

(43) International Publication Date
31 January 2013 (31.01.2013)(51) International Patent Classification:
A61M 16/00 (2006.01)(21) International Application Number:
PCT/US2012/048465(22) International Filing Date:
27 July 2012 (27.07.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
13/191,709 27 July 2011 (27.07.2011) US(71) Applicant (for all designated States except US):
NELLCOR PURITAN BENNETT LLC [US/US]; 6135
Gunbarrel Avenue, ATTN IP Legal, Boulder, Colorado
80301 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **JAFARI, Mehdi**
[US/US]; 25982 Anacapa St., Laguna Hills, California
92653 (US). **DOYLE, Peter** [US/US]; 1948 Casablanca
Ct., Vista, California 92081 (US). **JIMENEZ, Rhomere**
[US/US]; 145 Avenida Altamira, Chula Vista, California
91914 (US). **AVIANO, Jeffrey** [US/US]; 1946 RockSprings Rd., Escondido, California 92026 (US). **MCCOY, Edward** [US/US]; 1118 Countrywood Lane, Vista, California 92081 (US). **UPHAM, Gayle** [US/US]; 1625 Winterwarm Rd., Fallbrook, California 92028 (US).(74) Agent: **ANDERSON, Matthew**; Nellcor Puritan Bennett
LLC, 6135 Gunbarrel Avenue, ATTN IP Legal, Boulder,
Colorado 80301 (US).(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM,
ZW.(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,

[Continued on next page]

(54) Title: METHODS AND SYSTEMS FOR MODEL-BASED TRANSFORMED PROPORTIONAL ASSIST VENTILATION

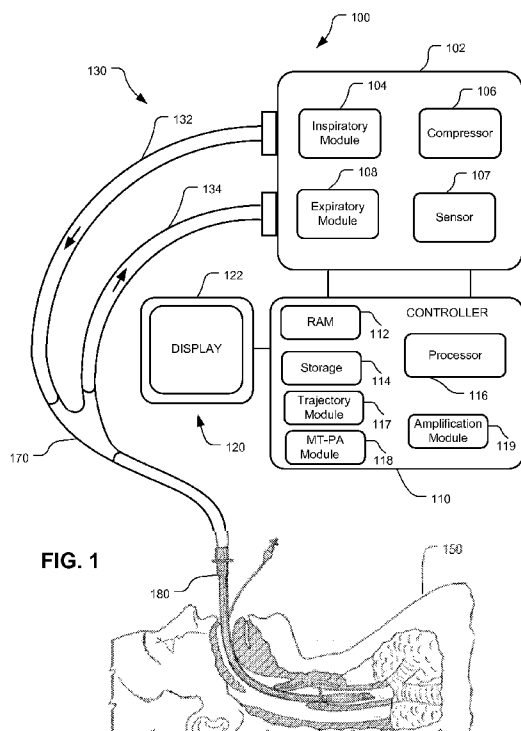


FIG. 1

(57) Abstract: This disclosure describes systems and methods for providing a model-based transformed proportional assist breath type during ventilation of a patient. The disclosure describes a novel breath type that delivers a target pressure calculated based on a predetermined trajectory and a support setting to a triggering patient.



TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, **Published:**

EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,

LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,

GW, ML, MR, NE, SN, TD, TG).

— *with international search report (Art. 21(3))*

Methods and Systems for Model-Based Transformed Proportional Assist Ventilation

Introduction

5 Medical ventilator systems have long been used to provide ventilatory and supplemental oxygen support to patients. These ventilators typically comprise a source of pressurized oxygen which is fluidly connected to the patient through a conduit or tubing. As each patient may require a different ventilation strategy, modern ventilators can be customized for the particular needs of an individual patient. For example, several
10 different ventilator modes have been created to provide better ventilation for patients in various different scenarios.

Model-Based Transformed Proportional Assist Ventilation

This disclosure describes systems and methods for providing a model-based
15 transformed proportional assist breath type during ventilation of a patient. The disclosure describes a novel breath type that delivers a target pressure calculated based on a predetermined trajectory (representing a physiologic-based functional morphology) and a support setting to a triggering patient.

In part, this disclosure describes a method for ventilating a patient with a
20 ventilator. The method includes:

- a) monitoring at least one patient parameter;
- b) detecting an inspiratory trigger based on the at least one monitored patient parameter;
- c) receiving a predetermined pressure trajectory;
- 25 d) calculating a target pressure based at least on the predetermined pressure trajectory and a support setting; and
- e) delivering the target pressure to a patient based on the detected inspiratory trigger.

Yet another aspect of this disclosure describes a ventilator system that includes:
30 a pressure generating system adapted to generate a flow of breathing gas; a ventilation tubing system including a patient interface for connecting the pressure generating system to a patient; one or more sensors operatively coupled to at least one of the pressure generating system, the patient, and the ventilation tubing system, a trajectory module

determines a pressure trajectory; a MT-PA module, and a processor in communication with the pressure generating system, the one or more sensors, the trajectory module, and the MT-PA module. At least one sensor of the one or more sensors is capable of generating an output indicative of an inspiration flow. The MT-PA module calculates at least one target pressure based at least on the pressure trajectory and a support setting. Further, the MT-PA module utilizes the output indicative of the inspiration flow to determine a patient trigger for delivery of a breath to the patient.

The disclosure further describes a computer-readable medium having computer-executable instructions for performing a method for ventilating a patient with a

ventilator. The method includes:

- a) repeatedly monitoring at least one patient parameter;
- b) repeatedly detecting an inspiratory trigger based on the at least one monitored patient parameter;
- c) repeatedly receiving a predetermined pressure trajectory;
- d) repeatedly calculating a target pressure based at least on the predetermined pressure trajectory and a support setting; and
- e) repeatedly delivering the target pressure to a patient based on the detected inspiratory trigger.

The disclosure also describes a ventilator system including means for monitoring at least one patient parameter; means for detecting an inspiratory trigger based on the at least one monitored patient parameter; means for receiving a predetermined pressure trajectory; means for calculating a target pressure based at least on the predetermined pressure trajectory and a support setting; and means for delivering the target pressure to a patient based on the detected inspiratory trigger.

These and various other features as well as advantages which characterize the systems and methods described herein will be apparent from a reading of the following detailed description and a review of the associated drawings. Additional features are set forth in the description which follows, and in part will be apparent from the description, or may be learned by practice of the technology. The benefits and features of the technology will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.

Brief Description of the Drawings

The following drawing figures, which form a part of this application, are illustrative of embodiments of systems and methods described below and are not meant to limit the scope of the invention in any manner, which scope shall be based on the claims appended hereto.

FIG. 1 illustrates an embodiment of a ventilator.

FIG. 2 illustrates an embodiment of a method for ventilating a patient on a ventilator.

Detailed Description

15 Although the techniques introduced above and discussed in detail below may be implemented for a variety of medical devices, the present disclosure will discuss the implementation of these techniques in the context of a medical ventilator for use in providing ventilation support to a human patient. A person of skill in the art will understand that the technology described in the context of a medical ventilator for human
20 patients could be adapted for use with other systems such as ventilators for non-human patients and general gas transport systems.

Medical ventilators are used to provide a breathing gas to a patient who may otherwise be unable to breathe sufficiently. In modern medical facilities, pressurized air and oxygen sources are often available from wall outlets. Accordingly, ventilators may provide pressure regulating valves (or regulators) connected to centralized sources of pressurized air and pressurized oxygen. The regulating valves function to regulate flow so that respiratory gas having a desired concentration of oxygen is supplied to the patient at desired pressures and rates. Ventilators capable of operating independently of external sources of pressurized air are also available.

30 While operating a ventilator, it is desirable to control the percentage of oxygen in the gas supplied by the ventilator to the patient. Further, as each patient may require a different ventilation strategy, modern ventilators can be customized for the particular

needs of an individual patient. For example, several different ventilator breath types have been created to provide better ventilation for patients in various different scenarios.

Effort-based breath types, such as proportional assist (PA) ventilation, determine a dynamic profile of ventilatory support derived from continuous estimation of patient effort and respiratory characteristics. This desired dynamic profile is computed in real-
5 or quasi-real-time and used by the ventilator as a set of points for control of applicable parameters.

