(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 April 2010 (01.04.2010)

PCT

(10) International Publication Number
WO 2010/036816 A1

(51) International Patent Classification:
A61M 16/00 (2006.01)

(21) International Application Number:
PCT/US2009/058252

(22) International Filing Date:
24 September 2009 (24.09.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/100,212 25 September 2008 (25.09.2008) US

(71) Applicant *(for all designated States except US)*: **NELLCOR PURITAN BENNETT LLC** [US/US]; 6135 Gunbarrel Avenue, Boulder, CO 80301 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **JAFARI, Mehdi** [US/US]; 25982 Anacapa Street, Laguna Hills, CA 92653 (US). **AVIANO, Jeffrey** [US/US]; 1946 Rock Springs Rd., Escondido, CA 92026 (US). **MCCOY, Edward** [US/US]; 1118 Countrywood Lane, Vista, CA 92081 (US). **JIMENEZ, Rhomere** [US/US]; 31643 Umbria Lane, Winchester, CA 92596 (US).

(74) Agent: **DOUGHERTY, Thomas**; 6135 Gunbarrel Avenue, Boulder, CO 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, 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, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM,

[Continued on next page]

(54) Title: INVERSION-BASED FEED-FORWARD COMPENSATION OF INSPIRATORY TRIGGER DYNAMICS IN MEDICAL VENTILATORS

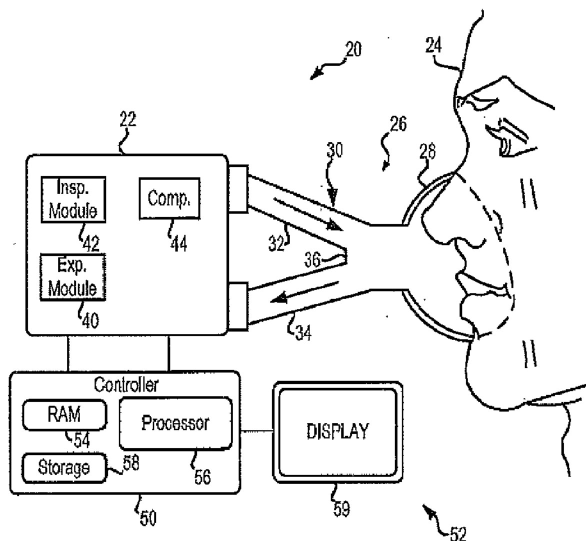


Fig. 1

(57) Abstract: A ventilator and method of ventilator control. The ventilator includes a pneumatic system (22) for providing and receiving breathing gas, and a controller (50) operatively coupled with the pneumatic system. The controller employs closed-loop control to provide positive breathing assistance to a patient. Supplemental feed-forward compensatory assistance is also provided, in addition to and independently of that commanded by the closed-loop control. The supplemental assistance may be determined, set or selected based on a ventilator parameter and/or an operator parameter, and/or as an automatic ongoing compensatory mechanism responding to varying patient respiratory demand.

WO 2010/036816 A1

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

INVERSION-BASED FEED-FORWARD COMPENSATION OF INSPIRATORY TRIGGER DYNAMICS IN MEDICAL VENTILATORS

5

Related Application

This application claims the benefit of U.S. Provisional Application No. 61/100212
10 filed September 25, 2008 and U.S. Non-Provisional Application No. 12/566119 filed
September 24, 2009, which applications are hereby incorporated herein by reference.

Background

15 The present description pertains to ventilator devices used to provide breathing assistance. Modern ventilator technologies commonly employ positive pressure to assist patient-initiated inspiration (inhalation). For example, after detecting that the patient wants to inhale, the ventilator control systems track a reference trajectory to increase pressure in an inhalation airway connected to the patient, causing or assisting the
20 patient's lungs to fill. The tracking fidelity of the generated pressure (compared against the desired reference trajectory) and timely delivery of demanded flow are important factors impacting patient-ventilator synchrony and patient's work of breathing. Upon reaching the end of the inspiration, the patient is allowed to passively exhale and the ventilator controls the gas flow through the system to maintain a designated airway
25 pressure level (PEEP) during the exhalation phase.

Modern ventilators typically include microprocessors or other controllers that employ various control schemes. These control schemes are used to command a pneumatic system (e.g., valves) that regulates the flow rates of breathing gases to and from the patient. Closed-loop control is often employed, using data from pressure/flow
30 sensors.

Generally, it is desirable that the control methodology cause a timely response to closely match the desired quantitative and timing requirements of the operator-set ventilation assistance. However, a wide range of variables can significantly affect the way ventilator components respond to commands issued from the controller to generate
5 the intended pressure waveform. For example, the compliance of the patient breathing circuit, the mechanical and transient characteristics of pneumatic valves, the resistance of the circuit to gas flow, etc. and patient's breathing behavior can cause significant variation or delays in the resulting pressure/flow waveforms compared to the desired reference. Furthermore, even when very specific situational information is available
10 (e.g., concerning patient and device characteristics), existing control systems are often sub-optimal in leveraging this information to improve ventilator performance.

Brief Description of the Drawings

Fig. 1 is a schematic depiction of a ventilator.

Fig. 2 schematically depicts control systems and methods that may be employed
15 with the ventilator of Fig. 1.

Fig. 3 schematically depicts an exemplary lumped parameter model which may be used to derive supplemental control commands shown in Figs. 4B, 4C and 4D.

Figs. 4A – 4D depict exemplary tidal breathing in a patient, and examples of control commands which may be employed in a ventilator to assist tidal breathing with
20 inspiratory pressure support.

Fig. 5 depicts a touch-sensitive display interface that may be used with the ventilator of Fig. 1.

