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(54) **ENDOTRACHEAL TUBE FOR MONITORING CO2**

ENDOTRACHEALTUBUS ZUR ÜBERWACHUNG VON CO2

SONDE D'INTUBATION ENDOTRACHÉALE DE SUIVI DU CO2

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Description

[0001] The invention generally relates to a double tube endotracheal tube and a breath sampling system comprising the same.

BACKGROUND

[0002] The prior art discloses a number of endotracheal catheters or tubes. For monitoring sleep disorders, WO 99/20332 A1 suggests a double catheter comprising two tubes fixed to each other.

[0003] EP 0 850 652 A2 discloses an endotracheal pressure monitoring and medication system which comprises a primary lumen and a secondary smaller lumen adjacent the primary lumen.

[0004] US 5,313,939 discloses an apparatus for topical targeted delivery of a substance to internal body tissues and walls of a tracheal-intubated patient's upper airway. A branched tube with a plurality of openings and connected to a medication applicator is inserted into a standard endotracheal tube.

[0005] WO 2005/107839 A2 discloses a jet endotracheal device comprising a first tube for delivering jet oxygen pulses and a further second tube for receiving a monitoring device. The second tube wall extends from the anterior exterior surface of the first tube wall

[0006] US 5,669,380 A1 discloses a laryngeal bypass device for transcutaneous insertion into a human sublaryngeal trachea has an outer tubular member coupled to an aspiration device and an inner tubular member disposed within the outer tubular member and coupled to a ventilation device.

[0007] Continuous noninvasive monitoring of carbon dioxide (CO_2) levels in infants, particularly in a Neonatal Intensive Care Unit (NICU), is considered very important mainly in order to protect subjects such as infants from the complications of hypocarbia (less than the normal level of carbon dioxide in the blood) and hypercarbia (more than the normal level of carbon dioxide in the blood) and to avoid extra blood sampling which may cause anemia, discomfort, and pain. Noninvasive monitoring of carbon dioxide (CO_2) levels typically refers to exhaled breath analysis also referred to as capnography.

[0008] Capnography is a common method of monitoring and optionally displaying the CO_2 level(s), CO_2 waveform(s) and/or other CO_2 related parameters, such as End Tidal CO_2 ($EtCO_2$), in exhaled breath. Capnography also provides information relating to cell metabolism, blood perfusion, alveolar ventilation and other body functions or conditions, and may enable real-time diagnosis of patho-physiological abnormalities as well as technical problems related to ventilation. In intubated subjects (such as patients) capnography is performed by sampling exhaled breath around the exit of the endotracheal tube (ETT) at a sampling region between the proximal end of the ETT (close to the subject's mouth) and the ventilator circuit. In intubated small children and infants, however, capnography is not commonly used since it does not consistently provide satisfactory results. One of the reasons for the lack of satisfactory results in small children, infants and/or neonates especially neonates, relates to the use of uncuffed endotracheal tubes (ETTs) during their ventilation. A cuff is an inflatable balloon on the outer surface of the ETT used to hold the ETT in place and to close off the ventilated air exiting the ETT at its distal end (towards the subject's lung) from escaping around the tube outwards. In case of small children and/or infants, and especially neonates, cuffed ETTs are generally not used due to the risk of perforating or otherwise harming the gentle membrane of their trachea. The use of uncuffed ETTs results in ventilated air escaping around the tube during inhalation. Although this can be compensated for by changing the ventilator parameters, a greater problem arises during breath sampling (both in mainstream and sidestream capnography) which depends on the exhaled breath returning back through the ETT towards the sampling region. The uncuffed ETT allows the exhaled breath to return between the ETT and trachea, and out through the mouth without returning back through the ETT towards the sampling region. This is further exaggerated, since with neonates the ETT internal diameter is very small, typically between 2.5 to 4mm, which imposes a large restriction, enhancing further the possibility of exhaled breath escaping round the tube. The small volume of exhaled breath (which is only a fraction of the low tidal volumes of infants and neonates) that does manage to return back through the ETT is also diluted with clean ventilated air (often present in a "dead space" of the ETT) which leads to difficult breath sampling and erroneous CO_2 readings.

[0009] This problem is further enhanced in mainstream capnography, in which the required airway section is connected inline between the proximal end of the ETT (close to the subject's mouth) and the ventilator circuit. Thus, it adds more dead space, competes for tidal volume, and may also cause a kink in the ETT, especially in small premature infants. When a flow sensor is connected to the ETT, the use of mainstream capnography is even more cumbersome.

[0010] There is thus a need in the art for methods, systems and apparatuses that would allow accurate CO_2 monitoring, particularly in small children, infants or neonates.

High Frequency Ventilation (HFV):

[0011] In addition to the problems discussed hereinabove, which relates to CO_2 monitoring, the ventilation itself,

particularly in neonates, but also with children and adults, still suffers from significant difficulties. Some neonates cannot be adequately ventilated even with sophisticated conventional ventilation. Therefore respiratory insufficiency remains one of the major causes of neonatal mortality. Intensification of conventional ventilation with higher rates and airway pressures leads to an increased incidence of barotrauma. Especially, the high shearing forces resulting from large pressure amplitudes damage the lung tissue. High Frequency Ventilation (HFV) has been shown to resolve or at least ameliorate this issue in many cases.

[0012] High Frequency Ventilation (HFV) is a technique of ventilation that uses respiratory rates that greatly exceed the rate of normal breathing. There are three main types of HFV:

1) High frequency positive pressure ventilation (HPPV, rate 60-150 breaths/minute);

2) High frequency jet ventilation (HFJV, rate 100-600 breaths/minute); and

3) High frequency oscillatory ventilation (HFOV, rate 300-3000 breaths/minute).

[0013] During conventional ventilation direct alveolar ventilation accomplishes pulmonary gas exchange. According to the classic concept of pulmonary ventilation an amount of gas reaching the alveoli equals the applied tidal volume minus the dead space volume. At tidal volumes below the size of the anatomical dead space this model fails to explain gas exchange. Instead, considerable mixing of fresh and exhaled gas in the airways and lungs is believed to be the key to the success of HFV in ventilating the lung at such very low tidal volumes. Among the advantages of high frequency oscillatory ventilation as compared to either conventional positive pressure or jet ventilation is its ability to promote gas exchange while using tidal volumes that are less than dead space. The ability of HFV to maintain oxygenation and ventilation while using minimal tidal volumes allows minimization of barotrauma and thus reduces the morbidity associated with ventilation.

[0014] Currently, two of the most important values that determine the respiratory therapy, such as HFV, is the Blood Gas CO_2 ($PaCO_2$) and the SpO_2 (the amount of oxygen being carried by the red blood cell in the blood). In order to monitor the subject's gas concentration in the blood, however, a blood sample must be taken. Blood sampling involves pain, discomfort and risk of infection. Especially with neonates, since the volume of blood is very small, each blood test takes a measurable percentage of the neonate's blood. This dictates periodic blood transfusions, where each blood transfusion promotes a further danger to the neonate or other subject.

[0015] There is thus a need in the art for methods, systems and apparatuses that would permit and facilitate accurate measurement(s) of medical parameter(s) for the evaluation and control of HFV therapy in subjects, particularly, but not only, in small children, infants or neonates.

SUMMARY

[0016] This summary section should not be construed as limiting the invention to any features described in this summary section.

General Sampling in Neonatal Environment

[0017] The present invention provides a solution for monitoring breath carbon dioxide (CO_2) in subjects, particularly, but not limited to, small children and infants, from a position much closer to the bronchial tubes than the current sampling position. This type of CO_2 sampling and evaluation may also be referred to as a "distal CO_2 measurement".

[0018] As discussed hereinabove, the current sampling configuration is problematic since it involves sampling from an area close to subject's mouth and to the proximal end of the ETT, wherein CO_2 is mixed with ventilated air, which eventually leads to erroneous CO_2 readings. This is particularly problematic when using an uncuffed endotracheal tube (ETT), which is very common in small children, infants and neonates. It was found that sampling breath from a position at a lower section of the trachea closer to the bronchial tubes (distal CO_2 measurement) may be less susceptible to air leak and/or mixing of the measured CO_2 with inhaled air. More particularly, sampling breath for distal CO_2 measurement may be performed at the distal end of the ETT which is adapted to be positioned inside the bronchial tube. Thus, sampling breath for distal CO_2 measurement may be performed by inserting a catheter into the ETT, wherein the catheter is adapted to sample CO_2. Alternatively, sampling breath for distal CO_2 measurement may be performed by sampling breath through the second (extra) lumen (typically having a very small diameter compared to the main lumen) of a double lumen ETT.

Sampling in subjects treated with High Frequency Ventilation (HFV):

[0019] The disclosed double tube endotracheal tube and breath sampling system can be used for capnography in monitoring breath carbon dioxide (CO_2) in subjects, particularly, but not limited to, small children and infants, who are ventilated by High Frequency Ventilation (HFV) technique.

[0020] When considering capnography for replacing at least some of the blood gas samples, and in general to provide continuous monitoring for HFV (such as HFOV) mode of ventilation, some difficulties arise:

a) Capnographs are generally designed to detect breath cycles up to rates of about 120-150 breaths per minute. As mentioned above, with HFV, frequencies are much higher. A limiting factor being the response time, which even for the fastest capnograph systems is generally more than 100msec, which is far too slow for this mode of ventilation. In addition, it is most probable, that even if one had a capnograph system that was faster and able to detect changes at frequencies similar to those of the HFV ventilation mode, no breath cycle would be seen Since the CO_2 is mainly diffusing out, and only ripples would be seen caused by the pressure fluctuations.

b) Capnographs are generally designed such that if a breath cycle (a minimal sinusoidal wave) is not detected, a "no breath" alarm is triggered.

c) More important, as mentioned herein the considerable mixing of fresh and exhaled gas in the airways and lungs creates a status where the CO_2 concentration along the subject's airway changes and decreases so that at the standard position for capnography sampling, either mainstream or sidestream, the concentration will be much lower than what is really occurring in the lungs. Hence, CO_2 as currently measured would not be comparative to the blood gas value, and even if it had some correlation, it would have very low resolution. It was found that the CO_2 concentrations at these standard positions to be about eight times lower than those measured for standard ventilation modes. It is also noted that since there is no breath cycle, the CO_2 concentration is also an average value without peaks.

[0021] The disclosed double tube endotracheal tube and breath sampling system overcome one or more issues related to difficulties such as those discussed hereinabove, and facilitate CO_2 sampling and monitoring in subjects (for example, but not limited to, children, infants, and neonates) ventilated by the HFV mode. According to the present invention, there are provided a double tube endotracheal tube and a breath sampling system comprising the same suitable for CO_2 sampling and monitoring in subjects (but not limited to, children, infants, and neonates) ventilated by the HFV mode.

