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(54) **MEDICAMENT DELIVERY DEVICE HAVING AN ELECTRONIC CIRCUIT SYSTEM**

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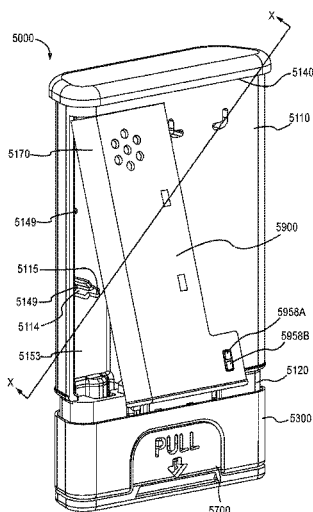
Related U.S. Application Data

(63) Continuation of application No. 14/993,234, filed on Jan. 12, 2016, now Pat. No. 10,076,611, which is a continuation of application No. 13/550,893, filed on Jul. 17, 2012, now Pat. No. 9,238,108, which is a continuation of application No. 12/119,016, filed on May 12, 2008, now Pat. No. 8,231,573, which is a continuation-in-part of application No. 11/679,331, filed on Feb. 27, 2007, now Pat. No. 9,022,980, which is a continuation-in-part of application No. 11/671,025, filed on Feb. 5, 2007, now Pat. No. 8,172,082, which is a continuation-in-part of application No. 11/621,236, filed on Jan. 9, 2007, now Pat. No. 7,731,686, which is a continuation-in-part of application No. 10/572,148, filed on Mar. 16, 2006, now Pat. No. 7,749,194, filed as application No. PCT/US2006/003415 on Feb. 1, 2006.

(60) Provisional application No. 60/648,822, filed on Feb. 1, 2005, provisional application No. 60/731,886, filed on Oct. 31, 2005, provisional application No. 60/787,046, filed on Mar. 29, 2006, provisional application No. 60/787,046, filed on Mar. 29, 2006, provisional application No. 60/787,046, filed on Mar. 29, 2006.

(57) **ABSTRACT**

Medicament delivery devices are described herein. In some embodiments, an apparatus includes a medical injector and an electronic circuit system. The medical injector includes a housing, a medicament container, and a medicament delivery member. The housing defines a first region and a second region. The first region includes the medicament container and is physically isolated from the second region. The electronic circuit system is configured to be disposed within the second region defined by the housing. The electronic circuit system is configured to output an electronic output associated with a use of the medical injector.



