

**SYSTEMS AND METHODS FOR VENTILATOR CONTROL INCLUDING
DETERMINATION OF PATIENT FATIGUE AND PRESSURE SUPPORT
VENTILATION (PSV) LEVEL**

5 TECHNICAL FIELD

The invention relates to the field of ventilators, in particular to a method and apparatus for controlling a ventilation therapy device including the determination of patient fatigue and a preferred pressure support ventilation level.

10 BACKGROUND

A patient receiving breath pressure support from a ventilator system typically receives breathing gas through a patient circuit of the ventilator. The patient circuit generally includes two conduits (e.g. flexible tubing) connected to a fitting referred to as a tubing circuit wye. The free ends of the conduits are attached to the ventilator so that one
15 conduit receives breathing gas from the ventilator's pneumatic system, and the other conduit returns gas exhaled by the patient to the ventilator. The wye fitting is typically connected to the patient's breathing attachment or enclosure, which conducts breathing gas into the lungs, and exhaled gas from the lungs to the exhalation branch of the patient circuit. The pneumatic system at the inhalation end of the patient circuit is typically closed
20 before a breath, and the exhalation valve at the exhalation end of the patient circuit is typically preceded by a one-way valve, to prevent gas from flowing in the exhalation branch of the patient circuit.

In mechanical ventilation, the pressure support ventilation (PSV) level may be an important parameter. If it is set too low it may lead to high effort from the patient; on the
25 other hand, if it is too high the patient could be making very low effort. In the first case, the patient can reach a fatigue status which means he/she will not be able to make the appropriate effort leading to an inability to maintain their ideal minute ventilation over time. Fatigue is one of the most common causes of weaning failure. For this reason, being able to detect fatigue may be important in setting the PSV level in a mechanically
30 ventilated patient. Selection of the appropriate PSV level setting in order to avoid respiratory muscle fatigue is a challenge even for experienced clinicians.

So, with mechanical ventilated patients, the PSV level coupled with patient effort may dictate the tidal volume and minute ventilation. As a consequence, if the pressure support is too low for that particular patient he/she has to increase their effort to a higher

level that will guarantee desired minute ventilation but it could generate fatigue. On the other hand, a caregiver cannot set the pressure support to a pressure value that is too high or a barotrauma may develop. Moreover, a caregiver should try to reduce the ventilation time as much as possible, otherwise the patient will get used to the ventilator and it will be more difficult to wean him/her off of the ventilator.

Accordingly, it may be desired to provide for the reliable determination of fatigue and indication of a PSV level in a ventilation breathing system.

SUMMARY

Embodiments of the invention may provide an apparatus, systems, methods, and computer-readable storage medium for determining a preferred pressure support ventilation (PSV) level based upon calculated patient fatigue. An embodiment that may achieve this is directed to a ventilator breathing system (VBS) to provide breathing gas to a patient. The VBS includes a gas supply, a patient tubing circuit coupled to the gas supply, and a monitoring system associated with the gas supply and patient tubing circuit and configured to monitor breath parameters including at least a breath duration. A control unit is coupled to the monitoring system and configured to determine a preferred pressure support ventilation (PSV) level of the VBS by calculating a patient fatigue indicator based upon patient respiratory muscles activity pressure and monitored breath cycle time.

In an embodiment, the control unit includes an estimator block and a fatigue indicator block, wherein the fatigue indicator block is configured to calculate the patient fatigue indicator based upon an estimated patient respiratory muscles activity pressure from the estimator block, an ascertained maximum patient respiratory muscles activity pressure, a monitored inhalation time, and a monitored breath duration. As such, in an embodiment, the patient fatigue indicator may be defined by a Tension Time index (TT_{di}) of the patient based upon the estimated patient respiratory muscles activity pressure (P_{mus}), the ascertained maximum patient respiratory muscles activity pressure (P_{musMax}), the monitored inhalation time (T_i), and the monitored breath duration (T_{tot}) in accordance with the equation: $TT_{di} = (P_{mus} / P_{musMax}) \times (T_i / T_{tot})$.

In an embodiment, the ascertained maximum patient respiratory muscles activity pressure (e.g. diaphragm muscle activity pressure) may be based upon by a patient occlusion maneuver. The ascertained maximum patient respiratory muscles activity

pressure may be calculated over a plurality of breath cycles or may be defined in a look-up table.

In an embodiment, a user display device is associated with the control unit, and the control unit is configured to provide the preferred PSV level, or other indication of a recommended change in the PSV level, for display on the user display device.

In an embodiment, a PSV controller is associated with the gas supply and configured to set a PSV level to the patient, and the control unit is configured to provide the preferred PSV level to the PSV controller for automated setting of the PSV level.

In an embodiment, the control unit is configured to determine the preferred PSV level of the VBS by comparing the calculated patient fatigue indicator to a threshold.

Embodiments of the invention are also directed to a method for determining a preferred pressure support ventilation (PSV) level of a ventilator breathing system (VBS) configured to provide breathing gas to a patient via a patient tubing circuit and having a breath cycle. The method includes monitoring breath parameters of the patient and VBS including at least breath inhalation time, breath duration and determining the preferred PSV level of the VBS by calculating a patient fatigue indicator based upon patient respiratory muscle activity pressure and monitored breath parameters.

In an embodiment of the method, calculating the patient fatigue indicator is based upon an estimated patient respiratory muscles activity pressure, an ascertained maximum patient respiratory muscles activity pressure, a monitored inhalation time, and a monitored breath total time. As such, in an embodiment of the method, the patient fatigue indicator may be defined by a Tension Time index (TT_{di}) of the patient based upon the estimated patient respiratory muscles activity pressure (P_{mus}), the ascertained maximum patient respiratory muscles activity pressure (P_{musMax}), the monitored inhalation time (T_i), and the monitored breath duration (T_{tot}) in accordance with the equation: $TT_{di} = (P_{mus} / P_{musMax}) \times (T_i / T_{tot})$.

In an embodiment of the method, the ascertained maximum patient respiratory muscles activity pressure is calculated based upon a patient occlusion maneuver, calculated over a plurality of breath cycles or defined in a look-up table.

In an embodiment, the method includes displaying the preferred PSV level on a VBS user display device.

In an embodiment, the method includes automatically setting a PSV level of the VBS based upon the determined preferred PSV level.

In an embodiment, the method includes determining the preferred PSV level of the VBS includes comparing the calculated patient fatigue indicator to a threshold.

