DISPENSER WITH DOSES' COUNTER

The present invention relates to a dispenser having an actuation indicator for indicating the number of actuations thereof. In particular, the invention relates to metered dose inhalers by means of which medicaments contained in an aerosol container may be administered to a patient.

It is well known to treat patients with medicaments contained in an aerosol, for example, in bronchodilator therapy. It is also known to use for such therapy, medicaments which are contained in an aerosol and are administered to a patient by means of an inhalation device comprising a tubular housing or sleeve in which the aerosol container is located and an outlet tube leading out of the tubular housing. The aerosol containers used in such inhalation devices are designed to deliver a predetermined dose of medicament upon each actuation by means of an outlet valve member at one end which can be opened either by depressing the valve member while the container is held stationary or by depressing the container while the valve member is held stationary. In the use of such devices, the aerosol container is placed in the tubular housing with the outlet valve member of the container communicating via a support with the outlet tube, for example a nozzle or mouthpiece. When used for dispensing medicaments, for example in bronchodilation therapy, the housing is then held by the patient in a more or less upright condition and the mouthpiece or nozzle of the inhalation device is placed in the mouth or nose of the patient. The aerosol container is pressed towards the support to dispense a dose of medicament from the container which is then inhaled by the patient.

A disadvantage arising from use of such known devices is that the patient cannot determine the amount of medicament in the container at any given time. In an extreme case this could mean that the patient, possibly suffering from severe bronchospasm and needing a dose of medicament, will find that the container will not dispense a dose because its contents have already been exhausted.

US Patent No. 4817822 describes an aerosol dispenser of the type described above having a dose indicating device which, in a first embodiment is removably attached to the end of the protruding portion of the aerosol container. The operating mechanism of the dose counter is located within a housing which extends from the end of the aerosol container along the external surface of the tubular housing. It is important with inhalation devices containing medicament that the contents of the aerosol container are clearly marked to ensure that the patient knows exactly what medication is contained. One disadvantage associated with this positioning of the dose indicating device is that the device obscures at least a part of the aerosol container and housing which creates labelling difficulties.

A further disadvantage of the device described is that if the dose indicating device is removably attached to the aerosol container, it is possible that the dose indicating device may become separated from its aerosol container with the result that the aerosol dispenser could be used without the dose indicating device, or the actuating mechanism of the indicating device could be tampered with leading to a false reading when the indicating device is re-attached to the dispenser. With patients having several different inhalers, it could even result in the indicating device being re-attached to the wrong dispenser.

In a second embodiment described in US4817822 the operating mechanism of the dose indicating device is located within a compartment in the housing and is actuated by means of an actuator member attached to the aerosol container. In this embodiment, once the aerosol container is fitted into the housing it cannot be removed. This makes cleaning of the housing very difficult. Even if the container were removable, the operating mechanism of the dose indicating device would be vulnerable to damage when washing with water, soap, disinfectant or antiseptic solutions. This is important because sprays of many aerosol formulations leave residues which can entrap dust and dirt particles. Some provide a media for the growth of undesired micro-organisms. If the growth of these micro-organisms is unchecked, they can serve as a source of infection for the patient and will often introduce pathogens into the patient's respiratory tract.

WO96/16686 describes an aerosol dispenser wherein the operating mechanism of the dose indicating device is electronic and wherein the actuating member comprises a microswitch set into the wall of the housing. The electronic counting mechanism and microswitch are contained within a hermetically sealed enclosure. However, electronic assemblies of this type are relatively expensive compared to equivalent mechanical mechanisms, typically costing five or six times as much to produce depending on quantities manufactured. Such expense must ultimately be borne by the customer and may be prohibitive.

US5482030 describes an aerosol dispenser having a mechanical dose indicator device located in and connected to the housing in the vicinity of the outlet tube of the aerosol container when fitted. Its mechanical construction makes it difficult to seal against moisture ingress and so this dispenser again is difficult to wash without damaging the operating mechanism of the dose indicating device.

