(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 September 2020 (10.09.2020)

WIPO | PCT

(10) International Publication Number
WO 2020/180483 A1

(51) International Patent Classification:
A61B 5/06 (2006.01) *A61B 5/08* (2006.01)

(21) International Application Number:
PCT/US2020/018614

(22) International Filing Date:
18 February 2020 (18.02.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
16/291,093 04 March 2019 (04.03.2019) US

(71) Applicant: **AVENT, INC.** [US/US]; 5405 Windward Parkway, Alpharetta, Georgia 30004 (US).

(72) Inventor: **ASHTAROLNAKHAI, Shadi**; c/o Avent, Inc., 5405 Windward Parkway, Alpharetta, Georgia 30004 (US).

(74) Agent: **RICHMOND, Allison, L.** et al.; Dority & Manning, P.A., P. O. Box 1449, Greenville, South Carolina 29602-1449 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(54) Title: SYSTEM, METHOD, AND APPARATUS FOR DETECTING TUBE MISPLACEMENT IN A PATIENT'S AIRWAY

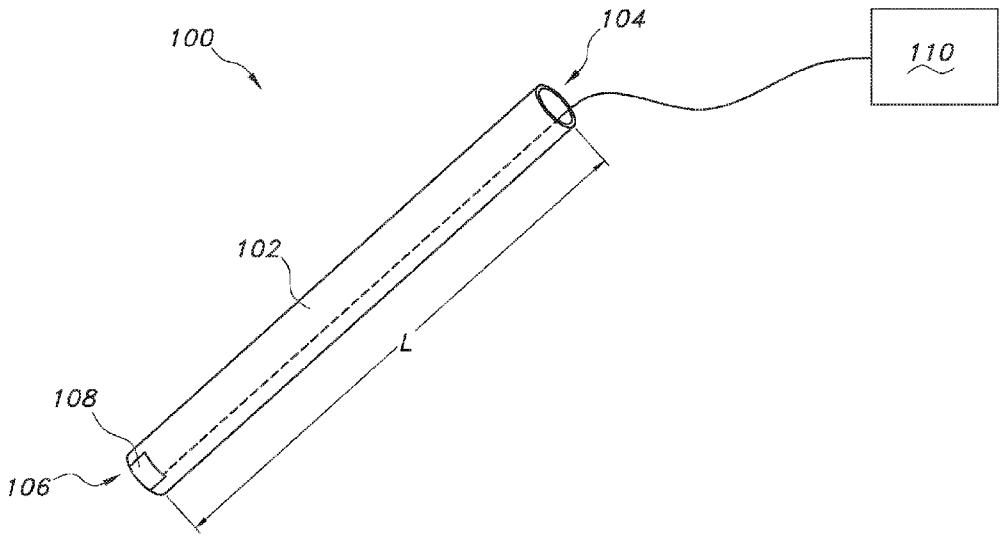


FIG. 1A

(57) Abstract: Tube tip detection systems, enteral tubes, and methods for detecting tube misplacement in a patient's airway are provided. For example, a tube tip detection system comprises an enteral tube having a tip, a first sensing component disposed at the tip, and a feedback display. Feedback from the first sensing component is displayed on the feedback display to indicate to a user of the tube tip detection system whether the tip is misplaced in a patient's airway. Similarly, an enteral tube comprises a tip, a length, and a sensing component. The sensing component is a micro-electro-mechanical system (MEMS) infrared carbon dioxide sensor. Further, a detection method comprises embedding a carbon dioxide sensing component into an enteral tube, inserting the enteral tube into the patient through the patient's nose or mouth, and monitoring feedback from the carbon dioxide sensing component to determine if the enteral tube is traveling into the patient's airway.

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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

SYSTEM, METHOD, AND APPARATUS FOR DETECTING TUBE MISPLACEMENT IN A PATIENT'S AIRWAY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Application Serial No. 16/291,093, filed March 4, 2019, the contents of which are incorporated herein by reference thereto.

FIELD

The present subject matter relates generally to a system, method, and apparatus for administering fluids to body cavities and, more particularly, to such systems, methods, and apparatus utilizing a carbon dioxide sensor to detect whether a tube is incorrectly inserted into a patient's airway.

BACKGROUND

Physicians and other health care providers frequently use catheters, which include tubes inserted into the human body, to treat patients. A nasogastric (NG) tube is one type of tube that is placed in the gastrointestinal tract for patients experiencing a variety of ailments. NG tubes are placed through the nasal cavity and are intended to traverse through the esophagus down into the stomach and into the small bowel, if desired. As the tube travels through the oropharynx and hypopharynx, the anatomy splits into the trachea and the esophagus. Tubes commonly are misplaced into the trachea, which can result in pneumonia, pneumothoraces, or even death. As such, there is a critical need for a way to determine when the tube has taken the path of the trachea as opposed to the desired path of the esophagus.

In some cases, health care providers use X-ray machines to gather information about the location of the catheters within the body. There are several disadvantages in using X-ray machines. For instance, X-rays from these machines are a known carcinogen, if received in sufficient doses. Also, X-ray machines are relatively large and heavy, consume a relatively large amount of energy, and may expose the patient to a relatively high degree of radiation. Moreover, these machines are typically not readily accessible for use because, due to their size, they are usually installed in a special X-ray room. This room can be relatively far away from the patient's room. Therefore, health care providers may find it inconvenient to use these machines for their catheter procedures. Further, it can be inconvenient to

transport these machines to a patient's home for home care catheter procedures. As such, X-ray confirmation of the tube tip position may be performed only when the position is uncertain, and the enteral tube position more commonly is checked by assessing the pH of tube aspirate. However, it can be difficult to determine a practical pH cutoff level for reliable confirmation of NG tube placement, particularly for pediatric patients.

In other cases, electromagnetism is used to monitor the location or position of the enteral tube tip. For example, an electromagnetic stylet inserted into the patient's body with the enteral tube may provide real-time location information on the tube tip placement within a patient's anatomy. A receiver unit outside the body detects an electromagnetic field transmitted by the stylet and provides on-screen visualization and, thereby, immediate feedback on tube placement. Nevertheless, due to, e.g., variation in placement of the receiver unit and user misinterpretations of the feedback from the electromagnetic stylet, a health care provider can fail to recognize a misplacement of the enteral tube tip within the patient's airway.

