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(71) Applicant (for all designated States except US):
MEDINGO LTD. [IL/IL]; Yoqneam Industrial Park,
Building 7, P.O. Box 261, 20692 Yoqneam Illit (IL).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **YODFAT, Ofer**
[IL/IL]; 72 Galil St., 71908 Maccabim-reut (IL). **NETA,**
Avraham [IL/IL]; D. N. Misgav, 20103 Gilon (IL). **DAN,**
Yair [IL/IL]; 18960 Kibutz Ein-harod Hioud (IL).

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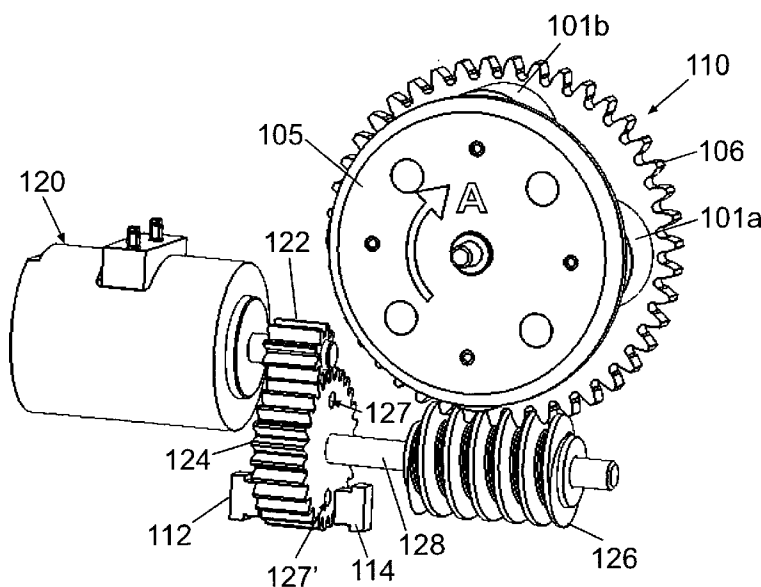


Fig. 4

(57) Abstract: An infusion system, method and device for delivering therapeutic fluid to the body of a patient are disclosed. The device includes a dispensing unit having a peristaltic pump for dispensing therapeutic fluid to the body of the patient. The peristaltic pump includes a driving mechanism. The device further includes a monitoring mechanism (112, 114) for monitoring operation of the driving mechanism and dispensing of therapeutic fluid to the body of the patient.

METHODS AND APPARATUS FOR MONITORING ROTATION OF AN INFUSION PUMP DRIVING MECHANISM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Patent Application No. 60/928,751, filed May 11, 2007 and incorporates disclosure of this application herein by reference in its entirety.

[0002] The present application also claims priority to U.S. Provisional Patent Application No. 60/928,815, filed on May 11, 2007, and entitled "A Positive Displacement Pump", and U.S. Provisional Patent Application No. 60/928,750, filed on May 11, 2007, and entitled "Fluid Delivery Device". This application incorporates disclosures of each of these applications herein by reference in their entireties.

[0003] The present application also relates to the co-owned/co-pending U.S. Patent Application No. XX/XXX,XXX, and International Patent Application No. PCT/IL08/XXXXXX, both filed on the even date herewith, and both entitled "A Positive Displacement Pump", and U.S. Patent Application No. XX/XXX,XXX, and International Patent Application No. PCT/IL08/XXXXXX, both filed on the even date herewith, and both entitled "Fluid Delivery Device". The disclosures of these applications are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

[0004] The present invention generally relates to apparatuses and methods for sustained medical infusion of fluids, and more particularly to a portable infusion device that can be attached to a patient's body and accurately dispense fluids to the patient's body. Particularly, the present invention relates to an infusion pump that includes two parts: a disposable part and a reusable part. More particularly, the present invention relates to apparatus and methods for monitoring rotation of the infusion pump driving mechanism components.

BACKGROUND OF THE INVENTION

[0005] Medical treatment of several illnesses requires continuous drug infusion into various body compartments, such as subcutaneous and intra-venous injections. Diabetes mellitus patients, for example, require administration of varying amounts of insulin throughout the day to control their blood glucose levels. In recent years, ambulatory portable insulin infusion pumps have emerged as a superior alternative to multiple daily syringe injections of insulin. These pumps, which deliver insulin at a continuous basal rate as well as in bolus volumes, were developed to liberate patients from repeated self-administered injections, and allow them to maintain a near-normal daily routine. Both basal and bolus volumes must be delivered in precise doses, according to individual prescription, since an overdose or under-dose of insulin could be fatal.

[0006] Several ambulatory insulin infusion devices are currently available on the market. Mostly, these devices have two portions: a reusable portion that contains a dispenser, a controller and electronics, and a disposable portion that contains a syringe-type reservoir, a needle assembly with a cannula and a penetrating member, and fluid delivery tube. Usually, the patient fills the reservoir with insulin, attaches the needle and the delivery tube to the exit port of the reservoir, and then inserts the reservoir into the pump housing. After purging air out of the reservoir, tube and needle, the patient inserts the needle assembly, penetrating member and cannula, at a selected location on the body, and withdraws the penetrating member. To avoid irritation and infection, the subcutaneous cannula must be replaced and discarded after 2-3 days, together with the empty reservoir. Examples of first generation disposable syringe-type reservoir and tubes were disclosed in U.S. Patent No. 3,631,847 to Hobbs, U.S. Patent No. 3,771,694 to Kaminski, U.S. Patent No. 4,657,486 to Stempfle, and U.S. Patent No. 4,544,369 to Skakoon. The driving mechanism of these devices is a screw-threaded driven plunger controlling the programmed movement of a syringe piston.

[0007] Other dispensing mechanisms have been also discussed, including peristaltic positive displacement pumps, in U.S. Patent No. 4,498,843 to Schneider and U.S. Patent No. 4,715,786 to Wolff. These devices represent an improvement over multiple daily injections, but nevertheless, they all suffer from several drawbacks. one of the main drawbacks is its large size and weight of the device, caused by the configuration and the relatively large size of the driving mechanism of the syringe and the piston. This relatively bulky device has to be carried in a patient's pocket or attached to the belt. Consequently, the fluid delivery tube is long, usually longer than 60cm, in order to permit needle insertion at remote sites of the body. These uncomfortable bulky devices with a long tube are rejected by the majority of

diabetic insulin users, since they disturb regular activities, such as sleeping and swimming. Furthermore, the effect of the image projected on a body of a teenager is unacceptable. In addition, the delivery tube excludes some optional remote insertion sites, like buttocks, arms and legs. To avoid the consequences of long delivery tube, a new concept, of second generation pump, was proposed. This concept includes a remote controlled skin adherable device with a housing having a bottom surface adapted to contact patient's skin, a reservoir disposed within the housing, and an injection needle adapted to communicate with the reservoir. These skin adherable devices should be disposed every 2-3 days similarly to available pump infusion sets. These devices were disclosed at least in U.S. Patent No. 5,957,895 to Sage, U.S. Patent No. 6,589,229 to Connelly, and U.S. Patent No. 6,740,059 to Flaherty. Additional configurations of skin adherable pumps were disclosed in U.S. Patent No. 6,723,072 to Flaherty and U.S. Patent No. 6,485,461 to Mason. These devices also have several limitations: they are bulky and expensive, their high selling price is due to the high production and accessory costs, and the user must discard the entire device every 2-3 days, including relatively expensive components, such as driving mechanism and other electronics.

[0008] e.g., i.e., i.e., i.e., e.g., As mentioned above, the volume of fluid infused to the patient must be delivered in precise doses, according to individual prescription, since an overdose or underdose of insulin could be fatal. The reliability of the infusion pump can be greatly enhanced by monitoring the rotation of the driving mechanism of the infusion pump.

[0009] Existing rotation monitoring devices include optic encoders comprising of a large disc mounted on the motor shaft and several sets of light emitting diodes ("LEDs") and light detectors, as disclosed, for example, in U.S. Patent No. 6,078,273 to Hutchins. These encoders occupy a large space and hence are not suitable for a miniature infusion pump. Moreover the use of several sets of LEDs and light detectors, which is highly expensive, is not required for the high precision of a stepper motor.

[0010] Furthermore, when the encoder is located on the motor shaft it monitors only the rotation of the motor itself, and cannot directly monitor rotations of shafts and gears. Moreover, it does not detect occurrences of electro-mechanical disassociation due to breakage of gears, dust, etc.

[0011] Another problem which exists in rotary peristaltic pumps is that the resulting delivery of fluid occurs in a series of pulses or surges, the frequency of which is equal to the frequency of the passage of successive rollers in contact with the delivery tube. This flow pattern is inherent in conventional rotary peristaltic pumps. The effect is that fluid is

delivered at a widely varying rate during a pump cycle and this can be unacceptable in infusion procedures in which uniformity of delivery rate is a requirement (e.g., insulin pumps). Moreover, the continuous change in flow rate can cause instability in sensitive feedback control systems which are designed to ensure that fluid is delivered at a constant rate. It was found that during the passage of each peristaltic pump roller in contact with the delivery tube, constant flow was maintained through a portion of the motor cycle, immediately followed by a period of no flow at all in the downstream or positive direction. During this dwell period, there is often some evidence of negative flow.

[0012] This means that in normal operation, the pump is delivering no fluid for a portion of its operating time and is delivering fluid at a higher rate than the average for the other cycle portion.

[0013] Having frequent periods in which there is no fluid flowing downstream, i.e., towards the patient's body, is extremely hazardous when dealing with therapeutic fluid such as insulin. When an insulin pump is set to its minimal flow rate, it is likely that the patient will not receive any insulin at all.

[0014] An example of a control apparatus for the drive motor of a peristaltic pump for maintaining a uniform flow rate is disclosed in, for example, U.S. Patent No. 4,604,034 to Wheeldon that discusses a control apparatus employing a photo sensor. The control apparatus, however, was not specified as to how it can be materialized, i.e., what the possible locations of the photo sensor are, if it can be employed in a miniature-size infusion pump, etc. Moreover, employment of a different type of sensor other than a photo sensor was not discussed.

i.e., e.g.,

SUMMARY OF THE INVENTION

[0015] To overcome the deficiencies of the above conventional devices, some embodiments of the present invention are directed to an improved method and device for monitoring the rotation of a driving mechanism (i.e., motor, gears, shafts, etc.) capable of detecting occurrences of electro-mechanical disassociation. In some embodiments, the present invention is directed to an appropriate size (e.g., miniature) device for monitoring the

rotation of a driving mechanism. The present invention also provides an efficient and cost-effective device for monitoring the rotation of a driving mechanism.

[0016] In some embodiments, the present invention is directed to an appropriately-sized device for monitoring the rotation of a driving mechanism of an infusion pump. The present invention also capable of monitoring the rotation of a driving mechanism of an infusion pump that can be attached to the patient's skin. In some embodiments, the appropriately-sized device for monitoring the rotation of a driving mechanism of an infusion pump includes two parts, e.g., a reusable part and a disposable part. In some embodiments, the device can be attached to and detached from the skin.

[0017] In some embodiments, the present invention is directed to an appropriately-sized device for monitoring the rotation of a rotary wheel of a positive displacement peristaltic pump and for providing a solution to the problem of having a no-flow or backflow of fluid as well as minimizing its effects on fluid delivery to the patient.

[0018] As can be understood by one skilled in the art, the appropriately-sized term can refer to a miniature size or any other size suitable for the purposes as discussed in the present application.

[0019] Some embodiments of the present invention relate to a method and a device for monitoring the rotation of an infusion pump driving mechanism (i.e., motor, gears, shafts, etc.).

[0020] In some embodiments, the present invention relates to a self-correction mechanism operating via a feedback control system that accounts for the occurrence of at least one of the following conditions: motor malfunction, electrical wire(s) disconnection, software and/or electronics error(s), battery voltage drop, and/or electro-mechanical disassociation due to breakage of gears, dust, etc.

[0021] In some embodiments, the present invention relates to a method and a system for alerting the patient if the above correction attempts fail.

[0022] In some embodiments, the present invention relates to a method for preventing or at least minimizing the occurrence(s) of no-flow or backflow in a positive displacement peristaltic pump and minimizing its effects on fluid delivery to the patient.

[0023] Some embodiments of the present invention relate to an infusion pump's driving mechanism, which may include DC motor, stepper motor, SMA actuator, etc. It should be noted that in stepper motors, detection of electro-mechanical disassociation is a

challenge because motor rotation can be ceased without concomitant voltage or current changes and for the patient it will seem that the motor continues to work properly.

[0024] Inefficiency of an infusion pump driving mechanism could be life threatening because of the likely possibility of drug (e.g., insulin) under-dosing. Thus, it would be important to monitor the rotation of an infusion pump's driving mechanism (especially, one employing a stepper motor), and to apply self-correction or alert the patient of incorrect drug delivery in the occurrence of motor malfunction or electro-mechanical disassociation.

[0025] Some embodiments of the present invention provide a solution for monitoring the rotation of a miniature infusion pump's driving mechanism in order to ensure that the patient is provided with required amounts of therapeutic fluid.

[0026] In some embodiments, the present invention relates to systems and methods for monitoring rotation of the driving mechanism of a miniature infusion pump having two parts: a reusable part and a disposable part, which can be adhered to the skin of the patient and can be attached to and detached from the skin.

[0027] Some embodiments of the present invention provide a solution for monitoring the rotation of different components of the infusion pump's driving mechanism so that it is possible to detect occurrences of electro-mechanical disassociation as well as motor malfunction.

[0028] Some embodiments of the present invention relate to systems and methods for preventing or at least minimizing the occurrence(s) of backflow in positive displacement peristaltic pumps, and minimizing its effects on fluid delivery to the patient.

[0029] Some embodiments of the present invention are directed to a miniature-size, cost-effective rotation monitoring devices, such as one which includes an encoder wheel, at least one light emitting diode ("LED") and at least one light detector located at opposite sides of the encoder wheel. The device monitors the rotation of at least one component of a driving mechanism (i.e., motor, gear, shaft, etc.), maintains required rotation rate and alerts the user if necessary.

[0030] Embodiments of the present invention also relate to a miniature-size, cost-effective rotation monitoring devices, such as one which includes a LED and a light detector located at opposite sides of the rotary wheel, when employing a positive displacement peristaltic pump. The device monitors the rotation of the rotary wheel and increases the motor speed during no-flow or backflow periods of the rotation cycle. For example, when

employing a stepper motor, the acceleration is for a predetermined number of pulse trains during the no flow or backflow cycle period.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] FIGS. 1a-c illustrate exemplary single-part patch unit, two-part patch unit and a remote control unit, according to some embodiments of the present invention.

[0032] FIGS. 2a-b illustrate an exemplary single-part patch unit (shown in FIG. 2a) and an exemplary two-part patch unit (shown in FIG. 2b) employing a peristaltic pumping mechanism, according to some embodiments of the present invention.

[0033] FIG. 3 illustrates exemplary components of the reusable part of the peristaltic dispensing unit, according to some embodiments of the present invention.

[0034] FIG. 4 illustrates an exemplary driving mechanism of the infusion pump, a LED and a light detector located on the opposite sides of the secondary gear, according to some embodiments of the present invention.

[0035] FIG. 5 illustrates exemplary driving mechanism of the dispensing unit, components of the printed circuit board (PCB), and connections to the LED and light detector, according to some embodiments of the present invention.

[0036] FIG. 6a is a longitudinal cross-sectional view of the secondary gear when one of its apertures is aligned with the LED and the light detector.

[0037] FIG. 6b is a longitudinal cross-sectional view of the secondary gear when none of its apertures are aligned with the LED and the light detector.

[0038] FIGS. 7a-d are perspective and front views of the secondary gear colored half white and half black and adjacently-situated LED and light detector.

[0039] FIG. 8 illustrates exemplary reusable part components of a peristaltic dispensing unit, according to some embodiments of the present invention.

[0040] FIG. 9 illustrates exemplary driving mechanism of the dispensing unit, an encoder wheel fixed on the worm shaft and a photointerruptor, according to some embodiments of the present invention.

[0041] FIGS. 10a-e are perspective and side views of an encoder wheel and a photointerruptor.

[0042] FIGS. 11a-d are front and perspective views of a round disc colored half white and half black and adjacently-situated LED and light detector.

[0043] FIGS. 12a-d illustrate an exemplary sharpened worm shaft and an adjacently-situated LED and light detector, according to some embodiments of the present invention.

[0044] FIGS. 13a-c illustrate an exemplary secondary gear with two magnets located either on the gear or within the gear's apertures or depressions, and a "Hall effect sensor", according to some embodiments of the present invention.

[0045] FIG. 14 illustrate an exemplary worm shaft with two magnets located at its tip and a "Hall effect sensor", according to some embodiments of the present invention.

[0046] FIG. 15 illustrates exemplary components of the reusable part of a syringe-type infusion pump, according to some embodiments of the present invention.

[0047] FIG. 16 is a block diagram of the feedback process, according to some embodiments of the present invention.

[0048] FIGS. 17a-d illustrate several exemplary consecutive positions of the rollers of a positive displacement peristaltic pump during the pumping cycle, according to some embodiments of the present invention.

[0049] FIG. 18 is a characteristic graph of a fluid flow rate (volume of fluid delivered over time) in a positive displacement peristaltic pump, according to some embodiments of the present invention.

[0050] FIG. 19 illustrates exemplary LED and light detector located at opposite sides of the rotary gear, according to some embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0051] To avoid the price limitation and to extend patient customization, next generation skin adherable dispensing patch unit ("dispensing unit" or "patch unit") was devised. An example of such device is discussed in a co-pending/co-owned U.S. Patent Application Serial No. 11/397,115 and International Patent Application No. PCT/IL06/001276, disclosures of which are incorporated herein by reference in their entireties. This next generation device is a dispensing unit having two parts:

- Reusable part - containing the at least a portion of driving and pumping mechanism, electronics and other relatively expensive components.
- Disposable part – containing cheap, discardable components such as reservoir and tubes.

