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(54) **REVERSE DUAL POSITIVE AIRWAY PRESSURE CHALLENGES FOR BREATHING DISORDER DIAGNOSTICS**

PROVOKATIONSTESTS FÜR UMGEKEHRTEN DUALEN POSITIVEN ATEMWEGDRUCK ZUR DIAGNOSE VON ATEMSTÖRUNGEN

TESTS DE PROVOCATION DE PRESSION EXPIRATOIRE POSITIVE DOUBLE INVERSE POUR DIAGNOSTICS DE TROUBLE RESPIRATOIRE

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(73) Proprietor: **Koninklijke Philips N.V.**
5656 AE Eindhoven (NL)

(72) Inventors:
- **COLBAUGH, Michael Edward**
  5656 AE Eindhoven (NL)
- **HUESER, Lauren Elizabeth**
  5656 AE Eindhoven (NL)
- **VISSAPRAGADA VENKATA SATYA, Surya Subrahmanya**
  Sreeram
  5656 AE Eindhoven (NL)

(74) Representative: **Schudelaro, Antonius Adrianus Petrus**
Philips Intellectual Property & Standards
High Tech Campus 5
5656 AE Eindhoven (NL)

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Description

BACKGROUND

1. Field

[0001] The present disclosure pertains to systems for classifying breathing disorders of subjects. In particular, the present disclosure pertains to adjusting the pressure level of a pressurized flow of breathable gas and determining a classification based on the respiratory response by a subject.

2. Description of the Related Art

[0002] Some types of respiratory therapy involve the delivery of a pressurized flow of breathable gas to the airway of a subject. A therapy session may (be intended to) span eight or more hours, and may (be intended to) coincide and/or overlap, at least in part, with a subject's daily and/or nightly sleeping period. A subject's comfort during a therapy session is a useful factor in therapy adoption rates and/or therapy success rates.

SUMMARY

[0003] Accordingly the present invention provides a system configured to classify a breathing disorder of a subject that includes a pressure generator, one or more sensors, and one or more physical processors according to claim 1. In some embodiments, the pressure levels during inspiration and expiration may be adjusted upward and/or downward independently of each other.

[0004] US5535738 discloses a proportional positive airway pressure device comprising a pressure generator configured to provide a pressurized flow of breathable gas at a pressure level to an airway of a subject; one or more sensors configured to generate output signals conveying information related to breathing of the subject; and one or more physical processors configured to obtain a recommended respiratory therapy regimen for the subject. These and other aspects, features, and characteristics of the present disclosure, 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 disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005]

FIG. 1 schematically illustrates a system to classify breathing disorders, according to certain embodiments;

FIG. 2 illustrates a method to classify a breathing disorder of a subject, according to certain examples, not part of the invention;

FIG. 3 illustrates a varying pressure level of a pressurized flow of breathable gas provided to a subject and further illustrates a corresponding flow rate of the subject that may be used to classify a breathing disorder according to certain embodiments.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0006] 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 to move as one while maintaining a constant orientation relative to each other.

[0007] 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 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).

[0008] 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.

[0009] A subject's comfort during a therapy session may be a useful and/or important factor in therapy adoption rates and/or therapy success rates. Due to poor comfort, many subjects do not like (CPAP) therapy. For example, approximately 50% of subjects quit using CPAP therapy within several months. It is generally held that 50% of the affected population does not choose to seek medical care for Sleep Disorder Breathing (SDB) in the first place, with one of the main reasons being that the CPAP is considered an unacceptable treatment. There are a growing number of alternative treatments that are viewed more favorably by the under-served, but the issue is that virtually all of those alternatives only treat specific segments of the patient population, due to the fact that

these alternatives treat only specific causes of obstruction or airway instability. These alternatives may be successful responsive to a given subject having success with treating their particular SBD root cause, in addition to the general use of the intervention being acceptable to them. By virtue of this disclosure, subjects may be increasingly confident in knowing that the treatment will work in a particular case, since the particular root cause may be determine and/or classified. Once a root cause has been determined and/or classified, more viable options may be provided to a subject that are customized for the individual subject's problems and preferences.

[0010] FIG. 1 schematically illustrates a system 100 configured to classify breathing disorders for subjects, for example a subject 106 having an airway. Classification of breathing disorders, in particular by the source or (root) cause of a disorder, may enable selection of a proper intervention and/or treatment. Classifying subjects or patients (based on the type of breathing disorder) may be referred to as phenotyping patients. A subject's phenotype may determine (and/or be used to determine) the interventions and type of care most likely and/or best suited to treat their condition or disease.

[0011] System 100 may be implemented as, integrated with, and/or operating in conjunction with a respiratory device that provides a pressurized flow of breathable gas along a flow path to subject 106. System 100 may include one or more of a pressure generator 140, a subject interface 180, one or more sensors 142, an electronic storage 130, a user interface 120, a processor 110, a therapy component 111, a timing component 112, a control component 113, a challenge component 114, a breathing parameter component 115, a classification component 116, a relief component 117, a stability component 118, and/or other components. System 100 may be configured to provide respiratory therapy to subject 106.

[0012] Pressure generator 140 of system 100 in FIG. 1 may be integrated, combined, or connected with a ventilator and/or (positive) airway pressure device (PAP/CPAP/BiPAP®/*etc.*) and configured to provide a pressurized flow of breathable gas for delivery to the airway of subject 106, *e.g.* via one or more subject interfaces 180. Subject interface 180 may sometimes be referred to as a delivery circuit.

[0013] As depicted in FIG. 1, pressure generator 140 fluidly communicates with subject interface 180. Subject interface 180 fluidly communicates, via a subject interface appliance 184, with the airway of subject 106. The configuration of various components in FIG. 1 is not intended to limit the scope of the described technology in any way. For example, in some examples, system 100 may include a humidifier and/or interface heating system disposed between pressure generator 140 and subject 106.

[0014] Respiratory therapy may be implemented as pressure control, pressure support, volume control, and/or other types of support and/or control. For example, to support inspiration, the pressure of the pressurized flow of breathable gas may be adjusted to an inspiratory positive airway pressure (interchangeably referred to as inspiratory pressure, IPAP, or IPAP level). Alternatively, and/or simultaneously, to support expiration, the pressure and/or flow of the pressurized flow of breathable gas may be adjusted to an expiratory positive airway pressure (interchangeably referred to as expiratory pressure, EPAP, or EPAP level). Other schemes for providing respiratory support and/or ventilation through the delivery of the pressurized flow of breathable gas are contemplated. Subject 106 may but need not initiate one or more phases of respiration. Devices that provide different IPAP and EPAP levels may be referred to as dual (positive) airway pressure devices. An example of a dual positive airway pressure device is a BiPAP® device. Typically for dual positive airway pressure devices, the IPAP level is higher than the EPAP level. As used herein, providing a lower IPAP level than EPAP level may be referred to as reverse dual positive airway pressure, since it is the opposite of typical dual positive airway pressure.

