(54) Title: SYSTEM AND METHOD FOR DETECTING VENTILATORY INSTABILITY
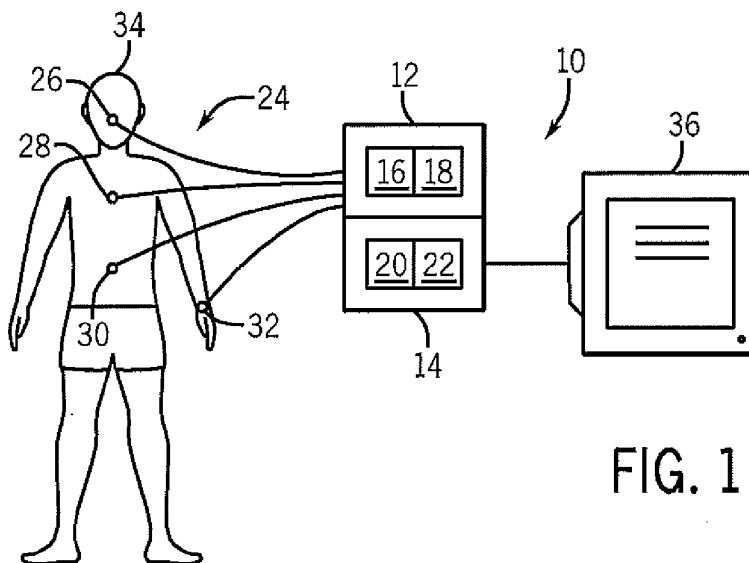
FIG. 1

(57) Abstract: Embodiments described herein may include systems and methods for detecting events that may be associated with
sleep apnea. Some embodiments are directed to a system and/or method for automated detection of reduction in airflow events us-
ing polysomnograph signals, wherein the reduction in airflow events may relate to sleep apnea. The PSG signals may be limited to
four signals, including data from an airflow channel, a blood oxygen saturation channel, a chest movement channel, and an ab-
domen movement channel. Using information from these channels, some embodiments may automatically identify reduction in
airflow events.

(88) Date of publication of the international search report:

6 May 2010

SYSTEM AND METHOD FOR DETECTING VENTILATORY INSTABILITY

BACKGROUND

5   The present disclosure relates generally to medical devices and methods and, more particularly, to an automated system and method for detecting events related to ventilatory instability, such as sleep apnea.

This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present disclosure, which are described and/or

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

Sleep apnea is generally described as a sleep disorder that is characterized by

15   episodes of paused breathing during sleep. These episodes of paused breathing may occur repeatedly throughout sleep, and each episode may last long enough to cause one or more breaths to be missed. Such episodes may be referred to as apneas. A typical definition of an apnea may include an interval between breaths of at least 10 seconds, with a neurological arousal and/or a blood oxygen desaturation of 3% or greater. The

20   actual duration and severity of each apnea may substantially vary between multiple patients. Further, duration and severity of apneas may vary throughout a period of sleep for a single patient. Indeed, sleep apnea may have a wide range of severity. For example, sleep apnea may include mild snoring, which may be related to incomplete and inconsequential airway obstruction, or severe apneas, which may result in hypoxemia.

25   Sleep apnea commonly results in excessive daytime sleepiness. Further, sleep apnea can

hinder cognitive function during the day due to sporadic sleep during the night resulting from recurrent arousals associated with the sleep apnea.

Although sleep apnea commonly affects obese patients, it may occur in patients with any body type. Indeed, sleep apnea is fairly common and causes undesirable

5   symptoms of excessive daytime sleepiness, morning headache, and decreasing ability to concentrate during the day. Thus, it is desirable to diagnose and treat sleep apnea. Traditionally, sleep apnea is diagnosed utilizing an overnight sleep test referred to as a polysomnogram. This is generally performed in a sleep lab and involves the continuous and simultaneous measurement and recording of an encephalogram, electromyogram,

10   extraoculogram, chest wall plethysmogram, electrocardiogram, measurements of nasal and oral airflow, and pulse oximetry. All or some of these and other channels may be measured simultaneously throughout the night, and complex recordings of such measurement may then analyzed by a highly trained clinician to determine the presence or absence of sleep apnea.

15   **BRIEF DESCRIPTION OF THE DRAWINGS**

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

FIG. 1 is a block diagram of a medical analysis system in accordance with some embodiments;

20   FIG. 2 is a process flow diagram of a method for detecting ventilatory instability related events in accordance with some embodiments;

FIG. 3 is a block diagram of a device and/or module capable of receiving and filtering signals in accordance with some embodiments;

FIG. 4 is a process flow diagram of a method for estimating a value for breathes per minute of a patient in accordance with some embodiments; and

FIG. 5 is a block diagram of the system of FIG. 1 communicatively coupled with a separate ventilatory instability detection system to facilitate calibration of the separate

5   system in accordance with some embodiments.

DETAILED DESCRIPTION

One or more embodiments of the present disclosure will be described below. In an effort to provide a concise description of the embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in

10   the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions may be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming,

15   but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

Some embodiments are directed to automated systems and methods for detecting events that may be associated with sleep apnea. Specifically, some embodiments are directed to a system and/or method for automated detection of reduction in airflow

20   events using polysomnograph (PSG) signals, wherein the reduction in airflow events may relate to sleep apnea. The PSG signals may be limited to four signals, including data from an airflow channel, a blood oxygen saturation (SpO_2) channel, a chest movement channel, and an abdomen movement channel. Using information from these channels, some embodiments may automatically identify reduction in airflow events.