Embodiments of the invention may also be directed to a non-transitory computer-readable storage medium having stored therein machine readable instructions configured to be executed by a processor to control a ventilator breathing system (VBS) to provide breathing gas to a patient via a patient tubing circuit and having a breath, the machine readable instructions being configured to cause the VBS to execute a process to determine a preferred pressure support ventilation (PSV) level of the VBS including: monitoring breath parameters of the patient and VBS including at least breath inhalation and breath duration; and determining the preferred PSV level of the VBS by calculating a patient fatigue indicator based upon patient respiratory muscles activity pressure and monitored breath parameters.

In an embodiment of the non-transitory computer-readable storage medium, calculating the patient fatigue indicator is based upon an estimated patient respiratory muscles activity pressure, an ascertained maximum patient respiratory muscles activity pressure, a monitored inhalation time, and a monitored breath duration. As such, in an embodiment of the medium, the patient fatigue indicator may be defined by a Tension Time index (TT_{di}) of the patient respiratory muscles based upon the estimated patient respiratory muscles activity pressure (P_{mus}), the ascertained maximum patient respiratory muscles activity pressure (P_{musMax}), the monitored inhalation time (T_i), and the monitored breath duration (T_{tot}) in accordance with the equation: $TT_{di} = (P_{mus} / P_{musMax}) \times (T_i / T_{tot})$.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more readily understood from the detailed description of exemplary embodiments presented below considered in conjunction with the accompanying drawings, as follows.

FIG. 1 is a schematic block diagram illustrating a ventilation breathing system including the determination of a preferred pressure support ventilation (PSV) level based upon calculated patient fatigue in accordance with features of an embodiment of the present invention.

FIG. 2 is a schematic block diagram illustrating details of the control unit of the VBS of FIG. 1.

FIGs. 3 and 4 are graphs in support of the present approach and illustrating the PSV

level with respect to a Tension Time index in a test conducted on an animal at Duke University.

FIG. 5 is a flowchart illustrating various steps in a method of determining a preferred pressure support ventilation (PSV) level based upon calculated patient fatigue in accordance with features of an embodiment of the present invention.

DETAILED DESCRIPTION

The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the present invention are shown.

10 The present invention may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided as teaching examples of the invention.

It is to be understood that the terminology used herein is for purposes of describing particular embodiments only, and is not intended to be limiting. Any defined terms are in addition to the technical and scientific meanings of the defined terms as commonly understood and accepted in the technical field of the present teachings.

As used in the specification and appended claims, the terms ‘a’, ‘an’ and ‘the’ include both singular and plural referents, unless the context clearly dictates otherwise. Thus, for example, ‘a device’ includes one device and plural devices.

20 As used in the specification and appended claims, and in addition to their ordinary meanings, the terms ‘substantial’ or ‘substantially’ mean to with acceptable limits or degree. For example, ‘substantially cancelled’ means that one skilled in the art would consider the cancellation to be acceptable.

As used in the specification and the appended claims and in addition to its ordinary meaning, the term ‘approximately’ means to within an acceptable limit or amount to one having ordinary skill in the art. For example, ‘approximately the same’ means that one of ordinary skill in the art would consider the items being compared to be the same.

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.

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. Relative terms, such as “above,” “below,” “top,”

5 “bottom,” “upper” and “lower” may be used to describe the various elements’ relationships to one another, as illustrated in the accompanying drawings. These relative terms are intended to encompass different orientations of the device and/or elements in addition to the orientation depicted in the drawings. For example, if the device were inverted with respect to the view in the drawings, an element described as “above” another element, for
10 example, would now be “below” that element. Similarly, if the device were rotated by 90° with respect to the view in the drawings, an element described “above” or “below” another element would now be “adjacent” to the other element; where “adjacent” means either abutting the other element, or having one or more layers, materials, structures, etc., between the elements.

15 Like numbered elements in these figures are either equivalent elements or perform the same function. Elements which have been discussed previously will not necessarily be discussed in later figures if the function is equivalent.

Initially, it is noted that a typical positive pressure ventilator includes a compressible air reservoir or turbine, air and oxygen supplies, a set of valves and tubes,
20 and a patient tubing circuit. The air reservoir is pneumatically compressed several times a minute to deliver room-air, or in most cases, an air/oxygen mixture to the patient. If a turbine is used, the turbine pushes air through the ventilator, with a flow valve adjusting pressure to meet patient-specific parameters. When overpressure is released, the patient will exhale passively due to the lungs' elasticity, the exhaled air being released usually
25 through a one-way valve within the patient tubing circuit called the patient manifold. The oxygen content of the inspired gas can be set, for example, from ambient air (21% at sea level) to 100 percent (pure oxygen). Pressure and flow characteristics can be set mechanically or electronically.

Ventilators may also be equipped with monitoring and alarm systems for patient-
30 related parameters (e.g. pressure, volume, and flow) and ventilator function (e.g. air leakage, power failure, and mechanical failure), backup batteries, oxygen tanks, and remote control. The pneumatic system may be replaced by a computer-controlled turbo pump.

Modern ventilators are electronically controlled by a small embedded system to

allow exact adaptation of pressure and flow characteristics to an individual patient's needs. Fine-tuned ventilator settings also serve to make ventilation more tolerable and comfortable for the patient. Respiratory therapists may be responsible for tuning these settings while biomedical technologists are responsible for the maintenance.

5 The patient tubing circuit usually includes a set of three durable, lightweight plastic tubes, separated by function (e.g. inhaled air, patient pressure, exhaled air). Determined by the type of ventilation needed, the patient-end of the circuit may be either noninvasive or invasive. Noninvasive methods may involve the use of a nasal mask. Invasive methods require intubation, which for long-term ventilator dependence will normally be a
10 tracheotomy cannula, as this is much more comfortable and practical for long-term care than is larynx or nasal intubation.

Referring initially to FIGs. 1 and 2, a ventilation breathing system (VBS) 10 in accordance with features of the invention will be described. FIG. 1 schematically illustrates a VBS 10 which may be an electronically controlled ventilation breathing system. The
15 VBS 10 provides breathing gas from a breathing gas supply 12 to a patient. In some embodiments, the breathing gas supply 12 may include a reservoir 32 and pump 34. In operation, the VBS 10 has a breath cycle including an inhalation phase and an exhalation phase. The VBS 10 includes a patient tubing circuit 14 coupled to the breathing gas supply 12, and a monitoring system 15 associated with the breathing gas supply 12 and patient
20 tubing circuit 14. The monitoring system 15 is configured to monitor breath parameters including inhalation time and breath duration, for example. As illustrated, the VBS 10 includes, for example, a plurality of sensors 16/18 positioned to measure parameters such as flow and pressure in the patient tubing circuit 14.

