



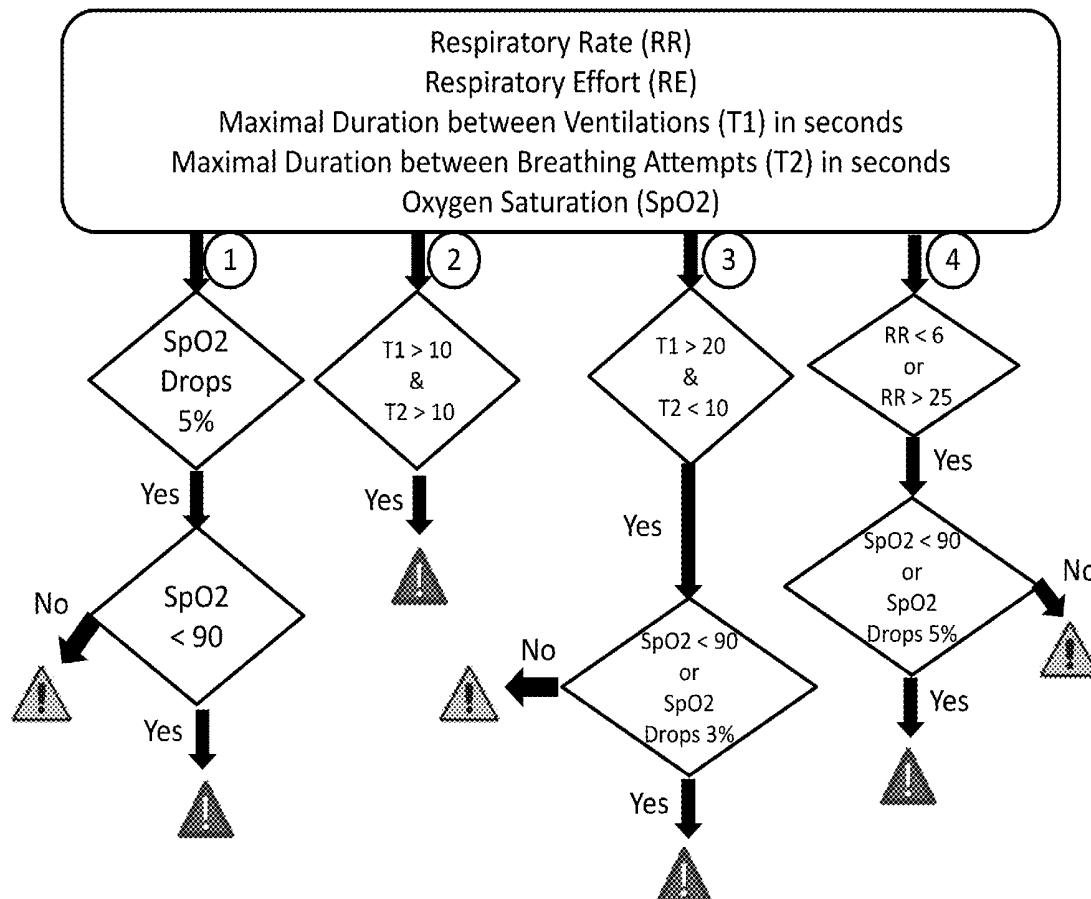
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(19) **United States**(12) **Patent Application Publication**
Shiau(10) **Pub. No.: US 2017/0035304 A1**(43) **Pub. Date: Feb. 9, 2017**(54) **METHODS AND DEVICES FOR
MONITORING RESPIRATION USING
PHOTOPLETHYSMOGRAPHY SENSORS**(71) Applicant: **Deng-Shan Shiau**, Gainesville, FL (US)(72) Inventor: **Deng-Shan Shiau**, Gainesville, FL (US)(21) Appl. No.: **15/230,409**(22) Filed: **Aug. 6, 2016****Related U.S. Application Data**

(60) Provisional application No. 62/202,141, filed on Aug. 6, 2015, provisional application No. 62/220,143, filed on Sep. 17, 2015, provisional application No. 62/239,148, filed on Oct. 8, 2015.

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A61B 5/746 (2013.01); *A61B 5/7282*
(2013.01); *A61B 5/02416* (2013.01)(57) **ABSTRACT**

Provided in embodiments herein are computer-implemented methods and systems for respiratory monitoring. Some embodiments include obtaining a PPG signal stream from a central source site of the individual; identifying peaks and troughs of the PPG signal stream within a predetermined epoch, wherein a time between peaks or a time between troughs corresponds to a heart rate of the individual; determining significant local maxima of peak amplitudes and significant local minima of trough amplitudes within the predetermined epoch, wherein each significant local maxima of peak amplitude corresponds to an onset of the individual's respiratory effort to exhale and each significant local minima of trough amplitude corresponds to an onset of the individual's respiratory effort to inhale; calculating the number of significant local maxima, significant local minima, or both, during the predetermined epoch to determine the number of respiratory efforts in the predetermined epoch; and displaying the number of respiratory efforts in the predetermined epoch on a computer monitor.



