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(54) **INFUSION PUMP WITH A CAPACITIVE DISPLACEMENT POSITION SENSOR**

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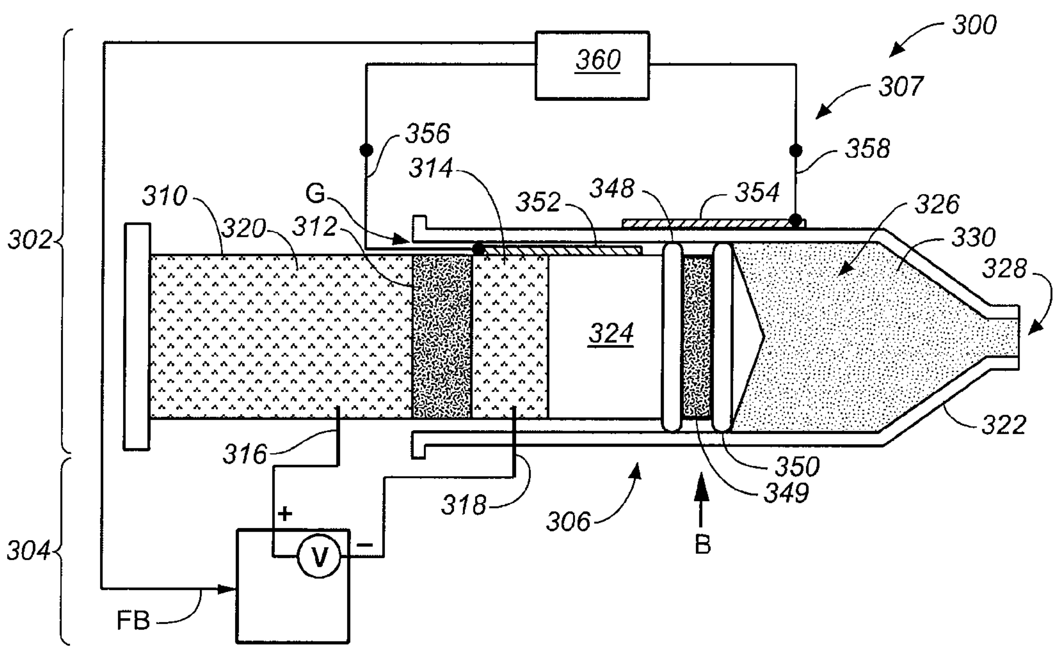
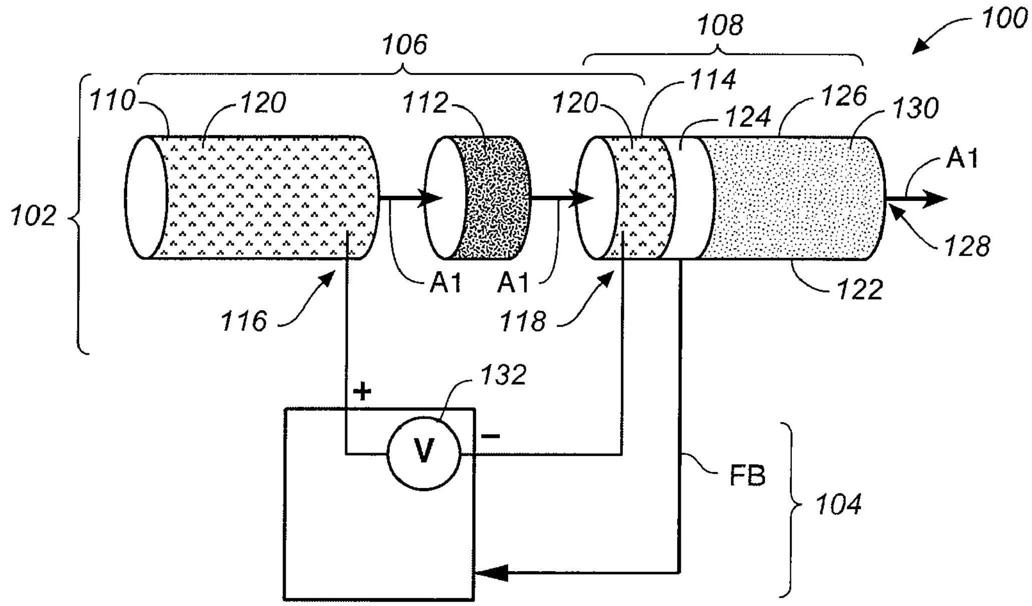
(57) **ABSTRACT**

Various methods and devices are provided for an electrokinetic infusion pump. In one embodiment of the invention, the infusion pump includes an infusion pump module, which can be configured to dispense an insulin containing infusion liquid, and an electrokinetic engine. The infusion pump module includes a capacitive displacement position sensor configured for sensing a dispensing state of the infusion pump module. The infusion pump module can include an infusion module housing and the electrokinetic engine can include a moveable partition. The capacitive displacement sensor includes a first capacitive plate disposed on the moveable partition and a second capacitive plate disposed on the infusion module housing. The capacitive displacement sensor is configured for measuring capacitance between the first capacitive plate and the second capacitive plate and can send a feedback signal to a closed loop controller that is indicative of the capacitance between the first and second capacitive plates.

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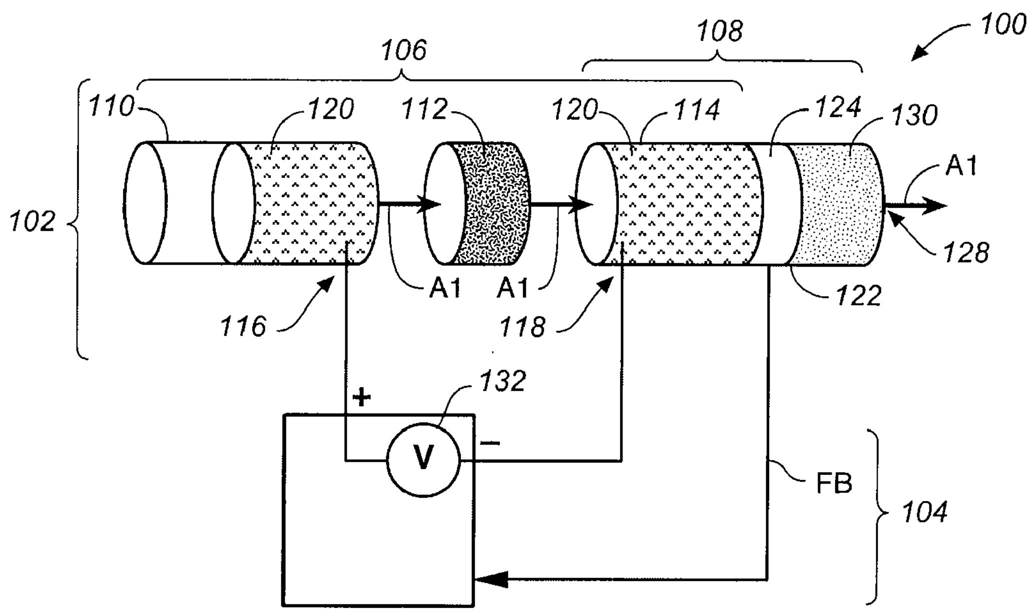
106
108
102
110
120
112
120
114
124
126
130
A1
128
A1
A1
122
116
118
132
+
V
−
FB
104

FIG. 1


100
106
108
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120
112
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130
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+
V
−
FB
104

