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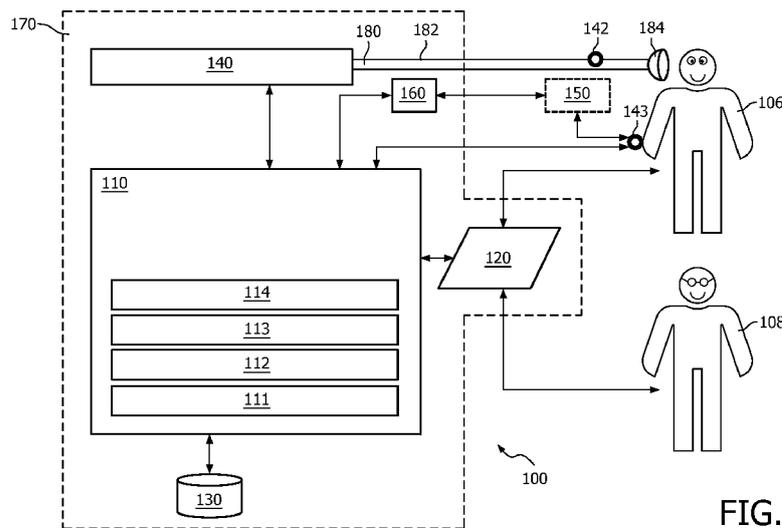


FIG. 1

(57) Abstract: A method and apparatus provide closed-loop control of the operation of a ventilator device based on physiological parameters received from and/or through a patient monitor device, which is a separate and discrete device from the ventilator device.

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Method and Apparatus for Controlling A Ventilation Therapy Device

BACKGROUND

1. Field

The present disclosure pertains to a method and apparatus controlling a ventilation therapy device, and, in particular, using physiological parameters, such as conveyed via a (patient) monitor signals and/or other physiological monitor signals, for closed-loop control of respiratory therapy regimens provided through a ventilator.

2. Description of the Related Art

It is well known to control a ventilator based on real-time measurements of gas parameters, such as pressure, flow, volume, gas mix, and/or other gas parameters, of the pressurized flow of breathable gas delivered to a subject through the ventilator. It is well known that patient monitors provide a variety of useful real-time information related to physiological parameters, such as heart rate, blood pressure, cardiac output, oxygen saturation, end-tidal carbon dioxide, and/or other physiological parameters of a subject.

SUMMARY

Accordingly, it is an object of one or more embodiments of the present invention to provide a ventilator comprising a pressure generator, a subject interface, a communications transceiver, and one or more processors. The pressure generator may be configured to generate a pressurized flow of breathable gas for delivery to the airway of a subject. The subject interface may be configured to interface between the pressure generator and a breathing circuit to deliver the pressurized flow of breathable gas to an artificial airway (*e.g.* endotracheal or tracheostomy tubes) or the natural airway of the subject through the outlet. The communications transceiver may be configured to receive communication signals from a patient monitor device, the communication signals comprising information related to physiological parameters of the subject, the patient monitor device being a separate and discrete device from the ventilator. The one or more processors may be configured to execute processing modules, including a control module and a regimen adjustment module. The control module may be configured to control the pressure generator 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. The regimen adjustment module may be configured to determine adjustments to respiratory therapy regimens based on the communication signals received from the patient monitor device such that the physiological parameters indicated in the communications signals are used for closed-loop control to adjust the respiratory therapy regimen.

It is yet another aspect of one or more embodiments of the present invention to provide a method of operating a ventilator device, comprising generating a pressurized flow of breathable gas within a ventilator device; delivering the pressurized flow of breathable gas from the ventilator device to the airway of a subject; receiving, at the ventilator device, communication signals from a patient monitor device, the communication signals comprising information related to physiological parameters of the subject, the patient monitor device being a separate and discrete device from the ventilator device; controlling the generation of the pressurized flow of breathable gas 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; determining adjustments to the respiratory therapy regimen based on the communication signals received from the patient monitor device such that the physiological parameters indicated in the communication signals are used for closed-loop control to adjust the respiratory therapy regimen; and implementing the adjustments to the respiratory therapy regimen.

It is yet another aspect of one or more embodiments to provide a ventilator comprising means for generating a pressurized flow of breathable gas, means for delivering the pressurized flow of breathable gas to the airway of a subject, means for receiving communication signals from a patient monitor device, means for controlling the generation of the pressurized flow of breathable gas 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, means for determining adjustments to the respiratory therapy regimen based on the communication signals received from the patient monitor device such that the physiological parameters indicated in the communication signals are used for closed-loop control to adjust the respiratory therapy regimen, and means for implementing the adjustments to the respiratory therapy regimen. The communication signals may include information related to physiological parameters of the subject. The patient monitor device may be a separate and discrete device from the ventilator.

