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APPARATUS FOR PATIENT-CONTROLLED INFUSION

This invention relates to an improved apparatus for effecting patient-controlled infusion of liquid medicaments and is particularly, but not exclusively, applicable to patient-controlled analgesia (PCA).

It has been recognised for some time that PCA is desirable in many situations of chronic or temporary (for example, post operative) pain. Before the advent of PCA, analgesia relied on periodic injections of drugs such as synthetic opioids by the physician or nurse, typically at 4-hour intervals. This has the disadvantage that for most of the time the patient's analgesic level is significantly above or below the optimum.

PCA improves on that prior art by enabling the infusion of small quantities of analgesics at regular intervals as perceived to be required by the patient. However, to date PCA has been effected by sophisticated electronic pump systems which have a number of disadvantages:

(a) They are expensive.

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b) They are complex and require skilled maintenance.

(c) They are capable of administering an overdose as a result of machine failure or of operator error in setting up; a number of deaths from this cause have been reported.

An object of the present invention is to provide an improved PCA apparatus which is simple and inexpensive to manufacture and use, and which has a high level of inherent safety.

The present invention accordingly provides apparatus for patient-controlled infusion of a liquid medicament, the apparatus comprising a reservoir for the medicament, a positive displacement pump having a predetermined working volume, a first conduit connecting the reservoir to the pump, a second conduit extending from the pump and having a distal end to be inserted in the patient, and a one-way valve in the second conduit permitting liquid flow from the pump to the patient and preventing reverse flow; the pump being manually operable to displace liquid through the valve and comprising resilient restoring means for returning the pump to its initial state while drawing liquid from the reservoir through the first conduit; and in which the first conduit has a restricted flow rate chosen in conjunction with the working volume of the pump to define a predetermined maximum dosage rate.

An important preferred feature of the invention resides in the provision of means for introducing a priming liquid into the second conduit without the priming liquid passing through the first conduit, which means

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may conveniently comprise a dismountable connection between the pump and the second conduit whereby the pump may be removed to allow the second conduit to be filled with priming liquid through said connection.

Preferably the pump is a syringe having a plunger biased outwardly by resilient means.

The second conduit preferably includes means for venting gas therefrom, suitably in the form of a filter which is also capable of removing bacteria.

In one form of the invention, means are provided for introducing liquid into the reservoir while the apparatus is in use, preferably in the form of a third conduit extending from the reservoir and terminating in an injection port.

The third conduit preferably includes a one-way valve, and may include an air-trapping filter or alternatively a branch for removing air.

For safety reasons, the injection port and/or the air removing branch if present may be provided with lockable covers.

The reservoir may suitably comprise a piston and cylinder or a flexible bag.

Embodiments of the invention will now be described, by way of example only, with reference to the drawings in which:

Fig. 1 is a schematic view of a PCA apparatus forming a first embodiment of the invention;

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Fig. 2 is a schematic view of a second embodiment containing additional features;

Fig. 3 is a similar view of a third embodiment being a modified version of the embodiment of Fig. 2;

Fig. 4 is a similar view of a further modified embodiment; and

Fig. 5 is a perspective view of a practical embodiment suitable for ambulatory use.

Referring to Fig. 1, the apparatus comprises a reservoir in the form of a syringe 3 which is in communication via a small bore tube 4 with a metering device in the form of an aspirating syringe 1 whose plunger 1a is biased upwardly by a return spring 2. The aspirating syringe 1 is arranged to discharge via a patient line comprising a one-way valve 5, tubing 6 and male luer lock connection 9 to an intravenous catheter secured to the patient. Interposed in the tubing 6 is a filter 7 of known type for preventing passage of bacteria and including a hydrophilic membrane 8 which discharges to atmosphere any air which inadvertently enters the system. The aspirating syringe 1 can be connected to and disconnected from the patient line by means of a connection joint 10.

In use, the reservoir 3 is filled with a quantity of analgesic suitable for pain control over a period, for example 4 hours. Once the system is primed with liquid and connected to the patient, depression of the plunger 1a causes a quantity of analgesic equal to the volume of the aspirating syringe 1, typically about 0.5ml, to

be infused. When the plunger 1a is released, it returns under the influence of the spring 2, but at a rate which is determined by the rate of flow of liquid from the reservoir 3 through the small bore tube 4. The overall infusion rate is thus controlled by suitable selection of the volume of the aspirating syringe 1 and the flow-resistance of the tube 4 in relation to a given liquid.

