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(54) **Title**: LEAK ESTIMATION USING FUNCTION ESTIMATION.

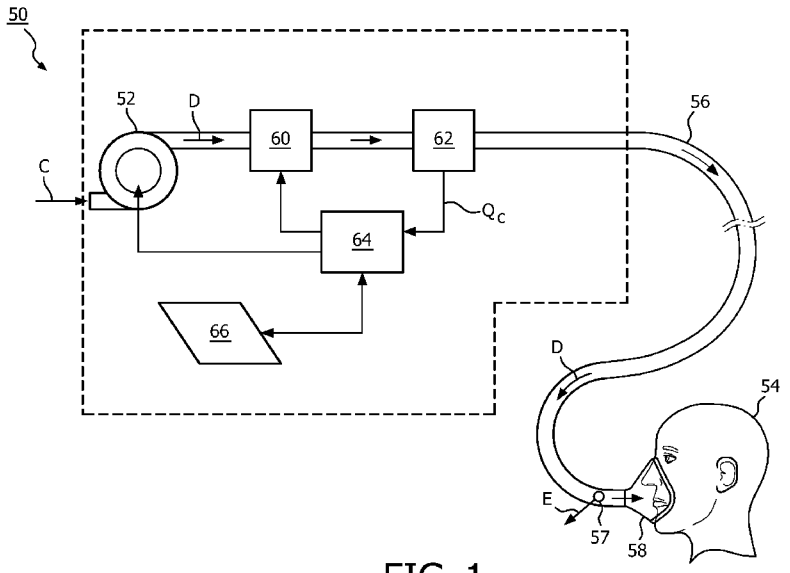

FIG. 1

(57) **Abstract**: The disclosed concept maintains that $Q_p = Q_c - Q_{leak}$, where, Q_p is the estimated patient flow, Q_{leak} is the estimated leak and Q_c is the measured total circuit flow. Q_{leak} is given by a transfer function $\varphi(\chi)$ where x is a set of independent measured or fixed variables. The transfer function is thus $Q_{leak} = \varphi(\chi)$. The transfer function $\varphi(\chi)$ is adjusted given the constraint that, Q_p shall be zero. The transfer function converges over time to accurately estimate the leak because over an extended time the mean patient flow will always be zero. In one example, $\varphi(\chi) = g_{orf}P^{\chi}$ and the coefficient g_{orf} is adapted until Q_p is zero.

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LEAK ESTIMATION USING FUNCTION ESTIMATION

This patent application claims the priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 61/368,058 filed on July 27, 2010, the contents of which are herein incorporated by reference.

The present invention relates to positive gas delivery systems, such as pressure support systems and other ventilator (e.g., invasive) systems, and, more particularly, to a method for estimating leak in a gas delivery system, and a gas delivery system employing such a method.

There are numerous situations where it is necessary or desirable to deliver a flow of breathing gas non-invasively to the airway of a patient, i.e., without intubating the patient or surgically inserting a tracheal tube in his or her esophagus. Such therapies are commonly referred to as non-invasive ventilation (NIV) therapies. For example, it is known to non-invasively deliver continuous positive airway pressure (CPAP) or variable airway pressure, which varies with the patient's respiratory cycle, to treat a medical disorder, such as sleep apnea syndrome, in particular, obstructive sleep apnea (OSA), or congestive heart failure.

NIV therapies involve the placement of a patient interface device including a mask component on the face of a patient. The mask component may be, without limitation, a nasal mask that covers the patient's nose, a nasal pillow/cushion having nasal prongs that are received within the patient's nares, a nasal/oral mask that covers the nose and mouth, or a full face mask that covers the patient's face. The patient interface device interfaces the ventilator or pressure support device with the airway of the patient through one or more delivery conduits (together commonly referred to as a patient circuit) so that a flow of breathing gas can be delivered from the pressure/flow generating device to the airway of the patient.

NIV using a single limb patient circuit has safely ventilated patients with respiratory insufficiency for over ten years and those with severe sleep apnea for over twenty years. In NIV, an accurate estimate of the patient flow is required for consistent and accurate volume delivery and for the ventilator to sense the patient's respiratory

drive. The accuracy of the estimated patient flow is dependent on two things: (i) the accuracy and precision of the total flow signal (which is measured at the ventilator outlet and which is the composite of the patient flow and the flow caused by leaks (both intentional and unintentional) about the patient interface) and, (ii) the ability to model the leak flow as a function of one or more parameters such as pressure. Thus, one of the key technologies for effective NIV is the estimation of leak flow.

