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(54) **Replaceable cap for a dosing device.**

(57) The invention is directed to a replaceable cap for a dosing device for administering a liquid to a patient, the cap comprising a timer, a timer display unit, a battery and a switch which switch is, in use, activated from an inactive to an active position when the dosing device is used, which active position results in a signal being sent to reset the timer.

NL C 2005017

REPLACEABLE CAP FOR A DOSING DEVICE

FIELD OF THE INVENTION

The present invention relates to a replaceable cap for a dosing device for administering a liquid to a patient.

BACKGROUND OF THE INVENTION

Insulin dependent diabetics are required to adhere to a strict prescribed regimen of liquid insulin injections in order to manage their disease. As is often the case, an inexpensive and reusable dosing device, for example a plastic syringe containing an insulin reservoir, and a cap commonly known as an "insulin pen" is used to administer the subcutaneous injections.

It is known from several published studies that multiple daily injections of insulin very quickly become so routine that any individual dose can easily be forgotten. In addition, there is no simple and reliable way to tell - using the prescribed insulin pen or by examining the injection area - whether or not a given injection has been administered. Missing a prescribed insulin dose or inadvertently taking too many doses in a short amount of time can lead to serious short and long-term health risks and complications for a diabetic, including hyperglycemia and hypoglycemia.

Several attempts have been made in the past to solve this problem and are known in the field. For example, US-A-2009076458 describes an insulin delivery device which is itself capable of signalling the time since the last injection. This device contains the insulin and syringe and flashes

a light in order to indicate the time since the last injection. While this invention seeks to solve the very same problem, the device of US-A-2009076458 has the disadvantage of forcing a diabetic patient to abandon and discard their preferred or prescribed insulin delivery system in favour of a new system, which is economically prohibitive for many users. Another disadvantage of this insulin delivery device is that the user would have to learn the meaning of the particular flashing light sequence devised by the inventors in order to signal the time since the last injection. This could be a significant obstacle for some diabetics, in particular the young or elderly.

US-A-2002126585 describes a closure cap including timer and cooperating switch member and associated methods for pill containers with a threaded cap.

The aim of the present invention is to provide a simple device for administrating a liquid to a patient, especially diabetic patients, which does not have the disadvantages of the prior art device of US-A-2009076458.

SUMMARY OF THE INVENTION

This aim is achieved with the following replaceable cap. A replaceable cap for a dosing device for administering a liquid to a patient, the cap comprising a timer, a timer display unit, a battery and a switch which switch is, in use, activated from an inactive to an active position when the dosing device is used, which active position results in a signal being sent to reset the timer.

Applicants found that by using the replaceable cap according to the invention a simple device is obtained which allows the patient to view how much time has elapsed since the last injection was administered without requiring the patient to alter their routine. The cap can be combined with patients' preferred brand or type of dosing device, e.g. injection pen. Thus by simply using the replaceable cap according to the invention in combination with known dosing devices a device is obtained which limits the risk of a patient administering too little or too much liquid medicine, i.e. insulin.

The present invention is also directed to a use of a replaceable cap in combination with a dosing device when administering a liquid to a patient by means of injection, wherein a switch automatically activates a timer when a user removes or replaces the cap on the dosing device or when using the dosing device itself and wherein a timer display subsequently shows the duration of time since the switch activated the timer.

Other advantages of the invention will be discussed in combination with the preferred embodiments below.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the replaceable cap according to the invention Replaceable on a dosing device in a closed position.

Fig. 2 is an alternative perspective view of the replaceable cap on a dosing device in a closed position.

Fig. 3 is a perspective view of replaceable cap according to the invention on a dosing device in a open position.

Fig. 4 is an exploded perspective view of the replaceable cap.

Fig. 5 is an orthogonal view of the cap opening.

Fig. 6 is a cross section through the switch mechanism.

Fig. 7 is an alternative embodiment of the replaceable cap.

Fig. 8 is an exploded view of an alternative embodiment of the replaceable cap.

Fig. 9 is an alternative embodiment of the replaceable cap and a dosing device.

Fig. 10 is another alternative embodiment of the replaceable cap and a dosing device.

is an alternative embodiment of the replaceable cap and a dosing device.

Fig 11A and Fig 11B shows a cross-sectional view of an alternative embodiment for the cap as placed on a dosing device.

Fig 12 shows another alternative embodiment of the replaceable cap and a dosing device.

DETAILED DESCRIPTION OF THE INVENTION

The invention is directed to a replaceable cap for a dosing device for administering a liquid to a patient, the cap comprising a timer, a timer display unit, a battery and a switch. The switch is, in use, activated from an inactive to an active position when the dosing device is used, which active position results in a signal being sent to reset the timer. The switch may be any switch capable of being operated manually by the user of the dosing device

or a switch which is activated to an active position when a user removes or replaces the cap on the dosing device or when the user uses the dosing device itself. Suitably the switch is activated from an inactive to an active position when the cap is replaced onto the dosing device.

A preferred switch comprises an operative element which is displaceable along a radially outward directed line starting at a longitudinal axis of the cap. The preferred operative element can move from the inactive position into the active position when, in use, the cap is removed from the dosing device or when the cap is placed on the dosing device. More preferably, when in use, a signal is sent when the cap is replaced upon the dosing device and wherein the operative element is displaced radially outward from the inactive position to the active position. When a user replaces the cap on a dosing device, and thus has used the dosing device, the switch automatically resets and activates the timer that subsequently displays the duration of time since the cap was replaced. When used by a diabetic patient replacing the cap immediately after taking the injection is typical for his or her routine. Thus an automatic activation of the timer is a suited method to determine the time elapsed since the last injection.

