MULTIFUNCTIONAL BREATHALYZER FOR THE PURPOSE OF DETECTION OF INFECTIOUS DISEASE ACROSS DIFFERENT TEST PLATFORM

Background of invention

We designed a Multifunctional Breathalyzer specially for the point-of-care detection of infectious diseases through breath across different test platforms. Breathalyzer is a device to detect volatile organic compounds in breath (BVOCs) and has been heavily deployed for law enforcement, such as for the on-site estimation of blood alcohol content. Notably, the sensitive detection of BVOCs is also an emerging approach to diagnose human health because of the direct connection between BVOCs and the (bio)chemistries occurring in a human body. For instance, small chemical molecules, such as formaldehyde, butane, isoprene, pentane, have been used as recognition biomarkers for many diseases including tuberculosis, and colorectal and lung cancers. Compared to conventional bio-diagnostic methods such as blood sampling, breath-based diagnosis excels as a non-invasive method that can be performed frequently for real-time and rapid monitoring/screening even by non-medicallytrained personnel. Breath-based diagnosis is thus critical for pre-early disease identification, facilitating treatment and recovery.

Currently, commercial breathalyzer diagnostic kits typically comprise of a breath chamber and a compartment containing a sensor to detect BVOCs. Typically, a human subject blows into a breath chamber via a mouthpiece and the breath is directed into the sensory compartment for detection. The breath chamber will also contain an outlet so that pressure is not be built up in the breathalyzer, ensuring smooth and continuous flow of breath to accumulate target analyte. The breathalyzer (both breath chamber and sensor) is designed for repeated usage, and only the mouthpiece is replaced after every testing. Together with the release of breath samples into the environment, the exposure of breathalyzers to multiple human subjects is a major flaw that prevents them from being employed as healthcare diagnostic tools, especially for patients suffering or potentially suffering from infectious diseases. Thus, there is a need for a breathalyzer design that is isolated, free of contamination before and after usage, and possesses security measure to avoid accidental re-using. These criteria are important to develop portable diagnosis device for public healthcare, even for infectious diseases that pose huge risk for human- to-human transmission.

Brief Description of the Drawings

The above and other problems are solved by features and advantages of a system and method in accordance with the present invention described in the detailed description and shown in the following drawings.

Figure 1 illustrating an exploded view of the multifunctional breathalyser in accordance with embodiments of the invention;

Figure 2 illustrating multiple views of the multifunctional breathalyser in accordance with embodiments of the invention;

Figure 3 illustrating an irreversible capping system in accordance with embodiments of the invention; and

Figure 4 illustrating a zoomed in cross sectional view of the capping system in accordance with embodiments of the invention.

Description of the invention

Our invention focuses on a unique breathalyzer design to address the aforementioned limitations by separating and isolating the breath chamber and the sensory compartment. To do this, we design the breath chamber to be a standalone, disposable accessory that is the only part of the breathalyzer that is in contact with the patient. Notably, our breath chamber has the following features that render it suitable for use in the diagnosis of infectious disease:

1) An Irreversible capping mechanism that will lock the breathalyzer to prevent tempering and accidental reuse of the device. The cap can only be released upon breaking of the secure catch on the cap with substantial force. The broken catch and loose holding of the cap will be evidence that the device will be deem invalid.

2) An outlet containing medical-grade filter that is BFE & VFE 95% and above that is well-established to filter out pathogens. This design is to ensure that breath can flow through the breath chamber without building up excessive pressure within the chamber while enabling the accumulation of substantial samples for detection. More importantly trapping and isolating any possible infectious pathogen within the breath chamber. This effectively prevents possible contagious breath releasing to the exterior environment. In this way, we can isolate any pathogen within the breath chamber and effectively eliminating any possibilities for bio- contamination during the diagnosis.

3) QR or Barcode labels can be easily applied to the Breathalyzer with ease as the material used is not only medical grade but compatible to most bio-compatible adhesive in the market. The QR and Barcode create an unique ID to individuals. This serves as a matured linking tools to computer systems and servers where data base can be recorded automatically. This will ensure fast, efficient process especially in the event of high throughput screening during a pandemic.

4) A diagnosis window can be customized to integrate with the sensory module without direct exposing the breath to the sensors. For instance, in the case where infrared or Raman spectroscopy is used, this window will be made of bio-compatible transparent materials to allow light beams and scattered light to freely transmit between the sensory module and breath chamber. This property will allow us to probe the BVOCS within the air chamber in a contactless manner. The diagnostic window is also safely sealed off to prevent any leakage of possible infectious pathogen present in breath.

