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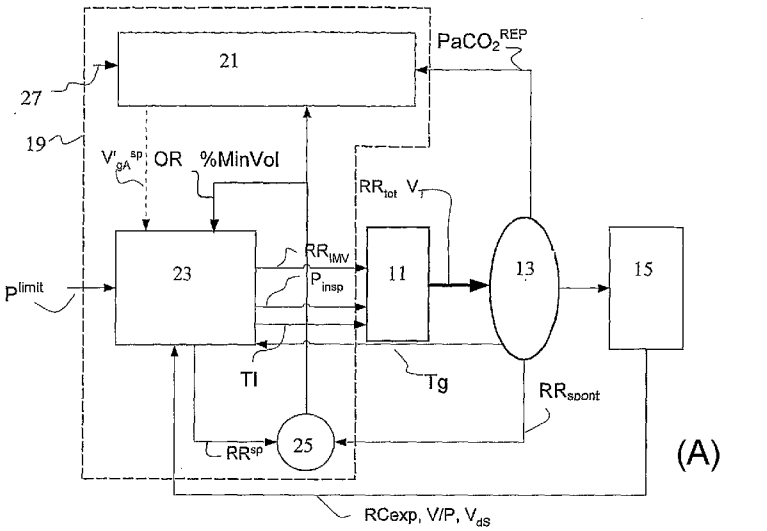
(54) Title: AN APPARATUS FOR REGULATING A MECHANICAL VENTILATION



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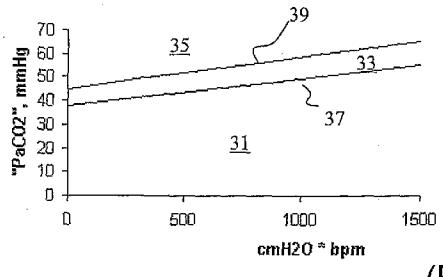

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(57) Abstract: The invention relates to a device, with which one is to prevent a patient who breathes on Ms own and who desires a lower CO_2-partial-pressure than is achieved by the set Ventilation from tiring. It comprises the following means for the regulation of a changing intensity of a mechanical Ventilation: • means for determining a target frequency RR^{sp}, • means for determining a spontaneous frequency RR_{spont} • means for comparing the spontaneous frequency RR_{spont} with the target frequency RR^{sp}. wherein adapting a Ventilation target value (%MinVol, $V'_{gA}{}^{sp}$) on account of the result of the comparison of the spontaneous frequency RR_{spont} with the target frequency RR^{sp} and • means for adapting the parameters determining the intensity of the Ventilation, on account of the Ventilation target value (%MinVol, $V'_{gA}{}^{sp}$). This so-called pump support System (PSS)is activated (PSS on) when the patient breathes in an adequately spontaneous manner (Criterion 1). With an insufficient individual activity of the patient, his behaviour is taken as a basis for the control of the regulation. The control or regulation of the Ventilation is assumed by a fixed setting of a Ventilation target value (%MinVol), or a CO_2-controller, as soon as the patient breathes in a manner which is not spontaneous enough.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

An apparatus for regulating a mechanical ventilation

The invention relates to an apparatus for regulating a mechanical ventilation.

CO_2 produced in the body of a patient by way of metabolism, is transported into the lung with the blood and is breathed out there. The higher the CO_2-production of the body, the higher must the alveolar ventilation be, in order to keep the arterial CO_2-partial-pressure constant. An increase of the alveolar ventilation is achieved with mechanical ventilation by way of a recruitment of inactive lung shares or by way of increasing the minute volume.

Minute volume (MV) is indicated as the volume of air which is breathed in and out again in one minute. The minute volume may be computed from the respiratory frequency and the breath volume. The breath volume is the quantity of air which is breathed in per breath.

The measured minute volume thereby is dependent on the respective person and his circumstances, i.e. his exertion, his constitution, his health condition, his volume and his body size. The minute volume with bodily exertion may increase by 3-4 times. Furthermore, there are unhealthy conditions, such as fever, lung embolism, metabolic acidosis and disturbance of the respiratory centre, which may increase the MV. Hyperventilation of course entails an increased minute volume.

The minute volume during sleep, sinks to below the daily resting values. When taking sedatives, a reduction of the MV occurs with a higher dose. The expenditure of oxygen may lead to a reduction of the MV with people who are chronically adapted to an increased, arterial CO_2-partial-pressure.

A minute volume according to the person may be calculated from details on this person. A minute volume calculated in this manner is indicated as a 100% minute volume. Deviations in the minute volume of this person may then relate to this 100% Min Vol. This percentage minute volume (%Min Vol) is therefore a variable, which is related to the minute volume corresponding to the respective person. These values, in contrast to the nominal value of the minute volume or the alveolar ventilation, provide relative information concerning the person, as to whether the person is greatly or weakly ventilated.

With a computation of the necessary total ventilation, amongst other things, one may take into account the fact that on ventilation, apart from the effective alveolar ventilation, a ventilation of the alveolar dead space (alveoli not circulated with blood) and of the serial dead space (tubus and upper airways) is effected, said ventilation not being effective. The minute ventilation (MV) is composed of the total alveolar ventilation ("gross alveolar ventilation" $'V'_{gA}$) and the serial dead space ventilation. V'_{gA} is

composed of the effective alveolar ventilation (V'_A) and of the alveolar dead space ventilation (V'_{dA}). The serial dead space ventilation is the product of the ventilation rate times the serial dead space (V_{dS}).

The benefits and risks are to be weighed up with the mechanical ventilation of the lungs of a patient. The ventilation must be increased in order to reduce the CO_2-content in the blood. The frequency and the ventilation pressure (the volume) may be increased in order to increase the ventilation volume. Each increase of these parameters however entails risks.

An apparatus for the spontaneous ventilation with a variable breathing aid is known from EP-A 0 347 282. This apparatus has the aim of preventing an unnecessary tiring of the patient by way of keeping the respiratory frequency constant. This apparatus produces a ventilation control signal on account of a pressure sensor in the insufflation conduit. The supplied control signal is representative of the determined change of the respiratory frequency with respect to a predefined reference respiratory frequency. A positive pressure level is adapted on account of this control signal, so that the respiratory frequency remains essentially constant at the value of the predefined reference respiratory frequency.

If the respiratory frequency assumes a value above a predefined range, the breathing support is increased, in order to relieve the patient from the increased work for breathing, until the respiratory frequency has returned back into the preselected frequency range. If the respiratory frequency lies below this range, the breathing support is reduced, until the patient has increased the respiratory frequency to such an extent, that it lies in the predefined frequency range.

The disadvantage with this device is the fact that the rate is set in a fixed manner. If the physician sets the rate too low, then one ventilates with a high pressure. If however the rate is set too high, the patient obtains too little support and tires despite this.

It is therefore the object of the invention to provide a device and a method, with which one may control a ventilator in a manner such that the ventilated patient is ventilated as optimally as possible. The object in particular lies in preventing a patient who breathes independently and wishes CO_2-partial-pressure which is lower than is achieved by way of the set ventilation, from tiring.

According to the invention, this object is achieved by a device according to claim 1.

Such a device for the regulation of an intensity of a mechanical ventilation comprises the following means:

- means for determining a target frequency RR^{sp},

- means for determining a spontaneous frequency RR_{spont},
- means for comparing the spontaneous frequency RR_{spont} with the target frequency RR^{sp}.

This device according to the invention is characterised by

- means for adapting a ventilation target value by way of the result of the comparison of the spontaneous frequency RR_{spont} with the target frequency RR^{sp} and
- means for adapting the parameters determining the intensity of the ventilation, by way of the ventilation target value.

The device according to the invention is characterised preferably by means for setting the target rate RR^{sp} by way of the adapted ventilation target value (%MinVol,V'_gA^{sp}). Very advantageously, the device also comprises means for setting the ventilation pressure or the breath volume by way of the adapted ventilation target value (%MinVol, V'_gA^{sp}).