Accordingly, some embodiments may facilitate automated detection and/or diagnosis of sleep apnea in patients. For example, some embodiments may be utilized to analyze data that has been acquired using a separate PSG system to determine whether sleep apnea related events have occurred. In another example, some embodiments may

5   be incorporated with a PSG system to automatically detect and/or diagnose sleep apnea while a patient is being monitored. Indeed, some embodiments may facilitate detection of events relating to sleep apnea and/or facilitate diagnosis of sleep apnea in real time. Further, some embodiments may be utilized to demonstrate or confirm the accuracy or reliability of other systems and/or methods for detecting events related to sleep apnea.

10   For example, some embodiments may be utilized in conjunction with a device configured to identify ventilatory instability (e.g., sleep apnea) based on an SpO_2 pattern recognition algorithm.

In some embodiments, a distinction may be made between whether identified sleep apnea events correspond to central sleep apnea or obstructive sleep apnea. Central

15   and obstructive sleep apnea may be distinguished based on the nature of their occurrence. For example, a lack of effort in breathing is generally the cause of interrupted breathing associated with central sleep apnea, while a physical block in airflow despite effort is generally the cause of interrupted breathing associated with obstructive sleep apnea. If a patient is or is not making an effort to breathe, the patient's

20   chest and abdomen activity may be indicative. Accordingly, some embodiments may distinguish between the two types of apnea by including devices or modules that are capable of quantifying phase differences between chest and abdomen signals. For example, some embodiments may include an algorithm stored on a memory that receives chest and abdomen signals and determines that certain events correspond to obstructive

sleep apnea when the chest and abdomen signals are out of phase, or that the events

correspond to central sleep apnea when there is no chest and/or abdomen movement, or

there is a decrease in chest and abdomen movement but signals are in phase.

5   **FIG. 1** is a block diagram of a medical analysis system in accordance with some

embodiments. The medical analysis system is generally indicated by reference numeral

10. The system **10** includes a PSG system **12** and an event detection (ED) system **14**.

The PSG system **12** and the ED system **14** may be separate or integrated in accordance

with some embodiments. The PSG system **12** may include, for example, hardware

and/or software products from Nellcor Puritan Bennett's Sandman® sleep diagnostics

10   line of products.

According to an embodiment, the PSG system **12** may include a memory **16** and

a processor **18**, and the ED system **14** may include a memory **20** and a processor **22**.

Programming stored on the respective memories **16** and **20** for the PSG system **12** and

the ED system **14** may be utilized in conjunction with each system's respective processor

15   **18** and **22** to facilitate performance of certain functions by the PSG system **12** and the

ED system **14**. For example, the memories **16** and **20** may include coded instructions

that may be utilized with the respective processors **18** and **22** to perform automated

methods in accordance with some embodiments. It should be noted that, in some

embodiments, the memories **16** and **20** may be integral with the respective processors **18**

20   and **22**. Further, if the PSG system **12** and ED system **14** are integral components of the

system **10**, the integrated PSG system **12** and ED system **14** may share a single memory

and/or a single processor.

According to an embodiment, the PSG system **12** may be capable of receiving

signals from various sensors **24** that are capable of measuring certain physiologic

parameters or patient activities. Specifically, the sensors **24** may include an airflow

sensor **26**, a chest sensor **28**, an abdomen sensor **30**, and a pulse oximeter sensor **32**.

Each of the sensors **24** may be attached to a patient **34** to facilitate measuring

physiologic parameters and/or physical activity (e.g., movement) of the patient **34**.

5   These four measured values from the sensors **24** may be transmitted as signals to the

PSG system **12** for processing. Thus, the sensors **24** may cooperate with the PSG system

12 to provide a polysomnogram. A polysomnogram may be described as a recording of

an individual's sleep characteristics (e.g., activities and physiological events occurring

during sleep), which may include an output of various measurements obtained by the

10   sensors **24**. Such an output may be recorded on a memory (e.g., a flash memory or hard

drive), presented on other tangible medium (e.g., printed on paper), or visually displayed

(e.g., displayed as video). For example, the polysomnogram, along with other data, may

be displayed on a video screen **36** of the medical analysis system **10**.

According to an embodiment, the ED system **14** may be capable of using data

15   acquired by the PSG system **12**, such as the polysomnogram, to automatically detect

events that may be associated with sleep apnea. For example, the ED system **14** may

automatically detect reduction in airflow events, which relate to sleep apnea, using four

PSG signals from the PSG system **12**. The PSG signals may be transferred to the ED

system **14** from the PSG system **14** in a number of ways. For example, data

20   corresponding to signals from the PSG system **12** may be manually entered into the ED

system **14**, transferred via a memory device (e.g., a flash memory), or directly

transmitted to the ED system **14** from the PSG system **12** for analysis. The PSG system

12 and the ED system **14** may receive and/or transmit signals corresponding to particular

signal types based on data in a memory (e.g., a flash memory or a memory of the PSG

system **12**) and/or directly from each of the sensors **24**. The PSG signals and/or signal

data may be referred to as channels corresponding to each signal, such as airflow, chest,

abdomen, and pulse oximetry channels.