The tube 4 is preferably a plastics tube having a very narrow bore and a relatively thick wall, the latter ensuring that it does not kink in use. Such a tube and the method of producing it are described in published International Patent Application WO88/02637. The tube 4 preferably has a length in the range 1 to 40cm and a lumen diameter in the range 0.001 inch (0.025mm) to 0.008 inch (0.20mm). In a particularly preferred form, the lumen diameter is 0.070mm and the tube length 23mm.

The use of fine bore tubing not only sets the refill time of the aspirating syringe 1, but also acts as a safety factor in inhibiting siphoning of liquid from the reservoir 3 to the patient. As an additional safety factor, the one-way valve 5 should have an opening pressure greater than the maximum possible hydrostatic pressure which could be present by elevating the reservoir above the patient to the maximum height permitted by the length of the tubing.

The embodiment of Fig. 2 is similar to that of Fig. 1 and like parts are denoted by like reference numerals. In this embodiment, the reservoir 3 is provided with a fill line 20 terminating in an injection site 21 where the system can be filled or emptied by means of a standard hypodermic syringe.

The embodiment of Fig. 3 is similar to that of Fig. 2, but the reservoir is in the form of a collapsible bag 30, and the aspirating syringe is replaced by a balloon 31. The balloon 31 is a thick-walled rubber balloon with sufficient recovery force to draw liquid from the reservoir 30 through the small bore tube 4.

Fig. 4 shows optional features which may be added to the systems of Figs. 2 and 3. A gas-trapping filter 40 may be included in the fill line 20 to prevent any air inadvertently introduced at the injection site 21 from reaching the reservoir 3. Alternatively a branch 41 may be provided, ending in a port 42 for removing from the system air either introduced inadvertently or at the initial purging of the system. A one-way valve 45 may be included in the fill line 20 to prevent removal of liquid from the system.

A cover 43 may be placed over the port 42 and secured in place by a padlock 44 to prevent accidental or unauthorised use. The cover 43 and padlock 44 may similarly be used to bar unauthorised access to the injection site 21.

Fig. 5 illustrates one presently preferred, practical implementation of the invention. Again, like parts are denoted by like reference numerals. In Fig. 5, the reservoir syringe 3 is enclosed within a transparent plastics bag 50 for reasons of safety and hygiene. The return spring of the aspirating syringe 1 is housed within a cylindrical casing 51, the plunger being actuated by a patient demand button 52 extending from the casing 51. The syringe 1 and the bag 50 are linked by a cord 53 which allows the apparatus to be hung around the patient's neck for ambulatory use.

An important preferred feature is the ability to remove the syringe 1 (or equivalent) to assist in priming the system. The tube 4 has such an extremely fine bore that it is difficult to force liquid through it from the reservoir 3 to prime the system, and such a procedure would take an extremely long time. Accordingly, to prime the system the aspiration syringe 1 is removed from the connector 10 and the patient line is filled with liquid, which may be done by connecting a relatively large syringe at the connector 10 and injecting from this to overcome the resistance of the one-way valve 5. In the case of the embodiments of Figs 2 to 5, the reservoir fill line is also primed with liquid at this stage.

The aspirating syringe 1 is then re-applied to the connector 10 with its plunger 1a held down. On release of the plunger 1a, fluid is drawn through the fine bore tube 4. This fluid is initially air which becomes trapped in the syringe 1, but the volume of air involved (equal to the internal volume of the tube 4) is so small that it does not affect the operation of the system.

The invention thus provides a patient-controlled apparatus which is of simple and inexpensive construction and has a high level of inherent safety. The apparatus is extremely simple to operate. Owing to its simplicity and cheapness it can be used as a disposable item. The apparatus can be manufactured for use with a particular medicament by suitable choice of aspirating syringe and bore of the flow control tube; on-site adjustment is then not required, and the apparatus can be used by nursing staff without specialist training who simply have to recharge the

reservoir from time to time, suitably by injecting a single standard 4-hour bolus into the reservoir.

Although described with particular reference to patient-controlled analgesia, the invention can be applied to patient-controlled infusion of other medicaments such as sedatives and antiemetics.

