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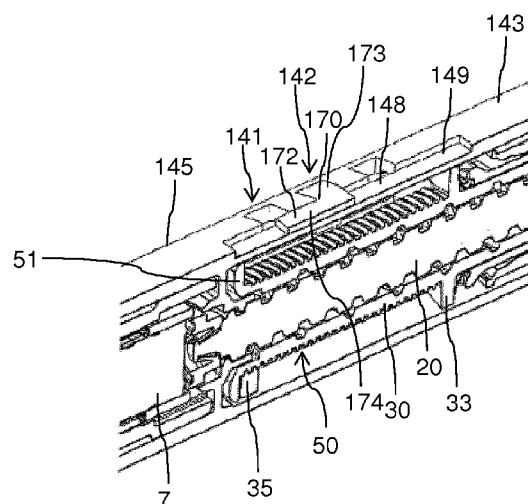


Fig. 14

(57) Abstract: The present disclosure relates to an injection device for setting and injecting a dose of a medicament, the injection device comprising: - an elongated housing (10) extending along an axial direction (z) and configured to accommodate a dose setting mechanism (9), wherein the housing (10) comprises a sidewall (43; 143) with at least a first fastening feature (41; 141) - a dose dial (12) rotatable relative to the housing (10) for setting of a dose, - a dose tracker (50) arranged inside the housing (10) and operably connectable to the dose dial (12), the dose tracker (50) comprises at least one tracking stop feature (51), wherein the dose tracker (50) is one of translationally or rotationally displaceable relative to the housing (10) during setting of a dose and wherein a positional state of the dose tracker (50) relative to the housing (10) is indicative of a size of the dose, and - a limiter (70; 170) attachable to the sidewall (43; 143) of the housing (10) from outside the housing (10) and engageable with the at least first fastening feature (41; 141), wherein the limiter (70; 170) comprises at least one limiter stop feature (71; 171) extending inwardly from the sidewall (43; 143) when the limiter (70; 170) is attached to the sidewall (43; 143), wherein the limiter stop feature (71; 171) and the tracking stop feature (51) are configured to mutually engage and to block a displacement of the dose tracker (50) beyond a predefined maximum dose positional state.

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Injection Device with a Dose Limiter

5 Description

The present disclosure relates in one aspect to injection devices, such as a pen-type injector for setting and dispensing of a dose of a medicament. In particular, the disclosure relates to an injection device providing a maximum dose mechanism, i.e. a dose setting and dispensing
10 mechanism that is only operable to dispense a dose that does not exceed a predefined maximum threshold.

Background

15 Injection devices for setting and dispensing a single or multiple doses of a liquid medicament are as such well-known in the art. Generally, such devices have substantially a similar purpose as that of an ordinary syringe.

Injection devices, in particular pen-type injectors have to meet a number of user-specific
20 requirements. For instance, with patient's suffering chronic diseases, such as diabetes, the patient may be physically infirm and may also have impaired vision. Suitable injection devices especially intended for home medication therefore need to be robust in construction and should be easy to use. Furthermore, manipulation and general handling of the device and its components should be intelligible and easy understandable. Moreover, the dose setting as well
25 as dose dispensing procedure must be easy to operate and has to be unambiguous.

Typically, such devices comprise a housing including a particular cartridge holder, adapted to receive a cartridge at least partially filled with the medicament to be dispensed. Such devices further comprise a drive mechanism, usually having a displaceable piston rod which is adapted
30 to operably engage with a piston of the cartridge. By means of the drive mechanism and its piston rod, the piston of the cartridge is displaceable in a distal direction or dispensing direction and may therefore expel a predefined amount of the medicament via a piercing assembly, which is to be releasably coupled with a distal end section of the housing of the injection device.

35 The medicament to be dispensed by the injection device is provided and contained in a multi-dose cartridge. Such cartridges typically comprise a vitreous barrel sealed in a distal direction by means of a pierceable seal and being further sealed in proximal direction by the piston. With

reusable injection devices an empty cartridge is replaceable by a new one. In contrast, injection devices of disposable type are to be discarded when the medicament in the cartridge has been dispensed or used-up.

- 5 For some applications it can be advantageous to limit a maximum size of a dose that can be dispensed or expelled from the cartridge. Then, unintended overdosing of the medicament could be prevented.

Objects

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It is therefore an object of the present disclosure to provide an injection device that provides a maximum dose function or a maximum dose limiter. The maximum dose function or the maximum dose limiter should be easily adaptable to existing designs of injection devices. The maximum dose function or maximum dose limiter should be also read configurable on demand and should provide an easy and intuitive approach to vary the size of the maximum dose that can be expelled with the injection device.

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An implementation of a maximum dose function should be achievable by only modifying a limited number of existing device components. It is a further aim to individually modify maximum dose values or dose sizes by changing only a single component or a few components of the device. Hence, the maximum dose function of the device or its drive mechanism should be configurable by changing only one or a few components of the device or of its drive mechanism. The maximum dose function or maximum dose limiter should be universally applicable to a large variety of drive mechanisms and injection devices. In particular, the maximum dose function or maximum dose limiter should be equally applicable to disposable injection devices as well as to reusable injection devices.

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Summary

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In one aspect there is provided an injection device for setting and dispensing, hence injection of a dose of a medicament. The injection device comprises an elongated housing extending along an axial direction. The housing is configured and sized to accommodate a dose setting mechanism. Typically, the housing is also sized and configured to accommodate a cartridge filled with a medicament. The housing comprises a side wall with at least a first fastening feature. Typically, the housing is of cylindrical or tubular shape. A cylinder long axis extends in axial direction and the sidewall is of tubular or cylindrical shape. The geometric shape of the sidewall of the housing may therefore define a radial direction and a circumferential direction.

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The injection device further comprises a dose dial. The dose dial is rotatable relative to the housing for setting of a dose. The dose dial may be rotatably supported on or in the housing. For instance, the dose dial may be rotatably supported at a proximal end section of the housing.

- 5 The dose dial is user actuatable. Hence, a user may grip and rotate the dose dial relative to the housing for setting or selecting of a dose of variable size.

The injection device further comprises a dose tracker that is arranged inside the housing. The dose tracker is operably connectable to the dose dial. The dose tracker comprises at least one
10 tracking stop feature. The dose tracker is at least one of translationally or rotationally displaceable relative to the housing during setting of a dose. A positional state of the dose tracker relative to the housing is indicative of a size of the dose. In the present context a 'positional state' of a component, e.g. of the dose tracker includes a position of the component and an angular orientation of the component relative to another component, e.g. relative to the
15 housing. The dose tracker may be rotationally supported inside the housing while being axially fixed. alternative, the dose tracker may be slidably supported inside and relative to the housing while being rotationally fixed to the housing. Furthermore, the dose tracker may be translationally and rotationally displaceable relative to the housing. It may be movable relative to the housing following a helical path. It may be threadedly engaged with the housing.

20 The dose tracker belongs to the dose setting mechanism. The positional state of the dose tracker relative to the housing is unequivocally correlated to the size of the dose actually set. Depending on the specific implementation of the dose tracker a degree of rotation and/or a degree of longitudinal or axial translation of the dose tracker relative to the housing is indicative
25 of a size of the dose actually set.

The injection device further comprises a limiter that is attachable to the sidewall of the housing. The limiter is attachable from outside the housing. It is engageable with the at least first fastening feature. The limiter comprises at least one limiter stop feature extending inwardly from
30 the sidewall when the limiter is attached to the side wall. The limiter stop feature and the tracking stop feature are configured to mutually engage and to block a displacement of the dose tracker beyond a predefined maximum dose positional state.

35 The limiter and the at least one limiter stop feature thereof is attachable and fixable to a specific portion of the sidewall of the housing that corresponds to a predefined maximum dose positional state of the tracking stop feature of the dose tracker. The specific portion of the housing to which the limiter and/or the limiter stop feature is attached to coincides with a position positional

state of the tracking stop feature when the dose tracker arrives at a maximum dose positional state.

- 5 In other words, when the dose tracker reaches a maximum dose positional state its tracking stop feature engages, e.g. abuts with the limiter stop feature that is fixed to a respective portion of the side wall. The limiter stop feature and the tracking stop feature may comprise mutually corresponding stop faces, e.g. extending in circumferential and radial direction so as to engage axially. Alternatively, the limiter stop feature and the tracking stop feature comprise mutually corresponding stop faces extending in axial direction and radial direction so as to engage
- 10 circumferentially. When configured to engage axially, the mutual engagement of the limiter stop feature and the tracking stop feature provides an axial stop thereby impeding and blocking a longitudinal or axial translation of the dose tracker beyond a predefined maximum axial dose positional state.
- 15 When configured to engage circumferentially or tangentially, the mutual engagement of the limiter stop feature and the tracking stop feature provides a rotational stop, thereby impeding and blocking a rotation of the dose tracker relative to the housing beyond a predefined maximum rotational dose positional state.
- 20 The predefined maximum dose positional state defines a maximum dose that is selectable and dispensable by the injection device. By placing the limiter stop feature to a predefined location on the sidewall of the housing that corresponds to the positional state of the dose tracker, in particular of the tracking stop feature, the maximum dose dispensable by the injection device can be defined.
- 25 Typically, the limiter is attachable to the sidewall of the housing by the at least first fastening feature. Here, the first fastening feature may provide a double function. First of all, the first fastening feature may provide a fastening structure to attach the limiter to a respective portion of the sidewall of the housing. Furthermore, the position of the first fastening feature on the
- 30 sidewall defines a maximum dose positional state for the dose tracker.
- The limiter is attachable to the sidewall from outside the housing. This allows for a maximum dose size modification of the injection device even after delivery to a patient or to medical staff. Attachment of the limiter to the housing from outside the housing enables a subsequent
- 35 modification of the injection device without the necessity to open the housing of the injection device.

With a further example the housing and in particular the sidewall of the housing comprises at least a second fastening feature that is separated from the at least first fastening feature with regard to one of an axial direction and a circumferential direction of the housing. Here, the limiter is selectively engageable with one of the at least first and second fastening features. The second fastening feature may be identically shaped and configured to the first fastening feature. The second fastening feature only distinguishes from the first fastening feature by its position or location on the sidewall of the housing. Feature and with a second fastening feature. The first and the second fastening features are separated from each other with regard to one of an axial direction (z) and a circumferential or tangential direction (w) of the housing.

All features and effects described below and above with regards to the first fastening feature may equally apply to the second fastening feature. Moreover, features and effects described below with regard to only one of the first and the second fastening feature or with regards to both, the first and the second fastening features equally apply to examples wherein the injection device only comprises a single, namely the first fastening feature on the sidewall of the housing.

Typically, the limiter is in principle engageable with both of the at least first and second fastening features. It is connectable or engageable with only one of the first and the second fastening features at a time. For instance, the limiter can be engaged with the first fastening feature while the second fastening feature remains disengaged. In this configuration the limiter and the attachment of the limiter to the sidewall at the first fastening feature defines a first maximum dose size of the injection device. On demand and if requested the limiter can be detached from the first fastening feature and can be attached to the second fastening feature. Then, the limiter and its limiter stop feature is located at a different position on the sidewall of the housing compared to the first fastening feature. In this second configuration the limiter and the attachment of the limiter to the sidewall and the second fastening feature defines a second maximum dose size of the injection device, which due to the spatial separation of the first and the second fastening features differs from the first maximum dose size.

