' station monitor, a wearable patient monitoring device, or so forth. Some illustrative examples of patient monitors include the various IntelliVue™ patient monitors available from Koninklijke Philips N.V., Eindhoven, the Netherlands. In other embodiments, the patient monitor **80** may be integrated with some other medical device – for example, the patient monitor **80** may be a component of a mechanical ventilator (not shown).

The electronic processor **84** of the illustrative patient monitor **80** of FIGURE 4 is further programmed to compute the Patient Safety Index (PSI) as diagrammatically shown in FIGURE 4. To this end, the SpO_2 value **72** is converted to an SpO_2 score or index **90**, and the SpO_2 index **90** and the respiratory well-being index (RWI) **50** are combined to generate a patient safety index (PSI) **92** which may be utilized in various ways. In the illustrative example of FIGURE 4, the PSI **92** is used as input to a decision operation **94** to detect a clinical problem. If the decision **94** is that a clinical problem is evidenced by the value of the PSI **92**, then a decision support analysis **96** is triggered to analyze the SpO_2 and capnography data to identify

alarm conditions such as low SpO_2 level, possible incorrect endotracheal tube placement, hypercarbia (i.e. abnormally elevated CO_2 in blood), or so forth. In an operation **98**, any such alarm conditions are displayed on the display **82** of the patient monitor **80**, e.g. as a list ranked by urgency (which in some embodiments may be a top-N list where N is a sub-set of the one, two, three, or more most urgent warnings).

In the following, an illustrative example of one suitable formulation of the PSI **92** is set forth.

In the illustrative example of the SpO_2 index **90**, the arterial blood oxygen saturation (SpO_2) measurement **72** is input into a scoring function which outputs a score between +10 and -10. If the arterial blood oxygen saturation **72** is above an upper threshold (e.g. 94%), then the scoring function outputs the maximum scoring value of 10. For lower values of the oxygen saturation **72**, the score decreases. If the arterial blood oxygen saturation **72** is below a lower threshold (e.g. 80%), then the scoring function outputs the minimum scoring value of -10.

In the illustrative example of calculating the PSI **92**, a weighting factor is applied to the oxygen saturation score **90** and to the calculated RWI **50** from the capnography device **10**. The weighted sum of these scores is the resulting PSI value. For example if the arterial blood oxygen saturation is 92% then the corresponding score may be 3. If the corresponding RWI is 5 and if the weights for both inputs is 0.5, the output PSI is 4, indicating that the patient may potentially be at risk. In the illustrative example, the choice of a scale in the range [-10,10] for the SpO_2 score ensures that a low SpO_2 value will draw down the combined PSI to ensure that it captures the clinically urgent situation in which the patient's blood oxygenation is low.

A variant embodiment of the arterial blood oxygen saturation scoring adjusts the SpO_2 score **90** for the SpO_2 when the patient is receiving supplemental oxygen. This adjustment captures the clinical reality that an arterial blood oxygen saturation that would be considered near normal (i.e. 94%) when the patient is breathing air would be considered low if the same patient is receiving supplemental oxygen through a nasal cannula, mask or endotracheal tube. To account for this difference in expected normal range, function generating the SpO_2 index **90** is shifted to lower value by a small amount (i.e. 2%) when it is known that the patient is receiving supplemental oxygen. This variant embodiment allows the PSI **92** to be more sensitive to low oxygen saturation values when the patient is receiving supplemental oxygen and saturation values are expected to be a little higher.

The determination that the patient is on supplemental oxygen may be based on a user input to the patient monitor **80** (e.g., when setting up the patient profile the nurse or other medical professional may select a radial input button indicating the patient is on supplemental oxygen). Alternatively, an automated mechanism for detecting that the patient is on supplemental oxygen may be utilized – for example, if the patient monitor **80** is integral with a mechanical ventilator or is connected to receive data from a mechanical ventilator, and the available data include fraction of inspired oxygen (FiO_2), then the patient monitor **80** may automatically detect whether the patient is on supplemental oxygen based on the FiO_2 value. In such embodiments, it is further contemplated to adjust the aforementioned small shift to lower value of the SpO_2 index **90** based on the supplemental oxygen level, e.g. a larger downward shift in the index value may be applied for higher FiO_2 value (as a higher fraction of inspired oxygen indicates more supplemental oxygen).

With reference to FIGURES 5 and 6, illustrative examples of the SpO_2 index-versus-SpO_2 value function suitably used to compute the SpO_2 index **90** are shown for the case of no supplemental oxygen (FIGURE 5) and for the case of supplemental oxygen (FIGURE 6). As seen in FIGURE 5, with no supplemental oxygen the SpO_2 index score remains at its maximum value of 10 for SpO_2 values down to 94% (i.e., the upper threshold is 94%). As seen in FIGURE 6, with supplemental oxygen the SpO_2 index score remains at its maximum value of 10 for SpO_2 values down to only 96% (i.e., the upper threshold is increased to 96%), reflecting that, for example, a 95% SpO_2 is usually deemed to be clinically acceptable for a patient without supplemental oxygen, but may be deemed to be abnormally low for a patient on supplemental oxygen. More generally, in some preferred embodiments the SpO_2 index **90** is computed using a monotonic function that has a minimum value (e.g. -10 in the illustrative examples) for values of SpO_2 at or below a lower threshold SpO_2 value (78% for the no supplemental oxygen scoring function of FIGURE 5, or 80% for the supplemental oxygen scoring function of FIGURE 6) and increases monotonically to a maximum value (e.g. +10 in the illustrative examples) for values of SpO_2 at or above an upper threshold SpO_2 value (94% for the no supplemental oxygen scoring function of FIGURE 5, or 96% for the supplemental oxygen scoring function of FIGURE 6).

