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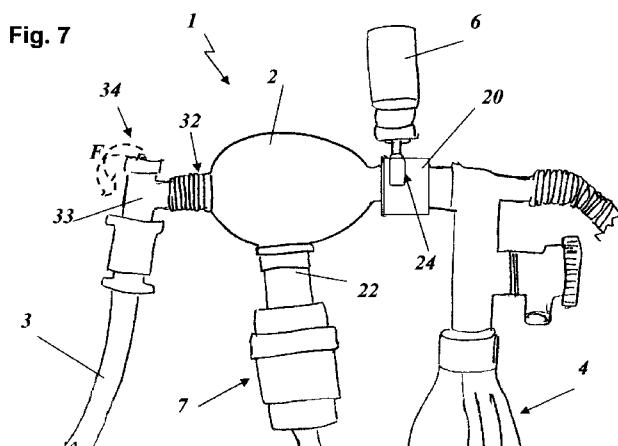
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(54) Title: CATHETER MOUNT

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(57) **Abstract:** The invention relates to a mount catheter usable for spraying a substance in a ventilation circuit comprising means (4) for sending a ventilation flow and means for the connection (3) to a patient; said mount catheter (1) being characterized in that it comprises: - a greater section portion (2) interposed between said means (4) for sending the ventilation flow and said means (3) for the connection to a patient, said greater section portion (2) being provided with a proximal joint (20) and with a distal joint (21; 34) usable, respectively, for the downstream connection to said means for the connection (3) to a patient and for the upstream connection to said means (4) for sending a ventilation flow; said proximal joint (20) being provided with an opening or aperture (24) which can be used for fixing means for reversibly connecting (5) a container (6) of substances apt to be sprayed; said opening (24) is disposed radially on a wall of said joint (20); said connecting means (5) to the container (6) comprising an introducer body (51) which passes through the same port (24) and is provided with an internal channel (57) provided with an input (56) matchable with said container (6) and an output (55) disposed in an area which is inside the joint (20) when the tubular body (51) is inserted within the same joint (20); - an additional joint (22), disposed in a central zone of said portion (2), usable for the connection to an ampoule containing the drug in liquid phase, which is connectable to an aerosol machine or to a high flow oxygen source for allowing the administration of the drug in a continuous way and in a spray.

TITLE: CATHETER MOUNT

* * *

DESCRIPTION

5 The present invention relates to an improved mount catheter. The mount catheter is a relatively short corrugated tube, which is used, connected to an endotracheal tube, in a oxygenating system, for example of the type called "rebreathing bag". The catheter makes it easier the injection of air, allowing the aspiration.

Furthermore, the mount catheter leaves the possibility to doctors, nurses or rescue teams to be able to move the oxygen systems without moving the endotracheal tube.

10 In particular, the present invention relates to an improved catheter mount usable for providing nebulized drugs in patients connected to a system of ventilation. In particular, the catheter mount of the invention is advantageously usable in cases of patients who are intubated critically ill, tracheostomised or actively ventilated through a facemask. Currently it is relatively complex to administer a drug to a patient spraying under the above 15 conditions. In fact, it is necessary to suspend the ventilation at least temporarily.

The aim of this invention is to allow the nebulization of medications directly within the ventilation circuit which serves the patients, without interruption in the ventilation treatment.

Another object of this invention is to increase the efficiency of the drug to the patient.

These and other results are reached in accordance with the invention by adopting the idea of a 20 mount catheter having the features described in claim 1. Other features are described in the dependant claims.

Among the advantages of the present invention are those described below.

The release of the medication sprayed to the patient is achieved without interrupting the ventilation.

25 There is a better administration of the drug thanks to the catheter which has a larger cross-section, oval shaped; said conformation maintains the drug in the gaseous form (minimizing the deposition of the drug on the walls) and driven by means of the positive airway pressure exerted by the ventilation system (e.g. by means of the rebreathing bag), penetrates better into the airways and increases the therapeutic efficacy.

30 Advantageously, it is also possible to associate to the ventilation system of an ampoule containing the aerosol drug in liquid form.

Downstream of the oval portion, the catheter includes a section of corrugated pipe; in this way it is possible to rotate of about 45° the oval zone in respect to the joint located downstream, i.e. in proximity of the patient.

In an alternative embodiment of the invention, the ovoid portion consists of two parts which can rotate between themselves; this feature allows the use of a phial/ampoule for spraying aerosol with side port. The possibility of divide this ovoid portion into two parts allows a more effective cleaning and disinfection for the re-use on the same patient.

5 Each technician who works in this field will better understand these advantages and further advantages and features of the present invention thanks to the following description and to the enclosed drawings as a practical explanation of the present invention which should not be considered in a limitative sense, wherein:

10 - Fig. 1 is a schematic side view of a possible embodiment of a catheter mount in accordance with the invention, in which the catheter is depicted in exploded, with its larger portion divided into two parts;

- Fig.2 is a schematic view of the catheter mount Fig.1, associated with an ampoule containing aerosol;

15 - Figs.2A, 2B relate to particulars showing a proximal joint represented, respectively, in configuration "free", i.e. without an associated bottle with the drug to be nebulized (2A) and with the bottle in configuration of nebulization (2B);

- Fig.3 represents, schematically, the example of Fig.1 in which the portion having the greater section is assembled;

- Fig.3A is relative to some details of the proximal joint of the catheter mount;

20 - Figs.4, 4A, 4B illustrate the catheter mount of the invention in different configurations of use which can be obtained by relative rotation of the two parties that form the largest portion of the catheter;

- Figs. 5, 6 show schematically some possible uses of the mount catheter of the invention; and

25 - Fig 7 shows an improved mount catheter according to the invention.

