

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
9 December 2010 (09.12.2010)

(10) International Publication Number
WO 2010/141563 A2

(51) International Patent Classification:

A61B 5/15 (2006.01) G01N 1/10 (2006.01)
A61B 5/157 (2006.01) A61B 17/34 (2006.01)
G01N 33/49 (2006.01)

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(21) International Application Number:

PCT/US2010/037043

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(22) International Filing Date:

2 June 2010 (02.06.2010)

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, 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, PE, PG, PH, PL, PT, RO, RS, RU, 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.

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/183,886 3 June 2009 (03.06.2009) US

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

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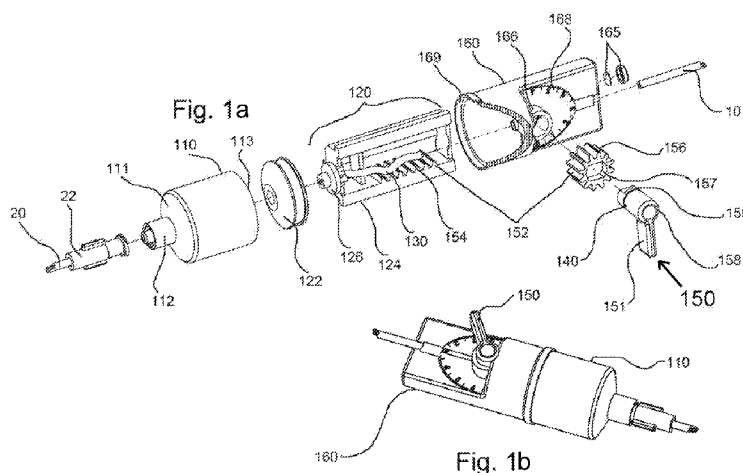
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(54) Title: A CLOSED IN-LINE APPARATUS AND METHOD FOR FLUID ASPIRATION



(57) Abstract: An in-line sampling apparatus and method for selectively introducing a fluid to and aspirating a fluid from a down-stream fluid conduit connected to a catheterized patient. The apparatus consists of syringe that has a fluid chamber into which fluid is aspirated. A volume regulator adjusts the volume of the fluid chamber. A fluid line passes through the syringe to a down-stream fluid conduit. A valve mechanism selectively allows fluid flow along the fluid line or prevents fluid flow along the fluid line while simultaneously aspirating a fluid and selectively shifts the volume regulator to adjust the volume of the fluid chamber. A housing joins the fluid chamber, the fluid line, the valve mechanism, the volume regulator and the control mechanism. An electronic control apparatus operates the valve mechanism. The method includes the capability of determining occlusions in the line.



WO 2010/141563 A2

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

**A CLOSED IN-LINE APPARATUS AND METHOD FOR FLUID
ASPIRATION**

Field of Invention

5 The present invention relates to the field of sampling devices. In particular,
the present invention relates to an in-line sampling device and method for
introducing fluid to and withdrawing (aspirating) fluid from an infusion or
arterial tube that is connected to a catheterize patient. More particularly,
the present invention relates to a syringe for either manually or
10 automatically, introducing and aspirating a fluid in a closed sterile
environment, sealed from the ambient air, and which reduces the risk of
error during the aspiration process due to its simplicity of operation.

Background of Invention

15 Some prior art blood sampling systems comprise a syringe comprising the
dual function of introducing an upstream sterile fluid (e.g. saline solution) to
a patient located downstream, and drawing back (aspirating) downstream
fluid into the syringe in a sealed sterile manner. Typically, a small amount of
infused fluid runs through the blood sampling line to the patient, when the
20 line is not in use. This enables the blood sampling line to maintain in a clear,
unblocked/unlogged condition. When it is desired to take a blood sample
from the patient, the fluid is aspirated beyond the sampling site so that a
clean blood sample may be withdrawn.

25 Relevant prior art documents that describe fluid sampling devices include the
following.

US 5,324,266 discloses an in-line sampling system having a blood sampling
device, with a fluid storage mechanism and a fluid draw element. The
30 aspiration is performed manually, similar to all prior art syringes. The

design of the device allows overshooting of fluid, such that over-aspiration may occur. The proposed sealing of the fluid chamber from the external surrounding air is achieved by a fairly large harmonica-like cylinder made of resilient material, which is difficult to keep in a tight and completely sealed stage during the aspiration of the fluid. This increases the risk of exposing the aspirated fluid to the contaminated hospital ward environment. Furthermore, when aspirating the fluid, the length of the syringe is almost doubled at the maximum volume of the fluid chamber, and therefore cumbersome to operate when the syringe is positioned on the patient's arm or next to the patient.

US 5,961,472 discloses a closed, one-handed blood sampling system which allows fluid do be drawn from a patient to a reservoir and returned thereto, but requires two independent squeezing motions. The blood sampling system comprises a spring-based drawback mechanism. The design of the device allows overshooting of fluid, such that over-aspiration may occur. The proposed sealing of the fluid chamber is attempted by use of a harmonica-like resilient material, which is difficult to seal on the plastic portion of the syringe, and can be easily perforated. This would expose the fluid to the ambient contaminated hospital ward environment. Furthermore, when aspirating the fluid, the length of the syringe is almost doubled at the maximum volume of the fluid chamber, and therefore cumbersome to operate when the syringe is positioned on the patient's arm or next to the patient.

US 5,374,401 discloses a blood sampling apparatus that allows the accumulator of blood and infusion solution mixtures remain sterile, for multiple uses. The apparatus comprises a screw-like transmission design, wherein a housing is closed off by a rotatable cover, which, in turn, seals off the housing with a rotatable seal. The cover and seal are threadingly connected via outer and inner threads. The screw-like transmission design

- 3 -

results in a low sensitivity to changes in resistance during the aspiration process. Thus, if an occlusion occurs, this will not be felt during aspiration. Moreover, it is not possible to determine the volume of aspirated fluid with the un-scaled fluid chamber. Furthermore, the existing design of the apparatus does not teach of an in-line device.

US 6,159,164 discloses a blood sampling system for sampling blood through an intravenous or intra-arterial tube. The system comprises a plunger for drawing fluid from a fluid from the tube into a chamber, and for expelling the fluid from the chamber in to the tube. In the sampling position, the plunger creates a vacuum in the chamber, thereby causing fluid to be aspirated into the chamber. Aspirating action causes fluid in the patient to be drawn up to the sampling site. The elevation of the plunger is accomplished via an actuator connected to a stick-like handle. This system is operable by one hand. However, due to the design of the actuator, the force required to elevate and lower the handle is not the same along the distance of the handle. Therefore, a varying resistance caused by occlusion will not be reflected in the pulling or pushing of the handle. Additionally, the design of the device allows overshooting of fluid, such that over-aspiration may occur, similar to that described with the above prior art. Moreover, it is not possible to determine the volume of aspirated fluid with the un-scaled fluid chamber. Furthermore, the existing design of the apparatus does not teach of an in-line device.

None of the prior art described herein above enable a predetermined volume of fluid to be aspirated.

Summary of Invention

It is therefore an object of the present invention to provide a syringe for selectively introducing fluid to a patient and withdrawing fluid into the syringe.

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It is an additional object of the present invention to provide a syringe that prevents overshooting during the withdrawing process.

It is yet another object of the present invention to provide a syringe that is operable by a single hand.

10

It is a further object of the present invention to provide a syringe that enables withdrawing of a predetermined volume of fluid.

It is still another object of the present invention to provide a syringe that allows constant resistance during withdrawing of fluid to enable indication of an occlusion with the change of resistance.

15

It is yet a further object of the present invention to provide a syringe that requires little or no skill to operate.

20

It is still a further object of the present invention to provide a syringe that is simple to operate and also avoids the need for opening and closing of additional valves or clamps, thereby reducing the risk of error during the aspiration process.

25

It is another object of the present invention to provide a syringe that can be operated manually or automatically when plugged in its electronic apparatus.

The foregoing objects are accomplished by an apparatus and method that consists of an in-line sampling syringe for selectively introducing a fluid to and aspirating a fluid from a downstream fluid conduit connected to a catheterized patient. The syringe comprises a fluid chamber into which fluid
5 is aspirated. A volume regulator is provided for adjusting the volume of the fluid chamber. A fluid line through which fluid flows through said syringe connects to a downstream fluid conduit. A valve mechanism is provided for selectively either allowing fluid flow along said fluid line or preventing fluid flow along said fluid line while simultaneously aspirating a fluid. This latter
10 effect is achieved by selectively shifting the volume regulator to adjust the volume of the fluid chamber. A housing joins the fluid chamber, the fluid line, the valve mechanism, the volume regulator and the control mechanism. An electronic control apparatus is provided for operating said valve mechanism.

15 The method comprises operating the in-line sampling system for selectively introducing fluid to and aspirating a fluid from a downstream fluid conduit connected to a catheterized patient as described above and includes a syringe as described. In addition a fluid reservoir is provided for storing external fluid, and connected to the syringe via an upstream fluid conduit. A catheter
20 is provided for insertion into a patient, and connected to said syringe via a downstream fluid conduit. A sampling port is situated along the downstream fluid. The method further determines the presence of an occlusion along a patient side fluid conduit by the steps of providing in-line sampling as described, positioning the valve mechanism at a first position for allowing
25 fluid flow along the fluid line, performing aspiration by shifting the position of the valve mechanism, measuring the increasing torque on the shaft of the motor connected to the syringe by one of taking constant measurements of the strain in the load cell and taking constant measurements of the current in the motor. From these measurements is can be determined whether an
30 occlusion is present along the patient side fluid conduit.

Additional objects and advantages of the present invention are described in detail herein below.

5 **Brief Description of the Figures**

In the drawings:

- Figs. 1a and 1b show an exploded perspective view (Fig. 1a) and an assembled perspective view (Fig. 1b) of a first embodiment of the present invention;
- 10 - Figs. 2a and 2b show a cross-sectional first side view of the assembled first embodiment of the present invention of Fig. 1b, in an initial position (Fig. 2a) and a final position (Fig. 2b);
- Fig. 3 shows a cross-sectional second side view of the first embodiment, shown in a 180 degree rotation about its horizontal
15 longitudinal axis, as compared to that shown in Fig. 2a;
- Fig. 4 shows a sampling system, comprising the syringe of the present invention in the initial position as shown in Fig. 2a;
- Fig. 5 shows an alternative aspect of the first embodiment of the present invention in an exploded view;
- 20 - Figs. 6a and 6b show an alternative aspect of the first embodiment, in an initial position (Fig. 6a) and a final position (Fig. 6b);
- Figs. 7a and 7b show an exploded perspective view of a second embodiment of the present invention (Fig. 7a) and an exploded view of the valve mechanism, the shifting mechanism and the motor
25 coupling (Fig. 7b);
- Figs. 8a and 8b show an assembled top perspective view of a sampling system (Fig. 8a) and an assembled bottom perspective view of the syringe (Fig. 8b) of the second embodiment;
- Fig 8c shows a partially cutout perspective view of the syringe of
30 the second embodiment;

- 7 -

- Figs. 9a, 9b and 9c show the plug element with the syringe in the pre-aspiration position (Fig. 9a), following initial aspiration (Fig. 9b) and after maximum aspiration (Fig. 9c);
- Fig. 9d shows a bottom perspective view of the syringe of the second embodiment with the sealing plug removed from the housing;
5
- Figs. 10a, 10b and 10c show one aspect of the sealing gasket, with the syringe in an initial position, pre-aspiration (Fig. 10a), following initial aspiration (Fig. 10b) and after maximum aspiration (Fig. 10c);
- Fig. 10d shows a perspective view of a first embodiment of the sealing gasket;
10
- Figs. 11a, 11b and 11c show an alternative embodiment of the sealing gasket, with the syringe in an initial position, pre-aspiration (Fig. 11a), following initial aspiration (Fig. 11b) and after maximum aspiration (Fig. 11c);
15
- Fig. 11d shows a perspective view of a second embodiment of the sealing gasket;
- Figs. 12a-b show an exploded perspective view of the third embodiment of the present invention (Fig. 12a) and an exploded view of the components of the pressure system (Fig. 12b);
20
- Fig. 12c shows a perspective view of a sampling system with the syringe of the third embodiment;
- Fig. 13 shows an assembled perspective view of the third embodiment of the present invention;
- Fig. 14 shows a perspective view of the assembled syringe with the fluid chamber partially cutout;
25
- Figs. 15a-d show a top cut view of the third embodiment of the syringe of the present invention in a zeroing position (Fig. 15a), a fluid flow (open) position (Fig. 15b) a closed position with initial aspiration (Fig. 15c) and further aspiration (Fig. 15d);
30

- Figs. 16a-d show cut perspective views of the syringe corresponding to Figs. 15a-d;
- Figs. 17a-d shows an alternative aspect of the third embodiment, wherein the pressure transducer connects directly to a power source in a partially cut view (Fig. 17a), a bottom exploded view (Fig. 17b), a bottom assembled view (Fig. 17c), and showing the exploded components of the pressure system (Fig. 17d);
- Figs. 18a-c show a fourth embodiment of the present invention in an assembled perspective view (Fig. 18a), in a partially cut perspective view (Fig. 18b) and a bottom perspective view (Fig. 18c);
- Figs. 19a-b show a manually operable syringe with external dpt, connected to the arm of a patient (Fig. 19a) and with an internal dpt, connected to the arm of a patient (Fig. 19b);
- Figs. 20a-b show a perspective view of the syringe of the second embodiment (Fig. 20a) and of the third embodiment (Fig. 20b);
- Figs. 21a-b show an automatically operable syringe with an external pressure transducer (Fig. 21a) and an internal pressure transducer (Fig. 21b), mounted on a electronic control apparatus;
- Figs. 22a-b show a front view of the electronic control apparatus and remote control device with the second embodiment of the syringe (Fig. 22a) and the third embodiment of the syringe (Fig. 22b) mounted thereon;
- Fig. 23 shows an exploded view of the electronic control apparatus;
- Fig. 24 shows an exploded view of the remote control device;
- Figs. 25a-c show two aspects of the third embodiment of the syringe (Fig. 25a, Fig. 25b) and the fourth embodiment of the syringe (Fig. 25c) mounted on the electronic control apparatus;
- Figs. 26a-d show sample pressure waveforms indicating different pressure conditions as measured by a pressure transducer;

- Figs. 27 a-c show the gauge of a syringe of the present invention showing different positions of the valve with respect to Figs. 26a-d;
- Figs. 28 a-c show a syringe of the second embodiment mounted on an electronic control apparatus showing different positions of the valve with respect to Figs. 26a-d;
- Figs. 29a and 29b show torque load on the electronic motor shaft graphically represented as waveforms of non-occluded (Fig. 29a) and occluded (Fig. 29b) lines; and,
- Figs. 30a and 30b shows a syringe in the open position, a syringe with the valve rotated, after aspiration has been performed along a non-occluded Fig. (30a) and occluded (Fig. 30b) line.

Detailed Description of the Preferred Embodiments

A first embodiment of the in-line sampling syringe of the present invention is shown in Fig. 1a in an exploded view and in Fig. 1b in an assembled perspective view, and designated generally by numeral (100). Syringe (100) selectively introduces a sterile fluid (e.g. saline solution) along a downstream fluid line (20) (e.g. an infusion or arterial tube) to a patient, and selectively withdraws the fluid from line (20) back into syringe (100). Thus, syringe (100) is understood to be a closed, sealed to the ambient air, in-line aspirating device. Syringe (100) comprises a fluid chamber (110) into which an infused fluid is aspirated from a downstream fluid conduit (20), a volume regulator (120) for adjusting the volume capacity of fluid chamber (110), a fluid line (130) along which fluid flows through syringe (100) towards a patient, and a valve mechanism (150) for regulating the fluid flow along fluid line (130) by selectively allowing fluid to flow along fluid line (130) towards a patient when desired, and preventing fluid to flow along fluid line (130) when aspirating the downstream fluid. Valve mechanism (150) additionally selectively shifts volume regulator (120) to adjust the volume of fluid chamber (110). Syringe

- 10 -

(100) further comprises a housing (160) for joining fluid chamber (110), fluid line (130), valve mechanism (150) and volume regulator (120).

The components of syringe (100) are preferably designed to be compact and small in size in order to be user friendly and to avoid potential risks during use as well as complications caused by the complexity of the procedure, which might normally be present in the prior art when such a device is mounted on the arm of a patient, or mounted on a bed or table near the patient.

Also shown in Fig. 1a is a section of an upstream fluid conduit (10) for connecting to a fluid reservoir (not shown in this figure) and a section of a downstream fluid conduit (20) for contact with the patient (not shown). A connector (22) joins downstream fluid conduit (20) with distal opening (112) of syringe (100) located at a first longitudinal (distal) end (111) of fluid chamber (110).

Still referring to Fig. 1a, it should be noted that fluid chamber (110) is shown in a preferred cylindrical shape, but may alternatively comprise any other suitable shape, depending on design, mechanical and/or other considerations.

As mentioned herein above, distal opening (112) of syringe (100) is located at first longitudinal end (111) of fluid chamber (110). A second longitudinal (proximal) end (113) of fluid chamber (110) comprises an opening in communication with the fluid line (130), as described herein below. The opening at second longitudinal end (113) is preferably larger than the opening at first longitudinal end (111), and enables at least a portion of volume regulator (120) to shift therethrough, as described further herein below.

When syringe (100) is assembled, the open end (169) of housing (160) is coupled with longitudinal end (113) of fluid chamber (110). The coupling of

housing (160) with fluid chamber (110) may be accomplished by any suitable fastening means such as threading, clips, etc.

A cross-section is cut longitudinally along the assembled syringe (100), and a first side of syringe (100) is shown in an initial position in Fig. 2a and in a final position in Fig. 2b. Fig. 4 shows a sampling system (101), comprising syringe (100) in the initial position as shown in Fig. 2a, a fluid reservoir (12) (e.g. an infusion bag) for storing, for example, saline solution, connected to syringe (100) via upstream fluid conduit (10), and a catheter (14), for insertion into a patient, connected to distal opening (112) of syringe (100) via downstream fluid conduit (20) and connector (22). Connector (22) is shown threadingly coupled with opening (112), however, any form of a removably connectable coupling may be used to join connector (22) with opening (112). A sampling port (16) is situated along downstream fluid conduit (20) for removing a blood sample at the site of the port via a blood sampling syringe (see Fig. 4).

Fluid line (130) is shown in one aspect of the first embodiment comprised of flexible tubing, as indicated illustratively by a bending (131), for instance, in Fig. 2a. It is understood that fluid line (130) preferably extends essentially straight, with minor bending, when fluid chamber (110) is in its initial position, as described herein.