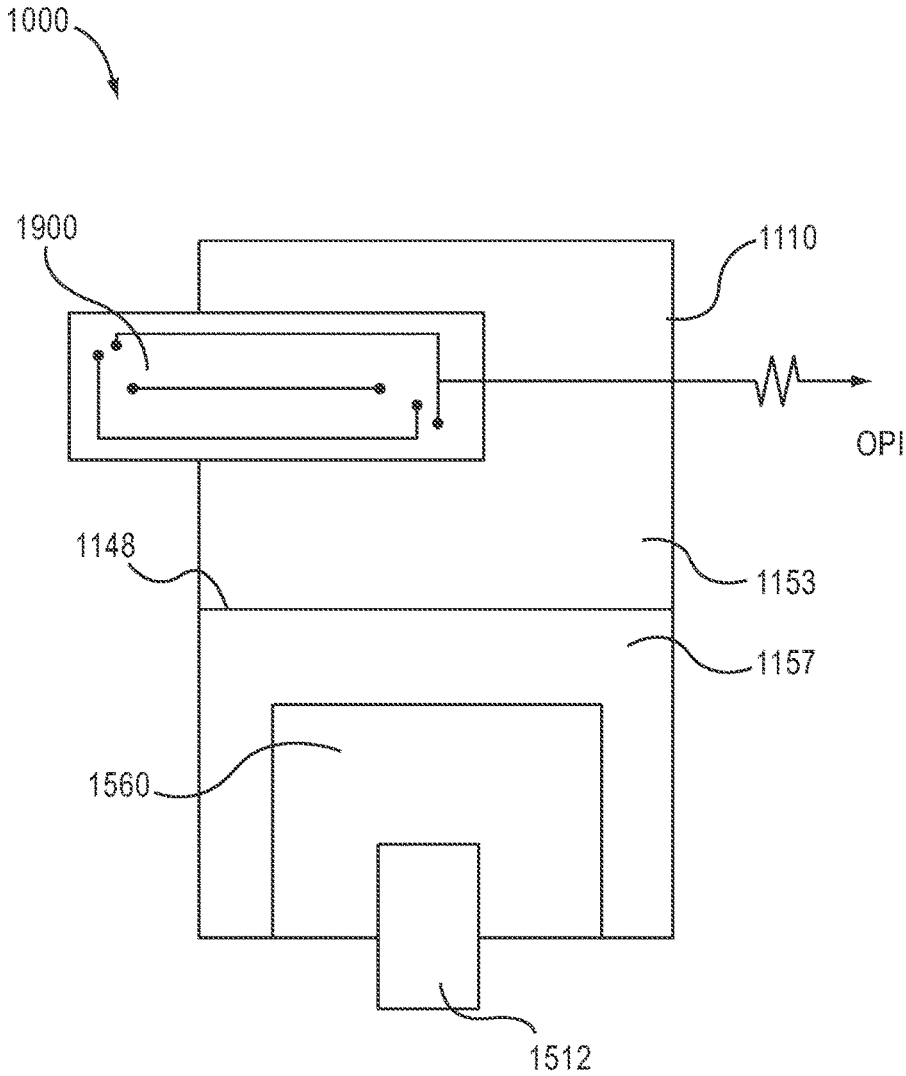


FIG.1

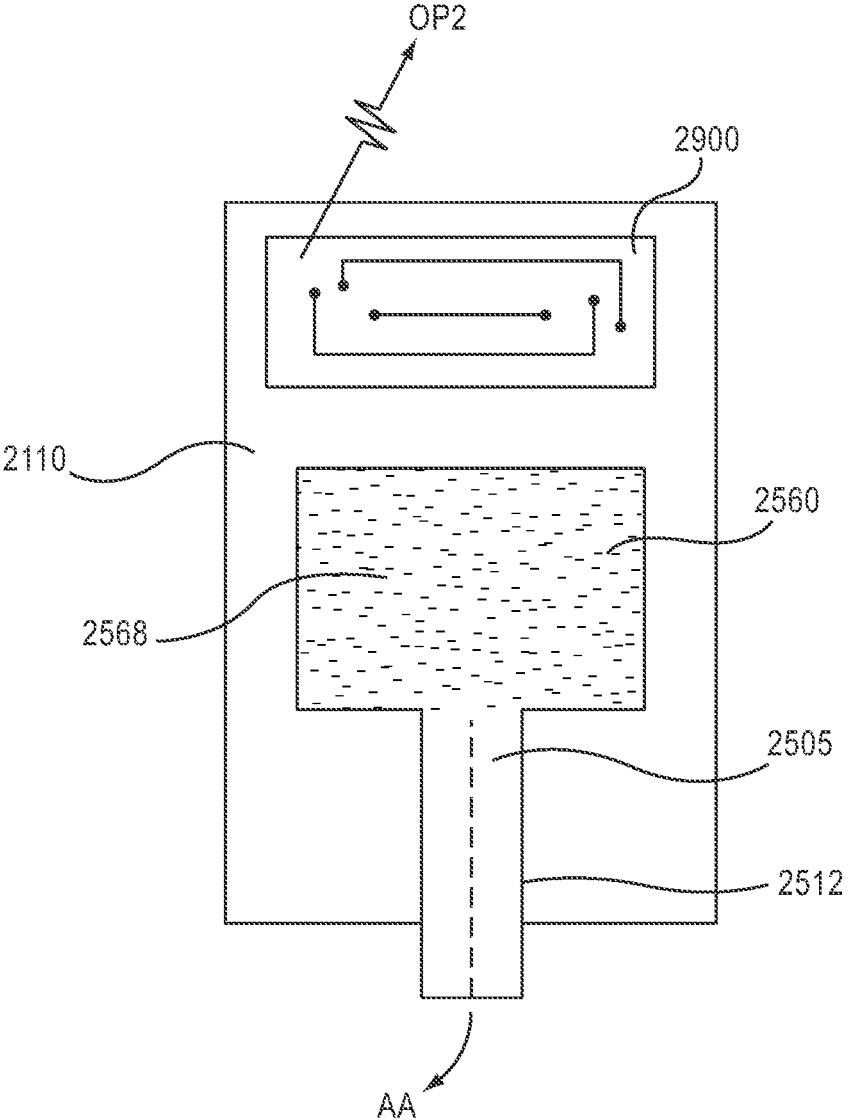


FIG.2

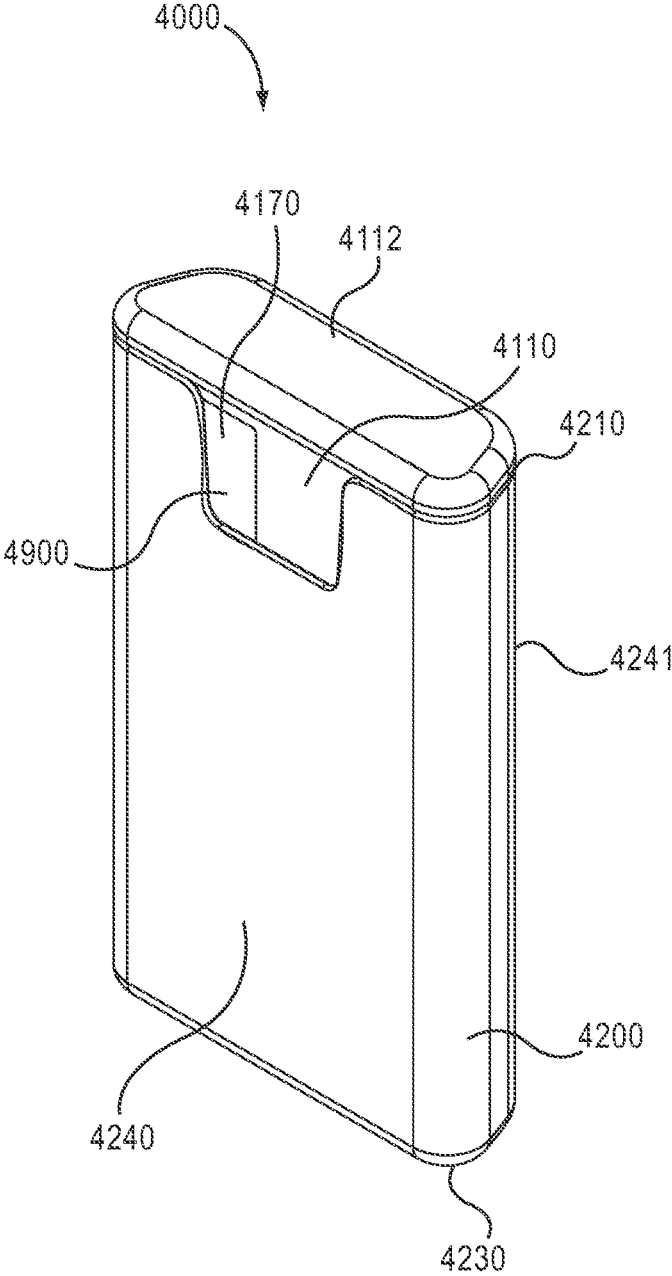


FIG.3

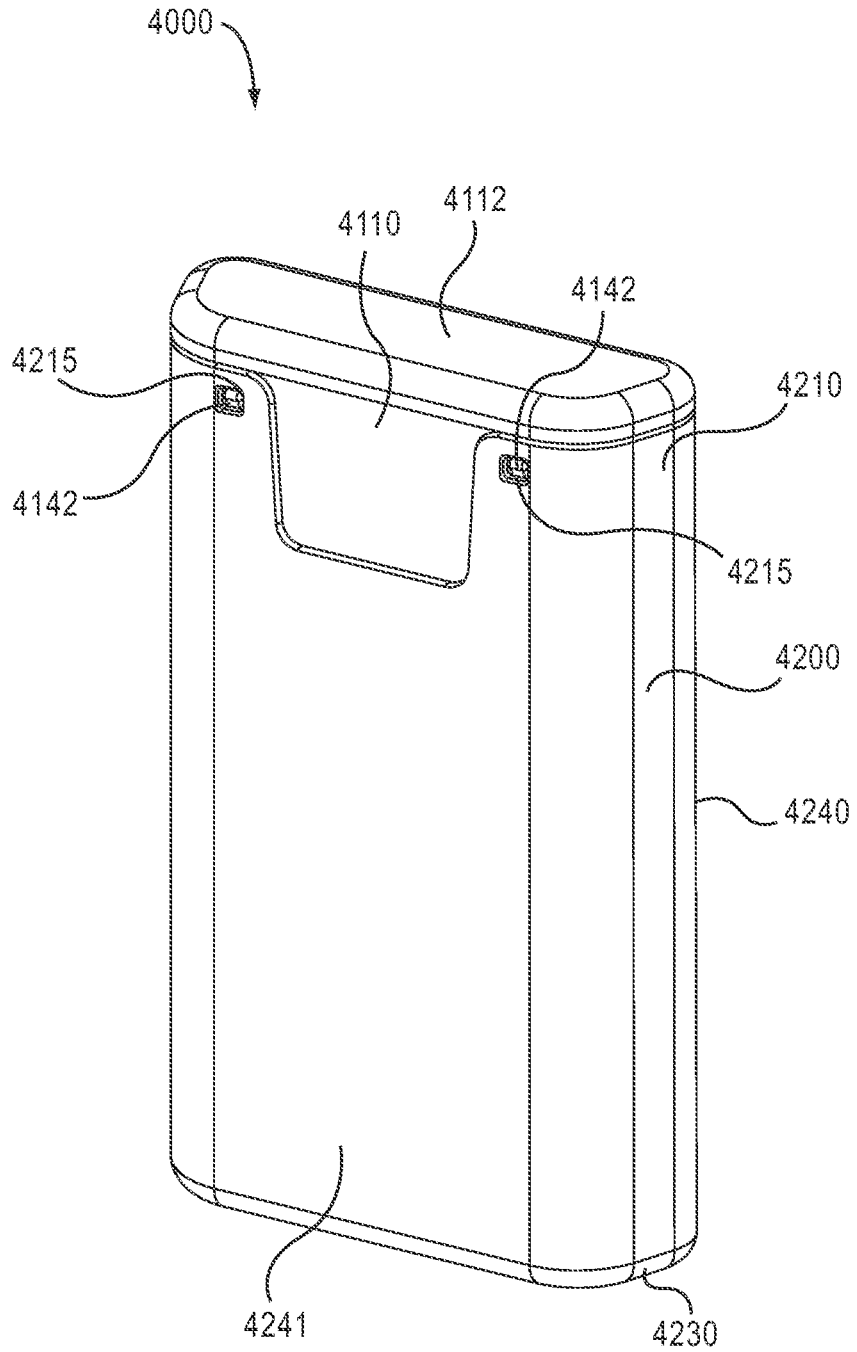


FIG. 4

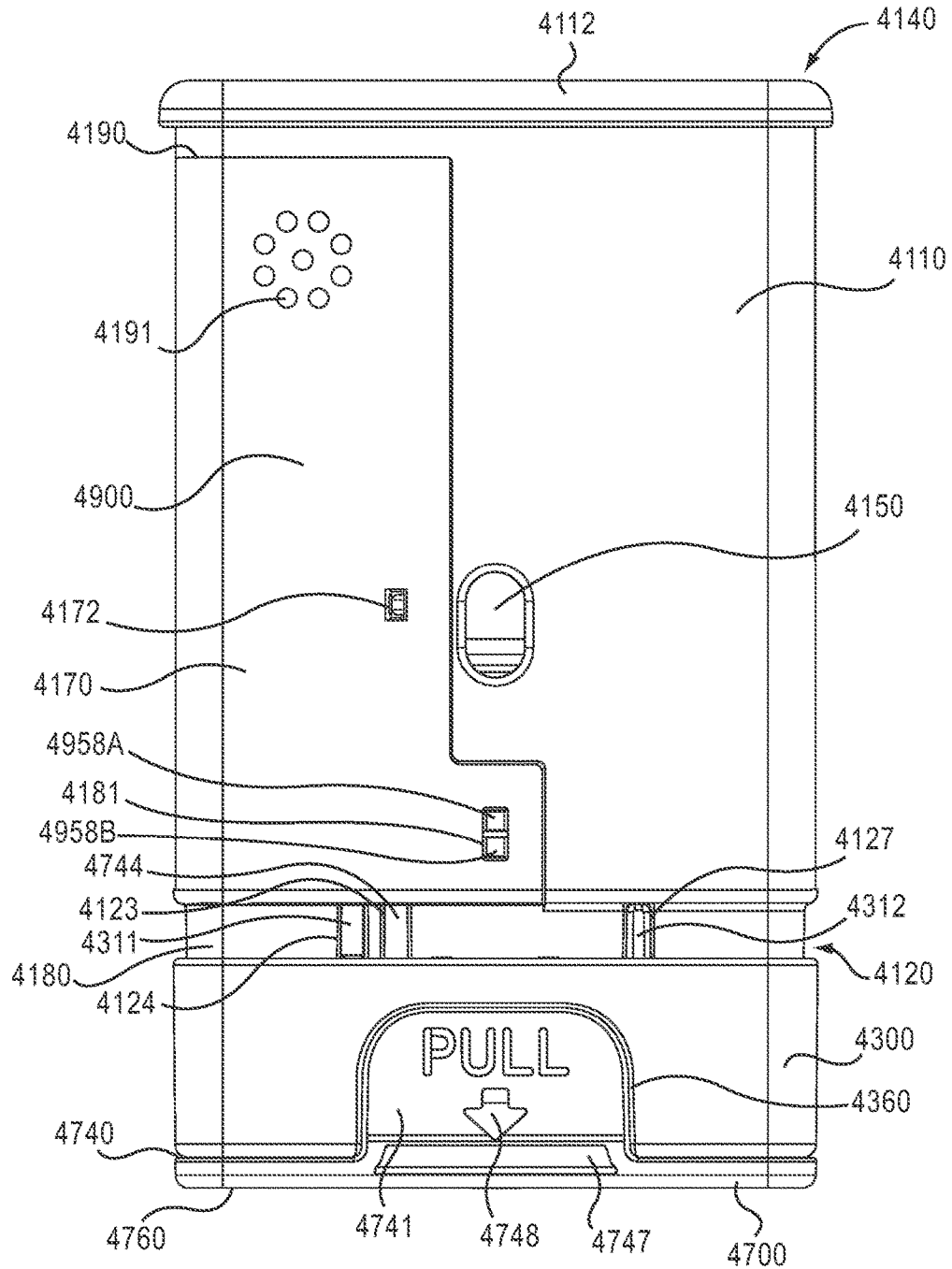


FIG.5

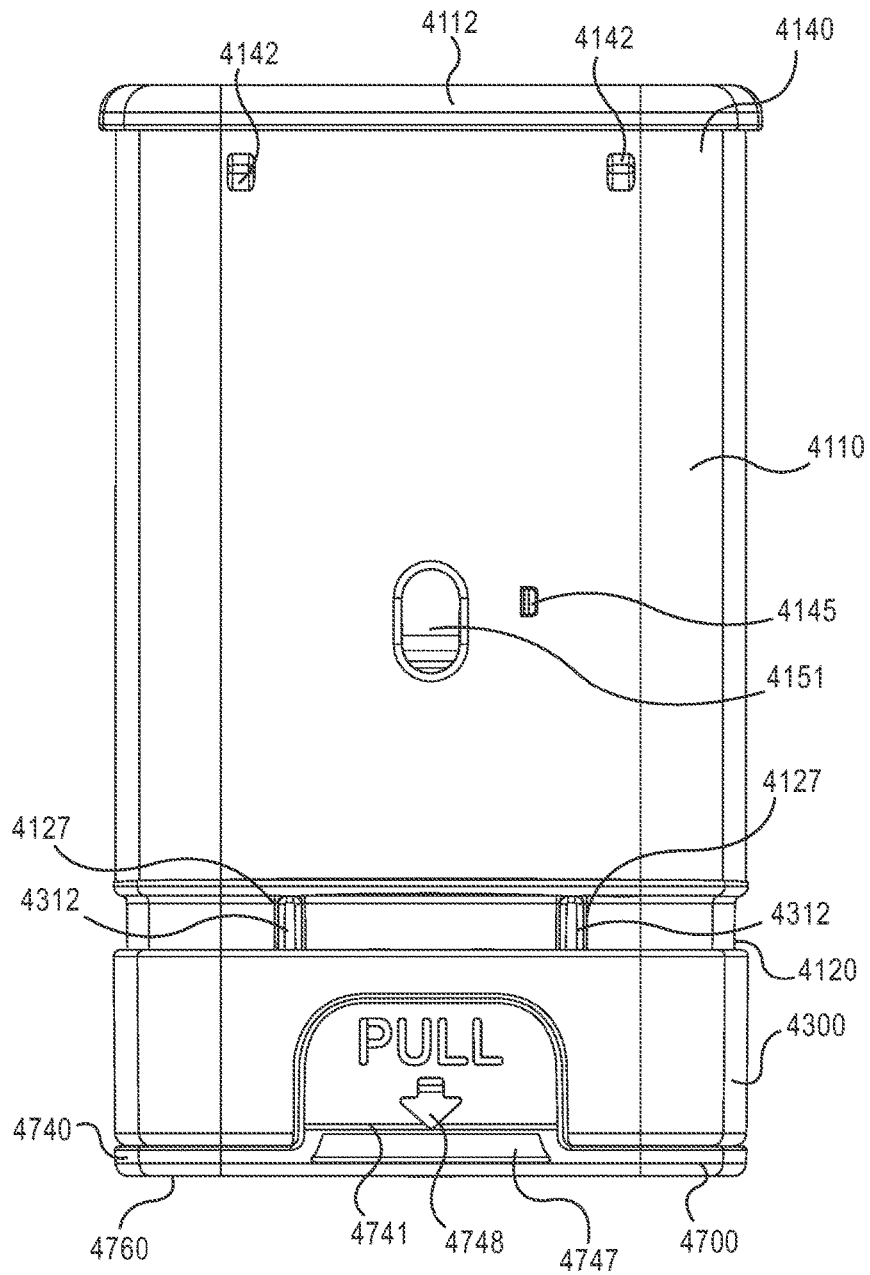


FIG. 6

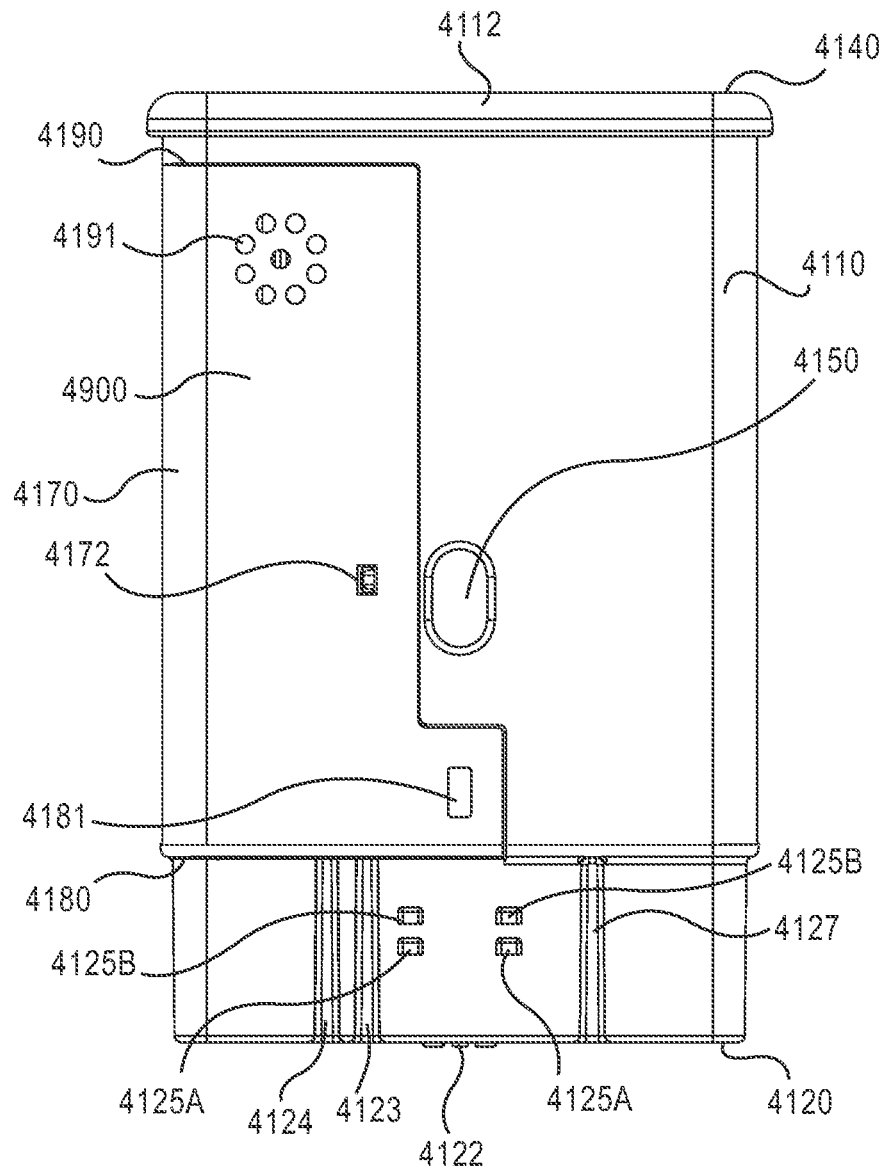


FIG.7

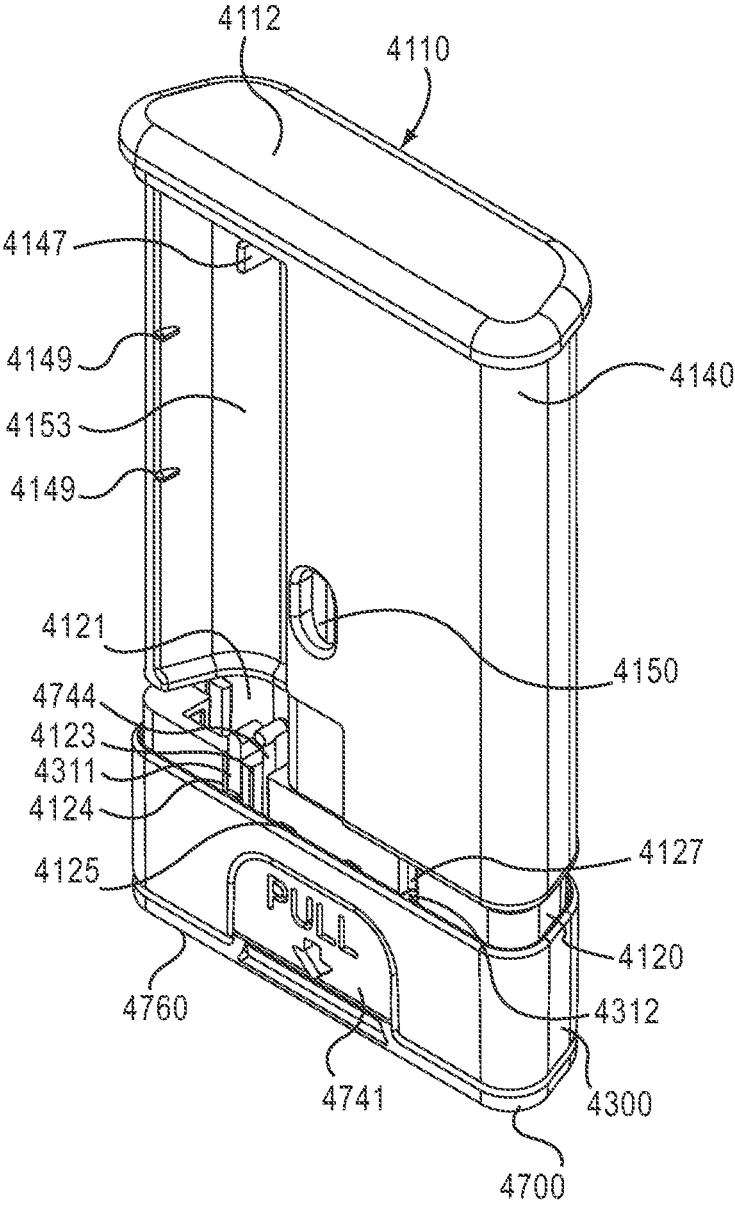


FIG.8

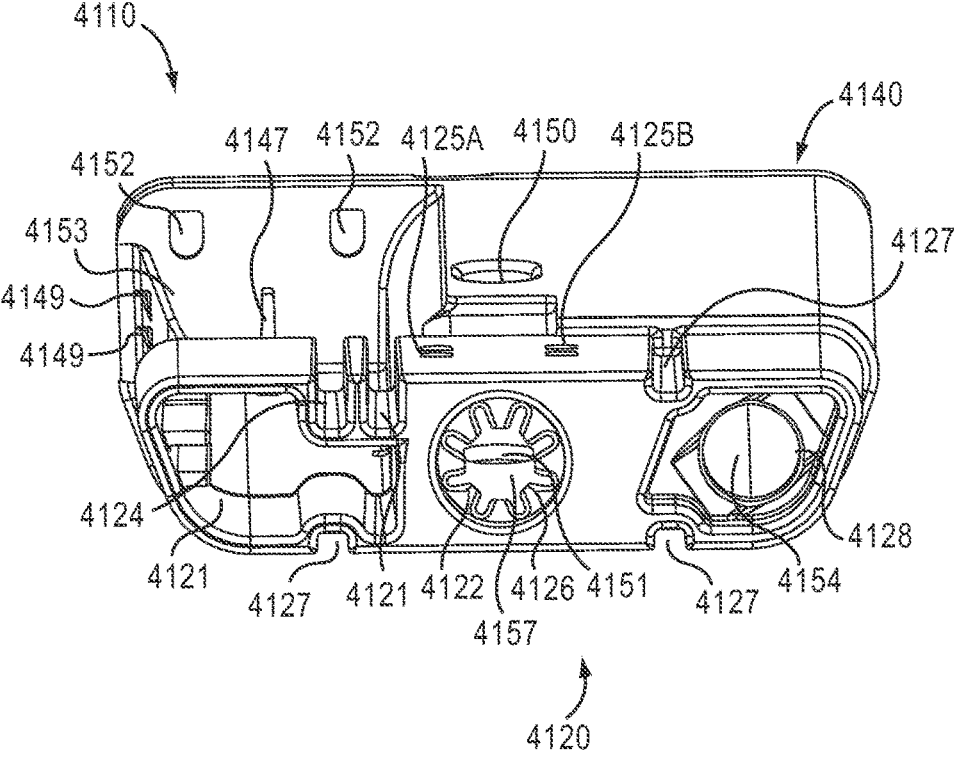


FIG.9

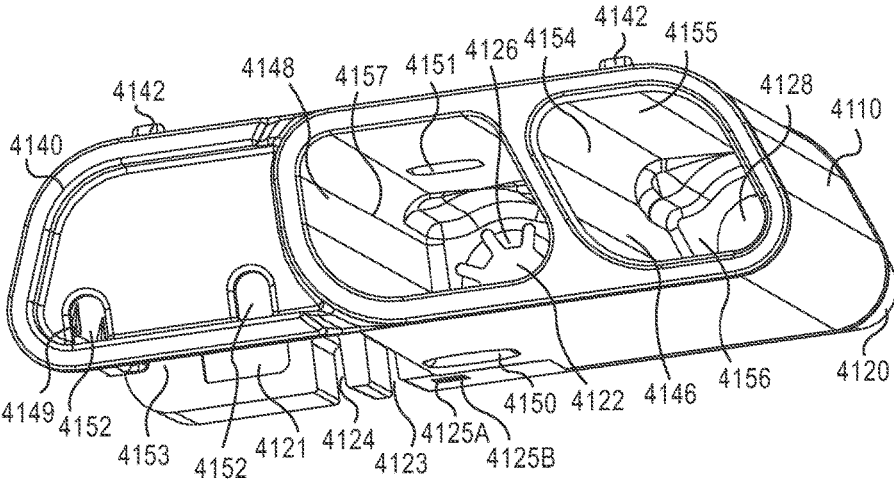


FIG.10

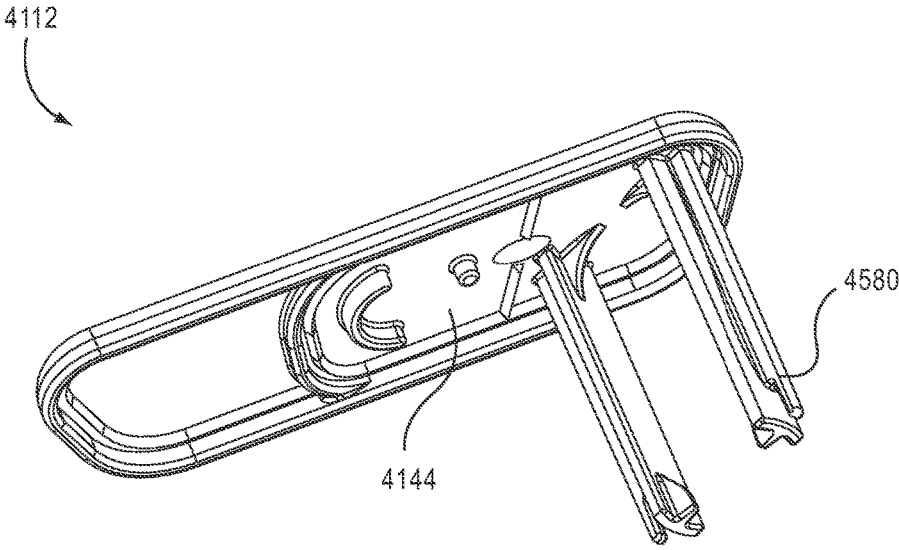


FIG.11

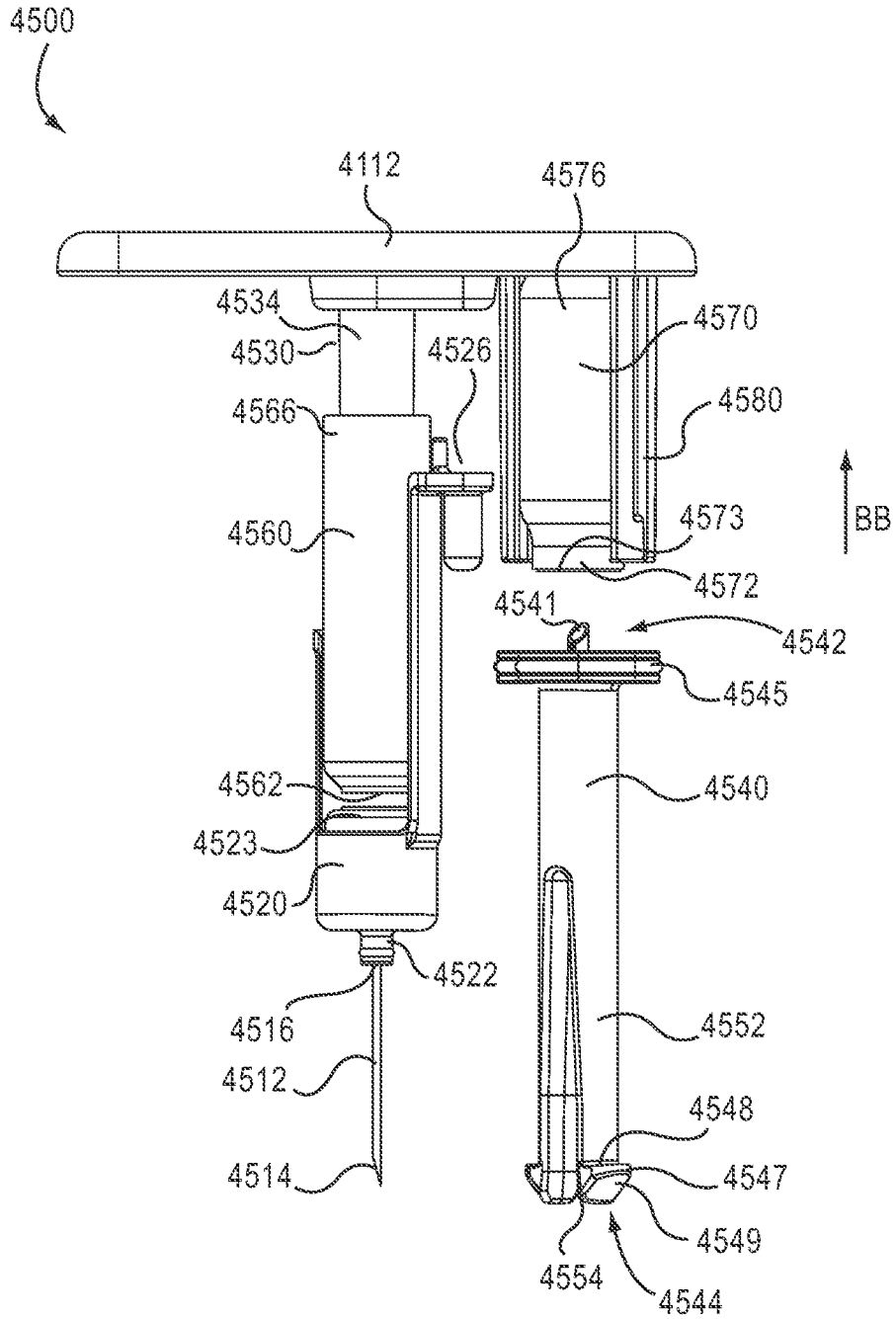


FIG.12

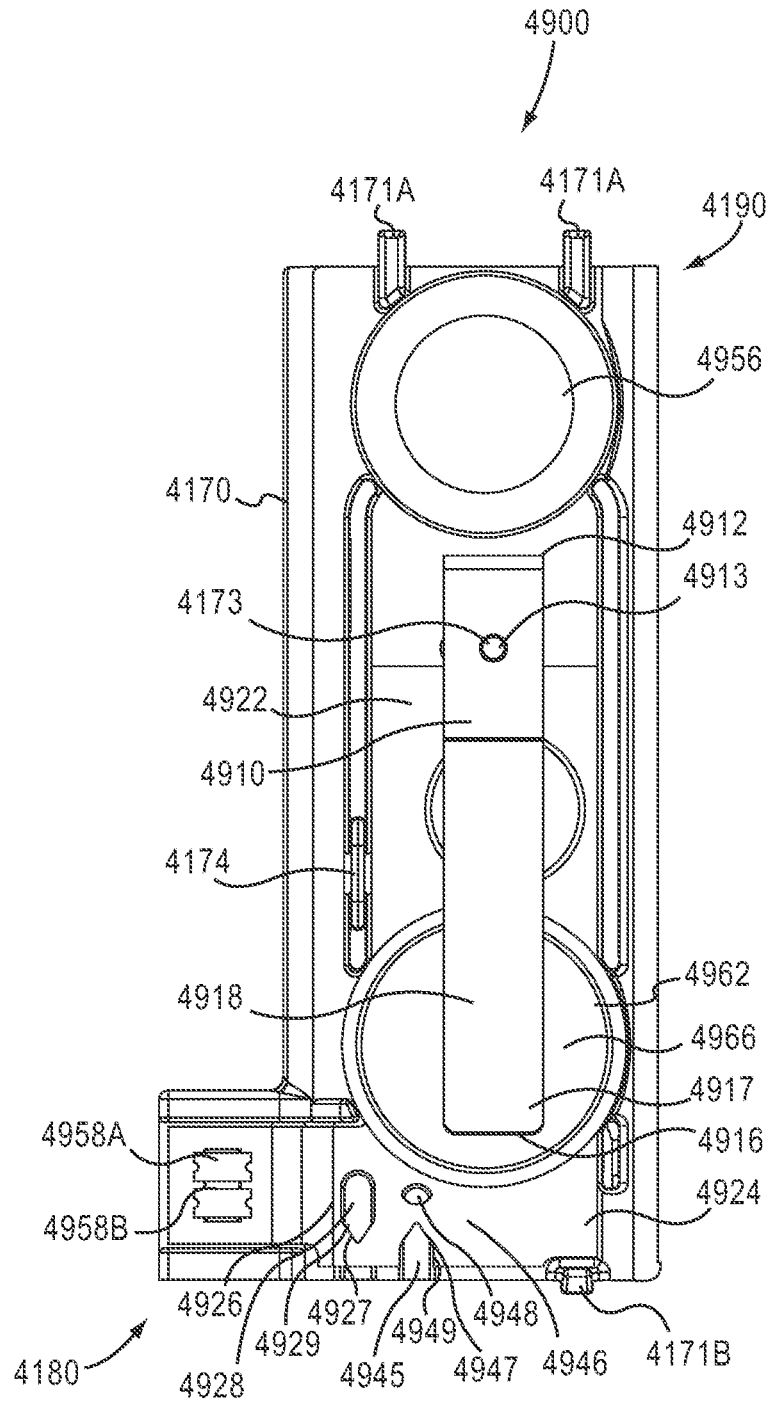


FIG.13

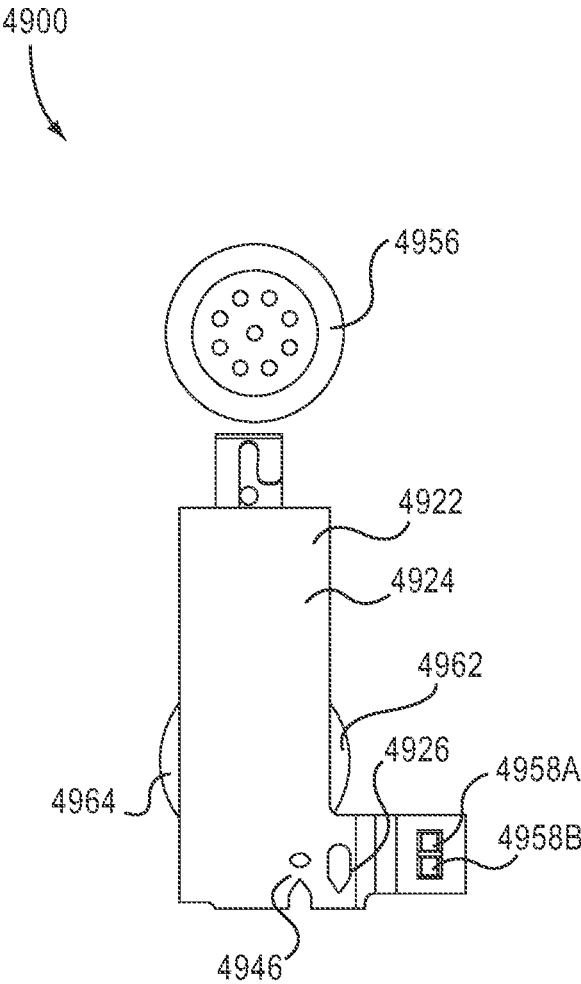


FIG.14

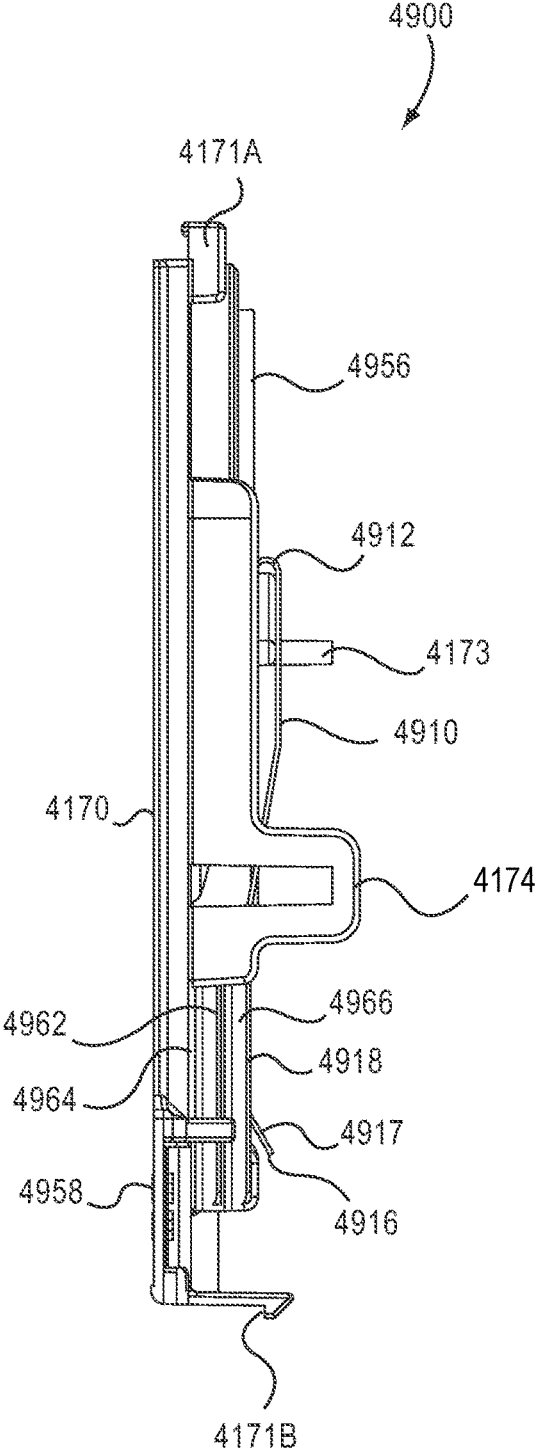


FIG. 15

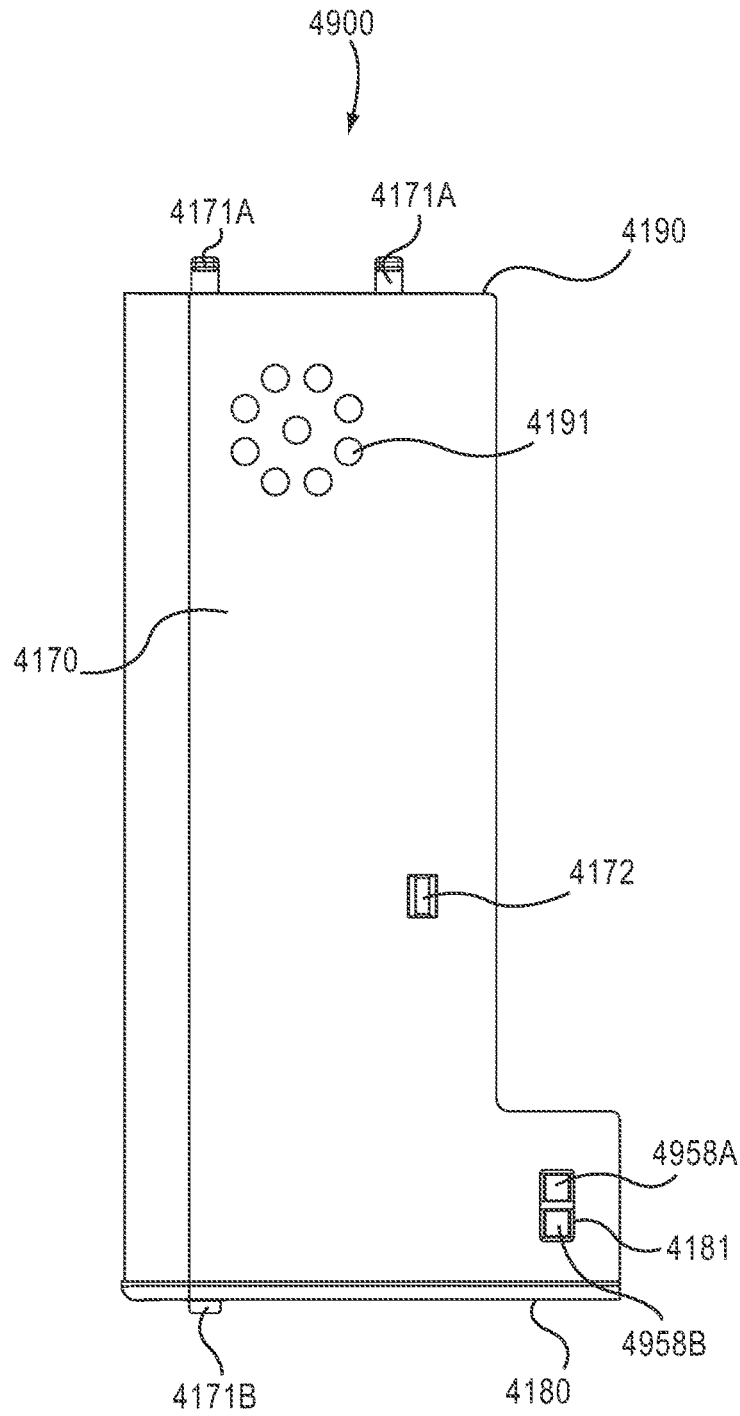


FIG. 16

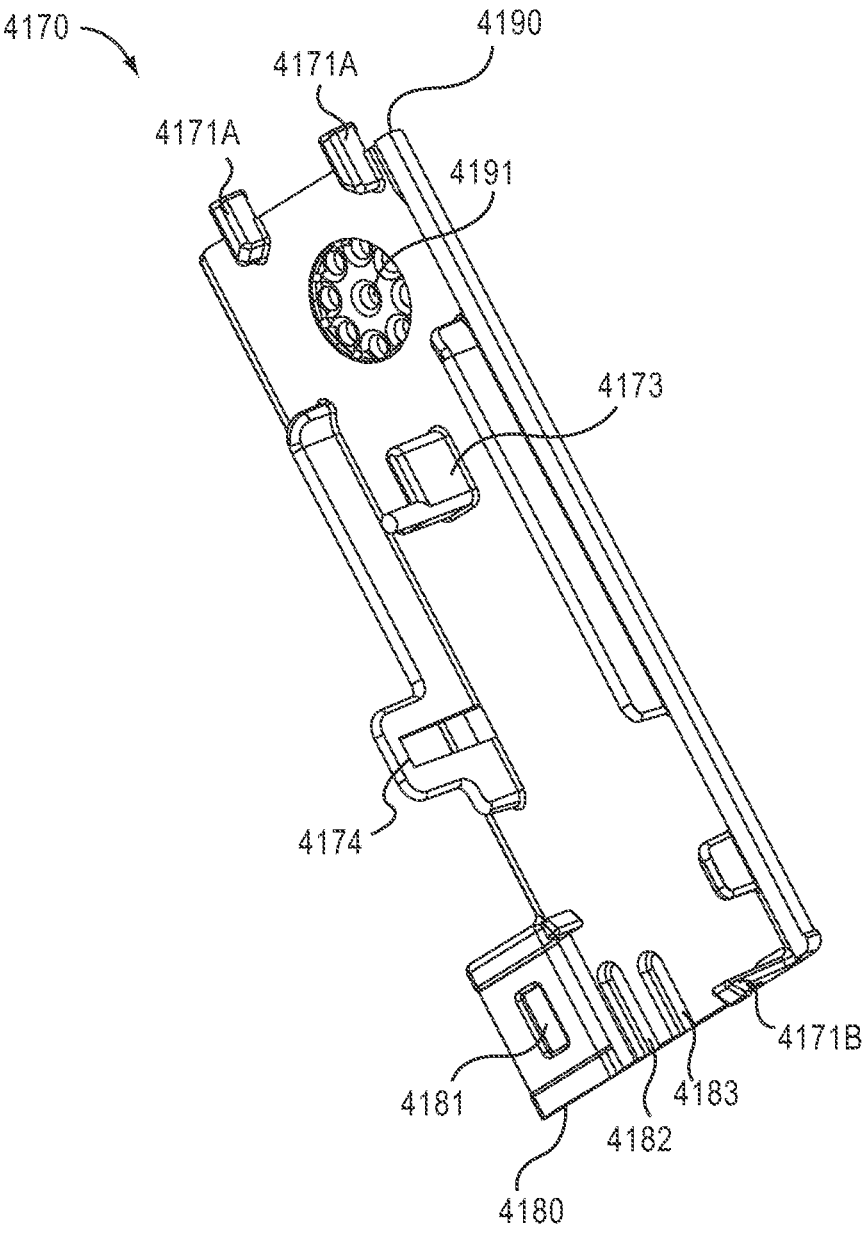


FIG.17

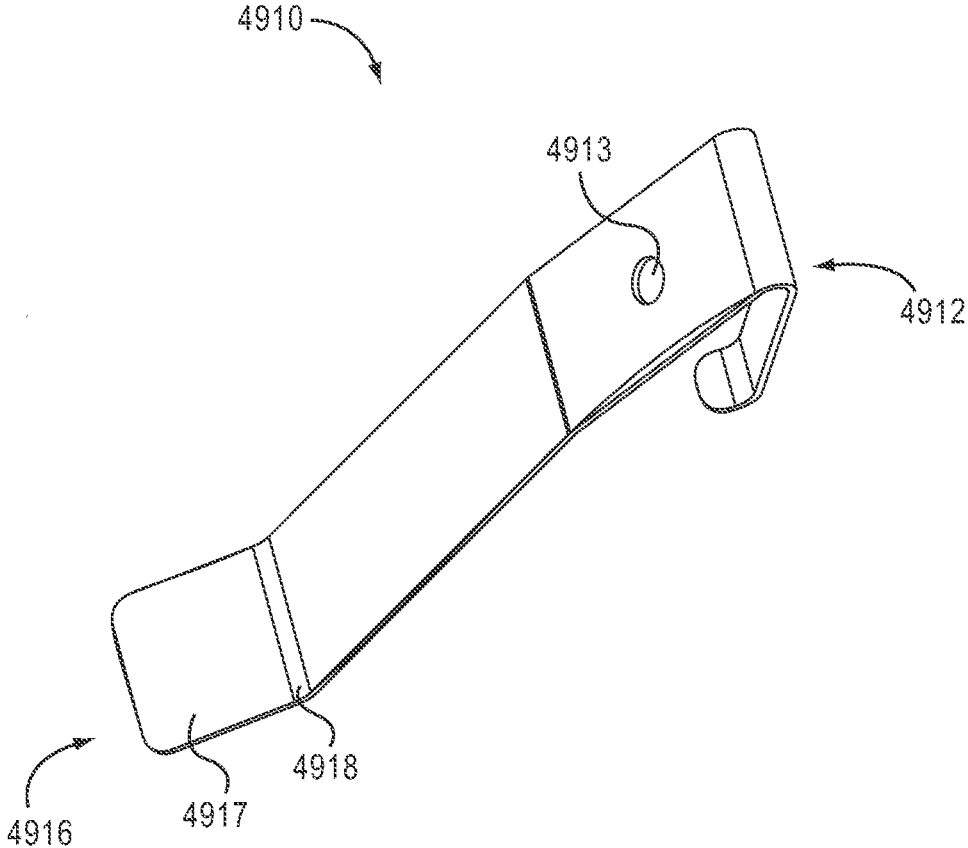


FIG.18

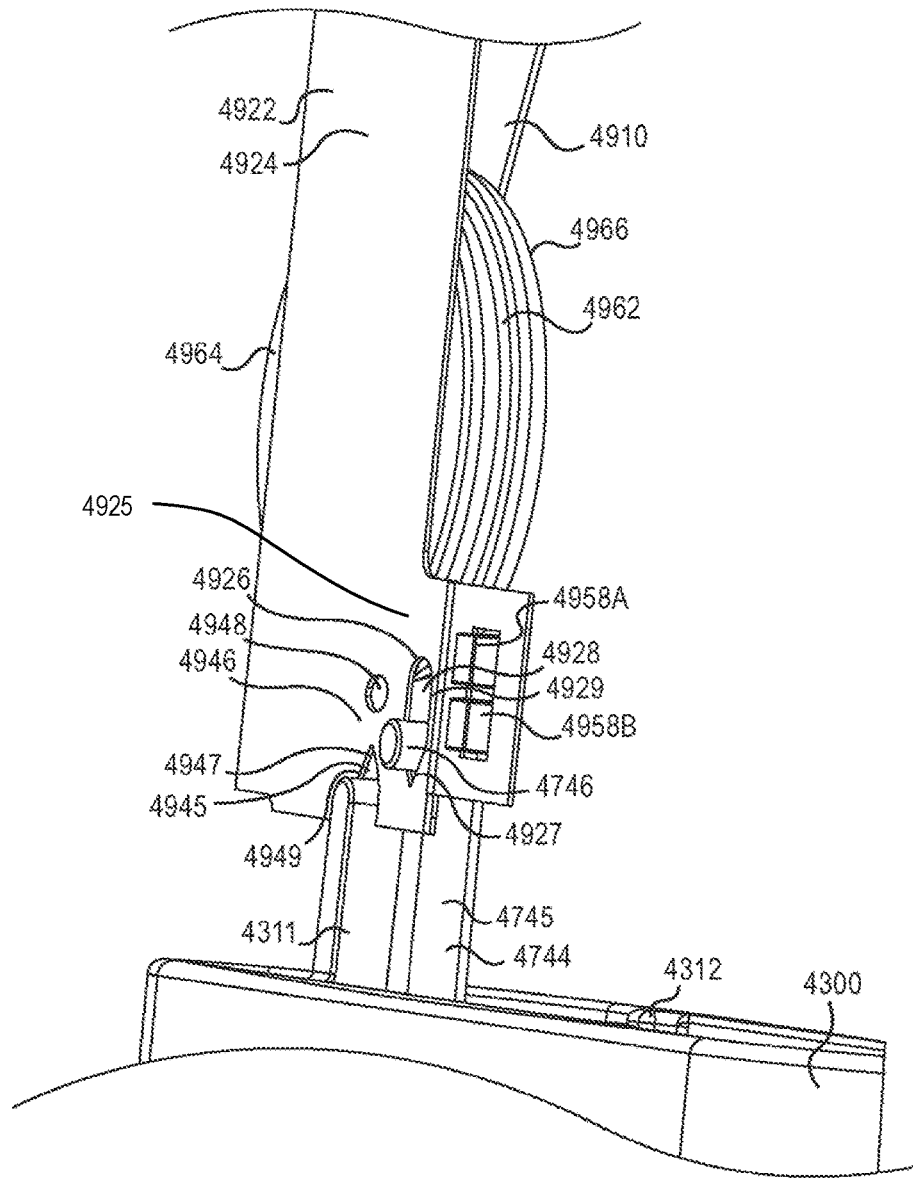


FIG.19

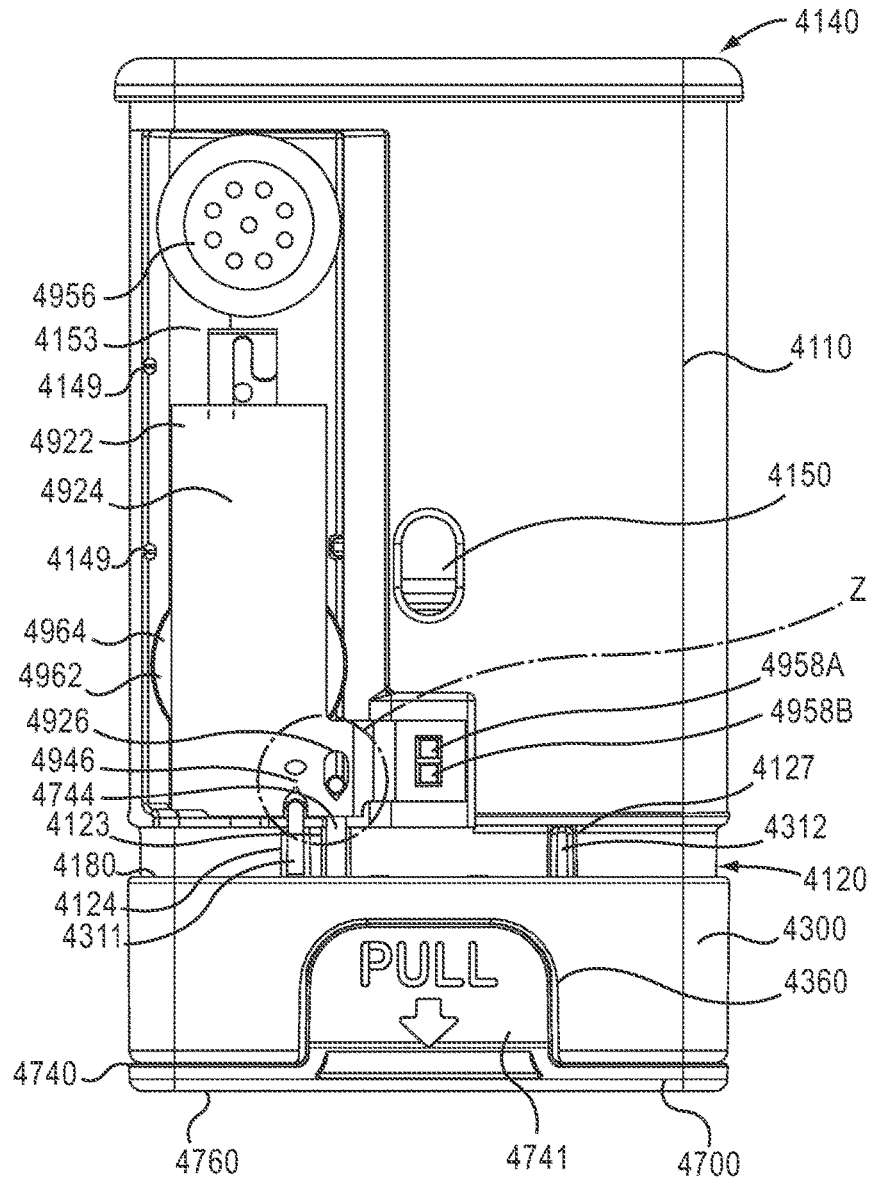


FIG. 20

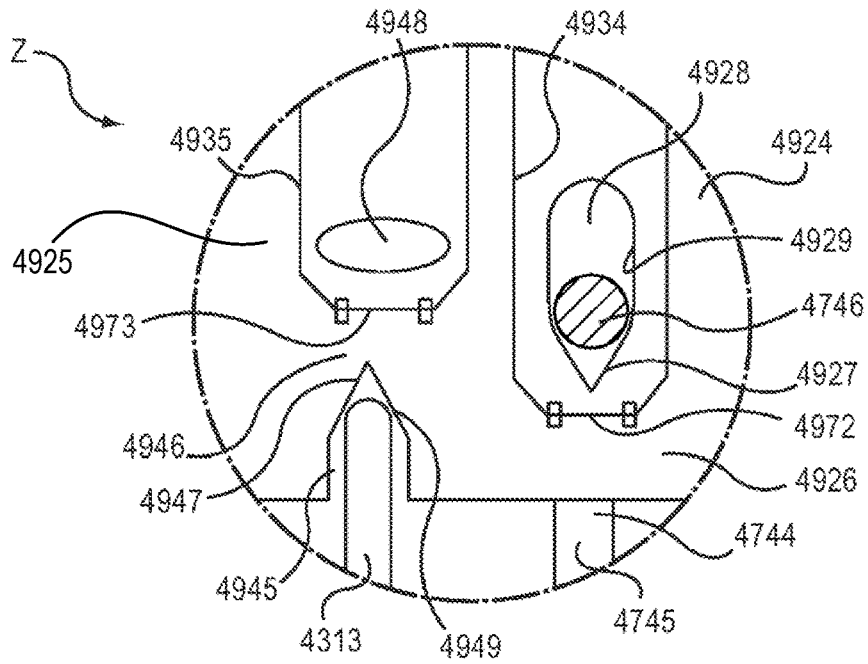


FIG. 21

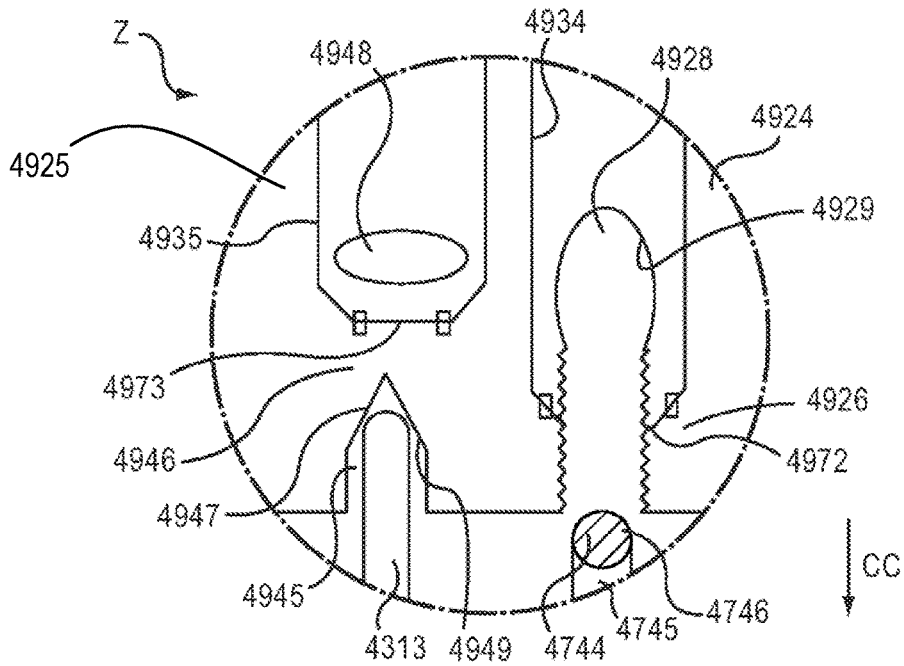


FIG. 22

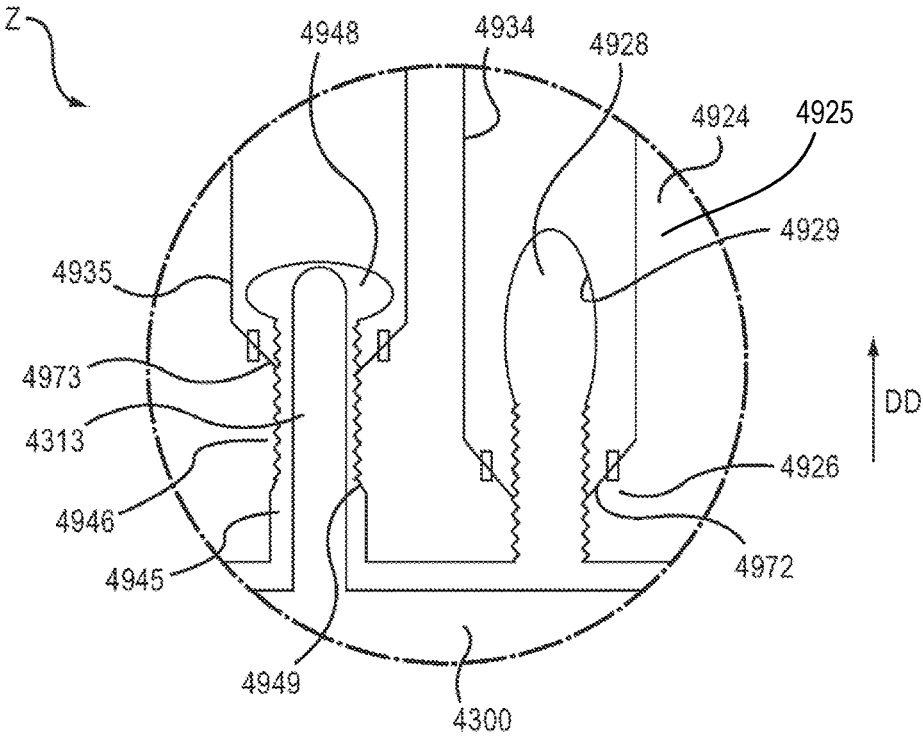


FIG. 23

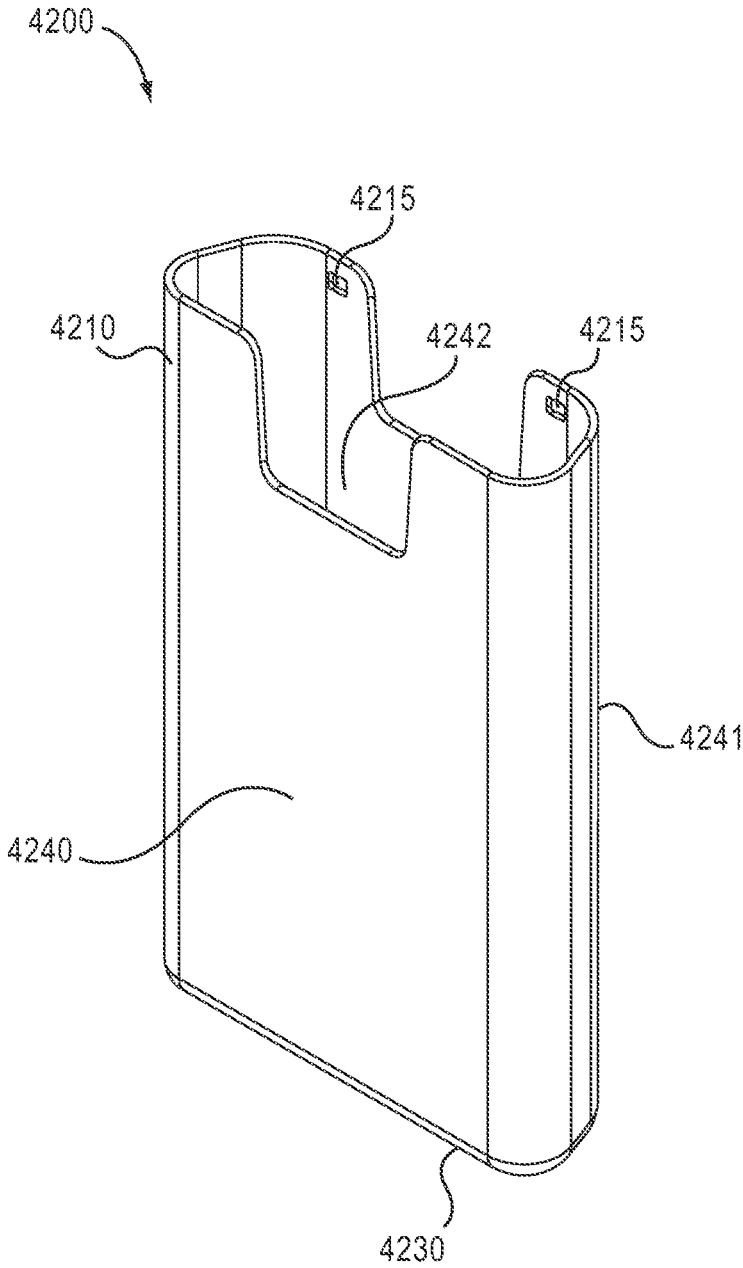


FIG.24

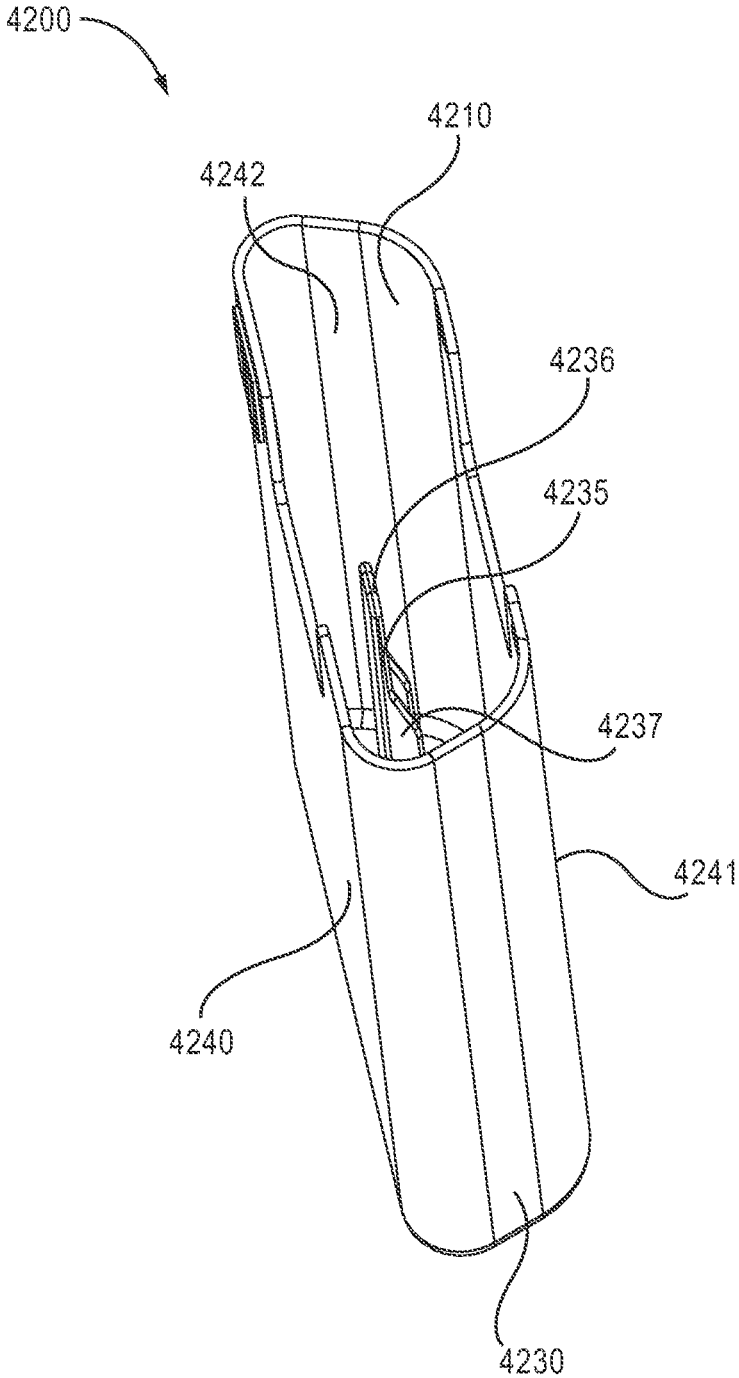


FIG.25

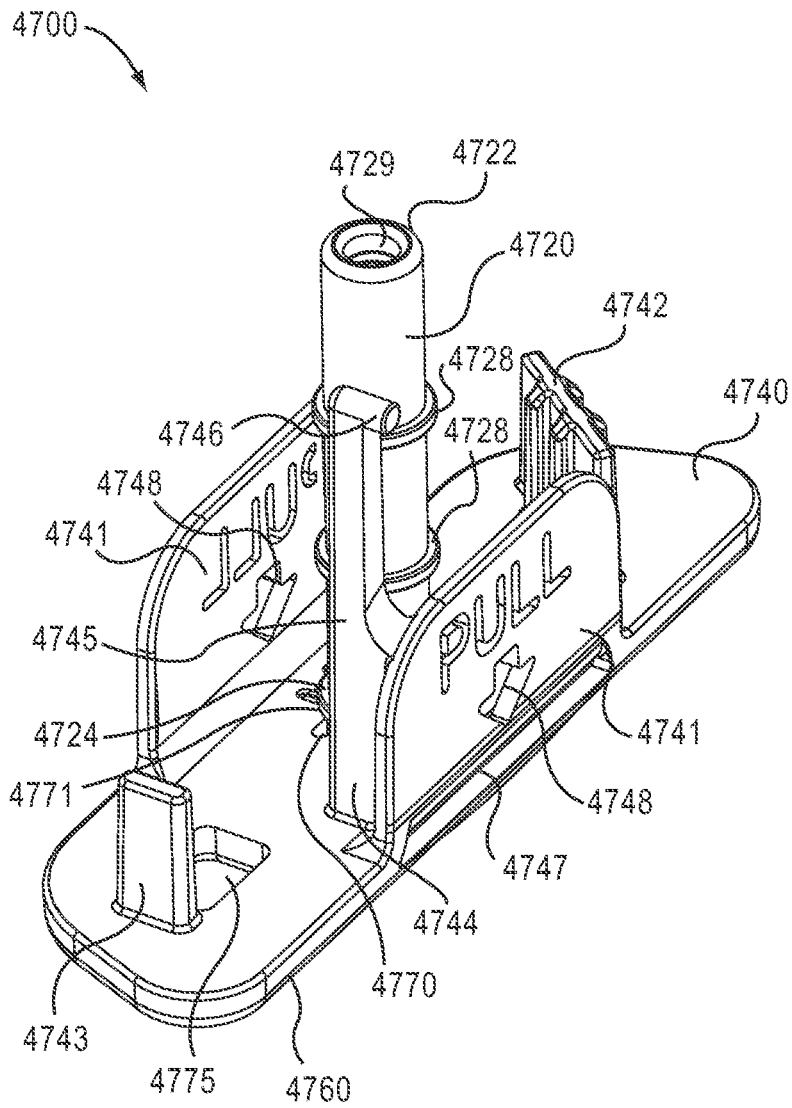


FIG. 26

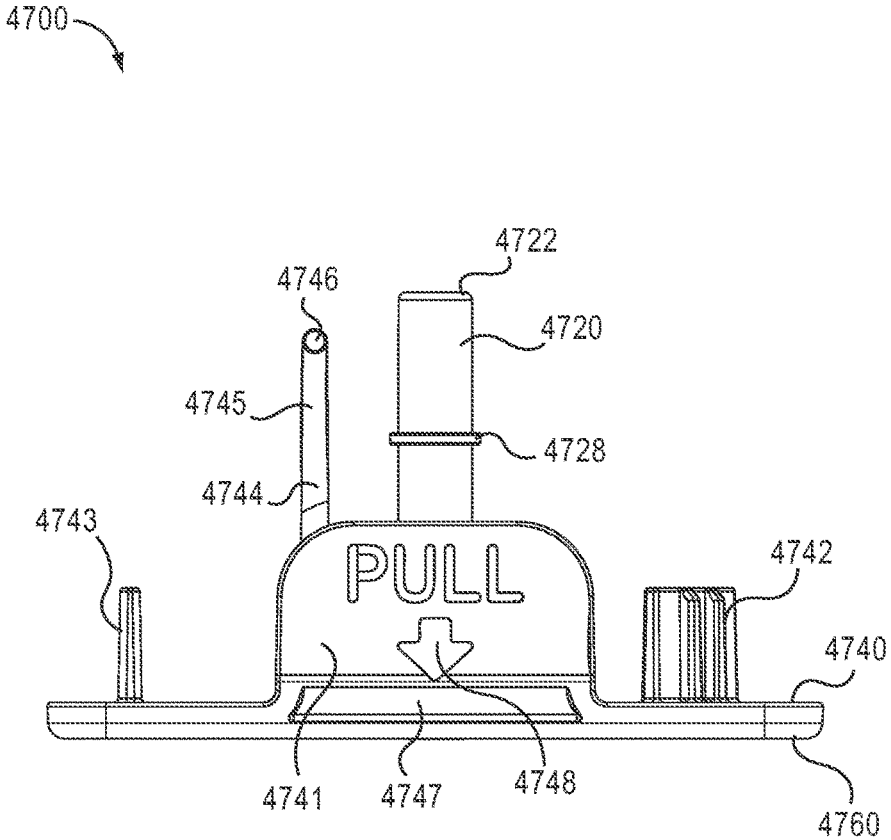


FIG.27

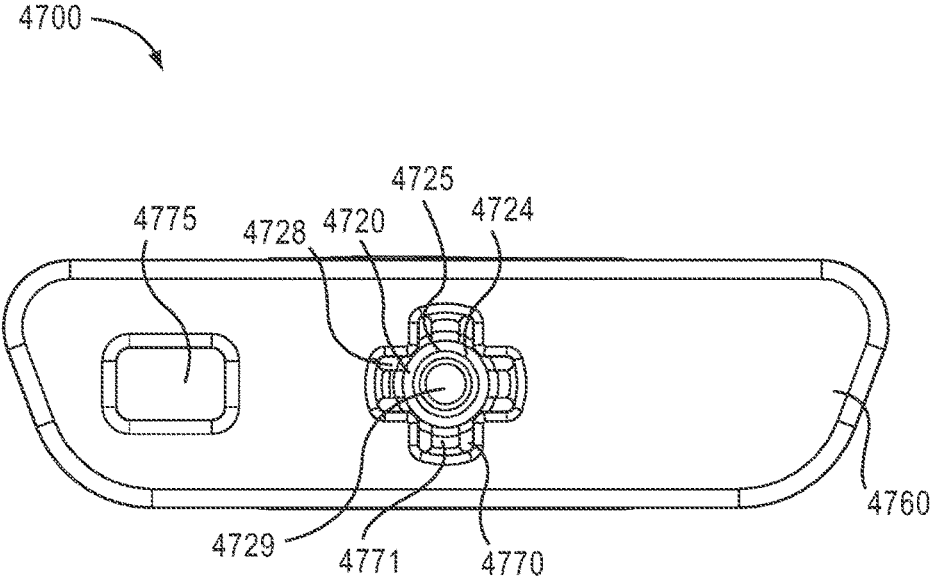


FIG.28

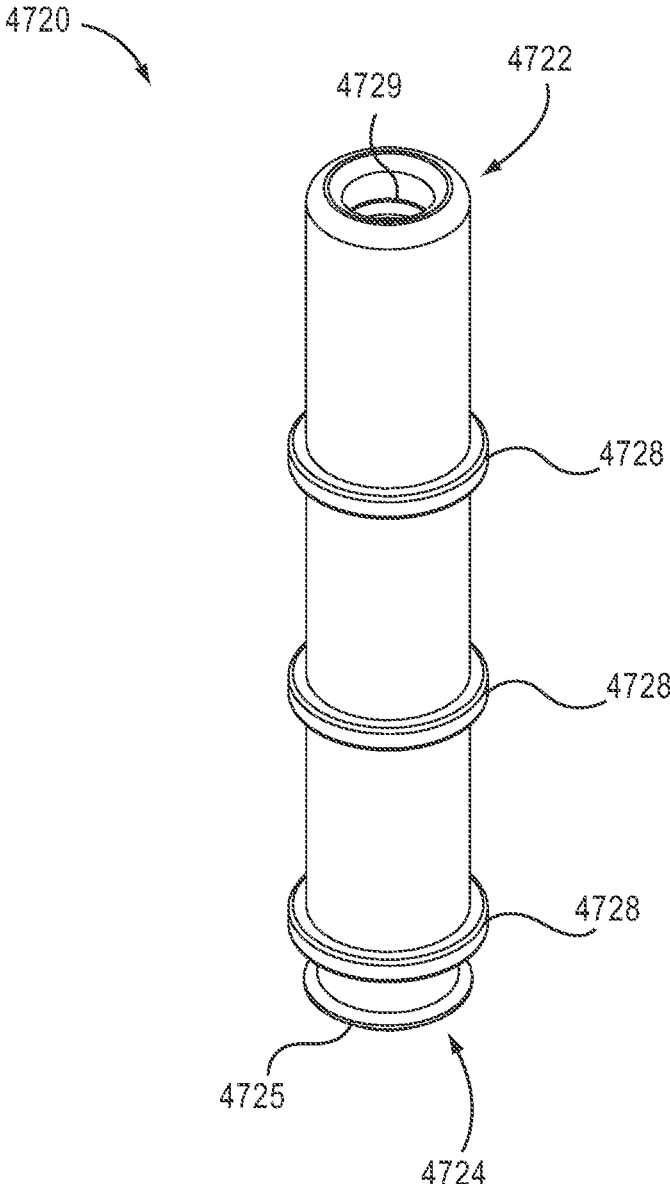


FIG.29

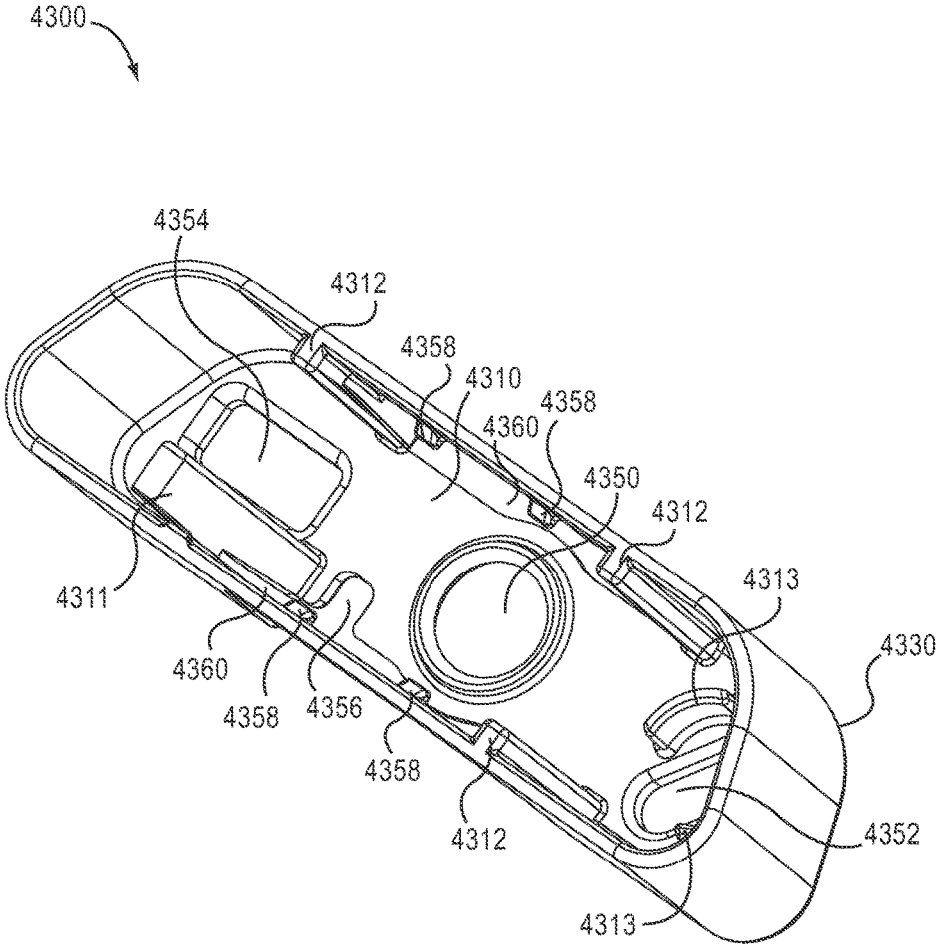


FIG.30

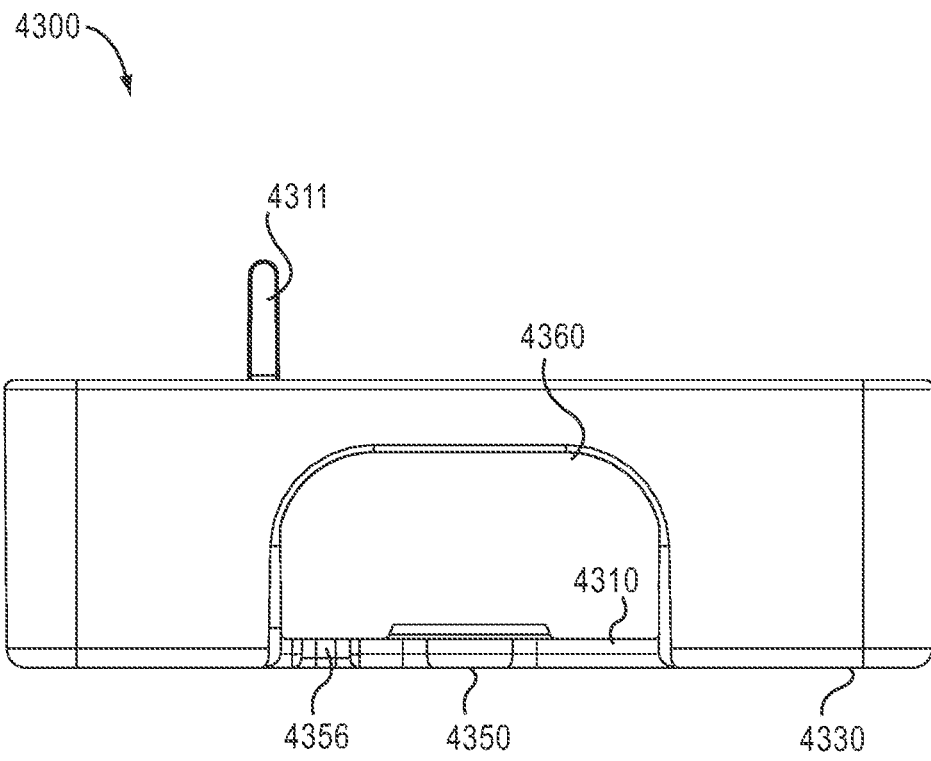


FIG.31

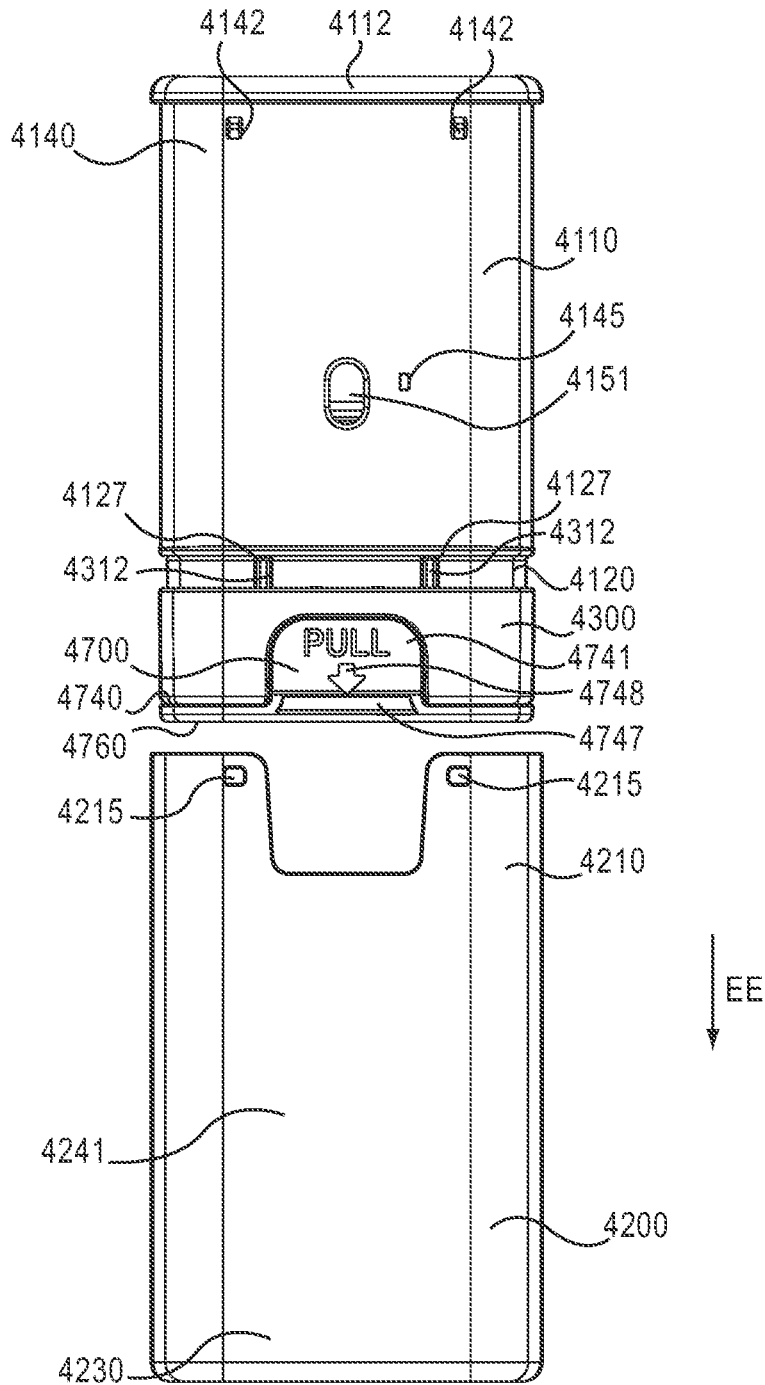


FIG. 32

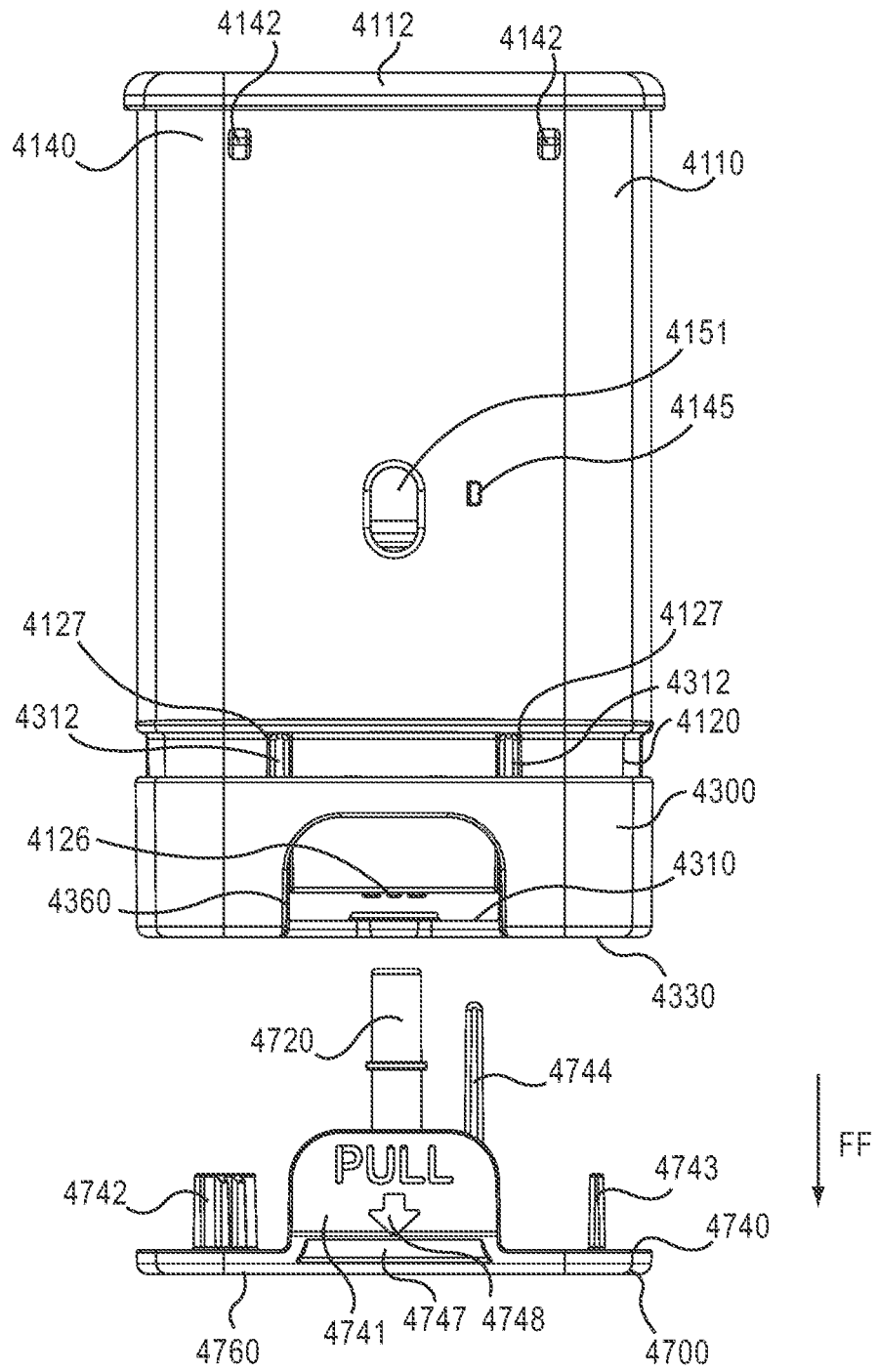


FIG.33

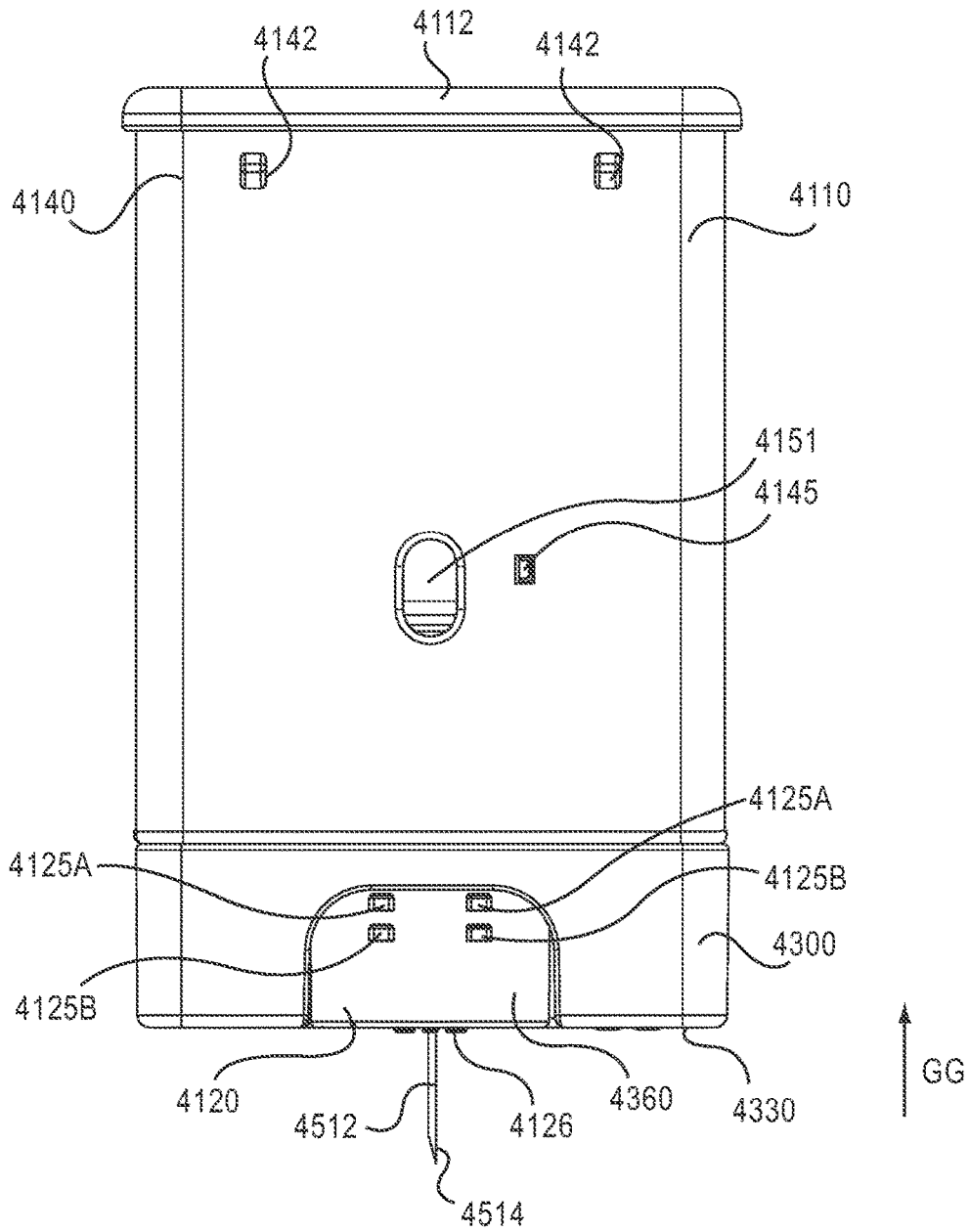


FIG. 34

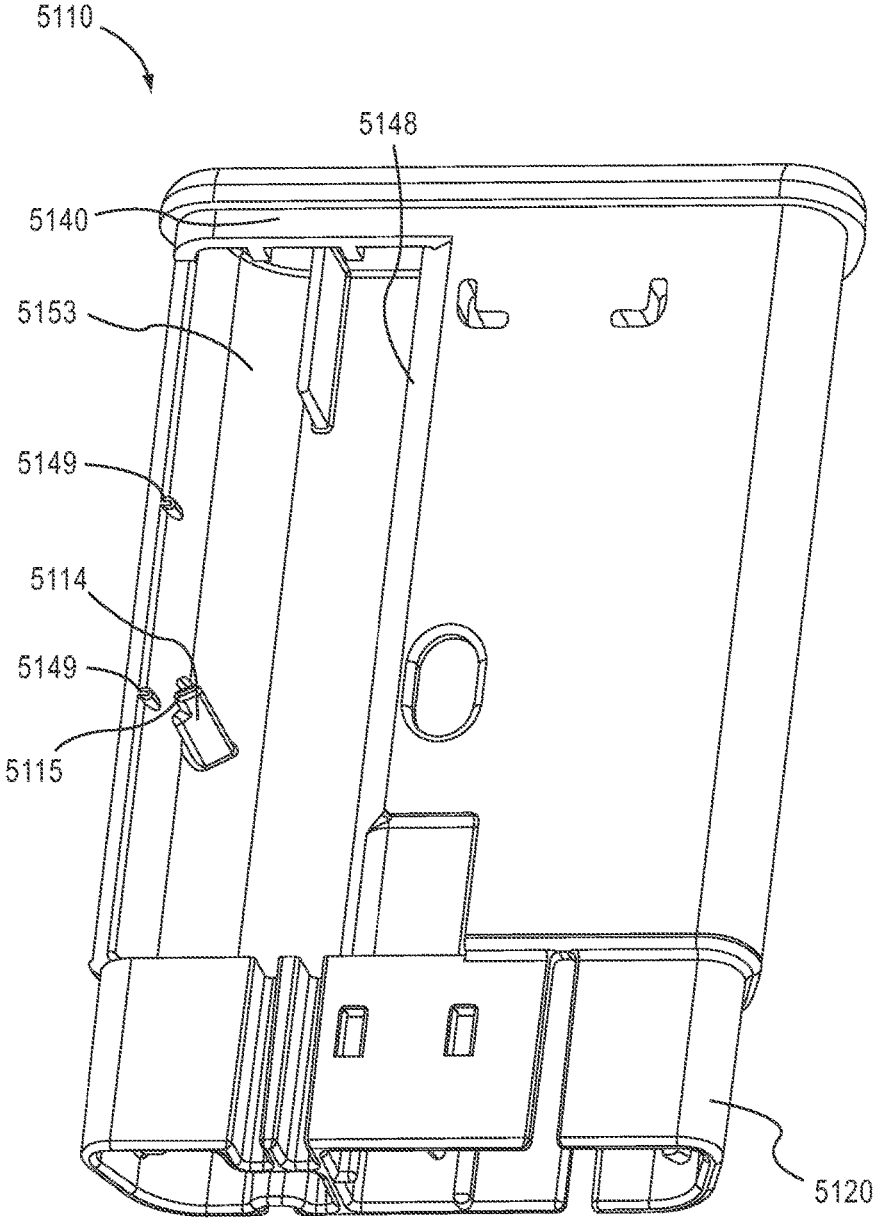


FIG.35

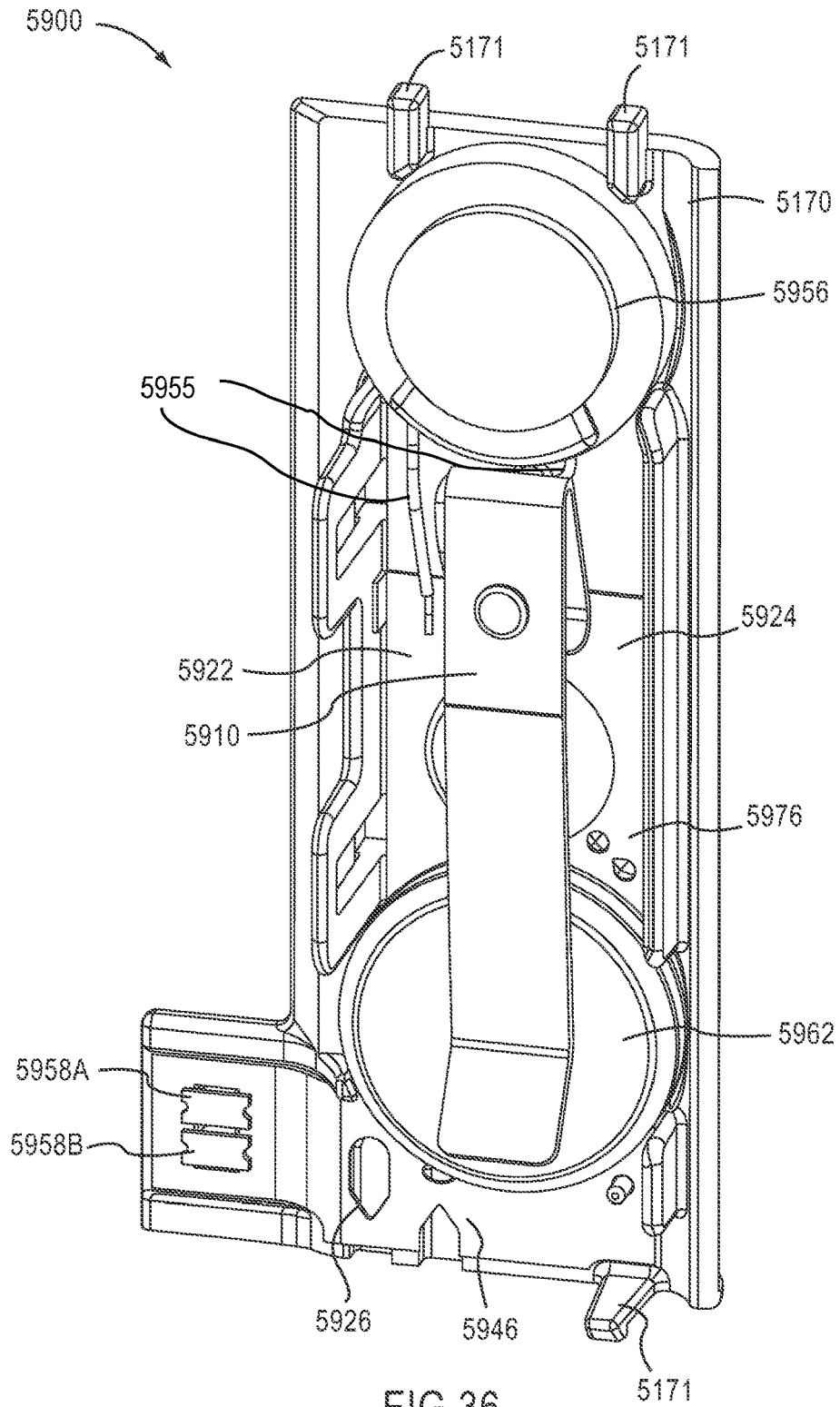


FIG.36

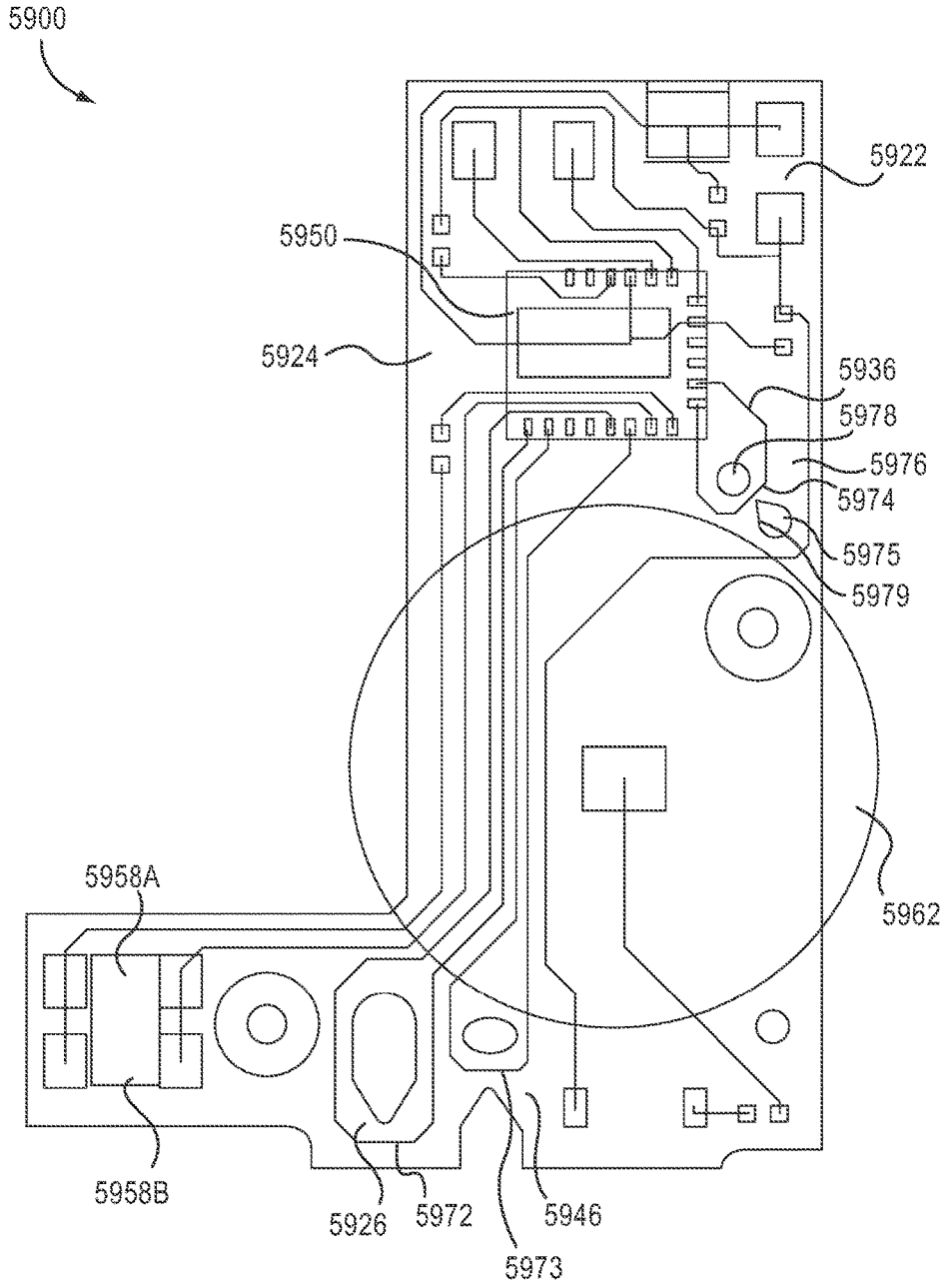


FIG.37

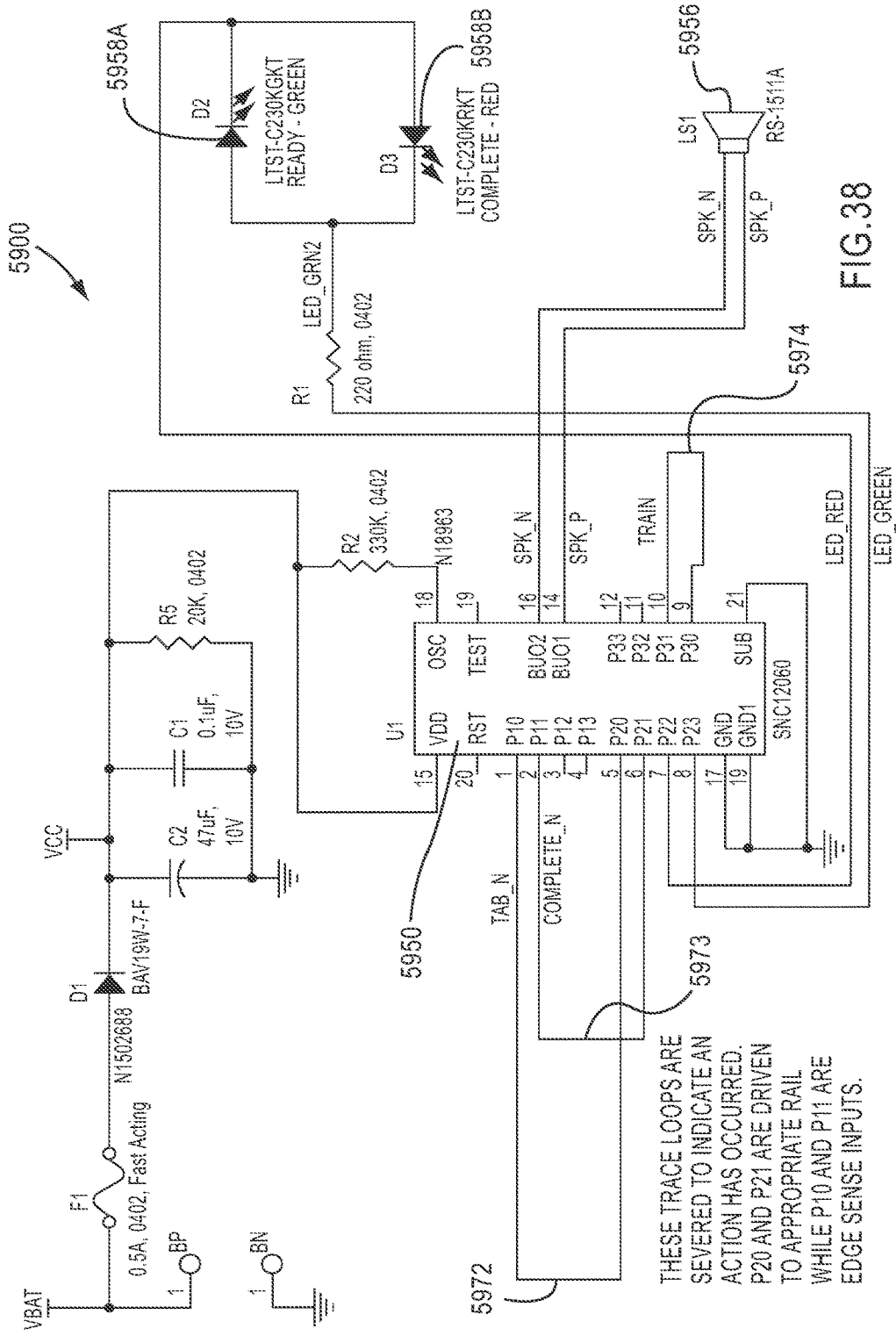


FIG.38

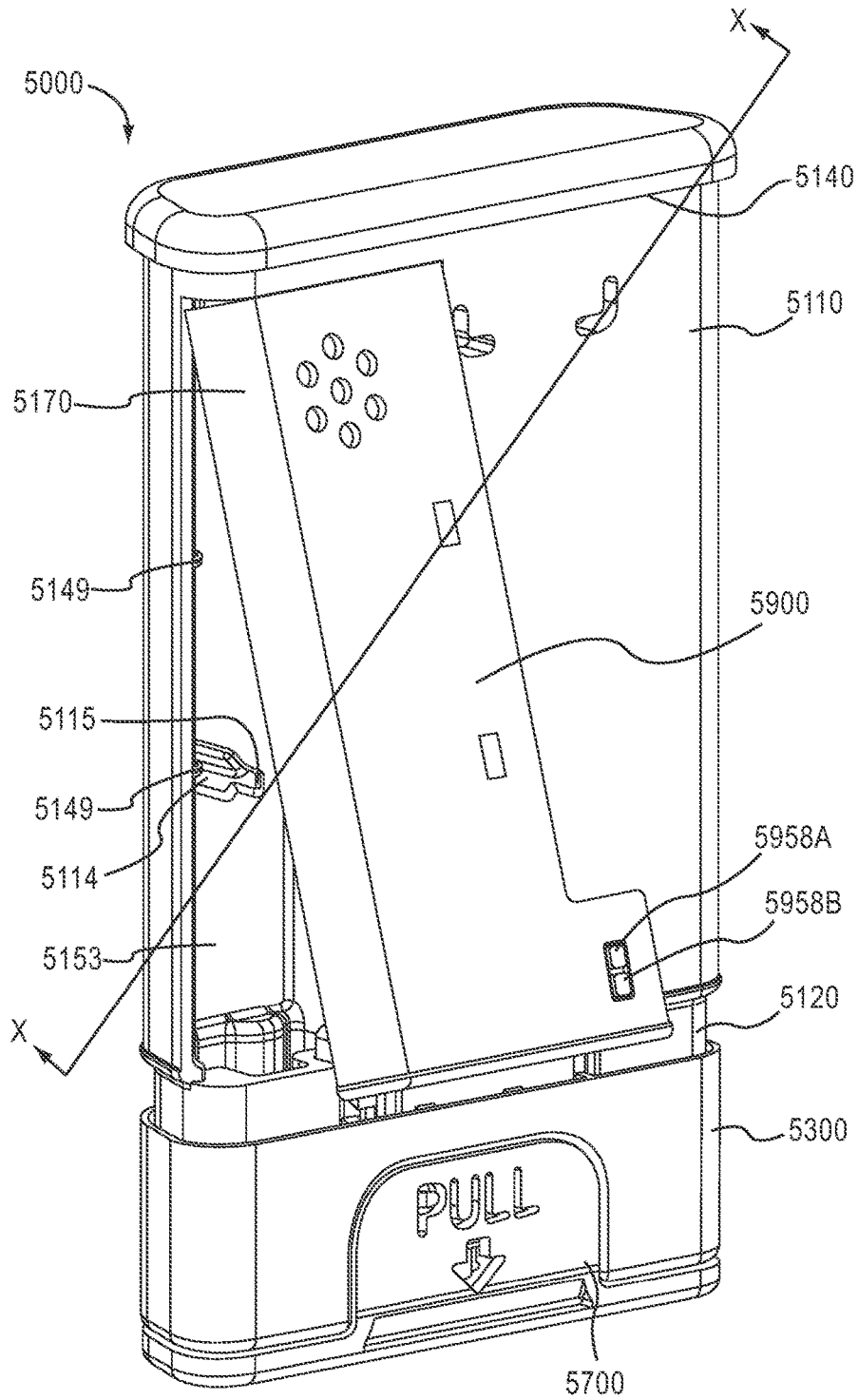


FIG.39

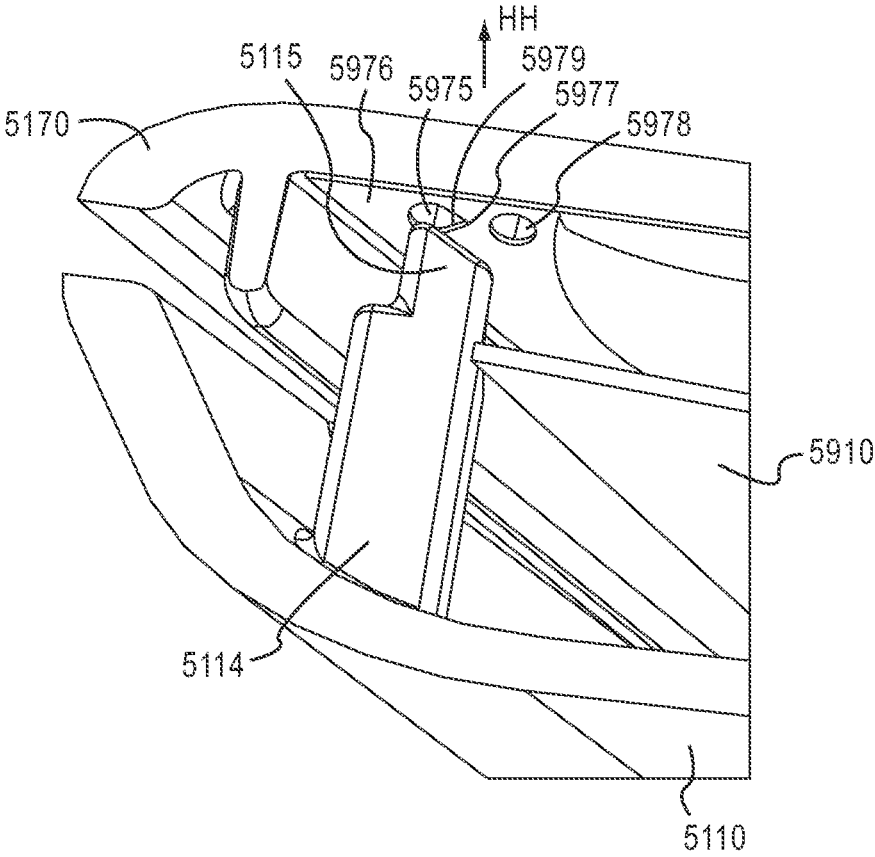


FIG. 40

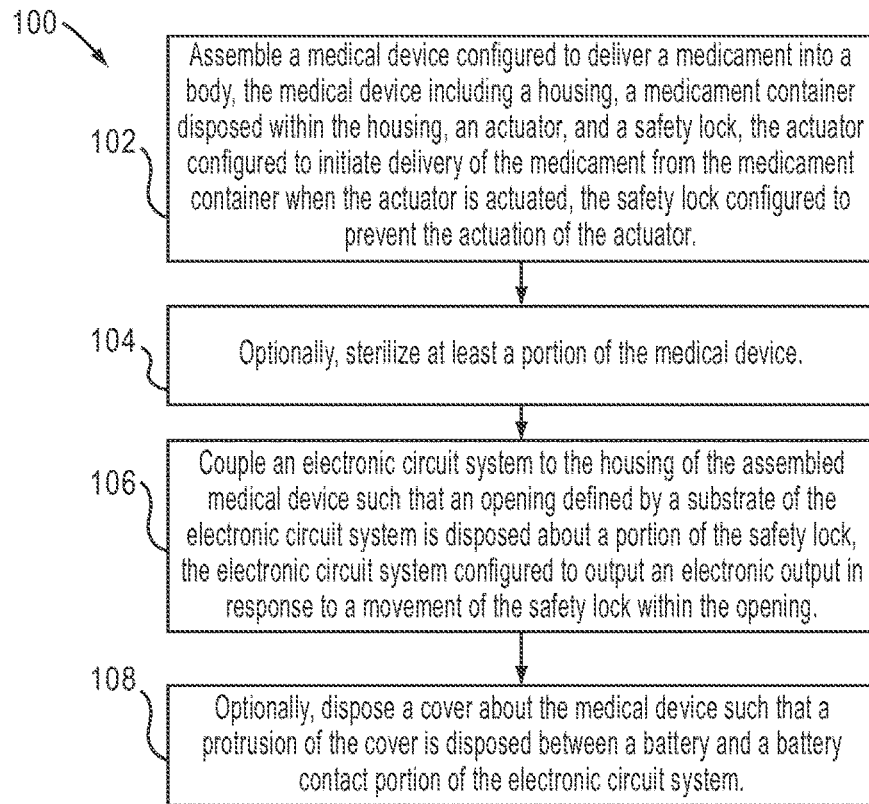


FIG.41

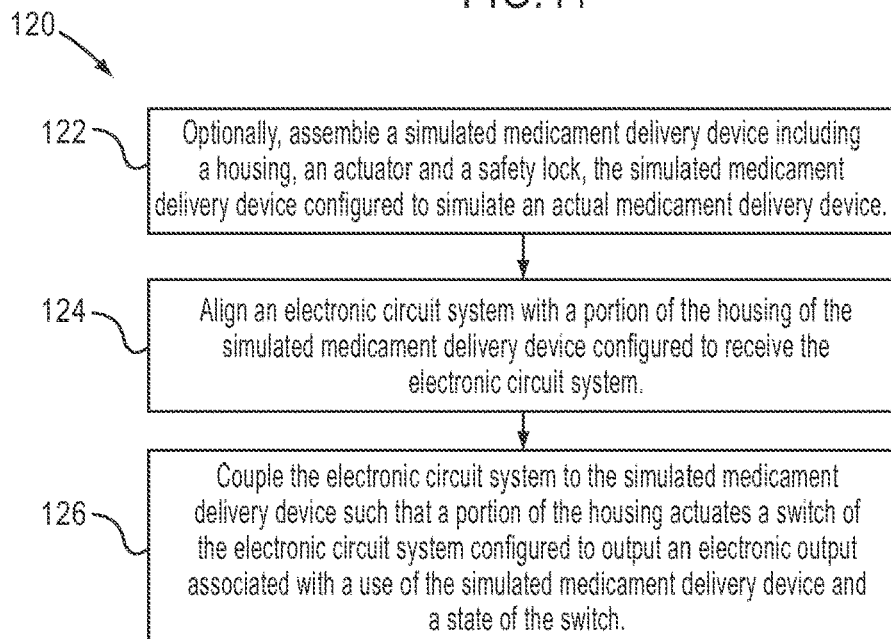


FIG.42

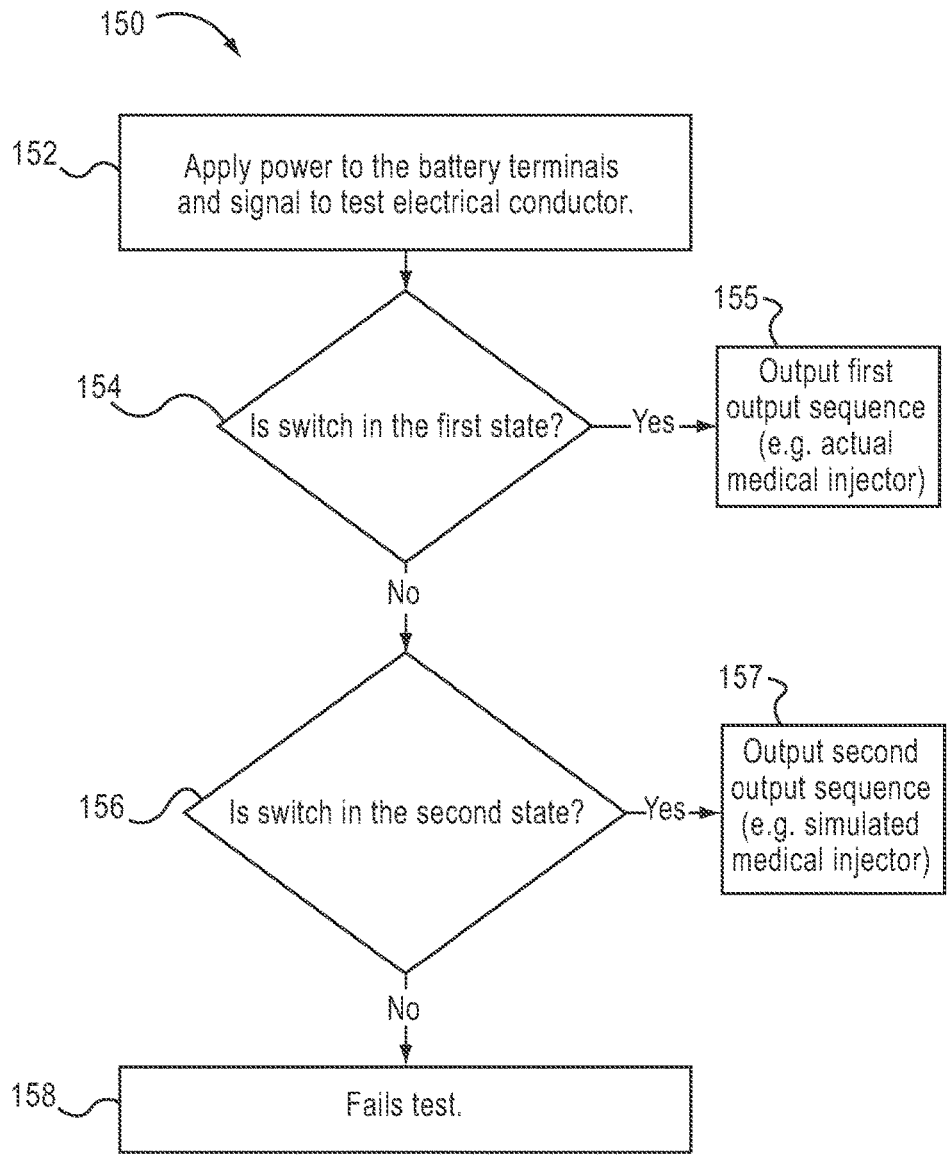


FIG.43

MEDICAMENT DELIVERY DEVICE HAVING AN ELECTRONIC CIRCUIT SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 14/993,234, entitled “Medicament Delivery Device Having an Electronic Circuit System,” filed Jan. 16, 2016, which is a continuation of U.S. patent application Ser. No. 13/550,893, now U.S. Pat. No. 9,238,108, entitled “Medicament Delivery Device Having an Electronic Circuit System,” filed Jul. 17, 2012, which is a continuation of U.S. patent application Ser. No. 12/119,016, now U.S. Pat. No. 8,231,573, entitled “Medicament Delivery Device Having an Electronic Circuit System,” filed May 12, 2008, which is a continuation-in-part of U.S. patent application Ser. No. 11/679,331, entitled “Medical Injector Simulation Device,” filed Feb. 27, 2007, which is a continuation-in-part of U.S. patent application Ser. No. 11/671,025, now U.S. Pat. No. 8,172,082, entitled “Devices, Systems and Methods for Medicament Delivery,” filed Feb. 5, 2007, which is a continuation-in-part of U.S. patent application Ser. No. 11/621,236, now U.S. Pat. No. 7,731,686, entitled “Devices, Systems and Methods for Medicament Delivery,” filed Jan. 9, 2007, which is a continuation-in-part of U.S. patent application Ser. No. 10/572,148, now U.S. Pat. No. 7,749,194, entitled “Devices, Systems and Methods for Medicament Delivery,” filed Mar. 16, 2006, which is a national stage filing under 35 U.S.C. § 371 of International Patent Application No. PCT/US2006/003415, entitled “Devices, Systems and Methods for Medicament