A control unit 20 is coupled to the monitoring system 15 and is configured to
25 determine a preferred pressure support ventilation (PSV) level of the VBS 10 by calculating a patient fatigue indicator based upon patient respiratory muscle activity pressure and monitored breath parameters such as inhalation time and breath duration. For example, the control unit 20 may be configured to determine the preferred PSV level of the VBS 10 by comparing the calculated patient fatigue indicator to a threshold. In an
30 embodiment, the control unit 20 is configured to calculate the patient fatigue indicator based upon an estimated patient respiratory muscle activity pressure, an ascertained maximum patient respiratory muscles activity pressure, a monitored inhalation time, and a monitored breath total time. As such, in an embodiment, the patient fatigue indicator may

be defined by a Tension Time index (TT_{di}) of the patient diaphragm based upon the estimated patient respiratory muscles activity pressure (P_{mus}), the ascertained maximum patient respiratory muscles activity pressure (P_{musMax}), the monitored inhalation time (T_i), and the monitored breath duration (T_{tot}) in accordance with the equation: $TT_{di} = (P_{mus}/$
5 $P_{musMax}) \times (T_i / T_{tot})$.

Generally, the control unit 20 can be implemented in numerous ways (e.g., such as with dedicated hardware) to perform various functions discussed herein. A “processor” is one example of a control unit 20 or a component of the control unit, and may employ one or more microprocessors that may be programmed using software (e.g., microcode) to
10 perform various functions discussed herein. The control unit 20 may be implemented with or without employing a processor, and also may be implemented as a combination of dedicated hardware to perform some functions and a processor (e.g., one or more programmed microprocessors and associated circuitry) to perform other functions. Examples of controller components that may be employed in various embodiments of the
15 present disclosure include, but are not limited to, conventional microprocessors, microcontrollers, application specific integrated circuits (ASICs), and field-programmable gate arrays (FPGAs).

In an embodiment, the ascertained maximum patient respiratory muscles activity pressure may be based upon by a patient occlusion maneuver, e.g. performed by a clinician
20 as would be appreciated by those skilled in the art. Additionally, the ascertained maximum patient respiratory muscles activity pressure may be calculated over a plurality of breath cycles and/or may be defined in a look-up table, for example, with respect to patient class.

In an embodiment, a user display device 42 is associated with the control unit 20, and the control unit 20 is configured to provide information indicative of the preferred PSV
25 level for display on the user display device 42. In an embodiment, a PSV controller 43 is associated with the breathing gas supply 12 and configured to set a PSV level to the patient, and the control unit 20 is configured to provide the preferred PSV level to the PSV controller 43 for automated setting of the PSV level, e.g. in a closed loop or semi-closed loop control approach. Of course, the monitoring system 15 and/or PSV controller 43
30 functionality may also be provided within the control unit 20.

Of course other visual, audible or other remote transmissions of such preferred PSV level are contemplated herein. The control unit 20 may access memory 44 for instructions, as described in more detail below. The memory 44 may be associated with one or more

computer-readable non-transitory storage media (generically referred to herein as “memory,” e.g., volatile and non-volatile computer memory such as random-access memory (RAM), read-only memory (ROM), programmable read-only memory (PROM), electrically programmable read-only memory (EPROM), electrically erasable and programmable read only memory (EEPROM), universal serial bus (USB) drive, floppy disks, compact disks, optical disks, magnetic tape, etc.). In some implementations, the computer-readable non-transitory storage media may be encoded with one or more programs that, when executed on the control unit 20, perform at least some of the functions discussed herein. Various computer-readable non-transitory storage media may be fixed within the control unit 20, or may be transportable, such that the one or more programs stored thereon can be loaded into a processor or controller so as to implement various aspects of the present teachings discussed herein. The terms “program” or “computer program” are used herein in a generic sense to refer to any type of computer code (e.g., software or microcode) that can be employed to program the control unit 20.

The breathing gas supply 12, control unit 20, monitoring system 15, PSV controller 43, user display device 42 and/or memory 44 may be carried in a housing 40, as shown, or may be provided as separate or external components to the VBS 10. Such housing 40 may also include a user interface (e.g. keyboard, touch screen etc. (not shown)) to input commands and/or settings from an operator (e.g. respiratory therapist).

The patient tubing circuit 14 may include a patient interface 22, an inspiratory branch 24 and an expiratory branch 26 each in fluid communication with each other via a tubing circuit wye 28 (or patient wye). As such, the plurality of sensors may include at least one inspiratory branch sensor 16 and at least one expiratory branch sensor 18. Each inspiratory branch sensor 16 and expiratory branch sensor 18 may include a respective transducer, for example, capable of measuring pressure and flow, or may include the use of separate sensors for each of pressure and flow. Of course various other numbers and arrangements of pressure and flow sensors associated with the patient tubing circuit 14 are considered.

The patient is connected to the patient tubing circuit 14 via the patient interface 22 (e.g. to receive breathing gas). Outputs from the sensors 16/18 are received by the control unit 20 (e.g. at inputs 21) which governs processor and/or microcomputer based functions of the VBS 10. Such control unit 20 could of course be a separate component from a primary processor and/or microcomputer of the VBS 10. Although not shown here, the

VBS 10 may also include pressure control valves controlling pressure of breathing gas delivered to the patient, and safety valves, typically connected to the expiratory branch 26, for relieving excessive pressure of the breathing gas in the patient tubing circuit 14.

5 The pump 34 (or pressure generator) may be, for example, integrated, combined, coupled, or connected with the breathing gas supply. 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, 10 though such a pressure level need not be constant throughout the inhalation phase. The pressure and/or flow levels may be either predetermined or fixed, follow a predetermined dynamic characteristic, or they may dynamically change breath-to-breath or over several breaths.

15 The patient 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 20 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.

25 The VBS 10 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 the patient. The one or more gas parameters may include one or more of flow, volume, pressure, humidity, gas mix, velocity, acceleration, gas leak, and/or other parameters. The VBS 10 may be configured to provide types of therapy including types of therapy where a subject performs inspiration and/or expiration of his/her own 30 accord and/or where the device provides mandatory controlled breaths.

