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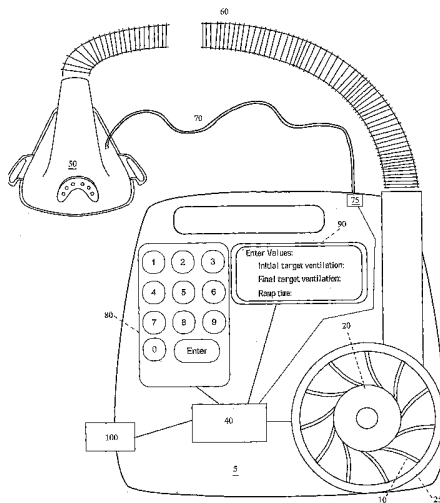
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(54) Title: ADJUSTMENT OF TARGET VENTILATION IN A SERVOVENTILATOR



(57) Abstract: A servoventilator control slowly changes the target ventilation over a period of time, according to a preprogrammed schedule adapted to be set by the physician. Preferably, the target ventilation stays constant at an initial target ventilation for an initial hold time, and then increases at a constant rate until it reaches a final target ventilation, whereupon it stays constant thereafter. If the pressure support level is too high, possibly indicating glottic or upper airway closure, the rate of increase of target ventilation may be lowered or the final target ventilation not reached.

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ADJUSTMENT OF TARGET VENTILATION IN A SERVOVENTILATOR

This application claims the benefit of the filing of Australian Provisional application AU 2004/905022 filed September 3, 2004.

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FIELD OF THE INVENTION

The present invention relates to the field of ventilatory assistance, and in particular, to methods and apparatus for determining suitable ventilator settings in patients with alveolar hypoventilation during sleep, and for delivery of those settings.

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BACKGROUND OF THE INVENTION

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In the field of noninvasive ventilation, for example as described in US Patent 6,532,957, a problem arises particularly in patients newly introduced to servoventilation. The patient's arterial CO₂ partial pressure (PCO₂) may be well above the value preferred by the clinician; for example, the PCO₂ may be 60 mm Hg, and the clinician would prefer to stabilize it at 45 mm Hg. This would require the patient's alveolar ventilation to be increased by a factor of approximately $60/45 = 4/3$. Yet if the clinician sets the target ventilation of the servoventilator to $4/3$ of the patient's current ventilation, such a large increase in ventilation, if it occurs immediately, is likely to abolish all respiratory drive and much of the upper airway drive (leading to problems with upper airway obstruction). It may cause glottic closure, preventing the ventilation from increasing to the target level, despite the ventilator delivering the maximum level of

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pressure support for which it is programmed, which may lead to arousal from sleep. If the arterial pH is relatively normal at the beginning of therapy, indicating a metabolic compensation for a relatively chronic respiratory acidosis, a sudden large increase in ventilation would result in a marked alkalosis, with undesirable electrolyte shifts, including hypokalaemia, with the potential for inducing cardiac arrhythmias.

For these reasons a progressive increase of target ventilation over a period of time, typically several days or weeks, is desirable. This might be achieved by frequent manual changes of the target ventilation, but this would be inconvenient, since the patient is likely to be at home at this stage.

BRIEF DESCRIPTION OF THE INVENTION

In accordance with my invention, a servoventilator incorporates a mechanism for slowly changing the target ventilation over a period of time, according to a preprogrammed schedule set by the physician. In most cases the intention will be that the target ventilation increases over a period of time, from a first level to a second level, then stay at the second level thereafter. This increase could occur according to any arbitrary increasing function of time.

In one form of my invention, the target ventilation stays constant at a first level, V_1 (the initial target ventilation) for a fixed period of time (the initial hold time) until time $t = t_1$, which might be zero, then increases at a constant rate until it reaches a second level, V_2 (the final

target ventilation), whereupon it stays constant thereafter.

The rate of increase, R may be calculated from the initial target ventilation V_1 , the final target ventilation V_2 , and a target ventilation ramp time t_r , all these settings being entered by the clinician using the following equations:

$$t_r = t_2 - t_1$$

$$R = \frac{V_2 - V_1}{t_r}$$

Various constraints may be added to modify the rate of increase of target ventilation. For example, if the pressure support level is too high, possibly indicating glottic or upper airway closure, the rate of increase of target ventilation may be lowered or even set to zero temporarily, so it takes longer to reach the final target ventilation, or in some cases the final target ventilation may never be achieved.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Fig. 1 illustrates an embodiment of my invention. The x-axis shows time, the y-axis shows ventilator target ventilation. Fig. 2 illustrates servo-ventilator apparatus 5 suitable to perform the invention. An electric motor 20 has an impeller 10 and is under the control of a controller circuit 40. In use the motor and impeller is housed in a volute 25, which in use allows a flow of pressurized air to pass along the air delivery conduit 60 to a suitable patient interface 50. The patient interface 50 may be a nasal mask, or nose and mouth mask, a full-face mask or

some other suitable device. A pressure sense tube 70 between the patient interface 50 and a pressure sensor 75 allows the controller 40 to sense pressure in the patient interface 50. The controller 40 can also determine the flow rate and of air along the air delivery conduit 60 via a flow sensor (not shown). The apparatus includes a display 90 and keyboard 80 which allow someone, for example a clinician, to set appropriate target ventilators and ramp times in accordance with an embodiment of the invention.

