APPARATUS AND METHOD FOR DETERMINING LOCATION OF A DISTAL END OF A TUBE INSERTED INTO A BODY CAVITY

Technical Field

[0001] The present disclosure relates to an apparatus and method for determining location of a distal end of a tube inserted into a body cavity, and in particular to location of a distal end of a nasogastric tube for tube feeding a patient.

Background

[0002] In healthcare settings, tubes often need to be inserted into parts of a body (whether human or animal) for various reasons. Evidently, the tube needs to be correctly placed in order for it to be of use. If the distal end of the inserted tube is in a wrong location, therapeutic agents that are provided through the tube will be administered to a wrong part of the body and can cause harm.

[0003] One commonly used tube is the nasogastric tube (NGT) which must be passed through the nose and oesophagus into the stomach for tube feeding patients who are unable to eat normally. During insertion of the NGT, misdirection may occur and the distal end of the NGT may end up in the lungs or pleural space instead of the stomach, leading to pneumothorax, pneumonia and/or feed empyema if liquid food is poured into such a NGT. To prevent this from occurring, caregivers are currently taught to draw aspirate from the inserted NGT and to test this aspirate for acidity to confirm if the distal end of the NGT has entered the stomach, as aspirate from the stomach is significantly more acidic than aspirate from the trachea or lungs. However, there are patients who have been prescribed proton pump inhibitors that reduce the production of stomach acid. Aspirate drawn from such patients has reduced acidity and therefore the acidity test cannot be used to confirm the location of the NGT distal end in such patients or in patients who produce no stomach aspirate. While it is possible to use a chest x-ray to determine the location of the distal end of an inserted NGT, it is not feasible nor desirable to perform a chest x-ray every time before each tube feeding.

[0004] To facilitate determination of the location of the NGT distal end, some systems have been developed that use one or more various sensors and devices provided at the distal end of the NGT. Such sensors and devices include an ultrasound transducer, pH sensor, contact pressure sensor, continuity monitor, fluid pressure sensor, microphone, vibrator, and wave

generator. However, it is not desirable to introduce sensors into the body to determine the distal end of the NGT, nor to have the sensors left inside for lengthy periods. Also, such sensors must be made biologically robust and biocompatible to withstand the corrosion from body fluids such as stomach acid or antibodies from the body's immunity system, thus driving up the cost of such sensors.

Summary

[0005] The present application discloses an apparatus and method for determining location of a distal end of a tube inserted into a body cavity. It can be used to determine the location of the distal end of an NGT before tube feeding commences. At all times, no part of the apparatus comes into contact with the body. The disclosed apparatus and method introduce no sensors into the body and is compatible with standard tubes that are in common use. The apparatus works for all patients, is readily portable, quick to set up and easy to operate. It allows for bedside point-of-care use and provide location confirmation within seconds. Issues with mess and contamination associated with drawing aspirate are avoided. The apparatus is easy to clean and can be used with multiple patients without causing cross-contamination or producing any radiation, thereby reducing costs and posing no health risks.

[0006] According to a first exemplary aspect, there is provided an apparatus for determining location of a distal end of a tube inserted into a body cavity, the apparatus comprising: a sensing unit having a fluid outlet provided to form a fluid communication with a proximal end of the tube; a fluid chamber provided in the sensing unit in fluid communication with the fluid outlet; a fluid bolus valve provided in fluid communication between the fluid chamber and the fluid outlet, wherein upon activation of the fluid bolus valve when the proximal end of the tube is in fluid communication with the fluid outlet and the distal end of the tube is inserted into a body cavity, the fluid bolus valve is opened for a predefined period of time to release a fluid bolus having a predefined pressure and a predefined volume that travels from the fluid chamber through the tube into the body cavity; a backpressure sensor provided in fluid communication with the fluid outlet to measure, over a predetermined period of time, backpressure that arises as the fluid bolus is released from the distal end of the tube into the body cavity; a microcontroller provided in communication with the backpressure sensor and configured to generate a backpressure profile from the measured backpressure, the microcontroller further configured to obtain characteristics of the generated backpressure profile and to determine the location of the distal end of the tube according to the obtained characteristics; a first switch provided on the sensing unit and activatable by a user to activate

the fluid bolus valve; and a first indicator provided on the sensing unit to indicate that the distal end of the tube is at a first predefined body cavity if so determined by the microcontroller.

[0007] The apparatus may further comprise a warning indicator provided on the sensing unit and activatable by the microcontroller to indicate a warning if the distal end of the tube is determined by the microcontroller to be not at the first predefined body cavity.

