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(71) Applicant (for all designated States except US):

**SANOFI-AVENTIS DEUTSCHLAND GMBH**  
[DE/DE]; Brüningstraße 50, 65929 Frankfurt (DE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **NAGEL, Thomas**  
[DE/DE]; Grudbachtal 29, 01737 Tharandt (DE).  
**RICHTER, René** [DE/DE]; Freiburger Str. 14, 01737  
Tharandt (DE). **WITT, Robert** [DE/DE]; Waldheimer  
Straße 5, 01159 Dresden (DE).

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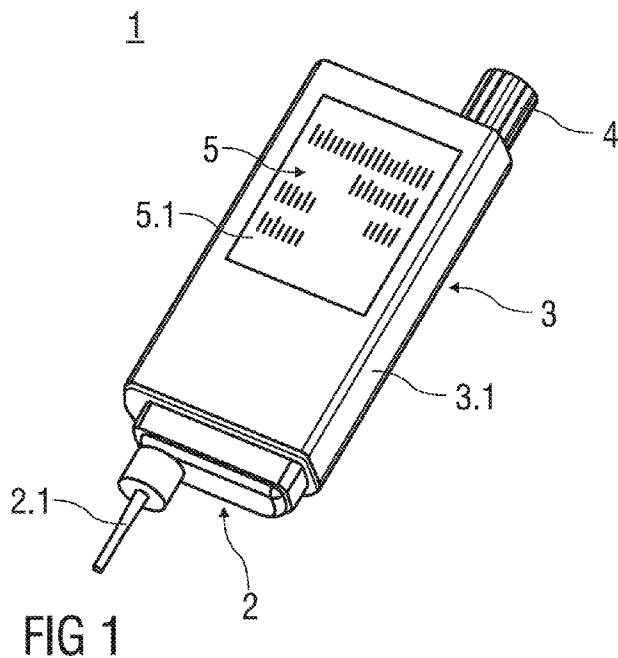
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(57) Abstract: The invention relates to an injection device (1), comprising: -a backend (3) in a housing (3.1), whereby the housing (3.1) accommodating a drug chamber (3.2) and an electronic device (3.7), -a pump unit (2) with an adapted needle (2.1), -a control element (4) which is moved relative to the housing (3.1) in response to set-up the injection, whereby -in an outer surface of the housing (3.1) a display unit (5) is integrated which is controlled at least by the control element (4) to set up, start and/or monitor the injection and which is designed to display a number of controllable and/or stored injection parameters of a current injection and/or previous and/or subsequent injections.

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## MODULAR INJECTION DEVICE WITH INTEGRATED DISPLAY

### TECHNICAL FIELD

The present invention relates to an injection device for a self-administration of liquid drugs especially in adjustable doses.

### BACKGROUND OF THE INVENTION

Injection devices of this type are well known in the art. E.g. in the therapy of insulin-dependent diabetes mellitus, pen-shaped administration or injection devices for self-administration of insulin in adjustable doses are widely used and well-known in the art. Such injection devices may be designed for ejecting a single, pre-installed insulin reservoir and to be disposed after fully emptying the reservoir.

The injection device usually comprises a drug chamber, e.g. a container, pre-filled with a medicine for multiple injections or inhalations with a pre-determined dose. For certain applications it may be desirable to set individual doses to be delivered. The user will know which dose is set.

In US 5,947,934 a dose display for an injection syringe is disclosed. The injection syringes comprises a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections. The syringe has a dose setting mechanism by which doses may be set by rotation a dose setting element relative to the housing and the dose set is indicated on a scale. The scale is formed as a clock dial for indicating the set dose.

### SUMMARY OF THE INVENTION

It is an object of the present invention to provide an injection device for self-administration of liquid drugs which is compact, simple to handle and allow reliable and complete injection recording and e.g. therapy recording.

An injection device according to the invention is designed to be held in a hand for drug administration and comprises a housing accommodating a drug device and an electronic device and a control element which is moved relative to the housing in response to setting up the injection. The injection device further comprises a display unit which is integrated in an outer surface of the housing, whereby the display unit is controlled at least by the control element to set-up, start and/or monitor the drug injection and which displays a number of controllable and/or stored injection parameter of a current and/or previous and/or subsequent injections.