The determination of target ventilation settings may be accomplished as described in US patent 6,644,312, the disclosure of which is incorporated by reference. In particular, suitable initial target ventilator settings for use with a servoventilator may be determined by measurements and observations made on the subject patient while awake during a learning period. Or, the target ventilation may be a fixed percentage of an average ventilation taken over a portion of the learning period. During the learning period the servo-control of ventilation is disabled, and the device is set to deliver a fixed minimum degree of support, typically 6 cmH₂O chosen to make the patient feel comfortable. During this learning period, ventilation is measured and oxygen saturation levels may be measured by an oximeter. A target ventilation for use during sleep is selected or determined based on the ventilation measurements and optionally oxygen saturation measurements. Where the PCO₂ of the subject patient would be higher than desired by the

clinician, a final target ventilation can be determined by multiplying an initial target ventilation by the ratio of the PCO₂ value to a desired PCO₂ value.

A clinical algorithm embodying the invention is:

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(i) use a suitable ventilator to learn the patient's awake ventilation (for example according to US patent 6,644,312;

(ii) set the initial target ventilation to a proportion of this ventilation;

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(iii) set the final target ventilation to the initial target ventilation multiplied by the ratio of the desired PCO₂ to the current PCO₂

(iv) set the target ventilation ramp time to some suitable value, depending on the clinical urgency of lowering the PCO₂ and the amount by which it is desired to lower the PCO₂ (all else being equal, larger falls might be expected to take longer)

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A similar principle can be applied to conventional bilevel ventilation. The pressure support level can be programmed, after an initial hold time, to increase at a certain rate until it reaches a final pressure support level.

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Thus in accordance with my invention there is provided a method of non-invasive ventilation of a patient comprising the steps of:

(i) ventilating a patient at a first level of ventilation for a first duration; and

(ii) At the expiration of the first duration, changing the level of ventilation from the first level to a second level over a second duration.

In one form of the invention, the second duration may be several weeks. In a preferred form, the change in level of ventilation is an
5 increase. In one preferred form of the invention, the change in level of ventilation is automatically controlled.

Although my invention has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention.

10 Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

Claims:

1. A method for determining suitable ventilator settings in patients with alveolar hypoventilation during sleep, and for delivery of those settings comprising the steps of:

5 measuring the ventilation of a patient during at least a latter portion of a learning period while the patient is awake;

 determining a target ventilation from said measure of ventilation; and

 slowly changing the target ventilation over a period of time,
10 according to a programmed schedule implemented in a ventilator controller.

2. The method for determining suitable ventilator settings of claim 1, wherein the step of changing the target ventilation over a period
15 of time, increases the ventilation from a first level to a second level, then stays at the second level.

3. The method for determining suitable ventilator settings of claim 2, wherein the target ventilation stays constant at a first level, for a
20 predetermined initial hold time, and then increases at a constant rate until it reaches a second level, whereupon it stays constant thereafter.

4. The method for determining suitable ventilator settings of

claim 1, wherein a rate of increase of the initial target ventilation is lowered if the pressure support level is too high to extend the time to reach a final target ventilation.

5 5. A method of non-invasive ventilation of a patient comprising the steps of:

 (i) ventilating a patient at a first level of ventilation for a first duration exceeding several breathing cycles; and

 (ii) at the expiration of the first duration, changing the level of
10 ventilation from the first level to a second level over a second duration.

 6. The method of non-invasive ventilation of claim 5, wherein the second duration is several weeks.

15 7. The method of non-invasive ventilation of claim 5, wherein the change in level of ventilation is an increase.

 8. The method of non-invasive ventilation of claim 5, wherein the change in level of ventilation is automatically controlled.

20 9. A method for determining suitable ventilator settings in patients with alveolar hypoventilation during sleep, and for delivery of those settings comprising:

 (i) using a ventilator to learn the patient's awake

ventilation;

(ii) setting an initial target ventilation to a proportion of said awake ventilation;

(iii) setting a final target ventilation to the initial target ventilation multiplied by the ratio of a desired PCO_2 value to a current PCO_2 value;

(iv) setting a target ventilation ramp time to a value, depending on the clinical urgency of lowering the PCO_2 and the amount by which it is desired to lower the PCO_2 .