Furthermore, the ability to accurately estimate leak flow is also important in situations where it is necessary to deliver a flow of breathing gas to the airway of a patient invasively, i.e., wherein the patient is intubated or has a surgically inserted tracheal tube. For example, while mask leak is predominant in NIV, cuff leak is important in invasive circuits. Also, many trached patients have no cuff and therefore the interface is inherently leaky.

Thus, in gas delivery systems such as positive pressure support system and invasive ventilatory system (e.g., that provide volume controlled ventilation), the leak flow that needs to be estimated accurately is defined as any flow escaping the ventilatory system that includes the machine, the patient interface and the patient's trachea and lungs.

The assignee of the invention described elsewhere herein has developed and employed a leak estimation method that is based on the simple principle that a person on a single breath will on average expire the same volume that he or she inspires. This method was based on Bernoulli's orifice flow model, set forth below:

$$Q = C_d A \sqrt{\frac{\Delta P}{\rho}},$$

where Q is the flow through an orifice, C_d is a discharge coefficient (less than 1) based on the principle of *vena contracta*, A is the cross sectional area of the orifice opening, ΔP is the pressure differential across the orifice and ρ is the fluid density. This equation was simplified to:

$$Q_{leak} = g_{orf} \sqrt{P_p},$$

where Q_{leak} is the estimated leak flow, g_{orf} is the lumped coefficient that includes area, discharge coefficient and density of the theoretical orifice causing the leak, and P_p is the patient pressure.

In addition, patient flow estimation is governed by the following equation:

$$Q_p = Q_c - Q_{leak},$$

where, Q_p is the estimated patient flow (e.g., computed every 10 milliseconds) and Q_c is the measured total circuit flow.

The current method makes some assumptions. First, it assumes that all leak is located proximal to the patient's applied pressure. Second, it assumes that the discharge coefficient, orifice area and fluid density are all constants throughout the breath. Also, in the current method, g_{orf} is computed on a breath by breath basis with an autoregressive filter according to the following:

$$g_{orf} += \frac{1}{2} \frac{\int_{T_{breath}} Q_p}{\int_{T_{breath}} \sqrt{P_p}}.$$

The original method has been effective without minor deviations in existing gas delivery systems. However, recent trials with trached, pediatric patients have shown that ventilation triggering algorithms employing the existing method at times miss triggers. In addition, recent studies by the assignee of the invention described herein have shown that irregular breathing drives the existing algorithm to compute erroneous leak characteristics. This is due to the fact that inherent in such an algorithm is a conceptual conundrum. More specifically, leak estimation is a key component of breath detection, but, as can be seen from the leak equation, breath detection is a key component of leak estimation. This type of circular dependence is inherently flawed. Therefore if either goes wrong, they both fail.

At least two failure modes should be considered which illustrate problems associated with the current method. In the first, assume a pediatric patient has very low unassisted flow. Triggering algorithms employing the current method may fail to detect

breaths due to errors in leak estimation, and because breaths are not detected, leak is never updated to correct the issue. In the second, assume a patient makes a sudden movement and causes a false trigger. The false trigger truncates the leak estimation algorithm and results in erroneous leak estimation. The next trigger will be negatively affected by the wrong leak estimation and the process repeats.

In one embodiment, the invention maintains that

$$Q_p = Q_c - Q_{leak},$$

where, Q_p is the estimated patient flow, Q_{leak} is the estimated leak (e.g., estimates may be computed every 10 milliseconds) and Q_c is the measured total circuit flow. Q_{leak} is given by a transfer function φ(x) where x is a set of independent measured or fixed variables. Thus, the transfer function may be expressed as follows:

$$Q_{leak} = \varphi(x).$$

The invention involves adjusting the transfer function φ(x) given the constraint that , Q_p shall be equal to some value, which in the exemplary embodiment is zero. The transfer function converges over time to accurately estimate the leak because over an extended time the mean patient flow will always be zero.

Thus, in one exemplary embodiment, a method of estimating leak flow Q_{leak} in a gas delivery system is provided that includes determining a patient flow Q_p, wherein the patient flow Q_p is a flow of gas delivered to the patient by the gas delivery system, and determining a transfer function φ(x) that estimates the leak flow Q_{leak}, where x is a set of independent measured or fixed variables, based on an adaptive filter constraining patient flow Q_p

In another embodiment, a gas delivery system, such as a positive pressure support system (e.g., a CPAP machine) or a ventilator capable of providing volume controlled ventilation invasively or non-invasively, is provided that implements and employs the method of leak estimation just described.

