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

(19) **World Intellectual Property Organization**
International Bureau

(43) **International Publication Date**
**6 November 2008 (06.11.2008)**

**PCT**

(10) **International Publication Number**
**WO 2008/131798 A1**

(51) **International Patent Classification:**
*A61B 5/0488* (2006.01) *A61M 16/00* (2006.01)

(21) **International Application Number:** PCT/EP2007/054156

(22) **International Filing Date:** 27 April 2007 (27.04.2007)

(25) **Filing Language:** English

(26) **Publication Language:** English

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(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, 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, 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:** AN EMG CONTROLLED VENTILATOR AND A METHOD FOR AN EMG CONTROLLED VENTILATOR

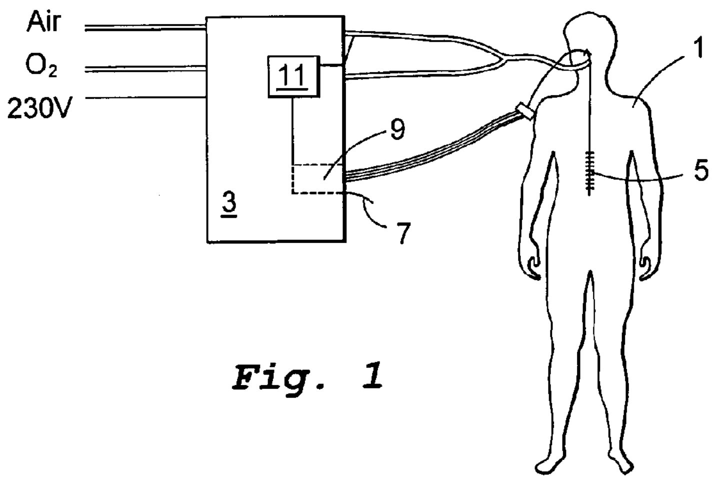


*Fig. 1*

(57) **Abstract:** A ventilator (3) arranged to provide breathing support to a patient (1) in EMG controlled mode, comprises input means (7) for receiving an EMG signal representative of breathing activity from the patient and a control unit (9) for controlling the ventilation in dependence of said EMG signal. The ventilator is characterized in that it comprises registration means (11) for registering the actual breathing support provided from the ventilator to the patient and a control unit (7) arranged to determine if there is asynchrony between the EMG signal and the breathing activity and, in case of asynchrony, switch from EMG controlled ventilation to a second ventilation mode not dependent on the EMG signal. If synchrony is detected the ventilator can return to EMG controlled ventilation.

WO 2008/131798 A1

# AN EMG CONTROLLED VENTILATOR AND A METHOD FOR AN EMG CONTROLLED VENTILATOR

## Technical Field

The present invention relates to a ventilator and a method for providing breathing support in EMG controlled mode.

## Background and Related Art

Ventilators are used to support breathing in patients are unable to breathe or whose breathing function is insufficient. Traditionally two different modes have been used. If the patient shows some breathing activity a support mode such as pressure support or volume support mode can be used, in which the patient's attempts to inhale are used to trigger an inspiration phase in the ventilator. If the patient shows no breathing activity controlled mechanical ventilation mode must be used, in which a respiratory rate is determined without any input from the patient.

Recently, ventilators have been disclosed that are neurally controlled, that is, controlled in dependence of electromyographic signal related to breathing. For example, US6588423 describes a ventilator that is controlled on the basis of an EMG signal from the diaphragm, referred to as an Edi signal (Electrial activity of the diaphragm). The EMG signal may be registered, for example by means of an oesophageal catheter in a manner well known in the art.

In some cases the detected EMG signal does not reflect correctly the actual breathing phases of the patient. In such cases there may be a mismatch when the ventilator tries to supply air to the patient while the patient is trying to exhale.

## Object of the Invention

It is an object of the invention to provide an improved ventilator and a method of controlling a ventilator based on EMG control.

Summary of the Invention

This object is achieved according to the present invention by a ventilator arranged to provide breathing support to a patient in EMG controlled mode, comprising input means for receiving an EMG signal representative of breathing activity from the patient and a control unit for controlling the ventilation in dependence of said EMG signal, said ventilator being characterized in that it comprises registration means for registering the actual breathing support provided from the ventilator to the patient and a control unit arranged to determine if there is asynchrony between the EMG signal and the breathing activity and, in case of asynchrony, switch from EMG controlled ventilation to a second ventilation mode not dependent on the EMG signal.