With reference to Fig. 2a, in the initial position of syringe (100), valve mechanism (150) is shown in an open position for allowing fluid to flow downstream through fluid line (130). The first end (142) of opening (140) in valve mechanism (150) serves as an inlet and is in communication with an elongated port (162) located at the proximal end (164) of syringe (100). Port (162) runs from valve mechanism (150) through the body (161) of housing (160), towards a first longitudinal (proximal) end (164) of housing (160). The

- 12 -

second end (144) of opening (140) valve mechanism (150) serves as an outlet and is in communication with the second end (134) of fluid line (130) through aperture (163) located in body (161) of housing (160). Valve mechanism (140) is rotatably disposed within a matching frame (166) in body (161) of housing
5 (160), as described herein below.

Volume regulator (120) (see Fig. 1a and Fig. 2b) comprises a sealing gasket (122) for preventing leakage of fluid out of fluid chamber (110), and a drive portion (124) for shifting sealing gasket (122) within fluid chamber (110).
10 Sealing gasket (122) is connected via coupling member (126) at the first longitudinal end (125) of drive portion (124). Sealing gasket (122) comprises an internal radial groove (121) (see Fig. 2a) within which a radial disk (127) of coupling member (126) is disposed. The geometrical shape of coupling member and the corresponding shape of sealing gasket (122) is not limited to
15 that shown herein, and may comprise an alternate design while performing essentially the same function as the components shown herein.

An anti-microbial vent (165) (see Fig. 1a), comprising a filter, is preferably located in an opening in housing (160) of syringe (100). The filtered vent
20 (165) prevents bacteria and/or other undesirable microorganisms from entering into syringe housing (160) when air is expelled out of vent (165) during the aspiration process, wherein sealing gasket (122) is shifted within fluid chamber (110), as well as when air is sucked into housing (160) through vent (165) when the syringe returns to the line-open position. Vent (165) or
25 at least a portion thereof also is preferably treated with an anti-microbial agent, such as silver ions.

In the initial position shown in Fig. 2a, the distal face (123) of sealing gasket (122) is in contact with the inner surface of first longitudinal end (111) of
30 fluid chamber (110). In this position, fluid chamber (110) is at its minimum

volume capacity, wherein preferably essentially zero amount of fluid may be accommodated therein, and fluid flows from fluid reservoir (12), shown in figure 4, through valve mechanism (150) and fluid line (130), and out of syringe (100) via distal opening (112).

5

Drive portion (124) comprises a shifting mechanism (152) (see Fig. 1a) for allowing drive portion (124) to shift sealing gasket (122) within fluid chamber (110). Shifting mechanism (152) is comprised of a rack (154) and pinion (156) pair of gears for translating the rotational motion of the handle (151) into
10 linear motion of drive portion (124), as described herein below, but may alternatively comprise any suitable mechanism for enabling the shifting of sealing gasket (122).

Fig. 3 shows a cross-sectional second side view cut longitudinally along syringe (100), seen from the perspective of the second side (i.e. the side facing
15 into the paper in Fig. 2a). For the sake of consistency in the direction of fluid flow, syringe (100) is shown in Fig. 3 after a 180 degree rotation about its longitudinal axis, such that, for instance, rack gear (154) is shown vertically below pinion gear (156) in Fig. 2a, and vertically above pinion gear (156) in
20 Fig. 3, relative to the correct orientation of the page. Pinion gear (156) is positioned axially with, and behind frame (166) (as seen in Fig. 3) of body (161) (see Fig. 2a) of housing (160), and engaged with rack (154).

Referring mainly to Figs. 1a and 3, valve mechanism (150) comprises a
25 handle (151), and an elongated insertion member (158) rotatable about its central longitudinal axis. Elongated insertion member (158) comprises a tip (159) shaped for disposing within slot (157) of pinion gear (156). Opening (140) is essentially a through hole extending through elongated insertion member (158).

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- 14 -

Valve mechanism (150) shifts between the open position as shown in Fig. 2a and a closed position as shown in Fig. 2b (as described herein below), by rotation of handle (151). The rotation between positions may be accomplished in a single motion, thereby reducing the steps required to be performed by the operator. This design is not only simple to operate but also
5 avoids the need for opening and closing of additional valves or clamps, thereby reducing the risk of error during the aspiration process.

When valve mechanism (150) is in the closed position, fluid flow from upstream fluid conduit (10) is stopped, and fluid is aspirated from
10 downstream (patient side) fluid conduit (20).

As seen in the figures, syringe (100) preferably further comprises a measuring gauge (168) for indicating the volume capacity of fluid chamber (110) according to the position of volume regulator (120). Gauge (168) is a
15 semi-circular indicator, comprising a flat scale numbered from 0-6cc. The rotation of handle (151) adjusts the volume capacity of fluid chamber (110) by shifting sealing gasket (122), as described herein below. The position of handle (151) along gauge (168) indicates the volume capacity of fluid chamber
20 (110), wherein when handle (151) is oriented towards the "zero" indicia, fluid chamber (110) is at the minimum volume capacity (or, the initial position), and when handle (151) is oriented towards the "six" indicia, fluid chamber (110) is at the maximum volume capacity (or, the final position).

It is understood that the measuring units and range used in gauge (168), as well as the geometric shape of gauge (168), depends on conventional measuring standards, the size of syringe (100), as well as other factors known by the man skilled in the art. Moreover, the size of syringe (100) may be designed according to the age/size of the patient. For instance, a smaller
25 aspiration volume is needed in the fluid chamber for neonates.
30

The design of gauge (168), in which the measuring units are shown on the front of gauge (168), and in which rotation of handle (151) for filling fluid chamber (110) is performed in a single motion, is advantageous when syringe
5 (100) is mounted on the arm of a patient or situated on a bed or table near the patient, in that such a design reduces the need for the practitioner who is operating syringe (100) to be involved in more than one action while performing the withdrawing operation. This reduces the risk of incorrect operation of syringe (100) as well as injury to the patient.

10

The initial rotation of handle (151) of valve mechanism (150) in the first embodiment simultaneously rotates opening (140) as well as pinion gear (156), for both preventing fluid flow downstream through fluid line (130) and drawing a fluid into fluid chamber (110) via a vacuum created within fluid
15 chamber (110). As mentioned above, the process between the initial shifting of handle (151) and the maximum rotation of handle (151) may be accomplished in a single motion. As seen in Fig. 2b, flexible fluid line (130) (shown partially cut) rolls up as the handle (151) is further rotated.

20 With reference to Fig. 2b, in the final position of syringe (100), valve mechanism (150) is shown in a closed position. Fluid chamber (110) is at the maximum volume capacity, wherein, although not shown in Fig. 2b, handle (151) is oriented at the "six" position, as described herein above.

25 A constant resistance force is present during the rotation of handle (151) and translation into a linear aspiration. An increase of resistance during the rotation of handle (151) may indicate an occlusion along fluid conduit (20).

An alternative aspect of the first embodiment is shown in an exploded view in Fig. 5, similar to that of Fig. 1a, wherein the fluid line (130') is comprised of two line sections (132a), (132b), telescopically arranged within syringe (100').

5 A cross-sectional side view (similar to the view shown in Fig. 2a) of the second aspect of the assembled syringe (100') is shown in Fig. 6a, wherein fluid chamber (110) is at the minimum volume capacity (or, the initial position), as seen enlarged in Detail A. Fluid line (130') extends essentially from distal opening (112) of syringe (100'), to second end (144) of opening
10 (140) of the valve mechanism (not seen). The first end (134b) of the second line section (132b) of fluid line (130') is disposed telescopically within the second end (134a) of the first line section (132a) of fluid line (130'). O-ring (135), situated on line section (132b), is for preventing leakage between telescopic line sections (132a) and 132b).

15

Fig. 6b shows the drawing of Fig. 6a, wherein fluid chamber (110) is at the maximum volume capacity (or, the final position), as seen enlarged in Detail B, wherein first line section (132a) telescopically overlaps first line section (132b).

20

A second embodiment of the syringe of the present invention is shown in Fig. 7a in an exploded view, in Fig 8a in an assembled top perspective view as part of a sampling system (201), and in Fig. 8b in an assembled bottom perspective view, referred to generally by numeral (200), and comprises all of
25 the essential features of the first embodiment, *mutatis mutandis*, with the differences described herein below. According to the second embodiment, syringe (200) comprises a fluid chamber (210) for withdrawing (aspirating) a fluid therein from a downstream fluid conduit, a volume regulator (220) for adjusting the volume capacity of fluid chamber (210), a rigid fluid line (230)
30 along which fluid flows through syringe (200) towards a patient, and a valve

mechanism (250) which allows fluid to flow along fluid line (230) towards a patient, and prevents fluid flow along fluid line (230) when withdrawing the downstream fluid. Valve mechanism (250) selectively alternates the orientation of opening (240) as well as selectively shifts volume regulator (220) to adjust the volume of fluid chamber (210). Syringe (200) further comprises a housing (260) for joining fluid chamber (210), fluid line (230), valve mechanism (250) and volume regulator (220) to form a single unit.

Rigid fluid line (230) is preferably prevented from bending and/or coiling, or otherwise adjusting in length, such as telescopically, as opposed to the fluid line according to the first embodiment of the present invention. This provides a mechanically more simple aspiration process than that of the first embodiment.

The distal opening (212) of syringe (200) is located at first longitudinal end (211) of fluid chamber (210). A second longitudinal (proximal) end (213) of fluid chamber (210) comprises an opening in communication with the fluid line (230), as described herein below. The opening at second longitudinal end (213) is preferably larger than the opening at first longitudinal end (211), and enables at least a portion of volume regulator (220) to shift therethrough.

When assembled, as seen in Figs. 8a and 8b, the open end (269) (Fig. 7a) of housing (260) is coupled with second longitudinal end (213) of fluid chamber (210). Additionally, fluid chamber (210) comprises wings (218) that fit into opposing slots (267) in housing (260), thereby providing additional connecting means between fluid chamber (210) and housing (260).

Fig. 8a shows sampling system (201), comprising syringe (200), a fluid reservoir (12) connected to syringe (200) via upstream fluid conduit (10), and a catheter (14), for insertion into a patient, connected to distal opening (212)

of syringe (200) via downstream fluid conduit (20) and connector (22). A sampling port (16) is situated along downstream fluid conduit (10) for removing a blood sample at the site of the port via a blood sampling syringe (not shown).

5

Fig. 8c shows a partially cutout perspective view of syringe (200), cut along housing (260) a fluid chamber (210). A sealing plug (265) is shown in the back wall of housing (260). Sealing plug (265) is best seen in Fig. 8b, and described further herein below.

10

In one aspect, an opening (not shown) in housing (260) allows air to be expelled when sealing gasket (222a) shifts within fluid chamber (210). An anti-microbial vent is present in housing (260) of syringe (200), similar to that described in the first embodiment.

15

In an alternative embodiment, as seen in Figs. 9a-d, instead of a vent, syringe (200) comprises a sealing plug (265) disposed in an opening (see Fig. 9d) in housing (260), for maintaining a totally closed environment, sealed from the ambient air and for preventing any contamination that might otherwise occur with the presence of a vent. Sealing plug (265) comprises an elastic membrane cover (271) situated at the outer end thereof, for preventing air from entering into and being released from housing (260). Referring particularly to Figs. 9a-c, when syringe is in the initial position (Fig. 9a), in which fluid flows through fluid line (230) and no aspiration is performed, membrane (271) lays essentially flat on plug (265). Upon performing an initial aspiration, as seen in Fig. 9b, membrane (271) expands outward due to pressure buildup of air within housing (260). Fig. 9c shows membrane (271) fully expanded when syringe (200) is in the final position of maximum aspiration.

30

A bottom perspective view of syringe (200) is shown in Fig. 9d with sealing plug removed from housing (260).

Syringe (200) further comprises means for setting a predefined maximum
5 volume of fluid chamber (210). According to a preferred embodiment, the
means comprises at least one protrusion (202) (five protrusions are shown in
the figures) extending outward, orthogonally from gauge (268), and a stopper
(204) for positioning over protrusion (202). Protrusions (202) extend outward
without preventing handle (251) from rotating, as described herein above.
10 When stopper (204) is positioned over protrusion (202), handle (251) is
prevented from further rotation. Thus, according to the second embodiment,
a predetermined rotational limit may be set for handle (251).

Preferably, stopper (204) is joined with syringe (200), such as, at handle (250)
15 via cord (205), or any alternative joining means.

Alternatively, (not shown) the means for setting a predefined maximum
volume of fluid chamber (210) comprises indentations within gauge (268) and
a stopper for positioning thereat.

20

It is advantageous to set a predefined maximum volume of fluid chamber
(210), as this prevents excess fluid aspiration, particularly when only a
limited amount of fluid is desired to be drawn into fluid chamber (210), such
as in cases of severe blood loss as well as in newborn infants.

25

With reference to Fig. 7a, Fig. 7b and Fig. 8b, according to the second
embodiment, a coupling (275) is provided in order to accommodate the shaft
of a motor (not shown), for enabling valve (250) to rotate via the motor, as
described herein below. Coupling (275) comprises a cavity portion (276) (Fig.
30 8b) for receiving the shaft of a motor (not shown) therein, and a coupling-

- 20 -

shaft portion (277), which is coupled to tip (259) of elongated insertion member (258) via slot (257) in pinion (256). Thus, when the shaft of a motor is disposed within cavity portion (276), rotation of the shaft in turn rotates coupling (275), which, in turn, rotates valve (250) about the central axis of elongated insertion member (258).

It should be noted that the coupling component for accommodating the shaft of a motor may be present in all embodiments of the present invention, *mutatis mutandis*.

10

Rotation of valve (250) may be accomplished manually, or by a motor of an electronic control apparatus as further described herein below with regards to alternative embodiment but relates to the second embodiment, *mutatis mutandis*. The advantages of rotating valve (250) via a motor include maintaining the sterile environment of syringe (200) by reducing potential contamination that could occur during manual handling of syringe (200). Moreover, the rotation of valve (250) via a motor enables the measuring of resistance of the movement of handle (251), as described further herein below. This allows the operator to determine possible occlusion in a more precise manner than simply attempting to “measure” the resistance by hand.

20

Referring to Figs. 10a-c, a partial cutout of a first side of fluid chamber (210) of the assembled syringe (200) is taken along a portion of fluid chamber (210), distally towards distal opening (212), and shown in Fig. 10a wherein syringe (200) is in the initial position, in which fluid flows through fluid line (230) and no aspiration is performed; in Fig. 10b, in which an initial aspiration is performed; and in Fig. 10c, in the final position in which maximum aspiration is performed.

25

Sealing gasket (222a) shown in a perspective view in Fig 10d, comprises a protruding ring element (228) located at the opening of gasket (222a), which is positioned around fluid line (230), as seen enlarged in Detail C in Fig. 10a. Protruding ring element enables a laminar blood flow, which thereby reduces the potential of hemolysis from occurring as the blood flows from fluid line (230). Ring element (228) is preferably an integral portion of gasket (222a).

An alternative embodiment of gasket (222b) is shown in Figs. 11a-d, and enlarged in Detail D, wherein in Fig. 11a syringe (200) is in the initial position, in which fluid flows through fluid line (230) and no aspiration is performed, in Fig. 11b an initial aspiration is performed, and in Fig. 11c, the final position in which maximum aspiration is performed. In this aspect, sealing gasket (222b) is shown without the ring element of Figs. 10a-c, which simplifies the manufacturing process and reduces costs.

A third embodiment of the syringe of the present invention is shown in an exploded view in Fig. 12a, and in an assembled view in Fig. 13, referred to generally by numeral (300), and comprises all of the essential features of the previous embodiments, *mutatis mutandis*, with the following differences. According to the third embodiment, syringe (300) comprises – as integral components thereof – a blood pressure measuring system for continuously measuring a patient's blood pressure, as well as a flushing mechanism (380) flushing the line before and/or after sampling takes place. The components of the blood pressure measuring system is shown in an exploded view in Fig. 12b, and described herein below.

Syringe (300) is shown as a component of a sampling system (301) in Fig. 12c, as described herein above with respect to the previous embodiments.

As described herein above, a sterile fluid such as saline is typically introduced to a patient along a fluid conduit in order to prevent blockage of the conduit. However, blockage may nevertheless occur. If a change in the blood pressure reading occurs, it must be determined whether the change is
5 due to an actual change in the physiological status of the patient, or due to a blockage or crimp in the fluid conduit joining the patient with the blood pressure reader, or any other glitch in one of the components of the system. The components of the third embodiment of the present invention enable the practitioner to determine the source of a change in blood pressure reading, as
10 described herein below.

Another means for indicating an occlusion, in addition to a change in the blood pressure reading, is a change in the resistance while withdrawing fluid into the fluid chamber, as mentioned herein above. The interlocking toothed
15 relationship between the gears of the pinion and rack preferably enables a relatively fast linear displacement of the volume regulator. This allows a sensitivity to even a slightly higher resistance than usual during the displacement process.

20 Flushing mechanism (380) of the present invention is situated upstream of proximal port (362), and is connected with an upstream coupler (11) for connecting to upstream conduit (10). A sealing plunger (388), for selectively allowing and preventing fluid flow is enclosed by a housing (391) and cover (392). Flushing mechanisms are standard features in the field, and have
25 various designs that are well known in the known in the art.

Referring particularly to Figs. 12a, 12b and 14, wherein Fig. 14 shows a perspective view of the assembled syringe (300) with fluid chamber (310) partially cutout, the blood pressure measuring system comprises a
30 differential pressure transducer (372) located within fluid chamber (310), for

- 23 -

measuring pressure along fluid line (330) and a stopcock valve (350) for selectively allowing and preventing fluid flow along fluid line (330), as well as for opening fluid line (330) to atmospheric pressure for calibration of pressure transducer (372) via outlet (381), as described herein below. Pressure transducer (372) is at least partially enclosed by casing (370), having an atmospheric air inlet (375). Atmospheric air inlet (375) is open to the atmosphere for allowing an internal membrane (not shown) within pressure transducer (372) to flex to enable pressure to be measured along fluid line (330). A cable (373) and connector (374) extend from pressure transducer (372) for connecting to a power supply. A clip (371) is shown for mounting syringe (300) on a mounting board (not shown).

Detail E, shown in Fig. 13, is an enlargement of the portion of syringe (300), illustrating a clamp (311) which secures cable (373) extending out of syringe (300) at the seam at which fluid chamber (310) and housing (360) are joined together. The outer tip of atmospheric air inlet (375) is shown extending out of clamp (311).