FIG. 2

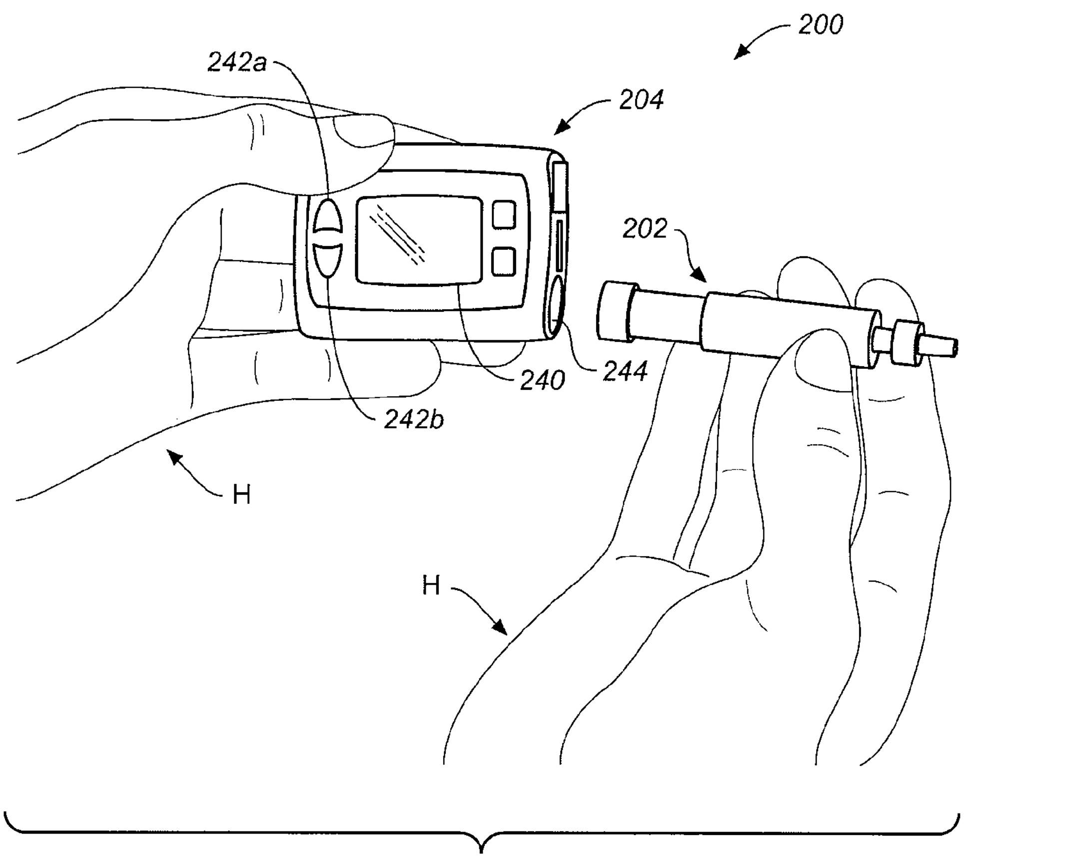


FIG. 3

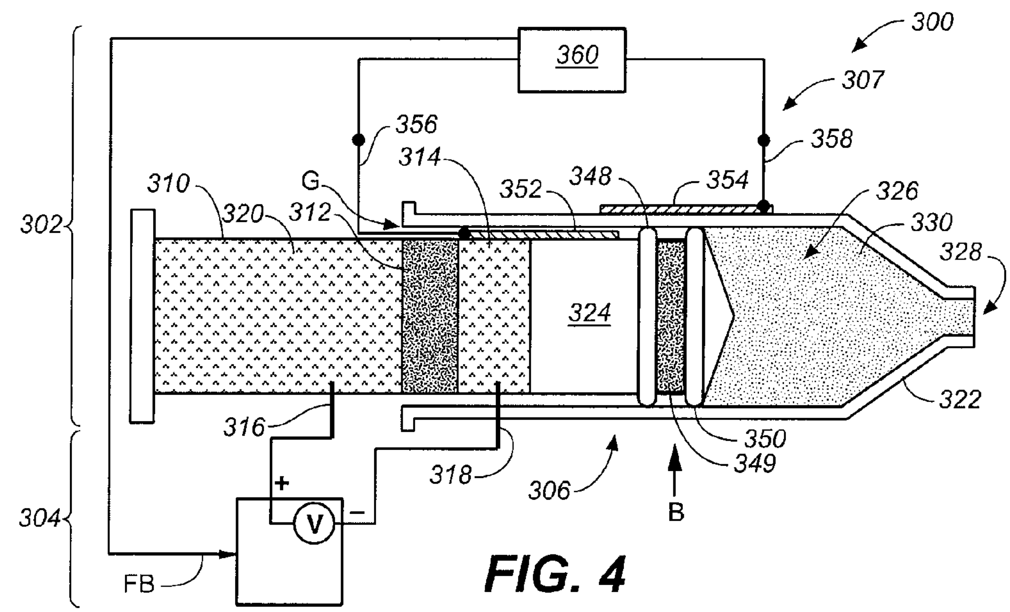
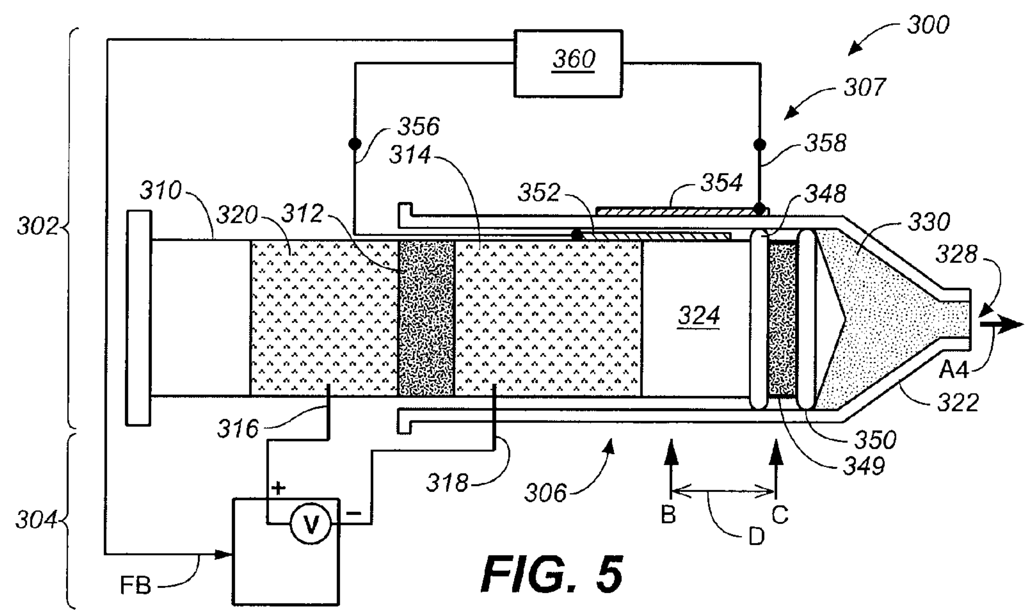

300
307
360
356
358
314
354
310
G
348
326
352
320
312
330
302
328
324
316
318
350
349
306
B
304
V
FB
+
−

FIG. 4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358
314
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348
320
312
330
302
328
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C
D
V
FB
+
−

