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DESCRIPTION

FIELD

[0001] THIS INVENTION relates to drug delivery pumps. More particularly, this invention relates to drive mechanisms for the controlled delivery of drug substances, drug delivery pumps with controlled delivery drive mechanisms, the methods of operating such devices, and the methods of assembling such devices.

BACKGROUND

[0002] Parenteral delivery of various drugs, i.e., delivery by means other than through the digestive track, has become a desired method of drug delivery for a number of reasons. This form of drug delivery by injection may enhance the effect of the substance being delivered and ensure that the unaltered medicine reaches its intended site at a significant concentration. Similarly, undesired side effects associated with other routes of delivery, such as systemic toxicity, can potentially be avoided through parenteral delivery. By bypassing the digestive system of a mammalian patient, one can avoid degradation of the active ingredients caused by the catalytic enzymes in the digestive tract and liver and ensure that a necessary amount of drug, at a desired concentration, reaches the targeted site.

[0003] Traditionally, manually operated syringes and injection pens have been employed for delivering parenteral drugs to a patient. More recently, parenteral delivery of liquid medicines into the body has been accomplished by administering bolus injections using a needle and reservoir, continuously by gravity driven dispensers, or via transdermal patch technologies. Bolus injections often imperfectly match the clinical needs of the patient, and usually require larger individual doses than are desired at the specific time they are given. Continuous delivery of medicine through gravity-feed systems compromises the patient's mobility and lifestyle, and limits the therapy to simplistic flow rates and profiles. Another form of drug delivery, transdermal patches, similarly has its restrictions. Transdermal patches often require specific molecular drug structures for efficacy, and the control of the drug administration through a transdermal patch is severely limited.

[0004] Ambulatory infusion pumps have been developed for delivering liquid medicaments to a patient. These infusion devices have the ability to offer sophisticated fluid delivery profiles accomplishing bolus requirements, continuous infusion and variable flow rate delivery. These infusion capabilities usually result in better efficacy of the drug and therapy and less toxicity to the patient's system. Currently available ambulatory infusion devices are expensive, difficult to program and prepare for infusion, and tend to be bulky, heavy and very fragile. Filling these devices can be difficult and require the patient to carry both the intended medication as well as filling accessories. The devices often require specialized care, maintenance, and cleaning to assure proper functionality and safety for their intended long-term use, and are not cost-effective for patients or healthcare providers.

[0005] As compared to syringes and injection pens, pump type delivery devices can be significantly more convenient to a patient, in that doses of the drug may be calculated and delivered automatically to a patient at any time during the day or night. Furthermore, when used in conjunction with metabolic sensors or monitors, pumps may be automatically controlled to provide appropriate doses of a fluidic medium at appropriate times of need, based on sensed or monitored metabolic levels. As a result, pump type delivery devices have become an important aspect of modem medical treatments of various types of medical conditions, such as diabetes, and the like.

[0006] While pump type delivery systems have been utilized to solve a number of patient needs, manually operated syringes and injection pens often remain a preferred choice for drug delivery as they now provide integrated safety features and can easily be read to identify the status of drug delivery and the end of dose dispensing. However, manually operated syringes and injections pens are not universally applicable and are not preferred for delivery of all drugs. There remains a need for an adjustable (and/or programmable) infusion system that is precise and reliable and can offer clinicians and patients a small, low cost, light weight, simple to use alternative for parenteral delivery of liquid medicines.

[0007] WO2008142394A1 discloses an infusion pump for administering controlled doses of a fluid. However, this document does not disclose the claimed arrangement including, for example, the status reader disposed adjacent the tether, the status reader being configured to provide a signal when slack occurs in the tether.

[0008] By way of further example, this document does not disclose the claimed arrangement including a gear assembly including a plurality of gears wherein at least one of said gears is configured to act as an encoder, or a compound gear engageably

connected to the worm gear.

[0009] By way of further example, this document also does not disclose status triggers incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control system to provide feedback to a user.

SUMMARY

[0010] Embodiments of present invention provides drive mechanisms for the controlled delivery of drug substances, drug delivery pumps with controlled delivery drive mechanisms, the methods of operating such devices, and the methods of assembling such devices. Notably, the drive mechanisms of embodiments of the present invention control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container. The novel embodiments of the present invention thus are capable of delivering drug substances at variable rates. The controlled delivery drive mechanisms of embodiments of the present invention may be pre-configurable or dynamically configurable, such as by control by the power and control system, to meet desired delivery rates or profiles, as explained in detail below. Additionally, the drive mechanisms of embodiments of the present invention provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug pump may provide an end-of-dose indication. Because the end-of-dose indication is related to the physical end of axial translation of one or more components of the drive mechanism, the drive mechanism and drug pump provide a true end-of-dose indication to the user. Through these mechanisms, confirmation of drug dose delivery can accurately be provided to the user or administrator. Accordingly, the novel devices of embodiments of the present invention alleviate one or more of the problems associated with prior art devices, such as those referred to above.

[0011] In a first embodiment, the present invention provides a controlled delivery drive mechanism which includes a drive housing, a piston, and a biasing member, wherein the biasing member is initially retained in an energized state and is configured to bear upon an interface surface of the piston. The piston is configured to translate substantially axially within a drug container having a plunger seal and a barrel. A tether is connected at one end to the piston and at another end to a winch drum of a delivery control mechanism, wherein the tether restrains the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The drug container may contain a drug fluid within a drug chamber for delivery to a user. Optionally, a cover sleeve may be utilized between the biasing member and the interface surface of the piston to hide the interior components of the barrel (namely, the piston and the biasing member) from view during operation of the drive mechanism. The tether is configured to be released from a winch drum of the delivery control mechanism to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon.

[0012] In another embodiment, the drive mechanism further includes a gear assembly. The gear assembly may include a winch gear connected to a winch drum upon which the tether may be releasably wound, a worm gear engageably connected to the winch gear, a compound gear engageably connected to the worm gear, and a motor having a pinion engageably connected to the compound gear, wherein the motor is configured to drive the gear assembly to release the tether from the winch drum to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The metering of the tether by the motor controls the rate or profile of drug delivery to a user. The piston may be one or more parts and connects to a distal end of the tether.

[0013] In yet another embodiment, the drive mechanism may include a status reader configured to read or recognize one or more corresponding status triggers. The status triggers may be incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control system to provide feedback to a user. The status reader may be an optical status reader and the corresponding status triggers are optical status triggers, an electromechanical status reader and the corresponding status triggers are electromechanical status triggers, or a mechanical status reader and the corresponding status triggers are mechanical status triggers.

[0014] In a further embodiment, the present invention provides a drug delivery pump with controlled drug delivery. The drug having a housing and an assembly platform, upon which an activation mechanism, an insertion mechanism, a fluid pathway connection, a power and control system, and a controlled delivery drive mechanism may be mounted, said drive mechanism having a drive housing, a piston, and a biasing member, wherein the biasing member is initially retained in an energized state and

is configured to bear upon an interface surface of the piston. The piston is configured to translate substantially axially within a drug container having a plunger seal and a barrel. A tether is connected at one end to the piston and at another end to a winch drum of a delivery control mechanism, wherein the tether restrains the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The drug container may contain a drug fluid within a drug chamber for delivery to a user. Optionally, a cover sleeve may be utilized between the biasing member and the interface surface of the piston to hide the interior components of the barrel (namely, the piston and the biasing member) from view during operation of the drive mechanism. The tether is configured to be released from a winch drum of the delivery control mechanism to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon.

[0015] In another embodiment, the drug pump further includes a gear assembly. The gear assembly may include a winch gear connected to a winch drum upon which the tether may be releasably wound, a worm gear engageably connected to the winch gear, a compound gear engageably connected to the worm gear, and a motor having a pinion engageably connected to the compound gear, wherein the motor is configured to drive the gear assembly to release the tether from the winch drum to meter the free expansion of the biasing member from its initial energized state and the free axial translation of the piston upon which the biasing member bears upon. The metering of the tether by the motor controls the rate or profile of drug delivery to a user. The piston may be one or more parts and connects to a distal end of the tether.

[0016] In yet another embodiment, the drug pump may include a status reader configured to read or recognize one or more corresponding status triggers. The status triggers may be incrementally spaced on the tether, wherein, during operation of the drive mechanism, interaction between the status reader and the status triggers transmit a signal to a power and control system to provide feedback to a user. The status reader may be an optical status reader and the corresponding status triggers are optical status triggers, an electromechanical status reader and the corresponding status triggers are electromechanical status triggers, or a mechanical status reader and the corresponding status triggers are mechanical status triggers.

[0017] In another embodiment, the power and control system of the drug pump is configured to receive one or more inputs to meter the release of the tether by the winch drum and thereby permit axial translation of the piston by the biasing member to translate a plunger seal within a barrel. The one or more inputs may be provided by the actuation of the activation mechanism, a control interface, and/or a remote control mechanism. The power and control system may be configured to receive one or more inputs to adjust the restrain provided by the tether and winch drum on the free axial translation of the piston upon which the biasing member bears upon to meet a desired drug delivery rate or profile, to change the dose volume for delivery to the user, and/or to otherwise start, stop, or pause operation of the drive mechanism.

