JC675 U.S. PTO
09/655922
09/06/00

ISSUE CLASSIFICATION	Subclass	Class
	181	604

PATENT NUMBER
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U.S. **UTILITY** Patent Application

O.I.P.E.	PATENT DATE
SCANNED 6/23 Q.A.	JUN 24 2003

APPLICATION NO.	CONT/PRIOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
09/655922	D F	604	181	3762 / 3744	ZEC

APPLICANTS
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Steffen Hansen
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Claus Moller

TITLE
Dose setting limiter

PTO-2040
12/99

ISSUING CLASSIFICATION

ORIGINAL CLASS	ORIGINAL SUBCLASS	CROSS REFERENCE(S) CLASS	CROSS REFERENCE(S) SUBCLASS (ONE SUBCLASS PER BLOCK)
604	181	604	186, 207, 208, 211, 224

INTERNATIONAL CLASSIFICATION
A61M 5/00
A61M 5/178
A61M 5/135

☐ Continued on Issue Slip Inside File Jacket

5/23/03 Formal Drawings / 2 sheet set 1 9/6/00

☒ TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg.	Figs. Drwg.	Print Fig.	Total Claims	Print Claim for O.G.
	2	3	1	4	1

☐ The term of this patent subsequent to _____ (date) has been disclaimed.	Filip Zec (Assistant Examiner) 2/4/03 (Date)	NOTICE OF ALLOWANCE MAILED
☒ The term of this patent shall not extend beyond the expiration date of U.S Patent. No. pending	William C. Doerrler	2-7-03
	William C Doerrler (Primary Examiner) 2-5-03 (Date)	ISSUE FEE: Amount Due $1300 / Date Paid 5/16/03
☐ The terminal ____ months of this patent have been disclaimed.	(Legal Instruments Examiner) 2/03 (Date)	ISSUE BATCH NUMBER

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Form **PTO-436A**
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ISSUE FEE IN FILE

Drawing

(FACE)

PATENT APPLICATION

09655922

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09/655922

SEP 220094

INITIALS

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U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

09/18/2000 DFLOYD 00000017 141447 09655922
01 FC:101 690.00 CH

PTO-1556
(5/87)

*U.S. GPO: 1999-459-082/19144

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Bib Data Sheet

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/655,922	09/06/2000 RULE _	604	3762	6036.200-US

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** CONTINUING DATA **********

THIS APPLN CLAIMS BENEFIT OF 60/155,612 09/23/1999

** FOREIGN APPLICATIONS **********

DENMARK PA 1999 01309 09/16/1999

IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 10/18/2000

Foreign Priority claimed	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☑ yes ☐ no	DENMARK	2	4	1

35 USC 119 (a-d) conditions met: ☐ yes ☐ no ☐ Met after Allowance

Verified and Acknowledged: Philip Tucci (Examiner's Signature) PZ (Initials)

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TITLE

Dose setting limiter

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
$20	No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

09-07-00

A

Attorney Docket No.: 6036.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FILING UNDER 37 C.F.R. 1.53(b)

Box Patent Application
Assistant Commissioner for Patents
Washington, DC 20231

Express Mail Label No. EL636737346US
Date of Deposit September 6, 2000

Sir:

This is a request for filing a patent application under 37 C.F.R. 1.53(b) of

Applicant(s): Klitgaard et al.

Title: Dose Setting Limiter

8 pages of specification 2 sheets of Formal Drawings

3 sheets of Declaration and Power of Attorney

[x] The filing fee is calculated as follows:

Basic Fee:	$690.00
Total Claims: 4 - 20 = 0 x 18 =	$0
Independent Claims: 1 - 3 = 0 x 78 =	$0
Total Fee:	$690.00

Priority of Danish application no. PA 1999 01309 filed on September 16, 1999 is claimed under 35 U.S.C. 119. A certified copy is submitted herewith.

Priority of U.S. provisional application no. 60/155,612 filed on September 23, 1999 is claimed under 35 U.S.C. 119.

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be $690, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: September 6, 2000

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DOSE SETTING LIMITER

Cross-Reference to Related Applications

This application claims priority under 35 U.S.C. 119 of U.S. provisional application no. 60/155,612 filed on September 23, 1999 and Danish application no. PA 1999 01309 filed on September 16, 1999, the contents of which are fully incorporated herein by reference.

Field of the Invention

The present invention relates to injection devices wherein the contents of a cartridge are injected as a number of individually set doses.

Such devices have a dose setting mechanism by which the doses are set for subsequent injecting when an injection button is operated. This can be obtained by moving a carrier along a piston rod a distance proportional to the wanted dose and subsequently moving the carrier back to its original position so that the carrier carries the piston rod with it instead of being moved along said piston rod.

Scope of the Related Art

From EP 327 910 is known a syringe by which a dose is set by screwing a nut member up along a threaded piston rod away from a stop in a housing. The set dose is injected by pressing the end of the nut member that forms an injection button whereby the nut member is moved back to abutment with the stop again. During the latter movement of the nut member the piston rod is carried along by the nut that does not move relative to this piston rod during the injection.

When a dose is set it is convenient if a limiting device is provided which makes it impossible to set a dose that exceeds the amount of medicament which is left in the cartridge. In EP 327 910 this is obtained by the fact that the thread of the piston rod has such a length that the cartridge is just emptied when the nut is screwed to the end of the thread and then pressed home to its abutment with the stop. By setting a dose the nut can only be screwed to the end of the thread and thereby the size of the last dose is limited to comprise the remaining amount in the cartridge.

The distance the injection button has to be moved corresponds to the distance the piston in the cartridge has to be moved to inject the set dose. Especially by larger cartridges with a large cross section diameter this distance can be very short. To obtain a larger movement of the injection button a sort of gearing may be used so that the distance the injection button has to be moved is proportional with the injected dose but is a number of times the movement of the piston in the cartridge.

EP 608 343 describes an example of such a geared dose setting and injection mechanism. In this device the carrier does not cooperate directly with the threaded piston rod but with a driver element which can move the piston rod when a set dose is injected. In this device the driver element comprises a nut member which is fixed against axial displacement in the injection device. The thread of the nut member engages an outer thread of the piston rod which is secured against rotation in the injection device. By the setting of a dose the carrier is rotated away from a stop to which it is returned when the injection button is operated. During its return the carrier rotates the driver element that moves the piston rod further into the cartridge to press the piston of this cartridge so that a set amount of the medicament in the cartridge is pressed out through an injection needle at the distal end of the cartridge. As the nut member is not moved relative to the piston rod during the setting of a dose, a limiting construction as described above cannot be provided limiting the dose so it does not exceed the amount of liquid left in the injection device.

Object and Summary of the Invention

An object of the invention is to provide a limiting mechanism which prevents setting of a dose that exceeds the amount of liquid left in a cartridge of an injection device of the geared type wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver element with it to rotate this driver element which moves the piston rod forward.

Such a mechanism is according to the invention characterized in that the driver element is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of said dose setting member. During the setting of a dose the track follower will be advanced in the track of the driver to a position depending on the set

dose as during dose setting the dose setting member and the driver are rotated relative to each other. As during the injection the driver follows the rotation of the dose setting member, the pin of the dose setting member will keep its position in the track of the driver when the set dose is injected. The length of the track is so adapted that the pin reaches the end of the track and makes an increase of the set dose impossible when a dose is set which corresponds to the amount of liquid remaining in the cartridge.

According to the invention the driver may be disk shaped and have a spiral shaped track which is engaged by a cam on a member which is flexibly coupled to the dose setting member so that the pin can be moved radially when it follows the track of the driver.

In another embodiment of the invention the driver may be cylindrical and have a helical track which is engaged by a cam on the dose setting member which is a cylinder concentric with the driver.

The track may be provided as a thread in the driver and the track follower may be a nut shaped member coupled to the dose setting member and provided with a thread engaging the thread of the driver. When a dose is set the dose setting member is screwed with its thread along the thread of the driver. The limitation of the set dose is obtained by giving the threads an appropriate length.

Brief Description of the Drawings

In the following the invention will be explained in further details with references to the drawing, wherein

Figure 1 shows an exploded view of a syringe with a dose limiter according to the invention;

Figure 2 shows an enlarged view of the dose setting element and the driver element of the syringe in figure 1; and

Figure 3 shows the dose setting member, the driver, and the track follower of another embodiment of an injection syringe.

Detailed Description of the Invention

The syringe in Figure 1 comprises a housing 1 accommodating a cartridge 2 from which the content can be pressed out by a piston rod 3 which is by injection via gear wheels 4 and 5 advanced a distance corresponding to a dose set by dose setting. A dose setting member 6 is provided with a toothed wheel 7 surrounding a central bore through which a pinion 8 on a driver 9 projects as it is shown in Figure 2. The dose setting element 6 is operated through an operation element 10 which has a finger grip 11, a carrier 12 which engages the dose setting member 6, and a arrow 13 pointing on a scale 14 provided on a lid 15 which forms a part of the housing 1. Figure 1 further shows a cap 25 which can be put on to protect a not shown needle which may be mounted on the syringe, and an injection button 16 which is sliding mounted in the housing 1 and which has a recess 17 which is on one of its side surfaces provided with a cogging 18.

In the assembled syringe the toothed wheel 7 on the dose setting member 6 engages the cogging 18 of the button element 16 whereas the pinion 8 on the driver 9 engages the part with the large diameter of the gear wheel 5 the part of which with the small diameter engages the other gear wheel 4 which further engages a cogging 19 on the piston rod 3.

The driver member 9 is provided with pawl 26 which with not shown teeth in the housing forms an unidirectional coupling allowing the driver 9 to rotate only in the direction by which the piston rod 3 is advanced into the cartridge 2. A ratchet is provided by saw tooth shaped protrusions on the dose setting element 6 engaging a saw tooth cogging 27 at the perimeter of the driver 9, this ratchet being so oriented that only rotation of the dose setting member 6 in the direction in which the driver 9 can move is transmitted from the dose setting member 6 to the driver 9. By rotation of the dose setting member 6 in the opposite direction the teeth of the ratchet parts will ride over each other.

To set a dose the finger grip 11 of the operation element 10 is gripped and the element 10 is rotated clockwise until the arrow points at the wanted dose on the scale 14. As mentioned this rotation will make the ratchet parts of the dose setting element and the driver ride over each other. If the dose setting member 6 is rotated in the clockwise direction to reduce the set dose, the ratchet will cause transmission of the rotation from the dose setting member 6 to the driver 9, but the when a torque in this direction is transmitted from the operating element through the carrier 12 to the dose setting member 6, this dose setting member is de-

formed so that the protrusion on the dose setting member 6 is drawn out of its engagement with the toothing 27 of the driver 9 and an anticlockwise rotation of the dose setting member 6 is allowed without the rotation being transmitted to the driver 9.

Due to the engagement between the toothed wheel 7 on the dose setting member 6 and the cogging 18 of the injection button 16 this button will be lifted from the end of the housing 1 when a dose is set and will be lowered when a dose is reduced.

When the injection button 16 is pressed to inject a set dose the engagement between the toothed wheel 7 on the dose setting member 6 and the cogging 18 of the injection button 16 will cause the dose setting member 6 to rotate in an anticlockwise direction. As the torque is not transmitted to the dose setting member 6 by the operating element 10, the ratchet coupling between the dose setting member 6 and the driver 9 will be active and the driver 9 will be rotated with the dose setting member 6 in the anticlockwise direction and will drive the piston rod 3 into the cartridge.

As it is seen in Figure 2 the disk shaped driver 9 has in its side facing the dose setting member 6 a spiral shaped track 20 which is engaged by a cam 21 provided at the end of an arm 22 which is by a flexible beam 23 fastened to the dose setting member 6 so that the arm 22 can swing to let the cam 21 move in the radial direction of the driver 9. When the dose setting member 6 during the setting of a dose is rotated relative to the driver 9 the cam is moved along the track 20 whereas the cam during the injection due to the concomitant rotation of the dose setting member 6 and the driver 9 remains in its position in the track 20 obtained during the dose setting. This way the position of the cam in the track reflects the total amount of medicine administered. When the cam 21 abuts the end wall 24 of the track 20 the set dose cannot be increased and by adapting the length of the track to the total amount of medicine in the cartridge it is ensured that a dose larger than the amount of medicine remaining in the cartridge cannot be set.

Figure 3 shows a dose setting member 30 surrounding a driver 31 of another embodiment of a dose setting limiter. The dose setting member 30 is cylindrical and is on its outer wall provided with a helical track 29 which is designed to co-operate with a helical inner ridge in a not shown housing so that the dose setting member 30 is screwed outward in said housing when rotated to set a dose and inward in said housing when rotated to reduce a too large set

dose. During the dose setting rotation the dose setting member 30 is rotated freely relative to the driver 31 which it surrounds. Between the dose setting member 30 and the driver 31 a nut member 32 is coupled which can when it is rotated relative to the driver 31 be screwed up along this driver which is at its outer surface provided with a helical track 33. At its outer wall the nut member 32 is in the axial direction provided with a recess 34 which is engaged by a ridge 35 in the axial direction on the inner side of the dose setting element 30.

During the setting of a dose the nut member 32 is due to the engagement between the ridge 35 and the recess 34 rotated with the dose setting member 30 relative to the driver 31 so that the position of the nut member 32 on this driver is dependent on the dose set. When the dose is injected by pressing a not shown injection button which is placed in an end part 36 of the dose setting member 30 this button presses a flange 37 at an end of the driver 31 into engagement with coupling teeth 38 at the bottom of the end part 36 of the dose setting member 30. On its lower not visible side the flange 37 is provided with coupling teeth corresponding to the coupling teeth 38 of the dose setting member 30 and when the dose setting member 30 is due to the engagement between the track 29 in the dose setting member 30 and the ridge in the housing forced to rotate relative to the housing when it is pressed into the housing the rotation will be transmitted to the driver 31 which due to the engaging coupling teeth is forced to rotated with the dose setting member and during this rotation the nut member 32 will maintain its position on the driver 31. This way the position of the nut member 32 on the driver 31 will always indicate the total sum of set and injected doses. When the length of the helical track 33 in the driver 31 is adapted to the amount of medicine in a cartridge the nut member 32 will reach the end of the track 33 and stop for setting a dose larger than the amount remaining in the cartridge.

What is claimed is:

1. A limiting mechanism which prevents setting of a dose that exceeds the amount of liquid left in a cartridge of an injection device wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver with it to rotate this driver which moves the piston rod forward, wherein the driver is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member.

2. The limiting mechanism of claim 1, wherein the driver is disk shaped and has a spiral shaped track which is engaged by a cam flexibly coupled to the dose setting member so that the cam can be moved radially when it follows the track of the driver element.

3. The limiting mechanism of claim 1, wherein the driver is cylindrical and has a helical track which is engaged by a cam coupled to the dose setting member which is a cylinder concentric with the driver.

4. The limiting mechanism of claim 3, wherein the track is provided as a thread in the driver and that the track follower is a nut shaped member coupled to the dose setting member and provided with a thread engaging the thread of the driver.

Abstract of the Disclosure

A limiting mechanism which prevents the setting of a dose, which exceeds the amount of liquid left in a cartridge of an injection device, is disclosed. The injection device is the type where a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device. The dose setting member interfaces the driver such that the dose setting member can be rotated in one direction without rotating the driver. The dose is injected by rotating back the dose setting member which during the backward rotation carries the driver with it. Rotating the driver causes the piston rod to move forward inside the cartridge and expel some of the liquid contained in the cartridge. The driver is provided with a track having a length which is related to the total amount of liquid in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member. Each time a dose is set and injected, the track follower moves further into the track. When the track follower reaches the end of the track the dose setting member can not be rotated further, and a dose larger than the remaining liquid in the cartridge cannot be set.

Fig.1

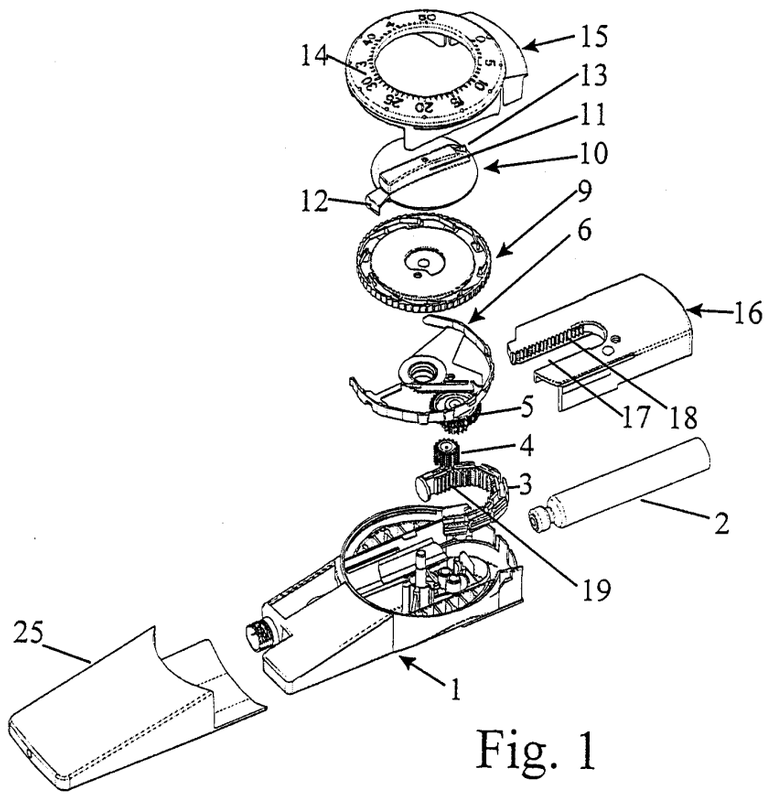

Fig. 1

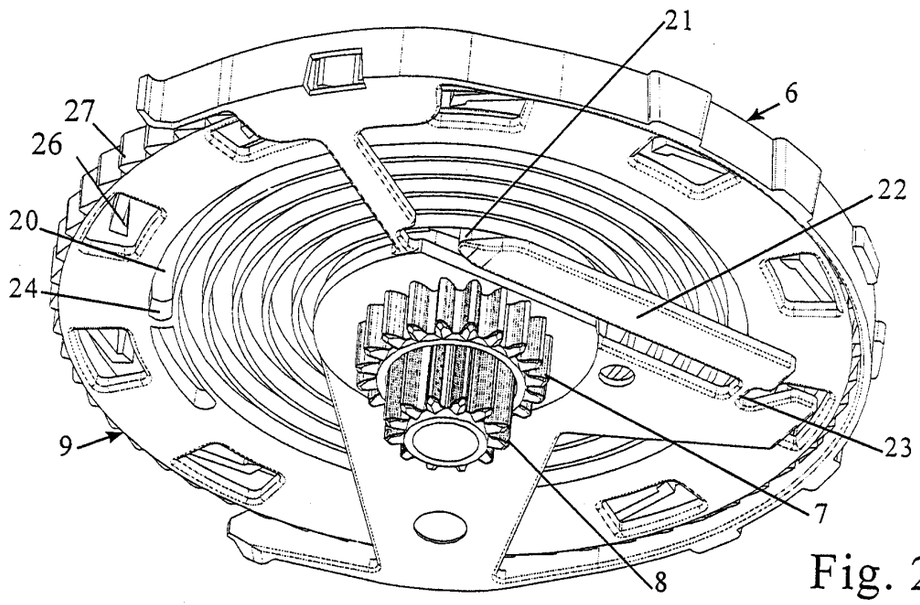

Fig. 2

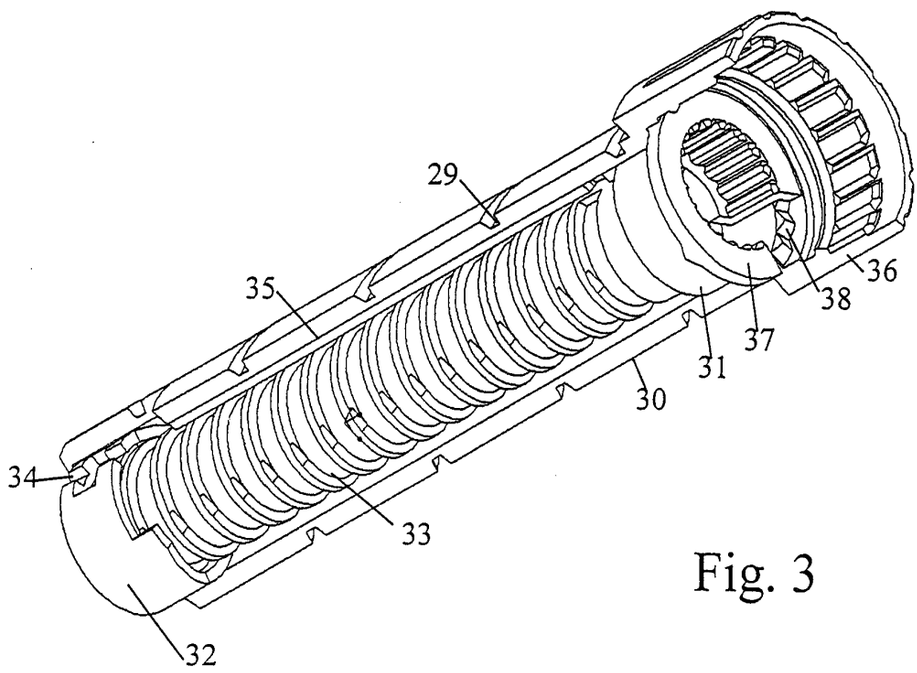

Fig. 3

PRINT OF DRAWINGS
AS ORIGINALLY FILED

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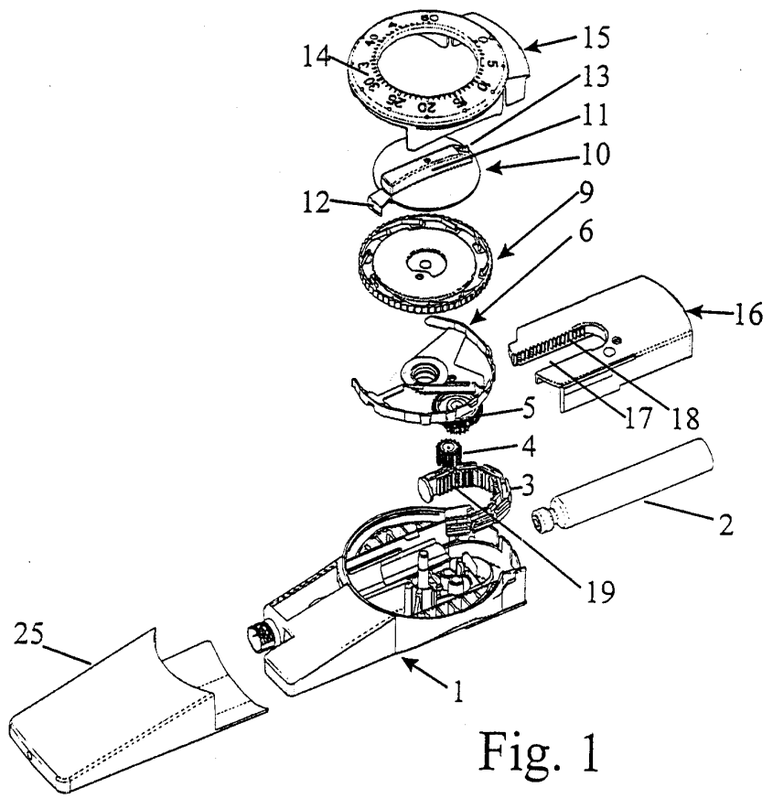

Fig. 1

PRINT OF DRAWINGS
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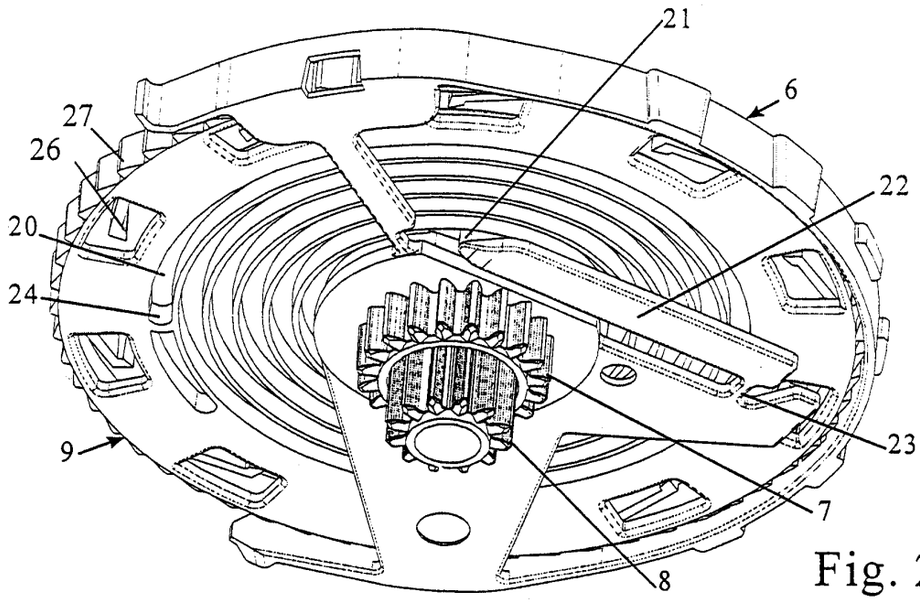

Fig. 2

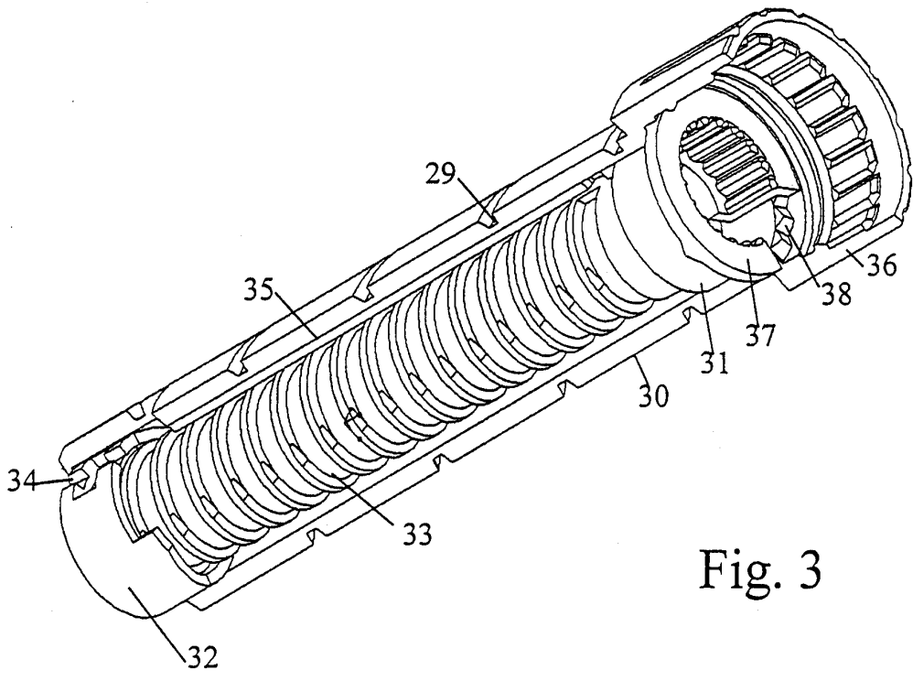

Fig. 3

COMBINED DECLARATION F 'ATENT APPLICATION AND POWER OF ORNEY (Includes Reference to PCT Interna.. ..al Applications)	Attorney's Docket Number: 6036.200-US

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Dose Setting Limiter

The specification of which (check only one item below):
[ ] is attached hereto
[**X**] was filed as United States application

Application No. To Be Assigned

on September 6, 2000
and was amended
on

[ ] was filed as PCT international application
Number
on
and was amended under PCT Article 19
on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by an amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code, §119 of any provisional or foreign application(s) for patent or inventor's certificate or of any PCT international applications(s) for patent or inventor's certificate or of any PCT international applications(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR U.S. PROVISIONAL/FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicated "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Denmark	PA 1999 01309	16 September 1999	[X] YES [ ] NO
United States	60/155,612	23 September 1999	[X] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

COMBINED DECLARATION I .'ATENT APPLICATION AND POWER OF ORNEY
(Includes Reference to PCT International Applications)

Attorney's Docket Number: **6036.200-US**

I hereby claim the benefit under Title 35, United States Code '120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, '112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, '1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned

PCT APPLICATIONS DESIGNATING THE U.S.					
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. Steve T. Zelson Elias J. Lambiris Valeta A. Gregg Carol E. Rozek Robert L. Starnes Reza Green, Reg. No. 30,335 Reg. No. 33,728 Reg. No. 35,127 Reg. No. 36,993 Reg. No. 41,324 Reg. No. 38,475

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COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Attorney's Docket Number:
6036.200-US

5	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
6	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
7	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
8	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
9	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Date	Date	Date
Signature of Inventor 4	Signature of Inventor 5	Signature of Inventor 6
Date	Date	Date
Signature of Inventor 7	Signature of Inventor 8	Signature of Inventor 9
Date	Date	Date

UNITED STATES PATENT AND TRADEMARK OFFICE

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WASHINGTON, D.C. 20231
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APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US

FORMALITIES LETTER

OC000000005484923

Steve T Zelson Esq
Novo Nordisk of North America Inc
405 Lexington Avenue Suite 6400
New York, NY 10174-6401

Date Mailed: 10/18/2000

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

- **The balance due by applicant is $ 130.**

A copy of this notice MUST be returned with the reply.

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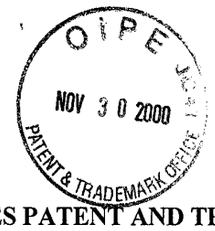
PART 3 - OFFICE COPY

#3

Attorney Docket No.: 6036.200-US



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Serial No.: 09/655,922 Group Art Unit: 3762

Filed: September 6, 2000 Examiner: To be assigned

For: Dose Setting Limiter

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Response to Notice to File Missing Parts (in duplicate)
2. Copy of Notice to File Missing Parts
3. Executed Combined Declaration and Power of Attorney

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on November 27, 2000.

Sylvia Gonzalez
(name of person mailing paper)

Sylvia Gonzalez
(signature of person mailing paper)

#3

Attorney Docket No.: 6036.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Serial No.: 09/655,922 Group Art Unit: 3762

Filed: September 6, 2000 Examiner: To be assigned

For: Dose Setting Limiter

RESPONSE TO NOTICE TO FILE MISSING PARTS

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Missing Parts dated October 18, 2000 (a copy thereof is attached hereto), Applicants submit the Combined Declaration and Power of Attorney signed and dated by Applicants for the above-captioned application.

Please charge the required fee, estimated to be $130.00, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. Please credit any overpayment to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

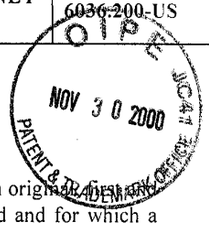
Date: November 27, 2000 Carol E. Rozek

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

#3

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Attorney's Docket Number: 6036.200-US



As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Dose Setting Limiter

The specification of which (check only one item below):
[ ] is attached hereto
[X] was filed as United States application

Application No. To Be Assigned

on September 6, 2000
and was amended
on

[ ] was filed as PCT international application
Number
on
and was amended under PCT Article 19
on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by an amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code, §119 of any provisional or foreign application(s) for patent or inventor's certificate or of any PCT international applications(s) for patent or inventor's certificate or of any PCT international applications(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR U.S. PROVISIONAL/FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicated "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Denmark	PA 1999 01309	16 September 1999	[X] YES [ ] NO
United States	60/155,612	23 September 1999	[X] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Attorney's Docket Number: **6036.200-US**

I hereby claim the benefit under Title 35, United States Code '120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, '112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, '1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned
PCT APPLICATIONS DESIGNATING THE U.S.				
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)		

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. Steve T. Zelson Elias J. Lambiris Valeta A. Gregg Carol E. Rozek Robert L. Starnes Reza Green, Reg. No. 30,335 Reg. No. 33,728 Reg. No. 35,127 Reg. No. 36,993 Reg. No. 41,324 Reg. No. 38,475

Send Correspondence to: Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
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3	Full Name of Inventor	Family Name: **Radmer**	First Given Name: **Bo**	Second Given Name:
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COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)				Attorney's Docket Number: 6036.200-US
5	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
6	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
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7	Full Name of Inventor	Family Name	First Given Name	Second Given Name
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8	Full Name of Inventor	Family Name	First Given Name	Second Given Name
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9	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Date 22.09.2000	Date 26/10-2000	Date 27/10-2000
Signature of Inventor 4	Signature of Inventor 5	Signature of Inventor 6
Date 1/11-2000	Date	Date
Signature of Inventor 7	Signature of Inventor 8	Signature of Inventor 9
Date	Date	Date

#3

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
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APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US

Steve T Zelson Esq
Novo Nordisk of North America Inc
405 Lexington Avenue Suite 6400
New York, NY 10174-6401

FORMALITIES LETTER

OC000000005484923

Date Mailed: 10/18/2000

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

- **The balance due by applicant is $ 130.**

---

*A copy of this notice **MUST** be returned with the reply.*

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Initial Patent Examination Division (703) 308-1202
PART 2 - COPY TO BE RETURNED WITH RESPONSE

12/04/2000 YPOLITE1 00000005 141447 09655922
01 FC:105 130.00 CH

Attorney Docket No.: 6036.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL CERTIFICATE

#4 13/19/01
PRIORITY DOCUMENT

Box Patent Application
Assistant Commissioner for Patents
Washington, DC 20231

Re: U.S. Patent Application for
Title: Dose Setting Limiter
Applicants: Klitgaard et al.

Sir:

Express Mail Label No. EL636737346US

Date of Deposit : September 6, 2000

I hereby certify that the following attached paper(s) or fee

1. Filing Under 37 C.F.R. 1.53(b) (in duplicate)
2. Patent Application
3. Unexecuted Combined Declaration and Power of Attorney
4. Certified Copy of Priority Application

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

Miriam Kelly
(Name of person mailing paper(s) or fee)

Miriam Kelly
(Signature of person mailing paper(s) or fee)

Mailing Address:
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10017
(212) 867-0123

Kongeriget Danmark

Patent application No.: PA 1999 01309

Date of filing: 16 September 1999

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following information:

- The specification, claims and drawings as filed with the application on the filing date indicated above.

Patent- og Varemærkestyrelsen
Erhvervsministeriet

TAASTRUP 02 August 2000

Karin Schlichting
Head Clerk

DOSE SETTING LIMITER

The invention relates to injection devices wherein the content of a cartridge injected as a number of individually set doses.

Such devices has a dose setting mechanism by which the doses are set for subsequent injecting when an injection button is operated. This can be obtained by moving a carrier along a piston rod a distance proportional to the wanted dose and subsequently move the carrier back to its original position so that the carrier carries the piston rod with it instead of being moved along said piston rod.

From EP 327 910 is known a syringe by which a dose is set by screwing a nut member up along a threaded piston rod away from a stop in a housing. The set dose is injected by pressing the end of the nut member which forms an injection button whereby the nut member is moved back to abutment with the stop again. During the latter movement of the nut member the piston rod is carried along by the nut which do no move relative to this piston rod during the injection.

When a dose is set it is convenient if a limiting device is provided which makes it impossible to set a dose which exceeds the amount of medicament which is left in the cartridge. In EP 327 910 this is obtained by the fact that the thread of the piston rod has such a length that the cartridge is just emptied when the nut is screwed to the end of the thread and the then pressed home to its abutment with the stop. By setting a dose the nut can only be screwed to the end of the thread and thereby the size of the last dose is limited to comprise the remaining amount in the cartridge.

The distance the injection button has to be moved corresponds to the distance the piston in the cartridge has to be moved to inject the set dose. Especially by larger cartridges with a large cross section diameter this distance can be very short. To obtain a larger movement of the injection button a sort of gearing may be used so that the distance the injection button have to be moved is proportional with the injected dose but is a number of times the movement of the piston in the cartridge.
EP 608 343 describes an example of such a geared dose setting and injection mechanism.

In this device the carrier do not co-operate directly with the threaded piston rod but with a driver element which can move the piston rod when a set dose is injected. In this device the driver element comprises a nut member which is fixed against axial displacement in the injection device. The thread of the nut member engage an outer thread of the piston rod which is secured against rotation in the injection device . By the setting of a dose the carrier is rotated away from a stop to which it is returned when the injection button is operated. During its return the carrier rotates the driver element which moves the piston rod further into the cartridge to press the piston of this cartridge so that a set amount of the medicament in the cartridge is pressed out through an injection needle at the distal end of said cartridge. As the nut member is not moved relative to the piston rod during the setting of a dose a limiting construction as described above cannot be provided limiting the dose so it does not exceed the amount of liquid left in the injection device.

An object of the invention is to provide a limiting mechanism which prevents setting of a dose which exceed the amount of liquid left in a cartridge of an injection device of the geared type wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver element with it to rotate this driver element which moves the piston rod forward.

