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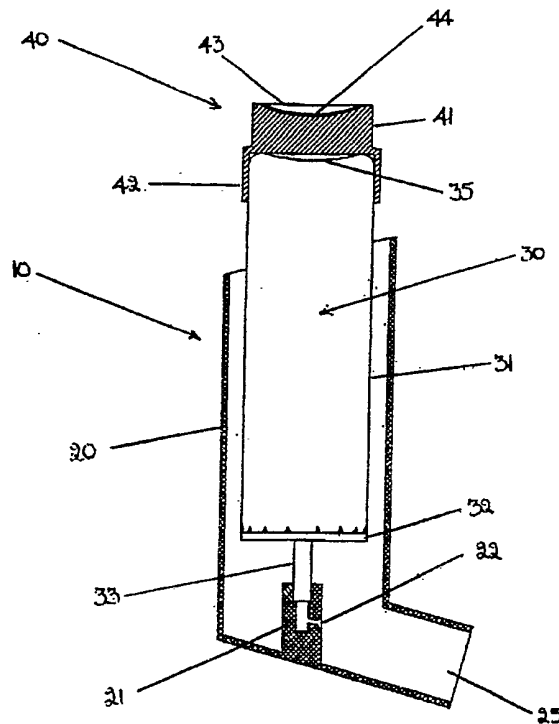
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US 5020527 A **US 4558710 A**

(58) Field of Search
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(54) **Inhaler dose counter**

(57) A dose counter for a metered dose inhaler comprises a button 41 attached to the closed end of a medicament-containing aerosol canister 30 by means of a resilient skirt 42. The button 41 has means for sensing applied pressure and, on its top surface is provided with a count display 43 which indicates the number of doses of medicament which have been delivered. Body portion 41 of the button houses a processing chip which determines whether a predetermined force has been applied to the pressure sensing means. When this force threshold is reached, the chip sends an electrical impulse to the count display 43 to increment it.



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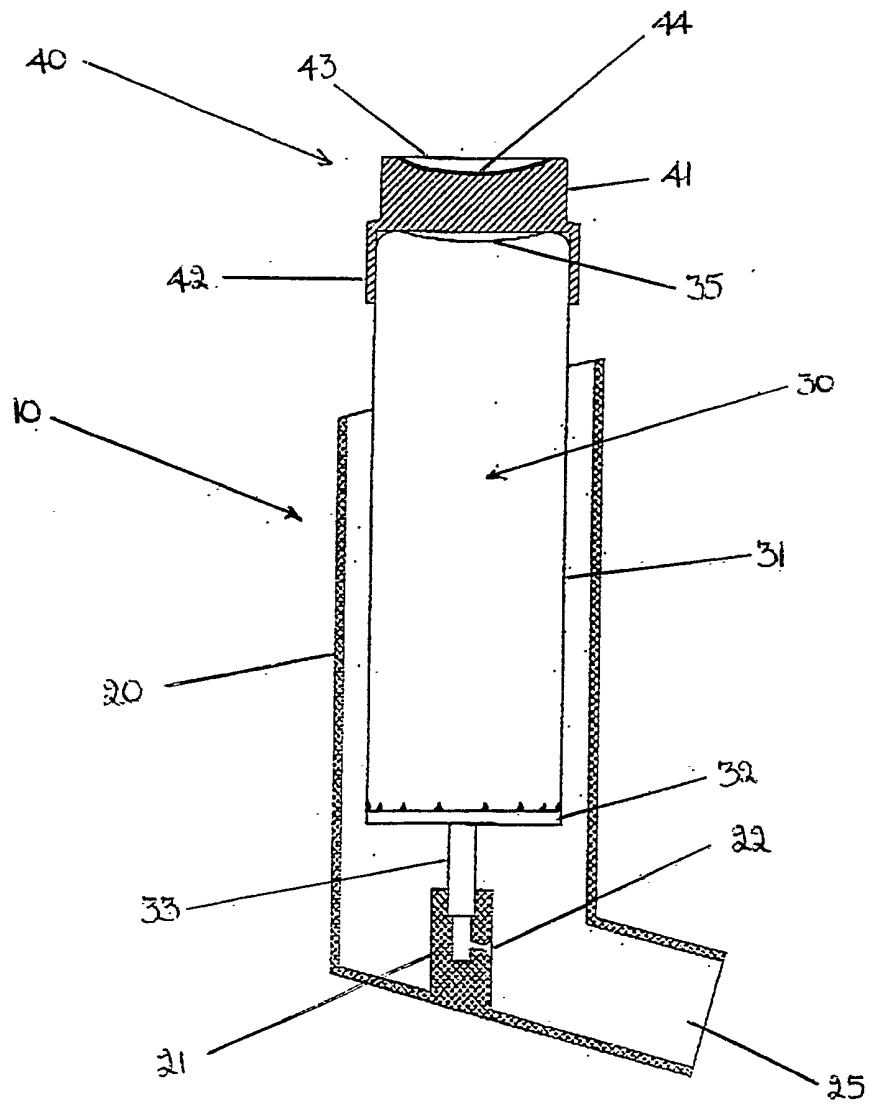