[0008] The apparatus may further comprise a second indicator provided on the sensing unit to indicate that the distal end of the tube is at a second predefined body cavity if so determined by the microcontroller.

[0009] The apparatus may further comprise a second switch provided on the sensing unit and activatable by a user to activate the fluid bolus valve, and wherein the warning indicator is further activatable by the microcontroller to indicate a warning if the distal end of the tube is determined by the microcontroller to be not at the second predefined body cavity.

[0010] The apparatus may further comprise a third indicator provided on the sensing unit and activatable by the microcontroller to indicate that location of the distal end of the tube is unknown if the distal end of the tube has been determined by the microcontroller to be neither at the first predefined body cavity nor at the second predefined body cavity.

[0011] The fluid may be air, wherein the sensing unit further comprises a fluid inlet, and wherein the apparatus further comprises a pump provided in fluid communication between the fluid inlet and the fluid chamber to pump ambient air into the fluid chamber.

[0012] The apparatus may further comprise a chamber pressure sensor provided to determine a chamber air pressure of air in the fluid chamber, wherein the microcontroller is in communication with the chamber pressure sensor and the pump, and wherein the pump is controllable by the microcontroller to keep the chamber air pressure at a preset chamber air pressure.

[0013] The apparatus may further comprise a filter provided between the fluid inlet and the fluid chamber to filter the ambient air that is pumped into the fluid chamber.

[0014] The sensing unit may further comprise an exhaust outlet and wherein the fluid chamber is in fluid communication with the exhaust outlet via an exhaust valve configured to allow excess air to leave the fluid chamber when the chamber air pressure exceeds a predetermined safety pressure.

[0015] The apparatus may further comprise a cartridge attachable to the sensing unit and to which the proximal end of the tube is connectable, the cartridge having a fluid passage therethrough to establish a fluid connection between the fluid outlet of the sensing unit and the proximal end of the tube, wherein a valve is provided in the fluid passage to prevent backflow of fluid from the tube to the fluid outlet.

[0016] The apparatus may further comprise a connecting tube to establish a fluid connection between the cartridge and the proximal end of the tube.

[0017] The microcontroller may be in communication with the first switch and the fluid bolus valve, and is configured to control activation of the fluid bolus valve upon activation of the first switch by the user.

[0018] The microcontroller may be further configured to compare the obtained characteristics with predetermined characteristics of predetermined body cavities and to classify the location of the distal end of the tube according to the predefined body cavity of which the predetermined characteristics correlate with the obtained characteristics.

[0019] According to a second exemplary aspect, there is provided a method of determining location of a distal end of a tube inserted into a body cavity, the method comprising the steps of:

(a) releasing at least one fluid bolus having a predefined pressure and a predefined volume from a fluid chamber into a proximal end of the tube;
(b) measuring, using a backpressure sensor, over a predetermined period of time, backpressure that arises as the at least one fluid bolus is released from the distal end of the tube into the body cavity;
(c) generating, using a microcontroller, a backpressure profile from the measured backpressure, obtaining, using the microcontroller, characteristics of the generated backpressure profile;
(d) determining, using the microcontroller, the location of the distal end of the tube according to the obtained characteristics; and
(e) indicating the location of the distal end of the tube using an indicator.

[0020] If the location determined in step (d) is a first predefined body cavity; step (e) may further comprise the microcontroller activating a first indicator provided to indicate that the distal end of the tube is at the first predefined body cavity.

[0021] If the location determined in step (d) is a second predefined body cavity, step (e) may further comprise the microcontroller activating a second indicator provided to indicate that the distal end of the tube is at the second predefined body cavity.

[0022] the location determined in step (d) is neither the first predefined body cavity nor the second predefined body cavity, step (e) may comprise the microcontroller activating a third indicator provided to indicate that the distal end of the tube is unknown.

[0023] The method may further comprise the microcontroller activating a warning indicator if step (a) was performed by activating a first switch and the location determined in step (d) is not the first predefined body cavity.

[0024] The method may further comprise the microcontroller activating the warning indicator if the location determined in step (d) is neither the first predefined body cavity nor the second predefined body cavity.

[0025] Step (a) may comprise releasing a plurality of fluid boli at predefined time intervals into the proximal end of the tube, and wherein step (b) comprises measuring the backpressure that arises as the plurality of fluid boli are released from the distal end of the tube into the body cavity.

