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Ambulatory Breath Analyzer and Uses Thereof

Abstract

Provided herein is a portable, handheld, non-invasive device for measuring and monitoring cardiac output in a subject. The device has a mouthpiece with a breath particle filter at the inlet on the device such that exhaled breath flows through the mouthpiece-filter into a chamber containing a CO.sub.2 meter and flow meter to measure CO.sub.2 concentration and volumetric breath flow. Measurements are sent as input data to a computer monitored by an operator whereupon an algorithm calculates cardiac output which is displayed or stored.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This non-provisional patent application claims benefit of priority under 35 U.S.C. § 119 (e) of provisional patent application U.S. Ser. No. 63/555,154, filed Feb. 19, 2024, the entirety of which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION
Field of the Invention
[0002] The present invention relates generally to the fields of cardiac care and cardiac output measurement devices. More specifically, the present invention relates to a handheld, non-invasive medical device to measure carbon dioxide and flow of exhaled breath to determine cardiac output in outpatient and at home settings.
Description of the Related Art
[0003] A failing heart produces low cardiac output (CO) that causes multi-organs damage and symptoms. Heart failure (HF) treatments aim to restore heart function to normalize cardiac output. Thus, knowing patients' cardiac output at home and at a clinic can optimize treatment and detect deterioration to trigger timely intervention. Current methods involve the use of a heart catheter and probes placed in large arteries. These methods are very invasive, and are typically only used for patients hospitalized for very severe heart problems. Due to their invasive nature and sensitive methods, current measurements of cardiac output need to be performed in specifically equipped hospitals using bulky equipment and require expert technicians, reading physicians, and insurance pre-approval.
[0004] Cardiac output can be measured from exhaled breath. The heart delivers blood with high CO.sub.2 to the lungs. The lungs then exchange CO.sub.2 in the blood for oxygen, and exhalation expels the CO.sub.2 from the lungs. Thus, cardiac output determines the amount of expelled CO.sub.2. Then, cardiac output can then be determined by analyzing the CO.sub.2 content of the exhaled breath. The currently accepted method for performing these measurements is the ‘inert gas rebreathing technique’. This method introduces inert blood-soluble gas to the inhaled air of the patient. The rate of change of inert gas concentration in exhaled breath is directly related to the cardiac output of the patient. Cardiac output rebreathing systems are normally used on intubated patients, and require matching of breath flow tubing to the patient lung anatomy. Rebreathing systems cannot be used continuously without risk of patient suffocation and require multiple breaths per measurement.
[0005] The high levels of humidity in exhaled breath can negatively impact measurements. Current methods for handling humidity in breath measurements include filtering, sampling, and trapping water in the breath flow. By design, all of these methods restrict the flow of exhaled breath and redirect it over large surface areas in order to reduce condensation. This negatively impacts measurements by smoothing out readings, reducing the effective response time of the sensor. Since CO.sub.2 levels vary rapidly over time during exhalation, these effects can be seriously detrimental to the quality of readings.
[0006] Thus, there remain unmet needs in the art for portable, non-invasive medical devices to measure cardiac output without utilizing rebreathing techniques that are usable in a variety of environments. More particularly, the art is deficient in ambulatory breath analyzers for measuring in real-time cardiac output resulting from each breath exhaled into the analyzer without

rebreathing. The present invention fulfills this longstanding need and desire in the art.

SUMMARY OF THE INVENTION

[0007] The present invention is directed to a device for analyzing breath exhalations in a subject. The device comprises a housing, a sensor rig disposed within the housing; and a computer operably connected to the sensor rig and comprising an algorithm configured to collect and process data and to display results. The present invention is directed to a related device where the housing further comprises a second filter in fluid connection with an outlet from the sensor rig.

[0008] The present invention is further directed to a method for measuring cardiac output in a subject. In this method, a breath is exhaled by the subject through a mouthpiece and first filter combination into the sensor rig in the device described herein. A concentration of carbon dioxide in the breath and volume of breath exhaled by the subject are measured via a CO.sub.2 meter and a flow meter disposed within a flow chamber within the sensor rig. The present invention is directed to a related method further comprising repeating the method steps at least once to monitor levels of cardiac output in the subject. The present invention is directed to another related method further comprising heating the flow chamber to prevent formation of condensation from the breath exhaled therein.

[0009] The present invention is directed further to a tool to monitor cardiac output in real-time in a patient in need thereof. The device has a portable, handheld breath analyzer that comprises a housing with a hand grip attached to an exterior bottom surface thereof and a mouthpiece and particle filter subassembly attached in fluid connection to an exterior front surface thereof. A flow chamber-CO.sub.2 meter subassembly is disposed within the housing and is in fluid connection with the particle filter and comprises opposing baffles disposed within the flow chamber and a resistive heater band disposed on an exterior surface thereof where the CO.sub.2 meter is inserted into the flow chamber to contact the opposing baffles. A flow meter is disposed in fluid connection with the CO.sub.2 meter and a computer is in electronic connection with the CO.sub.2 meter and the flow meter, where the computer is configured to process measurements received as input data therefrom via an algorithm. A related tool further comprises another particle filter disposed on a back surface of the housing and in fluid connection with the flow meter.

[0010] The present invention is directed further still to a method for monitoring cardiac output in real time in a patient in need thereof. In this method, the breath analyzer described herein is handheld by the patient and a breath is exhaled into the mouthpiece and particle filter subassembly, where the breath flows into the flow chamber-CO.sub.2 meter subassembly. A carbon dioxide concentration in the breath is measured as it flows through the CO.sub.2 meter and the volume of the breath is measured as it flows into the flow meter. The measured carbon dioxide concentration and the volume of the exhaled breath are input into the algorithm and the measured carbon dioxide concentration and volume of exhaled breath are processed as cardiac output data. The cardiac output data is output to a display. The method steps are repeated at least once over a period of time, thereby monitoring the cardiac output of the patient.

[0011] Other and further aspects, features, and advantages of the present invention will be apparent from the following description of the presently preferred embodiments of the invention. These embodiments are given for the purpose of disclosure.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] So that the matter in which the above-recited features, advantages and objects of the invention, as well as others which will become clear, are attained and can be understood in detail, more particular descriptions of the invention briefly summarized above may be had by reference to certain embodiments thereof which are illustrated in the appended drawings. These drawings form

a part of the specification. It is to be noted, however, that the appended drawings illustrate preferred embodiments of the invention and therefore are not to be considered limiting in their scope.