[0022] According to a first aspect, the present invention provides a double tube endotracheal tube comprising a first tube having a first diameter, a distal end, and a proximal end; a second tube located essentially inside the first tube and along the wall of the first tube and having a diameter smaller than the first diameter and comprising a distal opening and a second opening opposing the distal opening, said second opening having a connector; wherein the distal opening of the second tube is located a few millimeters before the distal end of the first tube and has several apertures; wherein the connector further includes a connecting element adapted to connect to the second tube; a sampling opening adapted to connect to a sampling line; a suction port; and a valve. The double tube endotracheal tube is characterized in that the second tube further comprises a drying tube adapted to absorb and/or pervaporate fluids present in sampled breath, and in that the suction port is adapted to allow application of agents such as surfactants and/or medications. The valve has two positions: a first position allowing the flow of air sampled through second tube to drying tube and sampling line and on to an analyzer, and the second position blocking the flow of air sampled through the second tube to drying tube and sampling line and allowing the flow towards suction port.

According to one embodiment, the second diameter is approximately 0.8 mm.

The number of apertures may be three.

According to another embodiment, the connector is integrally formed with the second tube.

According to a second aspect, the present invention provides a breath sampling system comprising the above double tube endotracheal tube being adapted for sampling breath from a subject for the evaluation of one or more parameters related to concentration of carbon dioxide (CO_2) in the sampled breath; and a breath sampling line adapted to connect to the second tube of the double tube endotracheal tube through the connector.

According to one embodiment, the one or more parameters related to concentration of CO_2 comprise spontaneous end tidal CO_2 (S-EtCO_2), spontaneous final inspired CO_2 (S-FiCO_2), continuous CO_2 (Cont. CO_2), diffusion CO_2 (DCO_2), density of spontaneous breathing or any trend thereof or any combination thereof.

BRIEF DESCRIPTION OF FIGURES

[0023] Examples illustrative of embodiments of the invention are described below with reference to figures attached

hereto. In the figures, identical structures, elements or parts that appear in more than one figure are generally labeled with a same numeral in all the figures in which they appear. Dimensions of components and features shown in the figures are generally chosen for convenience and clarity of presentation and are not necessarily shown to scale. The figures (FIGs.) are listed below.

Fig. **1A - C** schematically show double lumen Endotrachial Tubes (ETTs), wherein Figs. 1A and 1C do not form part of the present invention;

Fig. 2 shows an example of a capnograph display;

Fig. 3 A and B show the linear correlation between distal $EtCO_2$ ($dEtCO_2$) (A) and proximal $EtCO_2$ ($pEtCO_2$) **(B)** and arterial CO_2 ($PaCO_2$);

Figs. 4 A and B present the Bland-Altman plots of the differences between distal $EtCO_2$ ($dEtCO_2$) (A) and proximal $EtCO_2$ ($pEtCO_2$) **(B)** and arterial CO_2 ($PaCO_2$); and

Fig. 5 shows the linear correlation between distal $EtCO_2$ ($dEtCO_2$) and arterial CO_2 ($PaCO_2$) in subjects ventilated with High Frequency Ventilation (HFV).

DETAILED DESCRIPTION OF EMBODIMENTS

[0024] In the following description, various aspects of the invention will be described. For the purpose of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the techniques. However, it will also be apparent to one of skill in the art that the techniques may be practiced without specific details being presented herein. Furthermore, well-known features may be omitted or simplified in order not to obscure the description(s) of the techniques.

[0025] Sampling breath for CO_2 monitoring may be performed from a position much closer to the bronchial tube (at the lower section of the trachea) than the current sampling position. This type of CO_2 sampling and evaluation may also be referred to as a "distal CO_2 measurement". As discussed hereinabove, the current sampling configuration is problematic since it involves sampling from an area close to subject's mouth and to the proximal end of the ETT, wherein CO_2 is mixed with ventilated air, which eventually leads to erroneous CO_2 readings. It was found that sampling breath from a position closer to the bronchial tube (distal CO_2 measurement) may be less susceptible to air leak and/or mixing of the measured CO_2 with inhaled air. More particularly, sampling breath for distal CO_2 measurement may be performed at the distal end of the ETT which is adapted to be positioned inside the bronchial tube. Sampling breath for distal CO_2 measurement may be performed by inserting a catheter into the ETT, wherein the catheter is adapted to sample CO_2. The catheter may, however, partly occlude or add resistance to the airway. Also, sampling breath for distal CO_2 measurement may be performed through the distal part of what is known as a double lumen endotracheal Tube (ETT). Double lumen ETTs have been used so far as a means for suctioning and administration of surfactants and similar agents. The second (extra) lumen is typically a very small diameter tube which runs within the wall of the first lumen from about half way down to a point close to the distal exit of the ETT.

[0026] Reference is now made to **Fig. 1A** which does not form part of the present invention and schematically shows a double lumen endotracheal Tube (ETT). Endotracheal Tube (double lumen ETT) 100 includes a main endotracheal tube 102 having a larger diameter and a small diameter tube 104 (for example, approximately 0.8mm) located essentially inside and along the wall of main endotracheal tube 102. Small diameter tube 104 has a distal opening 106 a few millimeters before the distal end 108 (towards the subject's bronchial tube and lungs) of ETT 100. Small diameter tube 104 also includes, at its end opposing distal opening 106, a second opening having a connector 110, adapted to connect to or allow access to suction devices and/or to allow application of agents such as surfactants, medications or the like. Adapter 110 may be adapted to connect to a sampling line for sampling CO_2 in exhaled breath from distal end 108 of ETT 100 through small diameter tube 104. Proximal opening 130 of main endotrachial tube 102 is adapted to connect to a ventilator.

[0027] Sampling breath for CO_2 monitoring can be performed from the area of the distal end (such as distal end 108) of the double lumen ETT (such as double lumen ETT 100). The sampling is performed through the small diameter tube (such as small diameter tube 104) of the double lumen ETT.

[0028] Tests clearly showed that for subjects with and without High Frequency Ventilation (HFV) (adults, children, infants and/or neonates) distal CO_2 measurement performed, for example through a double lumen ETT, produced a significantly better or at least comparable correlation and agreement with arterial CO_2. For example, better correlation was obtained between distal $EtCO_2$ ($dEtCO_2$) with arterial CO_2 ($PaCO_2$) than the correlation of $pEtCO_2$ measured by mainstream or sidestream capnograph sampling at the subject airway proximally with arterial CO_2 ($PaCO_2$).

[0029] Sampling at the distal point of the ETT in subjects and particularly in neonates has another issue: there are many fluids at the distal point. In order to solve or reduce the fluid problem and prevent them from reaching the analyzer, a fluid reducing device may be used.

[0030] The fluid reducing device may include a standard airway adapter and sampling connector to the sampling line having a stop-cock type valve allowing in its first position to sample breath and in its second position to close the sampling line and open an opening for suction of fluids from the distal section of the trachea.

[0031] It may be beneficial if the breath sampling opening of the double lumen is several millimeters inside the endotrachial main tube, with possibly several small apertures (hence, if one aperture is covered with fluids, the sampling will continue through one of the remaining openings).

[0032] Reference is now made to **Fig. 1B** which schematically shows a double lumen Endotrachial Tube (ETT), according to the present invention. Endotrachial Tube (double lumen ETT) 200 includes a main endotrachial tube 202 having a larger diameter and a small diameter tube 204 (approximately 0.8mm) located inside and along the wall of main endotrachial tube 202. Small diameter tube 204 has a distal opening 206 a few millimeters before the distal end 208 (towards the subject's bronchial tube and lungs) of ETT 200. Distal opening 206 of small diameter tube 204 has several (in this case three) additional apertures 209. When one or more of apertures 209 is blocked with fluids, the sampling will continue through one or more of the remaining openings.

[0033] Small diameter tube 204 also includes, at its end opposing distal opening 206, a second opening having a connector 210. Connector 210 includes a connecting element 211 adapted to connect to small diameter tube 204. Connector 210 further includes a sampling opening 212 adapted to connect to a sampling line 214, optionally with drying tube 216 adapted to absorb and/or pervaporate fluids present in the sampled breath. Connector 210 also includes suction port 218 through which suction of fluids from the distal section of the trachea can be performed. Suction port 218 may also be adapted to allow application of agents such as surfactants, medications or the like. Connector 210 further includes valve 220. Valve 220 has two optional positions, a first position (as shown in Fig. 1B) allows the flow of air sampled through small diameter tube 204 to drying tube 216 and sampling line 214 and on to the analyzer (such as a capnograph). The second position (not shown) of valve 220 approximately perpendicular to the first position. In the second position, valve 220 blocks the flow of air sampled through small diameter tube 204 to drying tube 216 and sampling line 214 and allow the flow towards suction port 218. Valve 220 (or any other valve) may be adjusted by a user to allow sampling and from time to time, as needed or every period of time, allow suction or application of medication while blocking the sampling path. Proximal opening 230 of main endotrachial tube 202 is adapted to connect to a ventilator. Valve 220 (or any other valve) may also be automatically adjusted by a controller to allow sampling and every period of time trigger suction or application of medication while blocking the sampling path. The controller may also be adapted to stop the sampling pump upon blocking the sampling line.

[0034] According to embodiments of the invention, the connector (such as connector 210) may be integrally formed with the second endotrachial tube, which may also be referred to as small diameter endotrachial tube (such as small diameter tube 204), or may be adapted to be (removably or permanently) affixed or mounted on the proximal end of the second endotrachial tube.

[0035] Sampling breath for CO_2 monitoring can be performed from the area of the distal end (such as distal end 208) of the double lumen ETT (such as double lumen ETT 200). The sampling is performed through the small diameter tube (such as small diameter tube 204) of the double lumen ETT.

[0036] For clarification and the avoidance of doubt, a "double lumen ETT" or "double lumen endotrachial tube" includes an endotrachial tube with two or more lumens. The two or more lumens may have the same or different internal diameters.

[0037] The fluid reducing device also includes a drying tube, such as but not limited to a Nafion® tube or any other drying tube. In case of standard ventilation (where the waveform is analyzed) particularly in infants and neonates, it should be noted that using standard larger water traps, collectors, filters or the like may add extra dead space or minor interference to the breath flow which may effect the waveform.

[0038] In case of HFV it may be possible to add filter(s), liquid trap(s), dryer tubes or the like, since in HFV mode response time is less critical compared to standard ventilation, though its (their) size may dampen somewhat the spontaneous breaths.

[0039] One or more of the small diameter tubes of double-lumen ETTs (such as small diameter tubes 104 and 204) may be used for insertion of a sensor or a detector adapted to reach approximately the distal section of the trachea and sense (detect) breath elements such as CO_2. This may replace sampling or conducted in addition to sampling. Such sensor can be a chemical sensor, electronic sensor, optic sensor or any other sensor/detector. For example, the small diameter tubes of a double-lumen ETT may be adapted to receive a fiber optics adapted to transmit and return radiation (for example IR radiation at a wavelength that CO_2 absorbs), and thus detect one or more breath parameters (such as CO_2 levels or waveforms in case of standard ventilation). Radiation (such as light) may be emitted through the main endotrachial tube (such as main endotrachial tubes 102 and 202) in such way that light entered through the main endotrachial tube is reflected by an appropriate reflector back through an optical fiber in the small diameter tube back to an appropriate detector.

