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Pacey

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- (54) **INTUBATION INSTRUMENT**
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- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(57) **ABSTRACT**

The configuration and arrangement of the instrument greatly facilitate safe placement of the instrument and an associated endotracheal tube. The instrument includes a handle with an arm extending therefrom. The arm includes a base portion and a distal lifter portion preferably having an angle between 5° and 85°, inclusive, and the lifter is sized and shaped to engage or lift the patient's epiglottis, thereby to expose the glottis. In a preferred embodiment, the base portion and lifter portion are substantially the same length, and a viewing device, which is preferably a CCD or CMOS camera positioned near the transition portion between the base and lifter portions, is aligned to provide a perspective view toward the distal end of the lifter. Lights, which are preferably LED units, are positioned toward the distal end of the lifter to facilitate viewing. A transparent protective sheathing may be positioned over the assembly to facilitate cleaning and provide sterile multiple use of the device, and the lifter may be pivotally secured to the base portion to facilitate on-site adjustment by the practitioner.

This patent is subject to a terminal disclaimer.

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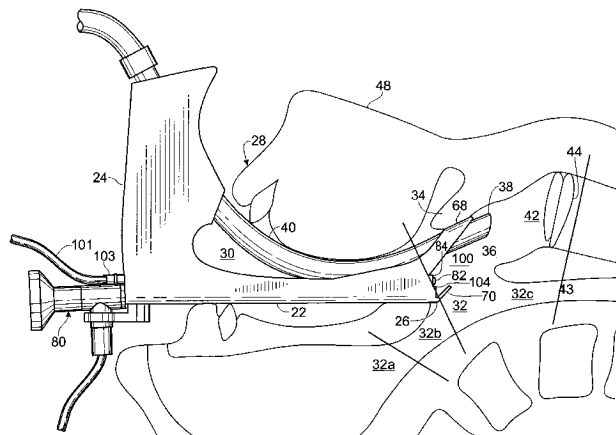
- (63) Continuation-in-part of application No. 09/704,507, filed on Nov. 2, 2000, now abandoned, which is a continuation of application No. 09/060,891, filed on Apr. 15, 1998, now Pat. No. 6,142,144.
- (60) Provisional application No. 60/067,205, filed on Dec. 1, 1997, provisional application No. 60/074,355, filed on Feb. 10, 1998, provisional application No. 60/168,711, filed on Dec. 6, 1999, and provisional application No. 60/223,330, filed on Aug. 7, 2000.
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- (52) **U.S. Cl.** **128/200.26; 128/207.14**
- (58) **Field of Search** 128/200.24, 200.26, 128/207.14, 207.15, 206.29, 911, 912, DIG. 26; 600/187, 188, 190, 194, 199

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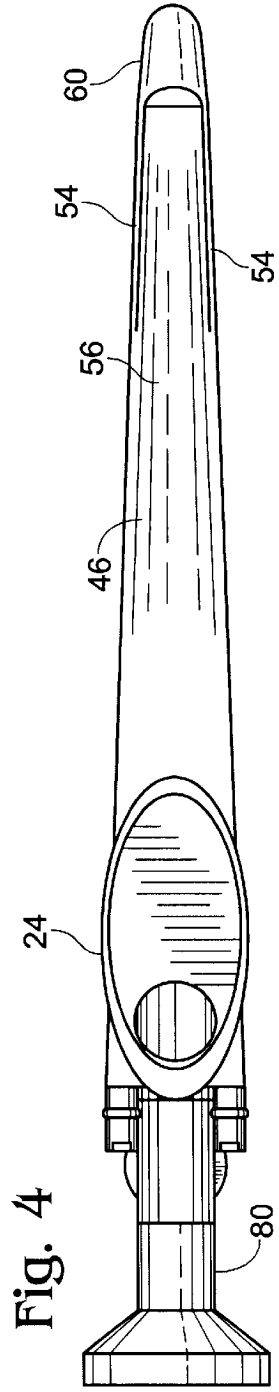
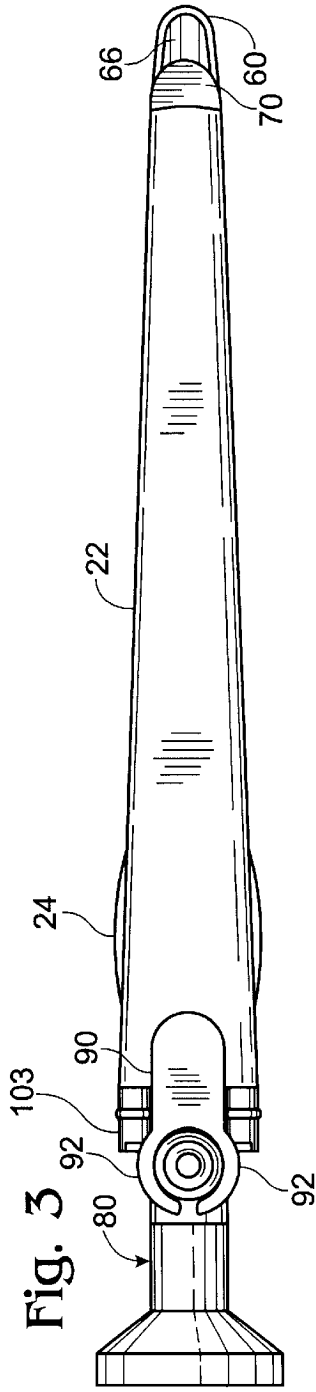
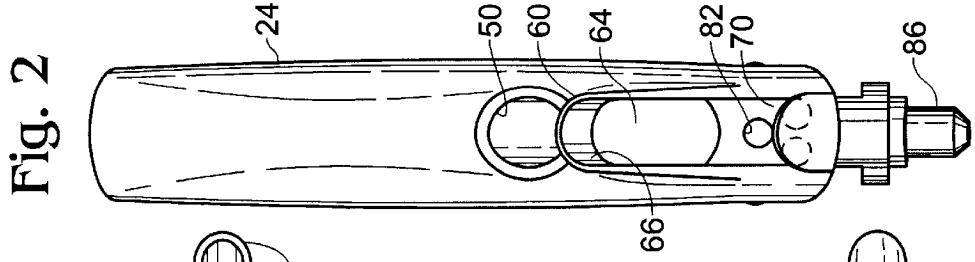
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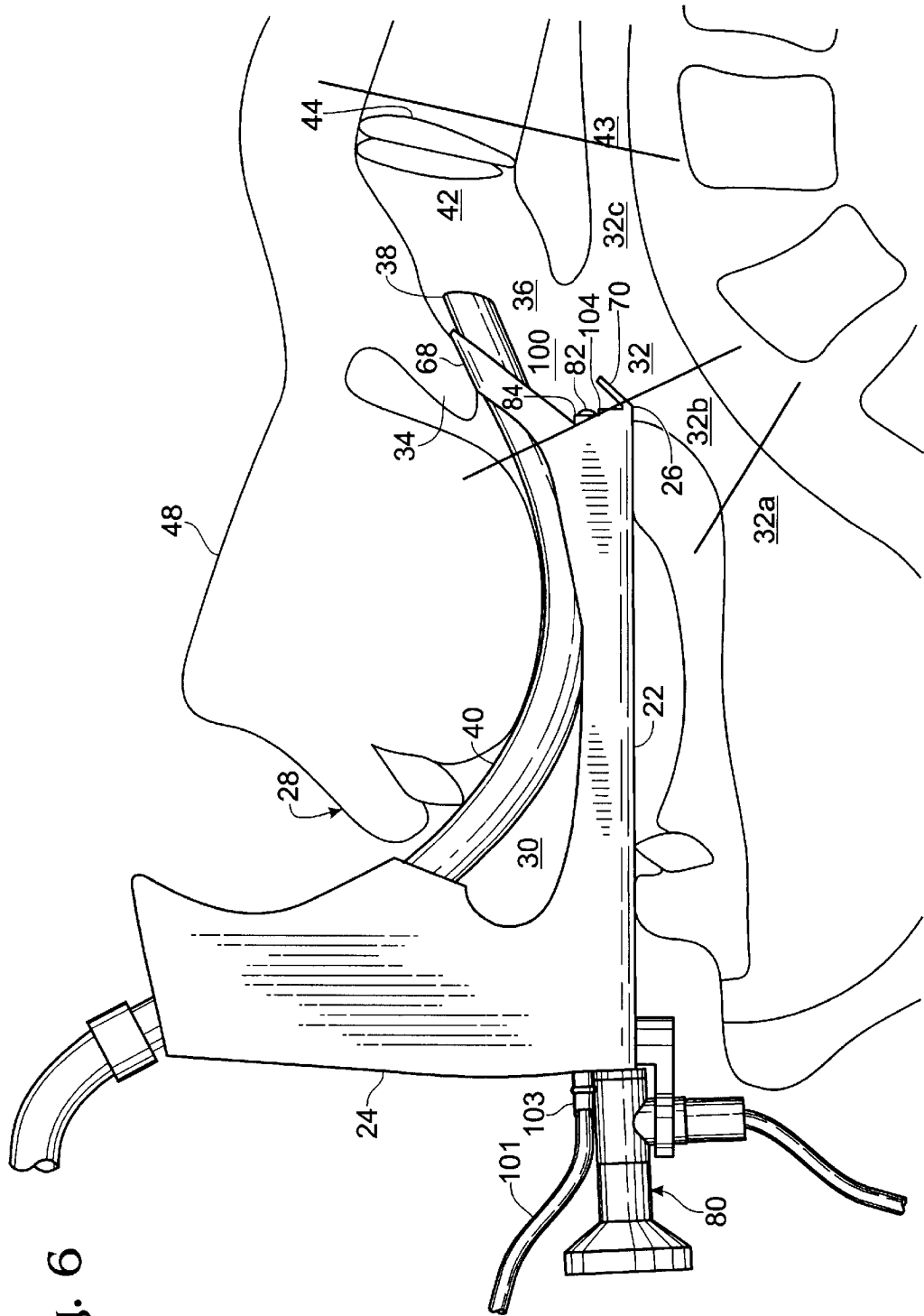


