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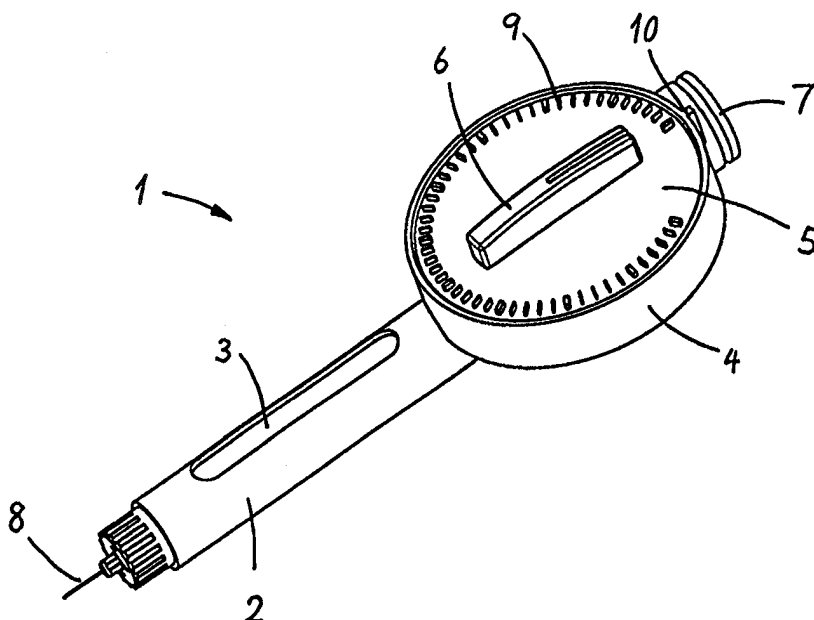
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(54) Title: A DOSE SETTING MECHANISM AND AN INJECTION SYRINGE HAVING SUCH A DOSE SETTING MECHANISM

(57) Abstract

A dose setting mechanism for a drug administration device and an injection syringe having such a dose setting mechanism are provided. The injection syringe has a housing accommodating an ampoule (3) containing medicine sufficient for a number of dosed injections, an injection press button (7), a piston rod (13) for co-operation with a piston in the ampoule (3) when injecting, and a dose setting mechanism comprising a rotatable dose setting element (5) interconnected with the press button. The dose setting mechanism further comprises a dose administration wheel (11) connected with the piston rod (13) and a coupling ring (12) connected with the dose setting element (5) and the press button (7). One of the dose administration wheel (11) and the coupling ring (12) at least partly surrounds the other, and the dose administration wheel (11) and the coupling ring (12) are arranged such that rotation of the dose setting element (5) allows the coupling ring (12) to be rotated in either direction in relation to the dose administration wheel (11), while activation of the press button (7), and thereby rotation of the coupling ring (12), causes the dose administration wheel (11) to be rotated.



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A dose setting mechanism and an injection syringe having such a dose setting mechanism

The invention relates to a dose setting mechanism for a drug administration device having a housing and a press
5 button connectable with a piston rod for administration of a set dose from a container, said dose setting mechanism comprising a rotatable dose setting element interconnected with the press button.

Drug administration devices having dose setting mechanisms are known in a number of different types, e.g. syringes, inhalators, atomisers, etc. The aim of these
10 drug administration devices is to make the user capable of setting an individual dose of drug to be administered.

Best known in the art are injection syringes for use by
15 patients, mainly diabetics, who have to inject themselves with individually set doses of medicine, e.g. insulin. Such syringes are often given a shape like a pen in order to be carried by the patient all through the day and are always ready for use.

20 When the dose is to be set in these pen-shaped injection syringes, a cap covering the needle portion of the syringe is rotated, causing a press button at the opposite end of the injection syringe to move outwards. The press button often has a scale on the shaft connecting the
25 press button with the interior of the injection syringe, and the dose set can be read on this scale. After setting the dose, the user removes the cap from the needle portion, inserts the needle in the area to be injected and injects the medicine by pressing the press button.
30 When the press button reaches its bottom, the set dose has been injected.

One disadvantage of these pen-shaped injection syringes is that the scale on the shaft of the press button has rather small divisions and digits owing to the limitations set by the perimeter of the shaft. If the user is
5 visually impaired, as can often be the case with diabetics, this may cause wrong dose settings having serious consequences for the user.