[0040] The main endotrachial tube may include, at or in proximity to its distal end, a mechanism that is adapted to open when positive pressure from a ventilator pushes in the air for ventilation, while close on exhalation. This way, the exhaled breath will be forced to return around the outside of the main endotrachial tube to be collected by the second endotrachial tube. It is noted however, that a mechanism such as mechanism 340 may apply to standard ventilation, while, in HFV where the main concept is base on diffusion, such mechanism may not be applicable.

[0041] Reference is now made to **Fig. 1C** which does not form part of the present invention and schematically shows a double lumen Endotrachial Tube (ETT). Endotrachial Tube (double lumen ETT) 300 includes a main endotrachial tube 302 and a second endotrachial tube 304 located outside and along the wall of main endotrachial tube 302. Second endotrachial tube 304 has a distal opening 306 at approximately one third of the way of main endotrachial tube 302, so that upon insertion to the trachea, it only would only reach the cavity of the mouth for sampling exhaled air that escaped around uncuffed ETT 300.

[0042] Second endotrachial tube 304 also includes, at its end opposing distal opening 306, a second opening having a connector 310. Connector 310 includes a sampling opening 312 adapted to connect to a sampling line 314. Connector 310 also includes suction port 318 through which suction of fluids from the distal section of the trachea can be performed. Suction port 318 may also be adapted to allow application of agents such as surfactants, medications or the like. Connector 310 further includes valve 320. Valve 320 has two optional positions, a first position (as shown in Fig. 1C) allows the flow of air sampled through small diameter tube 304 to sampling line 314 and on to the analyzer (such as a capnograph). The second position (not shown) of valve 320 approximately perpendicular to the first position. In the second position, valve 320 blocks the flow of air sampled through small diameter tube 304 to sampling line 314 and allow the flow towards suction port 318. Valve 320 (or any other valve) may be adjusted by a user to allow sampling and from time to time, as needed or every period of time, allow suction or application of medication while blocking the sampling path. Proximal opening 330 of main endotrachial tube 302 is adapted to connect to a ventilator. Valve 320 (or any other valve) may also be automatically adjusted by a controller to allow sampling and every period of time trigger suction or application of medication while blocking the sampling path. The controller may also be adapted to stop the sampling pump upon blocking the sampling line.

[0043] Main endotrachial tube 302 also includes, in proximity to its distal end 308, a mechanism 340 that is adapted to open when positive pressure from a ventilator pushes in the air for ventilation, while close on exhalation. It is noted however, that a mechanism such as mechanism 340 may apply to standard ventilation, while, in HFV where the main concept is base on diffusion, such mechanism may not be applicable. This way, the exhaled breath will be forced to return around the outside of the main endotrachial tube to be collected by the second endotrachial tube.

[0044] A miniature nano-technology CO_2 sensor may be placed in the trachea through the small diameter tube of the double lumen ETT. This configuration may allow measuring the CO_2 in-situ. The CO_2 nano sensor can also be placed in any ETT not necessarily double lumen ETT. Similarly, any other sensor, such as an O_2 sensor may also be placed in (and/or through) the small diameter tube of the double lumen ETT or any ETT in addition or instead of the CO_2 nano sensor. The sensor may be disposable.

High Frequency Ventilation (HFV):

[0045] Also disclosed but not forming part of the invention are a method and apparatus for using capnography in monitoring breath carbon dioxide (CO_2) in subjects, particularly, but not limited to, small children and infants, who are ventilated by High Frequency Ventilation (HFV) technique.

[0046] As discussed above when considering capnography for replacing at least some of the blood gas samples, and in general to provide continuous monitoring for HFV (such as HFOV) mode of ventilation, some difficulties arise. These difficulties include very high ventilation frequencies, lack of "clear", "textbook" breath cycle and when sampling at the standard position for capnography, either in mainstream or sidestream, the CO_2 concentration is much lower than what is really occurring in the lungs.

[0047] Since in HFV one can expect long periods without observing typical waveforms and breath cycles, which are not the result of apnea, the platform for CO_2 sampling in HFV subjects should take this into account or be insensitive to such instances.

New parameters to be provided to the user:

[0048] This following describes possible requirements, improvements and/or changes needed in order to provide an appropriate Capnography mode of operation with subjects ventilated with HFV.

[0049] New parameters for defining HFV mode are disclosed. These parameters may optionally have their own alarm management and trend characteristics. Of course, the names given to these parameters are not binding and are only optional.

[0050] The following parameters may be defined and used for capnography in subjects ventilated with HFV. Some of

these parameters may be used instead of or in addition to standard respiratory rate (RR), $EtCO_2$ parameters or other known standards.

a) Cont.CO_2 - Continuous CO_2: This is a main value used in HFV capnography and can be calculated as the average CO_2 reading (concentration) over the last "x" seconds (which could be 5 seconds or 1 to 60 seconds or any other period), updated every "y" second ("y" could be 1 to 60 seconds or any other period). If within this period a spontaneous breath is detected or even the possible beginning of such a breath is suspected (to be defined in section "e" below), then the last Cont.CO_2 value could be frozen until a new period (such as, a 5-second period) has passed without any identified spontaneous breath. If the spontaneous breaths continue for more than possibly "z" seconds (such as, 60 seconds) without a "w" second (for example, 5 second) gap, the Cont. CO_2 value may be determined and optionally displayed as invalid (for example a dash is provided in place of the value).

b) S-$EtCO_2$ - Spontaneous $EtCO_2$: If a spontaneous breath cycle (to be defined in section "e" below) is recognized (typically a result of spontaneous breathing), then the highest CO_2 (concentration) value of the breath, S-$EtCO_2$ (Spontaneous $EtCO_2$), may be measures and optionally displayed. The displayed value may be the highest result that was collected over the last "m" seconds (possibly 1 to 60 seconds). Again, it may be updated every period of time (once a second for example). If for "n" seconds (for example, 20 seconds) there is no new breath, the S-$EtCO_2$ value may be determined and optionally displayed as invalid (for example a dash is provided in place of the value).

c) S- $FiCO_2$ - Spontaneous fractional concentration of final inspired CO_2: If a breath cycle is recognized, then the lowest CO_2 (concentration) value in the breath cycle (Spontaneous fractional concentration of final inspired CO_2, S-$FiCO_2$) may be used and the value obtained and optionally displayed being the lowest collected over the last "u" seconds (possibly 1 to 60 seconds). Again, it may be updated every period of time (once a second for example). If for "t" seconds (for example, 20 seconds) there is no new breath, the S-$EtCO_2$ value may be determined and optionally displayed as invalid (for example a dash is provided in place of the value).

d) DCO_2 - Diffusion (gas transport coefficient) CO_2, DCO_2: This parameter may be similar to the conventional ventilation parameter that is the product of tidal volume and frequency, known as minute ventilation, which aptly describes pulmonary gas exchange. The gas transport coefficient which defines the CO_2 elimination correlates to the product of "oscillatory volume" squared and the frequency. For this purpose, it would be necessary to enable entering of the HFV ventilator parameters into the Capnograph.

e) Inst. CO_2 - Instantaneous CO_2: a raw unprocessed measurement of CO_2. Every period of time (for example, once every 50msec, a CO_2 measurement is performed). If the measured CO_2 change of at least "c" mmHg ("c" can for example be between 1 and 10mmHg) above (or below) the Cont.CO_2 current (latest) value and lasting for at least "k" milliseconds, msec (for example, 200msec), a spontaneous breath is suspected. The system may trace for a peak to peak (PTP) of "c" mmHg lasting more than a minimal "k" period, for example 200 msec. During this stage the Cont.CO_2 value may be frozen as stated above. In case of a timeout (of for example, 3 seconds) with no "c" mmHg PTP, the PTP trace may be stopped and the Cont.CO_2 calculation may be resumed. A spontaneous breath is counted every 2 consecutive occurrences of "c" mmHg PTP.

f) "Low CO_2": Since in HFV one can expect long periods without observing a typical waveforms and breath cycles, there is no meaning to the term "apnea" or "no breath", hence the term "low CO_2" may be used instead.

g) High and low Cont. CO_2 alarms: The alarms relating to RR, high and low $EtCO_2$ may be disabled and Cont. CO_2 high and low may be enabled.

h) Density of spontaneous breaths: The Density of spontaneous breaths may be calculated. This value may be obtained by calculating what percentage of the time the subject is spontaneously breathing

i) Trends of any CO_2 related parameter (such as Cont. CO_2 may be provided and optionally presented as a graph or table that demonstrates the change of the parameter over time.

j) The Cont. CO_2 value may be displayed at a position where in normal mode (non-HFV) the $EtCO_2$ value is displayed. The other two parameters (S-$EtCO_2$ and $FiCO_2$) may be displayed where in normal mode (no-HFV) the RR and $FiCO_2$ are displayed.

k) The display may include two parts:

1) A main waveform display having a sweep rate which is slower than the standard ventilation (non-HFV) generally in the range of 0.1 to 10 mm/second. This mode displays the Continuous (Cont. CO_2) with the sporadic spontaneous breaths superimposed on it. An example of a main waveform display can be seen in the top graph of Fig. 2, which shows an example of a capnograph display of a subject ventilated by HFV. The top graph shows the values of Cont. CO_2 in mmHg over time (seconds, sec). The sections of the graph having clear "dips" indicate spontaneous breathing.

2) A display having a slower sweep rate than that of the main waveform display (section 1 hereinabove), for example in the range of 0.1 to 10mm/min. This slower display shows the trend of the Continuous (Cont. CO_2), or in other words, how the Cont. CO_2 is changing over a period of time (for example, 90 min). This type of data may reduce or even eliminate the use of blood gas, since, for example, just by looking at it the doctor may know if the CO_2 level is improving since the last blood gas test obtained from the subject. An example of such a trend display can be seen in the bottom graph of Fig. 2, which shows the trend of Cont. CO_2 in mmHg over time (minutes, min). In addition to these graphs, values of Cont. CO2, S-$EtCO_2$, S-$FiCO_2$ as well as SpO2 and PR (pulse oximetery) may also be presented.

l) There is disclosed a means for manually (or automatically) entering an event mark, for example, defining a blood gas. A red spot, for example, or similar (possibly a sigh, a letter or a combination of letters such as "b.g.") may be placed on the slower trend display so that the doctor can easily see trends of CO_2 relative to the last blood gas time. It is preferred that one could also add the values of the blood gas in any form (values, graphical etc.) so that they can be displayed on the trend with the sampled CO_2 values.

[0051] The term "distal" or "distal end" may refer to a position located (or adapted to be located) towards a subject's lungs.

[0052] The term "proximal" or " proximal end" may refer to a position located (or adapted to be located) towards a subject's mouth.

[0053] The term "main endotracheal tube" may refer to a part of an endotracheal tube through which ventilation may be performed.

[0054] The term "second endotracheal tube" may refer to a part of an endotracheal tube which is not directly used for ventilation. A second endotracheal tube may be smaller in diameter than the main endotracheal tube. A second endotracheal tube may be integrally formed with the main endotracheal tube or connected thereto.

