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(54) Title: SKIN-MOUNTABLE MEDICAL DEVICE

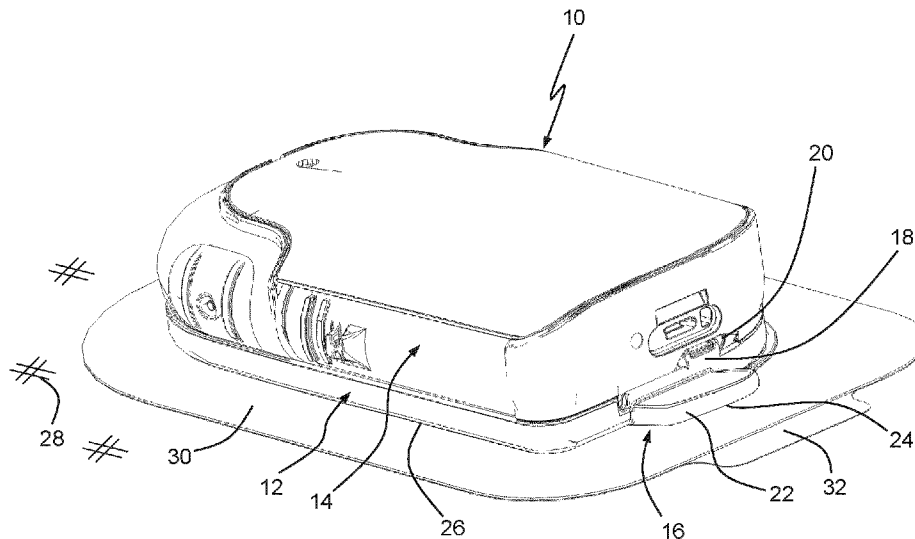


Fig. 1

(57) Abstract: The invention concerns a skin-mountable medical device (10) comprising a mounting plate (12) having a bottom side (26) attachable to the skin of a user, a medical module (14), in particular an analyte sensing device or a drug administration pump, and a snap connector (16) adapted to releasably attach the medical module (14) on the upper side (34) of the mounting plate (12), wherein the snap connector (16) has a release flap (16) that can be actuated by the user to detach the medical module (14), and the release flap (16) projects outwardly from the mounting plate (12) and at its bottom side (26) maintains a clearance (24) to avoid an interfering skin contact in use.

MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
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- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*
- *of inventorship (Rule 4.17(iv))*

Published:

- *with international search report (Art. 21(3))*
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Skin-mountable medical device**Description**

The invention relates to a skin-mountable medical
5 device comprising a mounting plate having a bottom side
attachable to the skin of a user preferably via an
adhesive pad, a medical module, in particular an
analyte sensing device or a drug administration pump,
and a snap connector adapted to releasably attach the
10 medical module on the upper side of the mounting plate
opposite to the bottom side.

Such medical device is known from WO 2009/125398 A2.
There, the device comprises a skin-adherable cradle
15 unit and a fluid dispensing unit, wherein the cradle
unit has two latches and the dispensing unit is snap-
fitted by operation of the latches 32, 34. For this
purpose, the latches are configured as hook-like
protrusions which are accommodated in complementary
20 shaped grooves of the dispensing unit. However, WO
2009/125398 A2 fails to disclose details for user
handling of the latches, and the latches appear
susceptible to breakage upon insertion of the
dispensing unit. Such breaking connections may lead to
25 a loss of the medical device, which may even go
unnoticed by the patient.

On this basis, the object of the invention is to
further improve the known medical devices and to

provide an easy-to-use design which simplifies user manipulation while avoiding assembly failures.

The combination of features stated in the independent
5 claim is proposed to achieve this object. Advantageous embodiments and further developments of the invention are derived from the dependent claims.

