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(54) **Title**: PEN- INJECTOR WITH MAGNETICALLY DRIVEN RODLESS PISTON

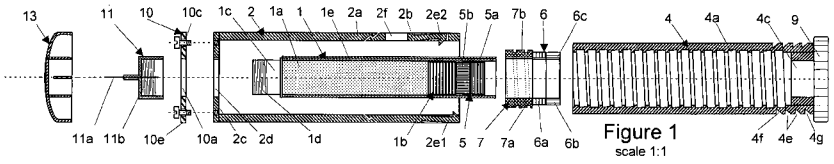

Figure 1
scale 1:1

(57) **Abstract**: Pen-Injector for effecting the delivery of an injectable product, especially Insulin. Contrary to the conventional Pens, which contain a rigid piston rod for power transmission, the new Pen-Injector includes two magnets (5, 6). One (5) of the magnets (5, 6) is positioned within the cartridge (1) in contact with the piston (1b). The other magnet (6) is positioned outside of the cartridge, but in a permanent close magnetic contact with the inner magnet (5). The two magnets (5, 6) are part of the driving means for the displacement of the piston (1b). The driving force is applied to the outer magnet (6) and from this to the inner magnet (5). Because of the omission of a rigid piston rod, the new Pen-Injector can be designed so that it is 40% shorter than the conventional pens. Such a short Pen-Injector can be easier stored in a garment pocket or handbag than a conventional Pen.

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PEN-INJECTOR WITH MAGNETICALLY DRIVEN RODLESS PISTON

Technical Field

[0001] The technical field is the injection of a liquid product, especially of a medication, into the human or animal body. Injector Pens are commonly used for the treatment of diabetes by self-injection with Insulin.

Prior Art

[0002] After a development period of 30 years nearly all pens, which are now on the market, have an elongated form like a penholder. They include - beside the cartridge - a manual operable drive mechanism, power transmitting means and dosing means. All components are positioned in a housing, which consists mostly of the two housing parts. The first housing part (later termed as “housing sleeve”) contains all components except the cartridge. The second housing part contains the cartridge and is positioned one after another with the first housing part. Nearly all known Pen-Injectors utilize a rigid piston rod for moving the cartridge piston. This piston rod must, of necessity be at least as long as the moving stroke of the piston in the cartridge. It is clear that such Pen-Injectors cannot be shorter than the total length of the cartridge and the piston rod. As one of the great numbers of the prior art documents which represent this pen-type shall be cited here EP 0245 312 B1. There were previous attempts to shorten the pens, for example, by using a flexible piston rod, which is guided around the edge of the cartridge (EP 0 901 194 B1). Another proposal to shorten the Pen-Injectors was, to change the standardized cartridges by providing their piston with a borehole, which has a female thread and to use a piston rod, which has a corresponding male thread, so that it can penetrate the piston (WO 2008/119691).

Object of the Invention

[0003] It is the object of the invention to provide an alternative solution for shortening the Pen-Injectors, which works with existing standardized cartridges.

Solution

[0004] The target is solved by a Pen-Injector according to the independent claim 1. The dependent claims contain further useful features.

[0005] The new Pen-Injector does not work with a rigid piston rod. The drive mechanism, the power transmitting means and the dosing means now surround the cartridge concentrically. The power transmitting means include – in place of the stiff piston rod - magnets, one of which is positioned outside of the cartridge and the other within the cartridge.

[0006] The magnets are kept permanently in an attraction relationship with a strong coupling. A movement of the outer magnet causes a corresponding movement of the inner magnet and therewith of the cartridge piston. The moving force is applied only onto the outer magnet. Both magnets are movable to a large extent synchronously at least over a part of the filled section of the cartridge, preferably over the complete filled section. It is possible thereby to move the piston of the cartridge without using a piston rod from outside of the cartridge.

[0007] The before mentioned features make it possible to reduce the pen length to about 9 cm (incl. the injection needle).

Further Prior Art

[0008] It is already known to use magnets in an injection device, but in a manner and for a purpose which are different from those of the invention.

[0009] DE 20 2005 010 389 U1 discloses a device including a stiff piston rod on which a magnetic member is disposed. If the piston rod is moved along its axis the magnetic member will be moved with the piston rod relative to a second magnetic member. The second magnetic member may be fixedly attached to the housing, or at least so that it does not move with the piston rod as it moves. Both magnetic members co-operate magnetically at least in one position of the piston rod. The target is to reduce or prevent the chance of an overdose of the product to be injected.

[0010] US 2002/0022807 A1 shows a syringe plunger locking mechanism including a plunger with a plunger support and an actuator for the plunger. The plunger support and the actuator are each provided with

a permanent magnet for connecting them. The magnets allow for an easy disengagement.

[0011] GB 2 342 047 A discloses a syringe with a base body and a plunger longitudinally guided in the base body. An injection needle is attached to the base in the distal direction of the syringe. The base and the plunger rod each have magnets, which interact with each other after an injection so that they magnetically stick together. Pulling back the plunger causes the base with the needle to be pulled back into the syringe base body so that there is no longer any risk of injury by the injection needle.

[0012] US 4,959,056 discloses a an injecting system including a syringe which can be driven out or pulled back depending on the magnetic coupling between two magnets. One of them is connected with the plunger of the syringe and the other is connected with a movable part of the system device.

[0013] The further prior art gives no indication of using magnets to shorten pen-injectors and to arrange the magnets as claimed.

Drawings

[0014] The invention will now be explained in greater detail below and with reference to the drawings.

[0015]

[0016] **Figure 1** shows an longitudinal section though a first embodiment of the new Injection Pen in an exploded view (in the scale 1:1 if it is printed in the format DIN A4);

[0017] **Figure 2** shows three individual components of the first embodiment (in the scale 1:1 if it is printed in the format DIN A4) namely

[0018] Figure 2 (a) a front view onto the cover flange,

[0019] Figure 2 (b) a front view into the threaded element with the outer magnet (the last not visible),

[0020] Figure 2 (c) a side view onto the threaded element with the outer magnet;

[0021] **Figure 3** shows a longitudinal section though the assembled first embodiment at the end of a dosing phase and before the next injection phase (in the scale 1:1 if it is printed in the format DIN A4);

[0022] **Figure 4** shows a longitudinal section though the first embodiment (like Figure 3) but at the end of the injection phase (in the scale 1:1 if it is printed in the format DIN A4);

[0023] **Figure 5** shows a side view onto the first embodiment at the end of an injection phase or at the beginning of the next dosing phase (like Figure 4 in the scale 1:1 if it is printed in the format DIN A4);

[0024] **Figure 6** shows the side view and the top view of the outer magnet with an indication of the magnetization;

[0025] **Figure 7** shows the side view and the top view of the inner magnet with an indication of the magnetization;

[0026] **Figures 8** (a)-(d) show a test arrangement for measuring the offset of the outer magnet relative to the inner magnet as a result of four different load conditions.

[0027] **Figure 9** shows the values measured with the test arrangement of Figure 8 as graph;

[0028] **Figure 10** shows a longitudinal section through a second embodiment of the new Pen Injector at the beginning of the first dosing phase (in the scale 2:1 if it is printed in the format DIN A4);

[0029] **Figure 11** shows a longitudinal section through the second embodiment (like Figure 10) but at the end of the dosing phase with a maximum dose (in the scale 2:1 if it is printed in the format DIN A4);

[0030] **Figure 12** shows a part of the second embodiment during the injection phase (in the scale 2:1 if it is printed in the format DIN A4);

[0031] **Figure 13** shows a longitudinal section though a third embodiment of the new Pen Injector a t the beginning of the first dosing phase (in the scale 2:1 if it is printed in the format DIN A4);

[0032] **Figure 14** shows a longitudinal section through the third embodiment (like Figure 21) but at the end of the dosing phase with a maximum dose (in the scale 2:1 if it is printed in the format DIN A4);

[0033] **Figure 15** shows a side view onto the third embodiment at the end of an injection phase or at the beginning of the next dosing phase (in the scale 1:1 if it is printed in the format DIN A4);

[0034] **Figure 16** shows a side view onto a conventional Injector Pen with a rigid piston (in the scale 1:1 if it is printed in the format DIN A4).

The Construction of the First Embodiment

[0035] The first embodiment of the new Pen-Injector is shown in the **Figures 1-5**. It consists of the following main components:

[0036] a cartridge 1,

[0037] a housing sleeve 2,

[0038] a drive sleeve 4,

[0039] an inner magnet 5,

[0040] an outer magnet 6,

[0041] a thread element 7,

[0042] an actuation element 9,

[0043] a cover flange 10,

[0044] a needle cap 11,

[0045] a protection cap 13.

[0046] The cartridge 1 is standardized and designed for holding 3 ml (= 3.000 mm^3) liquid. The cartridge which is used here for the first embodiment is a Novo-type cartridge. It is made from glass and contains the injection liquid 1a, as for example Insulin, and a slideable piston 1b. The proximal end of the cartridge is closed by an exit element 1c with an outer thread 1d. The exit element is closed by an elastic foil. On the outside of the cartridge 1, a guide strip 1e is glued, which extends in the axial direction. The guide strip 1e is made from hard plastic material and has a thickness of about 0,5 mm. The function of the guide strip 1e will be explained later.

[0047] The Novo-type cartridge has an inner diameter d = 9,20 mm and a cross-section area $F = \pi/4*d^2 = 66{,}44\ mm^2$. It contains 300 Insulin units (IE). 1 unit (IE) corresponds to 10 mm^3. The maximum dose is set to 60 units (IE), which corresponds to the volume V = 600 mm^3. The column with the volume V over the cross-section area F has a height H = V/A = 9,03 mm. This means that the piston 1b must move 9,03 mm to eject a liquid volume of 60 units (IE). To simplify the further calculation, we will round off the height H to 9,0 mm. To eject a dose of only 1 unit (IE), the piston 1b must be moved by 9,0/60 = 0,15 mm.

[0048] The housing sleeve 2 is made from plastic and consists of a front housing part 2a and the rear housing part 2b. The two housing parts

2a, 2b are connected but can be rotated against each other. The means of connection between the two housing parts 2a and 2b is not shown and is indicated only symbolically. The proximal end of the housing sleeve 2 is covered with a front flange 2c, which has a central through hole 2d for the exit element 1c of the cartridge 1. The central through hole 2d is extended at one point to a slot 2h for receiving the guide strip 1e. Two elastic latches 2e1, 2e2 with an inward peak are cut out of the wall of the rear housing part 2b and positioned opposite to each other. Further a dose window 2f is cut out of wall of the rear housing part 2b.

[0049] The drive sleeve 4 is made from plastic and has an inner helical groove 4a with a pitch of 4,5 mm per turn. Furthermore the drive sleeve 4 is provided with an outer helical groove 4e, which has the same pitch as the inner helical groove 4a. The outer helical groove 4e extends between two annular grooves 4f, 4g and cooperates with the two latches 2e whose point grips into the helical groove 4e or one of the annular groves 4f, 4g. The cavity of the drive sleeve 4 is extended at the distal end to a receiving space 4c, whose function is to receive the inner magnet 5 if a new cartridge 1 is inserted. The rear end of the drive sleeve 4 is used as actuation element 9. On the outer periphery of the drive sleeve 4 dosing numbers 4d in the form of a helix are printed. If the drive sleeve 4 is turned the dosing numbers 4e pass one after the other under the dose windows 2f and are therefore individually visible.

[0050] The inner magnet 5 is formed cylindrically and adapted to the inner form of the cartridge 1. The axial length of the inner magnet 5 is 8 mm. The air gap between the inner magnet 5 and the wall of the cartridge 1 should be as small as possible but large enough to allow the inner magnet 5 to move axially within the cartridge1. An air gap of 0,1 mm corresponds to this requirements. The inner magnet 5 is in close contact with the piston 1b but they are not connected.

[0051] The outer magnet 6 is shaped as a ring and has the same axial length as the inner magnet 5, namely 8 mm. Its wall thickness is 3 mm. The outer magnet 6 surrounds the cartridge 1. The air gap between the

outer magnet 6 and the cartridge wall should also be as small as possible but large enough to allow the outer magnet 6 to axially move relative to the cartridge 1. An air gap of 0,1 mm corresponds to this requirements. The outer magnet 6 has on its inner side an axial slot for receiving the guide strip 1e.