[0015] System 100 may be configured to adjust and/or maintain levels of pressure, flow, humidity, velocity, acceleration, and/or other parameters of the humidified, pressurized flow of breathable gas. One or more adjustments may occur in substantial synchronization with the breathing cycle of the subject. In some examples, one or more operating levels (*e.g.* pressure, volume, *etc.*) are adjusted on a relatively ongoing manner (*e.g.*, each breath, every few breaths, every few seconds, *etc.*) during an individual session of respiratory therapy to titrate the therapy. Alternatively, and/or simultaneously, adjustments to one or more operating levels of system 100 and/or any component thereof may be made more intermittently and/or between therapy sessions rather than during a particular therapy session.

[0016] Pressure generator 140 is configured to provide and/or deliver a pressurized flow of breathable gas to the airway of subject 106, *e.g.* via one or more subject interfaces 180. Subject interface 180 may include a conduit 182 and/or a subject interface appliance 184. As depicted in FIG. 1, subject interface 180 may include a conduit 182. Conduit 182 may include a flexible length of hose, or other conduit. As depicted in FIG. 1, conduit 182 may place subject interface appliance 184 in fluid communication with pressure generator 140. Conduit 182 may form a flow path through which the pressurized flow of breathable gas is communicated between subject interface appliance 184 and pressure generator 140.

[0017] Subject interface appliance 184 of system 100 in FIG. 1 is configured to deliver the pressurized flow of breathable gas to subject 106, *e.g.* to the airway of subject 106. Subject interface appliance 184 may be configured to reduce and/or inhibit condensation from forming along the path of delivery of a pressurized flow of breathable gas to subject 106. Subject interface appliance 184 may include any appliance suitable for the described function.

[0018] In some examples, pressure generator 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 example, subject interface appliance 184 is configured to engage the airway of subject 106 without an intervening appliance. In this example, 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 facemask, and/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.

[0019] Subject interface appliance 184 may be configured to be removably coupled to conduit 182. Subject interface appliance 184 may be configured to be installed in the face of subject 106 to place the airway of subject 106 in fluid communication with conduit 182 for delivery of a pressurized flow of breathable gas through conduit 182 to the airway of subject 106.

[0020] Electronic storage 130 of system 100 in FIG. 1 comprises physical electronic storage media that electronically stores information, *e.g*. digital 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*., EPROM, 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 gas and/or respiratory parameters (as discussed elsewhere herein), 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).

[0021] User interface 120 of system 100 in FIG. 1 is configured to provide an interface between system 100 and a user (*e.g*., a 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 user 108 is a report detailing operational settings of pressure generator 140 as selected and/or preferred by subject 106. An example of information that user 108 or subject 106 may provide to system 100 is a target temperature or target pressure level during respiratory therapy. Examples of interface devices suitable for inclusion in user interface 120 include a keypad, buttons, switches, a keyboard, knobs, dials, levers, a display screen, a touch screen, speakers, a microphone, an indicator light, an audible alarm, and a printer. Information may be provided to user 108 or subject 106 by user interface 120 in the form of auditory signals, visual signals, tactile signals, and/or other sensory signals.

[0022] It is to be understood that other communication techniques, either hardwired or wireless, are also contemplated herein as user interface 120. For example, in one example, 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 example 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.

[0023] One or more sensors 142 of system 100 in FIG. 1 are configured to generate output signals conveying information related to the breathing of subject 106 and/or to physiological parameters of subject 106, including but not limited to respiratory parameters. One or more sensors 142 may be in fluid communication with conduit 182, subject interface appliance 184, and/or other components of system 100. In some embodiments, the generated output signals may convey measurements related to parameters of the flow of breathable gas within system 100. By way of non-limiting example, the parameters may include respiratory parameters, timing parameters, physiological parameters, environmental parameters, medical parameters, and/or other parameters.

[0024] The parameters may include one or more of (peak) flow, flow rate, volume, leak flow, leak volume, (airway) pressure, barometric pressure, temperature, humidity, velocity, acceleration, and/or other parameters. The respiratory parameters may include respiratory timing parameters, including but not limited to parameters related to transitions in breathing between inhalations/inspirations and exhalations/expirations, transition time from peak inhalation flow rate to peak exhalation flow rate and/or *vice versa,* transitions moments or durations, breathing period, respiratory rate, inspiration time or period, expiration time or period, start and/or end in inspiratory phases, start and/or end of expiratory phases,

and/or other respiratory timing parameters.

[0025] Environmental parameters may be related to one or more of the parameters of electromagnetic radiation, various temperatures, humidity levels, and/or other environmental parameters, which may be related to environmental conditions near system 10 or near subject 106. One or more medical parameters may be related to monitored vital signs of subject 106, physiological parameters of subject 106, and/or other medical parameters of subject 106.

[0026] One or more sensors 142 may generate output signals conveying information related to parameters associated with the state and/or condition of an airway of subject 106, the breathing of subject 106, the breathing rate of subject 106, the gas delivered to subject 106, the composition, temperature, and/or humidity of the gas delivered to subject 106, the delivery of the gas to the airway of subject 106, and/or a respiratory effort by the subject. For example, a parameter may be related to a mechanical unit of measurement of a component of pressure generator 140 (or of a device that pressure generator 140 is integrated, combined, or connected with) such as valve drive current, rotor speed, motor speed, blower speed, fan speed, or a related measurement that may serve as a proxy for any of the previously listed parameters through a previously known and/or calibrated mathematical relationship. Resulting signals or information from one or more sensors 142 may be transmitted to processor 110, user interface 120, electronic storage 130, and/or other components of system 100. This transmission may be wired and/or wireless.

[0027] Physiological parameters may be related to patient movement, cardiovascular function, pulmonary function, central nervous system function, local motor-neuron function, mechanical motion of the body or its organs, and/or other parameters. In some examples, sensor 142 may include sensors to monitor subject 106, including, but not limited to, sensors to measure polysomnography, electro-encephalography (EEG), electro-oculography (EOG), electromyography (EMG), electro-cardiography (ECG), and/or sensors for other types of monitoring.

[0028] The illustration of sensor 142 including one member in FIG. 1 is not intended to be limiting. The illustration of a sensor 142 at or near subject interface appliance 184 is not intended to be limiting, though that location may be preferred in some examples to provide feedback and/or information regarding the current flow rate of the pressurized flow of breathable gas being delivered to the airway of subject 106. For example, this current flow rate may function as feedback for a target flow rate for controlling pressure generator 140.

[0029] Processor 110 of system 100 in FIG. 1 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, 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 examples, processor 110 includes a plurality of processing units.

[0030] As is shown in FIG. 1, processor 110 is configured to execute one or more computer program components. The one or more computer program components include one or more of therapy component 111, timing component 112, control component 113, challenge component 114, breathing parameter component 115, classification component 116, relief component 117, stability component 118, and/or other components. Processor 110 may be configured to execute components 111-118 by software; hardware; firmware; some combination of software, hardware, and/or firmware; and/or other mechanisms for configuring processing capabilities on processor 110.

