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(54) Respiratory muscle training device with connector with filter

(57) The present invention relates to a device (10) for training respiratory muscles comprising:
- one or more vertical chambers (11a, 11 b, 11c) with at least one aperture (12a, 12b, 12c) in their lower sections in order to place the interior of the chamber in communication with the outside environment, and an aperture in their upper wall (13a, 13b, 13c) to place the chamber in communication with a common conduit (14);
- a mobile obstacle (15a, 15b, 15c) in each vertical chamber, of similar cross-section and dimensions lower than those of the chamber, so that said obstacle does not completely obstruct the cross-section of the chamber;
- an aperture (16) in said common conduit, to which a tubular fitting (17) is connected;
- a flexible tube (20) fitted to said tubular fitting, with a mouthpiece (21) at the end opposite to that fitted to the tubular fitting; and
- a connector (18; 18a; 18b; 18c; 50) inserted between the tubular fitting and the flexible tube, inside of which a particle filter (19) is housed, and comprising a retaining element for said filter downstream of it, along the direction of the flow of air inside the device when this is in use.

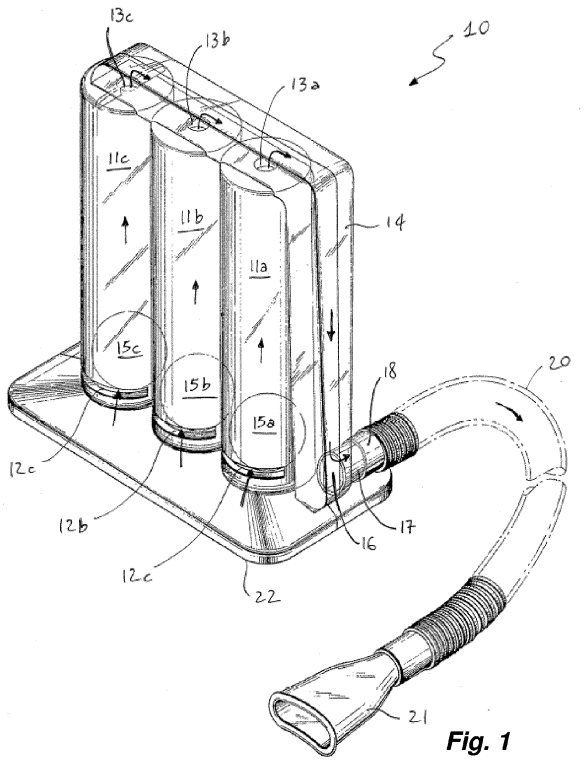

Fig. 1

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Description

Field of the invention

[0001] The present invention concerns a device for training the respiratory muscles comprising a detachable connector with filter.

[0002] Respiratory muscle training devices are used to improve respiratory capacity and strengthen the relevant muscular system in patients with respiratory insufficiencies, due to their general condition, as in the case of chronic bronchitis (CB) or the dysfunction known as "chronic obstructive pulmonary disease" (COPD), or the consequences of surgical procedures for example. Insufficient use of respiratory capacity can lead to complications such as pulmonary congestion or hypostatic pneumonia.

State of the art

[0003] Respiratory muscle training devices with various constructions and geometries are known in the art; in this matter, for example, reference should be made to the following patents US 3,695,608, US 4,060,074, US 4,171,804 and US 4,363,328.

[0004] A geometry of respiratory muscle training device that has found broad application in practice is the one described in patent US 4,060,074. This known device consists of three vertical chambers made of transparent plastic, each of which has at least one aperture in its lower section communicating the interior of the chamber with the external environment, and one aperture in the upper wall of the chamber communicating the latter with a common inhalation conduit. Besides the apertures, the inhalation conduit has at one end an additional aperture to which a tubular fitting is connected. The three chambers each contain a low-weight sphere of diameter less than the interior of the chamber; said three spheres are not all of the same diameter, and in particular, the spheres inside the two chambers closest to the tubular fitting have diameters equal to one another and greater than the sphere in the third chamber. At the time of use, a flexible tube is fixed to the fitting, at the opposite end of which a mouthpiece is fitted.