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CLAIMS

1 Apparatus for patient-controlled infusion of a liquid medicament, the apparatus comprising a reservoir for the medicament, a positive displacement pump having a predetermined working volume, a first conduit connecting the reservoir to the pump, a second conduit extending from the pump and having a distal end to be inserted in the patient, and a one-way valve in the second conduit permitting liquid flow from the pump to the patient and preventing reverse flow; the pump being manually operable to displace liquid through the valve and comprising resilient restoring means for returning the pump to its initial state while drawing liquid from the reservoir through the first conduit; and in which the first conduit has a restricted flow rate chosen in conjunction with the working volume of the pump to define a predetermined maximum dosage rate.

2 Apparatus according to Claim 1, including means for introducing a priming liquid into the second conduit without the priming liquid passing through the first conduit.

3 Apparatus according to Claim 2, in which said introducing means comprises a dismountable connection between the pump and the second conduit, whereby the pump may be removed to allow the second conduit to be filled with priming liquid through said connection.

4 Apparatus according to any preceding Claim, in which the pump is a syringe having a plunger biased outwardly by resilient means.

5 Apparatus according to any preceding Claim, in which

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the second conduit includes means for venting gas from the second conduit.

6 Apparatus according to Claim 5, in which the venting means comprises a filter which is also capable of removing bacteria.

7 Apparatus according to any preceding claim, further including means for introducing liquid into the reservoir while the apparatus is in use.

8 Apparatus according to Claim 7, in which said introducing means comprises a third conduit extending from the reservoir and terminating in an injection port.

9 Apparatus according to Claim 8, in which the third conduit includes a one-way valve.

10 Apparatus according to Claim 8 or Claim 9, in which the third conduit includes an air trapping filter.

11 Apparatus according to Claim 8 or Claim 9, in which the third conduit is provided with a branch for removing air.

12 Apparatus according to any preceding claim, in which the reservoir comprises a piston and cylinder.

13 Apparatus according to any of Claims 1 to 11, in which the reservoir comprises a flexible bag.

14 Apparatus according to any of Claims 8 to 11, in which the injection port is provided with a lockable cover.

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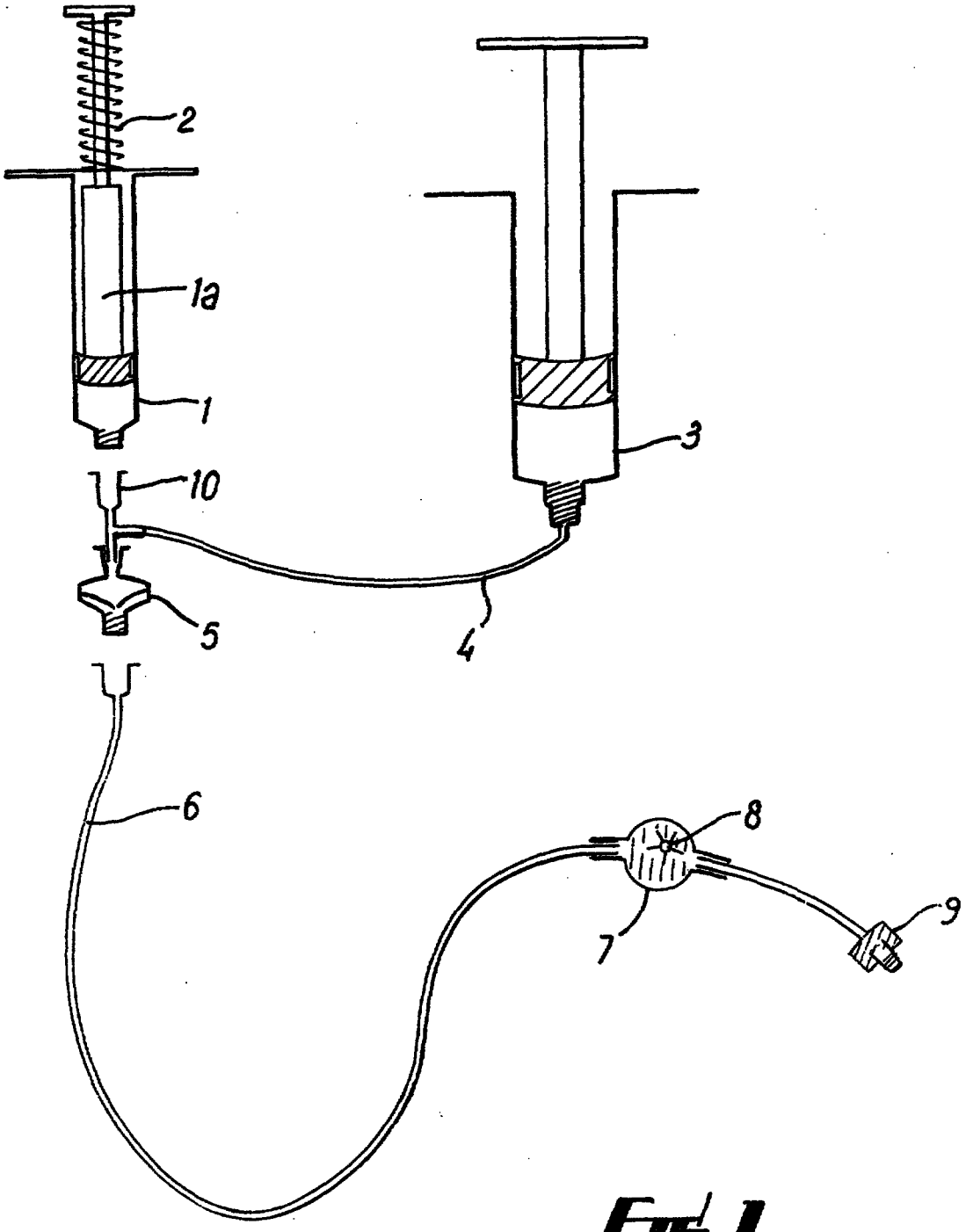