[0026] The fluid may be air and the method may further comprise pumping ambient air into the fluid chamber to keep a chamber air pressure of air in the fluid chamber at a preset chamber air pressure.

[0027] The method may further comprise comprising filtering the ambient air that is pumped into the fluid chamber using a filter.

[0028] The method may further comprise allowing excess air to leave the fluid chamber via an exhaust valve when the chamber air pressure exceeds a predetermined safety pressure.

[0029] The method may further comprise, before step (a), providing a cartridge in fluid connection between the fluid outlet and the proximal end of the tube to prevent backflow of fluid from the tube to the fluid outlet using a valve provided in the cartridge.

[0030] The method may further comprise, before step (a), establishing a fluid connection between the cartridge and the proximal end of the tube using a connecting tube.

[0031] Step (e) may comprise the obtained characteristics with reference characteristics of predetermined body cavities and classifying the location of the distal end of the tube according to the predefined body cavity where the reference characteristics correlate with the obtained characteristics.

Brief Description of the Drawings

[0032] In order that the invention may be fully understood and readily put into practical effect there shall now be described by way of non-limitative example only exemplary embodiments of the present invention, the description being with reference to the accompanying illustrative drawings.

FIG. 1 is a perspective view of an exemplary embodiment of a tube attached to an apparatus for determining location of a distal end of the tube when the tube is inserted into a body cavity.

FIG. 2 is a perspective view of exemplary components of the apparatus of FIG. 1 before assembly for use.

FIG. 3 is an exploded assembly view of a sensing unit of the apparatus of FIG. 1.

FIG. 4 is a close-up perspective view of some components within the sensing unit.

FIG. 5 is a top view of a first exemplary top surface of the sensing unit.

FIG. 6 is a top view of a second exemplary top surface of the sensing unit.

FIG. 7 is a top view of a third exemplary top surface of the sensing unit.

FIG. 8 is an exemplary backpressure profile obtained when the distal end of the tube is in the stomach.

FIG. 9 is a first exemplary backpressure profile obtained when the distal end of the tube is in the oesophagus.

FIG. 10 is a second exemplary backpressure profile obtained when the distal end of the tube is in the oesophagus.

FIG. 11 is a flowchart of an exemplary method of determining location of the distal end of the tube when the tube is inserted into a body cavity.

FIG. 12 is a schematic diagram of a fluid pathway and a signal pathway of the apparatus and method.

Detailed Description

[0033] Exemplary embodiments of the apparatus 100 and method 200 for determining location of a distal end 301 of a tube 300 inserted into a body cavity (not shown) will be described with reference to FIGS. 1 to 12 in which the same reference numerals are used across the figures to refer to the same or similar parts.

[0034] In general, as can be seen in FIGS. 1 and 2, the apparatus 100 comprises a sensing unit 10 having a fluid outlet 11 provided to form a fluid communication with a proximal end 302 of the tube 300. The sensing unit 10 is preferably easily portable in one hand, and may have a cuboid form with a housing 14 enclosing various components therein, as shown in FIG. 3. In some embodiments of the apparatus 100, the proximal end 302 of the tube 300 may be directly connected to the fluid outlet 11. Alternatively, in a preferred embodiment and for hygiene purpose, as shown in FIGS. 1 and 2, the apparatus 100 may further comprise a cartridge 80 attachable to the sensing unit 10 and to which the proximal end 302 of the tube 300 is connectable. Appreciably, the cartridge 80 has a fluid passage therethrough to establish a fluid connection between the fluid outlet 11 of the sensing unit 10 and the proximal end 302 of the tube 300. An anti-backflow valve (not shown) is preferably provided in the fluid passage of the cartridge 80 to prevent backflow of fluid from the tube 300 to the fluid outlet 11. Alternatively (not shown), the anti-backflow valve may be provided at the fluid outlet 11 on the sensing unit 10. Where the apparatus 100 includes the cartridge 80, the housing 14 of the apparatus may include a cartridge receiver 48 configured to form a fluid-tight seal with the cartridge 80 while allowing fluid communication from the housing 14 to the cartridge 80. The housing 14 and cartridge 80 are preferably made of a plastics material such as polycarbonate (PC), acrylonitrile butadiene styrene (ABS), or a mixture of PC and ABS, for example.

