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(71) Applicant *(for all designated States except US)*: **THE REGENTS OF THE UNIVERSITY OF CALIFORNIA** [US/US]; 12th Floor, 1111 Franklin Street, Oakland, California 94607-5200 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **HOFTMAN, Moshe Mike** [US/US]; 22205 Dardenne Street, Calabasas, California 91302 (US). **HOFTMAN, Nir N.** [US/US]; # 204, 1740 Malcolm Avenue, Los Angeles, California 90024 (US). **MAHAJAN, Aman** [IN/US]; 15475 Loom Place, Sherman Oaks, California 91403 (US).

(74) Agents: **KLEIN, Howard J.** et al.; Suite 510, 2 Park Plaza, Irvine, California 92614 (US).

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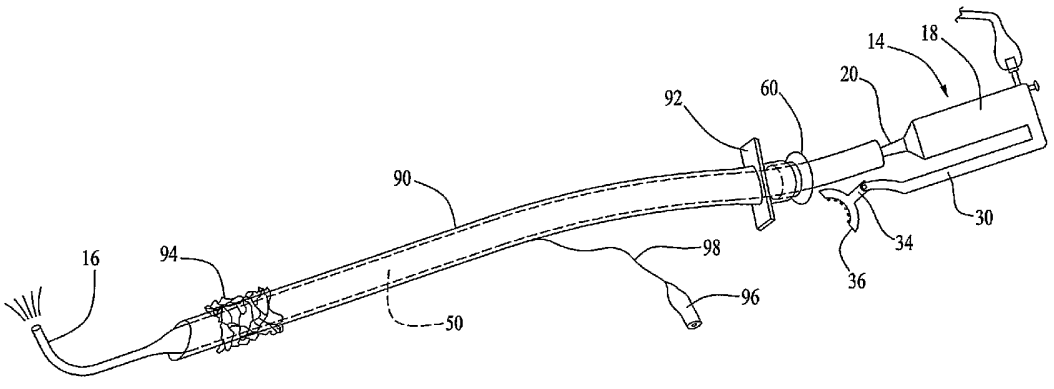
(54) Title: INTUBATING BRONCHOSCOPE



(57) **Abstract:** A bronchoscope (10) includes an optical tube (12) having a flexible distal end portion (16). A handle and control module (14) is attached to the proximal end of the tube (12) and includes an actuation mechanism operatively linked to the distal end portion (16) and operable by a control lever (36, 118) to move the distal end portion (16). The bronchoscope (10) further includes a semi-rigid sleeve (50) that fits over the optical tube (12) and that has a main portion (51) with a first outside diameter and a reduced-diameter flexible distal end portion (52) that encompasses the distal end portion (16) of the optical tube (12). The first outside diameter is selected to be approximately equal to the inside diameter of a pre-selected endoctracheal tube (90). A rotatable arm (120), operably connecting the control lever (36, 118) to the handle and control module (14), is attached to the module (14) so as to be rotatable at least about 180 degrees around the axis of the module (14).

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INTUBATING BRONCHOSCOPE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit, under 35 U.S.C. §119(e), of co-pending US Provisional Application No. 60/629,813, filed November 19, 2004, the disclosure of which is incorporated herein by reference.

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

[0002] This invention relates to the field of bronchoscopes, which are medical instruments employed for insertion into a patient's trachea for visualization in connection with endotracheal intubation, such as, for example, during the delivery of general anesthesia to a patient's pulmonary system.

[0003] Endotracheal intubation is frequently performed by direct laryngoscopy. In many cases, however, for a variety of reasons, direct laryngoscopy is difficult or awkward, or it yields suboptimal results. In such cases, a bronchoscope may be employed to assist in the intubation. The typical bronchoscope is a fiber-optic instrument that is configured for passage through the trachea, past the larynx, and that transmits images either to an eyepiece on the instrument itself, or to a console having a monitor on which the images are displayed in real time. The typical prior art bronchoscope, however, is itself an awkward instrument to use, frequently requiring two hands to manipulate and to hold in place, while surgical assistants or nurses are required to manipulate and to hold the patient's head in a position for optimal visualization.

[0004] More specifically, in a typical anesthesiology application, an anesthesiologist may perform a direct laryngoscopy by placing a blade into the oropharynx of the patient, thereby allowing the retraction of tissues and the alignment of the airway into a direct line of sight. An endotracheal tube (ETT) is then placed into the trachea under direct visual observation. There are times, however, when direct laryngoscopy cannot bring the airway into view, thus making

intubation much more difficult. In such cases, the practitioner may steer a fiber optic bronchoscope into the trachea, a procedure that requires two hands. An ETT, previously loaded onto the bronchoscope, is then passed into the trachea, using the bronchoscope as a guide. See, e.g., US 5,607,386, the disclosure of which is incorporated herein by reference. In such procedures, the tissue and the topography of the airway anatomy may create difficulty in locating the tracheal lumen. Furthermore, because the diameter of the ETT is typically larger than that of the bronchoscope, the ETT can get hung up on the laryngeal structures, making insertion difficult. Thus, the typical intubation using a fiber-optic bronchoscope is time-consuming and often requires at least two practitioners.

[0005] There is thus a need for a bronchoscope that is easier to use than prior art bronchoscopes, preferably being adapted for one-hand use, thereby allowing a user to have a free hand to use for direct laryngoscopy, while also maximizing the view of the airway. Thus, for example, such a simplified bronchoscope could act as an endotracheal tube video stylet, with the steerability of a typical fiber-optic bronchoscope. It would also be advantageous to provide such a bronchoscope with a sizer sleeve system that matches the ETT diameter to the bronchoscope diameter, while at the same time shielding the bronchoscope from contamination by the patient's bodily secretions.