[0005] During the respiratory muscle training exercise, the patient inhales air through the mouthpiece (preferably attempting to maintain regular and constant inhalation); this results in air being drawn through said tube, inhalation conduit and chambers from the external environment through the apertures in the lower sections of said chambers. The flow of air inside the three chambers moves upwards and encounters the three spheres as obstacles; given the differences in diameters, the spheres in the first two chambers offer greater resistance to the flow of air compared to the sphere in the third chamber. As a consequence of the different resistance to the passage of air in the chambers, the sphere inside the chamber closest to the fitting is initially carried towards the top of the chamber by the flow of air, and if the patient is capable of inhaling a sufficient quantity of air, the aperture in this chamber is closed; when this condition is achieved, the air inhaled is only that arriving from the second and third chambers (in order of distance from the fitting), and again the sphere offering greatest resistance to the air flow is carried upwards, namely the sphere inside the second chamber, until eventually the upper aperture in that chamber is closed. If also this aperture is closed as a result of inhalation by the patient, the inhaled air comes exclusively from the third chamber, and transports the third sphere towards the upper section thereof. If the patient has sufficient inhalation capacity to also raise the last sphere towards the upper part of the third chamber, the upper aperture in said chamber has a spacer preventing said aperture from being closed, that would result in the sudden stoppage of inhalation causing the patient possible decompensation.

[0006] Inside the inhalation conduit, at the aperture to which the fitting is connected, there is a filter, generally held in place by retaining elements. The purpose of said filter is to prevent particles entering the system through the lower apertures in the three chambers from being inhaled by the patient, with potential serious consequences such as coughing fits and severe respiratory decompensation. However, with time, the pores of the filter have a tendency to become clogged due to particles of dust that have entered through said lower apertures in the chambers being carried to the filter itself by the flow of air through the inhalation conduit. A clogged filter alters the functional characteristics of the system, requiring greater inhalation exertion the more the filter is clogged, until the device becomes unusable. Furthermore, the filter can also trap gasseous substances or vapours, bacteria or viruses exhaled by the patient during periods of rest between one inhalation cycle and another. These substances, bacteria or viruses can then be re-inhaled by the same patient during the subsequent inhalation cycle, or worse, by another patient, if the respiratory muscle training device is used by several people, thus with non-hygienic results; therefore, ideally, the filter should be washed after each respiratory muscle training session, or at most after a few of such sessions.

[0007] One problem with the aforementioned device, just as with other similar known devices, is that the filter is located in such a position that it cannot be removed for washing or regeneration, or for replacement.

[0008] The scope of the present invention is to provide an improved respiratory muscle training device that is free of the problems of the known devices.

Summary of the invention

[0009] These and other scopes are achieved with the present invention with a respiratory muscle training device comprising:

- one or more vertical chambers made of rigid trans-

parent material, with at least one aperture in their lower section placing the interior of the chamber in communication with the external environment, an aperture in their upper wall placing them in communication with a common conduit, and a spacer present in the single chamber, or in the chamber corresponding to the longest path of air in the common conduit, preventing a mobile obstacle present in this chamber, at its position of maximum height within the same, from completely obstructing said aperture in the upper wall;

- a mobile obstacle in each of said one or more vertical chambers, with similar cross section and dimensions less than those of the chamber in which said mobile obstacle is present, such as not to completely obstruct the section of the chamber;
- an aperture in said common conduit to which a tubular fitting is connected;
- a flexible tube connected to said tubular fitting, with a mouthpiece at the end opposite to that fitted to the connector;

characterised in that a removable and replaceable connector is inserted between said tubular fitting and said flexible tube, inside of which a particle filter is housed, and comprising a retaining element for said filter downstream of it, along the direction of the flow of air inside the device when it is in use.

Brief description of the figures

[0010]

- Figure 1 shows a generic embodiment of the respiratory muscle training device according to the invention;
- Figure 2 shows a prespective and cut-away view of a first embodiment of the connector for use in the device of the invention;
- Figure 3 shows a cross-section view of a second embodiment of the connector for use in the device of the invention;
- Figure 4 shows a cross-section view of a third embodiment of the connector for use in the device of the invention;
- finally, Figure 5 shows a variant of the connectors of Figures 2-4.

Detailed description of the invention

[0011] In the figures, the various parts of the device of the invention are not necessarilly to scale; identical numbers in the various figures indicate identical or corresponding elements. Furthermore, in the figures, the arrows indicate the direction of the air flow during the respiratory exercise performed by the patient.

[0012] The device of the invention may have any geometry or configuration among those known in the field, for example, it may be of the type with a single chamber containing a mobile obstacle to be raised by means of inhalation, such as those described in patents US 3,695,608 and US 4,171,804. In the remainder of the description however, particular reference is made to the type with three chambers, such as that described in patent US 4,060,074, since this is the most common configuration.