[0055] The term "sampling line" or "breath sampling line" may refer to any type of tubing(s) or any part of tubing system adapted to allow the flow of sampled breath, for example, to an analyzer, such as a capnograph. The sampling line may include tubes of various diameters, adaptors, connectors, valves, drying elements (such as filters, traps, trying tubes, such as Nafion® and the like).

EXAMPLES

EXAMPLE 1: Correlation between sampling through a double lumen ETT and blood gas

Sturdy design

[0056] A prospective observational study was conducted at Bnai-Zion Medical Center, Haifa, Israel. Infants were connected simultaneously to proximal and distal $EtCO_2$ monitors, and the measurements were compared to $PaCO_2$ drawn for patient care. Measurements of distal $EtCO_2$ ($dEtCO_2$) were not used for patients' clinical care. The study was approved by the institutional review board. All the parents signed an informed consent prior to participating in the study.

[0057] The primary outcome measure was to evaluate the accuracy and the correlation of Microstream $dEtCO_2$ with the gold standard of $PaCO_2$. The secondary outcome measure was to compare these findings to the more standard and commonly used method of mainstream $pEtCO_2$.

Study population

[0058] Included in the study were all intubated infants in the NICU during the study period, who had the double lumen endotracheal tubes (ETT) and that their parents signed an informed consent. Excluded were infants with a single lumen endotracheal tube.

[0059] All infants who needed an ETT were intubated in the delivery room or in the NICU by a double lumen tube

(Uncuffed Tracheal Tube, Mallinckrodt Inc., Chih, Mexico). This ETT has an extra small lumen for administration of exogenous surfactant or for measurements of distal pressures close to the carina. In this study this side port was used to measure dEtCO2 only.

[0060] Intubated infants were monitored by the two capnograms simultaneously. The side-stream $dETCO_2$ was measured distally by a Microstream capnograph via a Microstream cannula (Oridion Medical Inc., Needham, MA). The mainstream $pETCO_2$ was measured via capnogram connected to the proximal end of the ETT (Philips IntelliVue patient monitor, Capnography Extension M3014A, Philips, Boeblingen, Germany). Readings from the two methods were charted at the time of blood sampling for routine patient care via an indwelling arterial line and compared to $PaCO_2$ level (Omni AVL, Roche Diagnostic Gmbh, Graz, Austria). Before each blood sampling it was assured that an adequate reading of $pEtCO_2$ and a reliable waveform on the Microstream capnograph (continuous steady waveform of expired CO_2 throughout the ventilatory cycle), and cleared secretions from the side port of the ETT for $dEtCO_2$ measurement (by inserting 5 ml of air). Microstream cannulas blocked by secretions were replaced as needed.

[0061] Data on the patients' characteristics, type of their pulmonary or cardiac disease and the severity of pulmonary disease (by oxygenation index defined as fractional inspired of oxygen [FiO_2] X mean airway pressure/PaO_2 and by the level of ventilation perfusion mismatch assessed by PaO_2/PAO_2 ratio) was collected. Severe lung disease was defined as: PaO_2/PAO_2 ratio< 0.3 (18, 19) or OI >10; mild-moderate lung disease: PaO_2/PAO_2 ratio > 0.3 and OI <10 (PAO_2 was calculated by: FiO_2 X [Barometric pressure-47]-$PaCO_2$/0.8]. $PaCO_2$ was assumed the same as alveolar $PACO_2$.

[0062] A bias $\leq$ 5 mmHg was considered a low bias and >5 mmHg a high bias (9, 10).

[0063] The consistency of $EtCO_2$ monitoring (proximal and distal) within each patient was assessed by examining the relationship between the change in $PaCO_2$ and the change $EtCO_2$ in consecutive samples.

Statistical analysis

[0064] The correlation of distal and proximal $EtCO_2$ and $PaCO_2$ was evaluated by linear regression analysis and assessed the agreement between these measurements (bias [mean difference] and precision [standard deviation of the differences]) by the Bland-Altman technique (22).

[0065] The correlation between the changes in $PaCO_2$, and the simultaneous changes in proximal and distal $EtCO_2$ were evaluated for consecutive measurements within each patient by linear regression analysis.

[0066] Level of significance was set at $p<0.05$. SigmaStat version 2.03, Chicago, IL and the Minitab version 12.23, State College, PA statistical softwares were employed.

Results

[0067] Twenty-seven infants participated in the study and 222 measurements of distal $EtCO_2$ and 212 of proximal $EtCO_2$ were analyzed. In 10 infants proximal $EtCO_2$ could not be measured continuously. **Table 1** shows the characteristics of the patients who participated in the study.

Table 1: Patients' characteristics (n=27)

	Median	**Range**
Gestational age (weeks)	32.5	(24.8-40.8)
Birth weight (g)	1835	(490-4790)
Age of enrolment (days)	1	(1-26)
Number of observations	8	(1-24)
pH	7.34	6.5-7.5
FiO_2*	0.31	0.21-1.00
PaO_2/PAO_2 ratio**	0.50	0.06-2.38
Oxygenation index (OI)***	3.29	0.63-23.0
Primary diagnosis (n=27 infants)		
Respiratory distress syndrome		19
Tracheo-esophageal fistula and esophageal atresia		3
Pneumonia		1
Primary pulmonary hypertension		1
Meconium aspiration syndrome		1
Hypoxic ischemic encephalopathy		1

(continued)

	Median	Range
Necrotizing enterocolitis		1

* FiO_2 Inspired oxygen fraction;
** PaO_2/PAO_2 alveolar/arterial oxygen tension ratio;
*** OI = FiO_2 X mean airway pressure/PaO_2

[0068] The median (range) levels of $PaCO_2$, $dEtCO_2$, $pEtCO_2$ were 46.3 (24.5-99.7) mmHg, 46.0 (20.0-98.0) mmHg, and 37.0 (12.0-71.0) mmHg, respectively.

[0069] **Figs. 3 A and B** show the linear correlation between distal $EtCO_2$, $dEtCO_2$ (A) and proximal $EtCO_2$, $pEtCO_2$ **(B)** with arterial PCO_2. While the correlation coefficient (r) of $dEtCO_2$ and $PaCO_2$ was adequate (r = 0.72, p< 0.001), the r of the $pEtCO_2$ was poor (r = 0.21, p=0.002).

[0070] **Figs. 4 A and B** present the Bland-Altman plots of the differences between distal $EtCO_2$, $dEtCO_2$ **(A)** and proximal $EtCO_2$, $pEtCO_2$ **(B)** and arterial CO_2, $PaCO_2$. The mean difference (bias) and the standard deviation of the differences (precision) for the $dEtCO_2$ were -1.5±8.7 mmHg , and for the $pEtCO_2$ -10.2±13.7 mmHg, respectively. The correlating medians (25 and 75 percentiles) were: -1.1 (-5.6 and 2.7) and -10.3 (-16.0 and -0.8), respectively. Although both, distal and proximal $EtCO_2$ levels underestimated the $PaCO_2$ level, $dEtCO_2$ was more accurate than $pEtCO_2$ as a non-invasive measure of $PaCO_2$.

[0071] $dEtCO_2$ (21 samples) remained reliable as a measure of $PaCO_2$, while $pEtCO_2$ (19 samples) was distorted on the high range of $PaCO_2$ levels (≥60 mmHg) (r = 0.77, p<0.001 and r = 0.21, p = 0.38; bias ± precision: -4.8±7.9 and -33.3±20.0; respectively).

[0072] **Table 2** shows the effect of the severity of pulmonary disease (assessed by PaO_2/PAO_2 ratio or by OI) on the accuracy of distal and proximal $EtCO_2$ readings. It was found that $dETCO_2$ still correlated with $PaCO_2$, but its bias increased with the severity of pulmonary disease.

Table 2: Relation between $EtCO_2$ values and severity of lung disease

	Mild to Moderate Mean (SD); r, p value	**Severe lung disease** Mean (SD); r, p value
PaO_2/PAO_2 ratio	>0.3 (n=168)	≤0.3 (n=63)
P (Et-a distal) CO_2	-0.24±7.3; 0.74, <0.001	-4.2±10.5; 0.64, <0.001
P (Et-a proximal) CO_2	-9.1±14.0; 0.07, =0.34	-12.5±12.5; 0.35, <0.01
Oxygenation index	<10 (n=216)	≥10 (n-16)
P (Et-a distal) CO_2	-0.7±8.2; 0.69, <0.001	-9.0±8.1; 0.77, <0.001
P (Et-a proximal) CO_2	-9.8±13.9; 0.13, =0.07	-13.0±9.8; 0.52, =0.054
All CO_2 levels in mmHg		

[0073] The changes in $PaCO_2$, and the simultaneous changes in proximal and distal $EtCO_2$ were evaluated for consecutive measurements within each patient. The mean changes in $PaCO_2$ were 0.12±9.3 mmHg and in $dEtCO_2$ 0.90±10.8 mmHg, with r between the changes of 0.49, p<0.001. Mean change in $pEtCO_2$ was -0.02±8.5 mmHg, with r of 0.17, p<0.05, compared to the simultaneous changes in $PaCO_2$.

[0074] This study shows that the novel method of measuring dEtCO2 through a double-lumen ETT had a better correlation and agreement with $PaCO_2$ when compared to the standard mainstream $pEtCO_2$ method in neonates. The accuracy of $dEtCO_2$ decreased but it remained a reliable measure of $PaCO_2$ even in the high range of $PaCO_2$ (≥60 mmHg) or in conditions of severe lung disease.

[0075] It was found that $dEtCO_2$ was an accurate and reliable non-invasive method for estimating $PaCO_2$. It had a good correlation with $PaCO_2$ (n = 222, r = 0.72, p<0.001), which was slightly lower compared to mainstream $pEtCO_2$ (n = 411, r = 0.83, p<0.001) as previously reported for NICU infants by Rozycki *et al* (10). The bias reported for $dEtCO_2$ (-1.5±8.7 mmHg) was even smaller than that reported by Rozycki *et al* for mainstream $pEtCO_2$ (-6.9±6.9 mmHg), and was well < 5 mmHg, which is considered within the good agreement range (9, 10). In the study, the correlation and the agreement of $dEtCO_2$ with $PaCO_2$ were better than those for mainstream $pEtCO_2$. Several investigators reported similar results for distal and proximal sidestream $EtCO_2$ (17, 18) while others reported comparable accuracy of distal and proximal mainstream $EtCO_2$ (11). However, neither of these studies measured $dEtCO_2$ by a double lumen ETT, nor did they use the Microstream technique. The study results regarding the mainstream $pEtCO_2$ should be interpreted with

caution, as others reported better results for that method (10). This could result from different conditions in the different studies reflected by mixture of patients, severity of their lung disease, levels of leak around the ETT, and instrumentation used for measurements.

