

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
14 May 2009 (14.05.2009)

PCT

(10) International Publication Number
WO 2009/059792 A1

(51) International Patent Classification:

F04B 43/04 (2006.01) **H01L 41/09** (2006.01)
F04B 43/09 (2006.01) **A61M 5/145** (2006.01)

(74) Agent: **DISETRONIC MEDICAL SYSTEMS AG**;
Patent Department, Kirchbergstrasse 190, CH-3401
Burgdorf (CH).

(21) International Application Number:

PCT/EP2008/009452

(22) International Filing Date:

10 November 2008 (10.11.2008)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

11/936,813 8 November 2007 (08.11.2007) US

(71) Applicant (for DE only): **ROCHE DIAGNOSTICS GMBH** [DE/DE]; Sandhofer Strasse 116, 68305 Mannheim (DE).

(71) Applicant (for all designated States except DE, US): **F.HOFFMANN-LA ROCHE AG** [CH/CH]; Grenzacherstrasse 124, CH-4070 Basel (CH).

(72) Inventor: **ROE, Steven, N.**; 21 Hillbarn Court, San Mateo, CA 94403 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

[Continued on next page]

(54) Title: MINIATURE DRUG DELIVERY PUMP WITH A PIEZOELECTRIC DRIVE SYSTEM

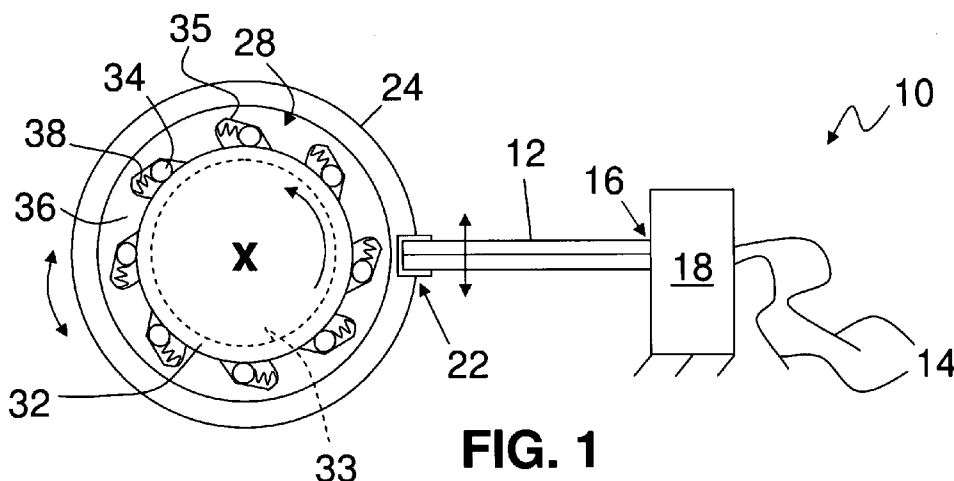


FIG. 1

(57) Abstract: A drug delivery pump which uses a piezoelectric drive system (10) to advance a small syringe piston to deliver a liquid drug is disclosed. The present invention has a cost and size advantage compared to traditional pumps and is a very compact and potentially disposable pump device design.

WO 2009/059792 A1



Published:

— *with international search report*

- 1 -

MINIATURE DRUG DELIVERY PUMP WITH A PIEZOELECTRIC DRIVE SYSTEM

FIELD OF THE INVENTION

[0001] The present invention is generally related to miniature drug delivery pumps, and in particular to a miniature drug delivery pump with a piezoelectric drive system having a unidirectional clutch.

BACKGROUND OF THE INVENTION

[0002] Typically miniature drug delivery pumps use an electric motor and a system of many gears to reduce the high speed motors down to a slower speed. The slower speed provides the precision needed to control the very small doses of a liquid drug being delivered by means of an advancing lead screw and nut moving the syringe piston. Due to the above performance requirements, such miniature drug delivery pump use an expensive high quality electric motor and the associated high quality gears, therefore making such pumps expensive and generally not disposable in nature.

SUMMARY OF THE INVENTION

[0003] It is against the above background that the present invention provides a drug delivery pump which uses a piezoelectric drive system to advance a small syringe piston to deliver a liquid drug and a method thereof. The present invention has a cost and size advantage compared to traditional pumps and is a very compact and potentially disposable pump device design.

[0004] In one embodiment, a drive system is disclosed, and comprises a lead screw having a rotational axis, a shaft extending along the rotational axis and configured to rotate the lead screw about the rotational axis, and a piezoelectric bender configured to produce reciprocating lateral motion adjacent the rotational axis. A clutch is coupled to the shaft and configured to rotate about the rotational axis. The drive system also includes a wheel mounted to the clutch and

- 2 -

operably connected to the piezoelectric bender, wherein the wheel is arranged to convert the reciprocating lateral motion of the piezoelectric bender into reciprocating rotary motion about the rotational axis which turns the clutch bi-directionally, and wherein the clutch in only one direction turns the shaft which advances the lead screw.

[0005] In another embodiment, a method for dispensing a liquid drug from a drug container having a piston is disclosed. The method comprises providing a lead screw connected to the piston of the drug container, wherein the lead screw has a rotational axis. The method also includes providing a shaft extending along the rotational axis and configured to rotate the lead screw about the rotational axis, providing a piezoelectric bender configured to produce reciprocating lateral motion adjacent the rotational axis, and providing a clutch coupled to the shaft and configured to rotate about the rotational axis. The method further includes providing a wheel mounted to the clutch and operably connected to the piezoelectric bender, wherein the wheel converts the reciprocating lateral motion of the piezoelectric bender into reciprocating rotary motion about the rotational axis turning the clutch bi-directionally, and wherein the clutch in only one direction turns the shaft which advances the lead screw and the piston dispensing the liquid drug from the drug container.

