(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 September 2016 (22.09.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/149697 A1

(51) International Patent Classification:
A61M 5/142 (2006.01) *F04B 43/00* (2006.01)
A61M 5/145 (2006.01) *F15C 3/04* (2006.01)

(21) International Application Number:
PCT/US2016/023375

(22) International Filing Date:
21 March 2016 (21.03.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/135,519 19 March 2015 (19.03.2015) US

(71) Applicant: **SFC FLUIDICS, INC.** [US/US]; 534 E. Research Blvd., Ste. 260, Fayetteville, Arkansas 72701 (US).

(72) Inventors: **PAYNE, Forrest**; 2525 E. Golden Oaks Dr., Fayetteville, AZ 72703 (US). **LAMPS, Greg**; 5005 Duxford Dr. SE, Smyrna, GA 30082 (US). **WASHBURN, Anna**; P.O. Box 9113, Fayetteville, AZ 72703 (US).

(74) Agent: **DOUGHERTY, J. Charles**; Wright, Lindsey & Jennings LLP, 200 W. Capitol Ave., Ste. 2300, Little Rock, AZ 72201 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) **Title**: DISPOSABLE METERING CHAMBER FOR RECIPROCATING DIAPHRAGM PUMPS

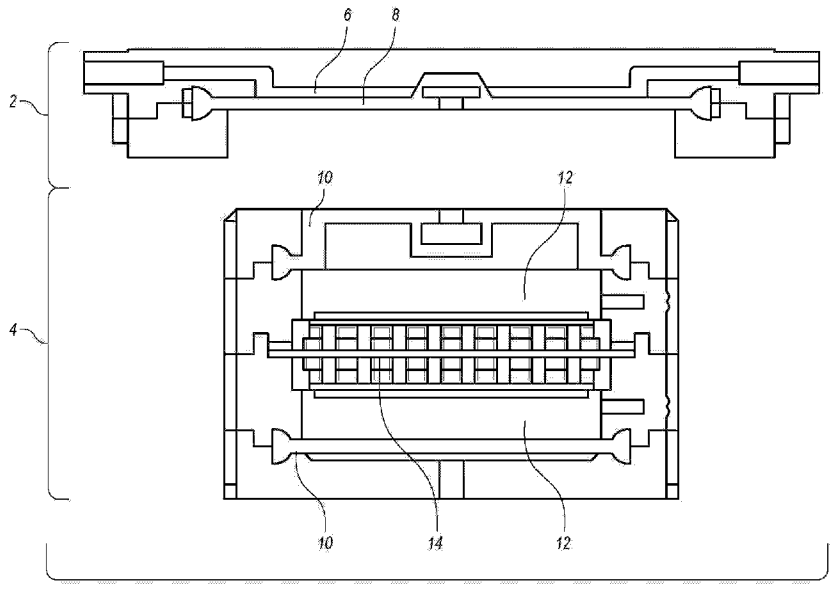

FIG. 1

(57) **Abstract**: A reciprocating pump apparatus includes a metering chamber capable of separating from the pump body for replacing the fluid line. A flexible diaphragm in the removable metering chamber body is in contact with a flexible diaphragm in the reusable pump body such that when the flexible diaphragm in the pump body expands and contracts due to an electrochemical reaction, so does the diaphragm in the metering chamber body. This expansion and contraction of the metering chamber diaphragm allows a fluid in the metering chamber to flow from the reservoir to the target.

WO 2016/149697 A1

DISPOSABLE METERING CHAMBER FOR RECIPROCATING DIAPHRAGM PUMPS

[0001] This application claims the benefit of US provisional patent application no. 62/135,519 filed on March 19, 2015, and entitled "Disposable Pump Chamber for Reciprocating Diaphragm Pumps." Such application is incorporated herein by reference in its entirety.