The patient tubing circuit 14 may be a conduit such as a single-limb or a dual-limb flexible length of hose, or other conduit, that places the patient interface 22 in fluid communication with the breathing gas supply 12. The patient tubing circuit 14 forms a

flow path through which the pressurized flow of breathable gas is communicated between the breathing gas supply 12 and the patient interface 22.

The patient interface 22 of VBS 10 in FIG. 1 is configured to deliver the pressurized flow of breathable gas to the airway of a patient. As such, the patient interface 22 may include any appliance suitable for this function. In certain embodiments, the patient interface 22 is configured to be removably coupled with another interface appliance being used to deliver respiratory therapy to the patient. For example, the patient interface 22 may be configured to engage with and/or be inserted into an endotracheal tube, a tracheotomy portal, and/or other interface appliance. In certain embodiments, the patient interface 22 may be configured to engage the airway of the patient without an intervening appliance. In such embodiment, the patient interface 22 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 appliance that communicates a flow of gas with an airway of a patient. The present disclosure is not limited to these examples, and contemplates delivery of the pressurized flow of breathable gas to a patient using any patient interface.

The present embodiments may provide a non-invasive approach to assess respiratory muscle fatigue continuously and in real time. The fatigue indication can be plotted on the ventilator display screen and can be compared with the tension time index threshold. In this way, it may be easier for the caregiver to understand how important fatigue is becoming for that particular patient.

Further details of a control unit 20 in accordance with features of the present approach are discussed with additional reference to the schematic diagram of FIG. 2. The control unit 20 includes an estimator block 45 which receives variables, e.g. airway pressure (P_{ao}) and flow (V) which are monitored or measured at the patient's mouth via sensors. Lung volume (V) may be obtained from the flow measurements via numerical integration. The measurements may be fed in real-time to the estimator block 45. From the estimator block 45 is possible to obtain the patient effort P_{mus} which is provided to the fatigue indicator block 47. The inhalation time T_i and the breath duration T_{tot} are also monitored, or otherwise obtained from the VBS 10, and provided to the fatigue indicator block 47. In this embodiment, the caregiver has to perform an occlusion maneuver 46 to the patient in order to obtain his/her maximal effort P_{musMax} which will also be provided to the fatigue indicator block 47. The fatigue indicator block 47 calculates a fatigue indicator

or index. If this index is close to 0.15, for example, a higher PSV level setting 48 will be suggested to the caregiver. On the other hand if the fatigue indication is too low, a lower PSV level setting 48 will be suggested to the caregiver.

So, after the fatigue indicator has been computed, e.g. based on the above equation, it can be subsequently used to suggest, or to automatically change, the PSV level setting. And, as discussed, there may be various approaches to accomplish the PSV level setting change task. For example, if the computed fatigue indication is close to 0.15 it may mean that patient has high chance of fatigue so it may be better to increase the adopted PSV level. Instead if it's too low, it could be better to decrease the PSV level in order to avoid atrophy and reduce the needed ventilation time. Also, for example, a lookup table could be defined a priori with PSV level settings vs. fatigue indication values. The table could be filled from clinical therapeutic experience using the fatigue indication or index. Once a fatigue indication value is computed based on the above equation, a corresponding PSV level setting may then be suggested. Alternatively, a semi-closed way to adjust the PSV level setting may be provided according to an equation similar to, for example: $PSV(N+1) = PSV(N) + K \cdot (TTdi - 0.15)$, whenever $TTdi \geq 0.15$, else PSV unchanged. N is the breath number, and thus $PSV(N+1)$ is the PSV level setting of the new (current) breath and $PSV(N)$ is the PSV level setting of the previous breath. Of course, the use of the fatigue indicator or index $TTdi$ being higher than, lower than or equal to a threshold is contemplated here.

Furthermore, in other embodiments, it may be possible to determine the fatigue indicator with the use of other parameters or information. For example, a diaphragm electromyogram (EMG) signal can be used synergistically with the tension time index in order to detect fatigue and adjust the PSV level of the ventilator setting accordingly. Also, the mean relaxation time (MRR) can also be used to detect fatigue. For example, if the estimator block 45 is able to detect a change in the relaxation time, this information may be used by the fatigue indicator block 47 for an enhanced estimation of fatigue. As a consequence, it will be easier to change the PSV level setting to avoid fatigue.

In FIGs. 3 and 4, it is possible to see the tension time index of an animal that was obtained during a test at Duke University. As it can be seen in FIG. 3, and as determined by the present inventors, the tension time index increased when the pressure support decreased so it can be seen as a good indicator of the patient effort, and as a consequence it can be used to indicate fatigue. In FIG. 4, the effect of different $FiCO_2$ setting can be seen.

More particularly, if the animal inhaled a higher CO₂ mixture, it had to increase its effort in order to maintain the proper minute ventilation. As a consequence, an increase of its effort via the Tension Time index can also be seen.

The present approach may provide a non-invasive approach to assess patient's respiratory status in real-time and such invaluable information can be applied to detect changes in the health conditions of the patient and avoid worsening of his/her status condition in terms of fatiguing or atrophying of the patient. The type of ventilation modalities for which this approach is relevant include, for example, invasive ventilation and non-invasive ventilation.

Embodiments of the invention are also directed to a method for determining a preferred pressure support ventilation (PSV) level of a ventilator breathing system (VBS) configured to provide breathing gas to a patient via a patient tubing circuit 14. An embodiment of the method will be described with additional reference to the flowchart of FIG. 5. The method begins 50 and includes: monitoring 52 breath parameters of the patient and VBS 10 including at least breath inhalation time and breath duration; calculating 54 a patient fatigue indicator based upon patient respiratory muscle activity pressure and monitored breath timing characteristics; and determining 56 the preferred PSV level of the VBS 10 by comparing the fatigue indicator to a threshold. Moreover, the method may include displaying or automatically setting a PSV level of the VBS 10 based upon the determined preferred PSV level, before the method ends 60. Of course, other indications based upon the preferred PSV level may also be displayed.

In an embodiment, calculating 54 the patient fatigue indicator may be based upon an estimated patient respiratory muscle activity pressure, an ascertained maximum patient respiratory muscles activity pressure, a monitored inhalation time, and a monitored breath total time. More specifically, in such an embodiment, the patient fatigue indicator may be calculated 60 or otherwise defined by a Tension Time index (TT_{di}) of the patient based upon the estimated patient respiratory muscle activity pressure (P_{mus}), the ascertained maximum patient respiratory muscles activity pressure (P_{musMax}), the monitored inhalation time (T_i), and the monitored breath total time (T_{tot}) in accordance with the equation: $TT_{di} = (P_{mus} / P_{musMax}) \times (T_i / T_{tot})$.

