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DRUG DELIVERY DEVICE CASSETTE

Abstract

A drug delivery device may include a cassette with a needle assembly and a cartridge. The cassette is configured to couple and decouple from a reusable module. The device may also comprise an orientation mechanism to orient the cassette in relation to another device, such as a reusable housing. The device may comprise an extendable and retractable needle assembly. The cassette configuration is adapted to have a stopper with a short travel (no more than 14 mm) to deliver 1 mL of medication. The cassette may have a ratio of height to diameter from 2:1 to 1:1. The cassette may include a pair of drivable interfaces for being driven to actuate the stopper to expel medication and to drive the needle assembly between a retracted and extended configuration for controlled fluid communication between the needle and reservoir.

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Background/Summary

FIELD OF THE DISCLOSURE

[0001] The present disclosure relates to a drug delivery device with a cassette. The cassette may comprise an extendable needle assembly.

BACKGROUND OF THE DISCLOSURE

[0002] Conventional injection devices are often used to drive a needle through a surface, for example in the injection of a drug, removing a fluid from a sealed container such as a vial, sampling within chemical instrumentation, and so on. Considering the example of injecting a patient with a drug, it is sometimes advantageous for the drug to be administered without the presence of a medical professional (e.g. when taken frequently). The use of standard glass cartridges may provide a challenge for developing a space-efficient injection device. Furthermore, the disposal of glass cartridges may incur more environmental costs when compared to other materials. Additionally, it may be a challenge to ensure that the injection device is properly assembled and oriented by a user before use.

SUMMARY

[0003] The present disclosure provides devices and methods for delivery of a medication comprising a cassette with a cartridge configured to retain a volume of a medication, and an extendable and retractable needle assembly.

[0004] According to an exemplary embodiment of the present disclosure, a drug delivery device includes a cassette that includes a cartridge configured to retain a volume of a medication; a stopper driving system configured to drive the medication from the cartridge, the stopper driving system including a stopper, wherein the stopper travels less than 10 mm to deliver a 1 mL volume of the medication; and a needle assembly directly coupled to the cartridge movable between an extended configuration and a retracted configuration, the needle assembly having an actuating gear movable between first and second positions, wherein in the extended configuration the actuating gear is in the second position and the needle assembly provides fluid communication between the cartridge and the needle assembly, wherein in the retracted configuration the actuating gear is in the first position and no fluid communication is provided between the cartridge and the needle assembly.

[0005] According to another embodiment of the present disclosure, a method of delivering a medication to a patient includes coupling a housing of a drug delivery device to a cassette; orienting the housing relative to the cassette; positioning the drug delivery device against a skin of the patient; actuating a needle assembly of the drug delivery device to extend a first needle into the skin of the patient and a second needle into a septum of a polymeric cartridge containing a volume of a medication; actuating a driving system to drive the medication from the polymeric cartridge through the needle assembly and to the patient; and retracting the first and second needles within the needle assembly.

[0006] According to another embodiment of the present disclosure, a drug delivery device includes a reusable housing; a cassette coupled to the reusable housing, wherein the cassette has a ratio of height to diameter from 2:1 to 1:1; a cartridge supported by cassette and configured to retain a volume of a medication; and an orientation mechanism configured to orient the cassette relative to the reusable housing.

[0007] According to another embodiment, a drug delivery device having a cassette to couple to a

reusable module is disclosed. The cassette includes a cartridge configured to retain a volume of a medication. The cartridge extends between a proximal end and a distal end along an axis that is centrally located. A stopper driving system is configured to drive the medication from the cartridge. The stopper driving system includes a stopper and an interfacing end coupled to the stopper and configured to be driven by a first motor or actuating device of the reusable module to move the stopper. A needle assembly is directly coupled to the cartridge movable between an extended configuration and a retracted configuration. The needle assembly has an actuating gear movable between first and second positions. The actuating gear is configured to be directly or indirectly driven by a second motor or actuating device of the reusable module. In the extended configuration, the actuating gear is in the second position and the needle assembly provides fluid communication between the cartridge and the needle assembly. In the retracted configuration, the actuating gear is in the first position and no fluid communication is provided between the cartridge and the needle assembly. The interfacing end extends from an upper end of the cartridge and coaxial with the axis, and the actuating gear is disposed to be engaged externally by the second motor or actuating device of the reusable module at a location offset from the axis.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The above-mentioned and other features and advantages of this disclosure, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

[0009] FIG. **1** is a simplified, cross-sectional view of an exemplary drug delivery device;

[0010] FIG. **2** is a simplified, cross-sectional view of another exemplary drug device with a detachable cassette and needle assembly;

[0011] FIG. **3** is a simplified, cross-sectional view of yet another exemplary drug delivery device with a detachable needle assembly;

[0012] FIG. **4** is a perspective view of yet another exemplary drug delivery device;

[0013] FIG. **5** is a cross-sectional view of the device of FIG. **4**;

[0014] FIG. **6** is a perspective view of still another exemplary drug delivery device;

[0015] FIG. **7** is a cross-sectional view of the device of FIG. **6**;

[0016] FIG. **8** is a perspective view of a driving system of the device of FIG. **4**;

[0017] FIG. **9** is a diagrammatic view of the driving system of FIG. **8**;

[0018] FIG. **10** is a diagrammatic view of a control system for the driving system of FIG. **8**;

[0019] FIG. **11** is a perspective view of an exemplary needle assembly;

[0020] FIG. **12** is a rear view of the needle assembly of FIG. **11**;

[0021] FIG. **13** is an exploded view of the needle assembly of FIG. **11**;

[0022] FIG. **14** is a cross-sectional view of the needle assembly of FIG. **11**;

[0023] FIGS. **15** and **16** are perspective views of a needle mechanism within the needle assembly of FIG. **11**;

[0024] FIGS. **17** and **18** are side elevational views of the needle mechanism of FIGS. **15** and **16** without the driving member;

[0025] FIGS. **19** and **20** are perspective views of a driving member of the needle mechanism of FIGS. **15** and **16**;

[0026] FIGS. **21** and **22** are side views of the needle mechanism of FIGS. **15** and **16** showing a motion of the needle mechanism from a first configuration in FIG. **21** to a second configuration in FIG. **22**;

[0027] FIG. **23** is a perspective view of yet another embodiment of a needle assembly;

[0028] FIG. **24** is an exploded view of the needle assembly of FIG. **23**;
[0029] FIG. **25** is a perspective view of a needle mechanism within the needle assembly of FIG. **23**;
[0030] FIG. **26** is a perspective view of a needle support of the needle mechanism of FIG. **25**;
[0031] FIG. **27** is a perspective view of a driving member of the needle mechanism of FIG. **25**;
[0032] FIG. **28** is a side view of a needle mechanism within the needle assembly of FIG. **23** showing a movement of the needle mechanism from a first configuration in FIG. **38**;
[0033] FIGS. **29** and **30** are perspective views of a needle mechanism within the device of FIG. **4**;
[0034] FIGS. **31-32** are perspective views of another needle mechanism within the device of FIG. **4**;
[0035] FIGS. **33-34** are perspective views of a needle mechanism within the device of FIG. **6**; and
[0036] FIG. **35** is diagrammatic view of an exemplary wireless communication system for use with a drug delivery device.
[0037] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate exemplary embodiments of the invention and such exemplifications are not to be construed as limiting the scope of the invention in any manner.
DETAILED DESCRIPTION
[0038] Exemplary drug delivery devices **11**, **12**, and **13** are illustrated in FIGS. **1-4** and **6**. Each of the shown devices **11**, **12**, and **13**, is a reusable pen-shaped medication injection device which may be manually handled by a user (e.g., a patient, a caregiver, or a healthcare professional) to deliver a medication to a patient. Cassettes **100**, **200** may also be referred to as drug delivery devices or as drug delivery cassettes. The combination of cassettes **100**, **200** with a motor housing system (that may be reusable) may also be considered a drug delivery device. In certain embodiments, the user may selectively set a dose and then to inject that set dose into the patient. Devices **11**, **12**, **13**, **100**, and **200** are intended to be illustrative and not limiting as the needle assemblies described further below may be used in other differently configured devices.
[0039] The medication may be any type that may be delivered by such a device **11**, **12**, **13**, **100**, and **200**. The medication may be in fluid form of various viscosities or any other suitable form. The medication includes one or more therapeutic agents including but not limited to insulins, insulin analogs such as insulin lispro or insulin glargine, insulin derivatives, GLP-1 receptor agonists such as dulaglutide or liraglutide, glucagon, glucagon analogs, glucagon derivatives, gastric inhibitory polypeptide (GIP), GIP analogs, GIP derivatives, dual agents of any combination above, such as, for example, GIP/GLP-1 receptor agonist, tirzepatide, retatrutide, oxyntomodulin analogs, oxyntomodulin derivatives, therapeutic antibodies including but not limited to IL-23 antibody analogs or derivatives, such as mirikizumab, IL-17 antibody analogs or derivatives, such as ixekizumab, therapeutic agents for pain-related treatments, such as galcanzeumab or lasmiditan, antibody analogs or derivatives related to treatment of atopic dermatitis, such a lebrikizumab, antibody analogs or derivatives related to treatment of neurodegeneration, such as donanemab, solanezumab, remternetug, and any therapeutic agent that is capable of delivery by the device **11**, **12**, **13**, **100**, and **200**. The medication as used in the device **11**, **12**, **13**, **100**, and **200** may be formulated with one or more excipients.
[0040] Referring first to FIG. **1**, an exemplary embodiment of a drug delivery device **11** is shown. Drug delivery device **11** extends from a proximal end **19** to a distal end **18**, and comprises a housing **15**, a first motor **22**, a driving system **25**, a cartridge **30** configured to retain the medication, and a needle assembly **50**. In the illustrated embodiment, drug delivery device **11** is configured to be positioned with distal end **18** near a patient's skin, such that needle assembly **50** may deliver the medication from within cartridge **30** to the patient. Cartridge **30** may also be described as a cassette, or a syringe, and is generally configured to contain and at least partially deliver the medication.
[0041] Cartridge **30** additionally comprises a fluid housing or barrel **31**, a plunger or stopper **33**, and a septum **35**. The medication is retained within fluid housing **31** by stopper **33**. The activation

