

Sampling Device

FIELD OF THE INVENTION

[0001] The present invention provides for systems and methods for the collection of air breath samples.

BACKGROUND OF THE INVENTION

[0002] Any discussion of the background art throughout the specification should in no way be considered as an admission that such art is widely known or forms part of common general knowledge in the field.

[0003] Point-of-care (POC) and patient self-testing improve patient's healthcare decision-making by providing medical professionals with the necessary information for rapid decisions, enhancing healthcare quality and efficiency.

[0004] Biological samples analysis by portable devices plays a critical role in point-of-care and self-testing of disease diagnosis and health monitoring. However, conventional techniques have a lot of limitations. Blood analysis is reliable and able to provide real-time information, but the sampling methods (finger prick or arterial sampling) are painful and invasive. On the other hand, urine sampling is non-invasive, but the sampling process is messy, and the results may not be timely.

[0005] As a real-time, painless, and non-invasive alternative for sampling of biological molecules, there has been an increasing interest in the analysis of volatile organic compounds (VOCs) in exhaled breath, as biomarkers for a range of diseases including oesophageal and gastric cancer, colorectal cancer, lung cancer, breast cancer, liver disease, asthma, chronic obstructive pulmonary disease, and inflammatory bowel disease.

[0006] There exists photonic sensing technology for measuring acetone from exhaled breath, which can be used for monitoring of diabetic ketoacidosis (DKA), and management of ketosis for health cautious applications. Despite the intrinsic advantages and promising potential applications of breath testing, it remains an underexploited diagnostic tool in real practice.

[0007] It is believed that the major hurdle of VOCs measurement from exhaled breath is the lack of standardisation of breath sampling.

[0008] Fig. 1 shows a typical gas exchange diagram 1 tracing concentration of CO₂ as the reference gas, i.e., capnography. The gas exchange from exhaled breath can be divided into 3 phases 2-4. In phase I (2) the exhaled breath is from dead spaces (e.g., mouth, trachea, and bronchi) where gas exchange does not take place, thus the concentration of measured gas is at a baseline. In phase III (4) the exhaled breath is from alveoli is the sites of gas exchange, which results in the highest concentration of the targeted gas in this portion of breath. Phase II (3) is the transition between phase I and phase III.

[0009] For sampling of exhaled breath, it can be broadly divided into 3 categories including mixed expiratory, late expiratory, and end-tidal samplings, of which the portions of the collected breath are different. Mixed expiratory comprises of total exhaled breath from phase I, II, and III. Late expiratory includes exhaled breath from phase II and III, and end-tidal contains exhaled breath from phase III only. In general, end-tidal breath minimizes the influences from the dead space, which shows the highest sampling consistency and thus is the most preferable one to sample.

[0010] There are many existing sampling methods for breath analysis. On-line sampling allows continuous monitoring of breath samples, which measures the concentration change of targeted molecules in real-time. Although this method can provide great details for full profile (including end-tidal) analysis of breath samples, the time interval for each measurement is only a few hundred milliseconds. In this regard, the amount of targeted molecules for analysis is at extremely low level and thus can only be measured by ultrasensitive instrument such as mass spectrometry, which is not practical for any decentralized applications.

[0011] Fig. 2 illustrates a prior art disposable airbag 20 which is another popular way for sampling of exhaled breath. Typical air bags are made by VOCs impermeable soft materials such as composite aluminium foil or Tedlar, which can be easily folded into small size for portable use. Fig. 3 illustrates an example face mask 31 and sample collection airbag 32. During sample collection, the user can switch on the sealing valve, and then directly exhale the breath into the air bag, and finally turn off the sealing valve for temporarily storage before analysis.

[0012] Despite of the intrinsic advantages of air bag for portable applications, its intrinsic disadvantages are significant. The major limitation for air bag is that this method can only be used to collect mixed expiratory breath, thus the sampling is highly inconsistent. Furthermore, as air bag is soft and the gas inlet allows bi-directional air flow, it is easily to trigger backflow of sampled breath by unconscious inhalation action or accidentally squeezing the bag. Some devices utilize an additional face mask with one-way valves to address this issue, however, the face mask is very bulky.