[0006] These and other features and advantages of the invention will be more fully understood from the following description of various embodiments of the invention taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The following detailed description of the various embodiments of the present invention can be best understood when read in conjunction with the following drawings, where like structure is indicated with like reference numerals and in which:

- 3 -

[0008] FIG. 1 is a side end view of one embodiment of a piezoelectric drive system having a unidirectional clutch suitable for use with a miniature drug delivery pump according to the present invention;

[0009] FIG. 2 is a side end view of another embodiment of a piezoelectric drive system having a unidirectional clutch suitable for use with a miniature drug delivery pump according to the present invention;

[0010] FIG. 3 is a side end view of still another embodiment of a piezoelectric drive system having a unidirectional clutch suitable for use with a miniature drug delivery pump according to the present invention;

[0011] FIG. 4 is an exploded view of a miniature drug delivery pump embodiment shown with the piezoelectric drive system of FIG. 3;

[0012] FIG. 5 is an exploded view of components of a piezoelectric drive system and their arrangement thereof according to the present invention; and

[0013] FIG. 6 is a perspective view of the miniature drug delivery pump embodiment of FIG. 4 according to the present invention.

DETAILED DESCRIPTION

[0014] It is against the above background that the present invention provides a miniature drug delivery pump which uses a piezoelectric drive system to advance a syringe piston to deliver a liquid drug and a method thereof. The present invention has a cost and size advantage compared to traditional miniature drug delivery pumps and is a very compact and potentially disposable pump device design due to cost.

- 4 -

[0015] In the following description of the embodiments of the invention, skilled artisans appreciate that elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of embodiment(s) of the present invention. Accordingly, the drawings are merely schematic representations, intending to depict only typical embodiments of the invention, and therefore should not be considered as limiting the scope of the invention. The invention will be described with additional specificity and detail through the accompanying drawings. The description of the invention may contain, for example, such descriptive terms as up, down top, bottom, right or left. These terms are meant to provide a general orientation of the parts of the invention and are not meant to be limiting as to the scope of the invention.

[0016] Referring now to FIGS. 1-3, various illustrative embodiments of a piezoelectric drive system according to the present invention are shown, and generally indicated by symbols **10**, **20**, and **30**. All embodiments of the drive system **10**, **20**, and **30** are reciprocating in design which turns lateral motion into rotary motion.

[0017] The present invention uses a simple back and forth flexing motion (i.e., lateral motion) of a piezoelectric bender **12**. The piezoelectric bender **12** may comprise any type of piezoelectric crystal. One example of the piezoelectric bender **12** is a laminate piezoelectric crystal stack, which is driven by a voltage applied via wires **14** through its range of motion. In that case, voltage changes across the piezoelectric bender **12** cause expansion or contraction of piezoelectric crystals in the stack to induce the desired lateral motion. Another example of the piezoelectric bender **12** is a "bi-morph" piezoelectric crystal structure, which comprises flat piezoelectric crystals that are glued together. A bi-morph piezoelectric crystal structure bends in response to voltage changes applied across the crystals because the different layers expand or contract differently. In the following description, it is assumed that piezoelectric bender **12** comprises a laminate piezoelectric crystal stack. However, the invention is not limited in this

- 5 -

respect and may find application with "bi-morph" piezoelectric crystal structures or other piezoelectric crystal elements.

[0018] In the illustrated embodiments of FIGS. 1-3, the piezoelectric bender **12** is fixed at one end **16** to a support **18**, which is best shown by FIG. 1. The other end **22** of the piezoelectric bender **12** is allowed to move laterally but is operably connected to a wheel **24** and causes the wheel **24** to oscillate on an axis of rotation, indicated by symbol "X", upon application of the voltage via wires **14**. It is to be appreciated that in the embodiment of the drive system **10** illustrated by FIG. 1, the piezoelectric bender **12** is orientated perpendicular to the axis of rotation X of the wheel **24**. In this embodiment, the end **22** of the piezoelectric bender **12** is coupled directly to the wheel **24**. In the embodiments of the other drive systems **20** and **30** illustrated by FIGS. 2 and 3, respectively, the piezoelectric bender **12** is orientated parallel to the axis of rotation X of the wheel **24** and operably connected to the wheel **24** via an extension **26**. In the embodiment of FIG. 2, the extension **26** is a wire of a suitable flexible material such as a metal, polymer, fiber, or combination thereof, that is connected at a first end to the end **22** of the piezoelectric bender **12**, wrapped partially or fully around the wheel **24**, and connected at a second end thereto. In this embodiment, the extension **26** has very little, if any, elongation as the wire is needed to pull on the wheel **24** in order to transfer the lateral movements of the piezoelectric bender **12** to the wheel **24**. A return spring **27** may also be provided to maintain the wire (extension **26**) under tension around the wheel and to provide the return force needed to slip the clutch in the non-drive direction **24**. Both the extension **26** and return spring may be fixed to the wheel **24** via gluing, pinning, or any other suitable joining means.

[0019] In the embodiment of FIG. 3, the extension **26** is a material such as a metal, polymer, or combination thereof, which has a first portion surrounding the end **22** of the piezoelectric bender **12** and a second portion provided a distance from the first portion which is coupled to the wheel **24**. In this embodiment, the extension **26** is fixed to the wheel **24** via a pin **29** that is fitted into a slot or recess **31** provided in the wheel **24**.

