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(54) Title: STORAGE CONTAINER FOR ELECTRONIC INJECTION DEVICE

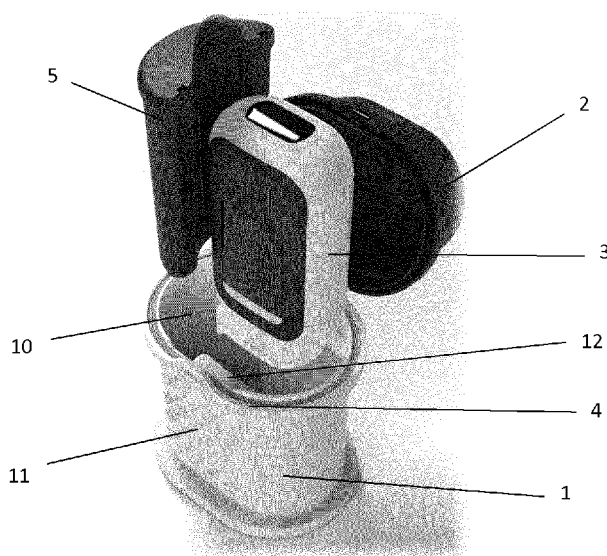


Figure 2

(57) Abstract: The present invention relates to storage containers for electronic injection devices. The storage container comprises a desiccant in airflow communication with an interior space of the storage container, the desiccant being replaceable for continued use of the storage container.



Storage Container for Electronic Injection Device

BACKGROUND OF THE INVENTION

The present invention is directed to storage containers for electronic injection devices, in particular for electronic injection devices comprising multiple doses of a medication. These storage containers are for storage of such electronic injection devices when not being in use, in particular during periods in between injections according to a dosage regimen of a medication.

Patients suffering from a variety of diseases often are able to treat themselves by self-administering appropriate doses of a medication. One type of delivery device that can be used by patients or care-givers includes electronic injection devices. Multi-dose cartridges in such electronic delivery devices make the use and adherence to a particular dosing regimen more convenient to the user. The electronics in such delivery devices add to the convenience of the patient or care giver by controlling the injection through operating for example the needle injection or delivery of the medication through a needle.

In a typical operation, users will store the electronic injection device containing the medication inside a refrigerator, for example a home refrigerator. Prior to use, users/patients (or care-givers) commonly remove the device (typically containing the medication) from the refrigerator and allow it to reach ambient temperature before injection. Once delivery is completed, the device containing the remaining medication is then returned to the refrigerator. Thus, the device stored in the refrigerator when not being used, is removed for use from the refrigerator for a short time, such as for example for 30 minutes, and after use is then placed back in the refrigerator for storage until its next use.

Removing and/or returning the electronic drug delivery device from the refrigerator, particularly in regions where there is a high ambient temperature and humidity, may result in the formation of condensation on and in the device. This condensation has the potential to damage the electronics and cause the device to malfunction or become inoperable.

Electronic injection devices are often provided with a storage case in which the device can be protectively stored when not in use. Typically, the device can be placed within a complementarily shaped mold provided in an interior space. However, such cases typically do not protect against the condensation of the electronic injection device when transferred from a location of storage to the use environment for the user which two locations have different temperatures. This is particularly problematic when the user of the electronic injection device is located in a region where there is a high ambient temperature and humidity.

Thus, it would be desirable to provide a storage case for an electronic injection device that addresses at least one of these shortcomings of the prior art storage cases.

BRIEF SUMMARY OF THE INVENTION

In one embodiment, the present invention provides a storage container for an electronic injection device comprising, a bottom part having an outer surface and defining an interior space for holding the electronic injection device, a movable top part for closing the interior space of the bottom part forming when closed a hermetically sealed interior compartment, and a desiccant in air flow communication with the interior compartment, wherein the desiccant can be replaceable

and/or rechargeable. The desiccant can be in a removable compartment in the interior space. Continued use of the storage container after the desiccant has been saturated with moisture can be through replacement of the desiccant compartment. Further, the used desiccant compartment can be recharged for example by evaporating the moisture captured by the desiccant in the desiccant compartment.

The top part or lid part may be removable from the bottom part to open and close the storage container. Alternatively, both parts are connected by one or more hinges so as to provide a pivotal means for opening and closing the storage container.