[0018] The novel embodiments of the present invention provide drive mechanisms which are capable of metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thereby, controlling the rate of delivery of drug substances. The novel control delivery drive mechanisms are additionally capable of providing the incremental status of the drug delivery before, during, and after operation of the device. Throughout this specification, unless otherwise indicated, "comprise," "comprises," and "comprising," or related terms such as "includes" or "consists of," are used inclusively rather than exclusively, so that a stated integer or group of integers may include one or more other non-stated integers or groups of integers. As will be described further below, the embodiments of the present invention may include one or more additional components which may be considered standard components in the industry of medical devices. For example, the embodiments may include one or more batteries utilized to power the motor, drive mechanisms, and drug pumps of embodiments of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The following non-limiting embodiments of the invention are described herein with reference to the following drawings, wherein:

FIG. 1A
: shows an isometric view of a drug delivery pump having a controlled delivery drive mechanism, according to one embodiment of the present invention;

FIG. 1B
: shows an isometric view of the interior components of the drug delivery pump shown in FIG. 1A (shown without the adhesive patch);

FIG. 1C
: shows an isometric view of the bottom of the drug delivery pump shown in FIG. 1A (shown without the adhesive patch);

FIG. 2
shows an isometric view of a controlled delivery drive mechanism, according to at least one embodiment of the present invention;

FIG. 3
shows an exploded view, along an axis "A," of the drive mechanism shown in FIG. 2 (but excluding the plunger seal, barrel, and cap for clarity);

FIG. 4A
shows an isometric view of the drive mechanism shown in FIG. 2 in an initial inactive state;

FIG. 4B
shows an isometric view of the drive mechanism shown in FIG. 2 in an actuated state as the mechanism controls the rate or profile of drug delivery;

FIG. 4C
shows an isometric view of the drive mechanism shown in FIG. 2 as the mechanism completes drug delivery;

FIG. 5A
shows a cross-sectional view of the drive mechanism shown in FIG. 4A in an initial inactive state;

FIG. 5B
shows a cross-sectional view of the drive mechanism shown in FIG. 4B in an actuated state as the mechanism controls the rate or profile of drug delivery;

FIG. 5C
shows a cross-sectional view of the drive mechanism shown in FIG. 4C as the mechanism completes drug delivery and, optionally, performs a compliance push to ensure completion of drug delivery;

FIG. 6
shows a perspective view of the drive mechanism which incorporates an incremental status indicator, according to a further embodiment of the present invention.

DETAILED DESCRIPTION

[0020] Embodiments of the present invention provide drive mechanisms for the controlled delivery of drug substances and drug delivery pumps which incorporate such controlled delivery drive mechanisms. The drive mechanisms of embodiments of the present invention control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thus, are capable of delivering drug substances at variable rates and/or delivery profiles. Additionally, the drive mechanisms of embodiments of the present invention provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug pump may provide an end-of-dose indication.

[0021] As used herein to describe the drive mechanisms, drug delivery pumps, or any of the relative positions of the components of embodiments of the present invention, the terms "axial" or "axially" refer generally to a longitudinal axis "A" around which the drive mechanisms are preferably positioned, although not necessarily symmetrically there-around. The term "radial" refers generally to a direction normal to axis A. The terms "proximal," "rear," "rearward," "back," or "backward" refer generally to an axial direction in the direction "P". The terms "distal," "front," "frontward," "depressed," or "forward" refer generally to an axial direction in the direction "D". As used herein, the term "glass" should be understood to include other similarly non-reactive materials suitable for use in a pharmaceutical grade application that would normally require glass, including but not limited to certain non-reactive polymers such as cyclic olefin copolymers (COC) and cyclic olefin polymers (COP). The term "plastic" may include both thermoplastic and thermosetting polymers. Thermoplastic polymers can be resoftened to their original condition by heat; thermosetting polymers cannot. As used herein, the term "plastic" refers primarily to moldable thermoplastic polymers such as, for example, polyethylene and polypropylene, or an acrylic resin, that also typically contain other ingredients such as curatives, fillers, reinforcing agents, colorants, and/or plasticizers, etc., and that can be formed or molded under heat and pressure. As used herein, the term "plastic" is not meant to include glass, non-reactive polymers, or elastomers that are approved for use in applications where they are in direct contact with therapeutic liquids that can interact with plastic or that can be degraded by substituents that could otherwise enter the liquid from plastic. The term "elastomer," "elastomeric" or "elastomeric material" refers primarily to cross-linked thermosetting rubbery polymers that are more easily deformable than plastics but that are approved for use with pharmaceutical grade fluids and are not readily susceptible to leaching or gas migration under ambient temperature and

pressure. "Fluid" refers primarily to liquids, but can also include suspensions of solids dispersed in liquids, and gasses dissolved in or otherwise present together within liquids inside the fluid-containing portions of the drug pumps. According to various aspects and embodiments described herein, reference is made to a "biasing member", such as in the context of one or more biasing members for asserting force on a plunger seal. It will be appreciated that the biasing member may be any member that is capable of storing and releasing energy. Non-limiting examples include a spring, such as for example a coiled spring, a compression or extension spring, a torsional spring, or a leaf spring, a resiliently compressible or elastic band, or any other member with similar functions. In at least one embodiment of the present invention, the biasing member is a spring, preferably a compression spring.

[0022] The novel devices of embodiments of the present invention provide drive mechanisms with integrated status indication and drug delivery pumps which incorporate such drive mechanisms. Such devices are safe and easy to use, and are aesthetically and ergonomically appealing for self-administering patients. The devices described herein incorporate features which make activation, operation, and lock-out of the device simple for even untrained users. The novel devices of embodiments of the present invention provide these desirable features without any of the problems associated with known prior art devices. Certain non-limiting embodiments of the novel drug delivery pumps, drive mechanisms, and their respective components are described further herein with reference to the accompanying figures.

[0023] As used herein, the term "pump" is intended to include any number of drug delivery systems which are capable of dispensing a fluid to a user upon activation. Such drug delivery systems include, for example, injection systems, infusion pumps, bolus injectors, and the like. FIGS. 1A-1C show an exemplary drug delivery device according to at least one embodiment of the present invention. The drug delivery device may be utilized to administer delivery of a drug treatment into a body of a user. As shown in FIGS. 1A-1C, the drug pump 10 includes a pump housing 12. Pump housing 12 may include one or more housing subcomponents which are fixedly engageable to facilitate easier manufacturing, assembly, and operation of the drug pump. For example, drug pump 10 includes a pump housing 12 which includes an upper housing 12A and a lower housing 12B. The drug pump may further include an activation mechanism 14, a status indicator 16, and a window 18. Window 18 may be any translucent or transmissive surface through which the operation of the drug pump may be viewed. As shown in FIG. 1B, drug pump further includes assembly platform 20, sterile fluid conduit 30, drive mechanism 100 having drug container 50, insertion mechanism 200, fluid pathway connection 300, and power and control system 400. One or more of the components of such drug pumps may be modular in that they may be, for example, pre-assembled as separate components and configured into position onto the assembly platform 20 of the drug pump 10 during manufacturing.

[0024] The pump housing 12 contains all of the device components and provides a means of removably attaching the device 10 to the skin of the user. The pump housing 12 also provides protection to the interior components of the device 10 against environmental influences. The pump housing 12 is ergonomically and aesthetically designed in size, shape, and related features to facilitate easy packaging, storage, handling, and use by users who may be untrained and/or physically impaired. Furthermore, the external surface of the pump housing 12 may be utilized to provide product labeling, safety instructions, and the like. Additionally, as described above, housing 12 may include certain components, such as status indicator 16 and window 18, which may provide operation feedback to the user.

[0025] In at least one embodiment, the drug pump 10 provides an activation mechanism 14 that is displaced by the user to trigger the start command to the power and control system 400. In a preferred embodiment, the activation mechanism is a start button 14 that is located through the pump housing 12, such as through an aperture between upper housing 12A and lower housing 12B, and which contacts a control arm 40 of the power and control system 400. In at least one embodiment, the start button 14 may be a push button, and in other embodiments, may be an on/off switch, a toggle, or any similar activation feature known in the art. The pump housing 12 also provides a status indicator 16 and a window 18. In other embodiments, one or more of the activation mechanism 14, the status indicator 16, the window 18, and combinations thereof may be provided on the upper housing 12A or the lower housing 12B such as, for example, on a side visible to the user when the drug pump 10 is placed on the body of the user. Housing 12 is described in further detail hereinafter with reference to other components and embodiments of the present invention.

[0026] Drug pump is configured such that, upon activation by a user by depression of the activation mechanism, the drug pump is initiated to: insert a fluid pathway into the user; enable, connect, or open necessary connections between a drug container, a fluid pathway, and a sterile fluid conduit; and force drug fluid stored in the drug container through the fluid pathway and fluid conduit for delivery into a user. One or more optional safety mechanisms may be utilized, for example, to prevent premature activation of the drug pump. For example, an optional on-body sensor 24 (shown in FIG. 1C) may be provided in one embodiment as a safety feature to ensure that the power and control system 400, or the activation mechanism, cannot be engaged unless the drug pump 10 is in contact with the body of the user. In one such embodiment, the on-body sensor 24 is located on the bottom of lower housing 12B where it may come in contact with the user's body. Upon displacement of the on-body sensor 24, depression of the activation mechanism is permitted. Accordingly, in at least one embodiment the on-body sensor 24 is a mechanical safety

mechanism, such as for example a mechanical lock out, that prevents triggering of the drug pump 10 by the activation mechanism 14. In another embodiment, the on-body sensor may be an electro-mechanical sensor such as a mechanical lock out that sends a signal to the power and control system 400 to permit activation. In still other embodiments, the on-body sensor can be electrically based such as, for example, a capacitive- or impedance-based sensor which must detect tissue before permitting activation of the power and control system 400. These concepts are not mutually exclusive and one or more combinations may be utilized to prevent, for example, premature activation of the drug pump. In a preferred embodiment, the drug pump 10 utilizes one or more mechanical on-body sensors. Additional integrated safety mechanisms are described herein with reference to other components of the novel drug pumps.

