



US006471658B1

(12) **United States Patent**
Daniels et al.

(10) **Patent No.:** **US 6,471,658 B1**
(45) **Date of Patent:** **Oct. 29, 2002**

(54) **RESPIRATORY PROFILE PARAMETER DETERMINATION METHOD AND APPARATUS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 12 days.

(21) Appl. No.: **09/733,776**

(22) Filed: **Dec. 8, 2000**

Related U.S. Application Data

(60) Continuation of application No. 09/334,778, filed on Jun. 16, 1999, now Pat. No. 6,179,784, which is a division of application No. 08/963,394, filed on Nov. 3, 1997, now Pat. No. 6,099,481.

(51) Int. Cl.⁷ **A61B 5/08**

(52) U.S. Cl. **600/538; 600/529**

(58) Field of Search **600/529, 531, 600/532, 533, 538**

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Primary Examiner—Kevin Shaver

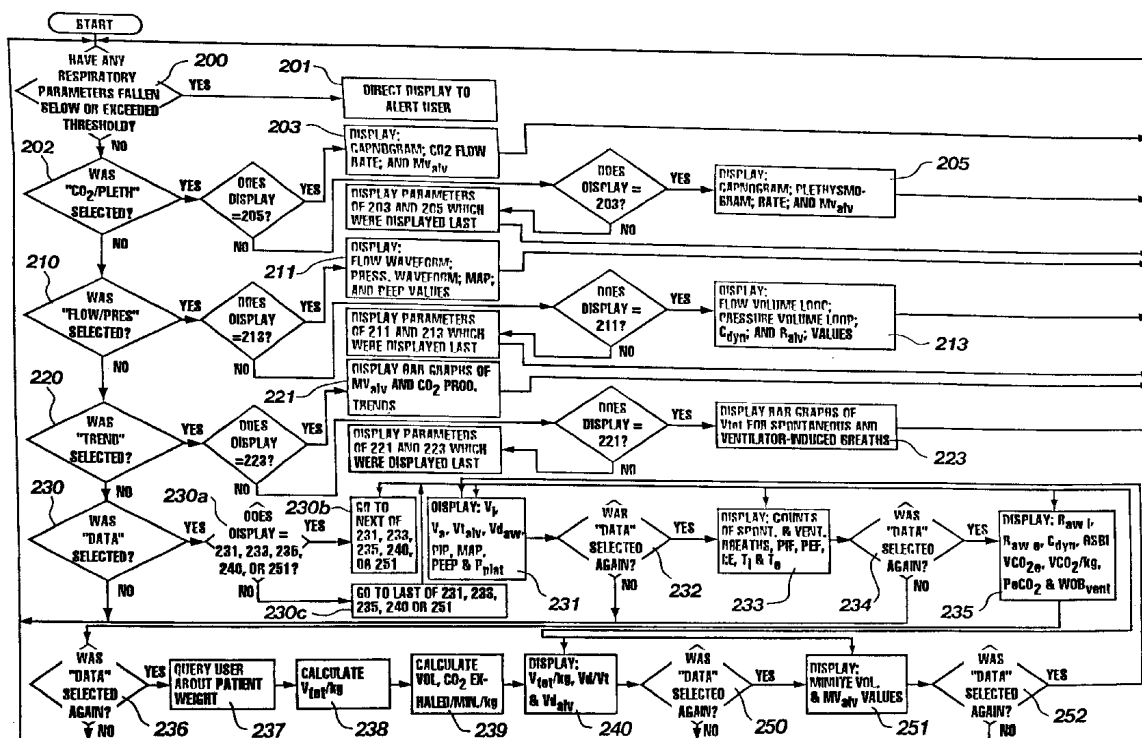
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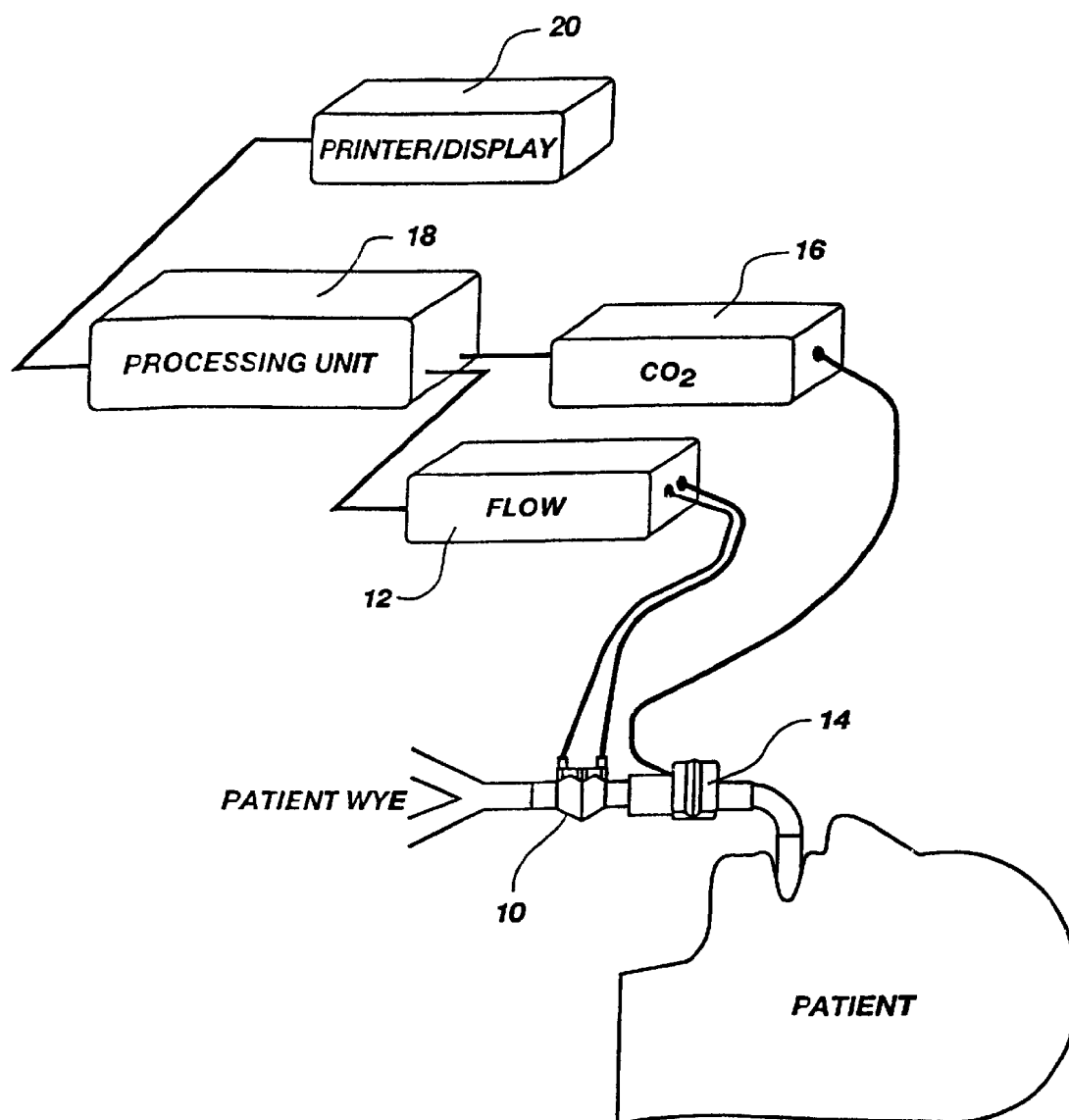
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(57) **ABSTRACT**

A method of sampling one or more respiratory profile characteristics and monitoring a variety of respiratory profile parameters. The sampled respiratory characteristics include respiratory flow rate, respiratory pressure, and partial pressure of at least one constituent of a patient's respiration. The method detects patient breaths, determines whether each breath is a spontaneous breath or a ventilator-induced breath and calculates various respiratory profile parameters based on the sampled measurements. The method displays the respiratory profile parameters in graphic and numeric forms. Preferably, the method allows a user to select the displayed respiratory profile parameters.