Initiation and execution of an effort-based breath, such as PA, has two operation prerequisites: (1) detection of an inspiratory trigger; and (2) detection and measurement
10 of an appreciable amount of patient respiratory effort to constitute a sufficient reference above a ventilator's control signal error deadband. Advanced, sophisticated triggering technologies detect initiation of inspiratory efforts more efficiently. In ventilation design, patient effort may be represented by the estimated inspiratory muscle pressure and is calculated based on measured patient inspiration flow. Patient effort is utilized to
15 calculate a target pressure for the inspiration.

A PA breath type refers to a type of ventilation in which the ventilator acts as an inspiratory amplifier that provides pressure support based on the patient's effort. The degree of amplification (the "support setting") is set by an operator, for example as a percentage based on the patient's effort. In one implementation of a PA breath type, the
20 ventilator may continuously monitor the patient's instantaneous inspiratory flow and instantaneous net lung volume, which are indicators of the patient's inspiratory effort. These signals, together with ongoing estimates of the patient's lung compliance and lung/airway resistance and the Equation of Motion, allow the ventilator to estimate a patient effort and derive therefrom a target pressure to provide the support that assists the
25 patient's inspiratory muscles to the degree selected by the operator as the support setting. The support setting input by the operator divides the total work of breathing calculated between the patient and the ventilator as shown in the equations below:

$$1) P_p(t) = (1.0 - k) * (\text{total support}); \text{ and}$$

$$2) P_v(t) = k * (\text{total support}).$$

30 P_p is the amount of pressure that must be provided by the patient at a time t , P_v is the amount of pressure provided by the ventilator at the time t , total support is the sum of contributions by the patient and ventilator, and k is the support setting (percentage of total support to be contributed by the ventilator) input by the operator. To solve for the

amount of pressure provided by the ventilator (P_V or target airway pressure), simply divide the second equation by the first equation listed above to get the following equation:

$$P_V(t) = P_P(t) * (k/(1.0 - k))$$

5 While an effort-based breath type is very beneficial to the patient, the computational cycle of the target pressure may be behind the actual demand of the patient. For example, the target pressure may be behind the actual demand by 5 to 50 milliseconds or more due at least to signal and/or calculation delays. Further, in aggressively breathing patients this time gap may be even larger.

10 Additionally, in one example, inspiratory muscle pressure, P_{mus} , (i.e., one example of how patient effort may be calculated) is a time-variant excitation function with inter- and intra-subject variations. It is hypothesized that in normal subjects P_{mus} is dependent on breath rate, inspiration time, and characteristic metrics of inspiratory pressure waveform. However, in actual patients, other factors related to demanded and
15 expendable muscle energy may critically influence muscle pressure generation, which are not accounted for in effort-based breath types. For example, for a given peak inspiratory pressure, the maximum sustainable muscle pressure may be affected by factors impairing muscle blood flow (blood pressure, vasomotor tone, muscle tension in the off-phase), blood substrate concentration (glucose, free fatty acids), and the ability to
20 extract source of energy from the blood. Thus, respiratory motor output may vary significantly in response to variations in metabolic rate, chemical stimuli, temperature, mechanical load, sleep state, and behavioral inputs. Moreover, the breath-by-breath variability in respiratory output could lead to tidal volumes varying by a factor of four or more. Accordingly, the patient may desire more or less pressure and/or breath than
25 being delivered by the ventilator in an effort-based breath type.

Further, the delivered target pressure in the effort-based breath type has no set trajectory and is determined arbitrarily based on patient effort. For example, the trajectory can be determined every command cycle using estimated patient respiratory parameters, instantaneous inspiratory lung flow, patient-generated muscle pressure, and a
30 clinician-set support setting. Therefore, inspiration and/or expiration may abruptly end or start based on these settings or parametric uncertainties and measurement and computational issues may cause morphological artifacts in the reference waveform trajectory. Patients, whether breathing aggressively, shallowly, or softly, typically

exhibit a smooth trajectory from inspiration to expiration making any abrupt changes in the trajectory uncomfortable for the patient.

Further, while earlier trigger detection reduces trigger delays, the corresponding inspiration flow at this earlier moment of triggering may be initially too weak causing
5 the algebraic magnitude of estimated lung flow to still be negative resulting in no delivery of a patient desired breath and/or the premature ending of a patient desired breath. Therefore, a weak triggering patient may not receive a breath and/or the amount of breath desired.

Accordingly, the current disclosure describes a model-based transformed
10 proportional assist (MT-PA) breath type for ventilating a patient. The MT-PA breath type delivers a target pressure to the patient calculated based on a predetermined pressure trajectory model representing a well-defined waveform morphology and a support setting for a triggering patient. The predetermined trajectory prevents the patient from experiencing any abrupt inspiration and exhalation changes.

15 Further, the trajectory model may be based on clinically observed breath trajectories. For example, the trajectory may be based on clinically observed trajectories for specific breathing rates and/or types, such as aggressive, weak, or shallow breathing patients. In some embodiments, the trajectory may be based on clinically observed trajectories for patients with common diseases, such as chronic obstructive pulmonary
20 disease (COPD), emphysema, or acute respiratory distress syndrome (ARDS). By utilizing a predetermined trajectory based on the patient and assigning or adaptively deriving appropriate quantitative values for the parameters of the model, the predetermined trajectory should already anticipate patient breath desires or be predictive of patient inspiratory muscle pressure. Accordingly, the predetermined trajectory should
25 minimize or eliminate any gaps between actual patient demand and the calculated target pressure delivered and converge towards meeting patient demands.

In some embodiments, a multiplier may be applied to the at least one monitored parameter when the monitored parameter is below a predetermined threshold for triggering the delivery of a breath, such as a low or negative lung flow with positive
30 (increasing) slope. The multiplier allows weak patients to receive desired breaths with pressure support. The predetermined trajectory in combination with the multiplier allows the ventilator to anticipate and deliver the type of breath desired by weak triggering patients.

FIG. 1 is a diagram illustrating an embodiment of an exemplary ventilator **100** connected to a human patient **150**. Ventilator **100** includes a pneumatic system **102** (also referred to as a pressure generating system **102**) for circulating breathing gases to and from patient **150** via the ventilation tubing system **130**, which couples the patient **150** to the pneumatic system **102** via an invasive (e.g., endotracheal tube, as shown) or a non-invasive (e.g., nasal mask) patient interface **180**.

Ventilation tubing system **130** (or patient circuit **130**) may be a two-limb (shown) or a one-limb circuit for carrying gases to and from the patient **150**. In a two-limb embodiment, a fitting, typically referred to as a “wye-fitting” **170**, may be provided to couple a patient interface **180** (as shown, an endotracheal tube) to an inspiratory limb **132** and an expiratory limb **134** of the ventilation tubing system **130**.

Pneumatic system **102** may be configured in a variety of ways. In the present example, pneumatic system **102** includes an expiratory module **108** coupled with the expiratory limb **134** and an inspiratory module **104** coupled with the inspiratory limb **132**. Compressor **106** or other source(s) of pressurized gases (e.g., air, oxygen, and/or helium) is coupled with inspiratory module **104** and the expiratory module **108** to provide a gas source for ventilatory support via inspiratory limb **132**.

The inspiratory module **104** is configured to deliver gases to the patient **150** according to prescribed ventilatory settings. In some embodiments, inspiratory module **104** is configured to provide ventilation according to various breath types, e.g., via volume-control, pressure-control, MT-PA, or via any other suitable breath types.

The expiratory module **108** is configured to release gases from the patient’s lungs according to prescribed ventilatory settings. Specifically, expiratory module **108** is associated with and/or controls an expiratory valve for releasing gases from the patient **150**.

The ventilator **100** may also include one or more sensors **107** communicatively coupled to ventilator **100**. The sensors **107** may be located in the pneumatic system **102**, ventilation tubing system **130**, and/or on the patient **150**. The embodiment of FIG. 1 illustrates a sensor **107** in pneumatic system **102**.