Many different pharmaceutical products are sold in the form of aerosol containers as discussed above, requiring different sized container bodies and/or valves according to the required specifications. It is therefore normal for there to be dimensional variations between different aerosol containers. Even between the same products there can be dimensional variations due to manufacturing tolerances. One problem which is common to all of the dose indicating devices discussed above is that the indicator mechanism, which is actuated by means of a switch which detects relative movement between the container body and housing, lacks any means of compensating for dimensional variations between different aerosol containers. Hence, the indicators described must be dimensioned according to the product with which they are to be used, and so will not be interchangeable with other products. Furthermore, in order for the dose indicators to work properly, the dimensions of the indicator, aerosol container and housing must be accurate.

It is an object to provide a dispenser having an actuation indicator which overcomes at least some of the above described disadvantages. It is a further object to provide such a dispenser which from the point of view of the patient closely resembles currently marketed dispensers in both external appearance and operation.

According to one aspect of the present invention there is provided a dispenser for dispensing medicament comprising a housing having a support; a container, locatable within said housing, having an outlet member, wherein said container is movable relative to the housing to enable dispensing therefrom and said outlet member is connectable with said support to prevent relative movement therebetween; and an actuation indicator, locatable within said housing, wherein the container and dose indicator are reversably removable from the housing as a single unit.

Suitably, the actuation indicator is engagable with the container in the vicinity of the outlet member. More preferably, the actuation indicator is engagable with the outlet member.

Suitably, the actuation indicator is provided with a grip member which is engagable with a neck portion of the container. Preferably, the neck portion is adjacent to or on the outlet member.

Suitably, the container is an aerosol container.

Suitably, the housing is provided with an outlet, more preferably in the form of a mouthpiece. Preferably, the dispenser comprises a passage through which dispensed doses may pass from the container to the outlet.

Suitably, the container provides measured doses.

Suitably, the actuation indicator indicates the number of doses dispensed from or remaining in the container.

Suitably, the actuation indicator comprises an indexing mechanism actuated by a predetermined movement of the aerosol container relative to the housing.

Preferably, the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement ('overtravel') of the aerosol container relative to the housing.

By use of a lost motion coupling it is possible to create an actuation indicator of one size which can accomodate valves and actuators made within a wide range of manufacturing tolerances and can even fit a range of dispensers made to different dimensions.

Suitably, the indexing mechanism indexes the actuation indicator by means of a predetermined rotary movement of a first member driven by movement relative to a second member during actuation of the aerosol dispenser.

Suitably, the second member remains stationary relative to the housing during actuation of the aerosol dispenser.

Suitably, the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack. Alternatively, the first member comprises a yoke and the second member comprises a post engaged by the yoke through the lost motion coupling.

Preferably, the lost motion coupling comprises a friction drive mechanism.

Suitably, the dispenser is a breath operated inhaler which is actuable in response to the inward breath of a user.

According to a particularly preferred aspect of the present invention there is provided an aerosol dispenser comprising a housing in which a container is removably located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet and housing to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container, characterised in that the dose indicating device is tightly connected to the container in the vicinity of the outlet member, such that the container and dose indicating device may be removed from the housing as a single unit.

According to a further aspect of the present invention there is provided an actuation indicating device for use with a dispenser comprising a housing and a container, locatable within said housing, having an outlet member, the actuation indicating device comprising attachment means to enable attachment to the container.

Suitably, the attachment means comprises a grip member which firmly engages a neck portion formed around the container. More preferably, the neck portion is located at the connection between the container and outlet member.

According to a particularly preferred aspect of the present invention the actuation indicating device has an actuation indicator for indicating the number of doses dispensed from or remaining in the container, wherein the actuation indicating device comprises attachment means to enable tight connection to the container in the vicinity of the outlet member.

By fixing the actuation indicating device to the container in the vicinity of the outlet member may be possible to make use of the physical dimensions of the crimped ferrule of standard containers to provide a tight snap fit between the dose indicating device and aerosol container for easy assembly yet which once assembled cannot be easily separated. This ensures that the actuation indicator presents accurate information concerning the container with which it is assembled.