Power and Control System:

[0027] The power and control system 400 includes a power source, which provides the energy for various electrical components within the drug pump, one or more feedback mechanisms, a microcontroller, a circuit board, one or more conductive pads, and one or more interconnects. Other components commonly used in such electrical systems may also be included, as would be appreciated by one having ordinary skill in the art. The one or more feedback mechanisms may include, for example, audible alarms such as piezo alarms and/or light indicators such as light emitting diodes (LEDs). The microcontroller may be, for example, a microprocessor. The power and control system 400 controls several device interactions with the user and interfaces with the drive mechanism 100. In one embodiment, the power and control system 400 interfaces with the control arm 40 to identify when the on-body sensor 24 and/or the activation mechanism 14 have been activated. The power and control system 400 may also interface with the status indicator 16 of the pump housing 12, which may be a transmissive or translucent material which permits light transfer, to provide visual feedback to the user. The power and control system 400 interfaces with the drive mechanism 100 through one or more interconnects to relay status indication, such as activation, drug delivery, and end-of-dose, to the user. Such status indication may be presented to the user via auditory tones, such as through the audible alarms, and/or via visual indicators, such as through the LEDs. In a preferred embodiment, the control interfaces between the power and control system and the other components of the drug pump are not engaged or connected until activation by the user. This is a desirable safety feature that prevents accidental operation of the drug pump and may additionally maintain the energy contained in the power source during storage, transportation, and the like.

[0028] The power and control system 400 may be configured to provide a number of different status indicators to the user. For example, the power and control system 400 may be configured such that after the on-body sensor and/or trigger mechanism have been pressed, the power and control system 400 provides a ready-to-start status signal via the status indicator 16 if device start-up checks provide no errors. After providing the ready-to-start status signal and, in an embodiment with the optional on-body sensor, if the on-body sensor remains in contact with the body of the user, the power and control system 400 will power the drive mechanism 100 to begin delivery of the drug treatment through the fluid pathway connection 300 and sterile fluid conduit 30. In a preferred embodiment of the present invention, the insertion mechanism 200 and the fluid pathway connection 300 may be caused to activate directly by user operation of the activation mechanism 14. During the drug delivery process, the power and control system 400 is configured to provide a dispensing status signal via the status indicator 16. After the drug has been administered into the body of the user and after the end of any additional dwell time, to ensure that substantially the entire dose has been delivered to the user, the power and control system 400 may provide an okay-to-remove status signal via the status indicator 16. This may be independently verified by the user by viewing the drive mechanism and drug dose delivery through the window 18 of the pump housing 12. Additionally, the power and control system 400 may be configured to provide one or more alert signals via the status indicator 16, such as for example alerts indicative of fault or operation failure situations.

[0029] The power and control system 400 may additionally be configured to accept various inputs from the user to dynamically control the drive mechanisms 100 to meet a desired drug delivery rate or profile. For example, the power and control system 400 may receive inputs, such as from partial or full activation, depression, and/or release of the activation mechanism 14, to set, initiate, stop, or otherwise adjust the control of the drive mechanism 100 via the power and control system 400 to meet the desired drug delivery rate or profile. Similarly, the power and control system 400 may be configured to receive such inputs to adjust the drug dose volume; to prime the drive mechanism, fluid pathway connection, and fluid conduit; and/or to start, stop, or pause operation of the drive mechanism 100. Such inputs may be received by the user directly acting on the drug pump 10, such as by use of the activation mechanism 14 or a different control interface, or the system 400 may be configured to receive such inputs from a remote control device. Additionally or alternatively, such inputs may be pre-programmed.

[0030] Other power and control system configurations may be utilized with the novel drug pumps of embodiments of the present invention. For example, certain activation delays may be utilized during drug delivery. As mentioned above, one such delay optionally included within the system configuration is a dwell time which ensures that substantially the entire drug dose has been

delivered before signaling completion to the user. Similarly, activation of the device may require a delayed depression (i.e., pushing) of the activation mechanism 14 of the drug pump 10 prior to drug pump activation. Additionally, the system may include a feature which permits the user to respond to the end-of-dose signals and to deactivate or power-down the drug pump. Such a feature may similarly require a delayed depression of the activation mechanism, to prevent accidental deactivation of the device. Such features provide desirable safety integration and ease-of-use parameters to the drug pumps. An additional safety feature may be integrated into the activation mechanism to prevent partial depression and, therefore, partial activation of the drug pumps. For example, the activation mechanism and/or power and control system may be configured such that the device is either completely off or completely on, to prevent partial activation. Such features are described in further detail hereinafter with regard to other aspects of the novel drug pumps.

Fluid Pathway Connection:

[0031] A number of fluid pathway connections may be utilized within the embodiments of the present invention. Generally, a suitable fluid pathway connection includes a sterile fluid conduit, a piercing member, and a sterile sleeve attached to a drug container or a sliding pierceable seal integrated within a drug container. The fluid pathway connection may further include one or more flow restrictors. Upon proper activation of the device 10, the fluid pathway connection 300 is enabled to connect the sterile fluid conduit 30 to the drug container of the drive mechanism 100. Such connection may be facilitated by a piercing member, such as a needle, penetrating a pierceable seal of the drug container of the drive mechanism 100. The sterility of this connection may be maintained by performing the connection within a flexible sterile sleeve. Upon substantially simultaneous activation of the insertion mechanism, the fluid pathway between drug container and insertion mechanism is complete to permit drug delivery into the body of the user.

[0032] In at least one embodiment of the present invention, the piercing member of the fluid pathway connection is caused to penetrate the pierceable seal of the drug container of the drive mechanism by direct action of the user, such as by depression of the activation mechanism by the user. For example, the activation mechanism itself may bear on the fluid pathway connection such that displacement of the activation mechanism from its original position also causes displacement of the fluid pathway connection. In one such embodiment, the fluid pathway connection may be substantially similar to that described in International Patent Application No. PCT/US2012/054861, which is included by reference herein in its entirety for all purposes. According to such an embodiment, the connection is enabled by the user depressing the activation mechanism and, thereby, driving the piercing member through the pierceable seal, because this prevents fluid flow from the drug container until desired by the user. In such an embodiment, a compressible sterile sleeve may be fixedly attached between the cap of the drug container and the connection hub of the fluid pathway connection. The piercing member may reside within the sterile sleeve until a connection between the fluid connection pathway and the drug container is desired. The sterile sleeve may be sterilized to ensure the sterility of the piercing member and the fluid pathway prior to activation.

[0033] Alternatively, the fluid pathway connection may be integrated into a drug container as described in International Patent Application No. PCT/US2013/030478, for example, which is included by reference herein in its entirety for all purposes. According to such an embodiment, a drug container may have a drug chamber within a barrel between a pierceable seal and a plunger seal. A drug fluid is contained in the drug chamber. Upon activation of the device by the user, a drive mechanism asserts a force on a plunger seal contained in the drug container. As the plunger seal asserts a force on the drug fluid and any air/gas gap or bubble, a combination of pneumatic and hydraulic pressure builds by compression of the air/gas and drug fluid and the force is relayed to the sliding pierceable seal. The sliding pierceable seal is caused to slide towards the cap, causing it to be pierced by the piercing member retained within the integrated sterile fluid pathway connection. Accordingly, the integrated sterile fluid pathway connection is connected (i.e., the fluid pathway is opened) by the combination pneumatic/hydraulic force of the air/gas and drug fluid within the drug chamber created by activation of a drive mechanism. Once the integrated sterile fluid pathway connection is connected or opened, drug fluid is permitted to flow from the drug container, through the integrated sterile fluid pathway connection, sterile fluid conduit, and insertion mechanism, and into the body of the user for drug delivery. In at least one embodiment, the fluid flows through only a manifold and a cannula and/or needle of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery.

[0034] Regardless of the fluid pathway connection utilized by the drug pump, the drug pump is capable of delivering a range of drugs with different viscosities and volumes. The drug pump is capable of delivering a drug at a controlled flow rate (speed) and/or of a specified volume. In one embodiment, the drug delivery process is controlled by one or more flow restrictors within the fluid pathway connection and/or the sterile fluid conduit. In other embodiments, other flow rates may be provided by varying the geometry of the fluid flow path or delivery conduit, varying the speed at which a component of the drive mechanism advances into the drug container to dispense the drug therein, or combinations thereof. Still further details about the fluid pathway connection

300 and the sterile fluid conduit 30 are provided hereinafter in later sections in reference to other embodiments.

Insertion Mechanism:

[0035] A number of insertion mechanisms may be utilized within the drug pumps of embodiments of the present invention. The pump-type delivery devices of embodiments of the present invention may be connected in fluid flow communication to a patient or user, for example, through any suitable hollow tubing. A solid bore needle may be used to pierce the skin of the patient and place a hollow cannula at the appropriate delivery position, with the solid bore needle being removed or retracted prior to drug delivery to the patient. As stated above, the fluid can be introduced into the body through any number of means, including but not limited to: an automatically inserted needle, cannula, micro-needle array, or infusion set tubing. A number of mechanisms may also be employed to activate the needle insertion into the patient. For example, a biasing member such as a spring may be employed to provide sufficient force to cause the needle and cannula to pierce the skin of the patient. The same spring, an additional spring, or another similar mechanism may be utilized to retract the needle from the patient. In a preferred embodiment, the insertion mechanism may generally be as described in International Patent Application No. PCT/US2012/53174, which is included by reference herein in its entirety for all purposes. Such a configuration may be utilized for insertion of the drug delivery pathway into, or below, the skin (or muscle) of the patient in a manner that minimizes pain to the patient. Other known methods for insertion of a fluid pathway may be utilized and are contemplated within the bounds of embodiments of the present invention.

[0036] In at least one embodiment, the insertion mechanism 200 includes an insertion mechanism housing having one or more lockout windows, and a base for connection to the assembly platform and/or pump housing (as shown in FIG. 1B and FIG. 1C). The connection of the base to the assembly platform 20 may be, for example, such that the bottom of the base is permitted to pass-through a hole in the assembly platform to permit direct contact of the base to the body of the user. In such configurations, the bottom of the base may include a sealing membrane that is removable prior to use of the drug pump 10. The insertion mechanism may further include one or more insertion biasing members, a needle, a retraction biasing member, a cannula, and a manifold. The manifold may connect to sterile fluid conduit 30 to permit fluid flow through the manifold, cannula, and into the body of the user during drug delivery.