FIG. 5

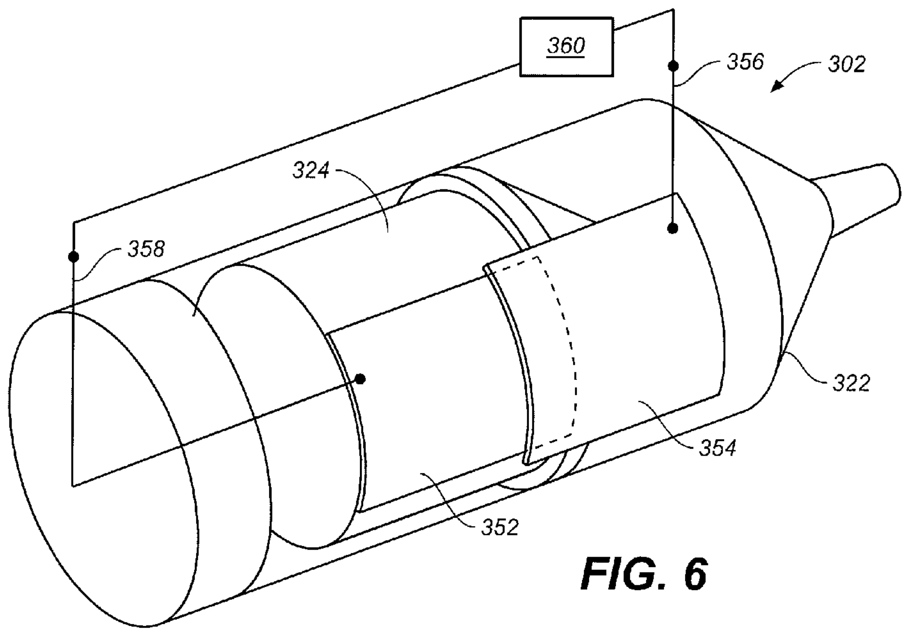


FIG. 6

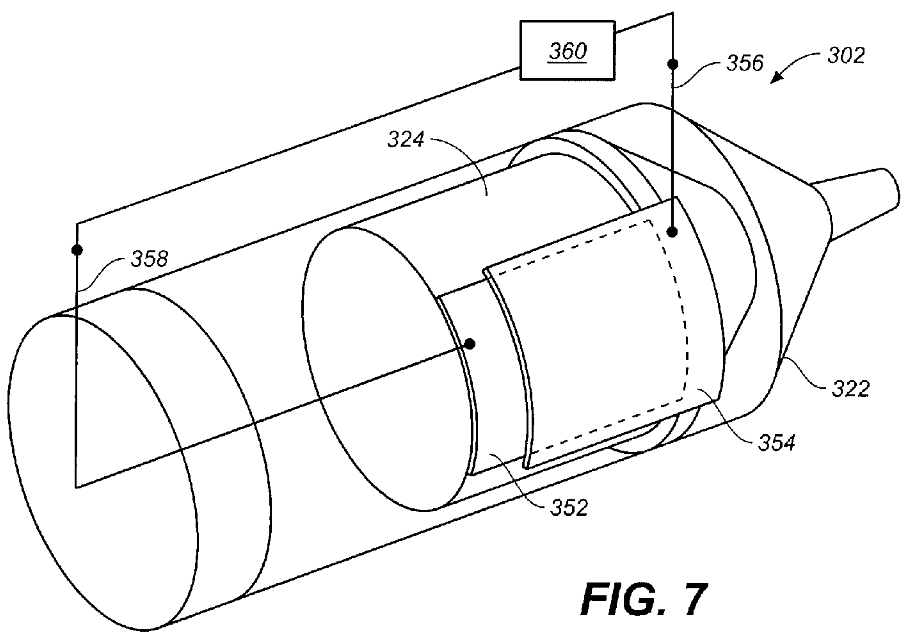
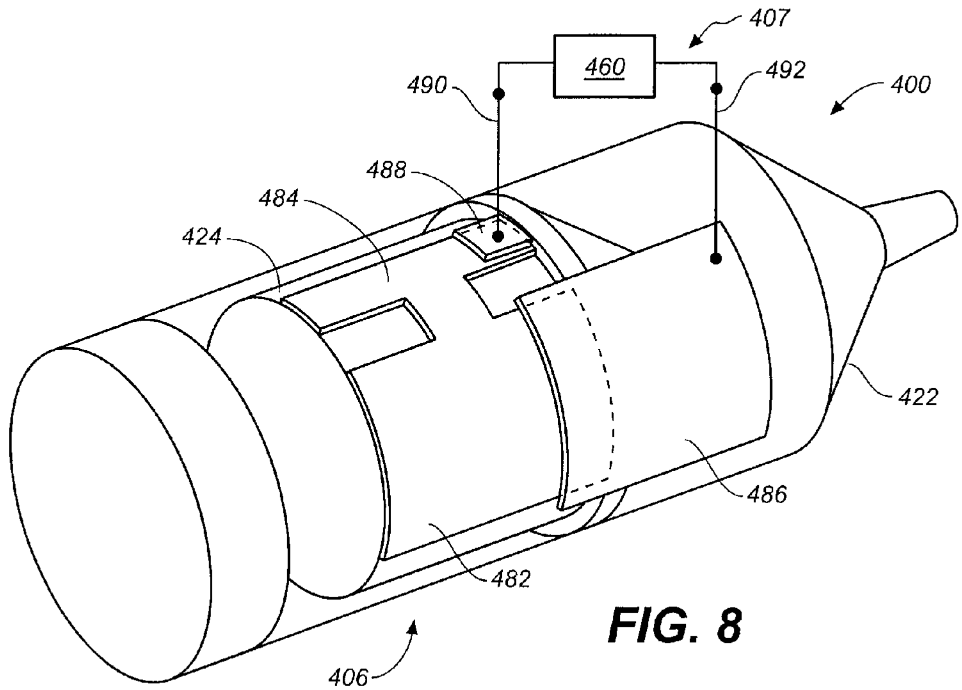


FIG. 7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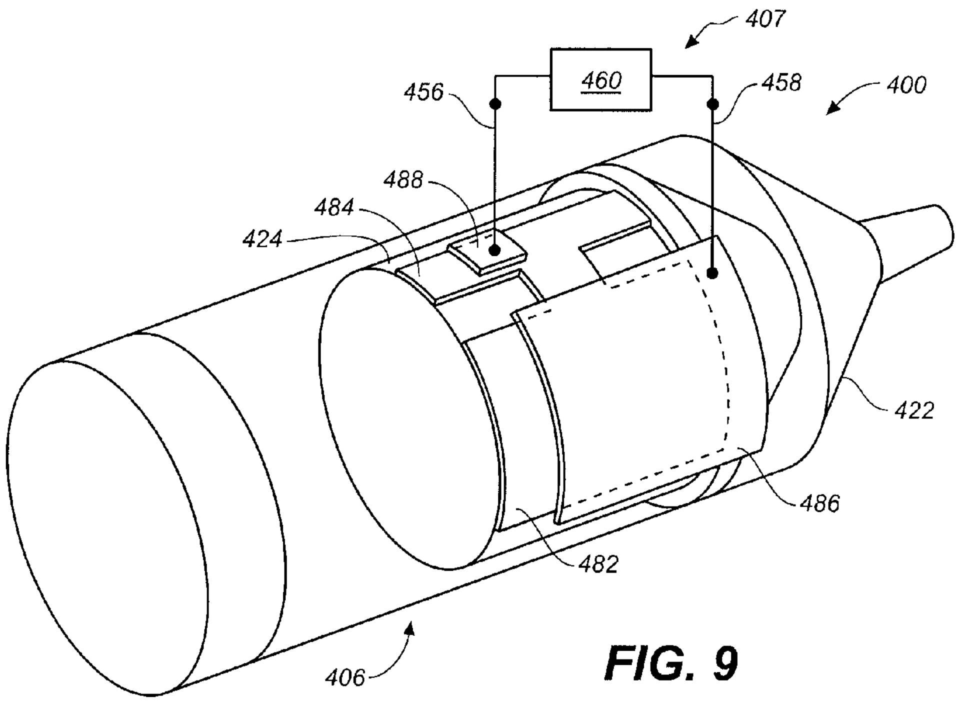
460
490
492
400
488
484
424
422
486
482
406

FIG. 8


407
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422
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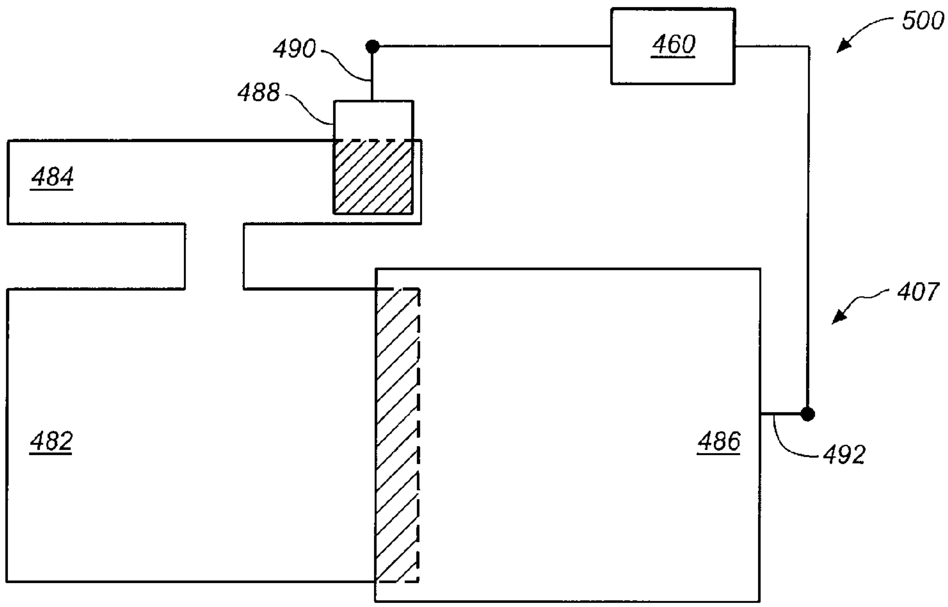
482
406

FIG. 9


500
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460
488
484
407
482
486
492