14 Claims, 12 Drawing Sheets



**Fig. 1**

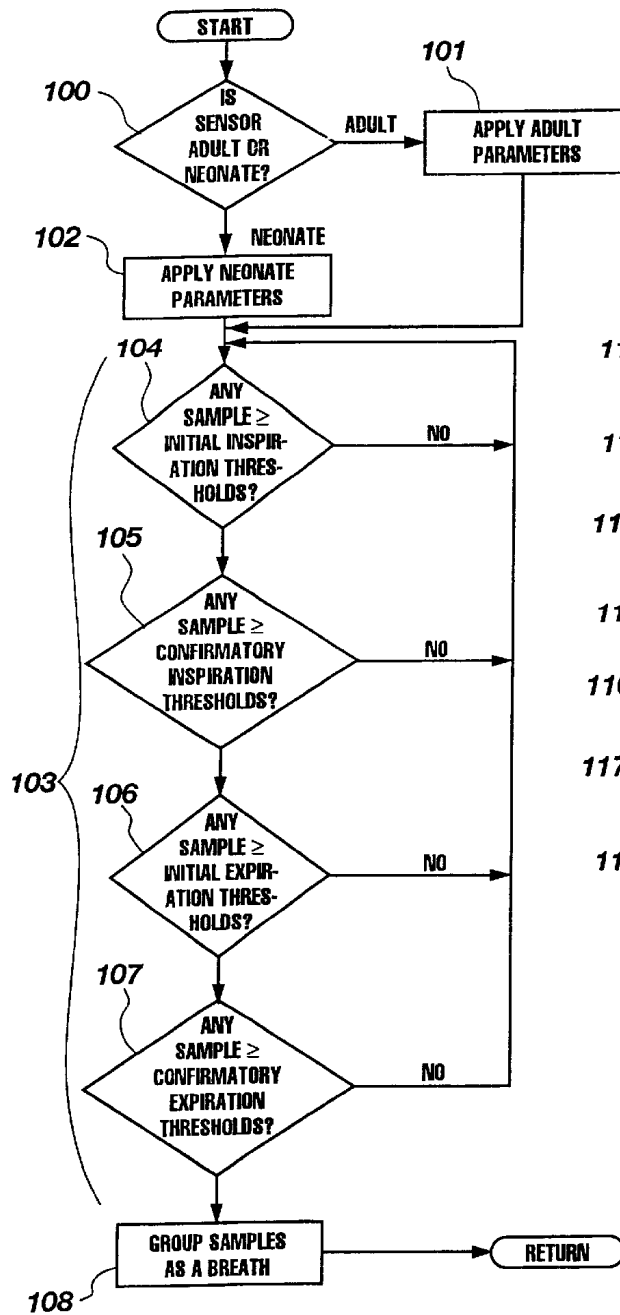


Fig. 2

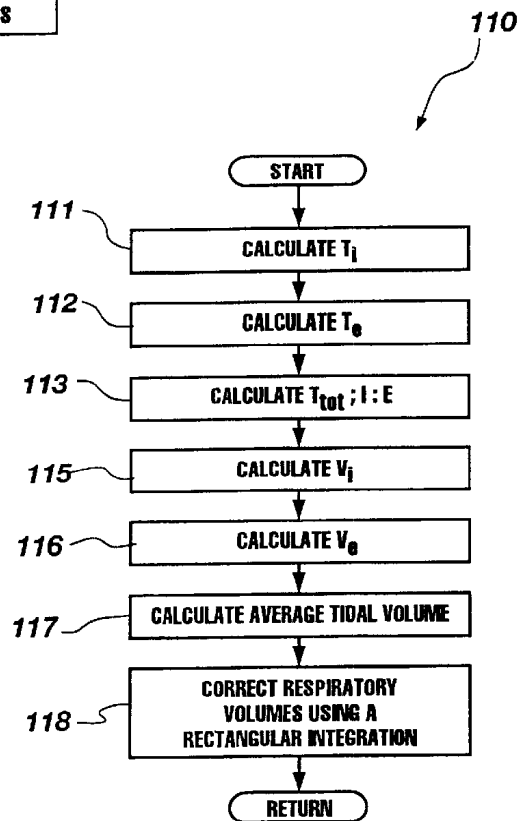
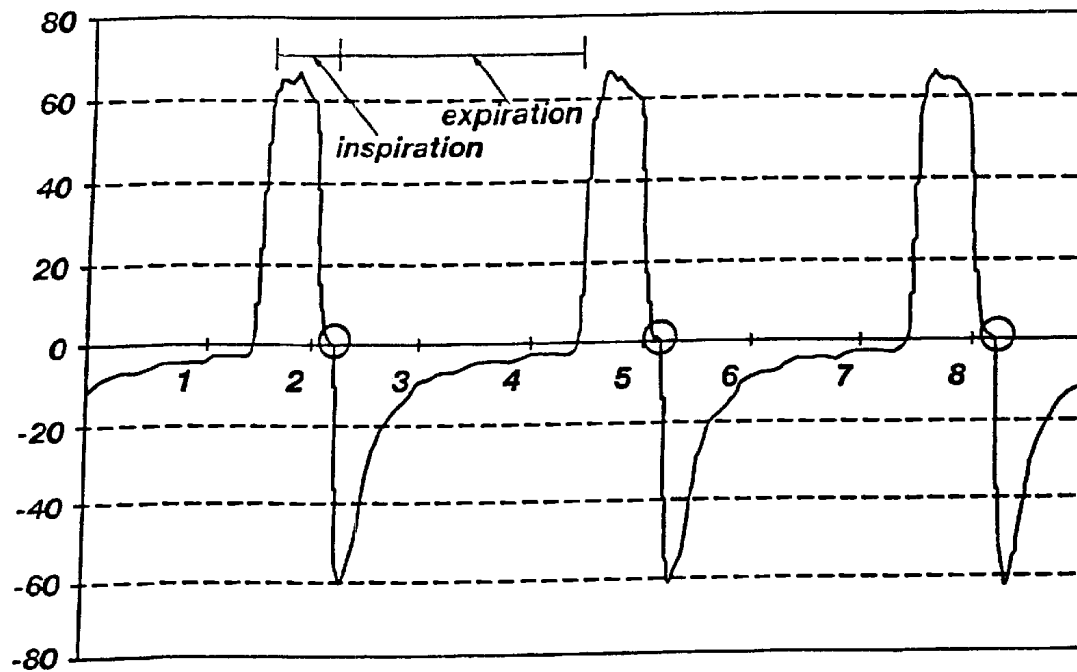
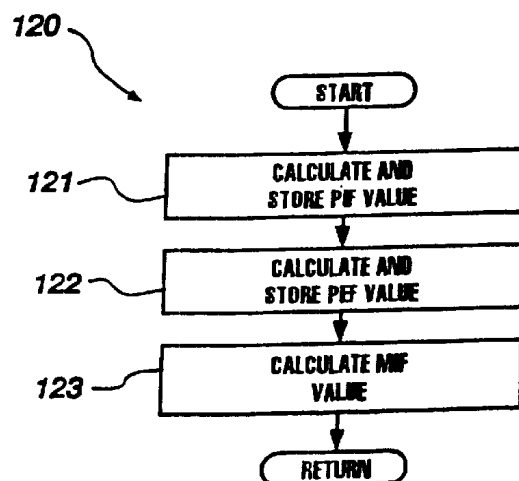