[0013] FIGS. **1**A-**1**D are perspective views of the assembled breath analyzer.

[0014] FIG. **2** illustrates the components of the breath analyzer.

[0015] FIGS. **3**A-**3**C illustrate the assembly of the mouthpiece-first filter sub-assembly (FIGS. **3**A-**3**B) and of securing the optional second filter to the flow meter (FIG. **3**C).

[0016] FIG. **4** illustrates the assembly of the resistive heater sub-assembly.

[0017] FIGS. **5**A-**5**C illustrates the assembly of the flow chamber (FC)-CO.sub.2 meter subassembly (FIGS. **5**B-**5**C) and the orientation of the CO.sub.2 meter to the baffles within the flow chamber (FIG. **5**C).

[0018] FIG. **6** illustrates the placement and securement of the flow meter within the case base.

[0019] FIG. **7** illustrates how the hand grip is secured to the case base.

[0020] FIG. **8** shows an example of the universal interface during measurement of cardiac output.

[0021] FIG. **9** is a flowchart of the algorithm used in the breath analyzer to determine cardiac output.

[0022] FIG. **10** is a plot of the regression line derived from equation 6 compared to known partial pressures of CO.sub.2 in mixed venous and arterial blood obtained over the course of exercise (3). Polynomial fit is degree 3 where R{circumflex over ( )}2=0.9959.

[0023] FIG. **11** compares cardiac output comparisons with echocardiogram measurements.

[0024] FIG. **12** compares difference vs. cardiac output average in a Bland-Altman analysis of cardiac output.

[0025] FIG. **13** compares Cardiac Index (CI) measurements from echocardiogram measurements and from breath. r=0.8239, R{circumflex over ( )}2=0.6787, and p<0.0001.

[0026] FIG. **14** compares difference vs. average in a Bland-Altman analysis of cardiac index.

[0027] FIGS. **15**A-**15**C shows breath analyzer measurements (n=10) post exercise over time for flow rate (FIG. **15**A), CO2 concentration percent (FIG. **15**B) and cardiac output (FIG. **15**C).

[0028] FIGS. **16**A-**16**C shows the results of calibration testing of the breath analyzer calculated cardiac output vs. an echocardiogram reference. FIG. **16**A is a linear transform when the breath analyzer is uncalibrated (FIG. **16**A). FIG. **16**B is a two-point calibration per subject for all breaths of the breath analyzer. FIG. **16**C is a one-point calibration per subject for all breaths of the breath analyzer.

DETAILED DESCRIPTION OF THE INVENTION

[0029] As used herein, the articles “a” and “an” when used in conjunction with the term “comprising” in the claims and/or the specification, may refer to “one”, but it is also consistent with the meaning of “one or more”, “at least one”, and “one or more than one”. Some embodiments of the invention may consist of or consist essentially of one or more elements, components, method steps, and/or methods of the invention. It is contemplated that any composition, component or method described herein can be implemented with respect to any other composition, component or method described herein.

[0030] As used herein, the term “or” in the claims refers to “and/or” unless explicitly indicated to refer to alternatives only or the alternatives are mutually exclusive, although the disclosure supports a definition that refers to only alternatives and “and/or”.

[0031] As used herein “another” or “other” may mean at least a second or more of the same or different claim element or components thereof.

[0032] As used herein, the terms “comprise” and “comprising” are used in the inclusive, open sense, meaning that additional elements may be included.

[0033] As used herein, the terms “consist of” and “consisting of” are used in the exclusive, closed sense, meaning that additional elements may not be included.

[0034] As used herein, the term “about” refers to a numeric value, including, for example, whole numbers, fractions, and percentages, whether or not explicitly indicated. The term “about”

generally refers to a range of numerical values (e.g., ±5-10% of the recited value) that one of ordinary skill in the art would consider equivalent to the recited value (e.g., having the same function or result). In some instances, the term “about” may include numerical values that are rounded to the nearest significant figure.

[0035] As used herein, the ordinal adjectives “first” and “second”, unless otherwise specified, are used to describe a common object and merely indicate that different instances of like objects are being referred to, and are not intended to imply that the objects so described must be in a given sequence, either temporally, spatially, in ranking, or in any other manner.

[0036] As used herein, the terms “ambulatory breath analyzer for measuring cardiac output” or “ABAMCO” and “breath analyzer” are used interchangeably and refer to the device presented herein.

[0037] As used herein, the terms “subject” and “patient” are used interchangeably and refer to an adult human of any age.

[0038] In one embodiment of the present invention, there is provided a device for analyzing breath exhalations in a subject, comprising a housing; a sensor rig disposed within the housing; and a computer operably connected to the sensor rig and comprising an algorithm configured to collect and process data and to display results.

[0039] In an aspect of this embodiment, the housing may comprise a hand grip attached to a bottom surface of the housing; and a mouthpiece and a first filter combination in fluid connection, where the first filter is in fluid connection with an inlet to the sensor rig. Further to this aspect, the housing may comprise a second filter in fluid connection with an outlet from the sensor rig. In both aspects of this embodiment the mouthpiece may be disposable.

[0040] In another aspect of this embodiment, the sensor rig may comprise a flow chamber in fluid communication with the mouthpiece and a first filter combination; a CO.sub.2 meter inserted within the flow chamber and in fluid communication therewith; and a flow meter attached to the flow chamber in fluid communication with the CO.sub.2 meter and configured to measure flow rate of breath through the flow chamber; where the flow meter comprises a display configured to receive processed data. In this aspect, the flow chamber may comprise a heated band disposed exteriorly on a surface of the flow chamber; and a pair of baffles disposed within the flow chamber. Particularly in this aspect, the CO.sub.2 meter is inserted upside down into and perpendicular to the flow chamber to rest on the set of baffles. In this aspect the CO.sub.2 meter may comprise non-dispersive infrared sensors.