[0076] Severity of disease was reported to affect the accuracy of capnometry in several studies. The more severe the ventilation perfusion mismatch, the higher the difference between $EtCO_2$ and $PaCO_2$ (9, 20). Parenchymal lung disease with ventilation perfusion mismatching is a common feature in NICUs. Sivan *et al* (20) reported that PaO_2/PAO_2 ratio > 0.3 was associated with better agreement between $EtCO_2$ and $PaCO_2$ and Hagerty *et al* (9) found a higher gradient between $EtCO_2$ and $PaCO_2$ when comparing newborn with pulmonary disease and those receiving mechanical ventilation for non-pulmonary conditions. Different results were reported by other investigators. Tingay *et al* (19) found that the $EtCO_2$ bias was independent of severity of lung disease and Rozycki *et al* (10) reported that measures of degree of lung disease (ventilation index and oxygenation index) had small influence on the degree of bias. In the study the agreement of $dEtCO_2$ and $PaCO_2$ decreased, but the bias in patients with PaO_2/PAO_2 ratio< 0.3 remained < 5 mmHg. It was assessed whether the level of $PaCO_2$ affected the accuracy of $EtCO_2$ readings, and found it to affect the $pEtCO_2$ much more than the $dEtCO_2$, which remained with adequate agreement with the $PaCO_2$. Rosycki *et al* did not find that the accuracy of $pEtCO_2$ was affected by the $PaCO_2$ level (10). The findings suggest that $dEtCO_2$ as evaluated in the study could be used as a reliable non-invasive method for $PaCO_2$ assessment in the full spectrum of NICU patients.

[0077] Although the Microstream sidestream capnography was used previously in (only) two studies in newborns (9, 19), this is the first time a double lumen ETT is used for the disclosed perpose, which allowed continuous measurement of $dEtCO_2$ via its extra lumen.

[0078] The intention of the Microstream technique is to improve the accuracy of sidestream capnomtery which is traditionally considered less accurate than the mainstream capnometry (11, 13, 14, 15, 16). Microstream capnography employs a sampling flow rate of 50 ml/min, approximately one third of that used by previous studies with conventional sidestream systems. This low flow rate eliminates the competition for tidal volume and also decreases condensation within the system. Because of the highly CO_2 - specific infrared source (emission that exactly matches the absorption spectrum of the CO_2 molecule), the sample cell utilizes a much smaller volume (15 μl) that permits a low flow rate without compromising response rate or accuracy. These features preserve accuracy by preventing mixing of the small inspiratory and expiratory volumes observed in newborns, while rapid response time is maintained by laminar gas flow throughout the breathing circuit (22). The new low-flow sidestream capnograph (Oridion Medical Inc., Needham, MA, USA) was tested when connected to the side port of the proximal ETT by Hagerty *et al* (9), and they reported a gradient of 3.4 ± 2.4 mmHg in ventilated infant without pulmonary disease and 7.4 ± 3.3 in those with pulmonary disease. Tingay *et al* (19) also used the Microstream technique (Agilent Microstream system, Andover, Massachusetts, USA) for monitoring $pEtCO_2$ in infants during neonatal transport. They reported that the $pEtCO_2$ had a linear relation with $PaCO_2$ but had an unacceptable underestimation of $PaCO_2$ (8.2 ± 5.2 mmHg), and did not trend reliably over time within an individual patient. In the study, using the Microstream technique (Oridion Medical Inc., Needham, MA, USA), but measuring $dEtCO_2$ via the side port of the double lumen ETT, the agreement with $PaCO_2$ improved, in infants with both mild and severe pulmonary disease (-0.24 ± 7.3, and -4.2 ± 10.5; respectively). The improvement could be related to distal measurements of $EtCO_2$. This technique which measures $EtCO_2$ close to the carina, may be less affected by the ventilatory circuit flow and leaks around the uncuffed ETTs used in neonates and thus better represent the accurate $PaCO_2$. $dEtCO_2$ as opposed to $pEtCO_2$ are not affected by flow sensors which are commonly used nowadays with the new ventilators (flow sensors in the study prevented the use of $pEtCO_2$ in few infants because of inadequate continuous measurements).

[0079] The novel method of measuring $dEtCO_2$ via a double-lumen endotracheal tube was found to have good correlation and agreement with $PaCO_2$, and is thus a reliable in conditions of severe lung disease $dEtCO_2$ was more accurate than the standard mainstream $pEtCO_2$ method as assessed in the study. $EtCO_2$ does not replace $PaCO_2$, but may be useful for trending and for real time continuous screening of abnormal $PaCO_2$ levels. As noninvasive CO_2 monitoring may be of importance for the short and long term outcome of intubated neonates, and as the current available methods are limited, medical teams should consider the use of this non-invasive method of assessing $PaCO_2$ in NICUs.

EXAMPLE 2: Correlation between sampling through a double lumen ETT and blood gas in patients ventilated by HFV

[0080] Eight patients ventilated by HFV were tested, comparing mainstream capnography to Microstream capnography wherein the sampling line is connected to the distal end of a double lumen ETT. In most of the cases 2.5mm ETT (internal diameter of the main endotracheal tube) were used. Correlation to blood gas was used as the reference.

[0081] Continuous distal sampling with minor liquid issues was conducted (without having to toggle). Further, two Nafion® pieces were placed along the sampling line, one next to the double lumen connector, and one about 40cm down the line. The second Nafion® was used since often the neonate is in a controlled humidified incubator, and hence one Nafion® must be placed also in the outside environment. The results are described in **Fig. 5** which shows the linear correlation between distal $EtCO_2$, $dEtCO_2$ and arterial CO_2, $PaCO_2$ in patients ventilated with High Frequency Ventilation (HFV). The correlation between $dEtCO_2$ and $PaCO_2$ was shown to be much better than the correlation between $pEtCO_2$

and $PaCO_2$.

[0082] In the description and claims of the application, each of the words "comprise" "include" and "have", and forms thereof, are not necessarily limited to members in a list with which the words may be associated.

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[0083]

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Claims

1. A double lumen endotracheal tube (200) comprising:

   a first tube (202) having a first diameter, a distal end (208), and a proximal end (230);
   a second tube (204) located essentially inside the first tube (202) and along the wall of the first tube (202) and having a diameter smaller than the first diameter and comprising a distal opening (206) and a second opening opposing the distal opening (206), said second opening having a connector (210);
   wherein the distal opening (206) of the second tube (204) is located a few millimeters before the distal end (208) of the first tube (202) and has several apertures (209):

   wherein the connector (210) further includes:

   a connecting element (211) adapted to connect to the second tube (204);
   a sampling opening (212) adapted to connect to a sampling line (214);
   a suction port (218); and
   a valve (220);
   characterized in that
   the second tube (204) further comprises a drying tube (216) adapted to absorb and/or pervaporate fluids present in sampled breath,
   and **in that** the suction port (218) is adapted to allow application of agents such as surfactants and/or medications;

   wherein the valve (220) has two positions, a first position allowing the flow of air sampled through second tube (204) to drying tube (216) and sampling line (214) and on to an analyzer, and the second position blocking the flow of air sampled through the second tube (204) to drying tube (216) and sampling line (214) and allowing the flow towards suction port (218).

2. The double lumen endotracheal tube (200) according to claim 1, wherein the second diameter is approximately 0.8 mm.

3. The double lumen endotracheal tube (200) according to claim 1 or 2, wherein the number of apertures (209) is three.

4. The double lumen endotracheal tube (200) according to any of the preceding claims, wherein the connector (210) is integrally formed with the second tube (204).

5. A breath sampling system comprising:

   a double lumen endotracheal tube (200) according to any of claims 1-4, being adapted for sampling breath from a subject for the evaluation of one or more parameters related to concentration of carbon dioxide (CO_2) in the sampled breath; and
   a breath sampling line (214) adapted to connect to the second tube (204) of the double lumen endotracheal tube (200) through the connector (210).

6. The breath sampling system according to claim 5, wherein the one or more parameters related to concentration of CO_2 comprise spontaneous end tidal CO_2 ($S\text{-}EtCO_2$), spontaneous final inspired CO_2 ($S\text{-}FiCO_2$), continuous CO_2 (Cont. CO_2), diffusion CO_2 (DCO_2), density of spontaneous breathing or any trend thereof or any combination thereof.

Patentansprüche

1. Endotrachealschlauch mit doppeltem Lumen (200) welcher umfasst:

   eine erste Röhre (202) mit einem ersten Durchmesser, einem distalen Ende (208), und einem proximalen Ende (230);
   eine zweite Röhre (204), die im Wesentlichen in der ersten Röhre (202) und entlang der Wandung der ersten Röhre (202) angeordnet ist und einen Durchmesser aufweist, der kleiner ist als der erste Durchmesser, und die eine distale Öffnung (206) und eine zweite Öffnung umfasst, die von der distalen Öffnung (206) abgewandt ist, worin die zweite Öffnung einen Verbinder (210) aufweist;

worin die distale Öffnung (206) der zweiten Röhre (204) ein paar Millimeter vor dem distalen Ende (208) der ersten Röhre (202) angeordnet ist und mehrere Öffnungen (209) aufweist;

worin der Verbinder (210) weiter umfasst:

ein Verbindungselement (211), das angepasst ist, mit der zweiten Röhre (204) verbunden zu werden;
eine Probennahme-Öffnung (212), die angepasst ist, mit einer Probennahme-Leitung (214) verbunden zu werden;
einen Sauganschluss (218); und
ein Ventil (220);
dadurch gekennzeichnet, dass
die zweite Röhre (204) weiter eine Trockenröhre (216) umfasst, das angepasst ist, in dem als Probe genommenen Atem vorhandene Fluide zu absorbieren und/oder zu verdampfen,
und dass der Sauganschluss (218) angepasst ist, eine Anwendung von Mitteln zu ermöglichen, wie oberflächenaktiven Mitteln oder Arzneimitteln;
worin das Ventil (220) zwei Positionen aufweist, eine erste Position, die einen Strom der als Probe genommenen Luft durch die zweite Röhre (204) zu der Trockenröhre (216) und der Probennahme-Leitung (214) und weiter zu einem Analysegerät ermöglicht, wobei die zweite Position den Luft-Strom durch die zweite Röhre (204) zu der Trockenröhre (216) und der Probennahme-Leitung (214) blockiert und einen Strom zu dem Sauganschluss (218) ermöglicht.

2. Endotrachealschlauch mit doppeltem Lumen (200) nach Anspruch 1, worin der zweite Durchmesser etwa 0,8 mm ist.

3. Endotrachealschlauch mit doppeltem Lumen (200) nach Anspruch 1 oder 2, worin die Anzahl an Öffnungen (209) drei ist.

4. Endotrachealschlauch mit doppeltem Lumen (200) nach einem der vorstehenden Ansprüche, worin der Verbinder (210) mit der zweite Röhre (204) einstückig ausgebildet ist.

5. Atemgewinnungs-System, welches umfasst:

einen Endotrachealschlauch mit doppeltem Lumen (200) nach einem der Ansprüche 1-4, der angepasst ist, eine Atemprobe von einem Individuum zu nehmen, um ein oder mehrere Parameter bezüglich der Konzentration an Kohlendioxid (CO_2) in dem als Probe genommenen Atem zu untersuchen; und
eine Atemprobe-Gewinnungsleitung (214, die angepasst ist, mit der zweite Röhre (204) des Endotrachealschlauchs mit doppeltem Lumen (200) über den Verbinder (210) verbunden zu werden.