[0052] The two magnets 5 and 6 are made from a very strong magnetic material called “Neodym”. Each of them has an attraction force – if it is connected with a 2 cm steel plate – of about 3 kg. Both magnets 5 and 6 are axially magnetized, i.e. the poles are aligned in the axial direction of the cylinder respectively the ring. After assembling the pen components opposite poles of the two magnets are adjacent and form a “magnetic trap”, which is explained in detail later.

[0053] The outer magnet 6 is firmly connected to a thread element 7 which is formed as a tube and made from plastic. The thread element 7 is provided with an outer protruding helical rib 7a, which corresponds to the inner helical groove 4a of the drive sleeve 4 and forms a thread connection 4/7. Thread element 7 has on its inner side an axial slot for receiving the guide strip 1e. Thread element 7 is dispensable if its function is replaced by the outer magnet 6 whose function takes. This requires that the outer magnet must be provided with the outer protruding helical rib 7a. However, it is more difficult to form the threads on the outer magnet 6 in such a way than on the plastic component 7.

[0054] The cover flange 10 is made from plastic and has a central through hole 10a for the cartridge exit element 1c. For fastening the cover flange 10 to the housing sleeve 2 with two screws 10c the cover flange is provided with two part-circular bayonet (banana shaped) slots 10b, each slot terminates with a hole 10d (see Figure 2a). The two screws 10c secure element 10 to the front flange 2c of the housing sleeve 2.

[0055] When assembled, the needle cap 11 is screwed with its inner thread 11b on the outer thread 1d of the cartridge exit element 1c. The needle cap 11 carries a needle 11a. The front end of the needle 11a pierces the elastic foil of the cartridge exit element 1c and is thereby connected with the liquid volume 1a of the cartridge 1.

[0056] To remove cartridge 1 from the pen, it is necessary to first unscrew the needle cap 11 from the cartridge exit element 1c. Then the cover flange 10 must be rotated in the appropriate direction until the pan heads of the two screws 10c are lined up with the holes 10d of the banana slots 10b. In this position the cover flange 10 can be removed from the housing sleeve 2. It is now it is possible to remove the cartridge 1 from the pen.

[0057] The procedure for inserting the cartridge 1 into the pen is the reverse. It is essential to ensure that the guide strip 1e slides through the receiving slots 2h in the housing front flange 2c as well as through the receiving slots 6b and 7b in the outer magnet 6 and in the tread element 7. If this is done, the needle cap 11 must be screwed onto the cartridge exit element 1c. Thus the cartridge 1 is fixed in respect to the front housing part 2a and secured against axial movement and rotation. On the other hand the guide strip 1e on the cartridge 1 causes that the outer magnet 6 and the thread element 7 are secured against rotation, but they can be axially moved.

[0058] In the non-use state, the front end of the needle 11a can be protected by putting the protection cap 13 onto the front end of the pen.

Operation Principle of the First Embodiment

[0059] The drive sleeve 4 is intended to serve both for dosing by rotation as also for injecting by axial movement. The thread connection 4/7 between the drive sleeve 4 and the threaded element 7 ensures an accurate dose.

[0060] If the drive sleeve 4 is rotated for dosing it moves axially out of the housing 2 by a distance, which corresponds to the next injection stroke of the cartridge piston 1b. During this dosing phase the position of the piston 1b remains unchanged because the threaded element 7 cannot rotate with the drive sleeve 4 but is prevented from a rotation by the guide strip 1e on the cartridge 1.

[0061] When thereafter - during the injection phase - the drive sleeve 4 is axially moved into the housing 2, it takes the threaded element 7 along, whereby the piston 1b is axially moved in the same direction.

The injection phase is finished, when the proximal end of the drive sleeve 4 abuts against the front flange 2c of the housing 2.

[0062] This simple operation principle is connected with two following problems:

[0063] To avoid that the drive sleeve 4 can be pulled out of the housing, the drive sleeve 4 is provided with an outer helical groove 4e which cooperates with the two latches 2e1, 2e2. The two latches are unique parts of the housing 2. The latches 2e1, 2e2 are partially cut out of the housing 2 but integrally connected to this. During the dosing phase the peak of both the latches 2e grips into the helical groove 4e or one of the annular groove 4f, 4g and prevents that the drive sleeve 4 can be drawn out of the housing 2. During the axial injection movement of the drive sleeve 4 however the latches 2e1, 2e2 are deflected by the oblique tooth flanks of the helical groove 4e or the annular grooves 4f, 4g and allows the drive sleeve 4 to return to its initial axial position (but not in the initial angle position).This is shown in **Figure 4**. In this initial axial position the latch 2e1 grips fully into the annular groove 4g (with the peak on the ground of the groove), whereas the latch 2e2 touches with its peak - if the dose is not exact 30 or 60 Insulin units (IE) – beside the ground of the helical groove 4e.

[0064] After each injection or before a new dosing action, a dosing reset is necessary. This can be effected in that the rear housing part 2b with the both latches 2e1, 2e2 is rotated relative to the front housing part 2a. The reset action causes the drive sleeve 4 to turn into the initial angle position, which is the basis for a new dosing 4 to turn phase. The helical grove 4e will be brought by the reset rotation in the initial angle position, in which the latch 2e2 can fully dip into the helical groove 4e and in which the dose number “0” appears in the dose window 2f.

The Magnetic Trap and the Design of the Magnets

[0065] The “magnet trap” will now be explained with reference to the **Figures 6-9**. The essential components for realizing the magnetic trap are the cartridge 1 with the piston 1b, the inner magnet 5 and the outer magnet 6 with the threaded element 7. As it can be seen from

drawings the opposite poles of the two magnets are positioned adjacent to each other when the assembly is completed. The inner magnet 5 is in contact with the piston 1b, but not connected with it.

[0066] There are several possibilities to assemble these components. One of them is to insert at first the inner magnet 5 into the cartridge 1 so that it pushes against the piston 1b. Then the outer magnet 6 must be moved from the back end of the cartridge 1 in forward direction against the repelling force of the two magnets 5, 6 until the outer magnet 6 jumps into the trap position.

[0067] **Figure 8** shows in four phases that an axial force F (in form of a load) is applied onto the outer magnet 6 in the proximal direction.

[0068] If the force is zero (0,0 kg) the neutral areas of the both magnets 5, 6 are aligned (**Figure 8(a)**).

[0069] If a load of 0,9 kg is brought onto the outer magnet 6, the outer magnet 6 will be displaced by a distance of 4 mm (**Figure 8(b)**). If the load is removed the outer magnet 6 returns into its initial (neutral) position.

[0070] A load of 1,1 kg causes an axial displacement of 10 mm (**Figure 8(c)**). If this load is removed the outer magnet 6 returns again into its initial (neutral) position.

[0071] A small increase of the load to 1,2 kg causes the magnetic coupling between the two magnets 5, 6 to break (**Figure 8(d)**). In this case the outer magnet 6 escapes the trap.

[0072] The magnetic trap also functions in the other (distal) direction. And it functions even when the outer magnet 6 is fixed and the force F is applied onto the inner magnet 5.

[0073] The trap effect is surprising at least at first glance if one considers that in **Figure 8(c)** equal poles are positioned not only side by side but that there is even - albeit small – axial distance between them. As we know equal poles repel each other. The explanation for this phenomenon is due to the rotationally symmetrical arrangement of the above mentioned components.

[0074] The graph in **Figure 9** shows that the axial displacement s of the outer magnet 6 is dependent on the force F (load), which is applied onto the

outer magnet 6. One can see that the trap area is extended in this special example between a displacement of – 10 mm to + 10 mm, wherein only the stable range between 0 and +10 mm is used. Within this stable range, the outer magnet element 6 always returns after a deflection to its neutral position. This is the case even if a force F is applied onto the outer magnet 6, which exceeds the limit value of 10,2 kg, provided that the axial movement of the outer magnet 6 is limited to +10mm. In the present case this can be realized by a corresponding dosing. As it can be seen from the **Figures 3 and 4** the offset of the outer magnet 6 relative to the inner magnet 5 is caused by the axial movement of the drive sleeve 4 in the proximal direction during the injection phase. This movement is stopped respectively limited when the drive sleeve 4 reaches its (initial) position, which it had before the dosing action. This means that the drive sleeve 4 can only moved by the distance, which was set before during the dosing phase. And this is independent of the force, which is brought onto the drive sleeve 4 for executing the injection.

[0075] Hence it follows that a break of the magnet coupling under normal conditions can be safely excluded, if the injection stroke in the present example is smaller than 10 mm.

[0076] At this point, the following calculation might be helpful:

[0077] As above mentioned, the maximum piston stroke for the cartridge 1 (“Novo”-Type) is 9,0 mm and therewith smaller than the limit value of the stable range which is 10 mm. Therefore a break of the magnetic coupling between the both magnets 5 and 6 can be safely excluded. The outer magnet 6 remains always trapped in the magnetic trap.

[0078] It is easy to see that it is possible to design the system based on this finding so that the stable range is bigger than the maximum single stroke of the piston. This can be realized for example by designing the axial length of the magnets correspondingly.

How to operate of the First Embodiment

[0079] To start the dosing phase, the dose number “0” must first appear in the dose window 2f. Then the actuation element 9 must be turned so that

the drive sleeve 4 axially moves out of the housing 2 until the selected dose number appears in the dose windows 2f.

[0080] For executing the injection the user must press with the thumb onto the actuation element 9 so that the drive sleeve 4 moves again axially into the housing 2 until it reaches again its initial (axial) position. During this axial movement the peaks of the latches 2e1, 2e2 chatter over the teeth formed by the outer helical groove 4e and the annular grooves 4f, 4g.

[0081] For subsequent resetting, the rear housing part 2b must be turned relative to the front housing part 2a (either clockwise or counter-clockwise), until the latch 2e1 locks fully into the annular groove 4g and the dose number “0” appears again in the dose windows 2f. During this resetting phase the drive sleeve 4 must be fixed with respect to the front housing part 2a by means, which are not shown here.

[0082] When the cartridge 1 is empty, the piston 1b, the inner magnet 5, the outer magnet 6 and the threaded element 7 are in their most forward (proximal) position. The drive sleeve 5 abuts against the front flange 2d of the housing 2. To replace the empty cartridge with a new filled cartridge, the actuation element 9 must be turned opposite to the dosing direction, whereby the drive sleeve 4 remains in contact with the front flange 2c. Thereby the threaded element 7, the outer magnet 6 and the inner magnet 5 move backwards until the inner magnet 5 reaches the reception space 4c in the actuation element 9. To get access to the empty cartridge 1, now the needle cap 11 and the cover flange 10 must be removed. Now the exchange can be carried out.

Dosing Accuracy and Ejection Time of a Pen with Magnet System

[0083] A comparison of the Magnet Pen with a conventional Pen (which has a rigid piston rod) brings forth the following two questions:

[0084] How is the accuracy (deviation of the ejected volume from the set dose)?

[0085] What time is necessary for a complete ejection of the set dose?

[0086] These questions have their background in the fact that the magnetic the two magnets 5, 6 transmit the actuating force like a compression spring, i.e. with a certain delay and resilience.

[0087] In this context it has to be noted that the magnets which are used here are very strong, and they are - due to the small air gaps - very intensively coupled. In respect to the ejection time it has further to be noted that the injection force which a user applies shock-like onto the actuation element is always the maximum force with the result that the outer magnet will be immediately displaced by the maximum value.

[0088] But how are the accuracy deviation and the ejection time actually?

[0089] Several tests were made with the following doses: 1, 2, 3, 4, 10, 20, 40, 50, 60 units (IE).

The maximum deviation of the ejected liquid volume from the set dose was 6%. The average deviation was 2,5%.

The doses between 1 and 30 units (IE) were completely ejected within 5 seconds. The ejection of the doses 40, 50 and 60 units (IE) was not fully completed within 5 seconds. In each case 5 more drops followed in the next seconds. These 5 further drops correspond to about 2 units (IE). This gives a worst case deviation of 5%.

[0090] If there is the desire to reduce the deviation values and/ or the ejection time further, this can be reached for example by using longer magnets (with a length of 10 mm instead of 8mm).