These and other objects, features, and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon

consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention..

FIG. 1 is a schematic diagram of pressure support system according to one particular, non-limiting embodiment in which the leak estimation methodology of the present invention may be implemented; and

FIG. 2 is a schematic diagram of a transfer function for estimating leak according to an exemplary embodiment of the present invention.

As used herein, the singular form of "a", "an", and "the" include plural references unless the context clearly dictates otherwise. As used herein, the statement that two or more parts or components are "coupled" shall mean that the parts are joined or operate together either directly or indirectly, i.e., through one or more intermediate parts or components, so long as a link occurs. As used herein, "directly coupled" means that two elements are directly in contact with each other. As used herein, "fixedly coupled" or "fixed" means that two components are coupled so as to move as one while maintaining a constant orientation relative to each other.

As used herein, the word "unitary" means a component is created as a single piece or unit. That is, a component that includes pieces that are created separately and then coupled together as a unit is not a "unitary" component or body. As employed herein, the statement that two or more parts or components "engage" one another shall mean that the parts exert a force against one another either directly or through one or more intermediate parts or components. As employed herein, the term "number" shall mean one or an integer greater than one (i.e., a plurality).

Directional phrases used herein, such as, for example and without limitation, top, bottom, left, right, upper, lower, front, back, and derivatives thereof, relate to the orientation of the elements shown in the drawings and are not limiting upon the claims unless expressly recited therein.

As described in greater detail herein, the present invention solves many of the problems of existing leak estimation methods by providing a leak estimation methodology that is a simplified approach to leak estimation and that has no dependence on breath detection. In the exemplary embodiment described elsewhere herein, the methodology still uses the patient pressure power law to maintain the pressure dependence. However, rather than attempting to zero the sum of the estimated patient flow on a breath by breath basis, the methodology of the present invention zeroes the estimated patient flow over an extended period of time.

FIG. 1 is a schematic diagram of pressure support system 50 according to one particular, non-limiting embodiment in which the leak estimation methodology of the present invention may be implemented. It should be understood that pressure support system 50, which is a NIV system, is meant to be exemplary only for purposes of illustrating and describing the present invention, and that the present invention may be implemented and employed in other types of gas delivery systems, such as, without limitation, a ventilator, such as an invasive ventilator system, that delivers volume controlled ventilation. One such alternative gas delivery system is described in PCT Publication No. WO 2010/044038, entitled "Volume Control in a Medical Ventilator," assigned to the assignee of the present invention, the disclosure of which is incorporated herein by reference. The system of WO 2010/044038 provides for invasive ventilation and for leak compensated volume control and delivery with an active circuit (the system includes an active exhalation valve with a proximal flow sensor). Thus, the present invention may be employed in any type of gas delivery system having leaks where it is necessary or desirable to model and compensate for leak flow.

Referring to FIG. 1, pressure support system 50 includes gas flow/pressure generator 52, such as a blower used in a conventional CPAP or bi-level pressure support device, piston, bellows, compressor, or any other device that receives breathing gas, generally indicated by arrow C, from any suitable source, e.g., a pressurized tank of oxygen or air, the ambient atmosphere, or a combination thereof. Gas flow/pressure generator 52 generates a flow of breathing gas, such as air, oxygen, or a mixture thereof,

for delivery to an airway of a patient 54 at relatively higher and lower pressures, i.e., generally equal to or above ambient atmospheric pressure.

The pressurized flow of breathing gas, generally indicated by arrow D from gas flow/pressure generator 52 is delivered, via a delivery conduit 56, to breathing mask or patient interface 58 of any known construction, which is typically worn by or otherwise attached to patient 54 to communicate the flow of breathing gas to the airway of the patient. Delivery conduit 56 and patient interface device 58 are typically collectively referred to as a patient circuit.

Although not shown in FIG. 1, the present invention also contemplates providing a secondary flow of gas, either alone or in combination with the primary flow of gas (arrow C) from atmosphere. For example, a flow of oxygen from any suitable source, such as an oxygen concentrator, or oxygen storage device (liquid or gas), can be provided upstream of gas flow/pressure generator 52 or downstream of the gas flow generator, for example, in the patient circuit or at the patient interface device, to control the fraction of inspired oxygen delivered to the patient.

