## (19) DANMARK

## (10) **DK/EP 2413995 T3**



(12)

# Oversættelse af europæisk patentskrift

#### Patent- og Varemærkestyrelsen

(51) Int.Cl.: A 61 M 37/00 (2006.01) A 61 M 5/00 (2006.01) A 61 M 5/20 (2006.01)

(45) Oversættelsen bekendtgjort den: 2022-12-12

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: 2022-09-21

(86) Europæisk ansøgning nr.: 10713891.9

(86) Europæisk indleveringsdag: 2010-03-31

(87) Den europæiske ansøgnings publiceringsdag: 2012-02-08

(86) International ansøgning nr.: EP2010054352

(87) Internationalt publikationsnr.: WO2010112565

(30) Prioritet: 2009-03-31 EP 09004674 2009-04-16 US 169880 P

- Designerede stater: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK SM TR
- (73) Patenthaver: Sanofi-Aventis Deutschland GmbH, Brüningstraße 50, 65929 Frankfurt am Main, Tyskland
- (72) Opfinder: HARMS, Michael, Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main, Tyskland RAAB, Steffen, Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main, Tyskland STAUDER, Udo, Sanofi-Aventis Deutschland GmbH, 65926 Frankfurt am Main, Tyskland AVERY, Richard, James, Vincent, 28 Nursery Close, Uk, Mickleton Gloucestershire GL55 6TX, Storbritannien LANGLEY, Christopher, Nigel, 120 Leicester Lane, Leamington Spa, Warwickshire CV32 7HH, Storbritannien SENIOR, James, Alexander, 8 Turberville place, Warwick Warwickshire CV34 4JZ, Storbritannien DAVIES, James, Alexander, 7 Old School Mews, Cubbington Road, Leamington Spa Warwickshire CV32 7XB, Storbritannien
- (74) Fuldmægtig i Danmark: RWS Group, Europa House, Chiltern Park, Chiltern Hill, Chalfont St Peter, Bucks SL9 9FG, Storbritannien
- (54) Benævnelse: DOSISKNAP TIL EN LÆGEMIDDELADMINISTRATIONSANORDNING OG FREMGANGSMÅDE TIL FREMSTILLING AF EN DOSISKNAP
- (56) Fremdragne publikationer:

WO-A-99/47062

WO-A-03/086511

WO-A-2007/060156

WO-A2-97/40875

DE-A1-2 915 339

GB-A-190 226 674

US-A-3 343 539

US-A-3 878 846

US-A- 4 610 666

US-A1-2005 119 622

## **DK/EP 2413995 T3**

Anonymous: "SHppitsy - Klaccifikatsiya i texholoGiya izGotoBlehiya shppitsoB", , 1 January 1980 (1980-01-01), pages 1-8, XP055593215, Retrieved from the Internet: URL:https://vuzlit.ru/895732/shpritsy [retrieved on 2019-05-31]

## **DESCRIPTION**

**[0001]** The present invention relates to a dose button for a drug delivery device as claimed in claim 1. Furthermore, the present invention relates to a method for manufacturing a dose button as claimed in claim 14.

[0002] Drug delivery devices are generally known for the administration of a drug, for example insulin, but also for other medicinal products for self-administration by a patient. Because of the daily necessity to use this drug delivery device there are ambitions to make the use of these drug delivery devices more comfortable and safer for the user. Mostly the drug delivery devices are pen-type injectors wherein a pre-set dose of the drug can be injected. Some examples are described in the document EP 1 923 085 A1 and EP 0 554 995 A1. Further examples of other drug delivery devices are described in documents: US4610666 A, WO99/47062 A; US2005/119622 A1; WO2007/060156 A; WO03/086511 A; US3343539 A; GB26674 A; WO97/40875 A2; DE2915339 A1; US3878846 A; and Anonymous: "SHppitsy - Klaccifikatsiya i texholoGiya izGotoBlehiya shppitsoB",, 1 January 1980 (1980-01-01), pages 1-8, XP055593215,Retrieved from the Internet:URL:https://vuzlit.ru/895732/shpritsy [retrieved on 2019-05-31].

[0003] In some cases it is necessary for a patient to use two different types of insulin or two different drugs. Then it is helpful for the patient to have one pen for one type of insulin and another pen for the other type. To avoid a mix-up the two insulin types, it is necessary to make the pens distinguishable.

[0004] It is an object to the present invention to provide a drug delivery device comprising a dose button which helps the user in operating a drug delivery device.