Thus, recognition of the airway when placing an enteral tube is an important way to prevent harm to a patient, and the art is continuously seeking new and improved systems, apparatus, and methods for determining a location of a tip of a catheter, such as an NG tube, being inserted into a patient. For instance, an improved enteral tube, such as an NG tube, incorporating means for detecting carbon dioxide to determine whether the enteral tube is being improperly inserted in a patient's airway would be useful. More particularly, embedding one or more CO_2 sensors in an enteral tube, such as an NG tube, for detecting the CO_2 concentration along the path of the tube would be desirable. Further, incorporating a micro-electro-mechanical system (MEMS) that detects CO_2 in a range of the CO2 concentration in a person's exhaled breath into, e.g., the tip of the enteral tube would be useful. Additionally, systems for conveying feedback from such carbon dioxide sensors to a health care provider would be beneficial. Moreover, methods for detecting a tube misplacement in a patient's airway utilizing such carbon dioxide sensors would be advantageous.

SUMMARY

Objects and advantages of the invention will be set forth in part in the following description, or may be obvious from the description, or may be learned through practice of the invention.

In one aspect, the present subject matter is directed to a tube tip detection system that comprises an enteral tube having a tip, a first sensing component disposed at the tip, and a feedback display. Feedback from the first sensing component is displayed on the feedback display to indicate to a user of the tube tip detection system whether the tip is misplaced in a patient's airway. It should also be understood that the system may further include any of the additional features as described herein.

In another aspect, the present disclosure is directed to an enteral tube that comprises a tip, a length, and a sensing component. The sensing component is a micro-electro-mechanical system (MEMS) infrared carbon dioxide sensor. It should also be appreciated that the enteral tube may further include any of the additional features as described herein.

In yet another aspect, the present disclosure is directed to a method for detecting a tube misplacement in a patient's airway. The method comprises embedding a carbon dioxide sensing component into an enteral tube, inserting the enteral tube into the patient through the patient's nose or mouth, and monitoring feedback from the carbon dioxide sensing component to determine if the enteral tube is traveling into the patient's airway. It should also be understood that the method may further include any of the additional features as described herein.

These and other features, aspects and advantages of the present subject matter will become better understood with reference to the following description and appended claims. The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and, together with the description, serve to explain the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

A full and enabling disclosure of the present subject matter, including the best mode thereof, directed to one of ordinary skill in the art, is set forth in the specification, which makes reference to the appended figures, in which:

FIG. 1A provides a schematic view of a tube tip detection system having an enteral tube, a sensing component embedded in the enteral tube, and a feedback display, according to an exemplary embodiment of the present subject matter.

FIG. 1B illustrates the tube tip detection system of FIG. 1A and provides an enlarged view of a tip of the enteral tube.

FIG. 2 illustrates a tube tip detection system according to another exemplary embodiment of the present subject matter, the system having an enteral tube and more than one sensing component embedded in the enteral tube.

FIG. 3 provides a side perspective view of a portion of an enteral tube having a plurality of sensing components disposed in a channel formed in a wall of the enteral tube.

FIG. 4 provides a schematic view of a human patient with a tip of an enteral tube entering the patient's airway and a sensing component disposed at or near the tip to detect that the tip is entering the patient's airway.

FIG. 5 provides a flow diagram illustrating a method for detecting a tube misplacement in a patient's airway.

DETAILED DESCRIPTION

Reference will now be made in detail to one or more embodiments of the invention, examples of the invention, examples of which are illustrated in the drawings. Each example and embodiment is provided by way of explanation of the invention, and is not meant as a limitation of the invention. For example, features illustrated or described as part of one embodiment may be used with another embodiment to yield still a further embodiment. It is intended that the invention include these and other modifications and variations as coming within the scope and spirit of the invention.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other

embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

Generally, the present subject matter provides catheters for intubating patients having one or more sensing components for sensing carbon dioxide to determine, using the carbon dioxide concentration sensed by the sensing component(s), whether the catheter is being inserted into the patient's airway. Certain catheters are inserted into through the patient's nose or mouth and extend into the patient's gastrointestinal tract and, thus, also may be referred to as enteral catheters or enteral tubes. More particularly, enteral tubes inserted through the patient's nose are called nasogastric (NG) tubes, which typically are feeding tubes. The feeding tube tip, through which a fluid flows into the patient, is disposed in the stomach or intestines, and a feeding source delivers liquid nutrient, liquid medicine, or a combination of the two to the patient. Because erroneous placement of the tube tip may injure or harm the patient, particularly if the tube is misplaced into the patient's airway, it is important to place the tip of the tube at the proper location within the patient's body. Thus, the present subject matter provides enteral tubes having one or more carbon dioxide sensors, which continuously sense carbon dioxide as the enteral tube is inserted into a patient such that a user (such as a health care provider) can determine whether the enteral tube is being misplaced into the patient's airway, where the carbon dioxide concentration is increased compared to the carbon dioxide concentration in the correct placement area, the patient's esophagus and gastrointestinal tract. Further, the present subject matter provides systems and methods for detecting a tube misplacement in a patient's airway.

Referring now to the drawings, FIGS. 1A and 1B illustrates a tube tip detection system 100 having an enteral tube 102 that includes a proximal end or head 104 and a distal end or tip 106. The enteral tube 102 has a length L between the proximal end 104 and the tip 106. Further, the enteral tube 102 should have an appropriate diameter and be sufficiently flexible for insertion through, e.g., a patient's nose or mouth and into the patient's gastrointestinal tract. For instance, the enteral tube 102 should have a size within a range of five to seven French (5 Fr to 7 Fr) for pediatric patients and within a range of ten to twelve French (8 Fr to 12 Fr) for adult patients.

In exemplary embodiments the enteral tube 102 is a nasogastric (NG) tube, which, through a process called nasogastric intubation, is inserted through a patient's nose into the patient's stomach. In other exemplary embodiments, the enteral tube 102 is an orogastric (OG) tube inserted during orogastric intubation through the patient's mouth into the stomach. Alternatively, the tube tip 106 may extend into the patient's intestines rather than the stomach. Whether the tip 106 is disposed in the stomach or intestines may depend on, e.g., the specific needs of the patient. For typical nasogastric intubations or orogastric intubations, the tube tip 106 should be in a sub-diaphragmatic position in the stomach, e.g., at least ten (10) centimeters (cm) beyond the gastro-esophageal junction (GOJ), also known as the oesophagogastric junction, which is the part of the gastrointestinal tract where the esophagus and stomach are joined.

As discussed herein, misplacement of the tip 106 in the patient's airway, e.g., the bronchi or the lungs, rather than in the patient's gastrointestinal tract is a complication of nasogastric or orogastric intubation. To avoid such misplacement, the present subject matter provides enteral tubes 102 with sensing components to detect whether the tube tip 106 is being misplaced in the patient's airway. In the depicted embodiment, a first sensing component 108 is disposed at the tip 106, and a feedback display 110 is disposed at the head 104. In exemplary embodiments, the first sensing component 108 is a micro-electro-mechanical system (MEMS) component, which provides a miniaturized sensor having appropriate dimensions to be embedded in a wall 112 of enteral tube 102 at its tip 106. More specifically, silicon-based MEMS sensors can be fabricated in small sizes, such as in micrometer (μm) to millimeter (mm) sizes, in clean rooms and then embedded in enteral tubes 102. Feedback from the first sensing component 108 is displayed on the feedback display 110 to indicate to a user of the tube tip detection system 100 whether the tip 104 is misplaced in a patient's airway or is properly placed in the patient's esophagus or gastrointestinal tract. The user may be a health care provider, such as a physician, clinician, nurse, etc.

