US009757518B2

(12) **United States Patent**
Chong

(10) **Patent No.: US 9,757,518 B2**
(45) **Date of Patent: *Sep. 12, 2017**

(54) **MECHANICALLY ACTUATED FLUID INFUSION DEVICE**

(71) Applicant: **MEDTRONIC MINIMED, INC.**, Northridge, CA (US)

(72) Inventor: **Colin A. Chong**, Glendale, CA (US)

(73) Assignee: **Medtronic MiniMed, Inc.**, Northridge, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/085,358**

(22) Filed: **Mar. 30, 2016**

(65) **Prior Publication Data**

US 2016/0206815 A1 Jul. 21, 2016

Related U.S. Application Data

(63) Continuation of application No. 13/533,797, filed on Jun. 26, 2012, now Pat. No. 9,333,292.

(51) **Int. Cl.**
A61M 5/168 (2006.01)
A61M 5/145 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 5/16881*** (2013.01); ***A61M 5/145*** (2013.01); ***A61M 5/1454*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC .. A61M 5/145; A61M 5/148; A61M 5/14244; A61M 5/14248; A61M 5/16881;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,151,616 A 10/1964 Selfon
3,631,847 A 1/1972 Hobbs, II
(Continued)

FOREIGN PATENT DOCUMENTS

DE 4329229 3/1995
EP 0319268 11/1988
(Continued)

OTHER PUBLICATIONS

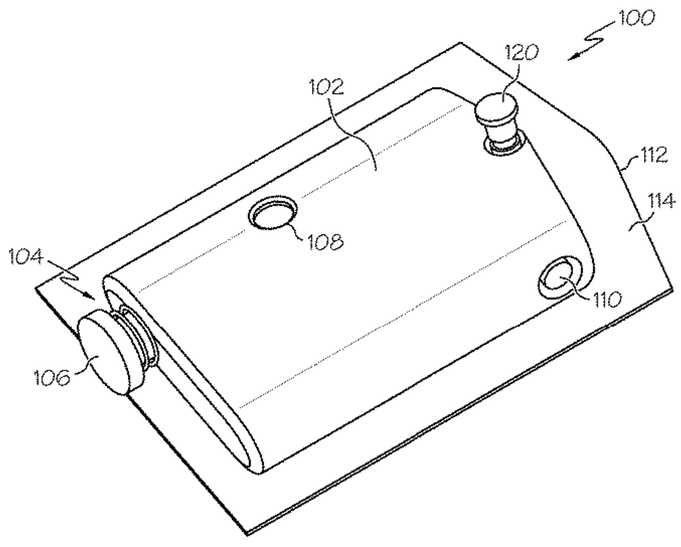
PCT Search Report (PCT/US02/03299), Oct. 31, 2002, Medtronic Minimed, Inc.
(Continued)

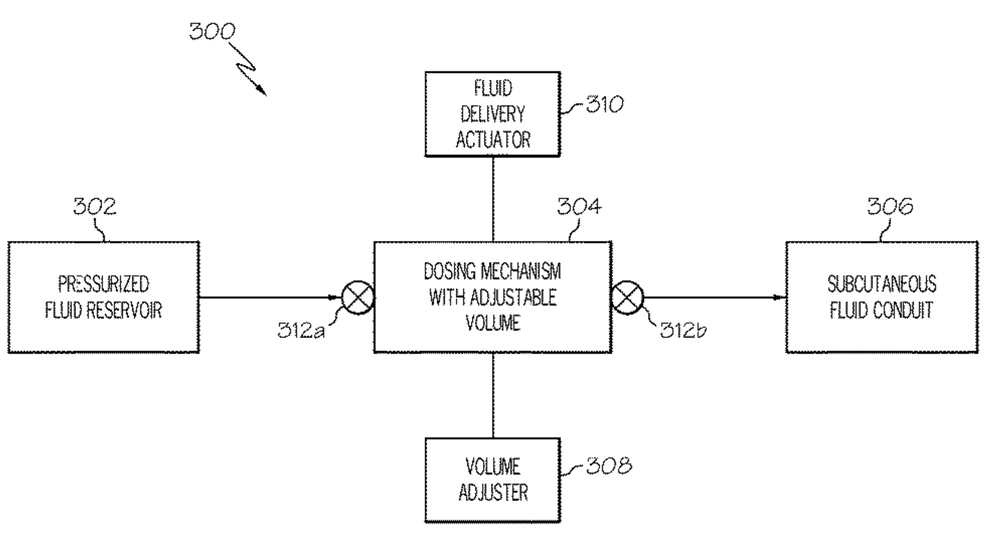
Primary Examiner — Manuel Mendez
(74) *Attorney, Agent, or Firm* — Lorenz & Kopf, LLP

(57) **ABSTRACT**

A fluid infusion device, for delivery of a medication fluid to the body of a user, includes a housing, a fluid reservoir for the medication fluid, a dosing mechanism, an infusion component, and a mechanical actuator. The fluid reservoir and the dosing mechanism are located in the housing, and the dosing mechanism is coupled to receive the medication fluid from the fluid reservoir. The dosing mechanism has an adjustable fluid chamber that defines a variable dosage volume. The infusion component is coupled to the dosing mechanism to receive the medication fluid from the adjustable fluid chamber. The mechanical actuator is coupled to the dosing mechanism such that operation of the mechanical actuator causes the medication fluid to be expelled from the adjustable fluid chamber to the infusion component.

20 Claims, 11 Drawing Sheets





(51) **Int. Cl.**

A61M 5/152	(2006.01)
A61M 5/148	(2006.01)
A61M 5/142	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 5/152*** (2013.01); *A61M 5/148* (2013.01); *A61M 5/14244* (2013.01); *A61M 5/14248* (2013.01); *A61M 2005/14506* (2013.01)

(58) **Field of Classification Search**

CPC A61M 5/1454; A61M 5/152; A61M 2005/14506

USPC 604/131–134, 65–67; 128/DIG. 12, 128/DIG. 13

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,212,738	A	7/1980	Henne
4,265,241	A	5/1981	Portner et al.
4,270,532	A	6/1981	Franetzki et al.
4,282,872	A	8/1981	Franetzki et al.
4,373,527	A	2/1983	Fischell
4,395,259	A	7/1983	Prestele et al.
4,433,072	A	2/1984	Pusineri et al.
4,443,218	A	4/1984	DeCant, Jr. et al.
4,494,950	A	1/1985	Fischell
4,542,532	A	9/1985	McQuilkin
4,550,731	A	11/1985	Batina et al.
4,559,037	A	12/1985	Franetzki et al.
4,562,751	A	1/1986	Nason et al.
4,671,288	A	6/1987	Gough
4,678,408	A	7/1987	Nason et al.
4,685,903	A	8/1987	Cable et al.
4,731,051	A	3/1988	Fischell
4,731,726	A	3/1988	Allen, III
4,781,798	A	11/1988	Gough
4,803,625	A	2/1989	Fu et al.
4,809,697	A	3/1989	Causey, III et al.
4,826,810	A	5/1989	Aoki
4,871,351	A	10/1989	Feingold
4,898,578	A	2/1990	Rubalcaba, Jr.
5,003,298	A	3/1991	Havel
5,011,468	A	4/1991	Lundquist et al.
5,019,974	A	5/1991	Beckers
5,050,612	A	9/1991	Matsumura
5,078,683	A	1/1992	Sancoff et al.
5,080,653	A	1/1992	Voss et al.
5,097,122	A	3/1992	Colman et al.
5,098,409	A	3/1992	Stock
5,100,380	A	3/1992	Epstein et al.
5,101,814	A	4/1992	Palti
5,108,819	A	4/1992	Heller et al.
5,153,827	A	10/1992	Coutre et al.
5,165,407	A	11/1992	Wilson et al.
5,247,434	A	9/1993	Peterson et al.
5,262,035	A	11/1993	Gregg et al.
5,262,305	A	11/1993	Heller et al.
5,264,104	A	11/1993	Gregg et al.
5,264,105	A	11/1993	Gregg et al.
5,284,140	A	2/1994	Allen et al.
5,299,571	A	4/1994	Mastrototaro
5,307,263	A	4/1994	Brown
5,317,506	A	5/1994	Coutre et al.
5,320,725	A	6/1994	Gregg et al.
5,322,063	A	6/1994	Allen et al.
5,338,157	A	8/1994	Blomquist
5,339,821	A	8/1994	Fujimoto
5,341,291	A	8/1994	Roizen et al.
5,342,313	A	8/1994	Campbell et al.
5,350,411	A	9/1994	Ryan et al.
5,356,786	A	10/1994	Heller et al.
5,357,427	A	10/1994	Langen et al.
5,368,562	A	11/1994	Blomquist et al.
5,370,622	A	12/1994	Livingston et al.
5,371,687	A	12/1994	Holmes, II et al.
5,376,070	A	12/1994	Purvis et al.
5,390,671	A	2/1995	Lord et al.
5,391,250	A	2/1995	Cheney, II et al.
5,403,700	A	4/1995	Heller et al.
5,411,647	A	5/1995	Johnson et al.
5,441,172	A	8/1995	Yu
5,482,473	A	1/1996	Lord et al.
5,485,408	A	1/1996	Blomquist
5,497,772	A	3/1996	Schulman et al.
5,505,709	A	4/1996	Funderburk et al.
5,543,326	A	8/1996	Heller et al.
5,569,186	A	10/1996	Lord et al.
5,569,187	A	10/1996	Kaiser
5,573,506	A	11/1996	Vasko
5,582,593	A	12/1996	Hultman
5,586,553	A	12/1996	Halili et al.
5,593,390	A	1/1997	Castellano et al.
5,593,852	A	1/1997	Heller et al.
5,594,638	A	1/1997	Illiff
5,609,060	A	3/1997	Dent
5,626,144	A	5/1997	Tacklind et al.
5,630,710	A	5/1997	Tune et al.
5,643,212	A	7/1997	Coutre et al.
5,660,163	A	8/1997	Schulman et al.
5,660,176	A	8/1997	Iliff
5,665,065	A	9/1997	Colman et al.
5,665,222	A	9/1997	Heller et al.
5,685,844	A	11/1997	Marttila
5,687,734	A	11/1997	Dempsey et al.
5,704,366	A	1/1998	Tacklind et al.
5,750,926	A	5/1998	Schulman et al.
5,754,111	A	5/1998	Garcia
5,764,159	A	6/1998	Neftel
5,772,635	A	6/1998	Dastur et al.
5,779,665	A	7/1998	Mastrototaro et al.
5,788,669	A	8/1998	Peterson
5,791,344	A	8/1998	Schulman et al.
5,800,420	A	9/1998	Gross et al.
5,807,336	A	9/1998	Russo et al.
5,814,015	A	9/1998	Gargano et al.
5,822,715	A	10/1998	Worthington et al.
5,832,448	A	11/1998	Brown
5,840,020	A	11/1998	Heinonen et al.
5,861,018	A	1/1999	Feierbach et al.
5,868,669	A	2/1999	Iliff
5,871,465	A	2/1999	Vasko
5,879,163	A	3/1999	Brown et al.
5,885,245	A	3/1999	Lynch et al.
5,897,493	A	4/1999	Brown
5,899,855	A	5/1999	Brown
5,904,708	A	5/1999	Goedeke
5,913,310	A	6/1999	Brown
5,917,346	A	6/1999	Gord
5,918,603	A	7/1999	Brown
5,925,021	A	7/1999	Castellano et al.
5,933,136	A	8/1999	Brown
5,935,099	A	8/1999	Peterson et al.
5,940,801	A	8/1999	Brown
5,956,501	A	9/1999	Brown
5,960,403	A	9/1999	Brown
5,965,380	A	10/1999	Heller et al.
5,972,199	A	10/1999	Heller et al.
5,978,236	A	11/1999	Faberman et al.
5,997,476	A	12/1999	Brown
5,999,848	A	12/1999	Gord et al.
5,999,849	A	12/1999	Gord et al.
6,009,339	A	12/1999	Bentsen et al.
6,032,119	A	2/2000	Brown et al.
6,043,437	A	3/2000	Schulman et al.
6,081,736	A	6/2000	Colvin et al.
6,083,710	A	7/2000	Heller et al.
6,088,608	A	7/2000	Schulman et al.
6,101,478	A	8/2000	Brown
6,103,033	A	8/2000	Say et al.
6,119,028	A	9/2000	Schulman et al.
6,120,676	A	9/2000	Heller et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,121,009	A	9/2000	Heller et al.	
6,134,461	A	10/2000	Say et al.	
6,143,164	A	11/2000	Heller et al.	
6,162,611	A	12/2000	Heller et al.	
6,175,752	B1	1/2001	Say et al.	
6,183,412	B1	2/2001	Benkowski et al.	
6,246,992	B1	6/2001	Brown	
6,251,098	B1	6/2001	Rake et al.	
6,259,937	B1	7/2001	Schulman et al.	
6,329,161	B1	12/2001	Heller et al.	
6,408,330	B1	6/2002	DeLaHuerga	
6,424,847	B1	7/2002	Mastrototaro et al.	
6,472,122	B1	10/2002	Schulman et al.	
6,484,045	B1	11/2002	Holker et al.	
6,484,046	B1	11/2002	Say et al.	
6,503,381	B1	1/2003	Gotoh et al.	
6,514,718	B2	2/2003	Heller et al.	
6,544,173	B2	4/2003	West et al.	
6,553,263	B1	4/2003	Meadows et al.	
6,554,798	B1	4/2003	Mann et al.	
6,558,320	B1	5/2003	Causey, III et al.	
6,558,351	B1	5/2003	Steil et al.	
6,560,741	B1	5/2003	Gerety et al.	
6,565,509	B1	5/2003	Say et al.	
6,579,690	B1	6/2003	Bonnecaze et al.	
6,591,125	B1	7/2003	Buse et al.	
6,592,745	B1	7/2003	Feldman et al.	
6,605,200	B1	8/2003	Mao et al.	
6,605,201	B1	8/2003	Mao et al.	
6,607,658	B1	8/2003	Heller et al.	
6,616,819	B1	9/2003	Liamos et al.	
6,618,934	B1	9/2003	Feldman et al.	
6,623,501	B2	9/2003	Heller et al.	
6,641,533	B2	11/2003	Causey, III et al.	
6,654,625	B1	11/2003	Say et al.	
6,659,980	B2	12/2003	Moberg et al.	
6,671,554	B2	12/2003	Gibson et al.	
6,676,816	B2	1/2004	Mao et al.	
6,689,265	B2	2/2004	Heller et al.	
6,728,576	B2	4/2004	Thompson et al.	
6,733,471	B1	5/2004	Ericson et al.	
6,746,582	B2	6/2004	Heller et al.	
6,747,556	B2	6/2004	Medema et al.	
6,749,740	B2	6/2004	Liamos et al.	
6,752,787	B1	6/2004	Causey, III et al.	
6,809,653	B1	10/2004	Mann et al.	
6,881,551	B2	4/2005	Heller et al.	
6,892,085	B2	5/2005	McIvor et al.	
6,893,545	B2	5/2005	Gotoh et al.	
6,895,263	B2	5/2005	Shin et al.	
6,916,159	B2	7/2005	Rush et al.	
6,932,584	B2	8/2005	Gray et al.	
6,932,894	B2	8/2005	Mao et al.	
6,942,518	B2	9/2005	Liamos et al.	
7,153,263	B2	12/2006	Carter et al.	
7,153,289	B2	12/2006	Vasko	
7,396,330	B2	7/2008	Banet et al.	
7,828,764	B2	11/2010	Moberg et al.	
7,905,868	B2	3/2011	Moberg et al.	
9,333,292	B2 *	5/2016	Chong	A61M 5/145
2001/0044731	A1	11/2001	Coffman et al.	
2002/0013518	A1	1/2002	West et al.	
2002/0055857	A1	5/2002	Mault et al.	
2002/0072733	A1	6/2002	Flaherty	
2002/0082665	A1	6/2002	Haller et al.	
2002/0137997	A1	9/2002	Mastrototaro et al.	
2002/0161288	A1	10/2002	Shin et al.	
2003/0060765	A1	3/2003	Campbell et al.	
2003/0078560	A1	4/2003	Miller et al.	
2003/0088166	A1	5/2003	Say et al.	
2003/0144581	A1	7/2003	Conn et al.	
2003/0152823	A1	8/2003	Heller	
2003/0176183	A1	9/2003	Drucker et al.	
2003/0188427	A1	10/2003	Say et al.	
2003/0199744	A1	10/2003	Buse et al.	
2003/0208113	A1	11/2003	Mault et al.	
2003/0220552	A1	11/2003	Reghabi et al.	
2004/0061232	A1	4/2004	Shah et al.	
2004/0061234	A1	4/2004	Shah et al.	
2004/0064133	A1	4/2004	Miller et al.	
2004/0064156	A1	4/2004	Shah et al.	
2004/0073095	A1	4/2004	Causey, III et al.	
2004/0074785	A1	4/2004	Holker et al.	
2004/0093167	A1	5/2004	Braig et al.	
2004/0097796	A1	5/2004	Berman et al.	
2004/0102683	A1	5/2004	Khanuja et al.	
2004/0111017	A1	6/2004	Say et al.	
2004/0122353	A1	6/2004	Shahmirian et al.	
2004/0167465	A1	8/2004	Mihai et al.	
2004/0263354	A1	12/2004	Mann et al.	
2005/0038331	A1	2/2005	Silaski et al.	
2005/0038680	A1	2/2005	McMahon et al.	
2005/0154271	A1	7/2005	Rasdal et al.	
2005/0192557	A1	9/2005	Brauker et al.	
2006/0229694	A1	10/2006	Schulman et al.	
2006/0238333	A1	10/2006	Welch et al.	
2006/0293571	A1	12/2006	Bao et al.	
2007/0088521	A1	4/2007	Shmueli et al.	
2007/0135866	A1	6/2007	Baker et al.	
2008/0154503	A1	6/2008	Wittenber et al.	
2008/0269687	A1	10/2008	Chong et al.	
2009/0081951	A1	3/2009	Erdmann et al.	
2009/0082635	A1	3/2009	Baldus et al.	
2009/0299290	A1	12/2009	Moberg	

FOREIGN PATENT DOCUMENTS

EP	0806738		11/1997
EP	0880936		12/1998
EP	1338295		8/2003
EP	1631036	A2	3/2006
GB	2218831		11/1989
WO	WO 96/20745		7/1996
WO	WO 96/36389		11/1996
WO	WO 96/37246	A1	11/1996
WO	WO 97/21456		6/1997
WO	WO 98/20439		5/1998
WO	WO 98/24358		6/1998
WO	WO 98/42407		10/1998
WO	WO 98/49659		11/1998
WO	WO 98/59487		12/1998
WO	WO 99/08183		2/1999
WO	WO 99/10801		3/1999
WO	WO 99/18532		4/1999
WO	WO 99/22236		5/1999
WO	WO 00/10628		3/2000
WO	WO 00/19887		4/2000
WO	WO 00/48112		8/2000
WO	WO 02/058537	A2	8/2002
WO	WO 03/001329		1/2003
WO	WO 03/094090		11/2003
WO	WO 2005/065538	A2	7/2005
WO	WO2009/102355	A2	8/2009

OTHER PUBLICATIONS

(Animas Corporation, 1999). Animas . . . bringing new life to insulin therapy.

