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NOTICE OF ENTITLEMENT

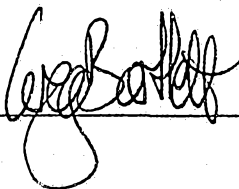
I, NORMAN PATTULLO, of 1 Redburn Avenue, Giffnock, Glasgow G46 6RH, United Kingdom, being the applicant in respect of an application in respect of an invention entitled "Fluid Delivery Apparatus" state the following:-

1. I am the Nominated Person to whom I request that the patent be granted.
2. The actual inventor is: O'NEIL, Alexander George Brian, of 200 Churchill Avenue, Subiaco, Perth, Western Australia, Australia, and I have entitlement from the actual inventor by virtue of the following facts:

I am the assignee of the inventor in respect of the invention.

3. I have entitlement from the applicant of the application(s) listed in the declaration under Article 8 of the PCT by Assignment.
4. The basic application listed in the declaration made under Article 8 of the PCT is the first application made in a Convention country in respect of the invention.

NORMAN PATTULLO
By his Patent Attorney



Date: 23 March 1995



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(57) Claim

1. Apparatus for delivery of fluid to a patient, the apparatus comprising a first reservoir for containing a pressurised first fluid, a second reservoir for containing the fluid to be delivered and having an outlet therefor, means between the first and second reservoirs for transferring a force produced by the pressure of the first fluid to the fluid of the second reservoir, characterised in that a tube having a narrow lumen is disposed between the outlet of the second reservoir and the patient, and where the rate of fluid delivery to the patient is determined by the diameter of the lumen of the tube.



PCT

under INID Number (74), replace the existing text by "ON
"Agent: PATTULLO, Norman; Murgitroyd & Company,
373 Scotland Street, Glasgow G5 8QA (GB)."

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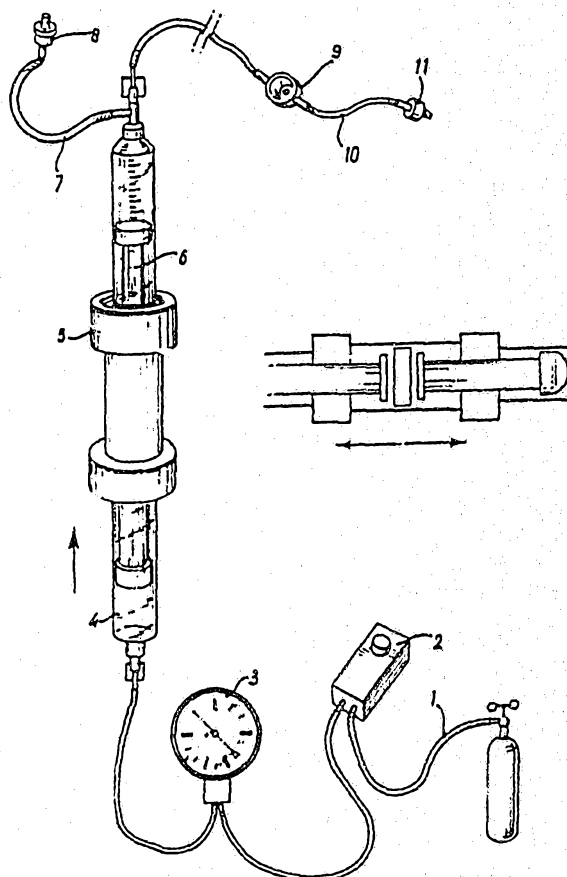
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(54) Title: FLUID DELIVERY APPARATUS

(57) Abstract

Fluid delivery apparatus comprising a first reservoir (4) for containing a first fluid under pressure, a second reservoir (6) for containing the fluid to be delivered and having an outlet therefor, means between the first and second reservoirs for transferring a force produced by the pressure of the first fluid to the fluid of the second reservoir, and fluid flow restricting means (10) in communication with the outlet of the second reservoir. Preferably means (2) are provided for varying the pressure of the first fluid in the first reservoir.



1 "Fluid Delivery Apparatus"

2

3 This invention relates to fluid delivery apparatus.

4

5 Conventional pumps used in the medical device industry
6 are primarily electronically controlled and
7 electronically driven. While the industry has focused
8 in this direction there are many disadvantages of
9 electronics. These include the risk of microelectric
10 shocks, variations in power supplies, lack of batteries
11 and cost.

12

13 In addition, a number of spring driven syringes have
14 been marketed together with fine port tubing to control
15 the flow rate of fluid. All of these spring driven
16 systems provide a fixed pressure profile and a fixed
17 flow rate controlled by the flow control tubing. They
18 are viscosity dependent and temperature dependent.

19

20 According to the present invention there is provided
21 fluid delivery apparatus comprising a first reservoir
22 for containing a first fluid under pressure, a second
23 reservoir for containing the fluid to be delivered and
24 having an outlet therefor, means between the first and

1 second reservoirs for transferring a force produced by
2 the pressure of the first fluid to the fluid of the
3 second reservoir, and fluid flow restricting means in
4 communication with the outlet of the second reservoir.

5
6 Preferably, the first reservoir has an inlet for
7 receiving said first fluid, the inlet being in
8 communication with a pressurised source of said first
9 fluid. The first fluid is preferably a gas, for
10 example air.

11
12 Preferably also, the second reservoir comprises a
13 cylinder and said means for transferring a force
14 comprises a piston movable therealong.

15
16 Further preferably, the first reservoir comprises a
17 cylinder and said means for transferring a force
18 comprises a piston movable therealong. The cylinders
19 of the first and second reservoirs may be for example
20 in the form of syringes, and they may be connected
21 together in tandem; this may be achieved by means of a
22 connector member which engages each of the cylinders
23 through a bayonet-type fitting.

24
25 Preferably the fluid flow restricting means comprises
26 tubing having a fine bore therethrough.

27
28 It is of especial advantage in the present invention
29 for the force produced by the pressure of the first
30 fluid and exerted on the fluid in the second reservoir
31 to be variable. This may be achieved by varying the
32 volume of the first reservoir, for example by means of
33 a portion of the reservoir wall being movable, possibly
34 through a screw or ratchet mechanism. Alternatively, a
35 supplementary reservoir can be provided in

1 communication with the first reservoir, the
2 supplementary reservoir being variable in volume.

3
4 Means may be provided, preferably automatically-
5 actuatable, for varying the volume of the first reservoir
6 in response to variations in ambient conditions or
7 variations in the parameters or characteristics, such
8 as viscosity, of the first and/or second fluid.

9
10 Preferably, means are provided for feeding periodically
11 to the second reservoir aliquots of uniform volume of
12 the fluid to be delivered.

13
14 Preferably also, the second reservoir has an inlet in
15 communication with a source of fluid to be delivered.
16 The inlet may be in communication with the source of
17 fluid to be delivered through a one-way valve which
18 prevents return flow of fluid from the reservoir to the
19 source.

20
21 In one embodiment of the invention the first fluid is
22 contained in a closed flow loop which includes the
23 first reservoir, the first reservoir being in
24 communication in the loop with a periodically-actuatable
25 fluid feed device for providing the first fluid to the
26 first reservoir.

27
28 Means can be provided for determining the rate of flow
29 of the second fluid through the fluid flow restricting
30 means. Such rate-determining means may comprise for
31 example a calibration chart for defining the flow rate
32 against such parameters as pressure, temperature,
33 nature of the first and second reservoirs and nature of
34 the fluid flow restricting means.

35

1 The fluid flow from the second reservoir may be non-
2 linear with respect to pressure; for example where the
3 reservoirs are syringes, at low pressure much of the
4 force generated may be used in overcoming the inertia
5 or friction of the plunger in the syringe, whereas at
6 high pressure most of the force generated will be
7 available to drive the fluid from the syringe through
8 the fluid flow restricting means. As an example of
9 this, if the pressure of the first fluid is 1 bar, it
10 may require a force deriving from 0.9 bar to move the
11 plungers along the syringes, leaving a net effective
12 pressure of 0.1 bar for driving the second fluid
13 through the flow restricting means. If on the other
14 hand the pressure of the first fluid is 2 bar, the net
15 effective pressure will be 1.1 bar. An increase of a
16 factor of 2 in the pressure of the first fluid
17 therefore produces an increase of a factor of 11 in the
18 effective force for driving the second fluid through
19 the flow restricting means.

20
21 It has been found that for a given flow restricting
22 means in the form of fine-bore tubing the flow rate
23 through it is directly proportional to the net pressure
24 induced in the second fluid.

25
26 The rate-determining means may be incorporated into
27 software for controlling the supply of pressure to the
28 first fluid.

29
30 Embodiments of the present invention will now be
31 described by way of example with reference to the
32 accompanying drawings, in which:

33
34 Figure 1(a) is a perspective view of a first embodiment
35 of apparatus of this invention.

1 Figure 1(b) is a longitudinal cross-sectional view
2 through the central connector 5 of Figure 1(a);
3 Figure 2(a), (b) and (c) are respectively a front, side
4 and rear perspective view of the apparatus of Figure 1
5 disposed in a housing;
6 Figure 3 (a) is a perspective view of a second
7 embodiment of the invention;
8 Figure 3 (b) is an end view of the central connector 15
9 of Figure 3 (a);
10 Figure 3 (c) is a longitudinal cross-sectional view
11 through an upper portion of the connector 15;
12 Figure 4 (a), (b) and (c) correspond to Figure 3(a),
13 (b) and (c) respectively for a third embodiment of the
14 invention, Figure 4 (a) being an exploded view;
15 Figure 5 (a) is a perspective view of a fourth
16 embodiment of the invention;
17 Figure 5 (b) are perspective views of alternative
18 reservoirs to reservoir 34 of Figure 5 (a);
19 Figure 6 (a), (b) and (c) are respectively a front,
20 back and side cross-sectional view of a fifth
21 embodiment of the invention;
22 Figure 6 (d) is a schematic view of the apparatus of
23 Figure 6 (a);
24 Figure 7 is a schematic cross-sectional view through a
25 first reservoir of an embodiment of the invention;
26 Figure 8 is a schematic view of a fifth embodiment of
27 the invention; and
28 Figure 9 is a schematic view of a sixth embodiment of
29 the invention.
30
31 In Figure 1:
32
33 1 represents an incoming gas supply line; 2 represents
34 a pressure control valve; 3 represents a pressure
35 gauge; 4 represents a gas-filled syringe; 5 represents

1 a connector having a bayonet fitting to receive a drug-
2 containing syringe. The gas-filled syringe is held in
3 the connector 5 either using a bayonet fitting or a
4 screw mechanism; 6 represents the drug-containing
5 syringe; 7 represents tubing from a T piece which
6 facilitates filling of the drug-containing syringe;
7 8 represents a one-way valve with a luer lock fitting
8 which allows filling of the drug-containing syringe;
9 9 represents extension tubing with a filter which
10 connects the drug-containing syringe with the
11 resistance tubing; 10 represents the resistance tubing;
12 11 represents a luer lock fitting which connects
13 directly to the patient's intravenous cannula.