Detailed Description

Fig. 1 depicts a ventilator 20 according to the present description. As will be described in detail, the various ventilator embodiments described herein may be provided with improved control schemes. These control schemes typically enhance closed-loop control performance, and may be operator-selected to account for specific factors relating to the device, patient and/or use setting. When implemented for spontaneous breathing, the control methodologies normally command a specified ventilatory support following detection of patient inspiratory effort. This compensatory support is in addition to that commanded by the primary closed-loop control system, and its application improves response time, patient-ventilator synchrony and other aspects of system performance. The compensatory support is (model) inversion-based and computed from known and/or estimated hardware and/or patient characteristics model(s) and measured parameters of breathing behavior. After determination of the quantity and temporal waveform of the compensation, it is delivered by feedforward mechanism as an added component to the desired signal reference trajectory generated by the ventilator's closed-loop controller. Also, it is envisioned that a compensatory mechanism could be designed based on the same concept and adapted as a transitory augmentation to the actuator command. The present discussion will focus on specific example embodiments, though it should be appreciated that the present systems and methods are applicable to a wide variety of ventilatory devices.

Referring now specifically to Fig. 1, ventilator 20 includes a pneumatic system 22 for circulating breathing gases to and from patient 24 via airway 26, which couples the patient to the pneumatic system via physical patient interface 28 and breathing circuit 30. Breathing circuit 30 typically is a two-limb circuit having an inspiratory limb

32 for carrying gas to the patient, and an expiratory limb 34 for carrying gas from the patient. A wye fitting 36 may be provided as shown to couple the patient interface to the two branches of the breathing circuit. The present description contemplates that the patient interface may be invasive or non-invasive, and of any configuration suitable for
5 communicating a flow of breathing gas from the patient circuit to an airway of the patient. Examples of suitable patient interface devices include a nasal mask, nasal/oral mask (which is shown in Fig. 1), nasal prong, full-face mask, tracheal tube, endotracheal tube, nasal pillow, etc.

Pneumatic system 22 may be configured in a variety of ways. In the present
10 example, system 22 includes an expiratory module 40 coupled with expiratory limb 34 and an inspiratory module 42 coupled with inspiratory limb 32. Compressor 44 is coupled with inspiratory module 42 to provide a gas source for controlled ventilatory support via inspiratory limb 32.

The pneumatic system may include a variety of other components, including
15 air/oxygen supply sources, mixing modules, valves, sensors, tubing, accumulators, filters, etc.

Controller 50 is operatively coupled with pneumatic system 22, and an operator interface 52 may be provided to enable an operator to interact with the ventilator (e.g., change ventilator settings, select operational modes, view monitored parameters, etc.).
20 Controller 50 may include memory 54, one or more processors 56, storage 58, and/or other components of the type commonly found in measurement, computing, and command and control devices. As described in more detail below, controller 50 issues commands to pneumatic system 22 in order to control the breathing assistance provided to the patient by the ventilator. The specific commands may be based on inputs

sensed/received from patient 24, pneumatic system 22 including transducers and data acquisition modules, operator interface 52 and/or other components of the ventilator. In the depicted example, operator interface includes a display 59 that is touch-sensitive, enabling the display to serve both as an input and output device.

5 Fig. 2 schematically depicts exemplary systems and methods of ventilator control. As shown, controller 50 issues control commands 60 to ultimately drive pneumatic system 22 and thereby regulate circulation (delivery and exhaust) of breathing gas to and from patient 24. The command(s) 60 to the Flow Controller 71 and ultimately to the pneumatic system actuator(s) to regulate flow rates of different gases 10 such as air and/or oxygen (as applicable based on set mix ratio) is (are) calculated and combined based on two methods: closed-loop control of the output signal and inversion-based compensatory feedforward. For example, in the case of a spontaneously breathing patient on Pressure Support, the closed-loop control system may be envisioned to consist of a closed-loop pressure controller in cascade with closed-loop flow controller 71 (more 15 than one flow controller in cases when flow rates of more than one gas need to be regulated). In this example, at every control cycle (e.g., every 5 ms) the closed-loop pressure controller computes a flow rate command based on the measured pressure error derived from a comparison against the desired pressure trajectory. The Supplemental Controller 50, under this example, utilizes an inversion-based method to compute from 20 known and/or estimated hardware models (breathing circuit resistance and compliance, actuator dead bands and delays, etc.) and/or patient characteristics (respiratory resistance and compliance) or measured parameters of breathing behavior (e.g., estimated pressure drop caused by patient inspiratory effort), or controller delays to determine the quantity and temporal waveform of the compensation and calculates the corresponding command

(in this example, the supplemental flow rate) for each control cycle. In this example, the additional (flow) command is added to the desired flow reference command generated by the pressure controller. The combined Supplemental flow command 60b and pressure Controller flow command 60a constitutes the reference input 60 to the flow controller 71. In general, in the case of Pressure Support, the closed-loop controller may be designed in different ways and as an example it could consist of a single pressure controller combined with a mix controller that closes the loop on the measured pressure signal. In this case or other closed-loop control design variations, the nature of the compensatory feedforward supplement would be determined in compliance with the physical units of the resulting command.

