Title: SYSTEM FOR CONTROLLING WORK OF BREATHING IN AN ASSISTED VENTILATION MODE AND METHOD OF OPERATION THEREOF

Abstract: A medical ventilator may include: at least one controller which may: obtain a reference work of breathing value (dWOB); analyze ventilation flow at a physical interface configured to be coupled to a user; estimate work of breathing value (eWOB) performed by a patient based upon analysis of the ventilation flow; determine a difference between the values of dWOB and the eWOB; and/or may set a pressure assist provided by the ventilator based upon the determined difference.
SYSTEM FOR CONTROLLING WORK OF BREATHING IN AN ASSISTED VENTILATION MODE AND METHOD OF OPERATION THEREOF

The present system relates to a system for regulating ventilators to control work-of-breathing of ventilated patients and, more particularly, to a system which estimates the work-of-breathing and automatically adjusts a pressure assist setting of a mechanical ventilator to reach a desired work-of-breathing profile, and a method of operation thereof.

Mechanical ventilators typically have a plethora of settings which must be set to assure proper ventilation to patients being ventilated. Unfortunately, adjustment of these settings is a time-consuming challenge for many clinicians. For example, there are many settings that need to be determined and set to deliver optimum pressure and flow of ventilation gas to patients being ventilated. Although clinical protocols exist which explain how to manually adjust settings, these protocols are far from optimum and often result in inopportune settings leading to insufficient ventilation of patients. Unfortunately, this insufficient ventilation may lead to various ventilator related complications such as barotrauma and ventilator-related lung injury. To address this problem, some fifty different control modes with corresponding settings have been proposed and ventilators may have dozens of these control modes. However, the sheer number of available control modes may further confuse clinicians who are unfamiliar
with many of them. Accordingly, very few of these control modes are ever used even when provided.

Due to the complexity of manually determining ventilation settings, clinicians often determine settings offsite (e.g., in a clinicians office) from a patient's ventilator. Accordingly, even after these settings are determined by the clinician, they are often unapplied until the clinician visits the patient and sets the ventilator in accordance with these settings. This process may delay the application of these settings and may lead to inopportune ventilation of the patient for extended periods of time. Meanwhile until the manually-determined ventilation settings are applied, the physiological needs of the patient may change and the yet to be applied ventilator settings may be far off from the optimal setting for the patient at the present time and/or when they are finally applied.

Accordingly, embodiments of the present system may overcome these and/or other disadvantages in the prior art systems.

The system(s), device(s), method(s), arrangements(s), user interface(s), computer program(s), processes, etc. (hereinafter each of which will be referred to as system, unless the context indicates otherwise), described herein address problems in prior art systems. In accordance with embodiments of the present system, there is disclosed a medical ventilator which may include: at least one controller which may:

obtain a reference work of breathing value (dWOB); analyze ventilation flow at a physical interface configured to be coupled to a user; estimate work of breathing value (eWOB) performed by a patient based upon analysis of the ventilation flow; determine a
difference between the values of dWOB and the eWOB; and/or may set a pressure assist provided by the ventilator based upon the determined difference.

In accordance with embodiments of the present system, it is further envisioned that the at least one controller may further be operative to compare the difference to a positive and a negative threshold error value \((\pm \varepsilon)\). It is further envisioned that when it is determined that the difference is greater than the positive threshold error value \((\varepsilon)\), the controller may be operative to decrease pressure assist. It is also envisioned that when it is determined that the difference is less than the negative threshold error value \((-\varepsilon)\), the controller may be operative to increase pressure assist. It is further envisioned that when it is determined that the difference is less than or equal to the positive threshold error value \((\varepsilon)\) and greater than or equal to the negative threshold value, the controller may be operative to maintain a current pressure assist.

In accordance with embodiments of the present system, the medical ventilator may further include at least one rendering device, wherein the at least one controller may be operative to render values of the dWOB and the eWOB upon the rendering device. It is also envisioned that the at least one controller may be further operative to generate a message requesting a user enter a desired work of breathing value and render this message on the at least one rendering device.

In accordance with embodiments of the present system, there is disclosed a method of operating a medical ventilator, the method may be performed by at least one controller and may include acts of: obtaining a reference work of breathing value (dWOB); analyzing a ventilation flow at a physical interface configured to be coupled to
a user; estimating work of breathing value (eWOB) performed by a patient based upon analysis of the ventilation flow; determining a difference between the values of dWOB and the eWOB; and/or setting a pressure assist provided by the ventilator based upon the determined difference.

It is further envisioned that the method may further include an act of comparing the difference to a positive and a negative threshold error value ($\pm \varepsilon$). It is further envisioned that the method may further include an act of decreasing pressure assist when it is determined that the difference is greater than the positive threshold error value ($\varepsilon$). It is further envisioned that the method may further include an act of increasing pressure assist when it is determined that the difference ($e$) is less than the negative threshold error value $-(\varepsilon)$. It is further envisioned that the method may further include an act of maintaining a current pressure assist when it is determined that the difference is less than or equal to the positive threshold error value ($\varepsilon$) and greater than or equal to the negative threshold value.

It is further envisioned that the method may further include an act of rendering values of the dWOB and the eWOB on at least one rendering device. It is further envisioned that the method may further include acts of: generating a message requesting a user enter a desired work of breathing value; and rendering this message on the at least one rendering device.

