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(54) Title: MEDICAL DEVICE AND TECHNIQUE FOR USING THE SAME

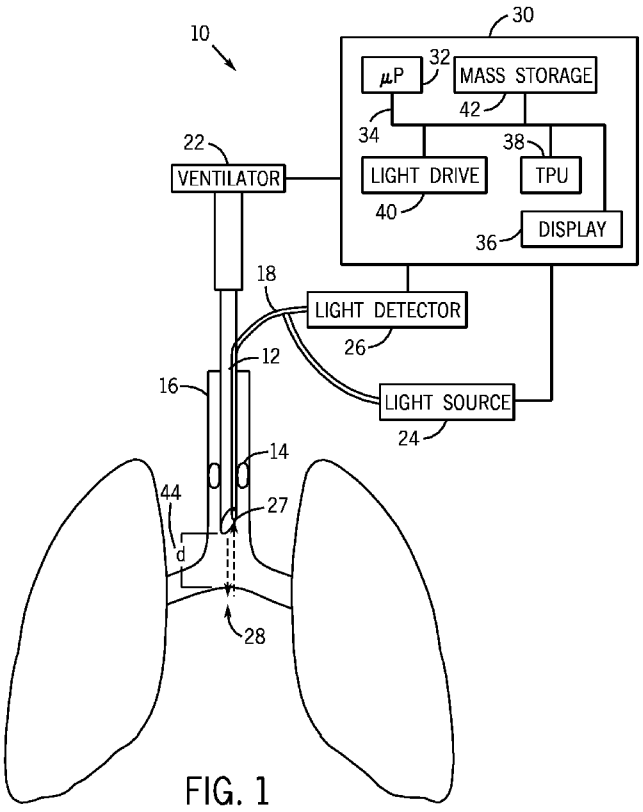

FIG. 1

(57) Abstract: According to various embodiments, a tracheal tube (12) may employ optical sensing techniques for determining a distance (d) between the inserted tube and an anatomical structure, such as a carina (28). The distance information may provide an indication as to whether or not the tracheal tube is properly placed within the trachea. The optical techniques may include backscattered intensity measurements.

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MEDICAL DEVICE AND TECHNIQUE FOR USING THE SAME

BACKGROUND

The present disclosure relates generally to medical devices and, more particularly, to airway devices, such as tracheal tubes.

This section is intended to introduce the reader to aspects of the art that may be related to various aspects of the present disclosure, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present disclosure. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

In the course of treating a patient, a tube or other medical device may be used to control the flow of air, food, fluids, or other substances into the patient. For example, tracheal tubes may be used to control the flow of air or other gases through a patient's trachea. Such tracheal tubes may include endotracheal (ET) tubes, tracheotomy tubes, or transtracheal tubes. In many instances, it is desirable to provide a seal between the outside of the tube or device and the interior of the passage in which the tube or device is inserted. In this way, substances can only flow through the passage via the tube or other medical device, allowing a medical practitioner to maintain control over the type and amount of substances flowing into and out of the patient.

For example, a patient may be intubated when an endotracheal tube is inserted through the patient's mouth and into the trachea. Often, such intubation procedures may be performed during medical emergencies or during critical care situations. As such, healthcare providers may balance a desire for speed of intubation with a desire for accurate placement of the tube within the trachea. However, proper placement of a tracheal tube may be complex. In certain situations, placement may be aided with visualization of the trachea performed during laryngoscopy. During an intubation procedure, a practitioner may employ a lighted laryngoscope during introduction of the endotracheal tube. However, often the visualization of the trachea is poor because of patient secretions that

may obscure the laryngoscope. In addition, such visualization during introduction of the tube may not account for ongoing changes in the tube's position within the trachea that may occur when a patient coughs, which may dislodge a tube from its desired location, or when a patient is jostled or moved within a care setting, which may change the position or angle of the tube within the trachea.

BRIEF DESCRIPTION OF DRAWINGS

Advantages of the disclosure may become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. 1 illustrates an exemplary system including an endotracheal tube with a coherent light source and detector according to embodiments;

FIG. 2A is a schematic diagram of optical sensing components including a beam splitter that may be coupled to a tracheal tube according to embodiments;

FIG. 2B is a schematic diagram of an alternative arrangement of optical sensing components including a beam splitter that may be coupled to a tracheal tube according to embodiments;

FIG. 2C is a schematic diagram of optical sensing components including an optical coupler that may be coupled to a tracheal tube according to embodiments;

FIG. 2D is a schematic diagram of optical sensing components including a multi-port circulator that may be coupled to a tracheal tube according to embodiments;

FIG. 3 is a flow diagram of a method of operating a tracheal tube according to embodiments;

FIG. 4 is a perspective view of an exemplary endotracheal tube of FIG. 3; and

FIG. 5 is a perspective view of an exemplary distal tip of a tracheal tube with embedded optical fibers for that may be coupled to a light source and photodetector.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

One or more specific embodiments of the present disclosure will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

A tracheal tube may be used to seal a patient's airway and provide positive pressure to the lungs when properly inserted into a patient's trachea. Positioning the tracheal tube at a desired position within the trachea, for example during endotracheal intubation, may improve the performance of the tracheal tube and reduce clinical complications. In particular, the distal inserted end of the endotracheal tube may be positioned in the patient's trachea at a location substantially between the patient's vocal cords and carina. If the tube cuff is not inserted far enough past the vocal cords, for example, the tube may become more easily dislodged. If the tube is inserted too far into the trachea, such as past the carina, then the tube may only function to adequately ventilate one of the lungs, rather than both. Thus, proper placement of the distal tip of the tube may result in improved ventilation to the patient.

Provided herein are tracheal tubes and systems for facilitating proper placement of the tracheal tube relative to certain anatomical structures in and around the patient's airway and trachea. Such tracheal tubes may include assemblies for shining light into the trachea and detecting the returned light. The intensity of the detected light may be affected by its interaction with an anatomical structure. Accordingly, information related to the intensity of the detected light may be used to determine a distance from the tube to the anatomical structure in question. In certain embodiments, a distance from the distal end of the tracheal tube to the carina may be determined. A healthcare provider may then use the information

about the location of the tracheal tube relative to the carina to determine whether the tube is properly placed or whether the position of the tube should be adjusted.

