

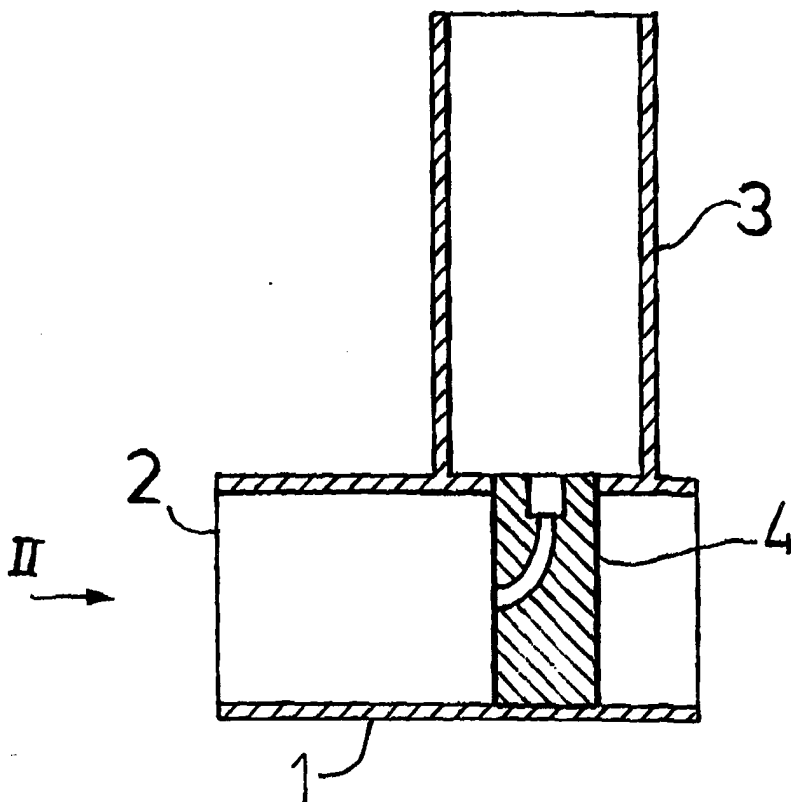


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(21) International Application Number: PCT/DK98/00021 (22) International Filing Date: 16 January 1998 (16.01.98) (30) Priority Data: 0057/97 17 January 1997 (17.01.97) DK (71)(72) Applicants and Inventors: DRACHMANN, Bo [DK/DK]; Dalbergstrøget 3, DK-2630 Taastrup (DK). ANDERSEN, Per [DK/DK]; Snerlehaven 61, DK-2630 Taastrup (DK). (74) Agents: JØRGENSEN, Bjørn, Barker et al.; Internationalt Patent-Bureau, Høje Taastrup Boulevard 23, DK-2630 Taastrup (DK).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>In English translation (filed in Danish).</i>

(54) Title: AEROSOL INHALER DEVICE**(57) Abstract**

The aerosol inhalation device is manually operated and comprises a holding part (3) for receiving an aerosol container with a valve and an outlet tip, and an inspiratory part (1), which at one end comprises a mouthpiece (2), in which inspiratory part (1) a member (4) for passage of aerosol is provided for receiving the outlet end of the aerosol container and comprising a conduit (5) with an outlet opening for discharging aerosol into the inspiratory part in the direction towards the mouthpiece (2). At the end opposite the mouthpiece (2) the inspiratory part (1) is open towards the surroundings such that air may pass freely from the surroundings past the member (4) for passage of aerosol and out through the mouthpiece (2).



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AEROSOL INHALER DEVICE

The present invention relates to a manually operated aerosol inhalation device comprising a holding part for receiving an aerosol container with a valve and an outlet tip, and an inspiratory part, which at one end comprises a mouthpiece, in which inspiratory part a member for passage of aerosol is provided for receiving the outlet tip of the aerosol container and comprising a conduit with an outlet opening for discharging aerosol into the inspiratory part in the direction towards the mouthpiece. Such inhalation devices are for instance known from DK-B-146675, DK-B-164082, DK-B-169464 and DK-B-169863.