In accordance with embodiments of the present system, there is disclosed a computer readable non-transitory medium having computer readable program code for operating on a computer for performing a method of operating a medical ventilator, the
method may include acts of: obtaining a reference work of breathing value (dWOB); analyzing a ventilation flow at a physical interface configured to be coupled to a user; estimating work of breathing value (eWOB) performed by a patient based upon analysis of the ventilation flow; determining a difference between the values of dWOB and the eWOB; and setting a pressure assist provided by the ventilator based upon the determined difference.

In accordance with embodiments of the present system, the method of the medium may further include an act of comparing the difference to a positive and a negative threshold error value ($\pm \varepsilon$). It is also envisioned that the method of the medium may further include an act of decreasing pressure assist when it is determined that the difference ($e$) is greater than the positive threshold error value ($\varepsilon$). It is also envisioned that the method of the medium may further include an act of increasing pressure assist when it is determined that the difference is less than the negative threshold error value ($-\varepsilon$). It is also envisioned that the method of the medium may further include an act of maintaining a current pressure assist when it is determined that the difference is less than or equal to the positive threshold error value ($\varepsilon$) and greater than or equal to the negative threshold value. It is further envisioned that the method of the medium may further include an act of rendering values of the dWOB and the eWOB on at least one rendering device.

The present invention is explained in further detail in the following exemplary embodiments and with reference to the figures, where identical or similar elements are
partly indicated by the same or similar reference numerals, and the features of various exemplary embodiments being combinable. In the drawings:

FIG. 1 shows a schematic block diagram of a portion of a ventilation control system operating in accordance with embodiments of the present system;

FIG. 2 shows a functional flow diagram of a ventilation control system in accordance with embodiments of the present system;

FIG. 3A shows a graph illustrating a pressure profile control signal (PPCS) and corresponding pressure assist and eWOB signals formed in accordance with embodiments of the present system;

FIG. 3B shows a graph illustrating another PPCS and corresponding pressure support ventilation (PSV) and PEEP values formed in accordance with embodiments of the present system; and

FIG. 4 shows a portion of a system in accordance with embodiments of the present system.

The following are descriptions of illustrative embodiments that when taken in conjunction with the following drawings will demonstrate the above noted features and advantages, as well as further ones. In the following description, for purposes of explanation rather than limitation, illustrative details are set forth such as architecture, interfaces, techniques, element attributes, etc. However, it will be apparent to those of ordinary skill in the art that other embodiments that depart from these details would still
be understood to be within the scope of the appended claims. Moreover, for the purpose of clarity, detailed descriptions of well known devices, circuits, tools, techniques, and methods are omitted so as not to obscure the description of the present system. It should be expressly understood that the drawings are included for illustrative purposes and do not represent the entire scope of the present system. In the accompanying drawings, like reference numbers in different drawings may designate similar elements. The term and/or and formatives thereof should be understood to mean that only one or more of the recited elements may need to be suitably present (e.g., only one recited element is present, two of the recited elements may be present, in any combination, etc., up to all of the recited elements may be present) in a system in accordance with the claims recitation and in accordance with one or more embodiments of the present system.

FIG. 1 shows a schematic block diagram of a portion of a ventilation control system 100 (hereinafter system 100) of a ventilator operating in accordance with embodiments of the present system. The system 100 may include one or more of user interface (UI) 102, a summation portion 104, a first control portion 107, a second control portion 108, a ventilator pump 110, a gas supply 116, a patient interface 112, a work of breathing (WOB) estimation portion 114, a memory 120 and a sensor portion 118. The memory 120 may include any suitable memory which may store information such as information generated by the system 100, applications, user information (e.g., user settings, etc.) and/or any other information used by the system 100. The memory 120 may include local and/or distributed memories operating in accordance with
embodiments of the present system. The memory 120 may include transient and/or non-transient memories.

The controller 106 may control the overall operation of the system 100 in accordance with embodiments of the present system. For example, the controller 106 may control one or more of the user interface (UI) 102, the summation portion 104, the first control portion 107, the second control portion 108, the ventilator pump 110, the gas supply 116, the patient interface 112, the work of breathing (WOB) estimation portion 114, the memory 120, and the sensor portion 118. Further, the controller 106 may be programmed to perform one or more processes and/or acts of the present system. Accordingly, the controller 106 may perform one or more algorithms of the present system and respond accordingly as described herein.

The patient interface 112 may couple a patient to the ventilator 110 so that the patient may receive ventilation gas (VG) to ventilate the patient from the ventilation pump 110. The patient interface 112 may include a physical interface such as a non-invasive physical interface (e.g., a nasal cannula, a mask, etc.) or an invasive physical interface (e.g., an intubation tube, etc.) which may be coupled to the patient to provide the patient with the ventilation gas for inspiration. The patient interface 112 may further receive expiration gases from the patient. In accordance with some embodiments, the patient interface portion 112 may include inspiration and expiration legs (e.g., patient and vent legs, respectively), to provide the ventilation gas for inspiration and receive the expiration gas for venting, respectively. For the sake of clarity, it will be assumed that the patient may initiate breaths (e.g., is spontaneously breathing).
The ventilator pump 110 may supply a ventilation gas (VG) to ventilate a patient under the control of the controller 106. More particularly, the ventilation pump 110 may obtain one or more gasses from a gas supply 116 and mix these gasses to form the ventilation gas (VG) which may be provided to the patient. The ventilation pump 110 may be coupled to the gas supply 116 to receive gasses therefrom. The gas supply 116 may include one or more gasses such as oxygen (O₂), nitrogen (N₂), air, etc. Additionally, the ventilation pump 110 may include one or more ventilation gas conditioners to condition the VG such as a water vapor conditioner which may add water vapor to the VG and/or a dryer (e.g., a condenser) which may remove water vapor from the VG. The ventilation pump 110 may control the flow and/or mixture of these and other gasses to form the VG which may be a mixture of one or more gasses. Further, the ventilation pump 110 may include one or more valves, pressure regulators, mixers, and/or pumps operating under the control of the controller 106 which may be operative to control characteristics of the VG under the control of the controller such as pressure (P) and flow (Q). For example, the ventilator 110 may receive a pressure profile control signal (PPCS) received from the second control portion 108 as will be disclosed elsewhere and may control its pumps to control one or more characteristics of the VG such as pressure, tidal volume and/or flow of the VG accordingly.

