(12) UK Patent Application (19) GB (11) 2 304 584 (13) A

(43) Date of A Publication 26.03.1997

(21) Application No 9617607.8

(22) Date of Filing 22.08.1996

(30) Priority Data
(31) PN4937 (32) 23.08.1995 (33) AU
PN7382 03.01.1996

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(51) INT CL^6
A61M 5/148

(52) UK CL (Edition O)
A5R RCH

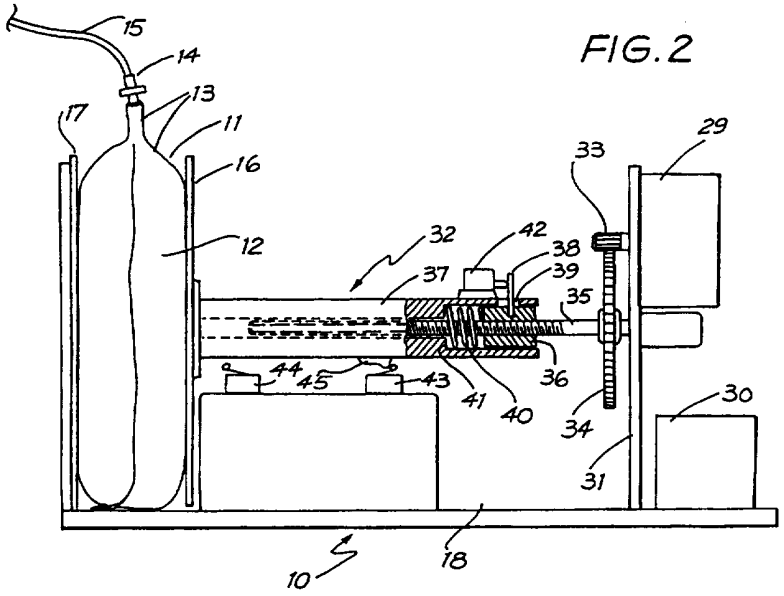
(56) Documents Cited
GB 2034183 A EP 0465267 A1 WO 95/05859 A1
WO 93/10832 A1 WO 89/11303 A1 US 5342313 A

(58) Field of Search
UK CL (Edition O) A5R RCH
INT CL^6 A61M 1/02 5/142 5/145 5/148 5/152
ONLINE: WPI

(54) Infusion device comprising a collapsible bag and a movable wall

(57) The apparatus includes a chamber 11 comprising a movable wall portion 16 and a fixed wall 17, which receives a collapsible infusion bag 12 therebetween. A drive mechanism 10, comprising a stepping motor 29 and reduction gearing 33, 34, pushes the movable wall 16 towards the fixed wall 17 compressing the bag and displacing fluid therefrom. A helical spring 40 in the gear mechanism allows forward movement of the wall 16 to be resisted if the delivery line is blocked or the bag is empty. Resistance is detected by microswitches 42, 43 which limit the drive motor. Control means are provided to allow the operating speed of the drive mechanism to be varied. Also, indicator means (23) provide, inter alia, an indication of the rate at which infusate is displaced from the collapsible bag 12. An in-line anti-syphoning valve is also disclosed.

FIG. 2



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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the formal requirements of the Patents Rules 1995

