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(54) Title: GAS-TREATMENT DEVICES AND APPARATUS

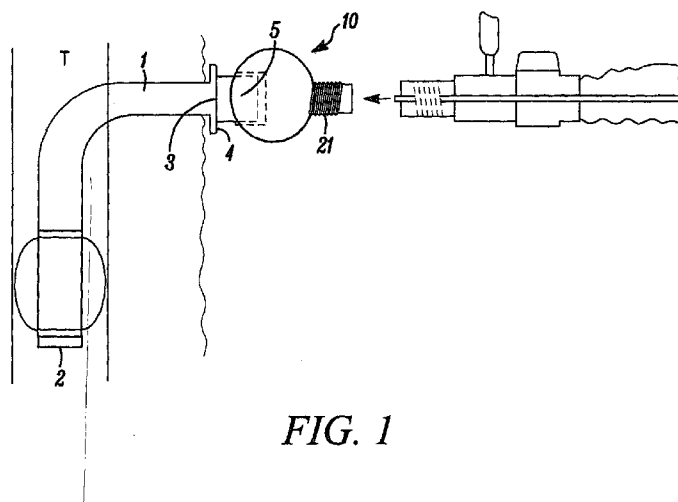


FIG. 1

(57) Abstract: An HME device (10) for a tracheal tube (1) has a housing (11) with an HME element (15) and (16) at each end and a central tracheal coupling (17) that fits on the machine end connector (5) of the tracheal tube. A suction port (20) is located directly opposite the tracheal coupling (17) and has an external screw thread (21) and an internal flap valve (22). A closed system suction catheter arrangement (30) has an internally threaded patient end fitting (31) that sealingly couples with the suction port (20). A suction catheter (35) extends from the patient end fitting (31) to a machine end fitting (40) adapted to connect with a suction source (41), (42), (43). A flexible, protective envelope (46) extends around and along the catheter (35) from the patient end fitting (31) to the machine end fitting (40). The suction catheter (35) can be advanced into the tracheal tube (1), through the HME device (10) by manipulation through the envelope (46) without the need to directly contact the catheter.

GAS-TREATMENT DEVICES AND APPARATUS

This invention relates to gas-treatment devices of the kind for a tracheal tube including a housing containing one or more gas-treatment elements through which gas passes to a tracheal tube, the device including a tracheal coupling adapted for connection with the tracheal tube and a suction port substantially aligned with the tracheal coupling.

The invention is more particularly concerned with devices such as HMEs and filters adapted for attaching to the machine end of a tracheal tube.

Where a patient breathes through a tube inserted in the trachea, such as a tracheostomy or endotracheal tube, gas flow to the bronchi is not warmed and moistened by passage through the nose. Unless the gas is warmed and moistened in some way it can cause damage and discomfort in the patient's throat. The gas can be conditioned by a humidifier in the ventilation circuit but, most conveniently, a heat and moisture exchange device (HME) is used. HMEs are small, lightweight devices including one or more exchange elements, such as of a paper or foam treated with a hygroscopic substance. When the patient exhales, gas passes through the exchange element and gives up a major part of its heat and moisture to the element. When the patient inhales, gas passes through the exchange element in the opposite direction and takes up a major part of the heat and moisture in the exchange element so that the gas inhaled by the patient is warmed and moistened. These HMEs are low cost and disposable after a single use. They can be connected in a breathing circuit or simply connected to the machine end of a tracheal tube and left open to atmosphere where the patient is breathing spontaneously.