Fig. 3 represents a simplified lumped-parameter analog model 81 for patient circuit and single-compartment respiratory system. Patient circuit is represented by resistance Rt 82 and compliance Ct 84. The patient's respiratory dynamics are captured by total respiratory resistance Rp 86, total respiratory compliance Cp 88, and patient-generated muscle pressure Pmus 90. Using this model, the time response of the airway pressure Paw 92 is a function of patient muscle pressure Pmus 90 and lung flow Qp 94 subsequent to ventilator output flow Qv 96 as determined and delivered by a ventilator 98 command and control subsystems and ventilator-patient interactive characteristics. In patient-initiated triggering, the airway pressure drops below the baseline and lung flow increases concomitantly as a result of the patient's inspiratory effort and the negative pressure generated in the lung. The current embodiment may employ this model as the inversion mechanism to compute an optimum additional volume of gas to be feed-forward as a supplement to the flow rates determined by the closed-loop controller. The additional volume will be commanded independent of the closed-loop pressure

regulation controller and delivered in accordance with a specified flow time trajectory. During the patient triggering process, the pressure drop generated by the patient effort will be indicated by a corresponding pressure drop at the patient wye and increasing flow into the lung. To bring back the lung pressure to the baseline level at the initial phase of an inspiration, one way to compute the volume of gas required to be added into the lung would be to estimate the lung pressure,

$$P_{lung}=P_{aw}-R_p*Q_p,$$

then, calculate the drop from baseline, and finally compute the additional volume using a given or an estimated value for lung compliance:

$$\Delta V = \Delta P * C_p$$

In this example, the proposed algorithmic process may consist of two basic steps:

1. The wye (proximal patient-circuit interface) pressure and lung flow waveforms during the triggering process leading to the ventilator's successful transition into inspiration may be used in conjunction with the estimated ventilator-plant parameters (including actuator and controller time delays and patient respiratory mechanics) and patient comfort considerations to compute an optimum gas volume to be supplemented as an added flow rate over time to the flow determined by the closed-loop controller(s). The feedforward flow is intended to enhance more effective pressure recovery to the designated baseline and thus minimizing the patient's triggering work of breathing and enhancing comfort.

2. The compensatory volume will be commanded independent of the closed-loop pressure regulation controller and delivered in accordance with a specified flow time trajectory. This trajectory will consist of two sections: an initial step of amplitude (Qaddmax) and duration Tstep 76 initiated immediately after trigger detection and

followed by a final exponential drop from Qaddmax plateau to zero by a specified time constant Tauexp 78, shown in Figs. 4B – 4D. These parameters may be set adaptively based on patient breathing behavior and ventilator performance or optimum fixed values could be determined to enable satisfactory performance for each patient type. The
5 ultimate goal would be to minimize the work or triggering, minimize tracking error, and ensure patient comfort and patient-ventilator synchrony.

The depicted schematic interaction between pneumatic system 22 and patient 24, as shown in Fig. 1 and Fig. 2, may be viewed in terms of pressure or flow "signals." For example, signal 62 may be an increased pressure which is applied to the patient via
10 inspiratory limb 32. Control commands 60 are based upon inputs received at controller 50 which may include, among other things, inputs from operator interface 52, and feedback from pneumatic system 22 (e.g., from pressure/flow sensors) and/or sensed from patient 24.

Controller 50, as shown in Fig. 1 and Fig. 2, may be configured to implement a
15 wide variety of control methodologies, though the present examples have proved particularly useful in the context of patient-triggered pressure-based ventilation. In particular, ventilator 20 is adapted to detect inspiratory efforts of patient 24, and respond by delivering positive pressure to assist the breathing effort. Magnitude, timing and other characteristics of the positive pressure assist may be controlled in response to
20 feedback received from the device (e.g., user interface 59, pneumatic system 22) or patient 24. In many cases, patient feedback is inferred from device data. For example, a relatively rapid pressure drop at the patient interface 36 may be used to infer an inspiratory patient effort. The magnitude of this pressure drop together with patient's respiratory mechanics parameters (given or estimated) and breathing circuit

characteristics could be used to estimate the gas volume required to be added into the lung to bring back the lung pressure to the baseline.

Ventilator control may be further understood with reference to Fig. 4A – 4D. Fig. 4A shows several cycles of typical tidal breathing, in terms of lung flow and airway
5 pressure. As discussed above, a patient may have difficulty achieving normal tidal breathing, due to illness or other factors. In some cases, normal lung volumes may be achieved without mechanical ventilation, but only with debilitating effort that can impede healing or cause further physiological damage. In other cases, disease factors prevent the patient from achieving tidal volumes without assistance.

10 Regardless of the particular cause or nature of the underlying condition, ventilator 20 typically provides breathing assistance via positive pressure during inspiration. Figs. 4B – 4D show example control signal waveforms, to be explained in more detail below, that may be used to drive pneumatic system 22 to deliver the desired pressure support. In many cases, the goal of the control system is to deliver a controlled
15 pressure profile or trajectory (e.g., pressure as a function of time) during the inspiratory or expiratory phases of the breathing cycle. In other words, control is performed to achieve a desired time-varying pressure output 62 from pneumatic system 22, with an eye toward achieving or aiding breathing.

As shown in Fig. 2, controller 50 includes a primary controller 70, also referred
20 to as the “feedback” controller, that generates command 60a intended to target the desired reference trajectory, and a supplemental controller 72 to augment the closed loop control with command 60b and proactively compensate for system latencies caused by multiple factors as discussed above. The compensatory quantity and its temporal

delivery characteristics are determined based on specific operational settings, to enhance patient-ventilator synchrony and control system dynamic effectiveness.

For a given respiratory therapy, the treatment goal is often set in terms of the timing and amount of increased pressure and gas mixture delivered to the patient during
5 inspiration and maintenance of a set airway pressure during exhalation. Accordingly, a design focus of the control system should be to quickly and accurately detect the beginning of the patient's attempted inspiration, and then have the mechanical system rapidly respond to track the desired pressure trajectory with optimum fidelity.

As shown in Fig. 2, controller 70 is designed to provide such closed-loop control.
10 In particular, controller 50 detects airway pressure (e.g., via feedback signal F) drop from baseline (Pressure Triggering mechanism) or increased lung flow (Flow Triggering mechanism) to establish initiation of inspiratory support. Closed-loop controller 70 and supplemental controller 72 then work in concert to command pneumatic system 22 to provide the desired inspiratory signal trajectory.