With reference to the examples of the drawings, a mount catheter (1) in accordance with the invention can be used for spraying a substance in a ventilation circuit comprising means (4) acts to send a ventilation flow and means for the connection (3) to a patient.

In the examples, which are not exhaustive of other possible embodiments, the means (4) for sending a ventilation stream consist of a socalled rebreathing bag or "Ambu ball".

30 Also the means for the connection (3) to a patient can be of different type: tight face mask, tracheostomy tube, oro-tracheal tube; these means are connected to the beak-junction which is placed at the proximal end of the catheter mount. (as in Fig 7).

The catheter mount (1) is provided with a portion having a larger section (2) interposed

between the means (4) for sending the ventilation flow and the means (3) for the connection to a patient; said portion having a larger section (2) is provided with a proximal joint (20) and a distal joint (21; 34); said joints are apt to connect, respectively, downstream to said means of connection (3) to a patient and upstream to said means (4) for sending the ventilation flow.

5 On the proximal joint (20) is disposed an opening or port (24) usable for attaching connecting resolvable means (5) for the connection to a container (6) of substances to be nebulized.

More specifically, with reference to Figs. 1, 2, 4 and 5, the portion (2) has a substantially oval shape and is formed of two parts: a proximal part (2b) and a distal one (2a) coupled in a stable but reversible way, for example with an interlocking joint.

10 It is possible to realize the connection between the two parts (2a) and (2b) in such a manner that it is allowed the rotation of the distal portion (2a) in respect to the proximal portion (2b). This feature further enhances the functionality of the catheter mount to use a cruet/ampoule of aerosol spray (7) with side port, as shown in the drawings of Figs.4-4B.

15 Moreover, the possibility of separating the oval portion (2) into two parts allows a more thorough cleaning and disinfection for reuse.

The proximal portion (2b) is provided with said proximal joint (20), which consists of a hollow cylinder (20) whose shape enables the tight connection with the means of ventilation (the rebreathing ball 4 of the examples). The hollow cylindrical body (20) communicates with the downstream ovoid portion ovoid (2) and, upstream, with the rebreathing ball (4).

20 Said opening or port (24) is disposed radially on the joint (20), that is, on its cylindrical wall, particularly in an area of said joint (20) which, in use, is disposed on the top.

The door (24) of the junction (20) is crossed by an introducer consisting of tubular body (51) provided with ends having a greater section with edges (53, 54). In practice, the edges (53) and (54) of the tubular body (51) are sized so they do not pass through the opening (24).

25 The tubular body (51) is provided with an internal channel (57) having an inlet (56) disposed at the top, that is, on its upper base (that is bounded by the edge 54), and an output (55) radially disposed in respect to the tubular body (51), in an area intended to be inside the joint (20) when the tubular body (51) is inserted within the same joint (20). In particular, the output (55) is facing downstream, that is to direct the flow towards to the ovoid portion (2).

30 The catheter mount can comprise means for preventing the rotation of the tubular body (51) when the same is cylindrical in shape; for example, it can comprise a vertical guide groove which, by preventing the rotation of the body (51) around its longitudinal axis, determines the positioning of the output (55) in direction of the oval portion (2). Alternatively, the tubular body (51) may have a polygonal section, without the necessity of a guide groove.

On the body (51) is fit a spring (52) whose ends are batting, respectively, against the upper surface of the joint (20) and against the lower edge (54) of the body (51). The compression due to the pre-loading of the spring (52) pushes the tubular body (51) to the outside in respect to the junction (20) in which it is partially inserted. In practice, the tubular body (51) is held normally "extracted", pushed to the outside and with its lower edge (53) batting against the inside face of the junction (20), around the opening (24).

The inlet (56) of the tubular body (51) is shaped so as to be coupled with the supplying nozzle of the container of the spray drugs.

For administering nebulized medications, it is sufficient to simply juxtapose the dispensing nozzle of the container at the upper hole (56), exerting a pressure on the same bottle, as indicated by the arrow in Fig.2B. The force exerted on the bottle will move the tubular body (51) inside the cavity of the junction (20), loading the spring (52); the medicine sprays out from the container (6) and passing through the channel (57) and the exit (55) is received nebulized within the oval portion (2).

Once the pressure on the bottle (6) ceases, the tubular body (51), due to the elastic recoil of the spring (52), is reported out of the cavity (20).

Simultaneously, the balloon (4) is squeezed, practicing so to the patients a forced ventilation which pushes actively (with positive pressure) through the respiratory tree the mixture O2-medication.