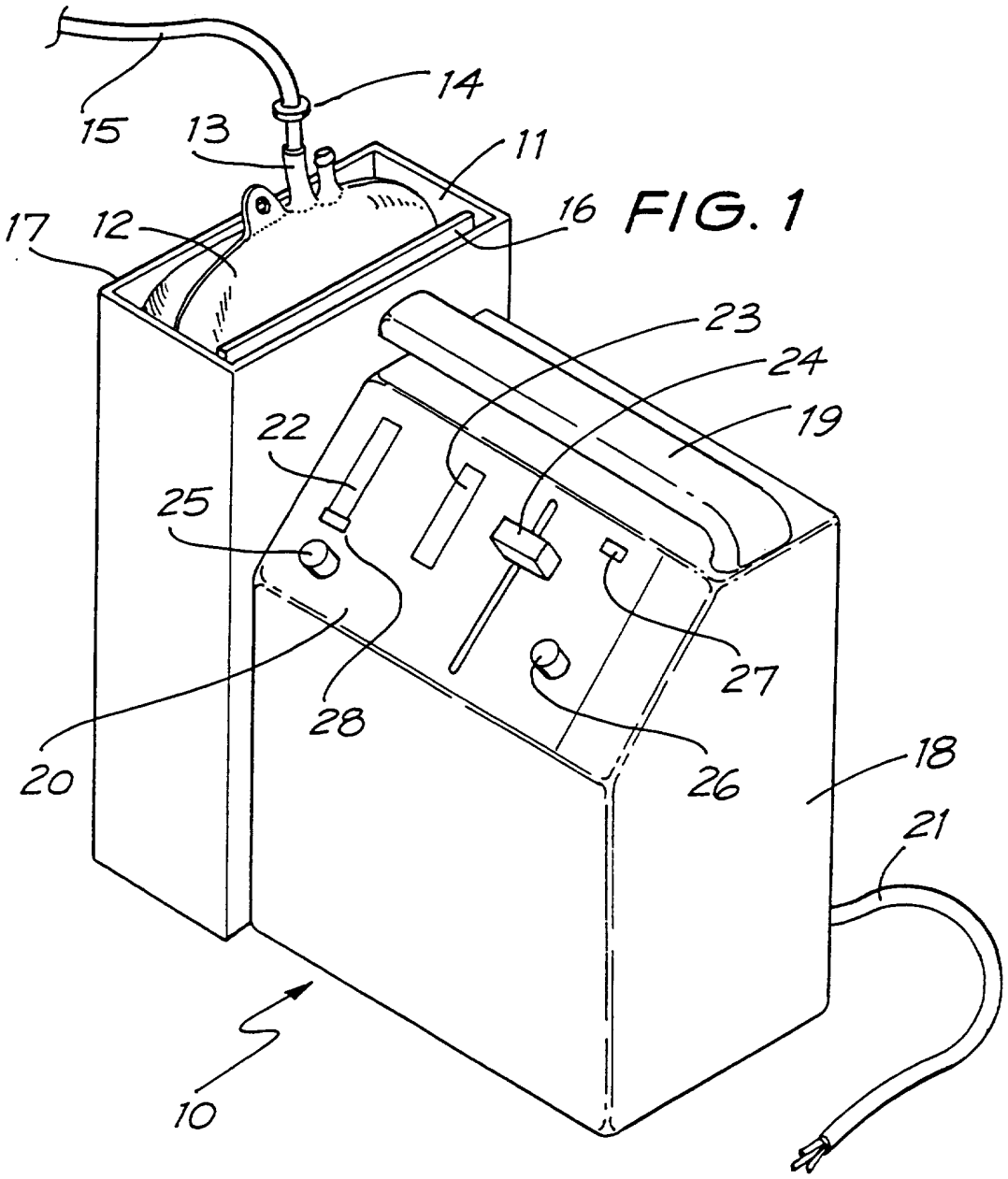
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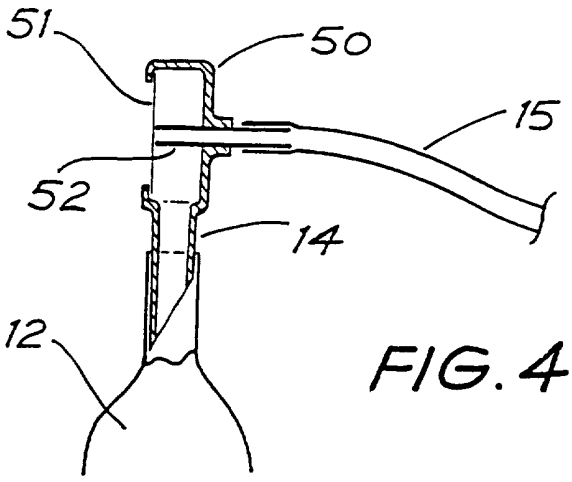
FIG. 1


51
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15
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12

