

[54] INFUSION SYSTEM

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[58] Field of Search **417/416, 417, 418;**
222/70, 76, 59; 128/DIG. 13, 230

[56]

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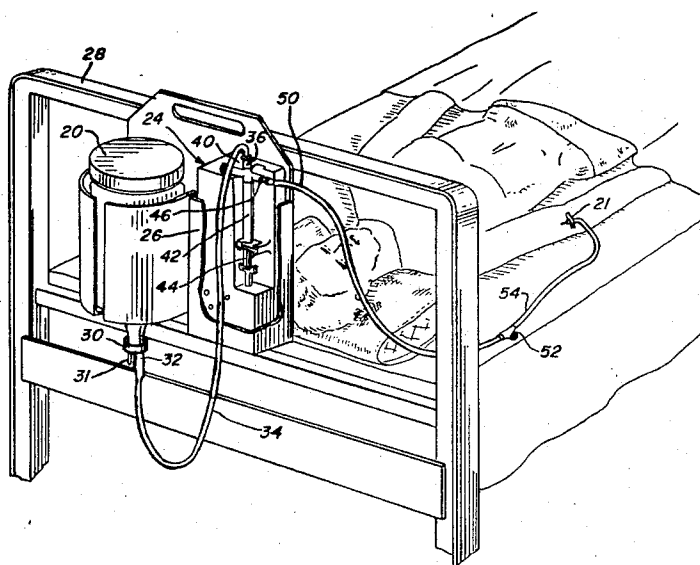
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[57]

ABSTRACT

A portable infusion system uses a disposable piston-type syringe and a disposable two-way valve 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. Safety circuits protect against deleterious conditions such as the passage of an air bubble, an over-pressure condition, or an excess pumping rate as could be caused by a component failure.

