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(54) Title: STARTING PRESSURE FOR RESPIRATORY THERAPY DEVICES

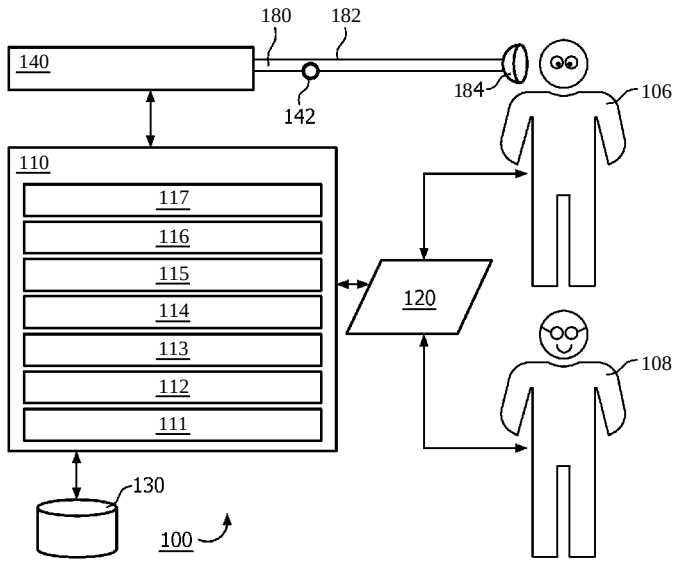

FIG. 1

(57) Abstract: Systems and methods for providing respiratory therapy to a subject respond and/or adapt to the detection of an occurrence of a respiratory event. For example, the pressure level of a pressurized flow of breathable gas may be increased responsive to the occurrence of one or more apneas. Based on usage information spanning more than one therapy session, such as the tracked pressure levels, a starting pressure level for a pressurized flow of breathable gas for a subsequent therapy session is determined. The starting level at the beginning of the subsequent therapy session(s) may be the 90% pressure level as determined during the preceding period during which usage information has been gathered.

WO 2013/144827 A1

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STARTING PRESSURE FOR RESPIRATORY THERAPY DEVICES

BACKGROUND

1. Field

[01] The present disclosure pertains to systems and methods for providing respiratory therapy of a subject. In particular, the present disclosure pertains to determining a smart starting level for a pressurized flow of breathable gas at the beginning of a therapy session, based on prior usage.

2. Description of the Related Art

[02] It is well known that some types of respiratory therapy involve the delivery of a flow of breathable gas to the airway of a subject. It is known that a therapy session may commonly 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. It is known that a subject's comfort during a therapy session is an important factor in therapy adoption rates and/or therapy success rates. It is known that a flow of breathable gas may be pressurized at varying levels of pressure, even during a single therapy session. It is known that respiratory events, in particular common events during sleep, may be prevented by increasing levels of pressure for the pressurized flow. It is known that increasing pressure levels have various downsides, including but not limited to reduced comfort. It is known that algorithms may operate to control the pressure level used in respiratory therapy during a therapy session. It is known that such algorithms may autonomously and/or automatically change the pressure level based on various conditions, settings, and/or occurrences of respiratory events. It is known that such algorithms may operate within a range of permitted pressure levels, including a minimum level and a maximum level that form the boundaries of such a range. It is known that many such algorithms reset the pressure level at the beginning of a therapy session to the minimum level.

SUMMARY

[03] Accordingly, it is an object of one or more embodiments of the present invention to provide a system to provide respiratory therapy of a subject having an airway. The system includes a pressure generator configured to generate a pressurized flow for delivery to the airway of the subject during respiratory therapy, wherein the pressurized flow includes breathable gas; one or more sensors configured to generate one or more output signals conveying information related to one or more gas parameters of the pressurized flow; and one or more processors configured to execute processing modules, the processing modules comprising: a control module configured to control the pressure generator to provide the pressurized flow during a therapy session; a therapy module configured to adjust levels of one or more gas parameters of the pressurized flow; a usage module configured to gather usage information based on the provided pressurized flow; and a starting level module configured to determine a starting level of one or more gas parameters of the pressurized flow, wherein the determination is based on the gathered usage information, wherein the usage information corresponds to therapeutic usage of the system spanning at least a threshold amount of usage, wherein the threshold amount of usage is more than one therapy session. The therapy module may be further configured to apply the starting level at a beginning of a therapy session.

[04] It is yet another aspect of one or more embodiments of the present invention to provide a method for providing respiratory therapy of a subject having an airway. The method includes generating a pressurized flow for delivery to the airway of the subject during respiratory therapy, wherein the pressurized flow includes breathable gas; generating one or more output signals conveying information related to one or more gas parameters of the pressurized flow; providing the pressurized flow to the subject during a therapy session; adjusting levels of one or more gas parameters of the pressurized flow; gathering usage information based on the provided pressurized flow; determining a starting level of one or more gas parameters of the pressurized flow, wherein the determination is based on the gathered usage information, wherein the usage

information corresponds to respiratory therapy spanning at least a threshold amount of usage, wherein the threshold amount of usage is more than one therapy session; and applying the starting level at a beginning of a therapy session.

[05] It is yet another aspect of one or more embodiments to provide a system configured to provide respiratory therapy of a subject having an airway. The system includes means for generating a pressurized flow for delivery to the airway of the subject during respiratory therapy, wherein the pressurized flow includes breathable gas; means for generating one or more output signals conveying information related to one or more gas parameters of the pressurized flow; means for providing the pressurized flow to the subject during a therapy session; means for adjusting levels of one or more gas parameters of the pressurized flow; means for gathering usage information based on the provided pressurized flow; means for determining a starting level of one or more gas parameters of the pressurized flow, wherein the determination is based on the gathered usage information, wherein the usage information corresponds to respiratory therapy spanning at least a threshold amount of usage, wherein the threshold amount of usage is more than one therapy session; and means for applying the starting level at a beginning of a therapy session.

[06] 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.

BRIEF DESCRIPTION OF THE DRAWINGS

[07] FIG. 1 schematically illustrates a system configured to provide respiratory therapy of a subject, according to certain embodiments; and

[08] FIG. 2 illustrates a method for providing ventilation to the airway of a subject through a ventilation system, according to certain embodiments.

