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(54) **ENDOTRACHEAL TUBE WITH SENSORS**

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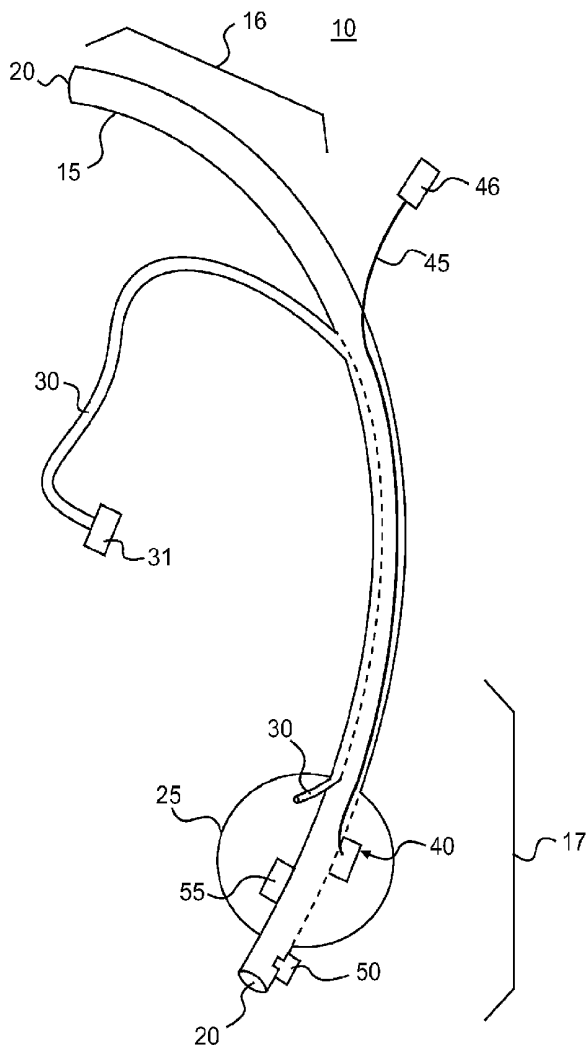
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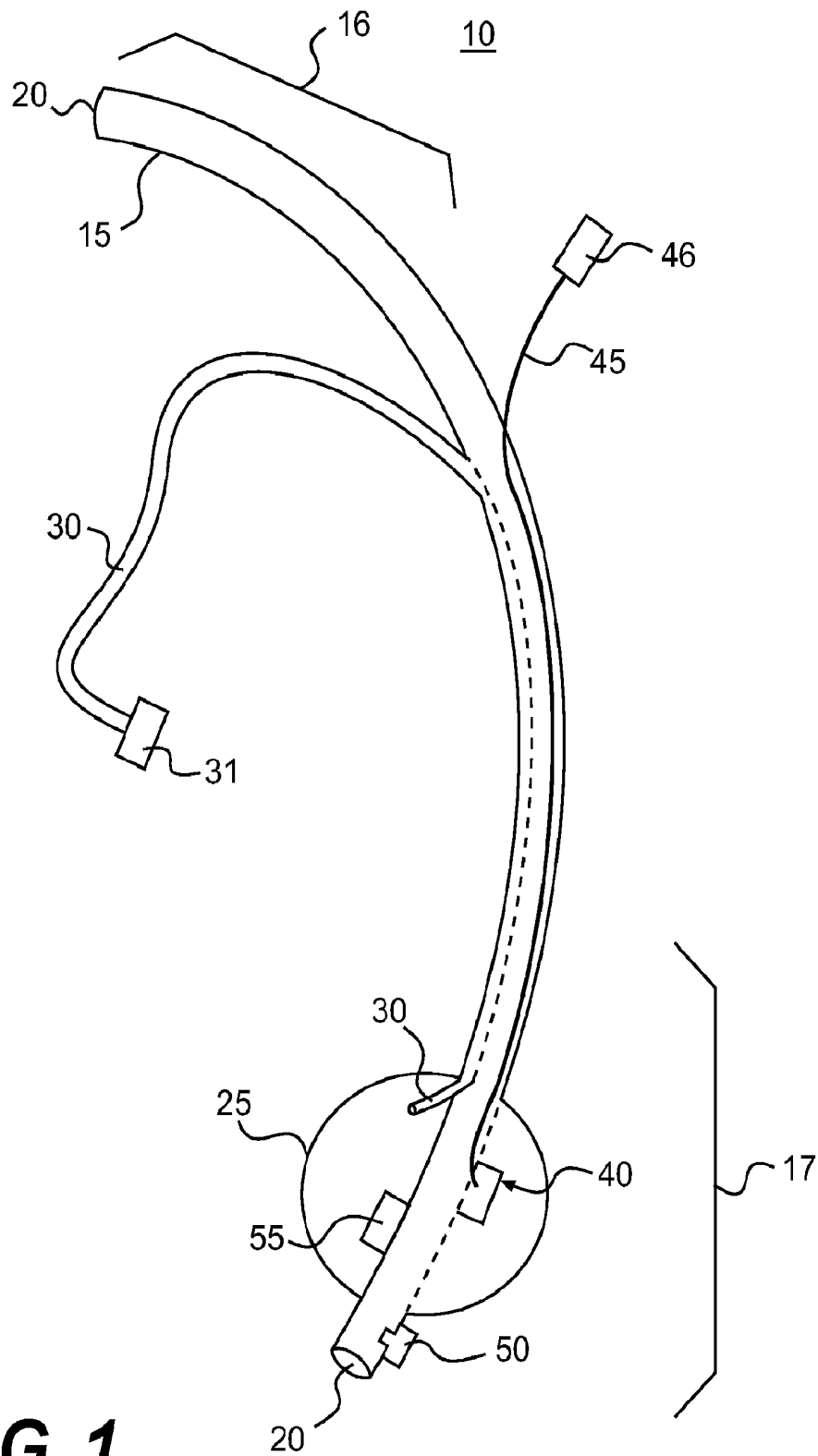
(57) **ABSTRACT**