Fig. 3

**Fig. 4****Fig. 5**

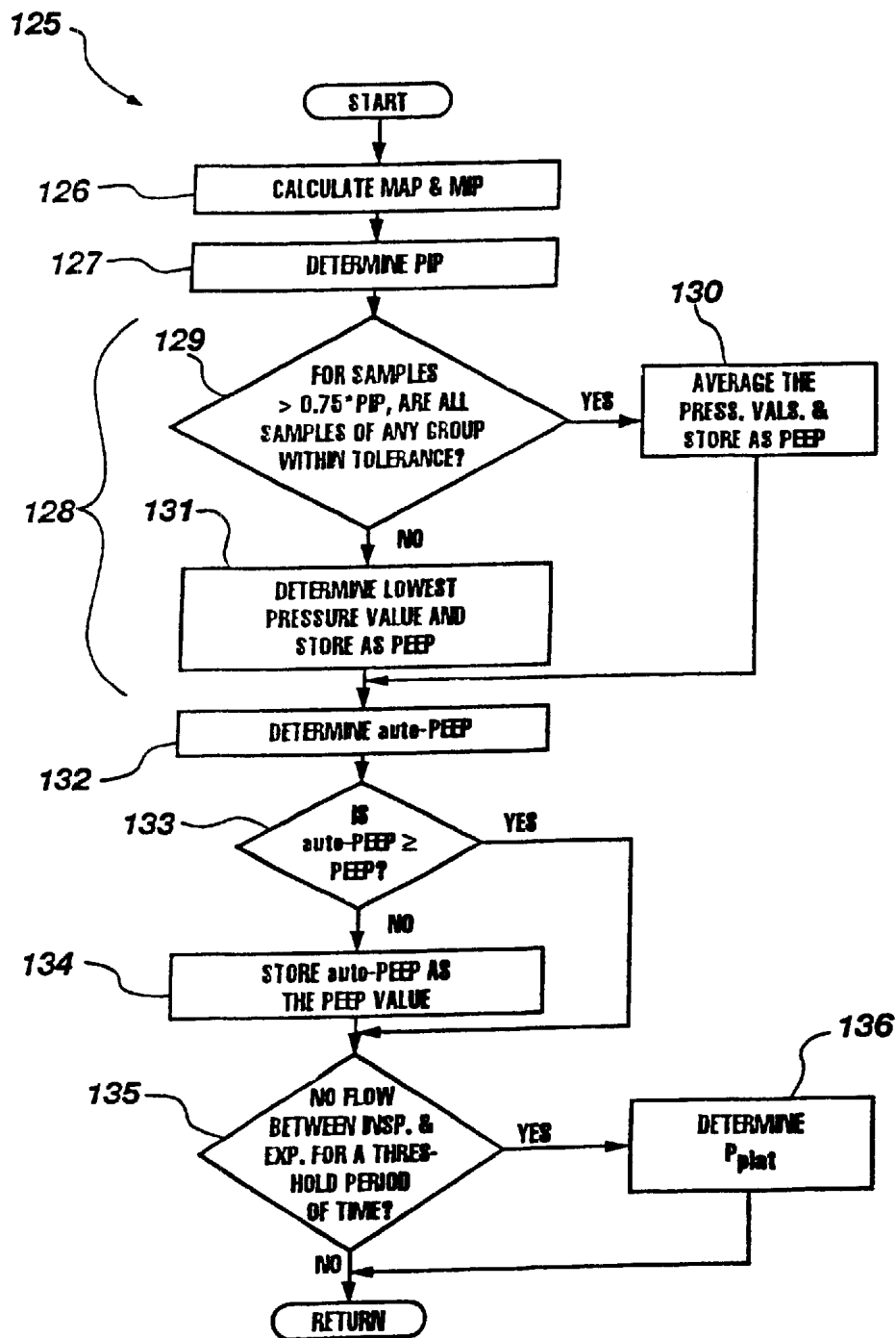


Fig. 6

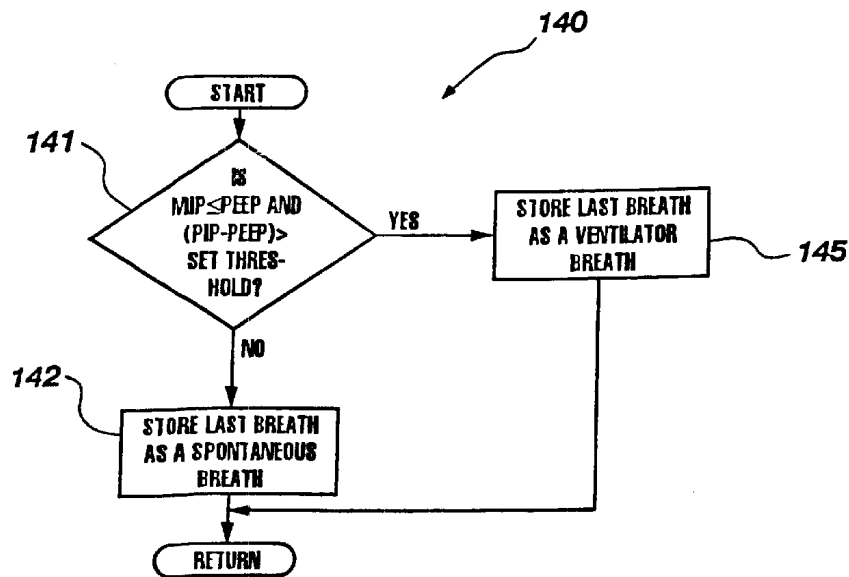


Fig. 7

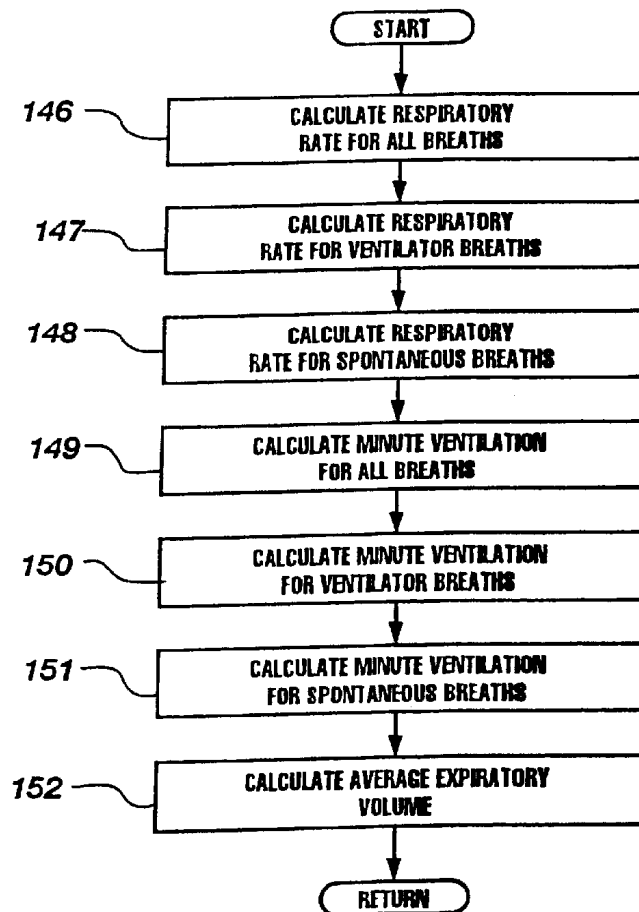


Fig. 8

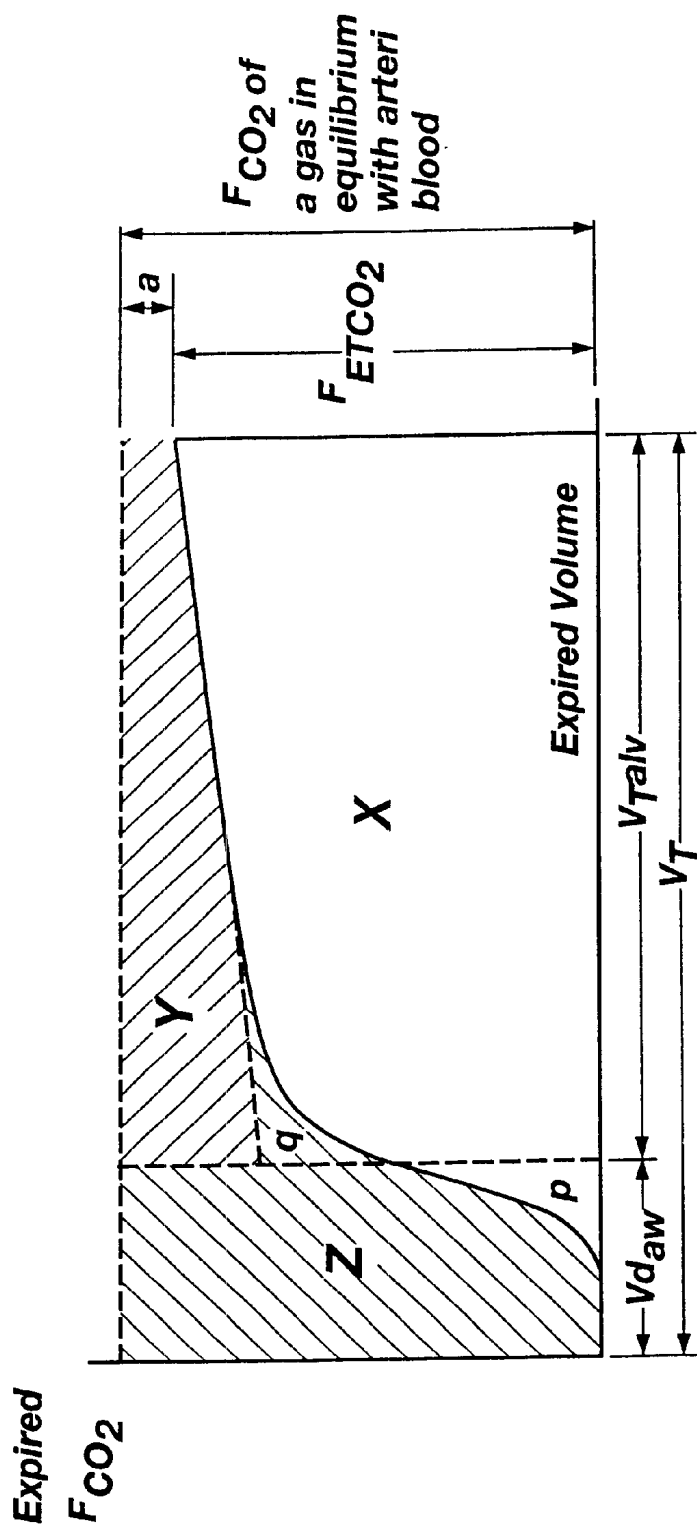
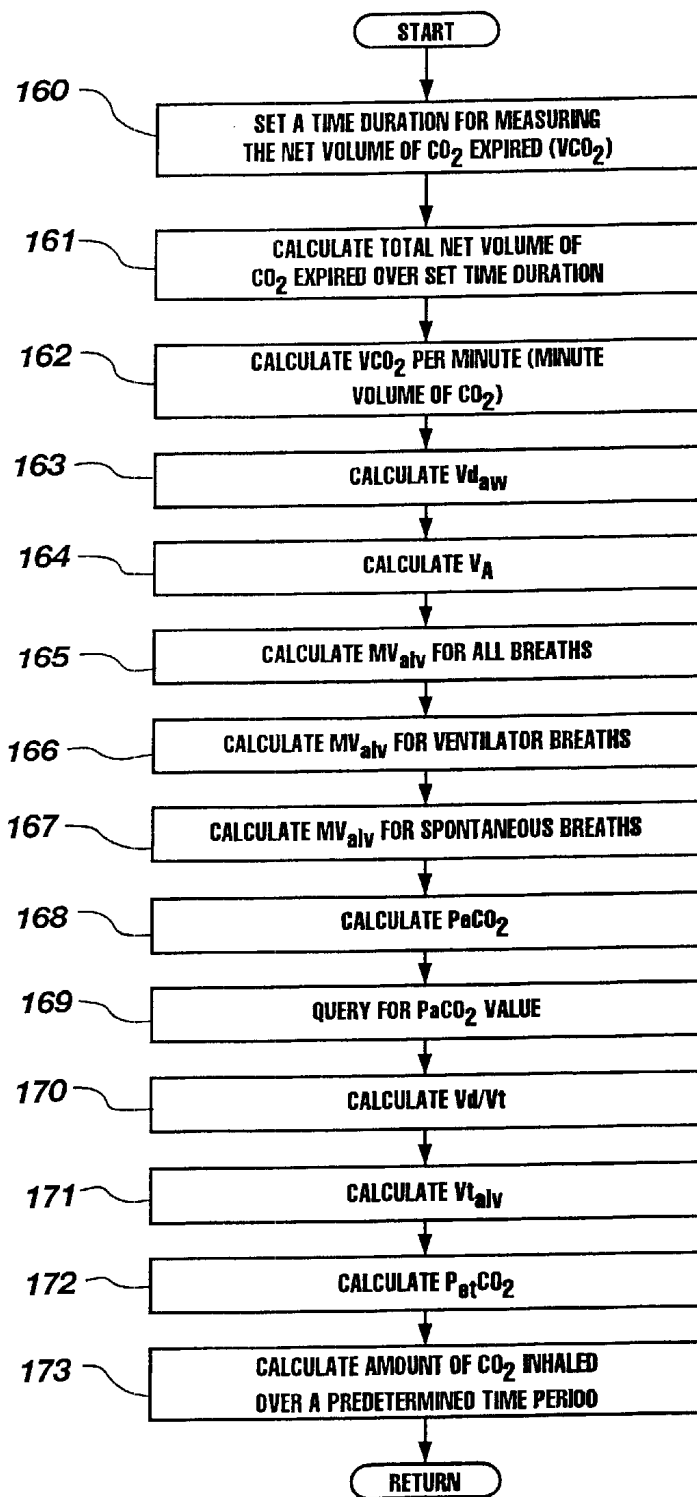
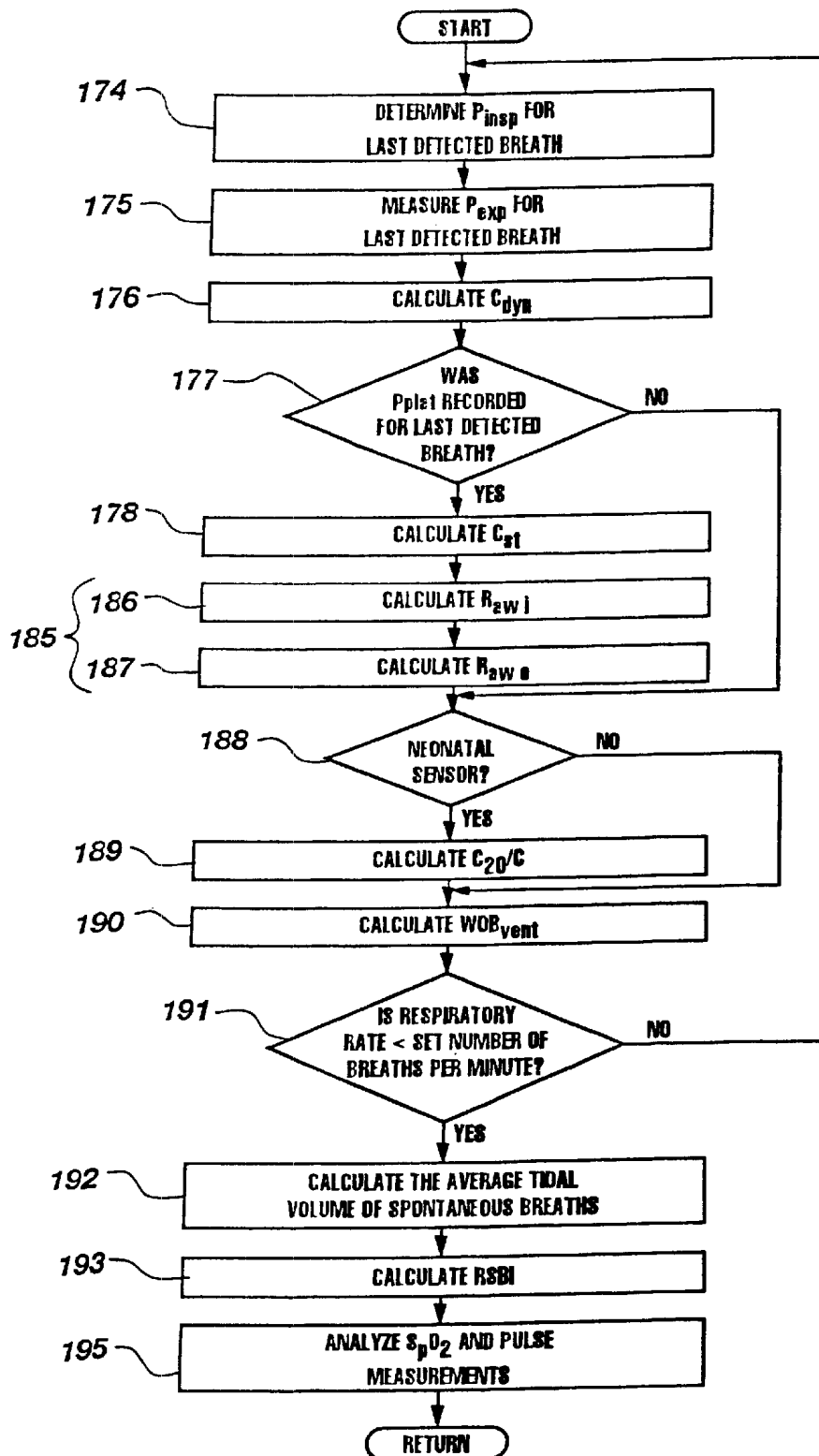