In certain embodiments, the disclosed tracheal tubes, systems, and methods may be used in conjunction with any appropriate medical device, including without limitation a feeding tube, an endotracheal tube, a tracheotomy tube, a circuit, an airway accessory, a connector, an adapter, a filter, a humidifier, a nebulizer, nasal cannula, or a supraglottic mask/tube. The present techniques may also be used to monitor any patient benefiting from mechanical ventilation, e.g., positive pressure ventilation. Further, the devices and techniques provided herein may be used to monitor a human patient, such as a trauma victim, an intubated patient, a patient with a tracheotomy, an anesthetized patient, a cardiac arrest victim, a patient suffering from airway obstruction, or a patient suffering from respiratory failure.

FIG. 1 shows an exemplary tracheal tube system **10** that has been inserted into a patient's trachea. The system **10** includes a tracheal tube **12**, shown here as endotracheal tube, with an inflatable balloon cuff **14** that may be inflated to form a seal against tracheal walls **16**. The tracheal tube **12** may also include one or more optical fibers **18** that are associated with the tube **12**. The optical source fiber **18** may be configured to pass light from a source **24** through a distal end **27** of the endotracheal tube and into a patient's trachea such that a portion of the emitted light may interact with a carina **28**. The emitted light may be transferred back through the optical fiber **18**, which may be coupled to a light detector **26**.

The system **10** may also include devices that facilitate positive pressure ventilation of a patient, such as a ventilator **22**, which may include any ventilator, such as those available from Nellcor Puritan Bennett LLC. The system may also include a monitor **30** that may be configured to implement embodiments of the present disclosure. The monitor **30** may be a stand-alone device or may be coupled to another patient monitor or to the ventilator **22**. The monitor **30** may include a microprocessor **32** coupled to an internal bus **34** and a display **36**.

The monitor **30** may include certain elements for controlling the light source **24** and the light detector **26**. The monitor **30** may drive light from source **24**, which in turn may be carried by optical fiber **18**. The light may pass into the tissue, where it may be variously scattered, absorbed, and/or reflected and then detected by detector **26**. A time processing unit (TPU) **38** may provide timing control signals to light drive circuitry **40**, which controls when the light source **24** is activated, and if multiple light sources **24** are used, the multiplexed timing for the different light sources. TPU **38** may also control the gating-in of signals from detector **26**.

In an embodiment, the monitor **30** may be configured to receive signals from the detector **26** and store the signals in a mass storage device **42**, such as a RAM, ROM, optical storage device, flash memory device, hardware storage device, magnetic storage device, or any other suitable device permitting memory storage. The signals may be accessed and operated according to microprocessor **32** instructions. In certain embodiments, the signals may be related to a placement of the tracheal tube **12** within the patient's trachea and may be processed by the monitor **30** to indicate whether the tracheal tube **12** is properly placed. The monitor **30** may be configured to provide an indication about the placement of the tracheal tube **12** within the patient's trachea, such as an audio alarm, visual alarm or a display message if the tracheal tube **12** is too far or too close to certain anatomical structures, such as the carina **28**, or outside of a predetermined placement range. In an embodiment, based at least in part upon the received signals corresponding to the light received through optical fiber **18**, microprocessor **32** may calculate a placement parameter of the endotracheal tube **12** using various algorithms. In an embodiment, the placement parameter may relate to a distance **44** between the distal end **27** of the tube **12** and the carina **28** or other anatomical structure.

FIGs. 2A-D are schematic representations of optical sensor arrangements that may be incorporated into system **10** for analyzing placement of a tracheal tube **12** within a patient's trachea. From the change in intensity of the returned light beam **48** after its interaction with the carina **28** or any other anatomical feature of interest, the distance **44** to the carina **28** may be estimated, as discussed in more detail below. In embodiments, such arrangements may involve measuring the intensity of the emitted light **46** to generate a

reference intensity measurement to which changes in the intensity of the returned light beam **48** may be compared. A calculated return distance, R, may be equal to the distance **44** (i.e., the distance between the distal end **27** and the carina **28**).

It should be understood that the depicted embodiments are exemplary, and the relationships between the optical components may vary. In particular, in embodiments in which optical fibers **18** are employed, the spatial relationships between light source **24**, detector(s) **26**, and beam splitter **50** (or optical coupler or multi-port circulator) may be altered. **FIG. 2A** depicts an embodiment in which one optical fiber **18a** is dedicated to transmit light **46** and a second optical fiber **18b** is dedicated to collect the returned light **48**. In embodiments, optical fibers **18a** and **18b** may be part of a single fiber bundle. As shown, the emitted light **46** is split at beam splitter **50** so that a portion of the light, light beam **46a**, is directed towards a detector **26a**, which may then generate a reference signal related to the intensity of the emitted light **46**. The light beam **46** may pass through the airway until the light interacts with an anatomical tissue structure, such as a carina **28**. The returned light beam **48** may be collected optical fiber **18b** and detected by light detector **26** to generate light intensity signals that may be analyzed by monitor **30**.

In one implementation, a single fiber **18** may be used to emit light and return the light that is reflected/scattered by an anatomical structure. In **FIG. 2B**, a light beam **46** from source **24** may be emitted and split at beam splitter **50** so that a portion of the light, light beam **46a**, is directed towards a detector **26a**, which may then generate a reference signal related to the intensity of the emitted light. The rest of the light beam **46** may be emitted from the distal end **27**of tube **12**. As noted, light from source **24** may be transmitted through optical fiber **18** and the returned light beam **48** may pass through the same fiber **18**. In an alternative embodiment, shown in **FIG. 2C**, instead of a beam splitter **50**, a 2x2 optical coupler **54** may be used to split off a portion of light, light beam **46a**, to impinge a detector **26a** and generate a reference intensity signal. **FIG. 2D** depicts an embodiment in which a multi-port circulator **56** may allow an arrangement in which a single detector may be used to detect the return beam **48**.