[0013] Turning now to Fig. 4, there is illustrated schematically the operation an example prior art device 40, which utilizes a rigid container with 2 openings 41, 42. As shown, the container has an air inlet and an air outlet and is made by incompressible materials as the container wall to prevent potential sample leakage by accidentally squeezing.

[0014] When user keeps exhaling into the rigid container, the breath sample enters the container from inlet, passes through the empty space inside, and finally leaves the container from outlet. Once the user stops exhaling, the container traps the last portion of the exhaled breath. In this regard, the collected breath can be considered as the end-tidal breath sample, with the sampling volume identical to the internal volume of the container. Fig. 5 shows a commercial breath sampler 50 known as the "BioVOCC-2" using this mechanism as described above. Nevertheless, all these devices occupy a lot of space as most of their volume is reserved for sample storage even before use, which is not favorable for carrying outside, especially for disposable devices.

[0015] To date, a truly portable device of end-tidal exhaled breath sampler for point-of-care and self-testing applications remains underdeveloped. It would be significant if an alternative form of sampling system was provided.

SUMMARY OF THE INVENTION

[0016] It is an object of the invention, in its preferred form to provide for an improved form of breath sampling for subsequent analysis.

[0017] In accordance with a further aspect of the present invention, there is provided an end-tidal breath sampling device including: an inlet port for the ingress of a breath sample, including a one way inlet valve allowing for the one way input of breathing samples into an air storage reservoir; an air storage reservoir connected to the inlet port for breath storage; and at least one outlet port for the temporary controlled egress of stored air when in use so that a positive air pressure is developed within the air storage reservoir.

[0018] In some embodiments, the at least one output port is sealable for extended storage of a breath sample within the air storage reservoir. Preferably, the one way inlet valve includes a flexible pressure activated one way valve including two abutting planar surfaces which are temporarily separated by a positive air pressure when a user breathes into the inlet port of the device. In some embodiments, the air storage reservoir comprises a flexible collapsible bag which can be folded when not in use. The outlet port can further include a sealing mechanism to prevent subsequent leakage of

the breath sample after sampling, including a clip like structure or sealing mechanism comprises a sealing ring for sealing the output port on demand.

[0019] In some embodiments, there also includes a bypass mechanism to bypass the input breath sample, which helps to control the flow rate of the air sample into the reservoir and reduce counter pressure during breath ingress. The bypass mechanism can be single or multi ported. Where the bypass mechanism is multi ported, with the ports can be of different sizes.

[0020] In some embodiments, the inlet port includes a moisture reduction element for reducing the moisture content of the sample. The moisture reduction element can comprise a structural flow member which induces high moisture content input air to flow out of a bypass port.

[0021] In accordance with another aspect of the present invention, there is provided a breath sampling device including: an inlet port for the ingress of a breath sample; an air storage reservoir connected to the inlet port for breath storage; an outlet port for the egress of stored air; including providing a pressure activated one way valve at the inlet port which allows passage of air from the inlet port to the air storage reservoir when a user is breathing into the inlet port, and the outlet port includes a clamping mechanism for stopping the egress of air upon activation by a user.

[0022] In some embodiments, the pressure activated one way valve includes two abutting planar surfaces which are separated by a positive air pressure when a user breathes into the inlet port of the device, the air storage reservoir comprises a flexible collapsible bag which can be folded when not in use, and the outlet port includes a sealing ring for sealing the outlet port on demand. The device can also include a pierceable membrane for subsequent sampling of the air within the air storage reservoir. In some embodiments, the device is activated between a breathing in, storage and analysis state by means of the rotation of a first tunable part including a mouthpiece relative to a second support member, and the air reservoir is pierceable by a separate adaptor piece for subsequent air sampling.

[0023] In accordance with a further aspect of the present invention, there is provided a breath sampling device including: an inlet port for the ingress of a breath sample; an air storage reservoir connected to the inlet port for breath storage; an outlet port for the egress of stored air; including providing a pressure activated one way valve at the inlet port which allows passage of air from the inlet port to the air storage reservoir when a user is breathing into the inlet port; and said outlet port includes a clamping mechanism for stopping the egress of air upon activation by a user.

