Patent
Examination
Board

P4 – Amendment of Specifications for United Kingdom Patents/Applications in Prosecution, Revocation Proceedings or Otherwise

Wednesday 1 October 2014
10.00 a.m. – 1.00 p.m.

Time allowed – THREE hours

INSTRUCTIONS TO CANDIDATES

1. The whole question is to be attempted.

2. Start each part of the question on a fresh sheet of paper.

3. Enter the question paper reference number (P4) and your candidate number in the appropriate boxes at the top of each sheet of paper.

4. The scripts are photocopied for marking purposes.
    a. Use **black ink**.
    b. Write on one side of the paper only.
    c. Write within the printed margins.
    d. Do not use highlighter pens on your answer script.

5. Do not state your name anywhere in the answers.

6. Write clearly, examiners cannot award marks to scripts that cannot be read.

INFORMATION FOR CANDIDATES

1. The total number of marks for this paper is 100.

2. At the end of the examination the invigilator will instruct you to:

    a. count the number of pages you have used;
    b. use the boxes on each page of the answer script to number pages in the format “1 of 25, 2 of 25 etc”;
    c. place your answer sheets in order in the white envelope, seal the envelope and leave the envelope on the desk.

3.
    a. Do not staple the pages, or use sellotape or treasury tags.
    b. You may take the examination paper with you.

4. This question paper consists of 21 pages in total, including this page, and comprises:
    Question [1 sheet]
    Client letter [1 sheet]
    Client's Application GB 1312321.8 [11 sheets]
    Official Letter [1 sheet]
    Prior art reference US 5,555,555 [5 sheets]
    A copy of claims for GB 1312321.8 for you to use in your answer [1 sheet]

Assessment task outline

A United Kingdom patent application comprising the attached specification (identified as GB 1312321.8) has been filed at the UK Intellectual Property Office without any claim to priority.

The UK Intellectual Property Office has now issued the attached Official Letter. You have received brief comments from your client in a letter, which is also attached.

Your task is to prepare:

1. A letter to the UK Intellectual Property Office in response to the Official Letter.

2. A set of amended claims, if considered necessary.

3. An outline memorandum for your client. This should:
    a) explain the actions you have taken and why;
    b) provide full reasoning for your actions;
    c) outline future actions that your client could take to secure full protection of their commercial interests.
        i. This advice should take into account that further information may be needed.
        ii. It should only relate to the invention(s) outlined in the client's letter to you.

The memorandum should be restricted to patent matters. You are NOT required to consider other matters such as copyright or design protection.

Note the following:

a) You are NOT required in this examination to make any amendments to the description of the client's patent application.

b) You should accept the facts given to you and base your answer on those facts. In particular you should NOT make any use of any special knowledge that you may have of the subject-matter concerned, and you must presume that the prior art referred to is exhaustive.

c) If you submit any amended claim set and/or divisional claims(s) please number the pages so as to readily identify the claims or claim sets.

Client letter

Dear Mr Clay-Mitt,

Thank you for sending to me the examination report, which I have had a chance to look through. With respect to the reference found by the examiner - I have to confess that this old hand-bulb means to inflate the catheter had completely slipped my mind, although they have been around for years. Most people still seem to use syringes nowadays; I think these bulbs had issues with controllability. I still think mine is better, because the system they describe requires a different bulb for each different width of catheter as the system is sealed so you cannot easily vary the inflation of the patient-end balloon. The point the examiner raises I guess is *technically* possible, you could make the teeth correspond to particular volumes (although I think it would be tricky to be precise), but it doesn't appear to have been the intention from their application. In fact the teeth are just there to stop the natural urge of the syringe-bulb to re-inflate itself. Even if in using D1 you wanted to set intermediate volumes other than the end volume, these would still be limited to pre-set intermediate volumes. In contrast, the system we are claiming is highly flexible allowing the user to select exactly what volume they wish to transfer into the patient-end balloon.

Anyway, I am glad that this came up as I had two related aspects that I wanted to discuss with you. The first relates to products that I am interested in marketing. When I originally devised the invention I was focussed on ETTs, but in conversations with hospitals I have discovered that actually they would be interested in devices that could clean any type of catheter – so urinary, vascular, and others. In fact, I would be supplying just the end device which they would then use with any of their catheters. So as a first priority I would like to ensure that my claims can capture all these different products.

The next question I had arose because I am having some work done on the house, and from watching the plumber work I think that it could also be used to clean drains and other pipes. So using an external bellows to inflate a balloon that would then be used to remove deposits within the drain. Is this also something I can capture within my claims as that could be a lucrative additional market to reach?

Finally, I have been increasingly thinking that the spacer is quite a good idea but I can't pursue it at the moment; can I keep it on hold for a while…?

I look forward to hearing your advice.

Kind regards,

Ian Fection

Science Director,

Succitan-C Medical Solutions Ltd

APPLICATION GB 1312321.8

MEDICAL CLEANING DEVICE WITH BALLOON CATHETER

FIELD OF THE INVENTION

The present invention relates to devices to control the inflation of a balloon catheter, i.e. a catheter or medical tube with a balloon at the operative end which can be inflated to engage the walls of the medical tube or cavity into which it is inserted.

BACKGROUND OF THE INVENTION

It is a common practice to insert tubes into a patient to convey fluids to or discharge fluids from the patient. These procedures facilitate recovery of the patient but may at the same time lead to complications due to the environment in which they operate.

