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Injection devices for wearable devices

(57)

An intra-muscular injection device (100) for injecting a fluid in a person, comprising a container (10) for containing the fluid, a needle (20) for administering the injection, said needle having a hollow core and being in fluid connection with the container (10), a plunger unit (30) being moveable with respect to the container, said plunger unit being mechanically connected to the needle, wherein the combination of the plunger unit (30) and the needle (20) is moveable with respect to the container between at least a first position and a second position, wherein in the first position the needle (20) is in a retracted position at least partially enclosed in the container (10) and wherein in the second position the needle (20) is exposed for injection and wherein upon movement from the first to the second position the fluid is urged from the container into the needle.

Injection devices for wearable devices

The present invention relates to injection devices, in particular compact injection devices for wearable devices, for instance watches or other personal items.

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Prefilled automatic injection devices are known in the art. In particular Epinephrine injection syringes, also called EpiPen, are widely used for treating life-threatening allergic reactions and present themselves in the form of auto-injectors with the shape of a pen. Patients have to carry these injection devices at all time with them. The existing injection devices are bulky and inherently do not cover the risk of not having the injection device at disposal at the crucial moment.

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An object of the invention, next to other objects, is to provide a compact and/or easy to use injection device, in particular capable of being integrated in a wearable device.

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This object, next to other objects, is met by an injection device according to claim 1. Specifically, this is met by an intra-muscular injection device for injecting a fluid in a person, comprising a container for containing the fluid, a needle having a hollow core for administering the fluid by injection, said needle being in fluid connection with the container and a plunger unit being moveable with respect to the container, said plunger unit being mechanically connected to the needle. The combination of the plunger unit and the needle is moveable with respect to the container between at least a first position and a second position, wherein in the first position the needle is in a retracted position at least partially enclosed in the container and wherein in the second position the needle is exposed for injection and wherein upon movement from the first to the second position the fluid is urged from the container into the needle. The incorporation of the needle into the plunger unit creates a compact design which can be partially enclosed inside the container self. The compactness of the solution allows meeting the contrary requirements of a certain length of the needle needed for intra-muscular injection and the inherent size constraints, which may be especially relevant in a wearable device like a watch. The needle may be entirely enclosed in the container depending on the constraints on the needle length versus the quantity of fluid and/or the length of the container.

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According to a preferred embodiment the needle extends from the plunger unit in an injection direction defined by the movement from the first position to the second position. In this way, the plunger is located behind the needle with respect to the injection direction, such that the needle is pushed out of the container while the fluid is compressed in the container. In this way a compact

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solution is created while respecting the constraints of the length of the needle and the quantity of fluid required.

According to a preferred embodiment, the plunger unit, or generally the combination of the needle and the plunger unit, comprises a conduit between the hollow core of the needle and the container, in particular the inside thereof. In this way, the fluid can flow from the container to the interior of the needle when the plunger is moved, such that the container can be emptied and the fluid can be injected.

According to a preferred embodiment, the plunger unit comprises at least a first aperture debouching in the container and at least a second aperture debouching in the hollow core of the needle. A chamber in the plunger may be created while the fluid is pressured inside said chamber by the movement of the plunger inside the container. In this way, the content of the whole container may be injected.

According to a preferred embodiment, the needle comprises a conduit between the hollow core of the needle and the container, in particular the inside thereof. In this way the fluid can flow directly from the container to the hollow core of the needle. The conduit may be an aperture in the needle, preferably extending radially and outwardly between its core and its outside layer. By placing the aperture rather at the base of the needle, close to its connection point to the plunger unit, the content of substantially the whole container may be injected.

According to a preferred embodiment, there is provided a moving mechanism for moving the plunger unit and the needle with respect to the container. In this way, the plunger is moved with respect to the container. The moving mechanism may be included in a common container housing with the container, the plunger and partially the needle or may be an external mechanism mechanically coupled to the container. Preferably the plunger unit is moved in translation with respect to the container, preferably along the inside of the common container housing enclosing the container, the plunger and partially the needle, allowing thus the compression of the fluid inside the container. Alternatively, the container may have its own housing and the plunger unit may be moved in translation with respect to the container to compress the housing of the container to decrease its internal volume.

Preferably the moving mechanism comprises resilient biasing means or mechanism, preferably in the form of a spring member, more preferably a compressed wave spring load. In this way, the compactness of the injection device is further supported by the compactness of the moving mechanism. Alternatively other moving mechanisms like user actuated mechanisms or

electronically actuated mechanisms or gravity actuated mechanism any other well known moving mechanism suitable for that use may be envisaged.

The biasing mechanism is preferably arranged to bias the plunger unit towards the second position.

- 5 Activation of the biasing mechanism then moves the plunger unit towards the second position for injection of the fluid.

According to a preferred embodiment, there is provided an activation mechanism for activating the moving mechanism. In this way the user may trigger the injection by activating the activation
10 mechanism setting in motion the moving means, moving in turn the needle and the plunger unit to inject the fluid. The activating mechanism may for instance comprise a retaining mechanism for retaining the plunger unit in the first position, wherein activation of the activation mechanism may release the plunger unit, which is preferably biased towards the second position. Releasing the plunger unit will then result in movement towards the second position.

15 According to a preferred embodiment, the injection device further comprises a housing, wherein in the first position the needle is entirely enclosed inside said housing. In this position, the needle preferably does not protrude from the housing. In the second position, the needle is exposed for injection outside of said housing. In this way, the internal elements like the needle, the plunger unit
20 and the container are protected from external environmental influences, like shocks and dirt while at the same time the user is protected from accidental puncture when the injection device is not used.

25 According to a preferred embodiment, a needle shield is moveable with respect to the container between a retracted position and a shielded position, said needle shield covering the distal end of the needle when in the shielded position. In this way, a user is protected after injection from accidental puncture by the needle. The needle shield may thereto be provided with suitable
30 engaging members for urging the needle shield towards the shield position upon engagement of the members.

According to a preferred embodiment, the container, the plunger unit and partially the needle are enclosed in a common container housing forming a tubular member extending in the direction of the movement from the first to the second position. Alternatively, the container is a tubular
35 member extending in the direction of the movement from the first to the second position. In this way, the injection device is made as compact as possible taking into account the quantity of fluid needed versus the length of the needle needed.

According to a preferred embodiment, the tubular member has an oval cross section. In this way the container, respectively the common container housing has a reduced dimension on the shorter side of the oval enabling its integration into a wearable device. Alternatively the tubular member may have a rectangular cross section with a shorter side, a circular cross section or a free-form section.

According to a preferred embodiment, in the first position the needle is entirely enclosed in the container. In this way the injection device is made as compact as possible. In addition, a stand alone injection device in which the needle is contained inside the container offers the advantage that such device can be used for vaccine or medication injection in subjects who are afraid for the needle. Using said device, vaccines or medication can be administered while the needle remains invisible for the subject who receives the injection.

According to a preferred embodiment, the injection device further comprises a sealing arrangement for sealing the container and the needle from the outside environment. In this way the fluid in the container and the needle can stay sterile when not used.

According to a preferred embodiment, the sealing arrangement comprises a releasable safety cover covering the distal end of the needle in the first position. In this way the needle and the fluid can stay sterile when the injection device is not used and the container may be filled via the needle prior to placing the safety cover. Preferably, there is provided a safety cover release mechanism for releasing the releasable safety cover. In this way a user may first remove the safety cover prior to starting the injection.

According to a preferred embodiment, the sealing arrangement comprises a closable opening. The closable opening may be a rubber stopper or other closable opening suitable material between the injection side and the skin, which may be punctured by the needle upon activation of the injection. Such a sealing is of particular use on the container in case of a needle entirely enclosed inside the container, but such a sealing could be integrated also in an embodiment with a needle only partially enclosed in the container by placing such a closeable opening on an external housing, for instance the external housing of the watch self. It may further be envisaged to combine the sealings by both a releasable safety cover and a closeable opening for extra safety and hygiene.

According to a preferred embodiment, the sealing arrangement comprises a guiding and sealing element for guiding the needle out of the container and sealing the connection area between the needle and the container. In this way leakages at the connection area between the container and the needle are avoided, while the needle is securely guided, improving the safety of the injection

processs. This sealing may be realised by rubber rings located in and/or outside of the container around the area of connection between the container and the needle during injection.

According to a preferred embodiment, the container further comprises protrusions extending in the container for limiting the movement of the plunger and the needle with respect to the container. In this way the container may not be totally emptied in order to meet legal medical regulations requiring some fluid to be left over. The protrusions extending from the side walls of the container serve as abutment points for the plunger which can not move beyond them in the injection direction. Other means for limiting the range of movement of the plunger in the injection direction may be envisaged like extra biasing means.

According to a preferred embodiment, the plunger further comprises at least one air-outlet opening for filling the container. In this way the container may be easily prefilled. Alternatiely an air-outlet opening may be envisaged in the container.

According to a preferred embodiment there is provided a wearable medical device for administering medication/drug, comprising an injection device described above. The injection device being compact makes it particularly suitable for wearable medical devices for administering emergency medication or drug, like epinephrine in case of an anaphylactic shock, or insulin for diabetic patients.

