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(71) Applicant: **BIOMETRIX LTD.** [IL/IL]; Kiryat Ada 4, P.O. Box 45057, 91450 Jerusalem (IL).

(71) Applicant *(for UG only)*: **FLEIT, Lois** [US/US]; 520 Brickel Key Drive, Apt. #A201, Maimi, FL 33131-2411 (US).

(72) Inventors: **MENDELS, Yair**; Harimon 18, Moza Elit, 90820 Israel (IL). **SHAMIR, Matan**; Halamed He St. 15, Jerusalem (IL).

(74) Agents: **FLEIT, Martin** et al.; Fleit Gibbons Gutman Bongini & Bianco Pl, 21355 E. Dixie Highway, Suite 115, Miami, FL 33180 (US).

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[Continued on next page]

(54) Title: IN LINE FLUID SAMPLING PORT

(57) Abstract: A fluid sampling ports for withdrawing and administering fluids from or to a sampling site. The sampling valve is interconnected in a line to and/or from a patient with the line carrying a fluid that one wishes to sample. In a particular example, the sampling valve or port is interconnected in an arterial line and/or serves as a dialysis fluid sampling port.

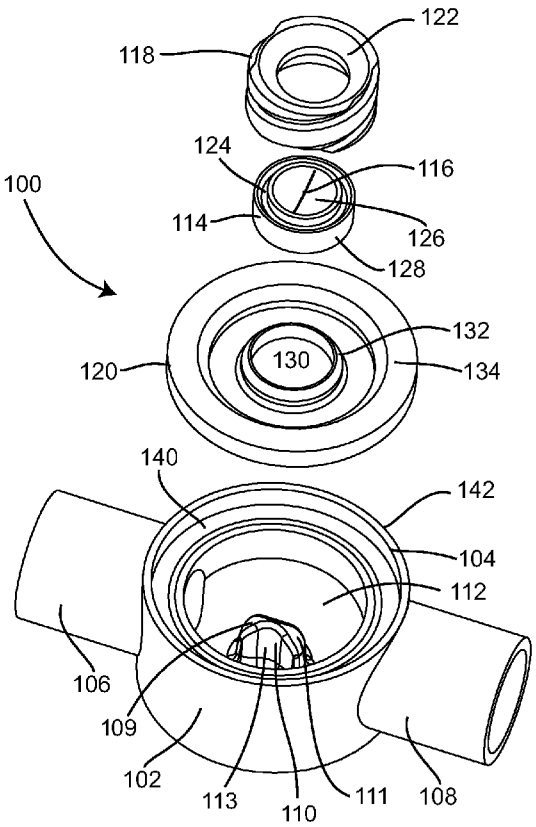

Fig. 1a

WO 2014/123678 A1

HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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— *of inventorship (Rule 4.17(iv))*

Published:

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

— *with amended claims (Art. 19(1))*

IN LINE FLUID SAMPLING PORT

FIELD OF THE INVENTION

The present invention relates to the field of fluid sampling ports. Particularly, the present invention relates to apparatus and a method for withdrawing and administering fluids from or to a sampling site. A sampling valve is provided that is interconnected in a line to and/or from a patient with the line carrying a fluid that one wishes to sample. More particularly the present invention relates to arterial line and dialysis fluid sampling ports.

SUMMARY OF THE INVENTION

In accordance with a preferred embodiment of the present invention, a fluid sampling port is disclosed, comprising a receptacle having an open portion, an inlet and an outlet, and a sampling valve held in position at the open portion by securing members, whereby the valve and the securing members together seal the open portion. The receptacle further comprises a valve separator extending from its surface toward the valve.

Preferably, the securing members comprise a rigid cylindrical element for positioning around the valve, and a rigid disc element for supporting the valve. The valve is preferably threadingly engaged with the securing members. The rigid cylindrical element is preferably externally threaded for mating with a needle-less connector.

Optionally, the valve separator is longitudinally oriented along the direction of fluid flow through the receptacle. Alternatively, the valve separator is longitudinally oriented orthogonal to the direction of fluid flow through the receptacle.

The slit of the valve is preferably oriented orthogonal to the longitudinal axis of the valve separator.

The valve separator preferably comprises a figure-eight cross-sectional shape when cut longitudinally, planar with the bottom surface of the receptacle, comprising wide ends and a narrow middle section.

Preferably, the valve slit separates upon contact with the valve separator. When the valve slit separates, a gap forms between the narrow middle section of the valve separator and the separated slit, through which a sampling fluid may be drawn.

BRIEF DESCRIPTION OF THE FIGURES

- Figs. 1a-c show a first embodiment of the fluid sampling port of the present invention in an exploded top view (Fig. 1a), an exploded bottom view (Fig. 1b) and an isometric assembled view (Fig. 1c);
- Figs. 2a-c show a cross-sectional side view of the assembled first embodiment of the sampling port cut longitudinally, with a male luer connector spaced apart from sampling port (Fig. 2a), mated with sampling port (Fig. 2b) and cut transversely mated with sampling port (Fig. 2c);
- Figs. 3a-b show the longitudinal cut line of Figs. 2a-b (Fig. 3a) and the transverse cut line of Fig. 2c (Fig. 3b);
- Fig. 4 shows a partially cut isometric view of the assembled sampling port with a luer connector mated therewith;
- Figs. 5a-c show a second embodiment of the fluid sampling port of the present invention in an exploded top view (Fig. 5a), an exploded bottom view (Fig. 5b) and an isometric assembled view (Fig. 5c);
- Figs. 6a-c show a cross-sectional side view of the assembled second embodiment of the sampling port cut longitudinally with a male luer connector spaced apart from sampling port (Fig. 6a), mated with sampling port (Fig. 6b) and cut transversely mated with sampling port (Fig. 6c);
- Figs. 7a-b show the longitudinal cut line of Figs. 6a-b (Fig. 7a) and the transverse cut line of Fig. 6c (Fig. 7b);
- Fig. 8 shows the receptacle portion of a third embodiment of the sampling port of the present invention with the valve separator oriented orthogonal to the direction of fluid flow through the receptacle; and,
- Fig. 9 shows a partially cut isometric view of the assembled sampling port of the third embodiment with a luer connector mated therewith.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The term, "fluid" as used herein refers to any fluid, including bio-fluid, such as blood, etc., as well as disinfectant fluid, therapeutic fluid, etc.

A first preferred embodiment of the fluid sampling port of the present invention is shown in Figs. 1a-c in an exploded top view (Fig. 1a), an exploded bottom view (Fig. 1b) and an isometric assembled view (Fig. 1c), and is designated generally by numeral (100). Sampling port (100) comprises a receptacle (102) having an open portion (104), an inlet (106) and an outlet (108). A valve separator (110) extends from the bottom surface (112) of receptacle (102) toward the sampling valve (114) for separating the slit (116) of valve (114) when a needle-less (luer) connector is inserted, as described herein below. Valve separator (110) is longitudinally oriented along the direction of fluid flow through receptacle (102), i.e. from inlet (106) to outlet (108), and comprises a figure-eight cross-sectional shape when cut longitudinally, planar with the bottom surface (112) of receptacle (102), having wide ends (109), (111) and a narrow middle section (113). When assembled, valve (114) is positioned at open portion (104) of receptacle (102) and held in position by securing members (118) and (120). Securing member (118) comprises a rigid cylindrical element for surrounding valve (114), having an inwardly declining upper lip (122) disposed within the groove ring (124) formed at the upper portion of valve (114) between the slit segment (126) and the outer wall (128). The outer surface of securing member (118) is threaded for mating with the luer connector described herein below. Securing member (120) comprises a rigid disc element having a central opening (130) surrounded by a protruding neck (132), and a raised outer periphery (134). When assembled, neck (132) is disposed within the groove ring (138) formed at the lower portion of valve (114) between slit segment (126) and outer wall (128). Raised periphery (134) of member (120) is positioned on the inwardly extending lip (140) slightly beneath the upper rim (142) of receptacle (102).