The present invention provides an endotracheal tube comprising one or more sensors. In some embodiments, one or more sensors are positioned in the interior of the cuff. Sensors may be used to detect any physiological parameter.

(30) **Foreign Application Priority Data**

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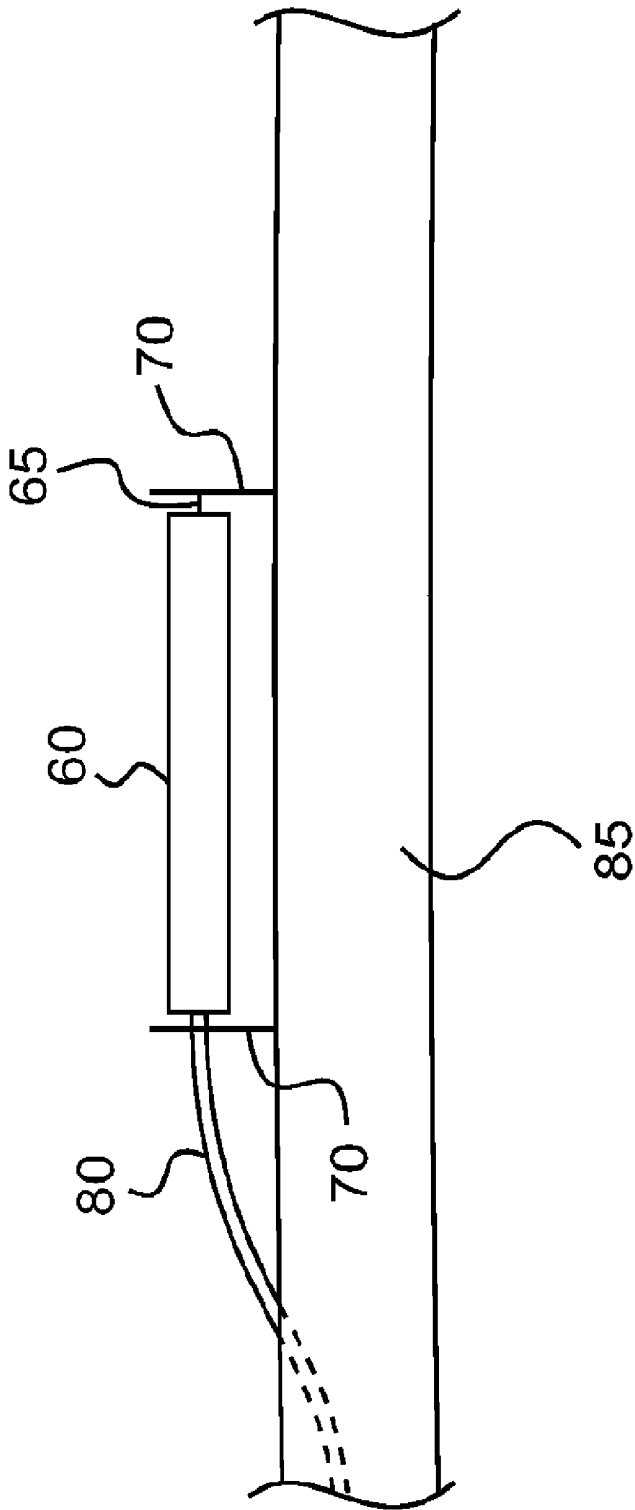


