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(54) AIRWAY-BASED CARDIAC OUTPUT MONITOR AND METHODS FOR USING SAME

(76) Inventor: James R. Mault, Evergreen, CO (US)

Correspondence Address:
GIFFORD, KRASS, GROH, SPRINKLE
ANDERSON & CITKOWSKI, PC
280 N OLD WOODARD AVE
SUITE 400
BIRMINGHAM, MI 48009 (US)

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(60) Provisional application No. 60/133,685, filed on May 10, 1999.

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(57) ABSTRACT

A respiratory gas analyzer for measuring the cardiac output of a subject includes a flow meter and an oxygen sensor interconnected with one another between a mouthpiece and a source of respiratory gases which may be a controlled source or the atmosphere. An oximeter provides measurements of the oxygen saturation of the subject. A computer connected to receive the signals from the flow meter, oxygen sensor, and oximeter can then calculate the subject's cardiac output.

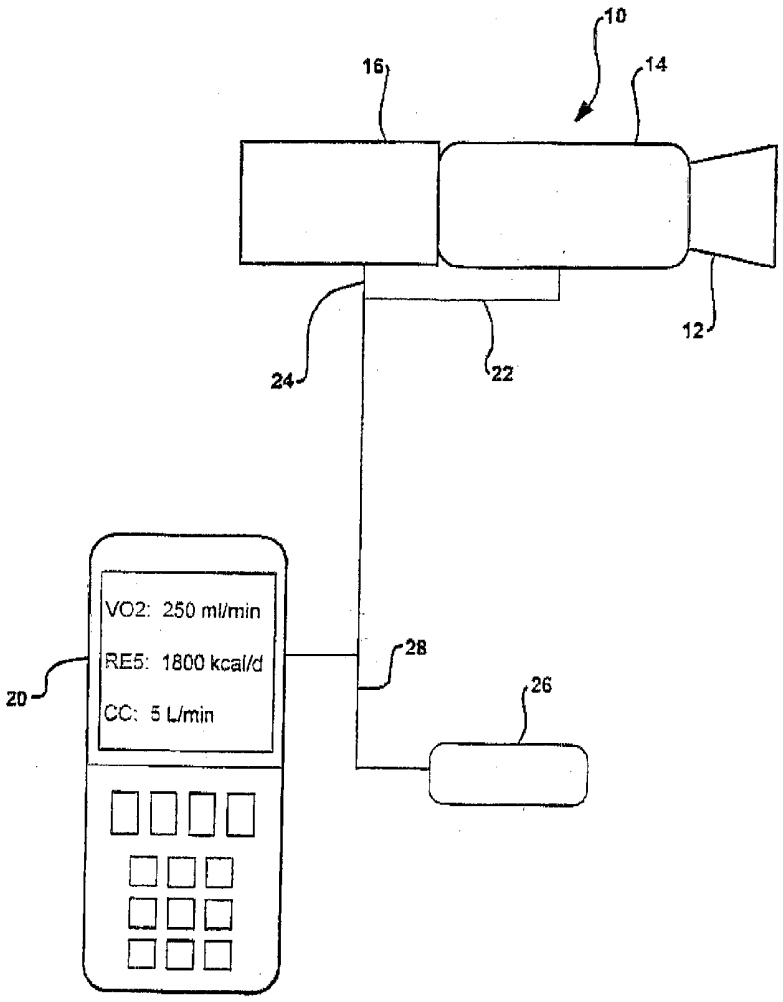


FIG - 1

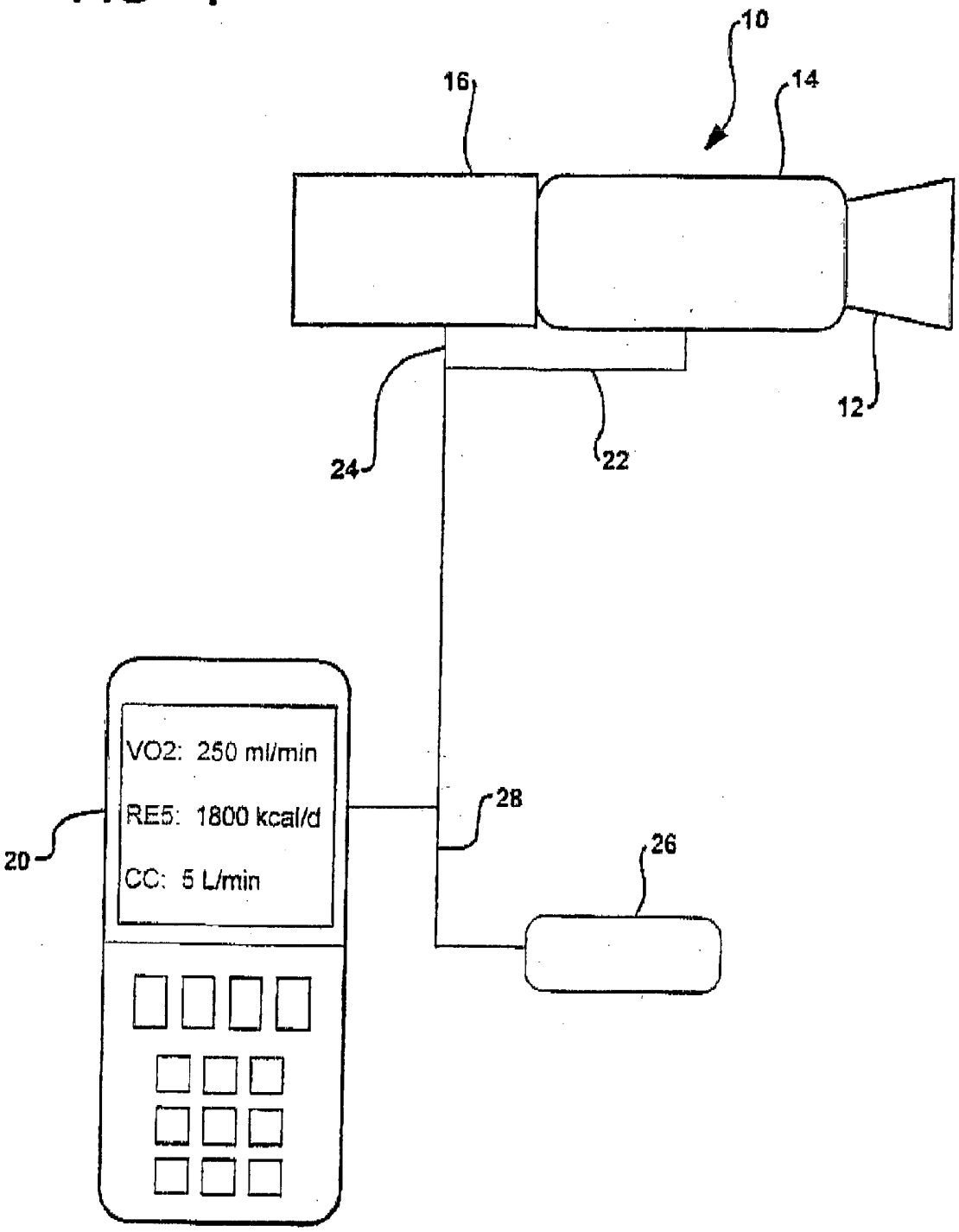


FIG - 2

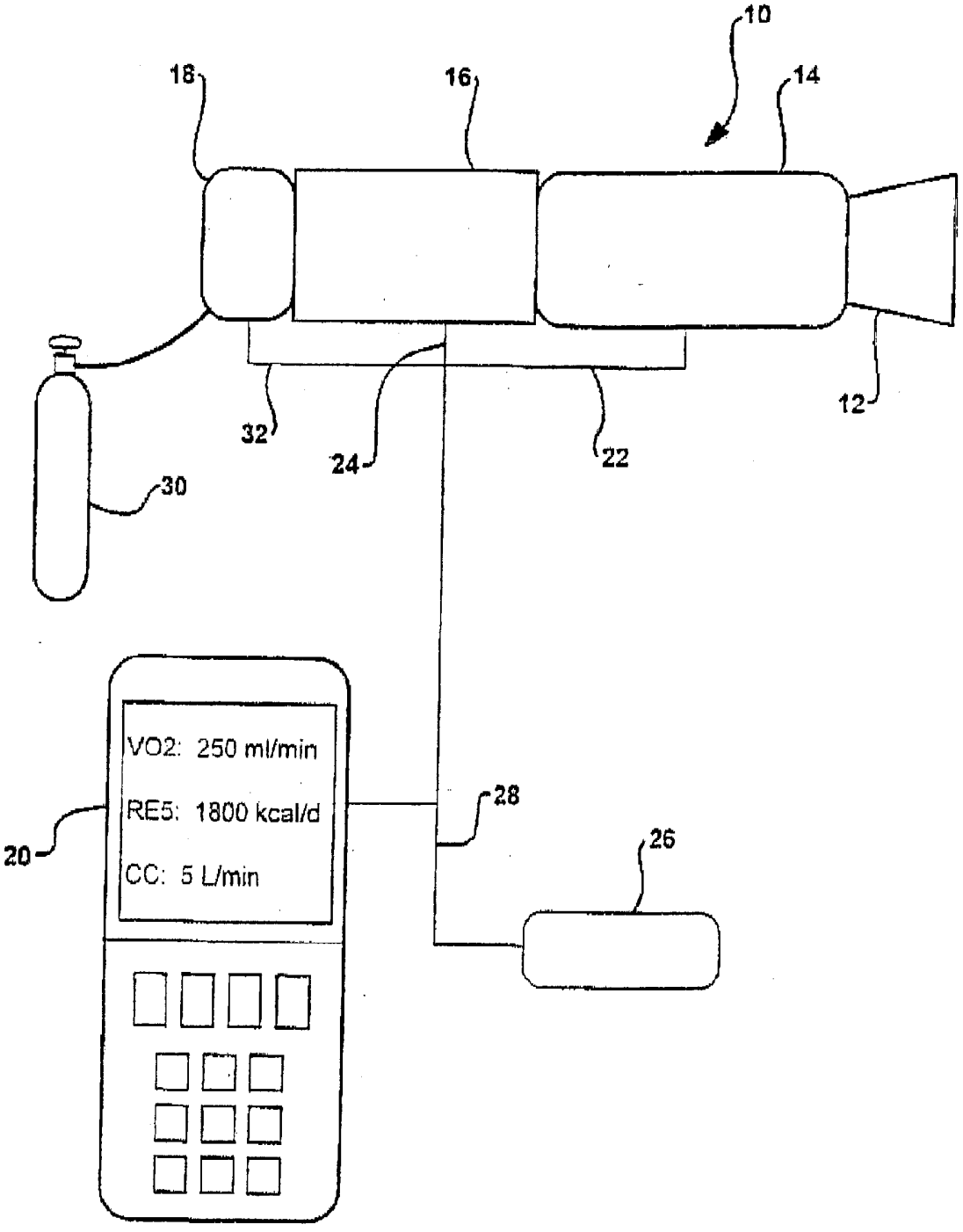
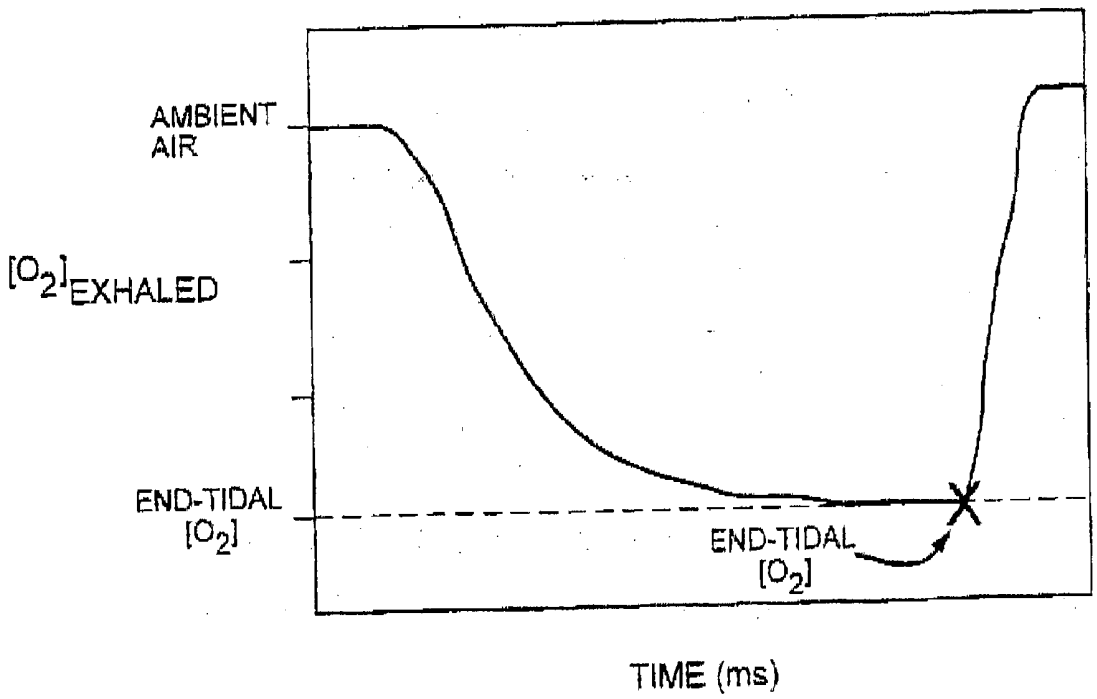