The advantage of the proposed injection device with an integrated display unit is that a user of the injection device may be controlled and monitored the injection via outputted visual information, e.g. injection parameter, such as numeric and/or graphic dose volumes, user instructions, language information, drug chamber information, injection log-book, remaining quantity, user advertising. Therefore, such an injection device with integrated display unit controlled by the control element allows setting e.g. variable dose volumes and/or variable number of doses in a very simple way. Different dose volumes and/or dose numbers can be modified simply by changing the displayed injection parameter. Furthermore, the kind of medicine and/or the date of expire of the medicine may be checked. This follows in a very small injection failure so that a high accuracy of each injection is allowed.

The liquid drug is preferably insulin or other drugs, e.g. a pain reliever, an analgetic, an anticoagulant. As controllable and/or stored injection parameter may be set and controlled e.g. insulin or carbohydrate amounts, the volume of the drug reservoir, e.g. 1.5 ml or 3 ml drug reservoir, dose volume, dose amounts, dose numbers, further therapy related data such as type classification of meals or illnesses, intake of other additional drugs, activities, e.g. a level and duration of activities, e.g. sportive activities. Furthermore, information of the drug reservoir may be read and stored and the history of previous injections, especially information about previous injections, e.g. dose volumes, dose numbers, injection cycle, may be controlled and displayed. Additionally,

manual, help function, operating guide, language or other information may be stored, displayed, set and/or controlled by the control element.

In a preferred embodiment, the display unit is a touch screen unit with a touch screen and integrated touch elements whereby the touch screen unit is controlled by the control element and/or touch elements of the touch screen to set-up, start and/or monitor the injection via the touch screen. Alternatively, the display unit may be provided as a numeric or alphanumeric display, a Liquid Crystal Display, which is controlled by the control element. Alternatively or additionally to the display unit, other types of information output means may be provided, such as acoustic indication means, e.g. loud speaker, signal alarm, and/or tactile indication means, such as a vibrator.

The electronic device comprises a control unit, a drive unit, a human machine interface as a user interface and an energy source or power unit, whereby the human machine interface is coupled with the control element and/or the touch elements. These components may be re-usable and may be integrated in one unit for an easy handling and assembling.

In a possible embodiment, the control unit is coupled in a way via the user interface with the control element and/or the touch elements of the display unit that setting-up, starting and/or monitoring of the injection is controllable by the control element and/or touch elements step-by-step (stepwise). However, several selectable menu items, e.g. injection plans, history of injections, and/or functions, which are displayed on the display unit, may be selected via the control element and/or the touch elements to automatically or step wisely start, set-up, control and/or monitor actual and/or previous injections. Especially, the injection may be performed automatically, e.g., whenever a user, e.g. a patient, starts the injection a communication between the control element and/or touch element and the control unit as well as the display unit is established to display injection parameters.

Preferably, the control button is a push button, e.g. a press and hold button. Alternatively, the control button may be provided as a turning knob. A further alternative is a voice control for the injection device. In a possible embodiment of the invention,

injection parameters and/or injection information may be selected, input and output e.g. via a menu-driven handling controlled by the control button or the voice control. Input and/or output may be performed by visually displaying and/or an acoustic input or output by voice recognition or voice synthesis, respectively.

For a very compact design of such controllable injection device, the pump unit comprises a pump chamber and a sensor element and one or more interfaces, e.g. data interface, to connect the pump unit with the electronic device.

Preferably, the control unit, the drive unit and the pump are coupled in a way that a dose volume and/or a dose number which is set via the human machine interface are stored in the control unit and are exchanged in a sensor set dose volume and/or sensor set dose number to control the control unit which set the drive unit with respect to the sensor set dose volume and/or the sensor set dose number to drive the pump.

For applying and permanent control of the injection at each step, the sensor element measures the injected medium volume and is coupled to the control unit to transfer and/or store the measured injected medium volume to the control unit and/or in the control unit.

In accordance with a further aspect of the invention, the control unit and the pump unit are coupled in a way that the control unit integrates the measured injected medium volume data and switches off the pump and/or the drive unit when the integrated injected medium volume equals the sensor set dose volume. Such coupling of control unit with pump allows a safe and easy dose setting and/or dose injection and/or dose monitoring.

In a further embodiment, the electronic device comprises at least one memory for storing the history of the injected number of dose and/or dose volumes, a operator manual, the history of the placed drug chamber and/or pump unit.