According to an embodiment, once the ED system **14** receives the PSG signals,

5   which may be in the form of signal data, the ED system **14** may perform an automated

process on the PSG signals to identify events related to sleep apnea, such as reduction in

airflow events. If certain events are identified in accordance with specified rules or

criteria, the ED system **14** may provide an indication of the presence of ventilatory

instability. For example, the ED system **14** may include hardware and/or software

10   components that filter one or more of the PSG signals and identify characteristics of the

signals that combine to suggest the presence of events related to sleep apnea.

Specifically, for example, after checking for invalid data, filtered and unfiltered PSG

signals may be utilized by the ED system **14** to estimate a value of breathes per minute

(BPM) of the patient **34**. The estimated BPM may then be utilized by the ED system **14**

15   to calculate a baseline for use in determining whether a threshold level of airflow

reduction is present. Further, the ED system **14** may determine whether certain other

events indicative of respiratory instability are present based on the PSG signals, as will

be discussed in further detail below. The ED system **14** may output values indicative of

whether respiratory instability is present based on whether certain events were identified.

20   For example, the ED system **14** may indicate the presence of sleep apnea and/or indicate

a type of sleep apnea (e.g., central or obstructive) based on results obtained through

analysis of a neural network of the ED system **14**. It should be noted that the

identification of events by the ED system **14** may be facilitated by an algorithm stored in

the memory **20**, which may cooperate with the processor **22** to implement methods in

accordance with some embodiments. It should further be noted that the algorithm may be tuned by adjusting constant values in the algorithm to correspond to particular situations or patients (e.g., a patient with a heart condition).

FIG. 2 is a process flow diagram illustrating a method in accordance with some embodiments. The method is generally indicated by reference number 100 and includes various steps or actions represented by blocks. It should be noted that the method 100 may be performed as an automated procedure by a system, such as the analysis system 10. Further, certain steps or portions of the method may be performed by separate devices. For example, a first portion of the method 100 may be performed by the PSG system 12 and a second portion of the method 100 may be performed by the ED system 14. In this embodiment, the method includes receiving and filtering signals (block 102), checking for invalid data (block 104), estimating BPM (block 106), determining a signal baseline for certain signals (block 108), determining whether certain criteria are met by acquired data (block 110), and outputting a result (block 112).

According to an embodiment, the method 100 begins with receiving and filtering signals, which may include signal data, as represented by block 102. Block 102 may include receiving and/or filtering signal data from several sensors, which may include the airflow sensor 26, the chest sensor 28, the abdomen sensor 30, and/or the pulse oximeter sensor 32. Specifically, block 102 may represent receiving data or signals from airflow, chest, abdomen, and pulse oximetry channels and filtering signals on a subset of the channels. Signals on the chest, airflow, and abdomen channels may be filtered, while signals on the pulse oximetry channel, which may relate to SpO_2 data, may remain unfiltered. For example, FIG. 3 illustrates a component 300 capable of filtering the chest, airflow, and abdomen channels in accordance with some embodiments. In some

embodiments, the component **300** may be a feature of the processor, or it may be

implemented using electronic circuits which preprocess and filter some or all of the PSG

signals. 22. Specifically, as illustrated in **FIG. 3**, a raw signal **302** from the PSG system

12, such as a signal on the chest, airflow or abdomen channel, may be received into the

5   component **300** of the ED system **114**. The raw signal **302** may pass through the

component **300**, which may include passing the raw signal through a band-pass filter **304**

and a low-pass filter **306** of the component **300**.

     According to an embodiment, the band-pass filter **304** may pass frequencies

within a selected range and attenuate frequencies that are outside of the selected range.

10   Specifically, for example, the band-pass filter **30** may include a .0833 – 1 Hz band-pass

filter that operates to pass frequencies corresponding to 5-60 BPM and filter out

frequencies above and below that range. An initial or default 5-60 BPM pass band may

be used since most human breathing rates will be within this range under typical sleep-

lab conditions. The pass band may be tuned (moved, narrowed, and/or widened) by the

15   operator based on known patient conditions to increase the specificity and/or sensitivity

of the ED system. Once the raw signal **302** has passed through the band-pass filter **304**, it

becomes a band-passed signal **308**. The band-passed signal **308** may be utilized in

conjunction with other input in the analysis and identification of ventilatory instability,

as will be discussed in further detail below.

20   According to an embodiment, the low-pass filter **306** may pass frequencies below

a cutoff level and attenuate frequencies higher than the cutoff level. Specifically, for

example, the low-pass filter **306** may attenuate frequencies lower than .04166 Hz, which

corresponds to 2.5 BPM. 2.5 BPM may be selected as the initial cutoff level since it is

unlikely that any patient will breathe slower than this rate, and therefore frequencies

below this level can be considered noise, or more specifically these frequencies can be

considered the DC offset of the PSG signal. The operate\or may move the low pass filter

level based on known patient conditions in an attempt to increase the specificity and

sensitivity of the ED system. Once the raw signal 302 has passed through the low-pass

5   filter 306, it becomes a low-passed signal 310. The low-passed signal 310 may be used

to calculate a noise signal 312 by passing it through a subtraction block 314 with the raw

signal 302 to get a difference between the raw signal 302 and the low-passed signal 310.

