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(54) Benevnelse **INSERT FOR A PUMP CAP FOR A PHARMACEUTICAL CONTAINER, PUMP CAP FOR A PHARMACEUTICAL CONTAINER, PHARMACEUTICAL CONTAINER WITH THE PUMP CAP, AND COMPUTER PROGRAM PRODUCT**

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A pump cap for a pharmaceutical container; inlay for a pump cap for a pharmaceutical container, pharmaceutical container with the pump cap; and computer program product

Specification

Technical field, prior art, technological background

The following is a description of a pump cap for a pharmaceutical container, an inlay for a pump cap for a pharmaceutical container, a pharmaceutical container with a pump cap and a computer program product that serves the pump cap jointly with an electronic unit.

Examples of administered, nasally and sublingually, controlled substances from containers are the well-known, various and costly aerosol metering valves and spray pumps by Aptar Pharma, for example (www.aptar.com).

Recording the discharge processes of such pharmaceutical dispensers can help count the number of discharge processes. The patient or the doctor can thus be provided with an overview of the discharge processes that were carried out. In this regard, DE 10 2010 042 007 A1 and DE 10 2008 064 559 A1 are also referred to as technological background.

From DE 10 2014 204 939 B3, a dispenser in the shape of an MDI (Metered Dose Inhaler) for discharging a pharmaceutical medium is popular. This dispenser has a sensor to record a discharge process and an electronic processing circuit to record and further process one of the signals emitted from the sensor. The sensor is part of a sensor unit, which has a radio transmitter to produce a radio signal and the processing circuit has a radio receiver adapted to receive radio signals produced from the radio transmitter.

US 2015/061867 A1 relates to devices and methods for the electronic surveillance and recording of the emission of particularly pharmaceutical substances through various donating devices, including the wireless transfer of the recorded data to an external electronic device.

WO 2014/068504 A2 discloses an inhalation device for donating pharmaceutical substances, which is appropriate and determined to dose a respectively administered medication by an external electronic device.

US 8,8071,131 B1 discloses a device and a method for surveilling the use of an inhaler by asthma patients, including a computer program product, which is determined for the use on smart phones or personal digital assistants (PDA).

Two electronic components are thus intended for this dispenser, which are integrated in a joint dispenser but are not galvanically coupled to each other. Instead, both electronic components, the sensor unit and the processing circuit are connected via a radio interface. This processing circuit has an energy source (battery or accumulator) that stores the radio receiver and display

device in a specific location in a dispenser and, if applicable, a storage device to save the discharge processes, taking into consideration the time of the discharge process. The sensor unit has a sensor, a radio transmitter and, if applicable, an energy source (battery and accumulator) for operating the radio transmitter. Instead of the energy source, a converter is intended to convert mechanical energy to electrical energy, which is identical with the sensor. The user thus uses it to convert the energy created by the discharge process into electrical energy for the radio transmitter. A piezoelectric generator serves as a converter.

Underlying problem

This arrangement has a string of disadvantages, of which only a few are mentioned here. It is a separate, receiving unit of a pharmaceutical container to be additionally purchased by the user (the patient). It makes the medication container to be carried by the patient bigger. Its operation is also conceptually very expensive. On one hand, the signal and energy producing piezoelectric generator is expensive. On the other hand, the arrangement of batteries and a display in the processing circuit located in the dispenser are also to be disposed of after the life span of the arrangement.

Solution to the problem

In order to at least partially solve the previously mentioned problems, a pump cap for a pharmaceutical container, an inlay for a pump cap for a pharmaceutical container, a pharmaceutical container with the pump cap and a computer program product for a personal digital assistant is suggested.

There is an electronic unit in the pump cap. This electronic unit is adapted, on one hand, to record the activation of a pump cap by a user to release the content of the container and, on the other hand, to release the reporting signals of the activations of the pump cap in a wireless manner, in order to allow the required operational energy to be led from outside in a wireless manner for the record of activations and release of signals.

The operational energy of the electronic unit will be transmitted from an electronic unit, independent of the pump cap, in the form of a so-called personal digital assistant (PDA), such as a mobile or cordless phone, a so-called smart phone, a so-called smart watch, a tablet computer, a notebook or something similar; the electronic unit is adapted to receive the operational energy of the personal digital assistant.

Advantages, designs

The pharmaceutical container with this kind of adapted pump cover is essentially less costly in production and thus also in disposal. The electronic unit with a pharmaceutical container comprising approximately 100 to 200 medications, independent of the pump cap, has a longer life and operational cycle than the pharmaceutical container with its pump cap. The costly disposable part of the discharge unit of DE 10 2014 204 939 B3 with batteries and an display is thus omitted. What's more, it is, nevertheless, common for a user these days to move around with such a personal digital assistant (PDA) at all times. Likewise, a patient who has to administer nasal and sublingual controlled (pharmaceutical) substances carries this pharmaceutical container about as a rule. As long as the user avoids the solution suggested here in terms of carrying unnecessary electronic appliances i.e. he passes on the pump cap on the pharmaceutical container on the processing circuits with batteries and accumulators suggested here, the radio receiver and the MDI display device of DE 10 2014 204 939 B3. Furthermore, the expensive cost-intensive piezoelectrical generator is omitted.

The electronic appliance, namely the personal digital assistant, has, on one hand, corresponding structural components in the form of one or several antennae or other emitters such as the associated control electronics and a processor with storage and input/output elements (touch-sensitive display panels). A computer program product is suggested for the processor of the personal digital assistant (a so-called app), which allows the control electronics of the antenna to release operational energy for the electronic unit of the pump cover in order to receive the signals released from the electronic unit in a wireless manner and, after their processing, to have the processor display the pump cap activations on the display of the electronic appliance.

The electronic unit of the pump cap is a transmitter, for example in the form of a RFID- Module (RFID = Radio Frequency Identification) and essentially has a chip module comprising an antenna designed as a coil or dipole. This chip module enables the contactless, automated registration and/or retrieval of data in / out of the chip of a transmitter. Such a transmitter comprises, for example, a coil-shaped transmitter antenna next to the chip, which enables contactless data access. A pump cap personalization, explained in detail below, is part of the registered data, more precisely relating to the pharmaceutical container, with regards to "pairing" with the computer program product of the personal digital assistant. The signals reported by the pump cap activations are part of the retrieved data.

The transmitter, thus the antenna and chip module, is integrated in the pump cap and receives its operational energy from the personal digital assistant (PDA) only if the user activates the corresponding computer program product on the personal digital assistant, or, permanently, as long as the pump cap on the pharmaceutical container is sufficiently close to the personal digital assistant and radiates energy via its corresponding antenna(e).

In a variant, the transmitter is adapted to transmit data via Near Field Communication (= NFC) via radio and within a short distance of approximately 10cm to 20cm. Details in this regard are also explained in ISO / IEC 14443 A and B or in ISO / IEC 15693. Data for the NFC Communication is thus transmitted at a 13.56 MHz range. In this regard, active and

passive NFC transformers can be used. Active NFC transmitters are able to initiate and communicate connections. Passive NFC transmitters are not able to build connections independently. They need an active partner, in this case the PDA, to test the data.

Active transmitters need a source of energy whilst the passive transmitter can manage without a source of energy. In order to state their information via the pumping operation(s), passive transmitters make use of the energy transferred from active readers. Energy is transferred to the transmitter via the active reader, in order to transmit information about the pumping operation(s) within a short distance of around 10 cm to 20 cm. In a variant, the operation energy storage of the transmitter is meant to be assigned, for example, in the form of a capacitor.

Since a diversity of smart phones (Apple 6, Android, BlackBerry, Windows, etc) is being planned or already exists, those equipped with NFC functionality (according to NFC-Standard ISO / IEC 14443 A and B or ISO / IEC 15693), namely coils, control electronics, appropriate NFC-control software (NFC protocol stack) in the processor-operational system of the Smart phone, the inlay / electronic unit of the pump cap in different smart phones or other personal digital assistants PDA are supplied with operational energy to respond and retrieve. Such a personal digital assistant is used for the collaboration of the pump cap described here and/or the inlay described below.