Such a mechanism is according to the invention characterised in that the driver element is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of said dose setting member. During the setting of a dose the track follower will be advanced in the track of the driver to a position depending on the set dose as during dose setting the dose setting member and the driver are rotated relative to each other. As during the injection the driver follows the rotation of the dose setting member, the pin of the dose setting member will keep its position in the track of the driver when the set dose is injected. The length of the track is so adapted that the pin reaches the end of the track and makes an increase of the set dose impossible when a dose is set which corresponds to the amount of liquid remaining in the cartridge.

According to the invention the driver may be disk shaped and have a spiral shaped track which is engaged by a cam on a member which is flexibly coupled to the dose setting member so that the pin can be moved radially when it follows the track of the driver.

In another embodiment of the invention the driver may be cylindrical and have a helical track which is engaged by a cam on the dose setting member which is a cylinder concentric with the driver.

The track may be provided as a thread in the driver and the track follower may be a nut shaped member coupled to the dose setting member and provided with a thread engaging the thread of the driver. When a dose is set the dose setting member is screwed with its thread along the thread of the driver. The limitation of the set dose is obtained by giving the threads an appropriate length.

In the following the invention will be explained in further details with references to the drawing, wherein

Figure 1 shows an exploded view of a syringe with a dose limiter according to the invention,

Figure 2 an enlarged view of the dose setting element and the driver element of the syringe in figure 1.

Figure 3 shows the dose setting member, the driver, and the track follower of another embodiment of an injection syringe.

The syninge in figure 1 comprises a housing 1 accommodating a cartridge 2 from which the content can be pressed out by a piston rod 3 which is by injection via gear wheels 4 and 5 advanced a distance corresponding to a dose set by dose setting. A dose setting member 6 is provided with a toothed wheel 7 surrounding a central bore through which a pinion 8 on a driver 9 projects as it is shown in figure 2. The dose setting element 6 is operated through an operation element 10 which has a finger grip 11, a carrier 12 which engages the dose setting member 6, and a arrow 13 pointing on a scale 14 provided on a Lid 15 which forms a part of

the housing 1. Figure 1 further shows a cap 25 which can be put on to protect a not shown needle which may be mounted on the syringe, and an injection button 16 which is sliding mounted in the housing 1 and which has a recess 17 which is on one of its side surfaces provided with a cogging 18.

In the assembled syringe the toothed wheel 7 on the dose setting member 6 engages the cogging 18 of the button element 16 whereas the pinion 8 on the driver 9 engaged the part with the large diameter of the gear wheel 5 the part of which with the small diameter engages the other gear wheel 4 which further engages a cogging 19 on the piston rod 3.

The driver member 9 is provided with pawl 26 which with not shown teeth in the housing forms an unidirectional coupling allowing the driver 9 to rotate only in the direction by which the piston rod 3 is advanced into the cartridge 2. A ratchet is provided by saw tooth shaped protrusions on the dose setting element 6 engaging a saw tooth cogging 27 at the perimeter of the driver 9, this ratchet being so oriented that only rotation of the dose setting member 6 in the direction in which the driver 9 can move is transmitted from the dose setting member 6 to the driver 9. By rotation of the dose setting member 6 in the opposite direction the teeth of the ratchet parts will ride over each other.

To set a dose the finger grip 11 of the operation element 10 is gripped and the element 10 is rotated clockwise until the arrow point at the wanted dose on the scale 14. As mentioned this rotation will make the ratchet parts of the dose setting element and the driver ride over each other. If the dose setting member 6 is rotated in the clockwise direction to reduce the set dose, the ratchet will cause transmission of the rotation from the dose setting member 6 to the driver 9 but the when a torque in this direction is transmitted from the operating element through the carrier 12 to the dose setting member 6, this dose setting member is deformed so that the protrusion on the dose setting member 6 is drawn out of its engagement with the toothing 27 of the driver 9 and an anticlockwise rotation of the dose setting member 6 is allowed without the rotation being transmitted to the driver 9.

Due to the engagement between the toothed wheel 7 on the dose setting member 6 and the cogging 18 of the injection button 16 this button will be lifted from the end of the housing 1 when a dose is set and will be lowered when a dose is reduced.

When the injection button 16 is pressed to inject a set dose the engagement between the toothed wheel 7 on the dose setting member 6 and the cogging 18 of the injection button 16 will cause the dose setting member 6 to rotate in an anticlockwise direction. As the torque is not transmitted to the dose setting member 6 by the operating element 10, the ratchet coupling between the dose setting member 6 and the driver 9 will be active and the driver 9 will be rotated with the dose setting member 6 in the anticlockwise direction and will drive the piston rod 3 into the cartridge.

As it is seen in figure 2 the disk shaped driver 9 has in its side facing the dose setting member 6 a spiral shaped track 20 which is engaged by a cam 21 provided at the end of an arm 22 which is by a flexible beam 23 fastened to the dose setting member 6 so that the arm 22 can swing to let the cam 21 move in the radial direction of the driver 9. When the dose setting member 6 during the setting of a dose is rotated relative to the driver 9 the cam is moved along the track 20 whereas the cam during the injection due to the concomitant rotation of the dose setting member 6 and the driver 9 remains in its position in the track 20 obtained during the dose setting. This way the position of the cam in the track reflects the total amount of medicine administered. When the cam 21 abuts the end wall 24 of the track 20 the set dose cannot be increased and by adapting the length of the track to the total amount of medicine in the cartridge it is ensured that a dose larger than the amount of medicine remaining in the cartridge cannot be set.

Figure 3 shows a dose setting member 30 surrounding a driver 31 of another embodiment of a dose setting limiter. The dose setting member 30 is cylindrical and is on its outer wall provided with a helical track 29 which is designed to co-operate with a helical inner ridge in a not shown housing so that the dose setting member 30 is screwed outward in said housing when rotated to set a dose and inward in said housing when rotated to reduce a too large set dose. During the dose setting rotation the dose setting member 30 is rotated freely relative to the driver 31 which it surrounds. Between the dose setting member 30 and the driver 31 a nut member 32 is coupled which can when it is rotated relative to the driver 31 be screwed up along this driver which is at its outer surface provided with a helical track 33. At its outer wall the nut member 32 is in the axial direction provided with a recess 34 which is engaged by an ridge 35 in the axial direction on the inner side of the dose setting element 30.

During the setting of a dose the nut member 32 is due to the engagement between the ridge 35 and the recess 34 rotated with the dose setting member 30 relative to the driver 31 so that the position of the nut member 32 on this driver is dependent on the dose set. When the dose is injected by pressing a not shown injection button which is placed in an end part 36 of the dose setting member 30 this button presses a flange 37 at an end of the driver 31 into engagement with coupling teeth 38 at the bottom of said end part 36 of the dose setting member 30. On its lower not visible side the flange 37 is provided with coupling teeth corresponding to the coupling teeth 38 of the dose setting member 30 and when the dose setting member 30 is due to the engagement between the track 29 in the dose setting member 30 and the ridge in the housing forced to rotate relative to the housing when it is pressed into said housing the rotation will be transmitted to the driver 31which due to the engaging coupling teeth is forced to rotated with the dose setting member and during this rotation the nut member 32 will maintain its position on the driver 31. This way the position of the nut member 32 on the driver 31 will always indicate the total sum of set and injected doses. When the length of the helical track 33 in the driver 31 is adapted to the amount of medicine in a cartridge the nut member 32 will reach the end of the track 33 and stop for setting a dose larger than the amount remaining in the cartridge.

Claims

1. A limiting mechanism which prevents setting of a dose which exceeds the amount of liquid left in a cartridge of an injection device wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver with it to rotate this driver which moves the piston rod forward, characterised in that the driver is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member.

2. according to claim 1, characterised in that the driver is disk shaped and has a spiral shaped track which is engaged by a cam flexibly coupled to the dose setting element so that said cam can be moved radially when it follows the track of the driver element.

3. A limiting mechanism according to claim 1, characterised in that the driver is cylindrical and has a helical track which is engaged by a cam coupled to the dose setting member which is a cylinder concentric with the driver.

4. A limiting mechanism according to claim 3, characterised in that the track is provided as a thread in the driver and that the track follower is a nut shaped member coupled to the dose setting member and provided with a thread engaging the thread of the driver.

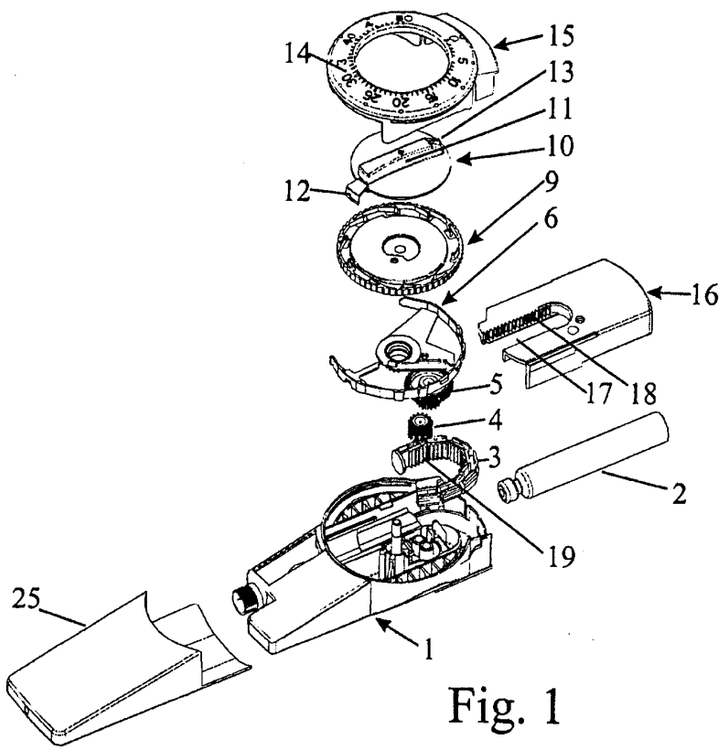

Fig. 1

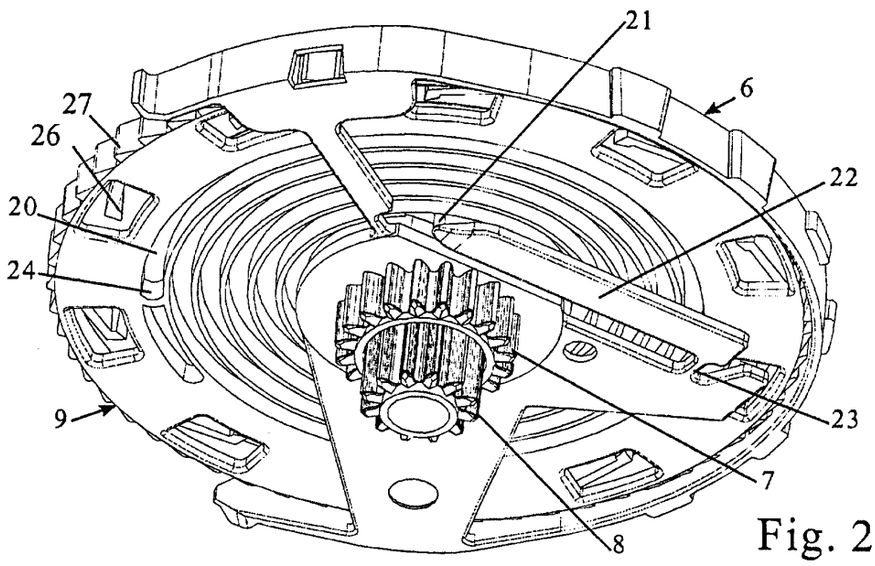

Fig. 2

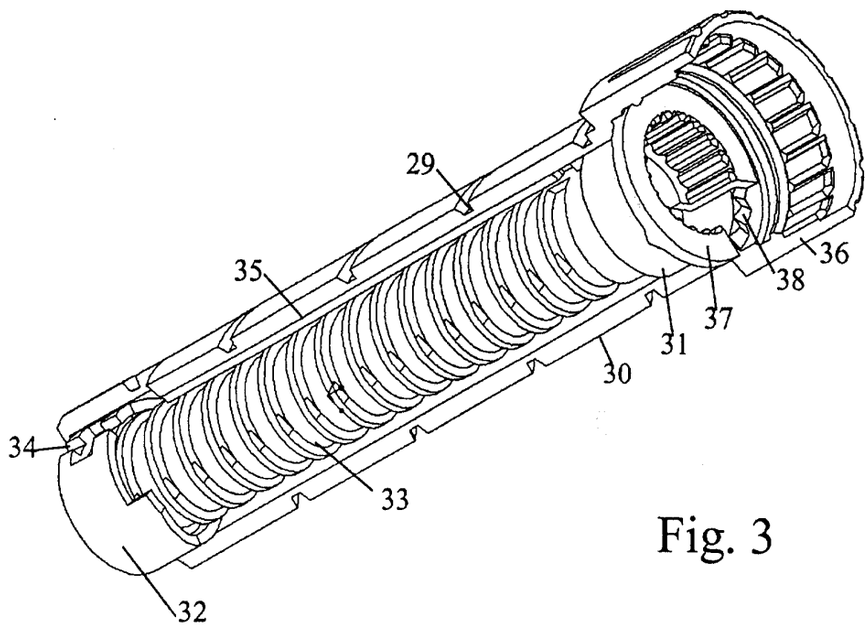

Fig. 3

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US	8564

7590 03/18/2002

Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue Suite 6400
New York, NY 10174-6400

EXAMINER	
ZEC, FILIP	
ART UNIT	**PAPER NUMBER**
3744	5

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

50

Office Action Summary	Application No.	Applicant(s)	
	09/655,922	KLITGAARD ET AL.	
	Examiner	Art Unit	
	Filip Zec	3744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 September 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 09/846,798. Although the conflicting claims are not identical, they are not patentably distinct from each other because they describe the same invention, an injection coupled to a dose setting limiter using gears and a cam, which records the length of path.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Filip Zec whose telephone number is (703) 306-3446 The examiner can normally be reached Monday through Friday, with the exception of every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Denise Esquivel can be reached on (703) 308-2597. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

Filip Zec
Examiner
Art Unit 3744

FZ
March 6, 2002

DENISE L. ESQUIVEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Notice of References Cited	Application/Control No. 09/655,922	Applicant(s)/Patent Under Reexamination KLITGAARD ET AL.	
	Examiner Filip Zec	Art Unit 3744	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Hansen et al., Injection Device, a Preassembled Dose Setting and Injection Mechanism for an Injection Device, and a Method of Assembling an Injection Device, 05/01/2001
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

#6

Attorney Docket No.: 6036.200-US PATENT

7/11/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Application No.: 09/655,922 Group Art Unit: 3744

Filed: September 6, 2000 Examiner: Filip Zec

For: Dose Setting Limiter

RESPONSE TO OFFICIAL ACTION OF MARCH 18, 2002

Commissioner for Patents
Washington, DC 20231

Sir:

This is a response to the Office Action mailed 3/18/2002.

REMARKS

In the March 18, 2002 Office Action, the Examiner provisionally rejected all pending claim in the present application under the judicial doctrine of obviousness type double patenting in view of co-pending Application Serial No. 09/846,798. Applicants submit herewith a terminal disclaimer pursuant to 37 CFR 1.321. Applicants note that both the instant application and the co-pending application have been assigned to Novo Nordisk A/S (see Reel/Frame 019968/0154, recorded September 19, 2001 for the '798 application and 011334/0405, recorded Feb. 24, 2001, for the above identified application) and therefore the filing of the terminal disclaimer is sufficient to overcome the provisional rejection.

It is respectfully submitted that this response presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above remarks and the terminal disclaimer filed herewith is requested.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: June 7, 2002

Marc A. Began, Reg. No. 48,829
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

COPY OF PAPERS
ORIGINALLY FILED

Attorney Docket No.: 6036.200-US PATENT

7-12-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Application No.: 09/655,922 Group Art Unit: 3744

Filed: September 6, 2000 Examiner: Filip Zec

For: Dose Setting Limiter

TERMINAL DISCLAIMER UNDER 37 CFR 1.321

Commissioner for Patents
Washington, DC 20231

Sir:

I am an attorney of record for the instant application.

Novo Nordisk A/S is the assignee of the entire interest in the above-identified application (assignment from the named inventors to Novo Nordisk A/S was recorded on Feb. 24, 2001, Reel / Frame 011334/0405).

The terminal part of the statutory term of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term of any patent granted on Application No. 09/846,798 is hereby disclaimed, except as provided below, and it is agreed that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to any patent granted on Application No. 09/846,798. This agreement runs with any patent granted on the above-identified application and is to be binding upon the grantee, its successors and assigns.

In making the above disclaimer, disclaimant does not disclaim the terminal part of any patent granted on the above-identified application that would extend beyond the expiration date of the full statutory term of any patent granted on Application no. 09/846,798 in the event that the latter later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed

in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued in any matter or is terminated prior to expiration of its full statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

Please charge the required fee, estimated to be $110.00, to Novo Nordisk of North America, Inc. Deposit Account No. 14-1447. Please credit any overpayment to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: June 7, 2002

Reza Green, Reg. No. 38,475
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

23650
PATENT TRADEMARK OFFICE

3744

COPY OF PAPERS
ORIGINALLY FILED

Attorney Docket No.: 6036.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Serial No.: 09/655,922 Group Art Unit: 3744

Filed: September 6, 2000 Examiner: Filip Zec

For: Dose Setting Limiter

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Amendment Fee Transmittal (in duplicate)
2. Amendment
3. Terminal Disclaimer under 37 CFR 1.1321

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

June 7, 2002

Sylvia Gonzalez
(name of person mailing paper)

(signature of person mailing paper)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US	8564

7590 10/24/2002

Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue Suite 6400
New York, NY 10174-6400

EXAMINER
ZEC, FILIP

ART UNIT	PAPER NUMBER
3744	8

DATE MAILED: 10/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/655,922	KLITGAARD ET AL.	
	Examiner	Art Unit	
	Filip Zec	3744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☒ Claim(s) *2-4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 September 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by PCT application WO 98/56436 by Hansen. Hansen discloses a dose setting mechanism for a drug administration device and an injection syringe having such a dose setting mechanism. The injection syringe has a housing accommodating an ampoule (3) containing medicine sufficient for a number of dosed injections, an injection press button (7), a piston rod (13) for co-operation with a piston in the ampoule (3) when injecting, and a dose setting mechanism comprising a rotatable dose setting element (5) interconnected with the press button. The dose setting mechanism further comprises a dose administration wheel (11), which applicant calls a "driver", connected with the piston rod (13) and a coupling ring (12) connected with the dose setting element (5) and the press button (7). One of the dose administration wheel (11) and the coupling ring (12) at least partly surrounds the other, and the dose administration wheel (11) and the coupling ring (12) are arranged such that rotation of the dose setting element (5) allows the coupling ring (12) to be rotated in either direction in relation to the dose administration wheel (11) tracking the amount of medication to be delivered from the cartridge (3), while activation of the press button (7), and thereby rotation of the coupling ring (12), causes the dose administration wheel (11) to be rotated.

Allowable Subject Matter

3. Claims 2-4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No.5,947,934 to Hansen, Steffen et al..

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Filip Zec whose telephone number is (703) 306-3446. The examiner can normally be reached Monday through Friday, with the exception of every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Denise Esquivel can be reached on (703) 308-2597. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

Filip Zec
Examiner
Art Unit 3744

FZ
October 21, 2002

WILLIAM DOERRLER
PATENT EXAMINER
GROUP 3400

Notice of References Cited	Application/Control No. 09/655,922	Applicant(s)/Patent Under Reexamination KLITGAARD ET AL.	
	Examiner Filip Zec	Art Unit 3744	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,947,934	09-1999	Hansen et al.	604/207
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	PCT WO 98/56436	12-1998	DK	Hansen	A61M 5/24, 5/31
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Attorney Docket No.: 6036.200-US PATENT

#9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Application No.: 09/655,922 Group Art Unit: To be assigned

Filed: September 6, 2000 Examiner: To be assigned

For: Dose Setting Limiter

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, DC 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in Form PTO-1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

1. WO 93/07922;
2. WO 91/14467;
3. WO 98/10813;
4. WO 89/07463;
5. EP 0 879 610 A2;

6. EP 0 498 737 A1;
7. EP 0 327 910 A2; and
8. EP 0 702 970 A2.

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

The information disclosure statement submitted herewith is being filed before the mailing date of a first Office action on the merits. Therefore, no fee is due.

Respectfully submitted,

Date: February 14, 2001

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

FORM PTO-1449 (Rev. 2-32)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Atty. Docket No. 6036.200-US	Serial No. 09/655,922
Applicant Klitgaard et al.	
Filing Date September 6, 2000	Group To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
FZ		WO 93/07922	04/29/93	WIPO				
FZ		WO 91/14467	10/03/91	WIPO				
FZ		WO 98/10813	03/19/98	WIPO				
FZ		WO 89/07463	08/24/89	WIPO				
FZ		EP 0 879 610 A2	11/25/98	EPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER Dilip Zec

DATE CONSIDERED 2/4/2003

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2-32)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Atty. Docket No. 6036.200-US	Serial No. 09/655,922
Applicant Klitgaard et al.	
Filing Date September 6, 2000	Group To be assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
FZ		EP 0 498 737 A1	08/12/92	EPO				
FZ		EP 0 327 910 A2	08/16/89	EPO				
FZ		EP 0 702 970 A2	03/27/96	EPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER Dilip Tec | DATE CONSIDERED 2/4/2003

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

#9 GP/3762
11/25/02

Attorney Docket No.: 6036.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Serial No.: 09/655,922 Group Art Unit: To be assigned

Filed: September 6, 2000 Examiner: To be assigned

For: Dose Setting Limiter

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Box DD
Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Information Disclosure Statement
2. Form PTO-1449
3. Copy of References

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Box DD
Commissioner for Patents
Washington, DC 20231

on February 14, 2001.

Carol McFarlane
(name of person mailing paper)

Carol McFarlane
(signature of person mailing paper)

Attorney Docket No.: 6036.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Serial No. 09/655,922 Group Art Unit: 3744

Filed: September 6, 2000 Examiner: Filip Zec

For: Dose Setting Limiter

AMENDMENT UNDER 37 C.F.R. 1.111

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action mailed October 24, 2002, please amend the above-captioned application as follows:

IN THE CLAIMS:

Please cancel claims 1-4 and substitute the following claims:

5. (New) A limiting mechanism that prevents setting of a dose that exceeds the amount of liquid left in a cartridge of an injection device wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver with it to rotate this driver which moves the piston rod forward, wherein the driver is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member and wherein the driver is disk shaped and the track has a spiral shape which is engaged by the track follower which is flexibly coupled to the dose setting member so that the track follower can be moved radially when it follows the track of the driver element.

6. (New) A limiting mechanism that prevents setting of a dose that exceeds the amount of liquid left in a cartridge of an injection device wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver with it to rotate this driver which moves the piston rod forward, wherein the driver is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member and wherein the driver is cylindrical and the track has a helical shape which is engaged by the track follower which is coupled to the dose setting member so that the track follower can be moved rotationally when it follows the track of the driver element.

7. (New) The limiting mechanism of claim 6, wherein the dose setting element is a cylinder concentric with the driver.

8. (New) The limiting mechanism of claim 7, wherein the track comprises a thread in the driver and that the track follower comprises a nut shaped member coupled to the dose setting member and provided with a thread engaging the thread of the driver.

REMARKS

Claims1-4 have been canceled without prejudice or disclaimer.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

In the previous Office Action, the Examiner rejected claim 1 but indicated that claims 2-4 would be allowable if rewritten in independent form. Accordingly, applicants have adopted the Examiner's suggestion and rewritten claim 2 as new, independent claim 5 and claim 4 as new, independent claim 6. Dependent claims 7-8 have also been added.

Conclusion

In view of the above, Applicants respectfully submit that all claims are in condition for allowance. Accordingly, Applicants respectfully request entry of this amendment and allowance of the pending claims.

The Examiner should feel free to contact the applicants' attorney by telephone if there are any questions concerning this amendment or application.

The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447.

Respectfully submitted,

Date: January 23, 2003

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

23650
23650
PATENT TRADEMARK OFFICE

Attorney Docket No.: 6036.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Serial No.: 09/655,922 Group Art Unit: 3744

Filed: September 6, 2000 Examiner: Filip Zec

For: Dose Setting Limiter

AMENDMENT NO FEE TRANSMITTAL

Commissioner for Patents
Washington, DC 20231

Sir:

Transmitted herewith is an Amendment for the above-identified application.

No fee is required for this Amendment. Please charge any additional fee to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447.

Respectfully submitted,

Date: January 23, 2003

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

3744

Attorney Docket No.: 6036.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Klitgaard et al.

Serial No.: 09/655,922 Group Art Unit: 3744

Filed: September 6, 2000 Examiner: Filip Zec

For: Dose Setting Limiter

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Amendment No Fee Transmittal
2. Amendment

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on January 23, 2003.

Rashida Haji
(name of person mailing paper)

Rashida Haji
(signature of person mailing paper)

Notice of Allowability	Application No.	Applicant(s)	
	09/655,922	KLITGAARD ET AL.	
	Examiner	Art Unit	
	Filip Zec	3744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed on 1/29/2003*.
2. ☒ The allowed claim(s) is/are *5-8*.
3. ☒ The drawings filed on *06 September 2000* are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
5☒ Information Disclosure Statements (PTO-1449), Paper No. *9*.
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
2☐ Notice of Informal Patent Application (PTO-152)
4☐ Interview Summary (PTO-413), Paper No.____ .
6☐ Examiner's Amendment/Comment
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

WILLIAM DOERRLER
PATENT EXAMINER
GROUP 3700

RW

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 02/07/2003

Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue Suite 6400
New York, NY 10174-6400

EXAMINER	
ZEC, FILIP	
ART UNIT	**CLASS-SUBCLASS**
3744	604-181000

DATE MAILED: 02/07/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US	8564

TITLE OF INVENTION: DOSE SETTING LIMITER

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	05/07/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE
Commissioner for Patents
Washington, D.C. 20231
Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

7590 02/07/2003

Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue Suite 6400
New York, NY 10174-6400

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US	8564

TITLE OF INVENTION: DOSE SETTING LIMITER

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	05/07/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
ZEC, FILIP	3744	604-181000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1_____
2_____
3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ❑ individual ❑ corporation or other private group entity ❑ government

4a. The following fee(s) are enclosed:

❑ Issue Fee
❑ Publication Fee
❑ Advance Order - # of Copies _____

4b. Payment of Fee(s):

❑ A check in the amount of the fee(s) is enclosed.
❑ Payment by credit card. Form PTO-2038 is attached.
❑ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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United States Patent and Trademark Office
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Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US	8564

7590 02/07/2003

Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue Suite 6400
New York, NY 10174-6400

EXAMINER	
ZEC, FILIP	
ART UNIT	**PAPER NUMBER**
3744	

DATE MAILED: 02/07/2003

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The patent term adjustment to date is 137 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 137 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US	8564

7590 02/07/2003

Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue Suite 6400
New York, NY 10174-6400
UNITED STATES

EXAMINER	
ZEC, FILIP	
ART UNIT	**PAPER NUMBER**
3744	

DATE MAILED: 02/07/2003

Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003; Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

OIPE JC16 MAY 06 2003 PATENT & TRADEMARK OFFICE

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12

B 5/23/03 KP

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE
Commissioner for Patents
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Fax (703)746-4000

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CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

7590 02/07/2003

~~Steve T. Zelson, Esq.~~ Marc A. Began, Esq.
~~Novo Nordisk of North America, Inc.~~
~~405 Lexington Avenue Suite 6400~~
~~New York, NY 10174-6400~~
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

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Rashida Haji	(Depositor's name)
R. Haji	(Signature)
5-2-03	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,922	09/06/2000	Peter Christian Klitgaard	6036.200-US	8564

TITLE OF INVENTION: DOSE SETTING LIMITER

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$0	$1300	05/07/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
ZEC, FILIP	3744	604-181000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

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☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Marc A. Began, Esq.
2 Richard W. Bork, Esq
3 Reza Green, Esq.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: NNA|S

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Bagsvaerd, Denmark

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☒ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☒ Issue Fee
☐ Publication Fee
☒ Advance Order - # of Copies 1

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number 14-1447 (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) Reg No. 44629 (Date) 5/2/03

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

05/06/2003 WRSFAM2 00000130 141447 09655922

01 FC:1501 1300.00 CH
02 FC:8001 3.00 CH

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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PATENT APPLICATION FEE DETERMINATION RECORD
Effective December 29, 1999

Application or Docket Number

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
FOR	NUMBER FILED	NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	2 minus 20=	*
INDEPENDENT CLAIMS	1 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT		

SMALL ENTITY TYPE ☐			OR	OTHER THAN SMALL ENTITY	
RATE	FEE			RATE	FEE
	345.00		OR		690.00
X$ 9=			OR	X$18=	
X39=			OR	X78=	
+130=			OR	+260=	
TOTAL			OR	TOTAL	690.00

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY			OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE			RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	
X39=			OR	X78=	
+130=			OR	+260=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE			RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	
X39=			OR	X78=	
+130=			OR	+260=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE			RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	
X39=			OR	X78=	
+130=			OR	+260=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
***If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875
(Rev. 12/99)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION			9/18/00
O.I.P.E. CLASSIFIER		32	
FORMALITY REVIEW	MS	9011	10/18/00
RESPONSE FORMALITY REVIEW	A-M	SC 580	12-12-00

INDEX OF CLAIMS

✔ ..... Rejected
= ..... Allowed
— (Through numeral)... Canceled
÷ ..... Restricted
N ..... Non-elected
I ..... Interference
A ..... Appeal
O ..... Objected

Claim		Date
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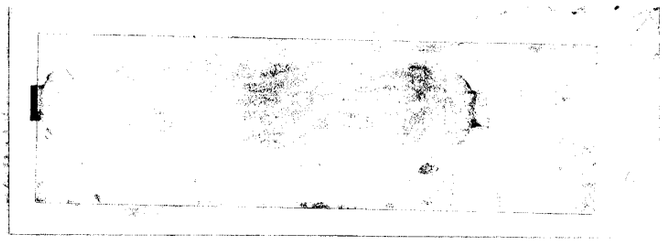

SEARCHED

Class	Sub.	Date	Exmr.
604	181	3/4/02	FZ
↓	186	↓	FZ
↓	207	↓	FZ
604	208	3/5/02	FZ
604	211	10/21/02	FZ
604	224	10/21/02	FZ

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
604	181	2/4/03	FZ
↓	186	↓	FZ
↓	207	↓	FZ
↓	208	↓	FZ
↓	211	↓	FZ
604	224	2/4/03	FZ

SEARCH NOTES
(INCLUDING SEARCH STRATEGY)

	Date	Exmr.

(RIGHT OUTSIDE)

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Remarks:
This application was filed on 14 - 08 - 1998 as a divisional application to the application mentioned under INID code 62.

(54) Recyclable medication dispensing divice

(57) A multi-use pen-shaped medication dispensing device (20) made of a plastic material that is recyclable after the contents of the medication cartridge (40) have been exhausted. The device (20) is made of a minimal number of parts, which include a housing (22), a dial assembly (34), a generally cylindrical button assembly (32) located within the proximal end (50) of the dial assembly (34), an internally threaded nut (36), and an externally threaded leadscrew (38). The device (20) is arranged so that the dial (34) must be rotated to the zero dose position prior to setting a dose. The device (20) includes a lockout mechanism (52) that prevents the dial (34) from being depressed during dosing. The device (20) further includes a mechanism (157) that limits the maximum dosage that can be dialed up and a mechanism (230, 234) that prevents the user from dialing up a dosage greater than that remaining in the cartridge (40).

EP 0 879 610 A2

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Description

The present invention relates generally to medical dispensing devices and, more particularly, to a recyclable dispensing device that permits selectively measured dosages of a liquid to be dispensed.

Patients suffering from diseases such as diabetes must inject themselves several times each day with an insulin solution. Since the volume of insulin solution to be injected varies from injection to injection, it is necessary for such patients to be able to measure a precise volume of insulin. Diabetics have conventionally used a syringe for injection of insulin. However, it is difficult to control the operation of the syringe as well as the quantity of drug injected.

In order to permit a diabetic to measure and administer a more accurate and controlled dosage, injector pens have been developed which enable a particular dosage to be accurately and conveniently measured. Generally, these pens are secured onto a cartridge having a particular quantity of liquid medication sealed therein. The cartridge includes a plunger and a mechanism for advancing the plunger in the cartridge in such a manner to dispense the medication. Injector pens may be reusable or disposable. In reusable pens, a user can change a spent cartridge and reset the leadscrew of the pen back to its initial position. In a disposable pen, the cartridge is permanently captured in the pen which is disposed of after the contents of the cartridge have been exhausted.

One such disposable pen that has functioned very adequately is disclosed in U.S.. Patent No. 5,295,976. Specifically, a dispensing device is disclosed and includes an internally threaded collar and an externally threaded plunger rod. In order to set a dosage of medication to be delivered, the collar is rotated thereby causing displacement of the collar toward the proximal end of the injection device. Rotation of the collar causes the integral cap to become effectively displaced both rotationally and axially toward the proximal end of the pen. As this displacement occurs, the segment of the dose-indicating scale which is visible through a window varies showing a linear increase in the number to indicate an increase dosage of liquid to be dispensed. Once the desired dosage is selected, a force is applied to the end of the cap causing a linear displacement of the cap, integral plunger rod, and piston to dispense liquid from the container. The dispensing displacement of the plunger rod is halted by abutting contact between the cap and a stop element.

In U.S. Patent No. 5,308,340, another recyclable injection device is disclosed. In particular, a plunger rod is received within the housing for exerting a force on a piston closing a second end of the container. The plunger rod has a noncylindrical cross section with a first surface including threads and a second surface which can, optionally, include a series of ratchet teeth. A collar is received within the housing adjacent the second end of the container for permanently retaining the container of liquid within the housing. The plunger rod passes through the noncylindrical opening in the collar and is prevented from rotating with respect to the housing by the collar. A hollow cap envelopes the plunger rod opposite the container of liquid. The skirt of the hollow cap extends inside the housing. The cap includes a threaded interior surface which movably engages the plunger rod for calibrated adjustment relative thereto. A stop is provided within the housing, and a distal facing surface is provided on the hollow cap for contacting the stop upon linear movement of the cap and plunger rod as a unit toward the container to dispense liquid therefrom. In operation, the cap is rotated in a counterclockwise direction causing the threads of the cap to travel along the threaded portion of the rod. This rotation does not cause displacement of the plunger rod with respect to the housing, but backs the distal end of the proximal cap portion away from a stop shoulder on the inside of the housing. When the cap has been positioned to the desired dosage, pressure is applied to the end of the cap for causing it to move linearly toward the distal end of the housing until a shoulder defined by a radially exposed portion of the distal end contacts a stop.

The present invention provides a medication injection device comprising a housing, a dose setting mechanism within the housing, and a delivery mechanism within the housing for advancing a leadscrew. A liquid medication product is housed in a variable volume cartridge within the housing of the device. Upon actuation of the delivery mechanism, the leadscrew is advanced against a movable piston in the cartridge to advance the piston thereby causing a preset quantity of medication to be delivered out of the needle of the device.

In one embodiment, the device is made entirely out of a recyclable plastic material, except for the glass container, steel needle and label. The dose setting mechanism comprises a dial assembly including a clutching device for engaging and disengaging a generally cylindrical internally threaded nut, which is threaded onto an externally threaded leadscrew. A dose is set by rotating the nut with respect to the leadscrew. The nut is rotated by rotating the dial. However, the nut must be engaged with the dial so that rotating the dial also rotates the nut. The clutching device comprises a series of splines on the inner cylindrical surface of the dial which axially engage corresponding splines on the outer surface of the nut. The splines are engaged with one another by retracting the dial with respect to the nut after the dial has been rotated to its zero dose position.

The dial assembly includes a mechanism that prevents the user from retracting the dial prior to rotating the dial to its zero dose position. This mechanism comprises a finger formed in the housing that rides within a groove formed at the distal end of the dial assembly as the dial assembly is rotated. The dial cannot be pulled out in any radial position other than the zero dose radial position due to the interference formed between the fin-

ger and the walls of the groove. In the zero dose position, the housing finger rides up within a spline that extends axially uninterrupted to enable the dial to be proximally retracted with respect to the housing only when the dial is in its zero dose radial position.

The device includes a mechanism that limits the maximum dosage that can be set. This mechanism comprises a helical groove formed in the housing and a pair of flexible fingers formed in the dial assembly. Upon rotating the dial to set a dose, the dial is retracted with respect to the housing because the dial fingers ride up the internal housing groove. Once the dial fingers reach the proximal end of the housing groove, further rotation of the dial is prohibited, thereby indicating to the user that the maximum dosage has been dialed.

The device further includes a mechanism for automatically locking out the dial from an inadvertent injection after the dial has been retracted to set a dosage. This lockout mechanism comprises the above-mentioned fingers in the dial assembly that fall into the helical groove in the housing upon retracting the dial with respect to the housing. The interference fit formed by the fingers in the groove prevents forward movement of the dial in the event of inadvertent pressure being applied to the end of the dial. The lockout mechanism is released by a button assembly that is disposed within the proximal end of the dial assembly. The button assembly is sized and configured so that it must be depressed upon initiating an injection. Upon depressing the button assembly, it bottoms out against the dial, whereupon the dial moves forwardly so that the flexible fingers move past the groove in the housing.