FIGURE 1

STAND-ALONE DOSE COUNTER

The present invention relates to a dose counter for a dispensing device of the type which is used for dispensing discrete amounts of a fluid or particulate material entrained in a propellant stream. In particular, the invention is
5 concerned with dose counters for dispensing devices of the metered dose inhaler type which are well known in the art of medicine for treatment of, or alleviation of the effects of, respiratory complaints such as asthma.

The standard metered dose inhaler consists of three main
10 parts: a pressurised canister, an actuator body and a drug delivery outlet. The pressurised canister contains a mixture of active drug and propellant and is usually formed from a deep drawn aluminium cup portion having a lid portion crimped thereto which carries the metering valve assembly. The
15 metering valve assembly is provided with a protruding valve stem which, in use, is inserted as a tight push fit into a so-called "stem block" in the actuator body.

Operation of the inhaler requires the user to apply a compressive force to the closed end of the canister. The
20 internal components of the metering valve assembly are spring loaded so that, typically, a compressive force of between 15 and 30 N is required to activate the device. In response to this compressive force, the canister moves axially with respect to the valve stem by an amount varying between about 2.0 and
25 3.5 mm. This degree of axial movement is sufficient to actuate the metering valve and cause a metered quantity of the drug and propellant to be expelled through the valve stem. This is then released into the mouthpiece via a nozzle in the stem block. A user inhaling through the drug delivery outlet of the device
30 at this point will thus receive a dose of the drug.

Metered dose inhalers as described above administer an accurate dose of medicament whenever required, which is particularly useful for users whose respiratory difficulties manifest themselves suddenly. Such has been the success of

these devices that they are now used throughout the world, where they are exposed to a wide variety of climatic conditions.

5 Unfortunately, one of the drawbacks of self-administration is that users often experience difficulty in determining when the drug in the aerosol canister has run out. Part of the reason for this difficulty is that a surplus of propellant may remain in the aerosol canister even though the drug supply is nearly used up. Thus, the illusion is created that the inhaler
10 is still capable of providing useful doses of medicament simply because the aerosol canister contains liquid. The situation may therefore arise in which the user is unaware that the drug supply is nearing exhaustion. This is potentially hazardous for the user since few people carry any back up device.

15 Many users have several different inhalers for the treatment of a variety of conditions. Others keep inhalers at a number of different locations such as at school, home, work etc. In these circumstances it is particularly difficult for the user to keep track of the amount of usage extracted from
20 each individual canister.

Clearly there is a need for a counter mechanism which is capable of counting the number of doses emitted from a canister. To this end, a number of counting mechanisms have been proposed in recent times which aid the management of
25 metered dosage. Such counters vary in complexity and sophistication, but they all have in common the feature that they detect relative movement between the canister and the actuator body and increment in response to such movement.

