

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
13 December 2007 (13.12.2007)

PCT

(10) International Publication Number
WO 2007/141787 A1

(51) International Patent Classification:
A61M 16/04 (2006.01)

(21) International Application Number:
PCT/IL2007/000685

(22) International Filing Date: 6 June 2007 (06.06.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/811,104 6 June 2006 (06.06.2006) US

(71) Applicant and

(72) Inventor: GILADI, Sagi [IL/IL]; 8/19 Haim Hazaz St.,
84373 Beer Sheva (IL).

(74) Agents: RUTMAN Pyernik et al.; Beit Etzion, 91 Herzl
St., P.O.Box 10012, 84106 Beer-Sheva (IL).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH,

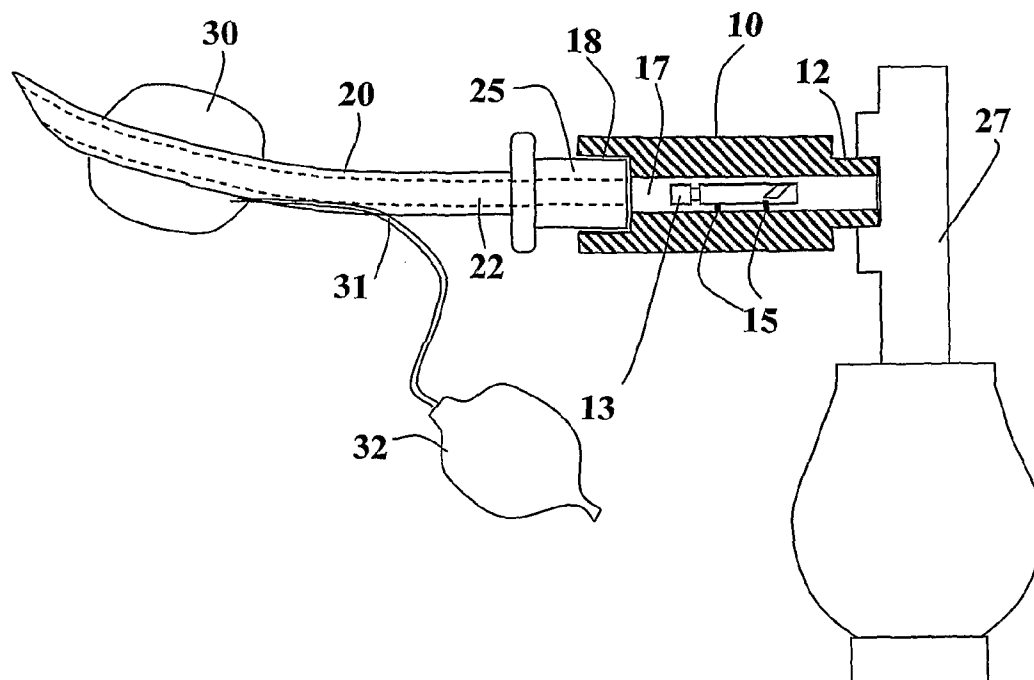
CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG,
ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL,
IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK,
LR, LS, LT, LU, LY, MA, MD, MG, MK, MN, MW, MX,
MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO,
RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL,
PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report
— before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: A DEVICE AND METHOD FOR ASSISTING PLACEMENT OF A TUBE DEVICE THROUGH A BODY PASSAGE



(57) Abstract: A device, and a method of use thereof, for aiding the proper insertion of a tube device (20) into the body of a patient via a body passage, said device comprises a pneumatic signal generator (13) and it is adapted to connect to the proximal end of a conventional tube device and provide gas (e.g., air) passage and connectivity to a gas source (27) for streaming gas streams therethrough, such that acoustic signals are produced by said pneumatic signal generator in response to the passage of said gas streams.

WO 2007/141787 A1

- 1 -

**A DEVICE AND METHOD FOR ASSISTING PLACEMENT OF A TUBE DEVICE
THROUGH A BODY PASSAGE**

Field of the Invention

The present invention relates to the placement of a tube device in the body of a treated subject. More particularly, the invention relates to a method and device for confirming placement of a tube device (e.g., Endotracheal tube) in the trachea of a treated subject.

Background of the Invention

Various treatment procedures requires placement of a tube device in the body of a treated subject. Typically, the tube device is advanced towards a desired location in the body of the treated subject via a body passage. For example, endotracheal tubes (ETT) are tube devices used for ensuring that there is an open pathway to the lungs of a patient, for ventilating the lungs. The process of inserting an ETT into the trachea, also known as intubation, may be carried out via the mouth, the nose (nasotracheal intubation), or directly through an incision performed in a surgical procedure (cricothyroidotomy) on the neck of the patient.

While ETT intubation may be performed "blind", it is usually performed by visualizing the larynx by means of a laryngoscope, or by other means (e.g., CO₂ detector, esophageal detector). In ETT intubation using direct laryngoscopy the laryngoscope is inserted into the mouth of the patient and used to push away the tongue and lift the epiglottis. This process is cumbersome to the practitioner.

An elongated flexible element is typically used as an introducer (stylet) in ETT intubation, wherein said

- 2 -

introducer is inserted into the ETT to enhance its stiffness and pushability during placement thereof in the patient's trachea, and it is removed thereafter. After placing the ETT in the trachea a ventilator, such as a bag valve mask, may be attached to the ETT for ventilating and oxygenating the lungs.