of first motor **22** actuates driving system **25** to drive stopper **33** downward to push the medication towards septum **35** and ultimately through needle assembly **50**. First motor **22** may be controlled by a motor controller (not shown) to adjust the force applied to driving system **25** and/or the rate that driving system **25** is actuated.

[0042] Needle assembly **50** additionally comprises a first needle **51**, a second needle **53**, a needle driving mechanism **55** coupled to the first and second needles **51**, **53**, and an optional second motor **57** configured to actuate needle driving mechanism **55**. Activation of second motor **57** actuates needle driving mechanism **55** and drives first needle **51** towards distal end **18** and drives second needle **53** towards proximal end **19** into an extended configuration whereby first needle **51** pierces at least the patient's skin, and second needle **53** pierces septum **35**. In some embodiments, drug delivery device **11** only comprises first motor **22** and does not comprise the second motor **57**. In such embodiments, first motor **22** may be coupled or linked to needle driving mechanism **55** such that activation of first motor **22** may additionally actuate needle driving mechanism **55**. In such embodiments, the first motor **22** may actuate different aspects of the drug delivery device **11** through a clutch mechanism. As will be described in more detail later, first needle **51** and second needle **53** are fluidly coupled together to allow flow of the medication from cartridge **30**, through second needle **53**, through first needle **51**, and ultimately to the patient.

[0043] Drug delivery device **11** is configured as a singular device and may also be configured to be disposable after use. In the illustrated embodiment, cartridge **30** and needle assembly **50** are fixedly coupled to and/or an integral part of drug delivery device **11**. Cartridge **30** may contain a single dose of the medication to be delivered or may contain the medication to be delivered in multiple doses/injections. In embodiments where cartridge **30** comprises multiple doses of the medication, first motor **22** may be configured to only push out a portion of the medication within cartridge **30** for each dose, and needle assembly **50** may comprise multiple sets of needles to inject one or more medications into a patient.

[0044] Referring now to FIG. **2**, another embodiment of a drug delivery device **12** is shown. Drug delivery device **12** functions similar to drug delivery device **11** of FIG. **1** and comprises similar components. However, drug delivery device **12** differs from drug delivery device **11** in that cartridge **30** and needle assembly **50** are removable from housing **15** of a reusable or durable housing component. Needle assembly **50** and cartridge **30** may be separate components from one another or may be one single component. In the illustrated embodiment, housing **15**, first motor **22**, driving system **25**, and second motor **57** may all be part of the reusable housing, and cartridge **30** and needle assembly **50** may be disposable. In such an embodiment, a user may insert, use, and remove multiple instances of cartridge **30** and needle assembly **50**, either together or separately. As was the case with drug delivery device **11**, cartridge **30** of drug delivery device **12** may still comprise the medication for a single dose or multiple doses. Cartridge **30** and needle assembly **50** may couple to housing **15** of drug delivery device **12** through any suitable coupling mechanism, including but not limited to threading, bayonet couplers, screws, rivets, snaps, ball-detent mechanisms, spring systems, pins, magnets, friction fitting, adhesives, or any other suitable coupling device, and combinations thereof. In embodiments where cartridge **30** and needle assembly **50** are separate components, any suitable coupling device such as those mentioned above may additionally be used to couple cartridge **30** and needle assembly **50**. In the illustrated embodiment, second motor **57** is coupled to housing **15**, and is not shown as part of needle assembly **50** or cartridge **30**, but instead couples to needle assembly **50** when needle assembly **50** is coupled to housing **15**. In other embodiments, second motor **57** may be part of needle assembly **50** and may be couplable and decouplable from housing **15** with needle assembly **50**.

[0045] Referring now to FIG. **3**, another embodiment of a drug delivery device **13** is shown. Drug delivery device **13** is similar to drug delivery device **11** of FIG. **1** and drug delivery device **12** of FIG. **2**, except that cartridge **30** is fixedly coupled to housing **15**, and needle assembly **50** is removably coupled to housing **15**. Needle assembly **50** may be disposable while cartridge **30** and/or

housing **15** may be reusable. In the illustrated embodiment, housing **15** and cartridge **30** may be used multiple times with different instances of needle assembly **50**. In some embodiments, cartridge **30** may be refillable with the medication. As mentioned before with respect to drug delivery device **12**, needle assembly **50** may be coupled to housing **15** through any suitable coupling device or system. Additionally, second motor **57** may be part of housing **15** or needle assembly **50**. Additional embodiments, configurations, and details of drug delivery devices and their components will be discussed below.

[0046] Referring now to FIGS. **4-5**, a cassette **100** for another embodiment of a drug delivery device like the one in FIG. **2** is shown. Cassette **100** comprises one or more of the following: a housing **115**, a stopper driving system **120**, a cartridge **130** which may be coupled to or integrally formed with housing **115**, a stopper **133**, a fluid housing **131**, a septum **135**, a cassette ID **175**, an orientation mechanism **180**, a needle assembly **400**, and a needle assembly actuating gear **154**. The cassette **100** may also comprise a reusable or durable housing (not shown) to which the housing **115** may be coupled. The reusable housing may also comprise a number of motors, such as the first motor **22** and second motor **57** described above, as well as a controller, processor, memory, user interface, and/or other features configured to interact with cassette **100**.

[0047] Cassette **100** is configured to retain a volume of a medication within fluid housing **131**, and to deliver the medication to a patient in a similar fashion to devices **11**, **12**, and **13** described above. Actuation of the needle assembly actuating gear **154** causes the needle assembly **400** (See FIG. **29**) to extend, piercing the septum **135** with a first needle, and a surface such as a patient's skin with a second needle. The cassette **100** may also comprise a seal **195** configured to seal at least a portion of needle assembly **400** within cassette **100** before the extension of the second needle. The seal **195** may also maintain a sterile environment within cassette **100**. When extended, needle assembly **400** provides fluid communication between the fluid housing **131** and the second needle. A motor and/or a user-activated actuator (e.g. a button, a knob, a plunger, etc.) may then cause stopper **133** to drive the medication out of fluid housing **131** through needle assembly **400** and to a patient. Needle assembly **400** may then be retracted through actuation, such as reverse actuation, of needle assembly actuating gear **154**.

[0048] The orientation mechanism **180** is configured to orient at least a portion of cassette **100** rotationally around a central axis A**1**. For example, orientation mechanism **180** may orient housing **115** at a particular angular orientation with respect to a reusable housing or with respect to a motor or actuation device. In the illustrated embodiments, orientation mechanism **180** is shown as a radial protrusion. The reusable housing or other device that contains a motor or actuation device comprises a complimentary recess or slot to receive the orientation mechanism **180**. Accordingly, when a user couples cassette **100** to the reusable housing, cassette **100** may be restricted to a certain orientation with respect to the reusable housing Achieving a desired orientation may allow a motor or other actuation device to operably couple with needle assembly actuating gear **154** and/or stopper driving system **120**. The desired orientation may also allow for cassette ID **175** to be positioned such that it may be read or scanned by a cassette ID reading system. Additionally, the orientation mechanism **180** may orient the cassette **100** with respect to a patient's skin, and/or orient the needle assembly **400** with respect to any other component of cassette **100**. While orientation mechanism **180** is illustrated as a protrusion, orientation mechanism **180** may also be a slot to interface with a protrusion on a reusable housing. Furthermore, orientation mechanism **180** may be a gear, a ramped or curved surface, a knob, a plurality of protrusions or slots, a screw, or any other mechanism configured to orient cassette **100**. In another embodiment, the loading of the cassette into the reusable housing is axial, whereas there are other embodiments where the loading of the cassette is radially into the reusable housing.