Sensors **107** may communicate with various components of ventilator **100**, e.g., pneumatic system **102**, other sensors **107**, processor **116**, trajectory module **117**, MT-PA module **118**, and any other suitable components and/or modules. In one embodiment, sensors **107** generate output and send this output to pneumatic system **102**, other sensors

107, processor 116, trajectory module 117, MT-PA module 118, and any other suitable components and/or modules. Sensors 107 may employ any suitable sensory or derivative technique for monitoring one or more patient parameters or ventilator parameters associated with the ventilation of a patient 150. Sensors 107 may detect
5 changes in patient parameters indicative of patient triggering, for example. Sensors 107 may be placed in any suitable location, e.g., within the ventilatory circuitry or other devices communicatively coupled to the ventilator 100. Further, sensors 107 may be placed in any suitable internal location, such as, within the ventilatory circuitry or within components or modules of ventilator 100. For example, sensors 107 may be coupled to
10 the inspiratory and/or expiratory modules for detecting changes in, for example, circuit pressure and/or flow. In other examples, sensors 107 may be affixed to the ventilatory tubing or may be embedded in the tubing itself. According to some embodiments, sensors 107 may be provided at or near the lungs (or diaphragm) for detecting a pressure in the lungs. Additionally or alternatively, sensors 107 may be affixed or embedded in
15 or near wye-fitting 170 and/or patient interface 180. Indeed, any sensory device useful for monitoring changes in measurable parameters during ventilatory treatment may be employed in accordance with embodiments described herein.

As should be appreciated, with reference to the Equation of Motion, ventilatory parameters are highly interrelated and, according to embodiments, may be either directly
20 or indirectly monitored. That is, parameters may be directly monitored by one or more sensors 107, as described above, or may be indirectly monitored or estimated by derivation according to the Equation of Motion.

The pneumatic system 102 may include a variety of other components, including mixing modules, valves, tubing, accumulators, filters, etc. Controller 110 is operatively
25 coupled with pneumatic system 102, signal measurement and acquisition systems, and an operator interface 120 that may enable an operator to interact with the ventilator 100 (e.g., change ventilator settings, select operational modes, view monitored parameters, etc.).

In one embodiment, the operator interface 120 of the ventilator 100 includes a
30 display 122 communicatively coupled to ventilator 100. Display 122 provides various input screens, for receiving clinician input, and various display screens, for presenting useful information to the clinician. In one embodiment, the display 122 is configured to include a graphical user interface (GUI). The GUI may be an interactive display, e.g., a

touch-sensitive screen or otherwise, and may provide various windows and elements for receiving input and interface command operations. Alternatively, other suitable means of communication with the ventilator **100** may be provided, for instance by a wheel, keyboard, mouse, or other suitable interactive device. Thus, operator interface **120** may accept commands and input through display **122**. Display **122** may also provide useful information in the form of various ventilatory data regarding the physical condition of a patient **150**. The useful information may be derived by the ventilator **100**, based on data collected by a processor **116**, and the useful information may be displayed to the clinician in the form of graphs, wave representations, pie graphs, text, or other suitable forms of graphic display. For example, patient data may be displayed on the GUI and/or display **122**. Additionally or alternatively, patient data may be communicated to a remote monitoring system coupled via any suitable means to the ventilator **100**.

Controller **110** may include memory **112**, one or more processors **116**, storage **114**, and/or other components of the type commonly found in command and control computing devices. Controller **110** may further include a trajectory module **117**, a MT-PA module **118**, and amplification module **119** configured to deliver gases to the patient **150** according to prescribed breath types as illustrated in FIG. 1. In alternative embodiments, the trajectory module **117**, the MT-PA module **118**, and the amplification module **119** may be located in other components of the ventilator **100**, such as the pressure generating system **102** (also known as the pneumatic system **102**).

The memory **112** includes non-transitory, computer-readable storage media that stores software that is executed by the processor **116** and which controls the operation of the ventilator **100**. In an embodiment, the memory **112** includes one or more solid-state storage devices such as flash memory chips. In an alternative embodiment, the memory **112** may be mass storage connected to the processor **116** through a mass storage controller (not shown) and a communications bus (not shown). Although the description of computer-readable media contained herein refers to a solid-state storage, it should be appreciated by those skilled in the art that computer-readable storage media can be any available media that can be accessed by the processor **116**. That is, computer-readable storage media includes non-transitory, volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage of information such as computer-readable instructions, data structures, program modules or other data. For example, computer-readable storage media includes RAM, ROM, EPROM,

EEPROM, flash memory or other solid state memory technology, CD-ROM, DVD, or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by the computer.

5 The inspiratory module **104** receives a breath type from the MT-PA module **118** and a predetermined trajectory for the breath type from the trajectory module **117**. In some embodiments, the MT-PA module **118** and/or the trajectory module **117** are part of the controller **110** as illustrated in FIG. 1. In other embodiments, the MT-PA module **118** and/or the trajectory module **117** are part of the processor **116**, pneumatic system
10 **102**, and/or a separate computing device in communication with the ventilator **100**.

 The trajectory module **117** receives a predetermined trajectory for the MT-PA breath type. Further, in some embodiments, the trajectory module **117** or any other suitable component of the ventilator **100**, such as the processor **116**, controller **110**, or pneumatic system **102**, estimates patient parameters based on the at least one monitored
15 patient parameter from the sensor(s) **107**. In some embodiments, the estimated parameters are calculated by entering the monitored parameters into the Equation of Motion. In further embodiments, the monitored patient parameters are inspiratory flow and/or net flow. In some embodiments, the estimated patient parameters are at least one of resistance, elastance, and/or compliance.

20 The predetermined trajectory is a model trajectory. In some embodiments, the predetermined trajectory is based on clinically observed trajectories for patients with specific breathing rates/types or for patients suffering from a specific disease state. For example, the predetermined trajectory may be based on clinically observed trajectories for patients with shallow breathing, aggressive breathing, COPD, ARDS, etc. The
25 predetermined trajectory based on clinically observed data anticipates the trajectory desired by the patient **150** by utilizing the patient's particular characteristics, such as disease state or rate of breathing. In some embodiments the trajectory is a sinusoidal, a modified sinusoidal, and/or a modified square model wave-form. Accordingly, in some embodiments, the predetermined trajectory is predictive of patient inspiratory muscle
30 pressure.

 In one embodiment, the predetermined trajectory is a sinusoidal model as illustrated below, which approximates actual clinically-observed inspiratory muscle pressures:

$$P_{musi} = -P_{\max} \left(1 - \frac{t}{t_v}\right) \sin\left(\frac{\pi t}{t_v}\right)$$

P_{musi} represents the magnitude of the negative muscle pressure generated by inspiratory muscles and is therefore equivalent to the amount of pressure that must be provided by the patient (or P_P) at a time t . Accordingly, P_{musi} can be substituted into the PA support
 5 setting equations illustrated above as $P_P(t)$ to solve for a target airway pressure at the time t (or $P_V(t)$) as illustrated below:

$$P_V(t) = P_{\max} \left(1 - \frac{t}{t_v}\right) \sin\left(\frac{\pi t}{t_v}\right) * (k/(1.0 - k))$$

$P_{\max}$ represents the maximum amount of muscle pressure (representing patient effort) that the patient should exert, t_v represents ventilator detected inspiration duration, and t
 10 represents elapsed breath time varying between 0 and the total sum of inspiration and expiration periods in the above equation. The $P_{\max}$ and t_v may be input by the operator, selectable by the operator from a group of predetermined values, and/or selected or estimated by the ventilator based on monitored patient parameters, estimated patient parameters, and ventilator parameters. In some embodiments, the parameters of the
 15 above equation are adjusted based on monitored patient parameters indicating and trending breathing behavior in conjunction with optimization algorithms to achieve a quantitatively defined objective (e.g., minimize work of breathing, minimize fatigue, optimize oxygenation, etc.). The sinusoidal model predetermined pressure trajectory illustrated above is merely exemplary and is not meant to be limiting. Any suitable
 20 predetermined pressure trajectory for a patient on a ventilator may be utilized by the trajectory module 117.

The predetermined trajectory may be input by an operator, selected by an operator from a group of predetermined trajectories, determined by the ventilator 100, or selected by the ventilator 100 from a group of predetermined trajectories. The ventilator
 25 100 may select or determine the predetermined trajectory by monitoring patient parameters, estimating patient parameters, and by monitoring ventilator parameters. In some embodiments, ventilator parameters include settings such as tidal volume, fractional inspired oxygen, and/or positive end-expiratory pressure. In some embodiments, the ventilator 100 determines the predetermined trajectory or adjusts the
 30 values assigned to the parameters of the predetermined trajectory on a breath-by-breath basis. In some embodiments, the ventilator 100 utilizes this data to determine if the

patient **150** suffers from a specific disease or to determine the patient breath rate, such as if the patient **150** is breathing aggressively or shallowly. During these embodiments, the ventilator **100** determines the best trajectory to utilize based on, for example, the breath rate, tidal volumes, and disease state determinations.