6. Atemgewinnungs-System nach Anspruch 5, worin der eine oder die mehreren Parameter in Bezug auf die CO_2-Konzentration spontanes dem Atemrhytmus unterworfenes End-CO_2 (S-EtCO_2) spontanes finales Einatmungs-CO_2 (S-FiCO_2), kontinuierliches CO_2 (kont. CO_2), Diffusions-CO_2 (DCO_2), Dichte spontanen Atmens oder jeden Trend davon oder jede Kombination davon umfassen.

Revendications

1. Tube endotrachéal à double lumière (200) comprenant :

un premier tube (202) possédant un premier diamètre, une extrémité distale (208), et une extrémité proximale (230) ;
un second tube (204) situé essentiellement à l'intérieur du premier tube (202) et le long de la paroi du premier tube (202) et possédant un diamètre inférieur au premier diamètre et comprenant une ouverture distale (206) et une seconde ouverture opposée à l'ouverture distale (206), ladite seconde ouverture comportant un connecteur (210) ;
dans lequel l'ouverture distale (206) du second tube (204) est située à quelques millimètres avant l'extrémité distale (208) du premier tube (202) et comporte plusieurs perforations (209) :

dans lequel le connecteur (210) comprend en outre :

un élément de liaison (211) adapté pour liaison au second tube (204) ;
une ouverture d'échantillonnage (212) adaptée pour liaison à une ligne d'échantillonnage (214) ;
un orifice d'aspiration (218) ; et
une soupape (220) ;
caractérisé en ce que
le second tube (204) comprend en outre un tube de séchage (216) adapté pour l'absorption et/ou la pervaporation de fluides présents dans l'haleine échantillonnée,
et **en ce que** l'orifice d'aspiration (218) est adapté pour permettre l'application d'agents tels que des tensioactifs et/ou des médicaments ;
dans lequel la soupape (220) possède deux positions, une première position permettant l'écoulement de l'air échantillonné à travers le second tube (204) vers le tube de séchage (216) et la ligne d'échantillonnage (214) et sur un analyseur, et la seconde position bloquant l'écoulement de l'air échantillonné à travers le second tube (204) vers le tube de séchage (216) et la ligne d'échantillonnage (214) et permettant l'écoulement en direction de l'orifice d'aspiration (218).

2. Tube endotrachéal à double lumière (200) selon la revendication 1, dans lequel le second diamètre est approximativement de 0,8 mm.

3. Tube endotrachéal à double lumière (200) selon la revendication 1 ou 2, dans lequel le nombre de perforations (209) est de trois.

4. Tube endotrachéal à double lumière (200) selon l'une quelconque des revendications précédentes, dans lequel le connecteur (210) est formé en une seule pièce avec le second tube (204).

5. Système d'échantillonnage d'haleine comprenant :

un tube endotrachéal à double lumière (200) selon l'une quelconque des revendications 1 à 4, étant adapté pour l'échantillonnage de l'haleine d'un sujet pour l'évaluation d'un ou plusieurs paramètres se rapportant à la concentration en dioxyde de carbone (CO_2) dans l'haleine échantillonnée ; et
une ligne d'échantillonnage d'haleine (214) adaptée pour liaison au second tube (204) du tube endotrachéal à double lumière (200) à travers le connecteur (210).

6. Système d'échantillonnage d'haleine selon la revendication 5, dans lequel le ou les paramètres se rapportant à la concentration en CO_2 comprennent le CO_2 spontané de fin d'expiration (S-EtCO_2), le CO_2 spontané inspiré final (S-FiCO_2), le CO_2 continu (CO_2 Cont.), le CO_2 de diffusion (DCO_2), la densité de respiration spontanée ou n'importe quelle tendance de ceux-ci ou n'importe quelle combinaison de ceux-ci.