Instead of a Near-Field Communication, (energy and) data transmission can also occur via Bluetooth Standard, Wibree Standard, ANT+-Standard or Zigbee Standard.

In a variant, the electronic unit of the pump cap is equipped with a sensor comprising a switch adapted to record a discharge process. This switch can be built in a particularly simple form through two electrical contacts that are electrically bridged to the opening of the pharmaceutical container via a metallic , for example aluminum, capsule if the user presses down the pump cover to cause a discharge process. If the opening of the pharmaceutical container is designed without a metal capsule, then the switch simply has an opening or closing switch. Aside from this switch sensor, a capacitive, magnetic or other form of recording of the pumping operation can be used to ensure that the electronic unit is capable of releasing an appropriate signal.

In an additional variant, an inlay in a pharmaceutical container is suggested, wherein the electronic unit for the inlay is a transmitter. The transmitter comprises essentially a chip module comprising an antenna designed as a coil or dipole for the contactless, automated registration and/or retrieval of data in and out of the chip, wherein the registered data comprises a personalized identifier of the inlay of the pump cap for pairing the electronic unit with a computer program product in the personal digital assistant (PDA) and/or the retrieved data comprise the signals reported by the activation of the pump cap.

The inlay comprises plastic wrap, whose outside diameter is smaller than the inside diameter of the pump cap. The inlay is shaped in a way that it is inserted and, if applicable, stuck into the pump cap to ensure that it is accommodated between the opening of the pharmaceutical container and one located at the pump operation toward the fixed pharmaceutical container wall and the pump cap. The plastic wrap of the inlay has an opening passage for a drug discharge socket. The plastic wrap carries the chip module of the transmitter and its antenna, which is equipped as a planar ring coil or dipole. In this variant, the electronic unit is also equipped with a sensor with a switch adapted for recording the discharge process. This switch can be built in a particularly simple form through two electrical contacts that are electrically bridged to the opening of the pharmaceutical container via a metallic, for example aluminum, capsule if the user presses down the pump cover to cause a discharge process. If the opening of the pharmaceutical container is designed without a metal capsule, then the switch simply has an opening or closing switch. Otherwise, capacitive, magnetic or other types of sensor systems are appropriate to record one or several occurring discharge processes. The discharge process is then transmitted via the transmitter to the personal digital assistant.

Foil material for the inlay can be wood-free paper, coating paper or paper stuffed with resin, synthetic and/or plastic foil from plastic material such as Polyethylene (PE), Polyvinyl chloride (PVC), Polyvinyl chloride-Acetate-Copolymer, Polyethylene terephthalate (PET) or Polyethylene terephthalate glycol-modified (PETG), Polyethylene naphthalate (PEN), Acrylonitrile-Butadiene-Styrene-Copolymers (ABS), Polyvinyl butyral (PVB), Polymethylmethacrylate (PMMA), Polyimide (PI), Polyvinyl alcohol (PVA), Polystyrene (PS), Polyvinyl phenol (PVP), Polyethylene (PE), Polypropylene (PP), Polycarbonate (PC) or their foil derivatives with a thickness of at least 75 µm or more. One or multiple layers of the support structure can be produced from this foil material in which one or several multi-layer spiral or cylindrical coil can be produced as antenna coil for Near-Field Communication. Furthermore, a capacitor can be included to store the operational energy for the electronic unit received via the antenna coil in or at such single or multi-layer support structures.

A shape (diameter and height) of a 1 Euro coin is thus produced for the inlay, for example, with a central passage opening (a few millimeters of the diameter or the lateral dimension) for the drug discharge socket of the pharmaceutical container.

This inlay is particularly advantageous provided it can be used in the readily conceived container from pump cap and pharmaceutical container prior to final assembly without any modification carried out on the pump cap or the pharmaceutical container. Through the small construction height, which is derived from the thickness of the foil material and of the chip as well as the sensor arrangement, the actuation path of the pump cap also does not undergo any practical change to ensure that the discharge volume of the medication during the activation of the pump cap also does not vary with the figure in the inlay located in the pump cap.

In one aspect an assembly is provided, comprising (i) a pharmaceutical container comprising a nasal spray, for example in the form of a solution or suspension, preferably Dymista® nasal spray (an

azelastine HCl/Fluticasone propionate combination), (ii) a pump cap connected to a drug discharge socket of the pharmaceutical container, and (iii) an electronic unit, which is either accepted in an insert provided between the pharmaceutical container and the pump cap, or directly in said pump cap. Here, the pump cap can be realized with the electronic unit and/or the insert provided between the pharmaceutical container and the pump cap in the variants described above.

In another aspect, a computer program product is provided for the personal digital assistant PDA, which is adapted and programmed so that an electronic unit is supplied in an inlay or, directly in a pump cap according to one of the previous claims by an appropriate control of the personal digital assistant PDA with operating energy and discharge processes from the pharmaceutical container is detected, comprising a preparation mode in order to implement a pairing of a respective electronic unit in an inlay in the pump cap or directly in a pump cap with a personal digital assistant, a wake-up mode in order to activate the electronic unit in the inlay and/or in the pump cap, a receiving mode in order to wait for the user to activate the pump cap so that the electronic unit transmits signals which reflect the discharge processes from the pharmaceutical container by activating the pump cap, an evaluation mode in order to measure the time elapsed between successive activations of the pump cap and to categorize different events based on the time elapsed.

Additional details are also defined in the dependent claims.

Brief description of the drawings

Additional goals, features, advantages, and potential applications are discernible from the following description of design examples with reference to the corresponding drawings, which shall not be considered limiting in any way. Here, all features described and/or illustrated by images show per se or in arbitrary combinations thereof the objective disclosed here, regardless of their grouping in the claims or their reference. The dimensions and proportions of the components shown in the figures are not necessarily true to scale here; in order to implement a design; they may deviate from the illustration.

Fig. 1 shows a variant of the pump cap in a schematic, lateral cross-section in cooperation with a computer program executed on a personal digital assistant PDA,

Fig. 1a shows a variant of an electronic unit for the pump cap with a transmitter and an antenna 12a designed as a coil in a schematic illustration,

Fig. 2 shows another variant of a pump cap in a schematic lateral cross-section in cooperation with a computer program product executed on a personal digital assistant,

Fig. 2a shows a variant of an electronic unit for the pump cap with a transmitter and an antenna designed as a coil in a schematic top view,

Fig. 3 shows another variant of a pump cap in a schematic lateral cross-section in cooperation with a computer program product executed on a personal digital assistant,

Fig. 4 shows the computer program product in cooperation with an electronic unit in the pump cap or the use with the personal digital assistant, on which the computer program product is executed.

Detailed description of the drawings

Fig. 1 shows a first design of a pump cap 10 made from plastic for a pharmaceutical container 18. This pump cap 10 is designed as an attachment for the pharmaceutical container 18. For this purpose, the pump cap 10 comprises an applicator socket 10a, which conically tapers towards its free end. The applicator socket 10a extends away from a seat 10c showing a constant radius arch, which is designed to accept the pharmaceutical container 18. This pharmaceutical container 18 comprises a fluid reservoir, not shown in greater detail, a metal, for example aluminum, capsule 18a and an outlet socket 18b. The metal capsule 18a and the outlet socket 18b can be displaced in reference to each other. Here, the pharmaceutical container 18 is designed such that by pushing down the seat 10c showing a constant radius arch, the pump cap 10 is pressed in the direction towards the metal capsule 18a of the outlet socket 18b into the neck of the pharmaceutical container 18, and here a defined volume of the pharmaceutical medium, previously located in the liquid reservoir of the pharmaceutical container 18, is discharged through the outlet socket 24. The outlet socket 24 is accepted in an outlet channel 10b allocated to the applicator socket 10a. The seat 10c with a constant radius arch shows a cover disk and a tubular section. The tubular section is open at one (lower) end and encompasses the neck and perhaps partially the upper section of the pharmaceutical container 18. The cover disk of the seat 10c with a constant radius arch closes the tubular section at its other (upper) end and is pressed for discharging the pharmaceutical medium in the direction towards the metal capsule 18a of the pharmaceutical container 18.