[0049] Any components of cassette **100**, such as housing **115**, cartridge **130** and/or fluid housing **131** may be composed of a polymer. Utilizing a polymeric cartridge instead of a standard glass cartridge provides more flexibility when manufacturing cassette **100**. For example, a polymeric

cartridge may be shaped differently than standardized glass cartridges, allowing for a more compact design while maintaining the same volume as a standard glass cartridge.
[0050] Furthermore, polymeric cartridges may be more easily manufactured, disposed of, and/or recycled compared to glass cartridges. Additionally, polymeric cartridges may be manufactured to directly interact with or couple with other components of cassette **100**. For example, cartridge **130** may couple with needle assembly **400** without the need for additional coupling components (e.g., fasteners), since cartridge **130** may be manufactured with integral coupling features, or may be integrally formed with needle assembly **400**. As another example, and as discussed above, cartridge **130** may be coupled to or integrally formed with housing **115**.
[0051] Use of polymeric material may reduce the form factor or aspect ratio of cassette **100** in comparison to a cassette that utilizes a standard glass cartridge, which may allow for more compact or efficient packaging. The cassette **100** may have a height of less than 75 mm, less than 70 mm, less than 65 mm, less than 60 mm, less than 55 mm, less than 50 mm, less than 45 mm, less than 40 mm, or any range including any two of these values as endpoints. The cassette 100 may have a diameter of less than 50 mm, less than 45 mm, less than 40 mm, less than 35 mm, less than 30 mm, less than 25 mm, less than 20 mm, less than 15 mm, or any range including any two of these values as endpoints. More specifically, the cassette may have a height from 45 mm to 60 mm, and a diameter of 25 mm to 35 mm. Stated differently, the cassette **100** may have an aspect ratio of height: diameter of X: Y where X and Y are each independently 5, 4.75, 4.5, 4.25, 4, 3.75, 2.5, 3.25, 3, 2.75, 2.5, 2.25, 2, 1.75, 1.5, 1, or any range including any two of these values as endpoints. For example, cassette **100** may have an aspect ratio from 2:1 to 1:1.
[0052] Reducing the aspect ratio of the cassette **100** and/or cartridge **130** may also reduce the distance that the stopper or a plunger may have to travel in delivery of medication. A standard 1.6 mL glass cartridge may have an inner diameter of around 9.25 mm, and require a stopper to travel at least 14 mm to fully deliver 1 mL of a medication from the cartridge. A standard 3.0 mL glass cartridge may have an inner diameter of around 9.7 mm, and may require a stopper to travel at least 13 mm to fully deliver 1 mL of medication from the cartridge. Alternatively, the cartridge **130** of cassette **100** may require a stopper travel distance of less than 10 mm, less than 9 mm, less than 8 mm, less than 7 mm, less than 6 mm, less than 5 mm, or any range including any two of these values as endpoints in order to fully deliver a medication from cartridge **130**. Stated differently, the ratio of the distance of stopper **133** travel to fully deliver a medication to the inner diameter of the cartridge **130** may be A: B where A and B are independently 1, 1.25, 1.5, 1.75, 2, 2.25, 2.5, 2.75, 3, or any range including any two of these values as endpoints. For example, the ratio of A: B may be from 1:1 to 1:3, or more particularly from 1:1.5 to 1:2.5. “Fully delivered” indicates that a full cartridge is essentially completely emptied of medication. Reduction in stopper travel length may reduce the complexity of moving parts within cassette **100** or within the overall drug delivery device. The volume of the cassette may provide any volume of medication, such as 0.5 mL, 1.0 mL, 2.0 mL, 3.0 mL, 10 mL, or the like.
[0053] In the illustrated embodiments, cassette ID **175** is positioned on the orientation mechanism **180**. Cassette ID **175** may be any sort of mechanism or device that provides data about a component of cassette **100**. For example, Cassette ID **175** may comprise a chip, an RFID indicator, a unique coded pattern, and/or an antenna that provides data regarding the type of medication within cassette **130** (e.g. specific medication, viscosity, volume, dosage, injection scheduling, etc.). The cassette ID **175** may also provide data related to the orientation or assembly of the cassette **100** (e.g. indicating whether or not the device is fully or properly assembled, whether the device is in the proper orientation, etc.). The cassette ID **175** may provide data from a sensor or a plurality of sensors within cassette **100**, such as a position sensor, a fluid level sensor, a damage or failure sensor, a battery level sensor, and/or a pressure sensor.
[0054] Referring now to FIGS. **6-7**, another embodiment of a cassette **200** is shown. Cassette **200** is similar to cassette **100** in overall operation and comprises similar components. Cassette **200**

comprises a housing **215**, a stopper driving system **220**, a cartridge **230**, a stopper **233**, a fluid housing **231**, a septum **235**, a cassette ID **275**, a needle assembly **401**, and a needle assembly actuating gear **254**. Cassette **200** and its components function in a similar fashion and have similar features as the corresponding components in cassette **100**. Furthermore, any reference to cassette **100** herein may be applied to cassette **200**.

[0055] Cassette **200** also comprises an external gear **280** which is configured to interface with needle assembly actuating gear **254** to actuate needle assembly **401**. A motor or a user-activated actuator from the reusable module may rotate external gear **280** which in turn may rotate relative to a lower housing **410** and cartridge **230** to rotate needle assembly actuating gear **254** to actuate needle assembly **401**, as will be described in additional detail herein. External gear **280** may comprise external gear teeth or other interface features **280**A (see FIG. **33**) to be driven by a motor or other actuating device, such as the second motor **57**. Cassette **200** may be configured such that it may be oriented in any axial/rotational position around central axis A**1** when coupled to a reusable or reusable housing. While cassette **100** comprises orientation mechanism **180** to orient cassette **100** relative to a housing, cassette **200** may not require any similar orientation. In some embodiments, external gear **280** may function as an orientation mechanism, similar to orientation mechanism **180**, to rotate cassette **200** or components thereof around central axis A**1**. A clutch or similar mechanism may be employed to cause the rotation of external gear **280** to rotate all of or a portion of cassette **200**, and the clutch may be activated to cause rotation of external gear **280** to then rotate needle assembly actuating gear **254**. Accordingly, external gear **280** may be utilized to orient components of cassette **200** with respect to a reusable housing, a motor, or another device external to cassette **200**. In some embodiments, cassette **200** may not need to be oriented relative to any other component, and may be assembled or coupled with a reusable housing in any axial position.

[0056] The cassette ID **275** of cassette **200** may be implemented such that a particular angular orientation can be avoided. For example, the cassette ID **275** is illustrated as a series of concentric rings on a proximal end of cassette **200**. Cassette ID **275** may be referred to as a circular cassette ID. Cassette ID **275** functions similarly to cassette ID **175**, with a different position and layout. Because cassette ID **275** extends entirely around the proximal end of cassette **200**, the cassette ID **275** may be read when cassette **200** is in any rotational position along its central axis A**1**. Accordingly, cassette **200** may not require rotational orientation to allow for reading of cassette ID **275**. Additionally, in embodiments where cassette **200** may be rotated by external gear **280**, cassette ID **275** may still be read from any rotational position.

[0057] Referring to FIG. **8**, the stopper driving system **120** is shown. Stopper driving system **120** comprises a driven body **122**, a driving screw **123**, and an interfacing end **121**. The interfacing end **121** is configured to interact with a motor or another actuating device (e.g. a knob). Rotation of interfacing end **121** causes rotation of driving screw **123**. Driving screw **123** is threadedly engaged with driven body **122**, such that rotation of driving screw **123** causes movement of driven body **122** up or down along a central axis A**1**. Driven body **122** may be in direct contact with a medication within fluid housing **131** (FIG. **5**) or may be in contact with a stopper that contacts the medication. Actuation of stopper driving system **120** pushes the medication out of fluid housing **131**. All features of stopper driving system **120** may also apply to driving system **220** of cassette **200**. Other exemplary embodiments of driving systems **250** are described in PCT Publication No. WO 2019/112886, the entire disclosure of which is incorporated by reference herein.

[0058] Referring to FIGS. **9-10**, first motor **22** is operably coupled to stopper driving system **120** such that activation of first motor **22** actuates stopper driving system **120**. Additionally, cassette **100** optionally comprises a second motor **57** (as shown in FIGS. **1-3**), configured to actuate a needle mechanism, such as any of the needle mechanisms **55**, **390**, **590** described herein. Cassette **100** may also optionally comprise a third motor **58** configured to drive orientation mechanism **180** in embodiments where the orientation mechanism **180**, **280** is a gear or another actuatable device.