If these means are present, it is then preferred for the device to have a controller, which is suitable for matching the parameters determining the intensity. Such parameters in particular are the ventilation pressure or the breath volume on the one hand, and the ventilation frequency (RR^{sp}, RR_{IMV}) on the other hand. Such a matching is usefully effected on account of patient parameters, which influence the optimisation of pressure and rate.

Furthermore, this device usefully comprises means for regulating or activating the ventilator according to the intensity of the ventilation which is determined by way of the above means, so that the patient may also be mechanically ventilated accordingly.

Thereby, usefully different deviations of the spontaneous frequency RR_{spont} from the predefined target value RR^{sp} are tolerated, depending on the goal of the therapy and the ventilation target value (or currently set %MinVol).

This tolerated deviation is in particular advantageously dependent on the goal of the therapy. It may, depending on the goal of the therapy, be defined as a constant number of breaths per unit of time, or depending on a ventilation intensity or a ventilation target value.

In the case that a normal withdrawal is defined as a therapy goal, and the tolerance range is defined as the number of breaths per minute, usefully between maximal 3 and maximal 8, particularly preferred between 4.5 and 5.5 breaths per minute should be tolerated. With a forced withdrawal however, these values increase to values between maximal 7 and maximal 15, particularly preferred between 9 and 11 breaths per minute.

If the tolerance range is defined depending on the supplied %MinVol, then a tolerance range which may be defined as the current %MinVol setting divided by a divisor may be considered as being useful. The number value of the divisor preferably lies in the region of 12 to 33, particularly preferably from 18 to 22. The tolerance range dependent on %MinVol is larger with a forced withdrawal than with a strategy which demands less of the patient.

This device has the advantage that the ventilation may be automatically adapted to the requirement of the patient, without a measurement of the arterial CO_2-partial-pressure being necessary for this. The body of the patient is used as a subjective CO_2-sensor.

Such a device may therefore complement the ventilator to the extent that this prevents a fatigue of the patient, independently of whether a ventilator is geared to a CO_2-measurement or not.

A ventilator may however have a regulation or control of the ventilation which is geared to a measurement which is representative of the arterial CO_2-partial-pressure.

Such a ventilator of course serves for the mechanical ventilation of the lung of a patient with the goal of keeping the arterial CO_2-partial-pressure of the patient in a target range by way of a continuously adapted regulation. This ventilator usefully includes the means for mechanical ventilation of the patient and possibly also the sensors required for a perfect functioning of the device. It however includes at least one electronic data processing unit with

- inputs for signals of sensors for readings with regard to the CO_2-partial-pressure in the blood of the patient, and for signals with regard to the ventilation parameters and other setting values of a ventilator,
- outputs for output signals, by way of which output signals, the ventilation parameters are set in the ventilator.

This data processing device furthermore requires memories with data which may be called up.

In one advantageous embodiment of the invention, such data includes

- characteristic line pairs which are stored in the memories, said characteristic line pairs comprising a first characteristic line defining a maximal arterial CO_2-partial-pressure $PaCO_2$, and at a distance to this, a second characteristic line defining a minimal $PaCO_2$, by way of which three regions are defined depending on a ventilation intensity,

specifically a first region "too high", a second region "normal" between the characteristic lines, and a third region "too low",

- and current values as well as values preceding these, with regard to changing ventilation parameters, said values being stored in the memories.

A single characteristic line may be stored instead of characteristic line pairs, and a correction factor for the correction of the ventilation target value which is defined depending on the deviation of a current reading for the arterial CO_2-partial-pressure $PaCO_2$ from this characteristic line, may be provided. The larger the distance between the reading and the characteristic line, the larger is also the correction of the ventilation target value. The correction factor may further be fixed depending on the direction of the deviation, as well as depending on the current intensity of the ventilation or the current ventilation target value. An effect comparable to both characteristic lines may be achieved by way of this, wherein added to this is the fact that the ventilation target value is practically continuously changed, in order to bring the current readings to the optimised value represented in the characteristic line, and is not merely changed until these readings come to lie in the region between the two characteristic lines.

One input possibility with this apparatus is advantageously the therapy target, specifically

- normal withdrawal or
- forced withdrawal.

Again, different characteristic line pairs or characteristic lines and correction factors are assigned to these therapy goal settings. The course of the two characteristic lines or the characteristic line or the correction factor is then optimised according to the therapy goal

Advantageously, a trigger signal which displays the patient's individual activity is taken into account with the computation of the output signals, so that one ventilates according to the wishes of the patient. Furthermore, the computation unit is programmed in such a manner as to determine a spontaneous rate RR_{spont} from a number of acquired trigger signals per time unit. This allows one to ascertain how active the patient is.

A device for regulating a mechanical ventilation of the lung of a patient, or for regulating an apparatus for ventilating the lung, said device being geared to a CO_2-reading, thanks to the following means, may achieve a continuously adapted CO_2-partial-pressure in the arterial blood of the patient, which is fitting for the patient:

- means for regulating or activating the ventilation for achieving a predefined CO_2-partial-pressure.

These means realise the ventilation of the patient e.g. in a conventional manner.

- means for determining a target frequency RR^{sp} as well as for determining a mechanical frequency RR_{IMV} for the ventilation, said mechanical frequency being determined in dependence on the target frequency RR^{sp} and, as the case may be, of a spontaneous frequency RR_{spont}.

A mechanical frequency RR_{IMV} is necessary, so that the ventilator steps in when the patient has not triggered the breath himself. The evaluation of the spontaneous frequency and the target frequency is necessary in order to be able to compare these.

- means for comparing a spontaneous frequency RR_{spont} with the target frequency RR^{sp} and
- means for adapting a ventilation target value by way of a deviation of the spontaneous frequency RR_{spont} from the target frequency RR^{sp}.
- and means for adapting the parameter determining the intensity of the ventilation by way of the ventilation target value.

The adaptation of the factors determining the intensity of the ventilation on account of the adapted ventilation target value serves for relieving the patient who breathes too rapidly.

In one embodiment, the means for adapting the ventilation target value are designed in a manner such that they multiply a target value for the total alveolar ventilation $V'_{gA}{}^{SP}$ by way of a factor larger than 1 should RR_{spont} lie above the computed target frequency RR^{sp} by a certain number of breaths per minute. Usefully, simultaneously with the increase of the target volume $V'_{gA}{}^{SP}$, they may also lower a target value for the ingoing, representative reading $PaCO_2{}^{REP}$ for $PaCO_2$. In another embodiment, the intensity of the ventilation is regulated via the %MinVol as a ventilation target value.

The treatment level which is the intensity of the ventilation may e.g. be defined as RR_{IMV}*(PEEP + P_{insp}). Thereby, RR_{IMV} is the mechanical frequency of the ventilation, PEEP the residual pressure (positive pressure with respect to the atmosphere) during expiration, and P_{insp} the additional pressure during inspiration. This intensity is then specified e.g. as cmH_2O*bpm (bpm = breaths per minute), and lies between 0 and 1500. The intensity of the ventilation may however also be defined in a different manner, e.g. as PIP (peak inspiratory pressure), PEEP + P_{insp}, Pinsp*RR_{IMV} or likewise. Usefully, the intensity of the ventilation is defined by the product of a pressure factor and a frequency factor, or of a volume factor and of a frequency factor.

The task of ventilating a patient according to requirements, is achieved by a method for the regulation of a mechanical ventilation of the lungs of a patient for achieving a continuously adapted CO_2-partial-pressure in the blood of a patient, which comprises the following method steps, or by way of an apparatus with this purpose which implements the following method steps:

- in the case that a CO_2-reading is present: regulating the ventilation for achieving a predefined CO_2-partial-pressure, as the case may be, with a known method. A certain intensity of the ventilation results by way of this.
- determining a target frequency RR^{sp} and a spontaneous frequency RR_{spont}, and as the case may be, a mechanical frequency RR_{IMV} for the ventilation, wherein the mechanical frequency is dependent on the target frequency RR^{sp} and, as the case may be, on a spontaneous frequency RR_{spont}.
- comparison of the spontaneous frequency RR_{spont} with the target frequency RR^{sp}, and
- adapting a ventilation target value on account of a deviation of the spontaneous frequency RR_{spont} from the target frequency RR^{sp}
- adapting the parameters determining the intensity of the ventilation on account of the ventilation target value.

