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(54) **Title:** MEDICAMENT DELIVERY DEVICE ADAPTED TO A SYRINGE, A SYSTEM COMPRISING THE MEDICAMENT DELIVERY DEVICE AND METHODS FOR USING SAID DEVICE OR SYSTEM

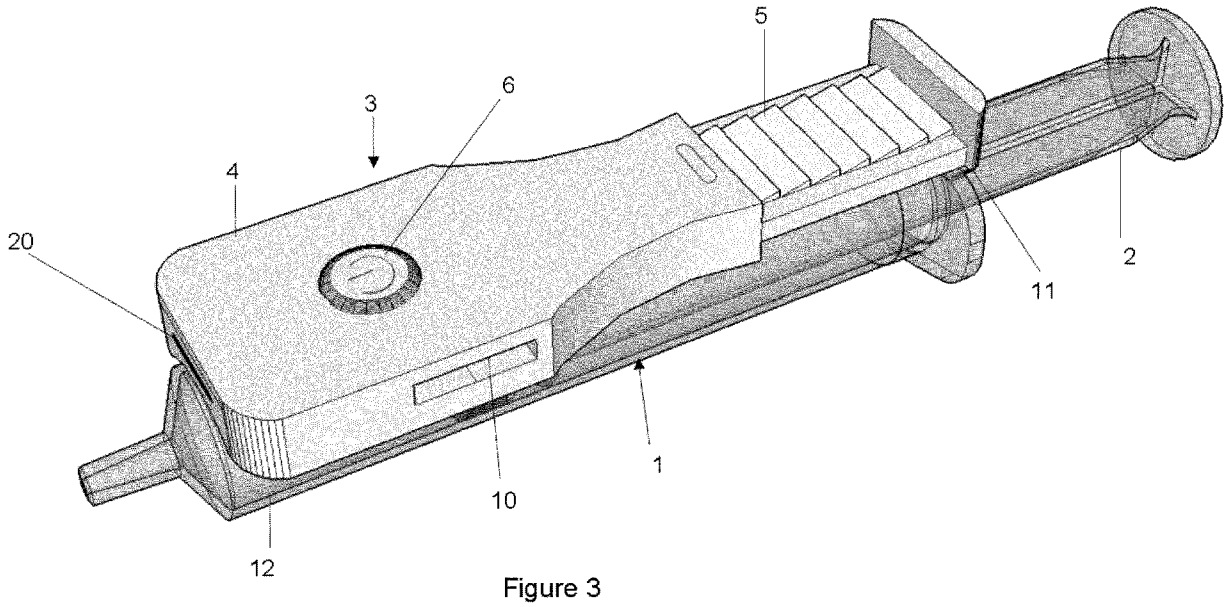

Figure 3

(57) **Abstract:** The present invention relates to a medicament delivery device adapted to a sy- ringe comprising (i) a sensor unit configured to determine the position of themedica- mentdelivery device relative to the injection area, (ii) a dosage assessment unit config- ured to determine amount or volume of the medicament to be delivered, (iii) a temper- ature measuring unit configured to determine the temperature of the medicament; and (iv) a microcontroller. Said medicament delivery device includes several sensors such as orientation sensors, temperature sensor and optical sensors. The present invention fur- ther relates to a system comprising the medicament delivery device and methods for using said device or system comprising a method of monitoring measured parameters, a method for real time visualization of said parameters and a method only directed to the system of improving a user's employment of a medicament delivery system.

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Medicament delivery device adapted to a syringe, a system comprising the medicament delivery device and methods for using said device or system

FIELD OF THE INVENTION

[0001] The present invention relates to a medicament delivery device adapted to a syringe comprising (i) a sensor unit configured to determine the position of the medicament delivery device relative to the injection area, (ii) a dosage assessment unit configured to determine amount or volume of the medicament to be delivered, (iii) a temperature measuring unit configured to determine the temperature of the medicament; and (iv) a microcontroller. The medicament delivery device includes several sensors such as orientation sensors, temperature sensor and optical sensors. The present invention further relates to a system comprising the medicament delivery device and methods for using the medicament delivery device or system comprising a method of monitoring measured parameters, a method for real time visualization of said parameters and a method only directed to the system of improving a user's employment of a medicament delivery system.

BACKGROUND OF THE INVENTION

[0002] Clinical trials generate data on safety and efficacy of new drugs. Depending on product type and development stage, researchers initially group volunteers and/or patients into small pilot studies, and subsequently conduct progressively larger scale comparative studies. Clinical study designs aim to ensure the scientific validity and repro-

ducibility of the results. In a number of clinical trials, the tested drug has to be administered as injection. Sometimes a volunteer has to be treated by single or multiple injections in various parts of the body with different injection forms, such as subcutaneous, intravenous, intra-arterial, or intramuscular injections. To achieve scientific validity and reproducibility of the results of these injections in clinical trials, a tracking system is needed, which measures a variety of specific parameters, and may also record and analyse these data. Furthermore, such a tracking system allows for an easy and precise error analysis.

[0003] A variety of diseases exists, in which a regular administration of a therapeutic agent via e.g. intravenous, subcutaneous or intramuscular injection is essential. One of the common diseases is Diabetes mellitus in which a medication of the diabetic patient via injection of insulin is already established. Insulin is usually taken as subcutaneous self-injections by single-use syringes with needles, an insulin pump, or by repeated-use insulin pens with needles.

[0004] Although many investigations have been conducted to develop injection devices, which measure the exact amount of the delivered drug and are capable of tracking the patient compliance, there is still a need for injection devices measuring more specific parameters, which ensures comparable conditions in clinical trials.

[0005] Already known in the art are injection pens for common self-injected medication of, e.g. insulin, in the treatment of diabetes. These pens have been further developed for automatic monitoring the dosage of insulin in a subject. For example, in WO 2014/020010 a supplemental device is attached to an injection device. For improvement of the conditions and use of the device, said supplemental device comprises a dose dialled detector and a processor to detect and monitor the dialled dose used in an insulin injection pen during an injection.

[0006] In WO 2016/026679 a medicament injection is described. The disclosed device can detect movements of the device and is configured to track behaviour of the user using this medicament injection device.

[0007] US 5,611,784 discloses a dispensing aid attachable to a syringe body. For determination of the exact volume of the delivered liquid, an electronic linear position-measuring device measures the position change of a dispensing aid plunger attached to the syringe plunger within the dispensing aid body. On the basis of this data, a processor calculates the exact volume, which has been injected in a subject.

[0008] Even though a variety of devices have been developed, which support the usage of injection devices and syringes measuring the exact amount of the injected solution, an injection device measuring more specific parameters, which ensures comparable conditions in clinical trials, has not been developed yet. These specific parameters, measured by the injection device, comprise, for example, the temperature of the medicament, the amount of drug injected, or the injection angle. Furthermore, for persons without prior medical knowledge or medical experience, it is often difficult to use a syringe and other medical injection devices correctly. In various parts of the world, in which the physician density is low and a lack of medical institution exists, an easy and safe use of medical devices is necessary for non-medically educated persons.

[0009] Thus, there is a need for injection devices suitable for the use in clinical trials, in which one injection or multiple injections of a medicament are required. These injection devices should be able to track the behaviour of the patient and ensure that comparable conditions have been adhered to by measuring, recording and analysing data, in which the medicaments are used. In addition, there is a need for an injection device providing a simple and safe use of syringes, even in different sizes of the syringes, and being applicable, even for a person without prior medical knowledge.

OBJECTS AND SUMMARY OF THE INVENTION

[0010] The present invention addresses these needs and provides a medicament delivery device adapted to a syringe comprising (i) a sensor unit configured to determine the position of the medicament delivery device relative to the injection area, (ii) a dosage assessment unit configured to determine amount or volume of the medicament to be delivered, (iii) a temperature measuring unit configured to determine the temperature of the medicament; and (iv) a microcontroller. The use of the medicament delivery device in clinical trials adapted to a syringe comprising a temperature measuring unit and a dosage assessment unit configured to determine amount or volume of the medicament in combination with the microcontroller ensures that comparable conditions are applied in clinical trials by measuring, recording and analysing data.

[0011] Measuring, recording and analysing these specific parameters by an injection device ensures that comparable conditions have been adhered to, in which the drugs are used. This comparability of the conditions, in which the medicament is used, is very important in clinical trials. Moreover, such a tracking system of injections provides an easier and more precise error analysis. Furthermore, these injection devices are suitable for a simple and safe use of syringes, even in different sizes of the syringes, and for various types of injections. Furthermore, by tracking the behaviour of a patient a safe use, even for persons without medical knowledge becomes possible.

[0012] Furthermore, the use of a medicament delivery device adapted to a syringe comprising a sensor unit configured to determine the position of the medicament delivery device relative to the injection area allows minimizing the pain of the person using the medicament delivery device. This is facilitated by measuring the angle of the syringe needle relative to the injection area. Even for a person without medical experience, it is thus easy to handle the injection device and to use it in a professional way.

[0013] Since the syringe is detachably fixed on the syringe body, the medicament delivery device can further be used several times. Moreover, the medicament delivery device can measure the temperature via the temperature measuring unit and the amount of the medicament used via the dosage assessment unit. By collecting and comparing these data via the microcontroller, it is possible to ensure comparable conditions, in which the medicaments are used, which is essential in clinical trials and can make delivery of known medicaments more convenient.

[0014] By measuring the amount of the medicament used by the subject in clinical trials and comparing these data with previous measured data or data of more than one patient participating in the clinical trial, optimal amounts of the medicament to be injected by a certain group of patient can be identified since these data can be stored and monitored by the device itself or connected units.

