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(54) **LEAK-COMPENSATED RESPIRATORY MECHANICS ESTIMATION IN MEDICAL VENTILATORS**

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USPC **128/204.21**; 128/202.22

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See application file for complete search history.

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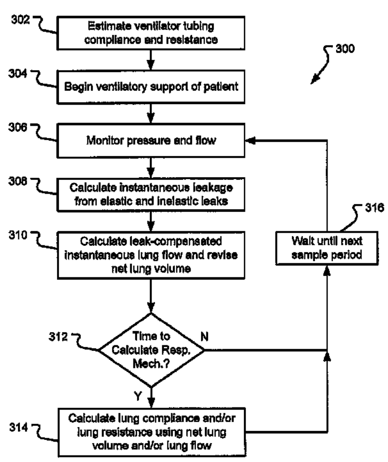
(57) **ABSTRACT**

This disclosure describes systems and methods for compensating for leakage when determining the respiratory mechanics of a patient during delivery of gas from a medical ventilator to a patient. The systems and methods include monitoring an instantaneous flow in the ventilation system based on one or more measurements of pressure and flow in ventilation system. The leakage is modeled using a predetermined leakage model. A leak-compensated instantaneous lung flow of gas inhaled or exhaled by the patient is estimated. Using the leak-compensated lung flow and a predetermined respiratory mechanics model, the respiratory mechanics of a patient may be estimated including at least one of a leak-compensated lung compliance and a leak-compensated lung resistance. The method may include using a dynamic respiratory mechanics model or a static respiratory mechanics model that requires use of a pause maneuver to collect the necessary data.

14 Claims, 5 Drawing Sheets



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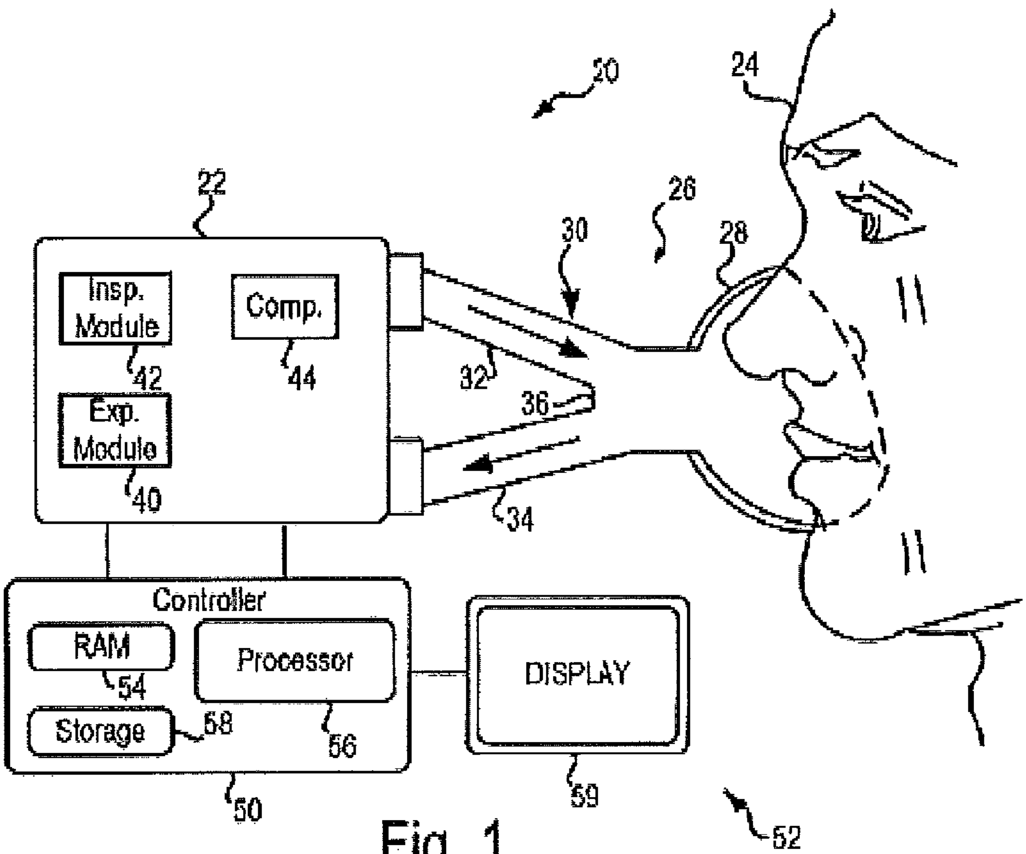
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24
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26
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28
Insp. Module
Comp.
42
44
32
36
Exp. Module
40
34
Controller
RAM
Processor
54
Storage
58
56
DISPLAY
50
59
52

