A dose counting device for indicating the number of doses of a medicament that have been dispensed from or remain in a canister located within the actuator of a pressurised metered dose inhaler. The dose counting device comprises a cylindrical body that is attachable to the base of the canister, a counting mechanism that is contained within the body, a trigger that protrudes from the cylindrical body for activating the counting mechanism and displays means that displays the number of doses of a medicament that have been dispensed from or remain in the canister. The trigger is formed to engage with the actuator of the inhaler when the dose counting device is displaced relative to the actuator thereby actuating the counting mechanism.
DOSE COUNTING DEVICE

The present invention relates to a dose counting device for a pressurised metered dose inhaler.

Inhalers are commonly used to administer medicaments to the pulmonary tracts of humans or animals to treat respiratory diseases such as asthma, chronic obstructive pulmonary disease and allergies.

A well-known type of inhaler comprises a medicament canister and an actuator. The medicament is formulated as a liquid and stored under pressure in the canister. The canister is located in the actuator and includes a valve stem that engages a support block within the actuator. The canister can be depressed relative to the actuator so as to dispense a metered dose of medicament in aerosol form through a mouthpiece that extends from the actuator. The valve stem, which is typically spring-loaded, biases the canister away from the support block so that after the dose has been dispensed the canister will move back again relative to the actuator. In this way a metered dose of medicament is administered by each cycle of linear reciprocal movement of the canister relative to the actuator.

Pressurised metered dose inhalers often include some means for counting the number of doses dispensed from or remaining in the canister so that the user can monitor the frequency of doses taken and be aware when the canister is almost empty.

A variety of dose counting devices for pressurised metered dose inhalers are known in the field but they are not entirely satisfactory to use or manufacture and thus can be improved. The present invention provides a dose counting device for a pressurised metered dose inhaler that overcomes certain problems associated with known dose counting devices for those inhalers or at least provides a useful alternative to such dose counting devices.

The invention in broad terms relates to a dose counting device suitable for indicating the number of doses of a medicament that have been dispensed from or remain in a canister located within the actuator of a pressurised metered dose inhaler, wherein the dose counting device comprises

a cylindrical body that is attachable to the base of the canister;
a counting mechanism that is contained in the body;

a trigger that protrudes from the cylindrical body for activating the counting mechanism; and

display means that displays the number of doses of a medicament that have been dispensed from or remain in the canister;

wherein the trigger is formed to engage with the actuator of the inhaler when the dose counting device is displaced relative to the actuator thereby actuating the counting mechanism.

The dose counting device is constructed to minimise stack-up tolerances on a canister-by-canister basis and/or a dose-by-dose basis.

Preferably the trigger converts the linear translational movement created by displacing the dose counting device with respect to the actuator to a radial translation movement that actuates the counting mechanism.

Preferably the trigger is one of a plurality of radially extending fingers of a count wheel. The count wheel, or at least the fingers thereof, is preferably composed of a flexible plastics material to avoid or at least minimise problems arising from tolerance issues associated with the manufacture and assembly of the inhaler.

Preferably the dose counting device is permanently fixed to the base of the canister, for example by an adhesive, especially a UV-activated adhesive.

Preferably the body of the dose counting device has a floor that is shaped to receive and accommodate the base of the canister. In a preferred embodiment a truncated cone extends from the body that is adapted to receive and accommodate the base of the canister.

Throughout this specification and in the claims that follow, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.
A preferred embodiment of the dose counting device of the present invention is illustrated in
the accompanying drawings in which:

Figure 1 shows a cutaway perspective side view of a pressurised metered dose inhaler with a
dose counting device of the present invention attached to the base of a medicament canister
that is located in the actuator of the inhaler.

Figure 2 shows the dose counting device shown in Figure 1 without the inhaler.

Figure 3 shows a cut-a-way side view of the dose counting device of Figure 1 attached to the
base of the medicament canister of inhaler.

Figure 4 shows a cut-a-way side view of an alternative embodiment of the dose counting device
of the present invention attached to the base of a medicament canister that is located in the
actuator of a pressurised metered dose inhaler.

Figure 5 shows a cut-a-way side view of another alternative embodiment of the dose counting
device of the present invention attached to the base of a medicament canister that is located in
the actuator of a pressurised metered dose inhaler.

Figure 6 shows a cut-a-way side view of a further alternative embodiment of the dose counting
device of the present invention that is attached to the base of a medicament canister in the same
way as the embodiment shown in Figure 5. However that the trigger takes the form of a toggle
that activates a count wheel that is shown in the drawing.

The dose counting device of the present invention is a device that is attached to the base of the
medicament canister of a pressurised metered dose inhaler. It records every time a user uses the
inhaler to administer medication stored in the canister of the inhaler.