Pressure support system 50 shown in FIG. 1 is a single-limb system, meaning that the patient circuit includes only delivery conduit 56 connecting the patient to the pressure support device. As such, active exhaust valve 57 is provided in the delivery conduit 56 for venting exhaled gasses from the system to atmosphere as indicated by arrow E. It should be noted that the exhaust valve 57 can be provided at other locations in addition to or instead of in the delivery conduit, such as in the patient interface device 58. It should also be understood that exhaust valve 57 can have a wide variety of configurations depending on the desired manner in which gas is to be vented from the pressure support system.

In the illustrated exemplary embodiment of the present invention, patient interface 58 is a nasal/oral mask. It is to be understood, however, that patient interface 58 can include a nasal mask, nasal pillows, tracheal tube, endotracheal tube, or any other device that provides the gas flow communicating function. Also, for purposes of the present invention, the phrase "patient interface" can include delivery conduit 56 and any other structures that connect the source of pressurized breathing gas to the patient.

It is to be understood that various components may be provided in or coupled to the patient circuit. For example, a bacteria filter, pressure control valve, flow control valve, sensor, meter, pressure filter, humidifier and/or heater can be provided in or attached to the patient circuit. Likewise, other components, such as muffler and filters can be provided at the inlet of gas flow/pressure generator 52 and at the outlet of valve 60 (described below).

In the illustrated embodiment, pressure support system 50 includes a pressure controller or flow controller in the form of motor or valve 60 provided in delivery conduit 56. Valve 60 controls the pressure or the flow of breathing gas from gas flow/pressure generator 52 delivered to patient 54. For present purposes, gas flow/pressure generator 52 and valve 60 are collectively referred to as a "pressure generating system" because they act in concert to control the pressure and/or flow of gas delivered to the patient.

It should be apparent that other techniques for controlling the pressure or the flow delivered to the patient by the gas flow/pressure generator, such as varying the blower speed, either alone or in combination with a pressure control valve, are contemplated by the present invention. Thus, valve 60 is optional depending on the technique used to control the pressure of the flow of breathing gas delivered to the patient. If valve 60 is eliminated, the pressure generating system corresponds to gas flow/pressure generator 52 alone, and the pressure of gas in the patient circuit is controlled, for example, by controlling the motor speed of the gas flow/pressure generator.

Pressure support system 50 further includes flow sensor 62 that measures the flow of breathing gas within delivery conduit 56. In accordance with the exemplary embodiment shown in FIG. 1, flow sensor 62 is interposed in line with delivery conduit 56, most preferably downstream of valve 60. Flow sensor 62 generates a flow signal Q_c (which, as described elsewhere herein, is the measured total circuit flow) that is provided to controller 64 and is used by controller 64 to determine the flow of gas at the patient Q_p. Flow sensor 62 may be included within system, 50, or provided extemally as part of 56.

Techniques for calculating Q_p based on Q_c are well known, and take into consideration the pressure drop of the patient circuit, known leaks from the system, i.e., the intentional exhausting of gas from the circuit as indicated by arrow E in FIG. 1, and

unknown leaks from the system, such a leaks at the mask/patient interface. As stated elsewhere herein, the present invention provides an improved methodology for calculating leak flow Q_{leak} (which is described in detail below), which may then be used in calculating Q_p based on Q_c.

Controller 64 includes a processing portion which may be, for example, a microprocessor, a microcontroller or some other suitable processing device, and a memory portion that may internal to the processing portion or operatively coupled to the processing portion and that provides a storage medium for data and software executable by the processing portion for controlling the operation of pressure support system 50, including estimating leak flow Q_{leak} as described in greater detail herein.

Input/output device 66 is provided for setting various parameters used by the variable positive airway pressure support system, as well as for displaying and outputting information and data to a user, such as a clinician or caregiver. It is to be understood that the present invention contemplates providing input/output terminals so that the operation information and data collected by the pressure support system can be monitored and controlled remotely.

In one exemplary embodiment, the present invention provides an improved methodology for leak estimation by employing a transfer function for determining Q_{leak} wherein $Q_{leak} = \varphi(g_{orf}, X_i)$. In the transfer function, X_i is one or more known, measured or estimated patient interface, respiratory or ambient condition parameters, and the transfer function is determined based on an adaptive filter constraining Qp to 0. As used herein, the term "adaptively filtered" or "adaptive filtering" shall mean any method in which the transfer function of the estimator is adapted based on feedback from the input parameters from sensors and/or user entered parameters and/or known characteristics of the system. In the exemplary embodiment, the patient interface parameters may include the type of mask or endotracheal tube used, the respiratory parameters may include patient respiratory mechanics including muscle effort, and/or lung resistance or compliance, and the ambient parameters may include ambient pressure, temperature, humidity and/or gas composition.

