PORTABLE INFUSION PUMP

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ABSTRACT

A portable infusion pump for constantly injecting therapeutic fluids into the human body at low positive pressures which has at least one piston for forcing the therapeutic fluid out of its associated fluid containing bag. The piston is moved by a constant force spring which is controlled by a timing device.

11 Claims, 4 Drawing Figures
PORTABLE INFUSION PUMP

BACKGROUND OF THE INVENTION

This invention relates to new and useful improvements in portable infusion devices and more particularly to a low pressure, constant and positive force, high reliability, unobtrusive, portable infusion pump adapted for such purposes as ambulatory therapeutic drug infusion over an extended period of time.

Various devices have been proposed in the prior art by which therapeutic fluids have been injected into the human body over an extended period of time. As for example, a rotary pump powered by a watch has been utilized to squeeze the tube of therapeutic fluid in order that the fluid might be forced into the body of the person carrying the portable infusion device. Such devices have not proven entirely satisfactory because of the difficulty in controlling the rate of flow from the devices, and the low reliability inherent in such designs.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to provide a portable therapeutic fluid infusion pump that over an extended period of time will maintain a constant rate of flow of fluid from the pump. A further object of this invention is to provide a portable infusion pump that is positively controlled to insure the systematic injection of fluid into the human body. A further object of this invention is to provide a portable infusion pump for constant injection of therapeutic fluids into the human body which pump may be readily refilled at the end of a prescribed period of time. Another object of this invention is to provide a lightweight and thoroughly portable but accurate infusion device. A further object of this invention is to provide a means to facilitate sterilization of the collapsible fluid receptacle and refilling of the collapsible fluid receptacle.

This invention contemplates a portable infusion pump consisting of a housing containing at least one collapsible fluid receptacle. Means are provided in association with the receptacle to provide for passage of fluid from the receptacle to appropriate connections to the human body. A force applying device is contained within the housing to collapse the receptacle and force the fluid through the fluid passage. The force applying means is operated by a constant force spring connected through a preloaded slip clutch to a torque motor.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:
FIG. 1 is a cross-sectional side elevational view of the infusion pump of this invention with the pump in its fully loaded position;
FIG. 2 is a partial cross-sectional view of the pump of FIG. 1 but illustrating portions of the pump in its substantially emptied condition;
FIG. 3 is a front elevational view of the device of this invention with a portion broken away; and
FIG. 4 is a rear elevational view of the device of this invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring now to the drawings wherein the preferred embodiment is illustrated, reference numeral 1 denotes the housing for the infusion pump of this invention. The housing 1 is substantially rectangular in cross section along its major axis and elliptical in cross section along its minor axis. The housing defines a substantially correspondingly shaped cavity 2 to contain various components of the infusion device or pump of this invention. The front end 4 of the housing 1 is provided with a separately formed or integrally cast partition 3 defining with the housing two spaced apart cylindrical bores 10. The partition 3 extends partially into the cavity 2 and it is provided with a central bore 5 relieved near its end 6 to provide a counter bore 7 and the opposite end 8 of the partition 3 is relieved to provide a counter bore 9, the function of which will be hereinafter explained. The internal diameters of the counter bores 7 and 9 are greater than the internal diameter of the bore 5.

The front end 6 of the partition 3 is provided with an externally threaded portion 11 whose function will be hereinafter explained. A pair of annular grooves 12 are provided on opposite sides of the end 8 of the partition 3 and spaced inwardly from the bores 10. A seal 13 is retained in each of the grooves 12 to provide appropriate sealing as will be explained hereinafter. The bores 10 near the front end 4 of the housing 1 are relieved to provide enlarged openings 24 and shoulders 14.

In order to retain the supply of therapeutic fluid or serum in the infusion device of this invention, two serum bag assemblies 15 are positioned within the bores 10 of the cavity 2 adjacent the front end 4 of the housing 1. A serum bag assembly 15 is positioned on opposite sides of the partition 3. The serum bag assembly 15 comprises a serum bag 16 of suitable resilient material, having an annular lip 17 defining an open mouth 18. The lip 17 is backed by a washer and retained between a shoulder 20 of an internally threaded nut 21 and an annular externally threaded cap 22. The nut 21 is dimensioned to come to rest against the shoulder 14 to retard inward movement of the serum bag assembly into the housing.

