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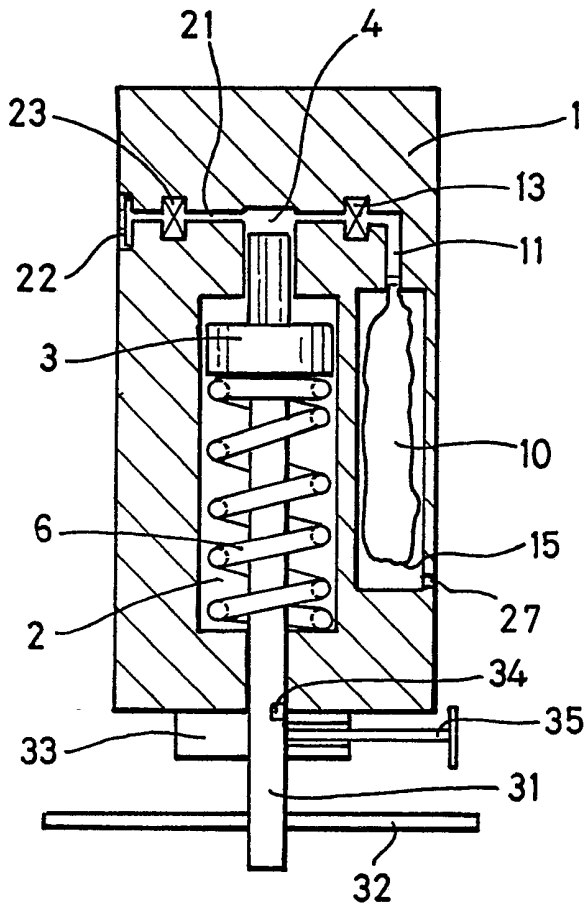


Fig. 1

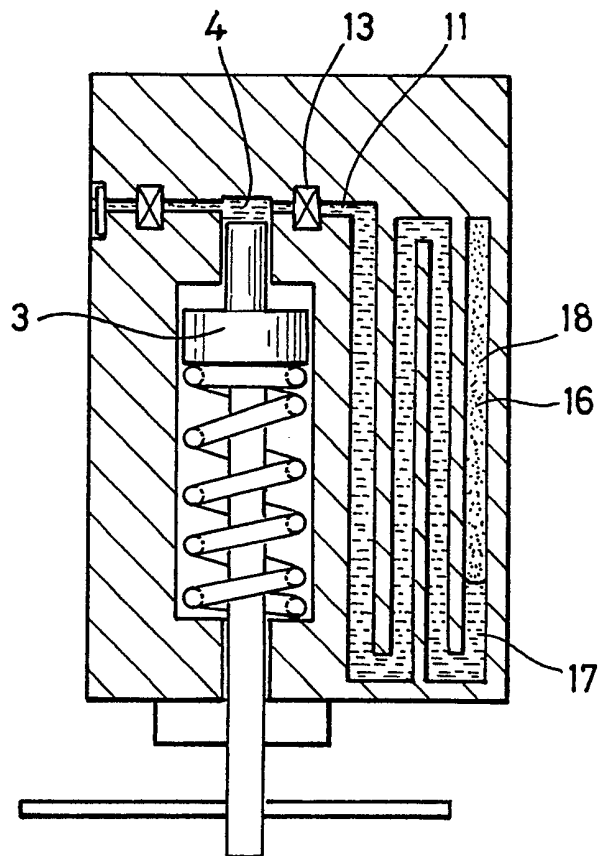
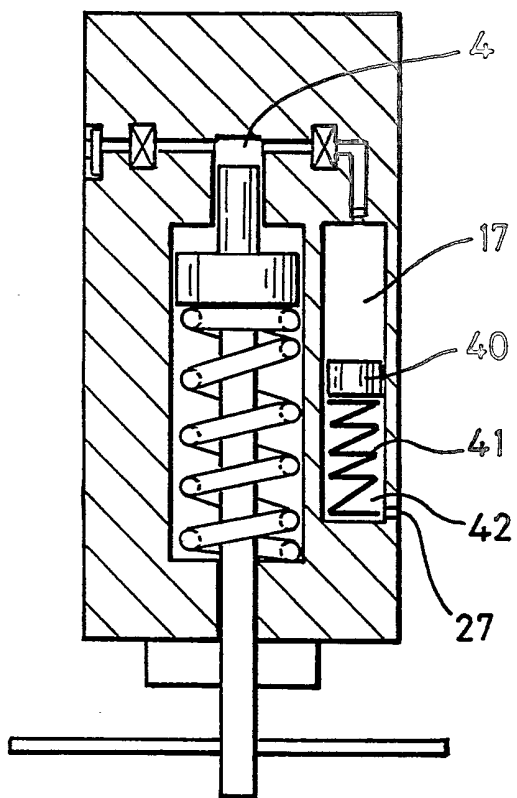
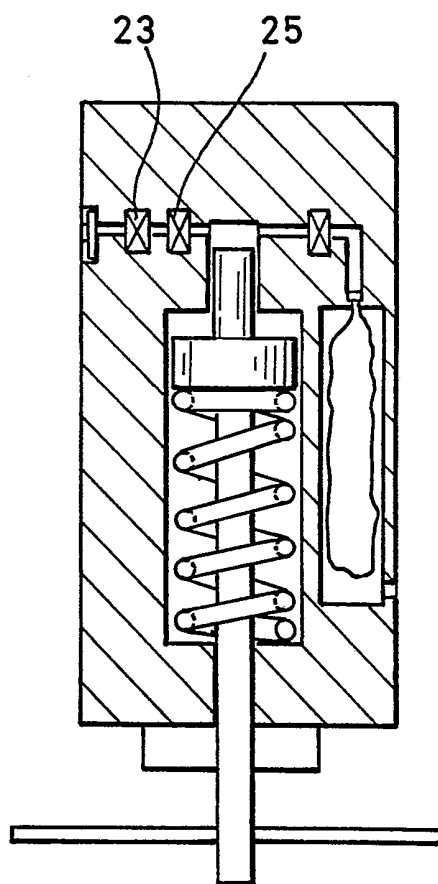