Bode B W, et al. (1996). Reduction in Severe Hypoglycemia with Long-Term Continuous Subcutaneous Insulin Infusion in Type I Diabetes. Diabetes Care, vol. 19, No. 4, 324-327.

Boland E (1998). Teens Pumping it Up! Insulin Pump Therapy Guide for Adolescents. 2nd Edition.

Brackenridge B P (1992). Carbohydrate Gram Counting a Key to Accurate Mealtime Boluses in Intensive Diabetes Therapy. Practical Diabetology, vol. 11, No. 2, pp. 22-28.

Brackenridge, B P et al. (1995). Counting Carbohydrates How to Zero in on Good Control. MiniMed Technologies Inc.

Farkas-Hirsch R et al. (1994). Continuous Subcutaneous Insulin Infusion: A Review of the Past and Its Implementation for the Future. Diabetes Spectrum From Research to Practice, vol. 7, No. 2, pp. 80-84, 136-138.

(56) **References Cited**

OTHER PUBLICATIONS

Hirsch I B et al. (1990). Intensive Insulin Therapy for Treatment of Type I Diabetes. Diabetes Care, vol. 13, No. 12, pp. 1265-1283.
Kulkarni K et al. (1999). Carbohydrate Counting a Primer for Insulin Pump Users to Zero in on Good Control. MiniMed Inc.
Marcus A O et al. (1996). Insulin Pump Therapy Acceptable Alternative to Injection Therapy. Postgraduate Medicine, vol. 99, No. 3, pp. 125-142.
Reed J et al. (1996). Voice of the Diabetic, vol. 11, No. 3, pp. 1-38.
Skyler J S (1989). Continuous Subcutaneous Insulin Infusion [CSII] With External Devices: Current Status. Update in Drug Delivery Systems, Chapter 13, pp. 163-183. Futura Publishing Company.
Skyler J S et al. (1995). The Insulin Pump Therapy Book Insights from the Experts. MiniMed•Technologies.
Strowig S M (1993). Initiation and Management of Insulin Pump Therapy. The Diabetes Educator, vol. 19, No. 1, pp. 50-60.
Walsh J, et al. (1989). Pumping Insulin: The Art of Using an Insulin Pump. Published by MiniMed•Technologies.
(Intensive Diabetes Management, 1995). Insulin Infusion Pump Therapy. pp. 66-78.
Disetronic My Choice™ D-TRON™ Insulin Pump Reference Manual. (no date).
Disetronic H-TRON® plus Quick Start Manual. (no date).
Disetronic My Choice H-TRONplus Insulin Pump Reference Manual. (no date).
Disetronic H-TRON® plus Reference Manual. (no date).
(MiniMed, 1996). The MiniMed 506. 7 pages. Retrieved on Sep. 16, 2003 from the World Wide Web: http://web.archive.org/web/19961111054527/www.minimed.com/files/506_pic.htm.
(MiniMed, 1997). MiniMed 507 Specifications. 2 pages. Retrieved on Sep. 16, 2003 from the World Wide Web: http://web.archive.org/web/19970124234841/www.minimed.com/files/mmn075.htm.
(MiniMed, 1996). FAQ: The Practical Things . . . pp. 1-4. Retrieved on Sep. 16, 2003 from the World Wide Web: http://web.archive.org/web/19961111054546/www.minimed.com/files/faq_pract.htm.
(MiniMed, 1997). Wanted: a Few Good Belt Clips! 1 page. Retrieved on Sep. 16, 2003 from the World Wide Web: http://web.archive.org/web/19970124234559/www.minimed.com/files/mmn002.htm.
(MiniMed Technologies, 1994). MiniMed 506 Insulin Pump User's Guide.
(MiniMed Technologies, 1994). MiniMed™ Dosage Calculator Initial Meal Bolus Guidelines / MiniMed™ Dosage Calculator Initial Basal Rate Guidelines Percentage Method. 4 pages.
(MiniMed, 1996). MiniMed™ 507 Insulin Pump User's Guide.
(MiniMed, 1997). MiniMed™ 507 Insulin Pump User's Guide.
(MiniMed, 1998). MiniMed 507C Insulin Pump User's Guide.
(MiniMed International, 1998). MiniMed 507C Insulin Pump for those who appreciate the difference.
(MiniMed Inc., 1999). MiniMed 508 Flipchart Guide to Insulin Pump Therapy.
(MiniMed Inc., 1999). Insulin Pump Comparison / Pump Therapy Will Change Your Life.
(MiniMed, 2000). MiniMed® 508 User's Guide.
(MiniMed Inc., 2000). MiniMed® Now [I] Can Meal Bolus Calculator / MiniMed® Now [I] Can Correction Bolus Calculator.
(MiniMed Inc., 2000). Now [I] Can MiniMed Pump Therapy.
(MiniMed Inc., 2000). Now [I] Can MiniMed Diabetes Management.
(Medtronic MiniMed, 2002). The 508 Insulin Pump A Tradition of Excellence.
(Medtronic MiniMed, 2002). Medtronic MiniMed Meal Bolus Calculator and Correction Bolus Calculator. International Version.
Abel, P., et al., "Experience with an implantable glucose sensor as a prerequiste of an artificial beta cell," Biomed. Biochim. Acta 43 (1984) 5, pp. 577-584.
Bindra, Dilbir S., et al., "Design and in Vitro Studies of a Needle-Type Glucose Sensor for a Subcutaneous Monitoring," American Chemistry Society, 1991, 63, pp. 1692-1696.
Boguslavsky, Leonid, et al., "Applications of redox polymers in biosensors," Sold State Ionics 60, 1993, pp. 189-197.
Geise, Robert J., et al., "Electropolymerized 1,3-diaminobenzene for the construction of a 1,1'-dimethylferrocene mediated glucose biosensor," Analytica Chimica Acta, 281, 1993, pp. 467-473.
Gernet, S., et al., "A Planar Glucose Enzyme Electrode," Sensors and Actuators, 17, 1989, pp. 537-540.
Gernet, S., et al., "Fabrication and Characterization of a Planar Electromechanical Cell and its Application as a Glucose Sensor," Sensors and Actuators, 18, 1989, pp. 59-70.
Gorton, L., et al., "Amperometric Biosensors Based on an Apparent Direct Electron Transfer Between Electrodes and Immobilized Peroxiases," Analyst, Aug. 1991, vol. 117, pp. 1235-1241.
Gorton, L., et al., "Amperometric Glucose Sensors Based on Immobilized Glucose-Oxidizing Enymes and Chemically Modified Electrodes," Analytica Chimica Acta, 249, 1991, pp. 43-54.
Gough, D. A., et al., "Two-Dimensional Enzyme Electrode Sensor for Glucose," Analytical Chemistry, vol. 57, No. 5, 1985, pp. 2351-2357.
Gregg, Brian A., et al., "Cross-Linked Redox Gels Containing Glucose Oxidase for Amperometric Biosensor Applications," Analytical Chemistry, 62, pp. 258-263.
Gregg, Brian A., et al., "Redox Polymer Films Containing Enzymes. 1. A Redox-Conducting Epoxy Cement: Synthesis, Characterization, and Electrocatalytic Oxidation of Hydroquinone," The Journal of Physical Chemistry, vol. 95, No. 15, 1991, pp. 5970-5975.
Hashiguchi, Yasuhiro, MD, et al., "Development of a Miniaturized Glucose Monitoring System by Combining a Needle-Type Glucose Sensor With Microdialysis Sampling Method," Diabetes Care, vol. 17, No. 5, May 1994, pp. 387-389.
Heller, Adam, "Electrical Wiring of Redox Enzymes," Acc. Chem. Res., vol. 23, No. 5, May 1990, pp. 128-134.
Jobst, Gerhard, et al., "Thin-Film Microbiosensors for Glucose-Lactate Monitoring," Analytical Chemistry, vol. 68, No. 18, Sep. 15, 1996, pp. 3173-3179.
Johnson, K.W., et al., "In vivo evaluation of an electroenzymatic glucose sensor implanted in subcutaneous tissue," Biosensors & Bioelectronics, 7, 1992, pp. 709-714.
Jönsson, G., et al., "An Electromechanical Sensor for Hydrogen Peroxide Based on Peroxidase Adsorbed on a Spectrographic Graphite Electrode," Electroanalysis, 1989, pp. 465-468.
Kanapieniene, J. J., et al., "Miniature Glucose Biosensor with Extended Linearity," Sensors and Actuators, B. 10, 1992, pp. 37-40.
Kawamori, Ryuzo, et al., "Perfect Normalization of Excessive Glucagon Responses to Intraveneous Arginine in Human Diabetes Mellitus With the Artificial Beta-Cell," Diabetes vol. 29, Sep. 1980, pp. 762-765.
Kimura, J., et al., "An Immobilized Enzyme Membrane Fabrication Method," Biosensors 4, 1988, pp. 41-52.
Koudelka, M., et al., "In-vivo Behaviour of Hypodermically Implanted Microfabricated Glucose Sensors," Biosensors & Bioelectronics 6, 1991, pp. 31-36.
Koudelka, M., et al., "Planar Amperometric Enzyme-Based Glucose Microelectrode," Sensors & Actuators, 18, 1989, pp. 157-165.
Mastrototaro, John J., et al., "An electroenzymatic glucose sensor fabricated on a flexible substrate," Sensors & Actuators, B. 5, 1991, pp. 139-144.
Mastrototaro, John J., et al., "An Electroenzymatic Sensor Capable of 72 Hour Continuous Monitoring of Subcutaneous Glucose," 14th Annual International Diabetes Federation Congress, Washington D.C., Jun. 23-28, 1991.
McKean, Brian D., et al., "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors," IEEE Transactions on Biomedical Engineering, Vo. 35, No. 7, Jul. 1988, pp. 526-532.
Monroe, D., "Novel Implantable Glucose Sensors," ACL, Dec. 1989, pp. 8-16.
Morff, Robert J., et al., "Microfabrication of Reproducible, Economical, Electroenzymatic Glucose Sensors," Annuaal International Conference of teh IEEE Engineering in Medicine and Biology Society, Vo. 12, No. 2, 1990, pp. 483-484.

(56) **References Cited**

OTHER PUBLICATIONS

Moussy, Francis, et al., "Performance of Subcutaneously Implanted Needle-Type Glucose Sensors Employing a Novel Trilayer Coating," Analytical Chemistry, vol. 65, No. 15, Aug. 1, 1993, pp. 2072-2077.

Nakamoto, S., et al., "A Lift-Off Method for Patterning Enzyme-Immobilized Membranes in Multi-Biosensors," Sensors and Actuators 13, 1988, pp. 165-172.

Nishida, Kenro, et al., "Clinical applications of teh wearable artifical endocrine pancreas with the newly designed needle-type glucose sensor," Elsevier Sciences B.V., 1994, pp. 353-358.

Nishida, Kenro, et al., "Development of a ferrocene-mediated needle-type glucose sensor covereed with newly designd biocompatible membrane, 2-methacryloyloxyethylphosphorylcholine -co-n-butyl nethacrylate," Medical Progress Through Technology, vol. 21, 1995, pp. 91-103.

Poitout, V., et al., "A glucose monitoring system for on line estimation oin man of blood glucose concentration using a miniaturized glucose sensor implanted in the subcutaneous tissue adn a wearable control unit," Diabetologia, vol. 36, 1991, pp. 658-663.

Reach, G., "A Method for Evaluating in vivo the Functional Characteristics of Glucose Sensors," Biosensors 2, 1986, pp. 211-220.

Shaw, G. W., et al., "In vitro testing of a simply constructed, highly stable glucose sensor suitable for implantation in diabetic patients," Biosensors & Bioelectronics 6, 1991, pp. 401-406.

Shichiri, M., "A Needle-Type Glucose Sensor—A Valuable Tool Not Only for a Self-Blood Glucose Monitoring but for a Wearable Artifiical Pancreas," Life Support Systems Proceedings, XI Annual Meeting ESAO, Alpbach-Innsbruck, Austria, Sep. 1984, pp. 7-9.

Shichiri, Motoaki, et al., "An artificial endocrine pancreas—problems awaiting solution for long-term clinical applications of a glucose sensor," Frontiers Med. Biol. Engng., 1991, vol. 3, No. 4, pp. 283-292.

Shichiri, Motoaki, et al., "Closed-Loop Glycemic Control with a Wearable Artificial Endocrine Pancreas—Variations in Daily Insulin Requirements to Glycemic Response," Diabetes, vol. 33, Dec. 1984, pp. 1200-1202.

Shichiri, Motoaki, et al., "Glycaemic Control in a Pacreatectomized Dogs with,a Wearable Artificial Endocrine Pancreas," Diabetologia, vol. 24, 1983, pp. 179-184.

Shichiri, M., et al., "In Vivo Characteristics of Needle-Type Glucose Sensor—Measurements of Subcutaneous Glucose Concentrations in Human Volunteers," Hormone and Metabolic Research, Supplement Series vol. No. 20, 1988, pp. 17-20.

Shichiri, M., et al., "Membrane design for extending the long-life of an implantable glucose sensor," Diab. Nutr. Metab., vol. 2, No. 4, 1989, pp. 309-313.

Shichiri, Motoaki, et al., "Normalization of the Paradoxic Secretion of Glucagon in Diabetes Who Were Controlled by the Artificial Beta Cell," Diabetes, vol. 28, Apr. 1979, pp. 272-275.

Shichiri, Motoaki, et al., "Telemetry Glucose Monitoring Device with Needle-Type Glucose Sensor: A useful Tool for Blood Glucose Monitoring in Diabetic Individuals," Diabetes Care, vol. 9, No. 3, May-Jun. 1986, pp. 298-301.

Shichiri, Motoaki, et al., "Wearable Artificial Endocrine Pancreas with Needle-Type Glucose Sensor," The Lancet, Nov. 20, 1982, pp. 1129-1131.

Shichiri, Motoaki, et al., "The Wearable Artificial Endocrine Pancreas with a Needle-Type Glucose Sensor: Perfect Glycemic Control in Ambulatory Diabetes," Acta Paediatr Jpn 1984, vol. 26, pp. 359-370.

Shinkai, Seiji, "Molecular Recognitiion of Mono- and Di-saccharides by Phenylboronic Acids in Solvent Extraction and as a Monolayer," J. Chem. Soc., Chem. Commun., 1991, pp. 1039-1041.

Shults, Mark C., "A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneously Implanted Glucose Sensors," IEEE Transactions on Biomedical Engineering, vol. 41, No. 10, Oct. 1994, pp. 937-942.

Sternberg, Robert, et al., "Study and Development of Multilayer Needle-type Enzyme-based Glucose Microsensors," Biosensors, vol. 4, 1988, pp. 27-40.

Tamiya, E., et al., "Micro Glucose Sensors using Electron Mediators Immobilized on a Polypyrrole-Modified Electrode," Sensors and Actuators, vol. 18, 1989, pp. 297-307.

Tsukagoshi, Kazuhiko, et al., "Specific Complexation with Mono- and Disaccharides that can be Detected by Circular Dichroism," J. Org. Chem., vol. 56, 1991, pp. 4089-4091.

Urban, G., et al., "Miniaturized multi-enzyme biosensors integrated with pH sensors on flexible polymer carriers for in vivo applciations," Biosensors & Bioelectronics, vol. 7, 1992, pp. 733-739.

Ubran, G., et al., "Miniaturized thin-film biosensors using covalently immobilized glucose oxidase," Biosensors & Bioelectronics, vol. 6, 1991, pp. 555-562.

Velho, G., et al., "In vivo calibration of a subcutaneous glucose sensor for determination of subcutaneous glucose kinetics," Diab. Nutr. Metab., vol. 3, 1988, pp. 227-233.

Wang, Joseph, et al., "Needle-Type Dual Microsensor for the Simultaneous Monitoring of Glucose and Insulin," Analytical Chemistry, vol. 73, 2001, pp. 844-847.

Yamasaki, Yoshimitsu, et al., "Direct Measurement of Whole Blood Glucose by a Needle-Type Sensor," Clinics Chimica Acta, vol. 93, 1989, pp. 93-98.

Yokoyama, K., "Integrated Biosensor for Glucose and Galactose," Analytica Chimica Acta, vol. 218, 1989, pp. 137-142.