The invention is based on the idea of improving user
10 interaction by avoiding interfering contours or contact in the mechanical movement paths. Accordingly, it is proposed that wherein the snap connector has a release flap that can be actuated or pushed by the user to detach the medical module, wherein the release flap
15 projects outwardly from the mounting plate and has an outer portion which at its bottom side maintains a clearance to avoid an interfering skin contact when used or pressed. In this way, the release flap is allowed to move prior to a skin contact, and the user
20 is prevented from applying excessive forces against a skin abutment which may lead to material failure. Moreover, the effort and force for insertion of the medical module is reduced, as no movable part of the snap connector comes into skin contact, thus also
25 avoiding a bending or deformation of the mounting plate. As a result, the user-device-interaction is improved, and the intended medical success is further supported.

Advantageously, where the bottom side of the mounting plate lies in a plane or is generally planar, the outer portion of the release flap should be arranged at a clearance distance of at least 2 mm, preferably at least 5 mm above this plane. In this way, there is provided sufficient tolerance for unimpeded movement of the flap.

In another advantageous configuration, where the release flap has an inner portion connected to the mounting plate, the distance of the inner portion to a plane which is defined by the bottom side of the mounting plate (or, in use, by the skin) should be smaller than the distance of the outer portion to said plane.

In this connection it is further advantageous when the bottom sides of the mounting plate and of the release flap each define a plane, and wherein said planes include an acute angle.

Preferably, said acute angle is at least 5° , preferably at least 10° .

In another advantageous embodiment, the bottom side of the release flap runs parallel to the bottom side of the mounting plate. In such a parallel configuration, the release flap may be directly attached to an upstanding part of a latch of the snap connector.

A particular advantageous embodiment further comprises that the release flap has an upstanding circumferential rim which in use faces away from the skin. Thereby, the user receives a haptic feedback when pressing his
5 finger against the flap. Furthermore, the rim facing upwards avoids unintended slipping of the finger and thereby supports higher pressing forces.

In an advantageous embodiment, the snap connector has a
10 latch that is connected to the mounting plate and engages with the medical module in a locking position, wherein the latch can be tilted outward by actuation of the release flap so as to disengage from the medical module in a release position.

15 For providing a mechanically secure connection, the latch has a hook portion which is adapted to snap into a recess of the medical module.

20 In order to support the application of the medical module onto the mounting plate, the snap connector has an inlet chamfer which is construed to guide the medical module into a locking position, wherein the inlet chamfer is arranged at an acute angle with
25 respect to the bottom side of the mounting plate.

Another possibility for facilitating handling and improving joining provides that a securing bracket is provided for attaching the medical module, wherein the

securing bracket and the snap connector are arranged at opposite ends of the mounting plate.

In still another advantageous configuration, the
5 mounting plate and the release flap are formed as an integral, preferably injection-moulded plastic part.

The medical device according to any of claims 1 to 12,
In an advantageous configuration for drug
10 administration, a fitting can be arranged on the bottom plate to provide a skin access preferably for a cannula assembly of the medical module.

In the following, the invention is further elucidated
15 on the basis of embodiment examples shown schematically in the drawings, where

Fig. 1 is a perspective view of a body-wearable
medical device including a mounting base with
20 an improved release mechanism;

Fig. 2 is a perspective view of the medical device of
fig. 1;

25 Fig. 3 is an enlarged view of the release mechanism of the medical device; and

Fig. 4 is a side view of the mounting base with a
further embodiment of the release mechanism.
30

Referring to fig. 1, a medical device 10 comprises a mounting base or plate 12, a medical module 14 in the form of a body-worn patch pump for administration of insulin and a release mechanism formed as a snap connector 16 which is adapted to releasably attach the medical module 14 on the mounting plate 12 e.g. for first time assembly or removal in case of temporarily non-use or replacement. For this purpose, the snap connector 16 comprises a latch 18 that engages with a recess or notch 20 in a sidewall of the medical module 14 and a release tap or flap 22 that can be pushed down by the user or patient into a bottom free space or clearance 24 such that the flap 22 is allowed to move prior to a skin contact.

