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(72) Inventor; and
(71) Applicant : **DHARA, Sasanka Sekhar** [AU/AU]; 16 Dresden St, Sandy Bay, Tasmania 7005 (AU).

(74) Agent: **HARKINS, Julie Margaret**; Tasmanian Patent Services, PO Box 294, Huonville, Tasmania 7109 (AU).

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[Continued on next page]

(54) Title: ENDOTRACHEAL TUBE AND METHOD OF USE

(57) Abstract: The present invention provides anendotracheal tubewith a tip suitable for traversing the laryngeal inlet and a guidingchannel-which allows wire guided intubation, a method and a kit relating to the same.

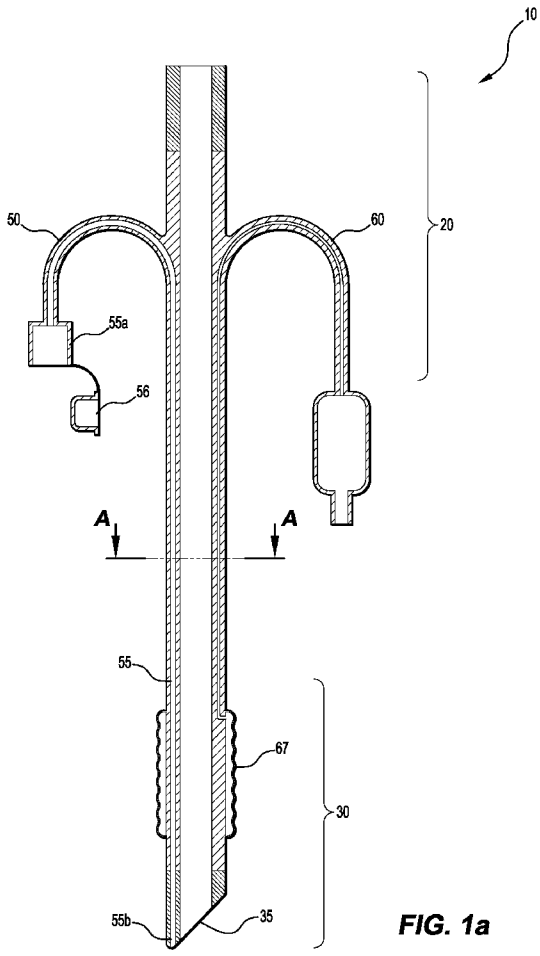

FIG. 1a

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Title: Endotracheal Tube and Method of Use

Field of Invention

[01] The present invention relates to equipment for use in and methods of performing anterograde or retrograde wire guided endotracheal intubation.

Background

[02] An endotracheal tube (ETT) is normally passed into the trachea of a patient to maintain a patent airway and allow the delivery of oxygen/air/anaesthetic gases and vapours to the patient. It may also be used to separate the lungs from the aero-digestive tract and protect from soiling due to aspiration of bodily fluids or to clear respiratory tract of secretions or blood. This is achieved by suction through the ETT. Such procedures may be necessary during resuscitation or general anaesthesia, in a patient being treated in an intensive care unit (ICU) or in an accident and emergency treatment area.

[03] Tracheal intubation over a guide wire previously placed inside the larynx or trachea is an alternative method for anticipated or unanticipated difficult intubation [1- 4]. The difficulties may arise mainly from anatomical variations, changes caused by disease, trauma, and/or surgical or radio therapeutic treatment in a patient.

[04] The guide wire may be placed in an anterograde (also known as antegrade) way through the mouth or nose and across the laryngeal inlet into the trachea or through a puncture at the space at the front of the neck between cricothyroid or criocotracheal junctions or upper tracheal rings and advanced upwards in a retrograde fashion [5 - 6].

[05] Wire guided intubation is also used for exchange of endotracheal tubes and for trial of extubation in patients who are at a risk of developing an airway obstruction in postoperative period leading to an endotracheal re-intubation [7 - 9].

[06] While there are reports of guiding a small tracheal tube directly over a guide wire [10] the current technique of wire guided blind tracheal intubation is facilitated by threading a hollow semi-rigid tubular guide over the guide wire to impart an increased diameter and stiffness closer to those of the tracheal tube to be guided over. Custom built exchange catheters, [Retrograde Intubation Kit, Cook Medical, USA], fibre-optic scopes and airway exchange catheters (AEC) [Cook Medical, USA] are commonly used for the purpose though various other materials have been reported in literature [11-13].

[07] Problems still exist with both above mentioned 'hollow' introducers and their solid counterparts used for anterograde intubation (gum elastic bougies and similar introducers made of synthetic materials). The tracheal tubes (PVC) used in daily practice have a consistency and a fixed curvature that may not negotiate the midline of mouth and pharynx or the acute

pharyngo-laryngeal angle well and are known to drag relatively more flexible and redundant loop of guide (bougie, introducer, fibreoptic scope, airway exchange catheter] into the oesophagus) [14]. Pressures from the tip of an advancing tube can be high on points of contact with tissues causing trauma to the airway structures [15-16].

[08] Silicone reinforced tubes follow guides more closely and easily conform to the anatomy of the upper airway. When the tip of the tube meets with an obstruction the silicone reinforced ones can bend laterally because of its flexibility and thus dissipate the pressure transmitted to the tip. Obtuse bevel in these tubes also help avoiding impingement on tissues causing trauma to airway structures [17].

[09] Another problem is 'snagging' of the tip of the tracheal tube at the laryngeal inlet [18-19] which can result in delay in intubation/ oxygenation, dislodgement of the tube from the larynx, oesophageal intubation and trauma to larynx and pharynx. To address this issue equipment like inflatable introducers (AirguideTM, RadlynTM), AintreeTM catheter, and tubes with modified consistency and tips (Parker-flexTM tubes), ILMATM tubes are used.