- 6 -

[0020] As shown by FIGS. 1-3, provided inside the wheel **24** is a unidirectional ratchet or clutch **28** such as, for example, a one-way roller clutch or Sprague clutch. The wheel **24** and clutch **28** may be fixed together via gluing, pinning, pressing, fitting, or any other suitable joining means. As the back and forth oscillation of the wheel **24** occurs, the clutch **28** will alternately slips in one direction (e.g., clockwise) and then grabs in the opposite direction (e.g., counter-clockwise) for each lateral cycle of the piezoelectric bender **12** i.e., the up and down motion of the piezoelectric bender **12** in references to the embodiment of FIG. 1, or side to side motion of the piezoelectric bender **12** in reference to the embodiments of FIGS. 2-3. As the clutch **28** turn in the non-slip direction, a shaft **32** which runs thru the clutch **28** also turns in the non-slip direction. In all the embodiments, the shaft **32** is a hollow tube having a center cavity, which is represented by a dashed line that is indicated by symbol **33**.

[0021] An example of a unidirectional clutch **28** which may be used is shown in detail by FIG. 1. In this example, the unidirectional clutch **28** is a one-way roller clutch; however, the invention is not limited in this respect and may find application with other unidirectional clutches. As the wheel **24** rotates in the counter-clockwise direction, clutch rollers **34** jam between the shaft **32** and the clutch body **36**, locking them together. This allows the angular displacement of the wheel **24** to be transmitted to the shaft **32**. As the wheel **24** and clutch **28** rotate in the opposite (clockwise) direction, springs **38** between the clutch rollers **34** and clutch body **36** are compressed by the rollers, the rollers **34** slip, and the wheel **24** and clutch body **36** rotate freely about the shaft **32**, so that no clockwise angular displacement of the wheel **24** is transmitted to the shaft **32**. Thus, in this embodiment, the roller clutch **28** transmits angular displacement of the wheel **24** to the shaft **32** only if the wheel **24** and clutch **28** move in the counter-clockwise direction when the rollers **34** are wedged between their respective tilted slope pockets **35** of the clutch body **36** and outer surface of the shaft **32**.

- 7 -

[0022] With reference to FIG. 4, an exploded view of an embodiment of a miniature drug delivery pump, generally indicated by symbol **40** is shown, for example, with the piezoelectric drive system shown in FIG. 3. In all embodiments, the unidirectional rotational motion of the shaft **32** is used to advance a lead screw **42** from the cavity **33** of the shaft **32**. In the illustrated embodiment shown by FIG. 4, a nut portion **41** is provided at the open end of the cavity **33** of the shaft **32**. The threads (not shown) of the nut portion **41** engage the threads of the lead screw **42** and cause the movement of the lead screw **42** upon rotation of the shaft **32**. Movement of the lead screw **42** advances a plunger or piston **44** to dispense a liquid drug from a drug container **46**. As shown, the drug container **46** is accommodated in a cradle **48** of a base **50** of the delivery pump **40**. In one embodiment, the lead screw **42** has a snap-in connection **49** to the piston **44** of the drug container **46**.

[0023] In one embodiment, the drug container **46** is removable from the cradle **48** of the delivery pump **40**, via removing a removable cap **52** from a cover **54** of the delivery pump **40** which permits removing and replacing the drug container **46** via an opening **56** defined in the cover **54**. In such an embodiment, the opening **56** and/or the drug container **46** may be keyed or provided in shape which ensures proper alignment of the piston **44** with the lead screw **42**. In another embodiment, the drug container **46** is not removable as the delivery pump **40** in such an embodiment is intended to be disposable after fully dispensing the liquid drug from the drug container **46**.

[0024] In the illustrated embodiment of FIG. 4, the cover **54** snaps onto the base **50** without requiring separate cover fasteners via projections **58** of a pliable material which extend from the base **50** and resiliently seat into notches **60** provided in the inside surface of the cover **54**. In an alternative embodiment, separate cover fasteners may be provided.

[0025] A battery **62** is also provided to power the drive system **30** of the delivery pump **40**. The battery **62** in the illustrated embodiment is a size AAAA, which is about 42.5 mm long and about

- 8 -

8.3 mm in diameter, weighing around 6.5 grams. Output of alkaline batteries in this size is 1.5 volts, 625 mA·h. Although elements in the figures may be exaggerated in portion to other components, it is to be appreciated that the approximate relative size between the delivery pump 40 and the battery 62 is intended to be shown in the embodiment illustrated by FIG. 4. Accordingly, as shown the drug delivery pump 40 is not much larger than the AAAA battery 62, and is in one embodiment about 61 mm long, about 32 mm wide, and 15.5 mm in height, and weighs about 25 grams, with the drug container 46 holding 2 ml of a liquid drug. Such dimensions of the drug delivery pump 40 is about one fourth the size of existing conventional pumps. The small size and weight of the drug delivery pump 40 makes it easier for the patient to hold the delivery pump in place, such via an adhesive on the skin and/or to conceal the delivery pump under clothing.

[0026] The battery 62 is held in a battery cradle 64 provided in the base 50 and contacts electrical terminal posts 66. The wires 14 (FIGS. 1-3) of the piezoelectric drive system 30 each connect to a respective one of the posts 66 via an electrical circuit 68, for example, provided as a electrical trace in the base 50. In one embodiment, a switch or button 67 is also provided to the base 50, such that pushing down on the button 67 completes the electrical circuit 68 and energizes the piezoelectric bender 12 of the drive system 30. It is to be appreciated that other electrical components, such as a DC to AC inverter to produce a suitable drive voltage to the piezoelectric bender 12, and other control components are provided, but are not shown for convenience of illustration as the actual control and electrical system of the drug pump is not the focus of the present invention.

[0027] The shaft 32 which extends through and supports the wheel 24 and clutch 28 about the axis of rotation X, is supported in turn by a pair of base supports 70. In addition, and in one embodiment, the lead screw 42 extends through a keyhole 72 of a provided release button 74. A pair of springs 76 in this embodiment are also provided to the base 50, which bias a bottom portion 78 of the keyhole 72 against the lead screw 42. In this manner, threads 80 (best shown

- 9 -

by FIG. 5) of the bottom portion 78 normally engage with the threads of the lead screw 42. Accordingly, in this embodiment where the drug container 46 is replaceable, pressing down on the release button 74 disengages the threads 80 with the threads of the lead screw 42 such that the lead screw 42 retracts back into the shaft 32 upon inserting a new drug cartridge into the delivery pump 40.