FIG. 10

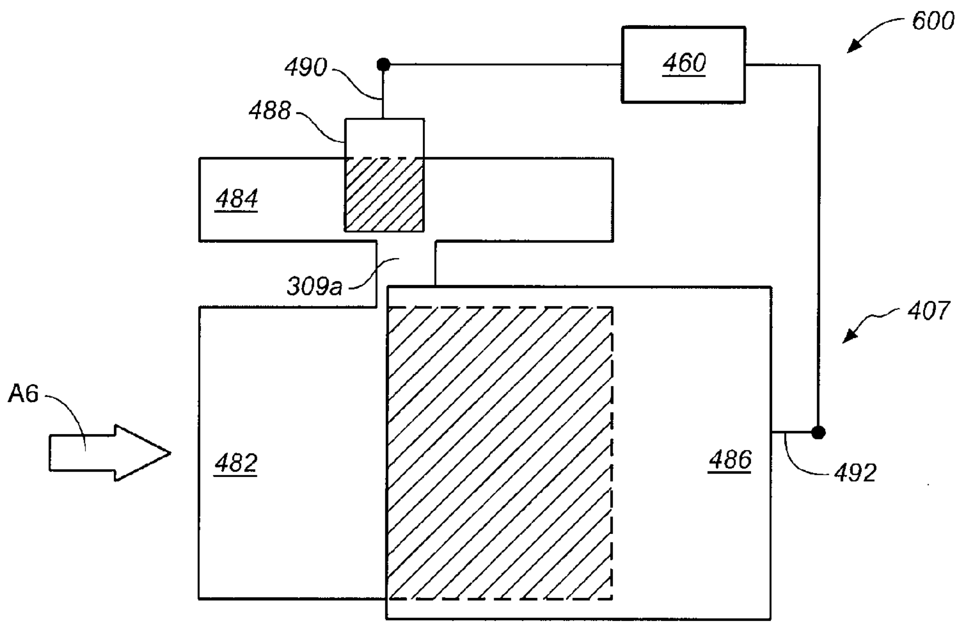
600
490
460
488
484
309a
407
A6
482
486
492

FIG. 11

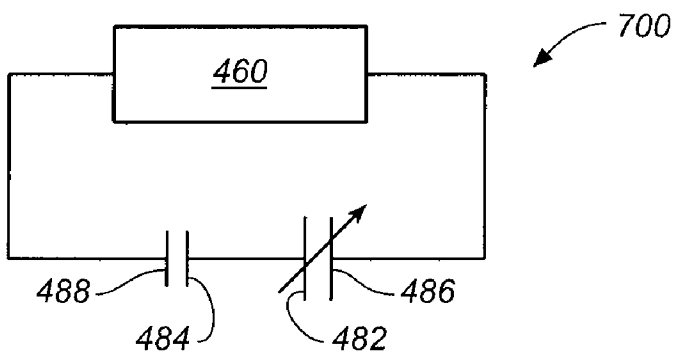
700
460
488
484
482
486

FIG. 12

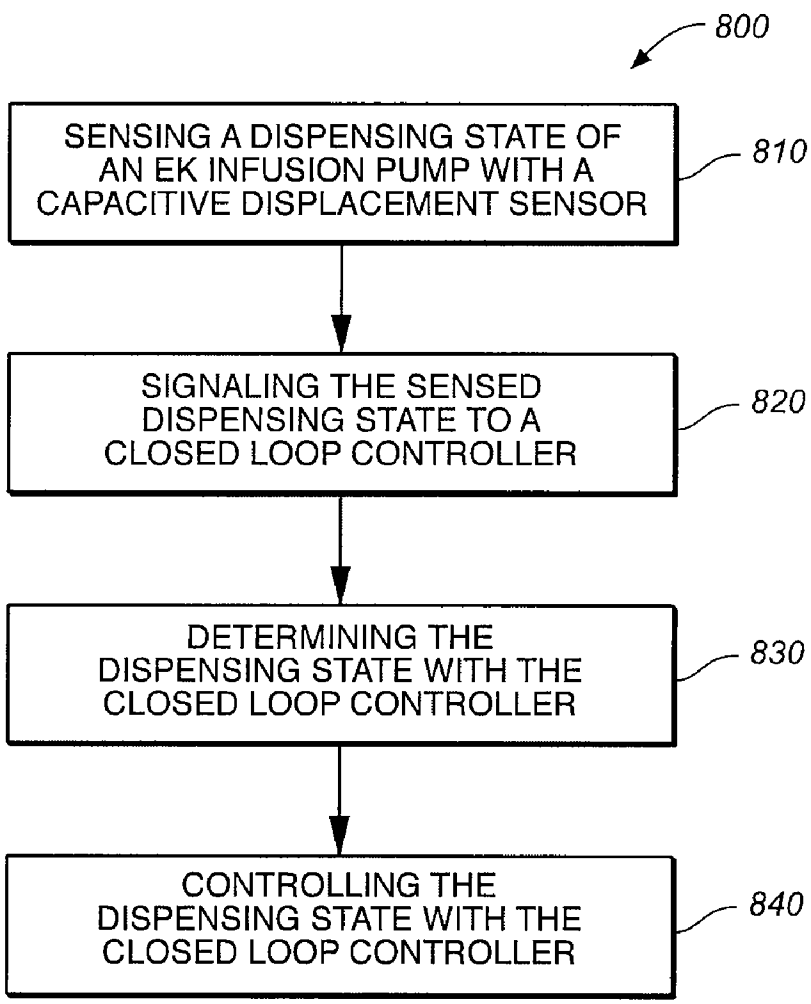
800
SENSING A DISPENSING STATE OF AN EK INFUSION PUMP WITH A CAPACITIVE DISPLACEMENT SENSOR
810
SIGNALING THE SENSED DISPENSING STATE TO A CLOSED LOOP CONTROLLER
820
DETERMINING THE DISPENSING STATE WITH THE CLOSED LOOP CONTROLLER
830
CONTROLLING THE DISPENSING STATE WITH THE CLOSED LOOP CONTROLLER
840

FIG. 13

INFUSION PUMP WITH A CAPACITIVE DISPLACEMENT POSITION SENSOR

FIELD OF THE INVENTION

[0001] The present invention relates, in general, to a medical devices and systems and, in particular, to infusion pumps, infusion pump systems and associated methods.

BACKGROUND

[0002] Electrokinetic (EK) pumps provide for liquid displacement by applying an electric potential across a porous dielectric media that is filled with an ion-containing electrokinetic solution. Properties of the porous dielectric media and ion-containing solution (e.g., permittivity of the ion-containing solution and zeta potential of the solid-liquid interface between the porous dielectric media and the ion-containing solution) are predetermined such that an electrical double-layer is formed at the solid-liquid interface. Thereafter, ions of the electrokinetic solution within the electrical double-layer migrate in response to the electric potential, transporting the bulk electrokinetic solution with them via viscous interaction. The resulting electrokinetic flow (also known as electroosmotic flow) of the bulk electrokinetic solution is employed to displace (i.e., "pump") a liquid. Further details regarding electrokinetic pumps, including materials, designs, and methods of manufacturing are included in U.S. patent application Ser. No. 10/322,083 (United States Published Application No. 2004/0074784) filed on Dec. 17, 2002, which is hereby incorporated in full by reference.

SUMMARY

[0003] The present invention provides various methods and devices for an electrokinetic infusion pump. In one embodiment, the electrokinetic infusion pump includes an infusion pump module, which can be configured to dispense a medicament or another treatment agent (e.g., an insulin containing infusion liquid), and an electrokinetic engine. The infusion pump module includes a capacitive displacement position sensor configured for sensing a dispensing state of the infusion pump module. The infusion pump module can include an infusion module housing and the electrokinetic engine can include a moveable partition. The capacitive displacement sensor includes a first capacitive element, such as a capacitive plate, disposed on the moveable partition and a second element, such as a capacitive plate, disposed on the infusion module housing. The capacitive displacement sensor is configured for measuring capacitance between the first capacitive element and the second capacitive element and can send a feedback signal to a closed loop controller that is indicative of the capacitance between the first and second capacitive plates. In one exemplary embodiment, the first capacitive plate and the second capacitive plate each have a width of approximately 10 mm and a length of approximately 20 mm. A gap between the first capacitive plate and the second capacitive plate can have a dimension in the range of approximately 10-1000 micrometers.

[0004] In another embodiment, the electrokinetic engine includes a moveable partition and the infusion pump includes an infusion housing, and the capacitive displacement sensor is a dual capacitive displacement sensor. The dual capacitive displacement sensor includes a first capacitive plate and a second capacitive plate disposed on the moveable partition and a third capacitive plate and a fourth capacitive plate disposed on the infusion housing. The first, second, third, and fourth capacitive plates are in operative electrical contact. An overlap between the second and fourth capacitive plate is constant and an overlap between the first capacitive plate and the third capacitive plate is dependent on a position of the moveable partition.

