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[54] INFUSION SYSTEM

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[52] **U.S. Cl.**.....**128/214 F,** 128/214 E, 128/DIG. 12, 128/DIG. 1, 128/DIG. 13, 417/45, 417/411

[51] **Int. Cl.**.....**A61m 05/00**

[58] **Field of Search**.....128/213, 214 R, 214 E, 128/214 F, 214 B, 214.2, 218 R, 218 A, 230, 234, 273, DIG. 1, DIG. 12, DIG. 13, DIG. 3, 2 R, 2.05 R; 417/45, 411

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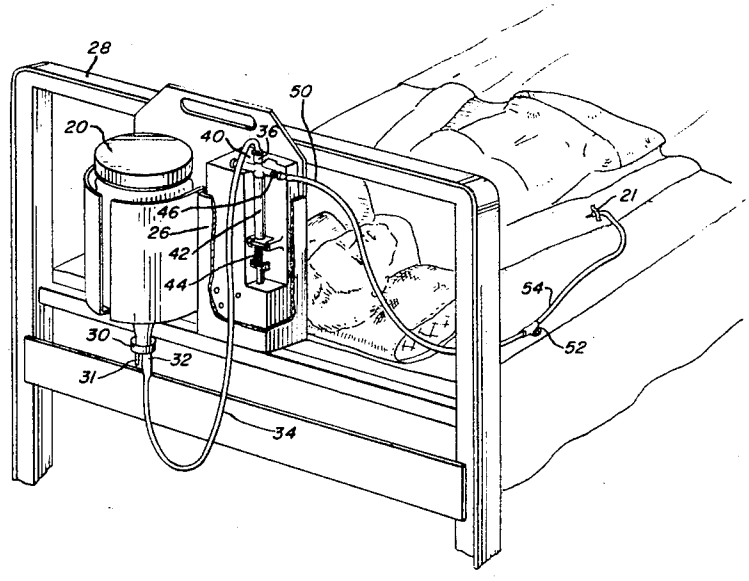
[57] **ABSTRACT**

A portable infusion system uses a disposable piston type syringe as a positive displacement pump. The syringe piston is reciprocally driven by a bidirectional DC motor under control of a battery powered circuit. Different selectable rates of pumping are maintained by controlling the width of bidirectional DC pulses coupled to the DC motor and by monitoring the motor back EMF during the off-time of the pulses. A disposable two-way valve connects the syringe pump with a fluid source and a catheter. Safety circuits protect against deleterious conditions such as the passage of an air bubble or an over-pressure condition.