[0028] With reference to FIG. 5, an exploded view of particular components of a piezoelectric drive system and their arrangement thereof according the above mentioned replaceable drug container embodiment of the present invention is shown. As in all the previous embodiments, the shaft 32 extends through a through bore 82 of the clutch body 36, and is rotatable mounted therein to rotate only unidirectionally with the clutch 28. In this embodiment, the lead screw 42 is slidably accommodated in the cavity 33 of the shaft 32, wherein the nut portion 41 (FIG. 4) of the previous non-replaceable drug cartridge embodiment is not provided. A detent portion 84 of the shaft 32 is provided inside the cavity 33 and rides in a longitudinally extending flat or slot 86 provided in the lead screw 42. In this manner, the lead screw 42 will rotate only in sync with the shaft 32, when the shaft 32 is rotated by the clutch 28. However, as the shaft 32 is rotated, the lead screw 42 both rotates and advances slidably out of the cavity 33 along the rotational axis X. As the mentioned above previously, movement of the lead screw 42 (i.e., translational along the rotational axis X) advances the piston 44 to dispense a liquid drug from the drug container 46. In one embodiment, the detent portion 84 is provided as a round bearing end to minimize friction due to the inherent thrust loads encountered in operation of the lead screw 42 pushing the piston 44 forward.

[0029] Optionally, a biasing member 90, such as a spring, may be provided in the cavity 33 to ensure contact of the lead screw 42 with the piston 44. The biasing member 90, however, provides a relatively weak pushing force which is less than the pushing force needed to move the piston 44 in order to dispense the liquid drug from the drug container 46 (FIG. 5). Table 1 below

- 10 -

discloses the pushing force generated by two illustrated drive systems embodiments according to the present invention which is applied to the piston **44**.

[0030] Table 1- Force Generation

Test No.	Bender Free length	Drive Voltage	Lead Screw	Force
#1	1.0 inch (25.4 mm)	+/- 170 DC Sine wave	.282 mm pitch SS 1.15 mm OD	9 Newton (stall)
#2	1.0 inch (25.4 mm)	+/- 170 DC Sine wave	0.453 mm pitch SS 1.87mm OD	24.3 Newton (near stall)

[0031] As shown by FIG. 6, the drug delivery pump **40** provides a scaled window **92** through which a portion of piston **44** is visible and by which the patient in one embodiment uses to determine the amount of drug remaining in the cartridge so that they don't inadvertently run out at an inconvenient time. In another embodiment, dispensing of very small amounts of the liquid drug can be provided by controlling the drive system with a timed switching circuit, wherein depressing button **72** activates the timed switching circuit which energizes the drive system for a predetermined period per button push. In another embodiment, a programmable constant rate or basal rate delivery with a manual override (for bolus delivery) may also be provided. The drug container **46** includes an injection site **94** which is used to connect a spike or other suitable type of connector **96** of an administration set **98** to the delivery pump **40**. The spike or other suitable type of connector **96** is connected to a fluid conduit **100** which at the distal end connects to a catheter **102**, which enters the patient's intravenous system through the skin for delivery of the liquid drug.

[0032] Although not limited to, some of the noted advantages of the present invention are as follows: the inherent precision of the motion from the piezoelectric bender which can be used to accurately deliver very small doses (i.e., about 0.003 ml), the ability to run at high frequency (up

- 11 -

to 100hz) to deliver quickly a large dose (i.e., 0.1 ml), nearly silent operation, fewer moving parts, and inexpensive parts. Such advantages result in an overall compact and low cost drug delivery pump for the consumer.

[0033] The foregoing description of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and other modifications and variations may be possible in light of the above teachings. The above embodiments disclosed were chosen and described to explain the principles of the invention and its practical application to thereby enable others skilled in the art to best utilize the invention. It is intended that the appended claims be construed to include other alternative embodiments of the invention except insofar as limited by the prior art.

[0034] What is claimed is:

- 12 -

CLAIMS

1. A drive system comprising:
 - a lead screw having a rotational axis;
 - a shaft extending along the rotational axis and configured to rotate the lead screw about the rotational axis;
 - a piezoelectric bender configured to produce reciprocating lateral motion adjacent the rotational axis; and
 - a clutch coupled to the shaft and configured to rotate about the rotational axis and operably connected to the piezoelectric bender, wherein the clutch is arranged to convert the reciprocating lateral motion of the piezoelectric bender into reciprocating rotary motion about the rotational axis, and wherein the clutch in only one direction turns the shaft which advances the lead screw.
2. The drive system according to claim 1, wherein the shaft has a nut portion which engages threads of the lead screw.
3. The drive system according to claim 1, wherein the shaft provides a cavity into which the lead screw is slidably accommodated.
4. The drive system according to claim 1, wherein the shaft provides a cavity into which the lead screw is slidably accommodated, and has a mating nut portion at the open end to provided advancement of the lead screw.
5. The drive system according to claim 1, wherein the shaft provides a cavity into which the lead screw is slidably accommodated, and has a detent or shaped portion acting as a key-way connection provided inside the cavity which rides in a longitudinally extending slot provided in the lead screw, and said drive system further comprises a release button having threads arranged to engage under spring tension with the lead screw such that as the shaft is rotated the lead screw

- 13 -

advances slidably out of the cavity, and to disengage the threads with the lead screw when the release button is pushed.

6. The drive system according to claim 1 wherein the shaft provides a cavity into which the lead screw is slidably accommodated, and a biasing member provided in the cavity and configured to urge the lead screw from the cavity.

