



(22) Date de dépôt/Filing Date: 1991/02/12

(41) Mise à la disp. pub./Open to Public Insp.: 1991/11/12

(45) Date de délivrance/Issue Date: 2005/01/04

(30) Priorité/Priority: 1990/03/11 (07/522,383) US

(51) Cl.Int.⁵/Int.Cl.⁵ G05D 7/06, A61M 16/00

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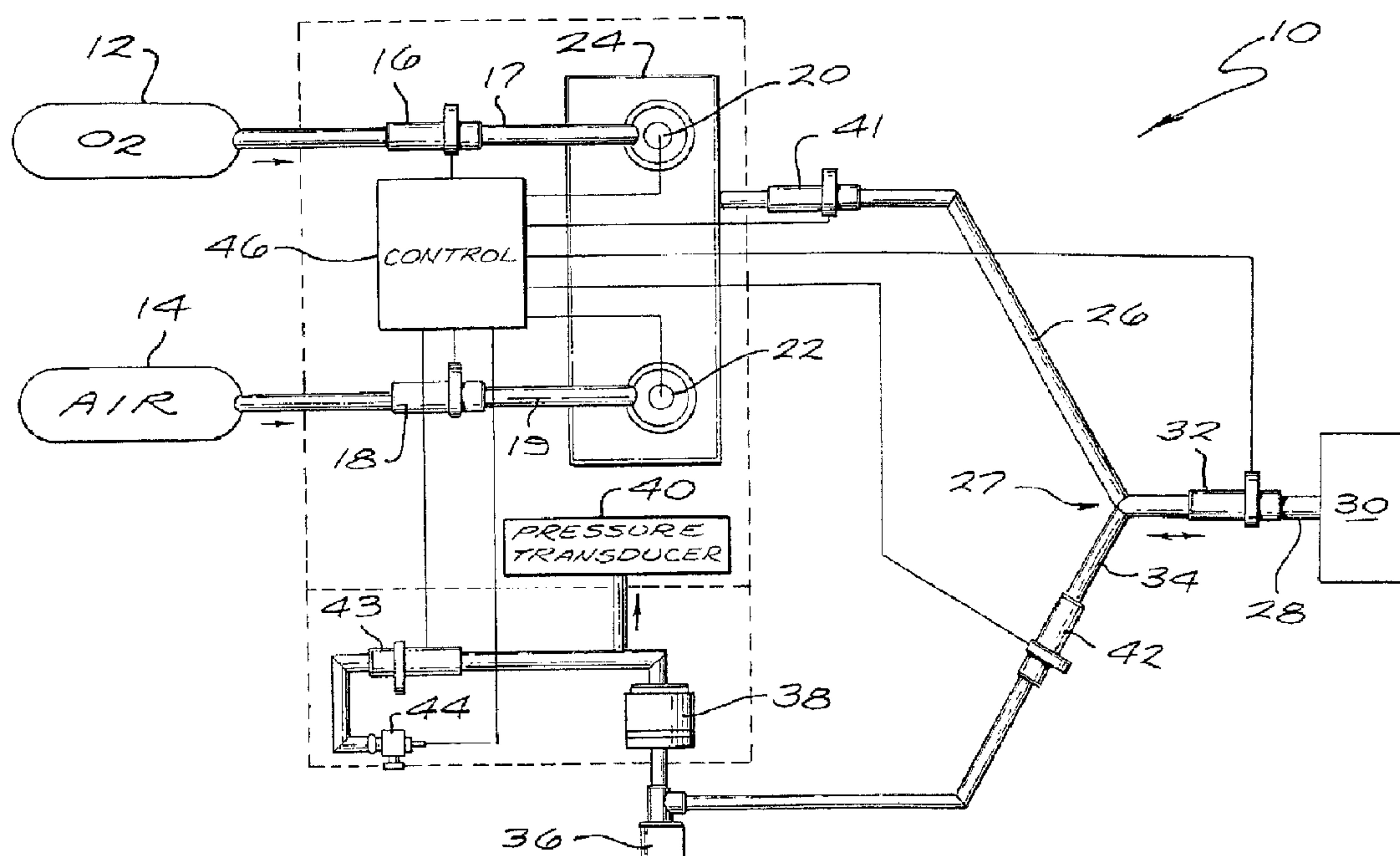
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(54) Titre : RESPIRATEUR MUNI D'UN DISPOSITIF DE DECLenchement DE L'INSUFFLATION, ET METHODE CONNEXE

(54) Title: SYSTEM AND METHOD FOR FLOW TRIGGERING OF PRESSURE SUPPORTED VENTILATION



(57) Abrégé/Abstract:

The system and method for flow triggering pressure supported ventilation include a source of a predetermined, preinspiratory, constant flow of breathing gas to a patient, one or more flow sensors for measuring the rate of gas flow in a flow path communicating with the patient, means for determining when inhalation from the flow path has occurred, and means for generating pressure support in the delivered gas flow in response to inhalation by the patient, means to terminate pressure support when inspiratory phase concludes, and means to reestablish the predetermined, preinspiratory, continuous flow of breathing prior to the patient's next inspiratory effort. A plurality of individual gas sources preferably provide a controlled mixture of breathing gas. In combination with pressure support to the patient during the inspiration effort, the flow triggering strategy of the invention offers significant improvements in providing breath support to patients having weakened respiratory capabilities.



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ABSTRACT OF THE DISCLOSURE

5 The system and method for flow triggering pressure supported ventilation include a source of a predetermined, preinspiratory, constant flow of breathing gas to a patient, one or more flow sensors for measuring the rate of gas flow in a flow path communicating with the patient, means for determining when inhalation from the flow path has occurred, and means for generating pressure support in the delivered gas flow in response to inhalation by the patient, means to terminate pressure support when inspiratory phase concludes, and means to reestablish the predetermined, preinspiratory, continuous flow of breathing prior to the patient's next inspiratory effort. A plurality of individual gas sources preferably provide a controlled mixture of breathing gas. In combination with pressure support to the patient during the inspiration effort, the flow triggering strategy of the invention offers significant improvements in providing breath support to patients having weakened respiratory capabilities.

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SYSTEM AND METHOD FOR FLOW TRIGGERING
OF PRESSURE SUPPORTED VENTILATION

BACKGROUND OF THE INVENTION

Field of the Invention:

5 This invention relates generally to breathing
ventilators, and more particularly relates to a
pneumatically driven, electronically controlled, ventilator
system for providing breathing gas to a patient, and a
10 system and method for flow triggering pressure support
during patient-initiated spontaneous breathing. Pressure
support is also known in the art by other names, e.g.
inspiratory assist, pressure assist, or inspiratory
pressure assist.

Prior Art:

15 Breathing ventilator systems conventionally
provide a breathing gas for either non-pressure supported
breaths during inspiration at a pressure level typically
no more than 2 cm. of water above or below the pressure
baseline or pressure-supported breaths of breathing gas at
20 a support pressure during inspiration as high as 70 - 100
cm. of water. Such breathing gas is often supplemented
with a higher proportion of oxygen than is found in the
ambient atmosphere. The respiration work performed by a
patient on a ventilator may be divided into two major
25 components: the work to initiate a breath and the work to
sustain a breath. It is desirable to reduce the effort
expended by the patient in each of these phases, since a
high level of such effort can cause further damage to a

weakened patient or be beyond the capabilities of small or disabled patients. As discussed below, a variety of strategies and systems have been developed to address these problems, but important issues still remain in the reduction of work demanded by ventilators to command and sustain a breath.

Ventilators presently known in the art are commanded to deliver inspiration support, or a specific flow of breathing gas during an inspiratory phase of breathing, based upon a "pressure trigger" as described below. With such a system, when a patient's spontaneous inspiratory effect withdraws a small volume of gas from the breathing-gas circuit, the corresponding drop in pressure in the closed ventilator circuit is monitored, and when a predetermined triggering pressure threshold is reached, a control mechanism causes the ventilator's pneumatic system to deliver breathing gas at the desired pressure or flow rate. This activation of the ventilator cycle by means of a patient-induced negative pressure may be termed "pressure triggering". A certain amount of lag time and associated negative pressure always occurs between the onset of inspiratory effort and the time that the gas pressure or flow reaches the patient's airway. This lag time (or delay) is generally referred to as a ventilator's response time, and commonly occupies a small but significant portion of a patient's total inspiration time.