[0091] A further point is that the spring force of a compression spring decreases the more it relaxes. The magnets show the same behaviour. At least in theory, they cannot overcome the small resistance of the static friction between the cartridge wall and the piston. The residual failure is very small because the replacement force which acts onto the piston (more than 1,2 kg) is much more higher than the before mentioned resistance of the static friction (about 100 g).

[0092] If there is the desire to compensate the resistance completely, there is a general solution for this problem. In case of a spring – the spring must be preloaded correspondingly. Applying this knowledge to the magnet system suggests that all doses must be chosen somewhat

larger. But as one can see from the above test values, this problem can be ignored.

Construction of the Second Embodiment

[0093] For the second embodiment, the **Figures 10-12** are relevant. As far as the components are equivalent, the same references are used as in the first embodiment (**Figures 1-9**).

[0094] The second embodiment includes the following components arranged in a concentric arrangement - from outside to inside (**Figure 10**):

[0095] a housing, comprising of a housing sleeve 2 and a cover flange 10,

[0096] a dose dial sleeve 12,

[0097] an intermediate sleeve 8,

[0098] a drive sleeve 4,

[0099] an annual thread element 7 and an annular outer magnet 6 (with its opposite pole parts 6a, 6b), both arranged one after another,

[00100] a cartridge reception sleeve 3,

[00101] The cartridge 1 contains the piston 1b and an inner magnet 5 (with its opposite pole parts 5a, 5b) positioned after another.

[00102] The cartridge further contains the injection liquid 1a, which is trapped between the cartridge piston 1b and a cartridge exit 1c. The inner magnet 5 is axially movable within the cartridge 1 and in touch with the piston 1b but not fixed to it.

[00103] The cartridge 1 which is used here is of the so-called “Lilly”-type. This type differs from the Novo-Type with regards to the construction of the exit as well as to some dimensions. The most important difference in the dimensions is the following: The Lilly-type cartridge has an inner diameter of d = 9,70 mm. It contains - like the Novo-type cartridge - 300 units (IE) of the liquid. The cross section area of the Lilly-type cartridge is $F = \pi/4*d^2 = 73{,}86\ mm^2$. A column with the volume $V = 10\ mm^3$ (1 unit) over this cross section area F has a height $h = V/F = 0{,}135$ mm (compared: for the Novo-type cartridge is $h = 0{,}15$ mm).

[00104] The housing sleeve 2 has at its proximal end a front flange 2c, on which other elements are to be fixed. The inner side of the housing sleeve 2 is provided with a helical groove 2k, which forms a thread

connection 2/12 with a corresponding helical protruding rib 12b on the outer side of the dose dial sleeve 12.

[00105] The cartridge reception sleeve 3 is designed to receive the cartridge 1 and has a front flange 3a which is fixed to the front flange 2c of the housing 2. The cartridge reception sleeve 3 further has at is back end a trap basket 3c for receiving the inner magnet 5 when this is moved backward - in case that the pen is used as reusable version - before a new cartridge 1 can be inserted.

[00106] The cartridge reception sleeve 3 might be replaced by other fixing means for the cartridge 1 if the pen should be used as a disposable pre-filled pen.

[00107] The drive sleeve 4 has on its inner side a helical groove 4a which forms a thread connection 4/7 with a corresponding helical rib 7a on the outer side of the thread element 7.

[00108] An outer magnet 6 with an annular shape is positioned between the container reception sleeve 3 and the drive sleeve 4. The outer magnet 6 is fixed to the annular thread element 7. The thread element 7 may be omitted if the outer magnet 6 is provided with the helical rib 7a of the tread element 7. The outer magnet 6 and the thread element 7 can be moved only in an axial direction but not turned. This is due to an axial guide strip 3b on the outside of the cartridge reception sleeve 3 and corresponding axial slots 7b and 6c in the thread element 7 and in the outer magnet 6.

[00109] The outer magnet 6 and the inner magnet element 5 are adapted to the circular cross shape of the cartridge 1. That means that the inner side of the annular shaped outer magnet 6 is closely fitted to the outer surface of the cartridge 1. The inner magnetic 5 has a cylindrical shape and is closely fitted to the inner surface of the cartridge 1. The air gape between each of the two magnets 5, 6 and the corresponding wall of the cartridge 1 should be made as small as possible, while still allowing the two magnets 5, 6 to easily move in an axial direction. The air gap should be as small as possible, preferably 0,1 mm. The axial length of two magnets 5, 6 should be selected between 5 and 10 mm, preferably 8 mm. A proper strong magnet material for this purpose is

available under the trade mark “Neodym”. The two magnets 5, 6 should be magnetized axially and so arranged that their opposite poles lie side by side. On this way it is possible to keep the two magnets 5, 6 permanently in a close and strong magnetic contact and to move them synchronously along the axis of the cartridge 1. The force for moving them must be applied only onto the outer magnet element 6. This force is transmitted by the strong magnetic coupling onto the inner magnet element 5, which is thereby able to force the piston 1b deeper into the cartridge 1 with the result that injection liquid is discharged.

[00110] The rear end of the pen is formed by a cap-like actuation element 9, which is connected with the drive sleeve 4 by a rotary coupling 4/9. The rotary coupling 4/9 is formed on the one side of a wheel like member 9u, which carries a number of axial extending ribs 9v and on the other side of corresponding grooves 4j on the outer side of the drive sleeve 4. The wheel like member 9u is fixed via a centrally positioned connecting pin 9x to the inner side of the actuation element 9. The rotary coupling 4/9 permits only a common rotation of the actuation element 9, the wheel-like member 9u and the drive sleeve 4, but it permits a free an axial movement of the actuation element 9 and the wheel-like member 9u on one side and the drive sleeve 4 on the other side.

[00111] The dose dial sleeve 12 is provided on its rear end with a wheel-like member 12a with a central boring. The connecting pin 9x is extending through this central boring. The two wheel-like members 9u and 12a form a friction clutch. They are pressed together by a pressure spring 9y. If an axial pressure is applied onto the actuation element 9, the members 9u and 12a will disengage. The friction clutch therefore can be regarded as a rotary coupling 9/12 which can - if necessary - deactivated. The rotary coupling 9/12 permits - when it is activated - only a common rotation of the coupled elements 9 and 12, whereas they can rotate independently when the rotary coupling is deactivated.

[00112] The intermediate sleeve 8 is connected to the housing sleeve 2 by a rotary stop means 2/8. This means 2/8 is formed by axial ribs 8c on

the outer side of the intermediate sleeve 8 and axial ribs 2n on the inner side of the housing sleeve 2, which ribs 8r and 2n gears into each other. The rotary stop means 2/8 permits an axial movement but no rotation of the intermediate sleeve 8 against the housing sleeve 2.

[00113] The intermediate sleeve 8 is further connected with the drive sleeve 4 by an axial movement coupling 4/8, which is formed by an annular groove 8s on the inner side of the intermediate sleeve 8 and a corresponding annular rib 4j on the outer side of the drive sleeve 4. This axial movement coupling 4/8 permits only a common axial movement of the drive sleeve 4 and the intermediate sleeve 8 but it allows a free rotation of this elements 4 and 8 against each other.

[00114] The intermediate sleeve 8 is connected with the dose dial sleeve 12 by a threaded connection 8/12, which is formed by a helical protruding rib 8t on the outer side of the gear sleeve 8 and a corresponding helical groove 12g on the inner side of the dose dial sleeve 12.

[00115] The pitch p3 of the thread connection 2/12 is greater than the pitch p1 of the thread connection 4/7 (p3 > p1). The pitch p2 of the tread connection 8/12 corresponds to the difference of the pitch p3 of the thread connection 2/12 and the pitch p1 of the thread connection 4/7 (p2 = p3 – p1).

[00116] The pitch p1 of the thread connection 4/7 is determined by the maximum dose of (here) 60 IE and the number of rotations of the drive sleeve 4, which are needed for expelling this maximum dose. In the present embodiment the dose of 60 IE should be expelled with two rotations of the drive sleeve 4. A column over this cross-section area F = 73,86 mm^2 and with the volume V = 600 mm^3 has a height h = V/F = 8,12 mm. This height h corresponds to the necessary piston stroke for expelling the maximum dose of 60 IE. To move the piston 1b correspondingly, the drive sleeve 4 must perform during the dosing phase two rotations. The pitch p1 of the thread connection 4/7 therefore must be p1 = 1/2 * h = 4,06 mm. To simplify the further calculation, this result is rounded off to p1 = 4 mm.

[00117] The pitch p3 of the thread connection 2/12 must be selected so that it is not self- blocking, i.e. that the dose dial sleeve 12 can freely rotate if

an axial pressure is exerted on the actuation element 9. In addition, the pitch depends on the diameter D of the dose dial sleeve 12 and on a friction parameter. It was found that the relationship p/D should preferably 0,75 or larger. In the present case the diameter D of the dose dial sleeve 12 is calculated as being 20 mm. The pitch p3 must be therefore p3 = 0,75 x 20 = 15 mm. This means that the dose dial sleeve 12 will be moved out of the housing sleeve 2 by a distance of 30 mm with two turns. This rather great distance guarantees a comfortable handling of the pen and sufficient place for the dose numbers on the outer side of the dose dial sleeve (to be explained later in detail).

[00118] The pitch p2 of the threaded connection 8/12 corresponds to the difference p1 = p3 – p2 = 15 mm – 4mm = 11 mm.

[00119] The rotation direction of the thread connection 2/12 and the rotation direction of the tread connection 8/12 are the same, for example both are left handed. The rotation direction of the tread connection 4/7 then must be opposite, i.e. in this case right handed. The reason for this is the following:

[00120] If the dose dial sleeve 12 is moved out of the housing sleeve 2 by one turn of the actuation element 9, the movement distance is 15 mm. The intermediate sleeve 8 will follow with an axial movement of 11 mm. The axial movement of the intermediate sleeve 8 causes a corresponding movement of the drive sleeve 4 in the same direction, i.e. drive sleeve 4 will be moved out of the housing sleeve 2 by 4 mm. Because of the opposite rotation direction of the tread connection 4/7 and due to the fact that the tread element 7 cannot be rotated but only moved axially, the tread element 7 will be made to move simultaneously into the housing sleeve 2 just by a distance of 4 mm. The axial movement of the intermediate sleeve 8 and the axial movement of the tread element 7 compensate each other with the result that the thread element 7 and the outer magnet 5 remain in their former position and the piston 1b will not be moved.

[00121] The front end of the pen is a disc-like formed cover flange 10. The cover flange 10 is designed so that it can be fixed and removed easily.

The edge of the cover flange 10 has ribbing 10e to facilitate turning. Cover flange 10 includes two banana shaped slots 10b. Each slot terminates in a hole (see **Figure 2a**). The diameter of the hole and is a little larger than the two pan head screws 10c. In addition to mounting cover flange 10 the two screws 10c, are also used for connecting the cartridge reception sleeve 3 and the cover flange 10 with the housing sleeve 2. The corresponding cover flange 10 has a cylindrical portion 10i for receiving the exit end 1c of the cartridge 1. The outer surface of this cylindrical portion 10i is provided with a male tread, which is matched to the female of the needle cap 11.

[00122] The dose numbers (not shown) are printed onto the outer side of the dose dial sleeve 12 in the form of two columns, which helically wind around the dose dial sleeve 12. Only every second dose number is printed so that each column has 15 numbers. The dose number which has been dialled appears in the dose number window 2b in the housing sleeve 2. With a diameter of 20 mm for the dose dial sleeve 12 and a corresponding circumference of about 60 mm and further with an axial feed rate of 4 mm for each turn a field of 4 x4 mm is available for each printed dose number. This allows for good visibility of the dose numbers.

[00123] For the case that the pen shall be used as a reusable version it must be provided with additional means (not shown) for keeping the clutch 9/12 temporarily in its disengaged position. This additional clutch 9/12 can be realized for example by a motion link mechanism, often used in ball point pens.

How to operate the Second Embodiment

[00124] Dosing (**Figure 10**)

[00125] At the beginning of the dosing phase the actuation element 9 is in its proximal position, and in the dose number “0” will appear in the window 2f. For setting a dosing number different from “0” the actuation element 9 must be turned in the dosing direction (for example counter-clockwise) until the desired dose number appears in the dose number window 2f.