15 As will be described in more detail below, the provision of a supplemental control enables the operator of the ventilator to more accurately account and compensate for various factors affecting system dynamics in a more timely fashion. For example, pneumatic system 22 contains many components that can significantly affect the response produced by a given control command, such as command 60a. Further, the
20 patient constitutes a major variable whose time-varying and hard-to-predict breathing behavior is unknown to typical ventilator closed-loop controllers and would cause variations and latencies in the controller's tracking performance.

In particular, pneumatic system 22 typically includes multiple modules, each having various components. Valve characteristics, the geometry and compliance of

pneumatic passages, conduit resistance to gas flow, actuator/controller time delays, humidifier parameters, filter types and a host of other factors can affect system dynamics. In particular, these components can create variable lags, such that the pressure in inspiratory limb 32 may rise more slowly than desired. This lagging of the
5 desired trajectory would require the patient to do more breathing work during inspiration, and thereby may negatively impact treatment.

A number of patient characteristics and breathing behavior can also affect the system's dynamic performance. The patient characteristics may define or describe physiological traits of the patient, including respiratory musculature, baseline or
10 expected respiratory performance, height, weight, specific disease/illness indications, age, sex, etc.

Closed-loop controller 70 may employ various control schemes, and typically is designed to command the output to a desired value or trajectory without addition of any model-based feedforward supplemental control regimes computed based on the
15 inversion of the ventilator-patient model under ongoing dynamic conditions using available measurements. However, due to the nature of the closed loop control and the potential wide variation in device and patient characteristics, signal 60a may produce sub-optimal pressure response and/or patient-device synchrony. Accordingly, supplemental controller 72 may provide an additional command signal 60b to
20 substantially decrease the patient work effort during inspiration, allowing the breathing assistance provided by the ventilator to be properly synchronized with the patient initiated breathing cycle. As one example, command signal 60b may be generated using a feed-forward predictive model, to be discussed in more detail herein, which leverages a richer data set concerning the device and/or patient to fine tune ventilator performance.

Indeed, command signal 60b may take into account plant parameters, such as delays caused by ventilator components, and/or patient parameters affecting system transfer functions. In this way proper triggering can occur and the performance of the overall pneumatic system can be better synchronized with the respiratory cycle of the
5 patient. Signal 60b typically is not intended to be used as the primary control strategy. Rather, it provides an additional feed-forward input to minimize delays and otherwise fine tune controller tracking fidelity during inspiration. Because the supplementary command acts as an adjunct to the primary closed-loop controller, instead of replacing it, the primary closed-loop feature would protect against delivery of excessively high
10 commands. In other words, even though the added control is feed-forward and independent of the closed-loop controller, the ultimate output flow to the patient is regulated by the closed-loop regime, i.e., at every control cycle (e.g., 5 ms), the contribution of the feedback controller to the total command would be promptly reduced in case of output deviation caused by the supplemental command.

15 Figs. 4B, 4C and 4D show exemplary control waveforms that may be provided by the supplemental feed-forward controller 72. The different supplemental waveforms 60b1, 60b2 and 60b3 are alternatives that may be selected for different circumstances. In other words, supplemental command 60b1 might be applied in a first operational environment, with supplemental command 60b2 being used in a different operational
20 environment, for example on a patient with a different breathing characteristic or type of illness (when available). In each of the three examples, the supplemental command is provided rapidly upon detection of the trigger (patient initiates in-breath), and the signal waveform may be described in terms of three aspects. The first aspect is gain or rise 74. The gain may be a simple step-up to the maximum flow rate Qmax, as shown in Figs.

4B and Fig. 4C. In another example, the gain may occur over time, as shown in Fig. 4D. Accordingly, the gain may be described in terms of magnitude Qmax and time. The second aspect, Tstep 76, is the amount of time over which Qmax is delivered. A third aspect is the exponential decay trajectory time constant Tauexp 78.

5 These control signal aspects may be modified as necessary to achieve control design and ultimately treatment objectives. In one example, the patient may periodically generate a larger inspiratory effort and demand an increased tidal volume and duration of the breathing cycle. To account for these variations, Qmax and Tstep, or Tauexp may be adjusted accordingly. Alternatively, the shape of the waveform generated by the 10 supplemental controller 72 may be trapezoidal, sawtooth or have other forms. The specific waveform 60b1, 60b2, 60b3 (or others) typically is selected based on desired output of the system and to account for device and patient characteristics.

The systems and methods described herein may employ this model as an inversion mechanism to compute an optimum additional volume of gas to be feed-15 forward as a supplement to the flow rates commanded by the primary controller 70. As further described herein, the additional volumes are determined independently of the closed-loop pressure regulation controller (controller 70) and in accordance with a specified flow time trajectory (see supplemental commands 60b1, 60b2, etc.)

The values of the various lumped-parameters may be calculated based on data 20 associated with the ventilator device, patient, operational setting, and ongoing pressure and flow measurements, etc. For example, inputs into operator interface 52 may be used to set values for the lumped parameters. Then, during operation of the ventilator, the supplemental controller calculates compensatory regimes to be feed-forward and commanded by the primary flow controller 71.

In other examples, the model may be expanded to include additional components to model further aspects of the patient-ventilator system. Alternatively, other types of predictive modeling may be used to synchronize the ventilator with the patient's breathing cycle and improve system response.

