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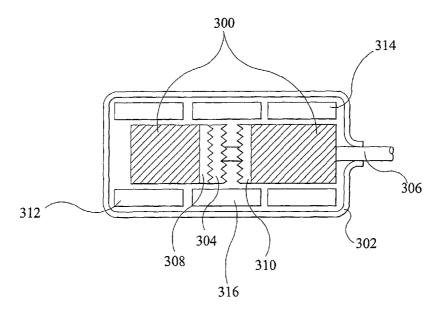
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[Continued on next page]

(54) Title: DRIVE MECHANISM FOR AN INJECTION DEVICE



(57) Abstract: A drive mechanism for an injection device is disclosed in wich piston means 306 are selectively driven to expel medicament from within a medicament cartridge 40. A drive mechanism for controlling the movement of the piston means is described comprising a housing 302, a shuttle 300 located for movement within the housing 302 along a longitudinal axis between a first position and a second position, and drive means to move the shuttle 300 within the housing 302. A gear component 304 is located within the housing 302 for rotation about the longitudinal axis and associated with the piston means 306, movement of the shittle 300 between each of the first and the second positions causing movement of the piston means 306.



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#### **Declarations under Rule 4.17:**

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#### 1

#### DRIVE MECHANISM FOR AN INJECTION DEVICE

The present invention relates to improvements in an injection device, and in particular to improvements in a portable injection device for dispensing controlled quantities of a medicament.

Typically such injection devices are used by those suffering from diabetes to administer a dose of insulin or insulin-type medicine to themselves. It will be understood that such injection devices are suitable for the injection of other medicines.

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At one time, such doses were administered by use of a disposable syringe; the syringe first being filled from a separate phial or other container and then used to inject the dose. However, there were a number of difficulties in such an arrangement. In particular, such an arrangement was not suitable for the infirm. For others, the social stigma associated with such syringes made their public use problematic.

To overcome these difficulties a number of so-called pen-type injectors have been developed. These devices are small, being capable of being carried in a jacket pocket or the like and allow a number of doses to be obtained from a cartridge or ampoule contained within the injector. The present invention has particular application to such pen-type injectors.

While such pen-type injectors are a considerable improvement upon disposable hypodermic syringes, problems nevertheless remain.

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In particular when considering the design of a drive system for a pen-type injector, there are a number of, sometimes, conflicting technical requirements. The drive system must be accurate and reliable, and at the same time compact and efficient. The drive system must be reliable and robust; being able to function for the life of the product. The drive system must also be intrinsically fail-safe.

It is an advantage of the present invention that it eliminates, or at least substantially reduces such problems. The present invention also provides for improved ease of use and improved interaction with a user.

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The invention will now be described, by way of example only, with reference to the accompanying drawings; in which:-

Figure 1 shows a plan view of a pen-type injector in accordance with the present invention;

- Figure 2 shows a similar view to Figure 1 with an end cap of the injector omitted;

  Figure 3 shows a cross-sectional view of the injector of Figures 1 and 2; and Figure 4 shows in plan view a part of a drive mechanism for use with an injector in accordance with the present invention.
- Referring first to Figures 1 to 3, there can be seen a pen-type injector 2 in accordance with the present invention. The injector 2 comprises a main housing 4 to which is releasably secured an end cap or cover 6.
  - At a first end of the main housing 4 there is provided a control panel region 8. This region includes a display panel 10, typically a LCD display, and a first dose button 12 and a second dose button 14, the first and second dose buttons being operated to increase or decrease a dose of medicament to be delivered. The control panel region 10 in the illustrated embodiment also includes an arm button 16.
- At the first end of the main housing there is also provided a dispense button 18.

  Preferably, when not depressed, the dispense button 18 is flush with the main housing 4.
  - Along a longitudinal axis of the injector 2, to each side of the control panel region 10 are provided a number of grooves or recesses 20. These aid in the gripping of the injector 2 by a user.

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At a second end of the main housing 4 a needle unit 22 is releasably secured to the main housing. The second end of the main housing 4 is also provided with a shaped portion 24.

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In use a cartridge 40 or ampoule of medicament is stored in the housing 4 behind the shaped portion 24. For preference, the shaped portion is transparent to permit the cartridge 40 to be seen by a user.

A primer button 26 is also provided on the second end of the housing 4. It will be understood that when the end cap 6 is in place over the second end of the housing, it will not be possible inadvertently to depress the primer button 26 or to be pricked by the needle unit 22. A cover detection switch 28 may also be included at the second end of

the main housing 4 to detect whether the end cap or cover 6 is in place or not.

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In Figure 3, there can be seen a priming contact 30, an arm contact 32, a first dose contact 34 and a second dose contact 36 corresponding to the respective buttons. A dispense contact 19 corresponding to the dispense button 18 is also shown.