Fig. 9

*Fig. 10*

**Fig. 11**

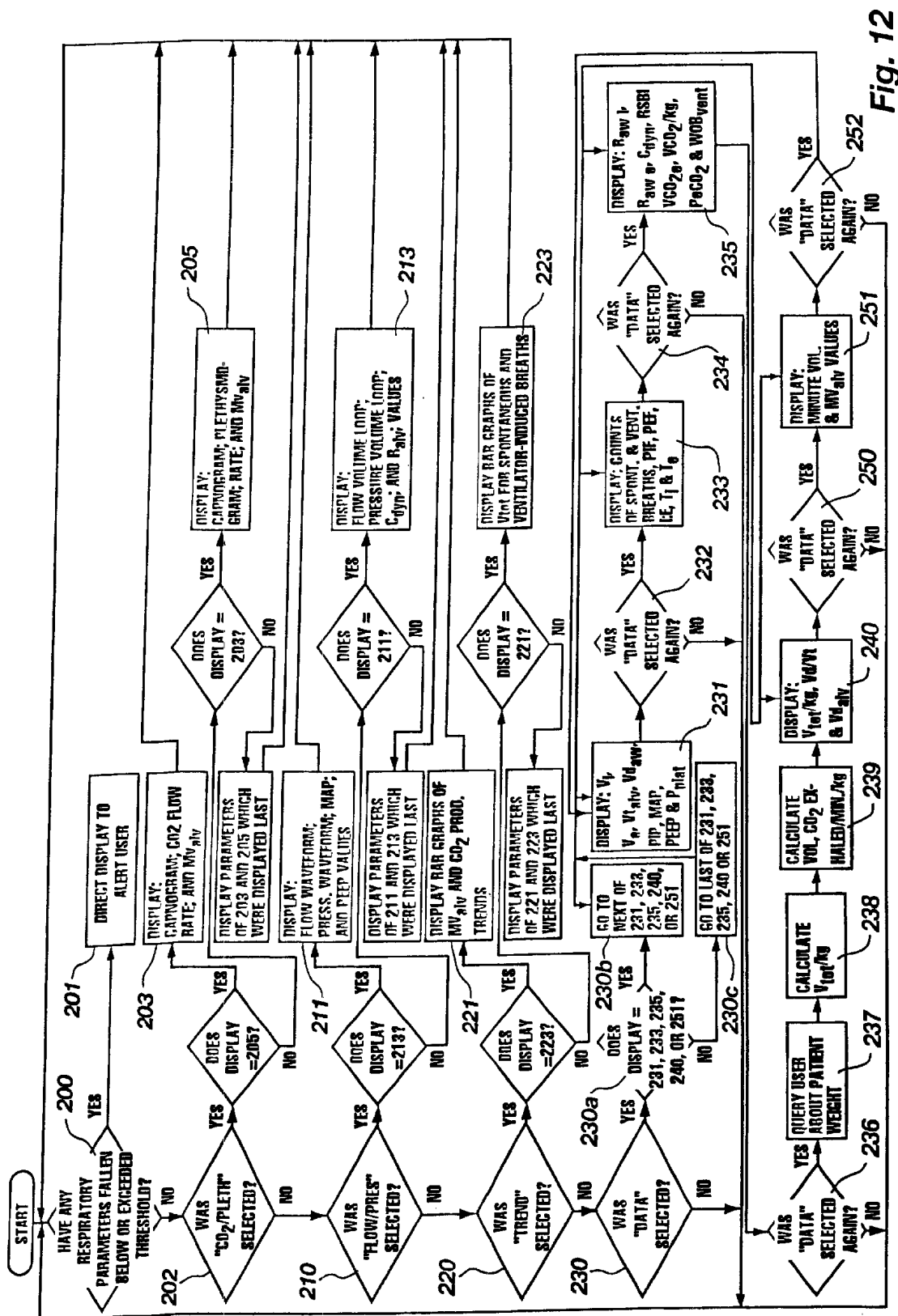


Fig. 12

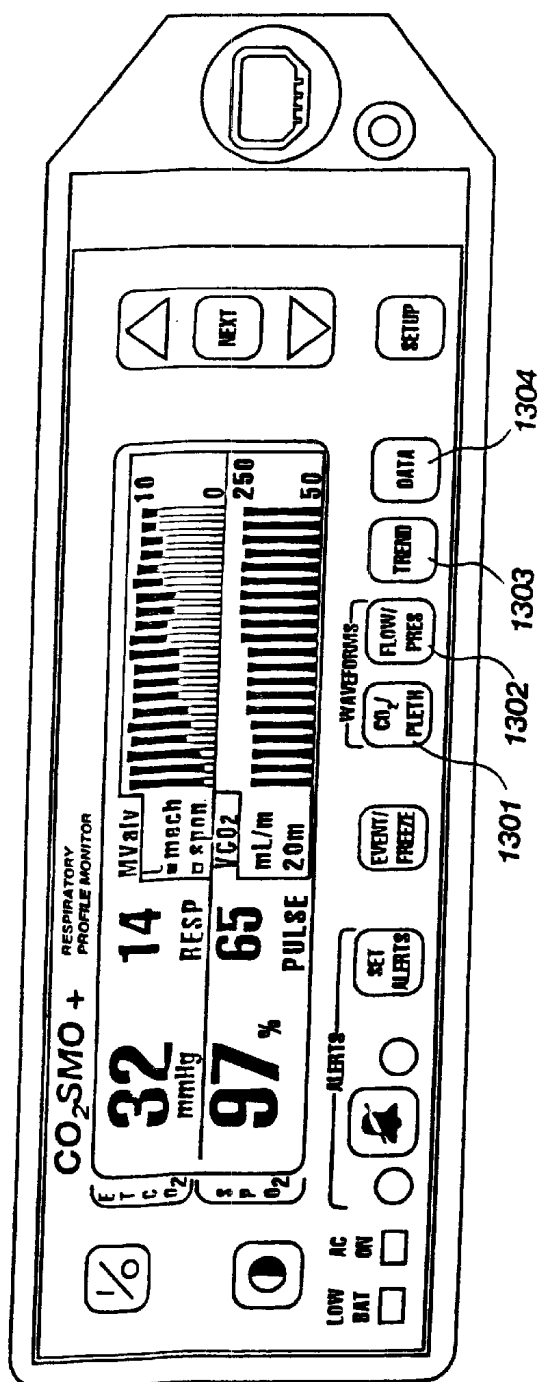


Fig. 13

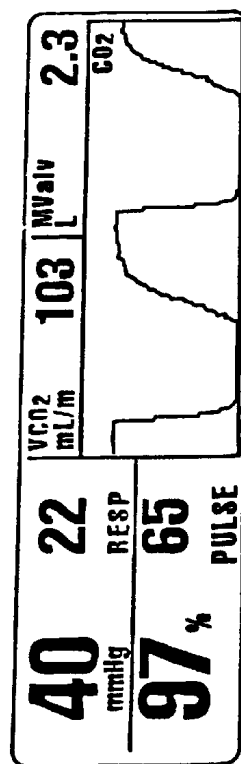


Fig. 14

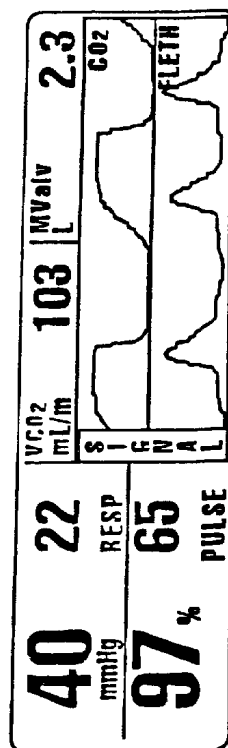
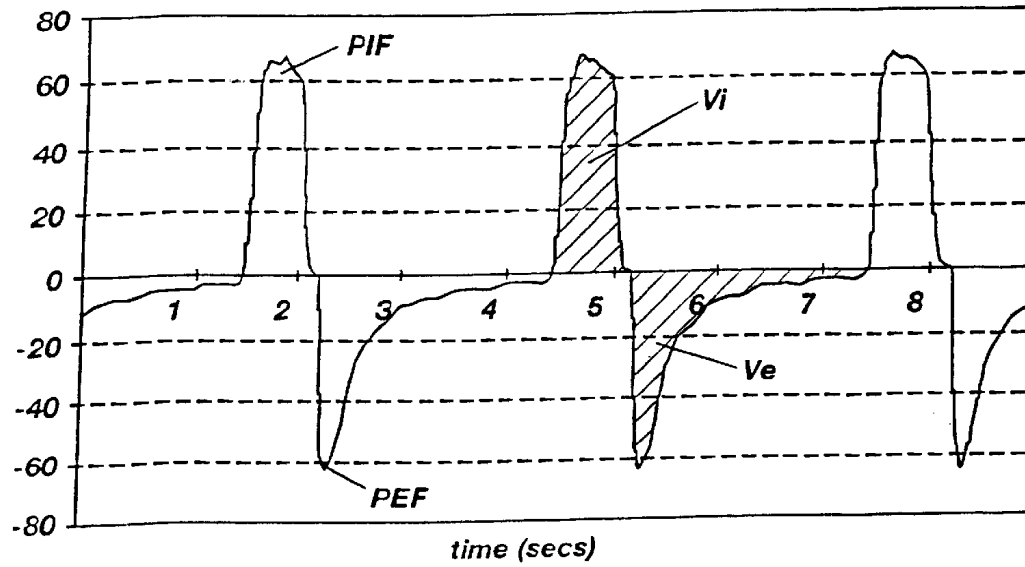
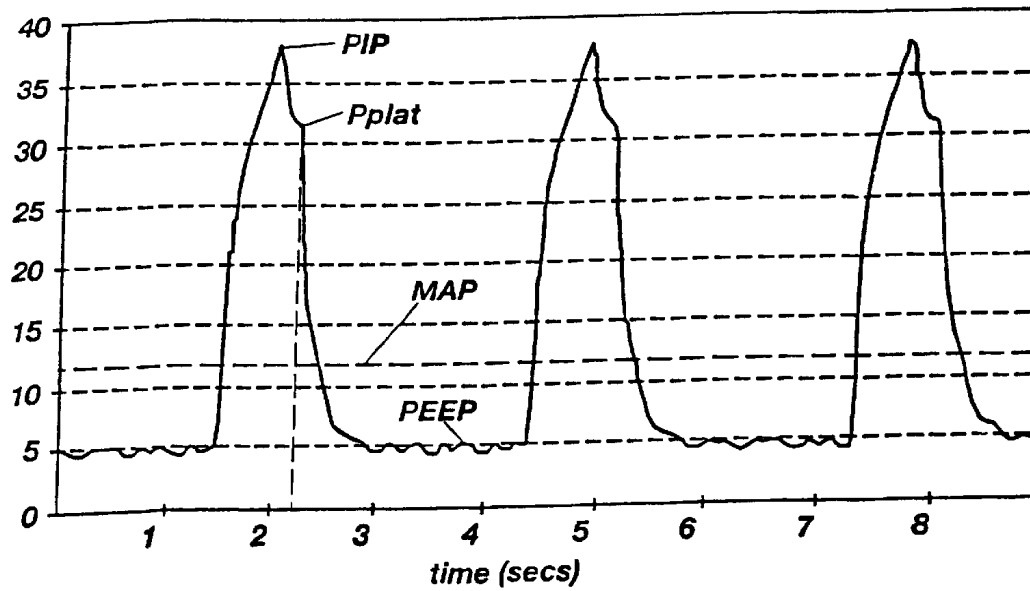
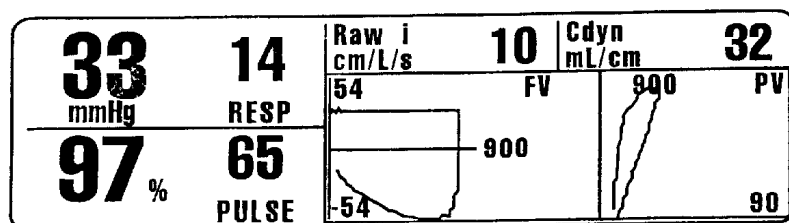
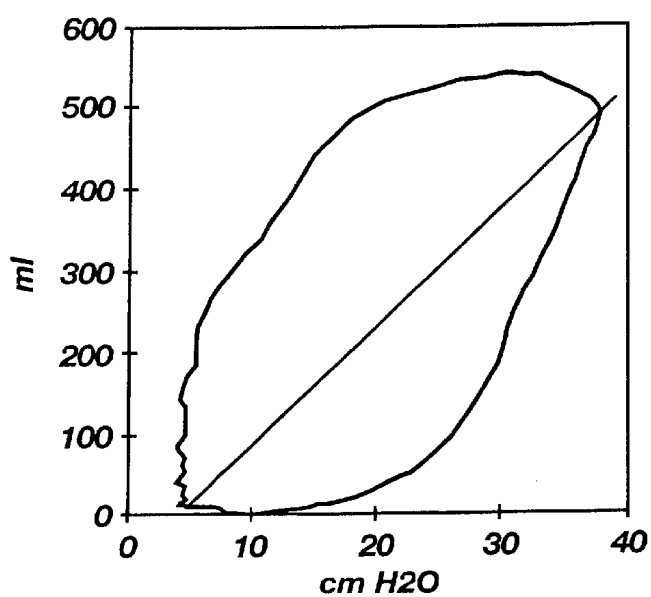
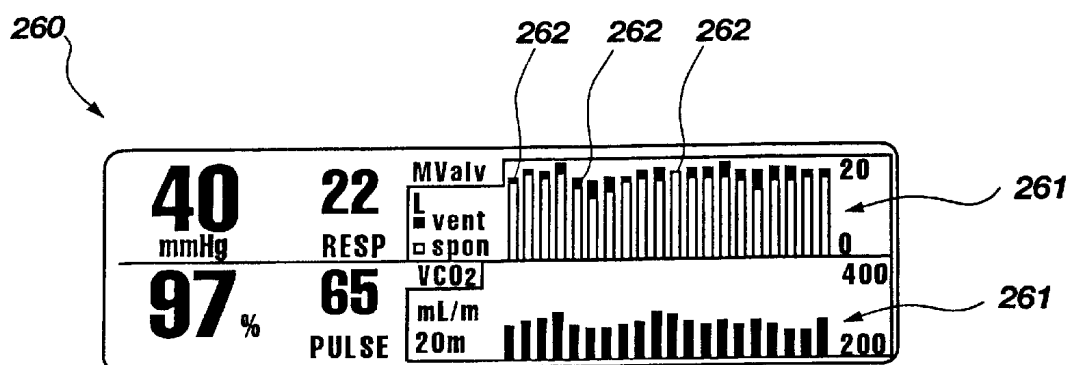