Referring to Figs. 2a-c and Figs. 3a-b, the assembled sampling port (100) is shown assembled with a male luer connector (144) threadingly mated therewith, in a cross-sectional side view (Fig. 2b) cut longitudinally along A-A of Fig. 3a, and in a cross-sectional side view (Fig. 2c) and cut transversely along B-B of Fig. 3b (orthogonal to A-A of Fig. 3a). Fig. 2a shows the same cross-sectional cut as Fig. 2b, but with luer

connector (144) spaced apart from sampling port (100). Figs. 2a-c will now be described in further detail.

As best seen in Fig. 2a (as well as in Fig. 1a), slit (116) of valve (114) is oriented orthogonally to the longitudinal axis of valve separator (110). Referring to Figs. 2b-c, when threadingly mating luer connector (144) with sampling port (100), male portion (146) of luer connector (144) presses slit segment (126) of valve (114) toward valve separator (110). Upon contact with valve separator (110), slit (116) of valve (114) separates, as shown in the figure. Each end of slit (116) is disposed over an opposing side of the narrow middle section (113) of valve separator (110), forming a gap between the separated opposing ends of slit (116) and valve separator (110) through which a sampling fluid may be drawn, as indicated by arrows (1) in Fig. 2c. This can be best seen in Fig. 4, showing a partially cut isometric view of assembled sampling port (100) with luer connector (144) mated therewith. Gap (148) is shown formed between one end of separated slit (116) and one side of the narrow middle section (113) of valve separator (110). An essentially identical gap is formed on the other side of narrow middle section (113) (not shown in the figures).

A second preferred embodiment of the fluid sampling port of the present invention is shown in Figs. 5a-c in an exploded top view (Fig. 5a), an exploded bottom view (Fig. 5b) and an isometric assembled view (Fig. 5c), and is designated generally by numeral (200), comprising the same essential features and elements of sampling port (100) of the first embodiment, *mutatis mutandis*, with the following differences.

Valve (214) comprises a slit segment (226) and an outer wall (228) protruding from the center of flange (229). When assembled, the periphery of flange (229) is positioned on the inwardly extending lip (240) slightly beneath the upper rim (242) of receptacle (202).

Securing member (220) comprises a rigid disc (221) having a central opening (230) surrounded by a protruding neck (232). Disc (221) is positioned over flange (229) of valve (214). The outer edge (223) of disc (221) extends orthogonally toward lip (240), forming a ring surrounding flange (229).

Figs. 6a-c show sampling port (200) in the same views as that shown in Figs. 2a-c of the first embodiment of sampling port (100), as cut along the lines indicated in Figs.

6a-b, *mutatis mutandis*. The main difference between the second embodiment of sampling port (200) and the first embodiment of sampling port (100) can be best seen in Fig. 6a. The lower contour (215) of valve (214) is shown shaped as a crest of a wave having a long wavelength and short amplitude. This design overcomes a drawback associated with prior art sampling port valves whose lower contour is shaped as a crest of a wave having a short wavelength and high amplitude. In the prior art design, therefore, fluid becomes trapped in the pocket formed by the contour of the valve. This fluid is difficult to wash away by the fluid that flows through the port. Consequently, the fluid sampling that is withdrawn is "old" fluid from the pocket, rather than "new" fluid obtained from continuous fluid flow through the port. This may effect the results from the fluid sample analysis. In contrast, contour (215) is designed to avoid collection of fluid such that smooth flow through receptacle (202) may be maintained. See also Fig. 2a, which shows the lower contour (115) of valve (114), having a slightly shorter wavelength than that of the second embodiment shown in Fig. 5a, but also avoids collection of fluid thereat.

Additionally, as seen in Fig. 6a, in the second embodiment of sampling port (200), flange (229) of valve (214) is sandwiched between disc (221) of securing member (220) and lip (240) of receptacle (202), for positioning valve (214) above and aligned with valve separator (210). This arrangement of the second embodiment is in contrast to the arrangement of the first embodiment of sampling port (100) (see Fig. 2a) in which valve (114) is maintained in position by lip (122) and neck (132) disposed in grooves (124) and (138) respectively, as described herein above.

An alternative aspect of the receptacle (302) of a fluid sampling port of the present invention is shown in Fig. 8 in an isometric view, with valve separator (310) extending from bottom surface (312), longitudinally oriented orthogonal to the direction of fluid flow through receptacle (302). This is in contrast to the first and second embodiments in which the valve separator is longitudinally oriented in the direction of fluid flow through the receptacle.

In the first and second embodiments, the sampling port would be useful mainly for sampling during a dialysis procedure because the valve separator provides minimal obstruction to the fluid flow. However, the alternative aspect of the sampling port is

preferably for arterial line use. Due to the orientation of valve separator (310), significant obstruction of fluid flow through receptacle (302) may occur. This can assist in "cleaning" the area below the valve after sampling.

With reference to Fig. 9 showing a partially cut isometric view of an assembled sampling port (300) having the alternative aspect of valve separator (310), with a luer connector (344) mated therewith, slit (316) of valve (314) is seen oriented orthogonal to the longitudinal orientation of valve separator (310) in order to form a gap (348), (350) between each end of separated slit (316) and the narrow middle section (313) of valve separator (310) as described herein above regarding the first embodiment.

Although Fig. 9 shows the fluid sampling port (300) with the alternative aspect of valve separator (310), and having essentially the same components as that of the first embodiment, it is understood that a sampling port having essentially the same components as that of the second embodiment may contain the alternative aspect of the valve separator (310) as well.

It should be noted that in all embodiments of the present invention the valve comprises a shore hardness that is determined depending on the application of the fluid sampling port. For instance, when used for arterial line sampling the shore hardness is chosen in order to avoid "dumping" of blood pressure. When used for dialysis the shore hardness is chosen such that the valve slit will not be affected, and opened due to the vacuum generated by the dialysis machine.

It is understood that the above description of the embodiments of the present invention are for illustrative purposes only, and is not meant to be exhaustive or to limit the invention to the precise form or forms disclosed, as many modifications and variations are possible. Such modifications and variations are intended to be included within the scope of the present invention as defined by the accompanying claims.

CLAIMS

1. A fluid sampling port comprising a receptacle having an open portion, an inlet and an outlet, and a sampling valve held in position at said open portion by securing members, whereby said valve and said securing members together seal said open portion, said receptacle further comprising a valve separator extending from its surface toward said valve.

