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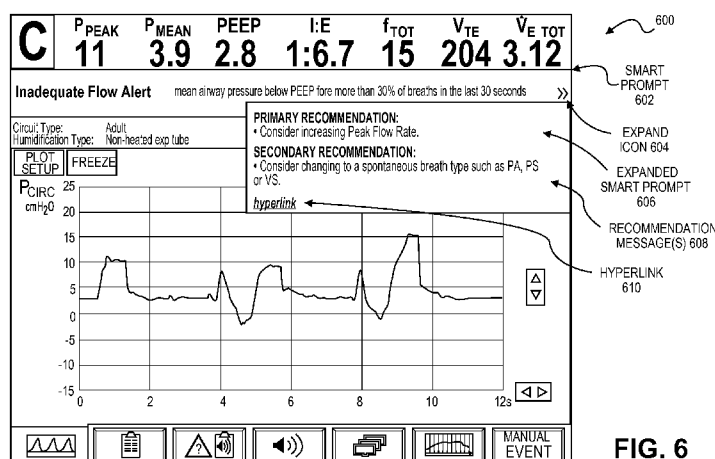
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(54) **Title:** VENTILATOR-INITIATED PROMPT REGARDING DETECTION OF INADEQUATE FLOW DURING VENTILATION

**FIG. 6**

(57) **Abstract:** This disclosure describes systems and methods for monitoring and evaluating ventilatory parameters, analyzing those parameters and providing useful notifications and recommendations to clinicians. That is, modern ventilators monitor, evaluate, and graphically represent multiple ventilatory parameters. However, many clinicians may not easily recognize data patterns and correlations indicative of certain patient conditions, changes in patient condition, and/or effectiveness of ventilatory treatment. Further, clinicians may not readily determine appropriate ventilatory adjustments that may address certain patient conditions and/or the effectiveness of ventilatory treatment. Specifically, clinicians may not readily detect or recognize the presence of inadequate flow during ventilation. According to embodiments, a ventilator may be configured to monitor and evaluate diverse ventilatory parameters to detect inadequate flow and may issue notifications and recommendations suitable for a patient to the clinician when inadequate flow is implicated. The suitable notifications and recommendations may further be provided in a hierarchical format.

**VENTILATOR-INITIATED PROMPT REGARDING DETECTION OF
INADEQUATE FLOW DURING VENTILATION**

Introduction

A ventilator is a device that mechanically helps patients breathe by replacing
5 some or all of the muscular effort required to inflate and deflate the lungs. In recent
years, there has been an accelerated trend towards an integrated clinical environment.
That is, medical devices are becoming increasingly integrated with communication,
computing, and control technologies. As a result, modern ventilatory equipment has
become increasingly complex, providing for detection and evaluation of a myriad of
10 ventilatory parameters. However, due to the sheer magnitude of available ventilatory
data, many clinicians may not readily assess and evaluate the diverse ventilatory data to
detect certain patient conditions and/or changes in patient conditions, such as an
inadequate set flow. For example, an inadequate set flow may lead to an increase in
work of breathing (i.e. the amount of patient effort exerted to breath).

15 Indeed, clinicians and patients may greatly benefit from ventilator notifications
when evaluation of various ventilatory data is indicative of certain patient conditions,
changes in patient conditions, effectiveness of ventilatory therapy, or otherwise.

**Ventilator-Initiated Prompt Regarding Detection of an Inadequate Set Flow
during Ventilation of a Patient**

20 This disclosure describes systems and methods for monitoring and evaluating
ventilatory parameters, analyzing ventilatory data associated with those parameters, and
providing useful notifications and/or recommendations to clinicians. Modern ventilators
monitor, evaluate, and graphically represent a myriad of ventilatory parameters.
However, many clinicians may not easily identify or recognize data patterns and
25 correlations indicative of certain patient conditions, changes in patient condition, and/or
effectiveness of ventilatory treatment. Further, clinicians may not readily determine
appropriate ventilatory adjustments that may address certain patient conditions and/or
the effectiveness of ventilatory treatment. Specifically, clinicians may not readily detect
or recognize the presence of inadequately set flow. According to embodiments, a
30 ventilator may be configured to monitor and evaluate diverse ventilatory parameters to
detect an inadequate flow and may issue notifications and recommendations suitable for
a patient to the clinician when an inadequate flow is implicated. The suitable

notifications and recommendations may further be provided in a hierarchical format such that the clinician may selectively access summarized and/or detailed information regarding the presence of an inadequate flow. In more automated systems, recommendations may be automatically implemented.

5 According to embodiments, ventilator-implemented methods for detecting an inadequate flow are provided. The methods include collecting data associated with ventilatory parameters and processing the collected ventilatory parameter data, wherein processing the collected ventilatory parameter data includes deriving ventilatory
10 parameter data from the collected ventilatory parameter data. The methods also include analyzing the processed ventilatory parameter data, which includes receiving one or more predetermined thresholds associated with the processed ventilatory parameter data and detecting whether the processed ventilatory parameter data breaches the one or
15 more predetermined thresholds. The methods include determining that an inadequate flow is implicated upon detecting that the processed ventilatory data breaches the one or more predetermined thresholds for more than a percentage of the patient-initiated
mandatory breaths (e.g., 10% or 30%) within a predetermined amount of time or that the processed ventilatory data breaches the one or more predetermined thresholds for more
20 than a certain number of breaths (e.g., 3 breaths) within a predetermined amount of time. When an inadequate flow is implicated, the methods include issuing a smart prompt.

 According to further embodiments, a ventilatory system for issuing a smart prompt when an inadequate flow is implicated during ventilation of a patient is provided. An appropriate notification message and an appropriate recommendation
25 message may be determined and either or both of the appropriate notification message and the appropriate recommendation message may be displayed.

 According to further embodiments, a graphical user interface for displaying one or more smart prompts corresponding to a detected condition is provided. The graphical user interface includes at least one window and one or more elements within the at least
30 one window comprising at least one smart prompt element for communicating information regarding the detected condition, wherein the detected condition is an inadequate flow.

 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.

5 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 claims.

Brief Description of the Drawings

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

FIG. 1 is a diagram illustrating an embodiment of an exemplary ventilator connected to a human patient.

FIG. 2 is a block-diagram illustrating an embodiment of a ventilatory system for
15 monitoring and evaluating ventilatory parameters associated with an inadequate flow.

FIG. 3 is a flow chart illustrating an embodiment of a method for detecting an implication of an inadequate flow.

FIG. 4 is a flow chart illustrating an embodiment of a method for issuing a smart prompt upon detecting an implication of an inadequate flow.

20 FIG. 5 is an illustration of an embodiment of a graphical user interface displaying a smart prompt having a notification message.

FIG. 6 is an illustration of an embodiment of a graphical user interface displaying an expanded smart prompt having a notification message and one or more recommendation messages.

Detailed Description

25 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 for use in a mechanical ventilator system. The reader will understand that the technology described in the context of a ventilator system
30 could be adapted for use with other therapeutic equipment for alerting and advising clinicians regarding detected patient conditions.

This disclosure describes systems and methods for monitoring and evaluating ventilatory parameters, analyzing ventilatory data associated with those parameters, and providing useful notifications and/or recommendations to clinicians. Modern ventilators monitor, evaluate, and graphically represent a myriad of ventilatory parameters.

5 However, many clinicians may not easily identify or recognize data patterns and correlations indicative of certain patient conditions, changes in patient condition, and/or effectiveness of ventilatory treatment. Further, clinicians may not readily determine appropriate ventilatory adjustments that may address certain patient conditions and/or the effectiveness of ventilatory treatment. Specifically, clinicians may not readily detect
10 or recognize the presence of an inadequate flow during ventilation of a patient.

According to embodiments, a ventilator may be configured to monitor and evaluate diverse ventilatory parameters to detect an inadequate flow and may issue suitable notifications and recommendations to the clinician when an inadequate flow is implicated. The suitable notifications and recommendations may further be provided in
15 a hierarchical format such that the clinician may selectively access summarized and/or detailed information regarding the presence of an inadequate flow. In more automated systems, recommendations may be automatically implemented.

Ventilator System

FIG. 1 is a diagram illustrating an embodiment of an exemplary ventilator **100**
20 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**.

25 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**.

30 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** to provide a gas source for ventilatory support via inspiratory limb **132**.

The pneumatic system **102** may include a variety of other components, including mixing modules, valves, sensors, tubing, accumulators, filters, etc. Controller **110** is
5 operatively 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, breath types, view monitored parameters, etc.). Controller **110** may include memory **112**, one or more processors **116**, storage **114**, and/or other components of the type commonly found
10 in command and control computing devices. In the depicted example, operator interface **120** includes a display **122** that may be touch-sensitive and/or voice-activated, enabling the display **122** to serve both as an input and output device.

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
15 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,
20 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
25 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.

30 Communication between components of the ventilatory system or between the ventilatory system and other therapeutic equipment and/or remote monitoring systems may be conducted over a distributed network, as described further herein, via wired or wireless means. Further, the present methods may be configured as a presentation layer built over the TCP/IP protocol. TCP/IP stands for "Transmission Control

Protocol/Internet Protocol” and provides a basic communication language for many local networks (such as intranets or extranets) and is the primary communication language for the Internet. Specifically, TCP/IP is a bi-layer protocol that allows for the transmission of data over a network. The higher layer, or TCP layer, divides a message into smaller packets, which are reassembled by a receiving TCP layer into the original message. The lower layer, or IP layer, handles addressing and routing of packets so that they are properly received at a destination.

Ventilator Components

FIG. 2 is a block-diagram illustrating an embodiment of a ventilatory system 200 for monitoring and evaluating ventilatory parameters associated with an inadequate flow.

Ventilatory system 200 includes ventilator 202 with its various modules and components. That is, ventilator 202 may further include, *inter alia*, memory 208, one or more processors 206, user interface 210, and ventilation module 212 (which may further include an inspiration module 214 and an exhalation module 216). Memory 208 is defined as described above for memory 112. Similarly, the one or more processors 206 are defined as described above for one or more processors 116. Processors 206 may further be configured with a clock whereby elapsed time may be monitored by the ventilatory system 200.

The ventilatory system 200 may also include a display module 204 communicatively coupled to ventilator 202. Display module 204 provides various input screens, for receiving clinician input, and various display screens, for presenting useful information to the clinician. The display module 204 is configured to communicate with user interface 210 and may 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 (i.e., visual areas) comprising elements for receiving user input and interface command operations and for displaying ventilatory information (e.g., including ventilatory data, alerts, patient information, parameter settings, etc.). The elements may include controls, graphics, charts, tool bars, input fields, smart prompts, etc.

Alternatively, other suitable means of communication with the ventilator 202 may be provided, for instance by a wheel, keyboard, mouse, or other suitable interactive device. Thus, user interface 210 may accept commands and input through display module 204. Display module 204 may also provide useful information in the form of various ventilatory data regarding the physical condition of a patient and/or a prescribed

respiratory treatment. The useful information may be derived by the ventilator **202**, based on data collected by a data processing module **222**, and the useful information may be displayed to the clinician in the form of graphs, wave representations, pie graphs, or other suitable forms of graphic display. For example, one or more smart prompts may be displayed on the GUI and/or display module **204** upon detection of an implication of an inadequate flow by the ventilator. Additionally or alternatively, one or more smart prompts may be communicated to a remote monitoring system coupled via any suitable means to the ventilatory system **200**.

Equation of Motion

Ventilation module **212** may oversee ventilation of a patient according to prescribed ventilatory settings. By way of general overview, the basic elements impacting ventilation may be described by the following ventilatory equation (also known as the Equation of Motion):

$$P_m + P_v = V_T/C + R \cdot F$$

Here, P_m is a measure of muscular effort that is equivalent to the pressure generated by the muscles of a patient. If the patient's muscles are inactive, the P_m is equivalent to 0 cm H₂O. P_m is calculated using the following equation: $P_m = \text{elastance} \times \text{volume} + \text{resistance} \times \text{flow}$. During inspiration, P_v represents the positive pressure delivered by a ventilator (generally in cm H₂O). V_T represents the tidal volume delivered, C refers to the respiratory compliance, R represents the respiratory resistance, and F represents the gas flow during inspiration (generally in liters per min (L/min)). Alternatively, during exhalation, the Equation of Motion may be represented as:

$$P_a + P_t = V_{TE}/C + R \cdot F$$

Here, P_a represents the positive pressure existing in the lungs (generally in cm H₂O), P_t represents the transairway pressure, V_{TE} represents the tidal volume exhaled, C refers to the respiratory compliance, R represents the respiratory resistance, and F represents the gas flow during exhalation (generally in liters per min (L/min)).

Pressure

For positive pressure ventilation, pressure at the upper airway opening (e.g., in the patient's mouth) is positive relative to the pressure at the body's surface (i.e., relative to the ambient atmospheric pressure to which the patient's body surface is

exposed, about 0 cm H₂O). As such, when P_v is zero, i.e., no ventilatory pressure is being delivered, the upper airway opening pressure will be equal to the ambient pressure (i.e., about 0 cm H₂O). However, when ventilatory pressure is applied, a pressure gradient is created that allows gases to flow into the airway and ultimately into the lungs of a patient during inspiration (or, inhalation).

According to embodiments, additional pressure measurements may be obtained and evaluated. For example, transairway pressure, P_t, which refers to the pressure differential or gradient between the upper airway opening and the alveoli, may also be determined. P_t may be represented mathematically as:

10

$$P_t = P_{awo} - P_a$$

Where P_{awo} refers to the pressure in the upper airway opening, or mouth, and P_a refers to the pressure within the alveolar space, or the lungs (as described above). P_t may also be represented as follows:

15

$$P_t = F \cdot R$$

Where F refers to flow and R refers to respiratory resistance, as described below.

20

Additionally, lung pressure or alveolar pressure, P_a, may be measured or derived. For example, P_a may be measured via a distal pressure transducer or other sensor near the lungs and/or the diaphragm. Alternatively, P_a may be estimated by measuring the plateau pressure, P_{plat}, via a proximal pressure transducer or other sensor at or near the airway opening. Plateau pressure, P_{plat}, refers to a slight plateau in pressure that is observed at the end of inspiration when inspiration is held for a period of time, sometimes referred to as an inspiratory hold or pause maneuver, or a breath-hold maneuver. That is, when inspiration is held, pressure inside the alveoli and mouth are equal (i.e., no gas flow). However, as a result of muscular relaxation and elastance of the lungs during the hold period, forces are exerted on the inflated lungs that create a positive pressure. This positive pressure is observed as a plateau in the pressure waveform that is slightly below the peak inspiratory pressure, P_{peak}, prior to initiation of exhalation. As may be appreciated, for accurate measurement of P_{plat}, the patient should be sedated or non-spontaneous (as muscular effort during the inspiratory pause may skew the pressure measurement). Upon determining P_{plat} based on the pressure waveform or otherwise, P_{plat} may be used as an estimate of P_a (alveolar pressure).

35

Flow and Volume

Volume refers to the amount of gas delivered to a patient's lungs, usually in liters (L) or milliliters (ml). Flow refers to a rate of change in volume over time ($F = \Delta V / \Delta t$). Flow is generally expressed in liters per minute (L/m or lpm) and, depending on whether gases are flowing into or out of the lungs, flow may be referred to as inspiratory flow or expiratory flow, respectively. According to embodiments, the ventilator may control the rate of delivery of gases to the patient, i.e., inspiratory flow, and may control the rate of release of gases from the patient, i.e., expiratory flow.

As may be appreciated, volume and flow are closely related. That is, where flow is known or regulated, volume may be derived based on elapsed time. Indeed, volume may be derived by integrating the flow waveform. According to embodiments, a tidal volume, V_T , may be delivered upon reaching a set inspiratory time (T_I) at set inspiratory flow. Alternatively, set V_T and set inspiratory flow may determine the amount of time required for inspiration, i.e., T_I .

Respiratory Compliance

Additional ventilatory parameters that may be measured and/or derived may include respiratory compliance and respiratory resistance, which refer to the load against which the patient and/or the ventilator must work to deliver gases to the lungs. Respiratory compliance may be interchangeably referred to herein as compliance. Generally, compliance refers to a relative ease with which something distends and is the inverse of elastance, which refers to the tendency of something to return to its original form after being deformed. As related to ventilation, compliance refers to the lung volume achieved for a given amount of delivered pressure ($C = \Delta V / \Delta P$). Increased compliance may be detected when the ventilator measures an increased volume relative to the given amount of delivered pressure. Some lung diseases (e.g., acute respiratory distress syndrome (ARDS)) may decrease compliance and, thus, require increased pressure to inflate the lungs. Alternatively, other lung diseases may increase compliance, e.g., emphysema, and may require less pressure to inflate the lungs.