10
18
16
14
12
32
24
22
30
VO2: 250 ml/min
RE5: 1800 kcal/d
CC: 5 L/min
20
28
26

FIG - 3



AIRWAY-BASED CARDIAC OUTPUT MONITOR AND METHODS FOR USING SAME

REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 09/674,899, filed Nov. 7, 2000, which is the U.S. National Phase of PCT/US00/12745, filed May 10, 2000, which claims priority from U.S. Provisional Patent Application Serial No. 60/133,685, filed May 10, 1999, the entire content of each being incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to measurement of cardiac output of a patient. More specifically, the present invention relates to an apparatus and method for non-invasive cardiac output measurement of a subject utilizing a respiratory gas analyzer employing a flow sensor, an oxygen sensor, and a pulse oximeter which are interconnected to measure the cardiac output of the subject.

BACKGROUND OF THE INVENTION

[0003] U.S. Pat. No. 5,836,300 to Applicant discloses a respiratory gas analyzer for measuring the metabolic activity and the cardiac output of a subject including a bi-directional flow meter and a capnometer sensor interconnected by conduits and valving between a mouthpiece and a source of respiratory gases which can be a controlled source or the atmosphere. A computer receiving signals from the flow meter and the capnometer can then calculate the subject's metabolic activity. When valving is shifted, a portion of the exhaled gases are stored in the conduit so that upon inhalation, the subject inhales a substantial portion of rebreathed gases. The computer can then calculate the patient's cardiac output as a function of the changes in total carbon dioxide content of the exhaled gas before and after the valve is shifted from a direct input to a rebreathed position and the difference in end-tidal carbon dioxide between the two positions.

[0004] The cardiac output of a patient, that is the volume of blood ejected from the heart per unit time, is an important measured parameter in hospitalized patients. Currently, cardiac output is routinely measured by invasive techniques including thermal dilution using an indwelling pulmonary artery catheter. This technique has several disadvantages including the morbidity and mortality risks of placing an invasive intracardiac catheter, the infectious disease risks, significant expense and the fact that it provides an intermittent rather than a continuous measurement. A noninvasive, reusable cardiac output measurement device would substantially improve patient care and reduce hospital costs.

[0005] The partial rebreathing technique mentioned above is a known method for cardiac output measurement. As described in Kapec and Roy, "The Noninvasive Measurement of Cardiac Output Using Partial CO_2 Rebreathing," IEEE Transactions on Biomedical Engineering, Vol. 35, No. 9, September 1988, pp. 653-659, the method utilizes well known Fick procedures, substituting carbon dioxide for oxygen, and employing a sufficiently short measurement period such that venous carbon dioxide levels and cardiac output can be assumed to remain substantially constant during the measurement.

[0006] U.S. Pat. No. 4,949,724 to Mahutte et al. discloses a method and apparatus for continuously monitoring cardiac output by utilizing a modified Fick equation. The Mahutte et al. patent replaces VO_2 in the Fick equation by VCO_2 divided by a constant representative of the gas exchange ratio of a patient in order to eliminate inaccuracies associated with monitoring the rate of uptake of oxygen.

[0007] In its original form, the Fick method of measuring cardiac output requires blood gas values for arterial and mixed venous blood as follows:

$$C.O. = \frac{VO_2}{CaO_2 - CvO_2}$$

[0008] where C.O. is cardiac output, VO_2 is oxygen consumption, CaO_2 is the arterial oxygen content, and C_vO_2 is the venous oxygen content.

[0009] By utilizing a respiratory analyzer with a fast-response oxygen sensor, the cardiac output can be determined based on the end-tidal oxygen concentration (EtO_2). End-tidal oxygen concentration is the lowest value of oxygen concentration in breath. The end-tidal oxygen concentration approximates the pulmonary capillary oxygen concentration.