Fig. 2



*Fig. 3*

*Fig 4*



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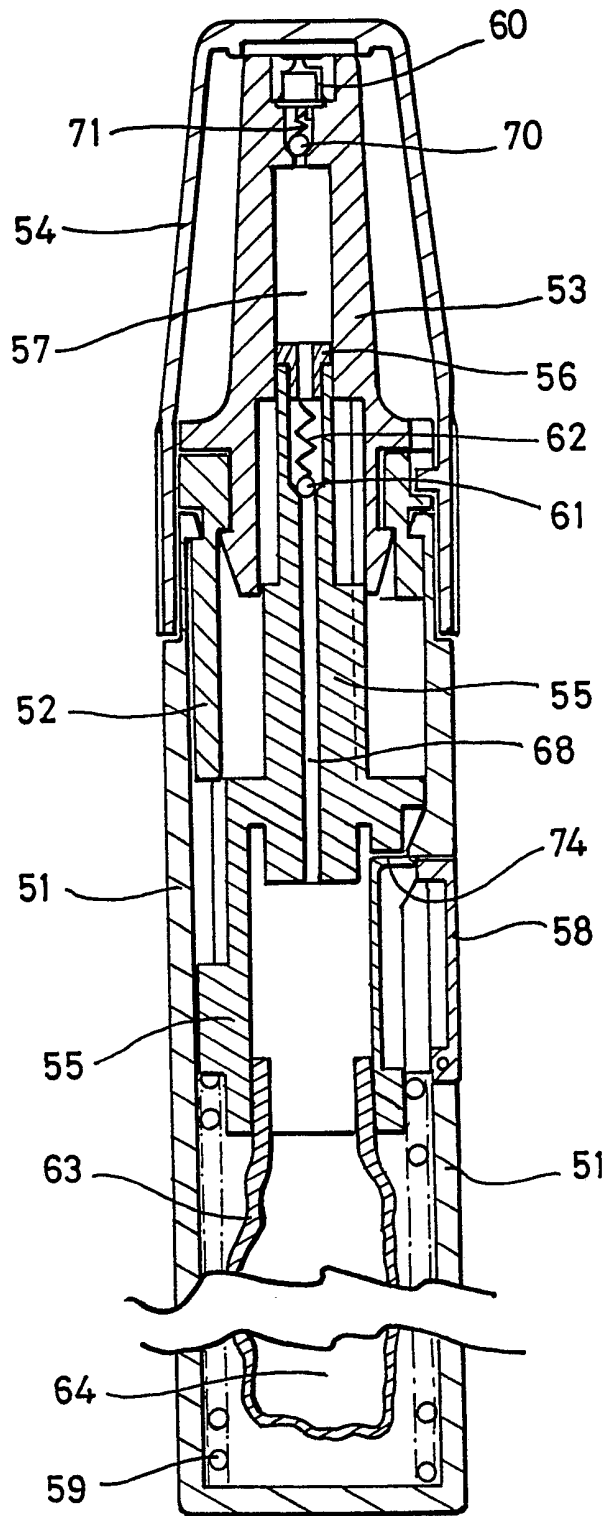