Fig. 15

**Fig. 16****Fig. 17**

*Fig. 18**Fig. 19**Fig. 20*

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RESPIRATORY PROFILE PARAMETER DETERMINATION METHOD AND APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of application Ser. No. 09/334,778, filed Jun. 16, 1999, now U.S. Pat. No. 6,179,784, issued Jan. 30, 2001, which is a divisional of application Ser. No. 08/963,394, filed Nov. 3, 1997 which issued as U.S. Pat. No. 6,099,481 on Aug. 8, 2000.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to systems which monitor both airway carbon dioxide concentration and respiratory flow. Specifically, the present invention relates to systems which monitor respiratory air flow, pressure and carbon dioxide levels, process those measurements to derive information about various respiratory-related functions and blood carbon dioxide levels, and display the measured and derived information.

2. Background of Related Art

Respiratory monitors are known in the art. Typically, respiratory monitors measure respiratory air flow rates at discrete sampling intervals. Many respiratory monitoring apparatus process respiratory samples to determine characteristics such as respiratory rate and depth of respiration. U.S. Pat. No. 5,273,036, issued to Harald Kronberg and Helmut Leist on Dec. 28, 1993 and U.S. Pat. No. 4,989,456, issued to Josef Stupecky on Feb. 5, 1991, disclose exemplary devices.

However, many respiratory monitors in the prior art sample only a limited aspect of a patient's respiration and display a limited number of directly measured respiratory characteristics rather than an overall profile of a patient's respiration. Moreover, many existing respiratory monitors do not allow a user to select the displayed respiratory profiles.

A system is needed which monitors a variety of respiratory profile parameters and displays data regarding those parameters. There is also a need for a system which, following measurement of some respiratory parameters, automatically generates data regarding other respiratory profile parameters.

SUMMARY OF THE INVENTION

The system of the present invention addresses the foregoing needs. The system of the present invention includes an apparatus which utilizes software to process respiratory pressure, flow, volume and gas content information and preferably displays such types of information in the forms of numeric values and graphs. The system of the present invention also processes the measured information in order to calculate or otherwise determine a wide variety of respiratory profile characteristics which are not directly measurable by noninvasive means.

In a preferred embodiment of the method of the present invention, respiratory measurements are taken at discrete time intervals. Preferably, respiratory samples are taken about once every 0.01 seconds (10 milliseconds). The respiratory measurements taken during each sample include, but are not limited to, the respiratory flow rate, respiratory pressures, respiratory carbon dioxide level, and other respiratory or respiratory-related characteristics. Blood oxygen

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saturation may also be measured by the system of this invention. Pulse oximetry methods which are known to those in the art are preferred for measuring blood oxygen saturation in connection with the present invention. Each piece of data is either sampled digitally or sampled by analog means, then digitized immediately following sampling. Methods and mechanisms for digital sampling and digitization of analog samples which are known to those of ordinary skill in the art are useful in the system of the present invention.

During respiratory monitoring and sampling, the system of the present invention calculates various respiratory profile characteristics, including, without limitation, the timing of the respiratory cycle and its intervals, respiratory flows and volumes, respiratory pressures, and carbon dioxide levels in the breath. The derivation of carbon dioxide and oxygen levels in a patient's arterial blood are also within the contemplated scope of the present invention. If a patient's respiration is controlled by a ventilator, the system of the present invention may also calculate respiratory mechanics characteristics.

Other advantages of the respiratory profile parameter processing and display system of the present invention will become apparent to those of skill in the relevant art through a consideration of the ensuing description and the appended drawing figures.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. 1 is a schematic illustration of a system which measures respiratory flow, pressure and gas content samples;

FIG. 2 is a flow chart of a preferred process for identifying and storing sampled data of a patient breath;

FIG. 3 is a flow chart of a method of calculating respiratory time and volume parameters;

FIG. 4 depicts a respiratory flow waveform;

FIG. 5 is a flow chart of a method of calculating respiratory flow parameters;

FIG. 6 is a flow chart of a method of calculating respiratory pressure parameters;

FIG. 7 is a flow chart of a preferred process for determining whether a patient breath was spontaneous or ventilator-induced;

FIG. 8 is a flow chart of a method of calculating various respiratory rate and minute ventilation parameters;

FIG. 9 is a graph which depicts the carbon dioxide fraction of expired gases plotted against a patient's total expired volume;

FIG. 10 is a flow chart of a method of calculating various respiratory carbon dioxide parameters;

FIG. 11 is a flow chart of a method of calculating various respiratory mechanic parameters;

FIG. 12 is a flow chart of a preferred process of displaying respiratory profile parameters in accordance with another aspect of the present invention;

FIG. 13 depicts a respiratory profile monitor that is useful for taking respiratory measurements in accordance with the present invention;

FIG. 14 depicts a capnogram;

FIG. 15 depicts a plethysmogram;

FIG. 16 depicts a flow waveform;

FIG. 17 depicts a pressure waveform;

FIG. 18 depicts a flow-volume loop;

FIG. 19 depicts a pressure-volume loop; and
FIG. 20 illustrates a trend display according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention includes a system for detecting and processing data of various respiratory flow and blood gas parameters. Apparatus which monitor respiratory flow and blood gas data are used to detect air flow pressures, air flow volumes, partial carbon dioxide pressure, and other breath characteristics. The method of the present invention is then employed to analyze the collected data, process the data to derive values for other respiratory characteristics, and display the collected and derived data.

Data Collection

Preferably, the inventive system, illustrated schematically in FIG. 1, includes a differential pressure flowmeter, which is also referred to as a pneumotachometer 10, a flow signal unit 12, a gas (CO₂) sensor 14, a CO₂ signal unit 16, a processing unit 18 and a data printer/display 20. This system can be used whether or not the patient is mechanically ventilated.

Many devices for measuring the volume of a person's expiratory breath already possess the capability to integrate a measured flow and can be used with the present invention. Typically, flow measuring devices use one of the following methods to determine flow:

1. measurement of pressure drop or differential pressure across a fixed resistance (differential pressure flowmeter or pneumotachometer),
2. measurement of the temperature change of a heated wire cooled by the airflow (hot wire anemometer),
3. measurement of frequency shift of an ultrasonic beam passed through the airstream (ultrasonic Doppler),
4. counting the number of vortices shed as air flows past a strut (vortex shedding), or
5. measurement of transmission time of a sound or heat impulse created upstream to a downstream sensor (time of flight device).

Alternatively, volume may be measured directly by counting revolutions of a vane placed in the respiratory flow path (e.g., a spinning vane). A discussion of the aforementioned devices and associated technology can be found in Sullivan, et al., *Pneumotachographs: Theory and Clinical Application*, Respiratory Care, Vol. 29-7, pages 736-749 (1984), which is incorporated herein by reference. Examples of known differential pressure flowmeters include those described in U.S. Pat. Nos. 4,047,521, 4,403,514, 5,038,773, 5,088,332, 5,347,843, 5,379,650 and 5,535,633, the disclosures of each of which are incorporated herein by reference.

The exemplary device for respiratory flow measurement is the differential pressure flowmeter 10 or "pneumotachometer", which provides a pressure differential indicative of respiratory flow, the differential pressure being converted via pressure transducers in flow signal unit 12 to electrical signals which are subsequently processed to provide flow rate and volume by processing unit 18. The flowmeter 10 is preferably the Pediatric/Adult Combined CO₂/Flow Sensor (Catalog No. 6719) or the Neonatal Combined CO₂/Flow Sensor (Catalog No. 6720), manufactured and sold by Novamatrix Medical Systems, Inc., Wallingford, Conn. However, any of the aforementioned types of flow measurement devices may be utilized in the inventive system.

Sensors that are capable of measuring the partial pressure of carbon dioxide content in a patient's breath are well known. The currently preferred device for measuring breath carbon dioxide content is a gas analyzer of the type employing non-dispersive infrared radiation which presents data representing the %CO₂ (or pCO₂) of a sample of exhaled breath. Examples of known infrared gas analyzers include those described in U.S. Pat. Nos. 4,859,858, 4,859,859, 4,914,720, 4,958,075, 5,146,092, 5,153,436, 5,206,511 and 5,251,121, the disclosures of each of which are incorporated herein by reference. Other technologies used to measure the concentration of carbon dioxide, such as Raman spectroscopy and mass spectroscopy, can also be used in connection with the system of the present invention.

An exemplary gas sensor 14 that is capable of measuring carbon dioxide content in a patient's exhaled breath is available from Novamatrix Medical Systems, Inc., Wallingford, Conn., under the trade name CAPNOSTAT™. Other methods of measuring carbon dioxide content, both at the airway (mainstream) or by removing a sample (sidestream), are known to those of ordinary skill in the art and are useful with the system of the present invention.

Gas analyzers of the types described above employ non-dispersive infrared radiation to measure the concentration of a selected gas in a mixture of gases. The infrared radiation can be emitted from a thick film source and focused by a mirror to pass through the mixture of gases being analyzed. After passing through the gas mixture, the infrared beam passes through a filter which reflects all of the radiation wavelengths except for those in the narrow bands centered around the wavelength which is absorbed by the gas of concern (such as CO₂) in the mixture being analyzed (such as the air flow from a person's expired breath). This narrow band of radiation, which typically extends approximately 190 angstroms to each side of the wavelength on which the radiation is centered, reaches a detector which is capable of producing an electrical output signal proportional to the magnitude of the infrared radiation impinging upon it, as the radiation in that band is attenuated to an extent which is proportional to the concentration of the designated gas in the mixture of gases being analyzed. The strength of the signal generated by the detector is inversely proportional to the concentration of the designated gas and can be inverted to provide a signal indicative of that concentration.

Non-invasive pulse oximetry sensors (SpO₂) that are capable of measuring a patient's pulse and the oxygen content of a patient's arterial blood are well known and may be used in the system of the present invention. Examples of known SpO₂ sensors include those described in U.S. Pat. Nos. 4,685,464, 4,825,879, 4,830,014, 4,865,038, 4,928,691, 5,179,786, 5,209,230, 5,217,012, 5,337,744, 5,469,845, and 5,438,986, the disclosures of each of which are incorporated herein by reference. Preferably, a non-invasive SpO₂ sensor, such as that sold under the trade name SUPER-BRIGHT® by Novamatrix Medical Systems, Inc., is used in the system of this invention. Other technologies used to measure pulse and/or arterial blood O₂ saturation can also be used in connection with the system of the present invention.