An attempt to overcome this disadvantage is disclosed in DE A1 4 208 677 showing an injection syringe provided
10 with a dose setting scale having large digits. The dose setting device consists of a box-like container in which an injection syringe may be placed. When setting the dose, a stop is moved on the piston rod of the injection syringe until the right dose, as read on the scale, has
15 been set. Then the user removes the injection syringe from the dose setting device and injects himself like with an ordinary injection syringe, while the stop on the piston rod determines the dose being injected.

All the known injection syringes having dose setting devices have the disadvantage that the dose setting device,
20 or at least a part of it, has to be removed from the injection syringe after the dose has been set but before injection can take place. Some of the injection syringes, as is the case with the one disclosed in DE A1 4
25 208 677, even have the disadvantage that the set dose cannot be checked after the dose setting device has been removed, as the injection syringe itself has no scaling means.

It is an object of the present invention to provide a
30 dose setting mechanism that can be built into a drug administration device, e.g. an injection syringe, is non-removable from it and provides the possibility of setting a dose and regretting the set dose. Further, there

should always be full correspondence between the movement of the dose setting element and the movement of the press button in order to assure the user of the dose set and the dose administered.

5 This is obtained by a dose setting mechanism of the type mentioned in the opening paragraph of this specification, which is characterized in that the dose setting mechanism further comprises a dose administration wheel connected with said piston rod and a coupling ring connected with
10 the dose setting element and the press button, one of said dose administration wheel and said coupling ring at least partly surrounding the other, said dose administration wheel and said coupling ring being arranged such that rotation of the dose setting element allows the coupling ring to be rotated in either direction in relation
15 to the dose administration wheel, while activation of the press button, and thereby rotation of the coupling ring, causes the dose administration wheel to be rotated.

Arranging the dose setting mechanism in this way provides
20 a dose setting mechanism which can be fully built into a drug administration device, e.g. an injection syringe, and has the possibility of setting a dose and regretting the set dose. As the dose setting element is connected with the coupling ring which is in turn connected with
25 the press button, full correspondence between the movement of the dose setting element and the movement of the press button is achieved.

In order to achieve the co-operation between the dose administration wheel and the coupling ring, these parts may
30 advantageously be arranged as stated in claim 2. Claim 3 discloses further arrangements according to a preferred embodiment. By incorporating all these features a particularly simple construction needing only four parts to

build the dose setting mechanism is achieved, i.e. the dose setting element, the dose administration wheel, the coupling ring and the press button.

5 The invention also relates to an injection syringe comprising a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections, an injection press button, a piston rod for co-operation with a piston in the ampoule when injecting, and a dose setting mechanism comprising a rotatable dose setting
10 element interconnected with the press button. The injection syringe is further characterized in that the dose setting mechanism includes the features mentioned in claim 1.

15 By arranging the injection syringe in this way, an injection syringe is obtained having a built-in dose setting mechanism with the possibility of setting a dose and regretting the set dose. As the dose setting element is connected with the coupling ring which is in turn connected with the press button, full correspondence between
20 the movement of the dose setting element and the movement of the press button is achieved.

The connection between the different parts of the dose setting mechanism is preferably as mentioned in claims 5 and 6, giving the advantages mentioned earlier.

25 In a preferred embodiment the housing has means for preventing the dose administration wheel from being rotated in one direction corresponding to withdrawal of the piston from the ampoule. This ensures, when the dose setting mechanism is used in an injection syringe, that the
30 piston rod can never be withdrawn from the piston in the ampoule but is always in firm contact with the piston. If the piston rod could be withdrawn from the piston, the

dose injected would not correspond to the dose set, owing to the gap between the piston rod and the piston.

The dose administration wheel is preferably connected with the piston rod via a gear wheel provided at the centre of the dose administration wheel.

Preferably the injection syringe is provided with a scale and a pointer indicating the dose set when the dose setting element is rotated.

More advantages and the mode of operation of the dose setting mechanism will be described more fully in the following with reference to the drawings in which

Figure 1 shows a top perspective view of an embodiment of an injection syringe having a dose setting mechanism according to the invention,

Figure 2 shows an exploded view of an embodiment of an injection syringe having a dose setting mechanism according to the invention,

Figure 3 shows the dose setting mechanism when setting a dose,

Figure 4 shows the dose setting mechanism when regretting a set dose, and

Figure 5 shows the dose setting mechanism when administering a set dose.