The object is also achieved by a method for providing EMG controlled breathing support to a patient, comprising the following steps:
receiving an EMG signal representative of breathing activity from the patient and controlling the ventilation in dependence of said EMG signal, said method being characterized by the steps of
registering the actual breathing support provided from the ventilator to the patient
determining if there is asynchrony between the EMG signal and the breathing activity and,
in case of asynchrony, switching from EMG controlled ventilation to a second ventilation mode not dependent on the EMG signal.

Hence, according to the invention, the signal received from the oesophageal catheter will only be used to control the ventilator if it is found that the signal truly represents the breathing activity of the diaphragm. If the signal is found to be inconsistent with the patient's own breathing activity, the ventilator will be controlled in another ventilation mode. Thus, the apparatus and method according to the invention ensure that if the signal from the oesophageal catheter will not be used if it is inconsistent with the patient's own breathing rhythm. This may be the case, for example if the catheter is placed incorrectly within the patient, or because of other disturbances or artefacts. EMG controlled mode should be understood to mean a support mode in which the ventilation support is based on the EMG signal from the diaphragm.

The control unit is preferably arranged to switch to a support mode. The switch may also be performed manually, in which case an alarm is issued if an asynchrony is detected, to prompt an operator to perform the switch.

In a first embodiment the control unit is arranged to determine whether an asynchrony is present based on a relationship between the inspiration time and total breath time for at least one breath as determined from the EMG signal or based on a relationship between the inspiration time and expiration time for at least one breath as determined from the EMG signal. These relationships normally lie within a well-defined interval. If they are outside of this interval, in particular, if the inspiration time is too long compared to the expiration time or the total time for one breath, this is an indication that something is wrong.

Alternatively, the control unit is arranged to determine whether an asynchrony is present based on a comparison of the actual respiratory rate provided by the ventilator and the respiratory rate calculated on the basis of the EMG signal. These two methods of detecting asynchrony are preferably used together for increased security.

When the ventilator is ventilating in the second ventilation mode, the control unit may be arranged to switch to EMG controlled mode if the EMG signal is found to be synchronous with the patient's breathing activity.

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 patient with an oesophageal catheter used to control a ventilator

Figure 2 illustrates the ideal situation of EMG controlled ventilation.

Figure 3 illustrates EMG controlled ventilation when the EMG signal does not reflect the patient's breathing activity.

Figure 4 is a flow chart of the inventive method

Figure 5 illustrates the use of the inventive method when a support ventilation mode has been activated

Detailed Description of Embodiments

Figure 1 is a schematic overview of a patient 1 connected to a ventilator 3 and having 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 to control the ventilating function of the patient 1. The catheter 5 comprises a number of electrodes, for example, nine electrodes placed equidistantly in an array along the catheter to produce eight subsignals, each subsignal being a difference signal between two neighbouring electrodes. The subsignals will be processed in a control unit 9 in the ventilator to produce the overall signal that can be used to control the ventilator.

In some cases the EMG signal will not correctly reflect the diaphragm activity. This may be the case if the catheter is inserted too far, or not far enough, into the patient's oesophagus, so that it will pick up signals from other muscles than the diaphragm, or no signal at all. If inserted to far, the catheter may pick up signals from expiratory muscles instead of the inspiratory activity of the diaphragm. In this case the EMG signal will have the opposite phase of the patient's actual breathing activity. The ventilator will then be triggered to start an inspiration while the patient is expiring and vice versa. There may also be other disturbances or leakages that will cause the EMG signal to deviate from the patient's breathing rate. According to the invention the ventilator comprises registration means 11 for registering the actual breathing support provided to the patient from the ventilator and provide them to the control unit 9. The control unit 9 is arranged to determine asynchrony between the EMG signal and the patient's own breathing activity based on the signal from the registration means 11 and the Edi signal. If asynchrony is detected, the control unit

9 is arranged to cause the ventilator to switch from EMG controlled mode to a ventilation mode that is not dependent on the EMG signal. Such a mode will generally be referred to as a support mode in this document.

Figure 2a illustrates an ideal situation in which the EMG signal, shown as a solid line along a time axis t, corresponds to the Edi signal. The ventilator curve is shown as a dashed line. As can be seen, the ventilator will trigger inspiration when the patient is actually trying to breathe in, and cycle off when the patient is actually trying to exhale.