FIG. 2

ENDOTRACHEAL TUBE WITH SENSORS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application for Patent Ser. No. 61/161,785 filed Mar. 20, 2009, the entire contents of which are specifically incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] An endotracheal tube (also called an ET tube or ETT) is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea in order to ensure that the airway is not closed off and that air is able to reach the lungs.

[0003] There are many types of endotracheal tubes which range in size from 2-10.5 mm in internal diameter (ID). The proper size endotracheal tube is selected based on the patient's body size with the smaller sizes being used for pediatric and neonatal patients.

[0004] Endotracheal tubes are typically equipped with an inflatable cuff at or near their distal end. After insertion of the endotracheal tube, the cuff may be inflated to form a seal between the outer surface of the endotracheal tube and the trachea. This helps to create a closed system to allow for the typical increase driving pressures used in mechanical ventilation as well as to reduce movement of the endotracheal tube ensuring that it remains where positioned. When properly positioned, the distal end of an endotracheal tube is typically located in the trachea in proximity to the ascending aorta, which is an optimum position from which to measure a variety of physiological parameters including cardiac output.

[0005] Cardiac output is the volume of blood which the heart pumps in one minute and is one of the most important cardiovascular parameters. The cardiac output reflects the supply of oxygen and nutrients to tissue. Measurements of cardiac output provide invaluable clinical information for quantifying the extent of cardiac and vascular dysfunction, indicating the optimal course of therapy, managing patient progress, and establishing check points for rehabilitation in a patient with a damaged or diseased heart, or one in whom fluid status control is essential.

[0006] Cardiac output can be measured using ultrasound and the Doppler Effect. The blood velocity through the heart causes a 'Doppler shift' in the frequency of the returning ultrasound waves. This Doppler shift can then be used to calculate flow velocity and volume and subsequently cardiac output. Doppler ultrasound is non-invasive, accurate and inexpensive and is a routine part of clinical ultrasound with high levels of reliability and reproducibility having been in clinical use since the 1960s.

[0007] Ultrasound is performed by emitting a pulse of high frequency sound (typically in the 1-12 MHz range) into a target and then measuring the reflected sound waves. Since ultrasound does not propagate well in gas, it is important that the ultrasound generator (e.g., a piezoelectric crystal) be in intimate contact with the target material.

