The present disclosure describes a dose counter assembly for use with an inhaler having a housing disposed about a longitudinal axis and a canister extending along a central axis. The dose counter assembly includes a counter body attached to an outer surface of the canister, wherein the counter body is adapted to be slideably movable along the central axis relatively to the canister, a ratchet wheel rotatably mounted on the counter body, a worm gear mounted on the ratchet wheel, an indicator rotatably mounted on the counter body, the indicator including a gear for engaging the worm gear, and activating means mounted on an outer surface of the canister for operatively engaging the ratchet teeth so as to rotate the ratchet wheel in response to the movement of the counter body to the counter body. The ratchet wheel drives the worm gear to rotate, which in turn, drives the indicator to rotate, thereby counting one dose dispensed from the canister.
CANISTER-SUPPORTED GAUGE-TYPE COUNT READOUT ASSEMBLY FOR A METERED DOSE INHALER

FIELD

[0001] This application relates to a dose counter assembly, and in particular, to a dose counter assembly having an improved dosage indicator for indicating the number of metered dosages that have been dispensed from, or remain in, a canister.

BACKGROUND

[0002] Patients having certain conditions, for example, asthma, can be treated with medicaments dispersed in an aerosol form and administered to that patient by inhalation. In one form, the aerosol and medicaments are contained in a canister or container, and dispensed in metered or measured dosages from an inhalation device. In such an arrangement, it is important for the patient to be able to ascertain the number of metered doses remaining in the canister, either by an indication of the number remaining therein or by knowledge of the number already dispensed therefrom, such that the patient is not caught unaware with an empty canister when in need of the medicament. Thus, it is important for the inhalation device to provide an accurate indication of either the number of doses remaining in the canister, or the number of doses already dispensed therefrom.

[0003] Typically, a conventional aerosol canister includes a body and a valve stem extending from one end of the body to emit a metered dose of aerosol and medicament. The canister is usually supplied with a predetermined number of metered doses, generally between 100 and 200 doses of medicament although products outside of this range exist.

[0004] In many of the prior art inhalers, the aerosol canister is removable from the inhaler housing to permit effective cleaning of the structure defining the airflow path. In some inhalers, the housing is designed to accept a succession of
user-introduced aerosol medicament canisters, as well as to provide for canister removal for cleaning.

[0005] In use of these devices, it is desirable that the user knows whether the canister in, or about to be placed in, the inhaler has an ample supply of doses of medicament for the near term, as well as for the long term. With that information, a user can know when to replace a given medicament canister.

[0006] U.S. Pat. No. 6,142,339 describes an inhalation device having a dose counter including a worm gear screw and a ratchet drive in a housing and an indicator having a circular gear thereon for engaging the worm gear screw. A canister is received within the housing and is reciprocally movable along a longitudinal axis of the housing. The reciprocal movement of the canister drives the ratchet and the worm gear to rotate, which in turn drives the indicator to advance and to count a dosage. The dose counter disclosed in the U.S. Pat. No. 6,142,339 is not linked to a specific canister or removable from the housing. If a user swaps a new canister with the canister associated with the housing, the dosage on the dose indicator which is attached to the housing does not show the correct remaining dosage of the new canister.

[0007] U.S. Pat. No. 6,435,372 describes a dose counter also attached to the housing, but not to the canister. Again, the device presents a danger that the dose indicator may show incorrect remaining dosage of the canister if the canister has been swapped with another canister by the user.

[0008] WO 2006/062450 describes a dose counter attached to the top of a canister, but does not mention whether the canister can be removed for cleaning, an essential requirement for long term use. Assuming arguendo, that the canister could be removed, the dose counter would be exposed to unintentional misuse or could be tampered with so that the dose indicator may show incorrect remaining dosage of the canister.

[0009] Because the dose counters for metered dose inhalers available currently are vulnerable to unintentional misuse scenarios, for example inadvertent triggering, swapping of the canister and the housing, and tampering with the
counter, there is a need for an improved dose counter assembly that keeps an accurate record of the number of doses used or remained in the canister.

[0010] Further, it is also desirable to improve the resolution of the count display of a dose counter so that it is easier to determine the current count, particularly as the canister provides its final doses before it is empty.

SUMMARY

[0011] In accordance with one aspect of the invention, a dose counter assembly is provided for use with a medicament dispensing device, preferably a metered dose inhaler. The dose counter assembly is canister-supported and has a gauge-type count readout. The inhaler includes a housing disposed about a longitudinal axis with a mouthpiece section at one end and an end cap at the other end, a canister extending along a central axis, and a dose counter assembly mounted on the canister. The gauge can show a complete range of fullness of the canister and the user can view an indication of the usage of, or remaining doses in the canister.