The distal portion (2a) of the oval portion (2) has two holes: a first hole disposed centrally (axially), in correspondence of the distal joint (21), another hole disposed on the side (radially in respect to the longitudinal development of the egg-shaped portion 2), in correspondence of a port or additional joint (22) constituted of a hollow cylinder. The distal junction (21; 34) may be cylindrical (21) and can connect directly to the ^{*}oro-tracheal tube or tracheal cannula (Figs. 5, 6) or it can be ^{*}beak-shaped (34); ^{*}in this latter case, there is a corrugated part (32) which is the continuatioli of oval portion and which has a joint (33) for the device directed to the patient in position orthogonal in respect to the corrugated portion (Fig. 7).

The additional joint (22), if not used as a gateway for the continuous delivery of nebulized drugs, is maintained sealed with a adapter cap (23). The cap is composed of two parts: a cap (23a) and an adapter (23b).

For allowing the continuous delivery of nebulized drugs, once removed the cap (23), it is possible to connect to the oval portion (2) an ampoule (7) for aerosol having a vertical connection (such as schematically illustrated in Fig.2) or side connection (see Figs. 4B). In the latter case it is necessary first to rotate the camera about 45° and then use the upper part (23b)

of the cap (23) which acts as an adapter. This feature allows to increase the possibilities of connection between different diameter pipes. When the oval portion consists of a single body, the directional rotation of the oval enlarged portion allows the use of the additional joint (22) by rotating the beak joint (see arrow F of Figure 7).

5 The presence of this additional access to the chamber defined by the enlarged portion thus allows many advantages when considering the benefits from the use of drugs directly involved in the respiratory tracts of acute and chronic pulmonary diseases, both primary and secondary.

10 In conclusion, it is possible to affirm that by means of the catheter mount of the invention the drug nebulizers, that otherwise could not be used, can be used (with the rebreathing ball or Ambu ball) for critical uncooperating patients (i.e., intubated or active ventilated patients) or for cooperating patients (tracheostomised), said patients having conditions which are progressively deteriorating.

15 It is possible the connection of the ampoule containing the drug in liquid form to a machine for aerosol or a source of oxygen at high flow.

20 The catheter mount (1) shown in Figure 7, is provided with a greater portion of ovoid-section (2) which downstream narrows into a smaller cross section portion (32) for connection with a beak joint (33) to which is associated the tube (3) attached to the patient. The lower section (32) and the beak joint (33) are the distal joint (34) of the greater cross-section portion (2) of the mount (1). In particular, the portion of lower section (32) is formed by a corrugated tube that allows rotation of about 45° of the larger section portion.

25 Furthermore, the oval portion (2) are provided, as in the examples described above, with a port (24) disposed at the proximal junction (20) that connects the re-breathing ball (4), and one additional port (22) for the association of another device, such as an ampoule (7) containing the drug in liquid form (aerosol).

The additional joint (22) is advantageously placed in correspondence of the central portion of the oval portion (2), i.e. at the greatest cross-section; this particular feature increases the effectiveness of drug treatment because it enables optimal distribution of the drug in the flow of air directed to the patient.

30 In conclusion, the present invention relates, in particular, to an improved catheter mount usable for administering nebulizable drugs to patients connected to a system of ventilation. The use of the catheter mount of the invention makes it extremely simplified the administration of these drugs in intubated critically ill patients, tracheostomised or actively ventilated through facemask. In other words, the administration of these drugs, which would

be considerably complicated with known type devices is extremely easy even in emergencies, in which small changes in the treatment and / or temporary changes in ventilation can cause severe damage to the patient.

5 The execution details may equally vary as regards shape, size, disposition of elements, kind of materials used, within the solution idea that has been adopted and within the limits of the protection offered by the present patent.

CLAIMS

1. Mount catheter usable for spraying a substance in a ventilation circuit comprising means (4) for sending a ventilation flow and means for the connection (3) to a patient; said mount catheter (1) being characterized in that:
 - it comprises a greater section portion (2) interposed between said means (4) for sending the ventilation flow and said means (3) for the connection to a patient, said greater section portion (2) being provided with a proximal joint (20) and with a distal joint (21; 34) usable, respectively, for the downstream connection to said means for the connection (3) to a patient and for the upstream connection to said means (4) for sending a ventilation flow; said proximal joint (20) being provided with an opening or aperture (24) which can be used for fixing means for reversibly connecting (5) a container (6) of substances apt to be sprayed; and in that
 - said connecting means (5) to the container (6) comprise an introducer body (51) which passes through the same port (24) and is provided with an internal channel (57) provided with an input (56) matchable with said container (6) and an output (55) disposed in an area which is inside the joint (20) when the tubular body (51) is inserted within the same joint (20); said introducer consisting of a tubular body (51) provided with ends having edges (53, 54) which are greater in respect to said opening (24), a spring (52) being fitted on said tubular body.
2. Mount catheter usable for spraying a substance in a ventilation circuit comprising means (4) for sending a ventilation flow and means for the connection (3) to a patient; said mount catheter (1) being characterized in that it comprises:
 - a greater section portion (2) interposed between said means (4) for sending the ventilation flow and said means (3) for the connection to a patient, said greater section portion (2) being provided with a proximal joint (20) and with a distal joint (21; 34) usable, respectively, for the downstream connection to said means for the connection (3) to a patient and for the upstream connection to said means (4) for sending a ventilation flow; said proximal joint (20) being provided with an opening or aperture (24) which can be used for fixing means for reversibly

connecting (5) a container (6) of substances apt to be sprayed; said opening (24) is disposed radially on a wall of said joint (20); said connecting means (5) to the container (6) comprising an introducer body (51) which passes through the same port (24) and is provided with an internal channel (57) provided with an input (56) matchable with said container (6) and an output (55) disposed in an area which is inside the joint (20) when the tubular body (51) is inserted within the same joint (20);

- an additional joint (22), disposed in a central zone of said portion (2), usable for the connection to an ampoule containing the drug in liquid phase, which is connectable to an aerosol machine or to a high flow oxygen source for allowing the administration of the drug in a continuous way and in a spray.