2. The sampling port according to claim 1, wherein the securing members comprise a rigid cylindrical element for positioning around the valve, and a rigid disc element for supporting said valve.

3. The sampling port according to claim 2, wherein the valve is threadingly engaged with said securing members.

4. The sampling port according to claim 2, wherein the rigid cylindrical element is externally threaded for mating with a needle-less connector.

5. The sampling port according to claim 1, wherein the valve separator is longitudinally oriented along the direction of fluid flow through the receptacle.

6. The sampling port according to claim 1, wherein the valve separator is longitudinally oriented orthogonal to the direction of fluid flow through the receptacle.

7. The sampling port according to claims 1, wherein the slit of the valve is oriented orthogonal to the longitudinal axis of the valve separator.

8. The sampling port of claim 1, wherein the valve separator comprises a figure-eight cross-sectional shape when cut longitudinally, planar with the bottom surface of the receptacle, comprising wide ends and a narrow middle section.

9. The sampling port of claim 1, wherein the valve slit separates upon contact with the valve separator.

10. The sampling port of claim 9, wherein when the valve slit separates a gap is formed between the narrow middle section of the valve separator and the separated slit, through which a sampling fluid may be drawn.

AMENDED CLAIMS
received by the International Bureau on 09 July 2014 (09.07.2014)

1. A fluid sampling port comprising:
   a. an open end receptacle having a closed end wall opposite the open end and a side wall;
   b. an inlet and outlet defined in opposite portions of said side wall to establish an elongated flow path through the receptacle;
   c. a first securing member including a planar element defining a central opening;
   d. a resilient valve member having a top surface and bottom surface supported by the first securing member and mounted to extend through the central opening;
   e. a second securing member surrounding and engaging said resilient valve member;
   f. said first and second securing members clamping the resilient valve member between them and sealing the open end of the receptacle; and
   g. an elongated profiled projection fixed on the inside surface of the closed end wall in alignment with the resilient valve member and positioned in the flow path through the receptacle;
   h. whereby the resilient valve can be forced to engage the elongated profiled projection and establish a sampling port for withdrawal of a fluid sample.