[0031] It should be appreciated that although components 111-118 are illustrated in FIG. 1 as being co-located within a single processing unit, in examples in which processor 110 includes multiple processing units, one or more of components 111-118 may be located remotely from the other components. The description of the functionality provided by the different components 111-118 described herein is for illustrative purposes, and is not intended to be limiting, as any of components 111-118 may provide more or less functionality than is described. For example, one or more of components 111-118 may be eliminated, and some or all of its functionality may be provided by other ones of components 111-118. Note that processor 110 may be configured to execute one or more additional components that may perform some or all of the functionality attributed below to one of components 111-118. In some examples, some or all of the described functionality of an individual computer program component may be incorporated, shared, embedded, and/or integrated into one or more other computer program components or elsewhere within system 100.

[0032] Therapy component 111 may be configured to obtain a respiratory therapy regimen for subject 106. For example, the obtained respiratory therapy regimen may be a recommended respiratory therapy regimen. In some examples, therapy component 111 may be configured to obtain a respiratory therapy regimen from a user (such as subject 106 and/or user 108, a caregiver, a therapy decision-maker, *etc.*). In some examples, therapy component 111 may be configured to obtain and/or receive a respiratory therapy regimen that may be determined and/or devised algorithmically based on, at least, subject-specific information. In some examples, therapy component 111 may be configured to determine a recommended respiratory therapy regimen, e.g. based on, at least, subject-specific information. Additional information that may be used to determine a respiratory therapy regimen may be obtained from and/or through a knowledge base (or knowledge database).

[0033] In some examples, the obtained respiratory therapy regimen may include a recommended inspiratory

positive airway pressure (IPAP) level, a recommended expiratory positive airway pressure (EPAP) level, and/or other recommended pressure levels. In some examples, the recommended pressure levels may be determined and/or selected to maintain breathing by subject 106 that is free of apneas, hypopneas, and/or other respiratory events, or at least expected to be so. In some examples, the recommended pressure levels may be determined and/or selected such that the airway of subject 106 is deemed and/or expected to be stable and/or unobstructed. In some examples, the recommended pressure levels may be selected to be below a prescribed continuous positive airway pressure (CPAP) level to treat apnea and/or other respiratory events. Determinations and/or selections by therapy component 111 may be based on determinations by other computer program components, including but not limited to stability component 118.

[0034] Timing component 112 may be configured to determine one or more timing parameters related to the breathing of subject 106, including but not limited to respiratory timing parameters described elsewhere in this disclosure. For example, timing parameters may include the moment of onset of inspiration, the moment of onset of expiration, (estimated or measured) duration or period of inspiration, (estimated or measured) duration or period of expiration, pause between inspiration and expiration and/or *vice versa,* transition time from peak inhalation flow rate to peak exhalation flow rate and/or *vice versa,* start and/or end in inspiratory phases, start and/or end of expiratory phases, and/or other respiratory timing parameters, combinations of respiratory timing parameters, and/or parameters based thereon.

[0035] Control component 113 may be configured to control operation of system 100, pressure generator 140, and/or related components. Control component 113 may be configured to perform control functionality in multiple modes of operation. Control component 113 may be configured to control transitions between different modes of operation. Control component 113 may be configured to determine what the current mode of operation is, and/or share such information with other components of system 100. Control component 113 may be configured to control pressure generator 140 such that one or more gas parameters of the pressurized flow of breathable gas are varied over time in accordance with a respiratory therapy regimen. Control component 113 may be configured to control pressure generator 140 to provide the pressurized flow of breathable gas at inhalation pressure levels (*e.g.* the recommended IPAP level) during inhalation phases, and at exhalation pressure levels (*e.g.* the recommended EPAP level) during exhalation phases. For example, a first mode may correspond to providing challenges to subject 106, as described elsewhere in this disclosure. A second mode of operation may correspond to providing relief to subject 106 after a particular obstruction or other respiratory event has occurred. Other modes of operation are envisioned within the scope of this disclosure.

[0036] Parameters determined by other computer program components and/or received through one or more sensors 142 may be used by control component 113, *e.g.* in a feedback manner, to adjust one or more therapy modes/settings/operations of system 100. Alternatively, and/or simultaneously, signals and/or information received through user interface 120 may be used by control component 113, *e.g.* in a feedback manner, to adjust one or more therapy modes/settings/operations of system 100. Control component 113 may be configured to time its operations relative to the transitional moments in the breathing cycle of a subject, over multiple breath cycles, and/or in any other relation to any detected occurrences or determinations by timing component 112.

[0037] Challenge component 114 may be configured to adjust one or more pressure levels of the pressurized flow of breathable gas being delivered to subject 106. In some examples, the provided pressure levels during inspiration and expiration may be adjusted upward and/or downward independently of each other. For example, challenge component 114 may be configured to reduce the inspiratory pressure level to be below the recommended IPAP level, for one or more breathing cycles. According to the invention, the reduced inspiratory level may be lower than the recommended and/or actually provided expiratory pressure level. In some examples, a subject may be initially titrated to a particular CPAP level or two particular BiPAP levels that may enable the subject to breathe normally (*i.e.* in a eupneic state, or a state of being treated), for example as characterized by the subject's body exhibiting compensatory functions at a minimum level of activity, *e.g.* removing the body's need to overcome a challenge, obstruction, condition, and/or disease. A set of one or more breathing cycles for which the inspiratory pressure level is reduced may be referred to as a challenge, since the subject will need to compensate in response. The response to the adjustment, e.g. to the reduced IPAP level, may be indicative of a type of obstruction, and/or may be used as a basis for a classification by classification component 116. Subjects having different types of breathing disorders may respond differently to certain challenges. In some examples, the response may be indicative of the airway reactivity to changes in lung volume and/or airway pressure. By virtue of separate and individual pressure control for the respiratory phases, interaction between the respiratory phases may be assessed.

[0038] In some examples, challenge component 114 may be configured to provide a set of challenges, *e.g.* such that subsequent challenges have different levels of inspiratory pressure levels. In some examples, the inspiratory pressure level may be repeatedly reduced through subsequent challenges until a particular condition occurs. The particular condition may include a timing parameter and/or breathing parameter breaching a particular threshold. In some examples, the particular condition may be a determination that the stability of the airway has been compromised, e.g. through an obstruction, an

arousal, a type of apnea, hypopnea, or other respiratory event, a type of sleep disordered breathing (SDB), *etc.* In some examples, the particular condition may be a determination that indicates airway instability. As used herein, an onset of airway instability may be considered an indication of airway instability. Alternatively, and/or simultaneously, a determination that the stability of the airway has been compromised may be considered an indication of airway instability. The particular challenge at which the particular condition occurs may be referred to as a point of interest for diagnostic purposes. For example, the IPAP level may be reduced gradually until some type of respiratory event (or obstruction in the airway of subject 106) occurs. The amount of reduced pressure needed to accomplish a particular occurrence may be used as a parameter by other computer program components, including but not limited to classification component 116. The IPAP level may be reduced temporarily, during challenges, to a pressure level below traditional treatment levels. For example, the reduced IPAP pressure level may be about 1 cm-H_2O, about 2 cm-H_2O, about 3 cm-H_2O, about 4 cm-H_2O, about 5 cm-H_2O, about 6 cm-H_2O, and/or another suitable pressure level.