SUMMARY OF THE INVENTION

[0006] The present invention, in a first aspect, is an intubating bronchoscope assembly comprising a bronchoscope adapted for one-hand operation, and an endotracheal tube (ETT) carried on the bronchoscope for intubating a patient. Broadly, a bronchoscope assembly in accordance with this first aspect of the present invention includes a bronchoscope comprising an elongate, flexible, optical tube having a proximal end attached to a handle and control module, and a distal end portion that is steerable, using one or more cables or cords extending longitudinally through the tube from an actuation mechanism in the handle and control module to the distal end portion of the tube. An ETT is carried coaxially on the optical tube by means of an isolating sizer sleeve that fits over the optical tube and that has an outside diameter that is approximately equal to the inside diameter of the ETT. Thus, the sizer sleeve increases the outside diameter of the optical tube to approximately the inside diameter of a conventional ETT, so that the ETT can be can be installed coaxially on the optical tube of the bronchoscope with a

snug fit, thereby reducing the likelihood of the ETT getting snagged on airway tissue. In addition, the sleeve isolates the optical tube from the bodily secretions of the patient, thereby eliminating the need to sterilize the bronchoscope between patients. Instead, the old sleeve is removed and discarded, and a new sleeve is installed.

[0007] The sizer sleeve is advantageously used in conjunction with an ETT holder, comprising a rigid tubular member that fits over the sleeve and that is retained near the proximal end of the optical tube. The outside diameter of the ETT holder is sized so that a standard ETT connector can snap onto the holder, so as to retain the ETT in place on the sleeve during intubation.

[0008] In accordance with another aspect of the present invention, the angle of the distal end portion of the optical tube is adjusted by a finger-operated control lever that is mounted on the handle and control module by means of an arm that is rotatable around the axis of the handle and control module. By actuating the control lever, the distal end portion of the optical tube can be moved through an angle of up to about 180 degrees for steering it around tissues or airway structures. The rotatable arm allows the position of the control lever to be selectively adjusted to accommodate the preferences of the practitioner using the device.

[0009] In another aspect of the present invention, the invention is a bronchoscope system that includes the above-described bronchoscope and a video display monitor that receives the optical signal from the bronchoscope, and that displays a corresponding image on a video screen. The image may be displayed in real time, or it may be stored for later viewing. The monitor is preferably compact and self-powered (e.g., by a battery), so that it may be clamped onto a standard IV pole, or it may include an attached foldable stand so that it can be supported on a flat surface.

[0010] The bronchoscope assembly in accordance with the present invention allows for convenient, one-handed use. Specifically, with an ETT installed on the optical tube of the bronchoscope by means of the isolating sizer sleeve and the ETT holder, the bronchoscope is held in one hand, and the optical tube, with its steerable distal end portion, is guided down the oropharynx. The other hand is thus free for other uses, such as, for example, to align the airway

via direct laryngoscopy. The video display monitor displays the image captured by the optics in the optical tube from the distal tip of the tube. Once the airway is properly visualized on the screen, the bronchoscope is advanced down the trachea, with the distal end portion being steered by means of the finger-actuated lever on the handle and control module. At this point, if a laryngoscope has been used, it is released, freeing the hand that was holding it to aid in advancing the ETT into the trachea using the bronchoscope as a guide.

[0011] As will be better appreciated from the detailed description that follows, the bronchoscope and bronchoscope system, in accordance with the present invention, allow for a quicker, more precise, and more convenient tracheal intubation than has heretofore been possible. Furthermore, the present invention is easily adapted for use with standard ETTs of different diameters, using removable sleeves and ETT connectors that may be made in a variety of sizes. Finally, the bronchoscope system of the present invention contemplates video monitoring of the intubation procedure in real time, as well as the storage of video images for later viewing and reference. These and other advantages of the invention will be understood from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Figure 1 is a side elevational view of a bronchoscope of the type used in accordance with a preferred embodiment of the invention;

[0013] Figure 2 is a side elevational view of an isolating sizer sleeve that is used with the bronchoscope of Fig. 1 in accordance with the present invention;

[0014] Figure 2A is an end elevational view of the isolating sizer sleeve, taken along line 2A – 2A of Fig. 2;

[0015] Figure 3 is a perspective view of an endotrachael tube holder, of the type employed with the isolating sizer sleeve of Fig. 2 and the bronchoscope of Fig. 1, in accordance with the present invention;

[0016] Figure 4 is a front elevational view of a video monitor of the type used in the bronchoscope system of the present invention;

[0017] Figure 5 is an end elevational view of the bronchoscope of Fig. 1, taken along line 5 – 5 of Fig. 1;

[0018] Figure 6 is a cross-sectional view taken along line 6 – 6 of Fig. 5;

[0019] Figure 7 is a side elevational view of the monitor of Fig. 4, showing the monitor clamped to an IV pole;

[0020] Figure 8 is a side elevational view, partially in cross-section, of a bronchoscope in accordance with a preferred embodiment of the invention, showing the isolating sizer sleeve of Fig. 2 and the endotracheal tube connector of Fig. 3 being installed;

[0021] Figure 9 is a side elevational view, partially in cross-section, similar to that of Fig. 8, but showing the sleeve and the endotrachael tube connector in place;

[0022] Figure 10 is a perspective view of a fully assembled bronchoscope in accordance with the present invention, with an endotracheal tube installed coaxially on the optical tube of the bronchoscope;

[0023] Figure 11 is a perspective view of a patient being intubated with a bronchoscope in accordance with the present invention; and