Delivery,” filed Feb. 1, 2006, which claims priority to U.S. Provisional Application Ser. No. 60/648,822, entitled “Devices, Systems and Methods for Medicament Delivery,” filed Feb. 1, 2005 and U.S. Provisional Application Ser. No. 60/731,886, entitled “Auto-Injector with Feedback,” filed Oct. 31, 2005, each of which is incorporated herein by reference in its entirety. U.S. patent application Ser. Nos. 11/621,236, 11/679,331 and 11/671,025 also claim priority to U.S. Provisional Application Ser. No. 60/787,046, entitled “Devices, Systems and Methods for Medicament Delivery,” filed Mar. 29, 2006, which is incorporated herein by reference in its entirety.

BACKGROUND

[0002] The invention relates generally to a medical device, and more particularly to a medicament delivery device, and/or a simulated medicament delivery device having an electronic circuit system.

[0003] Exposure to certain substances, such as, for example, peanuts, shellfish, bee venom, certain drugs, toxins, and the like, can cause allergic reactions in some individuals. Such allergic reactions can, at times, lead to anaphylactic shock, which can cause a sharp drop in blood pressure, hives, and/or severe airway constriction. Accordingly, responding rapidly to mitigate the effects from such exposures can prevent injury and/or death. For example, in certain situations, an injection of epinephrine (i.e., adrenaline) can provide substantial and/or complete relief from the allergic reaction. In other situations, for example, an injection of an antidote to a toxin can greatly reduce and/or eliminate the harm potentially caused by the exposure. Because emergency medical facilities may not be available

when an individual is suffering from an allergic reaction, some individuals carry a medicament delivery device, such as, for example, an auto-injector, to rapidly self-administer a medicament in response to an allergic reaction.

[0004] To actuate such a medicament delivery device, however, the user may be required to execute a series of operations. For example, to actuate some known auto-injectors, the user must remove a protective cap, remove a locking device, place the auto-injector in a proper position against the body and then press a button to actuate the auto-injector. Failure to complete these operations properly can result in an incomplete injection and/or injection into an undesired location of the body. In certain instances, for example, users who have become confused in the operation of some known auto-injectors have inadvertently injected the medicament into their thumb by improperly positioning the auto-injector.

[0005] The likelihood of improper use of known medicament delivery devices can be compounded by the nature of the user and/or the circumstances under which such devices are used. For example, many users are not trained medical professionals and may have never been trained in the operation of such devices. Moreover, in certain situations, the user may not be the patient, and may therefore have no experience with the medicament delivery device. Similarly, because some known medicament delivery devices are configured to be used relatively infrequently in response to an allergic reaction or the like, even those users familiar with the device and/or who have been trained may not be well practiced at operating the device. Finally, such devices are often used during an emergency situation, during which even experienced and/or trained users may be subject to confusion, panic, and/or the physiological effects of the condition requiring treatment.

