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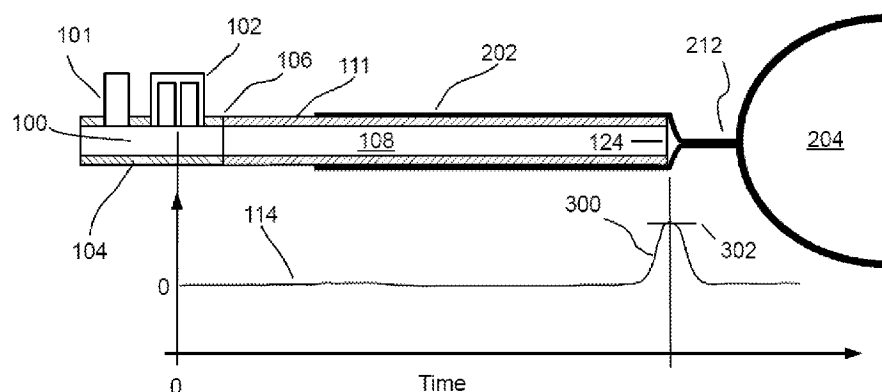


Fig. 4

(57) **Abstract:** A device and method for verifying the proper position of catheters in the body by means of acoustic reflectometry, the device including a sound source, one or more sound receivers, a tube with compliant walls and open distal end to be introduced through an entrance to a body cavity, the sound source and receiver(s) coupled to the proximal end of the tube, a processor for causing the sound source to generate an acoustic excitation signal, the processor processing the acoustic signals sensed by the sound receiver(s) and generating an approximation of the acoustic impulse response of the tube, and the processor analyzing the acoustic impulse response to determine the position of the tube in the body cavity.



ACOUSTIC REFLECTOMETRY DEVICE IN CATHETERS**CROSS-REFERENCE**

[0001] This application claims the benefit of U.S. Provisional Application No. 62/343,476, filed May 31, 2016, which application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] Nasogastric enteral access devices (for example, NG-EADs, enteral feeding tubes, nasogastric tubes, NG tubes, feeding tubes) are widely used in patients who require nutrition to be delivered directly to the stomach due to an inability to swallow foods on their own. For example, a patient who is being mechanically ventilated through an endotracheal tube (ETT) requires an NG tube because the ETT prevents the patient from swallowing without the risk of food being aspirated into the airways.

[0003] When properly positioning an NG tube in a patient, the tube tip is inserted through the nose into the esophagus and advanced into the stomach or farther into the duodenum. To confirm proper placement, a variety of methods are used according to the prior art, including chest x-rays and testing of aspirates for a pH reading between 1 and 5.5. However, errors in placement still occur either due to misinterpretation of the results (e.g. misreading of chest x-ray), unintentionally introducing substances in the NG tube that may cause false positive pH readings (flushing tube with water prior to placement), or failing to positively confirm placement in the first place. Accidental placement of the NG tube into the airway also is an ongoing concern and can lead to catastrophic consequences when fluids that are intended for the stomach are delivered directly into the lungs. This aspiration of fluids into the lungs frequently leads to pneumonia which carries risk of serious and potentially lethal complications. Accordingly, there is a need for an improved method and system for assisting in the proper placement of NG tubes.

[0004] Several apparatuses and methods for acoustically guiding, positioning, and monitoring tubes within a body are known. See, for example, U.S. Pat. Nos. 5,445,144 and 6,705,319 to Wodicka et al., the disclosure of which is incorporated herein by reference, which disclose an apparatus and method for acoustically monitoring the position of a tube (e.g., ETT) within an anatomical conduit. In various embodiments, a sound pulse is introduced into a wave guide and is recorded as it passes by one or more microphones located in the wave guide wall. As the sound pulse is propagating down the tube, reflected sound pulses arise from changes in cross-sectional area due to constrictions that may exist in the tube. The sound pulse is then emitted through the distal tip of the ETT into the airway (or wherever in the body the tip of the ETT is located) and an acoustic reflection propagates back up the ETT to the wave guide for measurement by the same microphone(s). The amplitude and the polarity of the incident and reflected sound pulse are used to estimate the characteristics of the airway and the ETT, and thereby guide the ETT placement or monitor the ETT for patency.

[0005] Another apparatus and method for examination and measurement of constrictions of passages in a cavity by means of acoustic reflectometry is described in U.S. Pat. No. 5,823,965 to Rasmussen. Rasmussen describes an acoustic reflectometer attached to a flexible closed-ended hose which is introduced into a cavity with the distal end of the hose placed past the zone of the passage to be examined. A transducer converts an activation signal from a signal generator to an excitation signal which is sent into the interior of the hose. A response signal which depends on the local deformation of the hose in the examined zone is picked up by a transducer and subjected to analysis in relation to the excitation signal. An analysis circuit and computer give an image on screen indicating the results of the examination.

[0006] Notably, Rasmussen teaches and claims a hose having only a closed distal end. Secondly, Rasmussen teaches and claims determining the internal cross-sectional shape of the

hose from the excitation and response signals while the present disclosure directly uses the reflection response signal to determine the location and degree of constrictions within the hose. The internal cross-sectional shape, or the cross-sectional area vs. distance profile, of the hose requires the additional step of calculating the profile using the Ware-Aki or similar algorithm as discussed in U.S. Pat. No. 4,326,416, which is cited by Rasmussen.

SUMMARY OF THE INVENTION

[0007] A method for use of acoustic reflectometry in nasogastric enteral access devices is disclosed. The method may include inserting a distal end of a nasogastric enteral access device through the nares a distance into a body and emitting sound waves from a sound generator into a proximal end of a nasogastric enteral access device. The method may also include detecting timings of returning acoustic reflections with at least one sound receiver, the acoustic reflections may include a first acoustic reflection of a first deformation in a wall of the nasogastric enteral access device from a first esophageal sphincter and using a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing timings of a first acoustic reflection to determine the distance the distal end of a nasogastric enteral access device is inserted into the body.

[0008] In some embodiments the method may include determining a length of the nasogastric enteral access device. In some embodiments the method may include determining the distance the distal end of the nasogastric enteral access device is inserted into the body based on the determined length of the nasogastric enteral access device and the timing of the returning acoustic reflections.

[0009] In some embodiments first esophageal sphincter is the lower esophageal sphincter. In some embodiments the first esophageal sphincter is the upper esophageal sphincter. In some embodiments, the returning acoustic reflections may include a second acoustic reflection of a second deformation in the wall of the nasogastric enteral access device from a second esophageal sphincter and may also include using the reflectometry device having the at least

one processor and the memory that is accessible to the processor for analyzing timings of the returning acoustic reflections to determine a distance the distal end of a nasogastric enteral access device is inserted past the second esophageal sphincter and indicating the distal end of the nasogastric enteral access device is in the stomach when the distal end of the nasogastric enteral access device is the distance passed the second esophageal sphincter.

[0010] In some embodiments, the first esophageal sphincter is a lower esophageal sphincter and may include using the reflectometry device having the at least one processor and the memory that is accessible to the processor for analyzing timings of the returning acoustic reflections to determine a distance the distal end of a nasogastric enteral access device is inserted past the lower esophageal sphincter. In some embodiments the method may include indicating that the distal end of the nasogastric enteral access device is in the stomach when the distal end of the nasogastric enteral access device is the distance passed the lower esophageal sphincter.

[0011] In some embodiments, determining a constant distance between the first deformation and the second deformation may include detecting a plurality of timings between the first and second acoustic reflections over a time period and comparing the plurality of timings and determining that that timings vary by less than 5% over the time period.

[0012] In some embodiments, the nasogastric enteral access device may be advanced or withdrawn within the esophagus or stomach during the time period.

[0013] In some embodiments, detecting amplitudes of the returning acoustic reflections with the at least one sound receiver may occur over a time period and include detecting a base and dynamic component of the amplitude over the time period. In some embodiments, the dynamic component coincides with a respiratory cycle of the patient.

[0014] In some embodiments, the method may include clearing the nasogastric enteral access device by providing positive pressure into the nasogastric enteral access device to push fluids out the distal end of the nasogastric enteral access device.