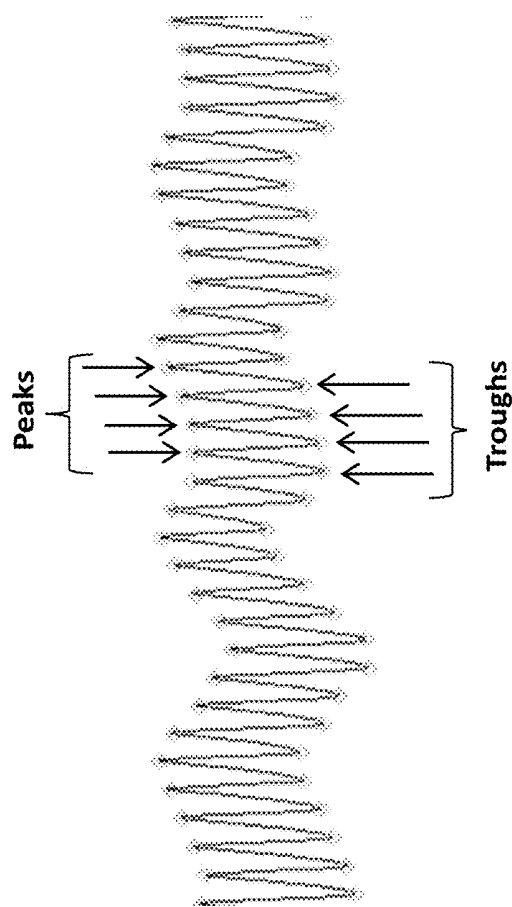


FIGURE 1

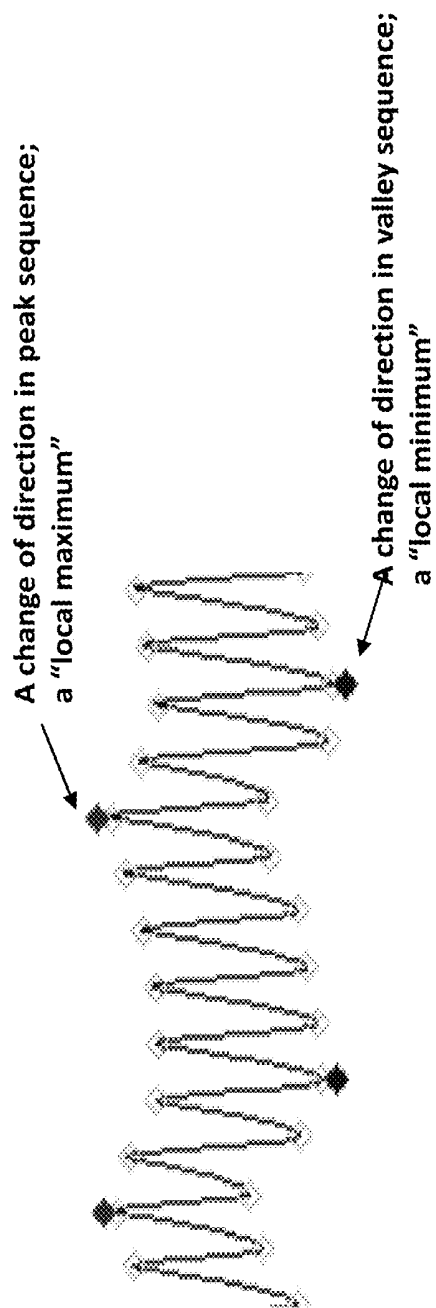


FIGURE 2

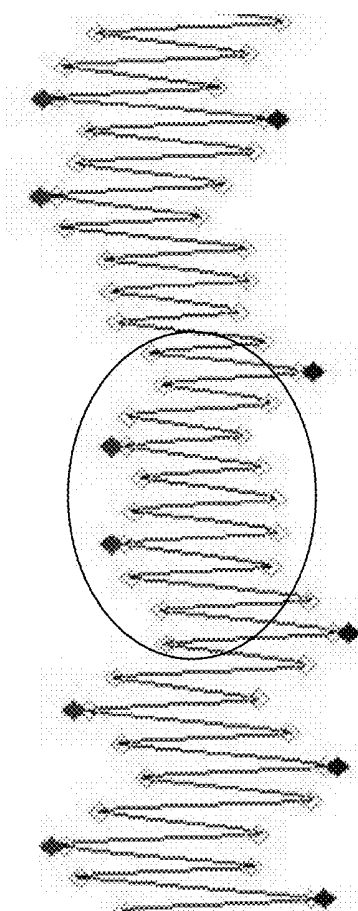


FIGURE 3

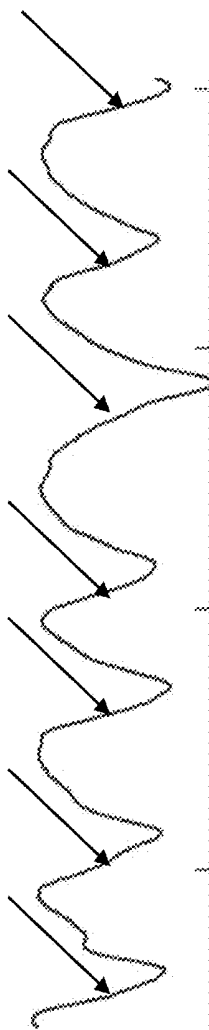


FIGURE 4

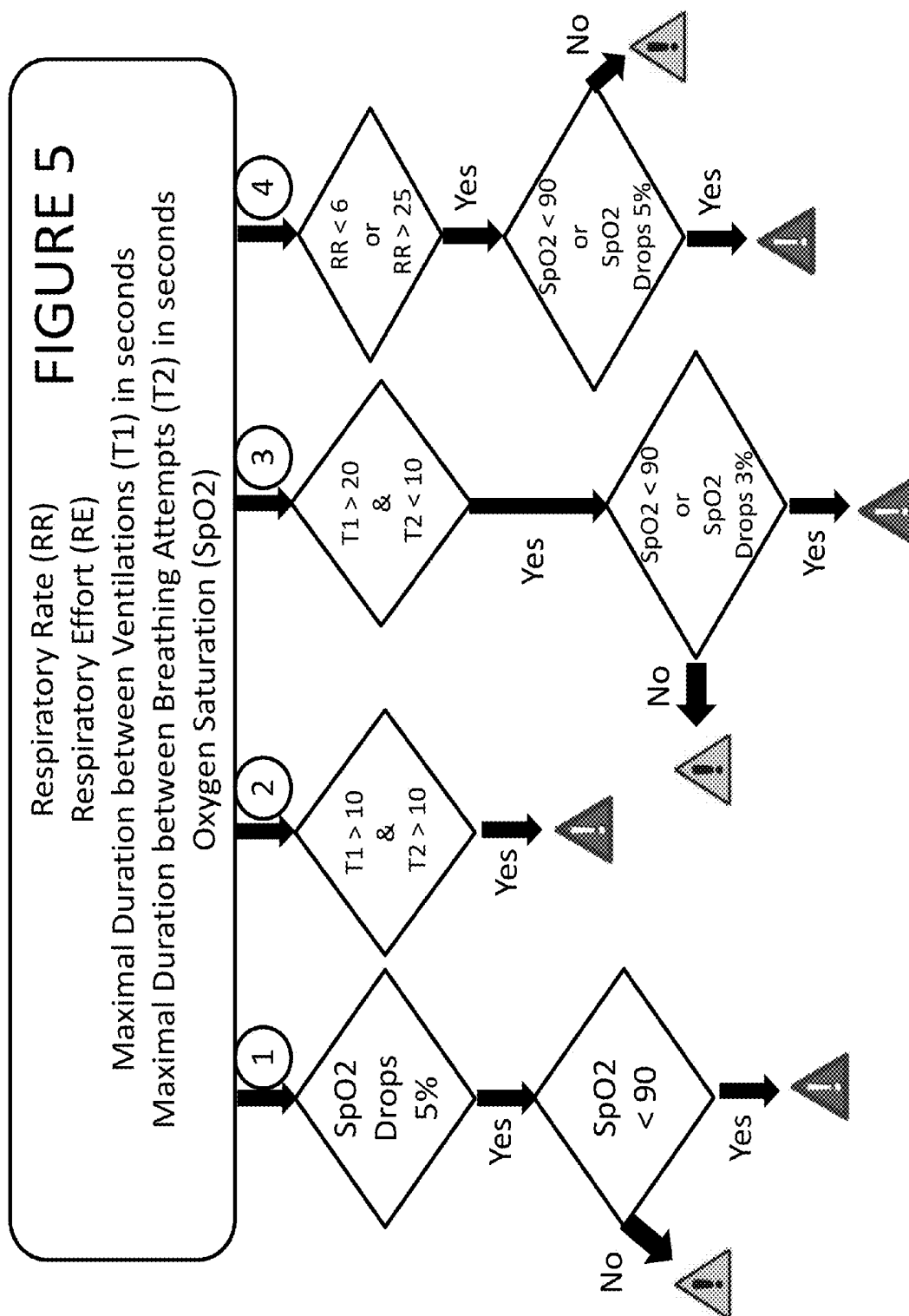
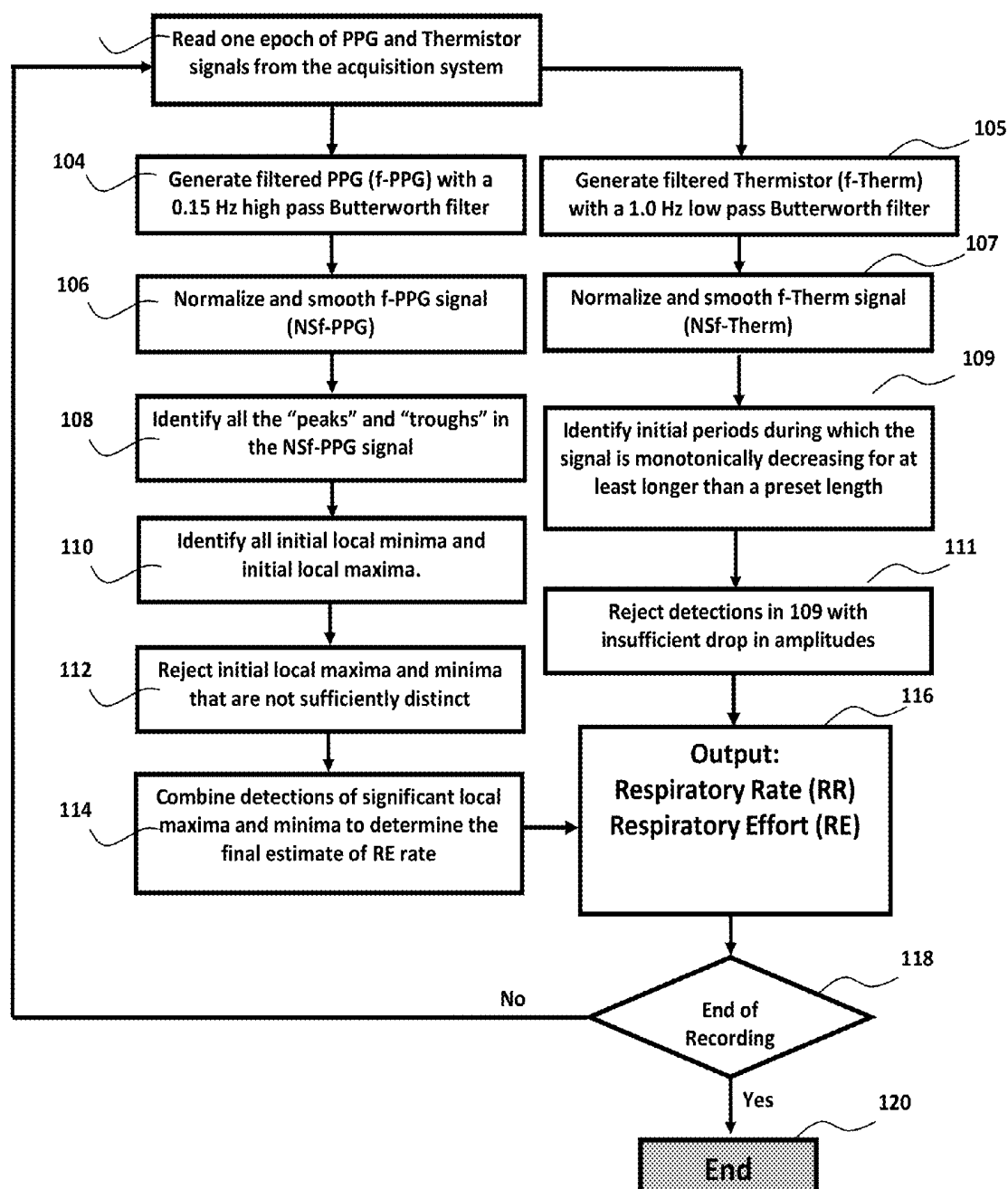
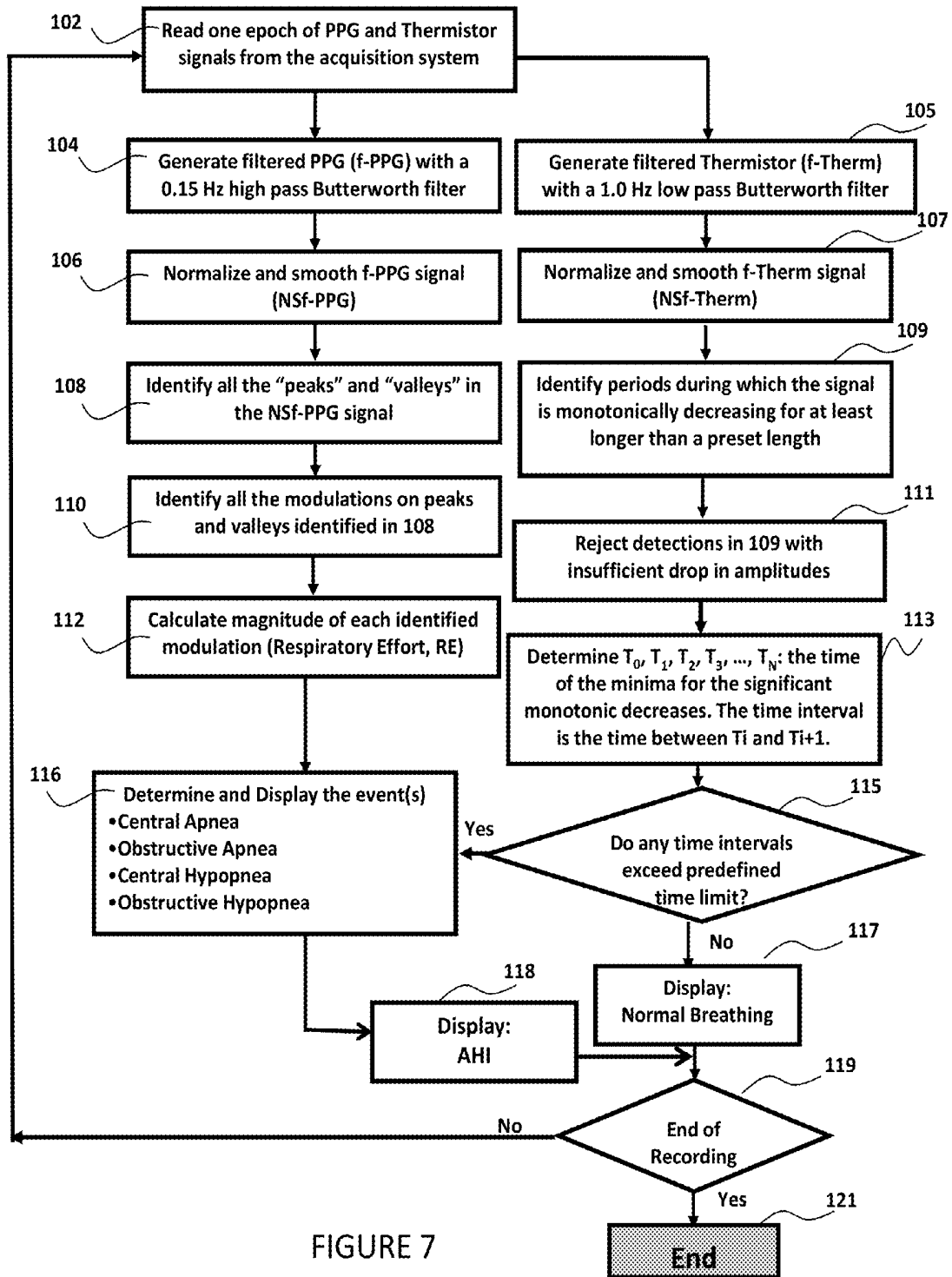