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

FIG. 1 schematically illustrates a ventilator device according to one or more embodiments; and

FIG. 2 illustrates a method for operating a ventilator device.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

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

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

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

FIG. 1 illustrates a ventilator device 100 configured to deliver respiratory therapy to a subject 106. In particular, ventilator device 100 may be configured to

mechanically ventilate subject 106 by providing a pressurized flow of breathable gas to an artificial airway of subject 106 or to the natural airway of subject 106 to inflate and/or deflate the lungs of subject 106. In some embodiments, the respiratory therapy regimen is configured to support the breathing of subject 106. In some embodiments, the respiratory therapy regimen is configured to cause subject 106 to breathe without any respiratory effort from subject 106. Ventilator device 100 may be configured such that the respiratory therapy regimen is controlled in a closed-loop manner using one or more physiological parameters, thus providing real-time control of oxygenation, ventilation, pressure support, and/or other services related to ventilation.

Ventilator device 100 may include one or more of a pressurized flow generator 140, a subject interface 180 (*i.e.* outlet for gas output and/or a combination of outlet and inlet), a subject interface appliance 184, a communications transceiver 160, one or more processors 110, and/or other components. Ventilator device 100 may operate in conjunction with a patient monitor device 150, which is a separate and discrete device from ventilator device 100, as indicated by the dotted box representing patient monitor device 150 in FIG. 1.

Patient monitor device 150 may be configured to monitor one or more physiological parameters of subject 106. In some embodiments, patient monitor device 150 may comprise a stand-alone physiological monitor rather than a standard patient monitor. Patient monitor device 150 may include, for example, a conventional monitoring device that measures a subject's vital signs and displays the data obtained through the measurements on an electronic display and/or transmits the data on a monitoring network. The physiological parameters may include one or more of blood pressure, heart rate, pulse oximetry, blood gas level, ECG, EEG, body temperature, (end-tidal) carbon dioxide concentration, parameters indicating pending cardiac conditions, cardiac output, sedation index and/or other physiological parameters. By way of non-limiting example, patient monitor device 150 may include one or more of the IntelliVue patient monitors by Philips (*e.g.*, IntelliVue MP90, MMX800, MMS X2), SureSigns patient monitors by Philips (*e.g.*, SureSigns VM8), and/or other patient monitoring devices. Patient monitor device 150 may include one or more of an electronic display, one or more patient monitor sensors 143, a user interface, one or more processors, and/or other components.

Patient monitor sensors 143 are configured to generate output signals conveying information related to physiological parameters, as described above, of subject 106. Patient monitor sensors 143 may be integrated and/or coupled to patient monitor device 150. Alternatively, and/or simultaneously, patient monitor sensors 143 may be separate and

discrete from patient monitor device 150, and configured such that the output signals generated by patient monitor sensors 143 may be transmitted to patient monitor device 150 and/or ventilator device 100 (or a component thereof). This transmission may be accomplished via wired and/or wireless communication media. The illustration of patient monitor sensor 143 as including a single member in FIG. 1 is not intended to be limiting.

Pressure generator 140 of ventilator device 100 may be integrated, combined, coupled, or connected with an airway pressure device. Respiratory therapy may recommend delivery of a pressurized flow of breathable gas to the airway of a subject, providing one or more inhalation pressure, flow, and/or volume levels during the inhalation phase, and one or more exhalation pressure, flow, and/or volume levels during the exhalation phase. Any pressure level during an inhalation phase may be referred to as an inhalation pressure level, though such a pressure level need not be constant throughout the inhalation phase. In addition to alternating between multiple levels, the inhalation pressure level may ramp up or down according to a predetermined slope (absolute and/or relative, *e.g.* dependent on breathing rate) for any specified section of a phase. The flow level during inhalation can follow a predetermined flow waveform like a square or ramp. Similar features may be available for exhalation phases. The pressure and/or flow levels may be either predetermined and fixed, follow a predetermined dynamic characteristic, or they may dynamically change breath-to-breath or over several breaths.

Pressure generator 140 of ventilator device 100 may be configured to provide a pressurized flow of breathable gas to the airway of subject 106. Subject 106 may or may not initiate one or more phases of respiration. Ventilatory support may be implemented as a higher and lower positive pressure of a (multi-level) PAP device. For example, to support inspiration, the pressure of the pressurized flow of breathable gas may be adjusted to an inspiratory pressure and/or may be adjusted to a flow level. Alternatively, and/or simultaneously, to support expiration, the pressure of the pressurized flow of breathable gas may be adjusted to an expiratory pressure. Other schemes for providing respiratory support (including Volume Control Ventilation (VCV), Pressure Control Ventilation(PCV), Airway Pressure Release Ventilation (APRV), Pressure Regulated Volume Control (PRVC), CPAP, BiPAP®, and/or other schemes) through the delivery of the pressurized flow of breathable gas are contemplated.