[0024] Preferably, the pressure activated one way valve includes two abutting planar surfaces which are separated by a positive air pressure when a user breathes into the inlet port of the device.

[0025] In some embodiments, the air storage reservoir comprises a flexible collapsible bag which can be folded when not in use.

[0026] In some embodiments, the outlet port includes a sealing ring for sealing the outlet port on demand.

[0027] The embodiments have the significant advantage in that they are able to collect end-tidal samples which include the last portion of a user's breath. In accordance with a further aspect of the present invention, there is provided an end-tidal breath sampling device including: an inlet port for the ingress of a breath sample; an air storage reservoir connected to the inlet port for breath storage; and an outlet port for the egress of stored air.

[0028] In some embodiments, there is provided an end tidal breath sampling device having an inlet port and outlet port designed so that a positive air pressure is developed inside an air storage reservoir during ingress of a user's breath.

[0029] Preferably, the inlet port includes a mechanism to prevent backflow and leakage of the breath sample. This can include a one-way valve. Preferably, the one-way valve includes a flexible pressure activated one way valve including two abutting planar surfaces which are separated by a positive air pressure when a user breathes into the inlet port of the device.

[0030] In some embodiments, the air storage reservoir comprises a flexible collapsible bag which can be folded when not in use. The outlet port can further include a sealing mechanism to prevent subsequent leakage of the breath sample after sampling. The sealing device can comprise a clip like structure or a sealing ring for sealing the output port on demand.

[0031] In some embodiments, the inlet port includes a bypass mechanism to bypass the input breath sample, which helps to control the flow rate of the air sample into the reservoir, and reduce counter pressure during breath ingress. The bypass mechanism can be single or multi ported, when multi ported, the ports can be of different sizes.

[0032] In some embodiments, the inlet port includes a moisture reduction element for reducing the moisture content of the sample. In some embodiments, moisture reduction element comprises a moisture absorber or mechanical element.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

[0034] Fig. 1 illustrates a graph of a typical gas exchange diagram tracing the concentration of CO₂ as the reference gas (capnography). (Retrieved from <https://www.nuemblog.com/blog/capnography>).

[0035] Fig. 2 is a photo a typical composite aluminium foil airbag of the prior art. Retrieved from <https://www.amazon.com/Sampling-1L-30Liter-Aluminum-Collection-Storage/dp/B08G8VP2VH>.

[0036] Fig. 3 is a photo an example face mask of the prior art to assist in breath sample collection using an airbag. Retrieved from https://www.researchgate.net/Fig./Breath-sampling-system-with-the-self-constructed-one-way-valve-The-one-way-valve-shifts_fig2_30813956

[0037] Fig. 4 illustrates schematically the end-tidal breath sample collection process.

[0038] Fig. 5 illustrates a typical commercial device of the prior art. Retrieved from <https://markes.com/shop/products/biovoc-2>

[0039] Fig. 6 illustrates a CAD design output of an initial prototype embodiment of the invention;

[0040] Fig. 7 illustrates a photograph of the prototype embodiment;

[0041] Fig. 8 illustrates a sectional CAD drawing of the prototype;

[0042] Fig. 9 is a schematic sectional view of the prototype, illustrating principals of operation;

[0043] Fig. 10 illustrates a photograph of the functional prototype of an embodiment in an extended form;

[0044] Fig. 11 illustrates a photograph of an embodiment in a packed form;

[0045] Fig. 12 and Fig. 13 illustrate schematic sectional views of the prototype illustrating principles of operation;

[0046] Fig. 14 to Fig. 16 illustrate the working mechanism of the sealer for temporarily storage of breath samples.

[0047] Fig. 17 to Fig. 19 illustrates the working mechanism of an alternative embodiment of the sealer for short-term storage of breath sample, with Fig. 17 illustrating an end cut away view and Fig. 18 and Fig. 19 illustrating schematic sectional views, illustrating the mechanism of stored breath sample injection using the embodiment for sample analysis.