FIGURE 6





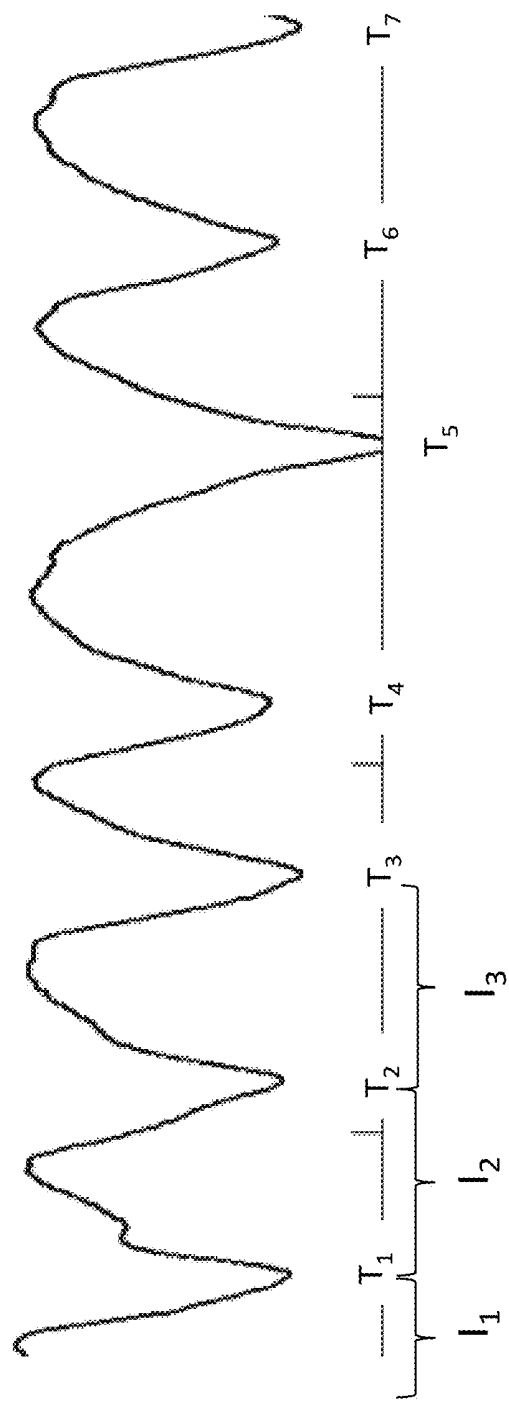


FIGURE 8

FIGURE 9

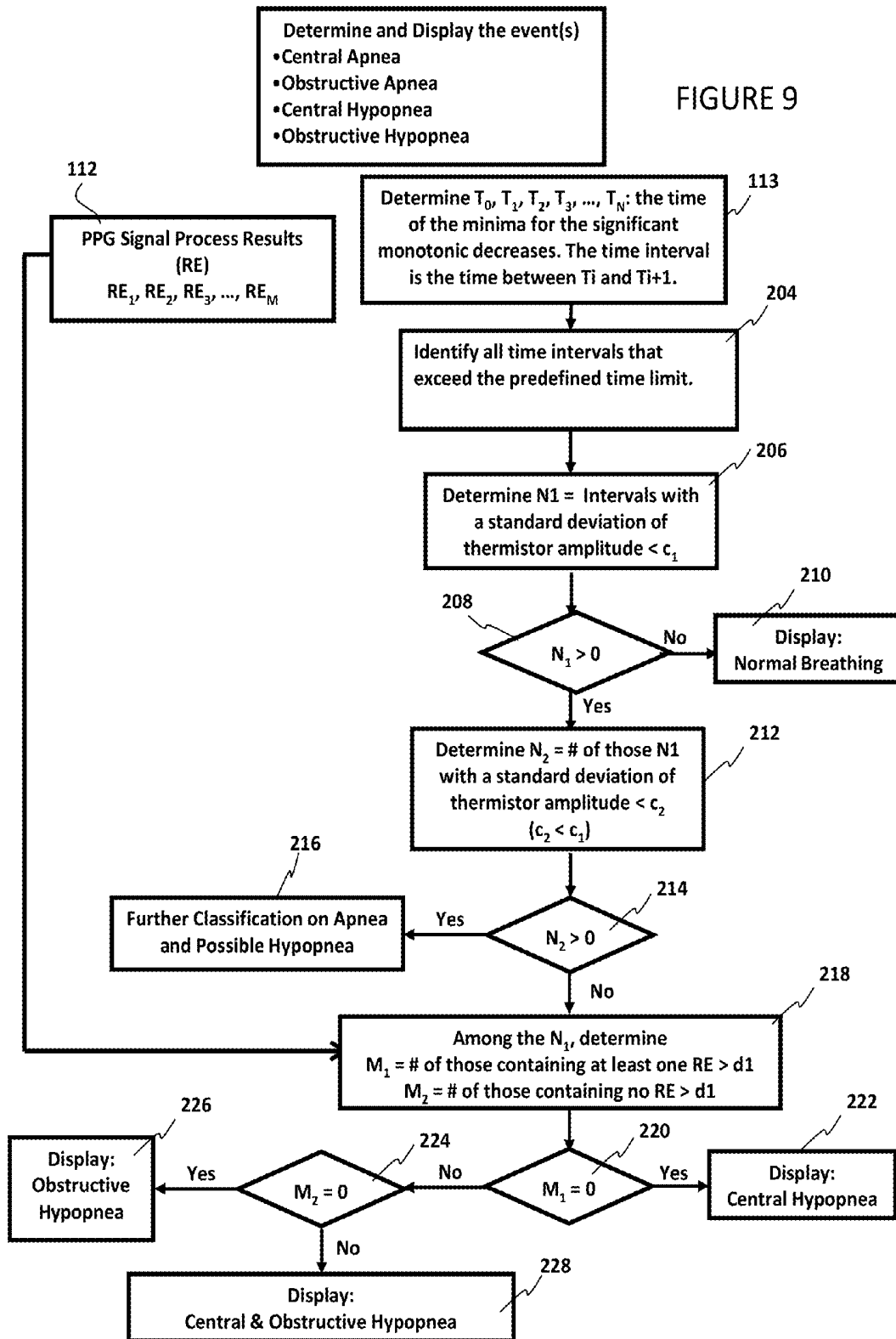
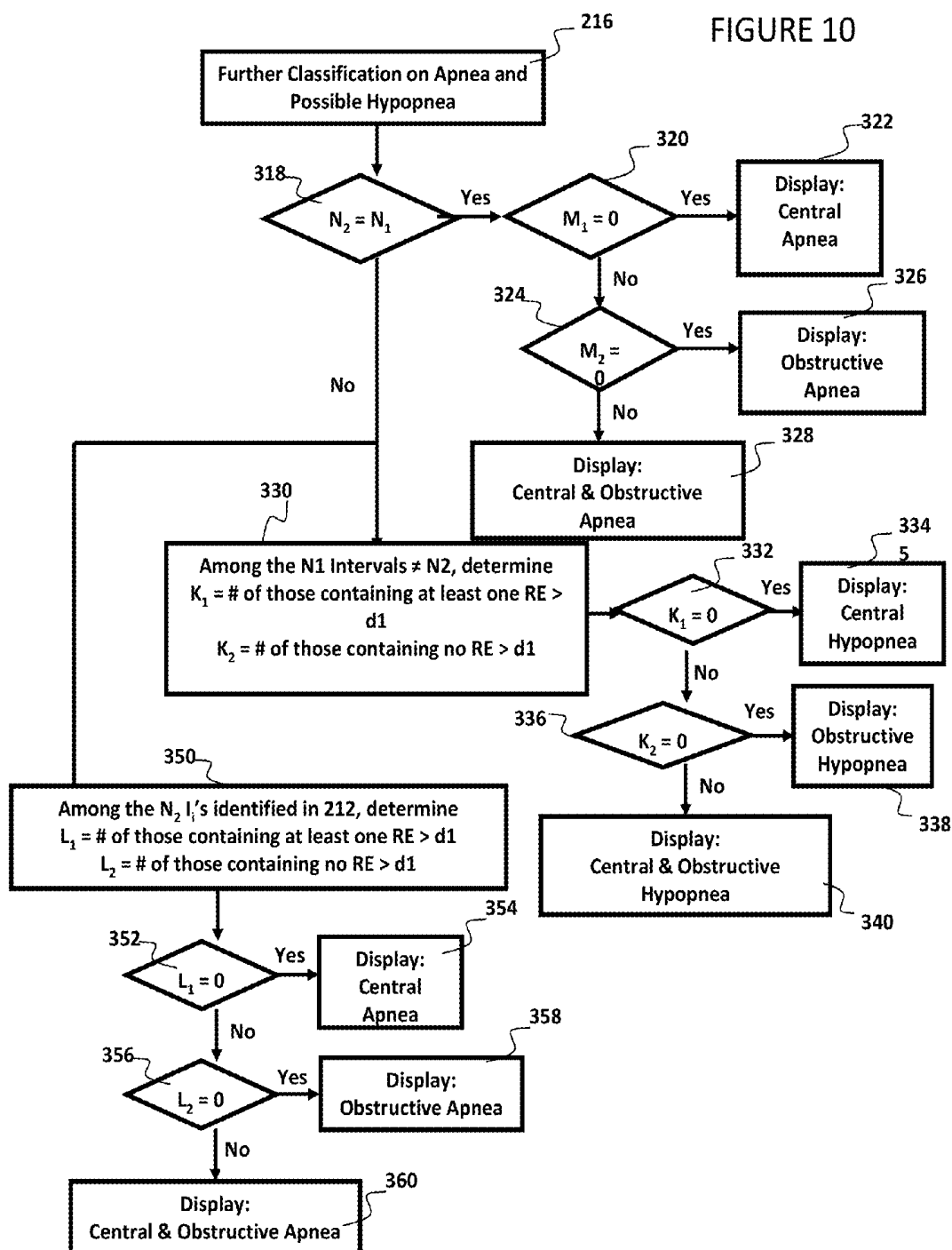


FIGURE 10



METHODS AND DEVICES FOR MONITORING RESPIRATION USING PHOTOPLETHYSMOGRAPHY SENSORS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/202,141, filed Aug. 6, 2015; U.S. Provisional Application No. 62/220,143, filed Sep. 17, 2015; and U.S. Provisional Application No. 62/239,148, filed Oct. 8, 2015, the contents of each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to biological sensors, and in particular, to the use of biological sensors to monitor physiological parameters of individuals. The present invention also relates to methods of processing data from biological sensors.