14

15 In Figure 2 the components of the apparatus have been
16 arranged in a housing:

17

18 12 represents a knob which allows variation of the
19 pressure control valve; 13 represents a chart which can
20 be inserted to represent a specific flow rate for a
21 specific fluid with a known viscosity at a known
22 temperature with pressure exerted against a known flow
23 control tube; 14 represents a knob that rotates the
24 pressure gauge while the flow control chart remains
25 fixed. This rotation of the pressure gauge allows
26 adjustments to be made for variations in temperature.
27 In routine clinical use the operating temperature is
28 set at 22°. Movement of this knob to the left or right
29 allows the calibration to be adjusted by moving the
30 pressure gauge; 15 represents a bayonet fitting
31 suitable for insertion of the drug-containing syringe.

32

33 In Figure 3 a standard syringe has been replaced with a
34 modified syringe. In this case a syringe barrel and a
35 plunger can be attached to the bayonet fitting 15. A

1 circular plastic rod with a formed end suitable to fit
2 onto a gasket of the syringe protrudes through the
3 bayonet fitting. The gas-driven system therefore
4 exerts pressure directly on to the drug-containing
5 syringe gasket through this longitudinally moving rod:
6

7 16 represents a recess on the bayonet fitting that the
8 syringe wings clip into; 17 represents the circular
9 plastic rod with the formed end suitable to fit onto
10 the syringe gasket; 18 represents the syringe gasket;
11 19 represents a refill port that allows backfilling of
12 the syringe; 20 represents a one way valve to
13 facilitate backfilling without the use of a tap;
14 21 represents extension tubing to convey fluid from the
15 syringe to the patient; 22 represents an air and
16 bacteria removing filter; 23 represents fine bore
17 tubing to control the rate of flow; 24 represents a
18 male luer lock fitting.

19
20 In Figure 4 the modified syringe of Figure 3 has been
21 replaced with a modified glass ampoule. This modified
22 glass ampoule is covered by an outer plastic casing to
23 prevent shattering of glass if excessive pressure is
24 used. The pressure is transmitted to the gasket again
25 by a longitudinally moving rod with a specially formed
26 end to fit the gasket;
27

28 25 represents a cover for the glass ampoule with a
29 perforating needle to go through a rubber membrane 26
30 at the end of the glass ampoule; 27 represents the
31 glass ampoule; 28 represents the rubber gasket of the
32 glass ampoule; 29 represents the syringe containing
33 compressed air; 30 represents the gasket in the syringe
34 containing compressed air which is attached to the
35 longitudinally moving rod which transmits the pressure

1 to the ampoule gasket; 31 represents the compressed air
2 tubing to the variable pressure source; 32 represents
3 an outer plastic casing which provides a protective
4 cover for a glass ampoule when significant pressure is
5 placed on the glass ampoule.

6
7 Figure 5 shows four alternative reservoirs 33 and 35.
8 Reservoirs 33 are each fixed though different size
9 reservoirs and 35 represents an adjustable size
10 reservoir.

11
12 In Figure 5, 36 represents a syringe connected to one
13 of the reservoirs 33. Prior to use the syringe is used
14 to compress air into the reservoir 33 and is then
15 inserted into a bayonet fitting 38. A bayonet fitting
16 39 holds in place the drug-containing syringe 40. The
17 syringe 36 has a pressure inversely proportional to the
18 size of the reservoir. The smaller reservoir 33
19 therefore produces a higher pressure than the larger
20 reservoir. In the case of the reservoir 35 the size
21 can be varied and the pressure can therefore be varied
22 accordingly:

23
24 41 represents a refill port that allows backfilling of
25 the syringe; 42 represents a one-way valve to
26 facilitate backfilling without the use of a tap; 43
27 represents an air and bacteria removing filter; 44
28 represents fine bore tubing to control the rate of
29 flow; 45 represents a male luer lock fitting.

30
31 This family of syringe-driven pumps allows for
32 extremely simple pumps to be designed where the
33 pressure can be changed by charging a gas-driven
34 reservoir with a fixed volume. Injecting a fixed
35 volume of air into that reservoir gives a fixed

1 pressure head. As an alternative system a more
2 sophisticated pump can be used where it is possible to
3 vary the pressure and control the pressure throughout
4 the full movement of the syringe. This range of pumps
5 gives significant benefits over electronic pumps.

6
7 In Figure 6 a further embodiment of the invention is
8 demonstrated. In this embodiment the variable gas-
9 driven pressure is calibrated so that a balloon 57
10 presses on a moveable segment 58 which causes pressure
11 on a minibag 49. The minibag then delivers fluid
12 through its tubing 50. The flow rate is controlled by
13 flow control tubing 53 which has a relatively narrow
14 lumen:

15
16 46 represents a calibrated flow rate diagram showing
17 flow in mls/hr and also in mgs/kg/hr; 47 represents a
18 segment of the diagram referring to calibration for
19 weight so that the flow can be calibrated in mgs/kg/hr
20 with a set pressure against a set resistor; 48
21 represents a gas supply to a pump; 49 represents a
22 flexible bag containing drug or fluid; 50 represents
23 tubing coming from the flexible bag or drug container
24 (minibag) 49;
25 51 represents a bacterial filter in the line; 52
26 represents an air removing filter in the line; 53
27 represents a segment of tubing with a narrow lumen
28 which controls the rate of flow from the minibag 49;
29 54 represents a male luer lock fitting which allows the
30 bag 49 to be connected to the patient; 55 represents a
31 pressure gauge; 56 represents a valve which can be
32 turned to control the pressure level; 57 represents an
33 elastic bag which can be inflated to produce pressure
34 on a mobile plate; 58 represents the mobile plate;
35 59 represents tubing between the pressure control valve

1 56 and the pressure gauge 55; 60 represents a ring
2 which allows suspension of the device from a drip pole;
3
4 61 represents a segment of the drip pole; 62 represents
5 a knob for moving the pressure gauge around its axis so
6 that adjustments can be made from variations in
7 temperature. These are made by adjusting the
8 orientation of the pressure gauge in relation to the
9 flow control chart above it; 63 represents a plate that
10 can slide into place after the minibag 49 has been
11 inserted; 64 represents an opening which allows the
12 tubing of the minibag to be inserted easily. The plate
13 63 is then inserted once the minibag is in place. It
14 is important that the plate 63 and a wall 65 of the
15 container are made of a clear transparent material so
16 that the minibag can be viewed at all times; 66
17 represents a balloon with a one way valve which allows
18 air to be pumped into the pressure device so as to give
19 a specific rate of flow from the minibag 49.

20
21 This arrangement of the pressure gauge has orientation
22 to the calibrated chart which can be varied. This
23 allows accurate flow rates to be expressed in
24 mgs/kg/min with variations in temperature taken into
25 consideration. It would be normal to provide a chart
26 for a drug of a specific viscosity as this allows
27 packaging of a drug of a specific viscosity in the
28 minibag with a known resistor. A combination of this
29 variable gas driven system together with the
30 temperature compensating technique allows this style of
31 pump to be designed for a specific drug with a specific
32 resistor. The drug can therefore be packaged in this
33 type of container.

34
35 These embodiments of the invention include syringe

1 pumps which can be powered by gas. This allows the
2 development of extremely low cost gas powered pumps.
3 This range includes some that allow the flow to be
4 turned up or down by increasing the gas pressure
5 driving a syringe while others allow variation in
6 pressure by varying the volume of a reservoir or
7 alternatively selecting reservoirs of an appropriate
8 volume so that an appropriate pressure will be
9 generated when a fixed volume of air is injected into
10 the reservoir.

11
12 Each of these pump designs involves a syringe which is
13 filled with a fluid, for example a gas, at a specific
14 pressure. The fluid then provides pressure on a
15 plunger which transmits force longitudinally to a
16 syringe which is placed back-to-back. The thumb piece
17 of the syringe containing air then presses directly on
18 the thumb piece of the syringe containing drug. The
19 wings of both syringes are held within an appropriately
20 designed housing that essentially provides a bayonet
21 fitting for the wings of each syringe. This provides a
22 system where the pressure in the gas-driven syringe is
23 transmitted directly to the fluid- or drug-containing
24 syringe with no risk of air leaks from the gas-driven
25 syringe to the drug-containing syringe.

26
27 The drug- or other fluid-containing syringe can be a
28 standard plastic syringe. Alternatively it may be in
29 the form of a glass ampoule with a moveable plunger
30 (Figure 4). In this embodiment the glass ampoule is
31 usually covered with a protective cover that fits
32 within the bayonet fitting and the gas-driven syringe
33 has a member that inserts into the rubber plunger of
34 the ampoule or into the rubber plunger of a modified
35 syringe. In the case of a modified syringe the syringe

1 barrel and rubber gasket form the drug container. This
2 modified syringe can be inserted into the bayonet
3 fitting and the gasket will be driven by the
4 longitudinal member that transmits pressure from the
5 gasket of the gas-driven syringe.