This and other features of noise calculation will be discussed in further detail below.

The calculated noise level may be utilized to clarify signal features by reducing noise

10   content. In some embodiments, features may be included that facilitate reading data

through the noise, rather than merely removing the noise (I put a more specific example

at the end of the next paragraph, maybe remove the last sentence in this paragraph, or

keep both).

       According to an embodiment, after the signals have been received and/or filtered

15   in block 102, the method 100 may proceed to block 104, which includes checking for

invalid data. Specifically, block 104 may represent receiving and processing a stream of

data to determine whether any portions of the data meet criteria indicating that the data

should be discarded. For example, block 104 may represent receiving a 10 minute

segment of data that is analyzed to determine if the following criteria are present: (1) the

20   SpO_2 signal is less than a designated value (e.g., less than a value of 20% SpO2, which

may indicate that the sensor is off or disconnected), (2) the signal to noise ratio for a

signal on the airflow channel is less than a designated value (e.g., 5 dB), (3) the signal to

noise ratio for a signal on the chest channel is less than a designated value (e.g.,. 0 dB),

and/or (4) a signal to noise ratio (SNR) for a signal on the abdomen channel is less than

a designated value (e.g., 0 dB). If it is determined in block **104** that any of the designated criteria, such as the criteria set forth above, are present for a designated period, e.g., 2 minutes, within the 10 minute segment of data, all or part of the 10 minute segment of data may be discarded as being invalid. In some embodiments, features may

5   be included that facilitate reading through data with a SNR below a threshold, rather than merely invalidating data because of low SNR values.

It should be noted that the signal to noise ratios referenced above may be automatically calculated in block **104** along with other determinations relating to identifying invalid data. For example, block **104** may represent calculating the signal to

10   noise ratio for a particular signal by first removing DC from the raw signal **302**. That is, the low-passed signal **310** (LPFilteredSignal) may be subtracted from the raw signal **302** (RawSignal) to obtain a raw signal without DC (RawSignalNoDC). This procedure may be represented by the following equation:

$$RawSignalNoDc = RawSignal - LPFilteredSignal.$$

15   Noise may then be calculated by subtracting the band-passed signal **308** (BPSignal) from the raw signal without DC. This procedure may be represented by the following equation:

$$Noise = RawSignalNoDC - BPSignal.$$

A statistical measure of magnitude, such as a root mean square, may then be

20   obtained for both the noise and the band-passed signal, and the signal to noise ratio (SNR) may be calculated by dividing the root mean square of the band-passed signal (RMS(Signal)) by the root mean square of the noise (RMS(Noise)), as represented by the following equation:

$$SNR = RMS(Signal)/RMS(Noise).$$

As will be appreciated, in some embodiments, different calculations or

procedures may be utilized to obtain the signal to noise ratio.

According to an embodiment, after invalid data has been removed in block **104**,

the method **100** may proceed to determine an estimated BPM based on the received data,

5   as represented by block **106**. As illustrated in **FIG. 4**, the BPM estimate may be

calculated using the chest, abdomen, and airflow signals. **FIG. 4** is a process flow

diagram of a method of estimating BPM in accordance with some embodiments. The

method of estimating BPM is generally indicated by reference number **400** and includes

various steps or actions represented by blocks. As with the other steps of the method

10   **100**, the method **400** may be performed as an automated procedure by the system **100** in

accordance with some embodiments.

According to an embodiment, the method **400** begins by receiving band-passed

airflow, chest, and abdomen signals, and converting the signals to the frequency domain

by performing a fast Fourier transform (FFT) on all three channels, as represented by

15   block **402**. Specifically, block **402** may represent determining an FFT for the three

channels a certain number of times per time period. For example, block **402** may

represent calculating an FFT for the band-passed airflow, chest, and abdomen signals

once every 2 minutes.

According to an embodiment, after performing the frequency conversion in block

20   **402**, the method **400** may proceed to block **404**, which represents normalizing the

frequency spectrums obtained in block **402**. The procedure represented by block **404**

may include various different types of normalization, which may result in ranging the

frequency spectrums from 0.0 to 1.0. For example, peak normalization may be

performed by dividing the amplitude at each point in the spectrum of each signal by the

maximum amplitude of that particular spectrum. Thus, the normalized spectrum may include intensities that range from as low as 0.0 to as high as 1.0. By normalizing the spectrums, certain discrepancies between the spectrums may be removed to facilitate proper combination or comparison of the different spectrums. It should be noted that

5   each spectrum may be based on a segment of data, such as a 10 minute segment of recorded sensor data.

According to an embodiment, after the spectrums have been normalized in block 404, all three frequency spectrums may be averaged, as represented by block 406, and an

10   estimate of BPM may be calculated based on the average, as represented by block 408. Specifically, blocks 406 and 408 may include averaging all of the histograms of the frequency spectrums and selecting a frequency from the average that has the highest amount of energy to determine the estimate BPM for the associated segment of data. This procedure may be represented by the following equation:

15   BPM Estimate = max(Average Frequency Spectrum).

According to an embodiment, the process of providing BPM estimates for a segment of data may be repeated for a series of data segments, as represented by arrow 410. The most recent BPM estimate obtained for a data segment may be referred to as the current estimate and the penultimate BPM estimate obtained for a previous data

20   segment may be referred to as the previous estimate. In other words, once a new segment of data has been received and processed, the BPM estimate that was the current estimate may become the previous segment and the BPM estimate for the most recent segment of data may become the current estimate. As represented by block 412, the

current and previous estimates may be averaged to provide a final BPM estimate, as

represented by the following equation:

Final BPM Estimate = 0.5 (Current Estimate + Previous Estimate).