The signal generated at one or more detectors **26** may be communicated to the monitor **30**. The incoming signals may include an emitted light intensity signal from the detector **26**, which may be a measure of the intensity of the emitted light beam **46**. The incoming signals may also include an intensity signal of the returned light beam **48**. The monitor **30** may control the light source **24** and light detector **26**. The TPU **38** may control the gating of signals from one or more light detectors **26** in conjunction with the light drive circuitry **40**. In embodiments, the monitor **30** may control a switch from emitting light to detecting light within the optical fiber **18**.

In embodiments, the intensity of the emitted light beam **46** may be estimated or determined without splitting a portion. For example, light source **24** may be factory calibrated such that the intensity is known. The intensity value may be stored as a calibration factor by the monitor **30** or by a separate encoder associated with the light source **24** that may be accessed and read by the monitor **30**.

The light source **24** and a detector **26** may be of any suitable type. For example, the light source **24** may be one or more light emitting diodes adapted to transmit one or more wavelengths of light, for example in the red to infrared range, and the detector **26** may be one or more photodetectors (e.g., photodiodes) selected to receive light in the range or ranges emitted from the light source **24**. A light source **24** may be a coherent light source, such as a laser diode or a vertical cavity surface emitting laser (VCSEL). The light source **24** may include a broadband or "white light" source, in which case the detector could include any of a variety of elements for selecting specific wavelengths, such as reflective or refractive elements or interferometers. It should be understood that, as used herein, the term “light” may refer to one or more of ultrasound, radio, microwave, millimeter wave, infrared, visible, ultraviolet, gamma ray or X-ray electromagnetic radiation, and may also include any wavelength within the radio, microwave, infrared, visible, ultraviolet, or X-ray spectra.

In embodiments, the light source **24** and detector **26** may be directly coupled to the distal end **27** of the tracheal tube **12**, such that the light does not first pass through an optical fiber **18** before being emitted or detected. In such an embodiment, any distance

between the light source **24** and detector **26** may be accounted for by measuring intensity profile of the returned light.

FIG. 3 is a process flow diagram illustrating a method in accordance with some embodiments. The method is generally indicated by reference number **64** and includes various steps or actions represented by blocks. It should be noted that the method **64** may be performed as an automated procedure by a system, such as system **10**. Further, certain steps or portions of the method may be performed by separate devices. For example, a first portion of the method **64** may be performed by a light source **24** and light detector **26**, while a second portion of the method **64** may be performed by a monitor **30**. In certain embodiments, the method **64** may be performed continuously or intermittently for long-term patient monitoring or at any appropriate interval depending on the particular situation of the intubated patient. Further, the steps of method **64** may be performed during insertion of the tracheal tube **12** into the patient.

According to an embodiment, the method **64** begins with emitting light, at step **66** from a light source **24**, which in embodiments may be coupled to one or more optical fibers **18**. The emitted light beam **46** is transmitted through fiber **18**, which is associated with tube **12** that is inserted into a patient's airway. The portion of the emitted light is split at step **68** into an intensity reference light beam **52**. The rest of the beam **46** may exit the distal end **27** of the tube **12** before interacting with anatomical structures in the patient. The returned light beam **48** that is returned through optical fiber **18** and received by the detector **26** at step **70** may carry information about the relative position of the tube **12** and the anatomical structure that is carried in the sample signal, generated at step **72**. The intensity of the returned light beam **48**, I_r, at the detector **26**, may be used to calculate a placement parameter. At step **74**, the intensity reference beam is detected by the detector **26** to generate the intensity reference signal, I_o, at step **76**.

A monitor **30** may perform analysis of the sample signal and the reference signal at step **78**. In embodiments, the monitor may amplify and/or filter one or both of the sample signal and the reference signal prior to the analysis. A monitor **30** may determine a placement parameter at step **80** to determine if this the distance **44** between the distal end

27 and the carina **28** associated with a desirable placement of the tracheal tube **12**. In one embodiment, the analysis may include determining the distance **44**, or R, between the distal end **27** to the carina **28**, which in embodiments may be determined by the following equation:

$$R = \tfrac{1}{2} (\mathcal{R} I_o / I_r)^{1/2},$$

where $\mathcal{R}$ a function of optical properties of the carina surface, I_o is the optical intensity of the light beam **46** at the fiber end, and I_r is the received intensity of the returned light beam **48**. In one embodiment, R may be the placement parameter. In certain embodiments, a placement parameter may be a ratio of a calculated distance and an empirically derived or clinically measured distance associated with proper tube placement. It should be appreciated that there may be several empirically derived distances, depending on the size, age, or sex of the patient. A placement parameter may also be an average or mean of multiple data points or measurements. A placement parameter may also include a graphical, visual, or audio representation of the tube/anatomical structure distance. For example, a placement parameter associated with proper placement may include green light indicated on a display or a short tone generated by a speaker associated with monitor **30**. Similarly, a placement parameter associated with improper placement of the tube **12** may trigger an alarm at step **82**, which may include one or more of an audio or visual alarm indication. In one embodiment, the alarm may be triggered if the placement parameter is substantially greater than a predetermined value, substantially less than a predetermined value, or outside of a predetermined range. For example, proper tube placement may involve comparing a measured distance R of the distal end **27** to carina **28** to a predetermined range of 1-5 cm. In an embodiment, the predetermined target distance may differ for adult men, who may have, in an embodiment, a target distance of 3-4cm, and adult women, for whom the target distance may be 2-3cm. In other embodiments, the alarm may be triggered if the measured distance R is less than 3 cm, less than 2cm, or less than 1cm.

FIG. 4 is a perspective view of an exemplary tracheal tube **12** according to certain embodiments. As shown, the tube **12** may include a cuff **14** that may be inflated via

inflation lumen **84**. The tracheal tube **12** may also include a suction lumen **86** for aspirating secretions that may form above the cuff **14**. The tracheal tube **12** may also include a plurality of fiber bundles **88**. Each fiber bundle may include one or more optical fibers **18**. In embodiments, the transmitting and detecting may also take place within a single fiber. As shown, the fiber bundles **88** may extend through the walls **90** of the tracheal tube **12** such that they are substantially in line with a flow path **92** of the tracheal tube **12**. The fibers bundles **88** may include any appropriate optical connector **94** for connecting the fiber bundles **88** to downstream components of the system **10**, such as the bean splitter **50** or the light source **24** or light detector **26**.