Figure 1 shows the dose counting device 1 attached to the base of a medicament canister 5 of a
standard pressurised metered dose inhaler 10. The canister contains a pressurised liquid
formulation of a medicament that is suitable for the treatment of a respiratory disease by
pulmonary inhalation, for example asthma or chronic obstructive pulmonary disease.

The inhaler has an actuator 15 that is substantially tubular in shape. The canister 5 is loaded
into one end of the actuator i.e. the canister-loading end 18. The other end of the actuator 15
forms a mouthpiece 20 that can be closed by attaching a removable cap 25. The aerosol canister 5 has a spring-biased valve stem 30 that rests in a support block 35 formed on the internal surface of the actuator 15 adjacent the mouthpiece 20. The support block 35 has a passage 40 that connects the end of the valve stem 30, when resting on the support block 35, and an outlet 45 that is directed towards the mouthpiece. The inhaler is constructed so that in use the user removes the removable cap 25, places his lips on the mouthpiece and depresses the canister 5 relative to the valve stem 30, whilst holding the actuator 15. This causes the valve to open and discharge a predetermined dose of the medicament from the canister through the passage 40 of the support block 35 and out of the outlet 45. The user inhales the medicament into his lungs through the mouthpiece 20. The valve stem is spring-loaded and biases the canister away from the support block so that after the dose has been dispensed the canister will move back again relative to the actuator. These steps are repeated to administer any further doses.

The dose counting device is shown in more detail in Figure 2. It has a substantially cylindrical body 50, which has a top 55, side 60 and floor (not shown). A dose counting display 70 is formed in the top 55 of the body 50. This displays the number of doses that have dispensed, or more preferably the number of doses that remain. The body 50 contains a trigger mechanism that is activated when the dose counting device is displaced linearly with respect to the actuator. Preferably the trigger mechanism converts this linear translational movement to a radial translation movement within the counting device. For example, the trigger mechanism comprises a count wheel that has a plurality of radially extending fingers and which is geared to a count mechanism (not shown). One of these fingers 75 of that count wheel is shown protruding from an aperture 80 that is formed in the side of 60 of the device.

The floor of the dose counting device is fixed to the base of the canister, preferably permanently, to avoid or at least minimise tolerances associated with the manufacture and assembly of the inhaler and dose counting device stacking in a manner that might prejudice accurate actuation and counting. This may be achieved by any suitable means known in the art however preferably the device is fixed to the base of the canister using an adhesive. In a particularly preferred embodiment, the adhesive is activated by UV radiation. Suitable UV-activated adhesives include LOCTITE™ 3301 and LOCTITE™ 3311 light cure acrylic adhesives (ex Henkel Loctite Corporation).

The floor of the dose counting device shown in Figure 1 is formed as a recess in the lower part of the body 50 of the dose counting device shown. This floor is seen in Figure 3. The recess is
shaped to receive and accommodate the base of the canister snugly however there may be a gap or buffer space to minimise the impact of any of the aforementioned tolerances, especially on a canister-by-canister basis. The dose counting device is preferably fixed to the base of the canister by an adhesive. This adhesive is preferably applied to the inner surface of the lower part of the body during manufacture i.e. where the base of the canister contacts the dose counting device and/or, more preferably, on the inner surface of the annular part of the body.

In use the user depresses the top 55 of the body 50 of the dose counting device to depress the canister 5 of the inhaler relative to the actuator of the inhaler. The fingers 75 are formed to engage with the actuator of the inhaler and cause the count wheel to rotate forward one notch or position when the dose counting device is displaced relative to the actuator. This action draws the exposed finger 75 into the aperture 80. In the preferred embodiment the fingers are formed to engage the lip of the canister-loading end 18 of the actuator. However the fingers might alternatively be formed to engage with some other part of the actuator, which might for example be formed specifically to receive the fingers 75.

The count wheel indexes a count mechanism (not shown) that displays the count in the dose counting display 70. The count wheel, or at least the fingers thereof, is preferably composed of a material that enables the fingers 75 to be flexible but resilient, for example a flexible plastics material such as polypropylene. This permits the count wheel mechanism to avoid or at least minimise problems arising from tolerance issues associated with the manufacture and assembly of the inhaler and the dose counting device, especially on a dose-by-dose basis.

After a dose of the medicament has been dispensed the user removes downwards pressure on the dose counting device and the spring-biased valve stem returns the dose counting device and canister to their original position. In doing so another finger 75 will emerge from the aperture 80 of the body 50. This cycle is repeated to administer multiple doses.

An alternative preferred embodiment of the dose counting device of the present invention is shown in Figure 4. In this embodiment a truncated cone depends from the body 50 which is adapted to receive and accommodate the base of the canister snugly.