An electronic unit 12 is allocated to the pump cap 10. Said cap in turn is adapted to detect an activation of the pump cap 10 by the user in reference to the pharmaceutical container 18, in order to discharge the content of the container. Furthermore, the electronic unit 12 is adapted to wirelessly transmit signals reflecting such activations of the pump cap 10. Finally, the electronic unit 12 is adapted to be wirelessly supplied with operating energy from the outside using an electronic device, here a personal digital assistant PDA for (i) detecting one or more actuations of the pump cap 10 by a user and for (ii) wirelessly transmitting signals regarding one or more activation(s) of the pump cap 10.

As also illustrated in Fig. 1a, the electronic unit 12 includes a transmitter, which essentially comprises a chip module and an antenna 12a designed as a coil or as a dipole. The electronic unit 12 is adapted for the contactless, automatic registering and/or retrieval of the data in/out of the chip. The data to be entered includes, for example, a personal identification to pair the electronic unit 12 with a computer program product on the personal digital assistant PDA. This way it is ensured that a pharmaceutical container 18, more precisely its pump cap / its electronic unit 12, communicates exclusively the pump processes to be counted to the computer program product on the personal digital assistant of a user of the pharmaceutical container 18. The data to be read from the electronic unit 12 includes the signals reflecting the activation of the pump cap 10. This data telegram to be transmitted can additionally include the personal identifications written during the pairing of the computer program product on the personal digital assistant PDA of the respective user in the electronic unit 12.

Via the antenna 12a, designed in Fig. 1a as a coil, the electromagnetic energy received by the antenna 12a, transmitted by the personal digital assistant PDA, can be collected in the electronic unit 12 via an energy generation circuit and saved as electric energy in the operating energy storage unit 12c here

realized as a capacitor. This way, the electric energy is available for subsequent energy supply of the chip module when transmitting the signals reflecting the actuation of the pump cap 10 (perhaps in the data telegram including the personalized identification).

In the variant of Fig. 1 the electronic unit 12 of the transmitter is integrated in the pump cap. The transmitter is adapted to only receive operating energy from the personal digital assistant when the user of the respective computer program product is activated on the personal digital assistant PDA. In this case, the PDA emits the energy via an appropriate antenna. Alternatively, the transmitter and/or its electronic unit 12 are adapted to permanently receive operating energy from the personal digital assistant PDA as long as the pump cap 10 is located on the pharmaceutical container 18 in a sufficient spatial proximity of the personal digital assistant PDA and this PDA emits via appropriate antenna(e) energy to the antenna 12a of the electronic unit 12.

The electronic unit 12 is equipped with a sensor 12b, which shows in one variant a switch adapted for recording an output process. This switch can be formed in a particularly simple form by two electric contacts, which are electrically bridged by a metal capsule 18a to close the pharmaceutical container 18 when the user pushes the pump cap 10 down to such an extent that a discharge process occurs. If the closure of the pharmaceutical container 18 was to be performed without any metal capsule 18a, for example designed by an electrically non-conductive plastic, the sensor 12b may represent a switch designed as a simple opening or closing switch sensor. Instead of this switch, here a capacitive, magnetic, or other sensor 12b may also be provided for detecting the pumping process so that the electronic unit 12 can emit a signal to the personal digital assistant PDA, respectively representing the discharge process.

For the electronic unit 12, such NFC-components of the companies NXP (www.nxp.com) or AMS (www.ams.com) may be used for example, respectively comprising a signal input, in order to record and process sensor signals, and to allow transmitting them via the antenna 12a to the personal digital assistant PDA.

In the variant illustrated in Fig. 1, the antenna 12a is embedded in the plastic material of the applicator socket 10a of the pump cap 10. Here, the coil antenna 12a designed as a loop shows several windings, which taper following the cone of the applicator socket 10a. In other variants, not shown here, the coil antenna 12a may also be accepted in the seat 10c with a constant radius arch, for example in the cover disk of the seat 10c with a constant radius arch or its tubular section.

In the variant shown in Figs. 2 and 3, the electronic unit 12 is not embedded in the plastic material of the pump cap 10. Rather, here the electronic unit 12 is a part of a separate insert in the form of an inlay for the pump cap 10 of a pharmaceutical container 18 that can be produced independently from the pump cap 10.

The tubular section of the pump cap 10 is open at one (lower) end and encompasses the neck and perhaps partially the upper section of the pharmaceutical container 18. The cover disk of the seat 10c with a constant radius arch closes the tubular section at its other (upper) end and is pressed in the direction towards the metal cap 18a of the pharmaceutical container 18 in order to discharge the pharmaceutical medium. The inlay is located at the interior wall of the cover disk of the seat 10c with a constant radius arch, for example adhered or fastened by way of spot welding. This inlay also shown in Fig. 2a shows a circular disk-shaped form with the diametric dimensions of approximately a 1-Euro

coin, here with a round, central penetrating opening (showing a few millimeters in diameter or lateral dimension) for the drug discharge socket 18c of the pharmaceutical container 18.

The inlay carries the electronic unit 12 at the side (in Fig. 2 at the bottom) facing the pharmaceutical container 18. Similar to the variant of Fig. 1, it is equipped with a sensor 12b, which in one variant shows a switch adapted to detect a discharge process. This switch can be formed in a particularly simple design by two electric contact sites, which are then electrically bridged by a metal capsule 18a for closing the pharmaceutical container 18 when the user pushes the pump cap 10 down to such an extent that a discharge process occurs. If the closure of the pharmaceutical container 18 is designed without a metal capsule 18a, for example made from an electrically not conducting plastic, the sensor 12b may represent a switch simply designed as an opening or closing switch. Instead of this switch sensor, here a capacitive, magnetic, or other sensor 12b may also be provided for detecting a pumping process, so that the electronic unit 12 can transmit to the personal digital assistant PDA a signal appropriately reflecting the drug discharge process.

Otherwise, the electronic unit 12 is consistent with the variant described in the context with Figs. 1 and 1a. The plastic material of the insert represents, in the variant of Fig. 2, a layer of plastic film, for example made from plastic, such as polyethylene (PE) or polyvinyl chloride (PVC) with a thickness of approximately 100 µm. The antenna 12a, here designed as a coil antenna, is applied on this plastic film and contacts the electronic unit 12, which comprises also the sensor 12b.

In the variant of Fig. 3, unlike in the variant of Fig. 2, the inlay is designed in several layers, with the plastic material of the inlay in the variant of Fig. 3 representing several laminated layers of synthetic film, for example plastics such as polyethylene (PE) or polyvinyl chloride (PVC) showing a thickness of 75 µm. The windings of the coil antenna 12a are located between the individual layers. In this stack of plastic films, in one variant, in addition to the antenna 12a also the operating energy storage unit 12c is located. With regards to sizing and design of the coil antenna 12a in its different variants discussed above, reference is made for example to “Antenna Circuit Design for RFID Applications”, AN710, Youbok Lee, Ph.D., 2003 Microchip Technology Inc. Another literature source for sizing and design of the coil antenna 12a, also dependent on the various different RFID-chips that can be inserted in the electronic unit, is “RFID Design Fundamentals and Applications”, Albert Lozano-Nieto, CRC Press Taylor & Francis Group 6000 Broken Sound Parkway NW, Suite 300 Boca Raton, FL 33487-2742, © 2011 by Taylor and Francis Group, LLC. Another example of literature for sizing and design of the coil antenna 12a is “Design of Antennas for RFID Application”, Ming-Tao Zhang et al. in “Development and Implementation of RFID Technology” edited by Cristina TURCU, ISBN 978-3-902613-54-7, pp. 554, February 2009, I-Tech, Vienna, Austria.