5 In other embodiments, once a predetermined trajectory is being delivered to the patient **150**, the ventilator **100** determines that the delivered trajectory is improper and should be changed. If the ventilator **100** detects that predetermined trajectory should be adjusted or changed, the ventilator **100** may notify the operator. The operator may be notified by the ventilator **100** with any visual, audio, and/or vibrational notification
10 systems and/or methods. For example, an alarm may sound and a prompt explaining the need for a change in the predetermined trajectory may be displayed. In some embodiments, if the ventilator **100** detects that the predetermined trajectory should be adjusted or changed, the ventilator **100** determines the proper trajectory that should be utilized. In some embodiments, the ventilator **100** determines that the predetermined
15 trajectory needs to be changed and/or what the proper trajectory should be by monitoring patient parameters, estimating patient parameters, and/or monitoring ventilator parameters. In further embodiments, the ventilator **100** determines if the predetermined trajectory needs to be changed and modified on a breath-by-breath basis or over a definite window of time or patient state (e.g., sleep or wakefulness).

20 For example, the ventilator may estimate patient effort by monitoring flow and derive a target pressure based on the estimated patient effort according to a PA breath type and then compare the estimated patient effort and/or derived target pressure to the predetermined trajectory. If the estimated patient effort and/or derived target pressure vary too much from the predetermined trajectory, the ventilator **100** may modify specific
25 parameters of the predetermined trajectory, such as $P_{\max}$ and t_v , or may change the predetermined trajectory to an entirely different model based on these comparison results.

 In these embodiments, the ventilator **100** may notify the operator of the needed change and recommend a new predetermined determined trajectory. In these
30 embodiments, the ventilator **100** may notify the operator of the needed change and recommend new parameters for the predetermined determined trajectory. Alternatively, in these embodiments, the ventilator **100** may simply change the predetermined trajectory to a new predetermined trajectory. Further, in these embodiments, the

ventilator **100** may simply change the parameters of the predetermined trajectory. In one embodiment, the trajectory parameters include maximum or peak amplitude, phase angle, $P_{\max}$, and/or t_v .

Initiation and execution of an MT-PA breath type has two operation prerequisites: (1) detection of an inspiratory trigger; and (2) determining and commanding a reference airway pressure trajectory to the controller for the duration of the just-started inspiration. A patient trigger is calculated based on a measured or monitored patient inspiration flow. In addition, the sensitivity of the ventilator **100** to changes in a monitored patient parameter, such as flow, may be adjusted such that the ventilator **100** may properly detect changes in the monitored parameter. For example, the lower the pressure or flow change threshold setting, the more sensitive the ventilator **100** may be to a patient initiated trigger. However, each ventilator **100** will have a minimum measurable inspiration flow and thereby have a change in flow that the ventilator **100** can not detect. Accordingly, a monitored parameter below a minimum measurable value will not be detected by the ventilator **100**.

Any suitable type of triggering detection for determining a patient trigger may be utilized by the ventilation system, such as nasal detection, diaphragm detection, and/or brain signal detection. Further, the ventilator **100** may detect patient triggering via a pressure-monitoring method, a flow-monitoring method, direct or indirect measurement of neuromuscular signals, or any other suitable method. Sensors **107** suitable for this detection may include any suitable sensing device as known by a person of skill in the art for a ventilator.

According to an embodiment, a pressure-triggering method may involve the ventilator **100** monitoring the circuit pressure, and detecting a slight drop in circuit pressure. The slight drop in circuit pressure may indicate that the patient's respiratory muscles are creating a slight negative pressure that in turn generates a pressure gradient between the patient's lungs and the airway opening in an effort to inspire. The ventilator **100** may interpret the slight drop in circuit pressure as a patient trigger and may consequently initiate inspiration by delivering respiratory gases.

Alternatively, the ventilator **100** may detect a flow-triggered event. Specifically, the ventilator **100** may monitor the circuit flow, as described above. If the ventilator **100** detects a slight drop in the base flow through the exhalation module during exhalation, this may indicate, again, that the patient **150** is attempting to inspire. In this case, the

ventilator **100** is detecting a drop in bias flow (or baseline flow) attributable to a slight redirection of gases into the patient's lungs (in response to a slightly negative pressure gradient as discussed above). Bias flow refers to a constant flow existing in the circuit during exhalation that enables the ventilator **100** to detect expiratory flow changes and patient triggering.

The MT-PA module **118** sends a MT-PA breath type to the inspiratory module **104**. The MT-PA breath type refers to a type of ventilation in which the ventilator **100** acts as an inspiratory amplifier that provides pressure support to the patient. The degree of amplification (the "support setting") is set by an operator, for example as a percentage based on the patient's effort. For example, if the operator sets the support setting to 30%, then the ventilator provides 30% of the desired pressure to the patient and the patient must provide the remaining 70% of the desired pressure.

The MT-PA breath type determines a target pressure by utilizing the support setting in combination with predetermined trajectory. The predetermined trajectory replaces the $P_p(t)$ parameter in the equation listed below for determining a target pressure (or $P_v(t)$) at a time t :

$$P_v(t) = P_p(t) * (k/(1.0 - k)).$$

In one implementation, every computational cycle (e.g., 5 milliseconds, 10 milliseconds, etc.), the ventilator calculates a target pressure, based on the support setting and the predetermined trajectory. In one embodiment, as discussed above, the predetermined trajectory is the following:

$$P_{musi} = -P_{\max} \left(1 - \frac{t}{t_v}\right) \sin\left(\frac{\pi t}{t_v}\right)$$

Accordingly, the target pressure (P_v) at time t is solved for by utilizing the following equation:

$$P_v(t) = P_{\max} \left(1 - \frac{t}{t_v}\right) \sin\left(\frac{\pi t}{t_v}\right) * (k/(1.0 - k))$$

The MT-PA module **118** begins inspiratory assist when a trigger is detected and/or when the at least one monitored parameter is detected by the MT-PA module **118**. However, if the patient ceases triggering inspiration, the assist also ceases. Accordingly, in some embodiments, the MT-PA module **118** includes a safety feature that has the

ventilator **100** deliver a breath to the patient or switches the breath type to a non-spontaneous breath type if a patient trigger is not detected for a set period of time or based on the occurrence of a set event. This safety feature ensures that if a patient stops triggering, the patient will not stop receiving ventilation by the medical ventilator.

5 Further, this functionality is often a problem for weak patients with weak detected triggers. A weak detected trigger may not generate a measurable flow for the delivery of a patient breath. Once a measurable, positive inspiration flow is detected by the ventilator, the ventilator applies the calculated target pressure to deliver a proportion (determined by the support setting) of the total demand as determined by the
10 predetermined pressure trajectory.

Accordingly, in some embodiments, the ventilator **100** utilizes an amplification module **119**. The amplification module **119** determines that a detected patient trigger is generated in the presence of a negative inspiration flow as measured by the ventilator (indicating that the patient is still exhaling) or an inspiration flow below a predetermined
15 threshold that typically would not provide a desired breath to the patient. The amplification module **119** applies a multiplier or multiplicative transformation to the monitored flow below the predetermined threshold to form an adjusted or amplified flow. As used herein, the terms “multiplier” and “multiplicative transformation” are considered to be interchangeable in the present disclosure and in the claims. While
20 “multiplier” and “multiplicative transformation” refer to different values, it is understood by a person of skill in the art that each may be used for the purposes of this disclosure and for the purposes of the claims. The adjusted or amplified flow is utilized by the MT-PA module **118** to determine a patient trigger for delivering a pressure supported breath to the patient. Accordingly, the amplification module **119** allows weak patients to trigger
25 a pressure supported breath. Since, the predetermined trajectory provided by the trajectory module **117** anticipates the desired trajectory of the patient, the pressure supported breath provided by the amplification module **119** should be close or equivalent to the breath desired by the weakly triggering patient.