**[0005]** According to a first aspect of the present invention, a dose button for a drug delivery device is provided. The dose button is manufactured by means of a cutting-off process. The dose button is a metal dose button.

**[0006]** In this process the dose button is brought to a specific geometry by removing excess material using various kinds of tooling. If a plastic dose button should be used the way of manufacture one would be by injection molding. This manufacturing method has the disadvantage that the production process is very complex. To create plastic parts by injecting molding, it is necessary to produce a casting mold. Such casting molds are expensive to manufacture. Another disadvantage of injection molding is that it is not flexible in producing different surface styles.

[0007] According to the invention the surface structure of the dose button is milled or lathed.

[0008] Modern CNC lathes can perform a vast number of complex operations. They can also carry out secondary operations, like milling, by using driven tools. By using the data of a CAD

database, it is possible to switch very quickly from one design to another.

[0009] According to the present invention, the material used for the dose button comprises metal.

**[0010]** There are a lot of possible varieties of this. The dose button can be coated with metal or can fully consist of metal. The material can be pure metal or an alloy. By using metal, there are some advantages which can be achieved, even if the material itself is more expensive than plastic. For instance it is more robust and easier to clean.

[0011] In one embodiment the metal used for the dose button is steel or aluminium.

[0012] But it is also possible to use any other metal.

[0013] According to the invention, the surface of the dose button has a specific structure.

**[0014]** This structure is three-dimensional for the aim that the dose buttons have haptic differences distinguishable by the user. It is not sufficient to distinguish the two pens by means of visual features, but also by means of tactile features. This is needed because one of the effects of diabetes is that it can lead to severe visual loss or blindness.

[0015] According to the invention the surface structure of the dose button is indicative of the drug to be contained in the drug delivery device.

**[0016]** By providing a three-dimensional surface structure of the dose button and the possibility of distinguishing two different drug delivery devices by the differences of the dose buttons, the user can distinguish two different insulin pens just by means of haptic features. Even for a user with impaired vision, it is possible to distinguish the pens by feeling the surface of the dose button.

[0017] In another embodiment the dose button is firmly connected with the drug delivery device.

**[0018]** By firmly connecting the dose button to the drug delivery device it is always possible to use the right pen for the right drug just by associating a special surface of the dose button with the contained drug.

[0019] In one embodiment the surface of the dose button forms a pattern.

**[0020]** The surface structure of the dose button may comprise one or more structural elements. The structural elements may form a pattern. In particular, structural elements may be grouped to form a pattern. There are a lot of different possible patterns like circles, crosses or bumps or even more intricate patterns. Every surface structure is possible which can be recognized by haptic perception.

[0021] In another preferred embodiment the surface of the dose button is colored.

[0022] The dose button can be colored by the metal used to form the dose button, but can also be colored after the manufacturing process.

[0023] Another aspect relates to a drug delivery device which comprises the dose button. The drug delivery device comprising the dose button is preferably reusable.

**[0024]** In this case, it may be possible for the user to choose a drug delivery device containing a drug with a specific dose button and use this for a long time by exchanging the vial in the drug delivery device once the drug is exhausted. Therefore, it is possible to use the same pen for the same drug. The metal dose button used is long living and the surface of the metal dose button does not wear off so fast in comparison to a plastic material.

**[0025]** According to the invention the dose button of the drug delivery device is pressed to inject a specific dose of the drug. In particular, pressing of the dose button may trigger a dose dispensing action.

**[0026]** By carrying out the necessary action of pressing the dose button to inject the drug, the user inevitably feels the surface of the dose button and it is possible for him to avoid using the wrong medicine.

**[0027]** According to an embodiment, the drug delivery device comprises the previously described dose button. The drug delivery device may comprise one, two, or more of a housing, a cartridge holder, a cartridge containing the drug, a label and a cap. One, two, or more of the housing, the cartridge holder, the cartridge, the label and the cap may comprise a respective surface structure. The respective surface structure may be substantially equivalent or identical with the surface structure of the dose button.

**[0028]** The substantially equivalent or identical surface structure may identify one type of drug held in the cartridge of the device. This may increase the user's confidence that he is administering the correct drug. Anytime during operation of the device, e.g. during setting and delivery of the dose and/or while preparing the device for operation, the user may view and/or contact at least one of the specific surface structures.