FIG. 1

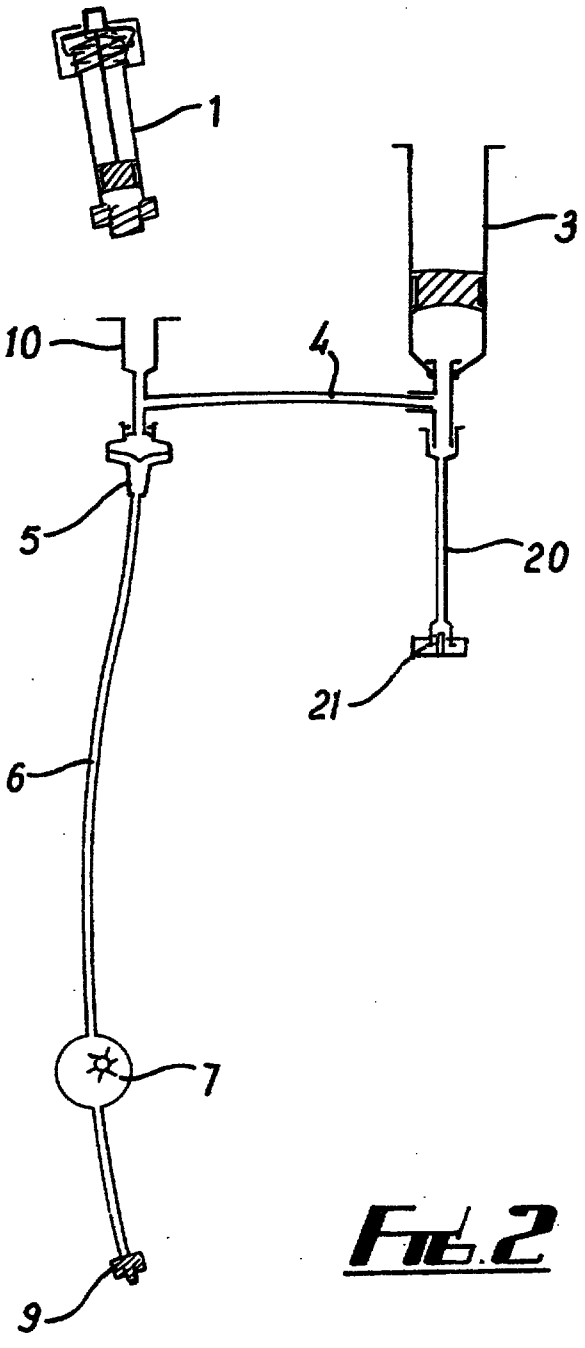


FIG. 2

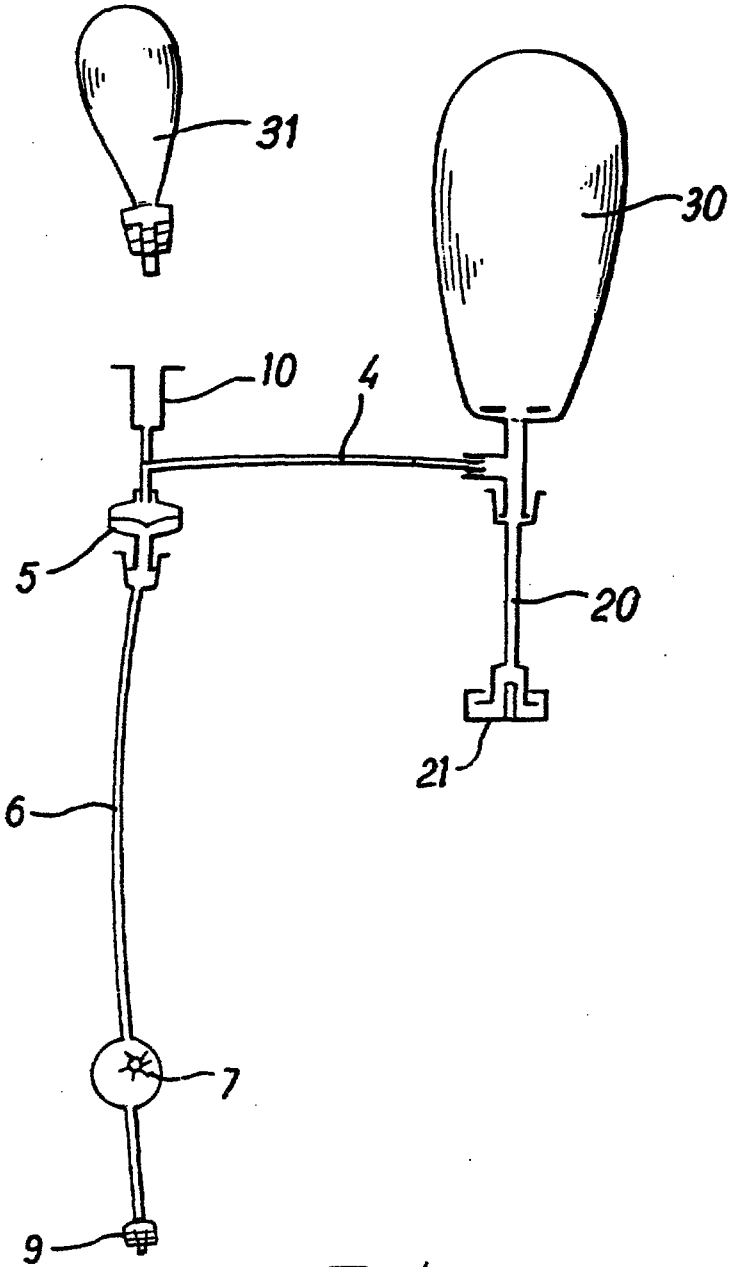


FIG. 3

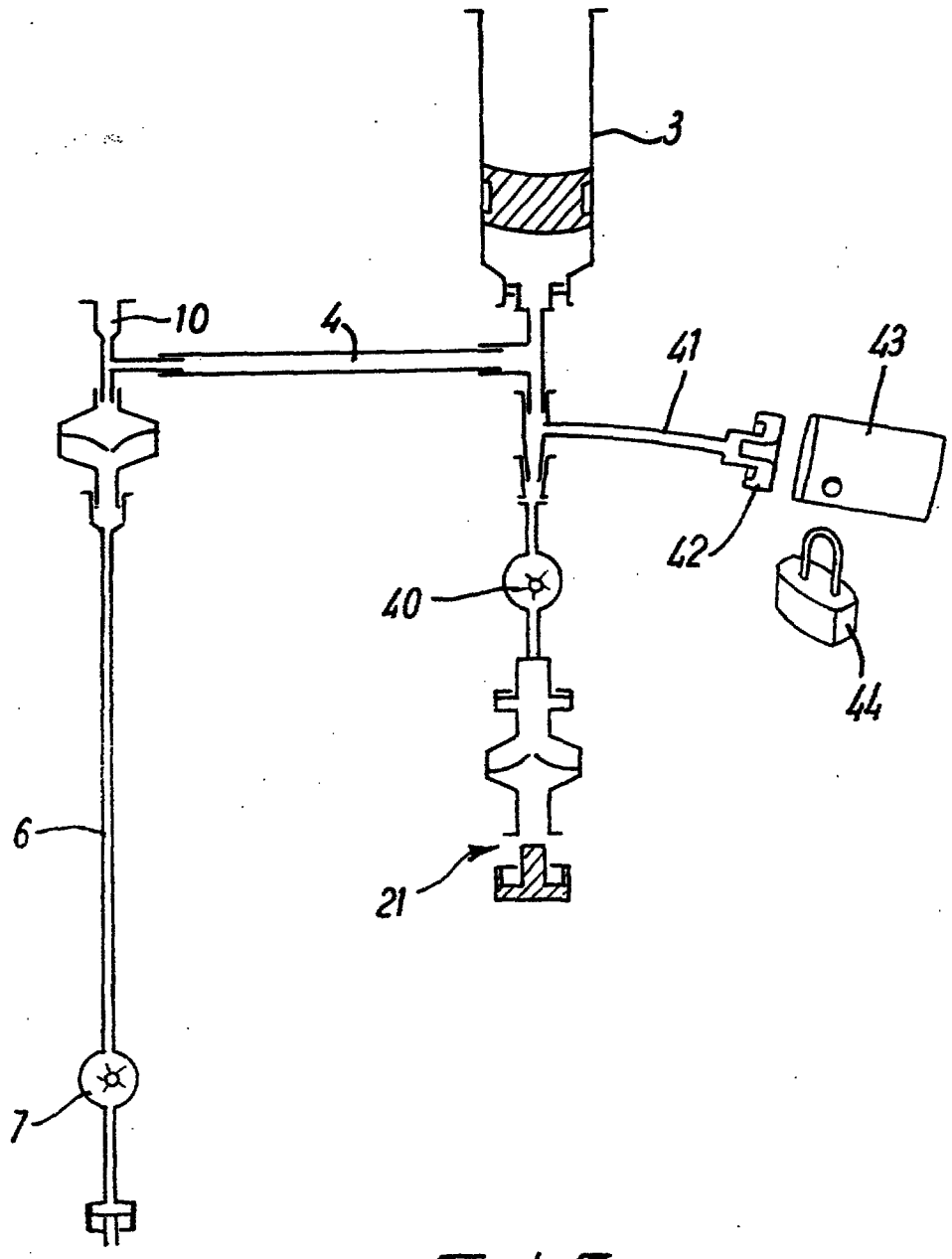


FIG. 4

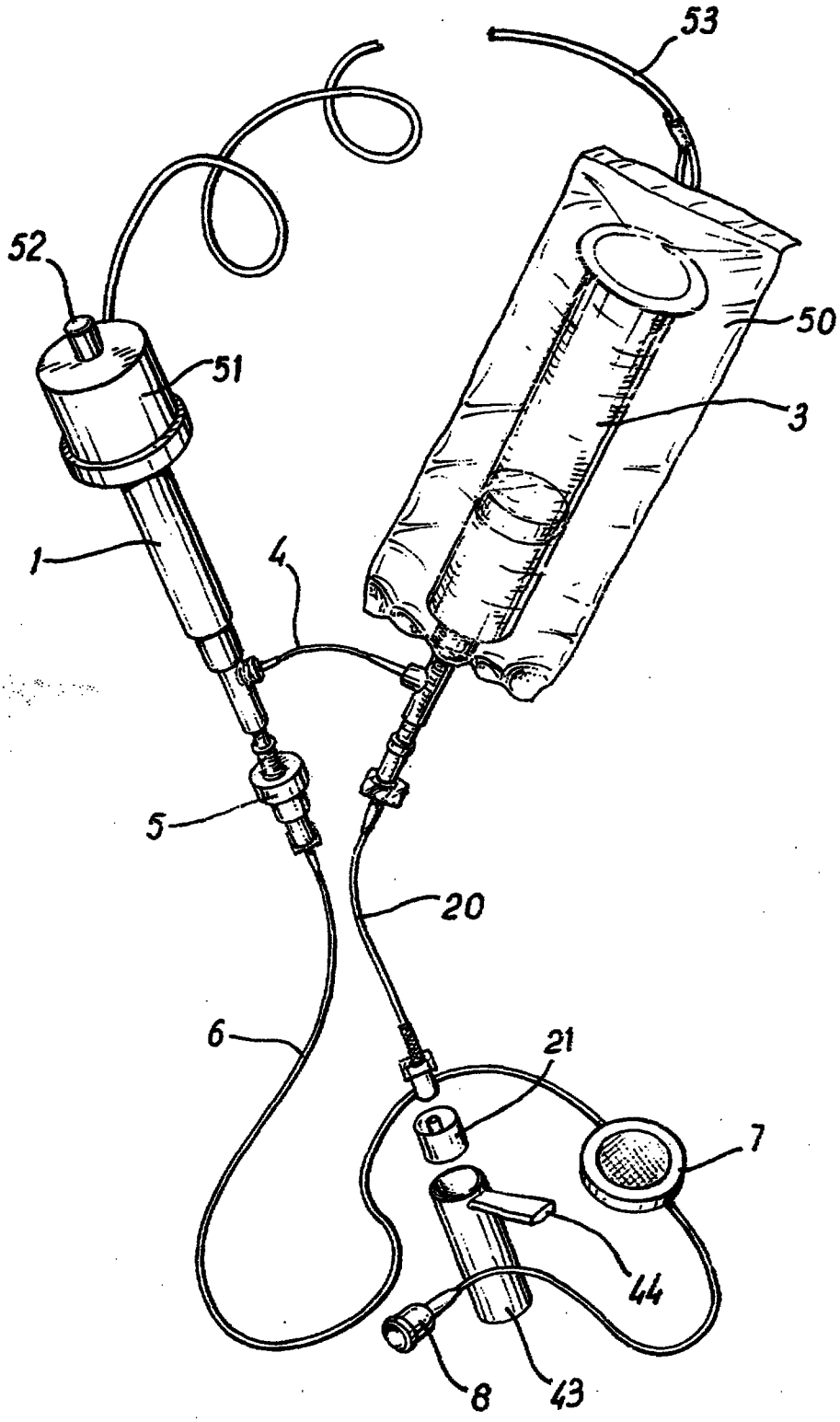


FIG. 5

ABSTRACT (FIG. 1)

"APPARATUS FOR PATIENT-CONTROLLED INFUSION"

A reservoir (3) is connected to a manually operable pump such as an aspirating syringe (1) via a flow control tube (4) which has a fine bore of accurately known size. Actuation of the syringe (1) by the patient discharges a fixed volume of drug via a non-return valve (5) to the patient. The