[0015] A method for use of acoustic reflectometry in nasogastric enteral access devices is disclosed. The method may include inserting a distal end of a nasogastric enteral access device through the nares a distance into a body and emitting sound waves from a sound generator into a nasogastric enteral access device. The method may also include detecting amplitudes and timings of returning acoustic reflections with at least one sound receiver at a plurality positions of the distal end of the nasogastric enteral access device within the body and using a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing amplitudes and timings of the returning acoustic reflections to detect a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, the positive amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

[0016] In some embodiments, the method may include indicating, based on the detection of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, that the distal end of the nasogastric enteral access device is above or at the lower esophageal sphincter, the positive amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

[0017] In some embodiments, the method may include using the reflectometry device having the at least one processor and the memory that is accessible to the processor for analyzing amplitudes and timings of the returning acoustic reflections to detect a negative amplitude deflection in the acoustic reflections at a second position of the distal end of the nasogastric enteral access device within the body, the second position being further advanced into the body as compared to the first position and the negative amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

[0018] In some embodiments, the method may include indicating, based on the detection of a positive amplitude deflection at the first position and the negative amplitude at the second position, that the distal end of the nasogastric enteral access device is within a stomach.

[0019] In some embodiments, the detecting may occur as the distal end of the nasogastric enteral access device is advancing in the body. In some embodiments, the detecting occurs while the distal end of the nasogastric enteral access device is stationary within the body.

[0020] In some embodiments, the method may include estimating a distance to the lower esophageal sphincter prior to inserting the nasogastric enteral access device into the stomach and indicating, based on the detection and timings of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body and the estimated distance to the lower esophageal sphincter, that the distal end of the nasogastric enteral access device is at the lower esophageal sphincter.

[0021] In some embodiments, the nasogastric enteral access device comprises a plurality of ports, and the method may include acoustically coupling an acoustic reflectometer, including the sound generator and a sound receiver, to a first of the plurality of ports and occluding a second or more of the plurality of ports not coupled to the sound generator.

[0022] In some embodiments, the method may include calibrating the nasogastric enteral access device using a reflectometry device having at least one processor and a memory that is accessible to the processor by determining the amplitude of an acoustic reflection arising from the distal end of the nasogastric enteral access device being open to air.

[0023] A method for use of acoustic reflectometry in nasogastric enteral access devices is also disclosed. The method may include estimating a distance to the lower esophageal sphincter prior to inserting the enteral access device into the stomach; inserting a distal end of a nasogastric enteral access device through the nares a distance into a body as indicated by a distance marking on the outside of the nasogastric enteral access device that is visible at the nares and emitting sound waves from a sound generator into a nasogastric enteral access

device. The method may also include detecting amplitudes and timings of returning acoustic reflections with at least one sound receiver at a plurality positions of the distal end of the nasogastric enteral access device within the body and using a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing amplitudes and timings of the returning acoustic reflections to detect a negative amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, the negative amplitude deflection in the acoustic reflection being from the distal end of the nasogastric enteral access device. In some embodiments, the first and second negative amplitude deflections may be consecutive.

[0024] In some embodiments, the method may include indicating, based on the detection of the first and second negative amplitude deflections at the first position, that the distal end of the nasogastric enteral access device is within a trachea.

[0025] In some embodiments, the method may include indicating, based on the detection of a negative amplitude deflection at a first position and the insertion distance of the first position being less than the estimated distance to the lower esophageal sphincter, that the distal end of the nasogastric enteral access device is within a trachea.

[0026] In some embodiments, the method may include indicating that the distal end of the nasogastric enteral access device is within a trachea upon detection of a second negative amplitude deflection in the acoustic reflections.

[0027] A system for use of acoustic reflectometry in nasogastric enteral access devices is also disclosed. The system may include a nasogastric enteral access device and a sound generator acoustically coupled to the proximal end of a nasogastric enteral access device to emit sound waves into the nasogastric enteral access device. The system may also include at least one sound receiver to detect timings of returning acoustic reflections, the acoustic reflections including a first acoustic reflection of a first deformation in a wall of the nasogastric enteral access device from a first esophageal sphincter and a reflectometry device having at least one

processor and a memory that is accessible to the processor for analyzing timings of the returning acoustic reflections to determine the distance the distal end of a nasogastric enteral access device is inserted into the body. In some embodiments, the reflectometry device is configured to determine the distance the distal end of the nasogastric enteral access device is inserted into the body based on a length of the nasogastric enteral access device and the timing of the first acoustic reflection.

[0028] In some embodiments, the first esophageal sphincter is a lower esophageal sphincter; and the reflectometry device is configured to indicate that the distal end of the nasogastric enteral access device is in the stomach when the distal end of the nasogastric enteral access device is a distance passed the lower esophageal sphincter.

[0029] In some embodiments, the returning acoustic reflections include a second acoustic reflection of a second deformation in the wall of the nasogastric enteral access device from a second esophageal sphincter and the reflectometry device may be configured to determine the distal end of the nasogastric enteral access device is in the stomach when the distal end of the nasogastric enteral access device is a distance passed the second esophageal sphincter.

[0030] In some embodiments, the reflectometry device may configured to determine a constant distance between the first deformation and the second deformation by detecting a plurality of timings between the first and second acoustic reflections over a time period and comparing the plurality of timings and determining that that timings vary by less than 5% over the time period.

[0031] In some embodiments, the reflectometry device may be configured to detect amplitudes of the returning acoustic reflections with the at least one sound receiver over a time period and detect a base and dynamic component of the amplitude over the time period.

[0032] A system for use of acoustic reflectometry in nasogastric enteral access devices is also disclosed. The system may include a nasogastric enteral access device and a sound generator to emit sound into the nasogastric enteral access device. The system may include at least one

sound receiver to detect amplitudes and timings of returning acoustic reflections at a plurality positions of a distal end of the nasogastric enteral access device within a body and a reflectometry device having at least one processor and a memory that is accessible to the processor configured to analyze amplitudes and timings of the returning acoustic reflections and to detect a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, the positive amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

[0033] In some embodiments, the reflectometry device may be configured to indicate, based on the detection of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, that the distal end of the nasogastric enteral access device is above or at the lower esophageal sphincter, the positive amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

[0034] In some embodiments, the reflectometry device may be configured to analyze amplitudes and timings of the returning acoustic reflections to detect a negative amplitude deflection in the acoustic reflections at a second position of the distal end of the nasogastric enteral access device within the body, the second position being further advanced into the body as compared to the first position and the negative amplitude deflection in acoustic reflections being from the distal end of the nasogastric enteral access device.

[0035] In some embodiments, the reflectometry device is configured to indicate, based on the detection of a positive amplitude deflection at the first position and the negative amplitude at the second position, that the distal end of the nasogastric enteral access device is within a stomach.

[0036] In some embodiments, the sound receiver is configured to detect the reflections as the distal end of the nasogastric enteral access device advances in the body. In some

embodiments, the sound receiver is configured to detect the reflections while the distal end of the nasogastric enteral access device is stationary within the body.

[0037] In some embodiments, the reflectometry device is configured with an estimate of a distance to the lower esophageal sphincter prior to inserting the nasogastric enteral access device into the stomach and to indicate, based on the detection and timings of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body and the estimated distance to the lower esophageal sphincter, that the distal end of the nasogastric enteral access device is at the lower esophageal sphincter.

[0038] In some embodiments, the nasogastric enteral access device comprises a plurality of ports, and the acoustic reflectometer is acoustically coupled to a first of the plurality of ports and a second or more of the plurality of ports not coupled to the sound generator are occluded.

[0039] A system for use of acoustic reflectometry in nasogastric enteral access devices is disclosed. The system may include a nasogastric enteral access device having a proximal end and a distal end and a sound generator to emit sound waves into a nasogastric enteral access device. The system may also include at least one sound receiver to detect amplitudes and timings of returning acoustic reflections a plurality positions of the distal end of the nasogastric enteral access device within a body and a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing amplitudes and timings of the returning acoustic reflections to detect first and second negative amplitude deflections in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body.

[0040] In some embodiments, the first and second negative amplitude deflections are consecutive.