[0015] Without measuring detailed data according to the temperature after packaging the syringe, e.g. during the transportation process and storing of the syringe, it may be difficult to ensure whether a cold chain has been maintained. If the cold chain has been interrupted, the effect of the medicament may be compromised and the medicament may unpredictable or even dangerous effects on the user. By adapting the medicament delivery device to the syringe used, e.g. in a clinical trial, prior the transportation process or storing, it is possible to monitor whether the cold chain has been continuously maintained or not, e.g. by performing a temperature measurement in predefined time intervals such as every 5, 10 or 15 minutes etc. These data may also be essential in clinical trials to exclude the factor that the cold chain has been interrupted and the effect of the medicament has been affected.

[0016] Thus, in contrast to classical medication methods based on pens or syringes, the present invention advantageously allows to measure several data, which may be essential for the documentation and performance of clinical trials and additionally provides means for an easy and self-controlling handling of syringes even in the absence of medical professionals.

[0017] In a preferred embodiment, the medicament delivery device has an adapter for standard syringes with different volumes between 0.5 mL and 250 mL.

[0018] In a further preferred embodiment, said sensor unit configured to determine the position of the medicament delivery device relative to the injection area is capable of determining the smallest angle between the injection area and the syringe.

[0019] In a particularly preferred embodiment, said sensor unit configured to determine the position of the medicament delivery device relative to the injection area comprises two or more selected from the group consisting of a confocal sensor and laser range finder, measuring the smallest distance from the laser connected to the syringe and the injection area.

[0020] In an additional, preferred embodiment, said sensor unit configured to determine the position of the medicament delivery device relative to the injection area is a combination of a magnetometer or a gyroscope sensor and a laser ranger finder or a confocal sensor.

[0021] In a yet another preferred embodiment, the medicament delivery device as described above comprises said dosage assessment unit. The dosage assessment unit configured to determine amount or volume of the medicament to be delivered is selected from the group consisting of a photo sensor, an ultrasonic sensor and a Hall sensor.

[0022] In a particularly preferred embodiment, said dosage assessment unit configured to determine amount or volume of the medicament to be delivered is an ultrasonic sensor.

[0023] In an additional, particularly preferred embodiment, said dosage assessment unit configured to determine amount or volume of the medicament to be delivered is a Hall sensor and wherein the syringe piston is labelled with magnets in equal intervals.

[0024] In a preferred embodiment, said temperature measuring unit configured to determine the temperature of the medicament is selected from the group consisting of an infrared sensor, a quartz resonator or a platinum measuring resistor as sensor and a silicon bandgap temperature sensor.

[0025] In yet another preferred embodiment, the medicament delivery device as described above further comprises a sensor for determining the components of the medical composition, preferably selected from the group consisting of a Raman spectrometer and an IR spectrometer.

[0026] In a particularly preferred embodiment, the medicament delivery device as described above further comprises a laser scanner for determining the components of the medical composition by reading a bar code.

[0027] In another preferred embodiment, the medicament delivery device as described above further comprises a sensor for testing the medical composition for contamination, preferably selected from the group consisting of a particle size analyzer and a Raman spectrometer and an IR spectrometer.

[0028] In yet another preferred embodiment, the medicament delivery device as described above further comprises a sensor for detecting gas bubbles in the medical composition, preferably selected from the group consisting of an ultrasound sensor, a sensor using light scattering.

[0029] In a particularly preferred embodiment, said medicament delivery device further comprises a locking unit.

[0030] In a further embodiment, the medicament delivery device as described above further contains an accumulator or a battery pack or uses induction as power source.

[0031] In another preferred embodiment of the medicament delivery device of the present invention as described above, said microcontroller further comprises a memory, a

microprocessor, an analog digital converter coupled to the dosage assessment unit and a transmitter to transmit the data stored in the memory.

[0032] In particularly preferred embodiment, said microcontroller is configured to transmit data wirelessly to a computer device external of the medicament delivery device for processing and visualizing measured data, preferably via a wireless personal area network (WPAN) connectivity such as Bluetooth (registered trade mark (RTM)) or wireless local area network (WLAN) connectivity.

[0033] It is preferred that said external computer device is a PC-computer, a server-computer, a tablet computer or a smart phone.

[0034] In a still further preferred embodiment, one or more parts of the medicament delivery device have a housing.

[0035] In another preferred embodiment, the medicament delivery device as described above, one or more parts, or its housing are solvent resistant.

[0036] In yet another preferred embodiment, said solvent resistance is conveyed by a solvent resistant coating layer, preferably selected from the group consisting of a resin composition and a polymer composition.

[0037] In another preferred embodiment, the medicament delivery device as described above further comprises an optical and/or audible warning system programmed for indicating the quality and/or correctness of one or more of the following parameters: coupling of the syringe and the medicament delivery device, position of the medicament delivery device relative to the injection area, temperature, medical composition, amount of dosage, presence of contamination and presence of gas bubbles.

[0038] In a further aspect, the present invention relates to a system comprising the medicament delivery device as mentioned above and a syringe.

[0039] In another aspect, the present invention relates to a system as mentioned above or comprising the medicament delivery device as mentioned above, comprising a separate receiving unit configured to receive and store data received from said medicament delivery device.

[0040] In a preferred embodiment, said receiving unit receives data wirelessly, preferably via a wireless personal area network (WPAN) connectivity such as Bluetooth (RTM), or a wireless local area network (WLAN) connectivity

[0041] In a further preferred embodiment, said receiving unit is connected to an interface unit configured to communicate or perform a dialogue with a user of the system.

[0042] In a particularly preferred embodiment, said interface unit is configured to register user input as to pain caused by the medicament delivery device and/ or subjective well-being subsequent to the delivery.

[0043] In another particularly preferred embodiment, said receiving unit is configured to analyze data received from said device and from said interface unit to provide the user with an advice with respect to the device's handling, preferably concerning at least one of the parameters:

(a) status of coupling of the syringe and the medicament delivery device

(b) degree of medicament delivery,

(c) position of the medicament delivery device relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination; and

(h) presence of gas bubbles in the syringe.

[0044] In a further aspect, the present invention relates to a method of monitoring at least one of the following parameters (a) to (h) received from a medicament delivery device adapted to a syringe comprising (i) a sensor unit configured to determine the

position of the medicament delivery device relative to the injection area, (ii) a dosage assessment unit configured to determine amount or volume of the medicament to be delivered, (iii) a temperature measuring unit configured to determine the temperature of the medicament and (iv) a microcontroller, or from the medicament delivery device as above, or from the system as defined above:

(a) status of coupling of the syringe and the medicament delivery device

(b) degree of medicament delivery,

(c) position of the medicament delivery device relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination; and

(h) presence of gas bubbles in the syringe.

[0045] In another aspect, the present invention relates to a method for real time visualization of parameters (a) to (h):

(a) status of coupling of the syringe and the medicament delivery device

(b) degree of medicament delivery,

(c) position of the medicament delivery device relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination; and

(h) presence of gas bubbles in the syringe,

preferably of the position of the medicament delivery device relative to the injection area and the temperature of the medical composition.

[0046] In a preferred embodiment of the methods of the present invention as described above, said monitoring and visualization is used to track a patient's compliance with respect to the administration of the medicament.

[0047] In another aspect, the present invention relates to a method of improving a user's employment of a medicament delivery device as defined above, comprising an evaluation of one or more of the parameters (a) to (h)

(a) status of coupling of the syringe and the medicament delivery device (3)
(b) degree of medicament delivery,
(c) position of the medicament delivery device (3) relative to the injection area,
(d) temperature of the medicament,
(e) composition of the medicament,
(f) amount of dosage,
(g) presence of contamination; and
(h) presence of gas bubbles in the syringe.

and/or of user input received from an interface unit:

(a) status of coupling of the syringe and the medicament delivery device (3)
(b) degree of medicament delivery,
(c) position of the medicament delivery device (3) relative to the injection area,
(d) temperature of the medicament,
(e) composition of the medicament,
(f) amount of dosage,
(g) presence of contamination,
(h) presence of gas bubbles in the syringe,
(i) a dialogue with a user of the system
(j) pain caused by the medicament delivery device (3), and
(k) subjective well-being subsequent to the delivery.

[0048] In a preferred embodiment of the method as described above, said user input comprises data on pain caused by medicament delivery and/or on subjective well-being subsequent to the delivery.

[0049] In a preferred embodiment, said improvement is an advice to the user with respect to the handling of the device during its future employment if one or more of parameters (a) to (h) as defined above are outside of a predefined range and/or if said user input indicates the presence of pain or a reduced subjective well-being subsequent to the delivery.

[0050] In a final aspect, the present invention relates to a method of improving a user's employment of a system as described herein above, comprising an evaluation of one or more of the parameters:

(a) status of coupling of the syringe and the medicament delivery device (3)
(b) degree of medicament delivery,
(c) position of the medicament delivery device (3) relative to the injection area,
(d) temperature of the medicament,
(e) composition of the medicament,
(f) amount of dosage,
(g) presence of contamination; and
(h) presence of gas bubbles in the syringe.

and/or of user input received from an interface unit:

(a) status of coupling of the syringe and the medicament delivery device (3)
(b) degree of medicament delivery,
(c) position of the medicament delivery device (3) relative to the injection area,
(d) temperature of the medicament,
(e) composition of the medicament,
(f) amount of dosage,
(g) presence of contamination,
(h) presence of gas bubbles in the syringe,
(i) a dialogue with a user of the system
(j) pain caused by the medicament delivery device (3), and

(k) subjective well-being subsequent to the delivery.