The MEMS component 108 includes one or more MEMS active and passive components that form a non-dispersive infrared (IR) sensor. Carbon dioxide (CO2) strongly absorbs infrared radiation at a wavelength of 4.3 μm. Further, the CO_2 concentration at the end of a person's exhaled breath is approximately 5% to 6% of the exhaled air, which corresponds to about 35 mmHg to about 45 mmHg.

Therefore, the MEMS infrared sensor is configured to detect CO_2 to determine whether the enteral tube is being misplaced in the patient's airway and may be referred to as a MEMS infrared carbon dioxide sensor 108. More particularly, the MEMS component 108 includes an IR emitter 108a and an IR receiver 108b, which form the MEMS infrared carbon dioxide sensor 108. The IR emitter 108a emits infrared radiation, and the IR receiver 108b receives any reflected radiation. An IR path length between the IR emitter 108a and the IR receiver 108b dictates the CO_2 concentration the IR carbon dioxide sensor 108 can detect. Thus, the MEMS component 108, particularly the IR emitter 108a and IR receiver 108b, should be constructed such that the sensor 108 can detect a CO_2 concentration of at least 30 mmHg to 50 mmHg and, in particular embodiments, of at least 35 mmHg to 45 mmHg.

Based on the reflected IR radiation, the tube tip detection system 100 determines how much IR radiation was absorbed by the air surrounding the enteral tube 102 and thereby determines the CO_2 concentration of the air within a pathway 114 (FIG. 4) being traversed by the tube 102. In some embodiments, if the CO_2 concentration is at least 30 mmHg, the tube tip detection system 100 may determine that the tip 106 of the enteral tube 102 is being misplaced in the patient's airway. In other embodiments, the tube tip detection system 100 may determine that the tip 106 of the enteral tube 102 is being misplaced in the patient's airway if the CO_2 concentration is at least 35 mmHg. That is, the first sensing component 108, or MEMS infrared carbon dioxide sensor 108, embedded in the enteral tube 102 near its tip 106 is configured to sense a CO_2 concentration of at least 30 mmHg, or in other embodiments, of at least 35 mmHg, which corresponds to the low end of the typical range of CO_2 concentration in a person's exhaled breath. When the sensing component 108 senses such a CO_2 concentration, the sensing component 108 provides feedback of the CO_2 concentration to the user via the feedback display 110. In some embodiments, the feedback from the sensing component 108 indicates the tip 106 is entering the airway when the CO_2 concentration sensed by the sensing component 108 is 30 mmHg or 35 mmHg. In other embodiments, if the CO_2 concentration continues to rise past 30–35 mmHg as the enteral tube 102 is advanced into the patient, as shown on the feedback display 110, the user may determine that the enteral tube 102 is being incorrectly placed in the patient's airway because the rising CO_2 concentration likely corresponds to the patient's respirations

conveyed through the patient's airway. Stated differently, using the CO_2 level or concentration that is detected by the first sensing component 108, the user can determine whether the enteral tube tip 106 resides in the patient's airway.

FIGS. 2 and 3 illustrate other exemplary embodiments of the tube tip detection system 100. As shown, in some embodiments, the enteral tube 102 includes a plurality of sensing components that are spaced apart from one another along the length L of the tube 102. As described above, each sensing component of the plurality of sensing components is a carbon dioxide sensor for detecting the CO_2 concentration in the air along the pathway traversed by the enteral tube 102 through the patient. More particularly, the embodiment illustrated in FIG. 2 comprises the first sensing component 108 disposed at the tube tip 106 and a second sensing component 116 disposed along the length L at a position spaced apart from the tip 106. For example, the second sensing component 116 may be disposed at a midpoint of the tube length L, i.e., halfway between the proximal end 104 and the tip 106. In other embodiments, such as depicted in FIG. 3, a third sensing component 118 also is disposed along the tube length L at a position spaced apart from the tip 106.

As shown in FIG. 3, to embed the sensing components 108, 116, and/or 118 in the enteral tube 102, in some embodiments a channel 122 is defined in the tube 102 during fabrication of the tube 102. Then, the first sensing component 108, the second sensing component 116, and/or the third sensing component 118 is disposed within the channel 122. Next, a filler material (not shown) is disposed within the channel 122 around the first, second, and/or third sensing components 108, 116, 118 such that the sensing component(s) 108, 116, 118 are embedded within the enteral tube 102. The sensing components 108, 116, 118 may be embedded within the tube 102 in other ways as well.

In some embodiments, like the exemplary embodiment of FIG. 3, the first sensing component 108, the second sensing component 116, and the third sensing component 118 are unequally spaced apart from one another. That is, the distance, or portion of the tube length L, between the first and second sensing components 108, 116 is different from the distance between the second and third sensing components 116, 118. In other embodiments, the first sensing component 108, the second sensing component 116, and the third sensing component 118 are equidistant from one another, i.e., the distance between the first and second

sensing components 108, 116 is the same as the distance between the second and third sensing components 116, 118. Also as illustrated in FIG. 3, in some embodiments the first sensing component 108 may not be disposed at the tip 106 of the enteral tube 102 but may be disposed along the tube length L such that the first sensing component 108 is spaced apart from the tip 106. In such embodiments, no sensing component may be disposed at the tip 106; that is, in some embodiments of the tube tip detection system 100, one or more sensing components are disposed on the tube 102 at a distance from the tube tip 106, with no sensing component disposed right at the tip 106. Thus, a variety of placements or positions for the one or more sensing components may be used in various embodiments of the tube tip detection system 100.

Further, in exemplary embodiments, each of the first, second, and third sensing components 108, 116, 118 is a MEMS infrared carbon dioxide sensor. The miniaturized sensors located on the tip 106 and/or other locations of the enteral tube 102 detect a CO_2 pattern in the air within the passage traversed by the tube 102. Because the enteral tube 102 has a known length L, the CO_2 pattern (a waveform, as the CO_2 concentration rises and falls with the patient's respirations, typically three (3) to four (4) respirations per minute) determines if the tube 102 has deviated to the patient's airway. Stated differently, the amount or length of the enteral tube 102 that has been inserted into the patient together with the CO_2 concentration detected by the sensor(s) 108, 116, 118 convey to a user of the tube tip detection system 100 whether the tube tip 106 is near the patient's airway and is possibly entering the patient's airway rather than continuing down the pathway toward the patient's stomach or intestines, the intended destination of the tube tip 106. For example, it is known that bifurcation of the pathway 114 into the esophagus and the trachea, as illustrated in FIG. 4, occurs at a certain distance from the entrance to the nostril in a patient, with the certain distance varying between pediatric and adult patients. Knowing this distance for a given patient, as well as the length L of the enteral tube 102, the user can determine how much (or what length) of the tube 102 has been inserted into the patient and, thus, know whether the tube tip 106 is at or near the point where the trachea branches off from the pathway 114, from which the tube 102 could be misplaced into the patient's airway.