In the exemplary embodiment, the transfer function used for leak estimation is

$$Q_{leak} = g_{orf} \cdot P_p^{\gamma},$$

where γ is the exponent that best approximates the fluid mechanics of leak and P_p is the patient pressure (set and controlled by controller 64). Alternatively, P_p may be measured using a pressure sensor provided as part of pressure support system 50. In the exemplary embodiment, γ is set to an empirically determined suitable value, such as, without limitation, 4/7. Furthermore, in the exemplary embodiment, the adaptation of the parameters in the transfer function is simplified to:

$$g_{orf} += K_{fg} Q_p,$$

where K_{fg} is a floating g_{orf} gain constant that controls the response time of the leak estimator and $K_{fg} << 1$.

In addition, practice has shown that it is more practical to split up the time constant into two parts. The first part is through a low pass filter for the estimated patient flow Q_p and the second part remains as the gain constant. FIG. 2 is a schematic diagram of the transfer function 70 of the exemplary embodiment of the present invention, wherein the adaptive filter is labeled with reference numeral 72 and includes low pass filter 74, wherein Q_c is measured by flow sensor 62, and wherein Q_p is the estimated patient flow and Q_{leak} is the estimated leak flow. As seen in FIG. 2, the current g_{orf} parameter is obtained by first filtering Q_p and then multiplying the filtered Q_p by K_{fg} and adding the resulting value to the previous g_{orf} parameter. That g_{orf} parameter may then be used to determine the current Q_{leak} based on $Q_{leak} = g_{orf} \cdot P_p^{\gamma}$.

The floating g_{orf} gain constant K_{fg} is in the exemplary embodiment tuned to provide a near critically damped response of the transfer function after anominal step changes in leak. A K_{fg} of 1/1230 has been found to be suitable for many cases when the sample rate is 10 msec.

In addition, in the exemplary embodiment, if g_{orf} ever becomes negative ($g_{orf} < 0$), which indicates a negative leak, then γ is set equal to zero until g_{orf} becomes positive again. Thus, during the time that g_{orf} is negative the transfer function is adapted

to the variant, $Q_{leak} = g_{orf}$. Such a condition may result from oxygen being injected into delivery conduit 56, from a nebulizer being used in conjunction with delivery conduit 56, or from other situations where a gas is being injected into delivery conduit 56.

In the exemplary embodiment, g_{orf} is set equal to zero when therapy using pressure support system 50 is initiated, and the methodology described herein is used to update g_{orf} and determine Q_{leak} periodically, such as, without limitation, every ten milliseconds.

Thus, in short, in the exemplary embodiment just described, the transfer function is given by $Q_{leak} = g_{orf} \cdot P_p^{\gamma}$, where γ is a predetermined exponent and P_p is patient pressure. In this embodiment, in order to produce zero patient flow, the coefficient g_{orf} is adjusted by filtering the patient flow Q_p to obtain a filtered Q_p, multiplying the filtered Q_p by a constant K_{fg} to obtain a product, and adding the product to the previous value of the g_{orf} coefficient.

In another, alterative exemplary embodiment, Q_{leak} or $\varphi(x)$ is a function of the coefficient g_{orf} and at least one patient interface parameter such as a known leak device inherent to the patient interface. In this embodiment, the transfer function $\varphi(x)$ may be expressed as follows:

$$Q_{leak} = g_{orf} \cdot P_p^{\gamma} + C_d A \cdot \sqrt{P_p},$$

where A is the known cross-sectional area of a leak device present in the system and C_d is a known discharge coefficient of the orifice.

Furthermore, in this embodiment, the parameters in the transfer function may depend on multiple estimated or measured ambient conditions upon which leak may depend, such as ambient pressure and temperature. In such a case, the transfer function $\varphi(x)$ may be expressed as follows:

$$Q_{leak} = g_{orf} \cdot P_p^{\gamma} + C_d A \cdot \sqrt{\frac{P_p}{\rho}},$$

where ρ is the density of the gas delivered as a function of ambient pressure and temperature.

