(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 July 2009 (02.07.2009)

PCT

(10) International Publication Number
WO 2009/082295 A1

(51) International Patent Classification:
A61M 16/00 (2006.01)

(21) International Application Number:
PCT/SE2007/051048

(22) International Filing Date:
20 December 2007 (20.12.2007)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant *(for all designated States except US)*: **MAQUET CRITICAL CARE AB** [SE/SE]; Röntgenvägen 2, S-171 95 Solna (SE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **LAKSOV, Joakim** [NO/SE]; Örtvägen 3, S-182 56 Danderyd (SE). **LAGERBORG, Johan** [SE/SE]; Sommarstigen 21, S-144 42 Rönninge (SE).

(74) Agent: **ALBIHNS AB**; P.O Box 5581, Linnégatan 2, S-114 85 Stockholm (SE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(54) **Title:** A COMPUTER PROGRAM PRODUCT, A CONTROL UNIT FOR A VENTILATOR, A VENTILATOR AND A METHOD FOR USE WITH A VENTILATOR

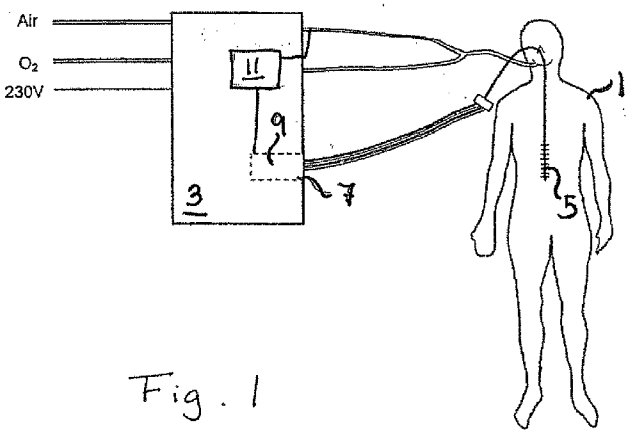

Fig. 1

(57) **Abstract:** To set trigger conditions correctly in pneumatic mode, a ventilator is controlled according to the following: - obtaining a measurement value of a bioelectric signal representative of the patient's own breathing function; - determining, based on the bioelectric signal, at least one point in time in which the patient starts inhalation, - obtaining a measurement value to be used for triggering an inspiration phase in the ventilator during said at least one point in time, - determining a trigger condition for the inspiration phase on the basis of the measurement value, - using the trigger condition to for initiating inspiration when ventilating the patient in support mode.

WO 2009/082295 A1

A COMPUTER PROGRAM PRODUCT, A CONTROL UNIT FOR A VENTILATOR, A VENTILATOR AND A METHOD FOR USE WITH A VENTILATOR

Technical Field

The present invention relates to a ventilator for use in support mode and a method for ventilating a patient in support mode.

Background and Related Art

A ventilator for providing breathing support to a patient can work in different modes, depending, i.a. on the patient's condition. If the patient is showing some breathing activity a support mode is often suitable, in which the ventilator provides extra breathing support in phase with the patient's own breathing activity. In this case the patient's own breathing activity must be monitored in an appropriate way in order to synchronize the breathing support provided by the ventilator with the patient's own breathing so that an inspiration phase is started by the ventilator when the patient starts inhaling. Typically a pneumatic trigger condition based on pressure and/or flow in the ventilator is set.

In some cases it is difficult to synchronize the ventilation correctly with the patient's breathing efforts. For example, if there is a leakage, it will be difficult to set a suitable pneumatic trigger level. Finding a suitable level may require a lot of trial and error. In particular, when ventilating children leakages generally occur, since in that case a cuff is typically not used around the tube.

Imperfect synchronization between the ventilator's and the patient's breathing cycles can lead to increased work for the patient. If the trigger is too insensitive an entire breath may be skipped. If the trigger is too sensitive an inspiration may be triggered in the ventilator when the patient is not ready to inhale.