BRIEF DESCRIPTION OF THE FIGURES

[0051] **Figure 1** shows a schematic top view representation of an embodiment of the medicament delivery device (3) according to the invention including a syringe (1) with a syringe piston (2), which is adapted to a medicament delivery device (3) comprising a housing (4), an extendable connection (5) and a power switch (6).

[0052] **Figure 2** shows a schematic side view representation of the same embodiment of the medicament delivery device (3) according to the invention as depicted in Figure 1 including the syringe (1) with the syringe piston (2) and a syringe body (12), which is adapted to a medicament delivery device (3) via an adapter unit (10), and a locking unit (11).

[0053] **Figure 3** shows a schematic tilted top view representation of the same embodiment of the medicament delivery device (3) according to the invention as depicted in Figure 1 and 2, wherein a window (20) is shown, essential for one or more distance sensors and IR spectrometers and Raman spectrometers.

[0054] **Figure 4** shows a schematic top view representation of the same embodiment of the medicament delivery device (3) according to the invention as depicted in Figure 1, 2 and 3, wherein Figure 4 shows the interior of the medicament deliver device and a typical arrangement of internal components according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0055] Although the present invention will be described with respect to particular embodiments, this description is not to be construed in a limiting sense. As will be appreciated to one skilled in the art, there are various ways to carry out examples of the medic-

ament delivery device of the invention disclosed herein. Reference will made to the figures, depicting one embodiment of the invention, respectively. These embodiments are not meant to be exhaustive of numerous different alternative designs and arrangements. Those skilled in the art will readily appreciate that several combinations can be made, without departing from the invention.

[0056] Before describing in detail exemplary embodiments of the present invention, definitions important for understanding the present invention are given.

[0057] As used in this specification and in the appended claims, the singular forms of "a" and "an" also include the respective plurals unless the context clearly dictates otherwise.

[0058] In the context of the present invention, the terms "about" and "approximately" denote an interval of accuracy that a person skilled in the art will understand to ensure still the technical effect of the feature in question. The term typically indicates a deviation from the indicated numerical value of ±20 %, preferably ±15 %, more preferably ±10 %, and even more preferably ±5 %.

[0059] It is to be understood that the term "comprising" is not limiting. For the purposes of the present invention, the term "consisting of" or "essentially consisting of" is considered to be a preferred embodiment of the term "comprising of". If hereinafter a group is defined to comprise at least a certain number of embodiments, this is meant to also encompass a group, which preferably consists of these embodiments only.

[0060] Furthermore, the terms "(i)", "(ii)", "(iii)" or "(a)", "(b)", "(c)", "(d)", or "first", "second", "third" etc. and the like in the description or in the claims, are used for distinguishing between similar elements and not necessarily for describing a sequential or chronological order. It is to be understood that the terms so used are interchangeable under appropriate circumstances and that the embodiments of the invention described herein are capable of operation in other sequences than described or illustrated herein. In case the terms relate to steps of a method or use there is no time or time interval

coherence between the steps, i.e. the steps may be carried out simultaneously or there may be time intervals of seconds, minutes, hours, days, weeks etc. between such steps, unless otherwise indicated.

[0061] It is to be understood that this invention is not limited to the particular devices, systems, methodology, protocols or compositions etc. described herein as these may vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present invention that will be limited only by the appended claims. Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art.

[0062] As has been set out above, the present invention concerns in one aspect a medicament delivery device adapted to a syringe comprising a sensor unit, which allows to determine the position of the medicament delivery device relative to the injection area, a dosage assessment unit, which allows to determine amount or volume of the medicament to be delivered, a temperature measuring unit, which allows to determine the temperature of the medicament; and a microcontroller. This medicament delivery device according to the present invention enables measurement and collection of data received during the usage of the device by a patient or a medical practitioner. These data may include temperature values, injection angles, information on the delivered amount of a medicament, time and day of employment, duration of injection, identity and production details of the injected medicament, etc. One or more of these data may be saved during an injection and may also be stored in the device, or may be stored outside of the device, e.g. in a connected memory, a connected storage unit or an external computer device. In a preferred embodiment, these data may be transmitted to an external computer device. Moreover, one or more of these measured data may be visualized in real time, may be displayed in a chronological sequence, may be compared with previous measured data, and may be compared with data of other users. Temperature data of the medicament may also be measured previously to the injection.

[0063] The term “syringe” or “standard syringe” as used herein refers to any syringe suitable for injecting solutions, liquids or dissolved compositions to a human patient or to an animal as known to skilled person. In one embodiment, the syringe may be a disposable syringe. The syringe may also be a prefilled syringe or may be filled by the user directly prior to the injection. The syringe may be filled with any kind of liquid or liquid composition such as a solution, medicament or a diluted active agent, which is suitable for an injection to the body, to the vascular system, to a tissue, etc. In certain embodiments, the liquid or liquid composition may be a solution, composition or medicament envisaged for the treatment of animals or humans. This liquid may already be known as medicament and is may be available on the market or may have approved by a regulatory agency, or may currently be tested in a clinical trial, or may be experimental or untested.

[0064] Furthermore, the syringe may have any suitable volume, preferably in the range of between about 0.5 mL and 250 mL. The syringe may, thus, preferably have a volume of between about 0.5 mL and 150 mL, more preferably of between about 0.5 mL and 100 mL, still more preferably of between about 0.5 mL and 50 mL, yet still more preferably of between about 0.5 mL and 10 mL, most preferably of between about 1 mL and 5 mL. The syringe may be filled with a corresponding volume of the solution or liquid composition to be injected or with a portion thereof. I. e. the syringe as defined above may be filled with between about 0.5 % to 100 % of the syringe’s maximum volume. For example, the filling may be about 10 %, 20 %, 30 %, 40 %, 50 %, 60 %, 70 %, 80 %, 90 %, or 95 % of the syringe’s maximum volume.

[0065] Accordingly, any suitable volume of the medicament, solution or liquid may be injected. For example, the injected volume may be about 0.001 mL to 250 mL, preferably about 0.01 mL to 150 mL, more preferably about 0.01 mL to 100 mL, about 0.01 mL to 50 mL, or about 0.05 mL to 10 mL, or most preferably 0.1 mL to 5 mL.

[0066] The medicament delivery device is adapted to the syringe via an adapter. The term “adapter” or “adapter unit” as used herein refers to an element, which is capable

of fastening a syringe to the medicament delivery device. The fastening may ensure a reuse of the medicament delivery device or may be, in other specific embodiments, a permanent fastening. Typically, an adapter unit provided on one side of the medicament delivery device connects the medicament delivery device to a syringe as defined above. The adapter unit may be a clip or a clamp or it may comprise a screw mechanism, a Velcro fastener or an adhesive. It is preferably a clip. This adapter unit allows fixing different sizes of syringes to the medicament delivery device or may in specific embodiments be designed to fit with a specific, predetermined syringe size. In a further specific embodiment, the present invention provides an extendable component, which allows the medicament delivery device to fix different sizes of syringes and ensures that a used detector is in the correct position if different sizes of syringes are used.

[0067] The medicament delivery device adapted to a syringe of the present invention further comprises a sensor unit to determine the position of the medicament delivery device relative to the injection area. The term "sensor unit to determine the position of the medicament delivery device relative to the injection area" as used herein relates to all suitable sensors or combinations of sensors, which are capable of determining the smallest angle between the needle and the injection area preferably during the injection. It may be a combination of confocal sensors, laser range finders, 3D-orientation sensors e.g. gyroscope sensors, magnetometers or accelerometers. In a preferred embodiment, this sensor unit comprises or consists of two confocal sensors. In a more preferred embodiment, this sensor unit comprises two laser range finder. One of the two laser range finder may measure the distance from a fixed point of the medicament delivery device along the syringe needle. The other laser range finder is capable of measuring the smallest distance of a fixed point of the medicament delivery device to the injection area**.** The term "injection area" as used herein, relates to the part of the body, to which the syringe is applied to. A preferred injection area is planar or almost planar. The absence or reduction of curvature in the injection area facilitates the calculation of the injection angle. In certain embodiments, the presence of a curvature or bulges may

be detected and be accounted for in the calculation of injection angles. In specific embodiments, the smallest angle is determined on the basis of the above mentioned methodology and the employment of correction factors in dependence on the form and type of injection area. Such correction factors may be predefined and/or reflect typically encountered or categorised curvature situations. Furthermore, an adjustment on the basis of the results of the laser range finder is envisaged.

[0068] The term “smallest angle” or “injection angle” as used herein refers to any injection angle in a range of 0° to 90°, which is the smallest angle that exists between the injection needle and the part of the body, in which the medicament is injected.

[0069] The device may be used for various injection forms, e.g. for subcutaneous, intravenous, intracutaneous, intra-arterial, intramuscular, intrathecal, intra-articular or intravitreal injections. These injections may have a preferred range of injection angles, in which the medicament is optimally administered being known to the person skilled in the art. In specific embodiments, the medicament delivery device may be programmed to allocate for each kind of injection an optimal injection angle for best use in order to minimize pain. For example, for subcutaneous injections angles of between 30° to 90° may be used, for intramuscular injections an angle of 75 to 90° may be used, for intracutaneous injections an angle of about 5° to 25 may be used, for intravenous injections angles of between 25° to 55° may be used, etc. The range of injection angles to be used, which may, in certain embodiments be predetermined in the device, may change in dependence on the tissue or the part of the body, where the injection is performed. The angle used for a subcutaneous injection may, in further embodiments, be displayed on an external computer device.