In embodiments where the drug delivery device does not comprise second motor **57**, first motor **22** may be configured to actuate the needle mechanism(s) **55**, **390**, **590**. In embodiments were the drug delivery device does not comprise a third motor **58**, first motor **22** may be configured to actuate the orientation mechanism **180**. In embodiments where the orientation mechanism **180**, **280** may also actuate the needle mechanism **55**, **390**, **590**, the second motor **57** or the third motor **58** may actuate both the orientation mechanism **180**, **280** and the needle mechanism **55**, **390**, **590**.

[0059] Each of the motors **22**, **57**, and **58** may be coupled to a reusable housing of cassette **100**, and/or coupled to cartridge **130**. In some embodiments, at least one motor **22**, **57**, and **58** is coupled to the reusable housing, and orientation mechanism **180** is configured to orient cartridge **130** with respect to the reusable housing and the at least one motor **22**, **57**, **58**, such that cartridge **130** and/or a component of cartridge **130** is operably coupled to the at least one motor **22**, **57**, **58**. For example, orientation mechanism **180** may be configured to orient cartridge **130** such that stopper driving system **120** is operably coupled to a motor **22**, **57**, **58**. Orientation mechanism may orient a needle assembly **300**, **400**, **401**, **500** relative to a reusable housing or a motor such that needle assembly **300**, **400**, **401**, **500** and/or needle mechanism **55**, **390**, **590** are operably coupled to motor **22**, **57**, **58**.

[0060] In one embodiment, a disposable medication cassette unit is provided for attachment and detachment from a reusable housing unit configured to receive the cassette unit. The cassette unit includes a cassette unit body extending along the central axis Al between a proximal end and a distal end. The proximal and distal ends may be defined by planar surfaces extending perpendicular to the central axis A**1**. Extending beyond the proximal end of the cassette unit is the interfacing end of the stopper driving system. The interfacing end is exposed outside the body of the cassette unit and disposed along the central axis A**1**. The unit body includes a proximal sleeve portion extending along a proximal portion of the cassette and a distal portion surrounding the needle assembly. Between the portions there can be an intermediate portion that is made of a material to allow the visibility of the cassette contained within.

[0061] Each of the first motor **22** and optional second motor **57** and optional third motor may be controlled by a motor controller **260**. The term “logic” or “control logic” as used herein may include software and/or firmware executing on one or more programmable processors, application-specific integrated circuits (ASICs), field-programmable gate arrays (FPGAs), digital signal processors (DSPs), hardwired logic, or combinations thereof. Therefore, in accordance with the embodiments, various logic may be implemented in any appropriate fashion and would remain in accordance with the embodiments herein disclosed. Controller **260** may be included in cassette **100** or may be external. Controller **260** may include at least one processor **262** (e.g. microprocessor) that executes software and/or firmware stored in a memory **264** of controller **260**. The software/firmware code contains instructions **265** that, when executed by the processor **262**, cause controller **260** to perform the functions of the control algorithm described herein. Controller **260** may receive information from a plurality of system components and feed the information (e.g. medication data, patient data, drug delivery device data, needle assembly data) into the control algorithm which determines at least one drug delivery control parameter which may in part govern operation of first motor **22**, second motor **57**, and/or third motor **58**. Controller **260** may include or be communicatively coupled to one or more interfaces to communicatively couple via one or more communication links to the cassette **100**. Examples interfaces include wired and wireless signal transmitters and receivers. Example communication links include a wired communication link (e.g. a serial communication), a wireless communication link such as, for example, a short-range radio link, such as Bluetooth, IEEE 802.11, a proprietary wireless protocol, and/or the like. The term “communication link” may refer to an ability to communicate some type of information in at least one direction between at least two devices. The communication links may be a persistent communication link, an intermittent communication link, an ad-hoc communication link, and/or the like. Information may be transmitted via the communication links.

[0062] FIG. **10** shows the controller **260** including memory **264** and processor **262** communicatively coupled to the one or more interfaces **268** and to each other. The memory **264** may include computer-readable storage media in the form of volatile and/or nonvolatile memory and may be removable, non-removable or a combination thereof. In embodiments, memory **264** stores executable instructions **265** (e.g. computer code, machine-useable instructions, and the like) for causing processor **262** to implement aspects of embodiments of system components discussed herein and/or to perform aspects of embodiments of methods and procedures discussed herein, including the control logic described in more detail below. The memory **264**, processor **262**, and interfaces **268** may be communicatively coupled by one or more busses. The data and/or information may be provided to controller **260** as acquired, on a predefined schedule, or queued inn memory and supplied to controller **260** when requested.
[0063] The logic of controller **260** may be configured to adjust the rate of actuation or the force of actuation provided by first motor **22**, second motor **57**, and/or third motor **58**. For example, if the medication in cartridge **130** is viscous, the force applied by first motor **22** to drive stopper **133** may be increased. In a further example, the rate of actuation for the first or second motor **22**, **57** may be adjusted to alter the rate of actuation for the needle mechanism. The needle mechanism may be actuated more slowly to improve patient comfort and reduce irritation. In some embodiments, the controller may alter the operating parameters of first and/or second motor **22**, **57** based on received information/data (e.g. patient data, medication data, historical use data, dose data, drug delivery device data, needle assembly data, cartridge data). Additionally, controller **260** may be configured to alter the speed of motors **22**, **57** over the course of activation such that motion of stopper driving system **120** and/or the needle mechanism is not constant or non-linear. For example, needle mechanism may be actuated such that the needles decelerate near the end of travel to prevent a hard stop. Controller **260** may also control timing of motor activation, for example activating first motor **22** before second motor **57**. Controller **260** may also receive data based on needle position indicating the location of at least one needle in the needle assembly, and may alter the speed, force, or positioning of the at least one needle based on the position data.
[0064] Referring now to FIGS. **11-14**, an exemplary embodiment of a needle assembly **300** is shown. Any of the illustrated needle assemblies or variations thereof may be used within cassette **100**. Furthermore, the needle assemblies disclosed may be used separately from cassette **100**, for example in chemical sampling instrumentation, or in other applications where a needle is used. Needle assembly **300** comprises an assembly housing **310**, an internal housing **312**, a first needle support **320** coupled to a first needle **330**, a second needle support **340** coupled to a second needle **350**, a movable connector **360**, a driving member **370**, and an O-ring **380**. Furthermore, needle assembly **300** comprises an exterior seal **395** and an interior seal **396**. Together, first needle support **320**, first needle **330**, second needle support **340**, second needle **350**, movable connector **360**, and movable connector **360** comprise a needle mechanism **390**. The exterior seal **395** and interior seal **396** are configured to seal the needle mechanism **390** within the needle assembly **300** before the needle assembly **300** is used and also to help maintain sterile conditions within needle assembly **300**. In some embodiments, interior seal **396** may not be included, and the coupling between needle assembly **300** and the rest of the cassette **100** may maintain sterility. Description of aspects of the drug delivery device and the needle assembly **300** can be found in PCT Publication No. WO2022/132675, filed on Dec. 14, 2021, titled “FLUID DELIVERY SYSTEM WITH NEEDLE ASSEMBLY”, the entire disclosure of which is incorporated by reference herein.
[0065] In the illustrated embodiment, needle assembly **300** is configured to interact with the patient's skin for delivery of the above-described medication. A first or distal end **392** of needle assembly **300** is positioned against the skin, and a second or proximal end **394** of needle assembly **300** interacts with cartridge **130**. The needle assembly **300** is configured to couple to cartridge **130** either directly, or through needle assembly coupler **210**. The first end **392** and/or the exterior seal **395** may comprise an adhesive to assist in positioning the needle assembly **300** against the patient's

skin and may also comprise fasteners or adhesives to secure the needle assembly **300** to cartridge **130**. As shown in FIG. **14**, the internal housing **312** is supported by the housing **310**, and the needle mechanism **390** is supported by the internal housing **312**. In other embodiments, needle assembly **300** may comprise only one housing, and internal housing **312** may be integral to assembly housing **310**.

[0066] Referring to FIGS. **14**, the needle mechanism **390** is configured to fit entirely within needle assembly **300** when in a first configuration. FIGS. **14-18** show various views of needle mechanism **390** in the first configuration. In the first configuration, first needle **330** and second needle **350** are approximately aligned parallel to one another in the direction of central axis A**1**. As shown, first needle **330** and second needle **350** are pointed in approximately opposite directions along axis A**1**. First needle **330** is pointed towards first end **392** of needle assembly **300**, and second needle **350** is pointed towards second end **394** of needle assembly **300**. As will be described later, first needle **330** and second needle **350** are configured to move generally along axis A**1** when the needle assembly **300** is activated.