10 Claims, 6 Drawing Figures



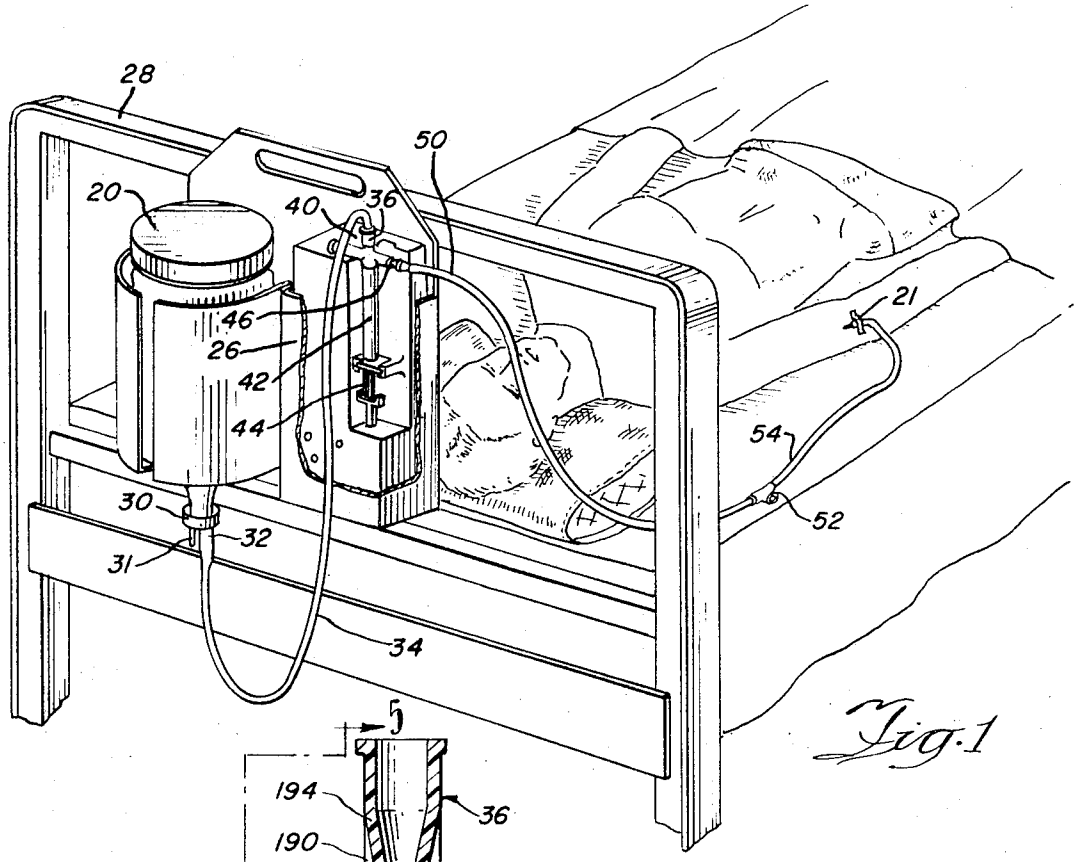


Fig. 1

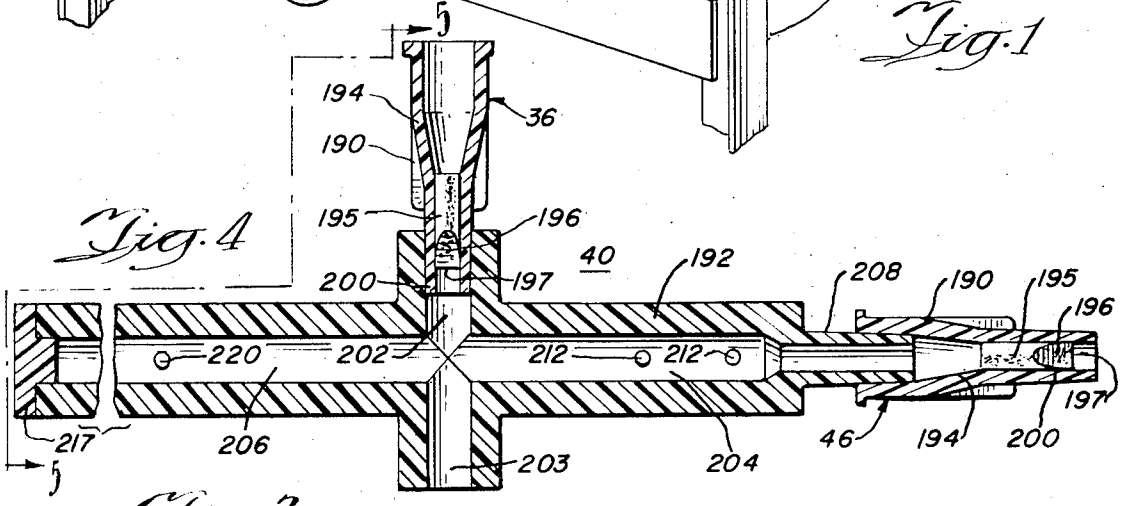


Fig. 4

Fig. 3

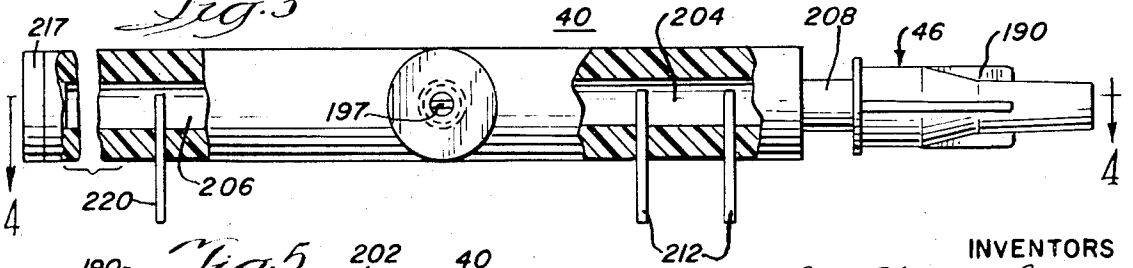


Fig. 5

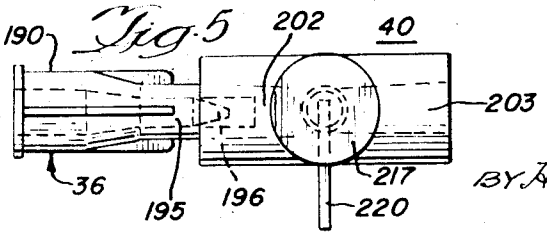


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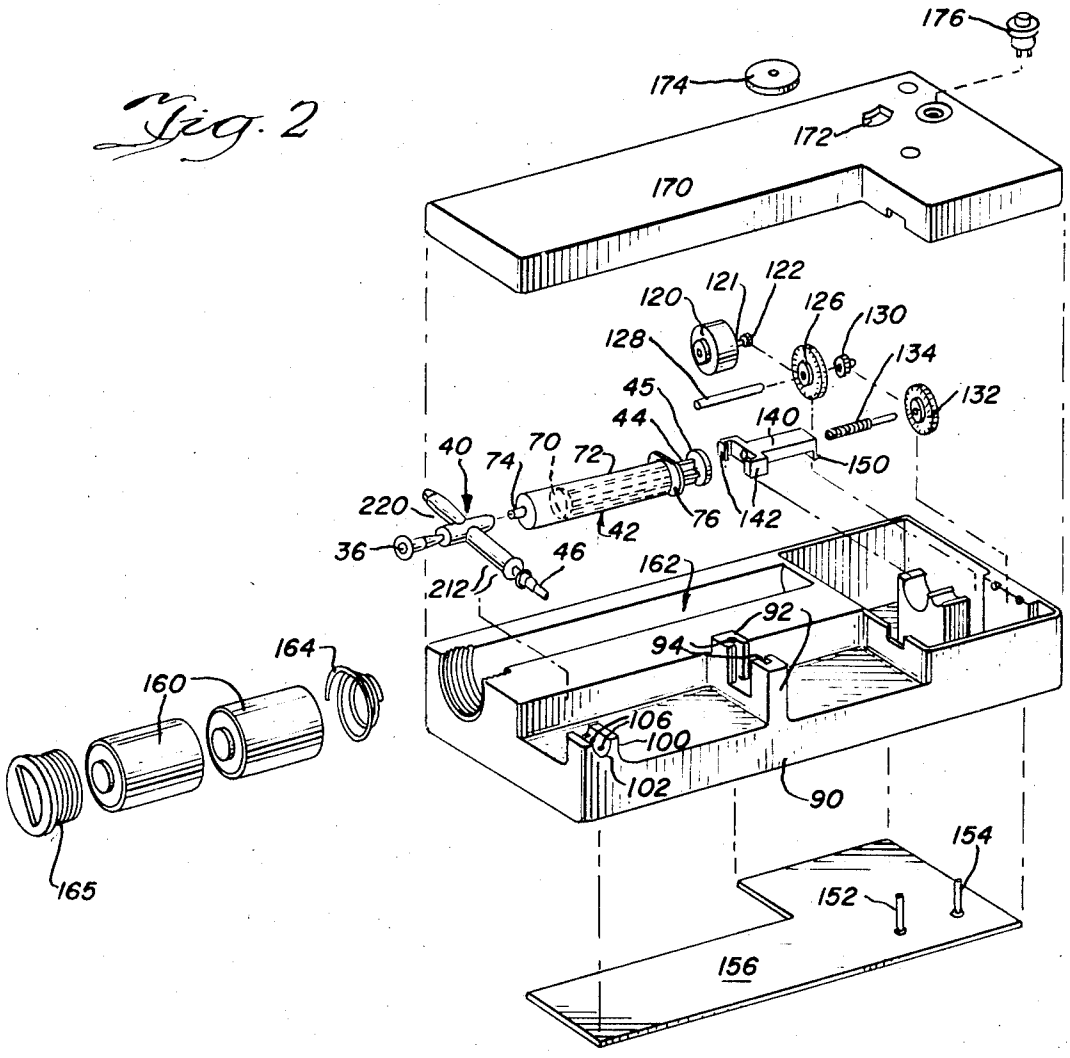
Fig. 2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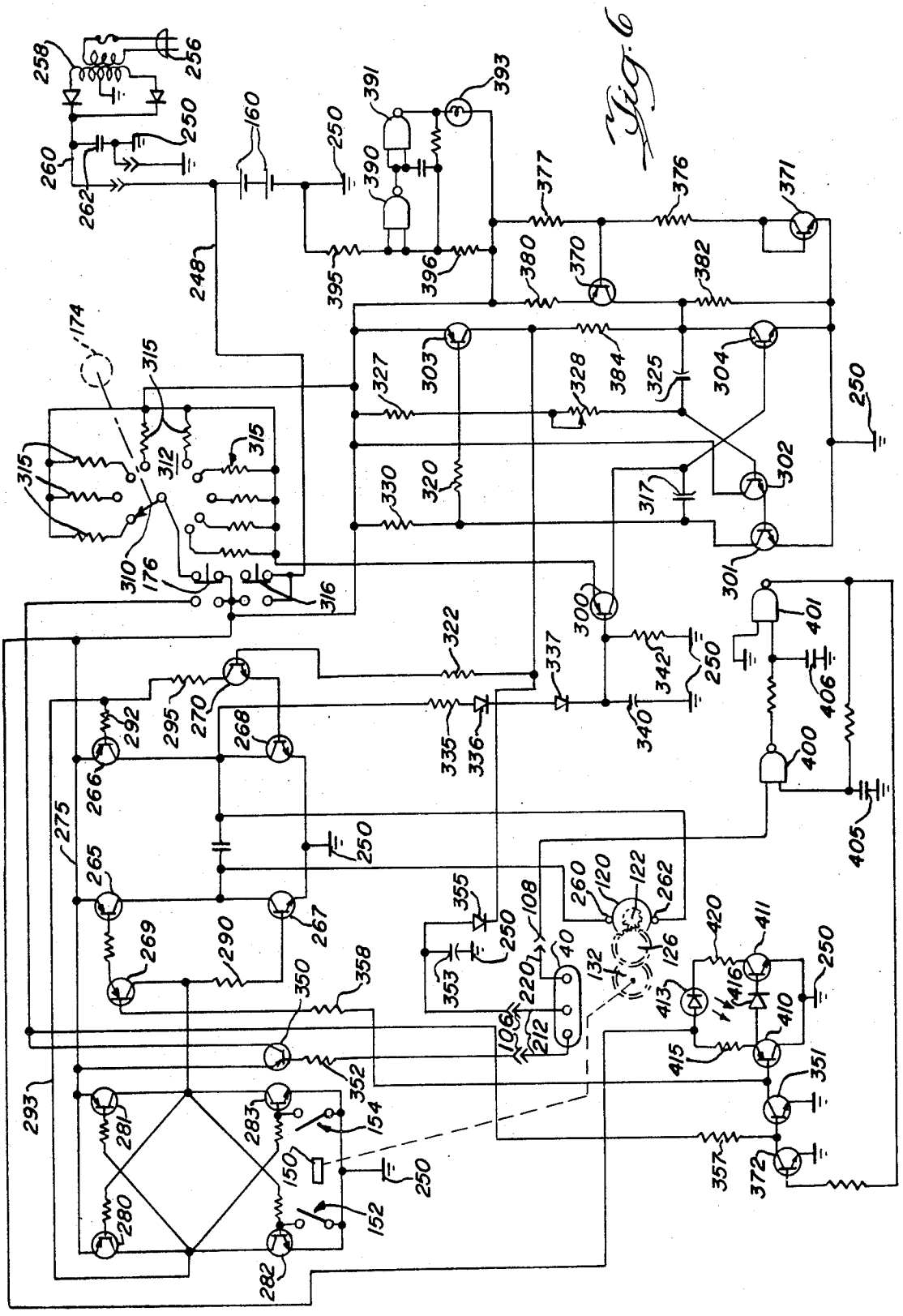
Fig. 6