[0012] The canister can be a known type of aerosol dispensing canister in the art, which generally has a cylindrical shape. In one preferred embodiment, a patient either presses downward so as to put downward pressure on the canister, or inhales at the mouthpiece causing the canister to move downward to an activated position, allowing the release of a measured dose of medicament through a dispensing nozzle of the canister and into the mouthpiece at the same time as the patient breathes in. Thus, the patient inhales air with a metered dose of medicament. The canister then returns to a rest position.

[0013] Typically, the canister is received within the housing, where the central axis of the canister is substantially coaxial with the longitudinal axis of the housing. The canister is reciprocally moveable along the longitudinal axis of the housing.

[0014] In one preferred embodiment, the dose counter assembly is attached to the canister and received within the housing of the inhaler. In another preferred embodiment the canister includes a sleeve, which has an annular shape and is
mounted on an outer surface of the canister, and the dose counter assembly is attached to an outer surface of the sleeve and received within the housing of the inhaler.

[0015] In one preferred embodiment of the invention, the dose counter assembly includes a counter body adapted to be attached to an outer surface of the sleeve, a ratchet wheel rotatably mounted on the counter body, a worm gear fixedly mounted on the ratchet wheel and being rotatable with the ratchet wheel, an indicator rotatably mounted on the counter body, and activating means mounted on the outer surface of the sleeve. The ratchet wheel has ratchet teeth on an outer circumference of the ratchet wheel and is rotatable about a central rotation axis. The worm gear has threads thereon and is rotatable with the ratchet wheel about the central rotation axis. The indicator includes a gear having teeth on an outer circumference of the gear for engaging the thread of the worm gear. The indicator further includes a pointer attached to the gear for indicating a dose number on a scale on a front surface of the counter body.

[0016] In a preferred embodiment of the invention, the counter body is attached to the sleeve by the following mechanism. The sleeve includes a tab and the counter body defines a first recess for receiving the tab of the sleeve. Preferably, the first recess defines a slot for slideably receiving the tab of the sleeve. The counter body further includes a clip and the sleeve further defines a second recess for receiving the clip of the counter body. The clip is constructed such that the clip can be disabled or detached from the second recess by an unlocking means, which is a key feature, preferably on an inner surface of the housing. The key feature can be configured in other ways, such as forming the key feature as a part of the internal and external surface of the housing, e.g., a protrusion of the housing wall. When the canister with the counter assembly is installed with the housing, the key feature engages and disables the clip, such that the counter body is slideably movable along the central axis relatively to the canister. The housing defines a recess for receiving and securing the counter body, such that the counter body cannot move relative to the housing, thereby allowing the canister to be
movable along the longitudinal axis relatively to the housing and the counter body.

[0017] In one preferred embodiment of the invention, the activating means is a pawl mounted on the outer surface of the sleeve. The pawl is adapted to operatively engage the ratchet teeth of the ratchet wheel so as to rotate the ratchet wheel in response to the reciprocal movement of the canister relative to the counter body when the second clip is detached from the sleeve.

[0018] In one preferred embodiment of the invention, the scale, which is on an outer surface of the counter body, has dosage indicia thereon for use with the counter assembly. The housing includes a window to show the scale. Alternatively, the scale may be printed directly on the window. The pointer registers against the scale to indicate a dosage on the scale. In use, when the canister is pressed downward by a user (or by breath actuation) to deliver a dose of medicament from the canister, the pawl engages and rotates the ratchet wheel. The worm gear rotates with the ratchet wheel. The worm gear teeth engage the teeth of the gear of the indicator and drives the gear to rotate. The pointer, which is attached to a gear, rotates with the gear, and advances one unit on the scale for each reciprocal motion of the canister. Thereby, the dose counter assembly counts one dose used by the user.

[0019] In another preferred embodiment of the invention, the gear includes dosage indicia thereon, which can be digits or other indication means, and a pointer is marked on the counter body. When the gear is driven to rotate by one step, the pointer points to the next digits on the indicia, and thereby, one unit is counted by the dose counter assembly.

