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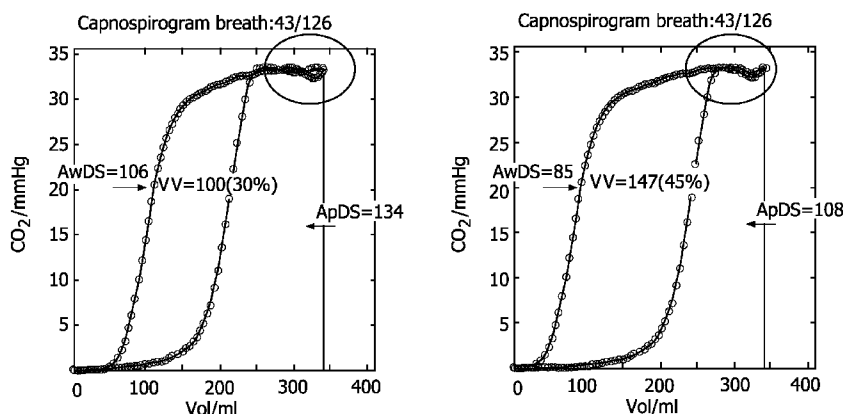


FIG. 2

(57) Abstract: The invention provides a method for obtaining and evaluating spirometric and gas exchange data, comprising measuring a concentration of a breathing gas $gc(V_x)$ for a plurality of volumes V_x of breathing gas mix, wherein the measuring is performed on inhaled breathing gas mix, further comprising determining an apparatus dead space $ApDS$, of breathing gas mix in the apparatus not taking part in gas exchange, by evaluating the measured concentrations $gc(V_x)$ as a function of the volume V of the inhaled breathing gas mix. The use of inhaled breathing gas mix allows to determine the apparatus dead space, which is an important parameter when evaluating ventilation efficiency and the like. Furthermore, the invention provides a method in which inhalation and exhalation parts of a spirogram are synchronised, by matching features thereof, in order to further improve the accuracy of gas exchange volumes and derived data. Finally, the invention provides a spirometric device and a patient ventilation apparatus, incorporating the present method.

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METHOD AND DEVICE FOR EVALUATION OF SPIROGRAPHIC AND GAS EXCHANGE DATA

FIELD OF THE INVENTION

The invention relates to methods and devices for the evaluation of spirographic and gas exchange data, to obtain more information and/or more accurate information therefrom.

5 BACKGROUND OF THE INVENTION

In the state of the art, it is known to obtain spirographic information. In known spirographic methods, such as described in WO2006/018237, the concentration of a gas in exhaled breathing gas mix, often carbon dioxide or oxygen, is measured for a plurality of values of expired volumes. In this way, one obtains the gas concentration as a function of
10 volume. From this function, one can estimate the airway dead space, which relates to a volume of breathing gas mix that is moved through the (upper) airway, such as the windpipe and bronchi, does not enter the alveoli, and hence does not take part in the gas exchange. Additionally, it relates to alveolar dead space, which is the volume of air that remains in the alveoli, even when exhaling to the max. Many methods have been designed to determine
15 these dead spaces, such as by Fowler, in "The Respiratory Dead Space", Am J Physiol 154, 405-416 (1948).

By means of these dead spaces, and of course other information, one can monitor the respiratory processes in a human or animal subject, in order e.g. to establish its health state and changes therein.

20 In practice, it has been found that the obtained information is not always sufficient or sufficiently accurate. For example, sometimes a correct diagnosis, monitoring, or adequate ventilation of the subject is not reliably possible.

OBJECT OF THE INVENTION

It is an object of the invention to improve the known spirographic and gas
25 exchange methods and apparatus, to allow more accurate information to be obtained.

SUMMARY OF THE INVENTION

To achieve the above object, in a first aspect, the invention provides a method for obtaining and evaluating spirographic data, comprising measuring a concentration of a breathing gas $gc(V_x)$ for a plurality of values of a volume V_x of breathing gas mix, for an animal or human being, with a suitable apparatus, wherein the measuring is performed on inhaled breathing gas mix, further comprising determining an apparatus dead space $ApDS$, of breathing gas mix in the apparatus not taking part in gas exchange, by evaluating the measured concentrations $gc(V_x)$ as a function of the volume V of the inhaled breathing gas mix.

The inventors have found that using the inspired part of a spirogram, instead of or in addition to the expired part, can give useful additional information. In particular, it allows to determine an apparatus dead space $ApDS$, which relates to (inter alia) tubing, filter between a gas sensor and a Y-piece towards a ventilator apparatus. This is also a volume that is moved when breathing, or ventilating, but which does not partake in the gas exchange and which is not determined with the known methods or apparatus.