In another example at least one of the first and the second fastening features comprises a through opening extending through the sidewall of the housing. Here, the limiter stop feature is shaped and configured to extend through the through opening. Providing of at least one through opening in the sidewall of the housing provides the possibility to attach the limiter to an outside surface of the housing and hence from outside the housing. Since the through opening and the limiter stop feature are complementary or correspondingly shaped the limiter stop feature is insertable from outside through the through opening in the sidewall so that a free end of the limiter stop feature protrudes from an inside surface of the sidewall. There, the limiter stop

feature may operably engage with the correspondingly shaped tracking stop feature so as to block and to impede a rotational and/or translational displacement of the dose tracker beyond the predefined maximum dose positional state.

- 5 Typically and according to another example each one of the at least first and second fastening features comprises a through opening extending through the side wall. Moreover, the first and the second fastening features may comprise equal or identical geometries. In this way, one and the same limiter may be selectively attached to one of the first and the second fastening features. This provides and enables a reconfiguration of the injection device. When for instance
10 attached to the first fastening feature thereby defining a first maximum dose size the limiter can be detached from the first fastening feature and can be attached to the second fastening feature in order to define a second maximum dose size that differs from the first maximum dose size.

In another example the limiter comprises a base portion. The limiter stop feature protrudes from
15 the base portion. When attached to the sidewall the base portion may be located outside the sidewall or may be located inside the sidewall. The base portion may be configured as a handle providing a well-defined gripping of the limiter. The base portion may further improve the fastening of the limiter to the sidewall. The base portion may be permanently attachable to the sidewall, e.g. by way of an adhesive or by way of welding.

20 The base portion may be shaped to cover the first and the second fastening features when it is attached to one of the first and the second fastening features. Consequently, the base portion may comprise a cover having a size that is at least equal to or larger than the distance between the first and the second fastening features on the sidewall of the housing. In this way and when
25 attached to the first fastening feature, e.g. by means of the first limiter stop feature, the base portion covers both, the first fastening feature and the second fastening feature. In another configuration and when attached to the second fastening feature, e.g. by means of the limiter stop feature, the base portion also covers both, the first fastening feature and the second fastening feature.

30 With either configuration it is also conceivable that the limiter is attached to the outside surface of the housing by means of the base portion. In another example a cross-section of the at least one through opening of the first and the second fastening features may be larger than the outer cross-section of the limiter stop feature of the limiter. This enables a rather smooth and easy
35 insertion of the limiter stop feature into and through the through opening of the first or second fastening features. For reconfiguring the injection device and its dose setting mechanism the

limiter stop feature may be also rather easily detached and withdrawn from the through opening of the first or second fastening features.

5 With another example the base portion is attachable to an outside surface of the sidewall. Since the limiter stop feature protrudes from the base portion the base portion may be located outside or at the outside surface of the side wall whereas the limiter stop feature extends through the side wall and protrudes from an inside surface of the sidewall so as to engage with the tracking stop feature of the dose tracker. Attachment to an outside surface of the base portion is further beneficial to have permanent access to the base portion and hence to the limiter. Since the
10 base portion remains at the outside surface it is accessible to a user or to medical staff, thereby enabling a detachment of the limiter from the side wall for reconfiguring the injection device if required.

15 In another example the limiter stop feature is insertable into and through the at least one through opening of the first and the second fastening features such that a free end of the limiter stop feature that faces away from the base portion protrudes inwardly from an inside surface of the sidewall. Consequently, the elongation, typically the radial elongation of the limiter stop feature is larger than the thickness of the sidewall and is also larger than the thickness of the through opening extending through the side wall. In this way, attachment and abutment of the
20 base portion to the outside surface of the sidewall leads to a configuration wherein the free end of the limiter stop feature protrudes inwardly from the inside surface of the sidewall.

With another example at least one of the first and the second fastening features comprises a recessed portion on the outside surface of the sidewall. The recessed portion is arranged
25 adjacent to the at least one through opening of the first and/or of the second fastening features. Typically, the recessed portion is shaped and configured to receive the base portion of the limiter therein. In this way, an outside facing surface of the base portion may flush with the outside surface of the sidewall of the housing. In effect, the outside surface of the housing may comprise a rather even and smooth shape free of protrusions or recesses when the limiter is
30 attached to one of the first and the second fastening features and when the limiter, in particular its base portion, covers both, the at least first and the second fastening features.

In another example the recessed portion comprises a depth that is equal to or larger than a thickness of the base portion. In this way, it is provided that the base portion can be entirely
35 received inside the recessed portion. When attached to and arranged in the recessed portion the base portion does not protrude from the outside surface of the sidewall. This provides a rather even and smooth shape of the outer circumference of the housing.

In another example the first fastening feature and the second fastening feature each comprise a recessed portion. Here, the recessed portions of the first fastening feature and of the second fastening feature merge into one another and form an elongated recess on the outside surface of the sidewall. Typically, the elongated recess on the outside surface of the sidewall provides a kind of a receptacle for the base portion of the limiter. When the base portion of the limiter is inserted into the elongated recess, the limiter stop feature thereof may extend into and reach through the through opening of the respective first or second fastening feature.

With another example the elongated recess extends along the axial direction and/or along the circumferential direction. The at least one through opening of one of the first and second fastening features is arranged tangentially or circumferentially or axially adjacent to the elongated recess. If the elongated recess extends along the axial direction the through opening is arranged tangentially or circumferentially adjacent to the elongated recess. When the elongated recess extends along the circumferential or tangential direction the at least one through opening of one of the first and the second fastening features is arranged axially adjacent to the elongated recess.

Typically, the first and the second fastening features each comprise a through opening, wherein these through openings are axially separated from each other. Both through openings are arranged circumferentially adjacent to the elongated recess. Typically, the limiter is shaped to attach to a portion of the elongated recess and to engage with only one of the through openings of the first and the second fastening features. Then, another through opening and a residual portion of the elongated recess may remain uncovered. This residual portion or the non-occupied through opening may be separately covered with a separate cover.

With another example there may be provided a set of at least two limiters that differ in shape. The at least two limiters may comprise an equal sized base portion that is configured to entirely fill the elongated recess. The two limiters may distinguish from each other by the shape and position of their at least one limiter stop feature relative to the base portion. A first limiter may comprise a limiter stop feature configured to engage with the first fastening feature when the limiter is attached to the sidewall of the housing. The second limiter may comprise a limiter stop feature exclusively configured to engage with the second fastening feature when the limiter is attached to the sidewall of the housing.

In this way, the first and the second limiter with equally shaped base portions may always entirely fill and cover the elongated recess on the outside surface of the sidewall. Depending on

a specific selection of one of the first and the second limiters only one of the first and second fastening features and only one of respective first and second through openings through the side wall will be occupied with a limiter stop feature.

5 In another example there may be provided only one limiter with a base portion being symmetric with regards to an axis of symmetry. Here, the recessed portion on the outside surface of the sidewall may comprise a corresponding symmetry so that the limiter is attachable and fastenable to the outside surface of the housing in a first configuration and in a second configuration, wherein the second configuration is e.g. rotated by 180° compared to the first configuration. Typically, the axis of symmetry coincides with a center of the distance between the first and the second fastening features. In this way, the limiter stop feature of the limiter engages the first fastening feature when in the first configuration and the limiter stop feature engages the second fastening feature when in the second configuration, e.g. when the limiter is rotated about 180°.

15 In another example the base portion is L-shaped and comprises a first leg and a second leg. The first and the second legs extend at 90° with respect to each other. When attached to the sidewall of the housing the first leg may extend along the circumferential direction of the sidewall and the second leg may extend along the axial direction of the sidewall. When the elongated recess extends along the axial direction, the second leg may extend along the elongated recess and the first leg may extend perpendicular thereto along the circumference of the sidewall.

25 An L-shaped base portion is beneficial for attachment of the limiter to the sidewall. The second leg may be attached to and may be received in the recessed portion or in the elongated recess on the outside surface of the sidewall, thereby defining a radial position of the limiter relative to the housing. The first leg may support the at least one limiter stop feature of the limiter extending radially inwardly into the interior of the housing. Here, the first leg with the at least one limiter stop feature attached thereto protrudes into the housing and engages with the tracking stop feature of the dose tracker whereas the second leg provides a well-defined attachment of the limiter at a well-defined radial position of the housing.

35 In a further example the limiter stop feature protrudes from an end portion of the first leg that faces away from the second leg. Here, the limiter stop feature may constitute the first leg and the second leg may be regarded as a flange portion of the limiter extending along the sidewall of the housing.

In a further example the injection device is equipped with a cover that is attachable to the outside surface of the sidewall. The cover is configured to cover at least the first fastening feature and the second fastening feature. The cover may be further configured to cover a recessed portion on the outside surface of the sidewall adjacent to the at least one through opening of the first and/or the second fastening feature. The cover effectively hides and conceals the position and the presence of the limiter when attached to the sidewall of the housing.

The cover may comprise a flexible foil adhesively attachable to the outside surface of the sidewall of the housing. The cover may be transparent. Alternatively, the cover may be opaque. The cover may comprise a printed surface. The cover may comprise a label attached to the outside surface of the housing. The label may contain instructions or information regarding the use of the medicament and/or regarding use of the injection device.

Instead of a flexible foil the cover may comprise a sleeve or a shell made from a plastic material or made from metal. The cover may be positively engageable to the elongated housing. The cover and the housing may comprise mutually corresponding fastening features, such as a protrusion and a correspondingly shaped recess. The cover and the sidewall of the housing may comprise mutually engaging clip or snap features that provide a detachable or non-detachable fastening of the cover to the sidewall of the housing.

For instance, the cover may comprise a shell in the form of a portion of a sleeve or cylinder, e.g. a half shell. The cover may comprise a radial protrusion or a radial recess on an inside surface portion to engage with a correspondingly shaped recess or protrusion provided on the outside surface of the sidewall of the housing of the injection device. In this way, the cover can be clipped or fixed to the sidewall of the housing. When the cover comprises a plastic shell the outside surface of the cover may comprise a label. The cover may be also fastened to the injection device by means of an adhesive or by means of an adhesive label. It is also conceivable that the cover is attached to the housing by means of welding.

In another example the injection device further comprises a piston rod. The piston rod is typically a component of a drive mechanism and/or of the dose setting mechanism. The piston rod is axially displaceable for dispensing of a dose of a medicament from a cartridge. When the injection device is in a dispensing mode, the drive mechanism and/or the dose setting mechanism thereof is configured to drive and to displace the piston rod longitudinally in an axial distal direction.

Typically, the injection device is provided with a cartridge filled with a medicament, e.g. a liquid medicament. The cartridge is typically sealed in proximal direction by means of a bung. The bung is axially displaceable inside the cartridge so as to expel the liquid medicament from a distal end thereof. The distal end of the cartridge is typically sealed by a pierceable seal. The pierceable seal is penetrable by means of a double -tipped injection needle. The injection needle is typically releasably attachable to a distal and or to a dispensing end of the housing of the injection device, typically to a distal end of a cartridge holder that belongs to the housing of the injection device.

In a further example the injection device comprises a cartridge at least partially filled with a medicament. The cartridge comprises a barrel filled with the medicament. The cartridge and hence the barrel is sealed in an axial proximal direction by the bung. The bung is axially displaceable relative to the barrel by means of the piston rod. When during dose dispensing the piston rod advances in distal direction it applies a driving pressure to the bung. Since the cartridge is fixed inside the housing the bung starts to move in distal direction, thereby increasing an inside pressure of the cartridge, thus leading to expelling the medicament from the cartridge.