[0039] In some examples, challenge component 114 may be configured to provide one or more challenges with respect to a point of interest. For example, challenge component 114 may be configured to reduce the EPAP level at such a point in order to determine (one or more parameters indicative of) how subject 106 responds. For example, the response may indicate a sensitivity of subject 106 to adjustments at or near a particular point of interest. In some examples, the response by subject 106 to a reduced EPAP level (in addition to a reduced IPAP level) may indicate severe airway instability (*e.g.* limited or no flow being measured). The particular EPAP adjustment that corresponds to such an indication may be referred to as a point of interest for diagnostic purposes. At various points of interest, adjustments to the inspiratory pressure and/or expiratory pressure may be made, in order to determine a response by subject 106. Responses by subject 106 to one or more pressure adjustments, in particular at or near points of interest, may be used as a basis for a classification by classification component 116.

[0040] Breathing parameter component 115 may be configured to determine one or more breathing parameters of subject 106, *e.g.* for the one or more breathing cycles that correspond to a challenge. Determinations by breathing component 115 may be based on output signals generated by one or more sensors 142 and/or determinations by other computer program modules. As used herein, breathing parameters may include gas parameters.

[0041] By way of non-limiting example, breathing parameters may include one or more of (peak) flow, flow rate, leak flow, leak correction volume, (estimated) flow limitation during exhalation, residual volume, maximum inspiratory flow per breath, (tidal) volume, minute volume, inhalation or exhalation pressures, respiratory rate, breathing period, inhalation time or period, exhalation time or period, 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, maximum proximal pressure drop (per breathing cycle and/or phase), change in pressure during the first 0.1 s of an inspiration, change in flow rate during the last 0.1 s of an exhalation, (estimated) airway resistance, (estimated) airway compliance, gas temperature, gas humidity, gas velocity, gas acceleration, gas composition (*e.g.* concentration(s) of one or more constituents such as, *e.g.*, CO_2), thermal energy dissipated, (intentional) gas leak, and/or other measurements related to the (pressurized) flow of breathable gas and/or other breathing parameters. In some examples, a breathing parameter may include ratios and/or other combinations of multiple other parameters. Some or all of this functionality may be incorporated, shared, and/or integrated into other computer program components in system 100.

[0042] By way of non-limiting example, the one or more breathing parameters may include a delay parameter that indicates a delay between an onset of an inspiratory phase that has a reduced pressure level and a change in inspiratory flow rate that corresponds to the onset of the inspiratory phase. In some examples, the delay parameter may have a different value for different types of challenges, depending on the type of obstruction and/or breathing disorder. The delay parameter may be indicative of a particular type of obstruction and/or breathing disorder. In some examples, the delay parameter may change between different challenges, which may be indicative of a particular type of obstruction and/or breathing disorder. In some examples, the delay parameter may be substantially constant between different challenges, which may be indicative of another particular type of obstruction and/or breathing disorder. In some examples, the delay parameter may be used as a basis for a classification by classification component 116.

[0043] Classification component 116 may be configured to determine classifications of breathing disorders of subjects. In some examples, a classification may pertain to a type of apnea, hypopnea, or other respiratory event. In some examples, a classification may pertain to a physical cause or a chemical cause, such as a particular chemical balance in the blood of subject 106. In some examples, a classification may pertain to a type of sleep disordered breathing (SDB), including but not limited to snoring, upper airway resistance syndrome (UARS), obstructive sleep apnea (OSA), and/or other types of sleep disordered breathing. In some examples, a classification may pertain to different types of snoring, *i.e.* types of snoring caused by or at different sites of a subject. For example, a classification may pertain to obstructions located at different sites and/or caused by different types of soft tissue, including but not limited to tongue, epiglottis, palate, esophageal flap, throat walls, airway walls,

pharyngeal walls, and/or other bulk tissue or soft tissue. For example, a classification may distinguish between two or more different types of obstructions. As used herein, the term obstruction may be interpreted to include collapses.

[0044] In some examples, determinations by classification component 116 may be based on one or more determinations by breathing parameter component 115, in particular for the one or more breathing cycles corresponding to a particular challenge. In some examples, a first determination by breathing parameter component 115 for the first breathing cycle of a particular challenge may be compared with a second determination by breathing parameter component 115 for the second breathing cycle of the particular challenge, and so forth.

[0045] In some examples, determinations by classification component 116 may be based on one or more determinations by breathing parameter component 115, in particular by comparing determinations for the one or more breathing cycles corresponding to a first challenge with determination for the one or more breathing cycles corresponding to a second and/or third challenge, and so forth. The classification component 116 may also use inputs from other systems, the subject's answers to questions, measured parameters, and/or ethnographic parameters in order to make determinations by classification component 116 more comprehensive, accurate, or precise.

[0046] Stability component 118 may be configured to determine whether the airway of subject 106 is stable and/or whether one or more parameters indicate airway instability. In some examples, stability component 118 may be configured to determine whether (an onset of) an obstruction, a type of apnea, hypopnea, or other respiratory event, or a type of sleep disordered breathing has occurred. For example, an onset of an arousal may be deemed to indicate airway instability. Alternatively, and/or simultaneously, stability component 118 may be configured to determine whether stability of the airway has been restored, or whether an obstruction, a type of apnea, hypopnea, or other respiratory event, or a type of sleep disordered breathing has been removed, reverted, and/or ceased. For example, a change in the one or more parameters that previously indicated airway instability may indicate that the airway instability has been remedied. For example, the body of subject 106 may react to airway instability through an arousal, an onset of an arousal, a precursor to an arousal, and/or other physical reactions that may lead to an arousal.

[0047] Relief component 117 may be configured to adjust one or more pressure levels of the provided pressurized flow of breathable gas, in particular in an attempt to restore stability of the airway of subject 106. For example, relief component 117 may be configured to increase the EPAP level and/or IPAP level responsive to a particular determination or condition, including but not limited to stability of the airway of subject 106 having been compromised, and/or airway instability being indicated by one or more parameters. The response to the adjustment, *e.g.* to an increased EPAP level, may be indicative of a type of obstruction, and/or may be used as a basis for a classification by classification component 116. Relief component 117 may be configured to repeatedly make adjustments, *e.g.* increase the EPAP level, until, *e.g.*, stability of the airway of subject 106 has been restored and/or airway instability is no longer indicated by the one or more parameters. The particular combination of inspiratory and expiratory levels at which the particular condition occurs, *e.g.* onset of airway instability, may be referred to as a point of interest for diagnostic purposes. The amount of adjusted pressure needed to accomplish this may be used as a parameter by other computer program components, including but not limited to classification component 116. For example, the amount of increased EPAP pressure needed to resolve snoring may be different (*e.g.* typically lower) than the amount of increased EPAP pressure needed to prevent apneas (*e.g.* typically higher). Either amount of pressure may correspond to a separate point of interest, and either point of interest may be used as a parameter by other computer program components, including but not limited to classification component 116.