INFUSION SYSTEM

This invention relates to an improved pumping system and an improved control circuit, particularly adapted for use in an infusion system.

During typical blood transfusions and intravenous injections, a solution bottle is usually hung above a patient to allow gravity feed of fluid through disposable venoclysis tubing to a catheter inserted in the vein of the patient. Transportation of the patient is difficult because the solution bottle must always be located above the patient, requiring an attendant to hold the solution bottle. Even when the patient is located in a hospital, periodic monitoring of the process is required, utilizing valuable personnel time. Despite periodic monitoring, certain malfunctions can occur which may go unattended for lack of a suitable indication of the malfunction. For example, during an injection, it is possible for a needle to become displaced from its position in a vein and become lodged in a muscle.

In accordance with the present invention, a novel portable positive displacement pumping system replaces the gravity feed system typically used for transfusions and injections. As a result, the solution bottle may be located at any reasonable height with regard to the patient. A novel battery powered control circuit for the pump system includes a number of safety circuits which automatically monitor for deleterious conditions, such as passage of air bubbles or the dislodgement of the intravenous needle into a muscle, eliminating the requirement that an attendant periodically monitor the process. Sterile conditions are easily maintained because the positive displacement pumping system uses a disposable syringe and a disposable two-way valve which can be discarded after use with each patient and replaced with a new sterile syringe and valve.

Some attempts have been made to use disposable piston type syringes for pumping fluids at fixed locations. For example, it has been proposed to drive the piston of a syringe by an AC motor connected to an external AC line source. To control the rate of pumping, adjustment is made of the length of the drive stroke for the piston. Such apparatus is not usable in an infusion system, since air bubbles may be passed to the patient, and other serious malfunctions might occur which could not be automatically cured. Also, such apparatus does not permit priming of the syringe, nor is accurate control possible, as is essential in an infusion system.

The applicants' novel control circuit for driving the novel pumping system includes a unique DC motor drive which can be used to accurately drive loads other than pumps. The drive automatically compensates for variations in the load, long term aging of batteries for powering the control circuit, and detection of deleterious conditions associated with the driven load. Bidirectional motor movement is accomplished by a simple reversing circuit controlled by movement of the motor armature. The control circuit uses the known techniques of driving the DC motor by variable width pulses, and monitoring the back EMF across the motor during the off-time of the pulses to control the on-time width of the pulses. However, a pair of such circuits has heretofore been required when driving a motor in both forward and reverse directions. The applicants' control circuit accomplishes the same degree of control while substantially simplifying the circuit.

One object of this invention is the provision of an improved infusion system in which the sterile parts in contact with the fluid being pumped are disposable and readily replaceable with new sterile parts.

Another object of this invention is the provision of an improved control circuit for driving a DC motor through a bidirectional cycle of operation.

