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(54) **METHOD AND SYSTEM TO DIAGNOSE CENTRAL SLEEP APNEA**

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CPC ***A61B 5/4818*** (2013.01); ***A61B 5/0803*** (2013.01)

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CPC A61B 5/0803; A61B 5/4818; A61B 5/08; A61B 5/0816; A61B 5/082; A61B 5/0826; A61B 5/087; A61B 5/0873; A61B 5/091
See application file for complete search history.

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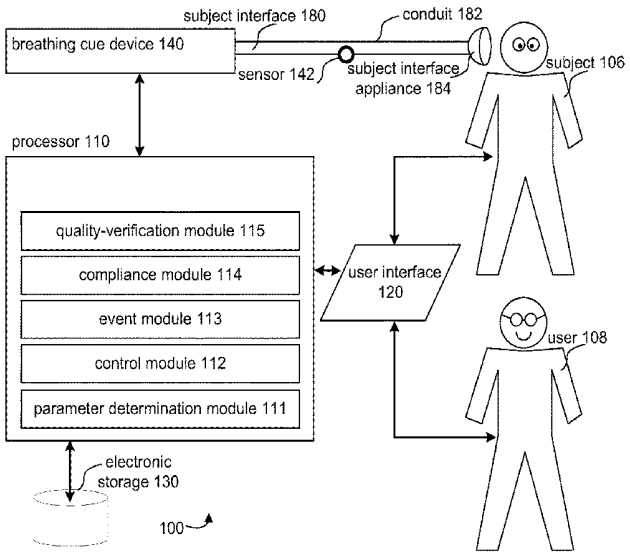
(57) **ABSTRACT**

Methods and system to diagnose central sleep apnea of a patient employ a relatively short test, combining few breathing parameters. The test is short in comparison to commonly used time-consuming and complex multi-parameter sleep studies. The patient uses a positive airway pressure device, and follows breathing cues. The occurrence of a central apnea during the delivery of breathing cues may support a diagnosis of central sleep apnea.

12 Claims, 2 Drawing Sheets



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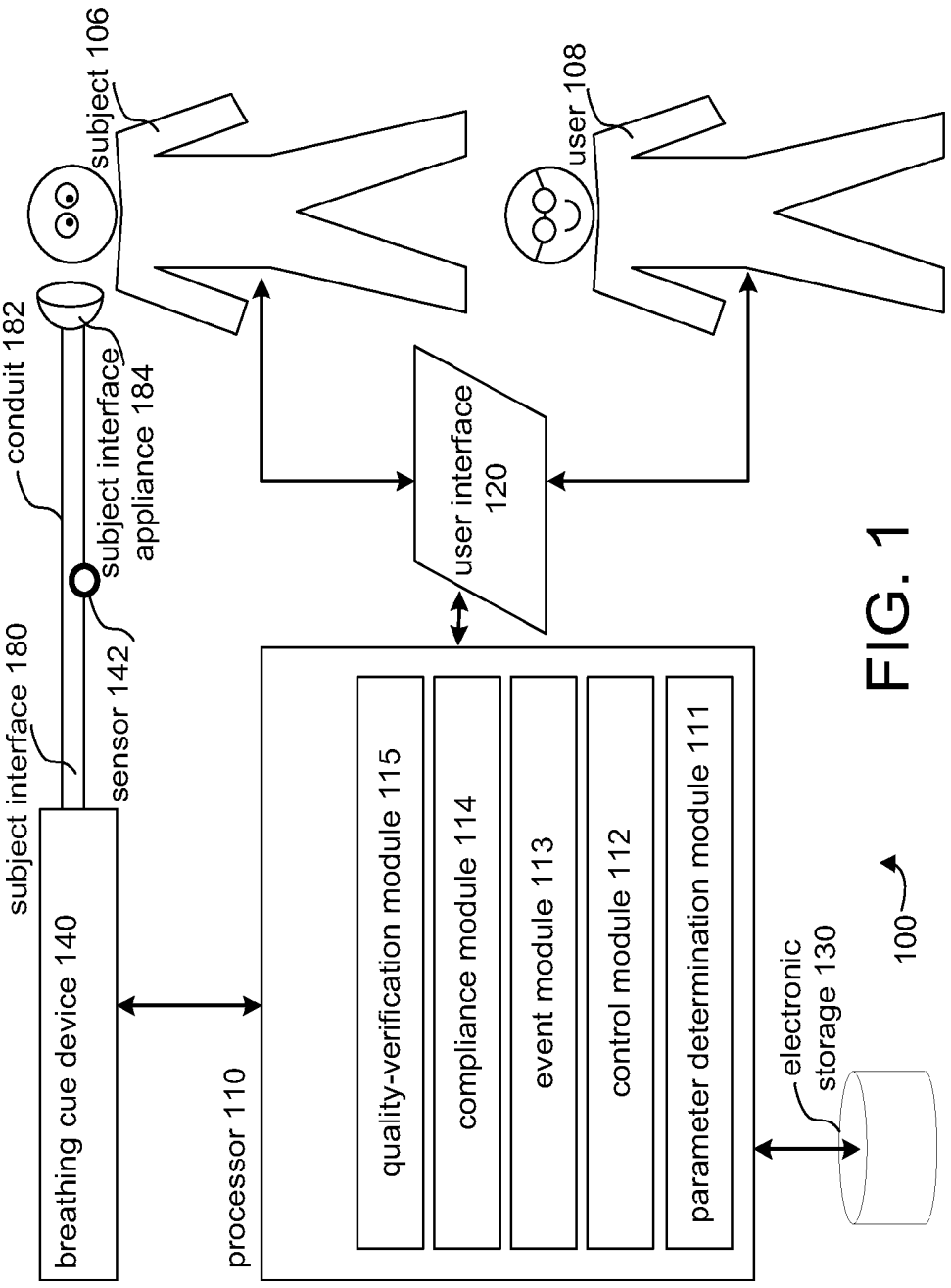
subject 106
user 108
conduit 182
subject interface appliance 184
subject interface 180
sensor 142
user interface 120
breathing cue device 140
processor 110
quality-verification module 115
compliance module 114
event module 113
control module 112
parameter determination module 111
electronic storage 130
100