- The device also includes a power supply, such as, one or more batteries. The batteries can be disposed in the disposable part, or reusable part, or the power supply can be shared by the disposable part and the reusable part.

[0052] This concept provides possibility for a cost-effective skin adherable infusion device and allows diverse usage of the device, e.g., the use of various reservoir sizes, various needle and cannula types and implementation of versatile operational modes. This generation of infusion pumps allows for various applicable types of pumping mechanisms for the two-part device configuration. The delivery mechanism can be the peristaltic positive displacement pumping mechanism also discussed in co-pending/co-owned U.S. Patent Application Serial No. 11/397,115 and International Patent Application No. PCT/IL06/001276.

[0053] Alternative driving mechanisms, which can be applied in any one of the various pumping mechanisms, may include DC motor, stepper motor, Shape Memory Alloy (SMA) actuator, etc. An exemplary driving mechanism includes a stepper motor due to its ability to be accurately controlled in an open loop system, i.e., no position feedback is needed, and therefore it is less costly to control.

[0054] Stepper motors may be activated discretely by series of sequential input pulses, i.e., "pulse trains", applied by the central processing unit (CPU), and transmit force and motion (i.e., torque) to the driving mechanism (e.g., "gear trains").

[0055] FIGS. 1a-c show an exemplary fluid delivery device having a dispensing unit (10) and a remote control unit (40), according to some embodiments of the present invention. In some embodiments, the dispensing unit (10) can include a single part (as illustrated in FIG. 1b) or two parts (as illustrated in FIG. 1c). In the two-part embodiment, the dispensing unit includes a reusable part (100) and a detachably-connectable disposable part (200). The remote control unit (40) communicates with the dispensing unit (10) and includes a display, control button(s), a processor, a memory, and any other components for communicating with the unit (10). The remote control unit (40) can communicate with the unit (10) using wired, wireless, RF, or any other suitable methods of communication. The remote control unit (40) can be any remote control, a cellular telephone, an iPod, a PDA, or any other suitable device.

[0056] The dispensing unit (10) may employ different dispensing mechanisms, such as a syringe-type reservoir with a propelling plunger, peristaltic positive displacement pumps, or any other suitable dispensing mechanism. The following description will refer to peristaltic positive displacement pumps for illustrative purposes only and is not intended to limit the

scope of the present invention. As can be understood by one skilled in the art, other dispensing can be used with the present invention.

[0057] FIG. 2a shows an exemplary single-part dispensing unit (10), according to some embodiments of the present invention. The single-part dispensing unit (10) has a single housing in which a peristaltic pump is employed for dispensing fluid to the body of a patient. The unit (10) includes a reservoir (220), a fluid delivery tube (230), a rotary wheel (110), an outlet port (213), a stator (190) elastically supported by a spring (191), a motor (120), electronics (130) (which can include a printed circuit board ("PCB") and/or other electronic components; throughout the following description, "electronics (130)" and "PCB (130)" will be used interchangeably and refer to the same element), an energy supply means (240), and control buttons (15a) and (15b). The reservoir (220) is in fluid communication with the outlet port (213) via the fluid delivery tube (230). The fluid delivery tube (230) is disposed between the rotary wheel (110) and the stator (190). The fluid delivery tube (230) is squeezed between the stator (190) that is elastically supported by the spring (191) and the rotary wheel (110) during delivery of the fluid via the fluid delivery tube (230). The motor (120) drives rotation of the rotary wheel (110). The energy supply means (240) (e.g., a battery) provides power to the unit (10) and to the motor (120). Electronics (130), which can include a processor, a memory, and other components, are coupled to the motor (120) and control buttons (15), and provide further control of fluid dispensing to the patient. The electronics (130) can also enable communication with the remote control unit (40) (not shown). The electronics (130) can determine the rate of fluid delivery to the patient, e.g., basal rate and/or bolus rate. The buttons (15) control electronics (130), turn the device on/off, and can provide any other desired functions (e.g., programming of the unit (10)). The fluid is delivered from the reservoir (220) through the delivery tube (230) to the outlet port (213).

[0058] The rotary wheel (110) includes a rotary gear (not shown), a rotary plate (not shown), and rollers (not shown). Rotation of the rotary wheel (110) and pressing of the rollers against one side of the fluid delivery tube (230), which is being pressed on by the stator (190) on the other side, periodically positively displaces the fluid within the delivery tube (230) by virtue of a peristaltic motion. An example of a suitable positive displacement pump is disclosed in co-pending/co-owned U.S. Patent Application Serial No. 11/397,115 and International Patent Application No. PCT/IL06/001276, the disclosures of which are incorporated herein by reference in their entireties. A motor (120), such as a stepper motor, a DC motor, a SMA actuator or the like, rotates the rotary wheel (110) and is controlled by the

electronic components schematically designated as electronics (130). As stated above, the electronic components include a controller, a processor and a transceiver. The energy supply means (240) can be one or more batteries. Infusion programming can be carried out by a remote control unit (not shown) or by manual buttons (15) provided on the dispensing unit (10).

[0059] FIG. 2b shows an exemplary two-part dispensing unit (10), according to some embodiments of the present invention. The unit (10) has a reusable part (100) and a disposable part (200), wherein each part is contained within its own housing. The reusable part (100) includes a positive displacement pump provided with the rotary wheel (110), the motor (120), the PCB (130) and manual buttons (15). The disposable part (200) includes the reservoir (220), the delivery tube (230), the energy supply means (240), the outlet port (213) and the stator (190).

[0060] In this embodiment, fluid dispensing is possible after connecting the reusable part (100) with the disposable part (200). Once the parts are connected, fluid dispensing can be performed in a similar fashion as in the single-part unit (10) shown in FIG. 2a. An example of this arrangement is disclosed in the co-pending/co-owned U.S. Patent Application Serial No. 11/397,115 and International Patent Application No. PCT/IL06/001276, the disclosures of which are incorporated herein by reference in their entireties. As can be understood by one skilled in the art, all embodiments of rotation monitoring means described hereafter can be implemented in a single-part dispensing unit, a two-part dispensing unit or a multi-part dispensing unit.

[0061] FIG. 3 shows an embodiment of the reusable part (100), according to some embodiments of the present invention. The driving mechanism of the reusable part (100) includes the rotary wheel (110) and the motor (120). The driving mechanism further includes a pinion (122), a secondary gear (124), a worm (126), and a shaft (128). The worm (126) is coupled to the shaft (128), which in turn is coupled to the secondary gear (124). The secondary gear (124) is coupled to the pinion (122) that is coupled to the motor (120). The worm (126) is coupled to the rotary wheel (110). Upon application of power from the energy supply means (240) (not shown in FIG. 3), the motor (120) causes rotation of the secondary gear (124) via pinion (122). The pinion (122) and the secondary gear (124) can include teeth that are configured to mate with each other and thereby cause rotational motion. As the secondary gear (124) is coupled to the shaft (128), rotation of the secondary gear (124) causes rotation of the shaft (128), thereby causing rotation of the worm (126). The worm

(126) can be similar to a thread, whose rotational motion is translated to the rotary wheel (110). The rotary wheel (110) can include a plurality of teeth that mate with the threads on the worm (126). The reusable part further includes the PCB (130), and manual buttons (15) and an alerting component (17). As stated above, the manual buttons (15) can activate/deactivate operation of the driving mechanism. Further details of the above arrangement are illustrated in FIG. 4 and are discussed below.

[0062] The driving mechanism of the reusable part (100) further includes a source of energy, such radiation, electromagnetic radiation, infrared radiation ("IR"), electrochemical energy, electromechanical energy, mechanical energy, or any other source of energy. In some embodiments, the source of such energy is an LED (112) and an electromagnetic radiation detector (114) that are disposed proximal to the secondary gear (124). In the further description, "source of electromagnetic radiation" will be referred-to as "light source" or as "LED", and "electromagnetic radiation detector" will be referred-to as "light detector". The LED (112) and the light detector (114) perform monitoring of the rotation of the secondary gear (124) of the driving mechanism. The LED (112) and the light detector (114) can be configured to be located on the opposite sides of the secondary gear (124), whereby LED (112) emits light toward the light detector (114) and interruption of the light emitted by LED (112) by the secondary gear (124) is detected by the light detector (114). The light detector (114) can be a phototransistor that can detect light emitted by the LED (112). Upon detection of the interruption of the emitted light, a signal is generated and then sent to the processor for processing. Such detection is further discussed below.

[0063] As can be understood by one skilled in the art, the LED (112) and the light detector (114) may be located on opposite sides of any rotating component which is a part of the driving mechanism of the dispensing unit (10), for example, the rotary gear (110). In the following description, the arrangement of the LED (112) and the light detector (114) will be discussed for exemplary, illustrative purposes and is not intended to limit the scope of the present invention. As can be understood by one skilled in the art, such arrangement is applicable to any other component in the dispensing unit (10).

[0064] FIG. 4 shows further detail of the driving mechanism of the dispensing unit (10) as shown in FIG. 3. As stated above, The motor (120) rotates the pinion (122), which is coupled to the secondary gear (124). The teeth of the pinion (122) are meshed with the teeth of the secondary gear (124), so that the teeth of the pinion (122) transmit torque to the teeth of the secondary gear (124). In some embodiments, the secondary gear (124) then rotates in a

direction opposite to the direction of rotation of the pinion (122). In some embodiments, the rotation is accomplished at an exemplary gear ratio of 3:1. The secondary gear (124) and the worm (126) are both mounted on the shaft (128), as such they are rotated at the same rotational velocity. The worm (126) is coupled to the teeth of the rotary gear plate (106) of the rotary wheel (110). As the worm (126) rotates, it transmits torque to the rotary gear plate (106), thereby rotating it. In some embodiments, the plane of rotation of the worm (126) is perpendicular to the plane of rotation of the rotary gear plate (106).

[0065] As illustrated in FIG. 4, the rotary wheel (110) includes a roller supporting plate (105) to which one or more rollers (101a), (101b) (in some embodiments, there can be four rollers; the additional two rollers are not shown in FIG. 4) are coupled. The roller supporting plate (105) is further coupled to rotary gear plate (106) and is capable of rotating around its axis, as indicated by the rotational arrow A in FIG. 4. As can be understood by one skilled in the art, the rotary wheel (110) can rotate in any desired direction. The rollers (101) (in the following description “rollers (101)” will refer to the plurality of rollers and “roller (101a)”, “roller (101b)”, etc. will refer to individual rollers) are rotationally secured to the roller supporting plate (105) and are placed between the roller supporting plate (105) and the rotary gear plate (106), as illustrated in FIG. 4. This means that the rollers (101) are capable of rotating as the rotary wheel (110) rotates around its axis. The combination of the roller supporting plate (105) and the rotationally-secured rollers (101) has a smaller diameter than the rotary gear plate (106). Such arrangement prevents interference of the rotary gear plate (106) with dispensing of the fluid through the delivery tube (not shown in FIG. 4). Further, the rollers (101) are disposed around the center of the rotary wheel (110). As the rotary wheel (110) rotates, the rollers (101) press against the delivery tube (not shown in FIG. 4), which is sandwiched between the rollers (101) and the stator (not shown in FIG. 4). The stator is applied to the delivery tube in way so that it does not interfere with the rotation of the rotary gear plate (106). Squeezing of the delivery tube by the rollers (101) periodically positively displaces fluid inside the delivery tube by virtue of the peristaltic motion. Based on the direction of rotation of the rotary wheel, the fluid inside the fluid delivery tube is displaced in the appropriate direction. As can be understood by one skilled in the art, the axis of rotation of the rotary wheel (110) can be coupled to the housing of the reusable unit (100).

[0066] As stated above, to monitor rotation of the secondary gear (124), the secondary gear (124) includes two equally disposed apertures (127) and (127'). The apertures (127) allow the passage of light emitted by the LED (112) through the secondary gear (124)

to the light detector (114). As can be understood by one skilled in the art, the LED (112) and the light detector (114) both have appropriate leads which are soldered to the PCB (130) (not shown in FIG. 4). The LED (112) and the light detector (114) are so positioned within the housing of the reusable unit (100) and adjacent to the secondary gear (124) as to allow passage of light from the LED (112) to the light detector (114).

[0067] As can be understood by one skilled in the art, there may be only one aperture (127) in the secondary gear (124) or more than two apertures (127) which can be equally spaced, and the apertures (127) may be of any size and shape. In some embodiments, the number of apertures determines the resolution of the monitoring. In the embodiment where the secondary gear (124) includes one aperture, signals transmitted by the light detector (114) indicate only when one full turn of the secondary gear (124) has been completed. In the embodiment, where the secondary gear (124) has two apertures, signals transmitted by the light detector (114) indicate when one-half of a turn of the secondary gear (124) has been completed. In multiple-aperture embodiments, the signals transmitted by the light detector (114) indicate when a part of a turn of the secondary gear (124) has been completed. Rotation of the secondary gear (124) and detection of rotational position of the gear (124) by the light detector (114) determines an amount of fluid to be dispensed through the fluid delivery tube (not shown) to the patient.

[0068] As stated above, upon rotation of the secondary gear (124) and alignment of the apertures (127) with the LED (112) and light detector (124), the light emitted by the LED (112) passes through the aperture (127) and is received by the light detector (124). Upon receipt of the emitted light by the light detector (124), the light detector (124) generates a signal that is sent to a processor or CPU (not shown but discussed below with regard to FIG. 5) disposed on the PCB (130), which along with other components processes this signal (in the following description and for ease of discussion, unless otherwise noted, the reference to "PCB (130)" will refer to appropriate components of the PCB (130), such as the processor, memory, etc. that perform functions that are being discussed, such as processing, determining, and others). Upon processing of the signal, the PCB (130) determines how many turns and/or portion of the turn the secondary gear (124) made and correlates that to a particular dosage of therapeutic fluid delivered to the patient. In some embodiments, the use of the secondary gear (124) or any other rotating component that is a part of the driving mechanism as an encoder wheel (or encoder vane) for the purposes of monitoring of an amount of fluid being delivered is highly advantageous as it obviates the need for an

additional space for monitoring components of the driving mechanism. As stated above and as can be understood by one skilled in the art, the LED (112) and the light detector (114) can be placed anywhere on any component of the driving mechanism or other carrier/platform such as the PCB, and monitor rotation of other components.

[0069] FIG. 5 is a perspective view of a dispensing unit's driving mechanism and the main components of the PCB (130). The LED (112) and the light detector (114) both have respective electrical leads (199) and (198) that are connected (e.g., soldered) to the PCB (130). The LED (112) and the light detector (114) are powered by at least one battery provided in the disposable or the reusable part (not shown in FIG. 5). The PCB (130) further includes a central processing unit ("CPU") (650) that activates the LED (112) and the light detector (114). Upon activation, the light detector (114) transmits signals (i.e., upon detection of light transmitted by the LED (112)) either directly to the CPU (650) or to another electronic component, e.g., a comparator (not shown in FIG. 5) for processing. As can be understood by one skilled in the art, the LED (112) and the light detector (114) can be located on different sides and not necessarily be arranged as shown in FIG. 5.

[0070] The motor (120) is coupled to the PCB (130) via electrical leads (125). The leads (125) provide power to the motor (120) from the energy supply means (not shown in FIG. 5). Additionally, the leads (125) provide commands from the CPU (650) to the motor, e.g., to rotate the pinion (122) at a certain speed and/or direction and/or stop.

[0071] FIG. 6a is a longitudinal cross-sectional view of the secondary gear (124) having two equally disposed apertures (127) and (127'). The secondary gear (124) is rotated by the pinion (122), which is rotated by the motor (120). As illustrated in FIG. 6a, the LED (112) and the light detector (114) are located below the shaft (128) and as further shown, the LED (112) transmits light through aperture (127) toward light detector (114). Specifically, the LED (112) emits light (1000) (indicated by an arrow) toward the secondary gear (124). When an aperture (127) in the secondary gear (124) is aligned with the LED (112) and the light detector (114) located at the opposite side of the secondary gear (124), the light (1000) passes through the aperture (127) and is detected by the light detector (114).

[0072] As illustrated in FIG. 6a, the light (1000) emitted by the LED (112) can pass directly from the LED (112) through an aperture (127) to the light detector (114). This is so in the case where the LED (112) and the light detector (114) face each other on the opposite sides of the gear (124). In some embodiments, a plurality of mirrors/reflecting surfaces can be used to allow reflection of the light in order for it to be aimed to pass through the aperture

(127). These embodiments are useful in the event, where the LED (112) and the light detector (114) are facing in various directions and/or are not necessarily disposed adjacent to the secondary gear (124) (or any other component of the driving mechanism). Upon detection of the light (1000), the light detector (114) generates a signal and transmits such signal to CPU (650) (not shown) for processing. Upon receipt of the signal, the CPU (650) determines how many turns and/or portions of a turn, the secondary gear (124) (or any other component) has completed.

[0073] FIG. 6b is another longitudinal cross-sectional view of the secondary gear (124). As shown in FIG. 6b, none of the apertures (127) in the secondary gear (124) are aligned with the LED (112) and the light detector (114). In this case, the light (1000) cannot pass through the apertures (127) and thus, reflected away from the secondary gear (124). Hence, no light is detected by the light detector (114). Since no light is detected by the light detector (114), the detector (114) does not generate a signal for transmission to the CPU (650).

[0074] As can be understood by one skilled in the art, the LED (112) can either emit light continuously or, in order to minimize energy consumption, can be activated (either by the CPU (650) or any other component) periodically according to a predetermined time schedule. When using a stepper motor, for example, the LED (112) may be activated by the CPU (650) only when the CPU (650) sends a pulse train to the motor (120). In some embodiments, the present invention can include a DC motor, an SMA actuator, or any other type of motor.