It should be noted that in some embodiments, more than two estimates may be

5   averaged to determine the final BPM estimate. For example, three or more estimates for

a series of data segments may be stored and averaged to determine a final BPM estimate

in accordance with some embodiments.

According to an embodiment, after estimating BPM in block 106, the method

100 may proceed to determining a signal baseline for each signal, as represented by

10   block 108. Specifically, for example, block 108 may include calculating a signal

baseline for the airflow, chest, and abdomen signals. In performing this calculation, a

root mean square value for the signal (e.g., the raw signal 302) may first be obtained

using the final BPM estimate and a running root mean square, as indicated by the

following equation:

15   Xrms = 0.5 BPM running RMS signal X.

This calculation may take into account every point of a signal such that the

results are indicative of the power of the signal at each point. The baseline value (X-

Baseline) for each particular signal may then be determined based on this root mean

square value (Xrms). Specifically, the baseline may be determined as the top 10% or

20   ninetieth percentile of the root mean square value, as represented by the following

equation:

X-Baseline = Top 10% (90th percentile) of Xrms.

According to an embodiment, once a baseline has been determined for the

airflow, chest, and abdomen signals, as represented by block 108, the method 100 may

proceed with determining whether certain criteria are met, as represented by block **110.**

The presence of characteristics that meet certain criteria may indicate and confirm that a

reduction in airflow (RAF) event occurred relative to a normal airflow. For example, a

determination may be made as to whether a certain level of reduction (e.g., a 40%

5   reduction) in airflow has occurred for at least a threshold amount of time (e.g., 10

seconds). This may be referred to as an RAF event. Specifically, in one embodiment, an

RAF event may be described as an interval where the amplitude envelope of a signal on

the airflow channel from the PSG system **12** is reduced at least 40% relative to the

baseline for at least 10 seconds consecutively. It should be noted that the amplitude

10   envelope may refer to the value of a function describing how the maximum amplitude of

the airflow signal changes over time.

According to an embodiment, once an RAF event has been identified, it may be

qualified for consideration based on certain scoring rules. For example, an RAF event

may be disqualified if there is not a specified amount of change in one or more other

15   signal measurements within a certain window of time with respect to the time the RAF

event occurred. For example, if the measured SpO_2 value does not change at least a

certain amount, e.g., 3%, during the RAF even or within a certain time, e.g., 30 seconds,

after the RAF event, the RAF event may be disqualified. Similarly, for example, if there

is not at least a certain change, e.g., a 40% reduction, in the chest or abdomen signal

20   from the PSG system **12** for at least part, e.g., half, of the interval of the RAF event, the

RAF event may be disqualified. Alternatively, if the available data meets these criteria,

the RAF event may be qualified and used to determine whether the data is indicative of

ventilatory instability in the patient that was or is being monitored.

According to an embodiment, block **110** may also represent determining whether a segment of data includes an indication of ventilatory instability based on a quantity of qualified RAF events that occur within the data segment. For example, block **110** may determine that a particular data segment is indicative of ventilatory instability if a certain

5   number, e.g., at least 5, of consecutive RAF events are qualified within a given portion, e.g., a 10 minute period, of the segment of data. Thus, segments of data may be divided into intervals, e.g., 10 minute intervals, in accordance with some embodiments. It should be noted that in order for the RAF events to be qualified as being consecutive, certain relative timing criteria may have to be met. For example, in one embodiment, for

10   a pair of qualified RAF events to be consecutive, the RAF events must occur within a certain time, e.g., 120 seconds, of one another.

According to an embodiment, block **110** may also represent determining a type of respiratory event, such as determining the presence of central or obstructive sleep apnea based on correlations between different signals, such as the chest and abdomen signals

15   being in or out of phase. As discussed above, central and obstructive sleep apnea may be distinguished based on the nature of their occurrence. For example, a lack of effort in breathing is generally associated with central sleep apnea, while a physical block in airflow despite effort is generally associated with obstructive sleep apnea. A patient's chest and abdomen activity may be utilized to distinguish between the two types of

20   apnea. Accordingly, some embodiments may include features that are capable of quantifying phase differences between chest and abdomen signals. For example, some embodiments may include features that determine that certain events correspond to obstructive sleep apnea when the chest and abdomen signals are out of phase, or that the events correspond to central sleep apnea when there is no chest and/or abdomen

16

movement, or there is a decrease in chest and abdomen movement but signals are in phase.