[0067] Referring to FIGS. **15-18**, an exemplary embodiment of needle mechanism **390** is shown. First needle support **320** and second needle support **340** are positioned generally along a common plane and are slidably coupled to one another through driving member **370**. A first side of first and second needle supports **320**, **340** is configured to interact with driving member **370**, and a second side of first and second needle supports **320**, **340** is configured to interact with and support first and second needles **330**, **350**. In the illustrated embodiment, first and second needle supports **320**, **340** are generally rectangular in shape and are configured to fit within needle assembly **300**, as shown in FIG. **20**. In other embodiments, first and second needle supports **320**, **340** may be any shape to accommodate motion of needles **330**, **350** and fit within needle assembly **300**. In the illustrated embodiment, needle mechanism **390** comprises a rack and pinion configuration, wherein each of first needle support **320** and second needle support **340** is a rack, and driving member **370** includes a pinion gear. First needle support **320** comprises a support body **324**, support engagement features **322**, and a needle retainer **326**. The needle retainer **326** is configured to couple with first needle **330** by inserting at least of portion of first needle **330** into needle retainer **326**, thereby coupling first needle **330** to first needle support **320**. Similarly, second needle support **340** comprises a support body **344**, support engagement features **342**, and a needle retainer **346**, and the second needle **350** is coupled to second needle support **340** through needle retainer **346**. As shown best in FIGS. **16** and **18**, one or both of first needle support **320** and second needle support **340** may additionally comprise a needle guard **352**, which may function to protect the needle and/or to provide additional strength to the needle. The illustrative needle guard **352** is a cylindrical housing with a bore extending therein, through which the respective needle **330**, **350** extends.

[0068] First needle **330** and second needle **350** are fluidly coupled to one another through movable connector **360**. Movable connector **360** is configured to be movable relative to each of the needles **330** and **350**. Movable connector **360** may be movable by flexing, bending, stretching, or otherwise deforming. Accordingly, movable connector **360** may be composed of a flexible material, such as an elastomer, thermoset polymer, or rubber. In an exemplary embodiment, movable connector **360** is composed of silicone. In another embodiment, movable connector **360** may be composed of rigid materials coupled together through flexible connections. In yet another embodiment, movable connector **360** may be formed of relatively rigid materials and may move through a telescoping action. In the illustrated embodiment of FIG. **24**, movable connector **360** is a flexible tube having a first end **362** fluidly coupled to the end of the first needle **330** and a second end **364** fluidly coupled to the end of the second needle **350**. The ends **362**, **364** of the flexible tube of the movable connector **360** may be coupled directly to the needle ends **330**, **350** or to the respective needle retainers **326**, **346**. As described further below, the ends **362**, **364** of the flexible tube are configured to move with the needles **330**, **350**.

[0069] As shown best in FIGS. **19-20**, driving member **370** comprises driving engagement features

372, and an actuating member **374**. The O-ring **380** may be provided on driving member **370** in order to provide a better seal between driving member **370** and assembly housing **310**, or to allow driving member **370** to rotate more easily within assembly housing **310**. The driving engagement features **372** are configured to interact with the support engagement features **322** and **342** (FIG. **17**). In the illustrated example, driving engagement features **372** and support engagement features **322** and **342** are teeth or protrusions configured to mesh together in a rack and pinion mechanism. In other embodiments, any of the engagement features within needle mechanism **390** may be other features configured to interact with one another such as protrusions and recessions, screws and threads, zipper type features, or any other complimentary engagement features. Furthermore, in the illustrated example, actuating member **374** is configured to be actuated by a rotation of a flat object, such as a flat-head screwdriver. In other embodiments, actuating member **374** may be actuated by an electric motor, a torsional spring, or human interaction such as rotation of a knob. In one exemplary embodiment, both the stopper driving system **120** and driving member **370** are each independently driven by an electric motor, such as first motor **22** and second motor **57** (FIG. **9**). One electric motor may control the movement of both stopper driving system **120** and driving member **370**, or they may each have their own respective actuating motors.

[0070] Referring now to FIGS. **21**-**22**, the needle mechanism **390** is configured to allow for movement of first needle support **320** and second needle support **340** upon activation of driving member **370**. Needle mechanism **390** is movable between a first, retracted configuration before use and/or after use, as shown in FIG. **21**, and a second, extended configuration during use, as shown in FIG. **22**. The needle mechanism can then return a third, retracted configuration after use to indicate to the patient that the injection is done and to hide the needle inside the assembly so that the patient does not need to see the needle or handle the needle when disposing the cassette.

[0071] In the first, retracted configuration of FIG. **21**, both first needle **330** and second needle **350** are axially positioned entirely within assembly housing **310**. Movable connector **360** may be arranged in a compressed (e.g., bent or looped) state between closely-positioned tube ends **362**, **364** and needles **330**, **350** in the first configuration, where the closely-positioned tube ends **362**, **364** are separated by a first distance. Upon rotation of driving member **370** in a direction C**1**, first needle support **320** and first needle **330** are driven in a direction D**1**, and second needle support **340** and second needle **350** are driven in a direction D**2** until the rotation of driving member **370** stops once the needle mechanism **390** is in the second configuration. In the illustrated embodiment, D**1** and D**2** are approximately parallel within a plane and are generally opposite of one another. Furthermore, they are approximately parallel to axis A**1** (See FIG. **14**). In other embodiments, D**1** and D**2** may be angled relative to one another, and may not be approximately parallel to A**1**.

[0072] In the second, extended configuration, first needle **330** extends axially beyond assembly housing **310** and passes through the outer seal **395** and into whatever surface needle assembly **300** is positioned against. Additionally, second needle **350** extends axially beyond assembly housing **310** and passes through interior seal **396** and septum **135** into fluid housing **131**. Because the movable connector **360** is movable, it maintains fluid communication between first needle **330** and second needle **350** throughout movement of the needle mechanism **390**. Movable connector **360** may be arranged in an extended state between the now-distant tube ends **362**, **364** and needles **330**, **350** in the second configuration, where the now-distant tube ends **362**, **364** are separated by a second distance larger than the first distance of the first configuration. In the second configuration, first needle **330** is fluidly coupled to cartridge **130**, so the medication within fluid housing **131** is capable of flowing through second needle **350**, movable connector **360**, and first needle **330** into whatever body or surface first needle **330** has pierced. In an exemplary embodiment, the stopper driving system **120** is activated after needle mechanism **390** is in the second configuration, and the medication within cartridge **130** is driven out and into the body or surface pierced by first needle **330**. In another embodiment, a number of components of needle mechanism **390**, and/or the internal housing **312** comprise a stopping feature to physically stop the movement of first needle

support **320** and second needle support **340** once needle mechanism **390** reaches the second configuration. Such a stopping feature may be a blocking member, a protrusion, a detent, or an absence of engagement members within a portion of the needle mechanism **390**.
[0073] From the second configuration, needle mechanism **390** is configured to be movable back to the first configuration through reverse activation of driving member **370** as well. As shown in FIG. **22**, driving member **370** may be rotated in a direction C**2**, which is generally opposite to C**1**, in order to drive first needle support **320** in the direction D**2**, and second needle support **340** in the direction D**1**. In an exemplary embodiment, needle mechanism **390** is moved from the second configuration to the first configuration after the medication has been driven out of cartridge **130** and through needle mechanism **390**. In an embodiment where cassette **100** is being used to deliver the above-described medication to the patient, extending the first needle **330** from needle assembly **300**, and then retracting the first needle **330** back into the needle assembly **300** after injection would allow the patient to be injected with a medication without needing to directly observe or handle the first needle **330**.
[0074] Referring now to FIGS. **23-24**, another embodiment of a needle assembly **500** is shown. Needle assembly **500** comprises a housing **510**, a rotating assembly **514**, and a plurality of needle mechanisms **590**. Each needle mechanism **590** comprises a first needle support **520** coupled to a first needle **530**, a second needle support **540** coupled to a second needle **550**, a movable connector **560**, a driving member **570**, a driving member actuator **578**, and an O-ring **580**. In the illustrated embodiments, a plurality of needle mechanisms **590** are shown, but any number of needle mechanisms **590** may be used, including a single needle mechanism **590**, similar to the embodiment shown in FIG. **11**. Movable connector **560** may have various features in common with the above-described movable connector **360**.
[0075] Rotating assembly **514** comprises an exposed driven gear **512** and is configured to couple with housing **510**. In an exemplary embodiment, driven gear **512** is driven by a motor to rotate housing **510** through rotating assembly **514**. In other embodiments, rotating assembly **514** may not comprise driven gear **512**, and may instead have a different feature to facilitate its rotation, such as a grip to be rotated by a user, or other engagement features to be rotated by a motor or another device. In still other embodiments, rotating assembly **514** may be configured to only rotate the needle mechanisms **590** within housing **510** instead of rotating the entire needle assembly **500**.
[0076] Referring now to FIGS. **25-28**, the needle mechanisms **590** of needle assembly **500** are configured as a drive screw assembly. Each of the first needle support **520** and the second needle support **540** comprise an engagement feature **522**, a support body **524**, and a needle retainer **526**. The first needle support **520** and second needle support **540** are configured to engage with driving member **570**. Each of first and second needle supports **520**, **540** is generally curved to accommodate interaction with driving member **570** and is configured to position first and second needles **530**, **550** generally proximate one another. In other embodiments, first and second needle supports **520**, **540** may be configured to position first and second needles **530**, **550** on opposite sides of a central axis from one another. Each engagement feature **522** is configured to interact with a driving engagement feature **572** of driving member **570**. In the illustrated embodiments, engagement feature **522** is in threaded engagement with the driving member **570**. Engagement feature **522** is shown as a thread, driving member **570** is shown as a threaded shaft such as a screw, and driving engagement feature **572** is a trough or root within the screw. The engagement feature **522** is configured to be received within or otherwise interact with the driving engagement feature **572** of driving member **570**. In the illustrated embodiment, driving engagement features **572** of driving member **570** are oppositely oriented along opposing halves of driving member **570** such that rotation of driving member **570** causes opposite axial movement of first and second needle supports **520**, **540**. A driving gear **578** is coupled to each driving member **570** such that rotation of driving member actuator **578** causes rotation of driving member **570**. Driving member **570** also comprises at least one stopping feature **573** configured to stop a movement of first needle support