Fig. 6

FIG. 7

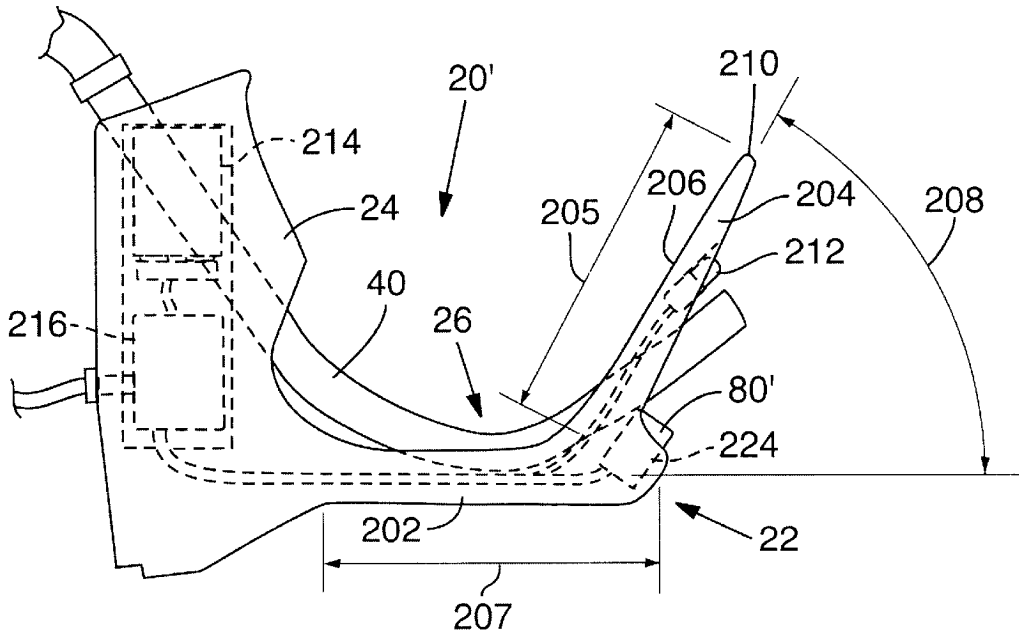
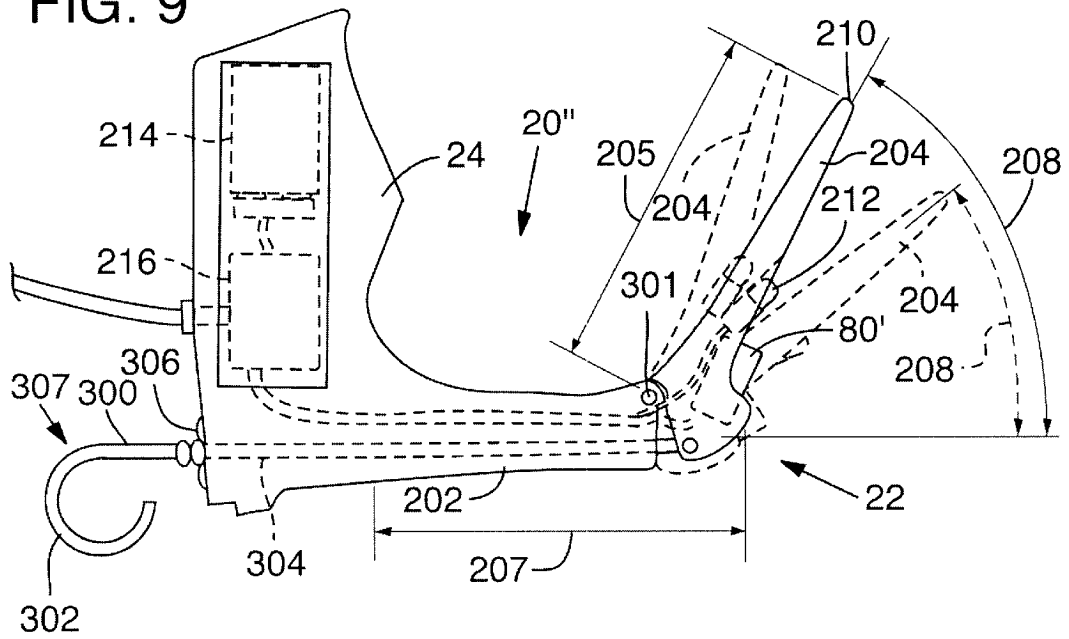
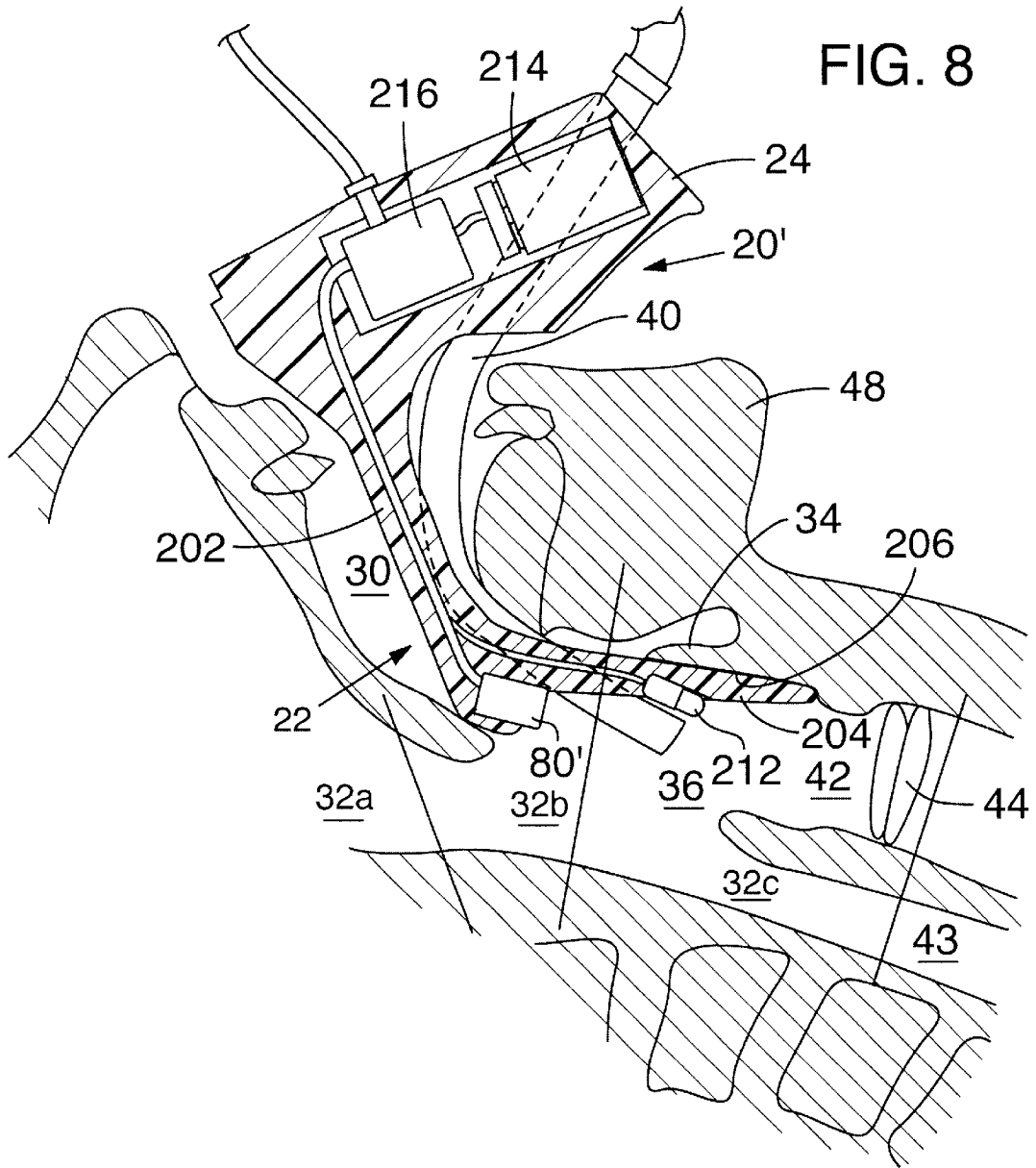


