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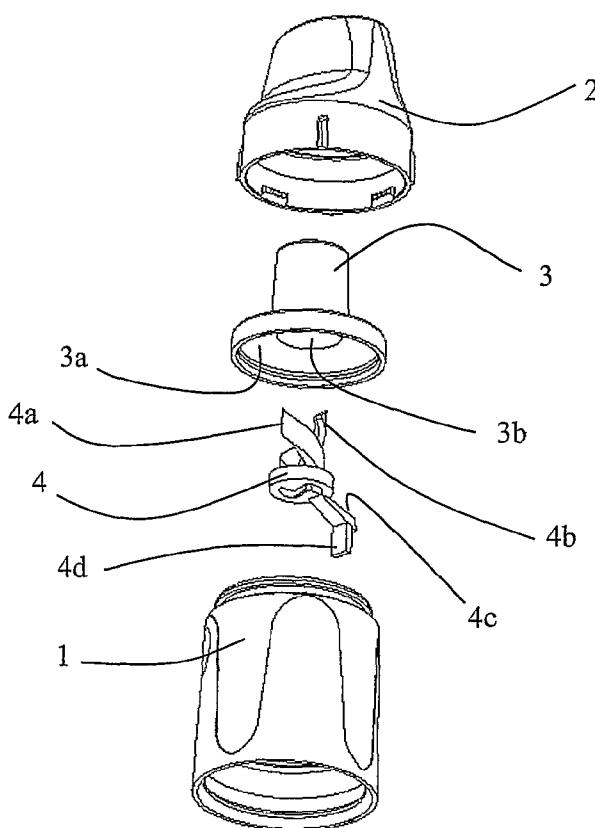
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## (54) Title: NEW DEVICE



**(57) Abstract:** The present invention relates to a delivery device for administrating particulate medicaments, such as a dry powder inhaler. The delivery device comprises a body, a flow path comprising a chamber with an inlet and an outlet for the stream of air. The chamber is mounted rotatable in relation to the body. Dislodging means are arranged in contact with the inner surface of the chamber. The dislodging means and the chamber are relatively rotatable in relation to one another, such that the inside of the chamber is cleaned by the dislodging means when the dislodging means and the chamber are rotated in relation to one another. The invention further relates to a method for cleaning such a delivery device.



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## NEW DEVICE

### Technical Field

The present invention relates to a delivery device, such as a dry powder inhaler, for 5 administering particulate medicaments. The delivery device comprises a body and a flow path defined by a plurality of surfaces through which a stream of air is in use drawn by a user. The flow path comprises a chamber with an inlet and an outlet for the stream of air. The chamber is mounted relatively rotatable in relation to the body. The delivery device also comprises dislodging means arranged in contact with the inner surface of the chamber.

10 The present invention further relates to a method for cleaning a delivery device.

### Background of the Invention

In some dry powder inhalers the mouthpiece is partly cleaned from retained drug powder by a wiper that wipes the flat horizontal surface of the mouthpiece insert upon 15 rotation of the mouthpiece. The wiper reduces powder retention in the mouthpiece significantly, verifying that the principle of rinsing with a wiper works. Powder, which may have accumulated on the inner surfaces of the inhaler, is dislodged from those surfaces prior to the next inhalation. In addition, by configuring the inhaler such that the mouthpiece is rotated automatically when the mouthpiece insert holder is removed, it is not necessary to 20 rely upon the user to remember to rotate the mouthpiece prior to each inhalation.

This product improvement has resulted in a correspondingly lower build-up of retained drug powder inside the inhaler, which has significantly lowered the risk of retention losses during use. However, it is clear that further reduction of retained drug powder inside other parts, such as the mouthpiece, of the inhaler is desirable. Improvement 25 of the cleaning function would give a further increased product robustness and reliability.

Mouthpieces for dry powder inhalers uses among other means helical devices for breaking up the particulate medicament that is being inhaled by the patient. Especially, cleaning of the channel of the mouthpiece is difficult when such helical device is used.

WO 01/95963 discloses a mouthpiece for a particulate inhaler. The known device discloses a mouthpiece provided with a helical member disposed between the inlet and the outlet of the mouthpiece. By air drawn by a user, the helical member undergoes an axial movement between a first and a second position such that it restricts the build up of 5 medicament on the inside of the mouthpiece.