The part of the method to determine the $ApDS$ itself can be chosen in accordance with any known method to determine a respiratory dead space, as will be exemplified below. And such method is not deemed to lie at the heart of the invention. This is rather realizing that the apparatus dead space is an important quantity, and realizing that this quantity may be determined with the help of the inhaled part of the spirogram. Similarly, any known apparatus suitable for obtaining a spirogram, in particular the inhaled part, may be used in the method.

Below, particular embodiments will be disclosed, which are only deemed examples of the general inventive principle.

In an embodiment, the step of determining $ApDS$ comprises applying a mathematical operation to the measured concentrations as a function of volume. In particular, said mathematical operation comprises determining a $gc(V_1)$ at a first volume V_1 at the beginning of inhaling, determining a $gc(V_4)$ at a second volume V_4 at the end of inhaling, and determining the $ApDS$ as the difference between V_1 and a volume V_2 at which $gc(V_2) = (gc(V_4) + gc(V_1))/2$, also coming down to about $0.5gc(V_1)$. The various volumes identified above may also be found in Figure 1b. Note that these volumes may be plotted as is usual, i.e. the origin being zero exhales volume, and exhales volume is plotted on the positive abscissa. Of course, if a different way of plotting is used, the skilled person will accordingly use minus signs etc. where needed. The above is one of the simplest (mathematical) methods to determine the $ApDS$. Alternatively, one could use a method similar to Fowler's, i.e. fit a

straight line to the data corresponding to the volumes of deepest exhaling, but in this case at the beginning of inhaling, and determine ApDS as the volume where the areas r and s in Fig 1b are equal. Many other methods have been found in the state of the art to determine airway dead space, such as in the mentioned document WO2006/018237. All such methods could be applied to determine the apparatus dead space, in accordance with the present invention.

In the present context, it is possible that the start and end points of consecutive breaths do not match, as individual breaths need not be equally deep. However, one could take average values. Furthermore, it is not always necessary to determine the final value of the gas concentration, i.e. at the end of inhaling, because in the majority of cases, this final value will be substantially equal to the value for fresh gas, often room air. Such value could be determined once. Of course, for the most accurate measurements, the final value is also measured.

Also disclosed are embodiments further comprising the steps of measuring $gc(V_x)$ for a plurality of values of a volume V_x of exhaled breathing gas mix and of determining an airway dead space AwDS and/or alveolar dead space AID_S by evaluating said measured concentrations. By combining the present invention with such a step, additional information about dead spaces may be obtained, which is useful when setting up a ventilation scheme for a patient, evaluating a spirogram of a patient, and so on. The airway dead space and/or alveolar dead space may be determined with the aid of any known method, such as the ones mentioned above and/or in e.g. WO2006/018237.

In a particular embodiment, the method further comprises the step of determining a ventilated volume VV as $VV = V1 - (ApDS + AwDS)$, and preferably comprising the step of determining a ventilation efficiency VE as $VE = VV/V1$. herein, V1 equals a total tidal volume, i.e. the difference between maximum measured volume and minimum measured volume. By including the ApDS, more accurate results may be obtained. This may be very important when establishing breathing efficiency of a subject, or ventilating a subject. The inventors have seen clinical recordings where the effective volume of a breath to remove CO₂ was only 40% of the total volume used to blow the lungs. This causes unwanted stress on the lungs and can cause lung damage and prolong weaning.

It is to be noted that the breathing gas in the present invention could be e.g. carbon dioxide or oxygen, although others such as water vapour are not excluded. In an embodiment, the concentrations of both carbon dioxide and oxygen are measured and evaluated. Preferably, at least one of ApDS, AwDS and AID_S is determined for both a

corresponding oxyspirogram and a capnospirogram. This gives more accurate results, since the results for carbon dioxide may be compared to those for oxygen, or vice versa.

Further information may be obtained in a method according to the invention, wherein the total eliminated carbon dioxide or uptaken oxygen is determined from a combination of the inhaled and exhaled part of the spirographic data. As is known per se, these quantities may be determined from a spirogram by determining the area between the expired and inspired part of the spirogram.

In an important further embodiment, the method further comprises the step of synchronizing an exhaled part and an inhaled part of the spirographic data by optimum matching between said exhaled and inhaled parts at the $V_{\max}$ end of the spirographic data. This is based on the insight that there may be a time delay between the measurements of volume and gas concentration, which may cause a shift of the gas concentration curves with respect to the volume. Realising that the "last" part, or end tidal volume part or $V_{\max}$ part, of the exhaled breath will be rebreathed, this shows that the gas concentration in the corresponding rebreathed volume will show substantially the same features as that in the last part of the exhaled breath. Optimum matching then comes down to finding the point at which concentration measurement corresponds to that point of reversal of breathing, which is symmetrically midway between those corresponding features.