Fig. 5

TITLE: METERED DOSE SPRAY SYSTEM

This invention relates to a metered dose spray system, notably to a portable device for delivering metered doses of  
5 liquid drugs, perfumes or other liquids in the form of a spray having a droplets size of 50 micrometres or less.

BACKGROUND TO THE INVENTION:

10 Most portable pocket size spray delivery systems are either powered by a reservoir of liquefied gas, usually a CFC or butane, or by pressure generated by the user, for example by squeezing a container or actuating a pump mechanism. Since there is widespread objection to the use of CFCs, most  
15 devices used to administer drugs into body cavities, such as the mouth, nose and eyes, are of the user powered type.

User powered metered dose pumps used for delivering accurate doses of liquid, such as nasal sprays, mouth fresheners and  
20 ear drops, suffer from a number of drawbacks. Firstly, the dosage is dependent on the user fully depressing the actuator. Secondly, the actuator moves relative to the main body of the device which leads to difficulties in directing the spray issuing from the device as the device is being  
25 actuated. For instance, with mouth fresheners, it can be quite difficult to avoid spraying the chin instead of the mouth. A further problem is that the size of the droplets produced by the mechanism will depend on the pressure exerted by the user on the actuating mechanism.

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In order to overcome the dependence of droplet size on the pressure generated by the user, it has been proposed to incorporate pressure-relief valves in the device. This prevents the spray action from commencing until a minimum  
35 pressure has been generated, to give what is known as a

"snap action" as the valve operating pressure is exceeded and the pressurised fluid is released through the valve. However, the use of a pressure relief valve does not prevent the user from over-pressurising the liquid leading to smaller than desired droplet sizes. An example of an improved "snap action" vertical axis pump is shown in International Patent Application No WO 87/04373.

An example of a liquefied gas powered device is described in US Patent No 4,896,832, where liquefied gas is used to keep a liquid reservoir at constant pressure. A conventional metered dose valve of the type used in inhalers is used to meter the drug to be dispensed.

We have now devised a spray generating device in which the pressure required for atomising the drug is produced by a piston driven by a spring, gas or other means.

SUMMARY OF THE INVENTION:

Accordingly, from one aspect of the invention, there is provided a metered dose aerosol delivery system comprising a spring or gas loaded piston, means of loading said piston, a cylinder in which the piston is located, an inlet valve connecting a container, which is preferably sealed from the atmosphere, to the cylinder said valve being of the non-return type and opening when loading the piston and closing when firing, and an exit non-return valve connecting said cylinder to an atomising nozzle having the reverse characteristics of the inlet valve.

When the delivery system is loaded, the piston is forced back against the spring causing a reduction in pressure within the cylinder, which causes liquid stored in the container to flow into the cylinder volume through the inlet

valve. Preferably, the piston or an operating shaft or lever operatively associated therewith is provided with a detent or latch mechanism whereby it can be retained in the loaded position. A trigger or other mechanism is then  
5 actuated by the user to release the piston which pressurises the liquid in the cylinder and forces it out through the exit non-return valve and atomising head.