Ventilator device 100 may be configured such that one or more gas parameters of the pressurized flow of breathable gas are controlled in accordance with a therapeutic respiratory regimen for subject 106. The one or more gas parameters may include one or

more of flow, volume, pressure, humidity, gas mix, velocity, acceleration, (intentional) gas leak, and/or other parameters. Ventilator device 100 may be configured to provide types of therapy including types of therapy where a subject performs inspiration and/or expiration of his/her own accord and/or where the device provides mandatory controlled breaths.

A pressurized flow of breathable gas may be delivered by pressure generator 140 to or near the airway of subject 106 via a subject interface 180 (also referred to herein as an outlet). Subject interface 180 may include a conduit 182, a subject interface appliance 184, and/or other components. Conduit 182 may be a single-limb or a dual-limb flexible length of hose, or other conduit, 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.

Subject interface appliance 184 of ventilator device 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 certain 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 is configured to engage with and/or be inserted into an endotracheal tube, a tracheotomy portal, and/or other interface appliances. In certain embodiments, subject interface appliance 184 is configured to engage the airway of subject 106 without an intervening appliance. In this embodiment, subject interface appliance 184 includes one or more of an endotracheal tube, a nasal cannula, a tracheotomy tube, a nasal mask, a nasal/oral mask, a full face mask, a total face mask, a partial rebreathing mask, or other interface appliances that communicate a flow of gas with an airway of a subject. The present disclosure is not limited to these examples, and contemplates delivery of the pressurized flow of breathable gas to subject 106 using any subject interface.

Referring to FIG. 1, ventilator device 100 may include electronic storage 130 comprising electronic storage media that electronically stores information. The electronic storage media of electronic storage 130 includes one or both of system storage/ventilator device storage that is provided integrally (*i.e.*, substantially non-removable) with ventilator device 100 and/or removable storage that is removably connectable to ventilator device 100 via, for example, a port (*e.g.*, a USB port, a FireWire port, *etc.*) or a drive (*e.g.*, a disk drive, *etc.*). Electronic storage 130 may include one or more of optically readable storage media

(*e.g.*, optical disks, *etc.*), magnetically readable storage media (*e.g.*, magnetic tape, magnetic hard drive, floppy drive, *etc.*), electrical charge-based storage media (*e.g.*, EEPROM, RAM, *etc.*), solid-state storage media (*e.g.*, flash drive, *etc.*), and/or other electronically readable storage media. Electronic storage 130 stores software algorithms, information determined by processor 110, information received via user interface 120, and/or other information that enables ventilator device 100 to function properly. For example, electronic storage 130 may record or store timing information (including duration of inhalation phases and exhalation phases as well as transitional moments therebetween), one or more (breathing) parameters and/or other parameters (as discussed elsewhere herein), pressure levels, information indicating whether the subject adequately complied with a prescribed respiratory therapy regimen, information indicating adequacy of treatment, and/or other information. Electronic storage 130 may be a separate component within ventilator device 100, or electronic storage 130 may be provided integrally with one or more other components of ventilator device 100 (*e.g.*, processor 110).

Patient monitor device 150 may include electronic storage having substantially similar functionality and capability as electronic storage 130, though pertaining to patient monitor 150 rather than ventilator device 100.

User interface 120 of ventilator device 100 in FIG. 1 is configured to provide an interface between ventilator device 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 ventilator device 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 ventilator device 100. 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, smartphones, smart touchpads, speakers, a microphone, an indicator light, an audible alarm, and a printer. Information is *e.g.* provided to subject 106 by user interface 120 in the form of auditory signals, visual signals, tactile signals, and/or other sensory signals.

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 is integrated with a removable storage interface provided by electronic storage 130. In this example, information is loaded into ventilator device 100 from removable storage (*e.g.*, a smart card, a flash drive, a removable disk, *etc.*) that enables the user(s) to customize the implementation of ventilator device 100. Other exemplary input

devices and techniques adapted for use with ventilator device 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), mobile phone and other wireless communication channels. In short, any technique for communicating information with ventilator device 100 is contemplated as user interface 120.

Patient monitor device 150 may include a user interface having substantially similar functionality and capability as user interface 120, though pertaining to patient monitor 150 rather than ventilator device 100.

Ventilation sensors 142 of ventilator device 100 in FIG. 1 is configured to generate one or more output signals conveying measurements related to the ventilation, oxygen saturation, and/or end-tidal carbon dioxide of subject 106. The measurements may relate to gas parameters and/or other parameters. Gas parameters may include flow, pressure, humidity, velocity, acceleration, and/or other gas parameters related to the pressurized flow of breathable gas delivered to subject 106. Output signals may convey measurements related to respiratory parameters. Ventilation sensor(s) 142 may be in fluid communication with conduit 182 and/or subject interface appliance 184.