In an alternative embodiment of the present invention, the outer surface of the bottom part comprises a material for creating a humidity barrier and which material is of a thickness that allows an equilibration period for equilibrating the temperature inside the interior compartment and outside of the storage container of less than 60 min.

In an alternative embodiment the bottom part of the storage container comprises feet on which the bottom part rests when placed in upright position when used to store an electronic injection device. The feet can provide airflow and ventilation underneath the storage container for increased heat exchange between the interior space and the ambient environment.

An advantage of the present invention is that a storage container for an electronic injection device is provided which reduces the likelihood of condensation forming on the device when not in use, which condensation could adversely impact the reliability of the device. Another advantage of the present invention is that a storage container is provided which while protecting the electronic injection device from potentially damaging humidity can equilibrate sufficiently rapidly to room temperature after removal from a cold storage compartment allowing the user or care-giver to manage the injection of the medication.

BRIEF DESCRIPTION OF THE DRAWINGS

The above-mentioned and other advantages and objects of this invention will become more apparent, and the invention itself will be better understood by reference to the following description of an embodiment of the invention together with the accompanying drawings, wherein:

FIG. 1 is a representation of a storage container for an electronic injection device. In figure 1A the container is in a closed view providing a seal between the bottom part and the top part. In figure 1 B the storage container is opened at the hinge between the bottom part and top part showing the electronic injection device and a compartment for desiccant placed in the bottom part of the storage container.

FIG. 2 is a top view of the storage container showing the interior space, for placing the electronic injection device and the compartment for desiccant. The outside surface of the bottom part is rough-patterned. Also shown is a mold inside the interior space to hold the electronic injection device in place.

FIG. 3 is a representation of the storage container in a closed view from which the outside surface of the bottom part has been removed revealing an interior lining of the interior space of the bottom part of the storage container.

FIG. 4 is a representation of the storage container showing the presence of feet supporting the bottom part of the storage container. Figures 4A, 4B and 4C provide different views showing the

feet on the bottom part of the storage container. In figure 4A the storage container is in a side view, in figure 4B the storage container is in a frontal view, and in figure 4C a bottom view is shown.

Corresponding reference characters indicate corresponding parts throughout the several views. Although the drawings represent an embodiment of the present invention, the drawings are not necessarily to scale, and certain features may be exaggerated or omitted in some of the drawings in order to better illustrate and explain the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, there is shown an exemplary embodiment of a storage container for an electronic injection device of the present invention. When in a closed arrangement shown in FIG. 1A, the storage container protectively houses the electronic injection device previously received therein. The storage container is shown having a bottom part (1) and a top part or lid (2). In the closed arrangement the container is hermetically sealed in part due to a seal (7), as shown in FIG 1B. Such seal (7) is located between the bottom (1) and top (2) parts of the storage container, in circumference of that portion of the bottom part (1) which is in contact with a rim (8) of the top part (2). Alternatively, the rim (8) of the top part (1) may also contain along its edge a seal. The seal (7) may be of any malleable material commonly used as a seal between two or more moveable parts. The seal material need to be able to provide a sufficient barrier between the interior space and the outside environment at a range of temperatures, preferably from 0°C to 60°C, more preferable from 0°C to 45°C. Examples of such seal material include silicon and rubber. Such seal (7) may be a tubular or squared, either of which may be solid or hollow, material forming a ring in circumference with the edge of either the bottom part (1) or top part (2) or both.

In order to more securely close the storage container one or more counterpart latches (9a, 9b) may be provided as shown in FIG. 1B. Each one of the counterpart latches (9a, 9b) being located on the edge of either the bottom part (1) or the top part (2) opposite the other of the counterpart latch (9a, 9b). The storage container may contain one or more of such counterpart latches. The latching mechanism may in addition prevent inadvertent opening of the case.

The top part or lid (2) may be removed away from the bottom part (1) so as to open the storage container. Alternatively, the top part or lid (2) may be hingedly connected to the bottom part (1) of the storage container with one or more hinges (6). Opening of the storage container can thus be accomplished in several manners such as for example the total removal of the top part or lid (2) from the bottom part (1), or by moving the top part or lid (2) by using one or more hinges (6). However, otherwise designed storage containers that may be opened and closed may naturally be employed within the scope of the invention.