Cleaning in this known device is achieved by axial movement of the helical member in relation to the mouthpiece. The movement of the helical member in axial direction requires that the length of the mouthpiece is long enough to enable such movements.

In this known device, the axial movement of the helical member is achieved by the 10 force of the air drawn by the user. Cleaning performance is thus depending of the flow rate achieved by the patient. The helical member is retained to its initial position by the force of a resilient arm. Thus, the efficiency of the cleaning procedure is depending on the users ability to breath strong enough to overcome the force of the spring and thereby achieve the axial movement of the helical member. If the device is used by a patient with poor 15 breathing capacity, the cleaning effect might be poor. In that case, medicaments might be built up in the mouthpiece, thus demanding a higher flow rate after each inhalation for achieving a cleaned mouthpiece. A further risk is that if medicaments continue to be built up on the inside of the inhaler after each inhalation, the helical member might get stuck during the axial movement. Further, for every inhalation a part of the force used by the 20 patient is consumed by the cleaning device, thus leaving less to actually inhale and deagglomerate the dose.

### **The Object of the Invention**

The object of the present invention is to provide a delivery device with an improved 25 cleaning function.

## Summary of the Invention

This object is achieved by providing a delivery device for administrating particulate medicaments, such as a dry powder inhaler, comprising a body and a flow path defined by a plurality of surfaces through which a stream of air is in use drawn by a user. The flow path comprises a chamber with an inlet and an outlet for the stream of air. The chamber is rotatable in relation to the body. The delivery device comprises dislodging means in contact with the inner surface of the chamber. The dislodging means and the chamber are relatively rotatable in relation to one another such that, the inside of the chamber is cleaned by the dislodging means when the dislodging means and the chamber are rotated in relation to one another. Building up of medicament on the inside of the chamber is thus restricted.

In another embodiment, the chamber is at least partly defined by a mouthpiece insert. The dislodging means and the mouthpiece insert are relatively rotatable in relation to one another such that the inside of the mouthpiece insert is cleaned by the dislodging means when the dislodging means and the mouthpiece insert are rotated in relation to one another. Building up of medicament on the inside of the mouthpiece insert is thereby restricted.

In another embodiment, the delivery device further comprising a helical member arranged between the inlet and the outlet of the delivery device, for, in use, imparting a rotational movement to the airflow drawn through the delivery device. The helical member is arranged in contact with the inside of the mouthpiece insert. The helical member is comprised in the dislodging means. The inner surface of the mouthpiece insert is cleaned by the helical member when the dislodging means and the mouthpiece insert are rotated in relation to one another.

In another embodiment, the helical member has a plurality of intertwined helical sections.

In yet another embodiment, the helical member has two intertwined helical sections.

In another embodiment, the helical member comprises biasing means for applying a force on the inside of the mouthpiece insert substantially perpendicular in relation to the longitudinal axes of the delivery device.

In yet another embodiment, the intertwined helical sections are resilient, thereby applying a force on the inside of the mouthpiece insert substantially perpendicular in relation to the longitudinal axes of the delivery device.

In another embodiment, the mouthpiece insert comprising a first portion and a second portion, and the dislodging means further comprises a dislodging member, arranged in contact with the inner surface of a portion of the mouthpiece, and the helical member is arranged in contact with the inner surface of the other portion of the mouthpiece, such that 5 the inner surfaces of the mouthpiece insert portions are cleaned by the member and by the helical member, respectively, when the dislodging means and the mouthpiece insert are rotated in relation to one another.

In another embodiment, the delivery device further comprises a mouthpiece insert holder, the mouthpiece insert and the mouthpiece insert holder each comprise parts that 10 engage to one another, such that the dislodging means and the mouthpiece insert are relatively rotated in relation to one another when screwing or unscrewing the mouthpiece insert holder. The cleaning occurs automatically when the inhaler is opened. Since the mouthpiece insert and the body is relatively rotated in relation to one another automatically when the mouthpiece insert holder is screwed off, it is not necessary to rely upon the user to 15 remember to rotate the mouthpiece prior to each inhalation.

In another embodiment, the dislodging means and the body each comprise parts that engage to one another, such that the body and the mouthpiece insert are firmly attached to one another.

In another embodiment, the dislodging means comprises a protruding member 20 arranged to engage with a cut out in the body, such that the body and the insert are firmly attached to one another.