[0041] In another embodiment of this invention, there is provided a method for measuring cardiac output in a subject, comprising exhaling a breath by the subject through a mouthpiece and first filter combination into the sensor rig in the device as described supra; and measuring a concentration of carbon dioxide in the breath and volume of breath exhaled by the subject via a CO.sub.2 meter and a flow meter disposed within a flow chamber within the sensor rig. Further to this embodiment, the method comprises repeating the method steps at least once to monitor levels of cardiac output in the subject. In both embodiments, the subject may be a healthy subject or a patient with a cardiac dysfunction.

[0042] In an aspect of both embodiments, the measuring step may comprise receiving the breath into the CO.sub.2 meter disposed within a flow chamber in the sensor rig; measuring a carbon dioxide concentration in the breath via the CO.sub.2 meter; measuring the volume of the breath via the flow meter in fluid communication with the flow chamber; inputting the measured carbon dioxide concentration and the volume of the exhaled breath into the algorithm; processing the measured carbon dioxide concentration and volume of exhaled breath as cardiac output data; and outputting the cardiac output data to a display. Further to this aspect, the method comprises heating the flow chamber to prevent formation of condensation from the breath exhaled therein.

[0043] In another aspect of both embodiments, the receiving step may comprise holding the device via a grip secured thereto; self-inserting the mouthpiece into the mouth of the subject; and exhaling

the breath into the mouthpiece and first filter combination thereby flowing into the flow chamber.
[0044] In yet another embodiment of the present invention, there is provided a tool to monitor cardiac output in real-time in a patient in need thereof, comprising a portable, handheld breath analyzer, comprising a housing with a hand grip attached to an exterior bottom surface thereof and a mouthpiece and particle filter subassembly attached in fluid connection to an exterior front surface thereof; a flow chamber-CO.sub.2 meter subassembly disposed within the housing and in fluid connection with the particle filter and comprising opposing baffles disposed within the flow chamber and a resistive heater band disposed on an exterior surface thereof, said CO.sub.2 meter inserted into the flow chamber to contact the opposing baffles; a flow meter disposed in fluid connection with the CO.sub.2 meter; and a computer in electronic connection with the CO.sub.2 meter and the flow meter, where the computer is configured to process measurements received as input data therefrom via an algorithm.
[0045] Further to this embodiment, the tool comprises another particle filter disposed on a back surface of the housing and in fluid connection with the flow meter. In both embodiments, the CO.sub.2 meter may be inserted upside down into and perpendicular to the flow chamber. Also, in both embodiments, the CO.sub.2 meter may comprise non-dispersive infrared sensors.
[0046] In yet another embodiment of the present invention, there is provided a method for monitoring cardiac output in real time in a patient in need thereof, comprising handholding the breath analyzer as described supra by the patient and exhaling a breath into the mouthpiece and particle filter subassembly, said breath flowing into the flow chamber-CO.sub.2 meter subassembly; measuring a carbon dioxide concentration in the breath as it flows through the CO.sub.2 meter; measuring the volume of the breath as it flows into the flow meter; inputting the measured carbon dioxide concentration and the volume of the exhaled breath into the algorithm; processing the measured carbon dioxide concentration and volume of exhaled breath as cardiac output data; outputting the cardiac output data to a display; and repeating the method steps at least once over a period of time, thereby monitoring the cardiac output of the patient. In this embodiment, the patient may have a cardiac dysfunction.
[0047] Provided herein is a device, i.e., an Ambulatory Breath Analyzer for Measuring Cardiac Output (ABAMCO), utilized to determine cardiac output from carbon dioxide (CO.sub.2) and volume of exhaled breath in a non-invasive manner. The subject or patient exhales into a portable handheld device. The device has a unique combination of an air mixing baffle, optical CO.sub.2 quantification, pathway heating to prevent condensation, flow rate metering, and an algorithm to measure cardiac output in real time via a novel CO.sub.2-Modified Fick equation. This device solves problems of condensing moisture, the need for measuring multiple gases, the need for measuring both inhalation/exhalation gases, rebreathing induced false dilutions, and immobile instrumentation.
[0048] Particularly, the device measures cardiac output, and the changes in cardiac output over time. The use of breath in order to analyze cardiac output enables collection of heart data in a manner that is simple, comfortable, and harmless to the patient. This information may be read immediately by an operator to make use of the valuable heart metrics.
[0049] Moreover, the device is portable and handheld, except for the operating computer, and when using a laptop may be operated exclusively on a dc battery supply. The light weight, small size, and flexibility in power source allow for extreme flexibility in the use environment. Further, the elimination of bulky humidity compensation techniques in favor of the special resistive heater makes the system smaller and even more lightweight.
[0050] Furthermore, a CO.sub.2 meter containing at least one CO.sub.2 sensor is mounted in a flow chamber with a novel resistive heater band thereon. This enables collection of CO.sub.2 data directly from the main flow of breath while eliminating the need for extra humidity compensation methods. The resistive heater uses heat to mitigate the negative effects of condensation without the detrimental effects of measures such as filtering or pump sampling of the breath would introduce to

the sensor readings. This enables accurate real-time measurement of the CO.sub.2 concentration of breath to produce good quality cardiac output measurements.

[0051] Also provided are methods for measuring and monitoring cardiac output in a subject. The breath analyzer may be used in a clinic or at home by healthy subjects or patients with, for example, heart failure or other cardiovascular conditions or cardiac dysfunction. In non-limiting examples, the breath analyzer is a tool to detect and diagnose cardiac dysfunction, to guide heart failure treatment, and guide enhancement of sport or athletic performance. One of ordinary skill in the, for example, a cardiologist or sports medicine physician, is well-able to determine a usage regimen for the subject or patient depending on the age, health and/or prognosis thereof and whether or not measurements should be taken in a clinic setting or taken in-home.

[0052] The present embodiments are best described by reference to those figures illustrating the same, but are not meant to limit the present invention in any fashion.