The top part or lid (2) may be a solid lid or alternatively includes an outer shell and an interior space. Such interior space may be contoured or molded to match and fit the exposed portions of the compartment(s) (5) and the electronic injection device (3), which are exposed from the bottom part after being received therein. However, the top part or lid (2) should not impede the temperature equilibration inside a closed storage container with the outside environment. As such the top part or lid (2) may be constructed of any rigid non-permeable material such as plastic, preferably a thermoplastic material of a limited thickness. Examples of such thermoplastic material includes acrylonitrile butadiene styrene (ABS), polypropylene (PP), polycarbonate (PC), polyethylene (PE), low density polyethylene (LDPE), high density polyethylene (HDPE), polyvinylchloride (PVC), polystyrene (PS) and polyethylene terephthalate (PET), preferable the thermoplastic material is polypropylene

(PP). Preferably the thickness of this material for the top part or lid (2) is from 0.5 mm to 3.0 mm, more preferably from 1.0 mm to 2.0 mm.

The interior space (10) of bottom part (1), as shown in FIG. 2, comprises a compartment (5) for containing a moisture absorbing material. In addition, this interior space may further contain
5 molded or contoured surface(s) (12), such as forming a recess, for providing a close fit for the electronic injection device (3) when housed in the bottom part (1) of the storage container. Such molded or contoured surface(s) (12) should not impede the heat exchange and equilibration of the temperature of the electronic injection device (3) when housed in a close storage container with the outside temperature. Preferably any such surface should have a thickness of less than 3.5mm, less
10 than 2.5 mm, or from 0.5 mm to 2.0 mm. The compartment (5) for holding a moisture absorbing material, desiccant, in a preferred embodiment of the present invention is also contoured or molded such that it will closely fit in the interior surface (10). Such contoured or molded compartment (5) may also further secure the electronic injection device (3) in place when it is housed in the storage container. The compartment (5) for holding the moisture absorbing material or desiccant further
15 comprises at least one opening for providing air flow communication between the interior space (10), also holding the electronic injection device (3), and the moisture absorbent or desiccant, such that moisture in that internal volume can be drawn off. This compartment (5) for containing the moisture absorbent or desiccant may be removed from the interior space (10) of the bottom part (1) and can be secured in place such as via snap fits, press fits, or another suitable manner. The removal
20 of this compartment (5) from the storage container allows for the replenishment or exchange to fresh moisture absorbent or desiccant for the continued use of the storage container after the moisture absorbent capacity of the desiccant has been exhausted, i.e. the desiccant is saturated with moisture and no longer operates efficiently as desiccant.

The storage container thus includes a moisture absorbing material or desiccant to reduce the
25 likelihood that the intended contents of the container, for example the electronic injection device (3), will be damaged from moisture when housed therein. The material can be in the form of a contained desiccant, such as a desiccant pack, held in the shown embodiment by the compartment (5) inside the interior space of the bottom part (1) of the storage container. Although shown being located only in that compartment, in alternative embodiments, the desiccant can be provided in one
30 or more such compartments which may also be located around the electronic injection device (3) or in the top part or lid (2) of the storage container. A suitable desiccant can be silica gel, molecular sieve, or clay.

The electronic injection (3) device may be any electronic injection device for delivering medication to a patient such as for example the device described in WO2005/077441. The electronic
35 injection device (3), when not being stored within storage container, is operable to deliver medication into a user in a known fashion. The electronic injection device uses electronic circuitry, such as circuitry used to accurately indicate the dose of medication being injected into the user, or to record data about the injection, or to actually drive the injection. The storage container advantageously provides for storing such devices having electronic components which are potentially
40 adversely impacted by moisture within the device.

Considering that certain electronic injection devices are stored containing a multi-dose medication cartridge inside the storage container of the present invention is particularly beneficial for such electronic injection device. However, the storage container should not impede the convenience of the user/patient in use. Accordingly, equilibration of the temperature of the
45 electronic injection device (3) housed in the closed storage container when removed from a refrigerator to an ambient environment should not be impeded. In fact, the period for equilibrating

such device temperature to the ambient temperature should be less than about 60 minutes, preferably less than about 30 minutes, more preferably less than about 20 minutes. Preferably the time period for equilibrating the electronic injection device after removing the storage container from the refrigerator (cooled storage conditions) is about 15 minutes or less.