BACKGROUND OF THE INVENTION

[0003] Photoplethysmography, or “PPG”, is an optical technique for detecting blood volume changes in a tissue. In this technique, one or more emitters are used to direct light at a tissue and one or more detectors are used to detect the light that is transmitted through the tissue (“transmissive PPG”) or reflected by the tissue (“reflectance PPG”). The volume of blood, or perfusion, of the tissue affects the amount of light that is transmitted or reflected. Thus, the PPG signal varies with changes in the perfusion of the tissue.

[0004] The blood volume in a tissue changes with each heartbeat, and so the PPG signal also varies with each heartbeat. Traditionally, this component of the PPG signal is referred to as the “AC component” of the signal, and is also often referred to as the “pulsatile component.” Blood volume is also affected by other physiological processes in the body, including respiration, venous blood volume, sympathetic and parasympathetic tone and certain pathologies. The changes in the PPG signal due to these and other physiological processes, along with changes in the PPG signal due to noise caused by non-physiological processes such as ambient light and bodily movement, have traditionally been referred to collectively as the “DC component.”

[0005] Pulse oximetry is a well-known physiological monitoring tool whereby PPG is used to monitor arterial blood oxygen saturation (SpO_2) in an individual. In typical pulse oximetry, red and IR radiation is transmitted through a tissue of the individual. The amplitude of the AC component of the PPG signal for IR and red wavelengths is sensitive to changes in SpO_2 due to the difference in the light absorbance of oxygenated and deoxygenated hemoglobin at these wavelengths. From their amplitude ratio, using the DC components to normalize their respective signals, the SpO_2 can be estimated. Traditionally, pulse oximetry has been performed at peripheral sites, but in recent years, alternative monitoring sites have been investigated, including at the nose (e.g., septum, nasal alar), ear (e.g., earlobe, concha), and forehead.

[0006] The nose, in particular the nasal alar, has recently been identified as a particularly promising site for PPG. Traditional sites for monitoring PPG, such as fingers and toes, generally provide a relatively small PPG signal, and the quality of this signal may be negatively impacted by sym-

pathetic innervation in these tissue sites. Thus, in some cases, pulse oximetry measurements at peripheral sites may be unavailable or unreliable. Furthermore, due to the small signal size, the DC component signal from traditional peripheral sites may not be of sufficient strength and quality to allow for the DC signal to be used to reliably monitor physiological processes.

[0007] The nasal alar region has been shown by the inventor to provide a very large PPG signal relative to other sites of the body, including the fingers, toes and ears, and a relatively high quality signal due to its lack of sympathetic innervation. The improved PPG signal at the nasal alar site has allowed for a number of physiological parameters, including respiration rate, blood flow, respiratory effort and venous capacitance to be effectively extracted from the DC signal. Examples of patents and applications that describe the use the nasal alar site to obtain PPG signals, as well as a description of parameters and physiological processes that may be extracted from such signals, include U.S. Pat. Nos. 6,909,912, 7,127,278, 7,024,235, 7,785,262, 7,887,502, 8,161,971, 8,679,028 and 8,641,635, the entire contents of each of which are incorporated herein by reference in their entirety.

SUMMARY OF EMBODIMENTS OF THE INVENTION

[0008] Provided according to embodiments of the invention are computer-implemented methods of monitoring respiration in an individual. Such methods may include obtaining a PPG signal stream from a central source site of the individual; identifying peaks and troughs of the PPG signal stream within a predetermined epoch, wherein a time between peaks or a time between troughs corresponds to a heart rate of the individual; determining significant local maxima of peak amplitudes and significant local minima of trough amplitudes within the predetermined epoch, wherein each significant local maxima of peak amplitude corresponds to an onset of the individual's respiratory effort to exhale and each significant local minima of trough amplitude corresponds to an onset of the individual's respiratory effort to inhale; calculating the number of significant local maxima, significant local minima, or both, during the predetermined epoch to determine the number of respiratory efforts in the predetermined epoch; and displaying the number of respiratory efforts in the predetermined epoch on a computer monitor.

[0009] In some embodiments of the invention, methods include determining the number of ventilations of the individual during the predetermined epoch. In some embodiments of the invention, the thermistor data is analyzed by a method comprising identifying significant monotonic decreases in the thermistor signal stream that occur for a time longer than a preset time period. In some cases, identifying significant monotonic decreases in the thermistor signal includes identifying initial monotonic decreases in the thermistor signal stream that occur for a time longer than a preset time period; rejecting the initial periods of a monotonic decrease having an amplitude decrease of less than a preset value; and designating the remaining initial periods of monotonic decrease as significant periods of monotonic decrease. In some cases, the number of ventilations and the number of respiratory efforts during the predetermined epoch are used to determine whether the individual has apnea.

[0010] In some embodiments of the invention, the evaluation to determine whether an apneic or hypopneic event has occurred includes determining a signal variation of the amplitude in each time interval that exceeds the predefined time limit; and if a time interval has a signal variation of greater than or equal to a first predefined value (c1), then the time interval is deemed to not include an apneic or hypopneic event; and if a time interval has a signal variation of less than the first predefined value (c1), then the time interval is deemed to include an apneic or hypopneic event.

[0011] In some embodiments, if a predetermined number of hypopneic and/or apneic events are indicated by the computer, a predetermined action is effected. For example, in some cases, the predetermined action includes at least one of initiate an alarm, rouse the individual, administer or increase oxygen supply to the individual or administer a narcotic reversal agent to the individual.

BRIEF DESCRIPTION OF THE FIGURES

[0012] FIG. 1 is a photoplethysmograph showing peaks and troughs that correspond to the individual's heart beat.

[0013] FIG. 2 is a photoplethysmograph showing peaks and troughs that correspond to the individual's heart beat.

[0014] FIG. 3 is a photoplethysmograph showing peaks and troughs that correspond to the individual's heart beat.

[0015] FIG. 4 is a thermistor signal stream according to an embodiment of the invention.

[0016] FIG. 5 is a flow chart summarizing a respiratory algorithm according to an embodiment of the invention.

[0017] FIG. 6 is a flow chart summarizing a respiratory algorithm according to an embodiment of the invention.

[0018] FIG. 7 is a flow chart summarizing a respiratory algorithm according to an embodiment of the invention.

[0019] FIG. 8 is a thermistor signal stream according to an embodiment of the invention.

[0020] FIG. 9 is a flow chart summarizing a respiratory algorithm according to an embodiment of the invention.

[0021] FIG. 10 is a flow chart summarizing a respiratory algorithm according to an embodiment of the invention.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0022] The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. However, this invention should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.

[0023] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups

thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items.

[0024] It will be understood that when an element is referred to as being "connected" or "coupled" to another element, it can be directly connected or coupled to the other element or intervening elements may be present. In contrast, when an element is referred to as being "directly connected" or "directly coupled" to another element, there are no intervening elements present. Like numbers refer to like elements throughout the specification. It will be understood that, although the terms first, second, etc. may be used herein to describe various elements, these elements should not be limited by these terms. These terms are only used to distinguish one element from another. Thus, a first element discussed below could be termed a second element without departing from the teachings of the present invention.

[0025] Provided according to embodiments of the present invention are computer-implemented methods of monitoring respiration in an individual using a photoplethysmography (PPG) signal secured to a central source site, and, optionally, at least one additional secondary respiration sensor. As used herein, an individual, also referred to as a patient, includes any mammal, including humans of any age. The individual may be monitored in any care setting including, but not limited to, hospitals (e.g., operating room (OR), intensive care unit (ICU), general care floors, or during transport therein), nursing homes, medical offices, medical transport and homes. The individual may be intubated or may be spontaneously breathing.

Detection of Respiratory Efforts Using PPG Monitoring

[0026] In embodiments of the invention described herein, the PPG sensor may be secured to any central source site, and in particular, to a portion of the nose (e.g., the nasal alar or nasal septum). However, in particular embodiments, the PPG sensor is secured to the nasal alar of the individual. The term "secure" means to attach sufficiently to the skin to allow for a suitable PPG signal to be generated. In some cases, the sensor body is configured to secure onto the skin such that no additional support is necessary to allow for a suitable PPG signal to be reliably generated. However, in some cases, the sensor may be secured with the aid of an external support, for example, an additional structural support, a wire or cord, or an adhesive product such as tape. Such supports may be desirable to stabilize the sensor to prevent against signal loss, for example, due to the patient's movement (e.g., shivering), or due to movement (e.g., jostling, pulling, pushing) of the sensor or a cable attached thereto.

[0027] The PPG sensors include one or more components that emit light, and such components will be referred to herein as "emitters." As used herein, the term "light" is used generically to refer to electromagnetic radiation, and so the term includes, for example, visible, infrared and ultraviolet radiation. Any suitable type of emitter may be used, but in some embodiments, the emitter is a light-emitting diode (LED). In particular embodiments, a first emitter emits light at a first wavelength, and a second emitter emits light at a second wavelength. In some cases, a single emitter may emit light at a first wavelength and a second wavelength. One or more photodetectors, also referred to as "detectors", are also included in the PPG sensor. The detector is configured to detect light from an emitter, and this detected light generates

a PPG signal. Any suitable photodetector may be used. However, examples of photodetectors include photodiodes, photoresistors, phototransistors, light to digital converters, and the like.

[0028] The computer-implemented methods described herein include one or more of the steps of: (1) identifying peaks and troughs of a PPG signal stream within a predetermined epoch, wherein the peaks (or troughs) occur at a heart rate of the individual; (2) determining significant local maxima of the amplitudes of the peaks (“peak amplitudes”) and significant local minima of the amplitudes of the troughs (“trough amplitudes”) within the predetermined epoch, wherein each significant local maximum of peak amplitudes corresponds to the onset of the individual’s respiratory effort to exhale and each significant local minimum of trough amplitudes corresponds to the onset of the individual’s respiratory effort to inhale; (3) calculating the number of significant local maxima, the significant local minima, or both, during the predetermined epoch to determine the number of respiratory efforts during the predetermined epoch; and optionally, (4) displaying the number of respiratory efforts in the predetermined epoch on a computer monitor, or using the number of respiratory efforts per epoch for further analysis of the individual’s respiration.