Additionally or alternatively, static compliance and dynamic compliance may be calculated. Static compliance, C_s , represents compliance impacted by elastic recoil at zero flow (e.g., of the chest wall, patient circuit, and alveoli). As elastic recoil of the chest wall and patient circuit may remain relatively constant, static compliance may generally represent compliance as affected by elastic recoil of the alveoli. As described above, P_{plat} refers to a slight plateau in pressure that is observed after relaxation of

pleural muscles and elastic recoil, i.e., representing pressure delivered to overcome elastic forces. As such, P_{Plat} provides a basis for estimating C_S as follows:

$$C_S = V_T / (P_{Plat} - EEP)$$

5

Where V_T refers to tidal volume, P_{Plat} refers to plateau pressure, and EEP refers to end-expiratory pressure, or baseline pressure (including PEEP and/or Auto-PEEP). Note that proper calculation of C_S depends on accurate measurement of V_T and P_{Plat} .

Dynamic compliance, C_D , is measured during airflow and, as such, is impacted by both elastic recoil and airway resistance. Peak inspiratory pressure, P_{Peak} , which represents the highest pressure measured during inspiration, i.e., pressure delivered to overcome both elastic and resistive forces to inflate the lungs, is used to calculate C_D as follows:

15

$$C_D = V_T / (P_{Peak} - EEP)$$

Where V_T refers to tidal volume, P_{Peak} refers to peak inspiratory pressure, and EEP refers to end-expiratory pressure. According to embodiments, ventilatory data may be more readily available for trending compliance of non-triggering patients than of triggering patients.

20

Respiratory Resistance

Respiratory resistance refers to frictional forces that resist airflow, e.g., due to synthetic structures (e.g., endotracheal tube, expiratory valve, etc.), anatomical structures (e.g., bronchial tree, esophagus, etc.), or viscous tissues of the lungs and adjacent organs. Respiratory resistance may be interchangeably referred to herein as resistance. Resistance is highly dependant on the diameter of the airway. That is, a larger airway diameter entails less resistance and a higher concomitant flow. Alternatively, a smaller airway diameter entails higher resistance and a lower concomitant flow. In fact, decreasing the diameter of the airway results in an exponential increase in resistance (e.g., two-times reduction of diameter increases resistance by sixteen times). As may be appreciated, resistance may also increase due to a restriction of the airway that is the result of, *inter alia*, increased secretions, bronchial edema, mucous plugs, brochospasm, and/or kinking of the patient interface (e.g., invasive endotracheal or tracheostomy tubes).

35

Airway resistance may further be represented mathematically as:

$$R = P_t / F$$

Where P_t refers to the transairway pressure and F refers to the flow. That is, P_t refers to
 5 the pressure necessary to overcome resistive forces of the airway. Resistance may be expressed in centimeters of water per liter per second (i.e., cm H₂O/L/s).

Pulmonary Time Constant

As discussed above, compliance refers to the lung volume achieved for a given amount of delivered pressure ($C = \Delta V / \Delta P$). That is, stated differently, volume
 10 delivered is equivalent to the compliance multiplied by the delivered pressure ($\Delta V = C * \Delta P$). However, as the lungs are not perfectly elastic, a period of time is needed to deliver the volume ΔV at pressure ΔP . A pulmonary time constant, τ , may represent a time necessary to inflate or exhale a given percentage of the volume at delivered pressure ΔP . The pulmonary time constant, τ , may be calculated by multiplying the
 15 respiratory resistance by the respiratory compliance ($\tau = R * C$) for a given patient and τ is generally represented in seconds, s. The pulmonary time constant associated with exhalation of the given percentage of volume may be termed an expiratory time constant and the pulmonary time constant associated with inhalation of the given percentage of volume may be termed an inspiratory time constant.

20 According to some embodiments, when expiratory resistance data is available, the pulmonary time constant may be calculated by multiplying expiratory resistance by compliance. According to alternative embodiments, the pulmonary time constant may be calculated based on inspiratory resistance and compliance. According to further
 25 embodiments, the expiratory time, T_E , should be equal to or greater than three (3) pulmonary time constants to ensure adequate exhalation. That is, for a triggering patient, T_E (e.g., determined by trending T_E or otherwise) should be equal to or greater than 3 pulmonary time constants. For a non-triggering patient, set respiration rate (RR) should yield a T_E that is equal to or greater than 3 pulmonary time constants.

Normal Resistance and Compliance

30 According to embodiments, normal respiratory resistance and compliance may be determined based on a patient's predicted body weight (PBW) (or ideal body weight (IBW)). That is, according to a standardized protocol or otherwise, patient data may be compiled such that normal respiratory resistance and compliance values and/or ranges of values may be determined and provided to the ventilatory system 200. That is, a

manufacturer, clinical facility, clinician, or otherwise, may configure the ventilator with normal respiratory resistance and compliance values and/or ranges of values based on PBWs (or IBWs) of a patient population. Thereafter, during ventilation of a particular patient, respiratory resistance and compliance data may be trended for the patient and
5 compared to normal values and/or ranges of values based on the particular patient's PBW (or IBW). According to embodiments, the ventilator may give an indication to the clinician regarding whether the trended respiratory resistance and compliance data of the particular patient falls into normal ranges. According to some embodiments, data may be more readily available for trending resistance and compliance for non-triggering
10 patients than for triggering patients.

According to further embodiments, a predicted T_E may be determined based on a patient's PBW (or IBW). That is, according to a standardized protocol or otherwise, patient population data may be compiled such that predicted T_E values and/or ranges of values may be determined based on PBWs (or IBWs) of the patient population and
15 provided to the ventilatory system 200. Actual (or trended) T_E for a particular patient may then be compared to the predicted T_E . As noted previously, increased resistance and/or compliance may result in an actual T_E that is longer than predicted T_E . However, when actual T_E is consistent with predicted T_E , this may indicate that resistance and compliance for the particular patient fall into normal ranges.

According to further embodiments, a normal pulmonary time constant, τ , may be determined based on a patient's PBW (or IBW). That is, according to a standardized protocol or otherwise, patient data may be compiled such that normal τ values and/or ranges of values may be determined based on PBWs (or IBWs) of a patient population and provided to the ventilatory system 200. A calculated τ may be determined for a
25 particular patient by multiplying resistance by compliance (as described above, resistance and compliance data may be more readily available for a non-triggering patient). As the product of resistance and compliance results in τ , increased resistance and/or compliance may result in an elevated τ value. However, when the calculated τ value for the particular patient is consistent with the normal τ value, this may indicate
30 that the resistance and compliance of the particular patient fall into normal ranges.

Inspiration

Ventilation module 212 may further include an inspiration module 214 configured to deliver gases to the patient according to prescribed ventilatory settings. Specifically, inspiration module 214 may correspond to the inspiratory module 104 or

may be otherwise coupled to source(s) of pressurized gases (e.g., air, oxygen, and/or helium), and may deliver gases to the patient. Inspiration module 214 may be configured to provide ventilation according to various ventilatory breath types, e.g., via volume-targeted, pressure-targeted, or via any other suitable breath types.

- 5 Volume ventilation refers to various forms of volume-targeted ventilation that regulate volume delivery to the patient. Different types of volume ventilation are available depending on the specific implementation of volume regulation. For example, for volume-cycled ventilation, an end of inspiration is determined based on monitoring the volume delivered to the patient. Volume ventilation may include volume-control
- 10 (VC), volume-targeted-pressure-control (VC+), or volume-support (VS) breath types. Volume ventilation may be accomplished by setting a target volume, or prescribed tidal volume, V_T , for delivery to the patient. According to embodiments, prescribed V_T and inspiratory time (T_I) may be set during ventilation start-up, based on the patient's PBW (or IBW). In this case, flow will be dependent on the prescribed V_T and set T_I .
- 15 Alternatively, prescribed V_T and flow may be set and T_I may result. According to some embodiments, a predicted T_E may be determined based on normal respiratory and compliance values or value ranges based on the patient's PBW (or IBW). Additionally, a RR setting, generally in breaths/min, may be determined and configured. For a non-triggering patient, the set RR controls the timing for each inspiration. For a triggering
- 20 patient, the RR setting applies if the patient stops triggering for some reason and/or the patient's triggered RR drops below a threshold level.

- According to embodiments, during volume ventilation, as volume and flow are regulated by the ventilator, delivered V_T , flow waveforms (or flow traces), and volume waveforms may be constant and may not be affected by variations in lung or airway
- 25 characteristics (e.g., respiratory compliance and/or respiratory resistance). Alternatively, pressure readings may fluctuate based on lung or airway characteristics. According to some embodiments, the ventilator may control the inspiratory flow and then derive volume based on the inspiratory flow and elapsed time. For volume-cycled ventilation, when the derived volume is equal to the prescribed V_T , the ventilator may
- 30 initiate exhalation.

 According to alternative embodiments, the inspiration module 214 may provide ventilation via a form of pressure ventilation. Pressure-targeted breath types may be provided by regulating the pressure delivered to the patient in various ways. For example, during pressure-cycled ventilation, an end of inspiration is determined based

on monitoring the pressure delivered to the patient. Pressure ventilation may include a pressure-support (PS), a proportional assist (PA), or a pressure-control (PC) breath type, for example. The proportional assist (PA) breath type provides pressure in proportion to the instantaneous patient effort during spontaneous ventilation and is based on the equation of motion. Pressure ventilation may also include various forms of bi-level (BL) pressure ventilation, i.e., pressure ventilation in which the inspiratory positive airway pressure (IPAP) is higher than the expiratory positive airway pressure (EPAP). Specifically, pressure ventilation may be accomplished by setting a target or prescribed pressure for delivery to the patient. During pressure ventilation, predicted T_I may be determined based on normal respiratory and compliance values and on the patient's PBW (or IBW). According to some embodiments, a predicted T_E may be determined based on normal respiratory and compliance values and based on the patient's PBW (or IBW). A respiratory rate (RR) setting may also be determined and configured. For a non-triggering patient, the set RR controls the timing for each inspiration. For a triggering patient, the RR setting applies if the patient stops triggering for some reason and/or patient triggering drops below a threshold RR level.

According to embodiments, during pressure ventilation, the ventilator may maintain the same pressure waveform at the mouth, P_{awo} , regardless of variations in lung or airway characteristics, e.g., respiratory compliance and/or respiratory resistance. However, the volume and flow waveforms may fluctuate based on lung and airway characteristics. As noted above, pressure delivered to the upper airway creates a pressure gradient that enables gases to flow into a patient's lungs. The pressure from which a ventilator initiates inspiration is termed the end-expiratory pressure (EEP) or "baseline" pressure. This pressure may be atmospheric pressure (about 0 cm H₂O), also referred to as zero end-expiratory pressure (ZEEP). However, commonly, the baseline pressure may be positive, termed positive end-expiratory pressure (PEEP). Among other things, PEEP may promote higher oxygenation saturation and/or may prevent alveolar collapse during exhalation. Under pressure-cycled ventilation, upon delivering the prescribed pressure the ventilator may initiate exhalation.

According to still other embodiments, a combination of volume and pressure ventilation may be delivered to a patient, e.g., volume-targeted-pressure-control (VC+) breath type. In particular, VC+ may provide benefits of setting a target V_T , while also allowing for monitoring variations in flow. As will be detailed further below, variations in flow may be indicative of various patient conditions.

Exhalation

Ventilation module **212** may further include an exhalation module **216** configured to release gases from the patient's lungs according to prescribed ventilatory settings. Specifically, exhalation module **216** may correspond to expiratory module **108** or may otherwise be associated with and/or controlling an expiratory valve for releasing gases from the patient. By way of general overview, a ventilator may initiate exhalation based on lapse of an inspiratory time setting (T_I) or other cycling criteria set by the clinician or derived from ventilator settings (e.g., detecting delivery of prescribed V_T or prescribed pressure based on a reference trajectory). Upon initiating the expiratory phase, exhalation module **216** may allow the patient to exhale by opening an expiratory valve. As such, exhalation is passive, and the direction of airflow, as described above, is governed by the pressure gradient between the patient's lungs (higher pressure) and the ambient surface pressure (lower pressure). Although expiratory flow is passive, it may be regulated by the ventilator based on the size of the expiratory valve opening.

Expiratory time (T_E) is the time from the end of inspiration until the patient triggers for a spontaneously breathing patient. For a non-triggering patient, it is the time from the end of inspiration until the next inspiration based on the set RR. In some cases, however, the time required to return to the functional residual capacity (FRC) or resting capacity of the lungs is longer than provided by T_E (e.g., because the patient triggers prior to fully exhaling or the set RR is too high for a non-triggering patient). According to embodiments, various ventilatory settings may be adjusted to better match the time to reach FRC with the time available to reach FRC. For example, increasing flow will shorten T_I , thereby increasing the amount of time available to reach FRC. Alternatively, V_T may be decreased, resulting in less time required to reach FRC.

As may be further appreciated, at the point of transition between inspiration and exhalation, the direction of airflow may abruptly change from flowing into the lungs to flowing out of the lungs or vice versa depending on the transition. Stated another way, inspiratory flow may be measurable in the ventilatory circuit until P_{peak} is reached, at which point flow is zero. Thereafter, upon initiation of exhalation, expiratory flow is measurable in the ventilatory circuit until the pressure gradient between the lungs and the body's surface reaches zero (again, resulting in zero flow). However, in some cases, as will be described further herein, expiratory flow may still be positive, i.e., measurable, at the end of exhalation (termed positive end-expiratory flow or positive EEF). In this case, positive EEF is an indication that the pressure gradient has not

reached zero or, similarly, that the patient has not completely exhaled. Although a single occurrence of premature inspiration may not warrant concern, repeated detection of positive EEf may be indicative of Auto-PEEP.

Ventilator Synchrony and Patient Triggering

5 According to some embodiments, the inspiration module 214 and/or the exhalation module 216 may be configured to synchronize ventilation with a spontaneously-breathing, or triggering, patient. That is, the ventilator may be configured to detect patient effort and may initiate a transition from exhalation to inspiration (or from inspiration to exhalation) in response. Triggering refers to the
10 transition from exhalation to inspiration in order to distinguish it from the transition from inspiration to exhalation (referred to as cycling). Ventilation systems, depending on their breath type, may trigger and/or cycle automatically, or in response to a detection of patient effort, or both.

 Specifically, the ventilator may detect patient effort via a pressure-monitoring
15 method, a flow-monitoring method, direct or indirect measurement of nerve impulses, or any other suitable method. Sensing devices may be either internal or distributed and may include any suitable sensing device, as described further herein. In addition, the sensitivity of the ventilator to changes in pressure and/or flow may be adjusted such that the ventilator may properly detect the patient effort, i.e., the lower the pressure or flow
20 change setting the more sensitive the ventilator may be to patient triggering.

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

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

detect expiratory flow changes and patient triggering. For example, while gases are generally flowing out of the patient's lungs during exhalation, a drop in flow may occur as some gas is redirected and flows into the lungs in response to the slightly negative pressure gradient between the patient's lungs and the body's surface. Thus, when the ventilator detects a slight drop in flow below the bias flow by a predetermined threshold amount (e.g., 2 L/min below bias flow), it may interpret the drop as a patient trigger and may consequently initiate inspiration by delivering respiratory gases.

Volume-Control Breath Type

In some embodiments, ventilation module 212 may further include an inspiration module 214 configured to deliver gases to the patient according to volume-control (VC). The VC breath type allows a clinician to set a respiratory rate and to select a volume to be administered to a patient during a mandatory breath. When using VC, a clinician sets a desired tidal volume, flow wave form shape, and an inspiratory flow rate or inspiratory time. These variables determine how much volume of gas is delivered to the patient and the duration of inspiration during each mandatory breath inspiratory phase. The mandatory breaths are administered according to the set respiratory rate.

For VC, when the delivered volume is equal to the prescribed tidal volume, the ventilator may initiate exhalation. Exhalation lasts from the time at which prescribed volume is reached until the start of the next ventilator mandated inspiration. This exhalation time is determined by the respiratory rate set by the clinician and any participation above the set rate by the patient. Upon the end of exhalation, another VC mandatory breath is given to the patient.

During VC, delivered volume and flow waveforms may remain constant and may not be affected by variations in lung or airway characteristics. Alternatively, pressure readings may fluctuate based on lung or airway characteristics. According to some embodiments, the ventilator may control the inspiratory flow and then derive volume based on the inspiratory flow and elapsed time.

In some embodiments, VC may also be delivered to a triggering patient. When VC is delivered to a triggering patient, the breath period (i.e. time between breaths) is a function of the frequency at which the patient is triggering breaths. That is, the ventilator will trigger the inhalation based upon the respiratory rate setting or the patient effort. If no patient effort is detected, the ventilator will deliver another mandatory breath at the predetermined respiratory rate. A patient-initiated mandatory (PIM) is a control breath that is triggered by the patient during a control mode such as VC or PC.