Prior to operating the blood pressure measuring system, pressure transducer (372) must be calibrated (zeroed) to ensure accurate readings. A top view of syringe (300) is shown in a partial cross-section in Figs. 15a-d, showing fluid chamber (310) partially cut along fluid line (330), as well as a cross-section of outlet (381). Syringe (300) is in the zeroing position in Fig. 15a, in the fluid flow (also referred to herein as pre-aspiration) position in Fig. 15b, in the initial aspiration position, wherein fluid line (310) is closed, in Fig. 15c, and in a further aspiration position in Fig. 15d. Figs. 16a-d show cut and partially cut perspective views of syringe (300), essentially corresponding to Figs. 15a-d.

- 24 -

- With reference to Figs. 15a and 16a, in order to zero the pressure transducer (372), stopcock valve (350) is turned to the “zero” indicia, in which the longitudinal axis of opening (340) is rotated such that fluid is prevented from flowing through fluid line (330), while simultaneously allowing communication between pressure transducer (372) and the atmosphere via outlet (381). Particularly with reference to Fig. 16a, valve (350) comprises an air-flow conduit (353) for enabling air flow between fluid line (330) and outlet (381).
- 10 Apertures (332) (see enlarged Detail F) located near the closed tip (333) of fluid line (330), through which fluid flows, are covered by ring element (328) of gasket (322) (see Fig. 15a) when zeroing pressure transducer (372), thereby blocking air-flow communication with the patient.
- 15 As mentioned, tip (333) of fluid line (330) is closed. In an alternative aspect (not shown), fluid line (330) is a solid line (i.e. without apertures (332)), and open at its tip, wherein a cap, comprising apertures around its periphery is fixedly positioned on the tip
- 20 A second end of pressure transducer (372) is in communication with the atmosphere via atmospheric air inlet (375) (see Fig. 14) extending from pressure transducer (372), and open to the atmosphere. The differential pressure is measured as zero, and indicated as zero pressure.
- 25 With reference to Figs. 15b and 16b, stopcock valve (350) is then turned to the “open” indicia, in which the longitudinal axis of opening (340) and the longitudinal axis of fluid line (330) are aligned. Ring element (328) shifts away from and thereby uncovers apertures (332), and fluid is allowed to flow from a fluid reservoir (not shown) to the patient (not shown). Pressure measurement can then be performed.
- 30

Outlet (381) is preferably covered with cap (383) when zeroing is not taking place. Outlet (381) preferably comprises an antibacterial filter, such as that described herein above

5

With reference to Figs. 15c and 16c, when it is desired to perform aspiration, valve (350) is turned to the “closed” indicia, in which the longitudinal axis of opening (340) is rotated such that fluid is prevented from flowing through fluid line (330), and simultaneously, an initial amount of fluid is aspirated
10 into fluid chamber (310).

Figs. 15d and 16d show further aspiration of fluid into fluid chamber (310).

In an alternative aspect of the third embodiment shown in a partially cutout
15 perspective view of syringe (300') in Fig. 17a, an exploded bottom perspective view in Fig. 17b and assembled in a bottom perspective view in Fig. 17c, the pressure transducer system comprises the pressure transducer (372') within fluid chamber (310). The components of the pressure transducer system of the alternative aspect of the third embodiment are shown in an exploded
20 view in Fig. 17d. Pressure transducer (372') is disposed within casing (370'), wherein casing (370') (see Fig. 17b) comprises a connector (374') having contacts that connect directly into a power supply (i.e. without a cable). Connector (374') extends out of the back (i.e. bottom) of syringe, although may be designed differently according to alternative specifications.
25 Atmospheric air inlet (375') is positioned between the contacts of connector (374').

A fourth embodiment of the present invention is shown in an assembled
perspective view in Fig. 18a, in a partially cut out perspective view in Fig.
30 18b and in a bottom perspective view in Fig. 18c, referred to generally by

numeral (400), and comprises all of the essential features of the third embodiment, *mutatis mutandis*, with the following differences. According to the fourth embodiment, the components of the blood pressure measuring system are situated outside of fluid chamber (410) of syringe (400).

5

As best seen in Fig. 18b, pressure transducer (472) is positioned downstream from fluid chamber (410). Zeroing valve (485) selectively allows and prevents fluid flow from the fluid line within syringe (400) to the downstream fluid conduit (not shown in the figure). In the figures, zeroing valve (485) is closed, for preventing fluid flow. Stopcock valve (374) is additionally joined with an outlet (481) to the atmosphere, directed away from syringe (400), for communication between pressure transducer (472) and the atmosphere for zeroing purposes, as described herein above regarding the third embodiment.

10

As described herein above, the various embodiments of the present invention may be operable manually or automatically (via motor). Fig. 19a shows a manually operable syringe (200) of the second embodiment of the present invention (shown conveniently enlarged in Fig. 20a) (or, alternatively, syringe (100) of the first embodiment) attached to the arm (50) of a patient, with infusion bag (12) for introducing sterile fluid through syringe (200). External pressure transducer (72) is connected to syringe (200), and measurement readings are displayed on monitor (80). Fig. 19b shows a manually operable syringe (300') of the third embodiment (shown conveniently enlarged in Fig. 20b) attached to the arm (50) of a patient, with infusion bag (12) for introducing sterile fluid through syringe (300'). The internal pressure transducer (not shown) is situated within fluid chamber (310) of syringe (300'), and measurement readings are displayed on monitor (80).

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- 27 -

In Fig. 21a, automatically operable syringe (200) of the second embodiment is mounted on an electronic control apparatus (60) which is attached to the bedside (54) of a patient (52), and an infusion bag (12) for introducing sterile fluid through syringe (200). Remote control device (90) for controlling
5 electronic control apparatus (60) is positioned as shown in Fig. 21a, or alternatively, remote control device (90) is positioned on top of electronic control apparatus (60) (see Fig. 22a). As seen in Fig. 21a, external pressure transducer (72) is connected to syringe (200). The pressure transducer should be positioned at the level of the measured organ. Measurement
10 readings are displayed on monitor (80).

In Fig. 21b, automatically operable syringe (300') of the third embodiment is mounted on an electronic control apparatus (60) which is attached to the bedside (54) of a patient (52), and an infusion bag (12) for introducing sterile
15 fluid through syringe (300'). Remote control device (90) for controlling electronic control apparatus (60) is positioned in a way that will enable the pressure transducer inside syringe 300' to be on the same horizontal plane of the organ that is monitored for pressure measurements.

20 Alternatively, remote control device (90) is positioned on top of electronic control apparatus (60) (see Fig. 22b). In the figures, the internal pressure transducer is situated within fluid chamber (310) of syringe (300'), and measurement readings are displayed on monitor (80).

25 In the embodiments shown in the figures, the remote control device and electronic control apparatus, as well as the monitor, are connected via a wire. In an alternative embodiment (not shown) a wireless remote control device for controlling the electronic control apparatus is utilized. The wireless remote control device, electronic control apparatus and monitor are wireless
30 communicatable with each other.

A local or remote control station (not shown in the figures) is optionally present for programming any one of the automatic operations described herein below to operate according to a predetermined routine based on preset
5 instructions, such as time of day, length of operation, threshold limits, etc.

Figs. 22a and 22b show the front panel of remote control device (90), wherein device is positioned on top of electronic control apparatus (60). The panel comprises an on/off button (93) and a selected volume display (94) with
10 buttons for raising and lowering the setting. Buttons for automatic aspiration (95), line opening (96), zeroing (97), performing an occlusion test (98) and base line (99) are present on the panel. A visual status lamp (57) of device (90) and automatic flushing button (not shown) are also preferably present.

15

Electronic control apparatus (60) and remote control device (90) are shown each in an exploded view in Fig. 23 and 24, respectively.

Referring to Fig. 23, electronic control apparatus (60) comprises a casing base
20 (61) and casing cover (62). Casing cover (62) comprises an opening (64) through which shaft (65) of the gear (66a) engages with motor (79). Upper and lower connectors (67a), (67b) are present for connecting the dpt connector of a syringe with the pressure transducer within the fluid chamber (connector (67a)) as well as with the pressure transducer outside the fluid chamber
25 (connector (67b)), respectively, as described herein above. Flushing plunger holder (68) grasps the flushing plunger of the syringe using a solenoid (not shown) when the plunger is designed and oriented accordingly. A syringe sensor (69) is a button sensor for determining whether no syringe is present, whether a large syringe is present, in which sensor (69) is pressed all the way
30 into casing cover (62), and whether a small syringe is present, in which

- 29 -

sensor (69) is partially pressed into casing cover (62). The syringe is affixed to apparatus (60) via a pair of clips (70). Switch (71) selectively turns electronics of casing on and off. Additionally or alternatively, a light indicator turns on when electronic control apparatus (60) is on and/or in use.

5

Casing base (61) comprises a connector (73) for the remote control wire, a connector (74) for the patient monitor output, a connector (75) for the dpt cable connector, and a DC power connector (76). Connector (75) is adaptable to receive the connector at the end of a cable extending from the pressure
10 transducer, as described herein above. The remote control device is hingedly connectable to casing base (61) via hinges (77).

The internal components of electronic control apparatus (60) consist of a rechargeable battery (85), a motor (79), as mentioned herein above, a gear
15 (66), a torque meter (66a) (seen in enlarged Detail F) and an encoder (78). PCB (81) comprises a microprocessor (82) and buzzer (83), as well as a wireless module (84).

When a syringe is connected to electronic control apparatus (60), motor shaft
20 (65) rotates the valve on the syringe of the present invention, as described herein above.

Remote control device (90), as seen in Fig. 24, comprises a casing base (85) and casing cover (86). Casing base comprises a DC connector (87) and a
25 connector (88) for communicating with the electronic control apparatus, and/or to a control station as mentioned herein above. Internal components of remote control device (90) consist of battery (89), PCB (91) and a wireless module (92). The front panel of casing cover (86) of remote control device is described herein above.

30

It is understood that at least some of the features of electronic control apparatus (60) and remote control device (90) are optional and some features may be interchanged with alternatively similar or dissimilar features and elements.

5

Fig. 25a shows a side view of electronic control apparatus (60) having one aspect of syringe 300' of the third embodiment mounted thereon. The pressure transducer is situated within fluid chamber (310), and a connector (374') connects directly into the upper connector of electronic control apparatus (60) (i.e. without a cable). Shaft (65) of electronic control apparatus (60) (see Fig. 23) is shown entering a coupling (275) (see Fig. 7b).

10

Fig. 25b shows a side view of electronic control apparatus (60) having syringe (400) of the fourth embodiment mounted thereon. The pressure transducer is situated downstream of fluid chamber (410), and a connector (374) connects directly into the lower connector of electronic control apparatus (60). Shaft (65) of electronic control apparatus (60) (see Fig. 23) is shown entering a coupling (275) (see Fig. 7b).

15

Fig. 25c shows a perspective view of electronic control apparatus (60) having one aspect of syringe (300) of the third embodiment mounted thereon. A cable (373) and an appropriate connector extend from the pressure transducer for connecting to electronic control apparatus as shown. Shaft (65) of electronic control apparatus (60) (see Fig. 23) is shown entering a coupling (275) (see Fig. 7b).

20
25

The operational options of electronic control apparatus (60) utilizing remote control device (90) are described as follows.

In the “Base Line” operation the valve is rotated by the shaft of the motor in order to aspirate a predetermined volume (wherein BLV = base line predetermined volume), and the time-volume-pressure characteristic is recorded (wherein BLC = base line characteristic). The shaft, and in turn,
5 the valve is then rotated back to the open position.

The steps of the “Occlusion Test” comprise first drawing the BLV, and recording the time-volume-pressure characteristic (wherein OTC = occlusion test characteristic). The BLC measurements are compared to the OTC
10 measurements and it is determined whether the OTC measurements are within the predefined limits of the BLC. If yes, the shaft, and in turn, the valve, is rotated back to the open position. If no, an indicative alarm sounds, after which the valve is rotated back to the open position.

15 For the “Zeroing” operation, when the pressure measurement system is present, the valve is first rotated via the motor shaft to the zero indicia on the gauge, and remains in that position for the predetermined zeroing delay time (ZTD). The valve is then rotated back to the open position.

20 In the aspiration process, the shaft rotates the valve to the selected aspiration volume (AV) position. The time-volume-pressure aspiration characteristics (AC) are measured and monitored, and a continuous comparison is made between the AC and OTC. If the measurements are not within the predefined limits, an indicative alarm is sounded and the shaft
25 rotates the valve back to the open position. If the measurements are within the predefined limits, a sample is taken, and then the valve is rotated back to the open position, via the line opening operation as described herein below.

In the “Line Opening” operation the motor shaft rotates the valve to the open
30 position, to allow fluid to flow through the fluid line. The line opening

operation is either performed by the operator pressing the appropriate button on the control panel after the sample is take, or may be automatically set to be performed after a predefined amount of time (or maximum time limit) after the shaft is first rotated prior to taking the sample.

5

The “Flushing” operation comprises the flushing fork (plunger) being manipulated as desired by pressing and letting go and/or pressing and holding the appropriate button.

10 Figs. 26a-d show pressure wave diagrams indicating different pressure conditions as measured by a pressure transducer, for instance, with respect to syringe (300') of the third embodiment of the present invention, wherein the pressure transducer is within the fluid chamber. The different positions of valve (350) are shown in gauge portion (368) in Figs. 27a, 27b', 27b" and
15 27c above the waveforms respectively, indicating a manual operation, and shown below the waveforms in Figs. 28a, 28b', 28b" and 28c respectively, mounted on electronic control apparatus (60), indicating automatic operation. The x-axis measures time and the y-axis measure pressure.

20 Fig. 26a shows a normal arterial line blood pressure waveform (302a) prior to positioning valve (350) at the “zero” indicia on gauge (368), thereby calibrating the pressure to zero, as indicated by the zero'd waveform (303). In the “Zeroing” operation shown in Fig. 27a, valve (350) is rotated manually; in Fig. 28a valve (350) is rotated by a motor shaft to the zero indicia on the
25 gauge, and remains in that position for the predetermined zeroing delay time (ZTD), as described herein above.

Fig. 26b shows the normal arterial line blood pressure waveform (302a) following the initial opening of the valve. Valve (350) is positioned at the
30 “open” indicia (i.e. the “line opening” operation) manually in Fig. 27b' and

automatically in Fig. 28b', in which fluid flow of saline through the syringe is allowed. In Figs. 27b" and 28b", valve (350) is positioned at the "closed" indicia by manual rotation (Fig. 27b") and automatic rotation (Fig. 28b"), thereby preventing fluid flow through the fluid line, however pressure
5 measurements may be taken.

Figs. 27c and 28c show the syringe after maximum aspiration. When it is desired to verify the non-occluded status of the downstream conduit, fluid is aspirated into the fluid chamber of the syringe (300') as described herein
10 above. A fast recovery is shown (304) in Fig. 26c along the waveform (302c), indicating a non-occluded conduit. When syringe (300') is pulled as described herein above, and a slow recovery (305) of the waveform (302c) occurs, as shown in Fig. 26d, this is an indication of a partial occlusion of the fluid conduit.

15 Figs. 29 and 30 show the torque based coagulation detection operation of the present invention, which is performed with the embodiments of the syringe that do not have the pressure sensor located within the fluid chamber, for instance, syringe (200) of the second embodiment. In this operation, the
20 increase of resistance required to rotate the valve in order to aspirate fluid is an indication of an occluded fluid conduit.

The torque load on the electronic motor shaft is graphically represented as waveforms (202), (203) in Figs. 29a and 29b respectively, wherein the x-axis
25 is a measurement of time and the y-axis is a measurement of torque. Fig. 29a depicts the torque required to retract the syringe for a non-occluded downstream (i.e. patient side) fluid conduit, whereas Fig. 29b depicts the torque developed in the shaft in an occluded or partially occluded downstream fluid conduit.

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- 34 -

Fig. 30a' shows syringe (200) in the open position, and Fig. 30a'' shows syringe (200) with valve (250) rotated, after aspiration has been performed along a non-occluded line. Fig. 30b' shows syringe (200) in the open position, and Fig. 30b'' shows syringe (200) with valve (250) rotated until the system
5 stops the automatic drawing due to the torque valve reaching a predefined upper limit.

Electronic apparatus (60) constantly measures the developed torque on the shaft by measuring the strain in the load cell, or alternatively, the current in
10 the motor. In order to prevent the creation of a vacuum in the syringe and patient side line, the torque load is not increased passed a predefined upper limit value above the base line. If excessive torque is measured, this indicates a high degree of occlusion. The process stops and an alert message is activated.

15

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
20 are intended to be included within the scope of the present invention as defined by the accompanying claims.

Claims:

1. An in-line sampling syringe for selectively introducing a fluid to and aspirating a fluid from a downstream fluid conduit connected to a catheterized patient, said syringe comprising:
- 5
- a. a fluid chamber into which fluid is aspirated;
 - b. a volume regulator for adjusting the volume of said fluid chamber;
 - c. a fluid line through which fluid flows through said syringe to a downstream fluid conduit;

10

 - d. a valve mechanism for:
 - i. selectively:
 - 1. allowing fluid flow along said fluid line; and,
 - 2. preventing fluid flow along said fluid line while simultaneously aspirating a fluid; and,

15
 - ii. selectively shifting said volume regulator to adjust the volume of said fluid chamber;
 - e. a housing for joining said fluid chamber, said fluid line, said valve mechanism, said volume regulator and said control mechanism; and,

20

 - f. a electronic control apparatus for operating said valve mechanism.
- 25
2. The syringe of claim 1, wherein the fluid chamber comprises a first longitudinal end having an opening for communication with a downstream fluid conduit, and a second longitudinal end having an opening for communication with the fluid line.
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- 36 -

3. The syringe of claim 2, wherein the valve mechanism comprises an open position for allowing fluid to flow through the fluid line and a closed position for preventing fluid flow through said fluid line.
- 5 4. The syringe of claim 3, wherein the valve mechanism comprises an opening having a first end functioning as the inlet, and a second end, functioning as the outlet.
- 10 5. The syringe of claim 4, wherein the first end of said valve mechanism is in communication with a port at the proximal end of said syringe, and the second end of the valve mechanism is in communication with the second end of the fluid line.
- 15 6. The syringe of claim 5, wherein the volume regulator comprises a sealing gasket for preventing leakage of fluid out of the fluid chamber, and a drive portion for shifting said sealing gasket within said fluid chamber.
- 20 7. The syringe of claim 6, wherein the sealing gasket is positioned at a first longitudinal end of the drive portion.
8. The syringe of claim 6, wherein the sealing gasket is shiftingly positioned at the second longitudinal end of the fluid chamber.
- 25 9. The syringe of claim 6, wherein the drive portion comprises a shifting mechanism for allowing said drive portion to shift the sealing gasket.
10. The syringe of claim 9, wherein the shifting mechanism comprises a rack and pinion gears mechanism.