Figure 2b illustrates a situation in which the EMG signal, shown as a solid line is not in the same phase as the ventilator curve, shown as a dashed line, which represents the support provided to the patient.

Figure 3 illustrates a situation in which the EMG signal used to control the breathing support has the opposite phase of the patient's own breathing. In this case the breathing support, if in EMG mode, will work against the patient's own breathing cycle. This may be the case, for example, if the oesophageal catheter is inserted too far into the patient's stomach so that the EMG from expiratory muscles in the abdomen is detected instead of the diaphragm. Again, the EMG signal is shown as a solid line while a dashed curve indicates the breathing support supplied by the ventilator.

The triggering method uses both EMG and airway inspiratory flow or pressure. The decisions for triggering and cycling off will be made by a logic circuit on a "first come, first served" basis, as disclosed in US 6,588,423, col. 12. In this case, while the ventilator is trying to supply air to the patient, the patient will generate an expiratory pressure that will work in the opposite direction. The magnitude of the expiratory pressure will vary depending on the patient's condition. When the expiratory pressure becomes too high, the patient will exhale despite the air supplied by the ventilator. As shown in Figure 3, the resulting curve for the breathing support delivered by the ventilator will vary with a higher frequency than the actual respiratory rate of the patient, that is, the patient will experience several short breaths instead of one proper breath.

Figure 4 is a flow chart of the inventive method while EMG controlled ventilation is provided to the patient.
Step S1: Ventilate patient in EMG controlled mode.
Step S2: Monitor the EMG signal used to control the ventilator.
Step S3: Monitor the breathing support supplied by the ventilator to the patient.
Step S4: Determine synchrony or asynchrony of the EMG signal and breathing support.
Step S5: If asynchrony is detected, switch to a support mode for the ventilation; if not, repeat procedure.

Although they are shown in Figure 4 as consecutive steps, it will be understood that steps S1 is performed until a switch to a support mode is made. Steps S2 and S3 are performed in parallel to enable the comparison performed in step S4. As an alternative, in Step S5 an alarm may be issued if asynchrony is detected, to prompt an operator to switch ventilation modes manually.

Two main principles are proposed for the detection of asynchrony in step S4. The first principle is based on inspiratory and expiratory phases as determined from the Edi signal. According to this first principle the relationship between the duration of the inspiratory phase and the duration of the total time required for an inspiratory and expiratory phase is used to detect asynchrony. As will be understood by the skilled person, the relationship between the duration of the inspiratory phase and the duration of the expiratory phase will serve as an indicator in substantially the same way. The second principle is based on a comparison between the actual respiratory rate delivered by the ventilator and the respiratory rate that would have been delivered by the ventilator if the patient had had no pneumatic activity.

The first principle mentioned above, is based on the assumption that the duration of the inspiratory time Ti will be relatively normal whereas the expiratory time Te will be shortened. Hence, the relationship between Ti and the total time for one breath Ttot=Ti+Te will be greater than normal in this case. An increase in the relationships Ti/Ttot or Ti/Te may indicate that the EMG signal that is recorded is not representative of the activity of the diaphragm, but instead of some other muscle or muscles, for example, expiratory muscles in the abdomen. It may also indicate that the EMG signal is affected by noise or other artefacts. Hence, in this case, the EMG signal supplied to the ventilator is not suitable for controlling the patient's breathing. In this case, as indicated above, the control mode of the ventilator should be switched from EMG controlled mode to a ventilation mode not dependent on the EMG signal, preferably a support mode.

With this first principle a number of breaths may be considered instead of just one breath. This may be done in several different ways. The values Ti, Te and/or Ttot for two or more breaths may be used to calculate sums or average values Tiav, Teav and/or Ttotav which can be used to obtain more reliable values than those obtained from only one breath. Alternatively, Ti:Te and/or Ti:Ttot may be determined for a number of breaths individually but considered together. If a certain fraction (for example, two out of three, or three out of five) of the breaths exhibit a too high Ti:Te or Ti:Ttot, this will be taken to indicate that there is a mismatch between the phases of the patient's own breathing activity and the breathing support provided by the ventilator. Alternatively, after a certain number of consecutive breaths exhibit a too high Ti:Te or Ti:Ttot, a mismatch will be considered to have been detected.