[0048] At various points of interest, adjustments to the inspiratory pressure and/or expiratory pressure may be made, in order to determine a response by subject 106. For example, at a point of severe airway instability, relief component 117 may be configured to increase the IPAP level to provide relief Responses by subject 106 to one or more pressure adjustments, in particular at or near points of interest, may be used as a basis for a classification by classification component 116.

[0049] By way of illustration, FIG. 3 illustrates a varying pressure level 30 of a pressurized flow of breathable gas provided to a subject and further illustrates a corresponding flow rate 40 of the subject that may be used to classify a breathing disorder. Periods 31, 33, 35, and 37 correspond to inspirations or inspiration phases of breathing cycles. Periods 32, 34, and 36 corresponds to expirations or expiration phases of breathing cycles. As depicted, the pressure levels during period 31 and period 32 may be the same. The corresponding patient flow 41-42 for the 31-32 periods show stable eupneic breathing. The combination of a period and the corresponding patient flow may be referred to as a segment, for example segment 31/41. Inspiratory flow rate 41, 43, 45a, and 47a correspond to periods 31, 33, 35, and 37, respectively. Expiratory flow rate 42, 44, and 46 correspond to period 32, 34, and 36, respectively. Period 33 corresponds to a first challenge for the subject, in this case a reduced inspiratory pressure level, as depicted by the difference in pressure level between the pressure level in period 31 and period 33. Period 33 and period 34 form a breathing cycle. Note that the expiratory pressure level in period 34 is the same as in period 32. The first challenge as depicted spans one breathing cycle, but this is merely exemplary. One or more characteristics of inspiratory

flow rate 43 (*e.g.* in comparison with inspiratory flow rate 41) may be used to determine a classification as described elsewhere herein. In this example, the patient's airway is exhibiting some level of flow limitation (*i.e.* flattening and broadening of the waveform in period 33, when compared to the waveform in period 31), because they are no longer experiencing treatment pressure during inhalation on this breath, and something about their anatomy fails to keep the airway completely open.

[0050] Period 35 corresponds to a second challenge for the subject, in this case an even more reduced inspiratory pressure level compared to period 33, as depicted by a difference 35a in pressure level between period 33 and period 35. The second challenge as depicted spans one breathing cycle, but this is merely exemplary. Inspiratory flow rate 45a indicates the measured inspiratory flow rate that corresponds to inspiratory period 35. Expected inspiratory flow rate 45b corresponds to the inspiratory flow rate as expected for a stable airway of the subject. The difference between measured inspiratory flow rate 45a and expected inspiratory flow rate 45b may indicate that the stability of the airway of the subject may have been compromised. One or more characteristics of this difference may be used to determine a classification as described elsewhere herein. For example, the difference may correspond to a lower-than-expected pressure induced volume. In other words, the second challenge was too great to maintain a stable airway. To relieve the subject, the expiratory pressure during period 36 may be increased compared to period 34, as indicated by a difference 36a. Inspiratory flow rate 47a indicates the measured inspiratory flow rate that corresponds to inspiratory period 37. Expected inspiratory flow rate 47b corresponds to the inspiratory flow rate as expected for a more stable airway of the subject; for instance in the 33/43 segment. The difference between measured inspiratory flow rate 47a and expected inspiratory flow rate 47b may indicate that the stability of the airway of the subject continues to be compromised to some degree, but appears to have improved since the amplitude of flow is higher than during segment 35/45, and the difference between measured inspiratory flow rate 45a and expected inspiratory flow rate 45b is greater than the difference between measured inspiratory flow 47a and expected inspiratory flow rate 47b. One or more characteristics of this difference may be used to determine a classification as described elsewhere herein. Note the different shape of measured inspiratory flow 47a compared to the measured inspiratory flow 45a. Note that measured inspiratory flow 47a is higher than the measured inspiratory flow 45a. In other words, the attempt to provide relief for the subject has not yet (*e.g.* fully) succeeded to restore stability of the airway of the subject. For example, perhaps an additional increase of the expiratory pressure level would restore the stability. The response of the inspiratory pressure level to various adjustments of inspiratory and/or expiratory pressure levels may indicate, for example in combination, a particular classification of a breathing disorder. Note that characteristics of differences between measured and expected flow rate are not limited to inspiratory phases, but may apply in a similar manner to expiratory phases.

[0051] FIG. 2 illustrates a method 200 to classify a breathing disorder of a subject, which is not part of the invention. The operations of method 200 presented below are intended to be illustrative. In certain examples, 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.

[0052] In certain examples, 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.

[0053] At an operation 202, a pressurized flow of breathable gas is provided at a pressure level to an airway of the subject. In some examples, operation 202 is performed by a pressure generator the same as or similar to pressure generator 140 (shown in FIG. 1 and described herein).

[0054] At an operation 204, output signals are generated conveying information related to breathing of the subject. In some examples, operation 204 is performed by one or more sensors the same as or similar to one or more sensors 142 (shown in FIG. 1 and described herein).

[0055] At an operation 206, a recommended respiratory therapy regimen is obtained for the subject that includes a recommended inspiratory positive airway pressure (IPAP) level and a recommended expiratory positive airway pressure (EPAP) level. In some examples, operation 206 is performed by a therapy component the same as or similar to therapy component 111 (shown in FIG. 1 and described herein).

[0056] At an operation 208, one or more timing parameters are determined related to the breathing of the subject based on the generated output signals. In some examples, operation 208 is performed by a timing component the same as or similar to timing component 112 (shown in FIG. 1 and described herein).

[0057] At an operation 210, the pressurized flow of breathable gas is controlled in accordance with the recommended respiratory therapy regimen such that the pressure level of the pressurized flow corresponds to the recommended IPAP level during inspirations and the

pressure level of the pressurized flow corresponds to the recommended EPAP level during expirations. Control is based on the one or more timing parameters. In some examples, operation 210 is performed by a control component the same as or similar to control component 113 (shown in FIG. 1 and described herein).

[0058] At an operation 212, the pressure level of the pressurized flow is reduced with respect to the recommended IPAP level during inspiration for one or more breathing cycles. In some examples, operation 212 is performed by a challenge component the same as or similar to challenge component 114 (shown in FIG. 1 and described herein).

[0059] At an operation 214, one or more breathing parameters of the subject are determined based on the generated output signals during the one or more breathing cycles, and. In some examples, operation 214 is performed by a breathing parameter component the same as or similar to breathing parameter component 115 (shown in FIG. 1 and described herein).

[0060] At an operation 216, a classification of a breathing disorder of the subject is determined based on the determined one or more breathing parameters during the one or more breathing cycles. In some examples, operation 216 is performed by a classification component the same as or similar to classification component 116 (shown in FIG. 1 and described herein).