Fig. 1

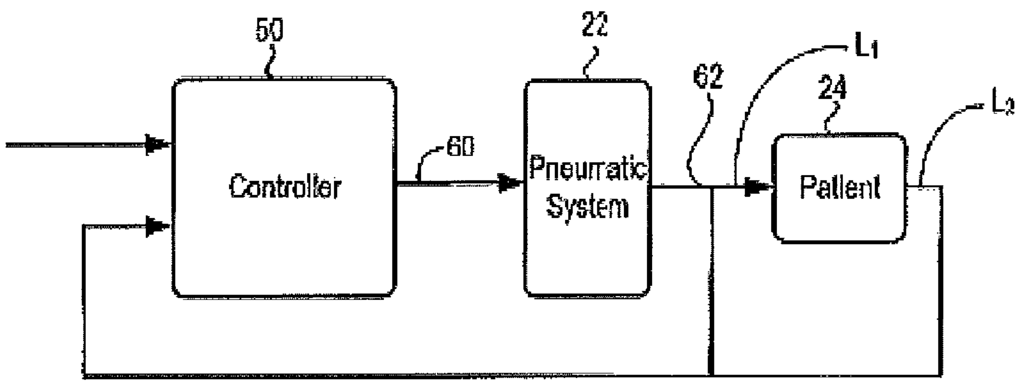
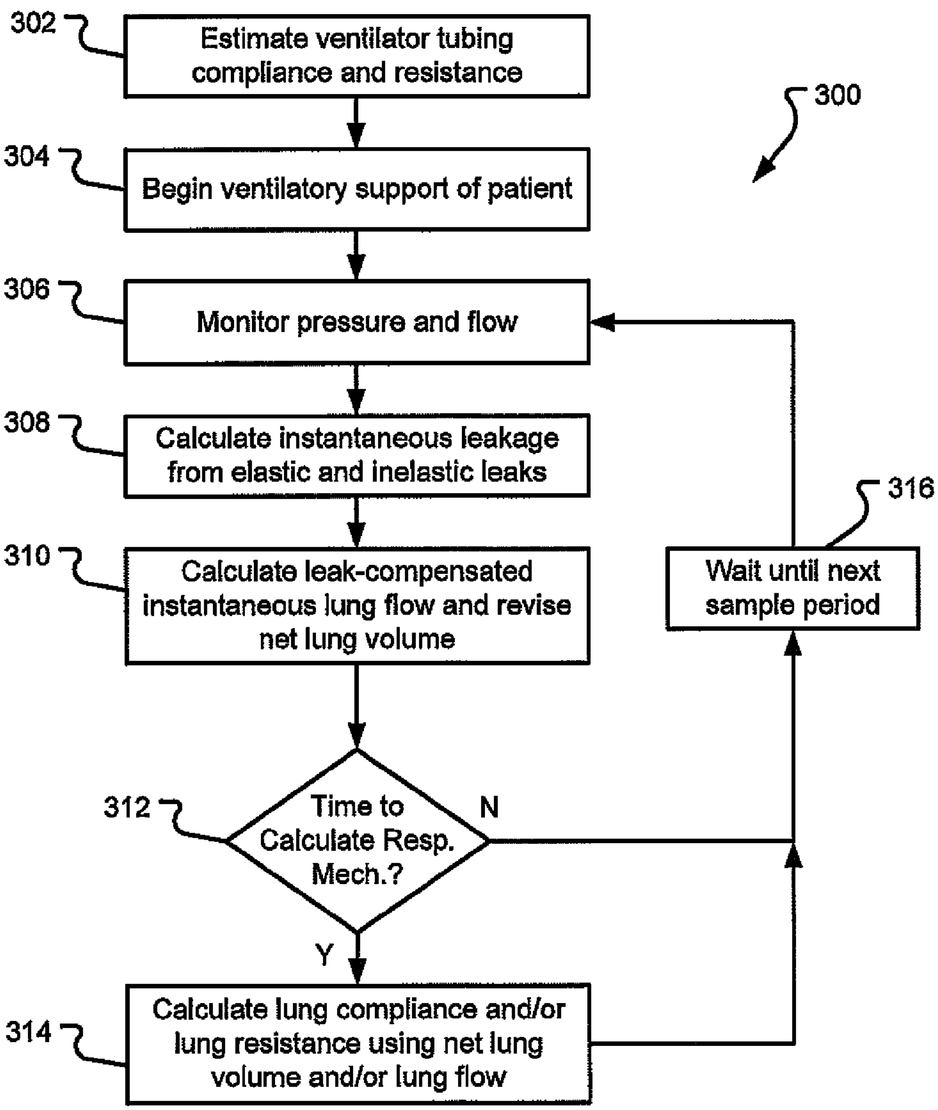
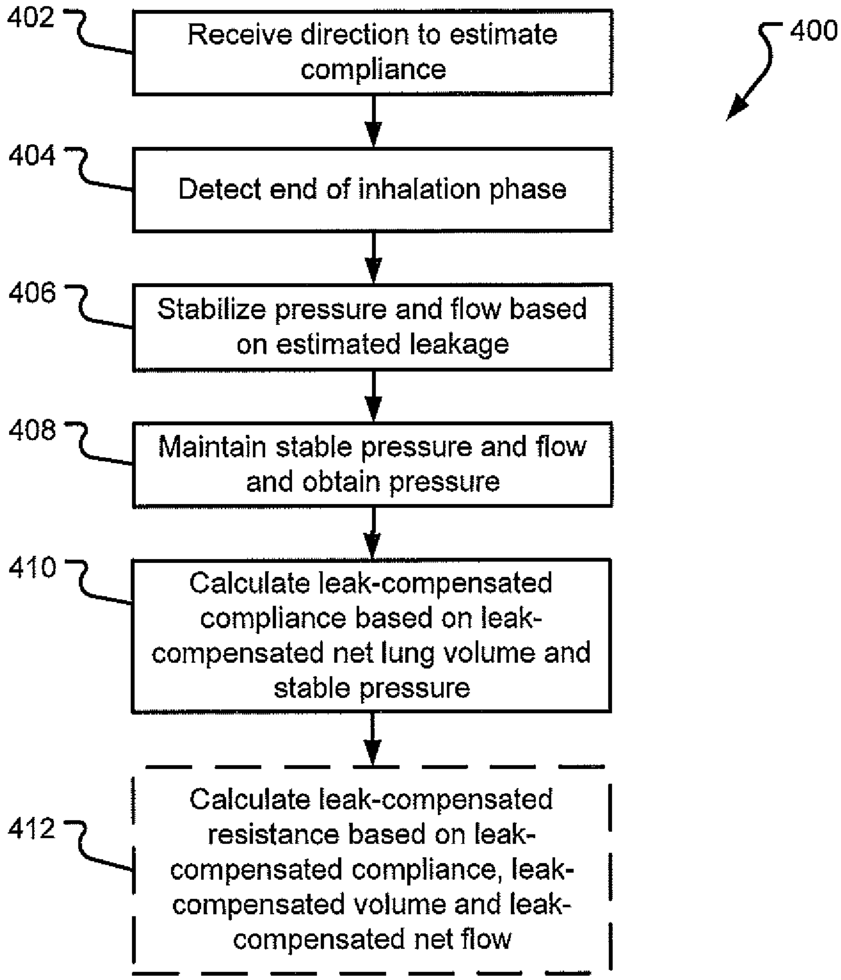

50
22
L1
62
24
L2
60
Controller
Pneumatic System
Patient

Fig. 2



300
302
Estimate ventilator tubing compliance and resistance
304
Begin ventilatory support of patient
306
Monitor pressure and flow
308
Calculate instantaneous leakage from elastic and inelastic leaks
310
Calculate leak-compensated instantaneous lung flow and revise net lung volume
312
Time to Calculate Resp. Mech.?
N
Y
314
Calculate lung compliance and/or lung resistance using net lung volume and/or lung flow
316
Wait until next sample period

FIG. 3



400
402
Receive direction to estimate compliance
404
Detect end of inhalation phase
406
Stabilize pressure and flow based on estimated leakage
408
Maintain stable pressure and flow and obtain pressure
410
Calculate leak-compensated compliance based on leak-compensated net lung volume and stable pressure
412
Calculate leak-compensated resistance based on leak-compensated compliance, leak-compensated volume and leak-compensated net flow

FIG. 4

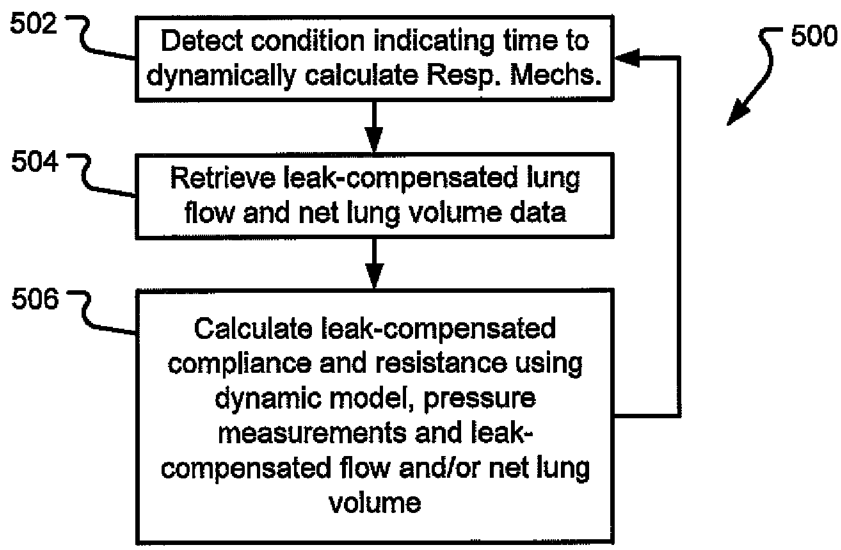

502
Detect condition indicating time to dynamically calculate Resp. Mechs.
504
Retrieve leak-compensated lung flow and net lung volume data
506
Calculate leak-compensated compliance and resistance using dynamic model, pressure measurements and leak-compensated flow and/or net lung volume
500