[0013] Figure 1 shows a possible device of the invention, in the preferred embodiment with three parallel chambers.

[0014] The device, 10, comprises three vertical chambers, 11 a, 11 b and 11c, made from transparent material, each of which has at least one aperture (12a, 12b and 12c) in its lower section, placing the inside of said chamber in communication with the external environment. Preferably, these apertures are in the form of slots, as shown in Figure 1; even more preferably, each chamber has two of said slot-shaped apertures, facing towards the two main faces of the device; the presence of double apertures in each chamber makes easier the entry of air into the same following inhalation by the patient, thus simplifying the breathing exercise. With the device in the resting state (*i.e*. not in use), these apertures (12a, 12b and 12c) must be located in a sufficiently low part of the chamber as to be below the mobile obstacle, if this is cylindrical in shape; if the mobile obstacle has a cross-section varying along the axis of the chamber, as in the case of a spherical obstacle, the apertures must be located at a level below that of the largest cross-section of the obstacle in the device while in the resting state. Each chamber then has an aperture (13a, 13b and 13c) in the upper section, placing the interior of the same in communication with a common conduit 14.

[0015] Inside each chamber is present a mobile obstacle of similar cross-section and dimensions lower than those of the chamber; even though chamber and obstacle could in theory have any cross-section (square for example), normally said cross-section is circular, also due to the simplicity of manufacturing with plastic materials. Figure 1 shows the obstacle in its most common embodiment, *i.e*. in spherical form. The three spheres 15a, 15b and 15c have diameters less than those of the corresponding chambers. The construction of the device 10 and selection of the three spheres 15a, 15b and 15c may be such that resistance to the passage of air is maximal in chamber 11a, intermediate in 11b, and minimal in 11c; this condition is obtained most conveniently by making the three chambers 11a, 11 b and 11 c of equal cross-section, and using three spheres with diameters decreasing in the order 15a > 15b > 15c. Preferably however, the device is such that resistance to the passage of air is equal in chambers 11a and 11 b and greater than that offered by sphere 15c in chamber 11c; this condition is conveniently obtained with chambers all of equal cross-section and spheres having diameters Ø15a = Ø15b > Ø15c, as described for the known device of patent US 4,060,074. These spheres must have reduced weight, in

the order of a few grams (for example between 2 and 10 grams) in order to be raisable by the air flow caused by the patient inhaling, and are generally made from plastic material and hollow inside.

[0016] The conduit 14 has an additional aperture, 16, connected to a tubular fitting 17; said aperture 16 and fitting 17 are normally of circular cross-section, as in the case represented in Figure 1.

[0017] Connected to the fitting 17 is a connector, 18, housing the filter 19 (not visible in Fig. 1) in its interior for preventing the inhalation of particulates by the patient during respiratory exercise.

[0018] The connector 18 is connected to the flexible tube 20 having the mouthpiece 21, appropriately shaped to allow easy inhalation by the patient; preferably, the mouthpiece 21 is removable and replaceable.

[0019] The base (22) of the device may be detachable from the chamber assembly, in order to allow periodic cleaning of the same.

[0020] As already mentioned, at least chambers 11a, 11b and 11c must be made from rigid transparent material, preferably plastic materials such as polycarbonate, polyethylene, or polyester (e.g. PET); for convenience, the entire device may be made from the same material as the chambers (using a single material simplifies production), aside from the tube 20, the filter 19 and possibly the spheres 15a, 15b and 15c. The tube 20 must be flexible, and is therefore generally produced from plastic materials such as polyethylene or polypropylene; the filter 19 may be produced using natural materials, such as washed cotton fibre, but is preferably produced using synthetic materials such as cross-linked polyester foams, soft polyeurethane foams, or the like. The filter pore size is generally between 0.2 and 1.2 mm. It is preferable to avoid excessively small pore sizes, below the lower limit inidicated, since a filter with excessively small pores might constitute an obstacle to the passage of air and would make the exercise excessively laborious. On the other hand, pore sizes in excess of the aforementioned maximum limit might not guarantee particulates being held; even if the value of 1.2 is relatively high with respect to the dimensions of particulates, the filter in any case remains effective due to the tortuous route particulates must take inside it, and the bottlenecks existing in the channels inside the filter itself.