In another aspect a method of modifying a maximum dose size of an injection device is provided. The method comprises the steps of providing an injection device. The injection device comprises an elongated housing extending along an axial direction and being configured to accommodate a dose setting mechanism. Typically, the housing is also configured to receive and to accommodate a cartridge filled with a medicament. The housing further comprises a sidewall with at least a first fastening feature. Typically, the sidewall also comprises at least a second fastening feature. The injection device further comprises a dose tracker arranged inside the housing. The dose tracker comprises at least one tracking stop feature. The dose tracker is at least one of translationally or rotationally displaceable relative to the housing during setting of a dose. A positional state of the dose tracker relative to the housing is unequivocally indicative of a size of the dose actually set.

The method of modifying the maximum dose size further comprises the step of attaching a limiter to the sidewall of the housing by means of the at least one fastening feature. The limiter comprises at least one limiter stop feature extending inwardly from the sidewall when attached to the sidewall. The limiter stop feature and the tracking stop feature are configured to mutually engage and to block a displacement of the dose tracker beyond a predefined maximum dose positional state.

Typically, the method of modifying a maximum dose size of an injection device is applicable to an injection device as described above. Consequently, all features, benefits and effects described above in connection with the injection device equally apply to the method of modifying the maximum dose size of an injection device.

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In the present context the term 'distal' or 'distal end' relates to an end of the injection device that faces towards an injection site of a person or of an animal. The term 'proximal' or 'proximal end' relates to an opposite end of the injection device, which is furthest away from an injection site of a person or of an animal.

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

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

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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,

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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,

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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 exendin-3 or exendin-4 or an analogue or derivative of exendin-3 or exendin-4.

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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-(ω -carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω -carboxyheptadecanoyl) 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-NH₂.

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

H-(Lys)4-des Pro36, des Pro37 Exendin-4(1-39)-NH₂,
 H-(Lys)5-des Pro36, des Pro37 Exendin-4(1-39)-NH₂,
 des Pro36 Exendin-4(1-39),
 des Pro36 [Asp28] Exendin-4(1-39),
 des Pro36 [IsoAsp28] Exendin-4(1-39),
 des Pro36 [Met(O)14, Asp28] Exendin-4(1-39),
 des Pro36 [Met(O)14, IsoAsp28] Exendin-4(1-39),
 des Pro36 [Trp(O₂)25, Asp28] Exendin-4(1-39),
 des Pro36 [Trp(O₂)25, IsoAsp28] Exendin-4(1-39),
 des Pro36 [Met(O)14 Trp(O₂)25, Asp28] Exendin-4(1-39),
 des Pro36 [Met(O)14 Trp(O₂)25, IsoAsp28] Exendin-4(1-39); or
 des Pro36 [Asp28] Exendin-4(1-39),
 des Pro36 [IsoAsp28] Exendin-4(1-39),
 des Pro36 [Met(O)14, Asp28] Exendin-4(1-39),
 des Pro36 [Met(O)14, IsoAsp28] Exendin-4(1-39),
 des Pro36 [Trp(O₂)25, Asp28] Exendin-4(1-39),
 des Pro36 [Trp(O₂)25, IsoAsp28] Exendin-4(1-39),
 des Pro36 [Met(O)14 Trp(O₂)25, Asp28] Exendin-4(1-39),
 des Pro36 [Met(O)14 Trp(O₂)25, IsoAsp28] Exendin-4(1-39),

wherein the group -Lys6-NH₂ may be bound to the C-terminus of the Exendin-4 derivative;

or an Exendin-4 derivative of the sequence

des Pro36 Exendin-4(1-39)-Lys6-NH₂ (AVE0010),

- 5 H-(Lys)6-des Pro36 [Asp28] Exendin-4(1-39)-Lys6-NH₂,
des Asp28 Pro36, Pro37, Pro38 Exendin-4(1-39)-NH₂,
H-(Lys)6-des Pro36, Pro38 [Asp28] Exendin-4(1-39)-NH₂,
H-Asn-(Glu)5des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-NH₂,
des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
10 H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
H-(Lys)6-des Pro36 [Trp(O₂)25, Asp28] Exendin-4(1-39)-Lys6-NH₂,
H-des Asp28 Pro36, Pro37, Pro38 [Trp(O₂)25] Exendin-4(1-39)-NH₂,
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O₂)25, Asp28] Exendin-4(1-39)-NH₂,
15 H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O₂)25, Asp28] Exendin-4(1-39)-NH₂,
des Pro36, Pro37, Pro38 [Trp(O₂)25, Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O₂)25, Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O₂)25, Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
H-(Lys)6-des Pro36 [Met(O)14, Asp28] Exendin-4(1-39)-Lys6-NH₂,
20 des Met(O)14 Asp28 Pro36, Pro37, Pro38 Exendin-4(1-39)-NH₂,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH₂,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH₂,
des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
25 H-Asn-(Glu)5 des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
H-Lys6-des Pro36 [Met(O)14, Trp(O₂)25, Asp28] Exendin-4(1-39)-Lys6-NH₂,
H-des Asp28 Pro36, Pro37, Pro38 [Met(O)14, Trp(O₂)25] Exendin-4(1-39)-NH₂,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH₂,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O₂)25, Asp28] Exendin-4(1-39)-NH₂,
30 des Pro36, Pro37, Pro38 [Met(O)14, Trp(O₂)25, Asp28] Exendin-4(1-39)-(Lys)6-NH₂,
H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O₂)25, Asp28] Exendin-4(S1-39)-(Lys)6-NH₂,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O₂)25, Asp28] Exendin-4(1-39)-(Lys)6-NH₂;

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or a pharmaceutically acceptable salt or solvate of any one of the afore-mentioned Exendin-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.

Antibodies are globular plasma proteins (~150kDa) that are also known as immunoglobulins which share a basic structure. As they have sugar chains added to amino acid residues, they are glycoproteins. The basic functional unit of each antibody is an immunoglobulin (Ig) monomer (containing only one Ig unit); secreted antibodies can also be dimeric with two Ig units as with IgA, tetrameric with four Ig units like teleost fish IgM, or pentameric with five Ig units, like mammalian IgM.

The Ig monomer is a "Y"-shaped molecule that consists of four polypeptide chains; two identical heavy chains and two identical light chains connected by disulfide bonds between cysteine residues. Each heavy chain is about 440 amino acids long; each light chain is about 220 amino acids long. Heavy and light chains each contain intrachain disulfide bonds which stabilize their folding. Each chain is composed of structural domains called Ig domains. These domains contain about 70-110 amino acids and are classified into different categories (for example, variable or V, and constant or C) according to their size and function. They have a characteristic immunoglobulin fold in which two β sheets create a "sandwich" shape, held together by interactions between conserved cysteines and other charged amino acids.

There are five types of mammalian Ig heavy chain denoted by α , δ , ϵ , γ , and μ . The type of heavy chain present defines the isotype of antibody; these chains are found in IgA, IgD, IgE, IgG, and IgM antibodies, respectively.

Distinct heavy chains differ in size and composition; α and γ contain approximately 450 amino acids and δ approximately 500 amino acids, while μ and ϵ have approximately 550 amino acids. Each heavy chain has two regions, the constant region (C_H) and the variable region (V_H). In one

species, the constant region is essentially identical in all antibodies of the same isotype, but differs in antibodies of different isotypes. Heavy chains γ , α and δ have a constant region composed of three tandem Ig domains, and a hinge region for added flexibility; heavy chains μ and ϵ have a constant region composed of four immunoglobulin domains. The variable region of the heavy chain differs in antibodies produced by different B cells, but is the same for all antibodies produced by a single B cell or B cell clone. The variable region of each heavy chain is approximately 110 amino acids long and is composed of a single Ig domain.

In mammals, there are two types of immunoglobulin light chain denoted by λ and κ . A light chain has two successive domains: one constant domain (CL) and one variable domain (VL). The approximate length of a light chain is 211 to 217 amino acids. Each antibody contains two light chains that are always identical; only one type of light chain, κ or λ , is present per antibody in mammals.

Although the general structure of all antibodies is very similar, the unique property of a given antibody is determined by the variable (V) regions, as detailed above. More specifically, variable loops, three each the light (VL) and three on the heavy (VH) chain, are responsible for binding to the antigen, i.e. for its antigen specificity. These loops are referred to as the Complementarity Determining Regions (CDRs). Because CDRs from both VH and VL domains contribute to the antigen-binding site, it is the combination of the heavy and the light chains, and not either alone, that determines the final antigen specificity.

An "antibody fragment" contains at least one antigen binding fragment as defined above, and exhibits essentially the same function and specificity as the complete antibody of which the fragment is derived from. Limited proteolytic digestion with papain cleaves the Ig prototype into three fragments. Two identical amino terminal fragments, each containing one entire L chain and about half an H chain, are the antigen binding fragments (Fab). The third fragment, similar in size but containing the carboxyl terminal half of both heavy chains with their interchain disulfide bond, is the crystalizable fragment (Fc). The Fc contains carbohydrates, complement-binding, and FcR-binding sites. Limited pepsin digestion yields a single $F(ab')_2$ fragment containing both Fab pieces and the hinge region, including the H-H interchain disulfide bond. $F(ab')_2$ is divalent for antigen binding. The disulfide bond of $F(ab')_2$ may be cleaved in order to obtain Fab'. Moreover, the variable regions of the heavy and light chains can be fused together to form a single chain variable fragment (scFv).

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⁺, or K⁺, or Ca²⁺, or an ammonium ion N⁺(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.

It will be further apparent to those skilled in the art that various modifications and variations can be made to the injection device without departing from the spirit and scope of what is disclosed herein. Further, it is to be noted, that any reference numerals used in the appended claims are not to be construed as limiting the scope of the invention.

Brief description of the drawings

In the following, embodiments of the drive mechanism and the injection device are described in detail by making reference to the drawings, in which:

Fig. 1 schematically shows an example of an injection device,

Fig. 2 shows an exploded view of the components of the injection device of Fig. 1,

Fig. 3 it is a side view of one example of the injection device with a limiter detached therefrom,

Fig. 4 is a side view of a limiter attachable to the sidewall of the injection device,

Fig. 5 as a bottom view of the limiter according to Fig. 4,

Fig. 6 is a side view of the in section device of Fig. 3 with the limiter of Fig. 4 and 5 attached thereto,

Fig. 7 is a side view of another example of an injection device,

Fig. 8 is a further view of the injection device of Fig. 7 slightly rotated with regards to the longitudinal axis,

Fig. 9 is an isolated perspective view of another example of a limiter,

Fig. 10 shows the limiter of Fig. 9 in another perspective,

Fig. 11 is indicative of the limiter of Fig. 9 attached to the sidewall of the injection device according to Figs. 7 or 8 in a first configuration,

Fig. 12 shows the limiter of Fig. 9 attached to the sidewall of the injection device in a second configuration,

Fig. 13 is a longitudinal cross-section through a portion of the injection device according to Figs. 7 or 8,

Fig. 14 is a cross-section according to Fig. 13 with the limiter attached thereto,

Fig. 15 is a planar view of the cross-section according to Fig. 14,

Fig. 16 shows a shell attachable to the housing of the injection device,

Fig. 17 shows an inside of the shell of Fig. 16,

Fig. 18 shows the shell of Figs. 16 and 17 with a label attached thereto and

Fig. 19 shows the injection device of Fig. 7 provided with a shell of Fig. 16.