Volume-Targeted-Pressure-Control Breath Type

In further embodiments, ventilation module 212 may further include an inspiration module 214 configured to deliver gases to the patient using a volume-targeted-pressure-control (VC+) breath type. The VC+ breath type is a combination of volume and pressure control breath types that may be delivered to a patient as a mandatory breath. In particular, VC+ may provide the benefits associated with setting a target tidal volume, while also allowing for variable flow. Variable flow may be helpful in meeting inspiratory flow demands for actively breathing patients.

As may be appreciated, when resistance increases it becomes more difficult to pass gases into and out of the lungs, decreasing flow. For example, when a patient is intubated, i.e., having either an endotracheal or a tracheostomy tube in place, resistance may be increased as a result of the smaller diameter of the tube over a patient's natural airway. In addition, increased resistance may be observed in patients with obstructive disorders, such as COPD, asthma, etc. Higher resistance may necessitate, *inter alia*, a higher inspiratory time setting for delivering a prescribed pressure or volume of gases, a lower respiratory rate resulting in a higher expiratory time for complete exhalation of gases.

Unlike VC, when the set inspiratory time is reached, the ventilator may initiate exhalation. Exhalation lasts from the end of inspiration until the beginning of the next inspiration. For a non-triggering patient, the expiratory time (T_E) is based on the respiratory rate set by the clinician. Upon the end of exhalation, another VC+ mandatory breath is given to the patient.

By controlling target tidal volume and allowing for variable flow, VC+ allows a clinician to maintain the volume while allowing the flow and pressure targets to fluctuate.

Volume-Support Breath Type

In some embodiments, ventilation module 212 may further include an inspiration module 214 configured to deliver gases to the patient according to volume-support (VS) breath type. The VS breath type is utilized in the present disclosure as a spontaneous breath. VS is generally used with a triggering (spontaneously breathing) patient when the patient is ready to be weaned from a ventilator or when the patient cannot do all of the work of breathing on his or her own. When the ventilator senses patient inspiratory effort, the ventilator delivers a set tidal volume during inspiration. The tidal volume may be set and adjusted by the clinician. The patient controls the rate, inspiratory flow,

and has some control over the inspiratory time. The ventilator then adjusts the pressure over several breaths to achieve the set tidal volume. When the machine senses a decrease in flow, or inspiration time reaches a predetermined limit, the ventilator determines that inspiration is ending. When delivered as a spontaneous breath,
5 exhalation in VS lasts from a determination that inspiration is ending until the ventilator senses a next patient effort to breath.

Pressure-Control Breath Type

In additional embodiments, ventilation module **212** may further include an inspiration module **214** configured to deliver gases to the patient according to the
10 pressure-control (PC) breath type. PC allows a clinician to select a pressure to be administered to a patient during a mandatory breath. When using the PC breath type, a clinician sets a desired pressure, inspiratory time, and respiratory rate for a patient. These variables determine the pressure of the gas delivered to the patient during each mandatory breath inspiration. The mandatory breaths are administered according to the
15 set respiratory rate.

For the PC breath type, when the inspiratory time is equal to the prescribed inspiratory time, the ventilator may initiate exhalation. Exhalation lasts from the end of inspiration until the next inspiration. Upon the end of exhalation, another PC mandatory breath is given to the patient.

20 During PC breaths, the ventilator may maintain the same pressure waveform at the mouth, regardless of variations in lung or airway characteristics, e.g., respiratory compliance and/or respiratory resistance. However, the volume and flow waveforms may fluctuate based on lung and airway characteristics.

In some embodiments, PC may also be delivered for triggering patients. When
25 PC is delivered with triggering, the breath period (i.e. time between breaths) is a function of the respiratory rate of the patient. The ventilator will trigger the inhalation based upon the respiratory rate setting or the patient's trigger effort, but cycling to exhalation will be based upon elapsed inspiratory time. The inspiratory time is set by the clinician. The inspiratory flow is delivered based upon the pressure setting and
30 patient physiology. Should the patient create an expiratory effort in the middle of the mandatory inspiratory phase, the ventilator will respond by reducing flow. If no patient effort is detected, the ventilator will deliver another mandatory breath at the predetermined respiratory rate.

PC with triggering overcomes some of the problems encountered by other mandatory breath types that use artificially set inspiratory flow rates. For example, if the inspiratory flow is artificially set lower than a patient's demand, the patient will feel starved for flow. This can lead to undesirable effects, including increased work of breathing. In addition, should the patient begin to exhale when using one of the traditional mandatory breath types, the patient's expiratory effort is ignored since the inspiratory flow is mandated by the ventilator settings.

Pressure-Support Breath Type

In further embodiments, ventilation module **212** may further include an inspiration module **214** configured to deliver gases to the patient according to a pressure-support (PS) breath type. PS is a form of assisted ventilation and is utilized in the present disclosure during a spontaneous breath. PS is a patient triggered breath and is typically used when a patient is ready to be weaned from a ventilator or for when patients are breathing spontaneously but cannot do all the work of breathing on their own. When the ventilator senses patient inspiratory effort, the ventilator provides a constant pressure during inspiration. The pressure may be set and adjusted by the clinician. The patient controls the rate, inspiratory flow, and to an extent, the inspiratory time. The ventilator delivers the set pressure and allows the flow to vary. When the machine senses a decrease in flow, or determines that inspiratory time has reached a predetermined limit, the ventilator determines that inspiration is ending. When delivered as a spontaneous breath, exhalation in PS lasts from a determination that inspiration is ending until the ventilator senses a patient effort to breath.

Expiratory Sensitivity

As discussed above, ventilation module **212** may oversee ventilation of a patient according to prescribed ventilatory settings. In one embodiment, the expiratory sensitivity (E_{SENS}) is set by a clinician or operator. According to embodiments, E_{SENS} sets the percentage of delivered peak inspiratory flow necessary to terminate inspiration and initiate exhalation. In some embodiments, the clinician or operator determines the E_{SENS} setting, which is adjustable from 1% to 80%. A lower set E_{SENS} increases inspiration time and a higher set E_{SENS} decreases inspiration time. The E_{SENS} setting may be utilized to limit unnecessary expiratory work and to improve patient-ventilator synchrony.

Ventilator Sensory Devices

The ventilatory system **200** may also include one or more distributed sensors **218** communicatively coupled to ventilator **202**. Distributed sensors **218** may communicate with various components of ventilator **202**, e.g., ventilation module **212**, internal sensors **220**, data processing module **222**, an inadequate flow detection module **224**, and any
5 other suitable components and/or modules. Distributed sensors **218** may detect changes in ventilatory parameters indicative of an inadequate flow, for example. Distributed sensors **218** may be placed in any suitable location, e.g., within the ventilatory circuitry or other devices communicatively coupled to the ventilator. For example, sensors may be affixed to the ventilatory tubing or may be imbedded in the tubing itself. According
10 to some embodiments, sensors may be provided at or near the lungs (or diaphragm) for detecting a pressure in the lungs. Additionally or alternatively, sensors may be affixed or imbedded in or near wye-fitting **170** and/or patient interface **180**, as described above.

Distributed sensors **218** may further include pressure transducers that may detect changes in circuit pressure (e.g., electromechanical transducers including piezoelectric,
15 variable capacitance, or strain gauge). Distributed sensors **218** may further include various flowmeters for detecting airflow (e.g., differential pressure pneumotachometers). For example, some flowmeters may use obstructions to create a pressure decrease corresponding to the flow across the device (e.g., differential pressure pneumotachometers) and other flowmeters may use turbines such that flow may be
20 determined based on the rate of turbine rotation (e.g., turbine flowmeters). Alternatively, sensors may utilize optical or ultrasound techniques for measuring changes in ventilatory parameters. A patient's blood parameters or concentrations of expired gases may also be monitored by sensors to detect physiological changes that may be used as indicators to study physiological effects of ventilation, wherein the
25 results of such studies may be used for diagnostic or therapeutic purposes. Indeed, any distributed sensory device useful for monitoring changes in measurable parameters during ventilatory treatment may be employed in accordance with embodiments described herein.

Ventilator **202** may further include one or more internal sensors **220**. Similar to
30 distributed sensors **218**, internal sensors **220** may communicate with various components of ventilator **202**, e.g., ventilation module **212**, internal sensors **220**, data processing module **222**, an inadequate flow detection module **224**, and any other suitable components and/or modules. Internal sensors **220** may employ any suitable sensory or derivative technique for monitoring one or more parameters associated with

the ventilation of a patient. However, the one or more internal sensors **220** may be placed in any suitable internal location, such as, within the ventilatory circuitry or within components or modules of ventilator **202**. For example, sensors may be coupled to the inspiratory and/or expiratory modules for detecting changes in, for example, circuit pressure and/or flow. Specifically, internal sensors **220** may include pressure transducers and flowmeters for measuring changes in circuit pressure and airflow. Additionally or alternatively, internal sensors **220** may utilize optical or ultrasound techniques for measuring changes in ventilatory parameters. For example, a patient's expired gases may be monitored by internal sensors **220** to detect physiological changes indicative of the patient's condition and/or treatment, for example. Indeed, internal sensors **220** may employ any suitable mechanism for monitoring parameters of interest 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 or indirectly monitored. That is, parameters may be directly monitored by one or more sensors, as described above, or may be indirectly monitored by derivation according to the Equation of Motion.

Ventilatory Data

Ventilator **202** may further include a data processing module **222**. As noted above, distributed sensors **218** and internal sensors **220** may collect data regarding various ventilatory parameters. Ventilator data refers to any ventilatory parameter or setting. A ventilatory parameter refers to any factor, characteristic, or measurement associated with the ventilation of a patient, whether monitored by the ventilator or by any other device. A ventilatory setting refers to any factor, characteristic, or measurement that is set by the ventilator and/or operator. Sensors may further transmit collected data to the data processing module **222** and, according to embodiments, the data processing module **222** may be configured to collect data regarding some ventilatory parameters, to derive data regarding other ventilatory parameters, and to graphically represent collected and derived data to the clinician and/or other modules of the ventilatory system **200**. Some collected, derived, and/or graphically represented data may be indicative of an inadequate flow. For example, data regarding expiratory time, exhaled tidal volume, inspiratory time setting (T_I), etc., may be collected, derived, and/or graphically represented by data processing module **222**.

Flow Data

For example, according to embodiments, data processing module 222 may be configured to monitor inspiratory and expiratory flow. Flow may be measured by any appropriate, internal or distributed device or sensor within the ventilatory system 200.

- 5 As described above, flowmeters may be employed by the ventilatory system 200 to detect circuit flow. However, any suitable device either known or developed in the future may be used for detecting airflow in the ventilatory circuit.

Data processing module 222 may be further configured to plot monitored flow data graphically via any suitable means. For example, according to embodiments, flow data may be plotted versus time (flow waveform), versus volume (flow-volume loop), or versus any other suitable parameter as may be useful to a clinician. According to
10 embodiments, flow may be plotted such that each breath may be independently identified. Further, flow may be plotted such that inspiratory flow and expiratory flow may be independently identified, e.g., inspiratory flow may be represented in one color and expiratory flow may be represented in another color. According to additional
15 embodiments, flow waveforms and flow-volume loops, for example, may be represented alongside additional graphical representations, e.g., representations of volume, pressure, etc., such that clinicians may substantially simultaneously visualize a variety of ventilatory parameters associated with each breath.

- 20 As may be appreciated, flow decreases as resistance increases, making it more difficult to pass gases into and out of the lungs (i.e., $F = P_r / R$). For example, when a patient is intubated, i.e., having either an endotracheal or a tracheostomy tube in place, resistance may be increased as a result of the smaller diameter of the tube over a patient's natural airway. In addition, increased resistance may be observed in patients
25 with obstructive disorders, such as COPD, asthma, etc. Higher resistance may necessitate, *inter alia*, a higher inspiratory time setting (T_I) for delivering a prescribed pressure or volume of gases, a higher flow setting for delivering prescribed pressure or volume, a lower respiratory rate resulting in a higher expiratory time (T_E) for complete exhalation of gases, etc.

- 30 Specifically, changes in flow may be detected by evaluating various flow data. For example, by evaluating FV loops, as described above, an increase in resistance may be detected over a number of breaths. That is, upon comparing consecutive FV loops, the expiratory plot for each FV loop may reflect a progressive reduction in expiratory flow (i.e., a smaller FV loop), indicative of increasing resistance.

Pressure Data

According to embodiments, data processing module **222** may be configured to monitor pressure. Pressure may be measured by any appropriate, internal or distributed device or sensor within the ventilatory system **200**. For example, pressure may be monitored by proximal electromechanical transducers connected near the airway opening (e.g., on the inspiratory limb, expiratory limb, at the patient interface, etc.). Alternatively, pressure may be monitored distally, at or near the lungs and/or diaphragm of the patient.

For example, P_{Peak} and/or P_{Plat} (estimating P_a) may be measured proximally (e.g., at or near the airway opening) via single-point pressure measurements. According to embodiments, P_{Plat} (estimating P_a) may be measured during an inspiratory pause maneuver (e.g., expiratory and inspiratory valves are closed briefly at the end of inspiration for measuring the P_{Plat} at zero flow). According to other embodiments, circuit pressure may be measured during an expiratory pause maneuver (e.g., expiratory and inspiratory valves are closed briefly at the end of exhalation for measuring EEP at zero flow).

Data processing module **222** may be further configured to plot monitored pressure data graphically via any suitable means. For example, according to embodiments, pressure data may be plotted versus time (pressure waveform), versus volume (pressure-volume loop or PV loop), or versus any other suitable parameter as may be useful to a clinician. According to embodiments, pressure may be plotted such that each breath may be independently identified. Further, pressure may be plotted such that inspiratory pressure and expiratory pressure may be independently identified, e.g., inspiratory pressure may be represented in one color and expiratory pressure may be represented in another color. According to additional embodiments, pressure waveforms and PV loops, for example, may be represented alongside additional graphical representations, e.g., representations of volume, flow, etc., such that a clinician may substantially simultaneously visualize a variety of parameters associated with each breath.

According to embodiments, PV loops may provide useful clinical and diagnostic information to clinicians regarding the respiratory resistance or compliance of a patient. Specifically, upon comparing PV loops from successive breaths, an increase in resistance may be detected when successive PV loops shorten and widen over time. That is, at constant pressure, less volume is delivered to the lungs when resistance is

increasing, resulting in a shorter, wider PV loop. According to alternative embodiments, a PV loop may provide a visual representation, in the area between the inspiratory plot of pressure vs. volume and the expiratory plot of pressure vs. volume, which is indicative of respiratory compliance. Further, PV loops may be compared to one another to determine whether compliance has changed. Additionally or alternatively, optimal compliance may be determined. That is, optimal compliance may correspond to the dynamic compliance determined from a PV loop during a recruitment maneuver, for example.

According to additional embodiments, PV curves may be used to compare C_S and C_D over a number of breaths. For example, a first PV curve may be plotted for C_S (based on P_{Plat} less EEP) and a second PV curve may be plotted for C_D (based on P_{Peak} less EEP). Under normal conditions, C_S and C_D curves may be very similar, with the C_D curve mimicking the C_S curve but shifted to the right (i.e., plotted at higher pressure). However, in some cases the C_D curve may flatten out and shift to the right relative to the C_S curve. This graphical representation may illustrate increasing P_t , and thus increasing R , which may be due to mucous plugging or bronchospasm, for example. In other cases, both the C_D curve and the C_S curves may flatten out and shift to the right. This graphical representation may illustrate an increase in P_{Peak} and P_{Plat} , without an increase in P_t , and thus may implicate a decrease in lung compliance, which may be due to tension pneumothorax, atelectasis, pulmonary edema, pneumonia, bronchial intubation, etc.

As may be further appreciated, relationships between resistance, static compliance, dynamic compliance, and various pressure readings may give indications of patient condition. For example, when C_S increases, C_D increases and, similarly, when R increases, C_D increases. Additionally, as discussed previously, P_t represents the difference in pressure attributable to resistive forces over elastic forces. Thus, where P_{Peak} and P_t are increasing with constant V_T delivery, R is increasing (i.e., where P_{Peak} is increasing without a concomitant increase in P_{Plat}). Where P_t is roughly constant, but where P_{Peak} and P_{Plat} are increasing with a constant V_T delivery, C_S is increasing.

30 Volume Data

According to embodiments, data processing module 222 may be configured to derive volume via any suitable means. For example, as described above, during volume ventilation, a prescribed V_T may be set for delivery to the patient. The actual volume delivered may be derived by monitoring the inspiratory flow over time (i.e., $V = F \cdot T$).

Stated differently, integration of flow over time will yield volume. According to embodiments, V_T is completely delivered upon reaching T_I . Similarly, the expiratory flow may be monitored such that expired tidal volume (V_{TE}) may be derived. That is, under ordinary conditions, upon reaching the T_E , the prescribed V_T delivered should be completely exhaled and FRC should be reached. However, under some conditions T_E is inadequate for complete exhalation and FRC is not reached.