One of the two flexible fingers of the dial assembly has an extension which, when the button is pressed, is pushed radially out. This finger falls within a separate groove in the housing as the "end-of-dose" stop surface of the dial engages the corresponding stop surface on the housing, thereby producing an audible "click" indicating that the entire dosage has been injected. The housing further includes radially inwardly extending tangs at the proximal end thereof which engage ratchet teeth in the leadscrew to prevent the leadscrew from backing up in the proximal direction. These tangs are in constant engagement with the leadscrew, thereby preventing the leadscrew from rotating upon rotation of the nut.

The device also includes a mechanism which indicates to the user that there is an insufficient dosage remaining in the container of medication. This mechanism prevents the user from setting a dosage greater than that available to be delivered. The insufficient dose remaining feature comprises a 350° helical thread on the inner cylindrical surface of the nut and a raised finger forward at the end of the leadscrew where the external thread terminates. As the nut rotates about the leadscrew, the ledge formed by the termination of the helical thread on the nut engages the finger, thereby positively preventing further rotation of the nut in that direction.

An advantage of the medication dispensing device of the present invention is that the dosing function is locked out until the dial has been rotated to its zero dose position, thereby ensuring an accurate dosage.

Another advantage of the present invention is that the device is an inexpensive recyclable pen that is designed to allow a user to dose in single unit increments, which are each displayed in a single unit display.

Another advantage of the present invention is that the end-of-dose click arrangement is adjacent the end-of-dose stop to provide increased accuracy of an end of dose.

Another advantage of the present invention is that the device includes a dosage lockout mechanism that prevents an inadvertent delivery of a dosage of medication.

A further advantage of the present invention is that the insufficient remaining dose mechanism comprises a radial stop which ensures that the user cannot dial up a dosage greater than that remaining in the cartridge.

Yet another advantage of the present invention is that the device is made of inexpensive materials and is nearly 100% recyclable after the contents of the cartridge have been depleted.

The present invention, in one form thereof, comprises an apparatus for effecting delivery of an injectable product. The apparatus comprises a housing and a container secured to the housing and including a piston, an exit, and an injectable product between the piston and the exit. A drive stem is disposed in the housing and is in engagement with the piston. The length of axial movement of the drive stem with respect to the housing between a pre-injection position and a post-injection position defines the stroke length of the drive stem. A manually adjustable dosage metering mechanism is disposed in the housing and is movable between a zero dose position, wherein the stroke length is zero, and a second dose position for enabling a user to selectively adjust the stroke length of the drive stem. The apparatus further includes means coupled to the dosage metering mechanism for preventing the stroke length of the drive stem from being adjusted until the dosage metering mechanism has been set to the zero dose position.

In another form of the present invention, the apparatus includes a drive assembly mounted to the housing and manually advanceable in the housing between a dose setting position and an injection position for manually moving the drive stem to drive the piston within a container. The drive assembly is locked from movement with respect to the housing along the axis of ejection while in the dose setting position. A disengaging device is secured to at least one of the drive assembly and the housing to unlock the drive assembly from the housing to enable the drive assembly to be axially advanceable with respect to the housing to move the drive assembly from the dose setting position to the injection position.

The present invention further includes a method of delivering a selected dosage of injectable product. The

method includes the step of rotating a knob extending from an injector housing to establish a zero dose rotational position of the knob, wherein rotation of the knob causes rotation of the dial assembly attached to the knob. The knob and dial assembly are retracted while in the zero dose position to cause the dial assembly to engage an internally threaded nut with the housing. The knob is then rotated to cause rotation of the dial and the nut which causes axial translation of the dial and the nut, thereby setting a desired dosage of injectable product to be delivered. The knob is then manually depressed to depress the dial assembly and the nut and drive stem to cause the drive stem to advance the piston within the container of injectable product, thereby forcing a set dosage of injectable product to be delivered out of the exit of the container. The step of depressing the knob causes the dial assembly to become disengaged from the nut so that the knob may be rotated independently of the nut after delivery of the set dosage of injectable product has been completed.

Fig. 1 is a perspective view of one embodiment of a medication dispensing device in accordance with the present invention;

Fig. 2 is an exploded view of the device of Fig. 1;

Fig. 3 is an enlarged longitudinal sectional view of a portion of the medication dispensing device of Fig. 1, particularly showing the button assembly disposed within dial assembly;

Fig. 4 is an enlarged perspective view, in partial section, of the medication dispensing device of Fig. 1, particularly showing the button assembly disposed in the dial assembly;

Fig. 5 is an enlarged cross sectional view of the medication dispensing device of Fig. 1, particularly showing the insufficient remaining dose stop on the nut approaching the corresponding stop on the leadscrew;

Fig. 6 is a view of Fig. 5, except that the insufficient remaining dose stop on the nut is in engagement with the stop on the leadscrew;

Fig. 7 is a perspective view, in partial section, of a housing part in engagement with the dial assembly, particularly showing the unit click finger in the zero position;

Fig. 8 is a view of Fig. 7, except that the unit click finger is behind the end-of-dose flange;

Fig. 9 is a view of Fig. 7, except that the unit click finger is shown in the dial splines during dosing;

Fig. 10 is an enlarged sectional view of a portion of the medication dispensing device of Fig. 1, particularly showing the relationship among the button assembly, dial assembly, and housing while the device is at the end of dose position;

Fig. 11 is a longitudinal sectional view of the medication dispensing device of Fig. 1, particularly showing the dial assembly after it has been rotated to the zero position;

Fig. 12 is a view of Fig. 11 except that the dial assembly has been retracted so that the splines of the nut are engaged by the splines of the dial assembly;

Fig. 13 is a view of Fig. 12, except that a desired dosage has been dialed up;

Fig. 14 is a view similar to Fig. 10, showing the dial assembly rotated 180°, and further showing the button initially depressed before dial movement takes place;

Fig. 15 is a view of Fig. 14, showing the dial having moved forward a small distance;

Fig. 16 is a view of Fig. 14, showing the dial having moved forward half of a thread pitch; and

Fig. 17 is a view of Fig. 13, except that the pen is shown in its end-of-dose position.

For purposes of this application, the term "proximal" shall designate a relative axial position toward the knob end of the delivery mechanism, and the term "distal" shall designate a relative axial position toward the delivery needle end of the delivery mechanism.

Referring to Figs. 1 and 2, there is shown an injection medication device 20 having the general appearance of a pen or mechanical pencil. The device comprises a mechanism housing 22 having a first part 24 and a second part 26 (Fig. 2). Housing parts 24 and 26 are secured together in a suitable fashion, e.g. chemical bonding with a suitable adhesive or a solvent. A cap 28 is snapped onto the distal end of mechanism housing 22. Cap 28 includes a clip 30 which cooperates with the side wall of cap 28 to provide a convenient means for holding the pen device 20 in a shirt pocket. Referring to Fig. 2, the major components of medication device 20 include a button assembly 32, a dial assembly 34, a nut 36, and a leadscrew 38. A cartridge 40 is inserted into a distal body 42 to which is attached a needle assembly 44 and needle cover 46. All of the components of medication device 20, except cartridge 40 and needle 44 may be made of a plastic material that is suitable for recycling. Suitable plastics are high flow polycarbonates resins which can be processed by conventional injection molding and extrusion. In one embodiment, the housing parts 24, 26 and distal body 42 are made from an optically clear polycarbonate material, and the remaining plastic components are made from ABS resins. These plastics are recyclable, thereby making disposal of the device environmentally desirable.

Referring to Fig. 4, button assembly 32 comprises a hollow cylindrical portion 48 having a proximal end 50. Cylindrical portion 48 includes a distal end 52 in the form of an annular bead and further includes an enlarged diameter ring 54 comprising a tapered surface 56 and an enlarged diameter flat surface 58. The inner section of surfaces 56 and 58 forms an enlarged diameter shoulder surface 60. The proximal end 50 of button assembly 32 comprises two flexible fingers 62, 64, each extending from a base surface 66. As shown in Fig. 4, each finger 62, 64 is L-shaped and includes a first leg which extends

from base surface 66 and is parallel with the axis of medical device 20, and a second leg extending radially about 90° from the first leg. Proximal end 50 of button assembly 32 further includes a finger-engageable end 68 having a recessed surface 70. End 68 is integrally connected to hollow cylindrical portion 48 by connection portions 72 (Fig. 3). Proximal end 68 includes a surface 74 (Fig. 3) that is formed from reduced length portion 76.

Referring to Figs. 3 and 10, dial assembly 34 is shown in detail. Dial assembly 34 is generally cylindrical in shape and is hollow throughout its axial length. The diameter of dial assembly 34 is at a maximum at its proximal end and is at a minimum at its distal end. Referring to Fig. 3, dial assembly 34 comprises a proximal portion 78, an intermediate portion 80, and a distal portion 82. Proximal portion 78 comprises an enlarged diameter portion 84, a tapered portion 86, and an end-of-dose ring 91 extending about the circumference of proximal portion 78 as shown in Fig. 3. Ring 91 includes a bottom surface 89 (Fig. 13) that constitutes a stop surface when engaged with the rear of the housing. Ring 91 also includes an enlarged "zero-dose" protrusion 88. A generally U-shaped groove 90 (Figs. 2, 3) is formed in proximal portion 78 to form a flexible section 92. The proximal inner surface of flexible section 92 includes a finger 94 having a tapered surface 96 adapted for engagement with tapered surface 56 of button assembly 32 and a complimentary tapered surface 98.

Proximal portion 78 of dial assembly 34 further includes a first U-shaped groove 100 (Fig. 2) and a second U-shaped groove (not shown) which form flexible legs 102, 104. Referring to Fig. 10, each leg 102, 104, includes an inwardly extending finger 106, 108, and an outwardly extending finger 110, 112, distal to the inwardly extending finger. Inwardly extending finger 106 includes proximal tapered surface 114, flat 116, and distal tapered surface 118. Likewise, finger 108 includes proximal tapered surface 120, flat 122, and distal tapered surface 124. Outwardly extending finger 110 comprises a proximal tapered surface 126, a flat 128, shoulder 130, enlarged diameter surface 132, and distal tapered surface 134. Inwardly extending finger 112 includes a proximal tapered surface 136, a shoulder 138, an enlarged diameter surface 140, and a distal tapered surface 142.

Referring to Fig. 3, a series of axial splines 142 are arranged circumferentially about the inner surface of dial assembly 34 at the area where proximal portion 78 meets intermediate portion 80. The circumferential array of splines 142 is interrupted by legs 102 and 104. In one embodiment, there are ten splines 142 positioned about the inner circumference of dial assembly 34. Referring to Figs. 3 and 10, there is shown a plurality of splines 144 extending circumferentially about the proximal interior surface of intermediate portion 80 of dial assembly 34. Unlike splines 142, splines 144 extend 360° about the inner circumference of intermediate portion 80. In one embodiment, eighteen splines 144 are positioned such that each spline is 20 circumferential degrees apart from an adjacent spline.

As best shown in Figs. 7-9, distal portion 82 of dial assembly 34 comprises a proximal flange 146, a reduced diameter portion 148, and a distal end comprising a series of elongated splines 150 extending externally about the circumference of distal portion 82. Splines 150 are in alignment with splines 144. Therefore, in one embodiment, there are eighteen splines 150, each corresponding to a respective spline 144. As shown in Figs. 8 and 9, two of the splines 150 extend axially into reduced diameter portion 148. These extensions are indicated as splines 152.

Referring to Fig. 10, housing parts 24 and 26 form a proximal groove 154 having a tapered surface 156. Housing parts 24 and 26 further form a helical spiral groove 158 and a tapered circumferential surface 160 as shown in Fig. 10. Housing part 24 further includes a semicircular ridge 164 near the distal end thereof. Two grooves are formed at the distal portion of housing part 24 to define a flexible finger 166. Housing part 26 includes grooves formed therein to define a flexible leg 168 having an inwardly extending finger 170 at the end thereof. Finger 170 includes a proximal tapered surface 172 which terminates in a flat 174 and a vertical edge 176. Housing parts 24 and 26 include transverse ledges 178, 180, respectively, to reduce the diameter through the proximal end of the housing. Ledges 178 and 180 include flexible tangs 182, 184, respectively.

As best shown in Figs. 11-13 and 17, medical delivery device 20 further includes nut 36 and leadscrew 38. Nut 36 is generally cylindrical in shape and includes a pair of axially extending grooves 186 (Fig. 2) to form resilient proximal legs 188. Each leg 188 includes a proximal raised portion 190 and two small axially extending splines 192. The distal end of nut 36 comprises an enlarged gear-like member 194 having a plurality of teeth 196 thereon. The interior surface of the distal end of nut 36 includes a helical thread 198. Thread 198 extends about 350° about the inner surface of nut 36. A groove 200 is formed at the distal end of leadscrew 138 to form legs 226, 228 (Fig. 2). Ratchet teeth 204 are located on two opposing sides of leadscrew 38 and axially extend along the length of leadscrew 38 from groove 200 to the distal end, which constitutes plunger engagement portion 206. Helical threads 208 extend along the axial length of leadscrew 36 legs 226, 228. Leadscrew 38 fits within the cylindrical opening of nut 36.

As shown in Figs. 11-14, plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40. Cartridge 40 is housed within cartridge retainer 42, which is permanently secured to housing parts 24 and 26. Cartridge 40 is manufactured of glass and comprises a tube defining an inner chamber 212 which openly terminates at its distal end in a neck 214 having a cap 216 including a rubber disc 218 disposed thereover. Needle assembly 44 comprises an internally threaded base 220 and a delivery needle 222. Internally threaded base 220 is threaded onto externally

threaded distal portion 224 of body 42. Needle cap 46 fits over needle 222 to prevent an inadvertent insertion of needle 222 into the patient. Cap 28 snaps onto cartridge body 42 to complete the pen-like mechanism.

In order to set a dose for injection, it is first necessary to manually zero the dial from the initial radial position of the dial resulting from the previous injection. The initial radial position of dial assembly 34 with respect to housing part 26 is shown in Fig. 8. Specifically, finger 170 of housing part 26 is located in groove 148 of dial assembly 34. Groove 148 can be rotated by rotating dial assembly 34 with respect to the housing. Dial assembly 34 cannot be axially retracted due to the interference between vertical edge 176 of housing finger 170 and ledge 149 of dial assembly 34. Likewise, dial assembly 34 cannot be forced axially forwardly due to the interference between surface 89 on ring 91 and end surfaces 33, 35 (Fig. 4) of housing parts 24, 26, respectively. If the user mistakenly believes that it is necessary to depress button assembly 32 to pull out the dial, finger 94 falls into groove 154 (Fig. 10), thereby creating an interference that prevents the dial from being pulled out. Upon continued rotation of dial assembly 34 with respect to housing 26, splines 152 are moved into engagement with finger 170, as shown in Fig. 7. This is the zero dose radial position of dial assembly 34. This zero dose position is communicated to a user in four ways. The user hears a click as splines 152 engage finger 170. The movement of finger 170 over the first spline 152 into the V-shaped recess 155 between splines 152 causes a vibration in device 20 that can be felt by the user. In addition, protrusion 88 on dial assembly 34 is in axial alignment with protrusion 153 of housing part 24, thereby providing a visual indication that the zero dose position has been reached. This is further visually communicated by the presence of a symbol in lens 25.

A series of numerals (not shown) are printed on the surface of intermediate portion 80 of dial assembly 34. These numerals are helically spaced about the circumference of portion 80 and may number from 1 to 60, in single increments, to indicate a desired dosage. The lens 25 in housing part 24 is aligned with the numbers so that the appropriate number appears in the lens upon dialing up the dosage. A raised rectangular portion lens 162 (Fig. 10) of lens 25 is located at the base of lens 25 to enhance the numerals thus making them easier to read.

In its zero dose position, dial assembly 34 may be axially retracted a predetermined distance, e.g. 3 to 5 mm, as illustrated in Fig. 12. As dial assembly 34 is retracted, ledge 149 is moved past housing finger 170 resulting in housing finger 170 being in engagement with splines 150. In addition, splines 144 of dial assembly 34 are moved into engagement with splines 192 of nut 36, as shown in Fig. 12. When engaged, rotation of dial assembly 34 causes corresponding rotation of nut 36. Rotation of leadscrew 38 is prevented by a key-keyway type of engagement between the anti-backup tangs 182 and 184 and leadscrew 38. As shown in Fig. 6, tangs 182, 184 form a key, and leadscrew 38 forms a keyway which comes into contact with the sides of the key.

Upon rotation of dial assembly 34, fingers 110, 112 move within housing groove 158 in the proximal direction to retract dial 34, thereby increasing the axial distance between stop surface 89 of ring 91 and stop surfaces 33, 35 of housing parts 24, 26. Rotation of dial assembly 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance. As shown in Fig. 9, rotation of dial assembly 34 causes splines 150 to move past housing finger 170. The rotation of each spline 150 past finger 170 constitutes a single unit of dosage. As each spline 150 moves past finger 170, it causes a "click" to occur, thereby providing an audible indication of each unit of dosage dialed up. In addition, a single numeral appears in lens 25 after each unit rotation indicating the current dose selected. Once a dosage has been selected, that dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction.

In one embodiment, dial assembly 34 includes eighteen splines 150 spaced 20° apart from one another. It is desired to limit the amount of dosage that can be dialed to prevent the entire contents of cartridge 40 to be delivered at once. For example, it may be desirable to limit a measured dosage to a maximum of 60 units. If the dial assembly includes eighteen splines, this would mean that a user could rotate the dial assembly for nearly 3 1/2 rotations. As shown in Figs. 12 and 13, as a dosage is being set, outwardly extending fingers 110 and 112 of dial assembly 34 ride in helical groove 158 of housing parts 24 and 26. Once a predetermined maximum dosage has been dialed up, e.g. 60 units, fingers 110 and 112 have reached the proximal end of the helical groove 158. Dial assembly 34 cannot be additionally rotated to further increase this maximum dosage due to an interference ledge at the end of helical groove 158. Button assembly 32 prevents the dial assembly 34 from being inadvertently pushed forwardly during the dosing process due to the interference between fingers 110, 112 of dial assembly 34, button surface 52, and helical spiral groove 158 in housing parts 24, 26, as shown in Fig. 4. Fingers 110, 112 must be moved out of groove 158 before the dial may be moved axially forwardly. Fingers 110, 112 can be moved out of engagement with groove 158 only after fully depressing button assembly 32, thereby moving distal button surface 52 out of engagement with fingers 110, 112.

Once a desired dosage has been set, cap 28 is removed and needle cover 46 is removed to expose needle 222. The needle is inserted into the patient, and recessed surface 70 of button assembly 32 is pushed. Figs. 14-16 illustrate the initial stages of the injection process. Referring to Fig. 14, as button surface 70 is pushed, button assembly 32 moves forwardly independ-

ently of dial 34 until button distal surface 52 bottoms out against internal dial shoulder 141. Thereafter, button 32 and dial 34 are moved together. Referring to Fig. 15, as dial 34 begins to move forwardly, tapered finger surfaces 134, 142 are forced out of their respective threads 158. This causes fingers 110, 112 to flex radially inwardly. As button 32 is further pressed, fingers 110, 112 move out of respective threads 158, as shown in Fig. 16. As button 32 continues to be pressed, fingers 110, 112 move into and out of the remaining threads 158 in a like manner until dial 34 reaches its end of dose position shown in Figs. 10 and 17. The movement of edge 95 (Fig. 4) of dial finger 94 past housing edge 157 (Fig. 4) and into groove 154 (Fig. 10) creates an audible "click" sound, thereby providing an audible confirmation that the entire dosage has been injected. Finger 94 is in close proximity to stop surfaces 89 and 33, 35.

As dial 34 is initially moved forwardly, splines 144 move out of engagement with splines 192 of nut 36 to decouple dial 34 from nut 36 prior to any axial movement of nut 36. Dial 34 moves axially with respect to nut 36 until the distal end 193 (Fig. 13) of dial 34 engages nut flange 194 and moves nut 36 and leadscrew 38 forwardly to deliver the set dosage of fluid.

Referring to Figs. 10 and 17, forward movement of dial assembly 34 and nut 36 is limited by the engagement of surface 89 of ring 91 with proximal end surfaces 33, 35 of housing parts 24, 26, respectively, as shown in Fig. 14. Referring to Fig. 14, there is a small clearance, e.g. 0.4 millimeters, between nut gear or flange 194 and internal ledges 178, 180 of housing parts 24, 26, respectively. In another embodiment, the end-of-dose stop may be designed to occur between nut flange 194 and ledges 178, 180.

Movement of leadscrew 38 is prevented in the proximal direction due to anti-backup tangs 182, 184 being in engagement with ratchet teeth 204. This assures that head 206 of leadscrew 38 remains at all times in constant engagement with piston 210.

Once a dosage has been completed, the user releases his finger from recessed button surface 70. Upon releasing pressure from surface 70, the flexible fingers or springs 62, 64 return from their stressed conditions back to their relaxed conditions, thereby automatically retracting the button assembly 32 back to the automatic lockout position shown in Fig. 11 to prevent the dial assembly 34 from being inadvertently advanced when it is again moved to its retracted position.

Medication device 20 further includes a mechanism to indicate to the user that there is an insufficient dosage of medication 212 remaining in cartridge 40. Referring to Figs. 5 and 6, leadscrew 38 comprises two legs 226 and 228. Leg 226 may be of a greater thickness than leg 228. Leg 226 includes an axially extending raised ledge 230 at the end of external thread 208. Leg 228 contains the end 232 of external thread 208. The internal helical thread 198 of nut 36 defines a stop surface 234 due to the fact that thread 198 extends less than 360° in circumference. As shown in Fig. 17, nut 36 moves toward legs 226, 228 of leadscrew 38 as leadscrew 38 moves within cartridge 40. Once nut 36 has axially moved entirely along thread 208 of leadscrew 38, stop 234 approaches axial ledge 230, as shown in Fig. 5. Additional rotation of nut 36 results in stop 234 engaging ledge 230, as shown in Fig. 6. This prevents the user from dialing up a higher dosage. Nut 36 may be rotated back in the opposite direction to reduce the dosage if desired. This rotational stop mechanism provides a very accurate indication to the user of the dosage remaining in the cartridge.

Claims

1. An apparatus (20) for the delivery of an injectable product, comprising:

   a housing (22);
   a container (40) mounted within said housing (22) and including a piston (210), an exit and an injectable product between said piston (210) and said exit, wherein movement of said piston (210) toward the exit defines an axis of ejection of the iniectable product from the container (40); and
   a drive stem (38) disposed in said housing (22) and drivingly coupled to said piston (210); said apparatus characterized by:
   a drive assembly (34) mounted to said housing (22) and manually axially advanceable in said housing (22) between a dose-setting position and an injection position for manually moving said drive stem (38) to drive said piston (210) within said container (40), said drive assembly (34) being locked from movement with respect to said housing (22) along the axis of ejection while in said dose setting position; and
   a disengaging device (32) secured to at least one of said drive assembly (34) and said housing (22) and manually actuable to unlock said drive assembly (34) from said housing (22) to enable said drive assembly (34) to be axially advanceable with respect to said housing (22) to move said drive assembly (34) from said dose setting position to said injection position.

2. The apparatus (20) of Claim 1, wherein said drive assembly (34) is characterized by a generally cylindrical dial (34) that is telescopingly disposed within said housing (22), said dial (34) having a flexible finger (110,112) formed therein that engages an internal groove (158) in said housing (22) while said drive assembly (34) is in said dose-setting position to form an interference fit therebetween, thereby preventing axial movement of said drive assembly (34) with respect to said housing (22).

3. The apparatus (20) of Claim 2, wherein said disengaging device (32) is characterized by a generally cylindrical button (32) that is telescopingly disposed within said dial (34), said button (32) including an enlarged diameter portion (54), which when advanced, disengages said flexible finger (110, 112) of said dial (34) to allow said finger (110, 112) to move out of engagement with said groove (158) in said housing (22) to enable said drive assembly to be axially advanced with respect to the housing (22).

4. The apparatus (20) of Claim 1 characterized in that said drive assembly includes a driver (34) for driving said drive stem (38), said driver (34) being locked from axial movement with respect to said housing (22) while in said dose-setting position and a manually adjustable dosage metering mechanism (34) disposed in said housing (22) and movable between a zero dose position, wherein the stroke length is zero, and a second dose position for enabling a user to selectively adjust the stroke length of said drive stem (38), and said disengaging device (32) includes said driver (34) and an unlocking mechanism (32) disposed in said housing (22) and positioned to unlock said driver (34) upon initiation of an injection to enable said drive stem (38) to move from said dose-setting position to said post-injection position.

5. The apparatus (20) of Claim 1, characterized in that said drive stem (38) is in continuous engagement with said piston (210), wherein a length of axial movement of said drive stem (38) with respect to said housing (22) between a pre-injection position and a post-injection position defines a stroke length of said drive stem (38), and wherein said dose setting assembly (34) is rotatable between a zero dose position, wherein the stroke length is zero, and a second dose position for enabling a user to selectively adjust the stroke length of said drive stem (38).

6. An apparatus (20) for effecting delivery of an injectable product, comprising:

a housing (22); and
a container (40) secured to said housing (22) and including a piston (210), an exit and an injectable product between said piston and said exit; said apparatus characterized by:
an externally threaded drive stem (38) disposed in said housing (22) and drivingly coupled to said piston (210);
an internally threaded nut (36) disposed about said drive stem (38);
a dial assembly (34) disposed in said housing (22) and coupled to said nut (36) such that rotation of said dial assembly (34) causes rotation of said nut (36) with respect to said drive stem (38) to set a desired dosage of injectable product to be delivered; and
means (234) on at least one of said nut (36) and said drive stem (38) for preventing rotation of said nut (36) with respect to said drive stem (38) as said nut (36) engages an end (230) of an external threaded surface (208) of said drive stem (210), thereby providing an indication to a user that an insufficient dosage of injectable product remains in said container (40).

7. A method of delivering a selected dosage of injectable product, the method characterized by the steps of:

rotating a knob (78) extending from an injector housing (22) to establish a zero dose rotational position of said knob (78), wherein rotation of the knob (78) causes rotation of a dial assembly (34) attached to the knob (78);
retracting the knob (78) and dial assembly (34) while in the zero dose position to cause the dial assembly (34) to engage an internally threaded nut (36) with the housing (22);
rotating the knob (78) thereby causing rotation of the nut (36) to cause axial translation of the nut (36) along an externally threaded drive stem (38) that is received within the nut (36), thereby setting a desired dosage of injectable product to be delivered; and
manually depressing the knob (78) to manually depress the dial assembly (34) and the nut (36) and drive stem (38) to cause the drive stem (38) to advance a piston (210) within a container (40) of injectable product, thereby forcing the set dosage of injectable product to be delivered out of an exit of the container (40), wherein the step of depressing the knob (78) causes the dial assembly (34) to become disengaged from the nut (36) so that the knob (78) may be rotated independent of the nut (36) after delivery of the set dosage of injectable product has been completed.

8. A method of Claim 7 further characterized by the steps of:

actuating an unlocking mechanism (54) which unlocks said locking mechanism (110, 112) to enable the knob (78) and dial assembly (34) to be manually advanced, thereby causing translation of the nut (36) and drive stem (38) to cause the drive stem (38) to advance a piston (210) within a container (40) of injectable product, thereby forcing the set dosage of injectable product to be delivered out of an exit of the con-

tainer (40), wherein the step of depressing the knob (78) and initial advancement of the dial assembly (34) causes the dose setting mechanism (34) to become disengaged from the nut (36) so that the knob may be rotated independent of the nut (36) after delivery of the set dosage of injectable product has been completed.

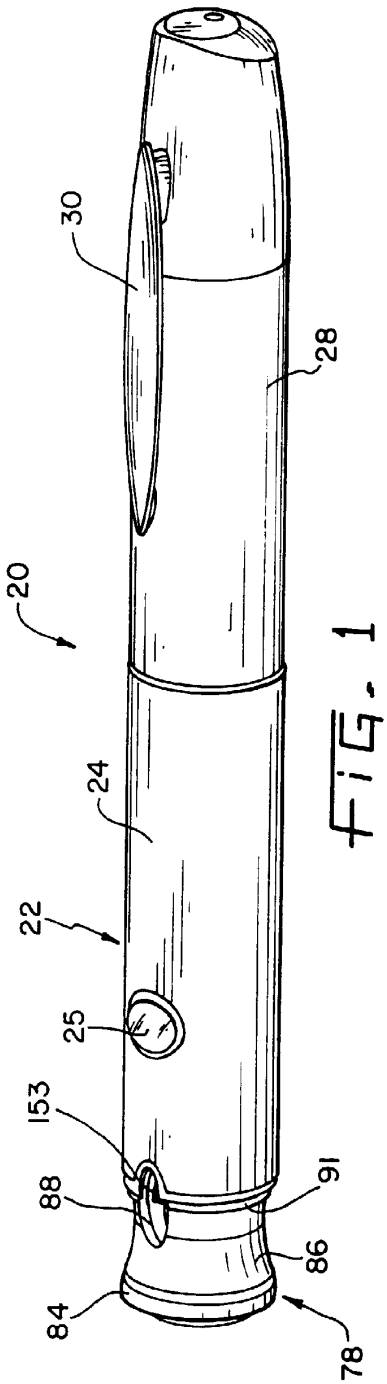


FIG. 1

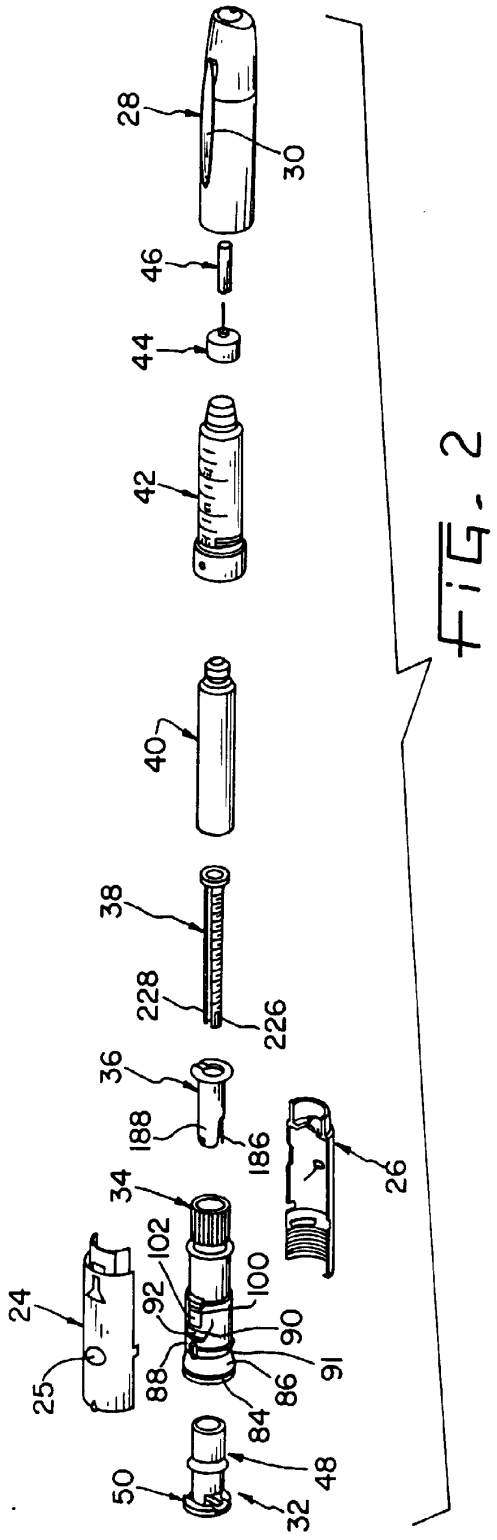
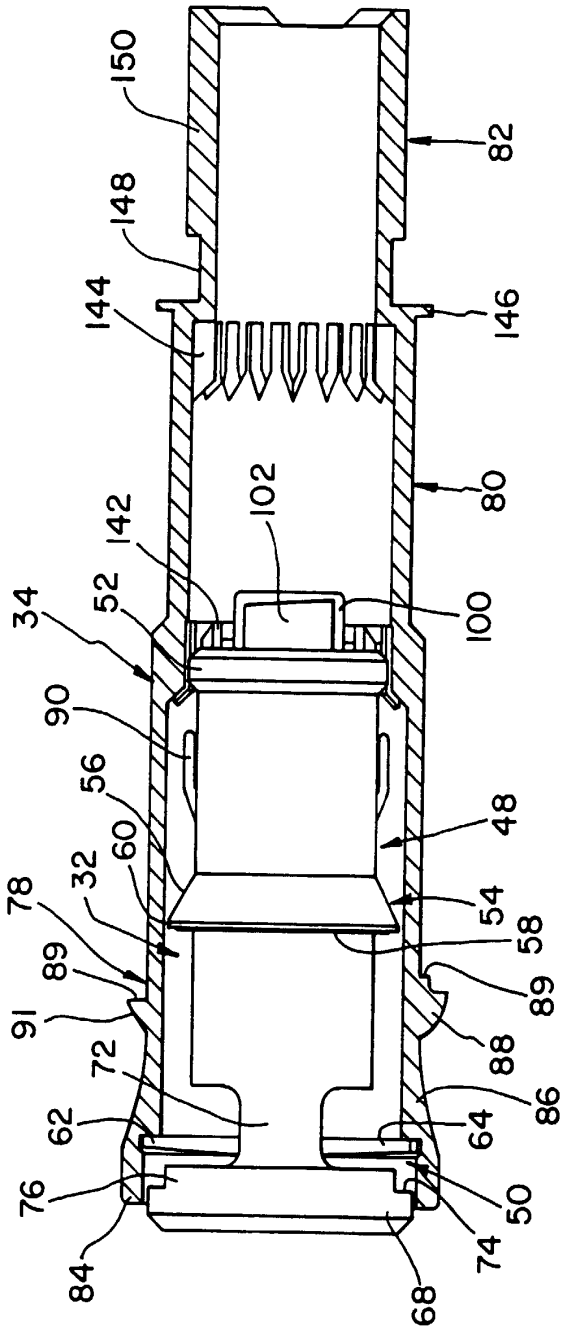


FIG. 2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148
144
146
102
80
142
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34
100
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56
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FIG. 3