The way in which this matching is optimised may be selected according to any known technique. The selected way may depend on the way of displaying the measured values, if these are displayed at all. If displayed, the spirogram may e.g. show the exhaled and inhaled parts in a single diagram. In such a case, an optimum match may be obtained when the exhaled part is shifted to the left or right over a volume V_{shift} and the inhaled part over a corresponding volume $-V_{\text{shift}}$, such that one or more features in the plateau part, preferably a local extreme value in one of the two parts is brought into register with the corresponding feature in the other of the two parts. It is noted that such a feature need not be found in every breath. In that case, matching would be an inaccurate operation, and it is preferred to do this matching in a subsequent respiration that does show a feature, such as a dip in the gas concentration. Note that the apparatus dead space is a constant for the apparatus, and need be determined only once. Of course, if a new tubing, sensor or the like is used, this apparatus dead space could be determined anew. In the proximity of $V_{\max}$ the inspired and expired parts are mirrored with respect to a vertical line at $V_{\max}$.

A basic way of mirroring and matching is of course by hand, judging with the eye which is the midpoint in the spirogram. Alternatively, mathematical functions could be

used, e.g. those that determine the quality of a match between curves by a least sum of squared differences or the like. The skilled person will know how to implement this according to his demands.

In a second aspect, the invention also relates to a spirographic device for obtaining and evaluating spirographic data, comprising a gas volume meter for measuring a volume V_x of at least inhaled breathing gas mix, a gas measuring probe for measuring a concentration $gc(V_x)$ of a breathing gas in said volume of breathing gas mix, wherein the device is arranged to perform a method according to the invention. Such a device can give accurate results for at least the apparatus dead space $ApDS$. Preferably, the device comprises a computer arranged to perform a suitable mathematical operation on the obtained spirographic data.

Herein, the gas volume meter is often a flow meter, that determines the flow of passing breathing gas mix.

In particular, the device, and/or the computer, is arranged to couple a measured gas concentration to a corresponding volume measurement, as is known in the art per se. Also, the device may be arranged for measuring carbon dioxide and/or oxygen, and/or another gas such as water vapour. A suitable probe or sensor is available.

The device and/or computer are arranged to carry out a mathematical operation on the spirographic data, for obtaining at least a value of the apparatus dead space, according to the invention. Such a method could be according to any method described above.

Of course, both in the method and in the device, it is provided that the values are stored at least long enough to perform the desired action upon them. A suitable memory is incorporated.

The invention also relates to a patient ventilation device, comprising a tubing to be inserted into a patient's airway, a controllable breathing gas supply means connected to said tubing and a spirographic device according to the invention. Such a ventilation device may make good use of the invention, in that the breathing efficiency may be determined more accurately and especially in that the ventilation efficiency may be set more expediently. This not only improves the patient's well-being, but could also prevent lung damage. In this ventilation device, the spirographic device allows to establish an apparatus dead space at any use.

The invention also relates to a patient ventilation device, comprising a tubing to be inserted into a patient's airway, a controllable breathing gas supply means connected to

said tubing, wherein the volume of breathing gas mix as supplied by the ventilation device is settable taking into account a predetermined apparatus dead space A_{pDS} as determined with the method according to the invention. In this device, use is made of the circumstance that the apparatus dead space need only be set once, at least if the apparatus is not modified. Hence, the manufacturer or first user may determine such apparatus dead space once, and set the device accordingly. For example, this volume is subtracted from the indicated ventilation volume. Of course, if the device is modified, such as when tubing or a sensor is replaced, a new gauge measurement may be carried out, such as according to the method or with the aid of the spirographic device of the invention.

The invention also relates to method of obtaining and evaluating spirographic data, comprising measuring a concentration of a breathing gas $gc(V_x)$ for a plurality of values of a volume V_x of breathing gas mix, for an animal or human being, with a suitable apparatus, both for breathing in and for breathing out until an end tidal volume V_{max} , further comprising the step of synchronizing an exhaled part and an inhaled part of the spirographic data by optimum matching between said exhaled and inhaled parts at the V_{max} end of the spirographic data. This is simply a method of determining the amount a breathing gas is exchanged, such as oxygen uptake or carbon dioxide elimination, but now without the feature of determining apparatus dead space, which is irrelevant here. Since synchronisation allows a more accurate coupling between volume and the corresponding gas concentration, more accurate values for such gas exchange may be obtained. Furthermore, all combinations with other features mentioned in the description above are possible.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1a shows schematically a capnospirogram, the expiration part of a breath cycle (also known as single-breath CO_2);

Fig 1b shows a complete capnospirogram including the inspiratory part and apparatus deadspace

Fig. 2 shows an example of a poorly synchronised spirogram to the left, and a spirogram correctly synchronised according to the invention, to the right;

Fig. 3 shows an oxyspirogram, in which O_2 concentration is plotted against volume; and

Fig. 4 shows a schematic example of a detail of a ventilation device, according to the invention.