In some embodiments, the amplification module **119** is activated by the operator.
30 In other embodiments, the amplification module **119** is activated by the ventilator. In some embodiments, the amplification module **119** is deactivated by the ventilator **100** and in other embodiments, the amplification module **119** is deactivated by the operator. In some embodiments, the amplification module **119** is activated and/or deactivated by

the ventilator **100** based on the monitoring of ventilator parameters, monitoring of patient parameters, the estimating of patient parameters and/or the occurrence of a predetermined event. For example, the predetermined event may include detecting a predetermined number of monitored parameters above or below the predetermined threshold in a predetermined amount of time. In another example, the predetermined event may be detecting a predetermined number of consecutive measured monitored parameters above or below the predetermined threshold. In a further example, the predetermined event is the detection of a predetermined number of monitored parameters above or below the predetermined threshold in a predetermined number of breaths.

The multiplier utilized by the amplification module **119** may be input by an operator, selected by an operator from a group of predetermined multipliers, determined by the ventilator **100**, or selected by the ventilator **100** from a group of predetermined multipliers. The ventilator **100** may select or determine the multiplier by monitoring patient parameters, estimating patient parameters, and by monitoring ventilator parameters. In some embodiments, the multiplier is adaptively modified by the ventilator **100** on a breath-by-breath basis based on at least one of the monitored patient parameters, the estimated patient parameters, and/or from monitoring ventilator parameters.

FIG. 2 illustrates an embodiment of a method **200** for ventilating a patient with a ventilator that utilizes a MT-PA breath type. The MT-PA breath type has a predetermined trajectory, so the target pressure is calculated based on the predetermined trajectory and a support setting. The predetermined trajectory prevents the patient from experiencing artifactual waveform patterns and/or any abrupt inspiration and exhalation changes. Further, because the predetermined trajectory is based on clinically observed trajectories, the predetermined trajectory may be adaptively adjusted on an ongoing basis to minimize any gap between actual patient demand and the calculated target pressure delivered.

As illustrated, method **200** includes a monitoring operation **202**. During the monitoring operation **202**, the ventilator monitors patient parameters. In some embodiments, the patient parameters include inspiratory lung flow, net lung flow, and/or airway pressure. The monitoring operation **202** may be performed by sensors and data acquisition subsystems. The sensors may include any suitable sensing device as known by a person of skill in the art for a ventilator. In some embodiments, the sensors are

located in the pneumatic system, the breathing circuit, and/or on the patient. In some embodiments, the ventilator during the monitoring operation **202** monitors the inspiration flow every computational cycle (e.g., 2 milliseconds, 5 milliseconds, 10 milliseconds, etc.) during the delivery of the control pressure.

5 Further, method **200** includes a detection operation **204**. During the detection operation **204**, the ventilator detects an inspiratory trigger. The inspiratory trigger may be detected by any suitable method for detecting an inspiratory trigger, such as nasal detection, diaphragm detection, brain signal detection, pressure monitoring detection, and/or flow monitoring detection. The triggering detection is based on sensor readings.

10 Sensors may include any suitable sensing device as known by a person of skill in the art for a ventilator.

In some embodiments, method **200** includes a parameter estimation operation **206**. During the parameter estimation operation **206**, the ventilator estimates patient parameters based on the measurements directly or indirectly related to monitored patient parameters. In some embodiments, the estimated patient parameters include lung

15 compliance (inverse of elastance) and/or lung/airway resistance. In further embodiments, the estimated lung compliance, lung elastance and/or lung/airway resistance are estimated based on monitored flow and/or the Equation of Motion. The estimated patient parameters may be estimated by any suitable processor found in the ventilator. In some embodiments, the estimated patient parameters are calculated by a

20 controller, a pneumatic system, and/or a separate computing device operatively connected to the ventilator.

As illustrated, method **200** includes a receiving operation **214**. During the receiving operation **214**, the ventilator receives a predetermined pressure trajectory. The

25 predetermined trajectory is a model trajectory. In some embodiments the predetermined trajectory is based on clinically observed trajectories for patients with specific breathing rates/types or for patients suffering from a specific disease state. For example, the predetermined trajectory may be for patients with shallow breathing, aggressive breathing, COPD, ARDS, etc. The predetermined trajectory anticipates the trajectory

30 generated by the patient (according to a PA breath type calculation) by utilizing the patient's particular characteristics, such as disease state or rate of breathing. In some embodiments the trajectory may be a sinusoidal, a modified sinusoidal, and/or a modified square model wave-form.

In one embodiment, the predetermined trajectory received by the ventilator during the receiving operation **214** is a model sinusoidal wave-form as defined below:

$$P_{musi} = -P_{max} (1 - (t/t_v)) \sin(\pi t/t_v).$$

P_{musi} represents the magnitude of the negative muscle pressure generated by inspiratory muscles and is therefore equivalent to the amount of pressure that must be provided by the patient (or P_p) at a time t . Accordingly, P_{musi} can be substituted into the PA support setting equations illustrated above as $P_p(t)$ to solve for a target pressure (or $P_v(t)$) as illustrated below:

$$P_v(t) = P_{max} (1 - \frac{t}{t_v}) \sin(\frac{\pi t}{t_v}) * (k/(1.0 - k))$$

As discussed above, the P_{max} and t_v may input by the operator, selected by the operator from a group of predetermined values, and/or selected or estimated by the ventilator based on monitored patient parameters, estimated patient parameters, and ventilator parameters. The sinusoidal model predetermined pressure trajectory illustrated above is merely exemplary and is not meant to be limiting. Any suitable predetermined pressure trajectory for a patient on a ventilator in an effort-based breath type may be received by the ventilator during receiving operation **214**.

The predetermined trajectory may be received from input by an operator, a selection by an operator from a group of predetermined trajectories, the ventilator, or a selection by the ventilator from a group of predetermined trajectories. The ventilator may select or determine the predetermined trajectory from the monitored patient parameters, the estimated patient parameters, and from monitoring ventilator parameters. In some embodiments, the ventilator may select or determine the predetermined trajectory from the monitored patient parameters, the estimated patient parameters, and from monitoring ventilator parameters on a breath-by-breath basis. In some embodiments, the ventilator utilizes this data to determine if the patient suffers from a specific disease or if the patient is exhibiting symptoms consistent with a condition of interest to be reported to the clinician by the ventilator. During these embodiments, the ventilator determines the best trajectory to utilize based on the breath rate and/or disease state determinations.

Next, method **200** includes a calculating operation **216**. During the calculating operation **216**, the ventilator calculates a target airway pressure based on the predetermined pressure trajectory and a support setting. The target pressure is calculated

for a point in the ventilation circuit that is proximal to the lung and would best assist the patient's inspiratory muscles to the degree selected by the operator as the support setting. In one embodiment, the support setting (or the degree of amplification) is set by an operator, for example as a percentage based on the patient's effort. The predetermined
5 trajectory replaces the amount of pressure that must be provided by the patient at a time t (or $P_p(t)$) in the equation listed below for determining a target airway pressure (or $P_v(t)$) at a time t :

$$P_v(t) = P_p(t) * (k/(1.0 - k)).$$

Method **200** also includes a delivery operation **218**. During the delivery
10 operation **218**, the ventilator delivers the target airway pressure to a patient based on the detected inspiratory trigger. A patient trigger is calculated based on the at least one monitored parameter, such as inspiration flow. In some embodiments, sensors, such as flow sensors, may detect changes in patient parameters indicative of patient triggering. In addition, the sensitivity of the ventilator to changes in the at least one monitored
15 parameter may be adjusted such that the ventilator may properly detect changes in flow. For example, the lower the pressure or flow change threshold setting, the more sensitive the ventilator may be to a patient initiated trigger. However, each ventilator will have a minimum measurable monitored parameter value and thereby a change in the monitored parameter that the ventilator can not detect. A monitored parameter below this
20 minimum change will not be detected by the ventilator.

Advanced, sophisticated triggering technologies detect initiation of inspiratory efforts more efficiently. However, while earlier detection of an inspiratory effort reduces trigger delays, the inspiratory flow at the time of triggering may initially be so weak that the ventilator may not be able to measure its magnitude. Further, the
25 inspiratory flow at the time of triggering may be negative if the patient triggers inhalation while still exhaling. Further, if the patient ceases inspiration, the inspiration flow is zero. Therefore, weak patients with weak triggers may not receive a desired breath.