[0006] Some known medicament delivery devices include printed instructions to inform the user of the steps required to properly deliver the medicament. Such printed instructions, however, can be inadequate for the class of users and/or the situations described above. Moreover, because some known medicament delivery devices, such as, for example, auto-injectors, pen injectors, inhalers or the like, can be compact, such printed instructions may be too small to read and comprehend during an emergency situation.

[0007] Some known medicament delivery devices are associated with simulated medicament delivery devices (e.g., “trainers”) to provide a method for users to practice using the medicament delivery device without being exposed to the medicament and/or needles typically contained therein. Such simulated medicament delivery devices, however, can also include inadequate use instructions as described above.

[0008] Monitoring the patient’s compliance with known medicament delivery devices can also be problematic. For example, some known medicament delivery systems include a medicament delivery device and an electronic system to assist the user in setting the proper dosage and/or maintaining a compliance log. Such known medicament delivery systems and the accompanying electronic systems can be large and therefore not conveniently carried by the user. Such known medicament delivery systems and the accompanying electronic systems can also be complicated to use and/or expensive to manufacture. Moreover, some known medicament delivery systems include sensors disposed

within the medicament delivery path, which can interfere with the delivery, result in contamination, or the like.

[0009] Thus, a need exists for medicament delivery systems and/or devices that provide instructions that can be easily understood by a user in any type of situation. Additionally, a need exists for simulated medicament delivery systems and/or devices that can provide instructions and that can be reused multiple times. Moreover, a need exists for medicament delivery systems and/or devices that can provide compliance information associated with the use of the device and/or that can communicate electronically with other communications devices.

SUMMARY

[0010] Medicament delivery devices are described herein. In some embodiments, an apparatus includes a medical injector and an electronic circuit system. The medical injector includes a housing, a medicament container, and a medicament delivery member. The housing defines a first region and a second region. The first region includes the medicament container and is physically isolated from the second region. The electronic circuit system is configured to be disposed within the second region defined by the housing. The electronic circuit system is configured to output an electronic output associated with a use of the medical injector.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is a schematic illustration of a medicament delivery device according to an embodiment of the invention.

[0012] FIG. 2 is a schematic illustration of a medicament delivery device according to an embodiment of the invention.

[0013] FIGS. 3 and 4 are perspective views of a medical injector according to an embodiment of the invention, in a first configuration.

[0014] FIG. 5 is a front view of the medical injector illustrated in FIG. 3 with the cover removed.

[0015] FIG. 6 is a back view of the medical injector illustrated in FIG. 3 with the cover removed.

[0016] FIG. 7 is a front view of a portion of the medical injector illustrated in FIG. 3.

[0017] FIG. 8 is a perspective view of a portion of the medical injector illustrated in FIG. 3.

[0018] FIG. 9 is a bottom perspective view of a housing of the medical injector illustrated in FIG. 3.