In an embodiment, the ascertained maximum patient respiratory muscle activity pressure is ascertained 62 based upon a patient occlusion maneuver, calculated over a plurality of breath cycles or defined in a look-up table, as discussed in detail above.

Embodiments of the invention may also be directed to a non-transitory computer-readable storage medium having stored therein machine readable instructions configured to be executed by a processor to control a ventilator breathing system (VBS) 10 to provide breathing gas to a patient via a patient tubing circuit 14 and having a breath cycle including an inhalation phase and an exhalation phase, the machine readable instructions being configured to cause the VBS 10 to execute a process to determine a preferred pressure support ventilation (PSV) level of the VBS 10 including: monitoring breath parameters of the patient and VBS 10 including at least breath inhalation time and breath duration; and determining the preferred PSV level of the VBS 10 by calculating a patient fatigue indicator based upon patient respiratory muscle activity pressure and monitored breath timing characteristics.

The term computer readable-storage medium also refers to various types of recording media capable of being accessed by the computer device via a network or communication link. For example a data may be retrieved over a modem, over the internet, or over a local area network. References to a computer-readable storage medium should be interpreted as possibly being multiple computer-readable storage mediums. Various executable components of a program or programs may be stored in different locations. The computer-readable storage medium may for instance be multiple computer-readable storage medium within the same computer system. The computer-readable storage medium may also be computer-readable storage medium distributed amongst multiple computer systems or computing devices.

‘Computer memory’ or ‘memory’ is an example of a computer-readable storage medium. Computer memory is any memory which is directly accessible to a processor. Examples of computer memory include, but are not limited to: RAM memory, registers, and register files. References to ‘computer memory’ or ‘memory’ should be interpreted as possibly being multiple memories. The memory may for instance be multiple memories within the same computer system. The memory may also be multiple memories distributed amongst multiple computer systems or computing devices.

‘Computer storage’ or ‘storage’ is an example of a computer-readable storage medium. Computer storage is any non-volatile computer-readable storage medium. Examples of computer storage include, but are not limited to: a hard disk drive, a USB thumb drive, a floppy drive, a smart card, a DVD, a CD-ROM, and a solid state hard drive. In some embodiments computer storage may also be computer memory or vice versa.

References to 'computer storage' or 'storage' should be interpreted as possibly including multiple storage devices or components. For instance, the storage may include multiple storage devices within the same computer system or computing device. The storage may also include multiple storages distributed amongst multiple computer systems or
5 computing devices.

A 'processor' as used herein encompasses an electronic component which is able to execute a program or machine executable instruction. References to the computing device comprising "a processor" should be interpreted as possibly containing more than one processor or processing core. The processor may for instance be a multi-core processor. A
10 processor may also refer to a collection of processors within a single computer system or distributed amongst multiple computer systems. The term computing device should also be interpreted to possibly refer to a collection or network of computing devices each comprising a processor or processors. Many programs have their instructions performed by multiple processors that may be within the same computing device or which may even be
15 distributed across multiple computing devices.

A 'user interface' as used herein is an interface which allows a user or operator to interact with a computer or computer system. A 'user interface' may also be referred to as a 'human interface device.' A user interface may provide information or data to the operator and/or receive information or data from the operator. A user interface may enable
20 input from an operator to be received by the computer and may provide output to the user from the computer. In other words, the user interface may allow an operator to control or manipulate a computer and the interface may allow the computer indicate the effects of the operator's control or manipulation. The display of data or information on a display or a graphical user interface is an example of providing information to an operator. The
25 receiving of data through a touch screen, keyboard, mouse, trackball, touchpad, pointing stick, graphics tablet, joystick, gamepad, webcam, headset, gear sticks, steering wheel, wired glove, wireless remote control, and accelerometer are all examples of user interface components which enable the receiving of information or data from an operator.

A 'hardware interface' as used herein encompasses an interface which enables the
30 processor of a computer system to interact with and/or control an external computing device and/or apparatus. A hardware interface may allow a processor to send control signals or instructions to an external computing device and/or apparatus. A hardware interface may also enable a processor to exchange data with an external computing device

and/or apparatus. Examples of a hardware interface include, but are not limited to: a universal serial bus, IEEE 1394 port, parallel port, IEEE 1284 port, serial port, RS-232 port, IEEE-488 port, Bluetooth connection, Wireless local area network connection, TCP/IP connection, Ethernet connection, control voltage interface, MIDI interface, analog input interface, and digital input interface.

A 'display' or 'display device' as used herein encompasses an output device or a user interface adapted for displaying images or data. A display may output visual, audio, and or tactile data. Examples of a display include, but are not limited to: a computer monitor, a television screen, a touch screen, tactile electronic display, Braille screen, Cathode ray tube (CRT), Storage tube, Bistable display, Electronic paper, Vector display, Flat panel display, Vacuum fluorescent display (VF), Light-emitting diode (LED) displays, Electroluminescent display (ELD), Plasma display panels (PDP), Liquid crystal display (LCD), Organic light-emitting diode displays (OLED), a projector, and Head-mounted display.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive; the invention is not limited to the disclosed embodiments.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims. In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. A single processor or other unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. A computer program may be stored/distributed on a suitable medium, such as an optical storage medium or a solid-state medium supplied together with or as part of other hardware, but may also be distributed in other forms, such as via the Internet or other wired or wireless telecommunication systems. Any reference signs in the claims should not be construed as limiting the scope.

CLAIMS

What is claimed is:

1. A ventilator breathing system (VBS) to provide breathing gas to a patient, the VBS comprising:

a gas supply;
a patient tubing circuit coupled to the gas supply;
a monitoring system associated with the gas supply and patient tubing circuit and configured to monitor breath parameters including at least breath inhalation time and breath duration; and

a control unit coupled to the monitoring system and configured to determine a preferred pressure support ventilation (PSV) level of the VBS by calculating a patient fatigue indicator based upon patient respiratory muscles activity pressure and monitored breath parameters.

2. The VBS of claim 1, wherein the control unit comprises an estimator block and a fatigue indicator block; and wherein the fatigue indicator block is configured to calculate the patient fatigue indicator based upon an estimated patient respiratory muscles activity pressure from the estimator block, an ascertained maximum patient respiratory muscles activity pressure, a monitored inhalation time, and a monitored breath duration.