Preferably, the injection device is provided as an electromechanical pen-shaped injector or any other kind of injection device.

## BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus, are not limitive of the present invention, and wherein:

Figure 1 is a perspective view of an injection device with an integrated display unit,

Figure 2 is a schematic view of the injection device, and

Figure 3 is a perspective view of components of the injection device in an unassembled state.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Corresponding parts are marked with the same reference symbols in all figures.

Figure 1 shows a perspective partial view of an injection device 1 for delivering a liquid medicine, e.g. for self administration of liquid drugs. It is especially suited for the administration of insulin but may be used for the administration of other liquid drugs, e.g. antihypertensive drugs, too.

In a possible embodiment, the injection device 1 may be provided as an electro-mechanical injector. Figure 1 shows such an electro-mechanical injector which comprises a replaceable pump unit 2 with an adapted hollow needle 2.1 and a reusable backend 3 in an assembled state. Most of the components of the injection device 1, e.g. exchangeable drug chamber 3.2, e.g. container or ampoule, re-usable electronic device 3.7 (see figure 2) with electronic components and re-usable drive mechanism are enclosed by a pen-shaped device housing 3.1.

Furthermore, a control element 4 is provided at the housing 3.1. The control element 4 projects from the housing 3.1 and is moved relatively to the housing 3.1 in response to set-up, start and/or monitor the injection.

The control element 4 is provided as a press and hold button and/or as a voice input/output mean for a voice control. Additionally or alternatively, the control element 4 may be rotated. The control element 4 is normally in an extended position outside the housing 3.1.

To set-up, start and/or monitor the injection, the control element 4 may be axially pushed in an operation position onto or into the housing 3.1.

In the extended position the control element 4 may be rotated clockwise for starting the injection, setting, e.g. increasing a dose amount to be administered or another injection parameter, e.g. dose number, drug chamber information, medicine information, history of previous injection. Alternatively, the control element 4 may be rotated anti-clockwise for decreasing a dose amount or another injection parameter, e.g. dose number or injection cycle, drug chamber information, medicine information, history of previous injection.

To set-up, start and/or monitor the injection or injection parameter, the injection device 1 comprises a display unit 5 which is integrated in the housing 3.1. The display unit 5 may be provided as a touch screen 5.1 with integrated touch elements or another suitable control and display unit. The touch screen 5.1 may be provided as a display with 176 x 128 pixel and 65000 colours.

Figure 2 shows a schematic view of the injection device 1,

The pump unit 2 is replaceably attachable to the reusable backend 3. The pump unit 2 comprises a medicine inlet 2.2, a medicine outlet 2.3 and a pump 2.4, e.g. a peristaltic, hose, diaphragm or geared pump, for delivering the liquid medicine from the inlet 2.2 to the outlet 2.3. Furthermore, the pump unit 2 comprises as a sensor element 2.5 a flow sensor for determining a flow volume of the injected drug or medicine. The sensor element 2.5 is further mentioned as flow sensor 2.5.

The reusable backend 3 comprises a replaceable drug chamber 3.2, e.g. a medicine container, and a reusable electronic device 3.7. The reusable electronic device 3.7

comprises a control unit 3.3, a drive unit 3.4 and an energy source 3.5 for powering the drive unit 3.4, the control unit 3.3 and/or the display unit 5.

The drug chamber 3.2 may have a septum which is pierced by the backwardly pointing needle 2.1 of the medicine inlet 2.2.

The flow sensor 2.5 is connectable to the control unit 3.3 thus allowing to control the volume of medicine to be delivered.

The medicine outlet 2.3 may have the hollow needle 2.1 attached for piercing a patient's P skin. Alternatively, a jet nozzle may be provided.

The pump 2.4 has an adapter (not shown) for engaging a drive shaft (not shown) connected to the drive unit 3.4 of the reusable backend 3.

The pump unit 2 has easily disconnectable interfaces - medicine inlet 2.2, data interfaces I1, I2, medicine outlet 2.3 - on the one hand to the drug chamber 3.2 (ampoule), the drive unit 3.4 and the control unit 3.3 and on the other hand to the hollow injection needle 2.1, e.g. by Luer-Lok® or Luer-Slip®.