This control loop serves for the prevention of a fatigue of a self-breathing patient who desires a more intensive ventilation, than results from the prior regulation or control of the ventilation.

Usefully, a target value for the total alveolar ventilation $V'_{gA}{}^{SP}$ is multiplied by a factor larger than 1 for adapting the intensity of the ventilation, in the case that RR_{spont} lies above the computed target frequency RR^{sp} more than a certain number of breaths per minute. Accordingly, with a regulation of the ventilation above the %MinVol, this %MinVol is multiplied by a factor larger than 1.

In the case that the basic regulation of the ventilation is geared to a reading which is representative of the $PaCO_2$ of the patient ($PaCO_2{}^{REP}$), then for the adaptation of the intensity of the ventilation, usefully simultaneously with the enlargement of $V'_{gA}{}^{SP}$ or %MinVol, a target value for the ingoing, representative reading $PaCO_2{}^{REP}$ for $PaCO_2$ is reduced. This ensures that a basic regulation directed to a CO_2-reading does not work against this correction on account of the respiration rate. The range for a normal $PaCO_2{}^{REP}$ is thus extended to the bottom by way of lowering the characteristic line for the minimal $PaCO_2{}^{REP}$, or shifted to the bottom by way of lowering the single characteristic line or both characteristic lines.

With a device with which a CO_2-controller is present, as soon as this is active, the respective, current representative reading $PaCO_2{}^{REP}$ is also incorporated into a regulation of the intensity of the

ventilation. This is advantageously effected in that the reading is compared to one or both characteristic lines, and the intensity of the ventilation is changed in a manner such that the representative reading $PaCO_2^{REP}$ tendentially approaches the single characteristic line or is to get between the two characteristic lines. With such a device, the means for adapting the intensity on account of the comparison of the spontaneous rate to the target rate partly assumes the regulation of the intensity of the ventilation instead of the CO_2-controller. These means further have the effect that at latest, with the adoption of the control by the CO_2-controller, the individual characteristic line or both characteristic lines are shifted to such an extent, that the lowered current, representative reading $PaCO_2^{REP}$ lies on the individual characteristic line or centrally between the two characteristic lines. Thereafter, the CO_2-controller again regulates the intensity of the ventilation.

Advantageously, first and second means for determining or adapting a ventilation target value are present. Means for switching-over from the first means to the second means for adapting the ventilation target value, switch over on account of certain criteria. These criteria indicate whether the patient breaths in an adequately spontaneous manner or not.

Advantageously, with a spontaneously breathing patient, the means for adaptation of the ventilation target value on account of the comparison of the spontaneous rate RR_{spont} to the target rate RR^{sp} assume the adaptation of the ventilation target value in accordance with the patient, since these react to the individual reaction of the patient. For this reason, with these, one may regulate the ventilation such that the patient is optimally ventilated in an individual manner and without CO_2-measurement. If the patient however breaths in a too little spontaneous manner, then a predefined setting of the ventilation target value is used as a basis for the respiration, or a CO_2-controller assumes the adaptation of the ventilation target value on account of a reading.

The means for adapting the ventilation target value on account of the comparison of the spontaneous- and target rate are advantageously activated continuously and by way of this adapt the ventilation target value to the requirements of the patient in breaths.

Brief description of the figures

Fig. 1 shows a sketch with a schematically represented electronic circuit, a ventilation device and a patient.

Fig. 2 shows a diagram with two characteristic lines for normal patients.

Fig. 3 shows a diagram with two characteristic lines for COPD-patients.

Fig. 4 shows a diagram with two characteristic lines for ARDS-patients.

Fig. 5 shows a diagram with two characteristic lines for patients with a brain injury.

Fig. 6 shows a diagram with the target frequency on the x-axis and the spontaneous frequency on the y-axis and with three regions, which define whether the percent minute volume is lifted, retained or lowered.

Fig. 7 shows a diagram with the intensity of the ventilation on the x-axis and with the arterial CO_2-partial-pressure on the y-axis, and with two characteristic lines for normal patients between two external regions, and with a reading for the CO_2-partial-pressure between the two characteristic lines.

Fig. 8 shows the diagram according to Figure 7, wherein it is shown that the characteristic lines have been lowered and the intensity of the ventilation has been increased, on account of the spontaneous frequency, with a reading for the CO_2-partial-pressure between the two lowered characteristic lines, achieved by way of this.

Fig. 9 shows a flow diagram which illustrates the regulation for switching over between a pump support system (PSS) -defined ventilation and a differently determined ventilation.

In many cases, the regulation of the ventilation according to the invention is carried out with an apparatus which takes into account a CO_2-reading. Such an apparatus is schematically represented in Fig. 1 and is described hereinafter. The teaching according to the invention described in this context indeed has the advantage that it also makes do without CO_2-measurement when the patient breathes in a spontaneous manner. With ventilators for patients breathing in a non-spontaneous manner however, the integration of a CO_2-controller is useful.

The sketch represented in Figure 1 apart from an electronic circuit 19 comprises a ventilation device 11 with which a patient 13 may be ventilated. The electronic circuit may comprise a CO_2-controller 21. The device according to the invention may however also make do without this CO_2-controller 21, and utilises the reaction of the spontaneously breathing patient, in order to draw conclusions on a ventilation matched to the patient and to approximate this.

The patient is monitored with various sensors. A trigger signal Tg is used in the case that the patient actively breathes in. In any case, these sensors provide a value for the respiratory frequency RR_{spont} triggered by the patient (or readings and setting values from which these values may be derived). These

sensors, with an apparatus provided with a CO_2-controller, provide a value $PACO_2^{REP}$ which is representative of the arterial CO_2-partial-pressure. Furthermore, they may provide the flow of the respiratory gases, the pressure of the respiratory gases and the CO_2-concentration in the respiratory gases FCO_2. From RR_{spont} of these last two values, one may calculate the expiratory time constant of the patient, the ratio V/P of the respiratory volume V to the ventilation pressure P, as well as the serial dead space V_{dS} of the patient lung, in a patient model 15.

The circuit 19 regulates the mechanical ventilation which is effected by the ventilator 11, on account of these signals and computation values.

The basis of the circuit 19 is an "ALV-controller" or an "ASV-controller" (AC) 23. An "ALV-controller" processes a target value for the total alveolar ventilation. An "ASV-controller" processes a target value as %MinVol. As a second member, a "pump support system" (PSS) according to the invention is present, which is indicted at the reference numeral 25. A CO_2-controller 21 may be present as a third member, which computes the target value for the ventilation from a representative reading for the arterial CO_2-partial-pressure as soon as the PSS may not assume its task. The PSS may not assume its task only when the patient breathes in too low a spontaneous manner.

The CO_2-controller (CC):

If a ventilation target value evaluation may not be carried out on account of the PSS, then either a safety setting is set up, or a regulation by way of a CO_2-controller (CC).

The CC 21 on account of an input (lung parameter/patient parameter/therapy goal 27) which defines the patient, in particular his lung condition, his disease or the treatment goal, on account of the representative reading $PaCO_2^{REP}$ for the arterial CO_2-partial-pressure of the patient, and from the present, total alveolar ventilation, calculates the total alveolar ventilation which this patient requires. The computed value for this total alveolar ventilation $V'_{gA}{}^{sp}$ (gross alveolar ventilation) also includes the ventilation of the alveolar dead space V'_{dA}. In place of this total alveolar ventilation $V'_{gA}{}^{sp}$, one may also compute the percent-minute volume %MinVol from the CC. The CC presents this ventilation target value to the ALV-controller or ASV-controlled, known from publications of the applicant, as a basis for the computation of the ventilation frequency and the ventilation pressure. In this context, the following description in which one only refers to the total alveolar ventilation $V'_{gA}{}^{sp}$ also implies %MinVol.

