US009604021B2

(12) United States Patent
Tehrani

(10) Patent No.: US 9,604,021 B2
(45) Date of Patent: Mar. 28, 2017

(54) AUTOMATIC CONTROL SYSTEM FOR MECHANICAL VENTILATION FOR ACTIVE OR PASSIVE SUBJECTS

(71) Applicant: **Fleur Taher Tehrani**, Anaheim, CA (US)

(72) Inventor: **Fleur Taher Tehrani**, Anaheim, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 196 days.

(21) Appl. No.: **14/193,864**

(22) Filed: **Feb. 28, 2014**

(65) **Prior Publication Data**

US 2014/0318541 A1 Oct. 30, 2014

Related U.S. Application Data

(62) Division of application No. 12/509,457, filed on Jul. 25, 2009, now Pat. No. 8,701,665.

(51) **Int. Cl.**
A61M 16/00 (2006.01)
A61B 5/08 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 16/0069*** (2014.02); ***A61B 5/085*** (2013.01); ***A61B 5/087*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 16/00–16/0012; A61M 16/0051–16/0084; A61M 16/0096; A61M 16/04–16/0402; A61M 16/06–16/0661; A61M 2016/0015–2016/0042; A61M 2016/0413; A61M 2230/00;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,986,268 A * 1/1991 Tehrani A61M 16/00 128/204.22
5,044,362 A 9/1991 Younes
(Continued)

OTHER PUBLICATIONS

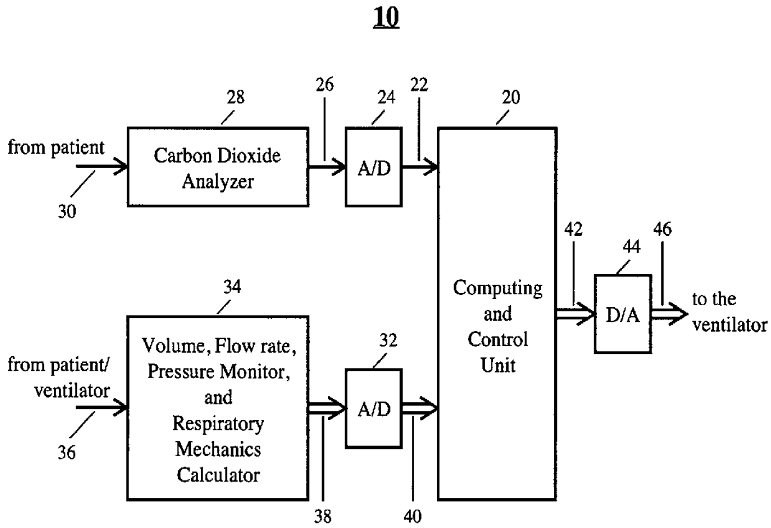
Otis, AB, et al., "Mechanics of Breathing in Man", Journal of Applied Physiology, vol. 2, No. 11, pp. 592-607, 1950.
(Continued)

Primary Examiner — (Jackie) Tan-Uyen T Ho
Assistant Examiner — Ned T Heffner

(57) **ABSTRACT**

A method and an apparatus for controlling a ventilator to automatically adjust ventilation assistance to an active or passive subject. The method includes determining volume and flow rate of gas to the patient during inspiration on an ongoing basis, and generating control signals in proportion to the volume and flow rate of gas to the patient wherein proportionality factors, and support levels for the elastic and resistive components of pressure are automatically adjusted by the ventilator. The ongoing pressure applied by the ventilator is a sum of elastic and resistive pressures that are automatically controlled by the system. When the patient breathes spontaneously, the support levels are automatically adjusted based on the patient's requirements. If the patient does not breathe spontaneously, the ventilator provides ventilation at an optimal level and rate. The method may be used in weaning or in a management phase of ventilation.

16 Claims, 3 Drawing Sheets



(51) **Int. Cl.**

A61B 5/083	(2006.01)
A61B 5/085	(2006.01)
A61B 5/087	(2006.01)
A61B 5/091	(2006.01)
A61B 5/00	(2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/0816*** (2013.01); ***A61B 5/0836*** (2013.01); ***A61B 5/091*** (2013.01); ***A61B 5/4836*** (2013.01); ***A61M 16/0003*** (2014.02); ***A61M 16/0051*** (2013.01); *A61M 2016/0027* (2013.01); *A61M 2016/0033* (2013.01); *A61M 2016/0036* (2013.01); *A61M 2230/202* (2013.01); *A61M 2230/432* (2013.01); *A61M 2230/46* (2013.01)

(58) **Field of Classification Search**
CPC A61M 2230/005; A61M 2230/202–2230/205; A61M 2230/40–2230/46; A61M 16/22; A61B 5/082–5/097
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,107,830	A *	4/1992	Younes	A61M 16/00 128/204.18
5,881,723	A *	3/1999	Wallace	A61M 16/0051 128/204.18
5,884,622	A	3/1999	Younes	
6,257,234	B1	7/2001	Sun	
6,575,163	B1	6/2003	Berthon-Jones	
2007/0163590	A1	7/2007	Bassin	
2008/0236582	A1	10/2008	Tehrani	

OTHER PUBLICATIONS

Tehrani, F., et al., “A dual closed-loop control system for mechanical ventilation”, Journal of Clinical Monitoring and Computing, vol. 18, No. 2, pp. 111-129, 2004.