[0008] Endotracheal tubes comprising ultrasound transducers are described in U.S. Pat. Nos. 4,671,295 to Abrams et al., 4,722,347 to Abrams et al. and 5,076,268 to Weber. The Abrams et al. patents address the requirement for intimate contact between ultrasound transducer and target by mount-

ing one or more transducers on the tube and equipping the tube with variously shaped inflatable balloons to urge the ultrasound transducers into contact with the inner wall of the trachea. U.S. Pat. No. 5,076,268 issued to Weber discloses an endotracheal tube having an ultrasound transducer assembly mounted at one end of the tube and an asymmetrically disposed balloon cuff to simultaneously seal the trachea and urge an ultrasound transducer into contact with the inner wall of the trachea. As acknowledged by Abrams et al., the inner wall of the trachea is irregularly shaped and relatively non-deformable cartilaginous tissue. To ensure a good contact between the ultrasound transducer and the inner wall of the trachea, the inventors suggest the use of an acoustical gel. Notwithstanding these arrangements, continuous contact between the tracheal wall and the ultrasound device is not adequately maintained by these devices.

[0009] There remains a need in the art for an endotracheal tube capable of monitoring physiological parameters including cardiac output. Such an endotracheal tube may be adapted to provide an acoustically transmissive contact between one or more ultrasound transducers and one or more targets. This need and others are met by the present invention.

SUMMARY OF THE INVENTION

[0010] The present invention provides materials and methods for monitoring physiological parameters including cardiac output. In some embodiments, the present invention provides an endotracheal tube. Such endotracheal tubes may comprise an elongate tubular member having a proximal end and a distal end and one or more flexible cuffs. Flexible cuffs of the invention may be positioned on the exterior of the elongate tubular member. A flexible cuff of the invention may have an interior space and one or more transducers (e.g., ultrasound transducers, sensors, transmitters etc) positioned in the interior space of the cuff. In some embodiments, 2, 3, 4, 5 or more transducers (e.g., ultrasound transducers, sensors, transmitters etc), which may be adapted to monitor the same or different physiological parameters, may be positioned in the interior of the cuff. In addition, one or more (e.g., 2, 3, 4, 5 etc) transducers (e.g., ultrasound transducers, sensors, transmitters etc), may be positioned on and/or in the tubular member not within the interior of the cuff. Typically, one or more transducers (e.g., ultrasound transducers, sensors, transmitters etc) positioned in the interior of the cuff comprises an ultrasound transducer, for example, an ultrasound transducer adapted to detect blood flow and/or measure cardiac output and/or monitor other hemodynamic parameters (e.g., left atrial occlusion pressure, vascular resistance, etc.).

[0011] In some embodiments, a flexible cuff of the invention may be inflated with an acoustically transmissive material. As used herein, an acoustically transmissive material is one that transmits ultrasound. Suitable examples of acoustically transmissive materials include, but are not limited to, fluids (e.g., water, saline solution, buffer solutions etc) and gels (e.g., acoustical gels). The flexible cuffs of the invention are typically constructed of a material that is sufficiently flexible to allow a contact with the inner wall of the trachea that allows ultrasound waves produced by a transducer in the interior of the cuff to pass into and through the inner wall of the trachea. Optionally, the exterior of the flexible cuff may be coated with an acoustically transmissive material such as an acoustical gel. In one particular embodiment, the invention comprises an endotracheal tube comprising an elongate tubular member and a flexible cuff disposed at or near the distal

end of the member wherein an ultrasound transducer is positioned within the interior of the cuff and the cuff is filled with an acoustically transmissive material (e.g., a fluid or gel).

[0012] The present invention also provides methods of performing surgical procedures. Such methods may comprise inserting into a patient an endotracheal tube as described above, using at least one transducer to detect at least one parameter (for example, cardiac output); and performing the procedure. Any surgical procedure known in the art may be performed. Surgical procedures may comprise applying a cryogen to a target tissue or using the cryogen to create an isotherm in proximity to the tissue. In methods of this type, cryogen may be applied to a tissue selected from the group consisting of esophageal tissue, lung tissue, tracheal tissue, laryngeal tissue, pharyngeal tissue and gastric tissue. Any suitable cryogen may be used, for example, the cryogen may be a liquefied gas. Examples of suitable cryogenes include, but are not limited to, nitrogen, oxygen, argon, carbon dioxide, nitrogen dioxide, nitrogen oxides, and air. Any suitable technique may be used to apply the cryogen, for example, the cryogen can be sprayed (e.g., from a catheter).