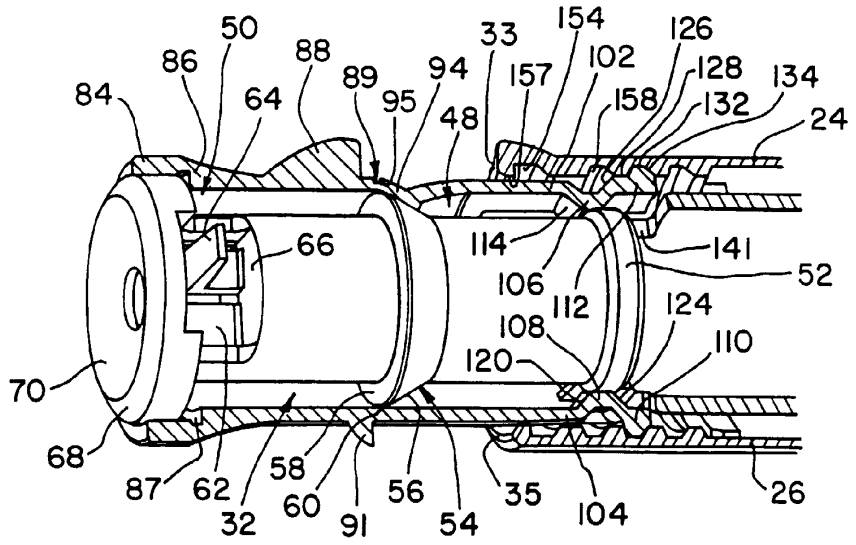

FIG. 4

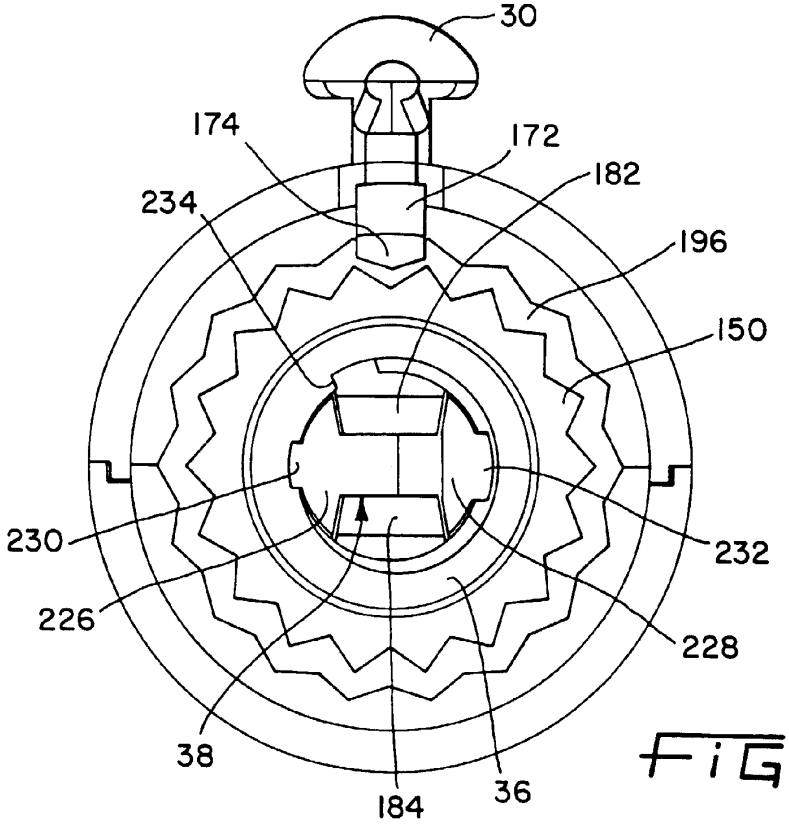

FIG. 5

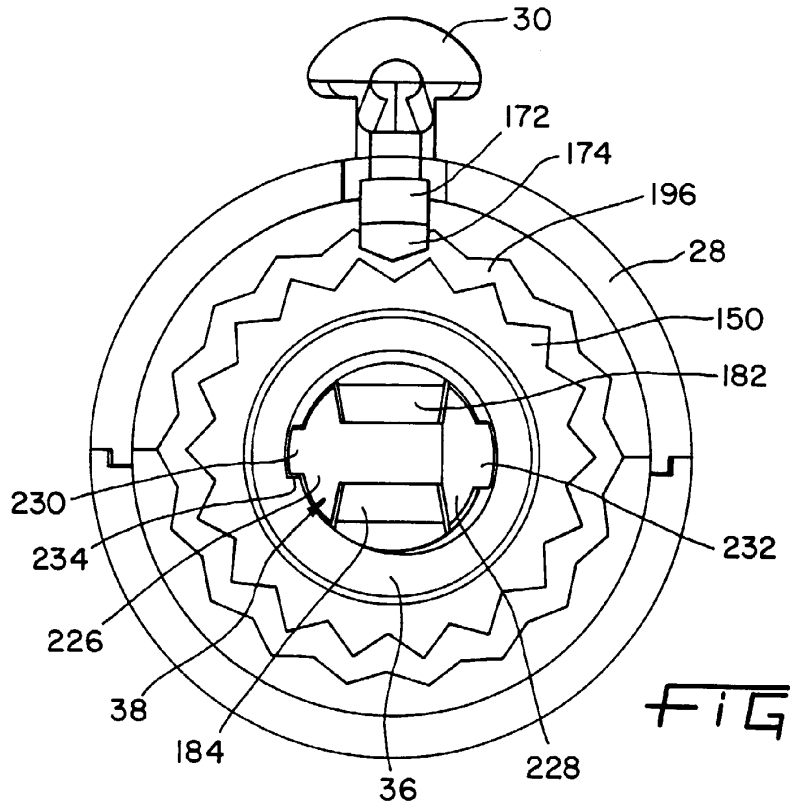

FIG. 6

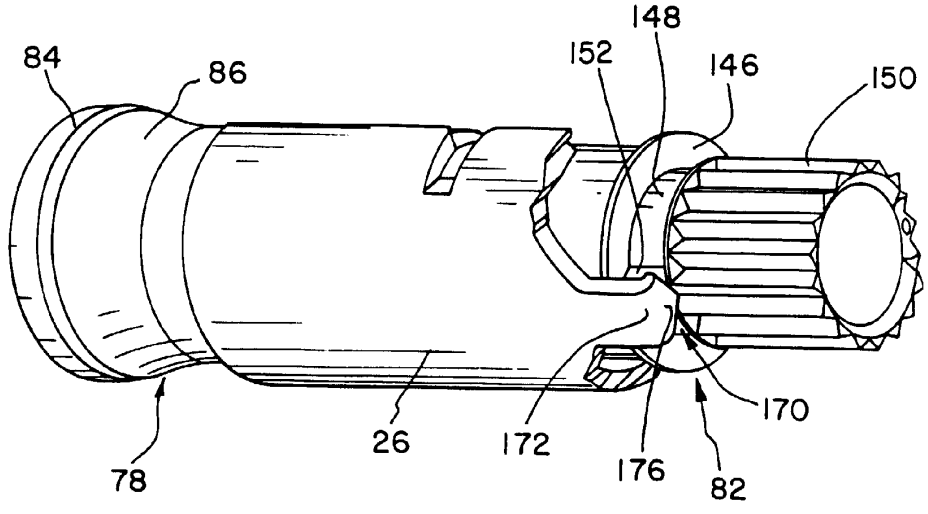

FIG. 7

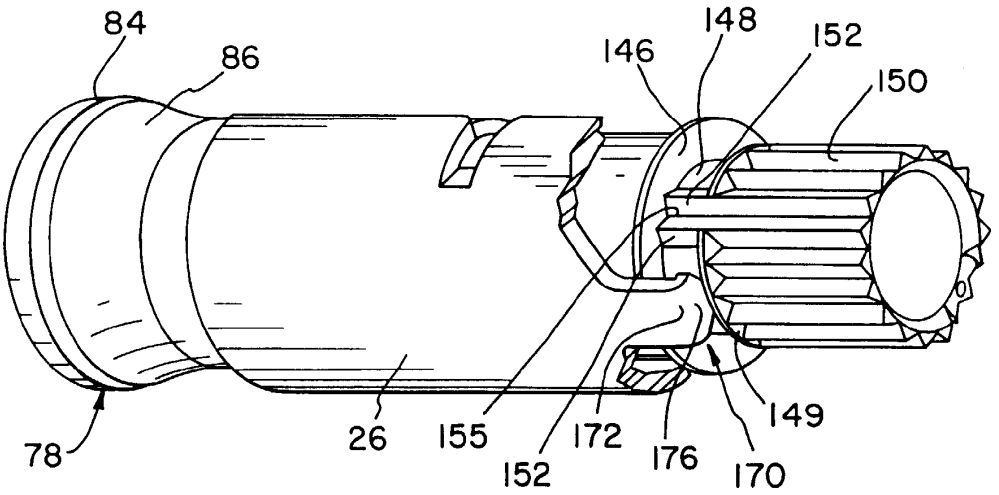

FIG. 8

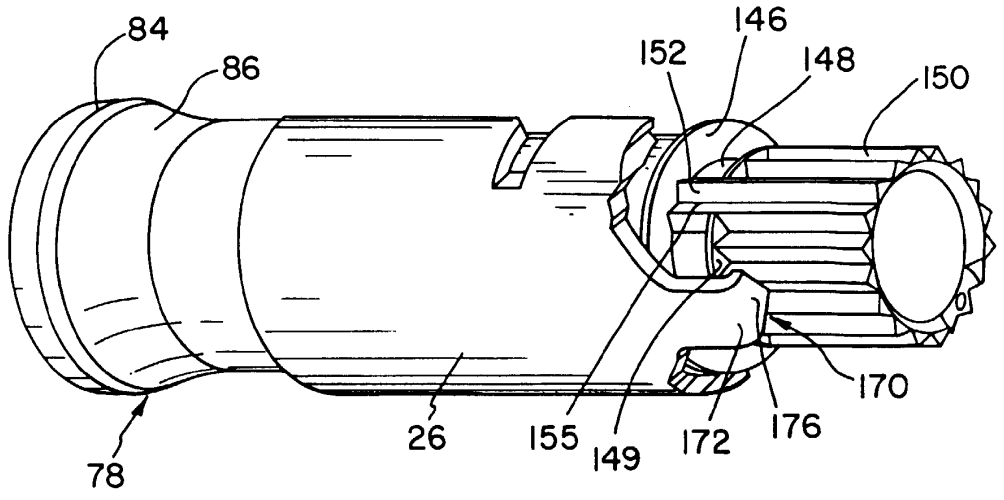

FIG. 9

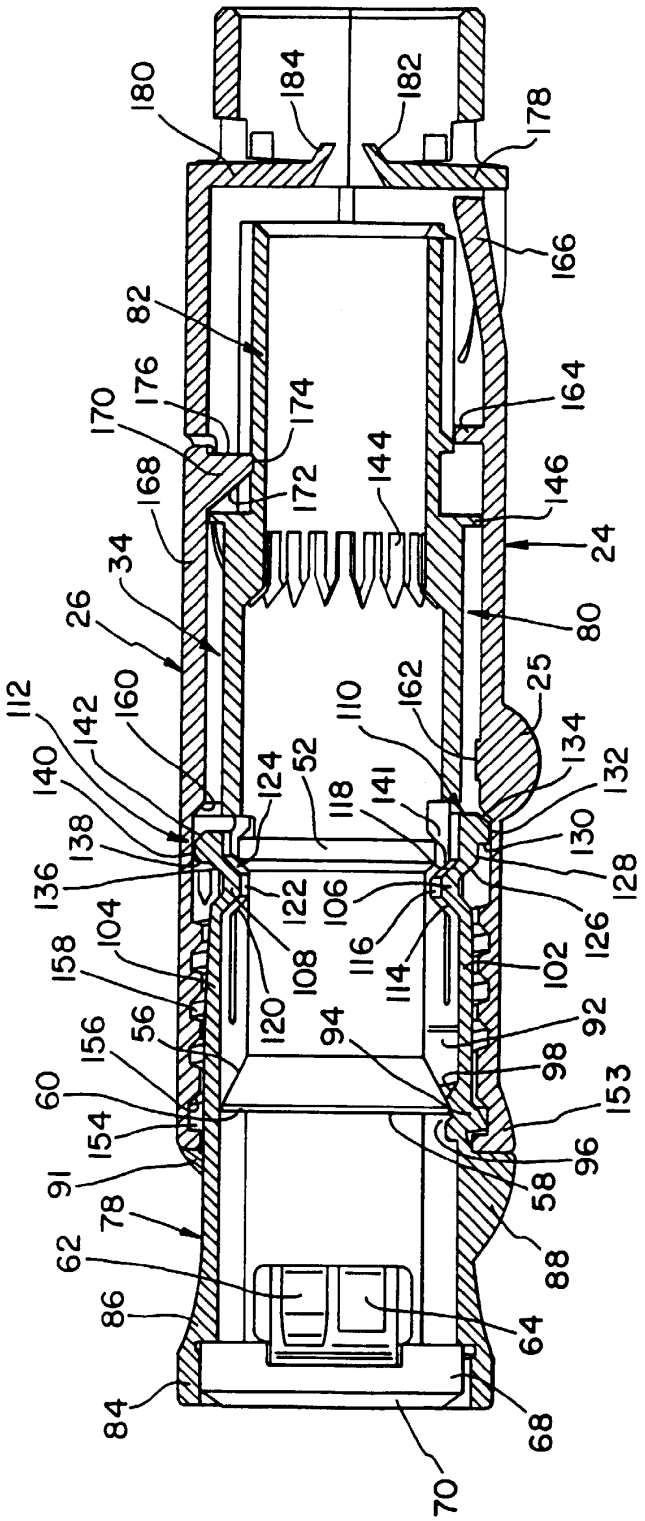

FIG. 10

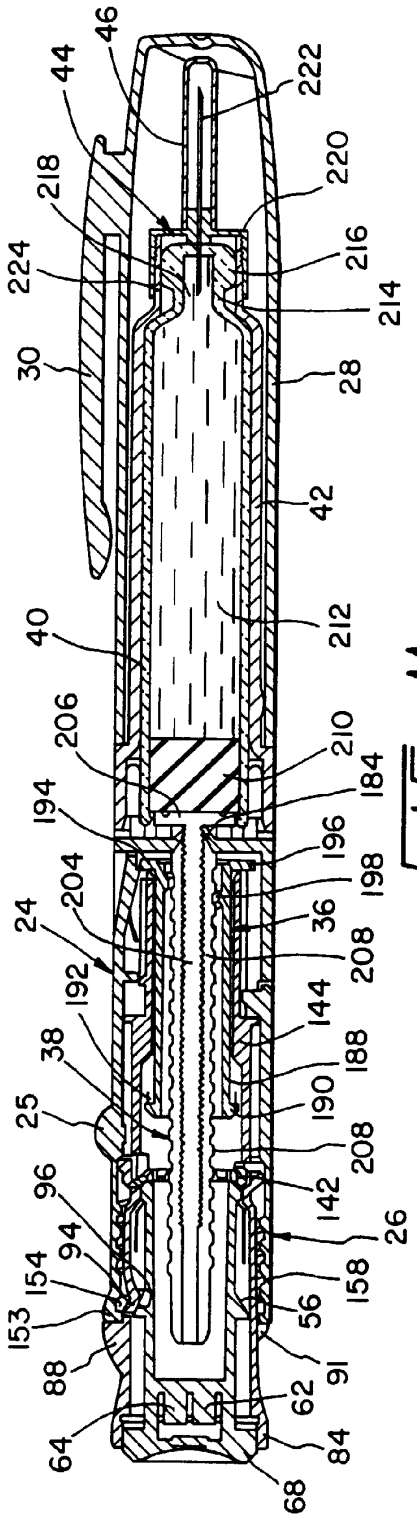

FIG. 11

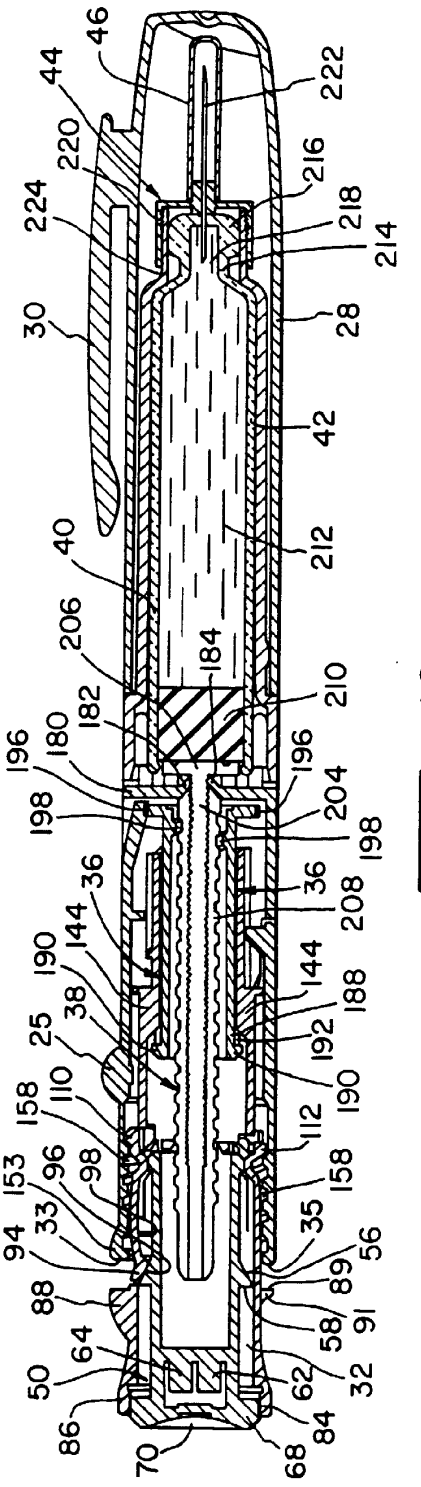

FIG. 12

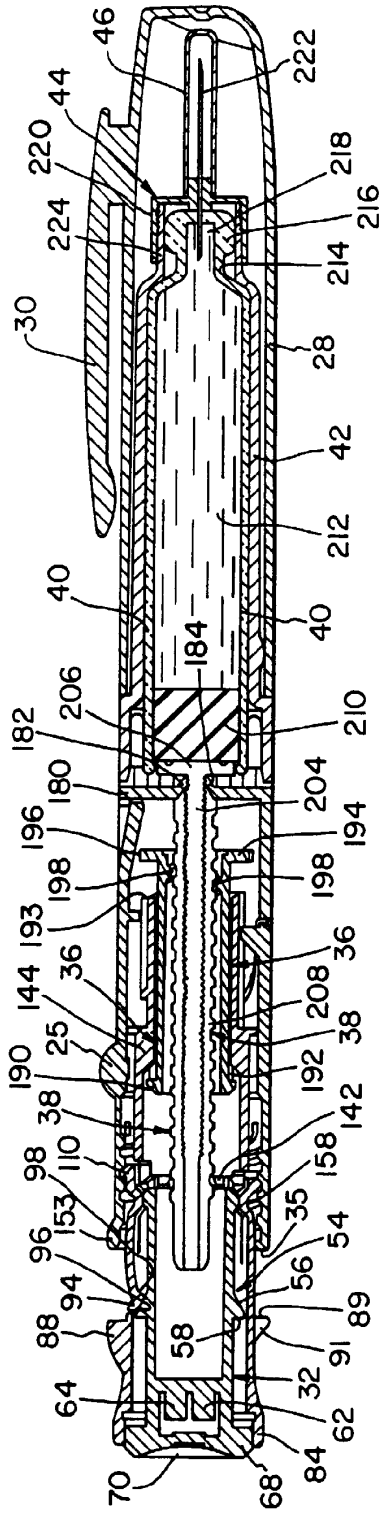

FIG. 13

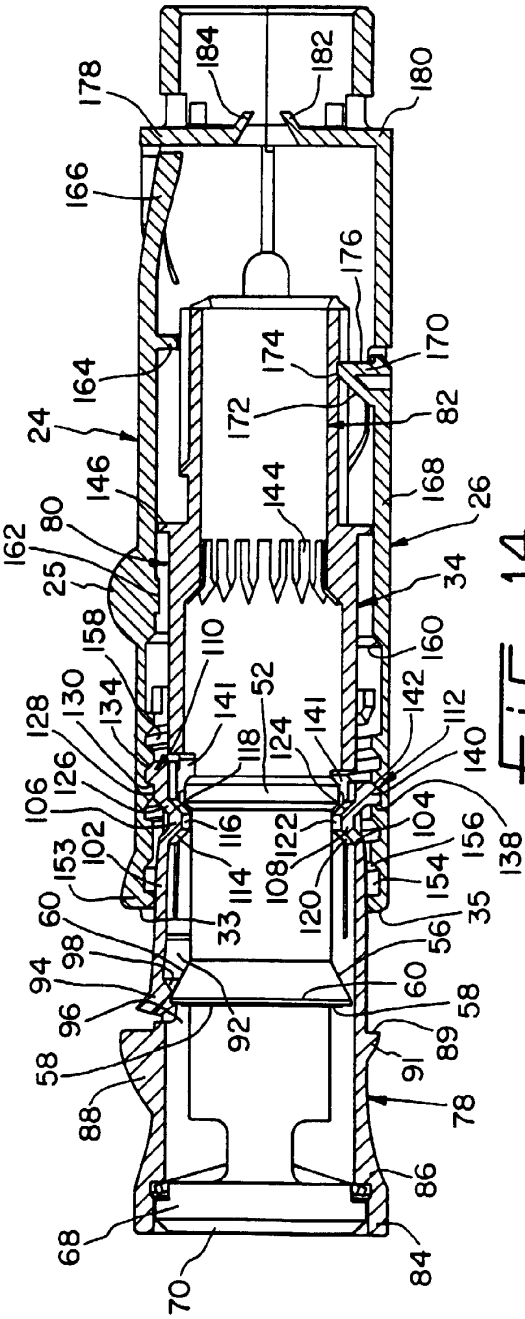

FIG. 14

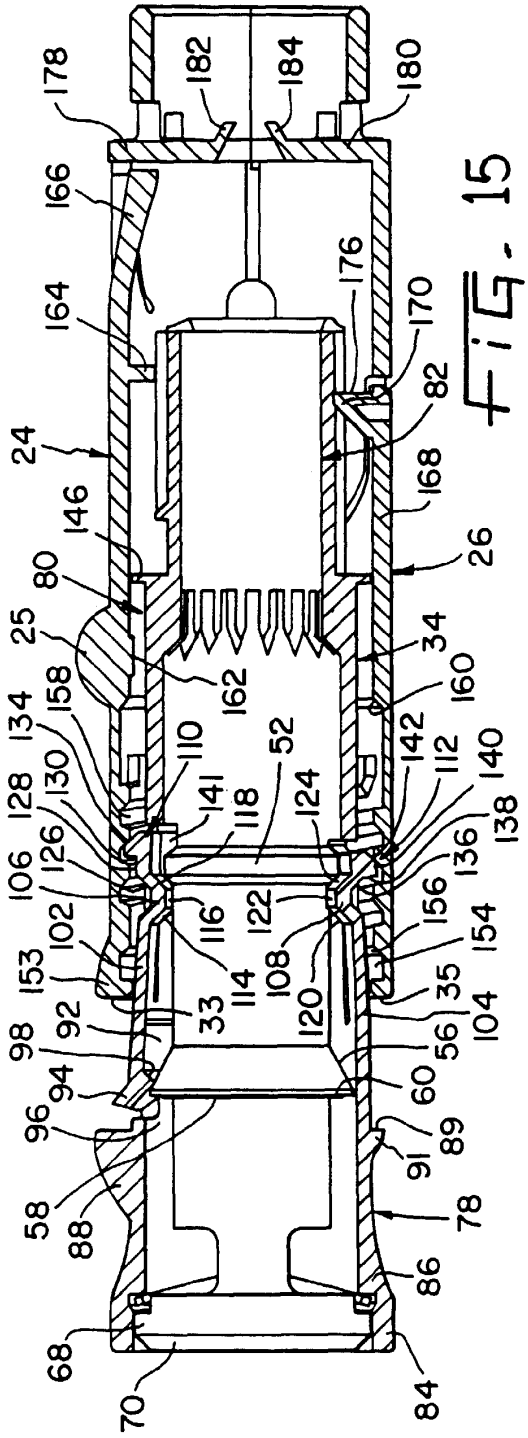

FIG. 15

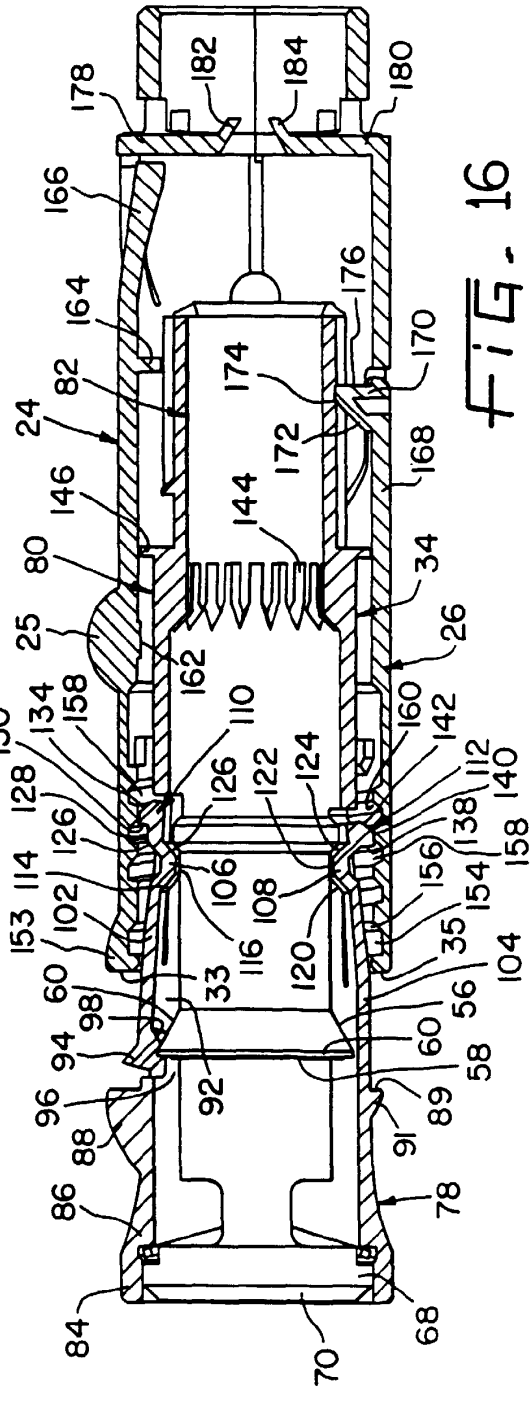

FIG. 16

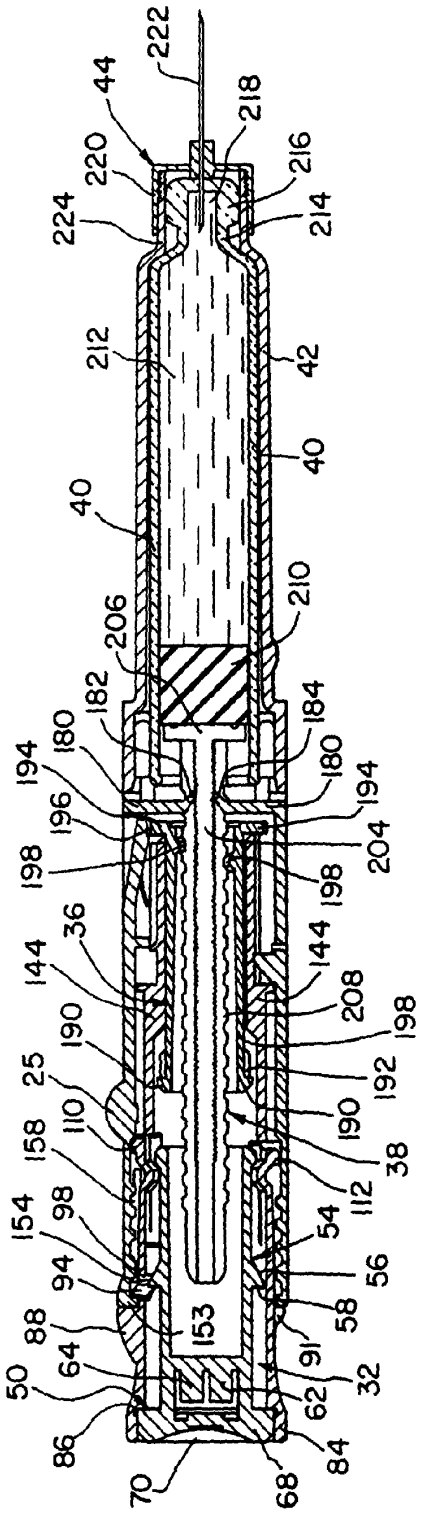

FIG. 17

US005947934A

United States Patent [19]

Hansen et al.

[11] **Patent Number: 5,947,934**

[45] **Date of Patent: Sep. 7, 1999**

[54] **DOSE DISPLAY FOR AN INJECTION SYRINGE**

[75] Inventors: **Steffen Hansen**, Hillerød; **Peter Christian Klitgaard**, Smørum, both of Denmark

[73] Assignee: **Novo Nordisk A/S**, Bagsvaerd, Denmark

[21] Appl. No.: **08/925,702**

[22] Filed: **Sep. 9, 1997**

Related U.S. Application Data

[60] Provisional application No. 60/049,062, Jun. 10, 1997, abandoned.

[30] **Foreign Application Priority Data**

Sep. 13, 1996 [DK] Denmark 0991/96

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/207**; 604/211; 604/232; 604/187

[58] **Field of Search** 604/207, 211, 604/232, 155, 187, 224

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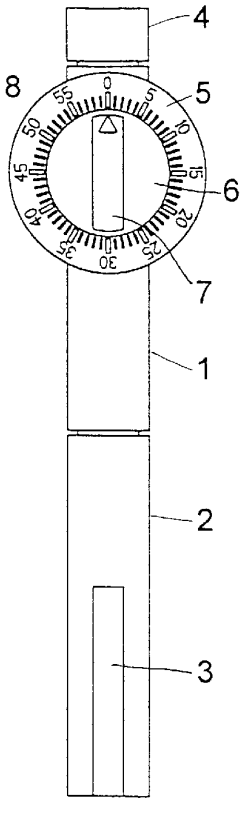
Primary Examiner—Ronald Stright
Assistant Examiner—Kent Gring
Attorney, Agent, or Firm—Steve T. Zelson, Esq.; Elias J. Lambiris, Esq.

[57] **ABSTRACT**

The present invention relates to injection syringes comprising a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections. The syringe has a dose setting mechanism by which doses may be set by rotating a dose setting element relative to the housing and the dose set is indicated on a scale. The scale is formed as a clock dial having a first part secured to the housing and a second part which is rotatable relative to the first part and which is coupled to the dose setting element, one of parts carries the scale and the other carries an indicating member indicating a point on the scale. The angular distance between the divisions of the scale corresponds to the minute divisions on an ordinary clock. Holes are provided along the scale which holes can receive a pin forming a stop which cannot be passed by the indicating member.

8 Claims, 1 Drawing Sheet



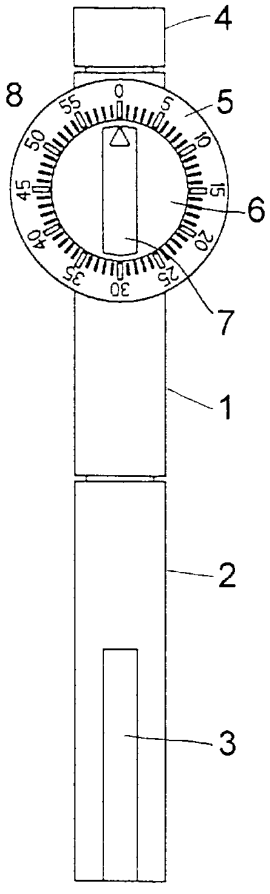


Fig. 1

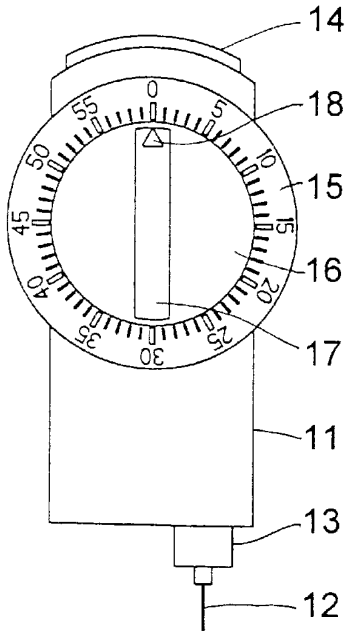


Fig. 2

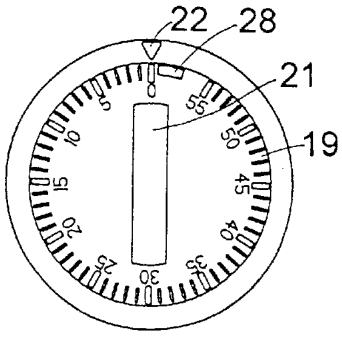


Fig. 3

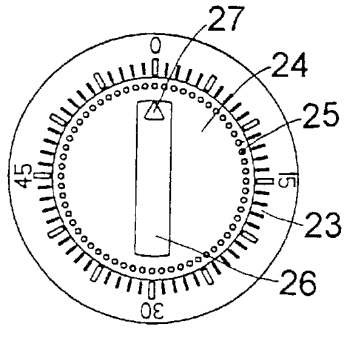


Fig. 4

DOSE DISPLAY FOR AN INJECTION SYRINGE

CROSS-REFERENCE OF RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of U.S. provisional application 60/049,062 filed Jun. 10, 1997 now abandoned and Danish application serial no. 0991/96 filed Sep. 13, 1996, the contents of which are fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to injection syringes of the kind comprising a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections, the syringe having a dose setting mechanism by which doses can be set from injection to injection by rotating a dose setting element relative to the housing the size of the set dose being indicated on a scale.

2 . Description of the Related Art

A problem by the scales is that the perimeter of the syringe sets a limit to the size of the scale and the digits on it. Especially where the syringe is used by people who have impaired sight, as it often may be the case by diabetics, a system allowing use of larger digits on the scale is wanted. Further hints of the size of the set dose may be obtained by studying the distance a injection button is elevated from the syringe but as the elevation pro unit is very small, sometimes of the order 0.15 mm, this will only give an imprecise impression of the size of the dose set.

It is an object of the invention to provide a syringe by which these limitations are overcome.

SUMMARY OF THE INVENTION

This is obtained by a syringe of the kind mentioned in the opening of this specification, which syringe is according to the invention characterised in that the scale is formed as a clock dial having a first part secured to the housing and a second part which is rotatable relative to the first part and which is coupled to the dose setting element, one of parts carries the scale and the other carries an indicating member indicating a point on the scale.

By shaping the dose indicating means as a clock dial this dial may be made arbitrarily large and the size is only limited by the fact that the device must not be too bulky and must be acceptable from a design point of view.

The second part of the dose indicating means may be coupled to the dose setting element through a gear mechanism. This may be necessitated by the fact that the relative rotation of the dose setting means may take place about the longitudinal axis of the syringe whereas the dial is placed so that the relative rotation of the first and the second part takes place around an axis perpendicular to the longitudinal axis of the syringe, however, gear couplings may also be used in syringes wherein the dial and the dose setting means rotate about parallel axes. The geared coupling may also be used to obtain that the relative angular rotation of the first and second part or the dose indicating means may be larger than the relative rotation of the dose setting elements.

As in egg timers a scale carrying divisions and digits may be arranged along the perimeter of the dial with a pointer on the part not carrying the divisions and the digits pointing at a point of the scale indicating the relative rotational position of the dose setting member and the housing and consequently the dose set by this rotation.

According to the invention the syringe may appropriately be of the type using a flexible piston rod to reduce the overall length of the syringe by deflecting the piston rod where it projects from the ampoule. Instead of the ordinary pen shape this type of syringes have a more parallelepiped shape with broad side walls suited as carriers of clock dials.

According to an embodiment of the invention a finger grip may be provided following a diameter on the second part of the dose indicating means, the grip being parallel with the longitudinal axis of the syringe when no dose is set. This grip may be used for setting a dose as rotation of said second part is transmitted to the rotatable dose setting element through the coupling between the second part and the dose setting element. The finger grip will conspicuously indicate whether a dose is set or not as even a small deviation from the position in the axial direction of the syringe is recognisable.

According to a further embodiment of the invention the angular distance between the divisions of the scale is 6° corresponding to the minute divisions of an ordinary clock. This makes it possible to the user to estimate the setting even when he cannot see the digits of the scale. This is due to the fact that the clock dial is so well established by most people that they can read the time on a clock dial without digits, even on a clock dial without divisions. Therefore the position of the indicating member in relation to the scale alone will let the user know the size of a set dose.

From DE 42 08 677 is known a pen shaped injection device having a dose setting mechanism which may be operated via a dose setting element. When not in use the syringe is stored in a box having a dose setting device comprising a large dial shaped scale with divisions and printings. When the syringe is stored in the box a dose may be set by operating the dose setting device on the box and the movements of this device is via a gear mechanism transmitted to the dose setting element of the syringe.

In the device according to the invention the clearly visible dial is carried by the injection device itself so that no setting may be made which is not shown on the dial. Even the device may be so designed that the indication on the dial is successively returned to zero during the injection so that the indication on the dial currently shows the dose which remains to be injected.

The injection syringe may have means by which the setting movement of the dose setting element is limited so that an upper limit is set to the dose which can be set. If by dose setting the dose setting element is moved until it is stopped by the limit a fixed dose is set.

According to an embodiment of the injection syringe according to the invention the limit may be provided by holes provided along the scale which holes each can receive a pin forming a stop which cannot be passed by the indicating member. This makes it possible to put a limit on the dose which may be set as the second part can only be rotated until the indicating member reaches the point on the scale where a pin is inserted in the hole. The pin may be installed by the a user who mostly use the same dose at each injection. When the pin is set in the hole at the division corresponding to the dose in question, the user can set the dose by rotating the second part until the rotation is stopped because the pin reaches a stop which prevent it from passing the indicating member. Alternatively the pin may be mounted by the user's physician to ensure that the user will not inject more than a limited number of units in one injection. Pins used for that

purpose may be so designed that a tool is needed to install and remove them. Especially when the device is used by children it is important that an upper limit may be set for the dose which can be injected.

BRIEF DESCRIPTION OF THE FIGS.

In the following the invention will be described in further details with references to the drawing, wherein

FIG. **1** shows a pen shaped syringe with a display according to the invention,

FIG. **2** shows a new designed short syringe with a display according to the invention

FIG. **3** shows an embodiment of a display according to the invention, and

FIG. **4** shows another embodiment of a display according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

In FIG. **1** is shown a pen shaped syringe comprising, a housing **1** containing a dose setting mechanism, a cap **2** protecting the needle end of the syringe which cap is provided with a clip **3** by which the syringe may be carried in a pocket like a fountain pen, and an injection button **4** which is elevated from the end of the housing **1** concurrently with the setting of a dose and which may be pressed back to abutment with the end of the housing to inject the set dose.

Further the syringe carries a display having the shape of an egg timer dial. The display comprises a scale **5** carrying equidistant marks corresponding to the marks of the minutes on an ordinary watch dial. The scale **5** is fixed to the housing **1**. A pointer is established by a circular plate **6** carrying a finger grip **7** having an arrow mark **8**. The circular plate **6** and the finger grip **7** form, a dose setting unit by which a dose may be set by gripping the grip **7** and rotating the plate **6** clockwise until the arrow mark points on the mark of the scale indicating the wanted dose. The plate **6** with the finger grip **7** is mounted on a not shown shaft which is journaled in the housing and through which combined with a gear mechanism the rotation of the dose setting unit is transmitted to a conventional dose setting mechanism in the housing **1**. The plate **6** may be omitted so that the dose setting unit comprises only the finger grip **7**.