[0019] FIG. 10 is a top perspective view of a housing of the medical injector illustrated in FIG. 3.

[0020] FIG. 11 is a perspective view of a proximal cap of the medical injector illustrated in FIG. 3.

[0021] FIG. 12 is a front view of a medicament delivery mechanism of the medical injector illustrated in FIG. 3.

[0022] FIG. 13 is a back view of an electronic circuit system of the medical injector illustrated in FIG. 3.

[0023] FIG. 14 is a front view of a portion of the electronic circuit system of the medical injector illustrated in FIG. 13.

[0024] FIG. 15 is a side view of the electronic circuit system of the medical injector illustrated in FIG. 13.

[0025] FIG. 16 is a front view of an electronic circuit system housing of the medical injector illustrated in FIG. 13.

[0026] FIG. 17 is a perspective view of the electronic circuit system housing of the medical injector illustrated in FIG. 16.

[0027] FIG. 18 is a perspective view of a battery clip of the medical injector illustrated in FIG. 13.

[0028] FIG. 19 is a perspective view of a portion of an electronic circuit system of the medical injector illustrated in FIG. 3, in a first configuration.

[0029] FIG. 20 is a front view of the medical injector illustrated in FIG. 3 in a first configuration showing the electronic circuit system.

[0030] FIGS. 21, 22, and 23 are front views of a portion of the electronic circuit system of the medical injector labeled as Region Z in FIG. 20 in a first configuration, a second configuration, and a third configuration, respectively.

[0031] FIGS. 24 and 25 are perspective views of a cover of the medical injector illustrated in FIG. 3.

[0032] FIG. 26 is a perspective view of a safety lock of the medical injector illustrated in FIG. 3.

[0033] FIG. 27 is a front view of the safety lock of the medical injector illustrated in FIG. 26.

[0034] FIG. 28 is a bottom view of the safety lock of the medical injector illustrated in FIG. 26.

[0035] FIG. 29 is a perspective view of a needle sheath of the safety lock of the medical injector illustrated in FIG. 26.

[0036] FIG. 30 is a perspective view of a base of the medical injector illustrated in FIG. 3.

[0037] FIG. 31 is a front view of the base of the medical injector illustrated in FIG. 3.

[0038] FIG. 32 is a back view of the medical injector illustrated in FIG. 3 in a second configuration.

[0039] FIG. 33 is a back view of the medical injector illustrated in FIG. 3 in a third configuration.

[0040] FIG. 34 is a back view of the medical injector illustrated in FIG. 3 in a fourth configuration.

[0041] FIG. 35 is a perspective view of a housing of a medical injector according to an embodiment of the invention.

[0042] FIG. 36 is a perspective view of an electronic circuit system of a medical injector according to an embodiment of the invention.

[0043] FIG. 37 is a back view of a printed circuit board of the electronic circuit system shown in FIG. 36.

[0044] FIG. 38 is a schematic illustration of the electronic circuit system shown in FIG. 36.

[0045] FIG. 39 is a perspective cross-sectional view of the housing and the electronic circuit system illustrated in FIG. 35 and FIG. 36 respectively.

[0046] FIG. 40 is a cross-sectional perspective view of a portion of the electronic circuit system illustrated in FIG. 36, taken along line X-X in FIG. 39.

[0047] FIG. 41 is a flow chart illustrating a method of assembling a medical injector according to an embodiment of the invention.

[0048] FIG. 42 is a flow chart illustrating a method of assembling a simulated medical injector according to an embodiment of the invention.

[0049] FIG. 43 is a flow chart illustrating a method of testing a medical injector according to an embodiment of the invention.