Figure 1 shows an injection syringe 1 having a dose setting mechanism according to the present invention. The syringe has a first housing part 2 containing an ampoule 3 with medicine, e.g. insulin, the ampoule 3 being seen through a window in the first housing part 2, and a second housing part 4 embracing the dose setting mechanism.

The first housing part 2 is generally pen-shaped, as is known from commercially available injection syringes. The syringe further comprises a dose setting mechanism, of which a rotatable, disc-shaped dose setting element 5 having a finger grip 6 and a press button 7 for injection are seen. Further, a needle 8 extending from the lower end of the injection syringe 1 is shown.

The size of the shown embodiment of an injection syringe 1 and in particular of the dose setting element 5 is such that it fits the user's hand, both when setting a dose of medicine by holding the injection syringe 1 in one hand and setting the dose by rotating the dose setting element 5 with the other hand, and when injecting the set dose by holding the injection syringe 1 in one hand and pressing the press button 7 with the thumb of the same hand.

A scale 9 is provided on the dose setting element 5, and a pointer 10 is provided at the second housing part 4.

Figure 2 shows the injection syringe 1 in an exploded view showing again the first and second housing parts 2 and 4, the ampoule 3, the dose setting element 5, the press button 7 and the needle 8. The injection syringe 1 further comprises a dose administration wheel 11, a coupling ring 12, a piston rod 13 and a needle coupling part 14.

The dose setting mechanism comprises the dose setting element 5, the dose administration wheel 11, the coupling ring 12 and the press button 7. These parts will be described in more detail in the following as these parts constitute a preferred embodiment of the invention.

The dose setting element 5 is disc-shaped having a finger grip 6 on its upper side and a downwardly projecting tenon 15 at the periphery, said tenon 15 interacting with a

notch 16 provided at the rim of the coupling ring 12. The coupling ring 12 is in turn in engagement with the press button 7 via a gear wheel 17 provided at the hub of the coupling ring 12 and a toothed part 18 of the press
5 button 7.

As the dose setting element 5 is connected with the coupling ring 12 which is in turn connected with the press button 7, full correspondence between the movement of the dose setting element 5 and the movement of the press button 7 is achieved. This means that whenever the dose
10 setting element 5 is rotated for setting or regretting a dose, the press button 7 moves out of or into the housing of the injection syringe 1. Similarly, when the press button 7 is pressed in order to inject a set dose, the
15 dose setting element 5 rotates back to its initial position. This means that the user can visually observe that the set dose is injected during the injection act.

The coupling ring 12 consists of a ring segment connected with a hub in each end thereof. At one end the ring segment is connected rigidly to the hub via a rigid part 19,
20 and at the other end the ring segment is connected flexibly with the hub via a flexible part 20. The flexible part 20 is included for facilitating the mounting of the coupling ring, but it may be omitted without changing the
25 working of the dose setting mechanism.

The interaction between the coupling ring 12 and the dose administration wheel 11 will now be explained fully with reference to Figures 3-5.

Figure 3 is a top view of the dose setting mechanism when
30 a dose is set, showing the first and second housing parts 2 and 4, the dose administration wheel 11, the coupling ring 12, the top part of the piston rod 13, the press button 7 and its toothed part 18. The dose setting ele-

ment 5 is omitted in order to show the interior of the dose setting mechanism, but in use its downwards projecting tenon 15 is in permanent engagement with the notch 16 provided at the rim of the coupling ring 12.

5 The coupling ring 12 is formed in such a way that it partly surrounds the dose administration wheel 11, and it is seen that the dose administration wheel 11 is provided with barbs 21 at its outer periphery, and that a part of the coupling ring 12 is provided with similar barbs 22.

10 When a dose is to be set, the dose setting element 5 is rotated clockwise according to the arrow S. This causes the coupling ring 12 to be rotated clockwise, the barbs 22 of the coupling ring 12 sliding over the barbs 21 of the dose administration wheel 11. The second housing
15 part 4 is provided with an inwardly projecting pawl 23, which, in co-operation with the barbs 21 provided on the dose administration wheel 11, prevents the dose administration wheel 11 from being rotated clockwise, which would cause the piston rod 13 to be withdrawn from the
20 ampoule 6.

Rotating the coupling ring 12 causes the press button 7 to move upwards according to the arrow U due to the engagement of the gear wheel 17 (Figure 2) on the coupling ring 12 and the toothed part 18 of the press button 7.

