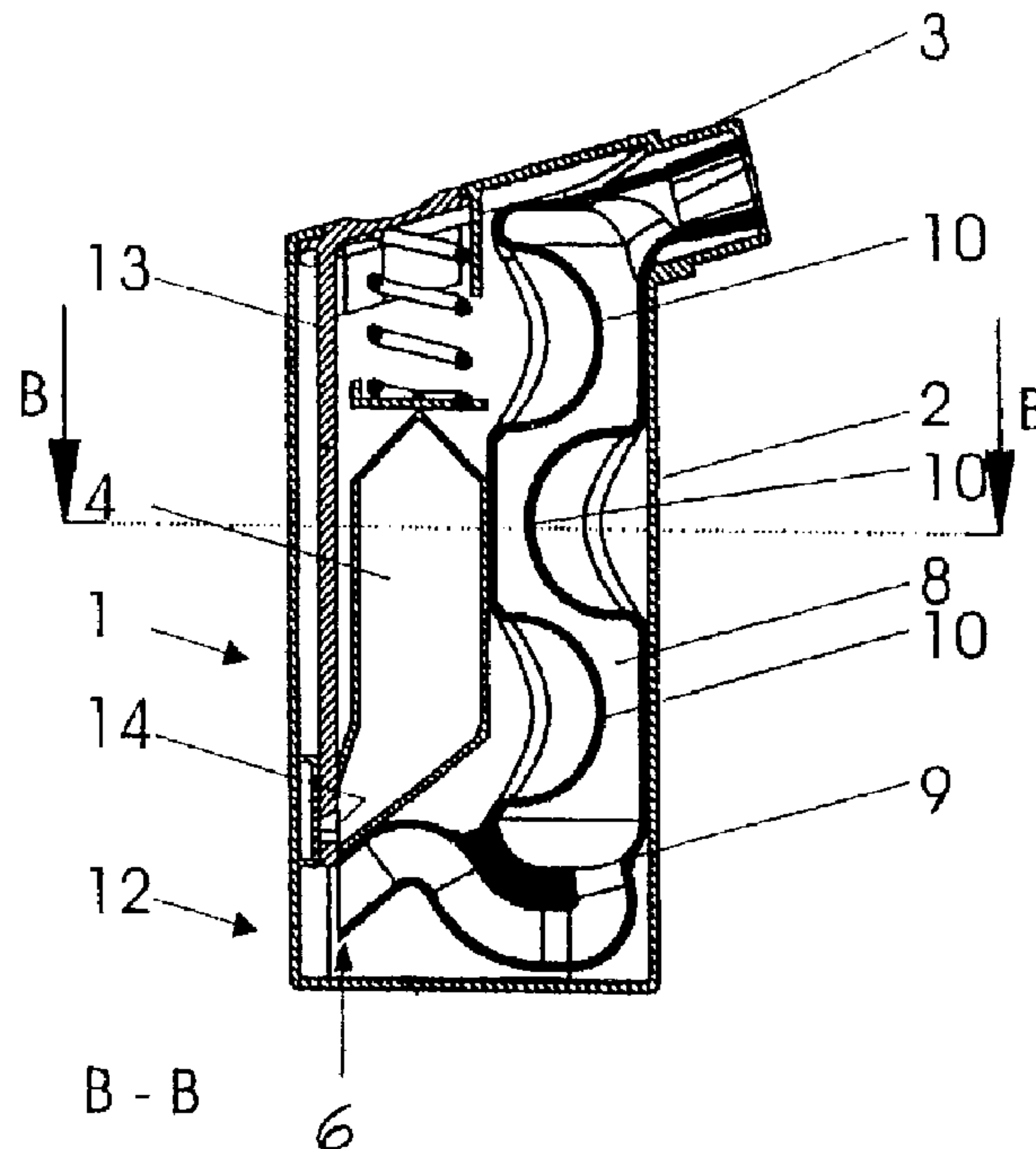




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(54) Titre : INHALATEUR DE RESPIRATION CONTROLÉE POUR POUDRE SECHE ET PROCÉDE DE REPARTITION UNIFORME DE LA POUDRE SECHE DANS L'AIR
 (54) Title: BREATHING-CONTROLLED INHALATION DEVICE FOR DRY POWDER AND METHOD FOR THE EVEN DISTRIBUTION OF SAID DRY POWDER IN THE AIR



(57) **Abrégé/Abstract:**

The invention relates to a breathing-controlled inhalation device for dry powder and is characterized by a simple design, small size and low production costs. The inventive device has a double dose protector and ensures complete and even distribution of the dry powder during the inhalation procedure. Also disclosed is a method which enables a complete and even respirable distribution of the dry powder to be inhaled in the air. The reservoir is coupled to a dosing conveyor dips into submerged in the transfer area in such a way that a predetermined amount of dry powder can be positioned directly at the beginning of the air guiding unit and flowing air guided by the air guiding unit takes on a three dimensional zigzag-like shape. Air drawn in during inhalation is channeled in such a way that acceleration and subsequent deceleration of the air stream occurs alternately and turbulence of the direction of flow is induced.