The illustration of ventilation sensor 142 as including a single member in FIG. 1 is not intended to be limiting. In certain embodiments ventilation sensor 142 includes a plurality of sensors operating as described above by generating output signals conveying information related to parameters associated with the gas breathed by subject 106, the delivery of the gas to subject 106, oxygen saturation of subject 106, and/or end-tidal carbon dioxide of subject 106. Alternatively, and/or simultaneously, a parameter may be related to a mechanical unit of measurement of a component of ventilator device 100 such as rotor speed, motor speed, blower speed, fan speed, or a related measurement that serves as a proxy for any of the breathing parameters listed herein through a previously known/calibrated mathematical relationship. Resulting signals or information from sensor 142 may be transmitted to processor 110, user interface 120, electronic storage 130, and/or other components of ventilator device 100. This transmission can be wired and/or wireless.

Communications transceiver 160 of ventilator device 100 in FIG. 1 is configured to receive communication signals from patient monitor 150, which is a separate and discrete device from ventilator device 100. The communication signals may comprise information related to physiological parameters of subject 106. The communication signals may comprise the same signals and/or information as one or more patient monitor sensors 143. Alternatively and/or simultaneously, the communication signals may comprise data that

is determined and/or generated by patient monitor device 150 based on output signals from patient monitor sensors 143. Such data may for example include minimum, maximum, mean, and/or average measured values, trend data for a particular patient monitor sensor 143 and/or a physiological parameter derived thereof, *e.g.* within a configurable period such as a minute, an hour, a day, a week, and/or another predetermined period. Communication signals may comprise information based on multiple signals and/or multiple physiological parameters derived therefrom.

In some embodiments, communications transceiver 160 may be configured to transmit signals, information, and/or alarms to patient monitor 150, *e.g.* for presentation on the user interface and/or the electronic display of patient monitor device 150. For example, a component of ventilator device 100 may determine a (real-time and/or continuous) parameter that is displayed on patient monitor 150, after transmission through communications transceiver 160. Such a parameter may be displayed along with other parameters based on output signals from patient monitor sensors 143.

Processor 110 of ventilator device 100 in FIG. 1 is configured to provide information processing capabilities within ventilator device 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.

Patient monitor device 150 may include one or more processors having substantially similar functionality and capability as processor 110, though pertaining to patient monitor 150 (and its components) rather than ventilator device 100 (and its components).

As is shown in FIG. 1, processor 110 is configured to execute one or more computer program modules. The one or more computer program modules include one or more of a parameter determination module 111, a control module 112, a regimen adjustment module 113, an alarm module 114, and/or other modules. Processor 110 may be configured to execute modules 111, 112, 113, and/or 114 by software; hardware; firmware; some combination of software, hardware, and/or firmware; and/or other mechanisms for configuring processing capabilities on processor 110. Processor 110 may be configured to execute one or more modules that receive and/or process the output signals generated by patient monitor sensors 143 and/or ventilation sensors 142. Based on the output signals

generated by patient monitor sensors 143, the processing modules may monitor the physiological parameters of subject 106. The processing modules are further configured to present information related to at least one physiological parameter. Processor 110 may be configured to execute one or more modules that receive and/or process signals and/or information obtained from patient monitor device 150.

It should be appreciated that although modules 111, 112, 113, and 114 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, 112, 113, and/or 114 may be located remotely from the other modules. The description of the functionality provided by the different modules 111, 112, 113, and/or 114 described below is for illustrative purposes, and is not intended to be limiting, as any of modules 111, 112, 113, and/or 114 may provide more or less functionality than is described. For example, one or more of modules 111, 112, 113, and/or 114 may be eliminated, and some or all of its functionality may be provided by other ones of modules 111, 112, 113, and/or 114. Note that processor 110 may be configured to execute one or more additional modules that may perform some or all of the functionality attributed below to one of modules 111, 112, 113, and/or 114. Note that one or more of modules 111, 112, 113, and 114, and/or some or all of their respective functionalities may be provided by patient monitor device 150 (or components thereof).

Parameter determination module 111 is configured to determine one or more gas parameter, breathing parameters, and/or other parameters from the output signals generated by patient monitor sensors 143 and/or ventilation sensors 142. Gas parameters of the (pressurized) flow of breathable gas may include one or more of (peak) flow, pressure, temperature, humidity, velocity, acceleration, gas composition (*e.g.* concentration(s) of one or more constituents), thermal energy dissipated, (intentional) gas leak, and/or other gas parameters related to the (pressurized) flow of breathable gas. Breathing parameters may be derived from the one or more gas parameters, and include one or more of tidal volume of the breathing of the subject, retrograde volume, respiratory rate, breathing period, inhalation time or period, exhalation time or period, inhalation volume, exhalation volume, peak flow, flow rate of the breathing of the subject, 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, pressure-volume loops, flow-volume loops, (intentional) gas leak, and/or other breathing parameters. Some or all of the stated functionality of parameter determination module 111 may be

incorporated or integrated into other computer program modules of processor 110 and/or patient monitor device 150.