25 If the set dose is regretted, the dose setting element 5 is rotated anti-clockwise according to the arrow R in Figure 4. Due to the flexible part 20 of the coupling ring 12 (Figure 2), the coupling ring 12 expands outwards, as shown, allowing the barbs 22 to slide over the
30 barbs 21 of the dose administration wheel 11. Hence the dose administration wheel 11 is not affected by this anticlockwise rotation of the coupling ring 12.

The anti-clockwise rotation of the dose setting element 5 causes the press button 7 to move downwards according to the arrow D. Some type of resistance against movement of the press button 7 may be provided in order to ensure
5 that the coupling ring 12 expands outwards when regretting a set dose.

When a set dose is to be injected, the press button 7 is pressed downwards according to the arrow P in Figure 5.

This causes the coupling ring 12 to be rotated in the
10 anti-clockwise direction as indicated by the arrow I due to the engagement of the toothed part 18 of the press button 7 with the gear wheel 17 (Figure 2) of the coupling ring 12. Due to the fact that the rotating force from the press button 7 is transferred to the ring segment of the coupling ring 12 via the rigid part 19, the
15 ring segment is not expanded, as was the case when regretting a set dose by rotating the dose setting element 5 anticlockwise, but is tightened around the dose administration wheel 11, causing the barbs 22 of the coupling
20 ring 12 to engage the barbs 21 of the dose administration wheel 11.

Some type of resistance against movement of the coupling ring 12 may be provided at the flexible connected end of its ring segment in order to ensure that it tightens
25 around the dose administration wheel 11 when injecting a set dose.

The engagement between the barbs 22 of the coupling ring 12 and the barbs 21 of the dose administration wheel 11 causes the dose administration wheel 11 to rotate anti-
30 clockwise, which in turn causes the piston rod 13 to move forwards in the ampoule 3 due to the interaction of a gear wheel 24 provided at the hub of the dose administra-

tion wheel 11 (Figure 2) and a toothed part 25 of the piston rod 13.

When the injection has been completed, the press button 7 and the dose setting element 5 have returned to their initial positions, ready for another dose setting.

If the injection syringe 1 is to be used by diabetics needing regular injections of insulin, the barbs 21 are preferably of a size corresponding to 1 IU (International Unit). Thereby, each click heard when setting a dose, corresponds to 1 IU, giving the user an audible indication of the dose set together with the visual indication on the scale 9. It further means that the dose can be set very precisely as an integer of International Units.

In the shown embodiment the coupling ring 12 surrounds the dose administration wheel 11. In an alternative embodiment the dose administration wheel surrounds the coupling ring, the dose administration wheel being provided with barbs on its inner periphery, and the coupling ring being provided with barbs on its outer periphery. Hence, if a set dose is to be regretted, the coupling ring must be arranged in such a manner as not to expand but to contract, allowing the barbs of the dose administration wheel and the coupling ring to slide in relation to each other.

The design of the injection syringe need not be pen-shaped as shown, but can be of a compact form having a flexible piston rod surrounding the gear wheel of the dose administration wheel. This provides an injection syringe which is a very handy unit having a size that fits an adult's hand.

In a special embodiment of this type of injection syringe, an extra gear wheel may be arranged between the

gear wheel of the dose administration wheel and the flexible piston rod in order to ensure that a relatively large change in the angular position of the dose setting element only causes a small change in the amount of medicine to be injected. Hence, the dose setting can be performed extremely precisely.

Preferably the injection syringe 1 as a whole is made of a plastics material in order to make the disposal after use environmentally correct, but it may also be made of other materials such as metals or any combination of materials.

The injection syringe may be of the disposable type, or it may be of a reusable type in which the ampoule can be replaced when emptied. However, the reusable type requires a special arrangement for retracting the piston rod from its foremost position.

Although the dose setting mechanism has been described in relation to an injection syringe, the dose setting mechanism may be applied to other drug administration devices in which individual doses of drug to be administered can be set.