The embodiment shown in FIG. **2** represents another type of syringes which due to the use of a flexible piston rod are made shorter than the pen type. The pen comprises a housing **11** containing a dose mechanism and accommodating a cartridge with a medicine to be apportioned. An injection needle **12** is mounted in a needle hub **13** which may be screwed onto the syringe. The end of the syringe carrying the needle may be covered by a not shown protection cap. The syringe has an injection button **14** which is elevated from the end of the housing **11** concurrently with the setting of a dose and which may be pressed back to abutment with the end of the housing to inject the set dose. Also in this embodiment a scale **15** is fixed on the housing and the dose is set by rotating clockwise a dose setting unit comprising a circular plate **16** carrying a finger grip **17** with an arrow mark **18** until the arrow mark point at the mark corresponding to the wanted dose. This rotation is transmitted through a not shown shaft carrying the dose setting unit and transmitting rotation of this unit to a dose setting mechanism in the housing. The button **14** is pressed home to abutment with the housing to inject the set dose and concomitantly with the injection the dose setting unit is rotated back so that the arrow mark points at the zero mark of the scale to indicate that the full dose is delivered.

Advantage is taken of the fact that watching a clock dial is so well promoted that most people will be able to estimate the minute number by just watching the position of a mark along the periphery of a circle. By making the divisions which indicates the set number of units of the medicine to be injected correspond to the minute divisions of a clock dial, the user will be able to estimate the size of a set dose with high precision even when the dose size is not indicated by a number at each division mark. When e.g. only every fifth division mark is provided with an dose indicating number, the digit of this number may be made very large an easy readable.

To take the full advantage of this fact it is preferred that the finger grip is rotated clockwise when a dose is set. In FIG. **3** where a scale **19** is carried by a circular plate **20** of a dose setting unit which may be rotated by a finger grip **21** and the arrow mark **22** is fixed in relation to the housing this clockwise rotation is obtained by positioning the scale marks and the numbers of the scale in an anticlockwise fashion. This way a clockwise rotation of the dose setting unit will bring increasing numbers abreast of the arrow mark.

In FIG. **3** the scale has a wide mark **28** which may be pointed at by the arrow when the finger grip is rotated anticlockwise. A stop is established so that the scale only be rotated further anticlockwise until the arrow points at the mark **28**. By this anticlockwise rotation a fixed small dose is set, e.g. corresponding to delivery of 10μl of the medicine. This small dose is set before the dose to be injected is set and is pressed out by pressing the injection button. Thereby air in the ampoule or and the needle is pressed out through the needle an visual inspection of the jet at the end of the needle can reveal if the air is expelled. The setting by anticlockwise rotation of the finger grip and subsequent pressing the injection button is repeated until a jet of liquid is seen at the end of the needle. The provision of the possibility of setting a small dose by anticlockwise rotation of the finger grip may be seen as a feature easing the air shot procedure which should else be performed by repetitively setting of small doses in the conventional way by clockwise turning of the finger grip.

In FIG. **4** is shown another display with a scale **23** which is fixed in relation to the housing. The dial carrying the scale **23** have a central part **24** which is also fixed relative to the housing and which at every mark of the scale indicating a unit of the medicine to be injected has a hole **25** into which a not shown pin may be inserted. The dose setting unit only consist of a finger grip **26** with an arrow mark **27** which unit is carried by a not shown shaft transmitting the rotation of the unit to a dose setting mechanism. Behind the dial carrying the scale said shaft has a pointer parallel with the finger grip and pointing from the shaft in the direction of the arrow mark. When a pin is mounted in one of the holes in the dial the pointer will abut this pin when the dose setting unit is rotated and will stop for further rotation in the dose setting direction but will allow the unit to rotate back when a set dose is injected. This way it may be ensured that a set maximum dose is not exceeded. It is further shown that the dose mark does not have to be numbered at each 5 units but e.g. only at each 15 units. In fact most designs known from egg timers and similar clocks may be used without deviating from the scope of the invention.

We claim:

1. An injection syringe comprising:

a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections,

a dose setting mechanism including a dose setting element which is rotatable relative to the housing and by which doses may be set by rotating a dose setting element

an injection button which is moved relative to the housing in response to rotating the dose setting element and which, when pressed, administers the set dose, and

a scale for indicating the set dose, having the general configuration of an egg timer dial, wherein the scale bears scale markings corresponding to a clock dial, wherein said scale has a first part fixedly secured to the housing and a second part which is rotatable relative to the first part, wherein the second part includes a grip, and is coupled to the dose setting element for rotating the dose setting element in order to set a dose, and wherein one of the parts carries the scale markings and the other g carries an indicating member indicating a point on the scale markings.

2. An injection syringe according to claim **1**, wherein the second part is coupled to the dose setting element through a gear mechanism.

3. An injection syringe according to claim **1**, wherein the syringe is of the type using a flexible piston rod.

4. An injection syringe according to claim **1**, wherein the syringe has a longitudinal axis, wherein the second part has an axis of rotation, and wherein the grip extends perpendicular to the axis of rotation of the second part and is parallel with the axis of the syringe when no dose is set.

5. An injection syringe according to claim **1**, wherein the angular distance between the scale markings of the scale is 6° corresponding to the minute divisions on an ordinary clock.

6. An injection syringe according to claim **1**, further comprising means by which the setting movement of the dose setting element is limited so that an upper limit is set to the dose which can be set.

7. An injection syringe according to claim **6**, wherein holes are provided along the scale which holes can receive a pin forming a stop which cannot be passed by the indicating member.

8. An injection syringe according to claim **1**, wherein said grip is coupled to the dose setting element such that clockwise rotation of the grip sets a dose.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,947,934
DATED : September 7, 1999
INVENTOR(S) : Hansen et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 5,
Line 16, please delete "g", and insert -- part --.

Signed and Sealed this

Eleventh Day of December, 2001

Attest:

Nicholas P. Godici

Attesting Officer

NICHOLAS P. GODICI
Acting Director of the United States Patent and Trademark Office

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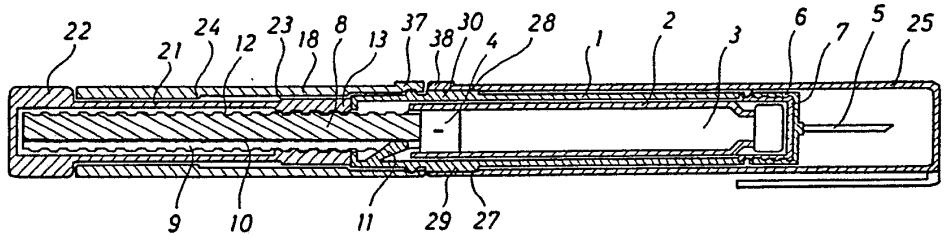
(54) Title: A DOSAGE UNIT FOR DOSING A NUMBER OF MEASURED QUANTITIES OF A LIQUID, SUCH AS AN INSULIN PREPARATION, FROM A CARTRIDGE



(57) Abstract

A dosage unit for dosing quantities of a liquid from a cartridge (2) by a piston rod (8) activating a piston (4) in the cartridge (2) comprises means (18) adjusting the length of the stroke of the piston rod. A ratchet device (10, 11) is situated between the casing (1) and the piston rod (8) and allows only displacement of said piston rod (8) towards an outlet needle (5). Between the piston rod (8) and the adjustment means (18) a nut means engages by way of an internal thread an external thread (12) on the piston rod (8) and engages on the outside in an axially displaceable manner the adjustment means (18). A rotation of the adjustment means (18) involves a rotation of the nut means (13) relative to the piston rod and a displacement of an indicator (21) fixedly connected to the nut means (13) and protruding from the end of the adjustment means (18). The dosing is carried out by pressing the piston rod (8) through the indicator (21).

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Title: A dosage unit for dosing a number of measured quantities of a liquid, such as an insulin preparation, from a cartridge

Technical Field

The invention relates to a dosage unit for dosing a number of measured quantities of a liquid, where the dosage unit comprises a cylindrical casing for the dose of the liquid in question, said liquid preferably being present in a separate cartridge, the distal end of said casing being provided with means for fastening a liquid outlet needle, said dosage unit further comprising a piston rod affecting a piston forcing out the liquid and situated in the cartridge and an adjustment means pivotally mounted on the casing and determining by way of adjustment the length of stroke of the piston rod relative to a measuring scale indicating the desired dosing quantity, and where the dosage unit in addition comprises a ratchet device situated between the casing and the piston rod and allowing displacement of said piston rod towards the distal end of the casing and preventing a displacement thereof in the opposite direction.

Background Art

Various types of dosage units are known for dosing suitable quantities of insulin, said units using cartridges containing different concentrations of insulin. Usually such a cartridge contains 1.5 ml (other cartridges contain 3 ml), and the insulin is for instance of a concentration of 100 insulin units per ml, whereby the cartridge contains 150 insulin units. When using the dosage unit a predetermined quantity is to be delivered per injection, preferably up to 40 insulin units per injection. Therefore the dosage unit can be used for several injections per cartridge. The latter procedure requires a very accurate adjustment

of the dosage to be injected per time.

The known dosage units are relatively complicated and often shaped such that their extent in the longitudinal direction decreases as more and more dosages are injected. Such dosage units are encumbered with drawbacks partly with respect to storage and partly because their appearance is gradually worsened. In addition, are more and more difficult to use as their extent in the longitudinal direction decreases.

Dosage units are known the extent of which is kept constant. Such units require, however, a stepwise injection of the dosing quantity in question. Alternatively the mechanism in question is relatively complicated the reason why the manufacture of the dosage unit is relatively expensive.

Disclosure of Invention

The object of the present invention is to provide a dosage unit maintaining a constant length in use and allowing a preadjustment of the total quantity to be dosed, and which simultaneously is inexpensive to manufacture.

The dosage unit according to the invention is characterised in that the adjustment means is non-displaceably mounted on the casing, that the piston rod is provided with an external thread and prevented from rotating relative to the casing, that a nut means is provided between the piston rod and the adjustment means, said nut means engaging by way of an internal thread the thread of the piston rod and on the outside engaging in an axially displaceable manner the adjustment means such that rotation of the adjustment means involves a rotation of the nut means relative to the piston rod, and that the nut means is connected to an indicator protruding from the end of the

adjustment means, said indicator comprising means stopping its axial movement towards the distal end of the dosage unit and further comprising a measuring scale indicating the extent of its axial displacement relative to the adjustment means and consequently the desired dosing quantity.

The resulting dosage unit is easily preadjusted to the desired dosing quantity as a turning of the adjustment means involves a turning of the nut means and consequently an axial displacement thereof and of the indicator connected thereto relative to the adjustment means and the piston rod. The desired dosing quantity is read by means of a suitable measuring scale indicating the displacement of the indicator relative to the adjustment means. After the preadjustment the injection in question is carried out merely by pressing on the indicator such that said indicator is axially displaced relative to the adjustment means back to its starting position relative thereto. As the nut means is engaging the piston rod and said piston rod is prevented from rotating relative to the casing, the displacement of the indicator results in movement of the piston rod and the piston of the cartridge as well. The ratchet device between the casing and the piston rod ensures that the piston is not pulled out of the cartridge during the adjustment.

According to the invention it is particularly advantageous when the nut means comprises at least one radially protruding, axially extending projection on the outside, said projection being slidably situated in an associated axially extending groove in the inner side of the adjustment means.

According to the invention the nut means and the indicator connected thereto may comprise means stopping their axial movement away from the distal end of the dosage unit,

whereby it is possible to prevent the dosage unit from being adjusted to a possibly dangerously high dosing quantity.

Moreover according to the invention the nut means and the indicator may be integrally shaped whereby a particularly simple embodiment of the invention is obtained.

According to the invention the nut means and the indicator may be substantially axially symmetrically shaped with a button at the external end, the outer diameter of said button corresponding to the outer diameter of the adjustment means. As a result the axial movement of the indicator and consequently of the piston rod and the piston towards the distal end of the dosage unit is stopped in a simple manner.

A dosage unit comprising a removable cap protecting the needle may according to the invention be shaped with the cap of such an axial extent that when mounted it abuts adjacent the distal end of the adjustment means, where the abutting ends of the cap and the adjustment means have correlative measuring scale portions indicating the dosing quantity set during the rotation of the adjustment means relative to the cap. Thus a careful adjustment of the desired quantity is allowed in a simple manner as the measuring scale portions indicate the quantity in questions by portions of a full turn of the adjustment means, while the measuring scale associated with the indicator indicates the dosing quantities of every full turn of the adjustment means.

According to a particularly advantageous embodiment of the invention marking means may be provided on the casing and the adjustment means, said marking means allowing a stepwise turning of the adjustment means with a tangible and optionally audible indication of this movement, whereas

the cap may be arbitrarily and unturnably situated with the associated measuring scale portion situated opposite the measuring scale portion of the adjustment means in any position thereof as a result of the stepwise turning thereof. In this manner it is always possible to situate the measuring scale portion of the cap opposite a fixed zero on the adjustment means, said zero forming the basis of the adjustment of the desired dosing quantity. A further advantage is that simultaneously the user of the dosage unit has a clear feeling of alterations of the adjustment whereby the security of a correct adjustment is particularly good.

Finally according to the invention the piston rod may be prevented from rotating relative to the casing by means of the ratchet device, as at least one pawl is provided on the casing, said pawl engaging a longitudinal groove in the piston rod, where the bottom of said groove is provided with a suitable toothing co-operating with the pawl.

Brief Description of Drawings

The invention is described in greater details below and with reference to the accompanying drawings, in which

Fig. 1 is a perspective view of a preferred embodiment of a dosage unit according to the invention, said dosage unit being ready for injection of a predetermined quantity of liquid,

Fig. 2 is an axial sectional view through the dosage unit before the adjustment of a predetermined dosing quantity,

Fig. 3 is an axial sectional view through the dosage unit of Fig. 1,

Fig. 4 is a sectional view taken along the line IV-IV of Fig. 3,

Fig. 5 is a sectional view taken along the line V-V of Fig. 3,

Fig. 6 is a perspective view of an embodiment of an indicator shaped integral with an associated nut means with portions removed for the sake of clarity, and

Fig. 7 is an axial sectional view through the embodiment of Fig. 6.

Best Mode for Carrying Out the Invention

The dosage unit according to the invention shown in Figs. 1-5 comprises a casing 1 for a cartridge 2 containing a liquid 3. The cartridge 2 comprises a piston 4 pressing the liquid 3 out through a needle 5 inserted in the opposite end, said needle being secured to the casing 1 in a generally known manner by screwing on of a cup-shaped cap 6. As indicated in Figs. 2 and 3 the cartridge 2 can be retained in the casing by means of a retaining cap 7 optionally secured to the casing by a snapping effect. The retaining cap 7 allows introduction of a protruding end (not shown) of the needle 5, said end optionally extending into the interior of the cartridge. This introduction and insertion of the needle 5 is preferably carried out during the screwing on of the needle-carrying cap 6 onto the retaining cap 7 of the casing 1.

At the end opposite the needle 5 the dosage unit comprises a piston rod 8 driving the piston 4 in the cartridge 2. This piston rod 8 comprises a longitudinal groove 9 provided in the bottom with transverse barbs 10 being serrated when seen as a longitudinal sectional view therethrough. These barbs co-operate with a pawl 11 shaped on the casing

1 and provided with barbs co-operating with said barbs 10 on the piston rod 8. These barbs 10 and the pawl 11 are shaped so as only to allow displacement of the piston rod 8 towards the piston 4 of the cartridge and to prevent displacement in the opposite direction. As indicated in Fig. 5 the pawl 11 and the groove 9 are of such a width that their co-operation prevents the piston from rotating relative to the casing.

The piston rod 8 comprises furthermore a thread 12 shaped along its external periphery, a nut means 13 being screwed onto said thread. On the outside the nut means 13 comprises radially protruding projections 14 and 15 extending axially along the outer side of the nut means 13 and received in corresponding grooves 16 and 17, respectively, cf. Fig. 4, in a surrounding sleeve-shaped adjustment means 18. At the end adjacent the casing 1 this adjustment means 18 comprises a circumferential groove 19 receiving a circumferential projection 20 on the casing 1. As a result it is possible to turn the adjustment means 18 simultaneously with preventing it from being axially displaced.

The nut means 13 is shaped integral with a tubular indicator 21 extending coaxially with the piston rod 8 away from the casing 1 between the piston rod 8 and the adjustment means 18. At the free end projecting outside the adjustment means the indicator 21 comprises an end button 22 of substantially the same outer diameter as the adjustment means 18. As indicated in Figs. 2 and 3 the nut means comprises a circumferential abutment surface 23 at the transition to the tubular indicator. Correspondingly the adjustment means 18 comprises an inner circumferential abutment surface 24, the abutment surface 23 on the nut means abutting said abutment surface 24 during the displacement of the nut means in axial direction relative to the piston whereby the movement in question is stopped on a desired location. The grooves 16 and 17 shaped on the

inner side of the adjustment means 18 are of such an extent that the nut means 13 can move freely in axial direction relative to the piston and the adjustment means between the adjacent end of the casing 1 and the inner abutment surface 24 on the adjustment means 18.

The dosage unit comprises furthermore a removable cap 25 protecting the needle 5 when the dosage unit is not used. This cap is of such an axial extent that when mounted its free rim 26 is situated adjacent the adjustment means 18. Axial recesses or grooves are provided close to the free rim 26 of the cap 25, said recesses being situated with the same mutual angular distance along the inner side of the cap. These recesses are indicated by the reference numerals 27 and 28 in Figs. 2 and 3 and receive correspondingly shaped protruding projections 29 and 30, respectively, on the outer side of the casing. In this manner the cap can always be situated in a predetermined turning position relative to the periphery of the casing 1. The projections 29 and 30 on the casing 1 can be received in a manner not described more detailed in the recesses 27 and 28 on the cap 25 by way of a snapping effect.

As shown in Fig. 5, the casing 21 is provided with axially shaped grooves 31, 32, 33, 34, and 35 along the circumference. These grooves are situated with the same mutual angular distance as the grooves or recesses 27 and 28 on the inner side of the cap. These grooves 31-35 on the outer side of the casing co-operate with a projection 36 on the adjustment means 18 which project inwards. The grooves 31-35 and the projection 36 are shaped such that a turning of the adjustment means 18 relative to the casing 1 can easily be carried out manually as the receiving of the projection 36 in the grooves ensures both an audible stepwise advancing of the adjustment means relative thereto and on a desired location also a retaining of the adjust-

ment means 18 relative to the casing 1.

A scale is present on the outer side of the adjustment means at the end adjacent the cap 25, cf. Fig. 1. This scale comprises a platform 37 with the number 0 thereon. Correspondingly, the cap 25 comprises a knob 38 to be situated opposite the platform 37. The arbitrary positioning of the cap 25 along the circumference of the casing and the corresponding positioning of the adjustment means 18 also relative to the circumference of the casing 1 renders it possible for the user always to be able to situate the knob 38 opposite the platform 37 before the adjustment is initiated.

The dosage unit operates in the following manner. Upon positioning of the knob 38 opposite the platform 37 of the adjustment means 18, the desired dosing quantity is set by turning the adjustment means 18 relative to the casing 1 and the cap 25 fixed thereon. As a result the nut means 13 is forced to follow the rotation, the abutment of said nut means 13 against the end of the casing 1 preventing a turning of the adjustment means 18 in the incorrect direction. The rotation of the nut means 13 relative to the piston rod 8 implies that it is forced away from the cartridge by the thread 12 whereby the indicator moves axially away from the free end of the adjustment means 18. As a result a rough measuring scale 39 appears on the outside of the indicator 21. The said scale can be divided up so as to allow a reading of the dosing quantity in question for every full turn of the adjustment means 18 relative to the knob 38 on the cap 25, while the scale 40 on the end of the adjustment means adjacent the cap 25 indicates the dosing quantity by portions of a full turn of the adjustment means 18 relative to the knob 38.

When the desired dosing quantity has been set, the turning

of the adjustment means 18 is stopped on a suitable location where the turning has been fixed by means of the receiving of the inner projection 36 in one of the grooves 31-35 on the outside of the casing. Subsequently, the user removes the cap 25 and places the dosage unit on the desired location by sticking in the needle 5. Then the indicator 21 is forced back into the adjustment means 18 by pressing on the end button 22 until said movement is stopped by the abutment of the nut means 13 against the end of the casing 1 or the abutment of the end button 22 against the adjacent end of the adjustment means. As the pawl 11 prevents the piston rod 8 from rotating, the displacement of the indicator 21 causes a displacement of the piston rod a corresponding distance, whereby the piston of the cartridge is pressed towards the outlet end of the liquid 3. As a result a quantity of liquid is pressed out of the cartridge, said quantity corresponding to the quantity measured on the measuring scales. After completion of the injection of liquid the dosage unit is of the same length as before the preadjustment and therefore it maintains an acceptable, uniform appearance.

A suitable choice of material allows the casing 1 to be transparent, whereby the user can always see whether liquid is left in the cartridge. The cap 25 ensures simultaneously that the content of the cartridge is protected against sunlight. The various parts of the dosage unit are advantageously made of plastics, such as polypropylene, by injection moulding and are relatively easy to manufacture. With respect to compatibility it is also possible to adapt the material in question of the dosage unit to the injection liquid.

Figs. 6 and 7 illustrate a second embodiment of the indicator 21 and the associated screw means 13. On the outside this indicator 21 comprises a protrusion 41 received in a corresponding groove on the inside of the adjustment means

18. At the end opposite the protrusion 41, a circumferential groove 42 is provided for the fastening of a loose end knob not shown and shaped like the end knob 22.

The invention has been described with reference to a preferred embodiment. Many modifications can be carried out without thereby deviating from the scope of the invention. The piston rod may for instance be of different cross sections depending on the shape of the ratchet device, where the prevention of the piston rod from rotating may be ensured by a suitable shaping of the opening through which the piston rod passes into the casing 1. Furthermore the piston rod 8 must always comprise a thread 12 co-operating with the nut means 13. A toothing may be provided on the end of the nut means 13 adjacent the casing 1 as well as on the abutting end of the casing 1. The toothing is shaped as co-operating barbs preventing a mutual rotation of the casing 1 and the nut means towards a stronger tension. These barbs allow a slight turning in the opposite direction.

In stead of using a separate cartridge as container for the injection liquid, it is also possible to use a container shaped integral with the casing with the effect that by a suitable reshaping of the casing, said casing can also be used as a container for the injection liquid simultaneously with co-operating with the cap, the adjustment means, and the piston rod.

As illustrated in Fig. 1, the cap 25 is of a non-circular cross section at the end opposite the adjustment means 18 when said cap is secured on the dosage unit. In this manner it is easy to handle the cap during the mounting procedure. Furthermore a clip 43 is provided which secure the dosage unit to a pocket like a fountain pen.

The dosage unit can also be used for other injection

preparations beyond insulin, such as for instance morphine.

Claims:

1. A dosage unit for dosing a number of measured quantities of a liquid, where the dosage unit comprises a cylindrical casing for the dose of the liquid in question, said liquid preferably being present in a separate cartridge, the distal end of said casing being provided with means for fastening a liquid outlet needle, said dosage unit further comprising a piston rod affecting a piston forcing out the liquid and situated in the cartridge and an adjustment means pivotally mounted on the casing and determining by way of adjustment the length of stroke of the piston rod relative to a measuring scale indicating the desired dosing quantity, and where the dosage unit in addition comprises a ratchet device situated between the casing and the piston rod and allowing displacement of said piston rod towards the distal end of the casing and preventing a displacement thereof in the opposite direction, c h a r a c t e r i s e d in that the adjustment means (18) is non-displaceably mounted on the casing (1), that the piston rod (8) is provided with an external thread (12) and prevented from rotating relative to the casing (1), that a nut means (13) is provided between the piston rod (8) and the adjustment means (18), said nut means engaging by way of an internal thread the thread of the piston rod (8) and on the outside engaging in an axially displaceable manner the adjustment means (18) such that rotation of the adjustment means (18) involves a rotation of the nut means relative to the piston rod (8), and that the nut means (13) is connected to an indicator (21) protruding from the end of the adjustment means (18), said indicator comprising means stopping its axial movement towards the distal end of the dosage unit and further comprising a measuring scale (39) indicating the extent of its axial displacement relative to the adjustment means (18) and consequently the desired dosing quantity.

2. A dosage unit as claimed in claim 1, c h a r a c t e r i s e d in that the nut means (13) comprises at least one radially protruding, axially extending projection (14, 15, 41) on the outside, said projection being slidably situated in an associated axially extending groove (16, 17) in the inner side of the adjustment means (18).

3. A dosage unit as claimed in claim 1 or 2, c h a r a c t e r i s e d in that the nut means (13) and the associated indicator (21) comprise means (23) stopping their axial movement away from the distal end of the dosage unit.

4. A dosage unit as claimed in claim 1, 2 or 3, c h a r a c t e r i s e d in that the nut means (13) and the indicator (21) are integrally shaped.

5. A dosage unit as claimed in claim 4, c h a r a c t e r i s e d in that the nut means (13) and the indicator (21) are substantially axially symmetrically shaped with a button at the external end, the outer diameter of said button corresponding to the outer diameter of the adjustment means (18).

6. A dosage unit as claimed in claim 1, 2, 3, 4 or 5 and comprising a removable cap protecting the needle, c h a r a c t e r i s e d in that the cap (25) is of such an axial extent that when mounted it abuts adjacent the distal end of the adjustment means (18), and that the abutting ends of the cap (25) and the adjustment means (18) have correlative measuring scale portions (37, 38, and 40) indicating the dosing quantity set during the rotation of the adjustment means (18) relative to the cap (25).

7. A dosage unit as claimed in claims 1-6, c h a r a c t e r i s e d in that marking means (31, 32, 33, 34,

35, and 36) are provided on the casing (1) and the adjustment means (18), said marking means allowing a stepwise turning of the adjustment means with a tangible and optionally audible indication of this movement, and that the cap (25) is arbitrarily and unturnably situated with the associated measuring scale portion situated opposite the measuring scale portion (37) of the adjustment means in any position thereof as a consequence of the stepwise turning thereof.

8. A dosage unit as claimed in claims 1-7, c h a r a c t e r i s e d in that the prevention of the piston rod (8) from rotating relative to the casing (1) is ensured by means of the ratchet device (10, 11), whereby at least one pawl (11) is provided on the casing (1), said pawl engaging a longitudinal groove (9) in the piston rod (8), where the bottom of the groove is provided with a suitable toothing co-operating with the pawl (11).

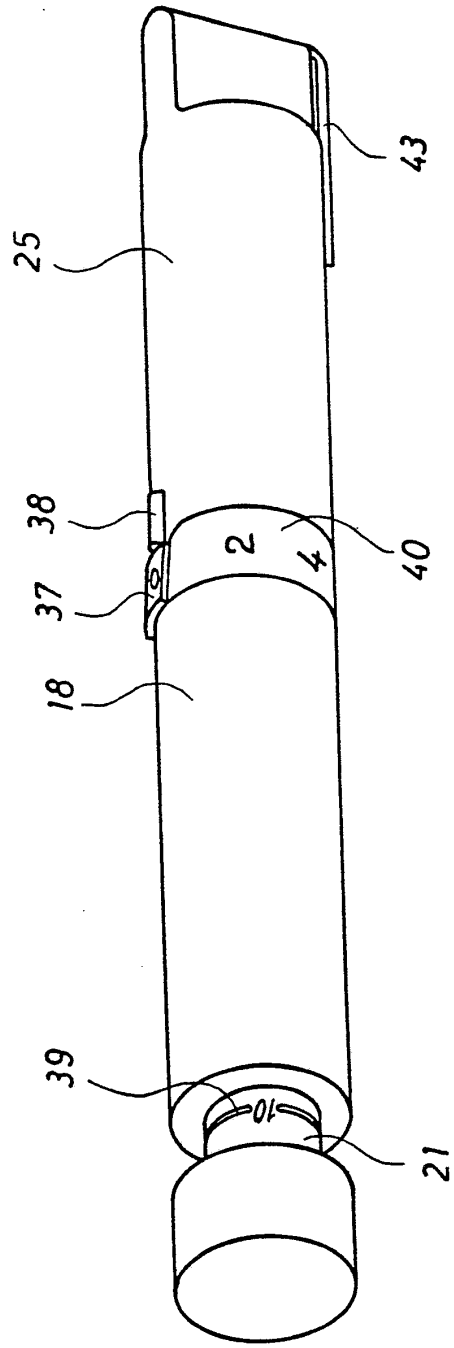

Fig.1

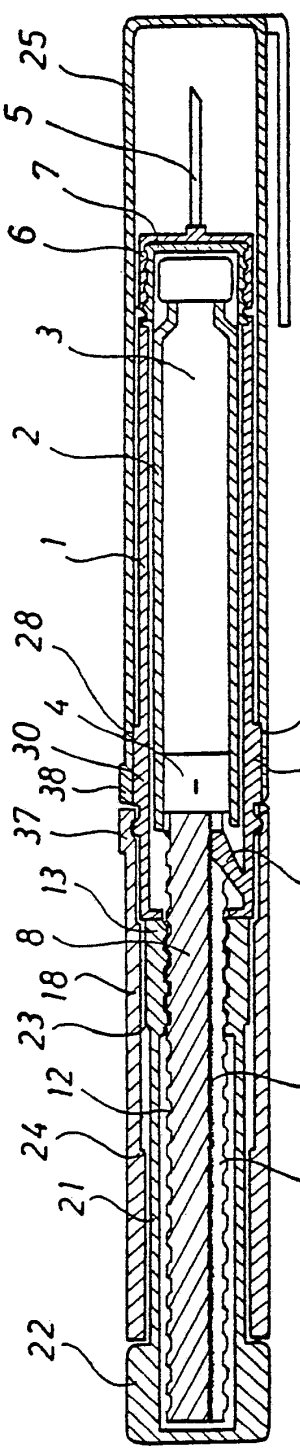

Fig.2

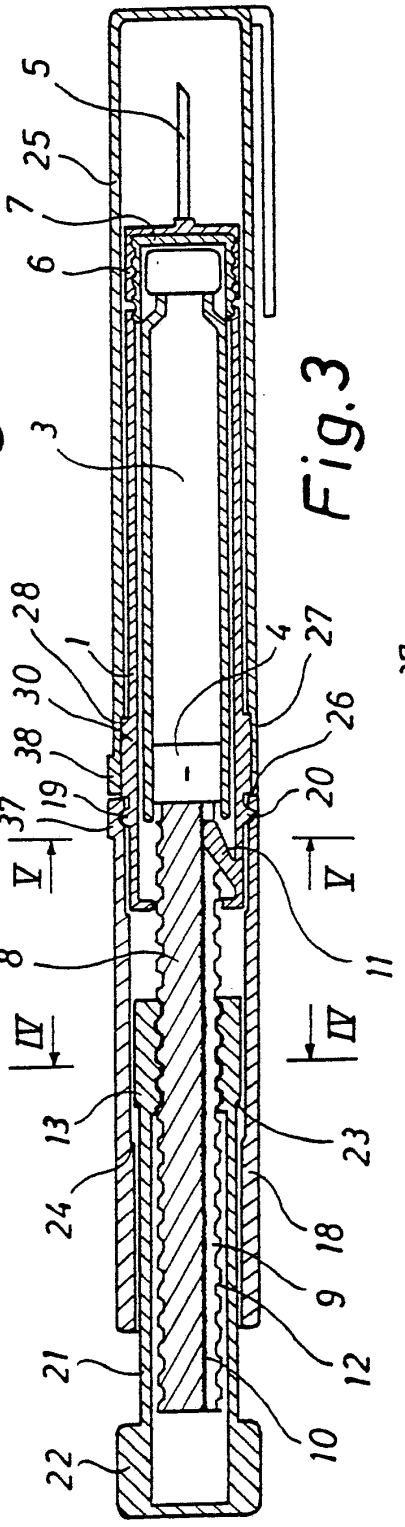

Fig.3

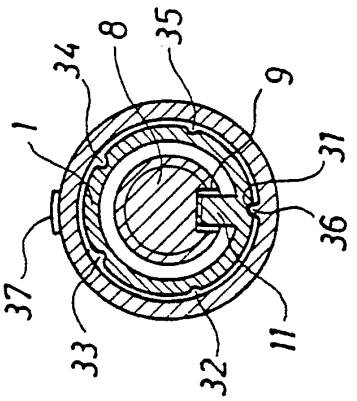

Fig.5

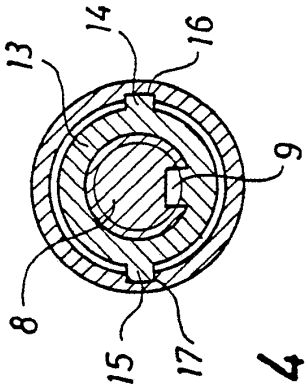

Fig.4

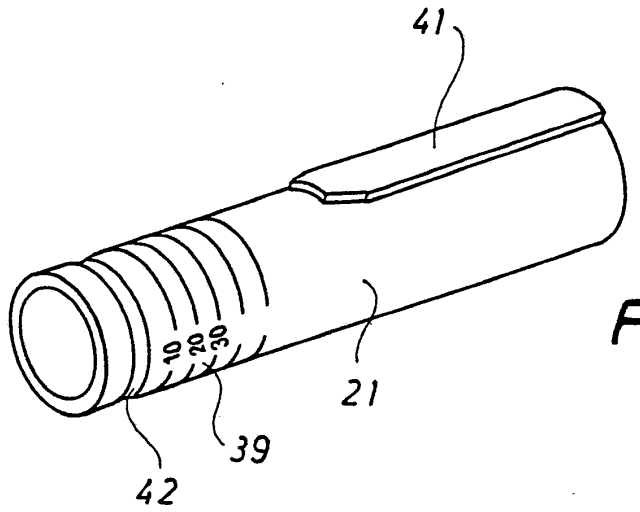

Fig.6

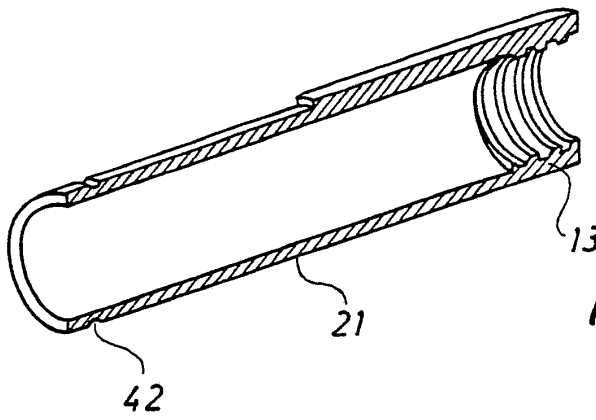

Fig.7

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK89/00023

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC 4

A 61 M 5/315

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC 4	A 61 M 5/18, 5/24, 5/315
US Cl	128:218, 218R, 218C, 218D, 218PA, 234
	604:207-211, 218

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	WO, A1, 87/02895 (DISETRONIC AG) 21 May 1987 See abstract; page 8, line 20 to page 9, line 23; figures 1-3	
A	EP, A1, 0 058 536 (TURNER, ROBERT CHARLES ET AL) 25 August 1982	
A	EP, A1, 0 115 931 (PORAT, AMIR ET AL) 15 August 1984	
A	US, A, 4 275 729 (SILVER ET AL) 30 June 1981	
A	US, A, 4 475 905 (HIMMELSTRUP) 9 October 1984	
P, A	WO, A1, 88/07874 (D.C.P. AF 1988 A/S ET AL) 20 October 1988	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
1989-05-08	~~1989~~ -05- 17
International Searching Authority	**Signature of Authorized Officer**
Swedish Patent Office	Folke Svensson

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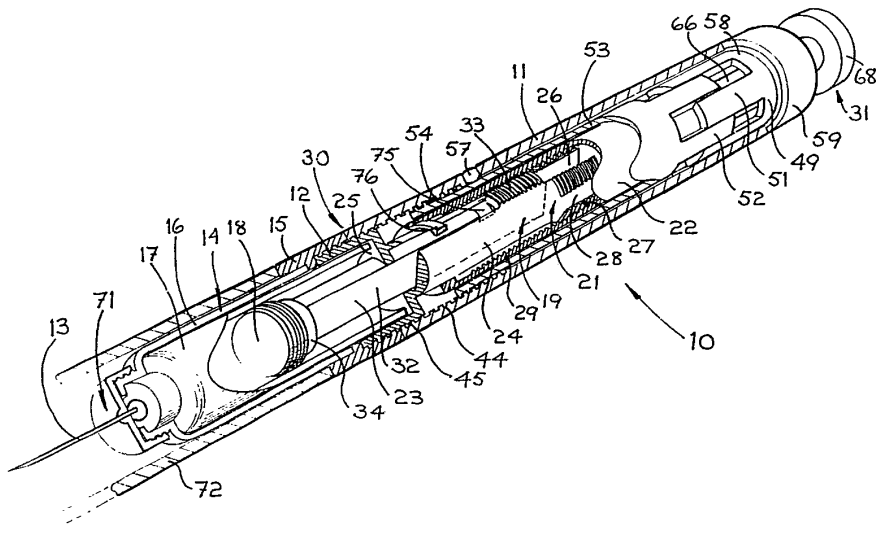
(54) Title: DISPENSING DEVICE

(57) Abstract

A dispensing device has a shell (11) which may be connected to a container (14) for a fluid to be dispensed, such as an injectable pharmaceutical compound. The device has a fixed first threaded member (21) and a second threaded member (22) surrounding the first member, the first and second members each having equispaced threaded segments (27 and 29) with non-threaded segments (28) therebetween whereby the second member will be wound axially when rotated about the first member but may be positioned for axial sliding movement with respect to the first member. A plunger (23) is slidably mounted within the first member (21) and has a portion (33) engageable with the threads of the second member. A dose setting sleeve (53) surrounds the second member and has threads (54) engaged with the device shell, the sleeve being coupled to the second member for rotation therewith. A dose is set by winding the second member (22) away from a fixed stop (25) until the sleeve (53) indicates the required dose amount, whereafter the second member (22) is slid axially back to the fixed stop (25), the plunger (23) being thrust forwardly thereby to expel fluid from the container.



