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(54) Benævnelse: **MEDICINSK INJEKTIONSANORDNING MED ELEKTRISK MOTORDRIVSTYRING**

(56) Fremdragne publikationer:
EP-A- 0 319 267
AU-B2- 525 126
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US-B1- 6 362 591

DESCRIPTION

[0001] This invention relates to injection devices for delivering medicine to the human or animal body and in particular, but not exclusively, to devices having a replaceable medicament cartridge, including auto-injectors. Such devices are commonly used by those with diabetes for the administration of insulin.

[0002] Medicament delivery devices are routinely used by persons without formal medical training, i.e. patients where self-management of their condition is increasingly common. These circumstances set a number of requirements for medicament delivery devices of this kind. The injector should be robust in construction, yet easy to use in terms of its operation by a user and the manipulation of the parts. In the case of those with diabetes, many users will be of impaired vision and may also be physically infirm. Devices that are too large of cumbersome may therefore prove difficult to use, particularly someone with reduced dexterity.

[0003] Patent Specification US 6,340,357 describes a drug delivery system in which the dose setting is read into an electronic circuit and the dose setting movement of the dose setting elements relative to each other is performed by an electromechanical device, e.g. a motor controlled by the electronic circuit in accordance with the read in dose setting. The electronic control enables the apparatus to intervene by resetting a dose if a miss-handling of the device by the user is detected during dose setting, such as opening of the cartridge holder.

[0004] Patent Specification WO 2007/094833 describes a metering system for automatically adjusting for differential thermal expansion/contraction for the efficient, accurate and reproducible metered delivery of fluids. The system allows the metering system drive to re-zero itself to produce an accurate volumetric delivery of fluid from the dispensing container.

[0005] Patent specification US6362591 describes a method for detecting occlusions or drive system failure in an ambulatory infusion device. The electrical current to an infusion pump is measured and compared against a baseline average current. If the current exceeds a threshold amount, an alarm is triggered.

[0006] Patent specification US4908017 shows an apparatus and method for controlling fluid flow from syringes. To effect movement of each piston of the syringes, a rack is provided, either as a part of the piston or secured thereto, and longitudinal movement of each rack is effected by rotating an associated pinion gear that is connected with a pulse-driven stepper motor. Error checks and data integrity verifications are provided to assure continued proper operation.

[0007] Patent specification GB2428745 describes a motor desynchronisation detection circuit that detects malfunctions in pipes due to chokes and incomplete switchings of an electromagnetic valve or a broken valve. Motor driving pulses supplied to a motor are measured and compared to pulses obtained by a rotary encoder in order to detect

desynchronization of the motor. In an origin position, an origin sensor supplies a stop signal to the motor driver.

[0008] Patent specification AU525126 describes a volumetric pump for pumping a volume of fluid at a preselected controlled rate between a patient and a source. A chamber is provided of a predetermined volume per increment for displacement of a plunger. The plunger moves within the chamber on an incremental basis in a first direction for filling the chamber, and in a second direction opposite the first direction for emptying the chamber, thus emptying the chamber to an output line. A plunger driving means comprising a stepper motor and controlled by a control means drives the plunger.

[0009] Patent specification US3701345 shows an angiographic injector control system for delivering a controlled volume of injection fluid. The injector has a motor driven piston for ejecting fluid from a syringe cartridge contained within a pressure jacket. The drive motor is operated in accordance with a command voltage corresponding to an incremental position of the injector piston, the command position signal also corresponding to the volume of fluid to be ejected from the cartridge. This command position voltage signal is compared to an actual position voltage to produce an error signal for operating the drive motor, whereby the syringe piston follows the position command signal.

[0010] Patent specification EP0319267 shows a fluid delivery monitoring and control apparatus for use in a medication infusion system. Fluid pumping is accomplished by controlling DC motors in the drive mechanism, each of which is coupled to two valves and a reciprocating piston for an individual pumping channel. The output flow rate of the pump is maintained by a digital feedback controller to provide accurate regulation.