[0035] A connecting tube 90 may additionally be provided in the apparatus 100 to establish a fluid connection between the cartridge 80 and the proximal end 302 of the tube 300. In a preferred embodiment, the connecting tube 90 may have a nozzle 91 provided at its distal end to facilitate connection with the proximal end 302 of the tube 300. In this way, where the tube 300 is a NGT used for tube feeding a patient in bed, for example, while the sensing unit 10 may be placed on a bedside table, the connecting tube 90 would allow a fluid connection to be established between the sensing unit 10 and the proximal end 302 of the tube 300 that is at a distance away and closer to the patient in bed. By providing the connecting tube 90 and cartridge 80 as lower-cost consumable items for single-patient use, the higher-cost sensing unit 10 can be shared between multiple patients that each have their own set of cartridge 80 and connecting tube 90, for example in healthcare institutions, thus lowering costs for patients.

[0036] In the apparatus 100, a fluid chamber 13 is provided in the sensing unit 10, as shown in FIG. 3. The fluid chamber 13 is in fluid communication with the fluid outlet 11. The fluid chamber 13 may be connected to the fluid outlet 11 via a chamber outlet tubing 13-2 for example, as shown in FIG. 4. A fluid bolus valve 17 is provided in fluid communication between the fluid chamber 13 and the fluid outlet 11, as shown in FIG. 4. The fluid bolus valve 17 may be a solenoid valve, for example. When the fluid bolus valve 17 is activated, the fluid bolus valve 17 is opened for a predefined period of time. This will release a fluid bolus (not shown) from the fluid chamber 13 to the fluid outlet 11. The fluid bolus has a predefined pressure and a predefined volume that may be determined from the fluid pressure in the fluid chamber 13 and the predefined period of time during which the fluid bolus valve 17 is open. When the fluid bolus valve 17 is opened while the proximal end 302 of the tube 300 is in fluid communication with the fluid outlet 11 and the distal end 301 of the tube 300 is inserted into a body cavity, the released fluid bolus will travel from the fluid chamber 13 into the tube 300 and leave the distal end 301 of the tube 300 to enter the body cavity.

[0037] As the fluid bolus is released from the distal end 301 of the tube 300 into the body cavity, backpressure in the tube 300 arises, as a result of resistance from the body cavity that is met by the exiting fluid bolus. To measure this backpressure over a predetermined period of time, a backpressure sensor 19 is provided in the sensing unit 10 in fluid communication with the fluid outlet 11 (for example via a backpressure sensor tubing 19-1 as shown in FIG. 4). The apparatus 100 also comprises a microcontroller 20 provided in the sensing unit 10 in communication with the backpressure sensor 19. The microcontroller 20 is configured to generate a backpressure profile from the backpressure measured over the predetermined period of time.

[0038] FIG. 8 shows an exemplary backpressure profile obtained when the distal end 301 of the tube 300 was confirmed to be in a patient's stomach (the stomach being an example of a body cavity) and the fluid bolus was released from the fluid chamber 13. FIGS. 9 and 10 show exemplary backpressure profiles obtained from two patients when the distal end 301 of the tube 300 was confirmed to be in each patient's oesophagus, the oesophagus being another example of a body cavity. As can be seen, the backpressure profiles for the body cavity being the oesophagus (FIGS. 9 and 10) both have significant initial peaks that drop sharply and then plateau, unlike the backpressure profile for the body cavity being the stomach (FIG. 8) which does not have an obvious initial peak and only has a small and smooth decrease before plateauing.

[0039] Appreciably, different patients will have different backpressure profiles as each person's body cavity will not react in exactly the same way as another person when the fluid bolus is released into the body cavity. However, from multiple backpressure profiles that have been obtained as mentioned above, it has been found that specific body cavities give rise to backpressure profiles with specific characteristics that are consistent across multiple patients, as can be seen in the similarities between FIGS. 9 and 10. Such specific characteristics differ between different body cavities. These backpressure profile characteristics can be extracted using signal processing, for example, to serve as reference characteristics that are specific to predefined body cavities. Using the apparatus 100, backpressure profiles have been obtained from different known body cavities of multiple patients, and the specific characteristics from these backpressure profiles have been subsequently obtained. In this way, reference characteristics that are specific to predefined body cavities have been obtained and can be used to determine the location of the distal end 301 of the tube 300 for most patients. The reference characteristics are stored in a data storage unit (not shown) that is in communication with the microcontroller 20 before use of the apparatus 100. The reference characteristics are stored when the apparatus 100 is being configured to specifically detect if the distal end 301 of the tube 300 is in one or more predefined body cavities.