[0010] Alternatively, at different points in time, it is also true that

$$C.O. = \frac{VO_{2(1)}}{CaO_{2(1)} - CvO_{2(1)}} = \frac{VO_{2(2)}}{CaO_{2(2)} - CvO_{2(2)}}.$$

[0011] If the oxygen concentration of the inspired gas is temporarily increased or decreased, the change in alveolar oxygen concentration will cause a transient uptake or release of oxygen across the pulmonary capillaries, thereby resulting in a change in the measured VO_2 and arterial oxygen content (CaO_2). If these parameters are measured during an interval of time less than the circulation time (i.e., less than approximately thirty-fifty seconds), then the venous oxygen content (C_vO_2) level remains essentially constant during this period and can be removed from the equation. Therefore, cardiac output can be determined based on the equation

$$C.O. = \frac{\Delta VO_2}{\Delta CaO_2}$$

[0012] The use of these novel concepts in combination with the apparatus and method of the present invention therefore allows for the non-invasive measurement of cardiac output utilizing measurements of airway gases and arterial oxygen concentrations, both of which can be done by non-invasive techniques.

SUMMARY OF THE INVENTION

[0013] The present invention is accordingly directed toward an airway-based respiratory gas analyzer for measuring the cardiac output of a subject. In a preferred embodi-

ment of the analyzer of the present invention, the analyzer includes a respiratory connector operative to be supported in contact with a subject so as to pass inhaled and exhaled gases as the subject breathes. A flow meter operatively connected to the respiratory connector generates electrical signals as a function of the volume of gases which pass therethrough and, in combination with the signals generated by an oxygen sensor, allows for the determination of oxygen consumption (VO_2) by integrating the flow and oxygen concentration signals over an entire breath. The oxygen sensor can also provide for the measurement of end-tidal (EtO_2) concentration. An oximeter provides measurements of the subject's oxygen saturation. A computation unit receives the output signals from the flow sensor, oxygen sensor and oximeter and calculates the cardiac output based on the generated signals.

[0014] An alternative mechanism for performing measurements of the subject's cardiac output includes the subject placing the mouthpiece of the analyzer into their mouth and breathing a first oxygen concentration for a first period of time. Typically, the source of respiratory gases is atmospheric air. As the subject breathes, oxygen consumption (VO_2) is determined as the integral of the flow and oxygen concentration signals over the entire breath. The oximeter provides a measurement of the subject's oxygen saturation which is utilized to calculate the subject's arterial oxygen content. After obtaining the measurement of the oxygen consumption (VO_2) and arterial oxygen content (CaO_2) over the first time period, the oxygen blender is caused to provide an increase or decrease in the airway oxygen concentration of the subject for a second period of time which is less than the subject's circulation time. The oxygen consumption (VO_2) and arterial oxygen content (CaO_2) are measured over this second time period on a breath-by-breath basis and are utilized in calculating the subject's cardiac output.

[0015] According to one aspect of the present invention, a respiratory gas analyzer for measuring cardiac output of a subject, is provided. The analyzer includes an apparatus for determining a cardiac output of a subject having a flow path through which respiratory gases pass, a flow rate sensor, and an oxygen sensor. The respiratory analyzer provides a flow signal correlating with a flow rate of respiratory gases through the flow path, and a respiratory oxygen concentration signal correlating with an oxygen concentration of respiratory gases. The analyzer also includes a computation unit that receives the respiratory oxygen concentration signal and the flow signal, and is operable to determine an oxygen consumption of the subject, to determine an end-tidal partial pressure of oxygen of at least one breath of the subject, and to determine the cardiac output of the subject using the oxygen consumption, the end-tidal partial pressure of oxygen, and an arterial oxygen saturation.

[0016] According to one preferred embodiment of the invention described below, the analyzer is used in a two-measurement procedure, wherein the computer calculates the cardiac output (C.O.) of the subject according to the following equation:

$$C.O. = \frac{\Delta VO_2}{\Delta CaO_2}$$

[0017] wherein: ΔVO_2 is the difference in said consumed oxygen in the two-measurement procedure, and ΔCaO_2 is the difference in said arterial oxygen in the two-measurement procedure;

[0018] and wherein: the two-measurement procedure involves:

[0019] (a) a first measurement of said consumed oxygen and said arterial oxygen during a first time interval, and

[0020] (b) a second measurement, following a change in the oxygen content of the inhaled air, during a second time interval having a duration less than the blood circulation time of the subject.