6
7 When using this technology the fluid-containing syringe
8 can be filled before use and then loaded into the
9 device. An alternative method of filling the syringe
10 allows filling from the distal end of the syringe by
11 use of a T-piece with a one way valve allowing direct
12 injection into the syringe. The direct injection into
13 the syringe is facilitated by the fact that the syringe
14 pumps against relatively high resistance tubing in
15 order to provide a constant infusion.

16
17 Conventional electronic pumps have a very wide range so
18 that the pump can run from 0mls per hour to 1,000mls
19 per hour. The air-driven pump system of these
20 embodiments of the invention can effectively work
21 between 0.5 and 4 bars pressure with commercial
22 syringes. While it may be possible to operate between
23 0 and 0.5 bars pressure the accuracy of the pump in
24 this low pressure range decreases because of the
25 variations in resistance caused by syringe gaskets.
26 For practical purposes therefore the pump will usually
27 be set at a standard operating level of 1 bar initially
28 where it can be increased four fold but not a thousand
29 fold as could occur with an electronic pump. This
30 limitation provides an element of safety in some
31 situations.

32
33 The pumps systems of these embodiments can be
34 calibrated for a specific drug with a specific
35 viscosity. This allows the pump to be calibrated to

1 give a specific drug in ml/kg/hr. This will ensure in
2 many situations that the pump can only be used for the
3 drug that it has been manufactured and designed for.

4
5 Some conventional electronic pumps are at risk of
6 sudden downloading of drugs accidentally from their
7 syringes, but in the apparatus of the present
8 embodiments of the invention the resistance tubing
9 prevents sudden downloading of drugs. Further, the
10 pressure gradient across the high resistance tubing
11 will usually be sufficient to prevent syphoning.

12
13 The present embodiments of the apparatus do not depend
14 on electronics and the patient is therefore protected
15 from microelectric shocks. The pump can be operated
16 from a conventional compressed air source, such as
17 compressed air bottles. In order to maximise safety in
18 the pump circuit it is essential to have a blow-off
19 valve if connected to a compressed air bottle. The
20 standard operating pressures in most theatres and
21 hospitals will have a maximum of 4 bar and it is easy
22 to produce plastic fittings safe at least to 4 bars
23 pressure while the valve is safe at approximately 6
24 bars pressure which is usually adequate to protect the
25 pump. This gives protection if connected directly to
26 the full pressure of a gas bottle.

27
28 An alternative form of compressed air is the use of a
29 standard foot pump or alternatively a syringe to inject
30 air through a one-way valve into a reservoir connected
31 to the driving syringe.

32
33 One of the disadvantages of electronic syringe pumps is
34 the difficulty of providing a continuous infusion at
35 the time of changing syringes. This often leads to an

1 absence of flow for one or two minutes while the
2 syringe is being changed. In the case of drugs with a
3 half life of one or two minutes this may predispose to
4 significant physiological changes that occur for the
5 patient.

6
7 The syringes of these embodiments of the invention
8 provide a system where the syringe can be refilled
9 without interruption of flow. The filling of the
10 syringe can be performed through a one-way valve. As
11 the syringe fills the plunger is pushed back. In the
12 case of the syringe pump driven with compressed air at
13 a preset level the pressure in the driving syringe is
14 maintained constant at all times by a valve that
15 controls this pressure level. The filling of the
16 syringe is therefore not associated with significant
17 increases in pressure in the drug-filled syringe as
18 there are minimal pressure changes in the drug-filled
19 syringe and the actual flow continues to be constant.
20 It is therefore possible to refill the syringe while
21 maintaining a constant flow. This provides a
22 significant advantage when using vasoactive drugs.

23
24 The apparatus of these embodiments use precalibrated
25 fine-bore resistance tubing controlling the rate of
26 flow of fluid from the drug-containing syringe.

27
28 The control of flow through fine-bore tubing is
29 viscosity dependent. This means that the calibrations
30 on the pump need to be set for a specific viscosity.
31 It is important that whoever uses the pump should
32 select a calibration system appropriate for the
33 appropriate viscosity.

34
35 The system is temperature dependent and it is therefore

1 necessary to adjust the calibration chart around the
2 pressure manometer against a specific temperature. In
3 Figure 1 the pressure gauge 3 is shown as a circular
4 dial with specific pressure readings consistent with
5 specific flow rates. In the design of instrument shown
6 in Figure 1 the dial can be moved a few degrees to the
7 right or to the left so that the relationship between
8 the dial and the chart shows flow rate changes. This
9 allows for a correction in flow rate that occurs with
10 temperature.

11

12 In general a 2.5% increase in flow rate will be noted
13 for each 1 degree centigrade rise in temperature. In
14 practice the pressure-reading dial can be turned to a
15 position that compensates for this variation in
16 temperature.

17

18 With the embodiment illustrated in Figure 5 a refill
19 port 41 is designed to allow backfilling of a syringe
20 40 and a filter 43 is placed in line between the
21 syringe 40 and the flow control tubing 44. This filter
22 43 eliminates air bubbles entering the flow control
23 tubing 44 and prevents bacteria reaching the patient.
24 This positioning of this filter 43 is integral to
25 getting maximum function from the flow control tube 44
26 (air bubbles tend to block the tube). The positioning
27 of the filter 43 is also critical in terms of
28 protecting the patient from any possible contamination
29 that might occur with repeated refilling of the syringe
30 40.

31

32 In these two-syringe systems one of the syringes can
33 have a volume which is variable and selectable by means
34 of a ratchet or screw mechanism. The other syringe can
35 have a plunger that moves in response to the pressure

1 in its chamber.

2

3 In the embodiment the pressure driving syringe can be
4 intermittently and selectively attached to any of a
5 series of reservoirs. The pressure in the pressure
6 driving syringe will be inversely proportional to the
7 size of the reservoir that it is connected to. When
8 connected to a small reservoir and depressed fully, the
9 pressure will be extremely high, while when connected
10 to a large reservoir the pressure will be low. By
11 appropriate labelling of each reservoir, it is possible
12 to have a known pressure within the syringe providing
13 no leaks occur within the system. Leaks may be
14 eliminated by a hydraulic seal gasket 68 (see Figure
15 7).

16

17 An alternative embodiment involves a system of
18 connecting the pressure driving syringe to a variable
19 reservoir, as for example in Figure 8. If the size of
20 the reservoir is varied, the pressure within the
21 pressure driving syringe varies itself. With this
22 embodiment the pressure within the pressure driving
23 syringe can be varied during use of an infusion pump.
24 The reservoir can be calibrated against pressure, flow
25 or mg/kg/minute of drug being infused.

26

27 In simple embodiments of the invention the pressure can
28 be calibrated on the series of reservoirs, or against a
29 known position on a variable reservoir syringe. With
30 some embodiments, a T-piece on the line connecting the
31 two syringes can allow a pressure gauge 70 to be
32 integrated into the circuit (see Figure 8). This
33 pressure gauge 70 can be connected electronically to an
34 appropriate computer or programme. This programme can
35 control flow in response to pressure, temperature,

1 viscosity, drug concentration and weight of the
2 patient. In this circumstance the computer can express
3 the number of milligrams per kilogram per hour with
4 corrections for viscosity and temperature variations
5 built in to the formula.

6
7 The apparatus can therefore include a series of
8 reservoirs or alternatively a variable reservoir. A
9 tube connects the variable reservoir to a pressure
10 driving syringe fixed in position within a syringe
11 holding device so that the thumb pieces on the barrel
12 push firmly on the distal end of the housing, and so
13 that the plunger connects directly with the plunger of
14 the drug-containing syringe with a longitudinal
15 connection between both of these. The pressure from
16 the pressure driving syringe therefore is transmitted
17 as direct pressure on the plunger of the drug-
18 containing syringe or other container.

19
20 In Figure 8, the drug-containing syringe 72 abuts
21 against the proximal end of the housing and has
22 pressure directly transmitted to its rubber plunger 74.
23 Its pressure is transmitted from the rubber plunger
24 onto the fluid contained with the syringe, which is
25 delivered slowly through finely calibrated flow control
26 tubing 76. This flow control tubing 76 then delivers
27 fluid at a predetermined rate to the patient.

28
29 In the event that the rate needs to be increased, the
30 pressure is increased by an appropriate amount.
31 Doubling the pressure will directly double the flow
32 rate. This can be achieved easily by decreasing the
33 space in the variable reservoir syringe 78, or
34 alternatively choosing a precalibrated pressure head at
35 the appropriate level.

1 In Figure 9 there is provided apparatus for delivering
2 fluid on a continuous basis from a first reservoir such
3 as a syringe or elastomer driven container and fluid as
4 required by the patient from a second reservoir such as
5 a syringe. Each reservoir can be independently
6 examined to confirm how much drug or fluid has been
7 delivered to the patient.

8
9 The energy to the constant-infusion syringe can be
10 delivered by a spring-driven syringe or elastomer. The
11 rate of egress of fluid is controlled by tubing with a
12 fine lumen sufficient to provide a resistance to flow
13 at a present rate.

14
15 The patient controlled circuit is hydraulically
16 controlled by an internal circuit that is reused and an
17 external circuit that controls the delivery of energy
18 of fluid from the internal circuit.

19
20 The internal circuit provides a time delay mechanism
21 and an energy-containing reservoir with a limited
22 energy store. The limited energy store delivers
23 pressure to a longitudinal syringe or piston which
24 delivers pressure to the patient controlled syringe or
25 reservoir.

26
27 The patient controlled syringe or reservoir then
28 delivers pressurised fluid to a flow control resistor
29 that controls the rate of delivery of fluid from the
30 patient controlled syringe. This resistor to flow in
31 Figure 9 is fine lumen tubing but can alternatively be
32 any form of resistance such as a fine aperture in a
33 membrane or a filter.