BACKGROUND

[0002] The field of the invention is pumps for fluid delivery applications, and in particular to the use of a disposable metering chamber in a pump for cost-effective replacement of fluidic lines. The present invention may be discussed and examples may be given in connection with drug delivery applications, but it is recognized that the present invention is not so limited. Instead, the invention may be useful in any application where it is necessary or advantageous to replace fluidic lines for reasons of disposability, cleanliness, or cross-contamination, while reusing pump electronics in order to reduce costs and waste production.

[0003] Generally, reciprocating pumps can be used to pump fluid from a reservoir to a target. An example of a reciprocating pump is the ePump developed by SFC Fluidics, Inc. (disclosed in U.S. Patent Nos. 7,718,047; 8,187,441; and 8,343,324; and U.S. Patent Application Publication No. US2013/057032), which may be used to draw a dose from a reservoir into a metering chamber on the instroke, and expel the dose from the metering chamber on the outstroke. This setup and the small size of the reciprocating ePump make the system ideal for drug delivery applications. For these drug delivery applications in particular, but also for other pumping applications as well, it is very important that the entire

fluid path from the reservoir to the target (in the case of drug delivery, the patient) be cleaned and sterilized at regular intervals. Given the complexity of the cleaning and sterilizing of these pathways, the patient or other consumer generally is incapable of conducting the cleaning. Instead, many consumers are required to replace the fluid path with a new, clean fluid path. For example, the need for a clean fluid path requires insulin patch pumps to be replaced every three days. The replacement of these pumps, however, can result in higher costs to the consumer, as replacing the expensive electronics and pump itself can be costly.

[0004] Therefore, it is desired to provide a way for consumers to replace the fluid lines in these pumps without requiring replacement of the pump electronics and the pump itself. As described herein, this is particularly important in drug delivery applications where the sterility/cleanliness of drug fluidic lines is of high importance and there is a regulatory limit to the number of days the fluidic path may be utilized. However, as noted above, the present invention is useful in any device where it is advantageous to replace fluidic lines for reasons of disposability, cleanliness, or cross contamination, while reusing the reciprocating pump/electronics in order to minimize cost and waste.

BRIEF SUMMARY

[0005] The present invention relates generally to reciprocating pump systems, and in particular to a disposable metering chamber that allows the user to replace the fluidic line in a reciprocating pump without requiring replacement of the entire pump assembly. It is an object of the present invention to allow a user

to replace, particularly in drug delivery applications but in other applications as well, the fluidic line such that the entire fluid path from the reservoir to the target remains clean and sterilized. In existing pump assemblies users are required to replace the entire assembly, including expensive electronics and the pump itself. It is an object of the present invention to allow users to replace only the fluidic line portion of the pump assembly, therefore reducing the cost and waste associated with replacing the entire apparatus.

[0006] In existing reciprocating pumps, a single flexible diaphragm is in direct contact with the fluid path leading from the reservoir to the target. This prevents replacement of the fluid line without replacing the entire assembly. In the present invention, a disposable metering chamber with a second flexible diaphragm is connected to the flexible diaphragm of the reciprocating pump. This second diaphragm allows the reciprocating pump to indirectly draw in and expel fluid via diaphragm-to-diaphragm contact with the disposable metering chamber. The metering chamber, thus, can be replaced without requiring replacement of the entire pump.

[0007] These and other features, objects and advantages of the disclosed subject matter will become better understood from a consideration of the following detailed description, drawings, and claims directed to the invention. This brief summary and the following detailed description and drawings are exemplary only, and are intended to provide further explanation of various implementations without limiting the scope of the invention as set forth in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Fig. 1 is a schematic diagram of one embodiment of the present invention broken down into its constituent components.

[0009] Fig. 2 is a schematic diagram showing prior art reciprocating pump technology, which does not allow replacement of the fluidic lines.

[0010] Fig. 3 is a schematic diagram of a first embodiment of the present invention assembled using a “T”-shaped connector.

[0011] Fig. 4 is a schematic diagram of a second embodiment of the present invention assembled using magnetic connectors.