Data processing module 222 may be further configured to plot derived volume data graphically via any suitable means. For example, according to embodiments, volume data may be plotted versus time (volume waveform), versus flow (flow-volume loop or FV loop), or versus any other suitable parameter as may be useful to a clinician. According to embodiments, volume may be plotted such that each breath may be independently identified. Further, volume may be plotted such that prescribed V_T and V_{TE} may be independently identified, e.g., prescribed V_T may be represented in one color and V_{TE} may be represented in another color. According to additional embodiments, volume waveforms and FV loops, for example, may be represented alongside additional graphical representations, e.g., representations of pressure, flow, etc., such that a clinician may substantially simultaneously visualize a variety of parameters associated with each breath.

Disconnection of the Patient Ventilator Circuit

According to embodiments, data processing module 222 may be configured to determine if the ventilation tubing system 130 or patient circuit has become disconnected from the patient or the ventilator during ventilation. Data processing module 222 determines that a patient circuit is disconnected by any suitable means. In some embodiments, data processing module 222 determines that the patient circuit is disconnected by evaluating data, such as exhaled pressure and/or exhaled volume. In further embodiments, data processing module 222 determines if the patient circuit is disconnected by determining if a disconnect alarm has been executed. A disconnect alarm is executed when the ventilation tubing system is disconnected from the patient and/or the ventilator. If the disconnect alarm has been executed, then data processing module 222 determines that the patient circuit is disconnected. If the disconnect alarm has not been executed, then data processing module 222 determines that the patient circuit is connected.

Breath Type

According to embodiments, data processing module **222** may be configured to identify the ventilator breath type. Data processing module **222** determines the breath type by any suitable means or methods. In some embodiments, data processing module **222** determines the breath type based on clinician or operator input and/or selection. In further embodiments, data processing module **222** determines the breath type based on ventilator selection of the breath type. For example, some breath types include VC, PC, VC+, PS, PA, and VS.

Inadequate Flow Detection

Ventilator **202** may further include an inadequate flow module **224**. Inadequate flow is detected when a patient is receiving less flow than desired by the patient during ventilation. Inadequate flow occurs when a flow rate is set too low, a peak flow rate is set too low, and/or the flow pattern does not match that of the patient's effort. Accordingly, inadequate flow can lead to patient discomfort, patient fatigue, hypercapnia, and/or hypoxemia.

According to embodiments, inadequate flow may occur as a result of various patient conditions and/or inappropriate ventilator settings. Thus, according to embodiments, inadequate flow detection module **224** may evaluate various ventilatory parameter data and ventilatory settings based on one or more predetermined thresholds to detect the presence of inadequate flow. For example, inadequate flow detection module **224** may evaluate circuit pressure, mean airway pressure, etc., and may compare the evaluated parameters to one or more predetermined thresholds. In order to prevent unnecessary alarms, prompts, notifications, and/or recommendations, thresholds and conditions are utilized by the inadequate flow detection module **224** to determine when inadequate flow has occurred with sufficient frequency to warrant notification of the operator. For example, in some embodiments, an inadequate flow that occurs in one breath in isolation from any other breaths with an inadequate flow will not be considered enough to warrant an occurrence of inadequate flow by the inadequate flow detection module **224**. As used herein any threshold, condition, setting, parameter, and/or frequency that are "predetermined" may be input or selected by the operator and/or may be set or selected by the ventilator.

In embodiments, the inadequate flow detection module **224** may detect an inadequate flow when one or more predetermined thresholds are breached at a predetermined frequency. In some embodiments, the inadequate flow detection module **224** may detect an inadequate flow when one or more predetermined thresholds are

breached at least three times within a predetermined amount of time. In alternative embodiments, the inadequate flow detection module **224** may detect an inadequate flow when one or more predetermined thresholds are breached by more than 30% of the PIM breaths within a predetermined amount of time. In some embodiments, the inadequate flow detection module **224** may detect an inadequate flow when one or more predetermined thresholds are breached in more than 10% of the PIM breaths within a predetermined amount of time. The predetermined amount of time may be any suitable range of time for determining if an inadequate flow has occurred, such as a time ranging from 30 seconds to 240 seconds. The frequency thresholds disclosed above are exemplary and do not limit the disclosure. Any suitable frequency threshold for determining that the patient is receiving an inadequate flow during ventilation may be utilized.

According to some embodiments, inadequate flow detection module **224** may detect an inadequate flow when a mean airway pressure for a PIM breath is below the set PEEP. In some embodiments, the mean airway pressure is compared to a predetermined pressure. For example, the predetermined pressure may be PEEP plus 1 cm H₂O, or PEEP minus 2 cm H₂O. The "mean airway pressure" referred to herein for a PIM breath is calculated between the beginning of inspiration and a point where a predetermined amount of tidal volume (e.g., 30%) has been delivered or a predetermined proportion of the inspiration time has expired in the PIM breath. According to embodiments, inadequate flow detection module **224** may detect an inadequate flow when more than three PIM breaths within the previous 60 seconds exhibit a mean airway pressure for a PIM breath below the set PEEP and the expiratory time is greater than a predetermined amount of time. According to further embodiments, inadequate flow detection module **224** may detect an inadequate flow when more than 30% of the PIM breaths within the previous 180 seconds exhibit a mean airway pressure for a PIM breath below the set PEEP and the expiratory time is greater than a predetermined amount of time. In one embodiment, the inadequate flow detection module **224** may begin the evaluation at the end of exhalation for each PIM breath.

In some embodiments, inadequate flow detection module **224** detects an inadequate flow when one or more of the following conditions are met for PIM breath:

1. the amount of pressure delivered when a predetermined amount of tidal volume has been delivered or a predetermined proportion of an inspiration time has expired in the PIM breath is less than the set PEEP; and
2. the amount of mean airway pressure for the PIM breath is less than the set PEEP.

Upon detecting one or more of the above conditions, the inadequate flow detection module 224 may also ensure that at least one of the following two conditions is met:

3. expiratory time for a PIM breath is greater than a predetermined amount of time;
4. the ventilation tubing system status is connected; and
5. no disconnect alarm is detected.

The confirmation conditions (3, 4, and 5) listed above confirm that the above pressure conditions (1 and 2) are the result of an inadequate flow, instead of another underlying condition. For example, if a disconnect alarm or the tubing status is

disconnected, then the above pressure conditions (1 and 2) are the result of a disconnected patient circuit and not the result of an inadequate flow. Accordingly, the ventilator will not issue a prompt for inadequate flow if these conditions are not met. In an alternative example, if the expiratory time is less than a predetermined amount, then the above pressure conditions (1 and 2) are most likely the result of double triggering.

Accordingly, the ventilator will not issue a prompt for inadequate flow, since the pressure condition was not caused by inadequate flow.

In further embodiments, condition number 3, listed above, may refer to any suitable expiratory time threshold. For example, in an alternative embodiment the expiratory time threshold is an expiratory time of greater than 190 ms, 200 ms, 210 ms, 220 ms, 230 ms, or 250 ms depending upon the type of ventilator, patient, breath type, ventilator parameters, ventilator settings, and/or ventilator modes, etc. In further embodiments, the predetermined tidal volume, listed above, may refer to any suitable amount of tidal volume during a PIM breath for measuring pressure during ventilation to determine inadequate flow during ventilation, such as 10%, 20%, 30%, 40% and 50%.

In some embodiments, the predetermined proportion of the inspiration listed above, may refer to any suitable proportion of the inspiration time during a PIM breath for measuring pressure during ventilation to determine inadequate flow during ventilation, such as 10%, 20%, 30%, 40% and 50% of the total amount of inspiration time. The ventilation tubing system status is: (1) connected when the ventilation tubing system is

connected to the patient and the ventilator; and (2) disconnected when the ventilation tubing system is not connected to the patient and/or the ventilator. Condition number 4 and condition number 5 listed above, are considered a “threshold” in the present disclosure and in the listed claims. Further, the detection of any yes/no “condition” is
5 considered a “threshold” in the present disclosure and in the listed claims.

The thresholds listed above are just one example list of possible conditions that could be used to indicate an inadequate flow. Any suitable list of conditions for determining the occurrence of an inadequate flow may be utilized. For example, other suitable conditions/thresholds that may be utilized to determine that an inadequate flow
10 is implicated include a comparison of the patient flow (i.e., the flow at the connection to the patient) with the flow delivered by the ventilator and a comparison of the pressure to a predetermined acceptable profile.

Smart-Prompt Generation

Ventilator 202 may further include a prompt such as a smart prompt module 226.
15 As may be appreciated, multiple ventilatory parameters may be monitored and evaluated in order to detect an implication of an inadequate flow. In addition, when an inadequate flow is implicated, many clinicians may not be aware of adjustments to ventilatory parameters that may reduce or eliminate the inadequate flow. As such, upon detection of an inadequate flow, the smart prompt module 226 may be configured to notify the
20 clinician that an inadequate flow is implicated and/or to provide recommendations to the clinician for mitigating the inadequate flow. For example, smart prompt module 226 may be configured to notify the clinician by displaying a smart prompt on display monitor 204 and/or within a window of the GUI. According to additional embodiments, the smart prompt may be communicated to and/or displayed on a remote monitoring
25 system communicatively coupled to ventilatory system 200. According to alternative embodiments, the smart prompt is any audio and/or visual notification. Alternatively, in an automated embodiment, the smart prompt module 226 may communicate with a ventilator control system so that the recommendation may be automatically implemented to mitigate the inadequate flow.

30 In order to accomplish the various aspects of the notification and/or recommendation message display, the smart prompt module 226 may communicate with various other components and/or modules. For instance, smart prompt module 226 may be in communication with data processing module 222, inadequate flow detection module 224, or any other suitable module or component of the ventilatory system 200.

That is, smart prompt module 226 may receive an indication that an inadequate flow has been implicated by any suitable means. In addition, smart prompt module 226 may receive information regarding one or more parameters that implicated the presence of an inadequate flow and information regarding the patient's ventilatory settings and treatment. Further, according to some embodiments, the smart prompt module 226 may have access to a patient's diagnostic information (e.g., regarding whether the patient has ARDS, COPD, asthma, emphysema, or any other disease, disorder, or condition).

Smart prompt module 226 may further comprise additional modules for making notifications and/or recommendations to a clinician regarding the presence of an inadequate flow. For example, according to embodiments, smart prompt module 226 may include a notification module 228 and a recommendation module 230. For instance, smart prompts may be provided according to a hierarchical structure such that a notification message and/or a recommendation message may be initially presented in summarized form and, upon clinician selection, an additional detailed notification and/or recommendation message may be displayed. According to alternative embodiments, a notification message may be initially presented and, upon clinician selection, a recommendation message may be displayed. Alternatively or additionally, the notification message may be simultaneously displayed with the recommendation message in any suitable format or configuration.

Specifically, according to embodiments, the notification message may alert the clinician as to the detection of a patient condition, a change in patient condition, or an effectiveness of ventilatory treatment. For example, the notification message may alert the clinician that an inadequate flow has been detected. The notification message may further alert the clinician regarding the particular ventilatory parameter(s) that implicated the inadequate flow (e.g., set flow resulted in a delivered pressure that is less than PEEP, etc.)

Additionally, according to embodiments, the recommendation message may provide various suggestions to the clinician for addressing a detected condition. That is, if an inadequate flow has been detected, the recommendation message may suggest that the clinician consider changing to a spontaneous breath type, such as PA, PS, or VS, etc. According to additional embodiments, the recommendation message may be based on the particular ventilatory parameter(s) (e.g., mean airway pressure, etc.) that implicated an inadequate flow. Additionally or alternatively, the recommendation message may be based on current ventilatory settings (e.g., breath type) such that suggestions are directed

to a particular patient's treatment. Additionally or alternatively, the recommendation message may be based on a diagnosis and/or other patient attributes. Further still, the recommendation message may include a primary recommendation message and a secondary recommendation message.

5 As described above, smart prompt module **226** may also be configured with notification module **228** and recommendation module **230**. The notification module **228** may be in communication with data processing module **222**, inadequate flow detection module **224**, or any other suitable module to receive an indication that an inadequate flow has been detected. Notification module **228** may be responsible for generating a
10 notification message via any suitable means. For example, the notification message may be provided as a tab, banner, dialog box, or other similar type of display. Further, the notification messages may be provided along a border of the graphical user interface, near an alarm display or bar, or in any other suitable location. A shape and size of the notification message may further be optimized for easy viewing with minimal
15 interference to other ventilatory displays. The notification message may be further configured with a combination of icons and text such that the clinician may readily identify the message as a notification message.

 The recommendation module **230** may be responsible for generating one or more recommendation messages via any suitable means. The one or more recommendation
20 messages may provide suggestions and information regarding addressing a detected condition and may be accessible from the notification message. For example, the one or more recommendation messages may identify the parameters that implicated the detected condition, may provide suggestions for adjusting one or more ventilatory parameters to address the detected condition, may provide suggestions for checking
25 ventilatory equipment or patient position, or may provide other helpful information. Specifically, the one or more recommendation messages may provide suggestions and information regarding an inadequate flow.

 According to embodiments, based on the particular parameters that implicated an inadequate flow, the recommendation module **230** may provide suggestions for
30 addressing the inadequate flow. That is, if an inadequate flow is implicated, the one or more recommendation messages may include suggestions or recommendations for the following:

- switching to a spontaneous breath type for one breath to measure an amount of flow desired by the patient;
- switching to a proportional assist (PA) breath type, a pressure-support (PS) breath type, or a volume-support (VS) breath type;
- 5 • switching to a VC+ or PC breath type;
- increasing a peak flow rate;
- increasing any suitable type of flow rate for mitigating inadequate flow;
- changing ventilator parameters and/or ventilator settings to indirectly increase a peak flow rate;
- 10 • changing the flow pattern from a decelerating ramp flow pattern to a square flow pattern; and
- any other suitable suggestion or recommendation.

According to still other embodiments, the recommendation message may include a primary message and a secondary message. That is, a primary message may provide
15 notification of the condition detected and/or suggestions that are specifically targeted to the detected condition based on the particular parameters that implicated the condition. Alternatively, the primary message may provide suggestions that may provide a higher likelihood of mitigating the detected condition. The secondary message may provide more general suggestions and/or information that may aid the clinician in further
20 addressing and/or mitigating the detected condition. For example, the primary message may provide a specific suggestion for adjusting a particular parameter to mitigate the detected condition (e.g., consider decreasing V_T). Alternatively, the secondary message may provide general suggestions for addressing the detected condition.

Additionally or alternatively, the one or more recommendation messages may
25 also be based on current ventilator settings for the patient. For example, if an inadequate flow was implicated during a VC breath type, where the patient's current ventilator settings included a flow pattern set to square, then the one or more recommendation messages may suggest increasing the peak flow rate or another suitable type of flow rate depending upon the ventilator settings, ventilator parameters, and
30 patient parameters. In further embodiments, the ventilator could suggest the adjustment of ventilator parameters and/or ventilator settings in order to indirectly change a flow rate to the patient. Further in this example, a secondary recommendation message may suggest changing the breath type to a spontaneous breath type, such as PA, PS, or VS.

Table 1 below lists various examples of primary and secondary recommendations for a VC breath type based on the listed additional current ventilator settings.

Table 1. VC recommendation messages based on current ventilator settings.

Breath Type	Additional Ventilator Settings	Primary Recommendation Message	Secondary Recommendation Message
VC	Flow pattern set to square	Inadequate flow detected. Consider increasing peak flow rate setting.	Consider changing to a spontaneous breath type such as PA, PS or VS.
VC	Flow pattern set to decelerating ramp.	Inadequate flow detected. Consider increasing peak flow rate setting and/or changing flow pattern to square.	Consider changing to a spontaneous breath type such as PA, PS or VS.
VC	N/A	Inadequate flow detected. Consider switching to a spontaneous breath type for one breath to measure the amount of flow desired by the patient.	Consider changing to a spontaneous breath type such as PA, PS or VS.
VC	Flow pattern set to square	Inadequate flow detected. Consider increasing peak flow rate setting.	Consider changing to a PC or VC+.
VC	Flow pattern set to decelerating ramp.	Inadequate flow detected. Consider increasing peak flow rate setting and/or changing flow pattern to square.	Consider changing to a PC or VC+.

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In some embodiments, when inadequate flow is implicated, the ventilator automatically switches to a spontaneous breath type for at least one breath to determine the amount of flow desired by the patient. In this embodiment, at least one of the primary or secondary recommendations suggests changing a ventilator setting or parameter by a specific amount to provide the patient with the amount of flow desired by the patient. The amount of flow desired by the patient may be calculated by any suitable means during the spontaneous breath, such as by measuring the amount of flow taken by the patient during the spontaneous breath or by measuring the P_m level during

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the spontaneous breath. The amount of flow desired by the patient may be calculated by utilizing the P_m level in the equation of motion.