The sensor portion 118 may include one or more sensors which may detect characteristics of the VG at the patient interface and may form corresponding sensor information (e.g., ventilation gas flow sensor information (VGSI)). This sensor information may then be transmitted to the WOB estimation portion 114 for further analysis. The sensor information may include, for example, sensor information suitable
for estimating (e.g., determining) a patient's work of breathing. The characteristics of
the VG may include information related to ventilation parameters and/or settings and/or
an effort of the patient.

For example, an embodiment of the present system may include a sensor portion
that may monitor a ventilation gas pressure (P) and/or flow (Q) to the patient and form
corresponding sensor information (e.g., and may be included within the VGSI).

The WOB estimation portion 114 may receive the sensor information (e.g., P and
Q, etc. which may be included within the VGSI) after a full breath for example after the
end of each breath and estimate WOB (eWOB) (e.g., determine an estimated WOB)
information for the patient based upon the sensor information which may reflect the
patient's work of breathing. More particularly, the WOB estimation portion 114 may
include a WOB estimation algorithm which may input the sensor information and output
eWOB information in accordance with embodiments of the present system. The eWOB
information may include a corresponding eWOB value or values and may be
determined in real time using any suitable method. The estimated WOB information
may be determined in real time and may be provided as a WOB.

The UI 102 may include any suitable user interface with which a user such as a
clinician may interact with the system 100 to read, hear, or otherwise receive
information generated and/or rendered by the system (e.g., desired work of breathing
value (dWOB), eWOB, ventilator settings, VG information, etc.) and/or to input
information desired by the system such as desired WOB information (e.g., a reference
value). For example, in accordance with some embodiments, the UI 102 may include a
touch-screen display with which a user may interact to enter desired value which may then be set as a value of dWOB. However, in yet other embodiments, the UI 102 may include other input devices and/or combinations thereof such as a keyboard, a mouse, a pointer device, a rotating dial, a slider, etc. In accordance with some embodiments, it is envisioned that the controller 106 may generate a message which may request a user to enter a desired work of breathing value (e.g., dWOB) and render this request on a rendering device of the system such as a display screen of the UI 102. In accordance with some embodiments, after the desired WOB value is entered, the controller 106 may store this value in the memory 120 for late use. In accordance with embodiments of the present system, the reference value may have a default value that is set by the system. For example, based on inputted characteristics of the patient's (such as age, lung capacity, etc.), and thereby, such as through use of a lookup table stored for example in the memory 120, set a default reference value. In accordance with embodiments of the present system, the user may enter a desired work of breathing value that overrides the default value.

The summation portion 104 may receive the estimated WOB information and the estimated WOB information and may determine a difference (e) between these two inputs which may represent an error between the eWOB and the dWOB provided thereto. The difference (e) may then be transmitted as a difference signal to the first control portion 107. The difference (e) may represent an error between the dWOB (e.g., as determined by the system and/or clinician and which may be considered a reference value) and the eWOB value that was determined by the estimation portion 114 and may be represented as difference (e).
The first control portion 107 may obtain the difference (e) from the difference signal and may determine a pressure assist (PA) value based at least in part upon the difference (e) in accordance with embodiments of the present system. The first control portion 107 may do this using any suitable method. For example, in accordance with embodiments of the present system, the process may determine whether the difference (e) is negative (indicating eWOB is greater than the desired dWOB), positive (e.g., indicating that the eWOB is less than the dWOB) or (substantially) equal to 0 (e.g., ± a threshold error value ε).

In a case wherein it is determined that the difference (e) is negative (e.g., less than 0), the first control portion 107 may act to increase a pressure assist value (PA) so that pressure assist provided by the ventilator 110 is also increased as discussed further herein. The increased pressure assist will have the effect of decreasing the eWOB as discussed further herein. In accordance with embodiments of the present system, to increase the PA, the process may add a pressure increment value (Pinc) to a current PA value so that PA=PA+Pinc.

In a case wherein it is determined that the difference (e) is positive (e.g., greater than 0), the first control portion 107 may act to decrease a pressure assist value (PA) so that pressure assist provided by the ventilator 110 is also decreased. The decreased pressure assist provided by the ventilator will have the effect of increasing the eWOB. To decrease the PA, the process may subtract the Pine from a current PA value so that PA=PA-Pinc.
Finally, in a case wherein it is determined that the difference is (substantially) equal to 0, the process may set PA=PA and thus set a current PA value equal to a previous PA value resulting in the pressure assist remaining the same and, as such the eWOB may remain the same or substantially the same.

With regard to the value of Pine, this value may be set by the system and/or user during, for example, an initialization of the system 100. However, as Pine is increased, the change in the value of PA may increase between iterations and vice versa. Accordingly, a change in the eWOB between iterations may also increase with the increase of Pine and vice versa. In accordance with embodiments of the present system it is envisioned, without limitation, that Pine may for example be to be set to 1 cmH₂O. However, other values for Pine are also envisioned such as 2 cmH₂O, 3 cmH₂O, etc.