FIG. 5

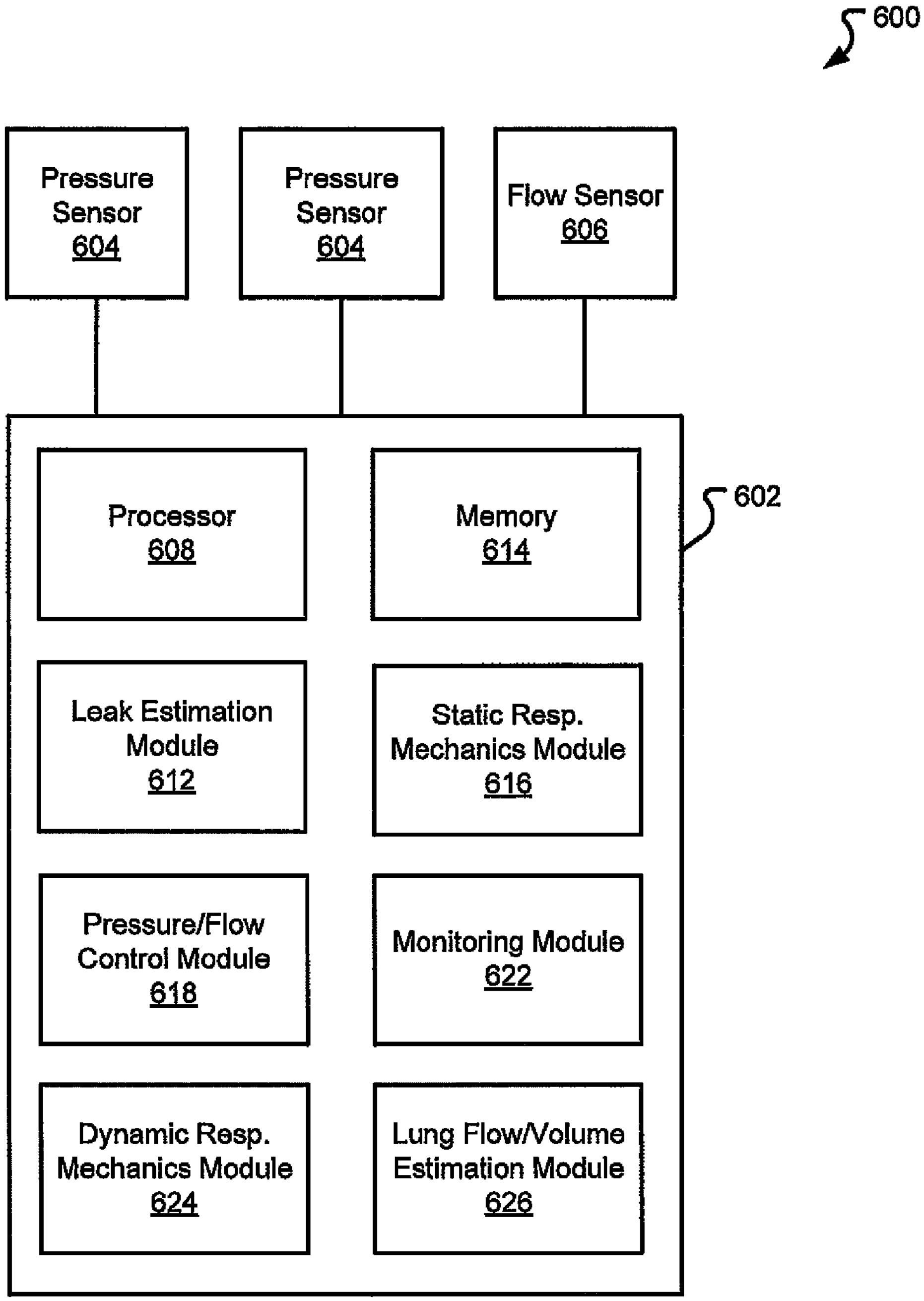

600
Pressure Sensor 604
Pressure Sensor 604
Flow Sensor 606
602
Processor 608
Memory 614
Leak Estimation Module 612
Static Resp. Mechanics Module 616
Pressure/Flow Control Module 618
Monitoring Module 622
Dynamic Resp. Mechanics Module 624
Lung Flow/Volume Estimation Module 626

FIG. 6

LEAK-COMPENSATED RESPIRATORY MECHANICS ESTIMATION IN MEDICAL VENTILATORS

INTRODUCTION

Despite its apparent complexity, various models have been proposed to represent the dynamics of breathing. These models often include one or more parameters, collectively referred to as the respiratory mechanics of the lung or, simply, the respiratory mechanics, that model different mechanical properties of the respiratory system such as lung resistance and lung compliance.

The respiratory mechanics of a patient are often used by treating physicians to determine the overall health of a patient's lungs and as an aid to diagnosis and determination of proper treatment. Thus, more accurate determination of respiratory mechanics often results in a more accurate treatment selection by the physician.

In addition, such respiratory models are also often utilized by medical ventilators during operation in order to provide effective and comfortable ventilation of patients. As part of the operation of such medical ventilators, the respiratory mechanics of a ventilated patient are often determined either at the onset of ventilation or during ventilatory support of the patient. Some aspects of the performance of a ventilator rely on the accurate determination of a patient's respiratory mechanics.

Leak-Compensated Respiratory Mechanics Estimation

This disclosure describes systems and methods for estimating respiratory mechanics such as dynamic lung compliance, static lung compliance and lung resistance in a manner that compensates for static and dynamic leaks from the ventilation system. The disclosure describes a model-based enhancement to conventional respiratory mechanics estimation methodologies that optimizes or attempts to optimize the accuracy of respiratory mechanics variables.

In part, this disclosure describes a method of compensating for leakage in a ventilation system during delivery of gas from a medical ventilator to a patient. The method includes monitoring an instantaneous flow in the ventilation system based on one or more measurements of pressure and flow in the ventilation system. The leakage is modeled as a first leakage component through a first orifice of a fixed size and a second leakage component through a second orifice of a varying size, wherein the first and second leakage components are different functions of instantaneous pressure in the ventilation system. A leak-compensated instantaneous lung flow of gas inhaled or exhaled by the patient is estimated based on the one or more measurements, the first leakage component and second leakage component. Using the leak-compensated lung flow and a predetermined respiratory mechanics model, the respiratory mechanics of a patient may be estimated including at least one of a leak-compensated lung compliance and a leak-compensated lung resistance. The method may include using a dynamic respiratory mechanics model or a static respiratory mechanics model that requires use of a pause maneuver to collect the necessary data.

This disclosure also describes a method of compensating for elastic leakage in a ventilation tubing system during delivery of gas from a medical ventilator to a patient. That method includes identifying an inelastic leakage in the ventilation system as a first function of at least one of a pressure measurement and a flow measurement in the ventilation system. The method also includes identifying an elastic leakage in the ventilation system as a second function of at least one of the pressure measurement and the flow measurement in the ventilation system. The method then estimates compliance and resistance of the ventilation tubing system and further estimates one or more of a lung compliance of the patient and a lung resistance of the patient based on the inelastic leakage, the elastic leakage, the compliance and resistance of the ventilation tubing system and the at least one of the pressure measurement and the flow measurement in the ventilation system.

The disclosure further describes a pressure support system that compensates for leakage when determining respiratory mechanics. The pressure support system includes: a pressure generating system adapted to generate a flow of breathing gas; a ventilation tubing system including a patient interface device for connecting the pressure generating system to a patient; one or more sensors operatively coupled to the pressure generating system or the ventilation system, each sensor capable of generating an output indicative of a pressure of the breathing gas; a processor; a leak estimation module that identifies an elastic leakage in the ventilation system; and a respiratory mechanics calculation module that generates at least one of a leak-compensated lung resistance and a leak-compensated lung compliance based on the elastic leakage and at least one output indicative of a pressure of the breathing gas.

The disclosure further describes a controller for a medical ventilator that includes a microprocessor and a module that compensates calculations of lung compliance and lung resistance based on instantaneous elastic leakage and instantaneous inelastic leakage of breathing gas from a ventilation system. The controller may also include a leak estimation module that identifies the instantaneous inelastic leakage from the ventilator and the instantaneous elastic leakage in the ventilator.