When properly positioned the distal end of the ETT is located slightly (about 2cm) above the carina (lungs bifurcation). However, in some instances the ETT is inserted past the carina, and in this case it mainly communicates with the right primary bronchus. In many other instances the ETT is inadvertently inserted into the esophagus, and in some cases the ETT distal tip moves proximally past either the carina or above the vocal cords, which diminishes lung respiratory efficiency and may result in severe medical complications.

There are various ETT sizes that suit different tracheal diameters and lengths. The proximal extremity of the ETT ends in a quick connector suitable for connecting it to ventilation devices. ETTs are also used for suctioning secretions and mucus that may block the passage of air to the patient's lung (deep suction), by means of a catheter device that is inserted through the ETT.

The ETT "blind" or laryngoscope based intubation methods commonly performed nowadays do not provide means for verifying proper insertion of ETTs into the trachea of patients, and they are not suitable for battlefield situations or events with a great number of casualties.

An audio aid for determining position of an ETT within a patient is described in US patent No. 6,3497,20. In this

- 3 -

patent a mechanical noise maker is formed upon the distal end of a cuffed ETT, such that whenever the distal end of the ETT has been sufficiently advanced into the trachea or esophagus during endotracheal intubation and an airway is established, the mechanical noise-making device formed upon the distal end of the ETT produces audible sounds as the patient inhales and exhales, or responsive to lungs ventilation carried out by means of a ventilation device.

Namely, the audio aid described in US 6,3497,20 can not be used with conventional ETTs, rather, a modified ETT having a noise-making device formed upon its end is required. Said modified ETT is therefore more susceptible to blockage by mucus and secretions due to the noise-making device formed upon its distal end, and for the same reason, it is not suitable for introducing medication into the patient's lungs, as sometimes needed, and it is not suitable for suctioning secretions and mucus blocking patient's air passage, since the suctioning catheter device can not pass the noise making device formed upon the distal end of the ETT.

Additionally, locating the noise-making device in the air passage of the ETT complicates conventional ETT placement procedures wherein an introducer is employed. Moreover, since the noise making device is located distally, remote from the ventilation device, the magnitudes of the stream of air reaching it are substantially reduced, and correspondingly the magnitudes of the audible sounds produced by it are diminished.

The term "advanced airway device" used herein generally refers to intubation devices (e.g., tubes) and airway devices used for opening a pathway to the lungs of a treated subject,

- 4 -

such as, but not limited to, ETT (tubus), laryngeal mask airway (LMA), combitube, king, and the like.

The methods described above have not yet provided satisfactory solutions for properly placing tube devices, such as, but not limited to, advanced airway devices, in the body of a treated subject. Therefore there is a need for a method and device that overcomes the above mentioned problems.

It is therefore an object of the present invention to provide a method and device for properly placing a tube device in a patient.

It is another object of the present invention to provide a method and device for identifying the location of the distal end tip of a tube device placed in a patient.

It is a further object of the present invention to provide a method and device for properly placing an advanced airway device in a patient by utilizing the standard advanced airway and intubation equipment commonly used nowadays.

It is yet a further object of the present invention to provide a method and device for properly placing a tube device in a patient which is simple to use and which may be implemented with low costs.

Other objects and advantages of the invention will become apparent as the description proceeds.

Summary of the Invention

The present invention is directed to a device and method for confirming placement of a tube device in the body of a treated subject. The device of the present invention is adapted to connect to the proximal end of conventional tube devices which are introduced into the body of a treated subject via a body passage, and it is designed to provide gas passage and connectivity to a gas source capable of streaming gas volumes therethrough. The gas passage of the device of the invention comprises a pneumatic signal generator capable of producing acoustic signals in response to the passage of gas therethrough. Said acoustic signals propagate through the tube device into the body of the patient and are used to indicate the location of the distal tip of the tube device.

The term "tube device" used herein refers to tubes suitable for insertion into the body of a treated subject via body passages. For example, said tubes may part of systems used for internal provision of medications or ventilation gases (e.g., air, oxygen).

In one preferred embodiment the device of the invention is used for the proper insertion of an advanced airway device into the trachea of a patient. In this preferred embodiment the device of the invention is adapted to connect to the proximal end of a conventional advanced airway device and it is designed to provide gas passage and connectivity to ventilation devices for ventilating the patient's lungs therethrough. The pneumatic signal generator provided in the device is adapted for producing acoustic signals in response to the passage of air through the device. Said acoustic signals propagate through the advanced airway device into the

- 6 -

body of the patient and are used to indicate the location of the distal tip of the advanced airway device.

The inventor hereof developed a new device, and a method of using the same, for assisting placement of tube devices in the body of a treated subject. The device of the invention is adapted to produce audible signals responsive to the passage of gas streams provided by a gas source to which the device is connected, said audible signals are produced by a pneumatic sound generator (e.g., whistle or reed) disposed in a gas passage provided thereinside.