[0021] Unlike known devices, in which the filter is located inside the common conduit 14, from where it is impossible to remove it for cleaning, in the device of the invention the filter 19 is located inside the connector 18. The connector may be made with several geometries, as illustrated below, so that the filter may be easily extracted for cleaning; even in the case where the filter may not be extracted from the connector, replacement of the filter only requires replacement of the connector, and not of the entire device. In the remainder of the description, the number 18 shall be used to indicate a connector of the invention in general, while the numbers 18a, 18b, 18c and 18d shall be used to indicate specific connectors with defined geometries.

[0022] Figure 2 shows a first potential embodiment, 18a, of the connector characterising the device of the invention. The connector 18a, shown fitted in the relevant part of the device, has an internal diameter equal to the external diameter of the fitting 17, and an external diameter equal to the internal diameter of the tube 20. Inside the connector 18a there is a holding element, 23, indicated by dotted lines, preventing the filter 19 from being transported by the air flow during breathing exercises; this element 23 may be a simple bar, a cross-shaped element, or a wide spaced grille, and is made as a single piece with the walls of the connector 18a using known methods in the plastic moulding sector. The connector has a narrowing in cross-section at its end, resulting in the formation of a ring 24 that holds the filter 19 in its housing inside the connector. In the case where the filter 19 is made from flexible material, it may be easilly extracted from said housing, for example using forceps, for washing. A connector, analogous to that in Figure 2, might be made without the ring 24 (a case not represented in the figures), further facilitating the extraction of the filter for cleaning or replacement.

[0023] Figure 3 shows a second possible embodiment of the connector characterising the device of the invention. This connector, 18b, has two ends, 30 and 30', for connection to fitting 17 and tube 20 respectively, and a central portion 31 with enlarged cross-section with respect to said ends, wherein the filter 19 is housed. In this case, the shape of part 31 itself constitutes the filter retaining element, preventing said filter from being moved by the flow of air during inhalation by the patient. A connector of type 18b has the advantage that the lateral surface of the filter is significantly greater with respect to the cross section of the fitting 17, of the tube 20 and of ends 30 and 30', thus reducing the effort required by the patient to inhale air. The connector 18b may be a single piece obtained by welding or gluing two halves.

[0024] Figure 4 shows a third possible embodiment of the connector characterising the device of the invention; in the left side of Figure 4 the fitting 17, the connector and the tube 20 are shown separated from one another, in order to highlight the relationships between said parts, while in the right side of Figure 4 the fitting 17, connector and tube 20 are shown connected to one another. This connector, 18c, has two parts with different cross-section, 40 and 41; part 40 has an internal diameter equal to the external diameter of the fitting 17, while part 41 has an external diameter equal to the internal diameter of the tube 20. With this embodiment, in the zone with narrowed cross-section between parts 40 and 41, a ledge is formed constituting the retaining element for the filter 19 and preventing it from being moved by the flow of air. As shown in the right side of Figure 4, by appropriately selecting the length of the part 40 and the thickness of the filter 19, it is possible to have it such that in the assembled device, the end of the fitting 17 constitutes a second ledge that holds the filter 19 fixed in position in-

side the assembled device of the invention. The filter 19 may easilly be removed from the connector of type 18c for cleaning, by extracting it from the part 40 using forceps, or by pushing it out of the part 40 using any kind of tool, or even by simply blowing from part 41. With this type of connector, the filter need not necessarilly be made of soft material to be extractable, and may be made from a rigid polymer foam (for example a rigid polyurethane foam).

[0025] Finally, Figure 5 shows a variant of the connector 18, which can be made with the connector geometries described above with reference to Figures 2, 3 and 4; this variant is exemplified with reference to the geometry of the connector 18a of Figure 2 (even if the connector in this case has an external diameter equal to the internal diameter of the part 17, and has no narrowing 24), but it would be apparent to one skilled in the art how to modify this structure in order to adapt it to the connectors of Figures 3 or 4. The connector of this variant, 50, includes a branch 51 for connection to another tube, through which the air inhaled by the patient can be enriched with oxygen (as shown by the arrow indicating O_2) . Again with the scope of avoiding the patient inhaling particulates, the insertion point of the branch 51 on the juction 50 is upstream of the filter 19 along the direction of the flow of air inhaled by the patient. The addition of small quantities of oxygen to the air inhaled by the patient is useful since it has therapeutic effects.