**[0029]** The substantially equivalent or identical surface structure may comprise an identical number and/or an identical shape of one, more or all structural elements which are grouped to form the surface structure. Preferably, said structural elements comprise a structural depth large enough to generate a tactile feedback when a user contacts the respective surface structure. The substantially equivalent or identical surface structure may comprise a different size and/or a different material of the structural elements. Though certain differences in size and/or material of the structural elements may be allowed, the respective surface structure is preferably adapted and arranged to provide the same information to the user, e.g. information

about the device and, in particular, the drug held in the cartridge of the device.

[0030] In one embodiment a set of at least two drug delivery devices comprising a dose button is provided, wherein each drug delivery device in the set is distinguishable from the others by a characteristic surface structure of its dose button.

[0031] In the set, there are different surface structures on every pen. If one needs to use for example two different types of insulin, maybe short-acting and long-acting insulin, one just needs to get the set and it is possible to distinguish the two drug delivery devices by the characteristic surface of the dose button.

[0032] It might be possible that the different pens just can be used with a special kind of vial and therefore with a special kind of drug. Then it is an advantage of the present invention that the user is prevented from inserting the wrong vial in a pen.

**[0033]** In another preferred embodiment a set of at least two drug delivery devices is provided. Every drug delivery device may carry a cartridge with a different drug.

[0034] If the user needs for example two types of insulin it is possible to buy these two types together with the fitting drug delivery devices. Furthermore, these two devices preferably comprise distinguishable dose buttons.

**[0035]** According to an embodiment, the previously described set of at least two drug delivery devices is provided. The respective drug delivery device may comprise one, two, or all of the following components: A cap for the drug delivery device, a cartridge holder for the drug delivery device, a cartridge for the drug delivery device, a housing for the drug delivery device and a label for the drug delivery device. One, two, more or all of the components may comprise a surface structure. The surface structure may be substantially equivalent or identical for the components of the respective device. Components of different devices may comprise different surface structures.

[0036] Components with different surface structures may be part of devices holding different drugs.

**[0037]** The components mentioned above may be assembled to form one single drug delivery device. In particular, components of one predetermined device may comprise the substantially equivalent or identical surface structure.

**[0038]** The at least two different drug delivery devices may be customized to the drug to be delivered by providing components with different surface structures. A specific surface structure may be chosen for all components of one of the devices which are provided with the surface structure. A different surface structure may be provided for the components of an other device. In particular, the different surface structures may be adapted to identify the drug held in the respective device.

[0039] The user may choose one first device and, thus, one first drug, he wants to use by viewing and/or contacting the surface structure on the components of the first device. The user may contact and/or move one component of said first device with respect to the main housing, e.g. for preparing the first device for operation. Afterwards, the user may put the first device aside, e.g. for preparing a second device providing components with a different surface structure which identifies a second drug held in the second device, for operation. Later on, when the user wants to dispense the first drug, the user grabs one of the two devices previously prepared for operation. By means of the surface structure provided on the components of said device, the user can verify at once, whether he has grabbed the right device, i.e. the first device holding the first the drug. Hence, provision of a device providing high safety for the user is facilitated.

**[0040]** According to the invention, a dose button tor a drug delivery device is provided which is manufactured by means of a cutting-off process.

**[0041]** The dose button comprises a surface structure, in particular a tactile marking. In particular, due to said manufacturing process, the dose button comprises a specific surface structure which is adapted to identify a drug held in a cartridge of the device.

**[0042]** According to the invention, a method for manufacturing a dose button for a drug delivery device is provided, the dose button comprising a metal, wherein the method comprises the step of a cutting-off-process.

**[0043]** In a first manufacturing step, a metal work piece is provided. In a second manufacturing step, material is cut-off from a surface of the work piece. The material is cut-off such that, at the end of the manufacturing process, the surface comprises a surface structure. The surface structure may be formed by cutting -off material which laterally surrounds the desired position of a desired surface structure but which is not required for forming the desired surface structure.

[0044] In the following the invention is described in further details with references to the drawings, wherein

#### Figure 1

shows a cross sectional view and a top view of a three possible dose buttons according to the invention,

#### Figure 2

shows a drug delivery device comprising a dose button according to the invention, and Figure 3

shows a further exemplary embodiment of a drug delivery device.

[0045] Some preferred embodiments of a dose button 1 according to the present invention will

now be discussed with reference to Figures 1 to 3. Identical reference signs denote identical or comparable components.