HMEs are sold by Smiths Medical International Limited of Hythe, Kent, England under the Thermovent name (Thermovent is a registered trade mark of Smiths Medical International Limited), by Hudson RCI AB under the TrachVent name (TrachVent is a registered trade mark of Hudson RCI AB), by DAR, Medisize, Intersurgical and other manufacturers. Examples of HMEs are described in GB 2391816, WO 01/72365, US 5505768, SE 516666, US 3881482, DE 20302580, DE 20114355U,

WO 97/01366, US 2002/0157667, US 6422235, EP 1208866, US 4971054, EP1699515 and US2008/0099013. The "Thermovent T" HME sold by Smiths Medical has a T-shape configuration with two HME elements mounted at opposite ends of a straight tubular housing extending transversely of the connection port by which the device is fitted onto a tracheostomy tube or the like. The tubular housing for the HME elements may be curved to follow the anatomical profile of the neck, as described in EP1888157. The T-shape HMEs may have a suction port aligned with the coupling by which the HME is attached with the tracheal tube. This enables a conventional suction catheter to be inserted through the HME and down the bore of the tracheal tube without the need to disconnect the HME. The suction port is usually closable by a tethered cap. The problem with suctioning in this way is that the user is exposed to contamination on the outside surface of the suction catheter when this is withdrawn from the tube. The suction catheter has to be handled carefully to avoid cross contamination and must be disposed of after a single use.

It is an object of the present invention to provide an alternative gas-treatment device and apparatus.

According to one aspect of the present invention there is provided a gas-treatment device of the above-specified kind, characterised in that the suction port includes a suction coupling adapted to mate with a cooperating coupling on a closed system suction catheter arrangement including a suction catheter such that the suction catheter can be advanced through the suction coupling and the tracheal coupling.

The housing preferably extends substantially transversely of the tracheal tube, the tracheal coupling being located substantially midway along the housing. The device preferably includes two gas-treatment elements located towards opposite ends of the housing. The or each gas-treatment element is preferably an HME element. The suction port preferably includes a valve, such as a flap valve, that is openable by advancing the suction catheter through the suction port. The suction coupling on the housing and the cooperating coupling on the closed system suction catheter arrangement may be provided with cooperating screw threads. The closed system suction catheter arrangement preferably includes a flexible protective sleeve extending from the cooperating coupling, around and

along the suction catheter to a machine end fitting including a manually-operable suction control valve.

According to another aspect of the present invention there is provided apparatus including a gas-treatment device according to the above first aspect of the present invention and a closed system suction catheter arrangement including a patient end fitting fitted with the suction coupling on the gas-treatment device, a suction catheter having a patient end slidable through the patient end fitting, a machine end fitting connected with the machine end of the suction catheter and adapted for connection with a source of suction and a flexible protective envelope extending around and along the suction catheter between the patient end fitting and the machine end fitting such that the suction catheter can be manipulated through the envelope and extended and withdrawn through the patient end fitting into and out of the gas-treatment device and the tracheal tube.

According to a further aspect of the present invention there is provided a tracheal tube assembly including a tracheal tube having a patient end located in the trachea and a machine end extending from the patient, and an HME device having a tracheal coupling fitted on the machine end of the tracheal tube and having a housing extending transversely of the tracheal tube, the housing containing an HME element mounted at opposite ends and a suction port opposite the tracheal coupling, characterised in that the assembly further includes a closed system suction catheter arrangement having a patient end fitting sealingly coupled with the suction port, that the closed system suction catheter arrangement has a suction catheter slidable through the patient end fitting and into or out of the tracheal tube, a machine end fitting to which the machine end of the suction catheter is attached and a flexible protective envelope extending between the patient end fitting and the machine end fitting around and along the suction catheter such that the suction catheter can be manipulated into and out of the tracheal tube through the envelope without direct contact with suction catheter.

A tracheostomy apparatus and assembly according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

- Figure 1 is a side elevation view of tracheostomy apparatus in use;
- Figure 2 is an enlarged cross-sectional plan view of an HME used in the apparatus;
- Figures 2A and 2B show different stages of insertion of the suction catheter; and
- Figure 3 shows an assembly of a closed system suction catheter connected to the HME.