DETAILED DESCRIPTION

[0050] In some embodiments, an apparatus includes a medical injector and an electronic circuit system. The medi-

cal injector includes a housing, a medicament container, and a medicament delivery member. The housing defines a first region and a second region. The first region includes the medicament container and is physically isolated from the second region. The electronic circuit system is configured to be disposed within the second region defined by the housing. The electronic circuit system is configured to output an electronic output associated with a use of the medical injector.

[0051] In some embodiments, an apparatus includes a medical injector and an electronic circuit system. The medical injector includes a housing, a medicament container, and a medicament delivery member. The medicament delivery member can be, for example, a needle or an injection nozzle. The housing defines a first region and a second region. The first region includes the medicament container and is physically isolated from the second region. The electronic circuit system is configured to be disposed within the second region defined by the housing. The electronic circuit system includes a printed circuit board having a substrate and an electrical conductor disposed on the substrate. The substrate of the printed circuit board is configured to receive an actuator configured to disrupt the electrical conductor. The actuator can be, for example, an actuator configured to initiate delivery of a medicament from the medical injector. The electronic circuit system is configured to output an electronic output associated with a use of the medical injector when the electrical conductor is disrupted. In some embodiments, the electronic output can be, for example, associated with recorded speech.

[0052] In some embodiments, an apparatus includes a medicament delivery device and an electronic circuit. The medicament delivery device, which can be, for example, a pen injector, an auto-injector, an inhaler or a transdermal delivery device, includes a housing, a medicament container, and a medicament delivery member. The medicament container and at least a portion of the medicament delivery member are disposed within the housing. The medicament container and the medicament delivery member define a medicament delivery path. The electronic circuit system is coupled to the housing and is physically isolated from the medicament delivery path. The electronic circuit system is configured to output an electronic output in response to a delivery of a medicament via the medicament delivery path. In some embodiments, the electronic output can be, for example, a visual output, an audible output, and/or a haptic output.

[0053] In some embodiments, an apparatus includes a medical injector having a housing, a medicament container and a medicament delivery member. The housing defines a first region including at least the medicament container and a second region configured to receive an electronic circuit system. The first region of the housing is physically isolated from the second region of the housing. The electronic circuit system is configured to output an electronic output associated with a use of the medical injector. In some embodiments, the medical injector is configured to deliver only a single dose of medicament into a body. In other embodiments, the medical injector is configured to be reusable.

[0054] In some embodiments, an apparatus includes an electronic circuit system configured to be coupled to a medical injector such that, the electronic circuit system is physically isolated from a medicament delivery path. The electronic circuit system is configured to output an elec-

tronic output in response to the delivery of a medicament via the medicament delivery path. The electronic output can be, for example, a visual output, an audible output, and/or a haptic output.

[0055] In some embodiments, a method includes assembling a medical device configured to deliver a medicament into a body of a patient. The medical device includes a housing, a medicament container, an actuator and a safety lock. The medicament container is disposed within the housing. The actuator is configured to initiate delivery of the medicament from the medicament container when the actuator is actuated. The safety lock is configured to prevent actuation of the actuator. An electronic circuit system is coupled to the housing of the assembled medical device such that an opening defined by a substrate of the electronic circuit system is disposed about a portion of the safety lock. The electronic circuit system is configured to output an electronic output in response to a movement of the safety lock within the opening.

[0056] In some embodiments, a method includes coupling an electronic circuit system to a simulated medicament delivery device such that a portion of the housing actuates a switch of the electronic circuit system. The simulated medicament delivery device is configured to simulate an actual medicament delivery device. The electronic system is configured to output an electronic output associated with a use of the simulated medicament delivery device and a state of the switch. The electronic output can be, for example, a visual output, an audible output, and/or a haptic output.

[0057] In some embodiments, an apparatus includes a simulated medicament delivery device and an electronic circuit system. The simulated medicament delivery device, which can be, for example, a pen injector, an auto-injector, an inhaler or a transdermal delivery device, is configured to simulate an actual medicament delivery device. The simulated medicament delivery device includes a housing, a safety lock and a cover. The safety lock is configured to simulate a safety lock of the actual medicament delivery device. The cover is removably disposed about at least a portion of the housing. The electronic circuit system is configured to output a first plurality of electronic outputs when the cover is removed from the housing a first time. The electronic circuit system is configured to output a second plurality of electronic outputs when the cover is removed from the housing a second time. The second plurality of electronic outputs are different from the first plurality of electronic outputs. In some embodiments, the first and/or the second plurality of electronic outputs can be, for example, visual outputs, audible outputs, and/or haptic outputs.

[0058] In some embodiments, a processor-readable medium storing code representing instructions to cause a processor to perform a process includes code to output a first electronic output associated with a use of a simulated medicament delivery device when a cover is removed from the simulated medicament delivery device a first time. The processor-readable medium includes code to output a second electronic output associated with a use of the simulated medicament delivery device when the cover is removed a second time. The second electronic output is different from the first electronic output. The simulated medicament delivery device can be, for example, a pen injector, an auto-injector, an inhaler or a transdermal delivery device. In some

embodiments, the first and/or second electronic outputs can be, for example, a visual output, an audible output, and/or a haptic output.

[0059] As used in this specification and the appended claims, the words “proximal” and “distal” refer to direction closer to and away from, respectively, an operator (e.g., surgeon, physician, nurse, technician, etc.) of the medical device. Thus, for example, the end of the medicament delivery device contacting the patient’s body would be the distal end of the medicament delivery device, while the end opposite the distal end would be the proximal end of the medicament delivery device.

[0060] FIG. 1 is a schematic illustration of a medical injector 1000, according to an embodiment of the invention. The medical injector 1000 includes a housing 1110, a medicament container 1560, a medicament delivery member 1512 and an electronic circuit system 1900. The housing 1110 includes a sidewall 1148 that defines a first region 1157 and a second region 1153 within the housing 1110. More particularly, the sidewall 1148 physically isolates the first region 1157 from the second region 1153. Said another way, the sidewall 1148 is devoid of openings such that the first region 1157 is fluidically and/or physically isolated from the second region 1153. Said yet another way, the sidewall 1148 is disposed between the first region 1157 and the second region 1153 such that the first region 1157 is separated from the second region 1153. Although the first region 1157 and the second region 1153 are shown in FIG. 1 as being two-dimensional areas, in some embodiments, the first region 1157 and/or the second region 1153, can be fully enclosed volumes within the housing, and/or volumes within the housing 1110 having an opening to an area outside of the housing. Similarly stated, the first region and/or the second region can be cavities, defined by the housing 1110 and/or the sidewall 1148.

[0061] The medicament container 1560, which can be, for example, a pre-filled cartridge, a vial, an ampule or the like, is disposed within the first region 1157 of the housing 1110. At least a portion of the medicament delivery member 1512 is disposed within the first region 1157 of the housing 1110. In some configurations, the medicament delivery member 1512 can be in fluid communication with the medicament container 1560. In this manner, a medicament can be conveyed from the medicament container 1560 to a region outside the housing 1110 via the medicament delivery member 1512. The medicament delivery member 1512 can include, for example, a needle and/or a nozzle.

[0062] At least a portion of the electronic circuit system 1900 is disposed within the second region 1153 of the housing 1110. Accordingly, the portion of the electronic circuit system 1900 is disposed within the housing 1110 such that the portion of the electronic circuit system 1900 is fluidically and/or physically isolated from the medicament container 1560 and/or the medicament delivery member 1512.

[0063] The electronic circuit system 1900 is configured to output an electronic output OP1 associated with a use of the medical injector 1000. For example, in some embodiments, the electronic output OP1 can be associated with an instruction for using the medical injector 1000. In other embodiments, the electronic output OP1 can be a post-use instruction, such as, for example, a recorded message notifying the user that the injection is complete, instructing the user on post-injection disposal and safety procedures, instructing the

user to seek post-injection medical treatment, and/or the like. In yet other embodiments, the electronic output OP1 can be associated with the patient’s compliance in using medical injector 1000. In some embodiments, the electronic output OP1 can be associated with an actuation of the medical injector 1000. Said another way, the electronic circuit system 1900 can be configured to output the electronic output OP1 in response to actuation of the medical injector 1000.

[0064] The electronic output OP1 can be, for example, a visual output such as, for example, a text message to display on a screen (not shown), and/or an LED. In some embodiments, the electronic output OP1 can be an audio output, such as, for example, recorded speech, a series of tones, and/or the like. In other embodiments, the electronic output OP1 can be a wireless signal configured to be received by a remote device.

[0065] The medical injector 1000 can be any suitable medical injector for injecting medicament into a body of a patient. For example, the medical injector 1000 can be a syringe, pen injector, auto-injector or the like. In some embodiments, the medical injector 1000 can be a chronic-care injector. Said another way, the medical injector 1000 can be a reusable device containing multiple doses of medicament. For example, a medical injector 1000 having multiple doses of medicament can be used to manage insulin delivery or the delivery of other medicaments (e.g., to treat Multiple Sclerosis, Anemia, Rheumatoid Arthritis, Osteoporosis or the like), which can require daily, weekly, and/or monthly injections. In other embodiments, the medical injector 1000 can be a single-use device. Said another way, the medical injector 1000 can contain a single dose of medicament. In some embodiments, medical injector 1000 can include the same dosage of a medicament, and can be prescribed as a part of a chronic-care medicament regimen, clinical trial, or the like. In other embodiments, medical injector 1000 can include different dosages, and/or different medicament compositions.

[0066] The sidewall 1148 can be any suitable structure to isolate the first region 1157 within the housing 1110 from the second region 1153 within the housing 1110. In some embodiments, the sidewall 1148 can be rigid. In other embodiments, the sidewall 1148 can be a movable member such as, for example, a piston. In yet other embodiments, the sidewall 1148 can be a flexible member such as, for example, a diaphragm. In some embodiments, the sidewall 1148 can be constructed from a transparent material such that light can pass from the first region 1157 to the second region 1153, and vice versa. A transparent sidewall can be used in conjunction with an optical sensor. The sidewall 1148 can be integrally formed with the housing 1110 or can be formed separately from the housing 1110.

[0067] The electronic circuit system 1900 can include any suitable electronic components operatively coupled to produce and/or output the electronic output OP1 and/or to perform the functions described herein. The electronic circuit system 1900 can be similar to the electronic circuit systems described in U.S. patent application Ser. No. 11/621,236, entitled “Devices, Systems and Methods for Medicament Delivery,” filed Jan. 9, 2007, which is incorporated herein by reference in its entirety.

[0068] FIG. 2 is a schematic illustration of a medicament delivery device 2000, according to an embodiment of the invention. The medicament delivery device 2000 includes a

housing **2110**, a medicament container **2560**, a medicament delivery member **2512** and an electronic circuit system **2900**. The medicament container **2560**, which can be, for example, a pre-filled cartridge, a vial, an ampule or the like, is disposed within the housing **2110**. At least a portion of the medicament delivery member **2512** is disposed within the housing **2110**. The medicament delivery member **2512** can include any suitable member configured to convey a medicament from the medicament container **2560** to a location within a patient's body. For example, in some embodiments, the medicament delivery member **2512** can be a needle, a nozzle, and/or an inhaler mouth piece.

[**0069**] In use, the medicament delivery member **2512** can be in fluid communication with the medicament container **2560**. In this manner, the medicament delivery member **2512** and the medicament container **2560** can define a medicament delivery path **2505** through which a medicament **2568** can be conveyed from the medicament container **2560** to a location outside the housing **2110** via the medicament delivery member **2512** as shown by arrow AA. In some embodiments, the medicament delivery path **2505** can include portions of a lumen defined by the medicament delivery member **2512** and/or the connection between the medicament delivery member **2512** and the medicament container **2560**.

[**0070**] The electronic circuit system **2900** is coupled to the housing **2110** and is fluidically and/or physically isolated from the medicament delivery path **2505**. The electronic circuit system **2900** is configured to output an electronic output OP2 in response to a delivery of the medicament **2568** via the medicament delivery path **2505**. In this manner, the electronic circuit system **2900** can output the electronic output OP2 in an unobtrusive manner and/or without impeding the delivery of the medicament **2568** through the medicament delivery path **2505**. In some embodiments, for example, the electronic output OP2 can be a post-use instruction, such as, for example, a recorded message notifying the user that the injection is complete, instructing the user on post-injection disposal and safety procedures, instructing the user on post-injection medical treatment, and/or the like. In other embodiments, the electronic output OP2 can be associated with the patient's compliance in using the medicament delivery device **2000**. For example, in some embodiments, the electronic output OP2 can be a signal sent to a compliance tracking monitor to record the data and/or time of use of the medicament delivery device **2000**.

[**0071**] The electronic output OP2 can be, for example, a visual output such as, for example, a text message to display on a screen (not shown), and/or an LED. In some embodiments, the electronic output OP2 can be an audio output, such as, for example, recorded speech, a series of tones, and/or the like. In other embodiments, the electronic output OP2 can be a wireless signal configured to be received by a remote device.

[**0072**] The medicament delivery device **2000** can be any suitable medicament delivery device for delivering the medicament **2568** to a body of a patient. For example, the medicament delivery device **2000** can be a syringe, pen injector, auto-injector, inhaler or the like. In some embodiments, the medicament delivery device **2000** can be a chronic-care delivery device. Said another way, the medicament delivery device **2000** can be a reusable device containing multiple doses of medicament **2568**. In other

embodiments, the medicament delivery device **2000** can be a single-use device. Said another way, the medicament delivery device **2000** can contain a single dose of medicament **2568**.

[**0073**] The electronic circuit system **2900** can include any suitable electronic components operatively coupled to produce and/or output the electronic output OP2 and/or to perform the functions described herein. The electronic circuit system **1900** can be similar to the electronic circuit system **1900** as described above with reference to FIG. 1.

[**0074**] FIGS. 3-34 show a medical injector **4000**, according to an embodiment of the invention. FIGS. 3-4 are perspective views of the medical injector **4000** in a first configuration (i.e., prior to use). The medical injector **4000** includes a housing **4110**, a delivery mechanism **4500** (see e.g., FIG. 12), an electronic circuit system **4900** (see e.g., FIGS. 13-23), a cover **4200** (see e.g., FIGS. 24-25), a safety lock **4700** (see e.g., FIGS. 26-29) and a base **4300** (see e.g., FIGS. 30-31). A discussion of the components of the medical injector **4000** will be followed by a discussion of the operation of the medical injector **4000**.

[**0075**] As shown in FIGS. 5-11, the housing **4110** has a proximal end portion **4140** and a distal end portion **4120**. The housing **4110** defines a first status indicator aperture **4150** and a second status indicator aperture **4151**. The first status indicator aperture **4150** defined by the housing **4110** is located on a first side of the housing **4110**, and the second status indicator aperture **4151** of the housing **4110** is located on a second side of the housing **4110**. The status indicator apertures **4150**, **4151** can allow a patient to monitor the status and/or contents of a medicament container **4560**. For example, by visually inspecting the status indicator apertures **4150**, **4151**, a patient can determine whether the medicament container **4560** contains a medicament and/or whether a medicament has been dispensed.

[**0076**] As shown in FIGS. 9 and 10, the housing **4110** defines a gas cavity **4154**, a medicament cavity **4157** and an electronic circuit system cavity **4153**. The gas cavity **4154** has a proximal end portion **4155** and a distal end portion **4156**. The gas cavity **4154** is configured to receive the gas container **4570** and the release member **4540** of the medicament delivery mechanism **4500** (see e.g., FIG. 12) as described in further detail herein. The proximal end portion **4155** of the gas cavity **4154** is configured to receive the gas container retention member **4580** of the proximal cap **4112** of the housing **4110**, as described in further detail herein. The gas cavity **4154** is in fluid communication with the medicament cavity **4157** via a gas passageway **4144**, as described in further detail herein, and the gas cavity **4154** is in fluid communication with a region outside the housing **4110** via a safety lock aperture **4128**.

[**0077**] The medicament cavity **4157** is configured to receive a portion of the delivery mechanism **4500**. In particular, the carrier **4520**, the moveable member **4530** and the needle **4512** of the medicament delivery mechanism **4500** are movably disposed in the medicament cavity **4157**. The medicament cavity **4157** is in fluid communication with a region outside the housing **4110** via a needle aperture **4122**.

[**0078**] The electronic circuit system cavity **4153** is configured to receive the electronic circuit system **4900**. The housing **4110** has protrusions **4149** (see e.g., FIG. 8) configured to stabilize the electronic circuit system **4900** when the electronic circuit system **4900** is disposed within the electronic circuit system cavity **4153**. The housing **4110** also

defines connection apertures **4152** configured to receive connection protrusions **4171** of the electronic circuit system **4900**, and aperture **4145** (see e.g., FIG. 6) configured to receive a portion of a protrusion **4174** of the electronic circuit system **4900**. In this manner, the electronic circuit system **4900** can be coupled to the housing **4110** within the electronic circuit system cavity **4153**. In other embodiments, the electronic circuit system **4900** can be coupled within the electronic circuit system cavity **4153** by other suitable means such as an adhesive, a clip and/or the like.

[0079] The electronic circuit system cavity **4153** is fluidically and/or physically isolated from the gas cavity **4154** and/or the medicament cavity **4157** by a sidewall **4148**. The sidewall **4148** can be any suitable structure to isolate the electronic circuit system cavity **4153** within the housing **4110** from the gas cavity **4154** and/or the medicament cavity **4157** within the housing **4110**. Similarly, the gas cavity **4154** and the medicament cavity **4157** are separated by a sidewall **4146**. In some embodiments, sidewall **4146** can be similar to the sidewall **4148**, which isolates the gas cavity **4154** and the medicament cavity **4157** from the electronic circuit system cavity **4153**. In other embodiments the gas cavity **4154** can be fluidically and/or physically isolated from the medicament cavity **4157**.

[0080] The proximal end portion **4140** of the housing **4110** includes a proximal cap **4112**, a speaker protrusion **4147** (see e.g., FIGS. 8 and 9), and cover retention protrusions **4142** (see e.g., FIGS. 4 and 6). The speaker protrusion **4147** is configured to maintain a position of an audio output device **4956** of the electronic circuit system **4900** relative to the housing **4110** when the electronic circuit system **4900** is attached to the housing **4110**, as described herein. Cover retention protrusions **4142** are configured to be received within corresponding openings **4215** on the cover **4200**. In this manner, as described in more detail herein, the cover **4200** can be removably coupled to and disposed about at least a portion of the housing **4110**.

[0081] As shown in FIG. 11, the proximal cap **4112** includes a gas container retention member **4580** and defines a gas passageway **4144**. The gas container retention member **4580** is configured to receive and/or retain a gas container **4570** that can contain a pressurized gas. The gas passageway **4144** is configured to allow for the passage of gas contained in the gas container **4570** from the gas cavity **4154** to the medicament cavity **4157**, as further described herein. Said another way, the gas passageway **4144** places the gas cavity **4154** in fluid communication with the medicament cavity **4157**.

[0082] As shown in FIGS. 7 and 9, the distal end portion **4120** of the housing **4110** defines a battery isolation protrusion aperture **4121**, a needle aperture **4122**, a safety lock actuator groove **4123**, a safety lock aperture **4128**, a base actuator groove **4124**, base retention recesses **4125A**, **4125B**, and base rail grooves **4127**. The battery isolation protrusion aperture **4121** is configured to receive the battery isolation protrusion **4235** of the cover **4200** (see e.g., FIG. 25), as described in further detail herein.

[0083] The needle aperture **4122** is configured to allow the needle **4512** (see e.g., FIG. 12) to exit the housing **4110** when the medical injector **4000** is actuated. The portion of the sidewall of the housing **4110** that defines the needle aperture **4122** includes multiple sheath retention protrusions **4126**. In some embodiments, the sheath retention protrusions can interact with the a plurality of ribs **4728** of the

needle sheath **4720** (see e.g. FIG. 29) to maintain a position of the needle sheath **4720** relative to the safety lock **4700** when the safety lock **4700** is coupled to the housing **4110** and/or when the safety lock **4700** is being removed from the housing **4110**.

[0084] The safety lock actuator groove **4123** is configured to receive an actuator **4744** of the safety lock **4700**. As described in more detail herein, the actuator **4744** is configured to engage and/or activate the electronic circuit system **4900** when the safety lock **4700** is moved with respect to the housing **4110**. The safety lock aperture **4128** is configured to receive a safety lock protrusion **4742** (see e.g., FIGS. 25 and 26). As described in more detail below, the safety lock protrusion **4742** is received within an opening **4554** between extensions **4552** of a release member **4540** such that activation of the medical injector **4000** is prevented when the safety lock **4700** is in place. The safety lock **4700**, its components and functions are further described herein.

[0085] The distal base retention recesses **4125A** are configured to receive the base connection knobs **4358** of the base **4300** (see e.g., FIG. 30) when the base **4300** is in a first position relative to the housing **4110**. The proximal base retention recesses **4125B** are configured to receive the base connection knobs **4358** of the base **4300** when the base **4300** is in a second position relative to the housing **4110**. The base retention recesses **4125A**, **4125B** have a tapered proximal sidewall and a non-tapered distal sidewall. This allows the base retention recesses **4125A**, **4125B** to receive the base connection knobs **4358** such that the base **4300** can move proximally relative to the housing **4110**, but cannot move distally relative to the housing **4110**. Said another way, the distal base retention recesses **4125A** are configured to prevent the base **4300** from moving distally when the base **4300** is in a first position and the proximal base retention recesses **4125B** are configured to prevent the base **4300** from moving distally when the base **4300** is in a second position. Similarly stated, the proximal base retention recesses **4125B** and the base connection knobs **4358** cooperatively prevent “kick-back” after the medical injector **4000** is actuated.

[0086] The base actuator groove **4124** is configured to receive an actuator **4311** of the base **4300**. As described in more detail herein, the actuator **4311** of the base **4300** is configured to engage the electronic circuit system **4900** when the base **4100** is moved with respect to the housing **4110**. The base rail grooves **4127** are configured to receive the guide members **4312** of the base **4300**. The guide members **4312** of the base **4300** and the base rail grooves **4127** of the housing **4110** engage each other in a way that allows the guide members **4312** of the base **4300** to slide in a proximal and/or distal direction within the base rail grooves **4127** while limiting lateral movement of the guide members **4312**. This arrangement allows the base **4300** to move in a proximal and/or distal direction with respect to the housing **4110** but prevents the base **4300** from moving in a lateral direction with respect to the housing **4110**.

[0087] FIG. 12 shows the medicament delivery mechanism **4500** of the medical injector **4000**. The medical injector **4000** is similar to the auto-injectors described in U.S. patent application Ser. No. 11/562,061, entitled “Devices, Systems and Methods for Medicament Delivery,” filed Nov. 21, 2006, which is incorporated herein by reference in its entirety. Accordingly, only an overview of the medicament delivery mechanism **4500** and related operation of the medical injector **4000** is included below.

[0088] The medicament delivery mechanism 4500 includes a needle 4512, a carrier 4520, a movable member 4530, a medicament container 4560, a gas container 4570, and a release member 4540. As described above, the needle 4512, carrier 4520, movable member 4530 and medicament container 4560 are disposed within the medicament cavity 4157 of the housing 4110. The gas container 4570 and the release member 4540 are disposed within the gas cavity 4154 of the housing 4110.

[0089] The release member 4540 has a proximal end portion 4542 and a distal end portion 4544, and is movably disposed within the distal end portion 4156 of the gas cavity 4154. The proximal end portion 4542 of the release member 4540 includes a sealing member 4545 and a puncturer 4541. The sealing member 4545 is configured to engage the sidewall of the housing 4110 defining the gas cavity 4154 such that the proximal end portion 4155 of the gas cavity 4154 is fluidically isolated from the distal end portion 4156 of the gas cavity 4154. In this manner, when gas is released from the gas container 4570, the gas contained in the proximal end portion 4155 of the gas cavity 4154 is unable to enter the distal end portion 4156 of the gas cavity 4154. The puncturer 4541 of the proximal end portion 4542 of the release member 4540 is configured to contact and puncture a frangible seal 4573 on the gas container 4570 when the release member 4540 moves proximally within the gas cavity 4154, as shown by the arrow BB in FIG. 12.

[0090] The distal end portion 4544 of the release member 4540 includes extensions 4552. The extensions 4552 include projections 4547 that include tapered surfaces 4549 and engagement surfaces 4548. Further, the extensions 4552 define an opening 4554 between the extensions 4552. The tapered surfaces 4549 of the projections 4547 are configured to contact protrusions 4313 on a proximal surface 4310 of the base 4300 (see e.g., FIG. 30). The engagement surfaces 4548 of the projections 4547 are configured to extend through the safety lock aperture 4128 of the housing 4110 and contact a distal surface of the housing 4110. In this manner, the engagement surfaces 4548 of the projections 4547 limit proximal movement of the release member 4540 when the engagement surfaces 4548 are in contact with the distal surface of the housing 4110.

[0091] The opening 4554 defined by the extensions 4552 is configured to receive the safety lock protrusion 4742 of the safety lock 4700 (see e.g., FIG. 27). The safety lock protrusion 4742 is configured to prevent the extensions 4552 from moving closer to each other. Said another way, the safety lock protrusion 4742 is configured to ensure that the extensions 4552 remain apart and the engagement surfaces 4548 of the projections 4547 remain in contact with the distal end portion 4120 of the housing 4110. In some embodiments, for example, the release member 4540 and/or the extensions 4552 can be constructed from any suitable material configured to withstand deformation that may occur when exposed to a load over an extended period of time. In some embodiments, for example, the release member 4540 and/or the extensions 4552 can be constructed from brass.

[0092] The gas container 4570 includes a distal end portion 4572 and a proximal end portion 4576, and is configured to contain a pressurized gas. The distal end portion 4572 of the gas container 4570 contains a frangible seal 4573 configured to break when the puncturer 4541 of the proximal end portion 4542 of the release member 4540 contacts the frangible seal 4573. The gas container retention

member 4580 of the proximal cap 4112 of the housing 4110 is configured to receive and/or retain the proximal end portion 4576 of the gas container 4570. Said another way, the position of the gas container 4570 within the gas cavity 4154 is maintained by the gas container retention member 4580.

[0093] The medicament container 4560 of the medicament delivery mechanism 4500 has a distal end portion 4562 and a proximal end portion 4566, and is configured to contain a medicament. The distal end portion 4562 of the medicament container 4560 contains a seal 4523. The seal 4523 is configured to burst when punctured by the proximal end 4516 of the needle 4512, as described below. The proximal end portion 4566 of the medicament container 4560 is configured to receive a piston portion 4534 of the movable member 4530.

[0094] The movable member 4530 of the medicament delivery mechanism 4500 is movably disposed within the medicament cavity 4157. The movable member 4530 includes a piston portion 4534 having a plunger at the distal end portion of the piston portion 4534. The piston portion 4534 is configured to move within the medicament container 4560. In this manner, the piston portion 4534 of the movable member 4530 can apply pressure to a medicament contained in the medicament container 4560. The piston portion 4534 can be constructed of a resilient, durable, and/or sealing material, such as a rubber.

[0095] The carrier 4520 of the medicament delivery mechanism 4500 includes a distal end portion 4522 and a proximal end portion 4526. The medicament container 4560 is coupled to the carrier 4520 via a "snap-fit" connection (not shown) such that the medicament container 4560 can move relative to the carrier 4520 between a first configuration and a second configuration during an injection event. In the first configuration, the carrier 4520 is configured to move within the medicament cavity 4157 such that movement of the carrier 4520 within the medicament cavity 4157 causes contemporaneous movement of the medicament container 4560 within the medicament cavity 4157. The proximal end portion 4516 of the needle 4512 is spaced apart from the seal 4523 of the medicament container 4560 when the carrier 4520 is in the first configuration. In the second configuration, the medicament container 4560 releases from the "snap-fit" causing the medicament container 4560 to move distally with respect to the carrier 4520, causing the proximal end portion 4516 of the needle 4512 to pierce the seal 4523. In this manner, the needle 4512 can be selectively placed in fluid communication with the medicament container 4560 to define a medicament delivery path (not shown).