Detailed Description

The injection device 1 as shown in Figs. 1 and 2 is a pre-filled disposable injection device that comprises a housing 10 to which an injection needle 15 can be affixed. The injection needle 15 is protected by an inner needle cap 16 and either an outer needle cap 17 or a protective cap 18 that is configured to enclose and to protect a distal section of the housing 10 of the injection device 1. The housing 10 may comprise and form a main housing part configured to accommodate a drive mechanism 8 as shown in Fig. 2. The injection device 1 may further comprise a distal housing component denoted as cartridge holder 14. The cartridge holder 14

may be permanently or releasably connected to the main housing 10. The cartridge holder 14 is typically configured to accommodate a cartridge 6 that is filled with a liquid medicament. The cartridge 6 comprises a cylindrically-shaped or tubular-shaped barrel 25 sealed in proximal direction 3 by means of a bung 7 located inside the barrel 25. The bung 7 is displaceable
5 relative to the barrel 25 of the cartridge 6 in a distal direction 2 by means of a piston rod 20. A distal end of the cartridge 6 is sealed by a pierceable seal 26 configured as a septum and being pierceable by a proximally directed tipped end of the injection needle 15. The cartridge holder 14 comprises a threaded socket 28 at its distal end to threadedly engage with a correspondingly threaded portion of the injection needle 15. By attaching the injection needle 15 to the distal end
10 of the cartridge holder 14 the seal 26 of the cartridge 6 is penetrated thereby establishing a fluid transferring access to the interior of the cartridge 6.

When the injection device 1 is configured to administer e.g. human insulin, the dosage set by a dose dial 12 at a proximal end of the injection device 1 may be displayed in so-called
15 international units (IU, wherein 1 IU is the biological equivalent of about 45.5 μ g of pure crystalline insulin (1/22 mg).

As shown further in Figs. 1 and 2, the housing 10 comprises a dosage window 13 that may be in the form of an aperture in the housing 10. The dosage window 13 permits a user to view a
20 limited portion of a number sleeve 80 that is configured to move when the dose dial 12 is turned, to provide a visual indication of a currently set dose. The dose dial 12 is rotated on a helical path with respect to the housing 10 when turned during setting and/or dispensing or expelling of a dose.

25 The injection device 1 may be configured so that turning the dosage knob 12 causes a mechanical click sound to provide acoustical feedback to a user. The number sleeve 80 mechanically interacts with a piston in the insulin cartridge 6. When the needle 15 is stuck into a skin portion of a patient, and when the trigger 11 or injection button is pushed, the insulin dose displayed in display window 13 will be ejected from injection device 1. When the needle 15 of
30 the injection device 1 remains for a certain time in the skin portion after the trigger 11 is pushed, a high percentage of the dose is actually injected into the patient's body. Ejection of an insulin dose may also cause a mechanical click sound, which is however different from the sounds produced when using the dose dial 12.

35 In this embodiment, during delivery of the insulin dose, the dose dial 12 is turned to its initial position in an axial movement, that is to say without rotation, while the number sleeve 80 is rotated to return to its initial position, e.g. to display a dose of zero units.

The injection device 1 may be used for several injection processes until either the cartridge 6 is empty or the expiration date of the medicament in the injection device 1 (e.g. 28 days after the first use) is reached.

5

Furthermore, before using injection device 1 for the first time, it may be necessary to perform a so-called "prime shot" to remove air from the cartridge 6 and the needle 15, for instance by selecting two units of the medicament and pressing trigger 11 while holding the injection device 1 with the needle 15 upwards. For simplicity of presentation, in the following, it will be assumed that the ejected amounts substantially correspond to the injected doses, so that, for instance the amount of medicament ejected from the injection device 1 is equal to the dose received by the user.

The expelling or drive mechanism 8 as illustrated in more detail in Fig. 2 comprises numerous mechanically interacting components. A flange like support of the housing 10 comprises a threaded axial through opening threadedly engaged with a first thread or distal thread 22 of the piston rod 20. The distal end of the piston rod 20 comprises a bearing 21 on which a pressure foot 23 is free to rotate with the longitudinal axis of the piston rod 20 as an axis of rotation. The pressure foot 23 is configured to axially abut against a proximally facing thrust receiving face of the bung 7 of the cartridge 6. During a dispensing action the piston rod 20 rotates relative to the housing 10 thereby experiencing a distally directed advancing motion relative to the housing 10 and hence relative to the barrel 25 of the cartridge 6. As a consequence, the bung 7 of the cartridge 6 is displaced in distal direction 2 by a well-defined distance due to the threaded engagement of the piston rod 20 with the housing 10.

25

The piston rod 20 is further provided with a second thread 24 at its proximal end. The distal thread 22 and the proximal thread 24 are oppositely handed.

There is further provided a drive sleeve 30 having a hollow interior to receive the piston rod 20. The drive sleeve 30 comprises an inner thread threadedly engaged with the proximal thread 24 of the piston rod 20. Moreover, the drive sleeve 30 comprises an outer threaded section 31 at its distal end. The threaded section 31 is axially confined between a distal flange portion 32 and another flange portion 33 located at a predefined axial distance from the distal flange portion 32. Between the two flange portions 32, 33 there is provided a last dose limiter 35 in form of a semi-circular nut having an internal thread mating the threaded section 31 of the drive sleeve 30.

35

The last dose limiter 35 further comprises a radial recess or protrusion at its outer circumference to engage with a complementary-shaped recess or protrusion at an inside of the sidewall of the housing 10. In this way the last dose limiter 35 is splined to the housing 10. A rotation of the drive sleeve 30 in a dose incrementing direction 4 or clockwise direction during consecutive dose setting procedures leads to an accumulative axial displacement of the last dose limiter 35 relative to the drive sleeve 30. There is further provided an annular spring 40 that is in axial abutment with a proximally facing surface of the flange portion 33. Moreover, there is provided a tubular-shaped clutch 60. At a first end the clutch 60 is provided with a series of circumferentially directed saw teeth. Towards a second opposite end of the clutch 60 there is located a radially inwardly directed flange.

Furthermore, there is provided a dose dial sleeve also denoted as number sleeve 80. The number sleeve 80 is provided outside of the spring 40 and the clutch 60 and is located radially inward of the housing 10. A helical groove 81 is provided about an outer surface of the number sleeve 80. The housing 10 is provided with the dosage window 13 through which a part of the outer surface of the number 80 can be seen. The housing 10 is further provided with a helical rib at an inside sidewall portion of an insert piece 62, which helical rib is to be seated in the helical groove 81 of the number sleeve 80. The tubular shaped insert piece 62 is inserted into the proximal end of the housing 10. It is rotationally and axially fixed to the housing 10. There are provided first and second stops on the housing 10 to limit a dose setting procedure during which the number sleeve 80 is rotated in a helical motion relative to the housing 10.

The dose dial 12 in form of a dose dial grip is disposed about an outer surface of the proximal end of the number sleeve 80. An outer diameter of the dose dial 12 typically corresponds to and matches with the outer diameter of the housing 10. The dose dial 12 is secured to the number 80 to prevent relative movement therebetween. The dose dial 12 is provided with a central opening.

The trigger 11, also denoted as dose button is substantially T-shaped. It is provided at a proximal end of the injection device 10. A stem 64 of the trigger 11 extends through the opening in the dose dial 12, through an inner diameter of extensions of the drive sleeve 30 and into a receiving recess at the proximal end of the piston rod 20. The stem 64 is retained for limited axial movement in the drive sleeve 30 and against rotation with respect thereto. A head of the trigger 11 is generally circular. The trigger side wall or skirt extends from a periphery of the head and is further adapted to be seated in a proximally accessible annular recess of the dose dial 12.

To dial a dose a user rotates the dose dial 12. With the spring 40 also acting as a clicker and the clutch 60 engaged, the drive sleeve 30 the spring or clicker 40, the clutch 60 and the number sleeve 80 rotate with the dose dial 12. Audible and tactile feedback of the dose being dialed is provided by the spring 40 and by the clutch 60. Torque is transmitted through saw teeth between the spring 40 and the clutch 60. The helical groove 81 on the number sleeve 80 and a helical groove in the drive sleeve 30 have the same lead. This allows the number sleeve 80 to extend from the housing 10 and the drive sleeve 30 to climb the piston rod 20 at the same rate. At a limit of travel a radial stop on the number sleeve 80 engages either with a first stop or a second stop provided on the housing 10 to prevent further movement. Rotation of the piston rod 20 is prevented due to the opposing directions of the overall and driven threads on the piston rod 20.

The last dose limiter 35 keyed to the housing 10 is advanced along the threaded section 31 by the rotation of the drive sleeve 30. When a final dose dispensed position is reached, a radial stop formed on a surface of the last dose limiter 35 abuts a radial stop on the flange portion 33 of the drive sleeve 30, preventing both, the last dose limiter 35 and the drive sleeve 30 from rotating further.

Should a user inadvertently dial beyond the desired dosage, the injection device¹, configured as a pen-injector allows the dosage to be dialed down without dispense of the medicament from the cartridge 6. For this the dose dial 12 is simply counter-rotated. This causes the system to act in reverse. A flexible arm of the spring or clicker 40 then acts as a ratchet preventing the spring 40 from rotating. The torque transmitted through the clutch 60 causes the saw teeth to ride over one another to create the clicks corresponding to dialed dose reduction. Typically, the saw teeth are so disposed that a circumferential extent of each saw tooth corresponds to a unit dose.

When the desired dose has been dialed the user may simply dispense the set dose by depressing the trigger 11. This displaces the clutch 60 axially with respect to the number sleeve 80 causing dog teeth thereof to disengage. However, the clutch 60 remains keyed in rotation to the drive sleeve 30. The number sleeve 80 and the dose dial 12 are now free to rotate in accordance with the helical groove 81.

The axial movement deforms the flexible arm of the spring 40 to ensure the saw teeth cannot be overhauled during dispense. This prevents the drive sleeve 30 from rotating with respect to the housing 10 though it is still free to move axially with respect thereto. The deformation is subsequently used to urge the spring 40 and the clutch 60 back along the drive sleeve 30 to

restore the connection between the clutch 60 and the number sleeve 80 when the distally directed dispensing pressure is removed from the trigger 11.

5 The longitudinal axial movement of the drive sleeve 30 causes the piston rod 20 to rotate through the through opening of the support of the housing 10, thereby to advance the bung 7 in the cartridge 6. Once the dialed dose has been dispensed, the number sleeve 80 is prevented from further rotation by contact of at least one stop extending from the dose dial 12 with at least one corresponding stop of the housing 10. A zero dose position may be determined by the abutment of one of axially extending edges or stops of the number sleeve 80 with at least one
10 or several corresponding stops of the housing 10.

The expelling mechanism or drive mechanism 8 as described above is only exemplary for one of a plurality of differently configured drive mechanisms that are generally implementable in a disposable pen-injector. The drive mechanism as described above is explained in more detail
15 e.g. in WO2004/078239A1, WO 2004/078240A1 or WO 2004/078241A1 the entirety of which being incorporated herein by reference.

The dose setting mechanism 9 as illustrated in Fig. 2 comprises at least the dose dial 12 and the number sleeve 80. As the dose dial 12 is rotated during and for setting of a dose the number
20 sleeve 80 starts to rotate relative to the housing along a helical path as defined by the threaded engagement of its outer thread or helical groove 81 with a correspondingly shaped threaded section at the inside surface of the housing.