FIG. 9





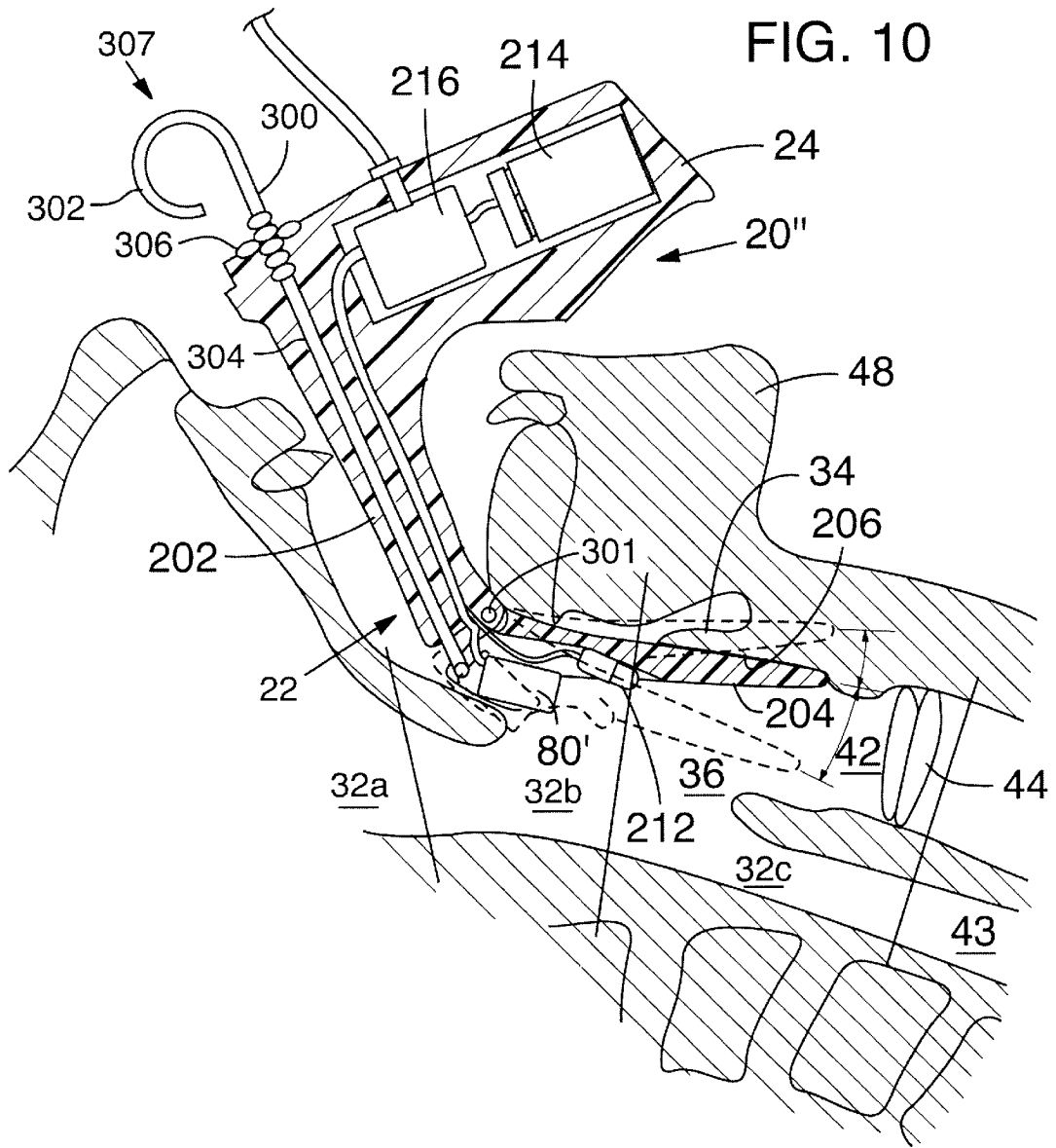


FIG. 11A 222

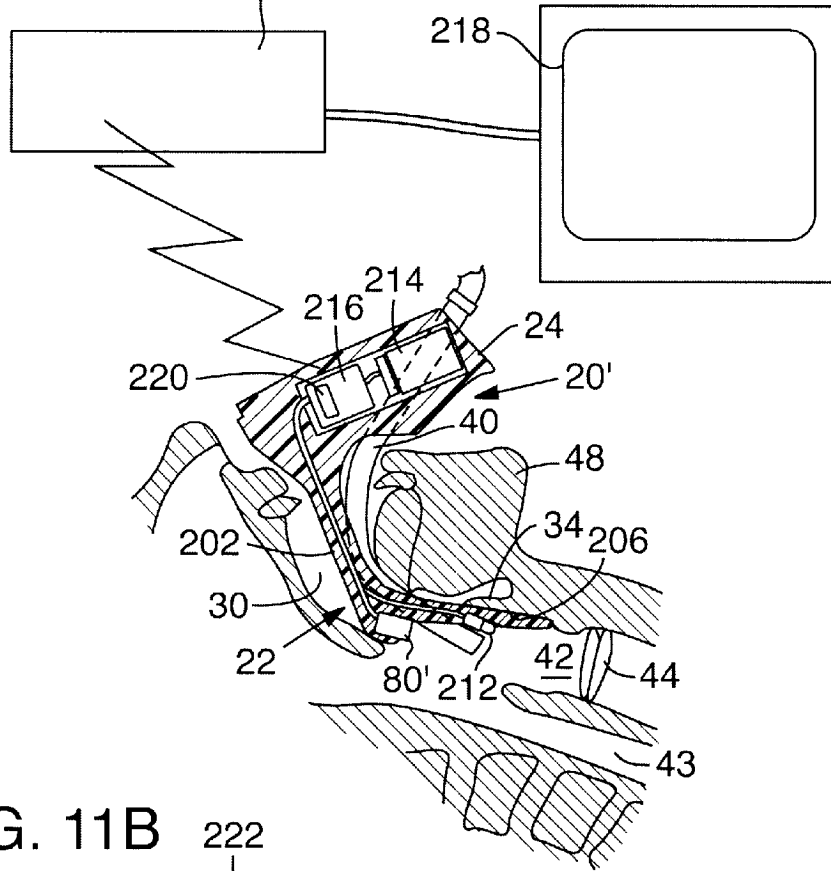
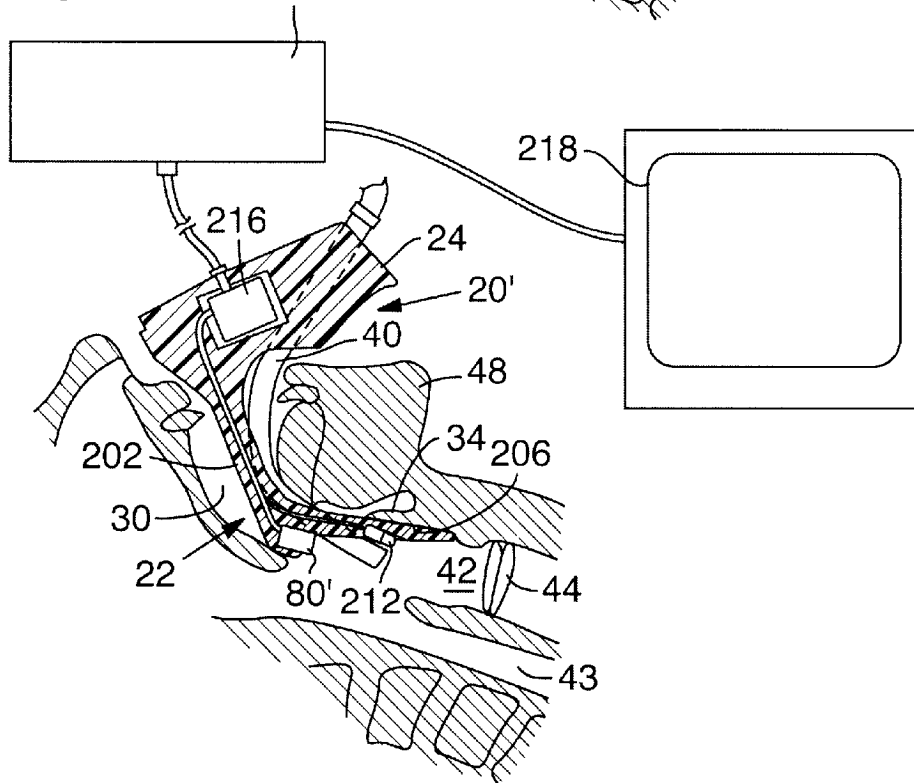