Accordingly, in some embodiments, method **200** further includes a decision
30 operation **210** and an application operation **212** after the performance of the detection operation **204** by the ventilator. The decision operation **210** determines if the at least one monitored parameter, such as flow, is less than a predetermined threshold. If the ventilator during the decision operation **210** determines that the at least one monitored

parameter is equal to or greater than a predetermined threshold, then the ventilator selects to perform receiving operation **214**. If the ventilator during the decision operation **210** determines that the monitored parameter is less than the predetermined threshold, then the ventilator selects to perform an application operation **212**. In some
5 embodiments, the predetermined threshold is a monitored parameter, such as flow, that is too low for the delivery of a breath by the ventilator during the delivery operation **218**.

In further embodiments, method **200** includes the application operation **212**. The ventilator during application operation **212** applies a multiplier or a multiplicative transformation to the monitored patient parameter. Accordingly, the ventilator during
10 the delivery operation **218** utilizes the monitored parameter, such as flow, after the monitored parameter has been adjusted or amplified by the ventilator during the application operation **212**. The multiplier may be input by an operator, selected by an operator from a group of predetermined multipliers, from the ventilator, or selected by the ventilator from a group of predetermined multipliers. The ventilator may select or
15 determine the multiplier from the monitored patient parameters, the estimated patient parameters, and/or from monitoring ventilator parameters. In some embodiments, the multiplier is adaptively modified by the ventilator on a breath-by-breath basis based on at least one of the monitored patient parameters, the estimated patient parameters, and/or from monitoring ventilator parameters.

In some embodiments, the decision operation **210** and application operation **212**
20 are utilized by the ventilator during method **200** when activated by the operator. In other embodiments, the decision operation **210** and application operation **212** of method **200** are activated by the ventilator. In some embodiments, the decision operation **210** and application operation **212** of method **200** are deactivated by the ventilator and in other
25 embodiments, the decision operation **210** and application operation **212** of method **200** are deactivated by the operator. In some embodiments, the decision operation **210** and application operation **212** of method **200** are activated and/or deactivated by the ventilator based on the monitoring of ventilator parameters, monitoring of patient parameters, the estimating of patient parameters and/or the occurrence of a
30 predetermined event. For example, the predetermined event may include detecting a predetermined number of patient triggers with a monitored parameter above or below the predetermined threshold in a predetermined amount of time. In another example, the predetermined event may be detecting a predetermined number of consecutive patient

triggers above or below the predetermined threshold. In a further example, the predetermined determined event is the detection of a predetermined number of triggers with a flow above or below the predetermined threshold in a predetermined number of breaths.

5 In other embodiments, method **200** includes a display operation. The ventilator during the display operation displays any suitable information for display on a ventilator. In one embodiment, the display operation displays at least one of the predetermined trajectory, a recommended trajectory, a pressure waveform, the target pressure, a support setting, the monitored patient parameters, a multiplier, and/or estimated patient
10 parameters.

 In other embodiments, method **200** includes a trajectory decision operation after the ventilator performs the delivery operation **218**. The ventilator during the trajectory decision operation determines if the predetermined trajectory is improper and should be changed and/or adjusted. In some embodiments, the ventilator determines that the
15 predetermined trajectory needs to be changed based on the monitored patient parameters, the estimated patient parameters, and/or monitored ventilatory parameters. In some embodiments, the monitored patient parameters, the estimated patient parameters, and/or monitored ventilatory parameters are utilized in accordance with an optimization algorithm to determine that the predetermined trajectory needs to be changed. In some
20 embodiments, the ventilator determines that the predetermined trajectory needs to be changed or adjusted on a breath-by-breath basis. If the ventilator during the trajectory decision operation detects that predetermined trajectory does not need to be changed, the ventilator selects to perform monitoring operation **202**. If the ventilator during the trajectory decision operation detects that the predetermined trajectory should be changed,
25 the ventilator selects to perform at least one of a notification operation, a recommendation operation, and/or change operation.

 In some embodiments, method **200** includes a notification operation. The ventilator during the notification operation notifies the operator with any suitable visual, audio, or vibrational notification methods for a ventilator system that the predetermined
30 trajectory is improper. For example, the ventilator during the notification operation may sound an alarm and display a prompt explaining the need to change the predetermined trajectory.

In some embodiments, method **200** includes a recommendation operation. In some embodiments, the ventilator during the recommendation operation recommends that the operator change the predetermined trajectory to a different predetermined trajectory. In other embodiments, the ventilator during the recommendation operation recommends that the operator change inputs of the predetermined trajectory to different values, such as $P_{\max}$, t_v , peak amplitude, inspiration duration, and/or phase angle. The ventilator during the recommendation operation determines a better predetermined trajectory or inputs of the predetermined trajectory by monitoring patient parameters, estimating patient parameters, and/or monitoring ventilator parameters. In some embodiments, the ventilator during the recommendation operation determines a better predetermined trajectory or inputs of the predetermined trajectory on a breath-by-breath basis. The ventilator recommends a better predetermined trajectory or input by any suitable notification method for a ventilator, such as any visual, audio, or vibrational notification method.

In some embodiments, method **200** includes a change operation. In some embodiments, the ventilator during the change operation changes the predetermined trajectory to a different predetermined trajectory. In other embodiments, the ventilator during the change operation changes the inputs of the predetermined trajectory. The ventilator during the change operation determines a more appropriate predetermined trajectory or inputs for the predetermined trajectory by utilizing the monitored patient parameters, the estimated patient parameters, and/or monitored ventilator parameters. In some embodiments, the ventilator during the change operation determines a more appropriate predetermined trajectory or inputs for the predetermined trajectory on a breath-by-breath basis.

In some embodiments, a microprocessor-based ventilator that accesses a computer-readable medium having computer-executable instructions for performing the method of ventilating a patient with a medical ventilator is disclosed. This method includes repeatedly performing the steps disclosed in method **200** above and/or as illustrated in FIG. 2.

In some embodiments, the ventilator system includes: means for monitoring at least one patient parameter; means for detecting an inspiratory trigger based on the at least one monitored patient parameter; means for receiving a predetermined pressure trajectory; means for calculating a target pressure based at least on the predetermined

pressure trajectory and a support setting; and means for delivering the target pressure to a patient based on the detected inspiratory trigger.

Those skilled in the art will recognize that the methods and systems of the present disclosure may be implemented in many manners and as such are not to be limited by the foregoing exemplary embodiments and examples. In other words, functional elements
5 being performed by a single or multiple components, in various combinations of hardware and software or firmware, and individual functions, can be distributed among software applications at either the client or server level or both. In this regard, any number of the features of the different embodiments described herein may be combined
10 into single or multiple embodiments, and alternate embodiments having fewer than or more than all of the features herein described are possible. Functionality may also be, in whole or in part, distributed among multiple components, in manners now known or to become known. Thus, myriad software/hardware/firmware combinations are possible in achieving the functions, features, interfaces and preferences described herein. Moreover,
15 the scope of the present disclosure covers conventionally known manners for carrying out the described features and functions and interfaces, and those variations and modifications that may be made to the hardware or software firmware components described herein as would be understood by those skilled in the art now and hereafter.

Numerous other changes may be made which will readily suggest themselves to those skilled in the art and which are encompassed in the spirit of the disclosure and as
20 defined in the appended claims. While various embodiments have been described for purposes of this disclosure, various changes and modifications may be made which are well within the scope of the present invention. Numerous other changes may be made which will readily suggest themselves to those skilled in the art and which are
25 encompassed in the spirit of the disclosure and as defined in the appended claims.