[0011] It is also known to detect a stall of the motor that drives the dose delivery and to warn the user if a dose fails to be delivered. However, there remains a problem in the resetting of the device following detection of a motor stall event.

[0012] It is an aim of the present invention to provide a medication delivery device that alleviates this problem.

[0013] According to the present invention, there is provided a controller for controlling operation of an injection device for delivering a medicament to a patient, as claimed in claim 1.

[0014] The input drive signal may be stepper pulses for driving the motor. The encoder output signal may be a pulsed signal having a timing characteristic that corresponds to the output drive of the motor. A plurality of reference points may be included in the device, each reference point being indicative of a different operational aspect of the device, including any one or more of: backstop position; dose delivered; door position; drive position; and reset threshold. The reference points preferably relate to the input drive signal such that respective reference points correspond to respective counts of the stepper pulses with reference to a device datum. A comparison between counts of the pulsed encoder output with counts of the stepper pulses

may be indicative of motor slip. In the event that motor slip or stall is detected the control means is operative for determining the quantum of slip relative to one of the reference points whereupon said varying means adjusts the operational control of the device according to a predetermined criteria. The variation in operation control may be such as to urge the device to a target operational state, For example, when the quantum exceeds a predetermined threshold value, the motor may be deliberately stalled against a predetermined reference point representative of the target state. For example, the motor drive may be varied so the state of the device is changed to a dose reset position or a cartridge door open state' for enabling replacement of the cartridge. Alternatively, the motor may be controlled such as to rewind the piston rod to a backstop which defines a device datum or device reset position.

[0015] Embodiments of the present invention are advantageous in that the injector automatically initiates a reset action when necessary and without needing user interaction. This leads to an improvement in battery life and an avoidance or reduction in motor stall noise.

[0016] The invention will now be further described by way of example with reference to the accompanying drawings, in which like reference numerals designate like elements:

Figure 1 is a front view of an auto-injector that may include an embodiment of the present invention;

Figure 2 is a front view of the auto-injector of Figure 1 with a medicament cartridge door shown in an open position for receiving a medicament cartridge;

Figure 3 is a perspective view of a motor for use in embodiments of the present invention;

Figure 4 is a side view of the motor of Figure 3 with an encoder;

Figure 5a is a timing chart of motor drive and encoder output;

Figure 5b is a timing chart of motor drive and encoder output showing motor slip;

Figure 6 is a flow chart illustrating a decision sequence that may be performed by the control means; and

Figure 7 is a functional block diagram of the control means.

[0017] In figure 1, an auto-injector 1 comprises a case 2 having a display 3 for displaying functional information relating to the operation of the auto-injector, including the set dose, number of doses remaining in the medicament cartridge. User interface buttons 4, 5 and 6 are provided to allow the user to operate the injector including priming, setting a dose, opening a medicament cartridge holder and door 7, and activating the dispensing of the set dose. A threaded needle attachment 8 is provided to which a needle can be attached for dose delivery and subsequently removed and discarded. A cover (not shown) may be provided to fit over the lower portion of the case 2 to assist in protect the device from the ingress of particles and fluid.

Figure 2 shows the auto-injector 1 with the cartridge holder and door 7 in an open position for receiving a replacement medicament cartridge 9.

[0018] Figure 3 shows a motor 13 within a drive mechanism (see figure 7). The motor is provided with a pair of flags 15 disposed at 180 degrees with reference to one another. An output gear 17 engages with a gear train (not shown) of the drive mechanism for driving the piston rod of the auto-injector 1. The motor 13 may be a stepping motor driven by a pulsed drive signal or stepper pulses illustrated schematically in Figures 5a and 5b below. The pulsed drive signal is generated by an electronic control circuit within the control means. The control means will be described in more detail with reference to figures 5a to 7.