[0041] In some embodiments, the reflectometry device is configured to indicate, based on the detection of the first and second negative amplitude deflections at the first position, that the distal end of the nasogastric enteral access device is within a trachea.

[0042] In some embodiments, the reflectometry device is further configured to indicate, based on the detection of a negative amplitude deflection at a first position and the insertion distance of the first position being less than an estimated distance to the lower esophageal sphincter, that the distal end of the nasogastric enteral access device is within a lower airway.

[0043] In some embodiments, the reflectometry device is configured to indicate that the distal end of the nasogastric enteral access device is within a trachea upon detection of a second negative amplitude deflection in the acoustic reflections, the first negative amplitude deflection being from the distal end of the nasogastric enteral access device and the second negative amplitude deflection being from a location within an airway, distal to the distal end of the nasogastric enteral access device.

INCORPORATION BY REFERENCE

[0044] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0045] The features and advantages of this disclosure, and the manner of attaining them, will be more apparent and better understood by reference to the following descriptions of the disclosed methods and systems, taken in conjunction with the accompanying drawings, wherein:

[0046] FIG. 1 shows a drawing of the acoustic reflectometry system connected to a tube which is inserted into a body cavity containing a constriction.

[0047] FIG. 2 illustrates the placing of an NG tube with attached acoustic reflectometer into body passages leading to the stomach.

[0048] FIG. 3 illustrates the placing of an NG tube with attached acoustic reflectometer into body passages leading to the lungs.

[0049] FIG. 4 shows a drawing of the acoustic reflectometry device connected to a tube with the distal tube end inserted into an esophagus.

[0050] FIG. 5 shows a drawing of the acoustic reflectometry device connected to a tube with the distal tube end inserted into a stomach.

[0051] FIG. 6 shows a drawing of the acoustic reflectometry device connected to a tube with the distal tube end inserted into a trachea.

DETAILED DESCRIPTION OF THE INVENTION

[0052] For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of this disclosure is thereby intended.

[0053] The present disclosure includes disclosure of devices and methods for verifying the proper position of catheters in a human body by means of acoustic reflectometry. The device comprises a sound source, one or more sound receivers, and a tube with compliant walls and open distal end to be introduced through an entrance to a body cavity. The sound source and receiver(s) are coupled to the proximal end of the tube. The device includes a processor for causing the sound source to generate an acoustic excitation signal. The processor then processes the acoustic signals sensed by the sound receiver(s), generates an approximation of the acoustic impulse response of the tube, and analyzes the acoustic impulse response to determine the position of the tube in the body cavity.

[0054] The embodiment of the present disclosure shown in FIG. 1 uses an acoustic reflectometry device **100** which includes a sound generator **101** and one or more sound

receivers **102** embedded into the wall of a wave tube **104**. The sound generator **101** and sound receiver(s) **102** are in communication with a processor **105** with attached display **107**. Two sound receivers may be used as described in Wodicka 6,705,319 for a compact acoustic reflectometer that provides the means to separate the incident and reflected acoustic signals and thereby simplifies the calculation of an approximation of the acoustic impulse response (reflection waveform) **114**. The acoustic impulse response **114** can be calculated using an excitation signal from the sound generator **101** that comprises acoustic energy over the frequencies of interest (e.g. 0.1-10 kHz), including a broadband sound pulse or white noise. The distal wave tube end **106** is coupled to the proximal end of an open-ended NG tube **108**. When NG tube **108** is inserted into a body cavity **109**, there may arise one or more local deformations **110** of the tube wall **111** due to a narrowed or constricted region **112** within the passageway **109** such as from a sphincter or other structure that applies pressure on the compliant tube wall **111**. The corresponding acoustic impulse response **114** derived by the processor from the sound receiver **102** signals contains a sound reflection **116** that arises from the constriction **110** within the tube **108**. The time delay **118** (t_c) of the sound reflection **116** and the speed of sound c in air are used to calculate a first distance **120** (d_1) between the sound receiver(s) **102** and the tube constriction **110** using the equation, $d = \frac{ct_c}{2}$, where the 2 in the divisor accounts for the round trip travel of the sound between the sound receiver(s) **102** and tube constriction **110**. A second distance **122** (d_2) between the constriction **110** and the distal tube end **124** is calculated by subtracting the first distance **120** (d_1) from the tube length **126** (d_{tube}). The tube length **126** may either be known in advance, provided by the user, or determined during a calibration step to estimate the tube length **126**. The calibration step to estimate the tube length **126** could consist of obtaining an acoustical measurement prior to inserting the tube **108** into the body passageway **109** and calculating tube length **126** by using

the time delay of the sound reflection from the distal tube end **124** obtained from the corresponding acoustic reflection waveform **114**.

[0055] FIG. 2 depicts one embodiment of the acoustic reflectometer **100** attached to NG tube **108** which is inserted into a body cavity comprising a nasal cavity **200**, esophagus **202**, and stomach **204**. The NG tube **108** may have a first local deformation **206** at the upper esophageal sphincter (UES) **208** and a second local deformation **210** at the lower esophageal sphincter (LES) **212**. The locations of the first and second local deformations **206** and **210** along the NG tube **108** are estimated using the delay times of their respective sound reflections using the equation previously described. The distance **122** by which the distal tube end **124** is past the LES **212** extending into the stomach **204** is calculated as previously described using the distance of the second local deformation **210** and the NG tube length **126** (from FIG. 1). This distance **122** can be used to guide the position of the distal tube end **124** into the desired location in or past the stomach **204**. For example, if it is desired to position the tube end **124** through the stomach **204** into the duodenum **205**, then distance **122** as reported by the system can be increased an amount determined by the user to put the tube end **124** approximately into the duodenum **205**.

[0056] It is possible that fluids such as from the nasal passageway **200**, esophagus **202**, stomach **204**, or elsewhere, or any combination thereof, may enter the distal tube end **124** and result in a false positive detection of a constriction of the NG tube wall **111**. As a preventative measure, it may be necessary to connect a device such as an air filled syringe to the wave tube proximal end **212** and provide a bolus of positive pressure air with the syringe to flow air through the NG tube and push fluids through the NG tube **108** and out of the distal tube end **124**.

[0057] Positive confirmation of the distal tube end **124** into the stomach **204** is provided when the device detects the second local deformation **210** arising from the LES **212** constricting the tube wall **111**. An additional positive confirmation of the NG tube **108**

traversing the length of the esophagus **202** with the distal tube end **124** located past the LES **212** is the presence of the first and second local deformations **206** and **210** that arise from the UES **208** and LES **212**, respectively. Further confirmation that the NG tube **108** is inserted fully through the esophagus **202** is the observation of a constant distance between the deformations **206** and **210** in the NG tube **108** as it is advanced into or withdrawn from the stomach **204**. A constant distance may be determined based on multiple distance observations being within a threshold value of each other. For example, the distance variance may be within 1%, 5%, or 10% of each other, or within 0.5 cm, 1 cm, 2 cm, or 3 cm of each other.

[0058] It is possible that additional structures within the body cavities traversed by the NG tube **108** may cause temporary local deformations in the tube wall **111**. These structures may include the nasopharynx **214** which may close voluntarily by the patient or involuntarily during swallowing. There may also be other structures within the upper airway that may cause local deformations in the tube wall **111**.

[0059] The lower esophageal sphincter **212** has several characteristics that allow discrimination of the deformation of the tube wall **111** due to the LES **212** from deformation due to other structures. The LES base pressure is typically between 6-20 mmHg and has a dynamic component that increases 15-20 mmHg during the inspiratory phase of tidal inspiration, and with forceful inspiration the increase can be 100-150 mmHg. The dynamic component may be periodic. This varying pressure on the tube wall **111** causes the tube wall **111** deformation to also vary such that the degree of constriction of the NG tube **108** is correlated to the pressure. This varying NG tube constriction due to the LES **212** can be observed as a change in amplitude of the sound reflection **116** (Figure 1) arising from the constriction. If the acoustic reflectometry device **100** is configured to collect a complete acoustic reflection waveform **114** multiple times per second, then the change in constriction size as a function of time (over seconds) can be observed and used as a positive confirmation that the constriction in the NG tube **108** is from the LES **212**.