34
35 In the preferred embodiment each independent syringe

1 can be filled through a one-way valve which allows
2 refilling of the syringe. A tap mechanism allows the
3 internal circuit to be opened to allow fluid to return
4 to a flexible reservoir when the patient controlled
5 reservoir or syringe is being refilled.

6
7 80 represents a reservoir in the form of a flexible bag
8 within the reusable internal circuit. This flexible
9 bag contains fluid and acts as a flexible reservoir for
10 the internal hydraulic circuit.

11
12 82 represents the fine bore tubing which provides a
13 restriction to flow of fluid between the reservoir 80
14 and an aspirating syringe 84. The fine bore tubing 82
15 restricts the flow of fluid and controls the rate of
16 filling of the aspirating syringe 84.

17
18 The aspirating syringe 84 is spring loaded and
19 aspirates fluid from the internal circuit. The rate at
20 which fluid is aspirated is controlled by the fine bore
21 tubing 82. It should be noted that one-way valve 86
22 prevents entry of fluid from a balloon energy-
23 containing reservoir 88. The aspirating syringe 84 has
24 a spring contained within a housing which provides a
25 push-button appearance and controls the length of
26 longitudinal movement of the syringe. The housing
27 therefore controls the filling volume of the syringe.
28 The aspirating syringe 84 therefore has an ability to
29 fill to a fixed volume at a fixed rate.

30
31 90 represents a strong housing shaped around the
32 elastomeric balloon 88. The housing 90 controls the
33 volume to which the balloon 88 can be filled. The
34 housing 90 is therefore shaped internally in the same
35 shape as the balloon 88 when filled. The housing 90

1 can limit the volume in the energy-containing balloon
2 88 to a volume similar to the volume contained in the
3 aspirating syringe 84. In this way the housing 90 can
4 control the number of boluses of fluid in the energy
5 reservoir of the elastomeric balloon 88 at any one
6 time.

7
8 88 represents the elastomeric balloon with relatively
9 thick walls. This elastomeric balloon can generate
10 quite high pressures which can be transferred on to a
11 longitudinal driving syringe 92. The elastomeric
12 balloon 88 is filled when the aspirating syringe 84 is
13 depressed by the patient or nurse. The balloon 88 then
14 contains a fixed volume of fluid with a pressure
15 generated by the walls of the elastomer. The pressure
16 is transferred to the driving and patient controlled
17 syringes 92, 94.

18
19 96 represents a one-way valve which prevents the return
20 of fluid from the driving syringe 92 to the elastomeric
21 balloon 88.

22
23 98 represents a one-way valve which prevents the return
24 of fluid from the reservoir fluid bag 80 to the driving
25 syringe.

26
27 100 represents a spring-loaded tap which is usually in
28 the closed position during use preventing any flow of
29 fluid from the driving syringe 92 to the flexible
30 reservoir bag 80. During refilling of the patient
31 controlled syringe 94 the tap 100 is opened to allow
32 fluid to move from the driving syringe 92 direct to the
33 flexible reservoir bag 80.

34
35 102 represents a filter to protect the patient from any

1 bacterial contamination of the fluid within the
2 external patient circuit.

3

4 104 represents a hydrophobic air removing filter to
5 protect the patient from any air bubbles within the
6 circuit.

7

8 106 represents a male luer lock fitting to connect the
9 infusion device to a standard intravenous line.

10

11 The driving syringe 92 is held in a longitudinal tube.
12 The driving syringe 92 receives pressure from the
13 elastomeric balloon 88 when it is filled with fluid.
14 The pressure is transmitted to a rubber seal 108 by the
15 fluid within the driving syringe 92. The pressure in
16 the driving syringe 92 becomes equal to the pressure in
17 the elastomeric balloon 88. This pressure is
18 transmitted onto the rubber seal and transferred along
19 the longitudinal member to the patient controlled
20 syringe 94. This patient controlled syringe 94 is held
21 in a bayonet fitting 110 with the plunger thumb or
22 piece 114 of the patient controlled syringe 94 abutting
23 directly against the plunger or thumb piece 112 of the
24 driving syringe 92. The pressure within the driving
25 syringe 92 is therefore transferred to the patient
26 controlled syringe 94 so that the pressure in the fluid
27 compartment of the patient controlled syringe 94 is a
28 similar pressure to the pressure in the driving syringe
29 92. The difference in pressure between the two
30 syringes relates to the amount of energy taken up by
31 the resistance in the plungers of the driving syringe
32 92 and the patient controlled syringe 94.

33

34 In ideal circumstances this resistance is close to
35 zero.

1 116 represents an energy-containing spring on a
2 constant infusion syringe 22.

3
4 118 represents a stem which prevents kinking of the
5 long spring 116 of the constant infusion syringe 122.

6
7 120 represents a bayonet fitting which receives the
8 wings of the patient controlled syringe 94. A similar
9 bayonet fitting is used to hold the wings of the
10 spring-loaded constant infusion syringe 122.

11
12 124 represents fine bore tubing which controls the
13 egress of fluid from the constant infusion syringe 122.

14
15 126 represents fine bore tubing which controls the rate
16 at which energy or fluid is delivered from the patient
17 controlled syringe 94.

18
19 128 represents a high pressure valve which is designed
20 to prevent any risk of syphoning of fluid from either
21 syringe 94, 122. This high pressure valve 128 has an
22 opening pressure for the valve which is significantly
23 higher than could occur between the top of the device
24 and the patient at any time. This anti-siphon valve
25 128 simply protects the patient from the syphoning of
26 fluid.

27
28 130 represents a one-way valve designed to allow
29 injection of fluid directly into the patient controlled
30 syringe 94. When this is being performed it is
31 important that the tap 100 is open so that as the
32 patient controlled syringe 94 fills, and as fluid is
33 pushed from the driving syringe 92 that fluid returns
34 directly to the flexible reservoir bag 80.

35

1 132 represents a one-way port into the continuous
2 infusion syringe 122.

3
4 134 represents a housing which contains the spring of
5 the constant infusion syringe 122 and fits inside the
6 continuous infusion syringe. It is designed in such a
7 way that it can move longitudinally the full distance
8 of the constant infusion syringe 122 and push the
9 rubber plunger as far as the end of the patient
10 controlled syringe 94. The continuous infusion syringe
11 122 can move up and down its longitudinal compartment.
12 This housing 134 provides a system whereby the spring
13 can effectively travel virtually the full length of the
14 continuous infusion syringe 122.

15
16 This embodiment provides the basic principles of an
17 internal hydraulic circuit with a time delay switch and
18 an energy containing reservoir with a limited volume.
19 The external circuit as described provides a rate
20 controlling mechanism for transfer of energy from this
21 internal circuit. The rate controlling mechanism plus
22 the anti-siphon valve provides the patient with
23 protection. The patient is further offered protection
24 by the internal circuit and its time delay mechanism as
25 well as the limited quantity of energy which can be
26 stored in the internal circuit at any time.

27
28 This device therefore provides a background infusion
29 and intermittent boluses as required. Many
30 applications with medicine require a background
31 infusion and a maximum infusion rate, and this device
32 can be applied to such situations in medicine and also
33 to other industrial applications.

34
35 Modifications and improvements may be incorporated

1 without departing from the scope of the invention.

2

3 For example, Figure 10 is a schematic diagram of a part
4 of fluid delivery apparatus in accordance with a
5 further embodiment of the invention in which a first
6 syringe 140 is powered by its connection to an inlet
7 142 which has along it four branch inlets 144, 146,
8 148, 150. Each of the branch inlets is connected to
9 the main inlet 142 through a valve 152, 154, 156, 158
10 each of which is selectively actuatable independently of
11 the others. The branch inlets receive compressed gas
12 from respective balloon reservoirs 160, 162, 164, 166
13 which have different gas pressure levels. Each of the
14 balloon reservoirs has a one way valve 168, 170, 172,
15 174 for charging with gas.

16

17 In this modification, the volume of each balloon
18 reservoir 160, 162, 164, 166 is greater than the volume
19 of the syringe 140, to the effect that the pressure is
20 constant for 90% of the reservoir's volume, as shown in
21 the graph of Figure 11.

The claims defining the invention are as follows:

1. Apparatus for delivery of fluid to a patient, the apparatus comprising a first reservoir for containing a pressurised first fluid, a second reservoir for containing the fluid to be delivered and having an outlet therefor, means
5 between the first and second reservoirs for transferring a force produced by the pressure of the first fluid to the fluid of the second reservoir, characterised in that a tube having a narrow lumen is disposed between the outlet of the second reservoir and the patient, and where the rate of fluid delivery to the patient is determined by the diameter of the lumen of the tube.
10
2. Apparatus as claimed in claim 1, wherein means are provided for varying the pressure of the first fluid in the first reservoir.
3. Apparatus as claimed in claim 1 or 2, wherein the first reservoir has an inlet for receiving said first fluid, the inlet being in communication with a
15 pressurised source of said first fluid.
4. Apparatus as claimed in claim 1, 2 or 3, wherein the second reservoir comprises a cylinder and said means for transferring a force comprises a piston movable therealong.
5. Apparatus as claimed in any preceding claim, wherein the first reservoir
20 comprises a cylinder and said means for transferring a force comprises a piston movable therealong.
6. Apparatus as claimed in claim 5 when dependent on claim 4, wherein said cylinders are connected together in tandem.
7. Apparatus as claimed in claim 6, wherein the cylinders are connected together through a connector member which engages each of the cylinders through a bayonet-type fitting.
25



8. Apparatus as claimed in any one of the preceding claims, wherein the first reservoir is variable in volume.
9. Apparatus as claimed in claim 8, wherein the volume of the first reservoir is variable by means of a screw or ratchet mechanism.
- 5 10. Apparatus as claimed in claim 9, wherein a supplementary reservoir is in communication with the first reservoir, the supplementary reservoir having a variable volume.
- 10 11. Apparatus as claimed in claim 8, 9 or 10, wherein means are provided for varying the volume of the first reservoir in response to variations in ambient conditions.
12. Apparatus as claimed in any one of claims 8 to 11, wherein means are provided for varying the volume of the first reservoir in response to one or more parameters of the fluid to be delivered.
- 15 13. Apparatus as claimed in any one of the preceding claims, wherein means are provided for feeding periodically to the second reservoir aliquots of uniform volume of the fluid to be delivered.
14. Apparatus as claimed in any one of the preceding claims, wherein the second reservoir has an inlet in communication with a source of fluid to be delivered.
- 20 15. Apparatus as claimed in claim 14, wherein the inlet is in communication with the source of fluid to be delivered through a one-way valve which prevents return flow of fluid from the reservoir to the source.
16. Apparatus as claimed in any one of the preceding claims, wherein a filter for removal of bacteria is provided downstream of the second reservoir.