520 and/or second needle support **540** along driving member **570**. In the illustrated embodiment, driving member **570** comprises a stopping feature **573** on each half of driving member **570**.
[0077] Referring now to FIG. **28**, the needle mechanisms **590** may be extended and retracted similarly to the needle mechanisms **390**, but through the use of a different driving mechanism. More specifically, the needle mechanisms **590** may be moved between a first, retracted configuration before use and/or after use, as shown in FIG. **38**, and a second, extended configuration during use (not shown). Within a needle mechanism **590** of needle assembly **500**, the driving member actuator **578** is rotatable locked with the driving member **570**, and thus when rotated, the rotation of driving member **570** is caused. The engagement feature **522** on first needle support **520** and second needle support **540** are configured to move first needle support **520** and second needle support **540** in opposite axial directions along driving member **570** when driving member **570** is rotated. Each needle mechanism **590** begins in the first configuration, as shown in FIG. **38**, and rotation of driving member **570** in a first direction causes first needle support **520** to move in the direction D**1**, and second needle support **540** to move in the direction D**2**, thereby moving the needle mechanism **590** into the second configuration. The driving of member actuator **578** stops the movement of first needle support **520** and second needle support **540** once the needle mechanism **590** reaches the second configuration. The driving member **570** may then rotate in a second, opposite direction to move the needle mechanism **590** from the second configuration to the first configuration by moving first needle support **520** in the direction D**2**, and second needle support **540** in the direction D**1**. All previous disclosure related to the first configuration, second configuration, needles, uses, etc. as discussed regarding needle assembly **300** may be applied to needle assembly **500**. Utilizing a screw mechanism as in needle assembly **500** may allow needle assembly **500** to occupy less space than rack and pinion mechanisms as in needle assembly **300** and needle assembly **400**.
[0078] One or more benefits can be realized with any of the cassette with any of needle mechanisms disclosed herein being movable between the first and second configurations where the fluid path between the medication reservoir and the needle injecting into the patient is created (first configuration) and removed (second configuration), that is the fluid path between the medication reservoir and the needle injecting into the patient is decoupled. One benefit of this decoupling may be that the dose delivery accuracy may be potentially improved because of the absence of drool from the plunger decompressing (which can maintain a slight internal pressure). This can result in reduced hold time of the device at the treatment site by the patient to achieve dose accuracy. One or more of the benefits for gearing mechanisms and needle supports described herein is having very tightly guided needle movement. Accordingly, such tightly guided control can more effectively hitting a small septum target and/or pushing the needle straight in and out of the patient skin (less likely to hit a proximal nerve).
[0079] As shown in FIG. **25**, multiple needle assemblies may be used. Additional details regarding the use of multiple needle assemblies, as well as needle assemblies which may be operated with two needles oriented along different axis (e.g. perpendicular needles), may be found in the above-incorporated U.S. Provisional Application No. 63/126,552.
[0080] Referring now to FIGS. **29**-**30**, needle assembly **400** is shown configured to be used with needle mechanism **390**. Needle assembly **400** may comprise similar features to needle assembly **300** as described above. Assembly **400** may have a lower tubular body and an intermediate portion extending axially from the lower tubular body. The lower tubular body may define a radial recess in which the gear **154** resides (the face of gear facing radially outward). The rotating axis of gear **154** may be perpendicular to the central axis, as shown in the figures. The intermediate portion forms an enclosure about the needle mechanism **390**. The intermediate portion may include a radial opening in which a shaft from gear **154** extends radially inward into the intermediate portion. The intermediate portion may include an opening in which the needle from needle mechanism **390** selectively extends therethrough. Needle assembly actuating gear **154** is configured to actuate

driving member **370** and thereby activate needle mechanisms **390**. As described above, actuating gear **154** may be actuated by a motor within a reusable housing, or manually by a user.
[0081] Referring now to FIGS. **31**-**32**, needle assembly **402** is shown configured to be used with needle mechanism **590**. Needle assembly **402** may comprise similar features to needle assembly **500** as described above. Needle assembly actuating gear **155** is configured to mesh with and rotate driving member actuator **578**, thereby actuating driving member **570** and actuating needle mechanisms **590**. Assembly **402** may have a lower tubular body and an intermediate portion extending axially from the lower tubular body. The lower tubular body may define a recess in which the shaft of gear **155** resides (face of gear facing axially). The intermediate portion forms an enclosure about the needle mechanism **590**. The intermediate portion may include a first axial opening in which driving member **570** extends therethrough. Driving member actuator **578** is rotationally fixed to the driving member **570** and is drivably engaged with gear **155**. The intermediate portion may include another axial opening in which the needle from needle mechanism **590** selectively extends therein.
[0082] Referring to FIG. **33**, needle assembly **401** is shown without a needle assembly housing. Needle assembly **401** is configured to be used with needle mechanism **390**. Needle assembly **401** may comprises similar features to needle assembly **300** as described above. Needle assembly actuating gear **254** is configured to actuate driving member **370** thereby activating needle mechanisms **390**. Gear **254** can be driven by external gear **280**. Gear **280** can be formed in a ring shape with gear driving teeth **281** formed along an edge **283** of its body for axial engagement with the gear **254**. External gear **280** may include at least a partially circumferential radial lip **285** extending from the outer surface of the gear **280** that is slidably engaged with the upper edge of the lower portion **410** (as shown in FIG. **7**). External gear may include one or more driven teeth or gear interfacing features **280**A that are driven by the motor or user. The driven teeth may be circumferentially spaced from one another along the outer surface. In one embodiment, the driven teeth **280**A are shown as axially extending protrusions extending away from the radial lip **285**. The gear interfacing features **280**A may include recesses instead of protrusions. As external gear **280** rotates, being driven, for example, by second motor, the gear driving teeth **281** drivably engage the teeth of gear **254** thereby moving the needles as described above, for example, with reference to FIGS. **21**-**22**.
[0083] Referring now to FIGS. **34**, needle assembly **403** is shown configured to be used with needle mechanism **590**. Needle assembly **403** may comprise similar features to needle assembly **500** as described above. Needle assembly actuating gear **255** is configured to mesh with and rotate driving member actuator **578**, thereby actuating driving member **570** and actuating needle mechanisms **590**. The rotating axis of the gear **255** may be offset and parallel with the central axis, as shown in the figures. The rotating axis of the gear **578** may be offset and parallel with the central axis, and offset from the rotating axis of gear **255**, as shown in the figures. Gear **255** can be driven by external gear **281**. Gear **281** is formed in a ring shape with gear teeth formed radially inward facing along an edge of its body for radial engagement with the gear **255**. In one embodiment, the driven teeth or external gear interface features are disposed circumferentially spaced from one another around the axis (not shown) may be axially extending protrusions along the outer surface, similar to gear **280**. As external gear **281** rotates, being driven, for example, by second motor, the gear driving teeth drivably engage the teeth of gear **255** that drivably engages the teeth of the driving member actuator **578** thereby moving the needles as described above.
[0084] Referring now to FIG. **35**, a computing device **700** may be used to communicate with and/or operate any of the drug delivery devices **11**, **12**, **13**, **100** described herein, illustratively cassette **100**. Computing device **700** illustratively includes a mobile device, such as a smartphone. Alternatively, any suitable computing device may be used, including but not limited to a laptop, desktop, tablet, or server computer, for example.
[0085] The computing device **700** includes at least one processor **710** that executes software and/or

firmware stored in memory **720** of device **700**. The software/firmware code contains instructions that, when executed by processor **710**, causes device **700** to perform the functions described herein. The at least one processor **710** illustratively includes control logic and/or an application **715** operative to activate cassette **100**. Memory **720** is any suitable computer readable medium that is accessible by processor **710**. Memory **720** may be a single storage device or multiple storage devices, may be located internally or externally to processor **710**, and may include both volatile and non-volatile media. Exemplary memory **720** includes random-access memory (RAM), read-only memory (ROM), electrically erasable programmable ROM (EEPROM), flash memory, a magnetic storage device, optical disk storage, or any other suitable medium which is configured to store data and which is accessible by processor **710**.