[0029] As used herein, the “PPG signal stream” is the waveform that is generated from the PPG sensor, and the “predetermined epoch” is any interval of time, for example, 10 seconds, 30 seconds, 1 minute, 2 minutes, etc. In some cases, the predetermined epoch is in the range of 10 seconds to 1 minute. This epoch provides a standard time period for counting respiratory efforts (e.g., RE per minute), and in some cases, ventilations, of the individual so that changes in respiration can be monitored over time.

[0030] As used herein, the term “respiratory effort” is meant to refer to an attempt by the individual to take a breath, whether or not ventilation occurs. Respiratory efforts imply that the muscles of respiration are contracting in response to signals from the brainstem. The degree of contraction of the respiratory muscles determines the tidal volume (V_T) when the airway is patent. If airway obstruction occurs, muscle contraction may result in decreased V_T or in the case of complete obstruction, no airway movement despite muscle contraction. Numerous brainstem inputs including the arterial oxygen saturation (P_aO_2), arterial CO_2 (P_aCO_2) and inputs from various receptors in the respiratory muscles determine the degree of contraction of the respiratory muscles. Disease states (CNS and non-CNS), medications (e.g. opioids, benzodiazepines, etc.) and other inputs may alter the “gain” of the brainstem and may decrease or prevent contraction of the respiratory muscles. As the PPG signal may be modulated in response to changes in intrathoracic pressure, including the changes in intrathoracic pressure due to respiratory effort-related muscle contractions, PPG may be used to monitor respiratory effort. The significant local minima of trough amplitudes of the PPG signal correlate to the onset of the individual’s attempt to inhale and the significant local maxima of the peak amplitudes correlate to the onset of the individual’s attempt to exhale.

[0031] The PPG sensor transmits raw PPG signals to a signal processing device, which will be discussed in further detail below. In some cases, the raw PPG signals are “conditioned” or filtered or smoothed before being analyzed to determine respiratory efforts. In general, such conditioning is achieved by band pass filters, which may filter out

undesirably high or low frequency noise in the signal. While in some embodiments, the PPG signal from only one wavelength of light is processed and/or monitored, in other embodiments, PPG signals may be obtained from two or more wavelengths of light (e.g., IR and red wavelengths) and in some cases, comparing the PPG signal (or respiratory efforts per epoch calculated therefrom) at different wavelengths may be useful.

[0032] The peaks and troughs that correspond to the individual’s heart beat are shown, for example, in FIG. 1. The amplitude of the peaks and troughs are monitored over time. As used herein, the amplitude is measured from a center or mean of the waveform. The “local maxima” and “local minima” of the amplitudes of the peaks (“peak amplitudes”) and troughs (“trough amplitudes”), respectively, are identified by a change of direction in the instantaneous rate of change (slope) of the peak and trough amplitudes over time. For example, a local maximum of peak amplitudes occurs when the instantaneous rate of change of peak amplitudes changes from positive to negative, and a local minimum of trough amplitudes occurs when the instantaneous rate of change of trough amplitudes changes from negative to positive. See FIG. 2.

[0033] A local minimum or local maximum may be deemed a significant local maximum or significant local minimum, respectively, at the outset, or the algorithm in the signal processor may determine initial local maxima and initial local minima, and designate additional criteria that must be met before the initial local maxima or minima is deemed a significant local maxima or minima, respectively. For example, the algorithm may reject an initial local maximum if the local maximum deviates in amplitude from at least one preceding peak by less than a preset value. Alternatively, or additionally, the algorithm may reject an initial local maximum if the local maximum deviates in amplitude from at least one peak immediately following it by less than a preset amount. Thus, a local maximum that is very similar in amplitude to the peak(s) immediately before and/or after it may be rejected as not being a significant local maximum because it is not sufficiently distinct (in amplitude) from the peak(s) immediately before and/or after it. The algorithm may also reject an initial local minimum in the same manner. If a local minimum deviates in amplitude from at least one trough immediately preceding it and/or at least one trough immediately following it by less than a preset amount, it may be rejected as not being a significant local minimum. Thus, a local minimum that is very similar in amplitude to the trough(s) immediately before and/or after it may be rejected as not being a significant local minimum because it is not sufficiently distinct in amplitude from the trough(s) immediately before and/or after it.

[0034] The computer/signal processor calculates the number of significant local maxima, the number of significant local minima, or both, during the epoch to determine the number of respiratory efforts during the epoch. Each respiratory effort is a combined inhalation and exhalation, and so the computer can calculate the respiratory efforts from the number of significant local maxima, the number of significant local minima, or both. If both the significant local maxima and significant local minima are used, the values obtained by each may be compared and evaluated to provide further confidence in the determinations. In particular embodiments, the significant local minima are counted to determine the number of respiratory efforts in the predeter-

mined epoch. The respiratory efforts per epoch can then be displayed on a computer monitor or screen to guide the medical care of the individual, or the number of respiratory efforts per epoch may be used for further analysis of the individual's respiration, as described below. The calculation may be performed on a rolling basis so that the number of respiratory efforts per epoch is updated regularly, such as, for example, every 1, 2, 5, 10, 15 or 30 seconds.

[0035] In some embodiments of the invention, the algorithm in the signal processor may have an additional step to detect onset of inhalations and onset of exhalations that were not detected as significant local maxima or significant local minima, respectively, via the methods described above. In some cases, before the number of respiratory efforts during the epoch is calculated, the algorithm evaluates whether there are any missed onset of inhalations and/or any missed onset of exhalations. For example, referring to FIG. 3, in some cases the algorithm analyzes whether there is a missing onset of inhalation (missing local minima) by noting portions of the PPG signal stream where two or more significant local maxima occur without any local minima occurring at a time there between. In this case, the algorithm will count a missed onset of inhalation as having occurred, and therefore if the significant local minima are used to calculate respiratory efforts in the epoch, then this missed onset of inhalation adds an additional respiratory effort to the count. Conversely, in some embodiments, the algorithm may further analyze whether there is a missing onset of exhalation (missing local maxima) by noting portions of the signal stream where two or more significant local minima occur without any local maxima occurring at a time there between (not shown in figures). In this case, the algorithm will count a missed onset of exhalation as having occurred, and thus, if the significant local maxima are used to calculate respiratory efforts in the epoch, then this missed onset of exhalation adds an additional respiratory effort to the count.

[0036] In some embodiments of the invention, missed onset of inhalations or exhalations may alternatively or additionally be determined by other methods. For example, with respect to determining a missed onset of inhalation, in some cases, the algorithm may evaluate the waveform to determine portions of the PPG signal wherein a local maximum occurs between two local minima and the local maximum is separated from each of the two local minima by more than a preset amount of time. If the two local minima are significantly separated from the significant local maximum, then the algorithm counts an additional significant local minimum as occurring there between. Thus, if the number of respiratory efforts determined during the epoch are determined using the significant local minima, then an additional respiratory effort will be added based on the missed onset of inhalation detection.

[0037] With respect to determining a missed onset of exhalation, in some cases, the algorithm may evaluate the waveform to determine portions of the PPG signal wherein a local minimum occurs between two local maxima and the local minimum is separated from the two local maxima by a preset amount of time. If the two local maxima are significantly separated from the significant local minimum, then the algorithm counts an additional significant local maximum as occurring there between. Thus, if the number of respiratory efforts determined during the epoch are deter-

mined using the significant local maxima, then an additional respiratory effort will be added based on the missed onset of exhalation detection.

Detection of Ventilations by Secondary Respiration Detectors

[0038] As used herein, "ventilation" is meant to refer to air movement that results in exchange of CO₂ and oxygen in the individual. A "ventilation" may also be referred to herein as a "breath". Respiratory efforts may result in ventilation, but in some cases, such as when the individual has obstructive apnea, the individual may make respiratory efforts but due to the obstruction, no ventilation occurs.

[0039] In some embodiments of the invention, a secondary respiration sensor at the nose is used to determine actual ventilation by the patient. Secondary respiration sensors may be used to compare with the respiratory information obtained from the PPG sensor(s). Such sensors include, but are not limited to, nasal air flow sensors, nasal pressure sensors, capnometers, thermistors, acoustic sensors, differential pressure transducers, and the like. In some cases, both the PPG sensor(s) and the secondary respiration sensor(s) are situated at the nose, and in some cases, a single device or system (e.g., an array) may include both the PPG sensor(s) and the secondary respiration sensor(s).

[0040] In particular embodiments, the secondary respiration sensor detects respiratory airflow or temperature changes at the nostril, such as with a thermistor. For example, during inhalation, a thermistor placed at the nostril detects a relative decrease in temperature compared to exhalation since, in most situations, body temperature, and therefore exhaled breath temperature, is higher than ambient temperature. Thus, detection of changes in temperature may be a suitable means to determine respiratory air flow and therefore, if ventilation occurred. Air flow from one or both nostrils may be monitored and compared with the PPG information.

[0041] FIG. 4 shows a thermistor signal stream. The arrows point to monotonic decreases in slope of the signal due to a decrease in temperature detected during inhalation. In some embodiments of the invention, the computer-implemented methods described above may further include analyzing a thermistor signal stream obtained from nasal airflow of the individual during the predetermined epoch. Thus, the PPG signal stream and thermistor signal stream are synchronized chronologically and so each respiratory effort via PPG can be compared with thermistor data to see if the respiratory effort resulted in ventilation.

[0042] In some embodiments of the invention, the algorithm analyzes the thermistor signal stream to identify when significant signal decreases (e.g., monotonic decreases, such as those shown in FIG. 4) occur for longer than a preset time period. The monotonic decreases longer than the preset time period are deemed to be inhalations that result in ventilation. Any suitable preset time period may be used. For example, in some cases, the time period is a range of 0.2 to 1 s, or in some cases 0.5 s. As with the PPG signal stream, in some cases, the thermistor signal stream is band pass filtered, smoothed, or both, prior to identifying the significant periods of (monotonic) decrease.

[0043] In some cases, all monotonic signal decreases longer than the preset time period are deemed significant monotonic decreases. However, in some cases, the algorithm identifies initial monotonic decreases longer than a preset

time and then rejects those monotonic decreases that have an amplitude decrease of less than a preset value, which in some embodiments is less than one standard deviation of the waveform for the epoch. The remaining initial monotonic decreases longer are then designated as significant monotonic decreases, and each significant monotonic decrease during the predetermined epoch is counted to determine the number of ventilations during the predetermined epoch. In other embodiments of the invention, in a first step, the algorithm first identifies monotonic decreases in amplitude that are greater than a preset value to arrive at the initial monotonic decreases. Then, the algorithm rejects initial monotonic decreases that decrease for less than a preset time period, and the remaining initial monotonic decreases are deemed significant monotonic decreases for the purposes of the methods described herein.