[0096] FIGS. 13-22 show the electronic circuit system 4900. The electronic circuit system 4900 of the medical injector 4000 includes an electronic circuit system housing 4170, a printed circuit board 4922, a battery assembly 4962, an audio output device 4956, two light emitting diodes (LEDs) 4958A, 4958B and a battery clip 4910. As shown in FIG. 20, the electronic circuit system 4900 is configured to fit within the electronic circuit system cavity 4153 of the housing 4110. Accordingly, as described above, the electronic circuit system 4900 is physically and/or fluidically isolated from the medicament cavity 4157, the gas cavity 4154 and/or the medicament delivery device 4500. As

described herein, the electronic circuit system **4900** is configured to output an electronic output associated with the use of the medical injector **4000**.

[**0097**] The electronic circuit system housing **4170** of the electronic circuit system **4900** includes a distal end portion **4180** and a proximal end portion **4190**. The proximal end portion **4190** includes connection protrusions **4171A** and a battery clip protrusion **4173**. The connection protrusions **4171A** extend from the proximal end portion **4190** of the electronic circuit system housing **4170**, and are configured to be disposed within the connection apertures **4152** of the housing **4110**, as described above. In this manner, the electronic circuit system **4900** can be coupled to the housing **4110** within the electronic circuit system cavity **4153**. In other embodiments, the electronic circuit system **4900** can be coupled to the housing **4110** by other suitable means such as an adhesive, a clip and/or the like. As described in more detail herein, the battery clip protrusion **4173** is configured to hold the battery clip **4910** in place.

[**0098**] The proximal end portion **4190** of the electronic circuit system housing **4170** defines multiple sound apertures **4191**. The audible output device **4956** is disposed against the proximal end portion **4190** of the electronic circuit system housing **4170** such that the front face of the audible output device **4956** is disposed adjacent the sound apertures **4191**. In this manner, the sound apertures **4191** are configured to allow sound from an audio output device **4956** to pass from the audio output device **4956** to a region outside of the housing **4110**.

[**0099**] As shown in FIGS. **16** and **17**, the distal end portion **4180** of the electronic circuit system housing **4170** includes a connection protrusion **4171B**, a stiffening protrusion **4174**, and defines an LED aperture **4181**, an aperture **4172**, a safety lock actuator groove **4182**, and a base actuator groove **4183**. The LED aperture **4181** is configured to receive the LEDs **4958A**, **4958B** such that a user can view the LEDs **4958A**, **4958B**, which are described in more detail herein.

[**0100**] The connection protrusion **4171B** extends from the distal end portion **4180** of the electronic circuit system housing **4170**, and is configured to attach the electronic circuit system **4900** to the housing **4110**, as described above. The stiffening protrusion **4174** is configured to have at least a portion received within and/or accessible via the aperture **4145** in the housing **4110** (see e.g., FIG. **6**). The stiffening protrusion **4174** is configured to limit the bending (e.g., buckling) of the electronic circuit system housing **4170** when the electronic circuit system housing **4170** is coupled to the housing **4110**. Moreover, a user can access the stiffening protrusion **4174** via the aperture **4172**. In this manner, for example, the user can disengage the stiffening protrusion **4174** from the aperture **4145**.

[**0101**] The safety lock actuator groove **4182** of the electronic circuit system housing **4170** is configured to be disposed adjacent the safety lock actuator groove **4123** of the distal end portion **4120** of the housing **4110**. In this manner, the safety lock actuator groove **4182** of the electronic circuit system housing **4170** and the safety lock actuator groove **4123** of the distal end portion **4120** of the housing **4110** collectively receive the actuator **4744** of the safety lock **4700**, which is described in more detail herein. Similarly, the base actuator groove **4183** of the electronic circuit system housing **4170** is configured to be disposed about the base actuator groove **4124** of the distal end portion **4120** of the housing **4110**. The base actuator groove **4183** of

the electronic circuit system housing **4170** and the base actuator groove **4124** of the distal end portion **4120** of the housing **4110** collectively receive the actuator **4311** of the base **4300**, which is described in more detail herein.

[**0102**] The printed circuit board **4922** of the electronic circuit system **4900** includes a substrate **4924**, a first actuation portion **4926** and a second actuation portion **4946**. The substrate **4924** of the printed circuit board **4922** includes the electrical components necessary for the electronic circuit system **4900** to operate as desired. For example, the electrical components can be resistors, capacitors, inductors, switches, microcontrollers, microprocessors and/or the like. The substrate **4924** includes a series of electrical conductors, such as for example, copper traces, etched thereon. The substrate **4924** can be constructed from any material having suitable electrical properties, mechanical properties and flexibility, such as, for example Mylar®, Kapton® or impregnated paper. A mask layer **4925** (shown as being transparent in FIGS. **21-23** to allow viewing of the components below the mask layer) is disposed over the substrate **4924** to electrically isolate selected portions of the electrical conductors (e.g., the first electrical conductor **4934**) from adjacent components. The electrical conductors operatively couple the above-mentioned circuit components in a predetermined arrangement. In this manner, the electronic circuit system **4920** can be configured to output a predetermined sequence of electronic outputs during the use of the auto-injector **4002**.

[**0103**] As shown in FIGS. **21-23**, the first actuation portion **4926** includes a first electrical conductor **4934** and defines an opening **4928** having a boundary **4929**. The opening **4928** of the first actuation portion **4926** is configured to receive a protrusion **4746** of the actuator **4744** of the safety lock **4700**. The boundary **4929** of the first opening **4928** has a discontinuous shape, such as, for example, a teardrop shape, that includes a stress concentration riser **4927**. The discontinuity and/or the stress concentration riser **4927** of the boundary **4929** can be of any suitable shape to cause the substrate **4924** to deform in a predetermined direction when the protrusion **4746** of the actuator **4744** of the safety lock **4700** is moved relative to the opening **4928**, as shown by the arrow CC in FIG. **22**.

[**0104**] The opening **4928** is defined adjacent the first electrical conductor **4934** that electronically couples the components included in the electronic circuit system **4900**. The first electrical conductor **4934** includes a first switch **4972**, which can be, for example a frangible portion of the first electrical conductor **4934**. In use, when the safety lock **4700** is moved from a first position (see e.g., FIG. **21**) to a second position (see e.g., FIG. **22**), the actuator **4744** moves in a direction substantially parallel to a plane defined by a surface of the first actuation portion **4926** of the substrate **4924**. The movement of the actuator **4744** causes the protrusion **4746** to move within the first opening **4928**, as indicated by the arrow CC in FIG. **22**. The movement of the protrusion **4746** tears the first actuation portion **4926** of the substrate **4924**, thereby separating the portion of the first electrical conductor **4934** including the first switch **4972**. Said another way, when the safety lock **4700** is moved from its first position to its second position (see e.g., FIG. **33**), the actuator **4744** moves irreversibly the first switch **4972** from a first state (e.g., a state of electrical continuity) to a second state (e.g., a state of electrical discontinuity). Said yet another way, when the safety lock **4700** is moved from its

first position to its second position, the actuator 4744 disrupts the first electrical conductor 4934.

[0105] The second actuation portion 4946 includes a second electrical conductor 4935 and defines an opening 4945, having a boundary 4949 and a tear propagation limit aperture 4948. As shown in FIGS. 20-23, the opening 4945 of the second actuation portion 4946 is configured to receive a portion of an actuator 4311 of the base 4300. The boundary 4949 of the opening 4945 has a discontinuous shape that includes a stress concentration riser 4947. The discontinuity and/or the stress concentration riser 4947 of the boundary 4949 can be of any suitable shape to cause the substrate 4924 to deform in a predetermined direction when the actuator 4311 of the base 4300 is moved in a proximal direction relative to the opening 4945, as shown by the arrow DD in FIG. 23.

[0106] The second electrical conductor 4935 includes a second switch 4973 disposed between the opening 4945 and the tear propagation limit aperture 4948, which can be, for example, a frangible portion of the second electrical conductor 4935. In use, when the base 4300 is moved from its first position to its second position (see e.g., FIG. 34), the actuator 4311 moves in a proximal direction, substantially parallel to a plane defined by a surface of the second actuation portion 4946 of the substrate 4924. The proximal movement of the actuator 4311 tears the second actuation portion 4946 of the substrate 4924, thereby separating the portion of the second electrical conductor 4935 including the second switch 4973. Said another way, when the base 4300 is moved from its first position to its second position, the actuator 4311 moves irreversibly the second switch 4973 from a first state (e.g., a state of electrical continuity) to a second state (e.g., a state of electrical discontinuity). The tear propagation limit aperture 4948 is configured to limit the propagation of the tear in the substrate 4924 in the proximal direction. Said another way, the tear propagation limit aperture 4948 is configured to ensure that the tear in the substrate 4924 does not extend beyond the tear propagation limit aperture 4948. The tear propagation limit aperture 4948 can be any shape configured to stop the propagation of a tear and/or disruption of the substrate 4924. For example, the tear propagation limit aperture 4948 can be oval shaped. In other embodiments, the proximal boundary of the tear propagation limit aperture 4948 can be reinforced to ensure that the tear in the substrate 4924 does not extend beyond the tear propagation limit aperture 4948.

[0107] The battery assembly 4962 of the electronic circuit system 4900 comprises two batteries stacked on top of one another. The battery assembly 4962 has a first surface 4964 and a second surface 4966. The first surface 4964 of the battery assembly 4962 can contact an electrical contact (not shown) disposed on the substrate 4924. The second surface 4966 of the battery assembly 4962 is configured to contact a contact portion 4918 of a distal end portion 4916 of a battery clip 4910. When both the electrical contact of the substrate 4924 and the contact portion 4918 of the distal end portion 4916 of the battery clip 4910 contact the battery assembly 4962, the batteries of the battery assembly 4962 are placed in electrical communication with the electronic circuit system 4900. Said another way, when the electrical contact of the substrate 4924 and the contact portion 4918 of the distal end portion 4916 of the battery clip 4910 contact

the battery assembly 4962, the battery assembly 4962 is configured to supply power to the electronic circuit system 4900.

[0108] The battery clip 4910 (shown in FIG. 18) includes a proximal end portion 4912 and a distal end portion 4916. The proximal end portion 4912 defines a retention aperture 4913. The retention aperture 4913 is configured to receive the battery clip protrusion 4173 of the electronic circuit system housing 4170. In this manner, the battery clip protrusion 4173 maintains the position of the battery clip 4910 with respect to the electronic circuit system housing 4170 and/or the battery assembly 4962.

[0109] The distal end portion 4916 of the battery clip 4910 includes a contact portion 4918 and an angled portion 4917. As described above, the contact portion 4918 is configured to contact the second surface 4916 of the battery assembly 4962 to place the battery assembly 4962 in electrical communication with the electronic circuit system 4900. The angled portion 4917 of the distal end portion 4916 of the battery clip 4910 is configured to allow a proximal end portion 4236 of a battery isolation protrusion 4235 (see e.g., FIG. 25) to be disposed between the second surface 4966 of the battery assembly 4962 and the contact portion 4918 of the distal end portion 4916 of the battery clip 4910. When the battery isolation protrusion 4235 is disposed between the second surface 4966 of the battery assembly 4962 and the contact portion 4918 of the distal end portion 4916 of the battery clip 4910, the electrical path between the battery assembly 4962 and the remainder of the electrical circuit system 4900 is severed, thereby removing power from the electronic circuit system 4900. The contact portion 4918 of the distal end portion 4916 of the battery clip 4910 is biased such that when the battery isolation protrusion 4235 is removed, the contact portion 4918 will move into contact the second surface 4916 of the battery assembly 4962, thereby restoring electrical communication between the battery assembly 4962 and the electronic circuit system 4900. In some embodiments, the battery isolation protrusion 4235 can be repeatedly removed from between the second surface 4966 of the battery assembly 4962 and the contact portion 4918 of the distal end portion 4916 of the battery clip 4910 and reinserted. Said another way, the battery isolation protrusion 4235 and the battery clip 4910 collectively form a reversible on/off switch.

[0110] The audio output device 4956 of the electronic circuit system 4900 is configured to output audible sound to a user in response to a use of the medical injector 4000. In some embodiments, the audible output device 4956 can be a speaker. In some embodiments, the audible sound can be, for example, associated with a recorded message and/or a recorded speech. In other embodiments, the audible instructions can be an audible beep, a series of tones and/or the like.

[0111] In other embodiments, the medical injector 4000 can have a network interface device (not shown) configured to operatively connect the electronic circuit system 4900 to a remote device (not shown) and/or a communications network (not shown). In this manner, the electronic circuit system 4900 can send information to and/or receive information from the remote device. The remote device can be, for example, a remote communications network, a computer, a compliance monitoring device, a cell phone, a personal digital assistant (PDA) or the like. Such an arrangement can be used, for example, to download replacement processor-

readable code from a central network to the electronic circuit system 4900. In some embodiments, for example, the electronic circuit system 4900 can download information associated with a medical injector 4000, such as an expiration date, a recall notice, updated use instructions or the like. Similarly, in some embodiments, the electronic circuit system 4900 can upload compliance information associated with the use of the medical injector 4000 via the network interface device.

[0112] FIGS. 24 and 25 show the cover 4200 of the medical injector 4000. The cover 4200 includes a proximal end portion 4210 and a distal end portion 4230, and defines a cavity 4242. The cavity 4242 of the cover 4200 is configured to receive at least a portion of the housing 4110. The proximal end portion 4210 defines apertures 4215 configured to receive the cover retention protrusions 4142 of the housing 4110 (shown in FIGS. 4 and 6). In this manner, the apertures 4215 and the cover retention protrusions 4142 of the housing 4110 removably retain the cover 4200 about at least a portion of the housing 4110. Said another way, the apertures 4215 and the cover retention protrusions 4142 of the housing 4110 are configured such that the cover 4200 can be removed from a portion of the housing 4110 and then replaced about the portion of the housing 4110.

[0113] The distal end portion 4230 of the cover 4200 includes a battery isolation protrusion 4235. The battery isolation protrusion 4235 includes a proximal end portion 4236 and a tapered portion 4237. The proximal end portion 4236 of the battery isolation protrusion 4235 is configured to be removably disposed between the second surface 4966 of the battery assembly 4962 and the contact portion 4918 of the distal end portion 4916 of the battery clip 4910, as described above.

[0114] FIGS. 26-29 show the safety lock 4700 of the medical injector 4000. The safety lock 4700 of the medical injector 4000 includes a proximal surface 4740, a distal surface 4760 opposite the proximal surface 4740 and a needle sheath 4720. The safety lock 4700 defines a needle sheath aperture 4770 and a battery isolation protrusion aperture 4775. The battery isolation protrusion aperture 4775 is configured to receive the battery isolation protrusion 4235 of the cover 4200 such that the battery isolation protrusion 4235 can be disposed within the electronic circuit system cavity 4153 or the electronic circuit system 4900, as described above. Similarly stated, the battery isolation protrusion aperture 4775 of the safety lock 4700 is aligned with the battery isolation protrusion aperture 4121 of the housing 4110, such that the battery isolation protrusion 4235 can be disposed within the electronic circuit system cavity 4153 when the cover 4200 is disposed about a portion of the housing 4110.

[0115] The proximal surface 4740 of the safety lock 4700 includes a safety lock protrusion 4742, a stopper 4743, an actuator 4744 and two opposing pull tabs 4741. As described above, when the safety lock 4700 is in a first (locked) position, the safety lock protrusion 4742 is configured to be disposed in the opening 4554 defined by the extensions 4552 of the distal end portion 4544 of the release member 4540. Accordingly, the safety lock protrusion 4742 is configured to prevent the extensions 4552 from moving closer to each other, thereby preventing proximal movement of the release member 4540 of the medicament delivery mechanism 4500 and/or delivery of a medicament. The stopper 4743 of the safety lock 4700 is a protrusion extending from the proximal

surface 4740 of the safety lock 4700. The stopper 4743 is configured to contact a portion of the housing 4110 to limit the proximal movement of the safety lock 4700 relative to the housing 4110. In other embodiments, the stopper 4743 can be any structure configured to limit the proximal movement of the safety lock 4700.

[0116] The actuator 4744 of the safety lock 4700 has an elongated portion 4745 and a protrusion 4746. The elongated portion 4745 extends in a proximal direction from the proximal surface 4740. In this manner, the elongated portion 4745 can extend through a safety lock actuator opening 4356 of the base 4300 (see e.g., FIG. 30) and within the safety lock actuator groove 4123 of the housing 4110 and the safety lock actuator groove 4182 of the electronic circuit system housing 4170. The protrusion 4746 extends in a direction substantially transverse to the elongated portion 4745 and/or substantially parallel to the proximal surface 4740 of the safety lock 4700. As described above, the opening 4928 of the first actuation portion 4926 is configured to receive the protrusion 4746 of the actuator 4744 of the safety lock 4700.

[0117] The pull tabs 4741 of the safety lock 4700 include a grip portion 4747 and indicia 4748. The grip portion 4747 of the pull tabs 4741 provides an area for the user to grip and/or remove the safety lock 4700 from the rest of the medicament delivery system 4700. The indicia 4748 provides instruction on how to remove the safety lock 4700. In some embodiments, for example, the indicia 4748 can indicate the direction the user should pull the safety lock 4700 to remove the safety lock 4700.

[0118] As shown in FIG. 28, the needle sheath 4720 of the safety lock 4700 includes a distal end portion 4724, a proximal end portion 4722 and a plurality of ribs 4728. The needle sheath 4720 can also define a lumen 4729. The lumen 4729 of the safety lock 4700 is configured to receive the needle 4512. In this manner, the needle sheath 4720 can protect the user from the needle 4512 and/or can keep the needle 4512 sterile before the user uses the medical injector 4000. The proximal end portion 4722 of the needle sheath is configured to contact the distal end portion 4522 of the carrier 4520 of the medicament delivery mechanism 4500.

[0119] The distal end portion 4724 of the needle sheath 4720 has an angled ridge 4725. The angled ridge 4725 is configured to allow the proximal end portion 4722 of the needle sheath 4720 to irreversibly move through the needle sheath aperture 4770 of the safety lock 4700 in a distal direction. Said another way, the angled ridge 4725 can be configured in such a way as to allow the proximal end portion 4722 of the needle sheath 4720 to move through the needle sheath aperture 4770 in a distal direction, but not in a proximal direction. The needle sheath aperture 4770 has retaining tabs 4771 configured to engage the proximal end of the angled ridge 4725 when the needle sheath 4720 is moved in a proximal direction. In this manner, the retaining tabs 4771 prevent the proximal movement of the needle sheath with respect to the safety lock 4700. Further, the retaining tabs 4771 are configured to engage the proximal end of the angled ridge 4725 when the safety lock 4700 is moved in a distal direction. Said another way, as shown in FIG. 33, the needle sheath 4720 is removed from the needle 4512 when the safety lock 4700 is moved in a distal direction with respect to the housing 4110.

[0120] FIGS. 30-31 show the base 4300 of the medical injector 4000. The base 4300 includes a proximal surface 4310, a distal surface 4330 and base connection knobs 4358.

The base **4300** defines a needle aperture **4350**, a safety lock protrusion aperture **4352**, a battery isolation protrusion aperture **4354**, a safety lock actuator opening **4356**, and pull tab openings **4360**. The needle aperture **4350** is configured to receive the needle **4512** when the medical injector **4000** is actuated. The safety lock protrusion aperture **4352** of the base **4300** receives the safety lock protrusion **4742** of the safety lock **4700**. The battery isolation protrusion aperture **4354** of the base **4300** receives the battery isolation protrusion **4235** of the cover **4200** and the stopper **4743** of the safety lock **4700**. The safety lock actuator opening **4356** receives the safety lock actuator **4744** of the safety lock **4700**. The pull tab openings **4360** are configured to receive the pull tabs **4741** of the safety lock **4700**.

[0121] The proximal surface **4310** of the base **4300** includes an actuator **4311**, guide members **4312**, and protrusions **4313**. The actuator **4311** is an elongate member configured to engage the substrate **4924** of the electronic circuit system **4900**. As described above, the opening **4945** of the second actuation portion **4946** is configured to receive the actuator **4311** of the base **4300**. The guide members **4312** of the base **4300** are configured to engage and/or slide within the base rail grooves **4127** of the housing **4110**, as described above. The protrusions **4313** of the base **4300** are configured to engage the tapered surfaces **4549** of the extensions **4552** of the release member **4540**. As described in further detail herein, when the safety lock **4700** is removed and the base **4300** is moved in a proximal direction with respect to the housing **4110**, the protrusion **4313** of the base **4300** are configured to move the extensions **4552** of the release member **4540** closer to each other, actuating the medicament delivery mechanism **4500**. As described above, the base connection knobs **4358** are configured to engage the base retention recesses **4125A**, **4125B** in a way that allows proximal movement of the base **4300** but limits distal movement of the base **4300**.

[0122] As shown in FIG. 32, the medical injector **4000** is first enabled by moving the medicament delivery device from a first configuration to a second configuration by moving the cover **4200** from a first position to a second position. The cover **4200** is moved from the first position to the second position by moving it with respect to the housing **4110** in the direction shown by the arrow EE in FIG. 32. When the cover **4200** is moved with respect to the housing **4110** in the direction EE, the battery isolation protrusion **4235** is removed from the area between the battery clip **4910** and the second surface **4966** of the battery assembly **4962**. In this manner, the battery assembly **4962** can be operatively coupled to the electronic circuit system **4900** when the cover **4200** is removed, thereby providing power to the electronic circuit system **4900**.

[0123] When power is provided, as described above, the electronic circuit system **4900** can output one or more predetermined electronic outputs. For example, in some embodiments, the electronic circuit system **4900** can output an electronic signal associated with recorded speech to the audible output device **4956**. Such an electronic signal can be, for example, associated with a .WAV file that contains a recorded instruction instructing the user in the operation of the medical injector **4000**. Such an instruction can state, for example, "remove the safety tab near the base of the auto-injector." The electronic circuit system **4900** can simultaneously output an electronic signal to one and/or both of the LEDs **4958A**, **4958B** thereby causing one and/or both of

the LEDs **4958A**, **4958B** to flash a particular color. In this manner, the electronic circuit system **4900** can provide both audible and visual instructions to assist the user in the initial operation of the medical injector **4000**.

[0124] In other embodiments, the electronic circuit system **4900** can output an electronic output associated with a description and/or status of the medical injector **4000** and/or the medicament contained therein. For example, in some embodiments, the electronic circuit system **4900** can output an audible message indicating the type of medicament contained in the medical injector **4000**, the expiration date of the medicament, the dosage of the medicament or the like.

[0125] As described above, the medical injector **4000** can be repeatedly moved between the first configuration and the second configuration when the cover **4200** is moved repeatedly between the first position and the second position respectively. Said another way, the cover **4200** can be removed and replaced about the housing **4110** any number of times. When the cover **4200** is moved from the second position to the first position, the battery isolation protrusion **4235** is inserted between the battery clip **4910** and the second surface **4966** of the battery assembly **4962**, deactivating the electronic circuit system **4900**. When the cover is moved from the first position to the second position a second time, the electronic circuit system **4900** is once again activated. In this manner, the cover **4200** can be removed and the electronic circuit system **4900** can output an electronic output without compromising the sterility of the needle **4512**.

[0126] After the cover **4200** is removed from the housing **4110**, the medical injector **4000** can be moved from the second configuration to a third configuration by moving the safety lock **4700** from a first position to a second position. The safety lock **4700** is moved from a first position to a second position by moving the safety lock **4700** with respect to the housing **4110** in the direction shown by the arrow FF in FIG. 33. When the safety lock **4700** is moved from the first position to the second position, the safety lock protrusion **4742** is removed from between the extensions **4552** of the release member **4540**, thereby enabling the medicament delivery member **4500**. Moreover, as shown in FIGS. 21 and 22, when the safety lock **4700** is moved from the housing **4110**, the actuator **4744** of the safety lock **4700** moves in the direction CC as shown in FIG. 22, irreversibly moving the first switch **4972** from a first state (e.g., a state of electrical continuity) to a second state (e.g., a state of electrical discontinuity). When the actuator **4744** of the safety lock **4700** moves irreversibly the first switch **4972** of the electronic circuit system **4900** to the second state, the electronic circuit system **4900** can output one or more predetermined electronic outputs. For example, in some embodiments, a processor (not shown) can output an electronic signal associated with recorded speech to the audible output device **4956**. Such an electronic signal can be, for example, associated with a recorded message notifying the user of the status of the medical injector **4000**. Such a status message can state, for example, "The medical injector is now enabled." The electronic circuit system **4900** can also simultaneously output an electronic signal to one and/or both of the LEDs **4958A**, **4958B**, thereby causing one and/or both of the LEDs **4958A**, **4958B** to stop flashing, change color or the like.

[0127] In some embodiments, the first actuation portion **4926** and the actuator **4744** can be configured such that the

actuator 4744 must move a predetermined distance before the actuator 4744 engages the boundary 4929 of the opening 4928. For example, in some embodiments, the actuator 4744 must move approximately 0.200 inches before the actuator 4744 engages the boundary 4929 of the opening 4928. In this manner, the safety lock 4700 can be moved slightly without irreversibly moving the first switch 4972 of the electronic circuit system 4900 to the second state. Accordingly, this arrangement will permit the user to inadvertently and/or accidentally move the safety lock 4700 without actuating the electronic circuit system 4900.

[0128] In some embodiments, the electronic circuit system 4900 can be configured to output the status message for a predetermined time period, such as, for example, five seconds. After the predetermined time period has elapsed, the electronic circuit system 4900 can output an audible message further instructing the user in the operation of the medical injector 4000. Such an instruction can state, for example, "Place the base of the auto-injector against the patient's thigh. To complete the injection, press the base firmly against the patient's thigh." In some embodiments, the electronic circuit system 4900 can simultaneously output an electronic signal to one and/or both of the LEDs 4958A, 4958B, thereby causing one and/or both of the LEDs 4958A, 4958B to flash a particular color. In this manner, the electronic circuit system 4900 can provide both audible and/or visual instructions to assist the user in the placement and actuation of the medical injector 4000. In some embodiments, the electronic circuit system 4900 can be configured to repeat the instructions after a predetermined time period has elapsed.

[0129] As described above, in other embodiments, the medical injector 4000 can have a network interface device (not shown) configured to operatively connect the electronic circuit system 4900 to a remote device (not shown) and/or a communications network (not shown). In this manner, the electronic circuit system 4900 can send a wireless signal notifying a remote device that the safety lock 4700 of the medical injector 4000 has been removed and that the medical injector 4000 has been armed.

[0130] After the safety lock 4700 is moved from the first position to the second position, the medical injector 4000 can be moved from the third configuration to a fourth configuration by moving the base 4300 from a first position to a second position. The base 4300 is moved from its first position to its second position by placing the medical injector 4000 against the body of the patient and moving the base 4300 with respect to the housing 4110 in the direction shown by the arrow GG in FIG. 34. Moving the base 4300 from the first position to the second position causes the protrusions 4313 on the proximal surface 4310 of the base 4300 to engage the tapered surfaces 4549 of the extensions 4552 of the release member 4540, causing the release member 4540 to actuate the medicament delivery mechanism 4500 and deliver a medicament to a body of a patient.