[09] FIG. 3A-3B illustrate exemplary diagrams of pressure levels provided during therapy sessions of respiratory therapy, according to certain embodiments.

[10] FIG. 4 illustrates an exemplary diagram depicting the changing starting level of a particular gas parameter over time.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[11] 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.

[12] 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).

[13] 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.

[14] FIG. 1 schematically illustrates a system 100 configured to provide respiratory therapy to the airway of a subject 106. System 100 may be implemented as, integrated with, and/or operating in conjunction with a respiratory therapy device. System 100 uses gathered usage information, pertaining to subject 106 using system 100, to determine smart starting levels to apply to subsequent sessions of respiratory therapy.

[15] A therapy "session" of using system 100 may be defined as a period of substantially uninterrupted therapeutic usage of system 100, not to exceed some upper threshold of (consecutive) hours. The upper threshold may be, for example, about 10 hours, about 12 hours, about 16 hours, about 24 hours and/or other time periods. If the respiratory therapy is used to treat sleeping disorders the related session length may correspond to the sleeping pattern of a subject. A typical session length may thus be about eight hours. Alternatively, and/or simultaneously, a therapy session may be defined as a period of substantially uninterrupted therapeutic usage of system 100, not to span less than some lower threshold of (consecutive) units of time, and/or at least a minimum period of time apart from a previous session. For example, a minute of usage may be too short to be regarded as a session. For example, two 4-hour periods of usage separated by a 15-minute gap may be regarded as one session rather than two sessions. Individual therapy sessions may have a beginning and an end.

[16] In some embodiments, one or more operative 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 therapy session to titrate the therapy. Alternatively, and/or simultaneously, adjustments may be made more intermittently and/or only between therapy sessions rather than during therapy sessions.

[17] System 100 includes one or more of a pressure generator 140, a delivery circuit 180, one or more sensors 142, an electronic storage 130, a user interface 120, a processor 110, a control module 111, a respiratory event module 112, a therapy module

113, a usage module 114, a starting level module 115, a parameter determination module 116, a timing module 117, and/or other components.

[18] 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/BiPAPO/eic.) and configured to provide a pressurized flow of breathable gas for delivery to the airway of subject 106, *e.g.* via delivery circuit 180. Delivery circuit 180 may sometimes be referred to as subject interface 180. Subject 106 may or may not initiate one or more phases of respiration. 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 pressure. 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 pressure. Adjustments may be made numerous times in implementations using auto-titrating for providing respiratory support through the delivery of the pressurized flow of breathable gas. Pressure generator 140 is configured to adjust one or more of pressure levels, flow, humidity, velocity, acceleration, and/or other parameters of the pressurized flow of breathable gas, *e.g.* in substantial synchronization with the breathing cycle of the subject.

[19] A pressurized flow of breathable gas is delivered from pressure generator 140 to the airway of subject 106 via a delivery circuit 180. Delivery circuit 180 may include a conduit 182 and/or a subject interface appliance 184. Conduit 182 may include a flexible length of hose, or other conduit, either in single-limb or dual-limb configuration that places subject interface appliance 184 in fluid communication with pressure generator 140. Conduit 182 forms a flow path through which the pressurized flow of breathable gas is communicated between subject interface appliance 184 and pressure generator 140.

[20] Subject interface appliance 184 of system 100 in FIG. 1 is 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 some embodiments, 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 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 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.

[21] Electronic storage 130 of system 100 in FIG. 1 comprises 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.,* 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).

[22] User interface 120 of system 100 in FIG. 1 is 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 user 108 is a report detailing occurrences of respiratory events throughout a period during which the subject is receiving therapy. 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 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.

[23] 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 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.

[24] One or more sensors 142 of system 100 in FIG. 1 are configured to generate output signals conveying measurements related to parameters of respiratory airflow and/or airway mechanics. These parameters may include one or more of flow,

(airway) pressure, humidity, velocity, acceleration, and/or other parameters. Sensor 142 may be in fluid communication with conduit 182 and/or subject interface appliance 184. Sensor 142 may generate output signals related to physiological parameters pertaining to subject 106.

[25] The illustration of sensor 142 including a single member in FIG. 1 is not intended to be limiting. The illustration of sensor 142 at or near subject interface appliance 184 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 state and/or condition of an airway of subject 106, the breathing of subject 106, the gas breathed by subject 106, the composition of the gas breathed by 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.

[26] 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, 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 embodiments, processor 110 includes a plurality of processing units.

[27] 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 control module 111, respiratory event module 112, therapy module 113, usage module 114, starting level module 115, parameter determination module 116, timing module 117, and/or other modules. Processor 110 may be configured to execute modules 111-117 by software; hardware; firmware; some combination of software, hardware, and/or firmware; and/or other mechanisms for configuring processing capabilities on processor 110.

[28] It should be appreciated that although modules 111-117 are illustrated in FIG. 1 as being co-located within a single processing unit, in embodiments in which processor 110 includes multiple processing units, one or more of modules 111-117 may be located remotely from the other modules. The description of the functionality provided by the different modules 111-117 described herein is for illustrative purposes, and is not intended to be limiting, as any of modules 111-117 may provide more or less functionality than is described. For example, one or more of modules 111-117 may be eliminated, and some or all of its functionality may be incorporated, shared, integrated into, and/or otherwise provided by other ones of modules 111-117. 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 111-117.

[29] Parameter determination module 116 of system 100 in FIG. 1 is configured to determine one or more gas parameters, breathing parameters, and/or other parameters from output signals generated by sensor(s) 142. The one or more gas parameter may include and/or be related to one or more of (peak) flow, flow rate, (tidal) volume, pressure, temperature, humidity, velocity, 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. One or more breathing parameters may be derived from gas parameters and/or other output signals conveying measurements of the pressurized flow

of breathable gas. The one or more breathing parameters may include one or more of 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), and/or other breathing parameters.