* cited by examiner

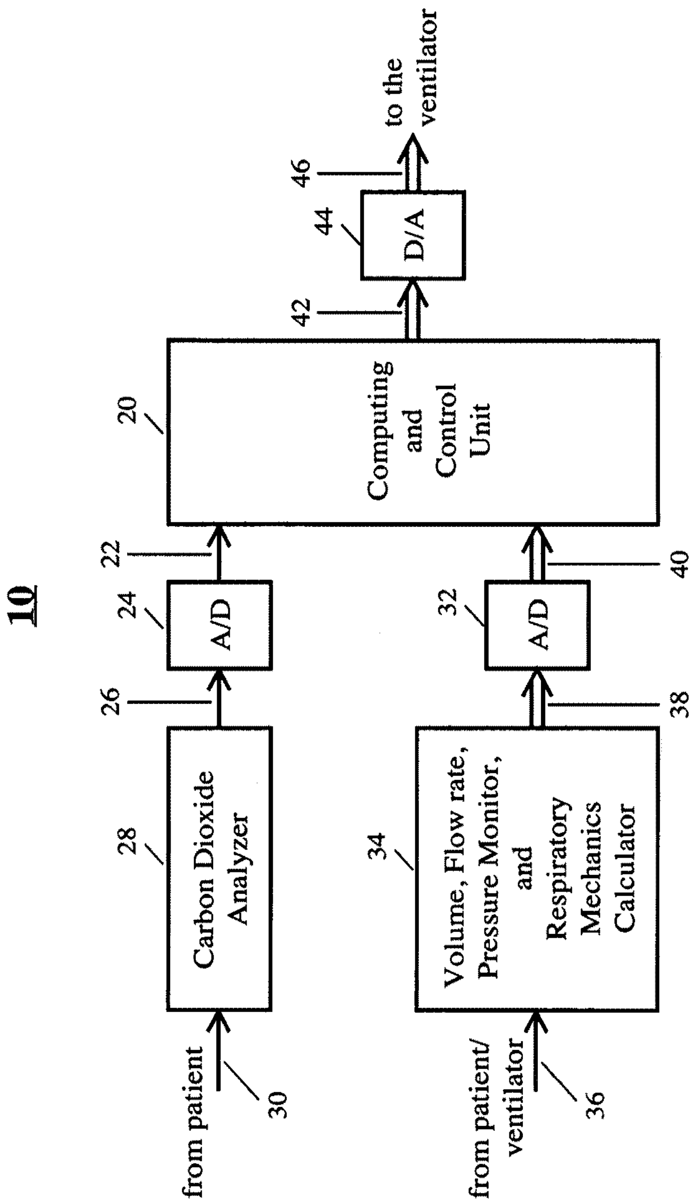

10
from patient
30
Carbon Dioxide Analyzer
28
26
A/D
24
22
Computing and Control Unit
20
42
D/A
44
46
to the ventilator
from patient/ ventilator
36
Volume, Flow rate, Pressure Monitor, and Respiratory Mechanics Calculator
34
38
A/D
32
40

FIG. 1

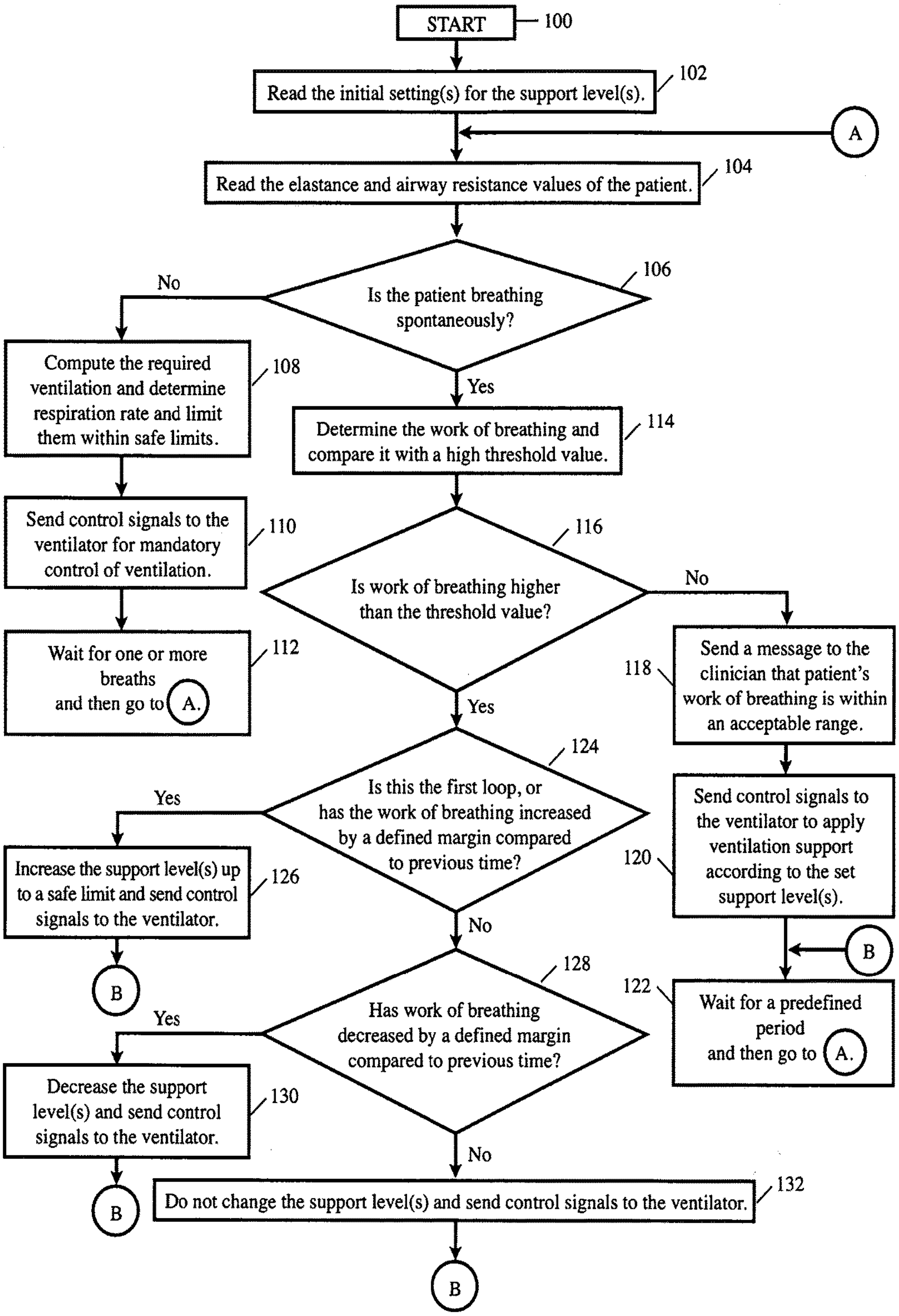

START
100
Read the initial setting(s) for the support level(s).
102
A
Read the elastance and airway resistance values of the patient.
104
Is the patient breathing spontaneously?
106
No
Compute the required ventilation and determine respiration rate and limit them within safe limits.
108
Send control signals to the ventilator for mandatory control of ventilation.
110
Wait for one or more breaths and then go to A.
112
Yes
Determine the work of breathing and compare it with a high threshold value.
114
Is work of breathing higher than the threshold value?
116
No
Send a message to the clinician that patient's work of breathing is within an acceptable range.
118
Send control signals to the ventilator to apply ventilation support according to the set support level(s).
120
B
Wait for a predefined period and then go to A.
122
Yes
Is this the first loop, or has the work of breathing increased by a defined margin compared to previous time?
124
Yes
Increase the support level(s) up to a safe limit and send control signals to the ventilator.
126
B
No
Has work of breathing decreased by a defined margin compared to previous time?
128
Yes
Decrease the support level(s) and send control signals to the ventilator.
130
B
No
Do not change the support level(s) and send control signals to the ventilator.
132
B