[0024] Figures 12 and 13 are side elevational views of an alternative configuration for the handle and control module of a bronchoscope in accordance with the present invention.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

[0025] Referring first to Figure 1, a bronchoscope 10 in accordance with a preferred embodiment of the invention is shown. The bronchoscope 10 includes a long, flexible optical tube 12 attached at its proximal end to a handle and control module 14. The optical tube 12 has a main portion and a flexible and steerable distal end portion 16 that can be moved through an angle of approximately 180 degrees by means of a cable mechanism to be described below. Advantageously, the distal end portion 16 may be approximately 4 cm in length, but this dimension is not critical, and the length of the steerable distal end portion 16 may deviate from this preferred length, depending on the needs of the patient and the preferences of the practitioner. The overall length of the optical tube 12 is preferably about 40 cm, which is considerably shorter than the optical tube on conventional bronchoscopes. This shorter length facilitates the one-handed operation, described below, that makes the present invention advantageous in many applications.

[0026] The handle and control module 14 includes a housing 18 having a tapered distal portion 20 to which the proximal end of the optical tube 12 is attached. The back or proximal end of the housing 18 is provided with a cable connector 22 for attachment of a cable to a video monitor as described below. The housing 18 may also be provided with an oxygen or gas port 28, for purposes to be described below. The housing 18 contains a light source (not shown), including a power supply, as in conventional bronchoscopes, for generating an illuminating beam, as will be described below. The light source may be an LED, as is well-known in the art.

[0027] Attached to the back or proximal end of the housing 18 of the handle and control module 14 is a rigid arm 30 that extends distally parallel to the housing 18. Attached to the distal end of the arm 30 by a pivot connection 32 is a control lever 34 that terminates in a finger grip 36. The control lever 34 is connected, via a linkage (not shown) that passes through the arm 30 into the housing 18, where the linkage connects to an actuation mechanism (not shown) that operates the steerable distal end portion 16 of the optical tube 12, as will be described below. The linkage and the actuation mechanism used in the bronchoscope 10 of the present invention may be of any of the conventional types used in current state of the art bronchoscopes, and will be familiar to those of ordinary skill in the pertinent arts.

[0028] The construction of the optical tube 12 is illustrated in Figures 5 and 6. As shown, at least one cable or cord 38 (two are shown) passes longitudinally through the optical tube 12, the distal end of each cable or cord 38 being secured to the distal end portion 16 of the optical tube 12, and the proximal end of each cable or cord 38 being connected to the actuation mechanism in the housing 18. An illuminating fiber optic light guide 40 extends longitudinally from the light source in the housing 18 through the optical tube 12 to a focusing lens 42 at the distal tip of the optical tube 12. An imaging fiber optic bundle 44 also extends longitudinally through the optical tube 12, terminating at its distal end in an imaging lens 46. The imaging fiber optic bundle 44 extends proximally into the housing and has a proximal end (not shown) that connects to the interior portion (not shown) of the cable connector 22. As an alternative, the imaging fiber optic bundle 44 may be replaced by a semiconductor video chip (e.g., a CCD, not shown), operating as a digital camera. The video chip would be connected by a cable or wire (not shown) passing longitudinally through the optical tube 12 into the housing 18 for connection to the cable connector 22.

[0029] The hollow interior of the optical tube may provide or include a passage 48 for the flow of oxygen, air or other respiratory gas from the oxygen or gas port 28 in the housing 18. The port 28 is connectable by a flexible conduit (not shown) to a gas supply (not shown), and it is connected, in the interior of the housing 18, to the proximal end of the optical tube 12. The passage 48 opens at or near the distal end of the optical tube 12 to insufflate oxygen thereto.

[0030] Referring now to Figure 2, an isolating sizer sleeve 50 for use in the present invention is shown. The sleeve 50 has an internal diameter dimensioned to fit snugly over the exterior of the optical tube 12. The sleeve 50 has a main portion 51, approximately corresponding in length to the main portion of the optical tube 12, that is formed of a semi-rigid, malleable plastic with a shape memory, of any suitable type well-known in the art. The main portion 51 of the sleeve 50 has an outside diameter that is selected to match the inside diameter of an endotracheal tube (ETT) that is to be installed on the bronchoscope, as will be described below. Thus, ETTs of different diameters may be installed, depending on the needs of the patient and the preferences of the practitioner. The sleeve 50 has a distal end portion 52, of reduced outside diameter, having a

length that is approximately equal to the length of the steerable distal end portion 16 of the optical tube 12. The distal end portion 52 of the sleeve 50 is made of a highly flexible polymeric material, so as to accommodate the movement of the steerable distal end portion 16 of the optical tube 12, and it is transparent to allow the passage of light through the distal end of the optical tube 12. The distal tip of the distal end portion 52 of the sleeve 50 may optionally be formed as or provided with an optical-quality plastic lens (not shown) to aid in acquiring or focusing the image acquired by the imaging fiber optic bundle 44 in optical tube 12.

[0031] The sleeve 50 may optionally have a longitudinal passage 54, as shown in Fig. 2A. The passage 54, which extends the length of the sleeve 50 from its proximal end to the tip of the distal end portion 52, may be used for oxygen insufflation or for suction, or it may also be used for the topicalization of airway tissues and structures, such as the oropharynx, the glottis, and the trachea. By facilitating precision topicalization using the direct visualization afforded by the bronchoscope itself, lower medicinal dosages may be used, and the need for other devices for the topical application of medication is eliminated. The sleeve 50 may be provided with a suitable connector (not shown) at the proximal end of the passage 54 that connects the passage 54 to an oxygen source, a negative pressure source (for suction), or a medication source, as the case may be.