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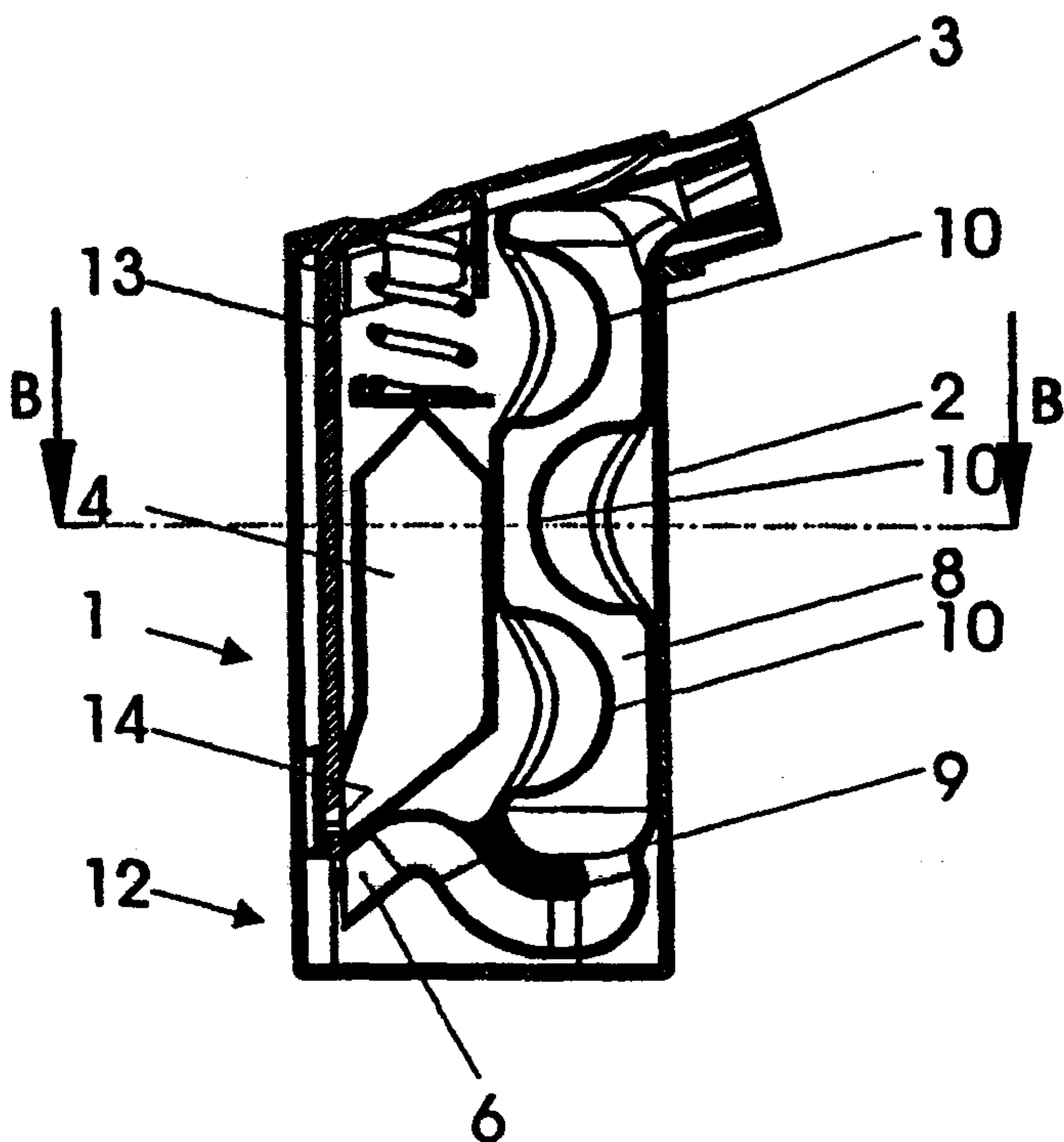
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(54) Title: BREATHING-CONTROLLED INHALATION DEVICE FOR DRY POWDER AND METHOD FOR THE EVEN DISTRIBUTION OF SAID DRY POWDER IN THE AIR

(54) Bezeichnung: ATEMZUGSKONTROLLIERTES INHALATIONSGERÄT FÜR TROCKENPULVER UND VERFAHREN ZUM GLEICHMÄSSIGEN VERTEILEN DES TROCKENPULVERS IN LUFT



(57) Abstract: The invention relates to a breathing-controlled inhalation device for dry powder and is characterized by a simple design, small size and low production costs. The inventive device has a double dose protector and ensures complete and even distribution of the dry powder during the inhalation procedure. Also disclosed is a method is disclosed which enables a complete and even respirable distribution of the dry powder to be inhaled in the air. The reservoir is coupled to a dosing conveyor dips into submerged in the transfer area in such a way that a predetermined amount of dry powder can be positioned directly at the beginning of the air guiding unit and flowing air guided by the air guiding unit takes on a three dimensional zigzag-like shape. Air drawn in during inhalation is channeled in such a way that acceleration and subsequent deceleration of the air stream occurs alternately and turbulence of the direction of flow is induced.

(57) Zusammenfassung: Der Erfindung, die ein atemzugskontrolliertes Inhalationsgerät für Trockenpulver betrifft, liegt die Aufgabe zugrunde, ein solches Gerät zu schaffen, das sich durch einen einfachen Aufbau, eine geringe Baugröße und geringe Herstellungskosten

auszeichnet, mit einem Doppeldosierschutz ausgestattet ist und eine vollständige und gleichmässige Verteilung des Trockenpulvers während des Inhalationsvorganges gewährleistet. Weiterhin soll ein Verfahren geschaffen werden, welches eine vollständige und gleichmässige lungengängige Verteilung des zu inhalierenden Trockenpulvers in der Atemluft ermöglicht. Diese Aufgabenstellung wird erfindungsgemäss dadurch gelöst, dass die Vorratskammer

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Veröffentlicht:

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- *Vor Ablauf der für Änderungen der Ansprüche geltenden Frist; Veröffentlichung wird wiederholt, falls Änderungen eintreffen.*

Zur Erklärung der Zweibuchstaben-Codes, und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

mit einem Dosierförderer gekoppelt ist, der in den Übergabebereich derart eintaucht, dass unmittelbar am Anfang der Luftführungseinheit eine vorgegebene Menge an Trockenpulver positionierbar ist und dass die durch die anschliessende Luftführungseinheit strömende Luft eine dreidimensionale mäanderähnliche Form aufweist. Ferner wird die der Erfindung zugrundeliegende Aufgabe dadurch gelöst, dass die infolge der Atmung angesaugte Atemluft derart durch eine Luftführungseinheit geführt wird, dass abwechselnd eine Beschleunigung und ein nachfolgendes Abbremsen des Luftstromes bei gleichzeitiger Verwirbelung und Änderung der Strömungsrichtung erfolgt.