[0060] Another characteristic of the LES **212**, as well as the UES **208**, is the relaxation that occurs during swallowing. During swallowing, the LES relaxation lasts 6-10 seconds. Again, if the acoustic reflectometry device **100** is configured to collect a complete acoustic reflection waveform **116** multiple times per second, then the change in constriction size as a function of time (over seconds) can be observed and used to confirm the presence of the relaxation period that is synchronized with swallowing. If this relaxation period is observed, then it can be used as another indicator of positive confirmation that the constriction in the NG tube **108** is from the LES **212**.

[0061] The abovementioned characteristics of the LES **212** that are observable in the acoustic reflection signal **114** may be used individually or in some combination to positively confirm that the NG distal tube end **124** is extended past the LES **212** into the stomach **204**.

[0062] FIG. 3 depicts the NG tube **108** erroneously advanced past the vocal folds **216** into the trachea **218**. In this case, the tube wall deformations due to compression by the UES **208** and LES **212**, respectively, along with their individual characteristics discussed above, will not be observed. It is possible that closure of the vocal folds **216** may pinch the tube **108** and be detected as a constriction by the acoustic reflectometer **100**, but this constriction will not have the same characteristics as those arising from the structures **208** and **212** within the esophagus **202**. The lower airway may be the airway below the vocal folds.

[0063] Referring to FIG. 4, if the NG tube wall **111** is not sufficiently compliant to deform from a narrowed or constricted region within the esophagus **202**, then there are alternate means to verify that the distal tube end **124** is past the LES **212** and extending into the stomach **204**.

[0064] The acoustic reflection **300** arising from the distal tube end **124** is related to the cross-sectional areas of the catheter lumen and the passageway immediately around the opening of the distal tube end **124**. This relationship is described as

$$S_1 = \left(\frac{1-R}{1+R} \right) S_0 \quad (1)$$

where S_0 and S_1 are the respective cross-sectional areas of the catheter lumen and passageway immediately around the opening of the distal tube end **124**, and R is the dimensionless reflection coefficient ($-1 \leq R \leq 1$) related to the amplitude **302** of the acoustic reflection **300** arising from the distal tube end **124**. The value of R for the acoustic reflection **300** can be determined by measuring the acoustic reflection amplitude, A_{cal} , arising for a known S_0 and S_1 during a calibration step and using this value to calculate R . For example, upon connection of the device **100** to the NG tube **108** and prior to insertion of the tube **108** into the patient, an acoustic measurement can be obtained while the distal tube end **124** is open to air (case where $S_1 \approx \infty$). The amplitude of the resulting acoustic reflection arising from the distal tube end **124**, A_{cal} , would represent the case for $R_{open} = -1$. Then, all subsequent amplitude measurements, A **302**, of the acoustic reflection **300** arising from the distal tube end **124** can be converted into a reflection coefficient using

$$R = R_{open} \frac{A}{A_{cal}} \quad (2)$$

Then R may be applied to (1) to estimate the cross-sectional area, S_1 , of the passageway immediately around the distal tube end **124**.

[0065] In an alternate embodiment, A_{cal} may be obtained *a priori* for catheters of a specified diameter, length, manufacturer, and model, and stored within a lookup table. It may be necessary to know the manufacturer and model of a catheter because the sound attenuation through the catheter may be affected by the catheter wall mechanical properties which may vary between manufacturers and models of catheters. In yet another embodiment, A_{cal} may be calculated from an equation, $A_{cal}(d, l)$ that is empirically derived using data points for A_{cal} that are obtained experimentally over varying catheter diameters, d , and lengths, l , (and manufacturers and models, if necessary).

[0066] Again, referring to FIG. 4, if the distal tube end **124** is located proximally to or at the LES **212** within the esophagus **202**, then the esophageal tissue will close off the distal tube end **124** by virtue of the tissue's collapsible nature over the tip opening and the resulting acoustic reflection **300** arising from the closed distal tube end **124** will be detected as a positive deflection **302** in the reflection waveform **114**. In contrast, as shown in FIG. 5, if the distal tube end **124** is located distal to the LES **212** within the stomach **204**, then the distal tube end **124** will be open into the cavity formed by the stomach **204**, and the resulting acoustic reflection **300** arising from the open distal tube end **124** will be detected as a negative deflection **304** in the reflection waveform **114**.

[0067] In some embodiments, prior to insertion, the proper insertion distance of the NG tube **108** into a patient is estimated using a commonly employed method of measuring the total distance from the nose to the ear lobe to the xiphoid process. During advancement of the NG tube into the body, the timings and amplitudes of the reflections of the waveform **114** are detected. In some embodiments, placement of the distal end of the NG tube at the LES may occur based on the detection and timings of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, for example, when the distal end of the NG tube is at the LES, and the estimated distance to the LES, that the distal end of the nasogastric enteral access device is at the lower esophageal sphincter.

[0068] By using the markings showing distance from the distal tube end **124** to the nares or mouth, typically provided along the outside of the NG tube **108**, one can note the presence or absence of a collapsed cavity (e.g. the esophagus, stomach, or trachea) around the distal tube end **124** while advancing the NG tube **108** by detecting the amplitude and polarity of the reflection wave **300** arising from the distal tube end **124**. Prior to insertion, the proper insertion distance of the NG tube **108** into a patient is estimated using a commonly employed method of measuring the total distance from the nose to the ear lobe to the xiphoid process.

During insertion of the NG tube **108**, guidance of the distal tube end **124** is provided by detecting the amplitude and timings of an acoustic reflection **300** that has either a positive deflection (collapsed esophagus) or small negative deflection (partially collapsed esophagus) while the distal tube end is advancing in the esophagus **202**. When the distal tube end **124** enters the stomach **204**, this is confirmed by detecting a large negative deflection **304** arising from the distal tube end **124**. The estimated proper insertion distance should approximately agree with the insertion distance at which the cavity around the distal tube end **124** transitioned from collapsed or partially collapsed (esophagus) to open (stomach).

[0069] Improper placement of the NG tube **108** into the trachea **218** (FIG. 6) is indicated by detecting an acoustic reflection **300** that has a significant negative deflection **306** (the trachea) at an insertion distance of the NG tube **108** significantly smaller than the estimated proper insertion distance to the stomach. This small insertion distance is due to the distal tube end **124** entering the trachea **218** where it would have instead started entering the esophagus just below the upper airway if proper placement had occurred. In addition, if the NG tube diameter **310** is of comparable size to that of the trachea **218**, there may be adequate acoustic energy transmission between the tube **108**, trachea **218**, and airways **312** to observe the characteristic echo **308** from the airways that arises from the branching generations where the total cross-sectional area grows rapidly. The presence of this negative going airway echo **308** in the acoustic reflection waveform **114** may provide an additional confirmation that the distal tube end **124** is improperly placed in the trachea **218**.

[0070] The proximal ports for NG tubes can vary in number depending on the intended use for the tube. For example, some NG tubes may have two or more ports to allow administration of both food and medications simultaneously. If an NG tube is used that contains two or more ports, it may be necessary to occlude all of the ports with plugs except for the one acoustically coupled to the acoustic reflectometer. This will prevent extraneous acoustic reflections arising from the ports from interfering with the reflections arising from

within the NG tube and cavities in which the tube is inserted. In one embodiment, the plug diameters are made to fit the inner diameter of the ports and the plug lengths are made to extend into the port far enough to completely fill the port and, therefore, minimize the increase in cross-sectional area of the NG tube resulting from the port. In another embodiment, a calibration procedure is used to measure the reflection echoes arising from the ports in their open or closed states and remove their effects on the entire acoustic reflection signal either through methods such as subtraction or deconvolution.

[0071] While this disclosure has been described as having preferred designs, the apparatus and methods according to the present disclosure can be further modified within the scope and spirit of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the disclosure using its general principles. For example, any methods disclosed herein and in the appended claims represent one possible sequence of performing the steps thereof. A practitioner may determine in a particular implementation that a plurality of steps of one or more of the disclosed methods may be combinable, or that a different sequence of steps may be employed to accomplish the same results. Each such implementation falls within the scope of the present disclosure as disclosed herein and in the appended claims. Furthermore, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this disclosure pertains.