17. Apparatus as claimed in any one of the preceding claims, wherein means for removing air from the fluid being delivered is located between the second reservoir and the tube.
18. Apparatus as claimed in any one of the preceding claims, wherein a pressure gauge is provided in communication with the first reservoir.
19. Apparatus as claimed in any one of the preceding claims, wherein the first fluid is contained in a closed flow loop which includes the first reservoir, the first reservoir being in communication in the loop with a periodically actuable fluid feed device for providing the first fluid to the first reservoir.
20. Apparatus as claimed in any one of the preceding claims, wherein means are provided for determining the rate of flow of the second fluid through the tube.



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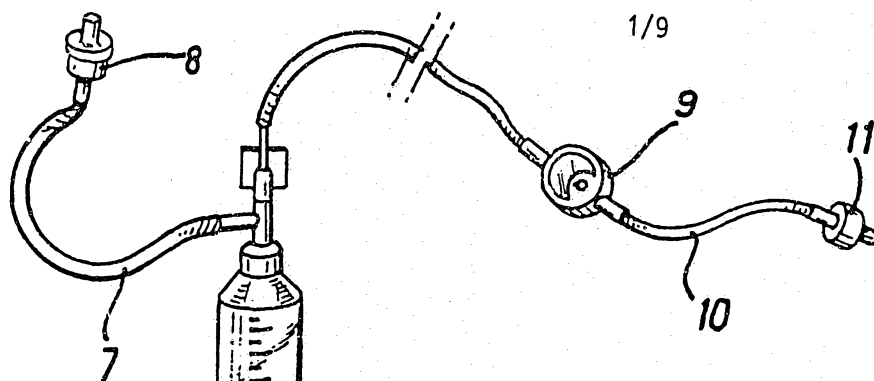


FIG. 1a

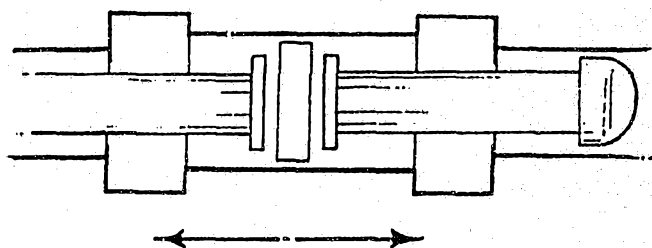
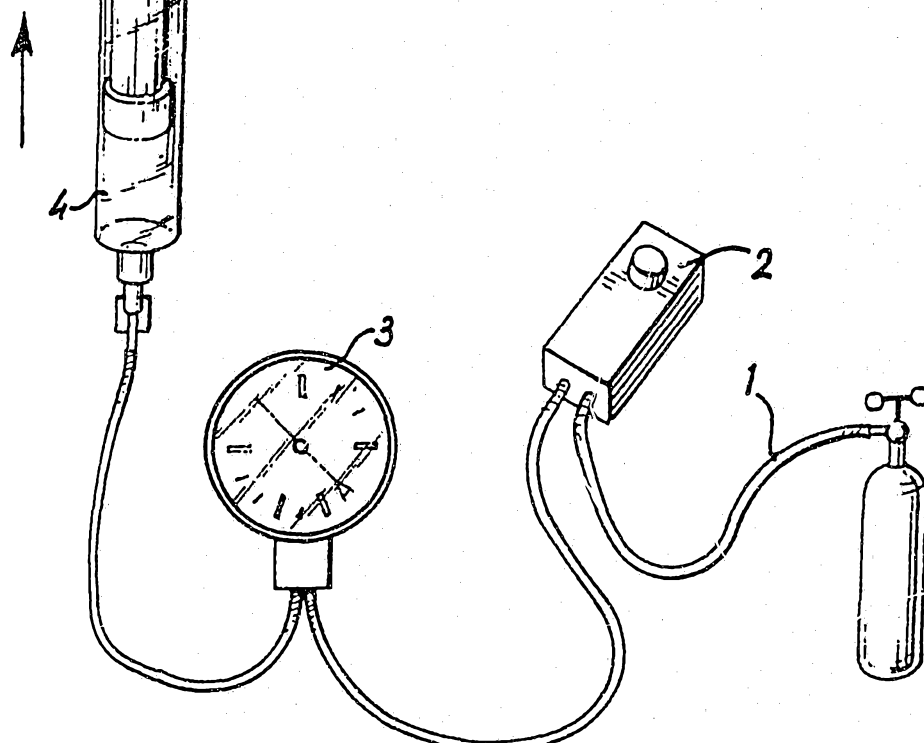


FIG. 1b



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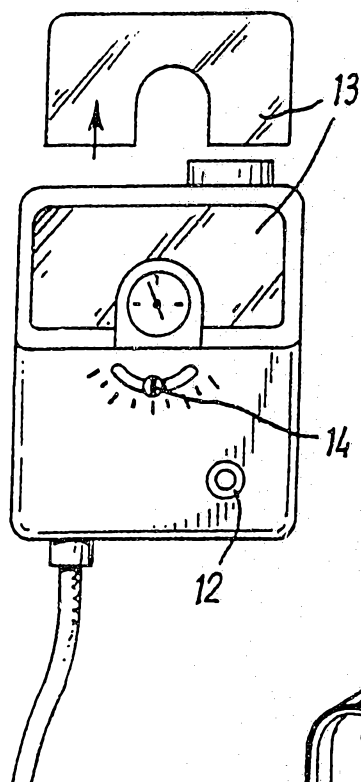