As an example, bifurcation typically occurs around 18–20 cm from the entrance to the nostril in adults; the area where bifurcation occurs may be referred

to as a bifurcation zone 120, which is depicted in FIG. 4. Thus, for nasogastric intubation of an adult patient, if the CO_2 concentration begins to increase when approximately 18 cm of the length L of the enteral tube 102 has been inserted into the patient, the user of the system 100 can conclude that the tube tip 106 is at or near the bifurcation zone 120. If the CO_2 concentration continues to increase as the tube 102 is further inserted, the user may determine that the tube tip 106 is or has entered the patient's airway and can correct the tube's position within the patient before continuing to insert the tube 102. If, however, the CO_2 concentration does not continue to increase past the bifurcation zone 120, the user may determine that the tube tip 106 is continuing on the correct pathway 114 (i.e., the tube 106 is within the esophagus rather than the trachea) to the patient's stomach or bowel.

Accordingly, the one or more sensing components 108, 116, 118 likely would register, and display on the feedback display 110, an elevated CO_2 concentration as the tip 106 of the enteral tube 102 nears the bifurcation zone 120. Thus, the user should monitor the CO_2 pattern to distinguish between an appropriately placed tube tip 106 and a misplaced tube tip 106. The CO_2 concentration for an appropriately placed tip 106 should decrease upon further insertion of the tube past the bifurcation zone 120, but the CO_2 concentration for a misplaced tip 106 should increase as a greater length of the tube 102 (greater than the length of tube 102 to reach the bifurcation zone 120) is inserted into the patient.

In some embodiments, e.g., as shown in FIG. 1B, the feedback display 110 is attached to the enteral tube 102, but in other embodiments, e.g., as shown in FIG. 1A, the feedback display 110 is separate from and not attached to the enteral tube 102. The feedback display 110 displays the actual CO_2 concentration detected by the one or more sensing components 108, 116, 118. Additionally or alternatively, the feedback display 110 displays a non-numerical visual indicator of the CO_2 concentration, such as one or more colors, symbols, or words. As an example, the visual indicator may comprise a plurality of light emitting diodes (LEDs), such as green, yellow, and red LEDs. In such embodiments, the feedback display 110 illuminates the green LED(s) if the sensed CO_2 concentration is below a typical low value of the CO_2 concentration of a person's exhaled breath (e.g., if the CO_2 concentration is below 30 mmHg), illuminates the yellow LED(s) if the CO_2 concentration is within a typical low range of the CO_2 concentration of a person's exhaled breath (e.g., if the CO_2 concentration is at or between 30 mmHg to

40mmHg), and illuminates the red LED(s) if the CO_2 concentration increases beyond an initial reading at the low end of typical CO_2 concentration in a person's exhaled breath. As another example, the feedback display 110 may illuminate a series of colored or non-colored LEDs or display words or symbols to indicate various states of the sensed CO_2 concentration (e.g., below low end, at low end, or increasing beyond low end of typical CO_2 concentration of a person's exhaled breath). In still other embodiments, the feedback display 110 may utilize audible feedback, such as one or more beeping or other sounds, in addition to or in lieu of visual feedback to convey to the user of the system 100 CO_2 concentration sensed by the one or more sensing components 108, 116, 118 disposed on the enteral tube 102.

The present subject matter also provides methods for detecting a tube misplacement in a patient's airway. Referring now to FIG. 5, an exemplary method 200 is illustrated. The method 200 comprises embedding a carbon dioxide sensing component 108 into an enteral tube 102, as shown at 202 in FIG. 5. The enteral tube 102 is configured as described herein, having a proximal end 104 and a tip 106 separated by a length L of tubing. Moreover, the sensing component 108 may be a MEMS-based infrared carbon dioxide sensor as described above. As shown at 204 in FIG. 5, the method 200 also includes inserting the enteral tube 102 into the patient through the patient's nose or mouth. Thus, the enteral tube 102 may be a nasogastric or orogastric tube as described herein. Further, as shown at 206 and 208 in FIG. 5, the method 200 includes monitoring feedback from the carbon dioxide sensing component 108 to determine if the enteral tube 102 is traveling into the patient's airway and, if so, then adjusting the location of the tube tip 106 such that it is no longer in the patient's airway. The feedback may be displayed on a feedback display 110 as described herein.

It will be appreciated that, in other embodiments, the method 200 may accommodate other configurations of the tube tip detection system 100 as described in greater detail herein. For example, step 202 of the method 200 may comprise embedding a plurality of sensing components into the enteral tube 102, e.g., a first and second sensing component 108, 116 as illustrated in FIG. 2 or a first, second, and third sensing component 108, 116, 118 as illustrated in FIG. 3. Of course, the method 200 may vary to include other configurations of the apparatus and system described herein.

Accordingly, the present subject matter provides a system and apparatus for detecting a tip of an enteral tube as it is inserted into a patient. In exemplary embodiments, the system uses MEMS sensor(s) on the tube to detect elevated levels of CO_2 if the tube is inserted into the airway instead of traveling past the bifurcation of the patient's trachea from the patient's esophagus toward the gastrointestinal tract. The system may utilize a single MEMS-based infrared carbon dioxide sensor disposed on the tip of the tube to sense the CO_2 concentration within the pathway being traversed by the tube. In other embodiments, the system utilizes a plurality of MEMS-based infrared carbon dioxide sensors disposed along the length of the tube to sense the CO_2 concentration within the pathway being traversed by the tube. The system provides feedback to the user of the system, e.g., a physician, clinician, nurse, or other caregiver, via a feedback display or other device for receiving feedback from the one or more sensing components such that the user can determine whether the tube tip is appropriately placed or is misplaced. Methods for detecting whether the tube tip is misplaced also are provided. Such methods, systems, and apparatus can help reduce the occurrence of misplaced enteral tubes, such as nasogastric or orogastric feeding tubes, thereby reducing complications from administering fluid to a patient through a misplaced tube. Further, the methods, systems, and apparatus described herein reduce such misplacements in a cost-efficient and time-efficient manner. More particularly, the carbon dioxide sensors described herein are a relatively low-cost solution and are easily embedded in enteral tubes during the manufacture of the tubes. Moreover, the system described herein allows real-time, bedside verification of the tube placement, which can save time and money, e.g., compared to existing systems that require tube placement to be verified by x-ray or the like. Other benefits and advantages of the present subject matter also may be recognized by those of ordinary skill in the art.