During dose setting and when the drive mechanism 8 or the dose setting mechanism 9 is in the
25 dose setting mode the drive sleeve 30 rotates in unison with the dose dial 12 and with the number sleeve 80. The drive sleeve 30 is threadedly engaged with the piston rod 20, which during dose setting is stationary with regard to the housing 10. Accordingly, the drive sleeve 30 is subject to a screwing or helical motion during dose setting. The drive sleeve 30 starts to travel in proximal direction as the dose dial is rotated in a dose incrementing direction 4, e.g. in a
30 clockwise direction. For adjusting off or correcting a size of a dose the dose dial 12 is rotatable in an opposite direction, hence in a dose decrementing direction 5, e.g. counterclockwise.

At least one of the drive sleeve 30 and the number sleeve 80 serves as a dose tracker 50 comprising a tracking stop feature 51. In the example as illustrated for instance in Figs. 13 to 15
35 one of the flanges 32 or 33 provides and coincides with a tracking stop feature 51 of the dose tracker 50. There is further provided a limiter 70 as a separate piece.

As illustrated in Figs. 3, 7 or 8 the housing 10 comprises a tubular - shaped or cylindrically-shaped sidewall 43, 143. The sidewall 43, 143 comprises a first fastening feature 41, 141 and a second fastening feature 42, 142. As indicated for instance in Fig. 3, the first fastening feature 41 is axially separated from the second fastening feature 42. In the example as shown, the first fastening feature 41 and the second fastening feature 42 each comprise a through opening 44 extending through the sidewall 43 of the housing 10.

The limiter 70 comprises a flat -shaped base portion 72 and a limiter stop feature 71 protruding from the base portion 72. The limiter stop feature 71 is configured and sized to mate with the first fastening feature 41 and with the second fastening feature 42. The limiter stop feature 71 is configured and sized to extend through the through opening 44 of one of the first and second fastening features 41, 42 at a time. The limiter stop feature 71 is either insertable into and through the through opening 44 of the first fastening feature 41 or of the second fastening feature 42, respectively.

As shown for instance in Fig. 15 the limiter 170 is attached to an outside surface 145 of the sidewall 143 in such a configuration that the limiter stop feature 171 extends through the second fastening feature 142 the limiter stop feature 171 or at least a free end thereof protrudes radially inwardly from an inside surface 146 of the sidewall. Since the limiter stop feature 71, 171 and the entire limiter 70, 170 is stationary fixed to the sidewall 43, 143 of the housing 10 it provides an axial stop for the tracking stop feature 51 of the dose tracker 50 during setting of a dose. The axial path the dose tracker 50 and its tracking stop feature 51 may travel in proximal direction during dose setting is limited by the position of the limiter 70, 170 and its limiter stop feature 71, 171.

Depending on the specific geometry of the mutually engaging stop features of the limiter 70, 170 and the dose tracker 50 it is also conceivable that the limiter stop feature 71, 171 blocks a rotation of the dose tracker 50 beyond a predefined maximum rotational position. In this way the limiter stop feature 71, 171 may be arranged and attached to a predefined portion of the sidewall 43, 143 of the housing 10 that corresponds to a predefined angular position of a dose tracker 50 rotatably supported inside the housing 10. For instance, the limiter stop feature 71, 171 may form a circumferential or radial stop for a tracking stop feature 51 provided on the outside surface of a dose tracker 50 formed by a number sleeve 80 as shown in Fig. 2.

Even though the presently illustrated examples all comprise a first fastening feature 41, 141 and a second fastening feature 42, 142 there are examples conceivable, wherein there is only provided a single, namely a first fastening feature 41, 141 in the sidewall 43, 143 of the housing

10. Here, the first fastening feature 41, 141 also comprises a through opening 44, 144 to receive the correspondingly shaped limiter stop feature 71, 171 therethrough. In addition to the limiter stop feature 71, 171 and the tracking stop feature 51 the drive mechanism 8 or the dose setting mechanism 9 may comprise an additional maximum dose limiter function. As illustrated in Fig. 2, there may be provided a tracking stop feature 51 on the outside surface of the number sleeve 80 which is configured to abut and to engage with a stop feature 63 of the insert piece 62. The insert piece 62 is stationary attached and fixed to the housing 10. As a maximum dose, e.g. of about 80 I.U. has been set the tracking stop feature 51 gets in an abutment with the stop feature 63 of the insert piece 62 thereby blocking a further rotation and/or translation of the number sleeve 80. In this embodiment the number sleeve 80 equally serves as a dose tracker 50.

In addition to this maximum dose limiter function provided by the mutual interaction of the number sleeve 80 and the insert piece 62 it may be sufficient when the sidewall 43, 143 of the housing 100 comprises only a first fastening feature 41, 141 for the limiter 70, 170. By attaching the limiter 70, 172 the sidewall 43, 143, an additional maximum dose stop is implemented and the originally provided maximum dose limiter function is overruled. By attaching the limiter 70, 172 the sidewall 43, 143, the maximum dose limiter function of the drive mechanism 8 or of the dose setting mechanism 9 is modified from outside the injection device 1.

The dose limiter function provided by the mutual interaction of the number sleeve 80 and the insert piece 62 may be replaced by the interaction of the dose tracker 50 and the limiter 70. With such embodiments it is of particular benefit when the housing 10 and the sidewall 43, 143 comprises at least a first and a second fastening feature 41, 42, 141, 142. Then, and in a first configuration the limiter 70 is engaged or attached to the first fastening feature 41 the limiter stop feature 71 protrudes from a first well-defined axial portion of the sidewall 43 of the housing 10. In a second configuration the limiter 70 is engaged or attached to the second fastening feature 41. Then, the limiter stop feature 71 protrudes from a second well-defined axial portion of the sidewall 43 of the housing 10. In the present example and as shown in Fig. 3, the second fastening feature 42 is located proximally from the first fastening feature 41. In the second configuration and when the limiter stop feature 71 protrudes through the through opening 44 of the second fastening feature 42 a maximum dose size is increased compared to the first configuration in which the limiter stop feature 71 protrudes through the through opening 44 of the first fastening feature 41.

When attached to the outside surface 45 of the housing 43 the flat-shaped base portion 72 of the limiter 70 is substantially flush with the outside surface 45 while the limiter stop feature 71 protrudes radially inwardly and into the interior of the housing 10. In the example as shown in Figs. 4 and 5 the limiter stop feature 71 comprises a pin extending perpendicular from the flat shaped base portion 72. The limiter stop feature 71 comprises a beveled section 73 at its free end in order to facilitate insertion and assembly of the limiter stop feature 71 into the through opening 44.

As illustrated in Figs. 3 to 5 the base portion 72 of the limiter 70 comprises an axial extension that is at least equal to or larger than a distance between the first fastening feature 41 and the second fastening feature 42. Moreover, the limiter stop feature 71 is arranged near an axial end of the base portion 72. In this way and when the limiter stop feature 71 is attached to the first fastening feature 41 the portion of the base portion 72 that faces away from the limiter stop feature 71 covers the second fastening feature 42. Vice versa, when the limiter stop feature 71 is attached to the second fastening feature 42 the remote portion of the base portion 72 covers the first fastening feature 41. In this way, the base portion 72 comprises a symmetric shape that allows a fastening and attachment of the limiter 70 in a first and in a second configuration, wherein the first configuration is transferable into the second configuration by rotating the limiter 70 by 180°.

In another example as illustrated in Figs. 7 to 15 the first and second fastening features 141, 142 are also separated from each other along the axial direction (z) on the outside surface 145 of the sidewall 143 of the housing 10. Each one of the fastening features 141, 142 comprises a through opening 144 extending through the sidewall 143. There is even provided a third fastening feature located proximally from the second fastening feature 142. The fastening features are equidistantly arranged on the housing 10. In the same way as described above the through openings 144 of the fastening features 141, 142 are configured to receive a limiter stop feature 171 of a limiter 170 which is illustrated in Figs. 9 and 10.

As shown in more detail in Fig. 11 the first fastening feature 141 comprises a recessed portion 147. In a similar way also the second fastening feature comprises a recessed portion 147. The recessed portions are located circumferentially yearly adjacent to the through openings 144 of the first and of the second fastening features 141, 142, respectively. As further illustrated in Figs. 11 and 12 the recessed portions 147 of the first fastening feature 141 and the second fastening feature 142 merge and form a common elongated recess 148 on the outside surface 145 of the sidewall 143. The elongated recess 148 comprises a longitudinal recessed portion extending along the longitudinal or axial direction (z) of the elongated housing 10.

The elongated recess 148 comprises a bottom 149 located at a radial distance from the outside surface 145 of the sidewall 143. This radial distance is at least equal to or larger than a thickness of a base portion 172 of the limiter 170. In this way the elongated recess 148 is configured to accommodate the base portion 172 of the limiter 170 in its entirety. When attached to the sidewall 143 the limiter 170 and its base portion 172 does not protrude radially from the outside surface 145 of the sidewall 143.

As illustrated in Figs. 9 - 12 the limiter 170 is L-shaped. The limiter 170 comprises a first leg 173 and a second leg 174. The first leg 173 and the second leg 174 extend at an angle of about 90°. When attached to the housing 10 the first leg 173 extends along the circumference (w) of the housing 10 and the second leg 174 extends along the axial elongation (z) of the housing 10. The first leg 174 and hence the base portion 172 is assembled inside the elongated recess 148 whereas the second leg 143 extends towards and into the through opening 144 of one of the first or second fastening features 141, 142. In Fig. 11, the limiter stop feature 171 and hence the first leg 173 extends into the first fastening feature 141. In Fig. 12, the limiter stop feature 171 and hence the first leg 173 extends into and engages with the second fastening feature 142.

When assembled to the housing 10 the base portion 172 of the limiter 170 is in abutment with the bottom 149 of the elongated recess 148. In this way the radial position of the limiter 170 is well-defined with regard to the housing 10.

As shown in Figs. 11 and 12 thereof further provided recessed sections 150 circumferentially adjacent to the elongated recess 148. The recessed sections 150 are located circumferentially opposite to the through openings 144 of the first and the second fastening features 141, 142. The recessed sections 150 merge with the elongated recess 148. They provide access to a side edge of the base portion 172 of the limiter 170 when attached to one of the first and the second fastening features 141, 142. In this way, and e.g. with the help of a tipped tool, such as a screwdriver the base portion 172 and hence the entire limiter 170 can be lifted radially outwardly so as to detach the limiter 170 from the housing 10. The limiter 170 may then attached to another fastening feature in order to modify the maximum dose size of the injection device 1.

The limiter 70, 170 may be frictionally or adhesively attached to the sidewall 43, 143 of the housing 10. The limiter 70, 170 may be fastened to the sidewall 43, 143 by means of a separate part, e.g. by means of a fastener. Such fastener may comprise an adhesive label or a cover 90 covering the limiter 70, 170 and fixing the same to the sidewall 43, 143. With the example of Figs. 11 or 12 the limiter 170 may be press fitted in in one of the elongated recess 148 or in one

of the through openings 144 of one of the first or second fastening features 141, 142. It may be also permanently attached and fixed to the housing 10 by way of an adhesive or by way of welding. The limiter 70, 170 and the housing 10 may comprise a moldable plastic material that is suitable for welding, such as laser welding or ultrasound welding.

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In order to temporarily or permanently fix the limiter 70, 172 to the housing 10 there may be provided a label 100 adhesively attachable to the outside surface 45, 145 of the sidewall 43, 143. The label 100 may be provided with readable information printed thereon. The information may include instructions or general information regarding the medicament and/or regarding

10 handling or use of the injection device 1.

The label 100 may entirely cover the limiter 70, 170 as well as the first and the second fastening features 41, 42, 141, 142.