Yet another object of this invention is the provision of improved pump means driven by a DC motor and feedback means for modifying the operation of a control circuit in accordance with external conditions related to the operation of the pump.

Further objects and features of the invention will be apparent from the following specification, and from the drawings, in which:

FIG. **1** is a perspective illustration of an infusion system incorporating the pumping system of the present invention;

FIG. **2** is an exploded view of the pumping system, with the syringe pump being illustrated for clarity as located on the opposite side of the pump housing shown in FIG. **1**;

FIG. **3** is a partly plan and partly sectional view of a disposable valve with embedded electrodes;

FIG. **4** is a sectional view taken along lines **4—4** of FIG. **3**;

FIG. **5** is a plan view taken along lines **5—5** of FIG. **4**; and

FIG. **6** is a schematic diagram of the control circuit for the pump system.

While an illustrative embodiment of the invention is shown in the drawings and will be described in detail herein, the invention is susceptible of embodiment in many different forms and it should be understood that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the embodiment illustrated.

GENERAL DESCRIPTION

Turning to FIG. **1**, a portable infusion system is illustrated for pumping fluids such as blood from a solution bottle **20** to a catheter **21** inserted into the vein of a patient. Fluid transfer is accomplished by a pumping apparatus **24** held by a caddy assembly **26** mounted to a rail **28** of a bed for the patient. The caddy **26** also removably holds the solution bottle **20**, which can be located at any reasonable altitude with respect to the patient.

Solution bottle **20** is of conventional construction, and includes a cap **30** having an air valve **31** and an output port **32** for fluid transfer. Disposable venoclysis tubing **34** couples the port **32** to an input port **36** in a disposable two-way valve **40** which forms a part of the pump apparatus **24**.

Pump apparatus **24** uses as a pump chamber a conventional disposable syringe **42** having a slidable piston **44** which can be reciprocated to pump fluid within a hollow syringe barrel coupled with the two-way valve **40** which includes an outlet or output port **46** connected by venoclysis tubing **50** with a conventional Y connector **52** for medication introduction. The output of the Y connector **52** is coupled by additional disposable venoclysis tubing **54** to the catheter **21**.

The control circuit for pump apparatus **24**, seen in detail in FIG. **3**, is completely contained within the housing for the pump apparatus, and can be either externally or internally powered. During a back stroke, in which the syringe piston **44** is driven away from the valve **40**, input port **36** admits fluids from solution bottle **20** into the syringe barrel. The valve in output port **46** is closed at this time. During a forward stroke, in which piston **44** is driven towards the valve **40**, the input port **36** is closed and the output port **46** is opened, pumping the solution through venoclysis tubing **52** and **54** to the catheter **21**.

The novel pumping apparatus **24** is seen in exploded view in FIG. **2**. A sterile, positive displacement pump is economically formed by using a conventional disposable syringe **42** in combination with a unique disposable valve **40**, to be described. Syringe **42** includes a gasket **70** fixedly mounted to the piston **44** for movement within a hollow barrel **72** which has a single fluid opening terminating in a needle connector **74**. The syringe includes extending finger grip arms **76**, which in the present invention are held by base means for the pump apparatus **24**.

Syringe **42** and valve **40** are removably held by housing means in order to allow disposal after use with each patient and replacement with a new presteriled syringe and valve. A lower molded case **90** includes a pair of upstanding arms **92** each having a slot channel **94** which slidably receives one of the extensions **76** of the syringe. Lower case **90** also includes an upstanding post **100** having a concave surface **102** for holding the valve **40** when it is mated to the syringe **42**, and for making electrical contact with electrodes embedded in the valve. A pair of female electrical sockets **106** in surface **102** receive air bubble detector electrodes, as will appear, and a female socket **108** (not illustrated in FIG. **2**), which may be separate from case **90** or similarly molded in a portion thereof, receives an over-pressure detector electrode. The sockets **106** and **108** are connected by wires to the circuit of FIG. **3** which is contained within the hollow case **90**.

The mechanical drive arrangement for piston **44** consists of a bidirectional DC motor **120** having an armature shaft **121** with an integral motor gear **122**. The motor gear **122** meshes with an idler gear **126** rotatable about an idler shaft **128** rigidly attached to a pinion gear **130**. The pinion gear **130** meshes with a drive gear **132** which is fixedly attached to the shaft of a jackscrew **134**. A syringe cylinder carrier **140** includes a gripping head **142** having an opening therein for slidably receiving the head **45** of piston **44**. The carrier **140** has an internally threaded central opening for engaging the threads of the jackscrew **134** to cause the carrier to act as a drive nut on the jackscrew.

When DC motor **120** is energized by voltage of predetermined polarity, the two-stage spur reduction gears rotate jackscrew **134** and cause the carrier **140** and attached cylinder **44** to be driven in a forward stroke. Carrier **140** includes a protrusion **150** with a permanent magnet which extends downward for magnetically actuating a sealed forward stroke limit switch **152** and a sealed reverse stroke limit switch **154**, mounted to a circuit board **156** which contains the circuit of FIG. **3**. The carrier **140** is driven in a forward stroke direction until protrusion **150** is directly over limit switch **152**, at which time the circuit of FIG. **3** reverses the polarity of voltage to DC motor **120** in order to rotate armature **121** in a reverse direction. The carrier **140** and cylinder **44** are now longitudinally moved through a back stroke until the protrusion **150** is directly over limit switch **154**, at which time the circuit of FIG. **3** again reverses the polarity of voltage to DC motor **120**. While magnetically actuated proximity switches are preferred, a mechanical switch arrangement could alternately be used, actuated by mechanical engagement with protrusion **150**.

Power for the DC motor **120** and the control circuit is obtained from a self-contained DC power source, as a pair of series connected DC batteries **160**. Desirably, batteries **160** are rechargeable, sealed nickel-cadmium batteries which allow the pump apparatus to be powered either from an external AC source, or internally powered in order to allow the unit to be completely portable. If the unit is constructed for portable use only, the batteries **160** may be conventional 1.5 volt "D" size. The DC batteries **160** are housed within a battery retainer cylinder **162** molded in lower case **90**. Electrical connection is made through a battery contact spring **164** and a contact on a battery retainer cap **165** which threads into the battery retainer cylinder wall to allow replacement of the batteries when necessary.