2. The fluid sampling port according to claim 1 wherein the second securing member is externally threaded for mating with a needle-less connector.
3. The fluid sampling port according to any preceding claim wherein the elongated profiled projection has enlarged end portions and a narrowed central portion
4. The fluid sampling port according to any preceding claim wherein the elongated profiled projection defines a figure eight configuration.
5. The fluid sampling port according to any preceding claim wherein the elongated profiled projection is longitudinally aligned with the flow path through the receptacle.
6. The fluid sampling port according to any preceding claim wherein the elongated profiled projection transversely extends across the flow path through the receptacle.

7. The fluid sampling port according to any preceding claim wherein the slit in the resilient valve is oriented orthogonal to the longitudinal axis of the elongated profiled projection.
8. The fluid sampling port according to any preceding claim wherein the second securing member is composed of a rigid cylindrical element.
9. The fluid sampling port according to any preceding claim wherein the resilient valve member defines grooves in its top surface and bottom surface and the first and second securing members define clamping elements that engage the grooves.
10. The fluid sampling port according to any preceding claim wherein the bottom surface of the resilient valve member has a contour shaped as the crest of a wave having a long wavelength and short amplitude.
11. The fluid sampling port according to any preceding claim wherein a conduit is connected to the inlet of the side wall, and a conduit is connected to the outlet of the side wall.
12. The fluid sampling port according to any preceding claim wherein the inlet and outlet of the side wall are diametrically opposite.
13. The fluid sampling port according to any preceding claim wherein the planar element of said first securing member is rigid and includes a neck surrounding the defined central opening, said planar element is seated on a shoulder defined just below the open end of the receptacle.
14. The fluid sampling port according to any preceding claim wherein the resilient valve member is composed of a flange on which is mounted a slit segment surrounded by a wall, and the flange is mounted on a shoulder located just below the open end of the receptacle, and the first securing member has a depending skirt that surrounds the flange of the valve member and contacts the shoulder.

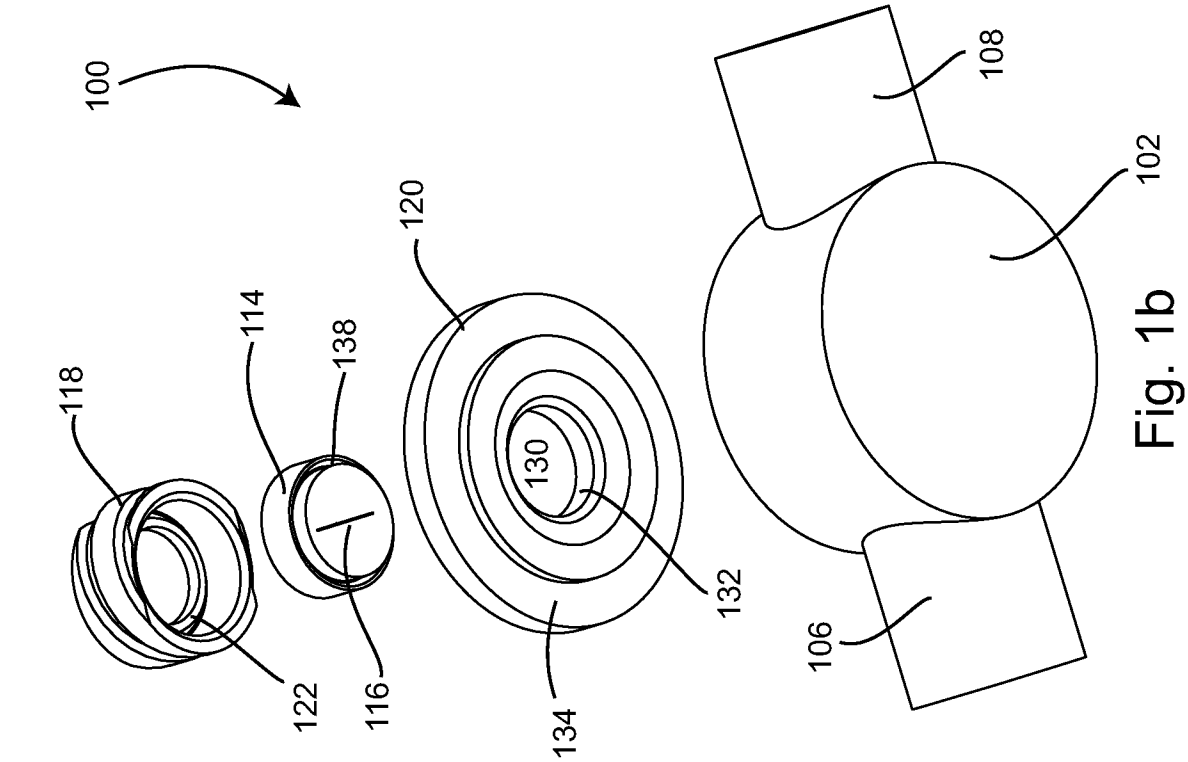
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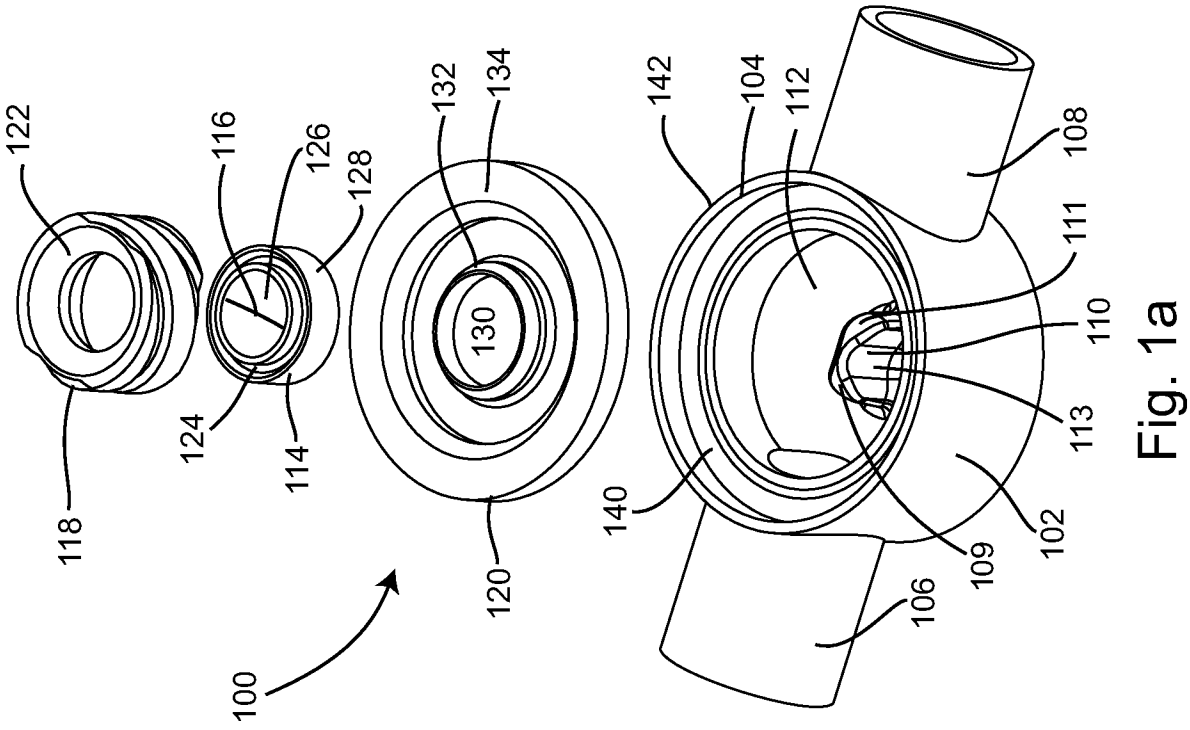
Fig. 1b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100