One such environment is when a respiratory tube known as an endotracheal tube (ETT) is inserted into the lungs of a patient. This tube conveys oxygen to the lungs. Secretions tend to be deposited on the wall of the tubes, which significantly reduce the cross-sectional area of the tube and, if left unattended, lead to secondary infections. Normally an attempt is made to remove the secretions by periodically inserting a suction tube into the ETT. However, using such tubes is inefficient, and a preferred way is to use a balloon catheter. This is an elongate tube having a plurality of radial passages through the wall of the tube at one end. A membrane surrounds these passages so that the membrane can be inflated to form a balloon when pressure is applied to these passages.

The present invention relates to a device which is able to control the inflation of this balloon.

The balloon catheters may be used in a variety of applications. For example, in addition to use in ETTs, the catheter might be inserted into other medical tubes (e.g. urinary catheters) or into a blood vessel. Frequently such catheters have two lumens, one of which is used to inflate the membrane and the other is used to extract materials from within the catheter.

The existing balloon catheters for use in clearing ETTs are shown in **Figs. 1a and 1b**. The catheter 1 is a tube with a narrow passageway 2 extending along it. The operative (i.e. patient) end of the narrow passageway 2 communicates with an expandable membrane or "balloon" 3 which is attached to the operative end of the catheter. Above the balloon 3 are apertures (4) which provide for fluid communication between the exterior and interior of the tube. In use, the catheter is inserted into an ETT 5, and, once the desired location is reached, the balloon 3 is inflated, via openings 6, using a syringe 7 connected to the narrow passageway 2, expanding the balloon until it seals against the walls of the ETT. The catheter is then withdrawn and secretions are removed by the interaction of the balloon wall against the ETT wall and by suction through a port 8 in the catheter, which draws the secretions into the tube via apertures 4.

Particular care must be taken when using balloon catheters, as over-inflation could cause damage to the tube or vessel against which the balloon engages, or alternatively cause damage to the catheter. Moreover, care must also be taken during insertion and extraction of the catheter to ensure that it does not unintentionally inflate or deflate.

Specifically, when cleaning an ETT, over-inflation of the catheter may cause it to bind to the walls of the tube and so inhibit its extraction. Likewise, unintentional inflation of the catheter during insertion may push secretions into the lung. Therefore, there is a need for a device which allows the user to control the inflation of a balloon catheter.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a device for controlling the inflation of a balloon catheter to permit its use in a number of environments.

According therefore to one aspect of the present invention, there is provided a device as defined in claim 1.

The device of the present invention provides for a controlled inflation and prevents unintentional inflation of the catheter. This device makes it possible to insert a balloon catheter into a tube reliably in a deflated condition, inflate the catheter to a precise and user-controlled extent and extract it from the tube, thus wiping the surfaces of the tube and removing secretions. In a particular embodiment, the device may be used in combination with a catheter as a method of cleaning such tubes.

The device of the invention in another aspect relates to a balloon catheter apparatus for cleaning a medical tube, with a spacer tube made of soft material and having calibrations, which can be cut to length to suit the length of the tube into which the catheter is to be inserted.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1a and 1b	show a prior-art device for inflating a catheter to be inserted into an ETT;
Fig. 2	is view showing a device in accordance with the invention, assembled and ready for use;
Fig. 3	is a detail of the operative end of the catheter;
Fig. 4	is an exploded view of the inflating device shown in Fig. 2;
Fig. 5	is a perspective cut-away view of a portion of the device shown in Fig. 4; and
Fig. 6	is a detail of a further feature of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 2 shows a cleaning device 11 to be introduced into an ETT 10 (**Fig. 3**), itself inserted into the lungs of a patient for connection to a ventilator. The ETT 10 is a standard medical tube of a predetermined length and diameter and made from a suitable non-invasive material compatible with the human body.

To clean the tube 10 and to remove secretions from it, the cleaning device 11 has a dual-lumen catheter 16 of known type, fitted to an inflation device 18 and inserted through a tubular spacer 20 into the tube 10. As shown more fully in **Fig. 3**, the catheter 16 includes a pair of lumens 22, 24 side by side. The inflation lumen 24 is provided with radial apertures 26, which are surrounded by a flexible and stretchable membrane 28 that is sealed to the lumen walls above and below the radial apertures 26. The suction lumen 22 is also provided with one or more radial apertures 30, located above the membrane 28, that allow movement of fluids into and out of it.

A series of radial vanes 31 is located on the catheter 16 adjacent to the membrane 28. These act to centralize the catheter and to minimize contact with the inner walls of the tube during insertion. The membrane 28 is made from a flexible and stretchable material such as latex, silicone or polyvinylchloride in a well-known manner and will not be described further.

The catheter 16 is connected to the device 18 for controlling inflation of the membrane 28. As best seen in **Fig. 4**, the inflation lumen 24 is connected to an outlet 32 moulded on a flexible bladder or bellows 34.

The bladder 34 is located within an actuator assembly 38 which includes a pair of wings 40, interconnected by a web 44 acting as a resilient hinge, so that the wings 40 pivot about their connection to the web 44, biased outwardly. Each of the wings 40 is formed as a hollow shell forming a cavity which provides a snug fit for the bladder 34. Thus movement of the wings 40 toward one another causes a decrease in the volume of the bladder 34, and the device expels air through the outlet 32, which connects to the lumen 24, which then extends through an aperture 84 provided in the web 44.

The actuator assembly 38 and the bladder 34 are located within a frame 52 formed as a hoop-like band with a downwardly extending flange 56. The band is contoured to provide a comfortable fit within the hand of an operator, as are the external surfaces of the wings 40.

The suction lumen 22 is connected to a passageway 58 integrally moulded with the flange 56 and terminates in a ribbed outlet 60 (as shown in **Fig. 4**) to which is attached a suction tube 62 shown in **Fig. 2**.

The flange 56 also has a vent 64 that extends from the upper surface of the frame 52 to intersect the passage 58.