[0037] As used herein, "needle" is intended to refer to a variety of needles including but not limited to conventional hollow needles, such as a rigid hollow steel needles, and solid core needles more commonly referred to as "trocars." In a preferred embodiment, the needle is a 27 gauge solid core trocar and in other embodiments, the needle may be any size needle suitable to insert the cannula for the type of drug and drug administration (e.g., subcutaneous, intramuscular, intradermal, etc.) intended. A sterile boot may be utilized within the needle insertion mechanism. The sterile boot is a collapsible sterile membrane that is in fixed engagement at a proximal end with the manifold and at a distal end with the base. In at least on embodiment, the sterile boot is maintained in fixed engagement at a distal end between base and insertion mechanism housing. Base includes a base opening through which the needle and cannula may pass-through during operation of the insertion mechanism, as will be described further below. Sterility of the cannula and needle are maintained by their initial positioning within the sterile portions of the insertion mechanism. Specifically, as described above, needle and cannula are maintained in the sterile environment of the manifold and sterile boot. The base opening of base may be closed from non-sterile environments as well, such as by for example a sealing membrane 254 (shown in FIG. 1C).

[0038] According to at least one embodiment of the present invention, the insertion mechanism is initially locked into a ready-to-use stage by lockout pin(s) which are initially positioned within lockout windows of the insertion mechanism housing. In this initial configuration, insertion biasing member and retraction biasing member are each retained in their compressed, energized states. As shown in FIG. 1B, the lockout pin(s) 208 may be directly displaced by user depression of the activation mechanism 14. As the user disengages any safety mechanisms, such as an optional on-body sensor 24 (shown in FIG. 1C), the activation mechanism 14 may be depressed to initiate the drug pump. Depression of the activation mechanism 14 may directly cause translation or displacement of control arm 40 and directly or indirectly cause displacement of lockout pin(s) 208 from their initial position within locking windows 202A of insertion mechanism housing 202. Displacement of the lockout pin(s) 208 permits insertion biasing member to decompress from its initial compressed, energized state. This decompression of the insertion biasing member drives the needle and the cannula into the body of the user. At the end of the insertion stage, the retraction biasing member is permitted to expand in the proximal direction from its initial energized state. This axial expansion in the proximal direction of the retraction biasing member retracts the needle, while maintaining the cannula in fluid communication with the body of the user. Accordingly, the insertion mechanism may be used to insert a needle and cannula into the user and, subsequently, retract the needle while retaining the cannula in position for drug delivery to the body of the user.

Drive Mechanism:

[0039] With reference to the embodiments shown in FIGS. 2 and 3, drive mechanism 100 includes a drive housing 130, and a drug container 50 having a cap 52, a pierceable seal (not visible), a barrel 58, and a plunger seal 60. A drug chamber 21, located within the barrel 58 between the pierceable seal and the plunger seal 60, may contain a drug fluid for delivery through the insertion mechanism and drug pump into the body of the user. The seals described herein may be comprised of a number of materials but are, in a preferred embodiment, comprised of one or more elastomers or rubbers. The drive mechanism may further include a connection mount 54 to guide the insertion of the piercing member of the fluid pathway connection into the barrel 58 of the drug container 50. The drive mechanism 100 may further contain one or more drive biasing members, one or more release mechanisms, and one or more guides, as are described further herein. The components of the drive mechanism function to force a fluid from the drug container out through the pierceable seal, or preferably through the piercing member of the fluid pathway connection, for delivery through the fluid pathway connection, sterile fluid conduit, and insertion mechanism into the body of the user.

[0040] In one particular embodiment, the drive mechanism 100 employs one or more compression springs as the biasing member(s). Upon activation of the drug pump by the user, the power and control system may be actuated to directly or indirectly release the compression spring(s) from an energized state. Upon release, the compression spring(s) may bear against and act upon the plunger seal to force the fluid drug out of the drug container. The compression spring may bear against and act upon a piston which, in turn, acts upon the plunger seal to force the fluid drug out of the drug container. The fluid pathway connection may be connected through the pierceable seal prior to, concurrently with, or after activation of the drive mechanism to permit fluid flow from the drug container, through the fluid pathway connection, sterile fluid conduit, and insertion mechanism, and into the body of the user for drug delivery. In at least one embodiment, the fluid flows through only a manifold and a cannula of the insertion mechanism, thereby maintaining the sterility of the fluid pathway before and during drug delivery. Such components and their functions are described in further detail hereinafter.

[0041] Referring now to the embodiment of the drive mechanism shown in FIG. 2 and FIG. 3, the drive mechanism 100 includes a drug container 50 having a cap 52, a pierceable seal (not visible), a barrel 58, and a plunger seal 60, and optionally a connection mount 54. The drug container 50 is mounted to a distal end of a drive housing 130. Compressed within the drive housing 130, between the drug container 50 and the proximal end of the housing 130, are a drive biasing member 122 and a piston 110, wherein the drive biasing member 122 is configured to bear upon an interface surface 110C of the piston 110, as described further herein. Optionally, a cover sleeve 140 may be utilized between the drive biasing member 122 and the interface surface 110C of the piston 110 to, for example, promote more even distribution of force from the drive biasing member 122 to the piston 110, prevent buckling of the drive biasing member 122, and/or hide biasing member from user view. Interface surface 110C of piston 110 is caused to rest substantially adjacent to, or in contact with, a proximal end of seal 60.

[0042] As shown in FIG. 3, the piston 110A, 110B may be comprised of two components and have an interface surface 110C to contact the plunger seal. A tether, ribbon, string, or other retention strap (referred to herein as the "tether" 512) may be connected at one end to the piston 110A, 110B. For example, the tether 512 may be connected to the piston 110A, 110B by retention between the two components of the piston 110A, 110B when assembled. The tether 512 is connected at another end to a winch drum 520 of a delivery control mechanism 500. Through the use of a motor 530, a gear assembly, and the winch drum 520 connected to one end of the tether 512, and the tether 512 connected at another end to the piston 110A, 110B, the delivery control mechanism 500 functions to control, meter, provide resistance, or otherwise prevent free axial translation of the piston 110A, 110B and plunger seal 60 utilized to force a drug substance out of a drug container 50. Accordingly, the delivery control mechanism 500 and the drive mechanism 100 (collectively referred to herein as the "controlled delivery drive mechanism") together function to control the rate or profile of drug delivery to the user.

[0043] Notably, the delivery control mechanisms 500 of embodiments of the present invention do not drive the delivery of fluid substances from the drug chamber 21. The delivery of fluid substances from the drug chamber 21 is caused by the expansion of the biasing member 122 from its initial energized state acting upon the piston 110A, 110B and plunger seal 60. The delivery control mechanisms 500 instead function to provide resistance to the free motion of the piston 110A, 110B and plunger seal 60 as they are pushed by the expansion of the biasing member 122 from its initial energized state. Because the motor 530 is utilized only to control, meter, provide resistance, or otherwise prevent free axial translation of the plunger seal, instead of driving the translation of the plunger seal, a smaller and/or more energy efficient motor may be utilized by the novel embodiments of the present invention. The delivery control mechanism 500, and specifically the motor 530, does not drive the delivery but only controls the delivery motion. The tether limits or otherwise restrains the motion of the piston 110, 110B and plunger seal 60, but does not apply the force for the delivery. According to a preferred embodiment, the controlled delivery drive mechanisms and drug pumps of embodiments of the present invention include a motor 530 indirectly or directly connected to a tether metering the axial translation of the piston 110A, 110B and plunger seal 60, which are being driven to axially translate by the biasing member

122. The motor 530 may, accordingly, be selected from a variety of electromechanical sources capable of incremental motion, such as brushed DC motors, EC motors, stepper motors, solenoids, or other technologies that can produce controlled motion. In at least one embodiment, the motor is most preferably a stepper motor.

[0044] The components of the drive mechanism 100, upon activation, may be used to drive axial translation in the distal direction of the plunger seal 60 of the drug container 50. Optionally, the drive mechanism 100 may include one or more compliance features which enable additional axial translation of the plunger seal 60 to, for example, ensure that substantially the entire drug dose has been delivered to the user. For example, the plunger seal 60, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container.

[0045] The novel controlled delivery drive mechanisms of embodiments of the present invention may optionally integrate status indication into the drug dose delivery. By use of one or more status triggers and a corresponding status reader, the status of the drive mechanism before, during, and after operation can be relayed to the power and control system to provide feedback to the user. Such feedback may be tactile, visual, and/or auditory, as described above, and may be redundant such that more than one signal or type of feedback is provided to the user during use of the device. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug pump may provide an end-of-dose indication. As the end-of-dose indication is tied to the piston reaching the end of its axial translation, the drive mechanism and drug pump provide a true end-of-dose indication to the user.

[0046] In at least one embodiment, as shown in FIG. 2 and FIG. 3, an end-of-dose status indication may be provided to the user once the status reader 544 contacts or recognizes the final status trigger 512A positioned on the tether 512 that would contact the status reader 544 at the end of axial travel of the piston 110A, 110B and plunger 60 within the barrel 58 of the drug container 50. For clarity, the tether 512 may have one or more status triggers 512A, such as electrical contacts, optical markings, or electromechanical pins or recesses, which are capable of contacting or being recognized by a status reader 544. The status reader 544 may be, for example, an electrical switch reader to contact the corresponding electrical contacts, an optical reader to recognize the corresponding optical markings, or a mechanical or electromechanical reader configured to contact corresponding pins, holes, or similar aspects on the tether. The status triggers 512A may be positioned along the tether 512 to be read or recognized at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery. As the drug pump is activated and drug delivery is begun by release of the biasing member 122 and the resulting force applied to the piston 110A, 110B and plunger seal 60, the rate or profile of drug delivery to the user is controlled by the motor 530, gear assembly, and winch drum 520 releasing the tether 512 and permitting expansion of the biasing member 122 and axial translation of the piston 110A, 110B and plunger seal 60. As this occurs, the status triggers 512A of the tether 512 are contacted or recognized by the status reader 544 and the status of the drive mechanism before, during, and after operation can be relayed to the power and control system to provide feedback to the user. Depending on the number of status triggers 512A located on the tether 512, the frequency of the incremental status indication may be varied as desired. As described above, a range of status readers 544 may be utilized depending on the status triggers 512A utilized by the system.