FIG. 11B 222



INTUBATION INSTRUMENT

REFERENCE TO RELATED APPLICATIONS

This application is a continuation in part of U.S. patent application Ser. No. 09/704,507, filed on Nov. 2, 2000, now abandoned, which is a continuation of U.S. patent application Ser. No. 09/060,891, filed on Apr. 15, 1998, which issued as U.S. Pat. No. 6,142,144 on Nov. 7, 2000. This application also claims the benefit of U.S. Provisional application Nos. 60/067,205, filed on Dec. 1, 1997, 60/074,355, filed on Feb. 10, 1998, 60/168,711 filed on Dec. 6, 1999, and 60/223,330, filed on Aug. 7, 2000.

FIELD OF THE INVENTION

This invention relates to endoscopic instruments, particularly to an intubation instrument, such as a laryngoscope.

BACKGROUND AND SUMMARY OF THE INVENTION

Intubation of the human trachea is carried out daily in operating rooms and emergency facilities in order to facilitate respiration of a patient. The goal of the intubation process is to locate the distal end of an endotracheal tube in the larynx with the proximal end outside the patient's mouth.

Safe and effective intubation requires controlled insertion of the endotracheal tube through a patient's mouth so that the tube is directed to the upper part of the larynx, the glottis, without damaging or being blocked by the patient's tissue. To this end, intubation instruments have been developed. Such instruments generally provide a somewhat rigid structure that is inserted into the mouth of the patient so that the distal end of the instrument is located in the glottis, adjacent to the vocal cords. An endotracheal tube is slid through the instrument during or after insertion of the instrument.

Advanced intubation instruments provide a lighted telescope or fiber optic viewing device. The telescope is carried by the instrument with the objective lens located at the distal end of the instrument and arranged so that the user may, via the proximal, viewing end of the telescope, observe the advancement of the instrument and the endotracheal tube. Such instruments are normally referred to as laryngoscopes.

In designing such intubation instruments it is important to provide a configuration that permits quick location of the instrument and tube without injurious or fatal delay that may occur with repeated attempts.

Precisely locating an endotracheal tube is certainly critical. Facial and neck trauma or the presence of blood, excoriation, mucus etc. may cause misdirection of the tube into the patient's esophagus.

Common laryngoscopes offer an elongate, substantially straight blade portion having a distal end inserted through a patient's mouth as previously described. Examples of such devices may be found in U.S. Pat. Nos. 4,360,008 to Corazzelli, Jr. ("Corazzelli Jr."), and 5,827,178 to Berall ("Berall"). The geometry of these devices allow a practitioner to insert them while directly viewing the line of sight of the blade as it is inserted through a patient's mouth and travels to the glottis. However, the path from the patient's mouth to the glottis is not straight. Accordingly, during insertion of such laryngoscopes, the practitioner must physically manipulate a patient's head, usually by pulling the patient's head back to elevate the patient's chin, in an effort to provide as straight a path for receiving the laryngoscope as possible. Such manipulation is undesirable, particularly where the patient may have an injured neck or head.

Moreover, the practitioner's line of sight for inserting such straight devices is often blocked by interfering tissue and the like.

Inventors have attempted to overcome these problems with known laryngoscopes by attempting to improve the practitioner's view during insertion. For example, Berall includes a camera mounted in the vicinity of the distal end of the blade and a viewer mounted to the laryngoscope, such that the practitioner has a simultaneous line of sight and camera view during insertion. However, such a camera view positioned toward the distal end is often, unprotected from tissue and debris, and therefore becomes easily blocked. Moreover, such positioning is usually too close to offer the practitioner a helpful perspective to facilitate proper insertion and alignment of the laryngoscope and endotracheal tube within the larynx. Also, the straight blade remains difficult to properly insert.

Another attempted improvement to known laryngoscopes involves contouring the blade as shown in U.S. Pat. No. 5,800,344 to Wood ("Wood"), and slidably securing an image sensor along such a blade to facilitate viewing. However, to be properly inserted, such devices still require undesirable manipulation of a patient's head and neck.

To facilitate insertion of these types of known laryngoscopes, some inventors have added moving tips to the blades as shown in Corazzelli, Jr. However, these tips are generally too small to adequately support the epiglottis, and they still require the practitioner to insert an elongate straight or substantially straight blade, thereby required undesirable manipulation of the patient's head and neck.

The present invention overcomes these and other problems of known intubation devices. It provides an intubation device that includes a configuration and arrangement of components that greatly facilitate rapid, safe placement of the instrument and associated endotracheal tube.

In accordance with one aspect of this invention, the instrument provides a blade or arm having an elongate base portion and an elongate lifter portion having a distal end thereof extending therefrom, preferably at an angle between 150 to 85°, inclusive. The lifter is sized and shaped to engage, lift and support the patient's epiglottis, thereby to expose the glottis. In a preferred embodiment, the base portion and lifter portion are substantially the same length, and a viewing device, which is preferably a Charged Coupled Device ("CCD") or Complementary Metal Oxide Semiconductor ("CMOS") camera positioned near the transition portion between the base and lifter portions, is aligned to provide a perspective view toward the distal end of the lifter. Lights, which are preferably Light Emitting Diode ("LED") units, are positioned toward the distal end of the lifter to facilitate viewing. A transparent protective sheathing may be positioned over the assembly to facilitate cleaning and provide sterile multiple use of the device.

In an alternative embodiment, the lifter is pivotally secured to the base portion such that the optimal angle for a particular patient may be selected on site by the practitioner.

The instrument can also provide a path for guiding movement of the endotracheal tube in a manner that permits the distal end of the tube to move along the instrument directly toward the glottis. In such case, the instrument includes a passage into which a telescope is mounted. The arrangement of the guide path and passage ensures that the distal end of the tube remains observable as it is advanced to the glottis.

The observation of the movement of the instrument and tube is enhanced by the creation of a clearing at the distal

end of the instrument. In this regard, the instrument includes structure for establishing a clearing at the distal end of the instrument, into which clearing the patient's tissue is prevented from entering. The inner end of the viewing device is located at this clearing, as well as advantageously placed suction tube(s) for ensuring that the clearing remains free of fluid and vapor that would otherwise obstruct the operator's view.