In one aspect, the present invention is directed to a device for confirming placement of a tube device in a body passage of a treated subject comprising a gas transferring element having first and second ends and a gas transfer passage passing therebetween, said first end is adapted to connect and communicate with a gas source capable of streaming a stream of gas through said gas transfer passage, and said second end is adapted to connect and communicate with said tube device, said gas transferring element further comprises a pneumatic sound generator disposed in said gas transfer passage, such that audible signals are produced by said pneumatic sound generator whenever gas streams provided by said gas source are transferred to said tube device via said gas transfer passage. The pneumatic sound generator may be attached (e.g., by glue or welding) to the inner wall of said gas transfer passage, or fitted thereinside. Additionally or alternatively, the pneumatic sound generator may be attached to the inner wall of the gas transferring element by means of supporting elements connected thereto.

- 7 -

The gas source may be a type of ventilation device as used for providing (manually or automatically) gas streams suitable for lung ventilation, such as, but not limited to, bag-valve or mechanical/automatic respiratory devices.

The device may further comprise filtering means disposed in the gas transfer passage, preferably near the first end, such that gas transferred therethrough is forced to pass through said filtering means. Alternatively, external filtering means may be employed by connecting the same to the first or second end of the device, wherein said filtering means is adapted to connect and communicated between the device and the gas source or the tube device.

Preferably, the first end of the gas transferring element is adapted to be received in connecting means provided in the gas source and the second end thereof is adapted to receive connecting means provided in the tube device.

In a specific embodiment of the invention the gas transferring element is constructed from coaxially connected tubes. Advantageously, one end of the gas transferring element is adapted to be received in connecting means provided in the gas source and its other end is adapted to be received in an opening of the tube device.

The pneumatic sound generator may be mounted concentrically in the gas passage by means of a plurality of radial arms.

In one preferred embodiment of the invention the tube device is (or part of) an advanced airway device. Advantageously, the gas transferring element may further comprise an inhalation gas entry. Preferably, said inhalation gas entry

- 8 -

is implemented by a lateral connecting means having a gas passage, said lateral connecting means is adapted to connect to, and communicate with, an inhalation gas supply conduit, such that inhalation gas streamed therethrough is introduced therethrough into the gas transfer passage of said gas transferring element.

In another aspect, the present invention is directed to a method for placing a tube device in a treated subject, comprising: advancing said tube device towards a desired location in the body of the treated subject through a body passage; connecting to said tube device a gas transferring element comprising a pneumatic sound generator disposed in gas transfer passage passing between first and second ends of said gas passage element; connecting to said gas transferring element a gas source; streaming volumes of gas from said gas source into the gas transferring passage of said gas transfer element; determining proper placement of said tube device whenever audible signals produced by said pneumatic sound propagate to the desired location in the body of the treated subject. The method may further comprise retracting portions of the tube device and reinserting the same towards the desired location whenever audible signals produced by the pneumatic sound generator do not propagate to said desired location.

The determination of proper placement of the tube device may be carried out by listening to the external areas on the body of the treated subject near the desired location with unaided ears or by means of a stethoscope, or palpably by sensing the vibrations transmitted due to the propagation of said audible signals.

- 9 -

The tube device may be (or part of) a type of advanced airway device. The method may further comprise connecting an inhalation gas source to the gas transferring element.

Brief Description of the Drawings

The present invention is illustrated by way of example in the accompanying drawings, in which similar references consistently indicate similar elements and in which:

- Fig. 1 shows a longitudinal-section view of the intubation assisting device of the invention when connected to an ETT and a ventilating device;
- Fig. 2 is a cross-sectional view of the intubation assisting device of the invention;
- Fig. 3 shows a longitudinal section view of the intubation assisting device of the invention having a filtering element;
- Fig. 4 exemplifies using the intubation assisting device of the invention with LMA; and
- Figs. 5A to 5C schematically illustrate another preferred embodiment of the intubation assisting device of the invention, wherein Fig. 5A is perspective view, Fig. 5B is a side view, and Fig. 5C is a back view.

It should be noted that the embodiments exemplified in the Figs. are not intended to be in scale and are in diagram form to facilitate ease of understanding and description.

Detailed Description of Preferred Embodiments

In one preferred embodiment the present invention relates to an intubation assisting device for assisting in properly inserting an advanced airway device into the trachea of a patient, for providing an airway to the patient's lungs, and for allowing lung ventilation (oxygenation). The device of the present invention is adapted to connect to the proximal end of the advanced airway device and it is designed to provide gas passage and connection to ventilation devices for maintaining positive airway pressure. The gas passage of the intubation assisting device of the invention comprises an audible signal generator capable of producing audible signals in response to the passage of air therethrough. Said audible signals propagate through the advanced airway device into the body of the patient and used to indicate the location of the distal end tip of the advanced airway device.

The audible signals propagating into the body of the patient can be heard by the practitioner by listening to the patient's lungs with unaided ears or by means of a stethoscope. Alternatively, said audible signals may be palpably sensed by the practitioner by placing both hands against the sides of the chest and sensing the vibrations transmitted due to the propagation of said audible signals, as performed in Tactile Fremitus lungs test. Hearing or sensing said audible signals in the lungs of the patient is used as an indication that the advanced airway device is properly placed in the trachea.

Fig. 1 schematically illustrates a longitudinal section view of an intubation system of the invention comprising an

- 11 -

advanced airway device **20** (e.g., ETT) connected by means of quick connector **25** to the intubation assisting device of the invention **10**, which may be connected by means of quick connector **12** to ventilation device **27** (e.g., bag-valve). Advanced airway device **20** is preferably a type of conventional intubation tube made from a flexible tube having an inner passage **22** and cuff **30** located at its distal end, said cuff **30** may be inflated by an air source **32** via inflating conduit **31**. Typically, such conventional advanced airway devices are inserted into the trachea by means of an introducer (not shown).