[10] Several other means like positional manipulation of head and neck, keeping the tongue out of the way with use of a laryngoscope, posterior presentation of the bevel of the tip of a tracheal tube at the laryngeal inlet [18] and external pressure on the larynx have been practiced to facilitate the process of guiding.

[11] For wire guided intubation sometimes another catheter with wider diameter (Aintree catheterTM) is loaded over the first introducer (AEC, Exchange catheter or Fibreoptic scope) before the tracheal tube is finally mounted over the (guide wire/ introducer catheter/ larger introducer) complex to build up a gradual increase in diameters between the guide wire to the tracheal tube at the tip – all for a smooth railroading process. It is apparent that presence of this rather solid complex will cause sizable obstruction inside the larynx and trachea making routine vital procedure like continuous delivery of Oxygen or monitoring of Capnography difficult to impossible. This guiding procedure being 'blind' and used as a rescue technique in a difficult intubation situation is likely to be performed on a sedated patient. Prevention of hypoxia and monitoring the progress and placement of the endotracheal tube are essential in such a situation. Attempts to deliver Oxygen by jet ventilation through the hollow introducer catheter have been associated with barotrauma of the lungs [20].

[12] The problem reported with wire guided retrograde intubation is unintentional dislodgement of the ETT from the shallow depth of insertion inside the larynx while the retrograde guide is being taken out to insert the tracheal tube further down into the trachea. Keeping an axial pressure on the ETT that is practiced to prevent such dislodgement can have

adverse physiological effects. With a modified technique using Cook retrograde intubation kit (Cook Medical, USA) in cadavers, success rate of retrograde intubation increased to 89% against 70% with the classic technique. The cause of failure in both groups was due to incorrect positioning of endotracheal tube due to early dislodgement of tracheal tube and the exchange catheter from the larynx [21].

[13] Again a rescue technique such as this deserves simpler instrumentation, facility for continuous delivery of Oxygen into patient's airway, continuous Capnography and better rate of success.

[14] Complications arising from use of semi-rigid introducers inside the airway are documented time and again in the literature [22- 27]. Performance of the introducers is highly variable posing difficulty with guiding capabilities [28].

[15] In addition to the above academic references a number of different endotracheal and systems have been described in the patent literature. These include US patent application 2009/0071484 in the name of Black et al which discloses an endotracheal tube with a large channel for suction occupying part of main lumen, US patent 4637389 in the name of Heyden which discloses an endotracheal tube with a large channel eccentric to the main lumen of the tube and with an internal valve for insertion of suction catheter, US patent application 2010/0113916 in the name of Kumar which discloses an endotracheal tube with a channel to introduce equipment probe to monitor position of the endotracheal tube and Chinese utility patent 202096565 which discloses an endotracheal tube with an external channel for specific control of nasal intubation.

[16] Further, a number of other proposals in the patent literature have been put forward regarding retrograde endotracheal intubation. These include Dhara and Yong (US Patent No. 5, 269, 769) which discloses a multi-lumen catheter guide system, not an endotracheal tube, which can hold and direct two guide wires.

[17] Another proposal is that of Ballew (US Patent No 4, 913, 139) which discloses a complex inflatable guide with a central channel for the retrograde wire over which the ETT is threaded.

[18] Yet another system, that of Fortune (US Patent No 5, 507,279) discloses a conical tip at the end of the ETT with a short channel which can be threaded with the retrograde wire.

[19] In summary several equipment and steps are used to perform current techniques of wire guided tracheal intubations. Oxygen delivery and ETCO2 monitoring, two vitally essential

modalities during the procedure are difficult to achieve. Failures and complications still arise from difficulties with smooth advancement of the tracheal tubes along the tortuous upper airway.

[20] While the above prior proposals may have merit the equipment used may be complex or expensive to manufacture and/or the steps involved in carrying out the medical procedure may be time-consuming or difficult.

[21] The present inventor aims to provide a simple easy to follow system using single piece of equipment and a single step for wire guided endotracheal intubation (i.e. once the guide wire is placed only a single piece of equipment is used). The simple system provides the opportunity to deliver oxygen throughout the procedure and to monitor $ETCO_2$ to indicate the progress and correct placement of the tube. This offers unprecedented safety for management of difficult airway using wire guided tracheal intubation technique.

[22] The above references to and descriptions of prior proposals or products are not intended to be, and are not to be construed as, statements or admissions of common general knowledge in the art.

Summary of the Invention

[23] In a first aspect the present invention provides an endotracheal tube for use in a wire guided intubation procedure, said tube comprising: a) a proximal end portion suitable for attachment to a breathing circuit which end portion in use protrudes from the mouth or nose of a patient; b) a distal end portion suitable for insertion into the nose and/or mouth of a patient, said distal end portion having a tip suitable for traversing the laryngeal inlet of a patient; and c) a guide housing means running between the portions having a proximal opening adjacent said proximal end portion and a distal opening adjacent to said tip, said guide housing means suitable for slidingly receiving an anterograde or a retrograde guide during an intubation procedure to allow the tube to follow the guide into the patient.

[24] The term "endotracheal tube" refers to a medical catheter that is inserted into the trachea through the nose or mouth in order to maintain a patent airway to deliver oxygen/ artificial ventilation/anaesthetic gases and vapours to a patient or to keep the tracheo bronchial tree clean by removing secretions or blood.

[25] The term “wire guided intubation procedure" includes anterograde intubation and retrograde intubation involving a guide wire or similar piece of equipment. Anterograde intubation simply involves passing the tube over the wire through the nose or the mouth and advancing it downwards into the larynx and into the trachea; the wire having been previously placed anterograde. Retrograde intubation refers to a procedure in which one end of a guide,

most commonly a guide wire, is introduced from the front of the upper neck of the patient and is threaded up through the larynx and either out through the mouth or nose. The end of the guide wire is then retrieved and used as a guide to 'railroad' an endotracheal tube into the larynx.