[0070] In specific embodiments, the angle for a subcutaneous injection may be in a range of about 35° to 90°, preferably in a range of about 40° to 90°, more preferably in a range of about 45° to 90°. The angle used for intramuscular injections is may be in also be in a range of about 80° to 90°, preferably in a range of about 85° to 90°. The angle

used for an intracutaneous injection may further be in a range of about 5° to 20°, preferably in a range of about 10° to 20°, more preferably in a range of about 12.5° to 17.5°, most preferably it may be about 15°. The angle used for in an intra-arterial and intravenous injection may further be in a range of about 25° to 50°, preferably in a range of about 30° to 50°, more preferably in a range of about 35° to 45°.

[0071] The term "sensor unit configured to determine the position" as used herein refers to any unit, which is capable of determining the position or orientation in the three dimensional space of the medicament delivery device adapted to the syringe. A suitable sensor unit configured to determine the position may be an orientation sensor, such as a gyroscope sensor, a magnetometer, an accelerometer, or any orientation sensor known in the art. This orientation sensor may be used to determine the injection angle in combination with a laser or confocal sensor. The orientation sensor may also be used to monitor the orientation of the monitoring device. The orientation sensor may, for example, monitor the orientation of the syringe and thereby allow recognizing, when a user injects the syringe's content. Such monitoring includes, for instance, detection whether the needle of the syringe is directed downwards. Alternatively, or in addition, the release of gas bubbles during the movement of the syringe piston may be detected, which would be indicated due to an upwards directed needle.

[0072] The "dosage assessment unit" as used herein refers to a sensor, which is capable of determining the volume of the liquid released from the syringe. Examples of such a sensor include an ultrasonic sensor, a photo sensor and a Hall sensor. In one embodiment, the dosage assessment unit may be a Hall sensor. The usage of a Hall sensor typically requires a modification of the syringe piston. Along the longitudinal axis of the piston, the piston may be provided with magnets in equal intervals. Based on magnetic interference, the movement of the modified piston can be detected by the Hall sensor, which allows determining the volume of the released liquid e.g. by calculations based on the capacity of the syringe. Any suitable magnets and any suitable interval of the magnets provided on the syringe piston may be used, e.g. intervals of between 0.3 cm

and 5 cm. In typical embodiments, the interval of the magnets provided on the syringe piston may be about 0.3 cm, 0.5 cm, 0.7 cm, 1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm or 5 cm. In a further embodiment of the dosage assessment unit, the movement of the piston is optically measured, preferably by a photo sensor. In a further embodiment, the flow of the liquid through the syringe may be measured by an ultrasonic sensor. The ultrasonic device is generally designed as ultrasonic flow meter, which is a type of flow meter that measures the velocity of a fluid with ultrasound to calculate volume flow. The employment of such a sensor allows for a direct determination of the volume, which has been released from the syringe. Examples for such ultrasonic sensors are a time transit flow meter, a Doppler flow meter or an Open-Channel flow meter. The preferred ultrasonic sensor used is a time transit flow meter.

[0073] The term “temperature measuring unit” is a unit, which is capable of measuring the temperature of the environment and the content of the syringe at one or more time points. The temperature measuring unit may be used in time intervals and may measure the temperature in a time interval of 1 s, 2 s, 5 s, 10 s, 30 s, 1 min, 2 min, 5 min, 10 min, 15 min 0.5 h, 1 h, 2 h, 5 h, 10 h, 24 h, 2 days, 3 days or 7 days or any suitable value between these values. In one embodiment, the temperature measuring unit may measure the temperature if the medicament delivery device is switched on. In another embodiment, the temperature measuring unit may measure the temperature if the medicament delivery device is switched off. The temperature measuring unit may be a unit measuring the temperature outside the syringe or of the syringe environment. It may be a unit measuring the temperature of the liquid content within the syringe. In a preferred embodiment, the temperature measuring unit may further measure the temperature of the environment of the syringe as well as the temperature of the liquid content of the syringe. The temperature measuring unit may measure the temperature before the injection and/or during the injection permanently or in specific time intervals. For measuring the temperature the temperature measuring unit may comprise an infrared sensor, a quartz resonator or a platinum measuring resistor as sensor and a silicon bandgap temperature sensor.

[0074] The term "microcontroller" as used herein refers to any suitable microcontroller known to the skilled person. This microcontroller may comprise an analog-to-digital converter, which converts the measured analogous signals of one or more sensors used in the medicament delivery device to digital signals; a microprocessor, which is able to process one or more measured data; a memory, which is able to store one or more measured data; a time measurement unit, which is able to sort one or more of the measured data chronologically; and a transmitter, which is able to transmit the data stored in the memory. In one embodiment, during the operation of the medicament delivery device, the microprocessor may actively record any measured data of one or more sensors. In a further embodiment, the medicament delivery device in connection with a time measurement unit is capable of determining when a defined measurement or a defined injection event took place and under which condition according to the measured parameters. In another embodiment, it may be desirable to store one or more data received from the various sensor units for later analysis. Thus, a memory device may be provided. In one embodiment, memory may be a non-volatile or persistent memory. In a further embodiment, said microcontroller may also be configured to transmit data wirelessly to a computer device external of the medicament delivery device for processing and visualizing measured data, preferably via a wireless personal area network (WPAN) connectivity such as Bluetooth (RTM) or wireless local area network (WLAN) connectivity. Alternatively, further technologies such as Near Field Communication (NFC) employing electromagnetic induction, ZigBee (RTM), CSS or UWB connectivity, infrared light based connectivity such as Infrared Data Association (IrDA), which would be known to the skilled person and whose specification can be derived from suitable literature sources including IEEE standards for communication, are also envisaged.

[0075] The term "sensor determining the components of the medical composition" as used herein relates to a sensor for determining the components of the medical composition or solutions. The sensor may, for example, be a Raman spectrometer or an IR spectrometer. The term "Raman spectrometer" relates to an apparatus capable of registering or producing a Raman spectrum of a substance or of a composition comprising

a substance. Typically, Raman spectroscopy uses inelastic or Raman scattering of monochromatic light which interacts with molecular vibrations, phonons or other excitations in a system, resulting in the energy of the light photons being shifted up or down. This shift provides information about vibrational modes in the system. Envisaged examples of Raman spectrometer are resonance Raman spectrometers, surface-enhanced Raman spectrometers, or any other sub-type of Raman spectrometers. The term "IR spectrometer" relates to an apparatus capable of producing an infrared spectrum, which is essentially a graph of infrared light absorbance or transmittance on the vertical axis vs. frequency or wavelength on the horizontal axis. An example of an IR spectrometer envisaged by the present invention is a Fourier transform infrared (FTIR) spectrometer. In a specific embodiment, the IR or the Raman spectrometer may be located on the surface of the device, on which a drop of the liquid can be directly analyzed. With such a sensor, the components of the medical composition may be determined and in addition, contaminations may be detected. Therefore, "a sensor for testing the medical composition for contamination" as used herein relates in particular to Raman and IR spectrometers, but may include further suitable sensor types known to the skilled person.

[0076] In a further specific embodiment, contaminations of a medical composition, e.g. in the liquid or in the syringe, may further be detected by particle size analysers and other suitable sensors known in the art which are capable of detecting contaminations. The term "contamination" as used herein includes solids such as clotted substances, granular particles, precipitates or plastic or glass debris, as well as toxic substances, bacteria, viruses, fungi, microorganisms and any other substance detrimental in an injection of a human being or an animal. The detection of a contamination may either be a qualitative or a quantitative analysis. For example, the presence of solids such as plastic or glass debris etc. may be detected qualitatively, i.e. if any such solid is detected it is registered as contamination. Alternatively, a contamination may be detected on a quantitative level, e.g. by making use of volume or concentration thresholds for the presence of substances or elements as defined above. For example, a volume or weight threshold for a contamination in a liquid contained in the syringe to be injected, may be 1 % (v/v)

or (w/v), preferably 0.5 % (v/v) or (w/v), more preferably 0.1% (v/v) or (w/v), still more preferably 0.01% (v/v) or (w/v), most preferably 0.001% (v/v) or (w/v). The threshold for concentrations of substances for the presence a contamination in a liquid contained in the syringe to be injected depends on the substances to be used. The threshold may further depend (and accordingly be adjusted) on the country or region where the administration takes place. For example, known and/or legally defined toxicity thresholds or limits may be used as threshold definitions for a detection of contaminations in liquids comprised in syringes according to the present invention. Examples of such thresholds or limits are those defined or provided by the German Bundesinstitut für Risikobewertung (www.bfr.bund.de) or those defined or provided by the German Umweltbundesamt. The present invention further envisages the use of similar information provided by other national or regional (e.g. European) agencies responsible for risk assessment, which are known to the skilled person. The presence of substances or elements may be detected by a sensor for testing the medical composition for contamination as mentioned above, e.g. a Raman or IR spectrometer.

[0077] The maximally tolerated amount of a contamination may depend on the contamination type, the context of usage, legal regulations etc. and may accordingly be adapted. Corresponding values may be provided in the microcontroller or an interactive unit connected with the medicament delivery device.