The upper surface of the frame 52 carries a latch assembly 66 shown in more detail in **Fig. 5**. The latch assembly includes an operating button 68 extending upwardly from one end of a bar 70. The middle of the bar 70 is connected through lateral extensions 72 which are connected to the frame 52 (the frame is not shown in **Fig. 5**) so that it can pivot as shown by the arrows. A transverse stop 74 is located at the other end of the bar and in its rest setting extends downwardly between the inside edges of the upper surfaces of the wings 40. The stop 74 therefore maintains the wings 40 in spaced relationship and prevents movement of the wings toward one another until the latch is released by pressing the operating button 68.

An abutment in the form of a wedge 76 is also carried by the frame 52 and is connected to a slider 78. This slider 78 is moveable within a longitudinal slot 80 on the band with a scale 81 being marked alongside the slot to correlate the position of the slider 78 with different diameters of the tube 10. This allows the user to move the slider 78 to freely select a position and define the volume of air to be expelled as will be explained. The wedge 76 moves forward and backwards in the slot 80, that is, toward and away from the pivot points of the wings 40 on the web 44, in order to vary the angle at which the wings will engage the wedge 76 and be therefore prevented from travelling further.

The operation of the device to clean the tube 10 will now be described. The catheter 16 is attached to the inflation device 18 so that the inflation lumen 24 is connected to the outlet 32 and the suction lumen 22 to the passageway 58. Initially the latch 66 is engaged, that is, the stop 74 prevents any movement of the wings 40. The slider 78 is moved by the user to the desired location as indicated by the scale 81, which will correspond to the diameter of the tube 10. The suction tube 62 is connected to the passageway 58, but suction is not yet applied to the lumen 22, as air just flows through the open vent 64. The catheter 16 is fed through the spacer 20 which is then connected to the inflation device 18.

The assembled catheter and inflation device as shown in **Fig. 2** is then inserted into the tube 10, with the membrane in a deflated condition. The catheter is inserted until the spacer 20 abuts the end of the tube 10, indicating that the tip of the catheter 16 is adjacent to the bottom of the tube. Since the latch 66 has not been released, any manipulation of the device 18 during insertion will not move the wings 40 and therefore cannot cause inadvertent inflation of the membrane 28.

With the catheter 16 in place, the button 68 is depressed to cause the bar 70 to pivot about the lateral extensions 72, and move the transverse stop 74 out of engagement with the wings 40. The operator squeezes the sides of the inflation device, so that the wings are pivoted toward one another about their connections with the web 44, expelling air from the bladder 34 into the lumen 24 to inflate the membrane 28 and bring it into engagement with the walls of the tube 10. The wedge 76 acts as an abutment for the wings 40 so that their movement toward one another, that is, the end-point of their

travel, is limited to a point set by the user. Over-inflation of the membrane 28 is thus prevented, but at the same time the operator is confident that the membrane has engaged the walls of the tube 10. The scale 81 is calibrated so that the volume of air to be expelled from the bladder inflates the membrane 28 just enough to place it in wiping contact with the wall without causing it to engage the wall of the tube 10 so firmly that it binds and will not move.

The catheter may now be withdrawn, wiping the surfaces of the tube 10 at the same time. As the catheter 16 is withdrawn, the operator selectively applies suction by covering and uncovering the vent passage 64 with his thumb. It will be noted that during removal of the catheter, any forces exerted on the wings 40 will not cause any further expulsion of air from the bladder 34 because of the abutment against the wedge 76. The catheter 16 continues to be removed until the membrane 28 leaves the tube 10 and enters the spacer 20. The spacer 20 can then be disconnected and the ventilator replaced on the tube 10.

The device 18 therefore provides for controlled inflation of the membrane 28 by virtue of the wedge 76, which is set to a position selected by the user which corresponds to the tube 10, and unintentional inflation of the catheter during insertion is avoided by the latch 66.

A further advantageous feature of the invention concerns the spacer 20. The forward face of the flange 56 is provided with a surface against which the spacer 20 sits. The lumen 24 passes through an aperture 84 provided in the web 44 to one side of the frame 54 so as to emerge alongside the passageway 58 in the vicinity of the abutment face. The spacer 20 thus encompasses both the lumens 22, 24.

As shown in **Fig. 6**, the spacer 20 is provided with a number of axially spaced indicia 86 which are correlated to the overall length of the tube 10 and the catheter 16. The tube 10 is provided in standard lengths, as is the catheter 16. To avoid the catheter extending beyond the length of the tube, the spacer 20 should be adjusted to have an overall length equivalent to the difference between the catheter 16 and the tube 10, and to this end it is cut to length with scissors. By using the indicia 86, the length of the tube can be selected to ensure that the catheter extends as close as possible to the bottom of the tube 10 without extending beyond it.

The spacer 20 may also be provided with two ports, one to provide a vent for the tube 10 as the catheter is inserted and withdrawn, and the other to permit the insertion of a diluting solution, e.g. a saline solution, to facilitate removal of the secretions.

Although the invention has been described with reference to the cleaning of an ETT, it will be appreciated that it has applicability in the insertion of catheters into other body cavities or medical tubes to perform similar functions or other procedures.

Claims

1. A device for cleaning the interior of an endotracheal tube using a balloon catheter, comprising an inflation device, a catheter attached at one of its ends to the inflation device and including an inflation lumen, and an inflatable membrane at the other end of the catheter, configured to be inflated by the inflation device; wherein the inflation device includes:

    a) a variable-volume chamber having an outlet for connection to the inflation lumen;
    b) an actuator movable to vary the volume of the chamber and to expel air from it to inflate the membrane so as to form a balloon;
    c) a releasable latch which in its closed position inhibits movement of the actuator relative to the chamber; and
    d) an abutment to limit movement of the actuator upon release of the latch so as to limit the volume of air expelled from the chamber to inflate the membrane.

