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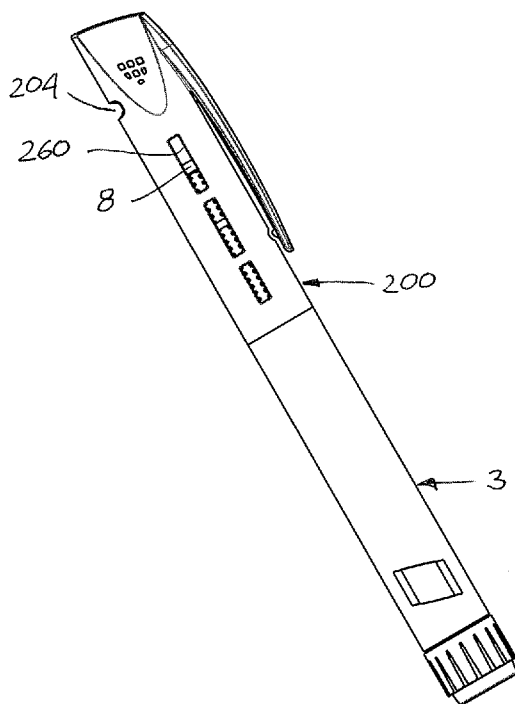


Fig. 7

(57) Abstract: A drug delivery device is provided comprising a main portion with a drug reservoir, and mounting means adapted for mounting a needle assembly distally relative to the drug reservoir. A cap portion is releasably mountable to the main portion and comprises a proximal portion adapted to cover the reservoir, and a distal portion adapted to cover the space distally of the reservoir adapted to house a needle assembly mounted on the main portion. The cap is provided with one or more inspection openings allowing a user to inspect the distal space, this allowing a user to inspect at least a portion of a needle assembly mounted on the main portion when the cap portion is mounted on the main portion.

WO 2010/142812 A1

**DRUG DELIVERY DEVICE WITH CAP FUNCTIONS FOR INSPECTION**

The present invention generally relates to medical delivery devices. In specific embodiments the invention relates to medical delivery devices adapted for mounting of a transcutaneous needle device.

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**BACKGROUND OF THE INVENTION**

In the disclosure of the present invention reference is mostly made to the treatment of diabetes by delivery of insulin, however, this is only an exemplary use of the present invention.

10 Drug Injection devices have greatly improved the lives of patients who must self-administer drugs and biological agents. Drug Injection devices may take many forms, including simple disposable devices that are little more than an ampoule with an injection means or they may be highly sophisticated electronically controlled instruments with numerous functions. Regardless of their form, they have proven to be great aids in assisting patients to self-  
15 administer injectable drugs and biological agents. They also greatly assist care givers in administering injectable medicines to those incapable of performing self-injections.

In particular pen-style injection devices have proven to provide an accurate, convenient, and often discrete, way to administer drugs and biological agents, such as insulin. Modern de-  
20 vices have become more sophisticated and often include diverse and robust functions, such as memories for remembering time and amount of last dose, as well as, in the case of insulin devices, blood glucose monitors. While pen-style injection devices are typically cylindrically shaped with a needle protruding from the most distal portion of one end of the device, some devices have other shapes with the needle no longer protruding from the most distal part of  
25 an end of the device, e.g. InnoVo ® and InnoLet ® from Novo Nordisk A/S Bagsvaerd Denmark.

Typically, injection devices use a pre-filled cartridge containing the medication of interest, e.g. 1.5 or 3.0 ml of insulin or growth hormone. The cartridge is typically in the form of a gen-  
30 erally cylindrical transparent ampoule with a needle pierceable septum at one end and an opposed piston designed to be moved by the dosing mechanism of the injection device. The injection devices generally are of two types: "Durable" devices and "disposable" devices. A durable device is designed to allow a user to replace one cartridge with another cartridge, typically a new cartridge in place of an empty cartridge. In contrast, a disposable device is  
35 provided with an integrated cartridge which cannot be replaced by the user; when the cartridge is empty the entire device is discarded. Most injection devices are provided with a re-

leasable pen cap covering the cartridge and the needle mount portion (see below), this allowing the user to inspect the content of the cartridge by removing the cap.

Cartridge-based drug delivery devices are typically designed for use with replaceable subcutaneous needle assemblies allowing a user to mount a fresh and sterile needle before each subcutaneous injection, however, many users decide to use a needle assembly more than one time. To allow a needle assembly to be mounted in fluid communication with the cartridge through the needle-pierceable septum, the injection device is provided with a needle mount which may be formed either as part of the device or as part of the cartridge, see e.g. US 5,693,027 and US 6,126,646, which are hereby incorporated by reference.

A typical subcutaneous injection needle assembly designed for use with a drug delivery device comprises a fine needle mounted in a hub having coupling means allowing the hub to be mounted on the injection device, thereby introducing the distal end of the needle through the cartridge septum. The hub may be cup-shaped with the inner mounting means adapted to engage corresponding mounting means on the injection device, e.g. a threaded connection or a bayonet coupling as disclosed in US 2008/0015519. The needle is normally provided in a container having an opening sealed by a peelable membrane, the container being in releasable, e.g. frictional, engagement with the needle hub. The coupling between container and hub allows the container to be used as a mounting tool when the membrane has been peeled off, just as it can be used as a tool for removing the needle after use. To further protect the pointed distal end of the needle and prevent unintentional user contact with the needle a needle cap is mounted on the hub covering the distal end of the needle. The needle cap will normally be removed just prior to use and remounted just after. Indeed, in case a user decides to remove the needle assembly from the injection device after an injection the container can be mounted on the needle assembly without the needle cap being in place. As many users prefer to use a needle assembly more than once the cap is normally designed to house a needle assembly including the needle cap. Indeed, this feature also allows a user to mount a fresh needle assembly in advance.