[0075] FIGS. 7a-d show another exemplary monitoring system of the driving mechanism, according to some embodiments of the present invention. In this embodiment, the secondary gear (124) is colored dichotomously, e.g., half white and half black, as shown in FIG. 7a. The light detector (114) is situated adjacent to the LED (112) and both are facing the secondary gear (124). The light detector (114) and the LED (112) may be two separately located components or fixed adjacently on a common support frame made of an opaque-material package. Both the LED (112) and the light detector (114) can have leads (similar to those shown in FIG. 5), which are coupled (e.g., soldered) to the PCB (130). When the light (1000) emitted by the LED (112) hits the white half of the secondary gear (124), the light (1000) is reflected from the secondary gear (124) and then detected by the light detector (114). FIG. 7b is a front view of the secondary gear (124) when the light (1000) emitted by the LED (112) hits the white half of the secondary gear (124). The light (1000) is reflected

from the secondary gear (124) and then collected by the light detector (114). FIGS. 7c-d are perspective and front views, respectively, of the secondary gear (124) at the time the light (1000) emitted by the LED (112) hits the black half of the secondary gear (124). In such a case, the light (1000) is absorbed by the secondary gear (124), and no light is collected by the light detector (114).

[0076] In this embodiment, the LED (112) either emits light continuously, or, in order to minimize energy consumption, is activated by the CPU (650) periodically according to a predetermined time schedule. When using a stepper motor, for example, the LED (112) may be activated by the CPU (650) when the CPU (650) sends a pulse train to the motor (not shown).

[0077] FIG. 8 illustrates an embodiment of the reusable part (100) having the components discussed above (i.e., the rotary wheel (110), the motor (120), the PCB (130), the pinion (122), the secondary gear (124), the worm (126), the shaft (128), the manual buttons (15) and the alerting component (17)), where monitoring of the driving mechanism is carried using a photointerruptor (113). The photointerruptor (113) includes a common support frame that secures the LED (112) and the light detector (114). As illustrated in FIG. 8, the LED (112) and the light detector (114) are secured in such a way that there is a space *S* formed between them. The support frame can be manufactured from an opaque-material. In this embodiment, the driving mechanism further includes an auxiliary element affixed to a rotating component (e.g. pinion, secondary gear, shaft, rotary wheel) of the driving mechanism. Optionally, the auxiliary element may be an integral part of the rotating component. Such an auxiliary element can be configured for example as an encoder vane (116) affixed to the shaft (128) as shown in FIGS. 8-9. The encoder vane (116) is coupled to the worm (126) via a portion of the shaft (128) that extends on the opposite side of the worm (126) as the other components of the driving mechanism. In some embodiments, the vane (116) has the same axis of rotation as the shaft (128) and the worm (126). As such, the vane (116) rotates at the same rotational velocity as the shaft (128). The encoder vane (116) can have variable shapes, e.g., a semi-circular shape, a circular shape, or any other shape. During rotation of the vane (116), at least a portion of the vane (116) passes through space *S* of the photointerruptor (113). Hence, as the encoder vane (116) rotates it passes through the space *S* between the LED (112) and the light detector (114). As soon as a particular portion of the vane (116) passes through the space *S*, the light emitted by the LED (112) is interrupted/blocked, hence, the light detector (114) fails to detect any light emitted by the

LED (112). As no light is detected by the light detector (114), the detector (114) generates a signal indicating “no detect” condition and sends it to the CPU (650) disposed on the PCB (130) (not shown) for processing. As can be understood by one skilled in the art, the detector (114) can generate a signal upon detection of the light, i.e., “no detect” condition is a normal operating condition and no signal is generated, and “detect” condition is an interrupted condition and signal is generated. As can be understood by one skilled in the art, the encoder vane (116) can be located on either at the end of the shaft (128), as illustrated in FIG. 8, or at any other location along the shaft (128), for example, between the secondary gear (124) and the worm (126). Moreover, the encoder vane (116) could be either a separate component mounted on the shaft (128), or an integral part of the shaft (128).

[0078] FIG. 9 is a perspective view of the dispensing unit's driving mechanism shown in FIG. 8 above. The encoder vane (116) can be configured as a 180° sector (e.g., the vane (116) has a substantially semi-circular shape) and affixed to the shaft (128), as shown in FIG. 8. This means that a portion of the vane is non-transparent (for the used range of wavelengths) and causes interruption of light transmitted by the LED (112). As can be understood by one skilled in the art, the vane (116) can have a circular shape and have one transparent portion and one non-transparent portion. The light emitted by the LED (112) can pass through the transparent portion, but cannot pass through the non-transparent portion. Having a circular shape of the vane (116) can provide an equal balancing of the vane (116) during rotation and thus, uniform speed of rotation. The LED (112) and the light detector (114) are coupled to the PCB (130) via a plurality of electrical leads (131a) and (131b), respectively. The leads (131) can be soldered to the PCB (130). PCB (130), via, for example, its CPU (650), supplies/transmits/receives current and signals via the leads (131). For example, electrical current is supplied to the LED (112) to transmit light toward the light detector (114). The light detector (114) also transmits signal via the leads (131) upon detection interruption of the transmitted light.

[0079] FIGS. 10a-b are perspective and side views, respectively, of the encoder vane (116) and the photointerruptor (113) when the vane (116) is located outside the space *S* between the LED (112) and the light detector (114). In this case, the light (1000) emitted by the LED (112) is detected by the light detector (114). Depending on how the system is set up, upon detection of a no-interruption condition, the light detector (114) does not generate any signals. Alternatively, the light detector (114) can generate a signal indicating no-interruption condition.

[0080] FIGS. 10c-d are perspective and side views, respectively, of the encoder vane (116) and the photointerruptor (113) when the encoder vane (116) is positioned in the space *S* between the LED (112) and the light detector (114). In this case, the encoder vane (116) blocks/interrupts the light (1000) emitted by the LED (112). Hence, the light (1000) is reflected from the vane (116) and no light is detected by the light detector (114). Thus, the light detector (114) can generate a signal indicating interruption condition. The reflected light can be collected by a separate light detector (not shown), which can generate the signal indicating interruption condition.

[0081] As can be understood by one skilled in the art, the present invention can encompass use of any number of encoder vanes (116) can be coupled to the shaft (128) at different locations. Additionally, the encoder vane (116) can have a plurality of sectors. For example, FIG. 10e shows an encoder vane (116) having one sector (1116) configured as a 180° sector, as shown in FIGS. 9-10d; FIG. 10f shows an encoder vane having two sectors (1116, 1116'), wherein each vane is configured to be a 90° sector separated by a 90° angle; and FIG. 10g shows an encoder vane having four sectors (1116, 1116', 1116'', 1116'''), wherein each sector is configured to be a 45° sector separated by a 45° angle.

[0082] The number of sectors determines the resolution of the monitoring, whereas when one sector is used, the signals transmitted by the light detector (114) will indicate whenever a full turn of the secondary gear (124) has been completed, when two sectors are used the signals transmitted by the light detector (114) will indicate whenever half a turn of the secondary gear (124) has been completed, and when four sectors are used the signals transmitted by the light detector (114) will indicate whenever one quarter of a turn of the secondary gear (124) has been completed, etc. As can be understood by one skilled in the art, any number of sectors corresponding to any number of detected turns can be used. Further, monitoring system of the present invention can use any number of light sources/light detectors (e.g., LEDs (112), light detectors (114)) that can be used with the encoder sector(s) 1116. Use of multiple light sources and/or multiple encoder vanes can provide more calibrated monitoring of the rotation motion of the driving mechanism. Such sources/detectors/vanes/sectors can be disposed throughout the driving mechanism.

[0083] FIGS. 11a-b are front and perspective views, respectively, of another exemplary monitoring mechanism having a dichotomously colored, e.g., half white-colored and half black-colored, round disc (118) affixed to the shaft (128), according to some embodiments of the present invention. The disc (118) rotates with the shaft (128) at the same

rotational velocity. The light detector (114) is situated adjacent to the LED (112) and both are facing the disc (118), as shown in FIG. 11b. The light detector (114) and the LED (112) used may be two separate components or fixed adjacently on a common support frame made of an opaque-material. Both the LED (112) and the light detector (114) have leads which are soldered to the PCB (130) (not shown). As the shaft (128) rotates, the disc (118) rotates, and when the light (1000) emitted by the LED (112) hits the white-colored half of the disc (118), the light (1000) is reflected from the disc (118) and is then detected by the light detector (114). As can be understood by one skilled in the art, the white-colored portion of the disc (118) can be painted using any reflective color and the black-colored portion can be painted with any non-reflective color. Alternatively, the white-colored portion can be a mirror that allows reflection of light emitted by the LED (112), whereas the black-colored portion can absorb the emitted light or deflect it away so that it is not detected by the light detector (114).

[0084] FIGS. 11c-d are front and perspective views, respectively, of the disc (118) when the light (1000) emitted by the LED (112) hits the black-colored half of the disc (118). In such a case, the light (1000) is absorbed by the disc, and no light is detected by the light detector (114). In this embodiment, the LED (112) can emit light continuously or, in order to minimize energy consumption, can be activated by the CPU (not shown) periodically based on a predetermined time schedule. When using a stepper motor, for example, the LED (112) may be activated by the CPU only when the CPU sends a pulse train to the motor (120). As can be understood by one skilled in the art, similar to the encoder vanes (116), the disc (118) can have multiple “white-colored” and “black-colored” portions. Further, the monitoring system of the present invention can have a multiple number of discs (118) located throughout the system for additional monitoring of the rotational motion of the driving mechanism. As can be understood by one skilled in the art, the designations of “white-colored” and “black-colored” are provided for purely illustrative and non-limiting purposes.

[0085] FIG. 12a shows another exemplary rotation monitoring system of the driving mechanism, according to some embodiments of the present invention. In this embodiment, the distal end of the shaft (128) is configured to have a flat portion (111) and a semi-circular portion (119). As the shaft (128) is circular, in some embodiment, a half of the cylindrical portion can be cut away from the distal tip of the shaft (128) to create the flat portion (111), as shown in FIG. 12a. The light detector (114) can be situated adjacent to the LED (112) and both can be further positioned so that, as the shaft (128) rotates, they are both facing either

the flat side (111) of the shaft (128) or the circular side of the shaft (128). The light detector (114) and the LED (112) used may be two separate components, as illustrated, or secured on a common support frame made of opaque-material. As can be understood by one skilled in the art, the LED (112) and the light detector (114) have leads which are soldered to the PCB (130) (not shown). During rotation of the shaft (128), when the flat side (111) of the shaft (128) faces the LED (112), the light (1000) emitted by the LED (112) is reflected from the flat side (111) and is then detected by the light detector (114), as shown in FIG. 12b. The flat side (111) can be any reflective surface that allows reflection of light, as it is emitted by the LED (112), toward the light detector (114).

[0086] FIGS. 12c-d show the light (1000) hitting the semi-circular side (119) of the shaft (128). In such a case, the light (1000) reflected from the shaft (128) is scattered in different directions, such that only a very small portion of the light can be collected by the light detector (114). Even though such minimal amount of light is collected by the light detector (114) and the light detector (114) may produce a signal indicating such detection, which is transmitted to the CPU (not shown). The CPU can distinguish between the signals produced as a result of the emitted light hitting the flat side (111) and the semi-circular side (119) of the distal end of the shaft (128). As can be understood by one skilled in the art, there can be a multiple number of sides (111) (thereby creating a plurality of partially-circular sides (119)). As stated above, the monitoring system can include a plurality of LEDs and light detectors.

[0087] FIGS. 13a-c show an alternate exemplary monitoring system of the driving mechanism that is based on the "Hall Effect" principle, according to some embodiments of the present invention. The Hall Effect relates to the formation of a difference in potential between opposite sides of an element composed of a conducting or a semi-conducting material through which an electric current is flowing, whereby a magnetic field is applied perpendicularly to the electric current. As shown in FIG. 13a, the monitoring system includes two equally spaced magnets (92) are either protruding from the secondary gear (124) or embedded inside appropriate apertures or depressions made in the gear (124), and a "Hall effect sensor" (90) positioned on the PCB (130). As can be understood by one skilled in the art, there can be any number of magnets (92) and sensors (90). Further the magnets (92) can be located anywhere on the gears or any other element of the driving mechanism. Referring back to FIG. 13a, as the secondary gear (124) rotates, the magnets (92) pass by the Hall effect sensor (90) and expose the sensor (90) to their magnetic field. As the magnets (92) pass

through the sensor (90), their magnetic field interacts with the electrical current flowing through the sensor (90), thereby creating a change in the electrical current (or electro-magnetic field) of the sensor (90). Upon detection of such change, the sensor (90) generates a signal and transmits it to the CPU or any other component disposed on the PCB (130) for processing.

[0088] FIG. 13b illustrates the situation when one of the magnets (92) located on the secondary gear (124) passes vis-à-vis the “Hall effect sensor” (90) and exposes the sensor (90) to its maximum magnetic field. As a result, the electrical signal transmitted by the “Hall effect sensor” (90) either to the CPU (not shown) or to another electronic component, e.g., a comparator (not shown), peaks. The “1” marked on the “Hall effect sensor” (90) in FIG. 13b indicates that a peak in the transmitted electrical signal may be assigned a digital “1” reference.

[0089] FIG. 13c shows a situation when none of the magnets (92) are located vis-à-vis the “Hall effect sensor” (90). In this case, the electrical signal transmitted by the “Hall effect sensor” (90) either to the CPU (not shown) or to another electronic component, e.g., a comparator (not shown), remains constant. The “0” marked on the “Hall effect sensor” (90) in FIG. 13c indicates that no change in the transmitted electrical signal may be assigned a digital “0” reference.

[0090] FIG. 14 shows another exemplary monitoring system employing the Hall Effect sensor (90), according to some embodiments of the present invention. In this embodiment, two equally spaced magnets (92) are placed at the end of the shaft (128) and a “Hall effect sensor” (90) is positioned to detect the magnetic field of the passing magnets (92). The sensor (90) can either face the tip of the shaft (128) without being coaxial with the shaft (128), as shown in FIG. 14, or to face the circumference of the tip of the shaft (128), as illustrated by the dotted line (90'). As the shaft (128) rotates, the electrical signal transmitted by the “Hall effect sensor” (90/90') either to the CPU (not shown) or to another electronic component, e.g., a comparator (not shown), will peak when a magnet (92) passes vis-à-vis the “Hall effect sensor” (90/90') and exposes the “Hall effect sensor” (90/90') to magnetic field. Thus, the electrical signal will peak twice for each revolution. As can be understood by one skilled in the art, instead of two magnets, it is possible to use only one magnet, provided that the outwardly facing side of the magnet comprises both north and south poles, and the same desired effect can be achieved. Further, it is possible to use more than two magnets, which can be equally spaced. The number of magnets determines the

resolution of the monitoring, whereas when two magnets (or one magnet having two poles) are used, the signals transmitted by the “Hall effect sensor” (90/90’) will indicate whenever half a turn has been completed, or, when three magnets are used, the signals transmitted by the “Hall effect sensor” (90/90’) will indicate whenever one third of a turn has been completed, etc.

[0091] FIG. 15 shows another exemplary embodiment of the infusion pump (10), according to the present invention. The shown infusion pump (10) is a syringe-type infusion pump having the reusable part (100) and the disposable part (200). The disposable part (200) includes the energy supply means (240) and the fluid reservoir (220) provided with a displaceable rubber seal (414), an inlet port with a self-sealing rubber septum (215) and an outlet port (213). The inlet port (215) is in fluid communication with the reservoir (220) and is used to fill the reservoir (220) with a therapeutic fluid (e.g., insulin). The outlet port (213) is also in fluid communication with the reservoir (220) and is used for delivery of fluid to the body of the patient.

[0092] The reusable part (100) has the PCB (130), the manual buttons (15), the driving mechanism having the pinion (122), the secondary gear (124), the worm (126), the shaft (128), a gear wheel (134), and a restraining component (132). After connection of the reusable part (100) and disposable part (200), fluid dispensing can be possible. The motor (120) rotates the pinion (122), which is coupled to the secondary gear (124). The teeth of the pinion (122) are meshed with the teeth of the secondary gear (124), so that the teeth of the pinion (122) transmit torque to the teeth of the secondary gear (124) which then rotates in the opposite direction. The secondary gear (124) and the worm (126) are both mounted on one shaft (128), so that they rotate at the same velocity, as discussed above with regard to FIGS. 1a-14. As shown in FIG. 15, the worm (126) rotates another gear wheel (134), which transfers movement to the lead-screw shaft of a piston (412). A restraining component (132) prevents the piston (412) from rotating, thus, allowing linear displacement of the piston (412). As the piston (412) is shifted forward, it pushes forward the displaceable rubber seal (414) of the fluid container (220), and fluid flows toward the outlet port (213). As can be understood by one skilled in the art, the above-described mechanism is one of many examples of a syringe-type infusion pump driving mechanism. The monitoring of the driving mechanism can be carried out using the LED (112) and the light detector (114), e.g., a phototransistor, located on opposite sides of the secondary gear (124), using the systems and methods discussed above with regard to FIGS. 3-14.

[0093] FIG. 16 is a block diagram of an exemplary closed loop system of the monitoring system, according to some embodiments of the present invention. The closed loop system (1600) includes a CPU (1602), a driving mechanism (1610), a rotation monitoring device (1608) and alerting components (1604) for executing the feedback process which is pertinent to all the abovementioned embodiments and which includes correction of the rotation (1606) of the driving mechanism, if such is desired. The CPU (1602) activates both the driving mechanism (1610) and the rotation monitoring device (1608). The rotation monitoring device (1608) includes an LED, a light detector, a photointerruptor, a "Hall effect sensor", etc., as discussed above with regard to FIGS. 3-14. The rotation monitoring device (1608) may be activated continuously or, for example, in order to minimize energy consumption, periodically based on a predetermined time schedule. When using a stepper motor, for example, the monitoring device may be activated by the CPU only when the CPU sends a pulse train to the motor.