[0048] Fig. 20 to Fig. 21 illustrates schematic sectional views illustrating the mechanism of stored breath sample injection using the embodiment for sample analysis.

[0049] Fig. 22 is a photograph of the use of the sample analyser of Fig. 20 and Fig. 21.

[0050] Fig. 23 illustrates a sectional view of the mechanical design of flow rate dependent moisture remover.

[0051] Fig. 24 shows an alternative embodiment with the gas inlet and outlet split into two parts, connecting to the soft reservoir bag and one-way valve, in an uninflated form.

[0052] Fig. 25 illustrates the arrangement of Fig. 24 in an inflated form.

[0053] Fig. 26 to Fig. 29 show a further alternative embodiment. Fig. 26 shows an initial 3D model. Fig. 27 illustrates the arrangement of Fig. 26 in cutaway form. Fig. 28 illustrates the operation of the alternative embodiment during storage. Fig. 29 illustrates the operation of the embodiment during an analysis stage.

[0054] Fig. 30 illustrates the computer modelling of a further alternative sampling system, where the gas inlet and outlets are fitted with one-way valves and are split into 2 individual parts connecting to the soft reservoir bag.

[0055] Fig. 31 illustrates the storage process of operation of the alternative embodiment.

[0056] Fig. 32 illustrates the analysis stage of the further alternative embodiment.

DETAILED DESCRIPTION

[0057] To achieve the ultimate goal of end-tidal breath sample collection, the embodiments provide for a number of devices.

[0058] The embodiments provide a disposable breath sampling device which is ideal for POC and self-testing applications with a handheld instrument. The breath sampling device of the embodiments shows some of the following features which differentiate this device from existing products: The majority parts of the device are made by flexible materials which can be compacted for storage and transportation; Collecting end-tidal samples from exhaled breath; including specially designed flexible pressure actuated air flow control valve to prevent backflow and leakage of breath sample; a design that allows temporarily and short-term gas sealing for storage; and designs to bypass excess breath and reduce moisture content in the collected breath.

[0059] An initial prototype 3D model embodiment is illustrated 60 in Fig. 6, with an actual prototype photograph shown 70 in Fig. 7. In general, the embodiment consists of a reservoir bag 61 for breath sample storage (the volume of the reservoir bag can be variable, in an initial case, the volume of the developed prototype is ~50mL), a pressure actuated one-way valve 62 for airflow control, and a rigid part 64 with other functional components. As the majority parts of this invention are made by flexible materials, it can be easily packed into compact size for storage and transportation.

[0060] Fig. 8 illustrates a sectional view through the arrangement of Fig. 6, illustrating the internal workings thereof wherein two flaps are force apart, thereby acting as a one way input valve.

[0061] Fig. 9 illustrates schematically the operation of the one way pressure actuated valve.

[0062] Fig. 10 shows the embodiment in an extended form 100 and Fig. 11 shows the embodiment in a compact packaged form 110.

[0063] Turning now to Fig. 12 and Fig. 13, there is shown the working principles of this embodiment.

[0064] During sampling, users can blow the breath into the device through the mouthpiece 121, which generates a higher air pressure. At this moment, as air pressure inside the one-way valve is higher than the pressure outside, this results in the membranes 122, 123 of the one-way valve being opened and breath sample can access into the reservoir bag 124. The reservoir bag is attached to an

air outlet 125, of which the air inlet and outlet are carefully adjusted such that the size of outlet is smaller than the size of inlet. This helps to generate a positive air pressure inside the reservoir and balloon the reservoir bag until it reaches the designated volume of breath sample storage. In this regard, when the user breaths into the device, the incoming breath sample from the mouthpiece flows into the reservoir bag via the one-way valve. The breath sample keeps filling the bag until it reaches the designated volume of storage, and then leaves the device through the outlet 125.

[0065] As shown in Fig. 13, when the user stops breath out, only the portion of end-tidal breath sample are trapped inside the reservoir bag, with the one way valve of the air bag comprising membranes 122, 123, being closed

[0066] Once the user stops breathing into the sample bag or even inducing a backflow by accidental inspiration, air pressure inside the reservoir bag is higher than that inside the one-way valve. This results in closure of the valve channel and thus backward flow of the sample inside the reservoir bag is not allowed. Moreover, the user can activate the seal 136 at the outlet 125 after sample collection. This prevents sample leakage from the outlet, at the same time the positive pressure developed inside the reservoir bag helps to maintain its shape.