11. The syringe of claim 10, wherein the fluid line extends at least partially along the drive portion.
12. The syringe of claim 11, wherein the fluid line comprises flexible
5 tubing.
13. The syringe of claim 11, wherein the fluid line comprises rigid tubing.
14. The syringe of claim 11, wherein the fluid line comprises telescopically
10 arranged tubing.
15. The syringe of claim 1, wherein the fluid line comprises a first end and a second end, wherein said first end is in communication with the fluid chamber and said second end is in communication with the valve
15 mechanism.
16. The syringe of claim 10, wherein the valve mechanism comprises a handle for actuating the rack and pinion gears mechanism.
17. The syringe of claim 16, wherein the valve mechanism comprises a
20 first position in which said valve mechanism is in an open position and the fluid chamber is at its minimum volume, and a second position in which said valve mechanism is in a closed position and the fluid chamber is at less than its maximum volume.
- 25
18. The syringe of claim 16, wherein the valve mechanism comprises a first position in which said valve mechanism is in an open position and the fluid chamber is at its minimum volume, and a second position in which said valve mechanism is in a closed position and the fluid
30 chamber is at its maximum volume.

19. The syringe of any one of claims 17 and 18, wherein essentially zero amount of fluid is accommodated in the fluid chamber when said fluid chamber is at its minimum volume.
- 5
20. The syringe of any one of claims 17 and 18, wherein the handle rotatingly changes positions.
21. The syringe of claim 5, wherein the housing comprises the port at the proximal end of the syringe.
- 10
22. The syringe of claim 1, wherein the housing comprises an opening having a filtered vent disposed therein, for allowing air to flow therethrough.
- 15
23. The syringe of claim 1, wherein the housing comprises an opening having an antimicrobial vent, wherein at least a portion of said vent is treated with an antibacterial material, such as silver ions.
- 20
24. The syringe of claim 1, wherein the housing comprises an opening having a plug disposed therein, wherein said plug comprises an elastic membrane cover for preventing air from entering into and being released from said housing
- 25
25. The syringe of claim 1, further comprising a measuring gauge having a dial for indicating fluid volume levels that may be accommodated in the fluid chamber.
- 30
26. The syringe of claim 25, wherein the handle of the valve mechanism comprises the gauge dial.

27. The syringe of claim 26, wherein the measuring gauge further comprises means for setting a predefined maximum volume of the fluid chamber.

5

28. The syringe of claim 27, wherein the volume setting means comprises at least one a stopper for preventing the handle from rotating.

29. The syringe of claim 28, wherein the stopper is joined with said syringe via a protrusion from said syringe.

10

30. The syringe of claim 26, wherein the rotation of the valve mechanism is performed manually.

15

31. The syringe of claim 26, wherein the rotation of the valve mechanism is performed by the electronic control apparatus.

32. The syringe of claim 31, wherein the electronic control apparatus comprises a motor for operating the valve mechanism, and wherein said syringe further comprises a coupling for joining said motor with said valve mechanism.

20

33. The syringe of claim 32, wherein the electronic control apparatus is controllable by a remote control device.

25

34. The syringe of claim 33, wherein the remote control device is capable of actuating any one of the following operations:

- a. Base line test;
- b. Occlusion test;
- c. Line opening; and,

30

d. Aspiration.

35. The syringe of claim 33, wherein the remote control device is in communication with the electronic control apparatus via cable.

5

36. The syringe of claim 33, wherein the remote control device is in communication with the electronic control apparatus via a wireless connection.

10

37. The syringe of claim 1, further comprising a blood pressure measuring system.

38. The syringe of claim 37, wherein the blood pressure measuring system comprises a pressure transducer and means for calibrating the pressure of said pressure transducer.

15

39. The syringe of claim 38, wherein the operation of the valve mechanism is performed by the electronic control apparatus.

20

40. The syringe of claim 39, wherein the electronic control apparatus comprises a motor for operating the valve mechanism, and wherein said syringe further comprises a coupling for joining said motor with said valve mechanism.

25

41. The syringe of claim 40, wherein the electronic control apparatus is controllable by a remote control device.

42. The syringe of claim 41, wherein the remote control device is capable of actuating any one of the following operations:

30

a. Base line test;

- b. Occlusion test;
- c. Zeroing;
- d. Line opening;
- e. Aspiration; and,
- 5 f. Flushing.

43. The syringe of claim 41, wherein the remote control device is in communication with the electronic control apparatus via cable.

10 44. The syringe of claim 41, wherein the remote control device is in communication with the electronic control apparatus via a wireless connection.

15 45. The syringe of claim 38, wherein the pressure transducer is situated within the fluid chamber.

46. The syringe of claim 45, wherein the calibrating means comprises the valve mechanism and an outlet communicatable with the atmosphere.

20 47. The syringe of claim 46, wherein the valve mechanism comprises a first position in which said valve mechanism is in a zeroing position wherein the pressure transducer is in communication with the atmosphere through the outlet; a second position in which said valve mechanism is in an open position wherein the fluid chamber is at its
25 minimum volume; and, a third position in which said valve mechanism is in a closed position and at least an initial aspiration is performed.

48. The syringe of claim 38, wherein the pressure transducer is situated downstream from the fluid chamber.

49. The syringe of claim 48, wherein the calibrating means comprises an additional valve mechanism situated downstream from the fluid chamber, and an outlet communicatable with the atmosphere.

5 50. The syringe of claim 49, wherein the additional valve mechanism comprises a first position in which said additional valve mechanism is in a zeroing position in which the pressure transducer is in communication with the atmosphere through the outlet and fluid is prevented from flowing to the downstream fluid conduit, and a second
10 position in which said additional valve mechanism is in an open position for allowing fluid to flow to the downstream fluid conduit.

15 51. The syringe of claim 37, wherein the blood pressure measuring system comprises a cable and connector for connecting to the electronic control apparatus.

20 52. The syringe of claims 37, wherein the blood pressure measuring system comprises a connector for directly connecting the electronic control apparatus.

25 53. An in-line sampling system for selectively introducing fluid to and aspirating a fluid from a downstream fluid conduit connected to a catheterized patient, said system comprising
a. the syringe of any one of claims 1 through 52;
b. a fluid reservoir for storing external fluid, and connected to said syringe via an upstream fluid conduit;
c. a catheter for insertion into a patient, and connected to said syringe via a downstream fluid conduit; and,
d. a sampling port situated along said downstream fluid.

30

54. A method of determining the presence of an occlusion along a patient side fluid conduit, said method comprising the following steps:

- a. providing the in-line sampling system of claim 53;
- b. positioning the valve mechanism at a first position for allowing fluid flow along the fluid line;
- c. performing aspiration by shifting the position of the valve mechanism;
- d. measure the increasing torque on the shaft of the motor connected to the syringe by one of:
 - i. taking constant measurements of the strain in the load cell; and,
 - ii. taking constant measurements of the current in the motor
- e. determining whether an occlusion is present along said patient side fluid conduit.

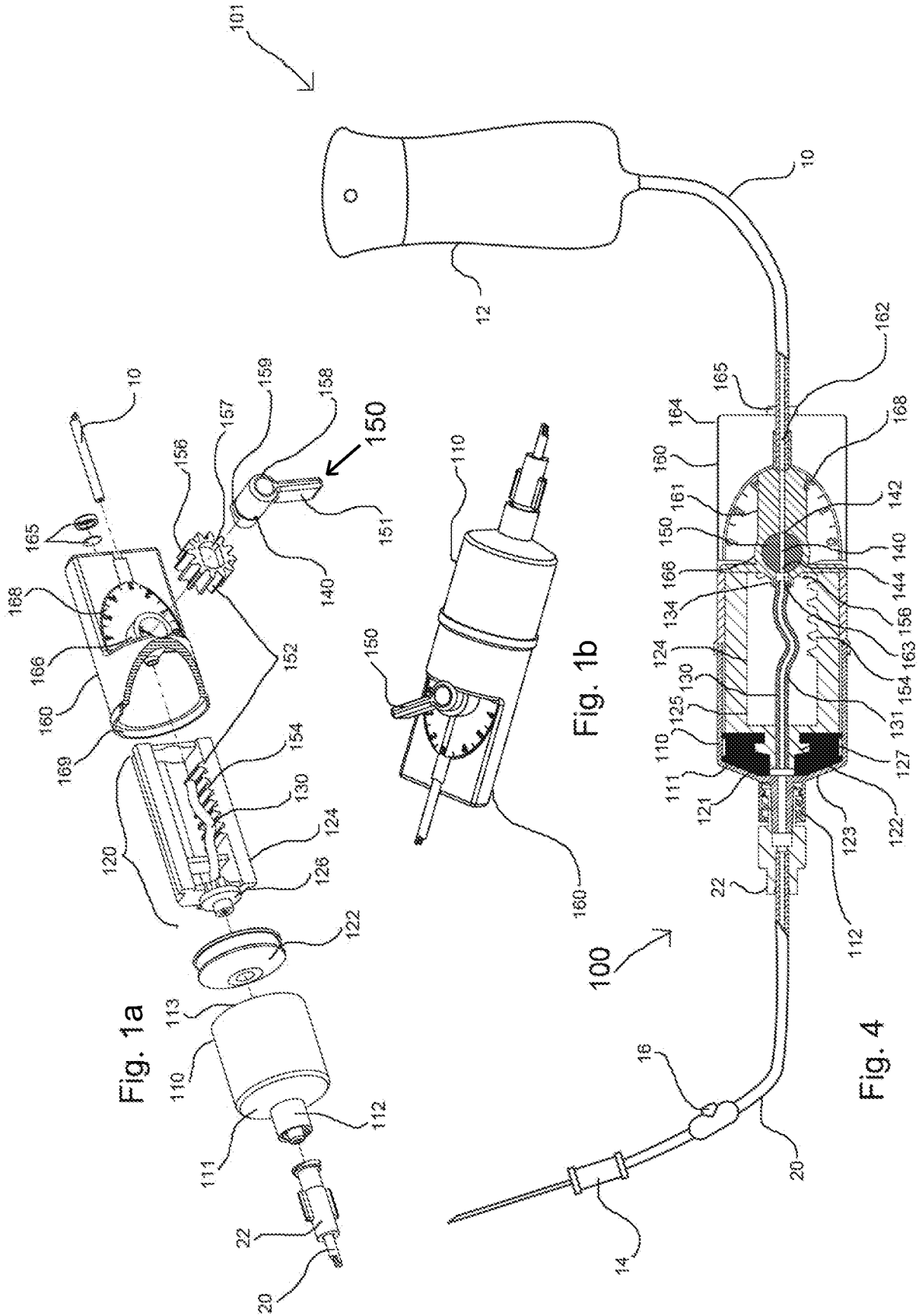
55. The method of claim 54, wherein the valve mechanism is shifted until the torque measurement reaches a predetermined value.

56. A method of determining the presence of an occlusion along a patient side fluid conduit, said method comprising the following steps:

- a. providing the in-line sampling system of claim 53, wherein the syringe comprises a blood pressure measuring system;
- b. positioning the valve mechanism at a first position for allowing fluid flow along the fluid line;
- c. performing aspiration of a predetermined base line volume by shifting the position of said valve mechanism;
- d. recording the time-volume-pressure base line characteristic;
- e. returning said valve mechanism to said first position;
- f. performing aspiration of a predetermined occlusion volume by shifting the position of said valve mechanism;

- 44 -

- g. recording the time-volume-pressure occlusion characteristic;
- h. comparing the values of the occlusion characteristic with said base line characteristic;
- 5 i. determining whether said occlusion characteristic is within the predefined limits of said baseline characteristic; and,
- 10 j. returning said valve mechanism to said first position when said occlusion characteristic is within the predefined limits of said baseline characteristic, and sounding an indicative alarm when said occlusion characteristic is outside of the predefined limits of said baseline characteristic followed by returning said valve mechanism to said first position.