Preferably, the piston is powered by a coiled spring where  
10 the diameter of the spring is greater than the piston diameter thus producing relatively high pressures with the force available from the spring by causing that force to act over a reduced area within the cylinder. Alternatively, a piston having two diameters is powered by compressed gas  
15 sealingly located behind the piston at the larger diameter end producing a pressure at the small end which is higher in proportion to the ratio of the two cross sectional areas of the piston.

20 In another aspect of the invention a second valve is located in the exit passageway being of the pressure release type which remains closed until the pressure in the cylinder reaches the required value so as to ensure that a minimum operating pressure is achieved for the atomization of the  
25 fluid at the atomising nozzle.

In a preferred embodiment of the invention the device is shaped like a pen for easy pocket portability and cocking of the device is by means of the pocket clip. In another  
30 embodiment of the pen shaped device, cocking is achieved by removing the cap. In yet another embodiment of the pen shaped device cocking is achieved by twisting the cap or by twisting a sleeve on the main body of the device.

35 BRIEF DESCRIPTION OF THE DRAWINGS:

The invention will now be described, by way of example only, with reference to the accompanying drawings, in which Figure 1 is an axial sectional view of a metered dose delivery system in accordance with the invention, with a collapsible bag holding the fluid to be dispensed; Figure 2 is a sectional view of the same device but with the liquid contained in a long tube; Figure 3 is a sectional view of the same device but with the liquid contained in a cylinder and piston arrangement; Figure 4 is a sectional view of the device shown in Figure 1 with the addition of a pressure relief valve; Figure 5 is a sectional view of a metered dose delivery system in accordance with the invention and shaped like a pen with the drug stored in a collapsible bag with cocking taking place by twisting the pen cap; and Figure 6 is a sectional view of the device of Figure 5, but with the liquid contained in a cylinder and piston arrangement.

DESCRIPTION OF THE PREFERRED EMBODIMENTS:

In the device shown in Figure 1, there is a body 1 in which the components are located. A cavity 2 split in two parts forms, with a piston 3, a volume 4 at the small end of said piston 3. At the opposite end of the piston 3 a pre-compressed spring 6 is located acting on said piston 3. The volume 4 is connected to a liquid reservoir 10 via a passageway 11. The reservoir shown in Figure 1 is of the collapsible bag type sealed from the atmosphere. The collapsible bag is located in a cavity 15 which can be open to atmosphere via a passageway 27 and at atmospheric pressure. A non-return valve 13 is located in the passageway 11 and allows liquid to travel only in the direction from the reservoir to the volume 4. A further passageway 21 connects the volume 4 to an atomising head 22 of the Mechanical Breakup type. A non-return valve 23 is located in said passageway and allows liquid to travel only

in the direction from the volume 4 to the atomising head 22. The piston 3 is attached to a piston rod 31 which protrudes from the body 1 and has means 32 for retracting the piston 3 against the action of the spring 6, and means 33 for locking the piston 3 in the retracted position comprising in Figure 1 a notch 34 in piston rod 31 and a bolt 35 which engages with notch 34 when fully the piston is fully retracted with spring 6 in the fully compressed position. In Figure 1 the mechanism is shown halfway between the compressed and expanded positions of the spring.

When in the loaded position with the piston fully retracted and the spring 6 compressed, the volume 4 is full of liquid. When the piston 3 is released by the mechanism 33, the liquid is forced out through the atomising head and atomised. The non-return valve 13 prevents liquid being forced into the reservoir 10. The pressure generated in the volume 4 is typically 3 to 10 bars and this is enough to atomise liquids to the required particle size, for instance 100 micrometres, for a nasal spray.

To re-load the device, the piston rod 31 is pulled back by means of the handle 32 and locked in position when bolt 35 engages notch 34. As the piston 3 moves back and creates the volume 4, liquid in the collapsible bag 10 is sucked into said volume 4 via passageway 11 and non-return valve 13. Non-return valve 23 prevents air being sucked into the volume 4.