[30] Timing module 117 is configured to determine whether a current respiratory phase of subject 106 is an inhalation phase or an exhalation phase. In some embodiments, timing module 117 may be configured to determine respiratory timing parameters and/or other timing parameters related to the operation of system 100, such as transitions in breathing between inhalations and exhalations. Respiratory timing parameters may include transitional moments that separate inhalation phases from exhalation phases and/or vice versa, breathing period, respiratory rate, inhalation time or period, exhalation time or period, start and/or end of inhalation phases, start and/or end of exhalation phases, and/or other respiratory timing parameters. Timing parameters related to the operation of system 100 may include therapy session length, session start time, session stop time, average and/or cumulative daily and/or nightly usage, amount of usage since the most recent pressure adjustment, and/or other timing parameters related to the operation of system 100.

[31] Control module 111 is configured to control operation of system 100 during a therapy session. Control module 111 may be configured to control the pressure generator to adjust one or more levels of gas parameters of the pressurized flow of breathable gas in accordance with one or more of a (respiratory) therapy regimen, level adjustments by therapy module 113, starting levels determined by starting module 115, one or more algorithms that control adjustments and/or changes in the pressurized flow of breathable gas, and/or other factors. Control module 111 may be configured to control pressure generator 140 to provide the pressurized flow of breathable gas. Control module 111 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 module 111 may be configured to control pressure generator 140 to provide the pressurized flow of breathable gas at inhalation pressure levels during inhalation phases, and/or at exhalation pressure levels during exhalation phases. Parameters determined by parameter determination module 116, timing module 117, and/or received through sensors 142 may be used by control module 111, *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 module 111, *e.g.* in a feedback manner, to adjust one or more therapy modes/settings/operations of system 100. Control module 111 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 module 117.

[32] Respiratory event module 112 is configured to detect occurrences of respiratory events, *e.g.* based on output signals generated by sensor 142. Respiratory event module 112 may be configured to detect occurrences of respiratory events based on parameters determined by parameter determination module 111. For example, respiratory event module 112 may detect occurrences of Cheyne-Stokes respiration, central apneas, obstructive apneas, hypopneas, snoring, hyperventilation, arousals, lack (or significantly reduced level) of respiratory effort, respiratory effort related arousals (RERAs), and/or other respiratory events. Such an occurrence may be used, automatically, autonomously, and/or manually, to alter the operating parameters of system 100 and/or its constituent components. In some embodiments, respiratory event module 112 may be configured to detect conditions that are indicative of a likely and/or imminent respiratory event. For example, one or more breathing parameters may indicate that subject 106 is likely to suffer an apnea very soon, though a particular adjustment in one or more levels of one or more gas parameters of the pressurized flow of breathable gas may prevent that apnea.

[33] Therapy module 113 is configured to adjust levels of one or more gas parameters of the pressurized flow of breathable gas such that an adjustment is based on a detected occurrence of a respiratory event. Threshold module 113 may be further configured to apply a starting level, *e.g.* such as determined by starting level module 115, at a beginning of a therapy session. In some embodiments, therapy module 113 may run and/or control a titrating algorithm to adjust levels of gas parameters throughout a therapy session. Titration and/or other adjustments may be performed in accordance with a therapy regimen and/or operating guidelines. For example, inspiratory pressure support may be adjusted within a range of pressures, having a minimum level and a maximum level of inspiratory pressure.

[34] By way of illustration, FIG. 3A illustrates a diagram 30a of a pressure level 36a as it varies over time for a particular therapy session spanning approximately over seven hours. In this example, pressure level 36a may be bound within a range defined by a maximum pressure level 32 and a minimum pressure level 31. A pressure level 33 at the start of the particular therapy session in diagram 30a is equal to the minimum pressure level 31. Pressure level 36a titrates up during, approximately, the first two hours depicted in FIG. 3A.

[35] Returning to FIG. 1, usage module 114 is configured to gather usage information based on the provided pressurized flow of breathable gas. Gathered usage information may be used for particular purposes by other modules, such as, *e.g.,* starting level module 115. Usage module 114 may be configured to retain only a certain amount of historic usage information.

[36] The gathered usage information used for a particular purpose may correspond to therapeutic usage of system 100 spanning at least a threshold amount of usage. The threshold amount of usage may be a predetermined amount of therapeutic usage. The predetermined amount of usage may be an hour, two hours, four hours, eight hours, ten hours, fifteen hours, 20 hours, 25 hours, 30 hours, 35 hours, 40 hours, 50 hours, about one therapy session, more than about one therapy session, more than about

two therapy sessions, more than about four therapy sessions, about a week of therapy sessions, and/or another amount of therapeutic usage, or any combination thereof. For example, the predetermined amount of usage may be at least 25 hours, rounded up to the next completed session. The predetermined amount of therapeutic usage used as the threshold amount may be constant across multiple sessions, weeks of usage, and/or months of usage. Alternatively, the predetermined amount of therapeutic usage used as the threshold amount may vary according to various factors, including, but not limited to, patient feedback, input from a medical professional, amount of system usage, and/or other factors.

[37] The gathered usage information used for a particular purpose may pertain to one or more levels of one or more gas parameters of the provided pressurized flow of breathable gas. For example, the gathered usage information may pertain to the level of (inspiratory) pressure of the pressurized flow of gas, historical pressure level, average pressure level, mean/median pressure level, a 90^{th} percentile pressure level, a 95^{th} percentile pressure level, a predetermined percentile pressure level, a predetermined range of percentile pressure levels, and/or another statistical metric based on the historic pressure level. Note that this exemplary use of the pressure level is not intended to be limiting in any way. The amount of historic information used to gather usage information may, *e.g.,* correspond to the threshold amount of therapeutic usage, described above. For example, in some embodiments, the 90^{th} percentile pressure level may correspond to a sliding window of the most recent 30 hours of usage, the most recent four therapy sessions, and/or other predetermined amount of therapeutic usage or combination thereof. Alternatively, such a window of historic information may have a fixed starting point, such as the beginning of a particular therapy session. Note that using too much historic information, *e.g.* all usage since the start of respiratory therapy, may decrease the responsiveness of system 100 to changing conditions.