[0005] In another exemplary embodiment, an infusion pump system is provided that includes an infusion pump, for example, an electrokinetic pump, having a capacitive displacement position sensor and a closed loop controller. The infusion pump and closed loop controller are in operative communication and configured such that the closed loop controller can determine and control a dispensing state of the infusion pump based on a feedback signal received from the capacitive displacement position sensor. The infusion pump further includes an infusion pump module and an electrokinetic engine. The capacitive displacement sensor is configured for sensing a dispensing state of the infusion pump module. The infusion pump can be configured to dispense, for example, an insulin-containing infusion liquid.

[0006] The infusion pump module can include an infusion module housing and the electrokinetic engine can include a moveable partition. The electrokinetic engine can also include an electrokinetic supply reservoir that is at least partially collapsible. The capacitive displacement sensor can include a first capacitive plate disposed on the moveable partition and a second capacitive plate disposed on the infusion module housing, and the capacitive displacement sensor can be configured for sensing a dispensing state by measuring capacitance between the first capacitive plate and the second capacitive plate. In one embodiment, the first capacitive plate and the second capacitive plate each have a width of approximately 10 mm and a length of approximately 20 mm, and a gap between the first capacitive plate and the second capacitive plate has a dimension in the range of approximately 10-1000 micrometer.

[0007] In one embodiment, the electrokinetic engine includes a moveable partition and the capacitive displacement sensor is a dual capacitive displacement sensor that includes first, second, third, and fourth capacitive plates. The first, second, third, and fourth capacitive plates are in operative electrical contact and an overlap between the second and fourth capacitive plate is constant and an overlap between the first capacitive plate and the third capacitive plate is dependent on a position of the moveable partition.

[0008] Methods for the closed loop control of an infusion pump are also provided, and in one embodiment the method can include sensing a dispensing state of an infusion pump, for example, an electrokinetic infusion pump, with a capacitive displacement position sensor and signaling the sensed dispensing state of the infusion pump to a closed loop controller via a feedback signal. The closed loop controller determines the dispensing state of the infusion pump based feedback signal and controls the dispensing state of the infusion pump by sending command signals from the closed loop controller to an engine driving the infusion pump. These steps can be repeated to maintain control of the electrokinetic infusion pump.

[0009] Sensing the dispensing state can include sensing a position of a moveable partition of the electrokinetic infusion pump by the capacitive displacement sensor. Sensing the dispensing state can also include sensing the position of the moveable partition due to a change in overlap between capacitive plates of the capacitive displacement sensor. The

dispensing state can be an infusion liquid displacement rate or an infusion liquid volume. The step of controlling the dispensing state can include controlling the dispensing state of an insulin containing infusion liquid. The capacitive displacement position sensor can be a dual capacitive displacement sensor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

[0011] FIG. **1** is an exploded schematic illustration of an electrokinetic infusion pump system with closed loop control according to an exemplary embodiment of the present invention in a first dispense state;

[0012] FIG. **2** is an exploded schematic illustration of the electrokinetic infusion pump system shown in FIG. **1** in a second dispense state;

[0013] FIG. **3** is a perspective illustration of an electrokinetic infusion pump system according to another exemplary embodiment of the present invention being manually manipulated;

[0014] FIG. **4** is a cross-sectional depiction of an electrokinetic infusion pump system according to a further exemplary embodiment of the present invention in a first dispense state;

[0015] FIG. **5** is a cross-sectional depiction of the electrokinetic infusion pump system shown in FIG. **4** in a second dispense state;

[0016] FIG. **6** is a perspective depiction of a portion of the electrokinetic infusion pump of the EK infusion pump system shown in FIG. **4**;

[0017] FIG. **7** is a perspective depiction of a portion of the electrokinetic infusion pump of the EK infusion pump system shown in FIG. **5**;

[0018] FIG. **8** is a perspective depiction of a portion of an electrokinetic infusion pump with capacitive displacement position sensors according to another exemplary embodiment of the present invention in a first dispense state;

[0019] FIG. **9** is a perspective depiction of the portion of an electrokinetic infusion pump shown in FIG. **8** in a second dispense state;

[0020] FIG. **10** is a schematic drawing depicting a capacitive plate configuration of the electrokinetic infusion pump shown in FIG. **8**;

[0021] FIG. **11** is a schematic drawing depicting a capacitive plate configuration of the electrokinetic infusion pump shown in FIG. **9**;

[0022] FIG. **12** is an electrical circuit schematic depicting the analog electric circuit formed by the capacitive displacement position sensor shown in FIGS. **8-11**; and

[0023] FIG. **13** is a flow diagram illustrating a method for the closed loop control of an electrokinetic infusion pump according to an exemplary embodiment of the present invention.

DETAILED DESCRIPTION

[0024] Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those skilled in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

[0025] Various exemplary methods and devices are provided for controlling the dispensing state of an infusion pump system. In particular, the methods and devices provide a capacitive displacement position sensor coupled with an infusion pump to control the dispensing of an infusion liquid from the infusion pump.

[0026] FIGS. **1-2** are exploded schematic illustrations of an electrokinetic (EK) infusion pump system **100** with closed loop control according to an exemplary embodiment of the present invention. FIG. **1**. illustrates the EK infusion pump system **100** in a first dispense state, while FIG. **2** depicts the EK infusion pump system **100** in a second dispense state.

[0027] Referring to FIGS. **1** and **2**, the EK infusion pump system **100** includes an electrokinetic (EK) infusion pump **102** and a closed loop controller **104**. The EK infusion pump **102** can include a capacitive displacement position sensor (not shown in FIGS. **1** and **2**). As is described in further detail below, the EK infusion pump **102** and the closed loop controller **104** are in operative communication such that the closed loop controller **104** can determine and control the dispensing state of the EK infusion pump **102** based on one or more feedback signals FB from the capacitive displacement position sensor. The EK infusion pump **102** and the closed loop controller **104** can be configured in a variety of ways. For example, the infusion pump **102** and the closed loop controller **104** can be entirely separate units, partially integrated (for example, predetermined components of the EK infusion pump **102** can be integrated within the closed loop controller **104**), or a single integrated unit.

[0028] The EK infusion pump systems according to embodiments of the present invention, including the EK infusion pump system **100**, can be employed to deliver a variety of medically useful infusion liquids such as, for example, insulin for diabetes; morphine and other analgesics for pain; barbiturates and ketamine for anesthesia; anti-infective and antiviral therapies for Acquired Immune Deficiency Syndrome (AIDS); antibiotic therapies for preventing infection; bone marrow for immunodeficiency disorders, blood-borne malignancies, and solid tumors; chemotherapy for cancer; dobutamine for congestive heart failure; monoclonal antibodies and vaccines for cancer, brain natriuretic peptide for congestive heart failure, and vascular endothelial growth factor for preeclampsia. The delivery of such infusion liquids can be accomplished via any suitable route including subcutaneously, intravenously or intraspinally.

[0029] The EK infusion pump **102** can also include an electrokinetic (EK) engine **106** and an infusion module **108**. The EK engine **106** can include an electrokinetic (EK) supply reservoir **110**, an electrokinetic (EK) porous media **112**, an electrokinetic (EK) solution receiving chamber **114**, a first electrode **116**, a second electrode **118**, and an electrokinetic (EK) solution **120** (depicted as upwardly pointing chevrons).

[0030] The pore size of the porous media **112** can be, for example, in the range of 100 nm to 200 nm. A person skilled in the art will appreciate that the porous media **112** can have any number of pores with any pore size that allows the appropriate amount of electrokinetic solution **120** to flow through it. Moreover, the porous media **112** can be formed of any suitable material including, by way of non-limiting example, Durapore Z PVDF membrane material available from Millipore, Inc. USA. EK solution **120** can be any suitable EK solution including, but not limited to, 10 mM TRIS/HCl at a neutral pH.

[0031] The infusion module **108** can include the EK solution receiving chamber **114** (which is also considered part of the EK engine **106**), an infusion module housing **122**, a movable partition **124**, an infusion reservoir **126**, an infusion reservoir outlet **128**, and an infusion liquid **130** (depicted as dotted shading). Although the capacitive displacement position sensor of the infusion module **108** is not depicted in FIGS. **1** and **2**, the feedback signal FB between the capacitive displacement position sensor and the closed loop controller **104** is shown.