[0026] The filter 19 may be humidified and/or soaked in balsam and/or therapeutic substances; humidification is particularly useful in the case where the air inhaled by the patient is enriched with oxygen (connector 50), because despite having therapeutic effects, oxygen tends to dry mucosae.

[0027] In all embodiments of the connector 18 (18a, 18b, 18c and 50), its connection to the fitting 17 and the tube 20 may be achieved by simply sliding the parts in relation to one another, which are held in position by friction; alternatively, the connector 18 and the parts 17 and 20 may have suitable threading and be screwed together.

[0028] The parts 17 and 20 and the connector 18 may have variable dimensions, and in particular diameters. Typical diameters of these parts are comprised between 10 and 15 mm; for example, in the configuration of Figure 2, typical values are an external diameter for the part 17, equal to the internal diameter of the connector 18a, of 11.5 mm, and an external diameter for the connector 18a, equal to the internal diameter of the tube 20, of 13.5 mm.

Claims

1. A device (10) for training respiratory muscles comprising:

- one or more vertical chambers (11a, 11b, 11c) made of rigid transparent material, with at least one aperture (12a, 12b, 12c) in their lower section placing the interior of the chamber in communication with the external environment, an aperture in their upper wall (13a, 13b, 13c) placing them in communication with a common conduit (14), and a spacer present in a single chamber, or in the chamber (11c) corresponding to the longest path of air in the common conduit, preventing a mobile obstacle present in this chamber, at its position of maximum height within the same, from completely obstructing said aperture in the upper wall;
- a mobile obstacle (15a, 15b, 15c) in each of said one or more vertical chambers, with similar cross section and dimensions lower than those of the chamber in which said mobile obstacle is present, such as not to completely obstruct the section of the chamber;
- an aperture (16) in said common conduit (14) to which a tubular fitting (17) is connected;
- a flexible tube (20) connected to said tubular fitting, with a mouthpiece (21) at the end opposite to that fitted to the connector;

characterised in that a removable and replaceable connector (18; 18a; 18b; 18c; 50) is inserted between said fitting and said flexible tube, inside of which a particle filter (19) is housed, and comprising a retaining element for said filter downstream of it, along the direction of the flow of air inside the device when it is in use.

2. The device according to claim 1, comprising:

- three vertical chambers (11a, 11 b, 11c) with at least one aperture (12a, 12b, 12c) in their lower section and an aperture in their upper wall (13a, 13b, 13c) placing them in communication with a common conduit (14);
- mobile obstacles (15a, 15b, 15c), one in each of said three vertical chambers, each one of similar cross-section and lower dimensions than those of the chamber in which it is present, such that the resistance to the passage of air offered by two of said mobile obstacles (15a, 15b) in the two chambers (11a, 11b) closest to the aperture (16) to which the tubular fitting (17) is connected is greater compared to the resistance to the passage of air offered by the third mobile obstacle (15c) in the third chamber (11c);
- a spacer in said third chamber (11c) preventing the mobile obstacle (15c) present in this chamber, in its position of maximum height inside the same, from completely obstructing said aperture (12c) in the upper wall (13c).

3. The device according to one of claims 1 or 2, wherein said one or more vertical chambers have two apertures in their lower section facing towards the two

main opposite faces of the device.

4. The device according to any one of the previous claims, wherein said one or more chambers are made from a plastic material selected from polycarbonate and a polyester, the flexible tube is made from a plastic material selected from polyethylene or polypropylene, and the filter is made from a material selected from cross-linked polyester foams and soft polyurethane foams.

5. The device according to any one of the previous claims, wherein the connector (18a) has an external diameter equal to the internal diameter of said fitting (17) and tube (20), is connected to said fitting and tube by sliding inside them, and has a retaining element (23) transversal to the axis of the connector and a narrowing of the cross-section upstream of the filter with the formation of a ring (24) holding said filter 19 in the defined position inside the connector.

6. The device according to claim 5, wherein said retaining element (23) is a bar, a cross-shaped element, or a wide-spaced grille.

7. The device according to any one of claims 1 to 4, wherein said connector has an internal diameter equal to the external diameter of said fitting (17) and said tube (20) and is connected to said fitting and tube by sliding over their exteriors.

8. The device according to any one of claims 1 to 4, wherein the connector (18b) has two ends (30, 30') for connecting to said fitting (17) and said tube (20) and a central portion (31) of enlarged cross-section with respect to said ends inside which the filter (19) is housed.