[0020] According to another aspect of the present invention, the dose counter assembly further includes reverse rotation prevention means mounted on the counter body to allow the ratchet wheel to rotate in a predetermined direction and prevent the ratchet wheel from rotating in a direction opposite the predetermined direction. The reverse rotation prevention means preferably is a clip adapted to engage the ratchet teeth of the ratchet wheel.
In accordance with yet another aspect of the present invention, a dose counter assembly is provided in which the resolution of the displayed count is variable or changes so that as the count progresses from a beginning count (when the canister is full) to its final count (when the canister is empty) the resolution improves. In various preferred embodiments, the resolution may be continuous, or it may be changed in two or more discrete steps.

In accordance with still another aspect the resolution of a single counter disk of a dose counter can be improved by using a dual disk arrangement.

The forms of the invention may include the various ones of the above described features.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and the objects of the invention, reference should be made to the following detailed description and the accompanying drawings in which like reference numerals refer to like elements and in which:

FIG.1 shows a perspective view of an inhaler according to one preferred embodiment of the present invention;

FIG.2A shows a perspective view of a canister with a sleeve mounted on an outer surface of the canister according to one preferred embodiment of the present invention;

FIG.2B shows a perspective view of a dose counter assembly mounted on the canister;

FIG.2C shows a perspective view of the canister with the dose counter assembly received in a housing of the inhaler;

FIGS.3A shows a front schematic view of the dose counter assembly according to a preferred embodiment of the present invention;
[0030] FIG. 3B shows a back schematic view of the dose counter assembly according to a preferred embodiment of the present invention;

[0031] FIG. 3C shows a side schematic view of the dose counter assembly according to a preferred embodiment of the present invention;

[0032] FIG. 4A shows a perspective view of the dose counter assembly according to another preferred embodiment of the present invention;

[0033] FIG. 4B shows a cross-sectional view of the counter body together with the sleeve according to one preferred embodiment of the present invention;

[0034] FIG. 5 shows a key feature on an inner surface of the housing of the inhaler according to one preferred embodiment of the present invention;

[0035] FIG. 6 shows a side view of the counter assembly together with the canister according to a preferred embodiment of the present invention;

[0036] FIG. 7 shows a scale for use with the dose counter assembly according to one preferred embodiment of the present invention;

[0037] FIG. 7A shows a rotating wheel with numbers thereon for use with the dose counter assembly according to another preferred embodiment of the present invention;

[0038] FIG. 7B shows a static pointer readout for use with the dose counter assembly according to yet another preferred embodiment of the present invention; and

[0039] FIGS. 8A and 8B illustrate reverse rotation prevention means mounted on the dose counter assembly according to a preferred embodiment of the present invention.

[0040] FIGS. 9A-9E show side schematic views sequentially illustrating the relative movement of parts of a multi-resolution gauge dose counter assembly providing a resolution that varies continuously or in one or more discrete steps as the counter progresses from its start and final positions;
FIG. 10 shows a front perspective, schematic view of a preferred embodiment of a dual disk counter assembly providing greater resolution;

FIG. 11 shows the front surface of the front disk of the FIG. 10 embodiment;

FIG. 12 shows a detail of the front disk of the FIG. 10 embodiment;

FIG. 13 illustrates a partial perspective view of the dual disk counter assembly of FIG. 10 showing details of the gear and the interrelationship of the front and back disks of the FIG. 10 embodiment;

FIG. 14 shows a perspective, schematic view of the back surface on the inside of the counter body of the embodiment shown in FIG. 10; and

FIGS. 15A-15F show frontal schematic views illustrating sequentially the relative movement of the two disks

DESCRIPTION OF THE PREFERRED EMBODIMENTS

An exemplary inhaler embodying the present invention is shown in FIGS. 1 and 2A-2C. As shown in the figures, the inhaler 110 includes a housing 112 disposed about a longitudinal axis A with a mouthpiece section 114 at one end and an end cap 116 at the other end, a canister 120 extending along a central axis B, and a dose counter assembly 130 mounted on the canister 120. The canister 120 is received within the housing 112, where the central axis B of the canister 120 is substantially coaxial with the longitudinal axis A of the housing 112 as shown in FIG. 2C. The canister 120 is reciprocally moveable along the longitudinal axis A of the housing 112.

The canister 120 can be a known type of aerosol dispensing canister in the art, which generally has a cylindrical shape. The aerosol dispensing canister 120 has a stem 121 which contains an aerosol dispensing valve (not shown). The inhaler 110 embodying the present invention can be a breath actuation inhaler or
pressure actuation inhaler (pressing the canister to deliver the medicament). A patient's pressing downward at the cap 116 or inhalation at the mouthpiece 114 causes the canister 120 to move downward to an activated position, resulting in the release of a measured dose of medicament through the dispensing nozzle and into the mouthpiece at the same time as the patient breathes in. Thus the patient inhales air with a metered dose of medicament. The canister 120 then returns to a rest position. Both actuation mechanisms can be used in the inhaler 110 embodying the present invention and both are known in the art, and are not described in detail in the present disclosure.