FIG. 2

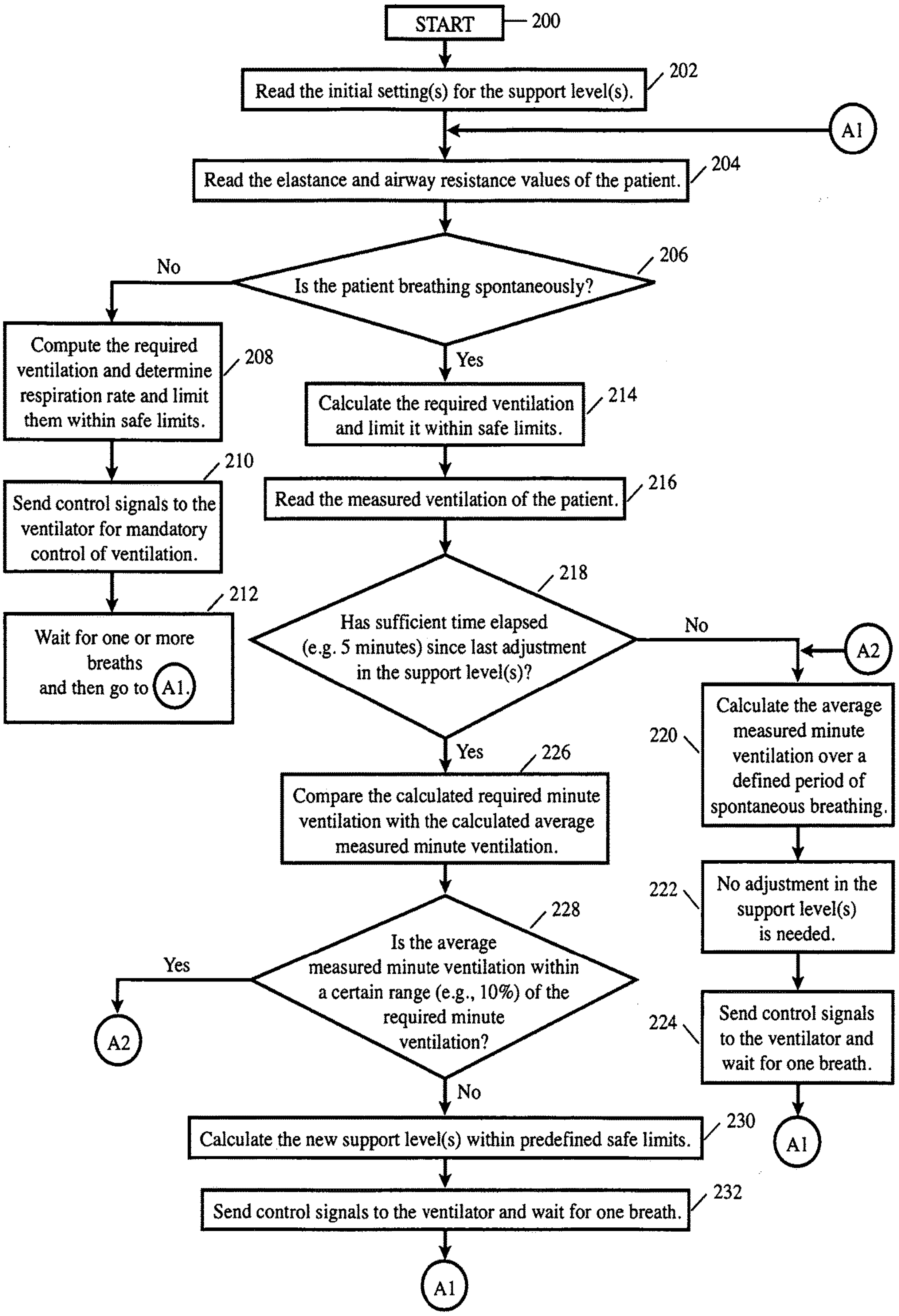

START
200
Read the initial setting(s) for the support level(s).
202
A1
Read the elastance and airway resistance values of the patient.
204
Is the patient breathing spontaneously?
206
No
Yes
Compute the required ventilation and determine respiration rate and limit them within safe limits.
208
Calculate the required ventilation and limit it within safe limits.
214
Send control signals to the ventilator for mandatory control of ventilation.
210
Read the measured ventilation of the patient.
216
Wait for one or more breaths and then go to A1.
212
Has sufficient time elapsed (e.g. 5 minutes) since last adjustment in the support level(s)?
218
No
A2
Yes
Calculate the average measured minute ventilation over a defined period of spontaneous breathing.
220
Compare the calculated required minute ventilation with the calculated average measured minute ventilation.
226
No adjustment in the support level(s) is needed.
222
Is the average measured minute ventilation within a certain range (e.g., 10%) of the required minute ventilation?
228
Yes
A2
Send control signals to the ventilator and wait for one breath.
224
No
Calculate the new support level(s) within predefined safe limits.
230
A1
Send control signals to the ventilator and wait for one breath.
232
A1

FIG. 3

AUTOMATIC CONTROL SYSTEM FOR MECHANICAL VENTILATION FOR ACTIVE OR PASSIVE SUBJECTS

CROSS-REFERENCE TO RELATED APPLICATION

The present application is a divisional application of U.S. Ser. No. 12/509,457, filed Jul. 25, 2009. This application is hereby incorporated by reference into the present application in its entirety as if fully sets forth herein, and for all purposes.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to mechanical ventilators, and more specifically, to a ventilator control system that automatically adjusts a supply of breathable gas to an active or passive subject to achieve an automatically determined support level.

2. Description of Related Art

Mechanical ventilation is a treatment technique for provision of full or partial respiration assistance to humans or animals with respiratory failure or those who due to surgeries or various other medical conditions cannot breathe on their own. During the course of this life-saving treatment, it is of paramount importance to provide optimal therapy to patients. The amount of ventilation needs to be adjusted in accordance with patient's requirements and the frequency of delivered breaths should be close to the natural respiration rate of the patient. Provision of inappropriate treatment can cause numerous untoward conditions in patients and induce asynchrony between the machine and the patient. Lack of synchrony between the patient and the ventilator can significantly increase work of breathing, necessitate administration of sedatives, prolong the treatment and delay weaning which can all cause complications that may lead to increased mortality and morbidity rates of patients on mechanical ventilation.

There have been many advances in mechanical ventilation in the past several decades. U.S. Pat. No. 4,986,268 (Tehrani) disclosed a novel technique for mechanical ventilation. Using that technique, tidal volume and respiration rate were automatically adjusted by the ventilator based on the bodily requirements of the patient. In that invention, the frequency of delivered breaths was automatically adjusted to minimize the work rate of breathing based on the changing respiratory mechanics of the patient. This was done to provide a breathing pattern that was close to natural for the patient and help synchronize the ventilator with the patient. This system was later adopted in ventilators and has been in use in practice for a number of years.

In order to improve mechanical ventilation during the weaning phase of the treatment, a system for automatic control of weaning was disclosed later in U.S. patent application Ser. No. 11/841,806. In an embodiment of that invention, the ventilator's output is adjusted automatically during weaning based on the strength of the patient's spontaneous breathing.