9. The device according to claim 8 wherein said connector (18b) is a single piece obtained by welding or gluing two halves.

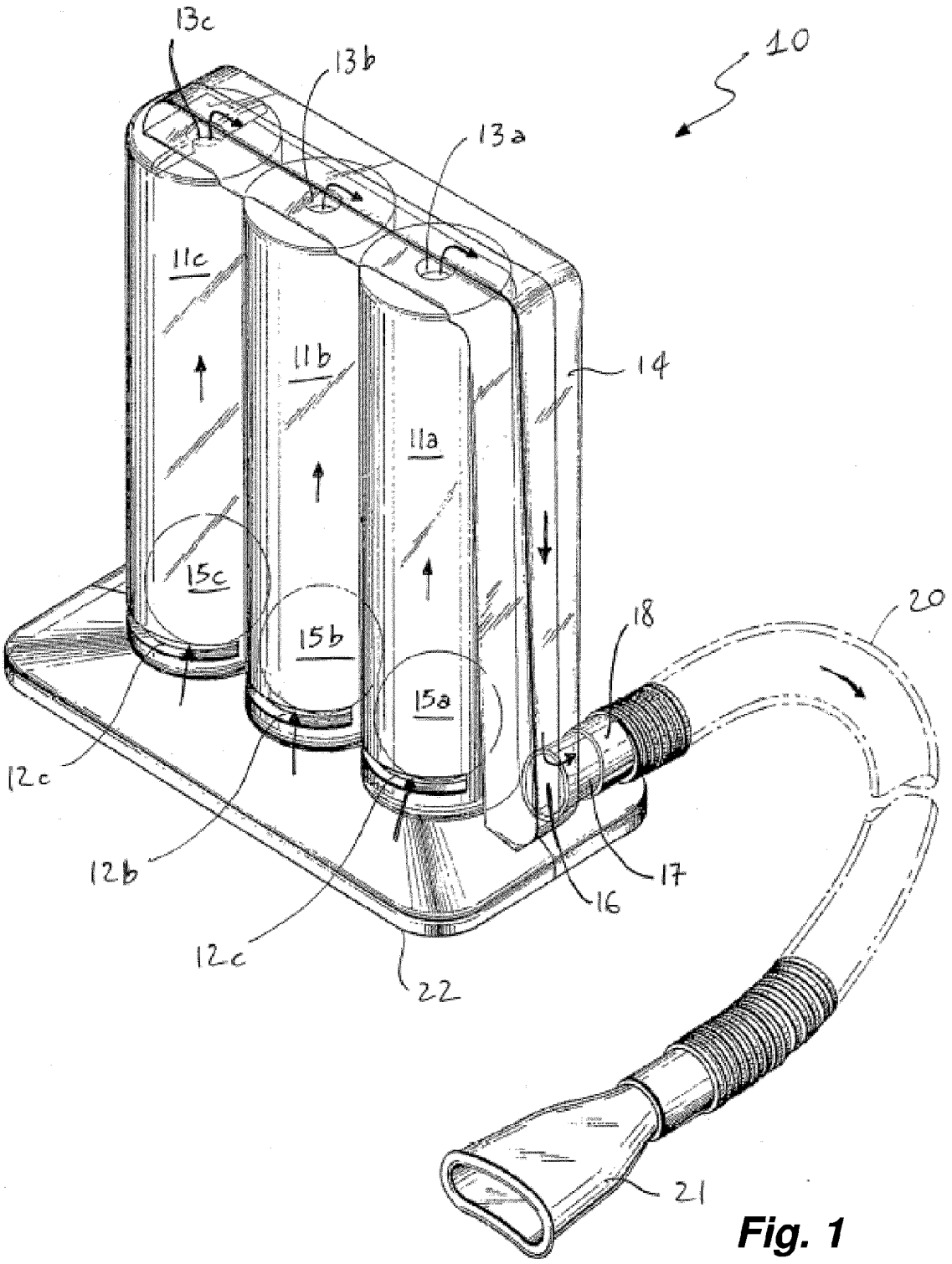
10. The device according to claim 8 wherein said connector (18b) consists of two threaded parts joined by being screwed together.

11. The device according to any one of claims 1 to 4, wherein the connector (18c) has two parts with different cross-sections (40, 41), the part with greater cross-section (40) having internal diameter equal to the external diameter of said fitting (17) and the part with lower cross-section (41) having external diameter equal to the internal diameter of said tube (20), with the narrowing in cross-section between said parts with different cross-sections forming a ledge constituting said retaining element.