[0049] In one preferred embodiment, as shown in FIG.2A, the canister 120 includes a sleeve 122, which has an annular shape and is mounted on an outer surface of the canister 120. As shown in FIG.2B, the dose counter assembly 130 is attached to an outer surface of the sleeve 122. FIG.2C shows the canister 120 with the dose counter assembly 130 is received within the housing 112.

[0050] FIG.3A shows a front view, FIG.3B shows a back view, and FIG.3C shows a side view of the dose counter assembly 130. As shown in FIGS.3A-3C, the dose counter assembly 130 includes a counter body 132 adapted to be attached to the outer surface of the sleeve 122, a ratchet wheel 140 rotatably mounted on the counter body 132, a worm gear 146 fixedly mounted on the ratchet wheel 140 and being rotatable with the ratchet wheel 140, an indicator 150 rotatably mounted on the counter body 132, and activating means 126 mounted on the outer surface of the sleeve 122. The ratchet wheel 140 is rotatable about a central rotation axis C and has ratchet teeth 142 on an outer circumference of the ratchet wheel 140. The worm gear 146 has threads 148 on an outer surface of the worm gear 146. The worm gear 146 is rotatable with the ratchet wheel 140 about the central rotation axis C. The indicator 150 includes a gear 152 having teeth on an outer circumference for engaging the threads 148 of the worm gear 146. The indicator 150 further includes a pointer 156 attached to the gear 152 for indicating a dose number on a scale 154 on front surface of the counter body 132.
[0051] In a preferred embodiment of the invention, the counter body 132 is
attached to the sleeve 122 by the mechanism described below. As shown in
FIG.3B and FIG.4A, the sleeve 122 includes at least one tab 133 and the counter
body 132 defines at least one recess (hereinafter referred to as a first recess 134)
for receiving the tab 133. The sleeve 122 further defines at least one recess
(hereinafter referred to as a second recess 135) for receiving at least one clip 136
on the counter body 132. The counter body 132 is attached to the sleeve 122
when the first recess 134 receives the tab 133 and the second recess 135 receives
the clip 136. FIG.4B shows a cross-sectional view of the sleeve 122 together
with the counter body 132 taken along a plane perpendicular to the central axis B.
As seen in FIG.4B, the sleeve 122 includes alignment means, which preferably
are two protrusions 144 extending along side walls of the sleeve 122 and the
counter body 132 defines two elongated channels 146 for receiving the elongated
protrusions 144, such that the sleeve 122 is slideably movable relatively to the
counter body 132, but cannot rotate with respect to the counter body 132. The
protrusions 144 and the elongated channels 146 maintain the correct alignment of
the counter body 132 with the sleeve 122 when the counter body 132 is attached
to the sleeve 122.

[0052] Preferably, the counter body and canister are constructed so that the
counter body can progressively move through its count when positioned in and
used with the housing, but will be unable to advance in its counts when the
canister and counter body are removed from the housing. This will prevent
unintentional misuse and miscounting when in fact no drag is being released. For
example, in one preferred embodiment, the first recess 134 on the counter body
132 defines a slot for slideably receiving the tab 133 of the sleeve 122. The clip
136 on the sleeve 122 is constructed such that the clip 136 can be disabled or
detached from the second recess 135 on the counter body 132 by an unlocking
means, which preferably is a key feature 138 on an inner surface of housing 112
as shown in FIG.5. While the key feature is shown on an inner surface of
housing 112, the key feature can be configured in other ways, such as forming the
key feature as a part of the internal and external surface of the housing, e.g., a
protrusion of the housing wall. When the canister 120 with the counter assembly 130 is installed within the housing 112, the key feature 138 engages and disables the clip 136, such that the counter body 132 is slideably movable along the central axis B relative to the canister 120. As shown in FIG.2C, the housing defines a recess 139 for receiving and securing the counter body 132, such that the counter body 132 cannot move relatively to the housing 112, thereby allowing the canister 120 to be slideably movable along the longitudinal axis A relatively to the housing 112 and the counter body 132.