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10. A servoventilator apparatus comprising

an electric motor having an impeller under the control of a controller circuit, that allows a flow of pressurized air to pass along an air delivery conduit to a patient interface;

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a pressure sense tube between the patient interface and a pressure sensor that allows the controller to sense pressure in the patient interface;

a controller that determines the flow rate of air along the air delivery conduit via a flow sensor;

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means to allow setting appropriate target ventilations and ramp times,

wherein the controller provides ventilation of a patient at a first level of ventilation for a first duration exceeding several breathing

cycles; and

at the expiration of the first duration, changes the level of ventilation from the first level to a second level over a second duration.

- 5 11. A bilevel ventilation apparatus having a pressure support level and a controller programmed to increase the pressure support level at a selected rate after an initial hold time until it reaches a final pressure support level.

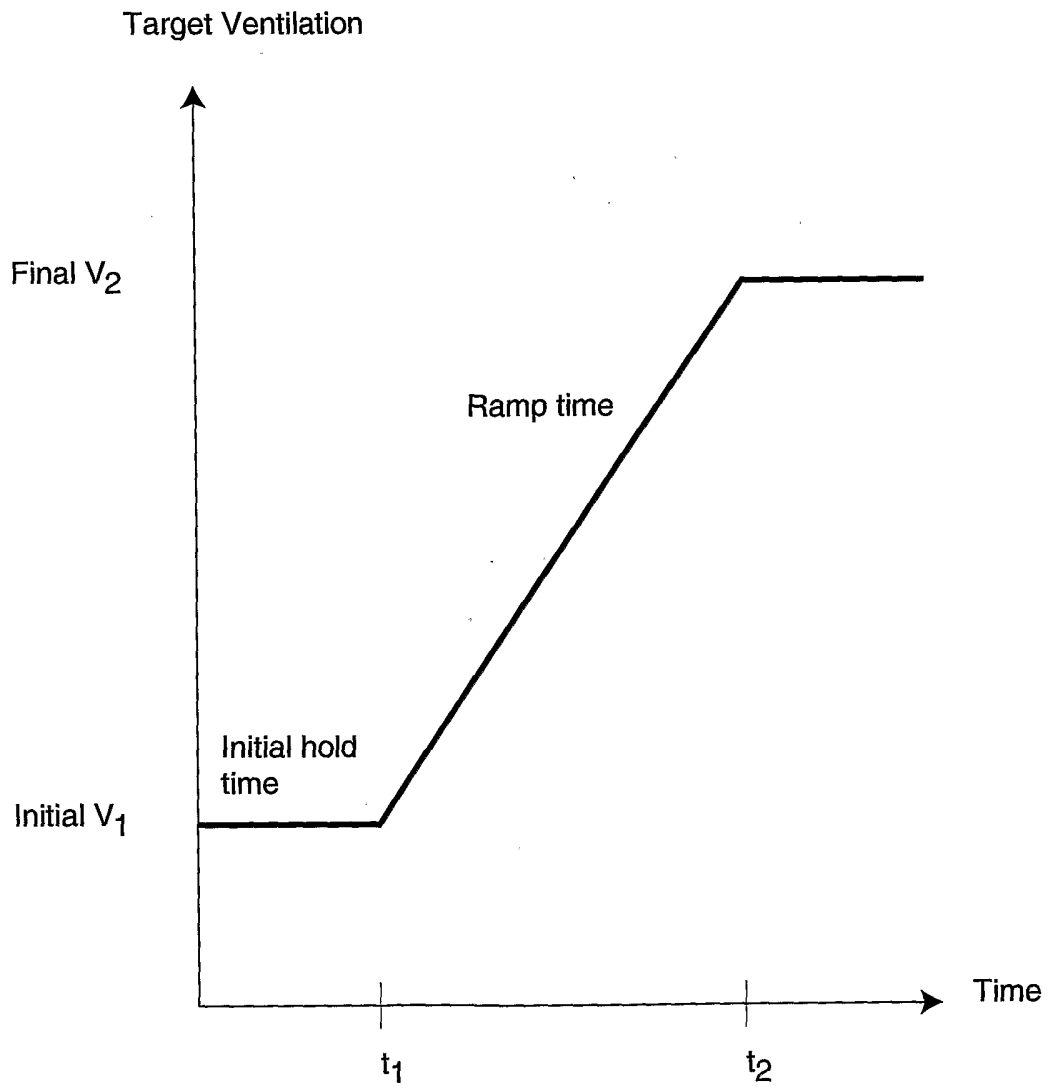


Fig. 1

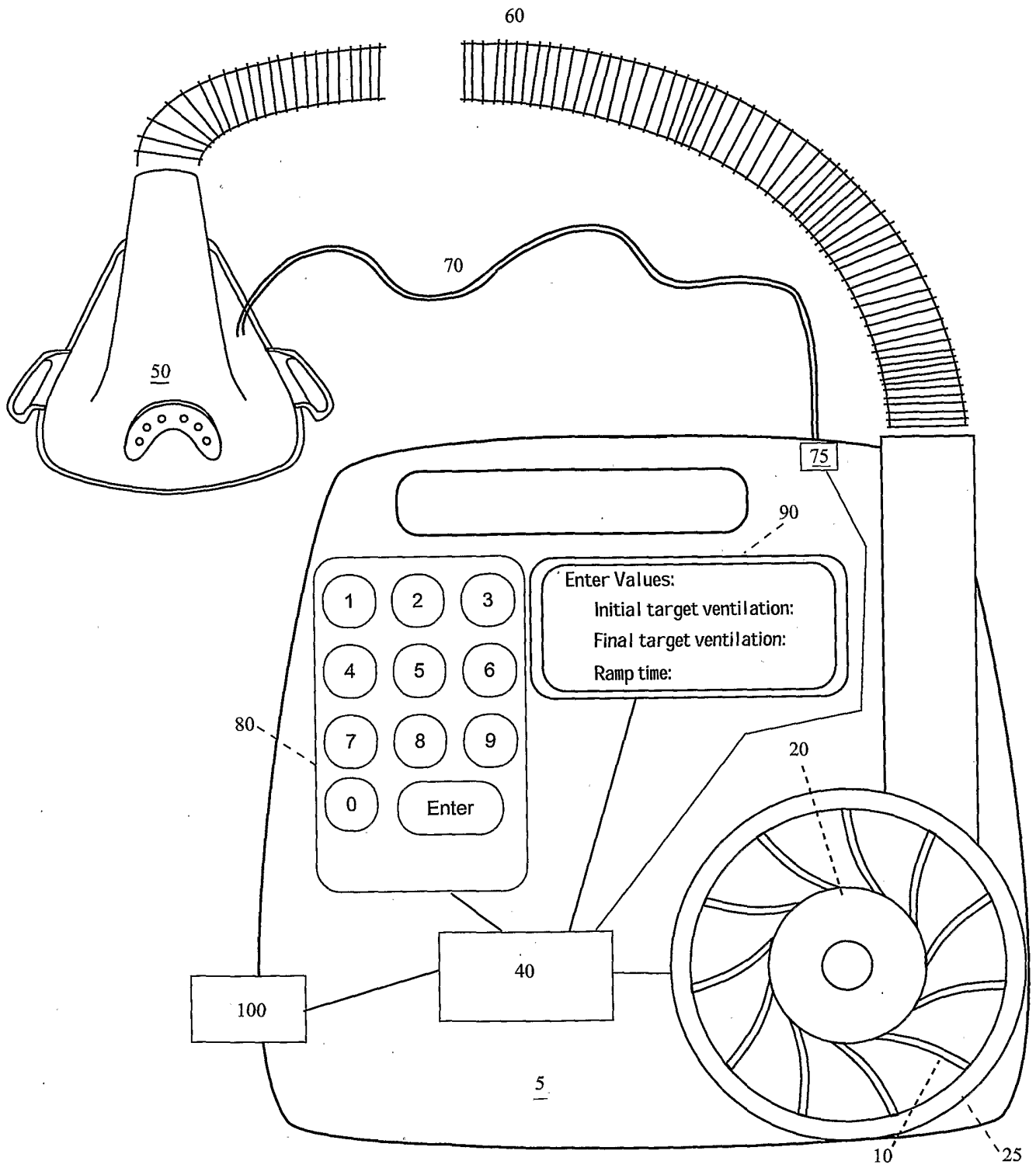


Figure 2

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2005/001336

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ⁷: A61M 16/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI - IPC A61M +keywords: respiration, initial, final, ramp, pressure and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,401,713 B1 (HILL et al) 11 June 2002 Abstract and figures 6A to 6C	5-8, 10, 11
X	WO 2003/075991 A1 (KAERYYS S.A.) 18 September 2003 Abstract	5, 7, 8, 10, 11
X	US 5,117,819 A (SERVIDIO et al) 2 June 1992 Abstract	5, 7, 8, 10, 11
A	US 5,682,878 A (OGDEN) 4 November 1997 Abstract	

Further documents are listed in the continuation of Box C See patent family annex

<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"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</p> <p>"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</p> <p>"&" document member of the same patent family</p>	
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Date of the actual completion of the international search 27 September 2005	Date of mailing of the international search report 30 SEP 2005
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2005/001336

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member			
US 6401713	AU 49772/00 WO 0067827	CA 2369305	EP 1177006	
WO 03075991	AU 2003214570 EP 1483007 US 2005166920 WO 03075990	AU 2003216622 EP 1485155 US 2005188989	AU 2003220760 EP 1485156 WO 03075989	
US 5117819				
US 5682878				
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.				
END OF ANNEX				