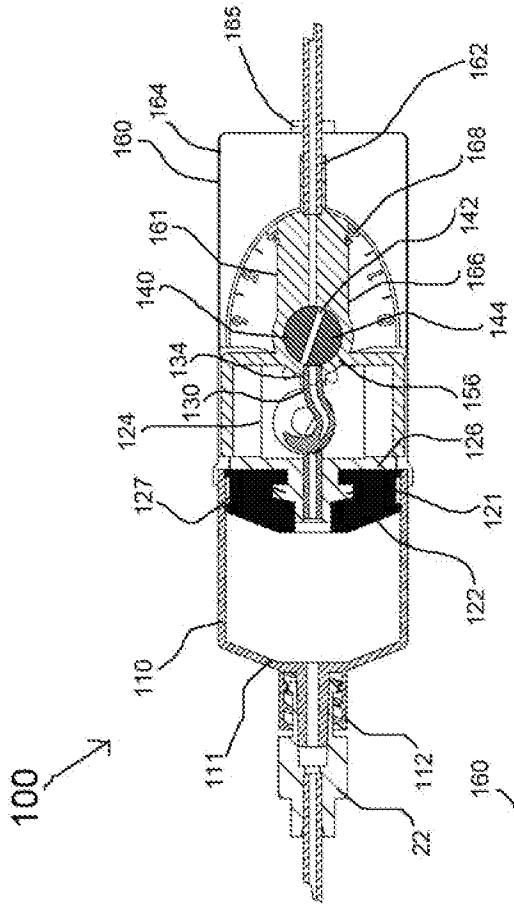


Fig. 2b

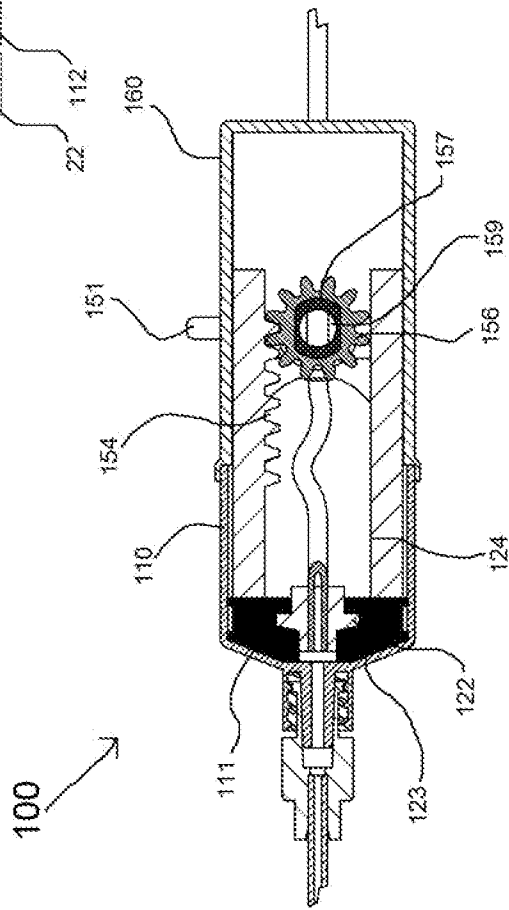


Fig. 3

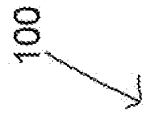
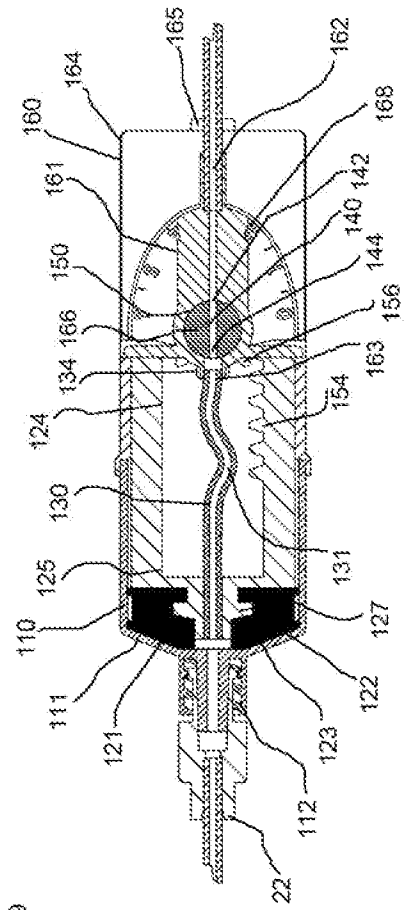
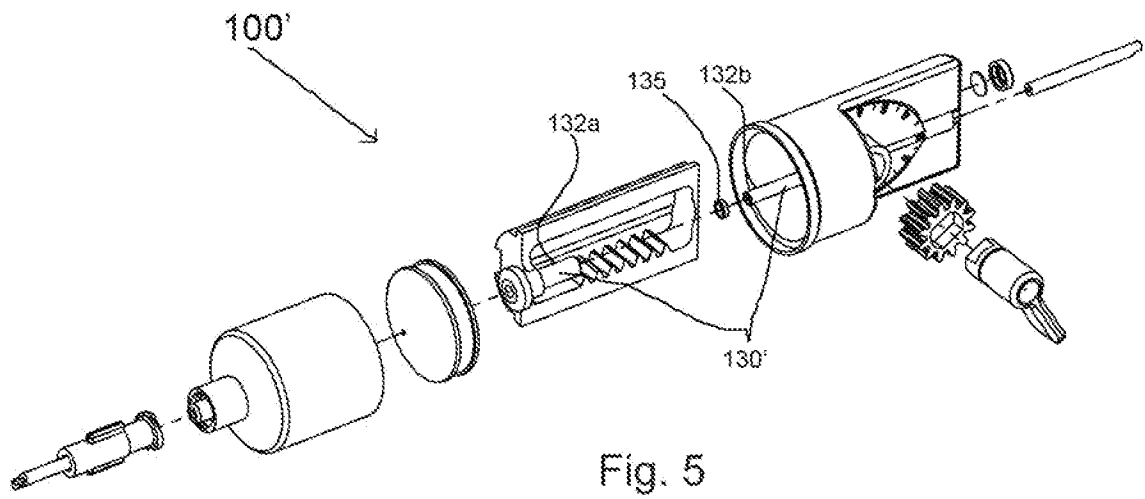
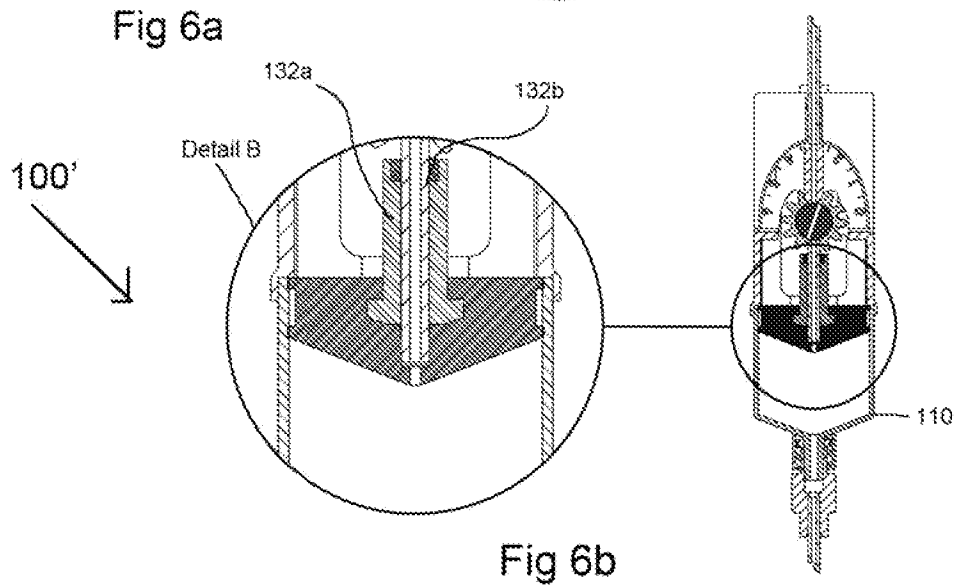
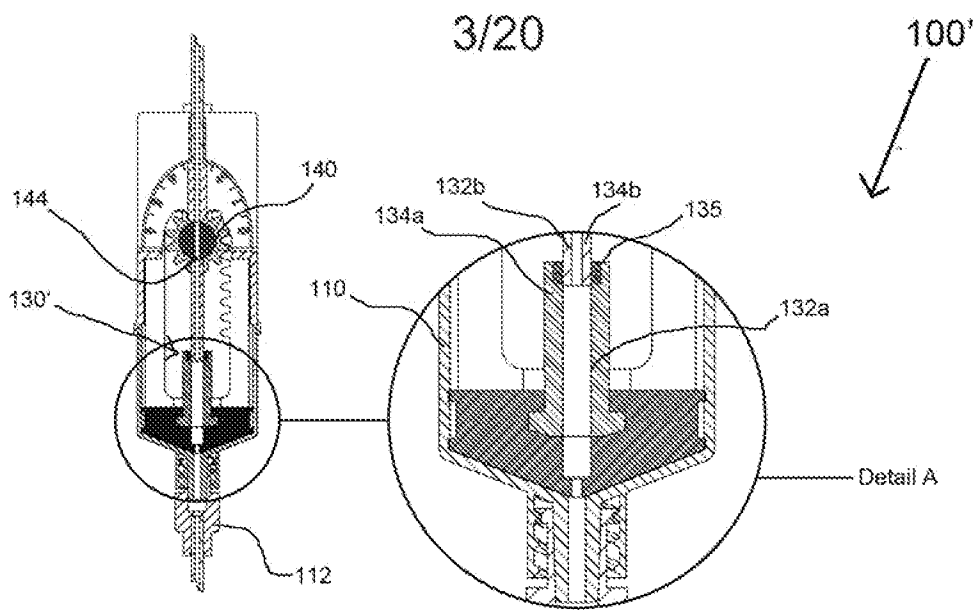


Fig. 2a





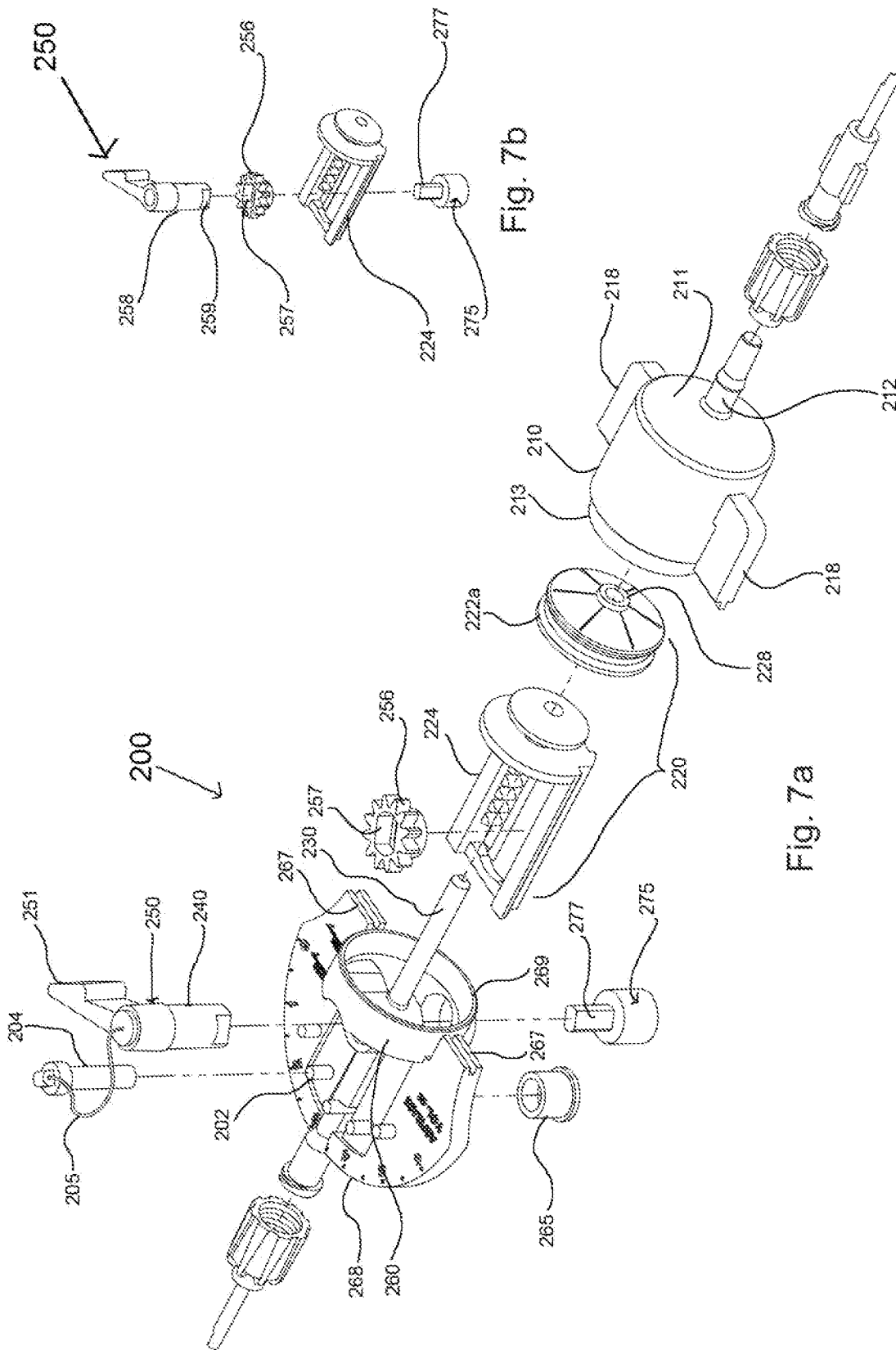
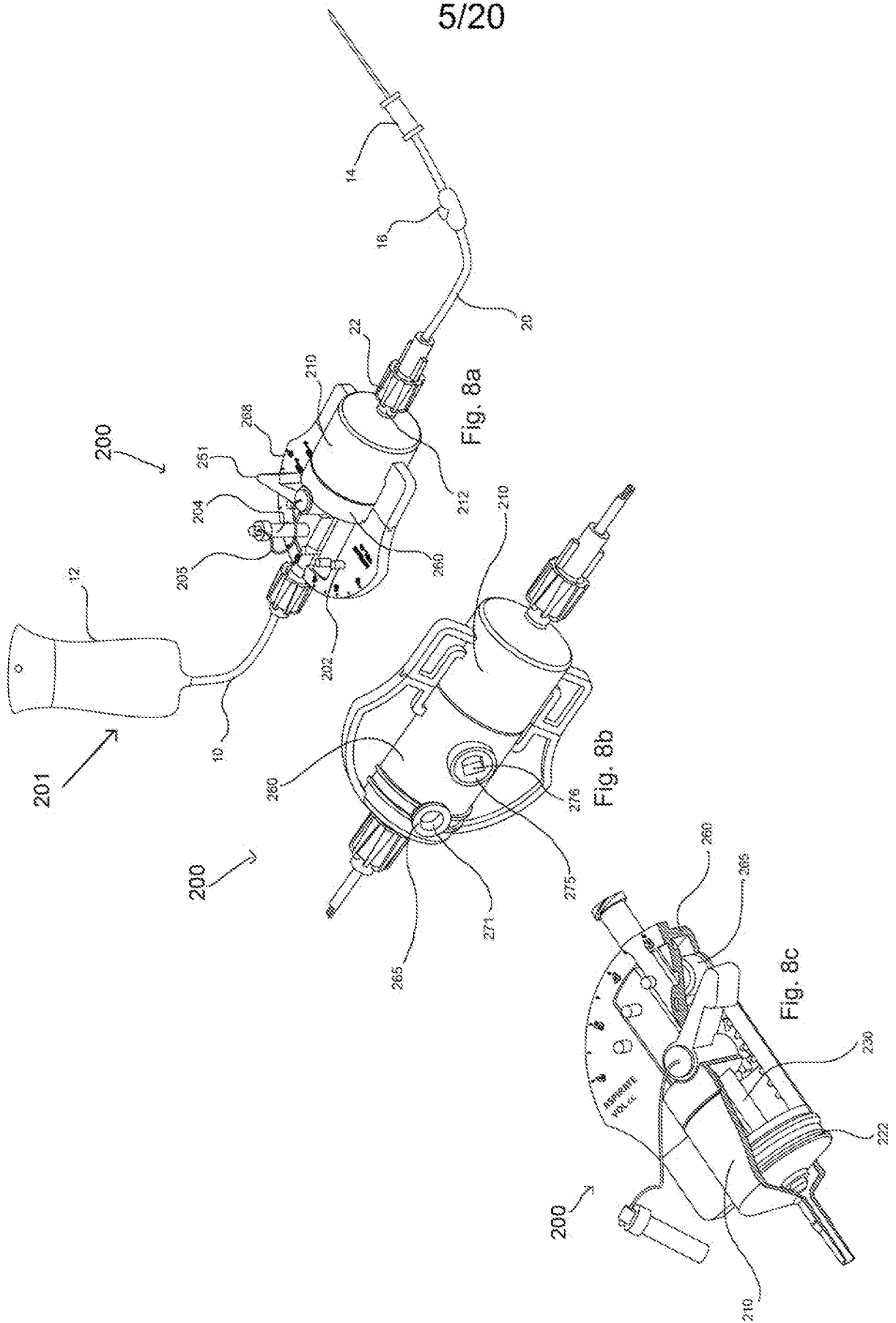