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DISPENSING DEVICE

The present invention relates to a dispensing device which is arranged to dispense an accurate and measured dose of a fluid. Typically such a fluid may be one which is itself or which contains a therapeutically or otherwise active compound or composition, such as insulin.

European Patent Specification No. 0,037,696 A discloses a dispensing device suitable for use in dispensing a predetermined quantity of material from a container comprising a tubular body member having an outlet at one end, and a plunger slidably movable in said body member towards said outlet. The dispensing device comprises an elongate body having a chamber for receiving a container with its outlet held in a first end portion of the elongate body, and a first drive member mounted in said body for use in driving said plunger. In the disclosed device said first drive member is slidably mounted for driving engagement via a unidirectional drive transmission with a second drive member having a free end drivingly engagable with said plunger of the container. In that manner said second drive member and said plunger can be driven by the first drive member via said unidirectional drive transmission means only in a direction towards the container outlet and the first end portion of the elongate body whilst permitting return movement of the first drive member. Preferably, the unidirectional drive transmission comprises a ratchet means.

For setting the dose to be dispensed the adjust knob is turned to align a pin with one of a series of channels of varying length (dependent on the size of dose required) in the push button (or vice versa). The length of the channel dictates the movement forward of the plunger and the multiple of doses is decided by how

many channels one can safely have around the circumference consistent with side walls to each channel and the size of the readout on the circumference.

A usable diameter gives eight variable doses. One could increase the diameter to give more channels and more variations of dose. However, the device would become more and more unwieldy as the number of channels is increased.

Another serious fault with this device is that it is easy to pump the push button so that the plunger moves forward without the pin ever reaching the bottom of its channel. This is unsafe.

European Patent Specification No. 0,295,075 A relates to a device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device. The device is adapted to receive the container at its forward end and to move the plunger axially forward towards the container so as to dispense a selected amount of fluid from the container upon each actuation of the device. The device comprises a drive mechanism adapted to be reciprocated axially of the device and to be positively engaged with the plunger for the forward stroke of the drive mechanism so as to prevent relative movement between the plunger and the drive mechanism and to move the plunger forward. The drive mechanism requires a positive action to disengage it from the plunger so as to permit relative movement between the plunger and drive mechanism for at least rearward movement of the drive mechanism. Also, the forward travel of the drive mechanism is limited by a fixed stop mechanism and the extent of the forward stroke of the drive mechanism is individually selectable for each actuation of the device by withdrawing the drive mechanism or a part

operatively associated therewith a selected distance from the said fixed stop.

The device of EP-0,295,075 A is designed to give a maximum of 36 units of insulin. For dose setting opposed jaws are pulled back in a slot by rotating a screw, the length of slot being determined by the length of the movement forward of the plunger at maximum dose. A larger dose means a longer slot and a corresponding lengthening of the device. In addition, to wind back the screw for an additional dose means a lengthening of the screw in the main body, thereby adding another additional dose length to the device. Also, in line with the jaws and screw is the readout which needs an additional dose length and a corresponding increase in body length. Thus, there is a ratio of 3:1 between body length and plunger length, which means that each time the does is increased there is an additional three millimetres of body length for every millimetre of plunger length necessary to give the higher dose setting.

In prior art dispensing devices, such as those outlined above, the usual dispensing increment is 2 units, but the amount dispensed for a given standard length of device is limited. Thus, in the case of a patient wishing to use a relatively large dose it may be necessary to use the device twice or even more times, each time to dispense a smaller dose.

This invention aims at overcoming the above-mentioned problems of the described prior art devices, and in particular at providing a dispensing device which can dispense relatively large doses and yet which has a body length to plunger length ratio of about 1:1.

Accordingly, in one aspect the present invention provides a device for dispensing a controlled amount of fluid from a container, which device comprises a device for dispensing controlled doses of fluid from a

container having a piston movable axially in increments thereby to dispense doses of fluid from an outlet of the container, which device comprises means to connect the device to a container, a plunger engageable with the container piston, and a dose setting and dispensing arrangement having first and second threaded members, the first member being fixed in relation to the device and the second member being mounted for rotation about the first member and having threads engageable with those of the first member, the plunger being slidably mounted within the first member and having a portion engageable with the threads of the second member, and the second member being rotatable to any one of a plurality of settings where its threads are engaged with said portion of the plunger but free of the first member whereby the second member and plunger may slide axially relative to the first member, movement of the second member in a direction towards the container connection means being limited by a fixed stop, the device further comprising dosage indicator means connected to the second member and arranged to indicate an ascending series of measured doses as the second member is rotated to move along the threads of the first member away from said fixed stop whilst the plunger remains stationary, and for each indicated dose the second member is disposed in one of its said settings relative to the first member where axial movement of the second member is permitted, the second member during such movement driving the plunger to act on the piston of a connected container and the dose expelled thereby being controlled by the axial distance of travel of the second member to the fixed stop from the position to which said member has been turned to indicate a desired dose.

The device of the invention is generally intended to be used as a hand portable device and preferably as

the dose dispensing portion of a syringe. Typically, such a syringe is of the kind used by diabetics to dispense insulin on a regular daily basis, but of course may be used by other patients and for other situations.

For use as a syringe the device is connected to a container provided with a reservoir of fluid which either itself may be an active material or may be the carrier for and contain an active material. The container at its outlet end typically may include connection means for a hypodermic needle and at its opposite end may include means for connection to the connecting means of the device. The latter means may comprise a threaded portion or a bayonet fixing arrangement. Known containers are generally tubular, and adapted to receive a fluid cartridge having a piston moveable therein.

The device preferably includes a cylindrical shell in which is fixed the first member, and within which the second member may rotate about the first member. The first member may be threaded externally with a plurality (and preferably four) of equi-spaced threaded arcuate sectors separated by a like plurality of non-threaded sectors. In this case, the second member should comprise a hollow cylinder threaded internally with threaded and non-threaded sectors arranged in essentially the same configuration as that of the first member. The second member will thus be free of the first member and free to move axially at some rotational dispositions, but at others will be engaged with the first member and so moved axially on being turned. To allow re-engagement of the respective threads when the second member has been moved axially to the fixed stop, the threads are preferably of multi-start form, advantageously of the same number of starts as threaded sectors. It will (of course) be understood

that other numbers of threaded and non-threaded sectors besides four may be used as desired, and that the invention is not limited to the described four.

In the above arrangement the second member may be wound backwards and forwards on the first member, but may be disposed relative to the first member to have their respective threads disengaged, whereby the second member is slidable axially of the first member and device shell.

The plunger is preferably slidably received within a slot in the first member, said portion engageable with the threads of the second member projecting through a non-threaded sector of the first member.

Said portion of the plunger may comprise one of an arcuate threaded portion of the same thread form as that of the second member. Alternatively, said portion may comprise a toothed wheel rotatably mounted on the plunger and having teeth formed to be engageable with the threads of the second member. Axial sliding movement of the second member will thus also slide the plunger by virtue of the interengagement of said plunger portion with the second member threads. Where said portion comprises a simple thread, the plunger will move together with the second member, but in the case of the said portion comprising a toothed wheel, a rack may be formed on a fixed part of the device and with which the wheel meshes, so that the wheel rotates on axial movement of the plunger; then the plunger will move through one half of the axial sliding movement of the second member as the wheel rolls along the rack.

Dose setting and dispensing is performed by initially winding the second member away from the fixed stop, the plunger remaining stationary, until the second member is spaced from that stop by some predetermined instance. The second member is set to permit axial sliding movement and is then slid back to

contact the fixed stop. During this, the plunger is thrust forward, so driving the cartridge piston and dispensing the required, set dose.

In order to permit the selection of a required dose, and so the distance from the fixed stop to which the second member is wound, the second member is linked to a dosage indicator means. Such means may comprise a sleeve carrying an ascending series of dose numbers, the sleeve being arranged to be threaded along the device shell as the second member is rotated, whereby the more the second member is threaded away from the fixed stop, the higher will the indicator dose number.

For each dose displayed by the indicator means, the second member is advantageously in one of its settings where its threads are disengaged from those of the first member. At each displayed dose, axial movement of the second member and linked plunger is permitted, to dispense the displayed dose by the plunger acting on the cartridge piston.

Said sleeve preferably has external threads engaged with internal threads on the device shell, said threads being of the same pitch as those of the first and second members so that the sleeve and second member move the same axial distance on each rotation thereof. A rotatable but axially fixed dose control knob may be provided linked to said sleeve and the second member by a splined connection.

In the device of the invention, the indicator means is preferably linked to the second member through a clutch arrangement. This conveniently is a form of dog-clutch having a like number of dogs and recesses as threaded sectors on the second member. After dispensing a set dose, the indicator sleeve may be wound back to zero, the dog clutch picking up the second member as the sleeve returns to its zero position, ready to be wound out together with the

second member to set a new dose.

Preferably lock means are provided to restrain rotation of the second member in a sense which moves the second member away from the fixed stop when the plunger projects from the second member by more than a pre-determined amount. Thus, should a user try to set a dose greater than that remaining in a cartridge connected to the device, the second member will be locked at the maximum possible dose from the connected cartridge, the indicator means indicating (at lock) the amount of that dose.

This invention extends to the combination of a dose dispensing device as described above in combination with a body defining a chamber for receiving a container for fluid, support means for a dispensing needle communicating with an outlet from the container. Such a combination may take the form of a medical syringe, typically for dispensing medications such as insulin.

By way of example only, specific embodiments of the device of the invention will now be described by way of example only and with reference to the accompanying drawings, in which:

Figure 1 is a cut-away perspective view of a dispensing device according to the invention;

Figure 2A is a cut-away perspective view from the rear of the device of Figure 1;

Figure 2B is a sectional view on the rear of the device;

Figures 3A and 3B are diagrammatic section views showing the cooperation between first and second threaded members and a plunger, firstly when set for dispensing and secondly after dispensing a dose;

Figures 3C and 3D are views similar to those of Figures 3A and 3B, but of a second embodiment of plunger having a toothed wheel;

Figures 4A and 4B are exploded perspective views respectively of the arrangements of Figures 3A and 3B, and of Figures 3C and 3D; and

Figures 5A and 5B show a lock which limits the rotation of the second threaded member.

Referring to Figure 1, the device 10 comprises a main body shell 11 which includes at its front end a threaded connector 12 by means of which the shell may be connected to a container 14 having a connector portion 15, to hold the device 10 and the container 14 in a fixed relationship. The container 14 is of known type comprising an outer protective plastics housing 16 in which is received an inner glass cartridge 17 having a captive piston 18 and containing the fluid to be dispensed (not shown) out of a hypodermic needle 13.

Within the body shell 11 there is a dose setting and dispensing arrangement 19 comprising first and second threaded members 21 and 22, and a plunger 23. First member 21 comprises side elements 24 held by ring 25 in a fixed relationship to form a slot 26 in which is slidable the plunger 23. The ring 25 is formed integrally with connector 12, which serves to hold member 21 in a fixed relationship to the shell 11.

Each element 24 comprises upper and lower threaded segments 27 separated by a non-threaded channel 28 so that member 21 overall comprises four threaded segments 27, each separated by one of four plain non-threaded segments as provided by channels 28 and slot 26.

First member 21 carries on its threaded segments 27 the second member 22 which is a hollow cylindrical collar having four threaded inner segments 29 the configuration of which matches that of the threaded segments 27. Thus, the member 22 may be wound e.g. towards the rear end 31 of the device 10, upon rotation of member 22, by the interengagement of the threaded segments 27 and 29, but that member 22 also

may slide e.g. towards the front end 30 of the device 10, when opposed threaded segments 29 are in register with channels 28. In the arrangement shown, each 90° of rotation of member 22 initially moves member 22 axially by the interaction of its threaded segments 29 with segments 27 of member 21, and then segments 29 come into alignment with the non-threaded portions of member 21, allowing member 22 to be pushed forwards or backwards with respect to member 21. The depth of the channels 28 thus need be only sufficiently deep to give clearance for the threaded segments 29 of member 22.

It would be possible to configure the members 21 and 22 with different numbers of threaded segments to permit sliding movement at positions other than at 90° spacings, and any suitable number of positions may be employed as desired.

Plunger 23 is elongate, as shown, and includes flat sides 32 which enable it freely to slide axially in slot 26. The plunger 23 has an upper threaded segment 33 which together with segments 27 form an arcuate thread on which member 22 is carried. However, when the device is in the dose dispensing mode where segments 29 are free of segments 27, segment 33 remains meshed with a segment 29 of the member 22, whereby forward movement of member 22 towards the fixed stop ring 25 carries the plunger 23 forward, to ensure that the correct measured dose is dispensed. The forward end 34 of the plunger 23 acts on the piston 18, to move the piston 18 within cartridge 17 and dispense the required dose.

When the member 22 is pushed forward to hit the stop ring 25, the member 22 will be in one of four rotational positions spaced by 90° (or some other number for different configurations). In order to pick up the threads on member 21 at each of the four possible positions of member 22 at the stop ring, the

thread helix should have a like number of starts as possible positions, and the threaded segment 33 of plunger 23 must have the same thread pitch. Therefore, in the preferred case of four possible positions spaced by 90°, a four start thread form should be used; and each 90° turn on the member 22 will move it a pre-set axial distance corresponding to one dose for the cartridge 17, on moving the piston 18 the same distance.

The front end 30 of shell 11 includes threads 44 into which connector 12 (which is part of member 21) is permanently screwed via its threads 45. Alternatively, the threads 45 may be omitted, the connector 12 being secured in place by other means, such as an adhesive.

To provide a visual indication of a dose set by winding member 22 away from the stop ring 25, the device includes a cylindrical shell 49 having a number of splines 51. These splines 51 mesh with and rotatably drive splines 52 on a rotating indicator sleeve 53, whilst allowing relative axial movement therebetween. Any suitable number of splines may be provided, and typically 2, 4, 6 or 8 splines may be furnished.

Indicator sleeve 53 surrounds with clearance member 22, and has on its outer surface a helical thread 54 which corresponds to and meshes with thread 44 at the front end 30 of shell 11. These threads have the same lead as the threads of the members 21 and 22, such that one full turn of sleeve 53 gives the same axial movement as one turn of member 22. Carried on the outer surface of the indicator are a multiplicity of numbers such as 0 to 52 in steps of 2 (i.e. 0, 2, 4, 6, etc. up to 52), or 0 to 26 in steps of 1 (i.e. 0, 1, 2, 3 etc. up to 26). Those numbers can be viewed through a window 57 in the shell 11.

Indicator sleeve 53 at its end most remote from

container 14 is prevented from moving beyond the position at which it indicates the highest reading (say 52 or 26) through window 57 by the bottoming of the splines 51 and 52 in the shell 49 and indicator 53, respectively. Ring 58 is part of shell 49 and acts both as a stop for rearward movement of sleeve 53, and as a mounting for a rotatable end piece 59 which provides a dose setting control knob. End piece 59 is held on shell 49 by a retention lip 60, and splines 61 on end piece 59 engage splines 62 on shell 49 (as shown in Figures 2A and 2B), whereby a required dose can be set to appear in window 57 by gripping end piece 59 between finger and thumb and rotating it. The turning movement is transmitted via spines 51 and 52 to indicator sleeve 53, to move the shell 53 on threads 54 and 55 either towards the front end of the device or away from that end, to show various dose numbers through window 57. The extent of forward movement towards the front end (zero reading) is limited by member 22 engaging stop 25.

At its end most remote from container 14, sleeve 53 includes a ring 63 (Figure 2) on which are formed two or preferably four sprung raised blocks 64, through other numbers of such blocks could be provided. The ring 63 includes a central circular through-aperture 65 which carries stem 66 of a pusher including an outer button 68 for performing actual dose dispensing when pushed to move stem 66 towards the front end of the device 10. The sprung blocks 64 may cooperate with four recesses 69 on the outer face 70 of member 22. There are the same number of recesses 69 on the face 70 as thread starts - namely four, at 90^{o} spacings in the case of a four-start thread, as illustrated.

A ball 80 is positioned in an opening in the end face of the cylindrical shell 49, which ball is urged rearwardly by spring blade 81 and may be partially

received in a recess 82 in lip 83 of the outer shell 11. For the described embodiment, four equi-spaced recesses are provided, to give four click-stop positions on each dose-setting turn of end piece 59.

In use, a fresh cartridge 17 containing a fluid to be dispensed (for example, insulin) is placed in container 14, and the container is connected to the device 10 via the threaded connector 12 of member 21. The captive piston 18 is of a sufficiently tight fit in cartridge 17 so that as the container is fitted, the piston bears on the front end 34 of plunger 23 and slides the plunger back in slot 26. Alternatively, plunger 23 may be pushed back by hand. To the front end of the container 14, at the outlet to cartridge 17, there is attached a needle arrangement 71, usually with a safety cap in place (not shown). Also, an additional or alternative safety cap 72 may cover the combination of needle arrangement and container.

For the purpose of dispensing a measured dose the device is set to dose zero by winding end piece 59 clockwise until indicator 53 is wound forward sufficiently to indicate "0" through window 57. In that configuration, blocks 64 engage with recesses 69 of face 70 and button 68 abuts or is closely adjacent end piece 59.

If a dose had fully been dispensed beforehand, member 22 rests on ring 25, whilst sleeve 53 still shows the set dose. The sleeve is wound clockwise by turning end piece 59, which drives the sleeve through splines 51 and 52, advancing the sleeve towards the front. As the blocks 64 protrude by a lesser dimension than the axial motion of member 22 when turned through 90°, re-engagement of the blocks 64 in recesses 69 takes place during the last 90° of movement of sleeve 53 to show "0" through window 57, so re-establishing a connection between member 22 and sleeve 53.

If the dose had not fully been dispensed, turning the end piece 59 will pick up member 22, and thread it forward before the sleeve 53 is reset to "0" by the action of the blocks 64 engaging in recesses 69.

When the member 22 bears on ring 25 and the blocks 64 are engaged in recesses 69, end piece 59 can be turned anti-clockwise to set a new dose to be dispensed.

Dose control knob (end piece 59) is turned anti-clockwise, this motion being transmitted to shell 49 through splines 61. Then, via splines 51 and 52, the dose indicator sleeve 53 is moved helically within the main body shell 11. The pitch on the threads 44 and 54 are the same as the lead on the four-start threads on the members 21 and 22 and plunger 23, and as the sleeve 53 rotates, it moves axially with member 22 and shows successive numbers corresponding to the dose being set by member 22. The numbers are arranged in staggered columns as shown in Figure 2 so that for each dose indicated the member 22 is set with its threaded segments 29 aligned with channels 28 and spaced from the fixed stop ring 25 by such a distance that corresponding movement of the piston 18 transmitted via the front end 34 of plunger 23 dispenses the indicated dose through the needle 13. Member 22 is then thrust forward by pressing button 68, stem 66 bearing on face 70 of member 22.

Referring now to Figures 3A and 3B, these show the arrangement of the two threaded members 21 and 22 and plunger 23 with threaded segment 33. In Figure 3A, member 22 is wound back on member 21 and plunger 23 to the position shown. Figure 3B shows the position of plunger 23 when member 22 is pushed forward by button 68 (not shown). This shows that the forward movement of member 22 gives an equivalent forward movement of plunger 23. The members and plunger are shown in

Figure 4A with member 22 sectioned and displaced from fixed member 21 and plunger 23, for clarity.

In the alternative arrangement shown in Figures 3C and 3D, the threaded segment 33 of member 23 is replaced by a toothed wheel 73 having a helically-formed teeth the pitch of which is the same as that of the threads on member 21. In the base of slot 26 of member 21 is a section of thread which is the same pitch form as the threads on members 21 and 22. In Figure 3C, member 22 is shown wound back on member 21 and wheel 73; in Figure 3D member 22 is shown pushed forward. Because wheel 73 rolls between the moving thread 29 of member 22 and the fixed thread 74 of member 21, the plunger 23 is moved forward half the distance travelled by member 22. Thus for the same dose setting arrangement as already described above, either half doses may be dispensed for each dose setting or, more importantly, if a larger (usually wider) cartridge is employed, similar doses to those of narrower cartridges can be dispensed by halving the forward movement of the plunger.

Figures 5A and 5B show a stop arrangement for the second member 22, to prevent that member being turned to select a greater dose than remains for dispensing within the container. The member 22 has four pawls 76 arranged on its front end and which bear on the outer surface of the first member 21 or on the upper surface of the plunger 23, as the member 22 is rotated. The plunger has a recess 75 on its upper surface adjacent its threaded segment 33, into which recess one of the pawls 76 will drop to restrain further rotation of the member 22 in a dose-setting sense when the plunger has been advanced by a pre-determined distance into a container. The splines 61 connecting the end piece 59 to member 22 may be arranged to slip in the event that a pawl 76 locks member 22; once this occurs, member 22

has to be wound back through 45° to release the lock, so that the plunger 23 can be pushed back without also pushing back member 22. Should however member 22 be pushed back as well on replacing cartridge 17, the user need merely wind the member 22 until "0" is showing once more through window 57, to reset the mechanism. It will be appreciated that at the point at which the lock occurs the dose indicator sleeve 53 will show the number of doses remaining in the cartridge.

CLAIMS

1. A device for dispensing controlled doses of fluid from a container having a piston movable axially in increments thereby to dispense doses of fluid from an outlet of the container, which device comprises means to connect the device to a container, a plunger engageable with the container piston, and a dose setting and dispensing arrangement having first and second threaded members, the first member being fixed in relation to the device and the second member being mounted for rotation about the first member and having threads engageable with those of the first member, the plunger being slidably mounted within the first member and having a portion engageable with the threads of the second member, and the second member being rotatable to any one of a plurality of settings where its threads are engaged with said portion of the plunger but free of the first member whereby the second member and plunger may slide axially relative to the first member, movement of the second member in a direction towards the container connection means being limited by a fixed stop, the device further comprising dosage indicator means connected to the second member and arranged to indicate an ascending series of measured doses as the second member is rotated to move along the threads of the first member away from said fixed stop whilst the plunger remains stationary, and for each indicated dose the second member is disposed in one of its said settings relative to the first member where axial movement of the second member is permitted, the second member during such movement driving the plunger to act on the piston of a connected container and the dose expelled thereby being controlled by the axial distance of travel of the second member to the fixed stop from

the position to which said member has been turned to indicate a desired dose.

2. A device according to claim 1, configured as the dose dispensing portion of a medical syringe, which device is adapted for connection to the body of the syringe, with the plunger acting on the syringe piston.

3. A device according to any of the preceding claims, wherein the first member is threaded externally with a plurality of equi-spaced threaded arcuate sectors separated by a like plurality of non-threaded sectors, and the second member comprises a hollow cylinder threaded internally with threaded and non-threaded sectors arranged in essentially the same configuration as that of the first member.

4. A device according to claim 3, wherein the first and second members each have four threaded and four non-threaded sectors, and the threads of both members are four-start threads.

5. A device according to claim 3 or claim 4, wherein the plunger is slidably received within a slot in the first member, said portion of the plunger projecting through a non-threaded sector of the first member to be engageable with the threads of the second member.

6. A device according to any of the preceding claims, wherein said portion of the plunger comprises one of an arcuate threaded portion or a toothed wheel rotatably mounted on the plunger whereby the threads of the second member may mesh with the teeth of the wheel.

7. A device according to claim 6 and wherein said plunger portion comprises a toothed wheel, there being a rack formed on a fixed part of the device and with which the toothed wheel meshes, so that the wheel rotates on axial movement of the plunger.

8. A device according to any of the preceding claims, which includes an actuation member at its end opposed to the container connection means and arranged to move

the second member and linked plunger axially towards the fixed stop, the actuation member moving with the second member away from the fixed stop during dose setting.

9. A device according to any of the preceding claims, wherein the indicator means comprises a rotatable sleeve surrounding the second member and carrying a series of dose numbers, and rotation means to rotate the sleeve and the second member so that the more the second member is threaded away from the fixed stop, the higher will be the indicated dose number.

10. A device according to claim 9, wherein co-operating threads are formed on the sleeve and on a fixed part of the device whereby the sleeve is moved axially as it is rotated.

11. A device according to any of claims 8 to 10, wherein there is provided a rotatable dose-setting piece linked through a sliding connector to the indicator means and the second member to effect rotation thereof whilst permitting axial movement of the indicator means and second member.

12. A device according to any of the preceding claims, wherein lock means are provided to restrain rotation of the second member in a sense which moves the second member away from the fixed stop when the plunger projects from the second member by more than a pre-determined amount.

13. A medication dispensing device comprising a body defining a chamber for receiving a container for fluid, support means for a dispensing needle communicating with an outlet from the container, and a dispensing device according to any of claims 1 to 12, the body having connection means interengageable with the connection means of said device and the plunger of the device being arranged to contact the piston of a received container.

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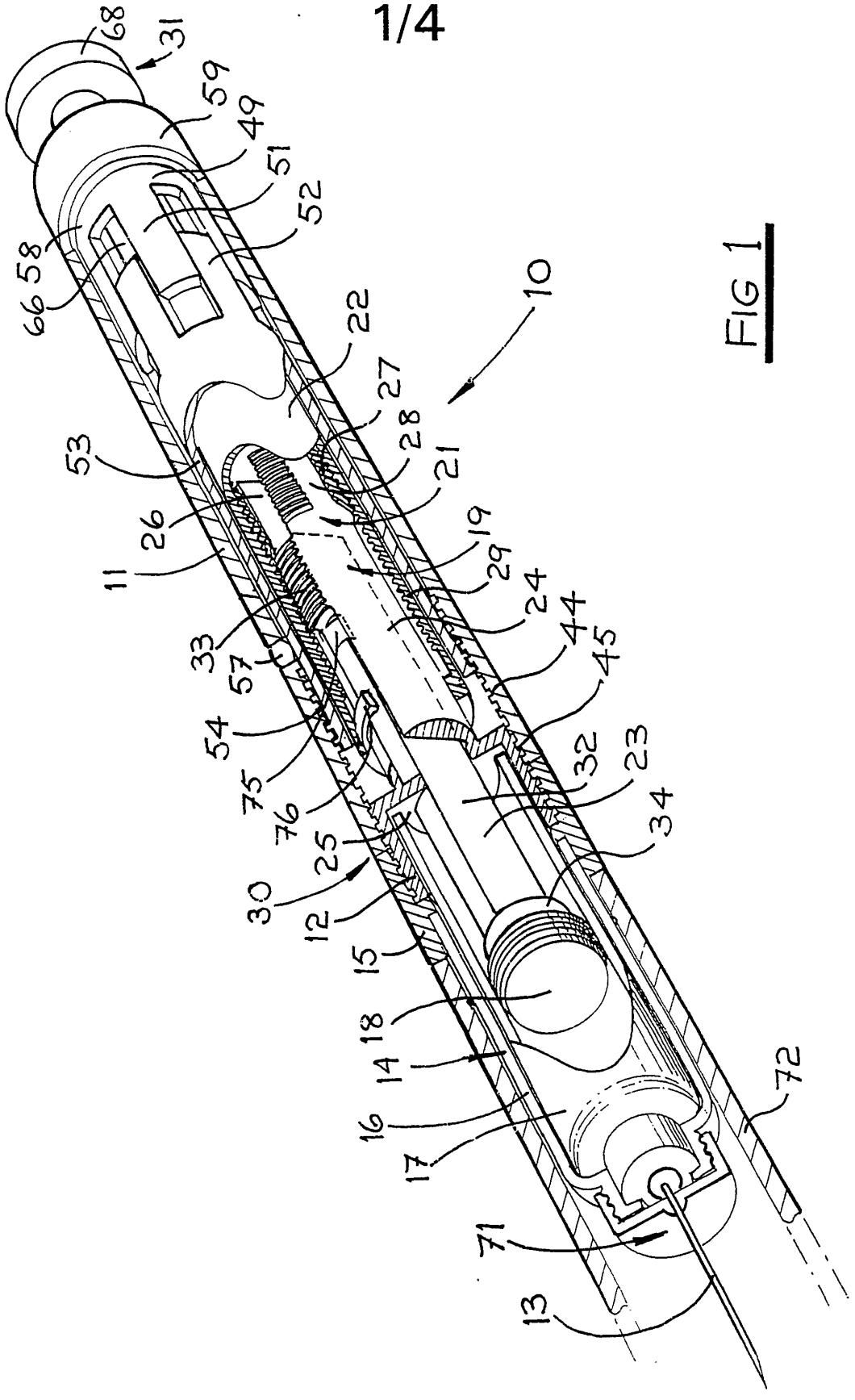
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FIG 1

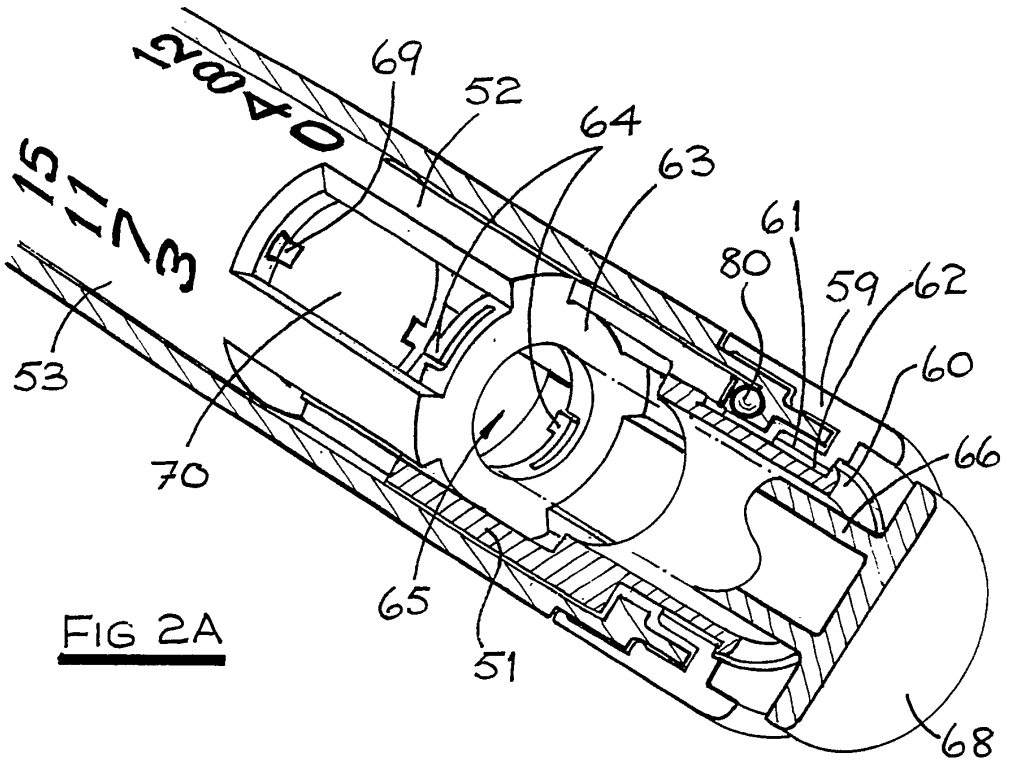
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FIG 2A

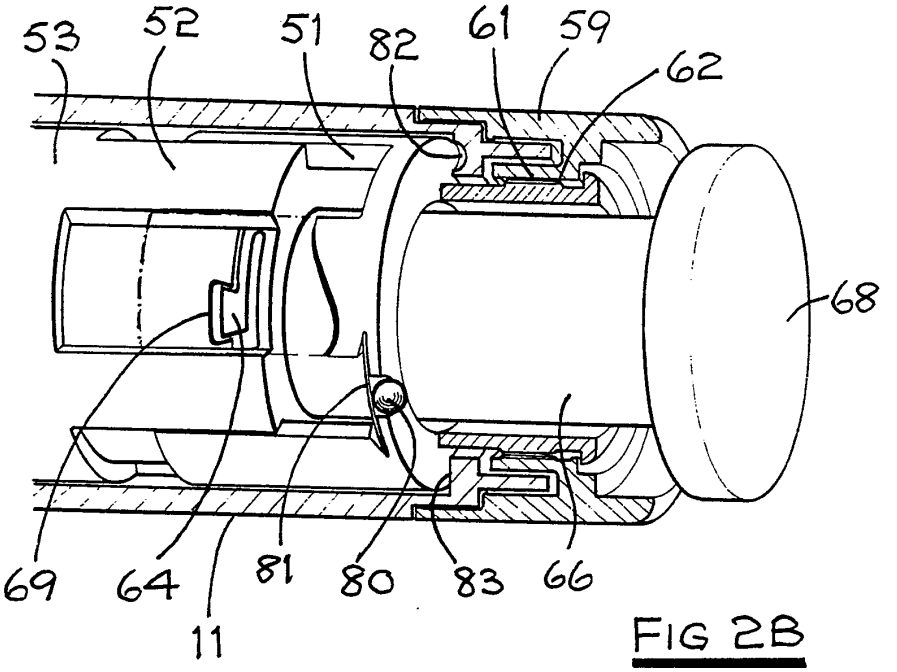
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FIG 2B

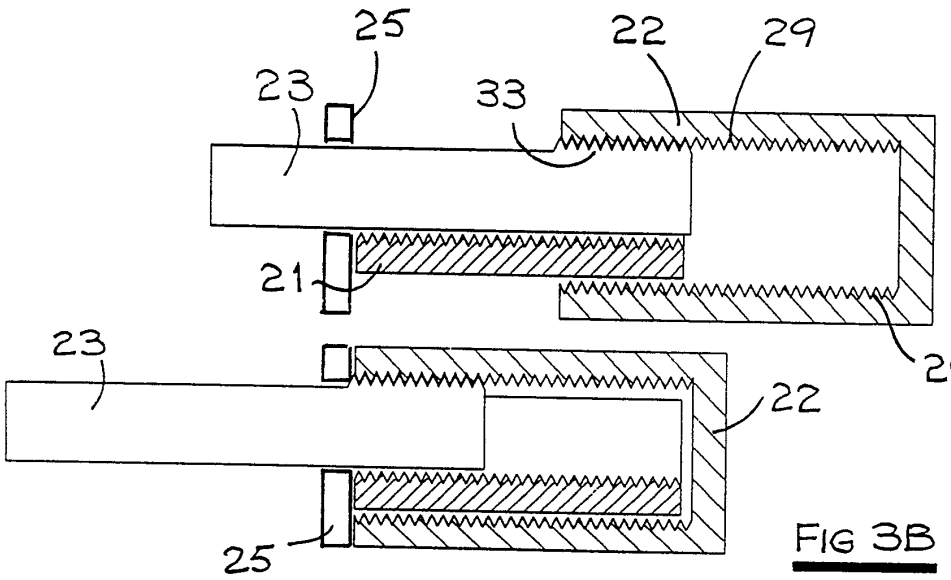

FIG 3A

FIG 3B

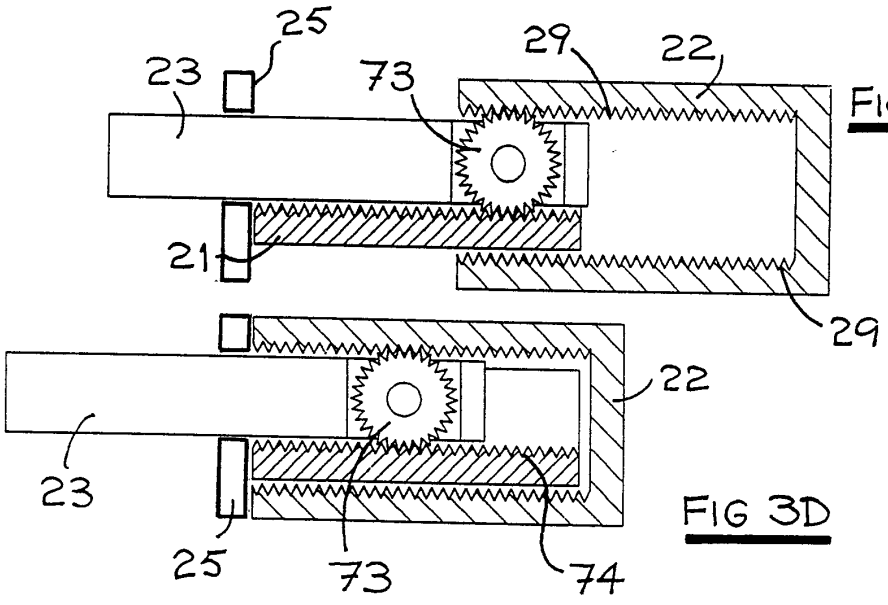

FIG 3C

FIG 3D

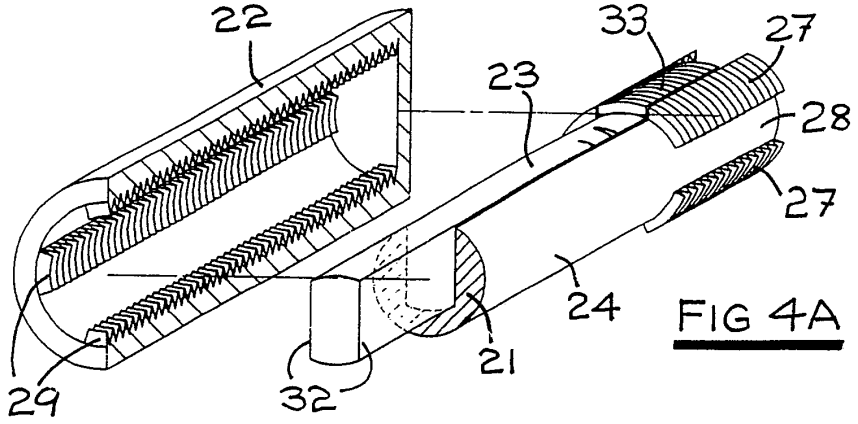

FIG 4A

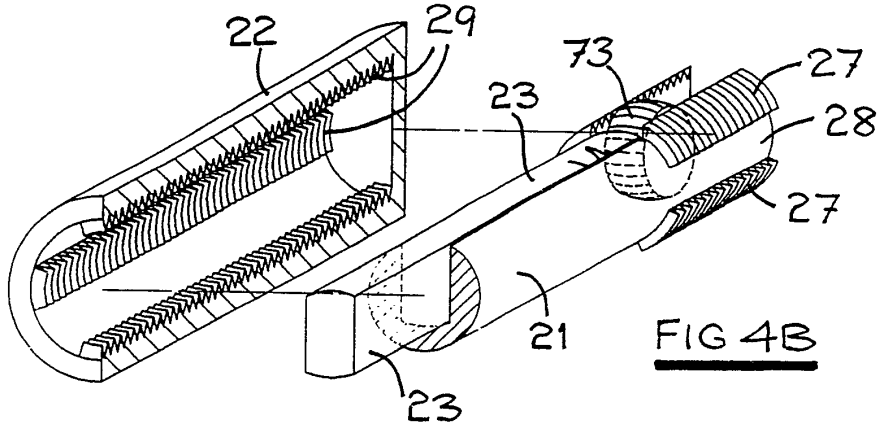

FIG 4B

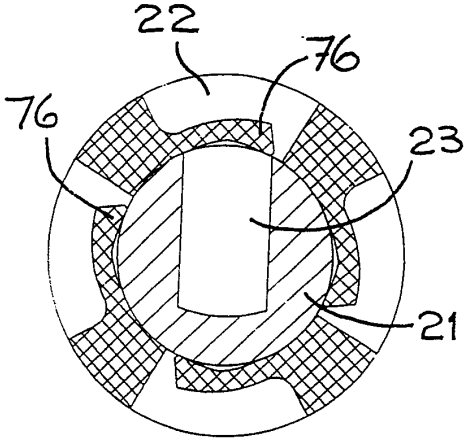

FIG 5A

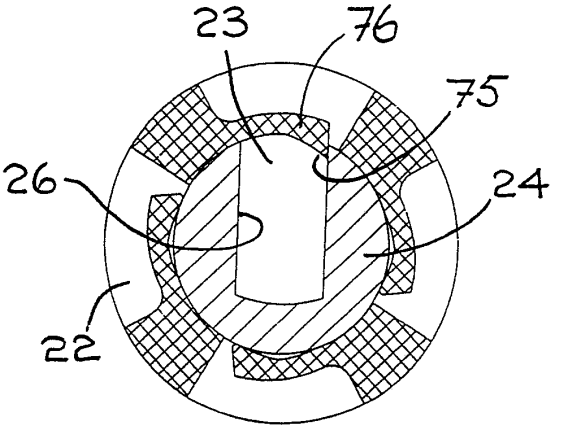

FIG 5B

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 91/00489

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M5/315

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	WO,A,8 907 463 (HOLM ET AL.) August 24, 1989 see page 1, line 5 - line 21 see page 2, line 21 - page 3, line 25 see page 4, line 4 - line 14 see page 9, line 2 - page 10, line 21 see abstract; claims 1-4; figures 1-5	1,2,6,8, 9,12,13
A	DE,A,3 840 000 (NOSTA AG) July 27, 1989 see abstract; claim 1; figure 1	1

° Special categories of cited documents : [10]

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"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
21 JUNE 1991	10 JUL 1991
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	GIMENEZ BURGOS R.