The pump cap with the corresponding electronic unit 12 according to Fig. 1, or the pump cap 10 with an inlay according to Figs. 2 and 3, is combined with a pharmaceutical container 18 to form another container, and a nasal spray is located in the pharmaceutical container, for example in the form of a solution or suspension, preferably Dymista® nasal spray, a combination of azelastine hydrochloride and Fluticasone propionate, with 1 g suspension comprising 1,000 microgram azelastine hydrochloride and 365 microgram fluticasone propionate, and with one jet of 0.14 g comprising 137 microgram azelastine hydrochloride and 50 microgram fluticasone propionate, and with the other components of the nasal spray representing disodium edetate, glycerol, micro-crystalline cellulose, and carmellose sodium, polysorbate 80, benzalconium chloride, phenyl-ethyl alcohol, and purified water.

The computer program product running on the personal digital assistant PDA in preparation mode VBM causes the pairing of a respective electronic unit 12 in (an inlay or directly in) the pump cap 10 with the personal digital assistant PDA. For this purpose, the user starts the preparation mode of the computer program product and brings the personal digital assistant PDA into the spatial proximity of the pump cap 10 comprising the electronic unit 12. In the preparation mode VBM of the computer program product, this initiates the emission of electromagnetic energy according to the NFC-standard ISO / IEC 14443 A and B or ISO / IEC 15693 via the NFC-functionality (coils, control electronic, appropriate NFC-control software (=NFC protocol stack) in the processor operating system) of the personal digital assistant PDA. As soon as the electronic unit 12 receives sufficient electromagnetic energy via its coil antennae 12a from the antenna in the personal digital assistant PDA, the electronic unit 12 is activated and reacts with the confirmation signal transmitted by its coil antenna 12a. Now, the personal digital assistant PDA transmits, for example an (alphanumeric) multi-digit individualized identification, which is received by the electronic unit 12 via the antenna 12a and is saved in a non-volatile storage unit of the chip of the electronic unit 12, the EEPROM, which is not shown in greater detail here.

Alternatively, it is also possible that after the activation of the electronic unit 12, said unit also transmits from the memory unit of the chip a multi-digit individualized identification stored there, for example an alphanumerical one, via the antenna 12a to the personal digital assistant PDA.

In both variants it is achieved that, on the one hand, the personal digital assistant PDA and, on the other hand, the electronic unit 12 in the pump cap 10 are adjusted to each other. Here, during the later receipt of discharge processes from the pharmaceutical container 18 from signals reflecting the activation of the pump cap 10, the computer program product can reliably allocate these signals exclusively to this very assembly, and not to any other one, and process them accordingly. Additionally, a discharge meter is reset to zero.

In order to record with the personal digital assistant PDA and the simultaneously running computer program product, any signals reflecting discharge processes from the pharmaceutical container 18 by activation of the pump cap 10 and to allow displaying them on the monitor of the personal digital assistant PDA, in a wake-up mode AWM, the electronic unit 12 is activated (located in an inlay or directly in) the pump cap 10. For this purpose, the user starts the computer program product and brings the personal digital assistant PDA into the spatial proximity of the pump cap 10 comprising the electronic unit 12. In the preparation mode VBM of the computer program product, it initiates the transmission of electromagnetic energy according to the NFC-standard ISO / IEC 14443 A and B or in ISO / IEC 15693 via the NFC-functionality (coils, control electronic, appropriate NFC-control software (=NFC protocol stack) in the processor operating system) of the personal digital assistant PDA. As soon as the electronic unit 12 receives sufficient electromagnetic energy via its coil antenna 12a from the antenna of the personal digital assistant PDA, the electronic unit 12 is activated. Once the transmitted electromagnetic energy is sufficient, the electronic unit 12 transmits a brief “active signal” together with its individualized identification to the personal digital assistant PDA. This occurs commonly within one or two seconds after the user has brought the personal digital assistant PDA into spatial proximity of the pump cap 10 comprising the electronic unit 12. The receipt of the “active signal” and thus the readiness of the personal digital assistant PDA to detect discharge processes from the pharmaceutical container 18 by signals reflecting the activation of the pump cap 10, processing and ability to display these signals on the monitor of the personal digital assistant PDA are indicated

by the computer program product by an appropriate acoustic or visual message on the monitor of the personal digital assistant PDA.

In the next step of the computer program product, the personal digital assistant PDA is kept in receiver mode EM. In this receiver mode EM, the computer program product waits for the user operating the pump cap 10 such that the electronic unit 12 transmits via its coil antenna 12a signals which reflect discharge processes from the pharmaceutical container 18 by activating the pump cap 10.

In order to prevent that the counting of the discharge processes is dependent on the operation of the pump cap 10 by the user, all activations of the pump cap 10 are transmitted by the electronic unit 12 to the personal digital assistant PDA. The computer program product however evaluates how much time elapses between two activations of the pump cap 10. If very short intervals (approximately 1 – 4 seconds) are signalized between two or more activations of the pump cap 10 by the electronic unit 12, this shall be categorized by the computer program product as a so-called priming of the pharmaceutical container 18; the computer program product abstains from increasing the discharge meter but shows the present status on the monitor of the personal digital assistant PDA.

If two activations of the pump cap 10 are signaled by the electronic unit 12 in short intervals (approximately 4 – 10 seconds) to the personal digital assistant PDA, this is categorized by the computer program product as two discharge events (one discharge process for each nostril of the user); the computer program product accordingly increases the discharge meter and shows the present status on the monitor of the personal digital assistant PDA. Additionally, this number of discharge processes is saved together with a current date/time stamp in the memory of the personal digital assistant PDA for later use.

In the present case, a differentiation is described between the so-called priming of the pharmaceutical container 18 and two discharge processes using different temporal intervals between two activations of the pump cap 10. In one variant, not shown in greater detail, it is provided in case of two activations of the pump cap 10, regardless of the time interval, to increase in the computer program product the discharge meter accordingly and to display the current status on the monitor of the personal digital assistant PDA. If more than two activations of the pump cap 10 are signaled within a predetermined period, e.g., 5 - 15 seconds, to the computer program product, in another variant, not shown in greater detail either, the discharge meter in the computer program product is increased by two and the current status is displayed on the monitor of the personal digital assistant PDA.

Another variant provides, after the pairing of a respective electronic unit 12 (in an inlay or directly in) the pump cap 10 with the personal digital assistant PDA, in a first step to prompt the user for priming using a message on the monitor of the personal digital assistant PDA. Here, the signalized interval is recorded and saved in the computer program product for comparison of the signal progression for later activations of the pump cap 10. In a second step, using a message on the monitor of the personal digital assistant PDA, then the user is prompted to execute two discharge processes (one discharge event for each nostril of the user). Here, the signaled interval is also recorded and saved in the computer program product for comparison of the signal progression in case of later operation of the pump cap 10.

In a subsequent operation of the pump cap 10, the temporal progression of the activations of the pump cap 10 signaled is compared to the saved progressions. Depending on the categorized activations of the pump cap 10, then the computer program product increases the discharge meter accordingly by

two (or not, if the operations were categorized as priming) and the current status is displayed on the monitor of the personal digital assistant PDA.

In addition to the above-described functionalities of the computer program product, here, a history display mode HDM is provided, which displays the discharge events counted since the most recent pairing of the respective electronic unit 12 of the pump cap 10 with the personal digital assistant PDA, respectively provided with time/date stamp, on the monitor of the personal digital assistant PDA. For this purpose, the discharge processes saved in the personal digital assistant PDA are read from the memory of the personal digital assistant PDA together with the respective date/time stamp and processed into a list or graph, and indicated for example along a timeline.

Furthermore, an application reminder mode EEM is provided, in which the user can enter one or more times of day or intervals at which the user shall respectively perform the next administration. It is displayed on the monitor of the personal digital assistant PDA how much time remains until the next administration. At the specified point of time of administration, the personal digital assistant PDA then triggers an optic and/or acoustic and/or haptic alarm.

The presently described functionalities of the computer program product can also be integrated in a computer program product (app), which furthermore allows a number of other functions and options for the user. For example, various symptoms can be documented in their severity and frequency and perhaps correlated to the administration cycle of the medication.