[0040] In the apparatus 100, the microcontroller 20 is configured to obtain the characteristics of the generated backpressure profile whenever the apparatus 100 is used, and to determine the location of the distal end 301 of the tube 300 according to the obtained characteristics. To do so, the microcontroller 20 may compare the characteristics obtained during use of the apparatus 100 with the stored reference characteristics and classify the location of the distal end 301 of the tube 300 as being in the predefined body cavity when the reference characteristics correlate with the obtained characteristics.

[0041] In embodiments where the fluid used in the apparatus 100 is air, a chamber pressure sensor 16 is preferably provided in fluid connection with the fluid chamber 13 (for example via a chamber pressure sensor tubing 16-1 as shown in FIG. 4). In such embodiments, the sensing unit 10 further comprises a fluid inlet 99 and a pump 97 provided in fluid communication between the fluid inlet 99 and the fluid chamber 13 (for example via an inlet tubing 99-1 and a pump tubing 97-1 as shown in FIG. 4). In this way, ambient air can be drawn through the fluid inlet 99 and pumped into the fluid chamber 13 using the pump 97. In such embodiments, the microcontroller 20 is in communication with the chamber pressure sensor 16 and the pump 97. The pump 97 is controlled by the microcontroller 20 to keep the chamber air pressure at a preset chamber air pressure. A filter (not shown) may be provided between the fluid inlet 99 and the fluid chamber 13 to filter the ambient air that is pumped into the fluid chamber 13, so

that the fluid bolus that is released into the body cavity comprises clean air. Further preferably, an exhaust outlet 95 also may be provided in the sensing unit 10, wherein the fluid chamber 13 is in fluid communication with the exhaust outlet 95 via an exhaust valve 94 (for example via an exhaust outlet tubing 95-1 and an exhaust valve tubing 94-1 as shown in FIG. 4). The exhaust valve 94 is in communication with the microcontroller 20 and is configured to be activated by the microcontroller to allow excess air to leave the fluid chamber 13 when the microcontroller 20 determines that the chamber air pressure (as measured by the chamber pressure sensor 16) exceeds a predetermined safety pressure.

[0042] In all embodiments of the apparatus 100, a first switch 21 is provided on the sensing unit 10. The first switch 21 is activatable by a user to activate the fluid bolus valve 17. In a preferred embodiment, the first switch 22 may comprise a push button switch provided on a top surface 18 of the housing 14 of the sensing unit 10, as shown in FIGS. 1-3 and 5-7. In alternative embodiments, other switch types (not shown) may be used. The first switch 21 is preferably connected to the microcontroller 20 so that when the first switch 21 is activated, the microcontroller 20 activates the fluid bolus valve 17 by opening the fluid bolus valve 17 for the predefined period of time. In this way, the fluid bolus that is released has the predefined pressure and predefined volume. For example, the fluid bolus may have a pressure ranging from 10 cmH_2O to 100 cmH_2O, and a volume ranging from 0.1 ml to 10 ml. For embodiments using air as the fluid, this can be controlled by the microcontroller based on the measurements of the chamber pressure sensor 16, the known size of the fluid outlet 11 and the predefined period of time for which the fluid bolus valve 17 is opened.

[0043] For all embodiments, in addition to the first switch 21, a first indicator 31 is also provided on the sensing unit 10, preferably also on the top surface 18 of the housing 14, as shown in FIGS. 1-3 and 5-7. The first indicator 31 is connected to the microcontroller 20. During use of the apparatus 100, after the first switch 21 has been activated and the fluid bolus has been released into the body cavity, as described above, the microcontroller determines the body cavity that the distal end 301 of the tube 300 is in according to the obtained characteristics of the backpressure profile that has been generated. Also as described above, this may comprise the microcontroller 20 comparing the obtained characteristics with the reference characteristics of a first predefined body cavity, for example the stomach. These reference characteristics have already been stored in a data storage unit (not shown) that is in communication with the microcontroller 20 before use of the apparatus 100. The reference characteristics are stored when the apparatus 100 is being configured to specifically detect if the distal end 301 of the tube 300 is in the first predefined body cavity. If the microcontroller 20 determines that the distal end 301 of the tube 300 is indeed at the first predefined body cavity, the first indicator 31

is activated by the microcontroller 20 to provide this indication to the user, for example by lighting up if the first indicator comprises a light emitting diode (LED).

[0044] In some embodiments as shown in FIGS. 5-7, the apparatus 100 may further include a warning indicator 33 provided on the sensing unit 10, preferably also on the top surface 18 of the housing 14. The warning indicator 33 is connected to and activatable by the microcontroller 20 to indicate a warning if the distal end 301 of the tube 300 is determined by the microcontroller 20 to be not at the first predefined body cavity, for example by lighting up if the warning indicator 33 is an LED.