[0032] Figure 3 illustrates an endotracheal tube (ETT) holder 60, of the type used in the present invention. The ETT holder 60 comprises a short, hollow, tubular portion 62 with an annular collar or rim 64 at its proximal end. The inside diameter of the ETT holder 60 is approximately equal to the outside diameter of the selected sizer sleeve 50 to be used with the invention, while the outside diameter of the tubular portion 62 of the ETT holder is approximately equal to the inside diameter of the conventional 15 mm connector at the proximal end of the selected ETT that will be used with the invention, as will be discussed below. Thus, the ETT holder 60 will be provided in a variety of sizes, for use with differently-sized ETTs, as circumstances dictate.

[0033] Figure 4 illustrates a portable, battery-powered video monitor 70, of the type used in present invention. The monitor 70 has a video display screen 72, and it is connected by a cable 74 to the handle and control module 14, so that it may receive the optical signals from the

imaging fiber optic bundle 44. The monitor 70 thus contains the electronic components (not shown) that convert the optical signal from the cable 74 into a video signal shown on the screen 72 in real time. Alternatively, the monitor 70 may receive its input signal wirelessly from the handle and control module 14 by a wireless transmitter (e.g., Bluetooth) in the handle and control module housing 18. The electronic circuitry of the monitor 70 is conventional, and need not be described here. The monitor 70 may also advantageously include a solid state memory (e.g., a hard drive or flash memory, not shown) that stores images for later viewing or for downloading to a computer. For the latter function, the monitor 70 advantageously includes a USB port or the equivalent (not shown). The monitor has several controls: an On-Off switch 76, image quality controls 78 (for controlling brightness and/or contrast, for example), and a stored image control 80 for selecting images stored in the internal memory. Other controls for the monitor 70 may suggest themselves. The monitor 70 may be self-supporting, such as by a foldable stand (not shown), or it may be attached to a vertical support, such as a conventional IV pole 82, as shown in Fig. 7, by means such as a clamp 84 having a threaded fitting 86 that threads into a threaded receptacle (not shown) in the back of the monitor 70.

[0034] Figures 8-10 show the assembly of the bronchoscope 10, the sizer sleeve 50, the ETT holder 60, and a conventional ETT 90 (Fig. 10) for use in the intubation of a patient. Referring first to Figure 8, the sleeve 50 is slipped onto the optical tube 12 of the bronchoscope 10. The outside diameter of the sleeve 50 is selected to match the inside diameter of the selected ETT 90. The sleeve 50 is pushed proximally onto the optical tube 12 until the proximal end of the sleeve 50 seats snugly against the tapered distal portion 20 of the handle and control module housing 18, as shown in Fig. 9. The taper of the distal housing portion 20 causes the proximal end of the sleeve 50 to expand elastically, thereby ensuring a tight fit therebetween. The ETT holder 60 is slipped over the sleeve 50, with the proximal collar 64 first, until the holder 60 is properly positioned for receiving the ETT 90. Finally, as shown in Fig. 10, the ETT 90, having a standard (i.e., 15 mm) ETT connector 92 at its proximal end, is installed over the sleeve 50 until the connector 92 is received on the tubular portion 62 of the ETT holder 60. As noted above, the ETT holder 60 is selected to have an inside diameter that matches the outside diameter of the sleeve 50, while the outside diameter of the tubular portion 62 of the ETT holder 60 matches the inside diameter of the ETT connector 92, so that there is a snug frictional fit therebetween. As

shown, the ETT 90 is of conventional design, having an inflatable cuff 94 near its distal end, the cuff 94 being inflated through an inflation valve 96 with a pilot balloon and an inflation conduit 98 communicating with an inflation lumen (not shown) in the ETT 90.

[0035] Figure 11 shows how the bronchoscope 10 in accordance with present invention may be used in the intubation of a patient 100 in conjunction with direct laryngoscopy. The practitioner accesses the airway of the patient 100 using a conventional laryngoscope 102 in one hand 104, while manipulating the bronchoscope 10 with the other hand 106. The ETT 90 has been pre-loaded onto the bronchoscope 10, as described above in connection with Figures 8-10. Specifically, the distal end portion 16 of the optical tube 12 of the bronchoscope is steered down the oropharynx, with the video monitor 70 providing real-time images to guide the steering process. The steering process is performed using the control lever 34 acting through the linkage and the actuation mechanism in the handle and control module and the cable or cables 38 in the optical tube 12. Once the airway is visible on the monitor screen 72, the bronchoscope 10 is advanced down the trachea past the larynx. At this point, the laryngoscope 102 is released, freeing up the one hand 104, which can now advance the ETT 90 into the trachea, using the bronchoscope 10 as a guide, thereby completing the intubation.

[0036] Figures 12 and 13 illustrate an alternative configuration for a handle and control module 110. In this configuration, the handle and control module 110 has a housing 112 with a tapered distal portion 114 having an annular slot or channel 116 just proximally of the distal portion 114. A control lever 118 is pivotably attached to an arm 120 that is mounted in the slot or channel 116 for rotation therein around the axis of the housing 112. Thus, the arm 120 and the control lever 118 can be rotated at least 180 degrees around the axis of the housing 112. Specifically, for example, in Figure 12, the lever 118 is oriented at 12 o'clock for manipulation by the index finger, while in Figure 13 the lever is oriented at 9 o'clock (from the viewpoint of the practitioner) for manipulation by the right thumb. Not shown is a possible orientation at 3 o'clock for manipulation by the left thumb. Optionally, the arm 120 can be made to rotate a full 360 degrees, so that the control lever 118 can be oriented at 6 o'clock for those who might prefer this position.