C l a i m s

1. A dose setting mechanism for a drug administration device having a housing and a press button (7) connectable
5 with a piston rod (13) for administration of a set dose from a container, said dose setting mechanism comprising a rotatable dose setting element (5) interconnected with said press button (7), c h a r a c t e r -
i z e d in that the dose setting mechanism further com-
10 prises a dose administration wheel (11) connected with said piston rod (13) and a coupling ring (12) connected with the dose setting element (5) and the press button (7), one of said dose administration wheel (11) and said coupling ring (12) at least partly surrounding the other,
15 said dose administration wheel (11) and said coupling ring (12) being arranged such that rotation of the dose setting element (5) allows the coupling ring (12) to be rotated in either direction in relation to the dose ad-
ministration wheel (11), while activation of the press
20 button (7), and thereby rotation of the coupling ring (12), causes the dose administration wheel (11) to be rotated.

2. A dose setting mechanism according to claim 1, c h a r a c t e r i z e d in that the dose administration
25 wheel (11) is provided with barbs (21) at its outer periphery, that the coupling ring (12) consists of a ring segment partly surrounding the dose administration wheel (11) and rigidly connected with a hub at one end and flexibly connected to said hub at the other end, said
30 ring segment being provided with barbs (22) over at least a part of its inner side, and that the connection between the dose setting element (5) and the coupling ring (12)

is provided at the end of the ring segment which is flexibly connected with the hub.

3. A dose setting mechanism according to claim 2, c h a r a c t e r i z e d in that the coupling ring (12)
5 is connected with the press button (7) via a gear wheel (17) provided at the centre of the coupling ring (12) and a toothed part (18) of the press button (7).

4. An injection syringe (1) comprising a housing accommodating an ampoule (3) containing medicine sufficient for
10 a number of dosed injections, an injection press button (7), a piston rod (13) for co-operation with a piston in the ampoule (3) when injecting, and a dose setting mechanism comprising a rotatable dose setting element (5) interconnected with said press button (7), c h a r a c t e
15 r i z e d in that the dose setting mechanism further comprises a dose administration wheel (11) connected with said piston rod (13) and a coupling ring (12) connected with the dose setting element (5) and the press button (7), one of said dose administration wheel (11) and said
20 coupling ring (12) at least partly surrounding the other, said dose administration wheel (11) and said coupling ring (12) being arranged such that rotation of the dose setting element (5) allows the coupling ring (12) to be rotated in either direction in relation to the dose ad-
25 ministration wheel (11), while activation of the press button (7), and thereby rotation of the coupling ring (12), causes the dose administration wheel (11) to be rotated.

5. An injection syringe according to claim 4, c h a -
30 r a c t e r i z e d in that the dose administration wheel (11) is provided with barbs (21) at its outer periphery, that the coupling ring (12) consists of a ring segment partly surrounding the dose administration wheel