5) The main chamber is built in 2 halves and a specially designed double wall at the joining area serves as a bonding groove while making sure that the device is fully leak proof. This is another safety feature carefully thought of in preparation for added security.

6) This Breathalyzer will also withstand a drop from 1.2M without cracks or shattering to pieces. It will also withstand a gas leak test of 4PSI all round, which is about 3 times more than a human breath.

7) With all these safety features in place, this makes disposal handling of such bio hazard waste more efficient, cost effective and safe.

8) Designed and build to perform safe and non-invasive breath diagnosis across different test platform that are applicable by simply changing an internal platform to suit different test platforms configuration.

For similar devices in the market, we do note that the breathalysers are usually integrated, whereby the breath chamber and sensory module are connected and this ensemble is reused. Only the mouthpiece is disposable or most having a thin disposable plastic sleeves. Moreover, the breath is allowed to flow out of the breath chamber and eventually contaminating the open environment. Common Breathalyzers are also non multifunctional, they are built specifically for a single test platform.

Advantages and improvement over existing methods

As mentioned in the previous section, our breathalyzer design aims to enable the use of human breath to profile human health and diagnose infectious disease. This is rendered possible due to the many safety measures that we have incorporated into our breathalyzer, especially on the breath chamber module. Briefly, the safety measures include (1) an air-trap system to prevent breath leakages, (2) irreversible capping system to prevent accidental reusing or tempering of samples, (3) medical grade filters with BFE & VFE of above 95% to prevent possible external contamination, (4) isolated and separated sensory and breath chamber modules to prevent contamination, and (5) the breath chamber (only part in direct contact with the patients) can be easily sealed, detached and disposed of. (6) Easy integration to existing IT system. (7) Ease, safe and cost effective of disposal. (8) Multifunctional usage across different test platform.

These features are not present in any commercial breathalyzer to the best of our knowledge.

Commercial applications of invention

Our ultimate goal for this breathalyzer system is to couple with various sensing technologies to realize a noninvasive and pre-early diagnosis of a diverse range of infectious/non-infectious diseases, including cancer, diabetes, respiratory failures, tuberculosis, COVID, etc. This will allow prompt intervention, enhance the chance of patients' survivability, and provide a way for mass screening in the case of an emergency like a pandemic.

CLAIMS:

1) An Irreversible capping mechanism that will lock the breathalyzer to prevent tempering and accidental reuse of the device. The cap can only be released upon breaking of the secure catch on the cap with substantial force. The broken catch and loose holding of the cap will be evidence that the device will be deem invalid.

2) An outlet containing medical-grade filter that is BFE & VFE 95% and above that is well-established to filter out pathogens. This design is to ensure that breath can flow through the breath chamber without building up excessive pressure within the chamber while enabling the accumulation of substantial samples for detection. More importantly trapping and isolating any possible infectious pathogen within the breath chamber. This effectively prevents possible contagious breath releasing to the exterior environment. In this way, we can isolate any pathogen within the breath chamber and effectively eliminating any possibilities for bio- contamination during the diagnosis.

3) QR or Barcode labels can be easily applied to the Breathalyzer with ease as the material used is not only medical grade but compatible to most bio-compatible adhesive in the market. The QR and Barcode create an unique ID to individuals. This serves as a matured linking tools to computer systems and servers where data base can be recorded automatically. This will ensure fast, efficient process especially in the event of high throughput screening during a pandemic.

4) A diagnosis window can be customized to integrate with the sensory module without direct exposing the breath to the sensors. For instance, in the case where infrared or Raman spectroscopy is used, this window will be made of bio-compatible transparent materials to allow light beams and scattered light to freely transmit between the sensory module and breath chamber. This property will allow us to probe the BVOCS within the air chamber in a contactless manner. The diagnostic window is also safely sealed off to prevent any leakage of possible infectious pathogen present in breath.

5) The main chamber is built in 2 halves and a specially designed double wall at the joining area serves as a bonding groove while making sure that the device is fully leak proof. This is another safety feature carefully thought of in preparation for added security.

6) This Breathalyzer will also withstand a drop from 1.2M without cracks or shattering to pieces. It will also withstand a gas leak test of 4PSI all round, which is about 3 times more than a human breath.

7) With all these safety features in place, this makes disposal handling of such bio hazard waste more efficient, cost effective and safe.

8) Designed and build to perform safe and non-invasive breath diagnosis across different test platform that are applicable by simply changing an internal platform to suit different test platforms configuration.