[00126] A rotation of the actuation element 9 causes the dose dial sleeve 12 and the rotary coupling 9/12 to be taken along by the actuation element 9. The result is that the dose dial sleeve 12 turns together with actuation element 9 and moves a first distance out of the housing sleeve 2. The rotation of the dose dial sleeve 12 causes an axial movement of the intermediate sleeve 8 out of the housing sleeve 2 but by a second distance which is less than the first distance. Simultaneously the drive sleeve 4 is forced by the coupling 4/7 to turn with the actuation element 9, whereby the threaded element 7 is urged to move axially into the housing sleeve 2 by a third distance, which is the same as the second distance but in the opposite direction. During this dose setting action the thread element 7 and thereby also the outer magnet 6 remain in its former position or - in other words – they do not move at all. This also means that the piston 1b in cartridge 1 does not move.

[00127] The dialled dose can be corrected - if necessary - by turning the actuation element 9 in the corresponding direction. Due to the fact that the thread element 7, the outer magnet 6, the inner magnet 5 and the piston 1b keep their position, even a correcting reduction of the set dose number does not effect that injection liquid will be expelled.

[00128] Injecting (Figure 11-12)

[00129] To start an injection phase the user must push, in an axial direction, onto the actuation element located on the front end of the pen. Thereby the pressure spring 9y will be compressed with the result that the dose dial sleeve 12 now - forced by the thread connection 2/12 - can freely rotate around the connecting pin 9x and move simultaneously into the housing sleeve 2. The dose dial sleeve 12 applies a part of the pressure force via the tread connection 8/12 onto the intermediate sleeve 8, which will be moved thereby axially back into the housing sleeve 2. Since the dose dial sleeve 12 and the intermediate sleeve 8 are decoupled during this injecting phase, the drive sleeve 4 will be moved axially back into the housing sleeve 2 without a rotation. This causes the tread 7 and the outer magnetic 6 to move also axially into the housing sleeve 2 by the above mentioned

second distance. The outer magnet 6 takes the inner magnet 5 along, whereby the piston 1b is moved deeper into the cartridge 1 with the result that the predetermined amount of injection liquid 1a will be discharged though the injection needle 11a.

[00130] When the injecting phase is finished, the drive sleeve 4, the intermediate sleeve 8 and the dose dial sleeve 12 are again in the position they had at the beginning of the dosing phase. The dose number “0” once again appears in the dose number window 2f. A reset is not necessary.

[00131] Change of the cartridge

[00132] If the pen is to be used as a reusable version, it is necessary to change an empty cartridge 1 for a new one. If the cartridge 1 is exhausted, the piston, the two magnets 5, 6 and the thread element 7 are in their most forward position. Before a new cartridge 1 can be inserted it is necessary to move the magnets 5, 6 and the thread element 7 back into their most distal position. The first step is to disengage the clutch 9/12 by pressing onto the actuation element 9 and to activate the means for keeping them temporarily in this disengaged condition. Now the user must turn the actuation element contrary to the dosing direction. Thereby only the drive sleeve 4 will be turned with the result that the thread element 7 is moved backward and it takes the two magnets 5, 6 along until all these elements reach their most backward position. The trap basket 3c prevents the inner magnet 5 from falling out of the end section of the cartridge 1 and from sticking to the outer magnet 6.

[00133] The user now must remove the injection needle cap 11 from the cover flange 10 and next remove the cover flange 10 from the housing sleeve 2. He is now able to draw the empty cartridge out of the container reception sleeve 3 and thereafter he has to push a new one into this reception sleeve 3.

[00134] Now the user must put the cover flange 10 again onto the housing sleeve 2 and fix it by turning. Then he has to screw the needle cap 11 onto the threaded cylindrical portion 10i of the cover 10. The last step

is to deactivate the means for keeping the clutch 4/12 temporarily in the disengaged condition.

Construction of the Third Embodiment

[00135] As far as the components are equivalent, the same references are used, as in the before described embodiments.

[00136] The fourth embodiment includes the following components - arranged concentrically - from inside to outside (**Figure 13**):

[00137] a cartridge 1 (here again a Lilly-type) with a piston 1b and the inner magnet element 5 (with its opposite pole parts 5a, 5b), both positioned one after another,

[00138] a cartridge reception sleeve 3,

[00139] an annual thread element 7 and an annular outer magnet 6 (with its opposite pole parts 6a, 6b), both positioned one after another,

[00140] a drive sleeve 4,

[00141] an intermediate sleeve 8,

[00142] a dose dial sleeve 12,

[00143] a housing sleeve 2 with a cover flange 10.

[00144] The cartridge 1 is a cylindrically shaped glass container containing the injection liquid 1a, which is trapped between a movable cartridge piston 1b and a cartridge exit 1c.

[00145] A cylindrically shaped inner magnet 5 is positioned in the cartridge 1. The inner magnet 5 is axially movable within the cartridge 1 and in touch with the piston 1b but not fixed to it.

[00146] The cartridge reception sleeve 3 is intended to receive the cartridge 1 and has a front flange 3a which is fixed to the front flange 2a of the housing 2. The cartridge reception sleeve 3 has at is back end a trap basket 3c for receiving the inner magnet 6 when a new cartridge 1 is inserted in the pen.

[00147] The outer magnet 6 and the thread element 7 are positioned - in radial direction - between the container reception sleeve 3 and the drive sleeve 4. The thread element 7 has on its outer side a helical protruding rib 7a, which projects beyond the periphery of the outer magnet 6 and mates with a helical groove 4a on the inner side of the drive sleeve 4 a thread connection 4/7. The outer magnet 6 is fixed to

the front side of the annular thread element 7. The thread element 7 may be omitted if the outer magnet 6 is provided with the helical protruding rib 7a of the tread element 7. The outer magnet 6 and the thread element 7 can be moved only in an axial direction but not turned. This is caused by an axial guide strip 3b on the outside of the container reception sleeve 3 and corresponding axial slots 7b and 6c in the threaded element 7 and in the outer magnet 6. These elements form a rotary stop 3/7.

[00148] The outer magnet 6 and the inner magnet 5 are adapted to the circular cross shape of the cartridge 1. This means that the inner side of the outer magnet 6 is closely fitted to the outer surface of the cartridge 1. The inner magnetic 5 is closely fitted to the inner surface of the cartridge 1. The air gape between each of the two magnets 5, 6 and the corresponding wall of the cartridge 1 should be kept as small as possible, while still permitting magnets 5, 6 to easily move in an axial direction. The air gap should be as small as possible, preferably 0,1 mm . The axial lengths of the both magnets 5, 6 are between 5 and 10 mm, preferably 8 mm. An adequately strong magnet material for this purpose is commercially available under the trademark “Neodym”. The two magnets 5, 6 should be magnetized axially. This means that the poles are aligned in the axial direction.

[00149] The two magnets are arranged such that the opposite poles of the two magnets 5, 6 are positioned side by side. Thereby the two magnets 5, 6 are in a close and strong magnetic contact. They can be moved synchronously to a large extent along the axis of the cartridge 1. The force for moving them axially must be applied onto the outer magnet 6 only. This force is transmitted by virtue of the strong magnetic coupling onto the inner magnet 5, which is thereby able to force the piston 1b deeper into the cartridge 1 with the result that injection liquid 1a is discharged.

[00150] Movement retainer means 2/4(1) prevents the drive sleeve 4 from an axial displacement against the housing sleeve 2 but permits a rotation. Retention is obtained by an annual groove 4c in the outer side of the drive sleeve 4, in which a retainer pin 2d projects.

[00151] The drive sleeve 4 furthermore has on its outer side ratchet means 2/4(2), which acts together with a toothed ring on the inner side of the housing sleeve 2. The teeth have an inclined and a radial projecting flank. They are positioned so that the ratchet means 2/4(2) allows a rotation of the drive sleeve 4 only in that rotary direction, in which the piston 1b will be moved to the exit 1c of the cartridge 1. The ratchet means 2/4(2) ensures that there is no operation phase in which air can be sucked into the cartridge.

[00152] The intermediate sleeve 8 is connected with the drive sleeve 4 by a rotary coupling 4/8, this forces the intermediate sleeve 8 and the drive sleeve 4 to have a common rotation, but it allows that the intermediate sleeve 8 can be axially moved against the drive sleeve 4 and the housing sleeve 2. The rotary drive coupling 4/8 is formed by an axial groove 4b on the outer side of the drive sleeve 4 and by an axial rail 8a, which is guided in the axial groove 4b.

[00153] The back end section of the intermediate sleeve 8 is terminated by a flange member 8b. The intermediate sleeve 8 is connected with the dose dial sleeve 12 by an axial movement coupling 8/12, which is formed by an annular rib 8d on the outer side of this distal end section of the intermediate sleeve 8 and by an annular groove 12e of the dose dial sleeve 12. This coupling 8/12 forces the intermediate sleeve 8 and the dose dial sleeve to a common axial movement but it allows an independent rotation of these two parts 8 and 12.

[00154] The dose dial sleeve 12 is connected with the housing sleeve 2 by a threaded connection 2/12, which is formed by a helical protruding rib 2c on the inner side of the housing sleeve 2 and by a helical groove 12b on the outer side of the dose dial sleeve 12. The back end section of the dose dial sleeve 12 is formed with a slightly larger diameter, which serves as a dose dial grip 12c. This diameter is equal to the diameter of housing sleeve 2. The dose dial grip 12c encloses a hollow space, in which a push-button 9 is positioned. The push-button 9 has a central pin 9a, which projects into a recess 8c on the back side of the flange member 8b. The central pin 9a is surrounded by a compression spring 9c, which tries to keep the flange member 8b and

the push-button 9 properly spaced. A push-plate 9b is positioned on the back side of the push-button 9. This push-plate 9b carries a pivot pin 9f with a tip and is anchored in a recess 9g of the push-button 9. The push-plate 9b is can rotate freely relative to push-button 9.

[00155] If the push-button 9 is pressed into the dose dial grip 12c, the dose dial sleeve 12 and the intermediate sleeve 8 on the one side and the push-button 9 on the other side will be coupled by a rotary coupling 8/9/12 for a common rotation. The rotary coupling 8/9/12 is formed by a front toothed sprocket 12f on the dose dial sleeve 12 and a front toothed sprocket 8e on the intermediate sleeve 8 on the one side and a front teeth sprocket 9e on the push- button 9 on the other side.

[00156] The pitch p2 of the thread connection 2/12 is larger than the pitch p1 of the first thread connection 4/7 (p2 > p1). The pitch p1 of the thread connection 4/7 is determined by the maximum dose of (here) 60 IE and the number of turns of the drive sleeve 4, which are needed for expelling this maximum dose. As already explained in connection with the second embodiment, the calculation of the pitch p1 results in p = 4mm.

[00157] The pitch p2 of the thread connection 2/12 must be selected so that it is not self-blocking, i.e. that the dose dial sleeve 12 can freely rotate if an axial pressure is exerted on the push-button 9. The pitch p2 depends moreover from the inner diameter D of the dose dial sleeve 12 and from a friction parameter. It was found that the relationship p2/D should be about 3/4 or larger. In the present case a pitch p2 = 16 mm was selected. The diameter D of the dose dial sleeve 12 was calculated with 20 mm. That means that the dose dial sleeve 12 will be moved out of the housing sleeve 2 by a maximum distance of 32 mm with two turns. This distance guarantees a comfortable handling of the pen and sufficient place for the dose numbers on the outer side of the dose dial sleeve (to be explained later in detail).

[00158] The front end of the pen is formed by a disc-like cover flange 10. The cover flange 10 is intended to be easily attached and removed. The edge of cover flange 10 has ribbing 10e to facilitate turning. Cover flange 10 includes two banana shaped slots 10b and 10d (**Figure 8c**).

Each slot terminates in a hole (see Figure 2a). The diameter of the hole is a little larger than the diameter of the pan head screws 10c. In addition to mounting cover flange 10 the two screws 10c, are also used to connect the cartridge sleeve 3 and the cover flange 10 with the housing sleeve 2. The cover flange 10 has a cylindrical portion 10i for receiving the cartridge exit 1c. The outer side of this cylindrical portion 10i is provided with a male tread, which is matched to a female thread of the needle cap 11.