[0053] FIGS. **1**A-**1**D show respective a perspective front, top and right side view, a front view, a right side view, and a bottom view of the fully assembled breath analyzer **1**. The perspective view of FIG. **1**A shows the housing **2** which is formed from the case lid **2***a* and the case base **2***b* which are secured together via 3 mm screw holes **2***c,d* on the case lid. The case lid has an opening **2***e* into the interior of the housing through which a display may be viewed (see FIG. **2**). A hand grip or case handle **3** is attached to the bottom surface of the case base. A mouthpiece **4** is connected to a first filter **5** in combination or as a sub-assembly **7** which is attached at **5***a* to the front surface of the housing and in fluid connection with the interior of the housing (see FIG. **3**A). A second filter **6** is attached at **6***a* to the back surface of the housing and in fluid connection with the interior of the housing (see FIG. **3**C).

[0054] With continued reference to FIG. **1**A, FIG. **2** shows the exterior and interior components of the breath analyzer **1**. The interior of the case lid **2***a* or top portion of the housing **2** shows the position of the screw holes **2***c,d* through which the screws (not shown) threadably engage the corresponding screw-type mounting holes **2***f,g* shown on the interior of the case base **2***b*. The case base also has screw-type mounting holes for the hand grip **3**, the flow meter **13** and the heater control circuit **16**. The case lid and case base when fastened together comprise the housing **2** which may be made out of a plastic to be lightweight and portable. The housing prevents the patient or other subject from touching any of the components and electronics contained therein.

[0055] The hand grip **3** is a handle secured to the housing via the opening and screw-type mounting holes, as described. The handle is held by the patient during measurements and supports the sensor rig **8** contained within the housing and comprising the components therein. The hand grip is hollow through which cables **9***a,b,c* are routed for convenience. The cables are connected to the computer and to a power source. Two USB cables **9***a,b* are for electronic communication and power delivery between the operating computer **20** and the CO.sub.2 meter **10** and the flow meter **13**. A third cable **9***c* carries power from an external supply or battery to the heater control circuit **16**.

[0056] The mouthpiece **4** is disposable and may be a spirometry mouthpiece. The disposable mouthpiece is placed in the mouth of the patient or other subject who breathes through the mouthpiece for the duration of the measurement. It is discarded between patients. The mouthpiece is fluidly connected to the first filter or breath particle filter **5** which in combination forms a sub-assembly **7**. The breath particle filter is disposable and is discarded between patients. The disposable breath particle filter keeps particles in the patient's breath from contaminating the device or damaging the CO.sub.2 sensors contained within the CO.sub.2 meter **10**. A second filter or second breath particle filter **6** is a disposable intake filter that may be optionally used in dusty environments. The second filter is the same type as the first filter and is attached to the tubing connection on the flow meter **13**.

[0057] A CO.sub.2 meter **10** is a component of the sensor rig **8** and is mounted up-side down within the flow chamber **12** (see FIG. **5**B). The CO.sub.2 meter uses at least one non-dispersive infrared (NDIR) CO.sub.2 sensor that measures how much light from a 4.25 micron laser is

absorbed by the gas from the breath passing through the meter to determine the relative concentration of CO.sub.2 in that gas. The CO.sub.2 meter reports these measurements electronically via the USB cables **9***a* to the operating computer. The operating computer sends the sensor power and commands to the CO.sub.2 meter. The CO.sub.2 meter is inserted into the interior of the flow chamber **12**.

[0058] The flow chamber **12** is a specially constructed gas distributor which connects the CO.sub.2 meter **10** and the flow meter **13** to patient breath collected from the mouthpiece **4**. This gas distributor is heated to prevent condensation on interior surfaces and has a set of opposing baffles **14***a,b* (see FIG. **5**C) which increase measurement speed and reliability through introduction of turbulence, and optimized flow geometry.

[0059] The flow meter **13** measures the volumetric flow rate of breath as it passes through the sensor rig **8** and has a display **13***a* to receive data viewable by the subject through opening **2***e*. The flow meter reports these measurements electronically via the cable **9***b* to the operating computer **20**. The operating computer sends the sensor power and commands to the flow meter via the same cables. The flow meter is attached to a tubing connection **30** (see FIG. **5**C) on the flow chamber **12**. The end of the flow meter farthest from the patient is left open to fresh air or connected to the disposable second breath particle filter **6**.

[0060] A resistive heater band **15** is an electronic resistive heater treated with an adhesive and applied to the flat surface **12***b* (see FIG. **5**C) of the flow chamber **12**. The resistive heater is used to heat the internal surfaces above the normal human body temperature and is controlled by the heater control circuit **16**.

[0061] A heater control circuit **16** is a circuit which controls delivery of power to a resistive heater band **15** to maintain a consistent temperature above human body temperature. The heater control uses a simple thermistor and comparator circuit and relay for power delivery. The heater control circuit is connected to the heated band by four small cables routed through the interior of the device. The heater is mounted to the case base **2***b* using screws. A cable **9***c* delivers power to the heater control circuit and for delivery to the heater.

[0062] The breath analyzer is operably linked to the operating computer **20**. The operating computer may be a standard laptop computer, such as, but not limited to, a DELL INSPIRON 3593, product of Dell Inc.) which is used to operate a program or algorithm or software which controls the meters, calculates the cardiac output from meter readings, and stores the measurements for review.

[0063] With continued reference to FIG. **1**A and FIG. **2**, FIGS. **3**A-**3**C illustrate the assemblies of the mouthpiece-first filter combination and the second filter to the breath analyzer. FIG. **3**A shows the assembly of the mouthpiece **4** and first filter **5** sub-assembly **7**. The sub-assembly is made of disposable parts and is discarded between each patient. The sub-assembly is press fit to a 22 mm ID male tubing connector **28** (see FIG. **5**C) on the flow chamber which is accessible through the inlet hole **5***a* in the housing **2**. FIG. **3**B shows the assembly of the components of the mouthpiece-filter sub-assembly **7**. The disposable mouthpiece **4** is press-fit to the high-flow breath particle filter **5** at **18**. FIG. **3**C shows the attachment of the optional second filter **6** to the flow meter via a press fit 15 mm connection to the flow meter male outlet **26***b* (see FIG. **6**) through outlet hole **6***a* in the housing **2**. Both the first filter and the second filter are standard high-flow ventilator filters.

[0064] With continued reference to FIG. **2**, FIG. **4** shows the assembly of the heater sub-assembly **21**. The heater sub-assembly has the resistive heater band **15** with a Thorlabs HT10k resistive heater. The heated band is applied to the surface of the flow chamber **12** using an adhesive. Four cables, represented by **22**, carry the heater power and thermistor voltage between the heater and heater control circuit which operates the heater. The heater control circuit comprises a circuit board **23**. A power cable **24** connects the control circuit to a 12v DC power source.