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As appears from the above, the mounting and use of disposable needle assemblies in connection with the use of drug delivery devices involves handling and keeping track of a number of members, e.g. especially the needle cap needs handling almost every time an injection is taking place. Further, to inspect the content of the cartridge or whether a needle assembly is mounted a user has to remove the pen cap.

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Having regard to the above, it is an object of the present invention to provide devices and methods allowing secure and easy operation of a drug delivery system comprising a drug delivery device with a reservoir and a thereto mountable needle assembly.

## 5 DISCLOSURE OF THE INVENTION

In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

10 Thus, a drug delivery device is provided comprising (a) a main portion comprising a drug reservoir, mounting means adapted for mounting a needle assembly distally relative to the drug reservoir, (b) a cap portion releasably mountable to the main portion and comprising a proximal portion adapted to cover the reservoir, a distal portion adapted to cover the space distally of the reservoir, the space being adapted to house a needle assembly mounted on the  
15 main portion, and one or more inspection openings or windows allowing a user to inspect at least a portion of the distal space, this allowing a user to inspect at least a portion of a needle assembly mounted on the main portion when the cap portion is mounted on the main portion.

In a specific embodiment a drug delivery system is provided comprising (a) a main portion  
20 comprising a drug reservoir or means for receiving a drug reservoir, and drug expelling means for expelling drug from the reservoir, (b) a needle assembly comprising a needle hub adapted to be mounted on the main portion, a hollow needle mounted in the needle hub and comprising a distal pointed end and a proximal end, the proximal end being adapted to be arranged in fluid communication with the reservoir when the hub is mounted on the main portion, and (c) a cap portion releasably mountable to the main portion and comprising one or  
25 more inspection openings or windows allowing a user to inspect at least a portion of a needle assembly mounted on the main portion when the cap portion is mounted on the main portion. By this arrangement a user can see whether a needle assembly is mounted without the need of taking off the cap. The needle assembly may also comprise a needle cap.

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The drug reservoir may comprise a user-inspectable portion and the cap portion may be adapted to cover the user-inspectable portion of the reservoir, the cap portion comprising one or more inspection openings or windows allowing a user to inspect at least a portion of the user-inspectable portion of the reservoir when the cap portion is mounted on the main  
35 portion. By this arrangement the user can inspect at least a portion of the reservoir without the need of taking off the cap. For example, the user-inspectable reservoir portion may com-

prise a transparent portion allowing a user to inspect drug contained in the reservoir or the position of a piston located in the reservoir.

5 In an exemplary embodiment the cap portion can be moved, e.g. rotated, between a first and a second mounted position, the second position allowing a user to inspect a larger portion of the reservoir than the first position. For example, in the first position the openings may be blocked, e.g. by a cartridge holder, this protecting the reservoir from ambient light, whereas in the second position the user can inspect a portion of the reservoir.

10 The cap portion may be generally non-transparent and be provided with one or more transparent windows, the transparent windows comprising means for reducing transmission of light detrimental to drug contained in the reservoir. In a system in which at least two main portions containing different types of drugs are provided, the user-inspectable reservoir portion may comprise a colour coding indicating the type of drug contained in the reservoir.

15 The drug delivery device or system may be provided with a cap portion comprising gripping means reversibly operatable between a first condition in which there is no gripping engagement between the mounted cap portion and the needle cap when the needle assembly is mounted on the main portion, this allowing the cap portion to be removed from the main portion without removing the needle cap from the hub, and a second condition in which the  
20 mounted cap portion grippingly engages the needle cap of a needle assembly mounted on the main portion, this allowing the needle cap to be removed from the hub together with the cap portion when the cap portion is removed from the main portion, as well as user actuation means for operating the gripping means between the two conditions. The cap portion may  
25 optionally be provided with the additional features described in respect of the first aspect of the invention.

In a further aspect a drug delivery device is provided comprising (a) a main portion, and (b) a cap portion. The main portion comprises a drug reservoir having a user-inspectable portion.

30 The a cap portion is releasably mountable to the main portion and adapted to cover the user-inspectable portion of the reservoir, the cap portion comprising one or more inspection openings or windows allowing a user to inspect at least a portion of the user-inspectable portion of the reservoir when the cap portion is mounted on the main portion.

35 In the above described embodiments the main portion of the drug delivery device comprises a reservoir, however, in alternative versions the different embodiments may be adapted to

receive a replaceable reservoir, e.g. a cartridge to be used in combination with a durable type injection device.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a cannula or hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides (e.g. insulins, insulin containing drugs, GLP-1 containing drugs as well as derivatives thereof), proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the exemplary embodiments reference will be made to the use of insulin containing drugs. Correspondingly, the term "subcutaneous" infusion is meant to encompass any method of transcutaneous delivery to a subject.

## 15 BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with reference to the drawings, wherein

fig. 1 shows a first embodiment of a drug delivery pen and a needle assembly,

fig. 2 shows in a cross-sectional view a pen cap,

20 fig. 3 shows in a cross-sectional view a pen cap as in fig. 2, the cross-section being rotated axially 90 degrees,

fig. 4 shows a partial cross-sectional view of the pen cap of fig. 2 wherein a needle cap is arranged in the interior of the cap,

fig. 5 shows the pen cap and needle cap of fig. 4 in gripping engagement,

25 fig. 6 shows a second embodiment of a drug delivery pen and a needle assembly, and

fig. 7 shows the drug delivery pen of fig. 6 with the pen cap mounted.