[0019] Figure 4 is a side view of the motor 13 showing an optical encoder 19 in registration with the flags 15. As the drive shaft of the motor 13 rotates the flags 15, every edge of a flag causes a change in the output of the optical encoder 19, so that the encoder outputs a series of output pulses representative of the angular velocity of the drive shaft. The control means (microcontroller/microprocessor - not shown) detects and counts these pulses. The encoder signal causes an interrupt in the microcontroller/microprocessor. An interrupt causes an interruption of the current software program flow, executes a special interrupt software routine and returns to the normal software flow after finishing the interrupt routine. This technique is used to react immediately to external signals to make sure that every signal is recognized by the microprocessor. In the embodiment shown in figure 4, a pair of flags 15 is located at 180° and will therefore generate 4 pulses per motor turn. One encoder pulse is therefore equivalent to 5 motor pulses, assuming 20 motor pulses for a single turn of the motor shaft.

[0020] Figure 5a illustrates the relative timing between the motor drive or stepper pulses and the encoder output pulses during normal drive mechanism movement of the device. In this example, there are 5 motor stepper pulses to one encoder output pulse, the control means being programmed to expect 5 motor stepper pulses to one encoder output pulse. Consequently, when 20 motor stepper pulses are counted at the same time that the control means counts 4 encoder output pulses, the control comparison determines that the device is driving normally. That is, there is no motor slippage or no motor stall. Figure 5a illustrates a situation where a count comparison between the encoder pulse output is such as to indicate 15 motor stepper pulses whereas the actual count by the control means corresponds to 19 or 20 pulses. In this case the control means determines from the comparison that the motor movement has encountered slippage. At this point, a subroutine is run by software programmed into the control means to make a determination as to the state of the auto-injector in relation to predetermined reference points and a device datum position. The position of the piston rod when in a fully retracted position may represent a backstop position or datum position (i.e. "zero") from which other device reference points may be referenced. The datum position also corresponds to an absolute motor position so that incremental movements relative to that correspond to other operational states of the device. These other device reference points are between zero and a maximum motor travel position through 26858 motor stepper pulses. For example, from the datum position, a medicament cartridge 9 door latch open position may be represented by, for example, a motor position that corresponds to

"datum position + 4 pulses". A priming dose may be determined to have been effected by movement of the motor 13 through 84 pulses from the backstop datum position.

[0021] Figure 6 shows an example of an administration routine that may be run with the control means software during the administration of medicament. At 60, the user inputs via input buttons 4-6 a desire to start the administration of a dose of medicament. The motor stepper and encoder pulse counts are examined at step 62 to determine if they differ from one another by more than a predetermined amount. If YES, the control means rewinds the drive mechanism until the motor stalls at the backstop, at which point the device may be datumed or reset. The control means software may then calculate the deficit in the medicament administered and perform means to administer this dose. If NO, the administration continues until the dose is completely expelled.

[0022] Figure 7 is a functional block diagram of the control means 70, to which is connected a user input 72 corresponding to the user interface buttons 4-6 of Figure 1, and the drive mechanism 74. The control means 70 includes dial buttons 76 through which the user can dial the required dose and an LC display 78 for displaying the set dose. The control means software sets a dose value corresponding to that set by the user at 80 and converts this into an appropriate pulse value for the stepper motor 13 at 82. At 84, the software determines the current position of the motor 13 by looking at the current pulse count of the stepper pulses generated by the motor and determines a motor target position 86 in terms of stepper pulses that corresponds to the reference point representative of the piston rod position that will deliver the dose set at 76/80. The control means software, motor control 88, generates the required stepper pulses to drive the motor 13 of the drive mechanism 74 and compares encoder and motor pulses.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US6340357B **[0003]**
- WO2007094833A **[0004]**
- US6362591B **[0005]**
- US4908017A **[0006]**
- GB2428745A **[0007]**