[0037] While a preferred embodiment of the invention has been described above, it will be understood that this embodiment is exemplary only, and that numerous variations and modifications may suggest themselves to those skilled in the pertinent arts. Such variations and modifications are to be considered within the spirit and scope of the invention, as defined in the claims that follow.

CLAIMS

WHAT IS CLAIMED IS:

1. A bronchoscope assembly, comprising a bronchoscope including an optical tube having a main portion and a flexible distal end portion, and a handle and control module and attached to a proximal end of the optical tube and including an actuation mechanism operatively linked to the distal end portion and operable to move the distal end portion through a predefined angular range, the bronchoscope assembly being characterized by:

a semi-rigid sleeve having a main portion with a first outside diameter and an inside diameter dimensioned to fit snugly over the main portion of the optical tube, the sleeve further having a flexible distal end portion dimensioned to encompass the distal end portion of the optical tube and having a second outside diameter that is substantially less than the first outside diameter; and

an endotracheal tube having an inside diameter that is approximately equal to the first outside diameter and dimensioned to fit coaxially over the main portion of the sleeve.

2. The bronchoscope assembly of claim 1, wherein the sleeve has a proximal end and the endotracheal tube has a proximal end connector, and wherein the bronchoscope assembly is further characterized by an endotracheal tube holder having a tubular portion with an inside diameter dimensioned to fit snugly around the outside diameter of the sleeve near the proximal end thereof, and an outside diameter dimensioned to receive and hold the proximal end connector of the endotracheal tube.

3. The bronchoscope assembly of claim 1, wherein the main portion of the sleeve is made of a malleable, shape memory plastic material.

4. The bronchoscope assembly of any of claims 1, 2, or 3, further characterized in that the actuation mechanism includes a finger-operable control lever operatively connected to the handle and control module by a rotatable arm that is rotatable at least about 180 degrees around the axis of the module.

5. The bronchoscope assembly of claim 4, wherein the rotatable arm is seated in an annular channel or slot in the handle and control module.

6. The bronchoscope assembly of claim 4, wherein the rotatable arm has a distal end, and wherein the control lever is pivotably connected to the distal end of the rotatable arm.

7. A bronchoscope system characterized by a bronchoscope assembly in accordance with any of claims 1, 2, or 3 in combination with a video display monitor that receives an image signal from the bronchoscope and that selectively displays (a) a real-time video image derived from the image signal and (b) a stored video image derived from the image signal.

8. The bronchoscope system of claim 7, wherein the monitor includes a clamp mechanism for attachment to a vertical support.

9. A bronchoscope comprising an optical tube having a main portion and a flexible distal end portion, and a handle and control module and attached to a proximal end of the optical tube and including an actuation mechanism operatively linked to the distal end portion and operable by a finger-operable control lever operably connected to the handle and control module to move the distal end portion through a predefined angular range, the bronchoscope being characterized by:

a semi-rigid sleeve having a main portion with a first outside diameter and an inside diameter dimensioned to fit snugly over the main portion of the optical tube, the sleeve further having a flexible distal end portion dimensioned to encompass the distal end portion of the optical tube and having a second outside diameter that is substantially less than the first outside diameter, wherein the first outside diameter is selected to be approximately equal to the inside diameter of a pre-selected endoctracheal tube; and

a rotatable arm, operably connecting the control lever to the handle and control module, that is attached to the module so as to be rotatable at least about 180 degrees around the axis of the module.

10. The bronchoscope of claim 9, wherein the sleeve has a proximal end and the pre-selected endotracheal tube has a proximal end connector, and wherein the bronchoscope is further

characterized by an endotracheal tube holder having a tubular portion with an inside diameter dimensioned to fit snugly around the outside diameter of the sleeve near the proximal end thereof, and an outside diameter dimensioned to receive and hold the proximal end connector of the pre-selected endotracheal tube.

11. The bronchoscope of claim 9, wherein the main portion of the sleeve is made of a malleable, shape memory plastic material.

12. The bronchoscope of any of claims 9, 10, or 11, wherein the rotatable arm is seated in an annular channel or slot in the handle and control module.

13. The bronchoscope of any of claims 9, 10, or 11, wherein the rotatable arm has a distal end, and wherein the control lever is pivotably connected to the distal end of the rotatable arm.

14. A bronchoscope system characterized by a bronchoscope in accordance with any of claims 9, 10, or 11 in combination with a video display monitor that receives an image signal from the bronchoscope and that selectively displays (a) a real-time video image derived from the image signal and (b) a stored video image derived from the image signal.

15. The bronchoscope system of claim 14, wherein the monitor includes a clamp mechanism for attachment to a vertical support.