[0046] Figure 1a shows a cross sectional view of a dose button 1. The dose button may consist of metal. Particularly, the dose button 1 may be a metal dose button. According

**[0047]** to the embodiment shown, the surface structure of the dose button 1 shows a bump 3. The bump 3 is arranged in the middle of the surface 2 which may be rounded down to prevent that the user of the drug delivery device 6 gets hurt while using it. The surface structure was milled or lathed by using a CNC lathe.

[0048] Figure 1b is a top view of the same dose button 1 as described in Figure 1a.

**[0049]** In Figure 1c a cross sectional view of another surface structure of a dose button 1 is shown. In this case there are two circle shaped protrusions on the surface 4, 41 with plain surface between the protrusions. One has a larger radius than the other. The outer circle 4 and the inner circle 41 are concentric. For a better view, a top view of this structure is shown in figure 1d.

**[0050]** In Figure 1e a cross sectional view is shown of a surface structure with a plurality of bumps 5 distributed over the surface. Apart from these bumps 5 a plain surface is shown. By taking a look at the top, as it is shown in figure 1f, one can see that the bumps 5 form a vertical and horizontal line. These lines intersect at the middle of the surface 2 of the dose button 1.

[0051] In Figure 2 a drug delivery device 6 is shown. The device 6 comprises a housing 7.

**[0052]** The drug delivery device 6 and the housing 7 have a distal end and a proximal end. The term "distal end" designates that end of the drug delivery device 6 or a component thereof which is or is to be arranged closest to a dispensing end of the drug delivery device 6. The term "proximal end" designates that end of the device 6 or a component thereof which is or is to be arranged furthest away from the dispensing end of the device 6.

**[0053]** The device 6 comprises a dose button 1. The dose button is arranged on the proximal end of the housing 7. The dose button 1 can be depressed by a user for delivering a pre-set dose of a drug. The drug may be held in a cartridge of the device 6 (not explicitly shown). The term "drug", as used herein, preferably means a pharmaceutical formulation containing at least one pharmaceutically active compound.

[0054] In a further embodiment the pharmaceutically active compound comprises at least one human insulin.

**[0055]** As already explained in connection with Figures 1a to 1f, the surface 2 of the dose button 1 can have any possible structure, including visual, e.g. colour, and haptic features. The surface structure may identify one predetermined drug held in the cartridge of the device 6.

**[0056]** On the basis of different colours and/or different tactile structures on the surface 2 of the dose button 1, it may be possible for a user to distinguish between different devices 6, in particular devices 6 holding different drugs. Therefore, the user knows which drug delivery device 6 he has to operate just by feeling and/or seeing the respective dose button 1, in particular the surface structure of the respective dose button 1.

[0057] Figure 3 shows a further exemplary embodiment of a drug delivery device.

**[0058]** The drug delivery device 6 comprises the previously mentioned housing 7. The housing 7 comprises a housing body 7A. The drug delivery device 6 comprises a cartridge holder 8. The cartridge holder 8 is permanently or releasably connected to the housing body 7A to form the housing 7 of the device 6. Preferably, the cartridge holder 8 is releasably connected, for example screwed, to the housing body 7A to allow for introducing a replacement cartridge into the device 6.

**[0059]** The drug delivery device 6 comprises a housing insert 7B. The housing insert 7B is part of the housing 7 of the device 6. The housing insert 7B is inserted into and, permanently or releasably, connected to the housing body 7A. Preferably, the housing insert 7B is releasably connected, for example snap-fitted, to the housing body 7A to allow insertion of a replacement housing insert 7B into the housing body 7A. The housing insert 7B is preferably arranged in a recessed section of the housing body 7A (not explicitly shown). Thus, the housing insert 7B does not significantly increase the radial extension of the device 6. Preferably, the housing insert 7B ends flush with the housing body 7A on an outer surface of the housing 7.

**[0060]** The housing insert 7B comprises a window section 11. The window section 11 is arranged in the proximal end section of the housing insert 7B. The window section 11 comprises a transparent or translucent window. The window may enable the user to view through the housing insert 7B. Preferably, the housing body 7A comprises an aperture with which the window section 11 overlaps. Thus, the user may view in the window section 11 through the housing 7 to a component housed therein, e.g. to members of a drive mechanism retained in the housing 7.

**[0061]** The housing insert 7B comprises a label section. The label section is arranged distally offset from the window section 11. The label section is configured for holding a label 12. The label 12 may be releasably or permanently attached to the label section. Preferably, the label 12 is releasably attached to the label section.