In combining the SpO_2 index **90** and the RWI **50** to generate the PSI **92**, the RWI and the SpO_2 values should reflect physiologic conditions corresponding to the same point in time. If these two input signals are misaligned in time, they may not work in concert to indicate patient safety. Because the RWI and the SpO2 are derived from different physiologic signals, one measured by the capnography device **10** and the other by the pulse

oximeter **70**, there is a possibility that one may reflect an event or conditions that occurred before or after the other. In other words, the data streams from the two different devices **10**, **70** may not be synchronized in time. Another cause of misalignment may be signal averaging. It may be beneficial to average the input signals to improve variability of the inputs. However, signal averaging delays the response of the signals, so that one or the other of the two signals may be delayed relative to the other signal (SpO_2 or capnometry). Various approaches can be used to synchronize the SpO_2 and capnography signals, e.g. using a common clock signal output to the two devices **10**, **70** from the patient monitor **80,** transmitting a synchronizing clock signal from one of the two devices **10**, **70** to the other, or so forth. In another approach, an identifiable landmark in the signals can be used, for example if the capnography device **10** is a multifunction patient monitoring device that also measures heart rate then this heart rate may be used to synchronize with the HR **74** measured by the pulse oximeter **70** to synchronize the signals from the two devices **10**, **70**. These are merely illustrative synchronization approaches.

With reference to FIGURE 4, some illustrative examples of embodiments of the decision support analysis **96** and decision support alarm messaging **98** are next described.

The PSI **92** may be displayed, e.g. as another patient data stream on the patient monitor **80**. However, in the illustrative example of FIGURE 4, the PSI **92** is not usually displayed, and in some embodiments is never displayed. Rather, the PSI **92** primarily serves as input to the decision **94** in order to detect a possible situation calling for clinical intervention. At the operation **94**, if the calculated PSI **92** is below a threshold then a message is displayed. However, simply displaying a warning such as "PSI below safe threshold" is not especially informative to the nurse, doctor, or other clinician. Rather, in the illustrative embodiment of FIGURE 4 the low PSI triggers the decision support analysis **96** which provides one or more clinically informative warning messages that are displayed in the alarm messaging operation **98**. These messages are selected, and optionally displayed in ranked fashion, based on the impact that each input (RWI or SpO_2 score) has on the calculated PSI **92**. The impact is the product of the imperfection in the score (10 – score) and the weighting factor applied to the input. For example, if the SpO_2 index **90** is 3 and the weighting factor is 0.5, then the impact of the SpO_2 score on the PSI would be 1.5. If the SpO2 has the higher impact on the PSI, then a message indication "low SpO_2" (or some other semantically similar message such as "Inadequate Oxygenation" or "Check Supplemental O_2") would be displayed. If on the other hand, the RWI has the higher impact on the score, then a message based on the RWI would be shown.

An illustrative monitoring process performed using the embodiment of FIGURE 4 is described in the following. For a given breath or period of time, calculate the RWI **50** from the capnography signal measured by the capnography device **10** as described previously herein with reference to FIGURE 1. The SpO_2 measurement **72** corresponding in time to the breaths when the RWI was calculated are received, e.g. from the illustrative pulse oximeter **70**. Based on the presence or absence of supplemental oxygen, select the correct score mapping function for SpO_2 (e.g. the scoring function of FIGURE 5 for no supplemental oxygen, or the scoring function of FIGURE 6 for supplemental oxygen. The SpO_2 value is mapped to the SpO_2 score or index **90** of FIGURE 4. The PSI index value **92** is calculated as a weighted sum of the SpO_2 index score and the RWI value. At the decision **94**, if the PSI index value **92** is less than a threshold value then the decision support analysis **96** is initiated. In one illustrative approach, a fault score is calculated for each of the inputs to the PSI **92** (that is, for each of the SpO_2 index score **90** and RWI **50**). The fault score is suitably calculated as the product of the weighting factor and 10.0 minus the feature value. It is then determined which input (SpO_2 or RWI) has the highest fault score. If the SpO_2 has the higher fault score, then in the operation **98** a message is displayed indicating a low SpO_2. If the RWI has the higher fault score, then in the operation **98** a message is displayed based on the RWI. This latter output optionally is generated by performing further decision support analysis on the capnography data, e.g. as described herein with reference to FIGURE 1.

Optionally, the PSI signal may be averaged over an extended time or over a number of breaths. For example, if the PSI is calculated every 5 seconds, it may be beneficial to display the average PSI calculated during the prior minute rather than display the resulting PSI as calculated every 5 seconds. This can help to avoid producing false alarms due to noise in the PSI data stream.