Once the current pressure assist (PA) value is determined, the first control portion 107 may transmit it to the second control portion 108.

Upon receiving the pressure assist (PA) value, the second control portion 108 may form a corresponding pressure profile control signal (PPCS) (e.g., see, FIG. 3B) which signal may be used to control pressure output of the ventilator pump 110. A profile of the PPCS signal may further be set in accordance with one or more operating parameters and/or settings of the ventilator such as rise time, Inspiratory to Expiratory Time Ratio (I:E ratio), triggering limit and/or cycling limit, as well as the response of the patient.
With regard to the first control portion 107 and the second control portion 108, these portions may form a two-tiered control system wherein the second control portion 108 may be considered a lower level control portion and the first control portion 107 may be considered a higher level control portion. However, it is also envisioned that these portions may be combined, if desired and may form a PPCS directly based upon the difference \( (e) \), if desired.

FIG. 2 shows a functional flow diagram that guidance process 200 (hereinafter process 200) performed in accordance with embodiments of the present system. The process 200 may be performed using one or more computers communicating over a network and may obtain information from, and/or store information to one or more memories which may be local and/or remote from each other. The process 200 may include one of more of the following acts. In some embodiments, the acts of process 200 may be performed using one or more suitable ventilator systems operating in accordance with embodiments of the present system. Further, one or more of these acts may be combined and/or separated into sub-acts, if desired. Further, one or more of these acts may be skipped depending upon settings. In operation, the process may start during act 201 and then proceed to act 203.

During act 203, the process may initialize. Accordingly, the process may obtain initialization parameters for initializing the process and/or a ventilator to ventilate a patient such as one or more of a dWOB, an initial pressure assist (PA) value, a threshold error value \((e)\), etc. The process may further obtain information relating to a control mode and associated parameters, as desired. In accordance with embodiments the value of dWOB may be obtained in real time or from a memory of the
system (e.g., such as a default value). For example, the process may form a graphical user interface (GUI) which may include an entry item (e.g., a menu item) for a user to enter a dWOB value. The GUI may then be rendered on a display of the system such as a touch-screen display for the user to interact with. After receiving a value of dWOB, the process may store the value of dWOB in a memory of the system and/or provide the value of dWOB to a WOB estimator portion operating in accordance with embodiments of the present system. After completing act 203, the process may continue to act 205. Values of dWOB may be set and/or reset by a user and/or may be stored in a memory of the system for later use, if desired. For example, in accordance with embodiments of the present system, a dWOB may be set to a value greater than 0 such as 0.4 joules. However, other values and/or ranges of values are also envisioned.

During act 205, the process may begin ventilation. Accordingly, the process may drive the ventilator to output a ventilation gas (VG) to ventilate a patient wherein the VG may have a desired characteristics such as pressure and/or flow (P, Q, respectively) profiles in time. The process may further obtain sensor information related to characteristics of the VG. Accordingly, the process may generate a pressure assist (PA) signal and provide this signal to a second control portion of the system to generate a corresponding pressure profile control signal (PPCS) which may be transmitted to a ventilator pump of the ventilator so as to control the characteristics of the VG provided by the ventilator. Accordingly, the ventilator pump may provide the VG with the desired pressure and/or flow. After completing act 205, the process may continue to act 207.

During act 207, the process may estimate a WOB value (e.g., eWOB) for the patient. Accordingly, the process may obtain sensor information relating to
characteristics of the VG such as pressure and flow and may determine the eWOB value using any suitable method. For example, an estimation algorithm operating in accordance with embodiments of the present system may input sensor information such as value of P and Q (e.g., determined proximal to the mouth of the patient) and may determine an eWOB value. After completing act 207, the process may continue to act 209.

During act 209, the process may determine a difference (e) value based upon a difference between the dWOB and the eWOB values. In accordance with embodiments of the present system, the process may determine the difference (e) using equation \( e = dWOB - eWOB \). After completing act 209, the process may continue to act 211.

During act 211, the process may determine whether an absolute value of the difference (e) (e.g., \(|e|\)) is less than a threshold error value \( \varepsilon \). The value of \( \varepsilon \) may be set by the user and/or system and may be varied depending upon several variables such as desired accuracy of estimation, size of a patient, etc. For example, in accordance with embodiments, the value of \( \varepsilon \) may range from 0.01 to 0.1 joules. However, other values may also be envisioned. Accordingly, in a case wherein it is determined that \(|e|\) is less than the threshold error value \( \varepsilon \), the process may continue to act 221. This may indicate that the eWOB is substantially close to the dWOB (e.g., within the threshold error value \( \varepsilon \) and may be considered substantially equal to 0 accordingly, a current value of PA may equal the previous value of PA) such eWOB may remain the same (e.g., does not have to be changed). However, in a case wherein it is determined that \(|e|\) is not less than (e.g., is greater than or equal to) the threshold error value \( \varepsilon \), the process may continue to act 215.
In accordance with embodiments, during act 211, in a case wherein it is determined that $|e|$ is less than the threshold error value $\varepsilon$, the process may end (e.g., rather than continuing to act 221 as discussed above), as desired (e.g., as eWOB may be considered to be substantially equal to dWOB). Further, in a case wherein it is determined that $|e|$ is not less than the threshold error value $\varepsilon$, the process may similarly continue to act 215.