Pressure triggering of inspiration support relies upon the transmission of pressure waves throughout the closed breathing-gas circuit. These pressure waves travel to the pressure sensor at the speed of sound in the gas, which is approximately 1 millisecond per foot. Although electronic processing of pressure-wave signals can occur

5 very rapidly, due to factors inherent in ventilator design,
patient-inspiration effort can typically continue for as
long as 40 to 50 milliseconds without ventilator
assistance. Under the conventional pressure-triggering
ventilation schemes, the pressure drop, which a patient is
10 required to create in a closed breathing-gas circuit in
order to trigger a breath, can require a significant
expenditure of energy by the patient. This imposed work on
the patient can be detrimental in that respiratory muscles
already fatigued by an operation or other patient condition
may fatigue. In addition, this respiratory work may be
beyond the capability of some patients, such as neonates,
small children, or patients severely weakened by trauma or
disease, resulting in the inability of the patient to
15 rhythmically trigger the inspiratory support of the
ventilator. If this process continues to worsen, the
patient may experience failure or severe compromise of the
ventilation process. Thus, the ventilator response time,
plus the lag time associated with pressure triggering, can
20 result in a significant expenditure of work by the patient
in order to command a breath from the ventilator.

25 The signal to cycle on the ventilator to deliver
pressure or volume support of patient breaths by monitoring
flow in the patient's breathing-gas circuit or inside the
ventilator has recently been accomplished in the context of
a closed breathing-gas circuit. In such a system, a single
flow sensor is typically positioned inside the ventilator
to monitor the flow of gas that a patient withdraws from
the closed system and trigger a pressure-or volume-based
30 breath when the patient's inspiratory flow equals a certain
predetermined level. However, such a closed-system, flow-
based trigger is not an improvement over a closed-system
pressure triggered arrangement, because all of the same

delays and work required of the patient are present. In addition, a significant negative pressure drop is still required to start the breath, and there is no continuous flow to support the earliest phase of the breath. Therefore, the patient must overcome the substantial inertia of the breath triggering process.

In order to decrease the work of sustaining the flow of a breath after it has been initiated, thereby reducing the work required of our patient, breathing ventilator systems conventionally provide a breathing gas for non-pressure supported breaths during inspiration at a pressure level typically no more than 2 cm. of water above or below the pressure baseline. In pressure-supported systems, breaths of breathing gas are delivered at a pressure support level during inspiration as high as 70-100 cm. of water. These higher pressures are used to supplement patient effort, overcome airway resistance, and reduce the work of breathing for the patient. This use of a higher pressure support level can provide enhanced comfort for the patient, and may facilitate the weaning of the patient from the ventilator.

To circumvent or overcome the problems associated with breath triggering in the context of a closed ventilator circuit, a continuous flow system may be employed. To ensure that the patient receives a flow of breathing gas immediately upon initiation of an inspiratory effort and with the appropriate oxygen concentration, a flow regulator is positioned at the inlet of the breathing-gas circuit to deliver a constant gas flow in excess of the peak-flow demand expected from the patient. This "continuous flow" approach eliminates the ventilator's delay time and significantly reduces the negative pressure

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work associated with closed ventilator systems.

An advantage of the continuous gas flow (available in an open breathing-gas system) is that a patient's inspiratory effort results in an immediate flow of breathing gas into his/her trachea, without the delays and with less negative pressure work inherent in closed ventilator systems. Thus, it would be desirable to provide pressure support to a patient in an initially, open continuous-flow system rather than from a closed breathing gas system. It would also be desirable to provide a method and system for triggering breaths which can be made to be more sensitive than previous pressure-based strategies.

From the above, it is clear that it would be desirable to combine the advantages of flow sensing and triggering in a functionally open, breathing-gas circuit with pressure support for the purpose of enabling the ventilator to reduce significantly both the work of breathing during the earliest phase as well as the patient's breathing work during the later phases of the inspiratory effort. The present invention accomplishes these goals.

In accordance with the present invention, there is provided a method of flow triggering of pressure supported ventilation in a functionally open breathing-gas circuit, supplied with a predetermined, preinspiratory, continuous gas flow ventilation system having a source of breathing gas, a ventilation flow path for said breathing gas in fluid communication with a patient, and flow sensor means for measuring the rate of gas flow in the flow paths, comprising: (a) delivering a predetermined rate of flow of said breathing gas from said source to said patient; (b) measuring the change

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in the rate of gas flow in said ventilation flow path due to inhalation; (c) generating pressure support in said delivered flow of gas when said change in the rate of gas flow due to inhalation exceeds a predetermined threshold value; and (d)
5 restoring the preinspiratory, continuous flow of breathing gas to a predetermined value before the patient's next inspiratory effort.

In accordance with the present invention, there is further provided a system of flow triggering pressure support
10 ventilation for use in a functionally open breathing-gas circuit, supplied with a predetermined, preinspiratory, continuous gas flow ventilation system having a source means of breathing gas, a flow path means for said breathing gas in fluid communication with a patient, and flow sensor means for
15 measuring the rate of gas flow in the flow paths, comprising:
(a) means for delivering a predetermined, continuous rate of flow of said breathing gas from said source to said patient;
(b) flow sensor means for measuring the rate of gas flow in said flow path due to inhalation; (c) means responsive to said
20 flow sensor means for generating pressure support in said delivered flow of gas when said change in the rate of gas flow due to inhalation exceeds a predetermined value; and (d) means for restoring the preinspiratory, continuous flow of a breathing gas to its predetermined value before the patient's
25 next inspiratory effort.

In accordance with the present invention, there is further provided a method of determining leaks in a flow-triggered, pressure-supported, preinspiratory, continuous gas flow ventilation system having a source of breathing gas, a
30 flow path for said breathing gas in fluid communication with a patient, and flow sensor means for measuring the rate of gas flow in the flow path, comprising: (a) delivering a predetermined continuous rate of flow of said breathing gas

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5b

from said source into said system (including said patient); and
(b) incrementally adjusting the flow trigger level until the
ventilation system self cycles.

In accordance with the present invention, there is
5 further provided a method of controlling flow of ventilation to
a patient supplied with a preinspiratory, continuous flow of
breathing gas from a ventilation system having a source of
breathing gas, a patient breathing attachment, an exhalation
valve, and a functionally open breathing gas flow path in fluid
10 communication with said source of breathing gas, said
ventilation flow path including at least one flow sensor
located between said patient breathing attachment and said
exhalation valve for measuring a flow rate of said breathing
gas from said patient breathing attachment through said
15 exhalation valve, the steps of the method comprising:
delivering a predetermined rate of flow of said breathing gas
from said source to said patient breathing attachment;
measuring said flow rate of breathing gas from said source of
breathing gas to said patient breathing attachment to determine
20 a gas supply flow rate; measuring said flow rate of breathing
gas from said patient breathing attachment through said
exhalation valve at a location in said ventilation flow path
between said breathing attachment and said exhalation valve to
determine an exiting gas flow rate; determining patient
25 inspiratory effort in said flow path by comparing said gas
supply flow rate with said exiting gas flow rate; generating
pressure support in said delivered flow of gas when said
inspiratory effort exceeds a predetermined threshold value; and
restoring delivery of said breathing gas from said source to
30 said patient breathing attachment at a preinspiratory,
continuous rate of flow before a patient's next inspiratory
effort.

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In accordance with the present invention, there is further provided a system for controlling flow of ventilation to a patient supplied with a preinspiratory, continuous flow of breathing gas from a ventilation system having a source of breathing gas, a patient breathing attachment, an exhalation valve, and a functionally open breathing gas flow path in fluid communication with said source of breathing gas, said patient breathing attachment and said exhalation valve, the system comprising: means for delivering said breathing gas from said source to said patient breathing attachment at said predetermined, continuous rate of flow; at least one flow sensor in said flow path for measuring the flow rate of said breathing gas from said source of breathing gas to said patient breathing attachment to determine a gas supply flow rate, and for measuring flow rate of said breathing gas from said patient breathing attachment through said exhalation valve at a location between said patient breathing attachment and said exhalation valve to determine an exiting gas flow rate; means responsive to said at least one flow sensor for determining patient breathing efforts by comparing said gas supply flow rate with said exiting gas flow rate to determine a flow rate change due to patient inhalation or exhalation; means for generating pressure support in said delivered flow of gas when said flow rate change exceeds a predetermined threshold value; and means for restoring delivery of said breathing gas from said source to said patient breathing attachment at said preinspiratory, continuous rate of flow before a next patient's inspiratory effort.