[0053] FIG.6 shows a side view of the counter assembly 130 (without the counter body 132) together with the canister 120. As seen in FIG.6, the activating means is a pawl 126 mounted on the outer surface of the sleeve 122. The pawl 126 is adapted to operatively engage the ratchet teeth 142 of the ratchet wheel 140 so as to rotate the ratchet wheel 140 in response to the reciprocal movement of the canister 120 relative to the counter body 132 when the second clip 136 is detached from the sleeve 122.

[0054] FIG.7 illustrates the scale 154 having dosage indicia thereon for use with the counter assembly 130. As shown in FIG.3A, the scale is on the outer surface of the counter body 132. The housing 112 includes a window to show the scale 154. Alternatively, the scale 154 can be printed on the window. The pointer 156 registers against the scale 154 to indicate a dosage on the scale 154. In use, when the canister 120 is pressed downward by a user (or by breath actuation) to deliver a dose of medicament from the canister 120, the pawl 126 engages and rotates the ratchet wheel 140. The worm gear 146 rotates with the ratchet wheel 140. The threads 148 on the worm gear 146 engages the teeth of the gear 152 of the indicator and drives the gear 152 to rotate. The pointer 156, which is attached to gear 152, rotates with the gear 152, and advances one unit on the scale 154. Thereby, the dose counter assembly 130 counts one dose used by the user.

[0055] Other indication mechanisms can also be used with the present invention. For example, the gear 152 may include dosage indicia thereon, which can be digits or other indication means as shown in FIGS.7A and 7B, and a pointer is
marked on the counter body 132. When the gear 152 is driven to rotate by one
step, the pointer points to the next digit on the indicia, and thereby one unit is
counted by the dose counter assembly 130 with each dose. Other indication
mechanisms are described herein..

[0056] As shown in FIGS. 8A and 8B, according to another aspect of the present
invention, the dose counter assembly 130 further includes reverse rotation
prevention means 145 mounted on the counter body 132 to allow the ratchet
wheel 140 to rotate in a predetermined direction and prevent the ratchet wheel
from rotating in a direction opposite the predetermined direction. The reverse
rotation prevention means 145 preferably is a clip adapted to engage the ratchet
teeth 142 of the ratchet wheel 140.

[0057] According to yet another aspect of the present invention, the counter can
be designed to provide a variable or changing resolution as the counter progresses
from a beginning count (when the canister is full) to its final count (when the
canister is empty). A coarser resolution at the beginning of the count is not as
important as providing a greater resolution as the counter nears its final count.
This enables the patient to clearly determine that the canister in use is nearly
empty, and will enable to patient to obtain a new canister to replace the old once
the use of the current canister is done. An example of a multi-resolution gauge
dose counter assembly is shown in FIGS. 9A-9E at 160. The assembly 160 is
similar to the assembly 130 of FIGS. 3A and 3B, except that it has been modified
so that as the ratchet wheel 162 and indicator 164 rotate in a non-uniform fashion.
Specifically, the ratchet wheel 162 is provided with two intersecting cam slots
166 and 168 which interact with the stationary pins 170 and 172, the latter being
attached to the counter body (not shown in FIGS. 9A and 9E). The sequence of
rotation of the ratchet wheel 162 is seen to provide a greater radial displacement
as the counter approaches its final count. Accordingly, the scale (not shown)
which is used with the indicator 164 to indicate the dose can provide indicia
markings that are greater apart for counts near the final count. The two slots can
be shaped in any workable manner so as to define the resolution with each count.
Thus, the resolution can vary continuously or in one or more discrete steps.
[0058] In addition, the resolution of the counter of the type shown in FIGS. 7A-7C can be improved by utilizing more than one disk. For example, as shown in FIG. 10, indicia markings which would be placed on one disk in the embodiment of FIGS. 7A-7C, are provided on two disks 180 and 182 so that the radial displacement from the beginning count to the end count can actually occur with a radial displacement of more that 360°, thus allowing for a greater radial displacement between each indicia marking. As shown in FIG. 10, the front disk 180 includes an arcuate slot 184 so that indicia on the rear disk 182 can be viewed. In general the disks are mounted to interact so that the rear disk is view from the beginning count to a predetermined intermediate count. As the canister is used, the rear disk 182 will rotate while the front disk 180 will remain stationary until the count progresses to some intermediate count (the last count for the rear disk). At this point the rear disk 182 will engage the front disk 180 so that the two will rotate together, so that the indicia on the front disk will now come into view. The two disks will continue to rotate with each count until the counter comes to its final count. An illustration of the sequence of movement of the two disks 180 and 182 is shown in FIGS. 15A-15F.