CLAIMS

WHAT IS CLAIMED IS:

1. A method for use of acoustic reflectometry in nasogastric enteral access devices, the method comprising:
 - inserting a distal end of a nasogastric enteral access device through the nares a distance into a body;
 - emitting sound waves from a sound generator into a proximal end of a nasogastric enteral access device;
 - detecting timings of returning acoustic reflections with at least one sound receiver, the acoustic reflections including a first acoustic reflection of a first deformation in a wall of the nasogastric enteral access device from a first esophageal sphincter; and
 - using a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing timings of the returning acoustic reflections to determine the distance the distal end of a nasogastric enteral access device is inserted into the body.
2. The method of claim 1, further comprising:
 - determining a length of the nasogastric enteral access device.
3. The method of any of preceding claims 1 or 2, wherein determining the distance the distal end of the nasogastric enteral access device is inserted into the body is based on the determined length of the nasogastric enteral access device and the timing of the first acoustic reflection.
4. The method of any of preceding claims 1 - 3, wherein the first esophageal sphincter is the lower esophageal sphincter.
5. The method of any of preceding claims 1 - 4, wherein the first esophageal sphincter is the upper esophageal sphincter.
6. The method of any of preceding claims 1 - 5, wherein the returning acoustic reflections include a second acoustic reflection of a second deformation in the wall of the nasogastric enteral access device from a second esophageal sphincter; and

using the reflectometry device having the at least one processor and the memory that is accessible to the processor for analyzing timings of the returning acoustic reflections to determine a distance the distal end of a nasogastric enteral access device is inserted past the second esophageal sphincter; and

indicating the distal end of the nasogastric enteral access device is in the stomach when the distal end of the nasogastric enteral access device is the distance passed the second esophageal sphincter.

7. The method of any of preceding claims 1 - 6, wherein the first esophageal sphincter is a lower esophageal sphincter; and

using the reflectometry device having the at least one processor and the memory that is accessible to the processor for analyzing timings of the returning acoustic reflections to determine a distance the distal end of a nasogastric enteral access device is inserted past the lower esophageal sphincter; and

indicating that the distal end of the nasogastric enteral access device is in the stomach when the distal end of the nasogastric enteral access device is the distance passed the lower esophageal sphincter.

8. The method of any of preceding claims 1 - 7, further comprising:

determining a constant distance between the first deformation and the second deformation by:

detecting a plurality of timings between the first and second acoustic reflections over a time period; and

comparing the plurality of timings and determining that that timings vary by less than 5% over the time period.

9. The method of claim any of preceding claims 1 - 8, wherein the nasogastric enteral access device is advanced or withdrawn within the esophagus or stomach during the time period.

10. The method of claim any of preceding claims 1 - 9, further comprising:

detecting amplitudes of the returning acoustic reflections with the at least one sound

receiver over a time period; and

detecting a base and dynamic component of the amplitude over the time period.

11. The method of any of preceding claims 1 - 10, wherein the dynamic component coincides with a respiratory cycle of the patient.

12. The method of claim any of preceding claims 1 - 11, further comprising:

clearing the nasogastric enteral access device by providing positive pressure into the nasogastric enteral access device to push fluids out the distal end of the nasogastric enteral access device.

13. A method for use of acoustic reflectometry in nasogastric enteral access devices, the method comprising:

inserting a distal end of a nasogastric enteral access device through the nares a distance into a body;

emitting sound waves from a sound generator into a nasogastric enteral access device;

detecting amplitudes and timings of returning acoustic reflections with at least one sound receiver at a plurality positions of the distal end of the nasogastric enteral access device within the body; and

using a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing amplitudes and timings of the returning acoustic reflections to detect a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, the positive amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

14. The method of claim 13, further comprising:

indicating, based on the detection of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, that the distal end of the nasogastric enteral access device is above or at the lower esophageal sphincter, the positive amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

15. The method of any of preceding claims 13 or 14, further comprising:

using the reflectometry device having the at least one processor and the memory that is accessible to the processor for analyzing amplitudes and timings of the returning acoustic reflections to detect a negative amplitude deflection in the acoustic reflections at a second position of the distal end of the nasogastric enteral access device within the body, the second position being further advanced into the body as compared to the first position and the negative amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

16. The method of any of preceding claims 13 - 15, further comprising:

indicating, based on the detection of a positive amplitude deflection at the first position and the negative amplitude at the second position, that the distal end of the nasogastric enteral access device is within a stomach.

17. The method of any of preceding claims 13 - 16, wherein the detecting occurs as the distal end of the nasogastric enteral access device is advancing in the body.

18. The method of any of preceding claims 13 - 17, wherein the detecting occurs while the distal end of the nasogastric enteral access device is stationary within the body.

19. The method of any of preceding claims 13 - 18, further comprising:

estimating a distance to the lower esophageal sphincter prior to inserting the nasogastric enteral access device into the stomach; and

indicating, based on the detection and timings of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body and the estimated distance to the lower esophageal sphincter, that the distal end of the nasogastric enteral access device is at the lower esophageal sphincter.

20. The method of any of preceding claims 13 - 19, wherein the nasogastric enteral access device comprises a plurality of ports, and further comprising:

acoustically coupling an acoustic reflectometer, including the sound generator and a

sound receiver, to a first of the plurality of ports; and

occluding a second or more of the plurality of ports not coupled to the sound generator.

21. The method of any of preceding claims 13 - 20, further comprising:

calibrating the nasogastric enteral access device using a reflectometry device having at least one processor and a memory that is accessible to the processor by determining the amplitude of an acoustic reflection arising from the distal end of the nasogastric enteral access device being open to air.

22. A method for use of acoustic reflectometry in nasogastric enteral access devices, the method comprising:

estimating a distance to the lower esophageal sphincter prior to inserting the nasogastric enteral access device into the stomach;

inserting a distal end of a nasogastric enteral access device through the nares the distance into a body as indicated by a distance marking on the outside of the nasogastric enteral access device that is visible at the nares; emitting sound waves from a sound generator into a nasogastric enteral access device; and

detecting amplitudes and timings of returning acoustic reflections with at least one sound receiver at a plurality positions of the distal end of the nasogastric enteral access device within the body; and

using a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing amplitudes and timings of the returning acoustic reflections to detect a negative amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, the negative amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

23. The method of claim 22, further comprising:

indicating, based on the detection of a negative amplitude deflection at a first position and the insertion distance of the first position being less than the estimated distance to the lower

esophageal sphincter, that the distal end of the nasogastric enteral access device is within a trachea.

24. The method any of preceding claims 22 or 23, further comprising, indicating that the distal end of the nasogastric enteral access device is within a trachea upon detection of a second negative amplitude deflection in the acoustic reflections.

25. A system for use of acoustic reflectometry in nasogastric enteral access devices, the system comprising:

a nasogastric enteral access device;

a sound generator acoustically coupled to the proximal end of a nasogastric enteral access device to emit sound waves into the nasogastric enteral access device;

at least one sound receiver to detect timings of returning acoustic reflections, the acoustic reflections including a first acoustic reflection of a first deformation in a wall of the nasogastric enteral access device from a first esophageal sphincter; and

a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing timings of the returning acoustic reflections to determine the distance the distal end of a nasogastric enteral access device is inserted into the body.

26. The system of claim 25, wherein the reflectometry device is configured to determine the distance the distal end of the nasogastric enteral access device is inserted into the body is based on a length of the nasogastric enteral access device and the timing of the first acoustic reflection.

27. The system of any of preceding claims 25 or 26, wherein the returning acoustic reflections include a second acoustic reflection of a second deformation in the wall of the nasogastric enteral access device from a second esophageal sphincter; and

the reflectometry device is configured to indicate the distal end of the nasogastric enteral access device is in the stomach when the distal end of the nasogastric enteral access device is a distance passed the second esophageal sphincter.

28. The system of any of preceding claims 25 - 27, wherein the first esophageal sphincter is a lower esophageal sphincter; and

the reflectometry device is configured to indicate that the distal end of the nasogastric enteral access device is in the stomach when the distal end of the nasogastric enteral access device is a distance passed the lower esophageal sphincter.