14 Claims, 9 Drawing Figures



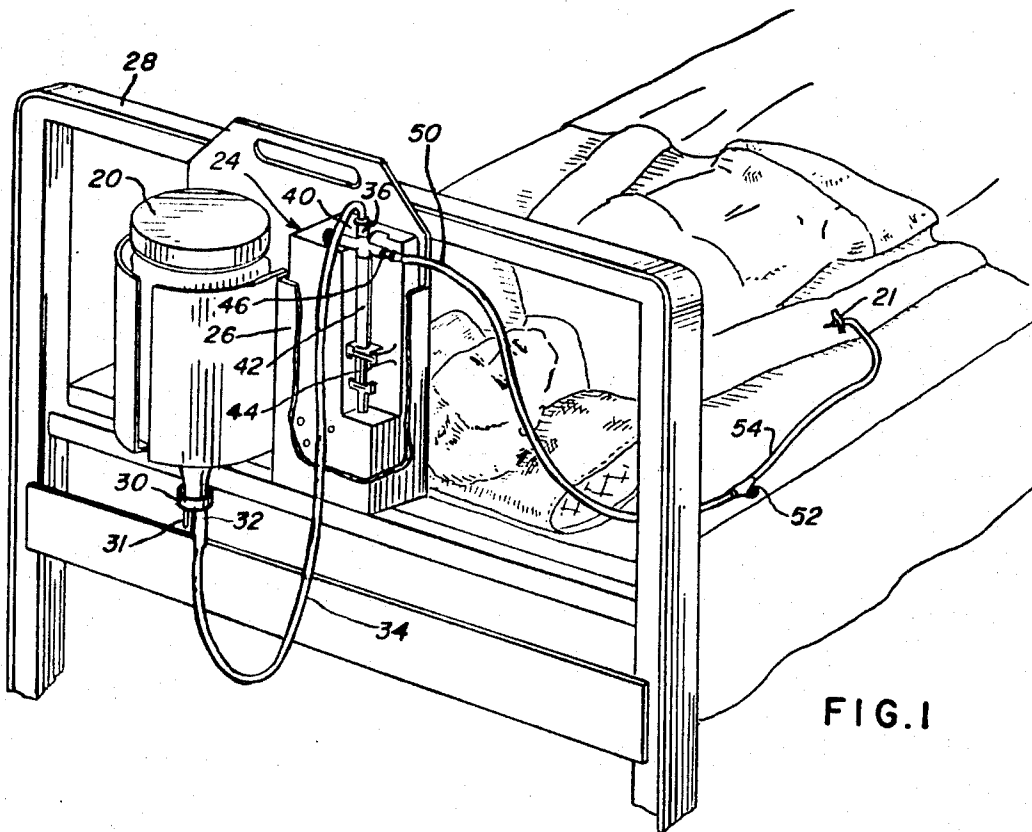
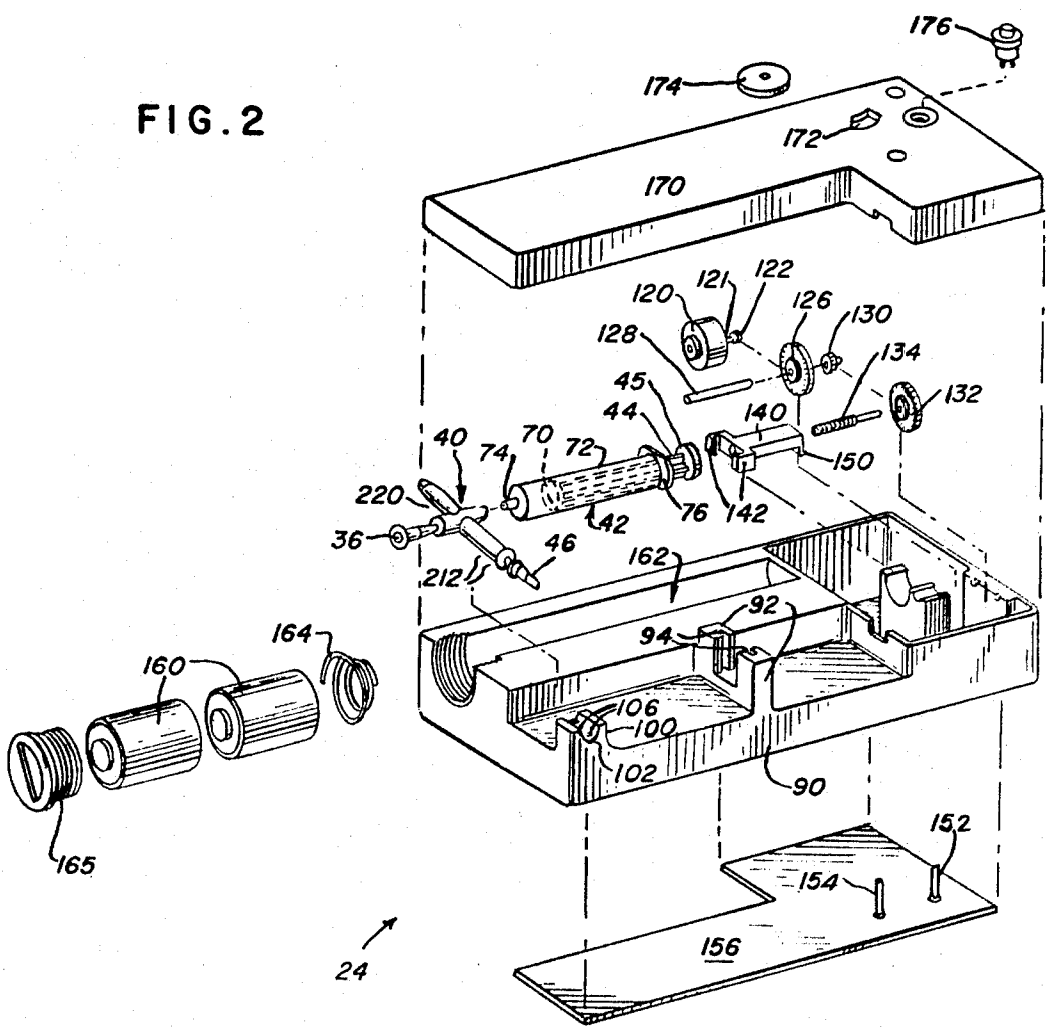