The mounting plate 12 has a bottom side 26 which is attachable at an infusion site to the skin 28 of the user via a self-adhesive pad 30 which is protected on its adhesive side by a peel-off foil 32.

As can be seen best in fig. 2, the mounting plate 12 has a top or upper side 34 which in use faces away from the skin 28 and supports the medical module 14. The latch 18 and a securing hook or bracket 36 are provided at opposite ends of the oblong mounting plate 12 as upstanding elements on the upper side 34. An upstanding hollow fitting or socket 38 provides skin access for a cannula assembly (not shown).

At the joining area of the latch 18, the flap 22 is moulded onto the edge of the mounting plate 12, such that it projects outwardly and is tilted upwards away from the skin 28, as will be explained in more detail
5 below. Advantageously, the flap 22 has a flat base portion 40 and an upstanding circumferential rim 42 on the free outer edge of the base portion facing away from the skin 28.

10 The mounting plate 12 including its attached elements, 18,22,36,38 may be formed as an integral one-piece plastic part, e.g. by injection-moulding.

As further illustrated in fig. 3, the outer portion 44
15 of the release flap 22 maintains at its bottom side clearance 24, such that the release flap 22 is allowed to move under a force implied by finger pressure without interference, thus avoiding contact to the skin 28 or the self-adhesive pad 30 arranged thereupon.

20 Then, the outer clearance distance to a plane 46 defined by the skin 28 (or, coinciding therewith, defined by the flat bottom side 26 of the mounting plate 12) should be about 5 mm, when viewed in direction perpendicular to the plane 46.

25

Fig. 3 further illustrates that the latch 18 has a hook portion 50 which is adapted to snap into the recess 20 of the medical module 14. The hook portion 50 is provided with an inlet chamfer 52 which guides the
30 medical module 14 when introduced into the shown

locking position. For this purpose, the inlet chamfer 52 is arranged at an acute angle with respect to the bottom side 26 of the mounting plate 12. For removal of the medical module 14, the latch 18 can be tilted
5 outward (to the right in fig. 3) by actuation of the release flap 22 so as to disengage from the recess 20 in a release position.

In the embodiment of fig. 3, in order to allow a
10 movement prior to an interfering skin contact, the distance of the connecting portion 48 of the flap 22 to the plane 46 should be smaller than the distance of the outer portion 44 to said plane 46. This can be realized arranging the flat bottom side 54 of the flap 22 under
15 an acute angle α with respect to the skin 28 or plane 46. Preferably, said angle α is above 5° , e.g. around 10° .

In the embodiment of fig. 4, similar parts are
20 indicated with similar reference signs as explained above. The main difference is in the arrangement of the release flap 22, which in this case on its bottom side runs at a distance parallel to the bottom side 26 of the mounting plate 12, thus maintain a free space with
25 a constant clearance 24. In this configuration, the release flap 22 may be directly attached to the upstanding section of the latch 18.

Patent Claims

1. Skin-mountable medical device comprising:
a mounting plate (12) having a bottom side (26)
5 attachable to the skin of a user preferably via an
adhesive pad (30),
a medical module (14), in particular an analyte
sensing device or a drug administration pump,
a snap connector (16) adapted to releasably attach
10 the medical module (14) on the upper side (34) of the
mounting plate (12) opposite to the bottom side (26),
wherein the snap connector (16) has a release flap
(16) that can be actuated by the user to detach the
medical module (14),
15 and the release flap (16) projects outwardly from the
mounting plate (12) and has an outer portion (44)
which at its bottom side (26) maintains a clearance
(24) to avoid an interfering contact in use.
- 20 2. The medical device of claim 1, wherein the bottom
side (26) of the mounting plate (12) lies in a plane
(46), and the outer portion (44) of the release flap
(16) is arranged at a clearance distance of at least
2 mm, preferably at least 5 mm above the plane (46).
25
3. The medical device of claim 1 or 2, wherein the
release flap (16) has an inner portion (48) connected
to the mounting plate (12), and the distance of the
inner portion to a plane (46) which is defined by the
30 bottom side (26) of the mounting plate (12) is

smaller than the distance of the outer portion (44) to said plane (46).