[0021] According to a second described preferred embodiment, the computer calculates the cardiac output (C.O.) of the subject computer calculates the cardiac output (C.O.) of the subject according to the following equation:

$$C.O. = \frac{VO_2}{CaO_2 - CvO_2}$$

[0022] wherein: VO_2 is the oxygen consumed during a breath; CaO_2 is the concentration of oxygen in the subject's arterial blood; and CvO_2 is the concentration of oxygen in the subject's venous blood, which is assumed to be the same as the end-tidal oxygen concentration in the exhaled air.

[0023] Other features, advantages and applications of the present invention will be made apparent from the following detailed description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Other advantages and applications of the present invention will be made apparent by the following detailed description of preferred embodiments of the invention. The description makes reference to the accompanying drawings in which:

[0025] **FIG. 1** is a schematic representation of a first embodiment of the present invention;

[0026] **FIG. 2** is a schematic representation of a second embodiment of the present invention; and

[0027] **FIG. 3** is a graph of oxygen concentration over time measured in milliseconds to illustrate oxygen concentration as recorded with a fast-response oxygen sensor and is also illustrative end-tidal oxygen concentration.

DETAILED DESCRIPTION OF THE INVENTION

[0028] Referring to **FIG. 1, a** preferred embodiment of the present invention includes an airway-based cardiac output analyzer, generally indicated at **10**, having a mouthpiece **12**, a flow sensor **14**, and a gas sensor **16**. The flow sensor **14** and the gas sensor **16** are disposed in fluid communication with one another.

[0029] The mouthpiece **12** is adapted to engage the inner surfaces of a user's mouth, so as to form the sole passage for flowing respiratory gases into and out of the mouth. A nose clamp of conventional construction (not shown) can be

employed in connection with the mouthpiece **12** to assure that all respiratory gas passes through the mouthpiece **12**. In alternative configurations, a mask that engages the nose as well as the mouth of the user can be employed or an endotracheal tube could also be utilized.

[**0030**] The mouthpiece **12** is located adjacent to a bi-directional volume flow sensor **14**. The flow sensor is preferably an ultrasonic flow meter such as an ultrasonic transit time flow meter such as that manufactured by NDD Medizintechnik AG, Zurich, Switzerland, and disclosed in U.S. Pat. Nos. 3,738,169; 4,425,805; 5,419,326; and 5,645,071. Preferably, the ultrasonic flow meter transmits and receives ultrasonic pulses along a path which is either parallel to or has a substantial component in the direction of the flow. The gas flow acts to advance or retard the flow of pulses so that the full transit time of the pulses is a function of the flow rate. Alternatively, the flow sensor **14** can be of the pressure differential type such as manufactured by Medical Graphics Corporation, St. Paul, Minn. under the trademark MEDGRAPHICS and of the general type illustrated in U.S. Pat. No. 5,038,773. Alternatively, other types of flow transducers such as pneumatics or spirometers could also be employed. The electrical output of the bi-directional flow sensor **14** is connected to a computation unit **20** through a conductive line **22**.

[**0031**] The other end of the flow sensor **14** is connected to the gas sensor **16**. The gas sensor **16** is preferably a fast-response (i.e. 50-80 millisecond response time), flow-through type oxygen sensor and is preferably of the fluorescent quench type as disclosed in U.S. Pat. Nos. 3,725,658; 5,517,313; and 5,632,958. The preferred embodiment can employ a sensor manufactured by Sensors for Medicine and Science, Inc., Germantown, Md. The electrical output of the gas sensor **16** is connected to the computation unit **20** through a conductive line **24**. The computation unit **20** can include a source (not shown) for directing exciting radiation to a fluorescent coating disposed on the oxygen sensor **16** and sensing the resulting fluorescence intensity which is diminished as a function of the concentration of oxygen in the gas flowing over its surface to produce a direct measurement of oxygen concentration. The exciting radiation and fluorescent signal can be carried to the sensor **16** by an optical fiber (not shown).

[**0032**] A pulse oximeter **26** can be utilized to monitor oxygen saturation by pulse oximetry. The pulse oximeter **26** provides an output signal which is received by the computation unit **20** which is indicative of saturation percentage. The output signal of the pulse oximeter **26** is connected to the computational unit **20** through a conductive line **28**. In a preferred embodiment, the pulse oximeter is preferably of the type manufactured by Datax-Ohmeda, Louisville, Colo. Alternatively, for most healthy individuals, the pulse oximeter **26** can be omitted and the oxygen saturation can be assumed to be approximately 95-96%.