The above-described variants as well as their design and operating aspects serve only for the better understanding of the structure, the functionality, and the features; they have no limiting effect upon the disclosure, for example to the design examples. The figures are partially schematic, with essential features and functions being shown sometimes considerably enlarged in order to illustrate functions, effects, technical designs, and features. Here, each functionality, each principle, each technical feature, and each characteristic disclosed in the figures or the text can be combined with all claims, all features in the text, and in the other figures, other functionalities, principles, technical designs, and features included in this disclosure or resulting therefrom, in a free and arbitrary fashion such that all possible combinations of the described variants shall be included, here.

Here, combinations between all individual designs in the text are also possible; this means in every section of the description, in the claims, and also combinations between different variants in the text, in the claims and the figures. The claims shall also not be considered limited to their disclosure and thus shall not exclude any potential combinations of all features shown. All disclosed features are explicitly also disclosed individually and in combination with all other characteristics. The invention is defined by the following claims.

Patentkrav

1. Pumpehetteinnsats for en farmasøytisk beholder (18),
hvor denne omfatter en eller flere plastfilmer, hvis ytre diameter er mindre enn den indre diameter av en pumpehette (10), og som hver har en gjennomgående åpning for en medikamentdispenserdyse (18c) av en farmasøytisk beholder (18), og
hvor innsatsen omfatter en elektronikkenhet (12), som er en sender, som i hovedsak har en chipmodul og en antenne (12a) utformet som en spole eller som en dipol, og
hvor chipmodulen til senderen og antennen (12a) er utformet som en plan ringspole eller som en dipol tilordnet plastfilmene, og
hvor elektronikkenheten (12) er konfigurert til
- å detektere en aktivering av pumpehetten (10) i forhold til den farmasøytiske beholderen (18) av en bruker for å dispensere innholdet av den farmasøytiske beholderen (18),
- trådløst sende ut signaler som representerer aktiveringer av pumpehetten (10), og
- å ha driftsenergi til
(i) å registrere en eller flere aktiveringer av pumpehetten (10) av en bruker og til
(ii) å trådløst avgi signaler som representerer en eller flere aktiveringer av pumpehetten (10)
som blir trådløst tilført eksternt av et elektronisk apparat i form av en personlig digital assistent (PDA).

2. Pumpehetteinnsats for en farmasøytisk beholder (18) ifølge krav 1, hvor elektronikkenheten (12) i innsatsen er anvendt for kontaktløs, automatisert innskriving og/eller avlesning av data inn/ut av chipen, og
hvor dataene som skal skrives inn inkluderer en personlig identifikasjonsidentifikator for innsatsen av pumpehetten (10), for paring med et datamaskinprogramprodukt på den personlige digitale assistenten (PDA), og dataene som skal avleses inkluderer signaler som representerer aktiveringen av pumpehetten (10).

3. Pumpehetteinnsats for en farmasøytisk beholder (18) ifølge et hvilket som helst av de foregående krav, hvor senderen er integrert i innsatsen og er konfigurert til enten å motta bare sin driftsenergi fra den personlige digitale assistenten når brukeren

aktiverer det aktuelle datamaskinprogramproduktet på den personlige digitale assistenten, eller er konfigurert til permanent å motta sin driftsenergi fra den personlige digitale assistenten (PDA) så lenge pumpehetten (10) med innsatsen på den farmasøytiske beholderen (18) er i umiddelbar nærhet til den personlig digitale assistenten, og denne avgir energi via dens tilhørende antenne(r).

4. Pumpehetteinnsats for en farmasøytisk beholder (18) ifølge et hvilket som helst av de foregående krav, hvor elektronikkenheten (12) er konfigurert til å motta driftsenergien fra den personlige digitale assistenten i form av en mobil- eller trådløs telefon, en såkalt smarttelefon, en smartklokke, et nettbrett, en bærbar PC, en personlig digital assistent (PDA) eller lignende, og/eller hvor elektronikkenheten (12) omfatter en sender som er konfigurert til å sende trådløst ut signaler som representerer aktiveringer av pumpehetten (10) via nærfeltkommunikasjon (NFC), og/eller trådløst mottak av driftsenergi, og/eller hvor elektronikkenheten (12) er utstyrt med en sensor (12b) med en bryter som er konfigurert til å detektere en utmatingsoperasjon, fortrinnsvis med to elektriske kontakter som er konfigurert og anordnet slik at de blir elektrisk omkoblet via en metalldel (18a) på den farmasøytiske beholderen (18) når brukeren presser pumpehetten (10) med innsatsen deri i en slik grad at en utmatingsoperasjon finner sted, eller sensoren (12b) er en åpnings- eller lukkeknapp hvis sensoren (12b) er konfigurert til å interagere med en farmasøytisk beholder (18), hvis lukking er konstruert uten en metallkapsel (18a).

5. Pumpehetteinnsats for en farmasøytisk beholder (18) ifølge et hvilket som helst av de foregående krav, hvor filmmaterialet i innsatsen er ett eller flere lag av trefritt papir, beleggpapir eller papir impregnert med harpiks, plastfilm fremstilt av plast, slik som polyetylen (PE), polyvinylklorid (PVC), polyvinylkloridacetatkopolymer, polyetylentereftalat (PET) eller glykolmodifisert polyetylentereftalat (PETG), polyetylennaftalat (PEN), akrylnitril-butadien-styrenkopolymerer (ABS), polyvinylbutyral (PVB), polymetylmetakrylat (PMMA), polyimid (PI), polyvinylalkohol (PVA), polystyren (PS), polyvinylfenol (PVP), polyetylen (PE), polypropylen (PP), polykarbonat (PC) eller derivater derav med en tykkelse på minst 75 µm eller mer.

6. Pumpehette (10) for en farmasøytisk beholder (18), omfattende en pumpehetteinnsats ifølge krav 1.

7. Pumpehette (10) for en farmasøytisk beholder (18) ifølge krav 6,

hvor elektronikkenheten (12) i innsatsen anvendes til kontaktløs, automatisert innskriving og/eller avlesing av data inn/ut av chipen, og
hvor dataene som skal skrives inn inkluderer en personlig identifikasjonsidentifikator for parring av elektronikkenheten (12) med et datamaskinprogramprodukt på den personlige digitale assistenten (PDA), og/eller dataene som skal avleses inkluderer signaler som representerer aktivering av pumpehetten (10).

8. Pumpehette (10) for en farmasøytisk beholder (18) ifølge krav 7, hvor senderen er konfigurert til enten å motta bare sin driftsenergi fra den personlige digitale assistenten når brukeren aktiverer det aktuelle datamaskinprogramprodukt på den personlige digitale assistenten, eller er konfigurert til permanent å motta sin driftsenergi fra den personlige digitale assistenten så lenge pumpehetten (10) på den farmasøytiske beholderen (18) er i umiddelbar nærhet til den personlig digitale assistenten, og denne avgir energi via dens tilhørende antenne(r).

9. Pumpehette (10) for en farmasøytisk beholder (18) ifølge krav 6 til 8, hvor elektronikkenheten (12) er konfigurert til å motta driftsenergien fra den personlige digitale assistenten, en såkalt personlig digital assistent (PDA), i form av en mobil- eller trådløs telefon, en såkalt smarttelefon, en smartklokke, et nettbrett, en bærbar PC eller lignende, og/eller hvor elektronikkenheten (12) omfatter en sender som er konfigurert til å sende trådløst ut signaler som representerer aktiveringer av pumpehetten (10) via nærfeltkommunikasjon (NFC), og/eller trådløst mottak av driftsenergi, og/eller hvor elektronenheten (12) i pumpehetteinnsatsen er utstyrt med en sensor (12b) med en bryter som er konfigurert til å detektere en utmatingsoperasjon, fortrinnsvis med minst to elektriske kontakter som er konfigurert og anordnet slik at de blir elektrisk omkoblet via en metalldel (18a) på den farmasøytiske beholderen (18) eller pumpehetten (10) når brukeren presser pumpehetten (10) i en slik grad at en utmatingsoperasjon finner sted, eller bryteren er en åpnings- eller lukkeknapp hvis sensoren (12b) er konfigurert til å interagere med den farmasøytiske beholderen, hvis lukking er konstruert uten en metallkapsel (18a).