4. The medical device according to any of claims 1 to 3,
5 wherein the bottom sides (26,54) of the mounting plate (12) and of the release flap (16) each define a plane, and wherein said planes (46) include an acute angle (α).
- 10 5. The medical device of claim 4, wherein said acute angle (α) is at least 5° , preferably at least 10° .
6. The medical device of claim 1 or 2, wherein the
15 bottom side (54) of the release flap (16) runs parallel to the bottom side (26) of the mounting plate (12).
7. The medical device according to any of claims 1 to 6,
20 wherein the release flap (16) has an upstanding circumferential rim (42) which in use faces away from the skin.
8. The medical device according to any of claims 1 to 7,
25 wherein the snap connector (16) has a latch (18) that is connected to the mounting plate (12) and engages with the medical module (14) in a locking position, and wherein the latch (18) can be tilted outward by actuation of the release flap (16) so as to disengage from the medical module (14) in a release position.

30

9. The medical device of claim 9, wherein the latch (18) has a hook portion (50) which is adapted to snap into a recess (20) of the medical module (14).
- 5 10. The medical device according to any of claims 1 to 9, wherein the snap connector (16) has an inlet chamfer (52) which is construed to guide the medical module (14) into a locking position, wherein the inlet chamfer (52) is arranged at an acute angle with
10 respect to the bottom side (26) of the mounting plate (12).
11. The medical device according to any of claims 1 to 10, further comprising a securing bracket (36) for
15 attaching the medical module (14), wherein the securing bracket (36) and the snap connector (16) are arranged at opposite ends of the mounting plate (12).
12. The medical device according to any of claims 1 to
20 11, wherein the mounting plate (12) and the release flap (16) are formed as an integral, preferably injection-moulded plastic part.
13. The medical device according to any of claims 1 to
25 12, further comprising a fitting (38) arranged on the bottom plate to provide a skin access preferably for a cannula assembly of the medical module (14).