During act 215, the process may determine whether the difference $(e)$ is less than 0. Accordingly, in a case wherein it is determined that the difference $(e)$ is less than 0 (e.g., $(e)$ is negative), the process may continue to act 217. However, in a case wherein it is determined that the difference $(e)$ is not less than 0 (e.g., $(e)$ is positive), the process may continue to act 219. Generally, during this act the process may determine whether the difference $(e)$ is negative (e.g., $(e)<0$) or positive (e.g., $(e)>0$) and performs a corresponding act based upon this determination.

During act 217, the process may set a current value of PA equal to the previous value of PA plus Pinc, where Pinc is a pressure increment value which may be set by the user and/or system (e.g., such as a default value). In other words, the process may set $PA=PA+Pinc$. More generally, the process may perform this act when it is determined that the eWOB is greater than the dWOB (as determined during acts 211 and 215 above) indicating that the estimated work of breathing of the patient may be greater than the desired work of breathing. Accordingly, the process may act to increase PA and, thus, pressure assist so that the ventilator may decrease the estimated work of breathing (e.g., at a future time) in an attempt to bring it closer to the
desired work of breathing. After completing act 217, the process may continue to act 221.

During act 219, the process may set a current value of PA equal to the previous value of PA minus Pinc. In other words, the process may set PA=PA-Pinc. More generally, the process may perform this act when it is determined that the eWOB is less than the dWOB (as determined during acts 211 and 215 above) indicating that the estimated work of breathing of the patient may be less than the desired work of breathing. Accordingly, the process may act to decrease PA and, thus, pressure assist so that the ventilator may increase the estimated work of breathing (e.g., at a future time) in an attempt to bring it closer to the desired work of breathing. After completing act 219, the process may continue to act 221.

With regard to the Pinc, in accordance with embodiments of the present system, this value may be adjusted based upon |e|. For example, the process may adjust Pinc based upon a value of |e|. Thus, as |e| increases Pinc may be linearly or nonlinearly adjusted based upon a value of |e|. Thus, as the error increases (e.g., |e| increases), the process may increase Pinc. Similarly, as the error decreases (e.g., |e| decreases) the process may decrease Pinc. This may provide for small pressure assist changes when |e| is small and larger pressure assist changes when |e| is large. Thus, when |e| is small, Pinc may be a small value to allow for minute changes of pressure assist so that the eWOB may be finely adjusted until it is substantially equal to the dWOB and when |e| is large, Pinc may be a relatively larger value to allow for larger changes of pressure assist so that the eWOB may be coarsely adjusted so that the eWOB may be rapidly changed to approximate the dWOB to bring the patient close to the dWOB.
quicker than in a case wherein only a smaller Pine is utilized. This may allow for pressure assist to be adjusted to bring the eWOB closer to the dWOB faster when the values of eWOB and dWOB greatly differ from each other and in accordance with embodiments of the present system, to be finely tuned when the values of eWOB and dWOB more closely match each other.

During act 221, the process may apply the PA value as determined above. Accordingly, the process may transmit the current PA information including the PA value determined above to a second control portion where a corresponding pressure profile control signal (PPCS) may be formed to form to drive a ventilator. Thus, the PPCS may be formed in accordance with the PA value. For example, FIG. 3A shows a graph 300A illustrating a pressure profile control signal (PPCS) 301 and corresponding pressure assist and eWOB signals 303 and 305, respectively, formed in accordance with embodiments of the present system. For example, the PPCS 301 may be generated by the process and provided to drive a ventilator to adjust the pressure assist as illustrated by the pressure assist signal 303 which illustrates a pressure profile of a ventilation gas output by the ventilator. When comparing the pressure assist and eWOB signals, 303 and 305, respectively, it is seen that as the pressure assist (e.g., 303) provided to a patient increases, the patient's eWOB (305) decreases and vice versa. The steps in the eWOB signal 305 are caused by changes in the PA which subsequently results in changes to the PPCS and consequently the pressure assist provided by the ventilator. By reducing the Pine these steps may be reduced in size and vice versa. In accordance with embodiments of the present system, only relatively larger or smaller changes in the PA may be utilized.
FIG. 3B shows a graph 300B illustrating a PPCS 300B generated over time in accordance with embodiments of the present system. More particularly, the PPCS 300B is illustrated in accordance with airway pressure (assist) over time. Illustrative values of pressure support ventilation (PSV) and extrinsic positive end-expiratory pressure PEEP values are shown.

Further, with regard to the PPCS 301 and the pressure assist signal 303, these signals may follow each other with a slight delay (Θ) as shown due to a delay time required to provide a desired pressure profile (P) by a control system (e.g., pump, valves, etc.) of the ventilator.

Referring back to FIG. 2, after completing act 221, the process may continue to act 223.

During act 223, the process may render information determined and/or otherwise obtained by the process. For example, in accordance with some embodiments, the process may render a values of PA, the dWOB, the eWOB, Pine, (e), ε, etc. on a rendering device of the system such as a display, a speaker, etc. in accordance with embodiments of the present system. Further, the process may render graphs illustrating dWOB and eWOB signals as shown in FIG. 3A. After completing act 223, the process may continue to act 225.

During act 225, the process may further update history information to reflect information determined by the process such as changes determined by the process. The history information may be stored in a memory of the system for later use. After completing act 225, the process may continue to act 227.
During act 227, the process may apply a delay until a time Td elapses. Thus, the process may wait for a delay time Td. Then, when the delay time Td elapses, the process may repeat act 207. The delay time Td may be set by the system (e.g., default value) and/or user and may be selected so that a desired amount is provided for the ventilation system to stabilize before repeating act 207 and/or possibly resetting the PA which may consequently effect the eWOB. In accordance with embodiments of the present system Td may be set to a desired value such as 5 minutes. However, without limitation, other values are also envisioned (e.g., 30 seconds, 1 minute, 2 minutes, ... 30 minutes, etc.).