In accordance with the present invention, there is further provided a method of flow triggering of breath support ventilation to a patient supplied with a predetermined, preinspiratory, continuous flow of breathing gas from a ventilation system having a source of breathing gas, a patient

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breathing attachment, an exhalation valve, and a functionally open breathing gas flow path in fluid communication with said source of breathing gas, said ventilation flow path including flow sensor means for measuring flow rate of said breathing gas from said patient breathing attachment to said exhalation valve, the steps of the method comprising: delivering said predetermined rate of flow of said breathing gas from said source to said patient breathing attachment; measuring said flow rate of breathing gas from said source of breathing gas to said patient breathing attachment to determine a gas supply flow rate; measuring said flow rate of breathing gas from said patient attachment to said exhalation valve to determine an exiting gas flow rate; determining patient inspiratory effort in said flow path by comparing said gas supply flow rate with said exiting gas flow rate, and determining a flow rate change due to patient inhalation or exhalation, thereby indicating the patient's breathing efforts; generating breath support in said delivered flow of gas when said flow rate change exceeds a predetermined threshold value; and restoring delivery of said breathing gas from said source to said patient breathing attachment at said preinspiratory continuous rate of flow before a patient's next inspiratory effort.

In accordance with the present invention, there is further provided a system of flow triggering breath support ventilation to a patient supplied with a predetermined, preinspiratory, continuous flow of breathing gas, comprising a ventilation system having a source of breathing gas, a patient breathing attachment, an exhalation valve, and a functionally open breathing gas flow path in fluid communication with said source of breathing gas, said patient breathing attachment and said exhalation valve, and flow sensor means for measuring flow rate of said breathing gas from said patient breathing attachment to said exhalation valve, the system further

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comprising: means for delivering said breathing gas from said source to said patient breathing attachment at said predetermined, continuous rate of flow; flow sensor means in said flow path for measuring flow rate of said breathing gas from said source of breathing gas to said patient breathing attachment to determine a gas supply flow rate, and for measuring flow rate of said breathing gas from said patient breathing attachment to said exhalation valve to determine an exiting gas flow rate; means responsive to said flow sensor means for determining patient breathing efforts by comparing said gas supply flow rate with said exiting gas flow rate to determine a flow rate change due to patient inhalation or exhalation efforts; means for generating breath support in said delivered flow of gas when said flow rate change exceeds a predetermined threshold value; and means for restoring delivery of said breathing gas from said source to said patient breathing attachment at said preinspiratory, continuous rate of flow before a next patient's inspiratory effort.

SUMMARY OF THE INVENTION

An excessively high expenditure of energy by the patient, early in the inspiratory process, can be detrimental to the patient. Patients may fatigue under these imposed workloads, leading to further respiratory distress and/or failure. The required energy expenditure can also create difficulties in weaning the patient from the ventilator, leading to patients who become ventilator dependent. Thus, reducing the energy expenditure while

breathing on a mechanical ventilator is advantageous for the patient.

5 The energy expended while breathing on a mechanical ventilator may be divided into two components. The first of such components is the energy required to trigger the ventilator to initiate inspiratory support. The second component is the energy required to maintain gas flow once the inspiration has been initiated. The use of flow triggering within the context of a continuous gas flow system minimizes the first component, since a patient has a continuous supply of appropriately mixed gas immediately available from which to draw, essentially eliminating the lag time and minimizing the earliest work of breathing for volume- or pressure-based, patient-initiated breaths. The strategy behind the pressure support mode of ventilation is to reduce the second component by providing a positive pressure to overcome airway resistance and to supplement patient effort. While each of these techniques is helpful in reducing the work to be performed by the patient on the respirator, it would be desirable to provide a ventilator system that combined these two work-reducing concepts, thereby enabling the ventilator to manage all phases of the energy expended by the patient. Such a level of performance is unavailable in current systems.

30 The present invention provides a system and method of triggering pressure supported breaths for a patient on a ventilation system that is initially open (and is provided with a pre-inspiratory flow of breathing gas) and that is equipped to measure the flow of inhaled gas into the patient and then triggers the delivery of pressure support when the flow of inhaled gas equals a preset,

threshold value of flow. By implementing flow sensing in an open-circuit design, in which setting the ventilator establishes a controlled and minimal, pre-inspiratory, continuous flow of gas in the breathing-gas circuit, the ventilator acquires the means to cycle on the pressure support function while eliminating the ventilator's lag time and minimizing the patient's earliest inspiratory efforts. When this method of flow triggering is combined with pressure support ventilation, the patient's work of breathing can be managed to virtually any desirable level. An additional benefit provided by flow triggering of pressure supported ventilation is the elimination of self-triggering of the ventilator due to leaks in the patient's physiology and/or the breathing-gas circuit, without degrading ventilator sensitivity. The system of the present invention also allows the measurement of these leaks, which can then be used to assess the condition of physiologic leaks in the patient.

Briefly and in general terms, the flow triggering system for delivering breathing gas to a patient of the present invention comprises a source means of a pre-inspiratory, constant flow of breathing gas to a patient, flow sensor means for measuring the rate of gas flow in a flow path means communicating with the patient, a means for determining when inhalation from said flow path has occurred, a means for generating pressure support during the inspiratory phase of the breath in response to inhalation by the patient, and a means for reestablishing the constant flow of breathing gas to a patient after the end of the inspiratory phase of the pressure supported breath and before the new inspiratory effort begins.

5 In the preferred embodiment of the system of the invention, a plurality of individual gas sources provides a controlled mixture of breathing gas. It is preferable to mount flow sensor means in both the flow path to (inspiration) and the flow path from (exhalation) the patient, and measure the flow extracted by the patient as the difference of the two. It is preferred to discontinue pressure support at the conclusion of the inspiratory phase of the breath. And it is also preferred to reestablish the continuing flow of breathing prior to the patient's next inspiratory effort.

15 In the preferred method of the invention, the flow triggering of pressure supported ventilation involves the steps of (1) providing a predetermined, pre-inspiratory, continuous flow rate of breathing gas from a source to the patient, (2) measuring the flow rate in the ventilation flow path due to the patient's inhalation as the difference between flow sensor means placed in the paths to and from the patient, (3) generating pressure support during the inspiratory phase of the breath when the flow due to inhalation exceeds a predetermined threshold value, and (4) reestablishing the predetermined, continuous flow rate of breathing gas from a source to the patient prior to his/her next respiratory effort. The method further preferably comprises mixing a plurality of individual gases from different sources, and controlling proportions of the mix of gases. It is currently preferred to discontinue pressure support when an exhalation effort is detected from a rise in pressure to a threshold value, or when flow declines to below a threshold value.

The approach of the present invention to the combination of flow triggering with pressure support

5 provides a spontaneous breath whose work of inspiration
can be closely controlled by an appropriate selection of
the level of support pressure. The energy required to
trigger the breath is minimal due to the flow triggering
10 strategy described in the invention. Once the breath is
triggered, the level of support pressure in combination
with the patient's airway resistance (including that of
the artificial airway and lumped chest wall and lung
compliance) allows the energy expended throughout the rest
15 of the inspiratory phase to be closely managed. There are
also other advantages to flow triggering of pressure-
supported ventilation when used for small children or
infants, where the high sensitivity of triggering is a
distinct advantage, since small patients find pressure
20 triggering more strenuous due to their weaker respiratory
systems. In addition, the dead space that must be evacuated
for pressure triggering is also more difficult for patients
with small lungs. Very often, patients who cannot
successfully pressure trigger a ventilator can flow trigger
the ventilation process.

25 These additional advantages of the present
invention derive in part from the physics of the flow-
triggering strategy. Before a patient initiates an
inspiratory effort, a predetermined, preinspiratory
controlled, and measured flow of breathing gas is delivered
into the patient's breathing-gas circuit. This breathing
gas (air or oxygen-enriched air) flows past the patient
30 wye, which is connected to the patient's breathing
attachment (artificial airway, face mask, nasal mask, or
the like), and then flows out of the breathing-gas circuit,
where it is measured by the flow-sensing means placed in
this flow path. Functionally, the patient's breathing
attachment is connected, via the patient's wye, to an

artificial atmosphere (either at or above the ambient atmospheric pressure), the oxygen concentration of which is determined by the setting from the plurality of gas sources. From the patient's reference point, the breathing-gas circuit is not closed as it is for the pressure triggering strategy, but open as provided for by the preinspiratory continuous flow of breathing gas. At the moment that the patient initiates an inspiratory effort and immediately thereafter, the flow past the patient wye will exceed the flow through his or her breathing attachment. Thus, in the flow triggering system, breathing gas flows with no delay into the patient's breathing attachment the moment that the inspiratory effort begins. In contrast, in the pressure triggering system flow through the patient's breathing attachment from the ventilator is delayed until the pressure threshold is attained and the ventilator senses this event, thereafter causing the flow source means to deliver flow into the breathing-gas circuit.