The transfer function may further include known or estimated respiratory parameters such as lung compliance or resistance such as in the case when invasive circuit are used. For example, when the trachea resistance, R, is well known, the transfer function φ(x) may be expressed as follows, which will be a more appropriate model for leak:

$$Q_{leak} = g_{orf} \cdot \left(P_p - RQ_p\right)^{\gamma}.$$

Lastly, because it is common that a fixed low flow is often added to the patient circuit, the transfer function may be adapted to include this flow. In such a case, the transfer function φ(x) may be expressed as follows:

$$Q_{leak} = g_{orf} \cdot \left(P_p\right)^{\gamma} - Q_{O2}.$$

According to the present invention, that all or some of the parameters in the transfer functions above may be adjusted by method of an adaptive filter using the constraint that patient flow is some predetermined value, which in the exemplary embodiment is zero. In each case, when adapted correctly the leak transfer function will converge to accurately estimate leak over the extended time as the mean patient flow will surely be zero.

Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

Claims

1. A method of estimating leak flow Q_{leak} in a gas delivery system (50), comprising:

determining a patient flow Q_p, wherein the patient flow Q_p is a flow of gas delivered to the patient by the gas delivery system; and

determining a transfer function $\varphi(x)$ that estimates the leak flow Q_{leak}, where x is a set of independent measured or fixed variables, based on an adaptive filter constraining patient flow Q_p.

2. The method according to claim 1, wherein the constraint regarding patient flow Q_p is patient flow Q_p equals zero.

3. The method according to claim 2, wherein the transfer function $\varphi(x)$ is $Q_{leak} = g_{orf} \cdot P_p^{\gamma}$, where γ is a predetermined exponent, P_p is patient pressure, and g_{orf} is a lumped coefficient, and wherein the coefficient g_{orf} is adapted until Q_p is zero.

4. The method according to claim 2, wherein the determining the transfer function includes adjusting the coefficient g_{orf} to produce zero patient flow Q_p by filtering the patient flow Q_p to obtain a filtered Q_p, multiplying the filtered Q_p by a constant K_{fg} to obtain a product, and adding the product to a previous g_{orf}

5. The method according to claim 4, wherein the filtering the patient flow Q_p comprises low pass filtering the patient flow Q_p.

6. The method according to claim 1, further comprising determining whether g_{orf} is less than 0, and if g_{orf} is less than 0, setting Q_{leak} equal to g_{orf}.

7. The method according to claim 1, wherein the set of independent measured or fixed variables comprises at least one of a patient interface parameter, a respiratory parameter and an ambient condition parameter.

8. The method according to claim 1, wherein the transfer function φ(x) is $Q_{leak} = g_{orf} \cdot P_p^{\gamma} + C_d A \cdot \sqrt{P_p}$, where γ is a predetermined exponent, P_p is patient pressure, g_{orf} is a lumped coefficient, A is the known cross-sectional area of a leak device present in the gas delivery system, and C_d is a known discharge coefficient of the leak device.

9. The method according to claim 1, wherein the transfer function φ(x) is $Q_{leak} = g_{orf} \cdot P_p^{\gamma} + C_d A \cdot \sqrt{\frac{P_p}{\rho}}$, where γ is a predetermined exponent, P_p is patient pressure, g_{orf} is a lumped coefficient, A is the known cross-sectional area of a leak device present in the gas delivery system, C_d is a known discharge coefficient of the leak device, and ρ is a density of gas delivered as a function of ambient pressure and temperature.

10. The method according to claim 1, wherein the transfer function φ(x) is $Q_{leak} = g_{orf} \cdot \left(P_p - RQ_p\right)^{\gamma}$, where γ is a predetermined exponent, P_p is patient pressure, g_{orf} is a lumped coefficient, and R is a trachea resistance.

11. A gas delivery system (50), comprising:

a pressure or flow generating system (52, 60) adapted to produce a first flow of gas;

a patient circuit (56, 58) operatively coupled to the pressure or flow generating system; and

a controller (64) operatively coupled to the pressure or flow generating system, the controller being programmed to estimate leak flow Q_{leak} in the gas delivery system (50) by:

determining a patient flow Q_p, wherein the patient flow Q_p is a flow of gas delivered to the patient by the gas delivery system; and

determining a transfer function φ(x) that estimates the leak flow Q_{leak}, where x is a set of independent measured or fixed variables, based on an adaptive filter constraining patient flow Q_p.

12. The gas delivery system according to claim 11, wherein the constraint regarding patient flow Q_p is patient flow Q_p equals zero.

13. The gas delivery system according to claim 12, wherein the transfer function φ(x) is $Q_{leak} = g_{orf} \cdot P_p^{\gamma}$, where γ is a predetermined exponent, P_p is patient pressure, and g_{orf} is a lumped coefficient, and wherein the coefficient g_{orf} is adapted until Q_p is zero.