Intubation assisting device **10** comprises a central bore **17** in which a pneumatic sound generator **13** is mounted by means of one or more supports **15**, as seen in the cross sectional view in Fig. 2. Alternatively, pneumatic sound generator **13** may be adhered or welded within the central bore **17**, fitted thereinside, or manufactured as an integral part of intubation assisting device **10**. Central bore **17** communicates with inner passage **22** of advanced airway device **20** via recess **18** formed at the distal end of intubation assisting device **10** and adapted to sealably and tightly fit over quick connector **25**. Quick connector **12** provided at the proximal end of intubation assisting device **10** is adapted to sealably connect to ventilation means **27**.

Intubation assisting device **10** may be manufactured by any suitable process known in the art, from any suitable type of plastic, rubber, or metal, preferably from plastic. The length of intubation assisting device **10** may generally be in the range of 3 to 8 cm, preferably about 7cm. The outer diameter of intubation assisting device **10** may generally be in the range of 1.5 to 2 cm, preferably about 1.7 cm, and the

- 12 -

inner diameter of its central bore **22** may generally be in the range of 1.1 to 1.7 cm, preferably about 1.5 cm.

Pneumatic sound generator **13** may be a type of small whistle or reed made from any suitable type of plastic, rubber, or metal. The length of pneumatic sound generator **13** may generally be in the range of 2 to 4 cm, preferably about 2.5 cm, and its diameter is generally in the range of 0.7 to 1.2 cm, preferably about 0.9 cm.

Quick connectors **25** and **12**, are preferably implemented by cylindrical parts adapted to sealably and tightly fit into recesses provided in the respective connecting means, **18** and connecting means of ventilation device **27**.

The practitioner may use an introducer (stylet) to assist in the intubation process. After placing advanced airway device **20** in the trachea of the patient the introducer is removed therefrom and the intubation assisting device **10** is connected thereto by means of quick connector **25**. The patient may be then ventilated by connecting ventilating device **27** to intubation assisting device **10** via quick connector **12**. During ventilation the air passing via central bore **22** of intubation assisting device **10** activates pneumatic sound generator **13** which in turn generates audible signals. The generated audible signals propagate distally via central bore **22** of advanced airway device **20** into the patient's body.

The audible signals propagating into the body of the patient can be heard by the practitioner by listening to the patient's lungs with unaided ears or by means of a stethoscope. When a stethoscope is used the practitioner may listen to left and right sides of the (anterior or posterior)

- 13 -

chest, for example, by placing the diaphragm of the stethoscope on the left and right sides of the patient's chest near the nipples. The practitioner may also place the diaphragm of the stethoscope on the patient's abdomen area (e.g., around the belly), and if the audible signals are heard in the stomach it is probably due to misplacement of the advanced airway device such that it entered the esophagus.

Alternatively, said audible signals may be palpably sensed by the practitioner by placing both hands against the sides of the chest and sensing the vibrations transmitted due to the propagation of said audible signals, as performed in Tactile Fremitus lungs test. Hearing or sensing said audible signals in the lungs of the patient is used as an indication that the advanced airway device is properly places in the trachea.

The intubation assisting device **10** of the present invention advantageously integrates with the standard intubation equipment commonly used nowadays in intensive care units and ambulances without requiring any modifications thereof. Moreover, since the pneumatic sound generator **13** of intubation assisting device **10** of the invention is not located in advanced airway device **20** it permits using a regular introducer during the intubation and there is no threat of it being occluded with secretions. In addition, whenever it is required to perform mucus or secretion suction, or to introduce medication into the lungs of the treated subject, the practitioner may simply remove the intubation assisting device **10** and perform the needed operations via the advanced airway device **20**, as conventionally performed in such cases.

- 14 -

It should be appreciated that the intubation assisting device **10** of the invention may be conveniently used with different intubation tubes having different sizes and lengths (e.g., for adults and children), and in combination with bacterial/viral filters. Bacterial/viral filters are commonly used nowadays with lungs ventilation equipment in order to prevent the spreading of contagious diseases between the different patients that are treated with the same ventilation equipment, and in order to avoid repeated sterilization procedures of said equipment after each use. In addition, the intubation assisting device **10** of the invention can also be used in patients having breathing difficulties, and as well in patients with apnea.

Fig. 3 demonstrates a preferred embodiment of the intubation assisting device **40** of the invention comprising a bacterial/viral filter **48**. Filter **48** is preferably placed in the proximal portion of central bore **17** and it may be manufactured from any suitable materials as conventionally used in the manufacturing of bacterial/viral filters. Alternatively, conventional filtering means (not shown) may be externally connected to the first or second end of the intubation assisting device, wherein said filtering means is adapted to connect and communicated between with the device and the ventilation device or the advanced airway device.

It should be noted that the intubation assisting device **10** (or **40**) of the invention may be used with other types of airway and ventilation devices, such as for example LMA (laryngeal mask airway) and combi-tube. Fig. 4 exemplifies using intubation assisting device **10** of the invention with LMA **47** comprising quick connector **45**, inner passage **42**, and

- 15 -

cuff **44** which may be inflated by an air source **32** via inflating conduit **41**.