[0047] In a preferred embodiment, as described herein with reference to FIG. 6, the status reader 544 may apply a tensioning force to the tether 512. When the system reaches end-of-dose, the tether 512 goes slack and the status reader 544 is permitted to rotate about a fulcrum (shown in FIG.6 as a cylindrical protrusion from the side of the status reader 544). This rotation may operate an electrical or electromechanical switch, for example a switch within sensor 540, signaling slack in the tether 512 to the power and control system 400. Additionally, the status gear 528 may act as an encoder along with sensor 540. The sensor/encoder combination is used to provide feedback of motor rotation, which in turn can be calibrated to the position of piston 110 when there is no slack in the tether 512. Together, the status reader 544 and sensor/encoder 540 provide positional feedback, end-of-dose signal, and error indication, such as an occlusion, by observing slack in the tether 512 prior to reaching the expected number of motor rotations as counted by the sensor/encoder 540.

[0048] Returning now to the embodiment shown in FIG. 2 and FIG 3, further aspects of the novel drive mechanism will be described with reference to FIGS. 4A-4C and 5A-5C. FIG. 4A shows an isometric view of the drive mechanism, according to at least a first embodiment, during its initial locked stage. A fluid, such as a drug fluid, may be contained within barrel 58, in a drug chamber 21 between plunger seal 60 and pierceable seal (not visible), for delivery to a user. The pierceable seal is adjacent or retained at least partially within cap 52. Upon activation by the user, a fluid pathway connection may be connected to the drug container through the pierceable seal 56. As described above, this fluid connection may be facilitated by a piercing member of the fluid pathway connection which pierces the pierceable seal and completes the fluid pathway from the drug container, through the fluid pathway connection, the fluid conduit, the insertion mechanism, and the cannula for delivery of the drug fluid to the body of the user. Initially, one or more locking mechanisms (not shown) may retain the biasing member 122 in an initial energized position

within piston 110A, 110B. Directly or indirectly upon activation of the device by the user, the locking mechanism may be removed to permit operation of the drive mechanism. As shown in FIG. 5A, the piston 110 and biasing member 122 are both initially in a compressed, energized state behind the plunger seal 60. The biasing member 122 may be maintained in this state until activation of the device between internal features of drive housing 130 and interface surface 110C of piston 110A, 110B. As the locking mechanism is removed or displaced, biasing member 122 is permitted to expand (i.e., decompress) axially in the distal direction (i.e., in the direction of the hatched arrow). Such expansion causes the biasing member 122 to act upon and distally translate interface surface 110C and piston 110, thereby distally translating plunger seal 60 to push drug fluid out of the drug chamber 21 of barrel 58.

[0049] As shown in FIG. 4B, such distal translation of the piston 110A, 110B and plunger seal 60 continues to force fluid flow out from barrel 58 through the pierceable seal 56. In at least one embodiment, an end-of-dose status indication may be provided to the user once the status reader 544 contacts or recognizes a status trigger 512A positioned on the tether 512 to substantially correspond with the end of axial travel of the piston 110A, 110B and plunger seal 60 within the barrel 58 of the drug container 50. As shown in FIG. 4B, the status triggers 512A are positioned along the tether 512 at various increments, such as increments which correspond to certain volume measurement, to provide incremental status indication to the user. In at least one embodiment, the status reader is an optical status reader configured to recognize the corresponding optical status triggers on the tether. As would be understood by an ordinarily skilled artisan, such optical status triggers may be markings which are recognizable by the optical status reader. In another embodiment, the status reader is a mechanical or electromechanical reader configured to physically contact corresponding pins, holes, or similar aspects on the tether. Electrical contacts could similarly be utilized on the tether as status indicators which contact or are otherwise recognized by the corresponding electrical status reader. The status triggers 512A may be positioned along the tether 512 to be read or recognized at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery. FIG. 5B shows a cross-sectional view of the view shown in FIG. 4B. As shown, tether 512 passes substantially axially through the drive mechanism housing 130, the biasing member 122, and connects to the piston 110 A, 110B to restrict the axial translation of the piston 110A, 110B and the plunger seal 60 that resides adjacent thereto.

[0050] As shown in FIG. 4C, the delivery control mechanisms 500 of embodiments of the present invention do not drive the delivery of fluid substances from the drug chamber 21. The delivery of fluid substances from the drug chamber 21 is caused by the expansion of the biasing member 122 from its initial energized state acting upon the piston 110A, 110B and plunger seal 60. The delivery control mechanisms 500 instead function to provide resistance to the free motion of the piston 110A, 110B and plunger seal 60 as they are pushed by the expansion of the biasing member 122 from its initial energized state. As the motor 530 and the delivery control mechanisms 500 release the tether 512, the biasing member 122 is permitted to continue its expansion from its energized state and drive the piston 110A, 110B and plunger seal 60 until the plunger seal 60 has substantially contacted the pierceable seal 56. This is visible in the cross-sectional view provided in FIG. 5C. At this point, substantially all of the drug substance has been pushed out of the drug chamber 21 through the fluid pathway connection 300 for drug delivery to the user. A status trigger 512A may be configured along the tether 512 to correspond with this position of the piston 110A, 110B, such that, as the piston 110A, 110B reaches its end of axial travel, a status trigger 512A is read or recognized by the status reader 544 to provide true end-of-dose indication to the user. As stated above, the status triggers 512A may be positioned along the tether 512 to be read or recognized at positions which correspond with the beginning and end of drug delivery, as well as at desired increments during drug delivery. The controlled delivery drive mechanisms and/or drug pumps of embodiments of the present invention may additionally enable a compliance push to ensure that substantially all of the drug substance has been pushed out of the drug chamber 21. The plunger seal 60, itself, may have some compressibility permitting a compliance push of drug fluid from the drug container. For example, when a pop-out plunger seal is employed, i.e., a plunger seal that is deformable from an initial state, the plunger seal may be caused to deform or "pop-out" to provide a compliance push of drug fluid from the drug container, as shown in FIG. 5C. Additionally or alternatively, an electromechanical status switch and interconnect assembly may be utilized to contact, connect, or otherwise enable a transmission to the power and control system to signal end-of-dose to the user. For example, the status switch may be located distal to the pierceable seal 56 and the interconnect located proximal to the plunger seal 60 such that, upon substantially complete axial translation (and optional compliance push) of the plunger seal 60 within the barrel 58, the status switch and interconnect coordinate to enable a transmission to the power and control system to signal end-of-dose to the user. This configuration further enables true end-of-dose indication to the user.

[0051] FIG. 6 shows a perspective view of certain components of a controlled delivery drive mechanism, according to at least one embodiment of the present invention. The controlled delivery drive mechanism incorporates an incremental status indicator mechanism having a status reader and one or more corresponding status triggers. In at least one embodiment, the gear assembly of the delivery control mechanism 500 utilizes a motor 530 with pinion 530A. The pinion 530A contacts a first gear 526A of a compound gear 526, and the second gear 526B of the compound gear 526 contacts a gear aspect 524B of a worm gear 524. The worm aspect 524A of the worm gear 524 contacts a drum gear 522 which is connected to a winch drum 520. The tether 512 is at least partially wrapped around the winch drum 520. As the motor 530 acts upon the gear assembly, the motion is

conveyed by interfacing gear teeth of the pinion 530A, compound gear 526, worm gear 524, and drum gear 522 to the winch drum 520 to unwind the tether 512 therefrom. As detailed above, unwinding the tether 512 reduces the resistance it provides on the piston 110A, 110B and permits the biasing member 122 to expand from its energized state, thereby driving the plunger seal 60 for drug delivery. As the tether 512 is unwound from the winch drum 520, a status reader 544 may read or recognize one or more corresponding status triggers 512A on the tether 512 to provide incremental status indication before, during, and after operation of the controlled delivery drive mechanism. As described above, a number of status readers may be utilized within the embodiments of the present invention. For example, the drive mechanism shown in FIG. 6 may utilize a mechanical status reader 544 which is physically contacted by ridges, holes, or other aspects incrementally spaced on the tether 512 to correspond with desired status indications (e.g., volume delivered, volume remaining, changes in delivery rates or profiles, etc.). As the status reader 544 is contacted by the status trigger(s) 512A, the status reader 544 causes the sensor 540 to measure the position of the status gear 528 and transmit a signal to the power and control system for status indication to the user. As described above, optical status readers and corresponding triggers, electromechanical status readers and corresponding triggers, and/or mechanical status readers and corresponding triggers may all be utilized by the embodiments of the present invention to provide incremental status indication to the user.

[0052] Assembly and/or manufacturing of controlled delivery drive mechanism 100, drug delivery pump 10, or any of the individual components may utilize a number of known materials and methodologies in the art. For example, a number of known cleaning fluids such as isopropyl alcohol and hexane may be used to clean the components and/or the devices. A number of known adhesives or glues may similarly be employed in the manufacturing process. Additionally, known siliconization and/or lubrication fluids and processes may be employed during the manufacture of the novel components and devices. Furthermore, known sterilization processes may be employed at one or more of the manufacturing or assembly stages to ensure the sterility of the final product.