[0065] With continued reference to FIG. **2**, FIGS. **5**A-**5**C shows the assembly of the flow chamber (FC)-CO.sub.2 meter subassembly or CO.sub.2 adapter tube. FIG. **5**A shows that the FC-CO.sub.2

subassembly **25** is attached by rocking the flow chamber **12** into the inlet hole in the housing at **5***a*, then sliding the flow chamber over the flow meter inlet male connector at **26***a*. A USB cable **27** carries sensor information from the CO.sub.2 meter **10** to the operating computer **20**. The operating computer sends power and commands to the device using this same cable. FIG. **5**B is an exploded view of the FC-CO.sub.2 subassembly. The CO.sub.2 meter is a SPRINT-IR **6***s* CO.sub.2 meter with a GSS NDIR gas sensing cavity. The USB cable has been excluded for clarity. The CO.sub.2 meter is inserted upside down into the flow chamber at **12***a* perpendicular to the breath flow and rests on the opposing baffles **14***a,b* of the flow chamber. Because the breath flow comprises extremely humid air, the upside down position ensures that water droplets are pulled away from the CO.sub.2 meter by gravity. FIG. **5**C is a cross-section of the flow chamber showing the opposing baffles disposed within. Two baffles introduce turbulence into breath flow for faster measurements. These baffles are thin and offer low resistance to breath. Also shown are the male **28** and female **29** 22 mm ID tubing connections for connection to the first filter **5** and to the flow meter **12**, respectively, and the surface **12***b* for mounting the resistive heater band.

[0066] With continued reference to FIG. **2**, FIG. **6** shows the assembly of the flow meter in the housing. The flow meter **13** is a TSI 5300 flow meter and is fastened to the case base **2***b* using three 3 mm screws **31***a,b,c*. The flow meter outlet male connector **26***b* is inserted into the outlet hole **6***a* on the case base, then rocked into place. A USB cable **9***b* carries sensor information to the operating computer **20**. The operating computer sends power and commands to the device using this same cable. When assembled the USB cable extends into and through the hollow hand grip **3** to the operating computer.

[0067] With continued reference to FIG. **2**, FIG. **7** shows how the case handle or hand grip **3** is attached to the case base **2***b*. The hollow hand grip has a first flange **3***a* and a second flange **3***b* extending outwardly from the opening at the top of the hand grip and substantially perpendicularly to the hand grip. The second flange has screw holes **3***d,e*. An opening **2***g* is formed in the case base such that the top opening in the hand grip aligns with the opening in the case base when the first flange hooks onto the edge thereof. The screw holes are threadably aligned to fasten the hand grip to the case base at **3***f,g*. This enables cables **9***a,b,c* to extend through the hand grip to the operating computer and to the heater control circuit.

[0068] FIG. **8** is a screenshot showing the universal interface (UI) for the operating program.

[0069] FIG. **9** is a flowchart of the computer analysis of exhalatory breath detected by the CO.sub.2 meter. During breath measurement the CO.sub.2 meter cycles at 20 Hz at **100** and the meter reading is sent in the format X=0040000 ppm at **103**. The query Is the Triggering flag set? is made at **105**. If the answer is YES, the query Is x above the trigger level? is made at **110**. If the answer is NO, the Trigger flag is set to FALSE at **111**, the most recent current breath measurement for VCO.sub.2/BV is saved at **112**, the current breath time list and the integrated sum is reset at **113**, and VE/VCO2=0 is returned at **114**. A linear fit is applied to VCO.sub.2/BV averages to convert to cardiac output at **130** and the system waits for a meter reading at **135**, then proceeds to **103**.

[0070] If the query at **110** is YES, the algorithm proceeds to **117***a* which occurs when the answer to step **105** is NO or default and the answer to the query Is x above the trigger level? is YES at **115**. In this instance, the Trigger flag is set to TRUE at **116**. This is followed by step **117***a* during which the current timestamp is added to the time List for all breaths and the current timestamp is added to the timeList for the current breath at **117***b*. Then at step **118** the ppm are converted to decimal form by dividing by 1000000 to convert from 040000 to 0.04. At step **119***a* x*5 ms is added to the sum variable to units of PPMs followed by dividing the sum by the total time to get the time-weighted average ppm for ALL breaths at **120***a*. At step **119***b* the sum is divided by the total time for the most recent breath to get average ppm for one breath followed by updating the Display for current breath VCO.sub.2/BV at **120***b*. Both **120***a* and **120***b* are followed by step **121** where the algorithm proceeds to RETURN VCO2/BV average. The algorithm then proceeds back to step **130**. If the query at **115** is NO, the algorithm proceeds to step **125** to RETURN VCO.sub.2/BV=0. The

algorithm then proceeds back to step **130**.

[0071] The following examples are given for the purpose of illustrating various embodiments of the invention and are not meant to limit the present invention in any fashion.

Example 1

Materials and Method

Ambulatory Breath Analyzer

[0072] The device uses [CO.sub.2] and volume of exhaled breath as input and has a heated breath flow path with baffles to account for the high humidity in breath. Exhaled flow rate of CO is measured, then divided by the difference between venous and arterial [CO.sub.2]. The difference is calculated from exhaled CO.sub.2 input to a formula derived in Example 2. Custom software then calculates cardiac output in real time. The exterior and interior components of the device are well-described in the figures.

Computer

[0073] The operating software is built in Python. The computer runs an operating program or algorithm which delivers commands to and controls the CO.sub.2 meter and the flow meter and collects data generated during cardiac output measurements. Collected data is quickly received as input and processed by the algorithm in real time and displayed to the user in a human-readable format (Live plots and regularly updating averages). Collected and calculated values also are organized and saved by the program. The operating program is configured to perform functions such as, but not limited to, the integration of flow readings into volume measurements, calculation of various metrics, i.e., VE, VE/VCO.sub.2, % CO.sub.2, display, and storage. The program may be operated on a standard laptop computer or a standard desktop computer or other smart or electronic device as are known in the art. The operating program uses a universal interface (UI) with intuitive plots and readouts for the operator. Latency is made as short as possible, so the operator is able to view real-time plots of readings and calculations.