[0078] In a further embodiment, the medicament delivery device may also be capable of recognizing the content of a syringe by using a laser scanner and barcode reading system. Hence, the content of the syringe may be determined by a sensor or reader determining the components of the medical composition via a barcode or another label, such as a QR code or a 2D code, stuck or printed on the outside of the prefilled syringe and/or provided on the prefilled syringe's packaging or the medicament's packaging. In another embodiment, the code may be a colour code and the scanner unit may be an optical detector. Other suitable readers known in the art, which are capable of reading a code are a charge-coupled device (CCD) scanner or a camera scanner. In a specific

embodiment, a barcode scanner comprises a decoder circuitry analysing the image data of the barcode provided by the sensor and wirelessly transmitting the encoded information to the microcontroller. In a further specific embodiment, the decoder circuitry analysing the image data of the barcode provided by the sensor and wirelessly transmitting the encoded information directly to an external computer device. In further preferred embodiments, the information encoded in the barcode and read with a barcode reader, scanner or other sensor as mentioned above is compared with information on the composition provided in the syringe to be injected that is stored in the medicament delivery device's microcontroller or in a connected external unit. In case of a lack of matching or concordance between the information encoded in the syringe's barcode and the information provided in the microcontroller or the external unit, the medicament delivery device may alert the user about this fact, e.g. by blinking or emitting sound signals, and/or suggest a suspension of operation and/or stop operating, e.g. by blocking the movability of the syringe's piston, e.g. with a locking unit as defined herein.

[0079] The present invention further envisages the use of a “sensor for detecting gas bubbles”. This sensor comprises a sensor for determining whether the liquid content within the syringe contains gas bubbles. For injections, such as an intravenous or an intra-arterial injection, it may become problematic and dangerous for the patient´s health leading to vascular embolisms, when a gas bubble, such as an air bubble, is injected. The gas bubble can occlude blood vessels if the bubble is large enough. This may stop the blood flow and can cause severe damage to the human or animal which gets the injection. Accordingly, a sensor, which is capable of detecting gas bubbles in a liquid contained in a syringe, may be used. Another advantage of the detection of gas bubbles is to ensure that the required amount of liquid has been injected. Preferably, the sensor is an ultrasound sensor or a sensor using light scattering. The gas bubbles in a syringe content to be injected, which can be detected, may have a minimum diameter of 3 mm, preferably 1 mm, more preferably 0.5 mm, yet more preferably 0.1 mm and most preferably 0.01 mm. The size, e.g. diameter, limit for gas bubbles in a liquid contained in a syringe to be still tolerable when operating the invention's medicament delivery device

may, in certain embodiments, also depend on the administration from, e.g. the type of injection which is envisaged. For example, only relatively small gas bubbles are accepted in the context of intravenous injections (see, for instance, Mirski et al., "Diagnosis and Treatment of Vascular Air Embolism", The Journal of the American Society of Anesthesiologists (2007), Vol. 106 (1): pp. 164–177, which indicates that an upper limit of an adult lethal dosis may be 3-5 ml/kg ; and D.J. Embey, K. Ho, ”Air embolus revisited - a diagnostic and interventional radiological perspective (bubble trouble and the dynamic Mercedes Benz sign)” South African Journal of Radiology (2006), Vol. 10 (1), pp. 3-7; both are incorporated herein by reference), whereas in subcutaneous injections larger sizes of gas bubbles can be tolerated without causing damages in the human or animal. A lethal risk may further result from a larger gas volume in the right ventricle and the gas may affect the pumping function of the heart. Even smaller amounts of gas may, however, cause severe diseases or arterial air embolism. For example, 2 mL air in the brain arteries may cause a fatal apoplexy, or 0.5 mL of air in the coronary arteries, a myocardial infarction. It is therefore envisaged by the present invention to implement a low limit for air bubbles in the syringe in the range of less than 2 ml, or less than 0.5 ml, or based on clinically established values for the acceptable bubble size in dependence on the administration area or type, as known to the skilled person. The corresponding size limit may be entered in the medicament delivery device's microcontroller or a connected external unit to allow for a comparison with measured bubbles sizes. The term “size of a bubble” or “size of a gas bubble” as used herein, refers to volume of a bubble. The term "diameter of a gas bubble" relates to an averaged diameter value across the centre of a gas bubble.

[0080] The present invention further envisages the use of a locking unit. The term “locking unit” as used herein relates to an element, which is able to block the piston of a syringe. In one embodiment, the locking unit may is capable of blocking the syringe piston at several time points or at motion steps during processing. In one embodiment, the locking unit is capable of blocking the syringe's piston before filling the syringe at-

tached to the medicament delivery device or, in a further embodiment, when the syringe is filled or, in a further embodiment, immediately before an injection. This blocking may have the form of an automatic blocking in accordance with predetermined limit values as to, e.g. bubble sizes, temperature, injection angle, amount of medicament, the presence of contaminants etc. as defined herein. The locking unit may accordingly be activated if one or more of the measured parameters, such as temperature, amount of the medicament, size of the gas bubbles, injection angle or amount of contamination is outside of a predefined range, or an incorrect medical composition is recognized e.g. by a barcode scanner or a sensor for determining the content of the syringe, if the content of the syringe was predefined.

[0081] The term “safe” or “safe use” as used herein means that a medicament delivery device as described above, which is used for an injection of a liquid drug, allows for the exclusion of situations, in which one or more of the parameters as mentioned above are outside of a predefined range or if the content of the syringe does not correspond to the an expected or predefined content. The safe use is accordingly implemented by starting a user alert, or by activating the locking unit, if such a situation is detected. Hence, the medicament delivery devices of the present invention advantageously allow for a hazard-fee use of syringes in comparison to the traditional usage of syringes and also in comparison to the use of medicament delivery devices without such measuring, warning and/or blocking system.

[0082] The power source of the medicament delivery device may be any suitable power source known to the skilled person. For example, in one embodiment, the power source may be a battery pack or an accumulator. In a further embodiment, the medicament delivery device may be a mechanically powered medicament delivery device. In yet another embodiment, the medicament delivery device may use induction such as linear induction as power source. Also envisaged is that medicament delivery device is powered by a linear induction power source in a shake type design, i.e. the medicament delivery device may be recharged by movement. Such a mechanical recharging of the

medicament delivery device is particularly advantageous in a situation, in which no access to electricity is available.

[0083] One or more of the measured parameters as mentioned above may be stored in the memory of the medicament delivery device and may be transmitted to an external computer device. In specific embodiments, the transmission of the data from the memory to an external computer device may either start immediately or shortly after usage, or may take place after a certain period of time, e.g. 30 or more minutes, 1 to 24 hours or 1 to 30 days or more, e.g. if an immediate connection with an external computer device is not possible due to a remote usage, connectivity problems etc. In further embodiments, recorded data may be transmitted in groups of packets after several uses, e.g. after 2, 3, 4, 5, 10 or more uses. In a preferred embodiment, the transmission of the data from the memory to an external computer device may take place in real time during the use of the medicament delivery device. The connection between the medicament delivery device and the external computer device may be a wired connection or may preferably be a wireless connection such as WLAN (wireless local area network)/WiFi (RTM), Near Field Communication (NFC) employing electromagnetic induction, radio or wireless personal area network (WPAN) connectivity such as Bluetooth (RTM), ZigBee (RTM), CSS or UWB connectivity, infrared light based connectivity such as Infrared Data Association (IrDA)-based systems, or any other wireless connectivity known in the art. The external computer device may be any suitable receiving electronic device, e.g. a PC- or a server-computer or preferably, a smart handled device, for example, a smart phone or a tablet. Also envisaged is the use of smart television sets, interactive audio devices which can be controlled by voice etc.

[0084] For preventing the sensors used in the medicament delivery device from being damaged and for an easy cleaning of the sensors, one or more of the sensors as defined above may be surrounded or covered, either singly or in groups or packets by a housing. In a further embodiment, the entire medicament delivery device may be surrounded or covered by a housing. In yet another embodiment, one or more parts of the medicament

delivery device may have a housing. In a specific embodiment, one or more parts of the housing or the entire housing may be solvent resistant. In another embodiment, the housing or parts of it may be waterproof. To ensure the solvent resistance of the housing or parts of it, the housing or one or more parts of it may be coated. For example, the coating of the housing may be a waterproof coating layer. Alternatively, the coating of the housing may be a solvent resistant coating layer. Solvent resistant coating layers are known to the skilled person. For example, the coating layers may be selected from the group consisting of a resin composition and a polymer composition. Examples of suitable coatings can be derived from suitable literature sources such as US 4246382 A; Rolland et al., "Solvent-Resistant Photocurable 'Liquid Teflon' for Microfluidic Device Fabrication", J. Am. Chem. Soc., 2004, 126 (8), 2322–2323; Chattopadhyay et al., "Structural engineering of polyurethane coatings for high performance applications", Progress in Polymer Science, 32, 3, 2007, 352–418, which are incorporated herein by reference.

[0085] The medicament delivery device of the present invention may further comprise an optical and/or audible warning system. Such a warning system is capable of alerting or informing the user if one or more of the measured parameters as defined herein are incorrect or outside of a specific, predefined range. Examples for such parameters, which may lead to an alert, include the coupling of the syringe and the medicament delivery device, the position of the medicament delivery device relative to the injection area, the temperature of the used medicament measured at the moment of the use of the device or over a period of time previous to the usage, the identity of the medical composition, the amount of dosage, the presence of contaminants and the presence of gas bubbles in the syringe. The warning system may comprise one or more alert signals, such as beep signals, an announcement from a loudspeaker, a spoken alert and/or light alerts, such as blinking LEDs, coloured LEDs, colour changes of LEDs, e.g. from green to red, lighting up of coloured LEDs etc. In a specific embodiment, a connected external computer device may provide a direct analysis, which parameter is incorrect or outside of the predefined range and/or which of the parameter needs to be changed and thus allow for the warning system to start.