[26] The term "breathing circuit" refers to a circuit or system that helps to connect the patient to the anaesthetic gas delivery machine.

[27] The term "having a tip suitable for traversing the laryngeal inlet of a patient" refers to an end or extremity of the distal end portion of the tube which has a suitable shape, and is made of suitably flexible material to pass smoothly through the laryngeal inlet.

[28] The term "a guide housing means" refers to a means for enclosing, or capturing the guide such that when the endotracheal tube is pushed over the guide, the tube will be able to closely follow the path of the guide. The housing means is of a suitable shape, configuration and size that will substantially follow the long axis of the guide with little lateral movement or play.

[29] The term "for slidably receiving a guide" refers to the guide housing means being of a size and suitable configuration to allow the endotracheal tube to slide along the guide when the guide is within the housing means.

[30] The term "follow the guide" refers to the tube following the path or the route that the guide has taken through the anatomical spaces or structures; for example through the centre of the mouth negotiating various degrees of angular bends between the pharynx, the larynx and into the trachea, ideally without straying off course or snagging on airway structures.

[31] The term "guide" used herein includes a guide wire and also contemplates other types of guides not made of wire. Many other materials had been used as guides including, epidural catheters or long CVP lines.

[32] Preferably the endotracheal tube is a flexible tube of suitable material which is reinforced along most of its length except for small sections at each end. The endotracheal tube may be made of silicon or other suitable softer non-allergenic materials.

[33] Preferably the tip of the distal end portion of the tube is in the form of a bevel with an appropriate angle. More preferably the bevel is made of soft and deformable material. Even more preferably the bevel wall is devoid of reinforcing. Preferably there are two apertures on the bevel wall (one on each side) to function as secondary routes to ventilation or suction on

occasions of obstruction to the main opening at the distal end of the tube. These are akin to the function of a Murphy eye.

[34] Preferably the guide housing means is in the form of a channel or passage adjacent the main lumen of the endotracheal tube. Even more preferably the guide housing means is integrated into the sidewall of the endotracheal tube. Still more preferably the guide housing means comprises a smooth continuous lumen.

[35] In another aspect the invention provides a kit for endotracheal intubation comprising: i) an endotracheal tube comprising: a) a proximal end portion suitable for attachment to a breathing circuit which end portion in use protrudes from the mouth or nose of a patient; b) a distal end portion for insertion into the nose and/or mouth of a patient, said distal end portion having a tip suitable for traversing the laryngeal inlet of a patient; and c) a guide housing means running between the portions having a proximal opening adjacent said proximal end portion and a distal opening adjacent to said tip, said guide housing means suitable for slidingly receiving a guide during an intubation procedure to allow the tube to follow the guide; and ii) a suitable guide.

[36] Preferably the suitable guide is a guide wire.

[37] In another aspect the invention provides an improved method of endotracheal intubation comprising: i) introducing an anterograde guide into the nose or mouth of a patient in a standard manner or introducing a retrograde guide by passing an end of a guide through into the larynx of a patient and retrieving the end from the nose or mouth of a patient in a standard manner; ii) advancing into the trachea of the patient an endotracheal tube of suitable length wherein said tube comprises: a) a proximal end portion suitable for attachment to a breathing circuit; b) a distal end portion having a tip suitable for traversing the laryngeal inlet of a patient and; c) a guide housing means running between the portions having a proximal opening adjacent said proximal portion and a distal opening adjacent to said tip, said guide housing means suitable for slidingly receiving the guide to allow the tube to follow the guide; iii) wherein the tube is advanced anterograde by sliding the tube over the guide into its desired position.

[38] The improvement resides in the fact that once the guide is in place, the design of the ETT allows it to be positioned in a single step. This saves time compared to the existing practice especially where in current retrograde procedure the retrograde guide is withdrawn whilst either pressure is exerted on the ETT to keep it in place or the guide catheter is removed from the retrograde guide and re-introduced into the lumen of the tracheal tube – all to prevent unintended displacement of the tube from the larynx. Thus the method of the present invention involves fewer pieces of equipment than existing methods resulting in less potential confusion

and lower costs. As the method involves fewer steps this saves crucial time in achieving intubation. In addition the method of the invention avoids certain undesirable effects of maneuvers required by current methods.

[39] The invention also provides a system for an endotracheal tube insertion.

[40] In another aspect the invention provides a method of making an endotracheal tube for use in a wire guided intubation procedure, said method comprising forming an endotracheal tube of suitable materials, said tube having a) a proximal end portion suitable for attachment to a breathing circuit; b) a distal end portion suitable for insertion into the nose and/or mouth of a patient, said distal end portion having a tip suitable for traversing a laryngeal inlet of a patient; and c) a guide housing means running between the portions having a proximal opening adjacent said proximal end portion and a distal opening adjacent to said tip, said guide housing means suitable for slidingly receiving a guide during an intubation procedure to allow the tube to follow the guide into a patient.

[41] Before describing the invention in detail it is helpful to understand the present practice.

[42] The current techniques of wire guided tracheal intubation consist of: a hollow semi-rigid introducer/ catheter- over the guide wire already placed inside the airway; sometimes using another larger introducer catheter (Aintree catheterTM) over the first introducer (FOS, AECs); or tracheal tube railroaded over the guide wire/introducer complex.

[43] The problems with these protocols include: restriction of size of a tracheal tube that can be used as it is determined by outer diameter of the guide (e.g. FOS); a gap between the guide and the tracheal tube which causes difficulties with placement; pressure (from tip of the tube) related injuries and oesophageal intubation; trauma from the semi-rigid guides inside airway; failure to railroad a tracheal tube over guides every time; continuous delivery of oxygen to the patient is difficult and delivery of oxygen through the hollow guide from a high pressure source (jet) had caused barotrauma; the procedure does not have definite marker for completion of a step before proceeding to the next step.