[0094] The rotation monitoring device (1608) monitors rotation of at least one component of the driving mechanism (i.e., motor, gear, shaft, etc.) and transmits a signal produced by the light detector or any other sensor to the CPU (1602) (or to another electronic component, e.g., a comparator (not shown), which is connected to the CPU). The CPU (1602) then processes the signal received from the monitoring device and derives from it the number of revolutions executed by the motor during a predetermined time period, or during the dispensing of a predetermined amount of therapeutic fluid, etc. The CPU (1602) computes the number of revolutions which should have been executed by the motor according to pre-programmed data regarding the amount of therapeutic fluid dispensed in the course of one motor revolution and data inputted by the patient regarding the amount of therapeutic fluid to be infused. The CPU compares the actual number of executed revolutions with the number of revolutions which should have been executed by the motor, and if they are dissimilar, i.e., if the motor has executed fewer revolutions than necessary, or more than necessary, the CPU will execute the needed correction of the revolution of the driving mechanism. For example, if the information derived from the signal transmitted by the monitoring device indicates that the motor has executed X rotations in a specific time period, whereas it should have executed Y rotations in the said period of time, the CPU will send a command to the motor to rotate an extra Z rotations during the following predetermined time period, whereas $Z=Y-X$. If correction attempts fail, the CPU will alert the patient via an alerting component located in the reusable part of the infusion pump and/or the remote control unit. The above mentioned

monitoring devices can also provide a solution to the backflow problem which is inherent in rotary peristaltic pumps.

[0095] FIGS. 17a-d show several consecutive positions of the rollers, as shown in FIG. 4), of a positive displacement peristaltic pump (for example, provided with four rollers) during a pumping cycle. FIG. 17a shows a roller (101) completely compressing the delivery tube (230) against the stator (190) (not shown) after the adjacent roller (104) has finished compressing the delivery tube (230) against the stator and has rotated away by the rotary wheel (110). FIG. 17b shows said roller (101) moving along the delivery tube (230) and compressing the tube (230) against the stator (not shown), thus, positively displacing fluid in a forward direction. FIG. 17c shows two rollers (101), (102) completely compressing the delivery tube (230) as roller (101) is about to rotate away from compressing the delivery tube (230). FIG. 17d shows roller (102) completely compressing the delivery tube (230) after the roller (101) has rotated away from the delivery tube (230). The pumping phases depicted in FIGS. 17a-c are characterized by a constant flow rate and in a forward direction, i.e., the direction of fluid delivery from the reservoir to the body of the patient, while the pumping phase depicted in FIGS. 17c-d is characterized by no-flow or backflow. In this case, backflow means a flow of therapeutic fluid in the direction opposite to the direction of forward flow of the fluid.

[0096] FIG. 18 is a characteristic graph of fluid flow rate (volume of fluid delivered over time) during one rotation of a rotary wheel of a positive displacement peristaltic pump provided with four rollers, for example. The points marked *a*, *b*, *c*, *d* on the graph indicate the positions of the rollers, as described in FIGS. 17a-d, which correspond to said marked points on the graph (whereas the position of the rollers as illustrated in FIG. 17a corresponds to the point on the graph marked “*a*”, and so forth). The section of the graph between points “*a*” and “*c*” is the cycle period when roller (101) (FIG. 17) is completely compressing the delivery tube (230), achieving constant forward flow motion. The section of the graph between points “*c*” and “*d*” is the cycle period when roller (101) (FIG. 17) is moving away from the tube allowing backward flow motion. The four nadir periods on the graph correspond to the cycle periods in which the four rollers are leaving the delivery tube (230).

[0097] FIG. 19 shows one preferred embodiment for correction of the widely varying flow rate during a pump cycle. The LED (112) and the light detector (114) are placed on opposite sides of the rotary gear plate (106), which has four equally spaced apertures (127), (127') (only two apertures are shown in FIG. 19) - one aperture is disposed between every

two adjacent rollers (101), (102, (103) (the fourth roller is not shown in FIG. 19). The LED (112) and the light detector (114) can be placed at any desired location on the rotary gear plate (106). When an aperture (127) is aligned with the LED (112) and the light detector (114), the light is detected by the light detector (114), which then transmits signals either directly to the CPU (not shown), or to another electronic component, for processing.

[0098] As can be understood by one skilled in the art, the same effect can be achieved by placing said apertures (127), (127') (only two apertures are shown) closer to the center of the rotary gear plate (106) and disposing four appropriate apertures on the rotary plate (109), so that every two corresponding apertures are aligned. In this case the LED (112) is located on the outer side of the rotary gear plate (106) and the light detector (114) is located on the outer side of the rotary plate (109), or vice versa, and in order for the light emitted by the LED (112) to be collected by the light detector (114), a pair of apertures (one on the rotary gear plate (106) and one on the rotary plate (109)) has to be aligned with the LED (112) and the light detector (114).

[0099] The light detector (114) and the LED (112) used may be two separately located components, as illustrated, or fixed adjacently on a common support frame made of an opaque-material package, e.g., a photointerruptor. As can be understood by one skilled in the art, a monitoring device based on the "Hall effect", employing magnets and a "Hall effect sensor", as shown in FIG. 14, can also be applied. As can be further understood by one skilled in the art, one rotation monitoring device, i.e., an LED and a light detector, a photointerruptor, a "Hall effect sensor", etc. can be used for both monitoring the rotation of the driving mechanism of the dispensing unit and minimizing the occurrence of no flow or backflow and its effects on fluid delivery accuracy, or otherwise two separate devices can be used, one for each purpose.

[00100] The closed loop system for executing a feedback process for the purpose of minimizing the occurrence of no flow or backflow and its effects on fluid delivery to the patient is similar to the one shown in FIG. 16. The CPU activates both the driving mechanism and the rotation monitoring device, which may include an LED and a light detector, a photointerruptor, a "Hall effect sensor", etc. The rotation monitoring device may be activated continuously, or, in order to minimize energy consumption, periodically according to a predetermined time schedule. When using a stepper motor, for example, the monitoring device may be activated by the CPU only when the CPU sends a pulse train to the motor.

[00101] The monitoring device monitors rotation of the rotary wheel and transmits an electronic signal produced by the light detector or other sensor to the CPU (or to another electronic component which is connected to the CPU). The CPU adjusts rotation speed according to the relative position of the rollers and the tube. In case of a stepper motor acceleration is achieved by continuously sending pulse trains to the motor. Acceleration of the rollers motion during no flow or backflow periods maintains a uniform flow rate. In an alternative embodiment, when a stepper motor is employed the CPU can be programmed to disregard the pulse trains resulting in no-flow or backflow due to the position of the rollers, and not count them in the calculation of total delivered fluid. In some embodiments, when stepper motor is employed the CPU can adjust the rotation speed according to the relative position of the rollers and the tube, and in addition be programmed to disregard these pulse trains and not count them in the calculation of total delivered fluid.

[00102] Example embodiments of the methods and components of the present invention have been described herein. As noted elsewhere, these example embodiments have been described for illustrative purposes only, and are not limiting. Other embodiments are possible and are covered by the invention. Such embodiments will be apparent to persons skilled in the relevant art(s) based on the teachings contained herein. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

What is claimed:

1. An infusion device for dispensing therapeutic fluid to a body of a patient, comprising:

a dispensing unit which is configured as a positive displacement pump for dispensing therapeutic fluid to the body of the patient;

said pump including a driving mechanism and a monitoring mechanism;

said monitoring mechanism is adapted for monitoring of operation of the driving mechanism and accordingly dispensing of the therapeutic fluid to the body of the patient.

2. The device according to claim 1, wherein said positive displacement pump is a peristaltic pump; and

said dispensing unit further comprises:

a reservoir containing therapeutic fluid;

a fluid delivery tube in fluid communication with the reservoir;

an outlet port for delivering therapeutic fluid to the patient, the outlet port is in fluid communication with the reservoir via the fluid delivery tube; and,

a stator elastically supported by a spring for interacting with the fluid delivery tube.

3. The device according to claim 2, further comprising
a power supply;
electronic components coupled to said power supply;
said electronic components having a processor and at least one button for operating the dispensing unit.

4. The device according to claim 3, wherein the driving mechanism comprises:
a motor powered by the power supply and controlled by the processor;
a pinion coupled to the motor and having a plurality of pinion teeth, the motor causes rotation of the pinion;
a secondary gear having a plurality of secondary gear teeth for interacting with the plurality of pinion teeth, wherein rotation of the pinion in a particular direction causes rotation of the secondary gear in an opposite direction;

a shaft coupled to the secondary gear and rotating in the same direction as the secondary gear;

a worm disposed on the shaft and rotating in the same direction as the shaft;
and

a rotary wheel having a plurality of rotary wheel teeth for interacting with the worm, wherein rotation of the worm causes rotation of the rotary wheel.

5. The device according to claim 4, wherein the rotary wheel further comprises one or more rollers disposed circumferentially at the rotary wheel;
wherein upon rotation of the rotary wheel, the one or more rollers are driven by the rotary wheel and interact with the fluid delivery tube;

wherein the fluid delivery tube is disposed between the stator and the one or more rollers;

the one or more rollers squeezes the delivery tube against the stator and displaces therapeutic fluid inside the delivery tube.

6. The device according to claim 5, wherein at least one roller squeezes the delivery tube in such extent that there is no backflow of therapeutic fluid in the fluid delivery tube.

7. The device according to claim 6, wherein the monitoring mechanism further comprises:

an energy source;

an energy detector for detecting energy emitted by the energy source;

the energy source and the detector detect rotation of at least one component of the driving mechanism;

the detector generates a signal for processing by the processor.

8. The device according to claim 7, wherein said energy is radiation energy.

10. The device according to claim 7, wherein said energy is selected from a group consisting of: infrared radiation, electromagnetic radiation, electrochemical energy, electromechanical energy, mechanical energy and other energy.

11. The device according to claim 7, wherein the at least one component of the driving mechanism is selected from a group consisting of: the pinion, the secondary gear, the shaft, the worm, and the rotary wheel.

12. The device according to claim 11, wherein the at least one component of the driving mechanism is provided with an auxiliary element rotatable by said at least one component.

13. The device according to claim 7, wherein the at least one component of the driving mechanism includes one or more openings for passing the emitted energy from the energy source;

wherein upon detection of the emitted energy by the energy detector, the energy detector generates a signal for processing by the processor, said signal indicates that the at least one component has completed at least a portion of its full revolution.

14. The device according to claim 13, wherein the energy source and the energy detector are disposed on opposite sides of the at least one component of the driving mechanism.

15. The device according to claim 7, wherein the at least one component of the driving mechanism comprises a reflective surface; and

wherein the emitted energy is reflected by the reflective surface for detection by the energy detector.

16. The device according to claim 15, wherein the energy source and the energy detector are disposed on the same side of the reflected surface.

17. The device according to claim 8, wherein the auxiliary element comprises an encoder vane coupled to the shaft of the driving mechanism;

upon rotation of the shaft, the encoder vane interrupts the energy emitted by the energy source causing the energy detector to generate a signal for processing by the processor.

18. The device according to claim 17, wherein the encoder vane is configured as at least one sector selected from a group consisting of: 180 degree sector, 90 degree sector and 45 degree sector;

wherein upon rotation of the at least one sector, it blocks the emitted energy from being detected by the energy detector.

19. The device according to claim 16, wherein said reflective is arranged at a tip of the shaft.

20. The device according to claim 6, wherein the monitoring mechanism further comprises:

a Hall effect sensor coupled to the processor;

one or more magnetic element coupled to at least one component of the driving mechanism for exposing the Hall effect sensor to a magnetic field of the one or more magnetic element.

21. The device according to claim 2, wherein the dispensing unit comprises:
a reusable part comprising the driving mechanism, the monitoring mechanism and electronic components having a processor;

a disposable part having the reservoir, the fluid delivery tube, the outlet port, the stator;

a power supply, wherein said electronic components are coupled to said power supply;

wherein upon connection of the reusable part and the disposable part, the fluid dispensing device becomes operational.

22. The device according to claim 21, wherein the disposable part comprises the power supply.

23. The device according to claim 21, wherein the driving mechanism comprises:
a motor powered by the power supply and controlled by the processor;
a pinion coupled to the motor and having a plurality of pinion teeth, the motor causes rotation of the pinion;

a secondary gear having a plurality of secondary gear teeth for interacting with the plurality of pinion teeth, wherein rotation of the pinion in a particular direction causes rotation of the secondary gear in an opposite direction;

a shaft coupled to the secondary gear and rotating in the same direction as the secondary gear;

a worm disposed on the shaft and rotating in the same direction as the shaft;
and

a rotary wheel having a plurality of rotary wheel teeth for interacting with the worm, wherein rotation of the worm causes rotation of the rotary wheel.

24. The device according to claim 23, wherein the rotary wheel further comprises one or more rollers disposed circumferentially at the rotary wheel;
wherein upon rotation of the rotary wheel, the one or more rollers are driven by the rotary wheel and interact with the fluid delivery tube;

wherein the fluid delivery tube is disposed between the stator and the one or more rollers;

the one or more rollers squeezes the delivery tube against the stator and displaces therapeutic fluid inside the delivery tube.

25. The device according to claim 24, wherein the monitoring mechanism further comprises:

a source of energy;

a detector for detecting energy emitted by the energy source;

the energy source and the detector detect rotation of at least one component of the driving mechanism;

the detector generates a signal for processing by the processor.

26. The device according to claim 25, wherein the at least one component of the driving mechanism is selected from a group consisting of: the pinion, the secondary gear, the shaft, the worm, and the rotary wheel.

27. The device according to claim 26, wherein the at least one component of the driving mechanism is provided with an auxiliary element rotatable by said at least one component.

28. The device according to claim 25, wherein the energy source and the detector are disposed on opposite sides of the at least one component of the driving mechanism.

29. The device according to claim 28, wherein the at least one component of the driving mechanism includes one or more openings for passing the emitted energy from the energy source;

wherein upon detection of the emitted energy by the detector, the detector generates a signal for processing by the processor, said signal indicates that the at least one component has completed at least a portion of its full revolution.

30. The device according to claim 25, wherein the at least one component of the driving mechanism comprises a reflective surface; and

wherein the emitted energy is reflected by the reflective surface for detection by the detector.

31. The device according to claim 30, wherein the energy source and the detector are disposed on the same side of the reflected surface.

32. The device according to claim 27, wherein the at least one component is the shaft, and said auxiliary element comprises an encoder vane;
wherein upon rotation of the shaft, the encoder vane interrupts the energy emitted by the energy source causing the detector to generate a signal for processing by the processor.

33. The device according to claim 32, wherein the encoder vane is configured as at least one sector selected from a group consisting of: 180 degree sector, 90 degree sector and 45 degree sector;

wherein upon rotation of the at least one sector, it blocks the emitted energy radiation from being detected by the detector.

34. The device according to claim 24, wherein the monitoring mechanism further comprises:

a Hall effect sensor electrically connected to the processor;
one or more magnetic element coupled to at least one component of the driving mechanism for exposing the Hall effect sensor to a magnetic field of the one or more magnetic element.

35. The device according to claim 25, wherein the source of energy either emits the radiation continuously, or periodically based on a predetermined time schedule.

36. The device according to claim 28, comprising a carrier accommodating at least some of the electronic components;

said source of energy and said detector are disposed on said carrier.

37. The device according to claim 36, wherein said carrier is a printed circuit board ("PCB").

38. The device according to claim 28, further comprising:
another gear wheel, a piston, a lead-screw shaft of the piston, a restraining component;

the worm rotates the another gear wheel;
the another gear wheel transfers movement to the lead-screw shaft of the piston;
the restraining component prevents the piston from rotating and allow linear displacement of the piston;

wherein as the piston is shifted forward, the piston pushes forward a displaceable rubber seal of the reservoir causing fluid to flow toward the outlet port.

39. The device according to claim 21, further comprising at least one manual button for controlling operation of said dispensing unit.

40. The device according to claim 21, further comprising a remote control unit for remotely controlling operation of said dispensing unit.

41. The device according to claim 25, further comprising an alerting component for generating an alert to the patient upon receiving a signal from said electronic components indicating that the motor has performed different number of rotations than necessary within a predetermined period of time.

42. A method for monitoring of dispensing of therapeutic fluid to the body of a patient using a dispensing unit having a closed loop monitoring system that includes a processor, a driving mechanism, a rotation monitoring device and an alerting component, said method comprising the steps of:

using the processor, activating the driving mechanism and the rotation monitoring device;

using the rotation monitoring device, monitoring rotation of at least one component of the driving mechanism;

transmitting a signal from the rotation monitoring device to the processor, wherein the processor, based on the received signal, determines an actual number of revolutions performed by a motor disposed within the driving mechanism based on at least one predetermined parameter;

using the processor, computing a preset number of revolutions that should be performed by the motor based on at least one predetermined parameter;

comparing the actual number of revolution and the preset number of revolutions;

using the processor, causing the motor to perform a corrective revolution based on the comparing step.

43. The method according to claim 42, further comprising alerting the patient when corrective revolution fails.

44. The method according to claim 43, wherein the rotation monitoring device includes at least one component selected from a group consisting of: an LED, a light detector, a photointerruptor, and a "Hall effect sensor".

45. The method according to claim 43, wherein said activating step is performed either continuously or periodically based on a predetermined time schedule.

46. The method according to claim 43, wherein the predetermined parameter is selected from a group consisting of: a predetermined time period, a predetermined amount of fluid to be dispensed, and pre-programmed data relating to the dispensing of fluid.