[0086] For example, a warning signal may occur if the coupling of the syringe and the medicament delivery device through the adapter unit is incomplete or if both parts are not at a predefined position. Moreover, if the position of the medicament deliver device relative to the injection area has been measured and the injection angle is outside of a specific predefined angle range for a specific injection type, e.g. as defined above, a warning signal may be produced. The predefined ranges of the injection angle leading to warning signals can assume different values for e.g. subcutaneous, intra-arterial, intravenous, intramuscular or intracutaneous injections as defined above. Furthermore, a warning signal may be produced if the temperature of the liquid or the temperature of the environment is or was outside of a predefined range of the storage or usage temperatures of the used injection composition for a predefined period of time. In case of detection of a contaminant, a limit as defined above may be used to trigger the warning system. The acceptable maximally tolerated amount of a contaminant in the used liquid may, in certain embodiments, depend on the kind of contaminant, as outlined above. In further embodiments, the medical composition present in the syringe can be recognized by a sensor for determining the components or e.g. by a bar code scanner. The amount of the dosage recognized by the dosage assessment unit, as described above, can be compared with predefined values and may be indicated to be correct or incorrect by the warning system. Furthermore, a warning signal may be produced if the size of gas bubbles detected by a sensor for detecting gas bubbles as mentioned above is outside of a predefined range.

[0087] The term “system” as used herein comprises one or more parts, e.g. all parts, or units of a medicament delivery device as described above and a syringe, e.g. a syringe as described above. In further embodiments, the system relates to one or more parts or units of a medicament delivery device as described above and may additionally comprise a separate receiving unit. Such a system may further comprise a syringe as defined above. The term “receiving unit” as used herein relates to an element, which is capable of receiving data from the medicament delivery device. In certain embodiments, the

receiving unit may also store the data. This receiving unit may receive the data for example via a wire, or wirelessly, e.g. via Bluetooth (RTM), NFC, radio or WLAN/WiFi (RTM) connectivity, as well as other connectivity technologies as described herein above. The receiving unit is, in a specific embodiment of the invention, connected to an interface unit. The receiving unit is preferably an external computer device as described above. In certain embodiments, an interface unit may be connected to the receiving unit. The term "interface unit" as used herein, relates to an element, which is configured to communicate or to perform a dialogue with a user of the system. For example, the interface unit may obtain input from the user as to pain or the degree of pain caused by the medicament delivery device. In a further embodiment, the interface unit may receive a user's input as to the subjective well-being after, or during an injection, or subsequent to the injection. In further embodiments, the interface may also or alternatively receive data with respect to one or more of the following: the temperature of the medicament, the injection angle as define herein above, the injected volume and the initially provided volume, the contamination of the medicament or syringe, the exact composition of the medicament and the injection velocity.

[0088] The term "user" of the medicament deliver device or the system relates to any person using the medicament delivery device and/or the system itself. The person may be a patient. The user may also be a person helping or assisting the patient to which the medicament delivery device is applied to, e.g. a medical practitioner or a nurse. The user may be a medical practitioner or a medically unexperienced person.

[0089] The one or more users of the medicament deliver device according to the invention, or of the system according to the invention, may further be questioned by the interface unit as to the handling of the medicament delivery device, e.g. in the form of a dialogue. This may be implemented by making use of a predefined questionnaire, e.g. stored in the device or its external unit. The questions may cover usage feedback, as well as general questions as to the patient's identity, age, gender etc.

[0090] In a further embodiment of the invention, the receiving unit may be capable of analysing data received from the medicament delivery device and may advise the user with respect to the handling of the medicament delivery device, e.g. via the interface unit. For example, the receiving unit may analyse measured data concerning one or more parameters as mentioned above, such as the status of coupling of the syringe and the medicament delivery device, the degree of medicament delivery, the position of the medicament delivery device relative to the injection area, the temperature of the medicament, the temperature of the medicament previous and during the injection, the composition of the medicament, the amount of dosage, the presence and degree of contamination, the kind of contamination, the presence of gas bubbles as well as the size of gas bubbles in the syringe. The term "degree of the medicament delivery" as used herein, relates to the percentage of the delivered liquid with regard to liquid being previously drawn into the syringe. Said analysis by the receiving unit may also include a visualization of the data, e.g. over a certain period of time, over several days, weeks, months or years etc. In another embodiment, a method for real time visualization of one or more measured parameters is provided. Such real time visualization may capture, for example, the position of the medicament delivery device relative to the injection area and the temperature of the medical composition in the syringe.

[0091] The present invention further envisages the improvement of the currently described device's employment by a user. Such an improvement may be an improvement of the handling of the system. For example, it may comprise the evaluation of measured data and/or of the patient's input with regard to pain and well-being during and/or after an injection. The usage improvement may accordingly comprise the provision of advices by the interface based on the previously collected data of the user and/or the comparison of available data of other users of using the same medication or corresponding database entries. In one embodiment, the data measured by the medicament delivery device and also the data of the input of the user may be transmitted to a medical practitioner, a hospital system, or any other external entity for further analysis and/or documentation. In a specific embodiment, the system is configured such that the medical

practitioner is capable of interacting with the user of the system e.g. via the interface as described above.

[0092] In a further embodiment of the invention, the patient's compliance may be tracked by monitoring and visualization of the measured data with respect to the administration of the medicament. The "patient's compliance" describes the degree to which a patient correctly follows medical advice. In one embodiment, the monitored compliance may refer to the drug compliance. Alternatively or in addition embodiment, the monitored compliance may refer to the use of the medicament delivery device.

[0093] Turning now to Figure 1, which shows a schematic top view representation of an embodiment of the medicament delivery device (3) according to the invention including a syringe (1). The syringe comprises a syringe piston (2). The syringe (1) is adapted to a medicament delivery device (3). As shown the medicament delivery device may comprise a housing (4), an extendable connection (5) and a power switch (6).

[0094] Figure 2 shows a schematic side view representation of the same embodiment of the medicament delivery device (3) according to the invention as depicted in Figure 1 including the syringe (1) with the syringe piston (2) and a syringe body (12), which is adapted to the medicament delivery device (3). As shown, the medicament delivery device (3) may comprise the housing (4) with the extendable connection (5), an adapter unit (10), which connects the medicament deliver device to the syringe and a locking unit (11), configured to automatically block the piston, if necessary.

[0095] Figure 3 shows a schematic tilted top view representation of the same embodiment of the medicament delivery device (3) according to the invention as depicted in Figure 1 and 2 including the syringe (1) with the syringe piston (2) and the syringe body (12), which is adapted to the medicament delivery device (3) comprising the housing (4), the extendable connection (5), the power switch (6), the adapter unit (10) and the locking unit (11). Additionally, a window (20) is shown, which is suitable for one or more distance sensors and IR spectrometers.

[0096] Figure 4 shows a schematic top view representation of the same embodiment of the medicament delivery device (3) according to the invention as depicted in Figure 1, 2 and 3 including the syringe (1) with the syringe piston (2) and the syringe body (12), which is adapted to the medicament delivery device (3) comprising the housing (4), the extendable connection (5), the power switch (6), the adapter unit (10) and the locking unit (11). Also depicted is the interior of the medicament deliver device (3) and a typical arrangement of internal components according to the invention. Close to the syringe outlet the medicament delivery device (3) comprises a sensor unit, configured to determine the position of the medicament delivery device (3) relative to the injection area (30), a dosage assessment unit (31), a temperature measuring unit (32) as well as a sensor for determining the components of medical composition (35) and a sensor for detecting gas bubbles (36). In the central part of the medicament delivery device (3) a microcontroller (33) is placed. Furthermore, an orientation sensor such as a gyroscope sensor (34) and a power source (37) may be provided.

[0097] The figures are provided for illustrative purposes. It is thus understood that the figures are not to be construed as limiting. The skilled person in the art will clearly be able to envisage further modifications of the principles laid out herein.

CLAIMS

1. A medicament delivery device (3) adapted to a syringe (1) comprising (i) a sensor unit configured to determine the position of the medicament delivery device (3) relative to the injection area (30), (ii) a dosage assessment unit (31) configured to determine amount or volume of the medicament to be delivered, (iii) a temperature measuring unit (32) configured to determine the temperature of the medicament; and (iv) a micro-controller (33).

2. The medicament delivery device (3) according to claim 1, wherein the medicament delivery device (3) has an adapter (10) for standard syringes with different volumes between 0.5 mL and 250 mL.

3. The medicament delivery device (3) according claim 1 or 2, wherein said sensor unit configured to determine the position of the medicament delivery device (3) relative to the injection area (30) is capable of determining the smallest angle between the injection area and the syringe (1).

4. The medicament delivery device (3) according to claim 3, wherein said sensor unit configured to determine the position of the medicament delivery device (3) relative to the injection area (30) comprises two or more selected from the group consisting of a confocal sensor and laser range finder measuring the smallest distance from the laser connected to the syringe (1) and the injection area.

5. The medicament delivery device (3) according any one of claims 1 to 4, wherein said sensor unit configured to determine the position of the medicament delivery device (3) relative to the injection area (30) is a combination of a magnetometer or a gyroscope sensor (34) and a laser ranger finder or a confocal sensor.

6. The medicament delivery device (3) according to any one of the preceding claims, wherein said dosage assessment unit (31) configured to determine amount or volume

of the medicament to be delivered is selected from the group consisting of a photo sensor, an ultrasonic sensor and a Hall sensor.

7. The medicament delivery device (3) according to claim 6, wherein said dosage assessment unit (31) configured to determine amount or volume of the medicament to be delivered is an ultrasonic sensor.

8. The medicament delivery device (3) according to claim 6, wherein said dosage assessment unit (31) configured to determine amount or volume of the medicament to be delivered is a Hall sensor and wherein the syringe piston (2) is labelled with magnets in equal intervals.