[00159] The dose numbers (not shown) are printed onto the outer side of the dose dial sleeve 12 in the form of two columns, which helically wind around the dose dial sleeve 12. Only every second dose number is printed so that each column has 15 numbers. The dialled dose number appears in the dose number window 2b that is provided in the housing sleeve 2. With a diameter of 20 mm for the dose dial sleeve 12 and a corresponding circumference of about 60 mm and further with an axial feed rate of 4 mm for each turn a field of 4 x4 mm is available for each printed dose number. This allows for good visibility of the dose numbers.

[00160] The above specification is limited to the essential functions of the pen. If it is intended to use the pen as a reusable version some additional features are necessary.

How to operate the Third Embodiment

[00161] Dosing (Figure 13)

[00162] At the beginning of the dosing phase the intermediate sleeve 8 and the dose dial sleeve 12 are in their proximal position (start position), and the dose number “0” will appear in the dose number window 2f. For setting a dose number different from “0” the dose dial grip 12a must be turned in the dosing direction (for example clockwise) until the selected dose number appears in the dose number window 2f.

[00163] A rotation of the dose dial grip 12c causes – due to the treaded connection 2/12 - the dose dial sleeve 12 to turn out of the housing sleeve 2. The dose dial sleeve 12 takes - because of the axial movement coupling 8/12 - the intermediate sleeve 8 along with it. The intermediate sleeve 8 can only move axially. It is prevented from

rotating by the rotary coupling 4/8. The rotary coupling 4/8 prevents the rotation because drive sleeve 4 cannot rotated clockwise due to the action of ratchet means 2/4(2).

[00164] If the user wishes to reduce the set dose number before an injection, he can turn the dose dial grip 12a counter-clockwise. The result is that that the dose dial sleeve 12 will again turn a corresponding distance into the housing sleeve 2, taking the intermediate sleeve 8 along with it. As was previously explained, the intermediate sleeve 8 moves only axially even though ratchet means 2/4(2) would allow a counter-clockwise rotation. The primary purpose of the ratchet means 2/4(2) is to prevent air being sucked into the cartridge 1. This is only possible if the piston 1b is moved backward, away from the cartridge exit 1c, and this only occurs with a clockwise rotation of the drive sleeve 4.

[00165] Injecting (**Figure 14**)

[00166] For starting the injection phase the user must press on the push-plate 9c of the push-button 9. This causes the compression spring 9b to be compressed and the pin 9a presses against the bottom of recess 8c, located in flange member 8a. Now the toothed sprockets 12b, 8e and 9d interlock, and the dose dial sleeve turns under the pressure counter-clockwise into the housing sleeve 2. Because the intermediate sleeve 8 is now coupled for a common rotation with the dose dial sleeve 12 by the rotary drive coupling 8/9/12, the intermediate sleeve 8 turns and moves together with the dose setting sleeve 12 back to the housing sleeve 2. The rotation of the intermediate sleeve 8 will be transmitted back to the rotary drive coupling 4/8 and onto drive sleeve 4 with the result that drive sleeve 4 will also be turned counter-clockwise. This is allowed by the ratchet means 2/4(2).

[00167] The counter-clockwise rotation of the drive sleeve 4 and the threaded connection 4/7, causes thread element 7 to move toward the cartridge exit 1c. The threaded element 7 is prevented from a rotation due to the rotary stop 3/7. The thread element 7 carries the outer magnet 6 along. The magnetic coupling pulls inner magnet 5 in the same axial direction. The final result is that injection liquid 1a will be ejected.

[00168] This ends, the injection phase. It is not necessary to reset the dose numbers because the number “0” will appear again in the dose number window 2b.

[00169] Inserting a cartridge

[00170] The user must first remove the injection needle cap 11 from the cover flange 10. Next the cover flange 10 must be removes from the housing sleeve 2. Now cartridge 1 can be inserted into the cartridge reception sleeve 3.

[00171] Now the user must replace cover flange 10 and secure it to the housing sleeve 2 using two pan head screws 10c. Finally he has to screw the needle cap 11 onto the threaded cylindrical portion 10i of the cover flange 10.

Comparison of the New Pen-Injector with a common Pen

[00172] **Figure 15** shows the fourth embodiment and below in **Figure 16** a common pen. It is seen that the new Pen-Injector has a length (with needle) of about 9 cm. The common pen is has a length of about 15-16 cm and is therewith longer by 72%.

[00173] The common pen includes beside the cartridge - a manual operable drive mechanism, power transmitting means and dosing means. All components are positioned in a pen-like housing, which consists of the two housing parts. The two housing parts are connected in longitudinal direction. The first housing part contains all components except the cartridge. The cartridge is positioned in the second housing part. The components include a rigid piston rod for moving the cartridge piston. This piston rod must, of necessity, be at least as long as the length of the piston travel inside the cartridge. It is clear that such Pen-Injectors cannot be shorter than the total length of the cartridge plus the piston rod.

[00174] The proposed new Pen-Injector does not use a rigid piston rod. The drive mechanism, the power transmitting means and the dosing means now surround the cartridge concentrically. The power transmitting means utilize – in place of a rigid piston rod - magnets, one of which is positioned outside of the cartridge and the other within the cartridge. The magnets form a closed magnetic circuit with strong

coupling. A movement of the outer magnet element causes a corresponding movement of the inner magnet element and therewith of the cartridge piston.

Claims

1. Pen-Injector for effecting delivery of an injectable product, comprising:
   (a) a housing sleeve (2),
   (b) a reception place for a cartridge (1), wherein said cartridge (1) includes
      (b1) an exit (1c),
      (b2) an open end,
      (b3) a movable piston (1b), and
      (b4) the injectable product between the exit (1) and said piston (1b),
   (c) an outer magnet (6), which is positioned outside of said cartridge (1),
   (d) an inner magnet (5), which is positioned within said cartridge (1) and in contact with said piston (1b),
   (e) an actuation element (9), and
   (f) power transmission means between said actuation element (9) and said outer magnet (6),
   wherein said two magnets (5, 6) are kept permanently in a close magnetic contact.
   (All Embodiments Figures 1-15)

2. Pen-Injector of claim 1, wherein said power transmission means are positioned alongside or around said cartridge (1).
   (All Embodiments Figures 1-15)

3. Pen-Injector of claim 1or 2, wherein said outer magnet (6) has an annular form and surrounds said cartridge (1), and wherein both magnets (5, 6) are adapted to the cross section of said cartridge (1).
   (All Embodiments Figures 1-15)

4. Pen-Injector of claim 1, wherein said magnets (5, 6) are axially magnetized and so arranged that their opposite poles are positioned side by side.
   (All Embodiments Figures 1-15)

5. Pen-Injector of claim 1, further comprising a drive sleeve (4), which surrounds said cartridge (1), wherein said outer magnet (6) is positioned between said

cartridge (1) and said drive sleeve (4), wherein said outer magnet (6) and said drive sleeve (4) are connected directly or indirectly by a thread connection (4/7), and wherein said drive sleeve (4) is a part of said power transmission means.
(All Embodiments Figures 1-15)

6. Pen-Injector of claim 5, wherein said indirect thread connection (4/7) between said outer magnet (6) and said drive sleeve (4) is formed by a thread element (7), which is provided with an outer thread and fixedly connected with said outer magnet (6).
(All Embodiments Figures 1-15)

7. Pen-Injector of claim 6, further comprising guide means (3b), which allow only an axial movement of said thread element (7) and/or said outer magnet (5) and which prevent a rotation.
(All Embodiments Figures 1-15)

8. Pen-Injector of claim 6 or 7, wherein said thread element (7) and/or said outer magnet (6) is/are provided with an axial slot (7b), which encompasses said guide means (3b).
(All Embodiments Figures 1-15)

9. Pen-Injector of the claims 5-8, wherein said drive sleeve (4) is connected directly or indirectly with said housing sleeve (2) by a thread connection (4/2).
(All Embodiments Figures 1-15)

10. Pen-Injector of claim 9, further comprising an intermediate sleeve (8), which is positioned between said drive sleeves (4) and said housing sleeve (4), and which forms a part of said indirect thread connection between the drive sleeve (4) and the housing sleeve (2).
(Second and Third Embodiment Figures 10-15)

11. Pen-Injector of claim 10, further comprising a dose dial sleeve (12), which is positioned between said intermediate sleeve (8) and said housing sleeve (2), and

which forms a further part of said indirect thread connection between said drive sleeve (4) and said housing sleeve (2).
(Second and Third Embodiment Figures 10-15)

12. Pen-Injector of one of the claims 1-11, wherein said actuation element (9) is connected direct or indirectly to the drive sleeve (4).
(First and Second Embodiment Figures 1-12)

13. Pen-Injector of claim 11, wherein the actuation element (9) is fixedly connected to or integral part of the dose dial sleeve (12).
(Third Embodiment Figures 13-15)

14. Pen-Injector of claim 11, wherein said dose dial sleeve (12) is connected with said housing sleeve (2) by a thread connection (2/12).
(Second and Third Embodiment Figures 10-15)

15. Pen-Injector of claim 11, wherein said dose dial sleeve (12) is additionally connected with said intermediate sleeve (8) by a thread connection (8/12).
(Second Embodiment Figures 10-12)

16. Pen-Injector of claim 11, wherein said dose dial sleeve (12), said intermediate sleeve (8) and said drive sleeve (4) are connected by a rotary drive coupling (4/8, 9/12), which ensures a common rotation of said three elements (4, 8, 12) as well an axial displacement of them against each other.
(Second Embodiment Figure 10-22)

17. Pen-Injector of claim 10, wherein said intermediate sleeve (8) and said housing sleeve (2) are connected by coupling means (2/8(1)), which ensure an axial displacement but prevent a rotation of said intermediate sleeve (8) against said housing sleeve (2).
(Second Embodiment Figures 10-12)

18. Pen-Injector of claim 10, wherein said intermediate sleeve (8) and said drive sleeve (4) are connected by a rotary drive coupling (4/8), which ensures a

common rotation of said both elements (4, 8) as well an axial displacement of them against each other.
(Third Embodiment Figure 13-15)

19. Pen-Injector of claim 5, wherein said drive sleeve (4) and the housing sleeve (2) are connected by retainer means 2/4(1), which prevent said drive sleeve (4) from an axial displacement against said housing sleeve (2), but allow a rotation of said drive sleeve (4) against said housing sleeve (2).
(Third Embodiment Figures 13-15)

20. Pen-Injector of claim 5, wherein said drive sleeve (4) and said housing sleeve (4) are connected by ratchet means 2/4(2), which allow a rotation of said drive sleeve (4) against said housing sleeve (2) only in that rotary direction, in which said piston (1b) will be moved to said exit (1c) of said cartridge (1).
(Third Embodiment Figures 13-15)

21. Pen-Injector of one of the claims 1-20, wherein said actuation element (9) includes a push button (9b), which is - if not actuated - maintained by spring force into a neutral position.
(Second and Third Embodiment Figures 10-15)

22. Pen-Injector of claim 21, wherein said push button (9b) acts - if actuated - upon said coupling means (4/8, 9/12) between said intermediate sleeve (8) and said housing sleeve (2) in such a way that said dial dose sleeve (12) will be disconnected from said intermediate sleeve (4) and said drive sleeve (4), whereby it can freely rotate due to said thread connection between dose dial sleeve (12) and said housing sleeve (2) into its initial position.
(Second Embodiment Figures 10-12)

23. Pen-Injector of claim 21, wherein said push button (9b) acts - if actuated - upon said rotary drive coupling (4/8) between said drive sleeve (4) and said intermediate sleeve (2) in such a way that said dose dial sleeve (12) is additionally coupled with said drive sleeve (4) and said intermediate sleeve (8) for a common rotation of said three elements (4, 8, 12), whereby said dose dial

sleeve (12) can rotate due to said thread connection (2/12) between said dose dial sleeve (12) and said housing (2) into its initial position and whereby it can transmit its rotation onto said both other elements (4, 8).
(Third Embodiment Figures 13-15)

24. Pen-Injector of claim 16, wherein said thread connection (2/12) between said dose dial sleeve (12) and said housing sleeve (2) is formed from a non-self-locking thread, which causes said dose dial sleeve (12) to rotate, when an axial force is acting on it.
(Second and Third Embodiment Figures 10-15)

25. Pen-Injector of claim 15, wherein the rotation direction of said thread connection (4/7) between said drive sleeve (4) and said thread element (7) is opposite to the direction of rotation of said thread connection (8/12) between said intermediate sleeve (8) and said dose dial sleeve (12) and also opposite to the direction of rotation of said thread connection between said dose dial sleeve (12) and said housing sleeve (2), and wherein the pitch of said thread connection (2/12) between said dose dial sleeve (12) and said housing sleeve (2) is equal to the difference of the pitches of said thread connection (8/12) between said intermediate sleeve (8) and said housing sleeve (2) on one the hand and said thread connection (4/7) between said drive sleeve (4) and said thread element (7) on the other hand.
(Second Embodiment Figures 10-12)

26. Pen-Injector of claim 23, wherein the ratio of the pitch of the thread connection (2/12) between the dose dial sleeve (4) and the housing sleeve (2) to the pitch of the thread connection (4/7) between the drive sleeve (4) and the tread element (7) is equal to the ratio of the displacement distance of the dose dial sleeve (12) to the displacement distance of the piston (1b).
(Third Embodiment Figures 13-15).