The illustrative example of FIGURE 4 employs the multi-parameter patient monitor **80** as the host computation/display device for performing the operations that integrate capnography and SpO_2 data for improved patient monitoring. Implementing this processing at the patient monitor **80** is advantageous as such a multi-parameter patient monitor is a common "hub" where capnography data and SpO_2 data are collected. In the illustrative example the RWI **50** is further computed by processing performed by the capnograph device **10** as described with reference to FIGURE 1. However, more generally, these various processing may be otherwise distributed over available electronic processing and display devices. For example, in another contemplated embodiment all processing is performed at the capnograph device, with the SpO_2 being an input to the capnograph device. In this arrangement the patient monitor may

optionally be omitted. In another contemplated embodiment the capnograph device outputs the raw capnogram waveform to a patient monitoring device which performs both the RWI computation and the subsequent operations integrating the RWI and SpO_2. This approach enables the patient monitor to provide PSI-based monitoring in conjunction with any capnograph device that can output the raw capnogram. It will be still further appreciated that the operations that integrate capnography and SpO_2 data for improved patient monitoring may be embodied by a non-transitory storage medium storing instructions that are readable and executable by a microprocessor, microcontroller, or other electronic processor to perform the disclosed processing. Such non-transitory storage media may, by way of non-limiting illustration, include a hard disk drive or other magnetic storage medium, a flash memory, read-only memory (ROM) or other electronic storage medium, an optical disk or other optical storage medium, various combinations thereof, or so forth.

As further contemplated variants, the disclosed RWI is to be understood to be a non-limiting illustrative example of a capnography index which represents the patient's well-being as indicated by the capnogram measured by the capnograph device **10**. More generally, other of capnography index formulations may be employed. As another illustrative example, the end-tidal CO_2 ($etCO_2$) may be used as the capnography index, optionally scaled between minimum and maximum index values similarly to the disclosed scaling operation for SpO_2 (e.g. the illustrative examples of FIGURES 5 and 6). It should be noted that the capnography index may be computed using any information derived from the capnogram, e.g. the illustrative RWI is computed based on the carbon dioxide concentration or partial pressure and also respiratory rate (RR) information derived from the capnogram.

The approach of FIGURE 4 and variants thereof in combining the capnography and arterial blood oxygen saturation data reduces uncertainty and confusion associated with capnometry and arterial blood oxygen saturation monitoring and allows clinicians with less expertise in interpreting capnography data to more effectively integrate capnography and SpO_2 monitoring into interpretation of patient monitoring. The invention has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS:

1. A patient monitoring device comprising:

a capnograph device (10);

a pulse oximeter (70); and

an electronic processor (84) programmed to:

generate a capnography index (50) indicative of patient well-being from a capnogram measured by the capnograph device;

generate an arterial blood oxygen saturation (SpO_2) index (90) indicative of patient well-being from SpO_2 (72) measured by the pulse oximeter;

compute a patient safety index (92) from the capnography index and the SpO_2 index; and

compute one or more clinical warnings determined based at least in part on the patient safety index; and

a display component (82) configured to display at least one of the computed one or more clinical warnings.

2. The patient monitoring device of claim 1 wherein the capnography index (50) is generated from information derived from the capnogram including at least a concentration or partial pressure of carbon dioxide and respiratory rate information.

3. The patient monitoring device of any one of claims 1-2 wherein the SpO_2 index (90) is generated using a monotonic function that has a minimum value for values of SpO_2 at or below a lower threshold SpO_2 value and increases monotonically to a maximum value for values of SpO_2 at or above an upper threshold SpO_2 value.

4. The patient monitoring device of claim 3 wherein the minimum value of the monotonic function is less than zero and the maximum value of the monotonic function is greater than zero.

5. The patient monitoring device of any one of claims 3-4 wherein the SpO_2 index (90) is generated using the monotonic function with higher values of the lower threshold SpO_2 value and the upper threshold SpO_2 value when the SpO_2 (72) is measured with supplemental oxygen and with lower values of the lower threshold SpO_2 value and the upper threshold SpO_2 value when the SpO_2 (72) is measured without supplemental oxygen.

6. The patient monitoring device of claim 5 wherein the electronic processor (84) is further programmed to identify whether supplemental oxygen is in use based on a received fraction of inspired oxygen (FiO_2).

7. The patient monitoring device of any one of claims 1-6 wherein the patient safety index (92) is computed as a weighted sum of the capnography index (50) and the SpO_2 index (90).

8. The patient monitoring device of any one of claims 1-7 wherein the electronic processor (84) is further programmed to threshold (94) the patient safety index (92) and to compute the one or more clinical warnings conditional on the thresholding.

9. The patient monitoring device of any one of claims 1-8 wherein the one or more clinical warnings are computed by operations including:

determining whether the capnography index (50) or the SpO_2 index (90) indicates a more urgent clinical warning by comparing a component of the patient safety index (92) computed from the capnography index and a component of the patient safety index computed from the SpO_2 index;

computing the clinical warning using the capnogram if the capnography index (50) indicates a more urgent clinical warning; and

computing the clinical warning using the SpO_2 (72) if the SpO_2 index (90) indicates a more urgent clinical warning.