FIG. 1

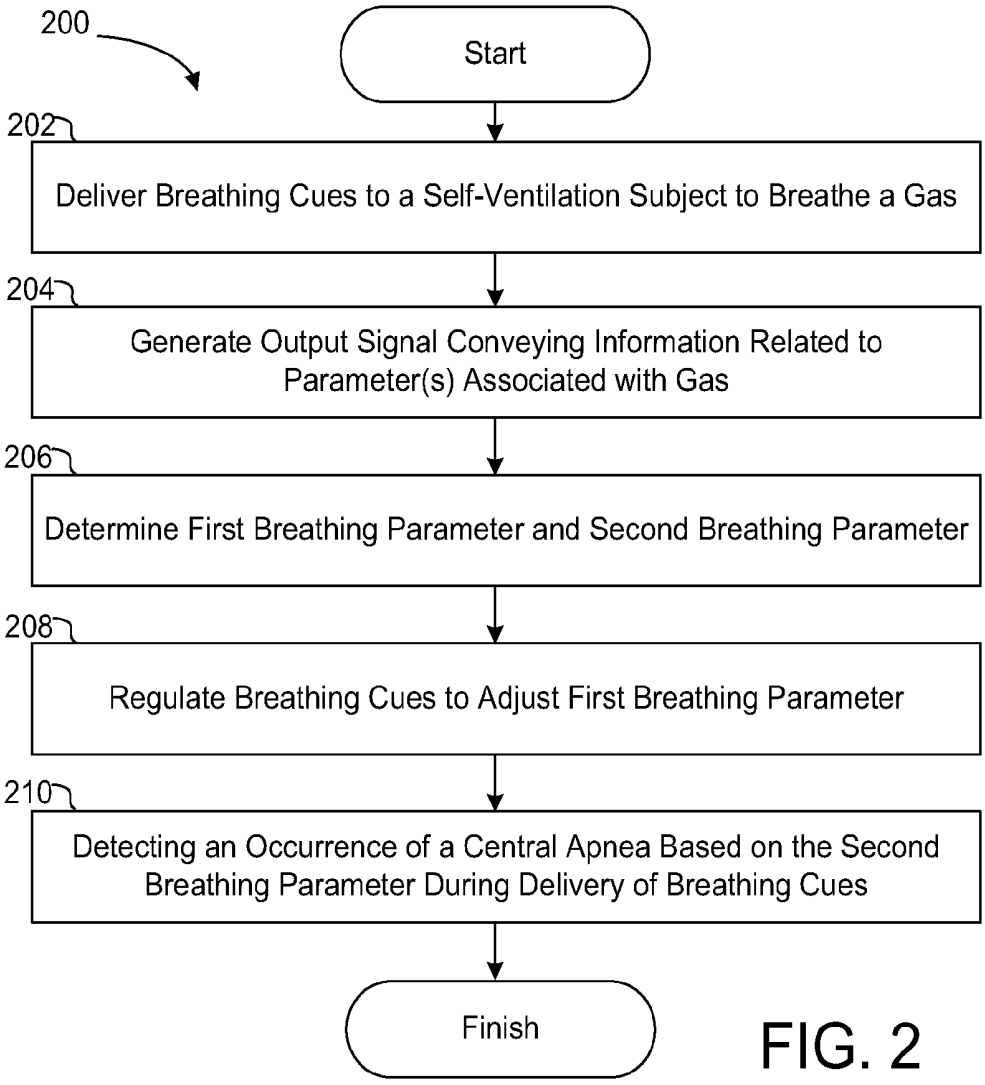
200
Start
202
Deliver Breathing Cues to a Self-Ventilation Subject to Breathe a Gas
204
Generate Output Signal Conveying Information Related to Parameter(s) Associated with Gas
206
Determine First Breathing Parameter and Second Breathing Parameter
208
Regulate Breathing Cues to Adjust First Breathing Parameter
210
Detecting an Occurrence of a Central Apnea Based on the Second Breathing Parameter During Delivery of Breathing Cues
Finish

FIG. 2

METHOD AND SYSTEM TO DIAGNOSE CENTRAL SLEEP APNEA

FIELD

The present disclosure pertains to a method and apparatus for diagnosing central sleep apnea for a patient, and, in particular, avoiding a complex and time-consuming polysomnogram to make such a diagnosis.