An upper case **170** mates with the lower case **90** to enclose the drive train assembly and the batteries **160**. Case **170** includes a window **172** through which indicia on a thumbwheel knob **174** may be observed in order to allow operator selection of different rates of pumping fluid. Desirably, the indicia on wheel **174** directly indicate pump rate, such as one liter of fluid per one, two, three, etc., hours. A different range of pump rates may be provided by replacing syringe **42** with a syringe of different capacity, and knob **174** may be so marked with alternate indicia. A syringe prime switch **176** allows an operator to override the setting selected by wheel **174** in order to rapidly reciprocate the piston **44** when first priming the syringe **42** to eliminate air bubbles. During the time the switch **176** is actuated, the air bubble protector circuit is disabled.

Disposable Valve Assembly

The disposable valve assembly **40** is illustrated in detail in FIGS. **3–5**. The assembly is economically formed by using a pair of identically manufactured valve units **190** mated in opposite fluid flow directions with a central fluid channel unit **192** so that one valve unit **190** forms input port **36** and the other valve unit **190** forms output port **46**.

Each valve unit **190** includes a fluid input port having a tapered conical wall **194** which directs fluid to a check valve **195** formed of flexible, resilient material such as rubber. Check valve **195** is formed by a hollow center portion with an integral tapering nose **196** terminating in a rectangular slit opening **197** which passes fluid to an output port defined by a tubular wall **200** which also serves to anchor the hollow center portion of the check valve. The check valve **195** is of conventional construction and allows fluid flow in a direction from the input port defined by conical wall **194** to the output port defined by the tubular wall **200**, but collapses to block fluid flow in an opposite direction.

The central fluid channel unit **192** includes an input fluid channel **202** into which is inserted the output port of the valve unit **190** which forms input port **36**. Opposite input fluid channel **202** is an output fluid port or channel **203** having a conical wall which receives the tapered syringe connector **94**. Contiguous with fluid channels **202** and **203** are an output fluid channel **204** and a closed fluid channel **206**. Channel **204** terminates in a neck portion **208** of reduced diameter which mates with the input port of the check valve **190** which serves as the output port **46** for passing fluid flow to the catheter.

To detect the presence of an air bubble in the fluid channel, a pair of metal rods or electrodes **212** extend through the wall of the valve assembly and into the fluid channel **204**. The electrodes **212** are spaced apart approximately 0.25 inches, and are placed ahead of the output functioning check valve **195**. When fluid of 0.001 percent salinity or higher is present between the electrodes **212**, the fluid completes a resistance path of sufficiently low impedance to allow the circuit of FIG. **6** to continue to operate. When an air bubble of predetermined size passes the electrodes, the impedance rises and breaks the circuit to cause the forward stroke of the pump to terminate.

To detect an over-pressure condition, as is caused when the catheter becomes lodged in a muscle, the closed fluid channel **206** forms a pressure detector. A cap **217** closes the end of fluid channel **206**, trapping air between the cap **217** and the fluid which enters the channel **206**. A single metal rod or electrode **220** is embedded through the wall of the valve assembly and into the fluid channel **206**. When an over-pressure condition occurs, the pressure of the fluid within central channel unit **192** further compresses the trapped air and allows fluid to further enter the closed channel **206** until it contacts the electrode **220**, thereby completing a circuit through the fluid to one of the electrodes **212** in order to indicate an over-pressure condition.

Desirably, electrodes **212** and **220** are an integral part of the valve assembly **40**, rather than a part of the syringe **42**. As a result, a conventional disposable syringe of low cost may be used as the pump. The valve assembly itself may be economically molded of plastic, except for the pair of check valves **190** which may be molded of rubber. The externally extending ends of the metal electrodes **212** and **220** are directly inserted in the female sockets **106** and **108**, respectively, as previously described.

Control Circuit

The control circuit for the pump assembly is illustrated in detail in FIG. **5**. DC power is provided between a DC potential line **248** and a source of reference potential or ground **250**. When external **115** volt AC is available, a plug **256** may be inserted into the external AC source so as to couple 115 volt AC to a stepdown transformer **258**. The transformer is connected through a full wave diode rectifier to a line **260** connectable through a socket with line **248**. The rechargeable batteries **160** form a filter capacitor for the full wave rectified AC voltage, reducing the ripple of the voltage on DC line **248**. If desired, an additional filter capacitor **262** may be provided. The stepdown transformer **258** and full wave rectifier may be housed within the plug **256**, and connected through a two-line cord to the socket receptacle on the pump assembly. When the pump assembly is to be used independent of the external AC source, the line plug is simply removed from the receptacle on the pump assembly, allowing the previously recharged batteries **160** to thereafter power the control circuit.

DC motor **120** is a shunt wound permanent magnet motor which rotates in a forward direction when current flows from a terminal **260** to a terminal **262**, and rotates in a reverse direction when current flows from terminal **262** to terminal **260**. As will appear, the motor is driven by pulses having a less than **100** percent duty cycle. During the off-time of the pulses, the motor **120** acts as a generator or tachometer, and the back EMF across the terminals is sensed and stored in order to control the duty cycle of the drive pulses.

An electronic reversing switch, including transistors **265, 266, 267, 268, 269**, and **270** forms a double-pole, double-throw switch. Transistors **265** and **268** are synchronously driven conductive to pass current in a forward direction through motor **120**. Alternatively, transistors **266** and **267** may be synchronously driven conductive to complete a reverse current path for motor **120** to drive the motor through its reverse or back stroke. When transistors **265** and **268** are on, current passes from a positive line **275** through transistor **265** to terminal **260** of motor **120**, through motor **120** and out terminal **262** to transistor **268**, and thence to ground **250**. When the forward limit of travel is reached, as indicated by the permanent magnet on protrusion **150** actuating limit switch **154**, a reversing switch driver, to be described, turns transistors **265** and **268** off and transistors **266** and **267** on. Current then flows from the positive line **275** through transistor **266** to terminal **262**, and thence through motor **120** and out terminal **260** to transistor **267** and thence to ground **250**.

The reversing switch driver, consisting of transistors **280, 281, 282**, and **283**, acts as a regenerative bistable switch useful to obtain the heavy drive capability which is necessary when using low supply voltage, such as 3.0 volts from the pair of batteries **160**. Transistors **280** and **283** drive each other into saturation when magnetic protrusion **150** actuates switch **152** at the end of a back stroke, grounding the base of transistor **282**. Alternatively, transistors **282** and **281** drive each other into saturation when magnetic protrusion **150** actuates the switch **154**, grounding the base of transistor **283** at the forward stroke limit of travel.