syringe (1) is refilled by a return spring (2) drawing liquid from the reservoir (3) at a rate controlled by the bore of the flow control tube (4), thus setting a maximum dosage rate.

b) They are complex and require skilled maintenance.

c) They are capable of administering an overdose as a result of machine failure or of operator error in setting up; a number of deaths from this cause have been reported.

WO 87/00758 in the name Baxter Travenol Laboratories Inc discloses a device for patient controlled delivery of beneficial agents comprising a resilient bag filled with beneficial agent attached to a control switch by means of a conduit incorporating a flow restrictor; the control switch is operable to compress a dose reservoir and discharge the beneficial agent through a further conduit to the patient.

WO 91/08002 in the name Prime Medical Products Inc discloses apparatus for patient control delivery of a beneficial agent which has a dose reservoir and a pump connected by tubing; the pump means also having an outlet tubing for discharging beneficial agent from the pump.

French Patent No 2,588,757 discloses injection apparatus comprising a reservoir, a pump intended to be placed under the skin of a patient, the pump being connected to the reservoir via a valve and having an outlet catheter which, in use, is disposed in communication with the spinal cord of the patient.

European Patent Application No 0,483,759 A1 in the name Baxa Corporation discloses a patient controlled infusion apparatus comprising a dose reservoir linked to a pump via a flow restrictor, the pump having an

REPLACEMENT SHEET

24 JUL 1999

outlet terminating in a needle for insertion into a patient.