General Method

[0074] A subject or adult patient places the mouthpiece into his mouth and exhales into it. The breath is filtered to remove particles and enters the flow chamber where exhaled flow rate of CO.sub.2 is measured, then divided by the difference between venous and arterial [CO.sub.2]. The difference is calculated from exhaled CO.sub.2 input by the novel CO.sub.2-Modified Fick equation (Example 2). Custom software then calculates cardiac output in real time. Cardiac output is measured at rest and after a set pace treadmill jogging for healthy subjects. Cardiac output of patients with heart failure or other cardiac dysfunction is measured only at rest.

Example 2

Calculating Cardiac Output

CO.SUB.2.-Modified Fick Equation

[0075] The CO.sub.2-Modified Fick equation is the Fick Equation for Cardiac Output using carbon dioxide instead of oxygen as the marker. Equations 1 and 2 are as follows:

[00001] $$Q_{ECO2} = (Q_{CO} \times C_{VCO2}) - (Q_{CO} \times C_{ACO2}) \quad \text{Eq. 1} \qquad Q_{CO} = \frac{Q_{ECO2}}{(C_{VCO2} - C_{ACO2})} \quad \text{Eq. 2}$$

TABLE-US-00001 Equation Legend Symbol Units Meaning Q.sub.ECO2 Liters/min Flow rate of exhaled CO.sub.2 Q.sub.CO Liters/min Flow rate of blood through the heart (cardiac output) Q.sub.VCO2 Unitless (0-1) Concentration of CO.sub.2 in the mixed venous blood Q.sub.ACO2 Unitless (0-1) Concentration of CO.sub.2 in the arterial blood

Input Values:

[0076] There are only two inputs required for this calculation: concentration of CO.sub.2 in exhaled breath, and the flow rate of exhaled breath. Averages may be used, but real-time measurements are ideal.

[0077] The conduct of the measurement subject has a large effect on these measurements. Body position, respiration rate, exercise state, and many other small factors can modulate the cardiac

output and strongly influence the quality of measurements. All measurements should be: [0078] i. Stationary. Subjects should remain still in a sitting or prone position without moving during the measurement. [0079] ii. Consistent. Subjects should breathe in a consistent and repeatable manner for measurements. Some preliminary testing indicated that a controlled rate of 4 seconds inhalation and 4 seconds exhalation were optimal. [0080] iii. Repeated. Subjects should take many breaths in one measurement. 10 breaths is the typical number, but anything from 5-20 is adequate. [0081] iv. Exclude the first measurement. Notably, the first breath in nearly every measurement has an artificially high CO.sub.2 and is normally discarded.

Volumetric Flow Rate of Exhaled Breath

[0082] Equation 3 is as follows:

[00002] $$Q_{\mathrm{ECO2}} = V_E \times C_{\mathrm{ECO2}} \quad \mathrm{Eq.3}$$

TABLE-US-00002 Equation Legend Symbol Units Meaning Q.sub.ECO2 Liters/min Flow rate of exhaled CO.sub.2 Q.sub.E Liters/min Flow rate of exhaled breath C.sub.ECO2 Unitless (0-1) Concentration of CO.sub.2 in the exhaled breath

[0083] The numerator of the CO.sub.2 modified Fick Equation may be represented by equation 3 above. This quantity is measured directly. The product of the measured CO.sub.2 concentration and flow rate of exhaled breath provides this measure. The units for this measurement are carried to the final result, as the denominator of the CO.sub.2 modified Fick equation is unitless.

Converting the Exhaled Concentration of CO.sub.2 to Partial Pressure of CO.sub.2 in the Mixed Venous Blood

[0084] Equations 4 and 5 are as follows:

[00003] $$P_{\mathrm{VCO2}} = C_{\mathrm{ECO2}} \times (760e^{-\frac{mgh}{RT}} - P_{H2O}) + 33 \quad \mathrm{Eq.4}$$

$$P_{H2O} = 7.50062 \times 0.61121e^{(18.678 - \frac{T}{234.5}) \times (\frac{T}{257.14+T})} \quad \mathrm{Eq.5}$$

TABLE-US-00003 Equation Legend Symbol Units Meaning P.sub.VCO2 Torr Partial pressure of CO.sub.2 in mixed venous blood C.sub.ECO2 Unitless (0-1) Concentration of CO.sub.2 in exhaled breath 760 Torr Conversion factor from atm to Torr at STP m Kg/mol Molar mass of air g m/s.sup.2 Gravitational acceleration constant h m Altitude of concentration measurement R (N*m)/(mol*k) Universal gas constant T k Standard atmospheric temperature at altitude of concentration measurement P.sub.H2O Torr Partial pressure contribution of water vapor 30 Torr Constant offset between exhaled partial pressure of CO.sub.2 and venous partial pressure of CO.sub.2

[0085] The denominator of the CO.sub.2-modified Fick equation is derived exclusively from measurements of exhaled concentration of CO.sub.2. It is more convenient to first convert from a measurement of CO.sub.2 concentration to a measurement of partial pressure of CO.sub.2 in the exhaled breath for the following steps, so this is performed first.

[0086] At atmospheric pressure, the partial pressure of CO.sub.2 would be equal to the product of CO.sub.2 concentration and the atmospheric pressure adjusted for elevation. The simple version of the barometric formula is used to correct this calculation for altitude differences from sea level. The pressure is approximated at measurement and in the alveoli to be local atmospheric pressure over the duration of the breath.

[0087] The barometric formula is for dry gas, but the error at low altitudes is very small. A much larger contribution to the partial pressure is the vapor pressure of the water in exhaled breath. The relative humidity of water in exhaled breath is normally near 100 percent. The contribution of vapor pressure in exhaled breath to the total partial pressure can be taken as the vapor pressure of water at body temperature. The Buck Equation (2) given in equation 5 is used to calculate this pressure calculation, resulting in a constant contribution of 47.1 Torr.