Monitoring Respiration Using Respiratory Efforts & Ventilations

[0044] The PPG signal stream is thus used to determine the number of respiratory efforts during the predetermined epoch and the thermistor signal stream is used to determine the number of ventilations during the predetermined epoch. The two numbers can be compared to assess the quality of the individual's breathing. For example, if the number of respiratory efforts exceeds the number of ventilations by a certain percentage or by a certain number, the individual may be experiencing periods of obstructive apnea. In such cases, a "predetermined action" may be effected. For example, one of the following actions may be effected: an alarm may be initiated or medical personnel notified in some manner, the individual may be awoken, oxygen may be administered to the individual (via medical personnel or via a closed loop device) or oxygen flow may be increased, and narcotic reversal agents may be administered (automatically or by medical personnel) to the individual.

[0045] In some cases, the number of respiratory efforts and/or ventilations in the epoch may be compared with a preset value (such as, for example, 4 or 6 breaths per minute) and if either or both fall below the preset value, the individual may be considered to be in respiratory depression, and a predetermined action may be effected. In some cases, if either or both of the number of respiratory efforts and/or ventilations in the epoch are below the preset value, the algorithm may further analyze the blood oxygen saturation (SpO₂) of the individual, and determine whether to effect a predetermined reaction based on the number of respiratory efforts and/or ventilations and the SpO₂ of the individual. Furthermore, in some cases, the magnitude or rate of decrease of either the number of respiratory efforts and/or ventilations in the individual, the magnitude or rate of change in the SpO₂, or both, may be used to determine whether to effect a predetermined reaction. For example, the algorithm may have as a condition that if the number of respiratory efforts and/or ventilations per epoch decreases by greater than 20%, the predetermined action is effected. In some cases, the algorithm may have as a condition that if the number of respiratory efforts and/or ventilations per epoch decreases by greater than 20%, and the SpO₂ decreases below a predefined limit, the predetermined action is effected.

[0046] In addition or alternative to the methods described above, the signal processing device may also use other algorithms for respiratory monitoring as shown in FIG. 5.

For example, pathway (1) shows a first algorithm based only on SpO₂. If the SpO₂ drops by a predefined amount or percentage ($\pm 5\%$) and the SpO₂ is below a predefined value (90%), then a predetermined reaction is effected (as identified by the red triangle). If the SpO₂ drops by at least the predefined amount or percentage ($\pm 5\%$) but the SpO₂ is still equal to or greater than the predefined value (90%), then a "warning" (visual, audible and/or only noted by the signal processing device) may be generated, but no alarm is sounded. The warning may cause no additional actions, or it may initiate a more rigorous level of analysis by the signal processing device. In FIG. 5, the warning is identified as the yellow triangle.

[0047] In the algorithm in pathway (2), the signal processing device detects the measurement between respiratory efforts and/or between ventilations. For T₁, the maximal duration between ventilations during the epoch is determined by the time between significant monotonic decreases. The time of each monotonic decrease may be determined using any consistent point, such as the time at the start of the monotonic decreases, the time at the mean of the monotonic decrease, and the like. For T₂, the maximal duration between respiratory efforts during the epoch is determined by the time between significant local maxima, significant local minima, or both. In the example in FIG. 5, if T₁ and T₂ are both greater than a predefined time period (and T₁ and T₂ can have different predefined time periods) in this case, 10 seconds, a predetermined action is effected.

[0048] In the algorithm illustrated in pathway (3) of FIG. 5, the signal processing device uses T₁ and T₂, as well as the SpO₂. If T₁ is greater than a predefined time (20 s) and T₁ is less than a predefined time (10 s), and the SpO₂ is less than a certain predefined value (90) or drops by at least a certain amount or percent (30%), then a predetermined action is effected. However, if T₁ is greater than the predefined time (20 s) and T₁ is less than the predefined time (10 s) but the SpO₂ is equal to or greater than the predefined value (90) and does not drop by at least the certain amount or percentage (3%), then only a warning results.

[0049] In the algorithm illustrated in pathway (4) of FIG. 5, the signal processing device uses the number or respiratory efforts (RE) and the number of ventilations (RR) per epoch, as well as using the SpO₂. In this example, if the RR is less than a predefined value (6) and the RE is greater than a predefined value (25), and the SpO₂ is greater than a predefined value (90), or the SpO₂ drops by at least a certain amount or percentage (5%), then a predetermined reaction is effected. However, if the RR is less than a predefined value (6) and the RE is greater than a predefined value (25), but the SpO₂ is greater than or equal to its predefined value, and the SpO₂ has not dropped by at least the certain percentage or amount, then only a warning is indicated.

Signal Processing

[0050] The PPG signals and secondary respiration signals are analyzed and algorithms are performed in any suitable fashion, but are typically monitored with a signal processing device, such as a general-purpose microprocessor, a digital signal processor (DSP) or application specific integrated circuit (ASIC). The singular term "signal processing device" may include two or more individual signal processing devices. Such signal processing devices may be adapted to execute software, which may include an operating system and one or more applications, as part of performing the

functions described herein. In electronic communication with the signal processing device may be a computer memory, such as a read-only memory (ROM), random access memory (RAM), and the like. Any suitable computer-readable media may be used in the system for data storage. Computer-readable media are capable of storing information that can be interpreted by microprocessor. This information may be data or may take the form of computer-executable instructions, such as software applications, that cause the signal processing device to perform certain functions and/or computer-implemented methods. Depending on the embodiment, such computer-readable media may include computer storage media and communication media.

[0051] Computer storage media may include volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage of information such as computer-readable instructions, data structures, program modules or other data. Computer storage media may include, but is not limited to, RAM, ROM, EPROM, EEPROM, flash memory or other solid state memory technology, CD-ROM, DVD, or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by components of the system.

[0052] Systems and devices for effecting the methods described herein are also disclosed herein. Computers or other signal processing devices, as well as software configured to perform such methods are included according to some embodiments of the invention.

Example 1

[0053] Referring to FIG. 6, in Block 102, the algorithm acquires one epoch of PPG and thermistor raw signals. In Block 104, to reduce the effects from the slow background shift unrelated to the respiratory effort (RE), the raw PPG signal is first high-pass filtered (f-PPG). As a specific example, the signal may be high-pass filtered at 0.15 Hz. In Block 106, to reduce the effects from the PPG amplitudes on detection of RE, the f-PPG signal is normalized (Nf-PPG). Furthermore, to reduce the high frequency noise (e.g., electrical noise), moving average (smoothing) is applied to the Nf-PPG signal (NSf-PPG). In Block 108, all the “peaks” and “troughs” in the NSf-PPG signal are identified (see FIG. 1).

[0054] Referring to FIG. 2, this is accomplished by searching all the local minimums and local maximums in the signal within the detection epoch. In Block 110, one of the most noticeable characteristics with respect to the PPG signal modulations due to RE is the instantaneous rate of change (i.e., the derivative) of the values of its peaks and troughs, respectively. Referring to FIG. 2, therefore, in this step, the algorithm searches for initial local maxima and initial local minima. Referring to Block 112, although (in Block 104) the algorithm has attempted to filter out the slow background activities in the PPG signal, there will still be peak or trough sequences that fit the patterns described in Block 110 due to the slow background activities. However, in almost all cases, the non-RE-related modulations have much smaller variation of values within the sequence when compared to those due to RE. Therefore, in Block 112, the algorithm examines initial local maxima and/or minima detected in Block 110 and rejects those with a standard deviation (within the sequence) smaller than a preset threshold to determine

significant local maxima and/or significant local minima. Referring to Block 114, typically there is one modulation on peaks (caused by the onset of exhalation) after a modulation on trough (caused by the onset of inhalation). However, respiratory efforts do not always provide clear PPG modulations on both peaks and troughs. Sometimes a RE only causes modulation on peaks and sometimes only on troughs. Hence, to enhance the sensitivity of the detection, the algorithm checks for possible missed onset of inhalations and onset of exhalations based on the variability and the occurrences of the detections from both peaks and troughs. For instance, referring to FIG. 3, when there are two modulations on peaks between two modulations on troughs, the algorithm checks the time intervals between these modulations and determines if there is a missed detection of a RE.

[0055] Referring to Block 105, to reduce the effects from the high frequency noise, the raw thermistor signal is first low-pass filtered, for example, at 1.0 Hz (f-Therm). In Block 107, to reduce the effects from the thermistor signal amplitudes in detection of respiratory rate (RR), the f-Therm signal is normalized (Nf-Therm). Moving average (smoothing) is also applied to the Nf-Therm signal (NSf-Therm) to further reduce the high frequency noise. In Block 109, since during inspiration, the drop of the temperature results in the thermistor signal amplitude decrease, the algorithm searches for periods of NSf-Therm signal exhibiting monotonically decrease for at least longer than preset time length (see FIG. 4). In Block 111, however, some monotonically decreasing periods (initial monotonic decreases) detected in Block 109 may not have sufficiently large decrease in amplitudes to be considered an inspiration. Therefore, the algorithm rejects the periods detected in Block 109 that have amplitude drop less than a preset amount to determine significant monotonic decreases in amplitude. In Block 116, after processing the PPG and thermistor signals for the given detection epoch, the algorithm generates an output box that displays RR and RE. In Block 118, after the detection process is finished for the current epoch, the system checks if the recording is ended, as depicted by Block 118. If the recording is finished, the system will be terminated, as illustrated by Block 120. If not, the system goes back to Block 102 and reads and processes the next epoch of PPG and thermistor signals.

Example 2

[0056] Also provided herein are algorithms that may be used in devices, systems and methods for the detection and classification of apneic and hypopneic, as shown in FIGS. 7-10, with further description below.

[0057] Referring to FIG. 7, in Block 102, the algorithm acquires one predetermined epoch of PPG and thermistor raw signals. In Block 104, to reduce the effects from the slow background shift unrelated to the respiratory effort (RE), the raw PPG signal is first high-pass filtered (f-PPG). As a specific example, the signal may be high-pass filtered at 0.15 Hz. In Block 106, to reduce the effects from the PPG amplitudes on detection of RE, the f-PPG signal is normalized (Nf-PPG). Furthermore, to reduce the high frequency noise (e.g., electrical noise), moving average (smoothing) is applied to the Nf-PPG signal (NSf-PPG). In Block 108, all the “peaks” and “troughs” in the NSf-PPG signal are identified (see FIG. 1).