It should also be appreciated that these procedures may involve treatment of humans by physicians, physician assistants, nurses, or other health care providers. In addition, these procedures may involve treatment of other mammals and animals by veterinarians, researchers, and others.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention,

which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable sub combination.

Although the present subject matter has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

This written description uses examples to disclose the invention, including the best mode, and also to enable any person skilled in the art to practice the invention, including making and using any devices or systems and performing any incorporated methods. The patentable scope of the invention is defined by the claims, and may include other examples that occur to those skilled in the art. Such other examples are intended to be within the scope of the claims if they include structural elements that do not differ from the literal language of the claims or if they include equivalent structural elements with insubstantial differences from the literal language of the claims.

WHAT IS CLAIMED IS:

1. A tube tip detection system, comprising:

an enteral tube having a tip;

a first sensing component disposed at the tip; and

a feedback display,

wherein feedback from the first sensing component is displayed on the feedback display to indicate to a user of the tube tip detection system whether the tip is misplaced in a patient's airway.

2. The tube tip detection system of claim 1, wherein the first sensing component is a micro-electro-mechanical system (MEMS) component.

3. The tube tip detection system of claim 2, wherein the MEMS component comprises an infrared carbon dioxide sensor.

4. The tube tip detection system of claim 3, wherein the infrared carbon dioxide sensor comprises an infrared emitter and an infrared receiver.

5. The tube tip detection system of claim 3, wherein the feedback from the infrared carbon dioxide sensor indicates the tip is entering the airway when the infrared carbon dioxide sensor senses a carbon dioxide concentration of 30 mmHg.

6. The tube tip detection system of claim 3, wherein the feedback from the infrared carbon dioxide sensor indicates the tip is entering the airway when the infrared carbon dioxide sensor senses a carbon dioxide concentration of 35 mmHg.

7. The tube tip detection system of any of the preceding claims, wherein the enteral tube has a length, and

wherein a second sensing component is disposed along the length at a position spaced apart from the tip.

8. The tube tip detection system of claim 7, wherein the second sensing component is disposed at a midpoint of the length.

9. The tube tip detection system of claim 7, wherein a third sensing component is disposed along the length at a position spaced apart from the tip.

10. The tube tip detection system of claim 9, wherein the first sensing component, the second sensing component, and the third sensing component are unequally spaced apart from one another.

11. The tube tip detection system of claim 9, wherein each of the first, second, and third sensing components is a micro-electrical mechanical system (MEMS) infrared carbon dioxide sensor.

12. The tube tip detection system of any of the preceding claims, wherein the feedback display is attached to the enteral tube.

13. The tube tip detection system of any of the preceding claims, wherein the feedback display is separate from and not attached to the enteral tube.

14. The tube tip detection system of any of the preceding claims, wherein the sensing component is embedded in the enteral tube.

15. The tube tip detection system of any of the preceding claims, wherein the enteral tube is a nasogastric tube.

16. An enteral tube, comprising:

a tip;

a length; and

a sensing component,

wherein the sensing component is a micro-electro-mechanical system (MEMS) infrared carbon dioxide sensor.

17. The enteral tube of claim 16, further comprising:

a plurality of sensing components spaced apart from one another along the length,

wherein each sensing component is a carbon dioxide sensor.

18. The enteral tube of claim 16 or claim 17, wherein the sensing component comprises an infrared emitter and an infrared receiver.

19. The enteral tube of any of claims 16 through 18, wherein the sensing component is disposed at the tip.

20. A method for detecting a tube misplacement in a patient's airway, comprising:

embedding a carbon dioxide sensing component into an enteral tube;

inserting the enteral tube into the patient through the patient's nose or mouth; and

monitoring feedback from the carbon dioxide sensing component to determine if the enteral tube is traveling into the patient's airway.