[0053] The drive mechanism may be assembled in a number of methodologies. In one method of assembly, the drug container 50 may first be assembled and filled with a fluid for delivery to the user. The drug container 50 includes a cap 52, a pierceable seal 56, a barrel 58, and a plunger seal 60. The pierceable seal 56 may be fixedly engaged between the cap 52 and the barrel 58, at a distal end of the barrel 58. The barrel 58 may be filled with a drug fluid through the open proximal end prior to insertion of the plunger seal 60 from the proximal end of the barrel 58. An optional connection mount 54 may be mounted to a distal end of the pierceable seal 56. The connection mount 54 may guide the insertion of the piercing member of the fluid pathway connection into the barrel 58 of the drug container 50. The drug container 50 may then be mounted to a distal end of drive housing 130.

[0054] A drive biasing member 122 may be inserted into a distal end of the drive housing 130. Optionally, a cover sleeve 140 may be inserted into a distal end of the drive housing 130 to substantially cover biasing member 122. A piston may be inserted into the distal end of the drive housing 130 such that it resides at least partially within an axial pass-through of the biasing member 122 and the biasing member 122 is permitted to contact a piston interface surface 110C of piston 110A, 110B at the distal end of the biasing member 122. An optional cover sleeve 140 may be utilized to enclose the biasing member 122 and contact the piston interface surface 110C of piston 110A, 110B. The piston 110A, 110B and drive biasing member 122, and optional cover sleeve 140, may be compressed into drive housing 130. Such assembly positions the drive biasing member 122 in an initial compressed, energized state and preferably places a piston interface surface 110C in contact with the proximal surface of the plunger seal 60 within the proximal end of barrel 58. The piston, piston biasing member, contact sleeve, and optional components, may be compressed and locked into the ready-to-actuate state within the drive housing 130 prior to attachment or mounting of the drug container 50. The tether 512 is pre-connected to the proximal end of the piston 110A, 110B and passed through the axial aperture of the biasing member 122 and drive mechanism 130, and then wound through the interior of the drug pump with the other end of the tether 512 wrapped around the winch drum 520 of the delivery control mechanism 500.

[0055] A fluid pathway connection, and specifically a sterile sleeve of the fluid pathway connection, may be connected to the cap and/or pierceable seal of the drug container. A fluid conduit may be connected to the other end of the fluid pathway connection which itself is connected to the insertion mechanism such that the fluid pathway, when opened, connected, or otherwise enabled travels directly from the drug container, fluid pathway connection, fluid conduit, insertion mechanism, and through the cannula for drug delivery into the body of a user. The components which constitute the pathway for fluid flow are now assembled. These components may be sterilized, by a number of known methods, and then mounted either fixedly or removably to an assembly platform or housing of the drug pump, as shown in FIG. 1B.

[0056] Certain optional standard components or variations of drive mechanism 100 or drug pump 10 are contemplated. For example, the embodiments may include one or more batteries utilized to power the motor, drive mechanisms, and drug pumps of embodiments of the present invention. A range of batteries known in the art may be utilized for this purpose. Additionally, upper or lower housings may optionally contain one or more transparent or translucent windows 18, as shown in FIG. 1A, to enable the

user to view the operation of the drug pump 10 or verify that drug dose has completed. Similarly, the drug pump 10 may contain an adhesive patch 26 and a patch liner 28 on the bottom surface of the housing 12. The adhesive patch 26 may be utilized to adhere the drug pump 10 to the body of the user for delivery of the drug dose. As would be readily understood by one having ordinary skill in the art, the adhesive patch 26 may have an adhesive surface for adhesion of the drug pump to the body of the user. The adhesive surface of the adhesive patch 26 may initially be covered by a non-adhesive patch liner 28, which is removed from the adhesive patch 26 prior to placement of the drug pump 10 in contact with the body of the user. Removal of the patch liner 28 may further remove the sealing membrane 254 of the insertion mechanism 200, opening the insertion mechanism to the body of the user for drug delivery (as shown in FIG. 1C).

[0057] Similarly, one or more of the components of controlled delivery drive mechanism 100 and drug pump 10 may be modified. For example, as described above, while the housing of drug pump 10 is shown as two separate components upper housing 12A and lower housing 12B, these components may be a single unified component. As discussed above, a glue, adhesive, or other known materials or methods may be utilized to affix one or more components of the controlled delivery drive mechanism and/or drug pump to each other. Alternatively, one or more components of the controlled delivery drive mechanism and/or drug pump may be a unified component. For example, the upper housing and lower housing may be separate components affixed together by a glue or adhesive, a screw fit connection, an interference fit, fusion joining, welding, ultrasonic welding, and the like; or the upper housing and lower housing may be a single unified component. Such standard components and functional variations would be appreciated by one having ordinary skill in the art.

[0058] It will be appreciated from the above description that the controlled delivery drive mechanisms and drug pumps disclosed herein provide an efficient and easily-operated system for automated drug delivery from a drug container. The novel embodiments described herein provide drive mechanisms for the controlled delivery of drug substances and drug delivery pumps which incorporate such controlled delivery drive mechanisms. The drive mechanisms of embodiments of the present invention control the rate of drug delivery by metering, providing resistance, or otherwise preventing free axial translation of the plunger seal utilized to force a drug substance out of a drug container and, thus, are capable of delivering drug substances at variable rates and/or delivery profiles. Additionally, the drive mechanisms of embodiments of the present invention provide integrated status indication features which provide feedback to the user before, during, and after drug delivery. For example, the user may be provided an initial feedback to identify that the system is operational and ready for drug delivery. Upon activation, the system may then provide one or more drug delivery status indications to the user. At completion of drug delivery, the drive mechanism and drug pump may provide an end-of-dose indication. The novel controlled delivery drive mechanisms of embodiments of the present invention may be directly or indirectly activated by the user. Furthermore, the novel configurations of the controlled delivery drive mechanism and drug pumps of embodiments of the present invention maintain the sterility of the fluid pathway during storage, transportation, and through operation of the device. Because the path that the drug fluid travels within the device is entirely maintained in a sterile condition, only these components need be sterilized during the manufacturing process. Such components include the drug container of the drive mechanism, the fluid pathway connection, the sterile fluid conduit, and the insertion mechanism. In at least one embodiment of the present invention, the power and control system, the assembly platform, the control arm, the activation mechanism, the housing, and other components of the drug pump do not need to be sterilized. This greatly improves the manufacturability of the device and reduces associated assembly costs. Accordingly, the devices of the present invention do not require terminal sterilization upon completion of assembly.

[0059] Manufacturing of a drug pump includes the step of attaching both the controlled delivery drive mechanism and drug container, either separately or as a combined component, to an assembly platform or housing of the drug pump. The method of manufacturing further includes attachment of the fluid pathway connection, drug container, and insertion mechanism to the assembly platform or housing. The additional components of the drug pump, as described above, including the power and control system, the activation mechanism, and the control arm may be attached, preformed, or pre-assembled to the assembly platform or housing. An adhesive patch and patch liner may be attached to the housing surface of the drug pump that contacts the user during operation of the device.

[0060] A method of operating the drug pump includes the steps of: activating, by a user, the activation mechanism; displacing a control arm to actuate an insertion mechanism; and actuating a power and control system to activate a controlled delivery drive mechanism to drive fluid drug flow through the drug pump according to a controlled rate or drug delivery profile. The method may further include the step of: engaging an optional on-body sensor prior to activating the activation mechanism. The method similarly may include the step of: establishing a connection between a fluid pathway connection to a drug container. Furthermore, the method of operation may include translating a plunger seal within the controlled delivery drive mechanism by the expansion of the biasing member acting upon a piston within a drug container to force fluid drug flow through the drug container, the fluid pathway connection, a sterile fluid conduit, and the insertion mechanism for delivery of the fluid drug to the body of a user, wherein a tether is utilized to restrain the free axial translation of the piston. The method of operation of the insertion mechanism and the drug pump may be better appreciated with reference to FIGS. 4A-4C and FIGS. 5A-5C, as described above.

REFERENCES CITED IN THE DESCRIPTION

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- US2012054861W [0032]
- US2013030478W [0033]
- US201253174W [0035]

DRIVMEKANISMER MED STYRET AFGIVELSE TIL LÆGEMIDDELAFGIVELSESPUMPER

PATENTKRAV

1. Drivmekanisme (100) med styret afgivelse til en lægemiddelbeholder med en stempeltætning (60) konfigureret til at bevæge sig inde i en cylinder (58), hvilken drivmekanisme (100) til styret afgivelse omfatter: et drevhus (130); et stempel (110A, 110B); et forspændingselement (122), hvor forspændingselementet (122) initialt er holdt i en forspændt tilstand og konfigureret til at hvile på en grænseflade (110C) af stemplet (110); en snor (512), der er forbundet ved én ende med stemplet (110A, 110B) og ved den anden ende med en spiltromle (520) af en afgivelsesstyringsmekanisme (500), hvor en spændingskraft påføres snoren (512) for at begrænse den frie ekspansion af forspændingselementet (122) fra dets oprindelige forspændte tilstand og den frie, aksiale forskydning af stemplet (110A, 110B), hvorpå forspændingselementet (122) hviler; kendetegnet ved, at en statuslæser (544) er placeret stødende op til snoren (512), hvor statuslæseren (544) er konfigureret til at tilvejebringe et signal, når der opstår slæk i snoren (512).

2. Drivmekanisme (100) ifølge krav 1, hvor statuslæseren (544) påfører snoren (512) en spændingskraft.

3. Drivmekanisme (100) ifølge et af kravene 1 eller 2, hvor statuslæseren (544) kan rotere omkring et omdrejningspunkt, når snoren (512) slækkes.