According to a preferred embodiment, there is provided a watch comprising a wrist band, a display window and an injection device as described above. Preferably the injection direction is in a plane parallel to the plane of a substantially flat surface of the back of the watch or of a substantially flat surface of the front of the display window area. In this way the invention is not intended for injection into the skin in contact with the watch but for injection into another part of the body. Preferably the wristband is arranged to be wrapped around the arm of a person and the injection direction is in a direction orthogonal to said arm direction. In this way the injection site may be for example an upper thigh of the person and the injection may be administered without removing the watch but by abutting directly one side of the watch to a suitable intra-muscular injection site, preferably an easily accessible injection site like the middle part of a thigh.

It is noted that instead of a watch, other wearable devices may be envisaged as possible application fields for the present injection device, for instance any type of wearables incorporated into clothing or worn on the body as accessories.

Although arranged for intramuscular injection, the injection device could be arranged for other type of injections in general, for instance subcutaneous, intradermal or even intravenous injections,

by adapting accordingly the length, and/or diameter of the needle, and/or volume of the container and/or relevant parameters like the direction of injection, the speed of injection among others. The principle of the injection device described here is therefore not limited to intramuscular injection insofar as the concept of a compact device as disclosed here may also be declined accordingly for other types of injection methods.

Alternatively, the device could be arranged to remove a fluid from the body, the container could then be arranged to be empty initially and upon movement from the second to the first position, a fluid could be urged from the body into the container. The plunger unit by moving linearly along the inside of the container in that alternative embodiment would then allow decompressing fluid from the body of a person, i.e. pumping the body fluid into the container.

This and other aspects of the present invention will now be described in more detail, with reference to the appended drawings showing currently preferred embodiments of the invention, wherein:

- Figure 1 illustrates an exploded view of a watch including the injection device;
- Figures 2A to 2C illustrate a longitudinal side view, a transversal cross section view and a top view of an injection device according to an embodiment of the invention;
- Figures 3 to 7 illustrate the successive steps of operation of the injection device in a configuration according to Figure 1 where the elements 700 and 300 have not been represented for the ease of the representation.
- Figure 8 illustrates a schematic drawing of an alternative embodiment to the embodiment of Figures 2A to 2C with a conduit in the needle.
- Figure 9 illustrate a longitudinal side view, a transversal cross section view and a top view of an injection device according to another embodiment of the invention;
- Figure 10 illustrates a transversal cross section of a further embodiment of the invention.

Figure 1 illustrates an exploded view of an intramuscular injection device 100 for injecting a fluid in a person, the device being further incorporated into a watch 1000. The watch 1000 comprises further an external housing and wristband element 200, shock proof foam layers 600 and 700 staggered around the injection device 100 for protecting it against shocks, a safety cover 400, a needle shield 500, a display window 300 that is possibly embodied with a clock function and a battery 800. The external housing and wristband 200 has a compartment 210 combined with an opening 220 for housing several elements (namely the device 100 itself, the safety cover 400 and the needle shield 500), as well as a compartment 260 for the battery 800. Further the external housing and wristband 200 contains a medication window 230 allowing a user to verify the

presence of the medication inside the device 100, activation buttons 240 for activating an injection and safety cover release buttons 250 for releasing a cover around the needle. Further details on these parts will be given in the rest of the description. The watch may be a smart watch provided for instance with a led light notification for drug expire date warning, one or more health care apps, one or more health care apps, an internet connection, apps for artificial intelligence data transfer.

Concerning the fluid contained inside the device 100, it may be a drug, a vaccine or any substance that needs to be administered deep in a muscle to be absorbed into the bloodstream quickly in case of a drug , or to optimize immunogenicity in case of a vaccine. Intramuscular injections are absorbed faster than subcutaneous injections because muscle tissue has a greater blood supply than the tissue under the skin. To reach the necessary depth the needle should have an appropriate length, preferably between 0,5 cm and 4 cm for an adult, and less for a child. Further the diameter of the needle should be selected depending on the fluid to be injected and other circumstances obvious to a skilled person.

The injection device 100 of Figure 1 is further detailed in Figures 2A, 2B and 2C. Figure 2A is a longitudinal side view, Figure 2B is a transversal cross section view and Figure 2C is a top view of the injection device 100 in a first position corresponding to a resting position when the device is not activated by a user, meaning prior to an injection.

Figure 2C shows in particular a container 10 for containing the fluid, and a needle 20 for administering the injection, said needle having a hollow core and being in fluid connection with the container 10. The container 10 is a hermetically closed chamber containing the injectable fluid and provides a sterile and protected environment for the fluid. The needle 20 is suitable for administering the injection as discussed above in terms of its length and diameter. The needle 20 has as usual for injection needles a hollow core and a sharp puncturing end. As mentioned above, the needle 20 is in fluid connection with the container 10, meaning that the hollow core of the needle 20 communicates with the inside of the container 10 and that the fluid from the container 10 can move between the inside of the container 10 and the inside of the hollow core of the needle 20.

The injection device further comprises a plunger unit 30 moveable with respect to the container 10. The plunger unit 30 is also mechanically connected to the needle 20. The mechanical connection between the needle 20 and the plunger unit 30 inhibits any relative movement between the two elements such that the needle 20 is locked to the plunger unit 30. The plunger unit 30 and the needle 20 are fixed together by for instance glue, welding or any other means. The plunger unit 30 can be linearly moved with respect to the container 10. The plunger unit 30 and the container 10 of

Figures 2A, 2B and 2C are further enclosed inside a common container housing 50. The container 10 is then actually a portion of the space containing the fluid inside the common container housing 50, while the plunger unit 30 defines a partition between the container 10 and the rest of the space inside the common container housing 50. In that configuration the plunger unit 30, acting like a piston, further fits tightly within the common container housing 50, acting like a cylinder barrel. In particular the plunger unit 30 can be moved in translation along the inside of the common container housing 50 allowing the compression of the fluid inside the container 10. The container housing remains still in the injection direction, because contained inside the compartment 220 of the external housing and wristband element 200.

Concerning how the fluid connection between the hollow core of the needle and the container is obtained, a first option is disclosed in Figures 2A, 2B and 2C by way of a conduit via apertures 31, 32 and 33 in the plunger unit 30 connecting the hollow core of the needle 20 to the inside of the container 10. In particular as illustrated in Figure 2C the plunger unit 30 has a front wall 36 in contact with the liquid in the container 10, a back wall 37 and a peripheral wall 38 extending between the front wall 36 and the back wall 37. The peripheral wall 38 fits tightly the longitudinal walls of the common container housing 50, while the back wall of the plunger unit is in a plane orthogonal to the injection direction A and to the longitudinal direction of the container 10 when in the first position. A plunger chamber 34 is in this manner defined inside the front wall 36, the back wall 37 and the peripheral walls 38 of the plunger unit. The front wall 36 of the plunger unit 30 comprises two apertures 31 and 32 debouching in the container 10 and at least a second aperture 33 debouching in the hollow core of the needle 20.

As will be explained in the Figures 3 to 7, the combination of the plunger unit 30 and the needle 20 is moveable with respect to the container 10 and the container housing 50 between at least a first initial resting position as defined in Figure 3 and a second injection position as defined in Figure 6. Figures 4 and 5 show intermediate steps of the operation sequence of the injection device for which the plunger unit and the needle are in intermediate positions between the first and the second extreme positions. Figure 7 shows a final step of the operation sequence of the injection device when the injection is finished and the needle shield 500 is ejected.

In the first position of Figures 2A-2C and Figure 3, the needle 20 is in a retracted position at least partially enclosed in the container 10 and more particularly totally enclosed into the housing of the watch 1000. In the first position the needle 20 is actually in its resting position, hidden inside the watch 1000. The first position represents the position, when the needle 20 is retracted at its maximum inside the container 10 and the container housing 50. As illustrated in figure 2C, the

needle 20 has a first portion 21 inside the container 10 and inside the container housing 50 and a second portion 22 including the distal end of the needle outside of the container 10 and outside of the container housing 50. The needle 20 extends beyond the container 10 and container housing 50 into an opening 220 inside the watch 1000. In a specific example the needle has a length of 4cm while the container housing 50 has a length of 3,8cm. In other words the needle is longer than the whole container housing 50 and definitely thus longer than the container 10 inside the container housing 50. In the embodiment shown the portion 21 has a length of 25 cm and the portion 22 a length of 15cm. The ratio between the enclosed length and the total length is thus here 5/8 but other values may of course be selected depending on the circumstances and how compact the device should be. The size of the container 10 and/or the container housing 50 is dimensioned in part by the quantity of the needed fluid from a medical point. Further although not represented sealing means at the connection part between the container housing 50 and the needle 20 are provided to insure that the container 10 stays a sealed chamber.

In the second position as illustrated in Figure 6, the needle 20 is exposed for injection, and extends outside of the watch 1000. The second position represents the extreme limit of the range of movement of the needle 20, when the needle is extended at its maximum outside the container 10 and the container housing 50. Upon movement from the first to the second position, not only is the needle 20 moved into an injection position but simultaneously the fluid is urged from the container 10 into the needle 20 via the conduit created by the apertures 31 to 33.

As further illustrated in Figure 2C, the needle 20 is locked into the plunger unit 30 by connecting elements 35 and extends from the plunger unit 30 in an injection direction A defined by the movement from the first position to the second position. The injection direction A extends in a longitudinal direction of the container 10 and the container housing 50. The axis A defined by the needle is parallel to a symmetry axis of the container and the plunger, and the needle 20 is decentred from the axis of symmetry of the plunger unit 30 and/or the container 10.