The flow-triggering method of the present invention may be implemented in the following preferred embodiment: The predetermined preinspiratory flow of gas that enters the breathing-gas circuit from the flow source means is preferably greater than the magnitude of the flow through the patient's breathing attachment, which is the actual threshold flow signal that causes the ventilator to cycle on and deliver the pressure-supported breath. Preferably, the predetermined flow into the breathing-gas circuit should exceed the value of the flow which results from the patient's inspiratory effort and which triggers the ventilator cycle on and deliver the pressure-supported breath. With this design, the patient's breathing-gas circuit functions as an open continuous flow system until

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and after the patient's inspiratory effort generates the flow-triggering signal.

5 A benefit of the present invention is that the pressure in the breathing circuit during the early exhalation phase may be kept low to limit the problems encountered when the patient tries to exhale against an artificially high back pressure due to high continuous flow. This feature improves the ability of the respirator to reduce the work of exhalation and still provide an
0 elevated pressure in the patient's airway to allow the practitioner to manage the work of initiating a breath and supporting the early phases of the breath.

5 Another benefit of the present invention is its ability to more efficiently deal with leaks in the patient and ventilator system. Leaks are a problem often encountered in pressure triggered ventilation systems. Leaks in the patient and ventilator system are quite common, making it difficult to maintain pressure in the breathing-gas circuit. These leaks may be external to the
0 patient, such as those in the tubing connections from the ventilator to the patient, or internal, such as those leaks in the patient physiology. Leaks with pediatric patients are common due to the use of uncuffed endotracheal tubes, which do not form a tight seal with the patient's airway. Whatever the source, the leak can cause false pressure
5 triggering of breaths, as the drop in pressure is interpreted as a patient inspiratory effort. To prevent false pressure triggering, sensitivity may be reduced, unfortunately making pressure triggering even more
0 difficult for a patient once the leak has been eliminated (e.g., the closing of a physiologic leak). On the other hand, leaks encountered during flow triggering can be

corrected without impairment of sensitivity because precise control of flow is an inherent component of the flow-triggering strategy. In addition, changes in the flow-trigger level do not affect sensitivity to the same extent as do changes to the pressure-trigger level. In patients with physiologic leaks, the flow-triggering system may be used to assess the magnitude of these leaks. By titrating the flow-trigger level until the ventilator self cycles, one can measure the physiologic leaks as well as system leaks. This technique can be used to monitor the opening or closing of these physiologic leaks throughout the patient's ventilator care.

From the above, it will be evident to those skilled in the art that flow triggering of pressure supported patient breaths from a continuous flow system provides important advantages over previous patient ventilation systems. Other aspects and advantages of the invention will become apparent from the following detailed description and the accompanying drawings, which illustrate by way of example the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a schematic diagram of a flow-triggered, open circuit ventilation system;

FIGURE 2a shows a graph of pressure measurements over time for a typical pressure-triggered breath without pressure support;

FIGURE 2b shows a graph of flow measurements over time for a typical pressure-triggered breath without pressure support;

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FIGURE 3a shows a graph of pressure measurements over time for a typical pressure-triggered, pressure-supported breath;

5 FIGURE 3b shows a graph of flow measurements over time for a typical pressure-triggered, pressure-supported breath;

FIGURE 4a shows a graph of pressure measurements over time for a typical flow-triggered, pressure-supported breath.

10 FIGURE 4b shows as graph of flow measurements over time for a typical flow-triggered, pressure-supported breath.

FIGURE 5a is an illustration of the patient flow during a single patient breath in a conventional system.

15 FIGURE 5b is an illustration of the flow delivered by the ventilator using the exhalation-flow reduction scheme of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 As is shown in the drawings, which are included for purposes of illustration and not by way of limitation, the invention is embodied in a system for flow triggering a pressure-supported ventilation system which reduces the patient work of breathing, provides improved triggering of the pressure supported breath and allows improved
25 management of the pressure support during a breath. The

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flow-triggering system is used in patient ventilation systems having a source of breathing gas for a patient, a flow-path communicating with the patient, and flow-sensor means for measuring the gas flow to and from the patient.

5 The breathing-gas source provides a predetermined, preinspiratory, continuous rate of flow of breathing gas to the patient and the flow-sensors measure the rate of gas flow to and from the patient. The system determines the difference between the measured flow rate from the patient

10 and the predetermined rate of delivered gas flow to the patient. The system then generates pressure support in the delivered flow of gas when the difference between the flows to and from the patient equals a predetermined threshold or trigger value. The breathing gas may be enriched with a

15 higher concentration of oxygen than normal air. The source of breathing gas may include more than one individual gas source and may also include a device for mixing and controlling the proportions of the individual gases. The system also preferably includes means for determining when

20 exhalation occurs, so that pressure support may be discontinued until it is again triggered.

In accordance with the present invention, there is provided a method for flow triggering of pressure-supported ventilation in open ventilation system having

25 a source means of breathing gas, a flow-path means for the breathing gas in fluid communication with a patient, and flow-sensor means for measuring the rates of gas flow in the flow path. The method comprises delivering a predetermined, continuous rate of flow of the breathing gas from the breathing gas source to the patient prior to

30 breath initiation; measuring the rates of gas flow in the ventilation flow path due to inhalation; generating pressure support in the delivered flow of gas when the rate

of gas flow due to inhalation equals a predetermined threshold value; termination of the pressure-supported breath when the patient initiates an expiratory effort, or when flow in to his or her breathing attachment declines to a predetermined level; and means to reestablish the predetermined continuous rate of flow of the breathing gas from the source to the patient prior to initiation of the next breath.

The present invention also provides for a system for flow triggering of pressure-supported ventilation for use in a functionally open ventilation system having a source means of breathing gas, a flow path means for the breathing gas in fluid communication with a patient, and flow sensor means for measuring the rate of gas flow in the flow path. The system includes means for delivering a predetermined, preinspiratory, continuous rate of flow of the breathing gas from the source to the patient; means for measuring the gas flow in the flow path due to inhalation; means for generating pressure support in the delivered flow of gas when the gas flow due to inhalation equals a predetermined threshold value; means for terminating the pressure-supported breath when the patient initiates an expiratory effort or when flow into his or her breathing attachment declines to a predetermined level; and means to reestablish the predetermined, preinspiratory, continuous rate of flow of breathing gas during the exhalation interval.

Figure 1 is a schematic of a present system for flow triggering ventilation according to the present invention. In the currently preferred embodiment, the system 10 includes a source of oxygen gas (O_2) 12, which is typically a pressurized tank of oxygen, and a source of

air 14, which may also consist of a high-pressure tank of air. The sources of air 14 and oxygen 12 may also typically include pressure regulators. The air supply source may also comprise an air compressor which supplies air taken from the ambient atmosphere. Other conventional sources of pressurized oxygen and air in hospital or patient-care settings would also be appropriate.

The source of oxygen is connected to a flow meter 16 in the oxygen line 17, and a similar flow meter 18 for the air source 14 is provided in the air line 19. The oxygen line 17 delivers oxygen to its proportional solenoid valve 20, and the air line 19 similarly delivers air to its proportional solenoid valve 22, the two valves releasing oxygen and air for mixing in the mixing chamber 24. Valves other than proportional solenoid valves and mixing means other than mixing chamber 24 may also be appropriate. The mixed gas is delivered from mixing chamber 24 through the airway conduit 26 to the patient wye fitting 27, which is connected to the patient breathing attachment 30 by breathing tube 28. The breathing attachment 30 may be simplified or replaced by other breathing means in certain implementations. In these implementations the breathing-gas flow may be delivered to the patient by means of a breathing tube (artificial airway) or by a breathing mask or other means for delivering breathing gas to the patient's trachea. In either implementation and prior to and immediately after the inspiratory flow, flow meters 16 and 18 monitor the flow of gas to the patient during the continuous flow of gas from the oxygen and air sources (up to and including the time at which the patient's inspiratory flow equals the triggering threshold flow signal) and during exhalation. Exhalation gas from the patient area flows through the exhalation conduit 34 and

5 exhalation flow meter 43. The difference between the sum
of flow meters 16 and 18, and exhalation flow meter 43
provides a measurement of flow of breathing air inhaled by
the patient from the continuous flow of breathing gas
delivered to the patient from the oxygen and air source
means. To assist control of the delivery of breathing gas
to the patient, the flow-control algorithm may monitor flow
sensors 16, 18, and 43. During operation of the flow-
triggering phase and for the restoration of the
10 preinspiratory, continuous flow during exhalation and prior
to the patient's next inspiration, flow sensors 16, 18, and
43 become primary inputs to the flow-control algorithm
prior to the initiation of the inspiratory effort,
immediately after the inspiratory effort, and during
15 exhalation when the preinspiratory, continuous flow is
being reestablished.