[0067] The sealing of the gas outlet can be achieved by two methods. There is a clip-like structure at the rigid part. For temporarily sealing after sampling, the user can gently press the rigid part of the device, and the sealing ring around the gas outlet which deforms the soft reservoir bag as shown in Fig. 14 to Fig. 16, causing air flow blockage from reservoir bag to the outlet. Considering that back flow of air has been already prevented by the pressure actuated one-way valve, the breath sample can be held inside the reservoir bag without potential leakage.

[0068] Alternative embodiments

[0069] Turning now to Fig. 17 to Fig. 19, an alternative embodiment can also include an additional sealer design at the gas outlet to achieve short-term storage after sampling. As shown in Fig. 17 to 19, the sealer can be a hollow structure with one end capped by aluminium foil, while airtightness of the design is secured by utilizing O-rings. During sampling (Fig. 18), the sealer is at the off position and gas from outlet can leave the device via the air ways on the sides. After sampling, the user can push the sealer into its "On" position (Fig. 19). As a result, the air ways are blocked by the sealer and O-ring, so that breath sample can be trapped inside the reservoir bag.

[0070] The mechanism of subsequent sample analysis of the stored breath sample via injection is shown in Fig. 20 to Fig. 22. The gas injection port of an analyzer is connected to an adaptor which is complementary to the gas outlet of this embodiment breath sampler. Airtightness is enhanced by O-rings inside the adaptor. Upon gas analysis, the user inserts the gas outlet part into the adaptor and the breath sample inside the reservoir bag can be injected into the analyzer by either an active sample injector or manually squeezing the reservoir bag. There is also a hollow pin 201 at the bottom of the adaptor, which is able to punch the aluminium foil 205 to break the sealing prior to the analysis, for the breath sampler with the sealer design as described in Fig. 17 to Fig. 19.

[0071] The sample from exhaled breath often contains a very high moisture content which could affect the operation of any gas analyser. Furthermore, the moisture content easily condenses into water droplets along the air way and inside the sample reservoir, which may alter the concentration of targeted molecules in breath samples and lead to carryover contamination. To reduce the moisture content of the sampled breath, in a further alternative embodiment a mechanical design of flow rate dependent moisture remover in front of the gas inlet can be utilised.

[0072] Turning now to Fig. 23, there is shown a sectional view of one form of moisture remover. In this design, the cross-section area remover is reduced, which results in an increment of air flow rate at this position. According to general air flow dynamic principles, the increasing air flow rate yields higher moisture removal rate, causing the moisture content to condense into larger water droplets. Behind the moisture remover, the bypass port is in-line with the remover while the gas inlet is in a perpendicular orientation to that. In this regard, a larger portion of the water droplets will spin out by inertia and be removed from the bypass port. Apart from the moisture removal function, the bypass port also helps the user breath more easily and works as a gas inlet if the user accidentally carries out inspiration (instead of exhalation as its intended design).

[0073] Apart from above design, many alternative designs are possible. For example, Fig. 24 shows a potential alternative embodiment in which the gas inlet and outlet are split into 2 individual parts, connecting to the soft reservoir bag and one-way valve. Fig. 24 illustrates the arrangement in an uninflated form with mouth piece 241, membranes 242 and outlet valve 243. Fig. 25 illustrating the alternative embodiment in an inflated form.

[0074] Fig. 26 to Fig. 29 show further alternative embodiments. In these embodiments, there is provided a design that includes a fixed part connecting to reservoir bag and a tuneable part which can be turned to operate a number of different modes. The fixed part and tuneable part contain different ports for air flow. Gas samples can passthrough only if the ports from these two parts are

aligned, otherwise the air flow is blocked. There are sealing materials between the fixed part and tuneable part to ensure airtightness.