5 As shown in Fig. 4, the control enhancement provided by supplemental controller 72 may take various forms. For example, commands 60b may be selected differently in order to provide different pressure trajectory enhancements, such as faster rise time, pressure boosts of varying magnitude/duration, etc. In various example embodiments, ventilator 20 may be configured to allow an operator to select control 10 enhancement via interaction with operator interface 52. For example, selection of a first parameter or parameter combination might cause controller 72 to produce commands 60b1, while a second parameter/combination might produce commands 60b2 and so on.

Fig. 5 schematically depicts an exemplary interface scheme for selecting various parameters to control operation of supplemental controller 72. The depicted exemplary 15 scheme may be applied to the controller through various input / interface mechanisms, including through use of operator interface 52. For example, touch-sensitive display 59 may include a high-level menu option, as indicated, for entering a portion of the interface where specific supplemental control parameters can be selected. As indicated, the operator may be permitted to select ventilator/device parameters and/or parameters 20 associated with the patient. As indicated ventilator/device parameters may include type of patient interface; etc. Patient parameters may include information concerning respiratory dynamics; respiration rates; patient physiological data; specification of whether the patient is adult, pediatric, neonatal, etc.; whether disease factors A, B and/or C, etc. are present. These are but a few of the many possible parameters that can be

selected (e.g., by an operator) or estimated online by the ventilator to tune the feed-forward trajectories commanded by supplemental controller 72. The main parameters to consider in conjunction with the lumped-parameter model are: tubing characteristics (resistance, compliance), patient respiratory mechanics (resistance, compliance), 5 actuator dead bands and controller delays.

A variety of advantages may be obtained through use of the exemplary control systems and methods described herein. Respiratory therapy can be effectively improved through provision of the independent enhanced controller 72, because it provides an operator tunable and/or patient-interactive model-based mechanism for enriching the 10 parameter set used to control the ventilatory assistance. In particular, a multitude of additional ventilator and patient variables may be selected to tune the controller and improve the fidelity with which the system tracks the desired output trajectory. The resulting speed and fidelity improvements lead to better synchrony of the device with the patient's spontaneous breathing operation, a key measure of ventilator performance. 15 Furthermore, since the primary closed-loop control system still constrains system output, integration of the enhanced supplemental control typically will not pose system overshoot or stability problems.

It will be appreciated that the embodiments and method implementations disclosed herein are exemplary in nature, and that these specific examples are not to be 20 considered in a limiting sense, because numerous variations are possible. The subject matter of the present disclosure includes all novel and nonobvious combinations and subcombinations of the various configurations and method implementations, and other features, functions, and/or properties disclosed herein. Claims may be presented that particularly point out certain combinations and subcombinations regarded as novel and

nonobvious. Such claims may refer to "an" element or "a first" element or the equivalent thereof. Such claims should be understood to include incorporation of one or more such elements, neither requiring nor excluding two or more such elements. Other combinations and subcombinations of the disclosed features, functions, elements, and/or
5 properties may be claimed through amendment of the present claims or through presentation of new claims in this or a related application. Such claims, whether broader, narrower, equal, or different in scope to the original claims, also are regarded as included within the subject matter of the present disclosure.

WHAT IS CLAIMED IS:

1. A ventilator, comprising:

a pneumatic system for providing and receiving breathing gas;

a controller operatively coupled with the pneumatic system; and

5 an operator interface, where the controller is operable to:

execute a control scheme to command the pneumatic system to provide pressure assistance to a patient during inspiration, where such pressure assistance is provided in response to the ventilator detecting that the patient is attempting to initiate inspiration; and

10 command delivery of additional breathing gas to the patient during inspiration, where such addition is commanded in response to operator selection of at least one of a ventilator parameter and a patient parameter at the operator interface.

2. The ventilator of claim 1, where the patient parameter enables specification of patient age.

15 3. The ventilator of claim 2, where the patient parameter enables specification that the patient is an adult patient.

4. The ventilator of claim 2, where the patient parameter enables specification that the patient is a pediatric patient.

5. The ventilator of claim 2, where the patient parameter enables

20 specification that the patient is a neonatal patient.

6. The ventilator of claim 1, where the patient parameter enables specification of a patient disease condition.

7. The ventilator of claim 1, where the patient parameter enables specification of a physiological characteristic of the patient.

8. The ventilator of claim 1, where the ventilator parameter enables specification of characteristics of airway components used to couple the patient to the
5 pneumatic system.

9. The ventilator of claim 1, where the ventilator parameter enables specification of characteristics of the pneumatic system.

10. A ventilator, comprising:

a pneumatic system for providing and receiving breathing gas; and

10 a controller operatively coupled with the pneumatic system, where the controller is operable to:

receive a baseline closed-loop input corresponding to a desired output pressure of breathing gas from the pneumatic system;

receive an additional feed-forward input corresponding to a desired boost
15 pressure waveform to be added to the desired output pressure, the additional feed-forward input being dependent upon at least one of an operator-selected ventilator parameter and an operator-selected patient parameter;

detect patient initiation of an inspiratory phase of a respiration cycle; and

during the inspiratory phase, command the pneumatic system to provide positive
20 pressure breathing assistance based on the closed-loop input and the additional feed-forward input, the positive pressure breathing assistance being constrained through application of a feedback signal to the controller.

11. The ventilator of claim 10, further comprising an operator interface operatively coupled with the controller and configured to enable an operator to select at least one ventilator parameter and patient parameter.

12. The ventilator of claim 10, further comprising a patient breathing circuit
5 and a physical patient interface configured to couple a patient to the pneumatic system.

13. The ventilator of claim 10, where the patient parameter includes specification of patient age.

14. The ventilator of claim 13, where the patient parameter includes specification that the patient is an adult patient.

10 15. The ventilator of claim 13, where the patient parameter includes specification that the patient is a pediatric patient.

16. The ventilator of claim 13, where the patient parameter includes specification that the patient is a neonatal patient.