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 91/00489

SA 46113

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 21/06/91
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-8907463	24-08-89	AU-A- 3066689	06-09-89
		EP-A- 0327910	16-08-89
		US-A- 4973318	27-11-90
DE-A-3840000	27-07-89	CH-A- 675078	31-08-90

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:	WO 93/07922
A61M 5/315, 5/24	A1	(43) International Publication Date:	29 April 1993 (29.04.93)

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(74) Common Representative: NOVO NORDISK A/S; Patent Department, EiT, Novo Allé, DK-2880 Bagsvaerd (DK).

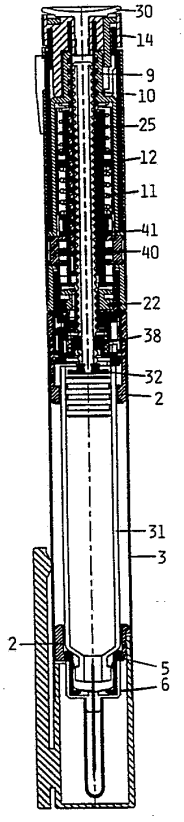
(81) Designated States: AU, BB, BG, BR, CA, CS, FI, HU, JP, KP, KR, LK, MG, MN, MW, NO, PL, RO, RU, SD, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).

Published
With international search report.

(54) Title: LARGE DOSE PEN

(57) Abstract

A pen shaped syringe for repetitive injection of individually set doses of a medicine from a cylinder ampoule reservoir comprises a dose setting member (10, 14, 15) which may be rotated to cause a rotative movement of a dosing member (18) and a combined rotative and axial movement of an indicator member (15) indicating the set dose, and a piston drive member (22) which when rotated in one direction moves the piston into the cylinder ampoule. A unidirectional coupling is established between the dosing member (18) and the piston drive member (22) by each member carrying a disc (20 and 21, respectively) having surfaces with sector shaped saw teeth riding over each other when the dosing member (18) is rotated in the dose setting direction and engaging each other when the dosing member (18) is rotated in the opposite direction corresponding to the direction of rotation by which the piston is moved into the cylinder ampoule. A nut/screw connection (9, 10) is established between a syringe housing (8) and the dose setting member (10, 14, 15), and means (13, 40) are provided to release the unidirectional coupling (20, 21) between the piston drive member (22) and the dosing member (18) by drawing the coupling discs (20, 21) away from each other.



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LARGE DOSE PEN

The invention relates to a pen shaped syringe for repetitive injection of individually set doses of a medicine from a reservoir in the syringe.

Such pen syringes are especially used by diabetics who have to inject themselves frequently with an insulin preparation to keep their blood glucose level within tolerable limits.

With the appearance of insulin preparations having a retarded action and of mixed preparations which make it possible to inject at the same time a preparation meeting an immediate need for insulin and a preparation covering the basic need for a long time, the time between injections is increased and so are the doses administered at each injection.

The doses are mainly set by rotating part of the pen syringe relatively to the rest of the syringe and numbers forming a scale along an edge of the one rotatable part of the syringe are moved in relation to an indicating mark on the rest of the syringe to indicate the set dose. Hereby the dose is limited by the fact that only a limited number of numbers can be placed along the edge of the rotatable part if they shall be readable at all. This problem is overcome by imparting the rotatable part an axial displacement concurrently with its rotation whereby instead of a circle a helical line becomes available for dose indicating numbers and even a scale covering rotation in excess of one turn.

The pen syringe should be as simple as possible to use, i.e. the normal use should only imply setting a dose and injecting the set dose, and both these steps should be simple to perform and this condition is met by most pen syringes. However, not all pen syringes offer the opportunity to cancel a set dose, so if a dose once set is not wanted for injection the only way to bring the syringe back in its neutral position is to spill the dose. With syringes by which large doses may be set this is not acceptable.

By a known type of syringe the scale is arranged along a helix having just one turn. A helical recess in a cylinder surface of a dose setting member is engaged by a pin on the syringe housing so that the dose setting member when rotated is axially displaced along its axis. After having been axially displaced by the

setting of a dose, the dose setting member is pressed home to inject the dose. The engagement between the pin and the helical recess will cause a rotation of the dose setting member when it is axially pressed home, this rotation being in the opposite direction of the rotation for setting the dose. The rotation of the dose setting member is transferred to a screw/nut mechanism driving a piston in the syringe forward a distance proportional to the rotation.

The ends of the one turn helical recess are connected by an axial recess. This enables the setting member to be pressed axially back without imparting a rotary movement to this member if the rotary position of the member is so that the pin on the syringe housing engages the axial recess instead of the helical part of the recess. In this way a set dose may be cancelled by turning the dose setting member further until the pin engages the axial recess. However, this cancelling feature limits the effective dose setting rotation of the dose setting member to a little less than one turn, and further, as the demands for precision of the injected dose set a limit to the size of the dose per turning of the screw/nut mechanism, the size of the possible set dose is heavily restricted.

Consequently, it is the object of the invention to provide a pen syringe by which large doses may be set, a set dose may be cancelled, and the possibility of cancellation does not influence the possible size of a set dose or the simplicity of the normal use of the syringe.

This is obtained by a pen shaped syringe for repetitive injection of individually set doses of a medicine from a cylinder ampoule reservoir, comprising a dose setting member which may be rotated to cause a rotative movement of a dosing member and a combined rotative and axial movement of an indicator member indicating the set dose, a piston drive member which when rotated in one direction moves the piston into the cylinder ampoule, a unidirectional coupling between the dosing member and the piston drive member, the coupling being so directed that a dose setting rotation of the dosing member is not transferred to the piston drive whereas a rotation in the opposite direction is, this syringe being characterized in, that a nut/screw connection is established between a syringe housing and the dose setting member, and that means are provided to release the unidirectional coupling between the piston drive member and the dosing member.

The nut/screw connection provides by mutual engaging threads a more stable guidance of the dose setting member than does a pin engaging a recess. As the cancelling mechanism is not based on an axial recess as a return path, the dosing rotation of the dose setting member may be performed for more than one turn, and thereby it is permitted to set a larger dose than the one which can be provided by rotating the piston drive one turn. The cancelling mechanism is realized as a coupling which may disconnect the dosing member from the piston drive, so that the dose setting member and the dosing member may be rotated back without the rotation being transmitted to the piston drive.

The thread of the screw/nut connection of the dosing member and the housing may have a pitch angle exceeding the friction angle of the nut and screw. Thereby the dosing rotation of the dose setting member may be obtained by simply pressing this member axially back, whereby the screw will automatically screw itself through the nut and provide a rotative movement of the dose setting member in the dosing direction. This automatic dosing screw function may more easily be obtained if the outer end of the dosing member is terminated by a knob wherein a press button is journaled, the button and the knob having mutually abutting surfaces made of materials having a friction angle lower than the friction angle of the nut/screw connection.

According to an embodiment of the invention, the dose setting member may comprise a threaded spindle, the dosing member may be tubular and fit over this spindle, and the spindle may have axial recesses engaged by corresponding axial beams on the inner side of the bore of the dosing member. Thereby a dosing member is provided which will follow rotary but not axial movements of the dose setting member.

The unidirectional coupling between the dosing member and the piston drive may be provided by coupling parts having circular surfaces provided with sector shaped teeth having an abrupt and a ramp shaped edge, the surfaces by a spring being forced against each other with the ramp shaped edge of the teeth on one surface abutting the ramp shaped edge of the teeth on the other surface. When the dose setting member is rotated in the dose setting direction, the teeth on the coupling parts will slide with their ramp shaped parts over each other, whereby the

dosing member is axially displaced against the force of the spring and will jump back each time an abrupt edge of the teeth is reached. Each jump back may be heard and sensed by the operator, and the pitch of the toothing may be chosen so that a jump back takes place each time the dose setting is increased by say one unit.

The coupling mechanism may be provided by the syringe having a tubular basic element, a tubular element surrounding the basic element coaxially with it and axially displaceable in relation thereto against the force of a spring forcing the tubular element to a fixed position on the basic element, and a lifting fork carried by the tubular element and engaging an outer annual projection on the dosing member to lift the coupling part thereof out of engagement with the coupling part of the piston drive when the tubular member is axially displaced on the basic element against the force of the spring away form its fixed position.

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

Figure 1 is a sectional side view of a pen shaped syringe according to the invention,

Figure 2 is an enlarged view of the part of the syringe in Figure 1 containing the dosing mechanism,

Figure 3 shows a cross section along the line III-III in Figure 2,

Figure 4 shows a side view of the pen syringe in Figure 1 separated into a part comprising the dosing mechanism, a cartridge holder, and a cap,

Figure 5 shows the syringe in Figure 4 put together,

Figure 6 shows a side view of the syringe with the cap removed and the dosing mechanism part and the cartridge holder drawn away from each other to allow a cancelling of a set dose, and

Figure 7 shows schematically the coupling discs of a unidirectional coupling.

The pen syringe shown in Figs. 1-6 is built up around a tubular basic member 1 having at its one end a part 42 with enlarged diameter, this part by an

annular projection being divided into two, a first part being provided with a thread onto which a cartridge holder 2 may be screwed and a second part receiving a tubular member 8. The cartridge holder 2 comprises a tubular element designed to accommodate a cartridge and having in its side walls axially extending openings through which the contents of the cartridge may be inspected. Along one of the openings a recessed part 4 of the side wall is provided with a scale showing the available amount of medicine, here as the number of international units of insulin. At its distal end the cartridge holder 2 is provided with not seen protrusions protruding inwardly from the cartridge holder wall to hold back the cartridge in the holder and cooperating with an adapter top 5 on the neck part of the cartridge. This adaptor top 5 protrudes from the end of the cartridge holder 2 and is provided with an outer thread onto which a needle hub 6 is screwed to secure the cartridge in the holder 2. A tubular protective cap 3 may be passed over the cartridge holder 2 when the syringe is not in use.

The tubular member 8 fits with its one end over the second part of the enlarged diameter part 42 of the one end of the basic member 1 and abuts with its edge against the annular projection 7. The other end of the tubular member 8 has a reduced diameter and fits over the basic member 1 and is at its outer end surmounted by a part 9 having a further reduced diameter and carrying an internal thread in engagement with an outer thread on a tubular spindle 10.

A spring 11 abutting at its one end an annular internal projection 12 in the bore of the basic member 1 and pressing at its other end against a bushing 41 transferring the pressure to a set of lifting forks 13, the function of which will be described below, and which forks 13 carried guidingly in openings spaced along the perimeter of the member 8 transfer the pressure to the member 8 keeping the edge thereof in abutment with the projection 7 on the basic member 1. Through slots 43 in the wall of the tubular basic member 1 the lifting forks 13 project into the bore of the basic member and may be displaced axially in these slots.

The spindle 10 is at its end extending beyond the part 9 secured to a dose setting knob 14 and may be rotated by rotating this knob 14. When rotated in one direction the spindle 10 and consequently the knob 14 are displaced axially away from the tubular member 8.

An indicating sleeve 15 is secured to the knob 14 and forms a skirt dependent from the knob 14 and being accommodated in the space between the member 8 and a tubular housing 16 mounted on the large diameter part of this member 8. A window in the tubular housing 16 is provided with a magnifying glass 17, through which the sleeve 15 may be inspected along a helical line, when it is rotated and simultaneously axially displaced along with the knob 14. Numbers indicating a set dose are printed along the helical line to show the actual dose through the magnifying glass 17.

Rotation of the spindle 10 is transferred to a tubular dosing member 18 fitting over the thread of the spindle 10. The transmission is accomplished by the spindle 10 having one or more axial recesses in its thread engaged by axial beams 19 on the inner surface of the dosing member 18. Thereby rotative motion is transferred whereas axial motion is not.

At its end opposite the knob 14 the dosing member 18 forms a part 20 of a unidirectional coupling through which the member 18 is coupled to a piston drive comprising a coupling part 21 and a drive nut 22 having an internal thread engaging an external thread on a piston rod 23 which is in its retracted position accommodated in the bore of the tubular spindle 10 and which is made unrotatable relatively to the basic member 1 by locking projections 24, which are mounted unrotatably in relation to the basic member 1 and engage axial slots in the thread of the piston rod 23.

The unidirectional coupling is provided by the dosing member 18 and the piston drive nut 22 having disc shaped coupling parts 20 and 21, respectively, having at the surfaces facing each other teeth each forming a part of a sector and each having a ramp shaped and an abrupt edge. These discs are shown schematically in Figure 7. The toothed surfaces are urged against each other by a spring 25 compressed between a shoulder 26 at the upper end of the tubular member 8 and an outward flange 27 at one end of a bushing 28 having at its other end an inward flange 29 abutting the upper edge of the dosing member. When the dosing member is rotated in the direction by which the knob is screwed outwardly, the ramp shaped edges slide along each other displacing the coupling members away from each other against the force of the spring 25 until the abrupt edge is

reached and the coupling part is displaced home by the force of the spring ready to start a new sliding along the ramp shaped parts. This overriding prevents the rotation from being transmitted to the piston drive nut 22 when the knob is rotated in the dose setting direction but is transmitted when the knob is rotated in the opposite direction, as the abrupt edges on the coupling parts will then engage each other. This rotation may be provided by pressing the knob home axially, the thread of the spindle having a pitch allowing it to transform the axial pressure to a rotation. To ease this mechanism the knob 14 is provided with a press button 30 journaled in the knob 14 with a lower surface of the button abutting an upper surface of the knob, the abutting surfaces being made of materials which ensure low friction.

The rotation is transmitted to the piston drive part 21 of the coupling and consequently to the piston drive nut 22. When the nut 22 is rotated by the transmitted rotation it will drive the unrotatable piston rod 23 in an axial direction towards the cylinder ampoule 31, and by a piston foot 32 the piston rod will press a piston 33 into the cylinder ampoule 31.

The piston drive part 21 of the coupling is at its periphery provided with resilient teeth 34 which collaborate with internal teeth 35 in a tubular member 36 rigidly mounted in the basic member 1 to provide a detent allowing rotation of the piston drive nut 22 in an injecting direction but preventing rotation of the nut 22 in the opposite direction.

The piston rod 23 is made unrotatable by having an axial recess engaged by locking projections 24 on a piston rod lock member 37. Against the force of a spring 38 this member is by the upper edge of the cylinder ampoule 31 pressed into the end of the basic member 1 in an unrotatable engagement. When cartridge holder 2 containing the cylinder ampoule 31 is dismounted by unscrewing it 3 from the basic member 1, the spring 38 will press the piston rod lock member 37 free of the basic member 1, and the piston rod may now be rotated as the lock member 37 may now rotate with it. Thereby the piston rod may be screwed back through the piston drive nut 22 to its retracted position. When the cartridge holder with a new ampoule is screwed onto the basic member 1, the lock member 37 is pressed back into its unrotatable engagement with the basic member and the piston rod is again made unrotatable.

From the functions described it is seen that a dose may be set by rotating the knob 14 in the direction causing a disengaging relative movement of the coupling parts 20 and 21. The parts 20 and 21 are appropriately toothed in a way making each of the hearable sudden displacements at the end of the ramps of a pair of teeth sliding along each other correspond to e.g. one unit. When the knob 14 is screwed home, which may be done by pressing the button 30, the rotation is transmitted to the piston drive nut 22 causing a forward movement of the piston corresponding to the set dose.

If a set dose should be cancelled it is obtained by gripping the cartridge holder 2, which is secured to the basic element 1, and the tubular housing 16, which is secured to the tubular member 8, and by drawing the cartridge holder 2 and the tubular housing 16 axially away from each other. Thereby the tubular member 8 is axially displaced in relation to the basic member 1, and the spring 11 maintaining the tubular member 8 in position on the basic member 1 is further compressed. By this displacement the lifting forks 13 inserted in openings in the tubular member 8 are displaced until the lower one of their prongs 39 extending inwardly through slots in the basic member 1 abuts an annular projection 40 on the dosing member 18. A further displacement against the force of the spring 11 will displace the dosing member 18 against the force of the spring 25 and bring the coupling parts 20 and 21 out of their mutual engagement. Now the dosing part can freely be rotated without the rotation being transmitted to the piston drive nut, and consequently a set dose may be cancelled by turning the dose setting knob 14 back to its initial position, possibly by pressing it home.

When released the member 8 will by the spring 11 be pressed back into its original position, and the dosing member 18 will be moved back by the spring 25 to its nut driving position.

CLAIMS

1. A pen shaped syringe for repetitive injection of individually set doses of a medicine from a cylinder ampoule reservoir, comprising a dose setting member (10,14,15) which may be rotated to cause a rotative movement of a dosing member (18) and a combined rotative and axial movement of an indicator member (15) indicating the set dose, a piston drive member (22) which when rotated in one direction moves the piston into the cylinder ampoule, a unidirectional coupling between the dosing member (18) and the piston drive member (22), the coupling being so directed that a dose setting rotation of the dosing member (18) is not transferred to the piston drive, whereas a rotation in the opposite direction is, characterized in, that a nut/screw connection (9,10) is established between a syringe housing (8) and the dose setting member (10,14,15), and that means (13,40) are provided to release the unidirectional coupling (20,21) between the piston drive member (22) and the dosing member (18).

2. A syringe according to claim 1, characterized in, that the thread of the nut/screw connection (9,10) has a pitch angle exceeding the friction angle of the nut and screw.

3. A syringe according to claim 2, characterized in, that the outer end of the dose setting member (10,14,15) is terminated by a knob (10) wherein a press button (30) is journaled, the button (30) and the knob (10) having mutually abutting surfaces made of materials having a friction angle lower than the friction angle of the nut/screw connection (9,10).

4. A syringe according to claim 1, 2 or 3, characterized in, that the dose setting member (10,14,15) comprises a threaded spindle (10), that the dosing member (18) is tubular and fits over this spindle (10), that the spindle (10) has axial recesses engaged by corresponding axial beams (19) on the inner side of the bore of the dosing member (18).

5. A syringe according to claim 4, characterized in, that the unidirectional coupling between the dosing member (18) and the piston drive (22) is provided by coupling parts (20,21) having circular surfaces provided with sector shaped teeth having an abrupt and a ramp shaped edge, the surfaces being by a spring (25) forced against each other with the ramp shaped edge of the teeth on one surface abutting the ramp shaped edge of the teeth on the other surface.

6. A syringe according to claim 5, characterized in, that it comprises a tubular basic element (1), a tubular member (8) surrounding the basic element (1) coaxially and being axially displaceable in relation thereto against the force of a spring (11) forcing the tubular member (8) to a fixed position on the basic element (1), and a lifting fork (13) carried by the tubular member (8) and engaging an outer annual projection (40) on the dosing member (18) to lift the coupling part (20) thereof out of engagement with the coupling part (21) of the piston drive (22) when the tubular member (8) is axially displaced on the basic element 1 against the force of the spring (11) away form its fixed position.

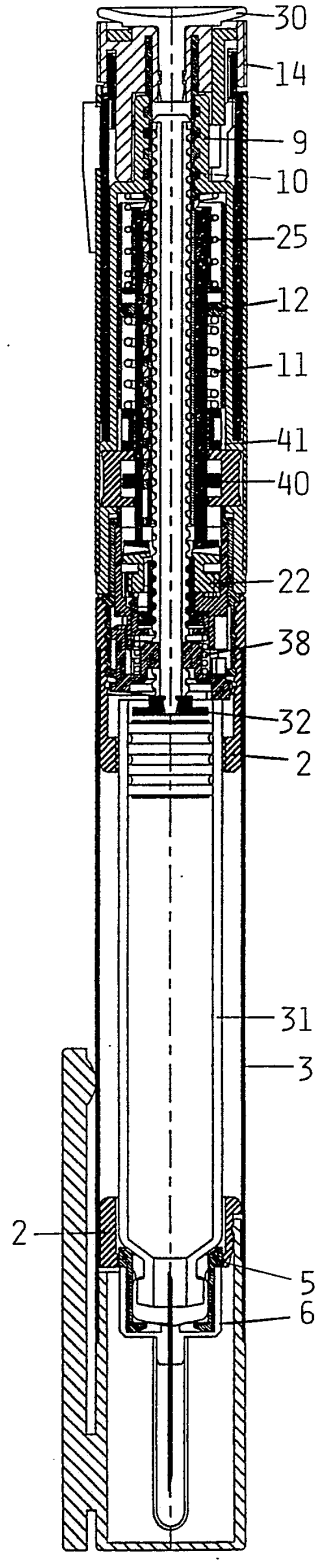
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Fig. 1

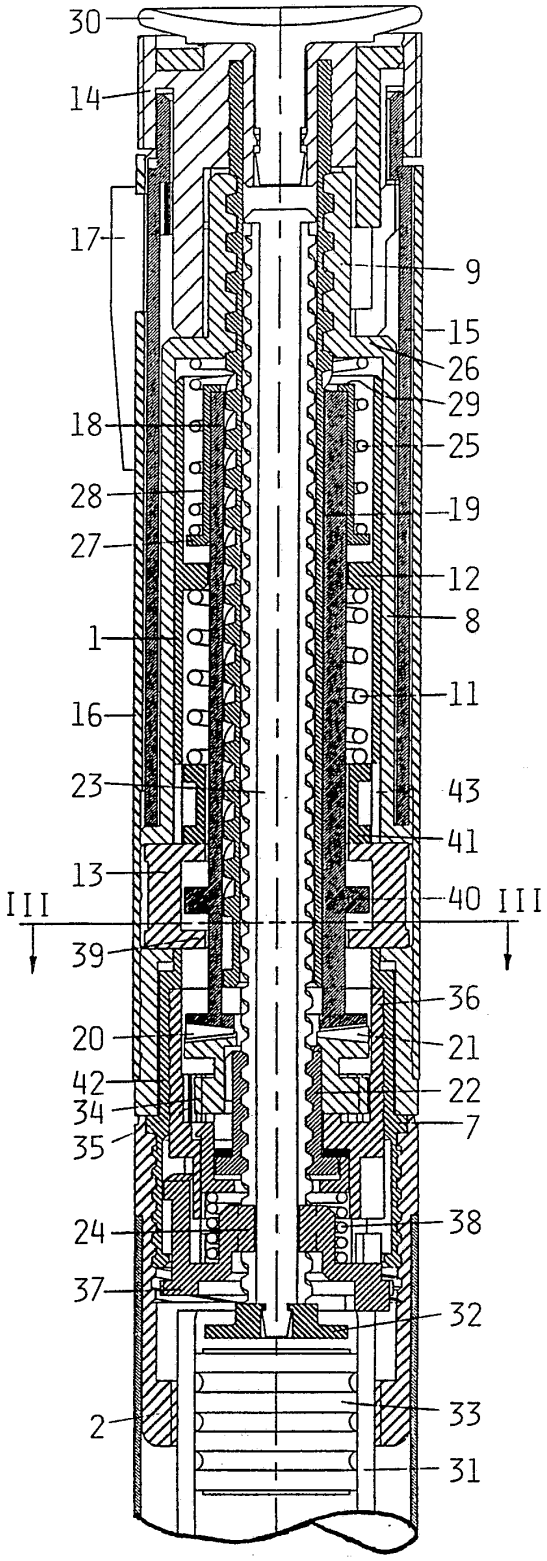
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Fig. 2

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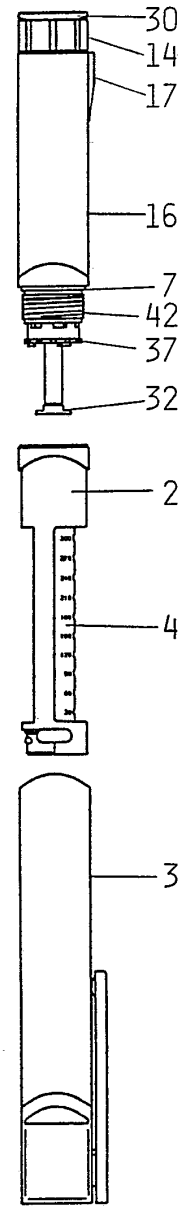

Fig. 4

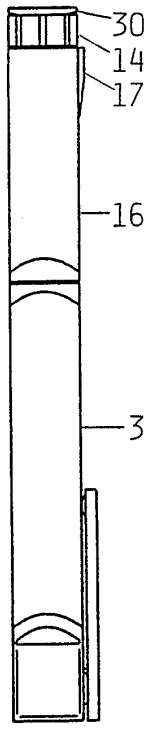

Fig. 5

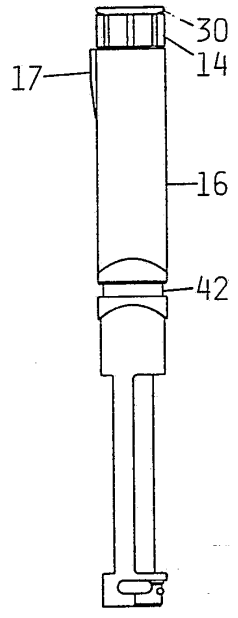

Fig. 6

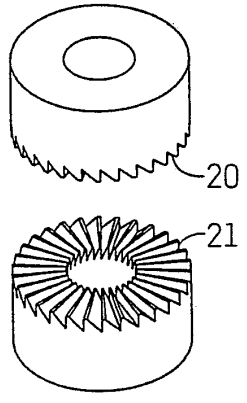

Fig. 7

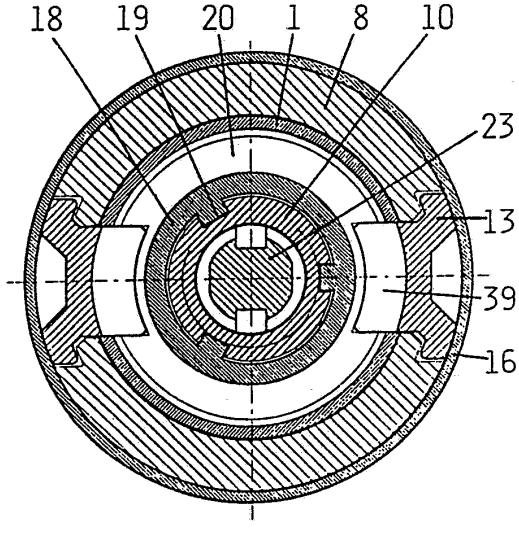

Fig. 3

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 92/00267

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 M 5/315, 5/24

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
IPC5	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched[8]

SE,DK,FI,NO classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category *	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	EP, A1, 0293572 (D.C.P. AF 1988 A/S) 7 December 1988, see the whole document --	1-6
A	EP, A2, 0327910 (D.C.P. AF 1988 A/S) 16 August 1989, see the whole document --	1-6
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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
15th January 1993	20 -01- 1993
International Searching Authority	**Signature of Authorized Officer**
SWEDISH PATENT OFFICE	May Hallne

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. PCT/DK 92/00267

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A1- 0293572	88-12-07	AU-B-	608603	91-04-11
		AU-D-	1627288	88-11-04
		JP-T-	2502883	90-09-13
		US-A-	5017190	91-05-21
		WO-A-	88/07874	88-10-20
		ZA-A-	8802334	88-09-23
EP-A2- 0327910	89-08-16	AU-D-	3066689	89-09-06
		CA-A-	1305003	92-07-14
		JP-T-	3503129	91-07-18
		US-A-	4973318	90-11-27
		WO-A-	89/07463	89-08-24
EP-A1- 0450905	91-10-09	AU-D-	7402691	91-10-10
		JP-A-	4224764	92-08-14

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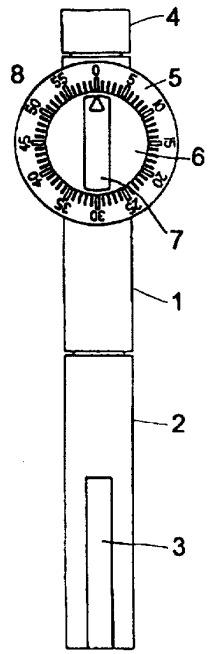
Published
With international search report.

(54) Title: DOSE DISPLAY FOR AN INJECTION SYRINGE

(57) Abstract

An injection syringe comprising a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections. The syringe has a dose setting mechanism by which doses may be set by rotating a dose setting element relative to the housing and the dose set is indicated on a scale. The scale is formed as a clock dial having a first part secured to the housing and a second part which is rotatable relative to the first part and which is coupled to the dose setting element, one of the parts carries the scale and the other carries an indicating member indicating a point on the scale. The angular distance between the divisions of the scale corresponds to the minute divisions on an ordinary clock. Holes are provided along the scale which holes can receive a pin forming a stop which cannot be passed by the indicating member.



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Dose display for an injection syringe

The invention relates to injection syringes of the kind comprising a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections, the syringe having a dose setting mechanism by which doses can be set from injection to injection by rotating a dose setting element relative to the housing the size of the set dose being indicated on a scale .

A problem by the scales is that the perimeter of the syringe sets a limit to the size of the scale and the digits on it. Especially where the syringe is used by people who has an impaired sight, as it often may be the case by diabetics, a system allowing use of larger digits on the scale is wanted. Further hints of the size of the set dose may be obtained by studying the distance a injection button is elevated from the syringe but as the elevation pro unit is very small, sometimes of the order 0.15 mm, this will only give an imprecise impression of the size of the dose set.

It is an object of the invention to provide a syringe by which these limitations are overcome.

This is obtained by a syringe of the kind mentioned in the opening of this specification, which syringe is according to the invention characterised in that the scale is formed as a clock dial having a first part secured to the housing and a second part which is rotatable relative to the first part and which is coupled to the dose setting element, one of parts carries the scale and the other carries an indicating member indicating a point on the scale.

By shaping the dose indicating means as a clock dial this dial may be made arbitrarily large and the size is only limited by the fact that the device must not be too bulky and must be acceptable from a design point of view.

The second part of the dose indicating means may be coupled to the dose setting element through a gear mechanism. This may be necessitated by the fact that the relative rotation of the dose setting means may take place about the longitudinal axis of the syringe whereas the dial is placed so that the relative rotation of the first and the second part takes place around an axis perpendicular to the longitudinal axis of the syringe, however, gear couplings may also be used in syringes wherein the dial and the dose setting means rotate about parallel axes. The geared coupling may also be used to obtain that the relative angular rotation

of the first and second part or the dose indicating means may be larger than the relative rotation of the dose setting elements.

As in egg timers a scale carrying divisions and digits may be arranged along the perimeter of the dial with a pointer on the part not carrying the divisions and the digits pointing at a point of the scale indicating the relative rotational position of the dose setting member and the housing and consequently the dose set by this rotation.

According to the invention the syringe may appropriately be of the type using a flexible piston rod to reduce the overall length of the syringe by deflecting the piston rod where it projects from the ampoule. In stead of the ordinary pen shape this type of syringes have a more parallelepiped shape with broad side walls suited as carriers of clock dials.

According to an embodiment of the invention a finger grip may be provided following a diameter on the second part of the dose indicating means, the grip being parallel with the longitudinal axis of the syringe when no dose is set. This grip may be used for setting a dose as rotation of said second part is transmitted to the rotatable dose setting element through the coupling between the second part and the dose setting element. The finger grip will conspicuously indicate whether a dose is set or not as even a small deviation from the position in the axial direction of the syringe is recognisable.

According to a further embodiment of the invention the angular distance between the divisions of the scale is 6° corresponding to the minute divisions of an ordinary clock. This makes it possible to the user to estimate the setting even when he cannot see the digits of the scale. This is due to the fact that the clock dial is so well established by most people that they can read the time on a clock dial without digits, yes indeed on a clock dial without divisions. Therefore the position of the indicating member in relation to the scale alone will let the user know the size of a set dose.

From DE 42 08 677 is known a pen shaped injection device having a dose setting mechanism which may be operated via a dose setting element. When not in use the syringe is stored in a box having a dose setting device comprising a large dial shaped scale with divisions and printings. When the syringe is stored in the box a dose may be set by operating

the dose setting device on the box and the movements of this device is via a gear mechanism transmitted to the dose setting element of the syringe.

In the device according to the invention the clearly visible dial is carried by the injection device itself so that no setting may be made which is not shown on the dial. Even the device may be so designed that the indication on the dial is successively returned to zero during the injection so that the indication on the dial currently shows the dose which remains to be injected.

The injection syringe may have means by which the setting movement of the dose setting element is limited so that an upper limit is set to the dose which can be set. If by dose setting the dose setting element is moved until it is stopped by the limit a fixed dose is set.