5 DETAILED DESCRIPTION OF EXAMPLES

Fig. 1a shows schematically a capnospirogram, plotting CO₂ concentration versus the volume, in arbitrary units, of exhaled breathing gas mix. The known, general features of the diagram are e.g. the low plateau for low volumes, indicating air from the subject's non-alveolar airway, such as the bronchi, followed by a steep rise, which indicates the mixing in of alveolar air, and the substantially linear slope at the end, which indicates the increasing CO₂ concentration during breathing out of additional alveolar air.

In order to obtain a value for the total expired volume of CO₂, one can e.g. apply a method in which a straight line A, with a slope s as a fitting parameter, is fitted to the substantially linear part. The second step is to find the volume V_3 for which the measured areas q and p , as indicated in the graph, are equal according to Fowler. The airway dead space equals said volume thus found. Note that other definitions are possible, such as the volume at which the gas concentration is 50% of its final, end tidal value, et cetera.

Fig. 1b shows a complete or full capnospirogram, including both the inspiratory part and the expiratory part, as well as airway dead space, alveolar deadspace and apparatus deadspace.

In the graph, V_1 denotes the volume at maximum breathing out, V_2 denotes a volume corresponding to the apparatus deadspace when subtracted from V_1 , and air actually breathed in begins to pass the flow meter, V_3 denotes a volume corresponding to the airway deadspace, and V_4 denotes the starting point of breathing out. V_4 could also be taken as the endpoint of breathing in other cases, as they need not be identical.

The expiratory part in the graph will be the same as that in Fig. 1a, but now the inspiratory part is included as the lower line in the graph. From the combination of both lines, the apparatus deadspace $ApDS$ may be determined as $V_1 - V_2$, where V_2 is the volume at which the CO₂ concentration, starting from V_1 , has dropped to 50% of its value at V_1 , or alternatively to halfway between the CO₂ concentrations at V_1 and V_4 , i.e. beginning and end of breathing in.

Furthermore, alveolar deadspace and airway deadspace may be determined according to all known techniques. Also, eliminated CO₂ volume may be determined as the area between the two lines.

In practice it is not always certain whether the concentration is associated with the correct volume, since often a sample is measured while separately a flow is measured. If there is a time delay between the two measurements, a correct association may not be obtained in some cases. This holds for both breathing in and breathing out.

5 Fig. 2 shows an example of such (apparent) poor synchronisation to the left, and a correctly synchronised graph to the right.

Both graphs show a full capnospirogram, similar to the one in Fig. 1b, in which the CO₂ concentration is plotted versus the volume of breathing gas mix that has passed the flow meter. The graph shows both an exhaling part on top in the graphs, and an
10 inhaling part, as measured when going from "high" volume values back to zero volume, below in the graphs. In this way a closed loop is obtained. In the left graph are indicated values for airway dead space, apparatus dead space and alveolar volume. The airway dead space A_{wDS} is determined e.g. according to the method described in connection with Fig. 1a. The apparatus dead space, A_{pDS} , the measurement of which is an aspect of the present
15 invention, may be determined with a similar method, but now for the inhaling (lower) part (refer to Fig 1b). The amount of exhaled CO₂ is determined as the surface area between the two graph parts. In the present case, the volumes were determined as 106 ml, 134 ml and 100 ml, respectively. The value of the alveolar volumen of 100 ml corresponds to 30% of the total tidal volume and represents the effective volume range for CO₂ elimination.

20 It was found that incorrect synchronisation of the gas concentration measurement and volume measurement can have severe effects on the determined quantities. In other words, in practice it occurred that values deemed to belong to the exhaling part actually should have been considered parts of the inhaling part of the fig. 2. In the graph, this would be expressed as a shift of the inspired and expired graphs to the right resp. left along
25 the horizontal volume axis. The graphs are shifted in opposite directions thus changing the enclosed area, the eliminated CO₂, significantly.