Object of the Invention

It is an object of the invention to improve the trigger conditions when ventilating a patient in support mode

Summary of the Invention

This object is achieved according to the present invention by a computer program product comprising a computer readable medium having stored thereon computer readable code means for controlling a ventilator providing breathing support in a support mode to a patient, said computer program product comprising computer readable instructions which, when run in a control unit controlling a ventilator will cause the control unit to perform the following steps:

- obtaining a measurement value of a bioelectric signal representative of the patient's own breathing function;
- determining, based on the bioelectric signal, at least one point in time in which the patient starts inhalation,
- obtaining a measurement value to be used for triggering an inspiration phase in the ventilator during said at least one point in time,
- determining a trigger condition for the inspiration phase on the basis of the measurement value,
- using the trigger condition to for initiating inspiration when ventilating the patient in support mode.

The object is also achieved by a method of controlling a ventilator providing breathing support in a support mode to a patient, characterized by the steps of

- measuring a bioelectric signal representative of the patient's own breathing function;
- determining, based on the bioelectric signal, at least one point in time in which the patient starts inhalation,
- measuring the pressure in the ventilator during said at least one point in time,
- determining a trigger condition for the inspiration phase on the basis of the measured pressure.

According to the invention, therefore, Edi signal is used to determine the point in time when the patient starts inhaling, and the triggering conditions for an inspiration phase in the ventilator may be adjusted based on measurements of pressure and/or flow performed in the ventilator at this point in time. The invention therefore facilitates ventilation in pneumatic mode that is adapted to the patient's own breathing cycle.

As will be understood by the skilled person, the method is performed by a computer program, preferably located in the control unit of the ventilator for controlling the ventilator. Hence, the invention also relates to a control unit for a ventilator comprising a computer program product as defined above and a ventilator comprising such a control unit.

Preferably, the control unit will be caused to adjust the trigger condition by an amount determined on the basis of the measurement value.

In one embodiment the code means is arranged to cause the control unit to determine the trigger condition on the basis of several measurement values, each obtained at a point in time when the patient starts inhalation, in different breaths. This will provide a more accurate value for the trigger condition.

In a preferred embodiment, the code means comprises computer readable instructions which, when run in a control unit controlling a ventilator will cause the control unit, after determining the start of inhalation and before measuring the pressure, to determine whether an inspiration phase in the ventilator was triggered before the start of inhalation and, if so, slightly delaying the ventilator's inspiration phase until the patient's own breathing attempt can be detected.

In one embodiment the code means is arranged to cause the control unit to adjust the trigger condition incrementally in such a way as to reduce the time difference be-

tween start of the ventilator's inspiration phase and the start of the patient's inspiration. The trigger condition may be adjusted, for example, in fixed increments or in increments determined on the basis of the difference between the measurement value and the trigger condition.

Brief Description of the Drawings

The invention will be described in more detail in the following, by way of example and with reference to the appended drawings in which:

Figure 1 illustrates a ventilator providing breathing support to a patient.

Figure 2 illustrates a situation where the trigger condition is too sensitive.

Figure 3 illustrates a situation where the trigger condition is too insensitive.

Figure 4 is a flow chart of an embodiment of the inventive method.

Figure 5 is a more detailed flow chart of one of the steps of Figure 4.

Detailed Description of Embodiments

Figure 1 is a schematic overview of a patient 1 connected to a ventilator 3. The ventilator is arranged to work in support mode but can also be arranged to work in a controlled mode. To capture the Edi signal, the patient 1 has an oesophageal catheter 5 inserted in order to record a myoelectric signal from the diaphragm. This myoelectric signal (EMG signal) is fed to a control input 7 of the ventilator 3 and processed in a control unit 9 in the ventilator to produce the overall signal, called an Edi signal. According to the invention, a bioelectric signal related to breathing, such as the Edi signal is used to adjust the pneumatic triggering criteria of the ventilator.

Typically the ventilator comprises registration means 11 for monitoring the pressure and/or flow of breathing gas in the breathing circuit 1. The control unit 9 comprises processor means and at least one computer program arranged to compare the patient's own breathing activity to the breathing support provided by the ventilator and to adjust, if necessary, the triggering of the inspiration to synchronize it better with the patient's own breathing. This will be discussed in more detail below.

In order to assist the patient's breathing in such a way that the patient's own attempts to inhale air are supported by an additional flow of breathing gas from the ventilator, the flow and/or pressure in the ventilator is measured. The pressure and/or flow sensors in the ventilator are used together with the trigger settings in order to detect the patient's attempt to inhale and initiate the inspiration phase. This is referred to as pneumatic triggering. Alternatively, an increased flow in the direction towards the patient is measured. Ideally the start of this inspiration phase should be perfectly synchronized with the start of the patient's own inhalation. To achieve this, the threshold value for the flow and/or pressure must be set correctly so that the flow and/or pressure measured in the ventilator will pass the threshold at exactly the same time as the patient starts inhaling. This is not always the case, as will be discussed in the following.