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With reference to Figure 3 it may be seen that there is provided a suitable location for a power source 38 such as a battery or batteries. There is also a suitable region in which a cartridge 40 or ampoule of medicament is to be located. This region may be accessed by way of the removable shaped portion 24 of the main housing 4 to allow for replacement of the cartridge 40 or ampoule as required by the user.

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In a third region of the main housing 4 there is provided a drive mechanism 42 which operates from the power source 38 and acts upon the cartridge 40 or ampoule of medicament.

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The cartridge 40 or ampoule comprises a container 44 or sleeve closed at one end by a cover 46 at a head end thereof, and sealed at the other by a movable bung 48 or stopper. When in position, the needle unit 22 pierces the cover 46 and movement of the bung 48 towards the cover 46 will cause the medicament contained within the cartridge 40 or ampoule to be expelled. The cartridge may be a 3ml cartridge in accordance with ISO/FDIS 11608 Part 3, or any other suitable cartridge to suit the injector.

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Movement of the bung 48 or stopper is caused by movement of a piston or plunger 50 forming a part of the drive mechanism 42. The piston or plunger 50 is movable between a first fully withdrawn position (not shown) which allows for the replacement of the cartridge 40 or ampoule and a second fully extended portion in which as much medicament as possible has been expelled from the cartridge 40 or ampoule. An end stop switch 52 may be provided in the main housing 4 to detect when the piston 50 is in the fully withdrawn position. Tripping of the switch end stop 52 may release a catch or other fastening device to allow access to the main housing 4 for replacement of the cartridge 40.

The drive mechanism 42 is operated by a motor 54 under the control of an electronic control unit (not shown). The motor 54 should be reversible in order to allow the piston 50 to be moved between the first and second positions. In Figure 3, the motor 54 can be seen to drive the piston 50 by way of a gear train 42, such that rotation of a third rotor 58 causes the piston 50 to be moved in relation to the third rotor 58.

Preferably, the user can feel the vibration of the motor 54 and the associated drive mechanism 42 and/or hear them in operation. In this way an added degree of confidence in the fact of the operation of the injector 2 is provided to the user.

In order to harness a solenoid for use in an injector, a mechanism has been developed to convert the reciprocating motion of a solenoid into an incremental linear motion to displace a cartridge bung.

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Referring to Figure 4, a two piece shuttle 300 is constrained rotationally within a housing 302 for free axial movement therein. A double faced gear component 304 is also located within the housing. The double faced gear component 304 is free for movement rotationally, but constrained axially. The double faced gear component 304 is coupled to a shaft 306 of a lead screw. The lead screw will be understood to comprise piston means for the advancement of bung 48 within a medicament cartridge 40 within the context of this description. The shuttle comprises two ferrite cores 308,310, each with teeth on an inner face thereof. At either end the housing 302 are disposed coils 312,314. An annular permanent magnet 316 is used to latch the mechanism in one of two end positions when the cores and their associated coils are not energised.

In the de-energised condition, the shuttle 300 is held latched to one end of the device by the magnet 316. The shuttle is held in position by a closed magnetic 'circuit' passing through one of the shuttle ferrite cores and a casing of the housing 302.

In order to move the shuttle 300 to the opposite end of the housing both coils 312,314 are energised. The coil at the 'latched' end is energised to oppose the magnetic field of the permanent magnet 316; the coil at the opposite end is energised to reinforce the permanent magnetic field. The shuttle 300 is thus pulled from the rest position to the opposite end of the housing 302. In moving from one end of the housing 302 to the other, the shuttle 300 engages with the double faced gear component 304 causing it to rotate by a fixed increment, thereby turning a shaft 320 of a lead screw.

25 When the shuttle 300 comes to rest at the opposite end of the housing 302, it is again latched in position by the permanent magnet 316.

The mechanism can be seen to work on both strokes of the solenoid. Also, it can be latched at either end allowing for finer control of the lead screw.