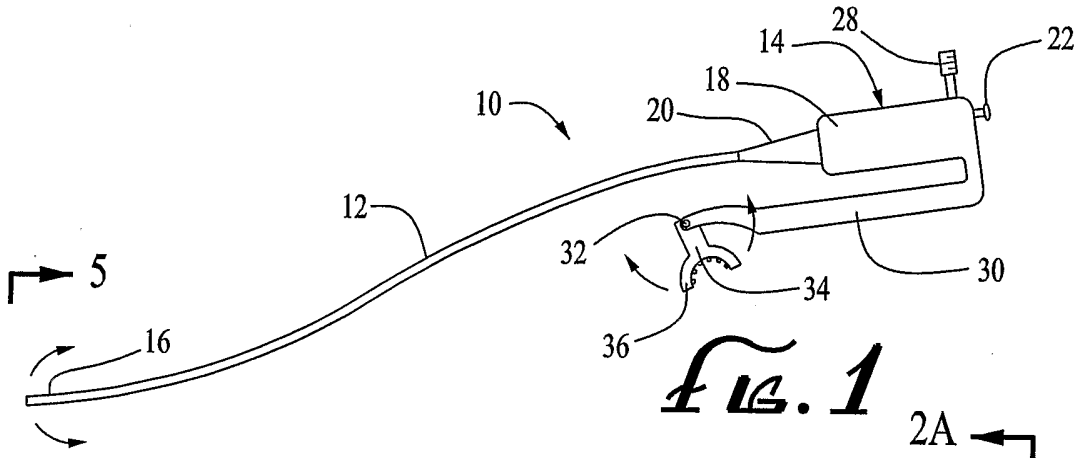

FIG. 1

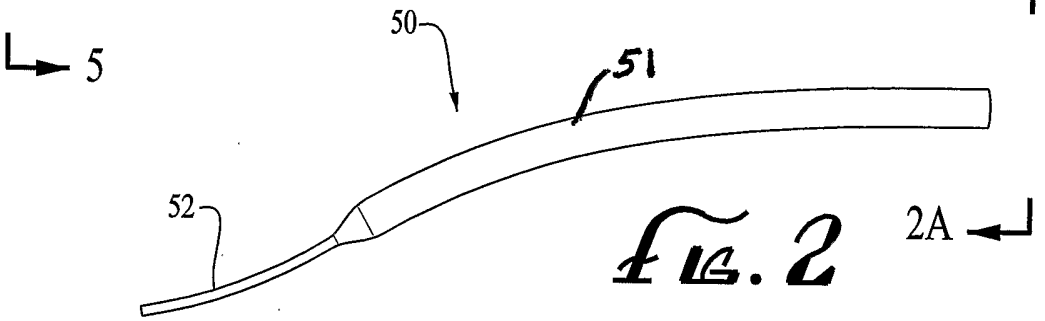

FIG. 2

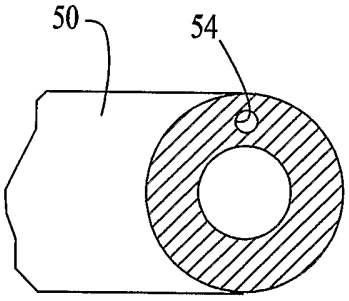

FIG. 2A

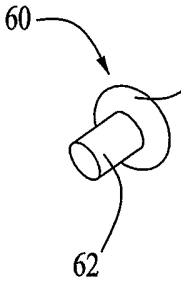

FIG. 3

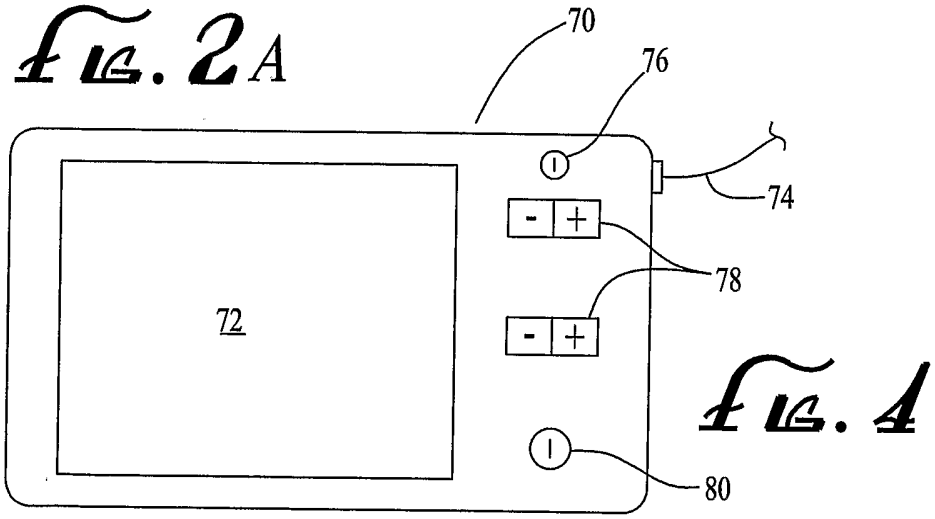