3. Mount catheter according to one of the preceding claims, characterized in that downstream of said larger cross-section portion (2), the distal joint comprises a portion of corrugated tube (32).

4. Mount catheter according to one of the preceding claims, characterized in that downstream of said larger cross-section portion (2), the distal joint comprises a portion of corrugated tube (32) and a beak joint (33).

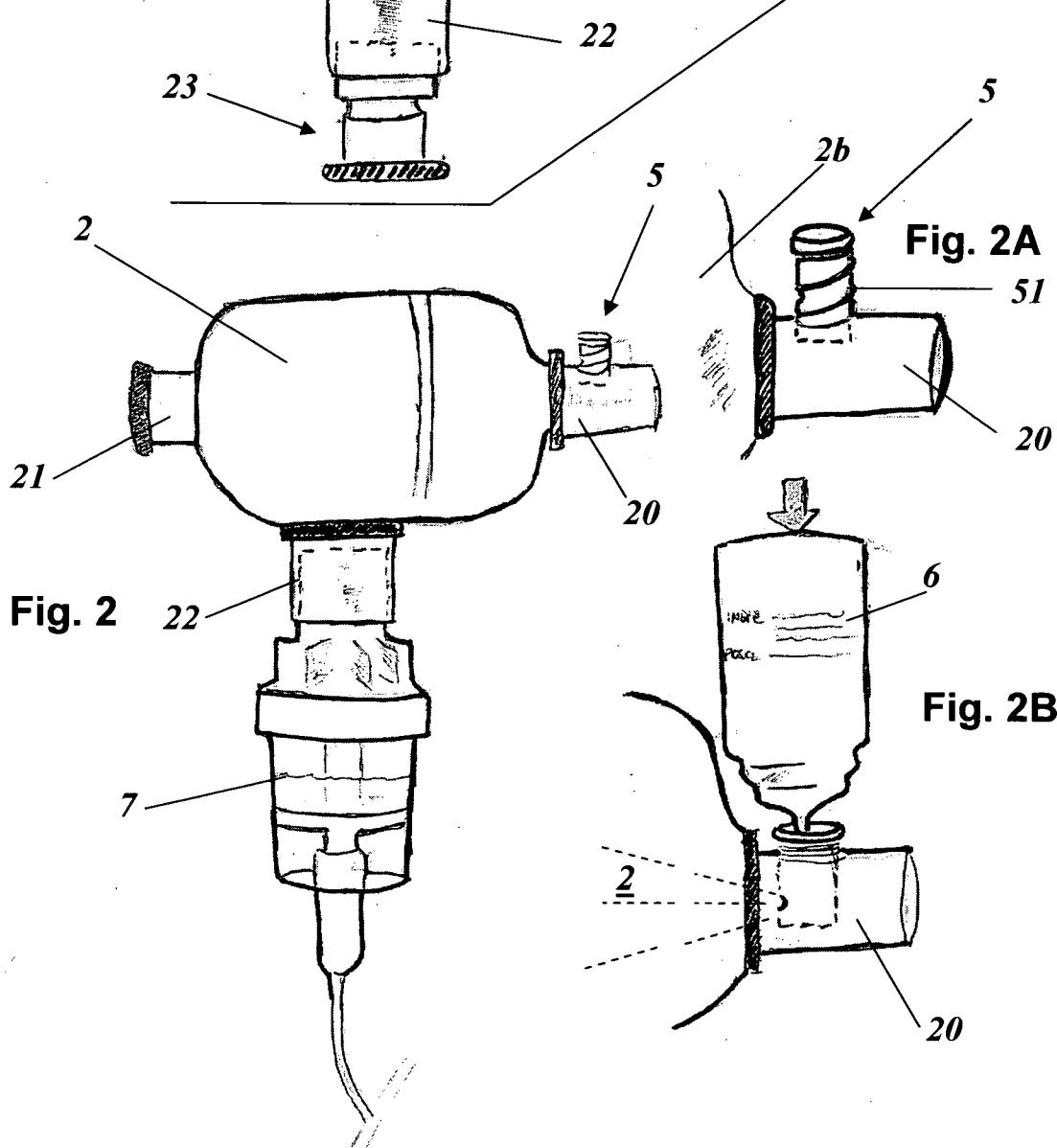
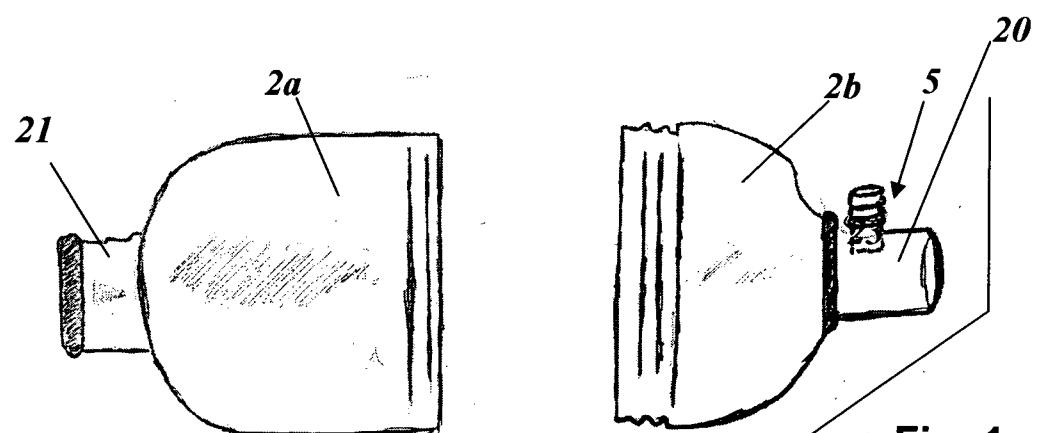
5. Mount catheter according to claim 1, characterized in that there are means for positioning said output (55) for keeping it facing downstream, for directing the relevant flow towards the larger cross-section portion (2).