Figs. 5A to 5C illustrates another preferred embodiment of an intubation assisting device **50** of the invention comprising connecting means **54** for connecting an inhalation gas supply conduit (not shown) to intubation assisting device **50** for supplying an inhalation (e.g., oxygen) and/or anesthetic gases to the lungs of the treated subject. Conventionally, an inhalation gas supply conduit (not shown) is used for supplying an inhalation gas supplied from an inhalation gas source (e.g., compressed inhalation gas tank) to an air enrichment bug (not illustrated) connected to the ventilation device **27**. Connecting means **54** may be advantageously employed as a backup connection for the inhalation gas supply conduit which may be needed whenever the air enrichment bug is accidentally torn or damaged.

With reference to the side view shown in Fig. 5B, intubation assisting device **50** may be constructed from two coaxially connected tubes, a first tube **52** having a first opening **52o** at one end thereof which is adapted to be received in connection means provided in ventilation device **27**, and adapted to communicate with ventilation device **27**, and a second tube **51** sealably attached at one end thereof to the other end of first tube **52** and having an opening **51o** at its other end which is adapted to be received in the gas passage of advanced airway device **20**, and adapted to communicate with advanced airway device **20**.

Pneumatic sound generator **53c** is preferably mounted in first tube **52** by means of radial arms structure **53** provided near the connection point of the tubes. Radial arms structure **53**

- 16 -

is designed to hold pneumatic sound generator **53c** concentrically in first tube **52** while allowing fluid (gas) passage therethrough.

Pneumatic sound generator **53c** may be attached to radial arms structure **53** by adhesive, welding, or it may be an integral part of said structure. As illustrated in the side and back views, respectively shown in Figs. 5B and 5C, connecting means **54** comprises a passage **54p**, used for communicating with the passage obtained through tubes **51** and **52**. In this way, intubation assisting device **50** can be used in assisting in the intubation process, as described hereinabove, while also providing inhalation gas enrichment to the gas (air) ventilating the lungs of the treated subject by connecting an inhalation gas source thereto by means of a conduit.

Intubation assisting device **50** may be manufactured from any suitable type of plastic, rubber, or metal, preferably from plastic. The length of first tube **52** may generally be in the range of 15 to 50 mm, preferably about 26.3 mm, its diameter may generally be in the range of 7 to 20 mm, preferably about 17.5 mm, and its wall thickness is preferably about 1.15 mm. The length of second tube **51** may generally be in the range of 15 to 50 mm, preferably about 20.6 mm, its diameter may generally be in the range of 5 to 18 mm, preferably about 13 mm, and its wall thickness is preferably about 1.15 mm.

The diameter of connecting means **54** may generally be about 3 to 8 mm and the diameter of passage **54p** provided thereinside may generally be about 4 to 6 mm. As shown in Fig. 5C, radial arms structure **53** is preferably constructed from a plurality of arm **53r** arranged such that one side of each of said arms **53r** is attached to the inner wall, and along the length of, a

- 17 -

section of the first tube **52**, and their other end is connected to pneumatic sound generator **53c** concentrically disposed in the passage within said first tube **52**. Preferably, more or less equal angles are obtained between arms **53r**. The length of arms **53B** may generally be about 8mm.

All of the abovementioned parameters are given by way of example only, and may be changed in accordance with the differing requirements of the various embodiments of the present invention. Thus, the abovementioned parameters should not be construed as limiting the scope of the present invention in any way. In addition, it is to be appreciated that the different tubes, connectors, and other members, described hereinabove may be constructed in different shapes (e.g. having oval, square etc. form in plan view) and sizes differing from those exemplified in the preceding description.

The above examples and description have of course been provided only for the purpose of illustration, and are not intended to limit the invention in any way. As will be appreciated by the skilled person, the invention can be carried out in a great variety of ways, employing more than one technique from those described above, all without exceeding the scope of the invention.

CLAIMS

1. A device for confirming placement of a tube device in a body passage of a treated subject, comprising a gas transferring element having first and second ends and a gas transfer passage passing therebetween, said first end is adapted to connect and communicate with a gas source, and said second end is adapted to connect and communicate with said tube device, said gas transfer passage further comprises a pneumatic sound generator disposed in said gas transfer passage, such that audible signals are produced by said pneumatic sound generator whenever gas streams are transferred via said gas transfer passage.
2. The device according to claim 1, further comprising filtering means disposed in the gas transfer passage of the gas transferring element.
3. The device according to claim 1, wherein the tube device is an advanced airway device.
4. The device according to claim 3, wherein the advanced airway device is a conventional endotracheal tube, or a type of laryngeal mask airway or combi-tube.
5. The device according to claim 1, wherein the first end of the gas transferring element is adapted to be received in connecting means provided in the gas source.
6. The device according to claim 1, wherein the second end of the gas transferring element is adapted to receive connecting means provided in the tube device.

- 19 -

7. The intubation assisting device according to claim 1, wherein the gas transferring element is constructed from coaxially connected tubes.

8. The intubation assisting device according to claim 1, wherein one end of the gas transferring element is adapted to be received in connecting means provided in the gas source and its other end is adapted to be received in an opening of the tube device.