U.S. Pat. Nos. 5,044,362 and 5,107,830 (Younes) described a novel technique for mechanical ventilation in which the ventilator applied additional airway pressure during the inspiratory phase of ventilation that was proportional to the patient's own developed airway pressure. In this technique, the volume of gas inhaled by the patient and the rate of gas flow to the patient were measured during inspiration and the pressure applied to the patient's airways by the ventilator was proportional to the elastic and resistive pressures developed by the patient's own inspiratory effort. In this technique, the ventilator followed the patient's spontaneous respiratory pattern, and therefore, there was significant synchrony between the machine and the patient. This technique, which has been used in mechanical ventilators in practice in recent years, is particularly suited to the needs of patients with significant spontaneous breathing activity and is most useful in the weaning phase of the treatment. A major drawback of this system, known as proportional assist ventilation, is that it cannot guarantee the delivery of a minimum amount of ventilation to the patient. This may lead to a hazardous situation if the patient's spontaneous breathing activity weakens with time or if the patient develops dyspnea due to fatigue or other causes.

Therefore, it is necessary to provide ventilatory support in concert with the patient's own breathing pattern that can guarantee the delivery of a minimum required ventilation regardless of the status of the patient and the strength of the patient's spontaneous breathing activity.

SUMMARY OF THE INVENTION

The present invention provides a method and apparatus for automatically controlling a ventilator, wherein the volume and flow rate of inspiratory gas to the patient are measured by the system on an ongoing basis (continually during inspiration). The pressure support generated by the system is the sum of elastic and resistive components of pressure, where the elastic component of pressure is proportional to the measured inspiratory gas volume, and the resistive component of pressure is proportional to the measured flow rate of the inspiratory gas. The proportionality factors of the elastic and resistive pressure components in proportion to said volume and flow rate of the inspiratory gas and the elastic and resistive pressure support levels applied by the ventilator are determined and adjusted automatically by the ventilator. The adjustments may be made in view of the measured ventilation and the amount of the patient's required ventilation determined by the ventilator. The system may also adjust the proportionality factors and support levels automatically to prevent fatigue if the work of breathing increases significantly. For passive patients or in case of development of apnea, the ventilator may determine the amount of required ventilation and the rate of respiration to minimize the work rate of breathing. In that case, the ventilator may deliver mandatory breaths based on the calculated required tidal volume at the calculated optimal rate to the patient.

The present invention realizes many advantages over the prior art. While it achieves a desired synchronization between the patient and the ventilator, it guarantees that the patient receives a minimum required ventilation regardless of the strength of the patient's spontaneous breathing effort, both passive and active patients can be treated by the system, and it may be used in the management as well as the weaning phase of ventilatory treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

Other systems, methods, features and advantages of the invention will be or will become apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be included within this description, be within the scope of the invention, and be protected by the accompanying claims. It is understood that the invention is not limited to the precise arrangements and instrumentalities shown in the drawings which show a presently preferred form of the invention. Component parts shown in the drawings are not necessarily to scale, and may be exaggerated to better illustrate the important features of the invention. In the drawings, like reference numerals designate like parts throughout the different views, wherein:

FIG. **1** is a schematic representation of one embodiment of an apparatus for carrying out a method for automatically controlling mechanical ventilation according to the invention.

FIG. **2** is a flow chart illustrating a sequence of steps executable by a programmable system in one embodiment of a method for automatically controlling mechanical ventilation according to the invention.

FIG. **3** is a flow chart illustrating another sequence of steps executable by a programmable system in one embodiment of a method for automatically controlling mechanical ventilation according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

The following disclosure presents exemplary embodiments of the invention for a ventilator control system. In this system, the volume and flow rate of the inspiratory gas are measured on an ongoing basis (i.e. continually) during inspiration. The pressure support level provided by the ventilator is automatically adjusted based on said measurements in order to adjust a supply of breathable gas to a patient or other user to ensure a minimum required ventilation, and/or to prevent dyspnea and fatigue, while preserving synchrony between the patient and the ventilator. One objective of the invention is to provide appropriate ventilation assistance to a patient regardless of whether the patient is breathing in an active or passive state. Another objective of the invention is to assure that the patient receives a comfortable ventilation assistance treatment in synchrony with the patient's natural breathing regardless of whether the patient is active or passive.

General Description of the Invention

In a ventilatory system known as proportional assist ventilation, for example, as disclosed in U.S. Pat. No. 5,107,830 to Younes, the ventilator provides additional pressure support in proportion to the patient's own inspiratory effort. The pressure applied by the ventilator to the patient's airways in this system is:

$$P_{aw}=K_1V+K_2V' \tag{1}$$

Where P_{aw} is the pressure applied by the ventilator, V is the volume of gas inhaled by the patient, V' is the rate of gas flow to the patient, K_1V is the elastic component of pressure support, K_2V' is the resistive pressure support provided by the ventilator, and K_1 and K_2 are proportionality factors for elastic and resistive pressures respectively. The pressure developed by the patient's own effort can be written as:

$$P_{muscle}=KV+K'V' \tag{2}$$

Where P_{muscle} is the pressure developed by the patient, K is the patient's respiratory elastance and K' is the patient's airway resistance. Concentrating on the elastic components of pressure only, KV represents the elastic pressure developed by the patient's muscles and K_1V is the added response of the ventilator. By using a step-by-step analysis, in the 1st step, the total elastic pressure applied to the patient's airway rises to $V(K+K_1)$. This amount of pressure increases the patient's gas intake to $V(K+K_1)/K$. This volume is then multiplied by K_1 to produce the total amount of elastic pressure applied by the ventilator in the next step as:

$$P_{aw}=K_1\left[\frac{V(K+K_1)}{K}\right]=K_1V+K_1^2\frac{V}{K} \tag{3}$$

Therefore, the total elastic pressure including the elastic pressure generated by the patient's muscle becomes:

$$P_{elastic}(\text{total})=KV+K_1V+\frac{K_1^2}{K}V \tag{4}$$

Therefore, the resulting inhaled volume rises to the ratio of this pressure to the patient's respiratory elastance, K. This volume will be:

$$\text{Volume}=V+\frac{K_1}{K}V+\left(\frac{K_1}{K}\right)^2V \tag{5}$$

Then at the next step, the total amount of elastic pressure applied by the ventilator rises to the product of this volume and the proportionality factor K_1, which will be:

$$P_{aw}=K_1V+\frac{K_1^2}{K}V+\frac{K_1^3}{K^2}V \tag{6}$$

If this iterative analysis is continued, the total elastic pressure applied by the ventilator turns out to be:

$$P_{aw}=K_1V+\frac{K_1^2V}{K}+\ldots+\frac{K_1^nV}{K^{n-1}} \tag{7}$$

Which can be rewritten as:

$$P_{aw}=K_1V\left[1+\frac{K_1}{K}+\ldots+\left(\frac{K_1}{K}\right)^{n-1}\right] \tag{8}$$

If n tends to be large:

$$P_{aw}=K_1V[1+\alpha+\alpha^2+\alpha^3+\ldots\alpha^{n-1}\ldots] \tag{9}$$

where:

$$\alpha=\frac{K_1}{K}$$

The geometric series inside the brackets in equation 9 converges only if $\alpha<1$ (i.e. $K_1<K$). In that case:

$$P_{aw}=\frac{K_1V}{1-\alpha} \tag{10}$$

Where P_{aw} in equation 10 is the total elastic pressure delivered by the ventilator. As can be seen, if $\alpha \geq 1$, the series inside the brackets in equation 9 will not converge, and as a result, the system will be unstable. A similar analysis on the resistive component of pressure yields that:

$$P_{aw}(\text{resistive}) = \frac{K_2 V'}{1-\alpha'} \tag{11}$$

where:

$$\alpha' = \frac{K_2}{K'}$$

P_{aw}(resistive) is the resistive component of pressure delivered by the ventilator in response to patient effort and α' must also be less than 1 for the system to be stable.