Figure 1 is an illustration of the above referred to preferred embodiment. Figure 1 shows a timer display unit (10), which is suitably a LCD display. In utilizing a numeric digital timer display users are not required to learn any new systems in order to monitor the time since last

injection. Assuming that users are familiar with a digital clock.

The replaceable cap (9) comprises of two plastic injection molded parts (12 and 18), referred to as replaceable cap top (12) and replaceable cap bottom (18). Figure 1 also shows a dosing device (28). The dosing device (28) may be a reusable syringe. The dosing device of Figure 1 is an example of a possible dosing device with which the cap (9) may be combined.

Figure 2 shows the dosing device (28) and the replaceable cap (9) of Figure 1 further provided with a pocket clip (26).

Figure 3 shows the dosing device (28) and the replaceable cap (9) of Figure 2 further provided with a switch comprising a shaped leaf spring feature (22). There are three cap pressure features (24) in equidistant radial pattern around the inside wall of the replaceable cap (9), one of which is located on the underside of the leaf spring feature (22).

Figures 4 and 5 shows an exploded perspective view and a cross-sectional view of the dosing device (28) and the replaceable cap (9) of Figure 3. Figure 4 shows a timer unit (16), also referred to as the drive electronics (16) and a battery (14) encased between replaceable cap top (12) and replaceable cap bottom (18). The LCD display (10), controlled by the drive electronics (16) and powered by a battery (14), resets every time the shaped leaf spring feature (22) is actuated. This happens when the replaceable cap (9) is inserted onto the dosing device(28), the force of insertion temporarily pushes the three cap pressure features (24) outward

over a lock ring (30) (as shown in Figure 6), as present on dosing device (28), before clipping in place to secure the cap(9) to the dosing device (28). The outward pressure actuates shaped leaf spring feature (22) and articulated switch contact pin (20) sub feature to be displaced radially outward from an inactive position to an active position. The active position resets the LCD timer (10). This effectively translates the linear mechanical force of removing and replacing the cap(9) into a perpendicular movement of the articulated switch contact pin (20), resulting in a pressure point onto the drive electronics (16).

In further detail, replaceable cap (9) is proposed for a known dosing device (28) having an original cap, not according to the invention. In order for the replaceable cap (9) to be as effective as the original cap on the dosing device (28), it is preferred that the dimensions of the replaceable cap (9) are such to provide a secure fit to different types and brands of replaceable dosing devices (28). By adjusting the mechanical clip mechanism geometry of the, preferably three or four, cap pressure features (24) and the lock ring (30) of a particular dosing device it is possible to easily customize the production on a per brand basis for numerous known dosing devices(28).

Figure 6 shows a cross-sectional view along the longitudinal axis of the cap (9) and dosing device (28) illustrating how cap pressure feature (24) operates shaped leaf spring feature (22) to activate switch contact pin (20) on electromechanical switch (32) when lock ring (30)of the dosing device (28) is pushed against cap

pressure feature (24). Figure 6 also shows drive electronics (16) and battery (14).

Preferably the LCD timer (10) will be a sourced subassembly with specific attention to temperature vulnerability, preferably requiring an operating temperature range for 0 to 50 °C. The battery (14) will suitably be a non rechargeable zinc anode cell capable of powering the drive electronics (16) and LCD timer (10) for at least 90 days. The drive electronics (16) will suitably consist of a PCB with integrated control chip architecture, imbedded firmware and electromechanical reset switch connected to the battery (14) and the LCD timer (10). The replaceable cap (9) is suitably a plastic injection molded part manufactured in two parts (12, 18). The replaceable cap top (12) will suitably require a basic two-part injection mold, while the replaceable cap bottom (18) will suitably require a multipart injection mold with gate features to shape the leaf spring feature (22). It should be considered that, in order to preserve the mechanical rigidity of the cap pressure features (24) and leaf spring feature (22), a plastic material with increased shore hardness be used than the cap of the dosing device which will be replaced by the cap according to the invention. Sub assembly of the timer display unit (10), the battery (14) and the drive electronics (16) will take place prior to final assembly of the clam shell architecture housing these parts inside the completed replaceable cap (9).

Figures 7 to 9 are directed to an alternative embodiment showing the same features as with previous design embodiments. There is a timer

display unit (10), drive electronics (16) and battery (14) encased between two plastic injection molded parts, replaceable cap top (12) and replaceable cap bottom (18). The replaceable cap (9) has a shaped Leaf spring feature (22) with articulated switch contact pin (20). There are three cap pressure features (24) in equidistant radial pattern around the inside wall of the replaceable cap (9), one of which is located on radially inward from the leaf spring feature (22).

Figure 10 shows another embodiment of the cap according to the present invention wherein the switch is present on the exterior of the cap (9). Figure 10 shows this cap (9) provided with LCD timer (10) in combination with dosing device (28). Preferably the switch is a touch sensitive switch (34). More preferably the touch sensitive switch (34) comprises two surface areas on the exterior of the cap (9) and wherein in use the switch is activated from an inactive to an active position when both areas are touched by at least two fingers of a user. Thus when the user removes or replaces the cap on the dosing device the timer is reset and starts to run.

Figures 11A and 11B show another embodiment of the cap according to the present invention wherein the switch comprises is a spring biased element (36) present at the closed end of the cap (9), which spring based element (36) is in the active position when compressed as in Figure 11A and wherein the spring based element (36) is compressed when the dosing device (28) is connected with the cap (9). Figure 11B shows when the spring based element (36) is in its extended position when the cap (9) is

partly removed from device (28). Thus when the user replaces the cap on the dosing device the timer is reset and starts to run.