As explained above the plunger unit 30 has a conduit formed by apertures between the hollow core of the needle 20 and the container 10. In this manner upon movement of the plunger unit 30, the surface of the front wall 36 in contact with the inside of the container 10 compresses the fluid in the container 10 such that said fluid is pushed, urged, into the apertures 31 and 32 towards the internal chamber 34 of the plunger unit 30, and from the internal chamber 34 into the second aperture 33 towards the hollow core of the needle 20. In this way upon movement from the first to the second position, the necessary quantity of fluid for injection is transferred from the container 10 to the body of the person via the chamber 34 inside the plunger unit 30 and the needle 20.

Figure 8 shows an alternative watch 2000 where, the needle 20 comprises a conduit connecting the hollow core of the needle 20 to the inside of the container 10. The conduit is for instance an aperture 25 in the needle 20 extending radially and outwardly between its core and its outside layer. In this way upon movement of the plunger unit 30, the fluid is compressed in the container 10 and urged into the aperture 25 inside the needle 20 towards the hollow core of the needle. Again upon movement from the first to the second position, the necessary quantity of fluid for injection is transferred thus from the container 10 to the body of the person. In that case the plunger unit 30 may be a solid plunger wall, and by placing the aperture 25 of the conduit rather at the base of the needle 20, close to the connection means 35 at the connection point to the plunger unit 30, the container 10 may be almost completely emptied. By insuring that the full content of the container can be injected, the container 10 may be made as small as the minimum necessary quantity of fluid and the compactness of the design is further increased.

Figures 9A-9C show another injection device 100 where the needle 20 is entirely enclosed inside the container 10. Similar references as for the embodiment of Figures 2A-2C will be used for similar elements in Figures 9A-9C. Figure 9A is a longitudinal side view, Figure 9B is a transversal cross section view and Figure 9C is a top view of the injection device 100 in a first position corresponding to a resting position when the device is not activated by a user, meaning prior to an injection.

It is noted that an injection device in which the needle is contained inside the container offers the advantage that such device can be used for vaccine or medication injection in subjects who are afraid for the needle. Using said device as a stand alone device, vaccines or medication can be administered while the needle remains invisible for the subject who receives the injection.

In the embodiment of Figures 9A-9C, the needle 20 is entirely enclosed in the container 10 and guided during the injection by a guiding and sealing element 70 through a closeable opening 60. The closeable opening 60 may be an internal or external closable opening (e.g. a rubber stopper or other closable opening suitable material) which is punctured by the needle upon activation of the injection. The closeable opening 60 may also be used for filling the container. Further the guiding and sealing element 70 may be a rubber ring fixed to the wall of the container housing 50 and fit tight around the needle 20 insuring the sealing of the connection area between the container 10 and the needle 20 as well as the guiding of the needle 20 during injection. The element 70 may also be used in embodiments with a needle only partially enclosed and in that case even duplicated on each side (internal and external) of the wall of the container 50 to increase the guidance and the sealing properties. In Figures 9A and 9C, two protrusions 91 and 92 extend in the container 10 from the peripheral wall of the container housing 50 and limit the movement of the plunger 30 and

the needle 20 with respect to the container 10. In this way the container may not be totally emptied in order to meet legal medical regulations requiring some fluid to be left over for control. The protrusions 91 and 92 serve as abutment points for the plunger which can not move beyond these points in the injection direction. Although shown here for an embodiment with a needle entirely enclosed, protrusions for limiting the movement of the plunger may also be used in embodiments with a needle only partially enclosed. Further an air-outlet opening 80 may be provided in the back wall 37 of the plunger 30 to enable filling the container 10. Although shown here for an embodiment with a needle entirely enclosed, an air-outlet opening may also be used in embodiments with a needle only partially enclosed.

Attention will now be directed towards the moving mechanism 40 provided for moving the plunger unit 30 and the needle 20 with respect to the container 10 and the container housing 50. As illustrated in Figures 2A till 8, the moving mechanism 40 is also included in the container housing 50. The moving mechanism 40 comprises resilient biasing means, in particular a compressed wave spring load. This type of actuator is compact, sufficiently powerful to administer the injection, reliable and can be manually actuated. It is noted that the compactness of the injection device is further supported by the compactness of this moving mechanism as it can also be integrated in the container. The compressed wave spring load 40 is abutted to the bottom surface 51 of the common container 50, the bottom surface 51 of the common container housing being substantially orthogonal to the injection direction A and orthogonal to the longitudinal direction of the container 10 and of the common container housing 50. The spring load 40 is further mechanically connected to the back wall 37 of the plunger unit 30. When released the spring load 40 will transmit a translation movement in the injection direction A to the plunger unit 30 and to the needle 20. Figures 4, 5 and 6 illustrate the different steps of the release of the spring load 40 and the related movement of the plunger 30 and needle 20 with respect to the container 10.

An activation mechanism for activating the moving mechanism 40 is present in the injection device. In particular two activation buttons 240 are provided on each side of the external housing and/or wristband 200 of the watch 1000 for simultaneous pressure and secure activation of the injection.

As already shown, the watch 1000 is such that in the first position the needle is entirely enclosed inside the housing of the watch 1000, and that in the second position, the needle 20 is exposed for injection outside of said housing. The external housing and/or wristband element 200 of Figure 1 includes a compartment 210 for housing the common container housing 50 and an opening 220 for housing the portion 22 of the distal end of the needle 20 that is never enclosed in the container housing 50. The opening 220 extends longitudinally in the injection direction A from the compartment 210 mentioned above. Further is present a releasable safety cover (400) covering the

distal end of the needle 20 when in the first position. The releasable safety cover 400 needs to be removed prior to injection as illustrated in Figure 4. This safety cover 400 has a tubular member 410 closed at one end to form a cap fitting around the needle 20 and sealing the opening 220 from the outside world such that the injection device 100 is totally enclosed inside the watch when not in use. The safety cover 400 insures in particular that the needle end, and as such the fluid inside the container, stays sterile when not used. A safety cover release mechanism 250 is further present for releasing the releasable safety cover 400. The safety cover release mechanism 250 includes for example two side buttons actuated by simultaneous pressure for removal of the cover 400. The removal of the safety cover 400 is illustrated in Figure 5 where the T shaped safety cover 4000 comprising a tubular member 410 and two side arms 420 is removed in the injection direction A. Although not represented spring means for facilitating the ejection may be envisaged.

A further element is presented in the exploded view of Figure 1, the needle shield 500. The needle shield 500 is moveable with respect to the container 10 between a retracted position and a shielded position, and covers a distal portion of the needle 20 when in the shielded position.. The operation of that element will now be explained particularly in relation with Figure 7 showing the step of the ejection of the needle shield 500 after the injection has occurred. The needle shield 500 is for example a tubular element 510 with two legs 520 extending further in the tube direction. In Figure 3 the needle shield is in its retracted position partially in the opening 220 and partially above the container 50 inside the compartment 210, while enclosing the needle 20.

The movement from the retracted position to the shielded position amounts to a translation inside the opening 210 of the housing. The displacement of the needle shield 500 may be realised by resilient biasing means, or other latching mechanisms.

The container housing 50 is a tubular member extending in the direction of the movement A from the first to the second position. The tubular member represented in the drawings of Figures 2A-2C, and Figures 9A-9C has an oval cross section such that the container housing has a reduced dimension on the shorter side of the oval enabling its integration into a wearable device. Due to the thinness of the injection device 100 in the short direction of the oval, the device 100 can be easily integrated in a watch 1000 under the display window 300. The tubular member may also have a cylinder shape with a circular cross section as illustrated in Figure 10. Although not all combinations have been explicitly shown, a skilled person would understand that any cross section shape, whether oval, circular or other, may be chosen without restriction to whether a needle is entirely or partially enclosed in the container.

In the case of a watch 1000 comprising an external housing and/or wrist band 200, a display window 300 and an injection device 100, the injection direction A is preferably in a plane parallel to the plane of a substantially flat surface of the front or the back of the display window area. The

injection direction A is directed thus towards the side of the watch and not the back of the watch, where the display window 300 defines a front side for display of time or other information to the person wearing the watch. The wristband 200 being arranged to be wrapped around the arm of a person, the injection direction is also preferably in a direction orthogonal to said arm direction B, giving the option to position the wrist and thus the watch in immediate contact and orientate the injection direction A orthogonally to the injection site for immediate administration of the injection. In this way the carrier of the watch 1000 may inject himself in the thigh for instance or somebody else in a suitable injection site without removing the wristband 200, by abutting the watch 1000 with the strength of the arm to the injection site. The injection device may be particularly interesting for emergency injections.

Whilst the principles of the invention have been set out above in connection with specific embodiments, it is understood that this description is merely made by way of example and not as a limitation of the scope of protection which is determined by the appended claims.

Conclusies

1. Intramusculair injectie-inrichting (100) voor het injecteren van een fluïdum bij een persoon, omvattende

- 5 - een container (10) voor het bevatten van het fluïdum,
- een naald (20) voor het toedienen van het fluïdum door middel van injectie, waarbij de naald een holle kern heeft en die in fluïdumverbinding staat met de container (10),
- een plunjereenheid (30) die beweegbaar is ten opzichte van de container, waarbij de plunjereenheid mechanisch is verbonden met de naald,
- 10 - waarbij de combinatie van de plunjereenheid (30) en de naald (20) ten opzichte van de container beweegbaar is tussen ten minste een eerste positie en een tweede positie, waarbij in de eerste positie de naald (20) in een ingetrokken positie ten minste gedeeltelijk is omsloten in de container (10) en waarbij in de tweede positie de naald (20) wordt blootgesteld voor injectie en waarbij bij het bewegen van de eerste naar de tweede positie, het fluïdum uit de container in de
- 15 naald wordt gedwongen.