5

**Breathing-Controlled Inhalation Device for Dry Powder and
Method for the Even Distribution of the Dry Powder in the
Air**

10 The invention relates to a breathing-controlled inhalation
device for dry powder, particularly dry powder which has
been mixed with medicines, and consists of a casing with a
mouthpiece, a reservoir for the dry powder located in the
15 casing, as well as an air guiding unit between a transfer
area for the dry powder and the mouthpiece, whereby the res-
ervoir is connected to a dosing conveyor which dips in the
transfer area in such a way that a predetermined amount of
dry powder can be positioned directly at the beginning of
the air guiding unit and the attached air guiding unit has
20 an air-flow channel which is provided alternately with nar-
rowings and subsequent enlargements. Furthermore, the inven-
tion relates to a method for the even distribution of the
dry powder with a breathing-controlled inhalation device.

25 For a long time, one of the primary methods for the treat-
ment of respiratory diseases has been the introduction of
suitable agents into the respiratory tract. In this regard,
the devices used for this - often also as mechanisms to
stimulate transport - have gained an ever-growing signifi-
30 cance because of the increase in the number of respiratory
diseases in the last number of years. In particular, breath-
ing-controlled devices, which represent a mild alternative
to propellant-controlled devices, are being increasingly
used, since they do not have the unpleasant effect of a
35 stimulating colds.

A device of this type is known from DE 40 04 904 A1, in which the agent is kept ready on the periphery of a dosing drum and is regulated radially. The inside of the dosing drum contains a control unit for the active output of the divided inhalation amount from open dosing recesses with a radially outwards direction. Moreover, the bottom of the equally-angled distributed arranged dosing recesses forming slides are centrally cam-controlled. Since this control mechanism is additionally activated by a control key which lies practically along the whole length of the device, the expenditure in this regard is considerable. Moreover, the dosed medicines can be added by means of a forced emptying of the dosing recess. This can lead to a dangerous overdosage. In terms of volume, the space which remains for the reservoir represents only a fraction of the pocket-format device.

The DE 198 25 434 A1 describes an inhalation device in which the dosing device is made taut before the intake of the medicine and is held in this condition on a stopper which can be moved during inhalation. The dosing device is released and accelerated during inhalation, so that the accelerated movement is abruptly interrupted in that the stopper on the dosing device strikes the casing or the bottom of the casing. This sudden interruption of the rotation of the dosing device results in the powdery medicine being released from the dosing cavity at greater speed and being widely distributed in the air channel. This design is also relatively complicated and, in addition, demonstrates the lack of inclusion of flow-orientated air guidance. The air channel has a straight design and does not permit any circulation or turbulence of the agents to be inhaled.

Finally, the DE 43 40 768 A1 describes a device for the inhalation of powdery agents, which is provided with a special turbulence chamber in spiral form. Incidentally, the complicated construction design is also in this case disadvantageous. Furthermore, the turbulence chamber does facilitate a

certain evenness in the distribution of the powder. Nevertheless, the spiral turning of the turbulence chamber leads increasingly to friction and resistance points which prevent complete passage of the particles.

5

Furthermore, the US-A-5, 699, 789, an inhaler for dry powder, in which a dosing conveyor is provided, shows that the reservoir container which projects into the air-flow channel takes a predetermined amount of dry powder and is positioned
10 inside the air guiding unit. The air which passes through the air-flow channel has to move around both the reservoir container and a nose located near the inlet opening. In this way, a certain turbulence of the air is achieved, though it cannot be ensured that all the conducted dry powder is con-
15 veyed through the inlet opening in a homogenously distributed manner.

In the EP-A-938907 an inhalation device for dry powder is described in which inwardly projecting plates are provided
20 alternately in the air-flow channel in order to achieve a turbulence of the air. Because of the high volume of clearance areas in this device it cannot be ensured that the total amount of dosed powder is conveyed outwards during inhalation.

25

A similar inhalation device is shown in the WO-A-993305. Powder residue can also remain in the device in this case, which adulterates the dosage.

30 The invention therefore relates to the creation of a breathing-controlled inhalation device of the type mentioned at the beginning, which, as a result of a simple design with few single components, can be cost-effectively manufactured, has a small size, is provided with a double dose protector,
35 and with which a complete and even distribution of the dry powder during the inhalation procedure can be attained. Furthermore, a method is to be created which enables a complete

and even respirable distribution in the breath of the dry powder to be inhaled.

The challenge involved in the invention is solved in that
5 the air guiding unit consists of an essentially cylindrical
central component which is provided alternately with semi-
spherical indentations which reach from opposite walls of
the central component into the air-flow channel, and in that
the air-flow channel has a rising inhalation area in the ap-
10 plication area of the inhalation device, and finally in that
the dosing conveyor can be positioned directly downwards in
front of the inhalation area. An air guiding unit designed
in this manner permits a very effective and complete distri-
bution of the dry powder during the inhalation procedure,
15 since the air which has been drawn in circulates and the
rising particles can be mixed with each other in an optimal
way.

By means of this special arrangement of the inhalation area
20 the dry powder can, when required, get directly into the
air-flow channel and can from there be directly drawn in. In
this way, the risk of the intrusion of moisture or of an un-
intentional proportional loss of portioning during inhala-
tion is reduced.

25
In a further favourable design of the invention the casing
is provided with an air inlet which is positioned downwards
opposite the inhalation area. The opening of the device in
the form of the air inlet permits an increased intake of the
30 particles, independent of the remaining air.

Moreover, a further design is so constructed that the reser-
voir opposite the inhalation area is blocked in that the
dosing conveyor is designed as a flat slide which has a lat-
35 erally positioned dosing bore hole for the intake of the dry
powder, whereby the dosing drill hole is located in the
closed condition of the reservoir in this and in dosing po-
sition directly in front of the inhalation area of the air

guiding unit and that the slide essentially keeps the reservoir permanently locked. In this way a double dose protector can be ensured, since only the amount of dry powder located in the dosing drill hole is available for each inhalation procedure. Should the inhalation procedure be broken off or interrupted then the remainder of the dry powder located in the dosing drill hole is conveyed back into the reservoir or is removed from the inhalation area and is thereby not any more available for a further inhalation procedure.

10

A favourable design here ensures that the slide is held in a spring-loaded start position in which the reservoir is locked and that the slide is moveable against a spring resistance in the dosing position. A spring-controlled movement mechanism guarantees that accidental escape, unintended intrusion of moisture or an unintentional actuation of the device are practically excluded. Moreover, an important advantage of this design is that, because of the simplicity of the functional construction, besides the necessary readjusting spring, only one moving part (dosing conveyor) is required, which further guarantees the constant availability for use of the device and minimizes the risk of any possible errors.