[44] A marker for completion of a step before proceeding to the next step provides a very important opportunity to correct a failed step immediately thereby saving time which is crucial in preventing hypoxia or the need for an emergency surgical airway. It will be appreciated that markers of completion of steps are important in a multi-step blind procedure. For example incorrect placement of tube is only diagnosed after guiding implements are withdrawn (except when FOS is used as guide).

[45] Another problem is the mass of guide/larger guide/ tracheal tube complex when presented at the larynx can cause sizable obstruction to the airway and it may be difficult for a patient to breathe. This problem can be even worse in a patient with a narrower larynx (laryngeal tumour) as the airway is simply plugged shut leaving no room to breathe; the number of steps and a certain sequence involved makes the procedure are lengthy and difficult.

Detailed Description of Illustrative Embodiments of the Invention

[46] The invention will now be described with reference to the following non limiting illustrative drawings.

[47] Figure 1a is a sectional longitudinal view of one embodiment the ETT.

[48] Figure 1b is a cross-section through the line A-A Figure 1a.

[49] Figure 1c is a schematic of another embodiment of the ETT.

[50] Figure 2 is a representation of a sectional view through part of a patient's head and neck showing alternative guide wire insertions (A being anterograde and B being retrograde) with the ETT railroaded over the guide prior to insertion of the ETT into the patient's mouth. The inflation cuff is omitted from the inserted tube for clarity.

[51] ETT 10 comprises a generally cylindrical sidewall 12 with a central lumen 15 which runs the entire length of the tube from proximal end portion 20 to distal end portion 30. Distal end portion 30 comprises beveled end 35. Inflation tube 60 which runs partway along the length of the ETT 10 is used to inflate inflatable annular cuff 67 once tube 10 is located within the trachea to create a fluid seal.

[52] Guide housing means 50 in the form of guiding channel 55 is located opposite inflation tube 60 in cylindrical sidewall 12 of ETT 10. Guiding channel 55 has a smooth, continuous (un-perforated) lumen and has a proximal opening 55a at one end and distal opening 55b at the other end adjacent tip 35a. Proximal opening 55a may be sealed by stopper 56.

[53] The diameter of guiding channel 55 is suitable to allow sliding movement of guide wire 70 within. The diameter of guiding channel 55 is wide enough to snugly accommodate a guide wire for example to accommodate a 0.038 inch (0.9652 mm) guide wire.

[54] ETT 10 is provided in a suitable length for either oral or nasal placement. Generally guiding channel 55 will run within sidewall 12 from tip 35a of beveled or slanted end 35 to where

it exits the sidewall of the tube and terminates in proximal opening 55a. Inflation tube 60 exits sidewall 12 at a similar point on the opposite side.

[55] Beveled end 35 comprises a beveled or slanted section at extreme end of distal portion 30. Tip 35a of beveled end 35 is suitable for traversing the nasal passages and the laryngeal inlet. Guiding channel 55 runs along the long axis of tube 10 from extremity of tip 35a to proximal end portion 20. Once tube 10 is threaded onto guide wire 70 via channel 55, channel 55 provides a 'backbone' around which beveled end 35 may deform. The beveled portion is composed of un-reinforced material (described in more detail below) which allows both sides of the tube adjacent the extremity of tip 35a to be deformed by bending inwards into the lumen of the tube making the tube particularly adapted to negotiate the laryngeal inlet. The size and shape of end 35 recover quickly to the original as soon as it gets past the narrow section of the larynx 96 and enters the subglottic area.

[56] ETT 10 comprises a reinforced section for most of its length from part of distal end portion 30 into proximal end portion 20. The reinforced section comprises a spiral metal member embedded in sidewall 12. The extreme end part of distal end portion 30 and the extreme end part of proximal end portion 20 comprise relatively short non-reinforced sections as shown by the different cross hatching in Figure 1a and can be more clearly seen in Figure 1c. The end 25 of proximal end portion 20 fits an intraluminal segment of a 15 mm tracheal tube connector suitable for connection to a breathing circuit or system as seen in Figure 1c. The unreinforced end of distal portion 30 adjacent bevel end 35 is pliant and easily deformable and comprises two standard apertures 37 similar to Murphy eyes (only one shown for illustration purposes).

[57] Persons skilled in the art of ETT production will be well versed in the manufacture of endotracheal tubes. ETT 10 may be made of any suitable material such as silicon that is non-reactive to tissues.

[58] ETT 10 is of a suitable diameter to fit a patient's anatomy (adult or child). In the example illustrated ETT 10 has an internal diameter of 7.5 mm with a wall thickness of 3.2 mm.

[59] The reinforced portion of ETT 10 has a number of benefits over normal PVC ETTs. These include flexibility which allows it to follow a retrograde guide easily across the tortuous upper airway. Where axial pressure is applied ETT 10 does not impinge adversely on tissues causing trauma. Further, it is kink resistant. In addition, having no pre determined curve ETT 10 can be easily rotated about its long axis.

[60] The ETT of the present invention is employed in intubation as follows:Thorough lubrication of the tip 35 and cuff area 67 of the ETT 10 and the guide wire 70 with suitable lubricant is performed. This is a very important step of preparation for the guiding at all times.

[61] Guide wire 70 in the form of a 0.038" diameter suitably coated wire is placed in the trachea 97 of a patient using one of the following techniques:

- Macintosh laryngoscope [e.g. in a grade 3 Lehane and Cormack] view of the larynx 96;
- Videolaryngoscope - when larynx 96 can be viewed round the bend but difficult to guide a tube;
- through a flexible fibreopticscope;
- through an endotracheal tube for exchange of ETT;
- through an endotracheal tube for 'trial of extubation' [staged extubation] in patients with possible postoperative airway obstruction;
- through the space at the front of the neck between cricothyroid cartilage 95 or cricotracheal junctions or upper tracheal rings and advanced upwards in a retrograde fashion (retrograde intubation).