Thus, in accordance with embodiments of the present system, values may be obtained for the desired and estimated work of breathing. Then, these values may summed to determine a difference (e) (e.g., an error) between them. Thereafter, the process may check the magnitude of the difference (e.g., |e|). If |e| is less than a threshold error value (ε) (e.g., indicative the estimated work of breathing being substantially equal to the desired work of breathing), there process may not adjust breathing support (e.g., provided to a patient) and the process may proceed to a delay phase to wait a delay time (Td). However in a case wherein it is determined that |e| is not less than (ε) (e.g., |e|>=£), the process may determine a sign of the difference (e). In a case wherein the sign of the difference is negative, the estimated work of breathing is greater than the desired work of breathing which indicates that a breathing load on the patient may be higher than that which is desired and, as such, the process may act to increase breathing support provided by a ventilator which results in higher pressure support. However, if the difference (e) is positive, then this may indicate that ventilator
may be performing more work that necessary and the process may be operational to reduce the pressure support by a threshold value. After each adjustment, the process may go to a delay phase for a period of time $T_d$ to allow the physiology of the patient to settle to this new pressure support input (e.g., change in pressure assistance provided to the patient).

Accordingly, embodiments of the present system may use an estimate of the work of breathing (e.g., eWOB) obtained by the process to adjust a level of pressure support provided by a ventilator to a subject being ventilated such as a patient, an animal, etc. Further, in accordance with embodiments of the present system, it may be assumed that the subject may initiate breaths.

In accordance with embodiments of the present system, there is provided a control algorithm for determining a safety limit based on minimum minute ventilation and tidal volume and/or on maximum tidal volume. Control algorithms operating in accordance with embodiments of the present system may continuously monitor the minimum minute ventilation and, when it is determined that a minimum minute ventilation is less than a corresponding minimum threshold, the control algorithm may be active to increase the PSV (e.g., by increasing PSV or returning the PSV to a previous higher value), as desired. Further, in accordance with embodiments of the present system, the control algorithm may be operative for spontaneous breaths and may be based on a pressure support ventilation (PSV) method.

In accordance with embodiments of the present system there is provided a system that may determine values for a desired work of breathing and an estimated
work of breathing. The system may compare these two values (e.g., the desired work of breathing and the estimated work of breathing) to determine whether the desired work of breathing is substantially equal to the estimated work of breathing. Accordingly, in a case wherein it is determined that the desired work of breathing is substantially equal to the estimated work of breathing (e.g., these two values are within a ± a threshold error value (ε) of each other), the system may be operative to keep current pressure support settings. However, in a case wherein it is determined that the desired work of breathing is not substantially equal to the estimated work of breathing, the system may be operative to determine a new (e.g., change) pressure support settings as set forth below. For example, the process may compare the desired work of breathing with the estimated work of breathing as set forth below.

Accordingly, in a case wherein it is determined that the desired work of breathing is greater than the estimated work of breathing (e.g., dWOB>eWOB), the process may be operative to decrease breathing support from the ventilator which results in lower pressure (P) of the ventilation gas (VG). This condition may be indicative of a low breathing load on the patient in comparison to a desired load such as set forth by the desired work of breathing which may be set by a clinician.

However, in a case wherein it is determined that the desired work of breathing is less than the estimated work of breathing (e.g., dWOB<eWOB), the process may be operative to increase breathing support from the ventilator which results in higher pressure (P) of the ventilation gas (VG). This condition (dWOB < eWOB) may be indicative of a high breathing load on the patient relative to a desired load.
The above-described acts may be repeated to finely adjust the estimated work of breathing so that it is substantially equal to the desired work of breathing at which time the process may stop or may continue to operate depending upon system and/or user settings.

In accordance with yet other aspects of the present system, there is described a process performed by an algorithm operating in accordance with embodiments of the present system. The process may determine a desired work of breathing value and an estimated work of breathing value. Then, the process may then compare these two values and if the work of breathing value is determined to be greater than the desired work of breathing value, the process may increase the pressure support by a threshold value. However, if the work of breathing value is determined to be less than the desired work of breathing value, the process may decrease pressure support by the threshold amount. Then after a fixed period of time, this process may be repeat until the actual work of breathing done by the patient is close enough to the desired work of breathing.

FIG. 4 shows a portion of a system 400 in accordance with embodiments of the present system. For example, a portion of the present system may include a processor 410 (e.g., a controller) operationally coupled to a memory 420, a rendering device such as a display 430, sensors 440, actuators 460, a network 480, and a user input device 470. The memory 420 may be any type of device for storing application data as well as other data related to the described operation. The application data and other data are received by the processor 410 for configuring (e.g., programming) the processor 410 to perform operation acts in accordance with the present system. The processor 410 so
configured becomes a special purpose machine particularly suited for performing in accordance with embodiments of the present system.

The user input 470 may include a keyboard, a mouse, a trackball, or other device, such as a touch-sensitive display, which may be stand alone or be a part of a system, such as part of a personal computer, a personal digital assistant (PDA), a mobile phone (e.g., a smart phone), a monitor, a wearable display (e.g., smart glasses, etc.), a smart- or dumb-terminal or other device for communicating with the processor 410 via any operable link. The user input device 470 may be operable for interacting with the processor 410 including enabling interaction within a user interface (UI) as described herein. Clearly the processor 410, the memory 420, display 430, and/or user input device 470 may all or partly be a portion of a computer system or other device such as a client and/or server.