In a preferred aspect, the dispenser is a metered dose inhaler comprising a housing in which the container is removably located, an outlet leading from the housing, a support in the housing arranged to receive the outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet and housing to dispense its contents in measured doses, and a window through which the dose indicator may be viewed.

The location of the dose indicator in the vicinity of the outlet member of the container in a metered dose inhaler provides the advantage that visually and operationally the device may appear very similar to current marketed metered dose inhalers without dose indicating devices such that when switched to the metered dose inhaler according to the invention, patients perceive little change over their conventional dispensers, so creating minimal impact upon patients and their use of the device.

A dispenser according to the invention will now be described with reference to the accompanying drawings in which:

Fig. 1 is a section through a standard inhalation device comprising an aerosol dispenser;

Fig. 2 is a section through the dose indicating device as fitted to an aerosol dispenser in an inhalation device;

Fig 2a is a sectional view of an aspect of a dose indicating device herein;

Fig. 3 is a perspective view of a counting mechanism used in the dose indicating device of Fig. 2;

Fig. 4 shows the sequence of operation of the counter mechanism of Fig. 3;

Fig. 5 shows a lateral and a longitudinal section through a second embodiment of the dose indicating device as fitted into the housing of an inhalation device;

Fig. 6 shows an exploded view of a dose indicating device according to a third embodiment of the invention;

Fig. 7 shows another exploded view of the dose indicating device of figure 6 together with an aerosol container and housing;

Fig. 8 shows a schematic section through an inhalation device comprising the dose indicating device of figure 6 in a rest position; and

Fig. 9 shows a schematic section through the inhalation device of figure 8 in an actuated position.

The standard metered dose inhaler shown in Fig 1 comprises a tubular housing 1 in which an aerosol container 2 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 3 leads laterally from the closed end of the housing 1. In the embodiment illustrated, the outlet 3 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

The aerosol container 2 has an outlet valve stem 4 at one end. This valve member can be depressed to release a measured dose from the aerosol container or, alternatively, the valve stem 4 can be fixed and the main body of the container can be moved relative to the valve member to release the dose.

As shown clearly in Fig 1, the aerosol container 2 is located in the housing 1 so that one end protrudes from its open top. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1. A support 5 is provided at the lower end of the housing 1 and has a passage 6 in which the valve stem 4 of the aerosol container 2 can be located and supported. A second passage 7 is provided in the support 5 and is directed towards the interior of the outlet 3. Thus, when the parts are in the positions shown in Fig 1, the protruding portion of the aerosol container 2 can be depressed to move the container relative to the valve stem 4 to open the valve and a dose of medicament contained in the aerosol will be discharged through the passage 7 and into the outlet 3 from which it can be inhaled by a patient. One dose will be released from the aerosol container each time it is fully depressed.

Fig 2 shows the lower part of a device similar to that of Fig 1 but incorporating a dose indicating device according to the invention. The dose indicating device comprises a body 8 firmly attached to the aerosol container by means of tubular portion 9 formed with grips 10. Tubular portion 9 tightly engages the periphery

of valve ferrule 11 while a grip in the form of lip 10 engages around neck 12 of valve ferrule 11 which is formed during assembly when valve ferrule 11 is crimped onto aerosol container 2. Thus the tubular portion 9 and lip 10 form a tight connection to the aerosol container which once assembled by pushing the tubular portion 9 over the valve ferrule 11 cannot easily be dissembled.

Below tubular portion 9, body 8 forms a cradle 22 for mounting counter mechanism 13 and drive pinion 14. Drive pinion 14 is friction mounted on counter mechanism drive shaft 15. Drive pinion 14 is formed with a number of teeth or pegs 21 which can engage with a number of recesses or grooves formed on post 17 in the form of a rack moulded inside housing 1 and extending from the base of the housing 1 parallel to valve stem 4.