29. The system of any of preceding claims 25 – 28, wherein:

the reflectometry device is configured to determine a constant distance between the first deformation and the second deformation by:

detecting a plurality of timings between the first and second acoustic reflections over a time period; and

comparing the plurality of timings and determining that that timings vary by less than 5% over the time period.

30. The system of any of preceding claims 25 - 29, wherein:

the reflectometry device is configured to detect amplitudes of the returning acoustic reflections with the at least one sound receiver over a time period and detect a base and dynamic component of the amplitude over the time period.

31. A system for use of acoustic reflectometry in nasogastric enteral access devices, the system comprising:

a nasogastric enteral access device;

a sound generator to emit sound into the nasogastric enteral access device;

at least one sound receiver to detect amplitudes and timings of returning acoustic reflections at a plurality positions of a distal end of the nasogastric enteral access device within a body; and

a reflectometry device having at least one processor and a memory that is accessible to the processor configured to analyze amplitudes and timings of the returning acoustic reflections and to detect a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, the positive amplitude deflection in the

acoustic reflections being from the distal end of the nasogastric enteral access device.

32. The system of claim 31, wherein:

the reflectometry device configured to indicate, based on the detection of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, that the distal end of the nasogastric enteral access device is above or at the lower esophageal sphincter, the positive amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

33. The system of any of preceding claims 31 or 33, wherein:

the reflectometry device is configured to analyzing amplitudes and timings of the returning acoustic reflections to detect a negative amplitude deflection in the acoustic reflections at a second position of the distal end of the nasogastric enteral access device within the body, the second position being further advanced into the body as compared to the first position and the negative amplitude deflection in acoustic reflections being from the distal end of the nasogastric enteral access device.

34. The system of any of preceding claims 31 - 33, wherein:

the reflectometry device is configured to indicate, based on the detection of a positive amplitude deflection at the first position and the negative amplitude at the second position, that the distal end of the nasogastric enteral access device is within a stomach.

35. The system of any of preceding claims 31 - 34, wherein the sound receiver is configured to detect the reflections as the distal end of the nasogastric enteral access device advances in the body.

36. The system of any of preceding claims 31 - 35, wherein the sound receiver is configured to detect the reflections while the distal end of the nasogastric enteral access device is stationary within the body.

37. The system of any of preceding claims 31 - 36, wherein:

the reflectometry device is configured with an estimate of a distance to the lower esophageal sphincter prior to inserting the nasogastric enteral access device into the stomach and to indicate, based on the detection and timings of a positive amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body and the estimated distance to the lower esophageal sphincter, that the distal end of the nasogastric enteral access device is at the lower esophageal sphincter.

38. The system of any of preceding claims 31 - 37, wherein the nasogastric enteral access device comprises a plurality of ports, and wherein the acoustic reflectometer is acoustically coupled to a first of the plurality of ports and a second or more of the plurality of ports not coupled to the sound generator are occluded.

39. A system for use of acoustic reflectometry in nasogastric enteral access devices, the system comprising:

- a nasogastric enteral access device having a proximal end and a distal end;
- a sound generator to emit sound waves into a nasogastric enteral access device;
- at least one sound receiver to detect amplitudes and timings of returning acoustic reflections a plurality positions of the distal end of the nasogastric enteral access device within a body;

and

a reflectometry device having at least one processor and a memory that is accessible to the processor for analyzing amplitudes and timings of the returning acoustic reflections to detect a negative amplitude deflection in the acoustic reflections at a first position of the distal end of the nasogastric enteral access device within the body, the negative amplitude deflection in the acoustic reflections being from the distal end of the nasogastric enteral access device.

40. The system of claim 39, wherein the reflectometry device is further configured to indicate, based on the detection of a negative amplitude deflection at a first position and the insertion distance of the first position being less than an estimated distance to the lower esophageal sphincter, that the distal end of the nasogastric enteral access device is within a lower airway.

41. The system of any of preceding claims 39 or 40, wherein:

the reflectometry device is configured to indicate that the distal end of the nasogastric enteral access device is within a trachea upon detection of a second negative amplitude deflection in the acoustic reflections, the first negative amplitude deflection being from the distal end of the nasogastric enteral access device and the second negative amplitude deflection being from a location within an airway, distal to the distal end of the nasogastric enteral access device.

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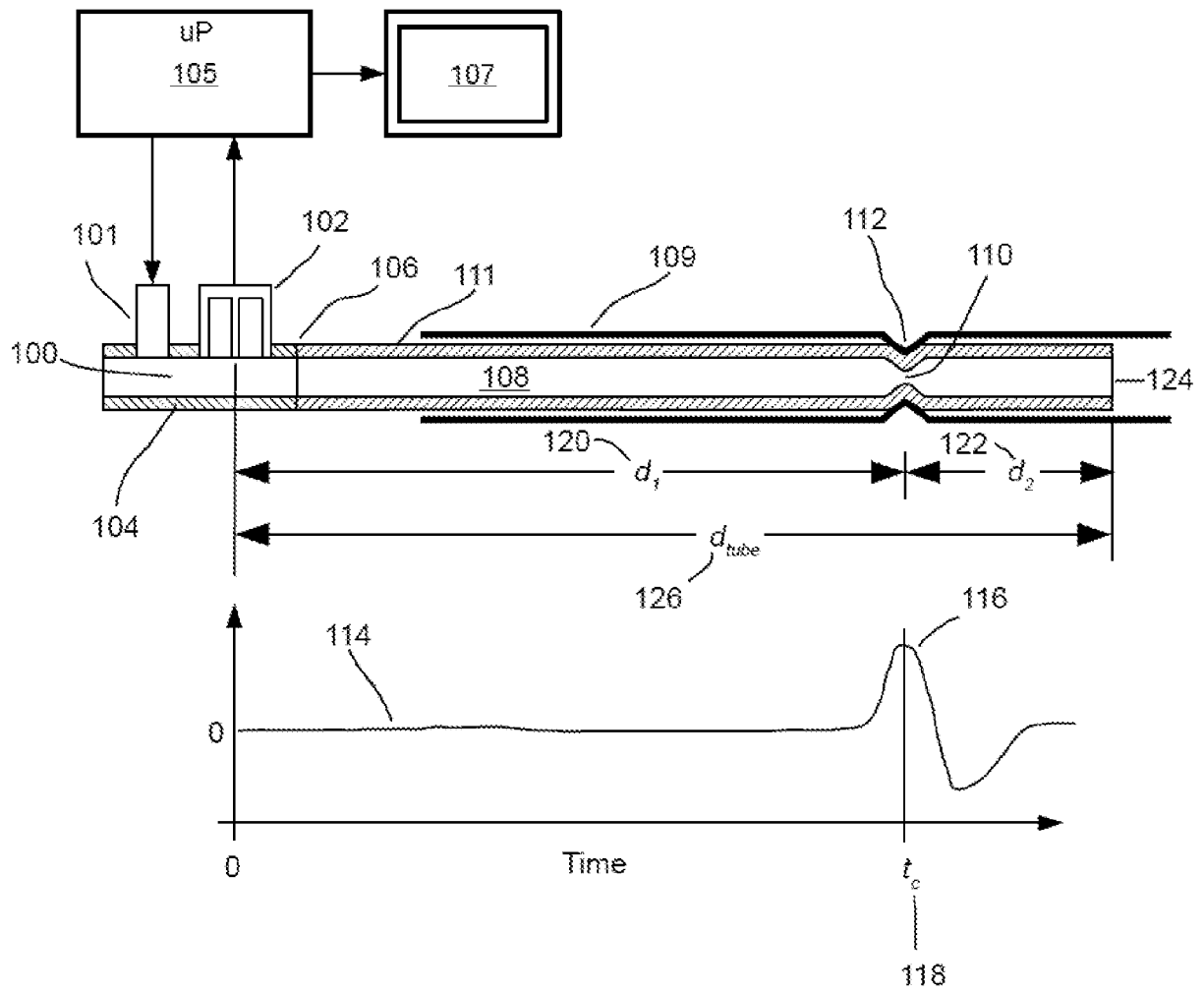