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

FIG. **1** illustrates an embodiment of a ventilator connected to a human patient.

FIG. **2** schematically depicts example systems and methods of ventilator control.

FIG. **3** illustrates an embodiment of a method of compensating for leakage when estimating the respiratory mechanics of a ventilated patient.

FIG. **4** illustrates an embodiment of a method for estimating respiratory mechanics of patient that utilizes a respiratory mechanics maneuver.

FIG. **5** illustrates an embodiment of a method for dynamically estimating respiratory mechanics of patient.

FIG. **6** illustrates a functional block diagram of modules and other components that may be used in an embodiment of ventilator that compensates for elastic and rigid orifice sources of leaks when determining patient respiratory mechanics.

DETAILED DESCRIPTION

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

FIG. **1** illustrates an embodiment of a ventilator **20** connected to a human patient **24**. Ventilator **20** includes a pneumatic system **22** (also referred to as a pressure generating system **22**) for circulating breathing gases to and from patient **24** via the ventilation tubing system **26**, which couples the patient to the pneumatic system via physical patient interface **28** and ventilator circuit **30**. Ventilator circuit **30** could be a dual-limb or single-limb circuit for carrying gas to and from the patient. In a dual-limb embodiment as shown, a wye fitting **36** may be provided as shown to couple the patient interface **28** to the inspiratory limb **32** and the expiratory limb **34** of the circuit **30**.

The present systems and methods have proved particularly advantageous in noninvasive settings, such as with facial breathing masks, as those settings typically are more susceptible to leaks. However, leaks do occur in a variety of settings, and the present description contemplates that the patient interface may be invasive or non-invasive, and of any configuration suitable for communicating a flow of breathing gas from the patient circuit to an airway of the patient. Examples of suitable patient interface devices include a nasal mask, nasal/oral mask (which is shown in FIG. **1**), nasal prong, full-face mask, tracheal tube, endotracheal tube, nasal pillow, etc.

Pneumatic system **22** may be configured in a variety of ways. In the present example, system **22** includes an expiratory module **40** coupled with an expiratory limb **34** and an inspiratory module **42** coupled with an inspiratory limb **32**. Compressor **44** or another source(s) of pressurized gas (e.g., air and oxygen) is coupled with inspiratory module **42** to provide a gas source for ventilatory support via inspiratory limb **32**.

The pneumatic system may include a variety of other components, including sources for pressurized air and/or oxygen, mixing modules, valves, sensors, tubing, accumulators, filters, etc. Controller **50** is operatively coupled with pneumatic system **22**, signal measurement and acquisition systems, and an operator interface **52** may be provided to enable an operator to interact with the ventilator (e.g., change ventilator settings, select operational modes, view monitored parameters, etc.). Controller **50** may include memory **54**, one or more processors **56**, storage **58**, and/or other components of the type commonly found in command and control computing devices.

The memory **54** is computer-readable storage media that stores software that is executed by the processor **56** and which controls the operation of the ventilator **20**. In an embodiment, the memory **54** comprises one or more solid-state storage devices such as flash memory chips. In an alternative embodiment, the memory **54** may be mass storage connected to the processor **56** through a mass storage controller (not shown) and a communications bus (not shown). Although the description of computer-readable media contained herein refers to a solid-state storage, it should be appreciated by those skilled in the art that computer-readable storage media can be any available media that can be accessed by the processor **56**. Computer-readable storage media includes volatile and non-volatile, removable and non-removable media implemented in any method or technology for storage of information such as computer-readable instructions, data structures, program modules or other data. Computer-readable storage media includes, but is not limited to, 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.

As described in more detail below, controller **50** issues commands to pneumatic system **22** in order to control the breathing assistance provided to the patient by the ventilator. The specific commands may be based on inputs received from an operator, the patient **24**, the pneumatic system **22** and sensors, the operator interface **52** and/or other components of the ventilator. In the depicted example, operator interface includes a display **59** that is touch-sensitive, enabling the display to serve both as an input and output device.

FIG. **2** schematically depicts exemplary systems and methods of ventilator control. As shown, controller **50** issues control commands **60** to drive pneumatic system **22** and thereby circulate breathing gas to and from patient **24**. The depicted schematic interaction between pneumatic system **22** and patient **24** may be viewed in terms of pressure and/or flow "signals." For example, signal **62** may be an increased pressure which is applied to the patient via inspiratory limb **32**. Control commands **60** are based upon inputs received at controller **50** which may include, among other things, inputs from operator interface **52**, and feedback from pneumatic system **22** (e.g., from pressure/flow sensors) and/or sensed from patient **24**.

In an embodiment, before the respiratory mechanics of a patient can be determined, the mechanics of the ventilation system may be determined. For example, when modeling the delivery of gas to and from a patient **24** via a closed-circuit ventilator, one simple assumption is that compliance of the ventilator circuit **30** (the "circuit compliance") is fixed and that all gas injected into the ventilator circuit **30** that does not exit the circuit **30** via the expiratory limb **34** (in a dual-limb embodiment) fills the circuit as well as the patient's lungs and causes an increase in pressure. As gas is injected (L_1), the lung responds to the increased gas pressure in the circuit **30** by expanding. The amount the lung expands is proportional to the lung compliance and is defined as a function of gas pressure differential (Compliance=volume delivered/pressure difference). As discussed in greater detail below, this assumption is not valid when leaks are present.

The term circuit compliance is used to refer to the amount the pressure in the ventilator circuit **30** (or ventilator circuit **30** and attached patient interface **28**, depending on how the compliance is determined) changes based on changes in volume delivered into the circuit. In an embodiment, the circuit compliance may be estimated by pressurizing the ventilator circuit **30** (or circuit **30** and interface **28** combination) when flow to the patient is blocked and measuring the volume of additional gas introduced to cause the pressure change (compliance=volume delivered/pressure different).

The term circuit resistance is used to refer to the amount the pressure changes between two sites upstream and downstream the ventilator circuit as a function of volumetric flow rate through that circuit. Circuit resistance may be modeled as a two-parameter function of flow and several methods for modeling and calculating circuit resistance are known in the art. For example, in an embodiment, the circuit resistance may be estimated by passing several fixed flow rates though the circuit and measuring the pressure difference between certain upstream and downstream sites and finding the best curve fit to the collected data.

Methods of determining circuit compliance and circuit resistance (such as those described above) may be executed by the operator prior to attaching the patient to the ventilator as part of the set up of the ventilator **20** to provide therapy. Other methods of determining circuit compliance and/or resistance are also known and could be adapted for use with the disclosed leak-compensation systems and methods described herein.

In many cases, it may be desirable to establish a baseline pressure and/or flow trajectory for a given respiratory therapy session. The volume of breathing gas delivered to the patient's lung (L_1) and the volume of the gas exhaled by the patient (L_2) are measured or determined, and the measured or predicted/estimated leaks are accounted for to ensure accurate delivery and data reporting and monitoring. Accordingly, the more accurate the leak estimation, the better the baseline calculation of delivered and exhaled flow rates and volumes.

Errors may be introduced due to leaks in the ventilation tubing system **26**. The term ventilation tubing system **26** is used herein to describe the ventilator circuit **30**, any equipment attached to or used in the ventilator circuit **30** such as water traps, monitors, drug delivery devices, etc. (not shown), and the patient interface **28**. Depending on the embodiment, this may include some equipment contained in the inspiration module **42** and/or the expiration module **40**. When referring to leaks in or from the ventilation tubing system **26**, such leaks include leaks within the tubing system **26** and leaks where the tubing system **26** connects to the pressure generator **22** or the patient **24**. Thus, leaks from the ventilation tubing system **26** include leaks from the ventilator circuit **30**, leaks from the patient interface **28** (e.g., masks are often provided with holes or other pressure relief devices through which some leakage may occur), leaks from the point of connection of the patient interface **28** to the patient **24** (e.g., leaks around the edges of a mask due to a poor fit or patient movement), and leaks from the point of connection of the patient interface **28** to the circuit **30** (e.g., due to a poor connection between the patient interface **28** and the circuit **30**).