In the figures like structures are mainly identified by like reference numerals.

## 30 DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms such as "upper" and "lower", "right" and "left", "horizontal" and "vertical" or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as their relative dimensions are intended to serve illustrative purposes only.

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Referring to fig. 1 a pen-formed drug delivery device 1 will be described. The pen comprises a cap portion (or "pen cap") 100 and a main portion 3 having a proximal part 4 in which a drug expelling mechanism is arranged, and a distal reservoir part 5 in which a drug-filled transparent cartridge 6 with a distal needle-penetratable septum is arranged and hold in place by a cartridge holder 7 mounted to the proximal part, the cartridge holder having openings allowing a portion of the cartridge to be inspected. The cartridge is provided with a piston 8 driven by a piston rod 9 forming part of the expelling mechanism. A proximal-most button 10 serves to manually set and expel a desired dose of drug. This type of a pen-formed drug delivery device is well known, see e.g. WO 99/38554 to which reference is made for further details in respect of the internal construction of the shown type of pen. In the shown embodiment the pen is a disposable pre-filled device in which the cartridge holder is permanently attached to the proximal part of the main part, the cartridge holder being provided with distal coupling means in the form of an external thread 11 adapted to engage an inner thread of a needle assembly, see below. Alternatively the pen may be a "durable" device in which the cartridge holder is releasably attached to the main part, this allowing the piston rod to be pushed back and a new cartridge to be mounted. In such an arrangement the connection for the needle assembly may be part of the cartridge. The pen cap 100 made from a non-transparent material comprises a generally cylindrical sleeve 101 with a proximal closed end and a distal opening 102, a pocket clip 103 and an inspection opening 104. The proximal end is provided with two opposed generally planar gripping surfaces 110.

Fig. 1 further shows a needle assembly comprising a hollow infusion needle 21 mounted a cup-formed hub 22 with an inner coupling means in the form of a thread adapted to connect to the external thread 11 of the pen device. The needle comprises a distal pointed portion protruding from the hub as well as a proximal pointed portion adapted to penetrate the cartridge septum when the hub 22 is mounted on the thread 11. In an alternative embodiment a bayonet coupling may be used instead of the threaded connection, e.g. the cup may be provided with a plurality of inwardly projecting protrusions adapted to engage corresponding grooves formed distally on the pen device. The needle assembly further comprises a needle cap 23 with a skirt portion 24 adapted to releasably engage the hub to thereby protect the distal end of the needle. The needle is normally provided sterile in a container (not shown) having an opening sealed by a peelable membrane, the container being in releasable, e.g. frictional, engagement with the needle hub. The pen-formed drug delivery device 1 and the needle assembly together form a system.

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Turning to figs. 2 and 3 showing sectional views of the pen cap 100, the pen cap is provided with coupling means 120, 121 at the distal end for releasably engaging corresponding coupling structures 12 on the main portion, as well as a number of structures adapted to engage a needle cap. More specifically, the pen cap is provided with two pairs of gripping ribs 130 arranged corresponding to the inner side of the gripping surfaces 110. As the pen cap is manufactured from a relatively flexible polymeric material forcing the two gripping surfaces against each other, e.g. when gripping the pen cap with the first and second fingers, the two pairs of ribs will be moved against in each other and thus into engagement with a needle cap when the latter is placed there between, this allowing the needle cap to be removed from the needle hub, see below. Alternatively the cap may be provided with a button member acting to move a gripping structure into engagement with the needle cap. The pen cap further comprises a pair of gripping flanges 140 adapted to engage and hold the needle cap in place inside the pen cap when it has been removed from the needle hub, however, these gripping flanges do not ensure a grip strong enough to remove the needle cap from the needle hub. Protrusions 141 projecting from the proximal end of the cap assure correct axial positioning of a needle cap. In the shown embodiment the pen cap is further provided with a plurality of longitudinal ribs 150, each rib having a step configuration with a distally facing surface 151, this allowing the pen cap to be coded to fit only on a correspondingly designed cartridge holder 7. This may be useful in case the pen cap is e.g. colour coded corresponding to the type of drug contained in the pen device for which the cap is intended to be used with.

Fig. 4 shows a needle cap 23 arranged inside the pen cap 100 corresponding to a position in which a needle assembly and the pen cap are mounted on the pen main portion. The two gripping surfaces 110 as well as the gripping ribs 130 are in their initial relaxed position in which there is no engagement between the pen cap and the needle cap.

In fig. 5 the two gripping surfaces 110 have been moved against each other, thereby providing a gripping engagement between the pen cap and the needle cap, this allowing in a situation of use the needle cap to be removed from the needle hub when the pen cap is removed from the pen main portion. When the user relaxes the pressure on the gripping surfaces 110 the gripping flanges 140 serve to hold the needle cap properly in place until it is time put on the pen cap again. The inspection opening 104 is arranged in such a way that a user can control if the skirt portion 24 of the needle cap is in place without having to take off the pen cap. If a needle assembly is mounted but the needle cap is missing the user will be able to see the distal portion of the needle hub through the opening whereas the needle cap will ap-

pear “empty” if no needle hub is mounted, i.e. when the pen cap is mounted on the pen main portion the opening 104 is positioned distally of the distal end of the coupling means 11.