Fig. 7b

Fig. 7a

5/20



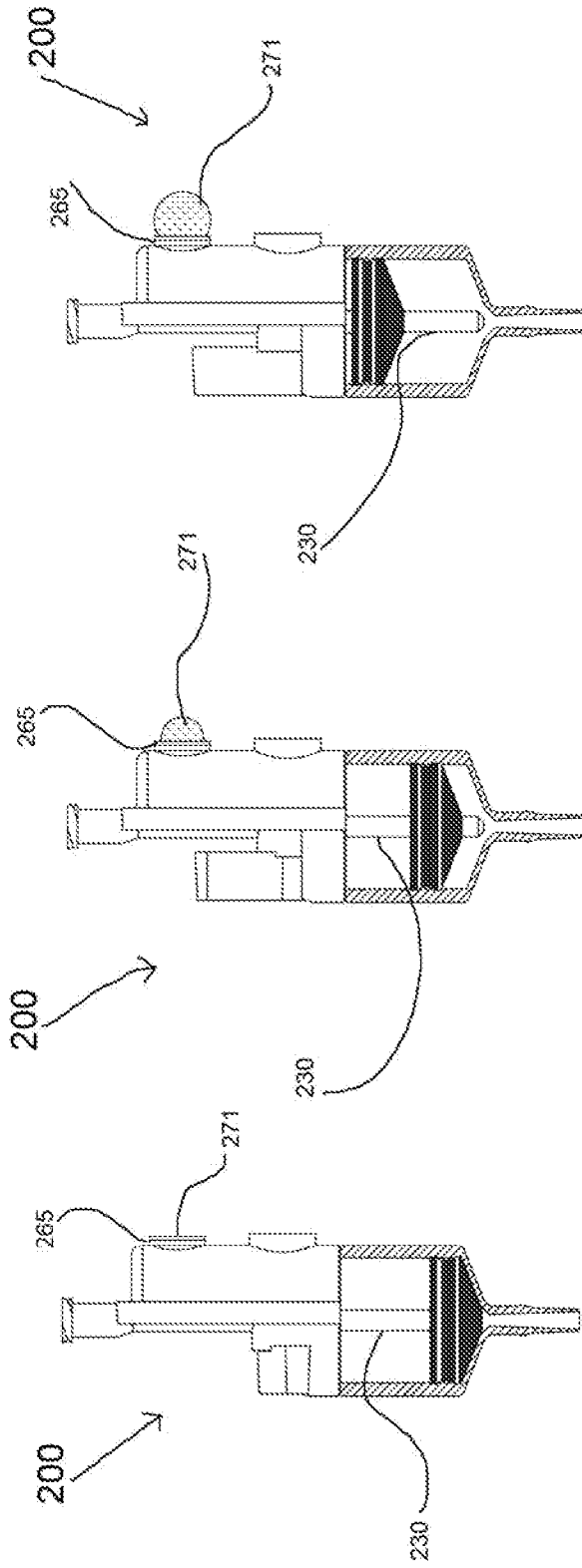


Fig. 9c

Fig. 9b

Fig. 9a

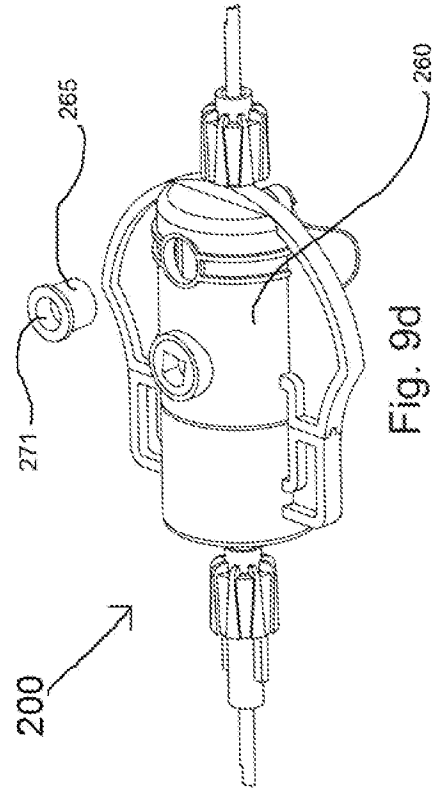
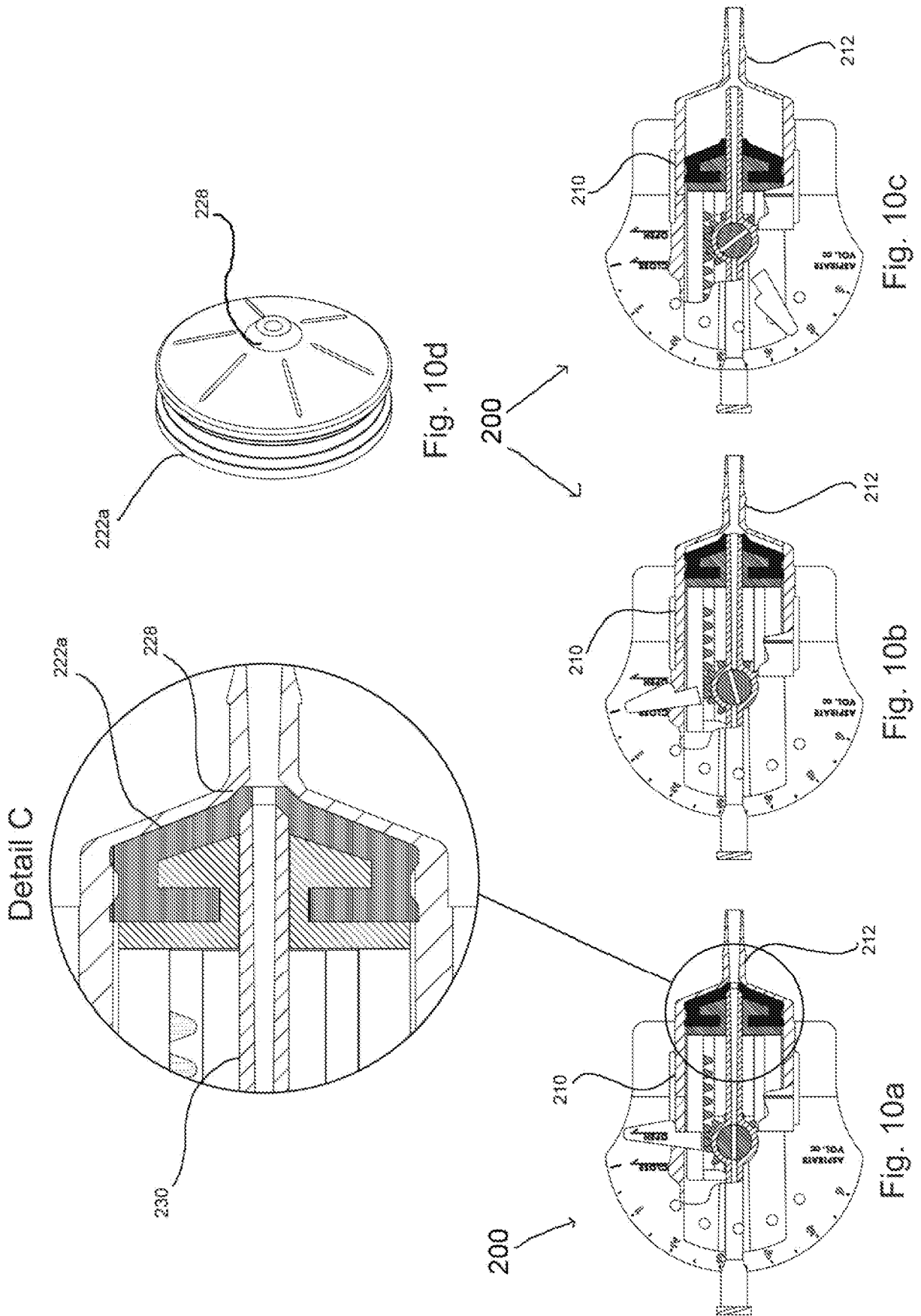
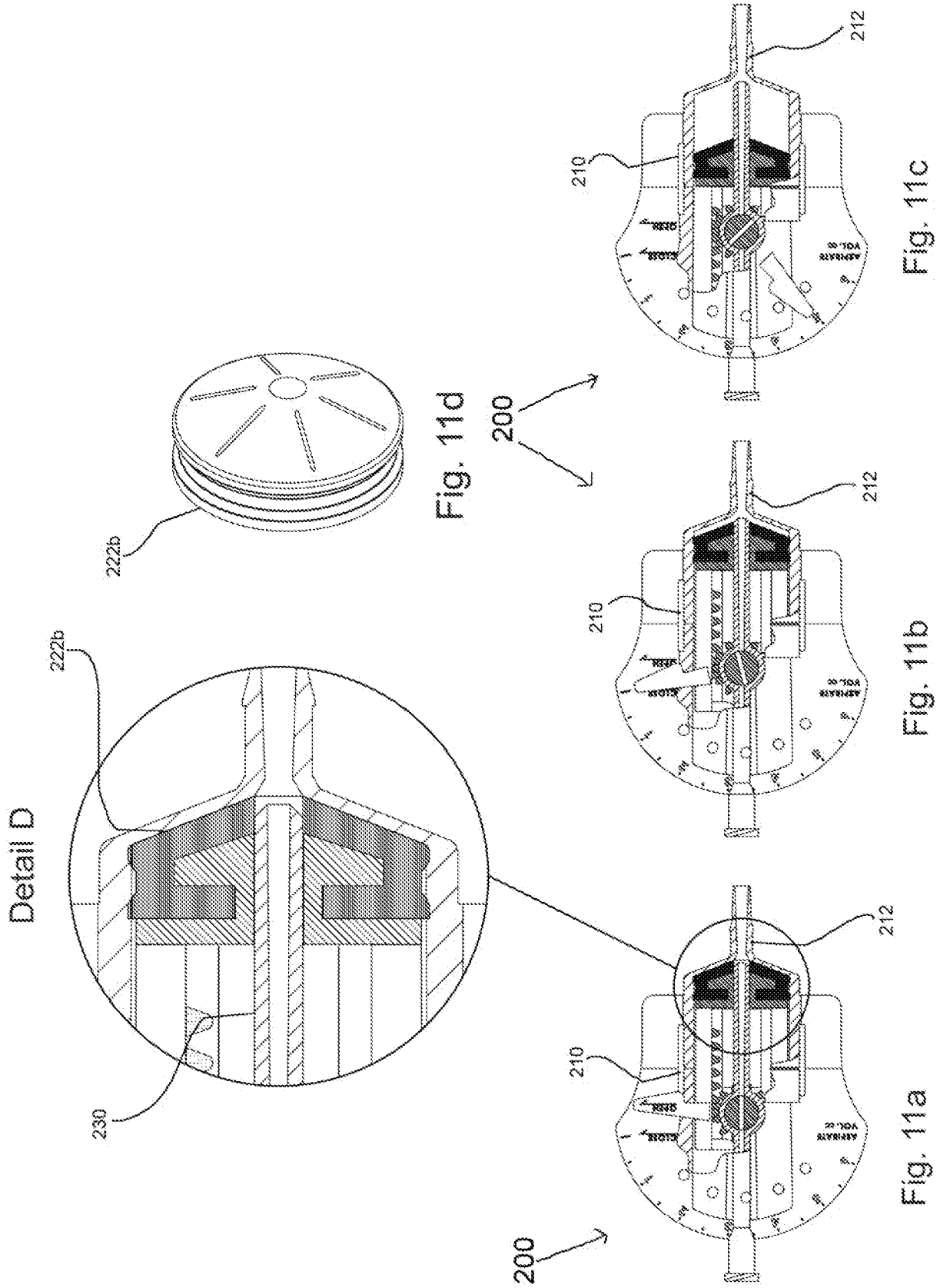