For the purpose of estimating how a leak flow rate changes based on changes in pressure in the ventilation tubing system **26**, the instantaneous leak may be modeled as a leak through a single rigid orifice or opening of a fixed size in which that size is determined based on comparing the total flow into the inspiratory limb **32** and out of the expiratory limb **34**. However, this leak model does not take into account any elastic component of leak source(s) in the system **26**, that is how much of the area of any of the holes or openings in the ventilation tubing system **26** through which leakage occurs may change due to an increase or decrease in pressure.

It has been determined that not accounting for elastic leakage from the ventilation tubing system **26** can cause many problems. First, if only the inelastic/fixed orifice model is used to estimate leak, the subsequent errors caused by ignoring the elastic effects of any actual leaks end up generating inaccurate estimates of flow rates into the lung. This can cause the ventilator **20** to estimate gas volume delivered into the lung inaccurately when, in fact, the elastic leaks in the system **26** have let more gas escape than estimated. Second, if the elasticity of the leak source is ignored, any other calculation, estimate, or action that the ventilator **20** may perform which is affected by the leak estimate will be less accurate.

In the systems and methods described herein, the respiratory mechanics of the patient are made more accurate by compensating for tubing system leakage. In the embodiments described herein fixed (rigid) and elastic components of the system leakage are used when determining the lung compliance and lung resistance of the patient; however, the reader will understand that this technology may be applied to any ventilator adapted to identify the leakage from the tubing system and is not limited to the exact methods described herein. This results in a more accurate determination of lung compliance and lung resistance and, therefore, diagnosis of patients based on respiratory mechanics. While the systems and methods are presented in the context of specific respiratory models, the technology described herein could be used to compensate the respiratory mechanics determined by any model for respiratory mechanics using any type of mechanical ventilator or other device that provides gas.

Lung compliance and lung resistance may be determined many different ways and by many different models. In particular, lung compliance and resistance may be determined either dynamically (i.e., during the delivery of gas by the ventilator without interrupting the therapy) or statically (e.g., by interrupting the normal delivery of gas and performing a series of actions in order to specifically determine either the lung compliance, lung resistance, or both). Regardless of how respiratory mechanics are estimated, compensating respiratory mechanics estimates for leaks in the ventilator tubing system will provide more accurate results. A generalized method for compensating respiratory mechanics estimates for leakage is discussed below with reference to FIG. **3**, while more detailed methods focusing on compensating dynamically-determined respiratory mechanics and statically determined respiratory mechanics are present with reference to FIGS. **4** and **5**.

FIG. **3** illustrates an embodiment of a method of compensating respiratory mechanics for leakage in a ventilation system during delivery of gas from a medical ventilator to a patient. In the method **300** shown, a medical ventilator such as that described above with reference to FIGS. **1** and **2** is used to provide ventilation to a patient.

In the method **300** illustrated, the ventilator circuit compliance and resistance may be estimated in a compliance/resistance estimation operation **302**. In an embodiment, this may be performed prior to connecting the ventilator to the patient (as previously described). Alternatively, it may be dynamically determined periodically throughout the delivery of ventilatory support to the patient.

In the method **300** illustrated, after the circuit compliance and resistance have been determined, the ventilator is connected to the patient and ongoing ventilatory support is initiated in a begin ventilation operation **304**. The remaining operations in FIG. **3** occur repeatedly while the ventilator is operating, such as once a sample period during ventilation.

During ventilation, the pressure and flow and other parameters of the system are monitored, illustrated by the monitoring operation **306**. In an embodiment, the monitoring operation **306** collects data including the instantaneous pressure and/or flow at or indicative of one or more locations in the ventilation tubing system. Depending upon how a particular leak model is defined, the operation **306** may also include making one or more calculations using data from pressure and flow measurements taken by the sensors. For example, a model may require a flow measurement as observed at the patient interface even though the ventilation system may not have a flow sensor at that location in the ventilation tubing system. Thus, a measurement from a sensor or sensors located elsewhere in the system (or data from a different type of sensor at the location) may be mathematically manipulated in order to obtain an estimate of the flow observed at the patient interface in order to calculate the leak using the model.

The data obtained in the monitoring operation **306** is then used to calculate leakage from the ventilator tubing system in a leakage calculation operation **308**. In an embodiment, the leakage calculation operation **308** uses the data obtained in the monitoring operation **306**, e.g., some or all of the instantaneous pressure and flow data collected during the monitoring operation **306** as well as information about the current respiratory phase (inhalation or exhalation).

The leakage calculation operation **308** calculates an instantaneous leakage flow or volume for the sample period. The instantaneous leakage is calculated using a mathematical formula that has been previously determined. In an embodiment, the mathematical formula is a leakage model that separates the leak into the sum of two leak components, inelastic leak and elastic leak, in which each component represents a different relationship between the quantity of leakage from the ventilation system and the measured current/instantaneous pressure and/or flow of gas in the ventilation system. As discussed above, the inelastic leak may be modeled as the flow through a rigid orifice of a fixed size while the elastic leak may be modeled as the flow through a different orifice of a size that changes based on the pressure (or flow) of the gas in the ventilation system.

An example of a method and system for modeling leak in a ventilation system as a combination of an elastic leak component and an inelastic leak component can be found in commonly-assigned U.S. Provisional Patent Application Ser. No. 61/041,070, filed Mar. 31, 2008, titled VENTILATOR LEAK COMPENSATION, which application is hereby incorporated by reference herein. The VENTILATOR LEAK COMPENSATION represents one way of characterizing the leak from a ventilation system as a combination of elastic and inelastic components. Other methods and models are also possible and may be adapted for use with this technology.

The mathematical formula used to calculate leakage may contain several parameters that are empirically determined and that may be periodically or occasionally revised in order to maintain the accuracy of the leakage estimate. For example, in an embodiment the parameters of a leakage formula include a first constant associated with the rigid orifice and a second constant associated with the variable-sized orifice. At various times during ventilation, the calculated leakage may be checked against a measured leakage and, if the estimate is significantly different from the measured leakage, the constants may be revised. This revision of the parameters in a leakage formula may be done as part of the leakage calculation operation **308** or may be done as a separate operation (not shown).

The term instantaneous is used herein to describe a determination made for any particular instant or sampling period based on the measured data for that instant. For example, if a pressure measurement is taken every 5 milliseconds (sample period), the pressure measurement and the leak model can be used to determine an instantaneous leak flow based on the instantaneous pressure measurement. With knowledge of the length of the sample period, the instantaneous flow may then be used to determine an instantaneous volume of gas leaking out of the circuit during that sample period. For longer periods covering multiple sampling periods the instantaneous values for each sampling period may be summed to obtain a total leakage volume. If a measurement is also the most recent measurement taken, then the instantaneous value may also be referred to as the current value.

After the current leak has been calculated, the method **300** further estimates the leak-compensated instantaneous lung flow to or from the patient in a lung flow estimation operation **310**. The estimated lung flow is compensated for the leak calculated in the instantaneous leak calculation operation **308** so that it represents a more accurate estimate of the actual flow into (or out of depending on the respiratory phase) the lungs of the patient.