[0045] In some embodiment as shown in FIGS. 6 and 7, the apparatus 100 may further include a second indicator 32 provided on the sensing unit 10. In such embodiments, before use, the apparatus 100 is configured to specifically detect whether the distal end 301 of the tube 300 is in a first predefined body cavity (for example the stomach) or whether the distal end 301 of the tube 300 is in a second predefined body cavity (for example the oesophagus). This may comprise storing the reference characteristics of the first predefined body cavity and the reference characteristics of the second predefined body cavity in the sensing unit 10 before use of the apparatus 100. The second indicator 32 is provided to indicate that the distal end 301 of the tube 300 is at the second predefined body cavity if so determined by the microcontroller 20 according to the obtained characteristics when the apparatus 100 is used. In this embodiment, the microcontroller 20 may be configured to activate the warning indicator 33 to indicate a warning if it 20 detects that the distal end 301 of the tube 300 is neither at the first nor the second predefined body cavity.

[0046] In a further embodiment as shown in FIG. 7, the apparatus 100 may further include a second switch 22 provided on the sensing unit 10, together with the second indicator 32 and the warning indicator 33. The second switch 22 is configured to be activatable by a user to activate the fluid bolus valve 17 when the user wishes to determine if the distal end 301 of the tube 300 is at the second predefined body cavity. In this embodiment, the microcontroller 20 may be configured to activate the warning indicator 33 to indicate a warning if the distal end 301 of the tube 300 is determined by the microcontroller 20 to be not at the second predefined body cavity after the second switch 22 has been activated. If the distal end 301 is determined to be at the first predefined body cavity, the first indicator 31 preferably also lights up together with the warning indicator 33. Similarly, if the user activates the first switch 21 in order to determine if the distal end 301 of the tube is at the first predefined body cavity and the microcontroller 20 determines that it 301 is instead at the second predefined body cavity, the microcontroller 20 may be configured to activate the warning indicator 33 to indicate a warning

if the distal end 301 of the tube 300 is determined by the microcontroller 20 to be not at the first predefined body cavity after the first switch 21 has been activated. In this embodiment, the microcontroller 20 may further be configured to activate the warning indicator 33 to indicate a warning if it 20 detects that the distal end 301 of the tube 300 is neither at the first nor the second predefined body cavity after either the first switch 21 or the second switch 22 is activated.

[0047] In the exemplary embodiment shown in FIGS. 1-3 and 5-7, the top surface 18 of the housing 14 may comprise a membrane switch panel 18 in which the switches and indicators of the sensing unit 10 are provided. In this way, the switches and indicators are protected by a waterproof membrane of the membrane switch panel 18 that serves as a user interface of the apparatus 100. Preferably, a power switch 29 is also provided on the top surface 18 of the housing 14 to turn on the sensing unit 10, although in other embodiments the first switch 21 can also be configured to additionally function as a power switch besides functioning to activate the fluid bolus valve 17. In the sensing unit 10, the microcontroller 20, the valves 17, 94, the pressure sensors 16, 19 and the fluid pump 97 may be provided on a printed circuit board 40 provided in the housing 14, as shown in FIGS. 3 and 4. The switches 21, 22, 29 and indicators 31, 32, 33 provided on the top surface 18 of the housing 14 may be connected to the PCB 40 in order to be in communication with the microcontroller 20.

[0048] FIG. 11 shows an exemplary embodiment of the method 200 for determining location of the distal end 301 of the tube 300 inserted into a body cavity. FIG. 13 shows a fluid pathway and a signal pathway showing how fluid and signals flow through the various components of the apparatus 100 when the method 200 is performed. Referring to FIG. 11, the method 200 comprises first releasing at least one fluid bolus having a predefined pressure and a predefined volume from the fluid chamber 13 into the proximal end 302 of the tube 300 (201). This occurs when the user activates the first switch 21. Next, the method 200 comprises measuring, using the backpressure sensor 19, over a predetermined period of time, backpressure that arises as the at least one fluid bolus is released from the distal end 301 of the tube 300 into the body cavity (202). The method 200 next comprises generating, using the microcontroller 20, a backpressure profile from the measured backpressure (203). Thereafter, the method 200 comprises obtaining, using the microcontroller 20, characteristics of the generated backpressure profile (204). This is followed by determining, using the microcontroller 20, the location of the distal end 301 of the tube 300 according to the obtained characteristics (205) and then indicating the location of the distal end 301 of the tube 300 using the indicator 31 (206). Notably, indicating the location (206) encompasses indicating a warning if the distal end

301 of the tube 300 is determined to be not at a predefined body cavity that the apparatus 100 has been specifically configured to detect.