The actuators 460 may be controlled by the processor 410 in accordance with embodiments of the present system. The actuators 460 may control one or more pumps, valves, etc. so as to control the flow of gasses to and/or from the system under the control of the processor 410 so as to control characteristics of a ventilation gas (VG) such as pressure (P) and flow (Q) of the VG. For example, in accordance with embodiments, the actuators 460 may include a motor controller which may control a pump which may pressurize the VG under the control of the processor 410. In accordance with yet other embodiments the actuators 460 may further control one or more active valves so as to open or close the corresponding valves. These valves may, for example, include pneumatic control valves which may control the flow of one or more gasses such as gasses for inhalation, recirculation, and/or exhaust.
The methods of the present system are particularly suited to be carried out by a computer software program, such program containing modules corresponding to one or more of the individual steps or acts described and/or envisioned by the present system. Such program may of course be embodied in a computer-readable medium, such as an integrated chip, a peripheral device or memory, such as the memory 420 or other memory coupled to the processor 410.

The program and/or program portions contained in the memory 420 may configure the processor 410 to implement the methods, operational acts, and functions disclosed herein. The memories may be distributed, for example between the clients and/or servers, or local, and the processor 410, where additional processors may be provided, may also be distributed or may be singular. The memories may be implemented as electrical, magnetic or optical memory, or any combination of these or other types of storage devices. Moreover, the term "memory" should be construed broadly enough to encompass any information able to be read from or written to an address in an addressable space accessible by the processor 410. The memory 420 may include a non-transitory memory. With this definition, information accessible through a network such as the network 480 is still within the memory, for instance, because the processor 410 may retrieve the information from the network 480 for operation in accordance with the present system.

The processor 410 is operable for providing control signals and/or performing operations in response to input signals from the user input device 470 as well as in response to other devices of a network and executing instructions stored in the memory 420. The processor 410 may include one or more of a microprocessor, an application-
specific or general-use integrated circuit(s), a logic device, etc. Further, the processor 410 may be a dedicated processor for performing in accordance with the present system or may be a general-purpose processor wherein only one of many functions operates for performing in accordance with the present system. The processor 410 may operate utilizing a program portion, multiple program segments, or may be a hardware device utilizing a dedicated or multi-purpose integrated circuit.

The methods of the present system are particularly suited to be carried out by processor programmed by a computer software program, such program containing modules corresponding to one or more of the individual steps or acts described and/or envisioned by the present system.

Accordingly, embodiments, of the present system may provide a system and/or a method to automatically monitor a patient's physiological condition and deliver a determined optimal amount of breathing load support by the ventilator.

While the present invention has been shown and described with reference to particular exemplary embodiments, it will be understood by those skilled in the art that present invention is not limited thereto, but that various changes in form and details, including the combination of various features and embodiments, may be made therein without departing from the spirit and scope of the invention.

Further variations of the present system would readily occur to a person of ordinary skill in the art and are encompassed by the following claims.

Finally, the above-discussion is intended to be merely illustrative of the present system and should not be construed as limiting the appended claims to any particular embodiment or group of embodiments. Thus, while the present system has been
described with reference to exemplary embodiments, it should also be appreciated that numerous modifications and alternative embodiments may be devised by those having ordinary skill in the art without departing from the broader and intended spirit and scope of the present system as set forth in the claims that follow. Accordingly, the specification and drawings are to be regarded in an illustrative manner and are not intended to limit the scope of the appended claims.

In interpreting the appended claims, it should be understood that:

a) the word "comprising" does not exclude the presence of other elements or acts than those listed in a given claim;

b) the word "a" or "an" preceding an element does not exclude the presence of a plurality of such elements;

c) any reference signs in the claims do not limit their scope;

d) several "means" may be represented by the same item or hardware or software implemented structure or function;

e) any of the disclosed elements may be comprised of hardware portions (e.g., including discrete and integrated electronic circuitry), software portions (e.g., computer programming), and any combination thereof;

f) hardware portions may be comprised of one or both of analog and digital portions;

g) any of the disclosed devices or portions thereof may be combined together or separated into further portions unless specifically stated otherwise;
h) each of these disclosed devices, portions thereof and/or combinations thereof should be understood to be a separate embodiment that is operable separately from any other embodiments and/or combinations thereof;

i) no specific sequence of acts or steps is intended to be required unless specifically indicated;

j) the term "plurality of an element includes two or more of the claimed element, and does not imply any particular range of number of elements; that is, a plurality of elements may be as few as two elements, and may include an immeasurable number of elements; and

k) the term and/or and formatives thereof should be understood to mean that only one or more of the listed elements may need to be suitably present in the system in accordance with the claims recitation and in accordance with one or more embodiments of the present system.
Claims

1. A medical ventilator (100, 400), comprising:

   at least one controller (106, 410) which:

   obtains a reference work of breathing value (dWOB);

   analyzes ventilation flow at a physical interface (112) configured to be coupled to a user;

   estimates work of breathing value (eWOB) performed by a patient (101) based upon analysis of the ventilation flow;

   determines a difference (e) between the values of dWOB and the eWOB;

   and

   sets a pressure assist provided by the ventilator based upon the determined difference (e).

2. The medical ventilator of claim 1, wherein the at least one controller further compares the difference (e) to a positive and a negative threshold error value (±ε).

3. The medical ventilator of claim 2, wherein when it is determined that the difference (e) is greater than the positive threshold error value (ε), the controller is operative to decrease pressure assist.