AMENDED CLAIMS
received by the International Bureau on 22 November 2012 (22.11.2012)

1. Pen-Injector for effecting delivery of an injectable product, comprising:
(a) a housing sleeve (2),
(b) within the housing sleeve (2) a standard cartridge (1) including
(b1) an exit (1c),
(b2) an open end,
(b3) a piston (1b) movable along the cartridge axis,
(b4) said injectable product between the exit (1) and said piston (1b),
(c) an actuation element (9),
(c1) on which a displacement force for the piston (1b) has to be applied,
(d) an outer magnet (6), which
(d1) surrounds said cartridge (1)
(e) power transmission means for the displacement force, which
(e1) are positioned between said actuation element (9) and said outer magnet (6) and
(e2) are arranged alongside or around said cartridge (1)
(f) an inner magnet (5), which is
(f1) positioned within said cartridge (1),
(f2) magnetically coupled to said outer magnet (6),
(f3) in contact with said piston (1b),
characterized in that
(g) said two magnets (5, 6) are
(g1) axially magnetized in direction of the cartridge axis,
(g2) arranged so that both opposite pole pairs are positioned side by side,
(g3) thereby locked in a magnetic trap,
(g4) but axially deflectable within a stable range of said magnetic trap,
(g5) so designed that their stable range is bigger than the maximum single stroke of said piston (1b), and
(g6) adapted to the cross section of said cartridge (1),
(All Embodiments Figures 1-15)

2. Pen-Injector of claim 1, wherein said outer magnet (6) has an annular form.
(All Embodiments Figures 1-15)

3. Pen-Injector of claim 1, further comprising a drive sleeve (4), which surrounds said cartridge (1), wherein said outer magnet (6) is positioned between said cartridge (1) and said drive sleeve (4), wherein said outer magnet (6) and said drive sleeve (4) are connected directly or indirectly by a thread connection (4/7), and wherein said drive sleeve (4) is a part of said power transmission means.
(All Embodiments Figures 1-15)

4. Pen-Injector of claim 3, wherein said indirect thread connection (4/7) between said outer magnet (6) and said drive sleeve (4) is formed by a thread element (7), which is provided with an outer thread and fixedly connected with said outer magnet (6).
(All Embodiments Figures 1-15)

5. Pen-Injector of claim 4, further comprising guide means (3b), which allow only an axial movement of said thread element (7) and/or said outer magnet (5) and which prevent a rotation.
(All Embodiments Figures 1-15)

6. Pen-Injector of claim 5, wherein said thread element (7) and/or said outer magnet (6) is/are provided with an axial slot (7b), which encompasses said guide means (3b).
(All Embodiments Figures 1-15)

7. Pen-Injector of claim 3, wherein said drive sleeve (4) is connected directly or indirectly with said housing sleeve (2) by a thread connection.
(First and Second Embodiments Figures 1-5 and 10-12)

8. Pen-Injector of claim 3, further comprising an intermediate sleeve (8), which is positioned between said drive sleeves (4) and said housing sleeve (4).
(Second and Third Embodiment Figures 10-15)

9. Pen-Injector of claim 8, further comprising a dose dial sleeve (12), which is positioned between said intermediate sleeve (8) and said housing sleeve (2).
(Second and Third Embodiment Figures 10-15)

10. Pen-Injector of claim 3, wherein said actuation element (9) is connected direct or indirectly to the drive sleeve (4).
(First and Second Embodiment Figures 1-12)

11. Pen-Injector of claim 9, wherein said actuation element (9) is fixedly connected to or integral part of the dose dial sleeve (12).
(Third Embodiment Figures 13-15)

12. Pen-Injector of claim 9, wherein said dose dial sleeve (12) is connected with said housing sleeve (2) by a thread connection (2/12).
(Second and Third Embodiment Figures 10-15)

13. Pen-Injector of claim 9, wherein said dose dial sleeve (12) is additionally connected with said intermediate sleeve (8) by a thread connection (8/12).
(Second Embodiment Figures 10-12)

14. Pen-Injector of claim 9, wherein said dose dial sleeve (12), said intermediate sleeve (8) and said drive sleeve (4) are connected by a rotary drive coupling (4/8, 9/12), which ensures a common rotation of said three elements (4, 8, 12) as well an axial displacement of them against each other.
(Second Embodiment Figure 10-12)

15. Pen-Injector of claim 8, wherein said intermediate sleeve (8) and said housing sleeve (2) are connected by coupling means (2/8), which ensure an axial displacement but prevent a rotation of said intermediate sleeve (8) against said housing sleeve (2).
(Second Embodiment Figures 10-12)

16. Pen-Injector of claim 8, wherein said intermediate sleeve (8) and said drive sleeve (4) are connected by a rotary drive coupling (4/8), which ensures a common rotation of said both elements (4, 8) as well an axial displacement of them against each other.
(Third Embodiment Figure 13-15)

17. Pen-Injector of claim 3, wherein said drive sleeve (4) and the housing sleeve (2) are connected by retainer means 2/4(1), which prevent said drive sleeve (4) from an axial displacement against said housing sleeve (2), but allow a rotation of said drive sleeve (4) against said housing sleeve (2).
(Third Embodiment Figures 13-15)

18. Pen-Injector of claim 3, wherein said drive sleeve (4) and said housing sleeve (4) are connected by ratchet means 2/4(2), which allow a rotation of said drive sleeve (4) against said housing sleeve (2) only in that rotary direction, in which said piston (1b) will be moved to said exit (1c) of said cartridge (1).
(Third Embodiment Figures 13-15)

19. Pen-Injector of one of the claims 1, wherein said actuation element (9) includes a push button (9b), which is - if not actuated - maintained by spring force into a neutral position.
(Second and Third Embodiment Figures 10-15)

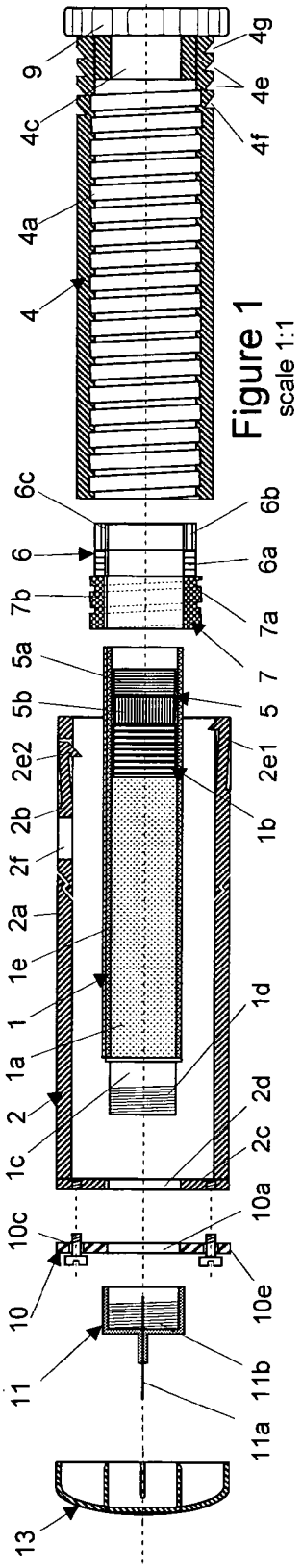
20. Pen-Injector of claims 14 and 19, wherein said push button (9b) acts - if actuated - upon said coupling means (4/8, 9/12) between said intermediate sleeve (8) and said housing sleeve (2) in such a way that said dial dose sleeve (12) will be disconnected from said intermediate sleeve (4) and said drive sleeve (4), whereby it can freely rotate due to said thread connection between dose dial sleeve (12) and said housing sleeve (2) into its initial position.
(Second Embodiment Figures 10-12)

21. Pen-Injector of claims 12, 16 and 19, wherein said push button (9b) acts - if actuated - upon said rotary drive coupling (4/8) between said drive sleeve (4) and said intermediate sleeve (8) in such a way that said dose dial sleeve (12) is additionally coupled with said drive sleeve (4) and said intermediate sleeve (8) for a common rotation of said three elements (4, 8, 12), whereby said dose dial sleeve (12) can rotate due to said thread connection (2/12) between said dose dial sleeve (12) and said housing sleeve (2) into its initial position and whereby it can transmit its rotation onto said both other elements (4, 8).
(Third Embodiment Figures 13-15)

22. Pen-Injector of claim 12, wherein said thread connection (2/12) between said dose dial sleeve (12) and said housing sleeve (2) is formed from a non-self-locking thread, which causes said dose dial sleeve (12) to rotate, when an axial force is acting on it.
(Second and Third Embodiment Figures 10-15)

23. Pen-Injector of claims 4, 12 and 13, wherein the rotation direction of said thread connection (4/7) between said drive sleeve (4) and said thread element (7) is opposite to the direction of rotation of said thread connection (8/12) between said intermediate sleeve (8) and said dose dial sleeve (12) and also opposite to the direction of rotation of said thread connection between said dose dial sleeve (12) and said housing sleeve (2), and wherein the pitch of said thread connection (2/12) between said dose dial sleeve (12) and said housing sleeve (2) is equal to the difference of the pitches of said thread connection (8/12) between said intermediate sleeve (8) and said housing sleeve (2) on one the hand and said thread connection (4/7) between said drive sleeve (4) and said thread element (7) on the other hand. (Second Embodiment Figures 10-12)

24. Pen-Injector of claims 4 and 12, wherein the ratio of the pitch of the thread connection (2/12) between the dose dial sleeve (12) and the housing sleeve (2) to the pitch of the thread connection (4/7) between the drive sleeve (4) and the tread element (7) is equal to the ratio of the displacement distance of the dose dial sleeve (12) to the displacement distance of the piston (1b).
(Third Embodiment Figures 13-15).