10. The patient monitoring device of any one of claims 1-9 comprising a multi-parameter patient monitor (80) including the display (82) and the electronic processor (84).

11. The patient monitoring device of claim 10 wherein the electronic processor (84) further includes an electronic processor (30) of the capnometer device (10), and at least the capnography index (50) is computed by the electronic processor (30) of the capnometer device (10).

12. A non-transitory storage medium storing instructions readable and executable by an electronic processor (84) to perform patient monitoring comprising:

generating a capnography index (50) indicative of patient well-being from a capnogram measured by a capnograph device (10);

generating an arterial blood oxygen saturation (SpO_2) index (90) indicative of patient well-being from SpO_2 (72) measured by a pulse oximeter (70); and

computing a patient safety index (92) from the capnography index and the SpO_2 index.

13. The non-transitory storage medium of claim 12 wherein the capnography index (50) is generated from information derived from the capnogram including at least a concentration or partial pressure of carbon dioxide and respiratory rate information.

14. The non-transitory storage medium of any one of claims 12-13 wherein the SpO_2 index (90) is generated using a monotonic function that has a minimum value for values of SpO_2 at or below a lower threshold SpO_2 value and increases monotonically to a maximum value for values of SpO_2 at or above an upper threshold SpO_2 value.

15. The non-transitory storage medium of claim 14 wherein the minimum value of the monotonic function is less than zero and the maximum value of the monotonic function is greater than zero.

16. The non-transitory storage medium of any one of claims 14-15 wherein the SpO_2 index (90) is generated using the monotonic function with higher values of the lower threshold SpO_2 value and the upper threshold SpO_2 value when the SpO_2 (72) is measured with supplemental oxygen is in use and with lower values of the lower threshold SpO_2 value and the upper threshold SpO_2 value when the SpO_2 (72) is measured without supplemental oxygen in use.

17. The non-transitory storage medium of claim 16 wherein the performed patient monitoring further comprises:

identifying whether supplemental oxygen is in use based on a received fraction of inspired oxygen (FiO_2).

18. The non-transitory storage medium of any one of claims 12-17 wherein the patient safety index (92) is computed as a weighted sum of the capnography index (50) and the SpO_2 index (90).

19. The non-transitory storage medium of any one of claims 12-18 wherein the performed patient monitoring further comprises:

computing one or more clinical warnings determined based at least in part on the patient safety index (92); and

displaying at least one of the computed one or more clinical warnings on a display component (82).

20. The non-transitory storage medium of claim 19 wherein the one or more clinical warnings are computed by operations including:

determining a more urgent component by comparing relative contribution to the patient safety index (92) of the capnography index (50) and the SpO_2 index (90), the clinical warning being computed using data of the more urgent component.

21. A patient monitoring method comprising:

measuring a capnogram using a capnograph device (10);

measuring arterial blood oxygen saturation (SpO_2) (72) using a pulse oximeter (70); and

using an electronic processor (84), generating a capnography index (50) indicative of patient well-being from the capnogram, generating an SpO_2 index (90) indicative of patient well-being from the SpO_2, and computing a patient safety index (92) from the capnography index and the SpO_2 index.

22. The patient monitoring method of claim 21 wherein:

the capnography index (50) is generated from information derived from the capnogram including at least a concentration or partial pressure of carbon dioxide and respiratory rate information; and

the SpO_2 index (90) is generated using a monotonic function that has a minimum value for values of SpO_2 at or below a lower threshold SpO_2 value and increases monotonically to a maximum value for values of SpO_2 at or above an upper threshold SpO_2 value.

23. The patient monitoring method of claim 22 wherein:

the minimum value of the monotonic function is less than zero and the maximum value of the monotonic function is greater than zero; and

the patient safety index (92) is computed as a weighted sum of the capnography index (50) and the SpO_2 index (90).

24. The patient monitoring method of any one of claims 21-23 further comprising:

using the electronic processor (84), computing one or more clinical warnings determined based at least in part on the patient safety index (92); and

displaying at least one of the computed one or more clinical warnings on a display component (82).