Figure 12 shows another show another embodiment of the cap according to the present invention wherein the cap (9) is connected to a switch (44) via a flexible wire (40). Flexible wire (40) is connected to cap (9) at wire attachment (39). Preferably the switch (44) is attached to the dosing device (28). The switch (44) is preferably a ring (42), which can be fixed, for example by means of an adhesive or by friction, to the dosing device (28). Ring (42) is provided with touch sensitive switches (34). Touch sensitive switch (34) comprises two surface areas. When the liquid, i.e. insulin, is administered the touch sensitive switch (34) is touched by at least two fingers resulting in that the timer is reset and starts to run. The wire (40) has the additional advantage that it serves as a leash keeping the cap (9) from being lost. The switch may in an alternative embodiment be a switch (44) as attached at the end of the dosing device (28) which switch is operated manually.

By altering the dimensions of the replaceable cap as described above, the replaceable cap can be fitted to many commonly used medication delivery injection pens, specifically medication delivery pens that are purposed for multiple injection use.

The invention is also directed to the use of a replaceable cap in combination with a dosing device when administering a liquid to a patient by means of injection, wherein a switch automatically activates a timer when a user removes or replaces the cap on the dosing device or when using the dosing device

itself and wherein a timer display subsequently shows the duration of time since the switch activated the timer. Preferably the liquid comprises insulin. Even more preferably the replaceable cap as described above is used.

CONCLUSIES

1. Vervangbare dop voor een doseerinrichting om een vloeistof toe te dienen aan een patiënt, waarbij de dop is voorzien van een timer, van een timerweergave-eenheid, van een batterij, en van een schakelaar, waarbij de schakelaar, tijdens het gebruik, wordt geactiveerd vanuit een inactieve naar een actieve positie wanneer de doseerinrichting gebruikt wordt, waarbij de actieve positie aanleiding geeft tot het versturen van een signaal om de timer te resetten.

2. Dop volgens conclusie 1, waarbij de schakelaar, tijdens het gebruik, wordt geactiveerd vanuit een inactieve naar een actieve positie wanneer de dop wordt vervangen op de doseerinrichting.

3. Dop volgens conclusie 1, waarbij de schakelaar is voorzien van een werkzaam element dat verplaatsbaar is langs een radiaal buitenwaarts gerichte lijn beginnende ter hoogte van een longitudinale as van de dop, en waarbij het werkzame element kan bewegen van de inactieve positie naar de actieve positie wanneer, tijdens het gebruik, de dop wordt verwijderd van de doseerinrichting of wanneer de dop op de doseerinrichting wordt aangebracht.

4. Dop volgens conclusie 3, waarbij, tijdens het gebruik, een signaal wordt verstuurd wanneer de dop wordt verwijderd en waarbij het werkzame element radiaal buitenwaarts wordt verplaatst vanuit de inactieve positie naar de actieve positie.

5. Dop volgens conclusie 1, waarbij de schakelaar aanwezig is op de buitenzijde van de dop.

6. Dop volgens conclusie 5, waarbij de schakelaar een touch-gevoelige schakelaar is.

7. Dop volgens conclusie 6, waarbij de touch-gevoelige schakelaar is voorzien van twee oppervlaktezones op de buitenzijde van de dop, en waarbij, tijdens het gebruik, de schakelaar wordt geactiveerd vanuit een inactieve positie naar een actieve positie wanneer beide zones worden aangeraakt door ten minste twee vingers van een gebruiker.

8. Dop volgens conclusie 1, waarbij de schakelaar is voorzien van een verend element dat aanwezig is aan het gesloten einde van de dop, waarbij het verende element zich in de actieve positie bevindt wanneer het is samengedrukt, en waarbij het verende element wordt samengedrukt wanneer de doseerinrichting verbonden is met de dop.

9. Dop volgens conclusie 1, waarbij de dop is verbonden met een schakelaar door middel van een flexibele draad.

10. Dop volgens conclusie 9, waarbij de schakelaar is verbonden met de doseerinrichting.

11. Dop volgens een der conclusies 9-10, waarbij de schakelaar manueel wordt bediend.

12. Dop volgens een der conclusies 9-10, waarbij de schakelaar is voorzien van twee oppervlaktezones die verbonden zijn met de buitenzijde van de doseerinrichting, en waarbij, tijdens het gebruik, de schakelaar wordt geactiveerd vanuit een inactieve positie naar een actieve positie wanneer beide zones worden aangeraakt door ten minste twee vingers van een gebruiker wanneer hij gebruik maakt van de doseerinrichting.