Turning to fig. 6 a second embodiment of a pen-formed drug delivery device and system 2 is shown. The embodiment corresponds to the first embodiment with the difference that the pen cap 200 has been provided with a number of inspection openings (or windows) 260, this allowing a user to inspect the interior of the pen cap. Otherwise the two pen caps are essentially identical.

Fig. 7 shows the pen cap 200 mounted on the pen main portion 3. As appears, the inspection openings 260 allow a user to inspect the content of the transparent cartridge 6 as well as the position of the piston 8. By this arrangement the user does not have to remove the cap to check the amount of drug remaining in the cartridge. The pen cap may advantageously be provided with a set of corresponding opposed openings, this allowing light to travel through the transparent cartridge to better allow a user to inspect the cartridge and the position of the piston. The inspection openings may advantageously be in the form of transparent windows comprising means for reducing transmission of light detrimental to drug contained in the reservoir, e.g. a UV filter. The filter may be contained in the polymer material forming the window or it may be a coating thereon.

As shown in fig. 2 the cap may be provided with coupling means 120, 121 for mounting the cap on the main portion. In the shown embodiment a circumferential groove 120 assures that the cap can be axially locked in place, whereas a second type of coupling in the form of one or more indentations 121 assures that the cap can be locked rotationally. Providing e.g. 4 indentations at 90 degrees spacing the cap portion could be rotated between a first and a second mounted position, the first position placing the openings 260 over the cartridge holder 7 thereby blocking for light, with the second position placing the openings over the transparent cartridge this allowing a user to inspect the reservoir.

If the drug delivery device is provided in different versions containing different types of drugs (e.g. different types, formulations or concentrations of insulins and GLP-1 like drugs) the cartridge holder 7 or other structures may be colour coded indicating the type of drug contained in the reservoir, such a colour coding being visible through the inspection openings.

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a

degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

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**CLAIMS**

1. A drug delivery system (1, 400) comprising:
  - (a) a main portion (3) comprising:
    - 5 - a drug reservoir (6) or means for receiving a drug reservoir, and
    - drug expelling means (9) for expelling drug from the reservoir,
  - (b) a needle assembly (20) comprising:
    - 10 - a needle hub (22) adapted to be mounted on the main portion,
    - a hollow needle (21) mounted in the needle hub and comprising a distal pointed end and a proximal end, the proximal end being adapted to be arranged in fluid communication with the reservoir when the hub is mounted on the main portion, and
  - (c) a cap portion (100) releasably mountable to the main portion and comprising:
    - 15 - one or more inspection openings or windows (204) allowing a user to inspect at least a portion of a needle assembly mounted on the main portion when the cap portion is mounted on the main portion.
2. A drug delivery system as in claim 1, wherein drug reservoir comprises a user-  
20 inspectable portion and the cap portion is adapted to cover the user-inspectable portion of the reservoir, the cap portion comprising:
  - one or more inspection openings or windows (260) allowing a user to inspect at least a portion of the user-inspectable portion of the reservoir when the cap portion is mounted on the main portion.
- 25 3. A drug delivery system as in claim 1, wherein the cap portion can be moved between a first and a second mounted position, the second position allowing a user to inspect a larger portion of the reservoir than the first position.
- 30 4. A drug delivery system as in claim 3, wherein the first position prevents a user from inspecting a portion of the user-inspectable portion of the reservoir.
- 35 5. A drug delivery system as in any of claims 2-4, wherein the user-inspectable reservoir portion comprises a transparent portion allowing a user to inspect drug contained in the reservoir or the position of a piston (8) located in the reservoir.

6. A drug delivery device as in any of claims 2-5, wherein the cap is generally non-transparent and is provided with one or more transparent windows, the transparent windows comprising means for reducing transmission of light detrimental to drug contained in the reservoir.

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7. A drug delivery system as in any of claims 1-6, comprising at least two main portions containing different types of drugs, wherein the user-inspectable reservoir portion or a structure (7) associated therewith comprises a user-readable coding indicating the type of drug contained in the reservoir.

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8. A drug delivery system as in any of the previous claims, wherein the needle assembly comprises a needle cap (23) releasably mountable on the hub to cover the distal pointed end, the cap portion further comprising:

- gripping means reversibly operatable between:

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(i) a first condition in which there is no gripping engagement between the mounted cap portion and the needle cap when the needle assembly is mounted on the main portion, this allowing the cap portion to be removed from the main portion without removing the needle cap from the hub, and

20

(ii) a second condition in which the cap portion grippingly can engage the needle cap of a needle assembly mounted on the main portion, this allowing the needle cap to be removed from the hub together with the cap portion when the cap portion is removed from the main portion,

and

- user actuation means (210) for operating the gripping means between the two conditions.

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9. A drug delivery system as in claim 8, wherein the cap portion comprises an outer shell portion with a pair of actuation areas (210), wherein movement of the actuation areas towards each other operates the associated gripping means between an initial and an actuated state.

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10. A drug delivery system as in claim 9, wherein the outer shell portion is flexible and the gripping means and actuation means are formed integrally there with.

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11. A drug delivery system as in any of the previous claims, wherein at least one of the inspection openings is arranged on a circumferential portion of the cap.