**[0062]** The housing 7 comprises an outer lateral surface 7C. The outer lateral surface 7C connects a distal end-face 13 of the drug delivery device 6, e.g. a distal end of the cartridge holder 8, and a proximal end-face 14 of the drug delivery device 6, e.g. the surface 2 of the dose button 1, with one another.

[0063] The device 6 comprises the previously mentioned cartridge (not explicitly shown). The

cartridge is retained in the cartridge holder 8. The cartridge holder 8 stabilizes the cartridge mechanically. The cartridge may hold a plurality of doses of the drug.

**[0064]** The device 6 comprises the previously described dose button 1. The dose button 1 comprises the surface 2, in particular an actuation surface. The surface 2 forms the proximal end-face 14 of the device 6. The user may contact the surface 2 and, hence, the previously described structure on the surface 2, when dispensing the set dose.

**[0065]** The drug delivery device 6 may be an injection device. The drug delivery device 6 may be a pen-type device, in particular a pen-type injector. The device 6 may be a disposable or a re-usable device. The device 6 may be configured to dispense fixed doses of the drug, in particular doses which may not be varied by the user, or variable, preferably user-settable, doses of the drug. The drug delivery device 6 may be a manually, in particular a non-electrically, driven device.

[0066] The drug delivery device 6 comprises a cap 9. The cap 9 is connectable to the housing 7. In particular, the cap 9 is securable to the distal end of the housing body 7A. In a storage mode of the device 6, the cap 9 is adapted and arranged to cover the dispensing end of the drug delivery device 6. The cap 9 is configured to cover the cartridge holder 8. For preparing the device 6 for operation and, in particular, for bringing the device into an operational mode, e.g. a mode which allows for setting and delivering drug, the cap 9 is unsecured from the housing body 7 A to uncover the cartridge holder 8.

**[0067]** The dose button 1 comprises the surface structure 10 as described in connection with Figures 1a to 1f and 2. The surface structure 10 of the dose button 1 identifies one predetermined drug held in the cartridge 8 of the device 6. According to the embodiment shown in Figure 3, the surface structure 10 comprises a tactile marking. Tactile markings may be especially suited for users with impaired vision, e.g. users suffering from diabetes. Additionally or alternatively, the surface structure 10 may comprise a colour marking.

**[0068]** In addition to the surface structure 10 of the dose button 1, the housing 7, in particular the housing insert 7B, may comprise a surface structure 10. An additional surface structure 10 may be provided on the cap 9. An additional surface structure 10 may be provided on the cartridge holder 8 and/or the cartridge. An additional surface structure 10 may be provided on the label 12.

[0069] The surface structure 10 of the dose button 1, the cartridge holder 8, the cartridge, the cap 9 and the label 12 may be substantially equivalent or identical, e.g. the surface structure 10 may comprise substantially equivalent or identical tactile markings as shown in Figure 3. In particular, the respective surface structure 10 may comprise the same shape and/or alignment of the structural elements with respect to each other. However, the respective surface structure 10 may comprise a different size and/or material. The respective surface structure 10 is adapted to generate a similar, preferably the same, tactile and/or visual feedback within the user. In particular, the surface structure 10 may provide the same information to the user. In

particular, the surface structure 10 is adapted and arranged to signal the user which device the user is operating and, in particular, which drug is actually set and dispensed during operation of the device 6. One set of substantially equivalent or identical surface structures 10 preferably identifies one predetermined device 6 and, hence, one predetermined drug held in the cartridge of said device 6.

**[0070]** The respective surface structure 10 is provided on the outer surface of the respective component, e.g. the surface 2 of the dose button 1, the outer surface of the cap 9, the outer surface of the cartridge, the outer surface of the cartridge holder 8 and/or the outer (lateral) surface 7C of the housing 7, in particular of the housing insert 7B. In this way, the user can easily contact the surface structure 10 when he holds the device 6 when preparing the device 6 for operation and/or when setting and/or when delivering a dose of the drug.

**[0071]** The surface structure 10 may help to distinguish two or more different devices 6 holding different drugs from each other. These drug delivery devices 6 may comprise a similar exterior shape. Furthermore, the different drug delivery devices 6 may comprise a similar colour. The different drug delivery devices 6 may be adapted to hold different drugs. Due to the similar exterior shape and/or colour, a user may easily mix-up the different drug delivery devices 6 if the devices are not marked differently, e.g. by different surface structures. This may have fatal or even lethal consequences to the user.