Whilst in the embodiment shown in Fig 2 the post 17 forms a moulded part of the housing other variations can be envisaged in which the post 17 forms a part of the dose indicating device itself. For example, Fig 2a shows a simplified representation of a dose indicating device in which the head of post 17 is receivable within a recess provided in the body 8 of the device. Teeth formed on the post 17 engage corresponding teeth on drive pinion 14. Spring 28 acts such as to urge the post from the recess. The protruding lip 24 of the post 17, however, abuts stop 26, thereby retaining at least a portion of the post 17 within the recess.

As shown in Figs 3 and 4, drive shaft 15 is connected to driver yoke 16 of counter mechanism 13. Driver yoke 16 has two switching latches 18a and 18b spaced either side of star wheel 19 such that driver yoke 16 may tilt about the axis of drive shaft 15 between a first position shown in Fig 4b in which switching latch 18a engages one side of star wheel 19, and a second position shown in Fig 4d in which switching latch 18b engages the other side of star wheel 19. Star wheel 19 is connected through a mechanism, similar to that described with reference to reference numerals 2 to 8 in Figs 1 to 3 of European Patent No. 0280104, to three digit wheels 33, which have numbers printed on their circumferential faces as described below. When located in the housing 1, counter mechanism 13 is small enough to be located to the sides of and behind

support 5 so as not to interfere with the aerosol flume as it emerges from passage 7.

The aerosol container 2 may be supplied to the patient with the dose indicating device ready assembled thereto. Alternatively, the housing 1 may be supplied to the patient with the dose indicating device located in the position shown in Fig 2 and the aerosol container 2 supplied separately. In this case, the patient is instructed to insert the aerosol container 2 into the housing 1 with the valve stem first. Upon first insertion of the container into the housing, the tubular portion 9 and lip 10 of the dose indicating device ride over the periphery of valve ferrule 11 of the aerosol container 2 until lip 10 snaps around neck 12. Thereafter, the dose indicating device is attached to the aerosol container 2.

Other means of attachment of the dose indicator to the container are envisaged including adhesive attachment; use of welded shrink sleeves; heat forming; crimping; ultra-sonic welding; and by the presence of an o-ring elastomer on the container which is fixedly piercable by barbs on the attachment member of the dose indicator. In one aspect, permanent means of attachment are preferred.

To actuate the device, the protruding portion of the aerosol container is depressed as described above with reference to Fig. 1. As the aerosol container carrying the dose indicating mechanism moves within housing 1, drive pinion 14 starts to turn, through its engagement with post 17, causing rotation of drive shaft 15 and driver yoke 16. As driver yoke 16 tilts with rotation of drive shaft 15 switching latch 18a moves into engagement with star wheel 19 (Fig 4a) causing an incremental anti-clockwise rotation of a half tooth pitch of the star wheel until the switching latch 18a can move no further in this direction, the switching latch being positioned between two adjacent teeth of the star wheel (Fig 4b). At this point, drive shaft 15 cannot rotate any further and any further movement of the aerosol container into housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15.

When the valve stem 4 has reached its fully depressed position and a metered dose of medicament has been discharged from the aerosol container, the

aerosol container is allowed to return to its original position. As the aerosol container and dose indicating mechanism return to their original position, drive pinion 14 starts to rotate in the opposite direction together with drive shaft 15 and driver yoke 16. Thus, driver yoke 16 tilts such that switching latch 18a moves out of engagement with star wheel 19 while switching latch 18b moves into engagement therewith (Fig 4c), causing further incremental anti-clockwise rotation of a half tooth pitch of the star wheel until switching latch 18b can move no further in this direction (Fig 4d). Again, drive shaft 15 cannot rotate any further at this point and any further movement of the aerosol container out of housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15. In this way it can be seen that the friction coupling acts as a lost motion coupling which allows the dose indicating device to be used with aerosol containers having valves with different lengths of travel of valve stem during actuation.

Each time the aerosol dispenser is actuated the star wheel is made to rotate through two incremental anti-clockwise movements as described above. These movements are translated through the counter mechanism into appropriate movements of the digit wheels 33, one number on each of the printed circumferential faces of the digit wheels being clearly visible through the widow 20 at the back of the housing 1 (as shown in Fig 2), to indicate that a further dose of medicament has been dispensed. By having three digit wheels 33 it is possible for the dose counter to be used to count hundreds of doses. Clearly if fewer than one hundred doses are to be contained within the dispenser, the dose counter could comprise fewer digit wheels. Alternatively, if a thousand or more doses are to be contained, then one or more additional digit wheels could be added as appropriate.