[38] Starting level module 115 is configured to determine one or more starting levels of one or more gas parameters of the pressurized flow of breathable gas. Starting

levels may pertain to the starting level of one or more gas parameters of the provided pressurized flow of breathable gas at the beginning of a therapy session, *e.g.* at the beginning of the therapy session following the determination of a particular starting level. Determinations by starting level module 115 are based on usage information gathered by usage module 114. For example, the particular purpose for which usage information is gathered by usage module 114 may be to determine a starting level by starting level module 115, as described herein. In some embodiments, consecutive adjustments of a starting level may be determined and/or applied at least a threshold amount of therapeutic usage of system 100 apart. For example, this threshold amount may be the same threshold amount as described in relation to usage module 114. In some embodiments, consecutive adjustments of a starting level may be determined and/or applied a different threshold amount of usage apart. Application of a starting level may be performed by therapy module 113.

[39] By way of illustration, FIG. 4 illustrates a diagram 40 depicting a starting pressure level 34 as it changes over time. In this example, starting pressure level 34 may be bound within a range defined by a maximum pressure level 32 and a minimum pressure level 31. Time in FIG. 4 may reflect days of respiratory therapy or therapy sessions, depending on the implementation. As depicted in this example, adjustments of starting pressure level 34 are determined and/or applied approximately 30 hours of therapeutic usage apart. In this example, 30 hours may be the threshold amount that subsequent adjustments are designed to be apart, as described elsewhere herein in relation to FIG. 1. Note that adjustments may be made during a therapy session.

[40] Returning to starting level module 115 and FIG. 1, in some embodiments, one or more determined starting levels of one or more gas parameters may be factors in an algorithm used to adjust levels of gas parameters throughout a therapy session. For example, a particular determined starting level - which may or may not be the same determined starting level as used at the beginning of a therapy session - may be used in a titrating algorithm that is controlled by therapy module 113. In some embodiments, the

algorithm may operate more aggressively depending on the current level of a gas parameter in comparison to a determined starting level for that gas parameter. For example, the algorithm may operate more aggressively responsive to the current pressure level being lower than the particular determined starting pressure level. "Operating" the algorithm may include responding to occurrences of respiratory events detected by respiratory event module 112.

[41] Operating "more aggressively" may include larger adjustments in the level of one or more gas parameters of the pressurized flow of breathable gas, more frequent adjustments therein, more sensitive and/or responsive triggers corresponding to adjustments therein, and/or other ways in which the algorithm may respond to operating conditions more aggressively. For example, operating "more aggressively" may include titrating to a higher pressure level in response to a predetermined number of respiratory events, wherein the predetermined number is relatively lower when the current pressure level is below the particular determined starting pressure level, and/or relatively higher when the current pressure level is above the particular determined starting pressure level. In some embodiments, aggressiveness may be defined using multiple levels such that "operating" the algorithm "more aggressively" may depend on the relation of the current pressure level and the particular determined starting pressure level. For example, the aggressiveness of the operation of the algorithm may increase as the difference between the current pressure level and a particular determined starting pressure level increases. In some embodiments, a determined starting level for a therapy session (and/or a pressure level based thereon) may function as a new minimum pressure level for the range of permitted pressure levels within which an algorithm operates.

[42] By way of illustration, and in contrast to FIG. 3A, FIG. 3B illustrates a diagram 30b of a pressure level 36b as it varies over time for a particular therapy session spanning approximately over seven hours. In this example, pressure level 36b may be bound within a range defined by a maximum pressure level 32 and a minimum pressure level 31. A pressure level 33 at the start of the particular therapy session in diagram 30b

is equal to a starting pressure level 34, which may be determined based on gathered usage information pertaining to the provided pressurized flow in at least one preceding therapy session. For example, starting pressure level 34 may have been determined by a starting level module similar to or substantially the same as starting level module 115 described elsewhere herein in relation to FIG. 1.

[43] Returning to FIG. 3B, pressure level 36b titrates up during, approximately, at least about the first hour depicted in FIG. 3B. The range of pressure levels between minimum pressure level 31 and starting pressure level 34 are indicated as range 35. When pressure level 36b is within range 35, titration may be performed more aggressively than when pressure level 36b is above range 35, as described elsewhere herein. As an example, when pressure level 36b is within range 35, titrating up to a higher pressure level may be performed after fewer detected occurrences of respiratory events than compared to a similar circumstance when pressure level 36b is above range 35. Alternatively, and/or simultaneously, titration example 37 depicted in FIG. 3B illustrates an implementation wherein a titration to a higher pressure level increases pressure level 36b from a level in range 35 directly to starting pressure level 34. This may be in contrast, for example, to the gradual increases in pressure level 36b as depicted in, approximately, the fourth hour of the particular therapy session illustrated in FIG. 3B. As depicted in FIG. 3B, no adjustments of starting pressure level 34 are illustrated. This is not intended to be limiting in any way. Such adjustments are illustrated in FIG. 4.

[44] FIG. 2 illustrates a method for providing respiratory therapy to the airway of a subject. The operations of method 200 presented below are intended to be illustrative. In certain 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.

[45] In certain 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.

[46] At an operation 202, a pressurized flow of breathable gas is generated for delivery to the airway of a subject. In one embodiment, operation 202 is performed by a pressure generator similar to or substantially the same as pressure generator 140 (shown in FIG. 1 and described above).

[47] At an operation 204, one or more output signals are generated that convey information related to one or more gas parameters of the pressurized flow of breathable gas. In one embodiment, operation 204 is performed by a sensor similar to or substantially the same as sensor 142 (shown in FIG. 1 and described above).

[48] At an operation 206, the pressurized flow of breathable gas is provided and/or controlled to be provided to the subject during a therapy session. In one embodiment, operation 206 is performed by a control module similar to or substantially the same as control module 111 (shown in FIG. 1 and described above).

[49] At an operation 208, occurrences of respiratory events are detected based on the one or more output signals. In one embodiment, operation 208 is performed by a respiratory event module similar to or substantially the same as respiratory event module 112 (shown in FIG. 1 and described above).