With reference first to Figure 1 there is shown a conventional tracheostomy tube 1 having a cuffed patient end 2 located in the trachea T and a machine end 3 extending through a tracheostomy opening in neck tissue. A flange 4 is mounted at the machine end 3 of the tube 1 to which a neck strap (not shown) is attached that is used to stabilise the tube about the neck. The machine end 3 of the tube 1 is terminated by a conventional 15mm male tapered connector 5. An HME 10, shown in more detail in Figure 2 is fitted onto the tracheal tube connector 5 to warm and humidify inhaled gas flowing into the tube 1 in the usual way.

With reference now also to Figure 2, the HME 10 has a moulded plastics outer housing 11 of a generally cylindrical shape extending transversely of the tracheostomy tube 1. The housing 11 is open at both ends 13 and 14 and encloses two conventional HME elements 15 and 16, such as of a coiled strip of corrugated paper, a foam or the like treated with a hygroscopic substance. The housing 11 includes a female tracheal coupling 17 in the form of a short collar projecting inwardly of the housing midway along its length such that the tracheal coupling extends orthogonally of the axis of the housing. The tracheal coupling 17 has a female tapered bore 18 that forms a luer slip fit about the connector 5 on the machine end of the tracheal tube 1. The bore 18 of the coupling 17 communicates with a passage 19 through the housing 11 so that gas can flow to and from the tracheal tube 1 via one or other or both of the HME elements 15 and 16 when the patient is breathing spontaneously. Directly opposite the tracheal coupling 17 a cylindrical stem projects

outwardly of the housing 11 to provide a suction port coupling 20 having an external screw thread 21. The suction port coupling could be of other kinds, such as including a taper fit or bayonet fitting. The suction coupling 20 opens into the passage 19 of the housing 11 directly aligned with the tracheal coupling 17. A hinged flap valve 22 inside the outer end of the suction coupling 20 normally adopts a closed position, blocking gas flow through the port, but can be opened by inserting a suction catheter, as explained later. Instead of a flap valve a cap or other closure could be used.

Referring now also to Figure 3 there is shown the arrangement of the HME 10 fitted with a closed system suction catheter 30. At its patient end the closed system suction catheter 30 has a patient end fitting or coupling 31 including a female screw thread 32 at one end, a flexible wiper seal 33 towards its opposite end and an optional irrigation port 34. A suction catheter 35 in the form of a simple, flexible tube with an external diameter of about 3mm extends along the length of the closed system 30. The open patient end 36 of the suction catheter 35 projects through the wiper seal 33 and lies within the patient end fitting 31 before use. At its rear, machine end 37 the catheter 35 is joined with a machine end fitting 40. The machine end fitting 40 is, in turn, connected at its rear end to suction tubing 41 extending to a source of suction provided by a secretions container 42 and a pump 43. The machine end fitting 40 preferably includes some form of manually-operable suction control valve 44. As illustrated, the valve 44 includes a simple sprung plunger 47 with a passage 45 through it that can be aligned with the passage along the machine end fitting 40. The user opens the valve 44 to allow suction through the suction catheter 35 simply by pressing down the plunger 47 so that the passage 45 aligns with the passage through the fitting 40. When released, the valve plunger 47 moves up and closes the passage through the end fitting 40. It will be appreciated that other forms of suction control valve could be used, such as the enclosed valves described in US4569344, US5269768, US5300043 or US7597686. The closed system suction catheter 30 is completed by a flexible, transparent plastics envelope or sleeve 46 attached at opposite ends to the patient end fitting 31 and the machine end fitting 40 respectively, extending around and along the suction catheter 35 so that this is completely enclosed and protected along its length. The suction catheter 35 can be manipulated into and out of the tracheostomy tube 1 through the envelope 46 without direct contact with suction catheter 35.