7. The drive system according to claim 1 wherein the piezoelectric bender extends longitudinally perpendicular to the rotational axis and is connected directly to a wheel mounted to the clutch.

8. The drive system according to claim 7 wherein the piezoelectric bender extends longitudinally parallel to the rotational axis and is connected to the wheel via an extension having a first portion surrounding an end of the piezoelectric bender and a second portion provided a distance from the first portion which is coupled to the wheel.

9. The drive system according to claim 7 wherein the piezoelectric bender extends longitudinally parallel to the rotational axis and is connected to the wheel via a wire wrapped at least partially around the wheel, wherein the wire is tensioned around the wheel via a spring.

10. The drive system according to claim 1 wherein the piezoelectric bender comprises a bi-morph piezoelectric crystal structure.

11. The drive system according to claim 11 wherein the bi-morph piezoelectric crystal structure is a laminate piezoelectric crystal stack.

12. The drive system according to claim 1 further comprising a battery to power the drive system.

- 14 -

13. The drive system according to claim 1 provided in a drug delivery pump having a drug container, wherein the lead screw has a snap-in connection to a piston of the drug container.
14. The drive system according to claim 1 provided in a drug delivery pump having a drug container, wherein the lead screw has a snap-in connection to a piston of the drug container, and the drug delivery pump is about 61 mm long, about 32 mm wide, and 15.5 mm in height, and the drug container holds 2 ml of a liquid drug.
15. The drive system according to claim 5 provided in a drug delivery pump having a drug container, wherein the lead screw has a snap-in connection to a piston of the drug container, and wherein the detent or shaped portion has a round bearing end to minimize friction due to the inherent thrust loads encountered in operation of the lead screw pushing the piston forward.
16. A method for dispensing a liquid drug from a drug container having a piston, said method comprising:
 - providing a lead screw connected to the piston of the drug container, the lead screw having a rotational axis;
 - providing a shaft extending along the rotational axis and configured to rotate the lead screw about the rotational axis;
 - providing a piezoelectric bender configured to produce reciprocating lateral motion adjacent the rotational axis;
 - providing a clutch coupled to the shaft and configured to rotate about the rotational axis; and
 - providing a wheel mounted to the clutch and operably connected to the piezoelectric bender, wherein the wheel converts the reciprocating lateral motion of the piezoelectric bender into reciprocating rotary motion about the rotational axis turning the clutch bi-directionally, and wherein the clutch in only one direction turns the shaft which

- 15 -

advances the lead screw and the piston dispensing the liquid drug from the drug container.

17. The method according to claim 16 further comprises activating the piezoelectric bender which turns the lead screw in the one direction and advances the piston to dispense the liquid drug from the drug container.

18. The method according to claim 16 further comprises provided the piezoelectric bender to extend longitudinally perpendicular to the rotational axis and connecting the piezoelectric bender directly to the wheel.

19. The method according to claim 16 further comprises providing the piezoelectric bender to extend longitudinally parallel to the rotational axis and connecting the piezoelectric bender to the wheel via an extension or wire.

20. The method according to claim 16 wherein the piezoelectric bender extends longitudinally perpendicular to the rotational axis and is connected directly to the wheel, and the method further comprises activating the piezoelectric bender which turns the lead screw in the one direction and advances the piston to dispense the liquid drug from the drug container.

21. The method according to claim 16 wherein the piezoelectric bender extends longitudinally parallel to the rotational axis and is connected to the wheel via an extension, and the method further comprises activating the piezoelectric bender which turns the lead screw in the one direction and advances the piston to dispense the liquid drug from the drug container.