Beginning with and immediately after the patient's
inspiratory effort, the flow of breathing gas to the
patient will exceed the flow of breathing gas from the
20 patient, and the difference between the flow to and from
the patient is compared with a predetermined, "flow-
trigger" threshold level. This measurement of flow inhaled
by the patient is used for triggering the initiation of
pressure-supported inspiration. In a preferred embodiment,
25 prior to return of the exiting or exhalation gases to the
ambient atmosphere, said gases are passed through a fluid
collector vial 36 and a heated bacteria filter 38 provided
in the exhalation conduit line. A pressure transducer 40
for measuring the pressure during both inspiration and
30 exhalation may also be provided in the exhalation conduit
34. The system may also include an exhalation valve 44 to
close the system to allow breaths and to open the system
for exhalation to the atmosphere, to thereby return the

filtered and cleaned exiting gas to the atmosphere from the open ventilator system.

5 The invention may use other methods for measuring the inhaled flow by the patient from the preinspiratory, continuous flow of breathing gas. A flow meter 32 may be placed between the patient wye 27 and the patient attachment 30 to measure patient inhalation flow directly. Alternatively, or in addition to flow meter 32, a delivery flow meter 41 may be provided in the airway conduit 26 for measuring the flow of mixed breathing gas delivered to the patient, and an exhalation flow meter 42 may be installed in the exiting airway conduit 34 for monitoring the flow of gas from the patient during inspiration effort and exhalation. The difference between flow meters 41 and 42 also provides a measurement of flow inhaled by the patient from the preinspiratory, continuous flow of breathing gas from the source means.

15 It will be understood by those skilled in the art that any combination of signals from flow meters 16, 18, 20 32, 41, 42, and 43 may be used for sensing and measuring the flow inhaled by the patient for use as a flow-trigger signal for inspiration.

25 An electronic control means 46, preferably including a microprocessor for controlling all of the functions of the ventilator control system, is connected to the oxygen-source flow meter 16, the air source flow meter 18, the oxygen proportional solenoid valve 20, the air proportional solenoid valve 22, the patient exhalation flow meter 43, and any additional flow meters (41) in the inspirational airway conduit 26, the patient wye flow meter 30 32, or flow meters (42) in the exiting or exhalation airway

5 conduit 34. Electronic control means 46 compares the rate
of flow to the patient through the patient wye 27 as derived
by any of the previously discussed means, with a
predetermined flow threshold level to detect whether the
10 patient's inspiratory effort has met the criterion for
triggering pressure support by operation of the
proportional solenoid valves 20, 22. The control means 46
also controls the proportional mixing through the
proportional solenoid valves 20, 22, and operates to open
15 the exhalation valve 44 and cause the proportional solenoid
valves 20, 22 to discontinue pressure support when the
exhalation effort of the patient is detected, returning the
flow of breathing gas to the patient to the preinspiratory
level of continuous flow in readiness for the patient's
next inspiratory effort.

20 The flow triggering of breaths involves monitoring
the flow of inhaled gas from the continuous flow of
breathing gas delivered to the patient, which reduces the
energy required from the patient to initiate a ventilator
breath, and turning on the inspiratory pressure support
when the patient's inspiratory flow meets the triggering
criterion. The continuous, minimal flow of breathing gas
delivered into the breathing circuit prior to the
initiation of the inspiratory effort serves two functions:
25 First, the continuous flow converts the normally closed
breathing-gas circuit into one that is functionally open.
Second, the continuous flow establishes a highly stable
flow of breathing gas which can be monitored by the flow
sensing means to determine when the patient begins his or
30 her inspiratory effort. This flow triggering approach
converts the initial work of inspiration from an
essentially isometric effort to a quasi-isotonic effort.
Both the level of continuous flow and the required change

in flow due to inhalation for inspiratory support triggering may be adjusted through the control means.

5 As previously discussed, the energy expended by a patient while breathing on a mechanical ventilator can be divided into two components. The first component is the energy required to trigger the ventilator to begin the inspiration. The second component is the energy required to maintain adequate gas flow once the ventilator has been triggered to deliver inspiratory support.

10 A primary purpose of the pressure support mode of ventilation is to reduce the second energy component. This is accomplished by providing a positive pressure level during the inspiratory phase of the breath. This positive pressure may be used to reduce or negate the imposed work
15 due to the resistance of the artificial airway, and/or the resistance and compliance intrinsic to the patient's respiratory system. In extremely weak patients, the application of pressure support can provide sufficient tidal volumes without using assist-control ventilation, and
20 can thereby increase patient comfort while returning to the patient some measure of control over his or her breathing pattern. Patients have been shown to expend less work or energy in breathing when pressure support is used. This can have important implications when weaning patients from
25 the ventilator, since the patient must then be progressively strengthened to breath without the pressure support to inspiration.

30 Figures 2a and 2b show traces of pressure over time and flow over time, respectively, as they vary from the patient pressure baseline 50 (Fig. 2a) and the patient flow baseline 52 (Fig. 2b) for a typical spontaneous, non-

pressure supported, ventilator-delivered breath. In Figure 2a, the area under pressure-time trace 53 which is below the pressure baseline 50 represents the work being done by the patient. The portion of the curve 53 in the pressure-time trace between point A and point B at the pressure trigger level 54 depicts the portion of this work required to trigger inspiratory support. The portion of the curve between points B and C represents the remaining work of inhalation 58 required to maintain an adequate gas flow to satisfy the inspiratory demands of the patient. In other terms, the area between B and C represents the work required of the patient to sustain the breath. Note (with respect to the pressure baseline 50) that, as shown in Figure 2a, the pressure is negative throughout inspiration, indicating that the patient is performing work during this entire period. It should also be noted that the peak negative pressure required of the patient is the level 55 noted on Figure 2a. The exhalation phase 60 begins at the end of the inhalation phase. Figure 2b shows the flow rates corresponding to the pressure-time curves of Figure 2a. It is evident that the flow prior to B, the point at which the pressure triggering is effecting is very low and that substantial work is still performed by the patient between B and C, even though the pneumatic system was cycled on at B.

Figures 3a and 3b show traces of pressure over time about a patient pressure baseline 62, and flow over time about a flow baseline 64, respectively, for a typical pressure-triggered, pressure-supported breath. Once the breath is triggered at B representing the pressure trigger level 66, the ventilator creates a positive pressure to reduce the patient's work of inspiration. Prior to the inspiration cycle 68, a negative pressure, and therefore an

expenditure of energy by the patient, is required to trigger the breath. Pressure support is discontinued when the patient exerts an expiratory effort or when flow into his/her lungs declines to a preselected value. At this point, the patient begins the exhalation phase 70. It may be seen that the flow level at the time of triggering 72 was relatively low, but rapidly increased in response to the pressure support supplied after pressure triggering. However, there remains a substantial amount of work which must be expended by the patient for this scheme as well.

As illustrated in Figures 4a and 4b, the present invention's combination of flow triggering with pressure support (with an appropriate selection of the support pressure) can reduce the energy expenditure by the patient to a virtually negligible level.

Figures 4a and 4b show traces of pressure over time about a patient pressure baseline 74, and flow over time about a flow baseline 78, respectively, for a typical, flow-triggered, pressure-supported breath according to one embodiment of the present invention. Comparison of Figures 3a and 4a shows that the pressure 66 required for pressure triggering is more negative compared with the pressure 76 resulting from flow triggering. The negative pressure component 66 (in the pressure-triggering example of Figure 3), representing the work done by the patient, is substantial, whereas the negative component 76 (with flow-triggering example, Figure 4) is minor. The flow 80 to the patient can be seen to be higher at the flow trigger level in the flow triggered system of Figure 4b than the flow level 72 in the pressure triggered system of Figure 3b. With respect to the flow-triggering traces in Figure 4, both the less negative triggering pressure and the higher

inspiratory flows early in the breath, compared to the pressure-triggered traces of Figure 3 result from the physical differences between the flow systems. In the flow-triggered case, the patient inhales from a functionally open system (i.e., the patient's earliest flow demands are met by the preinspiratory, continuous flow), whereas in the pressure-triggered case, the patient inhales from a closed system (i.e., the patient receives no flow until the pressure-trigger threshold is reached). Thus, it can be seen that the combination of flow triggering with pressure support of the present invention reduces the energy expended by the patient to trigger inspiratory support and also reduces the patient energy required to maintain the inspiratory phase. Thus, by combining flow triggering with pressure support according to the present invention, the work done by the patient to trigger pressure-supported breathing is minimized while the appropriate selection of the support pressure allows the patient's inspiratory work to be set at a desired level. From the above, it may be seen that the work associated with the interval A-B in Figures 2 and 3 may be substantially reduced with the present invention as illustrated by the interval A-B of Figure 4. Thus, while the patient work of Figure 3 is lower than that of Figure 2, representing the difference between pressure triggering of flow support and pressure triggering of pressure support, the latter representing a more aggressive technique for support to a pressure triggered system. The present invention further minimizes the patient work compared to these previous strategies.