Therefore, the total elastic pressure as the sum of the elastic component of the patient muscle pressure, KV, and the elastic component of pressure delivered by the ventilator, P_{aw}, from equation 10 becomes:

$$\text{Total elastic pressure} = V\left[K + \frac{K_1}{1-\alpha}\right] \tag{12}$$

where V is the volume of gas inhaled by the patient's own effort.

For this system to be stable, α and α' which are the support levels for elastic and resistive pressures respectively, must be less than 1, and they can be equal. The total volume of gas inhaled during inspiration can be found by dividing the total elastic pressure from equation 12 above by the patient's respiratory elastance, K as:

$$\text{Total volume} = \frac{V\left[K + \frac{K_1}{1-\alpha}\right]}{K} \tag{13}$$

Which yields:

$$\text{Total volume} = V\left[\frac{1}{1-\alpha}\right] \tag{14}$$

The main advantage of the above-described system of ventilation is that the ventilator follows patient's effort and there is significant synchrony between the patient and the machine. However, there is no guarantee in this system that the patient receives adequate ventilation. For example, if the patient's spontaneous effort decreases with time, the machine's support also proportionately decreases which can have serious consequences for the patient. The present invention aims at correcting this deficiency by automatically adjusting the level of support provided by the ventilator. In the system of the present invention, the patient's required ventilation is calculated by the machine and compared with the measured ventilation. The support level is adjusted as follows so that the patient receives adequate ventilation. If required minute ventilation, RMV, is calculated, it can be expressed using equation 14 as follows:

$$RMV = f_{mean} V_{mean}\left[\frac{1}{1-\alpha_1}\right] \tag{15}$$

Where V_{mean} is the average volume inhaled by the patient using the patient's own effort, f_{mean} is the average rate of breathing, and α_1 is the elastic pressure support level (which can be equal to the resistive pressure support level) required to provide the patient with his/her required minute ventilation, RMV.

The average measured minute ventilation, AMMV, can be expressed using equation 14 as:

$$AMMV = f_{mean} V_{mean}\left[\frac{1}{1-\alpha}\right] \tag{16}$$

Where α is the set support level. Dividing equation 16 by equation 15 yields:

$$\frac{AMMV}{RMV} = \frac{1-\alpha_1}{1-\alpha} \tag{17}$$

Equation 17 can be rearranged as:

$$\alpha_1 = 1 + \frac{AMMV}{RMV}(\alpha - 1) \tag{18}$$

Therefore, α_1, which is the required support level necessary to deliver the required ventilation can be calculated from equation 18 and automatically adjusted. If more push is desired such as in the weaning phase, RMV used in equation 18 may be a fraction of the actual required minute ventilation (e.g., 80% of the actual required value). In that case the required support level may be calculated as:

$$\alpha_1 = 1 + \frac{AMMV}{RMV} \cdot \frac{\alpha - 1}{\beta} \tag{19}$$

where β may be a weaning factor (e.g., 0.8). It should be noted that the required and average ventilation values used in equations 18 and 19 above do not have to be over one minute and can be taken over alternative desired periods of time such as over the interval of several breaths.

This system can also watch for the patient's work of breathing and increase the support level if the work of breathing increases significantly to prevent fatigue and dyspnea. Furthermore, the system of the present invention may provide optimal ventilation at a rate which may be the optimal rate of breathing to minimize the work rate of breathing to passive patients (i.e. patients who do not have spontaneous breathing activity).

Therefore, by using the technique of the present invention, it can be guaranteed that the patient receives a minimum required ventilation regardless of the strength of the patient's spontaneous breathing activity. The ventilator automatically adjusts its support level (α or α_1) to provide sufficient ventilation to the patient. The ventilator can also watch the patient's work of breathing and adjust the support level if the work of breathing increases in order to prevent fatigue and dyspnea.

The following example shows how a new support level can be calculated for a spontaneously breathing patient by using a preferred method of this invention.

EXAMPLE

During ventilatory treatment, the average measured minute ventilation, AMMV, is calculated to be 5 lit/min, the required minute ventilation, RMV, is calculated to be 7 lit/min, and the support level, α, is 0.5. Using equation 18, the new support level is calculated as:

$$\alpha_1=1+(AMMV/RMV)(\alpha-1)=1+(5/7)(0.5-1)=0.64$$

If more push is required in the weaning phase, and the weaning factor β is 0.8, then the new support level is calculated by using equation 19 as:

$$\alpha_1=1+(AMMV/RMV)(\alpha-1)(1/\beta)=1+(5/7)(0.5-1)(1/0.8)=0.55$$

Therefore, the new support level can be adjusted accordingly.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, wherein like numerals represent like elements, there is illustrated in FIG. **1** a schematic representation of an apparatus **10** for carrying out a method of the present invention.

A Computing and Control Unit **20** receives input data **22** from an A/D converter **24**. The input **26** to the A/D converter **24** may be provided by a CO_2 analyzer **28**, which measures the CO_2 level of a user or patient **30**. The CO_2 analyzer may be an end-tidal CO_2 analyzer that measures the concentration or the partial pressure of CO_2 in the exhaled gas of the patient. Alternatively, the CO_2 analyzer may be a transcutaneous CO_2 analyzer or an arterial analyzer that measure the blood CO_2 content of the patient. The CO_2 analyzer **28** and the A/D converter **24** are used in some embodiments of the invention and do not need to be used in some other embodiments as will be described later.

A Volume, Flow rate, Pressure Monitor and Respiratory Mechanics Calculator **34** may measure the volume of inhaled and exhaled gases of the patient, the flow rate of gas to and from the patient, and the airway pressure, and may calculate the patient's respiratory elastance (i.e. reciprocal of respiratory compliance) and airway resistance. Such monitors are well known to those skilled in the art such as monitors that have been used for many years in critical care ventilators or the apparatus that has been described in U.S. Pat. No. 5,884,622. An A/D converter unit **32** may receive data indicative of the measured volume, flow rate, pressure, and respiratory mechanics data on **38** from the monitor and calculator unit **34** and may provide the digitized version of that multiple data **40** to the Computing and Control Unit **20** which may comprise a digital processor or a microcomputer. The Computing and Control Unit **20** may process the input data and generate control signals **42** that may be input to a D/A converter unit **44** before being applied to the ventilator.