FIG. 4

FIG. 2

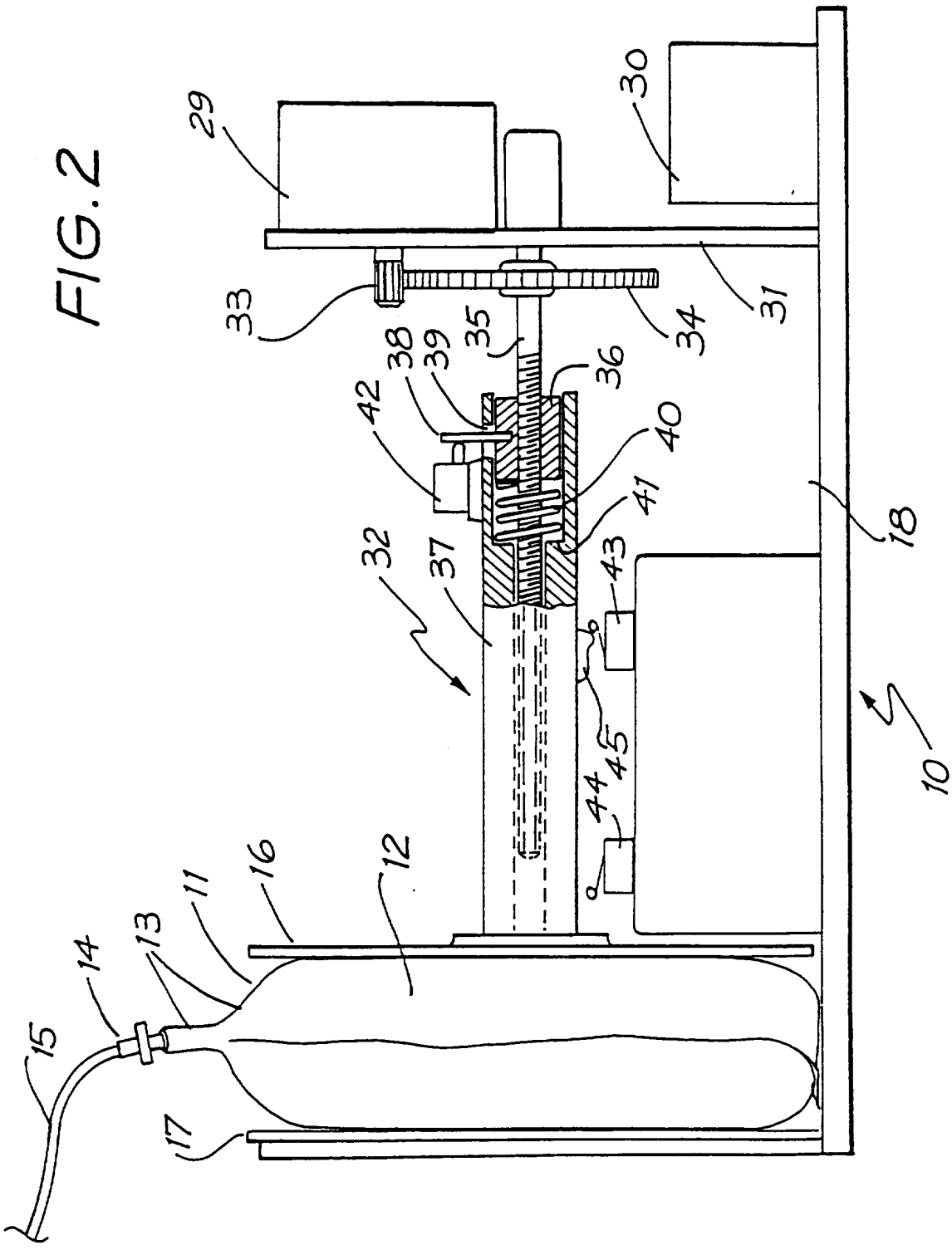