While pressure support of ventilation has a number of advantages as discussed above, the attendant high pressures in the exhalation limb of the patient's

breathing-gas circuit during the exhalation phase of the flow triggered pressure supported breath can be a cause of concern for the patient unless they are carefully controlled. Pressures above the PEEP (baseline pressure value) generally indicate that the patient's lungs are hyper-inflated. These events can place the patient's diaphragm and accessory inspiratory muscles in a position of relative inefficiency and may impose a higher work of breathing on the patient. If the patient is alert, he/she may also attempt to forcefully exhale to PEEP (baseline pressure value), which also adds extra work to the breathing effort. Thus it would be desirable to maintain the lowest possible pressures in the patient breathing circuit during exhalation. A long-recognized disadvantage of the earlier developed, continuous flow concept was the presence, in the exhalation limb of the patient's breathing-gas circuit, of the practitioner-selected, continuous flow in addition to the patient's own exhalation flow. This constant extra flow elevated the pressure in the patient's breathing-gas circuit (during exhalation), which could also lead to problems similar to those discussed above.

The present invention of flow triggering can be configured to minimize this extra, non-patient generated exhalation flow in the patient's breathing-gas circuit. According to a preferred embodiment of the invention, when the ventilator declares exhalation and (opens the exhalation valve) the pre-inspiratory, continuous flow of breathing gas is set to a minimal value. This minimal value is maintained throughout the most active phase of the patient's exhalation, then it is reset by the ventilator to the specified value for the pre-inspiratory, continuous flow of breathing-gas, in anticipation of the

next inspiratory effort.

5 Figure 5 illustrates the function of this preferred embodiment. Figure 5a illustrates the patient flow above and below baseline in a system of pressure supported breathes as previously described. Figure 5b illustrates the flow support time history delivered by this preferred embodiment, in which the flow is reduced during the early exhalation period and then returned to the practitioner-selected continuous base flow. By using this
10 scheme, the over-pressurization of the patient's airway is avoided during the early period exhalation, thus reducing the work performed by the patient and limiting the undesirable effects described above.

15 It may be seen from the foregoing description that the system and method of the present invention allow for reduction of patient discomfort and work of ventilator supported breathing by maintenance of a preinspiratory, continuous flow of breathing gas to the patient and by flow triggering of inspiratory support. In combination with
20 pressure support to the patient during the inspiration effort, the flow triggering strategy of the invention offers significant improvements in providing breath support to patients having weakened respiratory capabilities.

25 Although a specific embodiment of the invention has been described and illustrated, it is clear that it is susceptible to numerous modifications and embodiments within the ability of those skilled in the art and without the exercise of the inventive faculty. Thus, it should be understood that various changes in form, detail and
30 application of the present invention may be made without departing from the spirit and scope of this invention.

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CLAIMS:

1. A method of controlling flow of ventilation to a patient supplied with a preinspiratory, continuous flow of breathing gas from a ventilation system having a source of breathing gas, a patient breathing attachment, an exhalation valve, and a functionally open breathing gas flow path in fluid communication with said source of breathing gas, said ventilation flow path including at least one flow sensor located between said patient breathing attachment and said exhalation valve for measuring a flow rate of said breathing gas from said patient breathing attachment through said exhalation valve, the steps of the method comprising:

delivering a predetermined rate of flow of said breathing gas from said source to said patient breathing attachment;

measuring said flow rate of breathing gas from said source of breathing gas to said patient breathing attachment to determine a gas supply flow rate;

measuring said flow rate of breathing gas from said patient breathing attachment through said exhalation valve at a location in said ventilation flow path between said breathing attachment and said exhalation valve to determine an exiting gas flow rate;

determining patient inspiratory effort in said flow path by comparing said gas supply flow rate with said exiting gas flow rate;

generating pressure support in said delivered flow of gas when said inspiratory effort exceeds a predetermined threshold value; and

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restoring delivery of said breathing gas from said source to said patient breathing attachment at a preinspiratory, continuous rate of flow before a patient's next inspiratory effort.

2. The method of Claim 1, wherein said source of breathing gas comprises a plurality of different gas sources, and further comprises the step of mixing said plurality of different gases.

3. The method of Claim 2, further comprising the step of controlling the mixing of said different gas sources according to a predetermined proportion of said different gases.

4. The method of Claim 1, wherein said ventilation flow path includes an inhalation flow path to the patient breathing attachment, and the step of measuring the rate of gas flow into said patient breathing attachment comprises performing measurements of flow from said source of breathing gas to said breathing attachment at at least one position in the inhalation flow path.

5. The method of Claim 1, wherein said ventilation flow path includes a plurality of flow sensors, and said step of determining patient inspiratory effort comprises measurement at at least one of the flow sensors.

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6. A system for controlling flow of ventilation to a patient supplied with a preinspiratory, continuous flow of breathing gas from a ventilation system having a source of breathing gas, a patient breathing attachment, an exhalation valve, and a functionally open breathing gas flow path in fluid communication with said source of breathing gas, said patient breathing attachment and said exhalation valve, the system comprising:

means for delivering said breathing gas from said source to said patient breathing attachment at said predetermined, continuous rate of flow;

at least one flow sensor in said flow path for measuring the flow rate of said breathing gas from said source of breathing gas to said patient breathing attachment to determine a gas supply flow rate, and for measuring flow rate of said breathing gas from said patient breathing attachment through said exhalation valve at a location between said patient breathing attachment and said exhalation valve to determine an exiting gas flow rate;

means responsive to said at least one flow sensor for determining patient breathing efforts by comparing said gas supply flow rate with said exiting gas flow rate to determine a flow rate change due to patient inhalation or exhalation;

means for generating pressure support in said delivered flow of gas when said flow rate change exceeds a predetermined threshold value; and

means for restoring delivery of said breathing gas from

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said source to said patient breathing attachment at said preinspiratory, continuous rate of flow before a next patient's inspiratory effort.

7. The system of Claim 6, wherein said source of breathing gas comprises a plurality of different gas sources, and means for mixing said gas from said different gas sources.

8. The system of Claim 6, further including means for controlling the proportions in said mixture of said gas from said different gas sources.

9. The system of Claim 6, wherein said ventilation flow path includes an exhalation flow path from said patient breathing attachment, an inhalation flow path to said patient breathing attachment, and said at least one flow sensor comprises at least one flow sensor located in at least one location in said exhalation flow path between said patient breathing attachment and said exhalation valve, and at least one other flow sensor in at least one other location in said inhalation flow path.

10. The method of Claim 1, further including the step of reducing the gas supply flow rate for a predetermined period of time during exhalation following the step of generating pressure support in the delivered flow of gas and prior to the step of restoring delivery of said breathing gas

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at a preinspiratory, continuous rate of flow.

11. The system of Claim 6, further including means for reducing the gas supply flow rate for a predetermined period of time during exhalation.