FIG. 2a

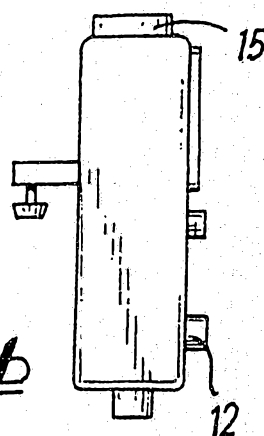


FIG. 2b

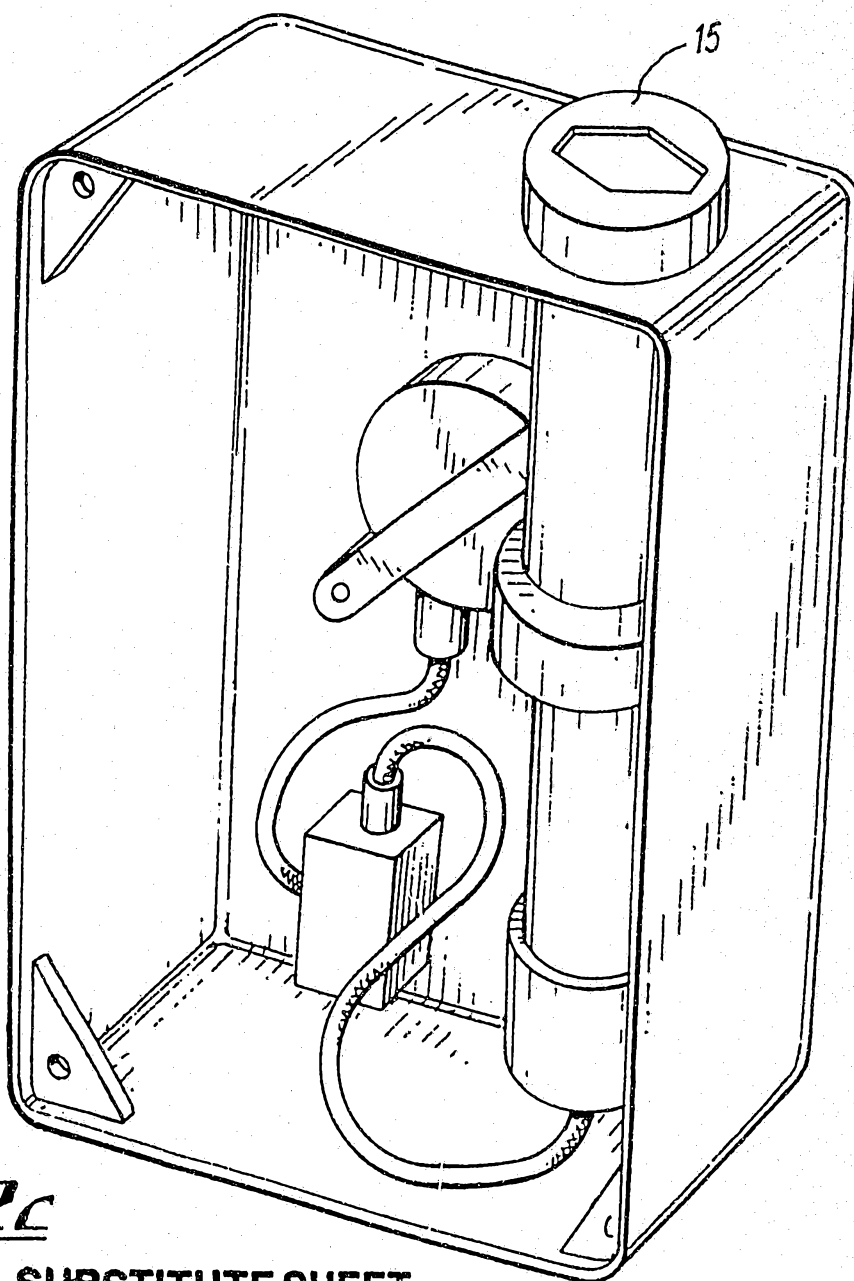


FIG. 2c

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FIG. 3a

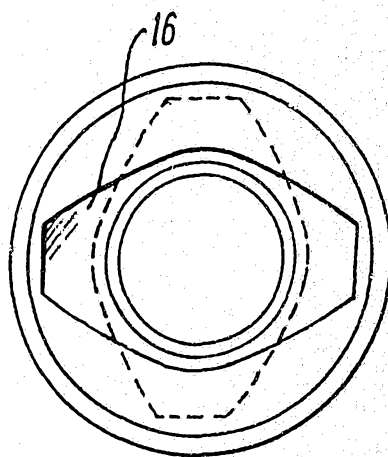
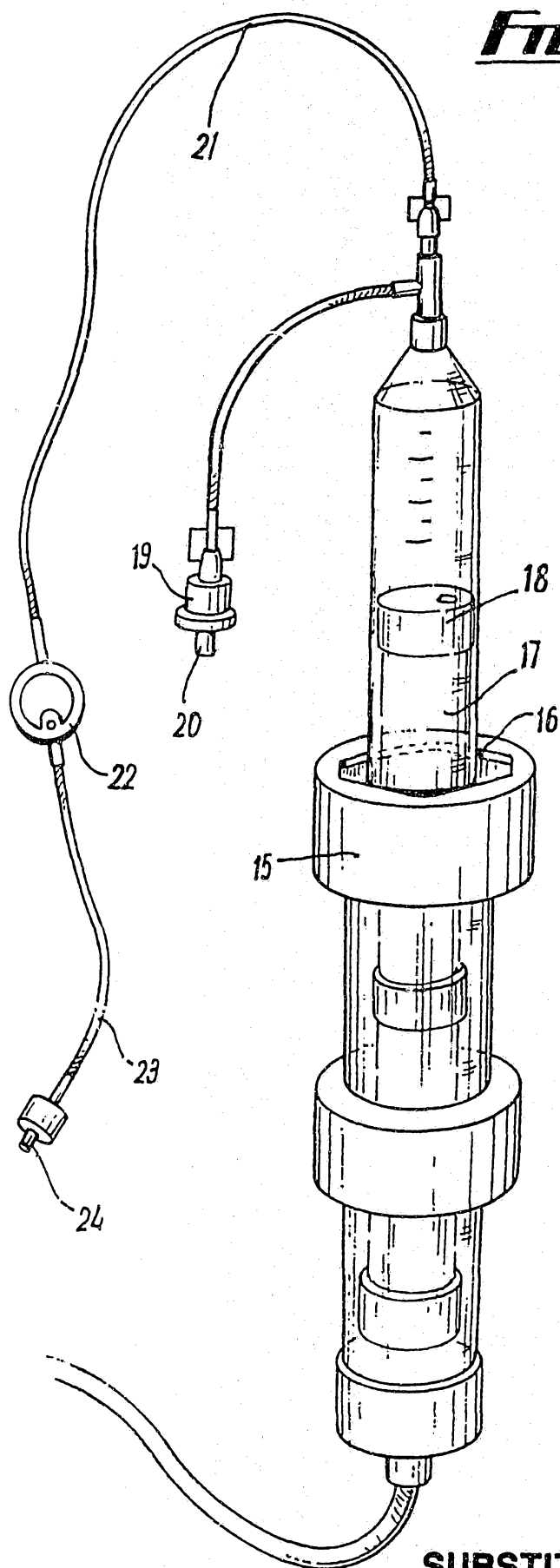


FIG. 3b

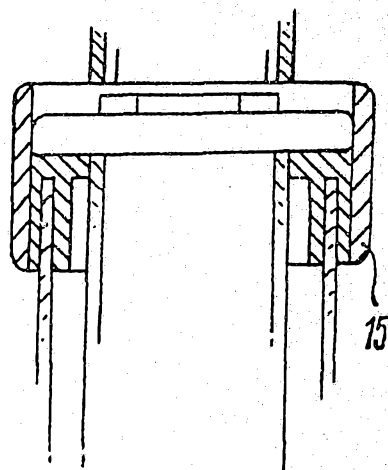
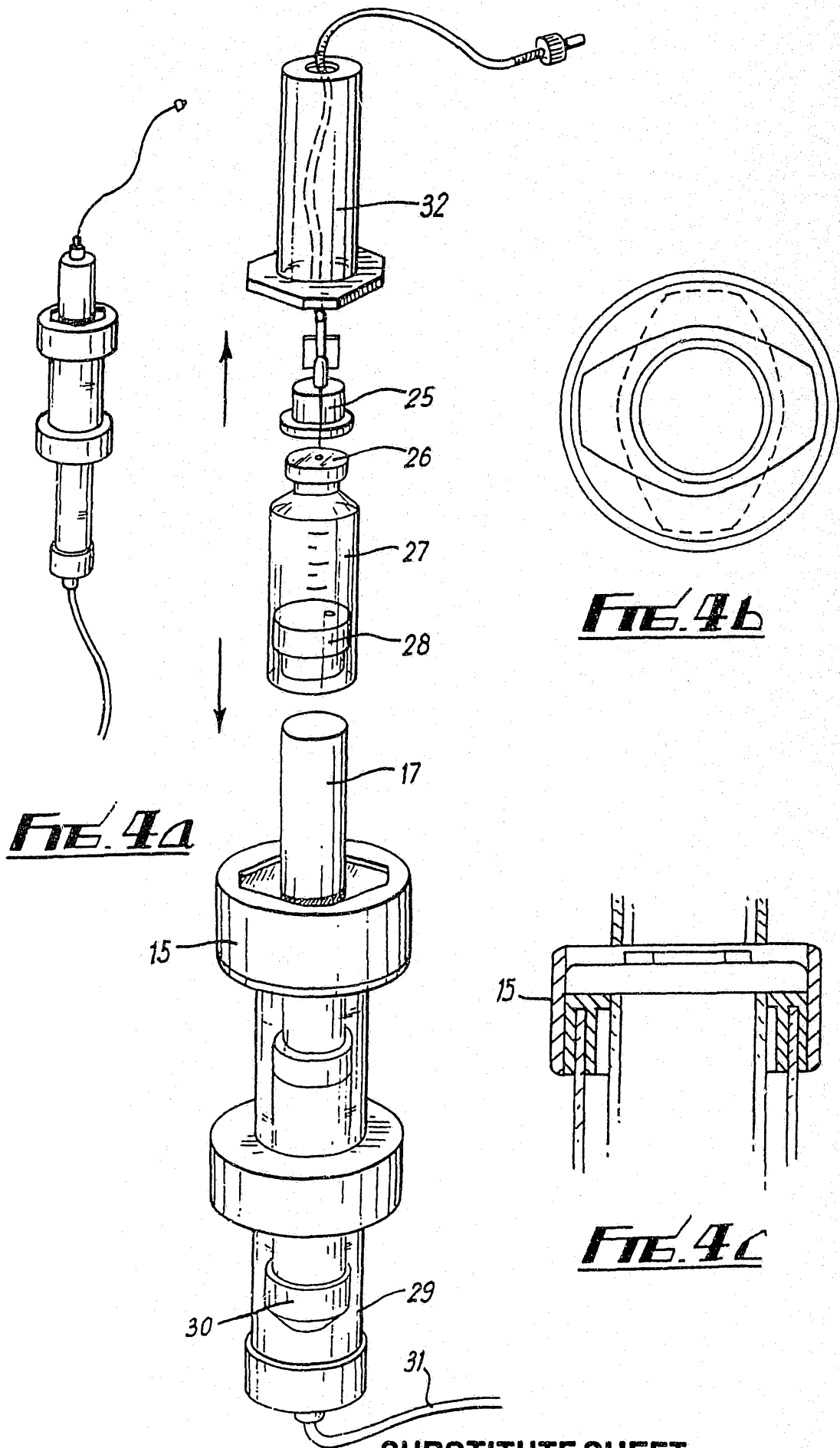


FIG. 3c



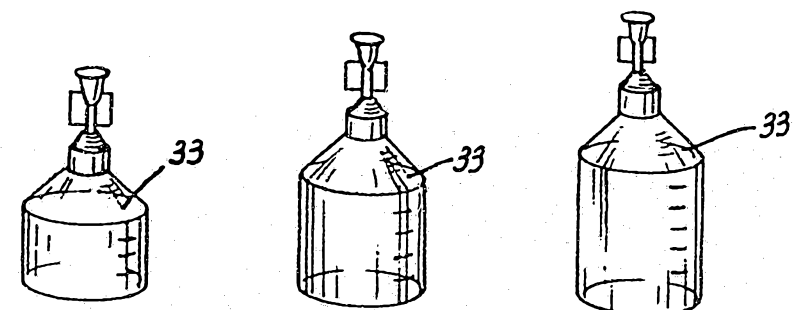
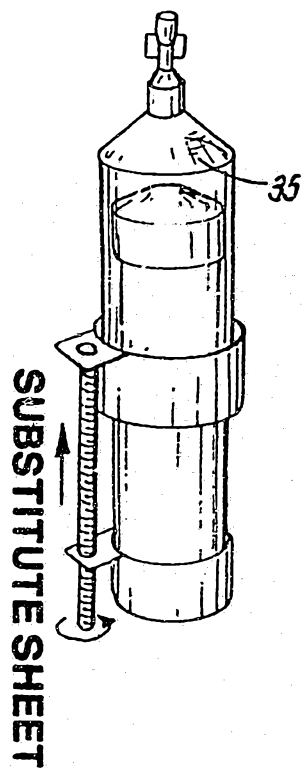