The representative reading is evaluated in that the end-tidal CO_2-content of the airway gases is measured by way of infrared absorption. This end-tidal CO_2-partial-pressure $P_{et}CO_2$ represents the arterial CO_2-partial-pressure $PaCO_2$ relatively well, as long as the alveolar dead space is small. With a larger

alveolar dead space VdA, this measured value may be multiplied by a correction factor. Such a correction factor may e.g. be evaluated with the help of a blood gas analysis and the CO_2-Kapnogram measured at the same time (see e.g. Brunner JX, Wolff G, Pulmonary Function Indices in Critical Care patients, Berlin, Springer publishing house 1988, pages 37 to 39).

The computation of the necessary ventilation by way of the CC is based on the representative value for the arterial CO_2-partial-pressure and the input 27 (lung parameter/patient parameter/therapy goal). The CC assesses the representative value $PaCO_2^{REP}$ differently in accordance with the input 27 (lung parameter/patient parameter/therapy goal). The assessment is effected on account of three regions for $PaCO_2^{REP}$, so that the value may be graded as "too high", "too low" or "normal". By way of changing the target value $V'_{gA}{}^{sp}$ for the ventilation, one attempts to be able to shift the arterial CO_2-partial-pressure in the direction of the region "normal".

As to what is to be assessed as "normal", is dependent on the lung parameter/patient parameter and on the therapy goal inputted by the operating personnel. A different assessment basis is applied depending on this or these input parameters 27.

Four bases for assessment are represented in the Figures 2 to 5. These figures show graphic representations of functions. The intensity of the ventilation is plotted on the x-axis of these representations. This intensity (treatment level) is the product of the mechanical respiration rate RR_{IMV} times the sum of the end-tidal expiration pressure PEEP (positive EndExpiratory pressure) and the insufflation pressure over PEEP:P_{insp}. This scale runs from 0 to 1500 cmH_2O*bpm. The value $PaCO_2^{REP}$ (or "$PaCO_2$") representative of the arterial CO_2-partial-pressure is plotted on the y-axis. This pressure may as a rule not increase above a value of 65 mmHg. This value should as a rule also not fall below a value of 33 mmHg, since otherwise the ventilation is operated too intensively. With normal patients without ARDS, COPD or brain injury, at least 38 is to be assumed as a lower value and maximally 65 as an upper value. With brain injuries, the normal region 22 is even tighter and to be understood as being lower between 33 and 400 mmHg. With ARDS-patients, a normal region 33 lies between 40 and 65 mmHg. With COPD-patients tendentially even greater between 45 and 65 mmHg. The specified values are merely provisional assumptions which need to be confirmed or corrected by way of experimental trials.

Each assessment basis has three regions "too high" 35, "normal" 33 and "too low" 31. These regions are separated by the characteristic lines 37, 39. The upper characteristic line 39 marks the upper limit for the CO_2-partial-pressure, the lower characteristic line 37 the lower limit for the CO_2-partial-pressure. Thus the normal region 33 lies between these characteristic lines. If the representative value $PaCO_2^{REP}$ (or "$PACO_2$") falls in this region, then a change in the target value $V'_{gA}{}^{sp}$ is carried out.

These characteristic lines do not run parallel over the whole x-axis, for optimising the treatment intensity and the CO_2-partial-pressure of the patient. The characteristic line increases from an intensity of the ventilation which is necessary for the survival of the patient (i.e. from a limit value between 250 and 350 cmH_2O*bpm). This means:

With a normal patient (Fig. 2), with a ventilation intensity of 300 mmH_2O*bpm, values for $PaCO_2^{REP}$ which lie in the region of 41.4 to 49 are considered as being alright. The more the intensity however increases, be it due to an increase of the mechanical respiration rate RR_{IMV}, due to an increase of the PEEP and/or due to an increase in the inspiratory pressure P_{insp}, the upper limit and the lower limit of the normal region 33 is lifted. The normal region therefore with an intensity of 1500 cmH_2O*bmp ends at a level of at least 55 (characteristic line 37) and at the most 65 mmHg (characteristic line 39). The characteristic lines with the specified, linear scales are straight lines and with an intensity of 0 end at the values 38 (characteristic line 37) and 45 mmHg (characteristic line 39).

The assessment basis for a COPD-patient is graphically represented in Fig. 3. The assessment basis for an ARDS-patient is graphically represented in Figure 4. The characteristic lines 37, 39 with both representations have a lowest value at 300 cmH_2O*bpm. This means below this limit value of the ventilation intensity, the region for values for $PaCO_2^{REP}$ are to be graded as normal, is lifted with an increasing intensity. This course of characteristic lines has the effect that the reduction of the intensity as well as the increase of the intensity below this limit value must tendentially have a greater extent, in order to correct a $PaCO_2^{REP}$-value outside the normal region 33, than is the case with an intensity above this limit value. For this reason one corrects in a finer manner above this limit value than below the limit value.

With ARDS-patients furthermore, one strives for a lower CO_2-partial-pressure than with COPD-patients. With brain injuries, one takes characteristic lines running in a flat manner which delimit a relatively tight region with a relatively low CO_2-partial-pressure as a normal region 33.

The extended ALV- or ASV-controller (AC):-

The AC on account of the ventilation target value predefined by the CC or the PSS computes a target value RR_{sp} for the respiration rate, and an inspiratory pressure P_{insp}. The AC on account of the serial dead space and the expiratory time constant of the respective patient, with the formulae of Otis and Mead, computes the respiratory frequency and the tidal volume necessary for achieving the predefined target value $V'_{gA}{}^{sp}$ or %MinVol. This AC is indicted here as extended, since, differently to the known ALV-controller, it also computes with the Mead formula.

The actual respiration rate RR_{tot} with a passive patient is equal to the machine respiration rate RR_{IMV}, and this is equal to the target value RR_{sp} for the respiration rate. An active patient on the other hand breathes himself, and by way of this activates the support by the ventilator himself. By way of a breath triggered by the patient, the actual respiration rate RR_{tot} is increased with respect to the machine respiration rate RR_{IMV}. This increase is recognised by the AC, and it sets the machine respiration rate RR_{IMV} lower that the target value RR^{sp}, so that the patient may trigger the breath himself. The higher the actual respiration rate RR_{tot} lies above the machine respiration rate, the more this machine respiration rate approaches a minimal rate. The target rate RR_{sp} on the other hand remains at the level which is always computed afresh on account of the setting of the CC.

The AC 23 according to Figure 1, depending on the activity of the patient, selects the formula according to Otis or the formula according to Mead for computing the tidal volume VT^{sp} and the appropriate frequency RR^{sp}. Subsequent regulators regulate RR_{IMV} and P_{insp} in order to achieve by RR^{sp} and VT^{sp}. The inspiration time TI is furthermore fixed.

The pump support system (PSS):

The PSS serves for preventing the fatigue of the patient, who desires a lower CO_2-content in his blood, than is achieved by the predefined setting, and therefore actively lifts the respiratory frequency. It regulates the ventilation on account of the active change of the spontaneous respiration rate, and therefore on account of patient behaviour, not on account of a CO_2-reading.

In a first embodiment, the PSS is designed as follows and has an influence on the CC:

At an interval of in each case 3 minutes, the difference between RR_{spont} minus RR^{sp} is checked. Thereby, a tolerance range of 5 breaths results. If a difference of >5 is ascertained, which is not caused by autotriggering, the ventilation target value $V'_{gA}{}^{sp}$ is increased by the CC by a factor of 1.02. Simultaneously, the lower characteristic line 37 is lowered to "current $PaCO_2^{REP}$ - 5mmHg", so that a lower CO_2-partial-pressure is assessed as normal. For this reason, the target value $V'_{gA}{}^{sp}$ as a result is not reduced by the CC when $PaCO_2^{REP}$ also drops below the uncorrected lower characteristic line 37. As soon as RR_{spont} again lies above RR^{sp} for 10 minutes within these 5 breaths/min, the characteristic line is then set back again. By way of this, the CC may adapt the target value $V'_{gA}{}^{sp}$ inasmuch as $PaCO_2^{REP}$ gets into the region 31 for values which are too low on account of this shifting of the characteristic line. The tolerance region is increased from 5 to 10 breaths/min with a strategy for withdrawal.