17. The ventilator of claim 10, where the patient parameter includes
15 specification of a patient disease condition.

18. The ventilator of claim 10, where the patient parameter includes specification of a physiological characteristic of the patient.

19. The ventilator of claim 10, where the ventilator parameter includes specification of characteristics of airway components used to fluidly couple the patient
20 to the pneumatic system.

20. The ventilator of claim 10, where the ventilator parameter includes specification of characteristics of the pneumatic system.

21. A method of operating a patient-triggered, positive pressure ventilator, comprising:

driving a pneumatic system of the ventilator with a closed-loop control regime to provide positive pressure breathing assistance during inspiration;

5 providing a supplemental added pressure boost during inspiration in addition to the breathing assistance commanded by the closed-loop control regime; and

setting the supplemental added pressure boost based on operator input of at least one of a ventilator parameter and a patient parameter.

22. The method of claim 21, where the supplemental added pressure boost is 10 applied during each of a plurality of respiration cycles, subsequent to patient-triggering of inspiration.

23. The method of claim 21, where the supplemental added pressure boost is tunable from one therapy session to the next, such that in a first therapy session, the positive pressure breathing assistance supplied by the closed loop-control regime is 15 supplemented with a first supplemental added pressure boost, while during a second therapy session, the positive pressure breathing assistance supplied by the closed loop-control regime is supplemented with a second supplemental added pressure boost which is different from the first, such difference being based on a change in at least one of the ventilator parameter and the patient parameter.