DETAILED DESCRIPTION

[0012] The present invention includes various manners of coupling a flexible diaphragm on an ePump (or other pump) to a diaphragm on a pumping reservoir. It should be noted that while the geometry shown in the figures refer to circular or approximately circular pumps and diaphragms, the present invention is not limited to such geometry and may employ oblong, semi-circular, polygonal, or other shaped pumps and/or diaphragms. In addition, this description generally refers to the ePump, an electro-chemiosmotic pump, but it is understood that the present invention may be used in conjunction with any pump which utilizes reciprocating diaphragms, pistons, or similar constructs.

[0013] Referring now to Fig. 1, the separate components of the present invention can be described for clarity. As shown, the invention comprises a disposable metering chamber body component 2 and a reusable pump body component 4. The present invention employs three flexible members, which may be

elastomeric diaphragms, pistons or plungers, immiscible fluid plugs, flexible plastic sheets, or any number of alternate forms. For ease of description, these flexible members will be referred to as diaphragms but it is understood that the present invention is not so limited. The first of the flexible diaphragms 8 is a part of the metering chamber body component 2, as shown. The other two flexible diaphragms 10 are a part of the reusable pump body component 4, as described below. This differs from existing technology, as shown in Fig. 2, which employs only the two flexible diaphragms 24 corresponding to the pump body 20. In the present invention, the addition of the flexible diaphragm 8 in the removable metering chamber body 2 is what allows the replacement of the fluidic lines in the present invention, which is not possible in the existing pump shown in Fig. 2.

[0014] The metering chamber body 2 comprises several components: the metering chamber 6 and metering chamber diaphragm 8. In the present invention, the metering chamber 6 and metering chamber diaphragm 8 are in contact such that, as the diaphragm 8 expands and contracts, the open volume within the metering chamber 6 is contracted or expanded (as the metering chamber diaphragm 8 is in contact with one of the pump body diaphragms 10, described below). This contraction/expansion of the volume within the metering chamber 6 results in the pumping of fluid between the metering chamber 6 and diaphragm 8. By the use of valves, the pumping action within the metering chamber 6 results in net transfer of fluid from an inlet reservoir to an outlet target.

[0015] The reusable pump body 4 comprises several components: pump body diaphragms 10, ePump half-cells 12, and ionic membrane 14. The ePump uses

an ionic fluid in two half-cells 12 that are separated by a selective ionic membrane 14. Application of current between electrodes in each of the two half-cells 12 causes an ionic imbalance to form between the two half-cells 12 resulting in ions and associated solvent molecules to flow across the membrane 14. Each of the two half-cells 12 works with one of the flexible members 10 found in the pump body 4 to allow the effective volume of the half-cells 12 to increase or decrease as ions and associated solvent materials travel across the membrane 14.

[0016] As opposed to the prior art pump shown in Fig. 2, where the pump body diaphragm 24 is directly in contact with the metering chamber 22, in the present invention one of the pump body diaphragms 10 is in contact with the metering chamber diaphragm 8 which is then in contact with the metering chamber 6. By connecting one of the pump body diaphragms 10 to the disposable metering chamber diaphragm 8, the two diaphragms 8, 10 move in unison during contraction and expansion of the volume of fluid in the respective ePump half-cell 12. In the prior art pump shown in Fig 2, because the pump body diaphragm 24 is in direct contact with the metering chamber 22 and the half-cell 26, the pump body diaphragm 24 is in direct contact with both the fluid in the metering chamber 22 and the ionic pumping solution. In the prior art pump, removal of the metering chamber 22 and diaphragm 24 for replacement would require opening the pump body 20, which could introduce air bubbles or other contaminants into the ionic solution or could result in the loss of some or all of the ionic solution. The present invention solves these problems, because the disposable metering chamber

body 2 allows the metering chamber 6 and diaphragm 8 to be easily removed without opening the pump body 4 and without exposing the ionic solution to contaminants.