9. The medicament delivery device (3) according to any one of the preceding claims, wherein said temperature measuring unit (32) configured to determine the temperature of the medicament is selected from the group consisting of an infrared sensor, a quartz resonator or a platinum measuring resistor as sensor and a silicon bandgap temperature sensor.

10. The medicament delivery device (3) according to any one of the preceding claims, wherein the medicament delivery device (3) further comprises a sensor for determining the components of the medical composition (35), preferably selected from the group consisting of a Raman spectrometer and an IR spectrometer.

11. The medicament delivery device (3) according to any one of the preceding claims, wherein the medicament delivery device (3) further comprises a laser scanner for determining the components of the medical composition by reading a bar code.

12. The medicament delivery device (3) according to any one of the preceding claims, wherein the medicament delivery device (3) further comprises a sensor for testing the medical composition for contamination, preferably selected from the group consisting of a particle size analyzer and a Raman spectrometer and an IR spectrometer.

13. The medicament delivery device (3) according to any one of the preceding claims, wherein the medicament delivery device (3) further comprises a sensor for detecting gas bubbles (36) in the medical composition, preferably selected from the group consisting of an ultrasound sensor and a sensor using light scattering.

14. The medicament delivery device (3) according to any one of the preceding claims, wherein the medicament delivery device (3) further comprises a locking unit (11).

15. The medicament delivery device (3) according to any one of the preceding claims, wherein the medicament delivery device (3) further contains an accumulator or a battery pack or uses induction as power source (37).

16. The medicament delivery device (3) according to any one of the preceding claims, wherein the microcontroller (33) further comprises a memory, a microprocessor, an analog-to-digital converter coupled to the dosage assessment unit (31) and a transmitter to transmit the data stored in the memory.

17. The medicament delivery device (3) according to any one of the preceding claims, wherein the microcontroller (33) is configured to wirelessly transmit data to a computer device external of the medicament delivery device (3) for processing and visualizing measured data, preferably via a WPAN or WLAN connectivity.

18. The medicament delivery device (3) according to claim 17, wherein the external computer device is a PC-computer, a server-computer, a tablet computer or a smart phone.

19. The medicament delivery device (3) according to any one of the preceding claims, wherein one or more parts of the medicament delivery device (3) have a housing (4).

20. The medicament delivery device (3) according to any one of the preceding claims, wherein the medicament delivery device (3), one or more parts, or its housing (4) are solvent resistant.

21. The medicament delivery device (3) according to claim 20, wherein said solvent resistance is conveyed by a solvent resistant coating layer, preferably selected from the group consisting of a resin composition and a polymer composition.

22. The medicament delivery device (3) according to any one of the preceding claims, wherein the medicament delivery device (3) further comprises an optical and/or audible warning system programmed for indicating the quality and/or correctness of one or more of the following parameters: coupling of the syringe (1) and the medicament delivery device (3), position of the medicament delivery device (3) relative to the injection area, temperature, medical composition, amount of dosage, presence of contamination and presence of gas bubbles.

23. A system comprising the medicament delivery device (3) of any one of claims 1 to 22 and a syringe (1).

24. A system comprising the medicament delivery device (3) of any one of claims 1 to 22 or the system of claim 23, wherein said system comprises a separate receiving unit configured to receive and store data received from said medicament delivery device (3).

25. The system of claim 24, wherein said receiving unit receives data wirelessly, preferably via a WPAN or WLAN connectivity.

26. The system of claim 24 or 25, wherein said receiving unit is connected to an interface unit configured to communicate or perform a dialogue with a user of the system.

27. The system of claim 26, wherein said interface unit is configured to register user input as to pain caused by the medicament delivery device (3) and/ or subjective well-being subsequent to the delivery.

28. The system of claim 26 or 27, wherein said receiving unit is configured to analyze data received from said medicament delivery device (3) and from said interface unit to

provide the user with an advice with respect to the medicament delivery device's (3) handling, preferably concerning at least one of the parameters:

(a) status of coupling of the syringe and the medicament delivery device (3)

(b) degree of medicament delivery,

(c) position of the medicament delivery device (3) relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination; and

(h) presence of gas bubbles in the syringe.

29. A method of monitoring at least one of the following parameters received from a medicament delivery device (3) adapted to a syringe (1) comprising (i) a sensor unit configured to determine the position of the medicament delivery device (3) relative to the injection area (30), (ii) a dosage assessment unit (31) configured to determine amount or volume of the medicament to be delivered, (iii) a temperature measuring unit (32) configured to determine the temperature of the medicament and (iv) a micro-controller (33), or from the medicament delivery device (3) as defined in any one of claims 1 to 22, or from the system of any one of claims 23 to 28:

(a) status of coupling of the syringe and the medicament delivery device (3)

(b) degree of medicament delivery,

(c) position of the medicament delivery device (3) relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination; and

(h) presence of gas bubbles in the syringe.

30. A method for real time visualization of any one of parameters:

(a) status of coupling of the syringe and the medicament delivery device (3)

(b) degree of medicament delivery,

(c) position of the medicament delivery device (3) relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination, and

(h) presence of gas bubbles in the syringe,

preferably of the position of the medicament delivery device (3) relative to the injection area and the temperature of the medical composition.

31. The method of claim 29 or 30, wherein a locking unit (11) as defined in claim 14 is automatically activated and blocks the piston, if one or more of the parameters (a), (c), (d), (g) and (h) as defined in claim 28 is outside a predefined range or if the parameter (e) as defined in claim 28 does not fit to a predefined content of the syringe (1).

32. The method of claim 29 or 30, wherein said monitoring or visualization is used to track a patient's compliance with respect to the administration of the medicament.

33. A method of improving a user's employment of a medicament delivery system as defined in any one of claims 1 to 22, comprising an evaluation of one or more of the parameters:

(a) status of coupling of the syringe and the medicament delivery device (3)

(b) degree of medicament delivery,

(c) position of the medicament delivery device (3) relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination; and

(h) presence of gas bubbles in the syringe.

and/or of user input received from an interface unit concerning at least one of the parameters:

(a) status of coupling of the syringe and the medicament delivery device (3)

(b) degree of medicament delivery,

(c) position of the medicament delivery device (3) relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination,

(h) presence of gas bubbles in the syringe,

(i) a dialogue with a user of the system

(j) pain caused by the medicament delivery device (3), and

(k) subjective well-being subsequent to the delivery.

34. The method of claim 33, wherein said user input comprises data on pain caused by medicament delivery and/or on subjective well-being subsequent to the delivery.

35. The method of claim 33 or 34, wherein said improvement is an advice to the user with respect to the handling of the medicament delivery device (3) during its future employment if one or more of parameters (a) to (h) as defined in claim 28 are outside of a predefined range and/or if said user input indicates the presence of pain or a reduced subjective well-being subsequent to the delivery.

36. A method of improving a user's employment of a system as defined in any one of claims 23 to 28, comprising an evaluation of one or more of the parameters:

(a) status of coupling of the syringe and the medicament delivery device (3)

(b) degree of medicament delivery,

(c) position of the medicament delivery device (3) relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination; and

(h) presence of gas bubbles in the syringe

and/or of user input received from an interface unit concerning at least one of the parameters:

(a) status of coupling of the syringe and the medicament delivery device (3)

(b) degree of medicament delivery,

(c) position of the medicament delivery device (3) relative to the injection area,

(d) temperature of the medicament,

(e) composition of the medicament,

(f) amount of dosage,

(g) presence of contamination,

(h) presence of gas bubbles in the syringe,

(i) a dialogue with a user of the system

(j) pain caused by the medicament delivery device (3), and

(k) subjective well-being subsequent to the delivery.