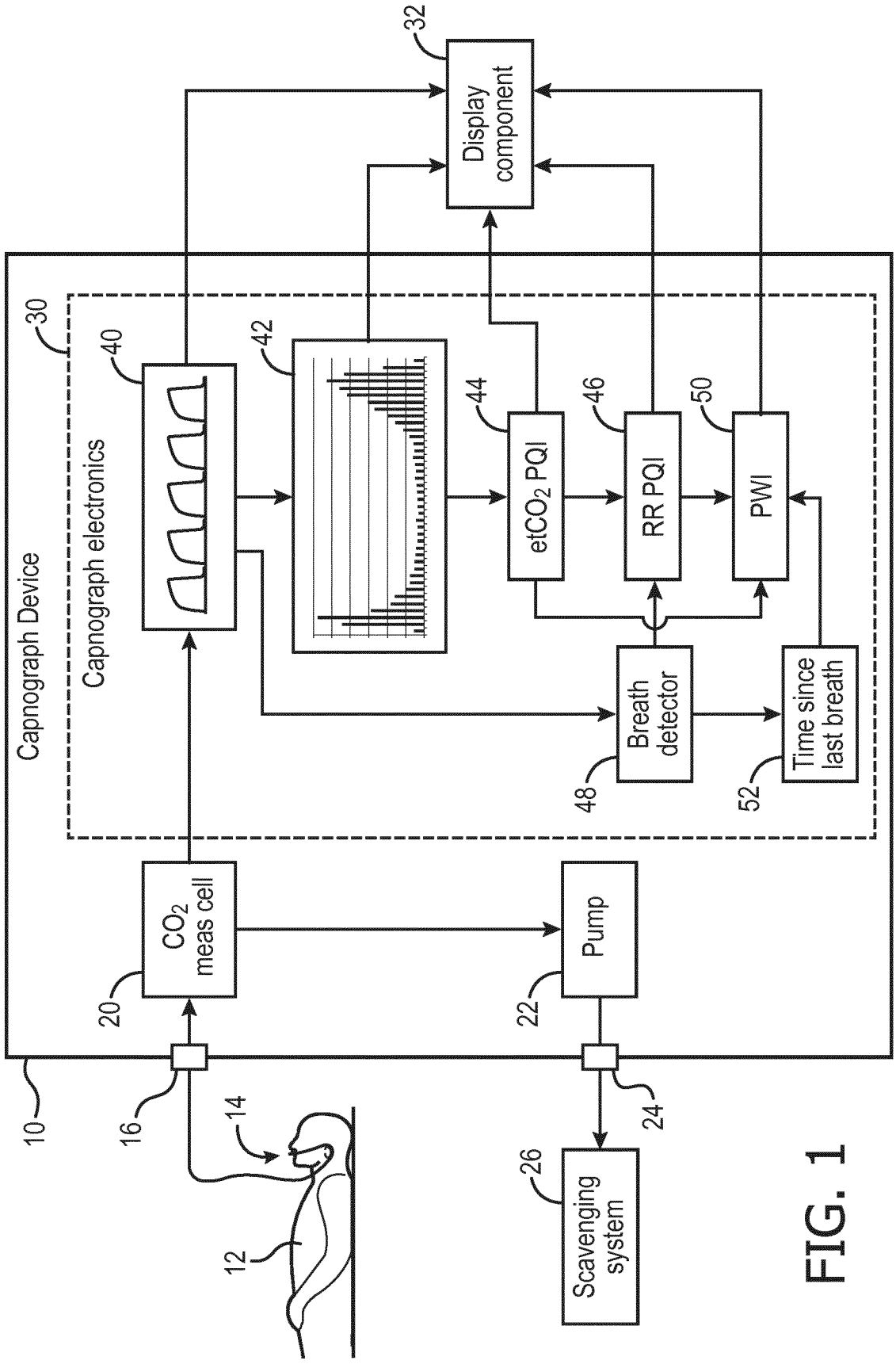
Capnograph Device
30
Capnograph electronics
40
42
44
46
50
32
Display component
etCO2 PQI
RR PQI
PWI
Breath detector
48
Time since last breath
52
CO2 meas cell
20
Pump
22
10
16
14
12
24
26
Scavenging system