The tube **12** and the cuff **14** may be formed from materials having suitable mechanical properties (such as puncture resistance, pin hole resistance, tensile strength), chemical properties (such as biocompatibility). In one embodiment, the walls of the cuff **14** are made of a polyurethane having suitable mechanical and chemical properties. An example of a suitable polyurethane is Dow Pellethane® 2363-80A. In another embodiment, the walls of the cuff **14** are made of a suitable polyvinyl chloride (PVC). In certain embodiments, the cuff **14** may be generally sized and shaped as a high volume, low pressure cuff that may be designed to be inflated to pressures between about 15cm H_2O and 30cm H_2O. The system **10** may also include a respiratory circuit (not shown) connected to the endotracheal tube **12** that allows one-way flow of expired gases away from the patient and one-way flow of inspired gases towards the patient. The respiratory circuit, including the tube **12**, may include standard medical tubing made from suitable materials such as polyurethane, polyvinyl chloride (PVC), polyethylene teraphthalate (PETP), low-density polyethylene (LDPE), polypropylene, silicone, neoprene, polytetrafluoroethylene (PTFE), or polyisoprene.

FIG. 5 is a side view of the distal end **27** of the tracheal tube **12**. As shown, the fiber bundles **88** may extend through the walls **90** of the tracheal tube. In certain embodiments, the fiber bundles **88** may be embedded or coextruded within an extruded tracheal tube **12**. When the tube **12** is manufactured, the distal end **27** may be cut on a slant to facilitate insertion of the tube **12** in the trachea. After the tube is cut, the fiber bundles **88** may be terminated by any suitable technique.

The fiber bundles **88**, or, in some embodiments, individual fibers, may be distributed around the circumference **96** of the tube wall **90**. In an embodiment, three optical bundles may be substantially evenly spaced about the circumference **96**.

As shown the positioning of the fiber bundles **88** or single fibers may influence the path of the light from the distal end **27** of the tube **12** to the anatomical structure. Arrows **98**, **100**, and **102** illustrate three different light paths from bundles **88a**, **88b**, and **88c,** respectively, to anatomical structures at or proximate to the carina **28**. Arrow **98** has a somewhat shorter path than arrow **100,** which is related to its position around the circumference **96** relative to the carina **28,** as well as differences in the topography of the carina **28**. In addition, slight changes in the angle within the trachea of the distal end **27** of the tube **12** may influence the path of light to and from the fiber bundles **88**. In certain embodiments, light detected from all three fiber bundles **88** may be combined or averaged to generate the data used to determine a placement parameter. In addition, the differences in path length between multiple bundles may be used to determine a placement parameter that is indicative of the orientation of the distal end **27** within the trachea. Changes in this orientation (e.g., angular displacement) may indicate a shift in tube placement that may influence cuff pressure and sealing.

In certain embodiments, the fibers or fiber bundles **88** may be formed from materials such as quartz, glass, or a transparent plastic, such as poly(methyl methacrylate) or polystyrene with a fluoropolymer cladding. Examples of optical fibers include single-mode fibers, multi-mode fibers, photonic-crystal fibers, hollow-core fibers, polarization-maintaining fibers and dual-clad fibers. Typical diameters for optical fibers are from 5 to 1,000 micrometers. The optical fiber may be a single-mode fiber or a multi-mode fiber.

While the disclosure may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the embodiments provided herein are not intended to be limited to the particular forms disclosed. Indeed, the disclosed embodiments may not only be applied to measurements of tracheal tube placement relative to anatomical structures in the tracheal, but these techniques may also be utilized for the measurement and/or analysis of the placement of

other suitable medical devices relative to other anatomical structures. For example, the present techniques may be utilized for the measurement and/or analysis of tracheal tubes relative to tracheal walls or the vocal cords. In addition, the present techniques may be employed in determining appropriate placement of any medical device, such as a stent, catheter, implant, feeding tube, cardiac device, drug delivery device, or pump. Rather, the various embodiments may cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure as defined by the following appended claims.

CLAIMS

1. A method for determining placement of a tracheal tube in a subject comprising:

emitting light from an optical conductor disposed in or on a tracheal tube disposed in a subject;

receiving returned light from an anatomical structure within the subject;

measuring an intensity of the returned light; and

determining a placement parameter based upon the intensity of the returned light.

2. The method of claim 1, comprising measuring an intensity of the emitted light, and wherein the placement parameter is determined based upon the intensity of the emitted light and the intensity of the returned light.

3. The method of claim 2, wherein the intensity of the emitted light is measured by a first photodetector and the intensity of the returned light is measured by a second photodetector.

4. The method of claim 2, wherein the intensity of the emitted light and the intensity of the returned light are measured by a single photodetector.

5. The method of claim 2, wherein the placement parameter is determined based upon an optical parameter of the anatomical structure.

6. The method of claim 1, wherein the placement parameter is representative of a distance between the tracheal tube and the anatomical structure.

7. The method of claim 6, wherein the anatomical structure comprises a carina.

8. The method of claim 7, comprising triggering an alarm or message when the distance between the tracheal tube and the carina is less than or greater than a

predetermined distance or when the distance between the tracheal tube and the carina falls outside of a predetermined range.

9. The method of claim 1, wherein the steps are performed during intubation of the subject.

10. The method of claim 1, wherein the steps are performed after intubation of the subject.

11. A method for determining placement of a tracheal tube in a subject comprising:

emitting light from an optical conductor disposed in or on a tracheal tube disposed in a subject;

determining an intensity of the emitted light;

receiving returned light from an anatomical structure within the subject;

determining an intensity of the returned light; and

determining a placement parameter based upon an algorithm that implements an equation generally of the form:

$$R = \tfrac{1}{2} (\mathcal{R} I_o / I_r)^{1/2},$$

where R is the placement parameter, $\mathcal{R}$ is a function of optical properties of the anatomical structure, I_o is the intensity of the emitted light, and I_r is the intensity of the returned light.