15 Furthermore and as illustrated in Figs. 16 to 19 there may be provided a separate cover 90. The cover 90 may comprise a plastic material. The cover 90 may comprise a somewhat tubular shape cut along a longitudinal direction so as to comprise a semicircular cross-section and to comprise the shape of a half-shell. Typically, the cover 90 comprises a circumference that is larger than half of the outer circumference of the housing 10. In this way, the cover 90 may be
20 clipped onto the outside surface 45, 145 of the housing 10. The cover 90 is elastically deformable so as to at least temporally enlarge the distance between free ends thereof and to allow a clip attachment of the cover 90 along the radial direction of the housing 10. In one example, the limiter 70, 170 and the the cover 90 may be integrally formed. Here, the limiter 70 may protrude from an inside surface of the cover 90. The limiter 70, 170 and the cover 90 might
25 be shaped and configured such that the limiter 70, 170 is located in one of the through openings 44, 144 as the cover 90 is attached and fixed to the housing 10.

In order to secure and to fix the cover 90 with regard to the axial and/or circumferential direction there may be provided mutually corresponding fastening elements 91, 151 on an inside surface
30 of the cover 90 and on the outside surface 145 of the housing 10. In the example as shown in Figs. 7, 8, 17 and 19 the fastening element 91 of the cover 90 comprises a radially inwardly protruding pin and fastening element 151 of the housing 10 comprises a correspondingly shaped recess. When correctly assembled the fastening element 91 snaps into the fastening element 151. In this way, the cover 90 is fixed to the housing 10 with regard to all three
35 dimensions.

In addition or alternative the label 100 may be used to fix the cover 90 to the housing 10. As indicated in Fig. 18, the label 100 may be adhesively attached to the cover 90 in such a way that a portion of the label 100 also covers a portion of the outside surface 145 of the sidewall 143 of the injection device 1 that is uncovered by the cover 90. Since the label 100 is adhesively
5 attached to both, the outside surface 145 of the housing 10 and to the outside surface of the cover 90 the cover 90 can be fixed to the housing 10 by means of the label 100.

Any features described above in connection with first and second fastening features 41, 141, 42, 142 are equally valid for an example or embodiment of the injection device having only one
10 fastening feature 41, 141 on the sidewall 43, 143 of the housing 10. Only as an example, the fastening feature 41, 141 may comprise a recessed portion 147 to receive the base portion 72, 172 of the limiter 70, 170. Moreover, the only and first fastening feature 41, 141 may be covered by a cover 90 and/or by a label 100.

List of reference numbers

	1	injection device
	2	distal direction
5	3	proximal direction
	4	dose incrementing direction
	5	dose decrementing direction
	6	cartridge
	7	bung
10	8	drive mechanism
	9	dose setting mechanism
	10	housing
	11	trigger
	12	dose dial
15	13	dosage window
	14	cartridge holder
	15	injection needle
	16	inner needle cap
	17	outer needle cap
20	18	protective cap
	20	piston rod
	21	bearing
	22	first thread
	23	pressure foot
25	24	second thread
	25	barrel
	26	seal
	28	threaded socket
	30	drive sleeve
30	31	threaded section
	32	flange
	33	flange
	35	last dose limiter
	36	shoulder
35	40	spring
	41	fastening feature
	42	fastening feature

	43	sidewall
	44	through opening
	45	outside surface
	50	dose tracker
5	51	tracking stop feature
	60	clutch
	62	insert piece
	63	stop feature
	64	stem
10	70	limiter
	71	limiter stop feature
	72	base portion
	73	beveled section
	80	number sleeve
15	81	groove
	90	cover
	91	fastening element
	100	label
	141	fastening feature
20	142	fastening feature
	143	sidewall
	144	through opening
	145	outside surface
	146	inside surface
25	147	recessed portion
	148	recess
	149	button
	150	recess
	151	fastening element
30	170	limiter
	171	limiter stop feature
	172	base portion
	173	leg
	174	leg

DE2017/060 WO PCT

Claims

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1. An injection device for setting and injecting a dose of a medicament, the injection device comprising:

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- an elongated housing (10) extending along an axial direction (z) and configured to accommodate a dose setting mechanism (9), wherein the housing (10) comprises a sidewall (43; 143) with at least a first fastening feature (41; 141)

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- a dose dial (12) rotatable relative to the housing (10) for setting of a dose,

- a dose tracker (50) arranged inside the housing (10) and operably connectable to the dose dial (12), the dose tracker (50) comprises at least one tracking stop feature (51), wherein the dose tracker (50) is one of translationally or rotationally displaceable relative to the housing (10) during setting of a dose and wherein a positional state of the dose tracker (50) relative to the housing (10) is indicative of a size of the dose, and

20

- a limiter (70; 170) attachable to the sidewall (43; 143) of the housing (10) from outside the housing (10) and engageable with the at least first fastening feature (41, 141), wherein the limiter (70; 170) comprises at least one limiter stop feature (71; 171) extending inwardly from the sidewall (43; 143) when the limiter (70; 170) is attached to the sidewall (43), wherein the limiter stop feature (71; 171) and the tracking stop feature (51) are configured to mutually engage and to block a displacement of the dose tracker (50) beyond a predefined maximum dose positional state.

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2. The injection device according to claim 1, wherein the sidewall (43; 143) comprises at least a second fastening feature (42; 142) that is separated from the at least first fastening feature (41; 141) with regard to one of an axial direction (z) and a circumferential direction (w) of the housing (10), and wherein the limiter (70; 170) is selectively engageable with one of the at least first and second fastening features (41, 42; 141, 142).

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3. The injection device according to claim 2, wherein the limiter (70; 170) is connectable or engageable with only one of the first and the second fastening features (41, 42; 141, 142) at a time.
- 5 4. The injection device according to claim 2 or 3, wherein the limiter (70; 170) defines a first maximum dose size of the injection device when attached to the sidewall (43) at the first fastening feature (41; 141) and wherein the limiter (70; 170) defines a second maximum dose size of the injection device when attached to the sidewall (43) at the second fastening feature (42; 142).
- 10 5. The injection device according to any one of the preceding claims, wherein at least one of the first and the second fastening features (41, 42; 141, 142) comprises a through opening (44; 144) extending through the sidewall (43; 143), wherein the stop feature (71; 171) is shaped and configured to extend through the through opening (44; 144).
- 15 6. The injection device according to any one of the preceding claims, wherein the limiter (70; 170) comprises a base portion (72; 172) and the limiter stop feature (71; 171) protrudes from the base portion (72; 172).
- 20 7. The injection device according to claim 6, wherein the base portion (72; 172) is attachable to an outside surface (45; 145) of the sidewall (43; 143).
8. The injection device according to any one of the claims 5 to 7, wherein the limiter stop feature (71; 171) is insertable into and through the through opening (44) such that a free end of the limiter stop feature (71; 171) protrudes inwardly from an inside surface (46) of the sidewall (43).
- 25 9. The injection device according to any one of the preceding claims 5 to 8, wherein at least one of the first and the second fastening features (141, 142) comprises a recessed portion (147) on the outside surface (145) of the sidewall (143) and wherein the recessed portion (147) is arranged adjacent to the at least one through opening (144).
- 30 10. The injection device according to claim 9, wherein the recessed portion (47) comprises a depth that is equal to or larger than a thickness of the base portion (72; 172).
- 35

11. The injection device according to claim 9 or 10, wherein the first fastening feature (141) and the second fastening feature (142) each comprise a recessed portion (147) and wherein the recessed portions (147) of the first fastening feature (141) and the second fastening feature (142) merge into one another and form an elongated recess (148) on the outside surface (145) of the sidewall (143).

12. The injection device according to any one of the claims 9 to 11, wherein the elongated recess (148) extends along the axial direction (z) and/or along a circumferential direction (w) and wherein the at least one through opening (144) of one of the first and second fastening features (141, 142) is arranged tangentially or circumferentially adjacent to the elongated recess (148).

13. The injection device according to claim 12, wherein the base portion (172) is L-shaped and comprises a first leg (173) and a second leg (174), wherein the first leg (173) extends in circumferential direction (w) and wherein the second leg (174) extends along the elongated recess (148).

14. The injection device according to claim 13, wherein the limiter stop feature (171) protrudes from an end portion of the first leg (173) that faces away from the second leg (174).

15. The injection device according to any one of the preceding claims, further comprising a cover (90) attachable to the outside surface (145) of the sidewall (143) and configured to cover at least the first fastening feature (141) and the second fastening feature (142).

16. The injection device according to any one of the preceding claims, further comprising a piston rod (20) and a cartridge (6), wherein the cartridge (6) comprises a barrel (25) filled with a medicament and sealed in an axial proximal direction (3) by a bung (7) that is axially displaceable relative to the barrel (25) by means of the piston rod (20).

17. A method of modifying a maximum dose size of an injection device, comprising the steps of:

- providing an injection device (1), comprising:

a) an elongated housing (10) extending along an axial direction (z) and configured to accommodate a dose setting mechanism (9), wherein the

housing (10) comprises a sidewall (43; 143) with at least a first fastening feature (41, 42; 141, 142),

- 5 b) a dose tracker (50) arranged inside the housing (10) and comprising at least one tracking stop feature (51), wherein the dose tracker (50) is at least one of translationally or rotationally displaceable relative to the housing (10) during setting of a dose, wherein a positional state of the dose tracker (50) relative to the housing (10) is indicative of a size of the dose,
- 10 - attaching a limiter (70; 170) to the sidewall (43) of the housing (10) by means of the at least one fastening feature (41, 42; 141, 142), wherein the limiter (70; 170) comprises at least one limiter stop feature (71; 171) extending inwardly from the sidewall (43; 143) when attached to the sidewall (43; 143), wherein the limiter stop feature (71; 171) and the tracking stop feature (51) are configured to mutually engage
- 15 and to block a displacement of the dose tracker (50) beyond a predefined maximum dose positional state.