Control module 112 is 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 112 may be configured to control pressure generator 140 to provide the pressurized flow of breathable gas at inhalation pressure levels during inhalation phases, and at exhalation pressure levels during exhalation phases. Parameters determined by parameter determination module 111 (and/or received through patient monitor sensors 143) may be used by control module 112, *e.g.* in a feedback manner, to adjust ventilator settings/operations. Alternatively, and/or simultaneously, signals and/or information received by communications transceiver 160 may be used by control module 112, *e.g.* in a feedback manner, to adjust ventilator settings/operations. Control module 112 may be configured to time its operations relative to the transitional moments in the breathing cycle of a subject and over multiple breath cycles.

Regimen adjustment module 113 is configured to determine adjustments to the respiratory therapy regimen. Adjustments may be based on communication signals received from patient monitor device 150 such that the physiological parameters indicated in the communication signals are used as closed-loop control parameters in adjusting the respiratory therapy regimen. Alternatively, and/or simultaneously, adjustments may be based on parameters determined by parameter determination module 111. Once determined, the adjustments may be implemented by regimen adjustment module 113, control module 112, and/or other components of ventilator device 100. In some embodiments, the communication signals are related in a known manner to the parameters determined by parameter determination module 111. In such a case, the determination by regimen adjustment module 113 is more robust than a similar determination for a ventilator that lacks the information transmitted from a patient monitor device. In some embodiments, the communication signals are unrelated (or not related in a known manner) to the parameters determined by parameter determination module 111. In such a case, the determination by regimen adjustment module 113 is based on more data (and different types of data) than a similar determination for a ventilator that lacks the information transmitted from a patient monitor device.

Alarm module 114 is configured to receive information and/or parameters from any component of ventilator device 100, any component of patient monitor 150, and/or any patient monitor sensor 143. Alarm module 114 may be configured to monitor any received information and/or parameter for alarm conditions, including exceeding an upper or

lower limit. Alarm conditions may be determined for mean or average values. Alarm conditions may be determined on a logical combination of multiple parameters. For example, an alarm condition could be programmed, *e.g.* through user interface 120, as a logical conjunction of a) a heart rate exceeding some predetermined value X , and, simultaneously, b) the respiratory rate exceeding some predetermined value Y . Additional logical conditions are considered, as are consecutive and/or nested alarm conditions that follow each other in time, such as a certain duration with an average heart rate exceeding X , followed within a certain duration by an occurrence of a respiratory rate exceeding Y .

Alarm module 114 may be configured to transmit, *e.g.* through communications transceiver 160, an occurrence of an alarm and/or a determination of an alarm condition to patient monitor device 150 for presentation to a user and/or subject.

Ventilator device 100 may include an external housing 170 that houses at least pressure generator 140 and one or more of processors 110. Patient monitor device 150 is outside of and physically separate from external housing 170.

FIG. 2 illustrates a method 200 for operating a ventilator device. 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.

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.

At an operation 202, a pressurized flow of breathable gas is generated within a ventilator. 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).

At an operation 204, the pressurized flow of breathable gas is delivered to the airway of a subject. In one embodiment, operation 204 is performed by an outlet or subject

interface similar to or substantially the same as subject interface 180 (shown in FIG. 1 and described above).

At an operation 206, communication signals are received from a patient monitor device. The communication signals comprise information related to physiological parameters of the subject. The patient monitor device is a separate and discrete device from the ventilator device. In one embodiment, operation 206 is performed by a communications transceiver similar to or substantially the same as communications transceiver 160 (shown in FIG. 1 and described above).

At an operation 208, the generation of the pressurized flow of breathable gas is controlled 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. In one embodiment, operation 208 is performed by a control module similar to or substantially the same as control module 112 (shown in FIG. 1 and described above).

At an operation 210, adjustments are determined to the respiratory therapy regimen based on the communication signals received from the patient monitor device such that the physiological parameters are used for closed-loop control to adjust the respiratory therapy regimen. In one embodiment, operation 210 is performed by a regimen adjustment module similar to or substantially the same as regimen adjustment module 113 (shown in FIG. 1 and described above).

At an operation 212, the adjustments to the respiratory therapy regimen are implemented. In one embodiment, operation 212 is performed by a regimen adjustment module 113 similar to or substantially the same as regimen adjustment module 113 (shown in FIG. 1 and described above).