The present invention corrects this phenomenon by correctly synchronising the two graph parts. Thereto, use is made of features in the high volume parts of the graph. In this case, for example, there is a dip in the concentration values, indicated in the
30 circumscribed detail. Such detail will return in the inhaling part, for example due to rebreathing the same volume. In that case, synchronisation may be obtained by shifting the two parts over equal volumes and mirror symmetrically with respect to the maximum measured volume, such that the corresponding features of both parts overlap optimally.

This method, according to the invention, has been followed in the right part of the Fig. 2, which shows the same measurements as for the graph to the left, but now synchronised such that the dips in the circumscribed detail in both parts overlap. Now the airway dead space (AwDS), the apparatus dead space (ApDS) and alveolar volume can be determined as 85 ml, 108 ml, and 147 ml, respectively. It is clear that there are large discrepancies between the synchronised values and the poorly synchronised values.

Fig. 3 shows an oxyspirogram, in which O₂ concentration is plotted against volume, again for an exhaled part (lower graph) and inhaled part (upper part). In similar ways as described for CO₂ above, airway dead space (AwDS), apparatus dead space (ApDS), alveolar volume and oxygen uptake may be determined. Also, the same synchronisation steps may be performed for this oxyspirogram, to improve the accuracy and reliability. Note that the values for, in particular, apparatus dead space for CO₂ and for O₂ could differ, for example if different sensors and tubing are used. Similar measurements and methods are also possible for other respiratory gases, or even anaesthetic gases and so on.

Fig. 4 shows a schematic example of a detail of a ventilation device, according to the invention.

Herein, 1 denotes a gas supply tubes, connected to a tracheal tube 2 with an opening 3. A flow meter 4, a first gas concentration meter 5 and a second gas concentration meter 8 are connected to a processing device 11, with a display 12. Many non-shown details, such as gas conditioning devices and so on, may be taken from any known design of ventilation apparatus in the art, as such details are not part of the gist of the present invention.

The first gas concentration meter 5 is connected to the tracheal tube 2 via a first sample tube 6 with a first sampling opening 7, while the second gas concentration meter 8 is connected to the tracheal tube 2 via a second sample tube 9 with a second sampling opening 10.

The flow meter 4 and the first and second gas concentration meters 5, 8 may be any respective suitable measuring devices known in the art. The first gas concentration meter 5 may for example be an O₂ meter, while the second gas concentration meter 8 may e.g. be a CO₂ meter, without being limited thereto. Furthermore, it is possible to use a single concentration meter device that is able to measure more than one type of gas. The measurements as obtained by the flow meter 4 and the first and second gas concentration meters 5, 8 are received by the processing device 11, such as a computer. The processing device 11 may display the measurements in a spirogram plot on a display 12 and/or output such results in any useful form, such as a data file. This allows a skilled person to perform the

method according to the invention. Preferably however, the methods of determining dead spaces and/or synchronising ex- and inhaling parts of the spirogram are automated, by means of suitable software or suitably programmed or designed hardware, in the processing device 11. The processing device 11 could then, very generally, output a synchronised spirogram, as
5 a display and/or as a data file, and/or it could output one or more values for airway dead space, apparatus dead space, and in particular effective uptake or emission of one or more gases such as oxygen or carbon dioxide.

The above embodiments are only exemplary, and are not intended to limit the invention, the scope of which is determined by the appended claims.

CLAIMS:

1. A method for obtaining and evaluating spirographic data, comprising measuring a concentration of a breathing gas $gc(Vx)$ for a plurality of values of a volume Vx of breathing gas mix, for an animal or human being, with a suitable apparatus,
wherein the measuring is performed on inhaled breathing gas mix,
5 further comprising determining an apparatus dead space $ApDS$, of breathing gas mix in the apparatus not taking part in gas exchange, by evaluating the measured concentrations $gc(Vx)$ as a function of the volume V of the inhaled breathing gas mix.
2. Method of claim 1, wherein the step of determining $ApDS$ comprises applying
10 a mathematical operation to the measured concentrations as a function of volume.
3. Method of claim 2, wherein said mathematical operation comprises:
- determining a $gc(V1)$ at a first volume $V1$ at the beginning of inhaling, determining a $gc(V4)$ at a second volume $V4$ at the end of inhaling, and determining the $ApDS$ as the
15 difference between $V1$ and a volume $V2$ at which $gc(V2) = (gc(V1) + gc(V4))/2$.
4. Method of any preceding claim, further comprising the steps of measuring $gc(Vx)$ for a plurality of values of a volume Vx of exhaled breathing gas mix and of determining an airway dead space $AwDS$ and/or alveolar dead space $AIDS$ by evaluating said
20 measured concentrations.
5. Method of claim 3 or 4, further comprising the step of determining a ventilated volume VV as $VV = V1 - (ApDS + AwDS)$,
and preferably comprising the step of determining a ventilation efficiency VE as $VE =$
25 $VV/V1$.
6. Method of any preceding claim, wherein the concentrations of both carbon dioxide and oxygen are measured and evaluated, and preferably at least one of $ApDS$, $AwDS$ and $AIDS$ is determined for both a corresponding oxyspirogram and a capnospirogram.