* cited by examiner

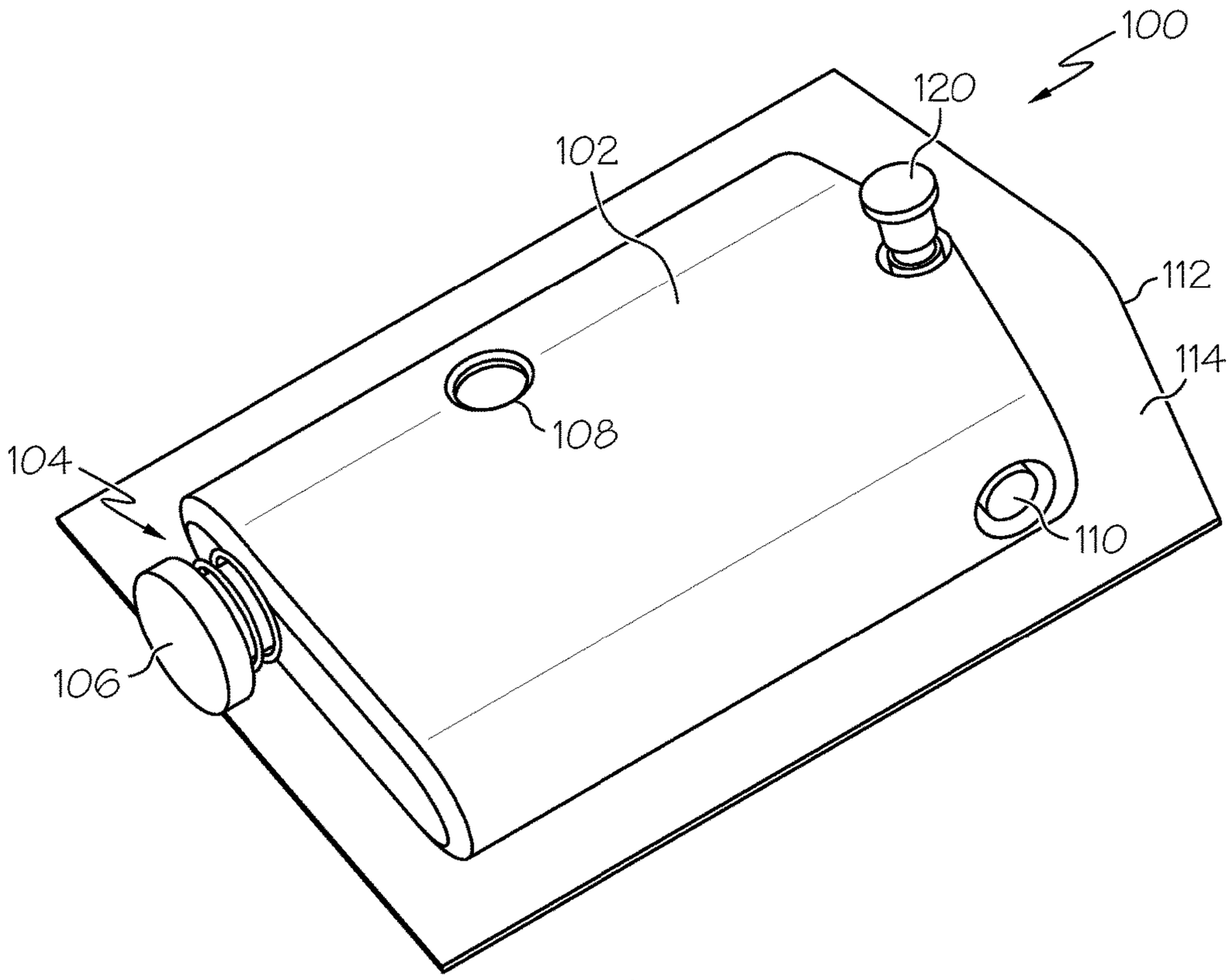

100
120
102
112
114
108
104
110
106

FIG. 1

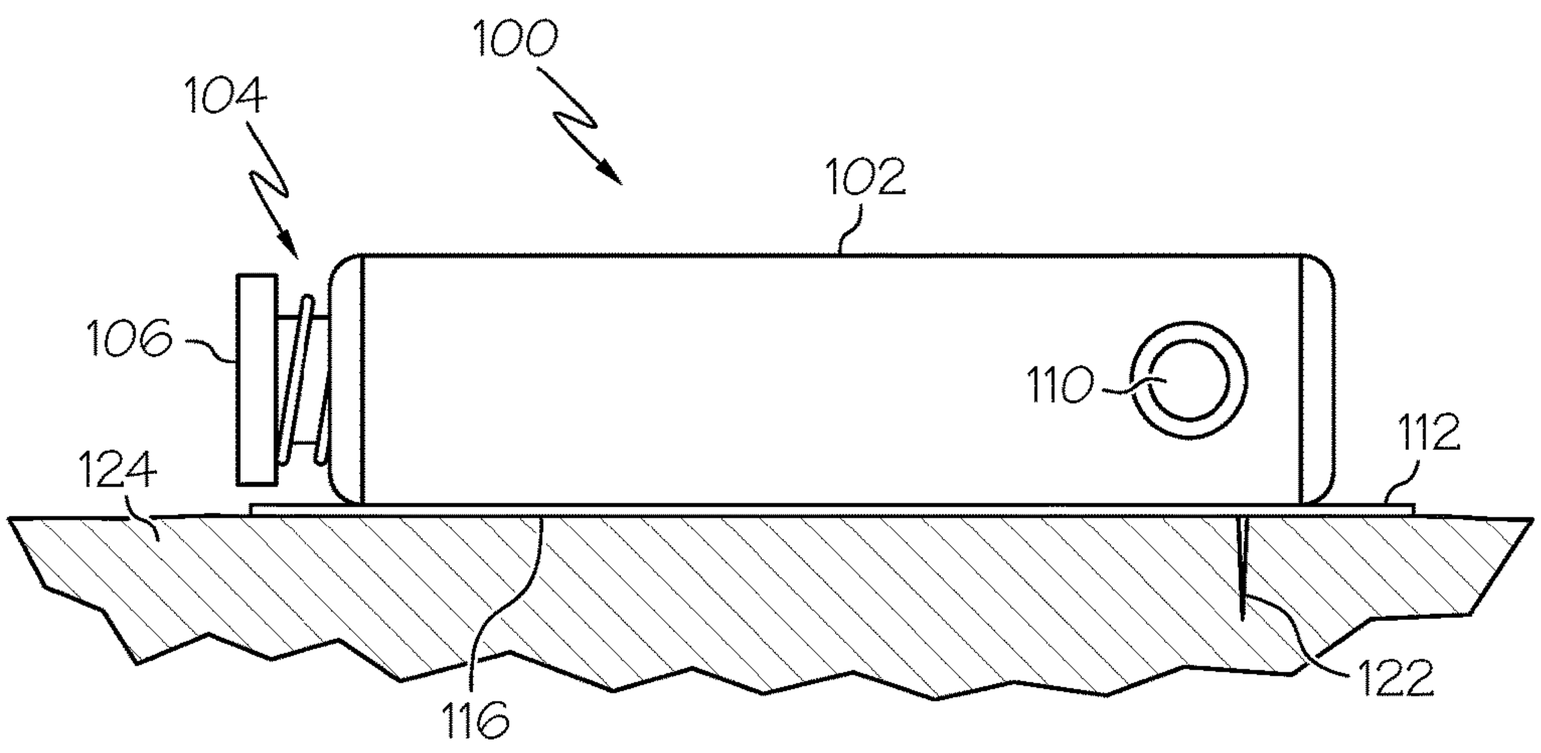

100
104
102
106
110
112
124
116
122

FIG. 2

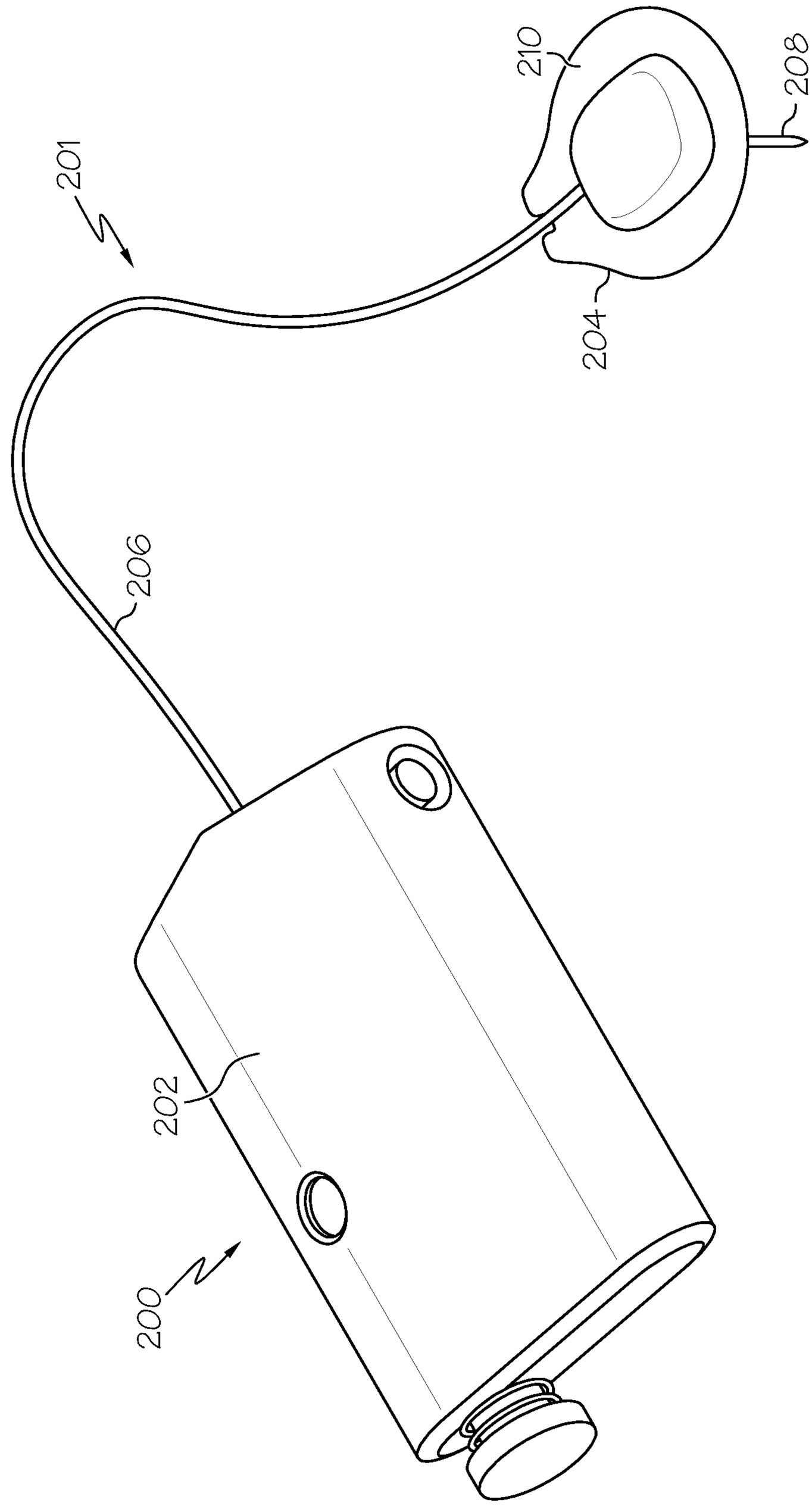


FIG. 3

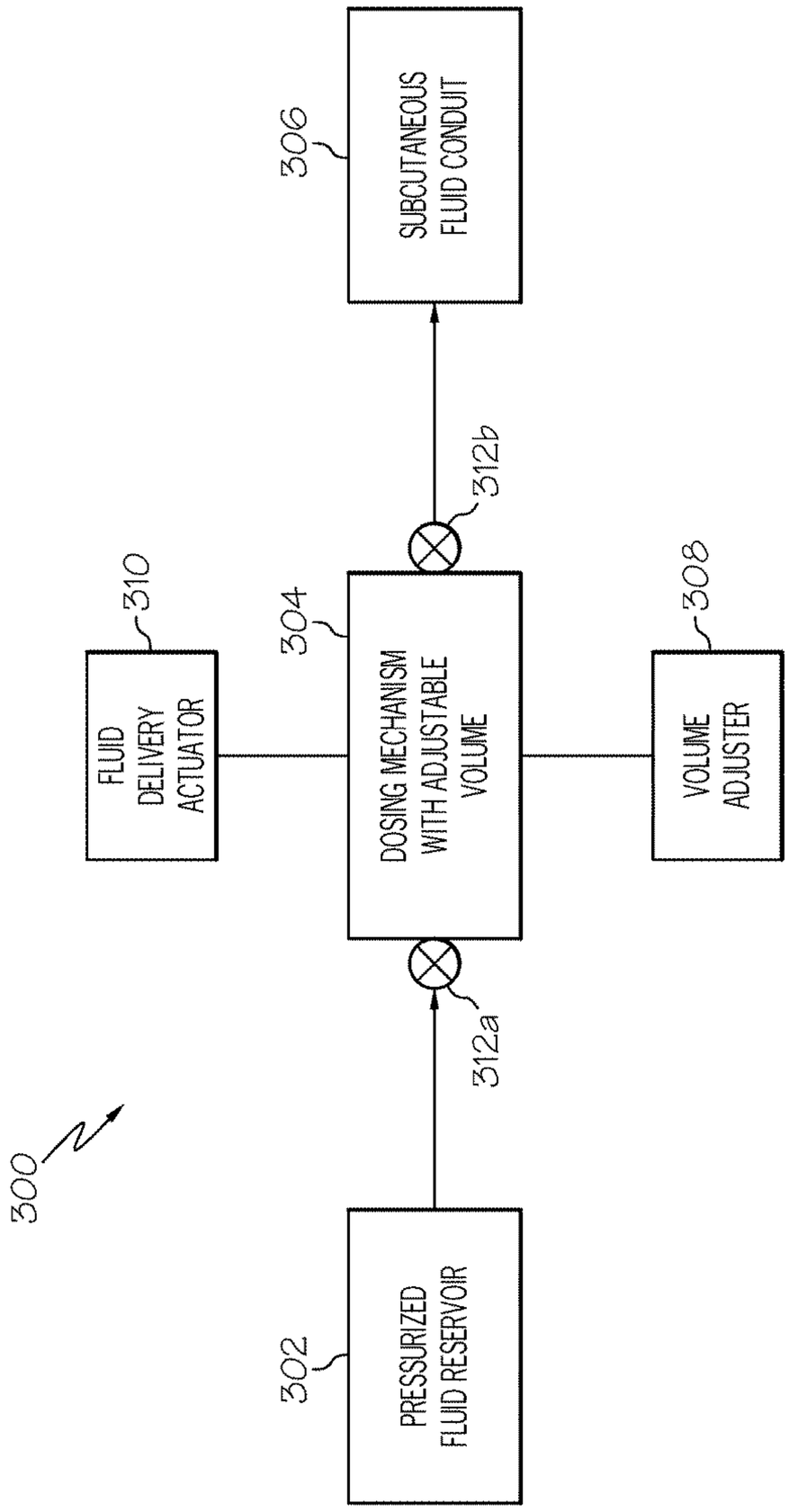

300
PRESSURIZED FLUID RESERVOIR
302
312a
DOSING MECHANISM WITH ADJUSTABLE VOLUME
304
FLUID DELIVERY ACTUATOR
310
VOLUME ADJUSTER
308
312b
SUBCUTANEOUS FLUID CONDUIT
306