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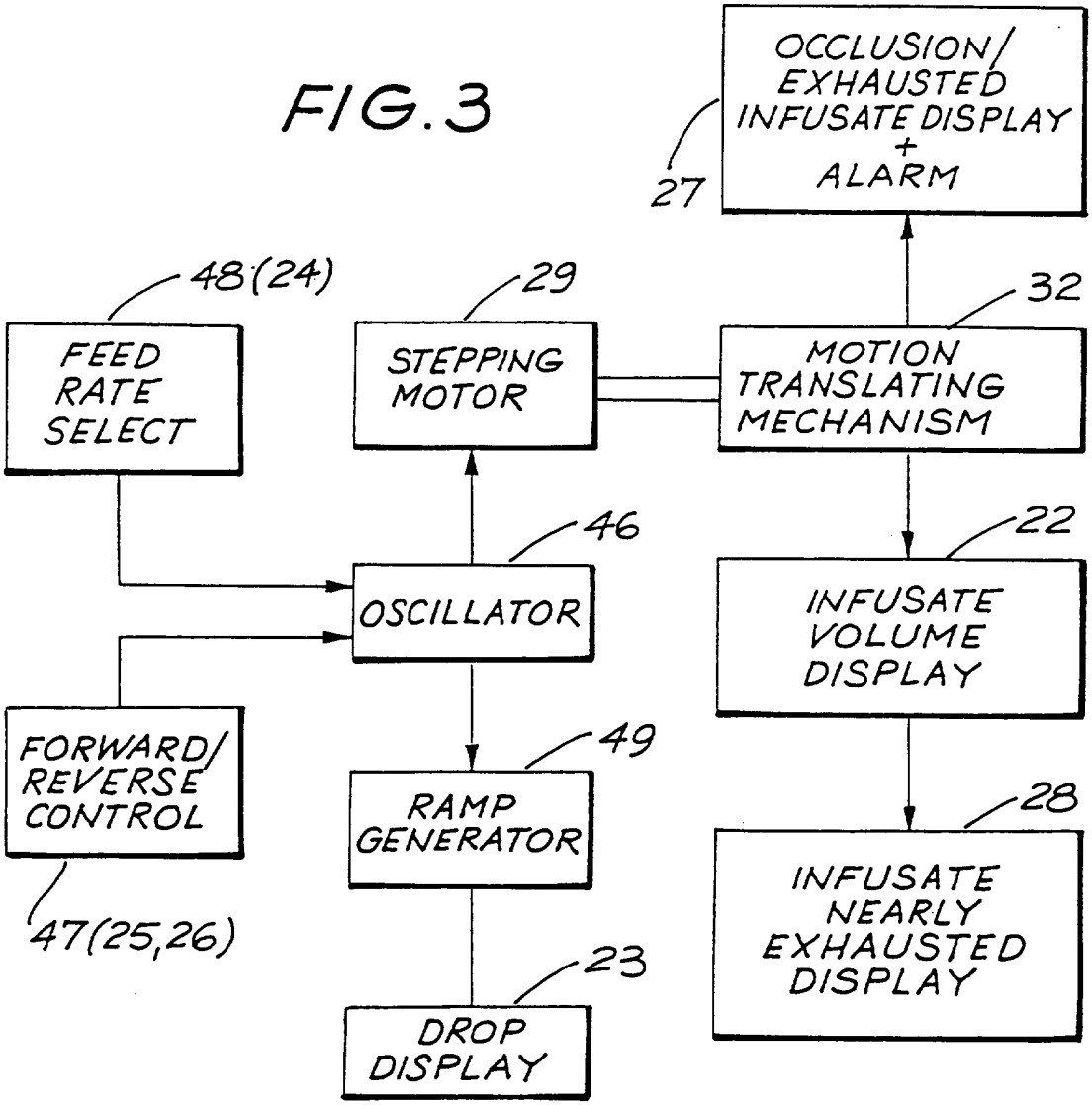
FIG. 3