[0049] Using the above-described apparatus 100 and method 200, the location of the distal end 301 of the tube 300 can be quickly determined and indicated to a user, in a matter of seconds. The apparatus 100 provides a user-friendly, point-of-care location determination of the distal end 301 of the tube 300 without requiring use of x-ray or drawing of aspirate in the case where the tube 300 is an NGT. In this way, the patient is not exposed to any harmful radiation, and no additional foreign materials are introduced into the patient as all components of the apparatus 100 do not come into contact with the patient at any time during use. Cross-contamination between patients can also be avoided when the sensing unit 10 is shared as the cartridge 80 and connecting tube 90 are single-patient use while the sensing unit 10 does not come into contact with any fluid from the patient thanks to the anti-backflow valve provided in the cartridge 80. The apparatus 100 can be configured to determine multiple different body cavities into which a tube may be inserted, by storing the reference characteristics of these multiple different body cavities for comparison against the characteristics that are obtained during use of the apparatus 100 and providing the requisite indicators to show when the distal end 301 of the tube 300 has been determined to be at a specific body cavity.

[0050] While there has been described in the foregoing description exemplary embodiments of the present invention, it will be understood by those skilled in the technology concerned that many variations in details of design, construction and/or operation may be made without departing from the present invention. It will be appreciated that many further alterations, modifications and permutations of various aspects of the described embodiments are possible that fall within the spirit and scope of the appended claims.

[0051] Throughout this specification and the claims which follow, unless the context requires otherwise, the words “comprise” and “include”, and variations such as “comprises”, “comprising”, “includes” and “including” will be understood to imply the inclusion of a stated integer or group of integers or steps but not the exclusion of any other integer or group of integers or steps.

Claims

1. An apparatus for determining location of a distal end of a tube inserted into a body cavity, the apparatus comprising:

a sensing unit having a fluid outlet provided to form a fluid communication with a proximal end of the tube;

a fluid chamber provided in the sensing unit in fluid communication with the fluid outlet;

a fluid bolus valve provided in fluid communication between the fluid chamber and the fluid outlet, wherein upon activation of the fluid bolus valve when the proximal end of the tube is in fluid communication with the fluid outlet and the distal end of the tube is inserted into a body cavity, the fluid bolus valve is opened for a predefined period of time to release a fluid bolus having a predefined pressure and a predefined volume that travels from the fluid chamber through the tube into the body cavity;

a backpressure sensor provided in fluid communication with the fluid outlet to measure, over a predetermined period of time, backpressure that arises as the fluid bolus is released from the distal end of the tube into the body cavity;

a microcontroller provided in communication with the backpressure sensor and configured to generate a backpressure profile from the measured backpressure, the microcontroller further configured to obtain characteristics of the generated backpressure profile and to determine the location of the distal end of the tube according to the obtained characteristics;

a first switch provided on the sensing unit and activatable by a user to activate the fluid bolus valve; and

a first indicator provided on the sensing unit to indicate that the distal end of the tube is at a first predefined body cavity if so determined by the microcontroller.

2. The apparatus according to claim 1, further comprising:

a warning indicator provided on the sensing unit and activatable by the microcontroller to indicate a warning if the distal end of the tube is determined by the microcontroller to be not at the first predefined body cavity; and/or

a second indicator provided on the sensing unit to indicate that the distal end of the tube is at a second predefined body cavity if so determined by the microcontroller.

3. The apparatus according to claim 2, further comprising:

a second switch provided on the sensing unit and activatable by a user to activate the fluid bolus valve, wherein the warning indicator is further activatable by the microcontroller to

indicate a warning if the distal end of the tube is determined by the microcontroller to be not at the second predefined body cavity; and/ or

a third indicator provided on the sensing unit and activatable by the microcontroller to indicate that location of the distal end of the tube is unknown if the distal end of the tube has been determined by the microcontroller to be neither at the first predefined body cavity nor at the second predefined body cavity.

4. The apparatus according to any one of claims 1 to 3, wherein the fluid is air, wherein the sensing unit further comprises a fluid inlet, and wherein the apparatus further comprises a pump provided in fluid communication between the fluid inlet and the fluid chamber to pump ambient air into the fluid chamber.