4. Drivmekanisme (100) ifølge et hvilket som helst af kravene 1-4, hvor statuslæseren (544) indbefatter en kontakt.

5. Drivmekanisme (100) ifølge et hvilket som helst af kravene 1-4, hvor lægemiddelbeholderen (50) indeholder et lægemiddelfluid inde i et lægemiddelkammer (21).

6. Drivmekanisme (100) ifølge et hvilket som helst af kravene 1-5, hvor der kan anvendes et beskyttelseshylster (140) mellem forspændingselementet (122) og grænsefladen (110C) af stemplet (110A, 110B).

7. Drivmekanisme (100) ifølge et hvilket som helst af kravene 1-6, hvor snoren (512) er konfigureret til at blive frigivet fra en spiltromle (520) af afgivelsesstyringsmekanismen (500) for at måle den frie ekspansion af forspændingselementet (122) fra dets oprindelige forspændte tilstand og den frie, aksiale forskydning af stemplet (110A, 110B), hvorpå forspændingselementet (122) hviler.

8. Drivmekanisme (100) ifølge et hvilket som helst af kravene 1-7, hvilken mekanisme endvidere omfatter en tandhjulsenhed med en flerhed af tandhjul, hvor mindst ét af tandhjulene (528) er konfigureret til at fungere som en koder.

9. Drivmekanisme (100) ifølge et hvilket som helst af kravene 1-8, hvilken drivmekanisme omfatter en tandhjulsenhed med et opviklingshjul (522), der er forbundet med en spiltromle (520), hvorpå snoren (512) aftageligt kan vikles, et snekkehjul (524), der er forbundet ved indgreb med opviklingshjulet (522), et sammensat hjul (526), der er forbundet ved indgreb med snekkehjulet (524), og en motor (530) med et tandhjulsdrev (530A), der er forbundet ved indgreb med det sammensatte hjul (526), hvor motoren (530) er konfigureret til at drive tandhjulsenheden for at frigive snoren (512) fra spiltromlen (520) for at måle den frie ekspansion af forspændingselementet (122) fra dets oprindelige forspændte tilstand og den frie, aksiale forskydning af stemplet (110A, 110B), hvorpå forspændingselementet (122) hviler.

10. Drivmekanisme (100) ifølge krav 7, hvor afmåling af snoren (512) ved motoren (530) styrer hastigheden eller profilen for lægemiddelafgivelse til en bruger.

11. Drivmekanisme (100) ifølge et hvilket som helst af kravene 1-10, hvor stemplet (110A, 110B) består af én eller flere dele og er forbundet med en distal ende af snoren (512).

12. Drivmekanisme (100) ifølge et hvilket som helst af kravene 1-11, hvor statuslæseren (544) kan være konfigureret til at læse eller genkende én eller flere tilsvarende statusudløsere (512A), der er placeret trinvist med afstand fra hinanden på snoren (512), hvor, under drivmekanismens (100) funktion, interaktion mellem statuslæseren (544) og statusudløserne (512A) transmitterer et signal til et energiforsynings- og styresystem (400) for at tilvejebringe feedback til en bruger.

13. Drivmekanisme (100) ifølge krav 12, hvor statuslæseren (544) er en optisk statuslæser og de tilsvarende statusudløsere (512A) er optiske statusudløsere.

14. Drivmekanisme (100) ifølge krav 12, hvor statuslæseren (544) er en elektromekanisk statuslæser og de tilsvarende statusudløsere (512A) er elektromekaniske statusudløsere.

15. Drivmekanisme (100) ifølge krav 12, hvor statuslæseren (544) er en mekanisk statuslæser og de tilsvarende statusudløsere (512A) er mekaniske statusudløsere.

16. Lægemiddelafgivelsespumpe (10) med styret lægemiddelafgivelse omfattende et hus (12) og en monteringsplatform (20), hvorpå der er en aktiveringsmekanisme (14), en indføringsmekanisme (200), en fluidbaneforbindelse (300), et energiforsynings- og styresystem (400) og en styret afgivelsesdrivmekanisme (100) ifølge et hvilket som helst af kravene 1-15.

17. Lægemiddelafgivelsespumpe (10) ifølge krav 16, hvor energiforsynings- og styresystemet (400) er konfigureret til at modtage ét eller flere input for at måle frigørelsen af snoren (512) ved spiltromlen (520) og derved muliggøre aksial forskydning af stemplet (110) ved forspændingselementet (122) for at forskyde en stempeltætning (60) inde i en cylinder (58).

18. Lægemiddelafgivelsespumpe (10) ifølge et af kravene 16 eller 17, hvor det ene eller flere input tilvejebringes af brugeren ved indvirkning på aktiveringsmekanismen (14).

19. Lægemiddelafgivelsespumpe (10) ifølge et af kravene 16 eller 17, hvor det ene eller flere input tilvejebringes af brugeren ved indvirkning på et styreinterface.

20. Lægemiddelafgivelsespumpe (10) ifølge et af kravene 16 eller 17, hvor det ene eller flere input tilvejebringes af brugeren ved indvirkning på fjernstyringsmekanisme.

21. Lægemiddelafgivelsespumpe (10) ifølge et hvilket som helst af kravene 16-20, hvor energiforsynings- og styresystemet (400) er konfigureret til at modtage ét eller flere input for at justere begrænsningen tilvejebragt af snoren (512) og spiltromlen (520) på den frie, aksiale forskydning af stemplet (110A, 110B), hvorpå forspændingselementet (122) hviler, for at opfylde en ønsket lægemiddelafgivelseshastighed eller -profil.

22. Lægemiddelafgivelsespumpe (10) ifølge et hvilket som helst af kravene 16-20, hvor energiforsynings- og styresystemet (400) er konfigureret til at modtage ét eller flere input for at justere begrænsningen tilvejebragt af snoren (512) og spiltromlen (520) på den frie, aksiale forskydning af stemplet (110A, 110B), hvorpå forspændingselementet (122) hviler, for at ændre dosisvolumenet til afgivelse til brugeren.

23. Lægemiddelafgivelsespumpe (10) ifølge et hvilket som helst af kravene 16-20, hvor energiforsynings- og styresystemet (400) er konfigureret til at modtage ét eller flere input for at justere begrænsningen tilvejebragt af snoren (512) og spiltromlen (520) på den frie, aksiale forskydning af stemplet (110A, 110B), hvorpå forspændingselementet (122) hviler, for at starte, stoppe eller sætte funktionen af drivmekanismen (100) på pause.