[50] At an operation 210, levels of one or more gas parameters of the pressurized flow of breathable gas are adjusted based on one or more detected occurrences of one or more respiratory events. In one embodiment, operation 210 is performed by a therapy module similar to or substantially the same as therapy module 113 (shown in FIG. 1 and described above).

[51] At an operation 212, usage information is gathered based on the provided pressurized flow of breathable gas. In one embodiment, operation 212 is performed by a usage module similar to or substantially the same as usage module 114 (shown in FIG. 1 and described above).

[52] At an operation 214, a starting level of one or more gas parameters of the pressurized flow of breathable gas is determined based on the usage information. The usage information corresponds to respiratory therapy spanning at least a threshold amount of usage, wherein the threshold amount of usage is more than one therapy session. In one embodiment, operation 214 is performed by a starting level module similar to or substantially the same as starting level module 115 (shown in FIG. 1 and described above).

[53] At an operation 216, the starting level is applied at a beginning of a therapy session. Method 200 may proceed at operation 202, such that method 200 is performed for subsequent therapy sessions. In one embodiment, operation 216 is performed by a therapy module similar to or substantially the same as therapy module 113 (shown in FIG. 1 and described above).

[54] 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.

[55] 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.

What is claimed is:

1. A system configured to provide respiratory therapy of a subject having an airway, the system comprising:

a pressure generator (140) configured to generate a pressurized flow for delivery to the airway of the subject during respiratory therapy, wherein the pressurized flow includes breathable gas;

one or more sensors (142) configured to generate one or more output signals conveying information related to one or more gas parameters of the pressurized flow; and

one or more processors (110) configured to execute processing modules, the processing modules comprising:

a control module (111) configured to control the pressure generator to provide the pressurized flow during a therapy session;

a therapy module (113) configured to adjust levels of one or more gas parameters of the pressurized flow;

a usage module (114) configured to gather usage information based on the provided pressurized flow; and

a starting level module (115) configured to determine a starting level of one or more gas parameters of the pressurized flow, wherein the determination is based on gathered usage information, wherein the usage information corresponds to therapeutic usage of the system spanning at least a threshold amount of usage, wherein the threshold amount of usage is more than one therapy session;

wherein the therapy module is further configured to apply the starting level at a beginning of a therapy session.

2. The system of claim 1, wherein the threshold amount of usage is at least eight hours of therapeutic usage of the system, and wherein the gathered usage information pertains to a predetermined percentile pressure level.

3. The system of claim 1, wherein the starting level module is further configured to adjust the starting level of the one or more gas parameters of the pressurized flow such that consecutive adjustments occur at least the threshold amount of usage apart.

4. The system of claim 1, wherein the levels of one or more gas parameters of the pressurized flow that are adjusted by the therapy module include a current pressure level of the pressurized flow, wherein the starting level of one or more gas parameters of the pressurized flow that is determined by the starting level module includes a current starting pressure level, wherein adjustments of levels of one or more gas parameters of the pressurized flow are controlled by an algorithm, and wherein the algorithm operates more aggressively responsive to the current pressure level being below the current starting pressure level.

5. The system of claim 4, further comprising a respiratory event module (112) configured to detect occurrences of respiratory events based on the one or more output signals,

wherein the therapy module is configured to adjust levels of one or more gas parameters of the pressurized flow such that an adjustment is based on a detected occurrence of a respiratory event,

wherein the algorithm operates more aggressively by one or both of an increased pressure increment, and/or an increased responsiveness to detected occurrences of respiratory events.

6. A method for providing respiratory therapy of a subject having an airway, the method comprising;

generating a pressurized flow for delivery to the airway of the subject during respiratory therapy, wherein the pressurized flow includes breathable gas;

generating one or more output signals conveying information related to one or more gas parameters of the pressurized flow;

providing the pressurized flow to the subject during a therapy session;

adjusting levels of one or more gas parameters of the pressurized flow;

gathering usage information based on the provided pressurized flow;

determining a starting level of one or more gas parameters of the pressurized flow, wherein the determination is based on the gathered usage information, wherein the usage information corresponds to respiratory therapy spanning at least a threshold amount of usage, wherein the threshold amount of usage is more than one therapy session; and

applying the starting level at a beginning of a therapy session.

7. The method of claim 6, wherein the threshold amount of usage is at least eight hours of respiratory therapy, and wherein the gathered usage information pertains to a predetermined percentile pressure level.

8. The method of claim 6, further comprising:

adjusting the starting level of the one or more gas parameters of the pressurized flow repeatedly such that consecutive adjustments occur at least the threshold amount of usage apart.

9. The method of claim 6, wherein adjusting the levels of one or more gas parameters of the pressurized flow includes adjusting a current pressure level of the pressurized flow, wherein determining the starting level of one or more gas parameters of

the pressurized flow includes a current starting pressure level, wherein adjustments of levels of one or more gas parameters of the pressurized flow are controlled by an algorithm, and wherein the algorithm operates more aggressively responsive to the current pressure level being below the current starting pressure level.

10. The method of claim 9, further comprising:

detecting occurrences of respiratory events based one the one or more output signals,

wherein adjusting levels of one or more gas parameters of the pressurized flow is performed such that an adjustment is based on a detected occurrence of a respiratory event,

wherein the algorithm operates more aggressively by one or both of an increased pressure increment, and/or an increased responsiveness to detected occurrences of respiratory events.

11. A system configured to provide respiratory therapy of a subject having an airway, the system comprising;

means (140) for generating a pressurized flow for delivery to the airway of the subject during respiratory therapy, wherein the pressurized flow includes breathable gas;

means (142) for generating one or more output signals conveying information related to one or more gas parameters of the pressurized flow;

means (111) for providing the pressurized flow to the subject during a therapy session;

means (113) for adjusting levels of one or more gas parameters of the pressurized flow;

means (114) for gathering usage information based on the provided pressurized flow;

means (115) for determining a starting level of one or more gas parameters of the pressurized flow, wherein the determination is based on the gathered usage information, wherein the usage information corresponds to respiratory therapy spanning at least a threshold amount of usage, wherein the threshold amount of usage is more than one therapy session; and

means (113) for applying the starting level at a beginning of a therapy session.