7. Method of any of claims 4-6, further comprising the step of synchronizing an exhaled part and an inhaled part of the spirographic data by optimum matching between said exhaled and inhaled parts around the V2 end of the spirographic data.

5

8. A spirographic device for obtaining and evaluating spirographic data, comprising a gas volume meter (4) for measuring a volume V_x of ex- and/or inhaled breathing gas mix, a gas measuring probe (5, 8) for measuring a concentration $gc(V_x)$ of a breathing gas in said volume of breathing gas mix,

10 and wherein the device is arranged to perform a method according to any preceding claim, preferably comprising a computer (11) arranged to perform a suitable mathematical operation on the obtained spirographic data.

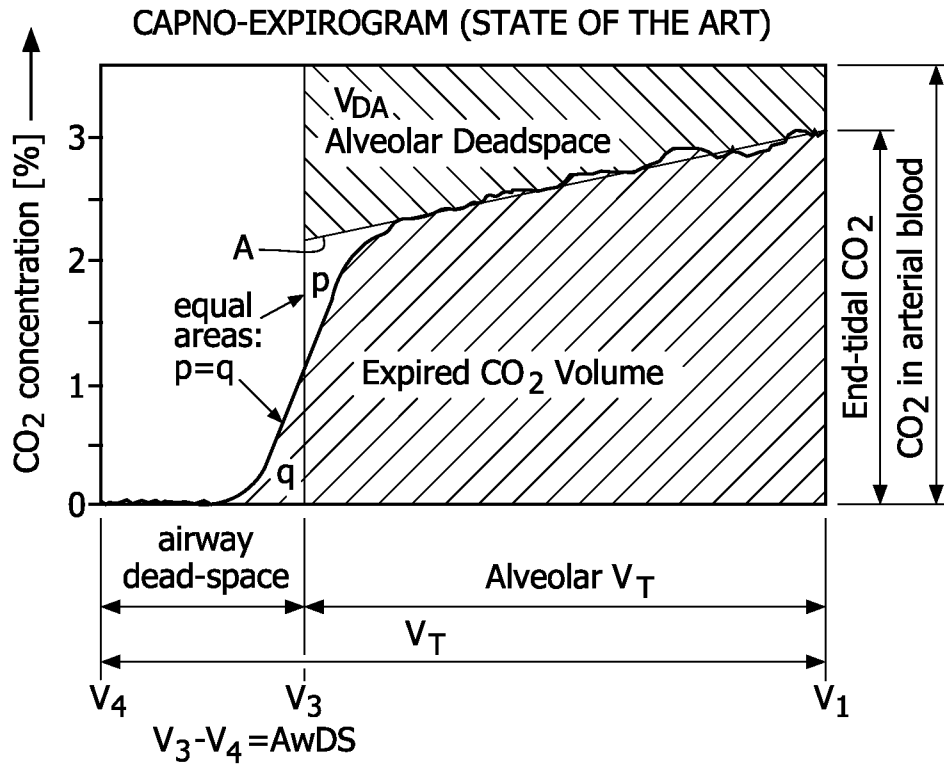
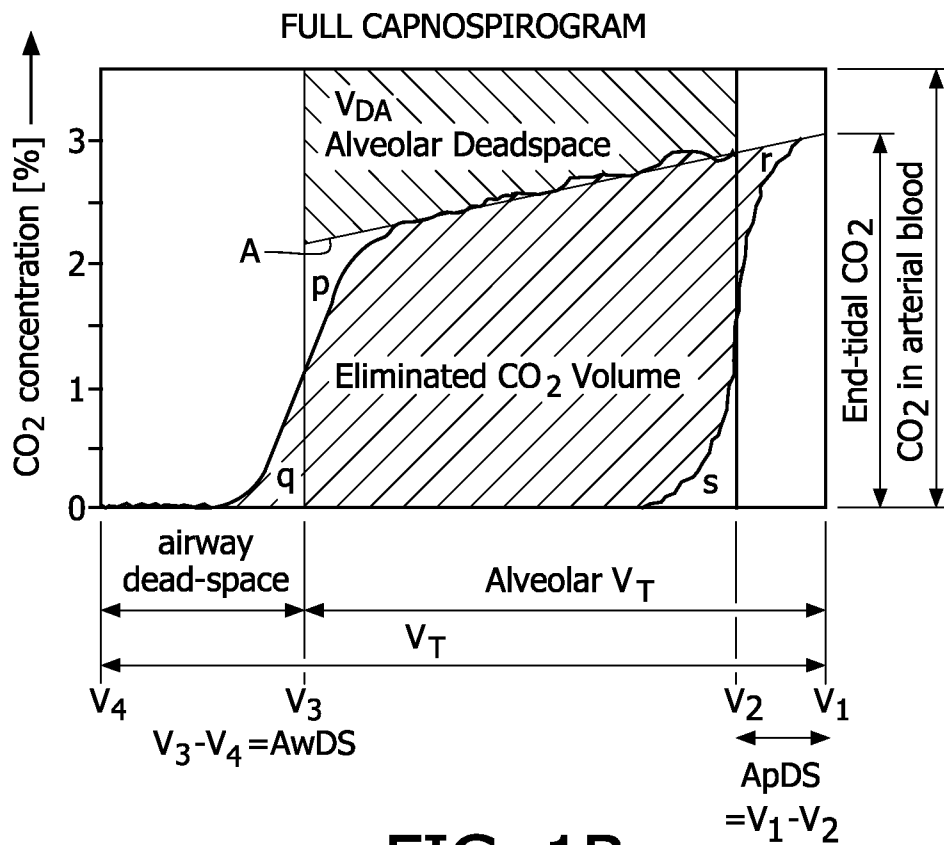
9. A patient ventilation device, comprising a tubing (2) to be inserted into a
15 patient's airway, a controllable breathing gas supply means connected to said tubing (2) and a spirographic device according to claim 8.