Moreover, a projecting guard is included for establishing the clearing. The guard is angled in a manner that permits smooth, sliding movement of the instrument across tissue to the desired, inserted position of the instrument.

In preferred embodiments of the invention, the instrument may include a second fluid passageway for delivering fluid to or from the distal end of the instrument. Moreover, the instrument can be configured to provide a channel for guiding secondary instruments, such as forceps, for clearly observed removal of foreign material in the larynx.

Other advantages and features of the present invention will become clear upon study of the following portion of this specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side, elevation view of a preferred embodiment of an instrument made in accordance with the invention shown carrying an endotracheal tube.

FIG. 2 is a front elevation view of the instrument shown in FIG. 1 with the endotracheal tube removed for clarity.

FIG. 3 is a bottom plan view of the instrument of FIG. 1

FIG. 4 is a top plan view of the instrument of FIG. 1.

FIG. 5 is a cross section taken about line 5—5 of FIG. 1.

FIG. 6 is a side view of the instrument of FIG. 1 shown inserted into the mouth of a patient.

FIG. 7 is a side, elevation view of a second alternative preferred embodiment of an instrument made in accordance with the invention shown carrying an endotracheal tube.

FIG. 8 is a side, elevation view of the instrument of FIG. 7 shown inserted into the mouth of a patient.

FIG. 9 is a side, elevation view of a third alternative preferred embodiment of an instrument made in accordance with the invention.

FIG. 10 is a side, elevation view of the instrument of FIG. 9 shown inserted into the mouth of a patient.

FIG. 11A is a block diagram of an exemplar viewing arrangement.

FIG. 11B is a block diagram of an alternative preferred exemplar viewing arrangement.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

An improved intubation instrument in accordance with preferred embodiments of the present invention is shown in FIGS. 1–11. In particular, FIGS. 1–6 show a first preferred embodiment, FIGS. 7, 8 and 11A–B show a second preferred embodiment, and FIGS. 9 and 10 show a third preferred embodiment. In order to avoid unnecessary repetition, common elements between these three embodiments are like numbered.

A. First Preferred Embodiment

With particular reference to FIGS. 1 and 6, a first preferred embodiment of an intubation instrument made and used in accord with the present invention includes a body 20

that generally comprises an elongated arm 22 with integrally attached handle 24. The instrument is preferably formed from metal or rigid plastic that can withstand sterilization.

The instrument arm has a distal end 26 that is inserted into the mouth 30 of a patient 28. Preferably, the instrument is inserted while the patient is recumbent, face-up, with the head tipped slightly backwardly, supported in what is known as the sniffing position. Before proceeding with the description of the instrument, it will be useful here to identify the relevant components of the human patient (FIG. 6).

As noted, the instrument is inserted, distal end 26 first, through the patient's mouth 30. As explained below, when properly inserted, the distal end of the endotracheal tube 40 resides in the pharynx 32. Recently, individual portions of the pharynx 32 have become more commonly referred by those skilled in the art as the nasopharynx 32a (FIG. 6), the oropharynx 32b (FIG. 6), and the laryngopharynx 32c (FIG. 6). Accordingly, using these commonly known and more precise terms of the human respiratory system, the endotracheal tube 40 resides in the laryngopharynx 32c (FIG. 6). The patient's epiglottis 34 is supported by the instrument in a manner to expose the glottis 36. In the present invention, the instrument provides for the telescopically observed advance of the leading end 38 of an endotracheal tube 40 through the glottis 36, into the larynx 42 adjacent to the vocal cords 44. As is known in the art, an endotracheal tube 40 permits air to be conducted to and from an incapacitated patient. The present instrument includes a number of features that greatly increase the ease with which the instrument and tube 40 can be properly located and continuously observed via a telescope or other optic device.

More particularly, the arm 22 of the instrument is configured to define in the handle 24 and on its anterior surface 46 a guide path for the smooth advance of the tube 40 relative to the inserted instrument. For the purpose of this description, the anterior surface 46 of the instrument is, as shown in FIG. 6 that facing the lower jaw 48 of the intubated patient.

More particularly, the arm 22 of the instrument 20 is configured to define in the handle 24 and on its anterior surface 46 a guide path for the smooth advance of the tube 40 relative to the inserted instrument 20. For the purpose of this description, the anterior surface 46 of the instrument is, as shown in FIG. 6, that facing the lower jaw 48 of the intubated patient.

The guide path includes a portion consisting of a channel 50 (FIG. 1) that is formed through the handle 24. It is noteworthy that the handle 24 extends in a generally perpendicular orientation relative to the elongated arm 22. The channel 50, however, extends through the handle 24 at a direction that is generally oblique to the length of the handle 24 and to the arm 22. Put another way, the channel orientation 50 is such that after the leading end of the tube 40 is advanced through the channel 50, it emerges to contact the anterior surface 46 of the instrument at an acute angle 52 to slide along that surface toward the distal end 26 of the instrument.

Approaching the distal end of the instrument, the opposing anterior side edges 54 are gradually built up to define, in combination with the anterior surface part between the edges 54 a groove 56 that is generally curved in cross section, as best shown in FIG. 5. Preferably, the radius of curvature of the groove 56 generally conforms to the outside diameter of the tube 40. As such, the leading end of the tube 40 is precisely and smoothly guided through this groove 56, which makes up another part of the above mentioned guide path.

The side edges **54** terminate in a loop **60** that is part of the instrument and protrudes from the distal end **26** of the instrument at an angle **55** (FIG. 1) of about 45 degrees relative to the length of the arm **22**. As viewed from the end (FIGS. 2 and 5), the loop defines an elongated opening **64** through which extends the leading end **38** of the tube **40**.

Here it is useful to note that an endotracheal tube **40** used with the preferred embodiment of the instrument is formed of flexible plastic tubing. One such tube is that manufactured by Mallinckrodt, Inc. of St. Louis Mo., under the trademark Mallinckrodt. The tube is constructed to assume a curved configuration when relaxed, although it is readily deformed as needed. In the present invention, the loop **60** is configured to permit the leading end **38** of the tube **40** to approach its curved, relaxed configuration as it passes through and out of the loop **60**.

More particularly, the elongated opening **64** (elongated, that is, in the direction away from the anterior surface of the arm **22**, as shown in FIGS. 2 and 5) permits the flexible tube **40** to resile away from the distal end **26** of the arm **22** to seat against the underside **66** of the loop **60**, as shown in FIG. 1. This underside **66** is curved to conform to the outside diameter of the tube, thereby providing in a manner similar to the above-mentioned groove **56**, precise and smooth guidance of the tube through the loop **60**. Thus, the loop makes up another part of the above mentioned guide path. The advantages of the just described tube movement are discussed more fully below.

The loop **60** includes a surface **68** that bears against the patient's epiglottis **34** when the instrument is fully inserted. As a result, the epiglottis **34** and surrounding tissue are held by the instrument in a position where they do not occlude the glottis **36**.

A guard **70** extends from the bottom of the instrument arm **22** at the distal end thereof. The guard is an extension of the arm **22** and is angled upwardly (as viewed in FIGS. 1 and 6) to present an underlying surface that acts like a skid upon insertion of the instrument to permit the distal end of the instrument to be advanced against the patient's tissue without damage to the tissue. Thus, the guard **70** reduces the effort needed to insert the device, while protecting the patient's tissue.

Once the arm **22** is in place, the guard **70** serves to prevent the tissue in the pharynx **32** from contacting the distal end **26** of the arm **22** and obstructing the view available to a viewer that is carried by the instrument. In this embodiment a telescope **80** is shown. In this regard, the telescope **80** is one that terminates in a long tubular member having an objective lens at its end **82**. The terminus of the telescope fits into a telescope passage **83** that is formed through the arm **22**. The telescope also includes a light post **86** that is mounted to the telescope **80** near the outer end **88** of the passage **83** and that provides illumination to the telescope **80**. In a preferred embodiment of the instrument, a suitable telescope is one having approximately a 25 degree viewing angle; such as manufactured by Henke-Sass, Wolf of America Inc., Southbridge, Mass., as model number 8853.42.