2. A device according to claim 1, wherein the chamber is formed by a flexible bellows located within a frame and the actuator is movable to engage the bellows and expel air from it.

3. A device according to claim 2, wherein the actuator is mounted for pivotal movement relative to the frame.

4. A device according to claim 2 or 3, further including a tubular spacer located adjacent to the frame with the catheter passing through it, the spacer being adapted to extend up to a tube into which the catheter is to be inserted, to limit movement of the catheter relative to the tube.

5. A device according to any preceding claim, wherein the frame is formed as an open loop configured to fit within a hand and the bellows is located within the loop.

6. A device according to claim 5, wherein the actuator includes a pair of rigid wings disposed on opposite sides of the frame and movable toward one another to engage the bellows.

7. A device according to claim 6, wherein the latch is mounted on the frame and is engageable with each of the wings to prevent relative movement between them.

8. A device according to claim 7, wherein the latch is biased to a position in which it engages the wings.

9. A balloon catheter substantially as described herein with reference to any of the attached drawings.

Fig.1a

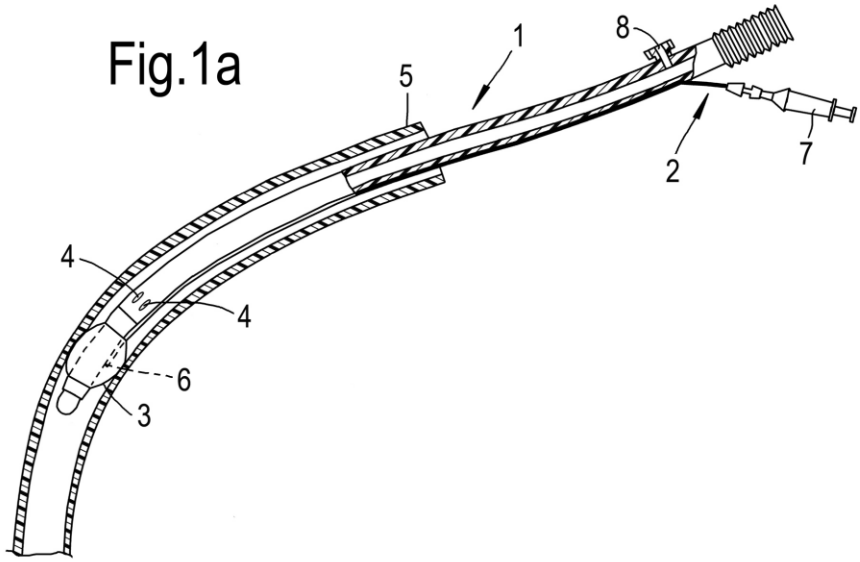

Fig.1b

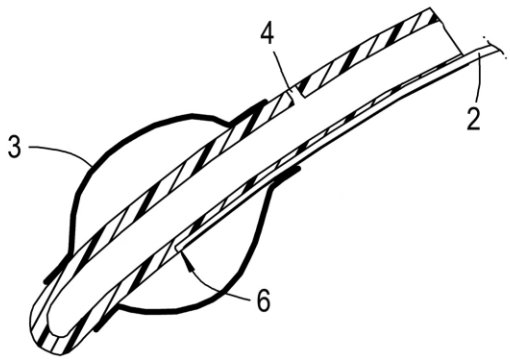

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Fig.2

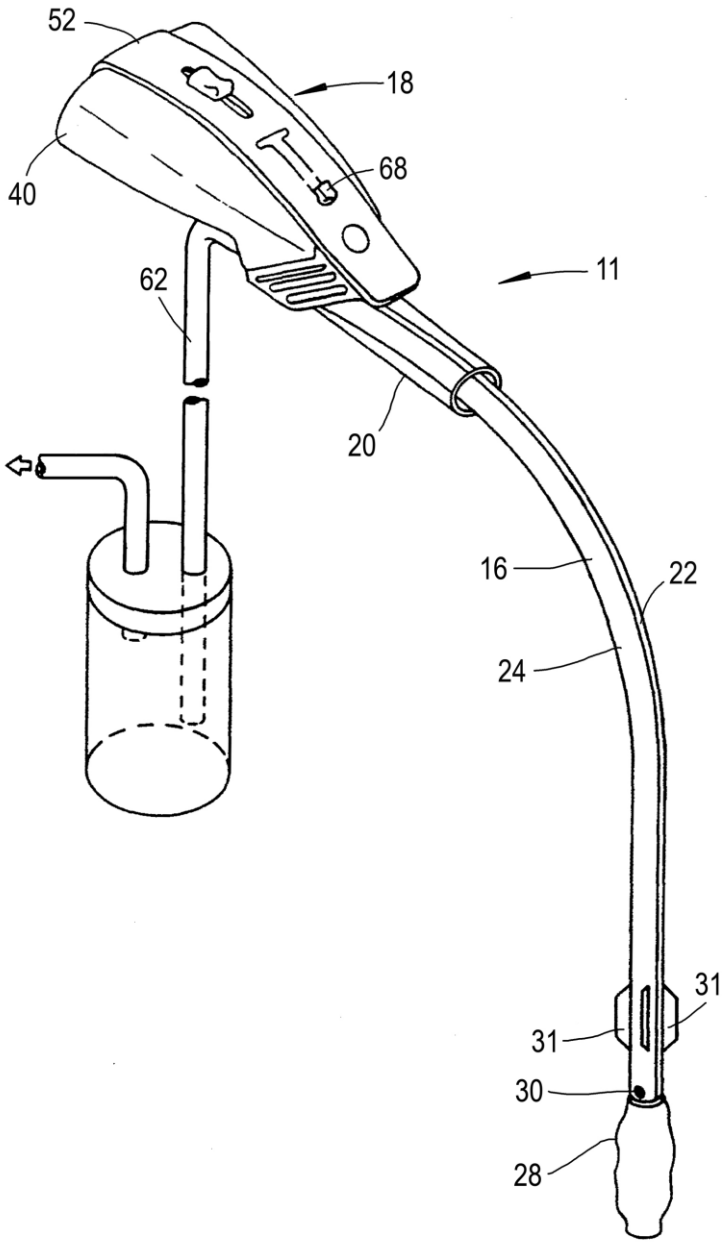

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Fig.3

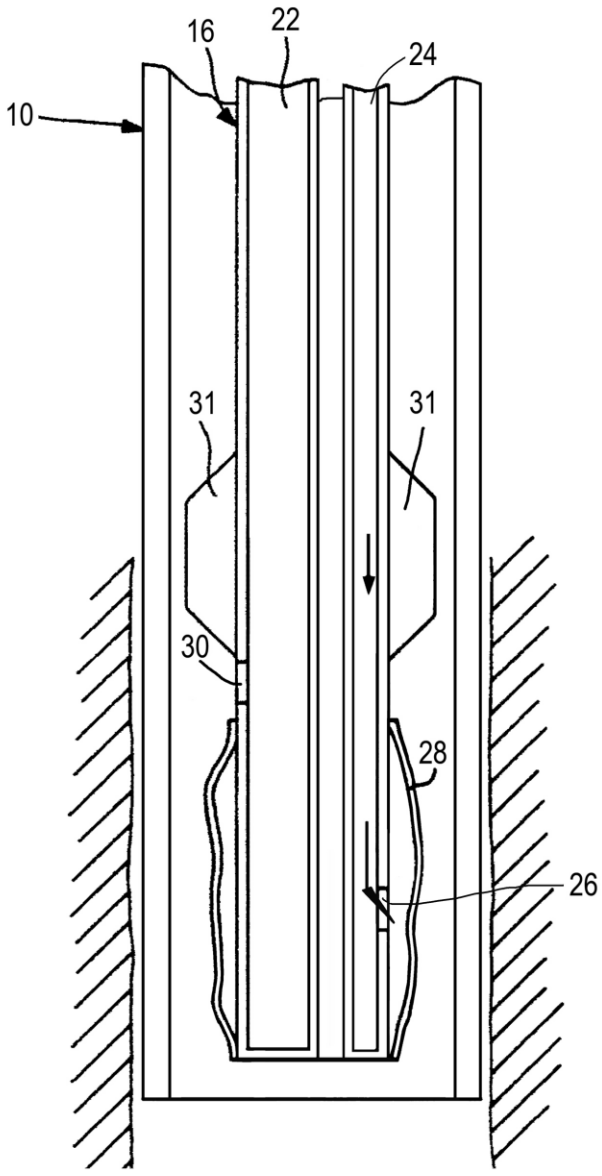