20

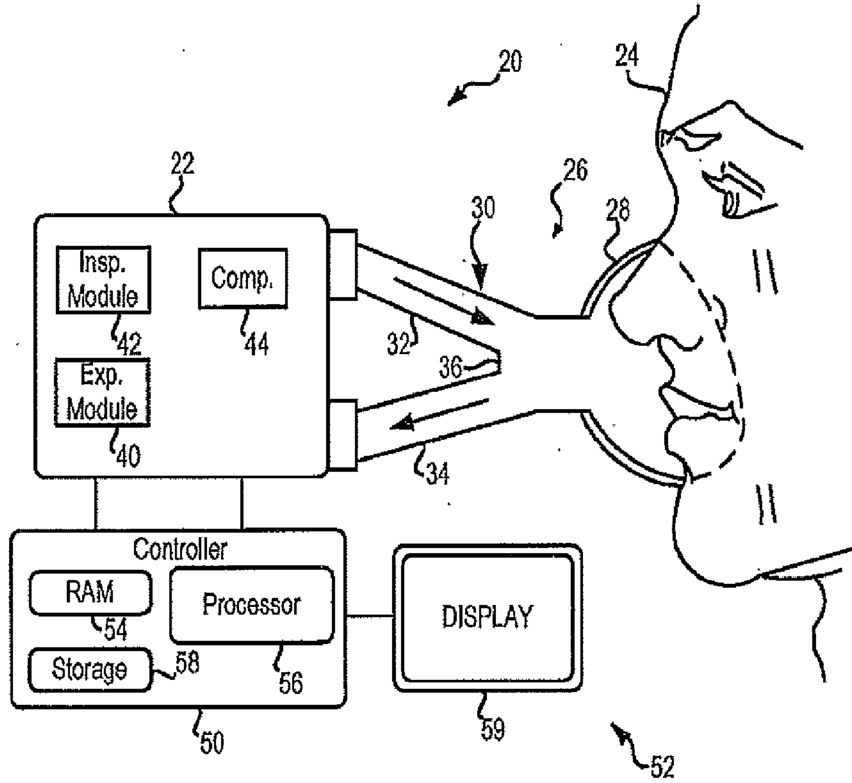


Fig. 1

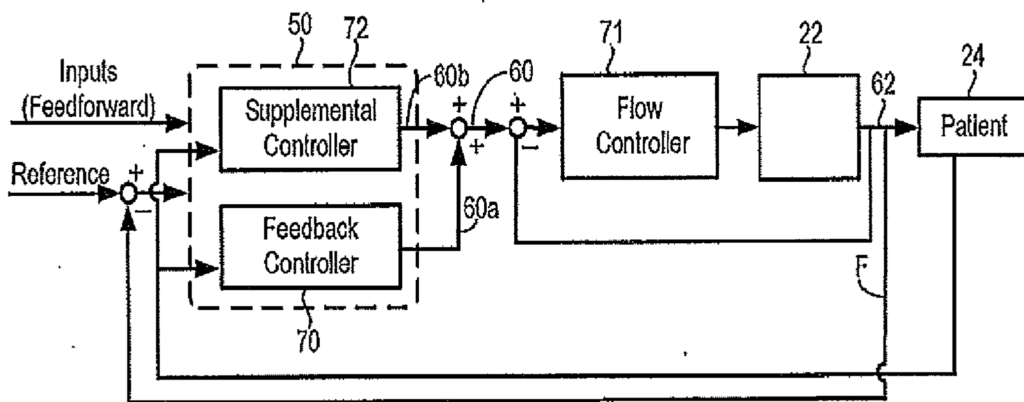


Fig. 2

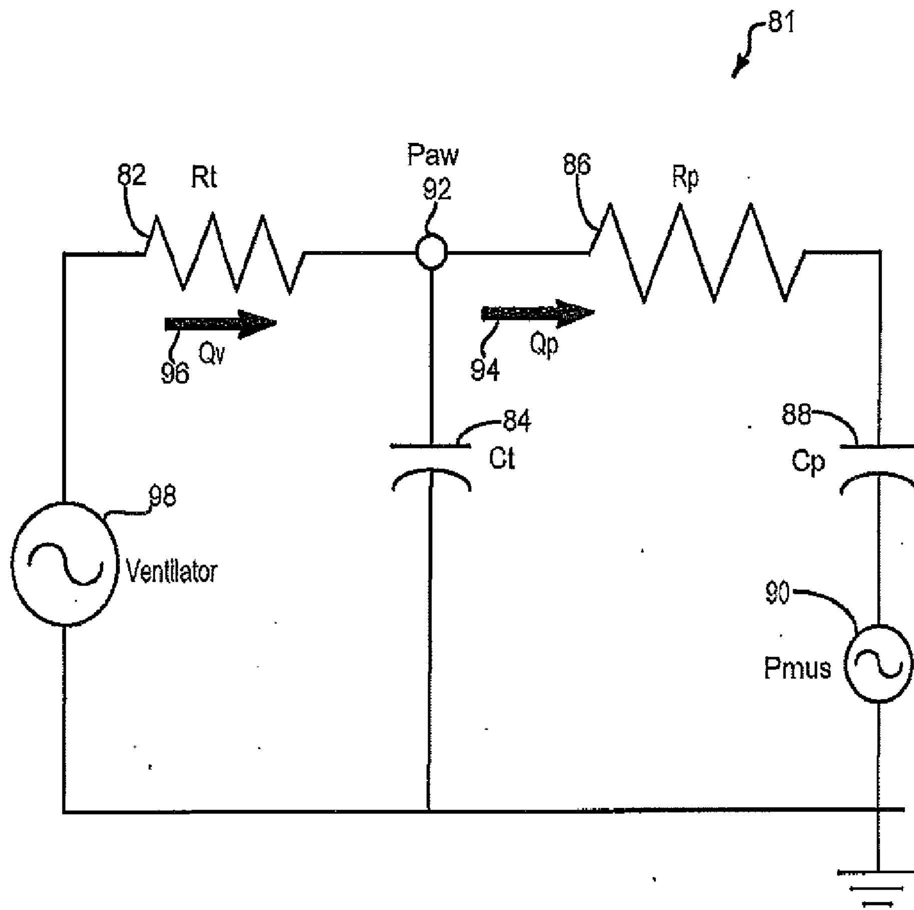
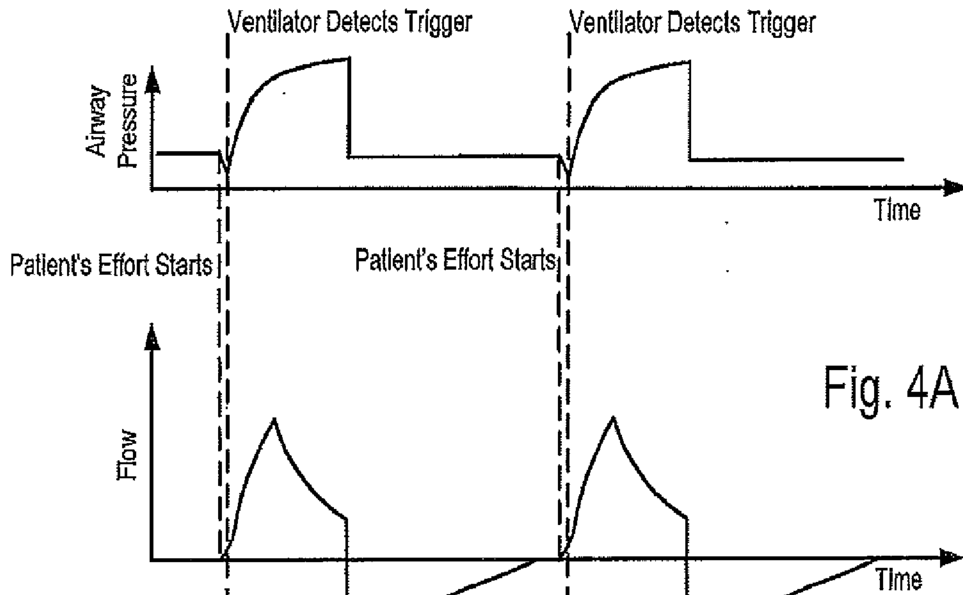
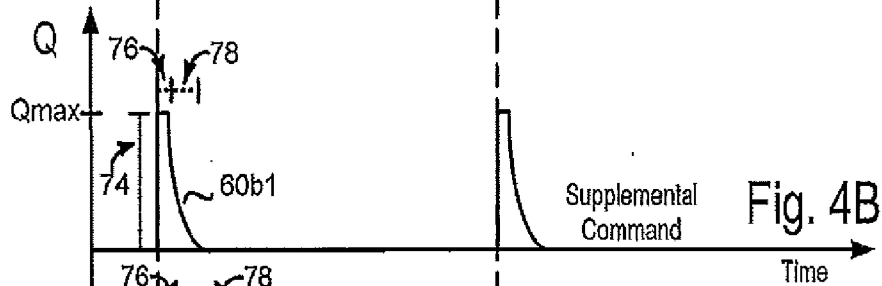
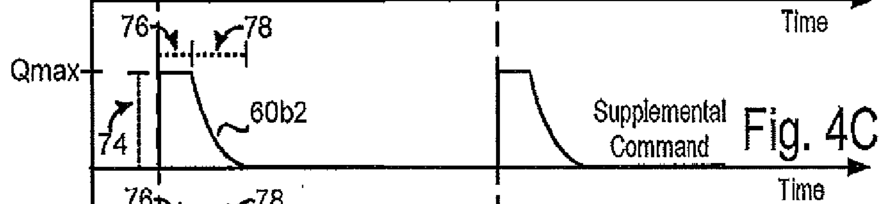
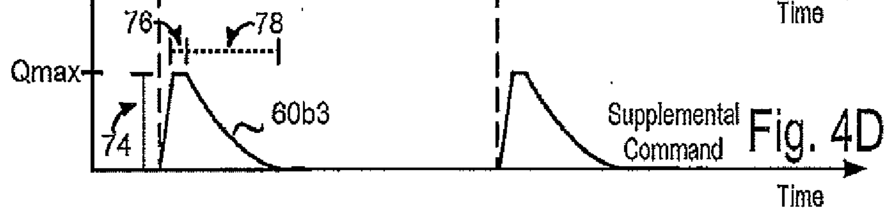