The patient end fitting 31 on the closed system suction catheter 30 is sealingly fitted on to the suction coupling 20 of the HME 10 by screwing into place. The tracheostomy tube 1 can now be suctioned by gripping the suction catheter 35 through the envelope 46 and pushing it forwardly through the wiper seal 33 in the patient end fitting 31. As the patient end 36 of the suction catheter 35 is extended it pushes open the flap valve 22 as shown in Figures 2A and 2B. The patient end 36 extends across the passage 19 of the housing 11, into the tracheal coupling 17 and the tracheostomy fitting 5. The patient end 36 of the suction catheter 35 is now pushed down the tracheostomy tube 1 to the desired extent. When this is reached and suctioning is to be applied, the user opens the suction control valve 44 by pushing down its plunger 47 so that suction is applied at the patient end tip 36 of the suction catheter 35. The user now slowly withdraws the suction catheter 35 while suction is being applied, to remove secretions along the length of the interior of the tracheostomy tube 1. The suction catheter 35 is pulled rearwardly until its patient end tip 36 lies again in the patient end 31 fitting just forwardly of the wiper seal 33. Where an irrigation inlet 34 is provided, the suction catheter 35 can be flushed through by dispensing saline through the irrigation inlet into the patient end fitting 31 while suction is applied.

If desired, the closed system suction catheter 30 may be left in place connected with the HME 10 so that it can be reused when suctioning is next required. Alternatively, the closed system suction catheter 30 could be removed and disposed of, the suction port 20 on the HME 10 being closed by the flap valve 22.

The arrangement of the present invention enables the risk of contamination from suction catheters to be reduced by protecting the suction catheter from contact during use. It also enables the same suction catheter arrangement to be used several times on the same tube.

The invention could be used on other tracheal tubes, such as endotracheal tubes. The invention is not confined to use with HMEs but could be used with other gas-treatment devices, such as filters.

CLAIMS

1. A gas-treatment device (10) for a tracheal tube (1) including a housing (11) containing one or more gas-treatment elements (15, 16) through which gas passes to a tracheal tube, the device including a tracheal coupling (17) adapted for connection with the tracheal tube (1) and a suction port (20) substantially aligned with the tracheal coupling (17), characterised in that the suction port (20) includes a suction coupling (21) adapted to mate with a cooperating coupling (31) on a closed system suction catheter arrangement (30) including a suction catheter (35) such that the suction catheter (35) can be advanced through the suction coupling (20, 21) and the tracheal coupling (17).
2. A gas-treatment device according to Claim 1, characterised in that the housing (11) extends substantially transversely of the tracheal coupling (17), and that the tracheal coupling (17) is located substantially midway along the housing (11).
3. A gas-treatment device according to Claim 2, characterised in that the device (10) includes two gas-treatment elements (15 and 16) located towards opposite ends of the housing (11).
4. A gas-treatment device according to any one of the preceding claims, characterised in that the or each gas-treatment element is an HME element (15, 16).
5. A gas-treatment device according to any one of the preceding claims, characterised in that the suction port (20) includes a valve (22) that is openable by advancing the suction catheter (35) through the suction port (20).
6. A gas-treatment device according to Claim 5, characterised in that the valve includes a flap valve (22).
7. A gas-treatment device according to any one of the preceding claims, characterised in that the suction coupling (20) on the housing (11) and the coupling (31) on the closed