The energy source 3.5 may be a galvanic cell or battery of galvanic cells in case the drive unit 3.4 comprises an electrical motor. Preferably, the energy source 3.5 is a rechargeable accumulator. The rechargeable accumulator may be replaceable or chargeable in place by an external charging device (not shown) arranged for holding the reusable backend 3.

The reusable backend 3 may further have a user interface 3.6 for user interaction. This may comprise the control element 4, e.g. a press and hold button, a dosing and/or trigger knob or wheel.

Via the user interface 3.6, the display unit 5, e.g. for displaying a dose volume or other injection parameters, is coupled with the control unit 3.3 and/or the control element 4. The energy source 3.5 may be also powered the display unit 5.



The housing 3.1 of the reusable backend 3 may further comprise a viewing window 3.8 for inspecting the contents of the drug chamber 3.2.

The pump unit 2 or the reusable backend 3 or the injection device 1 may preferably be used for delivering one of an analgetic, an anticoagulant, Insulin, Insulin derivate, Heparin, Lovenox, a vaccine, a growth hormone and a peptide hormone.

For performing an injection a user sets a required dose volume and/or a dose number as a target dose via the control element 4 at the user's interface 3.6. The required target dose is forwarded to the control unit 3.3 and is stored there and is exchanged in a sensor set dose volume and/or sensor set dose number to control the control unit 3.3 which respectively sets the drive unit 3.4. As soon as the user triggers the injection arrangement, e.g. by pushing the control element 4, the target dose is converted into a flow sensor setpoint, sensor set dose volume and/or sensor set dose number and the drive unit 3.4 is started. The drive unit 3.4 converts the electrical energy provided by the energy source 3.5 into mechanical energy and forwards it to the pump 2.4, where it is again converted into fluidic energy causing a volume flow of the medicine. The integrated flow sensor 2.5 acquires the volume flow, e.g. injected medium volume, and forwards measurement values to the control unit 3.3. The measurement values, particularly when in the shape of increments corresponding to volume increments, may be integrated by the control unit 3.3 and the drive unit 3.4 may be switched off upon delivery of the setpoint volume. After delivery of the setpoint volume the control unit 3.3 may generate a message for the user to be displayed by the display unit 5.

Figure 3 is a perspective view of components of the injection device 1 in an unassembled state.

The term "drug" or "medicament", as used herein, means a pharmaceutical formulation containing at least one pharmaceutically active compound,

wherein in one embodiment the pharmaceutically active compound has a molecular weight up to 1500 Da and/or is a peptide, a proteine, a polysaccharide, a vaccine, a

DNA, a RNA, a antibody, an enzyme, an antibody, a hormone or an oligonucleotide, or a mixture of the above-mentioned pharmaceutically active compound,

wherein in a further embodiment the pharmaceutically active compound is useful for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism, acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis,

wherein in a further embodiment the pharmaceutically active compound comprises at least one peptide for the treatment and/or prophylaxis of diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy,

wherein in a further embodiment the pharmaceutically active compound comprises at least one human insulin or a human insulin analogue or derivative, glucagon-like peptide (GLP-1) or an analogue or derivative thereof, or exedin-3 or exedin-4 or an analogue or derivative of exedin-3 or exedin-4.

Insulin analogues are for example Gly(A21), Arg(B31), Arg(B32) human insulin; Lys(B3), Glu(B29) human insulin; Lys(B28), Pro(B29) human insulin; Asp(B28) human insulin; human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

Insulin derivatives are for example B29-N-myristoyl-des(B30) human insulin; B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl-ThrB29LysB30 human insulin; B29-N-(N-palmitoyl-Y-glutamyl)-des(B30) human insulin; B29-N-(N-lithocholyl-Y-glutamyl)-des(B30) human insulin; B29-N-( $\omega$ -

carboxyheptadecanoyl)-des(B30) human insulin and B29-N-( $\omega$ -carboxyhepta-decanoyl) human insulin.

Exendin-4 for example means Exendin-4(1-39), a peptide of the sequence H His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys-Gln-Met-Glu-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu-Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH<sub>2</sub>.