[0032] The closed loop controller **104** can include a voltage source **132** and is configured to receive the feedback signal FB from the capacitive displacement sensor and to be in electrical communication with the first and second electrodes **116** and **118**. The EK engine **106**, the infusion module **108**, and the closed loop controller **104** can be integrated into a single assembly, into multiple assemblies, or can be separate units.

[0033] During operation of the EK infusion pump system **100**, the EK engine **106** provides the driving force for displacing (pumping) the infusion liquid **130** from the infusion module **108**. To do so, a voltage difference is established across the EK porous media **112** by the application of an electrical potential between the first electrode **116** and the second electrode **118**. This electrical potential results in an electrokinetic pumping of the EK solution **120** from the EK supply reservoir **110**, through the EK porous media **112**, and into the EK solution receiving chamber **114**.

[0034] As the electrokinetic solution receiving chamber **114** receives the EK solution **120**, the moveable partition **124** is forced to move in the direction of arrows μl, shown in FIGS. **1**-**2**. Such movement is evident by a comparison of the first dispense state shown in FIG. **1** to the second dispense state shown in FIG. **2**. As the moveable partition **124** moves in the direction of μl, the infusion liquid **130** is displaced (i.e., "pumped") out of the infusion reservoir **126** and through the infusion reservoir outlet **128** in the direction of arrow μl. The EK engine **106** can continue to displace the EK solution **120** until the moveable partition **124** reaches a predetermined point near the infusion reservoir outlet **128**, for example, a point just proximal of the infusion reservoir outlet **128**, thereby displacing a predetermined amount (e.g., essentially all) of the infusion liquid **130** from the infusion reservoir **126**.

[0035] It is evident from the description above and a comparison of FIGS. **1** and **2**, that the second dispensing state represented by FIG. **2** is achieved by electrokinetically displacing (i.e., pumping or dispelling) a portion of the infusion liquid **130** that is present within the infusion reservoir **126** in the first dispensing state represented by FIG. **1**.

[0036] The rate of displacement of the infusion liquid **130** from the infusion reservoir **126** is directly proportional to the rate at which the EK solution **120** is pumped from the EK supply reservoir **110** into the EK solution receiving chamber **114**. The proportionality between the rate of displacement of the infusion liquid **130** (such as an insulin containing infusion liquid) and the rate at which the EK solution **120** is pumped can be, for example, in the range of 1:1 to 4:1. Furthermore, the rate at which the EK solution **120** is pumped from the EK supply reservoir **110** is a function of the voltage and current applied by the first electrode **116** and the second electrode **118** and various electro-physical properties of the EK porous media **112** and the EK solution **120** (such as, for example, zeta potential, permittivity of the EK solution and viscosity of the EK solution).

[0037] The features disclosed herein are applicable to a variety of electrokinetic infusion pump systems, including, for example, the electrokinetic infusion pumps and electrokinetic infusion pump systems of the type disclosed in U.S. patent application Ser. No. 11/532,587, filed Sep. 18, 2006, entitled "Electrokinetic Infusion Pump System," which is incorporated herein in its entirety. In addition, features disclosed herein can be used in combination with electrokinetic infusion pump systems of the type disclosed in U.S. patent application Ser. No. 11/532,587, as well as with features of electrokinetic infusion pumps as disclosed in U.S. patent application Ser. No. 11/532,691, filed Sep. 18, 2006, entitled "Malfunction Detection With Derivative Calculation," and U.S. patent application Ser. No. 11/614,211, filed Dec. 21, 2006, entitled "Malfunction Detection In Infusion Pumps," both of which are likewise incorporated herein in their entirety.

[0038] Further details regarding EK engines, including materials, designs, operation and methods of manufacturing, are included in U.S. patent application Ser. No. 10/322,083 (United States Published Application No. 2004/0074784) filed on Dec. 17, 2002, which has been incorporated by reference. Although a particular EK engine is depicted in a simplified manner in FIGS. **1** and **2**, any suitable EK engine can be employed in embodiments of the present invention including, but not limited to, the EK engines described in the aforementioned U.S. patent application Ser. No. 10/322,083 and EK engines that substitute a media with a microchannel (s) for the aforementioned porous media.

[0039] The capacitive displacement position sensor of EK infusion pump **102** is configured to sense (determine) the position of the moveable partition **124**. Based on the sensed position of the moveable partition **124** (as communicated by feedback signal FB), the closed loop controller **104** can determine the dispensing state (e.g., the displacement position of the moveable partition **124** at any given time and/or as a function of time, the rate of displacement of the infusion liquid **130** from infusion reservoir **126**, the rate at which the EK solution **120** is pumped from the EK supply reservoir **110** to the EK solution receiving chamber **114**, and the volume of dispensed EK solution).

[0040] Based on such a determination of dispensing state, the closed loop controller **104** controls (i.e., can command and manage) the dispensing state by, for example, (i) adjusting the voltage and/or current applied between the first electrode **116** and the second electrode **118** or (ii) maintaining the voltage between the first electrode **116** and the second electrode **118** constant while adjusting the duration during which power is applied between the first electrode **116** and the second electrode **118**. For example, by adjusting the voltage and/or current applied across the first electrode **116** and the second electrode **118**, the rate at which the EK solution **120** is displaced from the EK supply reservoir **110** to the EK solution receiving chamber **114** and, therefore, the rate at which the infusion liquid **130** is displaced through the infusion reservoir outlet **128**, can be accurately and beneficially controlled.

[0041] The closed loop control of EK infusion pumps described above beneficially compensates for variations that may cause inconsistent displacement (i.e., dispensing) of the infusion liquid **130** including, but not limited to, variations in temperature, downstream resistance, and mechanical friction.

[0042] The EK supply reservoir **110** can have a variety of configurations. In one embodiment, the EK supply reservoir **110** can be partially or wholly collapsible. For example, the EK supply reservoir **110** can be configured as a collapsible sack. Such collapsibility provides for the volume of the EK supply reservoir **110** to decrease as the EK solution **120** is displaced therefrom. Such a collapsible EK supply reservoir **110** can also assist in the prevention of undesirable bubble formation within the EK supply reservoir **110**.

[0043] The infusion module housing **122** can also be configured in a variety of additional ways, and can be, for example, at least partially rigid to facilitate the movement of the moveable partition **124** and the reception of the EK solution **120** pumped from the EK supply reservoir **110**.

[0044] The moveable partition **124** can be configured to prevent migration of the EK solution **120** into the infusion liquid **130**, while minimizing resistance to its own movement (displacement) as the EK solution receiving chamber **114** receives the EK solution **120** pumped from the EK supply reservoir **110**. The moveable partition **124** can, for example, include elastomeric seals that provide intimate, yet movable, contact between the moveable partition **124** and the infusion module housing **122**. The moveable partition **124** can have a variety of configurations, such as, for example, a piston-like configuration, or the moveable partition **124** can be configured as a moveable membrane and/or bellows.

[0045] FIG. **3** is a perspective illustration of an electrokinetic (EK) infusion pump system **200** according to another exemplary embodiment of the present invention being manipulated by a user's hands (H). The EK infusion pump system **200** can include an electrokinetic (EK) infusion pump **202** and a closed loop controller **204**.

[0046] The EK infusion pump **202** and the closed loop controller **204** can be handheld, and/or mounted to a user by way of clips, adhesives or non-adhesive removable fasteners. For example, the EK infusion pump system **200** can be configured to be worn on a user's belt, thereby providing an ambulatory EK infusion pump system. In addition, the closed loop controller **204** can be directly or wirelessly connected to a remote controller or other auxiliary equipment (not shown in FIG. **3**) that provide analyte monitoring capabilities and/or additional data processing capabilities.

[0047] The EK infusion pump **202** and the closed loop controller **204** can include components that are essentially equivalent to those described above with respect to the EK infusion pump **102** and the closed loop controller **104**. In addition, the closed loop controller **204** can include a variety of features, including a display **240**, input keys **242***a* and **242***b*, and an insertion port **244**.

[0048] The display **240** can be configured, for example, to display a variety of information, including infusion rates, error messages and logbook information. During use of the EK infusion pump system **200**, and subsequent to the EK infusion pump **202** having been filled with infusion liquid, the EK infusion pump **202** can be inserted into the insertion port **244**. Upon such insertion, operative electrical communication is established between the closed loop controller **204** and the EK infusion pump **202**. Such electrical communication includes the ability for the closed loop controller **204** to receive a feedback signal FB from a capacitive displacement position sensor of the EK infusion pump **202** and operative electrical contact with first and second electrodes of the EK infusion pump **202**.