[0017] There are a number of manners in which the connection between the disposable metering chamber diaphragm 8 and the pump body diaphragm 10 can be achieved. A key feature of any connection is that it must be reversible without causing damage to the pump body 4 or its diaphragm 10. Figures 3-4 show two embodiments of the present invention, each employing different connective techniques. For example, a variety of adhesives may be used, including pressure sensitive, hot melt, and other adhesives which may allow the diaphragms to be separated from each other at the end of use by means of peelings, application of heat, or use of a solvent to disrupt the adhesive bond. Alternatively, mechanical means may be employed to create the connection. For example, male/female profiles may be mated, as shown in Fig. 3 as a T-shaped connector 30 where a “T” shape is inserted into a slot. In this embodiment, a stiff mechanical member is permanently attached to the diaphragm on the pump body side. This member has a T-shaped head that fits into a slot that is permanently attached to the diaphragm of the disposable metering chamber. Alternatively, hook and loop, mushroom-head snap fasteners, or other methods of connection may be employed.

[0018] In one embodiment, as shown in Figure 4, magnet attraction may also be used instead of, or in addition to, adhesive and mechanical connection means. In one embodiment, a permanent magnet 40 is molded into or attached to the

metering body diaphragm and the connecting pump body diaphragm also has a permanent magnet 42 or piece of iron, steel, or other ferromagnetic metal or material molded into or attached to it. The diaphragm on the pump body is formed so that it is brought in close proximity to the diaphragm on the pumping chamber over essentially its entire working surface. The magnets (or magnet and ferromagnetic material) are encapsulated on the opposite sides of the diaphragms from where they contact one another. For the disposable metering chamber diaphragm 40, a recess is provided in the metering chamber body for the overmolded magnet or ferromagnetic disk to nest within. When the diaphragms are brought into close proximity, the magnetic force will cause the two diaphragms to be connected to each other until such a time when sufficient force is applied to separate them. This connection/separation force can be optimized for the size of the diaphragms and the pumping force required by varying the size/magnetic force of the magnet(s).

[0019] In an alternative embodiment, an electromagnet can be molded into or attached to one of the diaphragms with a piece of iron, steel, or other ferromagnetic material molded into or attached to the connecting diaphragm. In this embodiment, as long as electric current is supplied to the electromagnet, the diaphragms will remain connected. Upon discontinuance of the electric current, the diaphragms can be easily separated, and the disposable metering chamber can be discarded. In a different embodiment, an electromagnet can be molded into or attached to one diaphragm and a permanent magnet can be molded into or attached to the connecting diaphragm. In an embodiment with this

arrangement, the permanent magnet can maintain the connection between the diaphragms without flow of electric current through the electromagnet. When appropriate current is applied to the electromagnet, however, it will repel the permanent magnet, which will allow the user to separate the connecting diaphragms.

[0020] It yet another embodiment, fine magnetic particles may be included in one or both of the connecting diaphragms. Where magnetic particles are included in only one of the diaphragms, iron powder or another similarly ferromagnetic powder may be used in the other diaphragm. This arrangement would allow the diaphragms to be attracted to each other in a similar fashion to the above mentioned permanent magnet solution but without a separate magnet or piece of ferromagnetic material molded into the diaphragms. Alternatively, magnetic flakes, particles, or film may be incorporated directly into the material that makes up the diaphragm. In this embodiment, the two diaphragms would contact each other at all points and could be more easily separated than if an adhesive were to be used. Lastly, it is understood that a combination of any of these methods of connecting the diaphragms may be used. For example, an embodiment may combine the use of a ferromagnetic powder and permanent magnet to facilitate the connection.

[0021] Unless otherwise stated, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any systems and materials similar or equivalent to those described herein can also be used in the practice or testing

of the present invention, a limited number of the exemplary systems and materials are described herein. It will be apparent to those skilled in the art that many more modifications are possible without departing from the invent concepts herein. All terms used herein should be interpreted in the broadest possible manner consistent with the context. Any ranges expressed herein are intended to include all particular values within the stated range, as well as all sub-ranges that fall within the stated range.

[0022] The present invention has been described with reference to the foregoing specific implementations. These implementations are intended to be exemplary only, and not limiting to the full scope of the present invention. Many variations and modifications are possible in view of the above teachings. The invention is intended to be limited only as set forth in the appended claims.