Fig. 1

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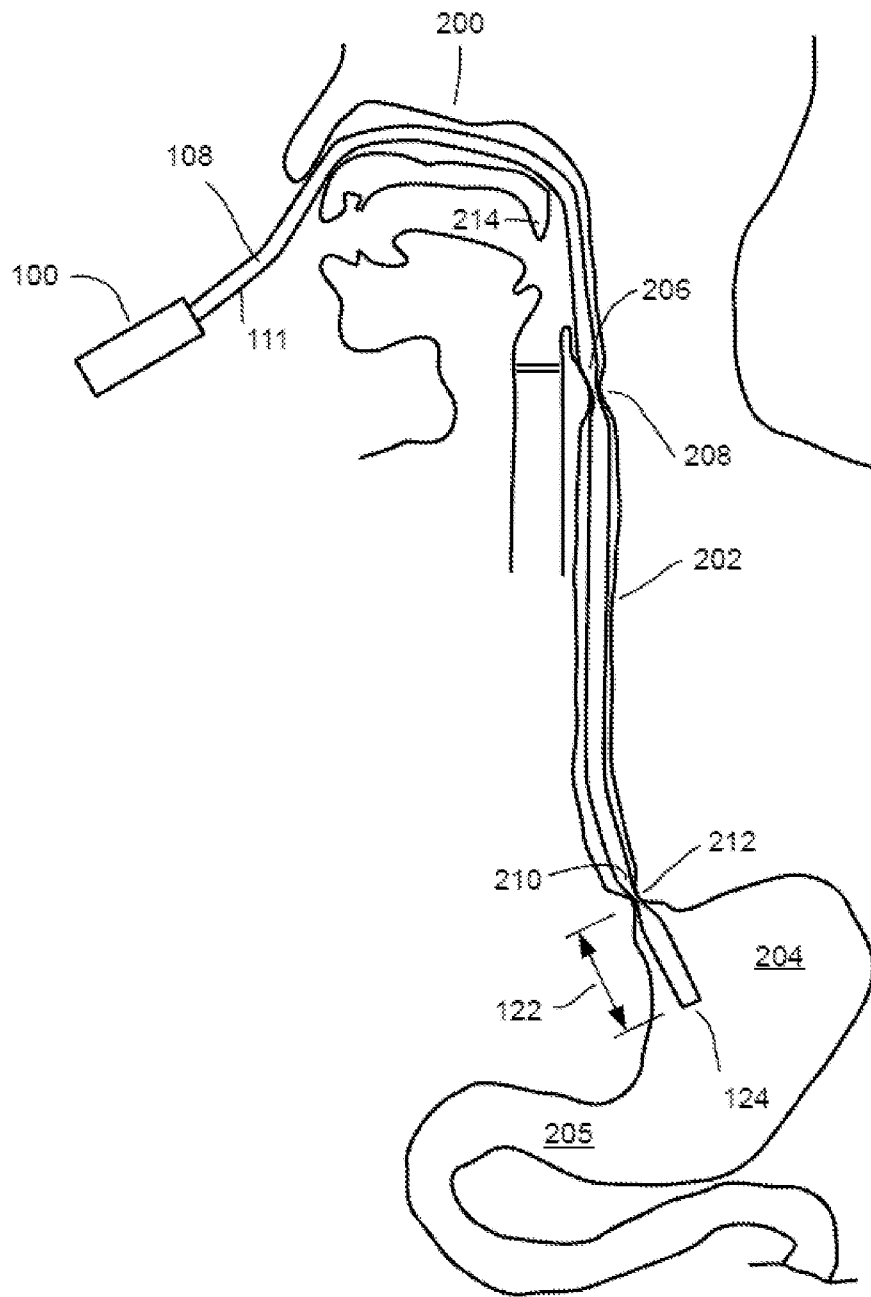