5 In order to achieve a sufficiently rapid heat exchange between the interior space (10) of the closed storage container and the outside environment after removal of the storage container from the cooled storage conditions the outer surface (4) of the bottom part (1) of the storage container is of a thermoplastic material which allows for such heat exchange. In addition, the outer surface (4) of the bottom part (1) should be of limited thickness. Preferably the thickness is from 0.5 mm to 3.5
10 mm, more preferably from about 1.0 mm to about 2.5 mm, even more preferably from about 1.5 mm to about 2.5 mm. The thermoplastic material for the outer surface (4) of the bottom part (1) of the storage container can be any non-permeable thermoplastic material preferably selected from for example acrylonitrile butadiene styrene (ABS), polypropylene (PP), polycarbonate (PC), polyethylene (PE), low density polyethylene (LDPE), high density polyethylene (HDPE), polyvinylchloride (PVC),
15 polystyrene (PS) and polyethylene terephthalate (PET). Preferable the thermoplastic material is polypropylene (PP). Alternatively in order to limit the thickness of the material of the outer surface (4) this surface can be formed from a hollow shell material with a surface facing outward and an internal liner (13) as shown in FIG. 3. The space in between the surface facing outward and the internal liner can be for example open to the air. As shown in FIG. 4, in one embodiment the storage
20 container comprises one or more feet (14) on which the bottom part rests when used to store an electronic injection device. Such one or more feet (14) can allow ventilation of the air underneath the bottom part of the storage container and/or air exchange of the air between the liner (13) and the outer surface (4). Airflow or ventilation of the air in close contact with that part of the bottom compartment which houses the electronic injection device (3) can improve the heat exchange
25 between the ambient environment and the interior space (10) of the storage container when removed from for example a refrigerated environment.

In an alternative embodiment the outer surface (4) on at least part of its surface contains a roughed profile (11). Such roughed profile (11) improves the grip for the user/patient on the storage container. This is particularly beneficial for patients who suffer from an illness or disease which
30 compromises their dexterity abilities. This may also be true for older patients or very young patients. Additionally, condensation on the outside of the storage container may impact the ease of gripping the container and such roughed profile (11) on the outer surface (4) of the storage container improves such ease of gripping the container.

Optionally, the storage container of the present invention is balanced such that the storage
35 container is stable in upright position when positioned on a smooth surface or grill type surface in for example a refrigerator. Such balance of the storage container is independent on whether the compartment (5) is filled with a moisture absorbent material (desiccant) or not.

While this invention has been shown and described as having preferred designs, the present invention may be modified within the spirit and scope of this disclosure. This application is therefore
40 intended to cover any variations, uses or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains.

We claim:

1. A storage container for an electronic injection device comprising;
a bottom part having an outer surface and defining an interior space for holding the
electronic injection device;
5 a movable top part for closing the interior space of the bottom part forming when closed a
hermetically sealed interior compartment; and
a desiccant in air flow communication with the interior space,
wherein the compartment containing the desiccant is replaceable from the interior space of the
storage container.
10
2. The storage container according to claim 1, wherein the desiccant is in a separate
compartment in the interior space of the bottom part of the storage container, the separate
compartment comprising at least one opening for providing air flow communication with the interior
space.
15
3. The storage container according to claim 1 or 2, wherein the outer surface of the bottom part
comprises a material for creating a humidity barrier and which material is of a thickness that allows
an equilibration period for equilibrating the temperature inside the interior compartment and
outside of the storage container of less than 60 min.
20
4. The storage container according to any of the preceding claims, wherein the bottom part of
the storage container comprises feet on which the bottom part rests.
5. The storage container according to any of the preceding claims, wherein the outer surface
25 comprises a non-permeable material.
6. The storage container according to any of the preceding claims, wherein the outer surface
comprises a thermoplastic material.
- 30 7. The storage container according to claim 6, wherein the thermoplastic material is selected
from acrylonitrile butadiene styrene (ABS), polypropylene (PP), polycarbonate (PC), polyethylene
(PE), low density polyethylene (LDPE), high density polyethylene (HDPE), polyvinylchloride (PVC),
polystyrene (PS) and polyethylene terephthalate (PET).
- 35 8. The storage container according to claim 7, wherein the thermoplastic material is
polypropylene.
9. The storage container according to any of the preceding claims, wherein the outer surface
has a thickness of less than 3.5 mm.
40
10. The storage container according to any of the preceding claims, wherein the equilibration
period is less than 15 min.
- 45 11. The storage container according to any of the preceding claims, wherein the storage
container is stable in upright position when positioned on a smooth surface or grill type surface in a
refrigerator.