12. The device according to any one of the previous claims, wherein said connector (50) comprises a branch (51) on one of the two parts to be assembled onto said fitting (17) or tube (20) for connecting to an additional tube by means of which it is possible to introduce oxygen into said flow of air.

13. The device according to any one of the previous claims, wherein the base (22) of the device may be disconnected from the chamber assembly in order to allow periodic cleaning of the same.

14. The device according to any of the previous claims, wherein the filter (19) is humidified and/or soaked in balsam and/or therapeutic substances.


13c
13b
13a
10
11c
11b
11a
14
15c
15b
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18
20
12c
12b
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17
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21

Fig. 1

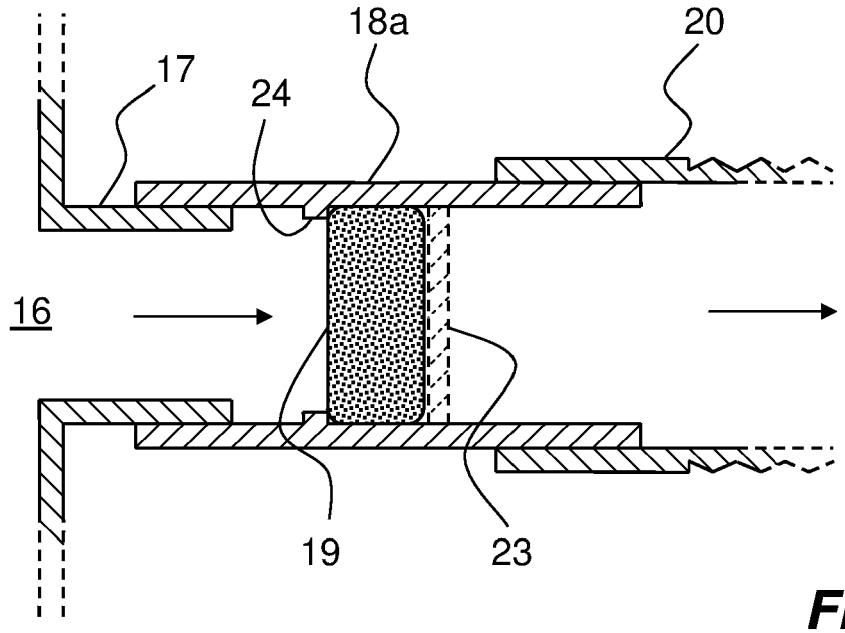


Fig. 2

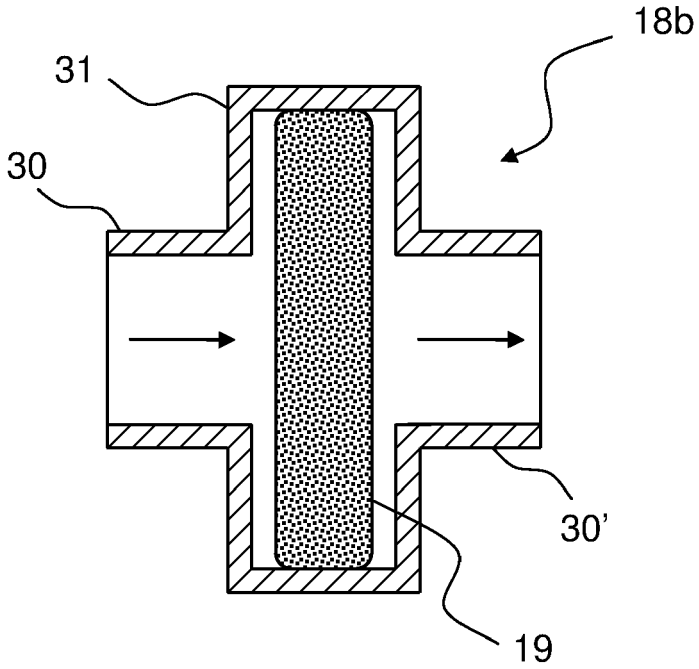


Fig. 3

Fig. 4

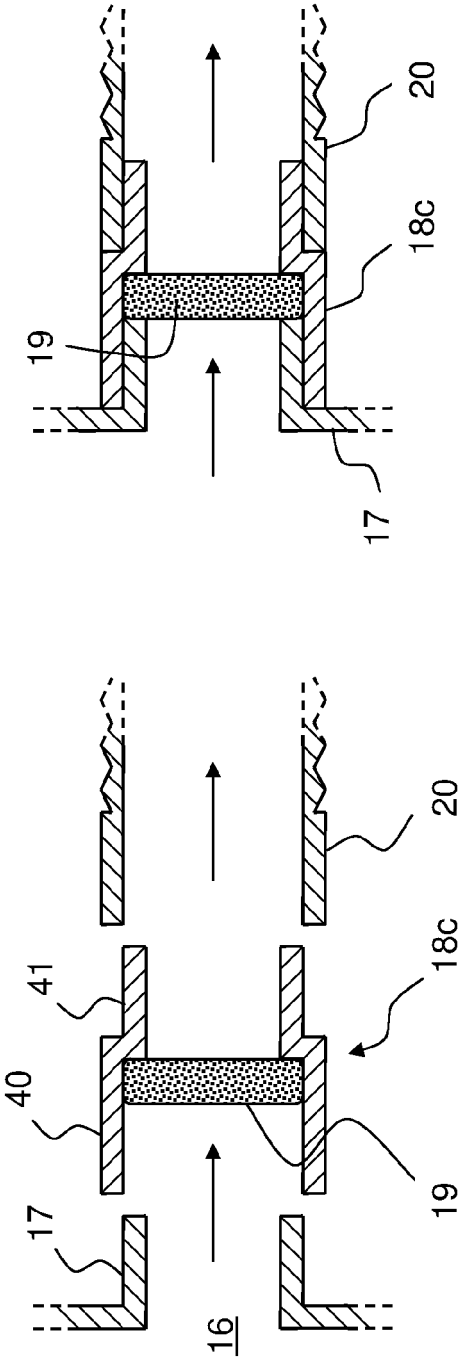
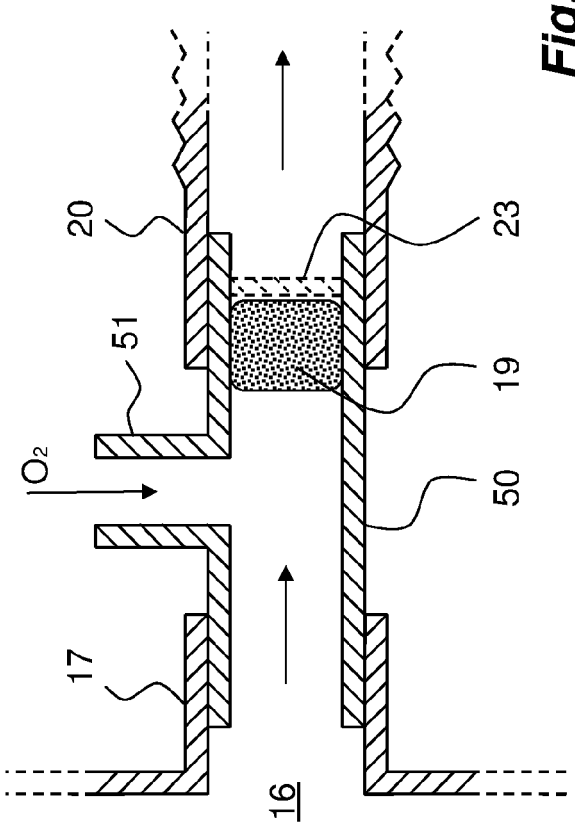


Fig. 5



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EUROPEAN SEARCH REPORT

Application Number
EP 12 16 0285

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
Y	US 4 114 607 A (RUSSO RONALD D) 19 September 1978 (1978-09-19) * claims 1-15; figures 1-15 *	1-14	INV. A61B5/08 A63B23/18 G01F1/22
Y	US 4 441 506 A (MCCOMBS NORMAN R [US] ET AL) 10 April 1984 (1984-04-10) * column 6, line 14 - column 7, line 55; figures 1-26 *	1-14	
Y	US 4 324 260 A (PUDERBAUGH GEORGE) 13 April 1982 (1982-04-13) * column 3, line 3 - column 3, line 64; figures 1-4 *	1-14	
			TECHNICAL FIELDS SEARCHED (IPC)
			A61B A63B G01F A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	28 September 2012	Shmonin, Vladimir

CATEGORY OF CITED DOCUMENTS

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1

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 12 16 0285

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28-09-2012

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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