Exendin-4 derivatives are for example selected from the following list of compounds:

H-(Lys)<sub>4</sub>-des Pro<sub>36</sub>, des Pro<sub>37</sub> Exendin-4(1-39)-NH<sub>2</sub>,  
 H-(Lys)<sub>5</sub>-des Pro<sub>36</sub>, des Pro<sub>37</sub> Exendin-4(1-39)-NH<sub>2</sub>,  
 des Pro<sub>36</sub> [Asp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [IsoAsp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Met(O)<sub>14</sub>, Asp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Met(O)<sub>14</sub>, IsoAsp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Trp(O<sub>2</sub>)<sub>25</sub>, Asp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Trp(O<sub>2</sub>)<sub>25</sub>, IsoAsp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Met(O)<sub>14</sub> Trp(O<sub>2</sub>)<sub>25</sub>, Asp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Met(O)<sub>14</sub> Trp(O<sub>2</sub>)<sub>25</sub>, IsoAsp<sub>28</sub>] Exendin-4(1-39); or

des Pro<sub>36</sub> [Asp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [IsoAsp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Met(O)<sub>14</sub>, Asp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Met(O)<sub>14</sub>, IsoAsp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Trp(O<sub>2</sub>)<sub>25</sub>, Asp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Trp(O<sub>2</sub>)<sub>25</sub>, IsoAsp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Met(O)<sub>14</sub> Trp(O<sub>2</sub>)<sub>25</sub>, Asp<sub>28</sub>] Exendin-4(1-39),  
 des Pro<sub>36</sub> [Met(O)<sub>14</sub> Trp(O<sub>2</sub>)<sub>25</sub>, IsoAsp<sub>28</sub>] Exendin-4(1-39),  
 wherein the group -Lys<sub>6</sub>-NH<sub>2</sub> may be bound to the C-terminus of the Exendin-4 derivative;

or an Exendin-4 derivative of the sequence

H-(Lys)<sub>6</sub>-des Pro<sub>36</sub> [Asp<sub>28</sub>] Exendin-4(1-39)-Lys<sub>6</sub>-NH<sub>2</sub>,

des Asp28 Pro36, Pro37, Pro38 Exendin-4(1-39)-NH<sub>2</sub>,  
H-(Lys)6-des Pro36, Pro38 [Asp28] Exendin-4(1-39)-NH<sub>2</sub>,  
H-Asn-(Glu)5des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-NH<sub>2</sub>,  
des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-(Lys)6-des Pro36 [Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-Lys6-NH<sub>2</sub>,  
H-des Asp28 Pro36, Pro37, Pro38 [Trp(O<sub>2</sub>)<sub>25</sub>] Exendin-4(1-39)-NH<sub>2</sub>,  
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-NH<sub>2</sub>,  
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-NH<sub>2</sub>,  
des Pro36, Pro37, Pro38 [Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-(Lys)6-des Pro36 [Met(O)<sub>14</sub>, Asp28] Exendin-4(1-39)-Lys6-NH<sub>2</sub>,  
des Met(O)<sub>14</sub> Asp28 Pro36, Pro37, Pro38 Exendin-4(1-39)-NH<sub>2</sub>,  
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Asp28] Exendin-4(1-39)-NH<sub>2</sub>,  
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Asp28] Exendin-4(1-39)-NH<sub>2</sub>,  
des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-Asn-(Glu)5 des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-Lys6-des Pro36 [Met(O)<sub>14</sub>, Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-Lys6-NH<sub>2</sub>,  
H-des Asp28 Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Trp(O<sub>2</sub>)<sub>25</sub>] Exendin-4(1-39)-NH<sub>2</sub>,  
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Asp28] Exendin-4(1-39)-NH<sub>2</sub>,  
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-NH<sub>2</sub>,  
des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>,  
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(S1-39)-(Lys)6-NH<sub>2</sub>,  
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)<sub>14</sub>, Trp(O<sub>2</sub>)<sub>25</sub>, Asp28] Exendin-4(1-39)-(Lys)6-NH<sub>2</sub>;

or a pharmaceutically acceptable salt or solvate of any one of the afore-mentioned Exedin-4 derivative.

Hormones are for example hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists as listed in Rote Liste, ed. 2008, Chapter 50, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatotropine (Somatotropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, Goserelin.

A polysaccharide is for example a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra low molecular weight heparin or a derivative thereof, or a sulphated, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium.