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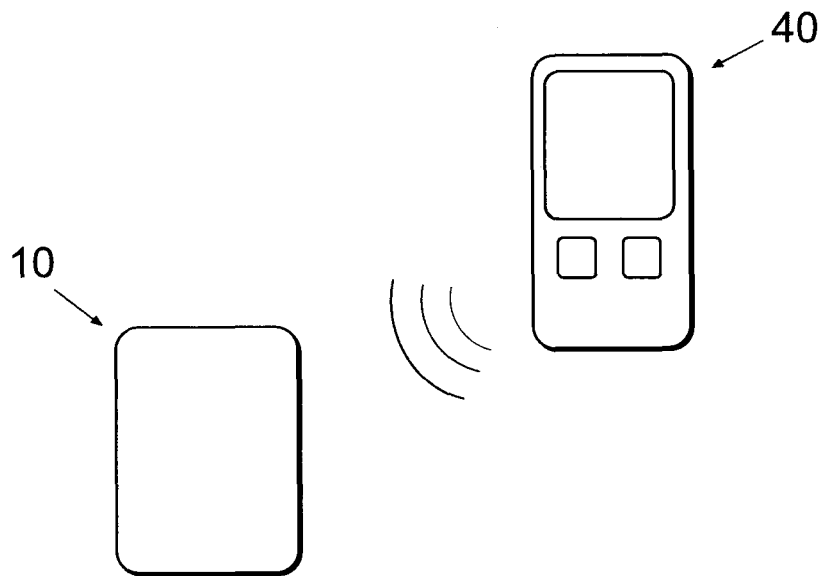


Fig. 1a

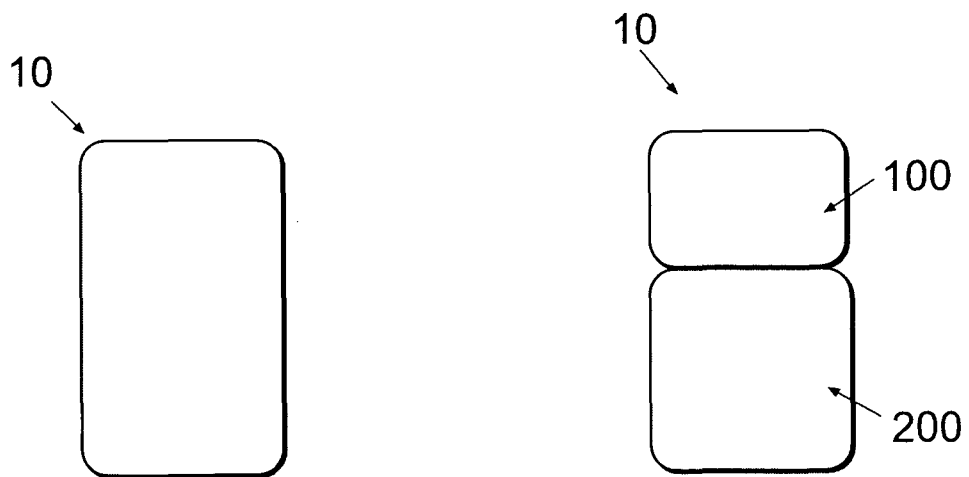


Fig. 1b

Fig. 1c

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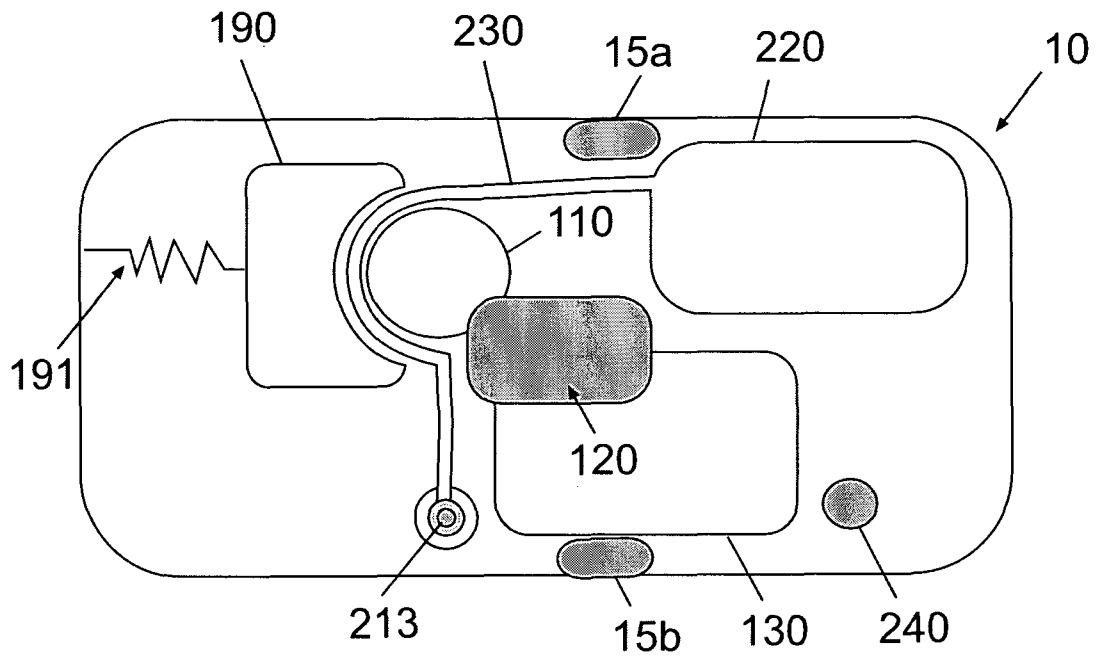


Fig. 2a

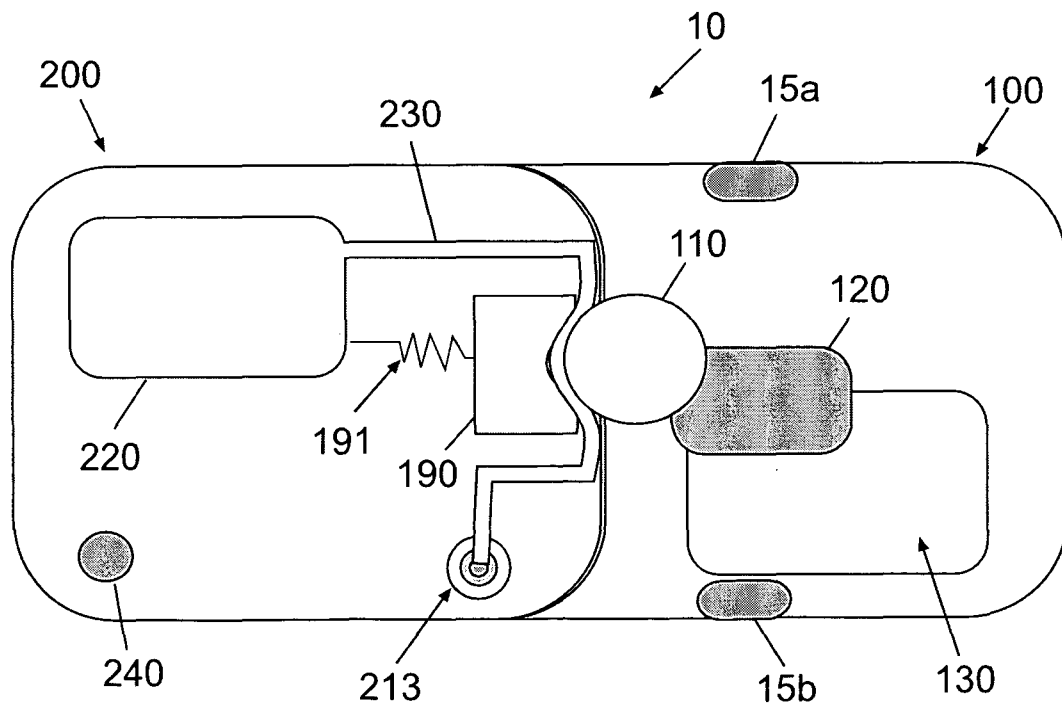


Fig. 2b

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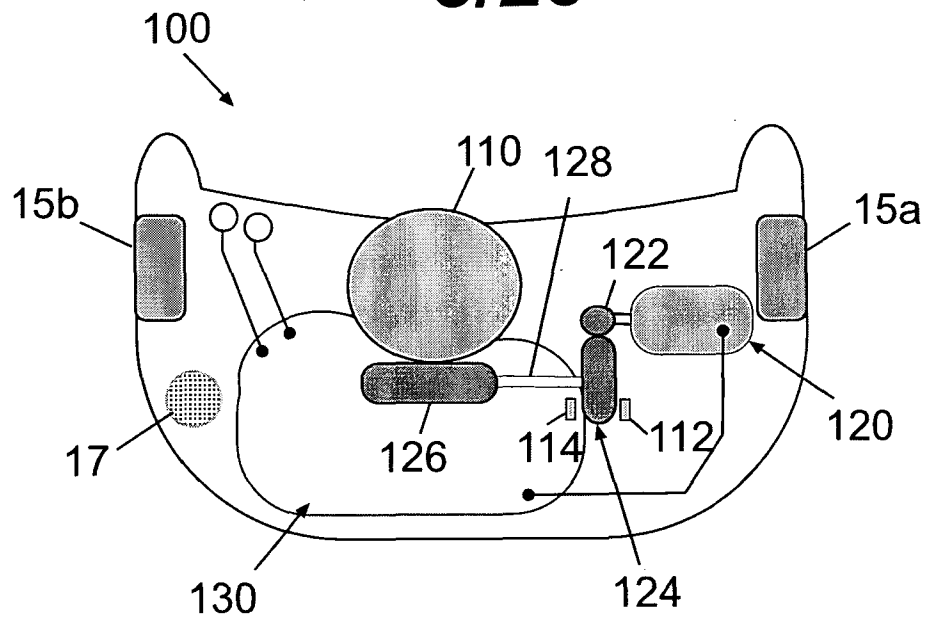


Fig. 3

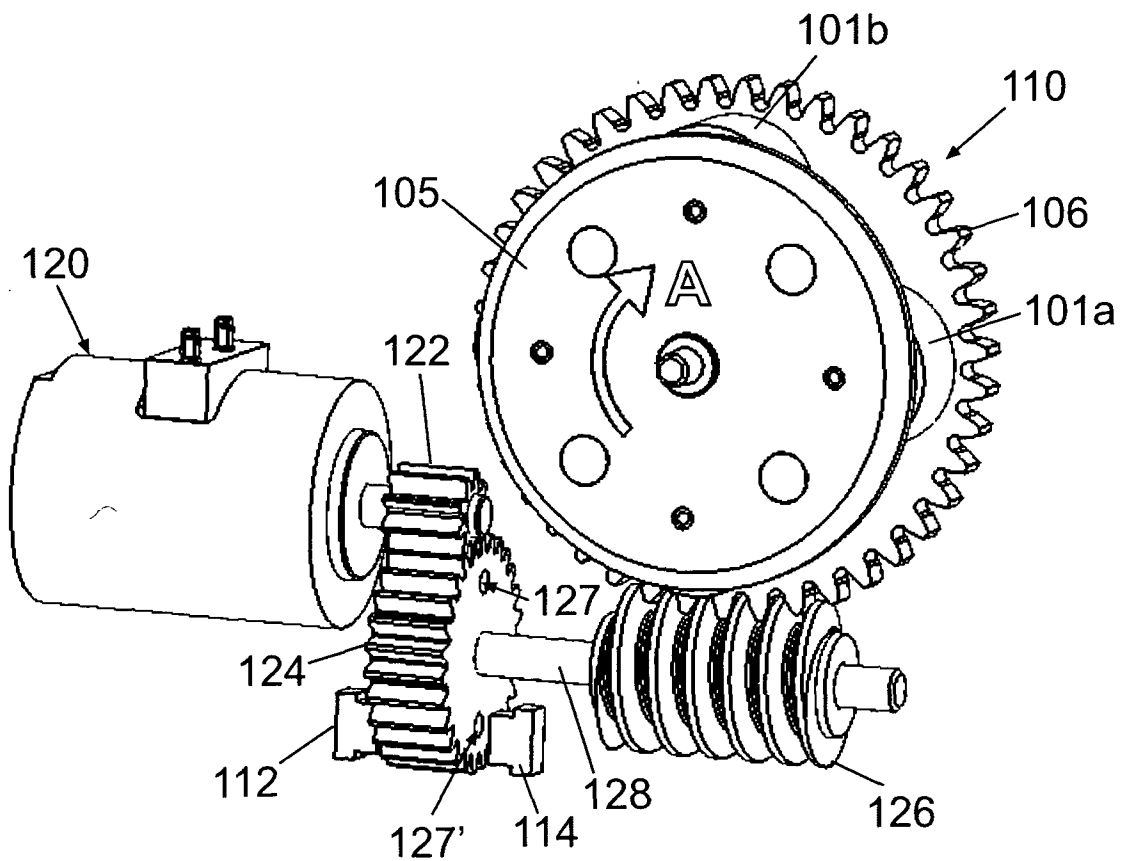


Fig. 4

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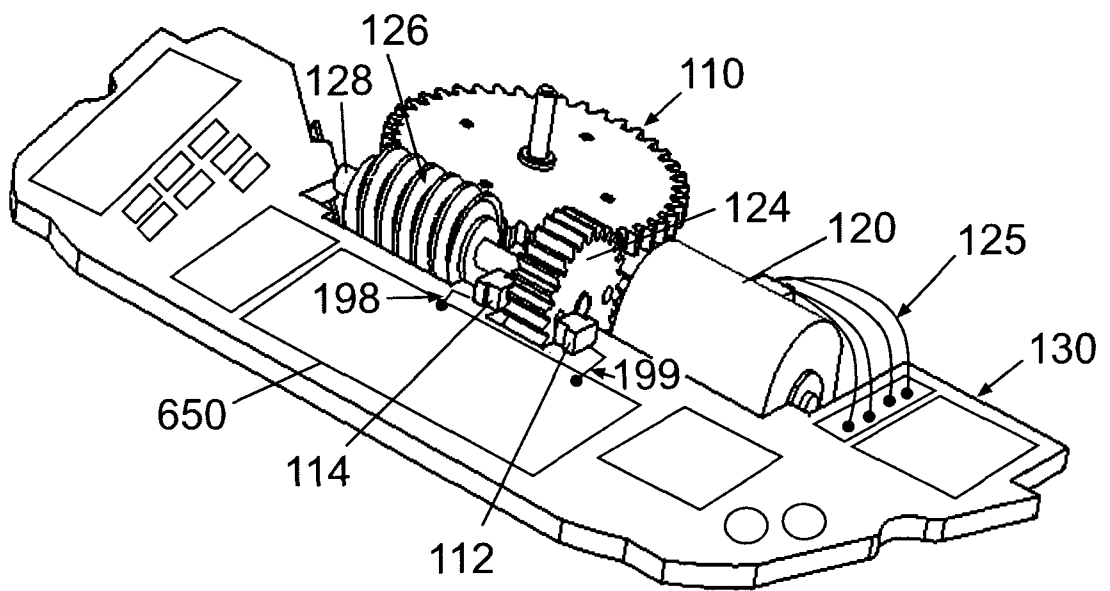
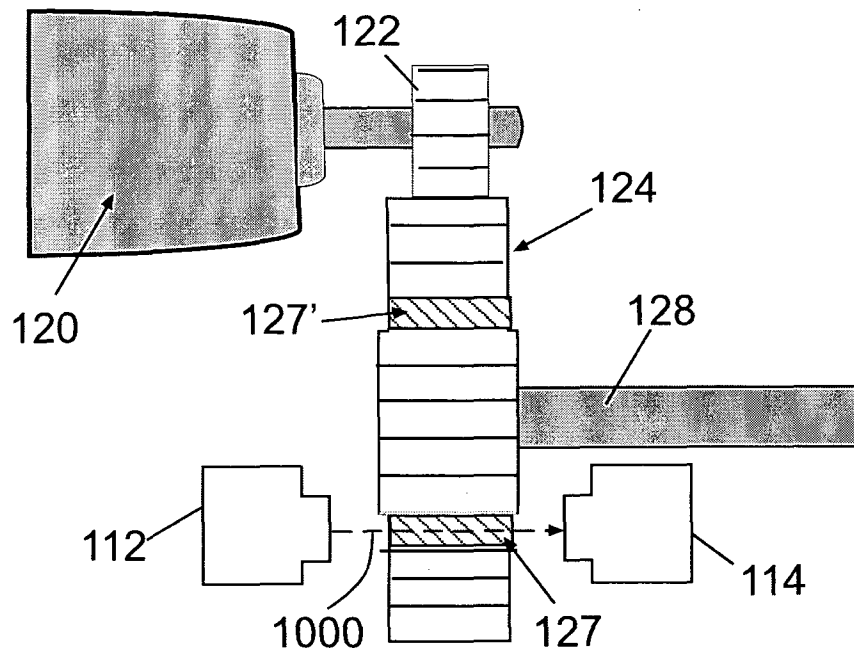
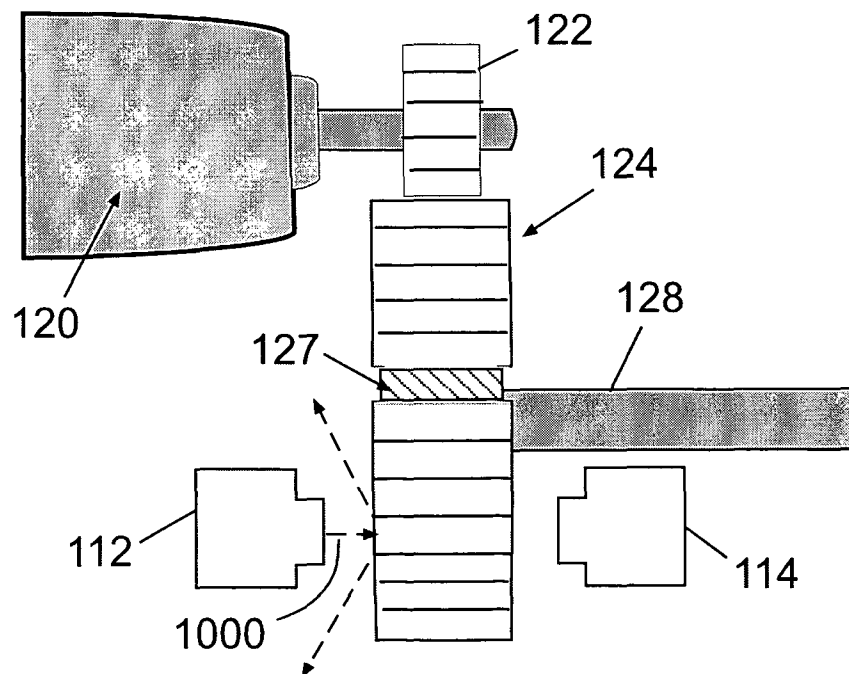