Fig. 2

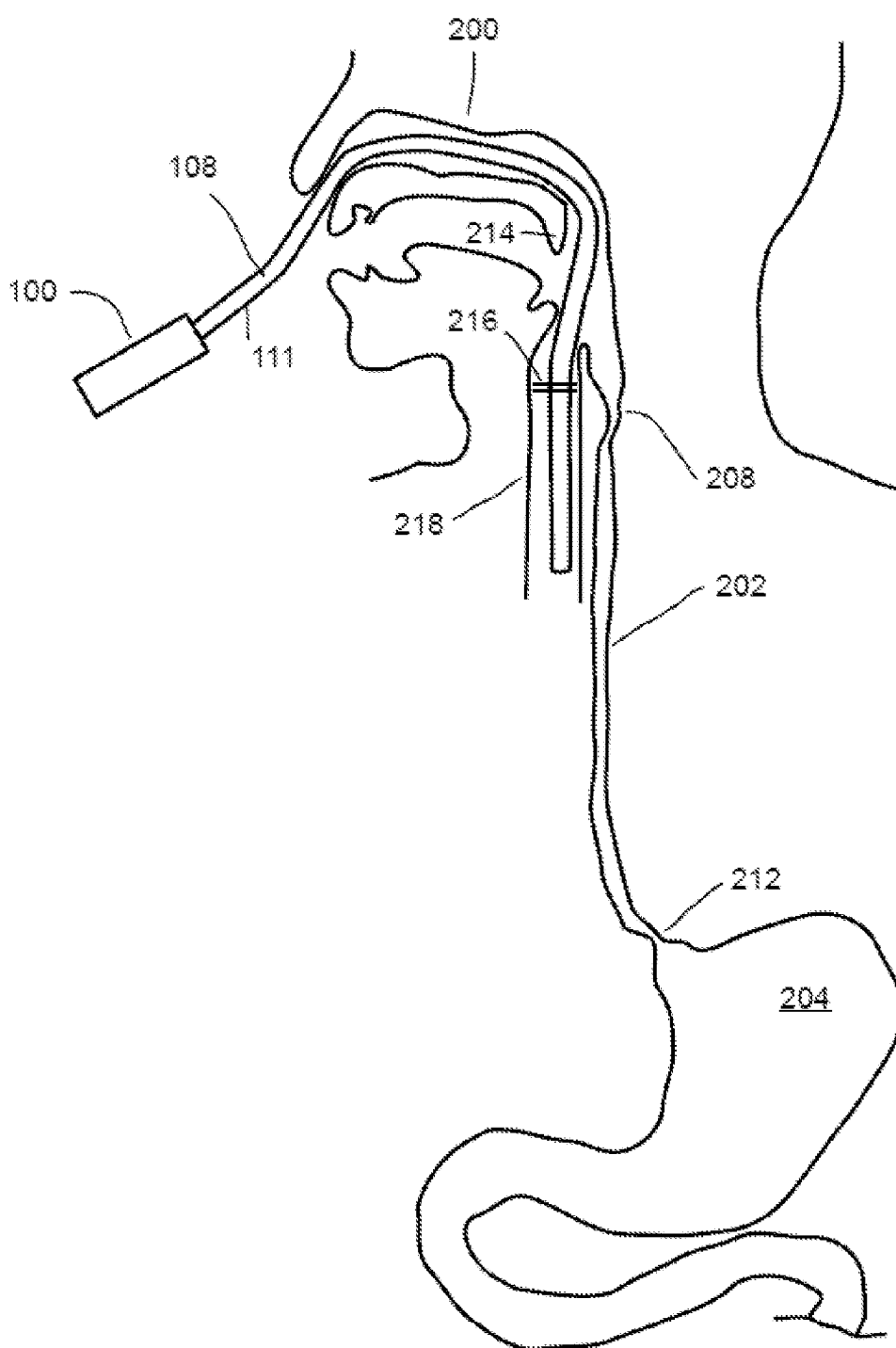


Fig. 3

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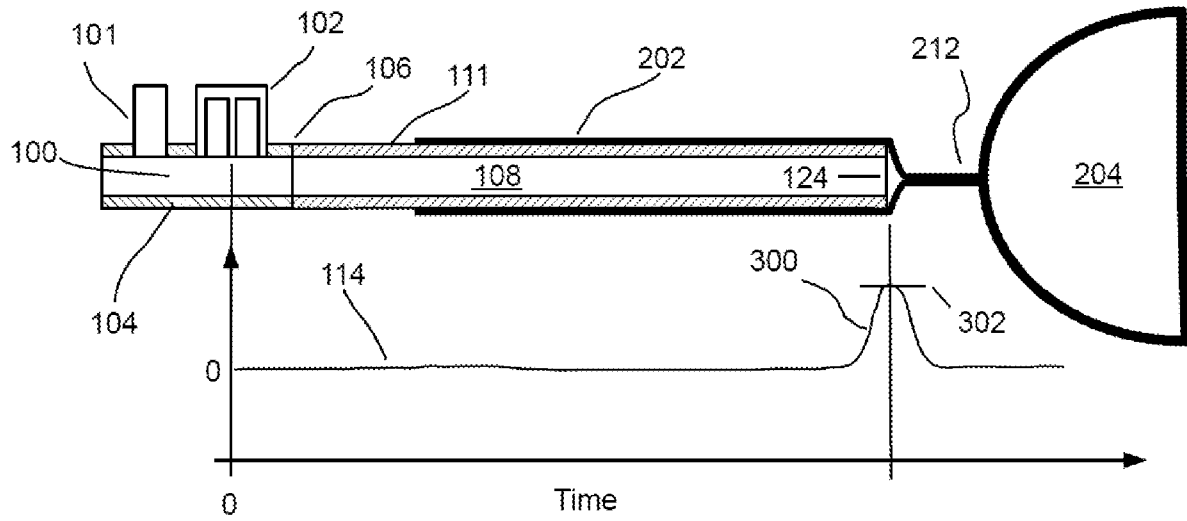


Fig. 4

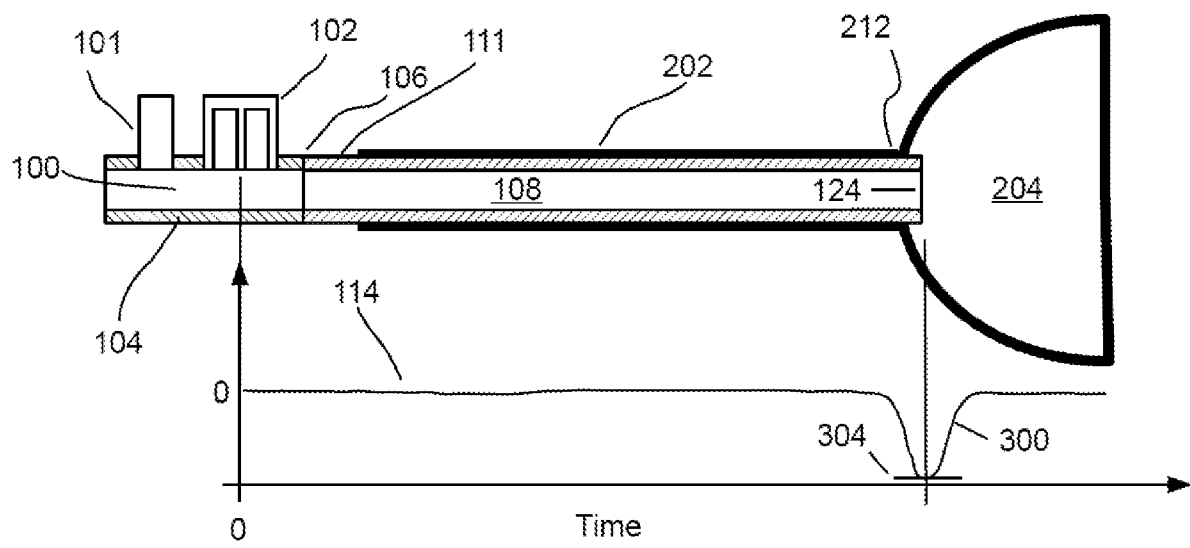


Fig. 5

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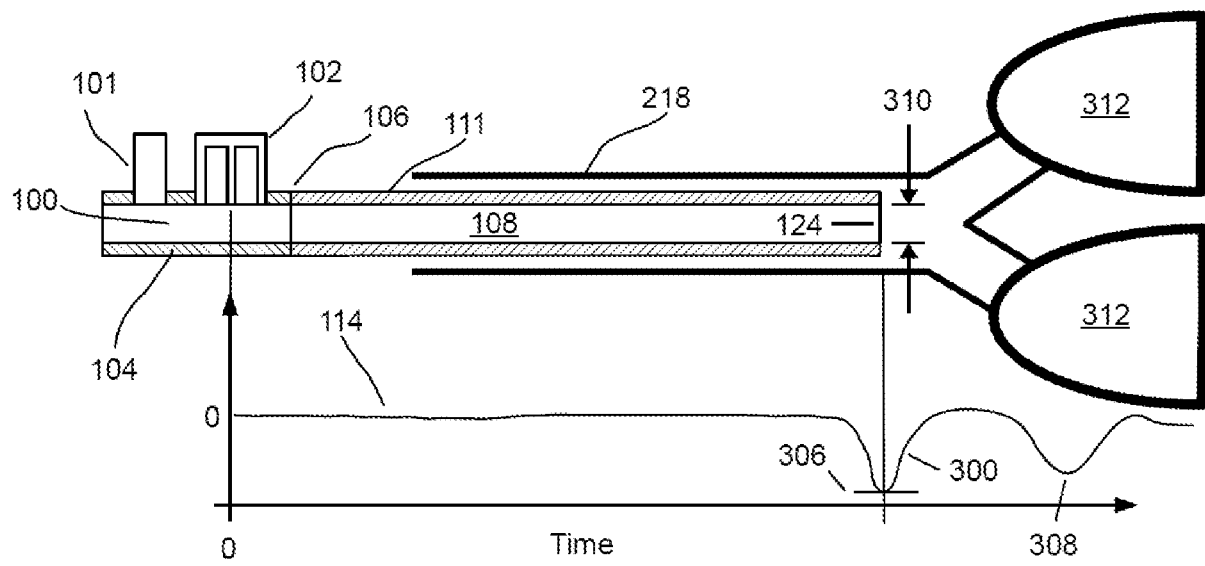


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/035299

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/00; A61B 5/06; A61M 16/00; A61M 16/04; A61M 25/01 (2017.01)

CPC - A61B 5/06; A61B 5/061; A61M 16/0411; A61M 16/0461; A61M 16/0465; A61M 16/0488; A61M 25/01; A61M 25/0105; A61M 2025/0166; A61M 2205/186; A61M 2205/3375; A61M 2210/1032 (2017.05)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC - 128/200.24; 128/202.22; 128/207.14; 600/424; 600/585; 604/528 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0187164 A1 (ROWE) 23 July 2009 (23.07.2009) entire document	13, 31
Y	US 2013/0255691 A1 (MANSFIELD et al) 03 October 2013 (03.10.2013) entire document	13, 31
A	US 2003/0034035 A1 (RAPHAEL) 20 February 2003 (20.02.2003) entire document	1-3, 13-15, 22-27, 31-33, 39-41
A	US 6,705,319 B1 (WODICKA et al) 16 March 2004 (16.03.2004) entire document	1-3, 13-15, 22-27, 31-33, 39-41
A	US 5,445,144 A (WODICKA et al) 29 August 1995 (29.08.1995) entire document	1-3, 13-15, 22-27, 31-33, 39-41

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 July 2017

Date of mailing of the international search report

10 AUG 2017

Name and mailing address of the ISA/US

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PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/035299

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4-12, 16-21, 28-30, 34-38
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

专利名称(译)	导管中的声反射计		
公开(公告)号	EP3463061A4	公开(公告)日	2019-12-11
申请号	EP2017807434	申请日	2017-05-31
[标]申请(专利权)人(译)	SONARMED		
申请(专利权)人(译)	SONARMED INC.		
当前申请(专利权)人(译)	SONARMED INC.		
[标]发明人	MANSFIELD JEFFREY LYONS LAURA L		
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摘要(译)

一种通过声反射法验证导管在体内的正确位置的装置和方法，该装置包括声源，一个或多个声音接收器，具有顺应性壁的管和要通过入口引入的远端开口 体腔，声源和接收器，其耦合到管的近端，处理器，用于使声源产生声激发信号，处理器处理由声接收器感测到的声信号并产生 使管的声脉冲响应近似，并且处理器分析声脉冲响应以确定管在体腔中的位置。