OCCLUSION/ EXHAUSTED INFUSATE DISPLAY + ALARM
27
48(24)
FEED RATE SELECT
29
STEPPING MOTOR
32
MOTION TRANSLATING MECHANISM
46
OSCILLATOR
22
INFUSATE VOLUME DISPLAY
FORWARD/ REVERSE CONTROL
47(25,26)
49
RAMP GENERATOR
28
INFUSATE NEARLY EXHAUSTED DISPLAY
23
DROP DISPLAY

INFUSATE DELIVERY SYSTEM

This invention relates to an apparatus for use in medical and/or veterinary applications, for delivering an infusate to a patient.

The traditional system for delivering liquid infusate to a patient involves the gravity feeding of drops of the liquid into a patient delivery line from a collapsible bag which is carried by a stand at a level above that of the patient. The delivery rate is controlled by adjusting a throttling device which acts to vary the dimension of the lumen in the delivery line and, in order to overcome the resistance to liquid flow within the delivery line, by adjusting the height of the bag relative to the patient. In developments of this system, various feedback mechanisms have been employed for measuring the drop rate, computing the corresponding flow rate and adjusting the throttling device to meet prescribed delivery rates.

Positive displacement pumps are employed as alternatives to the above described drip feed systems and they are characterised generally as volumetric infusion pumps (which include peristaltic pumps and cassette or chamber type infusion pumps) and syringe pumps. In the volumetric infusion pumps, the infusate generally is contained within a collapsible bag of the type used in the drip feed system and the pumps act on or are located within the infusate delivery line. In the syringe pumps, an electric motor drive is applied to a syringe plunger for the purpose of forcing infusate into the patient delivery line from the syringe.

In situations where liquid is to be delivered to a patient at a relatively high pressure or high flow rate, for example in the case of a flushing liquid or an arterial infusate, a different system sometimes is employed. In this case a reservoir of the liquid is pressurised and the rate of delivering the liquid into a delivery line is controlled by a regulator valve.

Each of the above described systems has its own advantages and disadvantages. For example, the traditional drip feed system has the merits of simplicity and relatively low cost, but the infusate bag support stand can be inconvenient, particularly in a crowded operating theatre. At the other extreme, the less intrusive syringe pump has a very limited volumetric capacity and provides less-than-smooth operation when effecting low flow-rate delivery.

The present invention seeks to provide an alternative infusate delivery system; one which permits the use of conventional infusate-containing bags but which obviates the need for support stands and which permits the selection of a desired flow rate within a wide range.

The present invention may be defined broadly as providing an apparatus for use in delivering infusate to a patient and which comprises a receiving station which is arranged to receive a collapsible bag of the infusate. The receiving station has a wall portion which is movable in a manner to reduce the contained volume of a bag of infusate within the receiving station, and a drive mechanism is provided for imparting movement to the wall portion. Control means are provided for varying the operating speed of the drive mechanism and, hence, the rate of movement of the wall portion, and indicator means are provided to give indication of the rate at which infusate is displaced from the collapsible bag as a function of the rate at which movement is imparted to the wall portion by the drive mechanism.

The apparatus of the present invention differs from all known prior art systems in that it provides for controlled positive displacement of infusate from the collapsible bag. It has been found that the rate of displacing the infusate may be varied linearly with linear variation of the operating speed of the drive mechanism, and that the rate of delivery can be controlled very accurately even when displacing liquid

from a relatively large volume infusate bag. This latter characteristic permits the administration of large volumes of drug solutions without significant dose variation.

The rate at which the infusate is displaced from the bag may be adjusted to correspond accurately with a desired rate of administration of the infusate. This means that the delivery line will not be subjected to expansion induced stress or other stress in normal operation of the apparatus, and it avoids the need to place a pressure-regulating valve or a flow rate control valve in the delivery line.

Indicator means preferably are provided to give indication of movement imparted to the movable wall portion in the direction of minimising the contained volume of the infusate bag. Thus, a "bag-empty" indication may be provided and, additionally, indication preferably is provided of an approaching bag-empty condition.

The receiving station preferably is in the form of a chamber which preferably is bounded by a base and four side wall portions, one of which is movable toward its opposite wall. However, it is sufficient that the bag of infusate be squashed between two confronting wall portions, and the remaining portion of the chamber may have a skeletal or other structure which functions simply to retain the bag until it is acted upon (i.e., clamped between) the two confronting wall portions.

The drive mechanism preferably comprises an electric motor and a motion translating mechanism for imparting linear movement to the movable wall portion with energisation of the motor. The electric motor most preferably comprises a stepping motor, and energising pulses delivered to the stepping motor may be employed also to drive the indicator means that provides indication of the rate at which infusate is displaced from the collapsible bag.

The apparatus may be positioned at approximately the same level as a patient who is to receive the infusate and, in such case, liquid may be delivered directly to the patient by way of a delivery line. However, an anti-syphon device preferably is incorporated in the apparatus, to be located in circuit with the delivery line, in order to prevent the syphoning of liquid in the event of a sufficiently high negative pressure differential between the apparatus and the infusate delivery point.