- AU525126 **[0008]**
- US3701345A **[0009]**
- EP0319267A **[0010]**

Patentkrav

1. Styreenhed (70) til styring af driften af en injektionsanordning (1) til administration af et medikament, hvor styreenheden omfatter:
en drivsignalgenerator (88), der er konfigureret til at generere et indgangsdrivsignal til en motor (13);
en koder (84), der er konfigureret til at generere et koderudgangssignal, der er indikation for et udgangsdrev for motoren; og
et middel til at variere operationel styring af anordningen afhængig af en sammenligning mellem et indgangsdrivsignal og koderudgangen,
hvor koderudgangssignalet er et pulserende signal med et tidskarakteristikum, der svarer til udgangsdrevet for motoren,
hvor en sammenligning mellem tælletal for den pulserende koderudgang og tælletal for step-impulser er en indikation for motorstop eller motorafbrydelse, og
er kendetegnet ved, at styreenheden er konfigureret til at:
generere et drivsignal til tilbagespoling af motoren, indtil motoren stopper ved et bagstop; og
beregne underskuddet i den administrerede dosis af medikament og styre administrationen af denne dosis.

2. Styreenhed ifølge krav 1, hvor indgangsdrivsignalet omfatter step-impulser til drivning af motoren.

3. Styreenhed ifølge krav 1 eller krav 2, hvor styreenheden i tilfælde af, at der påvises motorafbrydelse eller motorstop, er i stand til at bestemme mængden af afbrydelse i forhold til ét af en flerhed af referencepunkter.

4. Styreenhed ifølge et hvilket som helst af kravene 1 til 3, hvor styreenheden er konfigureret til forsætligt at stoppe motoren mod et forudbestemt referencepunkt, når mængden af afbrydelse overstiger en forudbestemt grænseværdi.

5. Injektionsanordning (1), der omfatter:

en styreenhed (70) ifølge et hvilket som helst af kravene 1 til 4; og
en flerhed af referencepunkter, hvor hvert referencepunkt er en indikation for forskellige operationelle aspekter af injektionsanordningen.

6. Injektionsanordning ifølge krav 5, hvor referencepunkterne indbefatter en eller flere vilkårlige af: bagstopposition, administreret dosis, lågeposition, drivposition og grænseværdi for geninstilling.

7. Injektionsanordning ifølge krav 5 eller krav 6, hvor referencepunkterne vedrører indgangsdrivsignalet, således at respektive referencepunkter svarer til respektive tælletal for step-impulserne med henvisning til et anordningsdatum.

8. Injektionsanordning ifølge et hvilket som helst af kravene 5 til 7, hvor injektionsanordningen er en autoinjektor.

DRAWINGS

Fig. 1

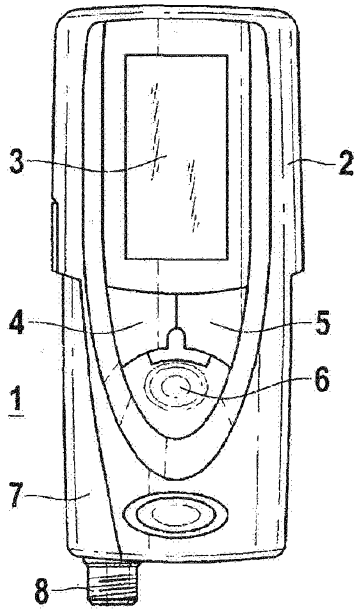
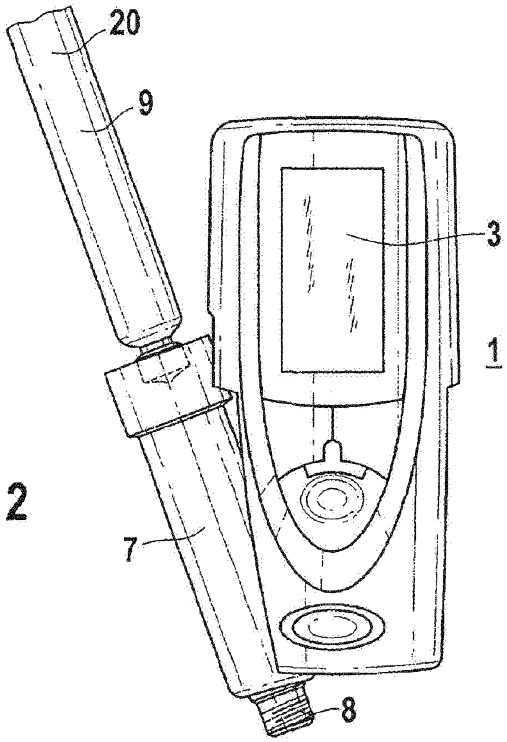