[0058] Referring to FIG. 1, this is accomplished by searching all the local minimums and local maximums in the signal within the predetermined epoch. In Block 110, one of the

most noticeable characteristics with respect to the PPG signal modulations due to RE is the instantaneous rate of change (i.e., the derivative) of the values of its peaks and troughs, respectively. Referring to FIG. 2, therefore, in this step, the algorithm searches for initial local maxima and initial local minima. Referring to Block 112, the algorithm then quantifies the magnitude of the PPG modulations resulting in local maxima and/or minima to estimate the magnitude of the respiratory effort. For example, the difference between the amplitude of the local maxima and the peaks immediately preceding it (e.g., the 1, 2, 3 or 4 peaks preceding it) and/or the peaks immediately following it (e.g., the 1, 2, 3 or 4 peaks following it) may provide a measure of the modulation in the signal, and therefore the magnitude of the signal. Conversely, the difference between the amplitude of the local minima and the valleys immediately preceding it (e.g., the 1, 2, 3 or 4 peaks preceding it) and/or the peaks immediately following it (e.g., the 1, 2, 3 or 4 peaks following it) may also provide a measure of the modulation in the signal, and therefore the magnitude of the signal.

[0059] Referring to Block 105, to reduce the effects from the high frequency noise, the raw thermistor signal is first low-pass filtered, for example, at 1.0 Hz (f-Therm). In Block 107, to reduce the effects from the thermistor signal amplitudes in detection of respiratory rate (RR), the f-Therm signal is normalized (Nf-Therm). Moving average (smoothing) is also applied to the Nf-Therm signal (NSf-Therm) to further reduce the high frequency noise. In Block 109, since during inspiration, the drop of the temperature results in the thermistor signal amplitude decrease, the algorithm searches for periods of NSf-Therm signal exhibiting monotonically decrease for at least longer than preset time length (see FIG. 4). In Block 111, however, some monotonically decreasing periods (initial monotonic decreases) detected in Block 109 may not have sufficiently large decrease in amplitudes to be considered an inspiration. Therefore, the algorithm rejects the periods detected in Block 109 that have amplitude drop less than a preset amount to determine significant monotonic decreases in amplitude.

[0060] Referring to FIG. 8, the algorithm next records the time interval between significant monotonically decreasing periods in the predetermined epoch. For example, in some cases, the algorithm measures the time difference between successive minima (whereby each minima is associated with a significant period of monotonic decrease), as shown in FIG. 8. In this figure, the time between the start of the predetermined epoch and T_1 is the first time interval I_1 , the time between T_1 and T_2 is the second time interval (I_2), etc. T_1, T_2, T_3 , etc. are the successive minima of the significant monotonic decreases in the thermistor signal. The time between the last significant monotonic decrease in the predetermined epoch (T_7 in FIG. 8) and the end of the predetermined epoch is the last time interval.

[0061] Referring back to FIG. 7, in Block 115 the time intervals are evaluated to determine whether they exceed a predefined time limit. In a particular example, the predefined time limit is in a range between 5 and 15 seconds, in some cases, between 7 and 12 seconds and in some cases, the predefined time limit is 8, 9, 10, 11 or 12 seconds. In this particular example, the predefined time limit is 10 seconds. In doing this, the algorithm is determining whether respirations, as determined by significant monotonic decreases, are sufficiently far apart to suggest that an apneic or hypopneic

event has occurred therebetween. Referring to Block 117, if no time intervals in the predetermined epoch exceed the predefined time limit, normal breathing is determined to have occurred. In some cases, a caregiver may be alerted to the fact that normal breathing is occurring (e.g., as shown on the computer monitor or with audible sounds) and in some cases, a determination of normal breathing may not be communicated. If normal breathing is determined to have occurred during the predetermined epoch, the algorithm checks whether the recording has ended, as shown in Block 119. If the recording has ended, the system will be terminated, as shown in Block 121. If recording has not ended, the algorithm proceeds again to Block 102 and reads and processes the next predetermined epoch of PPG and thermistor signals.

[0062] If in Block 115, any time intervals exceed the predefined time limit, such time intervals are further evaluated in Block 116 to both determine whether an abnormal breathing event has occurred and to classify the event as a central apnea, obstructive apnea, central hypopnea or obstructive hypopnea. The details of this analysis are shown in FIG. 9. FIG. 9 again shows Block 113 whereby the time intervals between significant monotonic decreases in the thermistor signal are measured. In Block 204, the time intervals that exceed a predefined time limit are identified. Next, in Block 206, the algorithm determines N_1 , the number of time intervals (I_{N1}) wherein the standard deviation of the amplitude of the thermistor signal is less than a predefined value, c_1 . In some cases, the predefined value may be based on the standard deviation of the thermistor signal for a time period prior to the time interval. For example, the predefined value may be 50% of the standard deviation of the thermistor signal for the 30 seconds prior to the time interval. While in this example, the standard deviation is used as a measure of the signal variation, other measures of signal variation (e.g., range, variance, etc.) may be used.

[0063] Referring to Block 208, if none of the time intervals that exceed the predefined time limit have a standard deviation in amplitude less than the predefined value, c_1 , N_1 is 0, and normal breathing is deemed to have occurred, as shown in Block 210. If at least one of the time intervals that exceeds the predefined time limit has a standard deviation in amplitude less than the predefined value, c_1 , then, as shown in Block 212, the algorithm will further determine if the standard deviation of the amplitude of the thermistor signal in each of such N_1 intervals is also less than c_2 , where $c_2 < c_1$. If so, the number of such time intervals is identified as N_2 and those intervals are defined as I_{N2} . In some cases, the predefined value c_2 may be based on the standard deviation of the thermistor signal for a time period prior to the time interval. For example, the predefined value c_2 may be 30% of the standard deviation of the thermistor signal for the 30 seconds prior to the time interval. While in this example, the standard deviation is used as a measure of the signal variation, other measures of signal variation (e.g., range, variance, etc.) may be used.

[0064] Analyzing the time intervals for those having a standard deviation of less than the first predefined value c_1 is meant to identify time intervals in which the signal does not vary greatly, so that while there may be small peaks and/or valleys, they are minor, and only a small amount of airflow is being detected by the thermistor during these time intervals. Analyzing the time intervals for those having a standard deviation of less than predefined value c_2 is meant

to identify time intervals having even smaller peaks and/or valleys, so that they might be considered close to flat signals, and thus, essentially no nasal airflow is detected by the thermistor during these time intervals. Therefore, if a particular time interval has a standard deviation in amplitude of less than c_1 but greater than c_2 (the time interval is one of the N_1 intervals but not among those N_2), the algorithm determines that the time interval includes a hypopneic event. When a particular time interval has a standard deviation in amplitude of less than both c_1 and c_2 (the time interval belongs to both of those N_1 and N_2 intervals), the algorithm determines that the time intervals includes an apneic event.

[0065] Thus, referring to Block 214, the algorithm may determine if any of the N_2 intervals are present in the predetermined epoch. If so, further analysis to determine the type of apnea (and possible hypopnea) may be performed, as shown in Block 216, which will be discussed further with reference to FIG. 10. If in Block 214, N_2 is determined to be zero, the algorithm proceeds to further analyze the N_1 time intervals by comparing the thermistor data with the corresponding PPG data (Block 218) to determine the type of hypopnea that has occurred.

[0066] As shown in Block 218, the algorithm looks at each of the N_1 intervals (that is not among N_2 , which further defined as I_{N1}^*) and identifies the corresponding portion of the PPG signal. If during any of the I_{N1}^* time intervals, the magnitude of the respiratory effort (as determined by the magnitude of the modulation of the significant local maxima or minima) is greater than a predefined value d_1 , then the algorithm designates this I_{N1}^* as an I_{M1} , which denotes that an obstructive event has occurred. If any I_{N1}^* time intervals in the predetermined epoch have a respiratory effort of less than predefined value d_1 , then these time intervals are designated as I_{M2} . Thus, for any given predetermined epoch, if there are no I_{M1} present, (see Block 220), then central hypopnea (Block 222) is deemed to have occurred. If there is at least one I_{M1} present, the algorithm evaluates if any I_{M2} are also present (Block 224). If I_{M2} are present along with I_{M1} in the predetermined epoch, then central and obstructive hypopnea are deemed to have both occurred (Block 228). If only I_{M1} time intervals are present (no I_{M2} present), obstructive hypopnea is deemed to have occurred (Block 226).

[0067] As discussed above, if in Block 214 of FIG. 9, any I_{N2} are present, apneic, and possibly also hypopneic, events are deemed to have occurred. To determine the types of apneic (and possibly hypopneic) events, the algorithm then follows the analysis summarized in FIG. 10. Referring to Block 318, if every I_{N1} is also an I_{N2} , then every time interval in the predetermined epoch that exceeds the predefined time limit has an extremely small variation in amplitude. Thus, only apnea is deemed to have occurred, and the PPG signal will then be compared with the thermistor signal to determine the type of apnea. If during a I_{N2} time interval, the magnitude of the respiratory effort (as determined by the magnitude of the modulation of the significant local maxima or minima) is greater than predefined value d_1 , the algorithm designates this I_{N2} as an I_{M1} , which denotes that an obstructive event has occurred. If any I_{N2} time intervals in the predetermined epoch have a respiratory effort of less than predefined value d_1 , then these time intervals are designated as I_{M2} . Thus, for any given predetermined epoch, if there are no I_{M1} present, (see Block 320), then central apnea (Block 322) is deemed to have occurred. If there is at least one I_{M1} present, the algorithm evaluates if

any I_{M2} are also present (Block 324). If I_{M2} are present along with I_{M1} in the predetermined epoch, then central and obstructive apnea are deemed to have both occurred (Block 328). If only I_{M1} time intervals are present (no I_{M2} present), obstructive apnea is deemed to have occurred (Block 326).

[0068] Referring back to Block 318, in the event that not every I_{N1} is also an I_{N2} , then the predetermined epoch is deemed to include both apneic and hypopneic events. The apneic and hypopneic events are evaluated separately. The time intervals in the predetermined epoch wherein I_{N1} is also I_{N2} are deemed to indicate apnea, and the analysis follows a pathway similar to that in Blocks 320-326. Referring to Block 350, if during a I_{N2} time interval, the magnitude of the respiratory effort (as determined by the magnitude of the modulation of the significant local maxima or minima) is greater than predefined value d_1 , the algorithm designates this I_{N2} as an I_{L1} , which denotes that an obstructive event has occurred. If any I_{N2} time intervals in the predetermined epoch have a respiratory effort of less than predefined value d_1 , then these time intervals are designated as I_{L2} . Thus, for any given predetermined epoch, if there are no I_{L1} present, (see Block 352), then central apnea (Block 354) is deemed to have occurred. If there is at least one I_{L1} present, the algorithm evaluates if any I_{L2} are also present (Block 356). If I_{L2} are present along with I_{L1} in the predetermined epoch, then central and obstructive apnea are deemed to have both occurred (Block 360). If only I_{L1} time intervals are present (no I_{L2} present), obstructive apnea is deemed to have occurred (Block 358).