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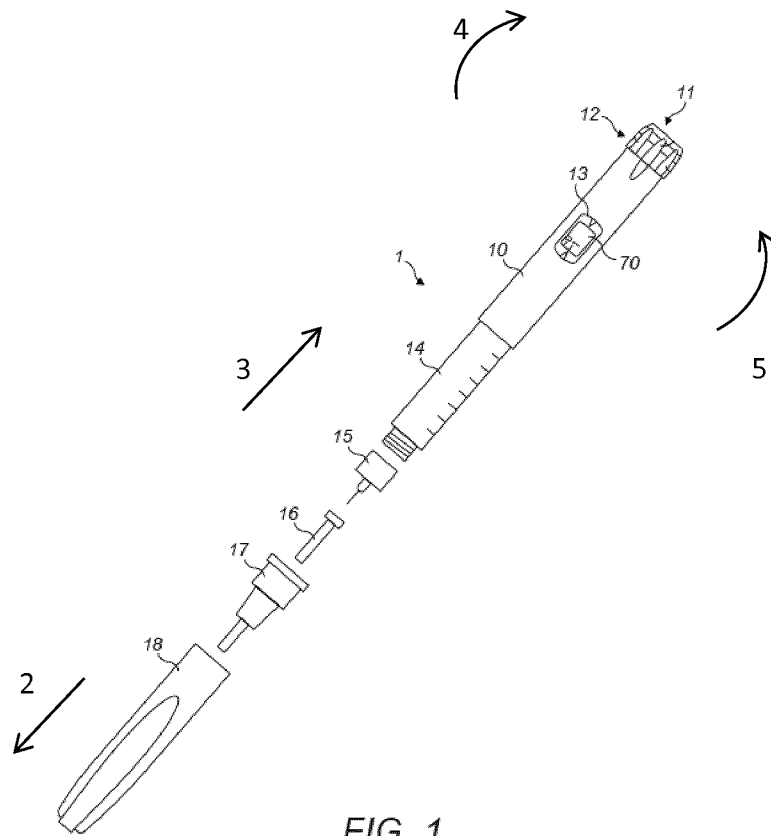


FIG. 1

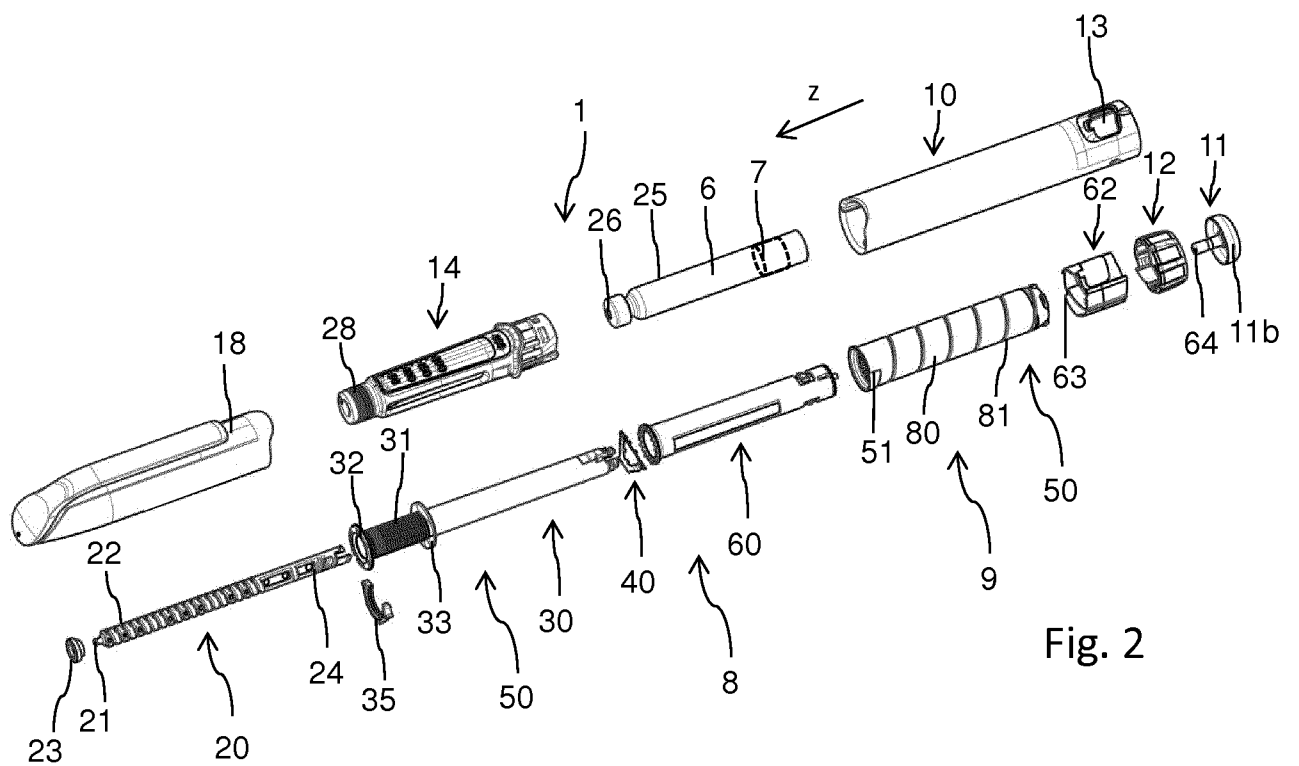


Fig. 2

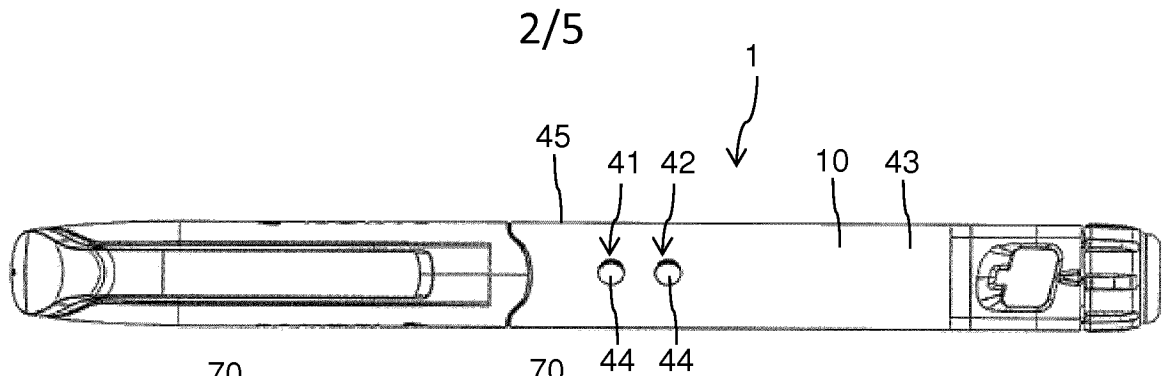


Fig. 3

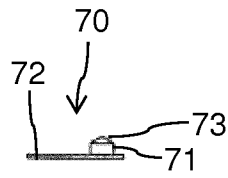


Fig. 4

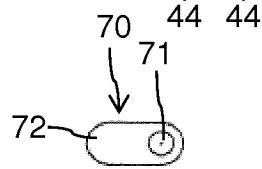


Fig. 5

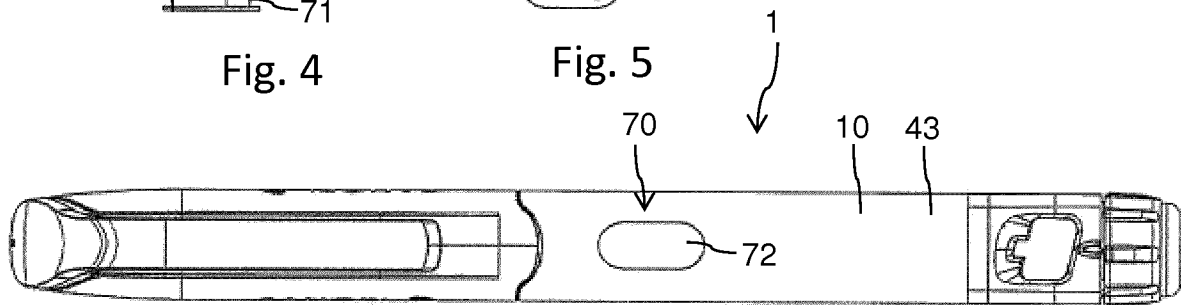


Fig. 6

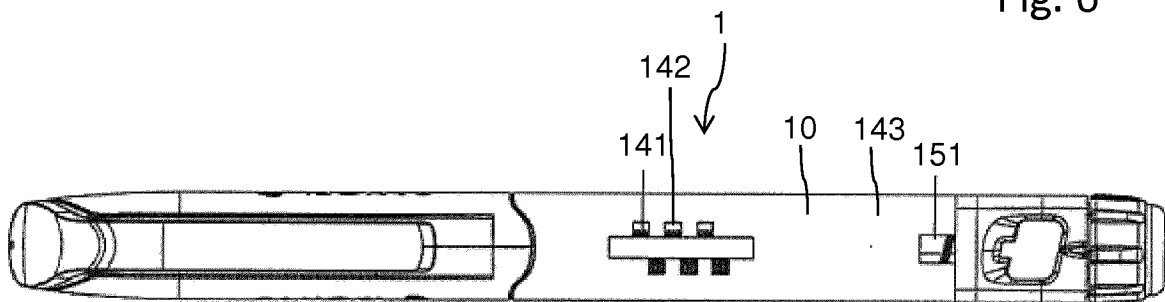


Fig. 7

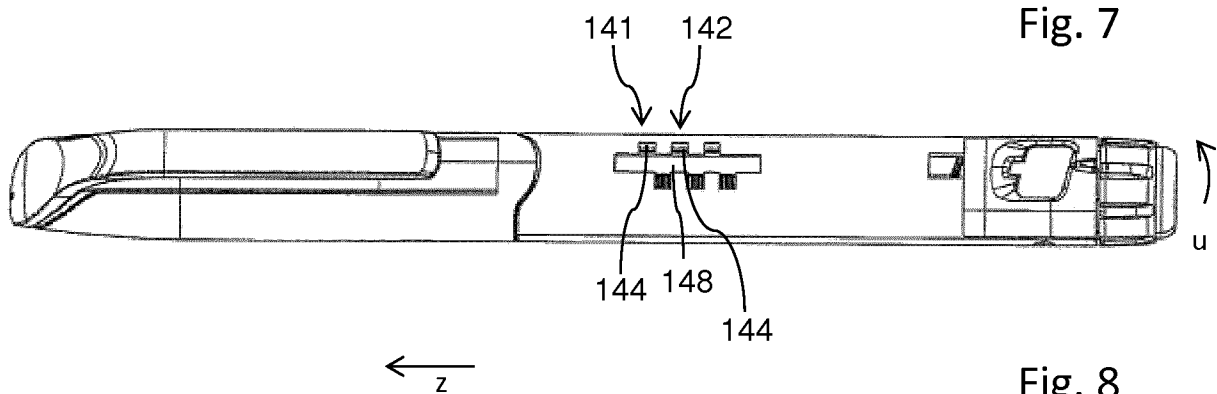
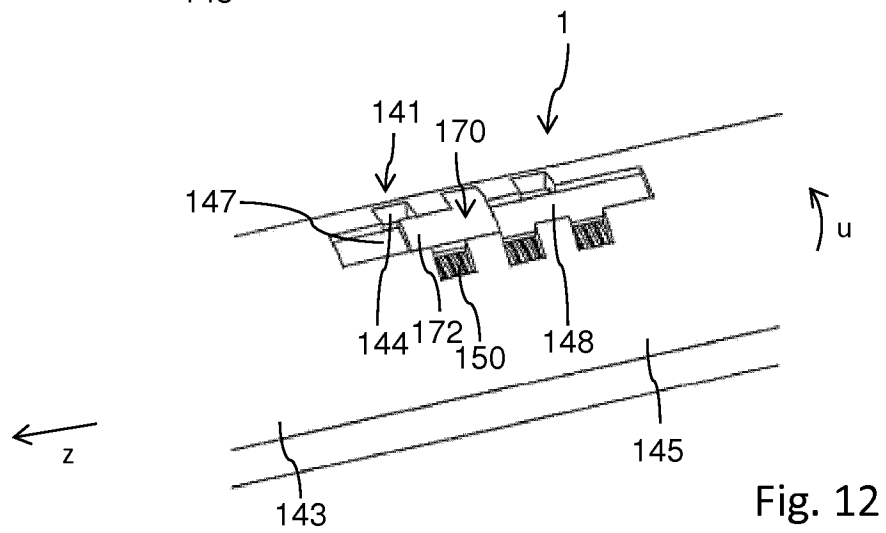
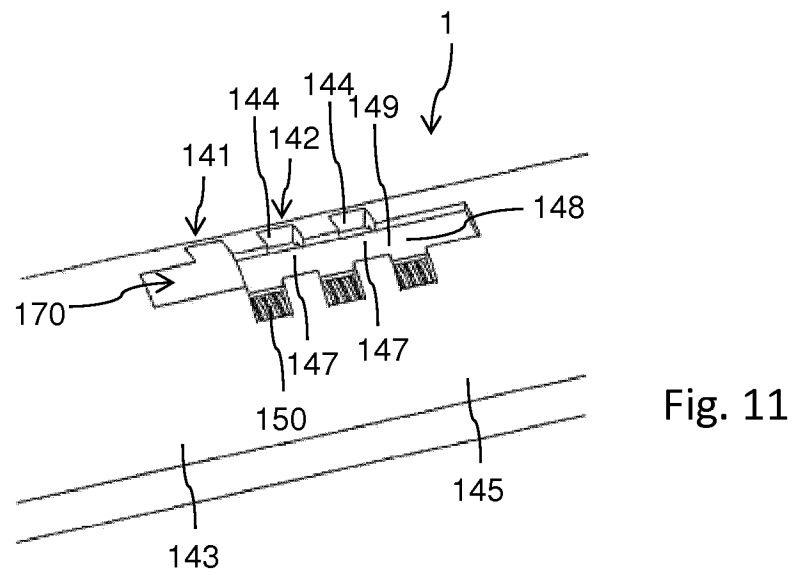
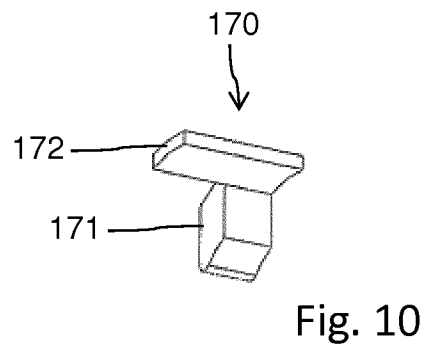
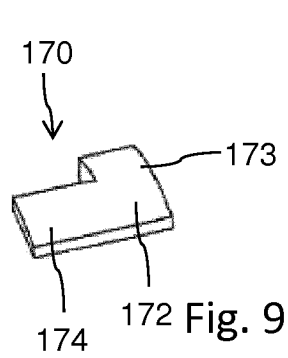