[62] Specifically in relation to the last method, after passing retrograde guide wire 70 into the patient between the thyroid and cricoid cartilages (92, 95) in the usual manner an end thereof is retrieved from mouth 80.

[63] The ETT 10 connected to breathing circuit with an attachment for Capnography is simply loaded over the guide wire 70 through the guiding channel 55 and advanced until the wire is out from proximal end 25. The guide wire 70 is now grabbed securely taking care not to push or pull it in any manner. ETT 10 is railroaded by grabbing it 8-10 cm from the tip at first and then similar distance from the top for the rest of the tube. If there is any resistance at the vocal cord level, pulling back the tube by few millimeters and then advancing it with a rotating motion may be necessary to negotiate the larynx 96. It is a surprisingly quick, single instrument and single step procedure.

[64] It should be noted that the fact that guiding channel 55 is aligned with tip 35a of tube 10 provides a convenient visual indicator of the orientation of the tip 35a.

[65] Important advantages of the ETT of the present invention are as follows:

- It is the same familiar tracheal tube little different from the ones used every day;
- Use of less equipment results in less costs, steps and time. Number of steps in a particular sequence for a procedure that is not done frequently will have an effect both on learning and retaining. Time is very crucial for a rescue technique or even as a first technique of choice in a sedated/anaesthetized patient;

- Definite markers of progress during and after the completion of endotracheal intubation are vital for a blind guided technique. With this novel tube $ETCO_2$ can be monitored from the fitted familiar 15mm connector and the waveforms used to determine the progress of the tube inside upper airway. Insertion of a thin fibreopticscope inside the tube can easily monitor progress and confirm correct placement of the tube inside the trachea;
- Continuous delivery of oxygen throughout the procedure is possible by connecting the tube to a source of oxygen namely anaesthetic breathing system;
- Clinician is not restricted to use a particular size of tracheal tube (as opposed to wire guided intubation over the fibreopticscope in children);
- Damage to the suction channel of a fibreopticscope caused by the guide wire can be avoided by using the channel in the tube instead. The fiberscope may be inserted inside the main lumen of the tube for monitoring the progress and position of the tube inside the airway;
- the concept is applicable to both children and adults;
- airway is open throughout the process of wire guided intubation over this tube.

Example 1: Intubation Study

[66] After initial bench testing on physical models and dedicated airway simulator (Airsim, Laerdal) the behavior of the prototypes were observed in dissected, intact and fresh cadavers.

[67] The snug relationship of diameters between a guide wire and the guiding channel ensure that the deformations in both are identical at all times during the process of railroading. This way, the pushing force applied on the upper part of the tube translates only to progress of the tip of the tube forward and is not wasted, as in a case of a guide through the main channel of a tube, in random lateral bending or snagging on structures on the way.

[68] The trajectory of the tip of the advancing tube is solely determined by the guide wire inside the airway.

[69] The soft non-reinforced section at the tip of the tube, while negotiating the vocal cords, deforms inwards to a smaller size but readily re-expands inside the wider subglottic space.

[70] Thorough lubrication of the tip and cuff area of the tracheal tube and the guide wire with suitable lubricant is a very important step of preparation for the guiding at all times.

[71] Progress of the tube inside the airway were observed and recorded using a flexible camera (Ambu) or a fibreopticscope (Olympus) from the mouth, from below the vocal cords and through the main lumen of the tube.

[72] Fluoroscopic video of wire guided intubation using this tube was recorded to illustrate the way it advances along the airway. The tube was found to follow the guide wire across the entire upper airway smoothly without straying.

[73] During retrograde tracheal intubation on cadavers, even while using cricothyroid membrane puncture (shallow depth of insertion), the soft, neutral tube could easily be stabilised inside the larynx during removal of guide wire.

[74] The present application is related to Australian provisional patent applications No. 2013903646 and 2014901331 filed 23 September 2013 and 11 April 2014 respectively, the specifications of which are herein incorporated by reference.

[75] Throughout this specification and the claims that follow, unless the context requires otherwise the words "comprise", "comprises", "comprising" will be understood to mean the inclusion of the stated integer, step or group of integers or steps but not the exclusion of any of other integer, step or group of integers or steps.

[76] Table 1: Parts List

Reference numeral	Feature
10	Endotracheal tube
12	Tube wall
15	Central lumen
20	Proximal end portion
25	End of proximal end portion
30	Distal end portion
35	Beveled end
35a	Tip of beveled end
37	Apertures
50	Guide wire housing
55	Guiding channel
55a	Proximal opening of guide wire channel
55b	Distal opening of guide wire channel
56	Stopper
60	Inflation tube
67	Annular inflation cuff
70	Guide wire
80	Mouth
85	Pharynx
90	Epiglottis
92	Thyroid cartilage
95	Cricoid cartilage
96	Larynx
97	Trachea

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The claims defining the invention are as follows:

1. An endotracheal tube for use in a wire guided intubation procedure, said tube comprising:
a) a proximal end portion suitable for attachment to a breathing circuit which end portion in use protrudes from the mouth or nose of a patient;
b) a distal end portion suitable for insertion into the nose and/or mouth of a patient, said distal end portion having a tip suitable for traversing the laryngeal inlet of a patient; and
c) a guide housing means running between the portions having a proximal opening adjacent said proximal end portion and a distal opening adjacent to said tip, said guide housing means suitable for slidingly receiving an anterograde or a retrograde guide during an intubation procedure to allow the tube to follow the guide into the patient.

2. The endotracheal tube of claim 1 wherein the distal end is slanted or beveled to create the tip.

3. The endotracheal tube of claim 1 or claim 2 wherein the distal opening is at an end of the tip.

4. The endotracheal tube of claim 2 or claim 3 wherein the guide housing means comprises a channel or a passage.

5. The endotracheal tube of claim 4 wherein the channel or passage runs along a long axis of the tube from said tip to said proximal end portion.