The invention further relates to a method for cleaning a delivery device. The delivery device comprises a flow path defined by a plurality of surfaces through which a stream of air is in use drawn by a user, and a body. The flow path comprises a chamber with an inlet 25 and an outlet for the stream of air. The chamber is rotatable in relation to the body. Further, the delivery device comprises dislodging means arranged in contact with the inner surface of the chamber. The method comprises rotating the dislodging means and the chamber in relation to one another, such that the inside of the mouthpiece is cleaned by the dislodging means, whereby building up of medicament on the inside of the mouthpiece is restricted.

30 In another embodiment, the method comprises the step of rotating the dislodging means and the mouthpiece insert in relation to one another prior to inhalation. Since the

cleaning procedure is achieved before and not during inhalation, the procedure is independent of the airflow drawn by the user.

In yet another embodiment, the method comprises the step of applying a force on the inside of the mouthpiece by biasing means, the force being substantially perpendicular in 5 relation to the longitudinal axes of the delivery device.

The method and the delivery device of the present invention may be used with any suitable form of powder, including powders introduced into the air stream in the raw state or as conglomerate, micronised or ordered mixture particles. Furthermore, the active ingredient or ingredients of the powder may be diluted with one or more substances such as lactose and 10 may include substances for the treatment of various conditions, not necessarily respiratory conditions. Indeed, the powder can include genetic material and need not be restricted to human use only.

Medicaments suitable for administration by the powder inhaler of the present invention are any which may be delivered by inhalation and include for example  $\beta$ 2-adrenoreceptor 15 agonists, for example, salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, indacaterol, procaterol, broxaterol, picumeterol, carmoterol (TA-2005), mabuterol and the like, and their pharmacologically acceptable esters and salts; anticholinergic bronchodilators, for example, ipratropium bromide and the like; glucocorticosteroids, for example, 20 beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone and the like, and their pharmacologically acceptable esters and salts; antiallergic medicaments, for example, sodium cromoglycate and nedocromil sodium; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists; phospholipase-A2 (PLA2) inhibitors; 25 platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments; tranquilisers; cardiac glycosides; hormones; antihypertensive medicaments; antidiabetic medicaments; antiparasitic medicaments; anticancer medicaments; sedatives; analgesic medicaments; antibiotics; antirheumatic medicaments; immunotherapies; antifungal medicaments; antihypotension medicaments; vaccines; antiviral medicaments; proteins; 30 polypeptides and peptides, for example, peptide hormones and growth factors; polypeptide

vaccines; enzymes; endorphines; lipoproteins and polypeptides involved in the blood coagulation cascade; vitamins; and others, for example, cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

##### 5      **Brief description of the Drawings**

Fig. 1 shows parts of a delivery device in an embodiment of the present invention.

Fig. 2 shows a cross-section of the top of a delivery device in an embodiment of the present invention.

##### 10     **Detailed Description of Preferred Embodiments**

Fig. 1 shows details of a delivery device according to one embodiment of the invention. The delivery device comprises a body 1 with a smooth top, and a chamber at least partly defined by a mouthpiece insert 3, and dislodging means 4 comprising a helical member and a dislodging member 4c. The dislodging member 4c may be of any suitable shape, such as a wiper arm. The mouthpiece insert 3 and the dislodging means 4 are mounted relatively rotatable in relation to one another. The dislodging means 4 is firmly attached to the body, whilst the mouthpiece insert 3 is attached to the mouthpiece insert holder 2. When the mouthpiece insert holder 2 is unscrewed and thus undergoes a rotational movement, the mouthpiece insert 3 also undergoes a rotational movement and the mouthpiece insert 3 and the dislodging means 4 are rotated relative to one another. The helical member is arranged in close contact with the inside of a portion 3b of the mouthpiece insert 3, and the dislodging member 4c is arranged in close contact with the inside of another portion 3b of the mouthpiece insert. Thus, during the relative rotational movement achieved by unscrewing mouthpiece insert holder 2, the helical member is wiping off any powder left on the inside of the portion 3b of the mouthpiece insert. At the same time, the dislodging member 4c is wiping off any powder left on the inside of the portion 3a of the mouthpiece. The helical member has two intertwined helical sections (4a, 4b).