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

Although various embodiments have 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 scope of this disclosure 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 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 ventilator comprising:
 - a pressure generator (140) configured to generate a pressurized flow of breathable gas;
 - a subject interface (180) configured to interface between the pressure generator and a breathing circuit to deliver the pressurized flow of breathable gas to the airway of a subject through the subject interface;
 - a communications transceiver (160) configured to receive communication signals from a patient monitor device, the communication signals comprising information related to physiological parameters of the subject, the patient monitor device being a separate and discrete device from the ventilator;
 - one or more processors (110) configured to execute processing modules, the processing modules comprising:
 - a control module (112) configured to control the pressure generator 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;
 - a regimen adjustment module (113) configured to determine adjustments to the respiratory therapy regimen based on the communication signals received from the patient monitor device such that the physiological parameters indicated in the communication signals are used for closed-loop control to adjust the respiratory therapy regimen.
2. The ventilator of claim 1, wherein the adjustments to the respiratory therapy regimen comprise adjustments to one or more of the gas parameters of the pressurized flow of breathable gas that are varied over time in accordance with the respiratory therapy regimen.
3. The ventilator of claim 1, wherein the respiratory therapy regimen is determined such that delivery of the pressurized flow of breathable gas to the airway of the subject controls one or more breathing parameters of the subject, and wherein the regimen adjustment module is configured to determine adjustments to the respiratory therapy regimen such that a breathing parameter of the subject is controlled based on the physiological parameters indicated in the communication signals.

4. The ventilator of claim 1, wherein the regimen adjustment module is configured to determine adjustments to the respiratory therapy regimen further based on the physiological parameters of the subject, wherein the adjustments pertain to control of one or more of nebulization, humidification, or inextufflation.

5. The ventilator of claim 1, further comprising an external housing (170) that houses at least the pressure generator and the one or more processors, wherein the patient monitor device is outside of and physically separate from the external housing.

6. A method of operating a ventilator device comprising:
generating a pressurized flow of breathable gas within a ventilator device;
delivering the pressurized flow of breathable gas from the ventilator device to the airway of a subject;

receiving, at the ventilator device, communication signals from a patient monitor device, the communication signals comprising information related to physiological parameters of the subject, the patient monitor device being a separate and discrete device from the ventilator device;

controlling the generation of the pressurized flow of breathable gas 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;

determining adjustments to the respiratory therapy regimen based on the communication signals received from the patient monitor device such that the physiological parameters indicated in the communication signals are used for closed-loop control to adjust the respiratory therapy regimen; and

implementing the adjustments to the respiratory therapy regimen.

7. The method of claim 6, wherein the adjustments to the respiratory therapy regimen comprise adjustments to one or more of the gas parameters of the pressurized flow of breathable gas that are varied over time in accordance with the respiratory therapy regimen.

8. The method of claim 6, wherein the respiratory therapy regimen is determined such that delivery of the pressurized flow of breathable gas to the airway of the subject controls one or more breathing parameters of the subject, and wherein the adjustments to the respiratory therapy regimen are determined such that a breathing parameter of the subject is controlled based on the physiological parameters indicated in the communication signals.

9. The method of claim 6, wherein the adjustments to the respiratory therapy regimen are further based on the physiological parameters of the subject, wherein the adjustments pertain to the control of one or more of nebulization, humidification, or inextufflation.

10. The method of claim 6, wherein the ventilator device comprises an external housing, and wherein the patient monitor device is outside of and physically separate from the external housing.

11. A ventilator comprising:

means for generating (140) a pressurized flow of breathable gas;

means for delivering (180) the pressurized flow of breathable gas from the means for generating to the airway of a subject;

means for receiving (160), at the means for generating, communication signals from a patient monitor device, the communication signals comprising information related to physiological parameters of the subject, the patient monitor device being a separate and discrete device from the ventilator;

means for controlling (112) the generation of the pressurized flow of breathable gas 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;

means for determining adjustments (113) to the respiratory therapy regimen based on the communication signals received from the patient monitor device such that the physiological parameters indicated in the communication signals are used for closed-loop control to adjust the respiratory therapy regimen; and

means for implementing the adjustments (113) to the respiratory therapy regimen.

12. The ventilator of claim 11, wherein the adjustments to the respiratory therapy regimen comprise adjustments to one or more of the gas parameters of the pressurized flow of breathable gas that are varied over time in accordance with the respiratory therapy regimen.

13. The ventilator of claim 11, wherein the respiratory therapy regimen is determined such that delivery of the pressurized flow of breathable gas to the airway of the subject controls one or more breathing parameters of the subject, and wherein the adjustments to the respiratory therapy regimen are determined such that a breathing parameter of the subject is controlled based on the physiological parameters indicated in the communication signals.

14. The ventilator of claim 11, wherein the adjustments to the respiratory therapy regimen are further based on the physiological parameters of the subject, wherein the adjustments pertain to the control of one or more of nebulization, humidification, or inextufflation.

15. The ventilator of claim 11, further comprising an external housing (170), and wherein the patient monitor device is outside of and physically separate from the external housing.