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is a schematic representation of an endotracheal tube of the invention.

[0014] FIG. 2 is a schematic representation of an adjustably mounted transducer.

DETAILED DESCRIPTION OF THE INVENTION

[0015] Endotracheal tubes are currently used as a means to provide ventilator support in a variety of medical situations, for example, during surgery. The present invention provides endotracheal tubes that can be equipped with a variety of different transducers (e.g., ultrasound transducers, sensors, transmitters etc). Suitable transducers include, but are not limited to, ultrasound transducers, temperature sensors, blood gas sensors (e.g., CO₂ and/or O₂ sensors, and infrared sensors to measure tissue oximetry), air flow sensors, sensors for an esophageal electrocardiogram, one or more sensors for sampling of exhaled gases, for example, nitrous or nitric oxide, and sensors for measuring humidity. Any sensor known to those skilled in the art that provides information of interest to an attending physician can be used in the practice of the invention. Information from the sensors can be used to measure metabolic rates, for example, the % consumption of oxygen and % production of CO₂ provide a measure of metabolism which can be used to monitor patient status in critical care situations.

[0016] FIG. 1 provides an endotracheal tube **10** of the invention. The endotracheal tube **10** includes elongate tubular member **15** that defines a passage **20** that allows fluid communication between the ambient atmosphere and the patient's lungs.

[0017] Endotracheal tube **10** also has a flexible cuff **25** that can be inflated to form a seal between the outer surface of the endotracheal tube and the inner wall of the trachea. The endotracheal tube **10** also includes an inflation tube **30** in fluid communication with the interior of cuff **25** through which material may be introduced into and may be removed from the interior of the cuff. Typically, such material will be acoustically transmissive. The distal end of tube **30** may be equipped with a valve **35** which can be used to control the flow of material into and out of the cuff.

[0018] Endotracheal tube **10** also includes a transducer (e.g., ultrasound transducer, sensor, transmitter etc) **40** positioned in the interior of cuff **25**. Transducer **40** may be an ultrasound transducer. Transducer **40** may be electrically coupled to any suitable device, for example, a directional pulsed or continuous wave Doppler ultrasound device, via electrical conductor **45** which may be attached to a connector **46**. As shown, transducers (e.g., ultrasound transducers, sensors, transmitters etc) of the invention are electrically coupled through wires to suitable devices for recording their output and/or directing input to them. Those skilled in the art will appreciate that transducers equipped with wireless transmission capability may be used and signals to and from such transducers may be sent and/or received by any suitable device.

[0019] In one embodiment, transducer **40** may emit an ultrasonic wave through the wall of the trachea and through the wall of the ascending aorta or the pulmonary artery and be reflected by the blood in the selected artery. Due to the movement of the blood in the artery, the reflected signal will have a different frequency than the transmitted signal and this difference (the Doppler shift) can be used to calculate the flow. The ultrasound waves are also reflected by the walls of the artery and these reflected waves can be used to calculate the cross sectional area of the artery.

[0020] As shown in FIG. 1, endotracheal tube **10** is equipped with additional transducers (e.g., ultrasound transducers, sensors, transmitters etc) **50** and **55**. In some embodiments, endotracheal tube **10** may be equipped with a plurality of transducers, for example, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more. Additional transducers (e.g., sensors) may be used to detect any desired physiological parameter. Suitable sensors include, but are not limited to, temperature sensors, blood gas sensors (e.g., CO₂ and/or O₂ sensors, and infrared sensors to measure tissue oximetry), air flow sensors, sensors for an esophageal electrocardiogram, sensors for sampling of exhaled gases, for example, nitrous or nitric oxide, and sensors for measuring humidity. Any sensor known to those skilled in the art that provides information of interest to an attending physician can be used in the practice of the invention. Information from the sensors can be used to measure metabolic rates, for example, the % consumption of oxygen and % production of CO₂ provide a measure of metabolism which can be used to monitor patient status in critical care situations.