12. The system of claim 11, wherein the threshold amount of usage is at least eight hours of respiratory therapy, and wherein the gathered usage information pertains to a predetermined percentile pressure level.

13. The system of claim 11, further comprising:

means (115) for adjusting the starting level of the one or more gas parameters of the pressurized flow repeatedly such that consecutive adjustments occur at least the threshold amount of usage apart.

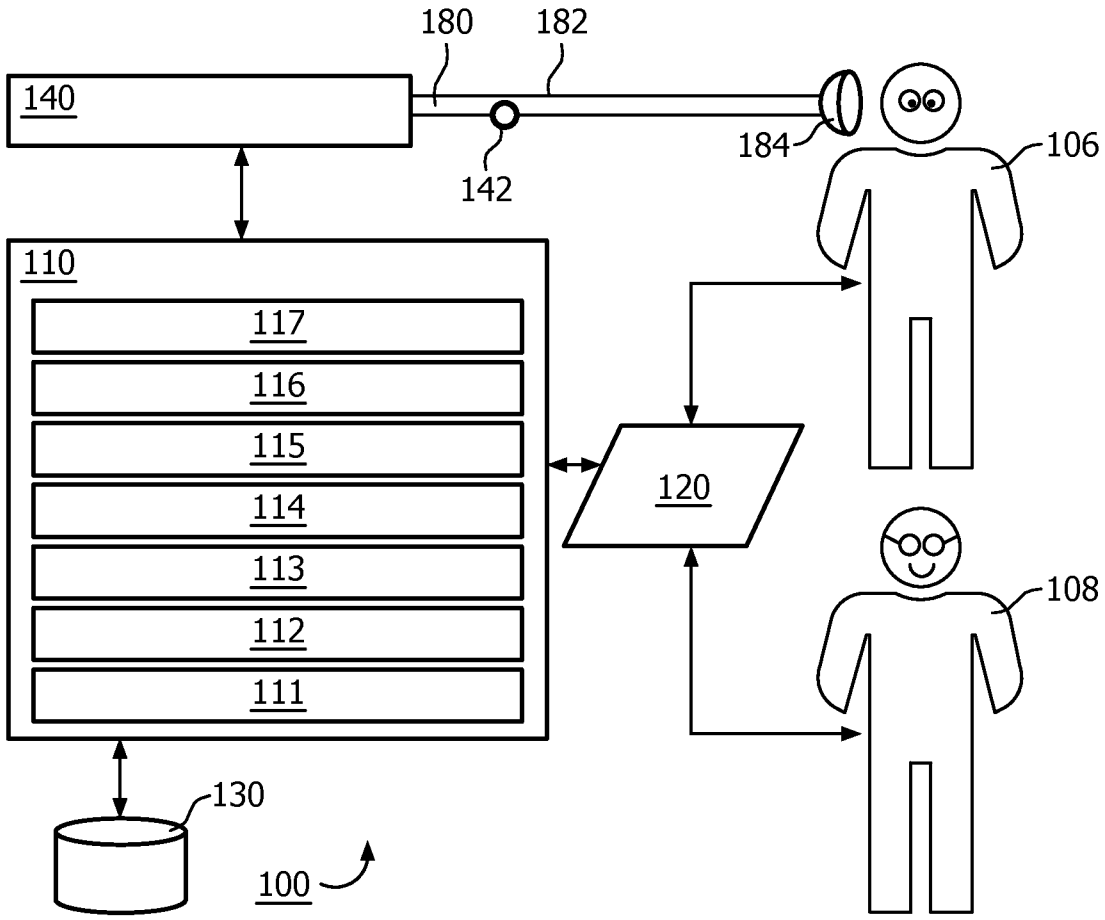
14. The system of claim 11, wherein the means (113) for adjusting the levels of one or more gas parameters of the pressurized flow is further configured to adjust a current pressure level of the pressurized flow, wherein the means (115) for determining the starting level of one or more gas parameters of the pressurized flow is further configured to determine a current starting pressure level, wherein operation of the means (113) for adjusting of levels of one or more gas parameters of the pressurized flow is controlled by an algorithm, and wherein the algorithm operates more aggressively responsive to the current pressure level being below the current starting pressure level.

15. The system of claim 14, further comprising:

means (112) for detecting occurrences of respiratory events based one the one or more output signals,

wherein the means (113) for adjusting levels of one or more gas parameters of the pressurized flow operates such that an adjustment is based on a detected occurrence of a respiratory event,

wherein the algorithm operates more aggressively by one or both of an increased pressure increment, and/or an increased responsiveness to detected occurrences of respiratory events.