- system suction catheter arrangement (30) are provided with cooperating screw threads (21 and 32).
8. A gas-treatment device according to any one of the preceding claims, characterised in that the closed system suction catheter arrangement (30) includes a flexible protective sleeve (46) extending from the cooperating coupling (31), around and along the suction catheter (35) to a machine end fitting (40) including a manually-operable suction control valve (44).
 9. Apparatus including a gas-treatment device (10) according to the any one of the preceding claims and a closed system suction catheter arrangement (30) including a patient end fitting (31) fitted with the suction coupling (20) on the gas-treatment device (10), a suction catheter (35) having a patient end (36) slidable through the patient end fitting (31), a machine end fitting (40) connected with the machine end of the suction catheter (35) and adapted for connection with a source of suction (41, 42, 43) and a flexible protective envelope (46) extending around and along the suction catheter (35) between the patient end fitting (31) and the machine end fitting (40) such that the suction catheter (35) can be manipulated through the envelope (46) and extended and withdrawn through the patient end fitting (31) into and out of the gas-treatment device (10) and the tracheal tube (1).
 10. A tracheal tube assembly including a tracheal tube (1) having a patient end (2) located in the trachea and a machine end (3) extending from the patient, and an HME device (10) having a tracheal coupling (17) fitted on the machine end of the tracheal tube and having a housing (11) extending transversely of the tracheal tube (1), the housing (11) containing an HME element (15 and 16) mounted at opposite ends and a suction port (20) opposite the tracheal coupling (17), characterised in that the assembly further includes a closed system suction catheter arrangement (30) having a patient end fitting (31) sealingly coupled with the suction port (20), that the closed system suction catheter arrangement has a suction catheter (35) slidable through the patient end fitting (31) and into or out of the tracheal tube (1), a machine end fitting (40) to which the machine end of the suction catheter (35) is attached and a flexible

protective envelope (46) extending between the patient end fitting (31) and the machine end fitting (40) around and along the suction catheter (35) such that the suction catheter can be manipulated into and out of the tracheal tube through the envelope (46) without direct contact with suction catheter.