DESCRIPTION OF THE RELATED ART

It is well known to diagnose central sleep apnea and similar breathing disorders by using a polysomnogram or sleep study. A polysomnogram is a complex, costly, and time-consuming multi-parameter test. A patient, or subject, is required to spend an entire night connected to a variety of sensors. There is a need for improved methods and systems to support a diagnosis of central sleep apnea.

Accordingly, it is an object of one or more embodiments of the present invention to provide a system configured to support diagnosis of central sleep apnea of a subject using a test. The system comprises a device configured to deliver breathing cues to a self-ventilating subject, one or more sensors that generate output signals conveying information related to parameters associated with the gas, and one or more executable computer program modules. The breathing cues prompt the self-ventilating subject to breathe a gas and/or consciously alter one or more breathing parameters. The computer program modules may include a parameter determination module, a control module, and an event module. The parameter determination module is configured to determine a first and a second breathing parameter from the output signals generated by the sensors. The control module is configured to control the device to regulate the breathing cues to adjust the first and/or second breathing parameter. The event module is configured to detect an occurrence of a central apnea based on the first and/or second breathing parameter during delivery of breathing cues.

It is yet another aspect of one or more embodiments of the present invention to provide a method of diagnosing central sleep apnea of a subject during a test. The method comprises delivering breathing cues that prompt a self-ventilating subject to breathe a gas, generating output signals conveying information related to parameters associated with the gas, determining a first and second breathing parameters from the generated output signals, regulating the breathing cues to adjust the first and/or second breathing parameter, and detecting an occurrence of a central apnea based on the first and/or second breathing parameter during delivery of breathing cues.

It is yet another aspect of one or more embodiments to provide a system configured to diagnose central sleep apnea of a subject during a test. The system comprises a means for delivering breathing cues to a self-ventilating subject that prompt the self-ventilating subject to breathe a gas, a means for generating one or more output signals conveying information related to one or more parameters associated with the gas, a means for determining a first breathing parameter and a second breathing parameter from the one or more generated output signals, a means for regulating the breathing cues to adjust the first and/or second breathing parameter, and a means for detecting an occurrence of a central apnea based on the first and/or second breathing parameter during delivery of breathing cues.

These and other objects, features, and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention.

FIG. **1** schematically illustrates a system configured to support diagnosis of central sleep apnea of a subject using a test; and

FIG. **2** illustrates a method for diagnosing central sleep apnea of a subject during a test.

As used herein, the singular form of "a", "an", and "the" include plural references unless the context clearly dictates otherwise. As used herein, the statement that two or more parts or components are "coupled" shall mean that the parts are joined or operate together either directly or indirectly, i.e., through one or more intermediate parts or components, so long as a link occurs. As used herein, "directly coupled" means that two elements are directly in contact with each other. As used herein, "fixedly coupled" or "fixed" means that two components are coupled so as to move as one while maintaining a constant orientation relative to each other.

As used herein, the word "unitary" means a component is created as a single piece or unit. That is, a component that includes pieces that are created separately and then coupled together as a unit is not a "unitary" component or body. As employed herein, the statement that two or more parts or components "engage" one another shall mean that the parts exert a force against one another either directly or through one or more intermediate parts or components. As employed herein, the term "number" shall mean one or an integer greater than one (i.e., a plurality).

Directional phrases used herein, such as, for example and without limitation, top, bottom, left, right, upper, lower, front, back, and derivatives thereof, relate to the orientation of the elements shown in the drawings and are not limiting upon the claims unless expressly recited therein.

Using a polysomnogram is a common way to diagnose central sleep apnea and similar breathing disorders in a patient, or "subject". The usage of polysomnograms is maligned for multiple reasons, including test complexity, test duration, patient discomfort, costs, and/or other reasons. Central sleep apnea (or central sleep apnea syndrome) is a collective term referring to breathing disorders including Cheyne-Stokes respiration, periodic breathing, and/or other breathing disorders.

FIG. **1** schematically illustrates a system **100** configured to support diagnosis of central sleep apnea of a subject using a test. In particular, system **100** delivers breathing cues to a subject **106**, monitors how well subject **106** follows the breathing cues during the comparatively short test detects any occurrence of central apneas during the test based on one or more breathing parameters, and supports a diagnosis of central sleep apnea by analyzing the monitored and detected information. The duration of the test is short compared to a full-night polysomnogram or sleep study, which can take eight hours or more. In one embodiment, system **100** comprises one or more of a processor **110**, a breathing cue device **140**, a sensor **142**, an electronic storage **130**, a user interface **120**, a subject interface **180**, and/or other components.