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

FIG. 1

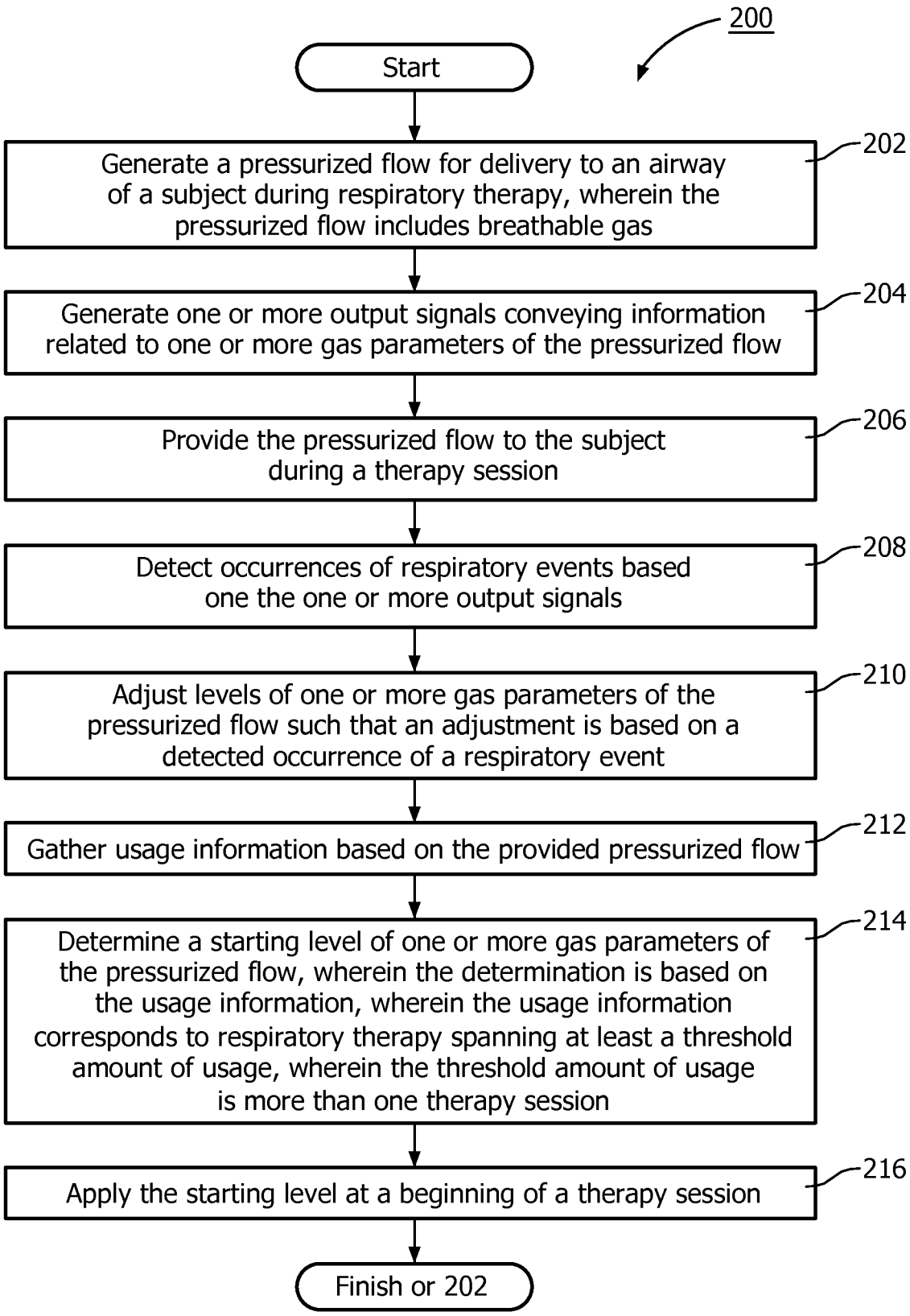
200
Start
Generate a pressurized flow for delivery to an airway of a subject during respiratory therapy, wherein the pressurized flow includes breathable gas
202
Generate one or more output signals conveying information related to one or more gas parameters of the pressurized flow
204
Provide the pressurized flow to the subject during a therapy session
206
Detect occurrences of respiratory events based one the one or more output signals
208
Adjust levels of one or more gas parameters of the pressurized flow such that an adjustment is based on a detected occurrence of a respiratory event
210
Gather usage information based on the provided pressurized flow
212
Determine a starting level of one or more gas parameters of the pressurized flow, wherein the determination is based on the usage information, wherein the usage information corresponds to respiratory therapy spanning at least a threshold amount of usage, wherein the threshold amount of usage is more than one therapy session
214
Apply the starting level at a beginning of a therapy session
216
Finish or 202

FIG. 2

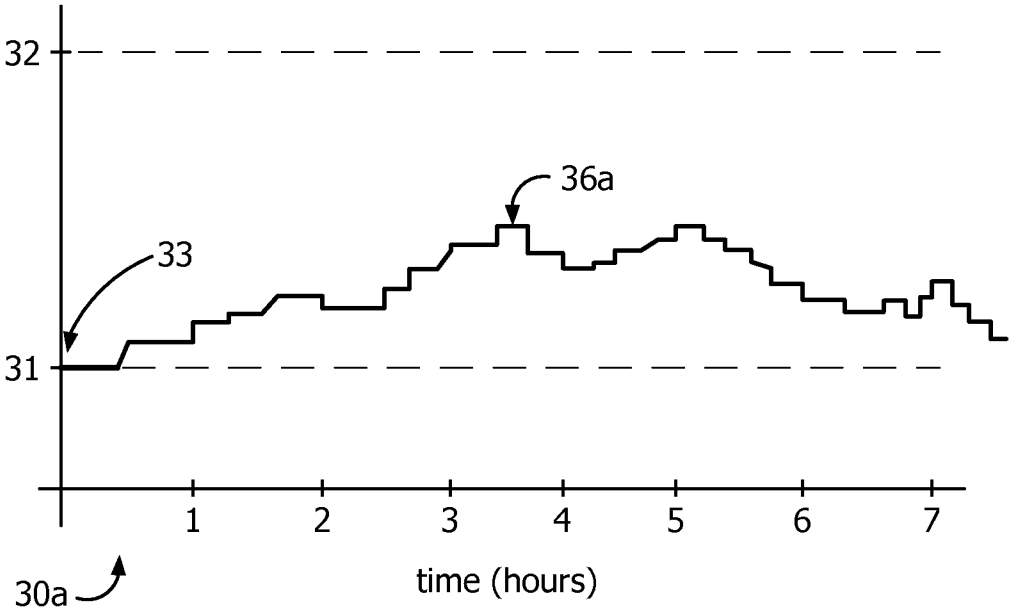
32
36a
33
31
1
2
3
4
5
6
7
30a
time (hours)