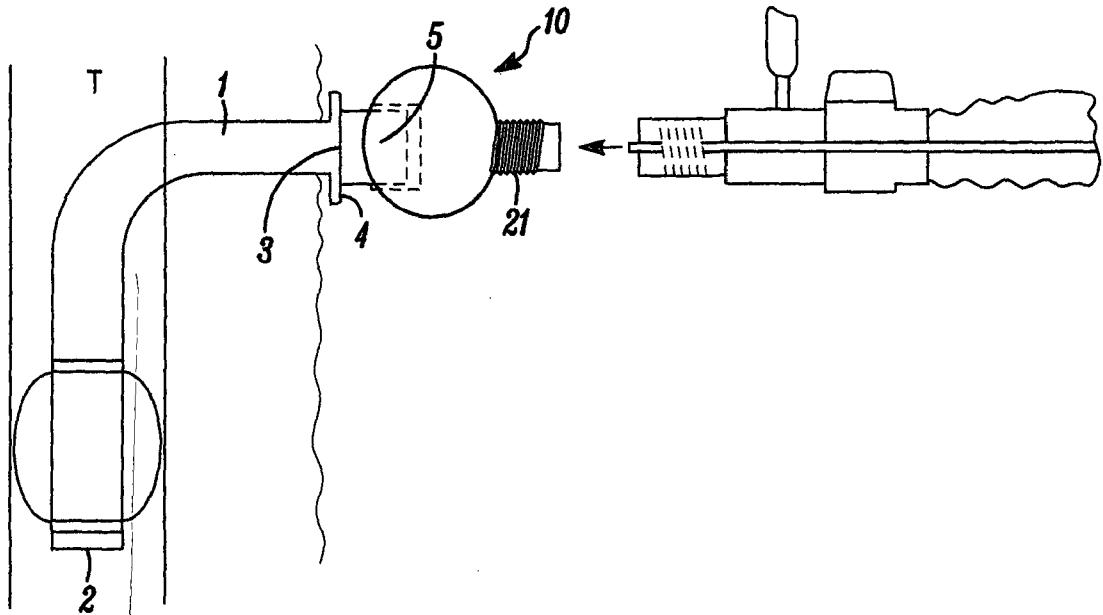


FIG. 1

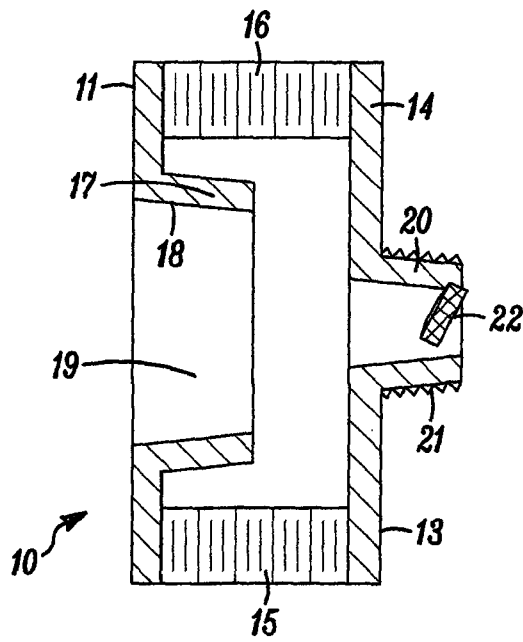


FIG. 2

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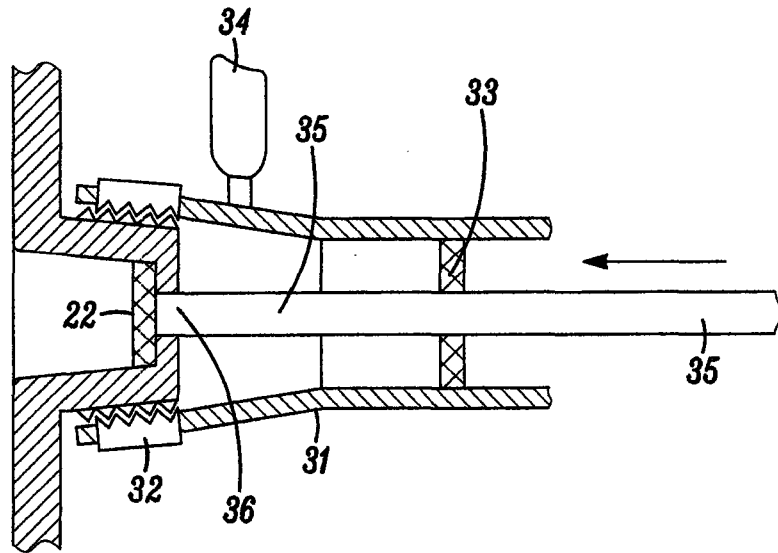