Breathing cue device **140** may be integrated, combined, or connected with a pressure generator or positive airway pressure (PAP) device configured to provide a pressurized flow of breathable gas to the airway of subject **106**, e.g. via subject interface **180**. Subject **106** may be self-ventilating and referred to as such throughout this specification. Self-ventilating, as used herein, refers to a subject initiating his or her own inspiration and/or expiration, regardless of pressure support or the occurrence of breathing cues. Breathing cue device **140** is configured to deliver breathing cues to subject **106** that prompt subject **106** to take respiratory action (e.g., begin an inhalation, begin an exhalation, and/or take other respiratory action). An example of a method implementing the stated function attributed to breathing cue device **140** is disclosed (as "paced breathing (PB) method") in U.S. patent application Ser. No. 11/836,292, filed Aug. 9, 2007, which is hereby incorporated by reference herein in its entirety.

In some embodiments, breathing cues prompting a subject to breathe in or out are implemented as a higher and lower positive pressure of a (multi-level) PAP device, respectively. For example, to prompt subject **106** to inhale, the pressure of the pressurized flow of breathable gas may be increased to an Inspiratory Positive Air Pressure (IPAP). Similarly, to prompt subject **106** to exhale, the pressure of the pressurized flow of breathable gas may be decreased to an Expiratory Positive Air Pressure (EPAP). Other schemes for providing breathing cues through the delivery of the pressurized flow of breathable gas are contemplated. A PAP device may be configured such that one or more gas parameters of the pressurized flow of breathable gas are controlled in accordance with a therapeutic respiratory regimen for subject **106**. The one or more gas parameters may include, for example, one or more of flow, pressure, humidity, velocity, acceleration, and/or other parameters. In one embodiment, breathing cue device **140** is part of a positive airway pressure device configured to provide types of therapy other than ventilation, including types of therapy where a subject performs expiration of his own accord or where the device provides negative pressure.

In certain embodiments, breathing cues may be sensory indications that one or more respiratory actions should be taken, that one or more events have occurred (or will occur), and/or indicating other information. Breathing cues may include one or more of an auditory indication, a visual indication, a tactile indication, and/or other indications. Indications may include a sequence of multiple auditory indications, visual indications, tactile indications, and/or other indications. An auditory indication may be an audible sound. A visual indication may be a flashing light. A tactile indication may be a vibration.

A pressurized flow of breathable gas may be delivered from breathing cue device **140** to the airway of subject **106** by a subject interface **180**. Subject interface **180** may include a conduit **182** and/or a subject interface appliance **184**. Conduit **182** may be a flexible length of hose, or other conduit, that places subject interface appliance **184** in fluid communication with breathing cue device **140**. Conduit **182** forms a flow path through which the pressurized flow of breathable gas is communicated between subject interface appliance **184** and breathing cue device **140**.

Subject interface appliance **184** may be configured to deliver the pressurized flow of breathable gas to the airway of subject **106**. As such, subject interface appliance **184** may include any appliance suitable for this function. In one embodiment, breathing cue device **140** is a dedicated ventilation device and subject interface appliance **184** is configured to be removably coupled with another interface appliance being used to deliver respiratory therapy to subject **106**. For example, subject interface appliance **184** may be configured to engage with and/or be inserted into an endotracheal tube, a tracheotomy portal, and/or other interface appliances. In one embodiment, subject interface appliance **184** is configured to engage the airway of subject **106** without an intervening appliance. In this embodiment, subject interface appliance **184** may include one or more of an endotracheal tube, a nasal cannula, a tracheotomy tube, a nasal mask, a nasal/oral mask, a full face mask, a total face mask, a partial rebreathing mask, or other interface appliances that communicate a flow of gas with an airway of a subject. The present disclosure is not limited to these examples, and contemplates delivery of the pressurized flow of breathable gas to subject **106** using any subject interface.

System **100** may include electronic storage **130** comprising electronic storage media that electronically stores information. The electronic storage media of electronic storage **130** may include one or both of system storage that is provided integrally (i.e., substantially non-removable) with system **100** and/or removable storage that is removably connectable to system **100** via, for example, a port (e.g., a USB port, a FireWire port, etc.) or a drive (e.g., a disk drive, etc.). Electronic storage **130** may include one or more of optically readable storage media (e.g., optical disks, etc.), magnetically readable storage media (e.g., magnetic tape, magnetic hard drive, floppy drive, etc.), electrical charge-based storage media (e.g., EEPROM, RAM, etc.), solid-state storage media (e.g., flash drive, etc.), and/or other electronically readable storage media. Electronic storage **130** may store software algorithms, information determined by processor **110**, information received via user interface **120**, and/or other information that enables system **100** to function properly. For example, electronic storage **130** may record or store one or more parameters (as discussed elsewhere herein), information indicating whether the self-ventilating subject adequately complied with the delivered breathing cues during the test, information indicating whether a central apnea occurred, and/or other information. Electronic storage **130** may be a separate component within system **100**, or electronic storage **130** may be provided integrally with one or more other components of system **100** (e.g., processor **110**).