[0086] Computing device **700** includes a user interface **705** in communication with processor **710** and operative to provide user input data to the system and to receive and display data, information, and prompts generated by the system. User interface **705** includes at least one input device for receiving user input and providing the user input to the system. In the illustrated embodiment, user interface **705** is a graphical user interface (GUI) including a touchscreen display operative to display data and receive user inputs. The touchscreen display allows the user to interact with presented information, menus, buttons, and other data to receive information from the system and to provide user input into the system. Alternatively, a keyboard, keypad, microphone, mouse pointer, or other suitable user input device may be provided.

[0087] Computing device communicates with cassette **100** through signal **750**. Signal **750** may be a wireless or wired signal. Cassette **100** may comprise a processor **760** similar to processor **710**, a cassette ID **770**, and/or a communication device **780**. Communication device **780** may send or receive a signal **750** to/from communication device **740**, or to/from other components of cassette **100** (e.g. cassette ID **770**). cassette ID **770** may be any sort of mechanism or device that provides data about a component of cassette **100**. For example, cassette ID **770** may be a chip or RFID indicator on cassette **100** (FIG. **12**) that provides data regarding the type of liquid or medication within cartridge **130** (e.g. specific medication, viscosity, volume, dosage, injection scheduling, etc.). Other components, such as a needle assembly or motor, may include an ID to communicate other data related to cassette **100** (e.g. needle assembly type, needle length/positioning, patient information, historical treatment information, motor type, motor characteristics, etc.).

[0088] In some embodiments, cassette **100** may comprise an indicator (not shown) that provides some sort of indication that the medication has been delivered to the patient. Such an indication may be an end of dose indication. The indicator may comprise, for example, a light (e.g. an LED), a visual display such as a screen, a vibration, a sound, the sending of a signal, an indication on a separate computing device (e.g. a smartphone or computer as discussed above), a mechanical visual indicator (e.g. a window in the device housing to show barrel movement), or any combination thereof. The indicator may also indicate to a user any other information about the operation of cassette **100** including, but not limited to, whether or not a cassette is inserted, whether a cassette is inserted properly, device power information (e.g. whether the device is on/off, battery level), patient information, any information that may be provided by ID's discussed above, or any combination thereof.

[0089] In some embodiments, cassette **100** may comprise a number of sensors (not shown) that sense information related to the device. In an exemplary embodiment, cassette **100** comprises a skin sensor which senses whether the device is properly positioned against a patient's skin. In some embodiments, the cassette **100** may not actuate a needle assembly or deliver a medication if the skin sensor does not indicate that the device is positioned properly. Other examples of optional sensors include, but are not limited to, a medication level sensor, a pressure sensor, accelerometers, a force/thrust sensor, a position sensor for elements of the driving system, cartridge, housing, and/or needle assembly, a pH sensor, or any combination thereof. A temperature sensor may be provided to sense ambient temperature, medication temperature, or another component's

temperature, and can be embodied, such as but not limited to a thermistor (e.g., a negative temperature coefficient (NTC) thermistor or a resistance temperature detector (RTD)), a thermocouple, or a semiconductor-based temperature sensor.

[0090] In some embodiments, the cassettes disclosed herein do not include the stopper drive systems **120**, **220**. Instead, the driving system of the housing of reusable portion is configured to engage with the stopper.

[0091] Some or all of the components of drug delivery devices disclosed herein, such as devices **11**, **12**, **13**, **100**, and **200** may be composed of a polymer or a disposable material. For example, some or all of the components of the drug delivery devices **11**, **12**, **13**, and/or cassettes **100**, and **200** may be composed of a cyclic olefin polymer. Additionally, some or all of the components of cassette **100** may be manufactured through additive manufacturing, extrusion, reductive machining, casting, molding, or any other suitable manufacturing process. In some embodiments, the housing, cartridge, fluid housing, orientation mechanism, driving system, and/or needle assemblies may be composed partially or entirely of a polymer. Producing certain components from a polymer may provide improved manufacturing tolerances compared to other materials such as glass, and may also reduce the impact of disposing of such devices or components.

[0092] The terms “first”, “second”, “third” and the like, whether used in the description or in the claims, are provided for distinguishing between similar elements and not necessarily for describing a sequential or chronological order. It is to be understood that the terms so used are interchangeable under appropriate circumstances (unless clearly disclosed otherwise) and that the embodiments of the disclosure described herein are capable of operation in other sequences and/or arrangements than are described or illustrated herein.

[0093] While this invention has been described as having exemplary designs, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

[0094] Various aspects are described in the description in this disclosure, which include, but are not limited to, the following aspects: [0095] 1. A drug delivery device including: a cassette comprising: a cartridge configured to retain a volume of a medication; a stopper driving system configured to drive the medication from the cartridge, the stopper driving system comprising a stopper, wherein the stopper travels less than 10 mm to deliver a volume of 1 mL of the medication; and a needle assembly directly coupled to the cartridge movable between an extended configuration and a retracted configuration, the needle assembly having an actuating gear movable between first and second positions, wherein in the extended configuration the actuating gear is in the second position and the needle assembly provides fluid communication between the cartridge and the needle assembly, wherein in the retracted configuration the actuating gear is in the first position and no fluid communication is provided between the cartridge and the needle assembly. [0096] 2. The drug delivery device of aspect 1, further including a reusable housing configured to receive the cassette and including a driving system, wherein the driving system is configured to operatively couple to at least the stopper driving system. [0097] 3. The drug delivery device of aspect 2, further including an orientation mechanism configured to orient the cartridge relative to the reusable housing when the cartridge is coupled to the reusable housing. [0098] 4. The drug delivery device of aspect 3, wherein the orientation mechanism includes a protrusion and the reusable housing includes a slot configured to receive the protrusion. [0099] 5. The drug delivery device of aspect 2, wherein the reusable housing is configured to receive the cassette at any rotational position around a central axis of the cassette. [0100] 6. The drug delivery device of any one of aspects 1-5, further including a first motor configured to actuate the stopper driving system to deliver the medication from the cartridge. [0101] 7. The drug delivery device of aspect 6, further including a second motor