30 One of the drawbacks of these known counters is that they rely on mechanical interaction between parts attached to the canister and parts provided on the actuator body. This means that routine cleaning of the inhaler, which requires removal of the canister from the actuator body, may result in damage to the counting mechanism. Also, the accumulated count may be
35 corrupted by this operation.

Another drawback is that such counters are difficult to manufacture with satisfactory tolerances. A factor which influences the effectiveness of known displacement-triggered counters is the variation in length of typical aerosol canisters. This variation results from the crimping operation used to connect the valve-carrying lid portion to the main cup portion. Although the technology involved is not especially demanding, it has been found that the amount of travel effective to actuate the metering valve of a typical medicament-containing aerosol canister may fall in a tolerance band as small as 0.5 mm. Thus it is difficult to provide a generic counter which increments accurately in response to every actuation. This is often true even when the counter, the aerosol canister and the inhaler housing have been specifically designed for use together. The problem may be worse in circumstances where different manufacturers' aerosol canisters, inhaler housings and displacement-triggered counters are used in combination.

It is therefore an object of the present invention to provide a counter for a metered dose inhaler which does not rely on displacement triggering or the mechanical engagement between parts carried on the aerosol canister and parts carried on the actuator housing.

It is a further object of the invention to provide a counter which allows removal of the aerosol canister from the actuator body for routine cleaning without the risk of count corruption.

The invention is a dose counter for a metered dose inhaler, the dose counter comprising a button adapted for attachment to the closed end of a medicament-containing aerosol canister, said button being provided with pressure sensing means, counting means having a count display and means to increment the count display in response to the application of a predetermined pressure upon the pressure sensing means.

One of the main advantages of a pressure-triggered counter compared to a displacement-triggered counter in the context of metered dose inhalers is that typical valve actuating pressures fall within a sensible range. It is therefore relatively
5 simple to provide a pressure-triggered device having a predetermined pressure threshold which renders it universally applicable. This is much easier to achieve in engineering terms than a displacement-triggered counter which is required to increment upon a relative displacement as low as 0.5 mm.

10 It is preferred that the value of the predetermined pressure applied to the pressure sensing means which causes the count display to increment should be no greater than the compressive force required to actuate the metering valve of the aerosol canister. If this criterion is not met, the dose
15 counter may undercount. This type of error could have serious consequences since the implication that effective doses of medicament remain when the drug supply is actually exhausted could be potentially life-threatening to the user.

Another important consideration is resistance to
20 vibration. Often, the directions for use instruct the user to shake the aerosol canister prior to administration of the metered dose. The dose counter should therefore be able to withstand vigorous shaking without corruption of the recorded count.

25 For the above reasons, a dose counter in accordance with the present invention will ideally meet certain physical requirements.

Preferably, the pressure sensing means is a solid state device, most preferably a piezo film sensor. In this
30 embodiment, the pressure sensing means generates an electrical output in response to the applied compressive force. The electrical output may then be fed into processing means such as a microprocessor in which the signal is analysed to determine whether the threshold of the predetermined minimum
35 pressure has been reached. If so, an electrical impulse is

sent to the counting means to effect incrementation of the count display.

Alternatively, the pressure sensing means may be a force-sensitive switch to which a predetermined force must be applied to overcome a biasing pressure that urges the switch contacts into an open condition. When the switch contacts are closed, an electrical circuit is completed which can be used to power the counting means in order to increment the count display.

In an especially preferred form of the invention, the count display is provided on the button itself, on the visible face thereof. This means that the display is visible to the user both before and after the administration of a dose of the drug. This embodiment is most conveniently implemented by means of an electronic chip with built-in display function.