2. Injectie-inrichting volgens conclusie 1, waarbij de naald (20) zich uitstrekt van de plunjereenheid in een injectierichting (A) die is gedefinieerd door de beweging van de eerste positie naar de tweede positie.

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3. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, waarbij de plunjereenheid (30) een leiding (31, 32, 33) omvat tussen de holle kern van de naald en de container.

- 25 4. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, waarbij de plunjereenheid (30) ten minste een eerste opening (31, 32) omvat die uitmondt in de container en ten minste een tweede opening (33) die uitmondt in de holle kern van de naald.

- 5. Injectie-inrichting volgens ten minste één van de conclusies 1 en 2, waarbij de naald (20) een
- 30 leiding (25) omvat tussen de holle kern van de naald (20) en de container (10).

6. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, verder omvattende een bewegingsmechanisme (40) voor het bewegen van de plunjereenheid (30) en de naald (20) ten opzichte van de container (10).

35

7. Injectie-inrichting volgens de voorgaande conclusie, waarbij het bewegingsmechanisme (40) veerkrachtige voorspanmiddelen omvat.

5 8. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, verder omvattende een activeringsmechanisme (240) voor het activeren van het bewegingsmechanisme.

9. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, verder omvattende een behuizing (200-700), waarbij in de eerste positie de naald (20) geheel is omsloten binnen de behuizing (200-700), en waarbij in de tweede positie de naald (20) wordt blootgesteld voor injectie
10 buiten de behuizing.

10. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, verder omvattende een naaldschild (500) die beweegbaar is ten opzichte van de container (10) tussen een ingetrokken positie en een afgeschermd positie, waarbij het naaldschild (500) het distale uiteinde van de naald
15 (20) afdekt in de afgeschermd positie.

11. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, waarbij de container (10), de plunjereenheid (20) en ten minste gedeeltelijk de naald (20) zijn omsloten in een gemeenschappelijke containerbehuizing (50) die een buisvormig orgaan vormt dat zich uitstrekt in
20 de richting (A) van de beweging van de eerste naar de tweede positie.

12. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, waarbij de container (10) een buisvormig orgaan is dat zich uitstrekt in de richting (A) van de beweging van de eerste naar de tweede positie.

25

13. Injectie-inrichting volgens conclusie 14 of 15, waarbij het buisvormige orgaan (10, 50) een ovale dwarsdoorsnede heeft.

14. Injectie-inrichting volgens conclusie 14 of 15, waarbij het buisvormige orgaan (10, 50) een
30 cirkelvormige dwarsdoorsnede heeft.

15. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, waarbij in de eerste positie de naald (20) geheel omsloten is in de container (10).

16. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, verder omvattende een afdichtingsopstelling (60, 70 400) voor het van de buitenomgeving afdichten van de container (10) en de naald (20).

5 17. Injectie-inrichting volgens de voorgaande conclusie, waarbij de afdichtingsopstelling (60, 70, 400) een verwijderbare veiligheidsafdekking (400) omvat die het distale uiteinde van de naald (20) in de eerste positie afdekt.

10 18. Injectie-inrichting volgens de voorgaande conclusie, verder omvattende een veiligheidsafdekking -ontgrendelingsmechanisme (250) voor het vrijgeven van de verwijderbare veiligheidsafdekking (400).

19. Injectie-inrichting volgens ten minste één van de conclusies 16-18, waarbij de afdichtingsopstelling (60, 70, 400) een afsluitbare opening (60) omvat.

15 20. Injectie-inrichting volgens ten minste één van de conclusies 16-19, waarbij de afdichtingsopstelling (60,70,400) een geleidings- en afdichtelement (70) omvat voor het uit de container (10) geleiden van de naald (20) en het afdichten van het verbingsgebied tussen de naald (20) en de container (10).

20 21. Injectie-inrichting volgens ten minste één van de voorgaande conclusies, waarbij de container (10) verder uitsteeksels (91, 92) omvat die zich in de container uitstrekken voor het beperken van de beweging van de plunjer (30) en de naald (20) ten opzichte van de container. Een injectie-inrichting volgens één van de voorgaande conclusies, waarbij de plunjer (30) verder ten minste één
25 luchttuitlaat-opening (80) omvat voor het vullen van de container (10).

22. Draagbare medische inrichting (1000) voor het toedienen van medicatie/medicijn, omvattende een injectie-inrichting (100) volgens ten minste één van de voorgaande conclusies

30 23. Horloge (1000) omvattende een polsband (200), een kijkvenster (300) en een injectie-inrichting (100) volgens ten minste één van de conclusies 1-15.

24. Horloge (1000) volgens de voorgaande conclusie, waarbij de injectierichting (A) is voorzien in een vlak parallel aan het vlak van een in hoofdzaak vlak oppervlak van de achterzijde van het
35 horloge of van een in hoofdzaak vlak oppervlak van de voorzijde van het kijkvenster-(300)-gebied.

25. Horloge volgens ten minste één van de conclusies 17 of 18, waarbij het polsbandje (200) is ingericht om rond de arm van een persoon te worden gewikkeld en de injectierichting (A) in een richting is die orthogonaal is ten opzichte van die armrichting (B).