DK-B-146675 describes an aerosol inhalation device with a swingably openable lid which in its closed position covers an inserted aerosol container to prevent activation thereof and which covers the mouthpiece to prevent it from becoming dirty.

DK-B-164082 describes an aerosol inhalation device with a lid and a rear piece, which are hinged in such a way that the rear piece, when the lid is open, acts as a trigger to facilitate activation of the aerosol container for dispensing a dose of aerosol.

DK-B-169464 describes an aerosol inhalation device, in which the member for passage of aerosol is designed with a special discharge spout which prevents depositing of hygroscopic aerosol particles at the outlet from the member for passage of aerosol.

DK-B-169863 describes another aerosol inhalation device with measures for preventing clogging of hydroscopic aerosol particles at the outlet from the member for passage of aerosol.

Common to these aerosol inhalation devices is, however, that air cannot flow freely through the device

past the member for passage of aerosol and out through the mouthpiece, the flow path towards the member for passage of aerosol being partly blocked by the aerosol container. The area of the flow cross section from the surroundings to the member for passage of aerosol to the mouthpiece is thus substantially limited relative to the area of the flow cross section from the member for passage of aerosol to the mouthpiece. This is a problem, as for instance asthmatics, which constitute a big group of users of aerosol inhalation devices, have difficulty in providing sufficient air flow for bringing the active particles of the aerosol down into the lungs. As a matter of fact in case of known devices only approx. 1/3 or less of the active particles is deposited in the lungs, whereas the rest is deposited in the mouth and the throat, where it is undesirable from a medical point of view.

The known manually operated aerosol inhalation devices are used in the manner that the user exhales into free air and then puts the inhalation device to his mouth, inspires and simultaneously presses on the aerosol container, for instance via a trigger, such that a dose of aerosol is dispensed. The air passage next to the container itself is, as mentioned, limited and does not provide the possibility of a proper inhalation through the mouth. The contents of the aerosol are injected as a jet of mist into the mouth towards the rear part of the throat, where the air flow from the nose catches the aerosol and takes its active particles and vehicles down into the lungs. By this method the mouth cavity acts like a relatively dead area with heavy fall-out of particles, and it is only possible for the part of the particles, which remains suspended in the air, to be brought further down into the lungs by means of the air flow from the nasal

intake of breath. Through good coordination and technique about one third or less of the active particles is deposited in the lungs by this method, and the rest is deposited at the back of the throat, where it is not
5 desirable from a medical point of view. A comparatively huge intake of breath is required to catch the suspended particles and to take them to the lungs, and in that respect asthmatics are often not able to produce such an intake of breath on account of the asthma. The
10 depositing of the active particles of the aerosol in undesired places may besides have some side effects in the form of local irritations or may for instance result in fungus. Therefore, patients are told to rinse the mouth after use of the aerosol, a request which,
15 however, is often not complied with.

In addition to the above manually operated aerosol inhalation devices, breath-activated devices are known, see for instance DK-B-136018, which shows a mechanic device, and WO-A-96/30068, which shows a computer-
20 controlled device. Common to these devices is, however, that they provide a pressure drop, which is used for activating a device for dispensing a dose of the aerosol. These pressure drops, however, undesirable for the above reasons.

25 US-A-4 984 158 discloses an apparatus for training a correct breathing performance and coordination with a view to the best possible exploitation of an inhalation device. The apparatus comprises an inspiration member which at one end is provided with a mouthpiece
30 and at its other end is provided with a flow-measuring device which provides a pressure drop, just as in case of the above-mentioned breath activated aerosol inhalation devices. The inspiration member carries a manually operated aerosol container, the discharge tip of which
35 points downwards towards a baffle plate which is to

guide the sprayed aerosol towards the mouth of the user. Such a baffle plate is, however, unreliable and thus unsuitable for conducting the aerosol in the desired direction.