Fig. 9d

7/20





9/20

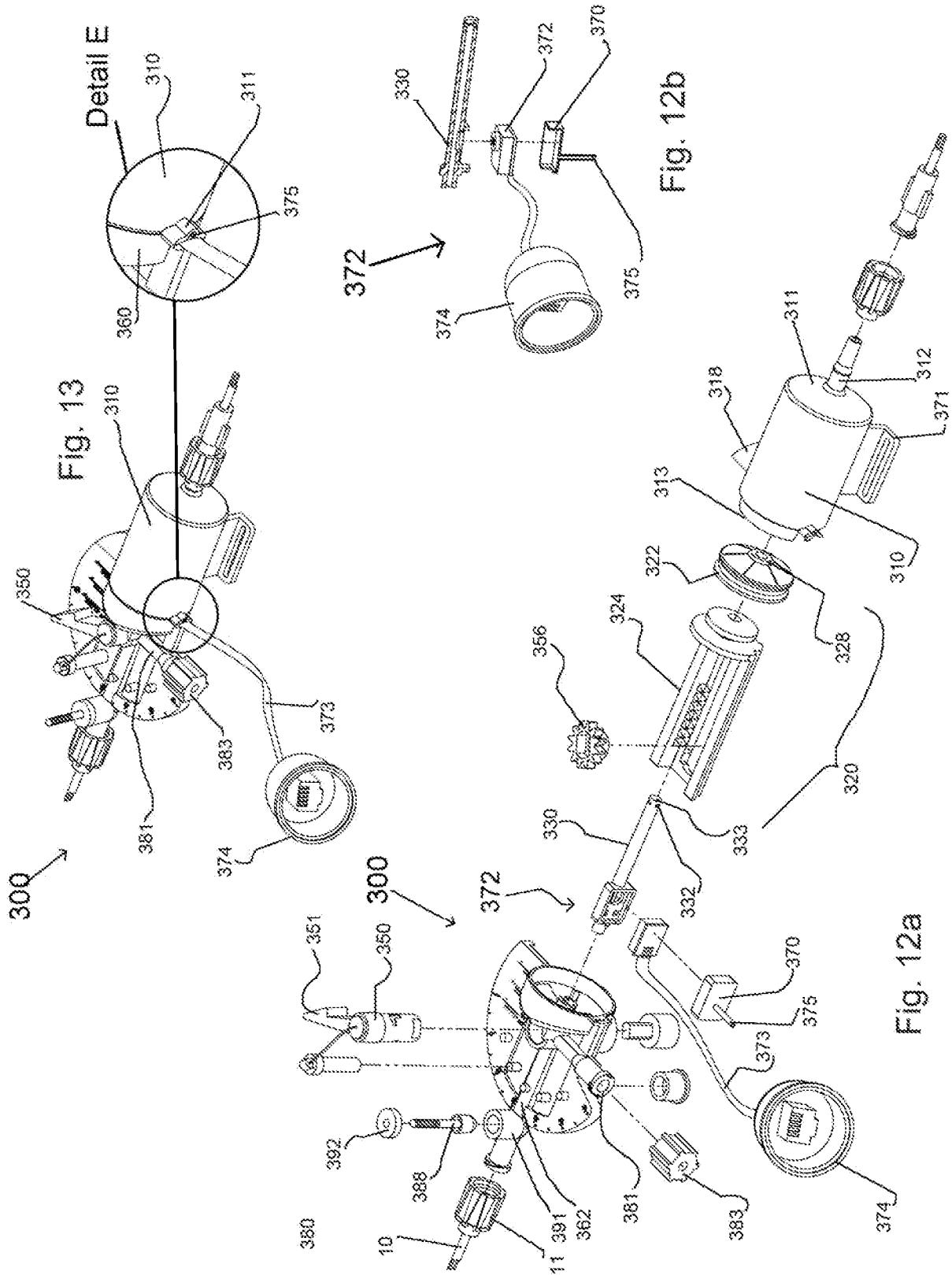


Fig. 12a

Fig. 12b

Fig. 13

Detail E

10/20

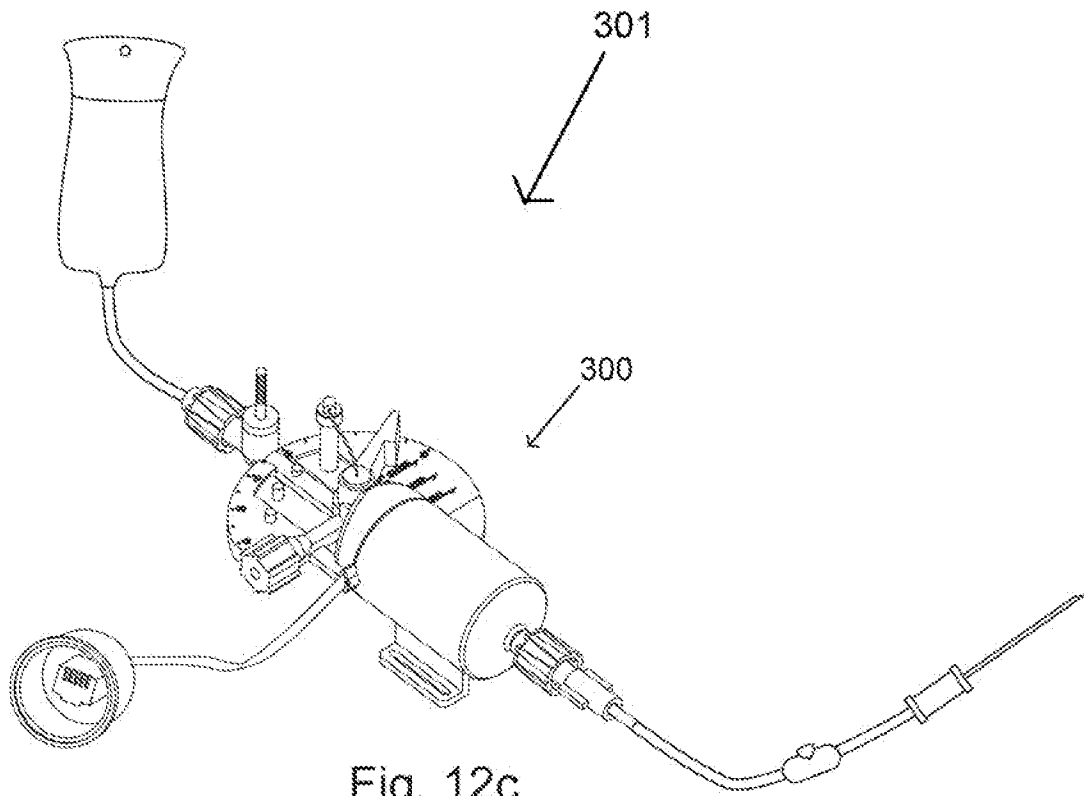


Fig. 12c

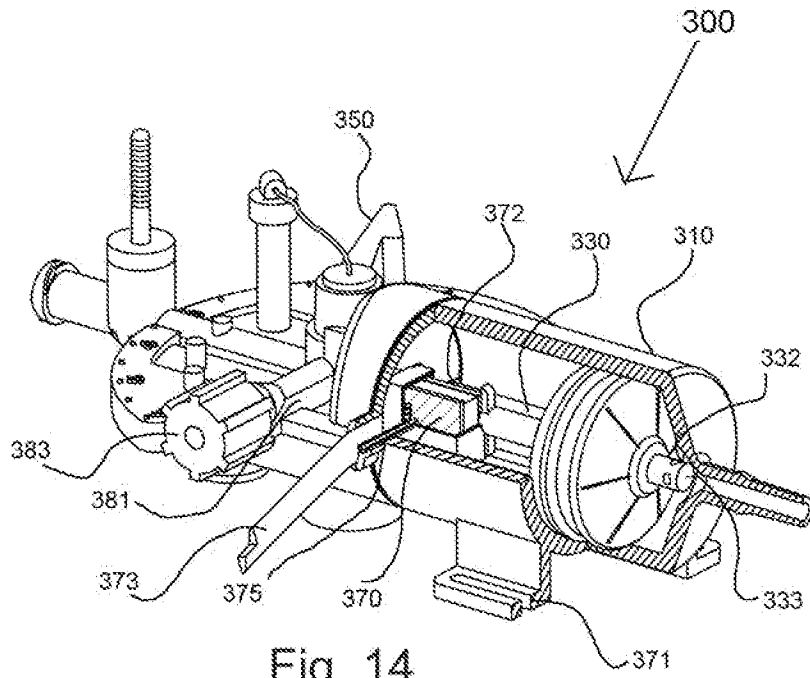
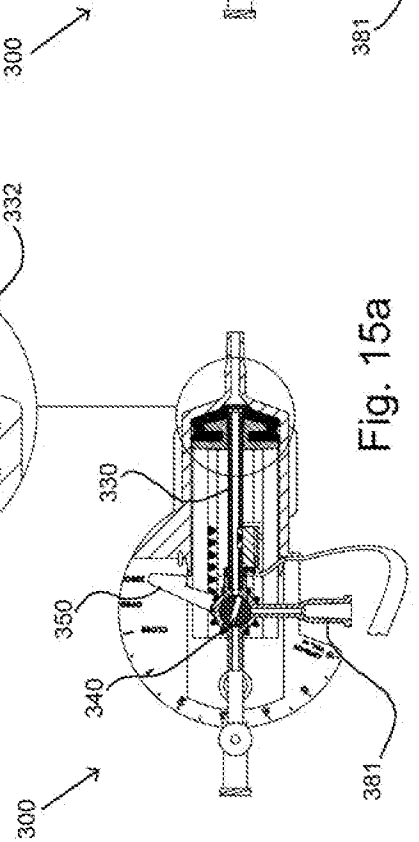
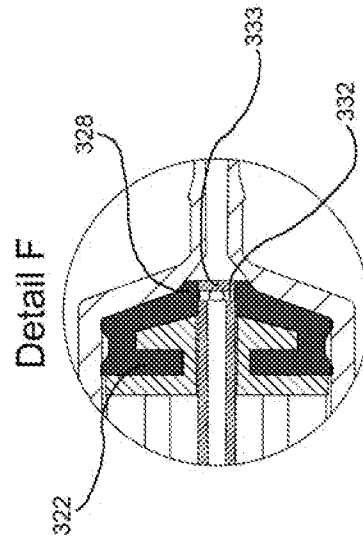
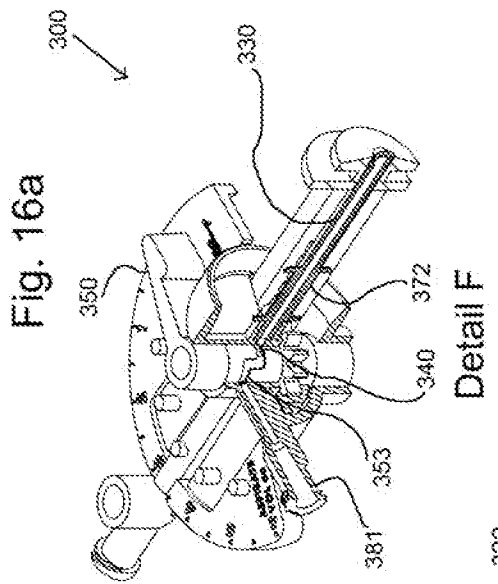
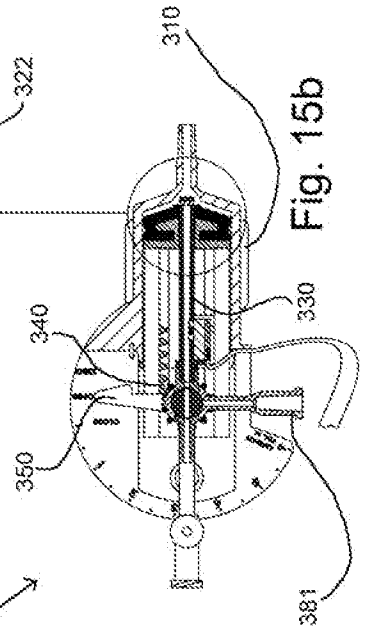
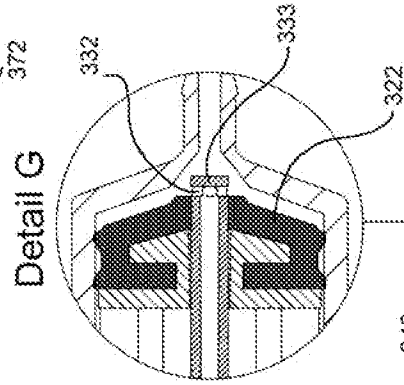
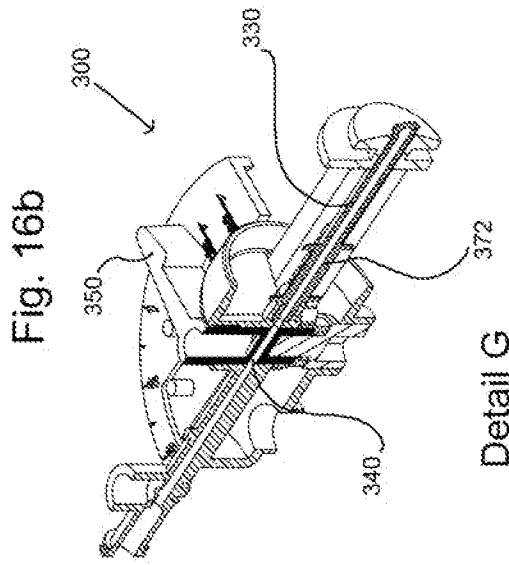
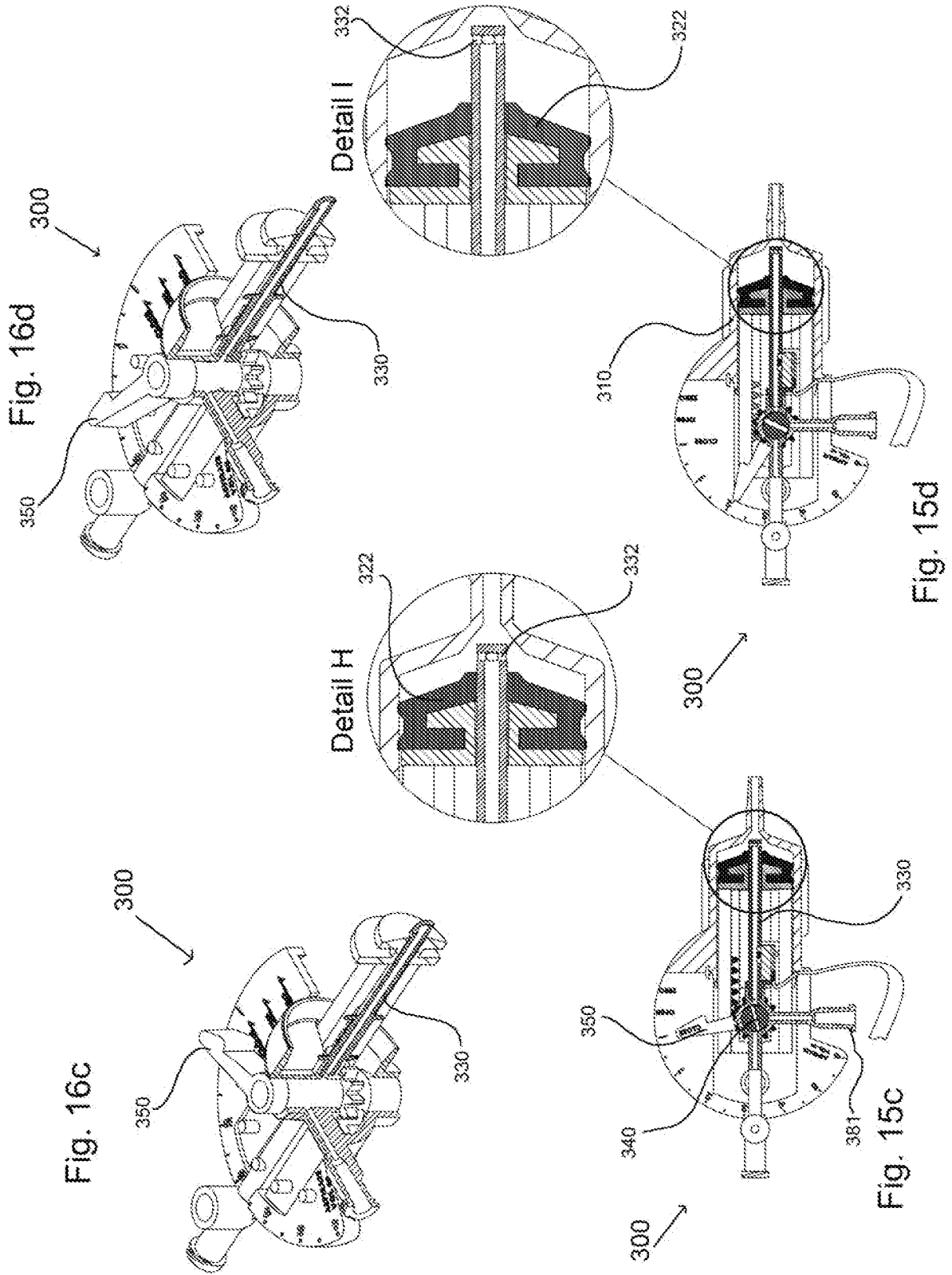
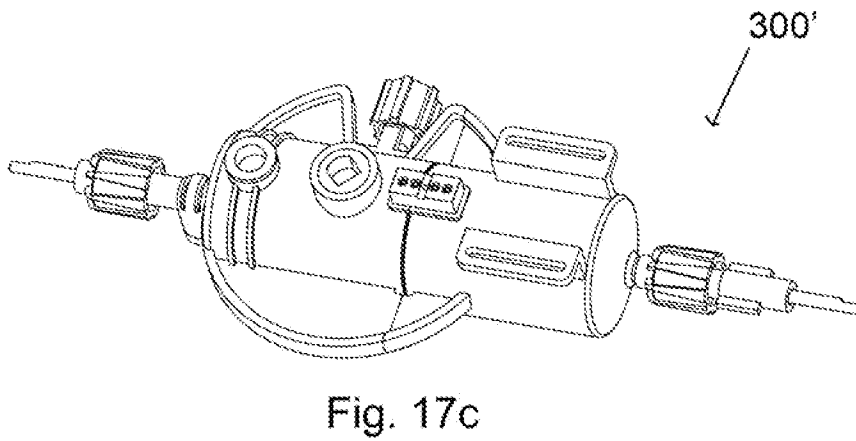
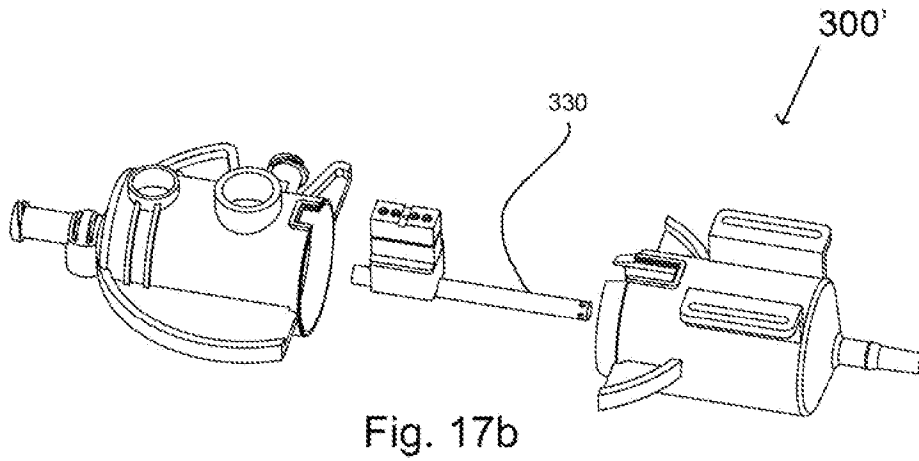
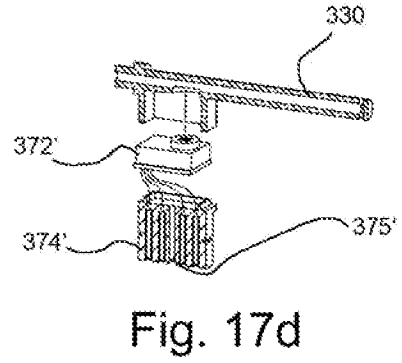
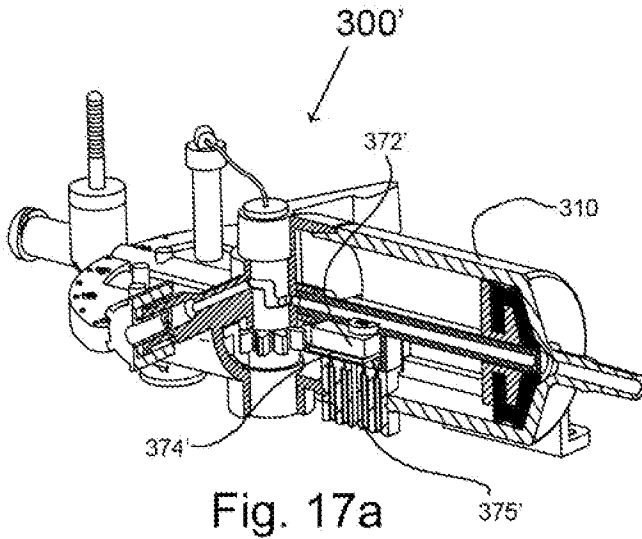


Fig. 14

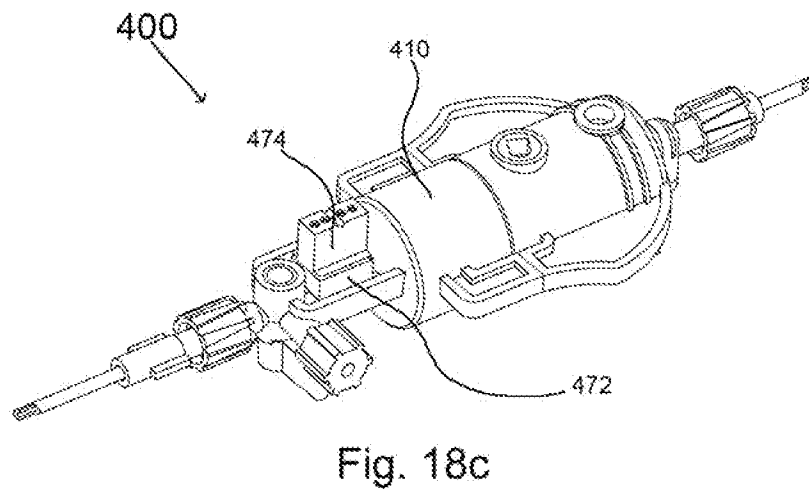
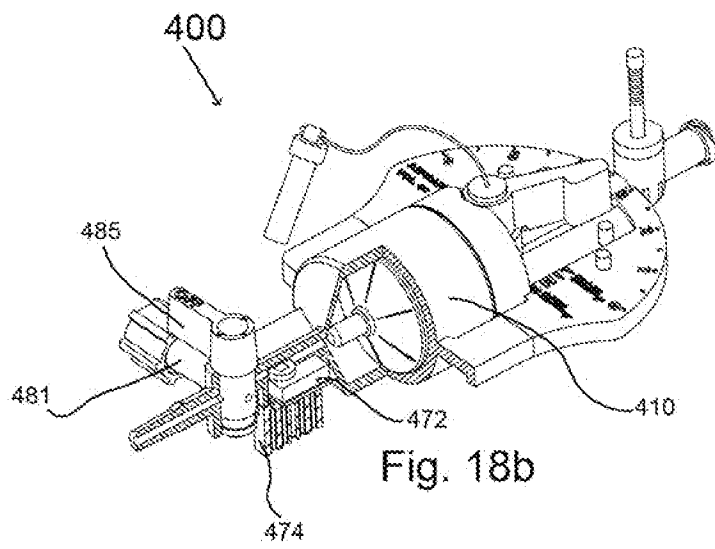
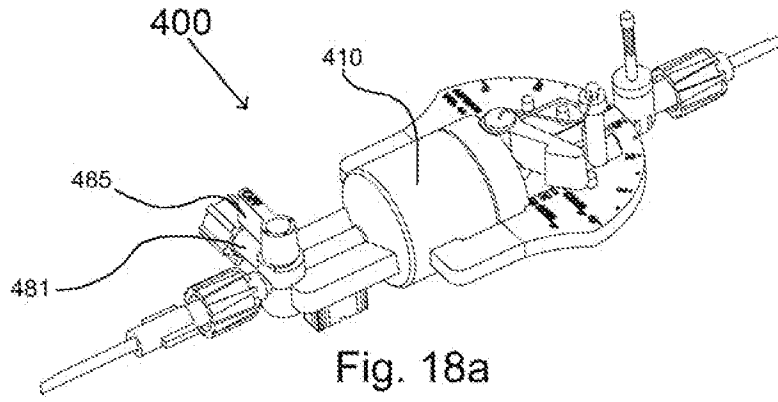