FIG. 1

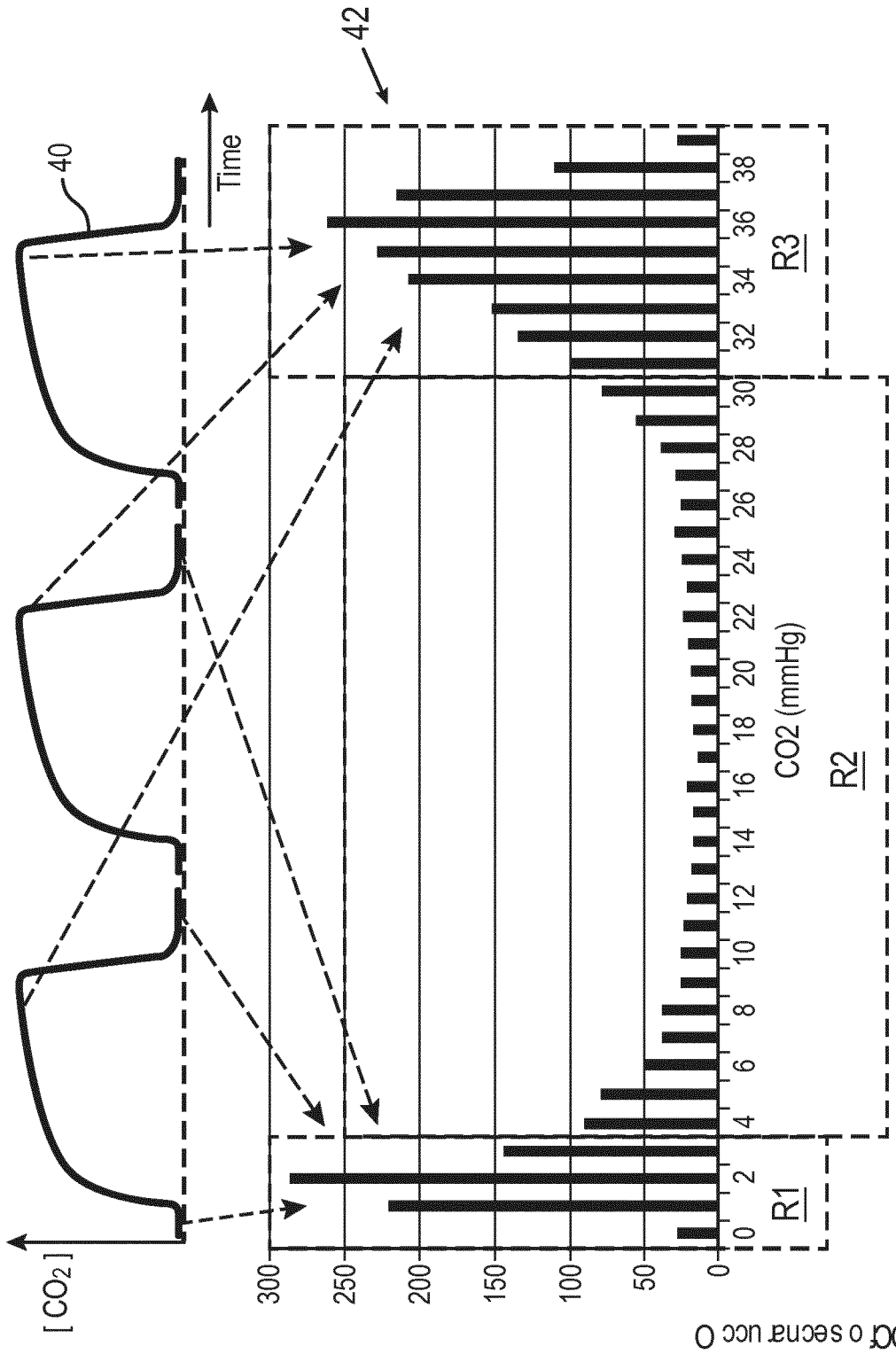
42
40
Time
[CO_2]
300
250
200
150
100
50
0
CO2 (mmHg)
R1
R2
R3
2
4
6
8
10
12
14
16
18
20
22
24
26
28
30
32
34
36
38