In order to prevent accidental dislodgment of the two serum bag assemblies 15, a bag cover 25 of substantially the same dimensions as the cross-sectional area of the housing 1 is secured to the housing by a threaded nut 26 secured to the threaded portion 11 of the front end 6 of the partition 3. The cover 25 is provided at both ends with a keyhole shaped slot 29, the function of which will be hereinafter explained.

The serum or therapeutic fluid contained in each of the serum bags 16 is dispensed through a check valve 27 aligned with a central opening 28 in the cap 22. This opening 28 is in open communication with the interior of the bag 16. The check valve 27 in the illustrated embodiment comprises a nipple shaped body 30 having an annular flange 31 at its upstream end and a slit-like opening 32 at its downstream end. The valve 27 is formed of rubber or other suitable resilient material and the resiliency of the material insures that the opening 32 is closed except when the fluid is being forced out of the bag 16 as will be hereinafter explained.

The check valves 27 are retained in alignment with the opening 28 by a hollow cylindrical stem member 33. The threaded end 34 of stem member 33 is turned into tapped opening 35 centrally located in the cap 22 and end 34 engages the flange 31 of the check valve 27.
holding it in proper position. The nipple 30 of the valve extends into the interior or bore 36 of stem member 33. The other end 37 of the stem member is closed with a rubber plug 38 having a plug portion 40 pressed into the other end 37 of the stem member and a sleeve portion 41 surrounding the exterior of the end 37 to seal that end of the stem member.

In order to provide for the flow of serum or fluid out of the stem member 33, three grooves 42 are provided on the exterior surface of the stem member intermediate its ends. The two outer grooves are provided with O-rings 43 and the inner groove 42 is provided with an opening 44 in open communication with the bore 36 of the stem member 33. An arm member 45 is affixed to the stem member 33 by a sleeve portion 46 surrounding the three grooves 42, thereby bringing the O-rings 43 into sealing engagement with the interior of the sleeve portion 46. A retaining ring 49 holds the arm member rotatably affixed to the stem portion 33.

In the illustrated embodiment, the arm member 45 is L-shaped in configuration with the sleeve portion 46 at one end. The arm member 45 is provided with a central bore 47 aligned with the central groove 42 to provide open communication with the bore of the stem member 33. The end of the arm member 45 opposite the sleeve portion 46 is provided with a connector 48 for suitable connection to body hookup tubes (not shown).

The serum is forced out of bags 16 by a pair of pistons 50 movably positioned within the housing 1. The face or forward end 51 of each piston 50 is located adjacent to and in contact with the bottom 52 of its associated bag 16. In the event that fluid escapes from the bags 16, it is prevented from escaping into the cavity 2 and about each piston 50 by the seals 13 that are maintained in sealing engagement with the outer periphery of the piston 50. Seals 13 each preferably comprise a low friction slip ring element backed by a resilient O-ring.

To provide for movement of the pistons 50, a boss 54 is provided on the end of each piston opposite the face 51. The bosses 54 are secured to a piston guide 55 by retaining rings 56 in order that the two pistons 50 will be advanced and retracted in unison. The piston guide 55 comprises a plate portion 57 having openings 58 near its outer extremity to receive the bosses 54 of the pistons. The plate portion 57 is provided with a centrally located embossment 60 having an opening 61 in its end remote from the plate portion and a central bore 62 of larger diameter than the opening 61.

In order to move the piston guide 55 and its associated pistons 50 to force the serum from the bags 16, a screw drive nut 63 is secured by conventional means to the embossment 60 and located within its bore 62. The screw drive nut 63 engages a screw 64 extending centrally through the screw drive nut 63 and the opening 61 in the embossment 60. The forward end 65 of the screw 64 is journaled in a bearing 66 located in the bore 5 of the partition 3. The shaft 67 of the screw is secured to a driving drum mechanism 68 in conventional manner. The shaft 67 is also journaled in a bearing 70 which bearing is positioned in an opening 71 in the endplate 72 closing the end of the cavity 2 of the housing 1 opposite the cover 25.

The driving drum mechanism 68 is driven by a constant force double coil spring 73 having one coil wound around and affixed to the drum 68 and the other coil wound around and affixed to a storage drum 74. The spring 73 is constructed and arranged to apply a constant turning force to the drum 68 as it unwinds from the storage drum 74 and onto the driving drum. The storage drum 74 is rotatably mounted on a spindle 75, which spindle is rotatably affixed to and extends between the end plate 72 and the motor housing 76. The spring is rewound on the storage drum 74 during the rewinding operation to be explained hereinafter.