[0049] One skilled in the art will recognize that an infusion set (not shown but typically including, for example, a connector, tubing, needle and/or cannula and an adhesive patch) can be connected to the infusion reservoir outlet of the EK infusion pump **202** and, thereafter, primed. As may be suitable for a particular infusion set, such attachment and priming can occur before or after EK infusion pump **202** is inserted into insertion port **244**. After determining the position of a movable partition of EK infusion pump **202**, voltage and current are applied across the EK porous media of EK infusion pump **202**, thereby dispensing (pumping) infusion liquid.

[0050] FIG. **4** is a cross-sectional depiction of an electrokinetic (EK) infusion pump system **300** according to a further exemplary embodiment of the present invention in a first dispense state, while FIG. **5** depicts the EK infusion pump system **300** in second dispense state. FIG. **6** is a further perspective depiction of a portion of the EK infusion pump system **300** in the first dispense state of FIG. **4**, while FIG. **7** is in the second dispense state of FIG. **5**. As will be evident from the discussion below, the focus of FIGS. **6** and **7** is the capacitive displacement position sensor of the EK infusion pump system **300**. Therefore, FIGS. **6** and **7** are further simplified versions of FIGS. **4** and **5** that serve to highlight the capacitive displacement position sensor.

[0051] Referring to FIGS. **4-7**, the EK infusion pump system **300** includes an electrokinetic (EK) infusion pump **302** and a closed loop controller **304**. As will be clear to one skilled in the art from the following description, the EK infusion pump **302** includes an integrated electrokinetic (EK) engine and infusion module (collectively element **306**) and a capacitive displacement position sensor **307**.

[0052] The integrated EK engine and infusion module **306** includes an electrokinetic (EK) supply reservoir **310**, an electrokinetic (EK) porous media **312**, an electrokinetic (EK) solution receiving chamber **314**, a first electrode **316**, a second electrode **318**, and an electrokinetic (EK) solution **320** (depicted as upwardly pointing chevrons). The integrated EK engine and infusion module **306** also includes an infusion module housing **322**, a movable partition **324**, an infusion reservoir **326**, an infusion reservoir outlet **328**, and an infusion liquid **330** (depicted as dotted shading).

[0053] The moveable partition **324** can have a variety of configurations, but in the illustrated embodiment can include a first infusion seal **348**, a spacer **349**, and a second infusion seal **350**. The spacer **349** is positioned between the first and second infusion seals **348**, **350**, with the first infusion seal positioned proximal of the spacer **349** and the second infusion seal **350** positioned distal of the spacer **349**. The spacer **349** of the moveable partition **324** is at a position B in the first dispense state a shown in FIG. **4**, and is at a position C in the second dispense state as shown in FIG. **5**. The distance between position B and position C is labeled D in FIG. **5**.

[0054] In an exemplary embodiment, the capacitive displacement position sensor **307** includes a first capacitive element **352**, such as a capacitive plate, a second capacitive element **354**, such as a capacitive plate, a first electrical contact **356**, a second electrical contact **358**, and a capacitance measurement module **360**.

[0055] The first capacitive plate **352** is mounted on the movable partition **324**, and moves parallel to the longitudinal axis of the infusion module housing **322** along with the movable partition **324**. The second capacitive plate **354** remains stationary and is mounted on the infusion module housing **322** such that there is a gap G (also referred to as a separation) between the first capacitive plate **352** and the second capacitive plate **354**. The gap G can be filled with any suitable material including, for example, air, a wall of the infusion module housing **322** (which is formed of plastic or other suitable electrically insulating material), other suitable electrically insulating material, and combinations thereof.

[0056] The first electrical contact **356** provides electrical contact between the first capacitive plate **352** and the capacitance measurement module **360**, while second electrical contact **358** provides electrical contact between second capacitive plate **354** and capacitance measurement module **360**. In the first dispense state depicted in FIGS. **4** and **6**, the moveable partition **324** is in a first position, and the first capacitive plate **352** partially overlaps the second capacitive plate **354**. The capacitance measurement module **360** is configured to provide a feedback signal FB to the closed loop controller **304** which is indicative of the capacitance between the first and second capacitive plates **352**, **354**. As the moveable partition **324** and the first capacitive plate **354** move and the capacitance between the first and second capacitive plates **352**, **354** changes, the closed loop controller **304** uses the feedback signal FB to control the dispense state, as will be described in more detail below.

[0057] As the capacitance between two capacitive plates is proportional to their overlapping area divided by the distance between the plates, a measured capacitance between the first capacitive plate **352** and the second capacitive plate **354** can be readily correlated to the extent of their overlap. Since the first capacitive plate **352** is attached to the moveable partition **324**, the extent of overlap and/or any change in overlap can be employed to determine the position (i.e., displacement position) of the moveable partition **324**. For example, in FIGS. **5** and **7**, the moveable partition **324** has moved relative to its position in FIGS. **4** and **6**, and the overlap between the first capacitive plate **352** and the second capacitive plate **354** has increased. This increase in overlap will result in an increase in the capacitance that is measured by the capacitance measurement module **360**.

[0058] The position of the movable partition **324** can then be readily derived from the change in capacitance between the two capacitive plates **352**, **354** since the measured capacitance C is proportional to A/G where A is the area of plate overlap and G is the gap dimension. In this regard, the first and second capacitive plates **352**, **354** have typical dimensions, for example, of 10 mm (width) by 20 mm (length). The area of overlap between the first and second capacitive plates **352**, **354** can vary depending on the placement of the first and second capacitive plates **352**, **354** on the moveable partition **324** and the infusion module housing **322**. For example, the largest overlap between the first and second capacitive plates **352**, **354** can be a substantially complete overlap of the first and second capacitive plates **352**, **354**, and the smallest overlap between the first and second capacitive plates **352**, **354** has typical dimensions, for example, of 10 mm (in width) by 5 mm (in length). In addition, the gap dimension G can have a range between 10 and 1000 micrometers, and, for example, it can be 0.5 mm.

[0059] In the embodiments shown in FIGS. **4-7**, both the first and second capacitive plates **352**, **354** are in direct electrical connection with the capacitance measurement module **360**. However, providing a direct electrical connection to the first capacitive plate **352** can raise the cost and complexity of manufacturing. FIG. **8** is a perspective depiction of a portion of an electrokinetic (EK) infusion pump **400** according to another embodiment of the present invention in a first dispense state. As is explained in more detail below, the EK infusion pump **400** employs a dual capacitive coupling configuration to address the issue of manufacturing cost and complexity. FIG. **9** is a perspective depiction of the portion of the EK infusion pump **400** in a second dispense state. FIGS. **8** and **9** are simplified in a similar manner to the simplified depictions of FIGS. **6** and **7**.

[0060] FIG. **10** is a schematic drawing depicting a capacitive plate configuration **500** of the first dispense state of FIG. **8**, while FIG. **11** is a schematic drawing depicting a capacitive plate configuration **600** of the second dispense state of FIG. **9**.

[0061] Referring to FIGS. **8-11**, the EK infusion pump **400** includes an integrated electrokinetic (EK) engine and infusion module **406**, and a dual capacitive displacement sensor **407**. The integrated EK engine and infusion module **406** includes an infusion module housing **422** and a moveable partition **424**.

[0062] The dual capacitive displacement sensor **407** includes a first capacitive plate **482**, a second capacitive plate **484** (configured as an extension of first capacitive plate **482**), a third capacitive plate **486**, a fourth capacitive plate **488**, a first electrical contact **490**, and a second electrical contact **492**.

[0063] The first and second capacitive plates **482**, **484** are mounted on the movable partition **424**, and move parallel to the longitudinal axis of the infusion module housing **422** together with the movable partition **424** (for example, in the direction of arrow A**6** as shown in FIG. **11**). The third and fourth capacitive plates **486**, **488** are mounted on the infusion module housing **422** such that there is a gap between the first capacitive plate **482** and the third capacitive plate **486**, as well as a gap between the second capacitive plate **484** and the fourth capacitive plate **488**. The gaps can be filled with any suitable material including, for example, air, a wall of the infusion module housing **422** (which is formed of plastic or other suitable electrically insulating material), other suitable electrically insulating material, and combinations thereof.