Processing unit 18 may be either a programmed personal computer employing a microprocessor in combination with a suitable digital interface for receiving the digital signals from the CO₂ signal unit 16 and flow signal unit 12, or any specially designed processor unit programmed as to be capable of calculating the respiratory parameters as disclosed further herein. Processing unit 18 may also direct the storage of all of the calculated respiratory parameters. An exemplary processor/display unit which has been designed

specifically for such purposes is the processor sold under the trade name CO₂SMO® Plus! by Novamatrix. Display 20 is any display that will display graphic information and/or numeric data as directed by processing unit 18. For example, when processing unit 18 is a personal computer, any compatible video monitor may be used as display 20. Display 20 may also include a mechanism which audibly alerts a user about various patient respiratory information. When processing unit 18 is a personal computer, any sound card and speaker which is compatible therewith will impart the system of the present invention with the ability to generate audible warnings and alarms.

Processing unit 18 is programmed to perform the method of the present invention, as set forth hereinbelow. Thus, processing unit 18 includes a plurality of logic circuits for performing the process of the present invention.

Data Processing and Storage

Referring now to the flow chart of FIG. 2, processing unit 18, in performance of the method, inquires at 100 whether the air flow sensor is an adult sensor or a neonatal sensor. If the sensor is a neonatal respiratory sensor, a neonatal sensor parameter set is applied to the monitored data as shown at 102. Otherwise, an adult sensor parameter set is applied to the data, as shown at 101.

Next, as shown at 103, a determination is made of whether a series of respiratory samples taken since the patient's last breath comprise a patient breath. Depending upon whether the patient is a neonate or an adult, certain threshold pressures and volumes are required during both inhalation and exhalation in order for a set of samples to be considered as a breath. First, as described in further detail below with reference to FIG. 3, using techniques which are known in the art, flow rate and fluid volumes are calculated from pressure and timing measurements. A determination is then made of whether any of the samples equaled or exceeded an initial inhalation threshold pressure level and an initial inhalation threshold volume level, as shown at 104. Then a determination is made, as shown at inquiry 105, whether the inspiration pressure and volume for a subsequent respiratory sample equaled or exceeded the inspiration confirmation thresholds. Next, the respiratory flow for subsequent respiratory samples must meet both initial and confirmatory expiration pressure and volume thresholds, as shown at inquiries 106 and 107, respectively. If neither of the thresholds were met in any of the four preceding inquiries, no breath is detected, and the sampled data is not recognized by the system as a breath. The system of the present invention continues to monitor respiratory flow and pressure until a breath is detected. When each of the four sets of thresholds have been met, a breath has been detected and the respiratory samples are identified as part of a breath, as shown at 108. The respiratory flow, pressure, gas levels and timing of the sample are then stored and processed.

The sampled pressure and gas (CO₂) levels for each breath and the time interval between samples are processed to determine various other respiratory parameters, including, but not limited to, duration of the breathing cycle, respiratory flow and volume characteristics, respiratory pressure characteristics, respiratory mechanics, carbon dioxide levels and related respiratory parameters.

FIG. 3 illustrates a preferred process for the collection of timing data, referred to collectively as step 110. The invention measures respiratory volume and pressure at specific time intervals.

FIG. 4 is a graph, referred to as a respiratory flow waveform, which illustrates respiratory flow rates over time.

Airflow into a patient's lungs is measured as positive airflow. Airflow out of a patient's lungs is measured as negative airflow. The beginning of inspiration is measured as respiratory airflow increases from about zero liters per minute (LPM). Inspiration continues until an inspiratory pause, when the airflow decreases, returning to about zero LPM. At about the point where airflow becomes negative, exhalation begins. Exhalation continues until the air flow reaches about zero LPM.

Referring again to FIG. 3, the inspiratory time (T_i) is measured as shown at 111. T_i is the length of time of the inspiratory phase of ventilation, typically when respiratory air flow is greater than about zero. Thus, T_i is equal to the difference in time between the first and last respiratory samples of each inspiratory period. As shown at 112, the expiratory time (T_e) is measured. T_e is the time duration of the expiratory phase of ventilation, typically when respiratory air flow is less than about zero. Thus, T_e is equal to the difference in time between the first and last samples of each expiratory period. The entire ventilatory period, also referred to as the total cycle time (T_{tot}), is calculated as shown at 113, by adding T_i and T_e . T_{tot} is the time from the start of inspiration of one detected breath to the start of inspiration for the subsequent detected breath. The ratio of inspiratory time to expiratory time (I:E) is also calculated as shown at 113 using the summed T_i and T_e for all detected breaths. Preferably, I:E is updated with each new detected breath.

The inspiratory volume (V_i), which is the volume of gas inhaled during the inspiratory phase of a detected breath, is determined as shown at 115. One method of calculating inspiratory volume includes summing the products of flow rate multiplied by the time interval between samples of each respiratory sample during an inspiratory phase. That measurement is stored. Other methods for determining V_i are also within the scope of the method of the present invention.

The volume of expired gas, also referred to as the expiratory volume (V_e), is determined as shown at 116. One method of calculating expiratory volume includes summing the products of flow rate multiplied by the time interval between samples of each respiratory sample during the expiratory phase, with trapezoidal integration of the samples. That measurement is then stored. Another method for calculating expiratory volume includes averaging the flow rates of each sample during the expiratory phase, then multiplying that value by T_e . Other methods for determining V_e are also within the scope of the method of the present invention. As shown at 117, the average tidal volume is calculated by averaging the V_e values over the lesser of the last eight breaths, or all of the complete breaths within the last minute.

Various factors, including, without limitation, zero point drift, coughing, swallowing, cardiogenic oscillations, and others, inhibit the automatic determination of the four breathing cycle phases. Thus, a preferred embodiment of the method of the present invention utilizes a dual level flow detection algorithm to minimize sensitivity to such factors. As shown at 118, respiratory volumes are computed using rectangular integration or trapezoidal integration (i.e., the running sums of the sampled volumes are scaled by the sampling interval).

With reference to FIG. 5, the determination of various flow and volume data measurements are made, referred to collectively as step 120. The largest inspiratory flow sample (i.e., highest positive flow value) measured for each detected breath is referred to as the peak inspiratory flow (PIF) value

for that breath. The PIF value for the last detected breath is determined and stored as shown at 121. Similarly, the largest expiratory flow sample (i.e., lowest negative flow value) measured for each detected breath is referred to as the peak expiratory flow (PEF) value for that breath. The PEF value of the last detected breath is determined and stored as shown at 122. Mean inspiratory flow (MIF) is calculated as shown at 123. MIF is determined by averaging each of the sampled flow values during the entire inspiratory phase. Preferably, MIF is calculated using inspiratory flow samples from each of the lesser of the last eight detected breaths, or from each of the detected breaths over the last minute.

FIG. 6 is a flowchart which shows the steps involved in making various respiratory pressure calculations, collectively referred to as step 125. As shown at 126, the mean airway pressure (MAP) and mean inspiratory pressure (MIP) are calculated. MAP is calculated by averaging all of the stored, sampled pressure values over the last detected breath. MIP is calculated by averaging all of the stored, sampled inspiratory pressure values over the last detected breath. The largest absolute pressure value measured during the last detected breath, referred to as the peak inspiratory pressure (PIP), is determined as shown at 127. The positive end-expiratory pressure (PEEP) is determined as shown at 128.

The PEEP determination, which is made as shown at 128, begins from the point where the respiratory pressure falls to about 75% of the latest PIP value. While the respiratory pressure remains below about 75% of the latest PIP value, a determination is made about whether all of the sampled pressures within each 50 millisecond (0.05 sec.) time period fall within a predetermined tolerance, as shown at inquiry 129. If so, the values over that 50 millisecond time period are averaged, stored and designated as the PEEP value as shown at 130. If, due to high frequency breathing or unstable breathing, no 50 millisecond window of measured pressure values contains values which are within the set tolerance, the lowest measured pressure value is determined, stored and designated as the PEEP value as shown at 131.

Next, as shown at 132, the respiratory pressure value measured at air flow reversal (i.e., between exhalation and inhalation) is stored and designated as the auto-PEEP value. Preferably, the auto-PEEP value is equal to the pressure at a sample taken closest to the mid-point of air flow reversal. Auto-PEEP may also be determined by averaging the pressures of the last exhalation sample of a first breath and the first inhalation sample of the next breath. As shown at 133, it is determined whether the auto-PEEP value is greater than or equal to the PEEP value. If so, the PEEP value remains the same. If not, the auto-PEEP value is designated and stored as the PEEP value, as shown at 134. Auto-PEEP is considered to exist when inspiration occurs and the expired flow has not reached zero (i.e., no pause is apparent) because insufficient time has elapsed to allow the lung to passively deflate (as depicted in the respiratory flow waveform of FIG. 4).

If no respiratory flow is detected between inspiration and expiration for at least a threshold period of time, a plateau pressure value (P_{plat}) is then determined and stored. Long no-flow periods are common during mechanical ventilation of a patient. If, as shown at inquiry 135, it is determined that the no-flow duration met or exceeded a threshold amount of time, the respiratory pressure measurement of the sample at or nearest to the end of the no-flow period is designated and stored as the plateau pressure (P_{plat}), as shown at 136. If the no-flow duration was within the threshold time period, no P_{plat} value determination is made or stored.

FIG. 7 illustrates a preferred process 140 for determining whether the last detected breath was a spontaneous breath or

a ventilator-induced breath. As shown at inquiry 141, the MIP and PEEP for the last detected breath are compared. Also at inquiry 141, process 140 determines whether the difference between PIP and PEEP is greater than a set ventilator pressure threshold. Preferably, the threshold pressure level is set to a default of 6 cmH₂O, and may be adjusted above or below that level. If the MIP is less than or equal to the PEEP and if the difference between PIP and PEEP is greater than the set threshold, the last detected breath is designated and stored as a ventilator breath as shown at 142. If MIP is greater than the PEEP, or if PIP minus PEEP is less than or equal to the set threshold, the last detected breath is designated and stored as a spontaneous breath as shown at 145.

Referring to FIG. 8, the respiratory rates, also referred to as respiratory frequency, for all breaths, for ventilator breaths, and for spontaneous breaths are measured as shown at 146, 147 and 148, respectively. The frequency of each breath is equal to $60/T_{tot}$, which supplies a value in units of breaths per minute. Preferably, each of the respiratory frequency values is determined by averaging the frequency values for the last eight breaths of each respective breath type (i.e., total, ventilator and spontaneous breaths).

Minute ventilation, the total quantity of gas exhaled by a patient over a time period of one minute, is calculated for the total volume exhaled, the volume exhaled during ventilator breathing, and the volume exhaled during spontaneous breathing as shown at 149, 150 and 151, respectively. Preferably, the minute ventilation calculations are equal to the average of V_e divided by T_e for each of the last eight detected breaths of a specific type. The minute ventilation calculations are preferably updated with each detected breath.

Referring to FIG. 10, the preferred method according to the present invention calculates several values related to levels of CO₂ exhaled and the amount of deadspace. One such value, the volume of CO₂ exhaled per minute, is determined by calculating, as shown at 161, the net volume of CO₂ exhaled for each breath over a set time duration, which is set as shown at 160. As shown at 161, the percent CO₂ is multiplied by the total volume inhaled and exhaled (i.e., the tidal volume) over a detected breath. That value is reduced by the inspired volume of CO₂ (i.e., CO₂% inhaled multiplied by V_i), then multiplied by one unit time and divided by the set duration of the detected breath (in either units of time or breath) to determine the net volume of CO₂ that was expired by the patient over the set duration (V_{CO_2e}). A preferred equation for calculating the volume of CO₂ exhaled per minute follows:

$$V_{CO_2e} = \sum FCO_2 \times V \times \Delta t,$$

where FCO₂ is the fraction of CO₂, V is the flow rate, and Δt is the change in time. As shown at 162, the V_{CO_2} values for each detected breath are then averaged over the duration set in step 160 above to provide an exhaled CO₂ value per minute. If the selected duration is a time duration, the value for the amount of CO₂ exhaled per unit of time is preferably updated at discrete time intervals. Preferably, the volume of CO₂ exhaled per unit of time is updated at least about every fifteen seconds. If the selected duration is calculated in number of breaths, the value for the volume of exhaled CO₂ per breath is preferably updated with each detected breath. The volume of CO₂ expired per minute is commonly referred to as "CO₂ production" and "CO₂ elimination" since it represents the volume of CO₂ exhaled over the set duration.