10. Farmasøytisk beholder (18) med en pumpehetteinnsats ifølge et hvilket som helst av kravene 1 - 5 eller en pumpehette (10) ifølge et hvilket som helst av kravene 6 til 9.

11. Farmasøytisk beholder (18) ifølge krav 10, hvor den farmasøytiske beholderen inneholder en nesespray, for eksempel i form av en løsning eller suspensjon, fortrinnsvis Dymista® nesespray, en azelastinHCl-/flutikasonpropionatkombinasjon.

12. Datamaskinprogramprodukt, som, via den tilsvarende styringen av et antenneelektronisk styringssystem av en personlig digital assistent (PDA), forårsaker å tilveiebringe en elektronikkenhet (12) i et innlegg eller direkte i en pumpehette (10) ifølge et hvilket som helst av kravene 6 -9 med driftsenergi og detektere utmatingsoperasjoner fra den farmasøytiske beholderen (18) ifølge et hvilket som helst av kravene 10-11, med

- en forberedelsesmodus (VBM), for å tilveiebringe en parring av en respektiv elektronikkenhet (12) i et innlegg eller i pumpehetten (10) med den personlige digitale assistenten,
- en våknemodus (AWM), for å aktivere elektronikkenheten (12) i innlegget eller pumpehetten (10),
- en mottaksmodus (EM), for å vente på at brukeren skal aktivere pumpehetten (10) slik at elektronikkenheten (12) overfører signaler som representerer utmatingsoperasjoner fra den farmasøytiske beholderen (18) via aktivering av pumpehetten (10),
- en evalueringsmodus (AM), for å måle tiden som er gått mellom suksessive aktiveringer av pumpehetten (10) og å kategorisere forskjellige hendelser avhengig av den forløpte tiden.

13. Datamaskinprogramprodukt ifølge krav 12, hvor i forberedelsesmodusen (VBM)

- strålingen av elektromagnetisk energi av den personlige digitale assistenten (PDA) utføres slik at elektronikkenheten (12) mottar elektromagnetisk energi fra antennen i den personlige digitale assistenten (PDA) via sin spoleantenne (12a), hvoretter elektronikkenheten (12) aktiveres og sender et bekreftelsessignal via sin spoleantenne (12a);
- en individualisert identifikator overføres slik at den mottas av elektronikkenheten (12) via sin antenne og lagres i elektronikkenheten (12), eller elektronikkenheten (12) sender en individualisert identifikator lagret deri via sin antenne til den personlige digitale assistenten (PDA), og
- en utmatingsteller er satt til null.

14. Datamaskinprogramprodukt ifølge krav 12 eller 13, hvor i våknemodusen (AWM)
- strålingen av elektromagnetisk energi av den personlige digitale assistenten (PDA) blir utført slik at elektronikkenheten (12) mottar elektromagnetisk energi fra antennen i den personlige digitale assistenten (PDA) via sin spoleantenne (12a) og sender et "aktivsignal" til den personlige digitale assistenten (PDA) sammen med sin individualiserte identifikator; og
- etter å ha mottatt "aktivsignalet" blir det utstedt et lyd- og/eller visuelt hint av den personlige digitale assistenten (PDA), for å indikere beredskapen til den personlige digitale assistenten (PDA), for å angi, bearbeide og/eller vise på skjermen av den personlige digitale assistenten (PDA) signaler som indikerer utmatingsoperasjoner fra den farmasøytiske beholderen ved å betjene pumpehetten (10), og/eller,
i evalueringsmodusen (AM)
- i tilfelle et veldig kort tidsintervall mellom to eller flere aktiveringer av pumpehetten (10) signalisert av elektronikkenheten (12), blir dette kategorisert som priming av den farmasøytiske beholderen (18), og utmatingstelleren blir ikke avansert;
- i tilfelle korte tidsintervaller på to eller flere aktiveringer av pumpehetten (10) signalisert av elektronikkenheten (12), blir dette kategorisert som to utmatingsoperasjoner, og utmatingstelleren blir avansert tilsvarende; og
- antall utmatingsoperasjoner lagres i den personlige digitale assistenten PDA sammen med en/et nåværende dato/klokkeslett, og/eller
- i en historievisningsmodus (HDM), blir utmatingsoperasjonene som er telt siden den siste parringen av en respektive elektronikkenhet (12) på pumpehetten med den personlige digitale assistenten (PDA), hver er tids-/datostemplet, vist på skjermen til den personlige digitale assistenten (PDA), og/eller,
- i en administrasjonspåminnelsesmodus (EEM), kan brukeren legge inn i den personlige digitale assistenten (PDA) en eller flere daglige tidspunkter eller intervaller hvor brukeren skal ta hver neste dose, hvor
- på skjermen til den personlige digitale assistenten PDA vises tiden som gjenstår til neste dose, og/eller
- på den planlagte tiden for dosen tilveiebringer den personlige digitale assistenten PDA en visuell og/eller akustisk og/eller haptisk alarm.

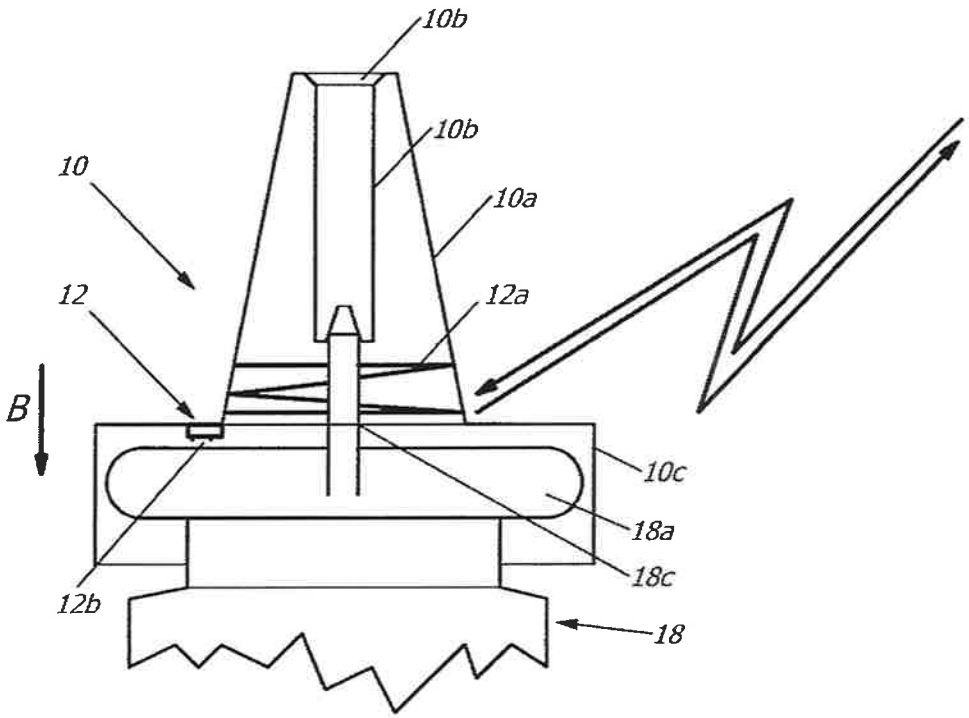
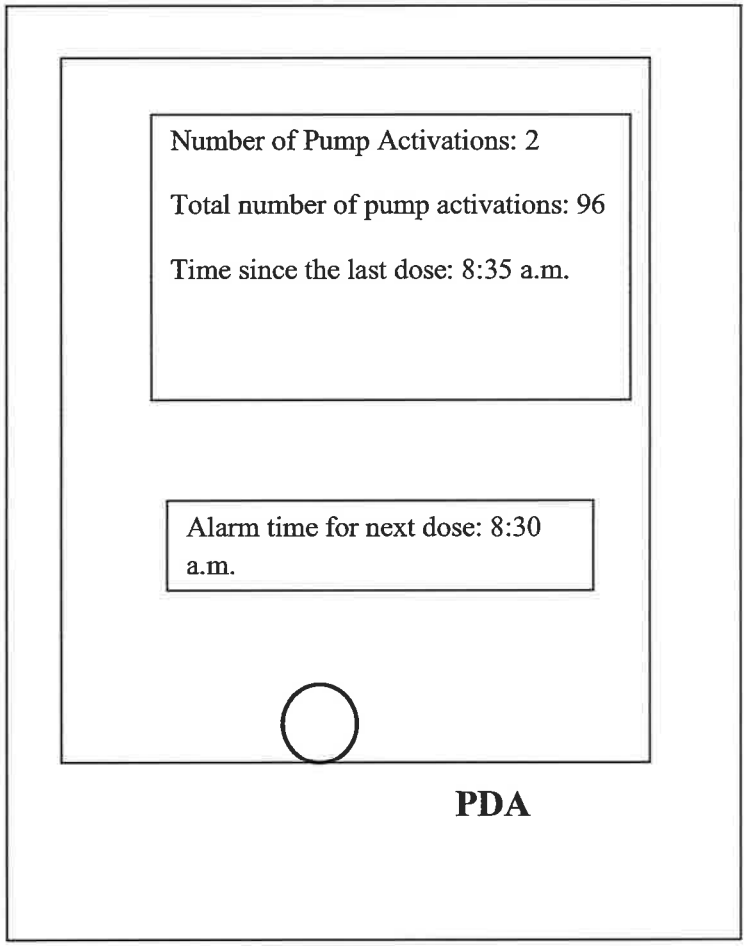