Figure 2 illustrates a situation in which the pneumatic trigger function is based on pressure measurements and is too sensitive, causing the inspiration to be triggered too early in the breathing cycle compared to the patient's own breathing. Three curves are shown varying along a time axis denoted t. The solid curve represents the Edi signal recorded in the patient, that is, it reflects the patient's own breathing activity. The positive flank represents an inhalation by the patient. The dashed curve is an ideal ventilator cycle, starting inspiration (positive flank) when the patient starts inhaling. The dotted curve is an example of the breathing support that will result if the trigger condition is too sensitive. In this case, the triggering should be made to start later to be in phase with the patient's own breathing.

Too early triggering, as illustrated in Figure 2, may be caused, for example, by a leakage in the breathing circuit or if there is water in the tubes. It may also be due to oscillations caused by variations in the patient's thorax, caused by heart activity. In the case shown in Figure 2, the pressure will drop below the trigger condition at a first point in time t1, which occurs before the patient actually starts inhaling, at a second point in time t2. Hence, the ventilator will start inspiration support before

the patient is ready to inhale. In this case, therefore, the pneumatic triggering should be delayed to be in phase with the patient's own breathing.

Figure 3, like Figure 2, illustrates a situation in which the pneumatic trigger function is based on pressure measurements. In Figure 3, the trigger function is not sensitive enough, causing the inspiration to be triggered too late in the breathing cycle compared to the patient's own breathing. Three curves are shown varying along a time axis denoted t. As in Figure 2, the solid curve represents the Edi signal recorded in the patient, that is, it reflects the patient's own breathing activity. The positive flank represents an inhalation by the patient. The dashed curve is an ideal ventilator cycle, starting inspiration (positive flank) when the patient starts inhaling. In Figure 3, the dotted curve is an example of a delayed triggering that will result if the trigger condition is too insensitive. In this case, when the patient starts inhaling, at a point in time t3, the pressure will drop but not enough to trigger an inspiration phase in the ventilator at once. Only at a second point in time t4 will the ventilator start its inspiration phase. Hence, there will be a time delay td between the point in time t3 when the patient starts to inhale and the point in time t4 when the ventilator starts an inspiration.

In both the cases illustrated in Figures 2 and 3, the correct triggering point in time, that is the point in time when the patient starts to inhale, can be determined by means of an Edi signal recorded on the patient. By monitoring the Edi signal, the point in time when the patient starts to inhale can be determined, as the start of the positive flank of the Edi signal shown in Figures 2 and 3.

A first preferred embodiment of the inventive method is shown in figure 4. In this embodiment, as well as Figures 2 and 3 above, the triggering is based on pressure measurements. The skilled person can easily modify this to triggering on flow criteria instead, or on a combination of flow and pressure criteria, if the ventilator supports this.

To initiate the method, in step S41, the Edi signal is monitored during at least one breath in the patient. In step S42, either the point in time when the Edi signal indicates patient inhalation during this breath, is determined, that is, the point in time in which the Edi signal raised above a certain predetermined value, or the point in time when the pneumatic trigger condition is reached, whichever occurs first. In step S43, preferably, it is determined if the ventilator is triggered before the start of inhalation. If yes, the triggering has to be delayed, in step S44. The point in time when the Edi signal indicates patient inhalation is then determined in step S45. After step S45, or after step S43 if the triggering was not too early, the pressure in the ventilator at the starting time of inhalation is measured in step S46. This pressure, that is, the pressure at the actual start of inspiration by the patient, is used in step S46 as an indicator of what the pneumatic trigger condition should be. Finally, in step S47 the new trigger condition is set to be used in the following breaths, or presented to the operator as a proposed new setting.

The method may be performed during one breath only, or may be performed during several breaths to obtain an average measured value. Such an average value will probably provide a more correct value of the pressure in the ventilator at the onset of the patient's own inspiration than a measured value obtained during only one breath. In both cases, the method may be performed again at certain time intervals to ensure correct timing of the breathing support. Alternatively, the procedure may be performed again if the difference between the start of the breathing cycle of the ventilator and that of the patient becomes too big.