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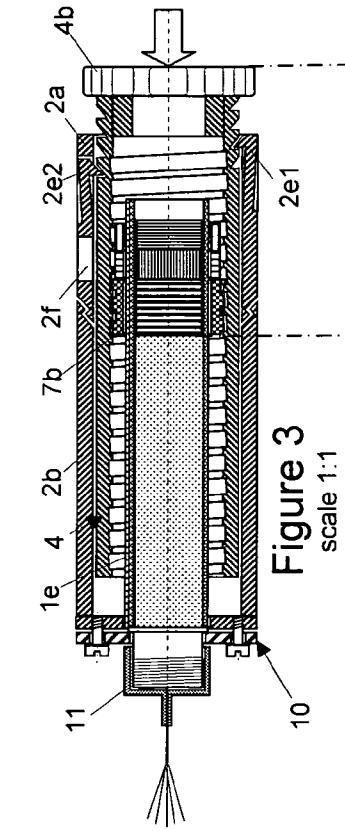
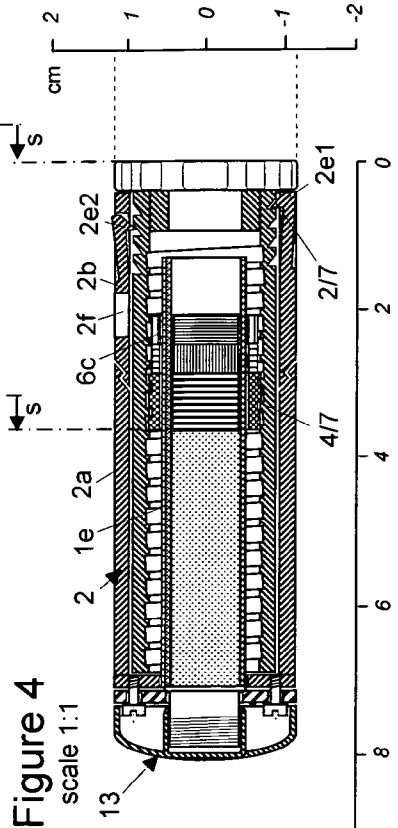


Figure 3
scale 1:1



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scale 1:1

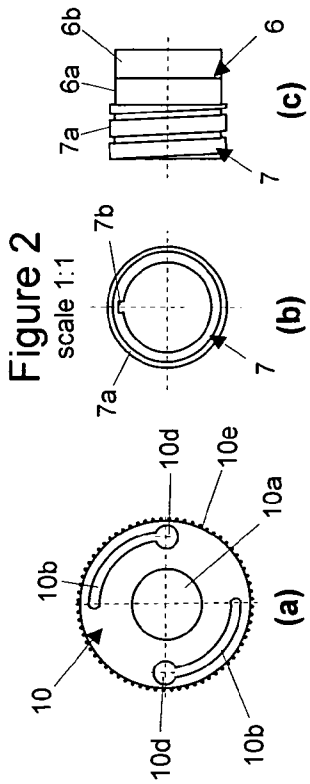

Figure 2
scale 1:1

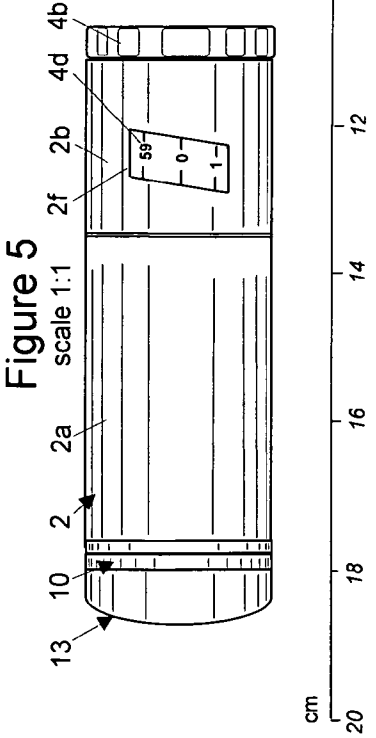

Figure 5
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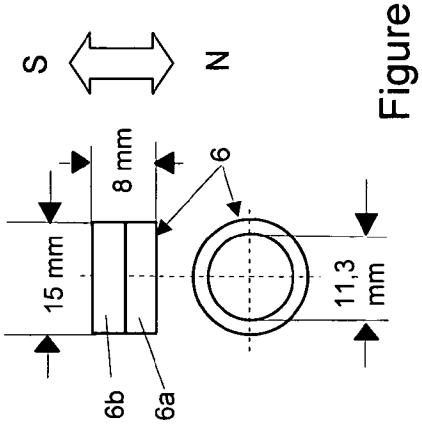


Figure 6

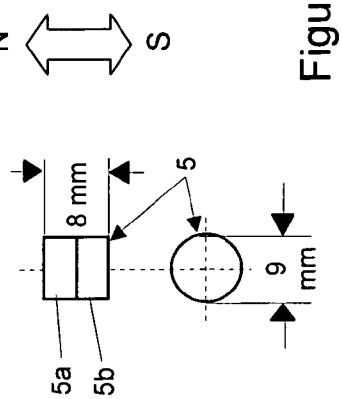


Figure 7

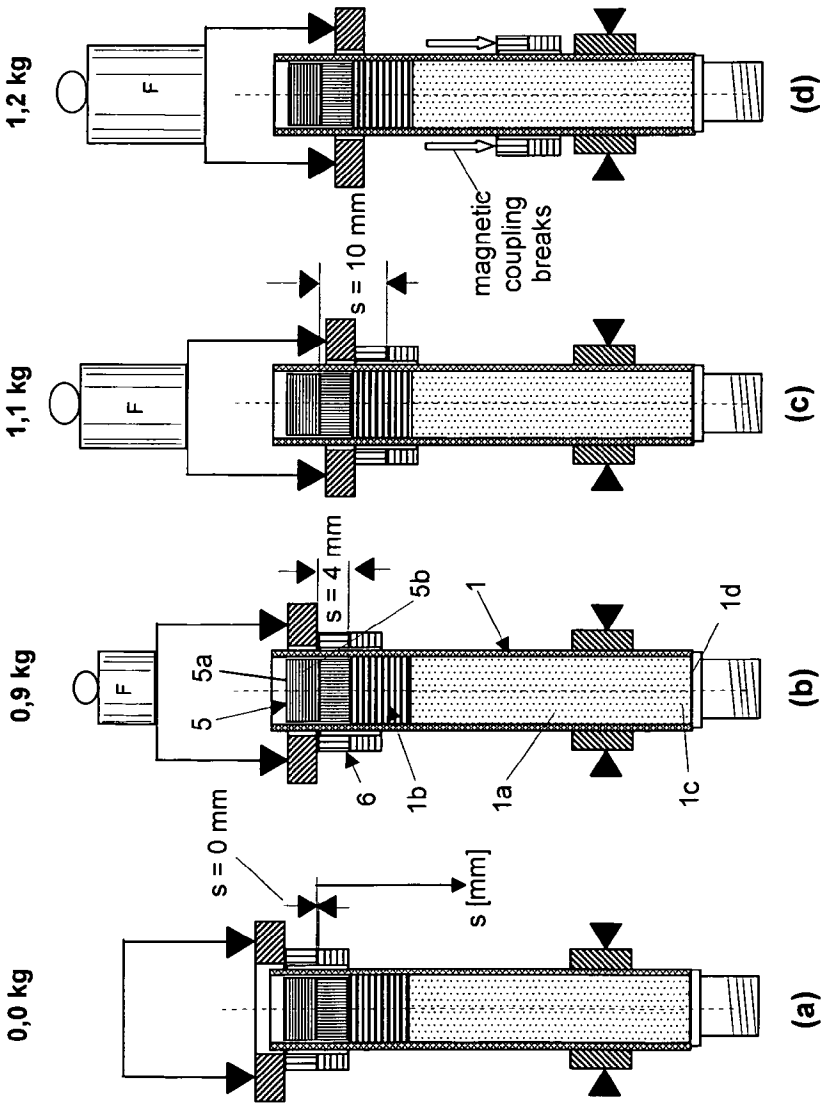
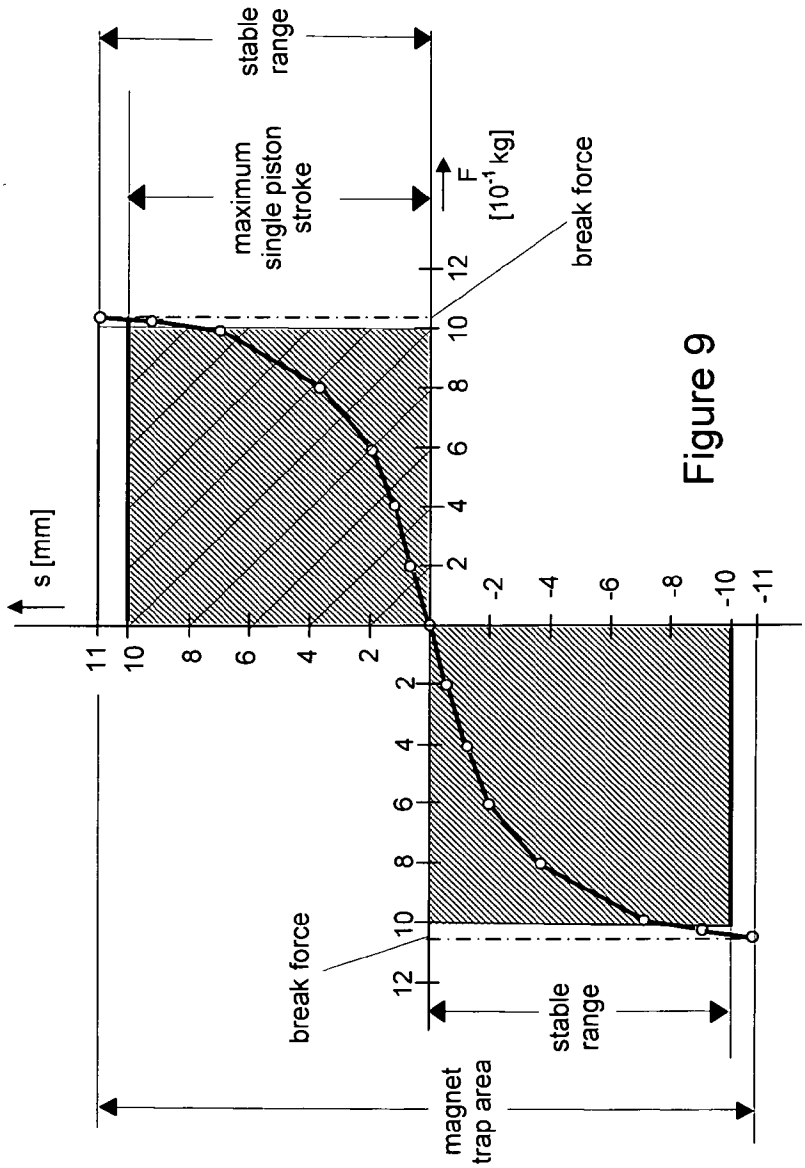


Figure 8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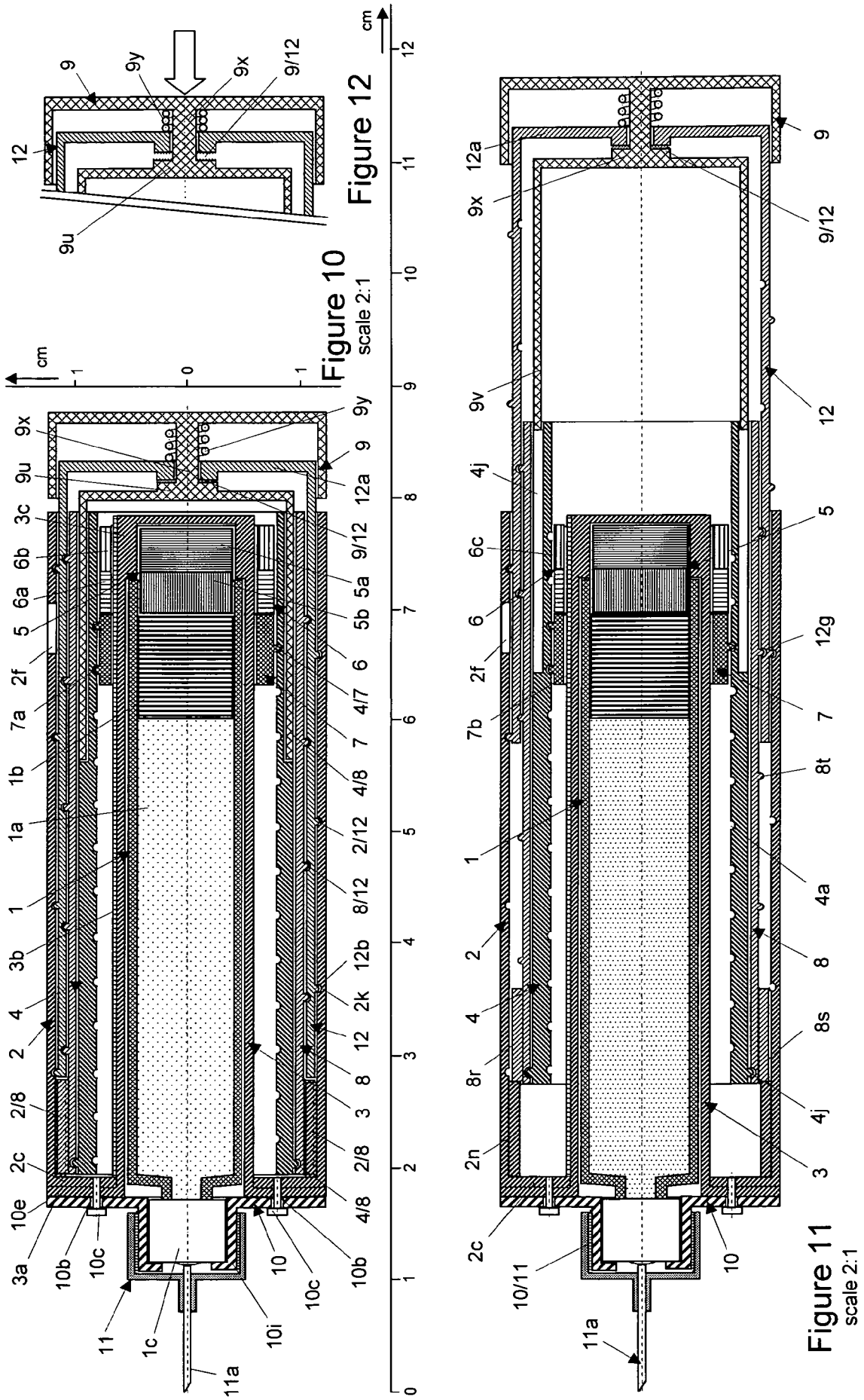
maximum single piston stroke
F [10-1 kg]
break force
s [mm]
11
10
8
6
4
2
2
4
6
8
10
12
12
10
8
6
4
2
-2
-4
-6
-8
-10
-11
break force
stable range
magnet trap area