Fig. 1



NO/EP3277350

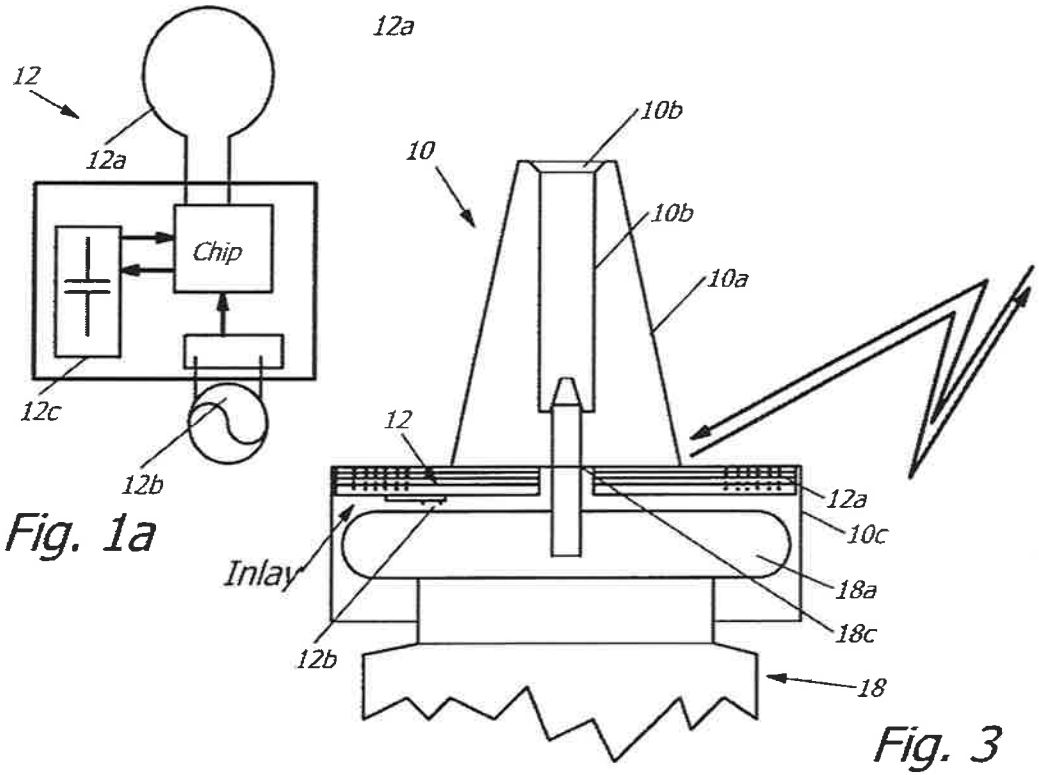
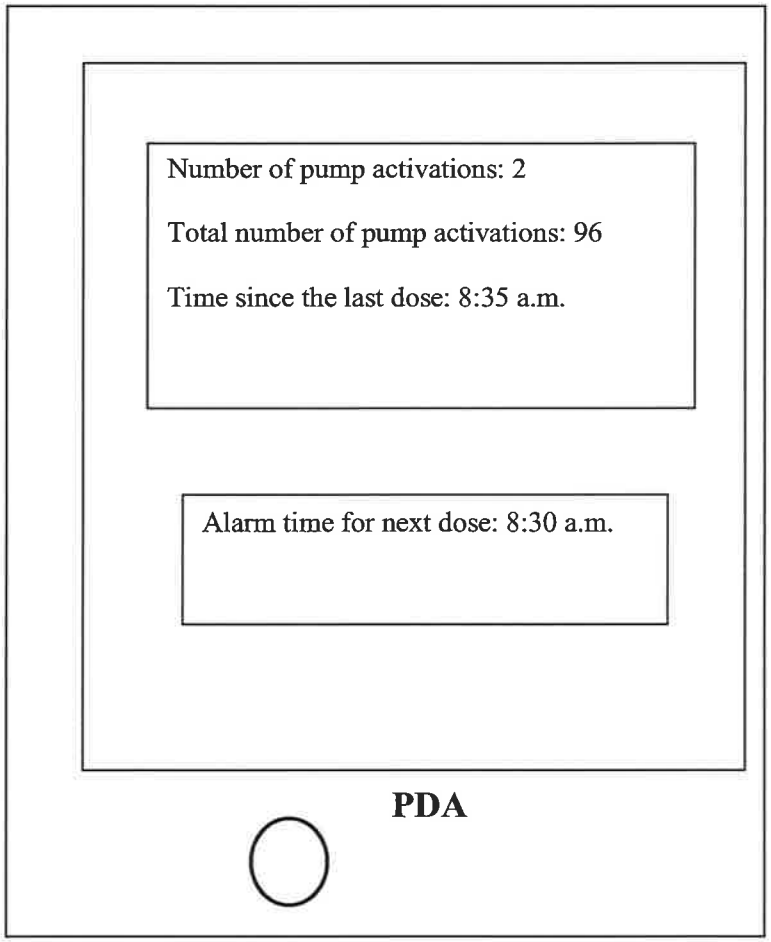


Fig. 1a

Fig. 3



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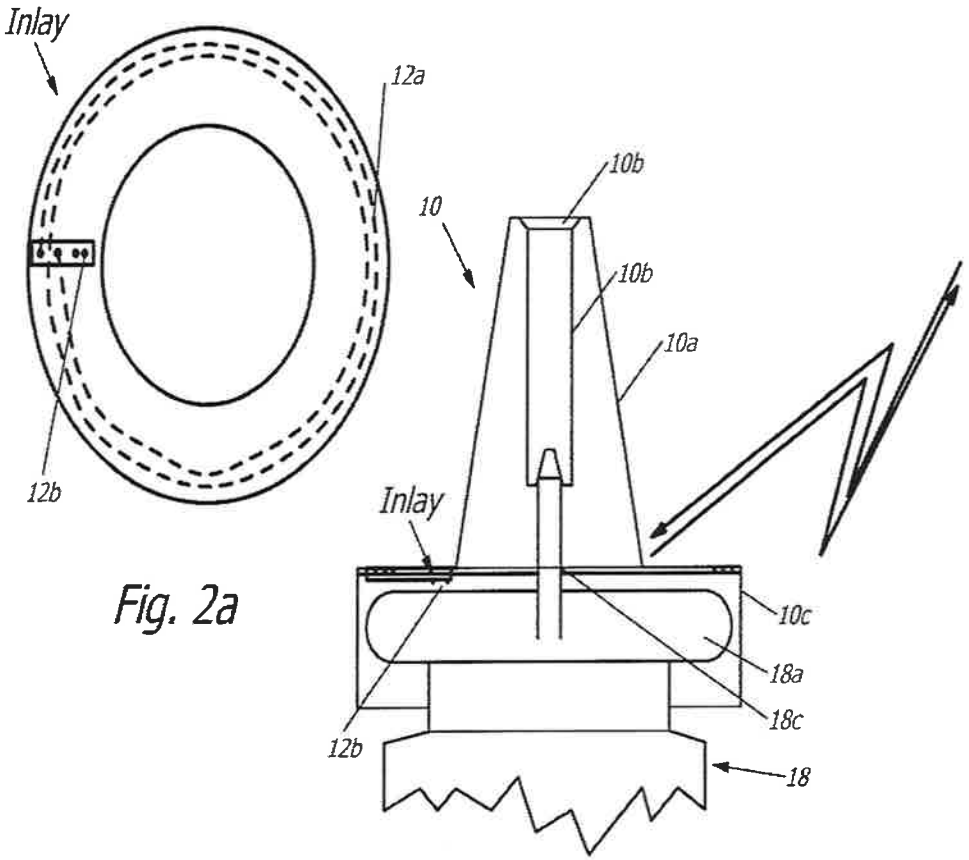