FIG. 2

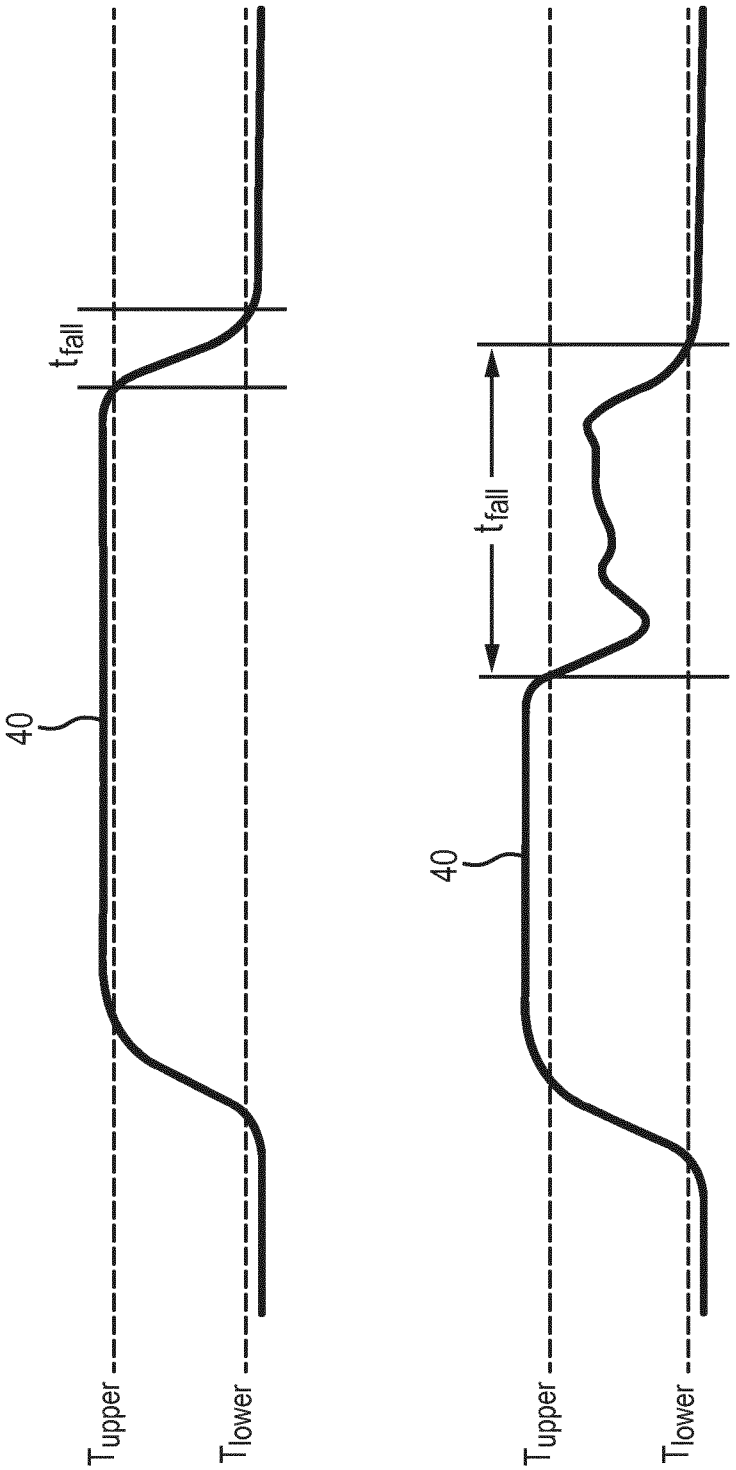

FIG. 3

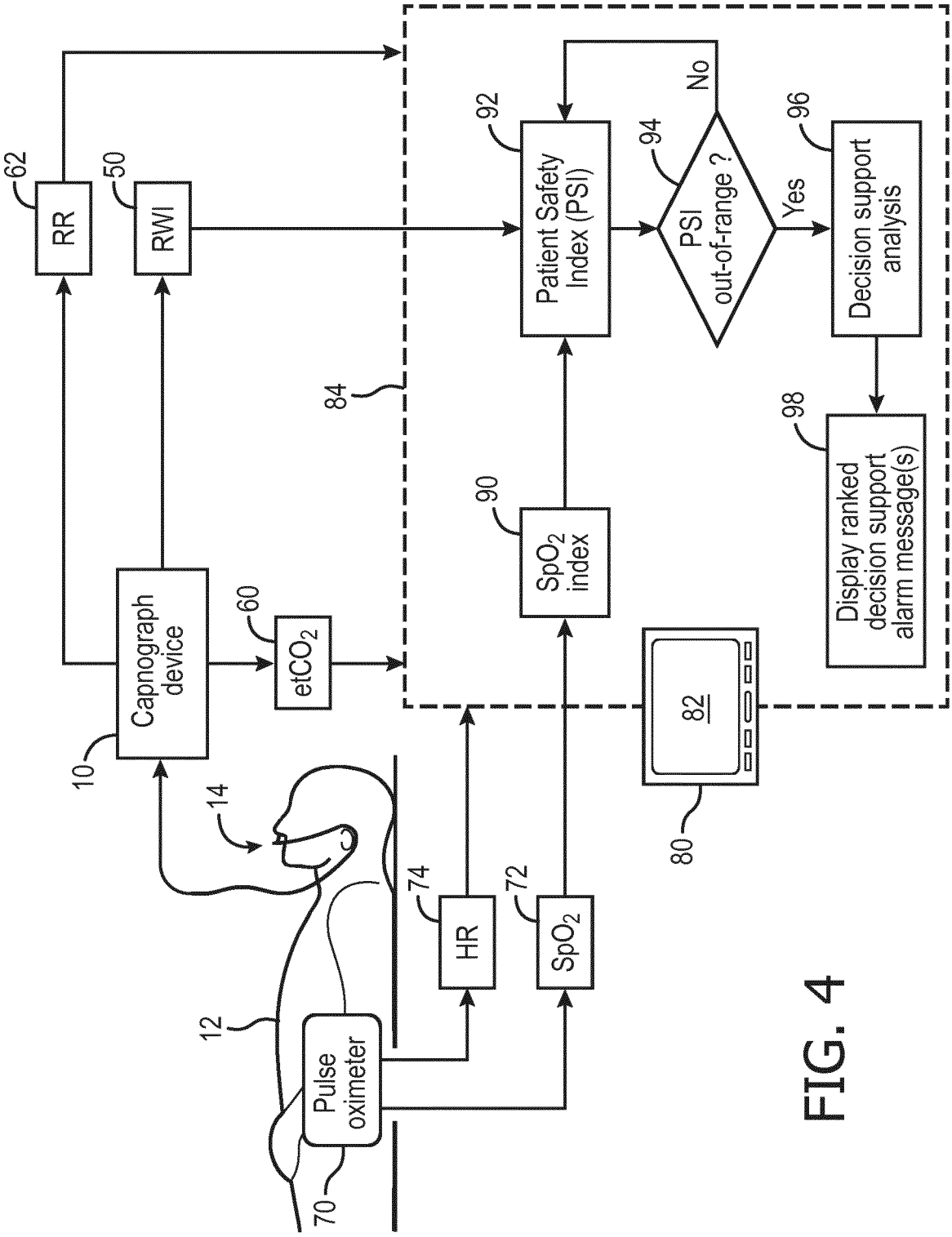
62
RR
50
RWI
Capnograph device
10
60
etCO2
14
12
Pulse oximeter
70
74
HR
72
SpO2
84
92
Patient Safety Index (PSI)
94
PSI out-of-range ?
No
Yes
96
Decision support analysis
98
Display ranked decision support alarm message(s)
90
SpO2 index
82
80