In a preferred embodiment of the invention the instrument is provided with a clip **90** that is mounted to the arm **22** near the outer end of the passageway **83**. The clip **90** includes two spaced-apart, arched arms **92** that spread apart slightly to releasably receive between them the generally cylindrical shaped light post **86** as the telescope is slid into position relative to the instrument **22**. The clip **90**, therefore, serves to retain the telescope in the correct location and within the

telescope passage **83** during use. Moreover, since the arms **92** of the clip engage a radial projection of the telescope (namely, the light post **86**), the telescope is held against inadvertent rotation out of the desired orientation relative to the arm **22**. The arms **92** of the clip **90** are resilient and readily move apart to release the light post **86** when the telescope is pulled from the instrument for replacement and cleaning.

Returning to consider the distal end **26** of the arm **22**, the end **82** of the telescope **80** is located at the inner end **84** of the passage **83** when the telescope is installed. As noted, the guard **70** prevents tissue from contacting the end of the telescope. More particularly, the telescope-guarding or tissue-retracting effect of both the loop **60** and the guard **70** has the effect of establishing a clearing **100** (FIG. 6), which is a space between the guard and loop, adjacent to the distal end of the instrument and free of view-obstructing tissue. The inner end **84** of the telescope passage (hence, the end **82** of an installed telescope) is in this clearing **100**. Thus, the telescope is unaffected by tissue that would otherwise obstruct, at least in part, the telescopic view of the advancing, leading end **38** of the endotracheal tube **40**.

As noted earlier, the loop **60** configuration is such that the tube that extends from the loop tends to assume its relaxed, curved shape. The leading end **38**, therefore, tends to veer upwardly (considering FIG. 6) toward the glottis **36** and away from what would be a dangerous entry into the patient's esophagus **43**.

The tube **40** is carried on the anterior surface **46** of the arm **22**, between the patient's lower jaw and the telescope passage **83**. This orientation, in combination with the curved guide path of the tube **40** ensure that the advancing, leading end **38** of the tube remains in the field of view of the telescope (as does the glottis) without crossing near the end **82** of the telescope, which crossing would obscure the view of the tube vis-a-vis the glottis **36**.

For example, if the lens carried in the end **82** of the telescope is angled upwardly to provide a view in a direction toward the glottis **36**, the movement of the tube end **38** out from beneath the underside of the loop **60** will be nearly parallel to a line defining the center of the field of view of the telescope. It has been found that this relative positioning of the telescope end **82** and tube end **38** greatly enhances viewing of the advancing tube as compared to instruments that went before.

The preciseness with which the present instrument may be inserted enables one to supply, during insertion, intermittent pulses of air (positive pressure) through the tube **40** to provide immediate respiration to the patient during the insertion process. Thus, the conventional air or oxygen supply to the tube may be so connected and controlled during insertion of the instrument.

The clearing **100** would, be susceptible to entry of fluids such as blood, exudate, mucus etc, which might be present in instances of neck trauma. In accord with another aspect of this invention, there is provided efficient suction removal of such matter. To this end, the arm **22** is provided with a passageway **102** having an interior end **104** that opens at the distal end **26** of the instrument, below the inner end **84** of the telescope passage **83**. A suction tube **101** (FIG. 6) may be attached to a connector **103** that is mounted to the instrument at the outer end of the passageway **102**. Suction is applied for removing any fluid that may begin to accumulate in the clearing **100**. It is noteworthy that the instrument is arranged so that the inner end of the telescope passage is above (FIG. 1) the interior end **104** of the suction passaway **102**. Thus,

the end **104** of the suction passageway resides in what may be called a sump portion of the clearing **100**. Unwanted fluids are removed before reaching a level that would obscure the end **82** of an installed telescope **80**.

It is contemplated that suction would be applied to the clearing **100** even in the absence of view-obstructing fluids because the application of suction would tend to cool the telescope (which is heated by the light source) or remove vapor that might otherwise tend to condense on the lens of the telescope.

Preferably, another passageway **106** (FIG. 5) is provided in the arm in a manner that substantially matches the suction passageway **102**. This other passageway is available to hold another suction tube (thus enhancing overall suction of the clearing **100**) or, alternatively, gas such as oxygen could be directed through this passageway **106** to increase the oxygen content of the glottis area.

The suction applied by one or both passages **102**, **106** provides a vortex of fluid flow in the vicinity of the inner end **84** of the telescope passage, thereby providing a particularly effective way to remove from the telescope end (lens) **82** any fluid contamination, such as blood, that would otherwise obscure the view through the telescope. Thus, the telescope need not be removed for clearing the lens.

It will be appreciated that the arrangement of the various components of the instrument presents an instrument that is substantially symmetrical about the long axis of the arm and handle. Thus the instrument is readily useable by a right- or left-handed operator.

It is also contemplated that the channel **50** in the handle **24** may be configured to open on one side of the handle, such as surface **25** (FIG. 1) thereby forming the channel **50** as a groove in the handle. As a result, the tube **40** could be inserted laterally into the channel/groove. At the junction of the channel **50** and surface **25**, the groove width could be narrowed somewhat, relative to the remainder of the groove, to a width just slightly narrower than the diameter of the flexible tube **40**. Such a configuration permits the tube to be secured by a snap-fit into this configuration of the channel.

B. Second Preferred Embodiment

With particular reference to FIGS. 7, 8, and 11, a second preferred embodiment of an intubation instrument made and used in accord with the present invention includes a body **20** that generally comprises an elongated arm **22** with integrally attached handle **24**, preferably integrally formed from metal or rigid plastic that can withstand sterilization. The arm includes an elongate base portion **202**, and a lifter portion **204** extending therefrom as best shown in FIG. 7. The overall length of the arm is optimally sized to be positioned within a patient as previously described, and the lifter portion **204** is sized and shaped to have an elongate smooth surface **206** for engaging or lifting the patient's epiglottis **34** (FIG. 8), thereby to expose the glottis as best shown in FIG. 8. As a result, the epiglottis **34** and surrounding tissue are held by the instrument in a position where they do not occlude the glottis **36**.

Preferably, the lifter portion **204** is at least approximately 3 centimeters long, and the angle **208** between the base portion **202** and lifter portion **204** is between 5° and 90°, inclusive. More preferably, the length **205** of the lifter portion **204** is between approximately 4 centimeters and 8 centimeters long, and the angle **208** between the lifter portion **204** and base portion **202** is between 300 and 600°. Even more preferably, the length **205** of the lifter portion **204** is approximately the same as the length **207** of the base

portion **202**, both of which are approximately 6 centimeters long, and the angle **208** between the lifter and base portions is approximately 45°. Obviously, the overall geometry between the base portion **202** and lifter portion **204** is important for effective operation of the instrument. Proportionately smaller sizes should be used for pediatric applications.

A viewing device, which is preferably a camera **80'** operably secured to the instrument, is preferably positioned along the posterior surface of the lifter portion **204**, near the transition portion between the base and lifter portions **202**, **204**, respectively, and aligned to provide a perspective view toward the distal end **210** of the lifter portion **204**. More preferably, the camera **80'** is mounted to the left side of the instrument when viewed from the handle **25**, thereby permitting passage directly down the midline of the patient's tongue. The lifter portion **204** protects the camera from being blocked by tissue and debris. Moreover, positioning the camera **80'** away from the distal end **210** of the lifter portion **204** provides the user with a clear perspective view of the entire area.

A viewing device, which is preferably a camera **80'** operably secured to the instrument, is preferably positioned along the posterior surface of the lifter portion **204**, near the transition portion between the base and lifter portions **202**, **204**, respectively, and aligned to provide a perspective view toward the distal end **210** of the lifter portion **204**. More preferably, the camera **80'** is mounted to the left side of the instrument when viewed from the handle **25**, thereby permitting passage directly down the midline of the patient's tongue. The lifter portion **202** protects the camera from being blocked by tissue and debris. Moreover, positioning the camera **80'** away from the distal end **210** of the lifter portion **204** provides the user with a clear perspective view of the entire area.

One or more lights, which are preferably Light Emitting Diodes **212** ("LED") are preferably positioned along the lifter portion to facilitate operator viewing. The use of one or more LED cold light elements in front of the camera lens provide needed light without-producing any heat. Accordingly, unlike traditional expensive Zenon lights typically used on fiber optic laryngoscopes, economical LED lights will not burn sensitive membranes and will not damage the thin plastic cuff found on most endotracheal tubes.