Claims

What is claimed is:

1. A method for ventilating a patient with a ventilator comprising:
monitoring at least one patient parameter;
5 detecting an inspiratory trigger based on the at least one monitored patient parameter;
receiving a predetermined pressure trajectory;
calculating a target pressure based at least on the predetermined pressure trajectory and a support setting; and
10 delivering the target pressure to a patient based on the detected inspiratory trigger.
2. The method of claim 1, wherein the predetermined pressure trajectory includes at least one of an inspiratory duration, a phase angle, and a peak amplitude.
15
3. The method of claim 2, wherein at least one of the inspiratory duration, the phase angle, and set peak amplitude are at least one of selected by an operator, input by an operator, and/or determined by the ventilator.
- 20 4. The method of claim 1, further comprising:
estimating patient parameters based on the at least one monitored patient parameter; and
determining that the predetermined pressure trajectory is improper for the patient based on at least one of the estimated patient parameters, the at least one monitored
25 patient parameter, and ventilator parameters.
5. The method of claim 4, further comprising:
adjusting at least one of a $P_{\max}$ and a t_v of the predetermined pressure trajectory based on the step of determining that the predetermined pressure trajectory is improper.
30

6. The method of claim 4, further comprising:
changing the predetermined pressure trajectory to a different model based on the step of determining that the predetermined pressure trajectory is improper.

5 7. The method of claim 4, further comprising:
displaying a recommended change in at least one of an inspiratory duration, a phase angle, a peak amplitude, a P_{max} , a t_v and the predetermined pressure trajectory based on the step of determining that the predetermined pressure trajectory is improper.

10 8. The method of claim 4, wherein the estimated patient parameters are compliance and resistance.

9. The method of claim 1, wherein the predetermined pressure trajectory is received from at least one of operator selection from a group of predetermined
15 trajectories, input by an operator, the ventilator based on at least one of the at least one monitored patient parameter, estimated patient parameters, and ventilator parameters, and ventilator selection from a group of predetermined trajectories based on at least one of the at least one monitored patient parameter, the estimated patient parameters, and the ventilator parameters.

20 10. The method of claim 1, further comprising:
determining that the at least one monitored patient parameter of the inspiratory trigger is below a predetermined threshold, wherein the at least one monitored patient parameter is a monitored flow; and

25 applying a multiplier to the monitored flow,
wherein the step of detecting the inspiratory trigger is based on the monitored flow after the monitored flow has been amplified by the multiplier.

11. The method of claim 10, wherein the multiplier is at least one of selectable
30 by an operator from a group of predetermined multipliers, input by the operator, determined by the ventilator based on at least one of the at least one monitored patient parameter, the estimated patient parameters, and ventilator parameters, and selected by the ventilator from a group of predetermined multipliers based on at least one of the at

least one monitored patient parameter, the estimated patient parameters, and the ventilator parameters.

12. The method of claim 10, wherein the multiplier is adaptively modified by the ventilator on a breath-by-breath basis based on at least one of the at least one monitored patient parameter, the estimated patient parameters, and ventilator parameters.

13. The method of claim 1, wherein the at least one monitored patient parameter is inspiratory flow.

10

14. The method of claim 1, further comprising:

displaying at least one of the predetermined pressure trajectory, a recommended pressure trajectory, a pressure waveform, the target pressure, the at least one monitored patient parameter, the support setting, a multiplier, and estimated patient parameters.

15

15. The method of claim 1, wherein the support setting is input by an operator.

16. A ventilator system comprising:

a pressure generating system adapted to generate a flow of breathing gas;

20

a ventilation tubing system including a patient interface for connecting the pressure generating system to a patient;

one or more sensors operatively coupled to at least one of the pressure generating system, the patient, and the ventilation tubing system, wherein at least one sensor is capable of generating an output indicative of an inspiration flow;

25

a trajectory module determines a pressure trajectory;

a MT-PA module, the MT-PA module calculates at least one target pressure based at least on the pressure trajectory and a support setting and utilizes the output indicative of the inspiration flow to determine a patient trigger for delivery of a breath to the patient; and

30

a processor in communication with the pressure generating system, the one or more sensors, the trajectory module, and the MT-PA module.

17. The ventilator system of claim 16, further comprising:

an amplification module, the amplification module determines that the output indicative of the inspiration flow is below a predetermined threshold and applies a multiplier to the output to form an amplified output, wherein the output utilized by MT-PA module is the amplified output.

18. The ventilator system of claim 16, further comprising:

a display in communication with at least one of the pressure generating system, the one or more sensors, the MT-PA module, the trajectory module, the processor, the MT-PA module, and an amplification module.

19. The ventilator system of claim 16, wherein the trajectory module determines if the pressure trajectory is proper based on parameters monitored by the one or more sensors, estimated parameters derived from the parameters monitored by the one or more sensors, and ventilator parameters.

20. The ventilator system of claim 19, wherein the trajectory module adjusts the pressure trajectory based on the parameters monitored by the one or more sensors, the parameters estimated from the parameters monitored by the one or more sensors, and the ventilator parameters.

21. The ventilator system of claim 19, wherein the trajectory module changes the pressure trajectory based on the parameters monitored by the one or more sensors, the parameters estimated from the parameters monitored by the one or more sensors, and the ventilator parameters.

22. A computer-readable medium having computer-executable instructions for performing a method of ventilating a patient with a ventilator, the method comprising:
repeatedly monitoring at least one patient parameter;
repeatedly detecting an inspiratory trigger based on the at least one monitored patient parameter;
repeatedly receiving a predetermined pressure trajectory;

repeatedly calculating a target pressure based at least on the predetermined pressure trajectory and a support setting; and

repeatedly delivering the target pressure to a patient based on the detected inspiratory trigger.

5

23. A ventilator system, comprising:

means for monitoring at least one patient parameter;

means for detecting an inspiratory trigger based on the at least one monitored patient parameter;

10

means for receiving a predetermined pressure trajectory;

means for calculating a target pressure based at least on the predetermined pressure trajectory and a support setting; and

means for delivering the target pressure to a patient based on the detected inspiratory trigger.