6. Mount catheter according to claim 1, characterized in that said larger cross-section portion (2) is formed by a proximal part (2b) and a distal part (2a) coupled each other in a stable and reversible way.

7. Mount catheter according to claim 6, characterized in that said larger cross-section portion (2) is formed by a proximal part (2b) and a distal part (2a) coupled each other in a stable and reversible way; one of said parts being provided with an additional joint (22), said two parts (2a, 2b) of the chamber being reciprocally positionable according to

different angles.

8. Mount catheter according to claim 1, characterized in that said larger cross-section portion (2) is of ovoid shape.



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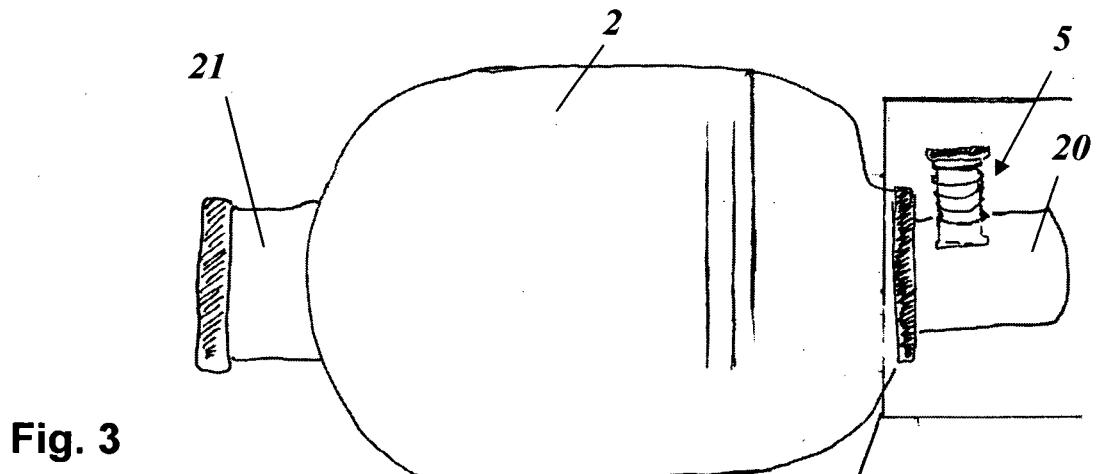