A correction of a ventilation target value or the intensity of the ventilation with the PSS is basically possible independently of whether a representative reading for the arterial CO_2-partial-pressure is available or not.

The PSS may therefore also be designed in the following manner, and, if a CC is present, may have no influence on this unless the CC is switched off when the patient breathes in an adequately spontaneous manner, and is switched on when he does not breathe in a sufficiently spontaneous manner.

The spontaneous frequency is compared to the target frequency over a certain number (e.g. 5, 8, 15 or 30) of consecutive breaths. If thereby, it is ascertained that the spontaneous frequency deviates from the target frequency by a distance value, then depending on this distance value, the %MinVol setting is increased, left alone or reduced. As a distance value within which no change of the %MinVol is carried out, it is suggested to take a fraction or percentage of the percent minute volume, thus of example the set %MinVol divided by 20. At 100%MinVol, the increased frequency results in a difference of up to 5 bpm from the target value, within which region the %MinVol is left unchanged. At 200%MinVol, this region is accordingly 10 bpm wide.

In the diagram according to Fig. 6, the target rate RR^{sp} of the ventilation is plotted on the x-axis and the spontaneous frequency RR_{spont} on the y-axis. The square spanned between both axes is divided into three regions:

A first region extends from the x-axis up to the diagonal through the axis intersection point and includes this diagonal. This diagonal is defined by $RR^{sp} = RR_{spont}$.

A second region borders this diagonal and in the y-direction has an extension k, wherein k may be dependent on the percent minute volume. It may also or alternatively be dependent on the target rate. In any case, this extension k of the second region is advantageously formed in a variable manner.

A third region fills the square between the second region and the y-axis.

Advantageously it is the case: if the spontaneous rate RR_{spont} drops into the first region ($RR_{spont} <$ or $= RR^{sp}$), the percent minute volume is reduced under certain circumstances. It may not be reduced if a minimal value (e.g. 100%) has already been reached and/or of the conditions apply, that one may not drop below the initial value defined by the physician, and/or an increase has not yet been carried out. If the spontaneous rate drops into the second region, the presently set percent minute volume is retained. If the spontaneous rate drops into the third region, the percent minute volume is lifted.

If a measurement representative of the arterial CO_2-partial-pressure is present, then the characteristic lines of the CC which define the permissible region for the arterial CO_2-partial-pressure, may be adapted on account of a deviation of the spontaneous frequency from the target frequency.

A reduction of the %MinVol on account of a comparison of RR_{spont} with RR^{sp} may also need to be carried out only if previously an increase of the %MinVol above a predefined lower limit value has taken place by way of such a comparison.

A reduction of the %MinVol may preferably always be carried out when the following conditions are fulfilled:
%MinVol above 100% and
$RR_{spont} <$ or $= RR^{sp}$.

With a reduction of the %MinVol as a result of a measurement of the $RR_{spont} <$ or $= RR^{sp}$, one may also differentiate as to whether a CO_2-measurement is available or not. If no CO_2-measurement is available, and if a CC with characteristic lines for the value representative of the arterial CO_2-partial-pressure is present, then the characteristic lines of the CC may be lowered. The present measurement value $PaCO_2^{REP}$ which lies in the region 35 as a result of the over- control of the CC by way of the PSS, and would therefore be graded as "too low" by the CC, on account of this, enters between the two characteristic lines into the normal region 33. Thereafter, the reduction of the %MinVol is left to the CC.

Characteristic line pairs 37, 39 are represented in Figure 7 and 8. These may be displaced within limits in order to meet the requirements of the patient. The displacement is however limited by the extreme regions 41 and 43 which may not fall into the normal region.

An initial position is represented in Figure 7. It is now assumed that the patient is be ventilated at 130%MinVol at a target rate RR^{sp} of 17pbm and thereby tires. For this reason, he breathes in a more rapid and shallower manner. The spontaneous rate RR_{spont} lies at 31 bpm for a minute. Since the spontaneous rate over 30 breaths exceeds the target rate RR^{sp} by more than 13 breaths (130%MinVol*mbp/10*10%), the PSS reacts by way of an increase of the %MinVol for example by 10%. By way of this, the intensity of the ventilation (or of the ventilation target value) is increased. The $PaCO_2^{REP}$ drops as a result. A reading would therefore no longer lie within the normal region.

It is to be expected that the limits for an increase of the %MinVol by way of the PSS is no longer achieved subsequent thereto. Assuming that the patient, as a result of his lower arterial CO_2-partial-pressure, now reduces the spontaneous rate RR_{spont} to 17bpm ($=RR^{sp}$) or less, then a reduction of the %MinVol is triggered. The PSS may give rise to the characteristic lines to be lowered according to Fig. 7,

until the representative measurement lies in the normal region (Fig. 8), and the reduction of the intensity of the ventilation may be left to the CC. Such an adaptation of the characteristics lines and the transfer to the CC may also be effected as soon as the PSS no longer needs to increase the %MinVol. Then, the over-controlling of the CC by the PSS may be ended, and the adaptation of the ventilation may be left to the CC.

If the patient however breathes in a sufficiently spontaneous manner, then preferably the ventilations continues to be regulated by the PSS.

The adaptation of the %MinVol by the PSS is limited. The PSS may not change the minute volume to below 100%, or, if desired, below the value defined by the CC or by the physician, and for example not to above 250%MinVol.

The flow diagram represented in Figure 9 illustrates the decision procedures for the connection and disconnection of the PSS in a preferred embodiment

If a ventilator provided with a PSS according to the invention is switched on, or the pump support system is switched on, then this is firstly not yet active (block "PSS off"). Prior to this, one ventilates according to a ventilation target value defined by a physician or the CC, and thereby checks as to whether the patient breathes in an adequately spontaneous manner (Rhombus "Criterion 1" between the blocks "PSS on" and "PSS off"). If this criterion is not fulfilled, the PSS remains inactivated (arrow "no" back).

If the criterion is fulfilled, the PSS is activated (block "PSS on"). With an activated PSS, one continuously monitors as to whether the breathing is still effected in a spontaneous manner (Rhombus "Criterion 2"). If it is ascertained that the patient breathes sufficiently spontaneously, then the PSS remains unchanged activated (arrow "no" back). If a switch-off criterion is however fulfilled because the patient no longer breathes sufficiently spontaneously, in order to be able to be applied as a "natural CO_2-sensor", one requires a decision. This decision (Rhombus "CO_2") is effected on account of the fact as to whether a CO_2-measurement is present or not. If no CO_2-measurement is present, because the apparatus for example has no CO_2-controller or because the CO_2 measurement does not function, then the PSS on a safety setting triggers an alarm (display) (arrow "no", block "100%MinVol"). The PSS is then inactivated in its regulating function (block "PSS off"). The safety setting ensures that the patient is ventilated in an adequate if not optimised manner, thus for example with the ventilation target value of 100%MinVol. This setting is then converted from the ASV-controller (or from the ALV- controller) into parameters of the mechanical ventilation which are adequate for the patient. This setting may be changed by the physician whose is called e.g. on account of the alarm. One may envisage the physical setting of the

physician being applicable each time when the PSS is inactivated, for a repeated exchange between ventilation target value evaluations determined by the PSS and those determined manually.

If however a CO_2-reading and a CO_2-controller are present, then this CO_2-controller is activated, in order to determine the ventilation target value on account of the CO_2-reading. The CO_2-controller assumes the task of the PSS, and the PSS is inactivated.

In this operating mode of the ventilator determined by the CO_2-controller, one again monitors as to whether the patient breathes sufficiently spontaneously, in order in this case to again activate the PSS and to again deactivate the CO_2-controller.