FIG. 4

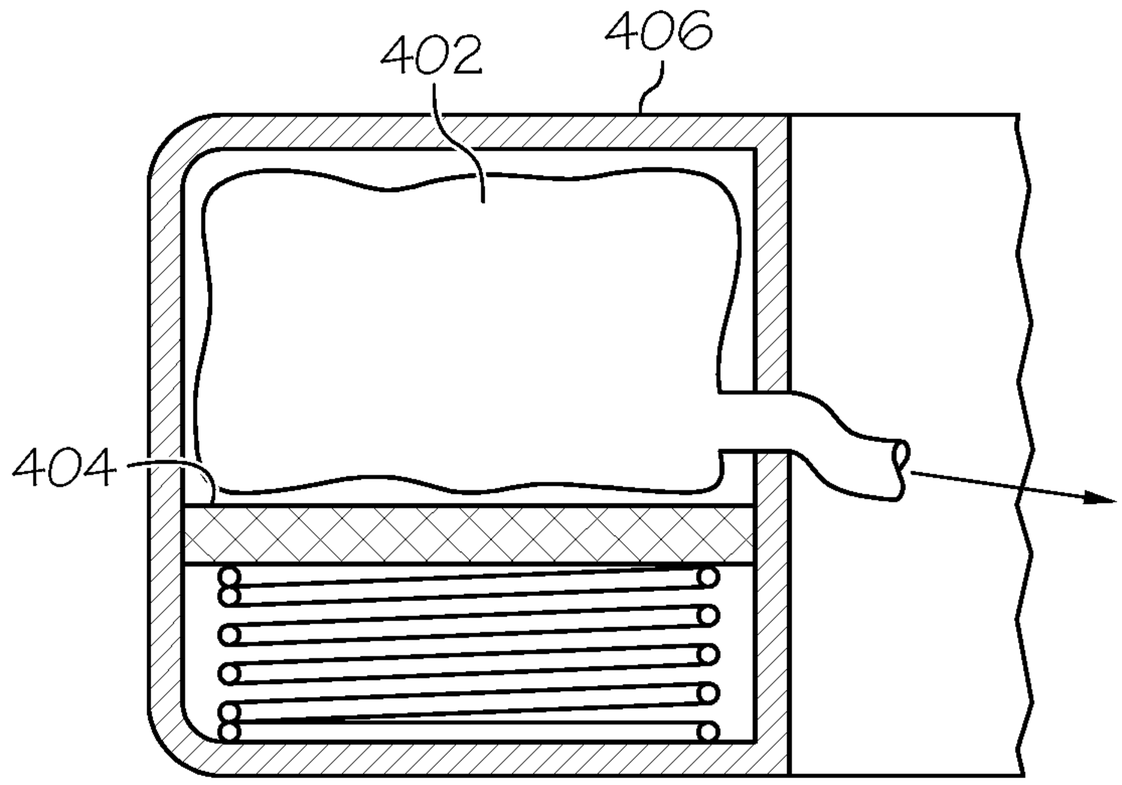


FIG. 5

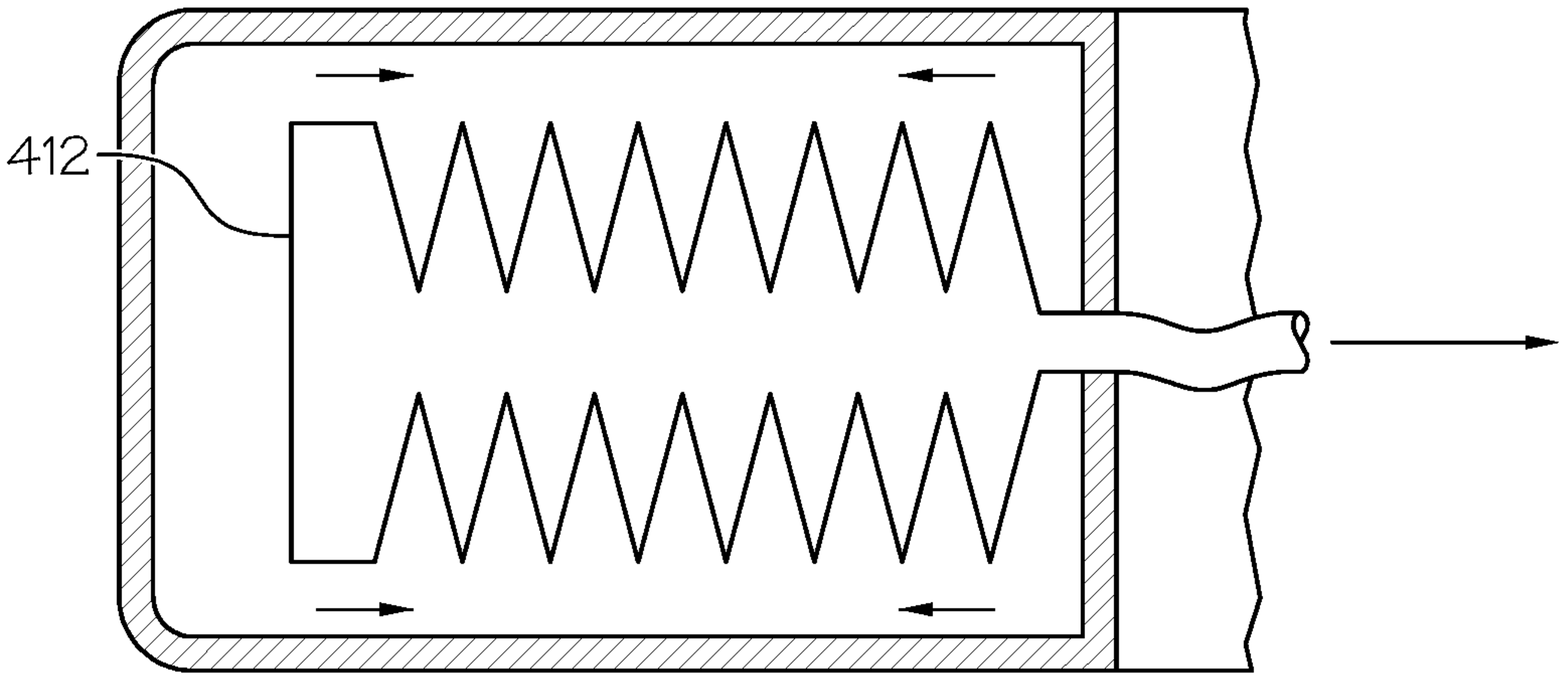


FIG. 6

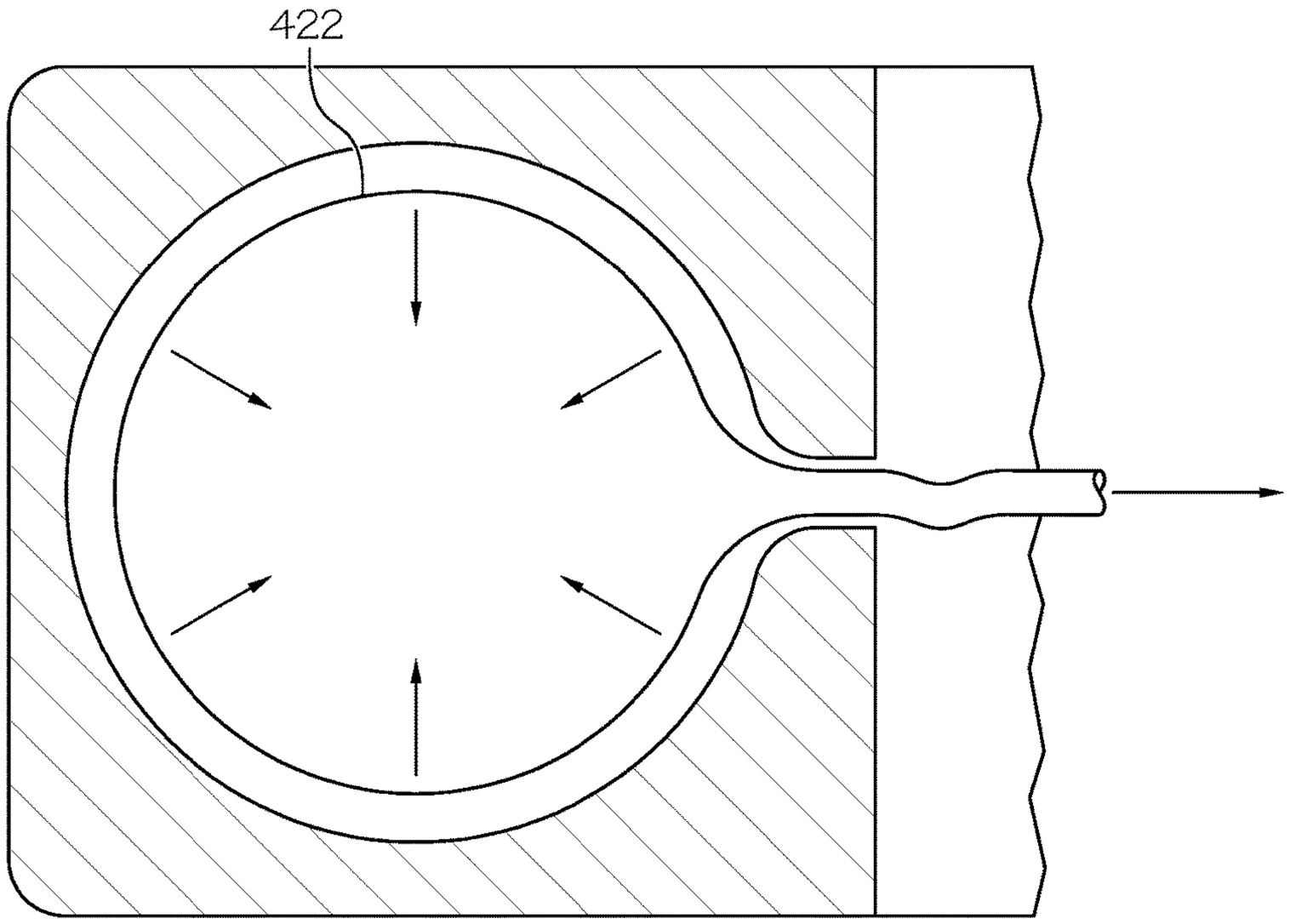


FIG. 7

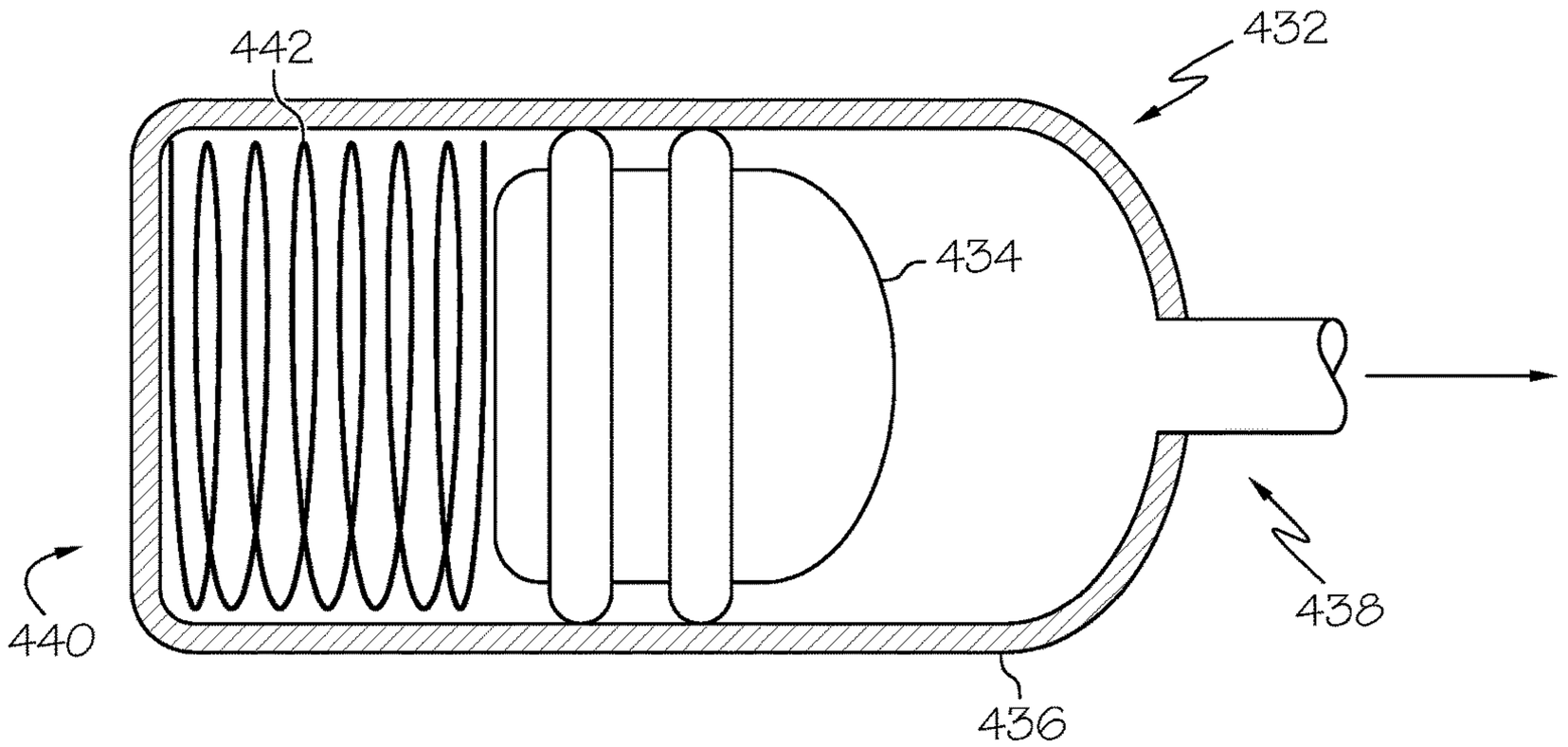


FIG. 8

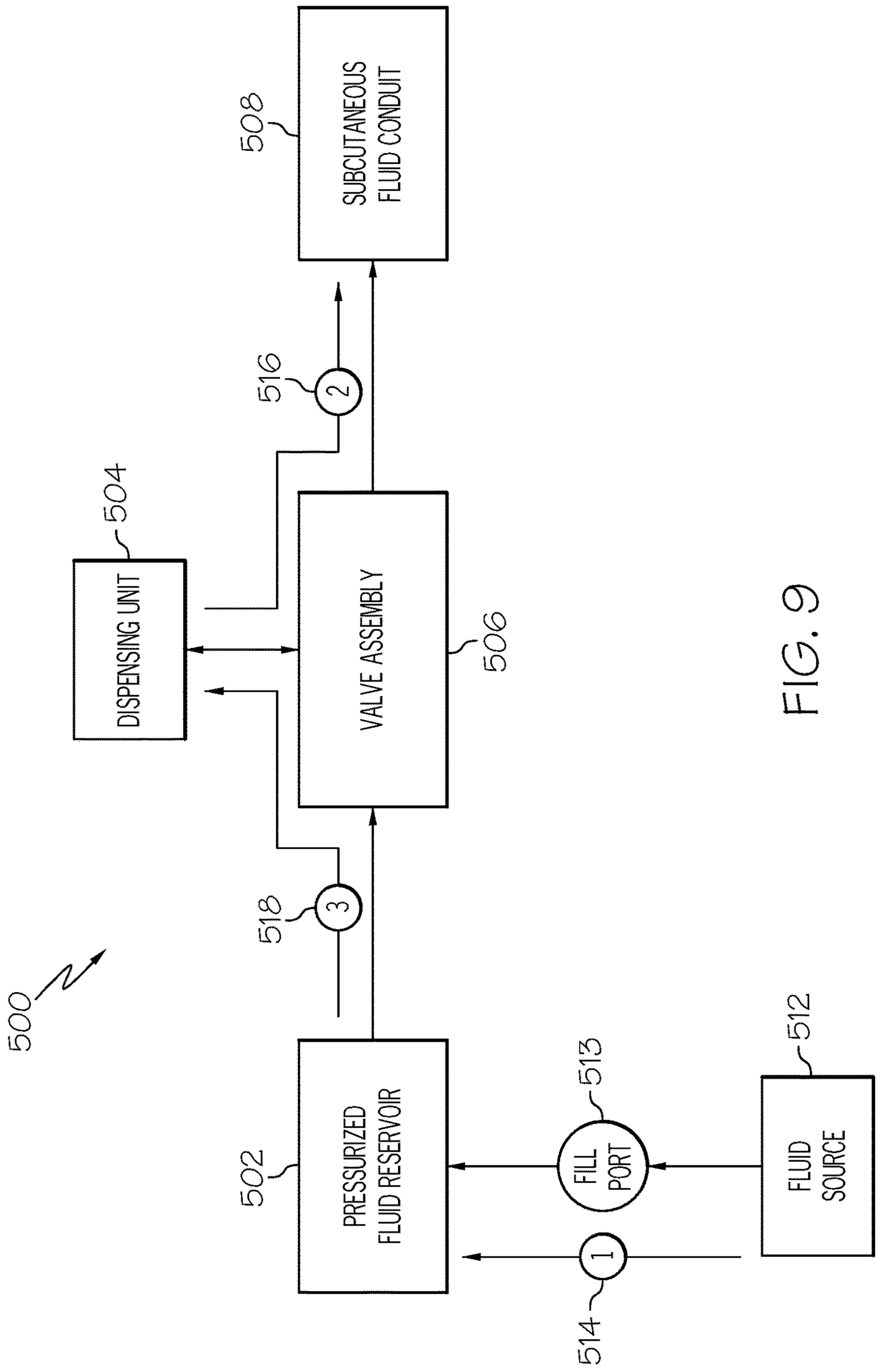

500
502
PRESSURIZED FLUID RESERVOIR
504
DISPENSING UNIT
506
VALVE ASSEMBLY
508
SUBCUTANEOUS FLUID CONDUIT
512
FLUID SOURCE
513
FILL PORT
514
1
516
2
518
3