14. The gas delivery system according to claim 12, wherein the determining the transfer function includes adjusting the coefficient g_{orf} to produce zero patient flow Q_p by filtering the patient flow Q_p to obtain a filtered Q_p, multiplying the filtered Q_p by a constant K_{fg} to obtain a product, and adding the product to a previous g_{orf}.

15. The gas delivery system according to claim 14, wherein the filtering the patient flow Q_p comprises low pass filtering the patient flow Q_p.

16. The gas delivery system according to claim 11, wherein the contoller is further programmed to determine whether g_{orf} is less than 0, and if g_{orf} is less than 0, setting Q_{leak} equal to g_{orf}.

17. The gas delivery system according to claim 11, wherein the set of independent measured or fixed variables comprises at least one of a patient interface parameter, a respiratory parameter and an ambient condition parameter.

18. The gas delivery system according to claim 11, wherein the transfer function φ(x) is $Q_{leak} = g_{orf} \cdot P_p^{\gamma} + C_d A \cdot \sqrt{P_p}$, where γ is a predetermined exponent, P_p is patient pressure, g_{orf} is a lumped coefficient, A is the known cross-sectional area of a leak device present in the gas delivery system, and C_d is a known discharge coefficient of the leak device.

19. The gas delivery system according to claim 11, wherein the transfer function φ(x) is $Q_{leak} = g_{orf} \cdot P_p^{\gamma} + C_d A \cdot \sqrt{\frac{P_p}{\rho}}$, where γ is a predetermined exponent, P_p is patient pressure, g_{orf} is a lumped coefficient, A is the known cross-sectional area of a leak device present in the gas delivery system, C_d is a known discharge coefficient of the leak device, and ρ is a density of gas delivered as a function of ambient pressure and temperature.

20. The method according to claim 11, wherein the transfer function φ(x) is $Q_{leak} = g_{orf} \cdot (P_p - RQ_p)^{\gamma}$, where γ is a predetermined exponent, P_p is patient pressure, g_{orf} is a lumped coefficient, and R is a trachea resistance.