FIG. 5b

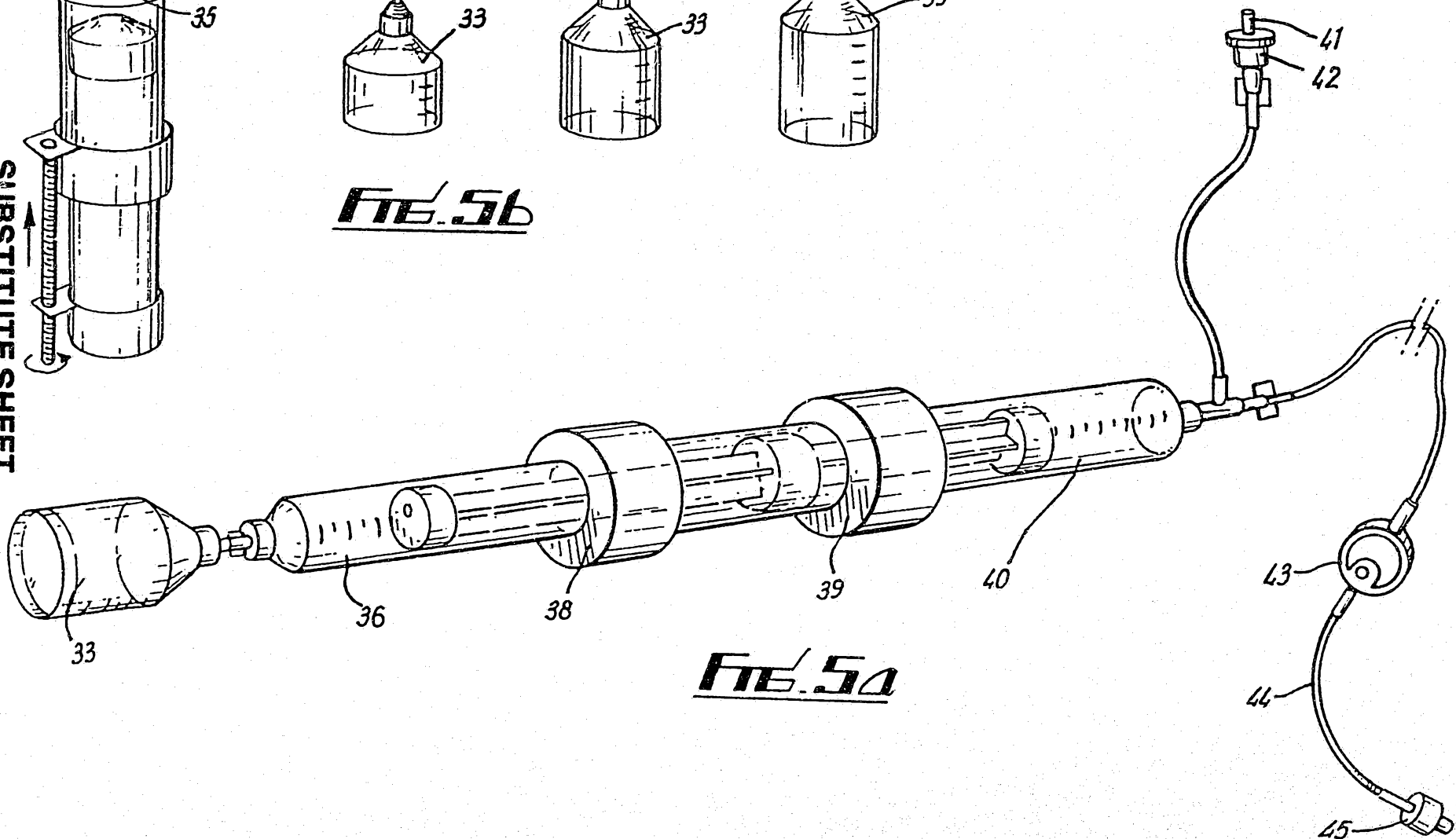


FIG. 5a

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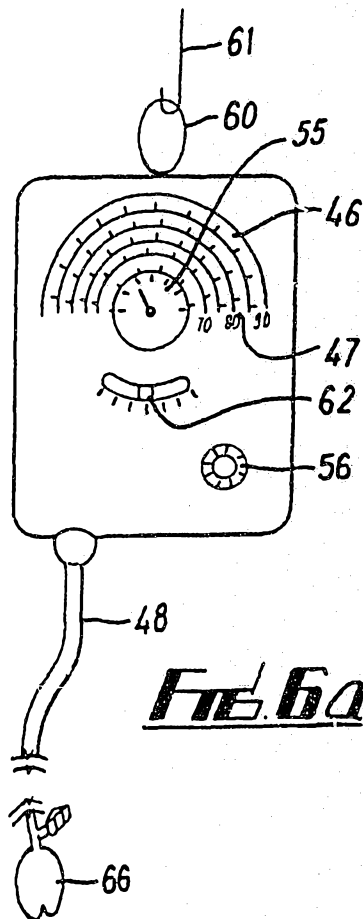


Fig. 6a

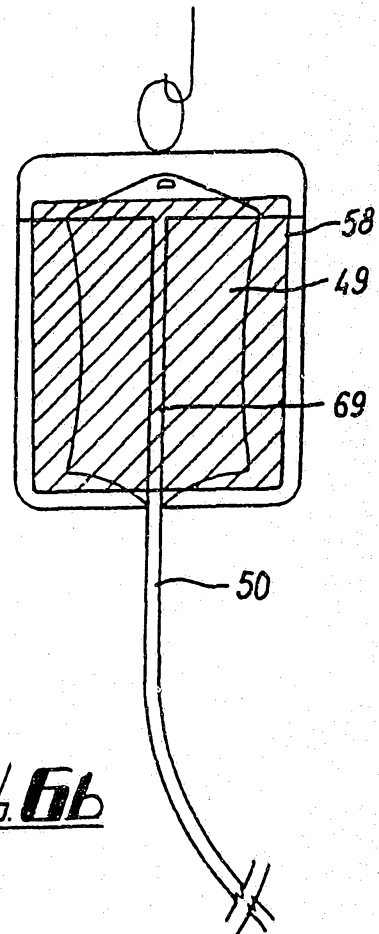


Fig. 6b

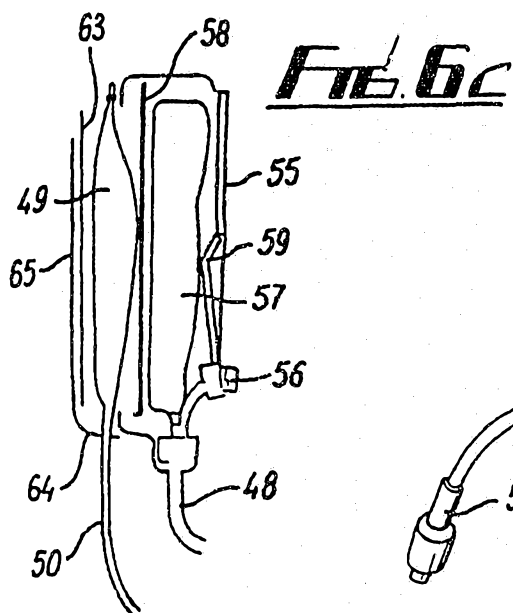


Fig. 6c

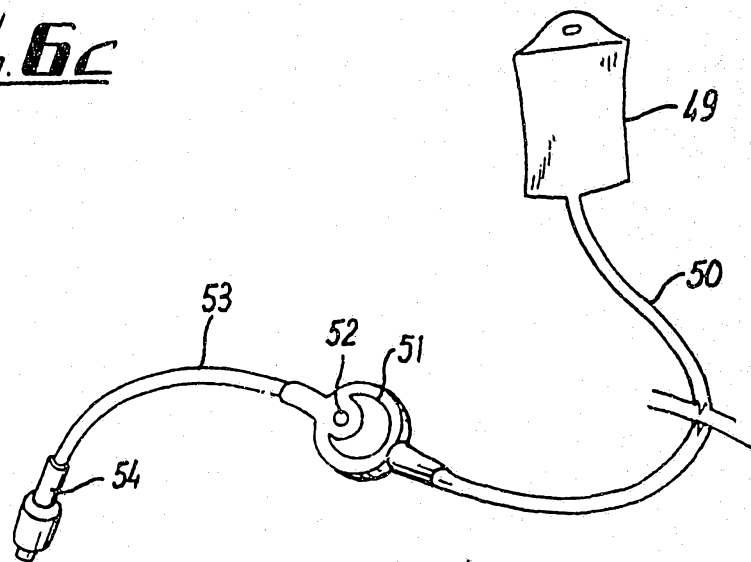


Fig. 6d

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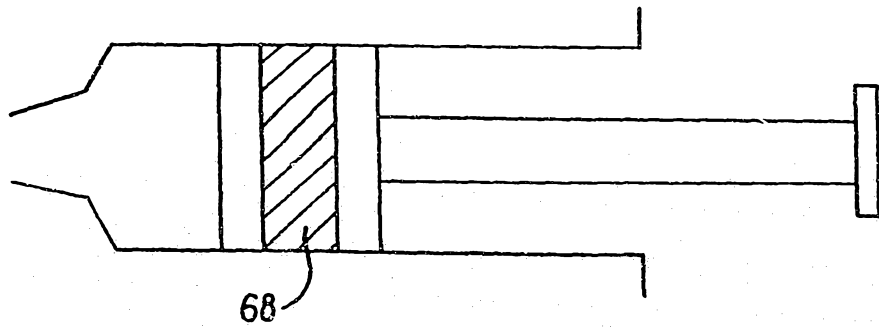