SMART & BIGGAR

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PATENT AGENTS

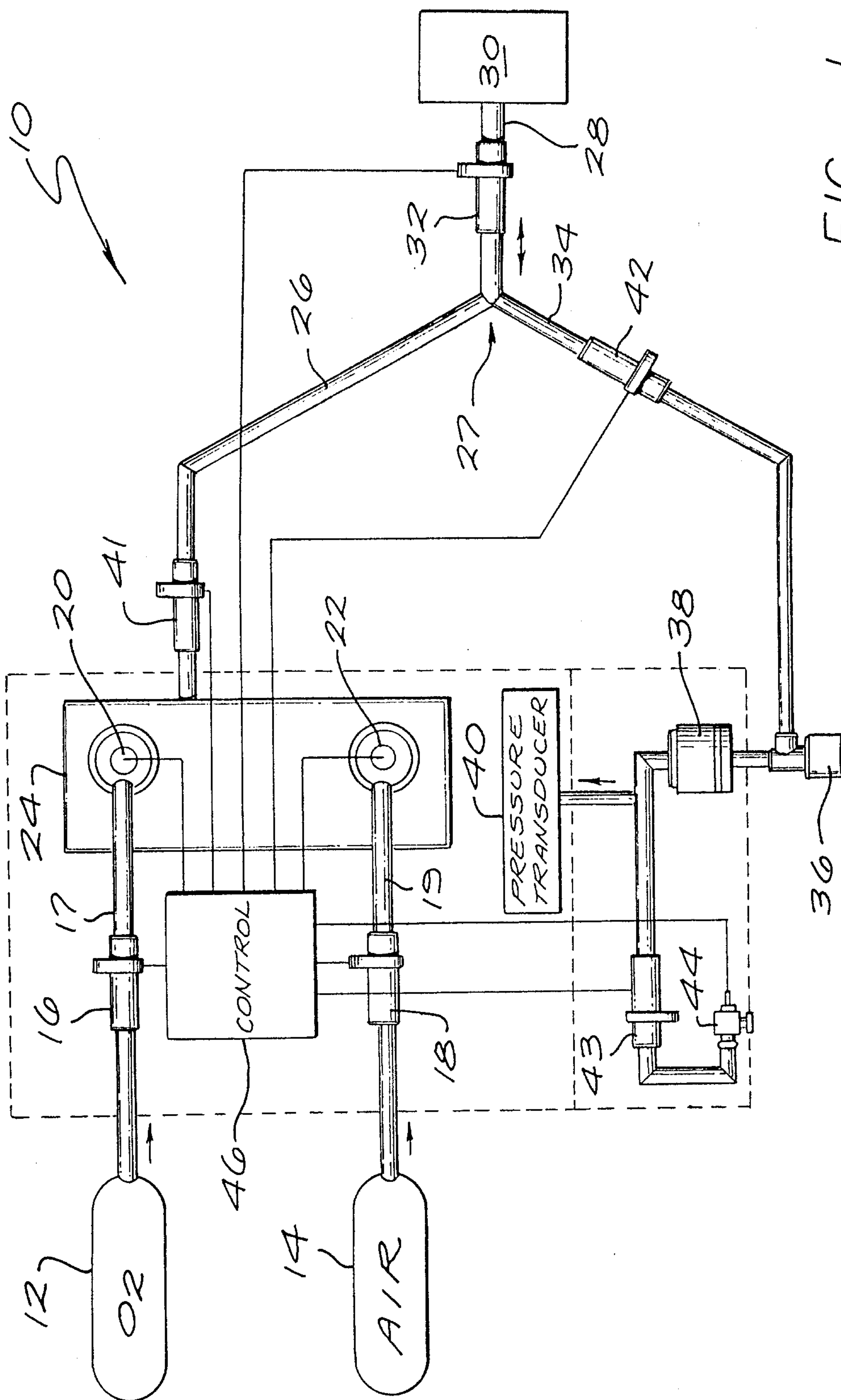
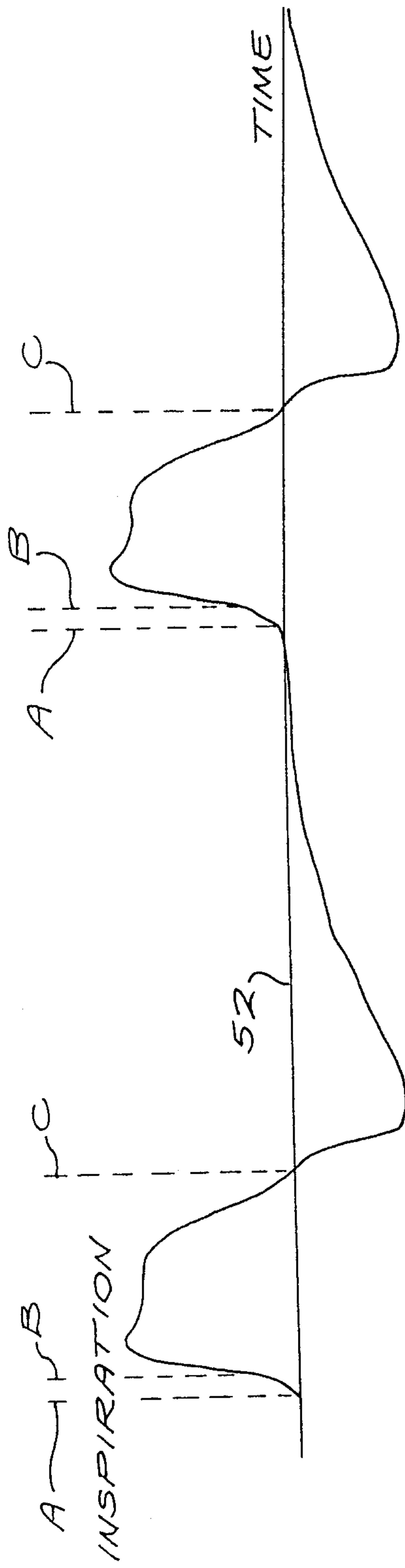
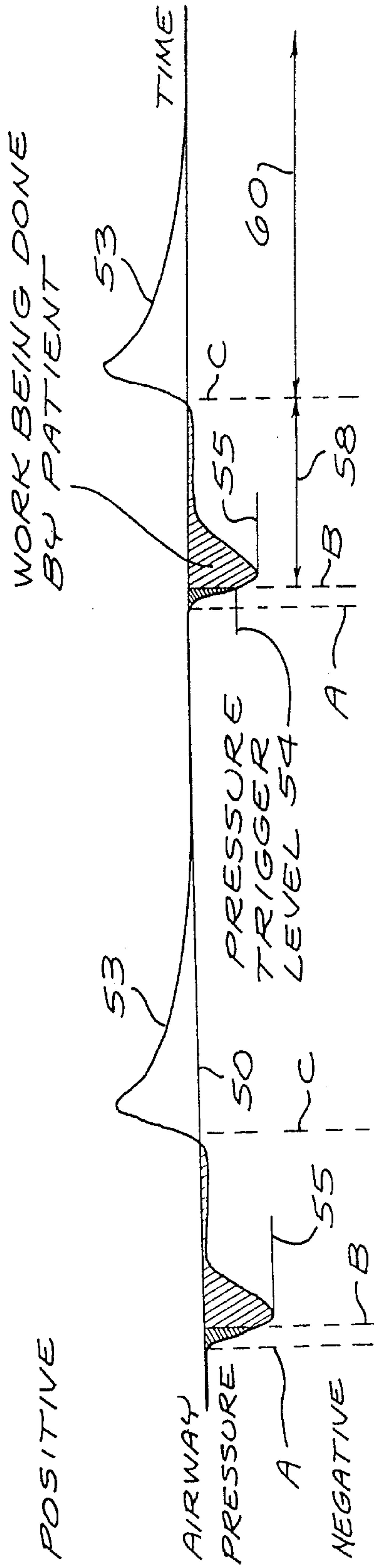