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#### **CLAIMS**

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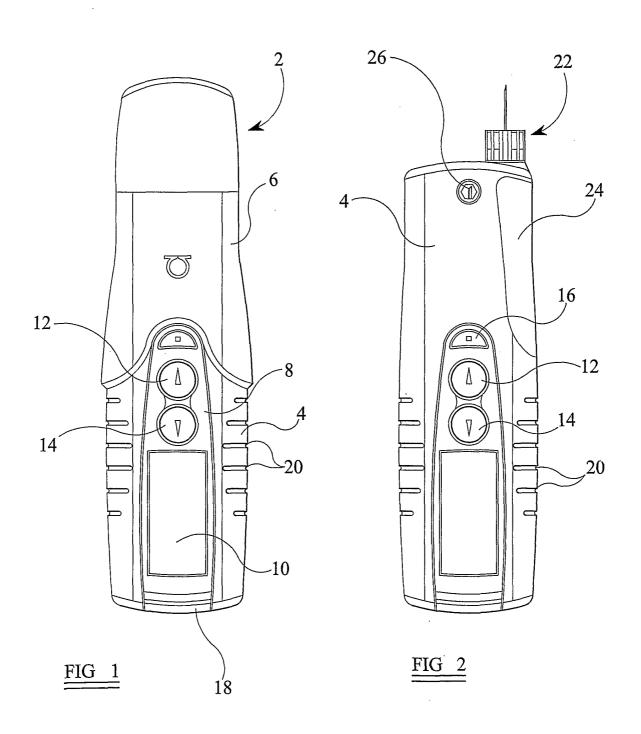
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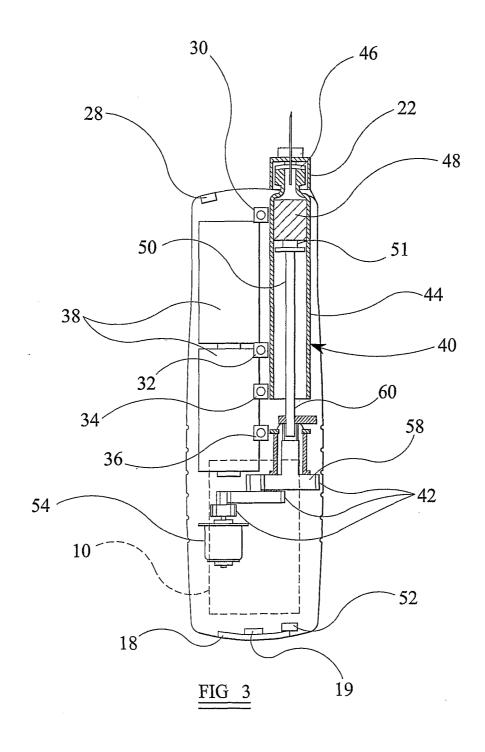
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- A drive mechanism for an injection device in which piston means 306 are selectively driven to expel medicament from within a medicament cartridge 40 and a drive mechanism for controlling the movement of the piston means, the drive mechanism comprising a housing 302, a shuttle 300 located for movement within the housing 302 along a longitudinal axis between a first position and a second position, drive means to move the shuttle 300 within the housing 302, a gear component 304 located within the housing 302 for rotation about the longitudinal axis and associated with the piston means 306, movement of the shuttle 300 between each of the first and the second positions causing movement of the piston means 306.
- A drive mechanism according to claim 1, characterised in that the drive means comprises separately energisable coils 312,314 located at each end of the housing 302 and an annular permanent magnet 316 located between the coils 312,314 acting upon the shuttle 300, the shuttle 300 comprising at least one ferrite core 308,310.
- A drive mechanism according to claim 1 or claim 2, characterised in that the shuttle 300 and the gear component 304 are each provided with teeth upon an annular surface thereof, engagement of the shuttle 300 with the gear component 304 causing the gear component 304 to be rotated by a fixed increment.

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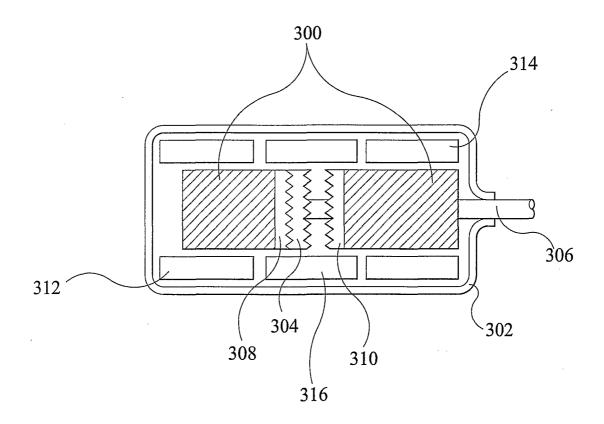


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FIG 4



#### INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61M5/145 A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

 $\begin{array}{ll} \mbox{Minimum documentation searched (classification system followed by classification symbols)} \\ \mbox{IPC} & 7 & \mbox{A61M} \end{array}$ 

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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X Furt	her documents are listed in the continuation of box C.	χ Patent family members are listed	ìn annex.		
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	actual completion of the international search	Date of mailing of the international se	arch report		
2	8 March 2002	09/04/2002			
Name and	mailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2  NL – 2280 HV Rijswijk  Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Nielsen, M			

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