In the embodiment illustrated the leak-compensated net lung volume is also calculated as part of the lung flow estimation operation **310**. In an embodiment, this may be performed by maintaining a running summation of net flow into/out of the lung over the period of a breath. For example, upon triggering inhalation, the ventilator may set a variable corresponding to net lung volume to zero and, each sample period, update this net lung volume to include the detected leak-compensated instantaneous lung flow delivered to the patient during that sample period.

The method **300** also periodically determines the respiratory mechanics from the leak-compensated lung parameters (e.g., pressure and/or flow), which is illustrated by the determination operation **312**. For example, in an embodiment respiratory mechanics may be calculated on a fixed schedule or calculated in response an explicit operator command. In addition, depending on the respiratory mechanics determination method used, there may be a requirement that the respiratory mechanics calculation (using data collected during the breath) be performed at a certain point within the patient's respiration such as at the end of the inspiratory phase or the end of the expiratory phase or after the completion of a specific maneuver (e.g., an Inspiratory Hold Maneuver). The respiratory mechanics calculation may also require the performance of a respiratory mechanics "maneuver", that is a specified set of controlled actions on the part of the ventilator, such as interrupting the therapeutic delivery of respiratory gas and monitoring and/or changing the pressure and flow, so that data concerning the response of the patient's lung to the controlled actions may be obtained. An example of a respiratory mechanics maneuver is provided below with reference to the static determination of lung compliance.

If it is time to calculate respiratory mechanics, a calculate respiratory mechanics operation **314** is performed. In the operation **314**, the necessary data for the respiratory mechanics model being used is retrieved and the respiratory mechanics parameters are estimated. In addition, the calculate respiratory mechanics operation **314** may also include performing the appropriate maneuver, as necessary to obtain the data for the respiratory mechanics model being used.

In the calculate respiratory mechanics operation **314** leak-compensated values are used to estimate the respiratory mechanics. For example, if the respiratory mechanics model being used requires a total delivered lung volume, the leak-compensated lung volume is used. Likewise, if an instantaneous lung flow is required, a leak-compensated instantaneous lung flow is used in generating the estimate.

The method **300** is then repeated, as illustrated by the feedback loop, so that the instantaneous lung flow and net lung flow are continuously determined and, when appropriate, the respiratory mechanics are recalculated based on the current leak-compensated data. In an alternative embodiment, the leak-compensation of lung flow and net delivered lung volume may be performed as part of the calculate respiratory mechanics operation **314** in order to reduce the number of calculations a processor must perform every cycle.

The following is a discussion of two embodiments of methods for compensating the estimation of respiratory mechanics for leaks. The first embodiment is that of applying leak compensation to a static compliance and resistance determination. The second embodiment is that of applying leak compensation to a dynamic compliance determination.

Leak-Compensation of Static Determination of Lung Compliance

FIG. **4** illustrates an embodiment of a method for estimating respiratory mechanics of patient that utilizes a respiratory mechanics maneuver. In the embodiment shown, the ventilator is providing respiratory gas to a patient in accordance with some mode of operation such as a mandatory mode or a pressure assist mode (e.g., a mandatory volume-controlled (VCV) inspiration under square waveform setting), as is well known in the art. During operation, an operator command to estimate the compliance of the patient is received in a receive command operation **402**. In an embodiment, the command may be entered by the operator of the ventilator via selection of a button or other interface element on a user interface of the ventilator. In an alternative embodiment, the ventilator may perform the method **400** automatically such as periodically or upon the detection of predetermined respiratory event.

In the embodiment shown, the user command is to perform a lung compliance estimation in a manner that requires a respiratory maneuver to be performed, that respiratory maneuver being the forced imposition of a stable period at the end of an inspiratory phase so that there is no flow delivery to or from the patient's lung. Thus, following the receipt of the command, the method **400** includes a delay until the next end of an inspiratory phase is detected, as illustrated by detect end of inspiratory phase operation **404**.

When the end of the inspiratory phase is detected, a stabilization operation **406** is performed. In an embodiment, the operation **406** includes stabilizing the pressure and flow in the patient circuit so that there is no flow into or out of the patient's lungs at the point in which the lungs have taken a breath and thus are expanded with a known volume of gas (as determined during normal operation of the ventilator as discussed above with reference to the leak-compensated lung volume).

The stabilization operation **406** and the maintain stable condition operation **408** (discussed below) may sometimes be referred to alternatively as a pause maneuver or a plateau maneuver. They are separated in this discussion for clarity purposes.

In order to stabilize the pressure and flow to achieve no flow between the circuit and the patient, if there are leaks in the tubing system these leaks are compensated for by the ventilator. Thus, in order to stabilize the flow the ventilator provides a leak-compensation flow that is equal to the amount of leakage from the system estimated by the leakage model at the stable pressure.

In practice, the stabilization of the pressure and flow is an iterative process in which the ventilator monitors the pressure and adjusts delivered flow until the pressure and flow stabilize at the point where the pressure and flow correspond to a solution to the leak model and the lung flow is practically zero, i.e., the current flow provided by the ventilator is the leakage flow determined from the model using the current pressure. In an embodiment, for a flow and pressure to be considered stable, a certain acceptable error may be allowed between the calculated leakage (calculated based on the current pressure) and the actual measured flow. Such an error may be predetermined amount or range based on an absolute difference between delivery and calculated flow or pressure or relative difference (e.g., calculated flow within x % of actual stable flow at a given pressure). Various methods for stabilizing pressure and flow in a ventilation tubing system are known in the art and any suitable method may be adapted for use in conjunction with the technology described in this disclosure.

When attempting to stabilize the pressure and flow during the stabilization operation **406**, the leakage model may be used to increase the speed of the stabilization through a prediction of the likely resulting leakage flow at different pressures. This information may be used to determine a more accurate initial starting point for the stabilization and determine more accurate selection of adjustments to be made in order to home in on the stable pressure and flow.

After a stable pressure has been achieved, in the embodiment shown a maintain stable condition operation **408** is performed. The maintain stable condition operation **408** may maintain the stable pressure and stable, leak-compensating flow for a predetermined period of time such as 25-200 milliseconds or more preferably between 50-100 milliseconds. During the operation **408**, the drop in pressure over the period of the maneuver may be monitored to ensure that it is within some acceptable performance threshold. If it is not, the ventilator may resume attempting to stabilize the pressure and flow or may abort the method and attempt the method **400** at the end of the next inspiratory phase.

The stable pressure observed during the maintain stable condition operation **408** is then used to calculate the leak-compensated compliance in a lung compliance calculation operation **410**. The pressure value used may be an actual pressure or an average pressure observed over the maneuver period. Alternatively, different values derived from or based on the observed stable pressure may be calculated and used depending on the data required by the particular respiratory mechanics model being utilized.

In addition to using the stable pressure obtained during the pause maneuver, the compliance calculation operation **410** further utilizes leak-compensated lung flow and leak-compensated net lung volume when performing the calculation.

As discussed above, any suitable model for calculating lung compliance may be used. For example, in an embodiment of the compliance calculation operation **410** compliance is calculated using the following simple model:

Stable pressure=Leak-Compensated Net Lung Volume/Compliance.

or, stated a different way,

Compliance Leak=Compensated Net Lung Volume/Stable pressure.

By using a leak-compensated value for lung volume and a stable pressure determined while compensating for leaks in the patient circuit, a more accurate leak-compensated lung compliance is estimated.