25

The air guiding unit can have a single-part or multi-part design, whereby glass or plastic as cost-effective materials have proved themselves to be particularly suitable. Other suitable materials, such as metals, may also of course be used for the manufacture of the air guiding unit.

30

Furthermore, the challenge involved in the invention is solved in that the acceleration of the air-flow is effected by means of cross section narrowings in the air guiding unit in the form of semi-spherical indentations which project alternately into the air-flow channel in the air guiding unit from opposite walls of the central component. The air circulation and flow guiding provided in this special method make effective turbulence of the individual dry powder particles

35

possible. The movements of the air spread the particles evenly and guarantee optimum distribution at the moment of inhalation.

5 By means of the concentration of the flow of particles with kinetic energy their movement and distribution capacity is increased and a possible loss of energy caused by gravity is compensated, which makes for an overall improvement of the turbulence effect.

10

The invention is to be explained in greater detail in the following on the basis of a sample design.

In this context are shown:

15

Fig. 1a a front view of an inhalation device in non-operational mode with open mouthpiece conforming to the invention;

Fig. 1b a sectional view along the line A-A according to
20 fig. 1a;

Fig. 1c a sectional view along the line B-B according to
fig. 2b;

Fig. 1d a perspective representation of the inhalation
25 device according to fig. 1a - 1c conforming to the invention;

Fig. 2a a front view of an inhalation device in non-operational mode with closed mouthpiece conforming to the invention;

Fig. 2b a sectional view along the line A-A according to
30 fig. 2a;

Fig. 2c a sectional view along the line B-B according to
fig. 2b;

Fig. 2d a perspective representation of the inhalation
35 device according to fig. 2a - 2c conforming to the invention;

Fig. 3a a front view of an inhalation device in inhalation operative mode with open mouthpiece conforming to the invention;

- Fig. 3b a sectional view along the line A-A according to fig. 3a;
- Fig. 3c a sectional view along the line B-B according to fig. 3b;
- 5 Fig. 3d a perspective representation of the inhalation device according to fig. 3a - 3c conforming to the invention;
- Fig. 4a a front view of an inhalation device in inhalation operative mode with closed mouthpiece conforming to the invention;
- 10 Fig. 4b a sectional view along the line A-A according to fig. 4a;
- Fig. 4c a sectional view along the line B-B according to fig. 4b;
- 15 Fig. 4d a perspective representation of the inhalation device according to fig. 4a - 4c conforming to the invention;
- Fig. 5 an explosion drawing of the individual components of the breathing-controlled inhalation device conforming to the invention.
- 20

As shown in fig. 2a-d and 3a-d, the reservoir 4 is essentially kept locked on a permanent basis both in non-operational and operational mode by means of a dosing conveyor 7 (shown separately in fig. 5) designed as a slide 13 (also shown separately in Fig. 5). With regard to the dry powder located in the reservoir an intrusion of external moisture or impurities can thereby be almost ruled out.

30 The dosing conveyor 7 has a laterally positioned dosing bore hole 14 (displayed in fig. 1b) for the intake of the dry powder. Before the beginning of the inhalation procedure the dosing drill hole 14 is located in the reservoir 4. A cap 16 (shown separately in fig. 5) provides hygienic protection for the mouthpiece 3. After the cap 16 has been removed (fig. 1a and b) the inhalation device 1 is held perpendicularly to the mouthpiece 3 upwards and away from the mouth. After the user has first of all breathed deeply out, avoid-

35

ing contact with the mouthpiece - i.e. without blowing into the mouthpiece 3 - he then covers the mouthpiece 3 with the lips. To start the inhalation procedure and to transfer the dosing conveyor 7 into the dosing position the former is pressed down against a force which is generated by a spring 15 shown separately in fig. 5 (fig. 3b and 3d, as well as fig. 4b and 4d).

The dosing drill hole 14 is now located directly in front of the inhalation area 11 of the air guiding unit 5 (fig. 4b and 3b). Since reservoir 4 is connected to the dosing conveyor 7 in such a way that the former dips into the transfer area 6 and the predetermined amount of dry powder can be positioned directly at the beginning of the air guiding unit 5, it is ensured that no unintended loss of portioning before or during inhalation occurs.

The user now breathes in as deeply as possible through the mouth. By means of an air inlet 12 located in casing 2, which - as shown in fig. 3b - is positioned downwards opposite the inhalation area 11, air is drawn in and an air-flow is created inside the inhalation device 1. This carries the particles of the dry powder via the dosing drill hole 14 through the transfer and inhalation area 6, 11 and finally through the air guiding unit 5 until an escape of the particles through the mouthpiece 3 directly into the user's respiratory tract takes place.

Should the inhalation procedure be broken off or interrupted then the remainder of the dry powder located in the dosing drill hole 14 is conveyed back into the reservoir 4, in that the spring transfers the dosing conveyor into the start position, or is removed from the inhalation area and is thereby not any more available for a further inhalation procedure. In this way, the danger of a double dosage is avoided.

The air drawn in as a result of inhalation is conducted through an air guiding unit - shown separately in fig. 5 - in such a way that an alternate acceleration and subsequent deceleration of the air-flow takes place in the case of simultaneous turbulence and change in the direction of the flow.

This is made possible in that the air guiding unit 5 consists of an essentially cylindrical central component 9 which is provided alternately with semi-spherical indentations 10 which reach from opposite walls of the central component 9 into the air-flow channel 8.

The air guiding unit 5 can have a single-part or multi-part design, whereby glass or plastic as cost-effective materials have proved themselves to be particularly suitable. Other suitable materials, such as metals, may also of course be used for the manufacture of the air guiding unit.

The acceleration of the air-flow is thereby effected by means of cross section narrowings in the air guiding unit 5, which are alternately located on opposite sides in the air guiding unit 5. The air guiding unit 5, designed in this manner, permits a very effective and complete distribution of the dry powder during the inhalation procedure, since the air which has been drawn in circulates and the rising particles can be mixed with each other in an optimal way.