The adjustment procedure may be initiated by an operator. Instead of automatic adjustment, the operator can also use the result to adjust the trigger condition manually, thereby adjusting the timing of the breathing support cycle.

In step S44 the triggering of the ventilator should be delayed so as to enable correct measurement of the pressure and/or flow at the point in time when the patient starts to inhale. Therefore, the triggering should not be performed until after the patient's

inhalation has started. However, a maximum delay should be set, to ensure that the breathing support delay will not be harmful to the patient.

The correction of the trigger condition, based on the value determined in step S47, may be carried out in different ways. The trigger condition, which, in the case of pressure triggering, will be a pressure value, which may be set as a function of the pressure measured in step S46.

It may be favourable to adjust the trigger condition in several steps. In this case, step S47 will comprise the following substeps, illustrated in Figure 5:
In step S51 comparing the pressure measured in step S43 to the actual trigger condition currently applied in the ventilator .
In step S52 adjusting the trigger condition in the direction of the measured pressure value. If the measured pressure value is lower than the pressure value that will trigger the inspiration phase, the threshold value should be lowered. If the measured pressure value is higher than the threshold pressure that will trigger the inspiration phase, the threshold value should be raised. The change in the threshold value may, however, be carried out stepwise, so that the trigger conditions will be refined gradually. The steps could be carried out, for example, in fixed increments, for example, 0.1 cmH2O at a time, or as a fraction of the difference, for example 10% of the determined difference each time. The procedure may be iterated a predetermined number of times, or until the difference between the trigger conditions and the measured pressure is within an acceptable interval. This is indicated by decision step S53 in Figure 5, which terminates the procedure if the difference is below a set limit and returns to step S51 if the difference is still too large. Instead of determining the difference between actual pressure and threshold value, in the decision step S53 the difference in time between the start of the patient's own inhalation and the start of the inspiration phase of the ventilator could be evaluated, that is, the difference between the first and second points in time t1 and t2, or the difference between the third and fourth points in time t3 and t4, as the case may be. In this case, if the time difference is longer than a predetermined time, for example 100 ms, the proce-

dure of Figure 5 should be reiterated. The predetermined time could be of the order of magnitude of 100 ms. It may be determined as a fix value, or based on duration of the patient's own breathing cycle, or inspiration phase.

Preferably, a pressure and/or flow interval is defined in which the trigger condition can be set, to avoid setting the trigger condition to a value that may be harmful to the patient.

Also, in step S44 a maximum delay should be set for the pneumatic triggering to avoid losing an entire breath. This maximum delay could be, for example 300 ms. It could also be based on a measured duration of the patient's breathing cycle or inspiration phase. If no Edi triggering has occurred after the maximum delay, then the triggering value could be set to the value measured in the ventilator at the maximum delay and this could be used as an initial value. If no breathing activity can be detected from the Edi signal, a breath should still be delivered to the patient within a suitable time.

A minimum pressure should be set, which will always trigger the ventilator, even when the maximum delay has not been exceeded. This should correspond to the least sensitive pressure that is allowed.
In order to evaluate the result of the adjustment, the time difference between the pneumatic control of the ventilator and the Edi signal may be determined continuously or at certain time intervals. In this way the changes in the time difference over time can be monitored and appropriate action can be taken when needed.

The Edi signal is prone to disturbances, for example, from stronger bioelectric signals in the patient's body. To avoid using an erroneous Edi signal as a basis for the trigger conditions, an automatic adjustment should not be allowed if the time difference between inspiration phase triggered by the ventilator and the patient's own inhalation is too great. Alternatively a quality indicator for the Edi signal could be

used, to ensure that the Edi signal actually reflects the patient's breathing activity, and not an artefact.

Before starting the actual adjustment of the trigger conditions, by performing the steps of Figure 4, it may be useful to measure the Edi signal and the ventilator's breathing cycle for some breaths to compare the timing of the two. This comparison will indicate if the inspiration support is triggered too early or too late compared to the patient's own breathing activity, thereby indicating in which direction the trigger condition should be adjusted. Such a comparison can also be performed continuously, or at certain time intervals, to evaluate the need for adjusting the trigger conditions. If the timing of the Edi signal and the breathing support cycle differs less than a certain limit no adjustment is needed. If the difference in timing exceeds this limit an adjustment procedure as the one shown in Figure 4 should be performed.