System **100** may include user interface **120** configured to provide an interface between system **100** and a user (e.g., user **108**, subject **106**, a caregiver, a therapy decision-maker, etc.) through which the user can provide information to and receive information from system **100**. This enables data, results, and/or instructions and any other communicable items, collectively referred to as "information," to be communicated between the user and system **100**. An example of information that may be conveyed to subject **106** is a breathing cue or an indication related to a breathing cue that substantially coincides with a breathing cue. Information related to a breathing cue may include, for example, an instruction to begin exhaling, to end exhaling, to begin inhaling, to end inhaling, to breathe faster, to breathe slower, to increase flow, to decrease flow, to pause respiration, and/or to otherwise consciously alter one or more breathing parameters. Examples of interface devices suitable for inclusion in user interface **120** include a keypad, buttons, switches, a keyboard, knobs, levers, a display screen, a touch screen, speakers, a microphone, an indicator light, an audible alarm, and a printer. Information related to the breathing cues may e.g. be provided to subject **106** by user

interface **120** in the form of auditory signals, visual signals, tactile signals, and/or other sensory signals.

By way of non-limiting example, user interface **120** may include a radiation source capable of emitting light. The radiation source may include, for example, one or more of at least one LED, at least one light bulb, a display screen, and/or other sources. User interface **120** may control the radiation source to emit light in a manner that conveys to subject **106** information related to the breathing cues being provided to subject **106** by the pressurized flow of breathable gas. For instance, the radiation source may emit light when the breathing cues are prompting subject **106** to inhale, and may stop emitting light, or emit light of a different color, when the breathing cues are prompting subject **106** to exhale. The intensity of the light emitted by the radiation source may convey to subject **106** the magnitude of the flow that the breathing cues are prompting subject **106** to generate during respiration. Note that the subject and the user of system **100** may be one and the same person.

It is to be understood that other communication techniques, either hard-wired or wireless, are also contemplated herein as user interface **120**. For example, in one embodiment, user interface **120** may be integrated with a removable storage interface provided by electronic storage **130**. In this example, information is loaded into system **100** from removable storage (e.g., a smart card, a flash drive, a removable disk, etc.) that enables the user(s) to customize the implementation of system **100**. Other exemplary input devices and techniques adapted for use with system **100** as user interface **120** include, but are not limited to, an RS-232 port, RF link, an IR link, modem (telephone, cable, Ethernet, internet or other). In short, any technique for communicating information with system **100** is contemplated as user interface **120**.

Sensor **142** is configured to generate one or more output signals conveying measurements related to respiratory parameters, including one or more of flow, pressure, humidity, velocity, acceleration, and/or other respiratory parameters. Output signals may convey measurements related to parameters of thoracic respiratory effort, abdominal respiratory effort, and/or other respiratory effort parameters. Based on these respiratory parameter and/or respiratory effort parameters, parameter determination module **111** (and/or other components of system **100**) may be configured to determine one or more breathing parameters, including (tidal) volume, respiratory rate, breathing period, inhalation time or period, exhalation time or period, peak flow, flow rate, respiration flow curve shape, transition time from inhalation to exhalation and/or vice versa, transition time from peak inhalation flow rate to peak exhalation flow rate and/or vice versa, respiration pressure curve shape, and/or other breathing parameters. For example, a thoracic respiratory effort sensor may be operatively connected to the chest of the subject, and comprise a so-called effort belt. Alternatively, and/or simultaneously, an abdominal respiratory effort sensor may be operatively connected to the abdomen of the subject, and comprise an effort belt. Sensor **142** may be in fluid communication with conduit **182** and/or subject interface appliance **184**.

The illustration of sensor **142** as including a single member in FIG. **1** is not intended to be limiting. In one embodiment sensor **142** includes a plurality of sensors operating as described above by generating output signals conveying information related to parameters associated with the gas breathed by subject **106**, the delivery of the gas to subject **106**, and/or a respiratory effort by the subject. For example, a breathing parameter may be related to a mechanical unit of measurement of a component of breathing cue device **140** (or of a device that breathing cue device **140** is integrated, combined, or connected with) such as rotor speed, motor speed, blower speed, fan speed, or a related measurement that may serve as a proxy for any of the previously listed breathing parameters through a previously known/calibrated mathematical relationship. Resulting signals or information from sensor **142** may be transmitted to processor **110**, user interface **120**, and/or electronic storage **130**. This transmission can be wired and/or wireless.