CLAIMS:

1. A reciprocating pump apparatus for pumping a fluid from a reservoir to a target, said reciprocating pump apparatus comprising:
   a. a pump body;
   b. a disposable metering chamber body;
   c. a plurality of pump body flexible members situated inside said pump body;
   d. a metering chamber flexible member situated inside said disposable metering chamber body, wherein said metering chamber flexible member is removably connected to one of said plurality of pump body flexible members; and
   e. a metering chamber situated inside said disposable metering chamber body, wherein said metering chamber is in contact with said metering chamber flexible member, further wherein said metering chamber comprises a first end and a second end, wherein said first end is in contact with said reservoir and said second end is in contact with said target, wherein said metering chamber is operable to transport said fluid from said reservoir to said target.
2. The reciprocating pump apparatus of claim 1, wherein said pump body comprises a plurality of half-cells, wherein each of said plurality of half-cells is in contact with one of said plurality of pump body flexible members.

3. The reciprocating pump apparatus of claim 2, wherein said plurality of half-cells are separated by a membrane.

4. The reciprocating pump apparatus of claim 3, wherein said plurality of half-cells each comprises an ionic fluid, wherein said ionic fluid comprises a plurality of ions and a plurality of solvent molecules.

5. The reciprocating pump apparatus of claim 4, wherein said plurality of half-cells further comprises a plurality of electrodes, wherein introduction of a current between said plurality of electrodes causes a number of said plurality of ions and a number of said plurality of solvent molecules to flow across said membrane.

6. The reciprocating pump apparatus of claim 5, wherein the flow of said plurality of ions and said plurality of said solvent molecules alternately increases and decreases the effective volume of said plurality of half-cells, thereby alternately expanding and contracting said pump body flexible member in contact with said half-cell, thereby alternately expanding and contracting said metering chamber flexible member, thereby pumping said fluid in said metering chamber from said reservoir to said target.

7. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member is removably connected to one of said plurality of pump body flexible members via an adhesive.

8. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member is removably connected to one

of said plurality of pump body flexible members via at least one magnet.

9. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member is removably connected to one of said plurality of pump body flexible members via a mechanical connector.

10. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member is removably connected to one of said plurality of pump body flexible members via an electromagnet coupled to a ferromagnetic material.

11. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member is removably connected to one of said plurality of pump body flexible members via a plurality of magnets coupled to a ferromagnetic material.

12. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member is removably connected to one of said plurality of pump body flexible members via an electromagnet coupled to a magnet.

13. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member is removably connected to one of said plurality of pump body flexible members via a magnetic powder coupled to a ferromagnetic material.

14. The reciprocating pump apparatus of claim 1, wherein said

metering chamber flexible member is removably connected to one of said plurality of pump body flexible members via magnetic particles, film or flakes embedded in the material of the flexible members.

15. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member and said plurality of pump body flexible members comprise flexible diaphragms.

16. The reciprocating pump apparatus of claim 1, wherein said metering chamber flexible member and said plurality of pump body flexible members comprise pistons.