FIG. 4

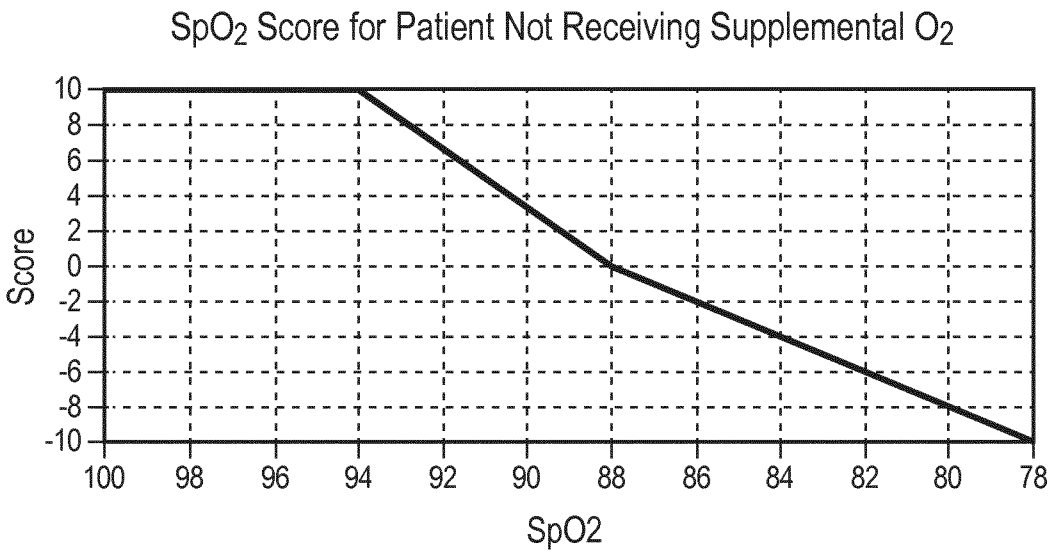
SpO2 Score for Patient Not Receiving Supplemental O2
Score
10
8
6
4
2
0
-2
-4
-6
-8
-10
100
98
96
94
92
90
88
86
84
82
80
78
SpO2

FIG. 5

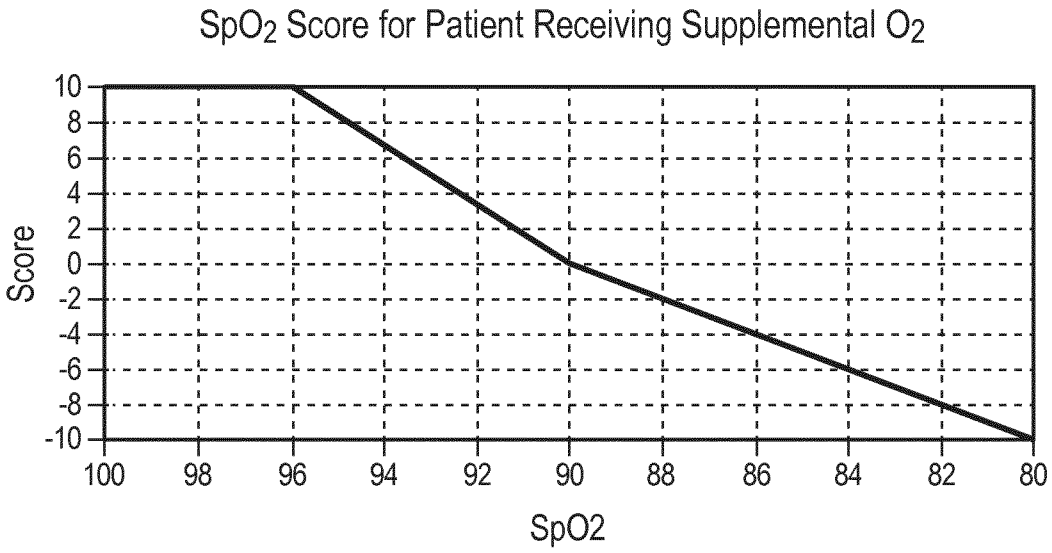
SpO2 Score for Patient Receiving Supplemental O2
Score
10
8
6
4
2
0
-2
-4
-6
-8
-10
100
98
96
94
92
90
88
86
84
82
80
SpO2

FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/050799

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/083 A61B5/1455
ADD.

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2010/150264 A1 (ORIDION MEDICAL 1987 LTD [IL]; LAIN DAVID [US]; COLMAN JOSHUA LEWIS [I) 29 December 2010 (2010-12-29) page 2, line 30 - page 17, line 20 page 19, line 28 - page 37, line 25 page 40, line 24 - page 42, line 3 page 47, line 11 - page 50, line 4 page 55, line 27 - page 62, line 30 page 64, line 1 - page 68, line 14 figures 1A-3,6A-8	1-24
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A	page 8, line 28 - page 10, line 3 page 13, line 11 - page 14, line 32 page 20, line 8 - page 21, line 9 figures 3-5	1-11, 13-20, 22-24

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"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
27 February 2018	08/03/2018

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	Van der Haegen, D

1

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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1

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Information on patent family members

International application No
PCT/EP2018/050799

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		DK 1642608 T3	01-08-2011
		EP 1455878 A1	15-09-2004
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