For ascertaining as to whether the patient breathes adequately spontaneously, (criterion 1), in order to activate the PSS, it is compared as to whether a number (e.g. 3) of directly consecutive breaths are effected spontaneously. The time period permissible for this is determined by way of the target frequency RR^{sp}.

A difference between the total respiratory frequency and the spontaneous respiratory frequency is monitored for ascertaining as to whether the patient no longer breathes in an adequately spontaneous manner, so that the PSS must be switched off. A predefined number of consecutive breaths (e.g. 8) are monitored, wherein this number is continuously monitored. This means that with each breath, in each case the last for example 8 breaths must be triggered alone by the patient, and may therefore not have any machine-triggered breaths. If this condition is fulfilled at least once within a defined period of time (e.g. one minute), then the PSS remain activated. The PSS is however relieved by a machine or manual evaluation of the ventilation target value geared to a CO_2-reading, if this number of directly consecutive spontaneous breaths directly occurs not once within this time period. In other words, if the ventilator within the selected time period within each sequence of the selected number of breaths adds a machine-triggered breath, then a setting of the ventilation target value is applied, which is different to the setting determined by the PSS.

Patent claims

1. A device with the following means for the regulation of a changing intensity of a mechanical ventilation:

- means for determining a target frequency RR^{sp},
- means for determining a spontaneous frequency RR_{spont},
- means for comparing the spontaneous frequency RR_{spont} with the target frequency RR^{sp},

characterised by

- means for adapting a ventilation target value (%MinVol, $V'_{gA}{}^{sp}$) on account of the result of the comparison of the spontaneous frequency RR_{spont} with the target frequency RR^{sp} and
- means for adapting the parameters determining the intensity of the ventilation, on account of the ventilation target value (%MinVol, $V'_{gA}{}^{sp}$).

2. A device according to claim 1, characterised by means for setting the target rate RR^{sp} on account of the adapted ventilation target value (%MinVol, $V'_{gA}{}^{sp}$).

3. A device according to claim 1 or 2, characterised by means for setting the ventilation pressure or the breath volume on account of the adapted ventilation target value (%MinVol, $V'_{g}A^{sp}$).

4. A device according to claim 2 and 3, characterised by a controller for matching the parameters determining the intensity, in particular of the ventilation pressure or the breath volume on the one hand, and the ventilation frequency (RR^{sp}, RR_{IMV}) on the other hand, on account of patient parameters.

5. A device according to one of the claims 1 to 4, characterised in that the means for adapting the ventilation target value increase this, when the spontaneous frequency RR_{spont} is greater that the target frequency RR^{sp} at least by a defined distance value.

6. A device according to one of the claims 1 to 5, characterised in that the means for adapting the ventilation target value reduce this, when the spontaneous frequency RR_{spont} is smaller than the target frequency RR^{sp}.

7. A device according to claim 6, characterised in that means for adapting the ventilation target value reduce this, when the spontaneous frequency RR_{spont} is equal to the target frequency RR^{sp}.

8. A device according to claim 5, characterised in that the distance value is defined depending on the presently set target frequency RR^{sp}.

9. A device according to claim 5, characterised in that the distance value is defined depending on the presently measured spontaneous frequency $RR_{spont.}$

10. A device according to claim 5, characterised in that the distance value is determined depending on the intensity of the ventilation.

11. A device according to one of the claims 5 to 9, characterised in that the distance value is determined as a fraction of the current %MinVol.

12. A device according to one of the claims 1 to 11, characterised in that the means for adapting the ventilation target value multiply this by a factor larger than 1, in particular by a factor of approx. 1.02 with a breath-wise correction of the ventilation target value, up to approx. 1.1 with larger correction intervals, in the case that RR_{spont} lies above the computed target frequency RR^{sp} by a certain number of breaths per minute.

13. A device according to claim 12, characterised in that means for the temporal control of the means for adapting the ventilation target value are present, which are of the nature such that the means for adapting the ventilation target value are activated in a periodic time interval, e.g. 1 minute, which may be set as the case may be.

14. A device according to claim 12, characterised in that the means for adapting the ventilation target value are continuously activated and adapt the ventilation target value in a breathwise manner.

15. A device according to one of the preceding claims, characterised in that second means for determining and/or adapting the ventilation target value are present, and means for switching-over from the first means to the second means for adapting the ventilation target value are present.

16. A device according to claim 15, characterised in that a CO_2-controller is present, which - if activated – incorporates respective, current representative readings $PaCO_2^{REP}$ into a regulation of the ventilation, in that the reading is compared to an individual or two characteristic lines, and the ventilation is changed in a manner such that the representative reading $PaCO_2^{REP}$ tendentially approaches the individual characteristic line or is to get between the two characteristic lines.

17. A device according to claim 16, characterised in that depending on how spontaneous the patient breathes, the means for adapting the ventilation target value on account of the comparison of the spontaneous rate RR_{spont} with the target rate RR^{sp}, or the CO_2-controller, assume the adaptation of the ventilation target value

18. A device according to claim 17, characterised in that at the latest with an adoption of the regulation by the CO_2-controller, the individual characteristic line or the two characteristic lines are displaced to such an extent, that the current, representative reading $PaCO_2^{REP}$ lies on the individual characteristic line, or centrally between the two characteristic lines.

19. A device according to one of the claims 1 to 18, characterised in that the means for adapting the ventilation target value increase this – specifically e.g. a target value for the total alveolar ventilation, a target value for the minute volume or for the %MinVol, in the case that RR_{spont} has a defined distance (k) to RR^{sp}.

20. A device according to claim 19, characterised in that the defined distance is dependent on the therapy goal and/or on the target rate RR^{sp}.

21. A device according to one of the preceding claims, characterised by means (11) for regulating or activating the ventilation according to the parameters which are determined by the specified means and which determine the intensity of the ventilation

22. A device according to one of the preceding claims, characterised in that the intensity of the ventilation or the treatment level is essentially determined by the product of a pressure factor (P) or volume factor (V), and a frequency factor (RR) of the present ventilation settings.

23. A device according to one of the claims 15 to 22, characterised in that a control loop is present, which for activating the first means for adapting the ventilation target value on account of the result of the comparison of the spontaneous frequency RR_{spont} with the target frequency RR^{sp}, monitors the fulfilment of a first criterion, and for switching from these first means to the second means for determining and/or adapting the ventilation target value, monitors the fulfilment of a second criterion, wherein the second criterion sets lesser demands on the spontaneous breathing of the patient than the first criterion.

24. A method for the automatic regulation of an intensity of a mechanical ventilation of the lung of a patient, carried out by an apparatus, which comprises

- determining a target frequency RR^{sp} and a spontaneous frequency RR_{spont},
- comparison of the spontaneous frequency RR_{spont} with the target frequency RR^{sp},

characterised by

- an automatic adaptation of a ventilation target value (%MinVol $V'_{gA}{}^{SP}$) on account of a deviation of the spontaneous frequency RR_{spont} from the target frequency RR^{sp},
- an automatic adaptation of parameters determining the intensity of the ventilation, on account of the ventilation target value.

25. A method according to claim 24, characterised in that the ventilation target value, specifically e.g. a target value for the total alveolar ventilation $V'_{gA}{}^{SP}$, the minute volume or the percent minute volume, is multiplied by a factor larger than 1, if RR_{spont} has a defined distance to RR^{sp}, i.e. lies above the computed target frequency RR^{sp} more than a certain number of breaths per minute, or lies above the computed target frequency more than a number of breaths per minute, which is dependent on the presently set ventilation target value.

26. A method according to claim 24 or 25, characterised in that depending on how spontaneously the patient breathes, the ventilation target value is adapted on account of the comparison of the spontaneous rate RR_{spont} with the target rate RR^{sp}, or on account of a CO_2-measurement.

27. A method according to claim 26, characterised in that with an adaptation of the ventilation target value on account of a reading, a respective current representative reading $PaCO_2{}^{REP}$ is incorporated into the regulation of the ventilation, in a manner such that the reading is compared to one or both characteristic lines, and the ventilation is changed in a manner such that the representative reading $PaCO_2{}^{REP}$ tendentially should approach an individual characteristic line or come between the two characteristic lines.