Figure 9


9
9y
9x
9/12
12
9u
cm
1
0
1
scale 2:1
9x
9u
3c
6b
6a
5
2f
7a
1b
1a
1
3b
4
2
2/8
2c
10e
3a
10b
10c
11
1c
11a
10i
10
10c
10b
9y
9
12a
9/12
5a
5b
6
4/7
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4/8
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8/12
12b
2k
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8
3
2/8
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4
5
6
7
8
9
10
11
12
Figure 10
Figure 12
12a
9x
9v
4j
6c
6
2f
7b
1
2
4
8r
2n
2c
10/11
11a
10
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9/12
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12g
7
8t
4a
8
8s
4j
3
Figure 11
scale 2:1

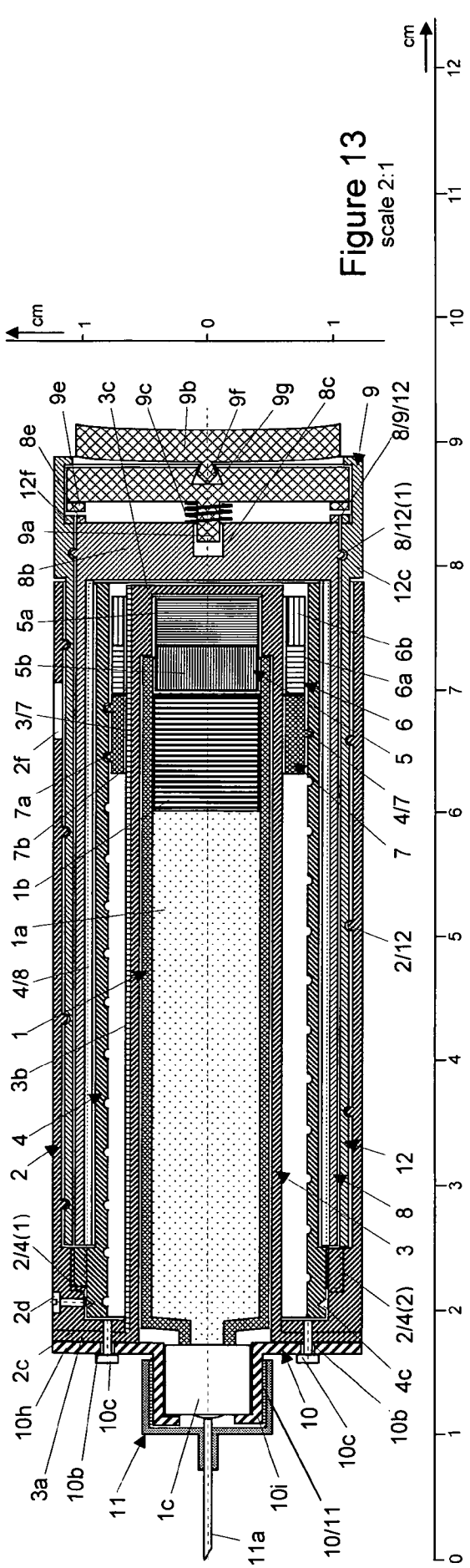


Figure 13
scale 2:1

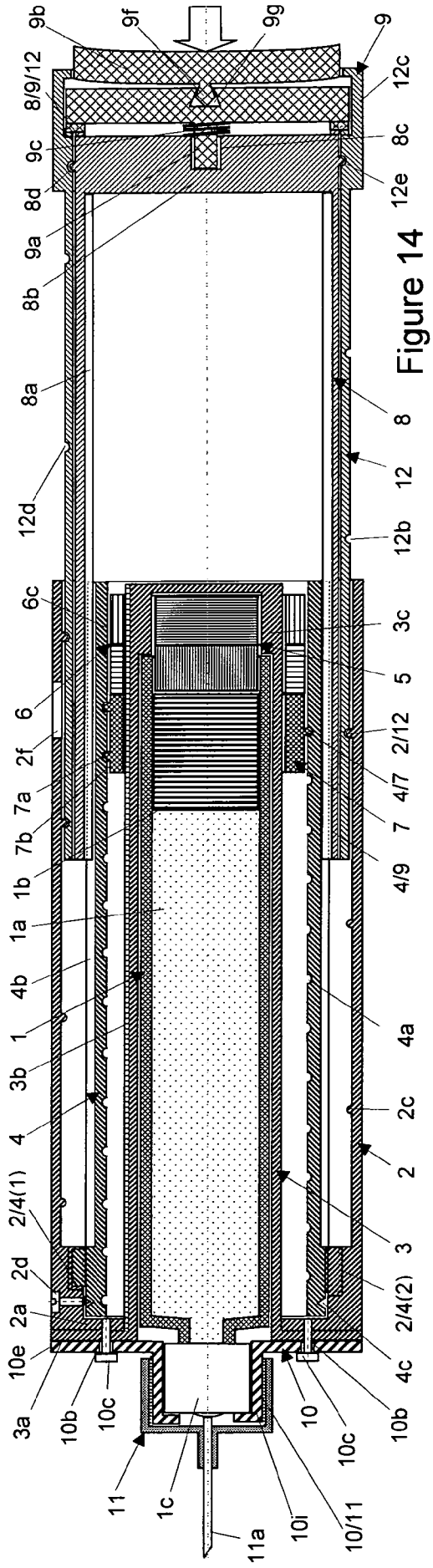


Figure 14
scale 2:1

Figure 15
scale 1:1

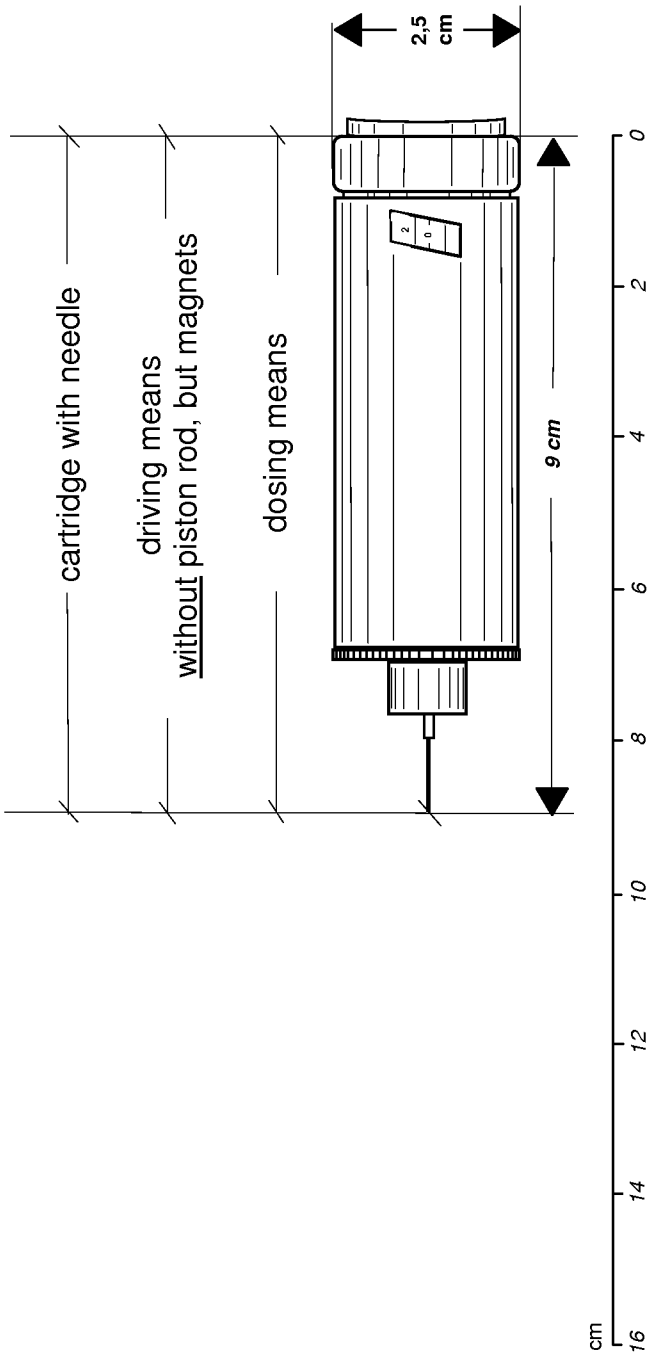
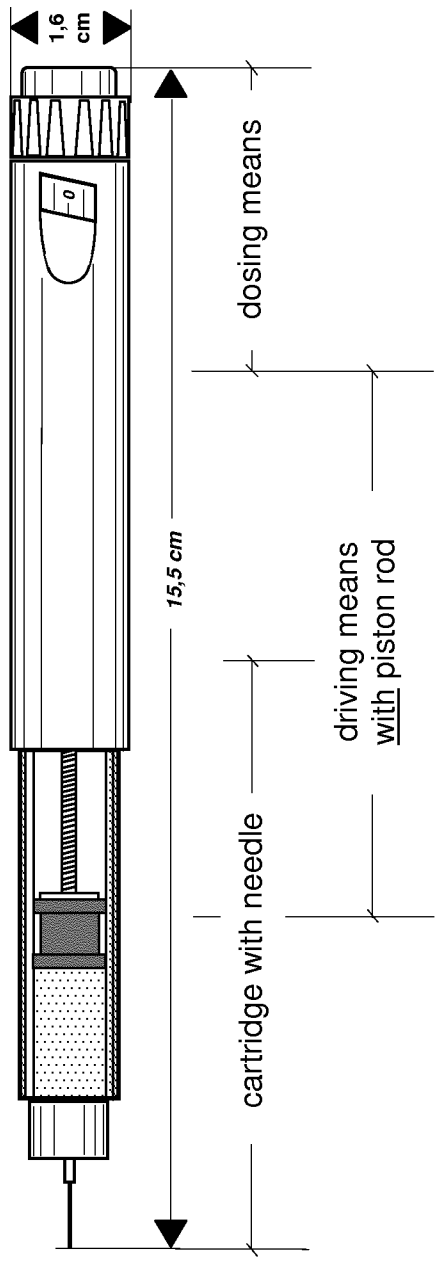


Figure 16
scale 1:1
(prior art)



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/066270

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/315
ADD. A61M5/24

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/030816 A1 (ZUBRY BORIS [US]) 9 February 2006 (2006-02-09) abstract; figures 1-3 paragraphs [0011] - [0014], [0027] - [0032], [0036] - [0037], [0044], [0051] - [0053]	1-26
X	US 2002/022807 A1 (DUCHON DOUGLAS [US] ET AL) 21 February 2002 (2002-02-21) cited in the application abstract; figure 25 paragraphs [0021], [0223] - [0224] claim 36	1
A	US 3 977 402 A (PIKE WILLIAM FLOYD [US]) 31 August 1976 (1976-08-31) the whole document	1-26

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 October 2012	07/11/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Petersch, Bernhard

1

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/066270

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	WO 2008/119691 A2 (SCHMIDT-EVERS JUERGEN [DE]; RUHLAND BERND [DE]; MICHELER CLEMENS [DE]) 9 October 2008 (2008-10-09) cited in the application the whole document	1-26

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2012/066270

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