Fig. 5

5/20**Fig. 6a****Fig. 6b**

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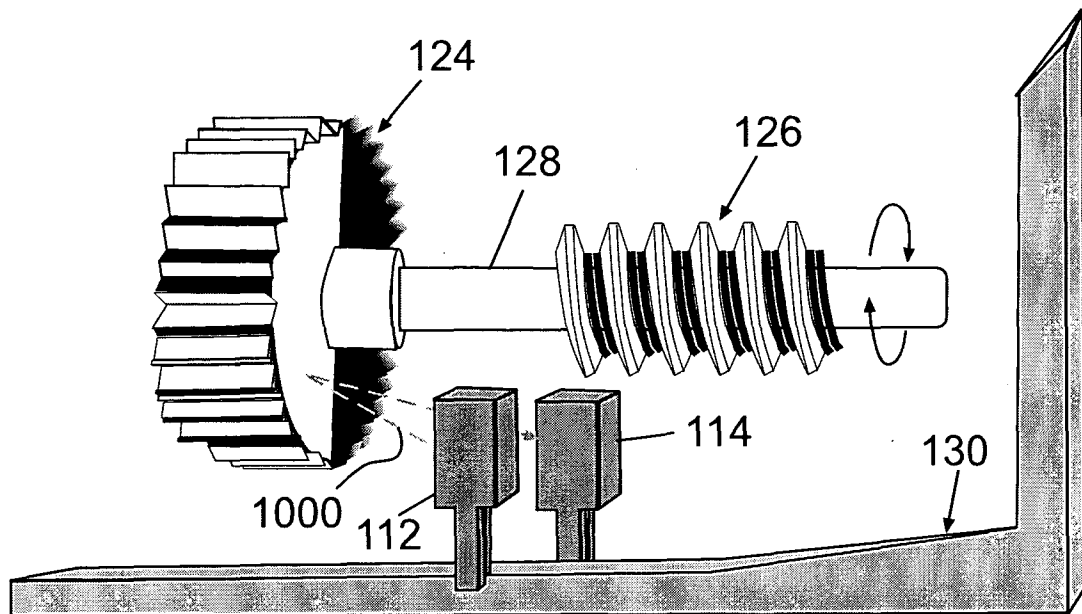


Fig. 7a

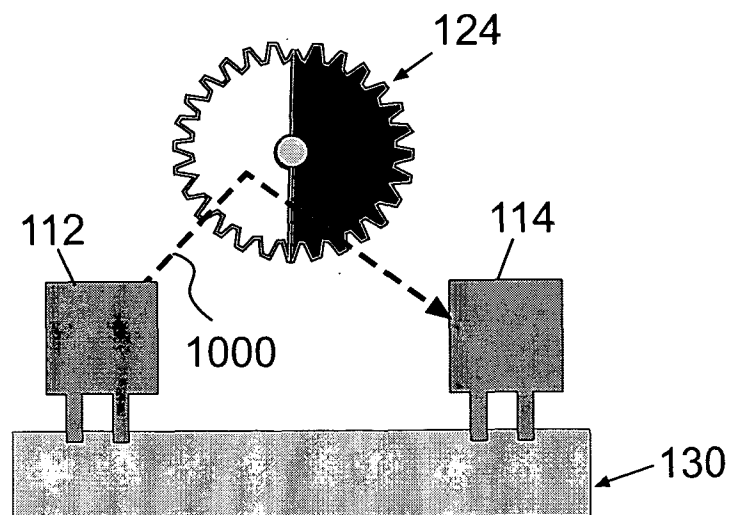


Fig. 7b

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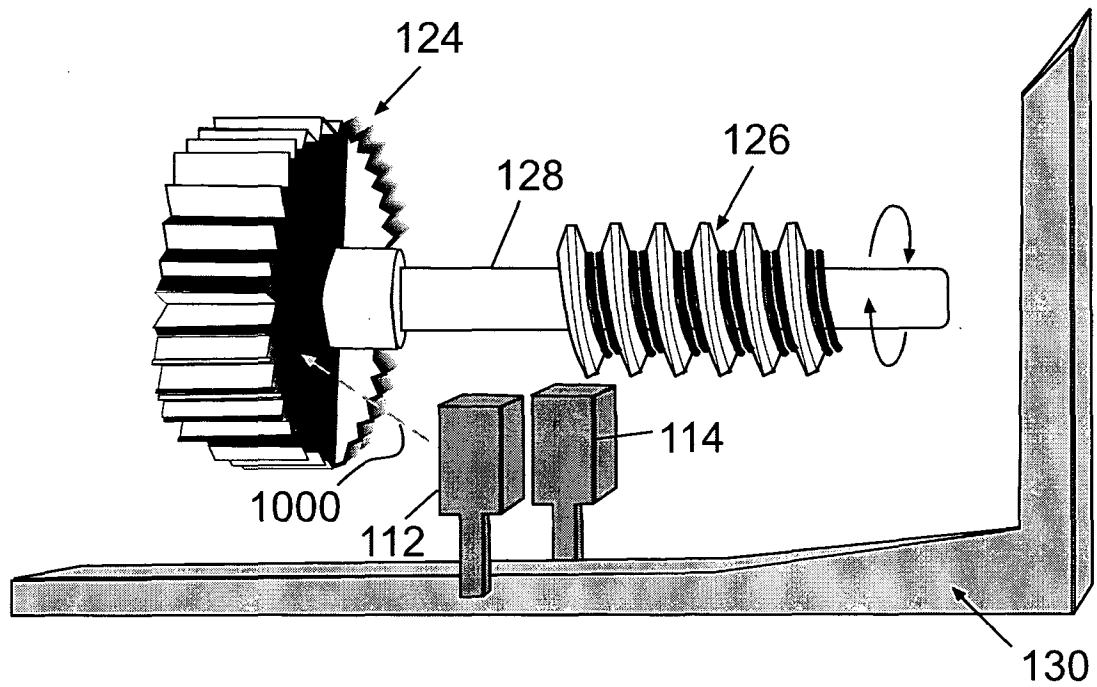


Fig. 7c

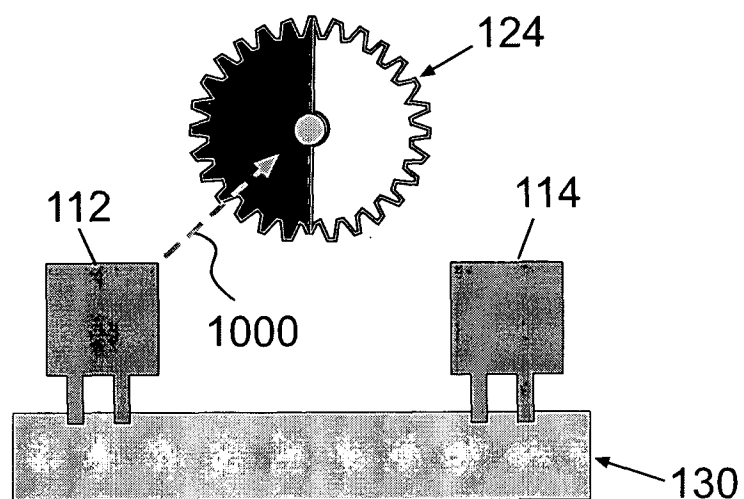


Fig. 7d

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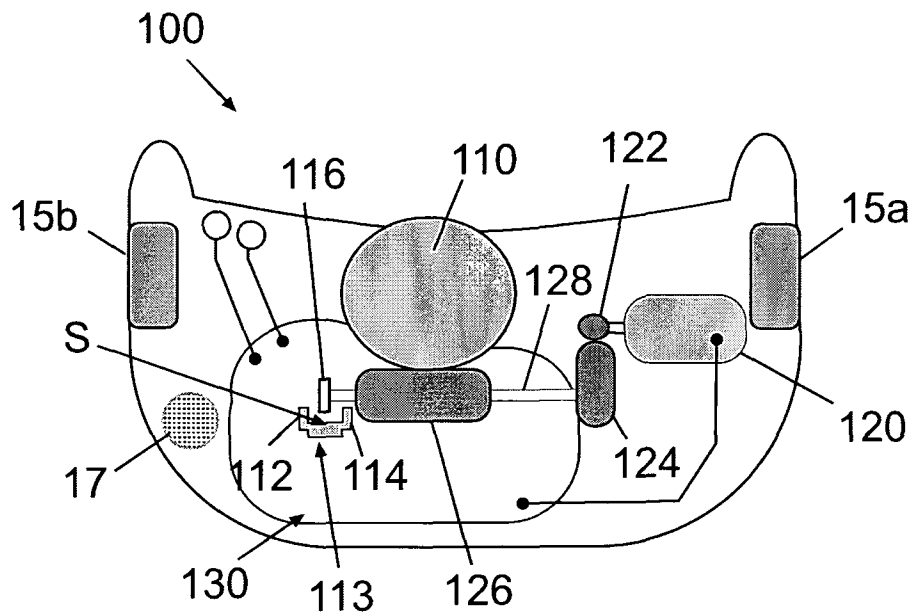


Fig. 8

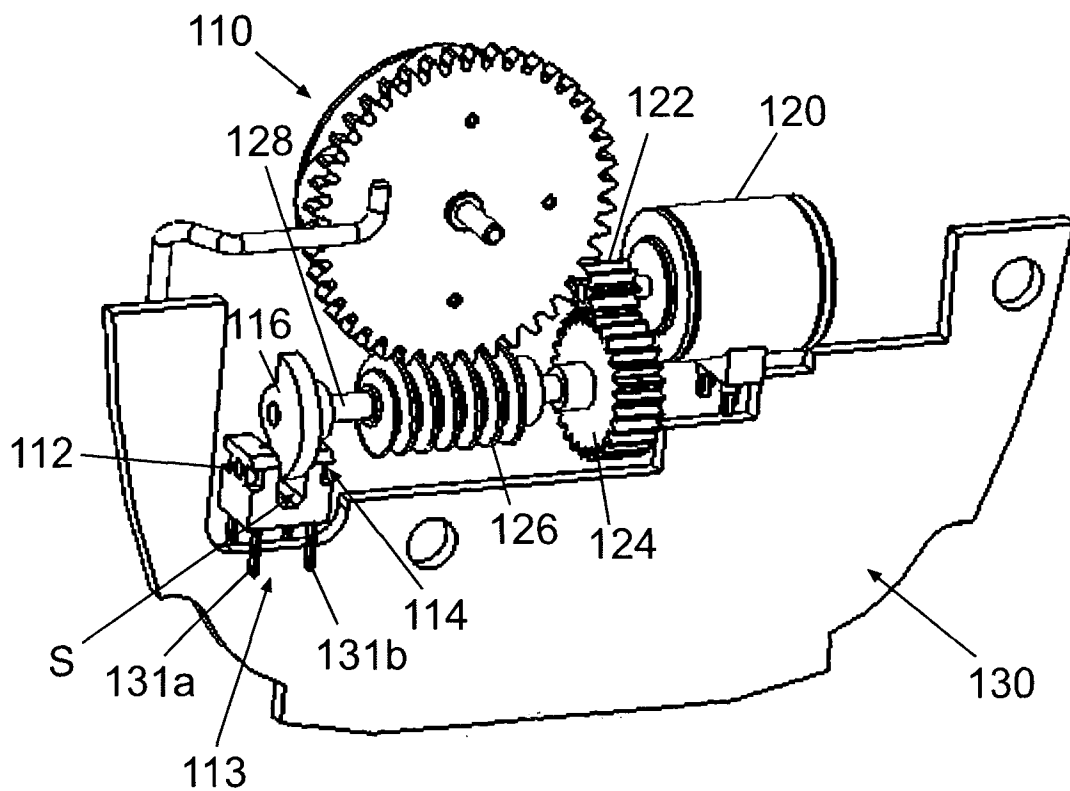
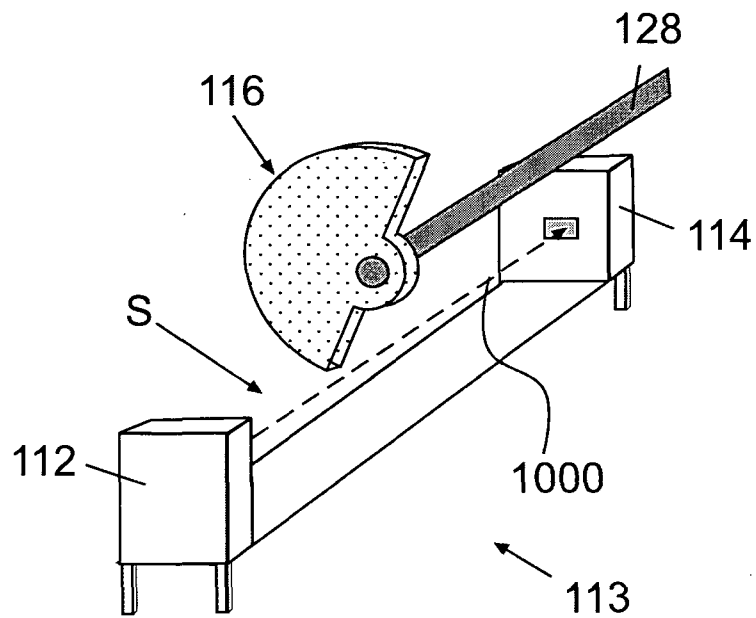
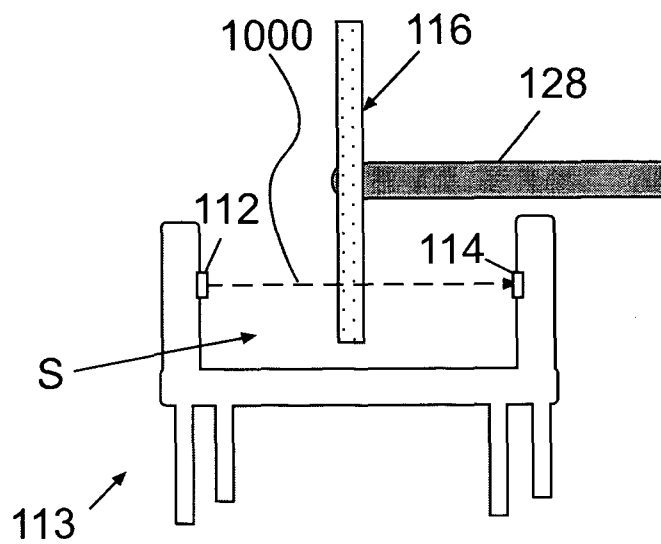


Fig. 9

9/20**Fig. 10a****Fig. 10b**

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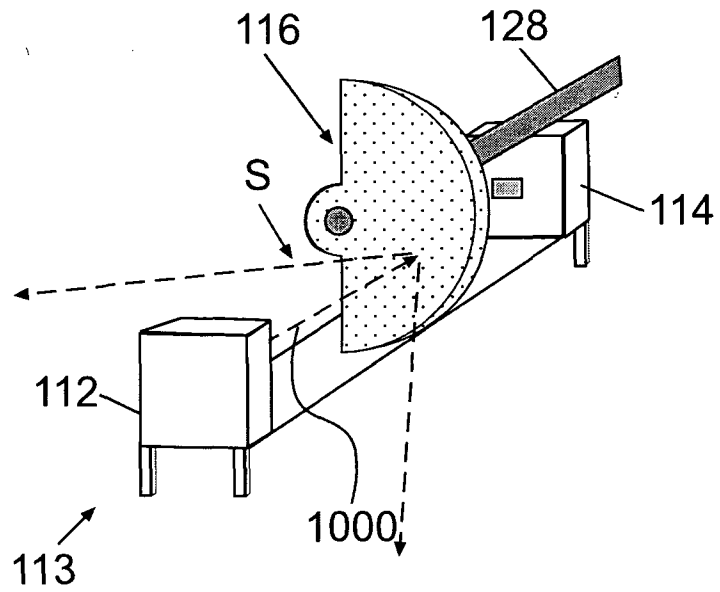