[0059] FIGS. 11-14 illustrate an example of how the rear disk can freely rotate relative to the front disk from the beginning count to the intermediate count, and engage the front disk at the intermediate count so that the two will rotate together until the final count. As shown in FIG. 13, the front disk 180 is provided with a circular slot 186, while the rear disk 182 is provided with driving teeth 188 that is slidable in the slot 186. The slot 186 and driving tooth 188 are position on the disks so that the driving tooth 188 freely slides in the slot 186 between the beginning count and the intermediate count. At the intermediate count the driving tooth 188 reaches the end of the slot 186 so that the front disk will begin to rotate with the rear disk until the end position.

[0060] As shown more clearly in FIG. 13, the rear disk 182 is preferably provided with gear teeth 190 on its periphery, which is driven by the worm gear (not shown). The front disk is not provided with teeth so that it will not rotate until the rear disk reaches a position corresponding to the intermediate count. In
order to prevent the front disk from rotating while the rear disk rotates between a position corresponding to the beginning count and a position corresponding to the intermediate count, a bump stop or clip 192 (best seen in FIG. 12), for example, can be provided so as to interact with each individual bump arranged in a circular configuration 194 on the inside of the counter body, indicated at 196 in FIG. 14). Thus, the bump stop 192 will engage a bump stop of circular configuration 194 as the rear disk rotates from a position corresponding to the beginning count to a position corresponding to the intermediate count. Driving tooth 188 will then reach the end of the slot 186. With the next count, sufficient radial force will be transferred from the worm gear to the rear disk, and from the rear disk to the front disk so that the front and rear disks will rotate together and advance one count wherein the bump stop 192 will advance one bump stop of the circular configuration 194.

[0061] The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.
What is claimed is:

1. A dose counter assembly for use with an inhaler having a housing disposed about a longitudinal axis and a canister extending along a central axis, said canister being adapted to be received within said housing, whereby said central axis is substantially coaxial with said longitudinal axis and said canister is reciprocally moveable along said longitudinal axis of said housing, said dose counter assembly comprising:

   a counter body attachable to an outer surface of the canister, wherein said counter body is adapted to be slideably moveable along said central axis relatively to said canister;

   a ratchet wheel rotatably mounted on said counter body, said ratchet wheel having ratchet teeth thereon and being rotatable about a central rotation axis;

   a worm gear mounted on said ratchet wheel and being rotatable with said ratchet wheel about said central rotation axis;

   an indicator rotatably mounted on said counter body, said indicator comprising a gear engaging said worm gear; and

   activating means mounted on an outer surface of the canister for operatively engaging said ratchet teeth so as to rotate said ratchet wheel in response to the movement of the canister relative to said counter body.

2. A dose counter assembly according to claim 1, wherein said canister includes a tab and said counter body defines a first recess for slideably receiving said tab of said counter body.

3. A dose counter assembly according to claim 2, wherein said counter body further includes a clip and said canister further defines a second recess for receiving said clip, wherein said clip is detachable from said second recess on said counter body.

4. A dose counter assembly according to claim 3 further comprising said housing and including unlocking means mounted on an inner surface of said
housing for engaging said clip and detaching said clip from said second recess of said canister, thereby allowing said canister to be slideably movable relatively to said counter body when said canister is installed within said housing.

5. A dose counter assembly according to claim 1, wherein said counter body comprises a scale having dosage indicia thereon, and wherein said indicator comprises a pointer for indicating a dosage on said scale, said pointer being connected to and rotatable with said gear of said indicator.

6. A dose counter assembly according to claim 1, wherein said gear includes dosage indicia thereon, and wherein said counter body includes a pointer for indicating a dosage on said dosage indicia on said gear.

7. A dose counter assembly according to claim 1, wherein said activating means includes a pawl mounted on said outer surface of the canister, said pawl being adapted to engage said ratchet teeth.

8. A dose counter assembly according to claim 1, wherein said canister further comprises a sleeve fixed to said outer surface of said canister, wherein said counter body is attached to an outer surface of said sleeve.

9. A dose counter assembly according to claim 8, wherein said activating means includes a pawl mounted on said outer surface of said sleeve, said pawl being adapted to engage said ratchet teeth.

10. A dose counter assembly according to claim 8, wherein said sleeve includes at least one alignment element extending along an axis parallel to said central axis of said canister, and wherein said counter body defines at least one elongated channel for receiving said alignment element.

11. A dose counter assembly according to claim 1 further comprising reverse rotation prevention means mounted on said counter body to allow said ratchet to rotate in a predetermined direction and prevent said ratchet wheel from rotating in a direction opposite said predetermined direction.