In order to make the dose counter fit a variety of aerosol canisters of different diameters, the button may be associated with auxiliary adaptor means which provides a seat for the button irrespective of the canister diameter. The auxiliary adaptor means may be in the form of a resilient collar, or the like, which is push-fitted over the end of the aerosol canister. The invention will now be described by way of example only with reference to the drawing, in which:

Figure 1 shows a schematic cross-sectional view of a metered dose inhaler apparatus fitted with a dose counter in accordance with the invention.

Referring now to the drawing, reference numeral 10 denotes a metered dose inhaler comprising an actuator body 20 having a drug delivery outlet 25, and an aerosol canister 30. The aerosol canister 30 is formed from a deep drawn aluminium cup section 31 to which a lid portion 32 is attached by crimping. The lid portion 32 carries a metering valve assembly having a protruding valve stem 33, the end of which is received as a tight push fit in a stem block 21 of the actuator body 20. Stem block 21 has a nozzle 22 communicating with the drug delivery outlet 25 so that, upon actuation of the metering valve assembly, a charge of the drug is emitted through the

nozzle 22 into the drug delivery outlet 25. A user inhaling through the drug delivery outlet 25 at this time will receive a metered dose of the drug.

5 The closed end 35 of aerosol canister 30 is provided with a dose counter 40 which comprises a body portion 41 and a depending skirt 42. The skirt 42 is formed of a resilient material which grips the outside of the aerosol canister 30 to maintain the dose counter 40 in position. Body portion 41 is in the form of a button which includes pressure sensing means and which has, on its top surface 42, a count display 43. Body
10 portion 41 includes a processing chip (not shown) which is configured to determine whether a predetermined force has been applied to the pressure sensing means. When this force threshold is reached, the chip sends an electrical impulse to
15 the count display 43 in order to effect incrementation thereof.

CLAIMS

1. A dose counter for a metered dose inhaler, the dose counter comprising a button adapted for attachment to the closed end of a medicament-containing aerosol canister, said button being provided with pressure sensing means, counting means having a count display and means to increment the count display in response to the application of a predetermined pressure upon the pressure sensing means.

2. A dose counter as claimed in claim 1 in which the pressure sensing means is a solid state device such as a piezo film sensor.

3. A dose counter as claimed in claim 1 or claim 2 wherein the pressure sensing means is a force-sensitive switch the contacts of which are held open by a biasing pressure corresponding to said predetermined force

4. A dose counter as claimed in any preceding claim in which a microprocessor is used to determine whether the threshold of the minimum predetermined pressure has been reached.

5. A dose counter as claimed in any preceding claim wherein the count display is provided on the visible surface of the button.

6. A dose counter as claimed in any preceding claim wherein the button has a resilient skirt depending therefrom for attaching the button to the closed end of a medicament-containing aerosol canister.

7. A dose counter for a metered dose inhaler, the dose counter comprising counting means having a count display and pressure sensing means operable to cause incrementation of the count display in response to direct application of a predetermined pressure.

8. A dose counter substantially as described herein with reference to Figure 1 of the drawings.

Relevant Technical Fields

- (i) UK Cl (Ed.M) G4D (DAC, DAX)
 (ii) Int Cl (Ed.5) A61M 15/00; G06M 1/00, 1/08, 1/10

Search Examiner
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Databases (see below)

(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE DATABASES: WPI

Documents considered relevant following a search in respect of Claims :-
 1-8

Categories of documents

- X:** Document indicating lack of novelty or of inventive step. **P:** Document published on or after the declared priority date but before the filing date of the present application.
- Y:** Document indicating lack of inventive step if combined with one or more other documents of the same category. **E:** Patent document published on or after, but with priority date earlier than, the filing date of the present application.
- A:** Document indicating technological background and/or state of the art. **&:** Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages	Relevant to claim(s)
X	US 5020527 (DESSERTINE) See column 2 line 19 - column 3 line 56	1, 3, 4, 7
X	US 4558710 (EICHLER) See column 2 line 58 - column 3 line 44, column 5 lines 6-43	7

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).