configured to actuate the actuating gear of the needle assembly. [0102] 8. The drug delivery device of any one of aspects 1-7, wherein the cassette has a height from 40 mm to 60 mm and a diameter from 20 mm to 40 mm. [0103] 9. The drug delivery device of any one of aspects 1-8, further including a cartridge ID coupled to the cartridge. [0104] 10. The drug delivery device of aspect 9, wherein the cartridge ID includes at least one circular ID, the circular ID configured to be read from a plurality of rotational orientations relative to a central axis of the circular ID. [0105] 11. The drug delivery device of aspect 9, wherein the cartridge ID includes at least one of an RFID indicator, a readable chip, and an antenna. [0106] 12. The drug delivery device of any one of aspects 1-11, wherein the cartridge, and at least a portion of the stopper driving system and the needle assembly are composed of a polymer. [0107] 13. A method of delivering a medication to a patient including: coupling a housing of a drug delivery device to a cassette with a needle assembly including a first needle and a second needle, wherein the needle assembly is in a retracted configuration where there is no fluid communication provided between the cartridge and the needle assembly; orienting the housing relative to the cassette; positioning the drug delivery device against a skin of the patient; actuating the needle assembly of the drug delivery device to extend the first needle into the skin of the patient and the second needle into a septum of a cartridge containing a volume of a medication; actuating a driving system to drive a stopper to travel less than 10 mm for a 1 mL volume of the medication from the cartridge through the needle assembly and to the patient; and retracting the first and second needles within the needle assembly, where there is no fluid communication provided between the cartridge and the needle assembly. [0108] 14. The method of aspect 13, wherein the orienting step is carried out through an orientation mechanism. [0109] 15. The method of aspect 14, wherein the orientation mechanism includes at least one of a protrusion, a slot, and a gear. [0110] 16. The method of any one of aspects 13-15, further including the step of decoupling the housing from the cassette after the retracting step. [0111] 17. The method of any one of aspects 13-17, further including a step of reading a cartridge ID on the housing. [0112] 18. A drug delivery device including: a reusable housing; a cassette coupled to the reusable housing, wherein the cassette has a ratio of height to diameter from 2:1 to 1:1; a cartridge supported by cassette and configured to retain a volume of a medication; and an orientation mechanism configured to orient the cassette relative to the reusable housing. [0113] 19. The drug delivery device of aspect 18, further including at least one motor supported by the reusable housing, wherein the orientation mechanism orients the cassette to operably couple the at least one motor with at least a portion of the cassette. [0114] 20. The drug delivery device of aspect 19, further including a needle assembly directly coupled to and at least partially within the cassette movable between an extended configuration and a retracted configuration, wherein in the extended configuration the needle assembly provides fluid communication between the polymeric cartridge and the needle assembly. [0115] 21. A drug delivery device including a cassette to couple to a reusable module, the cassette including: a cartridge configured to retain a volume of a medication, the cartridge extending between a proximal end and a distal end along an axis that is centrally located; a stopper driving system configured to drive the medication from the cartridge, the stopper driving system including a stopper and an interfacing end coupled to the stopper and configured to be driven by a first motor or actuating device of the reusable module to move the stopper; and a needle assembly directly coupled to the cartridge movable between an extended configuration and a retracted configuration, the needle assembly having an actuating gear movable between first and second positions, the actuating gear configured to be directly or indirectly driven by a second motor or actuating device of the reusable module, wherein in the extended configuration the actuating gear is in the second position and the needle assembly provides fluid communication between the cartridge and the needle assembly, wherein in the retracted configuration the actuating gear is in the first position and no fluid communication is provided between the cartridge and the needle assembly, wherein the interfacing end extends from an upper end of the cartridge and coaxial with the axis, and the actuating gear is disposed to be engaged externally by the second motor or

actuating device of the reusable module at a location offset from the axis. [0116] 22. The drug delivery device of aspect 21, wherein the actuating gear further includes an external gear drivably engaged with the actuating gear, the external gear including external gear interface features disposed circumferentially spaced from one another around the axis, wherein the external gear interface features of the external gear configured to be driven by the second motor or actuating device of the reusable module. [0117] 23. The drug delivery device of aspect 22, wherein the external gear has a ring-shaped body, and the external gear interface features are disposed along a circumferential surface of the ring shaped body, and the external gear includes gear driving teeth formed along an axial edge of the ring shaped body for axial engagement with the actuating gear. [0118] 24. The drug delivery device of any one of aspects 21-24, wherein the actuating gear further includes an external gear drivably engaged with the actuating gear, the external gear including external gear interface features disposed circumferentially spaced from one another around the axis, wherein the external gear interface features of the external gear configured to be driven by the second motor or actuating device of the reusable module. [0119] 25. The drug delivery device of aspect 24, wherein the external gear has a ring-shaped body, and the external gear interface features are disposed along a circumferential surface of the ring shaped body, and the external gear includes gear driving teeth formed radially along an axial edge of the ring shaped body for radial engagement with the actuating gear. [0120] 26. The drug delivery device of any one of aspects 21-25, wherein the actuating gear has a rotating axis that is perpendicular to the axis.

Claims

1-27. (canceled)
28. A cassette to couple to a drug delivery device comprising: a cartridge configured to retain a volume of a medication; a stopper drive system configured to drive the medication from the cartridge, the stopper drive system comprising a drive screw, a stopper, and an interfacing end configured to be driven by an external motor or actuating device of the drug delivery device in order to rotate the drive screw in a manner to move the stopper; and a needle assembly coupled to the cartridge and comprising a first needle and a second needle, the needle assembly having an extended configuration by which the first needle and the second needle are moved away from one another and a retracted configuration by which the first needle and the second needle are moved closer together, the needle assembly having an actuating gear rotatable between first and second positions, wherein in the extended configuration the actuating gear is in the second position and the needle assembly provides fluid communication between the cartridge and the needle assembly, wherein in the retracted configuration the actuating gear is in the first position and no fluid communication is provided between the cartridge and the needle assembly.
29. The cassette of claim 28, further comprising an orientation mechanism configured to orient the cartridge relative to the drug delivery device when the cartridge is coupled thereto.
30. The cassette of claim 29, wherein the orientation mechanism comprises a protrusion and a housing portion of the drug delivery device comprises a slot configured to receive the protrusion.
31. The cassette of claim 28, wherein a housing portion of the drug delivery device is configured to receive the cassette at any rotational position around a central axis of the cassette.
32. The cassette of claim 28, the actuating gear of the needle assembly is configured to be driven by a second external motor or actuating device of the drug delivery device.
33. The cassette of claims 32, wherein the second external motor or actuating device is axially offset from the external motor or actuating device.
34. The cassette of claim 28, further comprising a cartridge ID coupled to the cartridge.
35. The cassette of claim 34, wherein the cartridge ID comprises at least one circular ID, the circular ID configured to be read from a plurality of rotational orientations relative to a central axis of the circular ID.

36. The cassette of claim 35, wherein the cartridge ID comprises at least one of an RFID indicator, a readable chip, and an antenna.
37. The cassette of claim 28, wherein the cartridge holds the volume of the medication, and the medication includes one or more therapeutic agents including: an insulin, an insulin analog, insulin lispro, insulin glargine, an insulin derivative, a GLP-receptor agonist, dulaglutide, liraglutide, a glucagon, a glucagon analog, a glucagon derivative, a gastric inhibitory polypeptide (GIP), a GIP analog, a GIP derivative, a GIP/GLP-1 receptor agonist, tirzepatide, retatrutide, an oxyntomodulin analog, an oxyntomodulin derivative, an IL-23 antibody analog or derivative, mirikizumab, IL-17 antibody analog or derivative, ixekizumab, galcanzeumab, lasmiditan, lebrikizumab, donanemab, solanezumab, and remternetug.
38. The cassette of claim 28, wherein the stopper is configured to travel less than 10 mm to deliver a volume of 1 mL of the medication.
39. The cassette of claim 28, wherein the cassette has a ratio of height to diameter from 2:1 to 1:1.
40. A drug delivery device comprising: a reusable housing comprising the external motor or actuating device; and the cassette of claim 28, wherein the cassette is coupled to the reusable housing such that the interfacing end is operable by the external motor to rotate the drive screw.
41. A method of delivering a medication to a patient comprising: coupling a housing of a drug delivery device to a cassette with a needle assembly comprising a first needle and a second needle, wherein the needle assembly is in a retracted configuration where there is no fluid communication provided between the cartridge and the needle assembly; orienting the housing relative to the cassette; positioning the drug delivery device against a skin of the patient; actuating the needle assembly of the drug delivery device to extend the first needle into the skin of the patient and the second needle into a septum of a cartridge containing a volume of a medication; actuating a driving system of the cassette to rotate a driving screw and drive a stopper to move volume of the medication from the cartridge through the first and second needles of the needle assembly and to the patient; and retracting the first and second needles within the needle assembly, where there is no fluid communication provided between the cartridge and the needle assembly.
42. The method of claim 41, wherein the drug delivery device includes a first motor for actuating the needle assembly and a second motor for actuating the driving system.
43. The method of claim 41, wherein the orienting step is carried out through an orientation mechanism.
44. The method of claim 43, wherein the orientation mechanism comprises at least one of a protrusion, a slot, and a gear.
45. The method of claim 41, further comprising a step of reading a cartridge ID on the housing.
46. The method of claim 41, wherein during the actuating the driving system step the stopper can travel less than 10 mm for a 1 mL volume of the medication to move the medication from the cartridge through the needle assembly and to the patient.
47. The method of claim 41, wherein the medication includes one or more therapeutic agents including: an insulin, an insulin analog, insulin lispro, insulin glargine, an insulin derivative, a GLP-receptor agonist, dulaglutide, liraglutide, a glucagon, a glucagon analog, a glucagon derivative, a gastric inhibitory polypeptide (GIP), a GIP analog, a GIP derivative, a GIP/GLP-1 receptor agonist, tirzepatide, retatrutide, an oxyntomodulin analog, an oxyntomodulin derivative, an IL-23 antibody analog or derivative, mirikizumab, IL-17 antibody analog or derivative, ixekizumab, galcanzeumab, lasmiditan, lebrikizumab, donanemab, solanezumab, and remternetug.