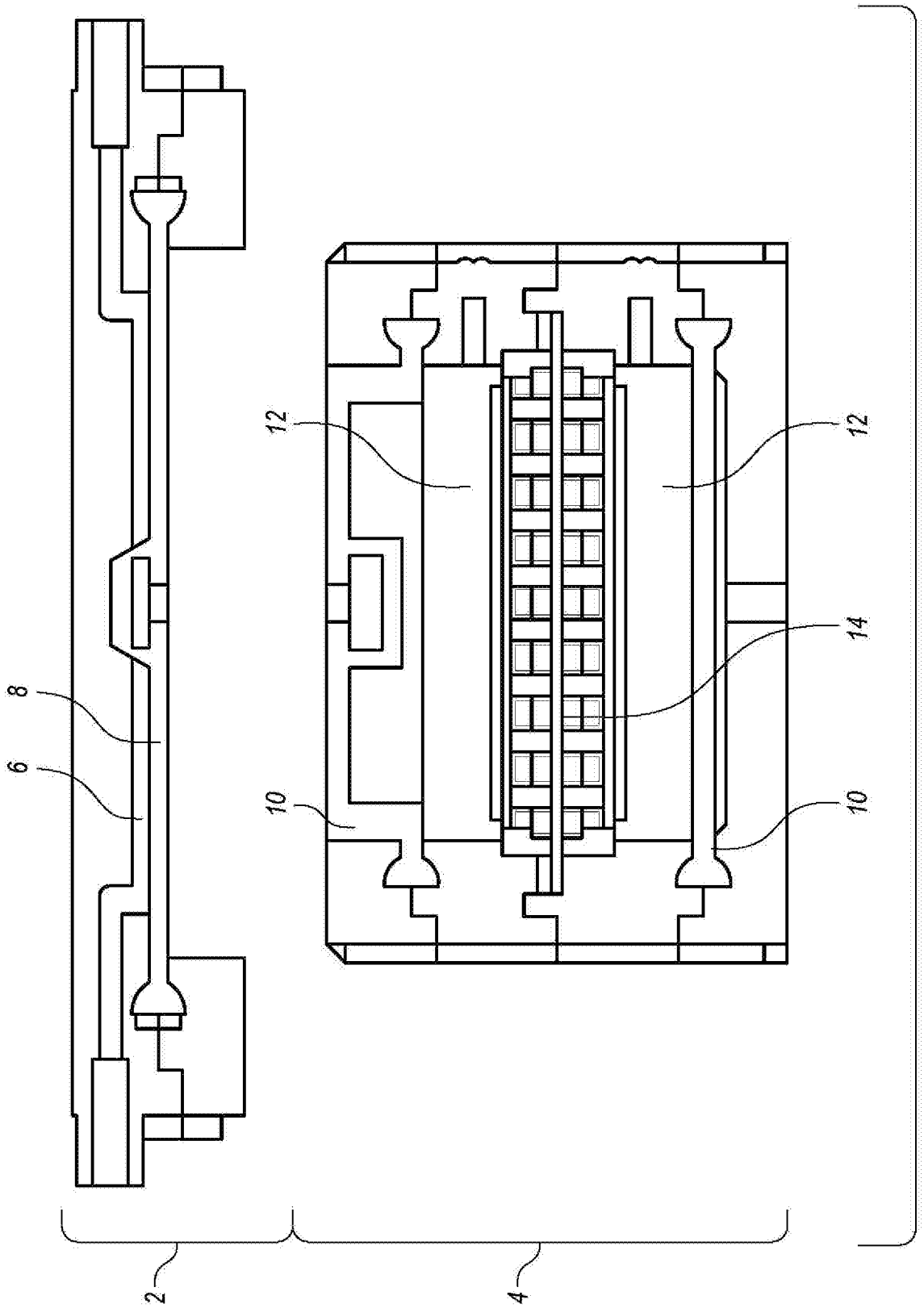

FIG. 1

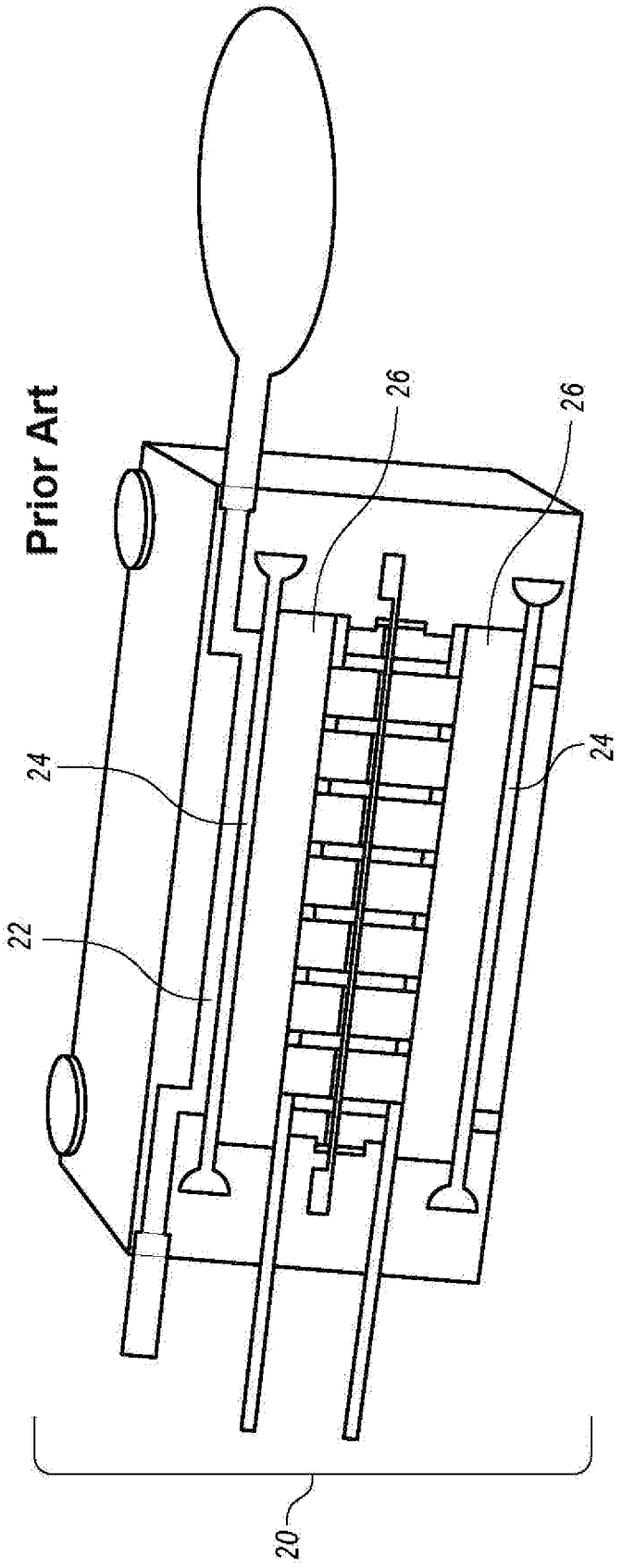

FIG. 2

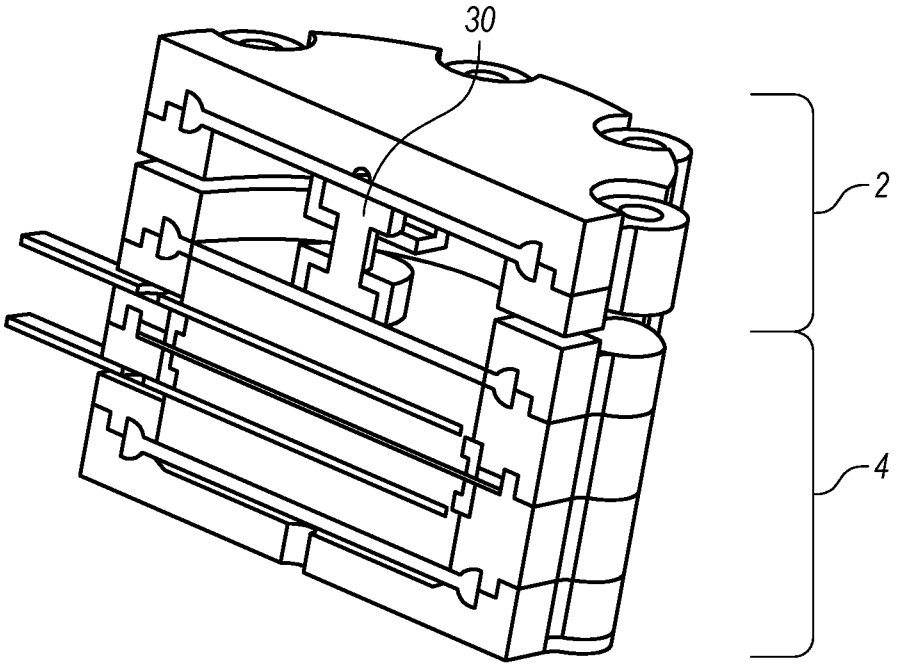

FIG. 3

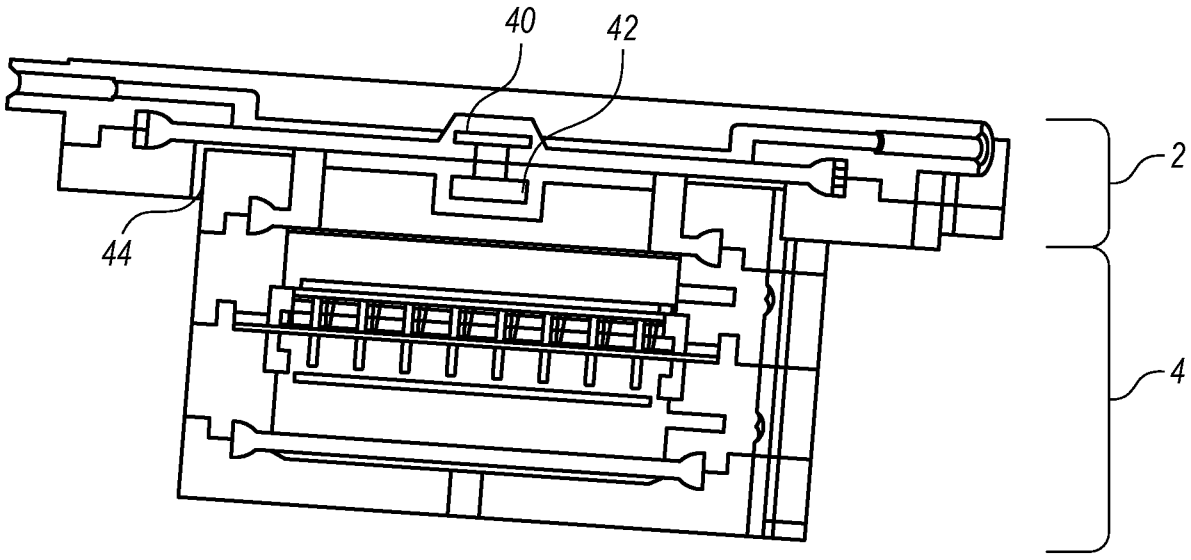

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/023375

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/142; A61M 5/145; F04B 43/00; F15C 3/04 (2016.01)
CPC - A61M 2005/14204; A61M 5/14224; A61M 2005/14268; A61M 5/14593; F04B 43/0054 (2016.05)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 5/142; A61M 5/145; F04B 43/00; F15C 3/04 (2016.01)
CPC - A61M 2005/14204; A61M 5/14224; A61M 2005/14268; A61M 5/14593; F04B 43/0054; F15C 3/04 (2016.05)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 137/565.01; 251/331; 417/412; 417/413.1; 417/478; 604/131; 604/152; 604/153; 604/207; 604/246; 604/249
(keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google Scholar, Google
Search terms used: reciprocating pump, reservoir, body, chamber, metering, flexible, diaphragm, piston, disposable, removably connected, fluid, magnet, ionic, half-cell

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,121,584 A (TURNER et al) 24 October 1978 (24.10.1978) entire document	1, 8-16 --- 2-7
Y	WO 2014/036112 A1 (SFC FLUIDICS, LLC et al) 06 March 2014 (06.03.2014) entire document	2-6
Y	US 2002/0169439 A1 (FLAHERTY) 14 November 2002 (14.11.2002) entire document	7
A	US 5,302,093 A (OWENS et al) 12 April 1994 (12.04.1994) entire document	1-16
A	US 2012/0310162 A1 (ROCHAT) 06 December 2012 (06.12.2012) entire document	1-16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 May 2016	10 JUN 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774