12. A dose counter assembly according to claim 1, wherein said canister includes at least one alignment element extending along an axis parallel to said
central axis, and wherein said counter body defines at least one elongated channel for receiving said alignment element.

13. A dose counter assembly according to claim 1, wherein the an indicator rotatably mounted on said counter body includes a pair of disks.

14. A dose counter assembly according to claim 13, wherein the counter body is constructed so that the current count of the number of doses remaining in the inhaler is visible, each of the disks being rotatably secured so that indicia markings representing the current count on a second disk are visible when the current count is between a beginning count and a predetermined intermediate count, and the indicia markings representing the current count on the first disk are visible the window when the count is between the intermediate count and a final count, and wherein only the second disk rotates between a beginning position corresponding to the beginning count, and the intermediate position corresponding to the intermediate count, and both the first and second disks rotate between the intermediate position corresponding to the intermediate count and a final position corresponding to the final count.

15. A dose counter according to claim 1, further including an indication mechanism including the indicator, for indicating a count representing the number of doses remaining in the inhaler, the indication mechanism including indicia having a resolution that varies (a) from a beginning count when the inhaler is substantially full, (b) to a final count when the inhaler is substantially empty.

16. A dose counter according to claim 15, wherein the indicator mechanism includes the ratchet wheel, and the ratchet wheel being rotatable about a central rotation axis relative to the housing between a beginning position and a final position, the dose counter further including a pair of cam slots for causing the amount of radial displacement of the ratchet wheel to vary as the ratchet wheel rotates from the beginning position and final position.

17. An inhaler comprising:

a housing disposed about a longitudinal axis;
a canister extending along a central axis, said canister being adapted to be
received within said housing, whereby said central axis is substantially coaxial
with said longitudinal axis and said canister is reciprocally movable along said
longitudinal axis of said housing;

a counter body attached to an outer surface of the canister, wherein said
canister is adapted to be slideably movable along said central axis relatively to
said counter body;

a ratchet wheel rotatably mounted on said counter body, said ratchet
wheel having ratchet teeth thereon and being rotatable about a central rotation
axis;

a worm gear mounted on said ratchet wheel and being rotatable with said
ratchet wheel about said central rotation axis;

an indicator rotatably mounted on said counter body, said indicator
comprising a gear engaging said worm gear; and

activating means mounted on an outer surface of the canister for
operatively engaging said ratchet teeth so as to rotate said ratchet wheel in
response to the movement of the canister relative to said counter body when said
second clip is detached from said canister.

18. An inhaler according to claim 17, wherein said housing defines a recess
for detachably receiving said counter body.

19. An inhaler according to claim 17, wherein said canister includes a tab and
said counter body defines a first recess for slideably receiving said tab of said
counter body.

20. An inhaler according to claim 17, wherein said counter body further
includes a clip and said canister further defines a second recess for receiving said
clip, wherein said clip is detachable from said second recess on said counter
body.

21. An inhaler according to claim 20, wherein said housing includes
unlocking means mounted on an inner surface of said housing for engaging said
clip and detaching said clip from said second recess of said canister, thereby allowing said canister to be slideably movable relatively to said counter body when said canister is installed within said housing.

22. An inhaler according to claim 17, wherein said counter body comprises a scale having dosage indicia thereon, and wherein said indicator includes a pointer for indicating a dosage on said scale, wherein said pointer is connected to and rotates with said gear.

23. An inhaler according to claim 17, wherein said gear includes dosage indicia thereon, and wherein said counter body includes a pointer for indicating a dosage on said dosage indicia.

24. An inhaler according to claim 17, wherein said activating means includes a pawl mounted on said outer surface of the canister, said pawl being adapted to engage said ratchet teeth.

25. An inhaler according to claim 17, wherein said canister further comprises a sleeve fixed to said outer surface of said canister, wherein said counter body is attached to an outer surface of said sleeve.

26. An inhaler according to claim 25, wherein said activating means includes a pawl mounted on said outer surface of said sleeve, said pawl being adapted to engage said ratchet teeth.

27. An inhaler according to claim 25, wherein said sleeve includes at least one alignment element extending along an axis parallel to said central axis of said canister, and wherein said counter body defines at least one elongated channel for receiving said alignment element.

28. An inhaler according to claim 17, further comprising reverse rotation prevention means mounted on said counter body to allow said ratchet wheel to rotate in a predetermined direction and prevent said ratchet wheel from rotation in a direction opposite said predetermined direction.