[0021] A transducer may or may not be equipped with an electrical conductor. In some embodiments, each transducer may have its own electrical conductor. Typically, an electrical conductor **45** will convey an electrical signal to and from a transducer to an additional piece of hardware appropriate for controlling the transducer and detecting the physiological parameter to be determined by the specific transducer. Electrical conductor **45** may be attached to the hardware via connector **46**. Any suitable type of connector may be used in the practice of the invention for example, a plug. For example, when the transducer is a piezoelectric ultrasound transducer, the electrical conductor may convey an alternating current to the transducer to induce production of the ultrasound wave and/or may convey the reflected signal back to a conventional ultrasound machine. Suitable ultrasound machines are known to those skilled in the art. Suppliers of suitable ultrasound devices include, but are not limited to, Siemens Medical, Edwards Life Sciences, Phillips Healthcare, and Olympus. Those skilled in the art will appreciate that an electrical con-

ductor may comprise more than one single conductor. In some embodiments, an electrical conductor may be a plurality of wires. In some embodiments, a transducer may not be equipped with an electrical conductor, in such cases, the transducer may receive and/or transmit a signal via radio wave or other form of electromagnetic radiation. Electrical conductors may be embedded in elongate tube **15**, run inside of passage **20**, run along the outside of elongate tube **15**, or be affixed to elongate tube **15** either on the inside or outside. In embodiments comprising a plurality of transducers equipped with electrical conductors, each electrical conductor may independently be arranged in one of these fashions.

[0022] Transducers (e.g., ultrasound transducers, sensors, transmitters etc) may be attached to the endotracheal tube of the invention by any method or material known to those in the art. For example, a transducer may be permanently affixed to the endotracheal tube by heat sealing or adhesive. A transducer may be removeably attached to the endotracheal tube of the invention, for example, by friction fitting the transducer in an appropriately shaped receptacle formed on the endotracheal tube. In some embodiments, the endotracheal tube of the invention may be equipped with a socket to which one or more electrical conductors is attached and a transducer may be equipped with one or more prongs adapted to engage holes in the socket to affix the sensor.

[0023] One or more transducers (e.g., ultrasound transducers, sensors, transmitters etc) may be in fluid communication with the passage **20** so as to sample the gas moving through the passage. Sampling the gas in the passage may be used to detect the concentration of one or more additives to the gases moving through the passage, for example, an anesthetic and a sensor may be used to monitor the concentration of anesthetic being administered to a patient. Any other characteristic of the gas may be measured, for example, CO₂ and/or O₂ content, rate of gas flow, content and/or concentration of exhaled gases, for example, nitrous or nitric oxide, and humidity. One or more of transducers **50** and **55** may be used to sense the temperature of the patient. In some embodiments, a sensor for determining the temperature of a patient may comprise a thermocouple.

[0024] In FIG. 1, the elongate tubular member **15** is depicted as a flexible curved tube. The endotracheal tubes of the invention may take any shape and size known to those skilled in the art and may be flexible or rigid. An elongate tubular member **15** of the invention may be constructed of any suitable material used for endotracheal tubes known in the art, e.g., any biocompatible material. Suitable examples of material that may be used to construct the endotracheal tubes of the invention include, but are not limited to, polyvinylchloride, latex, silicone, rubber, or other materials readily apparent to those skilled in the art. In one embodiment, an endotracheal tube of the invention may be constructed of a clear biocompatible material.

[0025] As shown in FIG. 1, the elongate tubular member **15** is curved and such a device may be inserted into the trachea via the mouth. Other shapes may be used for insertion through the nose and/or a tracheotomy.