The second principle is based on the fact that if the phases of the patient and the ventilator do not match, the breathing support provided by the ventilator will be influenced both by the EMG signal used to control the ventilator and by the actual pressure generated by the patient. Hence, the respiratory rate that would be delivered by the ventilator if the patient showed no pneumatic activity would be lower than the actual respiratory rate of the ventilator. In other words, as can be seen from

Figure 3, the patient will breathe more frequently than if the ventilator had been controlled by only the EMG signal.

Hence, according to the second principle asynchrony may be detected according to the following:

Determine the respiratory rate of the breathing support actually provided by the ventilator and the respiratory rate determined by the EMG signal. The latter respiratory rate is the one that would be provided by the ventilator if there was no pneumatic influence from the patient.

Compare the two respiratory rates to each other. If the patient and the ventilator are in phase these two respiratory rates will be approximately the same. If there are disturbances the two respiratory rates will differ from each other. A threshold may be set, defining the difference that will be acceptable. If the breathing rates differ by more than the threshold value an asynchrony is detected. The threshold value may be an absolute value, or may be determined as a fraction of the actual respiratory rate. A combination of an absolute value and a fraction may also be applied.

This second principle can only be used in an efficient manner if the patient's own breathing condition is strong enough to trigger and/or cycle off pneumatically. If this is not the case the patient's breathing activity will not influence the ventilator's respiratory rate to a sufficient degree. The first and the second principle for detecting asynchrony may be applied together, to increase security.

In the situation when the ventilator mode has been switched to a support mode according to the procedure of Figure 4, the synchrony between the EMG signal and the patient's own breathing activity is preferably monitored to determine if the ventilator can return to EMG controlled mode. One method of doing this is illustrated in Figure 5. Again, the Edi signal is shown as a solid line while the ventilator support is shown as a dashed line. The starting point of an inspiration triggered by the ventilator is marked t1. A window W is defined around the starting point of the pneumatic triggering. Synchrony is determined to exist if the Edi signal starts to indicate an inspiration some time within the window. Preferably the length of the window is determined based on the inspiration time Ti, for example as half the inspiration time Ti. This inspiration time is preferably determined based on a number of preceding breaths. The length of the window may also be determined as a fix time, or in relation to expiration time. Further, absolute minimum and maximum duration for the window may be set. An example of such minimum and maximum durations may be 65 ms and 200 ms, respectively.

The method of synchrony detection as described above can be improved by simultaneously monitoring Ti/Ttot as described above in connection with asynchrony detection. In this way it can be ensured that the ventilator does not switch to EMG controlled mode if there is not true synchrony. In particular, if Ti/Ttot is used to detect asynchrony using the same criterion to detect synchrony will help avoid an undue return to EMG controlled mode.

Figure 6 is a flow chart of the inventive method while pneumatic support ventilation is provided to the patient by a ventilator that is also capable of EMG controlled mode.

Step S61: Ventilate patient in a support mode.

Step S62: Monitor the EMG signal received from the patient.

Step S63: Determine synchrony or asynchrony of the EMG signal and breathing support.

Step S64: If synchrony is detected, switch to EMG controlled mode for the ventilation; if not, repeat procedure.

Of course, the procedure of Figure 6 may be performed also if the ventilation starts in a support mode. It is not a prerequisite that a switch from EMG controlled mode has been made first.

# CLAIMS

1. A ventilator (1) arranged to provide breathing support to a patient (3) in EMG controlled mode, comprising input means (7) for receiving an EMG signal representative of breathing activity from the patient and a control unit (9) for controlling the ventilation in dependence of said EMG signal, said ventilator being **characterized** in that it comprises registration means (11) for registering the actual breathing support provided from the ventilator to the patient and a control unit (7) arranged to determine if there is asynchrony between the EMG signal and the breathing activity and, in case of asynchrony, switch from EMG controlled ventilation to a second ventilation mode not dependent on the EMG signal.

2. A ventilator according to claim 1, wherein the control unit (9) is arranged to switch to a support ventilation mode.

3. A ventilator according to claim 1 or 2, wherein the control unit (9) is arranged to determine whether an asynchrony is present based on a relationship between the inspiration time and total breath time for at least one breath as determined from the EMG signal.

4. A ventilator according to any one of the preceding claims, wherein the control unit (9) is arranged to determine whether an asynchrony is present based on a relationship between the inspiration time and expiration time for at least one breath as determined from the EMG signal.