In a further preferred embodiment of the dose counting device of the present invention, shown in Figure 5, the diameter of the cylindrical body 50 of the dose counting device is substantially the same as the diameter of the canister 5 of the inhaler.
In a yet a further preferred embodiment of the dose counting device of the present invention, shown in Figure 6, the diameter of the cylindrical body 50 of the dose counting device is also substantially the same as the diameter of the canister 5 of the inhaler. However the trigger mechanism takes the form of a toggle or ratchet 85 that is hinged at pivot point 90 and activates a count mechanism 95 when the dose counting device is displaced linearly with respect to the actuator. The number of doses that remain in the medicament canister 5 is visible through the dose counting display 70.

The dose counting device of the present invention can be made of any suitable material, for example a tough plastics material such as acrylonitrile-butadiene-styrene (ABS) or polypropylene.

The foregoing description describes a dose counting device including preferred embodiments thereof. In practising the invention, it is to be understood that the use and construction of the various parts can be modified to meet specific requirements.
CLAIMS

1. A dose counting device suitable for indicating the number of doses of a medicament that have been dispensed from or remain in a canister located within the actuator of a pressurised metered dose inhaler, wherein the dose counting device comprises

   a cylindrical body that is attachable to the base of the canister;

   a counting mechanism that is contained in the body;

   a trigger that protrudes from the cylindrical body for activating the counting mechanism; and

   display means that displays the number of doses of a medicament that have been dispensed from or remain in the canister;

   wherein the trigger is formed to engage with the actuator of the inhaler when the dose counting device is displaced relative to the actuator thereby actuating the counting mechanism.

2. A dose counting device according to claim 1, wherein the trigger converts the linear translational movement created by displacing the dose counting device with respect to the actuator to a radial translation movement that actuates the counting mechanism.

3. A dose counting device according to claim 1 or 2, wherein the trigger comprises one of a plurality of radially extending fingers of a count wheel.

4. A dose counting device according to claim 1 or 2, wherein the trigger comprises a ratchet.

5. A dose counting device according to any preceding claim, wherein the trigger is composed of a flexible plastics material.

6. A dose counting device according to any preceding claim that includes an adhesive for permanently attaching the body to the base of the canister.
7. A dose counting device according to any preceding claim, wherein the body of the device has a floor that is shaped to receive and accommodate the base of the canister of the inhaler.

8. A dose counting device according to any one of claims 1 to 6, wherein a truncated cone depends from the body, which is adapted to receive and accommodate the base of the canister.

9. A dose counting device according to any one of claims 1 to 6, wherein the diameter of the body is substantially the same as the diameter of the canister.

10. A pressurised metered dose inhaler incorporating a dose counting device according to any one of claims 1 to 9.

11. The use of a dose counting device according to any one of claims 1 to 9 for the administration of a medicament that is suitable for the treatment of asthma or chronic obstructive pulmonary disease by pulmonary inhalation.

12. A dose counting device suitable for indicating the number of doses of a medicament that have been dispensed from or remain in a canister located within the actuator of a pressurised metered dose inhaler substantially as herein described with reference to any one or more of the accompanying drawings.
Fig 6
**A. CLASSIFICATION OF SUBJECT MATTER**

INV. 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)

A61M

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

Electronic database consulted during the international search (name of database and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<td>GB 2 372 542 A (BESPAK PLC [GB]) 28 August 2002 (2002-08-28) page 3, line 19 - page 9, line 9</td>
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**D. Further documents are listed in the continuation of Box C**

- Special categories of cited documents
- A: document defining the general state of the art which is not considered to be of particular relevance
- E: earlier document published on or after the international filing date
- L: document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- D: document referring to an oral disclosure, use, exhibition or other means
- P: document published prior to the international filing date but later than the priority date claimed

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**Name and mailing address of the ISA**

European Patent Office, P B 5818 Patentlaan 2 NL- 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx 31 651 epc nl, Fax (+31-70) 340-3016

**Authorized officer**

Kroeders, Marleen
Box II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. X Claims Nos.: 12
   because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy (claim 11)

2. X Claims Nos.: 12
   because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
   see FURTHER INFORMATION sheet PCT/ISA/210

3. □ Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. □ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. □ As only some of the required additional search fees were timely paid by the applicant, this international Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. □ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 

Remark on Protest

□ The additional search fees were accompanied by the applicant’s protest.

□ No protest accompanied the payment of additional search fees.
Continuation of Box II.1

Claims Nos.: 11, 12

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy (claim 11)

Continuation of Box II.2

Claims Nos.: 12

Claim 12 contains two technical features. It seeks to define its subject-matter solely by referring to other parts of the application, namely the drawings, contrary to the requirements of Rule 6.2(a) PCT.
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