[0069] The time intervals in the predetermined epoch wherein I_{N1} is not I_{N2} are deemed to indicate hypopnea, and the analysis follows a pathway similar to that in Blocks 320-326. Referring to Block 330, if during a I_{N1} time interval (that is not also I_{N2}), the magnitude of the respiratory effort (as determined by the magnitude of the modulation of the significant local maxima or minima) is greater than predefined value d_1 , the algorithm designates this I_{N1} as an I_{K1} , which denotes that an obstructive event has occurred. If any I_{N1} time intervals in the predetermined epoch have a respiratory effort of less than predefined value d_1 , then these time intervals are designated as I_{K2} . Thus, for any given predetermined epoch, if there are no I_{K1} present, (see Block 332), then central hypopnea (Block 334) is deemed to have occurred. If there is at least one I_{K1} present, the algorithm evaluates if any I_{K2} are also present (Block 336). If I_{K2} are present along with I_{K1} in the predetermined epoch, then central and obstructive hypopnea are deemed to have both occurred (Block 340). If only I_{K1} time intervals are present (no I_{K2} present), obstructive hypopnea is deemed to have occurred (Block 338).

[0070] Referring to FIG. 7, once the algorithm completes the identification and classification analyses in Block 116, the algorithm calculates an Apnea-Hypopnea Index (AHI), as depicted in Block 118. The AHI can be calculated as the total number of Apnea/Hypopnea events from the beginning of the study, the rate of the event occurrences per time period (e.g., hour), or both. The AHI may be displayed, for example, on a computer monitor to alert a caregiver. In some embodiments, if a certain number of apneic and/or hypopneic events occur, or if the AHI exceeds a predefined value, a predetermined reaction may be effected. For example, one or more of the following predetermined reactions may be effected: an alarm may be initiated, the individual may be

roused, the administration or increase in oxygen supply may be initiated, and a narcotic reversal agent may be administered.

[0071] In the specification, there have been disclosed embodiments of the invention and, although specific terms are employed, they are used in a generic and descriptive sense only and not for purposes of limitation, the scope of the invention being set forth in the following claims.

We claim:

1. A computer-implemented method of monitoring respiration in an individual comprising

obtaining a PPG signal stream from a central source site of the individual;

identifying peaks and troughs of the PPG signal stream within a predetermined epoch, wherein a time between peaks or a time between troughs corresponds to a heart rate of the individual;

determining significant local maxima of peak amplitudes and significant local minima of trough amplitudes within the predetermined epoch, wherein each significant local maxima of peak amplitude corresponds to an onset of the individual's respiratory effort to exhale and each significant local minima of trough amplitude corresponds to an onset of the individual's respiratory effort to inhale;

calculating the number of significant local maxima, significant local minima, or both, during the predetermined epoch to determine the number of respiratory efforts in the predetermined epoch;

displaying the number of respiratory efforts in the predetermined epoch on a computer monitor.

2. The computer-implemented method of claim 1, wherein the PPG signal stream is band pass filtered, smoothed, or both, prior to identifying the peaks and troughs.

3. The computer-implemented method of claim 1, wherein determining significant local maxima of peak amplitudes comprises

determining an amplitude of each peak in the PPG signal stream during the predetermined epoch;

determining an increase or decrease in successive peaks in the PPG signal stream to identify initial local maxima;

rejecting initial local maxima that deviate in amplitude from at least one immediately preceding and/or immediately following peak by less than a preset threshold; and

designating remaining initial local maxima as significant local maxima.

4. The computer-implemented method of claim 1, wherein determining significant local minima of trough amplitudes comprises

determining an amplitude of each trough in the PPG signal stream during the predetermined epoch;

determining an increase or decrease in successive troughs in the PPG signal stream to identify initial local minima;

rejecting initial local minima that deviate from at least one immediately preceding and/or immediately following trough by less than a preset threshold; and

designating remaining initial local minima as significant local minima.

5. The computer-implemented method of monitoring respiration of claim 1, wherein determining the number of

respiratory efforts in the predetermined epoch further comprises counting missed onset of inhalations, missed onset of exhalations, or both;

wherein a missed onset of exhalation is determined to have occurred when (a) two or more significant local minima occur without a significant local maxima occurring at a time there between, or (b) a local maximum occurs between two local minima and the local maximum is separated from each local minimum by more than a preset amount of time, and

wherein a missed onset of inhalation detection is determined to have occurred when (a) two or more significant local maxima occur without a significant local minima occurring at a time there between, or (b) a local minimum occurs between two local maxima and the local minimum is separated from each local maxima by more than a preset amount of time.

6. The computer-implemented method of monitoring respiration of claim 1, further comprising determining the number of ventilations of the individual during the predetermined epoch.

7. The computer-implemented method of claim 6, wherein the number of ventilations is determined by analyzing a thermistor signal stream obtained from nasal airflow of the individual during the predetermined epoch.

8. The computer-implemented method of claim 7, wherein the thermistor data is analyzed by a method comprising identifying significant monotonic decreases in the thermistor signal stream that occur for a time longer than a preset time period.

9. The computer-implemented method of claim 8, wherein the thermistor signal stream is band pass filtered, smoothed, or both, prior to identifying the significant periods of monotonic decrease.

10. The computer-implemented method of claim 8, wherein identifying significant monotonic decreases in the thermistor signal comprises

identifying initial monotonic decreases in the thermistor signal stream that occur for a time longer than a preset time period;

rejecting the initial periods of a monotonic decrease having an amplitude decrease of less than a preset value; and

designating the remaining initial periods of monotonic decrease as significant periods of monotonic decrease.

11. The computer-implemented method of claim 7, wherein the number of ventilations in the predetermined epoch is the number of significant monotonic decreases in the thermistor signal during the predetermined epoch.

12. The computer-implemented method of claim 7, wherein the number of ventilations and the number of respiratory efforts during the predetermined epoch are displayed on the monitor.

13. The computer-implemented method of claim 12, wherein the number of ventilations and the number of respiratory efforts during the predetermined epoch are used to determine whether the individual has apnea.

14. The computer-implemented method of claim 13, wherein the apnea is obstructive apnea.

15. The computer-implemented method of claim 1, wherein if the number of respiratory efforts is lower than a predetermined value, a predetermined action is effected.

16. The computer-implemented method of claim 15, wherein the predetermined action comprises at least one of

initiate an alarm, rouse the individual, administer or increase oxygen supply to the individual or administer a narcotic reversal agent to the individual.

17. The computer-implemented method of claim **1**, wherein the magnitude of the significant local maxima, significant local minima, or both are evaluated to determine the magnitude of the respiratory efforts in the predetermined epoch.

18. The computer-implemented method of claim **8**, further comprising determining time intervals between significant monotonic decreases in the thermistor signal.

19. The computer-implemented method of claim **18**, wherein determining the time intervals between significant monotonic decreases in the thermistor signal comprises:

determining an amplitude minimum for each significant monotonic decrease in the predetermined epoch;
measuring the time interval (a) between each successive amplitude minimum of each significant monotonic decrease, (b) between the start of the predetermined epoch and the first amplitude minimum; and (c) between the last amplitude minimum and the end of the predetermined epoch;

to determine the time intervals between significant monotonic decreases in the thermistor signal.

20. The computer-implemented method of claim **18**, wherein a time interval that exceeds a predefined time limit is evaluated by the computer to determine whether an apneic or hypopneic event has occurred.

21. The computer-implemented method of claim **20**, wherein the evaluation to determine whether an apneic or hypopneic event has occurred comprises

determining a signal variation of the amplitude in each time interval that exceeds the predefined time limit; and
if a time interval has a signal variation of greater than or equal to a first predefined value (c1), then the time interval is deemed to not comprise an apneic or hypopneic event; and

if a time interval has a signal variation of less than the first predefined value (c1), then the time interval is deemed to comprise an apneic or hypopneic event.

22. The computer-implemented method of claim **21**, wherein for those time intervals deemed to comprise an apneic or hypopneic event, the computer then evaluates whether signal variation of the amplitude during a time interval is less than a second predefined value (c2), wherein

if a signal variation of the amplitude of a time interval is less than the first predefined value (c1) but greater than the second predefined value (c2), the time interval is deemed to comprise a hypopneic event, and if wherein a signal variation of the amplitude of a time interval is less than the first predefined value (c1) and the second predefined value (c2), the time interval is deemed to comprise an apneic event.

23. The computer-implemented method of claim **22**, wherein a time interval deemed to comprise a hypopneic event, the PPG signal is evaluated to determine the magnitude of the respiratory effort during the time interval.

24. The computer-implemented method of claim **23**, wherein if a respiratory effort during the time interval deemed to comprise a hypopneic event exceeds a predefined value (d1), the computer indicates that an obstructive hypopneic event has occurred.

25. The computer-implemented method of claim **24**, wherein if no respiratory effort during the time interval deemed to comprise a hypopneic event exceeds the predefined value (d1), then the computer indicates that a central hypopneic event has occurred.

26. The computer-implemented method of claim **22**, wherein for a time interval deemed to comprise an apneic event, the PPG signal is evaluated to determine the magnitude of the respiratory effort during the time interval.

27. The computer-implemented method of claim **26**, wherein if a respiratory effort during the time interval deemed to comprise an apneic event exceeds a predefined value (d1), the computer indicates that an obstructive hypopneic event has occurred.

28. The computer-implemented method of claim **26**, wherein if no respiratory effort during the time interval deemed to comprise a hypopneic event exceeds the predefined value (d1), then the computer outputs an indication that a central hypopneic event has occurred.

29. The computer-implemented method of claim **24**, wherein if a predetermined number of hypopneic and/or apneic events are indicated by the computer, a predetermined action is effected.

30. The computer-implemented method of claim **19**, wherein the predetermined action comprises at least one of initiate an alarm, rouse the individual, administer or increase oxygen supply to the individual or administer a narcotic reversal agent to the individual.

* * * * *

专利名称(译)	使用光电容积脉搏波传感器监测呼吸的方法和装置		
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摘要(译)

在本文的实施例中提供了用于呼吸监测的计算机实现的方法和系统。一些实施例包括从个体的中心源站点获得PPG信号流;识别PPG信号流在预定时期内的峰和谷，其中峰之间的时间或谷之间的时间对应于个体的心率;确定所述预定时期内的峰振幅和谷振幅的显著局部最大值的显著局部最大值，其中峰振幅的每个显著局部最大值对应于所述个体的呼气呼气努力的呼气的开始，并且波谷振幅的每个显著局部最小值对应于开始的个人呼吸努力吸气;在所述预定历元期间计算有效局部最大值的数量，显著局部最小值或两者，以确定所述预定历元中的呼吸努力的数量;以及在计算机监视器上显示预定时期内的呼吸努力次数。