12. A drug delivery device (2) comprising:

(a) a main portion (3) comprising:

- a drug reservoir (6) or means for receiving a drug reservoir,

5 - mounting means (11) adapted for mounting a needle assembly distally relative to the drug reservoir,

(b) a cap portion releasably mountable to the main portion and comprising:

- a proximal portion adapted to cover the drug reservoir,

10 - a distal portion adapted to cover the space distally of the reservoir adapted to house a needle assembly mounted on the main portion,

- one or more inspection openings or windows (260) allowing a user to inspect at least a portion of the distal space, this allowing a user to inspect at least a portion of a needle assembly mounted on the main portion when the cap portion is mounted on the main portion.

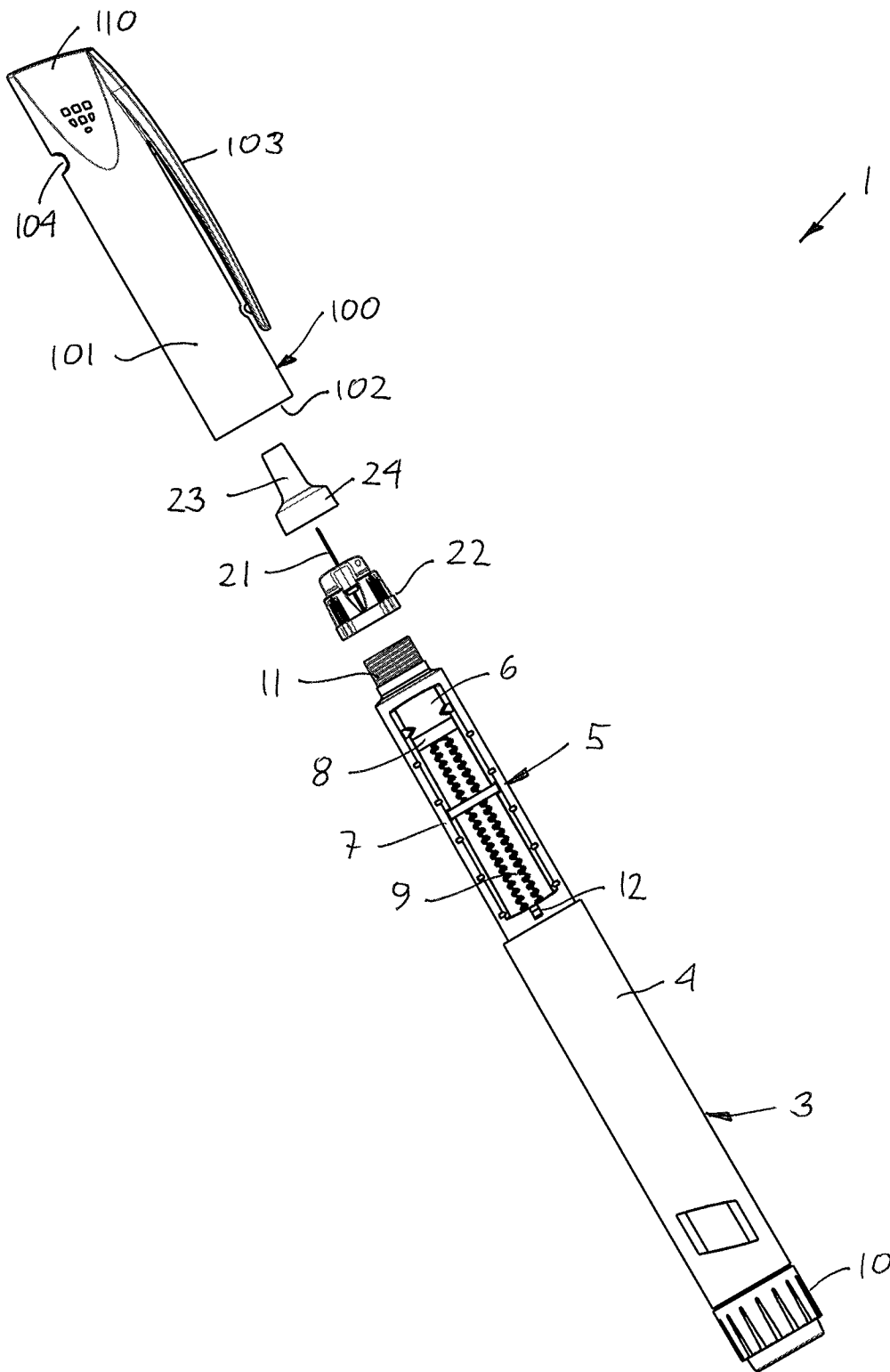
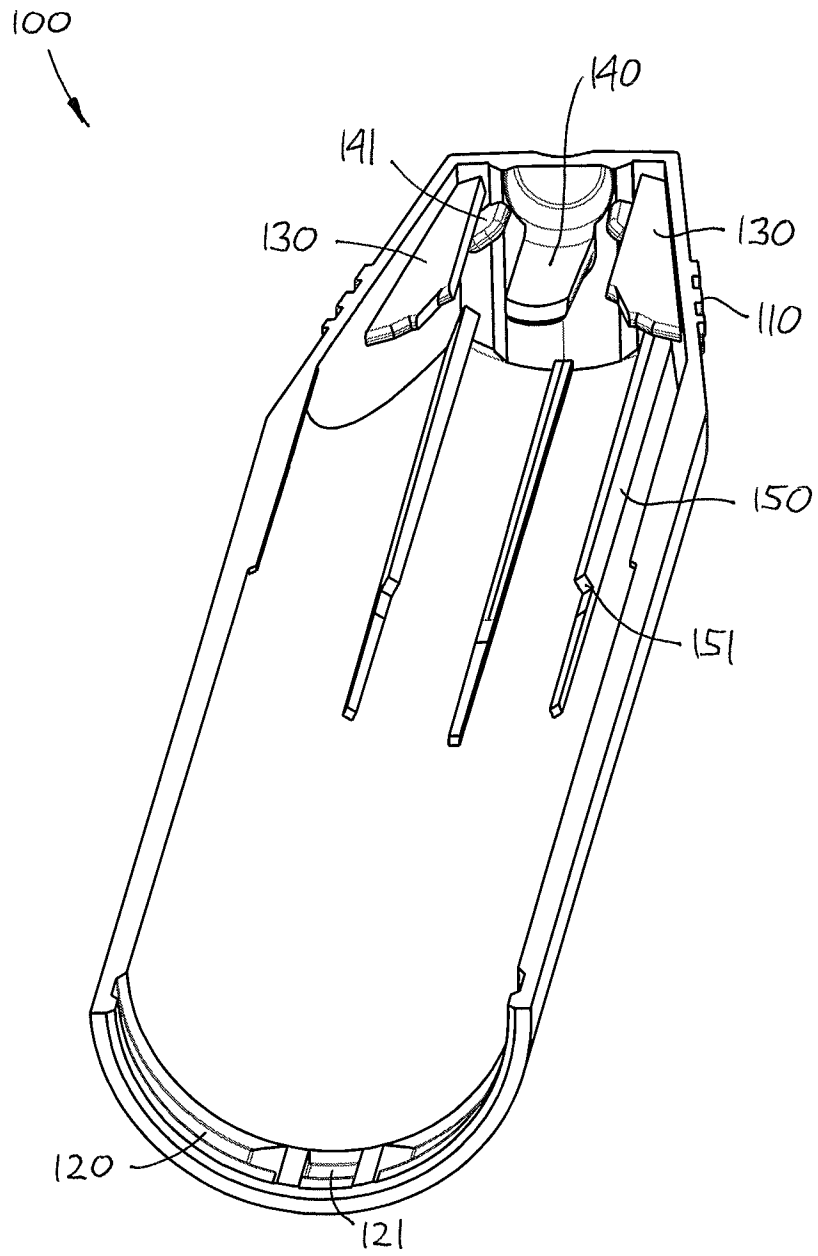