FIG. **2** shows a preferred sequence of steps in one embodiment of the invention that may be executed by a programmable computing system. In this method, the ventilator's support level is automatically controlled to prepare the patient for weaning and prevent fatigue and dyspnea when the patient's work of breathing is significantly higher than normal.

The procedure starts at step **100** and at the next step at **102**, the program reads the initial support level(s). A typical initial value may be 0.5. At the next step at A at **104** that follows, the values of patient's respiratory elastance K (which is the reciprocal of respiratory compliance, C), and respiratory airway resistance K' are read. These values may be measured during the breath, for every breath, or intermittently for every several breaths by the monitor and calculator unit **34** in FIG. **1**. It may be possible to enter this data and update it over longer periods of time if the patient's respiratory mechanics do not change significantly with time and the support level's maximum value is not close to 1. However, to assure stable operation of the system this data may be provided over short intervals such as during the breath, for every breath, or for every several breaths.

At step **106** that follows, it is checked whether the patient is active, meaning if the patient is breathing spontaneously and triggering the breaths. If the patient is passive (i.e. does not have spontaneous breathing activity), the next step at **108** is performed in which the patient's required ventilation and respiratory rate are determined. The following procedures and equations or their equivalents may be used for these determinations. The required alveolar ventilation may be calculated as:

$$VALV(rest)=0.061\times Weight \tag{20}$$

Where VALV(rest) represents alveolar ventilation in liters per minute at rest and Weight is the ideal body weight of the patient in Kg. The 0.061 factor in this equation may be adjusted based on the patient's basal metabolic rate. Also, VALV(rest) or Weight may be represented in terms of other factors such as patient's height, or basal metabolic rate, or VALV(rest) may be provided by the clinician. In all such or similar cases, the alternative representative factors will be data indicative of Weight and will work the same way.

The CO_2 level of the patient may be monitored and used to adjust the level of ventilation. If it is provided, the net effect of CO_2 on alveolar ventilation, VAC, may be calculated as:

$$VAC=K_3[K_5(P_{CO2}-K_4-39.2)+39.2]-K_6 \tag{21}$$

In equation 21, P_{CO2} is the CO_2 level of the patient which may be the end-tidal CO_2 pressure measured by a gas analyzer, or the CO_2 pressure measured by a transcutaneous or an intra-arterial sensor. K_5 is a smoothing factor used to prevent abrupt changes in ventilation and K_4 is a factor that can be used to set the desired level of P_{CO2} and may be calculated as:

$$K_4=P_{CO2}(\text{acceptable})-39.2 \tag{22}$$

For example, if the acceptable level of P_{CO2} (P_{CO2}(acceptable)) is 39.2 mmHg, then K_4 from equation 22 will be zero. However, if permissive hypercapnia is used to treat the patient and P_{CO2}(acceptable) is for example 48 mmHg, then K_4 from equation 22 will be:

$$K_4=48-39.2=8.8 \text{ mmHg}$$

Typical values of other coefficients used in equation 21 may be $K_3=0.405$, $K_5=0.5/6$, and $K_6=14.88$.

Then alveolar ventilation may be calculated to include the effect of P_{CO2} as:

$$VALV=VALV(rest)\times VAC \tag{23}$$

It should be noted that if P_{CO2} is very low, VAC from equation 21 can not be negative or zero and should have a minimum acceptable value (e.g., 0.5). Also, if P_{CO2} is not provided, alveolar ventilation, VALV, will be equal to VALV (rest) from equation 20, or it may be provided by the clinician.

After calculation of VALV, the physiological dead space can be estimated by using an empirical equation if it is not provided by measurement. An example empirical equation to calculate the dead space is the following:

$$VD=0.1698(VALV/60)+0.1587 \tag{24}$$

Where VD is physiological dead space in liters. Alternatively, VD may be found by using Weight (e.g., VD=0.0026×Weight). Then the total dead space volume may be calculated as:

$$VDt=VD+VDE \tag{25}$$

Where VDt is total dead space and VDE is the additional dead space due to tubes and connections to the ventilator.

Then the following equation may be used to calculate the optimum frequency of breathing to minimize the respiratory work rate as:

$$f = 60 \times \left[\frac{-K \times VD + \sqrt{(K \times VD)^2 + 4 \times K \times K' \times \Pi^2 \times \frac{(VALV)}{60} \times VD}}{2 \times K' \times \Pi^2 \times VD} \right] \tag{26}$$

Where K is respiratory elastance in cmH_2O/liter, K' is respiratory airway resistance in cmH_2O/lit/sec, and f is the optimal breathing rate in breaths/min. Equation 26 may be used to determine the optimal breathing rate of a passive patient. This is done in order to mimic the natural breathing rate of the patient and thereby improve synchrony between the ventilator and the patient and stimulate spontaneous breathing. Equation 26 was used in U.S. Pat. No. 4,986,268 to automatically control the breathing rate of a patient on mechanical ventilation. The unmodified version of this equation was derived in physiology in 1950, in Otis et al., "Mechanics of breathing in Man," Journal of Applied Physiology, vol. 2, pages 592-607, 1950.

The breathing frequency calculated from equation 26 needs to be checked to fall in a safe range. For example, its minimum value can be set at a low frequency such as 6 breaths/min, and its maximum level may be limited to K/5K' to prevent build up of intrinsic positive end-expiratory pressure.

The patient minute ventilation, MV, may then be calculated as:

$$MV=VALV+f\times VDt \tag{27}$$

Then the required tidal volume Vt can be found as:

$$Vt=MV/f \tag{28}$$

Then Vt may be checked to lie within a safe range. For example, the minimum Vt may be defined as (2VD+VDE), and maximum Vt may be the maximum allowed volume set by the clinician. Next, the required peak inspiratory pressure to deliver the calculated Vt may be found as:

$$P_{insp}=K\times Vt+PEEP \tag{29}$$

Where P_{insp} is the required peak inspiratory pressure, and PEEP is the positive end-expiratory pressure. The value of P_{insp} also needs to be checked to fall in a safe range. For example, its minimum level may be set to be 5 cmH_2O above PEEP, and its maximum level may be 8-10 cmH_2O less than the maximum pressure set on the ventilator or may be directly specified by the clinician.

At the next step **110**, the control signals to adjust the pressure support and breathing rate are sent to the ventilator. At the step that follows next at **112**, the algorithm will wait for the interval of one or more breaths before it goes back to A.

Back to step **106**, if the patient is breathing spontaneously, the program transfers to step **114** at which the delivered work of breathing is determined, which is airway pressure integrated over inspiratory volume. The work of breathing can be found based on the patient's measured values of tidal volume, respiratory elastance, airway resistance, inspiratory flow, and the dimensions of the tubes. This determined work of breathing that may be expressed as the amount of work necessary to deliver one liter of gas to the patient, is compared to a high threshold value set by the clinician (e.g., 1.1 joules/lit). At the next step at **116**, if the patient's work of breathing is lower than or equal to the threshold value, step **118** is followed at which a message is generated that patient's work of breathing is acceptable, and at the next step at **120**, control signals are sent to the ventilator according to the previous or set support level(s). Then at step **122** at B, the program waits for a predefined period (e.g., 5 minutes) before it goes back to A. It should be noted that if during this period apnea is detected, the program does not wait and automatically transfers to step **108**.