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Fig.4

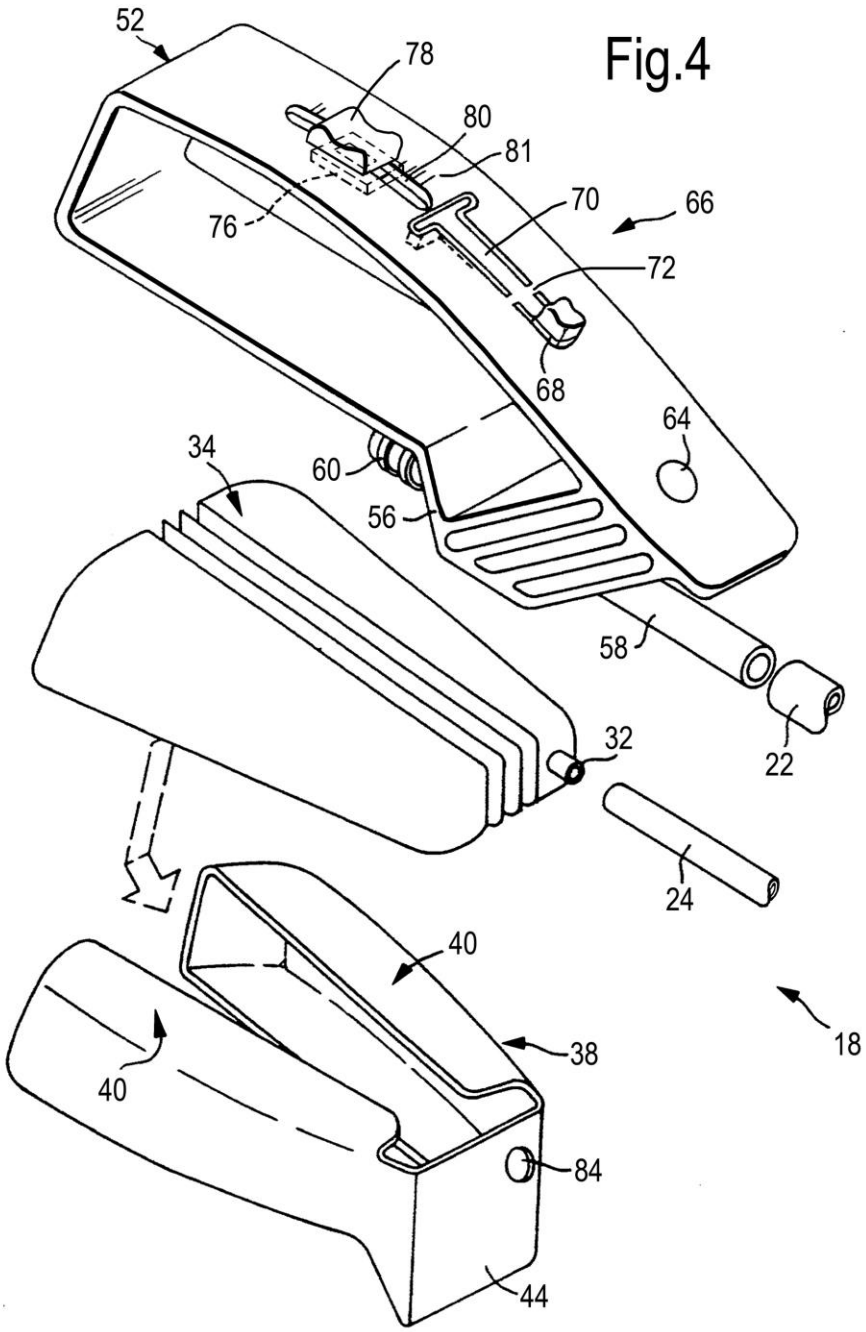

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Fig.5

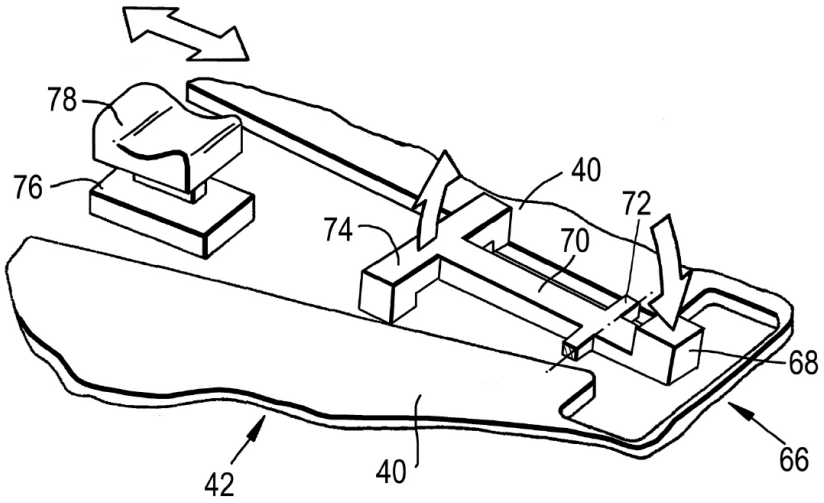
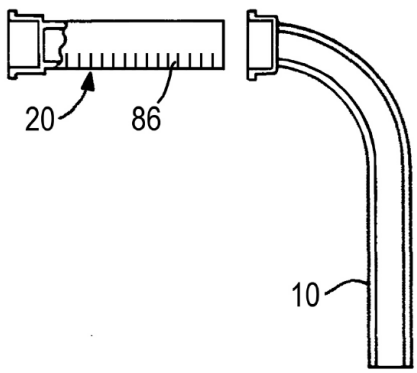


Fig.6



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IPO Examination Report

10th June 2014

Application No. 1312321.8

Applicant: Succitan-C Medical Solutions Ltd

Filing date: 24th July 2013

Latest Date for Reply: 10th October 2014

Patents Act 1977:

Examination Report under Section 18(3)

1. Clarity

Although the present application contains an omnibus claim referring to all the attached drawings, it is noted that Figure 1 is not part of the invention, but is rather a description of the prior art.

2. Novelty

D1 (US 5,555,555) discloses the use of a variable volume chamber (squeeze-bulb syringe, 20) with an outlet, an actuator (clip, Fig 3) to a releasable latch (curved strip, 31) and abutment (ratchet teeth 33, 34 and 35). Therefore, the subject matter of claim 1 lacks novelty.

D1 also discloses the subject-matter of many of the dependent claims:

Claim 2: syringe 20 is equivalent to bellows, frame is formed by parts 26 29, 31.

Claim 3: latch (slot 32) is movable by bending the strip 31.

Claim 4: actuator (strip 29) pivots about hinge 30.

Claim 6: frame 26, 29, 31 is an open loop.

Claim 7: base 26 and strip 29 constitute wings.

3. Inventive Step

In the event that novelty could be acknowledged, the present application only discloses routine alternatives to the inflation means disclosed in D1, which also provides for controlled inflation of a balloon catheter.

Other elements of the invention as claimed in the dependent claims appear to be no more than routine additions well within the knowledge of a person of skill in the art, many of them being present in the admitted prior art shown in Figure 1 .

US 5,555,555

Balloon-Bulb Catheter

The invention relates to an improved catheter combination having expandable and collapsible bulbs at each end, securely connected to each other by a small passageway in in the catheter wall.

It is known that a catheter 10 (**Fig. 1**) can be held in the desired position by inflating a small cylindrical space 14 between a thin outer wall 15 and a thicker inner wall 16 of the catheter at or adjacent to its inlet end (i.e. the end inserted into the patient) to form a balloon 15'. This inflation is typically accomplished by injecting a fluid through a small passageway 17 in the horizontal catheter wall which terminates in a small inflating tube 18 which branches from the catheter at the catheter discharge end. Since there is always the possibility that the balloon might break, great care has to be taken to be sure that the fluid is "inert," i.e., that it would not cause a toxic or an adverse effect if it were to come in direct contact with the patient's tissue. The fluid is generally introduced by a conventional syringe of the piston-and-cylinder type, and care has to be taken to obtain the right amount of fluid, and that all of the liquid is delivered to the balloon without leakage. The present invention provides an improved catheter that does not require the use of any extraneous fluids.