The apparatus preferably includes means for detecting for the existence of an occlusion in the delivery line and for de-energising the drive motor upon detection of an occlusion.

The invention will be more fully understood from the following description of a preferred embodiment of the infusate delivery system, the description being provided with reference to the accompanying drawings.

In the drawings:

Figure 1 shows a perspective view of the complete apparatus,

Figure 2 shows a partially diagrammatic elevation view of the interior of the apparatus which is illustrated in Figure 1,

Figure 3 shows a block diagrammatic representation of a motor control and operating display system in the apparatus, and

Figure 4 shows an elevation view of an anti-syphon valve for use in conjunction with the apparatus.

As illustrated, the apparatus comprises a portable case 10 which includes a chamber 11 which is shaped and dimensioned to receive a standard collapsible plastics material bag or pouch 12 in which infusate is supplied and into which supplementary drugs may be injected. The infusate-containing bag 12 is formed with a neck region 13 which is arranged to be pierced by and to receive the inlet end 14 of a patient delivery line 15.

The delivery line may be of a simple tube without a drip chamber.

The chamber 11 includes a movable wall portion 16 which is movable toward and away from a fixed wall portion 17 and which functions (with movement) to vary the effective contained volume of the chamber. The infusate bag 12 is clamped or squashed between the wall portions 16 and 17, and the infusate is displaced from the bag at a rate which varies with the rate at which the movable wall portion 16 is moved toward the fixed wall portion 17.

The infusate within the bag 12 is not pressurised other than to an insignificant extent as determined by back pressure within the delivery line-patient circuit. Rather, the bag 12 is squashed or, in other words, compressed between the fixed and moving wall portions 16 and 17, and infusate is displaced from the bag at a rate substantially equal to the rate at which the bag is squashed.

The casing 10 includes a portion 18 which contains a drive mechanism for the movable wall portion 16 and as shown in more detail in Figure 2. Also, a carrying handle 19 is secured to the casing and a control/display panel 20 is mounted to an inclined front face of the casing. The apparatus is connected to a mains electrical supply by a power cord 21, and the apparatus incorporates a battery powered back-up power supply (not shown) which is arranged to provide continuing short-time operation and/or an alarm in the event of loss of mains power.

A LED bargraph display device 22 is provided on the display panel 20 for displaying a current position of the movable wall portion and hence for displaying a measure of infusate present in the bag 12. A further LED bargraph display device 23 is also provided on the panel 20 for displaying the rate of activation of the drive mechanism and, hence, for providing an indication of the infusate delivery rate. A linear potentiometer slider 24 is provided for setting (i.e., selecting) the

infusate delivery rate. Alternatively, the delivery rate may be selected by depressing a selected one of a number of pushbutton switches (not shown) which are marked individually with specific flow rate measurements and which when actuated introduced incremental levels of resistance into an electrical control circuit.

A pushbutton switch 25 is provided for activating high speed forward excitation of the drive mechanism as shown in Figure 2, to permit priming of the delivery system. A further pushbutton switch 26 is provided for activating high speed reverse excitation of the drive mechanism, to permit removal of an exhausted infusate bag 12 and insertion of a new bag.

A LED display 27 is provided in conjunction with a sound emitting device (not shown) to provide visual and audible indication of line occlusion or an empty infusate bag, and a further LED display 28, which forms the lowermost part of display device 22, is provided to give a visual, flashing, indication of a near-empty bag.

As shown in Figure 2 of the drawings, the drive mechanism comprises a stepping motor 29 which is energised by way of electrical circuitry 30 to effect movement of the movable wall portion 16. The stepping motor is mounted to a structural support 31 and is connected to a motion translating mechanism 32 by way of reduction gearing 33, 34. The driven gear wheel 34 is carried by a lead screw 35 and the lead screw engages with a threaded bush 36.

The threaded bush 36 is carried within a counter-bored portion of a motion translating shaft 37 and is constrained against rotation by a pin 38 which projects radially outwardly through a slot 39 within the shaft 37. Also, a helical compression spring 40 is positioned between a driving end face of the bush 36 and an end wall 41 of the counter bore within the shaft 37.