5. The apparatus according to claim 4, further comprising:

a chamber pressure sensor provided to determine a chamber air pressure of air in the fluid chamber, wherein the microcontroller is in communication with the chamber pressure sensor and the pump, and wherein the pump is controllable by the microcontroller to keep the chamber air pressure at a preset chamber air pressure; and/or

a filter provided between the fluid inlet and the fluid chamber to filter the ambient air that is pumped into the fluid chamber,

wherein the sensing unit further comprises an exhaust outlet and wherein the fluid chamber is in fluid communication with the exhaust outlet via an exhaust valve configured to allow excess air to leave the fluid chamber when the chamber air pressure exceeds a predetermined safety pressure.

6. The apparatus according to any one of claims 1 to 5, further comprising:

a cartridge attachable to the sensing unit and to which the proximal end of the tube is connectable, the cartridge having a fluid passage therethrough to establish a fluid connection between the fluid outlet of the sensing unit and the proximal end of the tube, wherein a valve is provided in the fluid passage to prevent backflow of fluid from the tube to the fluid outlet; and/or

a connecting tube to establish a fluid connection between the cartridge and the proximal end of the tube.

7. The apparatus according to any one of claims 1 to 6, wherein the microcontroller is in communication with the first switch and the fluid bolus valve, and is configured to control activation of the fluid bolus valve upon activation of the first switch by the user; and/or

wherein the microcontroller is further configured to compare the obtained characteristics with predetermined characteristics of predetermined body cavities and to classify the location of the distal end of the tube according to the predefined body cavity of which the predetermined characteristics correlate with the obtained characteristics.

8. A method of determining location of a distal end of a tube inserted into a body cavity, the method comprising the steps of:

(a) releasing at least one fluid bolus having a predefined pressure and a predefined volume from a fluid chamber into a proximal end of the tube;

(b) measuring, using a backpressure sensor, over a predetermined period of time, backpressure that arises as the at least one fluid bolus is released from the distal end of the tube into the body cavity;

(c) generating, using a microcontroller, a backpressure profile from the measured backpressure;

(d) obtaining, using the microcontroller, characteristics of the generated backpressure profile, and then determining, using the microcontroller, the location of the distal end of the tube according to the obtained characteristics; and

(e) indicating the location of the distal end of the tube using an indicator.

9. The method according to claim 8,

wherein if the location determined in step (d) is a first predefined body cavity; step (e) comprises the microcontroller activating a first indicator provided to indicate that the distal end of the tube is at the first predefined body cavity;

wherein if the location determined in step (d) is a second predefined body cavity, step (e) comprises the microcontroller activating a second indicator provided to indicate that the distal end of the tube is at the second predefined body cavity; or

wherein if the location determined in step (d) is neither the first predefined body cavity nor the second predefined body cavity, step (e) comprises the microcontroller activating a third indicator provided to indicate that the distal end of the tube is unknown.

10. The method according to claim 9, further comprising:

the microcontroller activating a warning indicator if step (a) was performed by activating a first switch and the location determined in step (d) is not the first predefined body cavity; and/or

the microcontroller activating the warning indicator if the location determined in step (d) is neither the first predefined body cavity nor the second predefined body cavity.

11. The method according to any one of claims 8 to 10, wherein step (a) comprises releasing a plurality of fluid boli at predefined time intervals into the proximal end of the tube, and wherein step (b) comprises measuring the backpressure that arises as the plurality of fluid boli are released from the distal end of the tube into the body cavity.

12. method according to any one of claims 8 to 11, wherein the fluid is air and further comprising pumping ambient air into the fluid chamber to keep a chamber air pressure of air in the fluid chamber at a preset chamber air pressure.

13. The method according to claim 12, further comprising:

filtering the ambient air that is pumped into the fluid chamber using a filter; and/or

allowing excess air to leave the fluid chamber via an exhaust valve when the chamber air pressure exceeds a predetermined safety pressure.

14. The method according to any one of claims 8 to 13, further comprising, before step (a), providing a cartridge in fluid connection between a fluid outlet and the proximal end of the tube to prevent backflow of fluid from the tube to the fluid outlet using a valve provided in the cartridge; and/or before step (a), establishing a fluid connection between the cartridge and the proximal end of the tube using a connecting tube.

15. The method according to any one of claims 8 to 14, wherein step (e) comprises comparing the obtained characteristics with reference characteristics of predetermined body cavities and classifying the location of the distal end of the tube according to the predefined body cavity where the reference characteristics correlate with the obtained characteristics.