Back to step **116**, if the patient's work of breathing is higher than the threshold value, the program transfers to step **124**. At this point, if this is the 1^{st} loop, or if the patient's work of breathing has increased by a defined margin (e.g., at least 10%) compared to the previous time, the support level is increased at step **126**. This increase may be defined as proportional to the difference between the high threshold level of work of breathing and the patient's work of breathing in the 1^{st} loop, or if not in the 1^{st} loop, the increase in the support level may be proportional to the increase in the work of breathing compared to previous time. However, the maximum support level has to be kept less than 1 (e.g., 0.8) for the system to be stable. Afterwards, program transfers to step **122** at B which was described above.

Back to step **124**, if it is not the 1^{st} loop, and the patient's work of breathing has not increased by a defined margin compared to previous time, then step **128** is performed. At this point, it is checked whether the patient's work of breathing has decreased by a defined margin (e.g., at least 10%) compared to previous time. If it has, then at step **130** that follows, the support level is decreased and this reduction may be proportional to the difference between the patient's work of breathing compared to its previous value. Then control transfers to step **122** at B. Back to step **128**, if it is found that patient's work of breathing has not decreased by a defined margin compared to previous time, the next step at **132** is performed in which it is determined that no change in the support level(s) is needed, control signals are sent to the ventilator accordingly and program transfers to B at step **122**.

The procedure described in the flow chart of FIG. **2** is performed in one preferred embodiment of the invention in order to adjust the ventilator support level according to the patient's work of breathing. In this procedure, the patient is provided with higher support up to the allowed maximum limit if the patient's work of breathing increases significantly. This is done to prevent the patient from developing fatigue during spontaneous breathing. The system also provides full mandatory control of ventilation providing optimal ventilation at an optimal rate to the patient if the patient is passive or develops apnea as was described above.

FIG. **3** shows a preferred sequence of steps of the algorithm of a preferred method of the invention. As seen in this Figure, after the start of the program at **200**, the program reads the initial setting of the support level(s) at step **202**. A typical initial setting may be 0.5. At the next step at A**1** which is at step **204**, the patient's respiratory elastance and airway resistance values are read. The provision of these values can be done in the same ways that were described in step **104** in FIG. **2** before.

In the next step at **206**, it is checked whether the patient is breathing spontaneously. If the patient is not breathing spontaneously, the algorithm transfers to steps **208**, **210**, and **212** in sequence in which the same procedures and calculations are performed that were carried out in steps **108**, **110**, and **112** of FIG. **2** respectively, the patient's level and rate of ventilation are computed and controlled by the ventilator as was described before, and then the program returns to A**1** at step **204**. However, if at step **206** it is found that the patient is breathing spontaneously, at the next step that in this case is step **214**, the required minute ventilation, RMV (which is the same as MV), is calculated by using equations 20, 21, 22, 23, 24, 25, and 27 as these equations were described above. For these calculations, f in equation 27, is the measured patient's breathing rate. Also, equations 21, 22, and 23 are only used if patient's PCO_2 is measured and provided to the system. Otherwise, equations 21, 22, and 23 are not used and VALV will be the same as VALV(rest) from equation 20, or it may be provided by the clinician. It should be noted that the equations used in these steps can be replaced by their equivalents in which case the function of the procedure will not be different from the function described here and therefore, will be the same invention.

After the calculations of step **214**, the measured ventilation of the patient is read at step **216**. Then at step **218** that follows next, it is checked whether sufficient time has elapsed (e.g., 5 minutes) since the last adjustment in the support level(s). If sufficient time has not passed, then at the next step **220** at A**2**, the program continues by calculating the average measured minute ventilation (AMMV) value. This calculation is done over a short defined period (e.g., 3 minutes), and if the patient is partly breathing spontaneously, the average value (AMMV) may be calculated over the last period of spontaneous breathing (e.g., over a certain number of consecutive spontaneous breaths). Then at the next step at **222** it is determined that no adjustment in the support level(s) is needed, and at step **224**, control signals are sent to the ventilator and the algorithm transfers to A**1** at the end of the breath.

Back to step **218**, if sufficient time has elapsed since the last adjustment in the support level, program transfers to step **226** in which the required minute ventilation of the patient (RMV which is the same as MV) calculated at step **214** is compared to the average measured minute ventilation, AMMV. At the next step at **228**, if AMMV is within a defined range (e.g., 10%) of RMV calculated at step **214**, then program transfers to A**2** which was described above.

However, if at step **228**, AMMV is not within the defined range of RMV, then in the next step **230** that follows, new support level(s) is computed by using equation 18, or if additional push for weaning is required, by using equation 19 that were described earlier. Afterwards, control signals are sent to the ventilator at step **232**, and the algorithm transfers to A**1** at the end of the breath.

The flow chart shown in FIG. **3** illustrates a preferred procedure carried out in an embodiment of the invention to automatically adjust the ventilator's support level. By using this system it is guaranteed that a minimum ventilation is provided to the patient regardless of the strength of the patient's spontaneous breathing activity. Whenever adjusted, the support level is compared to a defined safe range and limited if necessary to remain within that range in the system of the invention.

Exemplary embodiments of the invention have been disclosed in an illustrative style. The present invention may be embodied in other specific forms without departing from the scope and attributes of the invention as will be understood to those well versed in the art. Accordingly, what is intended to be circumscribed within the scope of the patent warranted hereon are all such embodiments that reasonably fall within the scope of the advancement to the art hereby contributed, and that scope shall not be restricted, except in light of the appended claims and their equivalents.

What is claimed is:

1. A method for automatically controlling a ventilator, comprising:

executing instructions stored in a non-transitory computer readable medium which, when executed by a programmable controller, cause the programmable controller to perform steps comprising:

(a) Measuring ongoing volume and flow rate of gas to a patient on the ventilator during patient inspiration;

(b) providing respiratory elastance, K, and airway resistance, K', of the patient;

(c) generating control signals for controlling pressure applied by the ventilator as a sum of elastic and resistive components of pressure, with the elastic component of pressure having a proportionality factor, K_1, proportional to the determined volume of the inspiratory gas of the spontaneously breathing patient, and the resistive component of pressure having a proportionality factor, K_2, proportional to the determined flow rate of the inspiratory gas of the spontaneously breathing patient; and

(d) automatically adjusting a support level for the elastic component of pressure, $\alpha=K_1/K$, a support level for the resistive component of pressure, $\alpha'=K_2/K'$, and the proportionality factors K_1 and K_2, based on a comparison between a work of breathing for the patient determined by the programmable controller and a previously determined work of breathing.