[0061] 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.

[0062] Although the disclosure 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 disclosure is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within scope of the appended claims. For example, it is to be understood that the present disclosure 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.

Claims

1. A system (100) configured to classify a breathing disorder of a subject (106), the system comprising:

   a pressure generator (140) configured to provide a pressurized flow of breathable gas at a pressure level to an airway of a subject;
   one or more sensors (142) configured to generate output signals conveying information related to breathing of the subject; and
   a therapy component (111) configured to obtain a recommended respiratory therapy regimen for the subject that includes a recommended inspiratory positive airway pressure (IPAP) level and a recommended expiratory positive airway pressure (EPAP) level;
   a timing component (112) configured to determine one or more timing parameters related to the breathing of the subject based on generated output signals;
   one or more physical processors (110) configured to control the pressurized flow in accordance with the recommended respiratory therapy regimen such that the pressure level of the pressurized flow corresponds to the recommended IPAP level during inspirations and the pressure level of the pressurized flow corresponds to the recommended EPAP level during expirations, wherein control is based on the one or more timing parameters; **characterized in that** the one or more physical processors (110) are further configured to
   reduce the pressure level of the pressurized flow with respect to the recommended IPAP level during inspiration for one or more breathing cycles, wherein the reduced pressure level during inspiration is lower than the recommended and/or actually provided expiratory pressure level;
   and that the system further comprises a breathing parameter (115) component configured to determine one or more breathing parameters of the subject based on the generated output signals during the one or more breathing cycles; and
   a classification component (116) configured to determine a classification of a breathing disorder of the subject based on the determined one or more breathing parameters during the one or more breathing cycles for which the inspiratory pressure level is reduced.

Patentansprüche

1. Ein System (100), das konfiguriert ist, um eine Atemstörung einer Person (106) zu klassifizieren, wobei

das System umfasst:

einen Druckerzeuger (140), der konfiguriert ist, um einen mit Druck beaufschlagten Strom von atembarem Gas bei einem Druckniveau zu einem Atemweg eines Probanden bereitzustellen;
einen oder mehrere Sensoren (142), die konfiguriert sind, um Ausgangssignale zu erzeugen, die Informationen über die Atmung des Probanden übermitteln; und
eine Therapiekomponente (111), die konfiguriert ist, um ein empfohlenes Atemtherapieprogramm für den Probanden zu erhalten, das einen empfohlenen IPAP-Wert (Inspiratory Positive Airway Pressure) und einen empfohlenen EPAP-Wert (Exspiratory Positive Airway Pressure) beinhaltet;
eine Timing-Komponente (112), die konfiguriert ist, um einen oder mehrere Zeitparameter in Bezug auf die Atmung des Probanden basierend auf erzeugten Ausgangssignalen zu bestimmen;
einen oder mehrere physikalische Prozessoren (110), die konfiguriert sind, um einen mit Druck beaufschlagten Strom gemäß dem empfohlenen Atemtherapieprogramm so zu steuern, dass das Druckniveau des mit Druck beaufschlagten Stroms während der Einatmung dem empfohlenen IPAP-Niveau und das Druckniveau des mit Druck beaufschlagten Stroms während der Ausatmung dem empfohlenen EPAP-Niveau entspricht, wobei die Steuerung auf einem oder mehreren Timing-Parametern basiert;
dadurch gekennzeichnet, dass der eine oder die mehreren physikalischen Prozessoren (110) weiter konfiguriert sind, um das Druckniveau des druckbeaufschlagten Stroms in Bezug auf das empfohlene IPAP-Niveau während der Einatmung für einen oder mehrere Atemzyklen zu verringern, wobei das verringerte Druckniveau während der Einatmung niedriger ist als das empfohlene und/oder tatsächlich bereitgestellte Ausatmungsdruckniveau;
und dass das System ferner eine Atemparameterkomponente (115) umfasst, die konfiguriert ist, um einen oder mehrere Atemparameter des Probanden basierend auf den erzeugten Ausgangssignalen während des einen oder der mehreren Atemzyklen zu bestimmen; und
eine Klassifizierungskomponente (116), die konfiguriert ist, um eine Klassifizierung einer Atemstörung des Probanden basierend auf dem bestimmten einen oder den bestimmten mehreren Atemparametern während des einen oder der mehreren Atemzyklen, für die das Einatmungsdruckniveau verringert wird, zu bestimmen.

Revendications

1. Système (100) configuré pour classer un trouble respiratoire d'un sujet (106), le système comprenant :

un générateur de pression (140) configuré pour fournir un flux sous pression de gaz respirable à un niveau de pression à une voie aérienne d'un sujet ;
un ou plusieurs capteurs (142) configurés pour générer des signaux de sortie acheminant des informations en rapport avec la respiration du sujet ; et
un composant thérapeutique (111) configuré pour obtenir un régime de thérapie respiratoire recommandée pour le sujet qui comprend un niveau de pression de voie aérienne positive inspiratoire (IPAP) recommandée et un niveau de pression de voie aérienne positive expiratoire (EPAP) recommandé ;
un composant de synchronisation (112) configuré pour déterminer un ou plusieurs paramètres de synchronisation en rapport avec la respiration du sujet sur la base de signaux de sortie générés ;
un ou plusieurs processeurs physiques (110) configurés pour commander un flux sous pression conformément au régime de thérapie respiratoire recommandé de sorte que le niveau de pression du flux sous pression corresponde au niveau IPAP recommandé au cours d'inspirations et que le niveau de pression du flux sous pression corresponde au niveau EPAP recommandé au cours d'expirations, dans lequel la commande est basée sur les un ou plusieurs paramètres de synchronisation ; **caractérisé en ce que** les un ou plusieurs processeurs physiques (110) sont en outre configurés pour réduire le niveau de pression du flux sous pression par rapport au niveau IPAP recommandé au cours d'une inspiration pendant un ou plusieurs cycles respiratoires, dans lequel le niveau de pression réduit au cours d'une inspiration est inférieur au niveau de pression expiratoire recommandé et/ou fourni réellement ; et
le système comprend en outre un composant de paramètre respiratoire (115) configuré pour déterminer un ou plusieurs paramètres respiratoires du sujet sur la base des signaux de sortie générés au cours des un ou plusieurs cycles respiratoires ; et
un composant de classification (116) configuré pour déterminer une classification d'un trouble respiratoire du sujet sur la base des un ou plusieurs paramètres respiratoires déterminés au

cours des un ou plusieurs cycles respiratoires pour lesquels le niveau de pression inspiratoire est réduit.