5. A ventilator according to claim 1 or 2, wherein the control unit (9) is arranged to determine whether an asynchrony is present based on a comparison of the actual respiratory rate provided by the ventilator and the respiratory rate calculated on the basis of the EMG signal.

6. A ventilator according to any one of the preceding claims, wherein, when the ventilator is ventilating in the second ventilation mode, the control unit (9) is arranged to switch to EMG controlled mode if the EMG signal is found to be synchronous with the patient's breathing activity.

7. A ventilator according to any one of the preceding claims, wherein the control unit is arranged to switch to the second ventilation mode automatically, without manual intervention.

8. A method for providing EMG controlled breathing support to a patient, comprising the following steps:
receiving an EMG signal representative of breathing activity from the patient and controlling the ventilation in dependence of said EMG signal, said method being **characterized** by the steps of
registering the actual breathing support provided from the ventilator to the patient determining if there is asynchrony between the EMG signal and the breathing activity and,
in case of asynchrony, switching from EMG controlled ventilation to a second ventilation mode not dependent on the EMG signal.

9. A method according to claim 8, wherein the switch from EMG controlled ventilation is made to a support ventilation mode.

10. A method according to claim 8 or 9, wherein the step of determining whether an asynchrony is present is performed based on a relationship between the inspiration time and total breath time for at least one breath as determined from the EMG signal.

11. A method according to claim 8 or 9, wherein the step of determining whether an asynchrony is present is performed based on a relationship between the inspiration time and expiration time for at least one breath as determined from the EMG signal.

12. A method according to claim 8, 9 or 10, wherein the step of determining whether an asynchrony is present is performed based on a comparison of the actual respiratory rate provided by the ventilator and the respiratory rate calculated on the basis of the EMG signal.

13. A method according to any one of the claims 8-12, comprising the steps of when the ventilator is ventilating in the second ventilation mode, detecting synchrony between the EMG signal and the patient's breathing activity and, when such synchrony is detected, switching to EMG controlled mode.

14. A method according to any one of the claims 8-13, wherein the step of changing to the second mode is performed automatically without manual intervention.

15. A ventilator (1) arranged to provide breathing support to a patient (3) in EMG controlled mode, comprising input means (7) for receiving an EMG signal representative of breathing activity from the patient and a control unit (9) for controlling the ventilation in dependence of said EMG signal, said ventilator being **characterized** in that it is arranged to provide breathing support in a second ventilation mode not dependent on the EMG signal if asynchrony between the EMG signal and the breathing activity, and that it comprises registration means (11) and a control unit (7) arranged to determine if there is synchrony between the EMG signal and the breathing activity and, in case of synchrony, switch from the second ventilation mode to EMG controlled ventilation.

16. A ventilator according to claim 15, wherein the control means is arranged to determine synchrony based on a comparison of a starting point of an inspiration triggered by the ventilator and the phase of the Edi signal.

17. A ventilator according to claim 15 or 16, wherein the control means is arranged to determine synchrony based on a relationship between the inspiration time and total breath time for at least one breath as determined from the EMG signal.

18. A ventilator according to claim 15 or 16, wherein the control means is arranged to determine whether synchrony is present based on a relationship between the inspiration time and expiration time for at least one breath as determined from the EMG signal

19. A method for providing breathing support to a patient, comprising the step of ventilating in a second ventilation mode that is not dependent on an EMG signal, said method being **characterized** by the steps of
registering the actual breathing support provided from the ventilator to the patient
determining if there is synchrony between the EMG signal and the breathing activity and,
in case of synchrony, switching from the second ventilation mode to EMG controlled ventilation.

20. A method according to claim 19, wherein the step of determining whether synchrony is present is based on a comparison of a starting point of an inspiration triggered by the ventilator and the phase of the Edi signal.

21. A method according to claim 19 or 20, wherein the step of determining whether synchrony is present is performed based on a relationship between the inspiration time and total breath time for at least one breath as determined from the EMG signal.