FIG. 3A

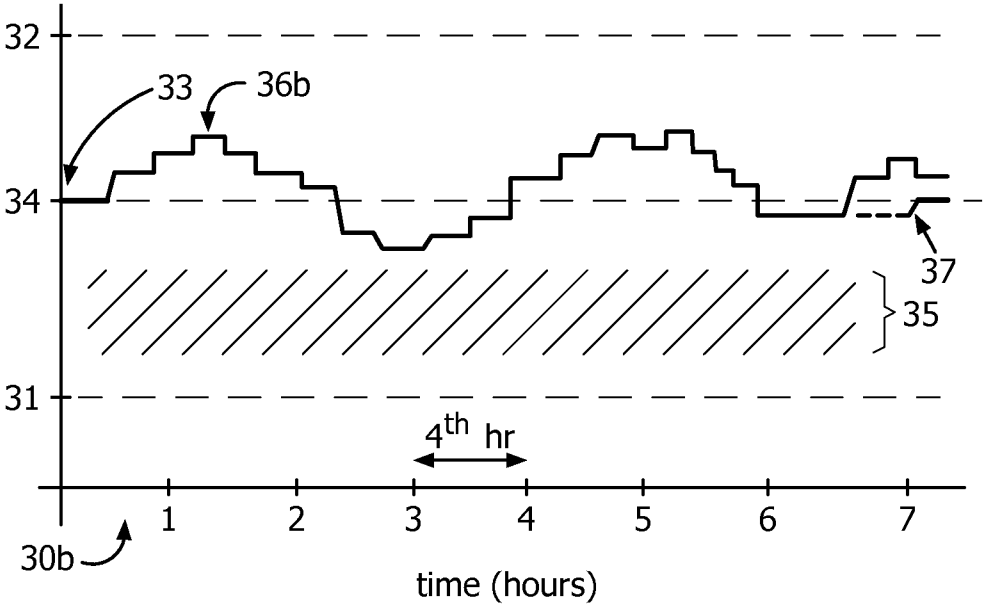
32
33
36b
34
37
35
31
4th hr
1
2
3
4
5
6
7
30b
time (hours)

FIG. 3B

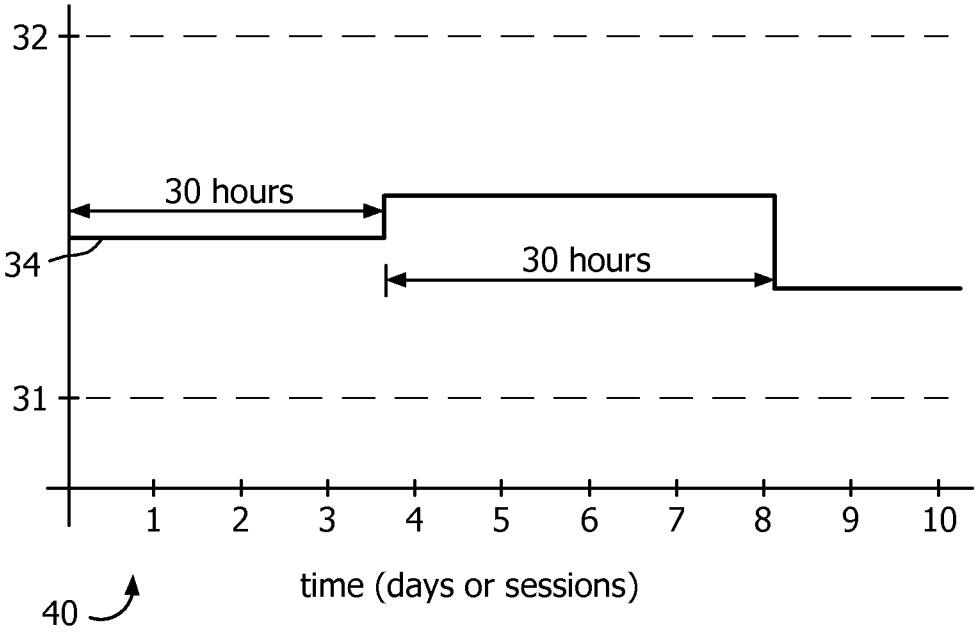
32
30 hours
34
30 hours
31
1
2
3
4
5
6
7
8
9
10
time (days or sessions)
40

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/052382

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal , WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/155134 Al (FARRUGIA STEVEN PAUL [AU]) 30 June 2011 (2011-06-30) figures 1-4 paragraph [0018] - paragraph [0022] paragraph [0028] - paragraph [0050] -----	I-5, II-15
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X	US 2009/038616 Al (MULCAHY DAVID [AU] ET AL) 12 February 2009 (2009-02-12) figures 1-8 paragraph [0015] - paragraph [0026] paragraph [0047] - paragraph [0055] paragraph [0061] - paragraph [0081] -----	I-5, II-15

-/ -

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) orwhich is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 July 2013	06/08/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Liess, Helmar

1

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/052382

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 401 713 Bl (HI LL PETER D [US] ET AL) 11 June 2002 (2002-06-11) f i gures 1-9 paragraph [0008] - paragraph [0009] paragraph [0016] - paragraph [0039] -----	I - 5 , II- 15
X	US 2007/221224 Al (PITTMAN STEPHEN D [US] ET AL) 27 September 2007 (2007-09-27) f i gures 1-15 paragraph [0017] - paragraph [0024] paragraph [0054] - paragraph [0086] -----	I - 5 , II- 15
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X	W0 2012/024733 A2 (RESMED LTD [AU] ; MULQUEENY QESTRA CAM I LLE [AU] ; TASSAUX DIDI ER [FR]) 1 March 2012 (2012-03-01) f i gures 1-10 paragraph [0008] - paragraph [0024] paragraph [0049] - paragraph [0052] -----	I - 5 , II- 15
X	US 2009/173347 Al (BERTH0N-J0NES MICHAEL [AU]) 9 July 2009 (2009-07-09) f i gures 1-8 paragraph [0054] - paragraph [0061] paragraph [0070] - paragraph [0086] paragraph [0110] - paragraph [0116] -----	I - 5 , II- 15
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1

INTERNATIONAL SEARCH REPORT

Information on patent family members

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2013/052382

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		JP 2009153991 A	16-07-2009
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		wo 2006133495 Al	21-12-2006

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2013/052382

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 6-10
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box III.1

Claims Nos.: 6-10

Method claims 6 to 10 are catered to medical methods for treatment of the human or animal body, namely a method for providing a respiratory therapy of a subject. For this reason they relate to a subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT, wherein no search and therefore no examination, Rule 66.1(e) PCT and Rule 67.1(iv), shall be required.