Fig. 2



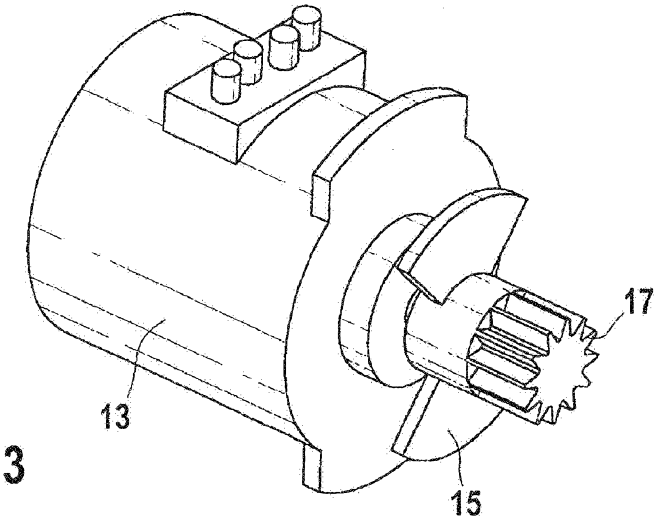


Fig. 3

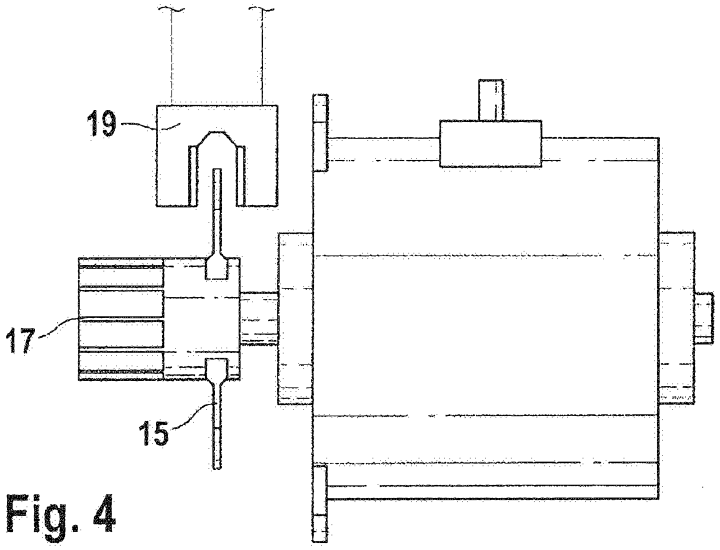


Fig. 4

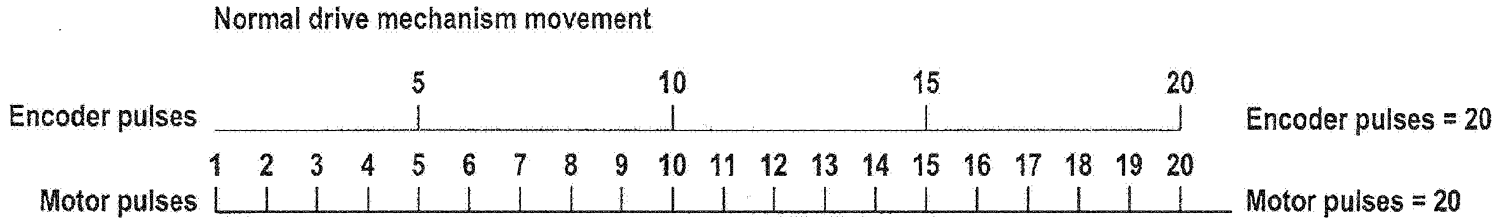


Fig. 5a

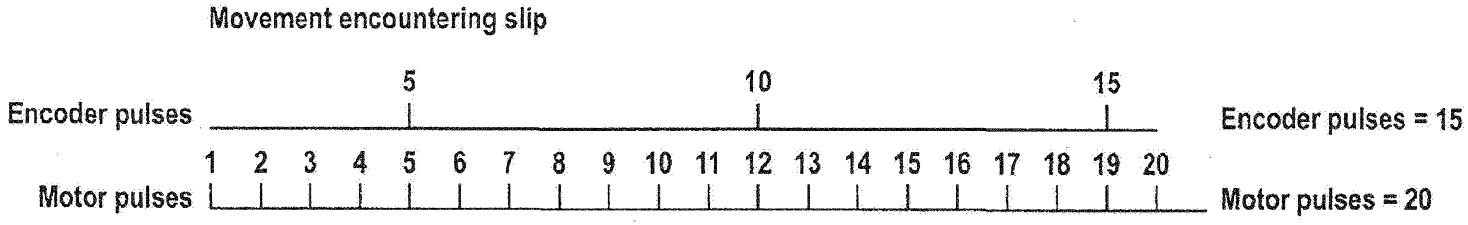


Fig. 5b

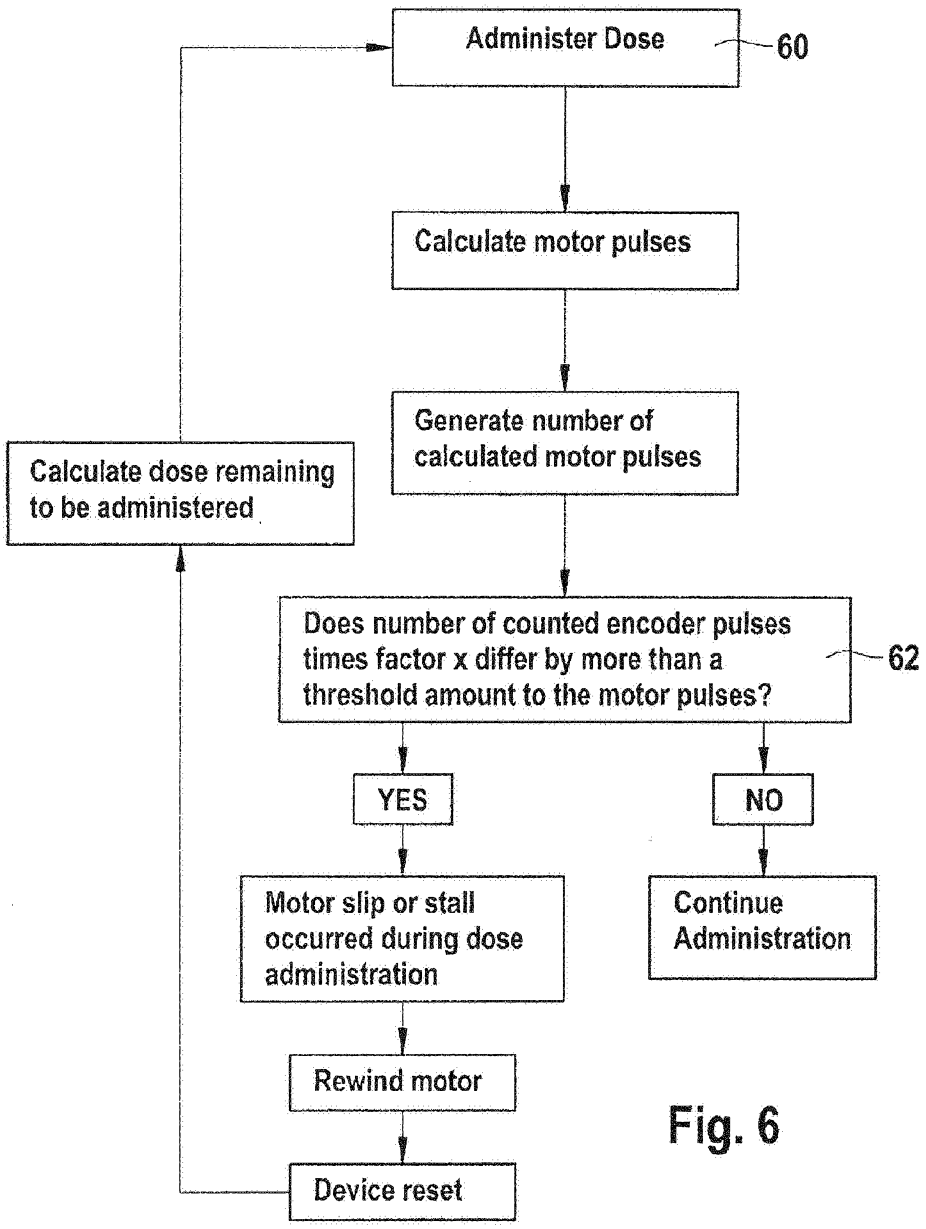

Administer Dose
60
Calculate motor pulses