5 Finally, DK-B-151934 discloses a powder inhalation device with a venturi-shaped air passage conduit for spraying a powdery medicament which is taken down into the air passage duct at its narrowest place. There is generally a considerable difference in the consider-
10 ations forming the basis of the design of an inhalation device for powders, which are allowed to drop down in an inspiratory air flow and the considerations forming the basis of the design of an inhalation device with a pressurized aerosol container, which sprays out the
15 substance.

The object of the invention is to provide an aerosol inhalation device which does not suffer from the above drawbacks of the prior art.

The object is according to the invention met by an
20 aerosol inhalation device of the type mentioned by way of introduction and which is characterized in that at the end opposite the mouthpiece the inspiratory part is open towards the surroundings such that air may pass freely from the surroundings past the member for
25 passage of aerosol and out through the mouthpiece, i.e. that the pressure drop at the flow of air from the surroundings to the member for passage of aerosol is not substantially bigger than the pressure drop occurring by the passage of air through the inspiratory part
30 from the member for passage of aerosol to the mouthpiece.

In a preferred embodiment the area of the flow cross section in the inspiratory part, possibly apart from the area around the member for passage of aerosol,
35 is substantially constant. This contributes to keeping

down the pressure drop through the inspiratory part.

In a further preferred embodiment the member for passage of aerosol is at its exterior side aerodynamically designed such that it offers the least possible resistance to the air flow in the inspiratory part and creates the least possible turbulence.

The outlet end of the conduit in the member for passage of aerosol is designed as a diffuser. In this way such a reduction of the velocity of the sprayed out aerosol is obtained that it is mainly taken in by the user through inspiration rather than sprayed into the mouth of the user.

In a practical embodiment the inspiratory part is a cylindrical tube which is open at both ends and between its ends carries the holding part for the aerosol container.

The invention will now be explained in detail in the following by means of an example of an embodiment with reference to the drawing, in which

Fig. 1 is a vertical sectional view through an inhalation device according to the invention,

Fig. 2 is a view of the inhalation device seen in the direction of the arrow II in Fig. 1,

Fig. 3 is a view of the inhalation device, seen from above, and

Fig. 4 is a view of the member for passage of aerosol, shown transparently in perspective obliquely from below.

The inhalation device comprises an inspiratory part 1, which in the present example of an embodiment is constituted of a circular cylindrical tube open at both ends. One end of the tube constitutes a mouthpiece 2. Between its ends the inspiratory part 1 carries a holding part 3 for an aerosol container.

The aerosol container which is not shown is of the

conventional type with a dispensing valve with an outlet tip in the form of a small tube.

In the inspiratory part 1 a member 4 for passage of aerosol is provided, said member being shown in detail in Fig. 4. The member 4 for passage of aerosol consists in the embodiment shown of a cylindric, aerodynamically designed body extending transversely through the inspiratory part 1. The member 4 for passage of aerosol has a conduit 5 with a first portion 10 6 adapted to receive the outlet tip of the aerosol container, and a second portion 7 designed as a conical tube for taking aerosol from the outlet tip into the inspiratory part 1 in a direction towards the mouthpiece 2, the velocity of the aerosol being at the same 15 time reduced.

Apart from the conduit 5, no connection between the compartment in the holding part 3 and the inspiratory part 1 has to be provided.

The inhalation device is used in the manner that 20 the user takes the mouthpiece 2 into his mouth, expiration is made through the inspiratory part 1, which is possible because it is open at both ends, and then a pressure is exerted on the aerosol container for release of a dose of aerosol and inhalation is performed without removal of the inhalation device from 25 the mouth. By use of this inhalation device it is to be expected that approx. 60% of the active substance will be deposited in the lungs compared to at the most 30% by use of the known devices, for which reason it will 30 be possible to reduce the size of the dosage. Due to the fact that the inspiration of the user takes the aerosol into the mouth cavity and further down into the lungs, it will moreover be possible to reduce the pressure in the aerosol container relative to what is 35 the case with commonly used devices.