Fig. 3

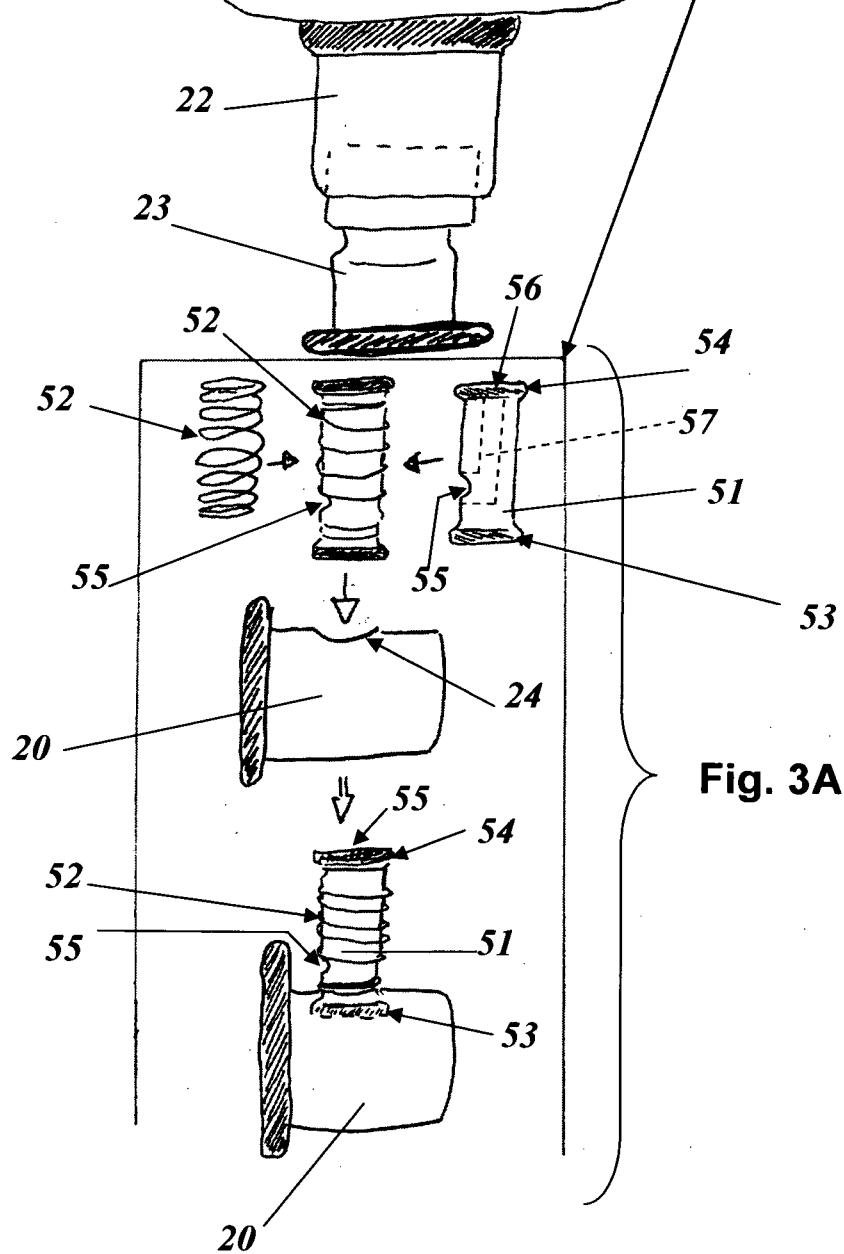
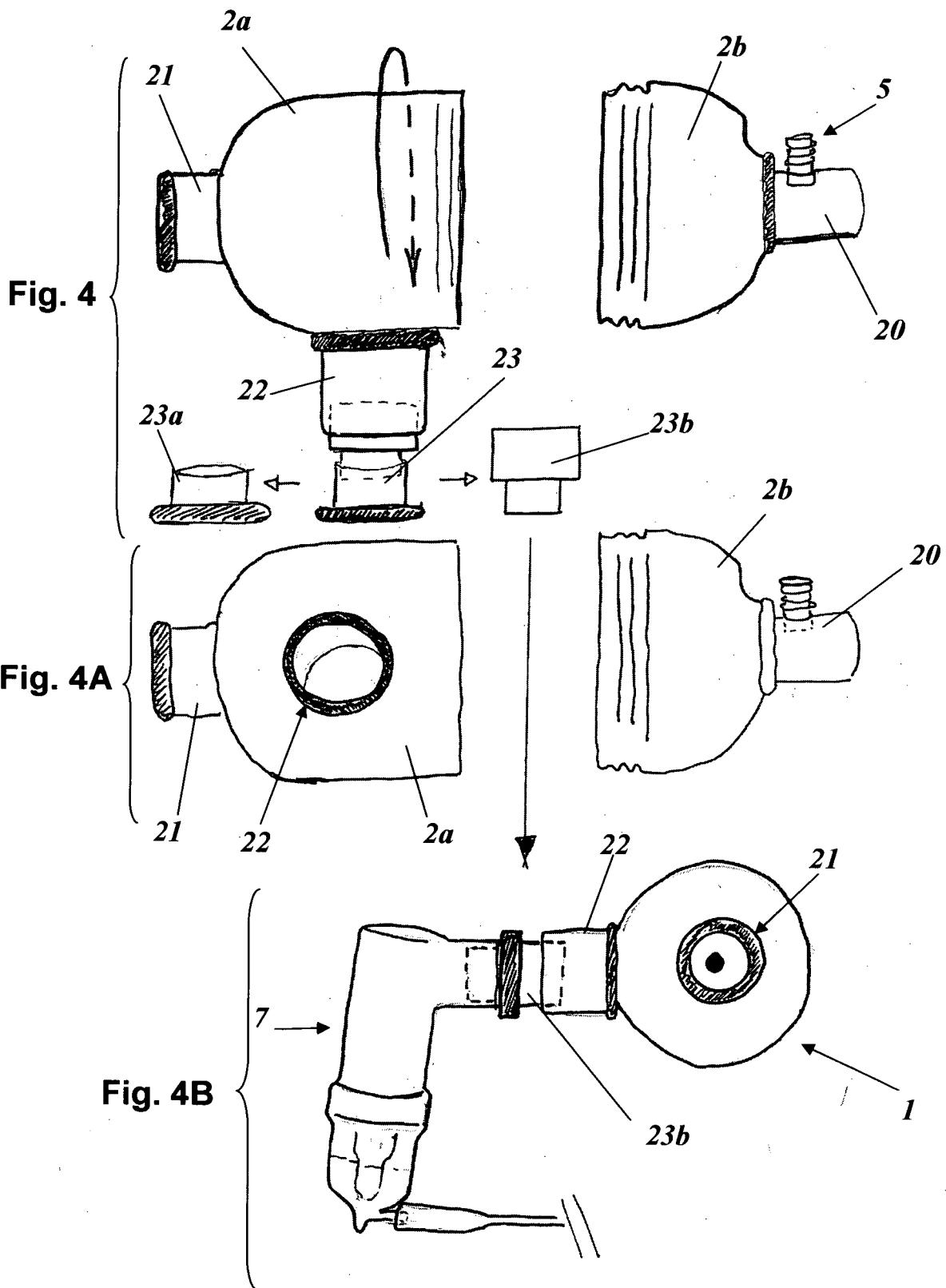