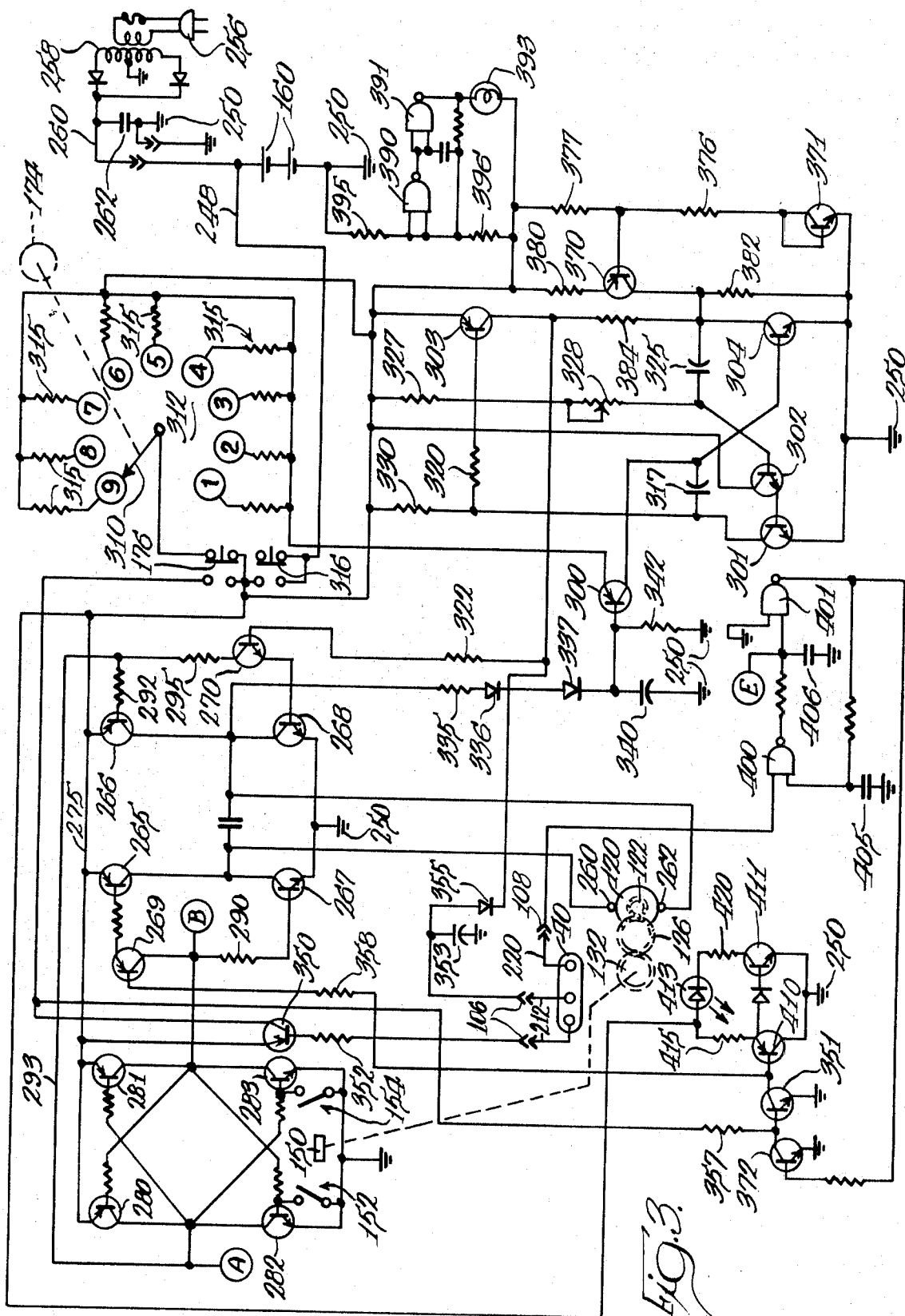
FIG. 1

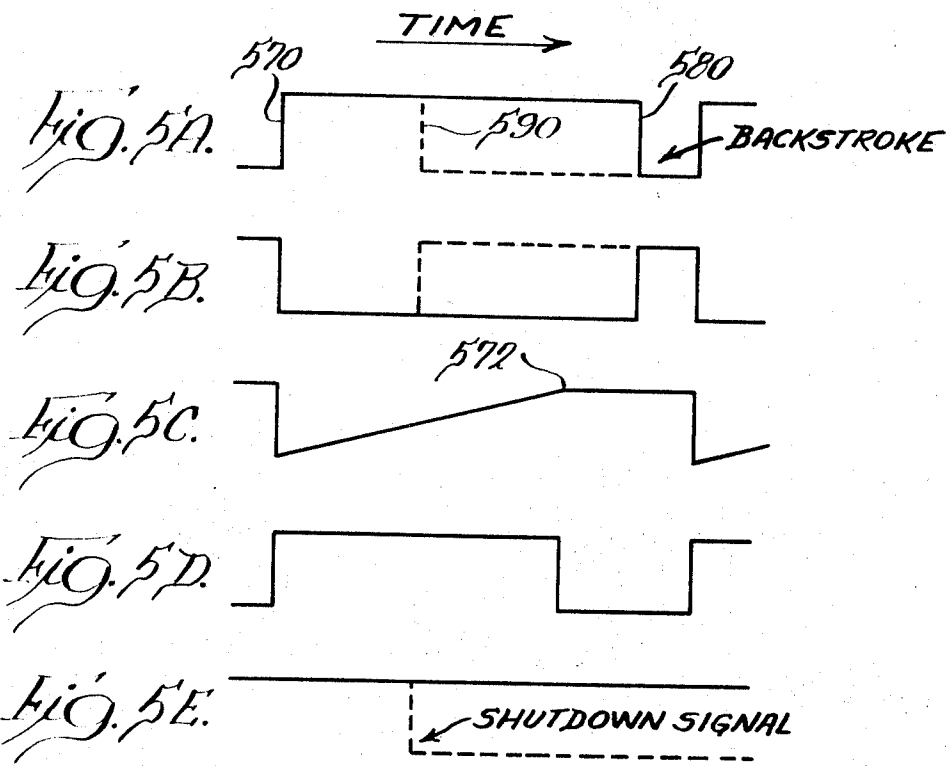