Pharmaceutically acceptable salts are for example acid addition salts and basic salts. Acid addition salts are e.g. HCl or HBr salts. Basic salts are e.g. salts having a cation selected from alkali or alkaline, e.g. Na<sup>+</sup>, or K<sup>+</sup>, or Ca<sup>2+</sup>, or an ammonium ion N<sup>+</sup>(R1)(R2)(R3)(R4), wherein R1 to R4 independently of each other mean: hydrogen, an optionally substituted C1-C6-alkyl group, an optionally substituted C2-C6-alkenyl group, an optionally substituted C6-C10-aryl group, or an optionally substituted C6-C10-heteroaryl group. Further examples of pharmaceutically acceptable salts are described in "Remington's Pharmaceutical Sciences" 17. ed. Alfonso R. Gennaro (Ed.), Mark Publishing Company, Easton, Pa., U.S.A., 1985 and in Encyclopedia of Pharmaceutical Technology.

Pharmaceutically acceptable solvates are for example hydrates.

## LIST OF REFERENCES

1 injection device

2 pump unit

needle

medicine inlet

medicine outlet

pump

flow sensor

3 reusable backend

housing

3.1.1 to 3.1.3 housing parts

drug chamber

control unit

drive unit

energy source

user interface

electronic device

viewing window

4 control element

5 display unit

5.1 touch screen

P patient

I1, I2 data interfaces

## PATENT CLAIMS

1. Reusable backend (3) for an injection device (1), the reusable backend (3) comprising a housing (3.1) arranged to accommodate an exchangeable drug chamber (3.2), wherein a display unit (5) is integrated in an outer surface of the housing (3.1), wherein the display unit (5) is controlled at least by a control element (4) to set up, start and/or monitor the injection and wherein the display unit (5) is designed to display a number of controllable and/or stored injection parameters of a current injection and/or previous and/or subsequent injections, wherein the housing (3.1) contains an electronic device (3.7), wherein the electronic device (3.7) comprises a control unit (3.3), a drive unit (3.4) and an energy source (3.5) for powering the drive unit (3.4), the control unit (3.3) and the display unit (5), characterized in that the reusable backend (3) is arranged to be attached to a replaceable pump unit (2) comprising a medicine inlet (2.2), a medicine outlet (2.3) and a pump (2.4) for delivering a liquid medicine from the inlet (2.2) to the outlet (2.3), wherein the pump unit (2) comprises a flow sensor (2.5) for determining a flow volume of the injected drug or medicine, wherein the control unit (3.3) is connectable to the flow sensor (2.5) and wherein a drive shaft connected to the drive unit (3.4) is arranged to engage an adapter of the pump (2.4).
2. Reusable backend (3) according to claim 1, characterized in that the display unit (5) is a touch screen unit with a touch screen (5.1) and integrated touch elements, whereby the touch screen unit is controlled by the control element (4) and/or touch elements of the touch screen (5.1) to set-up, start and/or monitor the injection via the touch screen (5.1).

3. Reusable backend (3) according to one of the claims 1 or 2, characterized in that the electronic device (3.7) comprises a user interface (3.6), wherein the user interface (3.6) is coupled to the control element (4) and/or the display unit (5).
4. Reusable backend (3) according to claim 3, characterized in that the control unit (3.3) is coupled via the user interface (3.6) with the control element (4) and/or the touch elements of the display unit (5) in such a manner that the setting up, starting and/or monitoring of the injection is controllable by the control element (4) and/or touch elements step-by-step.
5. Reusable backend (3) according to any of the preceding claims, characterized in that the control element (4) is a push button, especially a press and hold button.
6. Reusable backend (3) according to one of the claims 3 to 6, characterized in that the control unit (3.3), the pump (2.4) and the drive unit (3.4) are coupled in a way that a dose volume and/or a dose number which is set via the user interface (3.6) are stored in the control unit (3.3) and are exchanged in a sensor set dose volume and/or sensor set dose number to control the control unit (3.3) which set the drive unit (3.4) with respect to the sensor set dose volume and/or the sensor set dose number.
7. Reusable backend (3) according to one of the claims 3 to 6, characterized in that the control unit (3.3) and the pump unit (2) are coupled in such a manner that the control unit (3.3) integrates the measured injected medium volume data and switches off the pump (2.4) when the integrated injected medium volume equals the sensor set dose volume.
8. Reusable backend (3) according to any of the preceding claims, characterized in that the electronic device (3.7) comprises at least one memory for storing the history of the injected number of dose and/or dose volumes, an operator manual, the history of the placed drug chamber (3.2) and/or pump unit (2).
9. Injector arrangement (1) comprising a reusable backend (3) according to one of the preceding claims and a replaceable pump unit (2) comprising a medicine inlet (2.2), a medicine outlet (2.3) and a pump (2.4) for delivering a liquid medicine from the inlet (2.2) to the outlet (2.3), wherein the pump unit (2) comprises a



flow sensor (2.5) for determining a flow volume of the injected drug or medicine, wherein the control unit (3.3) is connectable to the flow sensor (2.5) and wherein a drive shaft connected to the drive unit (3.4) is arranged to engage an adapter of the pump (2.4).