10. A patient ventilation device, comprising a tubing (2) to be inserted into a patient's airway, a controllable breathing gas supply means connected to said tubing (2),
20 wherein the volume of breathing gas mix as supplied by the ventilation device is settable taking into account a predetermined apparatus dead space $ApDS$ as determined with the method according to any of claims 1-7.

11. A method of obtaining and evaluating spirographic data, comprising
25 measuring a concentration of a breathing gas $gc(V_x)$ for a plurality of values of a volume V_x of breathing air mix, for an animal or human being, with a suitable apparatus, both for breathing in and for breathing out until an end tidal volume $V1$, further comprising the step of synchronizing an exhaled part and an inhaled part of the spirographic data by optimum matching between said exhaled and inhaled parts around the $V1$ end of the spirographic data.

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**FIG. 1A****FIG. 1B**

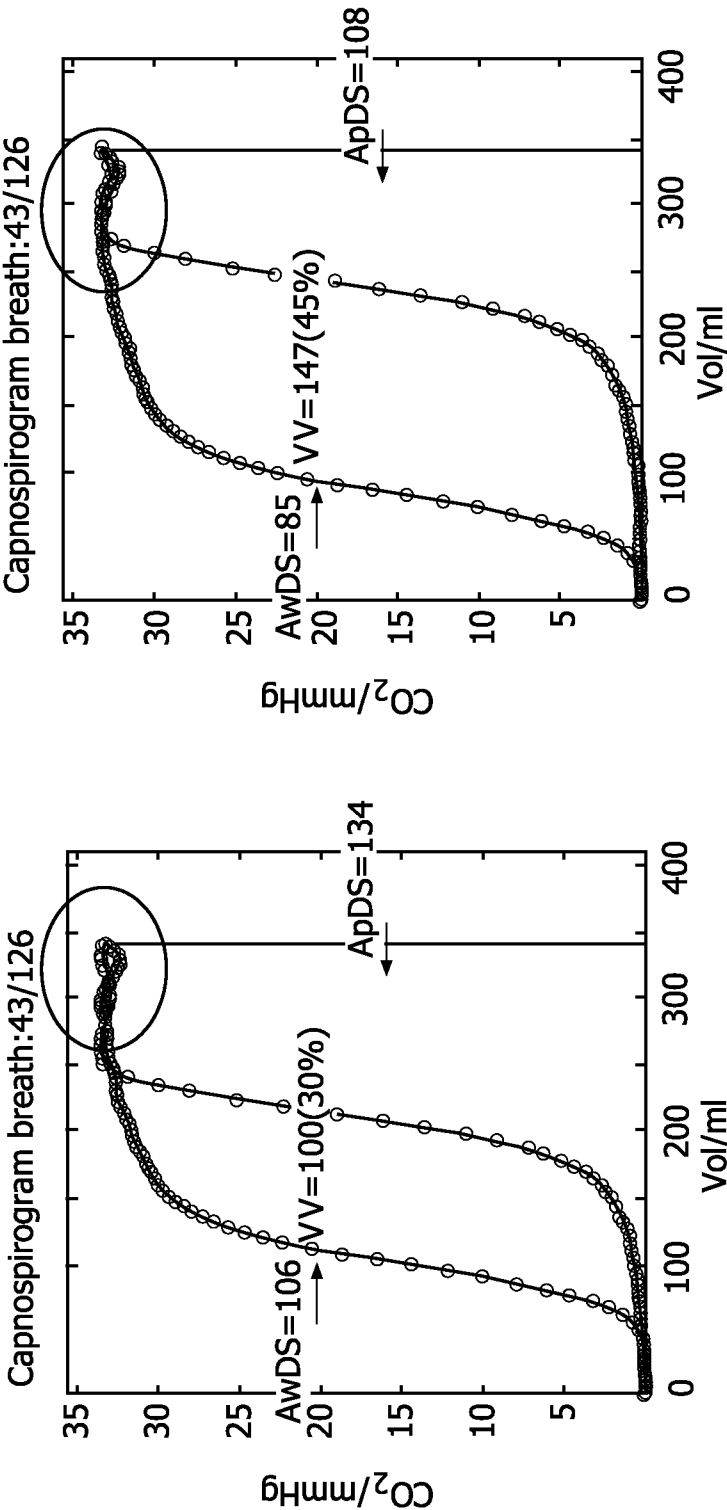


FIG. 2

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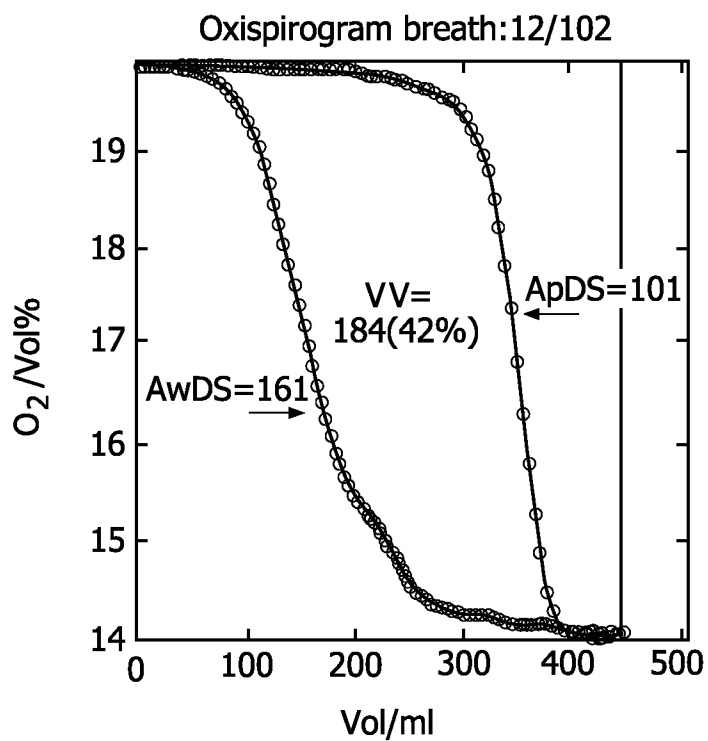


FIG. 3

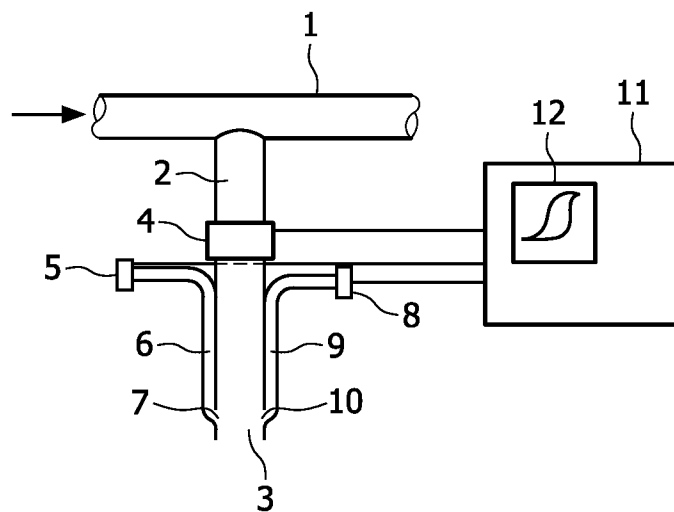


FIG. 4