3. The VBS of claim 2, wherein the patient fatigue indicator is defined by a Tension Time index (TT_{di}) of the patient based upon the estimated patient respiratory muscles activity pressure (P_{mus}), the ascertained maximum patient respiratory muscles activity pressure (P_{musMax}), the monitored inhalation time (T_i), and the monitored breath duration (T_{tot}) in accordance with the equation: $TT_{di} = (P_{mus} / P_{musMax}) \times (T_i / T_{tot})$.

4. The VBS of claim 2, wherein the ascertained maximum patient respiratory muscles activity pressure is based upon by a patient occlusion maneuver.

5. The VBS of claim 2, wherein the ascertained maximum patient respiratory muscles activity pressure is calculated over a plurality of breath cycles.

6. The VBS of claim 2, wherein the ascertained maximum patient respiratory

muscles activity pressure is defined in a look-up table.

7. The VBS of claim 1, further comprising a user display device associated with the control unit; and wherein the control unit is configured to provide information indicative of the preferred PSV level for display on the user display device.

8. The VBS of claim 1, further comprising a PSV controller associated with the gas supply and configured to set a PSV level to the patient; and wherein the control unit is configured to provide the preferred PSV level to the PSV controller for automated setting of the PSV level.

9. The VBS of claim 1, wherein the control unit is configured to determine the preferred PSV level of the VBS by comparing the calculated patient fatigue indicator to a threshold.

10. A method for determining a preferred pressure support ventilation (PSV) level of a ventilator breathing system (VBS) configured to provide breathing gas to a patient via a patient tubing circuit, the method comprising:

monitoring breath parameters of the patient and VBS including at least breath duration; and

determining the preferred PSV level of the VBS by calculating a patient fatigue indicator based upon patient respiratory muscles activity pressure and monitored breath duration.

11. The method of claim 10, wherein calculating the patient fatigue indicator is based upon an estimated patient respiratory muscles activity pressure, an ascertained maximum patient respiratory muscles activity pressure, a monitored inhalation time, and monitored breath duration.

12. The method of claim 11, wherein the patient fatigue indicator is defined by a Tension Time index (TT_{di}) of the patient based upon the estimated patient respiratory muscles activity pressure (P_{mus}), the ascertained maximum patient respiratory muscle activity pressure (P_{musMax}), the monitored inhalation time (T_i), and the monitored breath duration (T_{tot}) in accordance with the equation: $TT_{di} = (P_{mus} / P_{musMax}) \times (T_i / T_{tot})$.

13. The method of claim 11, wherein the ascertained maximum patient respiratory muscles activity pressure is: calculated based upon by a patient occlusion maneuver; calculated over a plurality of breath cycles; or defined in a look-up table.

14. The method of claim 10, further comprising displaying information indicative of the preferred PSV level on a VBS user display device.

15. The method of claim 10, further comprising automatically setting a PSV level of the VBS based upon the determined preferred PSV level.

16. The method of claim 10, wherein determining the preferred PSV level of the VBS includes comparing the calculated patient fatigue indicator to a threshold.

17. A non-transitory computer-readable storage medium having stored therein machine readable instructions configured to be executed by a processor to control a ventilator breathing system (VBS) to provide breathing gas to a patient via a patient tubing circuit, the machine readable instructions being configured to cause the VBS to execute a process to determine a preferred pressure support ventilation (PSV) level of the VBS comprising:

monitoring breath parameters of the patient and VBS including at least breath duration and inhalation time; and

determining the preferred PSV level of the VBS by calculating a patient fatigue indicator based upon patient respiratory muscles activity pressure and monitored breath parameters.

18. The non-transitory computer-readable storage medium of claim 17, wherein calculating the patient fatigue indicator is based upon an estimated patient respiratory muscles activity pressure, an ascertained maximum patient respiratory muscles activity pressure, a monitored inhalation time, and a monitored breath duration.

19. The non-transitory computer-readable storage medium of claim 18, wherein the patient fatigue indicator is defined by a Tension Time index (TT_{di}) of the patient based upon the estimated patient respiratory muscles activity pressure (P_{mus}), the ascertained

maximum patient respiratory muscles activity pressure (P_{musMax}), the monitored inhalation time (T_i), and the monitored breath duration (T_{tot}) in accordance with the equation: $TT_{\text{di}} = (P_{\text{mus}} / P_{\text{musMax}}) \times (T_i / T_{\text{tot}})$.

20. The non-transitory computer-readable storage medium of claim 18, wherein the ascertained maximum patient respiratory muscles activity pressure is: calculated based upon by a patient occlusion maneuver; calculated over a plurality of breath cycles; or defined in a look-up table.

21. The non-transitory computer-readable storage medium of claim 17, further comprising displaying information indicative of the preferred PSV level on a VBS user display device.

22. The non-transitory computer-readable storage medium of claim 17, further comprising automatically setting a PSV level of the VBS based upon the determined preferred PSV level.

23. The non-transitory computer-readable storage medium of claim 17, wherein determining the preferred PSV level of the VBS includes comparing the calculated patient fatigue indicator to a threshold.