[0026] The elongate tubular member **15** has a proximal portion **16** and a distal portion **17**. As used herein, proximal is used to indicate the portion of the endotracheal tube that lies outside of the patient after installation and distal is used to indicate the portion of the endotracheal tube that lies inside of the trachea of the patient after installation. Typically, the proximal portion **16** exits either the nasal cavity or the mouth

of the patient when installed in a patient. In some embodiments, the proximal portion may exit through a tracheostomy. When installed, passage **20** provides fluid communication from the outside of the patient to the lungs. As will be readily appreciated by those in the art, the proximal portion of the endotracheal tube of the invention may be attached to any device typically used to introduce gas into the lungs of the patient, for example, a bag ventilator or a mechanical ventilator.

[0027] The endotracheal tube **10** also comprises one or more cuffs **25**. The endotracheal tube shown in FIG. 1 comprises a single cuff; however, those skilled in the art are aware that endotracheal tubes comprising multiple cuffs may be constructed and such tubes are within the contemplated scope of the invention. A cuff of the invention is typically constructed of a flexible, biocompatible material, e.g., a biocompatible plastic such as polyvinyl chloride. In FIG. 1, cuff **25** is shown inflated. Any suitable material may be used to inflate cuff **25**. A material is suitable if it transmits ultrasound waves. Examples, include, but are not limited to, fluids (e.g., water, saline solution, buffer solutions and the like) and gels (e.g., acoustical gels). When inflated, cuff **25** forms a seal against the inner wall of the trachea that permits ultrasound waves to be transmitted from transducer **40** through the cuff **25**, through the wall of the trachea and into the patient. As depicted in FIG. 1, cuff **25** is symmetrically arranged around tubular member **15**. Those skilled in the art will appreciate that other arrangements of the cuff are possible, for example, the cuff may be asymmetrically arranged around the elongate tubular member. Cuff **25** is attached to elongate tubular member **15** by any method known to one skilled in the art, for example, by adhesive or heat seal. When attached, cuff **25** will retain material used to inflate it.

[0028] An endotracheal tube of the invention may also comprise one or more inflation tubes **30**. Typically, an endotracheal tube of the invention will comprise an inflation tube for each cuff with which it is equipped. The inflation tube **30** may be formed as integral part of elongate tubular member **15** or may be a separate tube. When separate, inflation tube **30** may run inside of passage **20**. The proximal end of inflation tube **30** remains outside of the patient after installation of endotracheal tube **10** while the distal end of inflation tube **30** is inside of cuff **25**. Thus, inflation tube **30** provides fluid communication from the outside of the patient to the interior of cuff **25**. The proximal end of inflation tube **30** can be equipped with valve **35**. Valve **35** can be used to control the flow of material into and out of cuff **25**. In a simple embodiment, valve **35** may consist of a Luer fitting and the fitting may be attached to a syringe of material to be used to inflate cuff **25**. Valve **35** may be any other suitable connector for controlling the flow of material from a dispenser through inflation tube **30** and into cuff **25**.

[0029] In some embodiments, one or more transducers (e.g., ultrasound transducers, sensors, transmitters etc) may be mounted on endotracheal tube **10** of the invention such that that are adjustable in relationship to the endotracheal tube. Transducers may be adjustable along the axis of the tube, for example, may be moveable along the length of the tube. Transducers may also be tilted laterally in relation to the tube. For example, as shown in FIG. 1, transducer **40**, which may be an ultrasound transducer, may be mounted on elongate member **15** such that the direction of the ultrasound emitted by sensor **40** can be varied as needed. For example, with reference to FIG. 2, the transducer **60** may be supported in a

bracket **70** mounted to tube **85**. A rod or wire **80** may be attached to transducer **60**, for example, at the midline of the transducer. The transducer **60** may be equipped with a pin **65** that rotatably engages bracket **70**. Rod **80** may be rotated by the user causing transducer **60** to tilt. Adjustably mounted transducers and/or sensors may be controlled using any techniques known in the art, for example, screw drives, gear drives, belt drives, telescoping rods, and/or inflatable bladders.