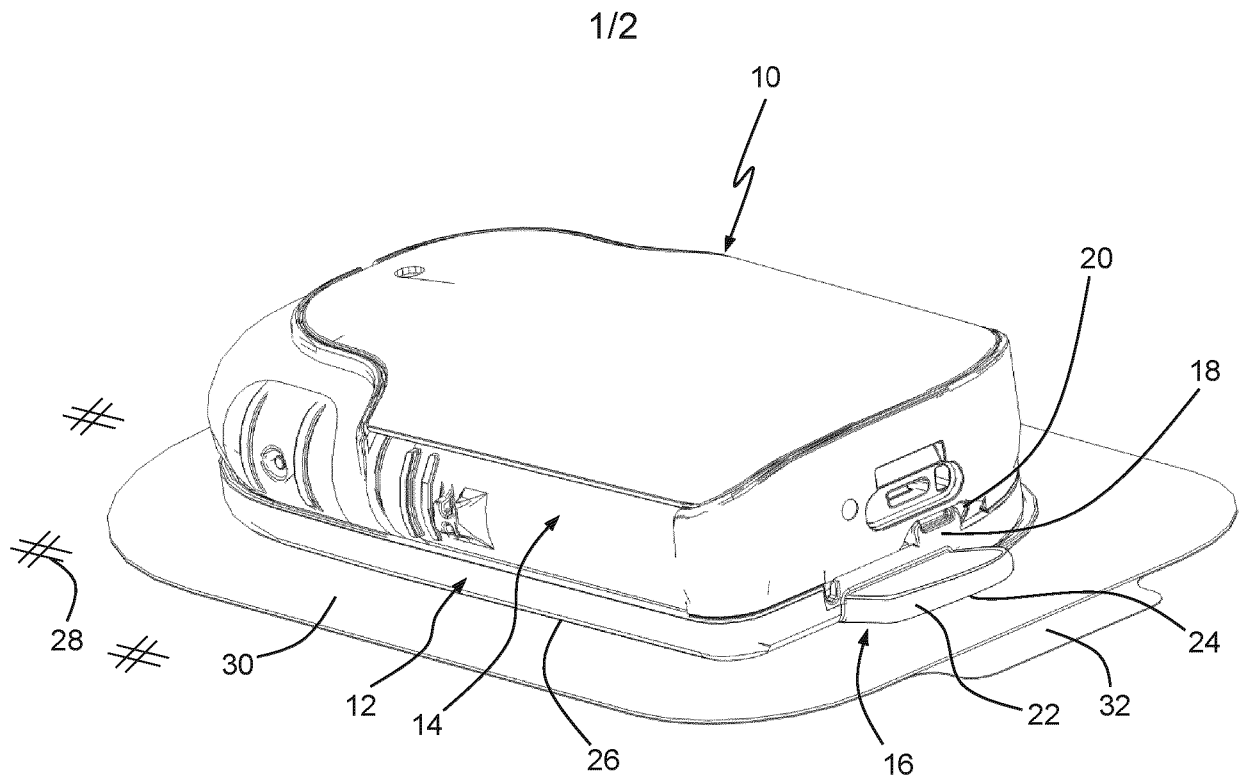


Fig. 1

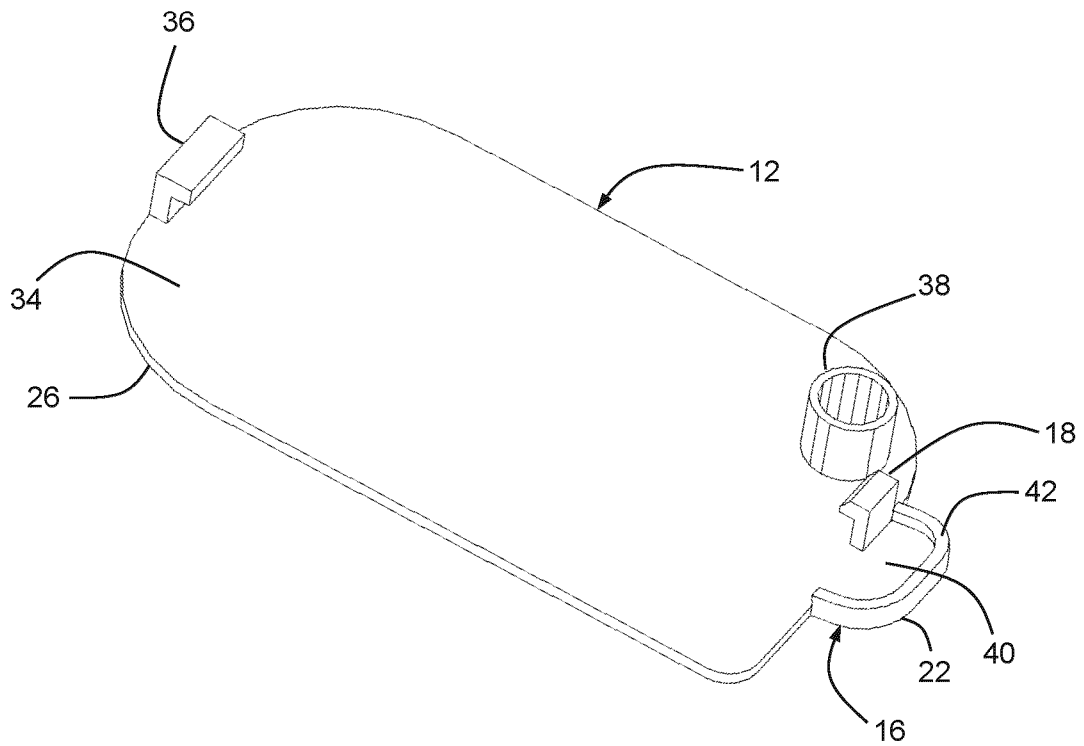


Fig. 2

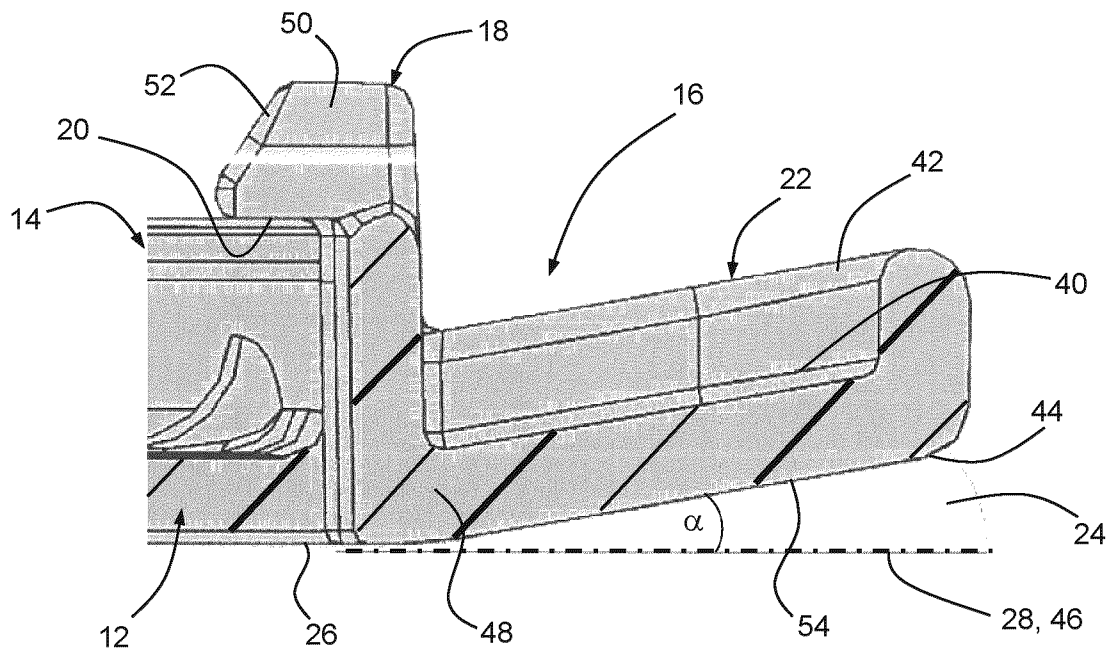


Fig. 3

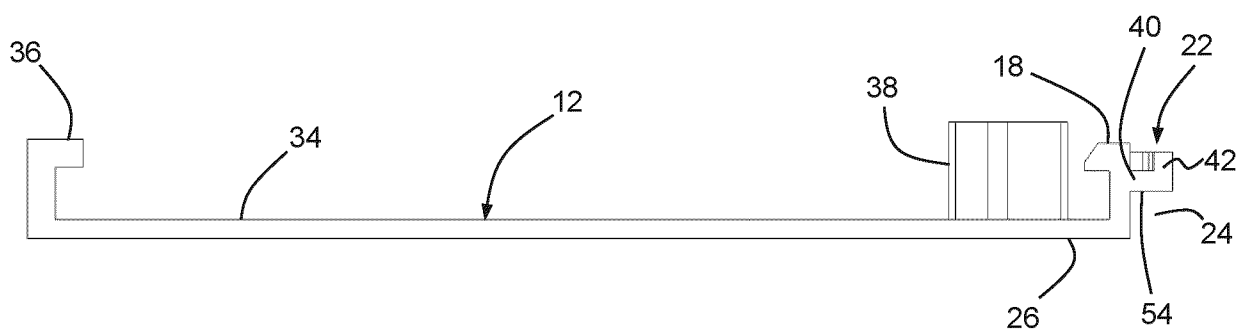


Fig. 4

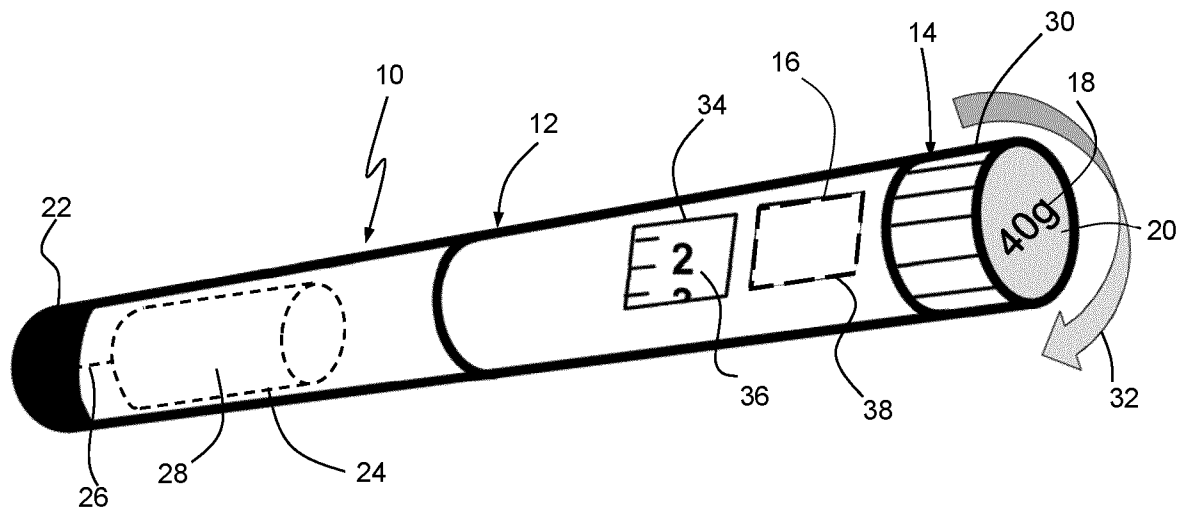


Fig. 1

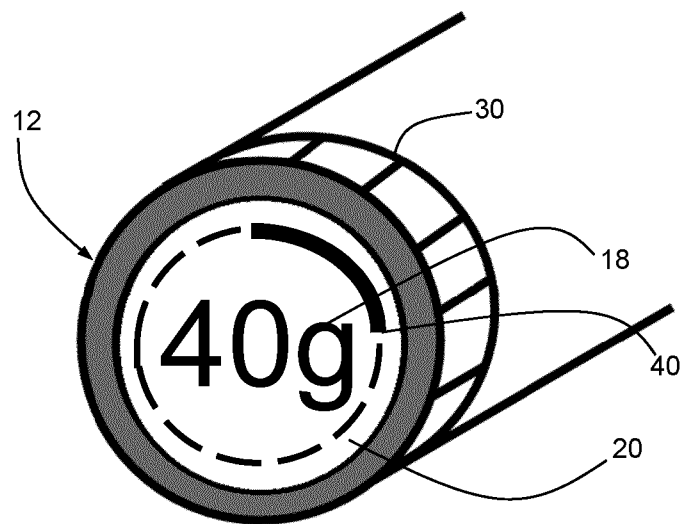


Fig. 2