During operation of this device, various forces may retard movement of the pistons that force fluid out of the serum bags, as for example, friction between the pistons 50 and the seals 13. Since these forces are not constant and the spring 73 is a constant force spring, a torque and timing motor 78 is connected to the driving drum 68 being driven by the spring 73. Torque and timing motor 78 runs at a constant speed. In the illustrated embodiment, the torque and timing motor 78 is an electrically operated watch of conventional design, the hour hand mechanism 78a of which is connected to a conventional slip clutch 80. One portion 79 of the clutch is connected to the hour hand mechanism 78a and the other portion 79a is connected by a tongue and groove arrangement 88 to the driving drum 68. The tongue and groove connection is maintained in releasable engagement by compression spring 88a acting between portions 79 and 79a of the clutch. The slip clutch 80 is set to slip or release at a preset torque value to prevent damage to the watch 78 during manual resetting and rewinding operations of the pump and to provide a positive driving connection between torque and timing motor 78 during normal pumping.

Constant force spring 73 exerts a constant torque on the driving drum 68 and, thus, on the screw 64. The applied torque tends to turn screw 64 in a direction to cause pistons 50 to expel the contents of bags 16. The drum 68 being connected to the torque and timing motor 78 through the slip clutch 80 will turn only at a rate determined by the torque and timing motor. Thus, the motor 78 tends to slow down the free rotation rate of the drum 68 due to the applied torque of spring 73 to the desired controlled rate of rotation. In the event that the forces exerted on the pistons 50 and the screw 64 are such that the spring does not rotate the drum at the desired rate, then the torque motor will provide the necessary increase in force to maintain the desired rate of rotation.

In order to return the pistons 50 to their original positions as shown in FIG. 1, to rewind the spring 73 and to prime the pump, a reset knob assembly 81 is positioned in the bore 5 of a partition 3 and spaced from the forward end 65 of the screw 64. The reset knob assembly comprises a shaft 82 extending into the bore 5 and having a slotted end portion 83 adapted to engage the end 65 of the screw 64. Except during resetting and rewinding, however, end portion 83 is spaced from the end of the screw 64. The other end of the assembly is provided with a turning knob 84 to impart rotation to the reset knob assembly when desired. During resetting and priming, the knob assembly 81 is pushed inwardly toward the screw 64 to engage the slotted end portion 83 and the end 65 of the screw 64. As indicated in FIG. 3, the resetting of the infusion pump is by rotation of the reset knob 84 in a clockwise
direction. The priming is by rotation of the reset knob 84 in the counterclockwise direction. Inward movement of the shaft 82 of the reset knob assembly 81 is retarded by a ball detent 99 extending through the wall of the partition 3 and into contact with the shaft 82 of the reset knob assembly 81.

In order to prevent damage to the torque motor 78 during hand rotation of the screw during rewinding and priming, a locking screw 85 is threaded into and through a threaded opening 86 in the motor housing 76. The screw 85 is provided with a pin portion 89 adapted to be forced into contact with the portion 79 of the slip clutch 80 to prevent its rotation and thus movement of the hour hand mechanism 78a of the torque motor 78. Manual winding is permitted by the release of slip clutch 80. The electrical plug 90 is removed to stop the torque and timing motor 78.

As shown in FIG. 1, the infusion device of this invention is in its fully loaded condition. In operation, the locking screw 85 is screwed into the motor housing 76 until the pin portion 89 contacts the portion 79 of the slip clutch 80 in order that any rotation of the screw 64 will not be transmitted to the torque and timing motor 78, thereby preventing any possibility of damage to the motor. Flushing fluid is injected by a needle (not shown) through the plug portion 40 of each rubber plug 38 to flush out the bore 36 of the stem member 33 and the bore 47 of the arm members 45 to insure that the same are cleared of any air.