The difference between the inspired and expired volumes may be used to evaluate whether there is any leakage before the trigger condition is adjusted. If a considerable leak is present the sensitivity of the adjusted trigger should preferably be limited.

As mentioned above, the triggering may be based on pressure or flow of gas in the ventilator. In the case of a leakage, pressure triggering will be more suitable than flow triggering, since a leakage will cause a flow, even if there is no patient activity.

Claims

1. A computer program product comprising a computer readable medium having stored thereon computer readable code means for controlling a ventilator providing breathing support in a support mode to a patient, said computer program product comprising computer readable instructions which, when run in a control unit controlling a ventilator will cause the control unit to perform the following steps:
   - obtaining a measurement value of a bioelectric signal representative of the patient's own breathing function;
   - determining, based on the bioelectric signal, at least one point in time in which the patient starts inhalation,
   - obtaining a measurement value to be used for triggering an inspiration phase in the ventilator during said at least one point in time,
   - determining a trigger condition for the inspiration phase on the basis of the measurement value,
   - using the trigger condition to for initiating inspiration when ventilating the patient in support mode.

2. A computer program product according to claim 1, wherein the code means comprises computer readable instructions which, when run in a control unit controlling a ventilator will cause the control unit to determine the trigger condition on the basis of several measurement values, each obtained at a point in time when the patient starts inhalation, in different breaths.

3. A computer program product according to claim 1 or 2, wherein the code means comprises computer readable instructions which, when run in a control unit controlling a ventilator will cause the control unit to adjust the trigger condition by an amount determined on the basis of the measurement value.

4. A computer program product according to any one of the preceding claims, wherein the code means comprises computer readable instructions which, when run in a control unit controlling a ventilator will cause the control unit, after determining the start of inhalation and before measuring the pressure, to determine whether an inspiration phase in the ventilator was triggered before the start of inhalation and, if so, slightly delaying the ventilator's inspiration phase until the patient's own breathing attempt can be detected.

5. A computer program product according to any one of the preceding claims, wherein the code means comprises computer readable instructions which, when run in a control unit controlling a ventilator will cause the control unit to adjust the trigger condition incrementally in such a way as to reduce the time difference between start of the ventilator's inspiration phase and the start of the patient's inspiration.

6. A computer program product according to claim 5, arranged to adjust the trigger condition in fixed increments.

7. A computer program product according to claim 5, arranged to adjust the trigger condition in increments determined on the basis of the difference between the measurement value and the trigger condition.

8. A control unit for a ventilator for use in support mode, said control unit comprising a computer program product according to any one of the claims 1-7, and processing means for controlling the ventilator in accordance with the instructions of the computer program product.

9. A ventilator for providing breathing assistance in support mode to a patient, said ventilator comprising a control unit according to claim 8 for controlling the ventilator.

10. A method of controlling a ventilator providing breathing support in a support mode to a patient, characterized by the steps of
    - measuring a bioelectric signal representative of the patient's own breathing function;
    - determining, based on the bioelectric signal, at least one point in time in which the patient starts inhalation,
    - measuring the pressure in the ventilator during said at least one point in time,
    - determining a trigger condition for the inspiration phase on the basis of the measured pressure.

11. A method according to claim 10, wherein the trigger condition is determined on the basis of several measurement values, each obtained at a point in time when the patient starts inhalation, in different breaths.

12. A method according to claim 10 or 11, comprising the step of adjusting the trigger condition by an amount determined on the basis of the measurement value.

13. A method according to any one of the claims 10-12, comprising the steps, performed after determining the start of inhalation, of determining whether an inspiration phase in the ventilator was triggered before the start of inhalation and, if so, slightly delaying the ventilator's inspiration phase until the patient's own breathing attempt can be detected.

14. A method according to any one of the claims 10-13, comprising the step of adjusting the trigger condition incrementally in such a way as to reduce the time difference between start of the ventilator's inspiration phase and the start of the patient's inhalation.

15. A method according to claim 14, wherein the trigger condition is adjusted in fixed increments.

16. A method according to claim 14, wherein the trigger condition is adjusted in increments determined on the basis of the difference between the measurement value and the trigger condition.