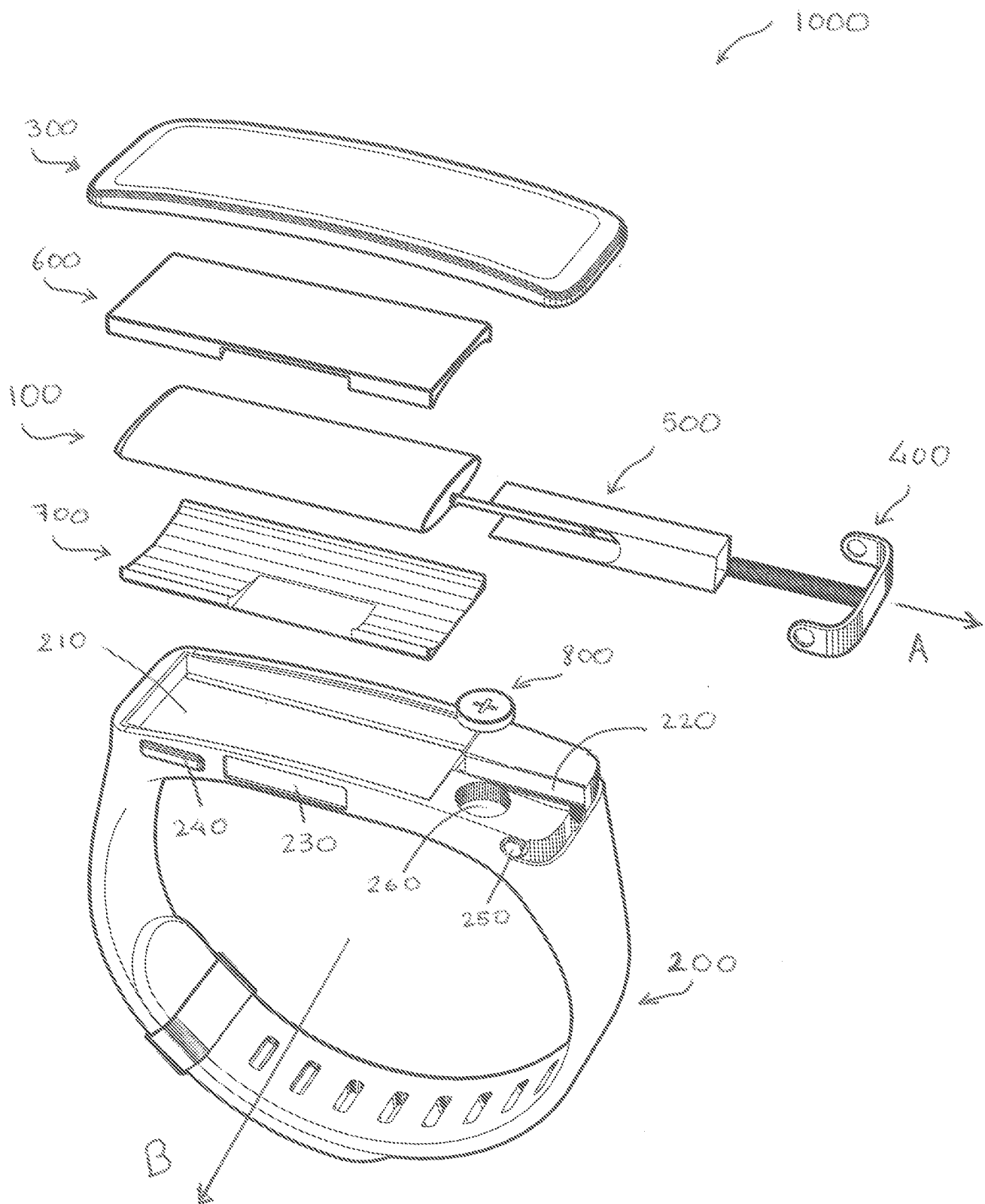


Figure 1

Figure 2A

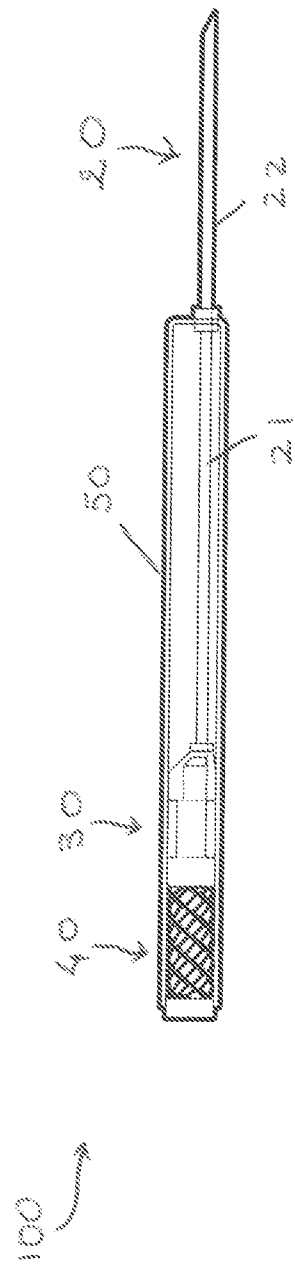


Figure 2B

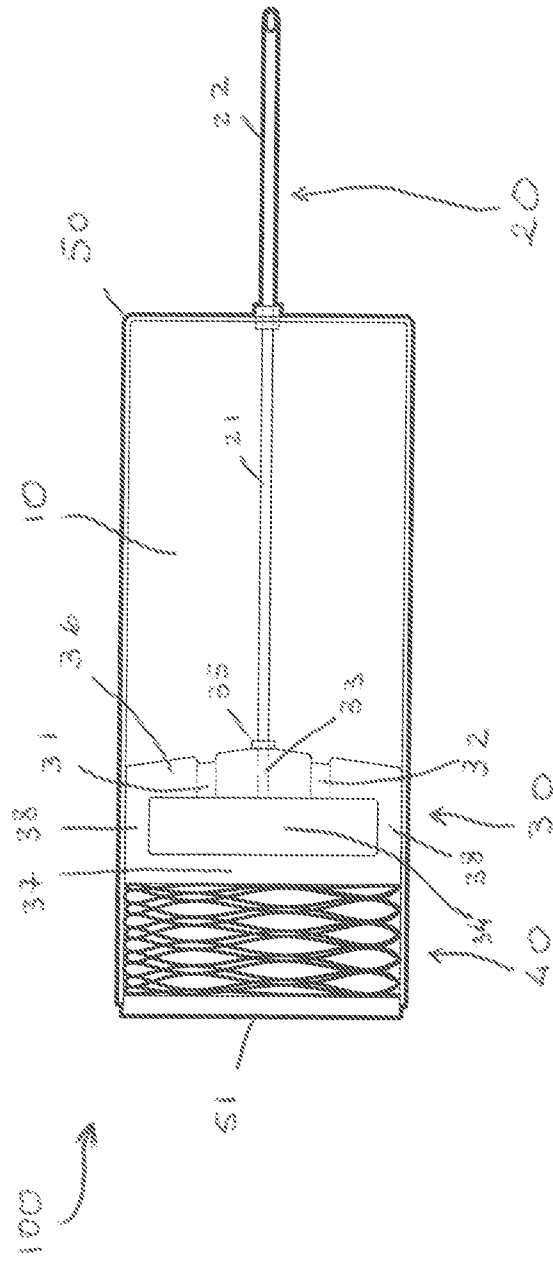
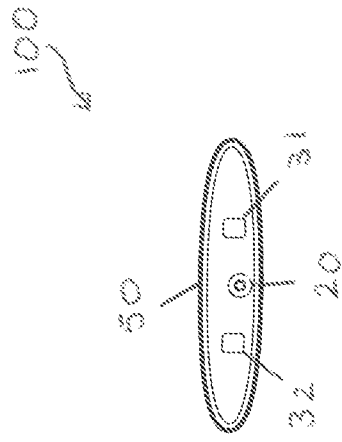