[0088] Lastly, the partial pressure of CO.sub.2 in exhaled breath is related to the partial pressure of CO.sub.2 in the mixed venous blood. Table 1 compares the average partial pressure of CO.sub.2 in

exhaled breath to the average partial pressure of CO.sub.2 in the mixed venous blood sample by Sun (3) over the course of exercise in healthy volunteer subjects. Comparing our rest values to their values of exercise after a short warmup and 5 minutes of exercise, it is clear that there is a constant offset of approximately 33 Torr for both exercise states. This term is added in equation 4 to reach the partial pressure of CO.sub.2 in venous blood, as measured from exhaled CO.sub.2.

TABLE-US-00004 TABLE 1 Exercise State Source Average Std. Deviation R Sun 46.8 2.6 Us 13.4388 3.7124 E Sun 50.7 2.8 Us 17.4721 3.8285

Calculating the Difference Between Partial Pressure of CO.SUB.2 .in the Mixed Venous Blood and Arterial Blood

[0089] Equation 6 is as follows:

[00004] $$P_{V\text{-}ACO2} = 0.0034 \times (0.4158 \times (P_{VCO2} - 33))^3 + (0.4158 \times (P_{VCO2} - 33)) \quad \text{Eq. 6}$$

TABLE-US-00005 Equation Legend Symbol Units Meaning ΔP.sub.V-A CO2 Torr Difference between partial pressure of mixed venous and arterial blood P.sub.VCO2 Torr Partial pressure of CO2 in mixed venous blood 0.0034 Unitless 3rd order scaling constant −33 Unitless X intercept scaling constant 0.4158 Unitless 1st order scaling constant

[0090] Equation 6 represents a critical step. This equation relates the difference in mixed venous and arterial blood partial pressures of CO.sub.2 to the measured partial pressure of mixed venous CO.sub.2. This equation was obtained by regression of the data presented in Sun et al. (3) and shown in FIG. **10**A. The resulting regression curve is shown in FIG. **10**B.

[0091] The construction of this equation for regression utilized the following logic:

[0092] The equation should be odd. Low CO.sub.2 concentrations in the mixed venous blood should not result in an increase in CO.sub.2 diffusion. This is especially true for values below the ‘zero point’ of approximately 33 Torr, which should be the minimum pressure necessary to diffuse CO.sub.2 as implied by the offset of 33 Torr above.

[0093] The equation should be non-linear. A third power equation is the minimum which could describe this relationship while still adhering to the previous principle.

[0094] The inflection point should occur at the ‘zero point’ where CO.sub.2 in the blood would be perfectly matched between the mixed-venous and arterial blood.

[0095] R for the resulting regression was 0.9980 with an R.sup.2 of 0.9960, indicating a high quality of fit.

Converting the Partial Pressure of CO.sub.2 in into Concentrations of CO.sub.2 in the Blood

[0096] Equation 7 is as follows:

[00005] $$C_{XCO2} = \frac{462 \times e^{0.00415 \times P_{XCO2}} - 340 \times e^{-0.0445 \times P_{XCO2}} + (97.5 - S_{XO2})}{1000} \quad \text{Eq. 7}$$

TABLE-US-00006 Equation Legend Symbol Units Meaning C.sub.ECO2 Unitless (0-1) Concentration of CO2 in X, where X is either the mixed venous or arterial blood 462 Unitless Scaling Constant from Regression 0I00415 Unitless Scaling Constant from Regression P.sub.ECO2 Torr Partial pressure of CO2 in x, where x is either the mixed venous or arterial blood 340 Unitless Scaling Constant from Regression −0.0445 Unitless Scaling Constant from Regression 07.5 % Scaling Constant from Regression Sx.sub.O2 % Anticipated % CO2 saturation in x, where x is either the mixed venous or arterial blood 1000 Unitless Scaling Constant from Regression

[0097] The denominator of the CO.sub.2-Modified Fick Equation requires a difference of concentration instead of a difference in partial pressures. To facilitate this, the CO.sub.2 disassociation curve was utilized. Equation 7 shows an empirical regression on the CO.sub.2 Disassociation curve, fully detailed in Meade (4). This curve is convenient for algorithmic implementation. The arterial oxygenation saturation is estimated at 97.2%, and the venous oxygenation saturation is estimated at 71.1. %. These values are based on the O2 saturation values given by Sun et al. (3).

[0098] Concentrations of CO.sub.2 can then be calculated in both the mixed-venous and arterial blood. The difference of these values then provides the denominator value necessary for final

calculation of cardiac output.

Example 3

Results with CO2-Modified Fick Equation

Cardiac Output Correlation

[0099] These methods were tested on 11 healthy patients, both at rest and after a five minute treadmill exercise. Comparisons were made to cardiac output derived from echocardiogram measurements. The overall correlation was extremely good, with very low scaling error. There was some offset, as breath measurements consistently over-estimated both cardiac output and cardiac index by a small amount.

[0100] Cardiac output comparisons with echocardiogram measurements resulted in an excellent correlation of R=0.8344, R{circumflex over ( )}2=0.6962, and p<0.0001 from n=21 (FIG. **11**). One measurement was excluded as an extreme outlier, >(75.sup.th percentile)+1.5*SD. Linear regression showed low scaling error, as the slope of the comparisons was 0.8516 with a 95% confidence interval of [0.5815,1.122]. This, combined with the correlation R{circumflex over ( )}2 indicates a lack of non-linear error between these devices. There is a constant offset error present, indicated by the y intercept value of 3.410. This would be simple to correct for with calibration.

Cardiac Output Bland-Altman

[0101] In FIG. **12** Bland-Altman analysis shows a bias of 2.364 with a 95% confidence interval of [−2.225,6.954]. There is, again, an indication of constant over-estimation of cardiac output by breath analysis. There do not appear to be any significant trends against the average measurement. Variance also appears constant across the measurement, providing further evidence that this fit is appropriate for the data.

Cardiac Index Correlation

[0102] Cardiac Index measurements also show good correlation with echocardiogram measurements with r=0.8239, R{circumflex over ( )}2=0.6787, and p<0.0001 (FIG. **13**). Linear regression shows a very low scaling error with slope of 0.9025 and 95% CI of [0.6044,1.201] indicating excellent agreement across all measured scales. There is little offset between the two devices, indicated by the low y intercept of 1.710 with 95% CI of [0.4171,3.003]. Cardiac Index was calculated as the cardiac output divided by the Mostellar BSA.