9. The device according to claim 1, wherein the pneumatic sound generator is mounted concentrically in the gas passage by means of a plurality of radial arms.

10. The device according to claim 3, further comprising an inhalation gas entry.

11. The device according to claim 10, wherein the inhalation gas entry comprises a lateral connecting means having a gas passage, wherein said lateral connecting means is adapted to connect to, and communicate with, an inhalation gas supply conduit.

12. The device according to claim 1, wherein the first or second end of said device is adapted to connect to an external filtering means, wherein said external filtering means is adapted to connect and communicated between said device and the gas source or the tube device.

13. A method for placing a tube device in the body of a treated subject, comprising:

- 20 -

advancing through a body passage said tube device towards a requisite location in the body of the treated subject;

connecting to said tube device a gas passage element comprising a pneumatic sound generator disposed in gas transfer passage passing between first and second ends of said gas passage element;

connecting to said gas transfer element a gas source;

streaming volumes of gas from said gas source into the gas transferring passage of said gas transfer element;

determining proper placement of said tube device whenever audible signals produced by said pneumatic sound generator propagate to the desired location in the body of the treated subject.

14. The method according to claim 13, further comprising retracting portions of the tube device and reinserting the same towards the desired location whenever audible signals produced by the pneumatic sound generator do not propagate to said desired location in the treated subject.

15. The method according to claim 13, wherein the determination of proper placement of the tube device is carried out by listening to external areas on the body of the treated subject adjacent to the desired location with unaided ears or by means of a stethoscope, or palpably by sensing the vibrations transmitted due to the propagation of said audible signals.

16. The method according to claim 13, wherein the tube device is a type of advance airway device.

- 21 -

17. The method according to claim 16, further comprising connecting an inhalation gas source to the gas transfer element.

18. The method according to claim 16, further comprising connecting an external filtering means to the first or second end of the gas passage element, wherein the tube device or the gas source is connected to said filtering means.