Figure 2C

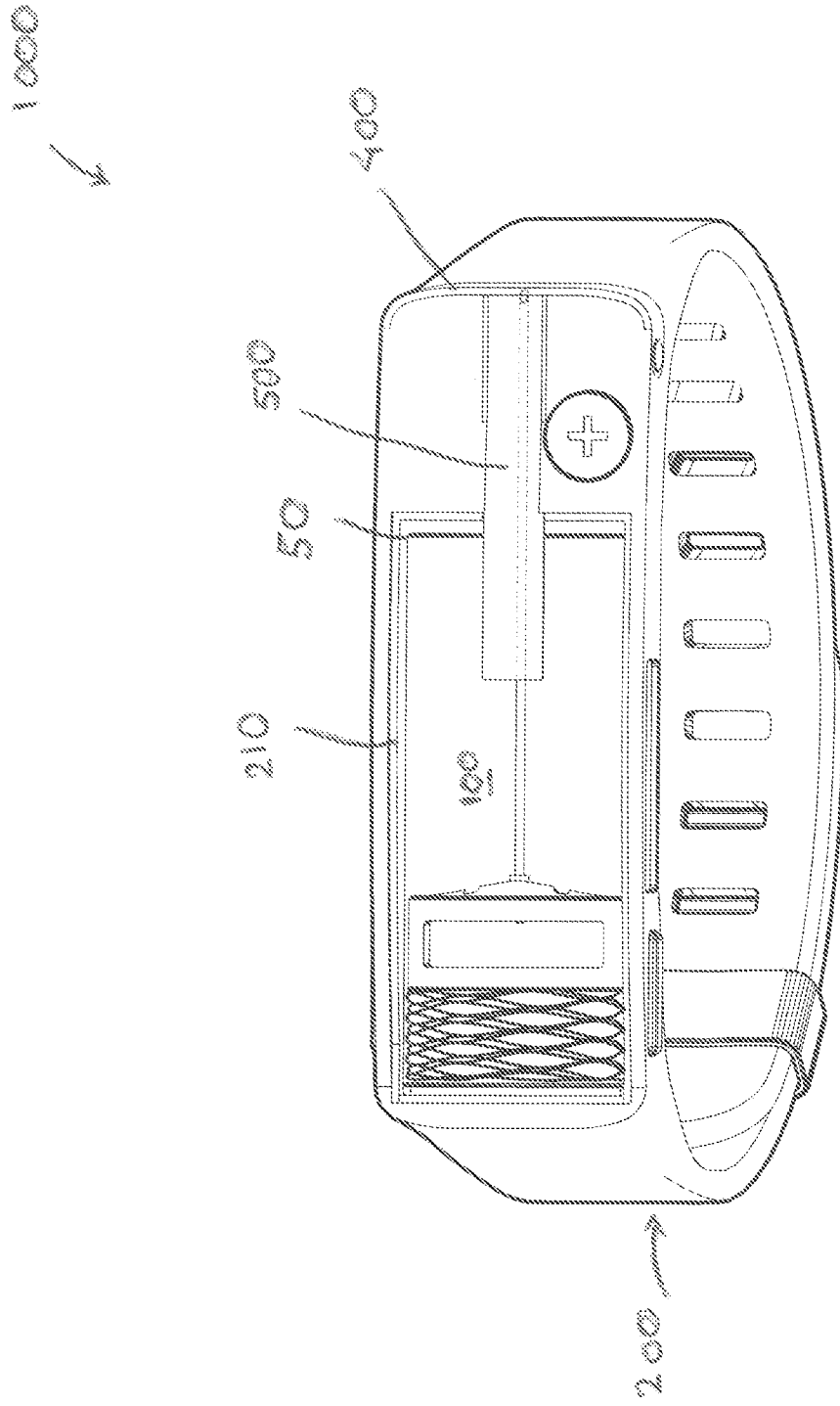


Figure 3

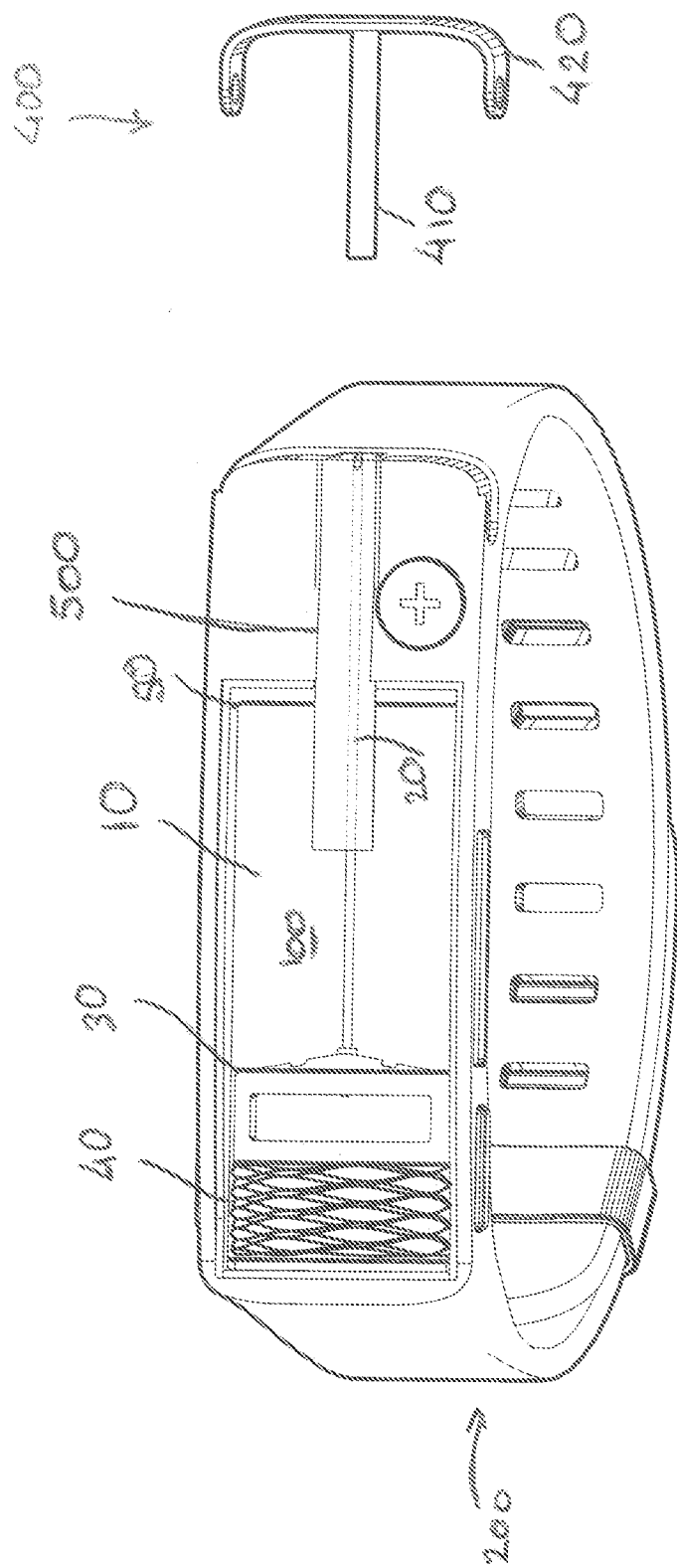


Figure 4

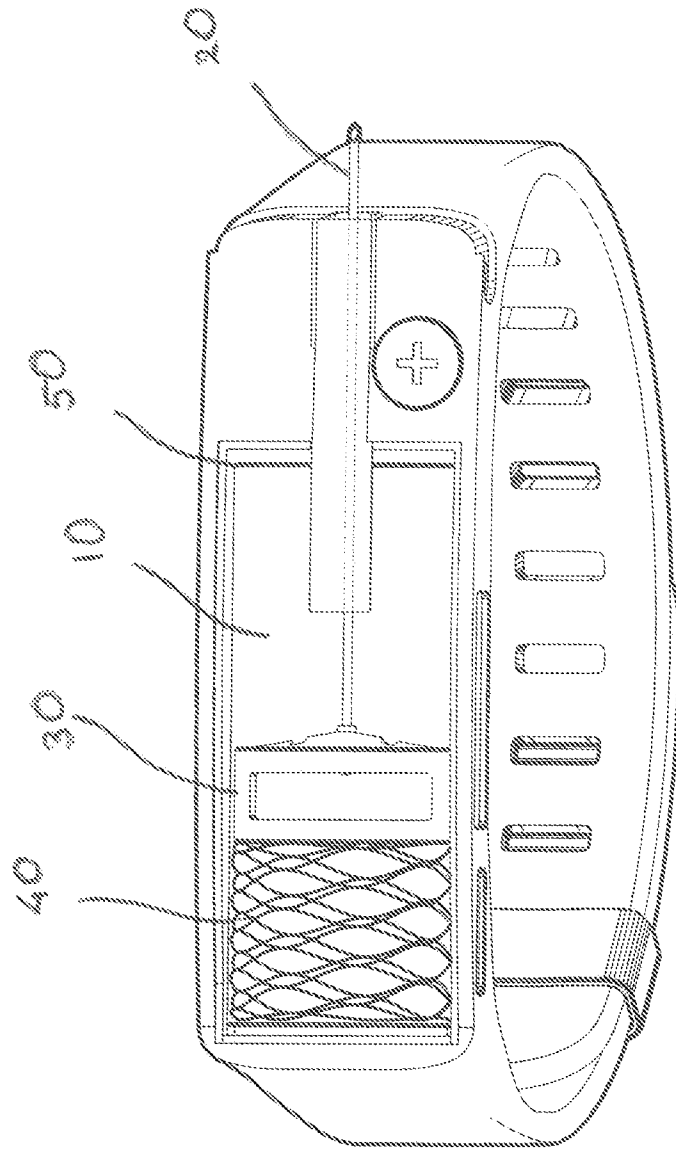


Figure 5

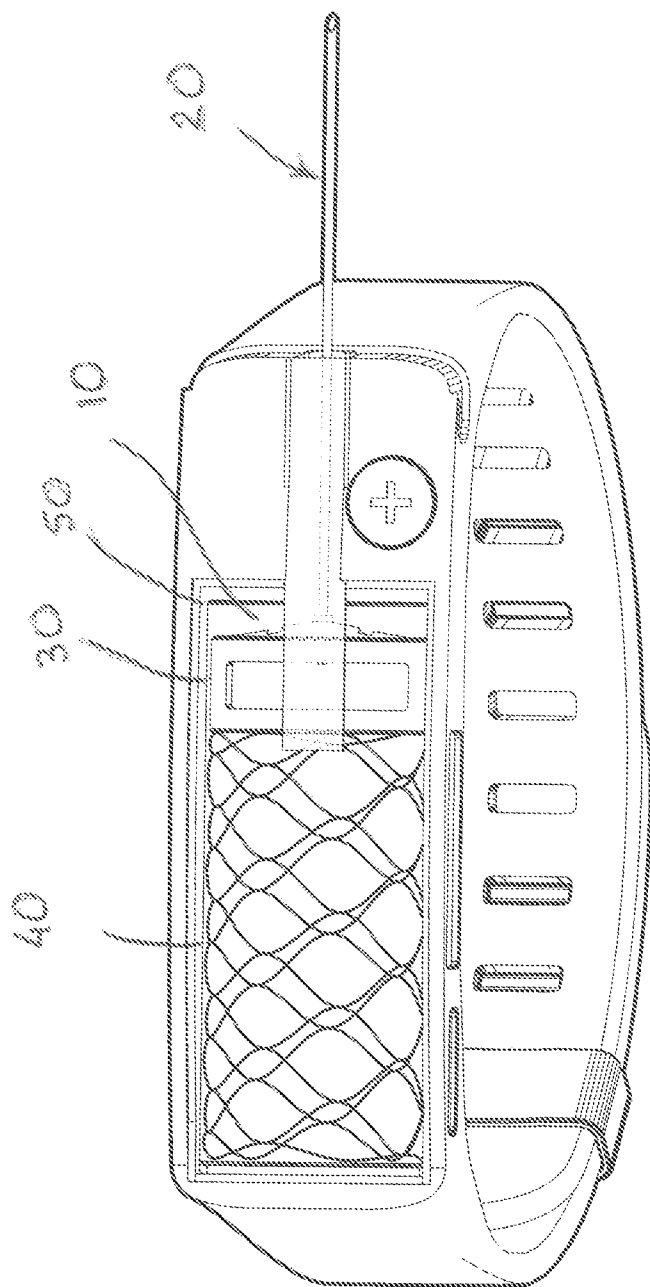


Figure 6

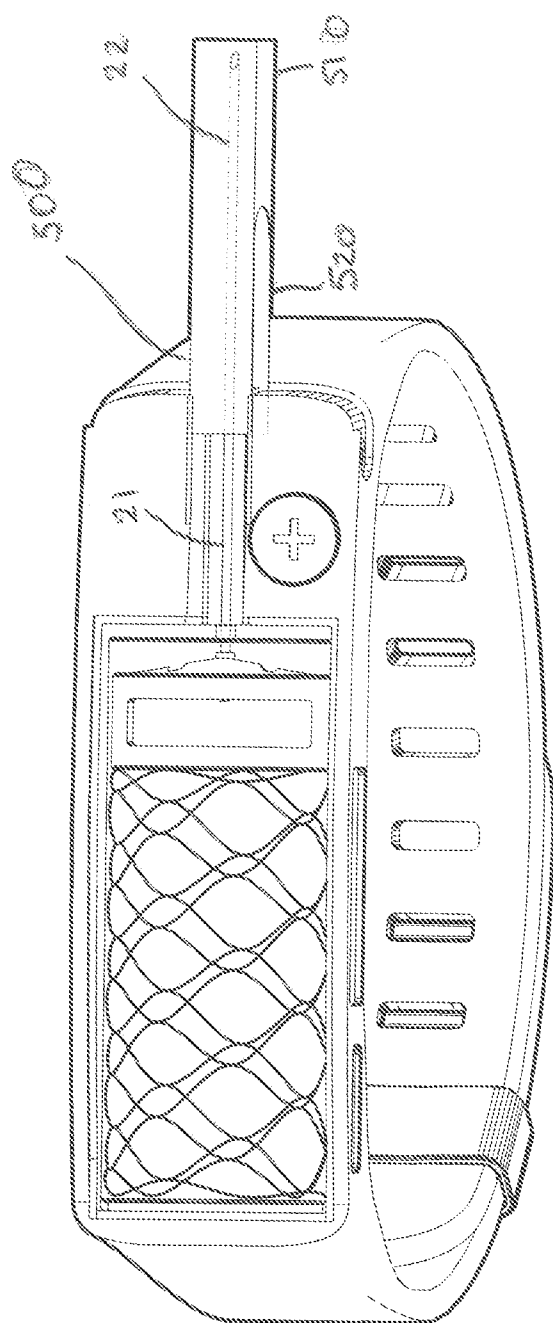


Figure 7

2000

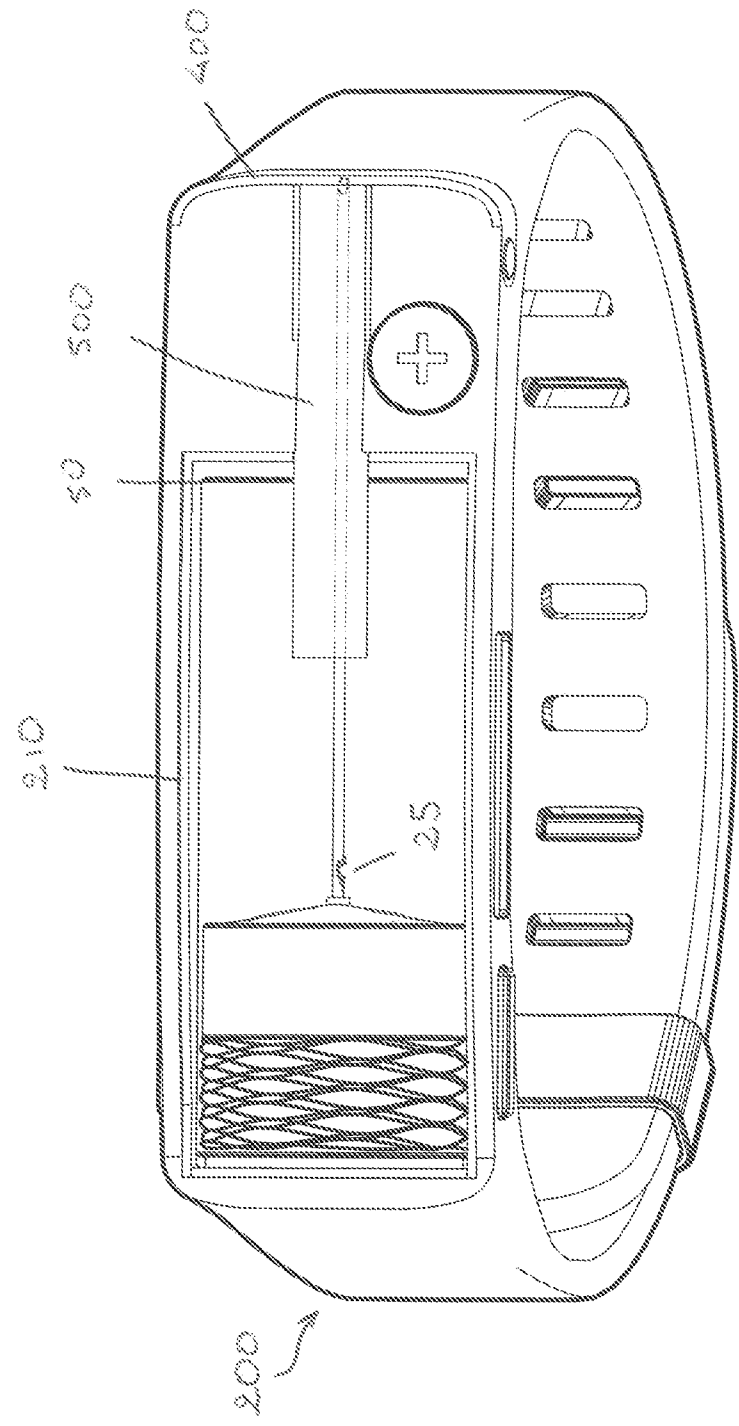


Figure 8

Figure 3A

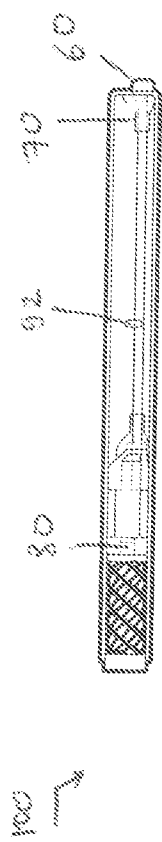


Figure 3B

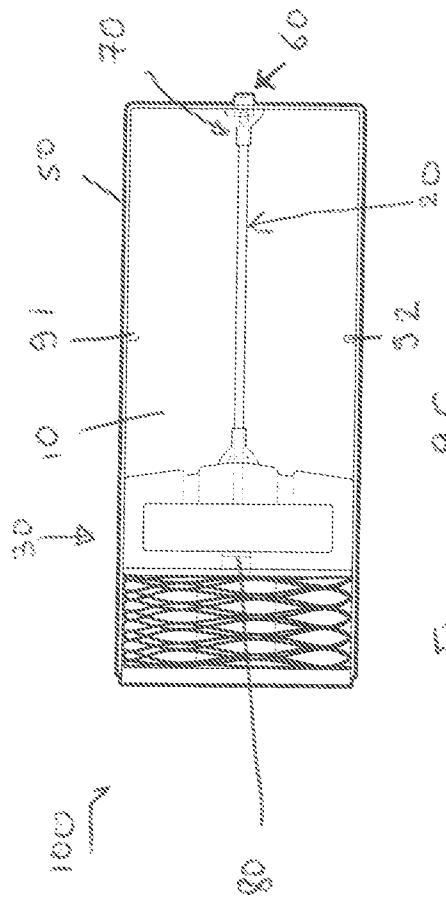
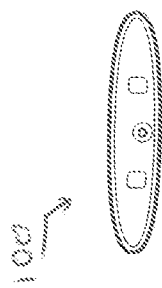
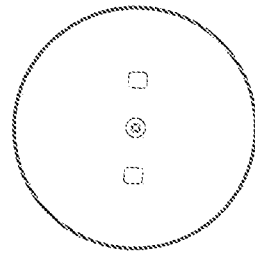


Figure 9C

Figure 10



SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	2T/P168981NL00
Nederlands aanvraag nr.	Indieningsdatum
2024968	21-02-2020
	Ingeroepen voorrangsdatum
Aanvrager (Naam)	
Amber Hélène Tamara Witteman	
Datum van het verzoek voor een onderzoek van internationaal type	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr.
11-07-2020	SN76504
I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)	
Volgens de internationale classificatie (IPC)	
Zie onderzoeksrapport	
II. ONDERZOCHE GEBIEDEN VAN DE TECHNIEK	
Onderzochte minimumdocumentatie	
Classificatiesysteem	Classificatiesymbolen
IPC	Zie onderzoeksrapport
Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen	
III. ☐	GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES (opmerkingen op aanvullingsblad)
IV. ☐	GEBREK AAN EENHEID VAN UITVINDING (opmerkingen op aanvullingsblad)

**ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Nummer van het verzoek om een onderzoek naar
de stand van de techniek
NL 2024968

A. CLASSIFICATIE VAN HET ONDERWERP INV. A61M5/32 A61M5/34 A61M5/142 ADD. A61M5/31 A61M5/315 A61M5/145																							
Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.																							
B. ONDERZOCHETE GEBIEDEN VAN DE TECHNIEK Onderzochte minimum documentatie (classificatie gevolgd door classificatiesymbolen) A61M																							
Onderzochte andere documentatie dan de minimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen																							
Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden) EPO-Internal, WPI Data																							
C. VAN BELANG GEACHTE DOCUMENTEN <table border="1"> <thead> <tr> <th>Categorie °</th> <th>Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages</th> <th>Van belang voor conclusie nr.