Cardiac Index Bland-Altman

[0103] Bland-Altman analysis of cardiac index shows a bias of 1.340 with a 95% confidence interval of [−1.298,3.977] (FIG. **14**). There is, again, an indication of constant over-estimation of CO by breath analysis. There do not appear to be any significant trends against the average measurement. Variance also appears constant across the measurement, providing further evidence that this fit is appropriate for the data.

Example 4

Results of Performance Testing of ABAMCO Device

[0104] Eleven healthy volunteer subjects were recruited. Reference echocardiogram estimates of cardiac output obtained from stroke volume x heart rate were taken for each. Subjects were measured standing at rest, then performed a controlled exercise regimen. Subjects were measured immediately post exercise for 10 breaths. FIGS. **15**A-**15**C show the results obtained over 100 sec. for flow rate, CO.sub.2 concentration (%) and cardiac output.

[0105] Calibration testing of the ABAMCO device was performed. Gain and offset parameters were used for the raw readings. One parameter was used to scale individual readings to the echocardiogram reference. Additional parameters for modeling the pulmonary arterial to pulmonary venous relationship were used. There are several calculation parameters that can be adjusted to population. ABAMCO calculated cardiac output vs. echocardiogram calculated cardiac output were plotted for uncalibrated ABAMCO, calibrated ABAMCO and rest calibrated ABAMCO (FIGS. **16**A-**16**C). Low cardiac output measurements exhibit lower variability than high

cardiac output measurements.

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Claims

1. A device for analyzing breath exhalations in a subject, comprising: a housing; a sensor rig disposed within the housing; and a computer operably connected to the sensor rig and comprising an algorithm configured to collect and process data and to display results.

2. The device of claim 1, wherein the housing comprises: a hand grip attached to a bottom surface of the housing; and a mouthpiece and a first filter combination in fluid connection, said first filter in fluid connection with an inlet to the sensor rig.

3. The device of claim 2, wherein the housing further comprises a second filter in fluid connection with an outlet from the sensor rig.

4. The device of claim 2, wherein the mouthpiece is disposable.

5. The device of claim 1, wherein the sensor rig comprises: a flow chamber in fluid communication with the mouthpiece and a first filter combination; a CO.sub.2 meter inserted within the flow chamber and in fluid communication therewith; and a flow meter attached to the flow chamber in fluid communication with the CO.sub.2 meter and configured to measure flow rate of breath through the flow chamber; said flow meter comprising a display configured to receive processed data.

6. The device of claim 5, wherein the flow chamber comprises: a heated band disposed exteriorly on a surface of the flow chamber; and a pair of baffles disposed within the flow chamber.

7. The device of claim 6, wherein the CO.sub.2 meter is inserted upside down into and perpendicular to the flow chamber to rest on the set of baffles.

8. The device of claim 5, wherein the CO.sub.2 meter comprises non-dispersive infrared sensors.

9. A method for measuring cardiac output in a subject, comprising: exhaling a breath by the subject through a mouthpiece and first filter combination into the sensor rig in the device of claim 1; and measuring a concentration of carbon dioxide in the breath and volume of breath exhaled by the subject via a CO.sub.2 meter and a flow meter disposed within a flow chamber within the sensor rig.

10. The method of claim 9, further comprising repeating the method steps at least once to monitor levels of cardiac output in the subject.

11. The method of claim 9, wherein the measuring step comprises: receiving the breath into the CO.sub.2 meter disposed within a flow chamber in the sensor rig; measuring a carbon dioxide concentration in the breath via the CO2 meter; measuring the volume of the breath via the flow meter in fluid communication with the flow chamber; inputting the measured carbon dioxide concentration and the volume of the exhaled breath into the algorithm; processing the measured carbon dioxide concentration and volume of exhaled breath as cardiac output data; and outputting the cardiac output data to a display.

12. The method of claim 11, further comprising heating the flow chamber to prevent formation of condensation from the breath exhaled therein.

13. The method of claim 11, wherein the receiving step comprises: holding the device via a grip secured thereto; self-inserting the mouthpiece into the mouth of the subject; and exhaling the breath into the mouthpiece and first filter combination thereby flowing into the flow chamber.

14. The method of claim 7, wherein the subject is a healthy subject or a patient with a cardiac dysfunction.

15. A tool to monitor cardiac output in real-time in a patient in need thereof, comprising: a portable, handheld breath analyzer, comprising: a housing with a hand grip attached to an exterior bottom surface thereof and a mouthpiece and particle filter subassembly attached in fluid connection to an exterior front surface thereof; a flow chamber-CO.sub.2 meter subassembly disposed within the housing and in fluid connection with the particle filter and comprising opposing baffles disposed within the flow chamber and a resistive heater band disposed on an exterior surface thereof, said CO.sub.2 meter inserted into the flow chamber to contact the opposing baffles; a flow meter disposed in fluid connection with the CO.sub.2 meter; and a computer in electronic connection with the CO.sub.2 meter and the flow meter, said computer configured to process measurements received as input data therefrom via an algorithm.

16. The tool of claim 15, further comprising another particle filter disposed on a back surface of the housing and in fluid connection with the flow meter.

17. The tool of claim 15, wherein the CO.sub.2 meter is inserted upside down into and perpendicular to the flow chamber.

18. The device of claim 15, wherein the CO.sub.2 meter comprises non-dispersive infrared sensors.

19. A method for monitoring cardiac output in real time in a patient in need thereof, comprising: handholding the breath analyzer of claim 15 by the patient and exhaling a breath into the mouthpiece and particle filter subassembly, said breath flowing into the flow chamber-CO.sub.2 meter subassembly; measuring a carbon dioxide concentration in the breath as it flows through the CO.sub.2 meter; measuring the volume of the breath as it flows into the flow meter; inputting the measured carbon dioxide concentration and the volume of the exhaled breath into the algorithm; processing the measured carbon dioxide concentration and volume of exhaled breath as cardiac output data; outputting the cardiac output data to a display; and repeating the method steps at least once over a period of time, thereby monitoring the cardiac output of the patient.

20. The method of claim 19, wherein the patient has a cardiac dysfunction.