[0064] The first electrical contact **490** provides electrical contact between the fourth capacitive plate **488** and the capacitance measurement module **460**, while the second electrical contact **492** provides electrical contact between the third capacitive plate **486** and the capacitance measurement module **460**.

[0065] The extent of overlap between the first capacitive plate **482** and the third capacitive plate **486** is variable as the moveable partition **424** moves, as evidenced by a comparison of FIGS. **8** and **9** or FIGS. **10** and **11**. However, the extent of overlap between the second capacitive plate **484** and the fourth capacitive plate **488** is constant as moveable partition **424** moves, as evidenced by a comparison of FIGS. **8** and **9** or FIGS. **10** and **11**. The position of the movable partition **424** can then be derived from a change in capacitance as measured by the capacitance measurement module **460**. The position of the moveable partition **424** can be readily derived since the total measured capacitance is the result of two capacitances in series, of which one is constant and one is variable with moveable partition position. In other words, $1/C_{tot}$ is equal to the sum of $1/C_c$ and $1/C_v$ (where C_{tot} is the measured total capacitance, C_c is the constant capacitance between the second and fourth capacitive plates **484**, **488** and C_v is the variable capacitance between first and third capacitive plates **482**, **486**).

[0066] FIG. **12** is an electrical circuit schematic depicting an electric circuit **700** that is essentially equivalent to the circuit formed by the capacitive plates depicted in FIGS. **8-11**. As depicted in FIG. **12**, the circuit includes one variable capacitor that includes the first and third capacitive plates (i.e., capacitive plates **482** and **486**) and one fixed capacitor that includes the second and third capacitive plates (i.e., capacitive plates **484** and **488**).

[0067] FIG. **13** is a flow diagram illustrating a method **800** for the closed loop control of an electrokinetic (EK) infusion pump according to an exemplary embodiment of the present invention. The method **800** includes, at step **810**, sensing a dispensing state of an EK infusion pump with a capacitive displacement position sensor. The capacitive displacement position sensor and the EK infusion pump can be any such sensor and EK infusion pump as described herein with respect to embodiments of the present invention.

[0068] Subsequently, the sensed dispensing state of the EK infusion pump is signaled to a closed loop controller via a feedback signal, as set forth in step **820**. The closed loop controller then determines the dispensing state of the electrokinetic infusion pump based on the feedback signal, as set forth in step **830**.

[0069] Subsequently, at step **840**, the dispensing state of the EK infusion pump (e.g., infusion liquid displacement rate) is controlled by the closed loop controller by the sending command signals from the closed loop controller to an electrokinetic engine of the EK infusion pump. The command signal can be, for example, based on a comparison of the determined dispensing state and a predetermined desired dispensing state and be a command signal that adjusts for any differences between the determined dispensing state and the predetermined desired dispensing state.

[0070] The method **800** can be practiced using EK infusion pump systems according to the present invention including the embodiments of FIGS. **1-12**. Moreover, steps **810** through **840** can be repeated as necessary to establish and maintain accurate control of the EK infusion pump dispensing state.

[0071] EK infusion pumps and EK infusion pump systems according to embodiments of the present invention are economical to manufacture since the capacitive plates of their capacitive displacement position sensors can be formed using conventional economical techniques such as laser ablation of thin metal layers, screen printing and offset printing. Moreover, since the plates can be manufactured economically, the capacitive displacement position sensors described herein can be included as a component within a disposable EK infusion pump.

[0072] In addition, capacitance can be measured using techniques with beneficially low power consumption, thus enabling EK infusion pumps and EK infusion systems with extended lifetimes. For example, capacitance-to-digital converter device AD7745 (commercially available from Analog Devices Inc., U.S.A.) can directly measure capacitance and convert the measured capacitance to a digital signal at an indicated power consumption of approximately 1 mW.

[0073] It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods within the scope of these claims and their equivalents be covered thereby

[0074] One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. An electrokinetic infusion pump comprising:

an infusion pump module; and

an electrokinetic engine,

wherein the infusion pump module includes a capacitive displacement position sensor configured for sensing a dispensing state of the infusion pump module.

2. The electrokinetic infusion pump of claim **1**, wherein:

the infusion pump module includes an infusion module housing;

the electrokinetic engine includes a moveable partition; and

the capacitive displacement sensor includes a first capacitive plate disposed on the moveable partition and a second capacitive plate disposed on the infusion module housing.

3. The electrokinetic infusion pump of claim **2**, wherein the first capacitive plate and the second capacitive plate each have a width of approximately 10 mm and a length of approximately 20 mm.

4. The electrokinetic infusion pump of claim **3**, wherein a gap between the first capacitive plate and the second capacitive plate has a dimension in the range of approximately 10-1000 micrometer.

5. The electrokinetic infusion pump of claim **2**, wherein the capacitive displacement sensor is configured for measuring capacitance between the first capacitive plate and the second capacitive plate.

6. The electrokinetic infusion pump of claim **1**, wherein the electrokinetic engine includes a moveable partition and the infusion pump includes an infusion housing, and wherein the capacitive displacement sensor is a dual capacitive displacement sensor that includes:

a first capacitive plate and a second capacitive plate disposed on the moveable partition; and

a third capacitive plate and a fourth capacitive plate disposed on the infusion housing;

wherein the first capacitive plate, the second capacitive plate, the third capacitive plate and the fourth capacitive plate are in operative electrical contact and wherein an overlap between the second and fourth capacitive plate is constant and an overlap between the first capacitive plate and the third capacitive plate is dependent on a position of the moveable partition.

7. The electrokinetic infusion pump of claim **1**, wherein the capacitive displacement sensor is configured to send a feedback signal to a closed loop controller, the feedback signal indicative of the capacitance between the first and second capacitive plates.

8. The electrokinetic infusion pump of claim **1**, wherein the infusion pump is configured to dispense an insulin containing infusion liquid.

9. An infusion pump system, comprising:

an infusion pump that includes:

a capacitive displacement position sensor; and

a closed loop controller,

wherein the infusion pump and closed loop controller are in operative communication and configured such that the closed loop controller can determine and control a dispensing state of the infusion pump based on a feedback signal received from the capacitive displacement position sensor.

10. The system of claim **9**, wherein the infusion pump is an electrokinetic pump.

11. The system of claim **10**, wherein the electrokinetic infusion pump further includes

an infusion pump module; and

an electrokinetic engine,

and wherein the capacitive displacement sensor is configured for sensing a dispensing state of the infusion pump module.

12. The system of claim **11**, wherein:

the infusion pump module includes an infusion module housing;

the electrokinetic engine includes a moveable partition; and

the capacitive displacement sensor includes a first capacitive plate disposed on the moveable partition and a second capacitive plate disposed on the infusion module housing.

13. The system of claim **12**, wherein the capacitive displacement sensor is configured for sensing a dispensing state by measuring capacitance between the first capacitive plate and the second capacitive plate.

14. The system of claim **13**, wherein the first capacitive plate and the second capacitive plate each have a width of approximately 10 mm and a length of approximately 20 mm.

15. The system of claim **14**, wherein a gap between the first capacitive plate and the second capacitive plate has a dimension in the range of approximately 10-1000 micrometer.

16. The system of claim **11**, wherein the electrokinetic engine includes a moveable partition and wherein the capacitive displacement sensor is a dual capacitive displacement sensor that includes:

a first capacitive plate;

a second capacitive plate;

a third capacitive plate; and

a fourth capacitive plate,

and wherein the first capacitive plate, the second capacitive plate, the third capacitive plate and the fourth capacitive plate are in operative electrical contact and wherein an overlap between the second and fourth capacitive plate is constant and an overlap between the first capacitive plate and the third capacitive plate is dependent on a position of the moveable partition.

17. The system of claim **11**, wherein the electrokinetic engine includes an electrokinetic supply reservoir that is at least partially collapsible.

18. The system of claim **9**, wherein the capacitive displacement sensor is configured to send the feedback signal to the closed loop controller.

19. The system of claim **9**, wherein the infusion pump is configured to dispense an insulin-containing infusion liquid.

20. A method for the closed loop control of an infusion pump, comprising:

sensing a dispensing state of an infusion pump with a capacitive displacement position sensor;

signaling the sensed dispensing state of the infusion pump to a closed loop controller via a feedback signal;

determining, with the closed loop controller, the dispensing state of the infusion pump based feedback signal; and

controlling the dispensing state of the infusion pump with the closed loop controller by sending command signals from the closed loop controller to an engine driving the infusion pump.

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