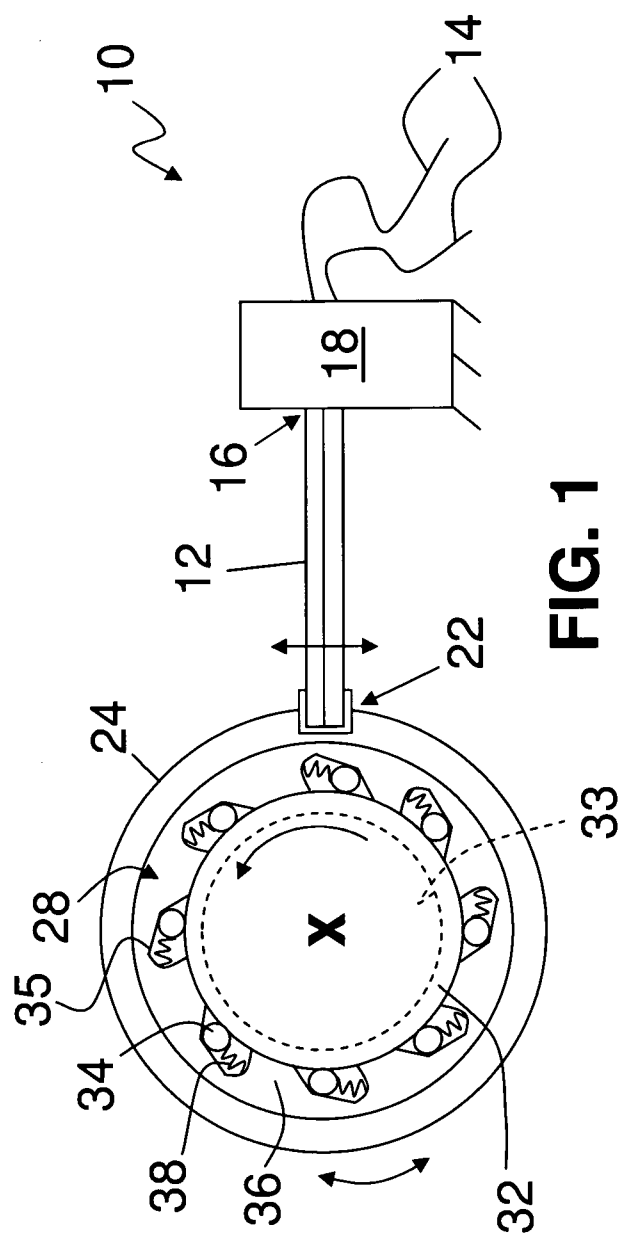


FIG. 1

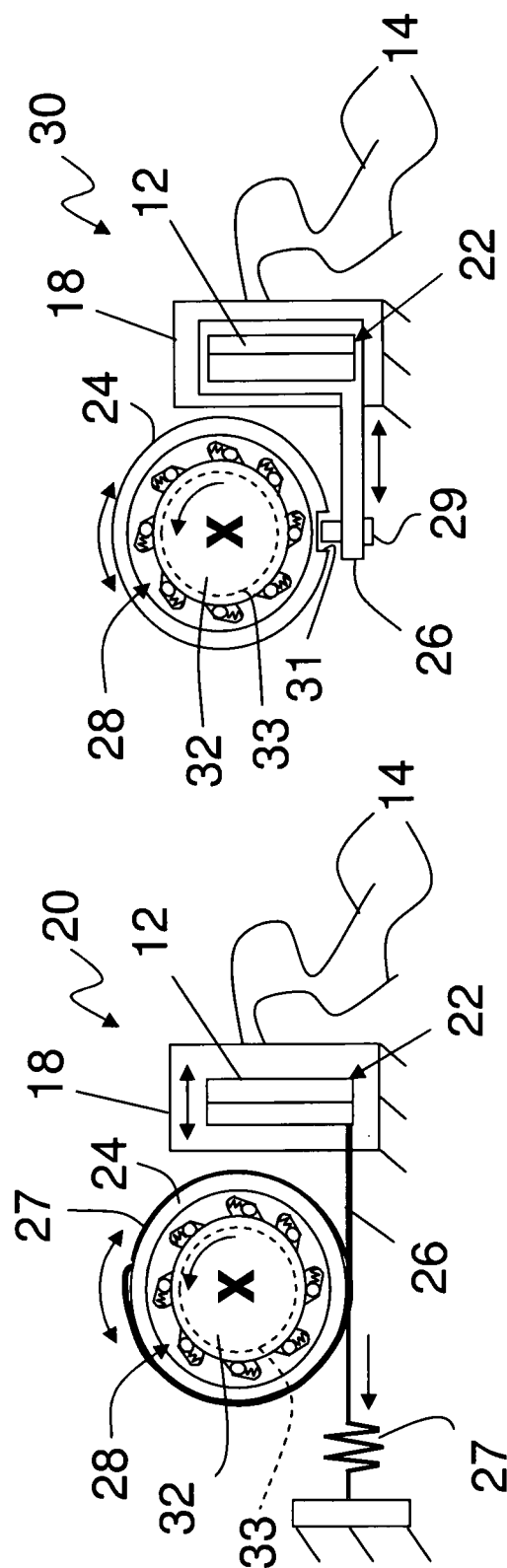


FIG. 3

FIG. 2

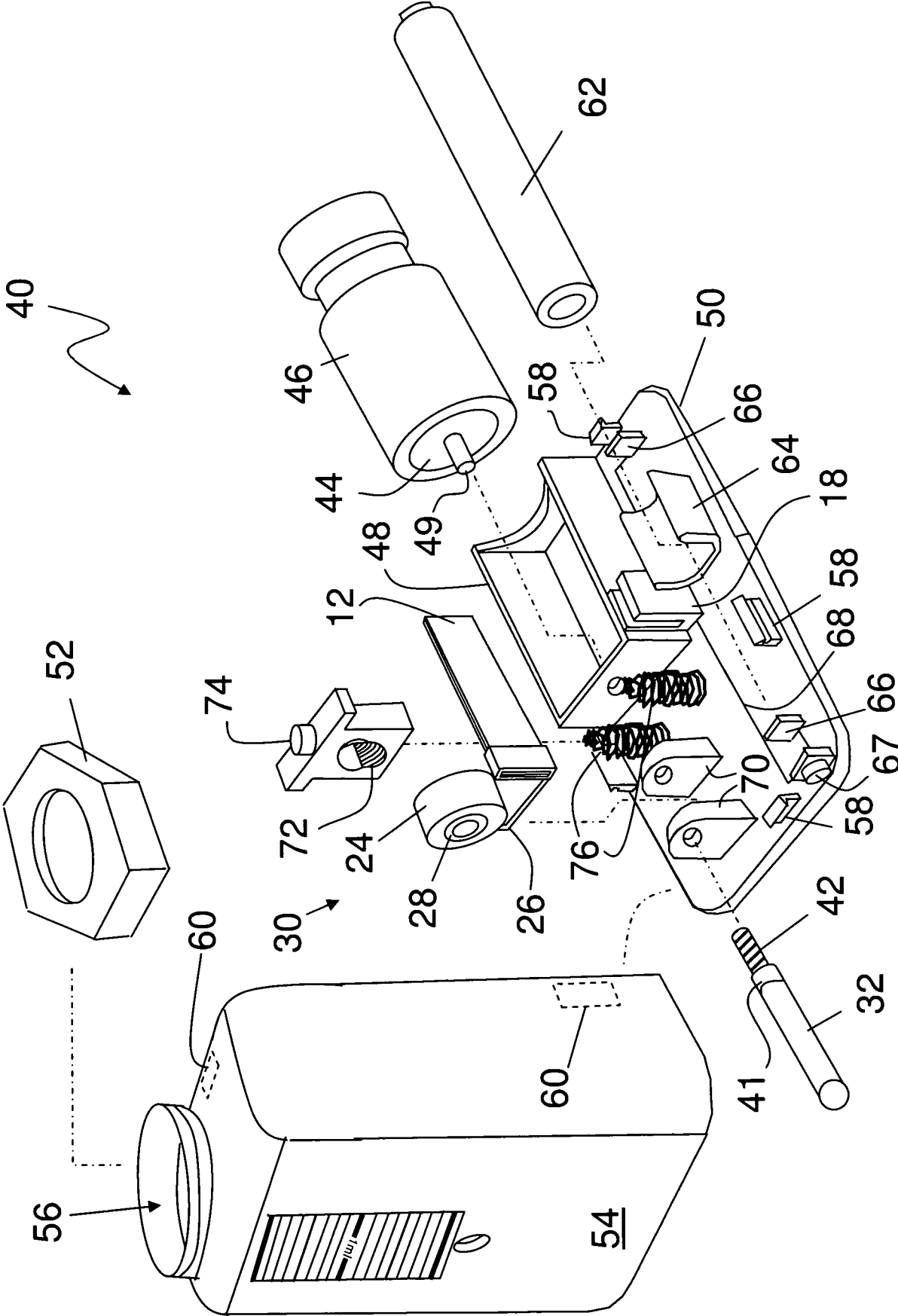


FIG. 4

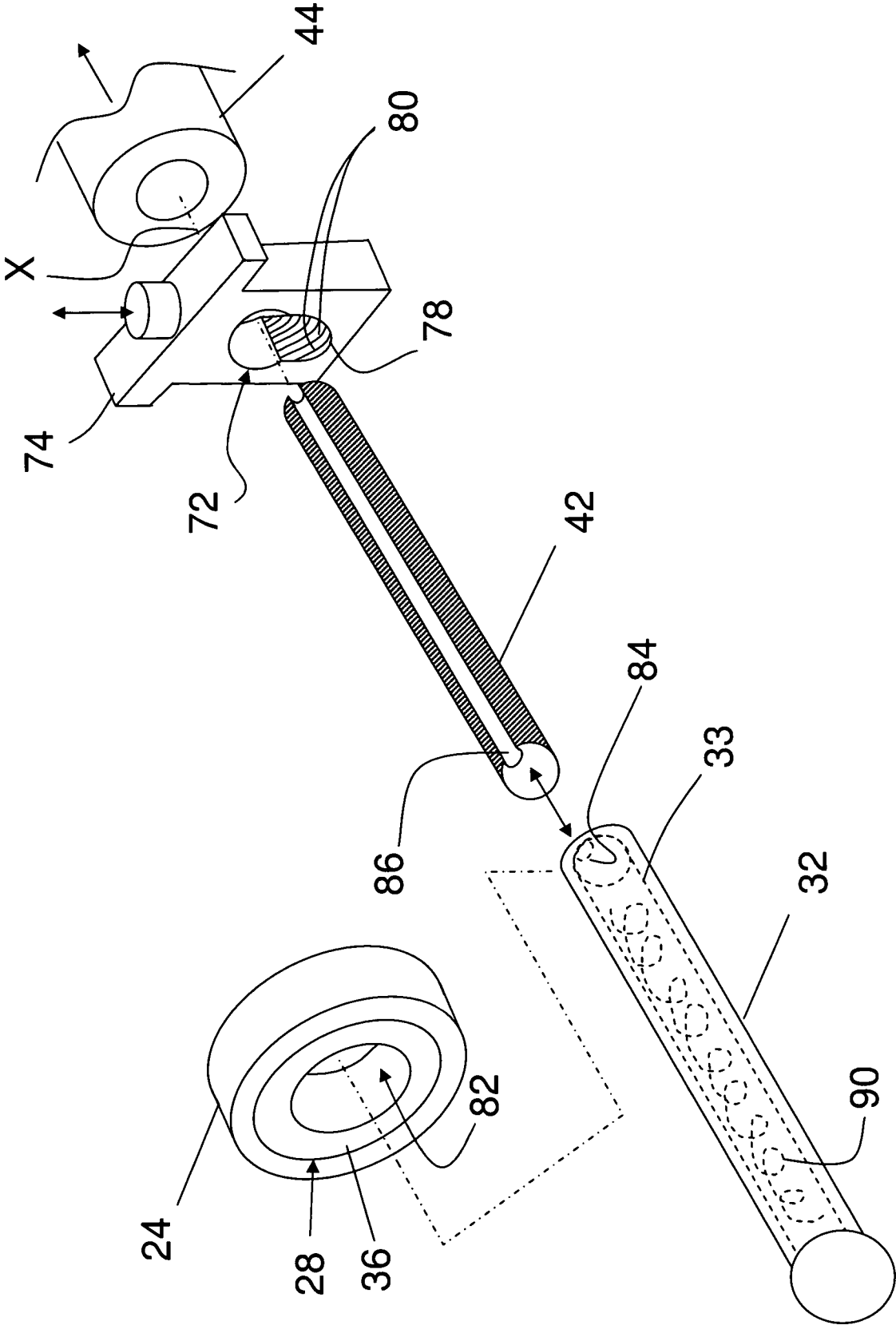


FIG. 5

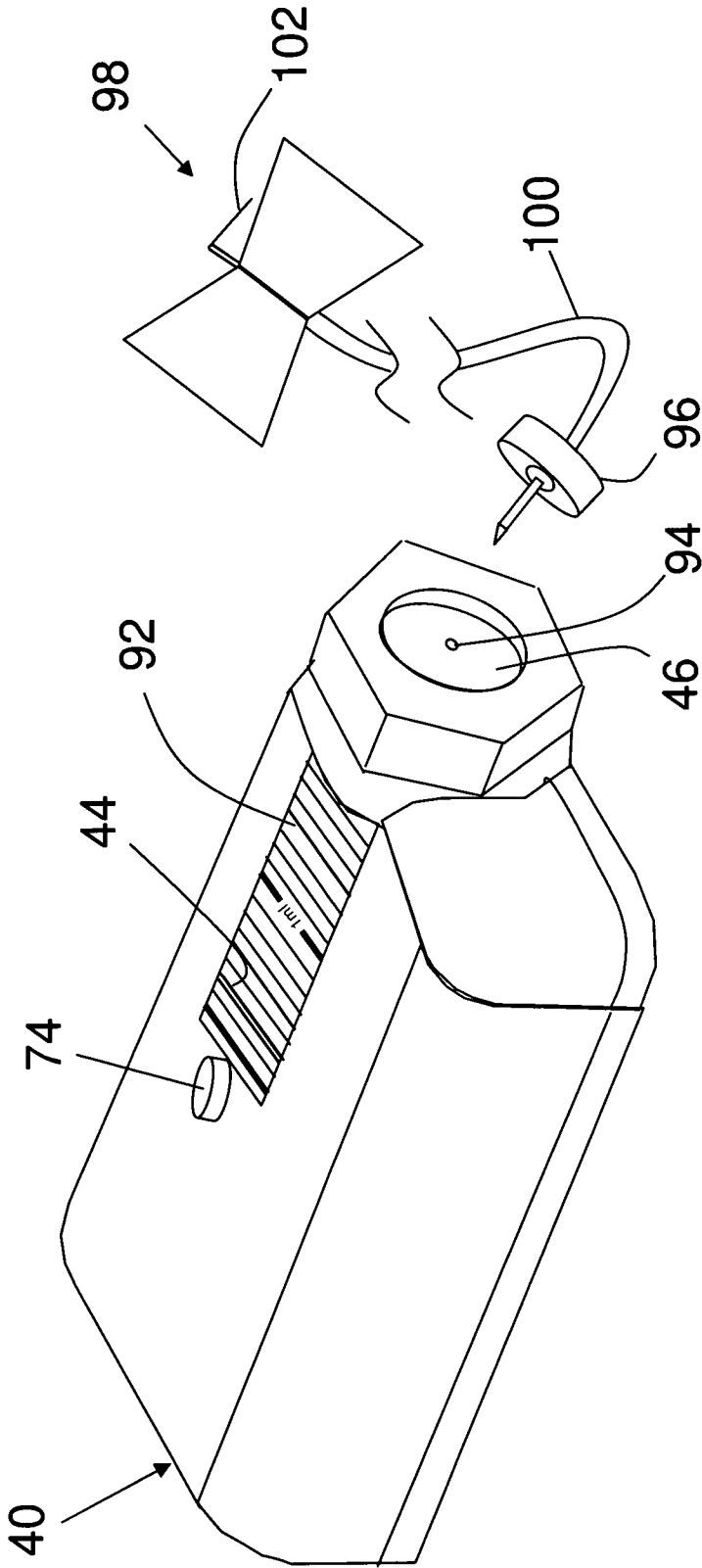


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2008/009452

A. CLASSIFICATION OF SUBJECT MATTER

INV. F04B43/04 F04B43/09 H01L41/09 A61M5/145

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)

F04B H01L A61M

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 10 2005 004498 A1 (ROCHE DIAGNOSTICS GMBH [DE]) 10 August 2006 (2006-08-10) the whole document -----	1-15
X	WO 02/071592 A (STANFORD RES INST INT [US]) 12 September 2002 (2002-09-12) abstract figures 4A, 4E page 3, line 23 - line 31 page 17, line 1 - line 12 page 43, line 23 - page 45, line 5 page 59, line 20 - page 60, line 29 -----	1-15
X	US 4 871 939 A (CLOUSER MICHAEL T [US]) 3 October 1989 (1989-10-03) the whole document ----- -/--	1-15