Fig. 10c

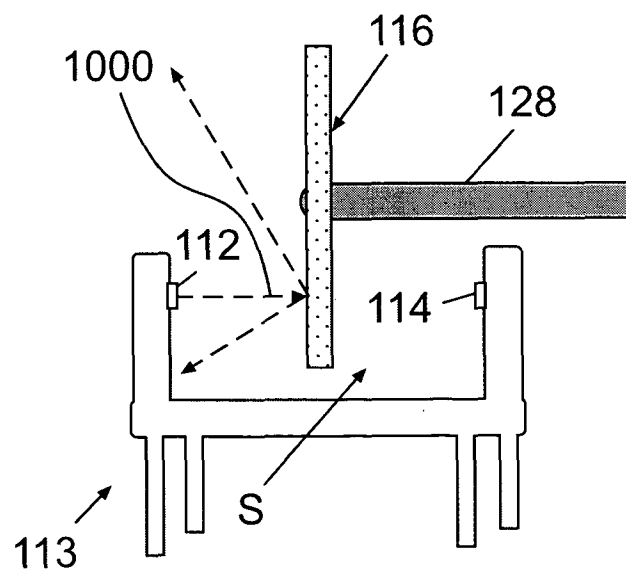


Fig. 10d

11/20

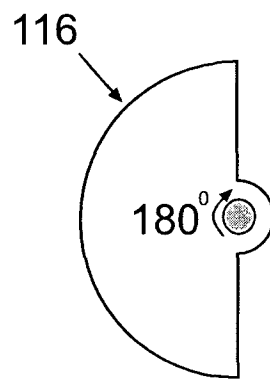


Fig. 10e

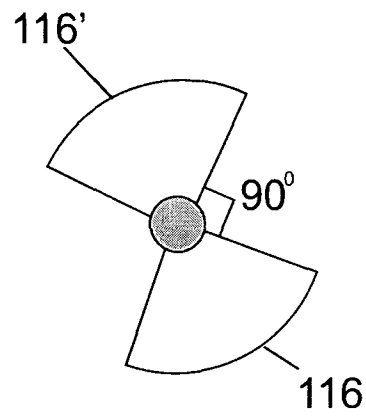


Fig. 10f

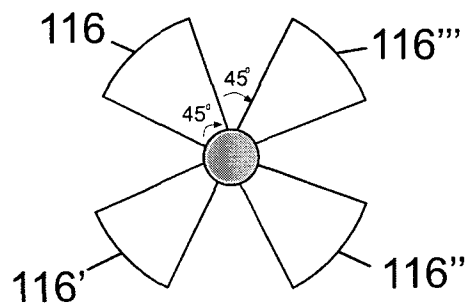
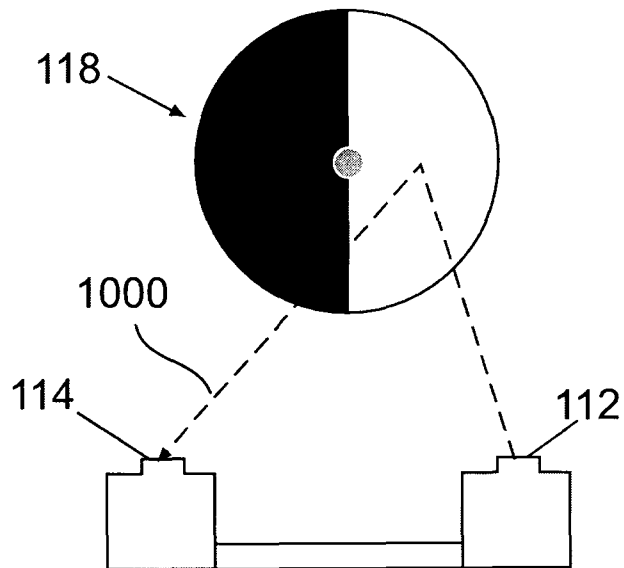
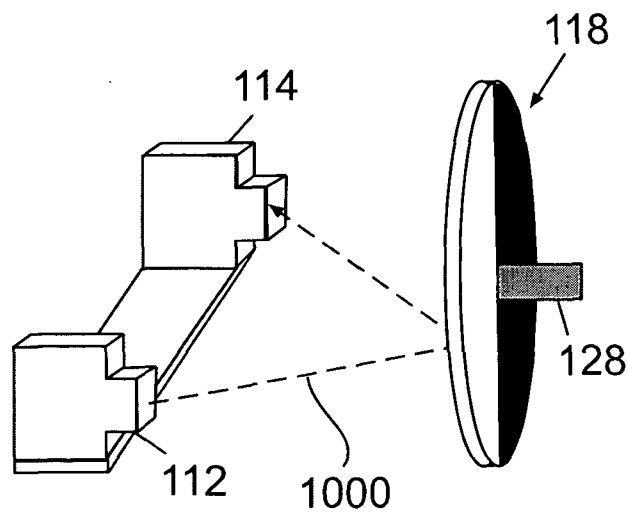


Fig. 10g

12/20**Fig. 11a****Fig. 11b**

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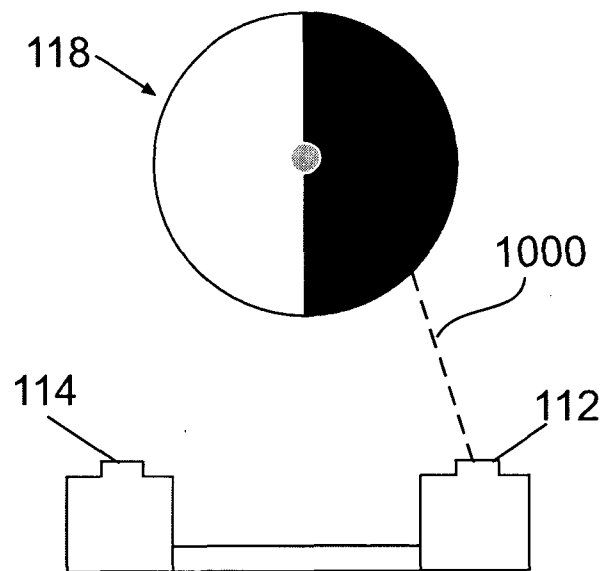


Fig. 11c

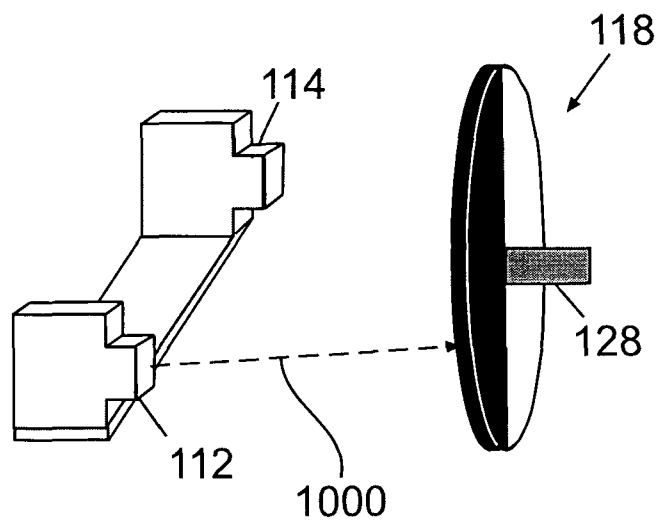


Fig. 11d

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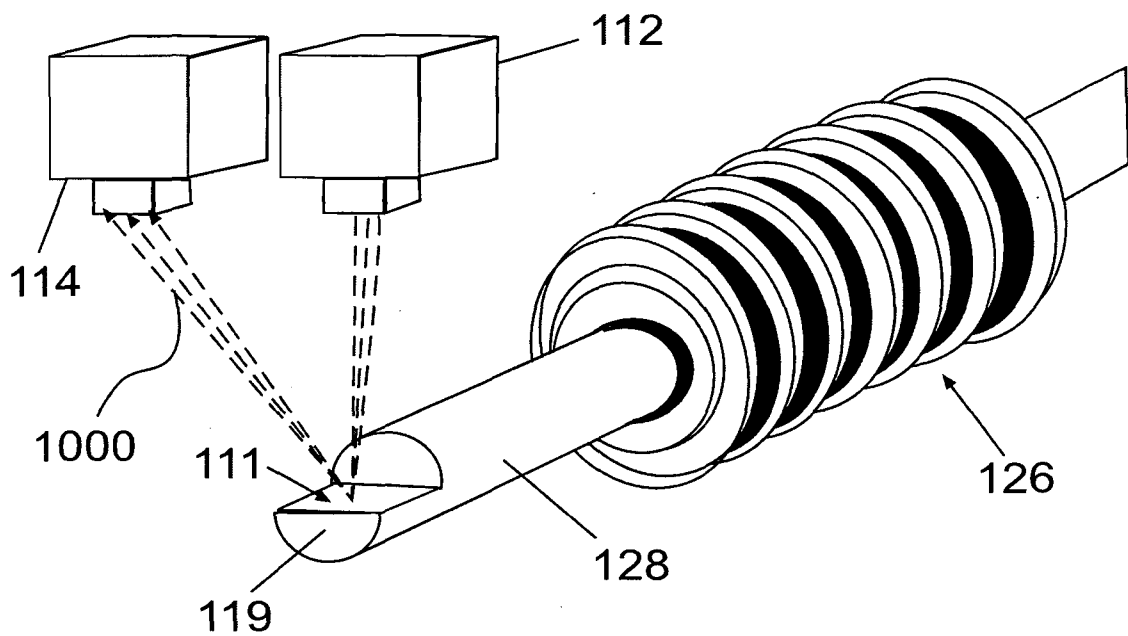


Fig. 12a

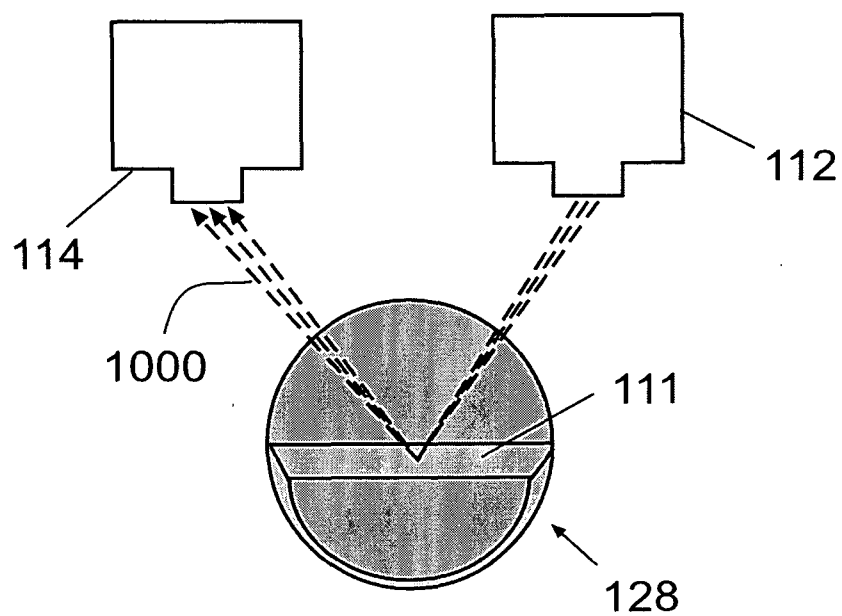


Fig. 12b

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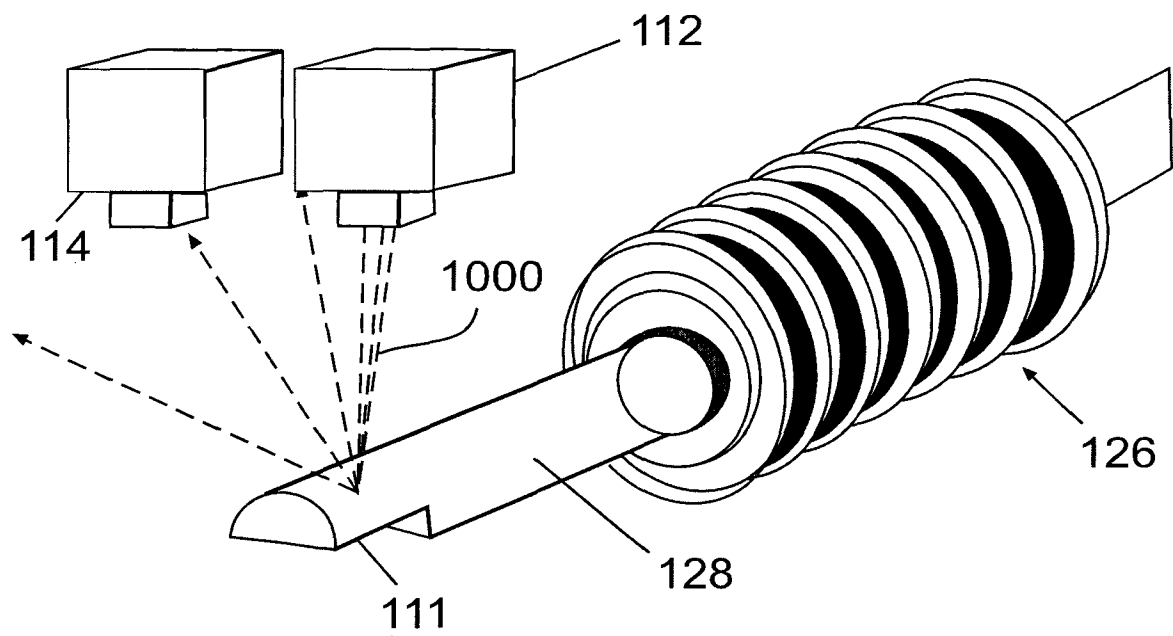


Fig. 12c

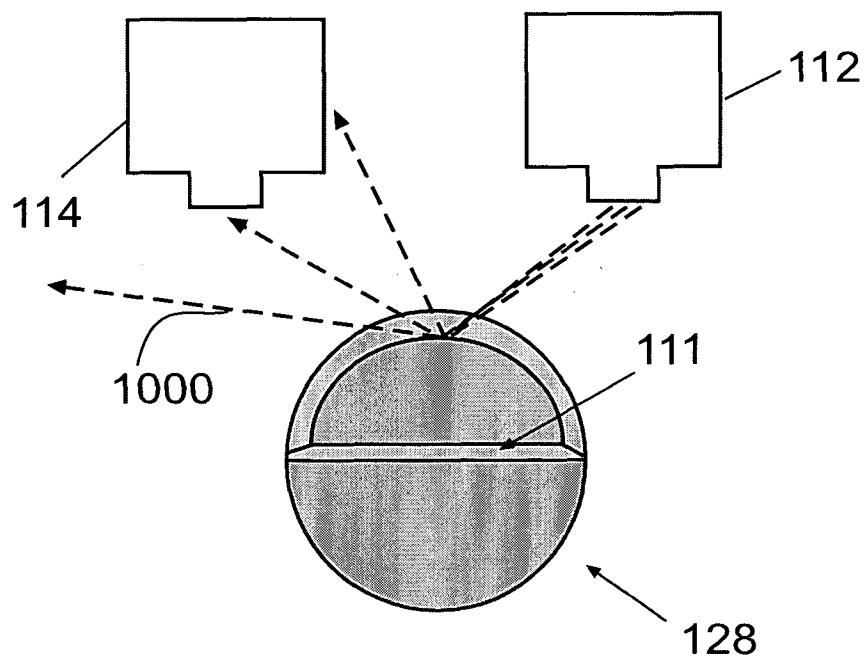


Fig. 12d

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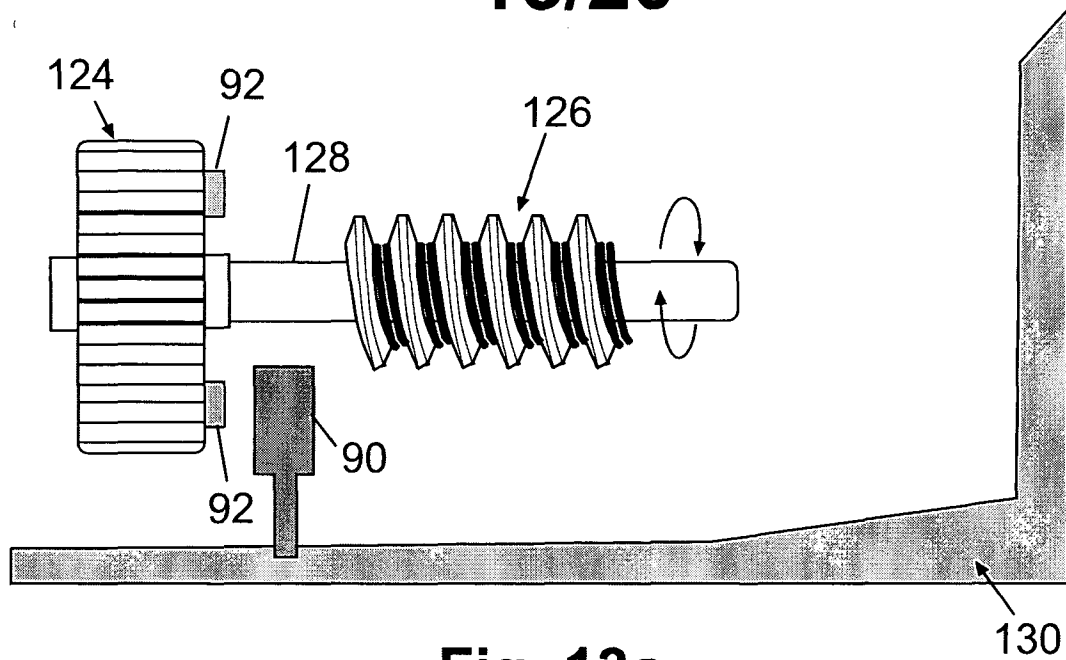


Fig. 13a

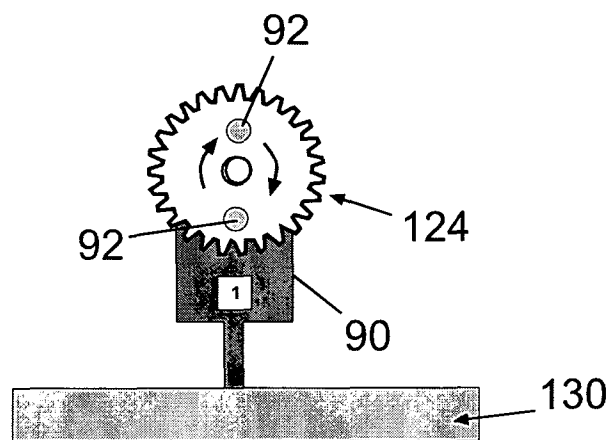


Fig. 13b

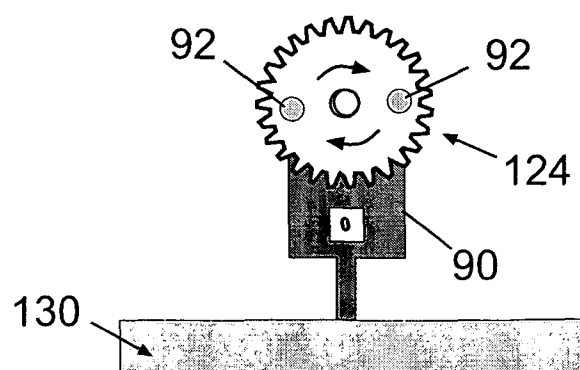


Fig. 13c

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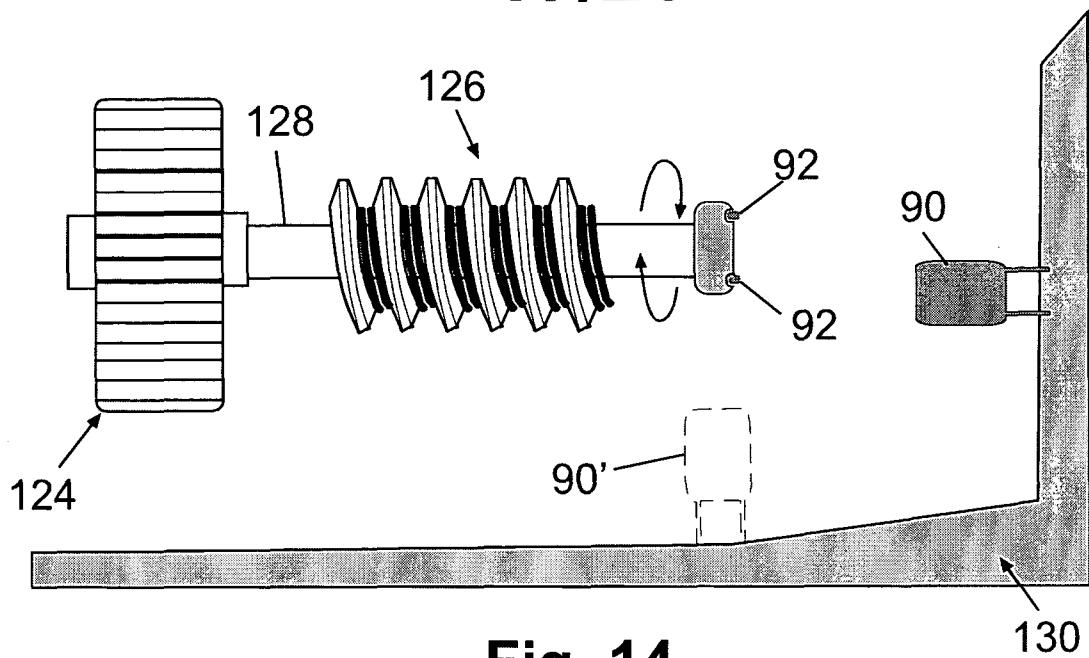