The camera **80'** is preferably a Complementary Metal Oxide Semiconductor ("CMOS") or Charged Coupled Device ("CCD") hybrid camera, both of which are more compact, light weight, light sensitive, and economical, than traditional cameras used in such applications. Known manufacturers and sellers of such cameras include Sun Microsystems, Amain Electronics, and Misumi Electronics. Preferably, the camera **80'** is operably connected to a power source **214**, such as a battery or A/C connection, and suitable related electronics **216**, which are stored in the handle **24** of the instrument. As best shown in FIGS. 11A&B, the camera **80'** is operably connected to a display **218**, either by a direct (FIG. 11B) or remote (FIG. 11A) connection. Such remote connections can include a transmitter **220** received within the instrument and the display **218** including a receiver **222** for receiving video signals from the transmitter **220**. Alternatively, such a system can include infrared technology or the like. The camera **80'** and related transmitter **220** can also communicate with a display, or other equipment such as remote locations via the evolving industry standard more commonly known as "bluetooth." Such communication can also be used to transmit the information via the Internet or

the like, thereby facilitating real-time remote incident analysis, advice, assistance, and/or teaching.

The display **218** may be detached from or attached to the instrument, and may also be configured to simultaneously display other relevant information such as the patient's vital signs and the like, thereby facilitating operator use of the instrument.

Preferably, the camera **80'** is secured within a sealed chamber **224** within the arm **22**, thereby protecting it from water, gasses, and chemicals used in sterilization procedures. More preferably, the chamber **224** contains nitrogen gas free from moisture, thereby avoiding undesirable condensation. Preferably, the CMOS or CCD camera body is also sealed.

A tightly fitted, transparent protective sheath (not shown) may be positioned over the assembly to facilitate cleaning and provide sterile multiple use of the device. The sheath is tightly fitted over the lens of the camera to prevent it from encumber the view. Preferably, the sheath is a transparent polymer, such as plastic, which sheds mucus and blood, has little tendency to fog during use, and equilibrates rapidly to airway temperature.

The instrument may also include paths (not shown) for transmitting oxygen and/or fluid to the camera lens, thereby assisting clearing and cleaning the lens during operation.

The embodiment can also include the guide path, groove and loop for slidably receiving an endotracheal tube **40** as with the first preferred embodiment. Alternatively, the instrument can be used as a conventional laryngoscope, without providing for receiving therein such an endotracheal tube **40**.

It will be appreciated that the arrangement of the various components of the instrument presents an instrument that is substantially symmetrical about the long axis of the arm and handle. Thus the instrument is readily useable by a right- or left-handed operator.

C. Third Preferred Embodiment

With particular reference to FIGS. **9** and **10**, a third preferred embodiment of an intubation instrument made and used in accord with the present invention is disclosed. It includes the body **20"** that generally comprises an elongated arm **22** with integrally attached handle **24** of the second preferred embodiment, including the viewer and light. However, the lifter portion **204** of the arm **22** is pivotally secured to the base portion **202** at pivot point **301** as best shown in FIG. **9**.

In particular, a locking mechanism **307**, such as an actuation lever **300** having a handle **302** at one end extends through a channel **304** in the base portion **202** to pivot the lifter portion **204** about pivot point **301**. Detents **306** between the actuation lever and base portion allow a user to select the desired angle **208** between the lifter portion **204** and base portion **202**, and lock that position in place. Accordingly, by manipulating the actuation lever, the optimal angle **208** between the lifter portion **204** and base portion **202** for a particular patient may be selected on site by the practitioner.

This embodiment can also include the guide path, groove and loop for slidably receiving an endotracheal tube **40** as with the first preferred embodiment. Alternatively, and as shown in FIG. **9**, the instrument can be used as a conventional laryngoscope, without providing for receiving therein such an endotracheal tube **40**.

While the present invention has been described in terms of a preferred embodiment, it will be appreciated by one of

ordinary skill that the spirit and scope of the invention is not limited to those embodiments, but extend to the various modifications and equivalents as defined in the appended claims. For example, other types of viewers could be used. Moreover, additional channels could be provided for delivering other devices to the distal end of the instrument. FIG. **1** shows in dashed lines **110** such an alternative channel that would permit the advance of elongated forceps to the distal end of the instrument to be used, for example, in removing foreign objects from the larynx.

What is claimed is:

1. An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, the patient having a respiratory system with an oropharynx, a laryngopharynx, and an epiglottis, said intubation instrument comprising:

a body having a handle attached thereto;

an elongate arm having an elongate base portion operably secured to said body at one end and an elongate lifter portion extending from said elongate base portion toward an opposite end of said elongate base portion thereby defining an angle between said elongate base portion and said elongate lifter portion,

said elongate base portion having a first defined length, said first defined length being long enough to extend through the patient's mouth into the patient's oropharynx;

said elongate lifter portion having,

a distal end for insertion distal-end first through a patient's mouth,

a second defined length, said second defined length being long enough to extend into the laryngopharynx and operably engage the epiglottis of the patient when the elongate base portion is extended into the patient's oropharynx, and,

a smooth surface for engaging the patient's epiglottis.

2. The intubation instrument of claim **1**, further including a viewer positioned substantially near where said elongate base portion meets said elongate lifter portion of the elongate arm, said viewer directed toward the distal end of said elongate lifter portion.

3. The intubation instrument of claim **2**, wherein said viewer is a telescope.

4. The intubation instrument of claim **2**, wherein said viewer is a Complementary Metal Oxide Semiconductor camera.

5. The intubation instrument of claim **2**, wherein said viewer is a Charged Coupled Device camera.

6. The intubation instrument of claim **2**, further including a light operably secured to said lifter portion.

7. The intubation instrument of claim **6**, wherein said light is a Light Emitting Diode.

8. The intubation instrument of claim **2**, further including a display for viewing video output from said viewer.

9. The intubation instrument of claim **8**, wherein said display is remotely connected to said camera.

10. The intubation instrument of claim **1**, wherein said angle is between 5° and 85° , inclusive.

11. The intubation instrument of claim **10**, wherein said angle, is between 30° and 60° , inclusive.

12. The intubation instrument of claim **10**, wherein said angle is approximately 45° .

13. The intubation instrument of claim **1**, wherein said elongate lifter portion is between 3–10 centimeters long, inclusive.

14. The intubation instrument of claim **13**, wherein said elongate lifter portion is between 4–8 centimeters long, inclusive.

15. The intubation instrument of claim 14, wherein said elongate lifter portion is approximately 6 centimeters long.

16. The intubation instrument of claim 1, wherein said first defined length and said second defined length are substantially the same length.

17. The intubation instrument of claim 1, wherein said lifter portion is pivotally secured to said base portion at a pivot point.

18. The intubation instrument of claim 17, further including a locking mechanism for actuating and holding said lifter portion in a predetermined position about said pivot point.

19. An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

- a body having a handle attached thereto;
- an elongate arm having an elongate base portion attached to the body and an elongate lifter portion having a smooth surface for engaging the patient's epiglottis, said elongate lifter portion having a distal end for insertion distal-end first through a patient's mouth;
- said elongate lifter portion being at least 3 centimeters long and extending from said elongate base portion by at least a 5 degree angle;
- a viewer positioned substantially near the area where said elongate base portion meets said elongate lifter portion of said elongate arm, said viewer directed toward the distal end of said elongate lifter portion; and,
- a light operably secured to said elongate lifter portion.

20. The intubation instrument of claims 19, wherein said light is a Light Emitting Diode.

21. The intubation instrument of claim 19, wherein said viewer is Complementary Metal Oxide Semiconductor camera and said light is a Light Emitting Diode operably secured to said elongate lifter portion.

22. An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

- a body having a handle attached thereto;
- an elongate arm having an elongate base portion attached to the body and an elongate lifter portion having a smooth surface for engaging the patient's epiglottis, said elongate lifter portion having a distal end for insertion distal-end first through a patient's mouth and pivotally secured to said elongate base portion at a pivot point;
- said elongate lifter portion being at least 3 centimeters long and extending from said elongate base portion by at least a 5 degree angle.

23. The intubation instrument of claim 22, further including a locking mechanism for actuating and holding said elongate lifter portion in a predetermined position about said pivot point.

24. The intubation instrument of claim 22, further including a viewer operably secured to said intubation instrument, and a display for viewing output from said viewer.