FIG. 9

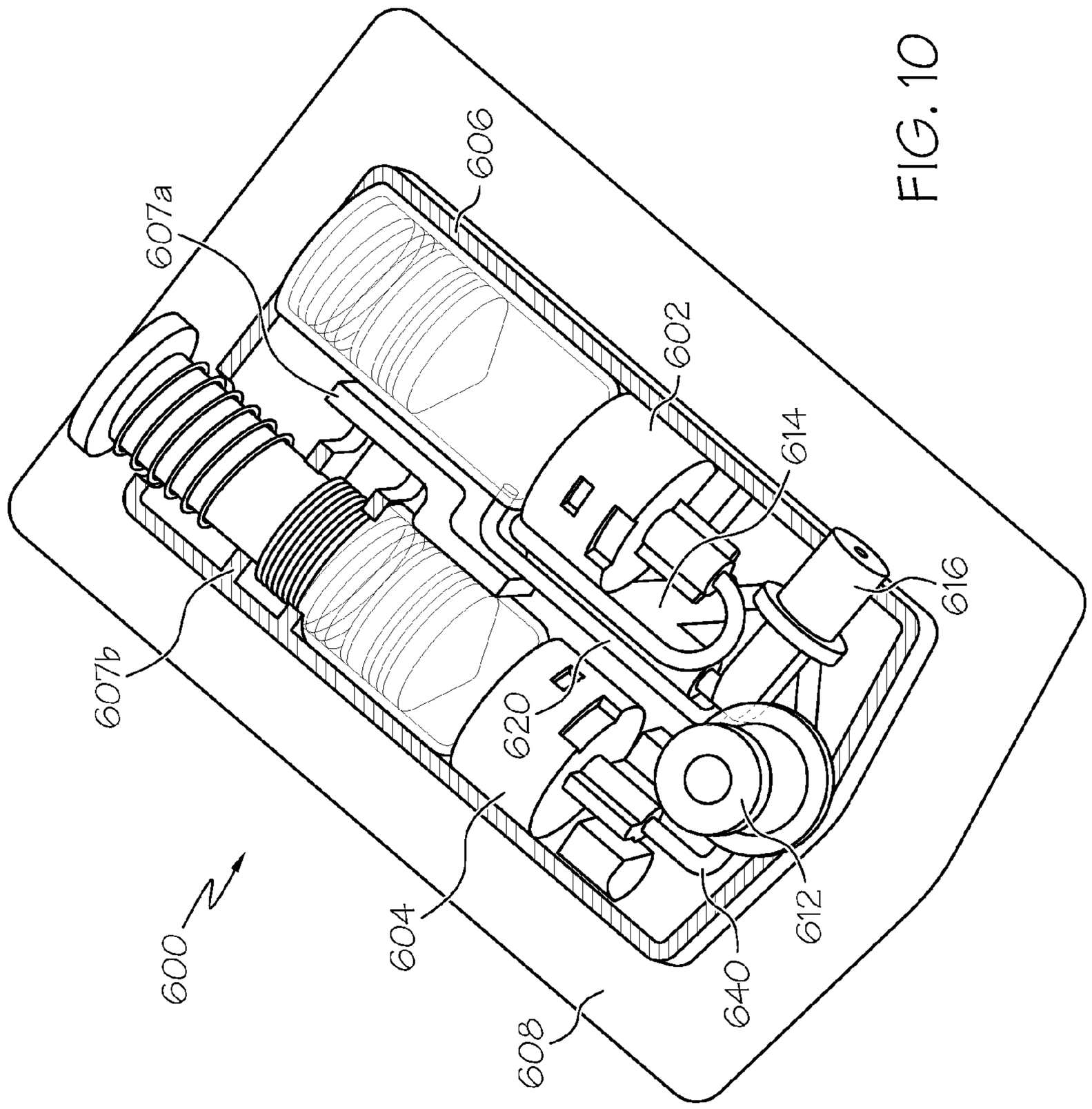


FIG. 10

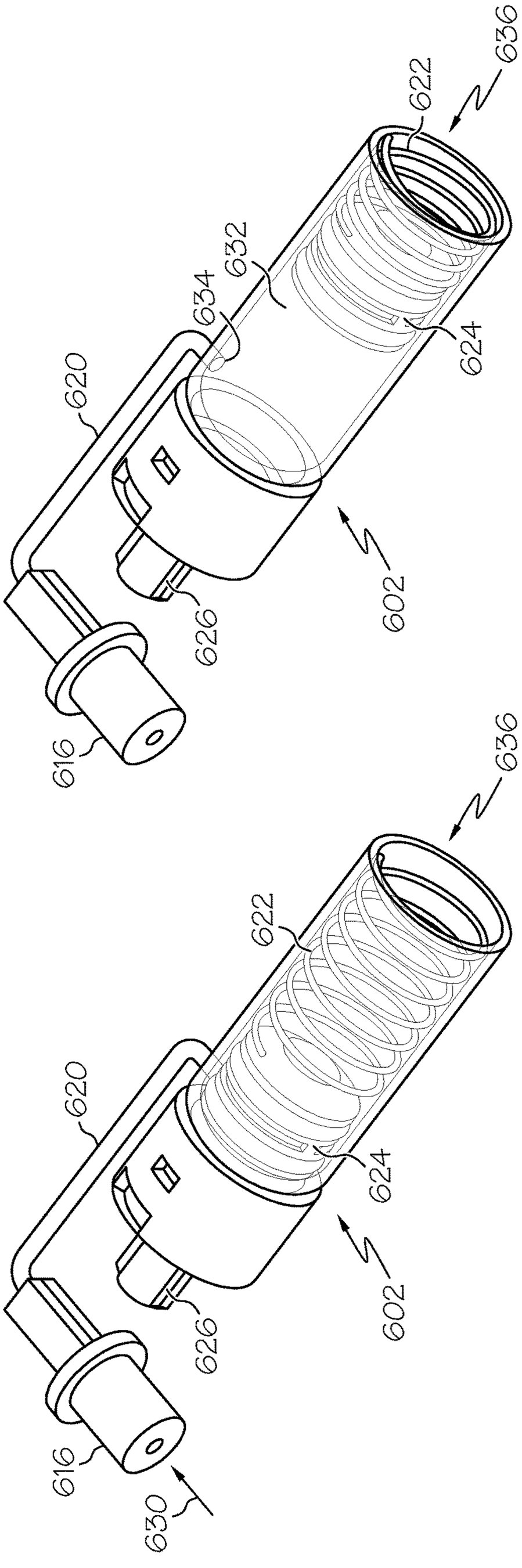

636
622
632
634
624
620
626
602
616
636
622
620
624
626
602
616
630

FIG. 12

FIG. 11

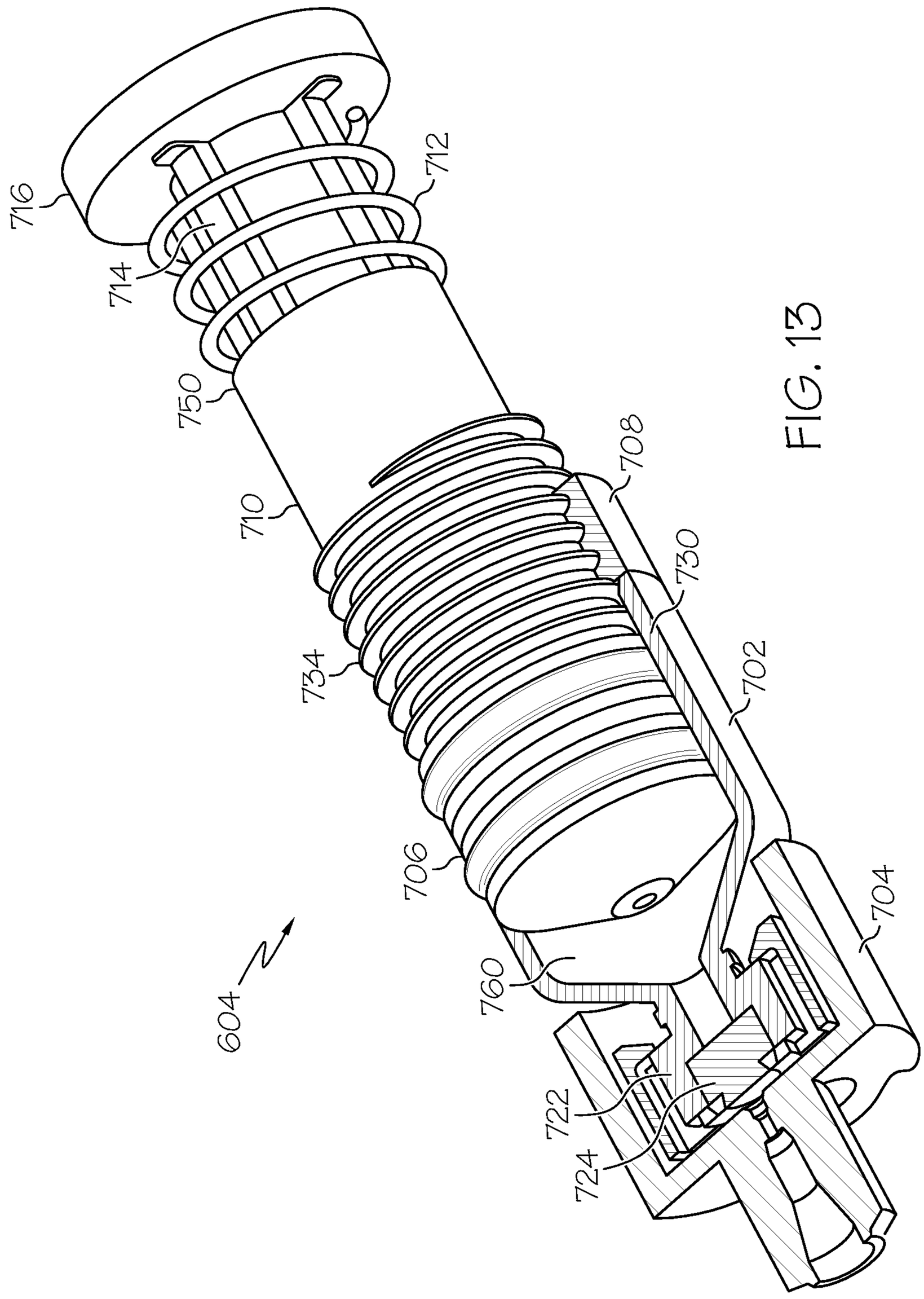


FIG. 13

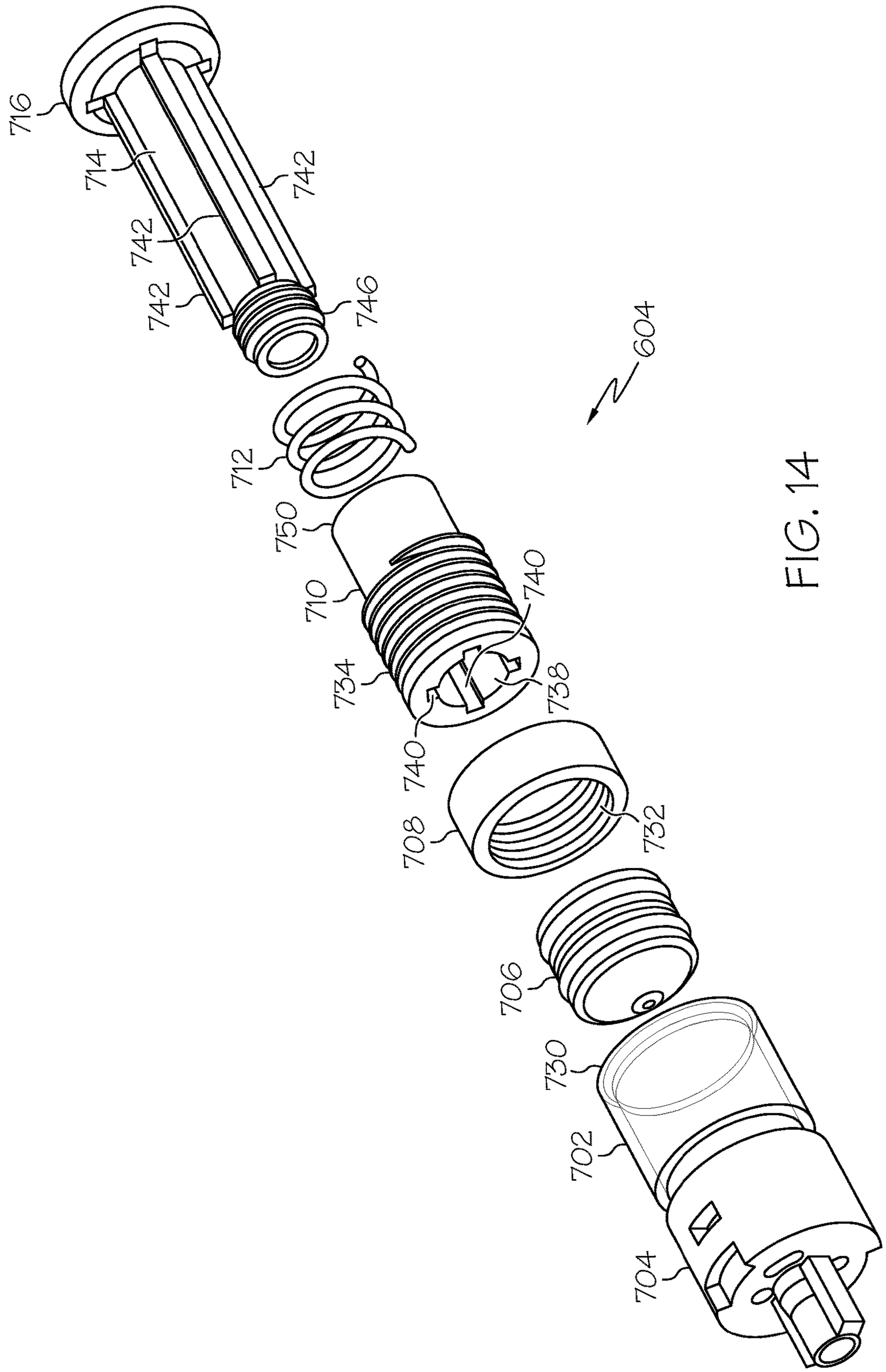

716
714
742
742
742
746
604
712
750
710
740
734
738
740
708
732
706
730
702
704

FIG. 14

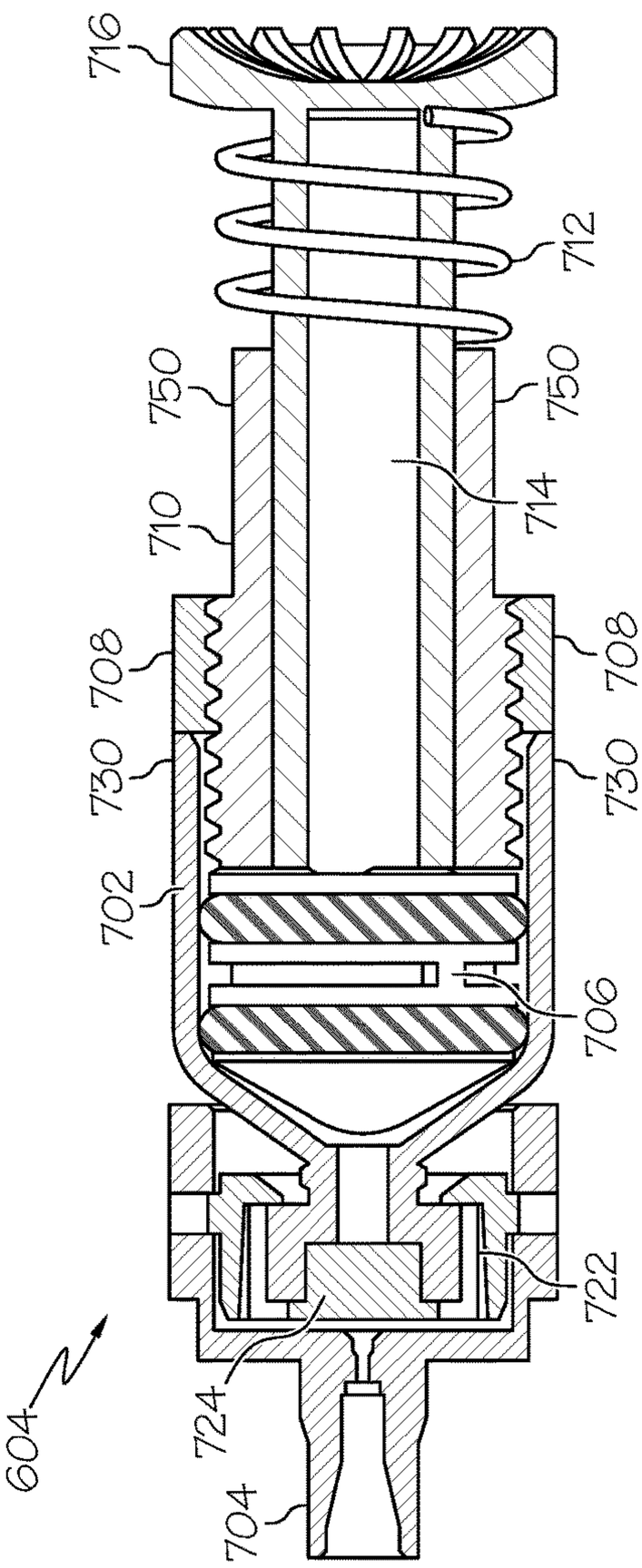

716
712
750
750
714
710
708
708
730
730
702
706
722
724
704
604

FIG. 15

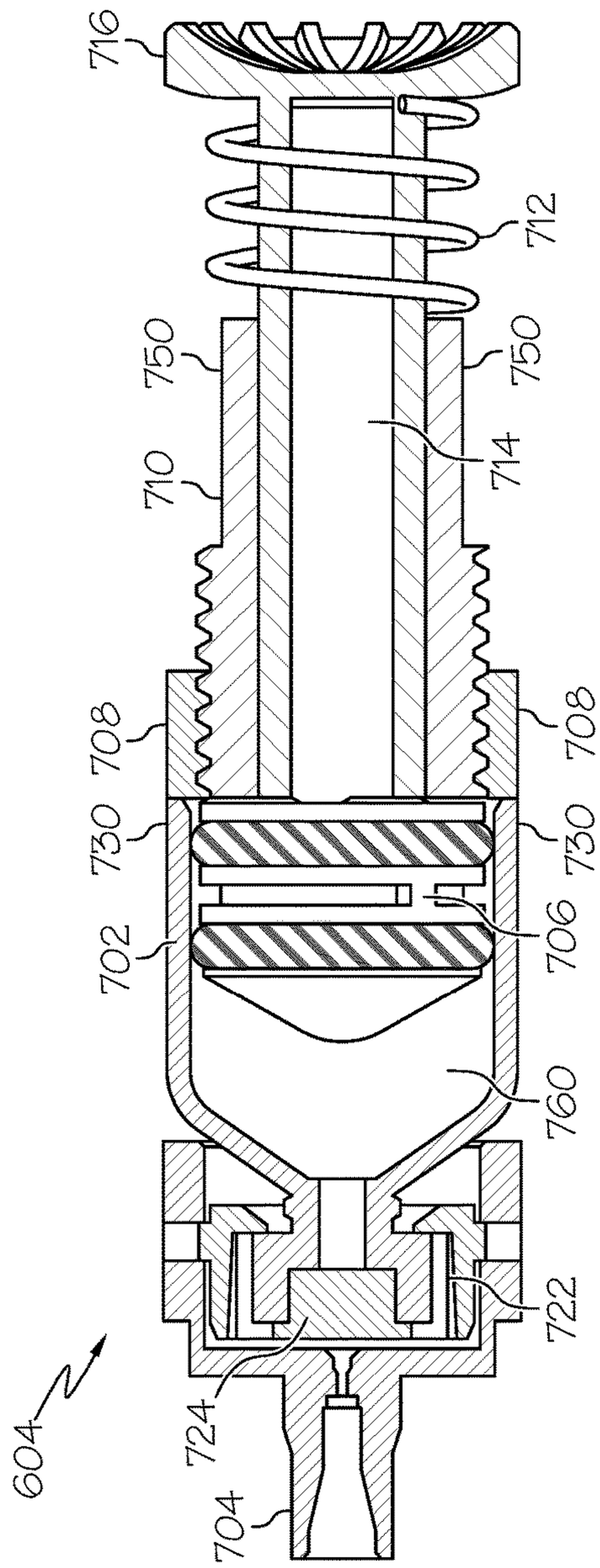

716
712
750
750
714
710
708
708
730
730
702
706
760
722
724
704
604

FIG. 16

MECHANICALLY ACTUATED FLUID INFUSION DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 13/533,797, filed Jun. 26, 2012.