28. A method according to claim 27, characterised in that before the adoption of the regulation by the CO_2-controller, the individual characteristic line or the two characteristic lines are displaced to such an extent that the representative reading $PaCO_2{}^{REP}$ which is present with the adoption lies on the individual characteristic line or centrally between the two characteristic lines.

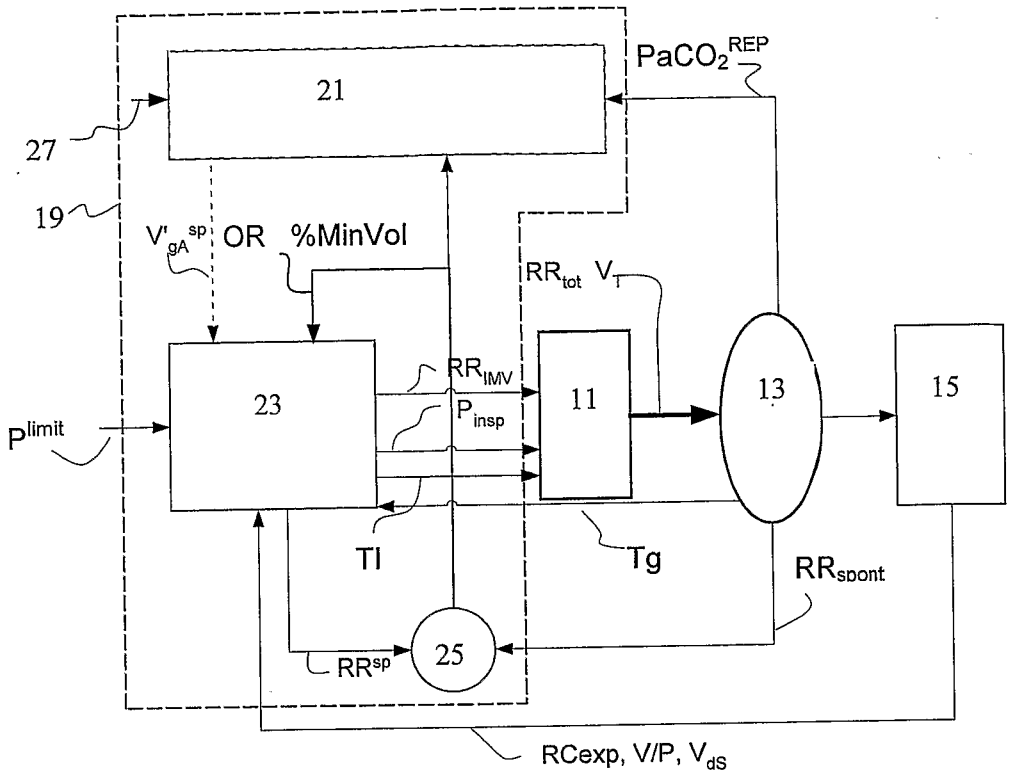
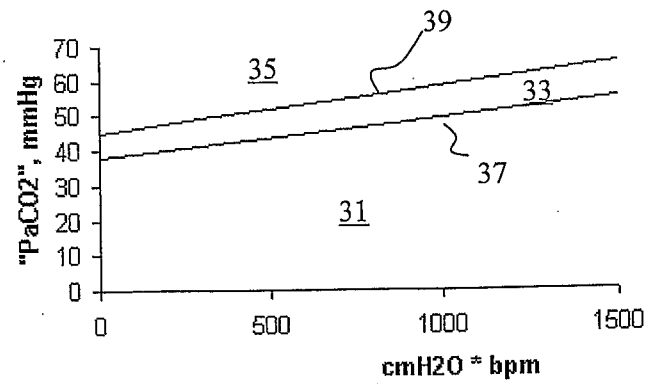

21
27
19
$PaCO_2^{REP}$
$V'_{gA}{}^{sp}$ OR %MinVol
RR_{tot} V_T
23
RR_{IMV}
P_{insp}
11
13
15
P^{limit}
TI
Tg
RR_{spont}
25
RR^{sp}
RCexp, V/P, V_{dS}

Fig. 1


39
35
33
37
31
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60
50
40
30
20
10
0
0
500
1000
1500
cmH2O * bpm