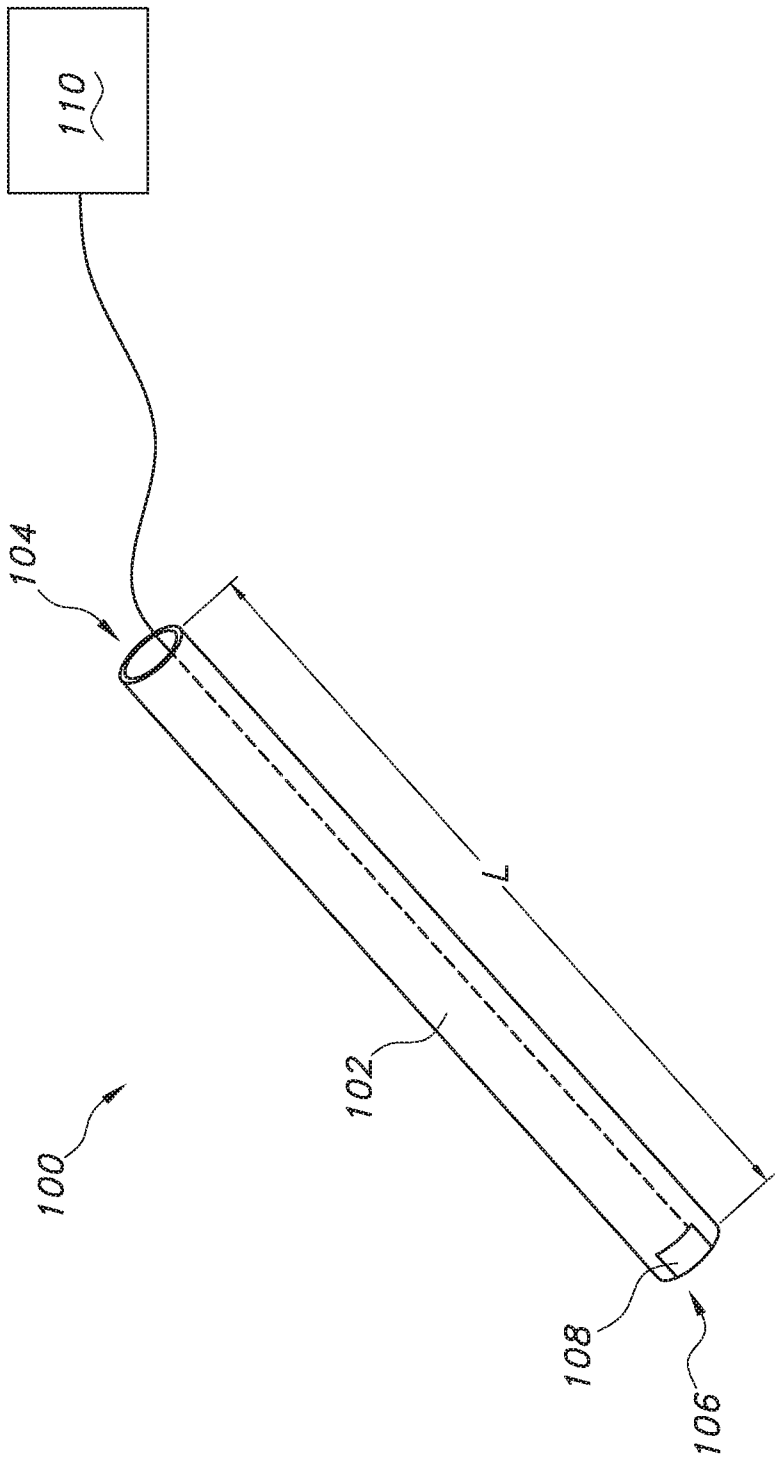


FIG. 1A

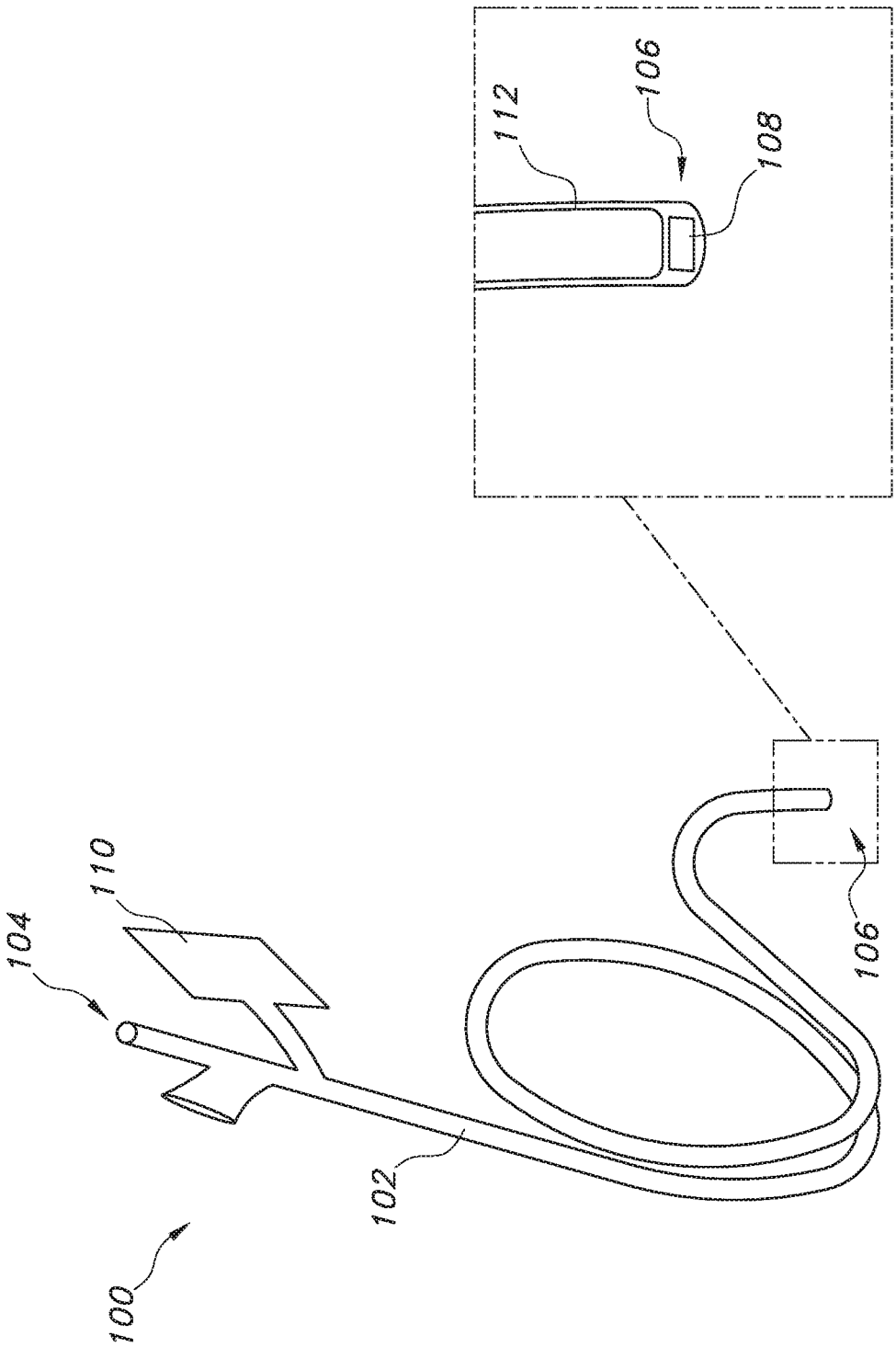


FIG. 1B

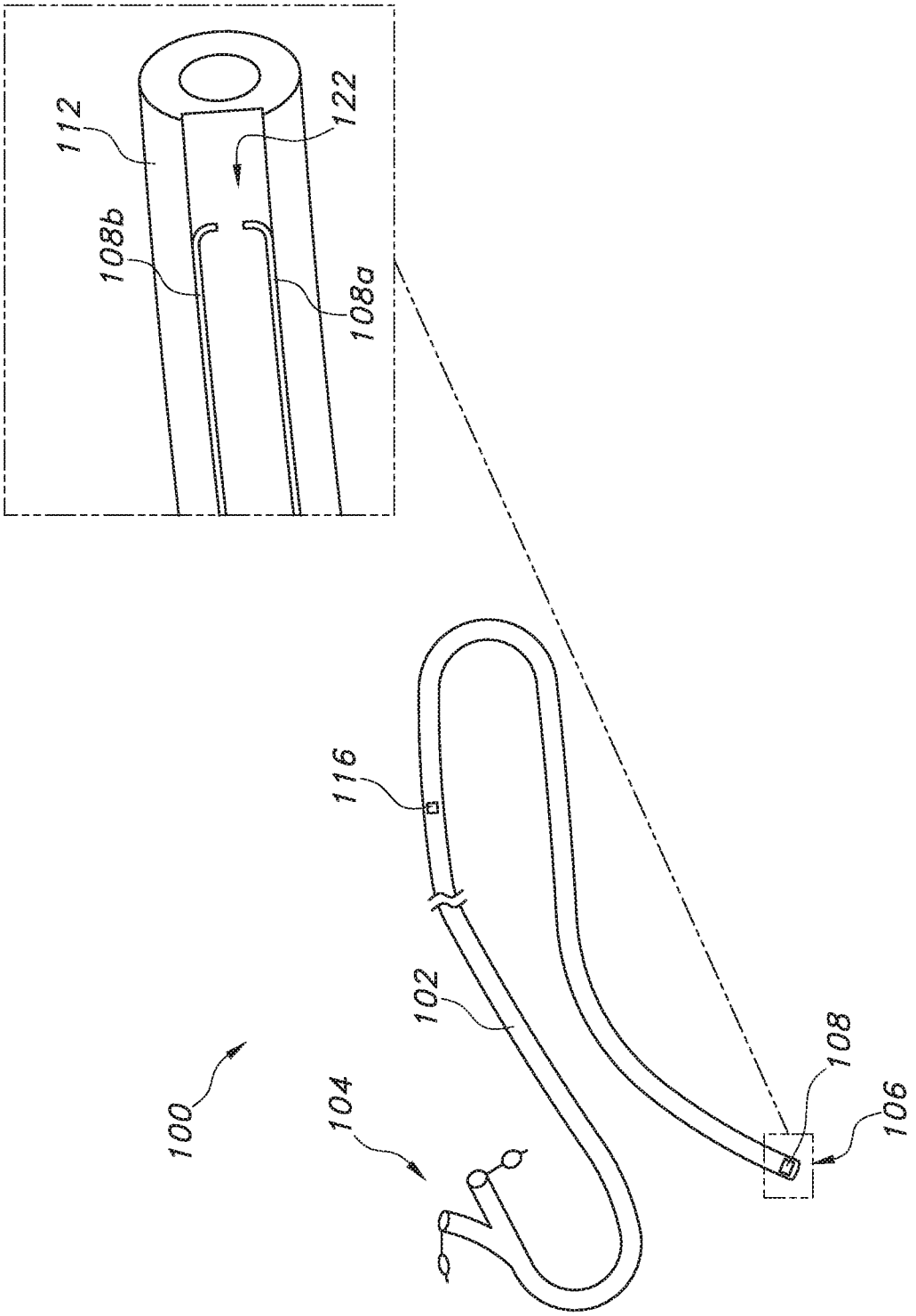


FIG. 2

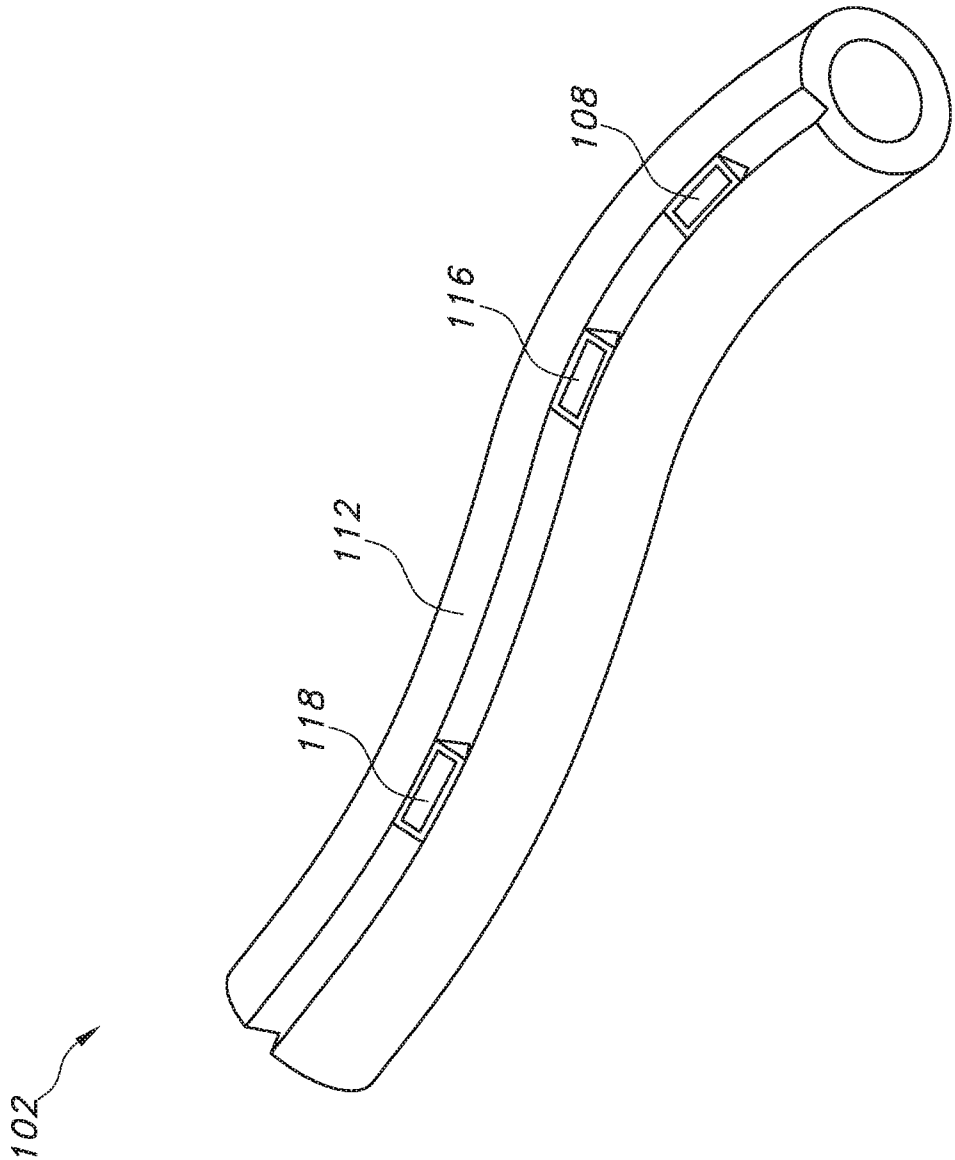


FIG. 3

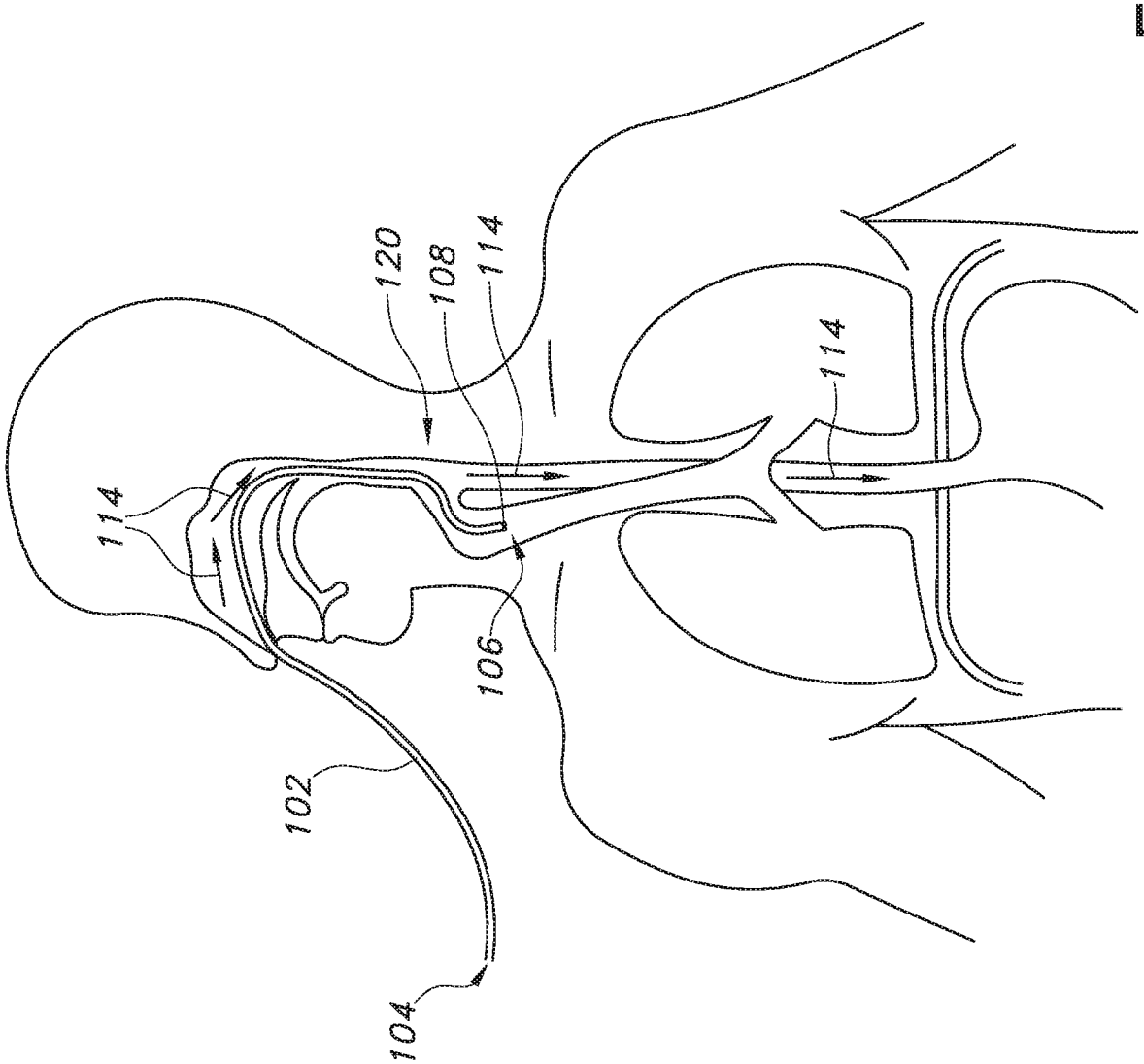


FIG. 4

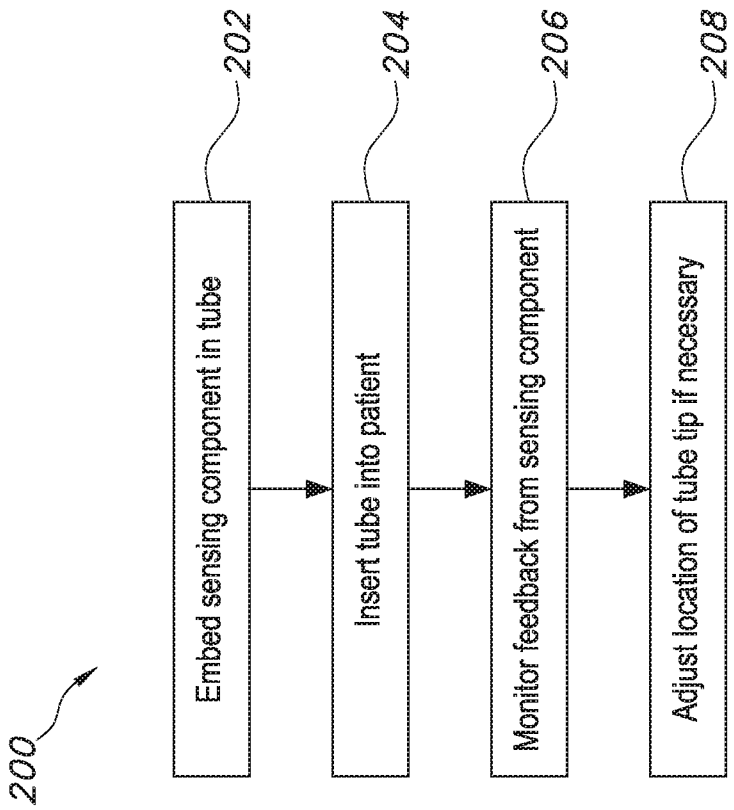

200
Embed sensing component in tube
202
Insert tube into patient
204
Monitor feedback from sensing component
206
Adjust location of tube tip if necessary
208

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/018614

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. [X] Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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.:
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 an 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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/018614

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/06 A61B5/08