**[0072]** However, the surface structure 10 of the components of one of the devices 6 may be different from the surface structure 10 of the components of any other of the device 6. In particular, the surface structure 10 may be different for different drugs held in the cartridge of the respective device 6. Accordingly, by means of the surface structure 10, the user may easily distinguish between the different drugs and, hence, between the different drug delivery devices 6. In particular, upon viewing and/or contacting the surface structure 10, the user may realize immediately which device 6 he is operating or intending to operate and, in particular, which drug is held in the cartridge of the respective device 6.

[0073] The present invention is defined by the appended claims.

#### Reference Numerals:

#### [0074]

Dose button

Surface of the dose button

Bump

4

Outer circle 4 Inner circle 5 Bump 6 Drug delivery device 7 Housing 7A Housing body 7B Housing insert 7C Outer lateral surface 8 Cartridge holder 9 Cap 10 Structure 11 Window section 12 Label 13 Distal end-face 14 Proximal end-face

## REFERENCES CITED IN THE DESCRIPTION

#### Cited references

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

#### Patent documents cited in the description

- EP1923085A1 [0002]
- EP0554995A1 [0002]
- <u>US4610666A</u> [0002]
- WO9947062A [0002]
- <u>US2005119622A1</u> [0002]
- WO2007060156A [0002]
- WO03086511A [0002]
- <u>US3343539A</u> [0002]
- GB26674A [0002]
- <u>WO9740875A2</u> [0002]
- DE2915339A1 [0002]
- <u>US3878846A</u> [0002]

#### Non-patent literature cited in the description

ANONYMOUSSHppitsy - Klaccifikatsiya i texholoGiya izGotoBlehiya shppitsoB, 1980, 1-8 [0002]

#### Patentkrav

20

- 1. Dosisknap (1) til en lægemiddeladministrationsanordning (6), der er fremstillet ved hjælp af en afskæringsproces, hvor materialet, der anvendes til dosisknappen (1), omfatter metal, 5 hvor dosisknappen (1) er konfigureret til at blive anbragt i en proksimal ende af et hus lægemiddeladministrationsanordningen (6) anbragt længst væk fra en dispenseringsende af anordningen (6) og til indtrykning til 10 injektion af en specifik dosis af et lægemiddel, hvor overflade (2) af dosisknappen er drejet eller fræset, hvor overfladen (2) af dosisknappen (1) som følge fremstillingsprocessen har en specifik tredimensionel struktur (10), hvor overfladestrukturen (10) af dosisknappen (1) 15 lægemidlet, der indeholdt. angivende for er i lægemiddeladministrationsanordningen (6).
  - 2. Dosisknap (1) til en lægemiddeladministrationsanordning (6) ifølge krav 1, hvor metallet er stål eller aluminium.
  - 3. Dosisknap (1) til en lægemiddeladministrationsanordning (6) ifølge et hvilket som helst af ovennævnte krav, hvor overfladestrukturen (10) på dosisknappen danner et mønster.
- 4. Dosisknap (1) til en lægemiddeladministrationsanordning (6) ifølge et hvilket som helst af ovennævnte krav, hvor dosisknappen (1) er fast forbundet med lægemiddeladministrationsanordningen (6).
- 5. Dosisknap (1) til en lægemiddeladministrationsanordning (6) ifølge et hvilket som helst af ovennævnte krav, hvor overfladen (2) på dosisknappen (1) er farvet.
- 6. Lægemiddeladministrationsanordning (6), som omfatter en dosisknap (1) ifølge et hvilket som helst af ovennævnte krav, som er genanvendelig.
  - 7. Lægemiddeladministrationsanordning (6) ifølge krav 6, hvor

et lægemiddel er indeholdt i en patron i anordningen (6).