According to an embodiment of the injection syringe according to the invention the limit may be provided by holes provided along the scale which holes each can receive a pin forming a stop which cannot be passed by the indicating member. This makes it possible to put a limit on the dose which may be set as the second part can only be rotated until the indicating member reaches the point on the scale where a pin is inserted in the hole. The pin may be installed by the a user who mostly use the same dose at each injection. When the pin is set in the hole at the division corresponding to the dose in question, the user can set the dose by rotating the second part until the rotation is stopped because the pin reaches a stop which prevent it from passing the indicating member. Alternatively the pin may be mounted by the users physician to ensure that the user will not inject more than a limited number of units in one injection. Pins used for that purpose may be so designed that a tool is needed to install and remove them. Especially when the device is used by children it is important that an upper limit may be set for the dose which can be injected.

In the following the invention will be described in further details with references to the drawing, wherein

Figure 1 shows a pen shaped syringe with a display according to the invention,

Figure 2 shows a new designed short syringe with a display according to the invention

Figure 3 shows an embodiment of a display according to the invention, and

Figure 4 shows another embodiment of a display according to the invention.

In figure 1 is shown a pen shaped syringe comprising, a housing 1 containing a dose setting mechanism, a cap 2 protecting the needle end of the syringe which cap is provided with a clip 3 by which the syringe may be carried in a pocket like a fountain pen, and an injection button 4 which is elevated from the end of the housing 1 concurrently with the setting of a dose and which may be pressed back to abutment with the end of the housing to inject the set dose.

Further the syringe carries a display having the shape of an egg timer dial. The display comprises a scale 5 carrying equidistant marks corresponding to the marks of the minutes on an ordinary watch dial. The scale 5 is fixed to the housing 1. A pointer is established by a circular plate 6 carrying a finger grip 7 having an arrow mark 8. The circular plate 6 and the finger grip 7 forms a dose setting unit by which a dose may be set by gripping the grip 7 and rotating the plate 6 clockwise until the arrow mark points on the mark of the scale indicating the wanted dose. The plate 6 with the finger grip 7 is mounted on a not shown shaft which is journaled in the housing and through which combined with a gear mechanism the rotation of the dose setting unit is transmitted to a conventional dose setting mechanism in the housing 1. The plate 6 may be omitted so that the dose setting unit comprises only the finger grip 7.

The embodiment shown in figure 2 represents another type of syringes which due to the use of a flexible piston rod are made shorter than the pen type. The pen comprises a housing 11 containing a dose mechanism and accommodating a cartridge with a medicine to be apportioned. An injection needle 12 is mounted in a needle hub 13 which may be screwed onto the syringe. The end of the syringe carrying the needle may be covered by a not shown protection cap. The syringe has an injection button 14 which is elevated from the end of the housing 11 concurrently with the setting of a dose and which may be pressed back to abutment with the end of the housing to inject the set dose. Also in this embodiment a scale 15 is fixed on the housing and the dose is set by rotating clockwise a dose setting unit comprising a circular plate 16 carrying a finger grip 17 with an arrow mark 18 until the arrow mark point at the mark corresponding to the wanted dose. This rotation is transmitted through a not shown

shaft carrying the dose setting unit and transmitting rotation of this unit to a dose setting mechanism in the housing. The button 14 is pressed home to abutment with the housing to inject the set dose and concomitantly with the injection the dose setting unit is rotated back so that the arrow mark points at the zero mark of the scale to indicate that the full dose is delivered.

Advantage is taken of the fact that watching a clock dial is so well promoted that most people will be able to estimate the minute number by just watching the position of a mark along the periphery of a circle. By making the divisions which indicates the set number of units of the medicine to be injected correspond to the minute divisions of a clock dial, the user will be able to estimate the size of a set dose with high precision even when the dose size is not indicated by a number at each division mark. When e.g. only every fifth division mark is provided with an dose indicating number, the digit of this number may be made very large an easy readable.

To take the full advantage of this fact it is preferred that the finger grip is rotated clockwise when a dose is set. In figure 3 where a scale 19 is carried by a circular plate 20 of a dose setting unit which may be rotated by a finger grip 21 and the arrow mark 22 is fixed in relation to the housing this clockwise rotation is obtained by positioning the scale marks and the numbers of the scale in an anticlockwise fashion. This way a clockwise rotation of the dose setting unit will bring increasing numbers abreast of the arrow mark.

In figure 3 the scale has a wide mark 28 which may be pointed at by the arrow when the finger grip is rotated anticlockwise. A stop is established so that the scale only be rotated further anticlockwise until the arrow points at the mark 28. By this anticlockwise rotation a fixed small dose is set, e.g. corresponding to delivery of 10 µl of the medicine. This small dose is set before the dose to be injected is set and is pressed out by pressing the injection button. Thereby air in the ampoule or and the needle is pressed out through the needle an visual inspection of the jet at the end of the needle can reveal if the air is expelled. The setting by anticlockwise rotation of the finger grip and subsequent pressing the injection button is repeated until a jet of liquid is seen at the end of the needle. The provision of the possibility of setting a small dose by anticlockwise rotation of the finger grip may be seen as a feature easing the air shot procedure which should else be performed by repetitively setting of small doses in the conventional way by clockwise turning of the finger grip.

In figure 4 is shown another display with a scale 23 which is fixed in relation to the housing. The dial carrying the scale 23 have a central part 24 which is also fixed relative to the housing and which at every mark of the scale indicating a unit of the medicine to be injected has a hole 25 into which a not shown pin may be inserted. The dose setting unit only consist of a finger grip 26 with an arrow mark 27 which unit is carried by a not shown shaft transmitting the rotation of the unit to a dose setting mechanism. Behind the dial carrying the scale said shaft has a pointer parallel with the finger grip and pointing from the shaft in the direction of the arrow mark. When a pin is mounted in one of the holes in the dial the pointer will abut this pin when the dose setting unit is rotated and

will stop for further rotation in the dose setting direction but will allow the unit to rotate back when a set dose is injected. This way it may be ensured that a set maximum dose is not exceeded. It is further shown that the dose mark does not have to be numbered at each 5 units but e.g. only at each 15 units. In fact most designs known from egg timers and similar clocks may be used without deviating from the scope of the invention.

Claims

1. An injection syringe comprising a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections, the syringe having a dose setting mechanism by which doses may be set by rotating a dose setting element relative to the housing and the dose set being indicated on a scale, characterised in that the scale is formed as a clock dial having a first part secured to the housing and a second part which is rotatable relative to the first part and which is coupled to the dose setting element, one of parts carries the scale and the other carries an indicating member indicating a point on the scale.

2. An injection syringe according to claim 1, characterised in that the second part is coupled to the dose setting element through a gear mechanism.

3. An injection syringe according to claim 1 or 2, characterised in that the syringe is of the type using a flexible piston rod .

4. An injection syringe according to any of the claims 1, 2 or 3, characterised in that a finger grip is provided following a diameter on the second part and being parallel with the axis of the syringe when no dose is set.

5. An injection syringe according to anyone of the preceding claims, characterised in that the angular distance between the divisions of the scale is 6° corresponding to the minute divisions on an ordinary clock.

6. An injection syringe according to anyone of the preceding claims, characterised in that it has means by which the setting movement of the dose setting element is limited so that an upper limit is set to the dose which can be set.

7. An injection syringe according to claim 6, characterised in that holes are provided along the scale which holes can receive a pin forming a stop which cannot be passed by the indicating member.

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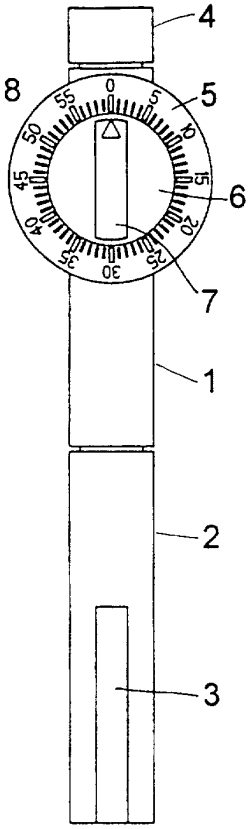

Fig. 1

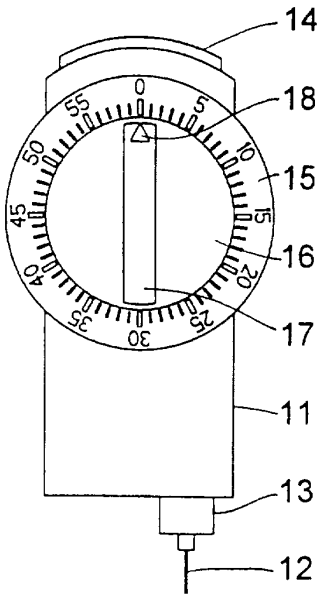

Fig. 2

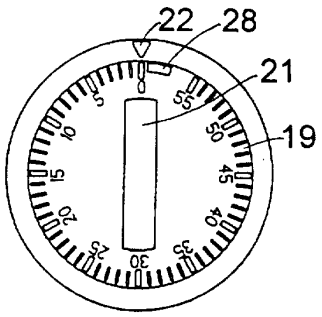

Fig. 3

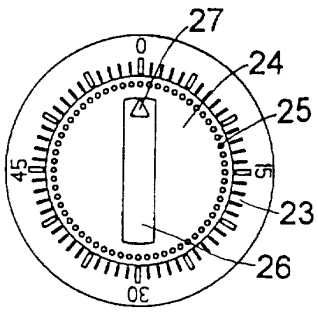

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 97/00380

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/24, A61M 5/20 // A61M 5/31
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO:WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 4208677 A1 (INJECTA GMBH STEINACH), 23 Sept 1993 (23.09.93), column 3, line 21 - line 24, figure 1	1-7
A	WO 94/13343 A1 (HABLEY MEDICAL TECHNOLOGY CORPORATION), 23 June 1994 (23.06.94), figure 1, abstract	1-7

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
1 December 1997	30 -12- 1997
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer May Hallne Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT
Information on patent family members

01/10/97

International application No.
PCT/DK 97/00380

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 4208677 A1	23/09/93	NONE	
WO 94/13343 A1	23/06/94	NONE	

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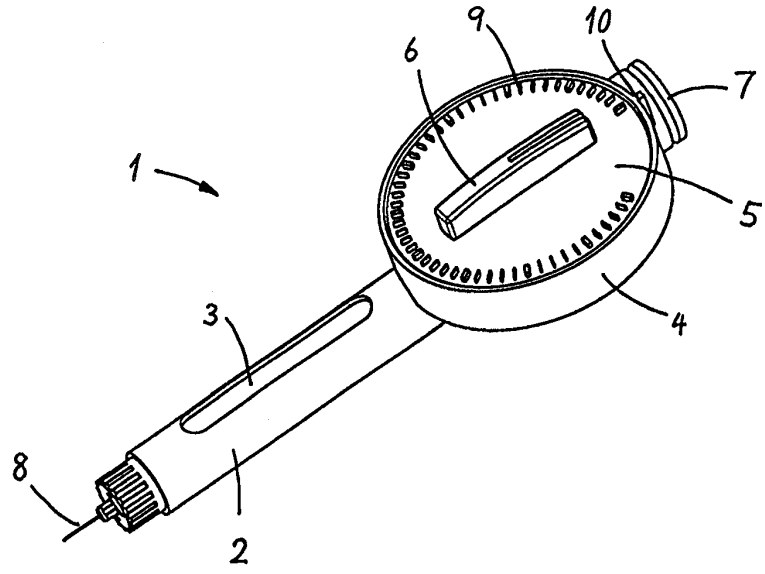
(54) Title: A DOSE SETTING MECHANISM AND AN INJECTION SYRINGE HAVING SUCH A DOSE SETTING MECHANISM

(57) Abstract

A dose setting mechanism for a drug administration device and an injection syringe having such a dose setting mechanism are provided. The injection syringe has a housing accommodating an ampoule (3) containing medicine sufficient for a number of dosed injections, an injection press button (7), a piston rod (13) for co–operation with a piston in the ampoule (3) when injecting, and a dose setting mechanism comprising a rotatable dose setting element (5) interconnected with the press button. The dose setting mechanism further comprises a dose administration wheel (11) connected with the piston rod (13) and a coupling ring (12) connected with the dose setting element (5) and the press button (7). One of the dose administration wheel (11) and the coupling ring (12) at least partly surrounds the other, and the dose administration wheel (11) and the coupling ring (12) are arranged such that rotation of the dose setting element (5) allows the coupling ring (12) to be rotated in either direction in relation to the dose administration wheel (11), while activation of the press button (7), and thereby rotation of the coupling ring (12), causes the dose administration wheel (11) to be rotated.



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A dose setting mechanism and an injection syringe having such a dose setting mechanism

The invention relates to a dose setting mechanism for a drug administration device having a housing and a press button connectable with a piston rod for administration of a set dose from a container, said dose setting mechanism comprising a rotatable dose setting element interconnected with the press button.

Drug administration devices having dose setting mechanisms are known in a number of different types, e.g. syringes, inhalators, atomisers, etc. The aim of these drug administration devices is to make the user capable of setting an individual dose of drug to be administered.

Best known in the art are injection syringes for use by patients, mainly diabetics, who have to inject themselves with individually set doses of medicine, e.g. insulin. Such syringes are often given a shape like a pen in order to be carried by the patient all through the day and are always ready for use.

When the dose is to be set in these pen-shaped injection syringes, a cap covering the needle portion of the syringe is rotated, causing a press button at the opposite end of the injection syringe to move outwards. The press button often has a scale on the shaft connecting the press button with the interior of the injection syringe, and the dose set can be read on this scale. After setting the dose, the user removes the cap from the needle portion, inserts the needle in the area to be injected and injects the medicine by pressing the press button. When the press button reaches its bottom, the set dose has been injected.

One disadvantage of these pen-shaped injection syringes is that the scale on the shaft of the press button has rather small divisions and digits owing to the limitations set by the perimeter of the shaft. If the user is visually impaired, as can often be the case with diabetics, this may cause wrong dose settings having serious consequences for the user.

An attempt to overcome this disadvantage is disclosed in DE A1 4 208 677 showing an injection syringe provided with a dose setting scale having large digits. The dose setting device consists of a box-like container in which an injection syringe may be placed. When setting the dose, a stop is moved on the piston rod of the injection syringe until the right dose, as read on the scale, has been set. Then the user removes the injection syringe from the dose setting device and injects himself like with an ordinary injection syringe, while the stop on the piston rod determines the dose being injected.

All the known injection syringes having dose setting devices have the disadvantage that the dose setting device, or at least a part of it, has to be removed from the injection syringe after the dose has been set but before injection can take place. Some of the injection syringes, as is the case with the one disclosed in DE A1 4 208 677, even have the disadvantage that the set dose cannot be checked after the dose setting device has been removed, as the injection syringe itself has no scaling means.

It is an object of the present invention to provide a dose setting mechanism that can be built into a drug administration device, e.g. an injection syringe, is non-removable from it and provides the possibility of setting a dose and regretting the set dose. Further, there

should always be full correspondence between the movement of the dose setting element and the movement of the press button in order to assure the user of the dose set and the dose administered.

This is obtained by a dose setting mechanism of the type mentioned in the opening paragraph of this specification, which is characterized in that the dose setting mechanism further comprises a dose administration wheel connected with said piston rod and a coupling ring connected with the dose setting element and the press button, one of said dose administration wheel and said coupling ring at least partly surrounding the other, said dose administration wheel and said coupling ring being arranged such that rotation of the dose setting element allows the coupling ring to be rotated in either direction in relation to the dose administration wheel, while activation of the press button, and thereby rotation of the coupling ring, causes the dose administration wheel to be rotated.

Arranging the dose setting mechanism in this way provides a dose setting mechanism which can be fully built into a drug administration device, e.g. an injection syringe, and has the possibility of setting a dose and regretting the set dose. As the dose setting element is connected with the coupling ring which is in turn connected with the press button, full correspondence between the movement of the dose setting element and the movement of the press button is achieved.

In order to achieve the co-operation between the dose administration wheel and the coupling ring, these parts may advantageously be arranged as stated in claim 2. Claim 3 discloses further arrangements according to a preferred embodiment. By incorporating all these features a particularly simple construction needing only four parts to

build the dose setting mechanism is achieved, i.e. the dose setting element, the dose administration wheel, the coupling ring and the press button.

The invention also relates to an injection syringe comprising a housing accommodating an ampoule containing medicine sufficient for a number of dosed injections, an injection press button, a piston rod for co-operation with a piston in the ampoule when injecting, and a dose setting mechanism comprising a rotatable dose setting element interconnected with the press button. The injection syringe is further characterized in that the dose setting mechanism includes the features mentioned in claim 1.

By arranging the injection syringe in this way, an injection syringe is obtained having a built-in dose setting mechanism with the possibility of setting a dose and regretting the set dose. As the dose setting element is connected with the coupling ring which is in turn connected with the press button, full correspondence between the movement of the dose setting element and the movement of the press button is achieved.

The connection between the different parts of the dose setting mechanism is preferably as mentioned in claims 5 and 6, giving the advantages mentioned earlier.

In a preferred embodiment the housing has means for preventing the dose administration wheel from being rotated in one direction corresponding to withdrawal of the piston from the ampoule. This ensures, when the dose setting mechanism is used in an injection syringe, that the piston rod can never be withdrawn from the piston in the ampoule but is always in firm contact with the piston. If the piston rod could be withdrawn from the piston, the

dose injected would not correspond to the dose set, owing to the gap between the piston rod and the piston.

The dose administration wheel is preferably connected with the piston rod via a gear wheel provided at the centre of the dose administration wheel.

Preferably the injection syringe is provided with a scale and a pointer indicating the dose set when the dose setting element is rotated.

More advantages and the mode of operation of the dose setting mechanism will be described more fully in the following with reference to the drawings in which

Figure 1 shows a top perspective view of an embodiment of an injection syringe having a dose setting mechanism according to the invention,

Figure 2 shows an exploded view of an embodiment of an injection syringe having a dose setting mechanism according to the invention,

Figure 3 shows the dose setting mechanism when setting a dose,

Figure 4 shows the dose setting mechanism when regretting a set dose, and

Figure 5 shows the dose setting mechanism when administering a set dose.

Figure 1 shows an injection syringe 1 having a dose setting mechanism according to the present invention. The syringe has a first housing part 2 containing an ampoule 3 with medicine, e.g. insulin, the ampoule 3 being seen through a window in the first housing part 2, and a second housing part 4 embracing the dose setting mechanism.

The first housing part 2 is generally pen-shaped, as is known from commercially available injection syringes. The syringe further comprises a dose setting mechanism, of which a rotatable, disc-shaped dose setting element 5 having a finger grip 6 and a press button 7 for injection are seen. Further, a needle 8 extending from the lower end of the injection syringe 1 is shown.

The size of the shown embodiment of an injection syringe 1 and in particular of the dose setting element 5 is such that it fits the user's hand, both when setting a dose of medicine by holding the injection syringe 1 in one hand and setting the dose by rotating the dose setting element 5 with the other hand, and when injecting the set dose by holding the injection syringe 1 in one hand and pressing the press button 7 with the thumb of the same hand.

A scale 9 is provided on the dose setting element 5, and a pointer 10 is provided at the second housing part 4.

Figure 2 shows the injection syringe 1 in an exploded view showing again the first and second housing parts 2 and 4, the ampoule 3, the dose setting element 5, the press button 7 and the needle 8. The injection syringe 1 further comprises a dose administration wheel 11, a coupling ring 12, a piston rod 13 and a needle coupling part 14.

The dose setting mechanism comprises the dose setting element 5, the dose administration wheel 11, the coupling ring 12 and the press button 7. These parts will be described in more detail in the following as these parts constitute a preferred embodiment of the invention.

The dose setting element 5 is disc-shaped having a finger grip 6 on its upper side and a downwardly projecting tenon 15 at the periphery, said tenon 15 interacting with a

notch 16 provided at the rim of the coupling ring 12. The coupling ring 12 is in turn in engagement with the press button 7 via a gear wheel 17 provided at the hub of the coupling ring 12 and a toothed part 18 of the press button 7.

As the dose setting element 5 is connected with the coupling ring 12 which is in turn connected with the press button 7, full correspondence between the movement of the dose setting element 5 and the movement of the press button 7 is achieved. This means that whenever the dose setting element 5 is rotated for setting or regretting a dose, the press button 7 moves out of or into the housing of the injection syringe 1. Similarly, when the press button 7 is pressed in order to inject a set dose, the dose setting element 5 rotates back to its initial position. This means that the user can visually observe that the set dose is injected during the injection act.

The coupling ring 12 consists of a ring segment connected with a hub in each end thereof. At one end the ring segment is connected rigidly to the hub via a rigid part 19, and at the other end the ring segment is connected flexibly with the hub via a flexible part 20. The flexible part 20 is included for facilitating the mounting of the coupling ring, but it may be omitted without changing the working of the dose setting mechanism.

The interaction between the coupling ring 12 and the dose administration wheel 11 will now be explained fully with reference to Figures 3-5.

Figure 3 is a top view of the dose setting mechanism when a dose is set, showing the first and second housing parts 2 and 4, the dose administration wheel 11, the coupling ring 12, the top part of the piston rod 13, the press button 7 and its toothed part 18. The dose setting ele-

ment 5 is omitted in order to show the interior of the dose setting mechanism, but in use its downwards projecting tenon 15 is in permanent engagement with the notch 16 provided at the rim of the coupling ring 12.

The coupling ring 12 is formed in such a way that it partly surrounds the dose administration wheel 11, and it is seen that the dose administration wheel 11 is provided with barbs 21 at is outer periphery, and that a part of the coupling ring 12 is provided with similar barbs 22.

When a dose is to be set, the dose setting element 5 is rotated clockwise according to the arrow S. This causes the coupling ring 12 to be rotated clockwise, the barbs 22 of the coupling ring 12 sliding over the barbs 21 of the dose administration wheel 11. The second housing part 4 is provided with an inwardly projecting pawl 23, which, in co-operation with the barbs 21 provided on the dose administration wheel 11, prevents the dose administration wheel 11 from being rotated clockwise, which would cause the piston rod 13 to be withdrawn from the ampoule 6.

Rotating the coupling ring 12 causes the press button 7 to move upwards according to the arrow U due to the engagement of the gear wheel 17 (Figure 2) on the coupling ring 12 and the toothed part 18 of the press button 7.

If the set dose is regretted, the dose setting element 5 is rotated anti-clockwise according to the arrow R in Figure 4. Due to the flexible part 20 of the coupling ring 12 (Figure 2), the coupling ring 12 expands outwards, as shown, allowing the barbs 22 to slide over the barbs 21 of the dose administration wheel 11. Hence the dose administration wheel 11 is not affected by this anticlockwise rotation of the coupling ring 12.

The anti-clockwise rotation of the dose setting element 5 causes the press button 7 to move downwards according to the arrow D. Some type of resistance against movement of the press button 7 may be provided in order to ensure that the coupling ring 12 expands outwards when regretting a set dose.

When a set dose is to be injected, the press button 7 is pressed downwards according to the arrow P in Figure 5.

This causes the coupling ring 12 to be rotated in the anti-clockwise direction as indicated by the arrow I due to the engagement of the toothed part 18 of the press button 7 with the gear wheel 17 (Figure 2) of the coupling ring 12. Due to the fact that the rotating force from the press button 7 is transferred to the ring segment of the coupling ring 12 via the rigid part 19, the ring segment is not expanded, as was the case when regretting a set dose by rotating the dose setting element 5 anticlockwise, but is tightened around the dose administration wheel 11, causing the barbs 22 of the coupling ring 12 to engage the barbs 21 of the dose administration wheel 11.

Some type of resistance against movement of the coupling ring 12 may be provided at the flexible connected end of its ring segment in order to ensure that it tightens around the dose administration wheel 11 when injecting a set dose.

The engagement between the barbs 22 of the coupling ring 12 and the barbs 21 of the dose administration wheel 11 causes the dose administration wheel 11 to rotate anti-clockwise, which in turn causes the piston rod 13 to move forwards in the ampoule 3 due to the interaction of a gear wheel 24 provided at the hub of the dose administra-

tion wheel 11 (Figure 2) and a toothed part 25 of the piston rod 13.

When the injection has been completed, the press button 7 and the dose setting element 5 have returned to their initial positions, ready for another dose setting.

If the injection syringe 1 is to be used by diabetics needing regular injections of insulin, the barbs 21 are preferably of a size corresponding to 1 IU (International Unit). Thereby, each click heard when setting a dose, corresponds to 1 IU, giving the user an audible indication of the dose set together with the visual indication on the scale 9. It further means that the dose can be set very precisely as an integer of International Units.

In the shown embodiment the coupling ring 12 surrounds the dose administration wheel 11. In an alternative embodiment the dose administration wheel surrounds the coupling ring, the dose administration wheel being provided with barbs on its inner periphery, and the coupling ring being provided with barbs on its outer periphery. Hence, if a set dose is to be regretted, the coupling ring must be arranged in such a manner as not to expand but to contract, allowing the barbs of the dose administration wheel and the coupling ring to slide in relation to each other.

The design of the injection syringe need not be pen-shaped as shown, but can be of a compact form having a flexible piston rod surrounding the gear wheel of the dose administration wheel. This provides an injection syringe which is a very handy unit having a size that fits an adult's hand.

In a special embodiment of this type of injection syringe, an extra gear wheel may be arranged between the

gear wheel of the dose administration wheel and the flexible piston rod in order to ensure that a relatively large change in the angular position of the dose setting element only causes a small change in the amount of medicine to be injected. Hence, the dose setting can be performed extremely precisely.

Preferably the injection syringe 1 as a whole is made of a plastics material in order to make the disposal after use environmentally correct, but it may also be made of other materials such as metals or any combination of materials.

The injection syringe may be of the disposable type, or it may be of a reusable type in which the ampoule can be replaced when emptied. However, the reusable type requires a special arrangement for retracting the piston rod from its foremost position.

Although the dose setting mechanism has been described in relation to an injection syringe, the dose setting mechanism may be applied to other drug administration devices in which individual doses of drug to be administered can be set.

C l a i m s

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1. A dose setting mechanism for a drug administration device having a housing and a press button (7) connectable with a piston rod (13) for administration of a set dose from a container, said dose setting mechanism comprising a rotatable dose setting element (5) interconnected with said press button (7), c h a r a c t e r i z e d in that the dose setting mechanism further comprises a dose administration wheel (11) connected with said piston rod (13) and a coupling ring (12) connected with the dose setting element (5) and the press button (7), one of said dose administration wheel (11) and said coupling ring (12) at least partly surrounding the other, said dose administration wheel (11) and said coupling ring (12) being arranged such that rotation of the dose setting element (5) allows the coupling ring (12) to be rotated in either direction in relation to the dose administration wheel (11), while activation of the press button (7), and thereby rotation of the coupling ring (12), causes the dose administration wheel (11) to be rotated.

2. A dose setting mechanism according to claim 1, c h a r a c t e r i z e d in that the dose administration wheel (11) is provided with barbs (21) at its outer periphery, that the coupling ring (12) consists of a ring segment partly surrounding the dose administration wheel (11) and rigidly connected with a hub at one end and flexibly connected to said hub at the other end, said ring segment being provided with barbs (22) over at least a part of its inner side, and that the connection between the dose setting element (5) and the coupling ring (12)

is provided at the end of the ring segment which is flexibly connected with the hub.

3. A dose setting mechanism according to claim 2, c h a r a c t e r i z e d in that the coupling ring (12) is connected with the press button (7) via a gear wheel (17) provided at the centre of the coupling ring (12) and a toothed part (18) of the press button (7).

4. An injection syringe (1) comprising a housing accommodating an ampoule (3) containing medicine sufficient for a number of dosed injections, an injection press button (7), a piston rod (13) for co-operation with a piston in the ampoule (3) when injecting, and a dose setting mechanism comprising a rotatable dose setting element (5) interconnected with said press button (7), c h a r a c t e r i z e d in that the dose setting mechanism further comprises a dose administration wheel (11) connected with said piston rod (13) and a coupling ring (12) connected with the dose setting element (5) and the press button (7), one of said dose administration wheel (11) and said coupling ring (12) at least partly surrounding the other, said dose administration wheel (11) and said coupling ring (12) being arranged such that rotation of the dose setting element (5) allows the coupling ring (12) to be rotated in either direction in relation to the dose administration wheel (11), while activation of the press button (7), and thereby rotation of the coupling ring (12), causes the dose administration wheel (11) to be rotated.

5. An injection syringe according to claim 4, c h a r a c t e r i z e d in that the dose administration wheel (11) is provided with barbs (21) at its outer periphery, that the coupling ring (12) consists of a ring segment partly surrounding the dose administration wheel

(11) and rigidly connected with a hub at one end and flexibly connected with said hub at the other end, said ring segment being provided with barbs (22) over at least a part of its inner side, and that the connection between the dose setting element (5) and the coupling ring (12) is provided at the end of the ring segment which is flexibly connected with the hub.

6. An injection syringe according to claim 5, c h a r a c t e r i z e d , in that the coupling ring (12) is connected with the press button (7) via a gear wheel (17) provided at the centre of the coupling ring (12) and a toothed part (18) of the press button (7).

7. An injection syringe according to any one of claims 4-6, c h a r a c t e r i z e d in that the dose administration wheel (11) and the housing have co-operating means for preventing the dose administration wheel (11) from being rotated in one direction corresponding to withdrawal of the piston rod (13) from the ampoule (3).

8. An injection syringe according to any one of claims 4-8, c h a r a c t e r i z e d in that the dose administration wheel (11) is connected with the piston rod (13) via a gear wheel (24) provided at the centre of the dose administration wheel (11).

9. An injection syringe according to any one of claims 4-8, c h a r a c t e r i z e d in that the dose setting element (5) is provided with a scale (9), and that the housing is provided with a pointer (10) pointing on said scale (9), said pointer (10) indicating the dose set when the dose setting element (4) is rotated.

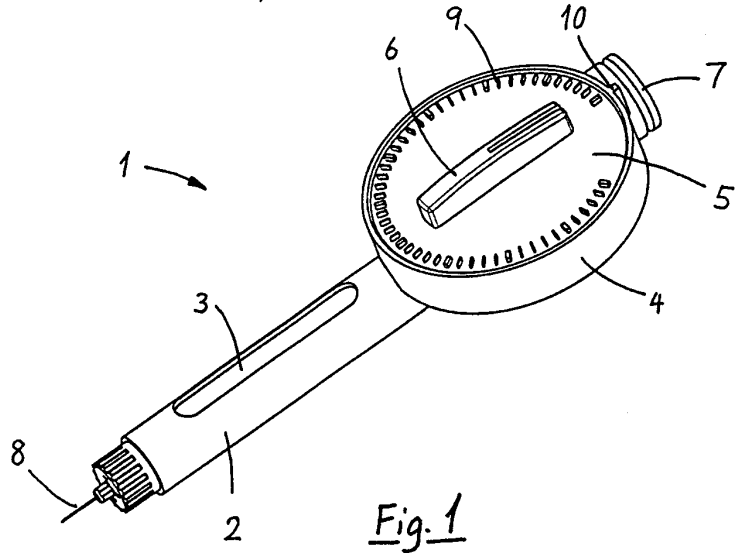

Fig. 1

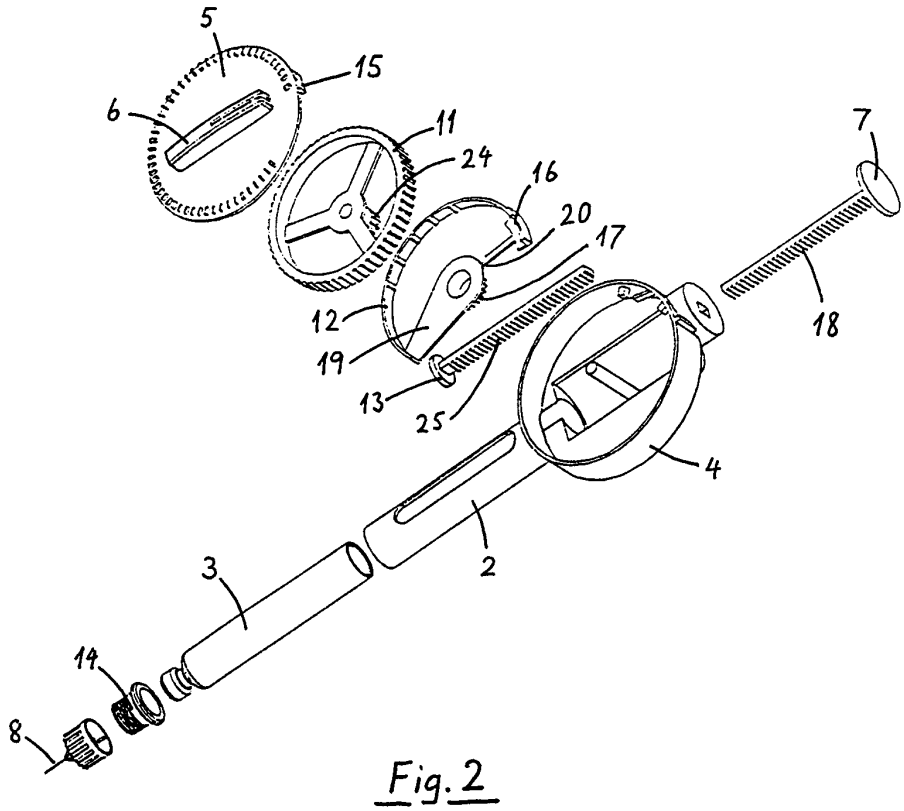

Fig. 2

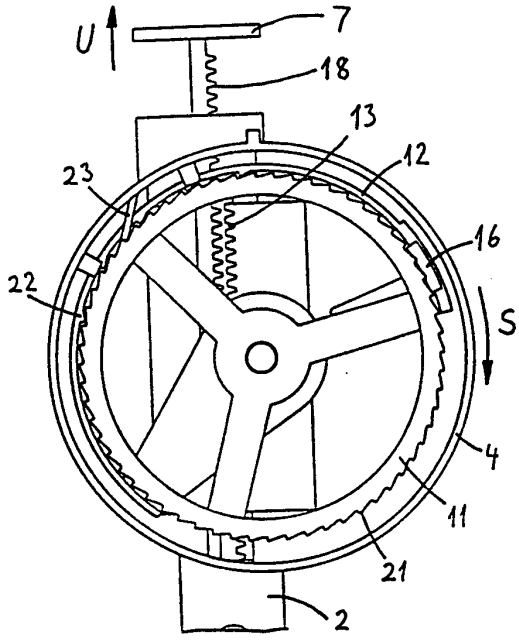

Fig. 3

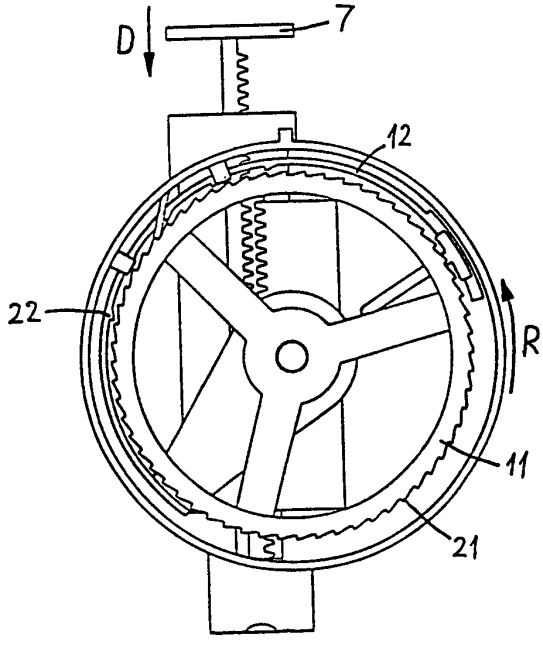

Fig. 4

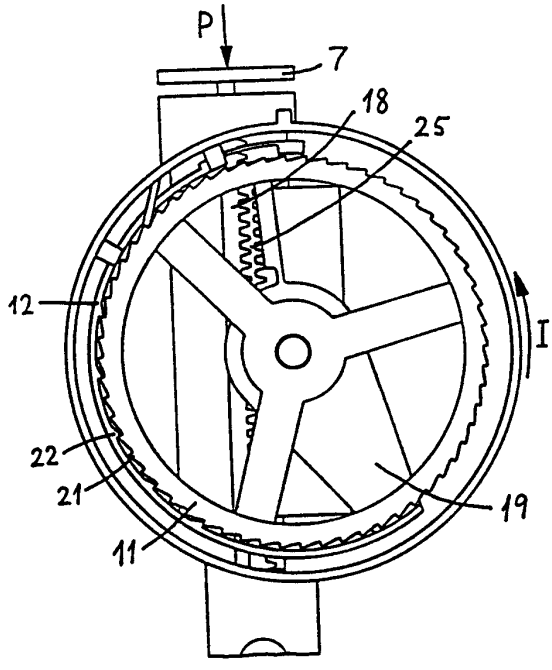

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 98/00239

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/24, A61M 5/31
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9413343 A1 (HABLEY MEDICAL TECHNOLOGY CORPORATION), 23 June 1994 (23.06.94), figure 3 ---	1-9
A	DE 4208677 A1 (INJECTA GMBH STEINACH), 23 Sept 1993 (23.09.93), figure 1 ---	1-9

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 Sept 1998	24 -09- 1998
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Ingrid Falk Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT

Information on patent family members

27/07/98

International application No.
PCT/DK 98/00239

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9413343 A1	23/06/94	US 5320609 A	14/06/94
DE 4208677 A1	23/09/93	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)