Fig. 8

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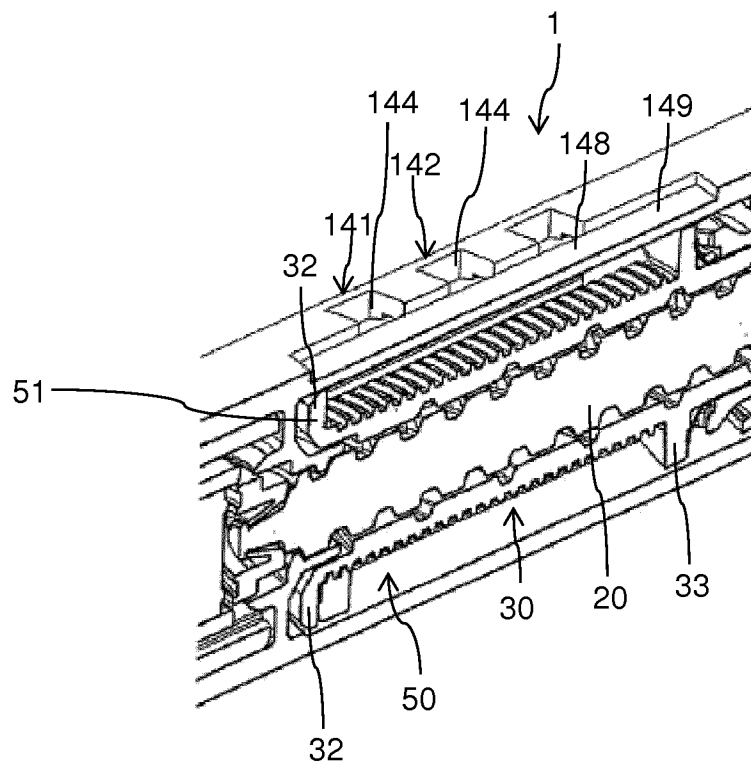


Fig. 13

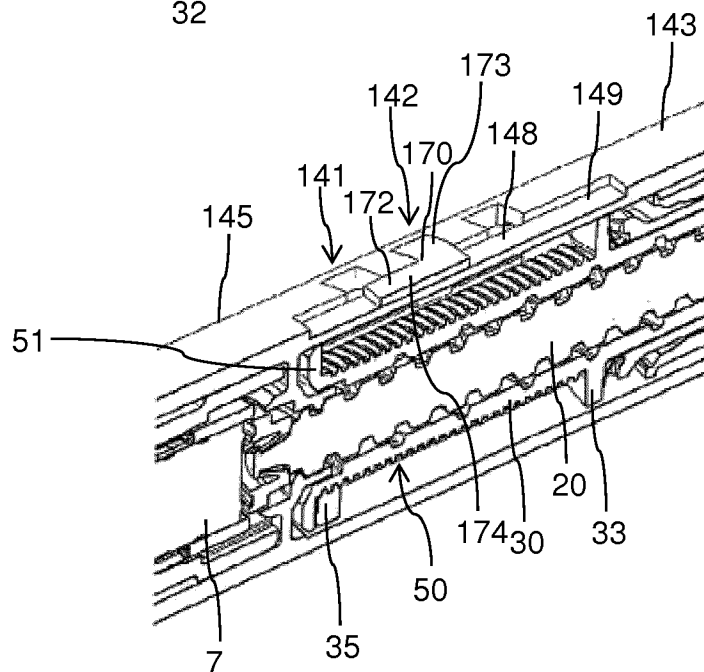


Fig. 14

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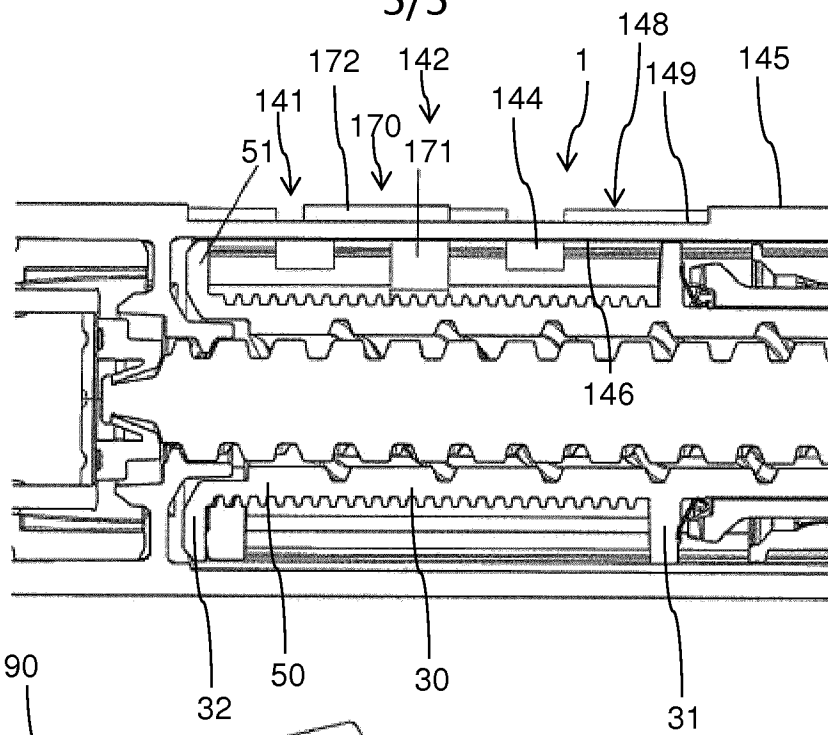


Fig. 15

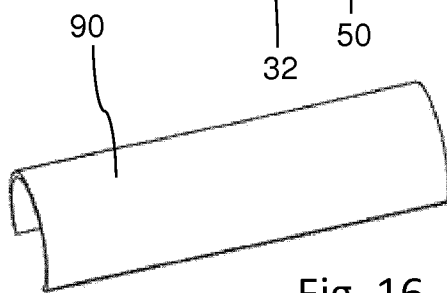


Fig. 16

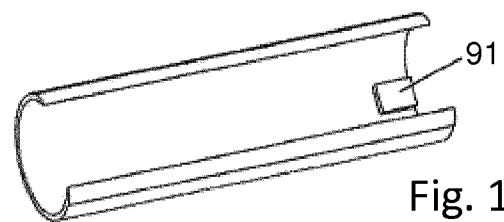


Fig. 17

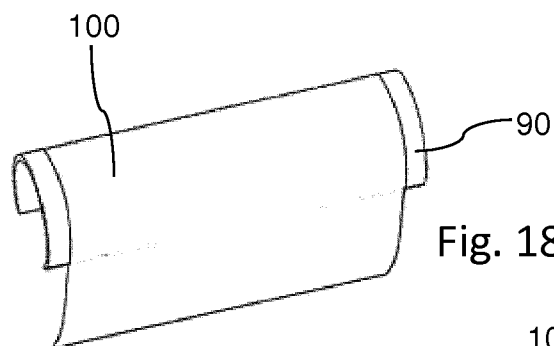


Fig. 18

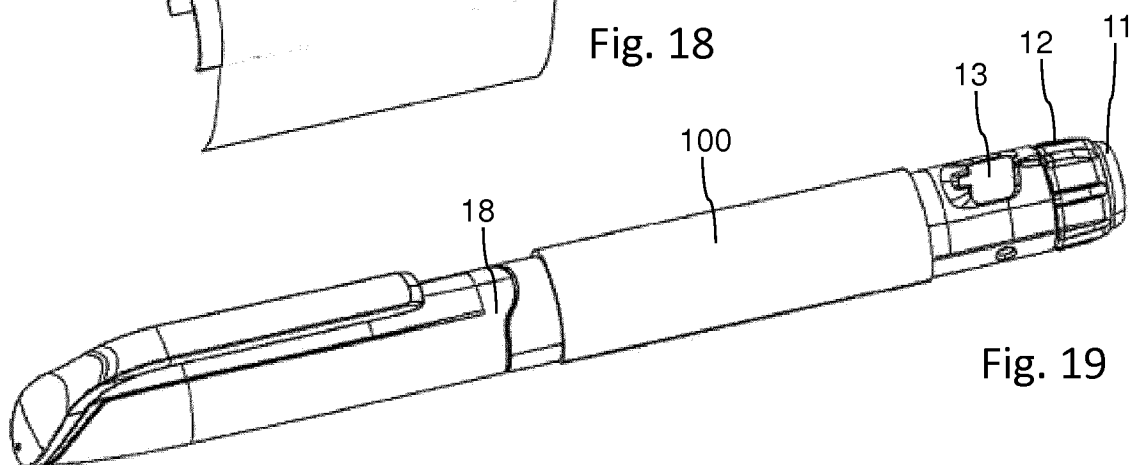


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/080076

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/315
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.
X	US 2011/313365 A1 (WIESELBLAD ANDERS [SE]) 22 December 2011 (2011-12-22) figures 1a - 3 paragraphs [0008], [0026], [0027] -----	1,5-17
X	EP 1 074 273 A1 (BECTON DICKINSON CO [US]) 7 February 2001 (2001-02-07) figures 4a, 4b paragraphs [0018], [0019] -----	1-4, 10-14, 16,17
A	US 2017/259006 A1 (AVERY RICHARD JAMES VINCENT [GB] ET AL) 14 September 2017 (2017-09-14) figure 13 paragraph [0197] -----	1-17



Further documents are listed in the continuation of Box C.



See patent family annex.

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"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

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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

29 November 2018

Date of mailing of the international search report

11/12/2018

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Petersheim, Markus

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2018/080076

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