12. The storage container according to any of the preceding claims, wherein either the top part is removable from the bottom part or the bottom part and top part are hingedly connected to be pivotably moveable between a closed and open position.
- 5 13. The storage container according to any of the preceding claims, wherein the interior space comprises a recess in which the electronic injection device fits at least partially.
14. The storage container according to any of the preceding claims, wherein at least a portion of the outer surface comprises a roughed profile.

Figure 1

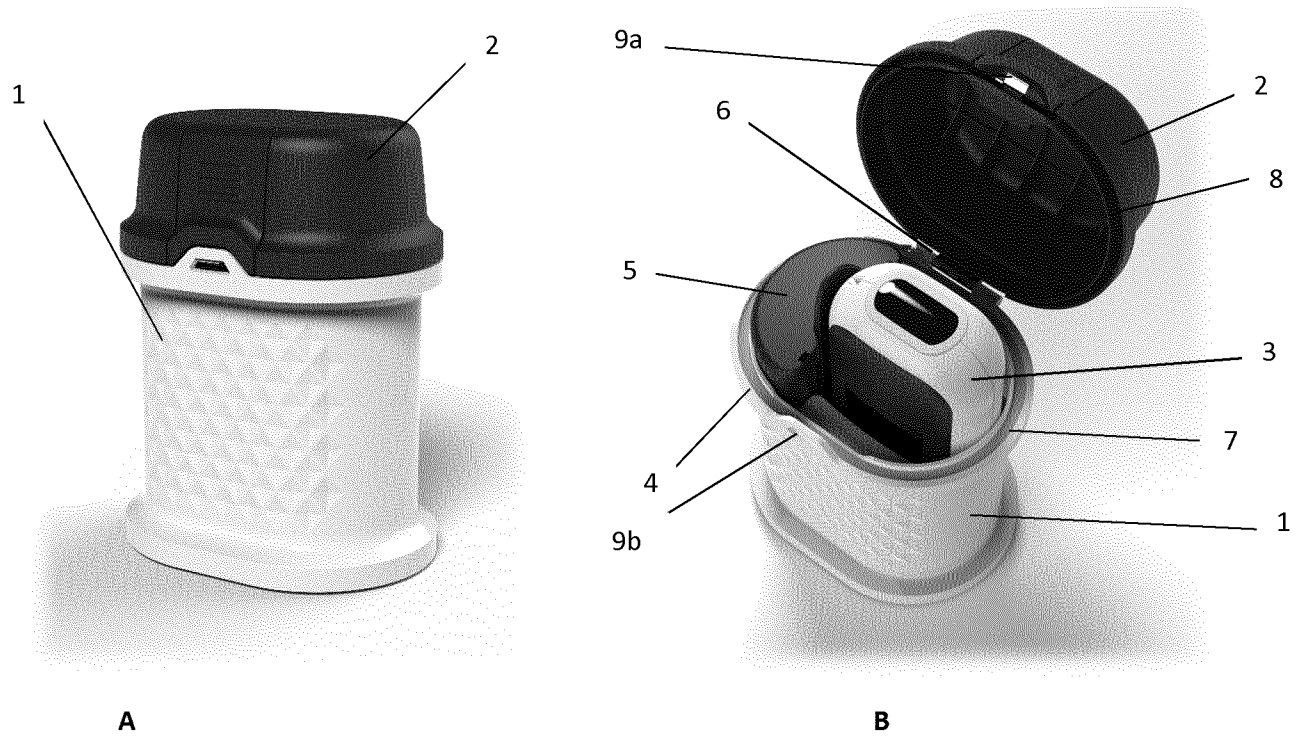


Figure 2

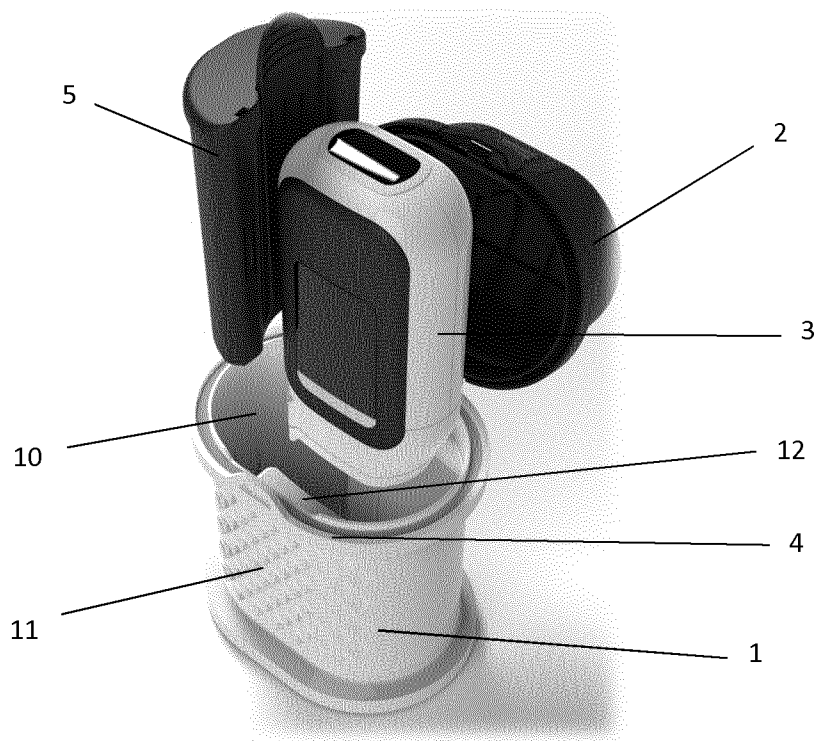


Figure 3

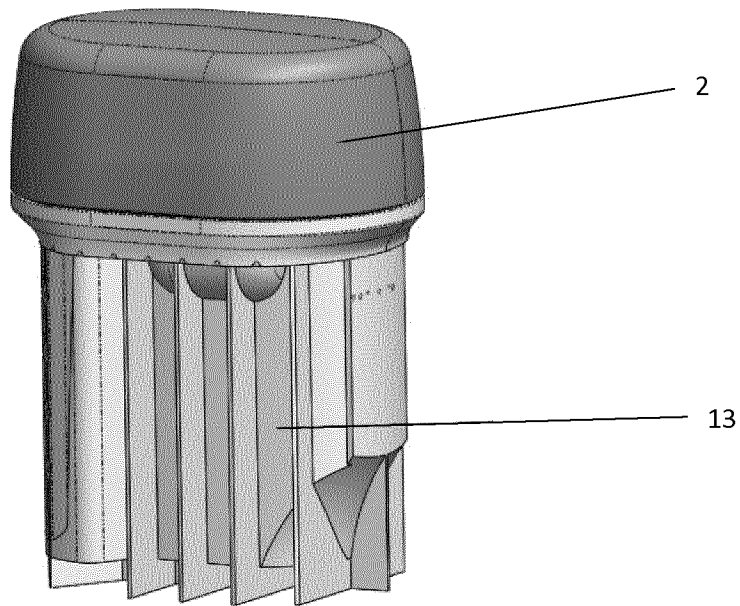
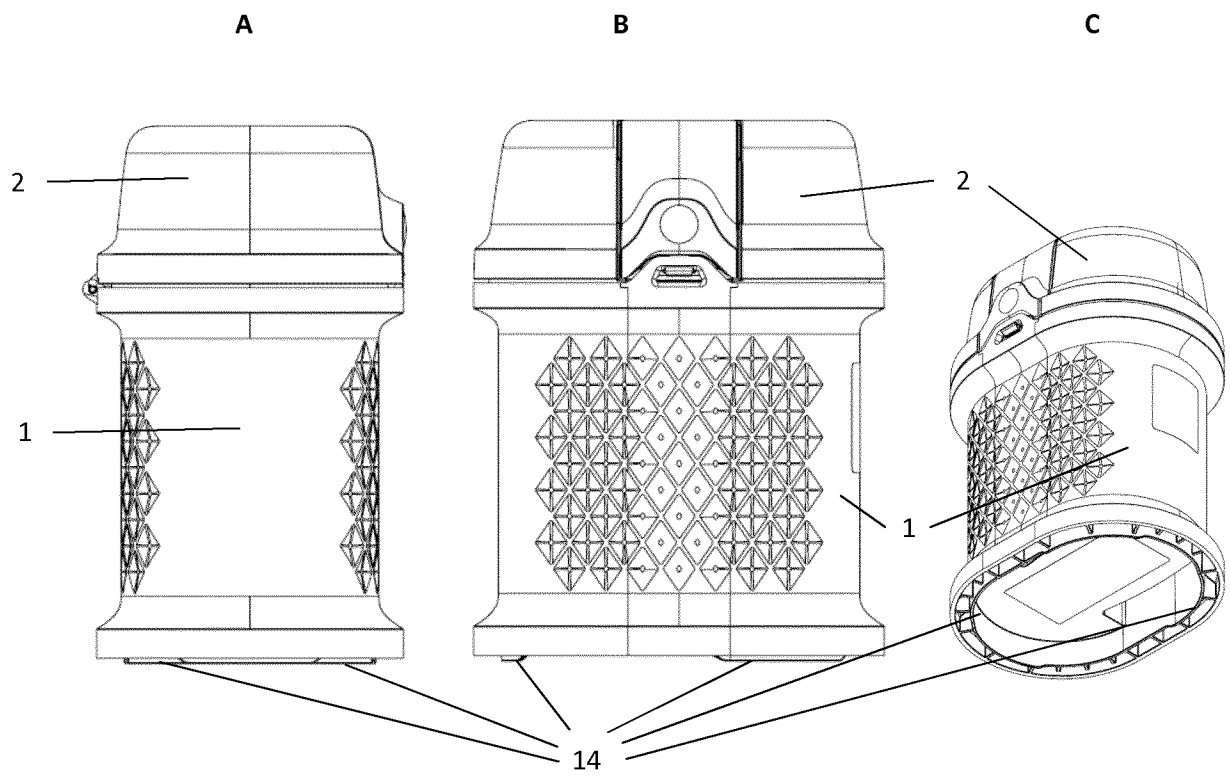