15

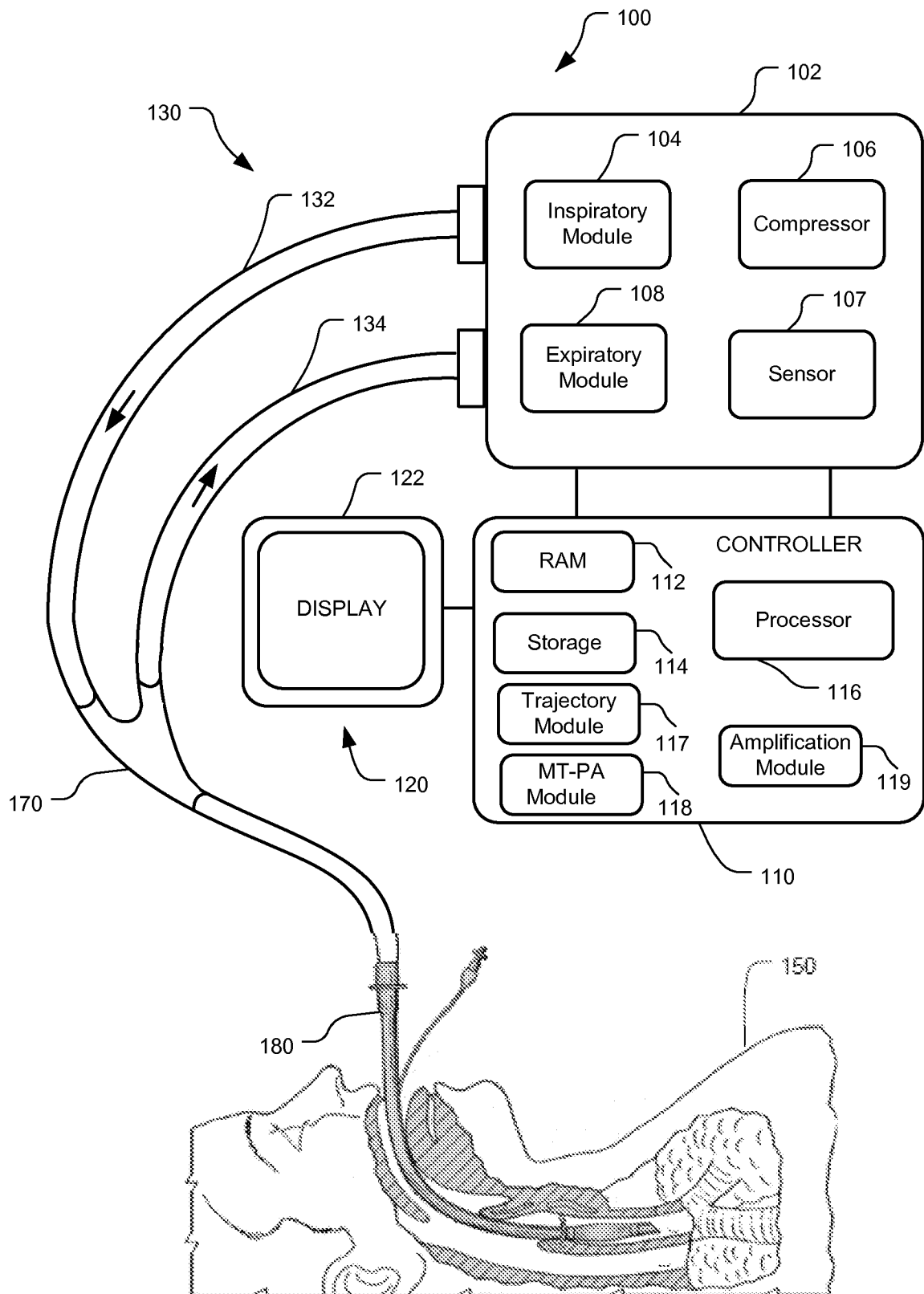


FIG. 1

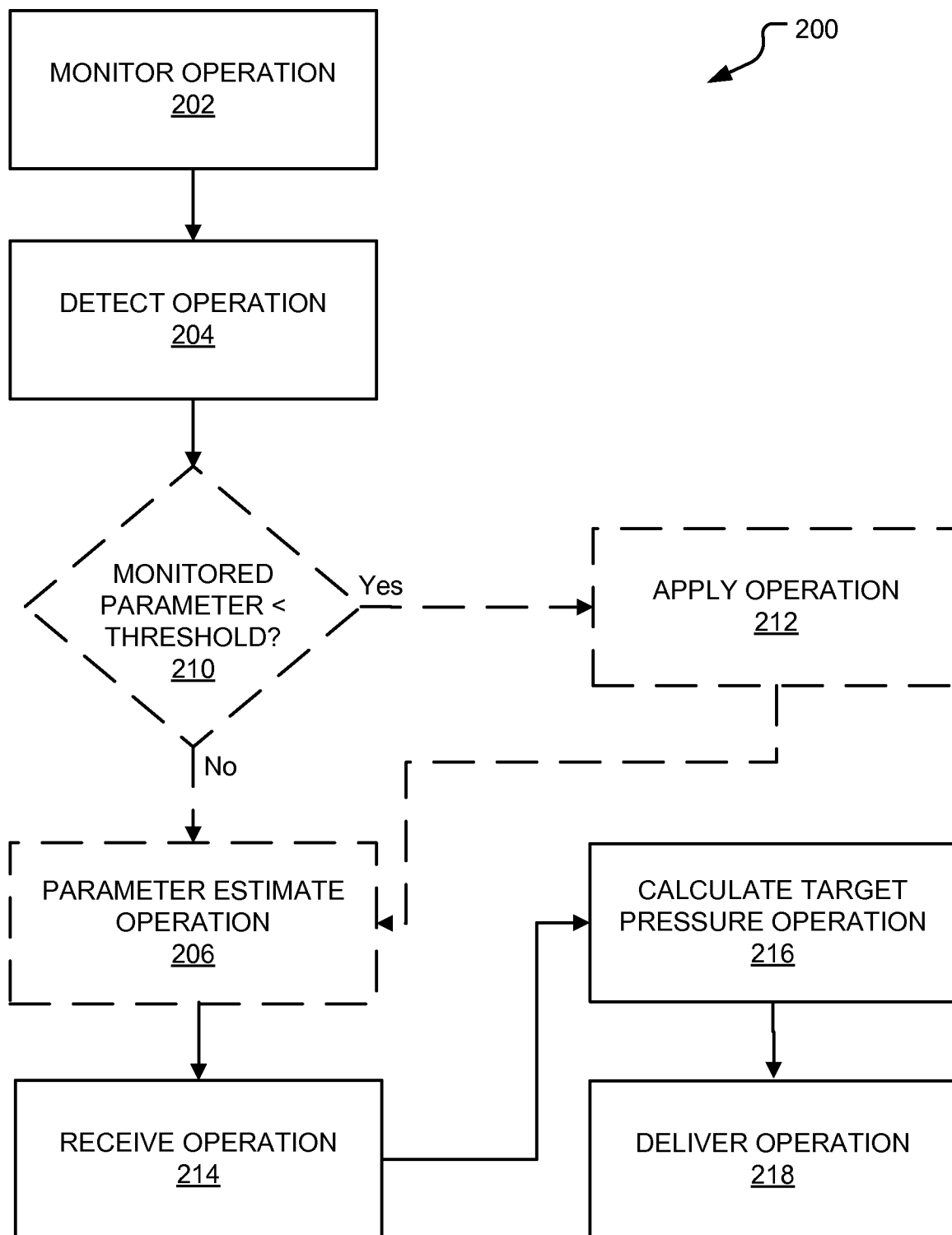


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/048465

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

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/071697 A1 (JAFARI MEDHI M [US] ET AL) 25 March 2010 (2010-03-25) abstract; figures 1,2 paragraph [0011] paragraph [0012] paragraph [0013] paragraph [0019] paragraph [0002] paragraph [0022] paragraph [0003] paragraph [0015] paragraph [0038] paragraph [0014] paragraph [0023] paragraph [0024] paragraph [0025] paragraph [0037] paragraph [0010] paragraph [0020] -/--	16-21,23



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

17 October 2012

Date of mailing of the international search report

24/10/2012

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Moraru, Liviu

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/048465

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	----- US 2010/071696 A1 (JAFARI MEHDI M [US]) 25 March 2010 (2010-03-25) abstract; figures 1,3,4,6,7,8 paragraph [0001] paragraph [0003] paragraph [0004] paragraph [0005] paragraph [0022] paragraph [0024] paragraph [0055] paragraph [0062] paragraph [0063] paragraph [0064] paragraph [0065] paragraph [0068] paragraph [0094] paragraph [0095] paragraph [0096] paragraph [0098] paragraph [0099] paragraph [0112] paragraph [0118] paragraph [0120] paragraph [0121] paragraph [0122] paragraph [0123] paragraph [0130] paragraph [0057] paragraph [0058] paragraph [0114] paragraph [0116] paragraph [0124] paragraph [0148]	16,18-22
A	----- JAFARI M M ET AL: "Robust Feedback Design for Proportional Assist Ventilation-System Dynamics and Problem Definition", DECISION AND CONTROL, 2005 AND 2005 EUROPEAN CONTROL CONFERENCE. CDC-E CC '05. 44TH IEEE CONFERENCE ON SEVILLE, SPAIN 12-15 DEC. 2005, PISCATAWAY, NJ, USA,IEEE, 12 December 2005 (2005-12-12), pages 4839-4844, XP010884460, ISBN: 978-0-7803-9567-1 the whole document	16
A	----- WO 2009/123977 A1 (NELLCOR PURITAN BENNETT LLC [US]; VANDINE JOSEPH DOUGLAS [US]; KUDARAV) 8 October 2009 (2009-10-08) the whole document	16-23
A	----- US 2010/236553 A1 (JAFARI MEHDI M [US] ET AL) 23 September 2010 (2010-09-23) the whole document -----	16-23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/048465

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

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

1. ☒ Claims Nos.: 1-15
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-15 concern a method for ventilating a patient. This implies therapy on a human or animal body and so falls within the meaning of Rule 39.1(iv) PCT.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/048465

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010071697 A1	25-03-2010	CA 2736540 A1 EP 2349420 A1 US 2010071697 A1 WO 2010036816 A1	01-04-2010 03-08-2011 25-03-2010 01-04-2010
US 2010071696 A1	25-03-2010	CA 2736528 A1 CN 102164540 A EP 2348995 A1 JP 2012503527 A US 2010071696 A1 WO 2010036653 A1	01-04-2010 24-08-2011 03-08-2011 09-02-2012 25-03-2010 01-04-2010
WO 2009123977 A1	08-10-2009	EP 2259823 A1 US 2011023879 A1 WO 2009123977 A1	15-12-2010 03-02-2011 08-10-2009
US 2010236553 A1	23-09-2010	NONE	