Processor **110** is configured to provide information processing capabilities in system **100**. As such, processor **110** includes one or more of a digital processor, an analog processor, a digital circuit designed to process information, an analog circuit designed to process information, a state machine, and/or other mechanisms for electronically processing information. Although processor **110** is shown in FIG. **1** as a single entity, this is for illustrative purposes only. In some implementations, processor **110** includes a plurality of processing units.

As is shown in FIG. **1**, processor **110** is configured to execute one or more computer program modules. The one or more computer program modules include one or more of a parameter determination module **111**, a control module **112**, an event module **113**, a compliance module **114**, a quality-verification module **115**, and/or other modules. Processor **110** may be configured to execute modules **111**, **112**, **113**, **114**, and/or **115** by software; hardware; firmware; some combination of software, hardware, and/or firmware; and/or other mechanisms for configuring processing capabilities on processor **110**.

It should be appreciated that although modules **111**, **112**, **113**, **114**, and **115** are illustrated in FIG. **1** as being co-located within a single processing unit, in implementations in which processor **110** includes multiple processing units, one or more of modules **111**, **112**, **113**, **114**, and/or **115** may be located remotely from the other modules. The description of the functionality provided by the different modules **111**, **112**, **113**, **114**, and/or **115** described below is for illustrative purposes, and is not intended to be limiting, as any of modules **111**, **112**, **113**, **114**, and/or **115** may provide more or less functionality than is described. For example, one or more of modules **111**, **112**, **113**, **114**, and/or **115** may be eliminated, and some or all of its functionality may be provided by other ones of modules **111**, **112**, **113**, **114**, and/or **115**. Note that processor **110** may be configured to execute one or more additional modules that may perform some or all of the functionality attributed below to one of modules **111**, **112**, **113**, **114**, and/or **115**.

Parameter determination module **111** is configured to determine one or more breathing parameters from the output signals generated by sensor **142**. The one or more breathing parameters may include a first breathing parameter, a second breathing parameter, and/or other parameters. A breathing parameter may include a respiratory parameter derived from one or more gas parameters of the pressurized flow of breathable gas. Such (gas) parameters may include one or more of a tidal volume of the breathing of the self-ventilating subject, a respiratory rate, an inhalation time, an exhalation time, a flow rate of the breathing of the self-ventilating subject, and/or other breathing parameters. Breathing parameters may be related to and/or derived from measurements of one or more of (peak) flow, pressure, temperature, humidity, velocity, acceleration, gas composition (e.g. concentration(s) of one or more constituents), thermal energy dissipated, and/or other gas parameters of the pressurized flow of breathable gas. Breathing parameters may be associated with specific timing within a breathing cycle or within

the duration of the test. For example, end pressure may be measured at the end of an expiration when the flow at of near the airway of the subject is minimized. Additionally, breathing parameters may indicate respiratory effort of subject **106**. This may include one or more of a thoracic respiratory effort, an abdominal respiratory effort of the self-ventilating subject, and/or other parameters indicating respiratory effort. In certain embodiments a breathing parameter may be related to and/or derived from a similar measurement as used to generate another breathing parameter, though using a different specific timing within a breathing cycle or within the duration of the test. For example, the first breathing parameter and the second breathing parameter could both be a duration of exhalation. As another example, the first breathing parameter and the second breathing parameter could both indicate thoracic respiratory effort.

Control module **112** is configured to control breathing cue device **140** in the provision of breathing cues to subject **106**. As such, control module **112** may control the timing, the type, the magnitude, and/or other aspects of the breathing cues in accordance with a therapy regime to adjust one or more parameters of the respiration of subject **106**. Such parameters may include a first breathing parameter determined by parameter determination module **111**. The determination of the first breathing parameter may be used by control module **112** in a feedback manner in determining the breathing cues that should be provided to subject **106**. For example, by increasing the rate of the breathing cues, the respiratory rate of subject **106** is increased. As another example, by increasing the rate of the breathing cues, the rate of signals indicating thoracic respiratory effort is increased.

In implementations in which the breathing cues include the elevation of pressure to IPAP to prompt inhalation, and the lowering of EPAP to prompt exhalation, control module **112** may determine the appropriate levels of IPAP and EPAP. This determination may be based on one or more user configurable settings, based on measurements taken during spontaneous respiration by subject **106**, responsiveness of subject **106** to the breathing cues, and/or other parameters. Control module **112** may be configured to adjust the pressure difference between IPAP and EPAP (e.g., on one or more of the basis described herein). Pressure differences may be less than 3 cm-H_2O, less than 4 cm-H_2O, less than 5 cm-H_2O, less than 6 cm-H_2O, more than 1 cm-H_2O, more than 2 cm-H_2O, between 2 and 6 cm-H_2O, between 1 and 5 cm-H_2O, and/or other pressure difference minimums, pressure difference maximums, or ranges of pressure differences. It will be appreciated that the unit of pressure used herein is not limited to cm-H_2O, which is commonly used in relation to the operation of PAP devices.