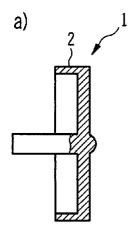
5

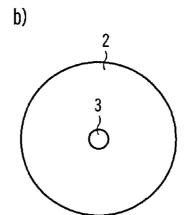
- 8. Lægemiddeladministrationsanordning (6) ifølge krav 7, hvor lægemidlet er en farmaceutisk formulering, der indeholder mindst én farmaceutisk aktiv forbindelse, hvilken farmaceutisk aktive forbindelse omfatter mindst ét humant insulin.
- 9. Lægemiddeladministrationsanordning (6) ifølge ét af kravene 6 til 8, hvor dosisknappen (1) trykkes ind til injektion af en specifik dosis af lægemidlet.
- Lægemiddeladministrationsanordning ifølge ét af kravene 6 til 9, som omfatter dosisknappen (1) ifølge krav 7 eller et hvilket som helst krav, der er afhængigt heraf, og en, to eller 15 flere af et hus (7), en patronholder (8), en patron, der indeholder lægemidlet, en etiket (12) og en hætte (9), hvor en, to eller flere af huset (7), patronholderen (8), patronen, hætten omfatter etiketten (12)oa (9) en respektiv overfladestruktur (10), hvor den respektive overfladestruktur 20 (10) er i det væsentlige tilsvarende eller identisk med overfladestrukturen (10) på dosisknappen (1).
- 11. Sæt af mindst to lægemiddeladministrationsanordninger (6), som hver omfatter en dosisknap (1) ifølge krav 3 eller et hvilket som helst krav, der er afhængigt heraf, hvor hver lægemiddeladministrationsanordning (6) i sættet adskiller sig fra hinanden ved den karakteristiske overfladestruktur (10) på dens dosisknap (1).
- 12. Sæt af mindst to lægemiddeladministrationsanordninger (6) ifølge krav 11, hvor hver lægemiddeladministrationsanordning (6) bærer en patron med forskellige lægemidler.
- 13. Sæt af mindst to lægemiddeladministrationsanordninger (6)
  35 ifølge krav 11 eller krav 12, hvor den respektive
  lægemiddeladministrationsanordning (6) omfatter en, to, flere
  eller alle af følgende komponenter:
  - en hætte (9) til lægemiddeladministrationsanordningen (6),

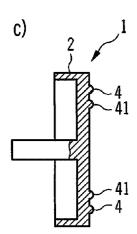
- en patronholder (8) til lægemiddeladministrationsanordningen (6),
- en patron til lægemiddeladministrationsanordningen (6),
- et hus (7) til lægemiddeladministrationsanordningen (6),
- 5 en etiket (12) til lægemiddeladministrationsanordningen (6), hvor en, to, flere eller alle af komponenterne omfatter en overfladestruktur (10), hvilken overfladestruktur (10) er i det væsentlige tilsvarende eller identisk for komponenterne i den respektive anordning (6), hvor komponenter i forskellige anordninger (6) omfatter forskellige overfladestrukturer (10), og hvor komponenter med forskellige overfladestrukturer er en del af anordninger (10), der indeholder forskellige lægemidler.
- Fremgangsmåde til fremstilling af en dosisknap (1) ifølge krav 1 til en lægemiddeladministrationsanordning (6), 15 omfatter et metal, hvilken fremgangsmåde omfatter et trin med en afskæringsproces, hvor der i et første fremstillingstrin tilvejebringes et metalråemne, og der i andet et skæres materiale fremstillingstrin af en overflade 20 arbejdsemnet, hvor dosisknappen (1) er konfigureret til at blive i proksimal ende af et hus en lægemiddeladministrationsanordningen (6) anbragt længst væk fra en dispenseringsende af anordningen (6) og til indtrykning til injektion af en specifik dosis af et lægemiddel, hvor 25 overflade er drejet eller fræset, hvor overfladen (2)dosisknappen (1) som følge af fremstillingsprocessen har en specifik tredimensionel struktur (10), hvor overfladestrukturen (10) af dosisknappen (1) er angivende for lægemidlet, der er indeholdt i lægemiddeladministrationsanordningen (6).

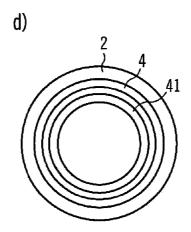
## **DRAWINGS**

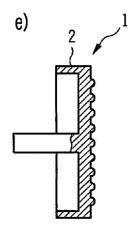
FIG 1











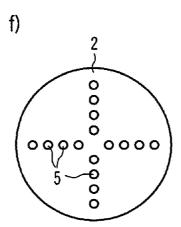


FIG 2

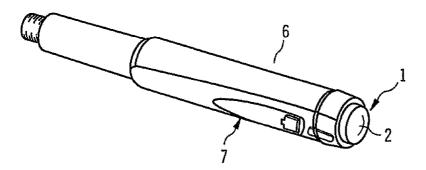


FIG 3