Fig. 14

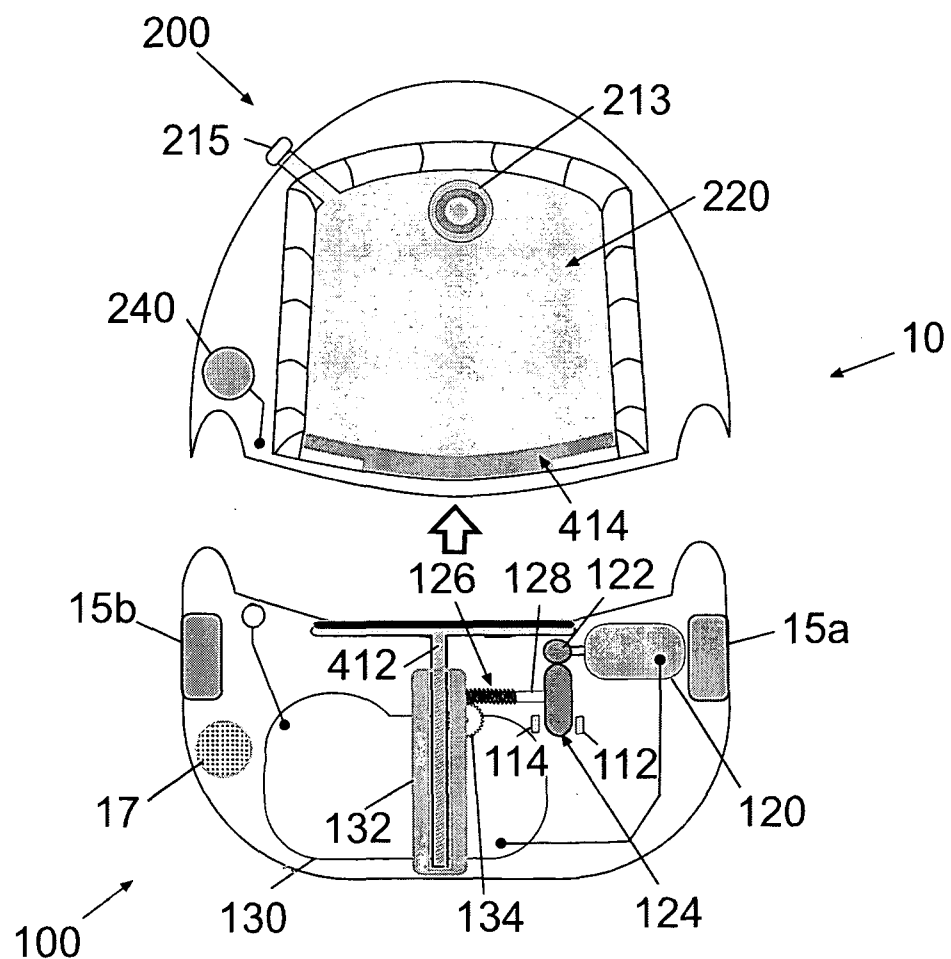
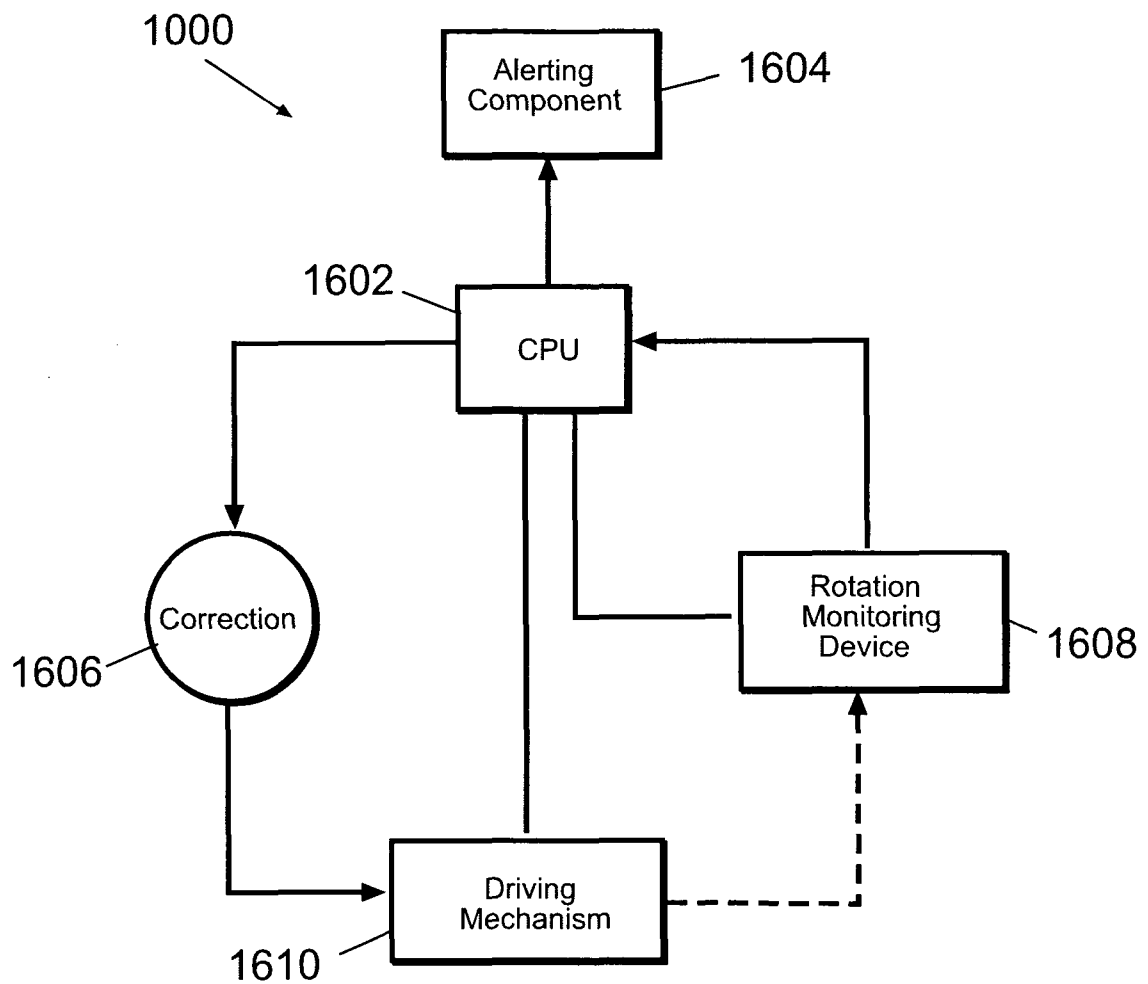


Fig. 15

18/20**Fig. 16**

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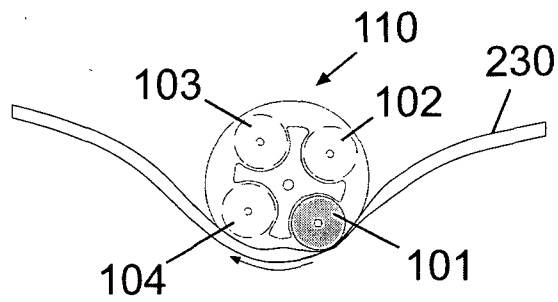


Fig. 17a

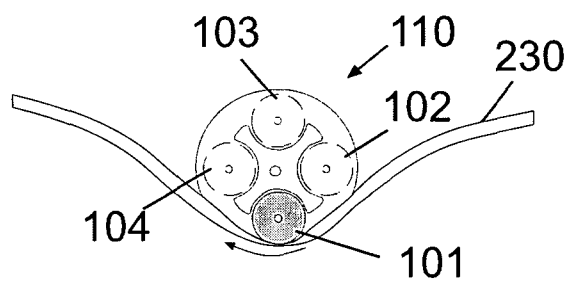


Fig. 17b

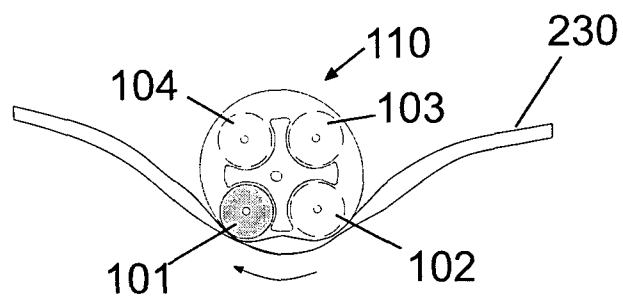


Fig. 17c

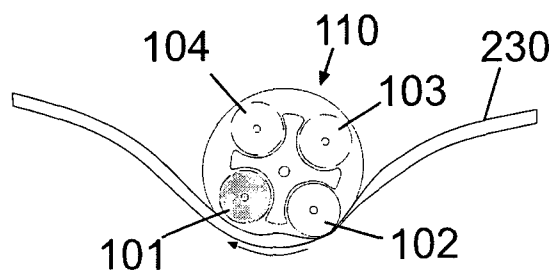


Fig. 17d

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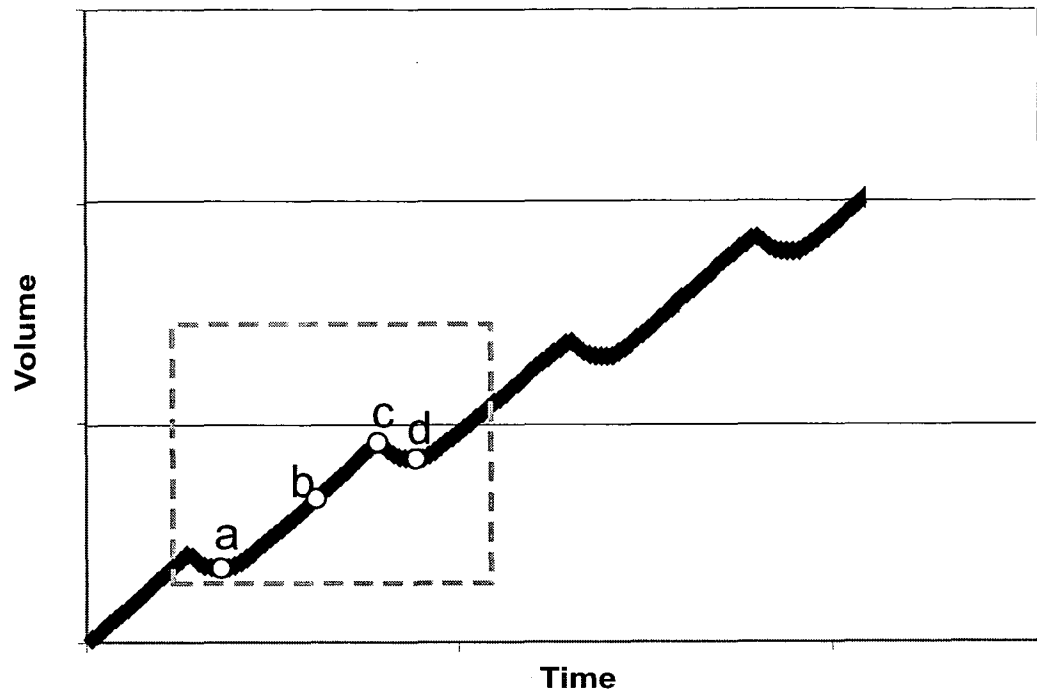


Fig. 18

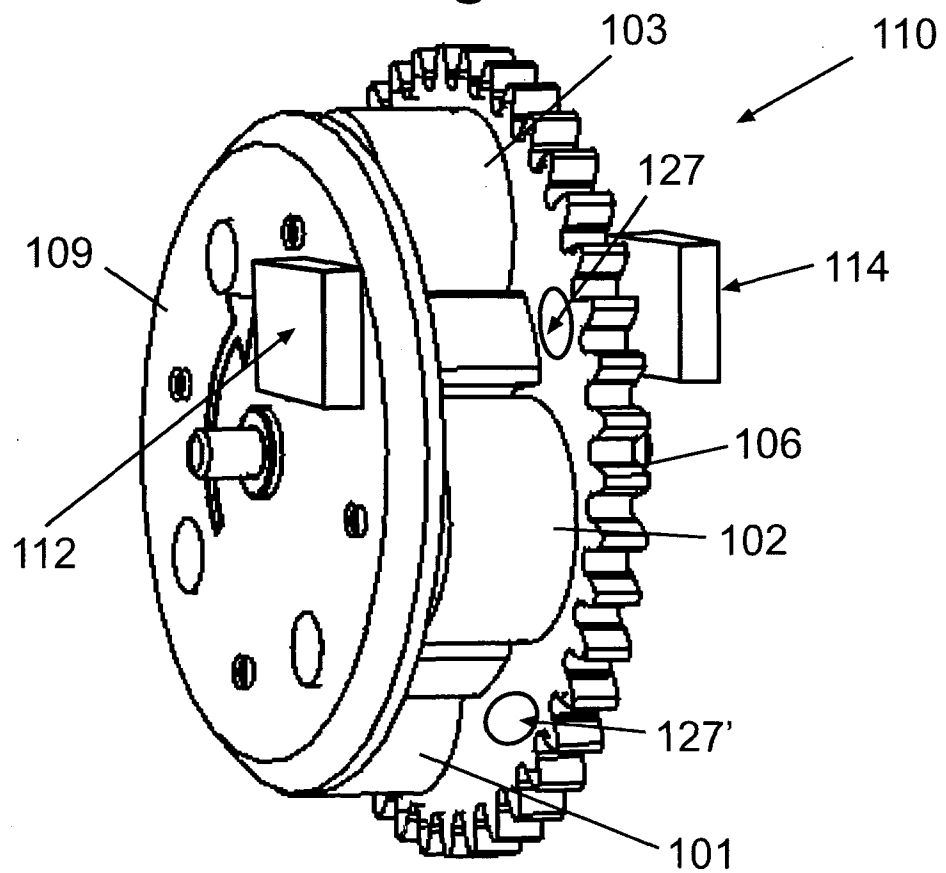


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2008/000642

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/142 A61M5/145 F04B43/12 F04B49/20

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)

A61M F04B

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	US 6 659 978 B1 (KASUGA MASAO [JP] ET AL) 9 December 2003 (2003-12-09) column 4, line 32 - column 5, line 36; figures 1-6	1-41
X	US 2003/163090 A1 (BLOMQUIST MICHAEL L [US] ET AL BLOMQUIST MICHAEL L [US] ET AL) 28 August 2003 (2003-08-28) paragraphs [0065], [0073], [0095], [0096]; figures 1-40	1-41
X	US 2007/106218 A1 (YODFAT OFER [IL] ET AL) 10 May 2007 (2007-05-10) paragraphs [0111], [0116], [0119], [0134], [0135], [0204]; figures 1-30	1-41
	----- -/--	



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
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- *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.

Z document member of the same patent family

Date of the actual completion of the international search

26 September 2008

Date of mailing of the international search report

10/10/2008

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

Björklund, Andreas

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2008/000642

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 2006/184119 A1 (REMDE AXEL [CH] ET AL) 17 August 2006 (2006-08-17) paragraphs [0033] - [0035], [0037], [0039]; figures 1-4 -----	1-41
X	US 2004/064088 A1 (GORMAN WILLIAM [US] ET AL) 1 April 2004 (2004-04-01) paragraphs [0091], [0092]; figures 12-15 -----	1-41
A	US 2006/184154 A1 (MOBERG SHELDON B. [US] ET AL) 17 August 2006 (2006-08-17) columns 140,143 -----	1-41
A	WO 2006/121921 A (MEDTRONIC MINIMED INC [US]; MOBERG SHELDON B [US]; HANSON IAN [US]; CH) 16 November 2006 (2006-11-16) paragraph [0026]; figures 1-33 -----	38

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 42-46

Claims 42-46 define methods of monitoring the dispensing of therapeutic fluid of a dispensing unit to a patient comprising the steps of activating a driving mechanism and correcting the revolution of a motor of the driving mechanism. This is done when the patient is connected, and consequently defines a method for treatment of the human or animal body by therapy (Rule 39.1(iv) PCT).

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2008/000642

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.: 42-46
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/IL2008/000642

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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