In addition, the leak-compensated compliance may be used in a subsequent, optional, operation to determine a leak-compensated lung resistance. In the embodiment of the method **400** shown, this is illustrated by optional resistance calculation operation **412**. In an embodiment of the optional resistance calculation operation **412** after the leak-compensated compliance has been determined, a resistance model that calculates lung resistance based on pressure, flow and compliance may be used to calculate resistance. An example of one such resistance model is as follows:

$$P(t_2)-P(t_1)=(V(t_2)-V(t_1))/C+R^*(Q(t_2)-Q(t_1))$$

In which t_1 and t_2 are different times during a breath, P(t) is the airway pressure at time t, V(t) is the delivered lung volume at time t, C is the lung compliance, R is the lung resistance and Q(t) is the net lung flow at time t. In the resistance model provided above, leak-compensated lung flow, leak-compensated net lung volume and leak-compensated lung compliance are utilized to obtain a leak-compensated resistance. This computation may be performed repeatedly over several appropriate time windows and combined together (e.g., by an averaging method) to generate an estimate for lung resistance. Also, lung resistance may be determined from the leak-compensated exhalation flow waveform subsequent to the inspiratory pause maneuver using algorithms for resistance estimation under no leak conditions.

In an alternative embodiment of method **400**, if it is determined that the ventilator has relatively low leakage, the lung compliance calculation operation **410** may forego the use of leak-compensated lung flow and net lung volume but still utilize the stable pressure determined through the provision of a leak-compensating flow during the pause maneuver. Lung compliance calculated in this fashion is still considered leak-compensated as the stable pressure was determined by compensating for leakage during the pause maneuver when generating the stable pressure.

Leak-Compensation of Dynamic Determination of Lung Compliance and Resistance

FIG. **5** illustrates an embodiment of a method for dynamically estimating respiratory mechanics of patient. In the embodiment shown, the ventilator is providing respiratory gas to a patient in accordance with some mode of operation such as a mandatory mode or a pressure assist mode, as is well known in the art. During operation, the ventilator detects a condition that indicates that it is time to estimate the respiratory mechanics of the patient. This is illustrated by the detection operation **502**. In an embodiment, the condition detected may be a command entered by the operator of the ventilator via selection of a button or other interface element on a user interface of the ventilator. Alternatively, the ventilator may perform the dynamic estimation automatically such as during every breath, after a predetermined period of time or after the detection of some occurrence such as once every 100 breaths or upon detection of certain flow conditions.

Following determination that it is time to calculate the dynamic respiratory mechanics, the method **500** retrieves and/or calculates leak-compensated lung flow and leak-compensated net lung volume as necessary depending on whether the leak-compensated data already exists or not. For example, in an embodiment the leak-compensated lung flows for each sampling period may be available but the leak-compensated net lung volume may only be available "as needed" by calculating it from the compensated lung flow data.

The method **500** then calculates the leak-compensated respiratory mechanics in a calculation operation **506**. The leak-compensated respiratory mechanics are calculated from a predetermined dynamic respiratory mechanics model using the leak-compensated lung flows, leak-compensated net lung volume(s) and pressure in order to obtain estimates of dynamic compliance and dynamic resistance that are compensated for the leaks in the tubing system. The method **500** is then repeated as necessary.

Any respiratory mechanics model may be used as long as the model may be adapted to be used in a dynamic calculation, that is without interrupting the ventilation of the patient. Many such models are known in the art, some requiring iterative solutions of a set of multiple equations using data obtained over of a period of time.

FIG. **6** illustrates a functional block diagram of modules and other components that may be used in an embodiment of ventilator that compensates for elastic and rigid orifice sources of leaks when determining patient respiratory mechanics. In the embodiment shown, the ventilator **600** includes pressure sensors **606** (two are shown placed at different locations in the system), flow sensors (one is shown), and a ventilator control system **602**. The ventilator control system **602** controls the operation of the ventilator and includes a plurality of modules described by their function. In the embodiment shown, the ventilator control system **602** includes a processor **608**, memory **614** which may include mass storage as described above, a leak estimation module **612** incorporating a parametric leak model accounting for both elastic and rigid orifice leak sources such as that described in U.S. Provisional Application 61/041,070 previously incorporated herein, a leak-compensated static respiratory mechanics module **616**, a pressure and flow control module **618**, a monitoring module **622**, a leak model module **620**, a leak-compensated dynamic respiratory compliance module **624**, and a leak-compensated lung flow and volume estimation module **626**. The processor **608** and memory **616** have been discussed above. Each of the other modules will be discussed in turn below.

The main functions of the ventilator such as receiving and interpreting operator inputs and providing therapy via changing pressure and flow of gas in the ventilator circuit are performed by the control module **618**. In the context of the methods and systems described herein, the module **618** will perform one or more actions upon the determination that a patient receiving therapy is inhaling or exhaling.

The static calculation of respiratory mechanics is performed by the leak-compensated static respiratory mechanics module **616**. The module **616** utilizes one or more respiratory models suitable for static determination of respiratory mechanics and one or more embodiments of the method **600** described above to calculate leak-compensated respiratory mechanics such as lung compliance and lung resistance. The module **616** uses leak-compensated values for one or both of lung flows and net lung volume. Leak-compensated values may be retrieved if they have already been calculated or may be calculated as needed from leakage information received from the leak-compensated lung flow and net lung volume estimation module **626**. When calculating static respiratory mechanics, the module **616** may control the operation of the ventilator so that a pause maneuver is performed. Alternatively, some or all of the actions required in a pause maneuver may be controlled by the control module **618** in response to a respiratory mechanics calculation request and the data obtained during the maneuver provided to the static respiratory mechanics module **616**.

The dynamic calculation of respiratory mechanics is performed by the leak-compensated dynamic respiratory mechanics module **624**. The module **624** utilizes one or more dynamic respiratory models and one or more embodiments of the method **500** described above to calculate leak-compensated respiratory mechanics such as lung compliance and lung resistance. The module **624** uses leak-compensated values for one or both of lung flows and net lung volume. Leak-compensated values may be retrieved if they have already been calculated or may be calculated from leakage information received from the leak-compensated lung flow and net lung volume estimation module **626**.

The current conditions in the ventilation system are monitored by the monitoring module **622**. This module **622** collects the data generated by the sensors **604**, **606** and may also perform certain calculations on the data to make the data more readily usable by other modules or may process the current data and or previously acquired data or operator input to derive auxiliary parameters or attributes of interest. In an embodiment, the monitoring module **622** receives data and provides it to each of the other modules in the ventilator control system **602** that need the current pressure or flow data for the system.

In the embodiment shown, compensated lung flows are calculated by the lung flow module **626**. The lung flow module **626** uses a quantitative model for lung flow of the patient during both inhalation and exhalation and from this characterization and pressure and flow measurements generates an estimate for instantaneous lung flow. In an embodiment, lung flow may be simply determined based on subtracting the estimated leak flow and measured outflow via the expiratory limb from the flow into the inspiratory limb, thereby generating a leak-compensated net flow into (or out of) the lung. The lung flow module **626** may or may not also calculate an ongoing leak-compensated net lung volume during a patient's breath as described above.

The leak model parameters are generated by the leak estimation module **612** which creates one or more quantitative mathematical models, equations or correlations that uses pressure and flow observed in the ventilation system over regular periods of respiratory cycles (inhalation and exhalation) and apply physical and mathematical principles derived from mass balance and characteristic waveform settings of ventilation modalities (regulated pressure or flow trajectories) to derive the parameters of the leak model incorporating both rigid and elastic (variable pressure-dependent) orifices. In an embodiment, the mathematical model may be a model such as:

$$Q_{inelastic}=R_1*P_i^x$$

$$Q_{elastic}=R_2*P_i^y$$

wherein $Q_{elastic}$ is the instantaneous leak flow due to elastic leaks in the ventilation system, $Q_{inelastic}$ is the instantaneous leak flow due to inelastic leaks in the ventilation system, R_1 is the inelastic leak constant, R_2 is the elastic leak constant, P_i is the current or instantaneous pressure measurement, x is an exponent for use when determining the inelastic leak and y is an exponent different than x for use when determining the elastic leak. The group $R_1*P_i^x$ represents flow through an orifice of fixed size as a function of instantaneous pressure P_i and the group $R_2*P_i^y$ represents flow through a different orifice that varies in size based on the instantaneous pressure. The equations above presuppose that there will always be an elastic component and an inelastic component of leakage from the ventilation system. In the absence of an elastic component or a leak source of varying size, R_2 would turn out be zero.