As noted above, according to embodiments, the notification message may be associated with a primary prompt and the one or more recommendation messages may be associated with a secondary prompt. That is, a primary prompt may provide an alert that an inadequate flow has been detected and may further provide one or more potential causes for the inadequate flow. Alternatively, an alert may be separately provided, indicating that an inadequate flow was detected, and the primary prompt may provide the one or more potential causes for the inadequate flow. According to additional or alternative embodiments, the secondary prompt may provide the one or more recommendations and/or information that may aid the clinician in further addressing and/or mitigating the detected condition. For example, the secondary prompt may recommend addressing the inadequate flow by investigating causes for the inadequate flow, by increasing peak flow rate, etc. Smart prompt module 226 may also be configured such that smart prompts (including alerts, primary prompts, and/or secondary prompts) may be displayed in a partially transparent window or format. The transparency may allow for notification and/or recommendation messages to be displayed such that normal ventilator GUI and respiratory data may be visualized behind the messages. This feature may be particularly useful for displaying detailed messages. As described previously, notification and/or recommendation messages may be displayed in areas of the display screen that are either blank or that cause minimal distraction from the respiratory data and other graphical representations provided by the GUI. However, upon selective expansion of a message, respiratory data and graphs may be at least partially obscured. As a result, translucent display may provide the detailed message such that it is partially transparent. Thus, graphical and other data may be visible behind the detailed alarm message.

Additionally, notification and/or recommendation messages may provide immediate access to the display and/or settings screens associated with the detected condition. For example, an associated parameter settings screen may be accessed from a notification and/or a recommendation message via a hyperlink such that the clinician may address the detected condition as necessary. An associated parameter display screen may also be accessed such that the clinician may view clinical data associated with the detected condition in the form of charts, graphs, or otherwise. That is, according to embodiments, the clinician may access the ventilatory data that implicated

the detected condition for verification purposes. For example, when an inadequate flow has been implicated, depending on the particular ventilatory parameters that implicated the inadequate flow, the clinician may be able to access ventilatory settings for addressing the inadequate flow (e.g., a settings screen for adjusting wave form shape, peak flow rate, etc.) and/or to view associated ventilatory parameters that implicated the inadequate flow (e.g., a graphics screen displaying historical flow waveforms, volume waveforms, and/or pressure waveforms that gave rise to implications of an inadequate flow).

According to embodiments, upon viewing the notification and/or recommendation messages, upon addressing the detected condition by adjusting one or more ventilatory settings or otherwise, or upon manual selection, the notification and/or recommendation messages may be cleared from the graphical user interface. According to some embodiments, smart prompt module 226 clears the one or more messages from the graphical user interface if the breath type is changed. In further embodiments, smart prompt module 226 clears the one or more messages from the graphical user interface if a ventilator setting change was performed by the operator and two consecutive PIM breaths are delivered where the mean airway pressure calculated between the beginning of inspiration and the point that a predetermined amount of the tidal volume (e.g., 30%) is delivered or a predetermined proportion of the inspiration time expires is greater than the set PEEP plus a predetermined amount of extra pressure (e.g., 5 cm H₂O). In further embodiments, smart prompt module 226 clears the one or more messages from the graphical user interface if two consecutive PIM breaths are delivered where the mean airway pressure calculated between the beginning of inspiration and the point that a predetermined amount of the tidal volume (e.g., 30%) is delivered or a predetermined proportion of the inspiration time expires is greater than the set PEEP. The smart prompt module 226 may clear the one or more messages from the graphical user interface when a

Inadequate Flow Detection during Ventilation of a Patient

FIG. 3 is a flow chart illustrating an embodiment of a method 300 for detecting an implication of inadequate flow.

As should be appreciated, the particular steps and methods described herein are not exclusive and, as will be understood by those skilled in the art, the particular ordering of steps as described herein is not intended to limit the method, e.g., steps may

be performed in differing order, additional steps may be performed, and disclosed steps may be excluded without departing from the spirit of the present methods.

The illustrated embodiment of the method **300** depicts a method for detecting an inadequate flow during ventilation of a patient. Method **300** begins with collecting data operation **304**. Collecting data operation **304** may include receiving data regarding one or more ventilatory settings associated with ventilation of a patient. For example, the ventilator may be configured to provide ventilation to a patient. As such, the ventilatory settings and/or input received may include a prescribed V_T , set flow (or peak flow), predicted or ideal body weight (PBW or IBW), etc. Collecting data operation **304** may include receiving data from sensors regarding one or more ventilatory parameters or receiving derived data from a processor. As discussed above, a ventilatory parameter refers to any factor, characteristic, or measurement associated with the ventilation of a patient, whether monitored by the ventilator or by any other device. The collected data may be transmitted by sensors. For example, data regarding circuit pressure, flow pattern, inspiratory time setting (T_I), etc., may be collected from the sensors, operator interface, and/or processor.

At deliver ventilation operation **308**, the ventilator provides ventilation to a patient, as described above. That is, according to embodiments, the ventilator provides ventilation based on the set breath type. For example, during a VC breath type, the ventilator provides ventilation based on a prescribed V_T . In this example, the ventilator may deliver gases to the patient at a set flow at a set RR. When prescribed V_T has been delivered, the ventilator may initiate the expiratory phase.

While ventilation is being delivered, the ventilator may conduct various data processing operations. For example, at data processing operation **310**, the ventilator may collect and/or derive various ventilatory parameter data associated with ventilation of the patient. For example, as described above, the ventilator may collect data regarding parameters including T_E , V_T , T_I , etc. Additionally, the ventilator may derive various ventilatory parameter data based on the collected data, e.g., IBW-predicted T_I , volume, respiratory resistance, respiratory compliance, etc. As described previously, measurements for respiratory resistance and/or compliance may be trended continuously for a patient because ventilatory data may be obtained without sedating the patient or otherwise. Additionally, the ventilator may generate various graphical representations of the collected and/or derived ventilatory parameter data, e.g., flow waveforms, pressure waveforms, pressure-volume loops, flow-volume loops, etc.

At analyze operation **312**, the ventilator may evaluate collected and/or derived data to determine whether a certain patient condition exists, such as ventilatory parameters and ventilatory settings. For example, according to embodiments, the ventilator may evaluate the various collected and derived data, including expiratory time, mean airway pressure, delivered tidal volume, etc., based on one or more predetermined thresholds. According to embodiments, the ventilator may further evaluate the ventilatory parameter data in light of the patient's specific parameter settings, including set tidal volume, etc., and/or the patient's diagnostic information. In some embodiments, the evaluation of the various collected and derived parameter data includes a patient circuit disconnection operation. The patient circuit disconnection operation determines whether the patient circuit has become disconnected from the patient and/or ventilator. The analyze operation **312** determines that a patient circuit is disconnected by any suitable means. In some embodiments, the analyze operation **312** determines that the patient circuit has become disconnected by evaluating exhaled pressure and/or exhaled volume. In further embodiments, analyze operation **312** determines if the patient circuit is disconnected by determining if a disconnect alarm has been executed. If the disconnect alarm has been executed, then analyze operation **312** determines that the patient circuit is disconnected. If the disconnect alarm has not been executed, then analyze operation **312** determines that the patient circuit is connected.

According to some embodiments, at detect inadequate flow operation **314** the ventilator may determine whether an inadequate flow is implicated by evaluating set flow rate, flow pattern, patient circuit connection, etc. and compare the evaluated parameters to one or more predetermined thresholds. In order to prevent unnecessary alarms, notifications, and/or recommendations, thresholds and conditions are utilized by the detect inadequate flow operation **314** to determine when an inadequate flow has occurred with sufficient frequency to warrant notification of the operator. For example, in some embodiments, an inadequate flow that occurs in one breath in isolation from any other breath with an inadequate flow will not be considered enough to warrant an occurrence of an inadequate flow by detect inadequate flow operation **314**.

In some embodiments, at detect inadequate flow operation **314** the ventilator may determine whether an inadequate flow is implicated based on a predetermined frequency of occurrence. In further embodiments, at detect inadequate flow operation **314** the ventilator may determine that an inadequate flow is implicated when (1) a mean airway pressure delivered is less than a set PEEP and the expiratory time is greater than

a predetermined amount of time; and (2) these events occur more than three times, for more than 30% of the PIM breaths, or for more than 10% of the PIM breaths within a predetermined amount of time (e.g. 60 seconds or 180 seconds). For example, an inadequate flow is detected when at least one of the following predetermined thresholds

5 are exceeded for a PIM breath:

1. the amount of pressure delivered when a predetermined amount of tidal volume has been delivered or a predetermined proportion of the inspiration time has expired in the PIM breath is less than the set PEEP; and
 2. the amount of mean airway pressure for the PIM breath is less than the set
- 10 PEEP.

In some embodiments, the mean airway pressure is compared to a predetermined pressure instead of the set PEEP. For example, the predetermined pressure may be PEEP plus 2 cm H₂O, or PEEP minus 1 cm H₂O. Upon detecting one or more of the above conditions, the inadequate flow is further confirmed by detecting that at least one

15 of the following predetermined thresholds are met:

3. expiratory time for a PIM breath is greater than a predetermined amount of time;
4. the ventilation tubing system status is connected; and
5. no disconnect alarm is detected.

20 The confirmation conditions (3, 4, and 5) listed above confirm that the above pressure conditions (1 and 2) are the result of an inadequate flow, instead of another underlying condition. For example, if a disconnect alarm or the tubing status is disconnected, then the above pressure conditions (1 and 2) are the result of a disconnected patient circuit and not the result of an inadequate flow. Accordingly, the ventilator during the detect inadequate flow operation 314 will not detect an inadequate flow. In an alternative example, if the expiratory time is less than a predetermined amount, then the above pressure conditions (1 and 2) are most likely the result of double triggering. Accordingly, the ventilator during the detect inadequate flow operation 314 will not detect an inadequate flow.

30 In further embodiments, threshold number 3, listed above, may be any suitable expiratory time threshold. For example, in an alternative embodiment the expiratory time threshold is an expiratory time of greater than 190 ms, 200 ms, 210 ms, 215 ms, or 230 ms depending upon the type of ventilator, patient, breath type, ventilator parameters, ventilator settings, and/or ventilator modes, etc. The thresholds listed above

are just one example list of possible conditions that could be used to indicate an inadequate flow. Any suitable list of conditions for determining the occurrence of an inadequate flow may be utilized. A disconnect alarm is executed when the ventilation tubing system is disconnected from the patient and/or the ventilator. In some
5 embodiments, the predetermined amount of time starts at the end of inspiration for each PIM breath.

 If an inadequate flow is implicated, the inadequate flow operation **314** may proceed to issue smart prompt operation **316**. If an inadequate flow is not implicated, the detect inadequate flow operation **314** may return to analyze operation **312**.

10 The thresholds listed above are just one example list of possible conditions that could be used to indicate an inadequate flow in the detect inadequate flow operation **314**. Any suitable list of conditions for determining the occurrence of an inadequate flow may be utilized by the detect inadequate flow operation **314**. As may be appreciated, the ventilator may determine whether an inadequate flow is implicated at
15 detect inadequate flow operation **314** via any suitable means. Indeed, any of the above described ventilatory parameters may be evaluated according to various thresholds for detecting an inadequate flow. Further, the disclosure regarding specific ventilatory parameters as they may implicate an inadequate flow is not intended to be limiting. In fact, any suitable ventilatory parameter may be monitored and evaluated for detecting an
20 inadequate flow within the spirit of the present disclosure. As such, if an inadequate flow is implicated via any suitable means, the detect inadequate flow operation **314** may proceed to issue smart prompt operation **316**. If an inadequate flow is not implicated, the detect inadequate flow operation **314** may return to analyze operation **312**.

 At issue smart prompt operation **316**, the ventilator may alert the clinician via
25 any suitable means that an inadequate flow has been implicated. For example, according to embodiments, the ventilator may display a smart prompt including a notification message and/or a recommendation message regarding the detection and/or cause of an inadequate flow on the GUI. According to alternative embodiments, the ventilator may communicate the smart prompt, including the notification message
30 and/or the recommendation message, to a remote monitoring system communicatively coupled to the ventilator. According to alternative embodiments, the issued smart prompt is any visual and/or audio notification.

 According to embodiments, the notification message may alert the clinician that an inadequate flow has been detected and, optionally, may provide information

regarding the ventilatory parameter(s) that implicated the inadequate flow. According to additional embodiments, the recommendation message may provide one or more suggestions for mitigating an inadequate flow. According to further embodiments, the one or more suggestions may be based on the patient's particular ventilatory settings (e.g. breath type, flow pattern, flow rate, etc.) and/or diagnosis. According to some embodiments, the clinician may access one or more parameter settings and/or display screens from the smart prompt via a hyperlink or otherwise for addressing inadequate flow. According to additional or alternative embodiments, a clinician may remotely access one or more parameter and/or display screens from the smart prompt via a hyperlink or otherwise for remotely addressing inadequate flow.

Smart Prompt Generation regarding Inadequate Flow Detection

FIG. 4 is a flow chart illustrating an embodiment of a method **400** for issuing a smart prompt upon detecting an implication of an inadequate flow.

As should be appreciated, the particular steps and methods described herein are not exclusive and, as will be understood by those skilled in the art, the particular ordering of steps as described herein is not intended to limit the method, *e.g.*, steps may be performed in differing order, additional steps may be performed, and disclosed steps may be excluded without departing from the spirit of the present methods.

The illustrated embodiment of the method **400** depicts a method for issuing a smart prompt upon detecting an inadequate flow during ventilation of a patient. Method **400** begins with detect operation **402**, wherein the ventilator detects that an inadequate flow is implicated, as described above in method **300**.

At identify ventilatory parameters operation **404**, the ventilator may identify one or more ventilatory parameters that implicated an inadequate flow. In order to prevent unnecessary alarms, notifications, and/or recommendations, thresholds and conditions are utilized by identify ventilatory parameters operation **404** to determine when inadequate flow has occurred with sufficient frequency to warrant notification of the operator. For example, in some embodiments, an inadequate flow that occurs in a breath in isolation from any other breath with an inadequate flow will not be considered enough to warrant an occurrence of an inadequate flow by identify ventilatory parameters operation **404**.

For example, the ventilator may recognize that an inadequate flow was implicated based on whether a mean airway pressure delivered is less than a set PEEP and the expiratory time is greater than a predetermined amount has occurred more than

three times, for more than 30% of the PIM breaths, or for more than 10% of the PIM breaths within a predetermined amount of time (e.g. 60 seconds or 180 seconds). For example, an inadequate flow is detected when at least one of the following predetermined thresholds are exceeded for a PIM breath:

- 5 1. the amount of pressure delivered when a predetermined amount of tidal volume has been delivered or a predetermined proportion of the inspiration time expires in the PIM breath is less than the set PEEP; and
2. the amount of mean airway pressure for the PIM breath is less than the set PEEP.

10 Upon detecting one or more of the above conditions, the inadequate flow is further confirmed by detecting that at least one of the following predetermined thresholds are met:

3. expiratory time for a PIM breath is greater than a predetermined amount of time;
- 15 4. the ventilation tubing system status is connected; and
5. no disconnect alarm is detected.

The confirmation conditions (3, 4, and 5) listed above confirm that the above pressure conditions (1 and 2) are the result of an inadequate flow, instead of another underlying condition. In further embodiments, threshold number 3, listed above, may refer to any suitable expiratory period. For example, in an alternative embodiment the

20 expiratory time threshold is an expiratory time of greater than 190 ms, 200 ms, 210 ms, 220 ms, or 230 ms depending upon the type of ventilator, patient, breath type, ventilator parameters, ventilator setting, and/or ventilator modes, etc. The disconnect alarm is executed when the ventilation tubing system is disconnected from the patient and/or the

25 ventilator. In some embodiments, the predetermined amount of time starts at the end of inspiration for each PIM breath. The thresholds listed above are just one example list of possible conditions that could be used to indicate inadequate flow in the parameters operation **404**. Any suitable list of conditions for determining the occurrence of an inadequate flow may be utilized by the parameters operation **404**. As may be

30 appreciated, the ventilator may use information regarding ventilatory parameters that implicated an inadequate flow in determining an appropriate notification and/or recommendation message of the smart prompt.

At identify settings operation **406**, the ventilator may identify one or more current ventilatory settings associated with the ventilatory treatment of the patient. For

example, current ventilatory settings may have been received upon initiating ventilation for the patient and may have been determined by the clinician or otherwise (e.g., breath type, oxygenation, PBW or IBW, disease conditions, etc.). For instance, current ventilatory settings associated with ventilation for a patient may include, V_T , T_I , flow, E_{SENS} , flow pattern, IBW-predicted based on T_I , etc. As may be appreciated, the ventilator may use information regarding current ventilatory settings in determining an appropriate notification and/or recommendation message of the smart prompt.