10. Injector arrangement (1) according to claim 9, characterized in that the pump unit (2) has a hollow needle (2.1) attached to its medicine outlet (2.3).
11. Injector arrangement (1) according to one of the claims 9 or 10, characterized in that the pump (2.4) is arranged as a peristaltic, hose, diaphragm or geared pump.
12. Injector arrangement 1 according to one of the claims 9 to 11, characterized in that an interface is provided between the medicine inlet (2.2) and the drug chamber (3.2).

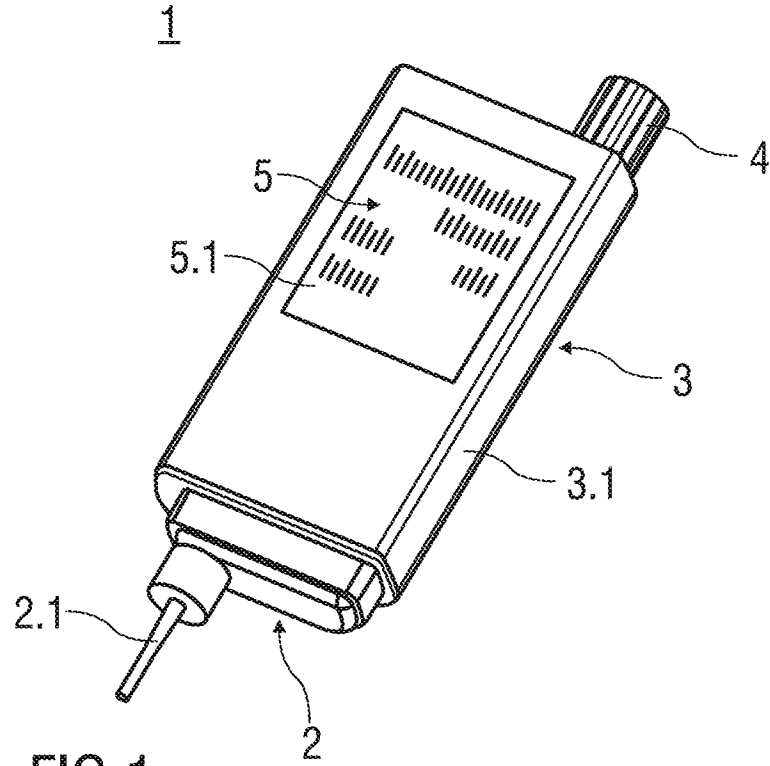


FIG 1

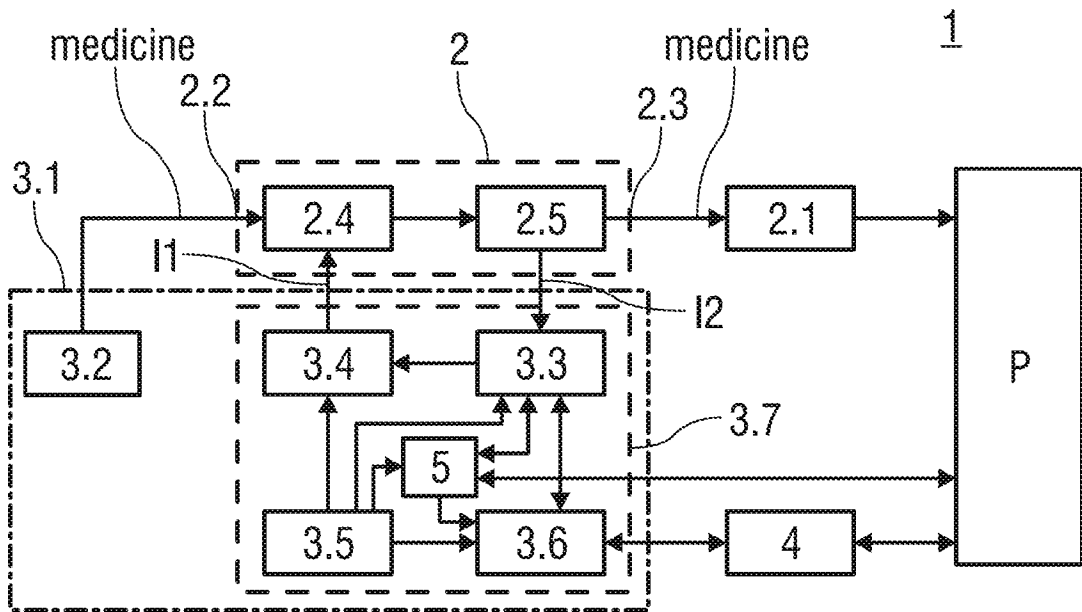


FIG 2

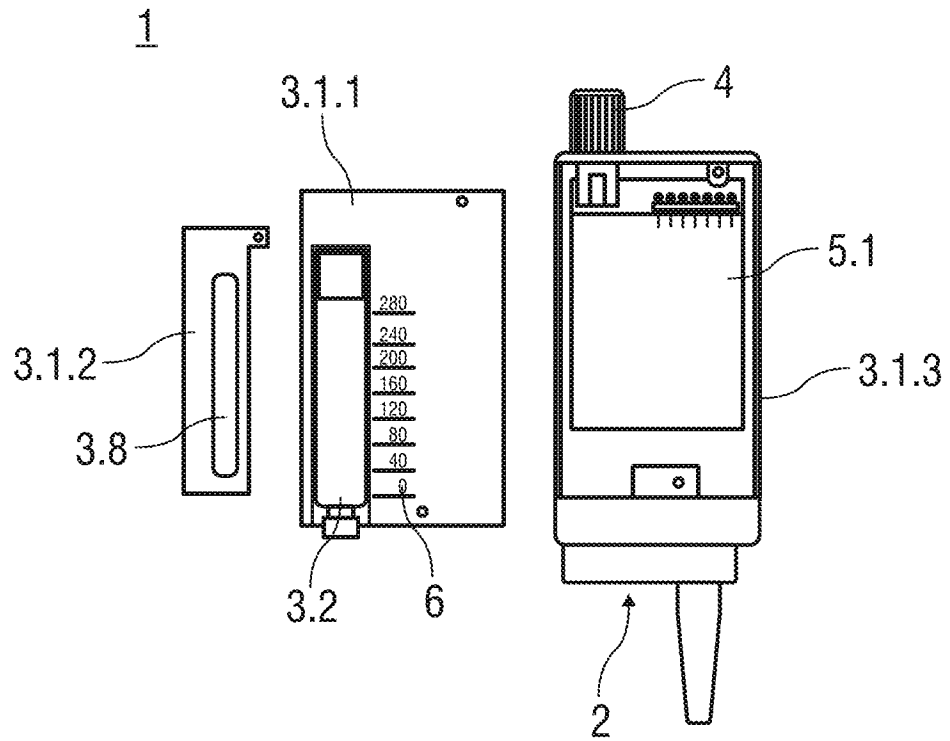


FIG 3

INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2010/062150

A. CLASSIFICATION OF SUBJECT MATTER  
 INV. A61M5/20 A61M5/14 A61M5/168  
 ADD. A61M5/142 A61M5/31 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 practical, search terms used)  
 EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	* abstract figures 1,6,11,13 paragraphs [0002], [0006], [0011], [0013] - [0017], [0037], [0042], [0045] - [0051], [0056] - [0068], [0071], [0072], [0075] - [0082], [0085], [0087] paragraphs [0088], [0092], [0106] - [0108], [0111] - [0117], [0125] ----- -/--	9-12

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search  4 February 2011	Date of mailing of the international search report  10/02/2011
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Petersch, Bernhard
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International application No  
PCT/EP2010/062150

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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Y	* abstract; figures 59A-E, 61C, 63A-C, 70A-D, 117 pages 2-21 page 35, line 23 - page 42, line 31 page 53, lines 14-25 page 59, line 1 - page 63, line 22 page 87, line 6 - page 103, line 22 page 123, line 6 - page 125, line 6 page 130, lines 4-9	9-12
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