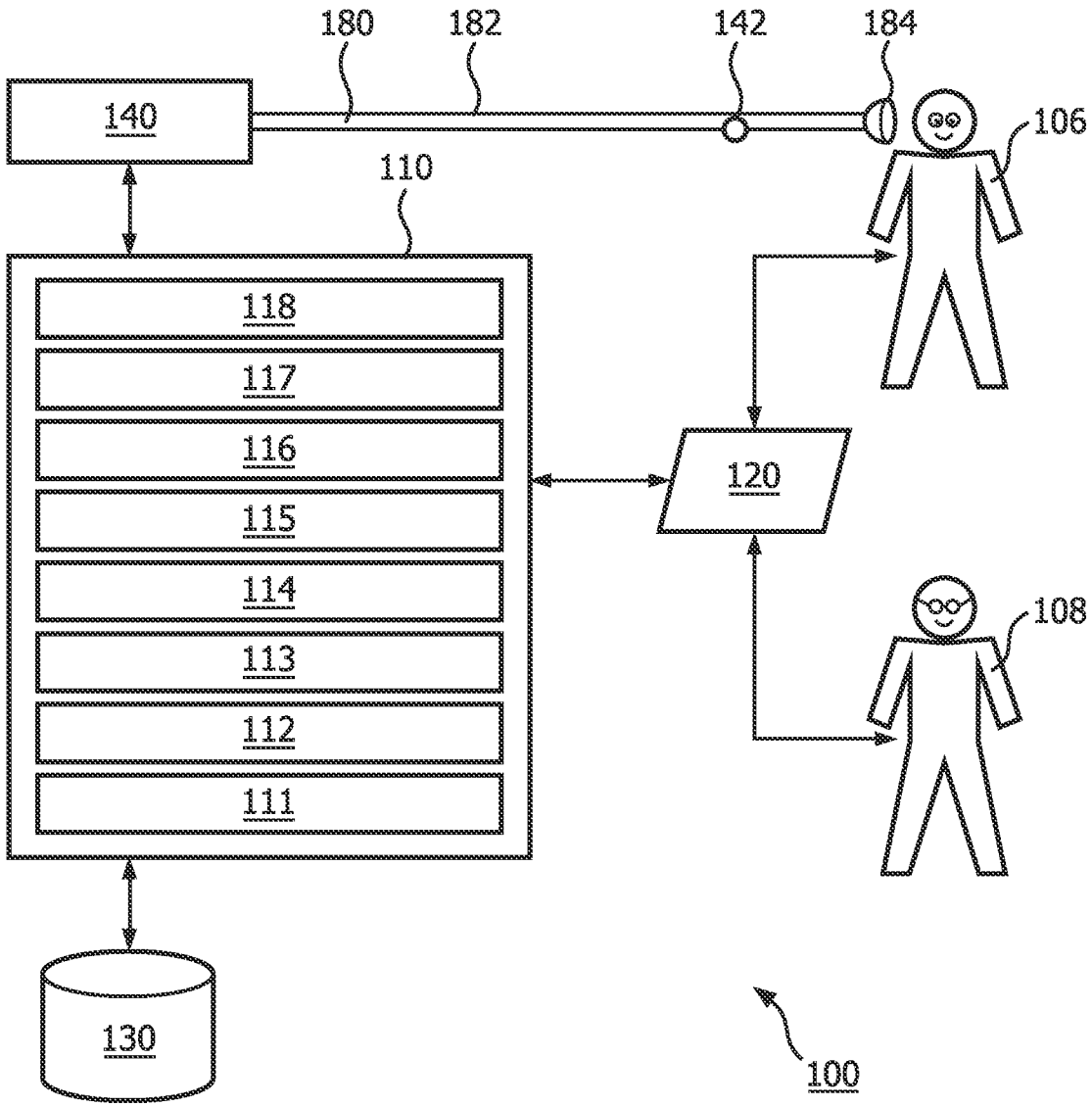
180
182
142
184
140
106
110
118
117
116
115
114
113
112
111
120
108
130
100

FIG. 1

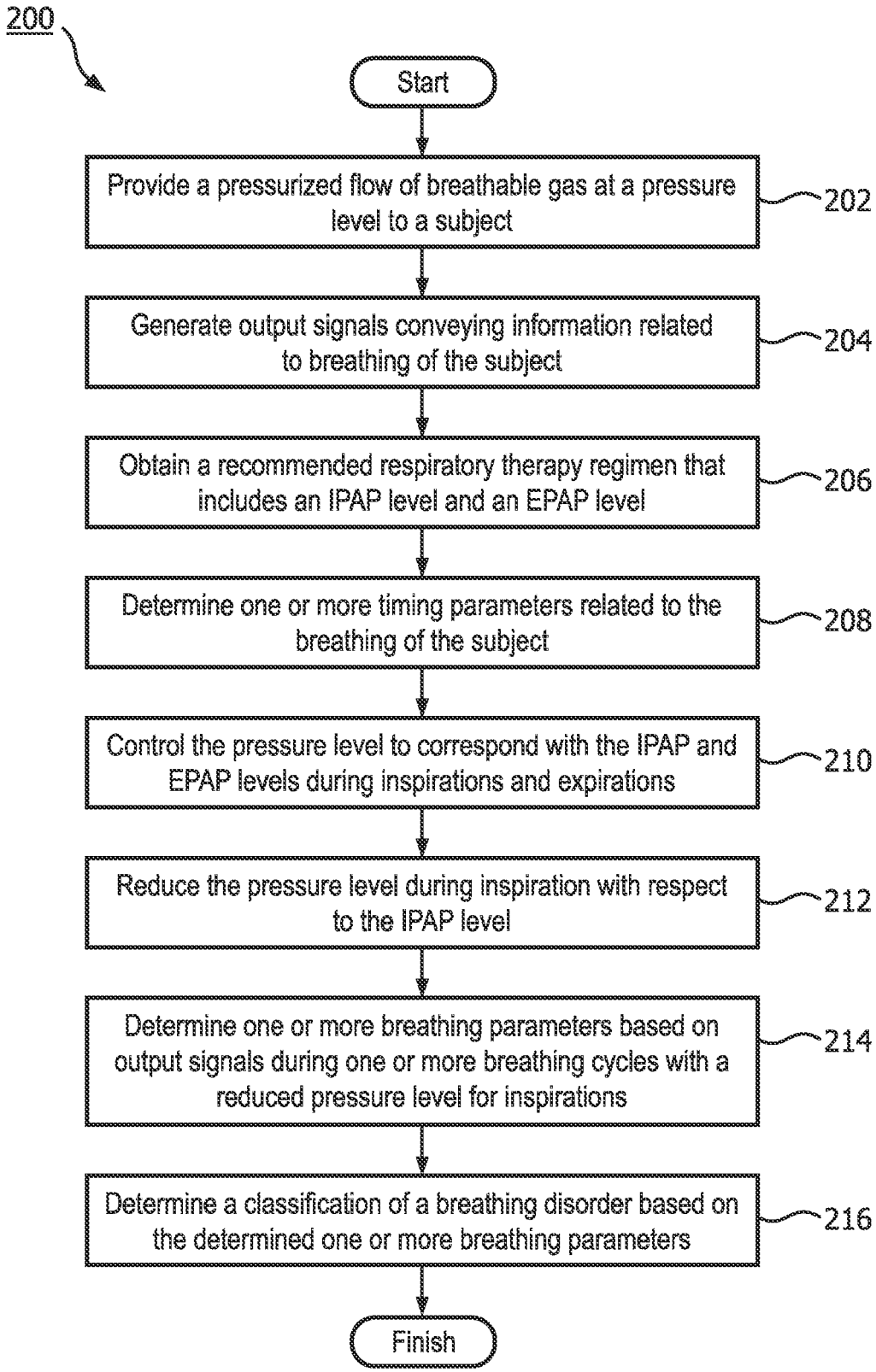
200
Start
Provide a pressurized flow of breathable gas at a pressure level to a subject
202
Generate output signals conveying information related to breathing of the subject
204
Obtain a recommended respiratory therapy regimen that includes an IPAP level and an EPAP level
206
Determine one or more timing parameters related to the breathing of the subject
208
Control the pressure level to correspond with the IPAP and EPAP levels during inspirations and expirations
210
Reduce the pressure level during inspiration with respect to the IPAP level
212
Determine one or more breathing parameters based on output signals during one or more breathing cycles with a reduced pressure level for inspirations
214
Determine a classification of a breathing disorder based on the determined one or more breathing parameters
216
Finish