Based on the criteria or rules discussed above, the method **100** may output an epoch score for each data segment, as represented by block **112**. For example, an epoch
5   score may be repeated once every time a segment of data has been analyzed (e.g., once every 10 minutes). In some embodiments, a system may utilize such a score in an algorithm to provide an indication of certain conditions relating to ventilatory instability. For example, the epoch score may include a value of 1 for an indication that sleep apnea has been detected, 0 for an indication that sleep apnea has not been detected, or -1 for an
10   indication of invalid data. The indicator provided by the system based on the score may include a textual indication of the detected condition, such as "sleep apnea detected," "sleep apnea not detected", or "unknown or invalid data." In some embodiments, a series of epoch scores may be combined for all or part of a sleep study to generate an aggregate score. For example, an average of all of the scores for each 10 minute
15   segment of a sleep cycle may be used to determine a summary score for a particular patient.

Further, in some embodiments, the severity of the ventilatory instability or apnea events may be quantified instead of merely providing binary outputs. For example, the depth of the airflow reduction may be used to quantify a severity of the ventilatory
20   instability. In some embodiments different aspects associated with qualified RAF events may be used to determine levels of severity. For example, a series of continually larger drops in airflow and/or continual failures to return to a baseline level of airflow may be correlated to a higher level of severity. Further, numerous clusters of RAF events or data segments including RAF events may be considered in determining a severity level. For

example, a large segment of data, e.g., 4 hours of data, may include various sub-segments having different levels of apnea. Each sub-segment may be analyzed separately based on certain criteria, such as a number of RAF events per time period, an amount of reduced airflow, or other characteristics, and the values associated with the

5   sub-segments may be combined to provide an overall ventilatory instability level for the large segment of data.

The ED system **14** may be utilized to demonstrate or confirm that other systems involving detection of ventilatory instability related events are properly calibrated and/or providing results that correlate to the results obtained by the ED system **14**. For

10   example, **FIG. 5** is a block diagram of the ED system **14** communicatively coupled with a separate ventilation analysis system **500** to facilitate calibration of the system **500** or to confirm its proper operation. The separate ventilation analysis system **500** may include a system such as that described in U.S. Patent No. 6,223,064. For example, the system **500** may include an SpO_2 pattern recognition system that is utilized to identify

15   ventilatory instability based on a series of SpO_2 values. The system **500** may include a memory **502** and a processor **504** that are capable of analyzing input received or previously acquired from a single SpO_2 sensor. Specifically, the system **500** may be capable of identifying certain patterns or clusters of measured SpO_2 values to identify events related to ventilatory instability.

20   According to an embodiment, the ED system **14** may facilitate adjustment and/or calibration of the system **500** to correlate with BPM estimates determined by the ED system **14**. For example, both systems **14** and **500** may be provided with data from a storage device **506**, wherein the data corresponds to certain ventilatory instability events that have been observed. During a calibration period, the system **500** may be adjusted to

correspond to the ED system **14**. In other words, the system **500** may be adjusted such that it detects a high percentage of the ventilatory instability events detected by the ED system **14**. For example, certain coefficients of an algorithm stored on the memory of the system **500** may be adjusted to improve correlations between the results for the

5   system **500** and the results for the ED system **14**.

In a specific example, the ED system **14** may utilize automated analysis of the data obtained via the various sensors **24** to confirm that the system **500** is properly tuned and/or providing corresponding output. Specifically, the ED system **14** may receive data from the storage device **506** corresponding to airflow, chest impendence, abdomen

10   impedance, and blood oxygen saturation, and use this data to provide results that include a BPM estimate. These results may be compared with similar results obtained by the system **500** using SpO_2 pattern recognition. Based on the comparison, certain features of the system **500** (e.g., features of a pattern recognition algorithm stored on the memory **502**) may be adjusted to achieve a desired correspondence. The automated analysis

15   provided by the ED system **14** may facilitate rapid adjustment and/or testing of systems such as the system **500**.

Specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the claims are not intended to be limited to the particular forms disclosed. Rather, the claims are to

20   cover all modifications, equivalents, and alternatives falling within their spirit and scope.

CLAIMS

What is claimed is:

1.   A method for automated detection of ventilatory instability, comprising:

5   calculating an output value of breathes per minute for a data segment based at least

in part upon signals of an airflow channel, a chest channel, and/or an abdomen channel

and/or combinations thereof;

        determining a baseline value for each of the airflow channel, the chest channel, and

the abdomen channel based at least in part upon the output value of breathes per minute

10   and/or a measure of the magnitude of the corresponding signals;

        determining whether a reduction in airflow above a minimum reduction level

relative to the baseline value for the airflow channel has been maintained for a period of

time, and identifying a reduction in airflow event if the reduction in airflow is above the

minimum reduction level; and

15   providing an indication of ventilatory instability if the reduction in airflow event is

identified and meets a set of criteria.

2.   The method of claim 1, further comprising converting the signals of the airflow

channel, the chest channel, and/or the abdomen channel to a frequency domain to

determine a plurality of frequency spectrums, wherein the plurality of frequency spectrums

20   comprises an airflow channel frequency spectrum, a chest channel frequency spectrum,

and/or an abdomen channel frequency spectrum.

3.   The method of claim 2, wherein calculating the output value of breathes per minute

comprises determining a highest frequency of an average of the plurality of frequency

spectrums.

4.   The method of claim 1, wherein calculating the output value of breathes per minute comprises averaging an estimate of breathes per minute for each of a plurality of data segments based at least in part upon the signals of the airflow channel, the chest channel, and/or the abdomen channel and/or combinations thereof.