The catheter of the invention has a fluid-containing, squeeze-bulb syringe of suitable flexible material with its discharge end securely attached to the inflating tube 18 so as to form a fluid-tight connection through the small passageway to the balloon. The squeeze-bulb syringe is preloaded with the desired kind of inert fluid in the exact amount desired for the size and type of balloon employed so that the fluid is sealed into the system and cannot escape or become contaminated.

Provision is made to keep the balloon from becoming inflated until the catheter is properly placed and to prevent fluid from leaving the balloon once it is inflated until so desired. This can be accomplished by means of a clip bearing directly against the squeeze-bulb syringe. Such a clip may serve the three functions of (1) preventing accidental or premature squeezing of the syringe, (2) controlling or regulating the extent to which the syringe is squeezed or collapsed and thus controlling the inflation of the balloon, and (3) holding the syringe in a collapsed condition and thereby preventing undesired return of fluid from the balloon to the syringe.

Description of the Drawings

Fig. 1 is a section through a conventional, balloon-equipped catheter.

Fig. 2 is a detail section showing a fluid-filled, squeeze-bulb syringe about to be securely bonded to the inflating tube.

Fig. 3 is a schematic view of a clip.

Fig. 4 is a schematic view of the catheter combination including the clip.

The present invention uses a standard catheter 10 as described above, **Fig. 1**. In accordance with the invention and as shown in **Fig. 2**, a squeeze-bulb syringe 20 is filled with an inert fluid, 21. The amount of fluid should approximate the capacity of the balloon plus the volume of the small passageway and should be carefully measured. The walls of the syringe 20 in this case are of a suitable flexible material, e.g. rubber. The syringe wall is, however, thicker than the thin outer wall 15 of the catheter, and it is pear-shaped with a discharge end 22 of about the same diameter and bore as the inflation tube 18. The outer portion 23 of the outlet 22 is shaped so that it will fit snugly into the end 19 of the inflation tube 18, and can be securely attached thereto.

The clip employed in the invention is shown in **Fig. 3**. A flat or base portion 26 has curved lugs 27, 27' and 28 which are designed to fit snugly over the catheter in the vicinity of the inflating tube 18. A pressure strip 29 is hinged to one end of the base 26 at a hinge 30. The other end of the pressure strip 29 bears against a curved strip 31, which is an extension of the base 26 and which is stressed always to exert pressure on the free end of the pressure strip 29. A slot 32 at the end of the curved strip 31 is designed to hold the pressure strip in a fixed outer position from which it may be disengaged by bending the curved strip 31 outwardly. When thus released the pressure strip 29 may be pressed toward the base 26 and it may be held in various intermediate positions by ratchet teeth 33, 34 and 35. The base 26 is provided with an opening 36 through which the inflation tube 18 may be inserted before attaching the syringe to the tube, thus preventing the clip from accidentally getting separated from the catheter.

The operation of the improved catheter combination will be described by reference to **Fig. 4,** which shows the position of the syringe within the clip, the inflating tube 18 extending through the hole 36, the curved lugs 27, 27' and 28 engaging the outside wall of the catheter, and the end of the pressure strip 29 being held by the slot 32 to prevent

accidental squeezing of the syringe 20. The syringe 20 is protected by the pressure strip 29, which is locked in the slot 32, from accidental discharge. When the catheter is inserted to its desired position, the operator flexes the curved strip 31 outwardly to permit the pressure strip 29 to be pressed toward the base 26 for squeezing the syringe 20 and forcing fluid 21 through the passageway 17 into the space for forming the desired balloon 15'. The ratchet 33 will hold the syringe in a partially collapsed position and thus prevent undesired return of fluid from the balloon. At the proper time the pressure strip 29 may be pressed further until it engages the ratchet 34; this further collapses or squeezes the syringe and the ratchet 34 again prevents undesired return of fluid from the balloon formed by the distended wall 15'. When the pressure strip 29 is held by the next and final ratchet 35 the syringe is collapsed and the balloon is fully distended. The balloon will remain distended till the curved strip 31 is moved outwardly to permit the syringe to assume its original position and thereby to suck all of the fluid out of the balloon. The catheter can then be removed, and it can be used over and over as long as the inner and outer walls of the catheter are kept or made clean and sterile.

Fig.1

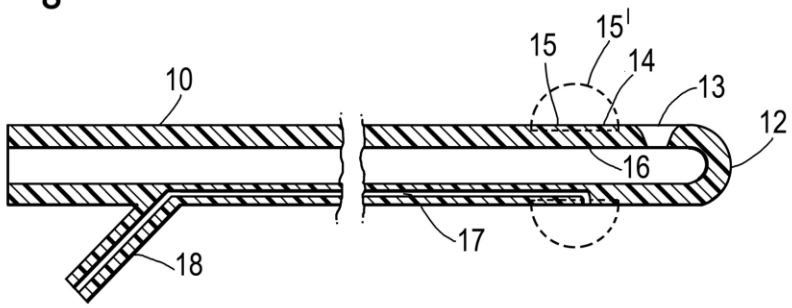
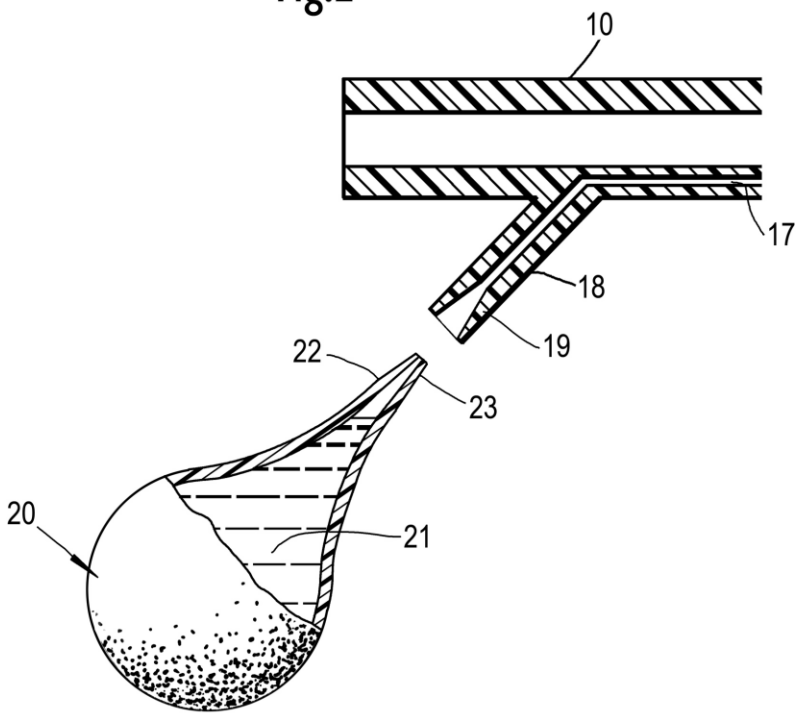