By means of the concentration of the flow of particles with kinetic energy their movement and distribution capacity is increased and a possible loss of energy caused by gravity is compensated, which makes for an overall improvement of the turbulence effect.

**Breathing-Controlled Inhalation Device for Dry Powder and Method
5 for the Even Distribution of the Dry Powder in the Air**

Reference List of Drawings

- 1 Inhalation device
- 10 2 Casing
- 3 Mouthpiece
- 4 Reservoir
- 5 Air guiding unit
- 6 Transfer area
- 15 7 Dosing conveyor
- 8 Air-flow channel
- 9 Central component
- 10 Indentation
- 11 Inhalation area
- 20 12 Air inlet (not shown)
- 13 Slide
- 14 Dosing drill hole
- 15 Spring
- 16 Cap

ClaimsWhat is claimed is:

1. Breathing-controlled inhalation device for dry powder, particularly of dry powder mixed with medicines,
5 consisting of a casing with a mouthpiece (3), a reservoir (4) for the dry powder located in the casing (2), as well as an air guiding unit (5) between a transfer area for the dry powder and the mouthpiece (3), whereby the reservoir (4) is connected to a dosing conveyor (7) which
10 dips in the transfer area (6) such that a predetermined amount of dry powder can be positioned directly at an end of the air guiding unit (5), characterized in that the air guiding unit (5) consists of an essentially cylindrical central component (9) with alternating semi-spherical indentations (10) along a longitudinal axis of
15 the air guiding unit (5) and opposite a plane collinear with said axis which reach from walls of the central component (9) into the air-flow channel (8) to form narrowings and enlargements, in that the air-flow channel (8) has a rising inhalation area (11), and in that the
20 dosing conveyor (7) can be positioned directly downwards in front of the inhalation area (11).
2. Breathing-controlled inhalation device according to claim 1, characterized in that the casing (2) is provided with
25 an air inlet (12) which is positioned downwards opposite the inhalation area (11).
3. Breathing-controlled inhalation device according to claims 1 and 2, characterized in that the reservoir (4) is located opposite the inhalation area (11), in that the
30 dosing conveyor (7) is designed as a flat slide (13) which has a laterally positioned dosing bore hole (14) for the intake of the dry powder, whereby the dosing bore hole (14) is in communication with the reservoir (4) and

in dosing position directly in front of the inhalation area (11) of the air guiding unit (5), and that the slide (13) essentially keeps the reservoir (4) permanently locked.

- 5 4. Breathing-controlled inhalation device according to claim 3, characterized in that the slide (13) is held in a spring-loaded start position, in which the reservoir (4) is locked and the slide (13) is moveable against a spring resistance in the dosing position.
- 10 5. Breathing-controlled inhalation device according to any one of the claims 1 to 4, characterized in that the air guiding unit (5) has a single-part or multi-part design.
6. Breathing-controlled inhalation device according to any one of the claims 1 to 5, characterized in that the air
15 guiding unit (5) is manufactured from glass, plastic or another suitable material.
7. Method for even distribution of dry powder in air with a breathing-controlled inhalation device for dry powder, in which the air drawn in as a result of inhalation is
20 conducted through an air guiding unit (5) with alternating acceleration and deceleration and with simultaneous turbulence and change in the direction of air-flow, whereby a predetermined amount of dry powder is in contact with the air-flow at an end of the air guiding
25 unit (5), characterized in that the acceleration of the air-flow is undertaken by means of cross section narrowings in the air guiding unit (5) in the form of alternating semi-spherical indentations (10) which project into the air-flow channel (8) in the air guiding
30 unit (5) from opposite walls of the central component (9).

8. A breathing-controlled inhalation device for dry powder medication comprising: a casing having a mouthpiece; a reservoir for dry powder medication within said casing; an air flow channel in said casing having an outlet coupled to said mouthpiece, an inlet and a transfer area, said channel comprising a generally cylindrical component having semispherical indentations formed alternately on opposite walls thereof and extending into said cylindrical component, said channel having a flow area which rises in the region immediately following said transfer area when said device is in the application position; and a dosing conveyor for delivering a predetermined amount of dry powder medication from said reservoir to said transfer area of said air flow channel.
9. The inhalation device of claim 8, wherein said reservoir has an outlet positioned above the inlet of said air flow channel and said dosing conveyor comprises a vertically movable slide member having a hole therein sized to receive a predetermined amount of dry powder medication, said slide member being sliceable between a first position at which said hole is opposite the outlet of said reservoir to receive said predetermined amount of dry powder medication and a second position at which said hole is opposite the inlet of said air flow channel to permit said predetermined amount of dry powder medication to be drawn into said air flow channel.
10. The inhalation device of claim 9, further comprising a spring normally urging said slide member to said first position, said slide member being manually movable against the spring resistance to said second position.
11. The inhalation device of claim 9 further comprising an air inlet in said casing opposite the inlet to said air flow channel.

12. The inhalation device of claim 9 wherein said slide member locks said reservoir against release of dry powder medication when in said second position and limits release of dry powder medication to the volume of said hole when in said first position.

5

13. The inhalation device of claim 8 wherein said indentations are integrally formed in the walls of said generally cylindrical component.

14. The inhalation device of claim 8 wherein said cylindrical component of said air flow channel is the flow area which rises in the region immediately following said transfer area and connects said transfer area to said mouthpiece.