5   5.   The method of claim 1, further comprising determining whether a criterion is met that requires a pulse oximetry channel to change by a defined percentage within a window of time generally relative to the reduction in airflow event.

6.   The method of claim 5, further comprising determining whether the pulse oximetry channel has changed by at least 3% relative to its baseline within 30 second of the

10   reduction in airflow event to determine if the criterion is met.

7.   The method of claim 1, further comprising determining whether a criterion is met that requires a reduction in the chest channel and/or the abdomen channel relative to the respective baseline values for a defined portion of the reduction in airflow event.

8.   The method of claim 7, further comprising determining whether there was at least a

15   40% reduction relative to the respective baseline values in the chest channel and/or the abdomen channel for at least half of the reduction in airflow event to determine if the criterion is met.

9.   The method of claim 1, further comprising discarding invalid data corresponding to the airflow channel, the pulse oximetry channel, the chest channel, and the abdomen

20   channel based on whether certain indicators are present in an associated data segment.

10.   The method of claim 1, wherein the data segment comprises a 10 minute data segment.

11.   The method of claim 1, wherein the minimum reduction level relative to the
baseline value for the airflow channel comprises a 40% reduction relative to the baseline
value for the airflow channel.

12.   The method of claim 1, comprising determining whether the reduction in airflow
5   above the minimum reduction level relative to the baseline value for the airflow channel
has been maintained for 10 seconds or more.

13.   A system, comprising:

        a processing device capable of calculating an output value of breathes per minute
for a data segment based on signals of an airflow channel, a chest channel, and/or an
10   abdomen channel and/or combinations thereof at least in part by determining a baseline
value for each of the airflow channel, the chest channel, and/or the abdomen channel based
at least in part upon the output value of breathes per minute and a measure of the
magnitude of the corresponding signals; determining whether a reduction in airflow above
a minimum reduction level relative to the baseline value for the airflow channel has been
15   maintained for a period of time and identifying a reduction in airflow event if the reduction
in airflow is above the minimum reduction level; and providing an indication of ventilatory
instability if the reduction in airflow event is identified and meets a set of criteria.

14.   The system of claim 13, comprising a filter capable of filtering the airflow channel,
the chest channel, and/or the abdomen channel.

20   15.   The system of claim 14, comprising a filter capable of band-pass filtering and low-
pass filtering the airflow channel, the chest channel, and the abdomen channel, while
passing the pulse oximetry channel.

16.   The system of claim 13, comprising a monitor capable of displaying the indication
of ventilatory instability.

22

17.   The system of claim 13, wherein the processing device is capable of determining whether the indication of ventilatory instability corresponds to central sleep apnea or obstructive sleep apnea based on signals of the chest channel and/or abdomen channel.

18.   The system of claim 13, comprising an integral polysomnograph system capable of providing the signals of the airflow channel, the chest channel, and the abdomen channel.

19.   The system of claim 13, comprising a pulse oximetry sensor, an airflow sensor, a chest sensor, and an abdomen sensor.

20.   A system, comprising:

a polysomnograph system capable of supplying signals of an airflow channel, a chest channel, an abdomen channel, and/or a pulse oximetry channel, and/or combinations thereof;

a pulse oximetry pattern recognition system capable of identifying ventilatory instability based at least in part upon a series of blood oxygen saturation values;

an event detection system capable of identifying ventilatory instability events based at least in part upon data from the airflow channel, the chest channel, the abdomen channel, and/or the pulse oximetry channel, and/or combinations thereof; and