The present invention provides apparatus for patient-controlled infusion of a liquid medicament, the apparatus comprising a reservoir for the medicament, a positive displacement pump having a predetermined working volume, a first conduit connecting the reservoir to the pump, a second conduit extending from the pump and having a distal end to be inserted in the patient, and a one-way valve in the second conduit permitting liquid flow from the pump to the patient and preventing reverse flow, the second conduit being connected to the pump by a dismountable connection adapted to be terminated and re-established repeatedly for introducing a priming liquid into the second conduit without the priming liquid passing through the first conduit; the pump being manually operable to displace liquid through the valve and comprising resilient restoring means for returning the pump to its initial state while drawing liquid from the reservoir through the first conduit; and in which the flow rate of liquid medicament through the first conduit is restricted to a rate chosen in conjunction with the working volume of the pump to define a predetermined maximum dosage rate.

REPLACEMENT SHEET

24 JUL 1999

Preferably the pump is a syringe having a plunger biased outwardly by resilient means.

The second conduit preferably includes means for venting gas therefrom, suitably in the form of a filter which is also capable of removing bacteria.

In one form of the invention, means are provided for introducing liquid into the reservoir while the apparatus is in use, preferably in the form of a third conduit extending from the reservoir and terminating in an injection port.

The third conduit preferably includes a one-way valve, and may include an air-trapping filter or alternatively a branch for removing air.

For safety reasons, the injection port and/or the air removing branch if present may be provided with lockable covers.

The reservoir may suitably comprise a piston and cylinder or a flexible bag.

Embodiments of the invention will now be described, by way of example only, with reference to the drawings in which:

Fig. 1 is a schematic view of a PCA apparatus forming a first embodiment of the invention;

REPLACEMENT SHEET
24 JUL 1999

CLAIMS

1. Apparatus for patient-controlled infusion of a liquid medicament, the apparatus comprising a reservoir (3) for the medicament, a positive displacement pump (1) having a predetermined working volume, a first conduit (4) connecting the reservoir (3) to the pump (1), a second conduit (6) extending from the pump and having a distal end to be inserted in the patient, and a one-way valve (5) in the second conduit (6) permitting liquid flow from the pump (1) to the patient and preventing reverse flow, the pump (1) being manually operable to displace liquid through the valve (5) and comprising resilient restoring means (2) for returning the pump (1) to its initial state while drawing liquid from the reservoir (3) through the first conduit (4); and in which the flow rate of liquid medicament through the first conduit (4) is restricted to a rate chosen in conjunction with the working volume of the pump (1) to define a predetermined maximum dosage rate characterised by the second conduit (6) being connected to the pump (1) by a dismountable connection (10) adapted to be terminated and re-established repeatedly for introducing a priming liquid into the second conduit (6) without the priming liquid passing through the first conduit (4).

2. Apparatus according to Claim 1, wherein the first conduit (4) has a length in the range 1cm to 40cm and a lumen diameter in the range 0.025mm to 0.20mm.

3. Apparatus according to Claim 1 or Claim 2, in which the pump (1) is a syringe having a plunger biased outwardly by resilient means (2).

4. Apparatus according to any preceding Claim, in

REPLACEMENT SHEET

24 JUL 1999

which the second conduit (6) includes means (8) for venting gas from the second conduit (6).

5. Apparatus according to Claim 4, in which the venting means (8) comprises a filter (7) which is also capable of removing bacteria.

6. Apparatus according to any preceding Claim, further including means (20) for introducing liquid into the reservoir (3) while the apparatus is in use.

7. Apparatus according to Claim 6, in which said introducing means comprises a third conduit (20, 41) extending from the reservoir (3) and terminating in an injection port (21, 42).

8. Apparatus according to Claim 7, in which the third conduit (20) includes a one-way valve.

9. Apparatus according to Claim 7 or Claim 8, in which the third conduit (20) includes an air trapping filter (40).

10. Apparatus according to Claim 7 or Claim 8, in which the third conduit (20) is provided with a branch for removing air.

11. Apparatus according to any preceding claim, in which the reservoir (3) comprises a piston and cylinder.

12. Apparatus according to any of Claims 1 to 10, in which the reservoir comprises a resilient bag (30).

REPLACEMENT SHEET
24 JUL 1999

13. Apparatus according to any of Claims 7 to 10, in which the injection port (42) is provided with a lockable cover (43).

REPLACEMENT SHEET
24 JUL 1999