Fig. 2a

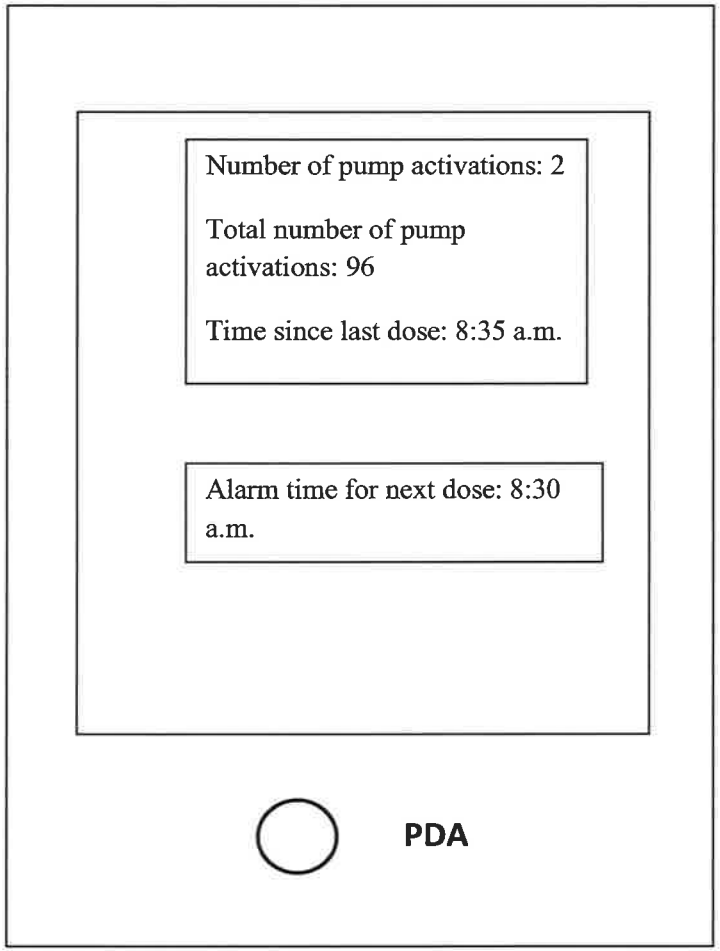
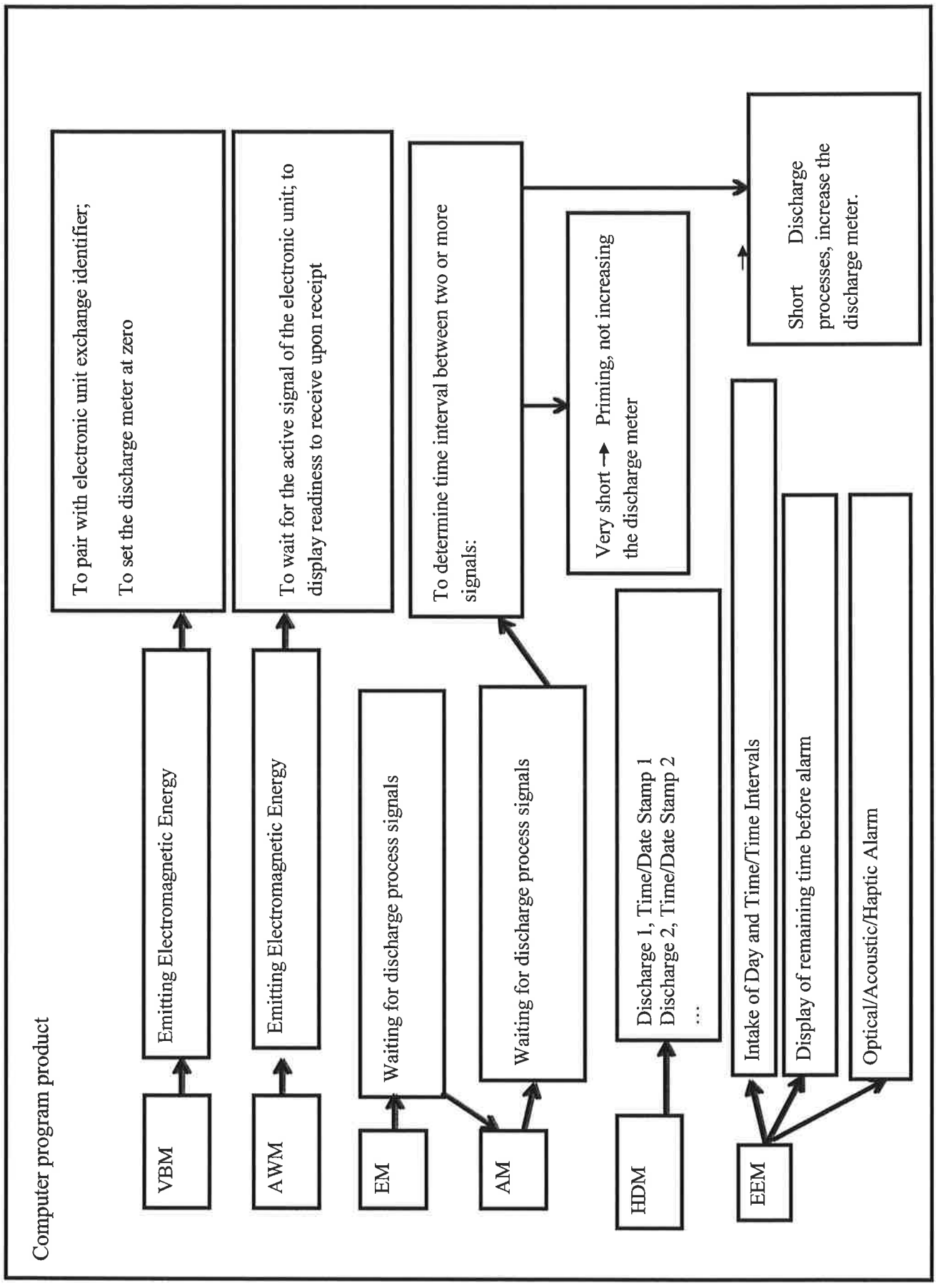


Fig. 2

NO/EP3277350


Computer program product
VBM
Emitting Electromagnetic Energy
To pair with electronic unit exchange identifier;
To set the discharge meter at zero
AWM
Emitting Electromagnetic Energy
To wait for the active signal of the electronic unit; to display readiness to receive upon receipt
EM
Waiting for discharge process signals
AM
Waiting for discharge process signals
To determine time interval between two or more signals:
Very short → Priming, not increasing the discharge meter
Short Discharge processes, increase the discharge meter.
HDM
Discharge 1, Time/Date Stamp 1
Discharge 2, Time/Date Stamp 2
...
EEM
Intake of Day and Time/Time Intervals
Display of remaining time before alarm
Optical/Acoustic/Haptic Alarm