To remove the aerosol container 2 from the housing for cleaning, the aerosol container 2 may be withdrawn from the housing 1 in the usual manner. As the container is withdrawn, the friction coupling between drive pinion 14 and drive shaft 15 allows such further movement as is required for the drive pinion to come out of engagement with the post 17 without causing any further indexing of the counter mechanism. Once removed, the housing 1 may be cleaned as

described without fear of interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container 2.

When the housing 1 is clean, the aerosol container 2 with dose indicating device may be re-inserted into the housing 1. During insertion, drive pinion 14 will engage post 17 and start to rotate until the aerosol container reaches its normal rest position with the valve stem 4 located in support 5. As the drive pinion 14 rotates, the friction coupling will act as a lost motion mechanism as described above, allowing for any travel of the aerosol container as between first engagement of drive pinion 14 and post 17, and location of valve stem 14 in support 5. In this way, the friction coupling automatically accommodates and compensates for different lengths of valve stems protruding from the ferrule.

Fig 5 shows an alternative lost motion coupling mechanism which may be used in an aerosol dispenser according to the invention. In this embodiment, instead of a pinion, driver yoke 16 is formed with two resilient arms 30 between which post 17 is grippingly engaged (Fig 5a). Post 17 is formed with ribs on its surface (not shown) which provide a rough surface finish to create the level of friction required between arms 30 and post 17 such that arms 30 will grip post 17 until the load applied overcomes the friction.

Upon actuation of the device, as the aerosol container and dose indicating mechanism move, the friction engagement between arms 30 and post 17 cause driver yoke 16 to tilt about the axis of shaft 15 (not shown in Fig 5), so moving switching latch 18a into engagement with star wheel 19 as discussed in relation to the first embodiment. As switching latch 18a reaches its limit of travel, driver yoke 16 can move no further, and any further movement of the aerosol container into housing 1 results in arms 30 slipping down post 17 by virtue of the friction coupling. Upon return to its original position, driver yoke 16 tilts in the other direction until switching latch 18b moves into engagement with star wheel 19 and can move no further. Any further movement of the aerosol container out of housing 1 results in arms 30 slipping up post 17.

Figures 6 to 9 show an inhalation device fitted with an electro-mechanical dose indicating device according to the invention. As with the mechanical

embodiments discussed above, the dose indicating device comprises a body 40 firmly attached to the aerosol container by means of tubular portion 41 formed with grips (not shown). Tubular portion 41 tightly engages the periphery of valve ferrule 11 while a grip in the form of a lip engages around neck 12 of valve ferrule 11. Thus the tubular portion 41 and lip form a tight connection to the aerosol container which once assembled by pushing the tubular portion 41 over the valve ferrule 11 cannot easily be disassembled.

Below tubular portion 41, body 40 forms a cradle for mounting counter mechanism 43, and defines a chamber for accommodating switch slide 44. Switch slide 44 is a cylindrical washer made of silicone rubber and having a bore of such a diameter that, with the can and dose indicating device mounted within the actuator housing, it provides a friction fit on pin 45, which is moulded in the housing and protrudes through a hole in body 40. The friction fit of switch slide 44 on pin 45 ensures the switch slide will not move along the pin unless pushed. Two contact members 46, 47, both of which comprise a switch contact and a circuit board contact, and one of which further comprises a battery contact, are mounted such that the battery and circuit board contacts are in constant contact with a first terminal of the battery 48 and printed circuit board (PCB) 49 respectively. The switch contacts do not contact each other but are positioned either side of pin 45, and define the upper limit of movement of the switch slide 44 within its chamber. Thus, when switch slide 44 is in its upper position as shown in figure 9, it makes contact with both switch contacts, so closing the circuit between them due to the electrical conductivity of the silicone rubber of the switch slide. Although in the embodiment described the switch slide is made of silicone rubber, it will be appreciated that it could alternatively be made of a non-conductive rubber having an insert at its upper face made of metal or some other conductive material.