13/20



14/20



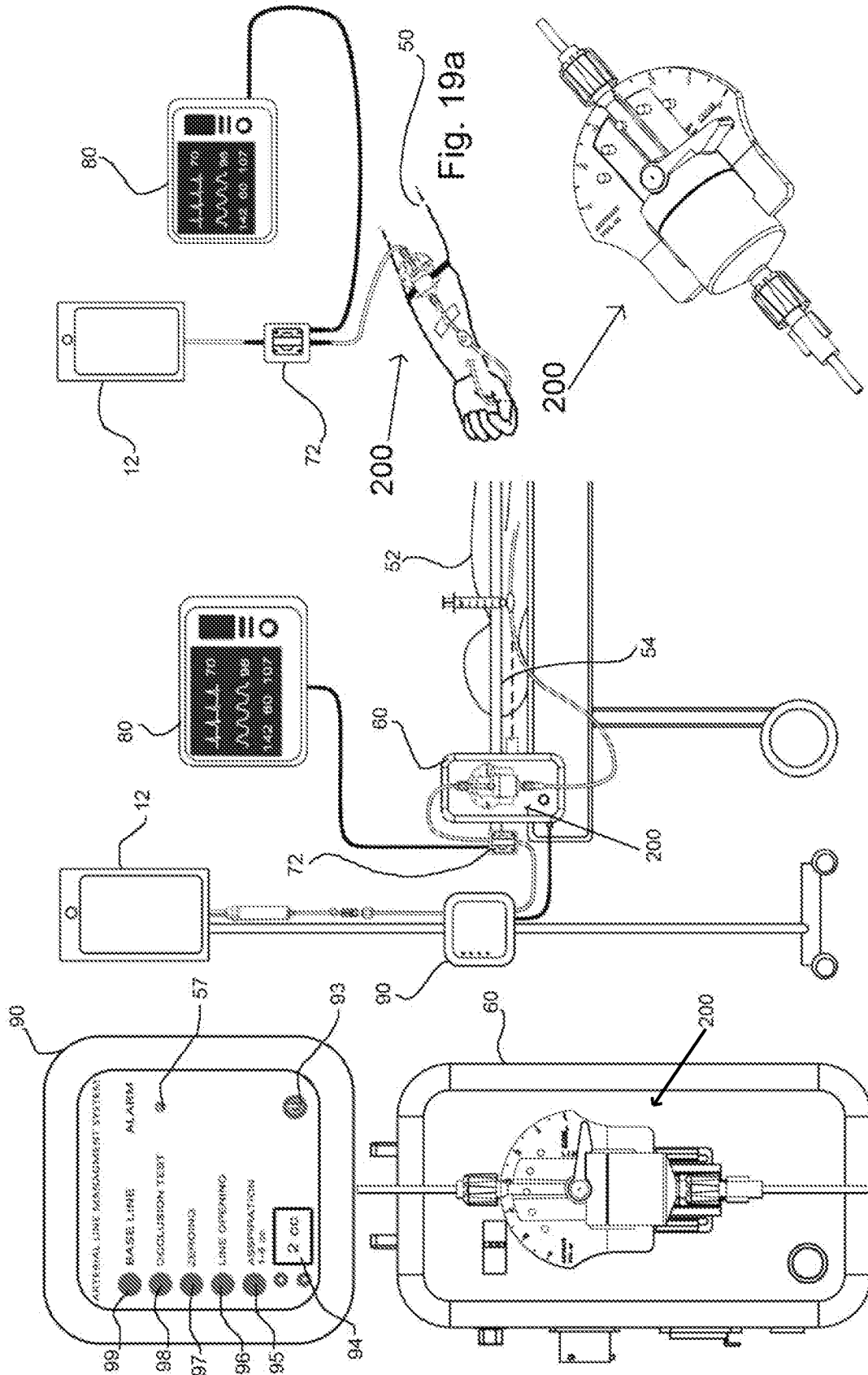


Fig. 20a

Fig. 21a

Fig. 22a

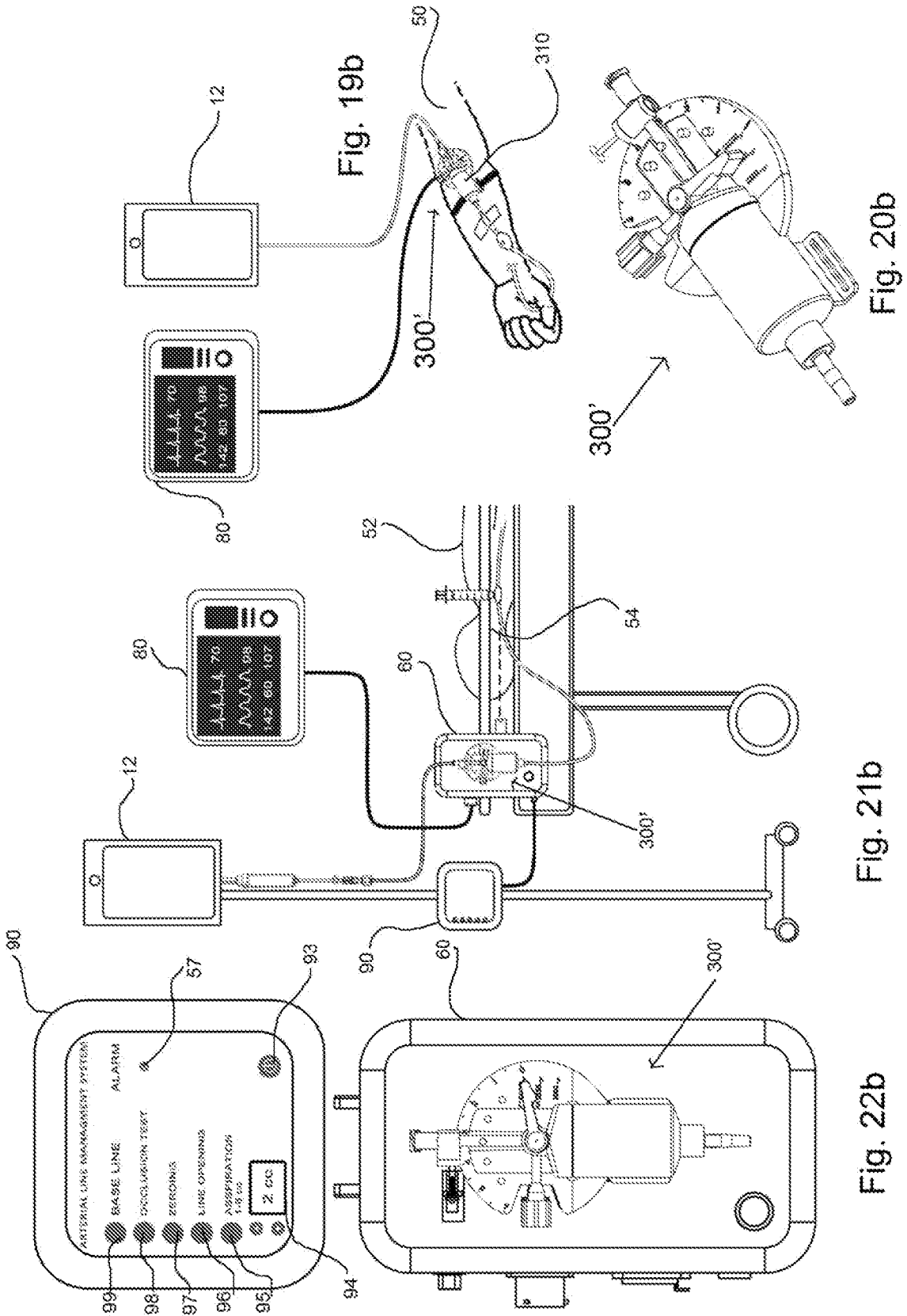


Fig. 19b

Fig. 20b

Fig. 21b

Fig. 22b

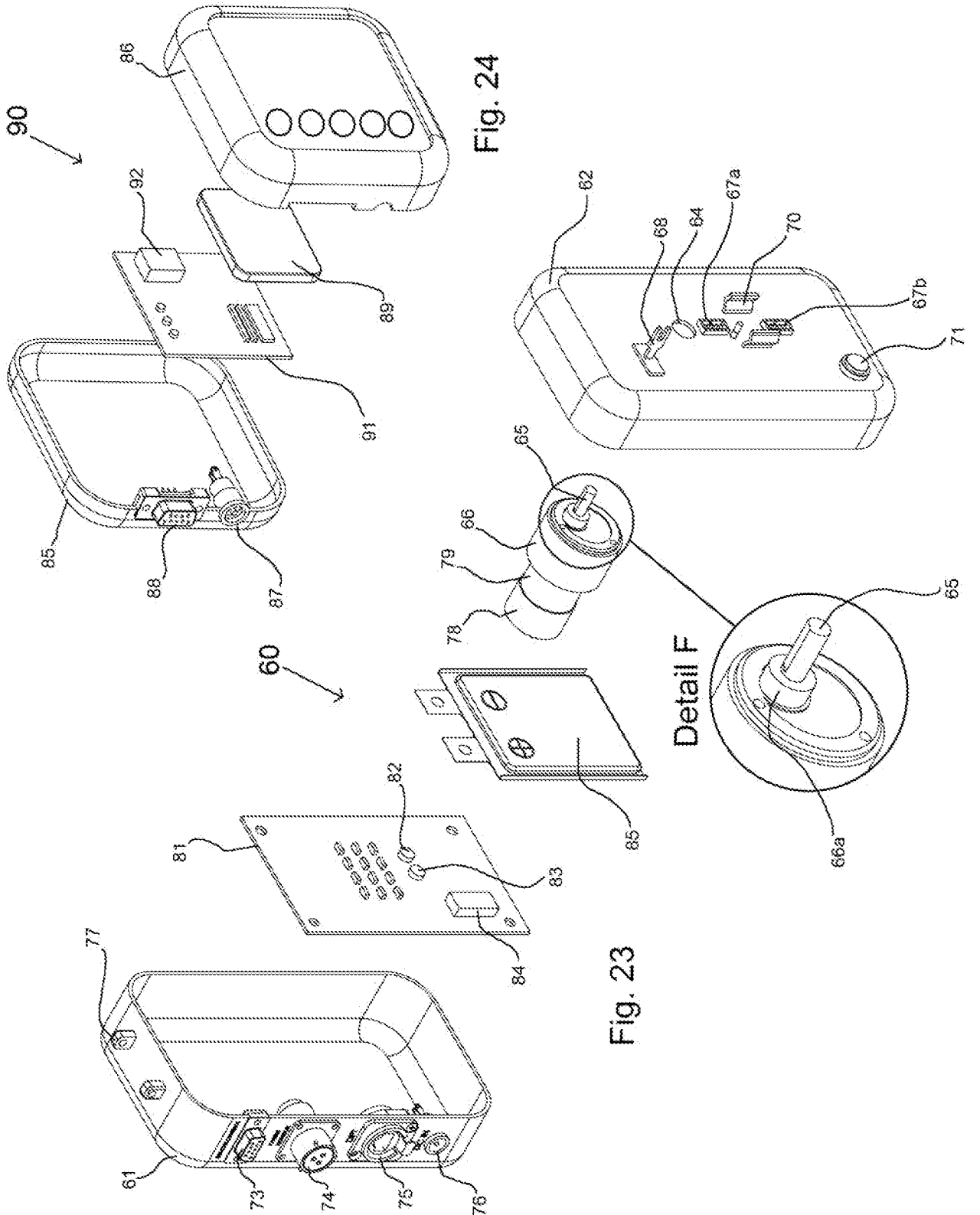


Fig. 24

Fig. 23

Detail F

18/20

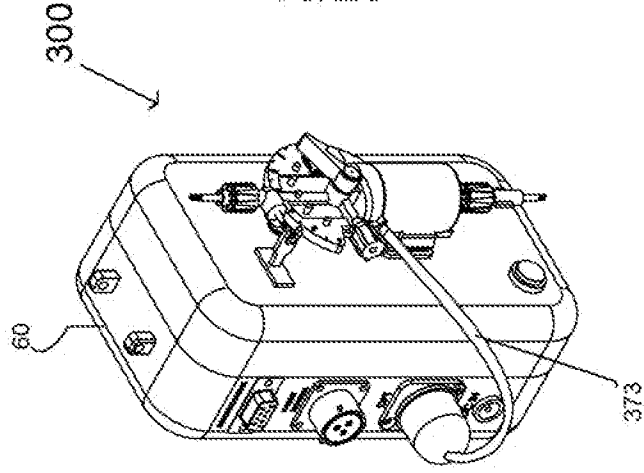


Fig. 25c

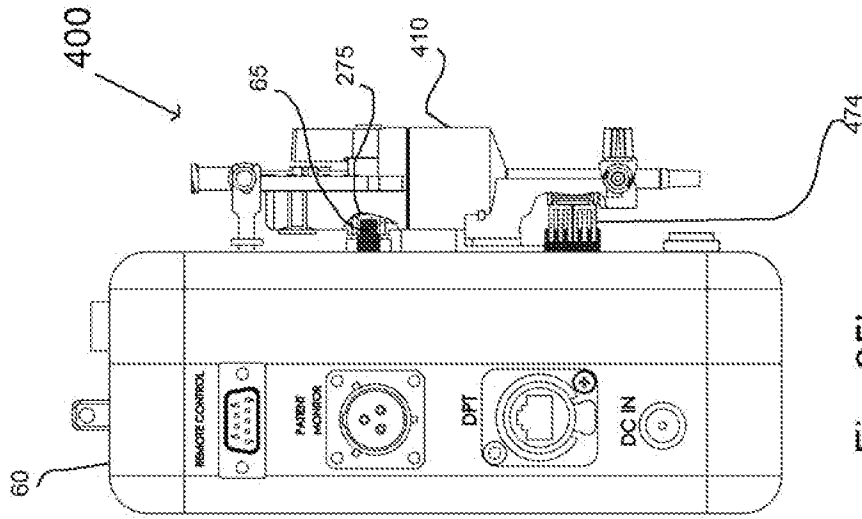


Fig. 25b

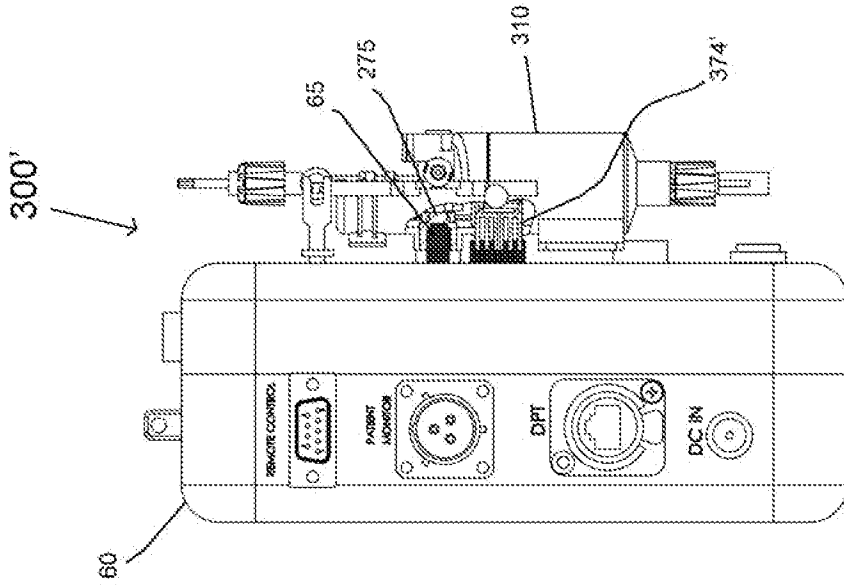


Fig. 25a

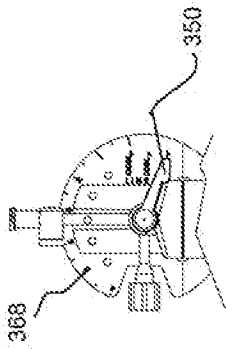


Fig. 27a

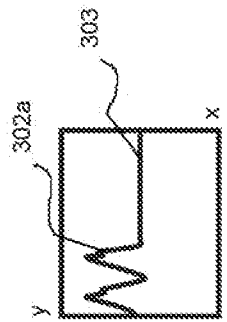


Fig. 26a

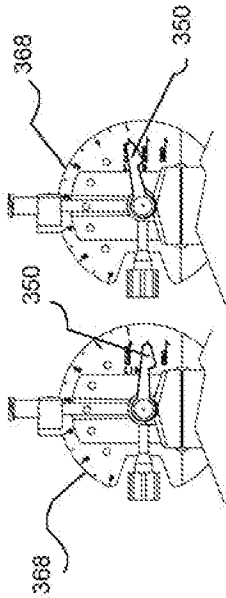


Fig. 27b'

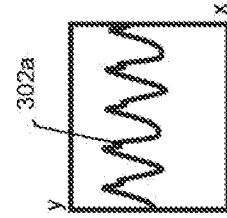


Fig. 26b

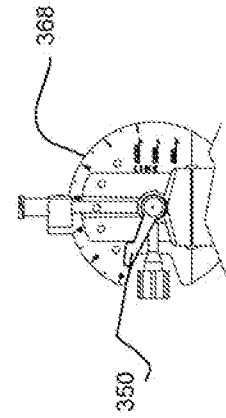


Fig. 27c

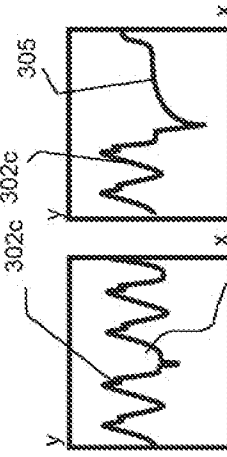


Fig. 26c

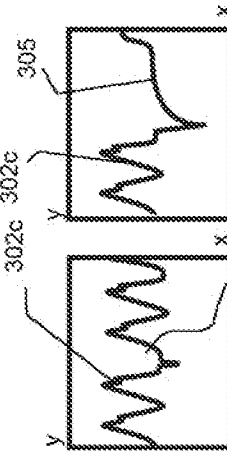


Fig. 26d

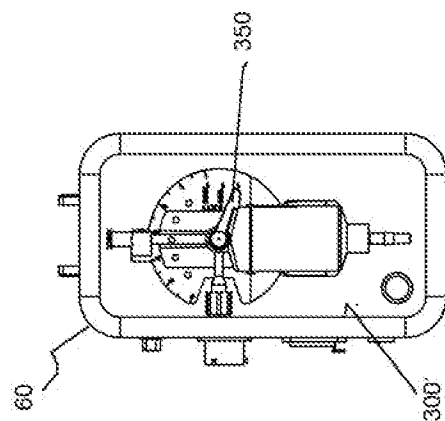


Fig. 28a

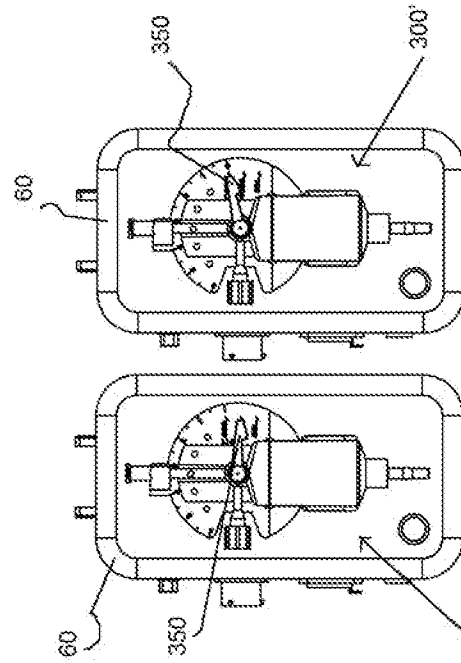


Fig. 28b'

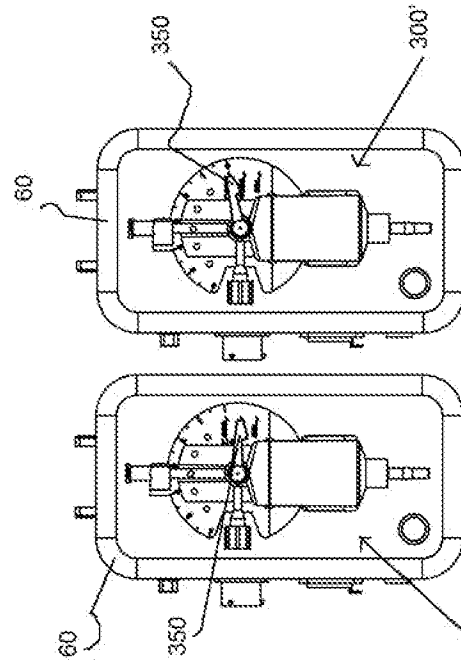


Fig. 28b''

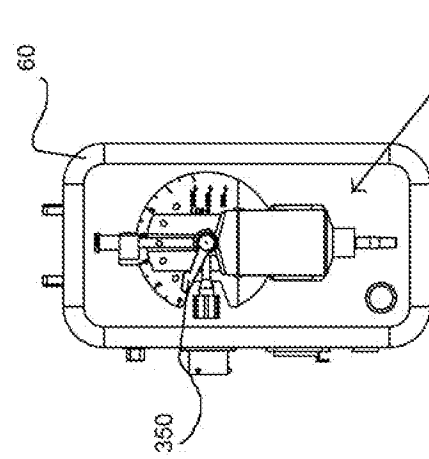


Fig. 28c

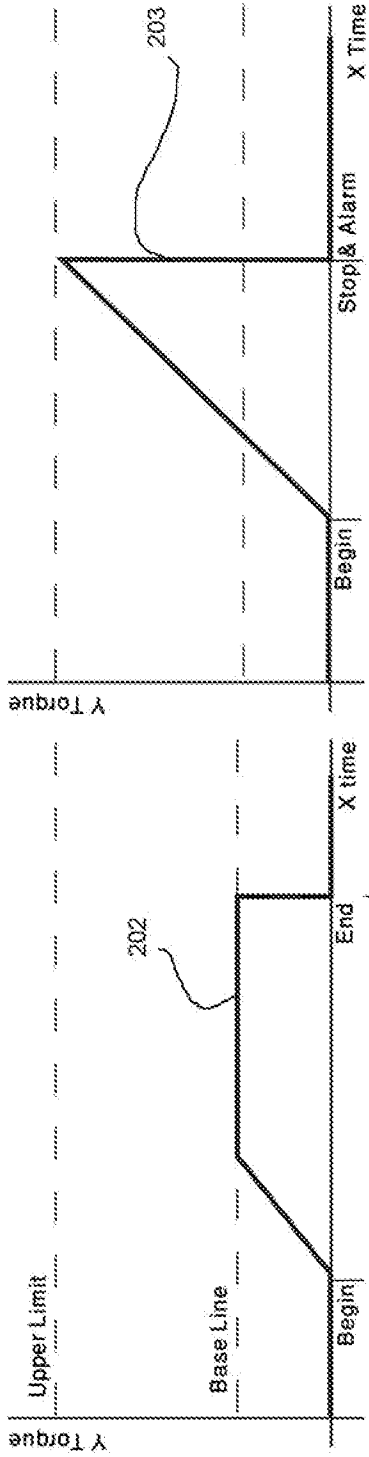


Fig. 29a

Fig. 29b

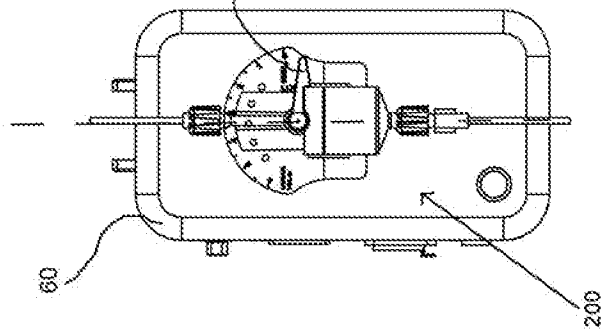


Fig. 30a'

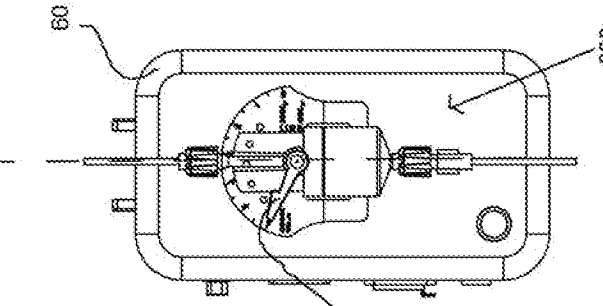


Fig. 30a''

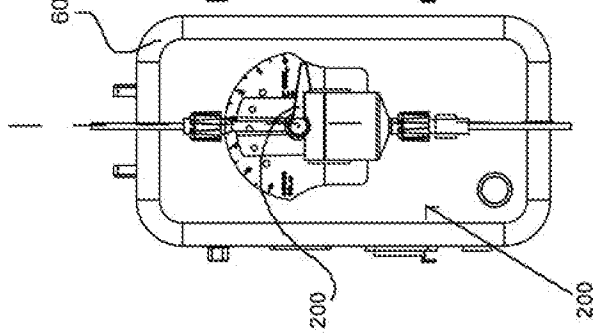


Fig. 30b'

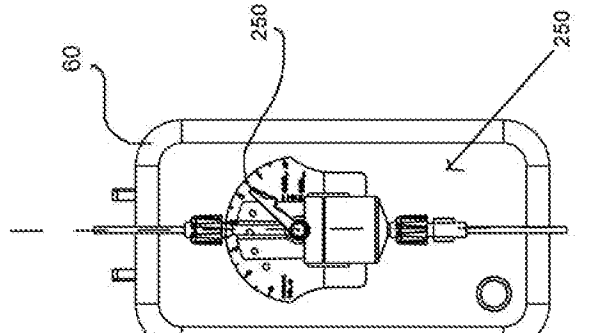


Fig. 30b''