Generate number of calculated motor pulses
Calculate dose remaining to be administered
Does number of counted encoder pulses times factor x differ by more than a threshold amount to the motor pulses?
62
YES
NO
Motor slip or stall occurred during dose administration
Continue Administration
Rewind motor
Device reset

Fig. 6

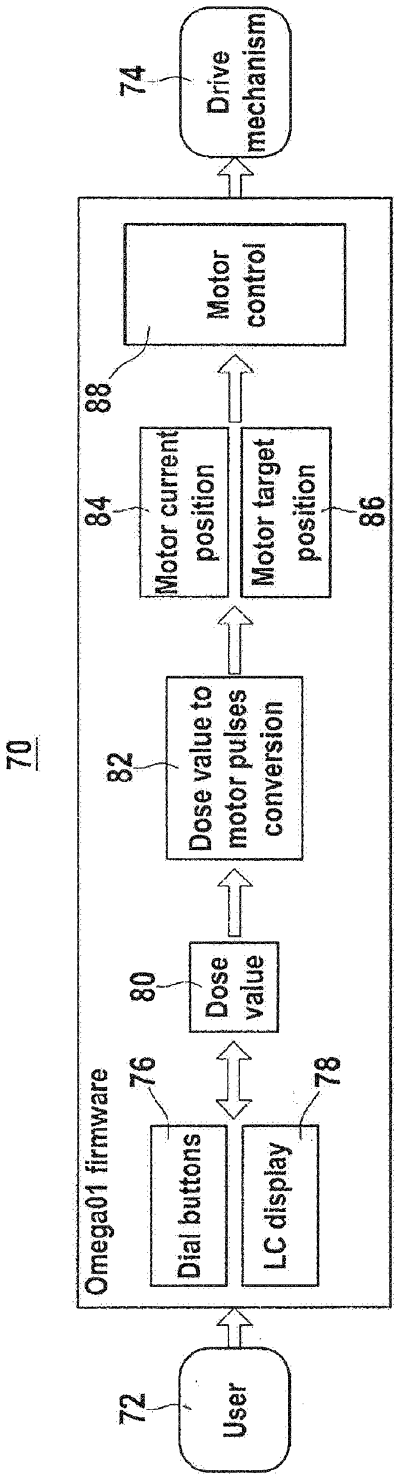

70
72
User
74
Drive mechanism
Omega01 firmware
76
Dial buttons
78
LC display
80
Dose value
82
Dose value to motor pulses conversion
84
Motor current position
86
Motor target position
88
Motor control

Fig. 7