Fig.2



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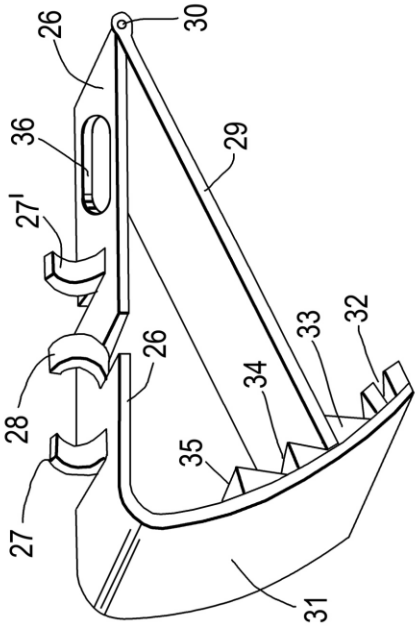
26
30
36
29
27'
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34
33
32
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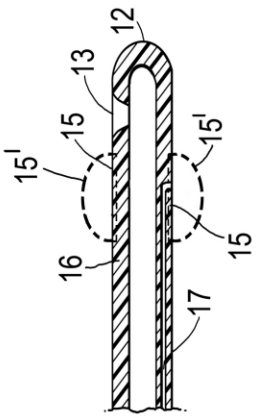
31

Fig.3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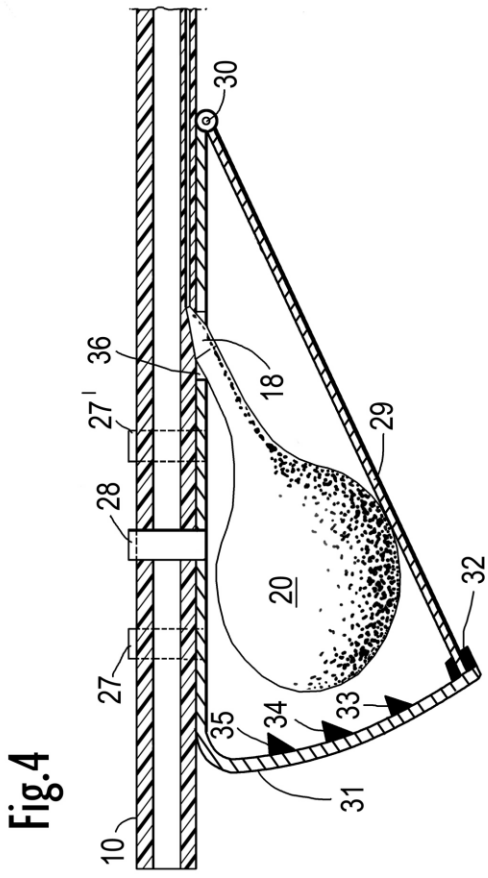
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Fig.4

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SPARE CLAIMS

Claims

1. A device for cleaning the interior of an endotracheal tube using a balloon catheter, comprising an inflation device, a catheter attached at one of its ends to the inflation device and including an inflation lumen, and an inflatable membrane at the other end of the catheter, configured to be inflated by the inflation device; wherein the inflation device includes:
    a) a variable-volume chamber having an outlet for connection to the inflation lumen,
    b) an actuator movable to vary the volume of the chamber and to expel air from it to inflate the balloon;
    c) a releasable latch which in its closed position inhibits movement of the actuator relative to the chamber; and
    d) an abutment to limit movement of the actuator upon release of the latch so as to limit the volume of air expelled from the chamber to inflate the membrane.

2. A device according to claim 1, wherein the chamber is formed by a flexible bellows located within a frame and the actuator is movable to engage the bellows and expel air from it.

3. A device according to claim 2, wherein the actuator is mounted for pivotal movement relative to the frame.

4. A device according to claim 2 or 3, further including a tubular spacer located adjacent to the frame with the catheter passing through it, the spacer being adapted to extend up to a tube into which the catheter is to be inserted, to limit movement of the catheter relative to the tube.

5. A device according to any preceding claim, wherein the frame is formed as an open loop configured to fit within a hand and the bellows is located within the loop.

6. A device according to claim 5, wherein the actuator includes a pair of rigid wings disposed on opposite sides of the frame and movable toward one another to engage the bellows.

7. A device according to claim 6, wherein the latch is mounted on the frame and is engageable with each of the wings to prevent relative movement between them.

8. A device according to claim 7, wherein the latch is biased to a position in which it engages the wings.

9. A balloon catheter substantially as described herein with reference to any of the attached drawings.