Fig. 1a

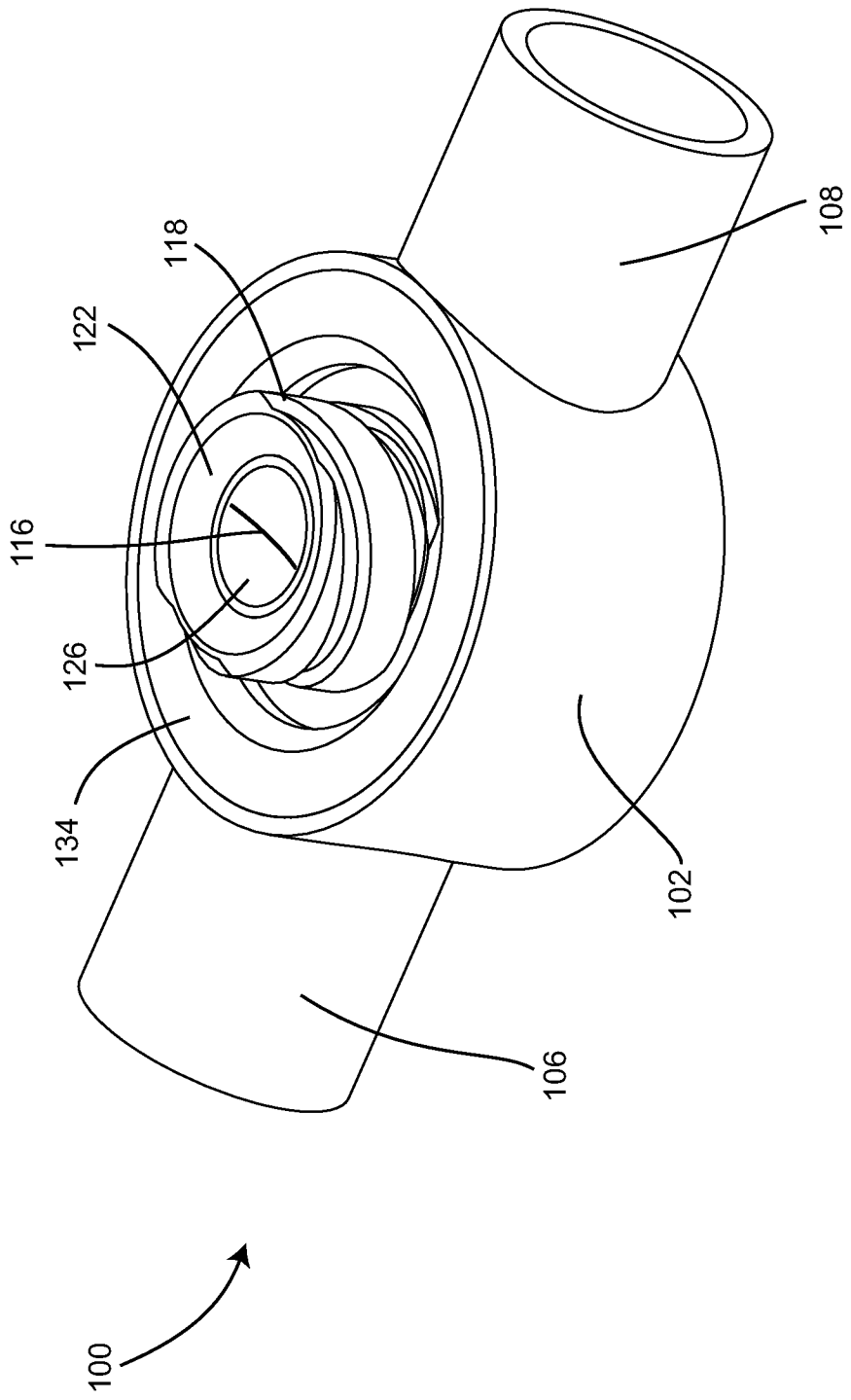

Fig. 1c

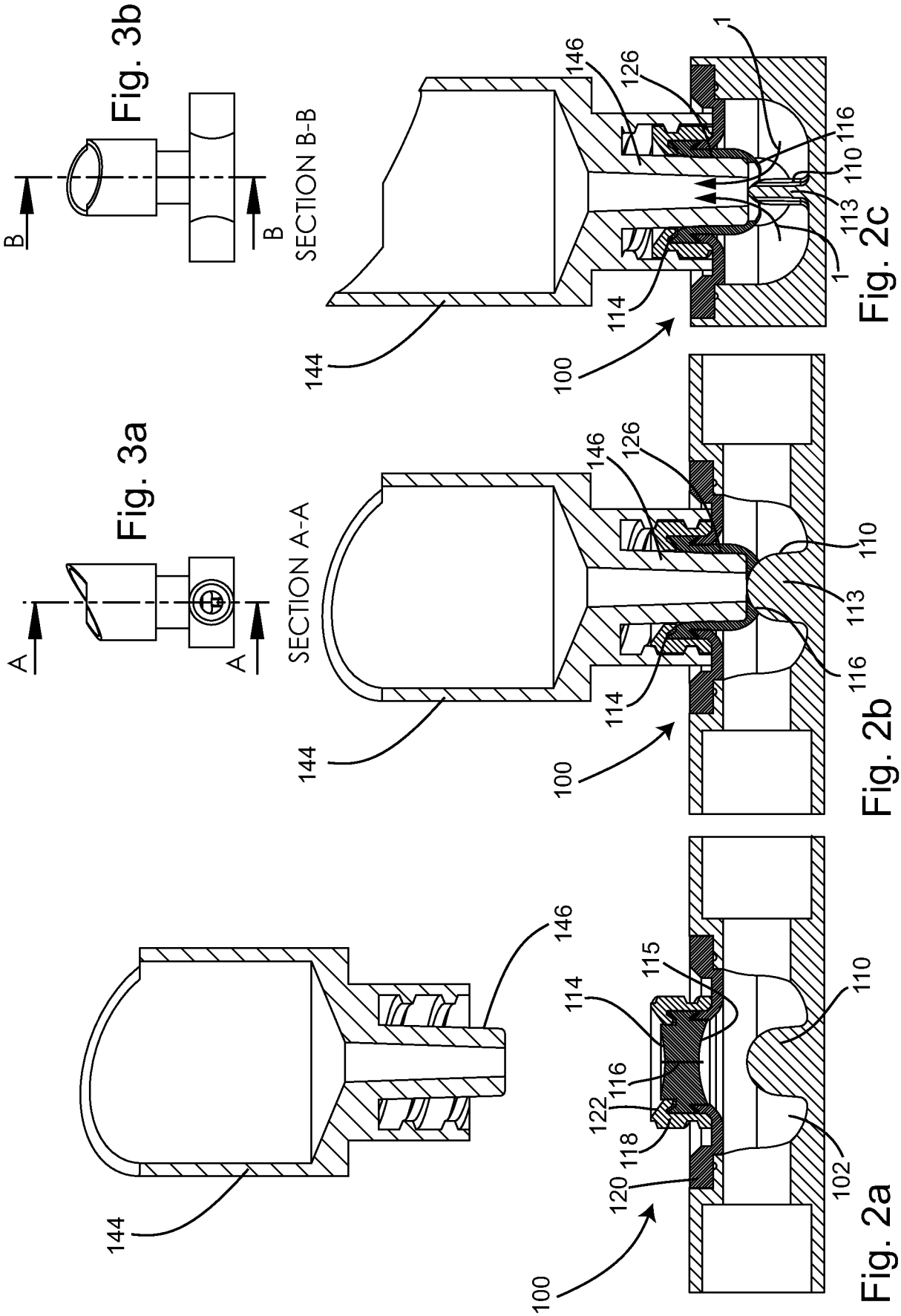
Fig. 3b
B
B
SECTION B-B
Fig. 3a
A
A
SECTION A-A
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146
126
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116
110
113
114
100
Fig. 2c
Fig. 2b
115
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120
102
Fig. 2a