1/2

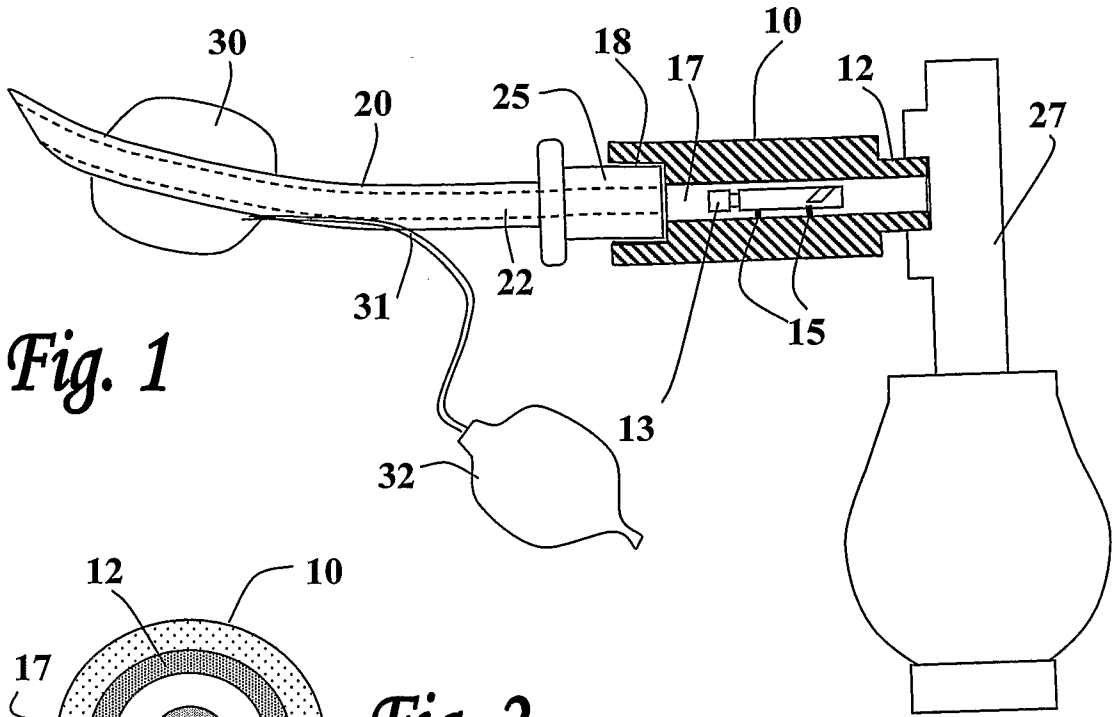


Fig. 1

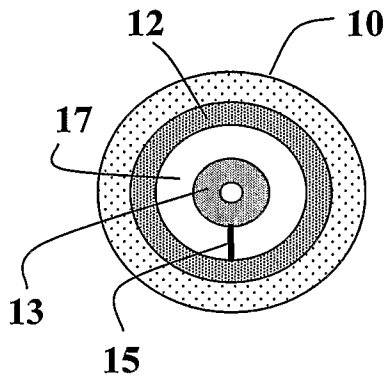


Fig. 2

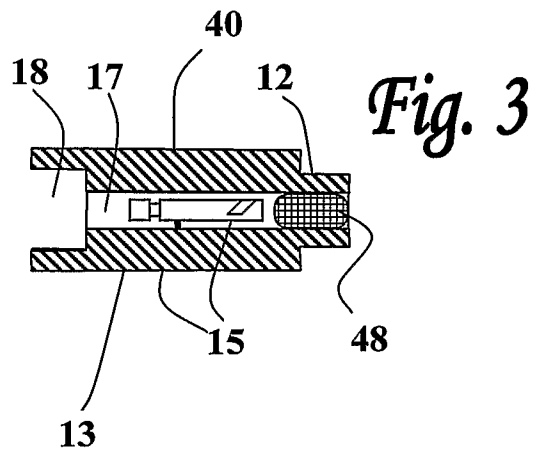


Fig. 3

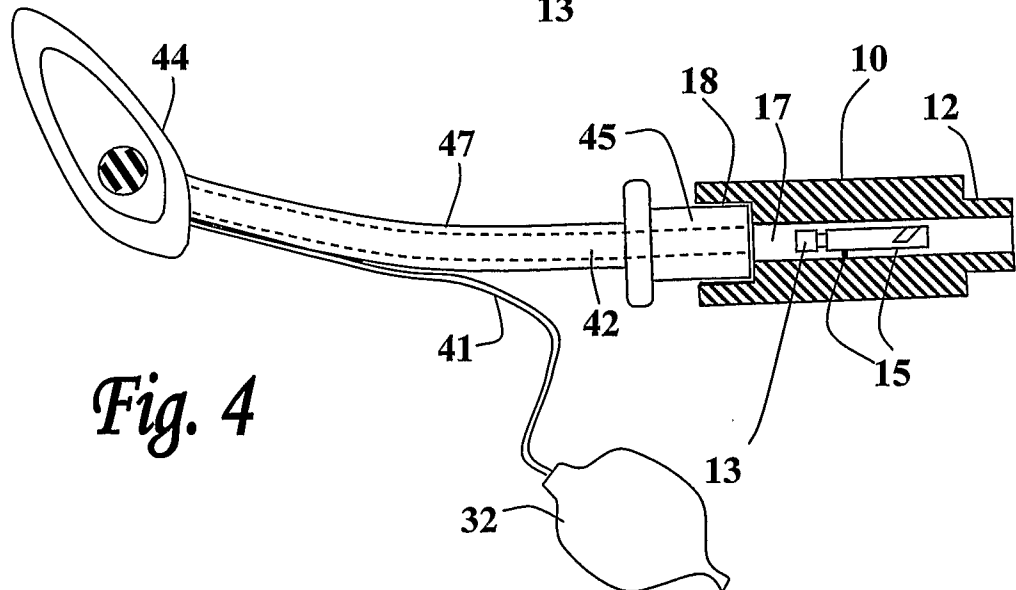
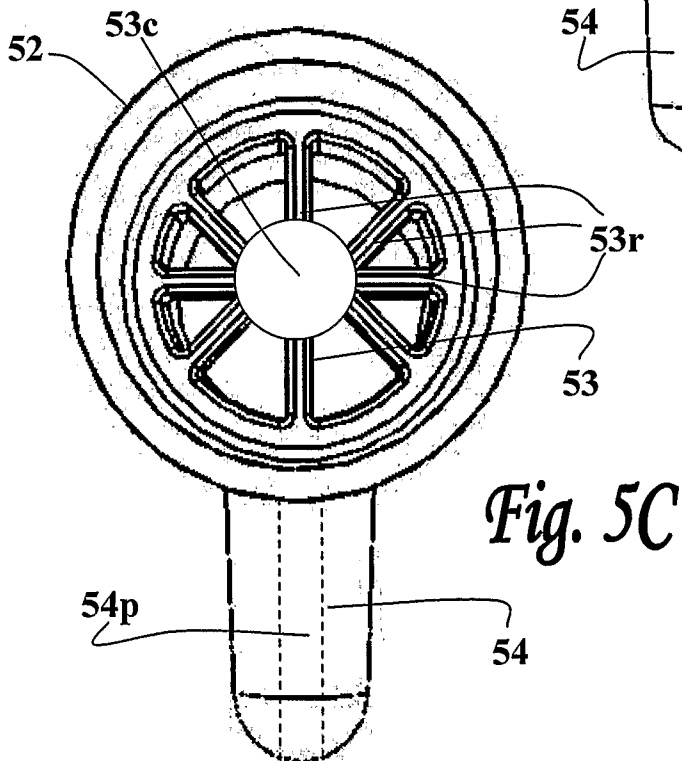
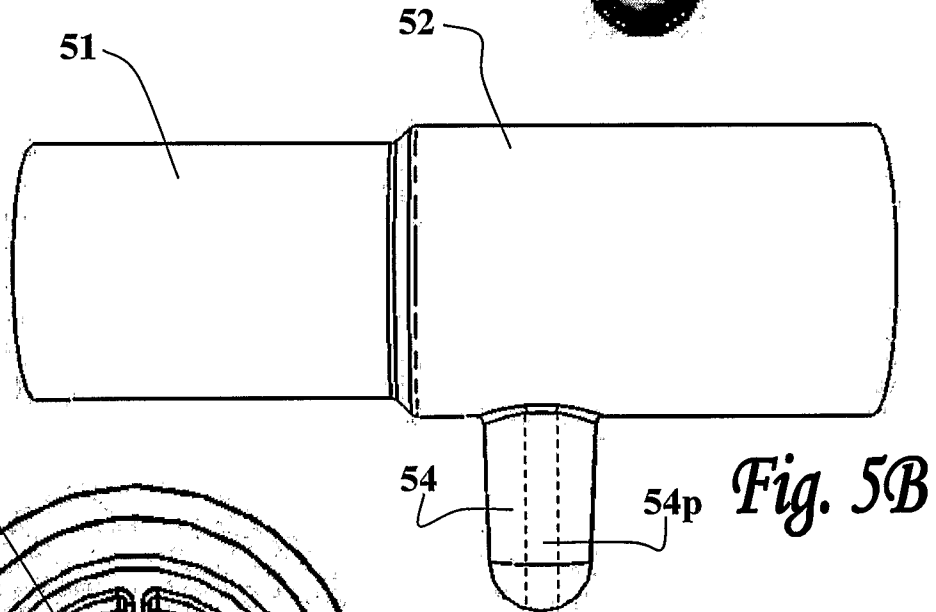
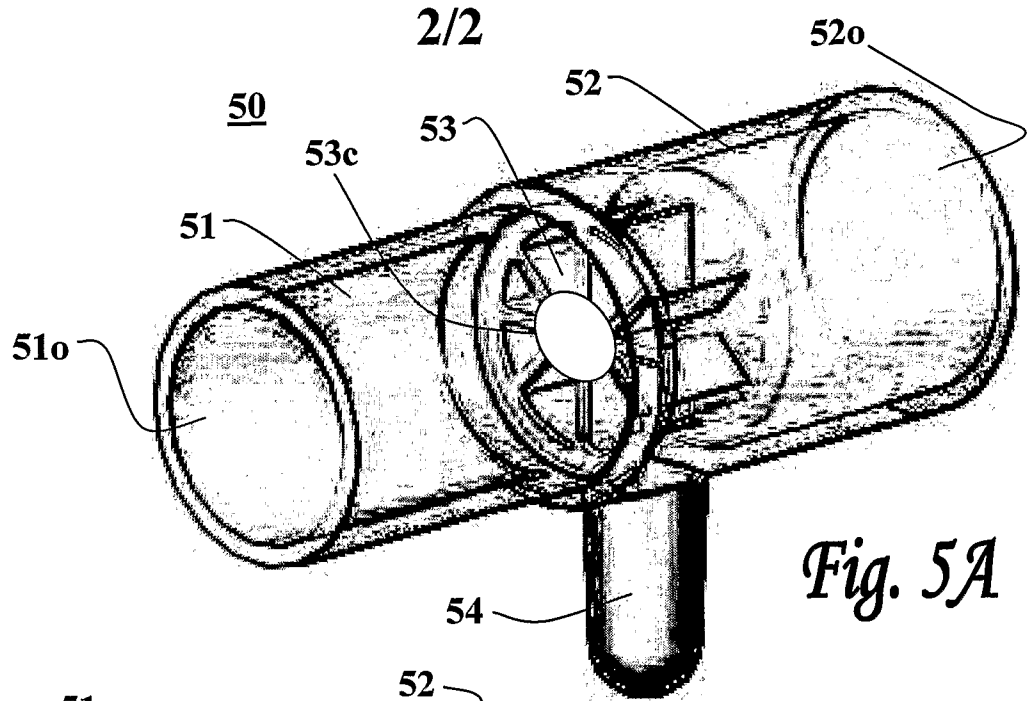