Event module **113** is configured to detect an occurrence of a central apnea based on a breathing parameter—determined by parameter determination module **111**—during delivery of breathing cues by breathing cue device **140**. For example, event module **113** can detect a lack (or significantly reduced level) of respiratory effort (e.g., thoracic respiratory effort and/or abdominal respiratory effort). The lack of effort may be accompanied by a significant reduction in tidal volume (and/or other breathing parameters). As another example, event module **113** can detect if cessation of breathing has occurred by monitoring, measuring, and/or analyzing tidal volume, duration of exhalation, and/or other (gas) parameters. Such a detection may indicate the occurrence of a central apnea during the test. The occurrence of a central apnea during a test duration is a prerequisite for a diagnosis of central sleep apnea.

Compliance module **114** is configured to determine whether the self-ventilating subject adequately complies with the breathing cue delivered by breathing cue device **140**. For example, compliance module **114** may compare (the timing of) breathing cues by breathing cue device **140** with measurements of a respiratory timing (e.g., inhalation start, exhalation start, respiratory rate, and/or other parameters indicating respiratory timing), to determine whether subject **106**, at least for a part of the test, follows the breathing cues properly. It will be appreciated that subject **106** does not follow breathing cues during the occurrence of a central apnea, compliance module **114** is configured to detect instances in which subject **106** is breathing spontaneously, but not following the breathing cues. Compliance with the breathing cues is a prerequisite for a diagnosis of central sleep apnea.

Quality-verification module **115** is configured to verify whether the test was conducted in compliance with a set of quality guidelines. The set of quality guidelines may include a minimum duration of the test, a proper (supine) positioning of subject **106** during the test, a leakage level of the delivery of gas within a predetermined level of acceptable leakage, a difference between higher and lower levels of pressure within a predetermined level of acceptable difference for a test of the nature described herein, and/or other quality guidelines. The test duration may be ten minutes, fifteen minutes, twenty minutes, more than 20 minutes, and/or other time durations. Any test duration shorter than eight hours is short compared to a full-night polysomnogram or sleep study. The methods disclosed herein may be conducted when the subject is awake (during wakefulness), at sleep onset, during sleep, or during a combination of the previous states.

FIG. **2** illustrates a method **200** for diagnosing central sleep apnea of a subject during a test. The operations of method **200** presented below are intended to be illustrative. In some embodiments, method **200** may be accomplished with one or more additional operations not described, and/or without one or more of the operations discussed. Additionally, the order in which the operations of method **200** are illustrated in FIG. **2** and described below is not intended to be limiting.

In some embodiments, method **200** may be implemented in one or more processing devices (e.g., a digital processor, an analog processor, a digital circuit designed to process information, an analog circuit designed to process information, a state machine, and/or other mechanisms for electronically processing information). The one or more processing devices may include one or more devices executing some or all of the operations of method **200** in response to instructions stored electronically on an electronic storage medium. The one or more processing devices may include one or more devices configured through hardware, firmware, and/or software to be specifically designed for execution of one or more of the operations of method **200**.

At an operation **202**, breathing cues are delivered to a self-ventilating subject that prompt the self-ventilating subject to breathe a gas. In one embodiment, operation **202** is performed by a breathing cue device similar to or substantially the same as breathing cue device **140** (shown in FIG. **1** and described above).

At an operation **204**, one or more output signals conveying information related to one or more parameters associated with the gas are generated. In one embodiment, operation **204** is performed by one or more sensors similar to or substantially the same as sensor **142** (shown in FIG. **1** and described above).

At an operation **206**, a first breathing parameter and a second breathing parameter are determined from the one or more generated output signals. In one embodiment, operation **206** is performed by a parameter determination module similar to or substantially the same as parameter determination module **111** (shown in FIG. **1** and described above), operating in conjunction with one or more sensors similar to or substantially the same as sensor **142** (shown in FIG. **1** and described above).

At an operation **208**, the breathing cues are regulated to adjust the first breathing parameter. In one embodiment, operation **208** is performed by a control module similar to or substantially the same as control module **112** (shown in FIG. **1** and described above), operating in conjunction with a parameter determination module similar to or substantially the same as parameter determination module **111** (shown in FIG. **1** and described above).

At an operation **210**, an occurrence of a central apnea is detected during delivery of breathing cues to a self-ventilating subject, based on the second breathing parameter. In one embodiment, operation **210** is performed by an event module similar to or substantially the same as event module **113** (shown in FIG. **1** and described above), operating in conjunction with a parameter determination module similar to or substantially the same as parameter determination module **111** (shown in FIG. **1** and described above). For example, method **200** may be used to diagnose central sleep apnea of a self-ventilating subject during a test of relatively short duration by combining a first breathing parameter, a second breathing parameter, the information whether the self-ventilating subject adequately complied with the delivered breathing cues during the test, the information whether a central apnea occurred, and/or other information.