FIG. 4

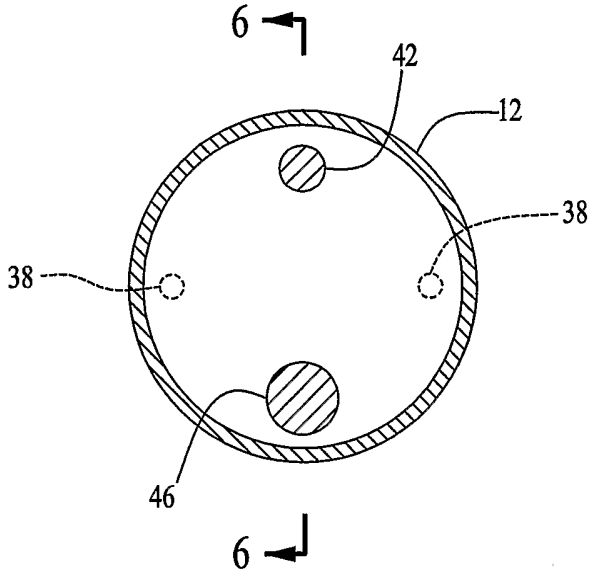

FIG. 5

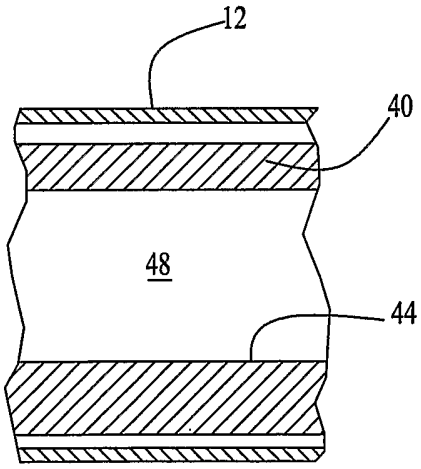

FIG. 6

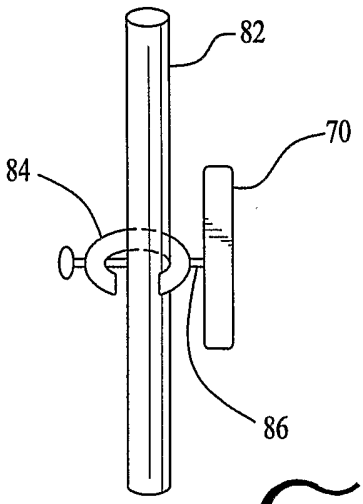

FIG. 7

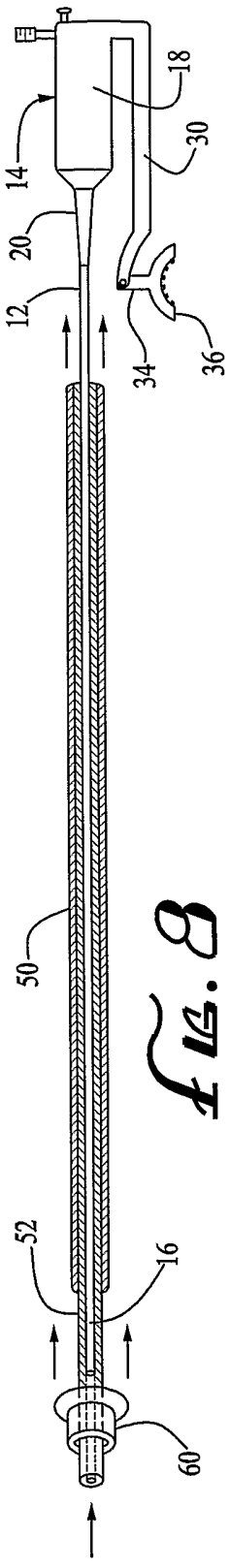

Fig. 8