The cover 87 for the turning knob 84 is removed and the knob 84 is pushed inwardly into the counter bore 7 and toward the screw 64 until the slotted end 83 contacts and mates with the end 65 of the screw 64. The knob is rotated counterclockwise to turn the screw 64 causing the screw drive nut 63 to move toward the end 65 of the screw 64 because it is prevented from rotating by a conventional connection to the piston guide 55. Since the screw drive nut is retained within the bore 62 of the embossment 60 of piston guide 55, any movement of the nut along the screw is transmitted to the embossment and thus to the piston guide 55, thereby moving it toward the serum bags 16. The pistons 50 are thus further advanced into the bottoms 52 of the serum bags. The pressure exerted on the bags forces fluid through the nipples 30 of the check valves 27 and into the bores 36 of the stem members 33 and into the bore 47 of the arm members 45. When fluid is observed leaving the connectors 48, the device is ready to be connected in conventional manner to body hookup tubes.

After connection to the tubes, the turning knob 84 is withdrawn from contact with the screw 64 and is returned to its position as shown in FIG. 1. The cover 87 is then replaced to prevent accidental movement of the turning knob 84.

In order to place the infusion device of this invention on automatic operation, the locking knob 85 is unscrewed to release the portion 79 of the slip clutch and the electrical plug 90 controlling the torque and timing motor is inserted. At this point, the torque and timing motor 78 and constant force spring 73 assume control of the rotation of the driving drum 68. Constant force spring 73 exerts a constant torque on the drum 68 and the torque and timing motor 78 maintains a constant rate of rotation of the drum. Depending upon the forces opposing the advance of pistons 50, the turning motor 78 may oppose or augment the torque provided by constant force spring 73 as necessary to maintain a constant rate of rotation of the screw 64 and, thus, a constant rate of advance of pistons 50.

Rotation of the drum and thus the screw 64 which is connected thereto moves the pistons 50 further into the serum bags 16, thereby forcing the serum out of the bags and into the body hookup tubes as previously explained. The spacing between the pistons 50 and the cavity 2 of the housing 1 is such that the bags roll back along the pistons 50 as is shown in FIG. 2.

The pistons 50, the piston guide 55 and the embossment 60 continue to move toward the partition 3 with the embossment being received within the bore 9 of the partition 3 until the embossment travels to the end of the bore 9. At such time, the pistons 50 will have substantially emptied the two serum bags 16 and the unit is ready for re-operation.

In the illustrated embodiment, the two bags 16 contain 12.5 cc of fluid each and the device is set to operate at a speed and pressure to force 2.50 cc from each bag per 24-hour period. Thus, the infusion pump as illustrated will inject 5 cc of fluid per 24 hours into the human body and the pump will operate without refilling for 5 days. When the bags 16 have been emptied, the cover 87 of the reset knob assembly is removed. The nut 26 holding the bag cover 25 in place is removed and the arm members 45 are aligned with the keyhole slots 29. Thereafter, the cover 25 may be removed from the housing, permitting removal of each serum bag assembly 15 and replacement of new assemblies by removing the nut 21 thereby releasing the bags 16. A new bag or a refilled bag may then be replaced and the assembly is ready for insertion into the proper position in the housing 1.

The removability of the bags 16 and fluid passages provides a particularly advantageous feature of this invention. The bags can be conveniently sterilized separately from the rest of the pump. Thus, the sterile conditions of the fluid containers and ducts can be easily and conveniently insured without having to attempt sterilization of the entire mechanism. Also, the pump can be quickly and completely emptied of its fluid contents and/or the contents changed and replaced.

Before the bag assemblies are replaced, the locking knob 85 is brought into contact with the portion 79 of the slip clutch. The turning knob is then pushed into contact with the screw 64 and rotated clockwise to return the pistons 50 to their original positions. Rotation of the screw 64 rotates the driving drum 68 and winds the constant force spring 73 therefrom and winds it onto the storage drum 74. The bags and cover 25 are then replaced and the pump is ready for another start-up operation as hereinbefore explained.

This invention also comprehends a particular form of the preferred embodiment described above. This modified form comprises the device as shown and described above, but with a conventional escapement mechanism substituted for torque and timing motor 78. This provides a fluid delivery system having high reliability and accuracy resulting primarily from the combination of the constant force motor powering the pump and for driving the escapement. In this embodiment, the constant force motor provides a torque for
powering the pistons and for driving the escapement which torque remains substantially constant at all times irrespective of the amount of energy stored in the spring. The constant force on the piston or displacement means contributes to the maintenance of a constant, though often very low, delivery rate even when the bags are nearly empty and the stored energy of the spring is almost exhausted. It also insures at all times the accuracy of the timing function performed by the escapement mechanism, and thus the overall accuracy and constancy of the rate of fluid delivery from the pump throughout the dispersing of an entire charge. Such results are often vital to the user of these devices.