[**0033**] Utilizing the Fick equation, in combination with the airway-based respiratory gas analyzer **10** having the flow sensor **14** and the fast-response oxygen sensor **16**, allows for the determination of a subject's cardiac output by utilizing measurements of end-tidal oxygen concentration and VO_2. The airway-based gas analyzer **10** allows for the determination of end-tidal oxygen concentration (EtO_2) as illustrated in **FIG. 3**. If one assumes that $EtO_2 \square PvO_2$ (dissolved venous oxygen concentration in the plasma), then using the PvO_2 and the hemoglobin concentration, the SvO_2 can be determined based on the oxygen dissociation curve. The pulse oximeter **26** can be used to obtain oxygen saturation movement so that based on the Fick equation of

$$C.O. = \frac{VO2}{CaO_2 - CvO_2}$$

[**0034**] wherein VO_2 is measured by the airway based respiratory analyzer, CaO_2 and CvO_2 are determined according to the equations

$CaO_2=[(SaO_2)(Hgb)(1.36)+(PaO_2)(0.0031)]$ and

$CvO_2=[(SvO2)(Hgb)(1.36)+(PvO_2)(0.0031)]$, respectively,

[**0035**] wherein SaO_2 is the oxygen saturation measurement obtained by pulse oximetry, Hgb is the hemoglobin concentration (which is entered as a known value or by direct measurement), and PvO_2 is obtained from the measurement of EtO_2. It is assumed that EtO_2 approximates PvO_2 and, if the PvO_2 and the hemoglobin concentrations are known, using the oxygen dissociation curve, SvO_2 can be determined. The pulse oximeter **26** measures SaO_2 (alternatively, SaO_2 and PaO_2 can be reasonably assumed).

[**0036**] Referring to **FIG. 2**, in an alternative embodiment of the present invention is shown wherein like numerals represent like elements among the embodiments, a gas blender **18** is disposed directly adjacent to and in fluid communication with the gas sensor **16**. The gas blender **18** is also in fluid communication with the atmosphere or a source and sink of respiratory gases. The gas blender **18** can also be connected to a ventilator or source of calibrated or known gases such as an external oxygen tank **30**. The gas blender **18** is preferably computer controlled and is in electrical communication with the computation unit **20** through a conductive line **32**. That is, the computation unit **20** can transmit signals to the gas blender **18** in order to modify, mix, or change the composition of the inhaled air passing through the cardiac output analyzer **10** to the subject. In other words, the gas blender **18** can be caused to allow an increase/decrease in the concentration of airway oxygen for a given or predetermined period of time.

[**0037**] In a further alternative embodiment, the pulse oximeter **26** can be replaced by a synchronized, side-port sampling oxygen sensor as is well known in the art. That is, a portion or sample of the gases flowing through the analyzer is directed via a port to an oxygen sensor.

[**0038**] The analyzer **10** can also incorporate an artificial nose and/or a bacterial filter as described in Applicant's previous patents or can incorporate a temperature sensor which provides a signal to the computation unit **20** to adjust the measurements as a function of breath and external air temperature.

[**0039**] In operation, in order to non-invasively obtain a measurement of the cardiac output of a subject, the subject attaches the pulse oximeter **22** to a suitable portion of their body such as a finger or earlobe, the subject then places the mouthpiece **12** into their mouth and the oxygen consumption (VO_2) is determined as the integral of the flow of oxygen

concentration signals over an entire breath. The arterial oxygen concentration is calculated according to the formula:

$$CaO_2=(SaO_2)(Hbg)(1.36)+(0.0031)(PaO_2)$$

[0040] where SaO_2 is the oxygen saturation measurement obtained by the pulse oximeter **22**, Hbg is the hemoglobin concentration (which is entered as a known value or obtained by direct measurement), and PaO_2 is the dissolved arterial oxygen concentration. After obtaining a stable measurement of VO_2 and CaO_2 over a first time period of approximately two to three minutes, the gas blender **18** is caused to increase/decrease the concentration of oxygen (preferably, at least a 10% change in FIO_2, e.g., 40% increased to 50%) supplied to the subject for a second time period less than the subject's circulation time of approximately thirty to fifty seconds. VO_2 and CaO_2 are monitored on a breath-by-breath basis during this time period and the cardiac output is then determined. Accordingly, the method and apparatus of the present invention take advantage of the phenomenon that if the oxygen concentration of the inspired gas is temporarily increased or decreased, the change in alveolar oxygen concentration will cause a transient uptake or release of oxygen across the pulmonary capillaries thereby resulting in a change in the measured VO_2 and arterial oxygen content (CaO_2). If these parameters are measured during an interval less than the circulation time (i.e., less than approximately thirty to fifty seconds), then the venous oxygen content (CvO_2) can be ignored and the cardiac output of the subject can be calculated based on the equation

$$C.O. = \frac{\Delta VO_2}{\Delta CaO_2}$$

[0041] In view of the teaching presented herein, other modifications and variations of the present invention will readily be apparent to those of skill in the art. The discussion and description are illustrative of some embodiments of the present invention, but are not meant to be limitations on the practice thereof. It is the following claims, including all equivalents, which defines the scope of the invention.