In an alternative embodiment, the collapsible bag 10 is located in a pressurised volume 15 filled via passageway 27 and the latter is sealed by a plug to prevent gas escaping, which helps to force the contents of the collapsible bag 10 into the volume 4 without the need to create sub-atmospheric pressures in volume 4. This reduces the formation of gas

bubbles in the liquid sucked into volume 4.

Figure 2 shows another embodiment of the invention where the liquid reservoir is formed as a long tube 16. Liquid 17 is stored in the tube with pressurised gas 18 stored at the blind end of the tube. As the piston 3 is pulled back, liquid is forced into the volume 4 via passageway 11 and valve 13 by the pressurised gas 18. As liquid 17 is used, the gas 18 expands into tube 16 pushing the liquid ahead of it and progressively losing pressure. The initial pressure of the gas 18 must be sufficient to maintain a pressure above atmospheric until all the liquid 17 is used up.

Figure 3 shows another embodiment of the invention where the liquid reservoir is formed by a volume 15 preferably of cylindrical configuration and a piston 40, with said piston 40 exerting constant pressure on the liquid stored 17 in cylindrical volume 15 by means of a spring 41. As the piston 3 is pulled back, liquid is forced into the volume 4 via passageway 11 and valve 13 by the pressure exerted by piston 40. As liquid 17 is used, spring 41 forces piston 40 along the cylinder 15 pushing the liquid ahead. The final pressure exerted on the liquid by the piston 40 must be sufficient to maintain a pressure above atmospheric until all the liquid 17 is used up. This prevents the formation of sub-atmospheric pressures in the liquid and the formation of gas bubbles. In another embodiment the spring 41 is not used and the piston 40 moves simply by the pressure difference between atmosphere on the open side 42 and the liquid 17 which is under vacuum (pressure less than atmospheric) when it is sucked into cylinder volume 4.

Figure 4 shows another embodiment of the invention where a second valve 25 is placed alongside non-return valve 23. Valve 25 is of the pressure release type and ensures that

liquid reaches the atomising head 22 only after it has reached a predetermined pressure to further aid atomization.

Figure 5 is an embodiment of the invention where the outer shape is pen like. A body 51 is clipped to a cam 52 which in turn is clipped to a cylinder and nozzle assembly 53. A cap 54 is located over the nozzle assembly 53 and engages cam 52 so that when cap 54 is rotated it rotates cam 52 forcing the piston assembly 55 away from the nozzle assembly 53, said piston assembly 55 having a corresponding moulded cam. As the piston assembly 55 is retracted, a metered volume 57 liquid is sucked from the collapsible bag 63 through the piston assembly passageway 68. A non-return valve formed by ball 70 and spring 71 prevents air entering the chamber 57. As shown on Figure 5, the piston 56 which is mounted at the end of the piston assembly 55 is in the loaded position with the metered volume 57 full of liquid and a lug 74 engages against the main body 51. To dispense the liquid, the cap 54 is removed and the button 58, which is moulded as part of the main body 51, is depressed by the user. This releases lug 74 and allows piston assembly 55 to be forced forwards by the pre-loaded spring 59, thus pressurising the liquid trapped in volume 57 and forcing it out through the spray nozzle 60. A non-return valve comprising a ball 61 and spring 62 prevents liquid being forced back into the collapsible bag 63 which holds the liquid 64 to be dispensed. To recharge the device, the cap 54 is replaced on body 51 and engages cam 52.

Figure 6 is a modification of the embodiment of Figure 5 where the collapsible bag is replaced by a cylinder and piston arrangement. The piston assembly 55 is extended to nearly the full length of the body 51 forming a cylinder 81 and a piston 80 is sealingly mounted within forming a liquid reservoir 85 sealing the liquid 64 from the atmosphere.

When the device is cocked as described above, negative pressures in the reservoir 85 and the atmospheric pressure maintained on the other side of piston 80 by a connecting hole 86, force the piston 80 to follow the liquid up the cylinder 81. A window 82 is located in piston assembly 55 and body 51 through which the piston 80 can be seen when the liquid reservoir 85 is nearly empty. Alternatively, body 51 and cylinder 81 can be moulded in transparent plastic, in which case the liquid level in reservoir 85 can be seen at all times.