It will be recognized that in both the preferred and modified embodiments of this invention, the rate of fluid delivery of the device can be easily varied in several ways. First, the speed of the screw stem can be selected to provide the desired rate of advance of a given size piston. Second, the lead of the screw can be varied; and, finally, the working area of the pistons and cooperating bags can be varied. Further, all of the cooperating sets of bags and pistons in each device need not be the same diameter; and, by using different diameters, differential quantities of different fluids may be simultaneously delivered.

It can be seen from the foregoing that the infusion device of this invention provides for the constant feeding of serum or other therapeutic fluid irrespective of changes in force exerted on the device, thereby insuring a constant flow of fluid from this device. It should be understood that various modifications of the preferred embodiment described herein may be made without departing from the spirit and scope of the appended claims.

What is claimed:
1. A small volume, positive pressure, self-contained, portable infusion pump comprising at least one fluid containing collapsible receptacle, fluid passage means in communication with said receptacle and adapted for body hookup, force applying means associated with said receptacle for collapsing said receptacle to move fluid from said receptacle into and through said fluid passage means, a constant force coil spring drivingly connected to said force applying means, a torque and timing motor, and a slip clutch drivingly connecting said torque and timing motor to said force applying means to regulate the rate at which fluid is moved from said receptacle.
2. An infusion pump according to claim 1 wherein said fluid passage means comprises a check valve in open communication with said receptacle, an L-shaped arm member having a bore in open communication with said valve, a plug member adapted to permit flushing of said bore, and connector means for connecting said pump to body hookup tubes.
3. An infusion pump according to claim 2 wherein said receptacle comprises an open ended bag of resilient thermoplastic material, said open end being provided with an annular flange, a retaining ring surrounding said open end and said flange, and a closure member connected to said arm member and adapted to retain said flange within said ring.
4. An infusion pump according to claim 1 wherein two receptacles are contained within said housing and each receptacle is provided with fluid passage means and force applying means.
5. An infusion pump according to claim 4 wherein said force applying means comprises a piston adapted to contact its associated receptacle to collapse the same thereby forcing fluid contained therein into and through said fluid passage means, means connecting said pistons for simultaneous movement into contact with said receptacles, said means being operatedly connected to said spring.
6. An infusion pump according to claim 5 wherein said piston connecting means comprises a plate portion having means at its extremities to be connected to said pistons, a hollow central embossment extending from said plate portion, a screw connected to said spring and adapted to be rotated thereby and a screw drive nut non-rotatably retained within said embossment and operatively connected to said screw whereby rotation of said screw moves said screw drive nut along the shaft of said screw thereby moving said piston connecting means and said pistons.
7. An infusion pump according to claim 1 wherein said torque motor comprises a battery operated electric watch mechanism operatively connected to said slip clutch.
8. An infusion pump according to claim 6 wherein means are provided to prevent rotation of said slip clutch.
9. An infusion pump according to claim 6 wherein rotatable means are provided for manual engagement with said screw for priming and rewinding said pump.
10. A small volume, positive pressure, self-contained, portable infusion pump comprising a housing having at least one fluid chamber, fluid passage means in communication with said chamber and adapted for delivery of the contents from said chamber, displacement means cooperating with said chamber for expelling the contents thereof through said fluid passage means, a driving motor operatively connected to said displacement means for supplying a driving force thereto, a constant speed timing motor connected to said displacement means for controlling the displacement thereof by opposing and aiding said driving motor to maintain a constant rate of displacement of said displacement means and thus provide a constant rate of discharge of the contents of said chamber.
11. A small volume, positive pressure, self-contained, portable infusion pump comprising a housing, at least one fluid containing collapsible receptacle in said housing, fluid passage means in communication with said receptacle and adapted for delivery of the contents from said receptacle, collapsible piston means for collapsing said receptacle and expelling the contents thereof through said fluid passage means, a constant force spring operatively connected to said collapsible piston means for supplying a constant displacement producing force thereto, a timing means associated with said collapsible piston means and said constant force spring for controlling the release of the constant force to said collapsible piston means to maintain a constant rate of displacement of said displacement means and thus provide a constant rate of discharge of the contents of said receptacle, said timing means being connected to said collapsible piston means to permit control of the displacement thereof by opposing and aiding said constant force spring.

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