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>WO 2014/096957 A2 (IINJEC TECHNOLOGIES INC [CA]) 26 juni 2014 (2014-06-26)</td> <td>1-21</td> </tr> <tr> <td>Y</td> <td>* alinea [00099] - alinea [000135]; figuren 1-29 *</td> <td>22-25</td> </tr> <tr> <td>Y</td> <td>----- US 2 605 765 A (PAUL KOLLSMAN) 5 augustus 1952 (1952-08-05) * kolom 7 - kolom 8; figuren 1-9 *</td> <td>22-25</td> </tr> <tr> <td>A</td> <td>----- US 2019/143042 A1 (HUGHES II PETER J [US]) 16 mei 2019 (2019-05-16) * het gehele document *</td> <td>1-25</td> </tr> <tr> <td>A</td> <td>----- WO 03/099358 A2 (SEEDLINGS LIFE SCIENCE VENTURE [US]) 4 december 2003 (2003-12-04) * het gehele document *</td> <td>1-25</td> </tr> <tr> <td></td> <td>----- -/-</td> <td></td> </tr> </tbody> </table>			Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.	X	WO 2014/096957 A2 (IINJEC TECHNOLOGIES INC [CA]) 26 juni 2014 (2014-06-26)	1-21	Y	* alinea [00099] - alinea [000135]; figuren 1-29 *	22-25	Y	----- US 2 605 765 A (PAUL KOLLSMAN) 5 augustus 1952 (1952-08-05) * kolom 7 - kolom 8; figuren 1-9 *	22-25	A	----- US 2019/143042 A1 (HUGHES II PETER J [US]) 16 mei 2019 (2019-05-16) * het gehele document *	1-25	A	----- WO 03/099358 A2 (SEEDLINGS LIFE SCIENCE VENTURE [US]) 4 december 2003 (2003-12-04) * het gehele document *	1-25		----- -/-	
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A	----- WO 03/099358 A2 (SEEDLINGS LIFE SCIENCE VENTURE [US]) 4 december 2003 (2003-12-04) * het gehele document *	1-25																					
	----- -/-																						
☒ Verdere documenten worden vermeld in het vervolg van vak C. ☒ Leden van dezelfde octrooifamilie zijn vermeld in een bijlage																							
° Speciale categorieën van aangehaalde documenten "A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft "D" in de octrooiaanvraag vermeld "E" eerdere octrooi(aanvraag), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven "L" om andere redenen vermelde literatuur "O" niet-schriftelijke stand van de techniek "P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur																							
"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvraag, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding "X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur "Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht "&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie																							
Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid		Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type																					
25 augustus 2020																							
Naam en adres van de instantie European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		De bevoegde ambtenaar																					
		Preller, D																					

ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar
de stand van de techniek
NL 2024968

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN		
Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	US 3 797 491 A (HURSCHMAN A) 19 maart 1974 (1974-03-19) * het gehele document * -----	1-25

**ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar
de stand van de techniek

NL 2024968

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
WO 2014096957	A2	26-06-2014	
		AU 2013366011 A1	28-05-2015
		AU 2018220025 A1	06-09-2018
		BR 112015010607 A2	05-12-2017
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		EP 2916893 A2	16-09-2015
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		JP 6603742 B2	06-11-2019
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		AT 354391 T	15-03-2007
		AU 2003239400 A1	12-12-2003
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		DE 60311988 T2	06-12-2007
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		EP 1782854 A2	09-05-2007
		EP 3006065 A1	13-04-2016
		ES 2282636 T3	16-10-2007
		ES 2562782 T3	08-03-2016
		US 6979316 B1	27-12-2005
		US 2005171477 A1	04-08-2005
		WO 03099358 A2	04-12-2003

US 3797491	A	19-03-1974	GEEN

WRITTEN OPINION

File No. SN76504	Filing date (<i>day/month/year</i>) 21.02.2020	Priority date (<i>day/month/year</i>)	Application No. NL2024968
International Patent Classification (IPC) INV. A61M5/32 A61M5/34 A61M5/142 ADD. A61M5/31 A61M5/315 A61M5/145			
Applicant Amber H��l��ne Tamara Witteman			

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the application
- ☒ Box No. VIII Certain observations on the application

	Examiner Preller, D
--	-------------------------------

WRITTEN OPINION

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the application as filed.
 - ☐ filed together with the application in electronic form.
 - ☐ furnished subsequently for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes: Claims	8-25
	No: Claims	1-7
Inventive step	Yes: Claims	
	No: Claims	1-25
Industrial applicability	Yes: Claims	1-25
	No: Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Application number
NL2024968

Box No. VIII Certain observations on the application

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 Reference is made to the following documents:
- D1 WO 2014/096957 A2 (IINJEC TECHNOLOGIES INC [CA])
26 juni 2014 (2014-06-26)
 - D2 US 2 605 765 A (PAUL KOLLSMAN)
5 augustus 1952 (1952-08-05)
 - D3 US 2019/143042 A1 (HUGHES II PETER J [US])
16 mei 2019 (2019-05-16)
 - D4 WO 03/099358 A2 (SEEDLINGS LIFE SCIENCE VENTURE [US])
4 december 2003 (2003-12-04)
 - D5 US 3 797 491 A (HURSCHMAN A) 19 maart 1974 (1974-03-19)
- 2 The present application does not meet the criteria of patentability, because the subject-matter of claim 1 is not new.
- 2.1 Document **D1** discloses (references in round brackets refer to D1; original claim wording is given in square brackets):
- An intra-muscular injection device (240) for injecting a fluid in a person (cf. Figs. 7 and 8), comprising [*intramusculair injectie-inrichting voor het injecteren van een fluïdum bij een persoon, omvattende*]
- a container (244, 245) for containing the fluid (see par. [000113]: "A plunger 246 slides within the barrel 244 defining a reservoir between the end wall 245 and the distal end of the plunger 246.") [*een container voor het bevatten van het fluïdum*],
- a needle (250) for administering the injection, said needle having a hollow core (260) and being in fluid connection with the container (244, 245) [*een naald voor het toedienen van het fluïdum door middel van injectie, waarbij de naald een holle kern heeft en die in fluïdumverbinding staat met de container*],
- a plunger unit (246) being moveable with respect to the container (244, 245), said plunger unit (246) being mechanically connected to the needle (250) [*een plunjereenheid die beweegbaar is ten opzichte van de container, waarbij de plunjereenheid mechanisch is verbonden met de naald*],

wherein the combination of the plunger unit (246) and the needle (250) is moveable with respect to the container (244, 245) between at least a first position and a second position [*waarbij de combinatie van de plunjereenheid en de naald ten opzichte van de container beweegbaar is tussen ten minste een eerste positie en een tweede positie*],

wherein in the first position the needle (250) is in a retracted position at least partially enclosed in the container (244, 245) (see in Fig. 8) and wherein in the second position the needle (250) is exposed for injection (see in par. [000116]: "In operation, when it is required to inject a vaccine or drug into a patient, the end wall 245 of the syringe 242 is applied to the skin of the patient and pressure is applied to the press plate 248 thus advancing the needle 250 through the septum 264 and the skin of the patient. As the plunger 246 advances, the sleeve 272 will be stretched and the liquid drug within the reservoir will expand the membrane 266 within the annular cavity 264. The pressure applied by the membrane 266 on the liquid forces the drug through the ports 256, the bore 260 of the needle 250 and into the patient.") [*waarbij in de eerste positie de naald in een ingetrokken positie ten minste gedeeltelijk is omsloten in de container en waarbij in de tweede positie de naald wordt blootgesteld voor injectie*]

and wherein upon movement from the first to the second position the fluid is urged from the container (244, 245) into the needle (250) (via ports in the needle in this embodiment, see par. [000115]: "The needle 250 includes ports 256 within the confines of the expansion chamber 252 for communicating the drug from the reservoir to the bore 260 of needle 250") [*en waarbij bij het bewegen van de eerste naar de tweede positie, het fluïdum uit de container in de naald wordt gedwongen*].

2.2 Hence, the subject-matter of claim 1 is not new over **D1**.

3 The features of claims 2-25 are known from the cited prior art or at least obvious in view thereof, as assessed in the following (note also the citations in the search report for further details).

3.1 In view of the needle movement of **D1** (see in section 3 above), also the features of **claim 2** are not new.

3.2 Regarding the underlying working principle of expelling fluid from the container, the following is noted. Reference is made to further embodiments in **D1**, where the working principle of expelling fluid from the chamber is the basically the same as discussed above, but the fluid is not drawn through ports in the needle,

- but through channels/ports in the plunger unit, see e.g. the embodiment according to Fig. 4A. Hence, also the features of **claims 3 and 4** are anticipated by **D1**.
- 3.3 The needle feature of **claim 5** have been demonstrated already by the citations in section 3 above.
- 3.4 As to **claims 6 and 7**, a respective *bewegingsmechanisme* (40) is disclosed in D1 for the same purpose by the spring-like sleeve 272, which according to D1, par. [000115] "may be of an elastomeric material acting as an energy storage device" used as pre-tensioned biasing element for expelling fluid through the needle.
- 3.5 The features of **claim 8** appear trivial in view of D1, since with a pre-tensioned biasing element a respective trigger arrangement is usually even mandatory. The features of **claim 9** appear to lie within the scope of customary practice followed by the skilled person without exercising inventive skill.
- 3.6 As to **claim 10**, reference is made to the needle protective plug 264 of D1.
- 3.7 Regarding **claims 11-21**, the features defined therein appear to refer merely to slight constructional change in the device(s) of the foregoing claims, coming within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Particularly since basic workmanship principles are defined therein such as selecting amongst design options, sealing fluid conduits at necessary locations, enclosing/extending a needle, etc.
- 3.8 Regarding **claims 22-25**, the principle of providing a wrist watch with an automatic syringe having an injection needle is already widely known in the art, see e.g. document **D2**, particularly Figs. 7 and 9. A combination of **D1** and **D2** would be obvious for the skilled person attempting to provide a wearable and somewhat appealing injection device, just as suggested in **D2**.

Re Item VIII

Certain observations on the application

- 4 Claim 1 does not meet the requirement of clarity because the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

Namely, according to claim 1 the needle (*naald voor het toedienen van het fluïdum door middel van injectie*) and the plunger unit (*plunjereenheid die beweegbaar is ten opzichte van de container*) are and remain mechanically connected to each other (*waarbij de plunjereenheid mechanisch is verbonden met de naald*), and in particular, upon movement from the first to the second position the fluid is urged from the container into the needle (*bij het bewegen van de eerste naar de tweede positie, het fluïdum uit de container in de naald wordt gedwongen*). However, since the needle and the plunger unit are connected with each other and a relative movement between these two items is not expected or foreseen, **it remains unclear how** the fluid can be urged from the container upon movement of the combined needle and plunger unit.

Indeed, **essential features** for defining the invention are lacking in claim 1, which are explained in the description in a limiting manner, and should be reflected in the claim:

1. the fluid apparently is arranged between the plunger unit 30 and the proximal wall, such that the needle is embedded in the fluid in the "first position" according to claim 1; and
2. the fluid connection between the hollow core of the needle and the container is provided by specific features of the plunger unit involving apertures 31, 32, 33, chamber 34, and the walls 36, 37, 38, see on page 8 of the description.