TECHNICAL FIELD

Embodiments of the subject matter described herein relate generally to medical devices such as fluid infusion devices. More particularly, embodiments of the subject matter relate to a low cost, mechanically actuated insulin infusion pump.

BACKGROUND

Certain diseases or conditions may be treated, according to modern medical techniques, by delivering a medication or other substance to the body of a patient, either in a continuous manner or at particular times or time intervals within an overall time period. For example, diabetes is commonly treated by delivering defined amounts of insulin to the patient at appropriate times. Some common modes of providing insulin therapy to a patient include delivery of insulin through manually operated syringes and insulin pens. Other modern systems employ programmable fluid infusion devices (e.g., insulin pumps) to deliver controlled amounts of insulin to a patient.

A fluid infusion device suitable for use as an insulin pump may be realized as an external device or an implantable device that is surgically implanted into the body of the patient. External fluid infusion devices include devices designed for use in a generally stationary location (for example, in a hospital or clinic), and devices configured for ambulatory or portable use (to be carried by a patient). External fluid infusion devices may establish a fluid flow path from a fluid reservoir to the patient via, for example, a suitable hollow tubing. The hollow tubing may be connected to a hollow fluid delivery needle that is designed to pierce the patient's skin to deliver an infusion medium to the body. Alternatively, the hollow tubing may be connected directly to the patient's body through a cannula or set of microneedles.

Portable insulin pump devices can be expensive to procure and maintain due to their extensive use of sensitive electronic components, batteries, microprocessor chips, electronic display elements, motors, controllers, and the like. Consequently, many diabetes patients continue to use the traditional low cost approach that involves patient-actuated syringes. Accordingly, it would be desirable to have a low cost portable fluid infusion pump device that need not rely on expensive electronic components for fluid delivery operations. Furthermore, other desirable features and characteristics will become apparent from the subsequent detailed description and the appended claims, taken in conjunction with the accompanying drawings and the foregoing technical field and background.

BRIEF SUMMARY OF EMBODIMENTS

An embodiment of a fluid infusion device is disclosed. The fluid infusion device is designed to deliver a medication fluid to the body of a user. The fluid infusion device includes a housing, a fluid reservoir for the medication fluid, a dosing mechanism, an infusion component, and a mechanical actuator. The fluid reservoir and the dosing mechanism are both located in the housing. The dosing mechanism is coupled to the fluid reservoir to receive the medication fluid from the fluid reservoir. The dosing mechanism includes an adjustable fluid chamber that defines a variable dosage volume. The infusion component is coupled to the dosing mechanism to receive the medication fluid from the adjustable fluid chamber. The mechanical actuator is also coupled to the dosing mechanism. Operation of the mechanical actuator causes the medication fluid to be expelled from the adjustable fluid chamber to the infusion component.

Another embodiment of a fluid infusion device is also disclosed. The fluid infusion device includes a housing, a fluid reservoir for the medication fluid, a valve assembly located in the housing, a dosing mechanism located in the housing, and a fluid conduit. The medication fluid in the fluid reservoir is maintained under positive pressure. The valve assembly is coupled to the fluid reservoir, and the dosing mechanism is coupled to the fluid reservoir via the valve assembly. The dosing mechanism includes an adjustable fluid chamber that defines a user-selectable dosage volume. The dosing mechanism also includes a mechanical actuator. The fluid conduit is coupled to the dosing mechanism via the valve assembly. At least a portion of the fluid conduit is external to the housing when the fluid infusion device is deployed for operation. Application of an actuation force to the mechanical actuator initiates a fluid delivery operation, and removal of the actuation force from the mechanical actuator initiates a refill operation. During the fluid delivery operation, the valve assembly allows the medication fluid to flow from the adjustable fluid chamber into the fluid conduit for delivery to the body of the patient, while inhibiting flow of the medication fluid from the adjustable fluid chamber into the fluid reservoir. During the refill operation, the valve assembly allows the medication fluid to flow from the fluid reservoir into the adjustable fluid chamber, while inhibiting flow of the medication fluid from the fluid reservoir into the fluid conduit.

Also provided here is an embodiment of a fluid infusion device for delivery of a medication fluid to the body of a user. The fluid infusion device includes a housing, a fluid reservoir to maintain the medication fluid under positive pressure, wherein the fluid reservoir is located in the housing, and a valve assembly located in the housing and coupled to the fluid reservoir. The fluid infusion device also includes a dosing mechanism located in the housing and coupled to the fluid reservoir via the valve assembly. The dosing mechanism includes a mechanical actuator to adjust a fluid chamber of the dosing mechanism such that the fluid chamber defines a user-selectable dosage volume. The fluid infusion device also includes a fluid delivery conduit coupled to the dosing mechanism via the valve assembly. In response to application of force to the mechanical actuator, the medication fluid in the fluid chamber is expelled through the fluid delivery conduit, while the valve assembly inhibits flow of the medication fluid from the fluid chamber to the fluid reservoir. In response to removal of the force, the mechanical actuator automatically retracts to refill the fluid chamber with the medication fluid from the fluid reservoir, while the valve assembly inhibits flow of the medication fluid from the fluid reservoir to the fluid delivery conduit and inhibits fluid flow from the fluid delivery conduit to the fluid chamber.

This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary is not intended to identify key features or essential features of the

claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the subject matter may be derived by referring to the detailed description and claims when considered in conjunction with the following figures, wherein like reference numbers refer to similar elements throughout the figures.

FIG. **1** is a perspective view of an exemplary embodiment of a mechanically actuated fluid infusion device;

FIG. **2** is a side view of the fluid infusion device shown in FIG. **1** after attachment to the body of a user;

FIG. **3** is a perspective view of another exemplary embodiment of a mechanically actuated fluid infusion device, shown with an infusion set component;

FIG. **4** is a schematic representation of various components of a mechanical fluid infusion device;

FIG. **5** is a simplified schematic side view of an embodiment of a pressurized fluid reservoir that cooperates with a force-imparting structure;

FIG. **6** is a simplified schematic side view of an embodiment of a self-contracting fluid reservoir;

FIG. **7** is a simplified schematic side view of an embodiment of a self-contracting fluid reservoir that resembles a resilient balloon;

FIG. **8** is a simplified schematic side view of an embodiment of a pressurized fluid reservoir that employs a spring loaded plunger;

FIG. **9** is a schematic representation of various components of an embodiment of a mechanical fluid infusion device;

FIG. **10** is a perspective top view of an exemplary embodiment of a mechanically actuated fluid infusion device, with a portion of its housing removed;

FIG. **11** is a perspective view of a fluid reservoir suitable for use with the fluid infusion device shown in FIG. **10**, prior to filling with a medication fluid;

FIG. **12** is a perspective view of the fluid reservoir shown in FIG. **11**, after filling with the medication fluid;

FIG. **13** is a perspective and partially sectioned view of a dispensing unit suitable for use with the fluid infusion device shown in FIG. **10**;

FIG. **14** is an exploded perspective view of the dispensing unit shown in FIG. **13**; and

FIGS. **15** and **16** are cross sectional views of the dispensing unit shown in FIG. **13**.

DETAILED DESCRIPTION

The following detailed description is merely illustrative in nature and is not intended to limit the embodiments of the subject matter or the application and uses of such embodiments. As used herein, the word "exemplary" means "serving as an example, instance, or illustration." Any implementation described herein as exemplary is not necessarily to be construed as preferred or advantageous over other implementations. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

Certain terminology may be used in the following description for the purpose of reference only, and thus are not intended to be limiting. For example, terms such as "upper", "lower", "above", and "below" may be used to refer to directions in the drawings to which reference is made. Terms such as "front", "back", "rear", "side", "outboard," and "inboard" may be used to describe the orientation and/or location of portions of a component within a consistent but arbitrary frame of reference which is made clear by reference to the text and the associated drawings describing the component under discussion. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import. Similarly, the terms "first", "second" and other such numerical terms referring to structures do not imply a sequence or order unless clearly indicated by the context.

The following description relates to a fluid infusion device of the type used to treat a medical condition of a patient. The infusion device is used for infusing fluid into the body of a user. The non-limiting examples described below relate to a medical device used to treat diabetes (more specifically, an insulin pump), although embodiments of the disclosed subject matter are not so limited. Accordingly, the infused medication fluid is insulin in certain embodiments. In alternative embodiments, however, many other fluids may be administered through infusion such as, but not limited to, disease treatments, drugs to treat pulmonary hypertension, iron chelation drugs, pain medications, anti-cancer treatments, medications, vitamins, hormones, or the like. For the sake of brevity, conventional features and characteristics related to infusion system operation, insulin pump and/or infusion set operation, fluid reservoirs, and subcutaneous fluid delivery components may not be described in detail here. Examples of infusion pumps and/or related pump drive systems used to administer insulin and other medications may be of the type described in, but not limited to: United States patent application number 2009/0299290 A1; United States patent application number 2008/0269687; U.S. Pat. Nos. 7,828,764; and 7,905,868 (the entire content of these patent documents is incorporated by reference herein).

The subject matter described here relates to various features, components, operating methodologies, and technology associated with a mechanical fluid infusion device. The fluid infusion device is "mechanical" in that it need not (and preferably does not) rely on any electronic components or power supply to support its primary fluid delivery operations. In certain exemplary embodiments, the activation and/or actuation of the fluid delivery function is achieved in a fully mechanical manner. Accordingly, an embodiment can be deployed with minimal or no electronic or electrical elements, components, power sources, sensors, motors, or the like. For this reason, a practical implementation of the mechanical fluid infusion device can be manufactured in a very cost efficient manner to provide a low cost alternative to the modern electronic and processor based infusion devices that are currently available. Moreover, the mechanical fluid infusion device could be designed to be a disposable single-use item, due to its low manufacturing cost.

Turning now to the drawings, FIG. **1** is a perspective view of one exemplary embodiment of a mechanically actuated fluid infusion device **100** prior to deployment, and FIG. **2** is a side view of the fluid infusion device **100** after attachment to the body of a user. The fluid infusion device **100** includes an outer housing **102** that represents the primary structural component of the fluid infusion device **100**. The housing **102** may be fabricated from a lightweight and tough material such as a molded plastic material. In practice, the housing **102** may be fabricated in two or more pieces that are assembled to form a shell for various internal components of the fluid infusion device **100**. For example, the housing **102**

may be manufactured in two halves that are bonded, welded, or otherwise attached together to enclose the internal components.

The fluid infusion device **100** includes a mechanical actuator **104** (e.g., a plunger, a dispensing unit, or the like) that is operated to deliver a metered dose of fluid to the body of the patient. As depicted in FIG. **1**, the mechanical actuator **104** may terminate at a knob **106** that protrudes from the outer housing **102**. For this particular embodiment, the user actuates (e.g., presses down on) the knob **106** to activate the fluid delivery operation of the fluid infusion device **100**. The housing **102** may incorporate or cooperate with one or more safety features to reduce the likelihood of accidental fluid delivery. For example, the housing **102** may include a locking mechanism for the knob **106** (e.g., a switch, a button, a slider, or the like) that must be released to actuate the knob **106**. As another example, the housing **102** may include one or more structural features that make it difficult for the knob **106** to be inadvertently actuated (e.g., a hood feature, guard tabs surrounding the knob **106**, or the like).

Moreover, rotation of the knob **106** adjusts the volume of a fluid chamber (hidden from view in FIG. **1**) such that a metered amount of fluid can be administered with each activation of the mechanical actuator. This adjustment feature is described in more detail below with reference to FIGS. **4** and **13-16**. In this regard, the fluid infusion device **100** may include a feature that indicates the dosage volume setting to the user. For example, the housing **102** may include a slot, a window, or an opening **108** formed therein. After adjusting the dosage volume to the desired setting, an identifier of the current volume setting will appear within the opening **108**. In practice, labels, numbers, color codes, symbols, or any type of indicia can be used for this purpose. For example, the fluid infusion device **100** may be suitably configured to provide a plurality of predetermined and calibrated dosage volumes, such that the desired dosage setting is visible within the opening **108** (e.g., 1 Unit, 5 Units, 10 Units, or any quantity or measurement using any convenient or standardized unit of measure).

The fluid infusion device **100** may also include a fill port **110** that is accessible from outside the housing **102**. The fill port **110** is fluidly coupled to a fluid reservoir (not visible in FIG. **1**) that is located inside the housing **102**. The fill port **110** is suitably configured to facilitate filling of the fluid reservoir with the desired fluid, e.g., a medication fluid such as insulin. Depending upon the embodiment and/or the desired application, the fill port **110** could be designed to accommodate filling of the fluid reservoir at the time of manufacture or to accommodate filling (and, in certain implementations, refilling) by the end user, a caregiver, a physician, or the like. In accordance with one embodiment, the fill port **110** includes a small opening or hole that accommodates a syringe needle such that a syringe can be used to fill the internal fluid reservoir. Moreover, the fill port **110** is preferably designed to be self-sealing such that the medication fluid does not leak out of the fill port **110** after the internal fluid reservoir has been filled. To this end, the fill port **110** may employ a resilient sealing element (such as a septum) through which the filling needle passes during the filling operation. In an alternative embodiment designed to be a single use and disposable unit, the internal fluid reservoir may be provided in a pre-filled state (filled during manufacturing), rendering the fill port **110** unnecessary.

The illustrated embodiment of the fluid infusion device **100** is intended to be affixed to the skin of the patient. Accordingly, the fluid infusion device **100** may include an adhesive patch **112** or an adhesive layer having a first side **114** affixed to the housing **102** and having a second side **116** (see FIG. **2**) for attachment to the body of the patient. The second side **116** of the adhesive patch **112** may be provided to the user with a removable liner (not shown) that is removed and discarded prior to use. Thus, the adhesive patch **112** allows the patient or caregiver to secure the fluid infusion device **100** to a convenient and discreet location on the body of the patient, as desired.

This particular embodiment of the fluid infusion device **100** includes an introducer **120** (see FIG. **1**) that is used to insert a fluid delivery conduit **122** (see FIG. **2**) into the skin of the patient. The fluid delivery conduit **122** is one suitable embodiment of an infusion component that is integrated with the housing **102** to accommodate direct attachment of the fluid infusion device **100** to the body of the user. The introducer **120** may include a needle that facilitates subcutaneous insertion of a flexible fluid delivery conduit **122**, e.g., a tube or a cannula. Thus, after the housing **102** is affixed to the skin **124** of the patient, the introducer **120** can be manipulated to insert the fluid delivery conduit **122** into the body of the patient. Accordingly, when the fluid infusion device **100** is deployed for operation in this manner, at least a portion of the fluid delivery conduit **122** is external to the housing **102**. The introducer **120** can be removed and discarded after insertion of the fluid delivery conduit **122**. Accordingly, the introducer **120** does not appear in FIG. **2**. After deployment, the fluid delivery conduit **122** functions as one part of the fluid delivery path associated with the fluid infusion device **100**, as is well understood.

FIG. **3** is a perspective view of another exemplary embodiment of a mechanically actuated fluid infusion device **200**. The fluid infusion device **200** is similar in many respects to the fluid infusion device **100** described above. The fluid infusion device **200**, however, cooperates with an infusion component **201** that is remote from the housing **202** of the fluid infusion device **200**. More specifically, the illustrated embodiment of the infusion component **201** includes an infusion set **204** and tubing **206** coupled between the infusion set **204** and the fluid source (not shown) located within the housing **202**. The infusion set includes a cannula **208** for subcutaneous insertion into the body of the user. Accordingly, the tubing **206** establishes and maintains a fluid flow path from the fluid source to the infusion set **204** and to the cannula **208**. The infusion set **204** may include an adhesive element **210** to accommodate direct attachment of the infusion set **204** to the body of the user. In practice, the fluid infusion device **200** could be affixed to the body of the patient (as described above for the fluid infusion device **100**), or it could be carried or worn by the patient in an appropriate manner (e.g., using a belt clip, in a pocket, or strapped to the body).