When transistor **281** saturates, current flows from its emitter to base and through a resistor **290** to the base of transistor **267** to provide drive for the reversing switch. At the same time, the voltage at the collector of transistor **281** rises to the potential of line **275**, back biasing transistors **269** and **265**. Transistor **282** is also saturated at this time, causing current to flow through the emitter-base of transistor **266**, through a resistor **292** and via a line **293** to the collector of transistor **282** and thence to ground **250**. This provides drive for the other half of the reversing switch. Since the collector voltage of transistor **282** is at approximately ground potential, no current flows through a resistor **295** to transistor **270**, nor transistor **268**. When the opposite stable state of the bistable is set by magnetic protrusion

150, transistors 280 and 283 act similar to the above described operation for transistors 281 and 282, providing drive for transistors 265 and 269, and transistors 268 and 270, as will be explained with reference to the bubble detector circuit.

During the forward stroke, transistor 270 is driven on by pulses having approximately a 25 percent duty cycle. For one circuit which was constructed, the drive pulses for minimum motor speed had a four millisecond on-time out of a sixteen millisecond interval, producing a sixty hertz frequency. The duty cycle during the forward stroke is adjustable, as will appear, and is controlled by a forward stroke control.

The reverse stroke always occurs at maximum speed since transistors 266 and 267 are fully saturated during reverse motor movement. As the DC voltage from batteries 160 slowly drops with age and use, lesser voltage is passed through the reverse stroke transistors 266 and 267 to the DC motor 120, resulting in a decreased speed of movement. As will appear, a battery voltage variation compensation circuit is responsive to decreased battery voltage to decrease the off-time of the pulses controlled by the forward stroke control, thus increasing speed in the forward stroke in order to maintain the selected rate of pumping.

The forward stroke control includes transistors 300, 301, 302, 303, and 304, connected basically as an unsymmetrical astable multivibrator. To allow selection of different rates of pumping, thumbwheel knob 174 is connected to the wiper 310 of multi-position switches 312. Wiper 310 is connected to any one of a plurality of resistors 315 each having a different resistance value. A master OFF switch 316 when actuated connects the wiper 310 to DC line 248, via prime switch 176. When the thumbwheel 174 is rotated to cause the wiper 310 of switch 312 to contact one particular resistor 315, a path is formed from DC line 248, through actuated switch 316 and unactuated switch 176 to wiper 310, and thence through the selected resistor 315 to the emitter of transistor 300. The collector of transistor 300 is connected through a capacitor 317 and thence through the collector-emitter of transistor 301 to ground 250. The duty cycle of the pulse coupled to transistor 270 is determined by the capacitance of capacitor 317, the selected value of resistor 315, and the voltage at the base of transistor 300 (from the velocity feedback circuit as will appear).

The on-time of the duty cycle is determined by the time period transistors 301 and 303 are saturated and transistors 302 and 304 are turned off. Transistor 300 acts as a controlled current source that discharges capacitor 317 during the time it holds transistor 304 turned off. When transistor 301 turns on, transistor 303 is turned on by current flowing from its base and through a resistor 320 and conducting transistor 301 to ground 250. Transistor 303 drives transistor 270 of the reversing switch driver through a resistor 322. Thus, the on-time of the duty cycle which controls the forward stroke of the motor is determined by saturation of transistor 303.

The off-time of the duty cycle is controlled by saturation of transistor 304, at which time transistors 301 and 303 are turned off. This off-time is determined by the capacitance value of a capacitor 325, the voltage to which the capacitor 325 is allowed to charge during the prior on-time, and the resistance values of a pair of series connected resistors 327 and 328. The allowable voltage to which capacitor 325 is allowed to charge is set by the battery voltage variation compensation circuit, to be explained.

The detailed operation of the forward stroke control circuit is as follows. Assume transistor 301 has just turned on with capacitor 317 fully charged and capacitor 325 fully discharged. When transistor 301 saturates, the negative terminal of capacitor 317 has a negative voltage equal to the supply potential. For this example, it will be assumed that the supply potential from batteries 160 is at maximum potential, or 3.0 volts. Current now flows from the +3.0 volt supply and through switches 316, 176 and 310 to the selected resistor 315 and thence through transistor 300 to discharge capacitor 317. When the negative terminal of capacitor 317 reaches 1.2 volts (the base-emitter drop of transistors 302 and 304), transistors 302 and 304 are turned on, turning transistor 301 off and recharging capacitor 317 to supply voltage through a resistor 330. Capacitor 325 discharges through the series resistors 327 and 328 until the base-emitter voltage of transistor 301 is reached, at which time transistor 301 turns on and the cycle is repeated.

During the forward stroke, the pulse coupled to the DC motor has an approximately 25 percent off-time at the maximum infusion rate selectable by switch 310. Due to mechanical inertia, the motor continues to turn and generates a back EMF proportional to the angular velocity of the armature. This voltage is sensed by a velocity feedback circuit and stored in order to control transistor 300 and adjust the on-time of the pulses to compensate for variations in load. Thus, various fluids and syringes may be used without effecting to any significant extent the calibration of thumbwheel knob 174.

During the forward stroke, transistor 265 is on, connecting terminal 260 to the supply voltage at line 275. During the off portion of the forward stroke pulse, transistor 270 is off, blocking transistor 268 and disconnecting ground 250 from the motor terminal 262. The back EMF across the motor terminal is now coupled through a resistor 335 and a pair of series connected diodes 336 and 337 to a capacitor 340 connected to ground 250. The capacitor 340 charges to a potential that is the sum of the supply voltage and the voltage generated by the motor.

During the on-time of the forward stroke control, transistor 270 is driven into conduction, driving transistor 268 into conduction and hence connecting motor terminal 262 to approximately ground potential, back biasing the diodes 336 and 337. The voltage charge across capacitor 340 is now used to control the base drive of transistors 300, establishing an on-time duration proportional to the voltage across the capacitor. A resistor 342 allows the voltage across capacitor 340 to slowly leak off. Since the emitter of transistor 300 is referenced to the DC supply voltage, the current through transistor 300 is dependent solely on the back EMF across the DC motor, eliminating the effect of supply voltage variations.

The control circuit also includes a number of special circuits described in the following sections.