Even though the inspiratory part 1 here is shown and described as being circular cylindrical, it should be understood that other types of cross sections may be used, for instance oval ones. It should further be
5 understood that a certain variation in the cross section area is not excluded. The important thing is that no flow resistance is present through the inspiratory part and that the user may breathe substantially freely through it.

P A T E N T C L A I M S

1. A manually operated aerosol inhalation device
5 comprising a holding part (3) for receiving an aerosol
container with a valve and an outlet tip, and an
inspiratory part (1), which at one end comprises a
mouthpiece (2), in which inspiratory part (1) a member
(4) for passage of aerosol is provided for receiving
10 the outlet tip of the aerosol container and comprising
a conduit (5) with an outlet opening for discharging
aerosol into the inspiratory part in the direction
towards the mouthpiece (2), c h a r a c t e r i z e d
in that at the end opposite the mouthpiece (2) the
15 inspiratory part (1) is open towards the surroundings
such that air may pass freely from the surroundings
past the member (4) for passage of aerosol and out
through the mouthpiece (2).

2. An aerosol inhalation device according to claim
20 1, c h a r a c t e r i z e d in that the area of the
flow cross section in the inspiratory part (1), poss-
ibly with the exception of the area around the member
(4) for passage of aerosol, is substantially constant.

3. An aerosol inhalation device according to claim
25 1 or 2, c h a r a c t e r i z e d in that the exterior
surface the member (4) for passage of aerosol is
aerodynamically designed such that it offers the least
possible resistance to the air flow in the inspiratory
part (1).

30 4. An aerosol inhalation device according to
claims 1 - 3, c h a r a c t e r i z e d in that the
outlet end (7) of the conduit (5) in the member (4) for
passage of aerosol is designed as a diffuser.

5. An aerosol inhalation device according to
35 claims 1-4, c h a r a c t e r i z e d in that the

9

inspiratory part (1) is a cylindrical tube, which is open at both ends, and between its ends carries the holding part (3) for the aerosol container.