[0075] As shown initially in Fig. 27, during sample collection, the device is turned at 0-degrees, so that the gas inlet via mouthpiece and a gas outlet are opened, and thus an end-tidal breath sample can be collected. Turning now to Fig. 28, during storage, the device is turned at 90-degree, so that all the gas ports are blocked. Turning now to Fig. 29, during analysis, only the outlet 291 is opened.

[0076] Fig. 31 to Fig. 33 illustrate a further alternative embodiment of the invention.

[0077] Turning initially to Fig. 30, in this alternative embodiment, the gas inlet and outlet are split into 2 individual parts 301, 302, connecting to the soft reservoir bag 303. Both the inlet and outlet consist of a one-way valve, while the valve at the outlet can be controlled by the user with a sealing strip 304.

[0078] The operation of the design includes 3 stages including sampling, storage, and analysis. During sampling, as illustrated 300 in Fig. 30, the one-way valve at the outlet is opened by the sealing strip 304. When the user keeps breathing out, the excess exhaled breath sample is released from outlet thus only end-tidal breath sample is contained in the reservoir bag 303.

[0079] Turning now to Fig. 31, once the sampling stage is completed, the user can pull out the sealing strip 310 to activate a one-way valve 311 of the outlet. In this regard, the breath sample is trapped inside the reservoir bag for temporary storage.

[0080] As shown in Fig. 32, prior to analysis of the breath sample, an adaptor 320 is used to bridge the outlet of this design to the sampling inlet of the breath analyzer. Upon insertion of the design into adaptor, the internal structure of the adapter will push back the sealing strip and re-open the one-way valve at the outlet, which allows the breath analyzer to drain out the breath sample for analysis.

[0081] **Conclusion**

[0082] It can therefore be seen that the emodiments provide for an improved form of sampling arrangement with a one way pressure activated valve allowing air to flow into the reservoir and the outlet valve being sealable by the user in use.

Interpretation

[0083] Reference throughout this specification to “one embodiment”, “some embodiments” or “an embodiment” means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases “in one embodiment”, “in some embodiments” or “in an embodiment” in various places throughout this specification are not necessarily all referring to the same embodiment, but may. Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to one of ordinary skill in the art from this disclosure, in one or more embodiments.

[0084] As used herein, unless otherwise specified the use of the ordinal adjectives "first", "second", "third", etc., to describe a common object, 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.

[0085] In the claims below and the description herein, any one of the terms comprising, comprised of or which comprises is an open term that means including at least the elements/features that follow, but not excluding others. Thus, the term comprising, when used in the claims, should not be interpreted as being limitative to the means or elements or steps listed thereafter. For example, the scope of the expression a device comprising A and B should not be limited to devices consisting only of elements A and B. Any one of the terms including or which includes or that includes as used herein is also an open term that also means including at least the elements/features that follow the term, but not excluding others. Thus, including is synonymous with and means comprising.

[0086] As used herein, the term “exemplary” is used in the sense of providing examples, as opposed to indicating quality. That is, an “exemplary embodiment” is an embodiment provided as an example, as opposed to necessarily being an embodiment of exemplary quality.

[0087] It should be appreciated that in the above description of exemplary embodiments of the invention, various features of the invention are sometimes grouped together in a single embodiment, Fig., or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the claims following

the Detailed Description are hereby expressly incorporated into this Detailed Description, with each claim standing on its own as a separate embodiment of this invention.

[0088] Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the invention, and form different embodiments, as would be understood by those skilled in the art. For example, in the following claims, any of the claimed embodiments can be used in any combination.

[0089] Furthermore, some of the embodiments are described herein as a method or combination of elements of a method that can be implemented by a processor of a computer system or by other means of carrying out the function. Thus, a processor with the necessary instructions for carrying out such a method or element of a method forms a means for carrying out the method or element of a method. Furthermore, an element described herein of an apparatus embodiment is an example of a means for carrying out the function performed by the element for the purpose of carrying out the invention.

[0090] In the description provided herein, numerous specific details are set forth. However, it is understood that embodiments of the invention may be practiced without these specific details. In other instances, well-known methods, structures and techniques have not been shown in detail in order not to obscure an understanding of this description.