Fig. 7

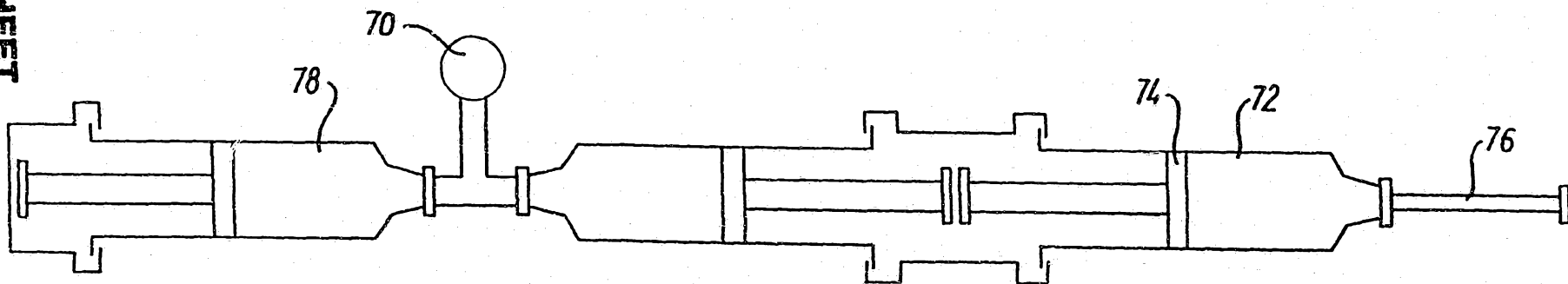
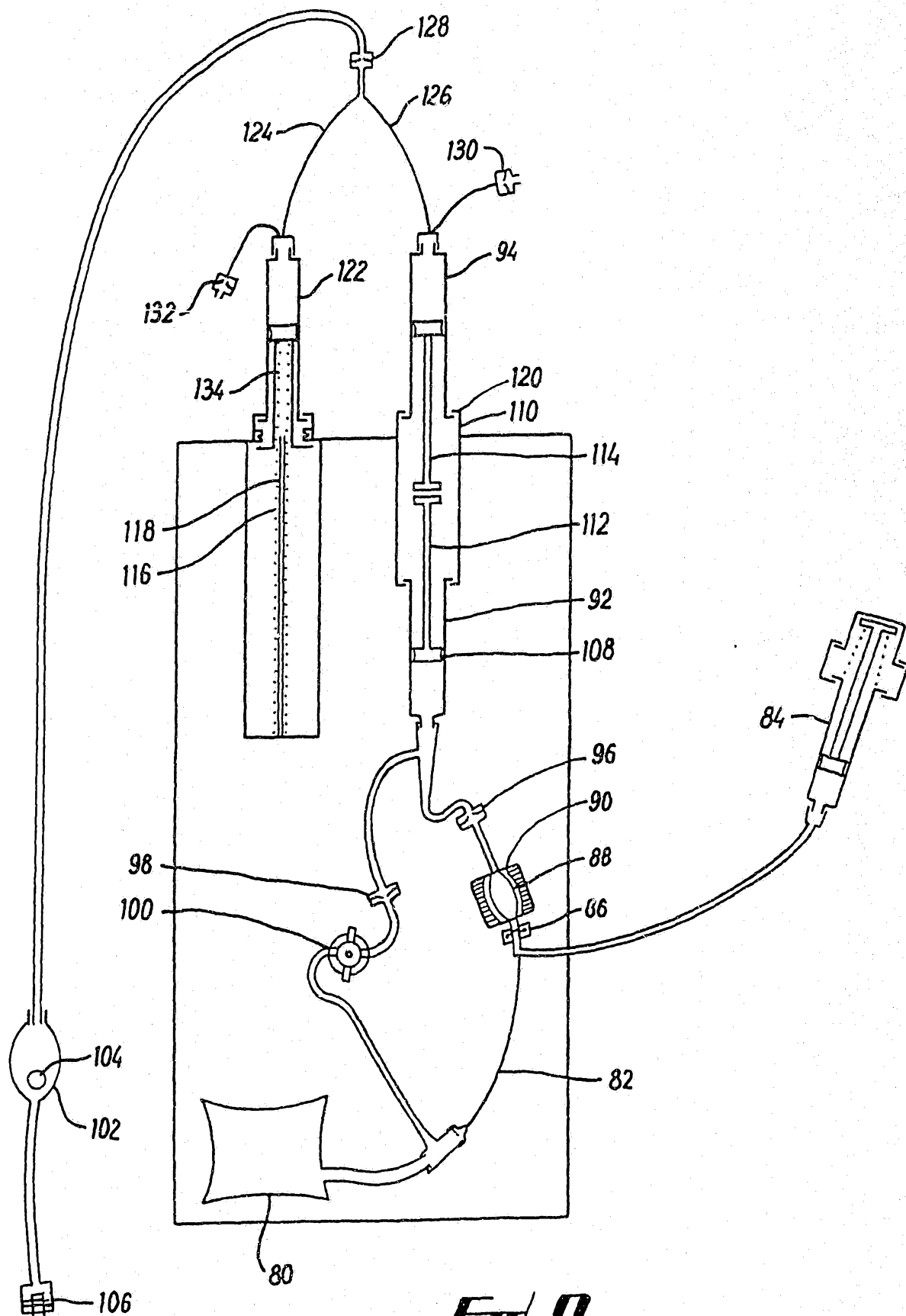
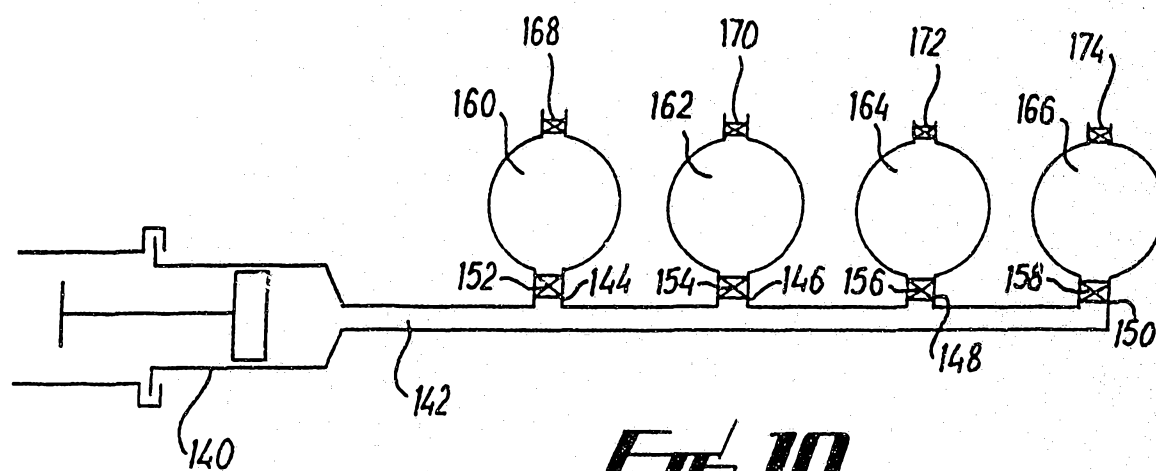
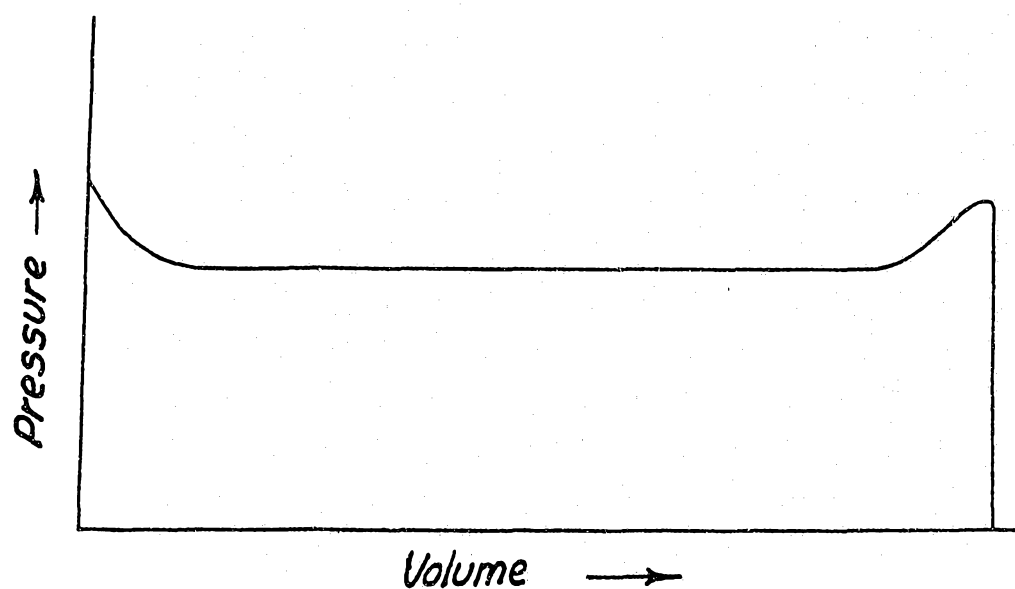


Fig. 8

**FIG. 9**

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**FIG. 10****FIG. 11**

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INTERNATIONAL SEARCH REPORT

Intern. Application No.
PCT/GB 93/02009

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61M5/145

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61M

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB,A,1 105 820 (GIDLUND) 13 March 1968 see page 2, line 32 - line 120; figure ---	1-6, 9, 10, 19, 22
X	FR,A,2 131 077 (DESANTI) 10 November 1972 see page 2, line 5 - page 3, line 7; figure ---	1-6, 9, 12, 13, 20, 21
X	WO,A,91 06338 (PRIME MEDICAL PRODUCTS) 16 May 1991 see page 8, last paragraph - page 9, paragraph 1 see page 17, paragraph 2 - last paragraph; figures --- -/--	1, 4-9, 14-16

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

4 January 1994

Date of mailing of the international search report

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Mir y Guillen, V

INTERNATIONAL SEARCH REPORT

International Application No
 PCT/GB 93/02009

(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 435 512 (BURRON MEDICAL INC.) 3 July 1991 see column 4, line 45 - column 7, line 10; figures	1,8, 14-17
A	US,A,4 744 786 (HOOVEN) 17 May 1988 see abstract; figures	11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 93/02009

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		EP-A- 0497923	12-08-92
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