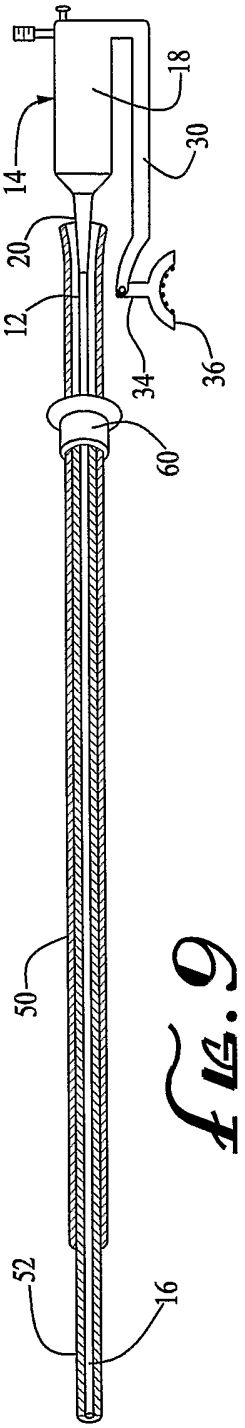

Fig. 9

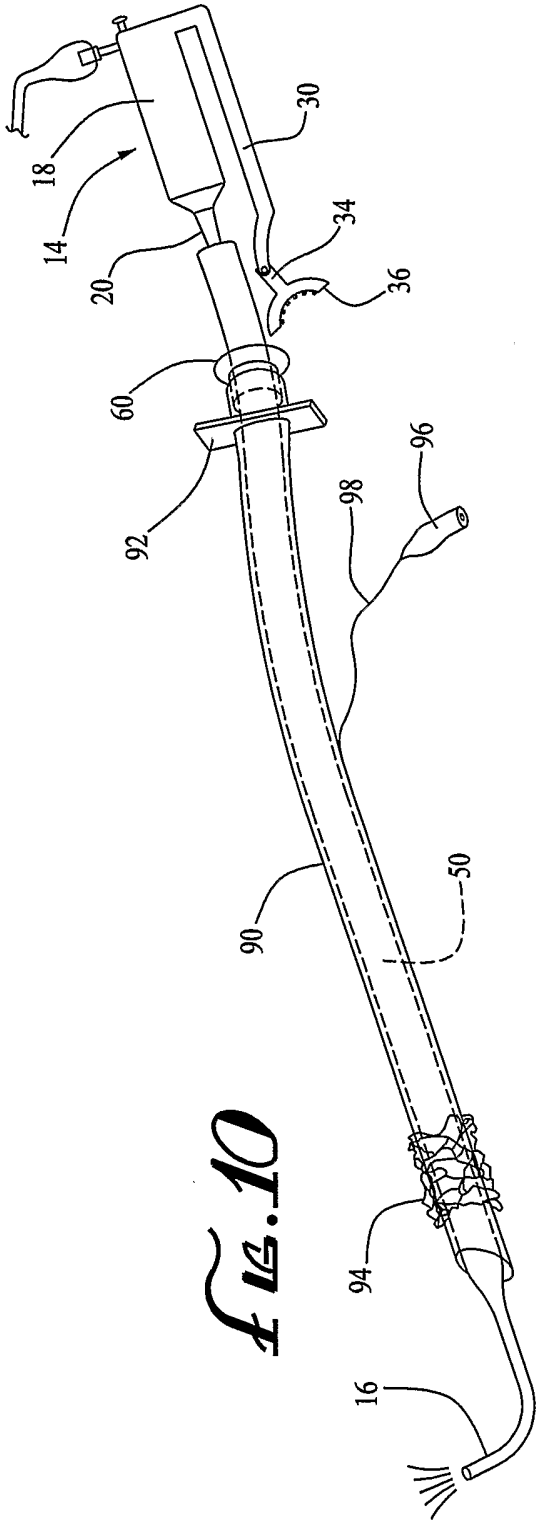

Fig. 10

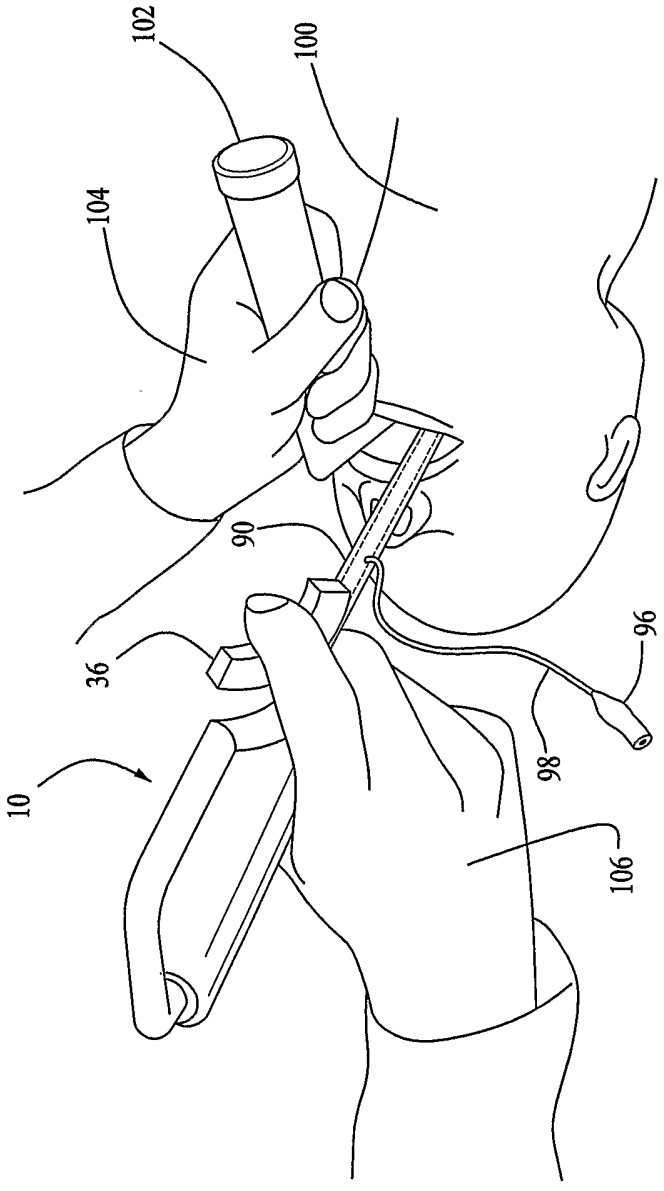

Fig. 11

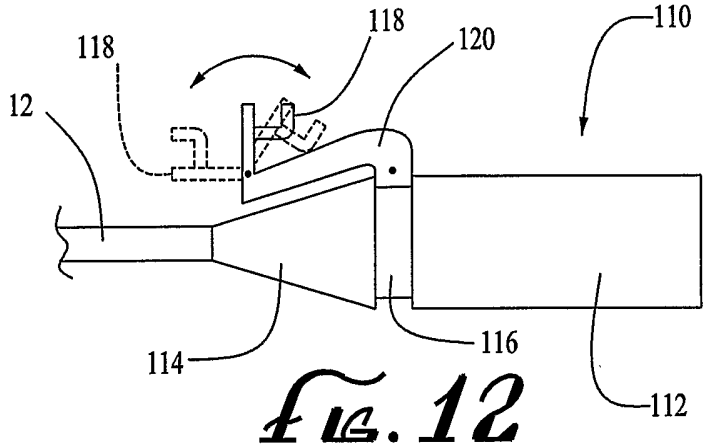

FIG. 12

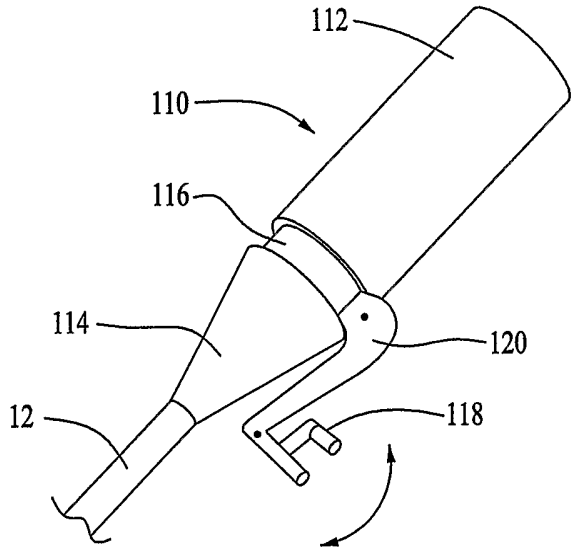

FIG. 13