Bubble Detector

The bubble detector circuit includes the bubble detector electrodes **212** and transistors **350** and **351**. When fluids having a conductivity equal to a salinity of 0.001 percent or greater are present between electrodes **212** which are spaced 0.25 inches apart, the resistance therebetween is on the order of 200 kilohms or lower. This causes current to flow from the supply line **275**, through the emitter-base of transistor **350**, through a resistor **352**, as 10 kilohms, to one electrode **212** and thence through the fluid to the other electrode **212** to charge a capacitor **353**, as 1.0 microfarads. Capacitor **353** is discharged by the forward stroke control circuit through a diode **355**. The time constants are chosen such that capacitor **353** is never charged to more than 0.1 volts unless the forward stroke control circuit fails. If the forward stroke control circuit fails in such a way that the forward stroke would be at full supply voltage across the motor **120**, capacitor **353** charges to supply voltage and turns transistor **350** off. This terminates operation. Thus, the patient is protected from excessive infusion rates which otherwise might be caused by failure of critical parts in the circuit. The current passing through the fluid is on the order of **10** microamps or less thereby creating no hazard of electrolysis or other hazard to the patient.

The current that charges capacitor **353** causes a current of at least 200 times magnitude to flow from the supply, through the emitter-collector of transistor **350**, through a resistor **357** and into the base of transistor **351**. This forward biases transistor **351**, creating a path to ground through the transistor **351** and a resistor **358** connected to the base of transistor **269**, thereby allowing drive for transistors **269** and **265** to flow when the transistors **269** and **265** are turned on by the reversing switch driver circuit. When an air bubble or cavity is present between the electrodes **212**, the current path is broken and transistor **351** is biased off. Therefore, the motor **120** stos on the forward stroke. Prime switch **176** in the forward stroke control circuit is used to override this shut-off during syringe priming.

The combination of the bubble detector circuit and the placement of the electrodes **212** and **220** in the two-way valve assembly **40** creates a fail safe apparatus which detects air leaks caused by a defect in the pump assembly itself. Referring to FIG. **4**, the electrodes **212** are located in the pressure side of the fluid channel, between the pair of check valves **195**. Should the metal electrodes **212** not be completely surrounded by the plastic material forming the wall of the valve channel, as might occur due to dropping of the valve assembly, for example, an air passageway or void would be created which would allow air to seep from the atmosphere into the fluid channel **204**. If the electrodes **212** were located in input port **36** upstream of the check valve **195**, the electrode located furthest downstream could leak air during a back stroke operation. If the bubble should pass the check valve **195**, it would escape detection by the bubble detector circuit.

To prevent such an occurrence, the electrodes **212** are located in a region which has high pressure during a forward stroke. During the forward stroke, the pressure in channel **204** is in excess of atmospheric pressure, therefore an air passageway adjacent either electrode **212** merely causes fluid to seep out of the channel **204**, but does not create an air bubble within the channel. During the back stroke, a low pressure region is formed in fluid channel **204**, allowing air to seep from the atmosphere into the channel **204**. Regardless of the electrode **212** which leaks air, the bubble will travel upstream towards the pump port **203**, so that the bubble will again have to pass the electrodes **212** during the forward stroke. This allows the air bubble to be detected in the same manner as if the bubble had been drawn in from the fluid supply.

The bubble detector control circuit serves the dual purposes of providing a safety device to prevent accidental passage of an air bubble, and also automatically shuts off the pumping apparatus when all the fluid in the solution bottle is used up. At the end of the supply of fluid, air is introduced into the solution bottle and is pumped to the valve assembly **40**. When the air reaches the point where the two sensing electrodes **212** are placed, the current path is broken and motor operation is terminated, turning off the pumping system.

Battery Voltage Variation Compensation

This circuit, consisting of transistors **370** and **371**, is responsive to decreases in the battery voltage to decrease the off-time of the pulses in the forward stroke control. As previously described, the back stroke is not controlled and will vary in speed with voltage variations. The time lost on the back stroke is gained by speeding up the motor on the forward stroke.

Transistor **371** acts as an ideal diode, establishing a reference voltage of approximately 0.6 volts at its collector, which is coupled in series through a resistor **376** and a resistor **377** to a line coupled through switch **316** with the positive potential line **248**. In shunt with resistors **376** and **377** and transistor **371** is a resistor **380** in series with the emitter of transistor **370**, and a resistor **382** in series between the collector of transistor **370** and ground **250**. The collector of transistor **370** is directly coupled to the junction between transistor **304** and capacitor **325**. As the battery supply voltage lowers, the current through resistor **380** changes linearly. This causes the collector voltage of transistor **370** to rise linearly at a rate established by the ratio of resistor **380** to resistor **382** and a resistor **384** in series between the collectors of transistors **303** and **304**. The voltage at the base of transistor **370** also varies, but at reduced ratio.

For the particular motor driven mechanism which was constructed, the circuit constants were chosen so that the voltage on the collector of transistor **370** and hence also transistor **304** lowered as the battery voltage lowered by a ratio of 1.5, that is, 0.1 volt battery variation produced 0.15 volts less charge on capacitor **325**. While this ratio produced the correct compensation, other ratios may be utilized for other loads driven by the motor. The range of the battery voltage compensation circuit is such that battery voltages down to approximately 2.0 volts may be tolerated, representing a decrease of **33** percent from the full battery voltage of 3.0 volts.

For the circuit constants disclosed above, a battery supply voltage of less than 2.0 volts indicates that the batteries must be replaced or recharged in order to maintain the calibrated accuracy of the pumping ap-

paratus. A low battery indicator circuit is formed by integrated circuit NOT gates **390** and **391** for energizing a low battery indicator lamp **393**. When the supply voltage is above 2.0 volts, a divider formed by resistors **395** and **396** in series between ground **250** and the supply line via switch **316** and line **248** produces a voltage above 0.8 volts at the junction between resistors **395** and **396** which causes NOT gate **390** to saturate, turning NOT gate **391** off and thus maintaining the lamp **393** off. When the supply voltage drops to 2.0 volts, gate **390** turns off, causing gate **391** to turn on and hence energize the lamp indicator **393**. The indicator lamp **393** is desirably located beneath a window in the upper case of the pump assembly so as to be visible by an operator.

Over-Pressure Detector

This circuit is formed by integrated circuit gates **400**, **401** and a transistor **372**. Gates **400** and **401** are connected to form a bistable multivibrator. During normal operation (no over-pressure condition), gate **401** is on and transistor **372** is off. To insure this state, a capacitor **405** is made five times as large as a capacitor **406**. When the control circuit is first energized, the capacitor **405** holds one input of gate **400** low long enough to set the bistable with gate **401** saturated and gate **400** off.