12. The method of claim 11, wherein the intensity of the emitted light is measured by a first photodetector and the intensity of the returned light is measured by a second photodetector.

13. The method of claim 11, wherein the intensity of the emitted light and the intensity of the returned light are measured by a single photodetector.

14. The method of claim 11, wherein the placement parameter is representative of a distance between the tracheal tube and the anatomical structure.

15. The method of claim 11, wherein the steps are performed during intubation of the subject.

16. The method of claim 11, wherein the distance is determined after intubation of the subject.

17. A system for determining placement of a tracheal tube in a subject comprising:

a light source configured to emit light through an optical conductor disposed in or on a tracheal tube disposed in a subject;

a photodetector configured to receive returned light from an anatomical structure within the subject and to determine an intensity of the returned light; and

a processor configured to determine a placement parameter based upon the intensity of the returned light.

18. The system of claim 17, comprising means for determining intensity of the emitted light.

19. The system of claim 18, wherein the means for determining the intensity of the emitted light comprises the photodetector.

20. The system of claim 17, wherein the processor is configured to determine the placement parameter based upon an algorithm that implements an equation generally of the form:

$$R = \tfrac{1}{2} (\mathcal{R} I_o / I_r)^{1/2},$$

where R is the placement parameter, $\mathcal{R}$ is a function of optical properties of the anatomical structure, I_o is the intensity of the emitted light, and I_r is the intensity of the returned light.

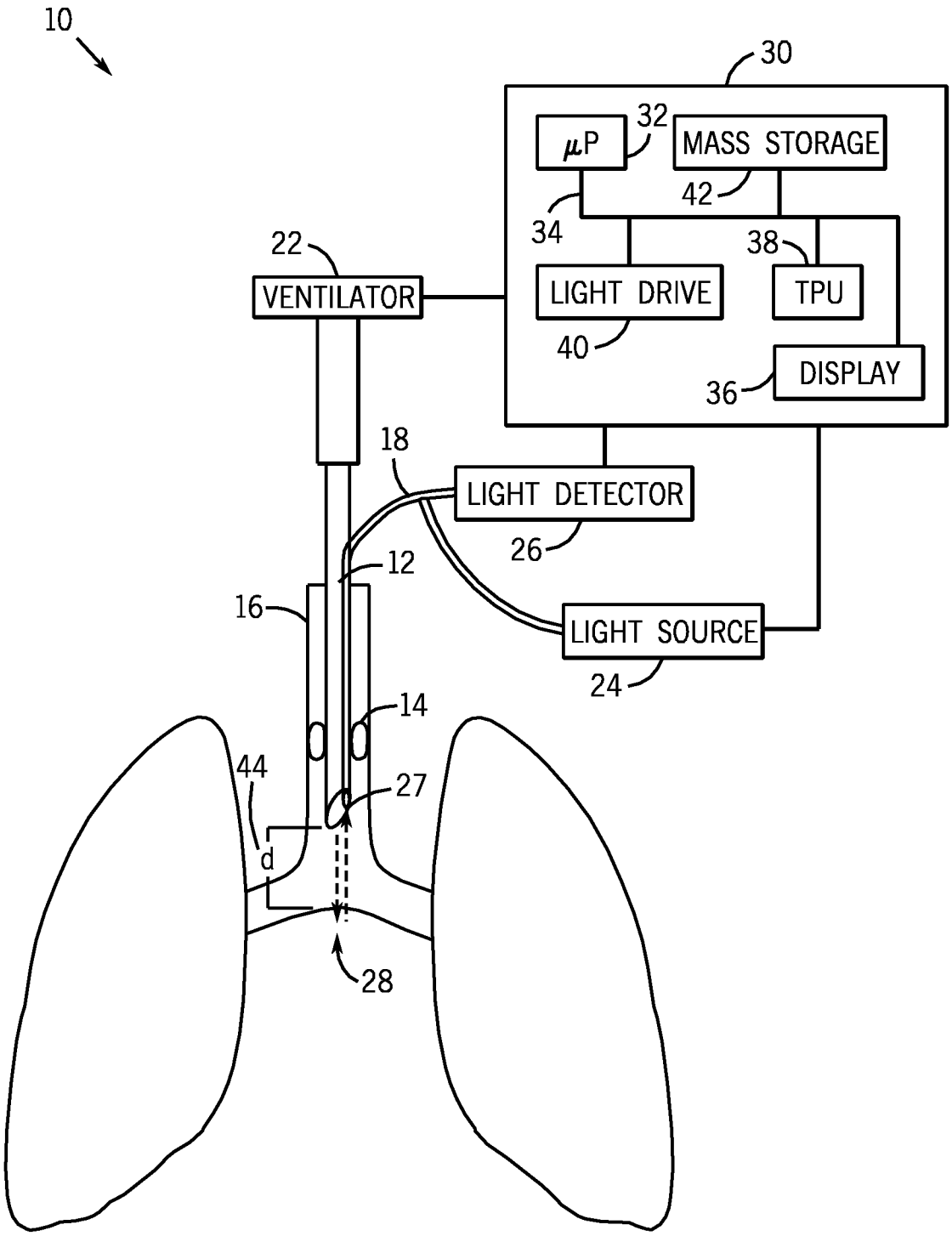

10
30
μP
32
MASS STORAGE
42
34
38
22
VENTILATOR
LIGHT DRIVE
TPU
40
DISPLAY
36
18
LIGHT DETECTOR
26
12
16
LIGHT SOURCE
24
14
44
27
d
28