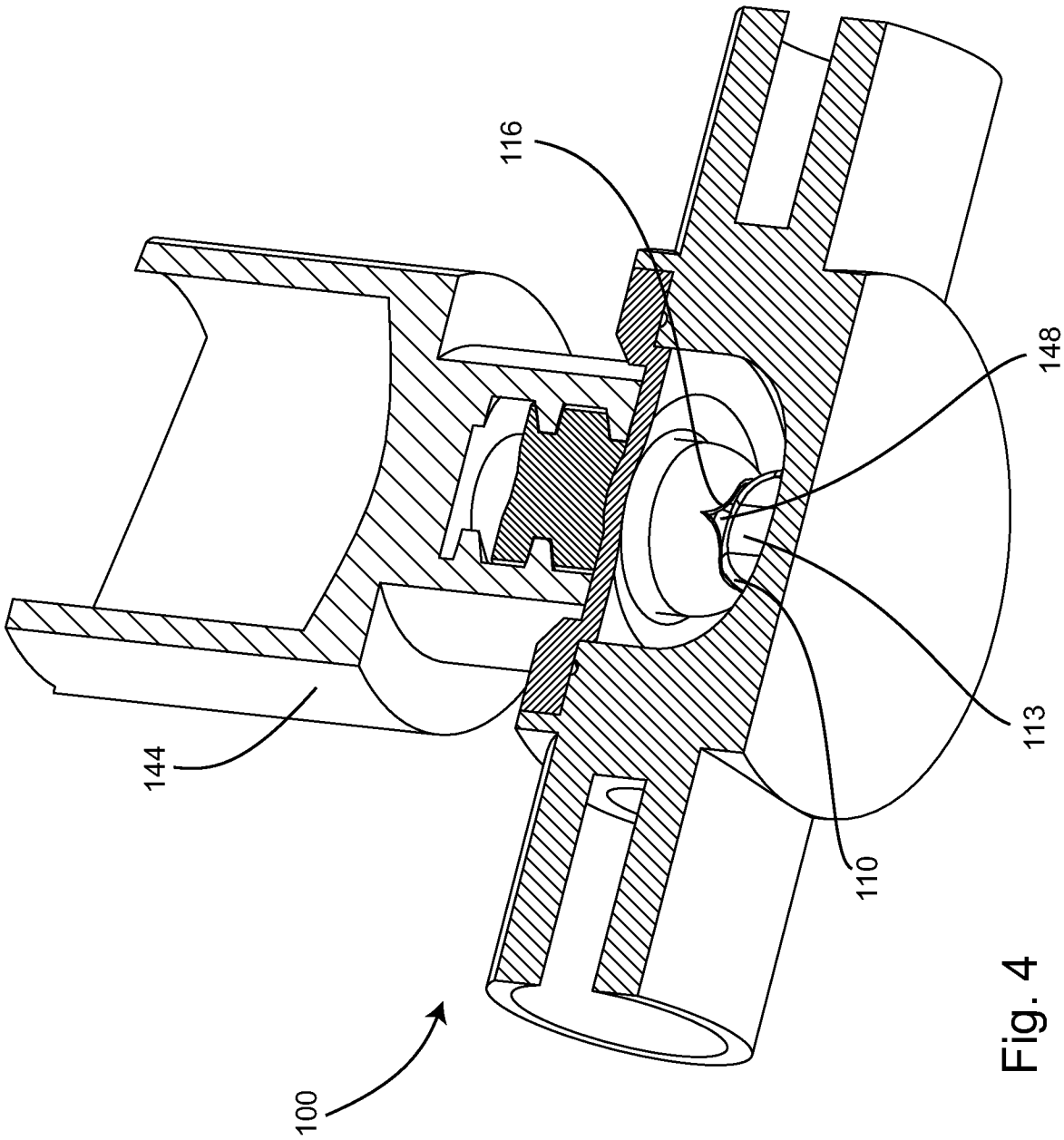

Fig. 4

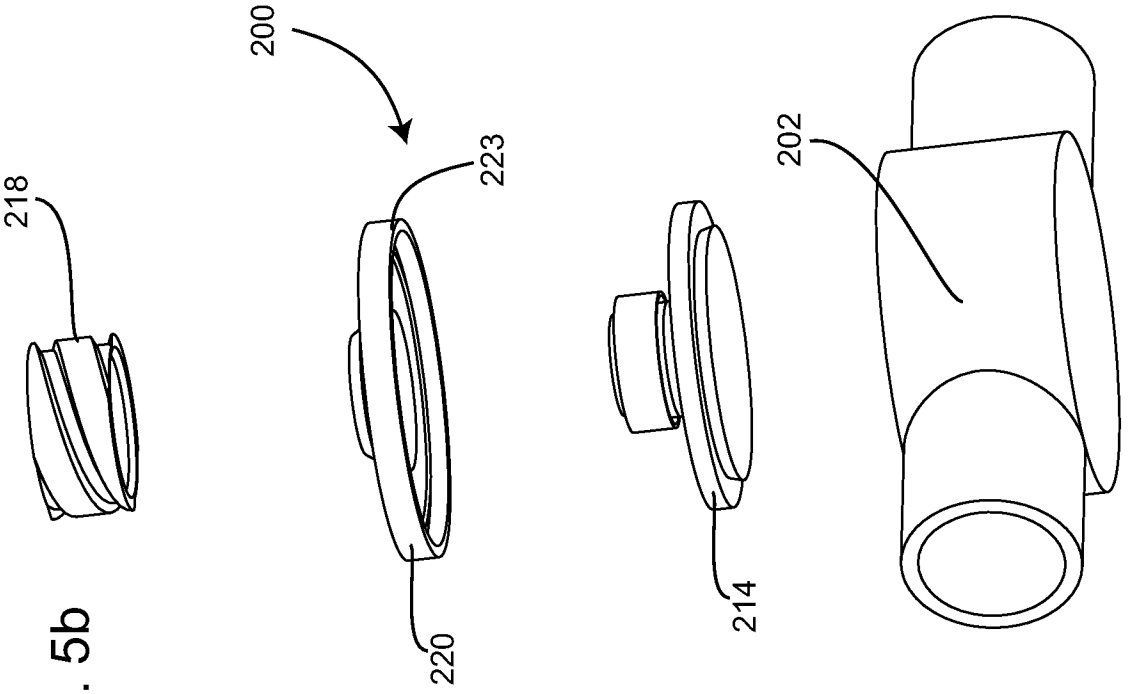
218
200
223
220
214
202

Fig. 5b

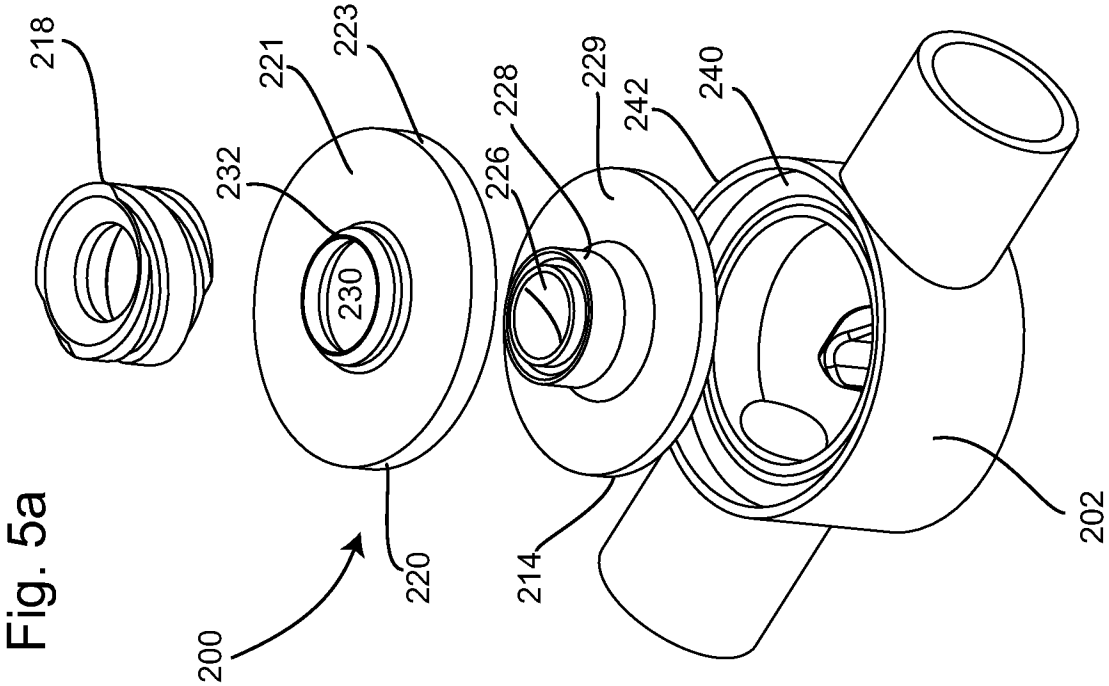
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Fig. 5a