10

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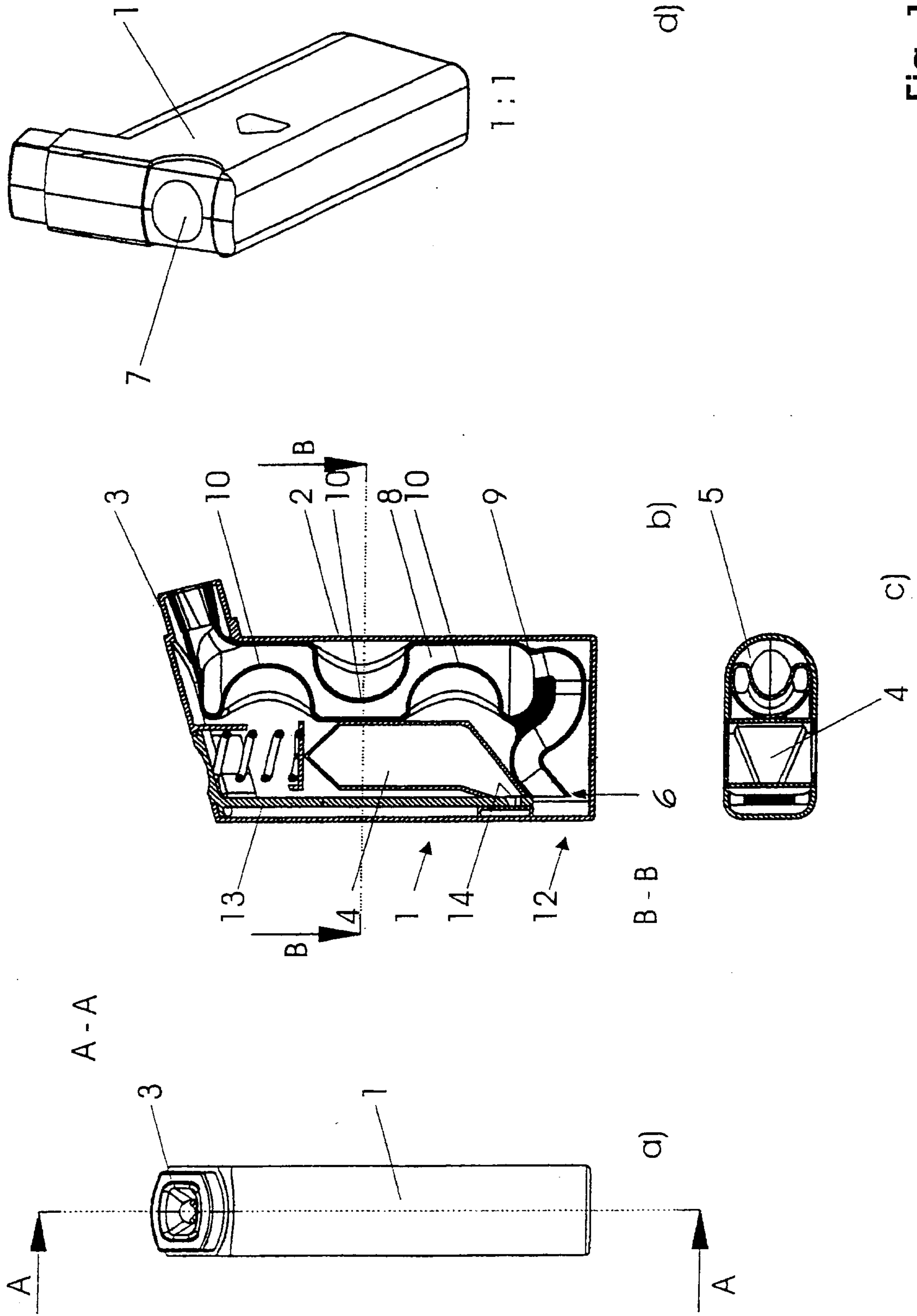