FIG. 2

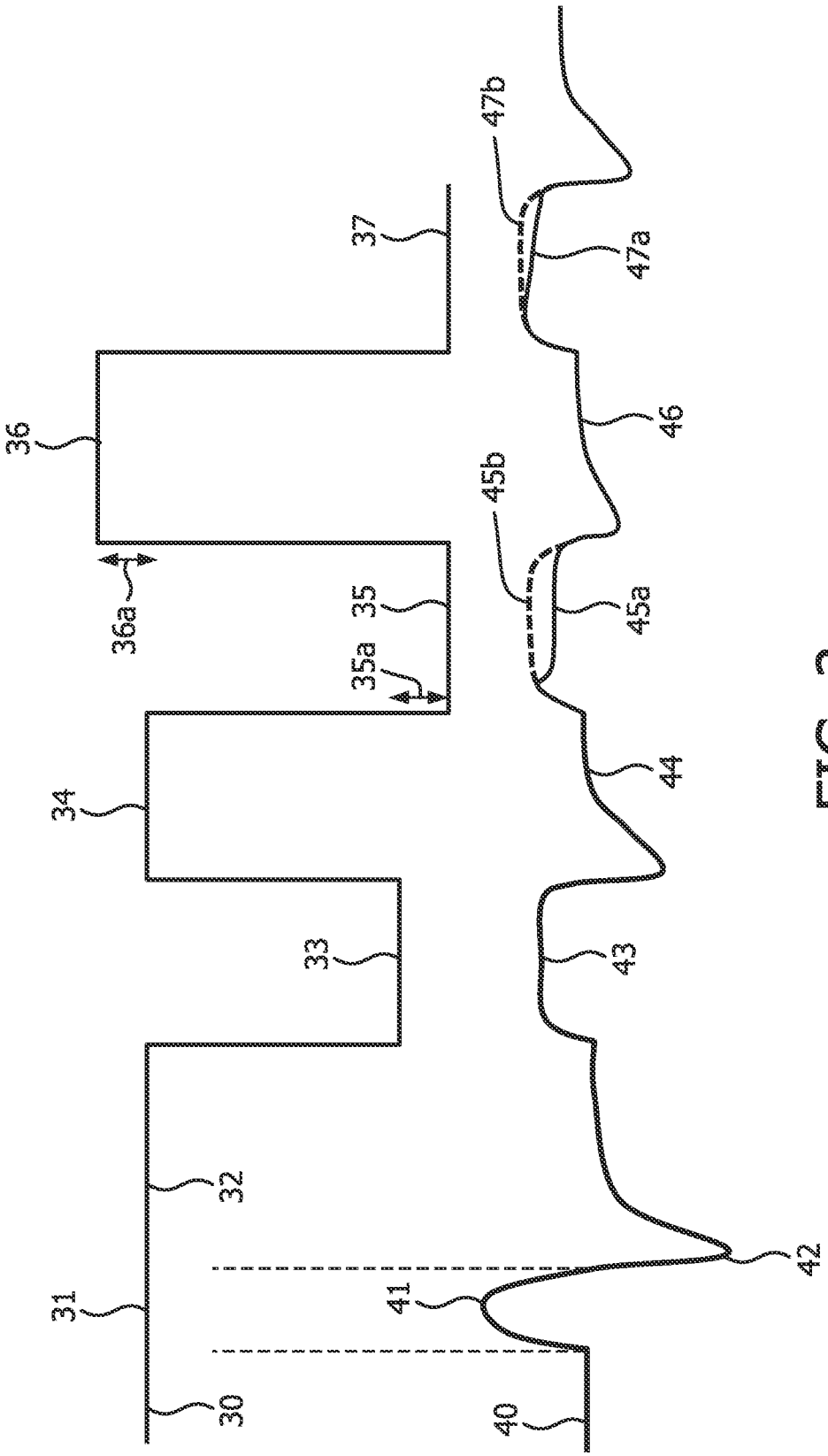

FIG. 3

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5535738 A **[0004]**

专利名称(译)	反向呼吸障碍诊断的双重气道正压力挑战		
公开(公告)号	EP3107608B1	公开(公告)日	2018-12-19
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[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	COLBAUGH MICHAEL EDWARD HUESER LAUREN ELIZABETH VISSAPRAGADA VENKATA SATYA SURYA SUBRAHMANYA SREERAM		
发明人	COLBAUGH, MICHAEL EDWARD HUESER, LAUREN ELIZABETH VISSAPRAGADA VENKATA SATYA, SURYA SUBRAHMANYA SREERAM		
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摘要(译)

用于对受试者的呼吸障碍进行分类的系统和方法基于对加压可呼吸气体流的压力水平的变化的呼吸响应。这种变化给受试者带来了呼吸挑战。挑战可能仅限于吸气呼吸阶段。在挑战期间，吸气压力水平可低于呼气压力水平。

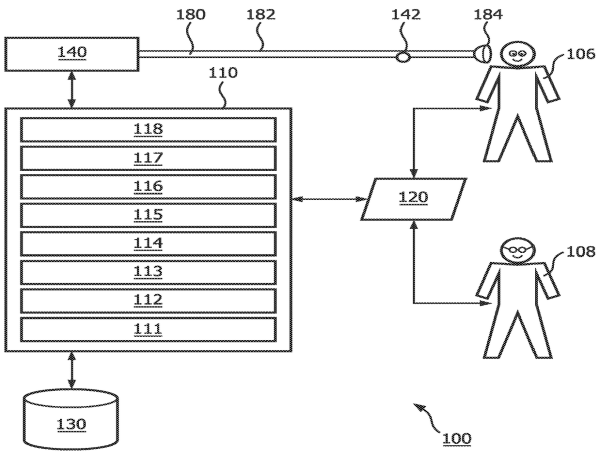

FIG. 1