a system calibration component capable of comparing results from the event detection system and the pulse oximetry pattern recognition system to facilitate adjustment of the pulse oximetry pattern recognition system.
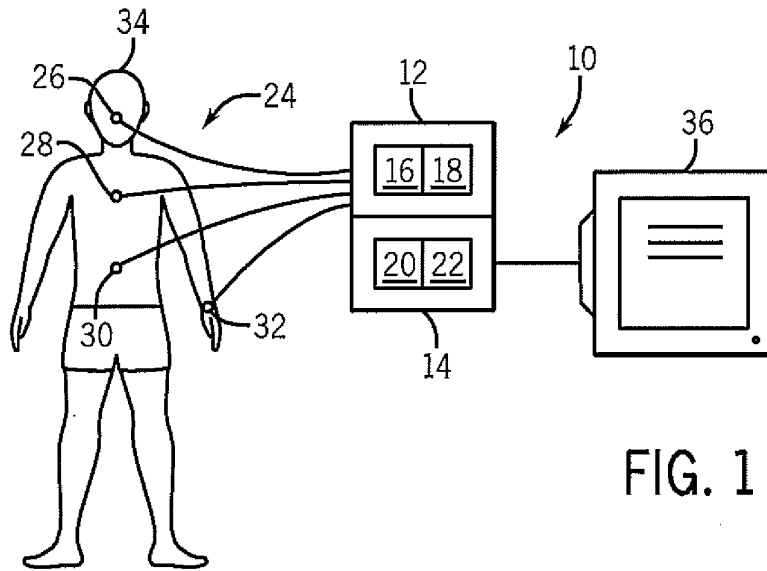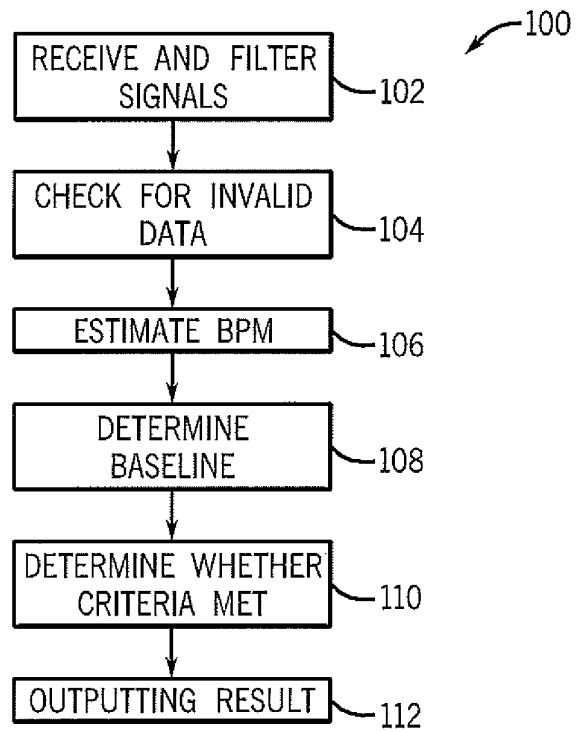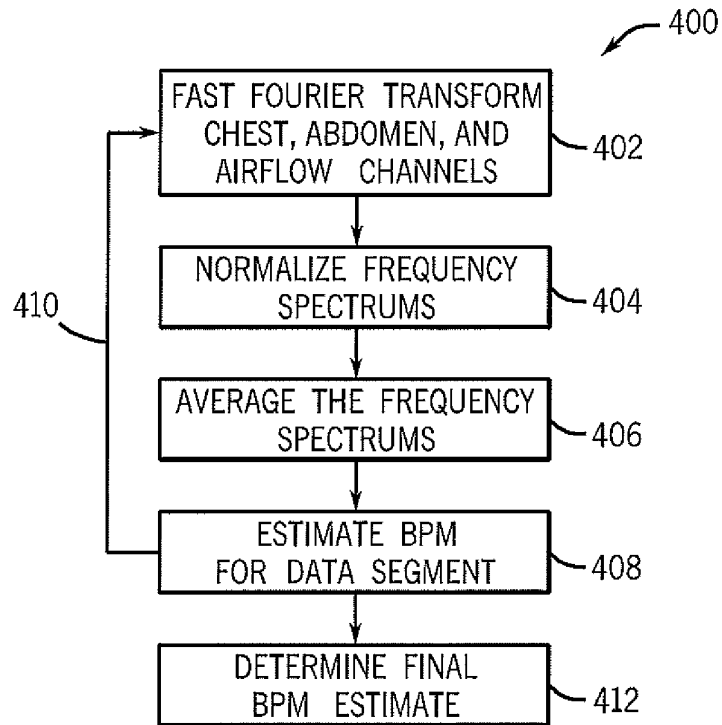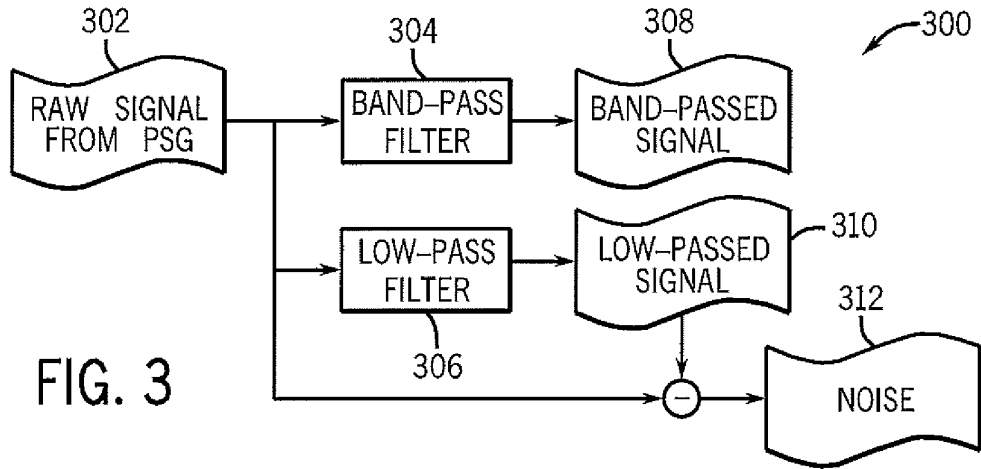
1/3

FIG. 1

FIG. 2

302

RAW SIGNAL
FROM PSG

304

BAND-PASS
FILTER

308

BAND-PASSED
SIGNAL

300

LOW-PASS
FILTER

LOW-PASSED
SIGNAL

310

312

NOISE

306

FIG. 3

400

FAST FOURIER TRANSFORM
CHEST, ABDOMEN, AND
AIRFLOW CHANNELS — 402

NORMALIZE FREQUENCY
SPECTRUMS — 404

AVERAGE THE FREQUENCY
SPECTRUMS — 406

410

ESTIMATE BPM
FOR DATA SEGMENT — 408

DETERMINE FINAL
BPM ESTIMATE — 412

FIG. 4

FIG. 5