1. An apparatus for determining a cardiac output of a subject, the apparatus comprising:

a respiratory analyzer, having a flow path through which respiratory gases pass, a flow rate sensor, and an oxygen sensor, the respiratory analyzer providing a flow signal correlating with a flow rate of respiratory gases through the flow path, and a respiratory oxygen concentration signal correlating with an oxygen concentration of respiratory gases; and

a computation unit, wherein said computation unit receives the respiratory oxygen concentration signal and the flow signal, the computation unit being operable to determine an oxygen consumption of the subject, to determine an end-tidal partial pressure of oxygen of at least one breath of the subject, and to determine the cardiac output of the subject using the oxygen consumption, the end-tidal partial pressure of oxygen, and an arterial oxygen saturation.

2. The apparatus of claim 1, further comprising a pulse oximeter operable to provide the arterial oxygen saturation.

3. The apparatus of claim 1, wherein the arterial oxygen saturation is a predetermined value for the subject.

4. The apparatus of claim 1, wherein the computation unit determines the cardiac output (C.O.) of the subject using a formula

$$C.O. = \frac{VO_2}{CaO_2 - CvO_2},$$

wherein VO_2 represents the oxygen consumption of the subject, CaO_2 represents an oxygen content of arterial blood, and CvO_2 represents an oxygen content of venous blood.

5. The apparatus of claim 4, wherein the computation unit is operable to determine the oxygen content of arterial blood (CaO_2) using an equation of the form

$$CaO_2=A(SaO_2)(Hgb)+B(PaO_2),$$

wherein A and B represent numerical values, SaO_2 represents the arterial oxygen saturation, Hgb represents a hemoglobin concentration, and PaO_2 represents a dissolved arterial oxygen concentration.

6. The apparatus of claim 5, wherein the computation unit uses a predetermined value for SaO_2 when calculating the oxygen content of arterial blood.

7. The apparatus of claim 5, wherein the computation unit uses the oxygen saturation signal and a predetermined value of Hgb when calculating the oxygen content of arterial blood.

8. The apparatus of claim 4, wherein the computation unit is operable to determine the oxygen content of venous blood (CvO_2) using an equation of the form

$$CvO_2=C(SvO_2)(Hgb)+D(PvO_2),$$

wherein C and D represent numerical constants, SvO_2 represents a venous oxygen saturation, Hgb represents a hemoglobin concentration, and PvO_2 represents a dissolved venous oxygen concentration.

9. The apparatus of claim 8, wherein the computation unit determines PvO_2 using the end-tidal partial pressure of oxygen.

10. The apparatus of claim 8, wherein the computation unit determines SvO_2 from PvO_2 using a predetermined relationship between SvO_2 and PvO_2.

* * * * *

专利名称(译)	基于气道的心输出量监测器及其使用方法		
公开(公告)号	US20030167016A1	公开(公告)日	2003-09-04
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[标]申请(专利权)人(译)	詹姆士R.莫特		
申请(专利权)人(译)	MAULT JAMES R.		
当前申请(专利权)人(译)	MAULT JAMES R.		
[标]发明人	MAULT JAMES R		
发明人	MAULT, JAMES R.		
IPC分类号	G01F1/00 A61B5/00 A61B5/026 A61B5/029 A61B5/08 A61B5/083 A61B5/087 A61B5/145 A61M16/00 G01F1/66 G01N21/64 G01N33/497		
CPC分类号	A61B5/029 A61B5/1455 A61B5/087 A61B5/083		
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外部链接	Espacenet USPTO		

摘要(译)

用于测量受试者的心输出量的呼吸气体分析仪包括流量计和氧气传感器，所述流量计和氧气传感器在接口管和呼吸气体源之间彼此互连，所述呼吸气体源可以是受控源或大气。血氧计提供对象的氧饱和度的测量。连接到接收来自流量计，氧传感器和血氧计的信号的计算机可以计算受试者的心输出量。