Fig. 3A

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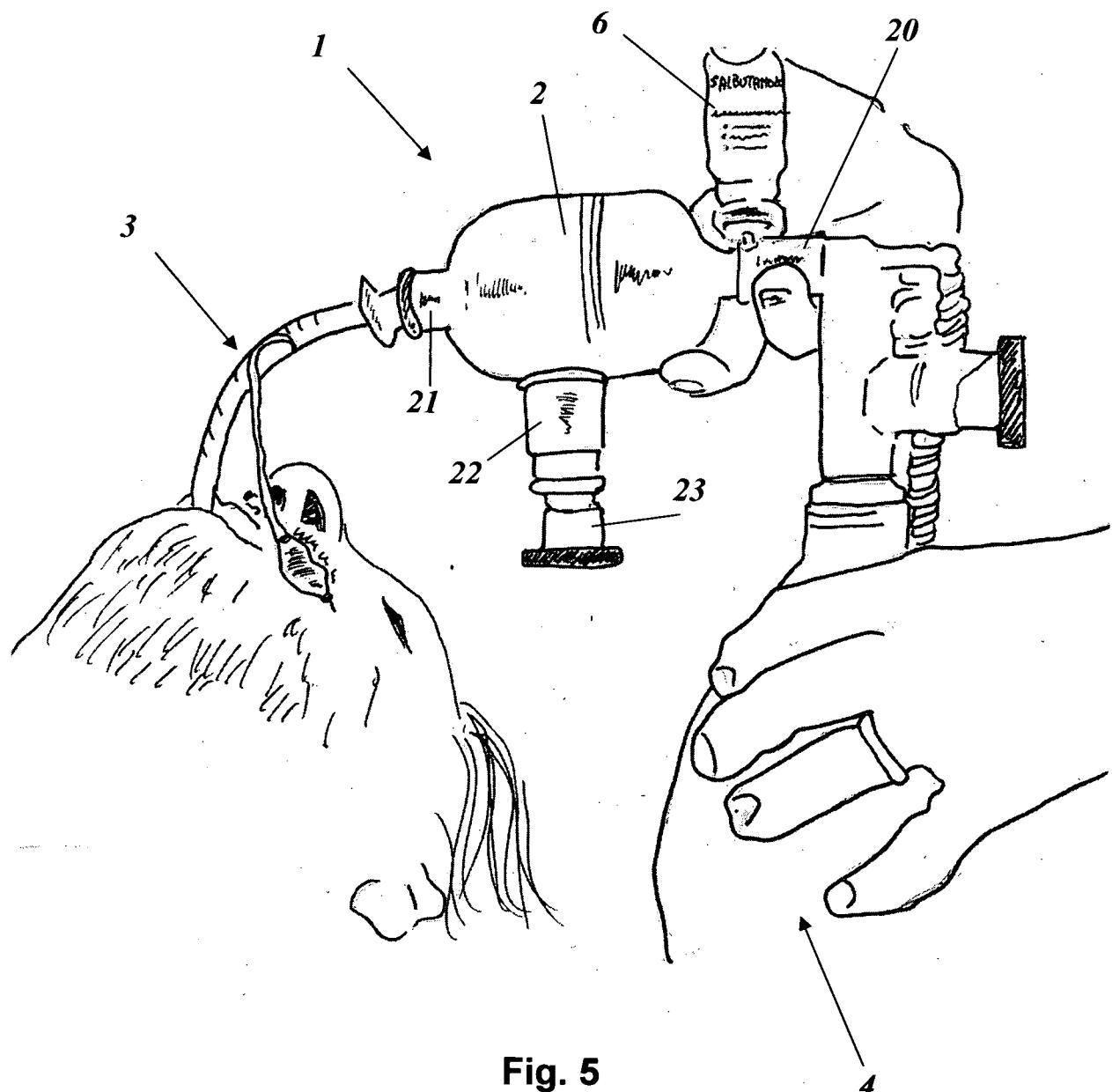