[0091] Similarly, it is to be noticed that the term coupled, when used in the claims, should not be interpreted as being limited to direct connections only. The terms "coupled" and "connected," along with their derivatives, may be used. It should be understood that these terms are not intended as synonyms for each other. Thus, the scope of the expression a device A coupled to a device B should not be limited to devices or systems wherein an output of device A is directly connected to an input of device B. It means that there exists a path between an output of A and an input of B which may be a path including other devices or means. "Coupled" may mean that two or more elements are either in direct physical or electrical contact, or that two or more elements are not in direct contact with each other but yet still co-operate or interact with each other.

[0092] Thus, while there has been described what are believed to be the preferred embodiments of the invention, those skilled in the art will recognize that other and further modifications may be made thereto without departing from the spirit of the invention, and it is intended to claim all such changes and modifications as falling within the scope of the invention. For example, any formulas

given above are merely representative of procedures that may be used. Functionality may be added or deleted from the block diagrams and operations may be interchanged among functional blocks. Steps may be added or deleted to methods described within the scope of the present invention.

CLAIMS:

1. An end-tidal breath sampling device including:

an inlet port for the ingress of a breath sample, including a one way inlet valve allowing for the one way input of breathing samples into an air storage reservoir;

an air storage reservoir connected to the inlet port for breath storage; and

at least one outlet port for the temporary controlled egress of stored air when in use so that a positive air pressure is developed within said air storage reservoir.
2. An end-tidal breath sampling device as claimed in claim 1 wherein said at least one output port is sealable for extended storage of a breath sample within the air storage reservoir.
4. A device as claimed in any previous claim wherein said one way inlet valve includes a flexible pressure activated one way valve including two abutting planar surfaces which are temporarily separated by a positive air pressure when a user breathes into the inlet port of the device.
5. A device as claimed in any previous claim wherein the air storage reservoir comprises a flexible collapsible bag which can be folded when not in use.
6. A device as claimed in any previous claim wherein the outlet port further includes a sealing mechanism to prevent subsequent leakage of the breath sample after sampling.
7. A device as claimed in claim 6 wherein said sealing device comprises a clip like structure.
8. A device as claimed in claim 6 wherein said sealing mechanism comprises a sealing ring for sealing the output port on demand.
9. A device as claimed in any previous claim wherein the inlet port includes a bypass mechanism to bypass the input breath sample, which helps to control the flow rate of the air sample into the reservoir, and reduce counter pressure during breath ingress.
10. A device as claimed in claim 9 wherein said bypass mechanism is single or multi ported.

11. A device as claimed in claim 10 wherein said bypass mechanism is multi ported, with the ports being of different sizes.
12. A device as claimed in claim 1 wherein the inlet port includes a moisture reduction element for reducing the moisture content of the sample.
13. A device as claimed in claim 13 wherein the moisture reduction element comprises a structural flow member which induces high moisture content input air to flow out of a bypass port.
14. A breath sampling device including:
- an inlet port for the ingress of a breath sample;
 - an air storage reservoir connected to the inlet port for breath storage;
 - an outlet port for the egress of stored air;
 - including providing a pressure activated one way valve at the inlet port which allows passage of air from the inlet port to the air storage reservoir when a user is breathing into the inlet port,
 - and said outlet port includes a clamping mechanism for stopping the egress of air upon activation by a user.
15. A device as claimed in claim 14 wherein said pressure activated one way valve includes two abutting planar surfaces which are separated by a positive air pressure when a user breathes into the inlet port of the device.
16. A device as claimed in claim 14 wherein said air storage reservoir comprises a flexible collapsible bag which can be folded when not in use.
17. A device as claimed in claim 14 wherein said outlet port includes a sealing ring for sealing the outlet port on demand.
18. A device as claimed in any previous claim, further including:
- a pierceable membrane for subsequent sampling of the air within the air storage reservoir.

19. A device as claimed in any previous claim, wherein the device is activated between a breathing in, storage and analysis state by means of the rotation of a first tunable part including a mouthpiece relative to a second support member.

20. A device as claimed in any previous claim, wherein said air reservoir is piercable by a separate adaptor piece for subsequent air sampling.