In the claims, any reference signs placed between parentheses shall not be construed as limiting the claim. The word "comprising" or "including" does not exclude the presence of elements or steps other than those listed in a claim. In a device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The word "a" or "an" preceding an element does not exclude the presence of a plurality of such elements. In any device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The mere fact that certain elements are recited in mutually different dependent claims does not indicate that these elements cannot be used in combination.

Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

The invention claimed is:

1. A system configured to support diagnosis of central sleep apnea of a subject using a test, the system comprising:

a device configured to deliver breathing cues by altering a pressure of a pressurized flow of breathable gas to a self-ventilating subject that prompt the self-ventilating subject to breathe the breathable gas;

one or more sensors that generate one or more output signals conveying information related to one or more parameters associated with the breathable gas; and

one or more processors configured by machine-readable instructions to:

determine a first breathing parameter and a second breathing parameter from the one or more output signals generated by the one or more sensors;

control the device to regulate the breathing cues provided to the self-ventilating subject to adjust the first breathing parameter;

detect an occurrence of a central apnea based on the second breathing parameter during delivery of breathing cues; and

verify whether the test was conducted in compliance with a set of quality guidelines, the set of quality guidelines including one or more of a minimum duration of the test; a proper positioning of subject during the test; a leakage level of the delivery of the breathable gas being within a predetermined level of leakage; or a difference between higher and lower levels of pressure being within a predetermined level of difference for the test.

2. The system of claim **1**, wherein the one or more processors are further configured to determine whether the self-ventilating subject adequately complies with the delivered breathing cues.

3. The system of claim **1**, wherein the one or more output signals convey information related to one or more of a tidal volume of the breathing of the self-ventilating subject, a respiratory rate, an inhalation time, an exhalation time, or a flow rate of the breathing of the self-ventilating subject.

4. The system of claim **1**, wherein the one or more output signals convey information related to one or both of a thoracic respiratory effort of the self-ventilating subject and/or an abdominal respiratory effort of the self-ventilating subject.

5. A method of diagnosing central sleep apnea of a subject during a test, the method comprising:

delivering, using a device, breathing cues by altering a pressure of a pressurized flow of breathable gas to a self-ventilating subject that prompt the self-ventilating subject to breathe the breathable gas;

generating, using one or more sensors, one or more output signals conveying information related to one or more parameters associated with the breathable gas;

determining, using one or more processors, a first breathing parameter and a second breathing parameter from the one or more generated output signals;

controlling, using the one or more processors, the device to regulate the breathing cues to adjust the first breathing parameter;

detecting, using the one or more processors, an occurrence of a central apnea based on the second breathing parameter during delivery of breathing cues, and

verifying, using the one or more processors, whether the test was conducted in compliance with a set of quality guidelines, the set of quality guidelines including one or more of a minimum duration of the test, a proper positioning of subject during the test, a leakage level of the delivery of the breathable gas being within a predetermined level of leakage, or a difference between higher and lower levels of pressure being within a predetermined level of difference for the test.

6. The method of claim **5**, further comprising determining whether the self-ventilating subject adequately complies with the delivered breathing cues.

7. The method of claim 5, wherein the one or more output signals convey information related to one or both of a thoracic respiratory effort of the self-ventilating subject and/or an abdominal respiratory effort of the self-ventilating subject.

8. The method of claim 5, wherein the one or more output signals convey information related to one or more of a tidal volume of the breathing of the self-ventilating subject, a respiratory rate, an inhalation time, an exhalation time, or a flow rate of the breathing of the self-ventilating subject.

9. A system configured to diagnose central sleep apnea of a subject during a test, the method comprising:

means for delivering breathing cues by altering a pressure of a pressurized flow of breathable gas to a self-ventilating subject that prompt the self-ventilating subject to breathe the breathable gas;

means for generating one or more output signals conveying information related to one or more parameters associated with the breathable gas;

means for determining a first breathing parameter and a second breathing parameter from the one or more generated output signals;

means for regulating the breathing cues to adjust the first breathing parameter;

means for detecting an occurrence of a central apnea based on the second breathing parameter during delivery of breathing cues; and

means for verifying whether the test was conducted in compliance with a set of quality guidelines, the set of quality guidelines including one or more of a minimum duration of the test; a proper positioning of subject during the test; a leakage level of the delivery of the breathable gas being within a predetermined level of leakage; or a difference between higher and lower levels of pressure being within a predetermined level of difference for the test.

10. The system of claim 9, further comprising means for determining whether the self-ventilating subject adequately complies with the delivered breathing cues.

11. The system of claim 9, wherein the one or more output signals convey information related to one or more of a tidal volume of the breathing of the self-ventilating subject, a respiratory rate, an inhalation time, an exhalation time, or a flow rate of the breathing of the self-ventilating subject.

12. The system of claim 9, wherein the one or more output signals convey information related to one or both of a thoracic respiratory effort of the self-ventilating subject and/or an abdominal respiratory effort of the self-ventilating subject.

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摘要(译)

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