The spring 40 is designed to provide a force which normally maintains a substantially constant axial spacing between the bush 36 and the shaft 37 when the movable

wall portion 16 is driven forwardly to displace infusate from the bag 12. However, the spring 40 is designed also to be compressed, so that the axial spacing between the bush 36 and the shaft 37 is reduced if forward movement of the wall is resisted, either as a result of an occlusion in the delivery line or maximum forward movement of the movable wall portion 16 being reached when all infusate is displaced from the bag 12.

A microswitch 42 is mounted to the shaft 37 and is arranged to be actuated by the pin 38 when forward motion of the movable wall portion 16 is resisted and the spring 40 is caused to compress to an extent that indicates that an occlusion has occurred in the infusate delivery line or that maximum forward movement of the movable wall portion has been reached.

Two further microswitches 43 and 44 are provided to be acted upon by a projection 45 on the shaft 37. The further microswitch 43 is connected electrically in circuit with the motor control circuitry 30 and functions to define a limit for the motor drive. The other microswitch 44 is connected in circuit with the display device 22 for the purpose of energising the LED display 28.

A slider potentiometer (not shown) associated with the shaft 37 is also connected in circuit with the display device 22 for the purpose of activating a display which gives indication of the position of the movable wall portion 16 and, hence, the volume of infusate remaining within the bag 12.

Figure 3 of the drawings shows a block diagrammatic representation of electrical circuitry that is associated with motor control and the functional displays that are embodied in the apparatus. The stepping motor 39 is energised by pulses which are generated by an oscillator 46 which is controlled by control circuit 47 to provide selectively for forward and reverse rotation of the motor. The pulse repetition rate of the oscillator and, hence, the speed of the stepping motor is controlled by

feed rate select circuitry 48 which includes the potentiometer (or pushbutton switches) 24 as shown in Figure 1. Also, the output pulses from the oscillator are applied to a ramp generator 49 which provides an output to the bargraph display device 23. The display device 23 is inverted relative to what would be its normal position, to provide an impression of falling droplets of the infusant. The bargraph display will vary as a function of the output from the ramp generator and, thus, at the rate of infusant delivery effected by rotation of the stepping motor.

The further display devices 22, 27 and 28 referred to previously are energised in response to positioning and/or movement of the shaft 37.

Figure 4 of the drawings illustrates an anti-syphoning valve which may be located in series with the infusate-containing bag 12 and the delivery line 15 to prevent syphoning of fluid from the bag 12. The valve is removably fitted to the neck region 13 of the bag by a conventional type of bag spike 14, and it comprises a casing 50 which carries a diaphragm 51. A rigid tube 52 is located within the casing 50 and forms an extension of the delivery line 15, and the diaphragm is arranged normally to exert a small positive sealing force against the open end of the tube 52.

In the event of negative pressure in the delivery line 15 such as might induce syphoning of infusate from the bag 12, the diaphragm 51 is drawn into positive sealing engagement with the end of the tube 52 to prevent flow of infusate from the bag. On the other hand, when the bag 12 is squeezed and infusate is displaced from the bag, the diaphragm is exposed to internal pressure and is caused to move away from the open end of the tube 52, so that the infusate will be free to pass from the bag and into the delivery line 15.

THE CLAIMS:

1. An apparatus for use in delivering infusate to a patient and which comprises: a receiving station which is arranged to receive a collapsible bag of the infusate, a wall portion which forms a part of the receiving station and which is movable in a manner to reduce the contained volume of a bag of the infusate when located within the receiving station, a drive mechanism for imparting movement to the movable wall portion, control means for varying the operating speed of the drive mechanism and, hence, the rate of movement of the wall portion, and indicator means arranged to provide indication of the rate at which infusate is displaced from the collapsible bag as a function of the rate at which movement is imparted to the movable wall portion by the drive mechanism.

2. The apparatus as claimed in claim 1 wherein the receiving station is in the form of a chamber which is bounded by a base and four side wall portions, one of which comprises the movable wall portion and which is movable in a direction toward its opposite wall.