When fluid reaches electrode **220**, indicating an over-pressure condition, a circuit path is formed from one input of gate **400** to the supply voltage line **275** via transistor **350** and the electrode **212** connected through resistor **352** to the base thereof, saturating gate **400** and turning gate **401** off. This turns transistor **372** on, turning off transistor **351** which in turn opens the bias path for transistors **269** and **265**. This stops the system on the forward stroke. The over-pressure detector circuit may be reset by turning the control circuit off and back on, causing capacitor **405** to again saturate gate **401**.

Bubble and Over-Pressure Indicator

This circuit consists of transistors **310** and **411** which control energization of a visual indicator, such as a light emitting diode (LED) **413**. Desirably, a light emitting diode is used rather than an incandescent lamp due to its low power consumption. When an air bubble or an over-pressure condition is detected by the circuits previously described, transistor **351** is turned off. This in turn biases off transistor **410**, ungrounding a junction formed between a resistor **415** and a diode **416** connected in series between the anode of LED **413** and the base of transistor **411**. The transistor **411** is thus forward biased, creating a current path for the LED **413** to ground through a resistor **420** and the collector-emitter junction of the conducting transistor **411**. The LED **413** is located adjacent a jewel lens mounted in case **170** in order to give a visual indication of a circuit shut-off caused by the detectn of an air bubble or an over-pressure condition.

For some applications, it may be desirable to include less than the number of individual circuits described above, or to include various combinations thereof, as will be apparent to one skilled in the art.

We claim:

1. In a portable infusion system for transferring fluid from a fluid source to a catheter, a positive displacement pumping system having disposable parts, comprising: a self-contained source of DC power; disposable syringe means having a barrel and a piston movable in said barrel along a path to move fluid within the barrel, said barrel having a fluid passage opening; disposable valve means having a pump port in fluid communication with said passage opening, input port means connected with said fluid source for passing fluid to said barrel, and output port means for connection with said catheter for passing fluid to said catheter; base means removably holding said syringe means and said valve means to allow disposal after use with a patient; a holding member removably connected to said piston and mounted on said base for reciprocal movement along said path; motor means energized by said DC power source for reciprocating said holding member and said piston, said motor means including gear means connected to said holding member to effect reciprocal movement of said holding member in response to rotation of said gear means, and a DC motor for rotating said gear means, means for selecting one of a plurality of rates of pumping including generator means for generating DC drive pulses having different duty cycles selectable to effect different rates of pumping, circuit means for coupling said DC drive pulses to said DC motor, and voltage variation compensation means including means responsive to decreasing voltage from said DC power source for increasing the duty cycle of at least some of said DC drive pulses.

2. The system of claim 1 wherein said DC motor is a bidirectional DC motor having an armature shaft rotatable in opposite directions when opposite polarity current is coupled to the DC motor, said gear means converting rotational movement of said armature shaft into translational movement which drives said holding member, and circuit means for periodically reversing the polarity of current passed from said DC power source to said DC motor.

3. The system of claim 1 wherein said valve means includes sensing means for detecting the presence of an air bubble, and safety means responsive to detection of an air bubble for terminating the operation of said motor means.

4. The system of claim 1 including over-pressure means for detecting when the pressure of fluid passed to said catheter exceeds a predetermined maximum, and indicator means actuated when said predetermined maximum is exceeded for providing an alarm indication.

5. In an infusion system for transferring fluid to catheter means, a pumping system comprising a source of fluid capable of passing electricity, a valve assembly having a fluid channel with an outlet adapted for connection with the catheter means for directing the flow of said fluid to the catheter means, fluid pump means including a chamber connected in fluid communication with said fluid source and said fluid channel, and drive means in said chamber actuable to effect movement of fluid from said fluid source and pump fluid through said fluid channel to the catheter means, unidirectional valve means connected in fluid communication with said fluid channel to permit fluid flow from said fluid channel to the catheter and prevent fluid flow from the

catheter to said fluid channel, said fluid channel including a fluid passageway having a fluid opening contiguous with said fluid channel for admitting fluid into said passageway a distance determined by the pressure of the fluid in said fluid channel, and a pair of electrode means located within said fluid channel and having extensions connectable with an external circuit, at least one of said pair of electrode means being located in said passageway a predetermined distance from said fluid opening so that the presence of fluid at said last named electrode means indicates a predetermined fluid pressure condition.

6. The pumping system of claim 5 further including third electrode means in said channel adjacent the other of said pair of electrodes, nd circuit means responsive to the presence of an air bubble between said third and other electrode means to provide a signal indicative thereof.

7. The pumping system of claim 5 wherein said fluid passageway has a closed end opposite said fluid opening for trapping a compressible gas between said closed end and the fluid admitted trough said fluid opening, said last named electrode means being surrounded by said compressible gas when the pressure of fluid in said fluid channel means is less than said predetermined pressure condition.

8. In an infusion system for transferring fluid to catheter means, a pumping system comprising a source of fluid capable of conducting electricity, a syringe having a barrel and a reciprocal plunger slidable in said barrel for moving fluid into and out of said barrel, a valve assembly having a fluid source inlet connected to said source of fluid, a pressure fluid inlet connected to said syringe barrel and in fluid communication with said fluid source inlet, and a channel connected in fluid communication with said pressure fluid inlet and having an outlet connectable with the catheter, first valve means connected in fluid communication with said source of fluid to permit fluid flow from said source to said syringe barrel and to prevent return fluid flow from said syringe barrel to said fluid source, second valve means connected in fluid communication with said channel to permit fluid flow from said channel to the catheter and prevent return fluid flow from the catheter to said channel, and means for reciprocating said plunger to draw fluid from said source into said barrel through said pressure fluid inlet during movement thereof in one direction and supply pressurized fluid to said channel from said barrel during movement thereof in the opposite direction to transfer the fluid to the catheter, said valve assembly including a pressure chamber connected at one end in fluid communication with said channel and closed at the opposite end thereof, an electrode within said chamber, gas disposed in said chamber normally between said electrode and said one end to prevent contact between said fluid and said electrode, said gas being compressible to permit said fluid to contact said electrode upon the occurrence of fluid pressure in said channel of a predetermined value, and circuit means connected with said electrode for detecting the contact between the fluid and said electrode.

9. The infusion system of claim 8 wherein said circuit means includes a second electrode disposed in said channel in contact with the fluid therein.

10. The infusion system of claim 8 further including a pair of closely spaced electrodes in said channel and normally bridged by the fluid to normally provide a predetermined value of impedance between said pair of electrodes, and circuit means connected to said pair of electrodes and responsive to a change in said value of impedance upon the occurrence of the presence of an air bubble between said electrodes to interrupt the reciprocation of said plunger.

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