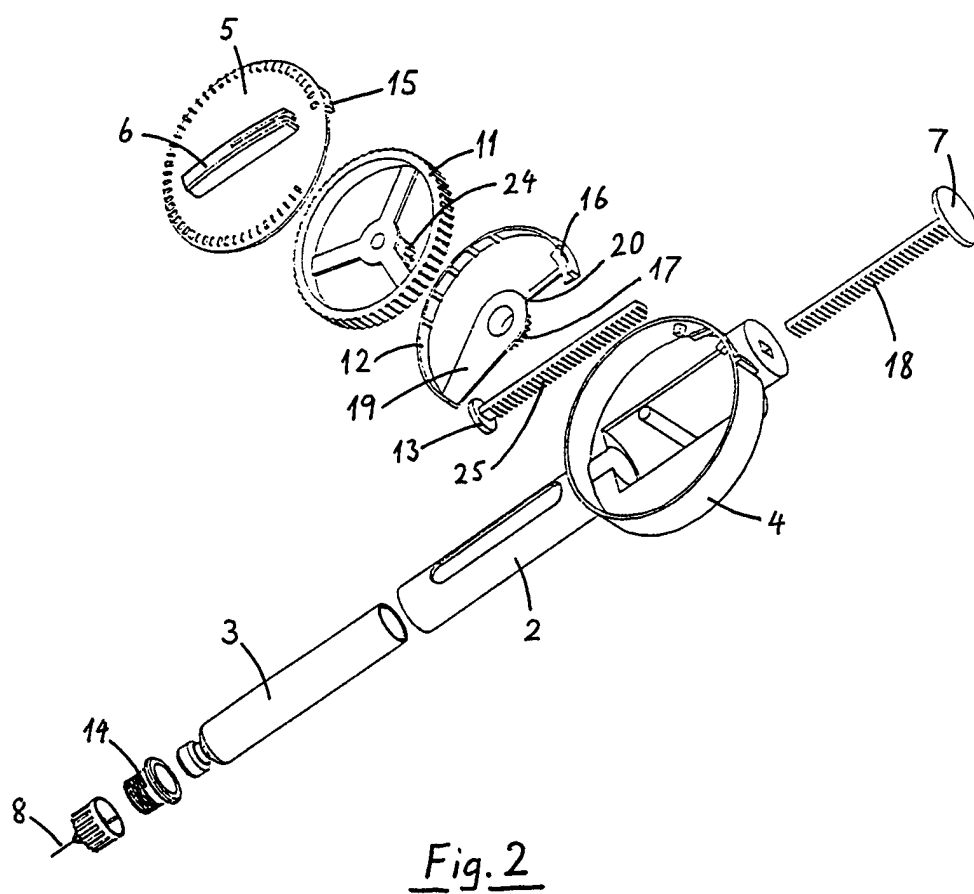
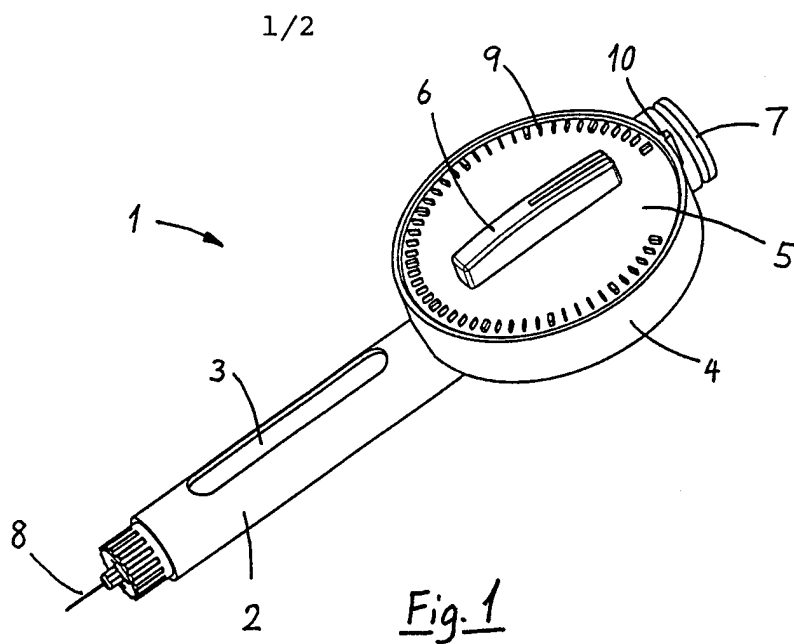
(11) and rigidly connected with a hub at one end and flexibly connected with said hub at the other end, said ring segment being provided with barbs (22) over at least a part of its inner side, and that the connection between the dose setting element (5) and the coupling ring (12) is provided at the end of the ring segment which is flexibly connected with the hub.

6. An injection syringe according to claim 5, characterized, in that the coupling ring (12) is connected with the press button (7) via a gear wheel (17) provided at the centre of the coupling ring (12) and a toothed part (18) of the press button (7).

7. An injection syringe according to any one of claims 4-6, characterized in that the dose administration wheel (11) and the housing have co-operating means for preventing the dose administration wheel (11) from being rotated in one direction corresponding to withdrawal of the piston rod (13) from the ampoule (3).

8. An injection syringe according to any one of claims 4-8, characterized in that the dose administration wheel (11) is connected with the piston rod (13) via a gear wheel (24) provided at the centre of the dose administration wheel (11).

9. An injection syringe according to any one of claims 4-8, characterized in that the dose setting element (5) is provided with a scale (9), and that the housing is provided with a pointer (10) pointing on said scale (9), said pointer (10) indicating the dose set when the dose setting element (4) is rotated.