ADD.

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)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2016/206189 A1 (NEARMAN HOWARD S [US] ET AL) 21 July 2016 (2016-07-21) paragraph [0007] - paragraph [0015] paragraphs [0058], [0059] paragraph [0102] figures 1-36	1,7-10, 12-15 2-6,11, 16-19
X	US 2009/209849 A1 (ROWE PHILIP STEPHEN [US] ET AL) 20 August 2009 (2009-08-20) paragraph [0020] - paragraph [0030] paragraph [0066] - paragraph [0067] figures 1-14	1
X	CN 108 159 541 A (LI WULAN) 15 June 2018 (2018-06-15) abstract	1

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[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
15 May 2020	28/05/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Abraham, Volkhard

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/018614

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	J J LAI ET AL: "MEMS integrated narrow band infrared emitter and detector for infrared gas sensor", JOURNAL OF PHYSICS: CONFERENCE SERIES, vol. 276, 1 February 2011 (2011-02-01), page 012129, XP055695836, DOI: 10.1088/1742-6596/276/1/012129 the whole document -----	2-6,11, 16-19

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/018614

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016206189 A1	21-07-2016	NONE	
US 2009209849 A1	20-08-2009	NONE	
CN 108159541 A	15-06-2018	NONE	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 20

According to Article 34(4)(a)(i) PCT and Rule 67.1 PCT no international preliminary examination is required to be carried out on claim 20 of the present application, because the subject-matter of this claim relates to a method for treatment of the human or animal body by surgery. The insertion of a enteral probe is regarded as being of surgical character.