[0030] In some embodiments, sensors may comprise a plurality of ultrasound transducers, e.g., may be an array of ultrasound transducers. For example, transducer **40** may be an array of ultrasound transducers. Any arrangement of transducers known in the art may be used in the practice of the invention. Examples of suitable arrays of ultrasound transducers include, but are not limited to, linear arrays, radial arrays, and curvilinear arrays. Such arrays may be used to create images of structures within the body of the patient, for example, images of the heart.

[0031] The endotracheal tubes of the invention may be used in any situation in which it is desirable to ensure that the patient airway is maintained. In some embodiments, the endotracheal tubes of the invention may be used in the practice of surgery where a patient is to ventilated and/or treated with anesthesia. In some embodiments, the endotracheal tubes of the invention may be used in conjunction with a cryosurgical procedure. The endotracheal tube of the invention is particularly well suited for monitoring patients in critical care situations.

[0032] The present invention has been illustrated and described in detail above. The embodiments described herein should be considered illustrative and not limiting of the scope of the invention. Those of skill in the art will appreciate that various changes and modifications can be made to the embodiments described above and those variations and modification are intended to be within the scope of the invention as set out in the appended claims. All references, patents and other printed materials mentioned above are specifically incorporated herein by reference in their entirety.

What is claimed is:

1. An endotracheal tube, comprising:
 - an elongate tubular member having a proximal end and a distal end;
 - a flexible cuff having an interior space positioned on the outer surface of the tubular member; and
 - at least one sensor positioned in the interior space of the cuff.

2. The endotracheal tube according to claim **1**, comprising two or more sensors.

3. The endotracheal tube according to claim **1** comprising **3** or more sensors.

4. The endotracheal tube according to any one of claims **1-3**, wherein at least one sensor comprises an ultrasound transducer.

5. The endotracheal tube according to claim **4**, wherein the sensor comprising an ultrasound transducer is adapted to detect blood flow.

6. The endotracheal according to claim **5**, wherein the cuff contains fluid.

7. The endotracheal tube according to claim **1**, wherein at least one sensor is detachable from the elongate tubular member.

8. The endotracheal tube according to claim **1**, wherein at least one sensor is movably attached to the elongate tubular member.

9. The endotracheal tube according to claim **1**, wherein the interior space of the cuff is filled with liquid and the sensor in the interior space of the cuff comprises an ultrasound transducer.

10. A method of performing a surgical procedure, comprising:

- inserting an endotracheal according to claim **1**;
- using at least one sensor to detect at least one parameter; and
- performing the procedure.

11. The method according to claim **10**, wherein the procedure comprises applying a cryogen to a target tissue or using the cryogen to create an isotherm in proximity to the tissue.

12. The method according to claim **11**, wherein the cryogen is applied to a tissue selected from the group consisting of esophageal tissue, lung tissue, tracheal tissue, laryngeal tissue, pharyngeal tissue and gastric tissue.

13. The method of claim **11**, wherein the cryogen comprises a liquefied gas.

14. The method according to claim **11**, wherein the cryogen is selected from the group consisting of nitrogen, oxygen, argon, carbon dioxide, nitrogen dioxide, and air.

15. The method according to claim **13**, wherein the cryogen is sprayed.

16. The method according to claim **15**, wherein the cryogen is sprayed using a catheter.

17. The method according to claim **10**, wherein the parameter detected is cardiac output.

* * * * *

专利名称(译)	带传感器的气管插管		
公开(公告)号	US20120215074A1	公开(公告)日	2012-08-23
申请号	US13/257840	申请日	2010-03-22
[标]申请(专利权)人(译)	KRIMSKY WILLIAM		
申请(专利权)人(译)	KRIMSKY WILLIAM		
当前申请(专利权)人(译)	KRIMSKY WILLIAM		
[标]发明人	KRIMSKY WILLIAM		
发明人	KRIMSKY, WILLIAM		
IPC分类号	A61M16/04 A61B8/12 A61B5/0205 A61B18/02 A61B5/029 A61B5/00 A61B8/06		
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摘要(译)

本发明提供了一种包括一个或多个传感器的气管内导管。在一些实施例中，一个或多个传感器定位在袖带的内部。传感器可用于检测任何生理参数。