Fig. 1

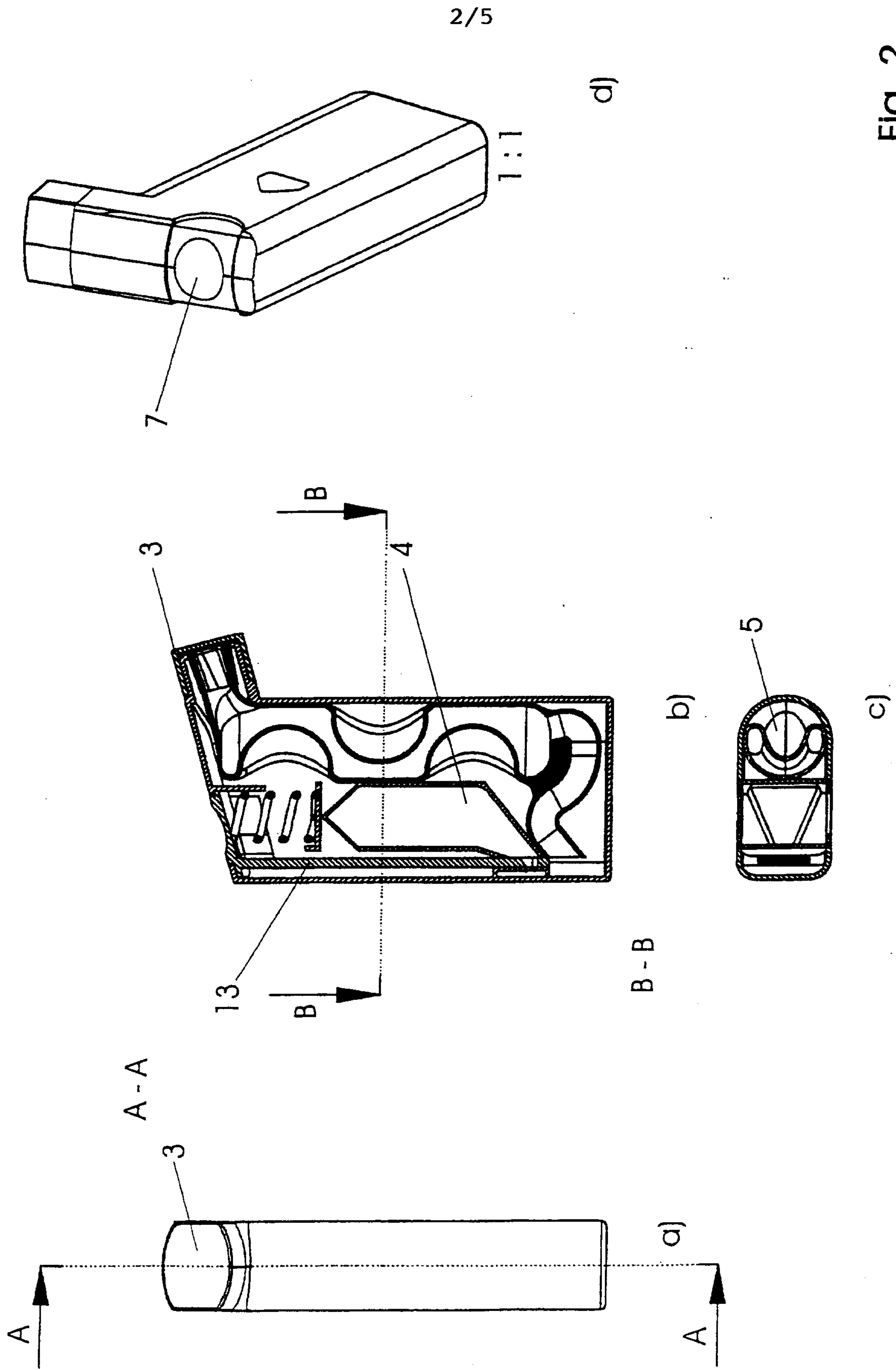


Fig. 2

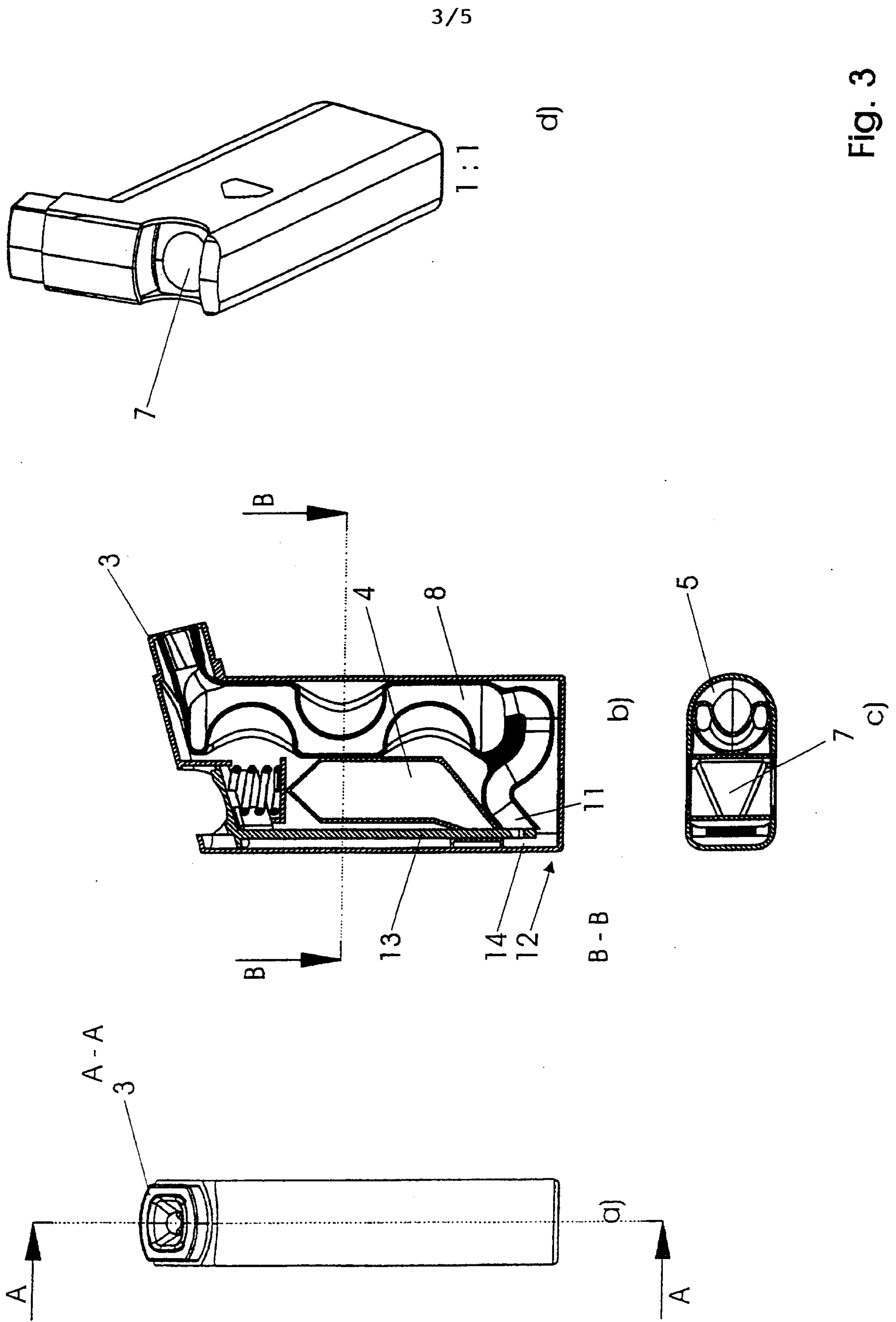