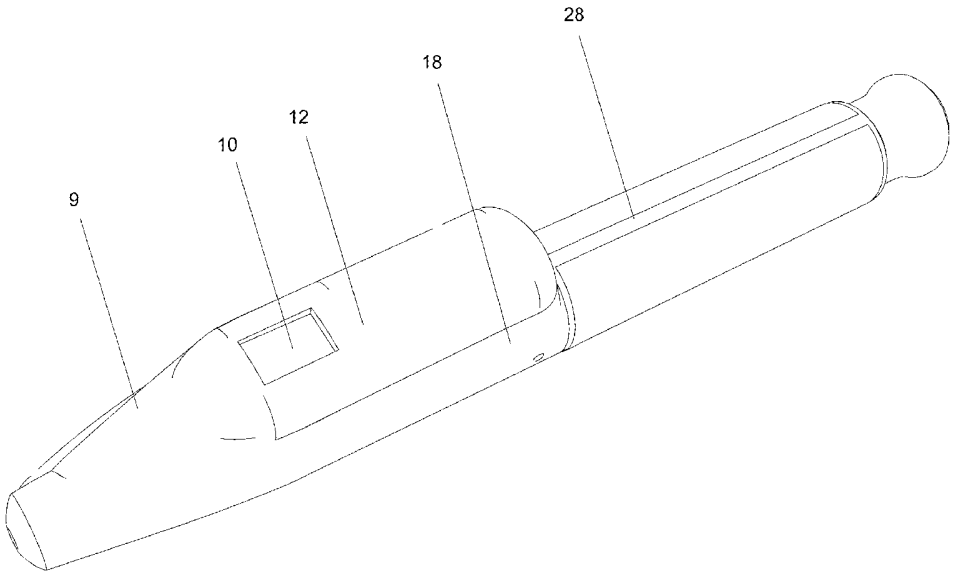

Fig. 1

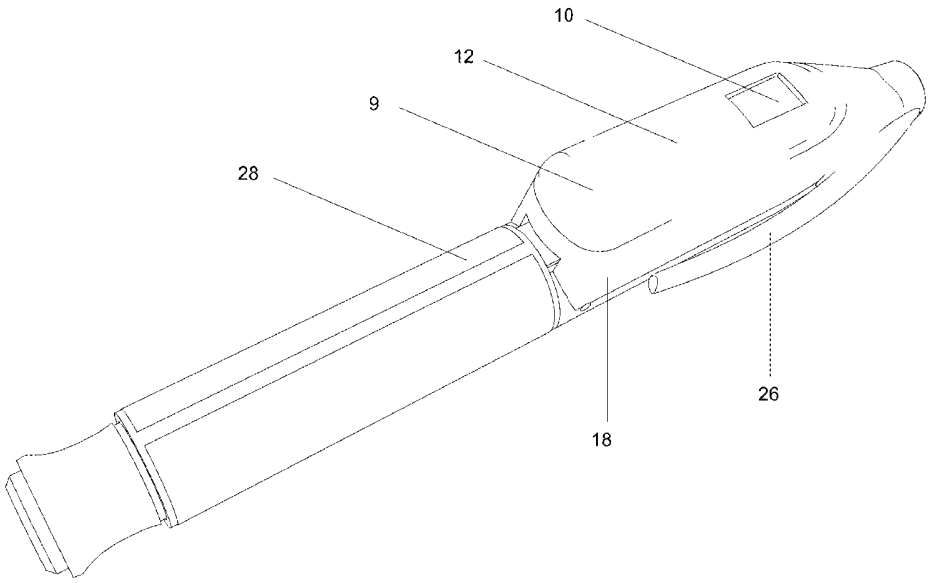

Fig. 2

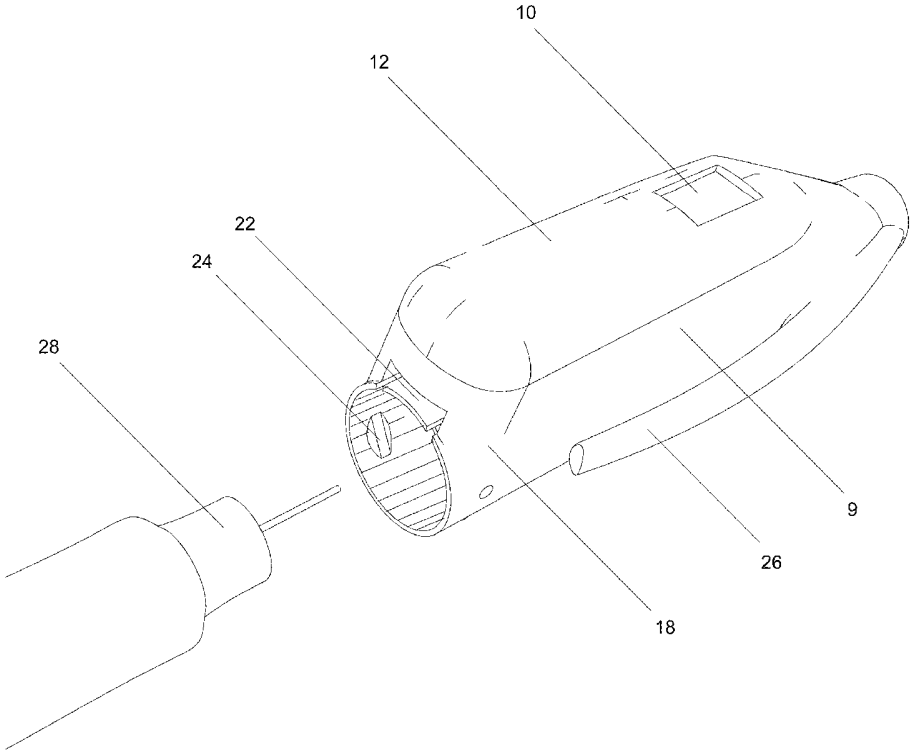

Fig. 3

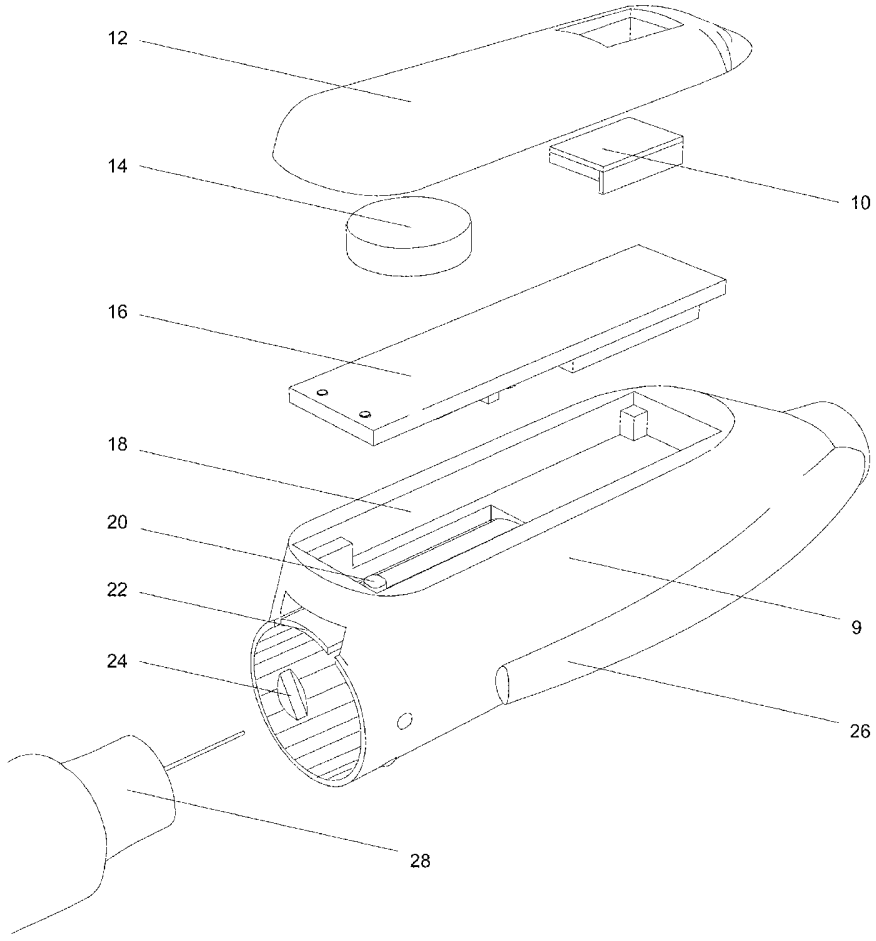

Fig. 4

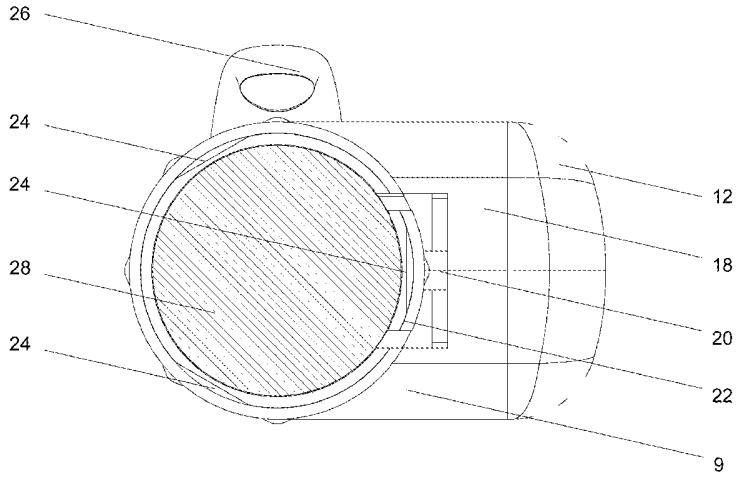

Fig. 5

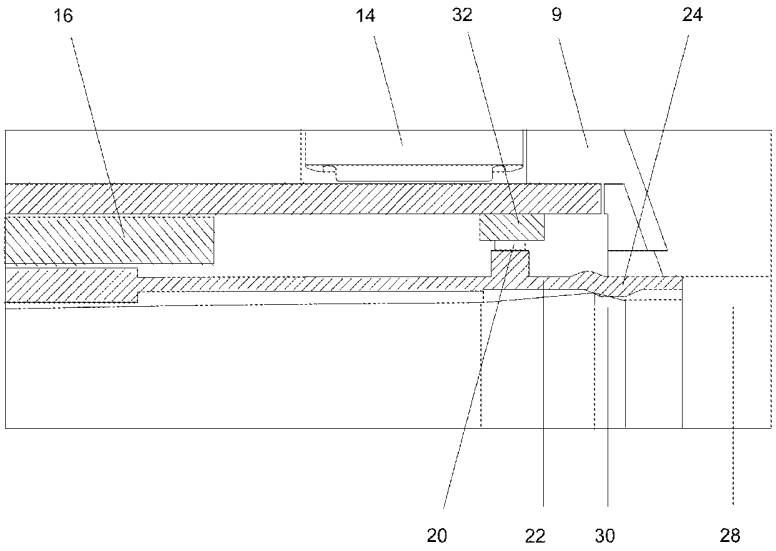

Fig. 6

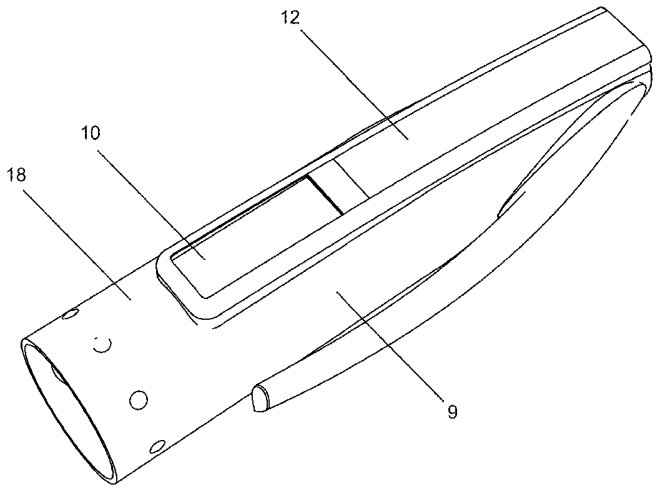

Fig. 7

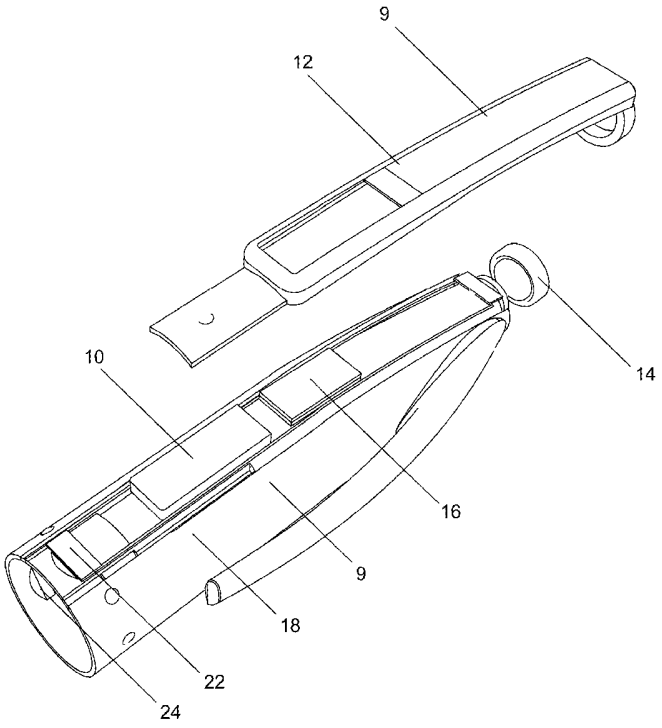

Fig. 8

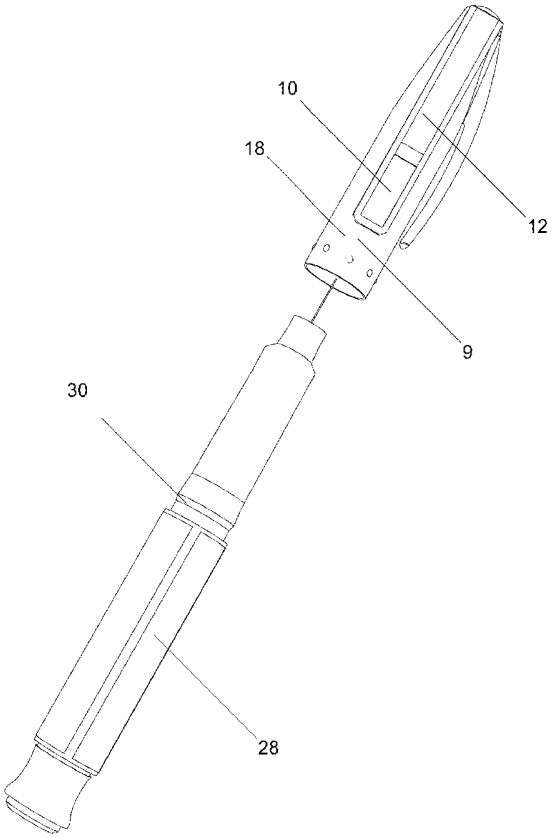

Fig. 9

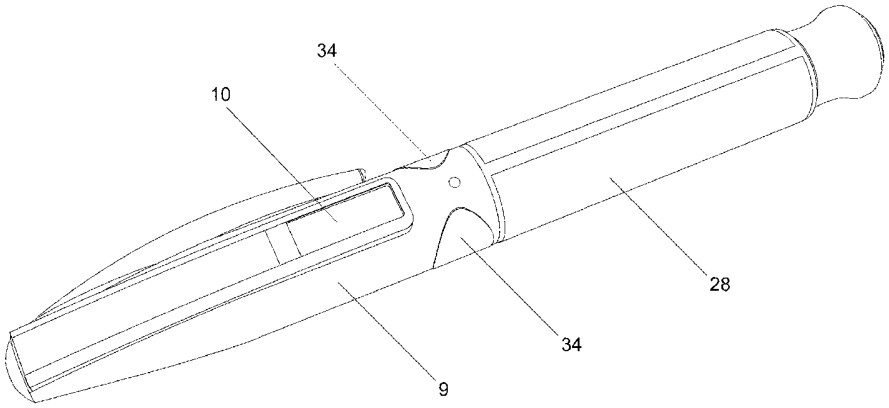

Fig. 10

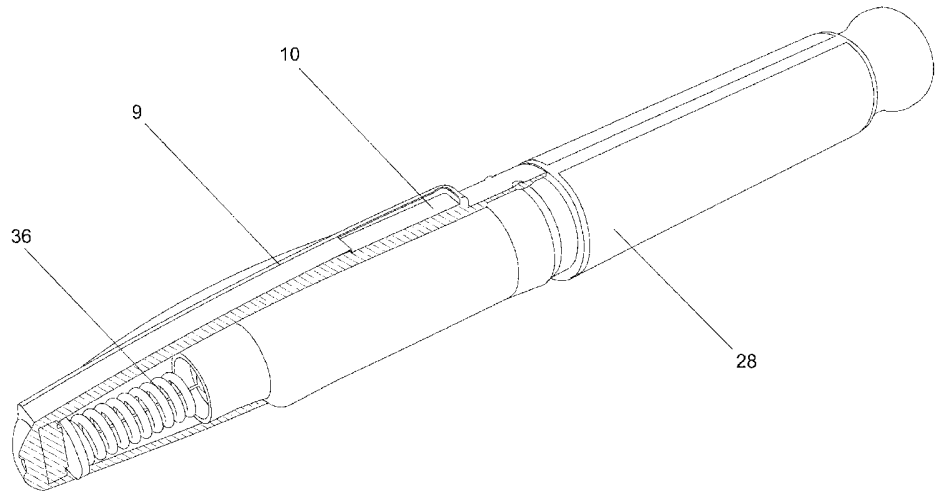

Fig. 11A

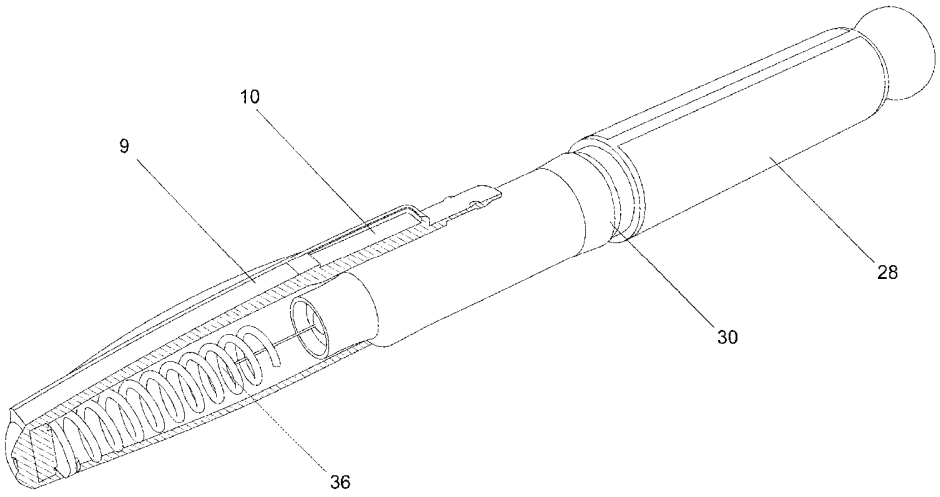

Fig. 11B