FIG. **4** is a schematic representation of various components of an exemplary embodiment of a mechanical fluid infusion device **300** that is suitably configured to deliver a medication fluid to the body of a user in response to user actuation. The components depicted in FIG. **4** may be found in an embodiment of the fluid infusion device **100** (FIG. **1**) and in an embodiment of the fluid infusion device **200** (FIG. **3**). The illustrated embodiment of the fluid infusion device **300** generally includes, without limitation: a pressurized fluid reservoir **302**; a dosing mechanism **304** having an adjustable fluid chamber that defines a variable dosage volume; a subcutaneous fluid conduit **306**; a volume or dosage adjuster **308**; and a mechanical fluid delivery actuator **310**. The fluid infusion device **300** may also incorporate a suitably configured valve assembly **312** having one or more fluid valves to regulate the flow of the medication fluid

throughout the fluid infusion device **300** and to regulate the delivery of the medication fluid from the fluid infusion device **300**. It should be appreciated that FIG. **4** represents a simplified functional representation of the fluid infusion device **300**, and that a working implementation of the fluid infusion device **300** may (and usually will) include additional elements, components, and structure that is neither shown nor described in detail here. FIG. **4** is presented here to provide a foundation for the following description of the general functionality of the mechanically actuated fluid infusion device **300**.

The fluid reservoir **302** may be provided as a pre-filled component, or it may be designed to accommodate filling by the end user, a caregiver, or the like. The fluid reservoir **302** holds a quantity of medication fluid and serves as the source of the medication fluid for the fluid infusion device **300**. For the exemplary embodiments described here, the fluid reservoir **302** is located and held in place in the housing (not shown in FIG. **4**) of the fluid infusion device **300**. The fluid reservoir **302** is pressurized in that the medication fluid in the fluid reservoir **302** is maintained under positive pressure using an appropriate methodology, technique, or structure. In other words, the medication fluid is held under pressure that would normally force the medication fluid out of the fluid reservoir **302**. The valve assembly **312** may include an inlet valve **312***a* between the fluid reservoir **302** and the dosing mechanism **304**, wherein the inlet valve **312***a* regulates flow of the medication fluid from the fluid reservoir **302** to the dosing mechanism **304**. For example, the inlet valve **312***a* may be realized as a one-way valve that inhibits flow of the medication fluid from the adjustable fluid chamber of the dosing mechanism **304** to the fluid reservoir **302**.

The dosing mechanism **304** is also located inside the housing of the fluid infusion device **300**, and is coupled to the fluid reservoir **302** to receive the medication fluid from the fluid reservoir **302** as needed. The dosing mechanism **304** has an adjustable fluid chamber that can be configured and set—by the patient, a caregiver, the manufacturer, the vendor, a physician, or the like—by manipulating the volume adjuster **308**. The volume adjuster **308** may be realized as one or more knobs, switches, buttons, sliders, levers, etc. In certain embodiments, the dosing mechanism **304** accommodates a plurality of different user-selectable and/or calibrated fluid delivery volumes (such as 1 Unit, 5 Units, and 10 Units), wherein only the pre-set volumes can be selected. Thus, the adjustable fluid chamber may be adjustable in discrete steps that define a plurality of predetermined and calibrated dosage volumes for the dosing mechanism **304**. In an alternative embodiment, the dosing mechanism **304** is continuously variable (between a minimum volume and a maximum volume) to provide the user with greater flexibility and more options. Once adjusted and set, however, the dosing mechanism **304** defines an accurate and metered dose of the medication fluid.

Each fluid delivery operation results in the delivery of one metered dose, as determined by the adjustable volume of the dosing mechanism **304**. Thus, if the fluid delivery volume is set at one Unit and the patient desires to administer a bolus of five Units, then the fluid delivery actuator **310** must be manipulated five times in succession to deliver a total of five Units. As another example, if the volume is set at five Units, then the fluid delivery actuator **310** must be activated twice to deliver a bolus of ten Units. Depending upon the particular implementation, the fluid delivery actuator **310** may be realized as a switch, a button, a lever, a plunger, or any suitably configured mechanical component. In an exemplary embodiment, the fluid delivery actuator **310** is realized as a mechanical plunger for the adjustable fluid chamber of the dosing mechanism **304**.

Operation of the fluid delivery actuator **310** forces the medication fluid out of the fluid chamber of the dosing mechanism **304**, and causes the medication fluid to be expelled from the fluid chamber to the fluid conduit **306**, which represents one suitable embodiment of an infusion component for the fluid infusion device **300**. In this regard, the fluid conduit **306** is coupled to the dosing mechanism **304** to receive the medication fluid from the adjustable fluid chamber as needed. As mentioned above with reference to FIGS. **1-3**, the fluid conduit **306** may be a rigid needle or a soft cannula that extends directly from the housing of the fluid infusion device **300**, or it may be a rigid needle or a soft cannula associated with an infusion set component that is fluidly coupled to the fluid infusion device **300** using a tube.

The valve assembly **312** may include an outlet valve **312***b* between the dosing mechanism **304** and the fluid conduit **306**, wherein the outlet valve **312***b* regulates flow of the medication fluid from the adjustable fluid chamber of the dosing mechanism **304** to the fluid conduit **306**. In this regard, the outlet valve **312***b* may be realized as a one-way valve that inhibits flow of the medication fluid from the fluid conduit **306** to the dosing mechanism **304**. Moreover, the valve assembly **312** may be suitably configured to inhibit flow of the medication fluid from the fluid reservoir **302** directly to the fluid conduit **306**. In other words, the valve assembly **312** may be designed to ensure that fluid from the fluid reservoir **302** must flow into the adjustable fluid chamber of the dosing mechanism **304** before it flows to the fluid conduit **306**.

FIG. **4** schematically depicts the dosing mechanism **304**, the volume adjuster **308**, and the fluid delivery actuator **310** as distinct functional elements. In practice, however, the dosing mechanism and the mechanical fluid delivery actuator **310** could form an integrated subassembly of the fluid infusion device **300**. Similarly, the dosing mechanism and the volume adjuster **308** could be fabricated as an integrated subassembly. In yet another embodiment, the dosing mechanism **304**, the volume adjuster **308**, and the fluid delivery actuator **310** are realized as a single cooperating subassembly (as described below with reference to FIGS. **9-16**).

As mentioned above, the medication fluid may be held under positive pressure to facilitate the fluid delivery action of the fluid infusion device. Accordingly, the fluid reservoir may be referred to here as a pressurized fluid reservoir. In this regard, a pressurized fluid reservoir can be achieved using a variety of reservoir configurations, as desired for the particular application. For example, FIGS. **5-8** schematically depict four different ways in which medication fluid can be maintained under positive pressure in the context of a fluid infusion device of the type described here. These examples are not intended to be exhaustive or to limit the scope and application of the embodiments presented here. Indeed, a pressurized fluid reservoir could be implemented using other techniques, components, and structures not shown or described in detail here.

FIG. **5** is a simplified schematic side view of an embodiment of a pressurized fluid reservoir **402** that cooperates with a force-imparting structure **404**. For this embodiment, the fluid reservoir **402** is realized as a resilient and compressible bladder or bag. Therefore, the fluid reservoir **402** could be fabricated from any flexible material that does not react with the medication fluid. The fluid reservoir **402** may be positioned within an interior pocket or cavity formed within the housing **406** of the fluid infusion device. The

structure **404** is operatively coupled to the fluid reservoir **402** to impart a compressive force to the fluid reservoir **402**. In this regard, the structure **404** may include or cooperate with a spring **408** or any suitable biasing element to form a spring loaded platform for the fluid reservoir **402**. In accordance with this arrangement, the structure **404** (e.g., the spring loaded platform) squeezes the resilient bladder of the fluid reservoir **402** against an interior surface of the housing **406** such that the external force on the bladder places the medication fluid in the bladder under positive pressure. Accordingly, the medication fluid naturally flows out of the fluid reservoir **402** (in the direction indicated by the arrow) unless the flow is inhibited by the valve assembly of the fluid infusion device. It should be appreciated that more than one force imparting structure could be deployed to compress the fluid reservoir **402** within the housing **406**. Moreover, the direction(s) in which the fluid reservoir **402** is compressed may vary from one embodiment to another.

FIG. **6** is a simplified schematic side view of an embodiment of a self-contracting fluid reservoir bag **412** that is suitable for use as a fluid reservoir for medication fluid. The reservoir bag **412** is realized as a self-contracting resilient bellows that naturally tends to "shrink" upon itself, as indicated by the opposing horizontal arrows in FIG. **6**. Thus, the reservoir bag **412** expands in volume when filled with the medication fluid, and such expansion inherently places the medication fluid under positive pressure. Accordingly, the medication fluid naturally flows out of the reservoir bag **412** (in the direction indicated by the outgoing arrow) unless the flow is inhibited by the valve assembly of the fluid infusion device. Moreover, the reservoir bag **412** naturally shrinks as the medication fluid exits.

FIG. **7** is a simplified schematic side view of another embodiment of a self-contracting fluid reservoir bag that is realized as a self-contracting balloon **422**. The balloon **422** is similar to the reservoir bag **412** shown in FIG. **6** in that the balloon **422** naturally tends to "shrink" upon itself, as indicated by the inwardly pointing arrows in FIG. **7**. Thus, the balloon **422** expands in volume when filled with the medication fluid, and such expansion inherently places the medication fluid under positive pressure. Accordingly, the medication fluid naturally flows out of the balloon **422** (in the direction indicated by the outgoing arrow) unless the flow is inhibited by the valve assembly of the fluid infusion device. Moreover, the balloon **422** naturally shrinks as the medication fluid exits.

FIG. **8** is a simplified schematic side view of an embodiment of a pressurized fluid reservoir **432** that employs a spring loaded plunger **434**. The fluid reservoir **432** includes a barrel body **436** (typically having a cylindrical shape) having a fluid delivery end **438** and a base **440** that is opposite the fluid delivery end **438**. The plunger **434** is located in the barrel body **436**, and the plunger **434** is suitably configured to travel within the barrel body **436**. The fluid reservoir **432** also includes a biasing element **442** (e.g., a spring) located in the barrel body **436** between the plunger **434** and the base **440**. In accordance with this arrangement, the biasing element **442** biases the plunger **434** toward the fluid delivery end **438**. Movement of the plunger **434** toward the fluid delivery end **438** causes the medication fluid to be dispensed from the fluid reservoir **432**.

The biasing element **442** cooperates with the plunger **434** to maintain the medication fluid in the fluid reservoir **432** under positive pressure. The tension of the biasing element **442** is low enough to allow filling of the fluid reservoir **432** with the medication fluid. In other words, during a fill operation the biasing element **442** retracts or compresses to allow the plunger **434** to move toward the base **440** to accommodate entry of the medication fluid into the fluid reservoir **432**. The biasing element **442** establishes the positive pressure that causes the medication fluid to naturally flow out of the fluid reservoir **432** (in the direction indicated by the arrow) unless the flow is inhibited by the valve assembly of the fluid infusion device.

An exemplary implementation of a mechanically actuated fluid infusion device employs a pressurized fluid reservoir of the type shown in FIG. **8**, along with a valve assembly that regulates fluid flow between the pressurized fluid reservoir, a dispensing unit, and a subcutaneous fluid conduit. In this regard, FIG. **9** is a schematic representation of various components of an embodiment of a mechanical fluid infusion device **500** having at least four primary components: a pressurized fluid reservoir **502**; a dispensing unit **504**; a valve assembly **506**; and a subcutaneous fluid conduit **508**. Some of the features, components, and functionality of the fluid infusion device **500** are similar (if not identical) to that described in detail above. For the sake of brevity, common aspects will not be redundantly described here in the context of the fluid infusion device **500**.

The pressurized fluid reservoir **502** is physically and fluidly coupled to the valve assembly **506** to accommodate transfer of the medication fluid from the fluid reservoir **502** to the valve assembly **506** as needed. The dispensing unit **504** is also physically and fluidly coupled to the valve assembly **506** to accommodate transfer of the medication fluid from the valve assembly **506** to the dispensing unit **504** (as needed), and to accommodate transfer of the medication fluid from the dispensing unit **504** to the valve assembly **506** (as needed). The fluid conduit **508** is also physically and fluidly coupled to the valve assembly **506** to accommodate transfer of the medication fluid from the valve assembly **506** to the fluid conduit **508**. In certain embodiments, the valve assembly **506** is fabricated as a single unitary component having three ports (a first port assigned and coupled to the fluid reservoir **502**, a second port assigned and coupled to the dispensing unit **504**, and a third port assigned and coupled to the fluid conduit **508**). The valve assembly **506** is suitably configured to allow or inhibit fluid flow between the components of the fluid infusion device **500** as needed to support the different functions, operations, and states of the fluid infusion device **500**.

The dispensing unit **504** depicted in FIG. **9** represents a subassembly that combines the features and functionality of an adjustable dosing mechanism, a mechanical fluid delivery actuator, and a volume adjuster (as described above with reference to FIG. **4**). Accordingly, although not depicted in FIG. **9**, the dispensing unit **504** includes an adjustable fluid chamber that defines a user-selectable dosage volume, wherein the amount of medication fluid in the fluid chamber can be delivered in response to mechanical actuation of an actuator.

The following description assumes that the fluid infusion device **500** is designed to accommodate filling of the fluid reservoir **502** by the patient, a caregiver, a doctor, or another person prior to use (i.e., the fluid reservoir **502** is not provided as a prefilled unit). Accordingly, a source **512** of the medication fluid can be fluidly coupled to a fill port **513** of the fluid infusion device **500** to fill the fluid reservoir **502** with the desired amount of the medication fluid. A first flow path **514** represents this filling operation. As explained above with reference to FIG. **8**, the fluid reservoir **502** becomes pressurized during the filling operation. During the filling operation, the valve assembly **506** reacts to certain fluid pressure differentials and reconfigures itself to inhibit

flow of the medication fluid to the fluid conduit **508**. In other words, the valve assembly **506** inhibits flow of the medication fluid from the fluid reservoir **502** such that the fluid source **512** can fill the fluid reservoir **502** in an efficient and safe manner. In certain embodiments, the valve assembly **506** reconfigures itself during the filling operation to inhibit flow of the medication fluid to the dispensing unit **504**. In this regard, the valve assembly **506** inhibits flow of the medication fluid from the fluid reservoir **502** to the adjustable fluid chamber of the dispensing unit **504** such that the fluid reservoir **502** can be filled in an efficient and safe manner. In alternative embodiments, the valve assembly **506** reconfigures itself during the filling operation to allow the medication fluid to flow to the dispensing unit **504**. In such embodiments, the filling operation may also serve to prime at least a portion of the fluid flow path of the fluid infusion device **500**. More specifically, during filling the fluid path between the valve assembly **506** and the fluid conduit **508** is blocked by the valve assembly **506**, such that the filling operation primes the fluid pathway except for the segment leading to the fluid conduit **508**. This remaining segment can be primed by the user (e.g., by performing one or more fluid delivery actuations) before inserting the fluid conduit **508**.

After filling the fluid reservoir **502**, filling the fluid chamber of the dispensing unit **504**, and priming the flow path of the fluid infusion device **500**, a user can manually operate the fluid infusion device as needed to initiate a fluid delivery operation. In response to the application of an external force to the mechanical actuator, the medication fluid is expelled from the dispensing unit **504** to flow through the valve assembly **506** and through the fluid conduit **508**. A second flow path **516** represents this fluid delivery operation. During the fluid delivery operation, the valve assembly **506** reacts to certain fluid pressure differentials and reconfigures itself to allow the medication fluid to flow from the adjustable fluid chamber of the dispensing unit **504** into the fluid conduit **508** for delivery to the body of the patient, while concurrently inhibiting flow of the medication fluid from the fluid chamber into the fluid reservoir **502**.

Removal of the actuation force from the mechanical actuator of the dispensing unit **504** initiates a refill operation for the fluid infusion device **500**. For this particular embodiment, when the external force is removed from the mechanical actuator, the actuator automatically returns to its nominal position. This action creates a pressure differential in the flow path, which in turn refills the fluid chamber of the dispensing unit **504** with medication fluid provided by the pressurized fluid reservoir **502**. A third flow path **518** represents this refill operation. During the refill operation, the valve assembly **506** reacts to certain fluid pressure differentials and reconfigures itself to allow the medication fluid to flow from the pressurized fluid reservoir **502** into the fluid chamber of the dispensing unit **504**, while concurrently inhibiting flow of the medication fluid from the fluid reservoir **502** to the fluid conduit **508**. Moreover, during the refill operation the valve assembly **506** reconfigures itself to inhibit fluid flow from the fluid conduit **508** to the fluid chamber of the dispensing unit **504**. After completion of the refill operation, the fluid chamber of the dispensing unit **504** is ready for the next metered delivery of the medication fluid.

A mechanical fluid infusion device having the features and functions described above can be implemented and realized in any number of ways, using different platforms and form factors as desired. In this regard, FIGS. **10-16** relate to one exemplary implementation of a mechanically actuated fluid infusion device **600**. More specifically, FIG. **10** is a perspective top view of the fluid infusion device **600** with a portion of its housing removed, FIG. **11** is a perspective view of a fluid reservoir **602** (in an empty state) of the fluid infusion device **600**, FIG. **12** is a perspective view of the fluid reservoir **602** in a filled state, FIG. **13** is a perspective and partially sectioned view of a dispensing unit **604** of the fluid infusion device **600**, FIG. **14** is an exploded perspective view of the dispensing unit **604**, FIG. **15** is a cross sectional view of the dispensing unit **604** in its nominal state prior to adjustment, and FIG. **16** is a cross sectional view of the dispensing unit **604** in its nominal state after adjustment. It should be appreciated that the fluid infusion device **600** is similar to the fluid infusion device **100** described above with reference to FIG. **1** and FIG. **2**. Accordingly, certain features, functions, and aspects that are common to the fluid infusion devices **100**, **600** will not be redundantly described here.

The fluid infusion device **600** includes a housing **606** to enclose and protect the internal components. For ease of illustration, the housing **606** in FIG. **10** is shown in cross section. The housing **606** may include or cooperate with certain internal features **607***a*, **607***b* that are designed to maintain the internal components of the fluid infusion device **600** in position and/or to provide structural rigidity to the housing **606**. The skin-facing side of the fluid infusion device **600** may be coupled to an adhesive patch **608** that accommodates attachment to the skin of the patient.