Fig. 2

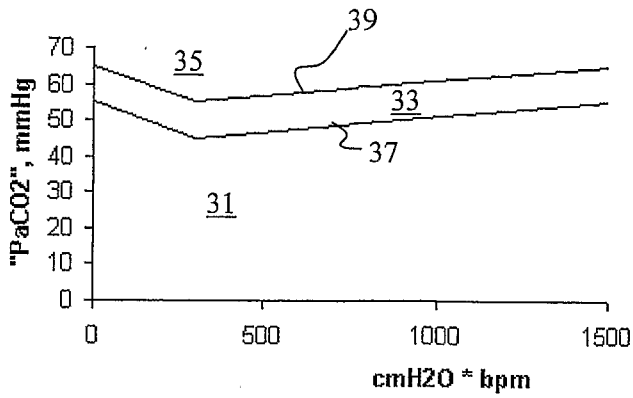

Fig. 3

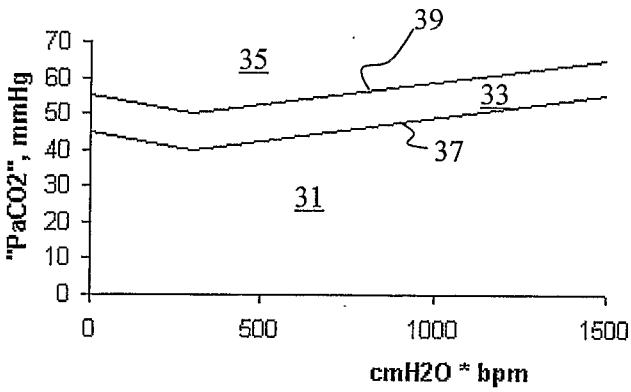

Fig. 4

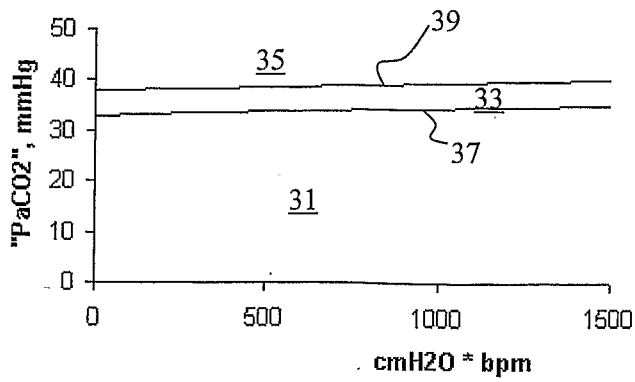

Fig. 5

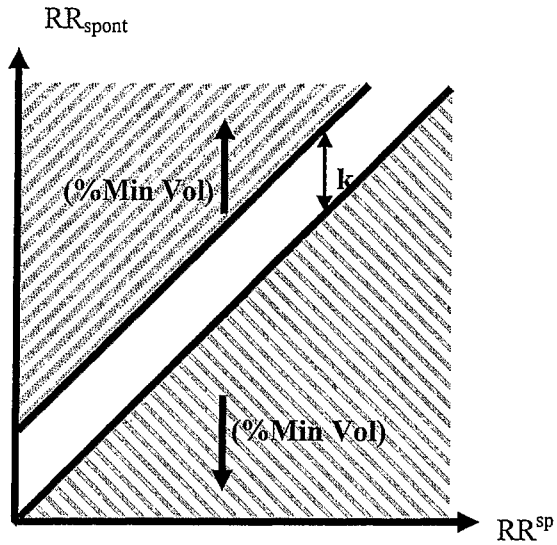

Fig. 6

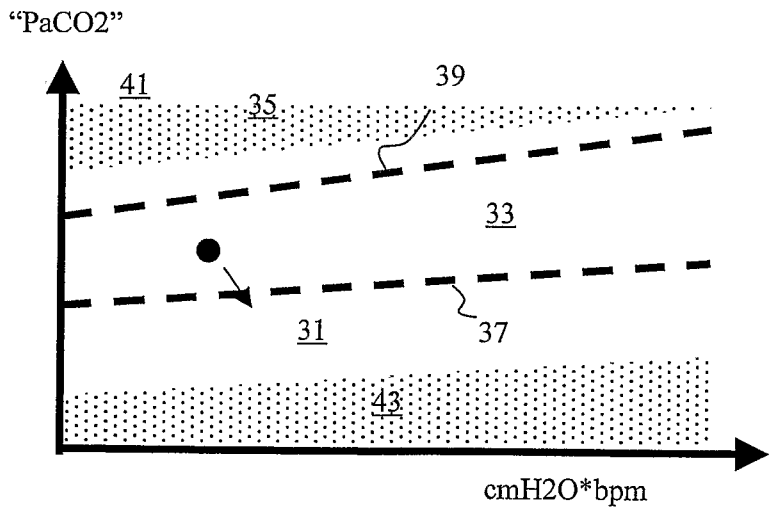

Fig. 7

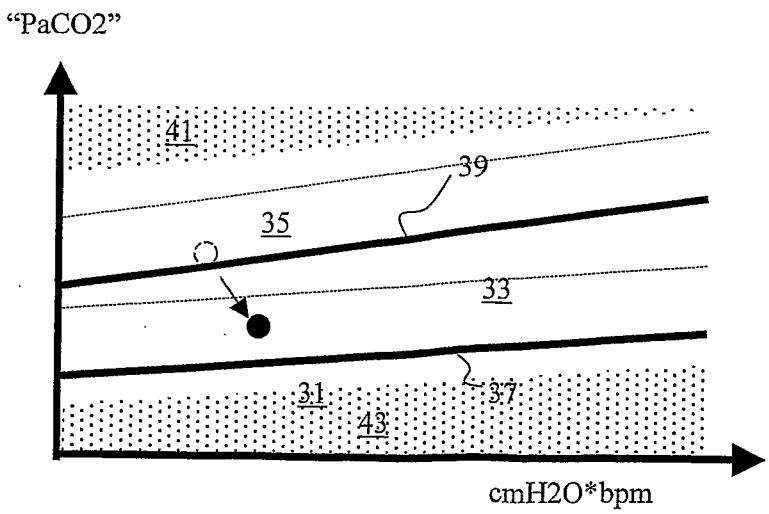

Fig. 8

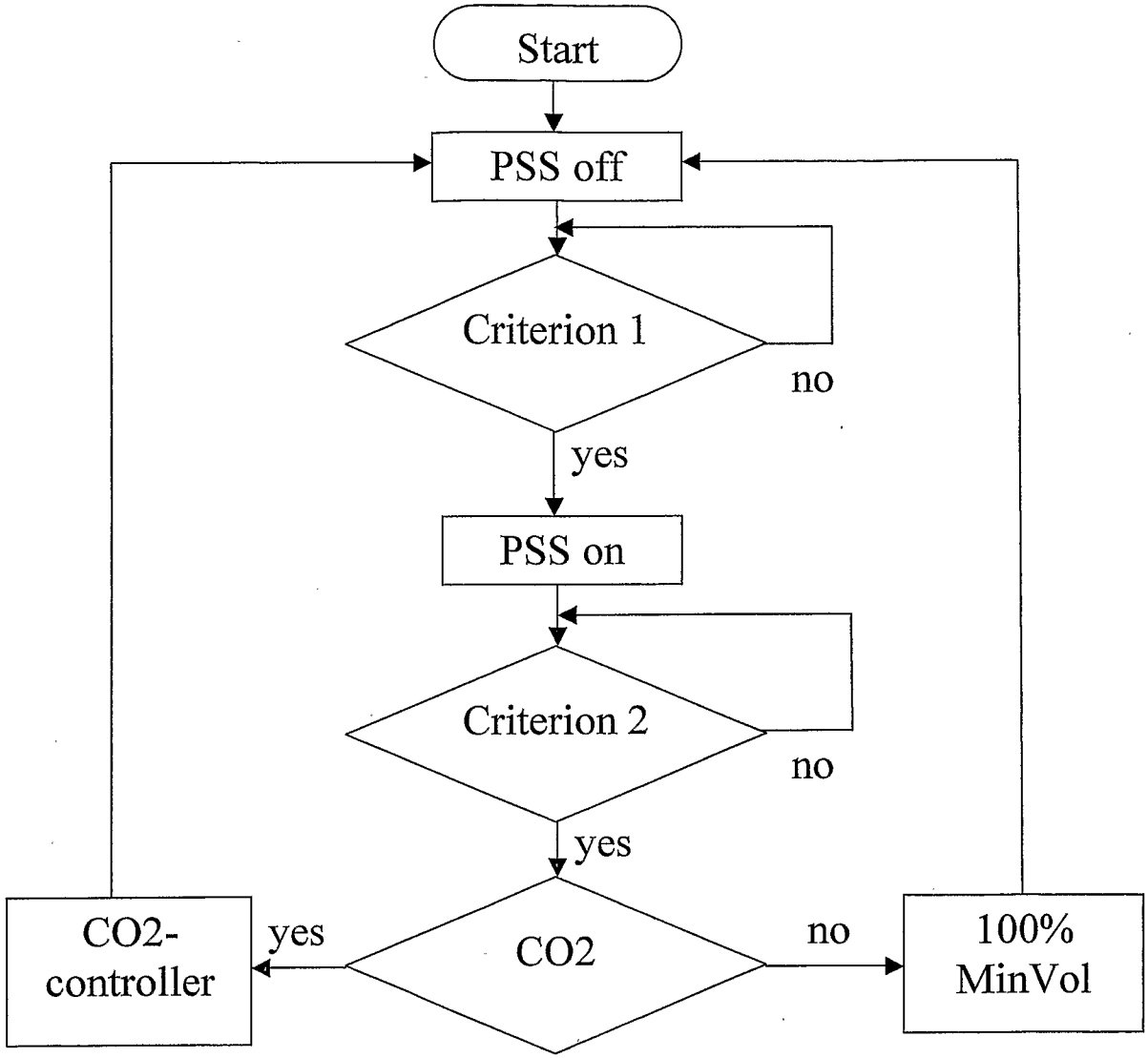
Start
PSS off
Criterion 1
no
yes
PSS on
Criterion 2
no
yes
CO2-
controller
yes
CO2
no
100%
MinVol

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2007/000040

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	J.M. CAIRO, S.P. PILBEAM: "Mosby's respiratory care equipment" 2004, MOSBY , US, ST LOUIS 288730 , XP002427922 page 477 - page 494; figures 12.44-12.54	1-23
X	EP 0 347 282 A1 (AIR LIQUIDE [FR]) 20 December 1989 (1989-12-20) cited in the application column 2, line 35 - column 4, line 26; figure 1	1-14, 19-23
X	EP 0 753 320 A (LACHMANN, BURKHARD, PROF; LACHMANN, BURKHARD, PROF. DR) 15 January 1997 (1997-01-15) column 7, line 41 - column 22, line 55; figures	1-23

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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"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
10 April 2007	23/04/2007

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	Zeinstra, Hilaire

INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2007/000040

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 578 575 B1 (JONSON BJOERN) 17 June 2003 (2003-06-17) column 1, line 46 - column 2, line 27 column 4, line 43 - column 11, line 10; figures 1-2A	1-23
A	US 6 071 237 A (WEIL ET AL) 6 June 2000 (2000-06-06) column 5, line 48 - column 9, line 62; figures	1,15-18
A	FR 2 356 408 A (INSERM) 27 January 1978 (1978-01-27) page 2, line 7 - page 5, line 36	1,15-18
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH2007/000040

Box 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.: 24-28
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 therapy

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 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 all searchable claims.

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

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers 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.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

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