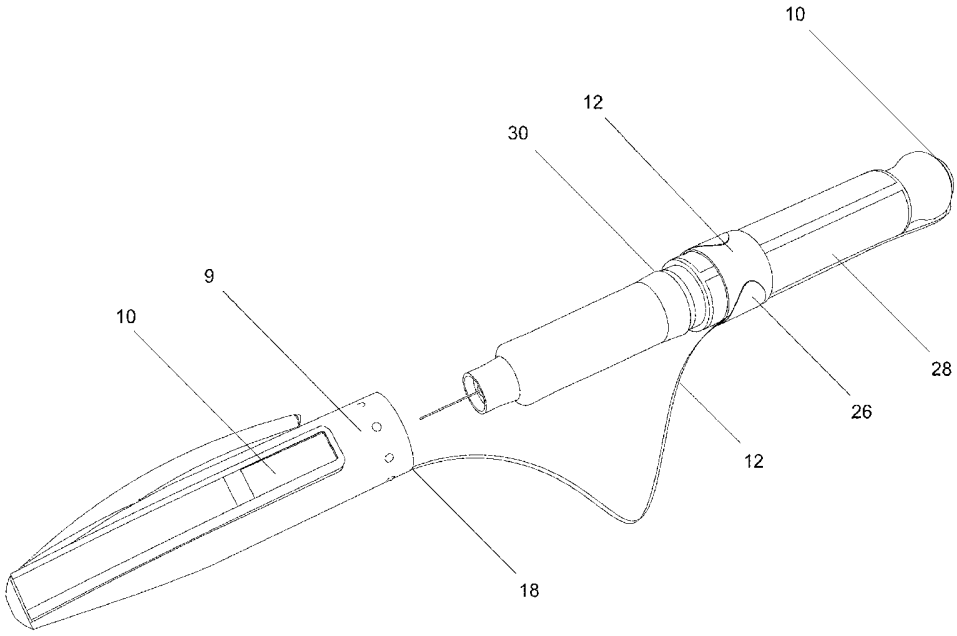

Fig. 12

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	P115257NL00
Nederlands aanvraag nr. **2005017**	Indieningsdatum **01-07-2010**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **Techlund AB**	
Datum van het verzoek voor een onderzoek van internationaal type **25-09-2010**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN54891**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

A61M5/32;A61M5/31;A61J7/04

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC8	**A61J;A61M**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III.	[X]	**GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES**	(opmerkingen op aanvullingsblad)
IV.	[ ]	**GEBREK AAN EENHEID VAN UITVINDING**	(opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2005017

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61M5/32
ADD. A61M5/31 A61J7/04

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
A61J A61M

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
	ONVOLLEDIG ONDERZOEK zie aanvullingsblad C -----	
X	US 2004/062148 A1 (SKYGGEBJERG OLE [DK] ET AL SKYGGEBJERG OLE [DK] ET AL) 1 april 2004 (2004-04-01)	1-4,10, 11
Y	* alinea [0045] - alinea [0051]; figuren 1-8 * * alinea [0062] - alinea [0064] * -----	5-9,12
X	WO 03/063754 A1 (GLAXO GROUP LTD [GB]; BONNEY STANLEY GEORGE [GB]; RAND PAUL KENNETH [G) 7 augustus 2003 (2003-08-07) * bladzijde 18, regel 8 - bladzijde 24, regel 9 * * figuren 1-4 * -----	1-4,10, 11
	-/--	

[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
2 februari 2011	
Naam en adres van de instantie European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	**De bevoegde ambtenaar** Reinbold, Sylvie

1

Formulier PCT/ISA/201 (tweede blad) (Januari 2004)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2005017