29. An inhaler according to claim 17, wherein said canister includes at least one alignment element extending along an axis parallel to said central axis, and
wherein said counter body defines at least one elongated channel for receiving said alignment element

30. An inhaler according to claim 17, wherein the indicator rotatably mounted on said counter body includes a pair of disks.

31. An inhaler according to claim 30, wherein the counter body is constructed so that the current count of the number of doses remaining in the inhaler is visible, each of the disks being rotatably secured so that indicia markings representing the current count on a second disk are visible when the current count is between a beginning count and a predetermined intermediate count, and the indicia markings representing the current count on the first disk are visible when the count is between the intermediate count and a final count, and wherein only the second disk rotates between a beginning position corresponding to the beginning count, and the intermediate position corresponding to the intermediate count, and both the first and second disks rotate between the intermediate position corresponding to the intermediate count and a final position corresponding to the final count.

32. An inhaler according to claim 17, further including an indication mechanism including the indicator, for indicating a count representing the number of doses remaining in the inhaler, the indication mechanism including indicia having a resolution that varies (a) from a beginning count when the inhaler is substantially full, (b) to a final count when the inhaler is substantially empty.

33. An inhaler according to claim 32, wherein the indicator mechanism includes the ratchet wheel, and the ratchet wheel being rotatable about a central rotation axis relative to the housing between a beginning position and a final position, the dose counter further including a pair of cam slots for causing the amount of radial displacement of the ratchet wheel to vary as the ratchet wheel rotates from the beginning position and final position.

34. A dose counter for keeping count of the number of doses administered from an inhaler, comprising an indication mechanism for indicating a count
representing the number of doses remaining in the inhaler, the indication mechanism including indicia having a resolution that is varies (a) from a beginning count when the inhaler is full (2) to a final count when the inhaler is substantially empty.

35. A dose counter according to claim 34, wherein the resolution varies as a continuous function.

36. A dose counter according to claim 35, wherein the dose counter includes a housing;
a pair of spaced apart pins fixed relative to the housing; and
a ratchet wheel, said ratchet wheel being rotatable about a central rotation axis relative to the housing between a beginning position and a final position, and including a pair of cam slots for causing the amount of radial displacement of the ratchet wheel to vary as the ratchet wheel rotates from the beginning position and final position.

37. A dose counter according to claim 34, wherein the resolution changes at least once between the beginning count and the final count.

38. A dose counter according to claim 37, where the resolution various in a plurality of discrete steps.

39. An inhaler for administering medication one dose at a time, comprising the dose counter according to claim 34.

40. A dose counter for keeping count of the number of doses administered from an inhaler, comprising a counter body and an indication mechanism for indicating a count representing the number of doses remaining in the inhaler, the indication mechanism including at least two disks each including indicia markings representing doses, wherein the counter body is constructed so that the current count of the number of doses remaining in the inhaler is visible, each of the disks being rotatably secured so that indicia markings representing the current count on a second disk are visible when the current count is between a beginning count and a predetermined intermediate count, and the indicia markings representing the current count on the first disk are visible the window when the
count is between the intermediate count and a final count, and wherein only the second disk rotates between a beginning position corresponding to the beginning count, and the intermediate position corresponding to the intermediate count, and both the first and second disks rotate between the intermediate position corresponding to the intermediate count and a final position corresponding to the final count.

41. An inhaler for administering medication one dose at a time, comprising the dose counter according to claim 40.
FIG. 4A
FIG. 6
FIG. 9A
FIG. 15C
FIG. 15E
## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M15/00

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 data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 5 349 945 A (WASS ET AL) 27 September 1994 (1994-09-27) column 5, line 27 - column 9, line 7</td>
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Further documents are listed in the continuation of Box C

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* Special categories of cited documents
  * A document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search: 7 December 2006

Date of mailing of the international search report: 15/12/2006

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 til,
Fax (+31-70) 340-3016

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

1. Claims Nos because they relate to subject matter not required to be searched by this Authority, namely

2. Claims Nos 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

3. Claims Nos because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 64(a)

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

see additional sheet

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 applicants protest

No protest accompanied the payment of additional search fees
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-14, 17-31

   a dose counter assembly, comprising
   A) a counter body
   B) a ratchet wheel
   C) a worm gear
   D) an indicator
   E) activating means
   and further features relating to the counter mechanism

2. claims: 1 + 15/16, 17 + 32/33, 34-41

   a dose counter, comprising:
   D) an indicator
   and further features relating to visual embodiment of the indicator
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