Fig. 3


Ventilator Detects Trigger
Ventilator Detects Trigger
Airway Pressure
Time
Patient's Effort Starts
Patient's Effort Starts
Flow
Time
Fig. 4A


Q
76
78
Qmax
74
60b1
Supplemental Command
Fig. 4B
Time


76
78
Qmax
74
60b2
Supplemental Command
Fig. 4C
Time


76
78
Qmax
74
60b3
Supplemental Command
Fig. 4D
Time

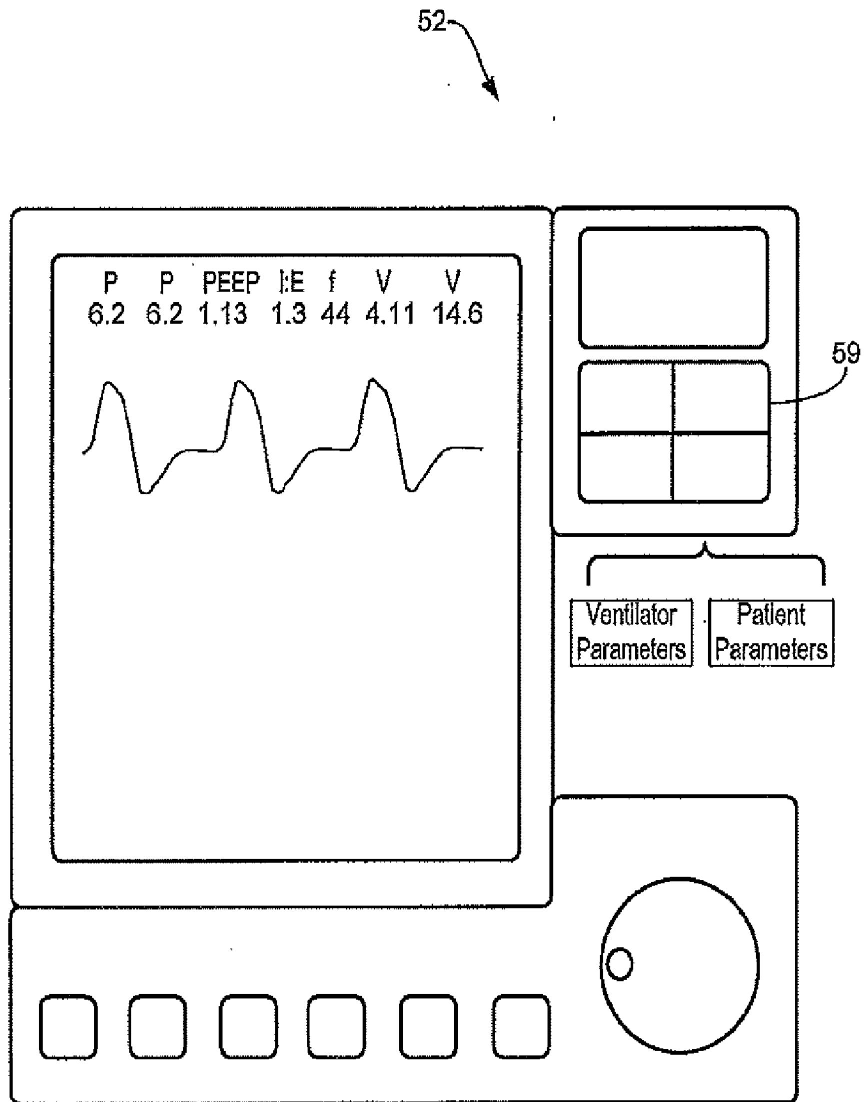


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/058252

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00

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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/178880 A1 (CHRISTOPHER KENT L [US] ET AL) 31 July 2008 (2008-07-31) paragraphs [0060] - [0092]	1-10, 21-23
A	US 2006/065270 A1 (LI KUN [US]) 30 March 2006 (2006-03-30) paragraphs [0009] - [0019], [0029] - [0056]	10-20
X	US 6 543 449 B1 (WOODRING PAUL L [US] ET AL) 8 April 2003 (2003-04-08) column 5, line 50 - column 13, line 6	1
A	US 2007/274693 A1 (FARBARIK JOHN M [US]) 29 November 2007 (2007-11-29) paragraphs [0021] - [0069]	1-23

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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 document 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	Date of mailing of the international search report
8 December 2009	17/12/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Loughman, John

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/058252

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 269 914 A (SIEMENS ELEMA AB [SE]) 2 January 2003 (2003-01-02) paragraphs [0029] - [0053]	1-23

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/058252

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008178880 A1	31-07-2008	EP 2111247 A2	28-10-2009
		US 2008178882 A1	31-07-2008
		WO 2008092021 A2	31-07-2008
US 2006065270 A1	30-03-2006	AU 2005289817 A1	06-04-2006
		EP 1799292 A1	27-06-2007
		JP 2008514287 T	08-05-2008
		WO 2006036695 A1	06-04-2006
US 6543449 B1	08-04-2003	NONE	
US 2007274693 A1	29-11-2007	WO 2007140208 A2	06-12-2007
EP 1269914 A	02-01-2003	JP 2003061933 A	04-03-2003
		US 2002193699 A1	19-12-2002