4. The medical ventilator of claim 2, wherein when it is determined that the difference (e) is less than the negative threshold error value -(ε), the controller increases pressure assist.
5. The medical ventilator of claim 1, wherein when it is determined that the difference (e) is less than or equal to the positive threshold error value (ε) and greater than or equal to the negative threshold value, the controller maintains a current pressure assist.

6. The medical ventilator of claim 1, further comprising at least one rendering device (102, 430), wherein the at least one controller is operative to render values of the dWOB and the eWOB upon the rendering device.

7. The medical ventilator of claim 1, further comprising at least one rendering device (102, 430), wherein the at least one controller is further operative to generate a message requesting a user enter a desired work of breathing value and render this message on the at least one rendering device.

8. A method of operating a medical ventilator (100, 400), the method performed by at least one controller (106, 410) and comprising acts of:

   - obtaining a reference work of breathing value (dWOB);
   - analyzing a ventilation flow at a physical interface (112) configured to be coupled to a user;
   - estimating work of breathing value (eWOB) performed by a patient (101) based upon analysis of the ventilation flow;
   - determining a difference (e) between the values of dWOB and the eWOB;

   and
setting a pressure assist provided by the ventilator based upon the determined difference \((e)\).

9. The method of claim 8, further comprising an act of comparing the difference \((e)\) to a positive and a negative threshold error value \((\pm \varepsilon)\).

10. The method of claim 9, further comprising an act of decreasing pressure assist when it is determined that the difference \((e)\) is greater than the positive threshold error value \((\varepsilon)\).

11. The method of claim 9, further comprising an act of increasing pressure assist when it is determined that the difference \((e)\) is less than the negative threshold error value \((-\varepsilon)\).

12. The method of claim 8, further comprising an act of maintaining a current pressure assist when it is determined that the difference \((e)\) is less than or equal to the positive threshold error value \((\varepsilon)\) and greater than or equal to the negative threshold value.

13. The method of claim 8, further comprising an act of rendering values of the dWOB and the eWOB on at least one rendering device (102, 430).

14. The method of claim 8, further comprising acts of:
generating a message requesting a user enter a desired work of breathing value;
and
rendering this message on the at least one rendering device (102, 430).

15. A computer readable non-transitory medium (120, 420) having computer readable
program code for operating on a computer (106, 410) for performing a method of
operating a medical ventilator (100, 400), the method comprising acts of:

obtaining a reference work of breathing value (dWOB);

analyzing a ventilation flow at a physical interface (112) configured to be
coupled to a user;

estimating work of breathing value (eWOB) performed by a patient (101)

based upon analysis of the ventilation flow;

determining a difference (e) between the values of dWOB and the eWOB;

and

setting a pressure assist provided by the ventilator based upon the
determined difference (e).

16. The medium of claim 15, the method further comprising an act of comparing the
difference (e) to a positive and a negative threshold error value (±ε).

17. The medium of claim 16, the method further comprising an act of decreasing
pressure assist when it is determined that the difference (e) is greater than the positive
threshold error value (ε).
18. The medium of claim 16, the method further comprising an act of increasing pressure assist when it is determined that the difference \( e \) is less than the negative threshold error value \(-\epsilon\).

19. The medium of claim 16, the method further comprising an act of maintaining a current pressure assist when it is determined that the difference \( e \) is less than or equal to the positive threshold error value \( \epsilon \) and greater than or equal to the negative threshold value.

20. The medium of claim 16, the method further comprising an act of rendering values of the dWOB and the eWOB on at least one rendering device (102, 430).
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201 Start

203 Initialize

205 Begin ventilation

207 Estimate WOB (eWOB)

209 \( (e) = dWOB - eWOB \)

211 \(|e| < \varepsilon \) yes

217 \( PA = PA + Pinc \) yes

215 \( e < 0 \) no

219 \( PA = PA - Pinc \) no

221 Apply PA

223 Render

225 Update history

227 Delay: Td

FIG. 2
FIG. 3A

FIG. 3B
FIG. 4
**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61M16/00 A61B5/08

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61M A61B

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**

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<td>wo 00/45880 AI (UNIV FLORIDA [US]) 10 August 2000 (2000-08-10) figures 1, 2, 5, 6 page 2, line 18 - page 3, line 7 page 7, line 4 - line 12 page 8, line 9 - line 20 page 10, line 1 - page 13, line 7 page 16, line 1 - page 17, line 2 page 20, line 15 - page 21, line 10 page 28, line 5 - page 28, line 18 page 30, line 6 - page 31, line 9 page 38, line 5 - page 42, line 19</td>
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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) on 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

**Date of the actual completion of the international search**

9 June 2016

**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

**Date of mailing of the international search report**

17/06/2016

Authorized officer

Cecchi, Stefano
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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.: 8-14
   because they relate to subject matter not required to be searched by this Authority, namely:
   
   see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

\[\square\] 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.

\[\square\] No protest accompanied the payment of additional search fees.
Continuation of Box II.1

Claims Nos.: 8-14

Claims 8-14 define a method of operating a medical ventilator including the step of setting a pressure assist provided by the ventilator based upon a calculated parameter. This step is explicitly a therapeutic step and thereby the nature of the whole method is rendered therapeutic. Thus, the subject-matter of claims 8-14 is regarded as a method for treatment of the human or animal body by therapy (Rule 39.1 (iv) PCT). Consequently, the subject-matter of claims 8-14 has not been searched and will not be examined (Rule 66.1 (e) PCT, Rule 67.1 (iv) PCT).
<table>
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