FIG. 1

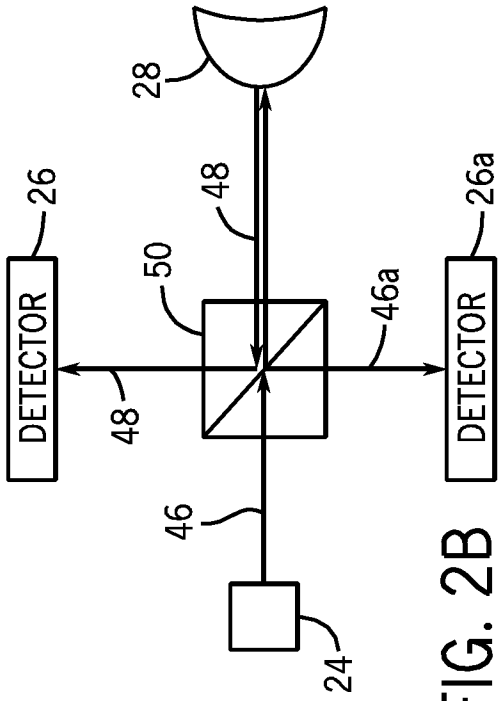


FIG. 2B

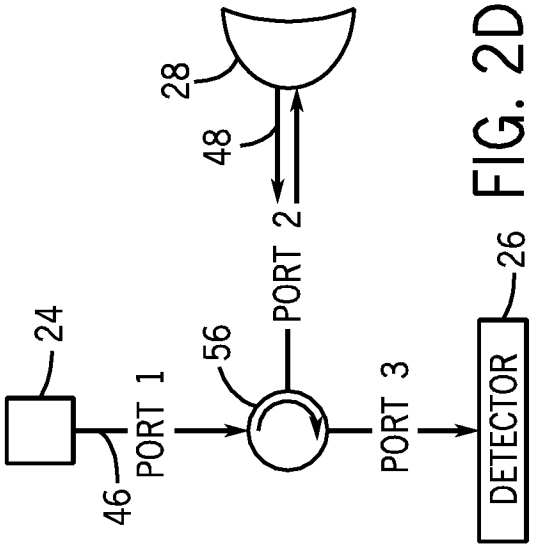


FIG. 2D

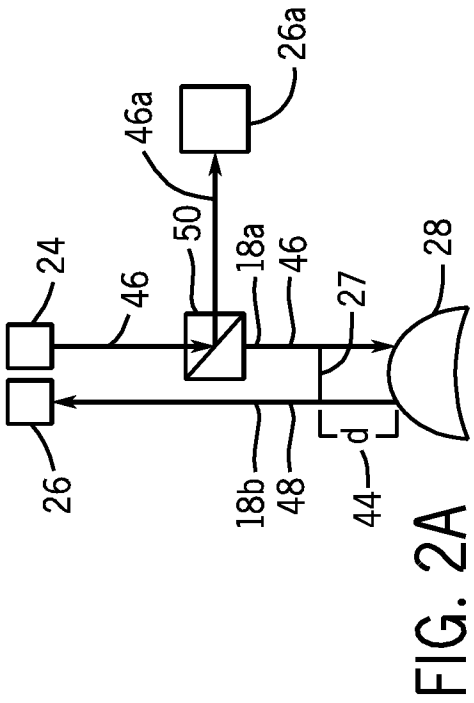


FIG. 2A

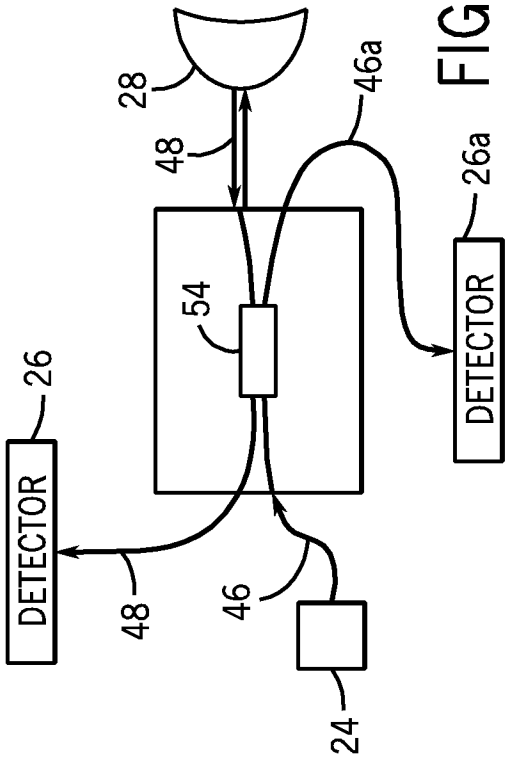
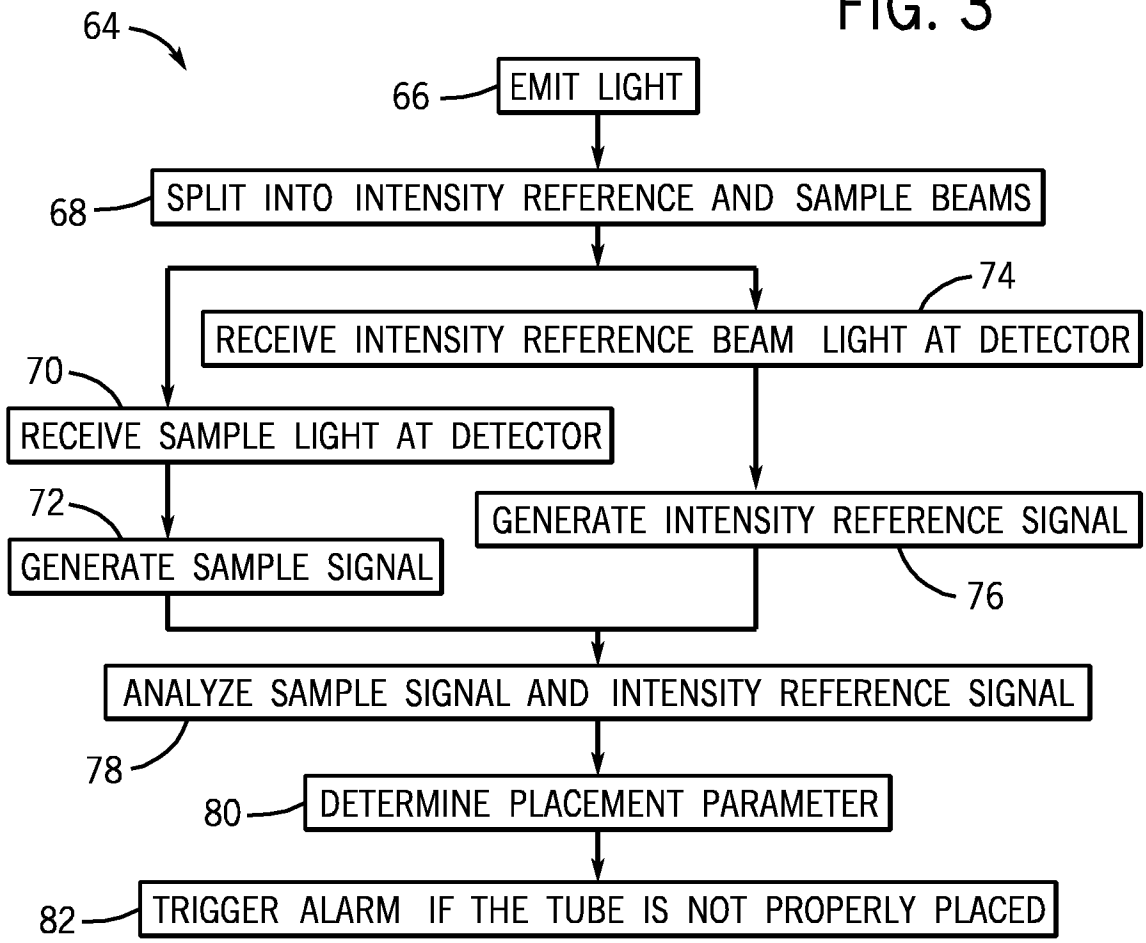