FIG. 2a



EXHALATION

FIG. 2b

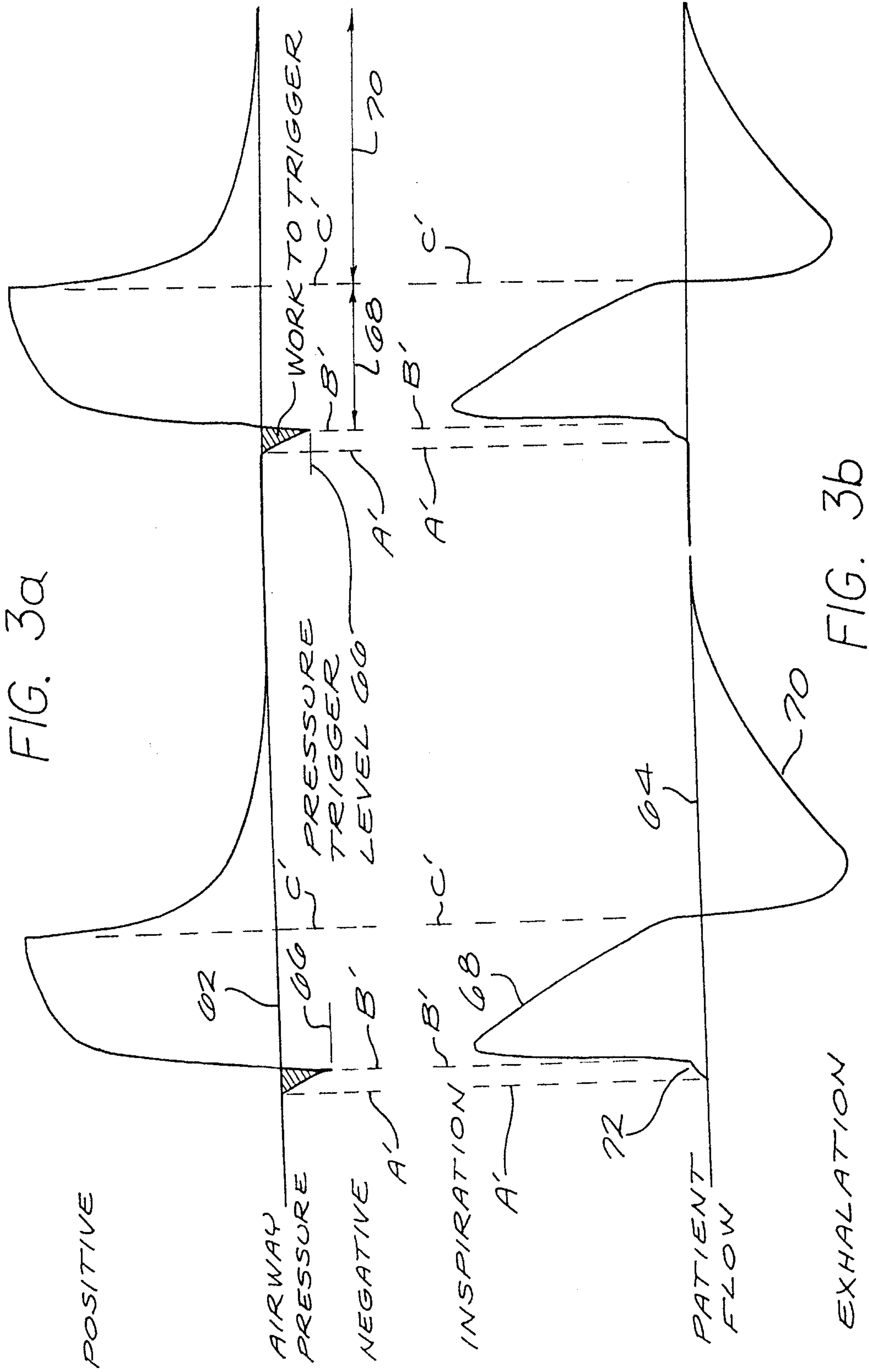


FIG. 4a

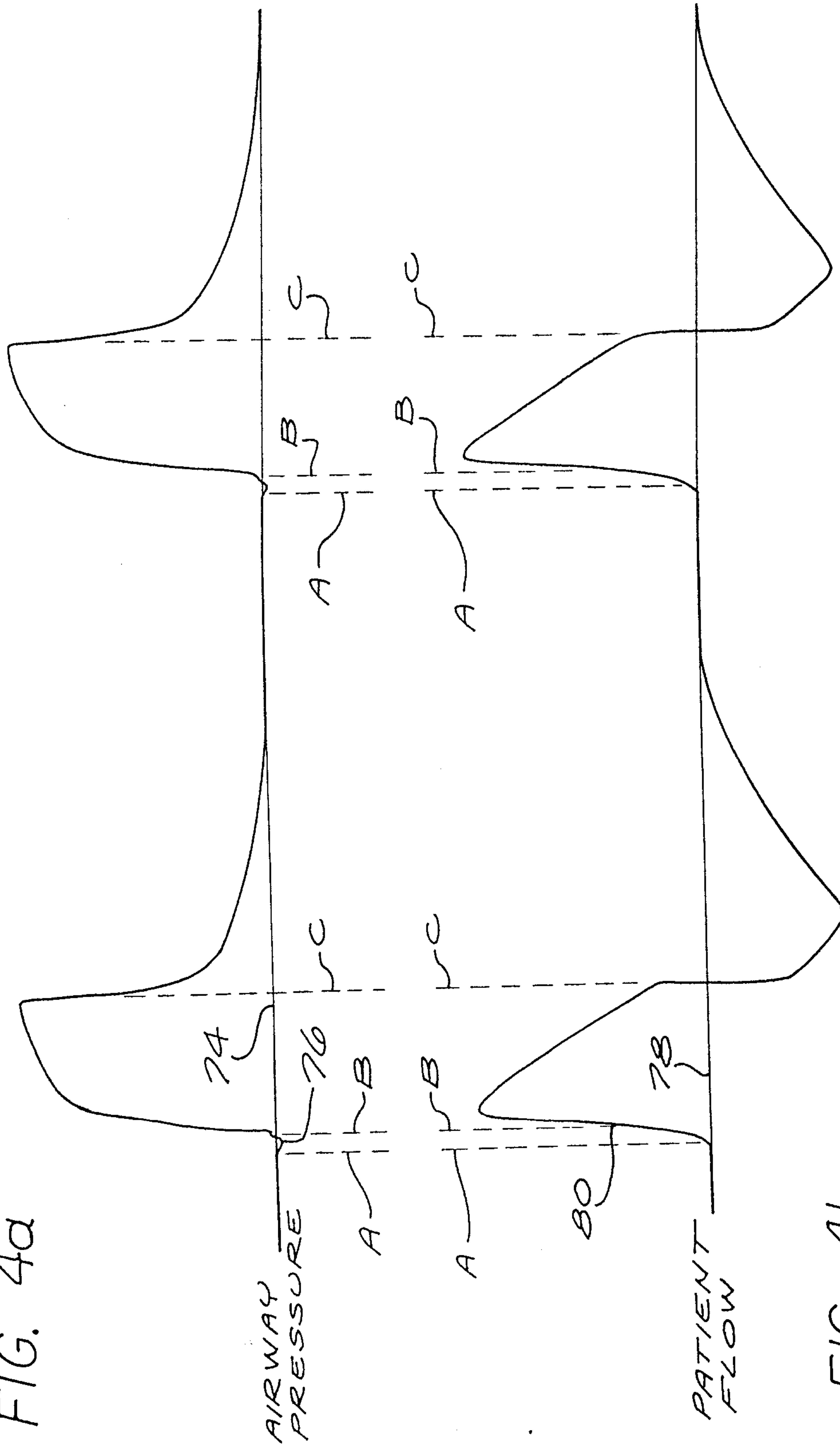
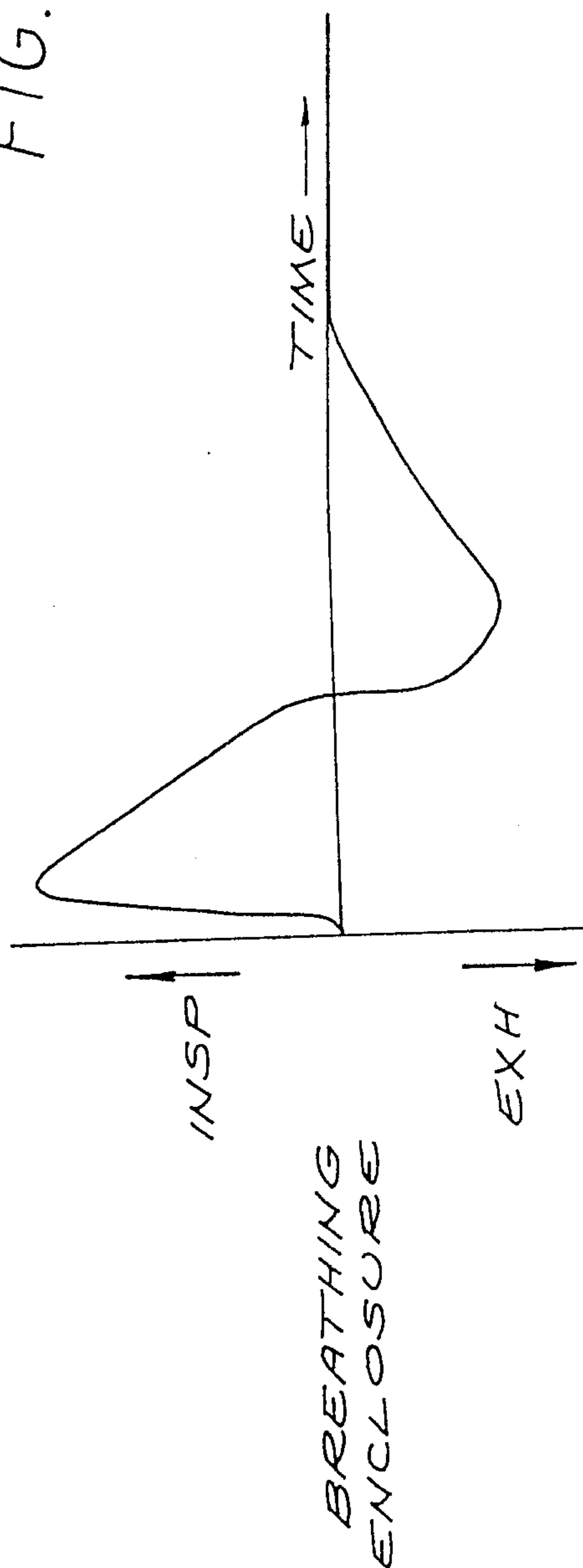


FIG. 4b

FIG. 5a



RESTORATION OF THE
PRACTITIONER SELECTED
CONTINUOUS BASE RATE FLOW

FIG. 5b