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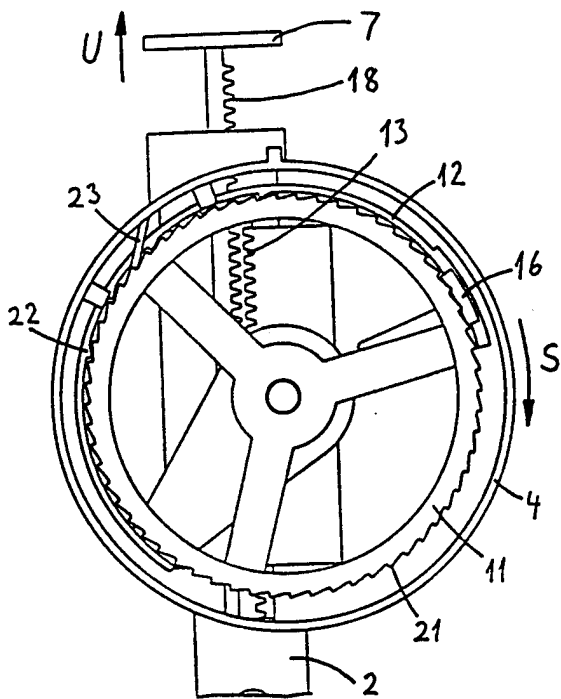


Fig. 3

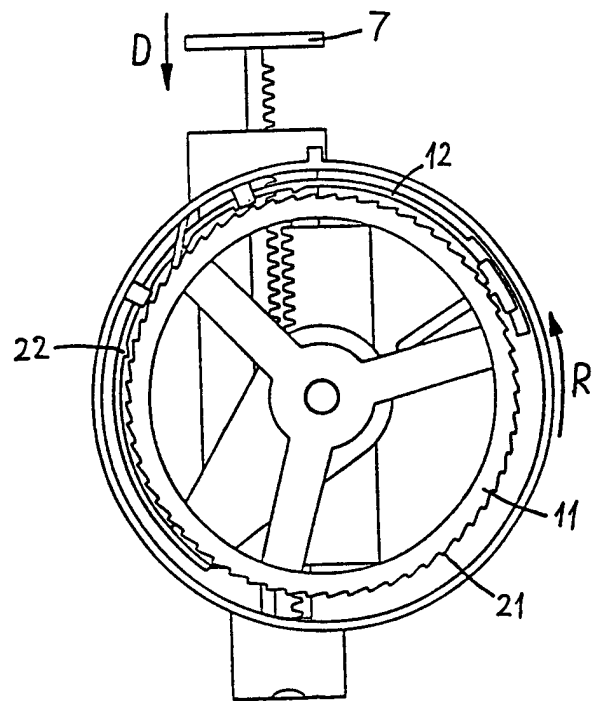


Fig. 4

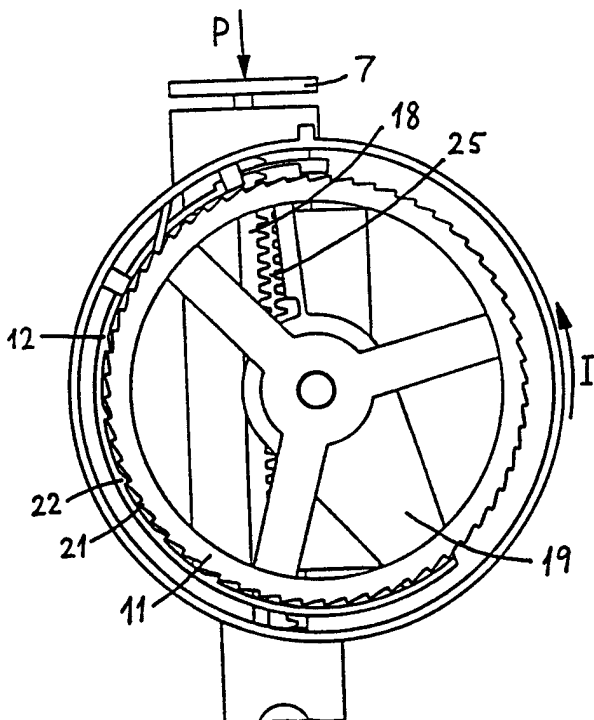


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00239

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/24, A61M 5/31

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)

IPC6: A61M

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

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9413343 A1 (HABLEY MEDICAL TECHNOLOGY CORPORATION), 23 June 1994 (23.06.94), figure 3 --	1-9
A	DE 4208677 A1 (INJECTA GMBH STEINACH), 23 Sept 1993 (23.09.93), figure 1 -- -----	1-9

☐

Further documents are listed in the continuation of Box C.

☒

See patent family annex.

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Date of the actual completion of the international search

15 Sept 1998

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INTERNATIONAL SEARCH REPORT

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27/07/98

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PCT/DK 98/00239

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
WO	9413343	A1	23/06/94	US 5320609 A	14/06/94
DE	4208677	A1	23/09/93	NONE	