Fig. 2 shows a cross-section of the top of the device. The device comprises an insert holder 2 and an insert 3 with a channel, and dislodging means 4 comprising a helical

member and a dislodging member 4c, in this embodiment shown as a wiper arm. The helical member and the dislodging member 4c are used for cleaning the portion 3b of the mouthpiece insert 3, and the portion 3a of the mouthpiece insert 3, respectively. The dislodging means 4 is in this embodiment firmly attached to the body 1 by a protruding member 4d, arranged to engage with a cut out (not shown) in the body 1. The mouthpiece insert 3 is attached to mouthpiece insert holder 2 and therefore rotates automatically in relation to the dislodging means 4 when the mouthpiece insert holder 2 is unscrewed and thus undergoes a rotational movement. The body 1 has a smooth top to minimize dead ends. \_\_\_\_\_

## CLAIMS

1. A delivery device, such as a dry powder inhaler, for administering particulate medicaments, comprising a flow path defined by a plurality of surfaces through which a stream of air is in use drawn by a user, and a body (1),

5 said flow path comprising a chamber with an inlet and an outlet for the stream of air, said chamber being rotatable in relation to the body (1),

dislodging means (4) arranged in contact with the inner surface of the chamber, **characterized in**

10 that the dislodging means and the chamber are relatively rotatable in relation to one another,

such that the inside of the chamber is cleaned by the dislodging means when the dislodging means and the chamber are rotated in relation to one another,

whereby building up of medicament on the inside of the chamber is restricted.

15

2. A delivery device according to claim 1,

**characterized in**

that the chamber is at least partly defined by a mouthpiece insert (3), the dislodging means and the mouthpiece insert being relatively rotatable in relation to one another such that the

20 inside of the mouthpiece insert is cleaned by the dislodging means when the dislodging means and the mouthpiece insert are rotated in relation to one another,

whereby building up of medicament on the inside of the mouthpiece insert is restricted.

3. A delivery device according to claim 2, further comprising a helical member

25 arranged between the inlet and the outlet of the delivery device, for, in use, imparting a rotational movement to the air flow drawn through the delivery device,

said helical member being arranged in contact with the inside of the mouthpiece insert,

**characterized in**

that the helical member is comprised in the dislodging means (4),

30 such that the inner surface of the mouthpiece insert is cleaned by the helical member,

when the dislodging means and the mouthpiece insert are rotated in relation to one another.

4. A delivery device according to claim 3,

**characterized in**

that the helical member has a plurality of intertwined helical sections (4a, 4b).

5 5. A delivery device according to claim 5,

**characterized in**

that the helical member has two intertwined helical sections (4a, 4b).

6. A delivery device according to any of claims 2-5,

10 **characterized in**

that the helical member comprises biasing means for applying a force on the inside of the mouthpiece insert (3), said force being substantially perpendicular in relation to the longitudinal axes of the delivery device.

15 7. A delivery device according to claim 5 or 6,

**characterized in**

that the intertwined helical sections are resilient, thereby applying a force on the inside of the mouthpiece insert (3), said force being substantially perpendicular in relation to the longitudinal axes of the delivery device.

20

8. A delivery device according to any of claims 2-7, wherein the mouthpiece insert (3) comprises a first portion (3a) and a second portion (3b);

**characterized in**

that the dislodging means (4) further comprises a dislodging member (4c), arranged in contact with the inner surface of the first portion (3a) of the mouthpiece insert, and that the helical member is arranged in contact with the inner surface of the second portion (3b) of the mouthpiece insert,

such that the said surfaces are cleaned by the dislodging member (4c) and by the helical member, respectively, when the dislodging means and the mouthpiece insert are rotated in relation to one another.

30

9. A delivery device according to any of claims 2-8, the delivery device further comprising a mouthpiece insert holder (2)

**characterized in**

that the mouthpiece insert (3) and the mouthpiece insert holder each comprise parts which engage to one another, such that the dislodging means (4) and the mouthpiece insert are relatively rotated in relation to one another when screwing or unscrewing the insert holder.

10. A delivery device according to any of claims 2-9,

**characterized in**

10 that the dislodging means (4) and the body (1) each comprise parts that engage to one another, such that the body and the mouthpiece insert are firmly attached to one another.

11. A delivery device according to claim 10,

**characterized in**

15 that the dislodging means (4) comprises a protruding member (4d) arranged to engage with a notch in the body (1), such that the body and the insert are firmly attached to one another.