At determine operation 410, the ventilator may determine an appropriate notification message. For example, the appropriate notification message may alert the clinician that an inadequate flow has been implicated and, optionally, may provide information regarding the ventilatory parameter(s) that implicated the inadequate flow. For example, the appropriate notification may alert the clinician that an inadequate flow was implicated because a mean airway pressure delivered is less than a set PEEP has occurred in more than 10% of the PIM breaths, more than 30% of the PIM breaths, more than three instances of the PIM breaths, more than eight instances of the PIM breaths, etc., within the predetermined amount of time. In some embodiments, the predetermined amount of time is measured at the end of inspiration for each PIM breath. For example, if an inadequate flow was detected because a mean airway pressure from between the beginning of inspiration to the point where 30% of the tidal volume has been delivered is less than a set PEEP and the expiratory time is greater than 210 ms was detected in three or more instances of the PIM breaths within the last 60 seconds, the ventilator may offer one or more notification messages that may include: "Inadequate flow has occurred in more than three instances of the breaths in one minute." In alternative embodiments, measured parameters such as mean airway pressure, may be utilized as the notification message.

At determine operation 412, the ventilator may determine an appropriate primary recommendation message. The appropriate primary recommendation message may provide one or more specific suggestions for mitigating an inadequate flow. According to some embodiments, in determining the appropriate primary recommendation message, the ventilator may take into consideration the one or more monitored ventilatory parameters that implicated an inadequate flow.

According to other embodiments, in determining an appropriate primary recommendation message the ventilator may take into consideration one or more of the patient's ventilatory settings. For example, if the breath type is volume-control (VC)

and if the flow pattern is set to square, the ventilator may offer one or more recommendation messages that may include: "Consider increasing the set peak flow rate; Consider changing to spontaneous breath type such as PA, PS, or VS; Consider changing to VC+ or PC breath type; and Consider switching to a spontaneous breath type for one breath to measure the amount of flow desired by the patient." In another example, if the breath type is volume-control (VC) and if the flow pattern is set to decelerating, the ventilator may offer one or more recommendation messages that may include: "Consider changing the flow pattern to square and/or increasing the set peak flow rate; Consider changing to spontaneous breath type such as PA, PS, or VS; Consider changing to VC+ or PC breath type; and Consider switching to a spontaneous breath type for one breath to measure the amount of flow desired by the patient." Any of the primary recommendations as discussed above for any breath type may be utilized by method 400.

According to further embodiments, in determining the appropriate primary recommendation message the ventilator in determine operation 412 may automatically switch to a spontaneous breath type for one breath to determine the amount of flow desired by the patient. In these embodiments, at least one of the primary or secondary recommendations suggests changing a ventilator setting or parameter by a specific amount to provide the patient with the amount of flow desired by the patient. The amount flow desired by the patient may be calculated by any suitable means during the spontaneous breath, such as by measuring the amount of flow taken by the patient during the spontaneous breath or by measuring the P_m level during the spontaneous breath. The amount of flow desired by the patient may be determined by utilizing the P_m level in the equation of motion.

At determine operation 414, the ventilator may determine an appropriate secondary recommendation message. The secondary recommendation message may provide one or more general suggestions for mitigating inadequate flow. For example, the secondary recommendation message may include: "Consider increasing the peak flow rate by the flow amount desired by a patient measured during a recent spontaneous breath; Consider changing to a spontaneous breath type such as PA, PS, or VS." The secondary recommendation message may provide additional recommendations for mitigating inadequate flow. In further embodiments, the appropriate secondary recommendation message may take into consideration the patient's current ventilatory settings. That is, during a VC breath type, the ventilator may suggest changing to a

spontaneous breath type such as PA, PS, or VS or suggest changing to a VC+ or PC breath type in the secondary recommendation message. As known by a person of skill in the art any notification, message, and/or recommendation disclosed herein may be suitable for use as a primary and/or secondary recommendation message.

5 At issue smart prompt operation 416, a smart prompt is issued. A smart prompt is issued when the ventilator alerts the clinician via any suitable means that an inadequate flow has been implicated. For example, according to embodiments, a smart prompt may include an appropriate notification message and an appropriate recommendation message regarding the presence of an inadequate flow. Additionally or
10 alternatively, the smart prompt may include an appropriate notification message, an appropriate primary recommendation message, and an appropriate secondary recommendation message. The smart prompt may be displayed via any suitable means, e.g., on the ventilator GUI and/or at a remote monitoring station, such that the clinician is alerted as to the potential presence of an inadequate flow and offered additional
15 information and/or recommendations for mitigating the inadequate flow, as described herein.

 In some embodiments, a ventilatory system for issuing a smart prompt when an inadequate flow is implicated during ventilation of a patient is disclosed. The ventilatory system includes: means for collecting data associated with ventilatory
20 parameters; means for processing the collected ventilatory parameter data, wherein the step of processing the collected ventilatory parameter data comprises deriving ventilatory parameter data from the collected ventilatory parameter data; means for analyzing the processed ventilatory parameter data; means for determining that an inadequate flow is implicated upon detecting that the processed ventilatory parameter
25 data breaches a received at least one predetermined threshold at a predetermined frequency; and means for issuing a smart prompt when the inadequate flow is implicated. In further embodiments, the means for the medical ventilator are illustrated in FIGS. 1 and 2 and are described in the above descriptions of FIGS. 1 and 2. However, the means described above for FIGS. 1 and 2 and illustrated in FIGS. 1 and 2
30 are but one example only and are not meant to be limiting.

Ventilator GUI Display of Initial Smart Prompt

 FIG. 5 is an illustration of an embodiment of a graphical user interface 500 displaying a smart prompt having a notification message 512.

Graphical user interface **500** may display various monitored and/or derived data to the clinician during ventilation of a patient. In addition, graphical user interface **500** may display various messages to the clinician (e.g., alarm messages, etc.). Specifically, graphical user interface **500** may display a smart prompt as described herein.

5 According to embodiments, the ventilator may monitor and evaluate various ventilatory parameters based on one or more predetermined thresholds to detect an inadequate flow. As illustrated, a pressure waveform may be generated and displayed by the ventilator on graphical user interface **500**. As further illustrated, the pressure waveform may be displayed such that pressure during inspiration **502** is represented in a
10 different color (e.g., green) than pressure during expiration **504** (e.g., yellow). In one embodiment, as illustrated, an inadequate flow **506** occurs when a mean airway pressure is delivered that is less than a set PEEP or predetermined pressure. Inadequate flow results when the patient desires more flow than being delivered by the ventilator to the patient. An inadequate flow may occur when a flow rate is set too low, a peak flow rate
15 is set too low, and/or the flow pattern does not match that of the patient's effort. The flow rate (e.g., peak flow rate) may be set by an operator, selected by an operator, or determined by the ventilator. In order to prevent unnecessary alarms, notifications, and/or recommendations, thresholds and conditions are utilized to determine when an inadequate flow has occurred with sufficient frequency to warrant notification of the
20 operator.

That is, an inadequate flow may be detected if a mean airway pressure delivered is less than a set PEEP has occurred more than three times, for more than 30% of the PIM breaths, or for more than 10% of the PIM breaths within a predetermined amount of time (e.g. 60 seconds or 180 seconds). For example, an inadequate flow is detected
25 when at least one of the following predetermined thresholds are exceeded for a PIM breath:

1. the amount of pressure delivered when a predetermined amount of tidal volume has been delivered or a predetermined proportion of the inspiration time expires in the PIM breath is less than the set PEEP; and
- 30 2. the amount of mean airway pressure for the PIM breath is less than the set PEEP.

Upon detecting one or more of the above conditions, the inadequate flow is further confirmed by detecting that at least one of the following predetermined thresholds are met:

3. expiratory time for a PIM breath is greater than a predetermined amount of time;
4. the ventilation tubing system status is connected; and
5. no disconnect alarm is detected.

5 The confirmation conditions (3, 4, and 5) listed above confirm that the above pressure conditions (1 and 2) are the result of an inadequate flow, instead of another underlying condition. For example, if a disconnect alarm or the tubing status is disconnected, then the above pressure conditions (1 and 2) are the result of a disconnected patient circuit and not the result of an inadequate flow. Accordingly, the ventilator will not issue a prompt for inadequate flow if these conditions are not met. In
10 an alternative example, if the expiratory time is less than a predetermined amount, then the above pressure conditions (1 and 2) are most likely the result of double triggering. Accordingly, the ventilator will not issue a prompt for inadequate flow, since the pressure condition was not caused by inadequate flow.

15 In further embodiments, threshold number 3, listed above, may be any suitable expiratory time threshold. For example, in an alternative embodiment the expiratory time threshold is an expiratory time of greater than 190 ms, 210 ms, 220 ms, 235 ms, or 255 ms depending upon the type of ventilator, patient, breath type, ventilator parameters, ventilator setting, and/or ventilator modes, etc. The disconnect alarm is
20 executed when the ventilation tubing system is disconnected from the patient and/or the ventilator. In some embodiments, the predetermined amount of time starts at the end of inspiration for each PIM breath. The thresholds listed above are just one example list of possible conditions that could be used to indicate an inadequate flow. Any suitable list of conditions for determining the occurrence of an inadequate flow may be utilized.

25 Upon a determination that an inadequate flow is implicated, the graphical user interface **500** may display a smart prompt, e.g., smart prompt **510**.

 According to embodiments, smart prompt **510** may be displayed in any suitable location such that a clinician may be alerted regarding a detected patient condition, but while allowing other ventilatory displays and data to be visualized substantially
30 simultaneously. As illustrated, smart prompt **510** is presented as a bar or banner across an upper region of the graphical user interface **500**. However, as previously noted, smart prompt **510** may be displayed as a tab, icon, button, banner, bar, or any other suitable shape or form. Further, smart prompt **510** may be displayed in any suitable location within the graphical user interface **500**. For example, smart prompt **510** may be located

along any border region of the graphical user interface **500** (e.g., top, bottom, or side borders) (not shown), across an upper region (shown), or in any other suitable location. Further, as described herein, smart prompt **510** may be partially transparent (not shown) such that ventilatory displays and data may be at least partially visible behind smart prompt **510**.

Specifically, smart prompt **510** may alert the clinician that an inadequate flow has been detected, for example by notification message **512**. As described herein, notification message **512** may alert the clinician that the inadequate flow is implicated via any suitable means, e.g., “Inadequate Flow Alert” (shown), “Inadequate Flow Detected” (not shown), or “Inadequate Flow Implicated” (not shown). Smart prompt **510** may further include information regarding ventilatory parameters that implicated the inadequate flow. For example, if an inadequate flow was detected based on a mean airway pressure being below a set PEEP in three or more instances in the last 30 seconds and the expiratory time being greater than or equal to 210 ms, this information may be displayed by the notification message **512** (e.g., “mean airway pressure below a set PEEP was found in three or more instances in the last 30 seconds and the expiratory time is greater than or equal to 210 ms,” shown). According to the illustrated embodiment, parameter information **514** is provided along with the notification message **512** in a banner. According to alternative embodiments, in addition to the notification message **512** and the parameter information **514**, one or more recommendation messages may be provided in an initial smart prompt banner (not shown). According to other embodiments, rather than providing information regarding ventilatory parameters that implicated an inadequate flow in the initial smart prompt, this information may be provided within an expanded portion (not shown) of smart prompt **510**.

According to embodiments, smart prompt **510** may be expanded to provide additional information and/or recommendations to the clinician regarding a detected patient condition. For example, an expand icon **516** may be provided within a suitable area of the smart prompt **510**. According to embodiments, upon selection of the expand icon **516** via any suitable means, the clinician may optionally expand the smart prompt **510** to acquire additional information and/or recommendations for mitigating the detected patient condition. According to further embodiments, smart prompt **510** may include links (not shown) to additional settings and/or display screens of the graphical user interface **500** such that the clinician may easily and quickly mitigate and/or verify the detected condition.

As may be appreciated, the disclosed data, graphics, and smart prompt illustrated in graphical user interface **500** may be arranged in any suitable order or configuration such that information and alerts may be communicated to the clinician in an efficient and orderly manner. The disclosed data, graphics, and smart prompt are not to be understood as an exclusive array, as any number of similar suitable elements may be displayed for the clinician within the spirit of the present disclosure. Further, the disclosed data, graphics, and smart prompt are not to be understood as a necessary array, as any number of the disclosed elements may be appropriately replaced by other suitable elements without departing from the spirit of the present disclosure. The illustrated embodiment of the graphical user interface **500** is provided as an example only, including potentially useful information and alerts that may be provided to the clinician to facilitate communication of detected set inadequate flow in an orderly and informative way, as described herein.

Ventilator GUI Display of Expanded Smart Prompt

FIG. 6 is an illustration of an embodiment of a graphical user interface **600** displaying an expanded smart prompt **606** having a notification message and one or more recommendation messages **608**.

Graphical user interface **600** may display various monitored and/or derived data to the clinician during ventilation of a patient. In addition, graphical user interface **600** may display an expanded smart prompt **606** including one or more recommendation messages **608** as described herein.

According to embodiments, as described above, an expand icon **604** may be provided within a suitable area of smart prompt **602**. Upon selection of the expand icon **604**, the clinician may optionally expand smart prompt **602** to acquire additional information and/or recommendations for mitigating the detected patient condition. For example, expanded smart prompt **606** may be provided upon selection of expand icon **604**. As described above for smart prompt **510**, expanded smart prompt **606** may be displayed as a tab, icon, button, banner, bar, or any other suitable shape or form. Further, expanded smart prompt **606** may be displayed in any suitable location within the graphical user interface **600**. For example, expanded smart prompt **606** may be displayed below (shown) smart prompt **602**, to a side (not shown) of smart prompt **602**, or otherwise logically associated with smart prompt **602**. According to other embodiments, an initial smart prompt may be hidden (not shown) upon displaying expanded smart prompt **606**. Expanded smart prompt **606** may also be partially

transparent (not shown) such that ventilatory displays and data may be at least partially visible behind expanded smart prompt **606**.

According to embodiments, expanded smart prompt **606** may comprise additional information (not shown) and/or one or more recommendation messages **608** regarding detected inadequate flow. For example, the one or more recommendation messages **608** may include a primary recommendation message and a secondary recommendation message. The primary recommendation message may provide one or more specific suggestions for mitigating the inadequate flow. For example, if the inadequate flow was implicated during volume-control ventilation and if the flow pattern is set to a decelerating ramp flow pattern, then the ventilator may offer one or more primary recommendation messages **608** that may include: "Consider increasing the set peak flow rate; Consider changing to a VC+ or PC breath type; Consider changing to spontaneous breath type such as PA, PS, or VS; and Consider switching to a spontaneous breath type for one breath to measure the amount of flow desired by the patient." The secondary recommendation message may provide one or more general suggestions for mitigating the inadequate flow. For example, the secondary recommendation message may include: "Consider changing to spontaneous breath type such as PA, PS, or VS; Consider increasing the peak flow rate by the flow amount desired by a patient measured during a recent spontaneous breath; Consider changing to a VC+ or PC breath type."

According to embodiments, expanded smart prompt **606** may also include one or more hyperlinks **610**, which may provide immediate access to the display and/or settings screens associated with detected inadequate flow. For example, associated parameter settings screens may be accessed from expanded smart prompt **606** via hyperlinks **610** such that the clinician may address detected inadequate flow by adjusting one or more parameter settings as necessary. Alternatively, associated parameter display screens may be accessed such that the clinician may view clinical data associated with the inadequate flow in the form of charts, graphs, or otherwise. That is, according to embodiments, the clinician may access the ventilatory data that implicated the inadequate flow for verification purposes. For example, when an inadequate flow has been implicated, depending on the particular ventilatory parameters that implicated the inadequate flow, the clinician may be able to access associated parameter settings screens for addressing the inadequate flow (e.g., settings screens for adjusting flow pattern, peak flow rate, breath type, etc.). Additionally or alternatively, the clinician

may be able to access and/or view display screens associated with the ventilatory parameters that implicated the inadequate flow (e.g., a graphics screen displaying historical flow waveforms, volume waveforms, and/or pressure waveforms that give rise to implications of the inadequate flow).

5 As may be appreciated, the disclosed smart prompt and recommendation messages 608 illustrated in graphical user interface 600 may be arranged in any suitable order or configuration such that information and alerts may be communicated to the clinician in an efficient and orderly manner. Indeed, the illustrated embodiment of the graphical user interface 600 is provided as an example only, including potentially useful
10 information and recommendations that may be provided to the clinician to facilitate communication of suggestions for mitigating detected inadequate flow in an orderly and informative way, as described herein.