25. The intubation instrument of claim 24, wherein said viewer is a camera and said display is remotely connected to said camera.

26. An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

- a body having a handle attached thereto;
- an elongate arm having an elongate base portion operably secured to said body at one end and an elongate lifter portion extending from said elongate base portion

toward an opposite end of said elongate base portion, said elongate lifter portion having a smooth surface for engaging the patient's epiglottis and a distal end for insertion distal-end first through a patient's mouth;

5 said elongate lifter portion being at least as long as said elongate base portion and extending from said elongate base portion by at least a 5 degree angle.

27. The intubation instrument of claim 26, further including a viewer positioned substantially near where said elongate base portion meets said elongate lifter portion of said elongate arm, said viewer directed toward the distal end of said elongate lifter portion.

28. The intubation instrument of claim 27, wherein said viewer is a Complementary Metal Oxide Semiconductor camera.

29. The intubation instrument of claim 28, wherein said viewer is a Charged Coupled Device camera.

30. The intubation instrument of claim 26, further including a light operably secured to said lifter portion.

31. An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

- a body having a handle attached thereto;
- an elongate arm having an elongate base portion attached to the body and an elongate lifter portion having a smooth surface for engaging the patient's epiglottis, said elongate lifter portion having a distal-end for insertion distal-end first through a patient's mouth and being approximately as long as said elongate base portion and extending from said elongate base portion by at least a 5 degree angle;
- a complementary metal oxide semiconductor camera positioned substantially where the elongate base portion meets said elongate lifter portion of said elongate arm, said complementary metal oxide semiconductor camera directed toward the distal-end of said elongate lifter portion; and,
- a light operably secured to said elongate lifter portion.

32. The intubation instrument of claim 31, wherein said light is a Light Emitting Diode.

33. The intubation instrument of claim 31, wherein said light is a Light Emitting Diode.

34. An intubation instrument, a portion of which is for insertion into a patient through the patient's mouth, comprising:

- a body having a handle attached thereto;
- an elongate arm having an elongate base portion attached to the body and an elongate lifter portion extending from said elongate base portion, said elongate base portion having a first defined length, said elongate lifter portion having a second defined length and a smooth surface for engaging the patient's epiglottis and a distal end for insertion distal-end first through a patient's mouth, said elongate arm defining an anterior side positioned toward said handle and an opposite posterior side;
- said second defined length being about as long as said first defined length; and,
- a viewer operably secured to said posterior side of said arm substantially where said elongate base portion meets said elongate lifter portion, said viewer directed toward the distal end of said elongate lifter portion.

35. The intubation instrument of claim 34, wherein the portion of the intubation instrument for insertion into a patient through the patient's mouth is elongate and has a longitudinal center, and said base portion meets said lifter portion substantially near said longitudinal center.

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36. The intubation instrument of claim 34, wherein said viewer is a Complementary Metal Oxide Semiconductor camera.

37. The intubation instrument of claim 36, further including a display operably secured to said camera.

38. The intubation instrument of claim 34, wherein said lifter portion is pivotally secured to said base portion.

39. The intubation instrument of claim 38, further including a Light Emitting Diode operably secured to said lifter portion.

40. An intubation instrument a portion of which is for insertion into a patient through the patient's mouth, comprising;

a body having a handle attached thereto;

an elongate arm having an elongate base portion attached to the body and an elongate lifter portion having a smooth surface for engaging the patient's epiglottis, said elongate lifter portion having a distal end portion for insertion distal end portion first through a patient's mouth, said elongate arm defining an anterior side positioned toward said handle and an opposite posterior side;

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a viewer operably secured to said posterior side of said elongate arm substantially near where said elongate base portion meets said elongate lifter portion, said viewer directed toward the distal end portion of said elongate lifter portion; and,

said elongate arm having a center, and said elongate base portion meets said elongate lifter portion substantially near said center.

41. The intubation instrument of claim 40, wherein said viewer is a Complementary Metal Oxide Semiconductor camera.

42. The intubation instrument of claim 41, further including a display operably secured to said Complementary Metal Oxide Semiconductor camera.

43. The intubation instrument of claim 40, wherein said elongate lifter portion is pivotally secured to said elongate base portion.

44. The intubation instrument of claim 43, further including a Light Emitting Diode operably secured to said elongate lifter portion.

* * * * *



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CONTROL NO.	FILING DATE	PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
95/000,161	07/28/06	6,543,447	

IPSOLON LLP
111 SW COLUMBIA
SUITE 710
PORTLAND, OR 97201

EXAMINER

Flanagan, Beverly

ART UNIT PAPER

3993

DATE MAILED:

05/04/07

**INTER PARTES REEXAMINATION
COMMUNICATION**

BELOW/ATTACHED YOU WILL FIND A COMMUNICATION FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE OFFICIAL(S) IN CHARGE OF THE PRESENT REEXAMINATION PROCEEDING.

All correspondence relating to this *inter partes* reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this communication.



DO NOT USE IN PALM PRINTER

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

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BOSTON, MA 02205

**Transmittal of Communication to Third Party Requester
Inter Partes Reexamination**

REEXAMINATION CONTROL NUMBER 95/000,161.

PATENT NUMBER 6,543,447.

TECHNOLOGY CENTER 3999.

ART UNIT 3993.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above-identified reexamination proceeding. 37 CFR 1.903.

Prior to the filing of a Notice of Appeal, each time the patent owner responds to this communication, the third party requester of the *inter partes* reexamination may once file written comments within a period of 30 days from the date of service of the patent owner's response. This 30-day time period is statutory (35 U.S.C. 314(b)(2)), and, as such, it cannot be extended. See also 37 CFR 1.947.

If an *ex parte* reexamination has been merged with the *inter partes* reexamination, no responsive submission by any *ex parte* third party requester is permitted.

All correspondence relating to this *inter partes* reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of the communication enclosed with this transmittal.

**OFFICE ACTION IN INTER PARTES
REEXAMINATION**

Control No.	Patent Under Reexamination	
95/000,161	6543447	
Examiner	Art Unit	
Beverly M. Flanagan	3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

Responsive to the communication(s) filed by:

Patent Owner on _____

Third Party(ies) on _____

RESPONSE TIMES ARE SET TO EXPIRE AS FOLLOWS:

For Patent Owner's Response:

2 MONTH(S) from the mailing date of this action. 37 CFR 1.945. EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.956.

For Third Party Requester's Comments on the Patent Owner Response:

30 DAYS from the date of service of any patent owner's response. 37 CFR 1.947. NO EXTENSIONS OF TIME ARE PERMITTED. 35 U.S.C. 314(b)(2).

All correspondence relating to this inter partes reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

This action is not an Action Closing Prosecution under 37 CFR 1.949, nor is it a Right of Appeal Notice under 37 CFR 1.953.

PART I. THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892
2. Information Disclosure Citation, PTO/SB/08
3. _____

PART II. SUMMARY OF ACTION:

- 1a. Claims 1-44 are subject to reexamination.
- 1b. Claims _____ are not subject to reexamination.
2. Claims _____ have been canceled.
3. Claims _____ are confirmed. [Unamended patent claims]
4. Claims _____ are patentable. [Amended or new claims]
5. Claims 1-44 are rejected.
6. Claims _____ are objected to.
7. The drawings filed on _____ are acceptable are not acceptable.
8. The drawing correction request filed on _____ is: approved. disapproved.
9. Acknowledgment is made of the claim for priority under 35 U.S.C. 119 (a)-(d). The certified copy has:
 been received. not been received. been filed in Application/Control No 95000161.
10. Other _____

DETAILED ACTION

Reexamination Procedures

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be an Action Closing Prosecution (ACP), will be governed by 37 CFR 1.116(b) and (d), which will be strictly enforced.

Issue Not Within Scope of Reexamination

It is noted that an issue not within the scope of reexamination proceedings has been raised. Specifically, third party requester has alleged the following: At page 12 of the request, the phrase "said camera" in claim 9 lacks proper antecedent basis and, at page 48 of the request, that claim 33 is a duplicate of claim 32 and therefore improper. These issues will not be considered in a reexamination proceeding. 37 CFR 1.552(c). While this issue is not within the scope of reexamination, the patentee is advised that it may be desirable to consider filing a reissue application provided that the patentee believes one or more claims to be partially or wholly inoperative or invalid based upon the issue.