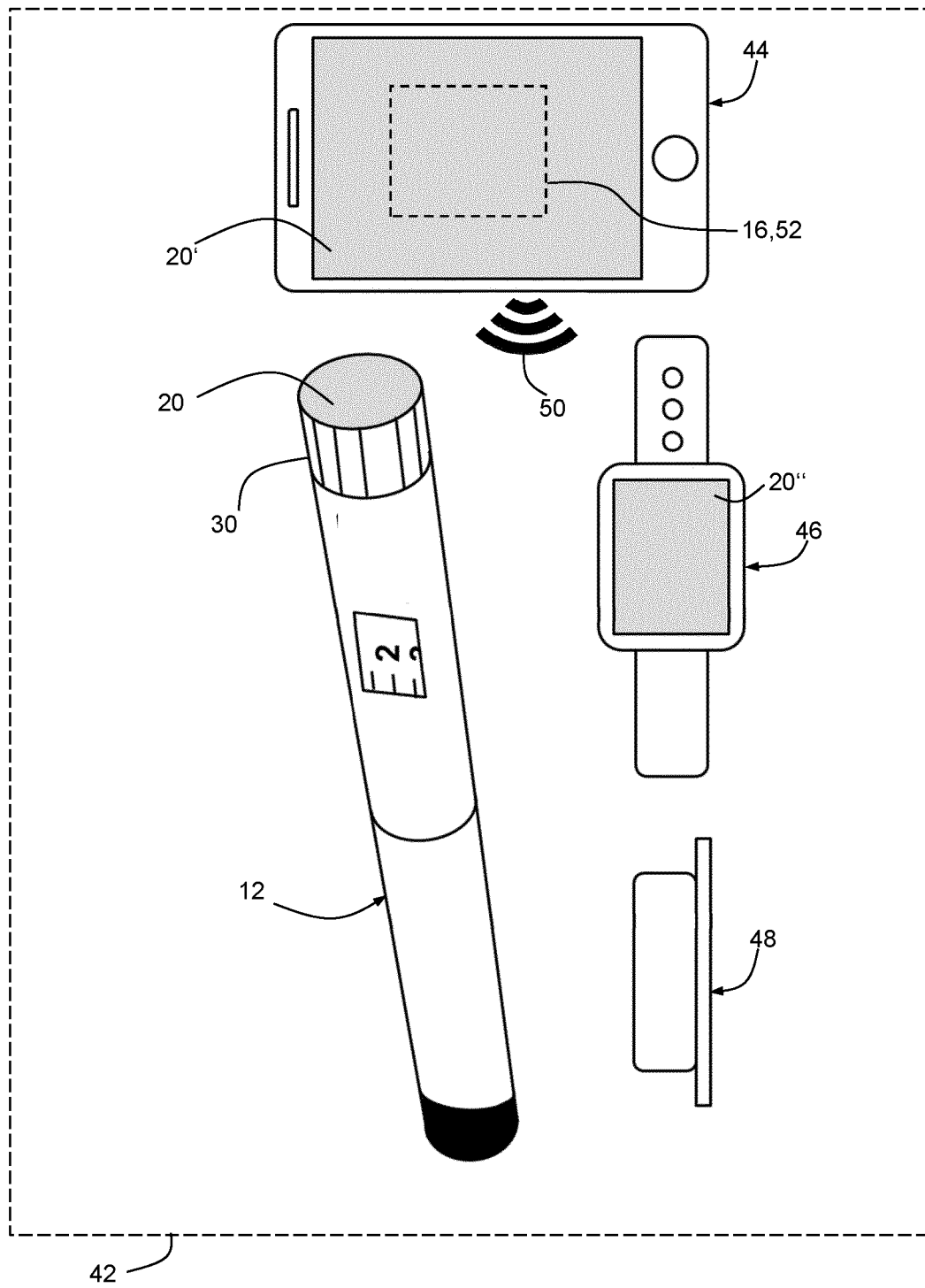


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2019/085524

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/142 A61M5/14
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 9 248 232 B2 (YODFAT OFER [IL]; ZNATI ELI [IL] ET AL.) 2 February 2016 (2016-02-02) figures 5-7, 33a, 38, 43a, 45, 46a column 17, lines 22-31 column 18, lines 35-46 -----	1-13
X	US 2017/224912 A1 (YODFAT OFER [IL] ET AL) 10 August 2017 (2017-08-10) figures 17A-17D, 19A-19D lines 110, 111, 115, 116, -----	1,8-13
A	US 6 302 866 B1 (MARGGI ROLF [CH]) 16 October 2001 (2001-10-16) the whole document -----	1-13



Further documents are listed in the continuation of Box C.



See patent family annex.

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

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2019/085524

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