FIG. 9 is a graph which includes the carbon dioxide fraction of expired gas (FCO_2) on its y-axis and the total expired volume on its x-axis. The graph of FIG. 9 illustrates respiratory measurements, including carbon dioxide elimination, airway dead space and physiologic dead space. The character "a" represents the difference between the fraction of end tidal carbon dioxide (ETCO_2) and the arterial FCO_2 . The Phase III slope is extrapolated to define the upper limit of "q". The area of "X" is equal to the volume of CO_2 in the expired breath. Areas "Y" and "Z" represent defects in carbon dioxide elimination, or wasted ventilation due to airway (anatomic) dead space (Vd_{aw}) and alveolar volume (Vt_{alv}). The location of the dividing line between Vd_{aw} and Vt_{alv} is determined by the areas of "p" and "q", which are equal. The areas of "p" and "q" are equal to the airway dead space. Thus, Vd_{aw} and Vt_{alv} are dependent upon and may be determined from the FCO_2 and the slope of the Phase III line.

The airway dead space, also referred to as the anatomic dead space, Fowler's Dead Space, or the ineffective tidal volume, is calculated as shown at 163. Anatomic dead space is the volume of gas that fills the airways following the inspiratory phase. The tidal volume is equal to the anatomic dead space plus the amount of gas coming from the alveoli. Preferably, Aitken and Clark-Kennedy's method for measuring anatomic dead space is employed. In Aitken and Clark-Kennedy's method, the Phase III slope is extrapolated, as represented in FIG. 9 by the diagonal dashed line. A vertical dividing line, represented in FIG. 9 by the vertical dashed line, is then positioned along the inclining portion of the fraction of expired CO_2 plot such that it intersects the Phase II line at a point where the areas marked "p" and "q" are equal. The expired volume value upon which the dividing line is located (along the x-axis) is the volume of anatomic dead space. Preferably, a linear regression is computed of the points bounded by 30 to 70% of expired CO_2 volume to determine the appropriate location for the dividing line.

More specifically, a threshold level of CO_2 is detected by finding the point where the curve transcends from a value below 0.5% to a value above 0.5%. In the instant invention, this point is used as the initial point of Phase II. From the threshold point, subsequent CO_2 data points are adjoined and tested for linearity to the data point where the signal deviates from a linear path. The amount of allowed deviation is typically 5% in adults. The point where the deviation occurs marks the termination of Phase II and the slope of the Phase II segment is derived. As described further herein, the Phase II slope is used later. The slope of Phase III is determined in an analogous manner by starting at the last data point of expiration ($\text{P}_{et} \text{CO}_2$) and regressing toward the termination point of Phase II. Once the Phase II and III slopes are computed, the remaining input variables are derived as the following:

TABLE I

Vd_{aw}	The anatomic dead space volume is determined by examining the volume that gives equal area between the start of the Phase II data and the start of the Phase III data. This computation is done by fractional difference. (Fowler W.S. Lung Function Studies II. The Respiratory Dead Space. Am. J. Physiol. 154: 405, 1948-the teachings of which are hereby incorporated by reference).
$\text{P}_{et} \text{CO}_2$	The end tidal value of pCO_2 . The last element in the $\text{CO}_2(\text{vol})$ data array is used for $\text{P}_{et} \text{CO}_2$.
V_e	The total volume of air exhaled expressed in ml.

Next, referring again to FIG. 10, as shown at 164, the alveolar tidal volume (V_A), which is also referred to as the

effective tidal volume, is calculated. Alveolar tidal volume is calculated by subtracting the anatomic dead space (Vd_{aw}) from the total tidal volume (V_t).

As shown at 165, the alveolar (effective) minute ventilation (MV_{alv}), which is the total quantity of gas exhaled from a patient's alveoli over a time period of one minute, is calculated. The alveolar minute ventilation is determined for each of total alveolar volume exhaled, the alveolar volume exhaled during ventilator breathing, and the alveolar volume exhaled during spontaneous breathing as shown at 165, 166 and 167, respectively. Preferably, the alveolar minute ventilation calculations are equal to the average of V_A divided by T_e (in minutes) for each of the last eight detected breaths of a specific type. The alveolar minute ventilation calculations are preferably updated with each detected breath.

The mixed expired carbon dioxide value (which is referred to as PeCO_2 when CO_2 is measured in units of mmHg or Kpa, and as FeCO_2 when CO_2 is measured in terms of percent) is determined as shown at 168 by dividing the volume of CO_2 in the breath by the mean expiratory volume, which was determined as shown at 118 of FIG. 3. Mixed Expired CO_2 , as defined herein, is the volume-weighted eight breath average amount of CO_2 and is updated with every breath.

As shown at 169, the system queries the user for the patient's partial pressure of arterial carbon dioxide (PaCO_2). The physiologic dead space (Vd/Vt) is then calculated as shown at 170 in accordance with the following equation:

$$\text{Vd}/\text{Vt} = (\text{PaCO}_2 - \text{PeCO}_2) / \text{PaCO}_2,$$

where PaCO_2 and PeCO_2 are the arterial and mixed expired CO_2 , respectively. Preferably, the PaCO_2 value is user entered. However, it may also be determined in accordance with the method disclosed in U.S. Pat. No. 5,632,281, the disclosure of which is hereby incorporated by reference. Alveolar dead space (Vt_{alv}) is then determined, as shown at 171, by subtracting the anatomic dead space (Vd_{aw}) from the physiologic dead space (Vd/Vt).

The end tidal partial pressure of CO_2 ($\text{P}_{et} \text{CO}_2$) is calculated as shown at 172. Preferably, each 80 millisecond group of CO_2 samples (exemplary) during expiration is averaged. The largest 80 millisecond average is set as the $\text{P}_{et} \text{CO}_2$ value. The end tidal partial pressure of CO_2 may be determined on a breath-to-breath basis, or over a set period of time. Other floating time periods are also within the scope of the method of the present invention.

The amount of carbon dioxide inhaled by the patient is determined as shown at 173. The CO_2 samples in each 80 millisecond group of CO_2 samples over a set time duration are averaged. The smallest 80 millisecond average is set as the inspired CO_2 value. Samples within other time periods may also be used to calculate the amount of CO_2 inhaled by the patient. In the preferred method, this value is reported only when the CO_2 level remains greater than 3 mmHg for an entire 20 seconds.

In instances where a respiratory ventilator controls a patient's breathing, certain respiratory mechanic parameters are measured and determined. FIG. 11 is a flow chart which illustrates a preferred process for determining respiratory mechanic parameters.

One such parameter, dynamic compliance (C_{dyn}), which is the ratio of the change in volume to the change in pressure during inspiration, is determined as shown at 176. At the point where flow crosses from inspiration to expiration (represented by circles in FIG. 4), the volume of inspired gases and the pressure, which is referred to as the initial inspiratory pressure (P_{insp}), are determined and stored as

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shown at 174. Flow also crosses or approaches zero after expiration. The volume at the point between inspiration and expiration is considered to be zero and the filtered pressure at that point, which is referred to as the initial expiratory pressure (P_{exp}) is measured and stored as shown at 175. The dynamic compliance is then computed, as shown at 176, as the ratio of the maximum inspiratory volume (V_i), determined as shown at 115 of FIG. 3, over the difference between P_{exp} and P_{insp} . Preferably, C_{dyn} is calculated by applying the least squares method to each respiratory sample over the entire breath.

As shown at 177, an inquiry is made about whether a P_{plat} value was measured during the last detected breath. If not, the system proceeds to step 188. Otherwise, the system continues to step 178.

Static compliance (C_{st}) is calculated, as shown at 178, for mechanical breaths that have an inspiratory pause. C_{st} is the ratio of the tidal volume at the beginning of the inspiratory hold (assumed to be at a maximum inspiratory tidal volume) divided by the difference between the plateau pressure (P_{plat}) and PEEP.

Airway resistance is determined as shown at 185. If a P_{plat} value was measured during the last detected breath, as shown at 186, the airway resistance during inspiration ($R_{aw\ i}$) is calculated using the least squares method by subtracting the end inspiratory pressure (i.e., the pressure of the last inspiratory phase sample) from P_{plat} , then dividing that value by the air flow measured at the end of inspiration. Next, the airway resistance during expiration ($R_{aw\ e}$) is determined using the least squares method, as shown at 187. $R_{aw\ e}$ is the ratio of driving pressure during expiration to the maximum expiratory flow. First, the maximum expiratory flow sample value during the last detected breath is determined. Next, the maximum expiratory flow value is subtracted from the P_{plat} . That value is then divided by the maximum expiratory flow value for the last detected breath to provide a $R_{aw\ e}$ value. The system then proceeds to step 188.

As shown at 188, an inquiry is made of whether, as shown at inquiry 100 of FIG. 2, it was determined that samples are being taken with a neonatal respiratory sensor. If not, the system proceeds to step 190. If the respiratory samples are being taken with a neonatal sensor, the system of the present invention proceeds to step 189 to calculate compliance over the last 20% of the patient's breath/ C_{dyn} (C_{20}/C). First, the peak inspiratory pressure is multiplied by 80%; the product is the $P_{0.8max}$. The corresponding volume of gases inspired during the sampling with the closest pressure value is then determined and set as the $V_{P_{0.8max}}$ value. $V_{P_{0.8max}}$ is then subtracted from the inspiratory volume (V_i). That value is then divided by PIP less $P_{0.8max}$ to provide a C_{20} value. C_{20} is then divided by the C_{dyn} value, obtained as shown at 176, to determine the C_{20}/C value.

As shown at 190, the ventilator's total inspiratory work of breathing (WOB_{vent} which is measured in J/L) is determined. WOB_{vent} is the work done by a ventilator on the respiratory system; it is the sum of the work required to ventilate the lung and the work required to move the chest wall of the relaxed or paralyzed patient. WOB_{vent} is calculated by summing, during the entire inspiratory phase, the product of the driving pressure (airway pressure) at each respiratory sampling and the volume change from the last sample, where driving pressure is equal to the difference between the airway pressure of the sample less the PEEP value for the last detected breath (PEEP is considered baseline pressure). This work is then normalized to the inspiratory tidal volume. All of the work calculations

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involve the computation of areas using forms of work= integral over the specified time interval of $P\ dv$, where P is the driving pressure and dv is change in volume (or similarly $PV\ dt$, where PV is the product of the driving pressure and volume).

As shown at 191, an inquiry is made about whether the respiratory rate is less than a set number of breaths per minute. If not, the system of the present invention repeats the foregoing steps for the next breath or time interval. If so, the system proceeds to step 192. First, the average of the tidal volume of spontaneous breaths is determined by averaging the V_e+V_i values for a set number (preferably eight) of the most recent spontaneous breaths, as shown at 192. As shown at 193, the rapid shallow breathing index (RSBI) is calculated. RSBI is equal to the respiratory rate (determined as shown at 146 of FIG. 8) divided by the average of the tidal volume of spontaneous breaths (determined as shown at 192).

As shown at 195, SpO_2 and pulse measurements are analyzed by the system of the present invention.

Data Display

The present invention also includes a display method, which comprises detecting a signal source and displaying data as indicated by the signal source. Signal sources include automatic sources such as warnings generated by the system and data which are always displayed, as well as user-input signals such as the parameter display keys that are disclosed in further detail below with reference to FIG. 13. The signals then direct the system to display data in the form of numeric values, graphical representations, or both.