3. The apparatus as claimed in claim 2 wherein the movable wall portion is arranged to maintain a parallel disposition relative to the opposite wall when moving in a direction toward and away from the opposite wall.

4. The apparatus as claimed in any one of claims 1 to 3 wherein the drive mechanism comprises an electric motor and a motion translating mechanism which is operable to impart linear movement to the movable wall portion responsive to energisation of the electric motor.

5. The apparatus as claimed in claim 4 or claim 5 wherein the electric motor comprises a stepping motor which is energised by an output signal from an oscillator which is controlled to provide a selectively variable pulse repetition rate.

6. The apparatus as claimed in claim 4 wherein the motion translating mechanism comprises a lead screw which is coupled to the motor and which is engaged in a

threaded bush, the bush being coupled to a shaft which is in turn coupled to the movable wall, and the bush being constrained against rotation with the lead screw whereby it functions to convert rotary motion of the lead screw into rectilinear motion which is imparted to the shaft.

7. The apparatus as claimed in claim 6 wherein a helical compression spring separates the bush and the shaft in an axial direction and is arranged to be compressed in the event that a force acts to impede rectilinear movement of the wall portion and the shaft coupled thereto.

8. The apparatus as claimed in claim 7 wherein a switch is provided and is arranged to be activated in the event of a predetermined relative axial movement between the bush and the shaft, and wherein the switch is connected to an electrical circuit which is arranged to generate a signal that is indicative of an occlusion in a delivery line that is connected to the infusate-containing bag or total displacement of infusate from the bag.

9. The apparatus as claimed in any one of claims 4 to 8 wherein means are provided for detecting the position of the movable wall portion by reference to the position of the motion translating mechanism and for generating electrical signals which are representative of the position of the movable wall portion and, hence the volume of infusate contained in the bag.

10. The apparatus as claimed in claim 9 wherein means are provided for signalling a position of the movable wall portion which is indicative of a near-empty condition of the bag.

11. The apparatus as claimed in claim 5 wherein the output signal from the oscillator is applied also to a ramp generator, the output of which is applied to a display device in the form of an LED bargraph.

12. The apparatus as claimed in any one of claims 1 to 11 wherein an infusate delivery line is connected to the infusate-containing bag by way of an anti-syphoning

device which is arranged to preclude flow of the infusate from the bag under conditions other than when a positive displacement force is applied to the bag by the movable wall portion, the device including a diaphragm which normally seals against an orifice and which is displaced from the orifice when the displacement force is applied to the bag.

13. An infusate delivery apparatus substantially as shown in the accompanying drawings and substantially as hereinbefore described and with reference thereto.

The Patent Office

12

Application No: GB 9617607.8
Claims searched: 1-13

Examiner: Dr J Houlihan
Date of search: 21 November 1996

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RCH)

Int Cl (Ed.6): A61M 1/02, 5/142, 5/145, 5/148, 5/152

Other: ONLINE: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 2034183	(RUNCIMAN S I C) page 1 lines 45-55 & 102-113; page 1 line 122-page 2 line 12; page 3 lines 25-32; Figures 2 & 3	1-3
X	EP 0465267 A1	(SEIKO EPSON CORP.) column 2 line 58-column 3 line 16; column 4 lines 5-11; column 5 line 51-column 6 line 1; column 6 line 48-column 7 line 18; Figures 1 & 7	1, & 3-6
X	WO 95/05859 A1	(KESKIVALI E & KYYHKYNEN H) page 4 lines 17-30; page 6 lines 29-31; page 7 lines 4-7; Figures 2 & 8	1-3
X	WO 93/10832 A1	(LE BOEUF G) page 5 lines 27-28; page 6 line 24-page 7 line 25; Figures 1,3 & 4	1-4
X	WO 89/11303 A1	(SOUDANT J A P & CHAUVEL J P R.) page 3 lines 11-28; page 4 lines 2-12; page 9 lines 25-28; Figure 1	1-3
X	US 5342313	(CAMPBELL R E *et. al.*) column 3 lines 3-22 & 27-56; column 4 line 51-column 5 line 23; column 11 lines 38-43; column 12 lines 1-9; Figures 2 & 7	1, 4, 5, 6, 9 & 10

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.