2. The method of claim **1** wherein the previously determined work of breathing is a specified constant level, and adjustments in the support levels, α and α', and proportionality factors, K_1 and K_2, are proportional to a difference between the specified constant level and the patient's determined work of breathing.

3. The method of claim **1** wherein the previously determined work of breathing is a work of breathing previously determined for the patient by the programmable controller, and adjustments in the support levels, α and α', and proportionality factors, K_1 and K_2, are proportional to a difference between the patient's previously determined work of breathing and an updated determined work of breathing.

4. The method of claim **1** further comprising determining, at a subsequent time, whether the patient is breathing spontaneously, and if the patient is not breathing spontaneously, then skipping steps (c) and (d), determining a required ventilation for the patient, and based on the patient's required ventilation and the patient's respiratory elastance and airway resistance, determining an optimal breathing rate for the patient, and providing mandatory ventilation to the patient according to the determined required ventilation and optimal breathing rate.

5. The method of claim **4** wherein the patient's required ventilation is determined based on a data indicative of an ideal body weight of the patient.

6. The method of claim 4 wherein the patient's required ventilation is determined based on a measured carbon dioxide level of the patient.

7. The method of claim 4 wherein the patient's optimal breathing rate is determined to minimize respiratory work rate.

8. The method of claim 7 wherein the following equation is used to calculate the optimal breathing rate:

$$f = 60 \times \left[\frac{-K \times VD + \sqrt{(K \times VD)^2 + 4 \times K \times K' \times \Pi^2 \times \frac{(VALV)}{60} \times VD}}{2 \times K' \times \Pi^2 \times VD} \right]$$

where VALV is a required alveolar ventilation for the patient per minute, VD is respiratory dead space found as $VD=C_1\times VALV+C_2$, where C_1 and C_2 are constants, and f is the optimal rate of breathing per minute.

9. An apparatus for automatically controlling a ventilator, comprising:

a computing system;

non-transitory digital readable memory coupled to the computing system;

one or more transducers for measuring ongoing volume and flow rate of a gas and providing, during inspiration of the patient, data to the computing system representing a patient's respiratory elastance and airway resistance values and ongoing volume and flow rate of the gas to the patient during inspiration; and

a program stored in the memory, the program when executed by the computing system determining a support level for elastic component of pressure $\alpha=K_1/K$, a support level for resistive component of pressure, $\alpha'=K_2/K'$, where K_1 represents the proportionality factor for the elastic component of pressure applied by the ventilator in proportion to the volume of the inspiratory gas of the spontaneously breathing patient and K_2 represents the proportionality factor for the resistive component of pressure applied by the ventilator in proportion to flow rate of the inspiratory gas of the spontaneously breathing patient and K and K' represent respiratory elastance and airway resistance of the patient respectively, based on a comparison between a work of breathing for the patient determined by the program and a previously determined level of work of breathing, and the program also determining a level of ongoing pressure support to the patient as a sum of the elastic and resistive pressures based on the determined support levels for elastic and resistive components of pressure and the data provided by the transducers, and the computing system generating control signals for the ventilator to achieve the determined support levels for elastic and resistive pressures and the level of ongoing pressure support.

10. The apparatus of claim 9 wherein the previously determined level of work of breathing is a specified constant level and the program stored in the memory determines the support levels and the level of ongoing pressure support to the patient based on a difference between the specified constant level and the patient's determined work of breathing.

11. The apparatus of claim 9 wherein the previously determined level of work of breathing is a work of breathing previously determined for the patient by the program, and the program determines the support levels and the level of ongoing pressure support to the patient based on a difference between the patient's updated work of breathing and the patient's previous work of breathing determined by the program.

12. The apparatus of claim 9 further comprising one or more A/D converters connected between the transducers and the computing system for converting analog signals from the transducers into digital form.

13. The apparatus of claim 9 further comprising one or more D/A converters for converting digital signals from the computing system to analog signals and supplying the analog signals to the ventilator as the control signals.

14. The apparatus of claim 9 wherein if the patient does not breathe spontaneously, the program stored in the memory does not determine the support levels and instead determines a required ventilation for the patient and an optimal respiration rate for the patient wherein the patient's optimal respiration rate is determined according to the following equation:

$$f = 60 \times \left[\frac{-K \times VD + \sqrt{(K \times VD)^2 + 4 \times K \times K' \times \Pi^2 \times \frac{(VALV)}{60} \times VD}}{2 \times K' \times \Pi^2 \times VD} \right]$$

where K is respiratory elastance, K' is airway resistance, VALV is a required alveolar ventilation for the patient per minute input to the program or found from data indicative of an ideal body weight for the patient, VD is respiratory dead space found as $VD=C_1\times VALV+C_2$, where C_1 and C_2 are constants, f is the optimal rate of breathing per minute, and the computing system generates output data indicative of the required ventilation and the optimal respiration rate.

15. The apparatus of claim 14 wherein the patient's required ventilation is determined by the program stored in the memory also on the basis of a measured level of carbon dioxide of the patient provided to the computing system by a carbon dioxide analyzer.

16. The apparatus of claim 15 wherein the carbon dioxide analyzer is selected from the group comprising an end-tidal gas analyzer, an arterial gas analyzer, and a transcutaneous CO_2 analyzer.

* * * * *

专利名称(译)	主动或被动对象机械通气自动控制系统		
公开(公告)号	[US9604021](US9604021)	公开(公告)日	2017-03-28
申请号	US14/193864	申请日	2014-02-28
[标]申请(专利权)人(译)	德黑兰尼FLEUR塔希尔		
申请(专利权)人(译)	德黑兰尼，芙蓉塔希尔		
当前申请(专利权)人(译)	德黑兰尼，芙蓉塔希尔		
[标]发明人	TEHRANI FLEUR TAHER		
发明人	TEHRANI, FLEUR TAHER		
IPC分类号	A61M16/00 A61B5/08 A61B5/00 A61B5/091 A61B5/087 A61B5/083 A61B5/085		
CPC分类号	A61M16/0069 A61B5/085 A61B5/087 A61B5/0816 A61B5/0836 A61B5/091 A61B5/4836 A61M16/0003 A61M16/0051 A61M2016/0027 A61M2016/0033 A61M2016/0036 A61M2230/202 A61M2230/432 A61M2230/46 A61M16/024		
其他公开文献	US20140318541A1		
外部链接	Espacenet USPTO		

摘要(译)

一种用于控制呼吸机以自动调节对主动或被动对象的通气辅助的方法和设备。该方法包括在持续吸气期间确定患者的气体体积和流速，并产生与患者气体的体积和流速成比例的控制信号，其中比例因子和弹性和电阻组件的支持水平。压力由呼吸机自动调节。呼吸机施加的持续压力是由系统自动控制的弹性压力和阻力压力之和。当患者自发呼吸时，根据患者的要求自动调节支撑水平。如果患者不自发呼吸，则呼吸机以最佳水平和速率提供通气。该方法可用于断奶或通气的管理阶段。