☒ 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 earlier 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

5 February 2009

Date of mailing of the international search report

13/02/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Petersch, Bernhard

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2008/009452

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7 170 214 B2 (HENDERSON DAVID [US] ET AL HENDERSON DAVID [US] ET AL) 30 January 2007 (2007-01-30) abstract figures 1-19,60-66 columns 1,3,5-7,, lines 10-13,18,19 -----	1-15
P,X	WO 2008/024808 A (MEDTRONIC MINIMED INC [US]; BIKOVSKY RAFAEL [US]; HANSON IAN B [US]; B) 28 February 2008 (2008-02-28) abstract figures 18,19 paragraphs [0115] - [0117], [0130], [0172] - [0175] -----	1-15

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 16-21

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy: claims 16-21 include "dispensing a/the liquid drug from a/the drug container", which constitutes a method of treatment of the human or animal body, practised on the human or animal body, also in the light of the description page 10, paragraph [0031], from which it is clear that the method is also surgical.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2008/009452

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 16-21
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2008/009452

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE 102005004498 A1		10-08-2006	CA 2596521 A1	10-08-2006
			CA 2605937 A1	10-08-2006
			CN 101111189 A	23-01-2008
			EP 1845850 A1	24-10-2007
			WO 2006082173 A1	10-08-2006
			JP 2008529562 T	07-08-2008
			US 2008007141 A1	10-01-2008
WO 02071592	A	12-09-2002	EP 1371130 A2	17-12-2003
			EP 1783843 A2	09-05-2007
			US 2002185937 A1	12-12-2002
US 4871939	A	03-10-1989	NONE	
US 7170214	B2	30-01-2007	CN 101283460 A	08-10-2008
			EP 1897156 A1	12-03-2008
			JP 2008544315 T	04-12-2008
			KR 20080042796 A	15-05-2008
			US 2005258714 A1	24-11-2005
			WO 2006138091 A1	28-12-2006
WO 2008024808	A	28-02-2008	NONE	