In the embodiment shown, the current or instantaneous elastic leak is calculated by the leak estimation module **612**. The calculation is made using the elastic leak portion of the leak model developed by the leak estimation module **612** and the pressure data obtained by the monitoring module **622**. The leak estimation module **612** may calculate a new instantaneous elastic leak flow or volume for each pressure sample taken (i.e., for each sampling period) by the monitoring module **622**. The calculated elastic leak may then be provided to any other module as needed.

In the embodiment shown, the current or instantaneous inelastic leak is also calculated by the leak estimation module **612**. The calculation is made using the inelastic leak portion of the leak model and the pressure data obtained by the monitoring module **622**. The leak estimation module **612** may calculate a new instantaneous inelastic leak flow or volume for each pressure sample taken (i.e., for each sampling period) by the monitoring module **622**. The calculated inelastic leak may then be provided to any other module as needed.

The system **600** illustrated will compensate lung flow for leaks due to elastic and inelastic leaks in the ventilation system. Furthermore, the system may perform a dynamic compensation of lung flow based on the changing leak conditions of the ventilation system and the instantaneous pressure and flow measurements. The system then compensates the respiratory mechanics calculations based on the estimated leakage in the system. By compensating for the inelastic as well as the elastic components of dynamic leaks, the medical ventilator can more accurately and precisely estimate the respiratory mechanics of a patient including estimating the lung compliance and lung resistance.

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. For example, the operations and steps of the embodiments of methods described herein may be combined or the sequence of the operations may be changed while still achieving the goals of the technology. In addition, specific functions and/or actions may also be allocated in such as a way as to be performed by a different module or method step without deviating from the overall disclosure. 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. In this regard, any number of the features of the different embodiments described herein may be combined into one single embodiment and alternate 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 technology described herein. For example, the systems and methods described herein could be adapted to automatically determine leak-compensated resistance and/or compliance and initiate an alarm if the leak-compensated values are outside of a specified range for predetermined leakage values, thus eliminating false resistance and compliance alarms due to changes in leakage. 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.

What is claimed is:

1. A method of compensating for leakage in a ventilation system during delivery of gas from a medical ventilator to a patient comprising:

monitoring an instantaneous flow in the ventilation system based on one or more measurements of pressure and flow in ventilation system;

modeling, by the medical ventilator, leakage as a first leakage component through a first orifice of a fixed size and a second leakage component through a second orifice of a varying size, wherein the first and second leakage components are different functions of instantaneous pressure in the ventilation system;

estimating a leak-compensated instantaneous lung flow of gas inhaled or exhaled by the patient based on the one or more measurements, the first leakage component and second leakage component; and using the leak-compensated lung flow and a predetermined respiratory mechanics model to estimate at least one of a leak-compensated lung compliance and a leak-compensated lung resistance.

2. The method of claim 1 wherein the method uses a dynamic respiratory mechanics model and the method further comprises:
detecting a condition indicating that leak-compensated lung compliance should be calculated;
retrieving one or more previously estimated leak-compensated instantaneous lung flows;
estimating a leak-compensated lung compliance and a leak-compensated lung resistance using the dynamic respiratory mechanics model and the retrieved one or more previously estimated leak-compensated instantaneous lung flows.

3. The method of claim 2 wherein the dynamic respiratory mechanics model requires input of a lung volume change over a predetermined time period and the method further comprises:
calculating a leak-compensated lung volume for the predetermined time period based on leak-compensated lung flows associated with the predetermined time period.

4. The method of claim 1 wherein the method calculates at least the leak-compensated lung compliance and the method further comprises:
calculating a leak-compensated lung volume based on the leak-compensated lung flow during an inspiratory phase;
stabilizing the delivery of gas so that the medical ventilator delivers a stable flow of gas at a stable pressure, wherein the stable flow and stable pressure are determined based on the first leakage component and second leakage component at the stable pressure;
maintaining the stable flow of gas at the stable pressure for at least a predetermined time interval; and
calculating the leak-compensated lung compliance based on the leak-compensated lung volume and the stable pressure.

5. The method of claim 4 wherein stabilizing further comprises:
stabilizing the delivery of gas by adjusting the instantaneous flow of gas to be within a predetermined amount of the first leakage component and second leakage component at the instantaneous pressure.

6. The method of claim 4 wherein stabilizing further comprises:
stabilizing the delivery of gas so that the stable flow of gas is equivalent to the first leakage component and second leakage component at the stable pressure.

7. The method of claim 6 wherein stabilizing further comprises:
stabilizing the delivery of gas so that the lung flow is practically zero.

8. The method of claim 4 further comprising:
calculating a leak-compensated lung resistance based on the leak-compensated lung compliance and one or more of a previously calculated leak-compensated lung flow, a previously calculated leak-compensated lung volume and a previously measured pressure.

9. The method of claim 4 wherein the stabilizing and maintaining operations are performed at the end of the inspiratory phase.

10. The method of claim 1 wherein the method calculates at least the lung compliance and the method further comprises:
calculating a leak-compensated lung volume based on the leak-compensated lung flow during an inspiratory phase and expiratory phase;
stabilizing the delivery of gas so that the medical ventilator delivers a stable flow of gas at a stable pressure, wherein the stable flow and stable pressure are determined based on the first leakage component and second leakage component at the stable pressure;
maintaining the stable flow of gas at the stable pressure for at least a predetermined time interval; and
calculating the leak-compensated lung compliance based on the leak-compensated lung volume and the stable pressure.

11. The method of claim 1 wherein the method first calculates a leak-compensated lung compliance and then, based on the leak-compensated lung compliance, calculates a leak-compensated lung resistance.

12. A method of compensating for leakage in a ventilation tubing system during delivery of gas from a medical ventilator to a patient comprising:
identifying, by the medical ventilator, an inelastic leakage in the ventilation system as a first function of at least one of a pressure measurement and a flow measurement in the ventilation tubing system;
identifying, by the medical ventilator, an elastic leakage in the ventilation system as a second function of at least one of the pressure measurement and the flow measurement in the ventilation tubing system;
estimating circuit compliance and circuit resistance of the ventilation tubing system; and
estimating one or more of a lung compliance of the patient and a lung resistance of the patient based on the inelastic leakage, the elastic leakage, the circuit compliance, circuit resistance and the at least one of the pressure measurement and the flow measurement in the ventilation system.

13. The method of claim 12 wherein estimating lung compliance further comprises:
generating a plurality of leak-compensated lung flows associated with a period of time based on the elastic leakage and at least one of the pressure measurements and the flow measurements associated with the period of time;
generating a leak-compensated net delivered lung volume for the period of time based on the plurality of leak-compensated lung flows; and
calculating lung compliance using the leak-compensated net delivered lung volume.

14. The method of claim 12 wherein estimating lung compliance and lung resistance further comprises:
generating a plurality of leak-compensated lung flows associated with a period of time based on the elastic leakage and at least one of pressure measurements and the flow measurements associated with the period of time;
generating a leak-compensated net delivered lung volume for the period of time based on the plurality of leak-compensated lung flows; and
calculating lung compliance and lung resistance using the leak-compensated net delivered lung volume, the plurality of leak-compensated lung flows for the period of time and the pressure measurements associated with the period of time.

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