Fig. 4



INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2007/000685A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/04

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 620 004 A (JOHANSEN AARON [US]) 15 April 1997 (1997-04-15) column 3, line 50 - column 4, line 49; claim 5; figures 1-5	1-12
A	US 2 638 096 A (WALDHAUS EDITH A) 12 May 1953 (1953-05-12) the whole document	1
A	US 5 885 248 A (DENTON MARSHALL T [US]) 23 March 1999 (1999-03-23) the whole document	1
A	US 6 164 277 A (MERIDETH JOHN H [US]) 26 December 2000 (2000-12-26) the whole document	1
	----- -/-- -----	

 Further documents are listed in the continuation of Box C. 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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

26 September 2007

Date of mailing of the international search report

10/10/2007

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Borowski, Aleksander

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2007/000685

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 218 515 A (AINSWORTH QUENTIN PAUL) 15 November 1989 (1989-11-15) the whole document -----	1
A	US 4 879 999 A (LEIMAN BASIL C [US] ET AL) 14 November 1989 (1989-11-14) the whole document -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2007/000685

Box 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. Claims Nos.: 13-18
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 (placing a tube in the body of a treated subject) and therapy (streaming volumes of gas from a gas source into a gas transferring passage, i.e. also into the airways of the treated subject).
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 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 fee, this Authority did not invite payment of any additional fee.
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.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IL2007/000685

Patent document cited in search report	Publication date	Publication date	Patent family member(s)	Publication date
US 5620004	A	15-04-1997	NONE	
US 2638096	A	12-05-1953	NONE	
US 5885248	A	23-03-1999	NONE	
US 6164277	A	26-12-2000	NONE	
GB 2218515	A	15-11-1989	NONE	
US 4879999	A	14-11-1989	JP 1924016 C	25-04-1995
			JP 6047010 B	22-06-1994
			JP 62236559 A	16-10-1987