FIGURES

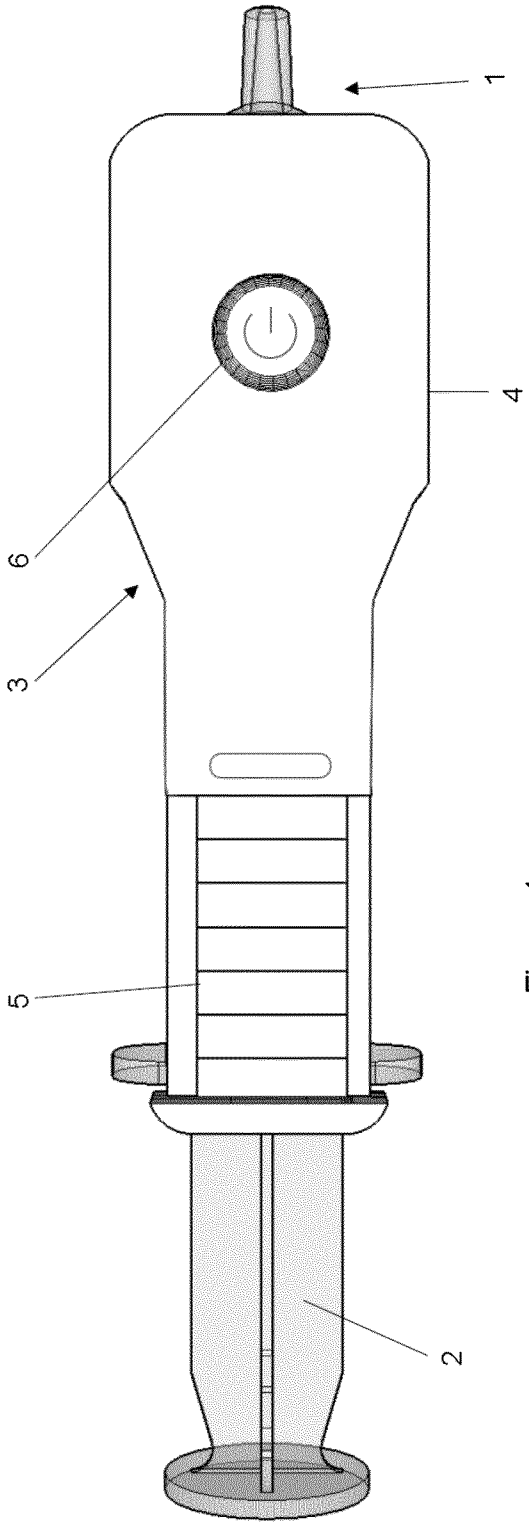

Figure 1

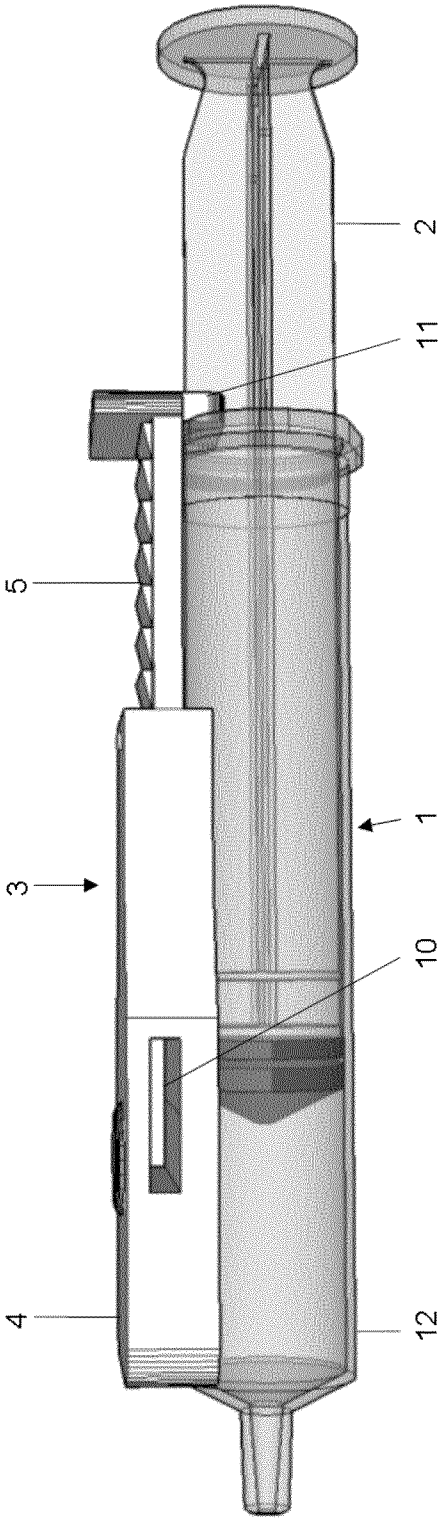

Figure 2

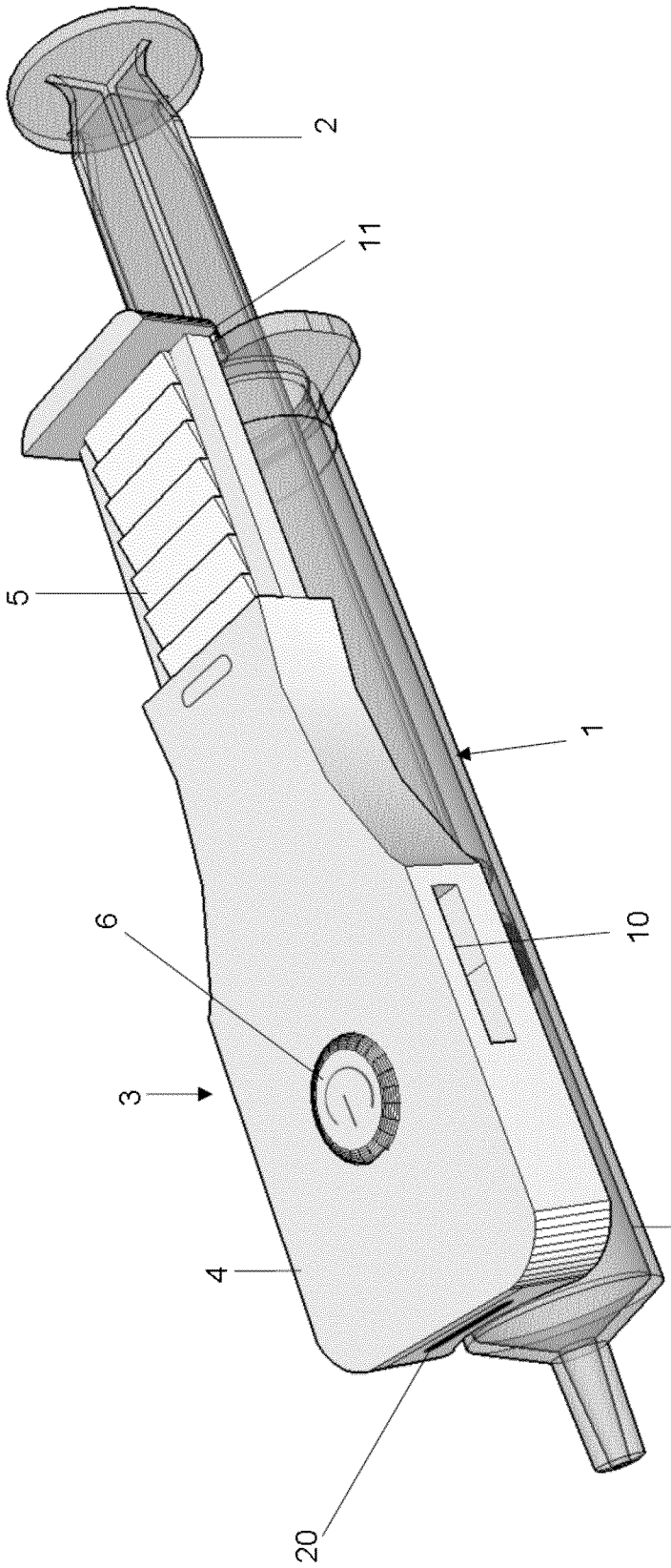

Figure 3

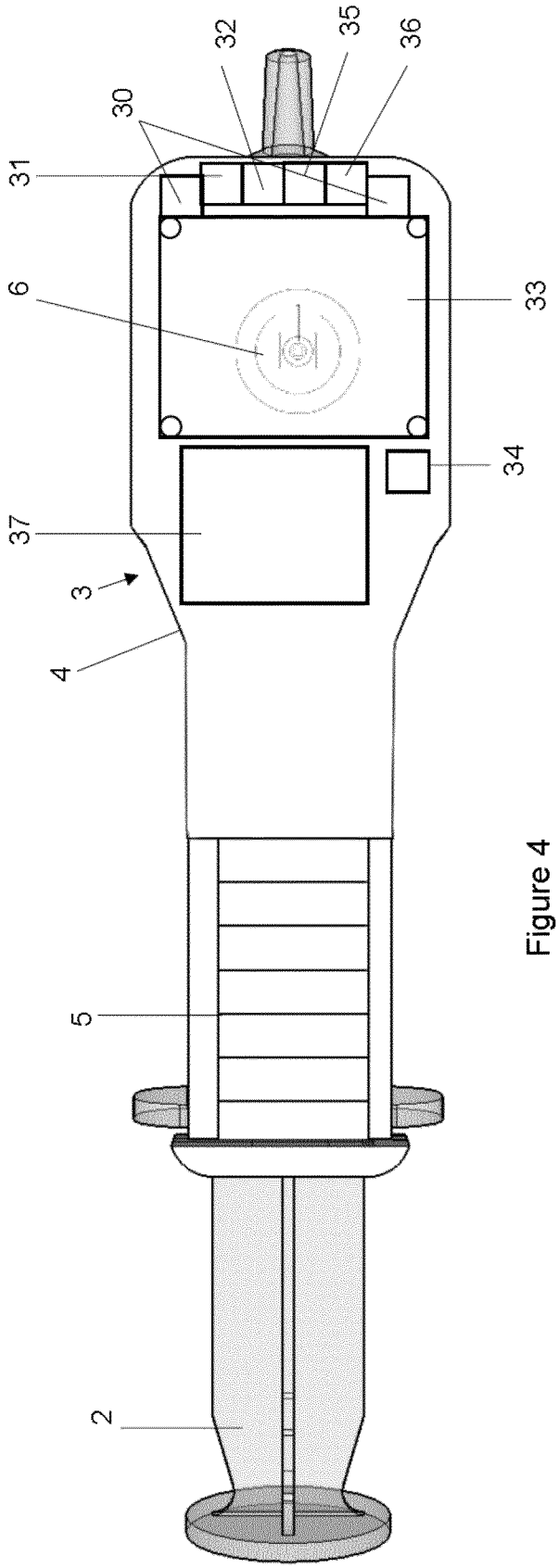

Figure 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/055766

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/20 A61M5/24 A61M5/315 A61M5/42
ADD.

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.
Y	WO 2016/118736 A1 (BECTON DICKINSONAND COMPANY [US]) 28 July 2016 (2016-07-28) the whole document	1-36
Y	WO 2016/140853 A1 (BIOGEN MA INC [US]) 9 September 2016 (2016-09-09) the whole document	1-36

☐ 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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"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	Date of mailing of the international search report
6 June 2018	18/06/2018

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2018/055766

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