The fluid infusion device **600** generally includes at least the following functional components: the fluid reservoir **602**; the dispensing unit **604**; an introducer **612** for a fluid delivery conduit (not shown in FIG. **10**); a valve assembly **614**; and a fill port **616**. As described above with reference to FIG. **9**, the valve assembly **614** fluidly and mechanically couples together the fluid reservoir **602**, the dispensing unit **604**, and the fluid delivery conduit. Although not labeled in FIG. **10**, the valve assembly **614** includes or cooperates with suitably shaped and configured conduits that route the respective fluid flow paths between the components. In certain embodiments, the valve assembly **614** may be realized as a three-way valve having an internal ball that moves in response to fluid pressure differentials to regulate the incoming and outgoing fluid flow paths as needed. The fill port **616** is fluidly and structurally coupled to the fluid reservoir **602** via a filling conduit **620**.

Referring to FIG. **11** and FIG. **12**, the fluid reservoir **602**, the fill port **616**, and the filling conduit **620** are depicted in an isolated manner. The illustrated embodiment of the fluid reservoir **602** is a self-pressurizing unit that is similar to the fluid reservoir **432** described above with reference to FIG. **8**. FIG. **11** shows the fluid reservoir **602** in an empty state, and FIG. **12** shows the fluid reservoir **602** in a filled state. In the empty state, a spring **622** (or any suitable biasing element) forces a plunger **624** upward and toward an outlet port **626** of the fluid reservoir **602**. In accordance with one exemplary filling operation, a needle of a filling source can be inserted into the fill port **616** (as indicated by the arrow **630** in FIG. **11**) such that the medication fluid can be forced under pressure into a chamber **632** of the fluid reservoir **602**. The fill port **616** may include a septum or other type of sealing element that accommodates the fill needle and forms a fluid seal after the fill needle is removed. As shown in FIG. **12**, the chamber **632** may be defined as the space between the top of the plunger **624** and the outlet port **626**. The filling conduit **620** may terminate at an opening **634** that is located above the plunger **624** when the fluid reservoir **602** is in the empty state. Consequently, the medication fluid fills the chamber

632, while urging the plunger **624** downward and toward a base **636** of the fluid reservoir **602**. During the filling operation, the spring **622** becomes compressed, which in turn pressurizes the fluid reservoir **602** to maintain the medication fluid under positive pressure. The spring **622** preferably keeps the medication fluid under constant pressure until the chamber **632** is empty (or near empty) for practical purposes. Upon completion of the filling operation, the needle is removed from the fill port **616** such that the fluid infusion device **600** can be prepared for use.

The dispensing unit **604** may be coupled to the valve assembly **614** via a dispensing conduit **640** (see FIG. **10**). For this particular embodiment, the dispensing unit **604** represents a subassembly that incorporates the structure and functionality of an adjustable fluid chamber, a dosing mechanism, a mechanical delivery actuator, and a volume adjuster for the adjustable fluid chamber. FIGS. **13-16** depict an exemplary embodiment of the dispensing unit **604** in greater detail.

The illustrated embodiment of the dispensing unit **604** includes, without limitation: a reservoir barrel **702**; a fitting **704** for the reservoir barrel **702**; a plunger stopper **706**; a dosage guide **708**; a dosage knob **710**; a spring **712** (or other suitable biasing element); and an actuator stem **714**, which may include, cooperate with, or be coupled to an actuation knob **716**. These elements of the dispensing unit **604** are coupled together or otherwise cooperate with one another to form a subassembly having the desired features and functionality described here.

The reservoir barrel **702** forms a part of the adjustable fluid volume that holds the desired metered amount of medication fluid for delivery to the patient. In certain embodiments, the reservoir barrel **702** may have a cylindrical cross section, and it may resemble the end portion of a syringe. The reservoir barrel **702** may terminate at a port **722**, which in turn may be coupled to the fitting **704**. The fitting **704** cooperates with the port **722** to establish a physical and fluid connection between the dispensing unit **604** and the valve assembly **614** (see FIG. **10**). Although not shown, the fitting **704** may employ a hollow needle that pierces a septum **724** located in the port **722**, wherein the hollow needle establishes a fluid flow path to and from the interior of the reservoir barrel **702**.

The dosage guide **708** may be affixed to a base **730** of the reservoir barrel **702**, as shown in FIGS. **13**, **15**, and **16**. For example, the rim of the dosage guide **708** could be glued, bonded, welded, or otherwise secured to the base **730** of the reservoir barrel **702** to form an integrated component. As shown in FIG. **14**, the dosage guide **708** resembles a ring with internal threads **732**. The internal threads **732** mate with and engage corresponding external threads **734** formed on the dosage knob **710**. The purpose and function of this threaded engagement are described in more detail below with reference to FIGS. **15** and **16**.

The dosage knob **710** includes a longitudinal opening **738** formed therein to receive and accommodate the actuator stem **714**. The longitudinal opening **738** is formed completely through the dosage knob **710** to allow passage of the actuator stem **714** (see FIGS. **15** and **16**). Notably, the dosage knob **710** and the actuator stem **714** are cooperatively configured to accommodate translation of the actuator stem **714** relative to the dosage knob **710**, while inhibiting rotation between the dosage knob **710** and the actuator stem **714**. Thus, the actuator stem **714** is free to slide within the dosage knob **710** between a nominal position and an actuated position. However, rotation of the actuator stem **714** results in a corresponding rotation of the dosage knob **710**, and vice versa. The illustrated embodiment achieves this functionality with a key/keyway arrangement. In this regard, the longitudinal opening **738** may define one or more keyways **740** that receive and cooperate with one or more counterpart keys **742** that protrude from the actuator stem **714**. Although not always required, the embodiment described here employs four keyways **740** and four cooperating keys to inhibit rotation of the actuator stem **714** relative to the dosage knob **710**. The keyway/key arrangement is suitably designed to allow translational movement of the actuator stem **714** within the longitudinal opening **738** of the dosage knob **710**.

The actuator stem **714** terminates at a plunger end **746** that is suitably configured to mate with and couple to the plunger stopper **706**. In certain embodiments, the plunger end **746** is threaded to mate with corresponding threads of the plunger stopper **706**. The illustrated embodiment employs an externally threaded plunger end **746** that screws into an internally threaded cavity (not shown) of the plunger stopper **706**. FIGS. **13**, **15**, and **16** depict the dispensing unit **604** after the plunger stopper **706** has been screwed onto the actuator stem **714**.

The spring **712** is installed over the actuator stem **714** such that it remains positioned between the actuation knob **716** and an end **750** of the dosage knob **710**. When the dispensing unit **604** is assembled, the spring **712** serves as a biasing element for the mechanical actuator, such that the spring **712** biases the actuator stem **714** and the plunger stopper **706** into a nominal pre-delivery position (see FIG. **13** and FIG. **16**). In practice, the spring **712** is compressed during a fluid delivery stroke such that it automatically springs back and moves the actuator stem **714** back into the nominal pre-delivery position following each operation of the mechanical actuator.

The dispensing unit **604** may be assembled in the following manner. The spring **712** is placed onto the actuator stem **714**, followed by the dosage knob **710**. The dosage guide **708** is threaded onto the dosage knob **710** (either before or after the dosage knob **710** is placed onto the actuator stem **714**, as desired). Next, the plunger stopper **706** is threaded onto the actuator stem **714** (and, if necessary, glued or otherwise affixed to the plunger stopper **706**). It may be necessary to move the actuator stem **714** and compress the spring **712** somewhat to expose the plunger end **746** of the actuator stem **714** before attaching the plunger stopper **706** to the plunger end **746**. Thereafter, the plunger stopper **706** can be introduced into the reservoir barrel **702**, and the rim of the dosage guide **708** can be affixed to the base **730** of the reservoir barrel **702**, resulting in the arrangement shown in FIGS. **13**, **15**, and **16**.

As explained above, the dispensing unit **604** can be manipulated to vary the volume of an adjustable fluid chamber **760** (see FIG. **13** and FIG. **16**). FIG. **15** depicts the state of the dispensing unit **604** with a minimum volume defined for the adjustable fluid chamber **760**, and FIG. **16** depicts the state of the dispensing unit **604** with a maximum volume defined for the adjustable fluid chamber **760**. For this particular embodiment, the user-selectable dosage volume is adjusted in response to rotation of the actuator stem **714** and/or rotation of the actuation knob **716**. Such rotation corresponds to rotation of the actuator stem **714** about its major longitudinal axis. Referring to FIGS. **13**, **15**, and **16**, rotation of the actuation knob **716** results in rotation of the actuator stem **714**, which in turn results in rotation of the dosage knob **710**. Rotation of the dosage knob **710** causes the dosage knob **710** to translate relative to the dosage guide **708** (the translation is depicted in FIG. **15** and FIG. **16**).

Translational movement of the dosage knob **710** alters the nominal pre-delivery and post-delivery position of the plunger stopper **706**, which in turn changes the nominal pre-delivery and post-delivery dosage volume of the fluid chamber **760**. Notably, the force imparted by the spring **712** causes the actuation knob **716** to be biased away from the end **750** of the dosage knob **710**, and this biasing action sets the actuator stem **714** and the plunger stopper **706** into the desired position that defines the fluid chamber **760**.

The dispensing unit **604** is actuated in response to the application of force in a direction that is aligned with the major longitudinal axis of the actuator stem **714**. In practice, the dispensing unit **604** is actuated when the user presses the actuation knob **716** down. Fully depressing the actuator stem **714** results in the delivery of the metered and calibrated amount of medication fluid contained in the fluid chamber **760**. As explained previously, the fluid reservoir **602** (see FIG. **10**) automatically refills the adjustable fluid chamber **760** with the medication fluid in response to the spring **712** returning the actuator stem **714** into the nominal pre-delivery position.

In certain embodiments, the dispensing unit **604** is designed to provide tactile and/or audible feedback to the user while the fluid chamber **760** is being adjusted. For example, the dispensing unit **604** may employ detents or tabs to provide "clicks" or other feedback that indicates a predefined volume graduation, e.g., 0.2 Units, 0.5 Units, or 1.0 Unit per click. Thus, adjustment of the dosage volume can be easily achieved by counting the number of clicks as the actuation knob **716** is being rotated (assuming that the adjustment operation begins at a known reference volume). Moreover, numerical or other indicia could be printed on the dosage knob **710** and/or elsewhere to indicate the dosage volume during the adjustment operation. As described above with reference to FIG. **1**, the housing **102** may include an opening **108** that allows the user to see the volume indicator(s) during the adjustment operation.

The dispensing unit **604** may also include a feature that locks the adjustment component(s) to inhibit rotation of the actuator stem **714** after the desired dosage volume has been selected. Accordingly, once set, the metered dosage volume remains fixed until the user or caregiver adjusts the volume again. Thereafter, the medication fluid can be delivered in metered increments by activating the actuation knob **716**, until the medication fluid is depleted. At that time, the entire fluid infusion device can be discarded. In certain alternative embodiments, the fluid reservoir can be refilled via the fill port to extend the useful life of the fluid infusion device.

While at least one exemplary embodiment has been presented in the foregoing detailed description, it should be appreciated that a vast number of variations exist. It should also be appreciated that the exemplary embodiment or embodiments described herein are not intended to limit the scope, applicability, or configuration of the claimed subject matter in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient road map for implementing the described embodiment or embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope defined by the claims, which includes known equivalents and foreseeable equivalents at the time of filing this patent application.

What is claimed is:

1. A fluid infusion device for delivery of a medication fluid to the body of a user, the fluid infusion device comprising:

a housing;

a fluid reservoir for the medication fluid, wherein the fluid reservoir is located in the housing;

a dosing mechanism located in the housing and coupled to the fluid reservoir to receive the medication fluid from the fluid reservoir, the dosing mechanism comprising an adjustable fluid chamber that defines a variable dosage volume;

an infusion component coupled to the dosing mechanism to receive the medication fluid from the adjustable fluid chamber; and

a mechanical actuator coupled to the dosing mechanism and having a knob that protrudes from the housing, wherein application of external force to the knob causes the medication fluid to be expelled from the adjustable fluid chamber to the infusion component.

2. The fluid infusion device of claim **1**, wherein the dosing mechanism and the mechanical actuator form an integrated subassembly.

3. The fluid infusion device of claim **1**, further comprising a valve assembly between the fluid reservoir and the dosing mechanism, wherein the valve assembly inhibits flow of the medication fluid from the adjustable fluid chamber to the fluid reservoir.

4. The fluid infusion device of claim **1**, further comprising a valve assembly between the fluid reservoir and the infusion component, wherein the valve assembly inhibits flow of the medication fluid from the fluid reservoir directly to the infusion component.

5. The fluid infusion device of claim **1**, further comprising a valve assembly between the dosing mechanism and the infusion component, wherein the valve assembly inhibits flow of the medication fluid from the infusion component to the dosing mechanism.

6. The fluid infusion device of claim **1**, further comprising a biasing element for the mechanical actuator, wherein the biasing element biases the mechanical actuator into a nominal pre-delivery position.

7. The fluid infusion device of claim **6**, wherein the biasing element moves the mechanical actuator into the nominal pre-delivery position following each operation of the mechanical actuator.

8. The fluid infusion device of claim **7**, wherein the fluid reservoir refills the adjustable fluid chamber with the medication fluid in response to the biasing element moving the mechanical actuator into the nominal pre-delivery position.

9. The fluid infusion device of claim **1**, wherein the fluid reservoir comprises a self-contracting reservoir bag.

10. The fluid infusion device of claim **1**, wherein the fluid reservoir comprises:

a resilient bladder; and

a structure operatively coupled to the resilient bladder to impart a compressive force to the resilient bladder.

11. The fluid infusion device of claim **1**, wherein the fluid reservoir comprises:

a barrel body having a fluid delivery end and a base opposite the fluid delivery end;

a plunger located in the barrel body; and

a biasing element located in the barrel body between the plunger and the base of the barrel body, wherein the biasing element biases the plunger toward the fluid delivery end.

12. The fluid infusion device of claim **1**, wherein the adjustable fluid chamber is adjustable in discrete steps that define a plurality of predetermined and calibrated dosage volumes for the dosing mechanism.

13. The fluid infusion device of claim 1, wherein the infusion component is integrated with the housing to accommodate direct attachment of the fluid infusion device to the body of the user.

14. The fluid infusion device of claim 1, further comprising:

a fill port accessible from outside the housing, wherein the fill port is fluidly coupled to the fluid reservoir to facilitate filling of the fluid reservoir with the medication fluid.

15. The fluid infusion device of claim 14, wherein the fill port is self-sealing.

16. The fluid infusion device of claim 1, further comprising a valve assembly coupled to the fluid reservoir, wherein:

in response to application of external force to the knob, the medication fluid in the fluid chamber is expelled through the infusion component, while the valve assembly inhibits flow of the medication fluid from the fluid chamber to the fluid reservoir; and

in response to removal of the external force, the mechanical actuator automatically retracts to refill the fluid chamber with the medication fluid from the fluid reservoir, while the valve assembly inhibits flow of the medication fluid from the fluid reservoir to the infusion component and inhibits fluid flow from the infusion component to the fluid chamber.

17. A fluid infusion device for delivery of a medication fluid to the body of a user, the fluid infusion device comprising:

a fluid reservoir for the medication fluid, wherein the medication fluid in the fluid reservoir is maintained under positive pressure;

a valve assembly coupled to the fluid reservoir;

a dosing mechanism coupled to the fluid reservoir via the valve assembly, the dosing mechanism comprising a mechanical actuator; and

a fluid conduit coupled to the dosing mechanism via the valve assembly; wherein:

application of an actuation force to the mechanical actuator initiates a fluid delivery operation;

removal of the actuation force from the mechanical actuator initiates a refill operation;

during the fluid delivery operation, the valve assembly allows the medication fluid to flow from the dosing mechanism into the fluid conduit for delivery to the body of the user, while inhibiting flow of the medication fluid from the dosing mechanism into the fluid reservoir; and

during the refill operation, the valve assembly allows the medication fluid to flow from the fluid reservoir into the dosing mechanism, while inhibiting flow of the medication fluid from the fluid reservoir into the fluid conduit.

18. The fluid infusion device of claim 17, wherein:

the valve assembly inhibits flow of the medication fluid from the fluid conduit to the fluid reservoir; and

the valve assembly inhibits flow of the medication fluid from the fluid conduit to the dosing mechanism.

19. A fluid infusion device for delivery of a medication fluid to the body of a user, the fluid infusion device comprising:

a fluid reservoir to maintain the medication fluid under positive pressure;

a valve assembly coupled to the fluid reservoir;

a dosing mechanism coupled to the fluid reservoir via the valve assembly, the dosing mechanism comprising a mechanical actuator to adjust a fluid chamber of the dosing mechanism; and

a fluid delivery conduit coupled to the dosing mechanism via the valve assembly; wherein:

in response to application of force to the mechanical actuator, the medication fluid in the fluid chamber is expelled through the fluid delivery conduit, while the valve assembly inhibits flow of the medication fluid from the fluid chamber to the fluid reservoir; and

in response to removal of the force, the mechanical actuator automatically retracts to refill the fluid chamber with the medication fluid from the fluid reservoir, while the valve assembly inhibits flow of the medication fluid from the fluid reservoir to the fluid delivery conduit and inhibits fluid flow from the fluid delivery conduit to the fluid chamber.

20. The fluid infusion device of claim 19, wherein:

the fluid chamber defines a user-selectable dosage volume;

the user-selectable dosage volume is adjusted in response to rotation of the mechanical actuator about a major longitudinal axis; and

the mechanical actuator is actuated in response to application of the force in a direction aligned with the major longitudinal axis.

* * * * *