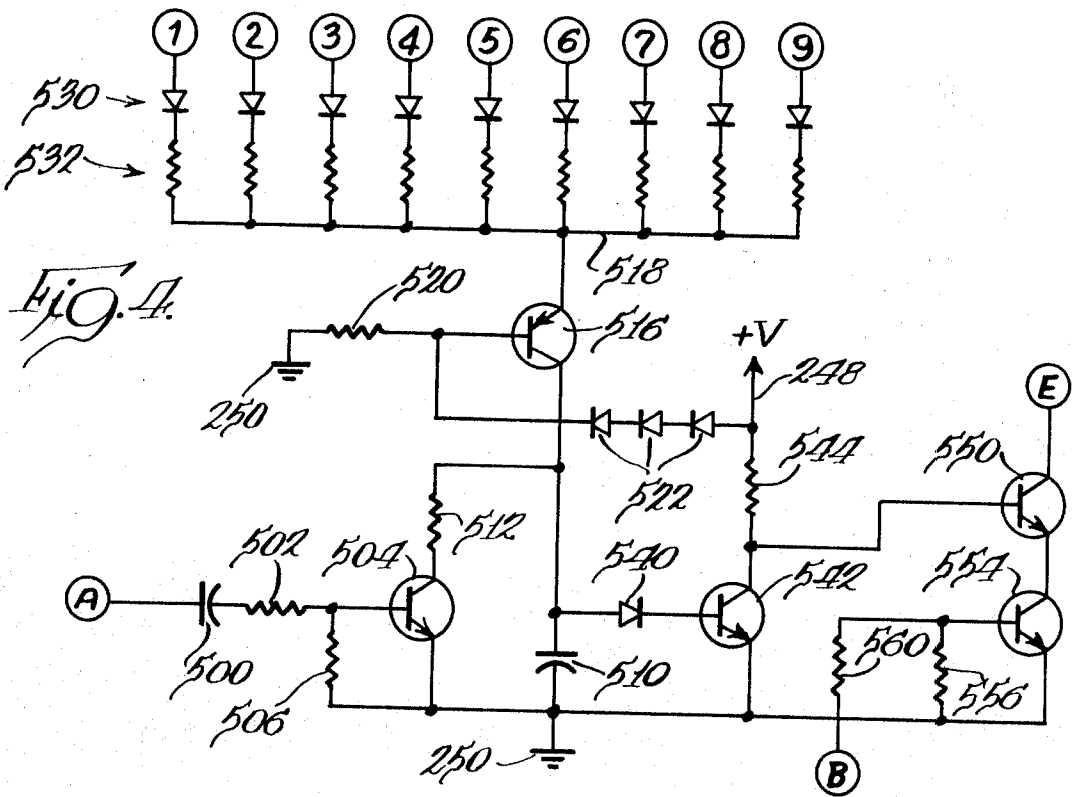
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FIG. 2