[0131] When the base 4300 is moved from the first position to the second position, the medicament delivery mechanism 4500 is actuated such that the puncturer 4541 of the release member 4540 is brought in contact with and/or punctures the frangible seal 4573 of the gas container 4570. In some embodiments, the movement of the release member 4540 can be caused by a spring (not shown in FIG. 12). After the frangible seal 4573 has been punctured, an actuating portion of a compressed gas can escape from the gas

container 4570 and flow via the gas passageway 4144 into the medicament cavity 4157. The gas applies gas pressure to the movable member 4530 causing the movable member 4530 and the carrier 4520 to move in a distal direction within the medicament cavity 4157. When the carrier 4520 moves distally within the medicament cavity 4157, the carrier 4520 and the medicament container 4560 are in a first configuration. Accordingly, as described above, the medicament container 4560 is connected to the carrier 4520 by a "snap fit" connection. In this manner, the medicament container 4560 and the needle 4512 contemporaneously move with movable member 4530 and/or the carrier 4520 in a distal direction. As described above, the proximal end portion 4516 of the needle 4512 is connected to the distal end portion 4522 of the carrier 4520 and is spaced from the seal 4523 of the medicament container 4560 when the carrier 4520 is in its first configuration. Said another way, the medicament container 4560 and the needle 4512 do not define a medicament delivery path when the carrier 4520 is in the first configuration. The movement of the needle 4512 in a distal direction causes the proximal end portion 4516 of the needle 4512 to exit the housing 4110 and enter the body of a patient prior to administering a medicament.

[0132] After the carrier 4520 and/or the needle 4512 have moved within the medicament cavity 4157 a predetermined distance, the carrier 4520 and the medicament container 4560 are moved from the first configuration to a second configuration. In the second configuration of the carrier 4520, the medicament container 4560 is released from the "snap-fit" allowing the medicament container 4560 and the movable member 4530 to continue to move in a distal direction relative to the carrier 4520. Said another way, the medicament container 4560 is configured to slidably move within the carrier 4520 when the carrier is moved from the first configuration to the second configuration. As the medicament container 4560 continues to move within the carrier 4520, the proximal end portion 4516 of the needle 4512 contacts and punctures the seal 4523 of the medicament container 4560. This allows the medicament contained in the medicament container 4560 to flow into the lumen (not shown) defined by the needle 4512, thereby defining a medicament delivery path.

[0133] As the medicament container 4560 contacts the distal end of the carrier 4520, the medicament container 4560 stops moving within the carrier 4520 while the movable member 4530 continues to move in a distal direction. This causes the piston portion 4534 of the movable member 4530 to sealingly slide and/or move within the medicament container 4560 containing a liquid medicament. As the piston portion 4534 of the movable member 4530 sealingly slides and/or moves within the medicament container 4560, the piston portion 4534 generates a pressure upon the medicament contained within the medicament container 4560, thereby allowing at least a portion of the medicament to flow out of the medicament container 4560 and into the lumen defined by the needle 4512. The medicament is delivered to a body of a user via the medicament delivery path defined by the medicament container 4560 and the needle 4512.

[0134] As described above, the actuator 4538 of the base 4300 actuates the electronic circuit 4900 to trigger a predetermined output or sequence of outputs when the base 4520 is moved from its first position to its second position (see, e.g., FIGS. 19-23). When the actuator 4538 is moved in a

proximal direction relative to the opening 4945, as shown by the arrow DD in FIG. 23, the electronic circuit system 4900 is actuated to output one or more predetermined electronic outputs. For example, in some embodiments, the electronic circuit system 4900 can output an electronic signal associated with recorded speech to the audible output device 4956. Such an electronic signal can be, for example, associated with an audible countdown timer, instructing the user on the duration of the injection procedure. Said another way, if it takes, for example, ten seconds to complete an injection, an audible countdown timer can count from ten to zero ensuring that the user maintains the medical injector 4000 in place for the full ten seconds. In other embodiments, the electronic signal can be, for example, associated with a recorded message notifying the user that the injection is complete, instructing the user on post-injection disposal and safety procedures, instructing the user on post-injection medical treatment or the like. Such a status message can state, for example, "The injection is now complete. Please seek further medical attention from a doctor." The electronic circuit system 4900 can also simultaneously output an electronic signal to one and/or both LEDs 4958A, 4958B, thereby causing one and/or both LEDs 4958A, 4958B to stop flashing, change color or the like, to provide a visual indication that the injection is complete. In other embodiments, the electronic circuit system 4900 can send a wireless signal notifying a remote device that the injection is complete. In this manner, a patient's compliance can be monitored.

[0135] In some embodiments, the second actuation portion 4946 and the actuator 4538 can be configured such that the base 4500 and/or the actuator 4538 must move a predetermined distance before the actuator 4538 engages the boundary 4949 of the opening 4945. For example, in some embodiments, the actuator 4538 must move approximately 0.200 inches before the actuator 4538 engages the boundary 4949 of the opening 4945. In this manner, the base 4700 can be moved slightly without irreversibly moving the second switch 4973 of the electronic circuit system 4900 to the second state. Accordingly, this arrangement will permit the user to inadvertently and/or accidentally move the base 4500 without actuating the electronic circuit system 4900.

[0136] Although the electronic circuit system 4900 is shown and described above as having two irreversible switches (e.g., switch 4972 and switch 4973), in other embodiments, an electronic circuit system can have any number of switches. Moreover, such switches can be either reversible or irreversible. For example, FIGS. 35-40 show portions of a medicament delivery device 5000 having an electronic circuit system 5900 having three irreversible switches.

[0137] The medicament delivery device 5000 is similar to the medical injector 4000 described above. As shown in FIG. 39, the medicament delivery device 5000 includes a housing 5110, a delivery mechanism (not shown), an electronic circuit system 5900, a cover (not shown), a safety lock 5700 and a base 5300. The structure and operation of the delivery mechanism, the cover, the safety lock 5700 and the base 5300 are similar to the structure and operation of the delivery mechanism 4500, the cover 4200, the safety lock 4700 and the base 4300, respectively. Accordingly, only the electronic circuit system 5900 and the housing 5110 are described in detail below.

[0138] As shown in FIG. 35, the housing 5110 has a proximal end portion 5140 and a distal end portion 5120. The housing 5110 defines a gas cavity (not shown), a medicament cavity (not shown) and an electronic circuit system cavity 5153. The gas cavity and medicament cavity of the housing 5110 of the medicament delivery device 5000 are similar to the gas cavity 4154 and the medicament cavity 4157, shown and described above with reference to FIGS. 9 and 10.

[0139] The electronic circuit system cavity 5153 is configured to receive the electronic circuit system 5900. As described above, the electronic circuit system cavity 5153 is fluidically and/or physically isolated from the gas cavity and/or the medicament cavity by a sidewall 5148. The housing 5110 has protrusions 5149 configured to stabilize the electronic circuit system 5900 when the electronic circuit system 5900 is disposed within the electronic circuit system cavity 5153. The housing 5110 also defines connection apertures (not shown) configured to receive connection protrusions 5171 of the electronic circuit system 5900 (see e.g., FIG. 36). In this manner, the electronic circuit system 5900 can be coupled to the housing 5110 within the electronic circuit system cavity 5153 (see e.g., FIG. 39). In other embodiments, the electronic circuit system 5900 can be coupled within the electronic circuit system cavity 5153 by any other suitable means, such as an adhesive, a clip and/or the like.

[0140] The housing 5110 includes an actuation protrusion 5114 disposed within the electronic circuit system cavity 5153. As described in more detail herein, an angled end portion 5115 of the actuation protrusion 5114 of the housing 5110 is configured to engage a third actuation portion 5976 of a substrate 5924 of the electronic circuit system 5900 when the electronic circuit system 5900 is coupled to the housing 5110.

[0141] As shown in FIG. 39, the electronic circuit system 5900 is configured to fit within the electronic circuit system cavity 5153 of the housing 5110. Accordingly, as described above, the electronic circuit system 5900 is physically and/or fluidically isolated from the medicament cavity, the gas cavity and/or the medicament delivery path within the medicament delivery device 5000 (not shown). As described herein, the electronic circuit system 5900 is configured to output an electronic output associated with a use of the medicament delivery device 5000.

[0142] As shown in FIG. 36, the electronic circuit system 5900 is similar to the electronic circuit system 4900 described above. The electronic circuit system 5900 of the medicament delivery device 5000 includes an electronic circuit system housing 5170, a printed circuit board 5922, a battery assembly 5962, an audio output device 5956, two light emitting diodes (LEDs) 5958A, 5958B and a battery clip 5910. The electronic circuit system housing 5170, the battery assembly 5962, the audio output device 5956 electrically coupled to the printed circuit board 5922 via wires 5955, the two light emitting diodes (LEDs) 5958A, 5958B and the battery clip 5910 are similar to the battery assembly 4962, the audio output device 4956, the two light emitting diodes (LEDs) 4958A, 4958B and the battery clip 4910 of the electronic circuit system 4900 described above. Thus, a detailed discussion of these components is omitted.

[0143] The electronic circuit system 5900 also includes a processor 5950 configured to process electronic inputs (e.g., from input switches) and produce electronic outputs. As

described herein, such electronic outputs can include audio or visual outputs associated with a use of the medicament delivery device 5000. The processor 5950 can be a commercially-available processing device dedicated to performing one or more specific tasks. For example, in some embodiments, the processor 5950 can be a commercially-available microprocessor, such as the Sonix SNC 12060 voice synthesizer. Alternatively, the processor 5950 can be an application-specific integrated circuit (ASIC) or a combination of ASICs, which are designed to perform one or more specific functions. In yet other embodiments, the processor 5950 can be an analog or digital circuit, or a combination of multiple circuits.

[0144] The processor 5950 can include a memory device (not shown) configured to receive and store information, such as a series of instructions, processor-readable code, a digitized signal, or the like. The memory device can include one or more types of memory. For example, the memory device can include a read only memory (ROM) component and a random access memory (RAM) component. The memory device can also include other types of memory suitable for storing data in a form retrievable by the processor 5950, for example, electronically-programmable read only memory (EPROM), erasable electronically-programmable read only memory (EEPROM), or flash memory.

[0145] FIG. 37 shows the printed circuit board 5922 of the electronic circuit system 5900. FIG. 38 is a schematic illustration of the electronic circuit system 5900. The printed circuit board 5922 of the electronic circuit system 5900 includes a substrate 5924, a first actuation portion 5926 (including a first switch 5972), a second actuation portion 5946 (including a second switch 5973), and a third actuation portion 5976 (including an electronic circuit system configuration switch 5974). The substrate 5924 of the printed circuit board 5922 includes the electrical components necessary for the electronic circuit system 5900 to operate as desired. For example, the electrical components can include resistors, capacitors, inductors, switches, microcontrollers, microprocessors and/or the like.

[0146] The first actuation portion 5926 and the second actuation portion 5946 are similar to the first actuation portion 4926 and the second actuation portion 4946 of the electronic circuit system 4900, described above (see e.g., FIG. 36), and are therefore not described or labeled in detail. The third actuation portion 5976 includes a third electrical conductor 5936 (see e.g., FIG. 37) and defines an actuation aperture 5975 having a boundary 5979, and a tear propagation limit aperture 5978. As shown in FIGS. 36 and 40, the actuation aperture 5975 of the third actuation portion 5976 is configured to receive the angled end portion 5115 of the actuation protrusion 5114 of the housing 5110 when the electronic circuit system 5900 is disposed within the electronic circuit system cavity 5153. The boundary 5979 of the actuation aperture 5975 has a discontinuous shape, such as, for example, a teardrop shape, that includes a stress concentration riser 5977. The discontinuity and/or the stress concentration riser 5977 of the boundary 5979 can be of any suitable shape to cause the substrate 5924 to deform in a predetermined direction when the angled end portion 5115 of the actuation protrusion 5114 of the housing 5110 is inserted into the actuation aperture 5975 (see e.g., FIG. 40), as described below.

[0147] The third electrical conductor 5936 includes the electronic circuit system configuration switch 5974 (see e.g.,

FIG. 37) disposed between the actuation aperture 5975 and the tear propagation limit aperture 5978, which can be, for example, a frangible portion of the third electrical conductor 5436. As shown in FIGS. 39 and 40, when the electronic circuit system 5900 is attached to the housing 5110, a portion of the angled portion 5115 of the actuation protrusion 5114 is disposed within the actuation aperture 5975 of the third actuation portion 5976, as shown by the arrow HH in FIG. 40. Continued movement of the angled portion 5115 of the actuation protrusion 5114 within the third actuation portion 5976 of the substrate 5924 causes the third actuation portion 5976 of the substrate 5924 to tear, thereby separating the portion of the third electrical conductor 5936 including the electronic circuit system configuration switch 5974. Said another way, when the electronic circuit system 5900 is attached to the housing 5110, the actuation protrusion 5114 moves irreversibly the electronic circuit system configuration switch 5974 from a first state (e.g., a state of electrical continuity) to a second state (e.g., a state of electrical discontinuity).

[0148] The tear propagation limit aperture 5978 is configured to limit the propagation of the tear in the substrate 5924. Said another way, the tear propagation limit aperture 5978 is configured to ensure that the tear in the substrate 5924 does not extend beyond the tear propagation limit aperture 5978. The tear propagation limit aperture 5978 can be any shape configured to limit the propagation of a tear and/or disruption of the substrate 5924. For example, the tear propagation limit aperture 5978 can be oval shaped. In other embodiments, the boundary of the tear propagation limit aperture 5978 can be reinforced to ensure that the tear in the substrate 5924 does not extend beyond the tear propagation limit aperture 5978. The angled end portion 5115 of the actuation protrusion 5114 ensures that the tear in the substrate 5924 propagates in the desired direction. Said another way, the angled end portion 5115 of the actuation protrusion 5114 ensures that the tear in the substrate 5924 occurs between the actuation aperture 5975 and the tear propagation limit aperture 5978.

[0149] When the actuation protrusion 5114 of the housing 5110 moves irreversibly the electronic circuit system configuration switch 5974 of the electronic circuit system 5900 from the first state to the second state, the electronic circuit system 5900 can be moved between a first configuration and a second configuration. For example, in some embodiments, irreversibly moving the electronic circuit system configuration switch 5974 of the electronic circuit system 5900 to the second state places the electronic circuit system 5900 in the second configuration such that when power is applied to the electronic circuit system 5900, the electronic circuit system 5900 recognizes that the medicament delivery device 5000 is a certain type of medicament delivery device and/or is in a certain configuration. In some embodiments, the housing can be devoid of the actuation protrusion 5114, thus the electronic circuit system configuration switch 5974 is maintained in its first state when the electronic circuit system 5900 is attached to the housing 5110. In this manner, the electronic circuit system configuration switch 5974 can enable the electronic circuit system 5900 to be used in different types and/or configurations of medicament delivery devices. The dual functionality of the electronic circuit system 5900 enables production of the same electronic circuit system 5900 for multiple devices, thereby permitting

mass production and decreasing the cost of production of the electronic circuit system **5900**.

[**0150**] For example, in some embodiments the electronic circuit system **5900** can be used in either an actual medicament delivery device or a simulated medicament delivery device. A simulated medicament delivery device can, for example, correspond to an actual medicament delivery device and can be used, for example, to train a user in the operation of the corresponding actual medicament delivery device.

[**0151**] The simulated medicament delivery device can simulate the actual medicament delivery device in any number of ways. For example, in some embodiments, the simulated medicament delivery device can have a shape corresponding to a shape of the actual medicament delivery device, a size corresponding to a size of the actual medicament delivery device and/or a weight corresponding to a weight of the actual medicament delivery device. Moreover, in some embodiments, the simulated medicament delivery device can include components that correspond to the components of the actual medicament delivery device. In this manner, the simulated medicament delivery device can simulate the look, feel and sounds of the actual medicament delivery device. For example, in some embodiments, the simulated medicament delivery device can include external components (e.g., a housing, a needle guard, a sterile cover, a safety lock or the like) that correspond to external components of the actual medicament delivery device. In some embodiments, the simulated medicament delivery device can include internal components (e.g., an actuation mechanism, a compressed gas source, a medicament container or the like) that correspond to internal components of the actual medicament delivery device.

[**0152**] In some embodiments, however, the simulated medicament delivery device can be devoid of a medicament and/or those components that cause the medicament to be delivered (e.g., a needle, a nozzle or the like). In this manner, the simulated medicament delivery device can be used to train a user in the use of the actual medicament delivery device without exposing the user to a needle and/or a medicament. Moreover, the simulated medicament delivery device can have features to identify it as a training device to prevent a user from mistakenly believing that the simulated medicament delivery device can be used to deliver a medicament. For example, in some embodiments, the simulated medicament delivery device can be of a different color than a corresponding actual medicament delivery device. Similarly, in some embodiments, the simulated medicament delivery device can include a label clearly identifying it as a training device.

[**0153**] The actuation of the medicament delivery device configuration switch **5974** can configure the electronic circuit system **5900** to output a different electronic output when the medicament delivery device **5000** is a simulated medical injector than when the medicament delivery device **5000** is an actual medical injector. Said yet another way, the electronic circuit system **5900** can be configured to output a first series of electronic outputs when the electronic circuit system configuration switch **5974** is in the first state and a second series of electronic outputs when the electronic circuit system configuration switch **5974** is in the second state. In this manner, the electronic circuit system configuration switch **5974** can enable the same electronic circuit system **5900** to be used in both simulated medicament

delivery devices and actual medicament delivery devices. When used on an actual medicament delivery device, for example, the housing can be devoid of the actuation protrusion **5114**. The dual functionality of the electronic circuit system **5900** can decrease the cost of production of the electronic circuit system **5900** of the medicament delivery device **5000**.

[**0154**] In other embodiments, moving the electronic circuit system configuration switch **5974** to the second state can place the electronic circuit system **5900** in any number of different functional configurations. For example, moving the electronic circuit system configuration switch **5974** from the first state to the second state can indicate the type of medicament in the medicament container, the dosage of the medicament and/or the language of the audible electronic outputs output by the electronic circuit system **5900**.

[**0155**] In still other embodiments, any number of electronic circuit system configuration switches can be used. For example, multiple switches can be used to configure the electronic circuit system **5900** to output usage instructions in any number of languages. For example, if an electronic circuit system contained three configuration switches (e.g., switches A, B and C), switch A can correspond to English instructions, switch B to Spanish instructions and switch C to German instructions. Further, moving both switch A and B to the second state might correspond to French instructions. In this manner, a single electronic circuit system **5900** can be configured to output instructions in multiple languages.

[**0156**] FIG. **41** is a flow chart of a method **100** according to an embodiment of the invention. The method includes assembling a medical device configured to deliver a medicament into a body of a patient, **102**. The medical device includes a housing, a medicament container disposed within the housing, an actuator, and a safety lock. In some embodiments, the housing, medical container, the actuator, and the safety lock can be similar to the corresponding components in the medical injector **4000** and/or the medicament delivery device **5000**, described above. The actuator of the medical device is configured to initiate delivery of the medicament from the medicament container when the actuator is actuated. The safety lock of the medical device is configured to prevent actuation of the actuator.

[**0157**] After the medical device is assembled, at least a portion of the medical device can optionally be sterilized, **104**. Various sterilization techniques may be utilized. In some embodiments, a suitable sterilization technique includes the use of one or more of ethylene oxide, gamma radiation, e-beam radiation, ultraviolet radiation, steam, plasma, or hydrogen peroxide. In some embodiments, the needle is sterilized prior to installing the needle cover. In some embodiments, the needle is sterilized after the needle cover is installed. For example, in some embodiments, the needle cover is installed and then a gas sterilant—is conveyed through at least a portion of the needle cover. The needle is sterilized using a gas sterilization technique that can penetrate one or more pores of a porous needle cover. In some embodiments, the needle can be sterilized using a gas sterilization technique that can penetrate one or more pores of a porous needle cover, but that will not react with a medicament in a medicament container disposed in the housing.

[**0158**] An electronic circuit system is then coupled to the housing of the assembled medical device, **106**. The elec-

tronic circuit system is coupled to the housing such that an opening defined by a substrate of the electronic circuit system is disposed about a portion of the safety lock. The electronic circuit system is configured to output an electronic output in response to a movement of the safety lock within the opening. In some embodiments, for example, the electronic circuit system can be similar to the electronic circuit system **4900** of the medical injector **4000** and/or the electronic circuit system **5900** of the medicament delivery device **5000**, as described above. In some embodiments, the electronic output can be, for example, a visual output, an audible output, and/or a haptic output, such as those described above. In other embodiments, the electronic output can be a wireless signal configured to be received by a remote device.

[0159] After the electronic circuit system is coupled to the housing, a cover can optionally be disposed about the medical device, **108**. The cover can have a protrusion disposed between a battery and a battery contact portion of the electronic circuit system. In some embodiments, for example, the cover can be similar to the cover **4200** of the medical injector **4000** and/or the cover **5200** of the medical injector **5000**.

[0160] FIG. **42** is a flow chart of a method **120** according to an embodiment of the invention. The method includes optionally assembling a simulated medicament delivery device, **122**. The medicament delivery device can include a housing, an actuator and a safety lock. The simulated medicament delivery device is configured to simulate an actual medicament delivery device. An electronic circuit system is then aligned with a portion of the housing configured to receive the electronic circuit system, **124**. Aligning the electronic circuit system with the housing ensures that portions of the housing align with corresponding portions of the electronic circuit system. If the corresponding portions do not align, a number of issues can arise. For example, the electronic circuit system may not function correctly and/or the electronic circuit system may be damaged as a result of improper alignment.

[0161] The electronic circuit system is then coupled to the simulated medicament delivery device such that a portion of the housing actuates a switch of the electronic circuit system, **126**. The electronic circuit system is configured to output an electronic output associated with a use of the simulated medicament delivery device and a state of the switch. The switch can be similar to the electronic circuit system configuration switch **5974** of the medicament delivery device **5000**. For example, the electronic circuit system can output a first electronic output associated with a use of the simulated medicament delivery device when the switch is in a first state and a second electronic output associated with a use of the simulated medicament delivery device when the switch is in a second state. In some embodiments, the electronic output can be, for example, a visual output, an audible output, and/or a haptic output, such as those described above. In other embodiments, the electronic output can be a wireless signal configured to be received by a remote device. As described above, any number of switches can be disposed on the electronic circuit system.

[0162] In some embodiments, an electronic self-test can be used to verify the integrity of an electronic circuit system and/or the switches of a medicament delivery device. FIG. **43** is a flow chart of a self-test method **150** that can be administered to ensure that a switch of the electronic circuit

system is in the proper state (i.e., a state that corresponds to the configuration of the medicament delivery device). For example, in some embodiments the method **150** can ensure that the electronic circuit system configuration switch is in the correct state (i.e., a first state if the medicament delivery device is an actual medicament delivery device or a second state if the medicament delivery device is a simulated medicament delivery device). The method includes applying power to the battery terminals, **152** and thus the electronic circuit system. If the electronic circuit system configuration switch is in the first state, **154**, the electronic circuit system will output a first output sequence, **155**. For example, the first output sequence can consist of the LEDs blinking in a first predetermined sequence (e.g., green-red-green) followed by an audible output. The first output sequence can indicate that the medicament delivery device is an actual medicament delivery device and not a simulated medicament delivery device. If the electronic circuit system configuration switch is in the second state, **156**, the electronic circuit system will output a second output sequence, different than the first, **157**. For example, the second output sequence can consist of the LEDs blinking in a second predetermined sequence (e.g., red-green-green) followed by an audible output. The second output sequence can indicate that the medicament delivery device is a trainer. If neither the first output sequence nor the second output sequence occurs, the medical injector has failed the test, **158**, indicating that an error exists within the electronic circuit system.

[0163] In other embodiments, different electronic output sequences can be used to indicate and/or test different modes of the medical injector. For example, the LEDs could blink in a third sequence to indicate a Spanish medical injector. Additionally, any number of self tests can be used to determine the state of each switch of the electronic circuit system. Further, the integrity of any number of electronic components of the medicament delivery device can be tested by the self-test. For example, the integrity of the LEDs and/or audio output device can be tested using a similar self-test as the one described above.

[0164] While various embodiments of the invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods described above indicate certain events occurring in certain order, the ordering of certain events may be modified. Additionally, certain of the events may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above.

[0165] For example, in some embodiments, the sidewall of the housing of a medicament delivery device can be rigid. In other embodiments, the sidewall can be a movable member such as, for example, a piston. In yet other embodiments, the sidewall can be a flexible member such as, for example, a diaphragm. In some embodiments, the sidewall can be transparent allowing light to pass from a first region to a second region and vice versa. A transparent sidewall can be used in conjunction with an optical sensor. The sidewall can be integrally formed with the housing or can be separately formed.

[0166] In other embodiments, the medicament container can be substantially cylindrical with a substantially round and/or substantially elliptical cross-sectional shape. Thus, the medicament container can define a longitudinal axis, the longitudinal axes of the medicament container can be par-

allel, non-coaxial, and/or co-planar. The longitudinal axis of the medicament container can be co-axial with a longitudinal axis of the piston portion of a movable member **4530**. In still other embodiments, a medicament delivery device can contain multiple medicament containers and thus, multiple doses of medicament.

[0167] Although medical devices having two LEDs and an audio output device have been shown, in other embodiments the medical device might have any number of LEDs and/or audio output devices. Additionally, other types of output devices, such as haptic output devices, can be used.

[0168] Although various embodiments have been described as having particular features and/or combinations of components, other embodiments are possible having a combination of any features and/or components from any of embodiments where appropriate. For example, electrical circuit system **4900** can include an electronic circuit system configuration switch similar to that of electrical circuit system **5900**.

What is claimed is:

1. An apparatus comprising:
 - a medicament delivery device configured to deliver a medicament, the medicament delivery device including a first housing and a medicament container, a distal end portion of the medicament container including a delivery member through which the medicament is conveyed, a side wall of the first housing defining an interior volume within which the distal end portion of the medicament container is movably disposed;
 - a second housing formed separately from the first housing, the second housing including a connection portion configured to be matingly coupled to a corresponding portion of the medicament delivery device; and
 - an electronic circuit system including a switch, a light output device and a wireless network interface device, the electronic circuit system configured to produce a light output via the light output device when the switch is changed from a first state to a second state, the electronic circuit system configured to receive an actuation signal associated with the actuation of the medicament delivery device, the electronic circuit system configured to output, via the wireless network interface device, a wireless signal associated with the actuation signal.
2. The apparatus of **1**, wherein the medicament delivery device is any one of a pen injector, an auto-injector, or an inhaler.
3. A method, including:
 - aligning an electronic circuit system with a medicament delivery device, the medicament delivery device including a first housing and a medicament container, a

distal end portion of the medicament container including a delivery member through which a medicament is conveyed, a side wall of the first housing defining an interior volume within which the distal end portion of the medicament container is movably disposed, the electronic circuit system coupled to a second housing, the electronic circuit system including a switch, a light output device and a wireless network interface device, the electronic circuit system configured to produce an electronic output via one of the light output device or the wireless network interface device when the switch is changed from a first state to a second state; and

coupling the second housing to the medicament delivery device such that a connection portion of the medicament delivery device changes the switch from the first state to the second state.

4. The method of **3**, wherein the medicament delivery device is any one of a pen injector, an auto-injector, or an inhaler.
5. An apparatus, comprising:
 - a simulated medicament delivery device configured to simulate an operation of an actual medicament delivery device, the simulated medicament delivery device being devoid of at least one of a medicament or a needle, the simulated medicament delivery device including a first housing defining an opening; and
 - a second housing formed separately from the first housing, the second housing including a connection portion configured to be matingly coupled to a corresponding portion of the simulated medicament delivery device; and
 - an electronic circuit system including a switch, a light output device and a wireless network interface device, the electronic circuit system configured to produce a light output via the light output device when the switch is changed from a first state to a second state, the electronic circuit system configured to receive an actuation signal associated with the actuation of the simulated medicament delivery device, the electronic circuit system configured to output, via the wireless network interface device, a wireless signal associated with the actuation signal.
6. The apparatus of claim **5**, wherein:
 - the first housing defines a status aperture; and
 - the simulated medicament delivery device includes a status indicator visible through the status aperture, the status indicator configured to display a visual indicia to simulate a status indicator of the actual medicament delivery device.

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