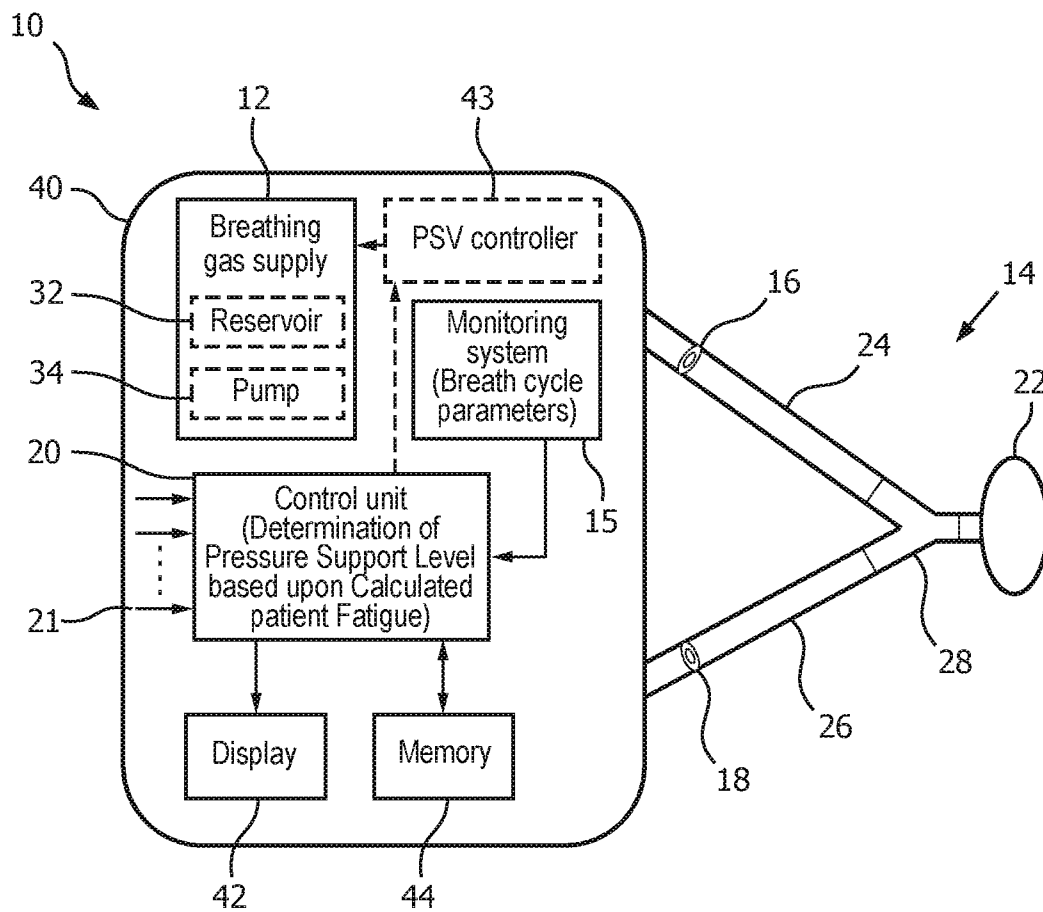


FIG. 1

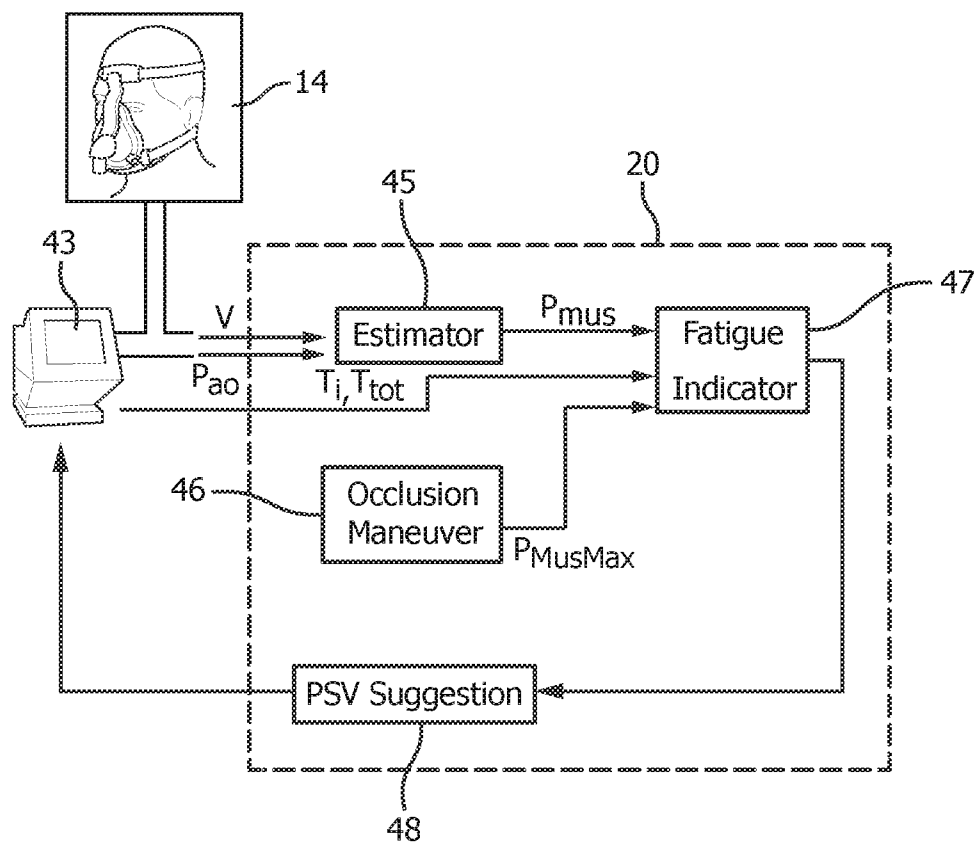


FIG. 2

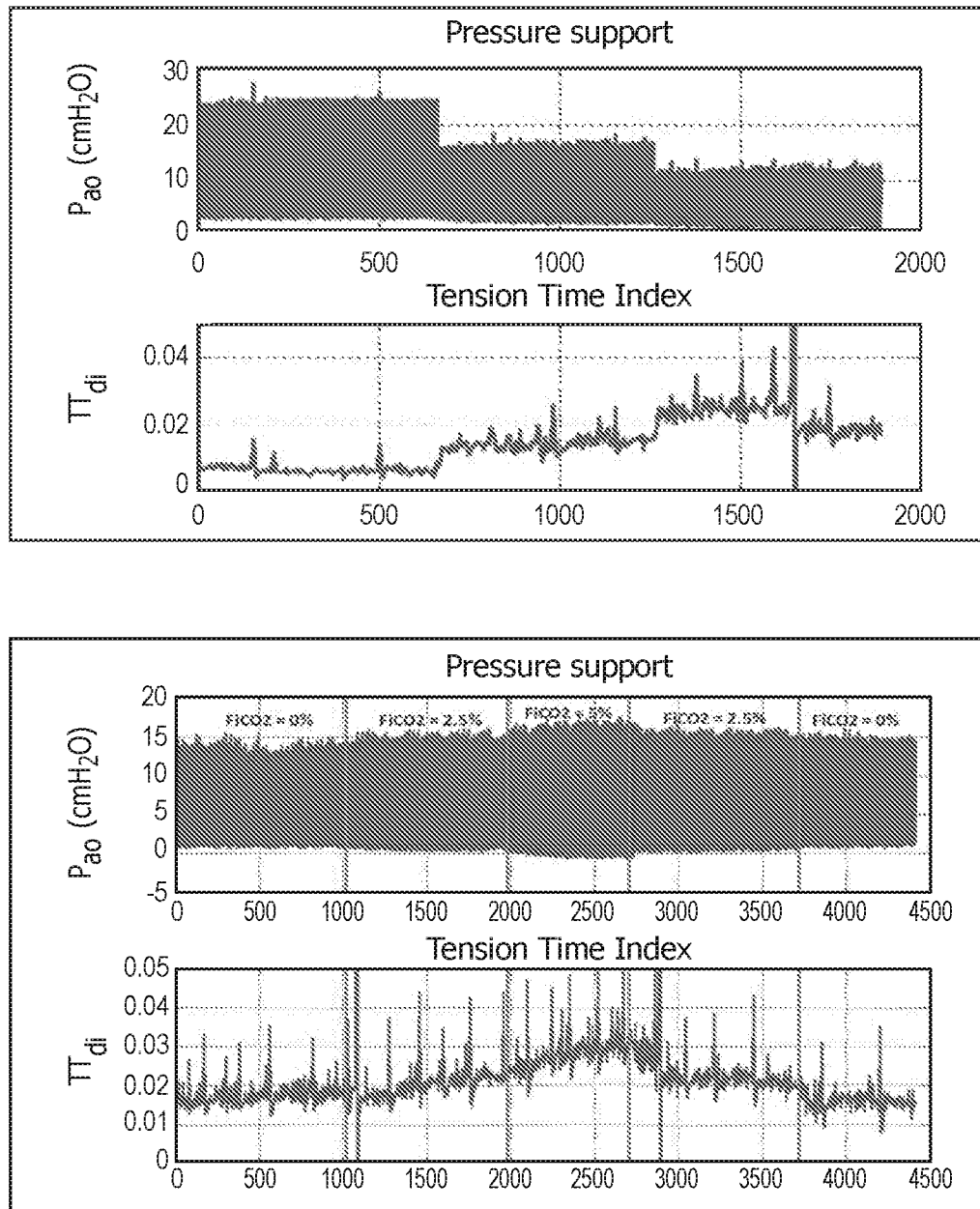


FIG. 3

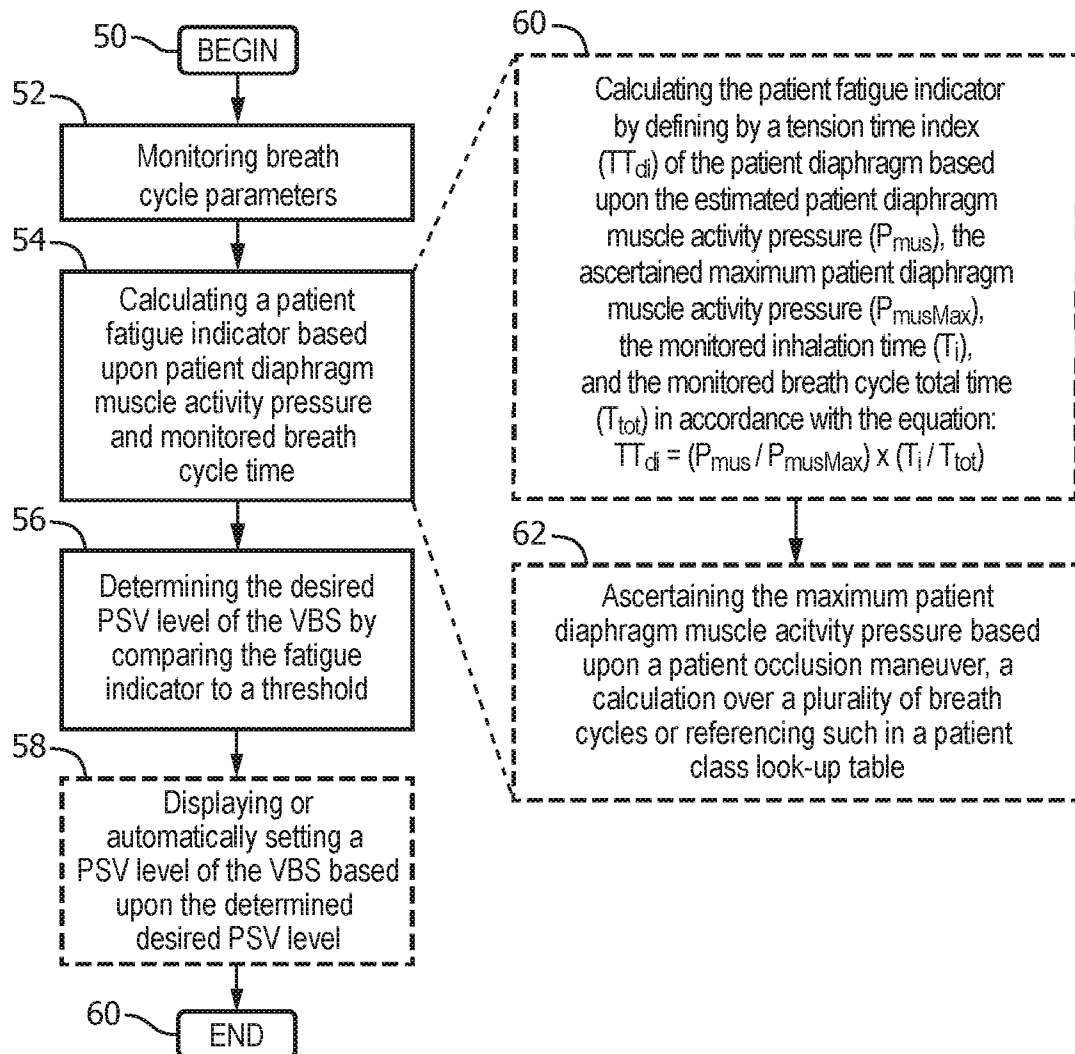


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2015/059822

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 2014/123979 A1 (DOYLE PETER [US] ET AL) 8 May 2014 (2014-05-08) paragraphs [0043] - [0058], [0085], [0086], [0163] - [0175]; figure 1 -----	1-23
A	US 8 256 419 B2 (SINDERBY CHRISTER [CA] ET AL) 4 September 2012 (2012-09-04) column 2, lines 36-55; figure 5 -----	1-23
A	CN 102 266 228 A (BEIJING AEONMED CO LTD) 7 December 2011 (2011-12-07) abstract; figures 1-3 -----	1-23



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"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

11 March 2016

Date of mailing of the international search report

21/03/2016

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2015/059822

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2014123979	A1	08-05-2014	NONE
US 8256419	B2	04-09-2012	CN 1960671 A 09-05-2007 EP 1715787 A1 02-11-2006 US 2008121231 A1 29-05-2008 WO 2005077268 A1 25-08-2005
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