FIG. 2C

FIG. 3


64
66
EMIT LIGHT
68
SPLIT INTO INTENSITY REFERENCE AND SAMPLE BEAMS
74
RECEIVE INTENSITY REFERENCE BEAM LIGHT AT DETECTOR
70
RECEIVE SAMPLE LIGHT AT DETECTOR
72
GENERATE SAMPLE SIGNAL
GENERATE INTENSITY REFERENCE SIGNAL
76
ANALYZE SAMPLE SIGNAL AND INTENSITY REFERENCE SIGNAL
78
80
DETERMINE PLACEMENT PARAMETER
82
TRIGGER ALARM IF THE TUBE IS NOT PROPERLY PLACED

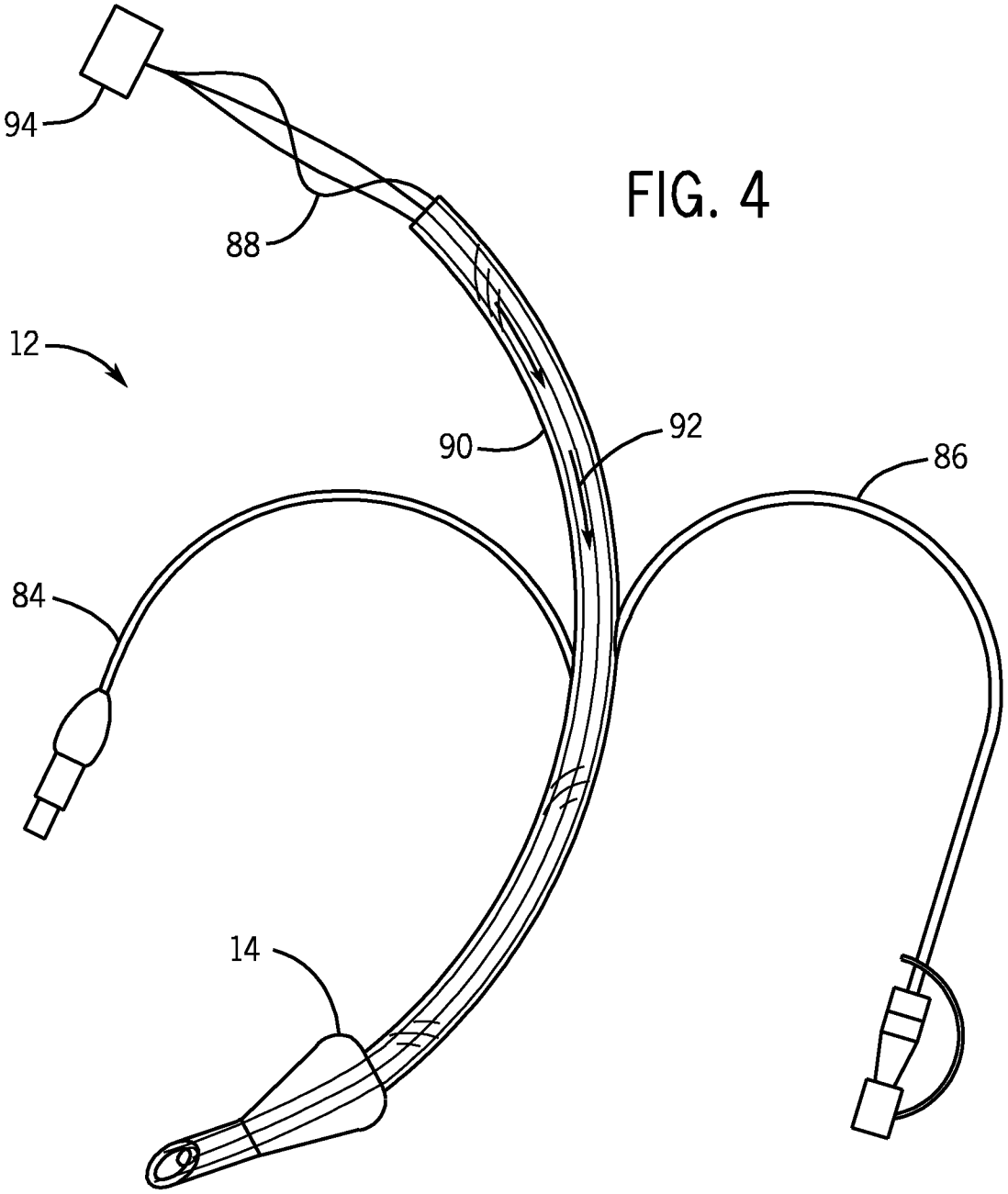


FIG. 4

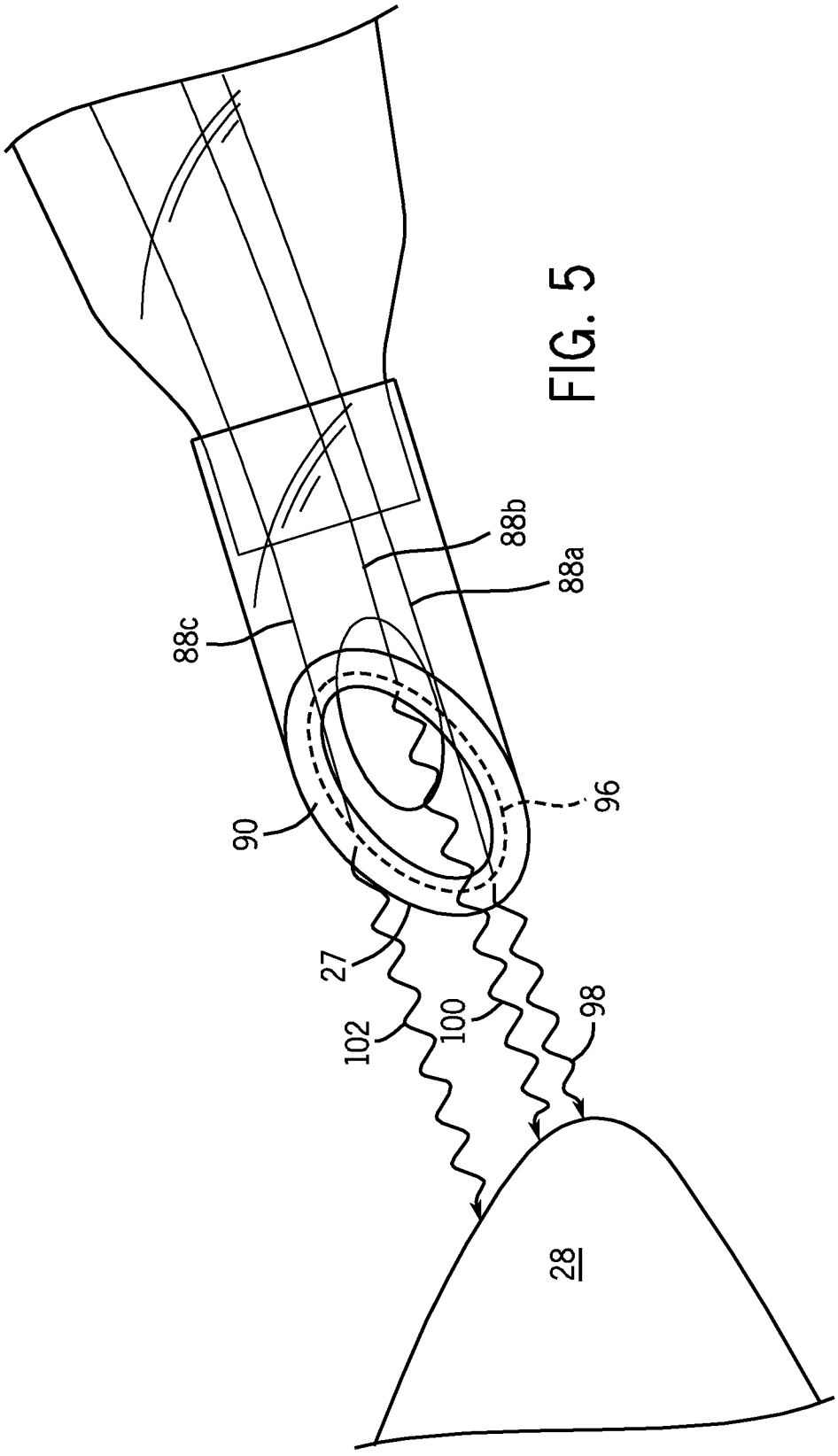


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/030070

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/04
ADD. A61M25/01 A61B5/00 A61B1/267 G01B11/02

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)
A61M A61B G01B

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/039252 A1 (KOCH KENNETH ELMON [US]) 26 February 2004 (2004-02-26)	10,17-19
A	the whole document	16,20
A	US 5 193 544 A (JAFFE RICHARD A [US]) 16 March 1993 (1993-03-16) column 2, line 64 - column 3, line 1 column 4, lines 18-42 column 5, lines 31-42 figures 1,2,5	10,16,17
A	DE 201 16 532 U1 (GRAS WILHELM [DE]) 17 January 2002 (2002-01-17) the whole document	10,16,17
A	US 2005/177024 A1 (MACKIN ROBERT A [US]) 11 August 2005 (2005-08-11) page 2, paragraphs 23,26; figures 1-3	10,16,17

-/--

[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 document 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
11 June 2010	21/06/2010

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	Azaïzia, Mourad

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/030070

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/015610 A2 (ALFRED E MANN INST BIOMED ENG [US]) 27 February 2003 (2003-02-27) the whole document	10,16,17
A	WO 01/91843 A1 (PURDUE RESEARCH FOUNDATION [US]) 6 December 2001 (2001-12-06) the whole document	10,16,17
A	US 5 445 144 A (WODICKA GEORGE R [US] ET AL) 29 August 1995 (1995-08-29) the whole document	10,16,17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/030070

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.: 1-9, 11-15
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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

Information on patent family members

International application No
PCT/US2010/030070

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004039252 A1	26-02-2004	NONE	
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		EP 1289594 A1	12-03-2003
		ES 2323040 T3	06-07-2009
		US 6705319 B1	16-03-2004
US 5445144 A	29-08-1995	NONE	