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	US 2002/096543 A1 (JUSELIUS RAIMO [FI]) 25 juli 2002 (2002-07-25) * alinea [0040] - alinea [0059] * * figuren 1-8 *	1-4,10, 11
X	WO 99/43283 A1 (JUSELIUS RAIMO [FI]) 2 september 1999 (1999-09-02) * bladzijde 3, regel 32 - bladzijde 11, regel 15 * * figuren 1-11 *	1,2,10, 11
Y,D	US 2002/126585 A1 (OSBERG JAMES ALAN [US] ET AL) 12 september 2002 (2002-09-12) in de aanvraag genoemd * figuren 1-4 * * alinea [0018] - alinea [0022] * * alinea [0029] *	5-9,12

1

ONVOLLEDIG ONDERZOEK
AANVULLINGSBLAD C

Octrooiaanvrage Nr.:
SN 54891
NL 2005017

Volledig onderzoekbare conclusie(s):
1-12

Niet onderzochte conclusie(s):
13-15

Reden voor de beperking van het onderzoek (niet octrooieerbare uitvinding(en)):

The use of claims 13 to 15 is carried out within a human body. As stated in the claims, the method relates to a therapeutical method to administer liquid to a patient into the tissue of the body. It is implicit that the timer display showing the duration of the time is the time of injection. Therefore these claims are a method of treatment of the human body and are excluded to patentability.

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2005017

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
US 2004062148 A1	01-04-2004	AU 2003254340 A1	09-02-2004
		WO 2004010231 A2	29-01-2004
		EP 1391794 A1	25-02-2004
		EP 1527376 A2	04-05-2005
		JP 4563174 B2	13-10-2010
		JP 2006507856 T	09-03-2006
		US 2007030764 A1	08-02-2007
WO 03063754 A1	07-08-2003	EP 1471868 A1	03-11-2004
		JP 2005515841 T	02-06-2005
US 2002096543 A1	25-07-2002	GEEN	
WO 9943283 A1	02-09-1999	AU 763048 B2	10-07-2003
		AU 2626899 A	15-09-1999
		BR 9908153 A	31-10-2000
		CA 2321555 A1	02-09-1999
		EE 200000480 A	15-02-2002
		EP 1056427 A1	06-12-2000
		FI 980447 A	27-08-1999
		JP 2002504397 T	12-02-2002
		NO 20004234 A	24-08-2000
US 2002126585 A1	12-09-2002	GEEN	

OCTROOICENTRUM NEDERLAND

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN54891	01.07.2010		NL2005017

International Patent Classification (IPC)
INV. A61M5/32
ADD. A61M5/31 A61J7/04

Applicant
Techlund AB

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the application
- ☒ Box No. VIII Certain observations on the application

	Examiner
	Reinbold, Sylvie

Application number

WRITTEN OPINION

NL2005017

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable have not been examined in respect of

☐ the entire application

☒ claims Nos. 13-15

because:

☐ the said application, or the said claims Nos. relate to the following subject matter which does not require a search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no search report has been established for the whole application or for said claims Nos. 13-15

☐ a meaningful opinion could not be formed as the sequence listing was either not available, or was not furnished in the international format (WIPO ST25).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; or such tables were not available in electronic form.

☐ See Supplemental Box for further details.

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	5-9, 12
	No:	Claims	1-4, 10, 11
Inventive step	Yes:	Claims	
	No:	Claims	1-12
Industrial applicability	Yes:	Claims	1-12
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the application

see separate sheet

Re Item III

Non- establishment of opinion with regard to novelty, inventive step and industrial applicability

The use of claims 13 to 15 is carried out within a human body. As stated in the claims, the method relates to a therapeutical method to administer liquid to a patient into the tissue of the body. It is implicit that the timer display showing the duration of the time is the time of injection. Therefore these claims are a method of treatment of the human body and are excluded to patentability.

Thus, the subject matter of these claims has not been searched and consequently no examination was carried out for those claims.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure:

D1 US 2004/062148

D2 WO 03/063754

D3 US 2002/096543

D4 WO 99/43283

D5 US 2002/126585

Novelty

2 The present application does not meet the criteria of patentability, because the subject-matter of **claims 1 to 4 and 10 to 11** is not new.

2.1 The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) a replaceable cap (20) (figure 1 to 8) for a dosing device for administering a liquid to a patient (10), the cap (20) comprising a timer (31), a timer display unit (24), a battery (energy source : paragraph 48) and a switch which switch is (35) (paragraph 50), in use, activated from an inactive to an active position when the dosing device is used, which active position results in a signal being sent to reset the timer.

Therefore the subject matter of claim 1 is not novel document D1.

2.2 Moreover document D1 shows the technical feature of claims 2 to 4 and 10 to 11.

2.3 In addition documents D2 to D4 describe the technical features of claims 1 to 4 and 10 to 11

Inventive Step

3 The present application does not meet the criteria of patentability, because the subject-matter of **claims 5 to 9 and 12** is not inventive.

In these claims a slight constructional change (features of the switch) in the replaceable cap of claim 1 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Feature of the switch is described in document D5 (paragraph 19, figure 2 and 3) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the cap described in document D1 in order to solve the problem posed. Consequently, the subject-matter of these claims also lacks an inventive step.

Further comments

4 The **relevant background** art disclosed in the documents D1- D5 are not mentioned in the description, nor are these documents identified therein.

5 Independent claim 1 is not in the two-part form, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble and the remaining features being included in the characterising part.

6 The features of claims 1 to 12 are not provided with reference signs placed in parentheses.

Re Item VIII

Certain observations on the application

7 **Claim 1** is not clear. Some of the features in the apparatus claim 1 relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features (a switch is in use activated from an inactive to an active position when the dosing device is used). The intended limitations are therefore not clear from this claim.