FIG. 2A

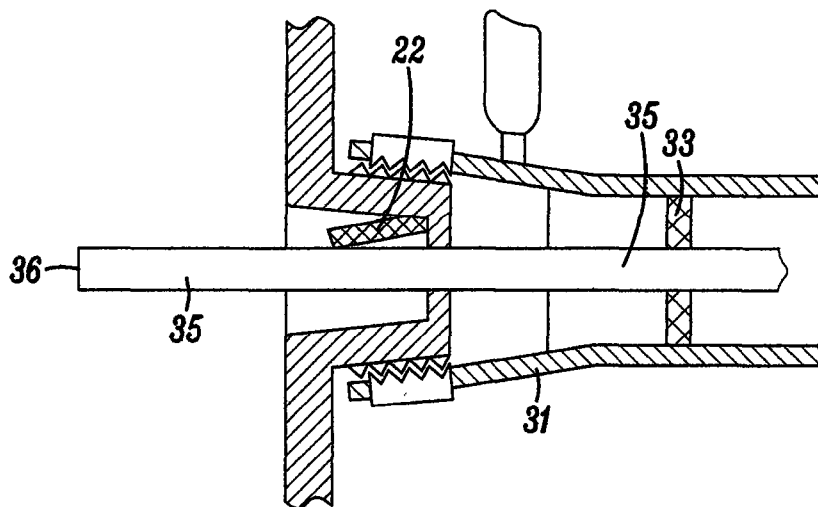


FIG. 2B

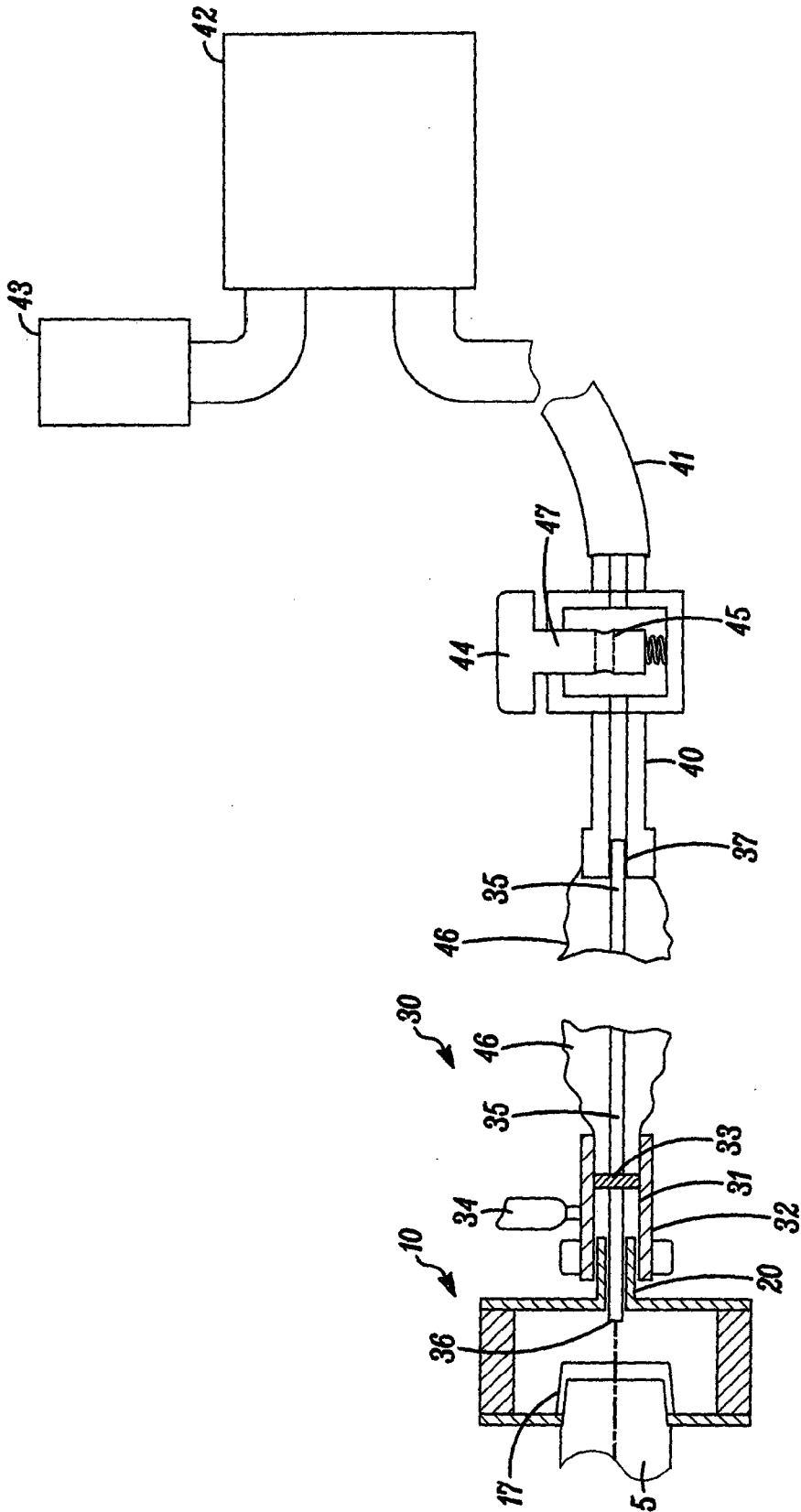


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61M16/04 A61M16/10
 ADD.

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 practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	abstract; figures 1-5 paragraphs [0016] - [0019]	7
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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