DRAWINGS

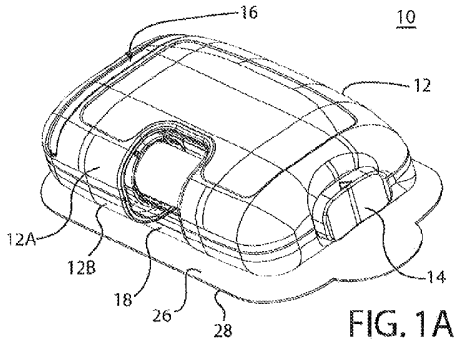

FIG. 1A

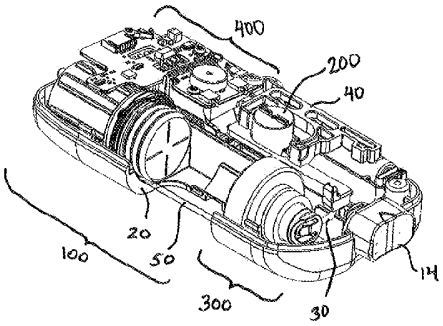

FIG. 1B

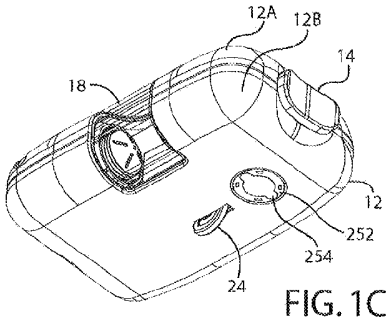

FIG. 1C

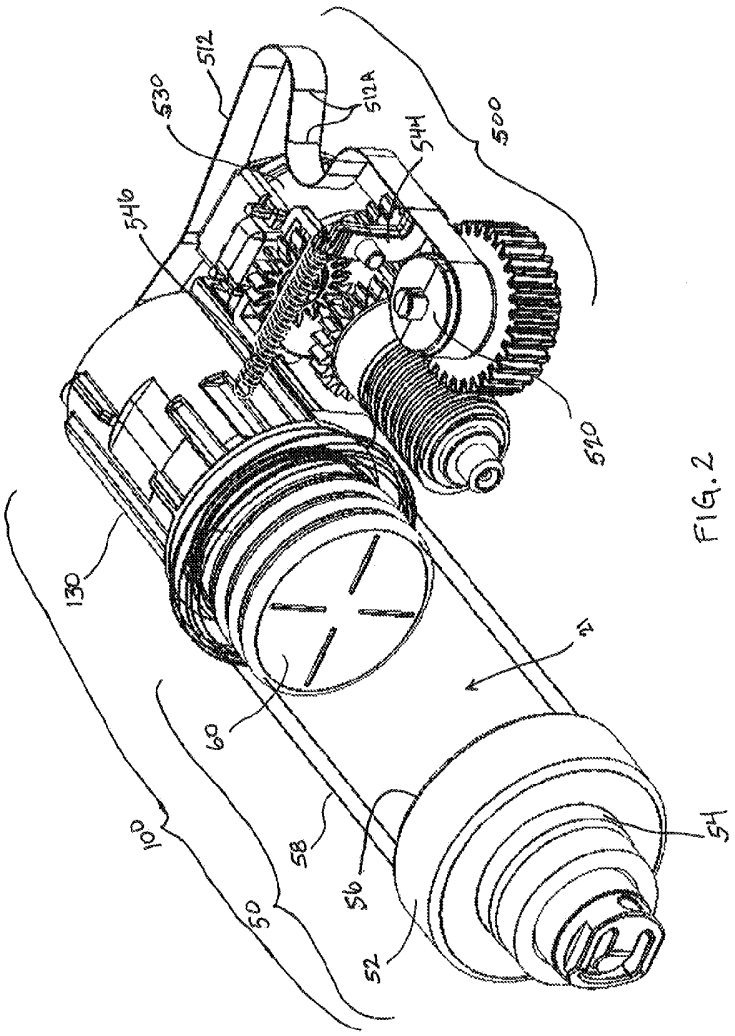

FIG. 2

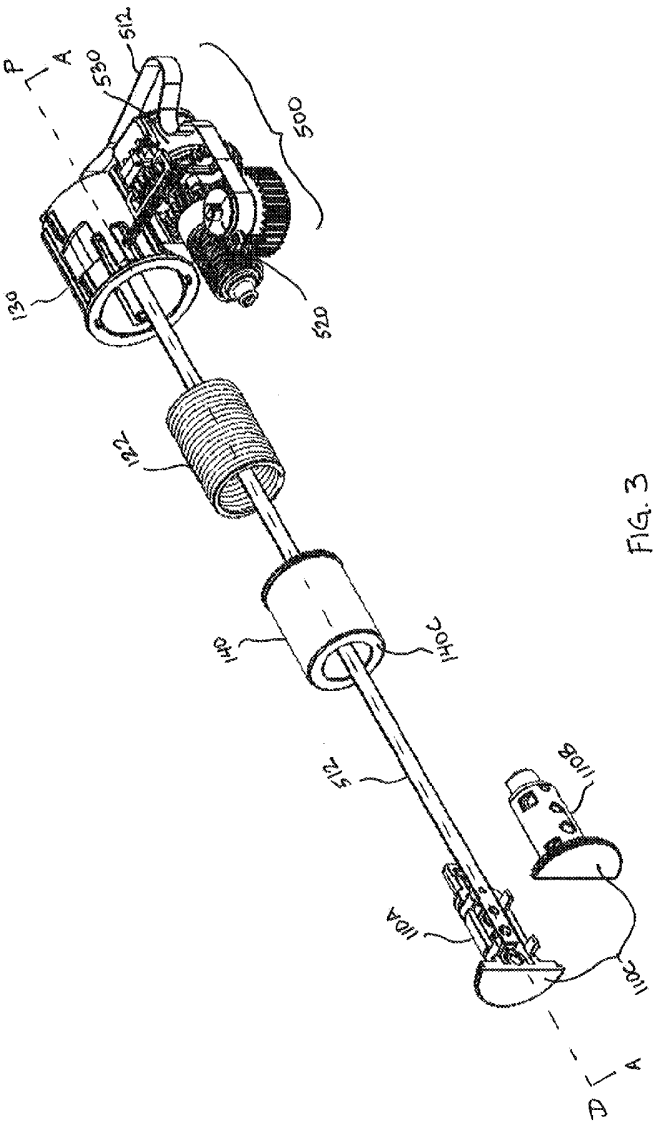

FIG. 3

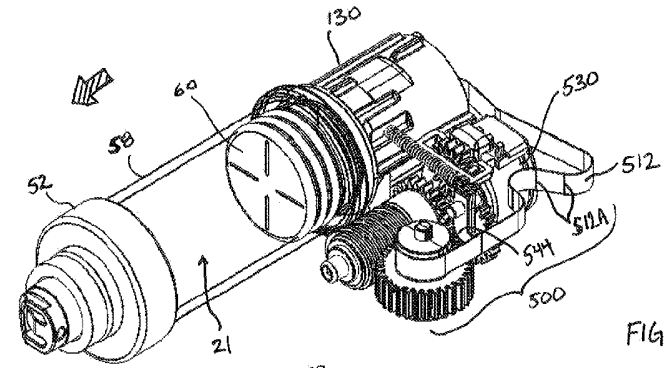

FIG. 4A

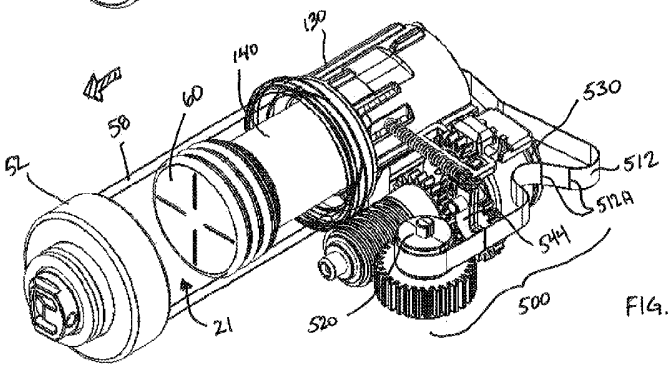

FIG. 4B

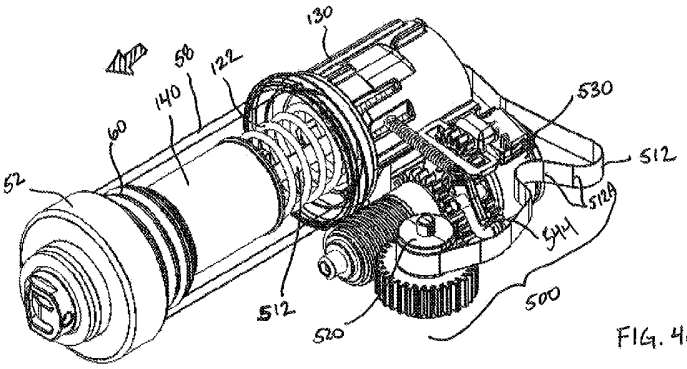

FIG. 4C

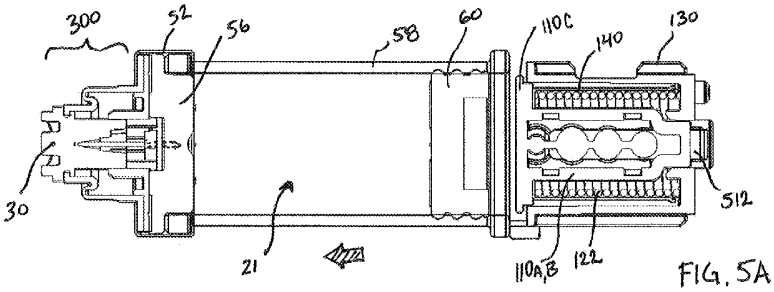

FIG. 5A

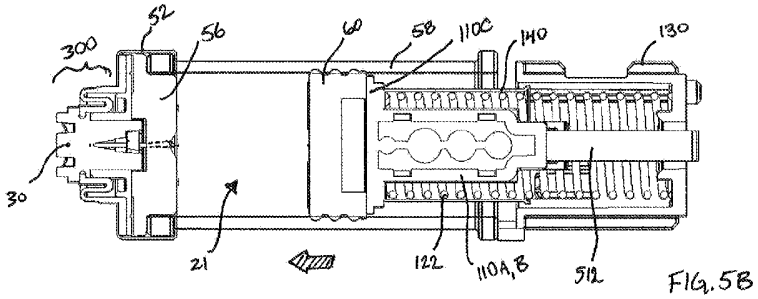

FIG. 5B

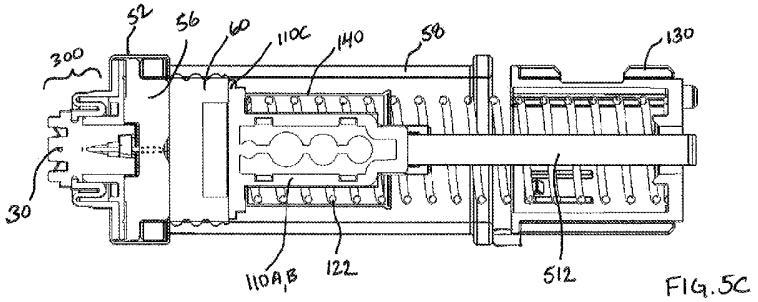

FIG. 5C

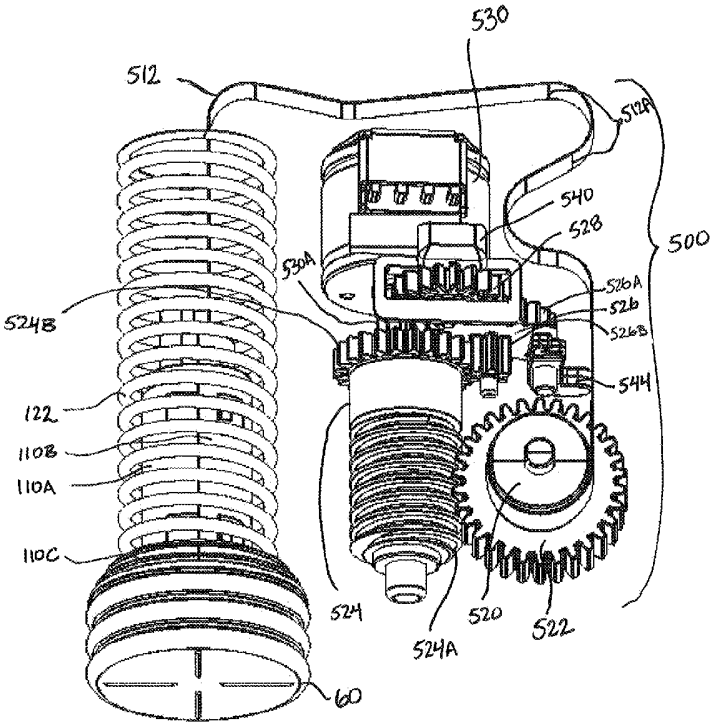
530
512
512A
540
528
500
530A
526A
526
526B
524B
544
122
110B
110A
110C
524
524A
520
522
60

FIG. 6