6. The endotracheal tube of claim 4 or claim 5 wherein the channel or passage is integral with a sidewall of the tube.

7. The endotracheal tube of claim 6 wherein said channel or passage has a smooth and continuous lumen.

8. The endotracheal tube of any one of claims 1 to 7 which is absent a predetermined curve.

9. The endotracheal tube of any one of claim 1 to 9 comprising silicone reinforced material except for the tip which is un-reinforced silicone and relatively more deformable.

10. A kit for wire guided endotracheal intubation comprising: i) an endotracheal tube comprising: a) a proximal end portion suitable for attachment to a breathing circuit which end

portion in use protrudes from the mouth or nose of a patient; b) a distal end portion for insertion into the nose and/or mouth of a patient, said distal end portion having a tip suitable for traversing the laryngeal inlet of a patient; and c) a guide housing means running between the portions having a proximal opening adjacent said proximal end portion and a distal opening adjacent to said tip, said guide housing means suitable for slidingly receiving a guide during an intubation procedure to allow the tube to follow the guide; and ii) a suitable wire guide.

11. An improved method of endotracheal intubation comprising: i) introducing an anterograde guide into the nose or mouth of a patient in a standard manner or introducing a retrograde guide by passing an end of a guide through into the larynx of a patient and retrieving the end from the nose or mouth of a patient in a standard manner;
ii) advancing into the patient's trachea an endotracheal tube of suitable length wherein said tube comprises: a) a proximal end portion suitable for attachment to a breathing circuit; b) a distal end portion having a tip suitable for traversing the laryngeal inlet of a patient and; c) a guide housing means running between the portions having a proximal opening adjacent said proximal portion and a distal opening adjacent to said tip, said guide housing means suitable for slidingly receiving the guide to allow the tube to follow the guide; iii) wherein the tube is advanced anterograde by sliding the tube over the guide into its desired position.

12. A method of making an endotracheal tube for use in a wire guided intubation procedure, said method comprising forming an endotracheal tube of suitable materials, said tube having a) a proximal end portion suitable for attachment to a breathing circuit; b) a distal end portion suitable for insertion into the nose and/or mouth of a patient, said distal end portion having a tip suitable for traversing a laryngeal inlet of a patient; and c) a guide housing means running between the portions having a proximal opening adjacent said proximal end portion and a distal opening adjacent to said tip, said guide housing means suitable for slidingly receiving a guide during an intubation procedure to allow the tube to follow the guide into a patient.

13. An endotracheal tube insertion system substantially as herein before described with reference to the drawings.

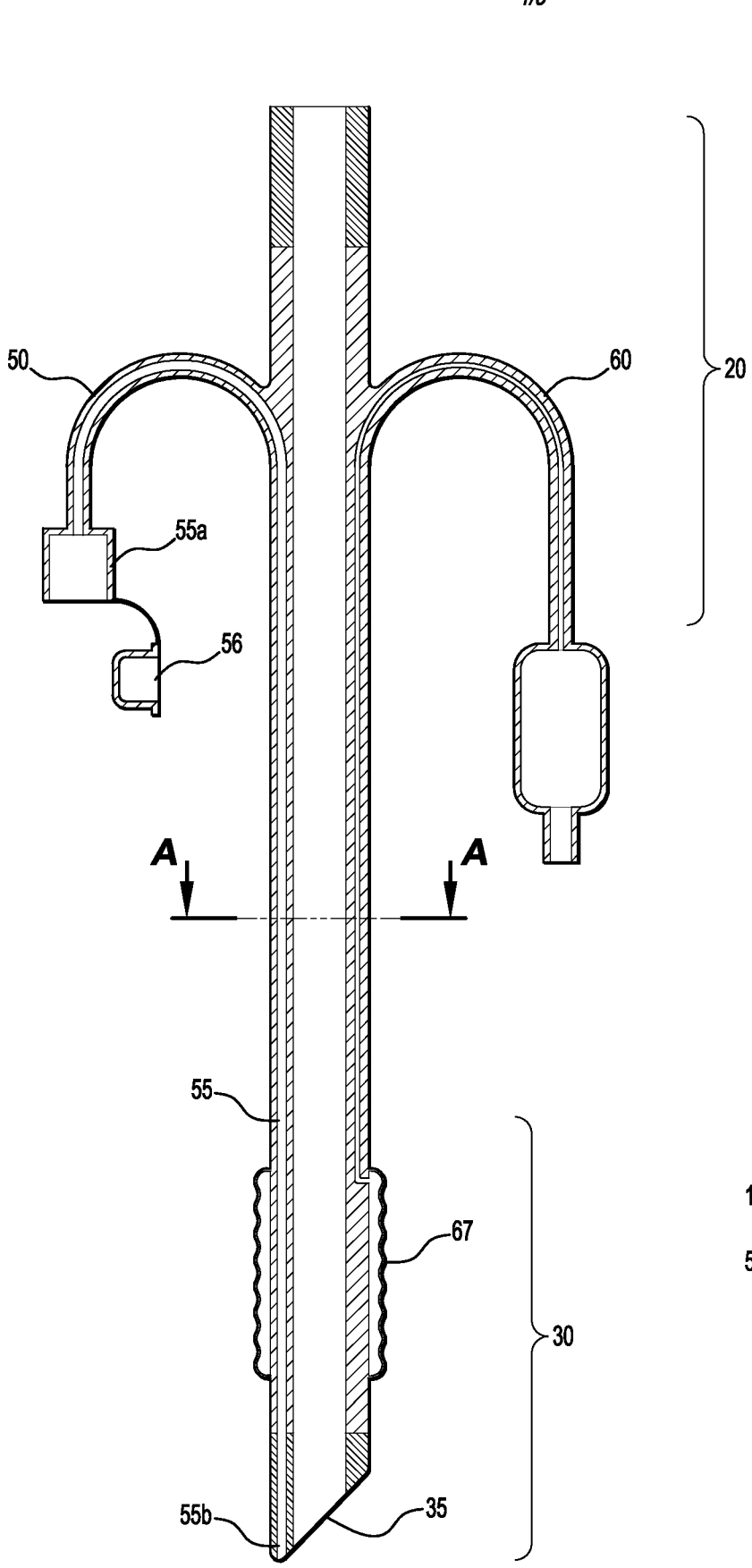
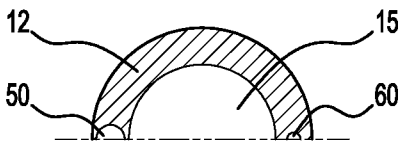