Fig. 3

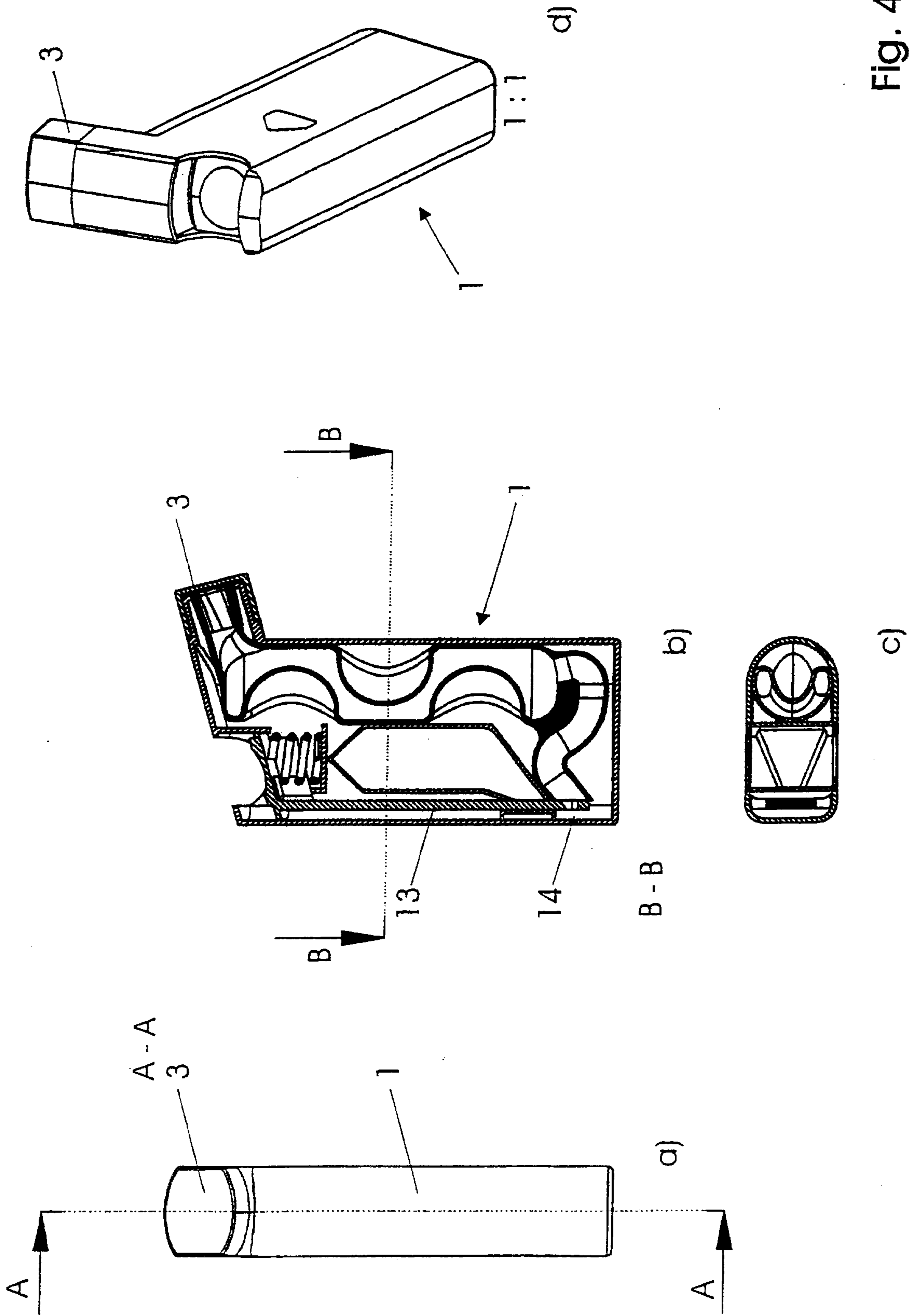


Fig. 4

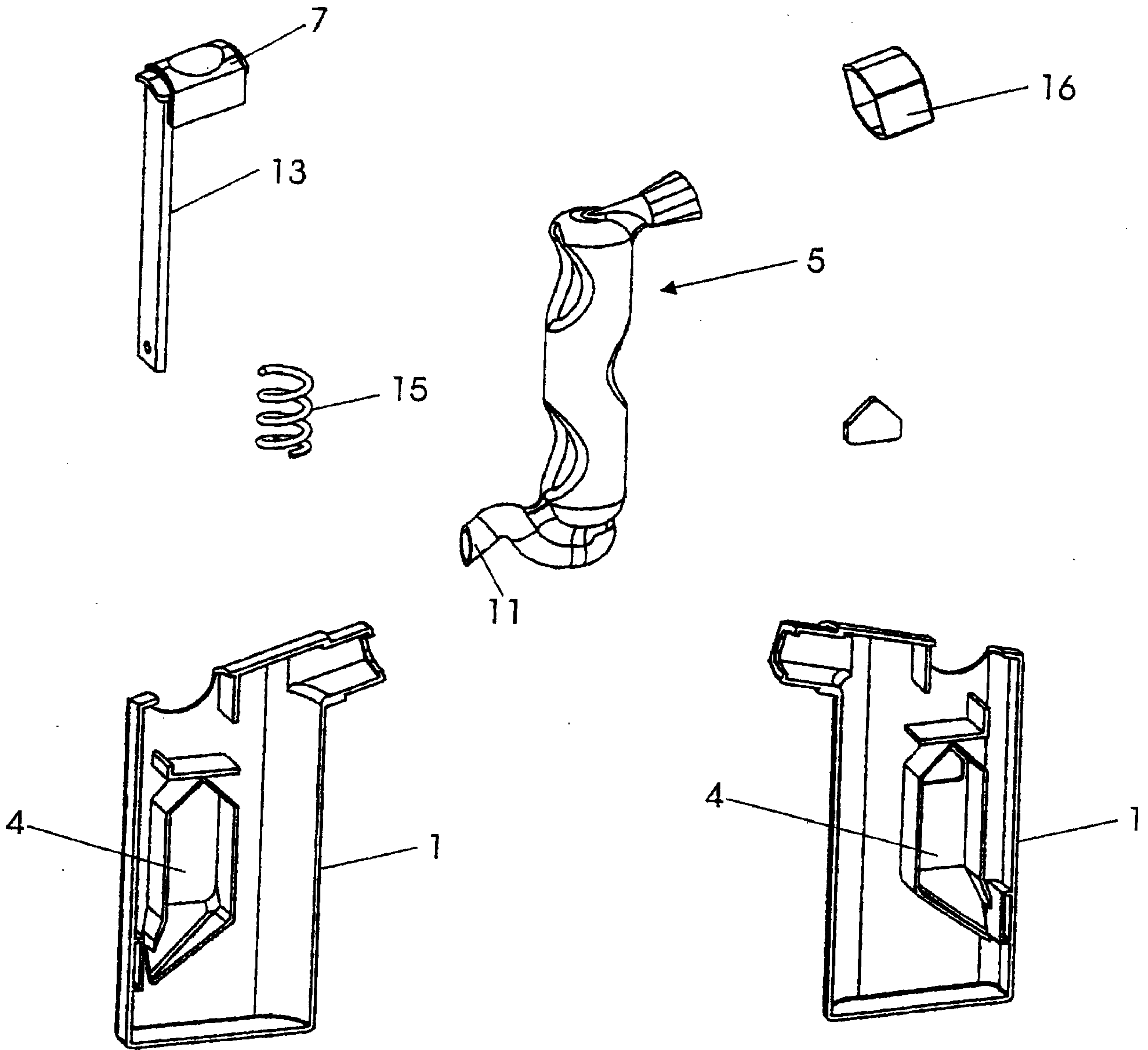


Fig. 5