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1/2

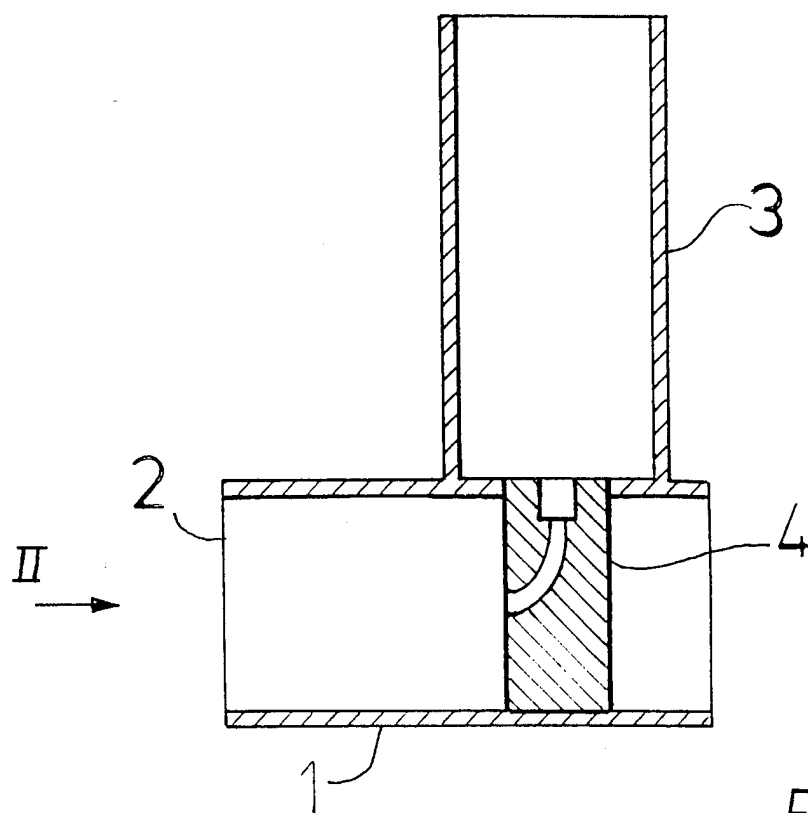


FIG. 1

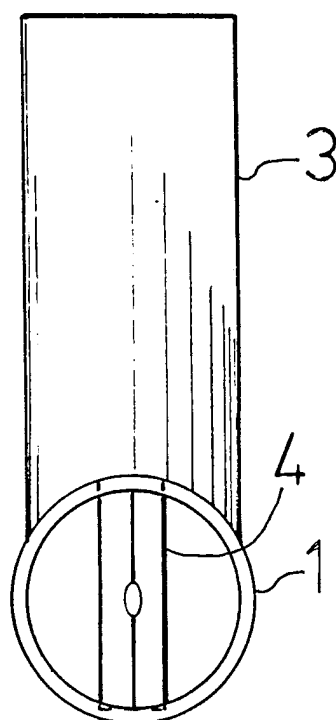


FIG. 2

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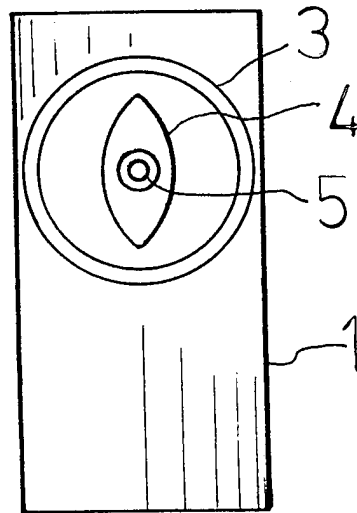


FIG. 3

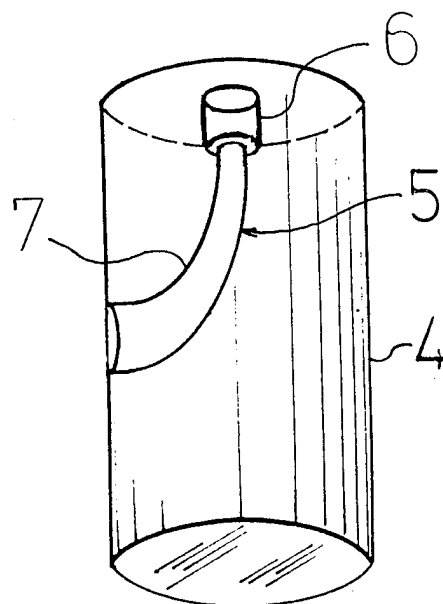


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00021

A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A61M 11/00, A61M 15/00 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)		
IPC6: A61M		
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Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9630068 A1 (ARADIGM CORPORATION), 3 October 1996 (03.10.96), page 51, line 7 - line 25, figure 1	1,2,4,5
Y	--	3
Y	FR 2605249 A1 (GAUCHARD FERNAND), 22 April 1988 (22.04.88), figure 1	3
A	WO 9700704 A1 (NILSSON, LARS, GUNNAR), 9 January 1997 (09.01.97), page 3, line 27 - page 4, line 17	1,2,4,5
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Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0360463 A2 (FISONS PLC), 28 March 1990 (28.03.90) -- -----	1-5

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/04/98

International application No.

PCT/DK 98/00021

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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EP 0360463 A2	28/03/90	SE 0360463 T3 CA 1325752 A DE 68907301 T DK 114790 A DK 169863 B EP 0388460 A IE 62780 B JP 3501225 T PT 91669 A,B US 5349944 A US 5490497 A WO 9002576 A	04/01/94 18/11/93 09/05/90 20/03/95 26/09/90 22/02/95 22/03/91 30/03/90 27/09/94 13/02/96 22/03/90