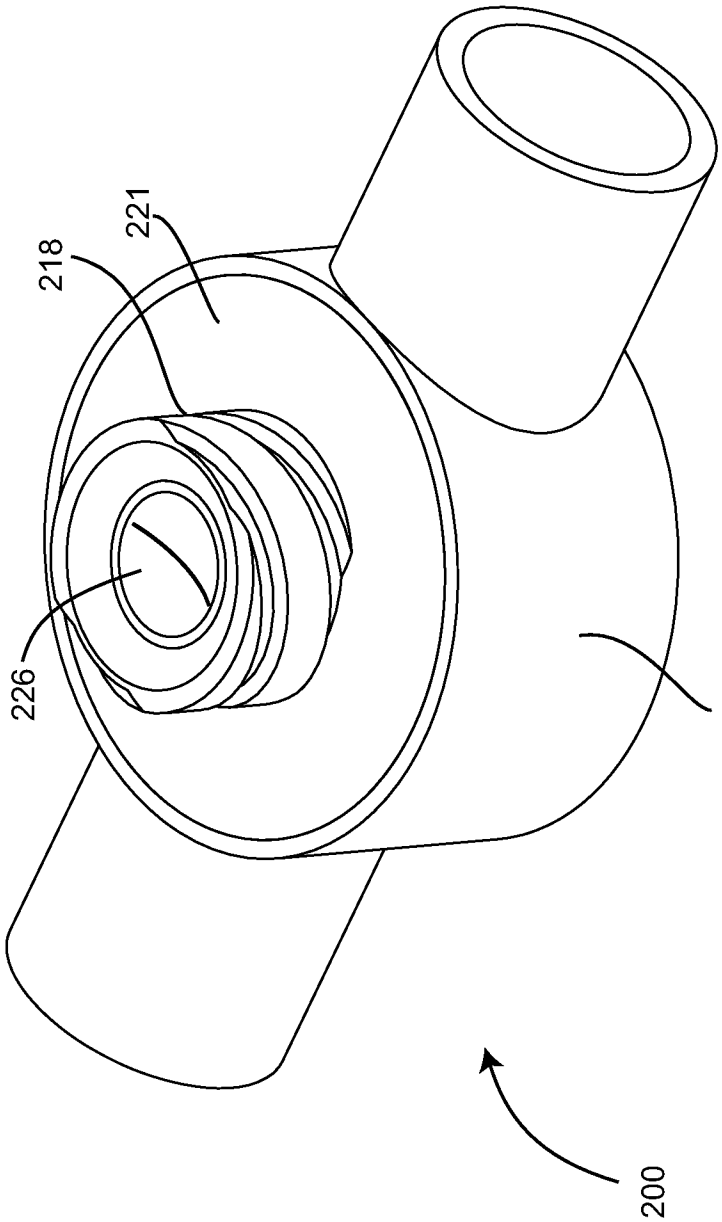

Fig. 5c

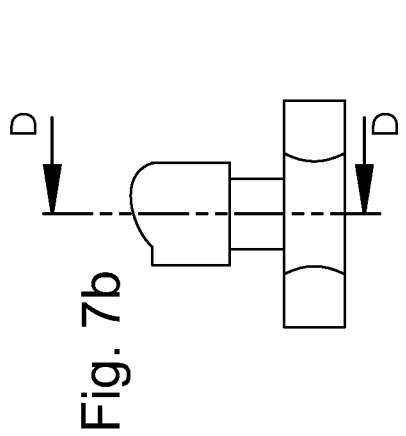

Fig. 7b

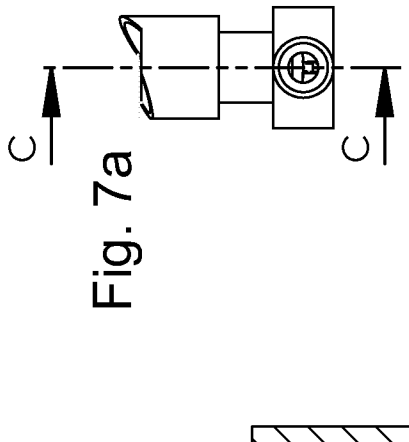

Fig. 7a

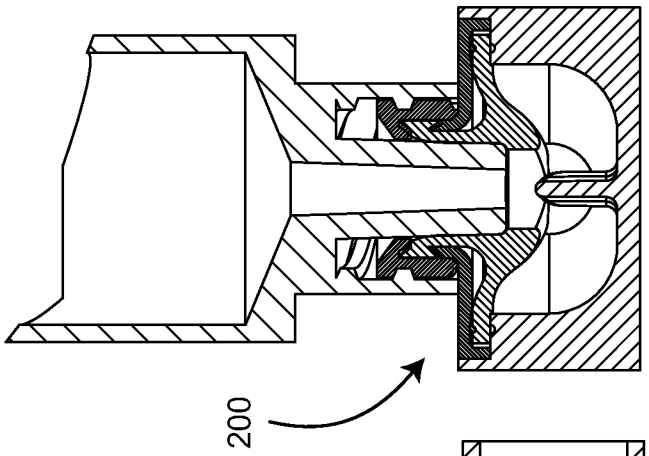

Fig. 6c

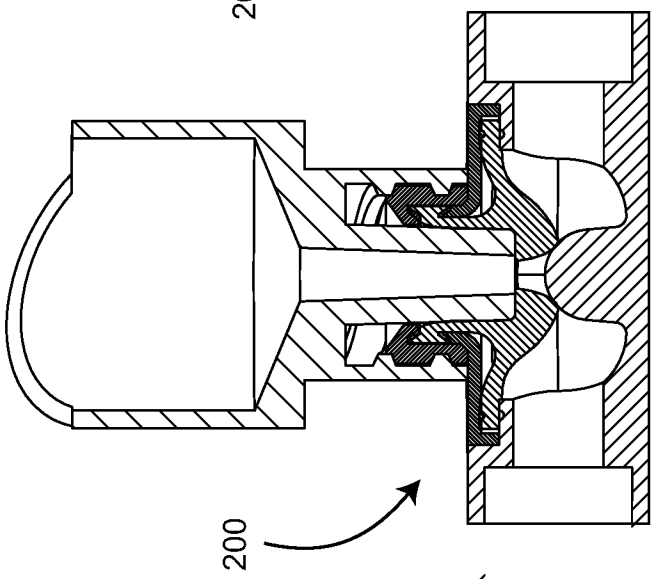

Fig. 6b

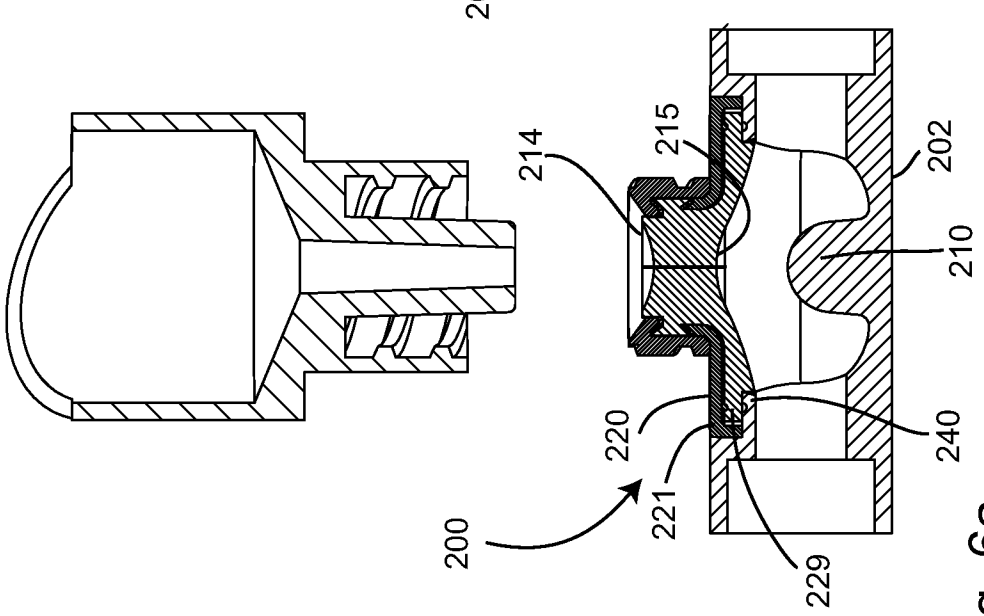

Fig. 6a

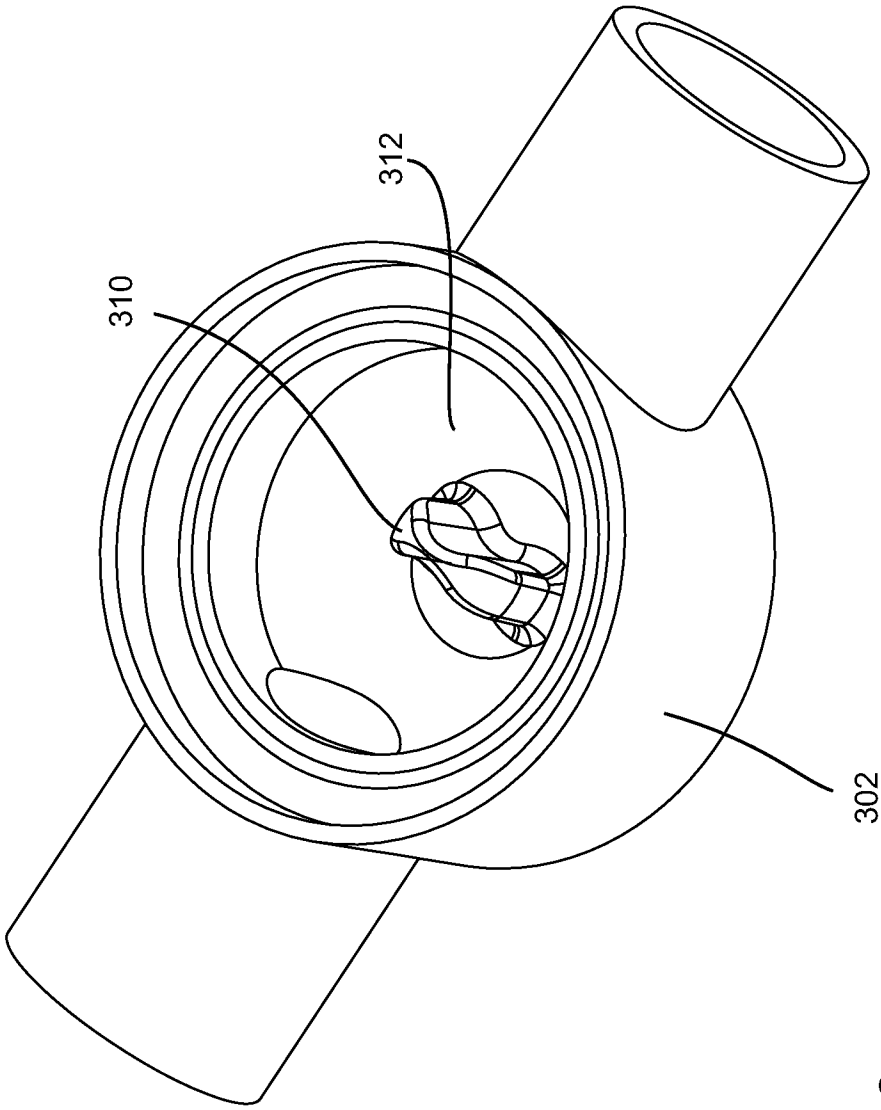

Fig. 8

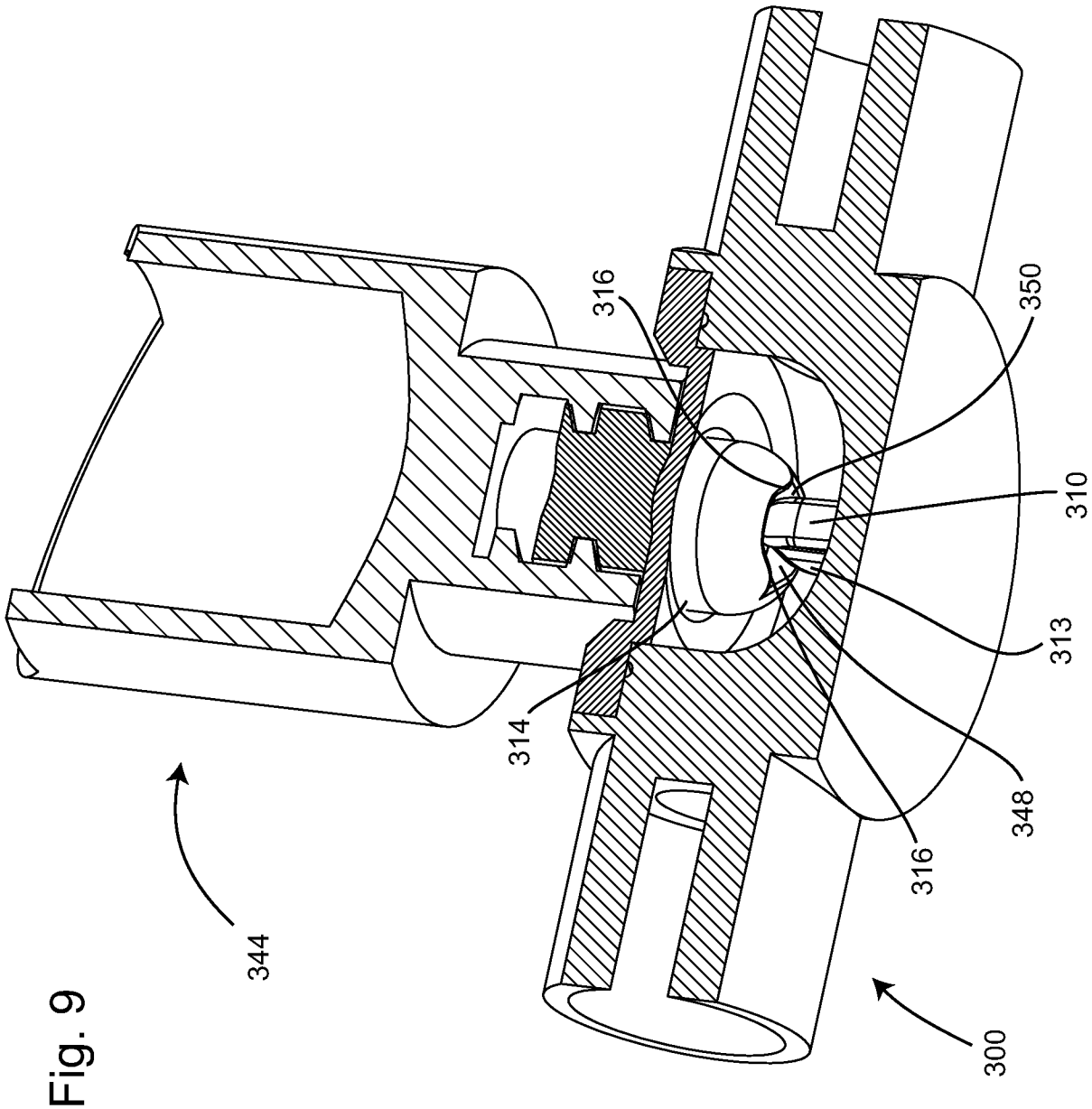

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2014/011966

A. CLASSIFICATION OF SUBJECT MATTER ***A61B 5/155*** *(2006.01)*
A61M 1/14 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/151, 5/153, 5/155, 5/157

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch (RUPTO internal), Espacenet, Google, Information Retrieval System of FIPS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 1995/000188 A1 (MAXIMWELL INTERNATIONAL CO. (U.S.A.) LTD. et al.) 05.01.1995, fig. 3, p. 5	1-10
Y	US 7972322 B2 (HYPROTEK, INC.) 05.07.2011, fig. 3	1-10

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/ FIPS Russia, 123995, Moscow, G-59, GSP-5, Berezhkovskaya nab., 30-1 Facsimile No. +7 (499) 243-33-37	Authorized officer L. Karimova Telephone No. (495)531-64-81