Figure 4



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/054417

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M5/00 B65D81/26 B65D81/00 A61J1/00 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 B65D A61J		
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	KR 101 638 405 B1 (DAE WOONG PHARMA [KR]) 11 July 2016 (2016-07-11) the whole document -----	1-14
X	US 2013/334074 A1 (WADA KIYOSHI [JP] ET AL) 19 December 2013 (2013-12-19) figures 1-14 paragraphs [0007] - [0016], [0039] - [0073] -----	1-14
X	US 2005/118071 A1 (SACHERER KLAUS-DIETER [DE]) 2 June 2005 (2005-06-02) figures 1, 2, 7 paragraphs [0021], [0047] ----- -/--	1-7,9-14
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 27 June 2018		Date of mailing of the international search report 06/07/2018
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 López García, Mónica

INTERNATIONAL SEARCH REPORT

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/084631 A1 (ANDERSON BRIAN S [US]) 21 April 2005 (2005-04-21) figures 1-3 paragraphs [0014] - [0022] -----	1-14
E	EP 3 299 050 A1 (CLARIANT HEALTHCARE PACKAGING FRANCE SAS [FR]) 28 March 2018 (2018-03-28) the whole document -----	1,2,5-8, 12,13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2018/054417

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
KR 101638405	B1	11-07-2016	NONE
US 2013334074	A1	19-12-2013	BR 112013022666 A2 14-11-2017 CN 103415449 A 27-11-2013 CO 6761331 A2 30-09-2013 EP 2573007 A1 27-03-2013 JP 5900030 B2 06-04-2016 JP 2012197117 A 18-10-2012 MY 165861 A 18-05-2018 US 2013334074 A1 19-12-2013 WO 2012120887 A1 13-09-2012
US 2005118071	A1	02-06-2005	DE 10353445 A1 16-06-2005 US 2005118071 A1 02-06-2005
US 2005084631	A1	21-04-2005	EP 1472157 A1 03-11-2004 JP 2005515869 A 02-06-2005 US 2005084631 A1 21-04-2005 WO 03064281 A1 07-08-2003
EP 3299050	A1	28-03-2018	EP 3299050 A1 28-03-2018 WO 2018055195 A1 29-03-2018