Fig. 1



**Fig. 2**

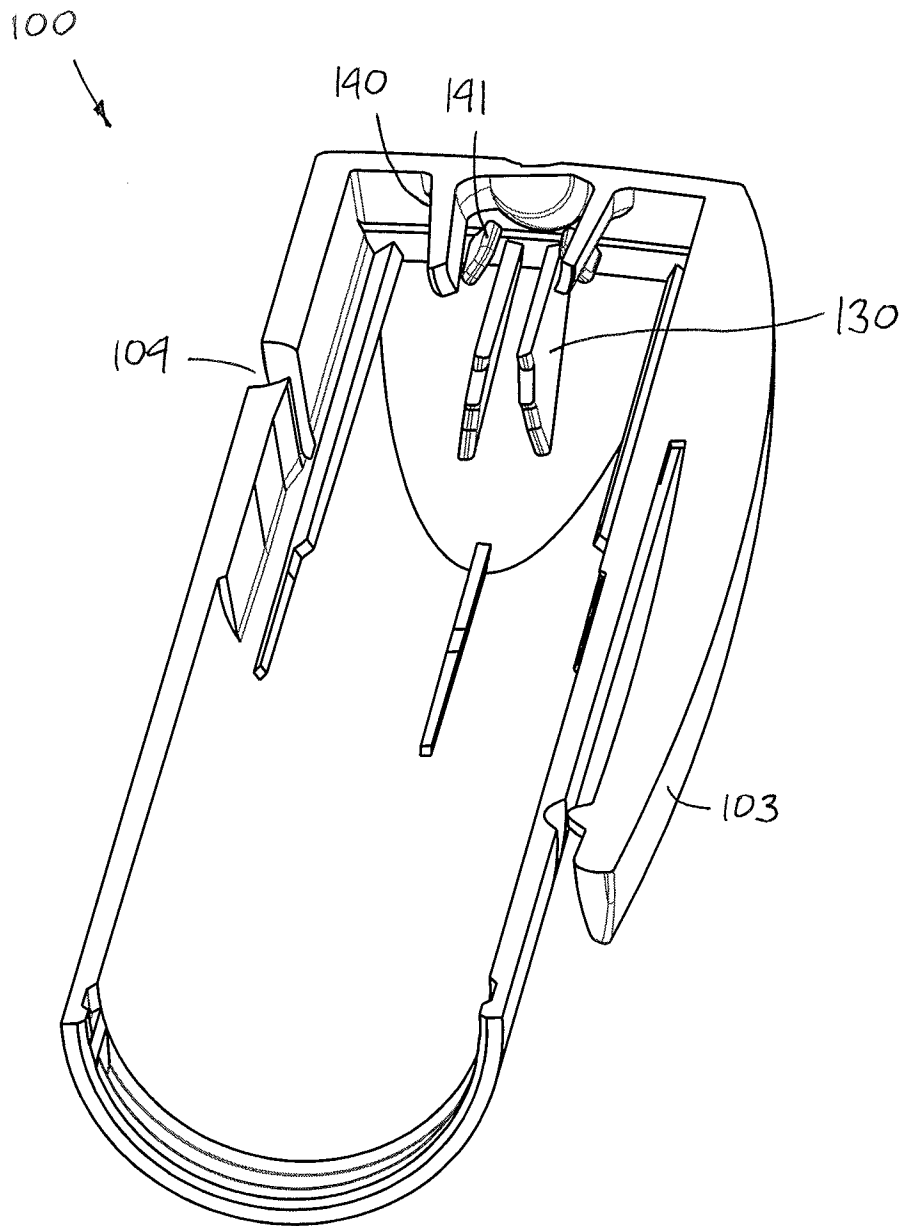
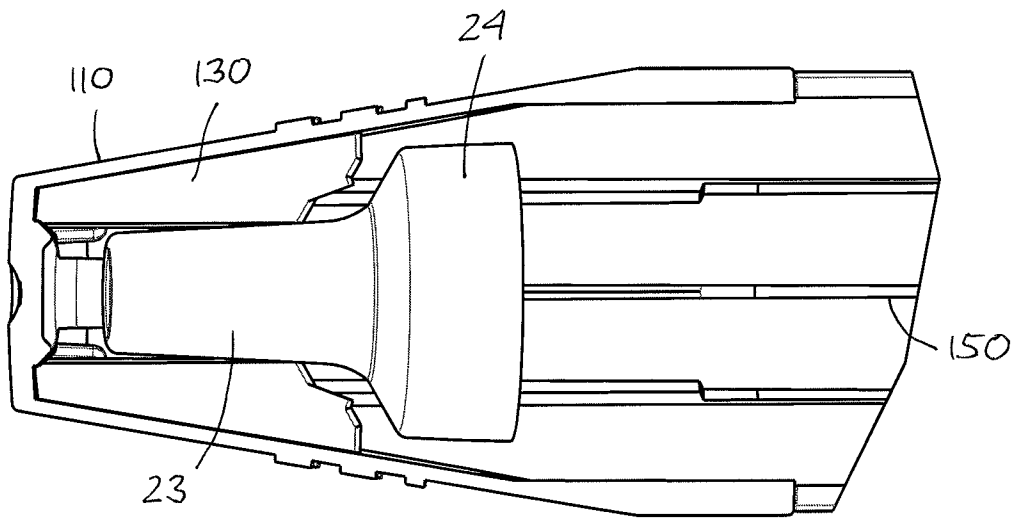
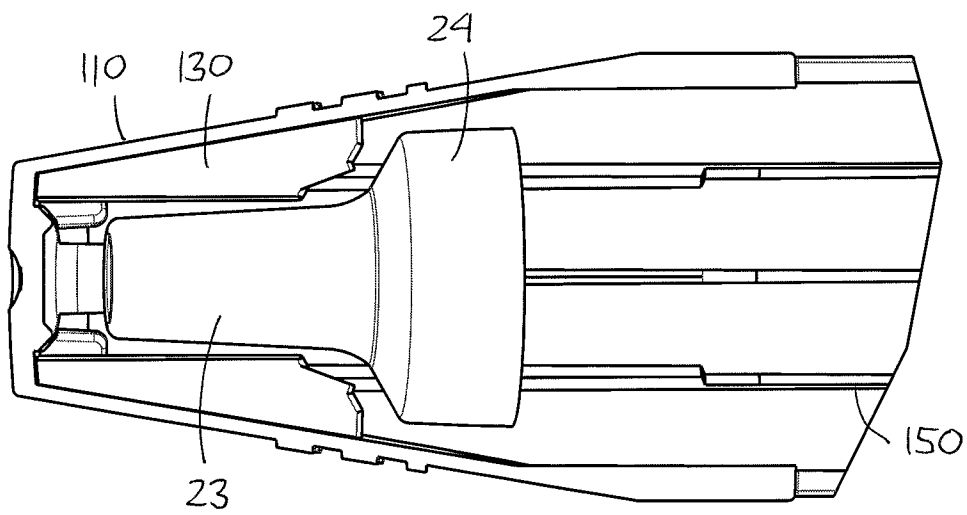