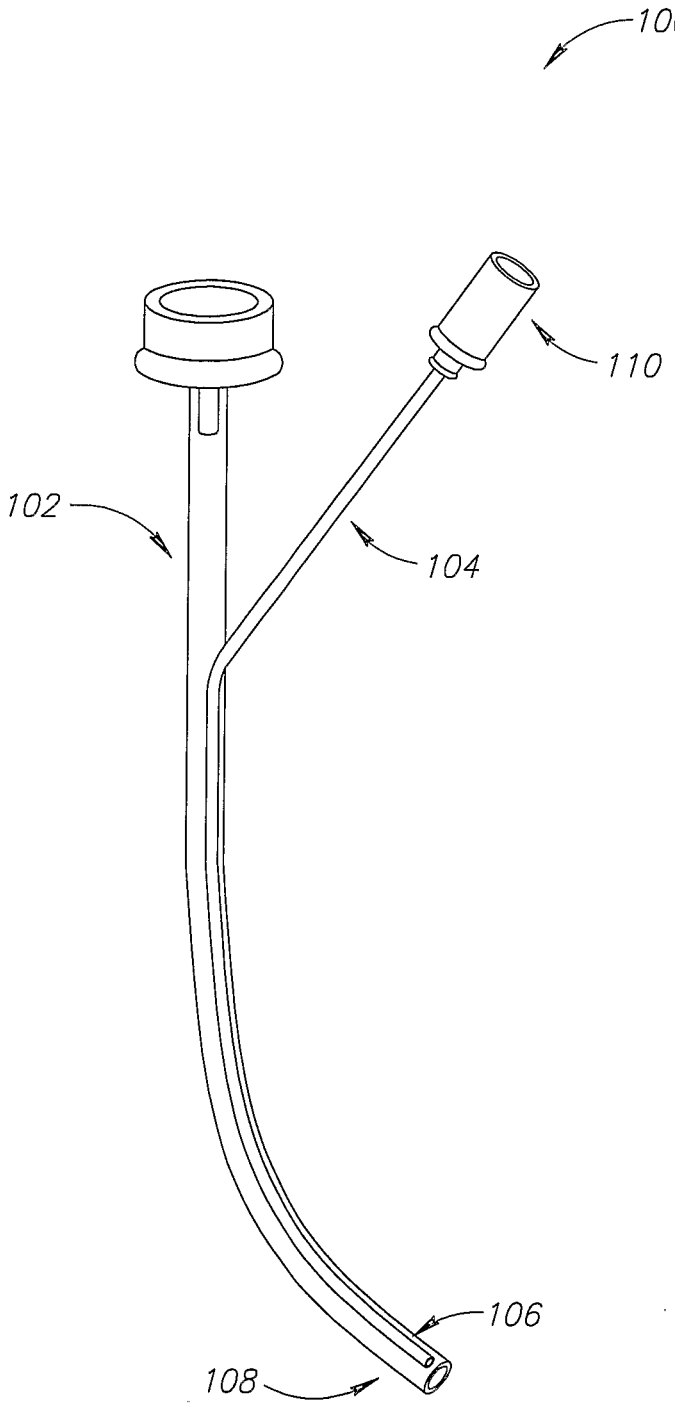

FIG.1A

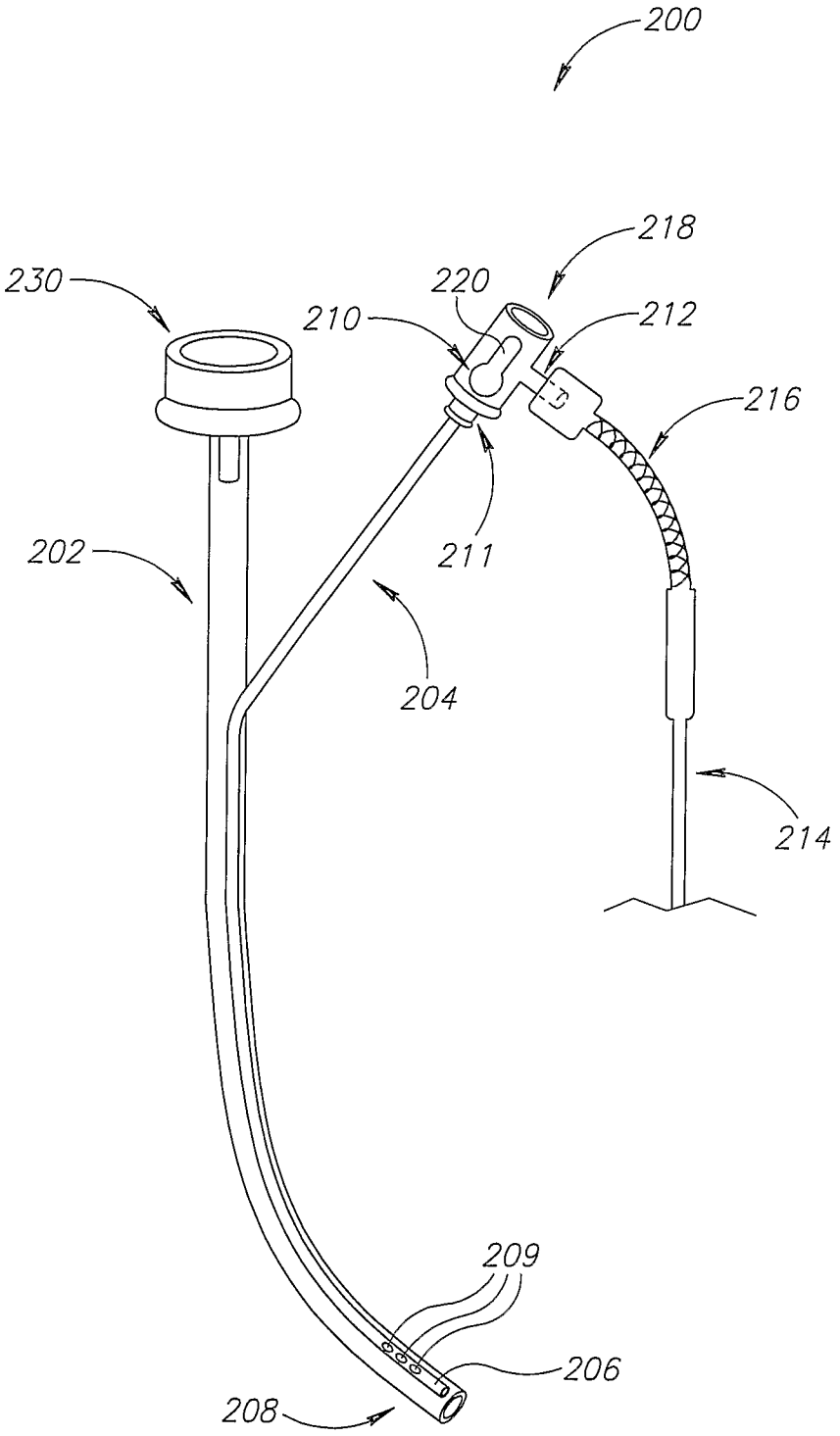

FIG.1B

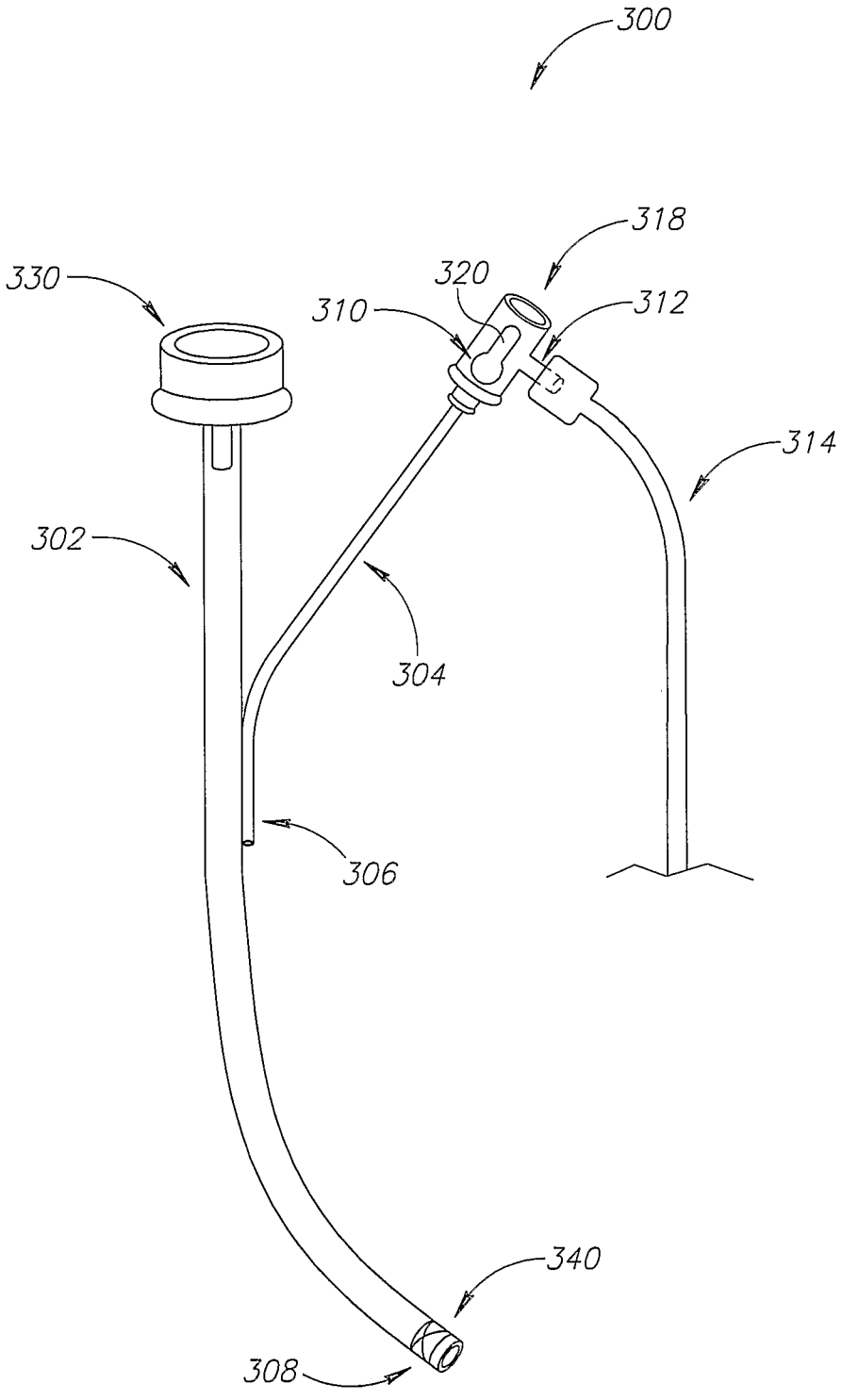

FIG.1C

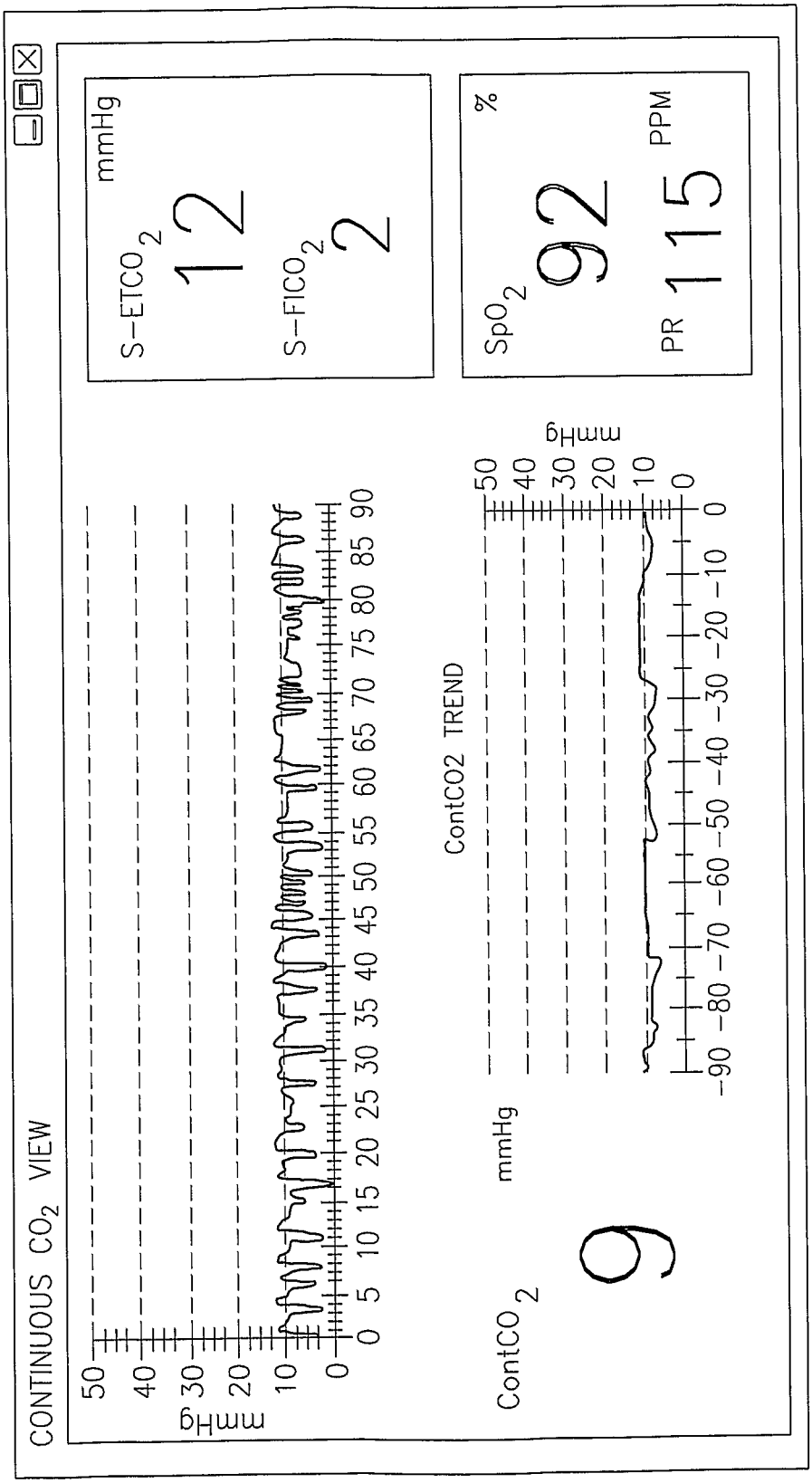
CONTINUOUS CO_2 VIEW
mmHg
50
40
30
20
10
0
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90
S-$ETCO_2$
mmHg
12
S-$FICO_2$
2
SpO_2
%
92
PR
PPM
115
ContCO2 TREND
mmHg
50
40
30
20
10
0
−90 −80 −70 −60 −50 −40 −30 −20 −10 0
mmHg
$ContCO_2$
9

FIG.2

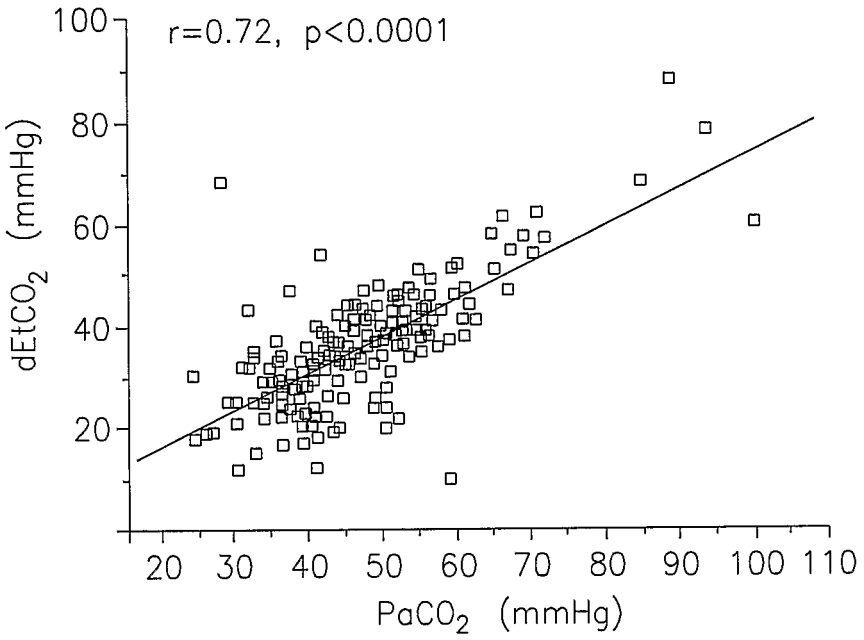
r=0.72, p<0.0001
dEtCO2 (mmHg)
PaCO2 (mmHg)
100
80
60
40
20
20 30 40 50 60 70 80 90 100 110

FIG.3A

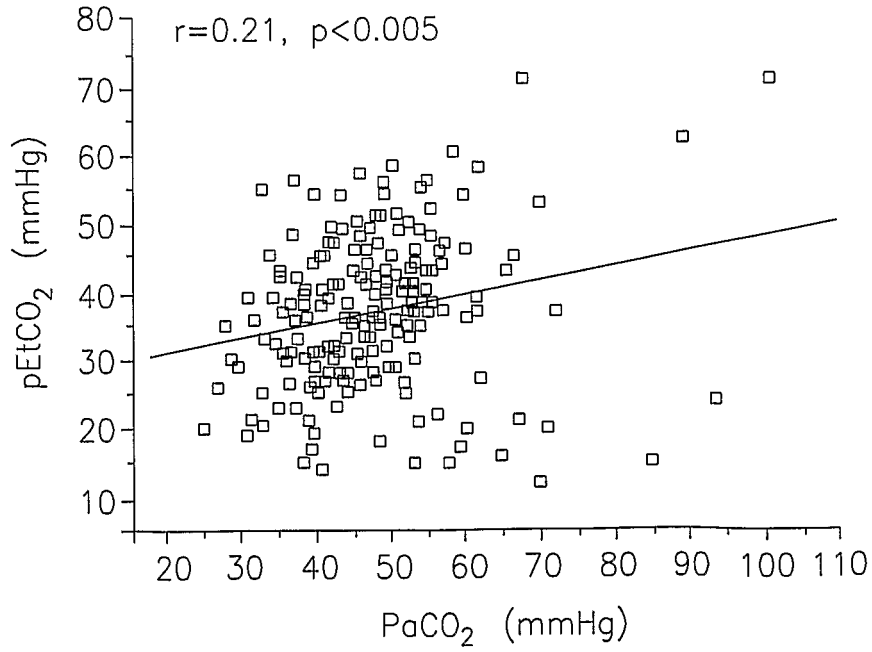
r=0.21, p<0.005
pEtCO2 (mmHg)
PaCO2 (mmHg)
80
70
60
50
40
30
20
10
20 30 40 50 60 70 80 90 100 110