With reference to FIG. 12, in a preferred display method according to the present invention, as shown at 200, an inquiry is made about whether any of the measured or calculated respiratory parameters have fallen below the minimum threshold or exceeded the maximum threshold for that particular parameter. If so, the processing unit (reference character 18 of FIG. 1) sends the appropriate information and/or alerts to display, as shown at 201.

Preferably, alerts are generated for end tidal partial pressure of CO_2 , respiration rate, SpO_2 and pulse rate. Minimum and maximum threshold values for each of these parameters are set by a user. As the end tidal partial pressure of CO_2 , respiration rate, SpO_2 and pulse rate are determined, they are compared to the set thresholds. Sampled values which fall below their respective minimum threshold or exceed their respective maximum threshold trigger an alert. Similarly, the monitoring of and alerts for other parameters are also within the scope of the present invention.

The system of the present invention also alerts a user when the system has not detected respiration from a patient for a set length of time. Preferably, an alert is generated when the system has not detected respiration for a predetermined (e.g., twenty seconds) or user-selectable time duration.

The system of the present invention also displays various respiratory parameters, including, without limitation, the end tidal carbon dioxide level (determined as shown at 172 of FIG. 10) and the respiratory rate (determined as shown at 146 of FIG. 8). These parameters are preferably displayed at all times during which the monitor is not in a setup, configuration, or similar mode. The system of the present invention may also display parameters such as blood oxygen saturation (SpO_2) and pulse rate.

A preferred respiratory profile monitor for use with the present invention, such as that sold under the trademark

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CO₂SMO® Plus! by Novamatrix shown in FIG. 13, includes parameter display keys 1301, 1302, 1303 and 1304 which direct the system to display other respiratory profile parameters. On the CO₂SMO® Plus! respiratory profile monitor, such keys are labeled "CO₂/Pleth" 1301, "Flow/Pres" 1302, "Trend" 1303 and "Data" 1304.

Referring again to FIG. 12, repeated and continual inquiries are made about whether any of the parameter display keys have been depressed. As shown at 202 of the flowchart, the system inquires whether the key labeled "CO₂/Pleth" has been pressed. If so, the system inquires whether any of the CO₂/plethysmogram displays are being shown (examples are described below). If not, the system shows the CO₂/plethysmogram display that was last shown. If so, the system shows the next CO₂/plethysmogram display. A first CO₂/plethysmogram display shows a capnogram (see FIG. 14) along with the flow rate of carbon dioxide and the alveolar minute volume, as shown at 203. A second CO₂/plethysmogram display shows a capnogram, a plethysmogram (see FIG. 15), the flow rate of carbon dioxide and the alveolar minute volume, as shown at 205.

Upon a depression of the "Flow/Pres" key, detected as shown at inquiry 210, the system inquires whether any of the flow/pressure displays are being shown (examples are described below). If not, the system shows the flow/pressure display that was last shown. If so, the system shows the next flow/pressure display. A first flow/pressure display shows a flow waveform (see FIG. 16) and a pressure waveform (see FIG. 17), and displays the MAP and PEEP values as shown at 211. A second flow/pressure display shows a flow volume loop (see FIG. 18), a pressure volume loop (see FIG. 19), C_{dyn} and R_{aw} (if determined as shown at 176 and 186 of FIG. 11), as shown at 213.

When the "Trend" key is depressed, detected at inquiry 220, the system of the present invention inquires whether any of the trend displays are being shown (examples are described below). If not, the system shows the trend display that was last shown. If so, the system shows the next trend display. A first trend display shows, as depicted at 221, a bar graph illustrating the trend of alveolar minute ventilation and the trend of CO₂ production, each over a set time duration. Preferably, the alveolar minute ventilation trend graph illustrates both the spontaneous and mechanical ventilator components thereof. An exemplary time duration for illustration of such trends is twenty minutes. A second trend display shows bar graphs which illustrate the trends, or recent histories, of tidal volume attributable to ventilator-induced breathing and tidal volume generated by a patient's spontaneous breathing, as shown at 223.

All of the respiratory parameters may be stored for a set duration of time by processing unit 18 (see FIG. 1), which generates and displays trend bar graphs. With reference to FIG. 20, the trend display 260 illustrates the trend of a particular respiratory profile parameter over a set duration of time (e.g., 20 minutes, 1, 4, 8, 12 or 24 hours) as a set number of values (e.g., 10, 20). Each displayed value (i.e., a bar 262 of the bar graph 261) is representative of all of the corresponding measured respiratory profile parameter values over a particular time interval (e.g., an average value, median value, low value, high value, etc.). Preferably, all of the displayed values (i.e., bars 262) represent the corresponding measured respiratory profile parameter values over consecutive time intervals of equal length. For example, if the bar graph 261 includes twenty bars 262 which represent a respiratory profile parameter trend over the past 24 hours, each displayed value (i.e., a bar 262 of bar graph 261) represents all of the corresponding actual respiratory profile parameter values of each consecutive 1.2 hour interval.

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When the key marked "Data" is pressed, detected as shown at inquiry 230, the system inquires whether any of the data displays are being shown (examples are described below). If not, the system shows the data display that was last shown. If so, the system shows the next data display. A first data display shows the following parameter values, as shown at 231: V_i , V_e , $V_{t_{alv}}$, $V_{d_{aw}}$, PIP, MAP, PEEP and P_{plat} . A second data display shows values for the number of spontaneous and ventilator-induced breaths, PIF, PEF, I:E ratio, T_i and T_e as shown at 233. A third data display shows, as depicted at 235, the R_{aw} , R_{aw} , C_{dyn} , RSBI, VCO₂, VCO₂/kg, $PeCO_2$ and WOB_{vent} values. A fourth data display directs a user to enter the patient's weight at 237. Following entry of the patient's weight, the system calculates the corrected tidal volume as shown at 238. Corrected tidal volume is equal to the mean expiratory volume (determined as shown at 118 of FIG. 3) divided by the patient's weight. As shown at 239, the system of the present invention divides the exhaled CO₂ value by the patient's weight to determine the volume of CO₂ exhaled per minute per kilogram. The system of the invention then displays, as shown at 240, the following values: V_{TOT} /kg, V_d/V_t and $V_{d_{alv}}$. A fifth data display shows the spontaneous, ventilator-induced and total minute volumes and the spontaneous, ventilator-induced and total alveolar minute volumes as shown at 251.

Although the foregoing description contains many specificities, these should not be construed as limiting the scope of the present invention, but merely as providing illustrations of selected presently preferred embodiments. Similarly, other embodiments of the invention may be devised which do not depart from the spirit or scope of the present invention. The scope of this invention is, therefore, indicated and limited only by the appended claims and their legal equivalents, rather than by the foregoing description. All additions, deletions and modifications to the invention as disclosed herein which fall within the meaning and scope of the claims are embraced within their scope.

What is claimed is:

1. A method for displaying data of a plurality of respiratory profile parameters and at least one respiratory-based estimate of a blood gas parameter, comprising: in response to a signal generated while monitoring at least respiration of an individual, displaying

a numeric value of a partial pressure of arterial carbon dioxide, an indicator of arterial blood oxygen saturation, a pulse rate, a respiratory rate, a partial pressure of end tidal carbon dioxide, and data of at least one other selected one of the plurality of respiratory profile parameters and at least one respiratory-based estimate of a blood gas parameter.

2. The method of claim 1, further comprising displaying a graphical representation of a selected one of the plurality of respiratory profile parameters and at least one respiratory-based estimate of a blood gas parameter in response to said signal.

3. The method of claim 2, wherein said displaying said graphical representation comprises displaying a multi-component bar graph including a plurality of bars, selected ones of said plurality of bars each including a first component and a discrete second component adjacent said first component.

4. The method of claim 3, wherein said first component represents a portion of a breath effected by a mechanical ventilator.

5. The method of claim 3, wherein said discrete second component represents a portion of a breath effected spontaneously by a patient.

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6. A method of displaying a plurality of respiratory profile data and at least one respiratory-based estimate of at least one blood gas parameter in response to a signal generated as respiration of an individual is monitored, comprising:

displaying a numeric value representative of at least one of the plurality of respiratory profile data and of the at least one respiratory-based estimate of the at least one blood gas parameter; and

displaying a graphical representation of at least one of the plurality of respiratory profile data.

7. The method of claim 6, wherein said displaying said graphical representation comprises displaying a multi-component bar graph including a plurality of bars, selected ones of said plurality of bars each including a first component and a discrete second component adjacent said first component.

8. The method of claim 7, wherein said first component represents a portion of a breath effected by a mechanical ventilator.

9. The method of claim 8, wherein said discrete second component represents a portion of a breath effected spontaneously by a patient.

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10. A method of displaying a plurality of respiratory profile data in response to a signal, comprising:

in response to a signal, displaying a multi-component bar graph including a plurality of bars, selected ones of said plurality of bars each including a first component and a discrete second component adjacent said first component.

11. The method of claim 10, wherein said first component represents a first respiratory profile parameter.

12. The method of claim 11, wherein said first component represents a portion of a breath effected by mechanical ventilator.

13. The method of claim 11, wherein said discrete second component represent a second respiratory profile parameter that corresponds to said first respiratory profile parameter.

14. The method of claim 12, wherein said discrete second component represents a portion of a breath effected spontaneously by a patient.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,471,658 B1
DATED : October 29, 2002
INVENTOR(S) : Rich H. Daniels et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4,

Line 51, change "5,179,786" to -- 5,170,786 --

Column 8,

Line 11, change "142" to -- 145 --

Line 14, change "145" to -- 142 --

Line 54, change "At" to -- Δt --

Column 9,

Line 62, TABLE 1, change "The last element in the CO₂" to -- The last element in the CO₂ --

Line 63, TABLE 1, change "PetCo." to -- PetCO₂. --

Column 10,

Line 52, change "calculated" to -- calculate --

Column 12,

Line 45, change "SpO²" to -- SpO₂ --

Column 13,

Line 4, at the end of the line delete the semicolon

Line 24, change "exarnples" to -- examples --

Column 14,

Line 7, change the comma after "P_{plat}" to a period

Column 16,

Line 11, after "by" and before "mechanical" insert -- a --

Line 14, change "represent" to -- represents --

Signed and Sealed this

Twenty-sixth Day of August, 2003

A handwritten signature in black ink, appearing to read "James E. Rogan", with a horizontal line drawn underneath it.

JAMES E. ROGAN

Director of the United States Patent and Trademark Office

专利名称(译)	呼吸概况参数确定方法和装置		
公开(公告)号	US6471658	公开(公告)日	2002-10-29
申请号	US09/733776	申请日	2000-12-08
[标]申请(专利权)人(译)	NTC TECH		
申请(专利权)人(译)	NTC TECHNOLOGY , INC.		
当前申请(专利权)人(译)	RIC投资有限责任公司.		
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IPC分类号	A61B5/087 A61B5/08 A61B5/083 A61M16/00 A61B5/024 A61B5/00		
CPC分类号	A61B5/083 A61B5/087 A61M16/00 A61M16/0051 A61B5/02416 A61B5/1455 A61M2016/0036 A61M2230/202 A61M16/021		
审查员(译)	刨 , KEVIN		
外部链接	Espacenet USPTO		

摘要(译)

一种采样一个或多个呼吸概况特征并监测各种呼吸概况参数的方法。采样的呼吸特征包括呼吸流速，呼吸压力和患者呼吸的至少一个成分的分压。该方法检测患者呼吸，确定每次呼吸是自发呼吸还是呼吸机引起的呼吸，并基于采样的测量结果计算各种呼吸分布参数。该方法以图形和数字形式显示呼吸轮廓参数。优选地，该方法允许用户选择显示的呼吸概况参数。