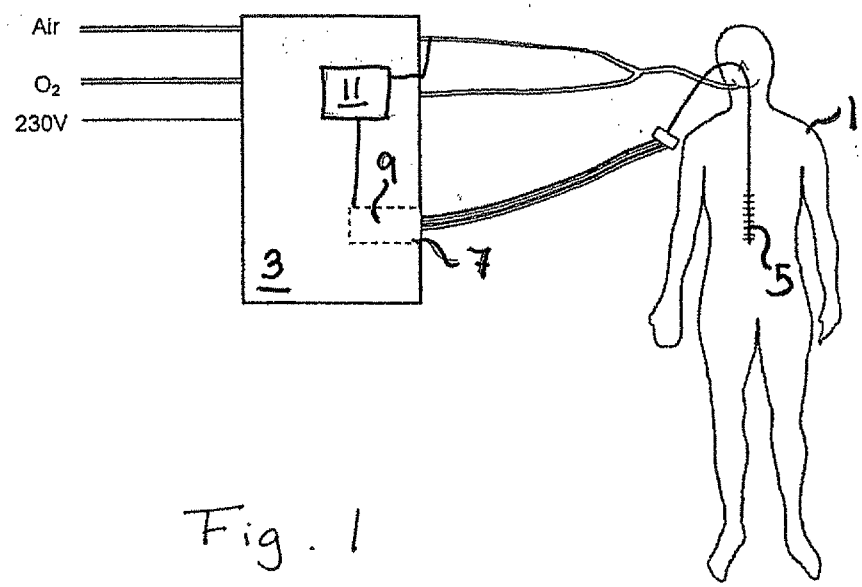

Fig. 1

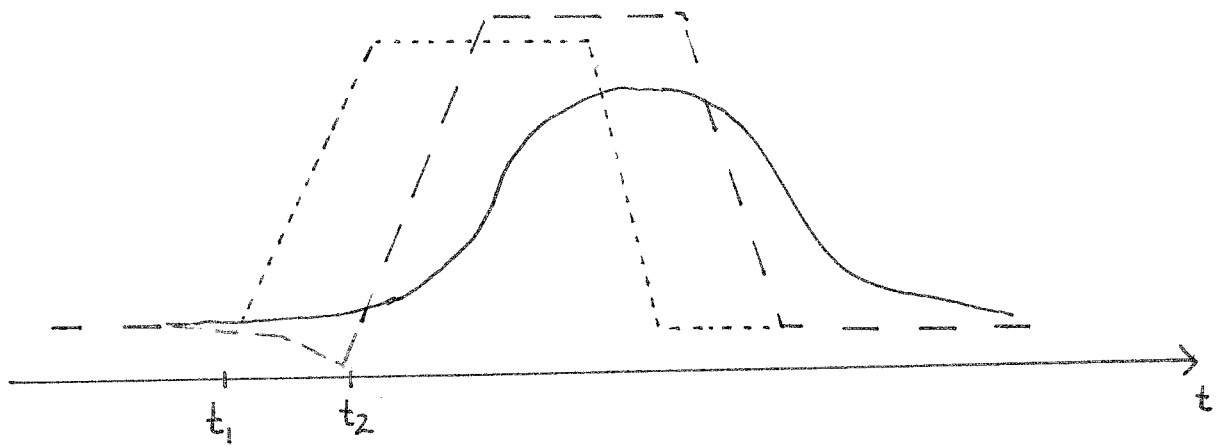

Fig. 2

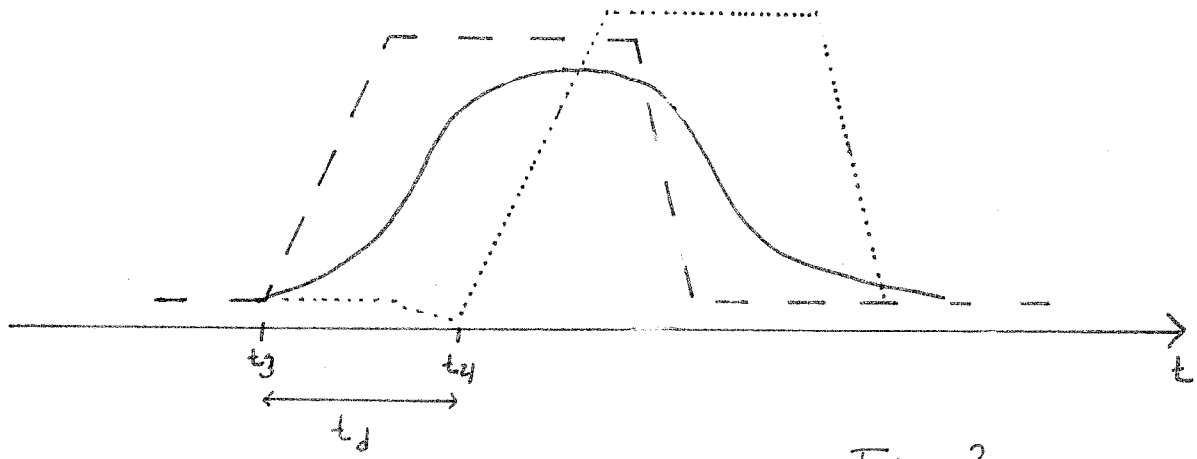

Fig. 3

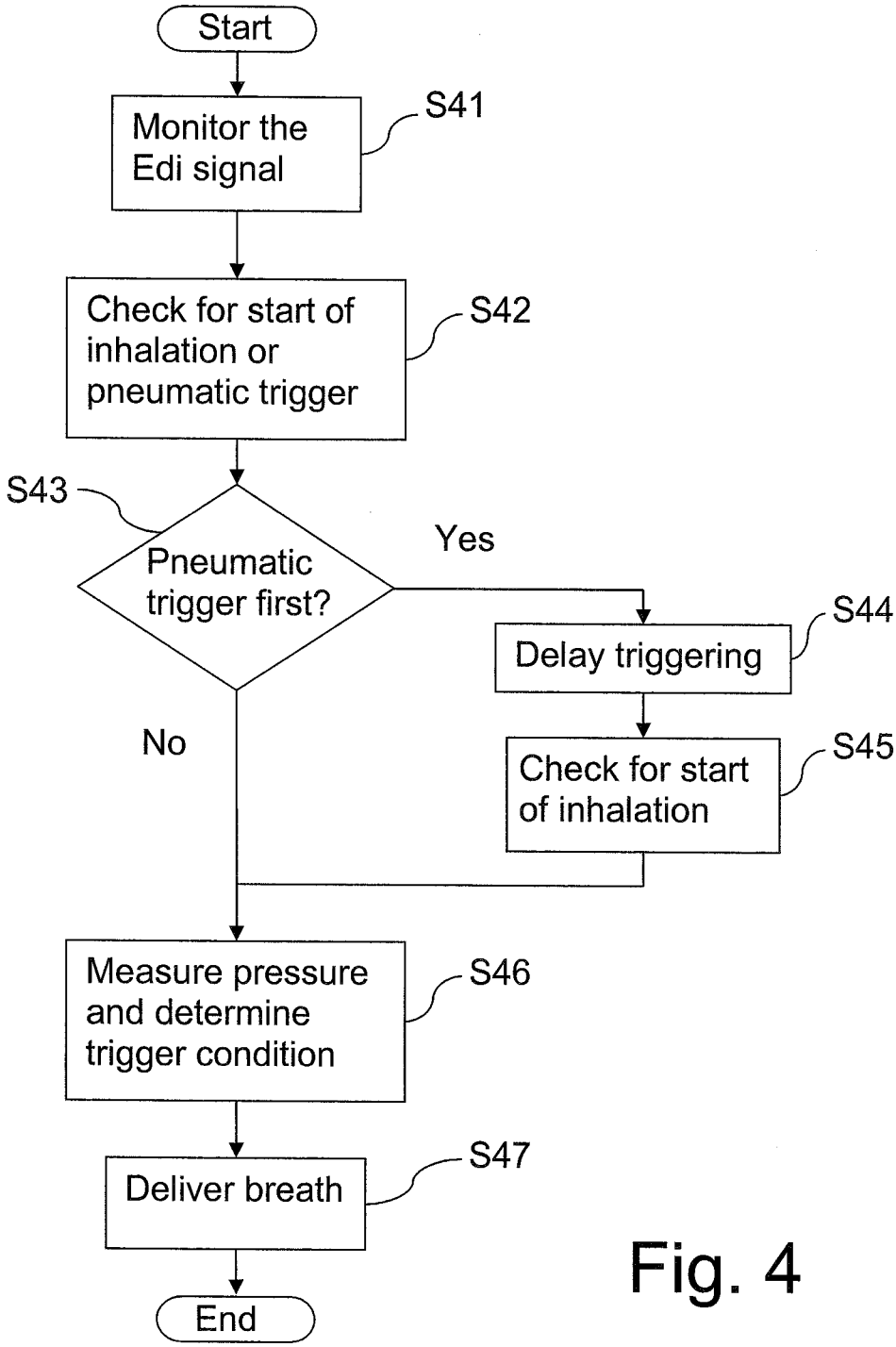
Start
Monitor the Edi signal
S41
Check for start of inhalation or pneumatic trigger
S42
S43
Pneumatic trigger first?
Yes
No
Delay triggering
S44
Check for start of inhalation
S45
Measure pressure and determine trigger condition
S46
Deliver breath
S47
End