 Unless otherwise indicated, all numbers expressing measurements, dimensions, and so forth used in the specification and claims are to be understood as being modified
15 in all instances by the term “about.” Accordingly, unless indicated to the contrary, the numerical parameters set forth in the following specification and attached claims are approximations that may vary depending upon the desired properties sought to be obtained by the present disclosure. Further, unless otherwise stated, the term “about” shall expressly include “exactly,” consistent with the discussions regarding ranges and
20 numerical data. Concentrations, amounts, and other numerical data may be expressed or presented herein in a range format. It is to be understood that such a range format is used merely for convenience and brevity and thus should be interpreted flexibly to include not only the numerical values explicitly recited as the limits of the range, but also to include all the individual numerical values or sub-ranges encompassed within
25 that range as if each numerical value and sub-range is explicitly recited. As an illustration, a numerical range of “about 4 percent to about 7 percent” should be interpreted to include not only the explicitly recited values of about 4 percent to about 7 percent, but also include individual values and sub-ranges within the indicated range. Thus, included in this numerical range are individual values such as 4.5, 5.25 and 6 and
30 sub-ranges such as from 4-5, from 5-7, and from 5.5-6.5, etc. This same principle applies to ranges reciting only one numerical value. Furthermore, such an interpretation should apply regardless of the breadth of the range or the characteristics being described.

 It will be clear that the systems and methods described herein are well adapted to attain the ends and advantages mentioned as well as those inherent therein. Those

skilled in the art will recognize that the methods and systems within this specification may be implemented in many manners and as such is not to be limited by the foregoing exemplified embodiments and examples. In other words, functional elements being performed by a single or multiple components, in various combinations of hardware and software, and individual functions can be distributed among software applications at either the client or server level. In this regard, any number of the features of the different embodiments described herein may be combined into one single embodiment and alternative embodiments having fewer than or more than all of the features herein described are possible.

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 disclosure. 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 defined in the appended claims.

Claims

What is claimed is:

1. A ventilator-implemented method for detecting inadequate flow during ventilation of a patient, the method comprising:
 - 5 collecting data associated with ventilatory parameters;
 - processing the collected ventilatory parameter data, wherein the step of processing the collected ventilatory parameter data comprises deriving ventilatory parameter data from the collected ventilatory parameter data;
 - analyzing the processed ventilatory parameter data;
 - 10 determining that an inadequate flow is implicated upon detecting that the processed ventilatory parameter data breaches a received at least one predetermined threshold at a predetermined frequency; and
 - issuing a smart prompt when the inadequate flow is implicated.
- 15 2. The method of claim 1, wherein the processed ventilatory parameter data comprises:
 - a mean airway pressure for a PIM breath calculated between a beginning of inspiration and a point where a predetermined amount of tidal volume has been delivered in the PIM breath, and
 - 20 wherein the step of determining that the inadequate flow is implicated comprises:
 - receiving a predetermined threshold for the mean airway pressure, the predetermined threshold for the mean airway pressure comprising:
 - 25 a mean airway pressure threshold of less than a set PEEP;
 - determining the set PEEP;
 - determining the mean airway pressure; and
 - determining that the mean airway pressure is less than the set PEEP.
3. The method of claim 2, wherein the processed ventilatory parameter data
30 comprises a disconnect alarm, and
wherein the step of determining that the inadequate flow is implicated further comprises:
 - determining that the disconnect alarm has not been executed.

4. The method of claim 2, wherein the processed ventilatory parameter data comprises a an expiratory time (T_E) for the PIM breath,

wherein the step of determining that the inadequate flow is implicated

5 comprises:

receiving the predetermined threshold for the expiratory time (T_E), the predetermined threshold comprising:

an expiratory time (T_E) threshold of greater than a predetermined amount of time;

10 determining the expiratory time (T_E); and

determining that the expiratory time (T_E) is greater than the predetermined amount of time.

5. The method of claim 1, wherein the processed ventilatory parameter data
15 comprises:

an airway pressure for a PIM breath calculated at a point where a predetermined portion of an inspiration time has expired during the PIM breath, and

wherein the step of determining that the inadequate flow is implicated comprises:

20 receiving a predetermined threshold for the airway pressure, the predetermined threshold for the airway pressure comprising:

an airway pressure threshold of less than a set PEEP;

determining the set PEEP;

determining the airway pressure; and

25 determining that the airway pressure is less than the set PEEP.

6. The method of claim 5, wherein the processed ventilatory parameter data comprises a ventilation tubing system connection status, and

wherein the step of determining that the inadequate flow is implicated further

30 comprises:

determining that a ventilation tubing system has not been disconnected from at least one of a ventilator and the patient.

7. The method of claim 5, wherein the processed ventilatory parameter data comprises a an expiratory time (T_E) for the PIM breath,

wherein the step of determining that the inadequate flow is implicated comprises:

5 receiving the predetermined threshold for the expiratory time (T_E), the predetermined threshold comprising:

an expiratory time (T_E) threshold of greater than a predetermined amount of time;

determining the expiratory time (T_E); and

10 determining that the expiratory time (T_E) is greater than the predetermined amount of time.

8. The method of claim 5, further comprising:

15 identifying one or more ventilatory settings associated with a ventilatory treatment of the patient; and

determining an appropriate recommendation message for the issued smart prompt based at least in part on evaluating the one or more ventilatory settings.

9. The method of claim 5, wherein the one or more ventilatory settings
20 include at least one of breath type, peak flow, tidal volume, and flow pattern.

10. A ventilatory system for issuing a smart prompt when inadequate flow is implicated during ventilation of a patient, comprising:

at least one processor; and

25 at least one memory, communicatively coupled to the at least one processor and containing instructions that, when executed by the at least one processor, perform a method comprising:

detecting that an inadequate flow is implicated for a patient;

determining an appropriate notification message;

30 determining an appropriate recommendation message; and

issuing at least one of the appropriate notification message and the appropriate recommendation message.

11. The ventilatory system of claim 10, further comprising:
determining processed ventilatory parameter data that implicated the inadequate
flow, and

5 wherein the step of determining the appropriate notification message is based at
least in part on the processed ventilatory parameter data that implicated the inadequate
flow.

12. The ventilatory system of claim 10, wherein the appropriate notification
message comprises an alert that the inadequate flow is implicated and information
10 regarding the processed ventilatory parameter data that implicated the inadequate flow.

13. The ventilatory system of claim 10, wherein the appropriate
recommendation message comprises a primary recommendation message and a
secondary recommendation message.

15

14. The method of claim 10, further comprising:
determining one or more ventilatory settings associated with a ventilatory
treatment of the patient; and
wherein the step of determining the appropriate recommendation message is
20 based at least in part on evaluating the one or more ventilatory settings.

15. The method of claim 14, wherein the one or more ventilatory settings is a
volume-control (VC) breath type.

25 16. The ventilatory system of claim 15, wherein the appropriate
recommendation message comprises a primary recommendation message and a
secondary recommendation message based at least in part on the breath type.

17. The ventilatory system of claim 16, wherein the primary recommendation
30 message comprises one of:
a recommendation to switch to a PC or VC+ breath type;
a recommendation to switch to a spontaneous breath type for one breath to
measure an amount of flow desired by the patient;

a recommendation to increase a peak flow rate if a flow pattern is set to a square flow pattern;

a recommendation to increase the peak flow rate if the flow pattern is set to a decelerating ramp flow pattern; and

5 a recommendation to change the flow pattern from the decelerating ramp flow pattern to the square flow pattern.

18. The ventilatory system of claim 16, wherein the secondary recommendation message comprises:

10 a recommendation to switch to a spontaneous breath type; and
a recommendation to switch to a PC or VC+ breath type.

19. The ventilatory system of claim 10, wherein the step of determining the appropriate recommendation message comprises:

15 switching to a spontaneous breath type for a single spontaneous breath;
detecting an amount of flow desired by the patient based on the single spontaneous breath; and

identifying that the appropriate recommendation message should include a setting change that will provide the patient with the amount of flow desired by the
20 patient.

20. The ventilatory system of claim 10, wherein the step of determining the appropriate recommendation message comprises:

switching to a spontaneous breath type for a single spontaneous breath;
25 determining a P_m level of the patient based on the single spontaneous breath;
determining an amount of flow desired by the patient based on the P_m level and an equation of motion; and

identifying that the appropriate recommendation message should include a setting change that will provide the patient with the amount of flow desired by the
30 patient.

21. A graphical user interface for displaying one or more prompts corresponding to a detected condition, a ventilator configured with a computer having a user interface including the graphical user interface for accepting commands and for displaying information, the graphical user interface comprising:

5 at least one window; and

one or more elements within the at least one window comprising at least one prompt element for communicating information regarding a detected condition, wherein the detected condition is an inadequate flow during ventilation of a patient.

10 22. The graphical user interface of claim 21, wherein the at least one prompt element further comprises at least one of a notification message and one or more recommendation messages, wherein the notification message comprises one or more alerts associated with a detected implication and cause of the inadequate flow, and wherein the one or more recommendation messages comprise one or more
15 recommendations for mitigating the inadequate flow.

23. The graphical user interface of claim 22, wherein the one or more recommendations during a volume-control (VC) breath type comprise one or more of:

consider switching to a PC or VC+ breath type;
20 consider switching to a spontaneous breath type for one breath to measure an amount of flow desired by the patient;
consider switching to a proportional assist (PA) breath type, a pressure-support (PS) breath type, or a volume-support (VS) breath type;
consider increasing a peak flow rate if a flow pattern is set to a square flow
25 pattern;
consider increasing the peak flow rate if the flow pattern is set to a decelerating ramp flow pattern; and
consider changing the flow pattern from the decelerating ramp flow pattern to the square flow pattern.

30

24. A ventilatory system for issuing a smart prompt when inadequate flow is implicated during ventilation of a patient, comprising:

means for collecting data associated with ventilatory parameters;

5 means for processing the collected ventilatory parameter data, wherein the step of processing the collected ventilatory parameter data comprises deriving ventilatory parameter data from the collected ventilatory parameter data;

means for analyzing the processed ventilatory parameter data;

10 means for determining that an inadequate flow is implicated upon detecting that the processed ventilatory parameter data breaches a received at least one predetermined threshold at a predetermined frequency; and

means for issuing a smart prompt when the inadequate flow is implicated.