Fig. 3



**Fig. 5**



**Fig. 4**

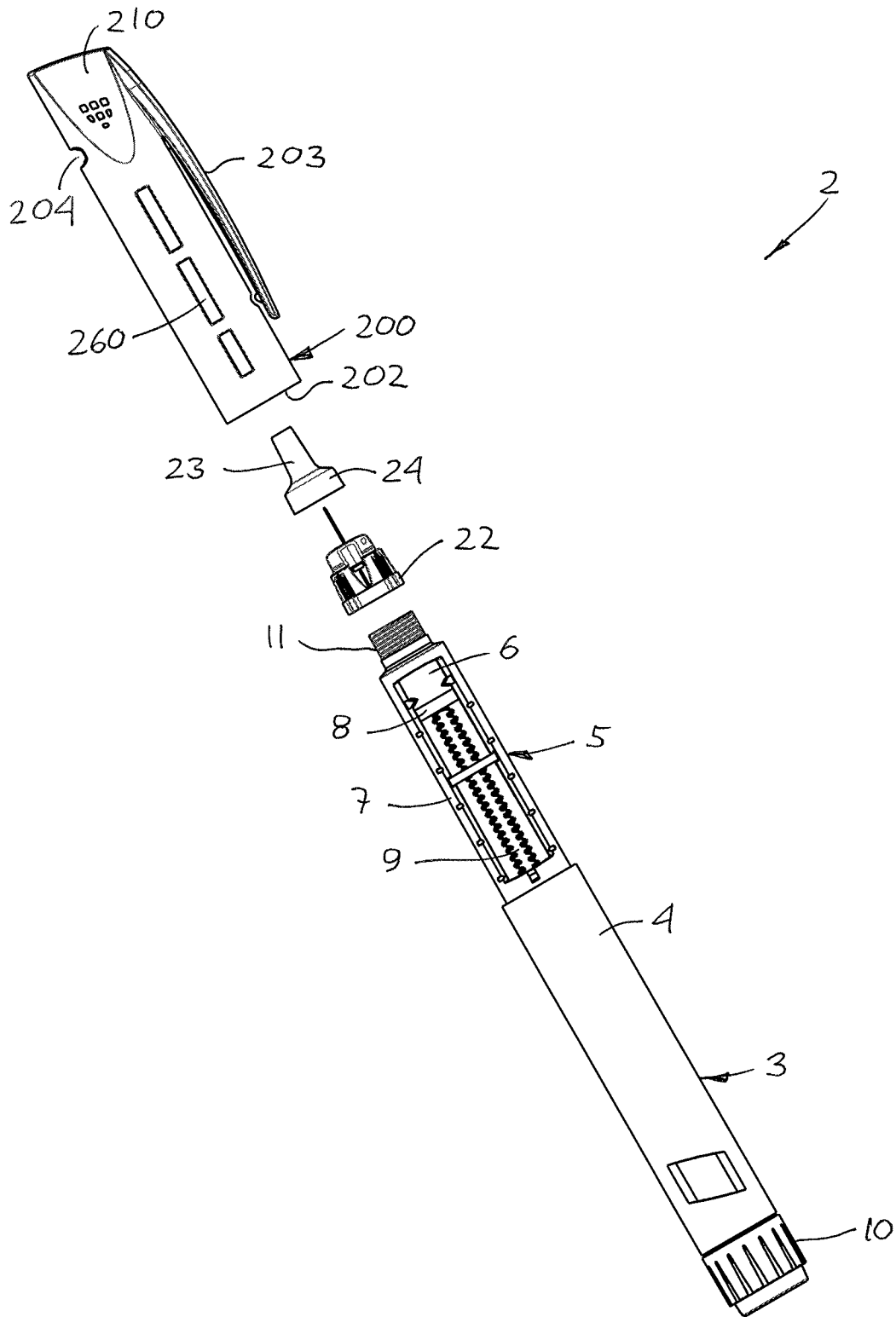


Fig. 6

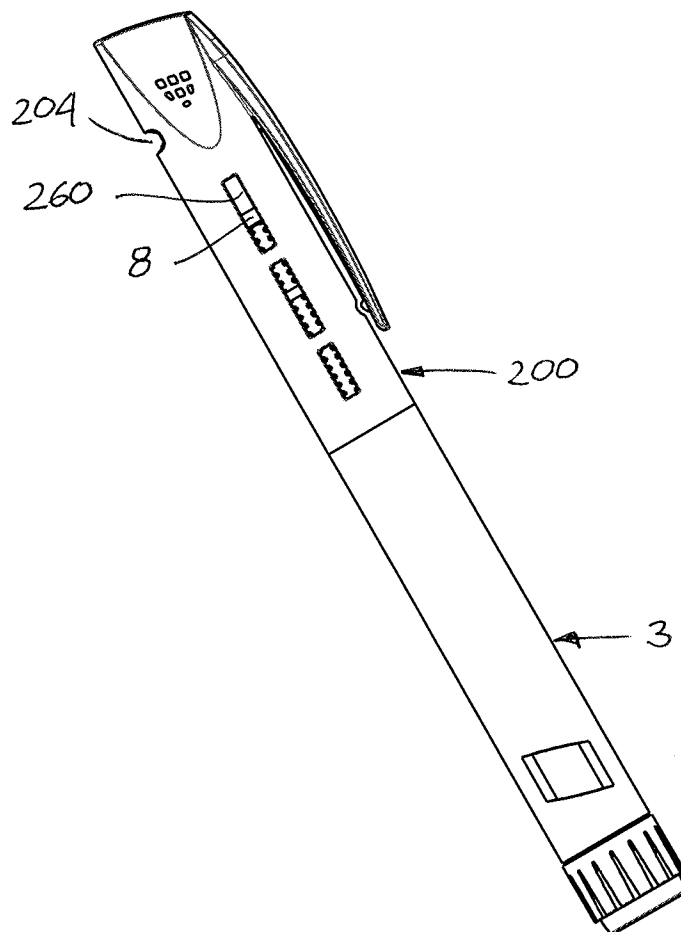


Fig. 7

**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/EP2010/058320

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61M5/32  
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 practical, search terms used)  
EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 199 09 824 A1 (VETTER & CO APOTHEKER [DE]) 7 September 2000 (2000-09-07) * abstract column 4, lines 10-16; figures 1,2,4,5	1,12
A	US 2006/089599 A1 (LYNN DANIEL [US] ET AL) 27 April 2006 (2006-04-27) * abstract paragraph [0056]; figures 2,3,9	1,12
A	US 2002/074345 A1 (SCHNEIDER PATRICIA G [US] ET AL) 20 June 2002 (2002-06-20) * abstract paragraphs [0059] - [0074]; figures 1,8	1,12
A	WO 2006/126902 A (KAPPA MEDILAB SP Z O O [PL]) 30 November 2006 (2006-11-30) page 5, paragraph 3; figure 3	1,12
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Further documents are listed in the continuation of Box C.       See patent family annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier document but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"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.
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  27 August 2010	Date of mailing of the international search report  06/09/2010
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Nielsen, Michael
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## INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2010/058320

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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