Other embodiments are possible but not shown here. The liquid could be stored in a coiled tube open at one end to the atmosphere of sufficiently small diameter to prevent liquid falling out under gravity. The cocking method can be of various kinds. Instead of a removable cap to load the device a permanent ring could be employed or a simple linear motion could be used to compress the spring or a pocket clip could be used as a lever linked mechanically to the piston.

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CLAIMS:

1. A metered dose aerosol delivery system comprising a spring or gas loaded piston, means of loading said piston,  
5 a cylinder in which the piston is located, an inlet valve connecting a container, which is preferably sealed from the atmosphere, to the cylinder said valve being of the non-return type and opening when loading the piston and closing when firing, and an exit non-return valve connecting said  
10 cylinder to an atomising nozzle having the reverse characteristics of the inlet valve.
2. A system as claimed in claim 1, wherein the piston or an operating shaft or lever operatively associated therewith  
15 is provided with a detent or latch mechanism whereby it can be retained in the loaded position.
3. A system as claimed in either of claims 1 or 2, wherein a trigger or other mechanism is adapted to be actuated by  
20 the user to release the piston which thereby pressurises the liquid in the cylinder and forces it out through the exit non-return valve and atomising head.
4. A system as claimed in any one of the preceding claims,  
25 wherein the piston is powered by a compression coil spring.
5. A system as claimed in claim 4, wherein the diameter of the spring is greater than the piston diameter.
- 30 6. A device as claimed in any one of claims 1 to 4, wherein a piston having two diameters is powered by compressed gas sealingly located behind the piston at the larger diameter end producing a pressure at the small end which is higher in proportion to the ratio of the two cross  
35 sectional areas of the piston.

7. A system as claimed in any one of the preceding claims,  
wherein a pressure relief valve is located in the exit  
passageway from the cylinder which valve is adapted to  
remain closed until the pressure in the cylinder reaches a  
5 predetermined minimum operating pressure.

8. A system substantially as hereinbefore described with  
respect to and as shown in any one of the accompanying  
drawings.

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9. A method for dispensing a fluid as a spray of droplets,  
wherein the fluid is dispensed using a device as claimed in  
any one of the preceding claims.

15 10. A method as claimed in claim 9, wherein the fluid is a  
fluid medicament.

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**Patents Act 1977**  
**Examiner's report to the Comptroller under**  
**Section 17 (The Search Report)**

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9125175.1

**Relevant Technical fields**

(i) UK Cl (Edition K ) F1W (WCP)

(ii) Int Cl (Edition 5 ) A61M; B05B (11/00);  
B65D (47/34); F04B; G01F

**Search Examiner**

S J CHURCH

**Databases (see over)**

(i) UK Patent Office

(ii)

**Date of Search**

27 MARCH 1992

Documents considered relevant following a search in respect of claims 1-10

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	GB 1389702 (THIOKOL) see figures and page 4 lines 35-76	1, 4 & 9
X	GB 1131918 (M B BURGESS) see figures 1 and 2 and page 5 lines 31-94	1-5 at least
X	GB 1014685 (NAT. RESEARCH) see figure 1 and page 3 lines 37-75	1-5 at least
X	GB 0931089 (KRANTZ) see figure and page 1 lines 8-10, also page 2 lines 30-72	1-5, 7 at least
X	US 4167941 (CAPRO) see figures and especially column 6 lines 53-64	1, 4, 9, and 10
X	US 3921861 (KONDO) see figures 2-4 and column 2 line 53 - column 6 line 49	1, 4 and 9
X	US 3790034 (HORVATH) see figures and column 5 line 23 - column 6 line 41 and column 2, lines 3-6	1, 4 and 9

Category	Identity of document and relevant passages	Relevant to claim(s)

### Categories of documents

**X:** Document indicating lack of novelty or of inventive step.

**Y:** Document indicating lack of inventive step if combined with one or more other documents of the same category.

**A:** Document indicating technological background and/or state of the art.

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