22. A method according to claim 19 or 20, wherein the step of determining whether synchrony is present is performed based on a relationship between the inspiration time and expiration time for at least one breath as determined from the EMG signal

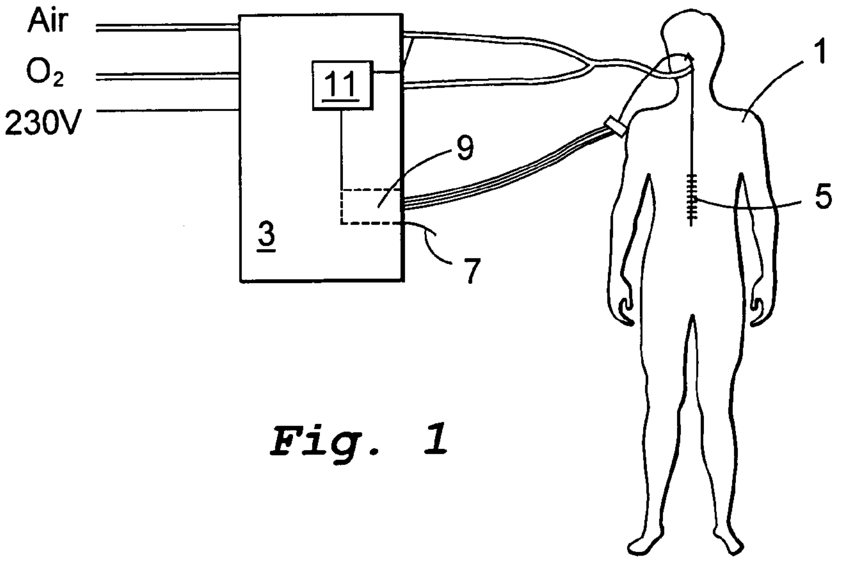


Fig. 1

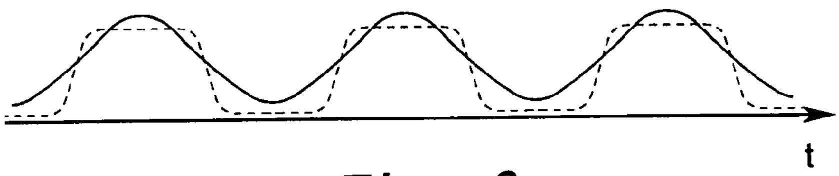


Fig. 2a

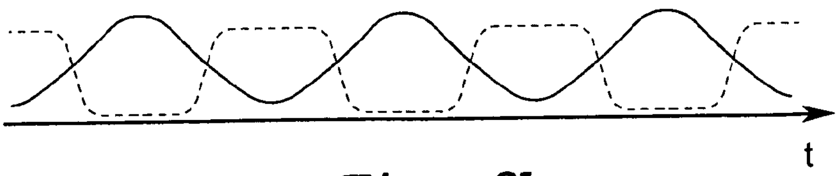


Fig. 2b

Fig. 3

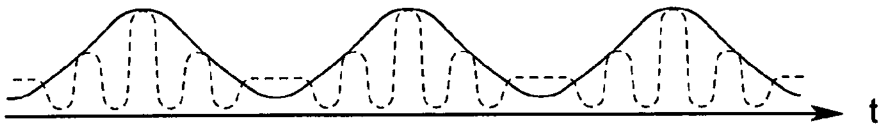
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Fig. 4

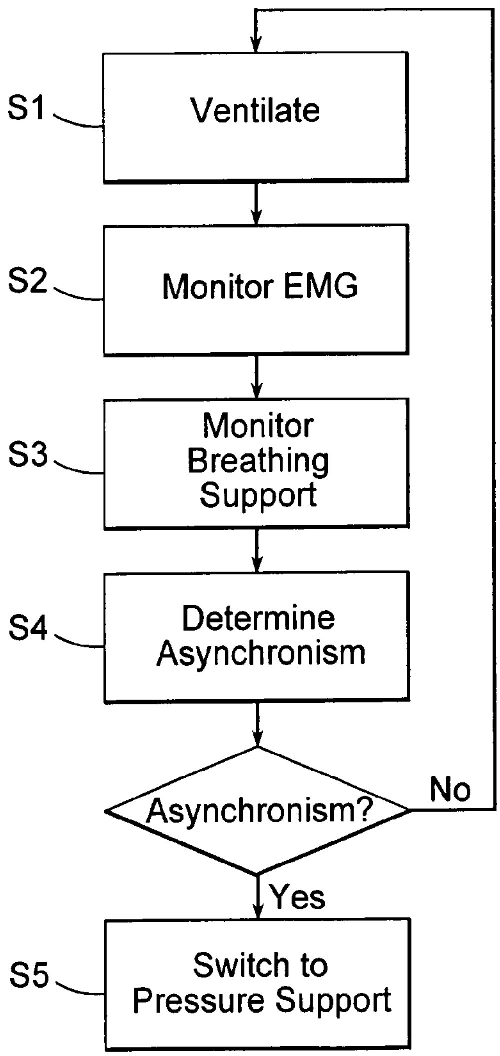

S1
Ventilate
S2
Monitor EMG
S3
Monitor Breathing Support
S4
Determine Asynchronism
Asynchronism?
No
Yes
S5
Switch to Pressure Support