FIG.3B

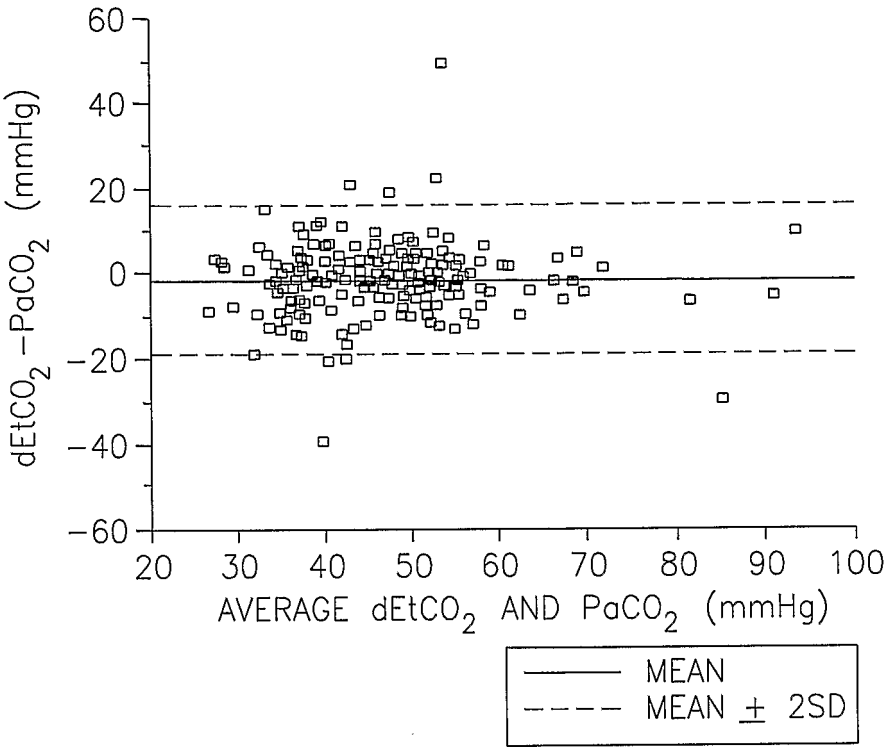
60
40
20
0
−20
−40
−60
dEtCO2 −PaCO2 (mmHg)
20 30 40 50 60 70 80 90 100
AVERAGE dEtCO2 AND PaCO2 (mmHg)
MEAN
MEAN ± 2SD

FIG.4A

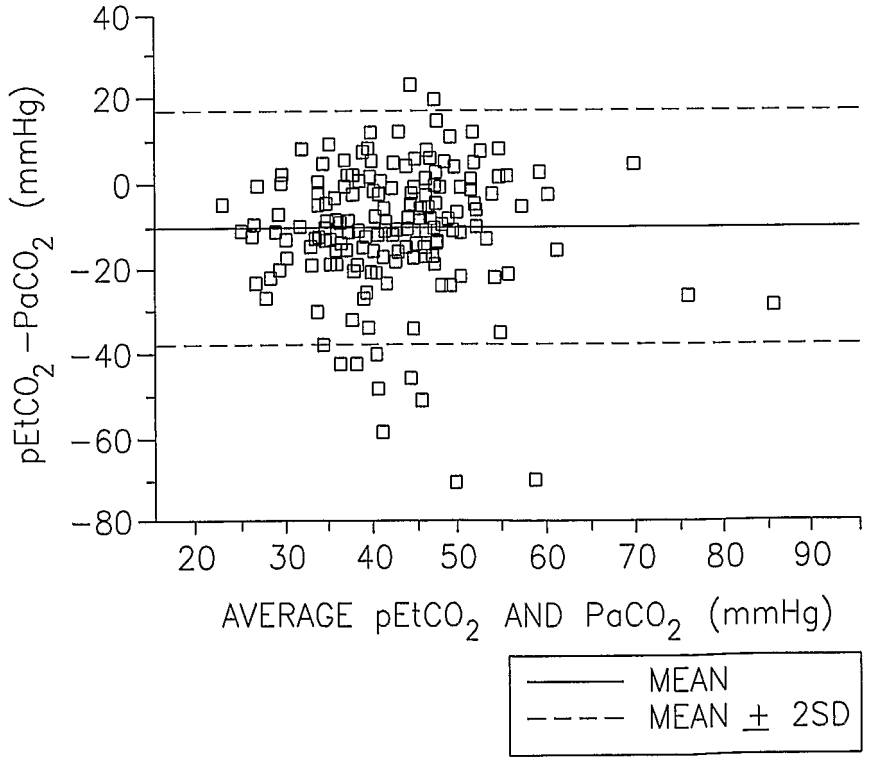
40
20
0
−20
−40
−60
−80
pEtCO2 −PaCO2 (mmHg)
20 30 40 50 60 70 80 90
AVERAGE pEtCO2 AND PaCO2 (mmHg)
MEAN
MEAN ± 2SD

FIG.4B

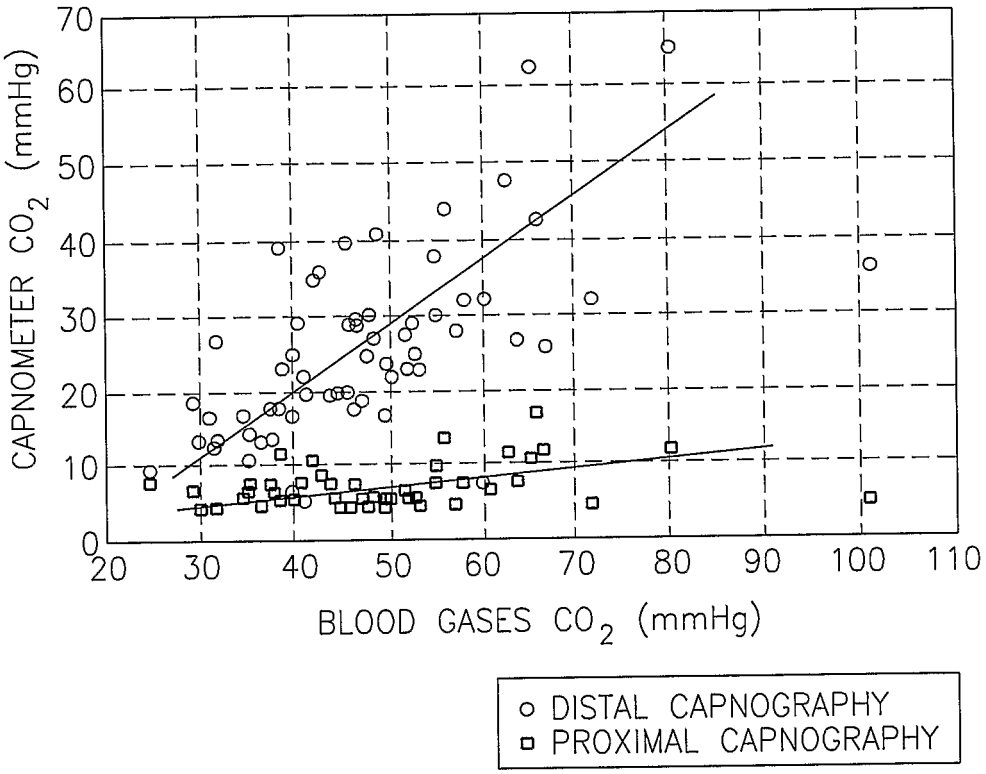
70
60
50
40
30
20
10
0
CAPNOMETER CO_2 (mmHg)
20
30
40
50
60
70
80
90
100
110
BLOOD GASES CO_2 (mmHg)
DISTAL CAPNOGRAPHY
PROXIMAL CAPNOGRAPHY

FIG.5

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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专利名称(译)	用于监测二氧化碳的气管插管		
公开(公告)号	EP2303376B1	公开(公告)日	2016-03-30
申请号	EP2009754350	申请日	2009-05-31
申请(专利权)人(译)	ORIDION MEDICAL 1987年LTD.		
当前申请(专利权)人(译)	ORIDION MEDICAL 1987年LTD.		
[标]发明人	COLMAN JOSHUA LEWIS SHALEV STEIN IRIS		
发明人	COLMAN, JOSHUA LEWIS SHALEV STEIN, IRIS		
IPC分类号	A61B5/0205 A61B5/083 A61B5/097 A61B5/00 A61M16/00 A61M16/10 A61M16/04 A61M16/08		
CPC分类号	A61B5/7282 A61B5/0205 A61B5/021 A61B5/024 A61B5/0402 A61B5/0476 A61B5/0816 A61B5/082 A61B5/0833 A61B5/0836 A61B5/087 A61B5/097 A61B5/7246 A61B5/7264 A61B5/742 A61B5/746 A61B10/00 A61B2010/0087 A61M5/1723 A61M16/0057 A61M16/0069 A61M16/0096 A61M16/04 A61M16/0463 A61M16/0484 A61M16/0486 A61M16/0488 A61M16/0816 A61M16/085 A61M16/20 A61M2016/0413 A61M2016/103 A61M2230/432 G06N5/04		
优先权	61/071959 2008-05-28 US		
其他公开文献	EP2303376A2		
外部链接	Espacenet		

摘要(译)

本文提供了用于评估受试者呼吸中的二氧化碳（CO 2）浓度的方法，装置和系统，例如在通过高频通气（HFV）通气的受试者中，该方法包括向受试者的气管插入气管内导管（ETT）），从位于气管内管（ETT）远端附近的气管区域取样呼吸，并评估采样呼吸的一个或多个CO2相关参数。

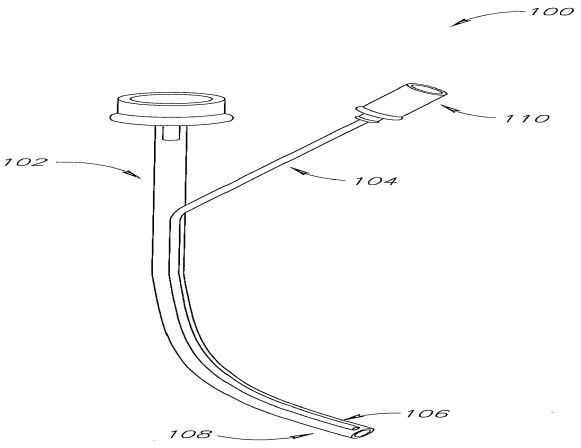

FIG.1A