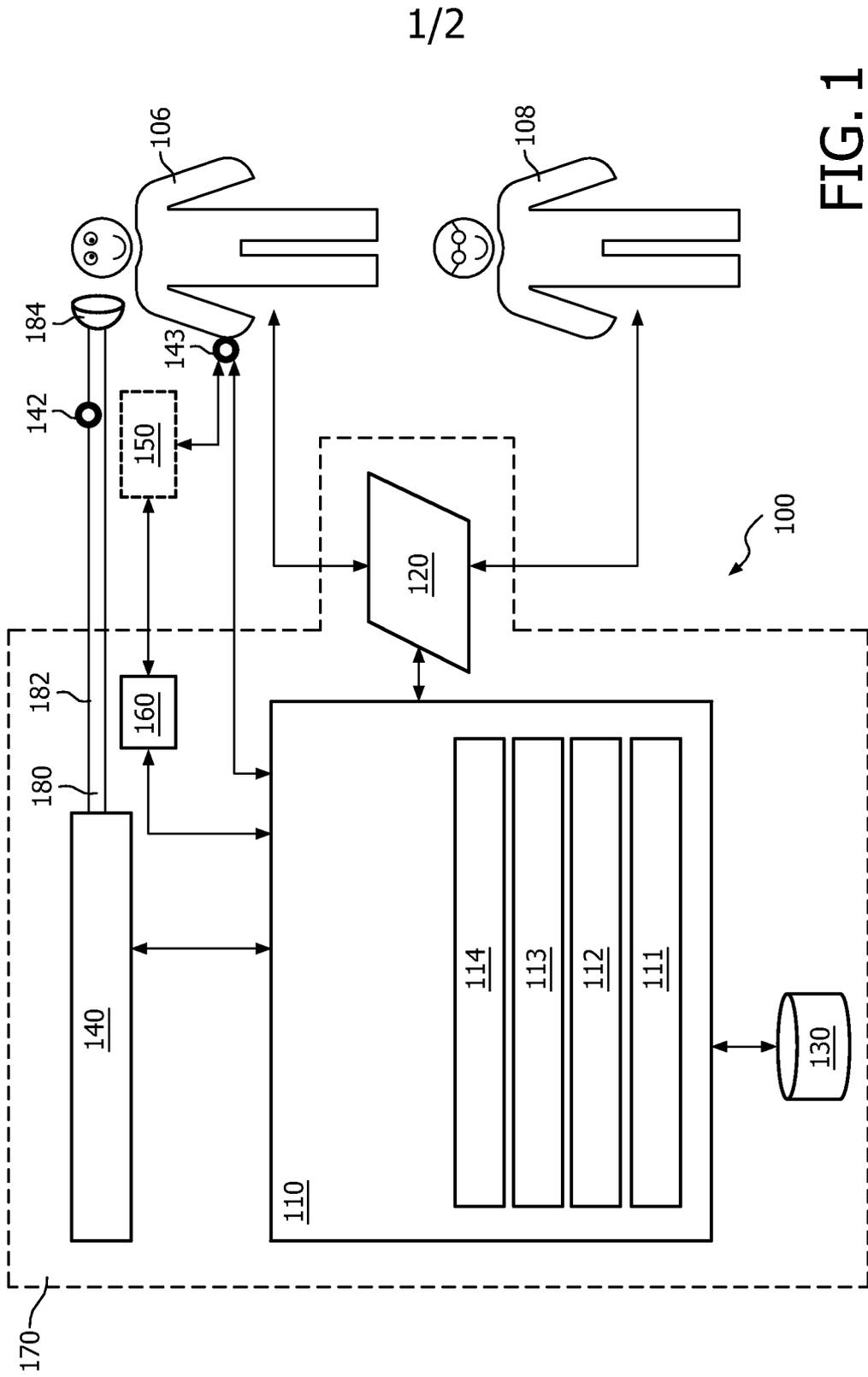


FIG. 1

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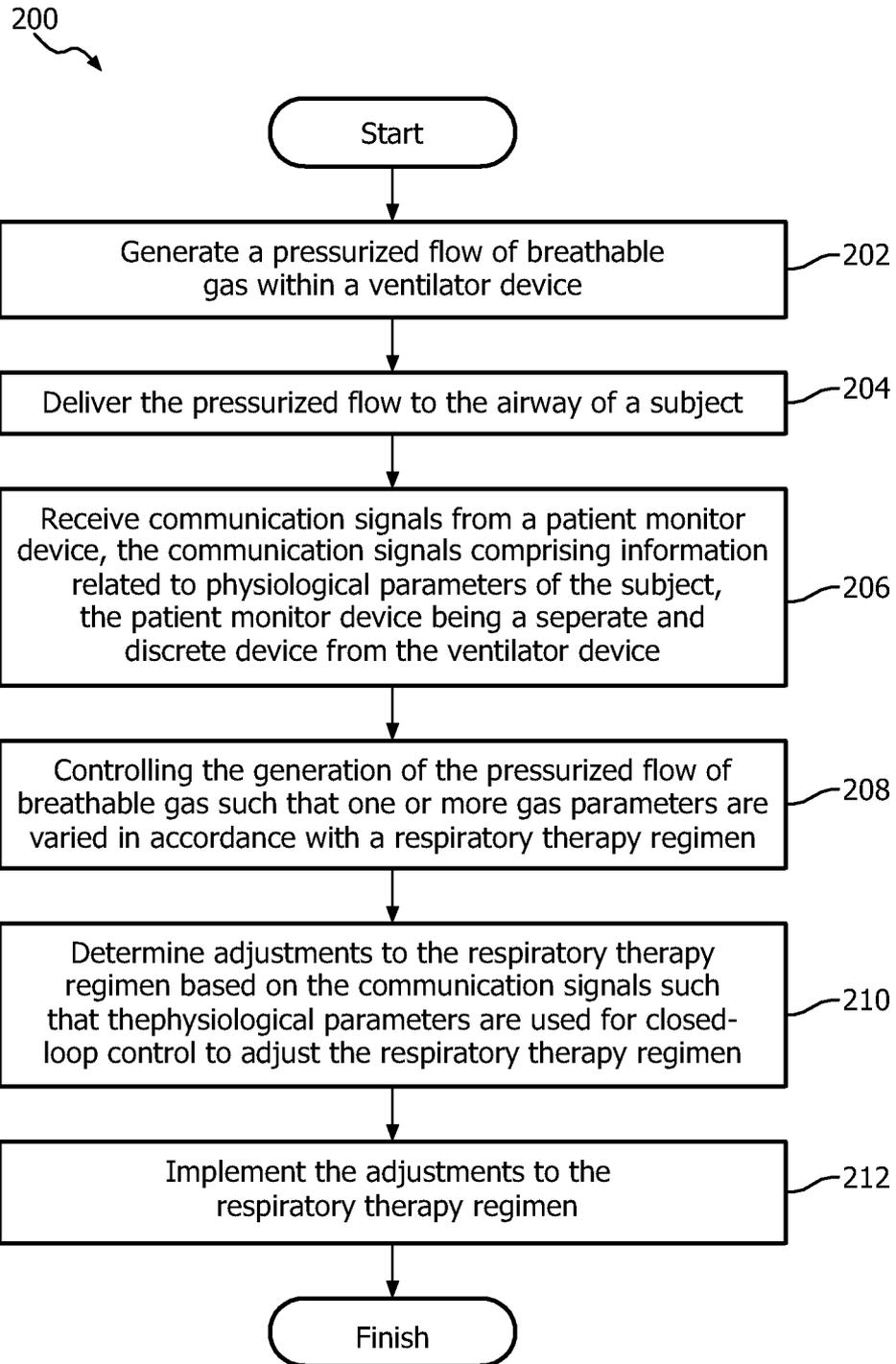


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2012/054119

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7 225 809 B1 (BOWEN KEVIN [US] ET AL) 5 June 2007 (2007-06-05) The whole document, especially column 9, line 58 - column 10, line 46. -----	1-5, 11-15
X	GB 2 396 426 A (DRAGERWERK MEDICAL [DE] DRAEGER MEDICAL AG [DE]) 23 June 2004 (2004-06-23) figure 1 page 3, paragraph 3 page 6, paragraph 3 - page 7, paragraph 1 -----	1-5, 11-15
X	US 5 365 922 A (RAEMER DANIEL B [US]) 22 November 1994 (1994-11-22) column 3, line 64 - column 4, line 22; figures 1,7a ----- -/--	1-5, 11-15

Further documents are listed in the continuation of Box C.

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) or which 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 29 November 2012	Date of mailing of the international search report 06/12/2012
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Borowski, Aleksander

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2012/054119

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/127356 A2 (VERSAMED INC [US]; MISHOLI BOAZ [US]) 30 November 2006 (2006-11-30) paragraph [0034]; figures 1,2 -----	1-5, 11-15
X	WO 02/078775 A2 (HEPTEC GMBH [DE]; GENGER HARALD [DE]; LAUK MICHAEL [DE]) 10 October 2002 (2002-10-10) Whole document, especially Fig. 1; page 10, line 13 - page 11, line 21; page 16, lines 17 - 33 -----	1-5, 11-15
X	US 2010/224192 A1 (DIXON PAUL [GB] ET AL) 9 September 2010 (2010-09-09) paragraph [0021]; figure 1 -----	1-5, 11-15
A	WO 2010/111073 A1 (NELLCOR PURITAN BENNETT LLC [US]; LOVEJOY DAVID [US]) 30 September 2010 (2010-09-30) -----	1,11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2012/054119

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. Claims Nos.: **6-10**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Claims 6-10 relate to a method for treatment of the human or animal body by therapy: delivering the pressurized flow of breathable gas from the ventilator device to the airway of a subject (cf. claim 6).
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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2012/054119

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