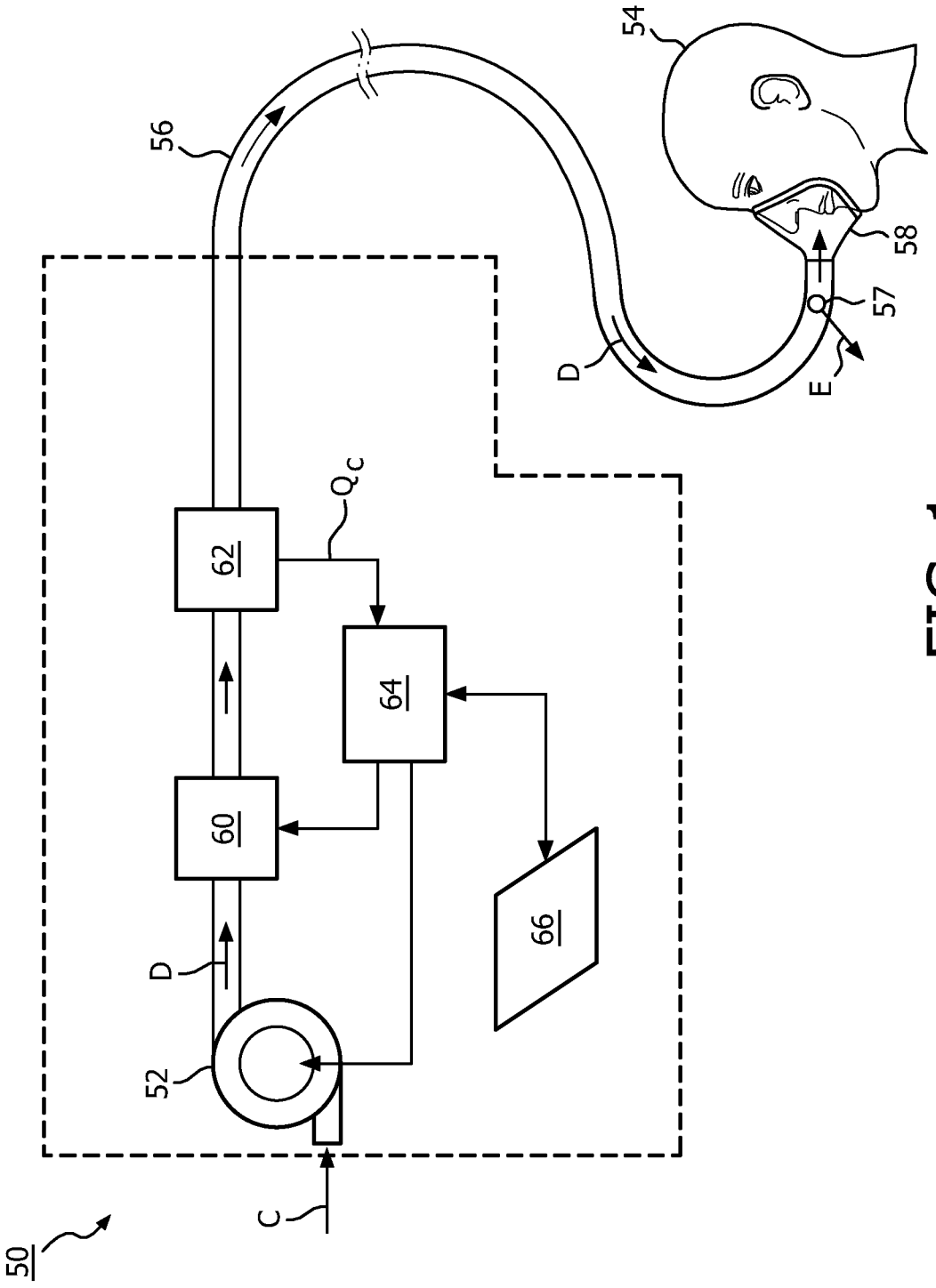

FIG. 1

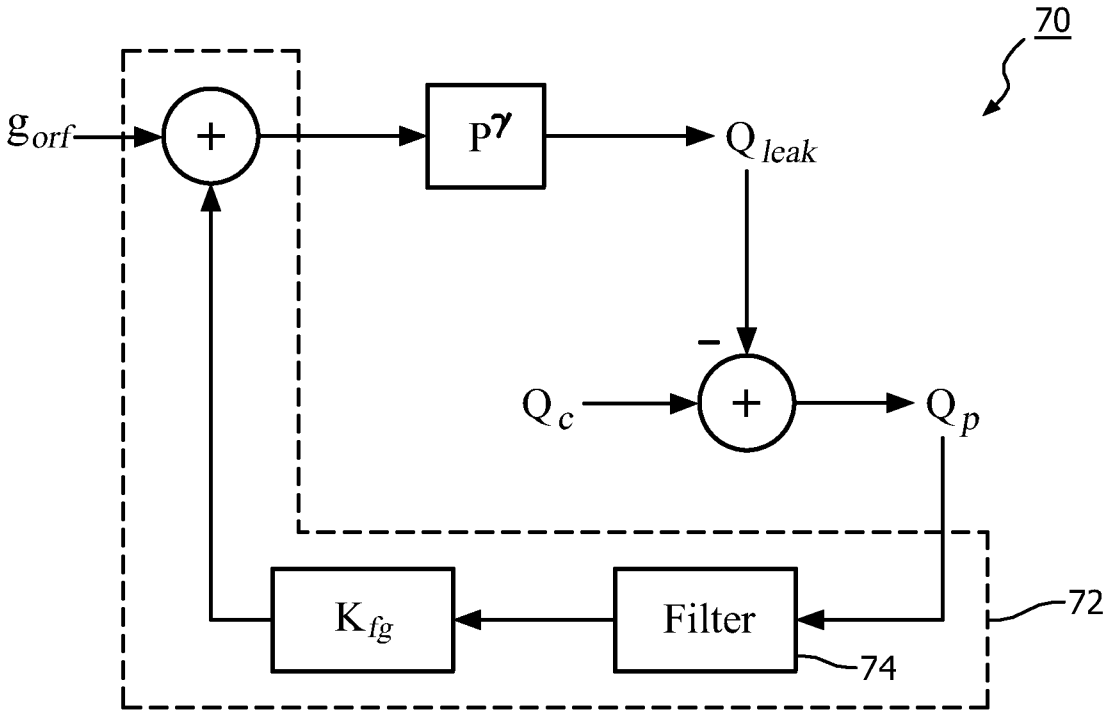

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/052973

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

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/06449 A1 (RESMED LTD [AU]; BERTHON JONES MICHAEL [AU]) 19 February 1998 (1998-02-19) The whole document, especially page 6, line 29 - page 10, line 12	1-7, 11-17
X	WO 2008/025064 A1 (RESMED LTD [AU]; BASSIN DAVID JOHN [AU]) 6 March 2008 (2008-03-06) page 5, line 26 - page 7, line 11	1,11

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 September 2011	04/10/2011

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/052973

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