FIG. 1a



(Scale 2:1)

FIG. 1b

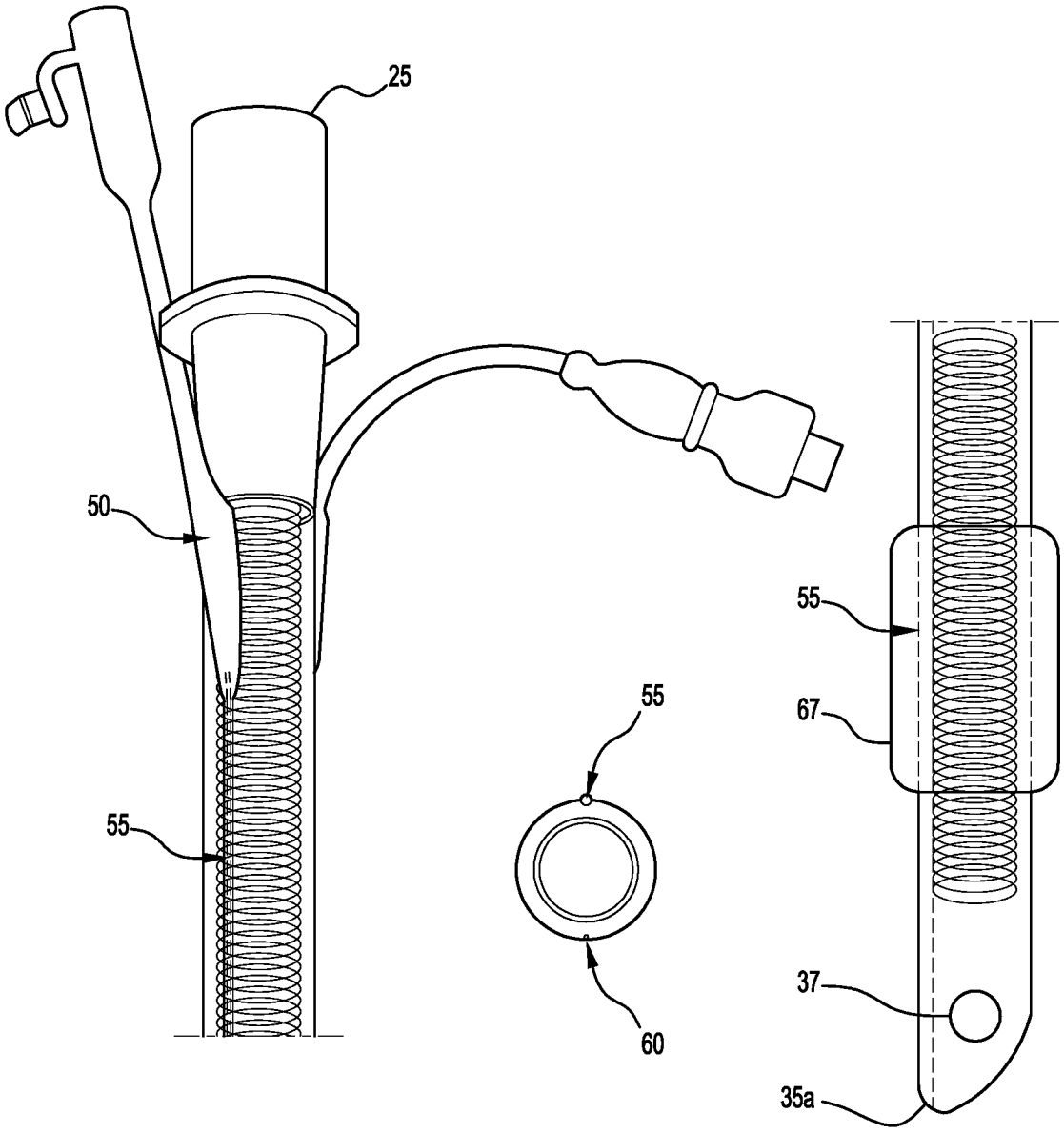


FIG. 1c

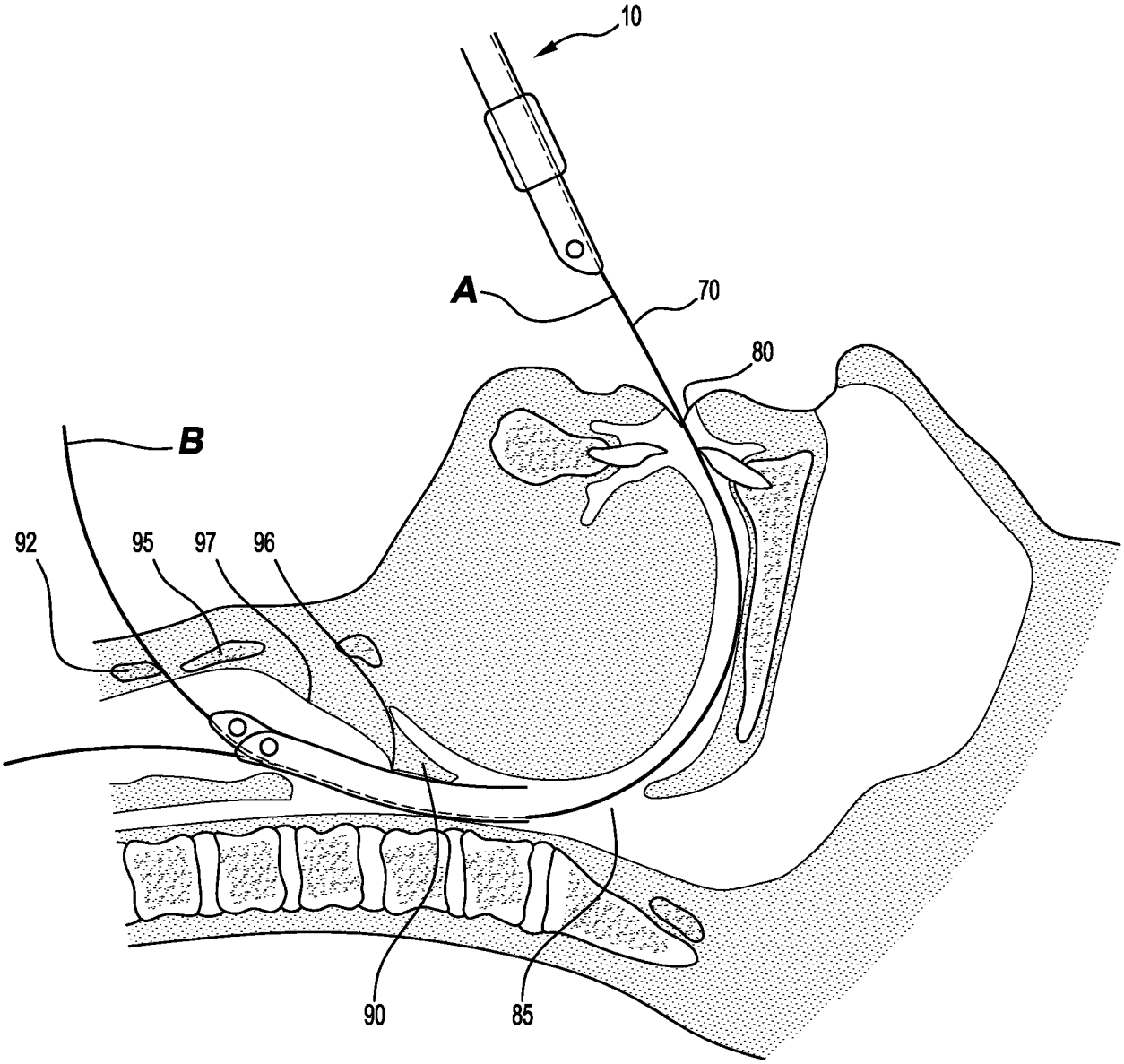


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2014/000784

A. CLASSIFICATION OF SUBJECT MATTER

A61M 16/04 (2006.01)

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)

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 practicable, search terms used)

Database: EPODOC, TXTE, ESPACENET

CPC: A61M16/0402, A61M16/0418, A61M16/0461, A61M16/0486, A61M16/0488

Keywords: 'railroad', 'retrograde', 'guide', 'guidewire', 'introducer' and like terms

Applicant - Inventor: Sasanka Dhara - Sasanka Dhara

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 September 2014	18 September 2014
Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Kiran Karve AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. (02) 6283 2824

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2014/000784**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5507279 A (FORTUNE et al.) 16 April 1996 Figures 6, 7; Column 5, lines 55 – 63, Column 6, lines 29 - 49, Column 7, lines 39 – 43.	1 - 12
Y	US 5269769 A (DHARA et al.) 14 December 1993 Figure 9; Column 6, lines 7 – 14, Column 7, lines: 47 – 69 , Column 8, lines: 4 – 7, 22 - 25.	1 - 12
A	US 6463927 B1 (PAGAN) 15 October 2002	1 - 12
A	US 2007/0017527 A1 (TOTZ) 25 January 2007	1 - 12
A	US 2009/0229615 A1 (STENZLER et al.) 17 September 2009	1 - 12
A	US 2002/0043266 A1 (TOTI et al.) 18 April 2002	1 - 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2014/000784

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:

because they relate to subject matter not required to be searched by this Authority, namely:

the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

2. ☒ Claims Nos.: **13**

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:

See Supplemental Box

3. ☐ Claims Nos:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT	International application No. PCT/AU2014/000784

Supplemental Box

Continuation of **Box II**

Claim 13 does not comply with Rule 6.2(a) because it relies on references to the description and/or drawings.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2014/000784**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 5507279 A	16 April 1996	None	
US 5269769 A	14 December 1993	WO 9324161 A1	09 Dec 1993
US 6463927 B1	15 October 2002	DE 19812506 A1	01 Oct 1998
		GB 2323534 A	30 Sep 1998
		GB 2323534 B	04 Apr 2001
		JP H10272185 A	13 Oct 1998
US 2007/0017527 A1	25 January 2007	US 7921847 B2	12 Apr 2011
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US 2009/0229615 A1	17 September 2009	US 8231606 B2	31 Jul 2012
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		AU 2009223583 B2	17 Oct 2013
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		EP 2254611 A2	01 Dec 2010
		JP 2011514214 A	06 May 2011
		RU 2010142008 A	20 Apr 2012
		WO 2009114455 A2	17 Sep 2009
US 2002/0043266 A1	18 April 2002	US 6553993 B2	29 Apr 2003
		AU 2002239351 A1	10 Jun 2003
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		BR 0117186 B1	13 Jul 2010
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		EP 1448258 A1	25 Aug 2004
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		JP 2005510310 A	21 Apr 2005
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		NO 20042169 A	22 Jul 2004
		US 6321749 B1	27 Nov 2001

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2014/000784**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		US 2002096177 A1	25 Jul 2002
		US 6761171 B2	13 Jul 2004
		US 2004139972 A1	22 Jul 2004
		WO 03045485 A1	05 Jun 2003
		WO 03101515 A1	11 Dec 2003

End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.