In addition to its connections with contact members 46, 47, PCB 49 also has connections to the other terminal of the battery and to a three digit liquid crystal display (LCD) 50 in a conventional manner. The PCB comprises an application specific integrated circuit (ASIC), which provides the logic by which the dose indicator can be checked, programmed and made operational, as discussed in more detail below. to keep a record of how many times the switch contact circuit

is closed and drives the LCD to display the number of doses remaining in the aerosol container. The ASIC is thus designed and programmed accordingly in a known manner.

Instead of a digital display, the LCD could alternatively be formatted to display an analogue indication. When the aerosol container is mounted in the actuator housing, LCD 50 is visible through window 20. In the embodiment depicted in figure 7, the LCD and window are located at the back of the housing, but they could equally be located at the front or some other part of the housing.

The Counter mechanism 43 is small enough to be located to the sides of and behind the stem block (support 5) moulded in housing so as not to interfere with the aerosol flume as it emerges.

To actuate the device, the protruding portion of the aerosol container when fitted into the actuator housing is depressed as described above. As the aerosol container carrying the dose indicating mechanism moves within the housing from its rest position (shown in figure 8), the chamber accommodating switch slide 44 moves down until the upper face of switch slide 44, which is mounted on pin 45, meets switch contacts 46, 47 and the switch circuit is closed. This causes the ASIC to decrement the number displayed by the LCD 50. As the aerosol container continues to move, a metered dose of medicament is discharged from the valve, while switch slide 44 is pushed down along pin 45 by virtue of the friction fit of the switch slide on the pin until the valve stem reaches its limit of travel and the aerosol container moves no further (figure 9). In this way, it can be seen that the friction fit of the switch slide 44 on pin 45 allows for over-travel of the valve stem after the switch circuit has been closed, so acting as a lost motion coupling. The aerosol container is then allowed to return to its original position within the housing, and as it returns, the chamber accommodating switch slide 44 moves up breaking the switch circuit as switch contacts 46, 47 move away from switch slide 44. Body 40 then meets the lower face of switch slide 44 and draws the switch slide up along pin 45 until the valve stem returns to its rest position (figure 8).

Because the dose indicating device is designed to be suitable for use in connection with different sized aerosol containers containing different numbers of doses to be delivered, the ASIC is designed to be factory set in accordance with the size of aerosol container with which the dose indicating device is assembled. After assembly of the dose indicating device and first connection of the battery, the ASIC enters a self-test mode. After this, the programming mode may be entered by activating the switch, allowing it to be programmed to count down from the appropriate number of doses (e.g. 200, 120, 80 or 60). This may be done automatically on a packing line. After programming has taken place, the ASIC enters the counting mode, where the LCD decrements upon closing of the switch contact circuit. When the count of zero is reached, the ASIC is designed to prevent the count from decrementing any further in a known manner. In order to prevent spurious readings due to the effects of switch 'bounce', the ASIC may be designed to decrement only after the switch circuit has been closed for a predetermined length of time in a known manner. In the event of the aerosol container getting jammed in the actuated position after operation, or the switch circuit jamming closed due to mechanical damage or contamination, the ASIC may be designed to blank the LCD to alert the user that there is a problem.

As with the other embodiments of the invention described above, the aerosol container may be withdrawn from the actuator housing in the usual manner. As the container is withdrawn, body 40 draws the switch slide up along pin 45 until it clears the pin altogether. Once removed, the housing may be cleaned without interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container.

During re-insertion of the aerosol container, which can only occur when the body of the dose indicating device is correctly orientated with respect to the housing by virtue of their respective shapes, switch slide 44 engages and is pushed up by pin 45 until the upper face meets the switch contacts. Further insertion of the aerosol container results in switch slide 44 being pushed down along pin 45 until the valve stem is seated back within support 5.