*Fig. 5*

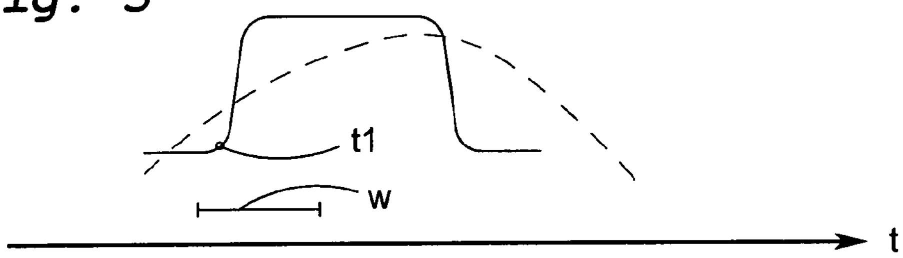
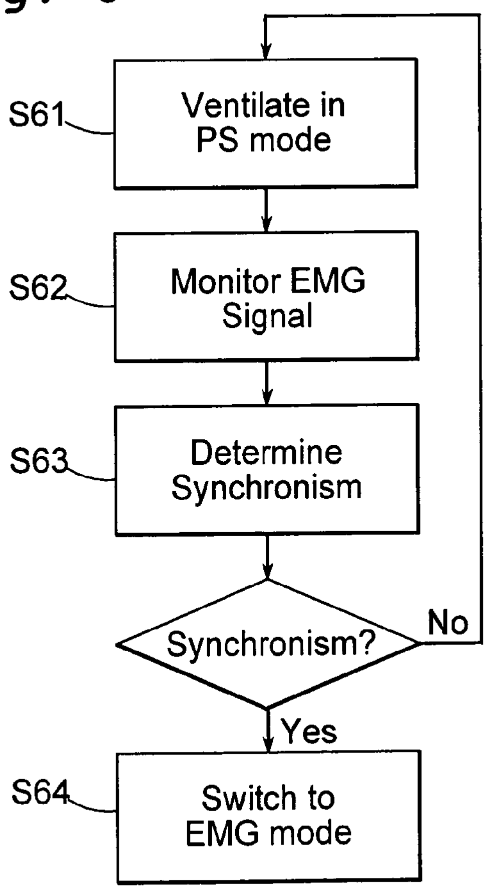

t1
w
t

*Fig. 6*


S61
Ventilate in PS mode
S62
Monitor EMG Signal
S63
Determine Synchronism
Synchronism?
No
Yes
S64
Switch to EMG mode

# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2007/054156

**A. CLASSIFICATION OF SUBJECT MATTER**
INV. A61B5/0488 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)
A61B 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. |
|---|---|---|
| Y | US 6 588 423 B1 (SINDERBY CHRISTER [CA]) 8 July 2003 (2003-07-08) cited in the application column 6, line 3 - line 41 column 11, line 39 - line 46 column 12, line 42 - line 60; figures 1-11 | 1,2,6-9, 13-15,19 |
| Y | US 2003/000526 A1 (GOBEL FRED [DE] GOEBEL FRED [DE]) 2 January 2003 (2003-01-02) paragraph [0086]; figures 1-8 | 1,2,6-9, 13-15,19 |
| A | EP 0 774 269 A (SIEMENS ELEMA AB [SE]) 21 May 1997 (1997-05-21) column 5, line 17 - line 26; figures 1,2 | 6,13,15, 19 |
| A | US 2003/100843 A1 (HOFFMAN ANDREW [US]) 29 May 2003 (2003-05-29) paragraphs [0003], [0108], [0125] | 1,8,15, 19 |

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 30 January 2008 | 14/02/2008 |

| Name and mailing address of the ISA/ | Authorized officer |
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# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2007/054156

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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