Fig. 4

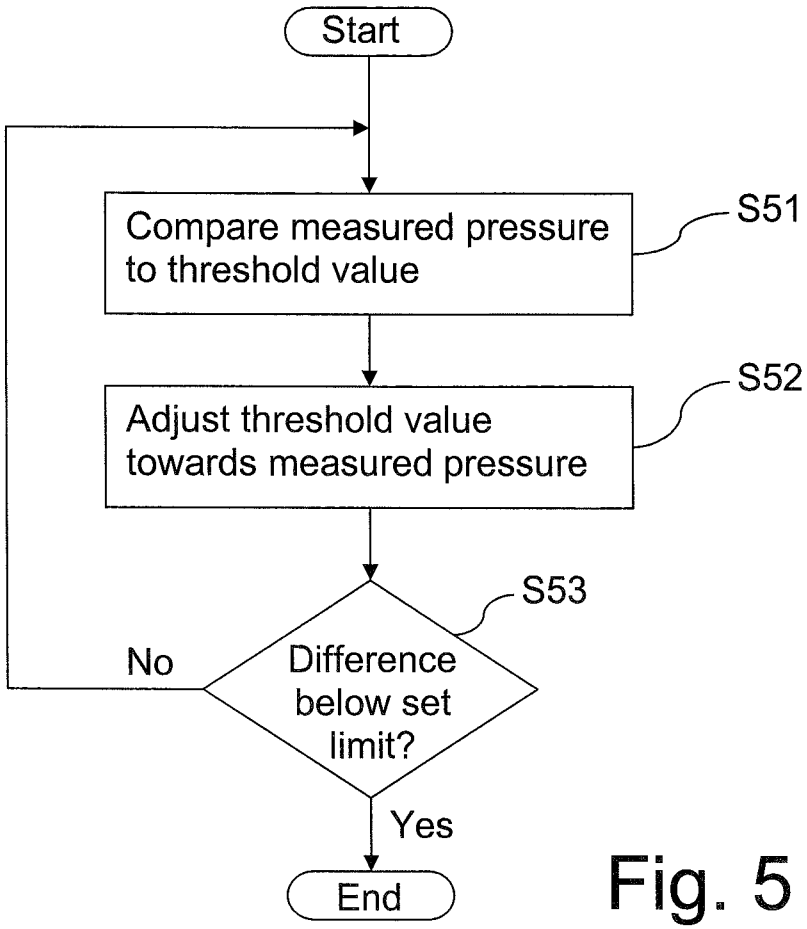
Start
Compare measured pressure to threshold value
S51
Adjust threshold value towards measured pressure
S52
Difference below set limit?
S53
No
Yes
End

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/SE2007/051048

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00

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)
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 99/43374 A (UNIV MONTREAL [CA]; SINDERBY CHRISTER [CA]) 2 September 1999 (1999-09-02) page 12, line 1 - page 30, line 2	1-9
X	WO 00/00245 A (SIEMENS ELEMA AB [SE]; WAARD LEIF [SE]) 6 January 2000 (2000-01-06) page 7, line 26 - page 12, line 18	1,3,5-9
X	US 4 440 176 A (MIODOWNIK SAUL [US]) 3 April 1984 (1984-04-03) column 3, line 46 - column 10, line 56	1,3-9
X	US 6 411 843 B1 (ZARYCHTA JAROSLAW [CA]) 25 June 2002 (2002-06-25) column 16, line 47 - column 17, line 18	1-3,8,9

☐ 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
12 September 2008	23/09/2008

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, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kroeders, Marleen

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2007/051048

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10-16
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapyRule 39.1(iii) PCT - Scheme, rules and method for performing mental acts

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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