12. Method for cleaning a delivery device, the delivery device comprising a flow path defined by a plurality of surfaces through which a stream of air is in use drawn by a user, and a body (1), the flow path comprising a chamber with an inlet and an outlet for the stream of air, the chamber being rotatable in relation to the body (1), dislodging means (4) arranged in contact with the inner surface of the chamber,

**characterized by**

rotating the dislodging means (4) and the chamber in relation to one another,

25 such that the inside of the chamber is cleaned by the dislodging means (4), whereby building up of medicament on the inside of the chamber is restricted.

13. Method according to claim 12,

**characterized by**

30 rotating the dislodging means (4) and the chamber in relation to one another prior to inhalation.

14. Method according to claim 12 or 13, said dislodging means (4) further comprising biasing means,

**characterized by**

that the biasing means is applying a force on the inside of the chamber,

5 said force being substantially perpendicular in relation to the longitudinal axes of the delivery device.

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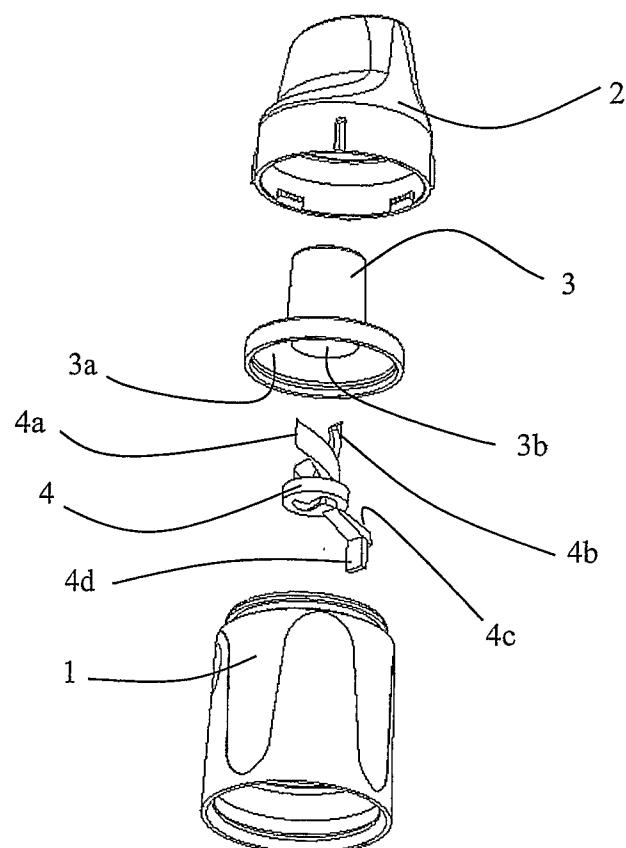


Fig.1

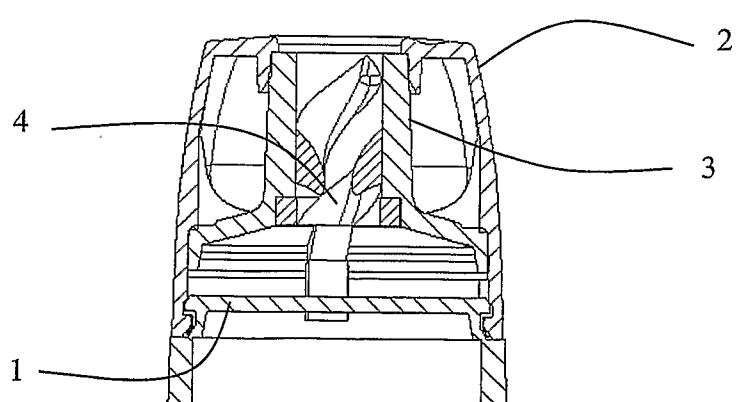


Fig.2

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2006/001466

## A. CLASSIFICATION OF SUBJECT MATTER

## IPC: see extra sheet

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)

IPC: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE, DK, FI, NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	EP 0573128 A2 (INNOVATA BIOMED LIMITED), 8 December 1993 (08.12.1993), whole document --	1-14
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 Further documents are listed in the continuation of Box C. See patent family annex.

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Date of the actual completion of the international search

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Cited literature, if any, will be enclosed in paper form.

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