Fig. 5

Fig. 6

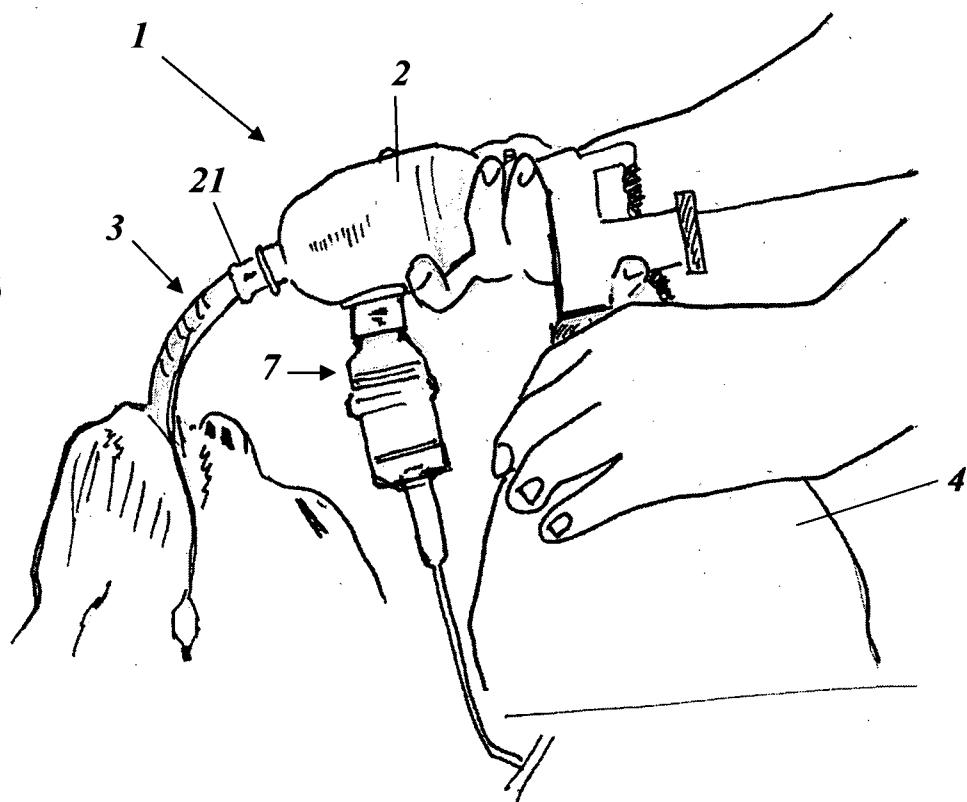
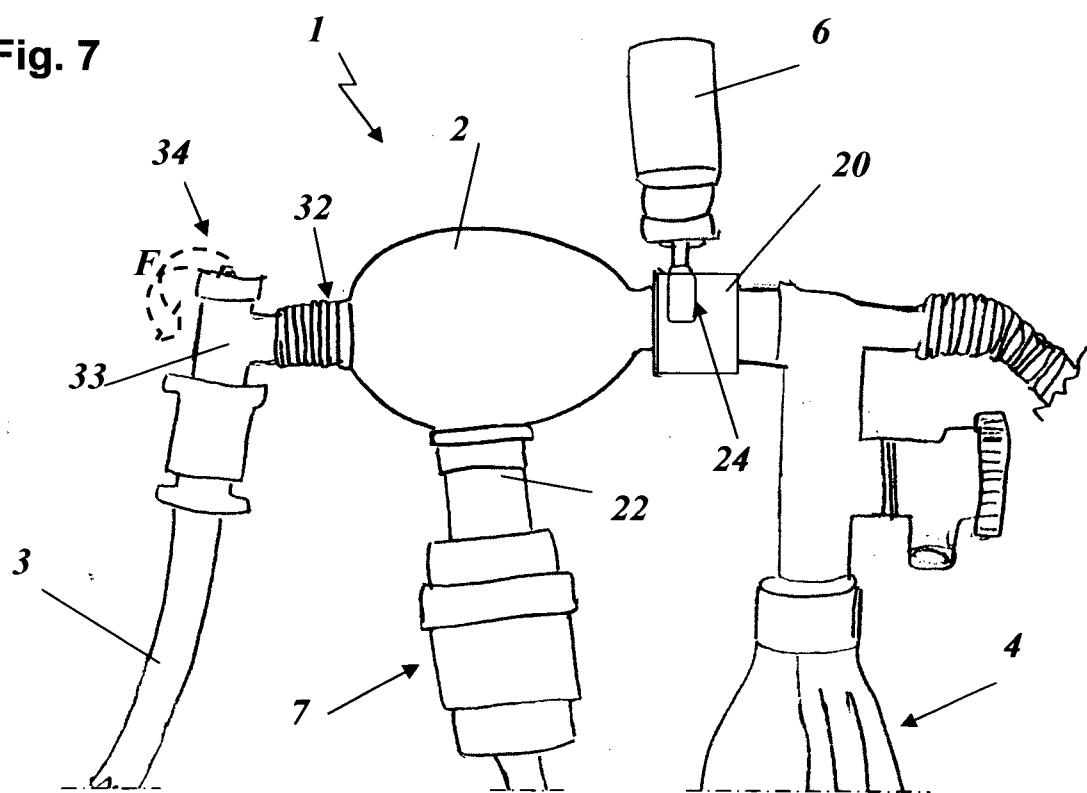


Fig. 7



INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2010/000454

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M15/00 A61M16/00
ADD. A61M16/08 A61M16/14

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
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A	US 2005/039746 A1 (GRYCHOWSKI JERRY R [US] ET AL) 24 February 2005 (2005-02-24) paragraphs [0004] - [0006], [0018] - [0036]; figure 1	1,3-8
A	US 2002/069869 A1 (FARMER MICHAEL W [US]) 13 June 2002 (2002-06-13) paragraphs [0010], [0015] - [0017]; figures 1-3	1-8
		- / --

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
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Date of the actual completion of the international search

17 May 2010

Date of mailing of the international search report

27/05/2010

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Authorized officer

Loughman, John

INTERNATIONAL SEARCH REPORT

International application No PCT/IB2010/000454	
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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