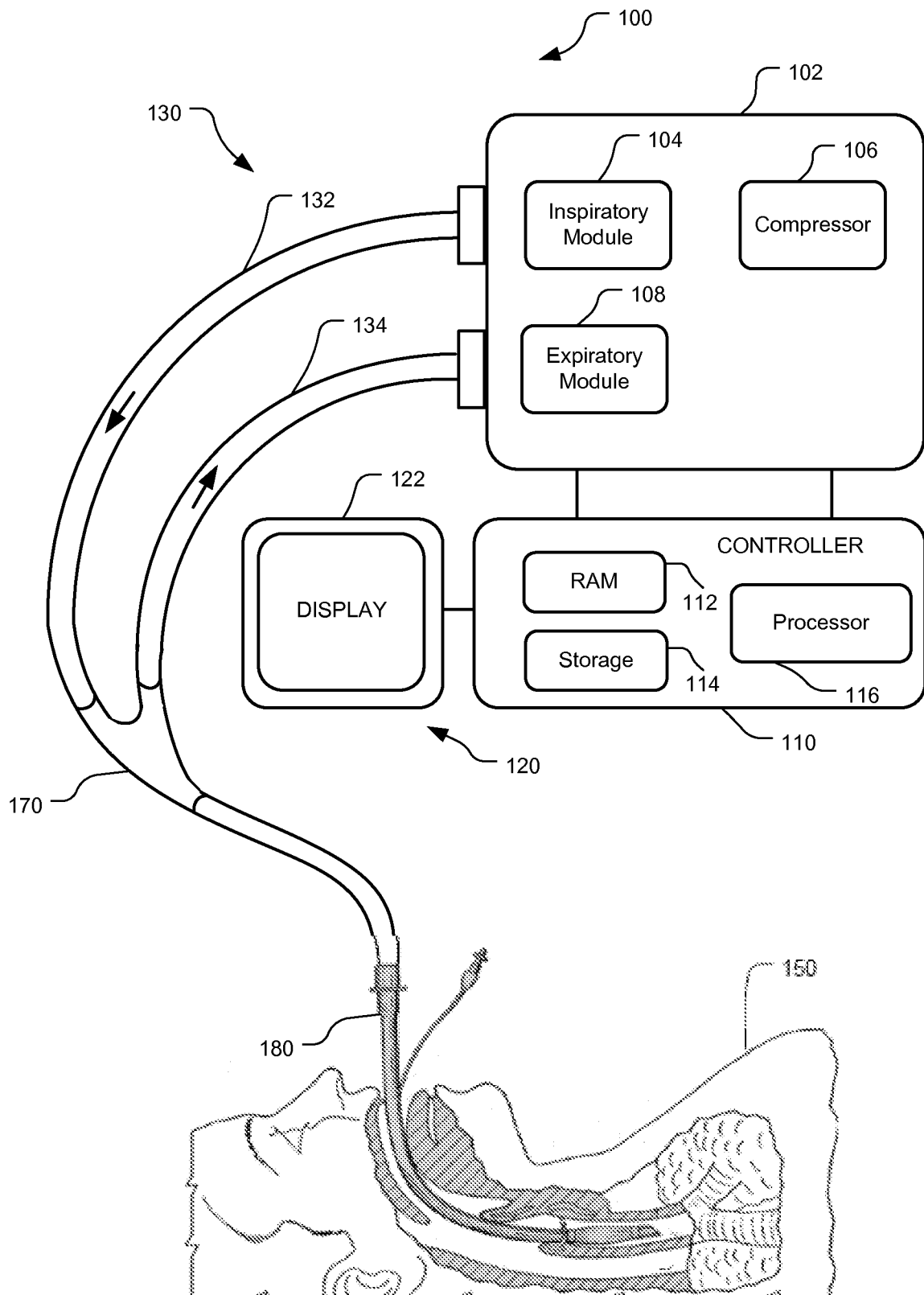
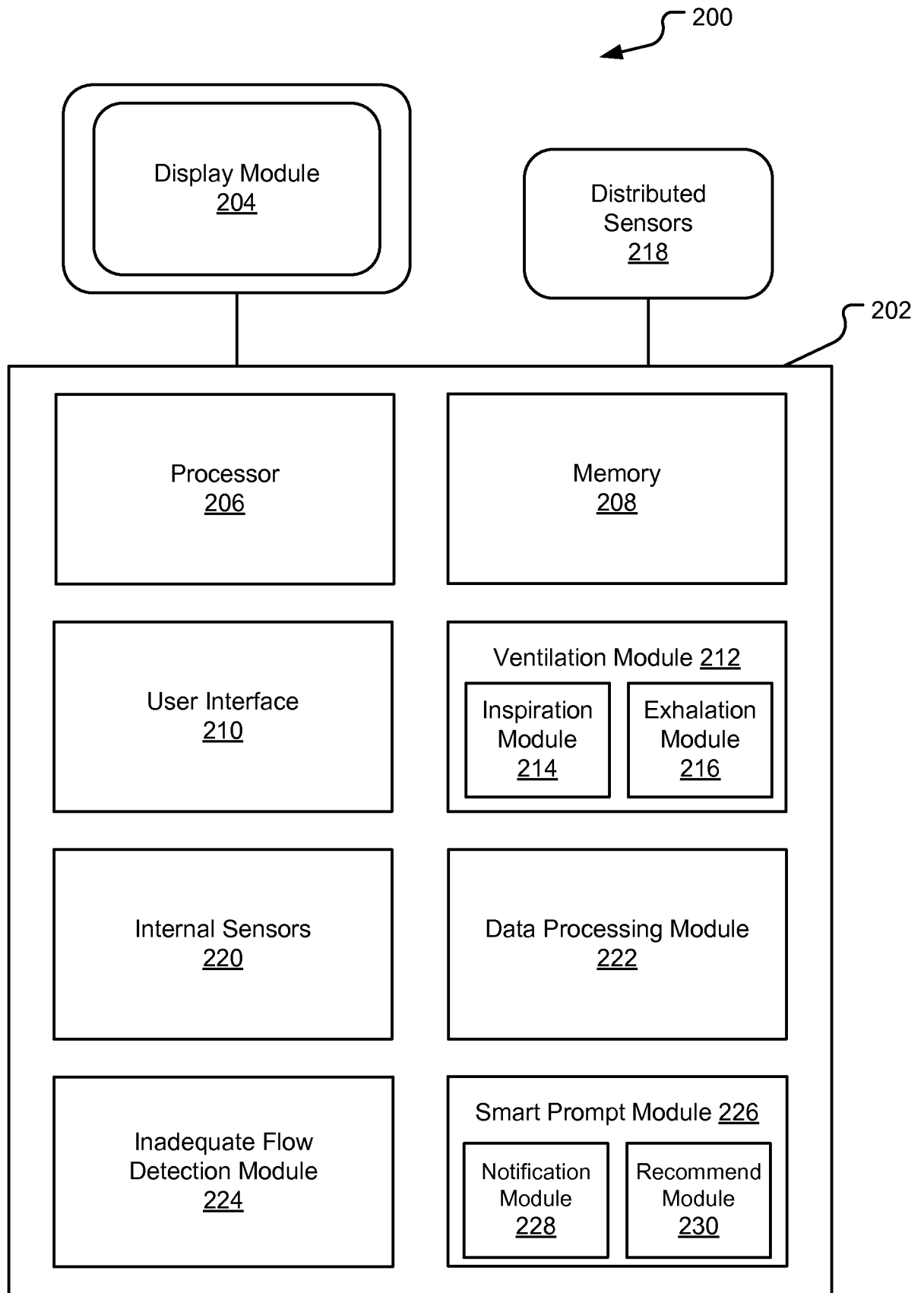
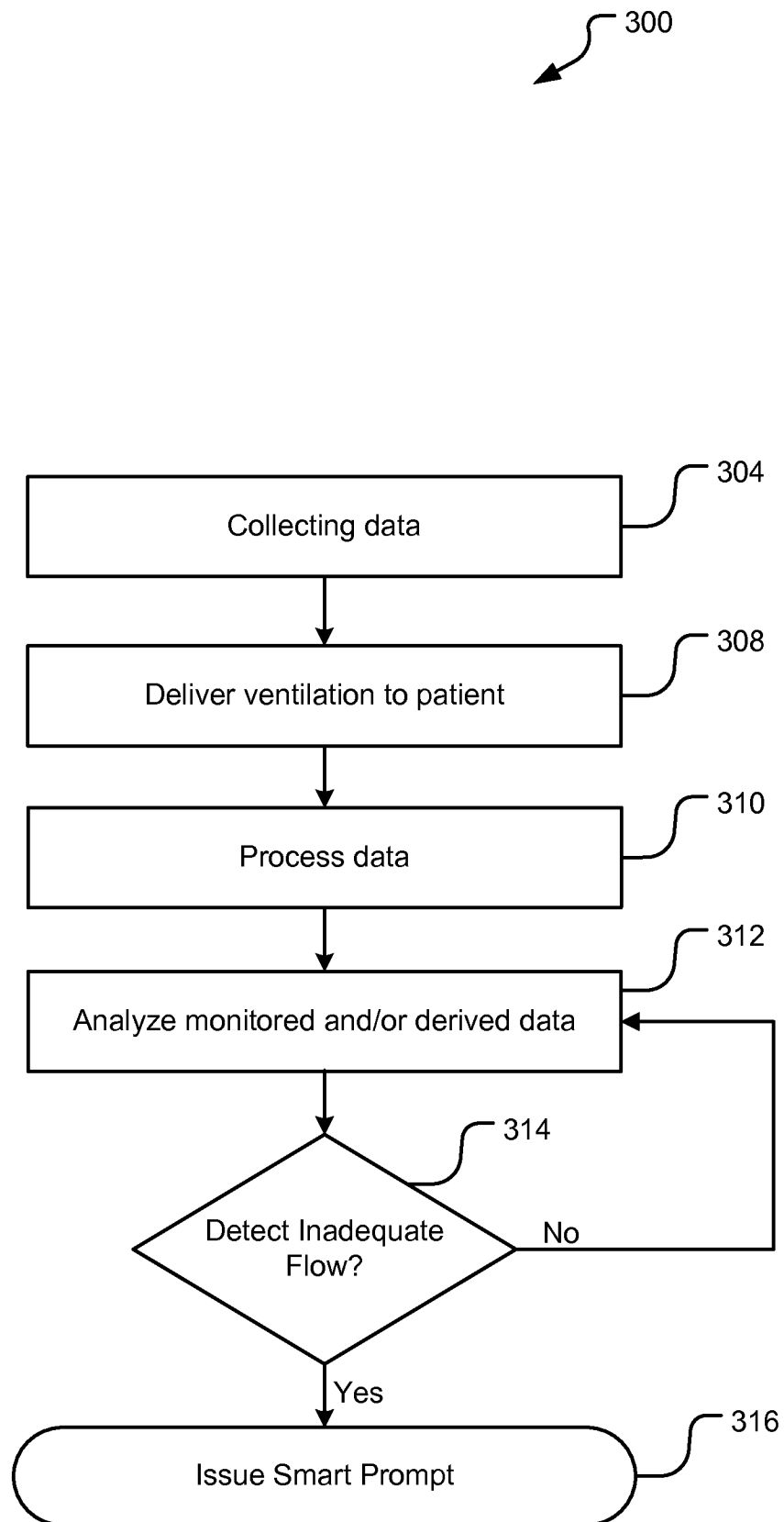
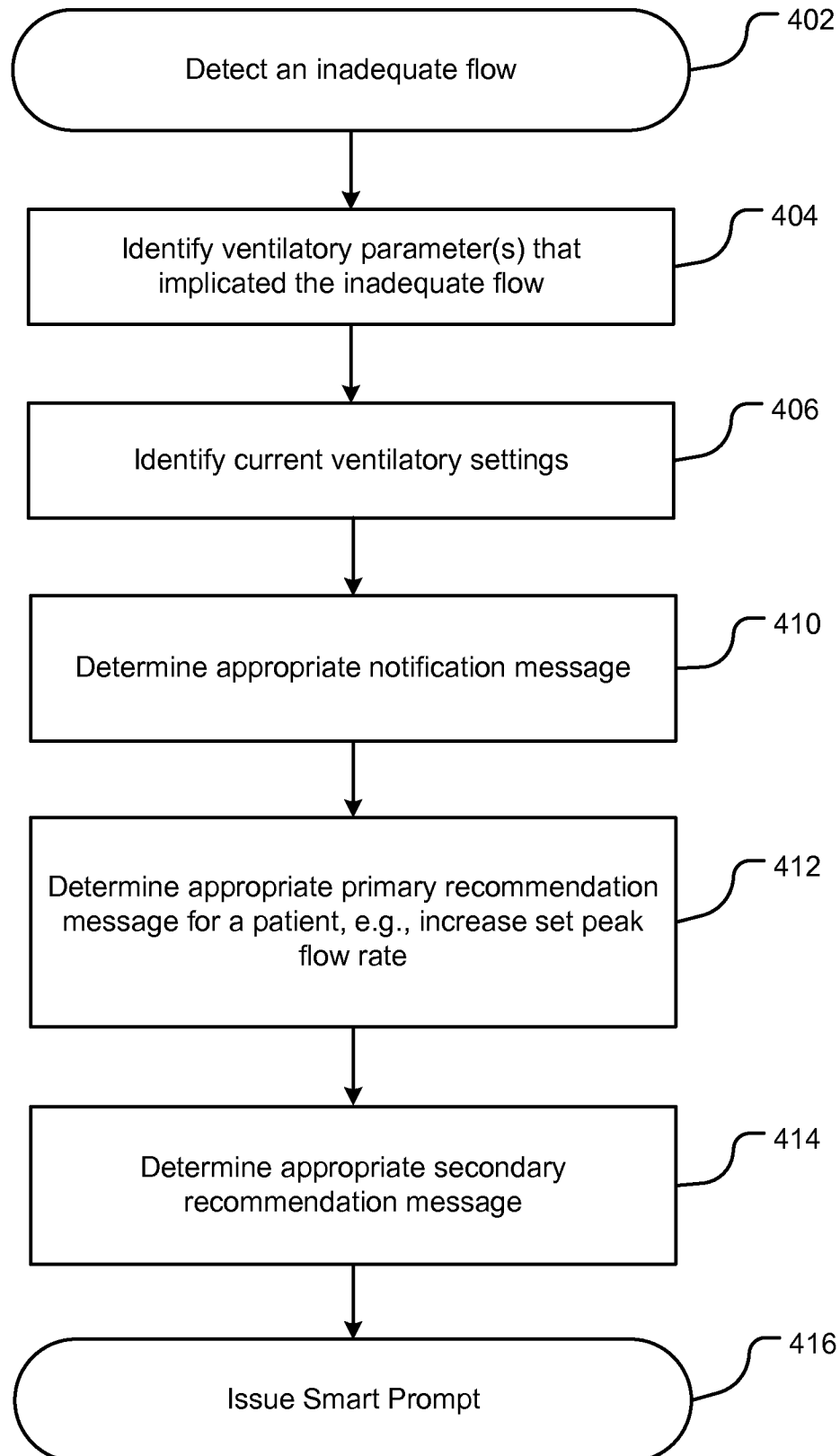


FIG. 1

**FIG. 2**

**FIG. 3**

**FIG. 4**

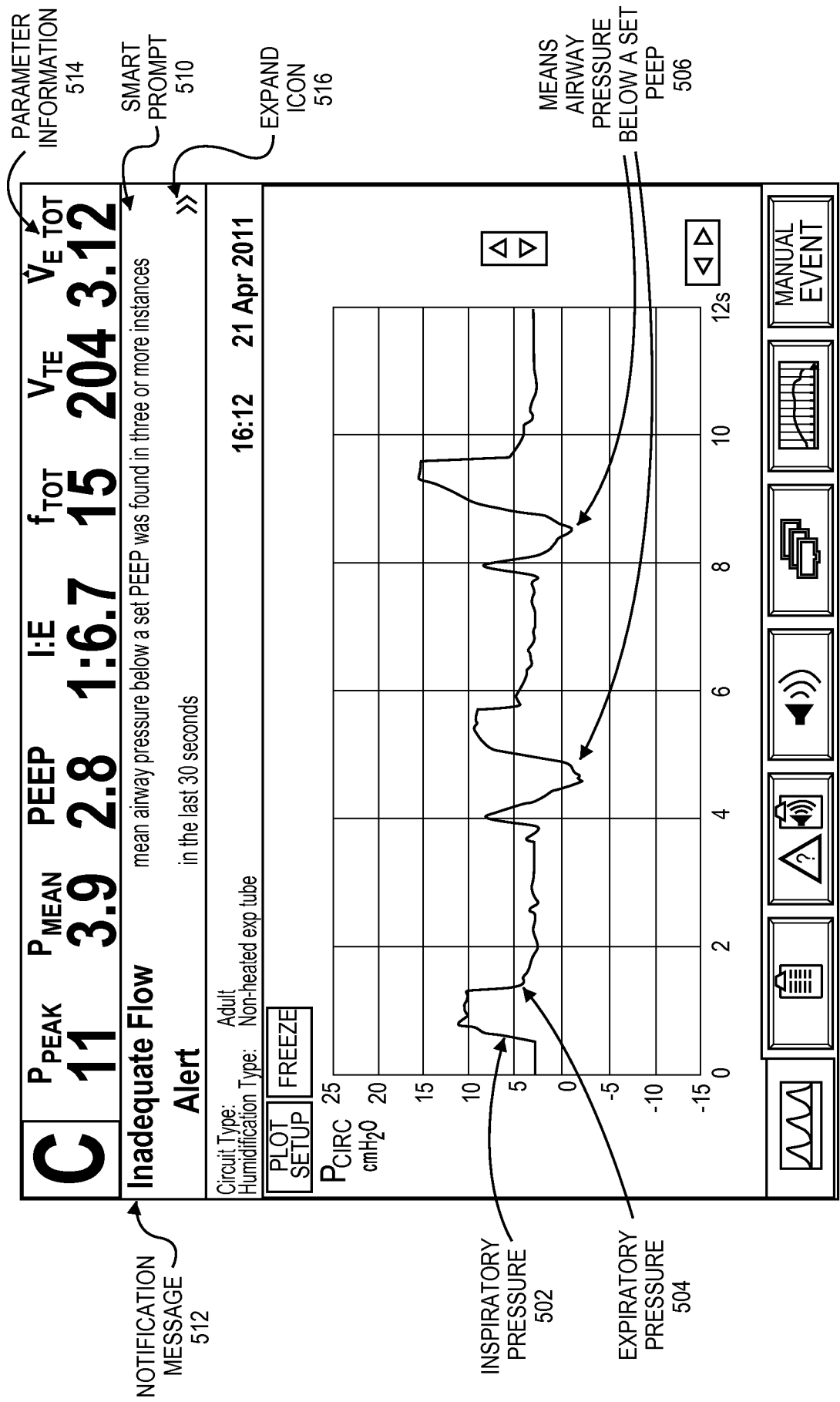


FIG. 5

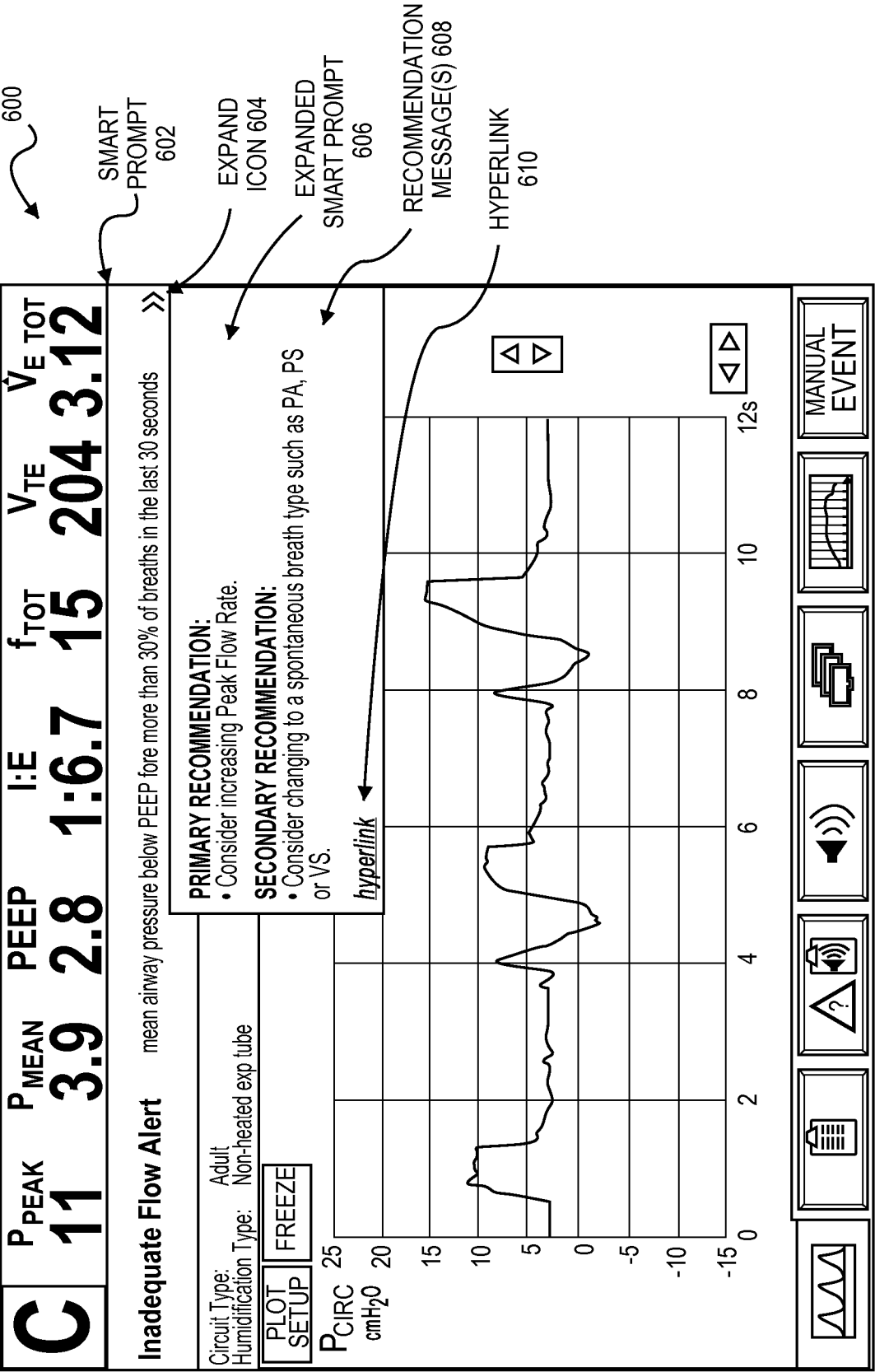


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/026242

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00 A61B5/08
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 A61B G06F

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)

EP0-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 2010/292544 A1 (SHERMAN LESLIE H [US] ET AL) 18 November 2010 (2010-11-18) the whole document	1-24
A	----- EP 1 449 558 A2 (NELLCOR PURITAN BENNETT INC [US]) 25 August 2004 (2004-08-25) column 5, lines 11-19 column 23, lines 10-20 figures	1-24
A	----- EP 0 901 798 A1 (SIEMENS ELEMA AB [SE]) 17 March 1999 (1999-03-17) the whole document	1-24
A	----- US 2008/072902 A1 (SETZER BONNY CARLENE [US] ET AL) 27 March 2008 (2008-03-27) the whole document	1-24
	----- -/-	

☒ 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

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

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

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

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

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

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Date of the actual completion of the international search

29 June 2012

Date of mailing of the international search report

05/07/2012

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2012/026242

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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