It will be appreciated that by programming of the ASIC, one design of dose indicating device could be used in conjunction with a range of aerosol containers

of various capacities. By virtue of the switch mechanism, the same design of dose indicating device can also be used in conjunction with a range of different valves having different lengths of valve stem and different stem travel specifications.

Whilst the present invention has been described in detail in respect of a metered dose inhaler actuatable manually by the patient it will be appreciated that other actuation mechanisms can be substituted. In particular, the use of a breath operated inhaler in which the actuation is assisted, and is responsive to, preferably triggered by, the inward breath of the patient, is also envisaged.

The dispenser of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro-α-[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclometasone dippropionate and salts or sovates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

CLAIMS:

1. A dispenser for dispensing medicament comprising

a housing having a support;

a container, locatable within said housing, having an outlet member, wherein said container is movable relative to the housing to enable dispensing therefrom and said outlet member is connectable with said support to prevent relative movement therebetween; and

an actuation indicator, locatable within said housing,

wherein the container and actuation indicator are reversably removable from the housing as a single unit.

2. A dispenser according to claim 1 wherein the actuation indicator is engagable with the container in the vicinity of said outlet member.

3. A dispenser according to claim 2 wherein the actuation indicator is engagable with the outlet member.

4. A dispenser according to any of claims 1 to 3, wherein the actuation indicator is provided with a grip member which is engagable with a neck portion of the container.

5. A dispenser according to claim 4, wherein the neck portion is adjacent to or on the outlet member.

6. A dispenser according to any of claims 1 to 5 wherein the container is an aerosol container.

7. A dispenser according to any of claims 1 to 6 wherein the housing is provided with an outlet, preferably in the form of a mouthpiece.

8. A dispenser according to claim 7 comprising a passage through which dispensed doses may pass from the container to said outlet.

9. A dispenser according to any of claims 1 to 8 wherein said container provides measured doses.

10. A dispenser according to any of claims 1 to 9 wherein said actuation indicator indicates the number of doses dispensed from or remaining in the container.

11. A dispenser according to any of claims 1 to 10, wherein the actuation indicator comprises an indexing mechanism actuated by a predetermined movement of the container relative to the housing.

12. A dispenser according to claim 11, wherein the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement of the container relative to the housing.

13. A dispenser according to either of claims 11 or 12, wherein the indexing mechanism indexes the actuation indicator by means of a predetermined rotary movement of a first member driven by movement relative to a second member during actuation of the dispenser.

14. A dispenser according to claim 13, wherein the second member remains stationary relative to the housing during actuation of the dispenser.

15. A dispenser according to claim 13 or 14, wherein the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack.

16. A dispenser according to claim 13 or 14, wherein the first member comprises a yoke for engagement with the second member through the lost motion coupling.

17. A dispenser according to any of claims 12 to 16, wherein the lost motion coupling comprises a friction drive mechanism.

18. A dispenser according to any of claims 1 to 17, actuable in response to the inward breath of a user.

19. An aerosol dispenser according to claim 1 comprising a housing in which a container is removably located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet member and housing to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container, characterised in that the dose indicating device is tightly connected to the container in the vicinity of the outlet member, such that the container and dose indicating device may be removed from the housing as a single unit.

20. An actuation indicating device for use with a dispenser comprising a housing and a container, locatable within said housing, having an outlet member, the actuation indicating device comprising attachment means to enable attachment to the container.

21. An actuation indicating device according to claim 20, wherein the attachment means comprises a grip member which firmly engages a neck portion formed around the container.

22. An actuation indicating device according to claim 21, wherein the neck portion is located at the connection between the container and outlet member.

23. An actuation indicating device according to claim 20, wherein the actuation indicating device has an actuation indicator for indicating the number of doses dispensed from or remaining in the container, wherein the actuation

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indicating device comprises attachment means to enable tight connection to the container in the vicinity of the outlet member.

24. Electromechanical dose indicating device according to any of claims 20 to 23.

25. Use of a dispenser according to any of claims 1 to 18 for dispensing medicament.

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