INFUSION SYSTEM

RELATED APPLICATION

This application is a continuation-in-part of our copending application, Ser. No. 81,926, filed Oct. 19, 1970, entitled "Infusion System", and assigned to the assignee of this application.

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

During typical blood transfusions and intravenous injections, a solution bottle is usually hung about 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 our copending application, a novel portable positive displacement pumping system is disclosed which can replace the gravity feed system typically used for transfusions and injections. As a result, the solution bottle can be located at any reasonable height with regard to the patient. The battery powered control circuit for the pump system includes a number of safety circuits which automatically monitors for deleterious conditions, such as the passage of air bubbles or the dislodgment of the intravenous needle into a muscle.

In accordance with the present invention, a further safety circuit is provided which eliminates deleterious conditions which could otherwise result due to a failure of the control circuit itself. An electrical analog of the pump is compared with the actual operation of the pump as indicated by external sensing associated with the pump drive. When the actual pump produces a rate of pumping in excess of the pumping rate of the analog circuit, a rate monitor circuit disables the pump. The analog circuit provides a safety range of allowable pump rates for each one of the plurality of pumping rates which are selectable under control of the control circuit. Desirably, the safety circuit and external pump sensing means use many parts already existing in the system, providing an additional safety factor with little increase in cost or number of components.

One object of this invention is the provision of an infusion system having improved safety circuits for modifying the operation of a control circuit for a pump means in accordance with sensed external and internal conditions.

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 applicants' pumping system;

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 schematic diagram of the control circuit for the pump system;

FIG. 4 is a schematic diagram of a rate monitor circuit for connection to the control circuit of FIG. 3; and
FIGS. 5A-5E are waveform diagrams illustrating waveforms generated by the circuit of FIG. 4.

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. Throughout the specification, values will be given for certain of the components in order to disclose a complete, operative embodiment of the invention. However, it should be understood such values are merely representative and are not critical unless specifically so stated.

GENERAL DESCRIPTION

FIGS. 1-3 show applicants' novel portable infusion system, as disclosed in our before identified copending application. For clarity, the operation of the apparatus and circuits of FIGS. 1-3 which are necessary to an understanding of the invention herein will be explained. For a more complete description of the operation of the portable infusion system, and for additional disclosure concerning the disposable valve assembly for use therewith, reference should be made to our before identified copending application, Ser. No. 81,926, filed Oct. 19, 1970, and incorporated by reference herein.

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 FIGS. 3 and 4, 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 fluid 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. 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 presterilized 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 154 and a sealed reverse stroke limit switch 152, 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 154, 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 152, 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.

The limit switches 152 and 154, in combination with the protrusion 150, also serve as a sensing means for determining the actual operation of the pump. As will appear, portions of the circuit of FIG. 3 which respond

to the limit switches are connected to the rate monitor circuit of FIG. 4 in order to provide an input (at connectors A and B) representative of the actual operation of the syringe pump.

Power for the DC motor 120 and the control circuit including the rate monitor circuit of FIG. 4 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 1 liter of fluid per 1, 2, 3, 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.

CONTROL CIRCUIT

The control circuit for the pump assembly is illustrated in detail in FIG. 3. 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 syn-
 5 chronously driven conductive to pass current in a forward direction through motor 120. Alternatively, transistors 266 and 267 may be synchronously driven con-
 ductive to complete a reverse current path for motor 120 to drive the motor through its reverse or back
 10 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
 15 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
 20 268 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
 25 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
 30 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
 35 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
 40 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
 45 292 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 po-
 50 tential, 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 de-
 55 scribed 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.
 60 For one circuit which was constructed, the drive pulses for minimum motor speed had a 4 millisecond on-time out of a sixteen millisecond interval, producing a 60 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
 65 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. A battery voltage variation compensation circuit is responsive to decreased battery
 70 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 un-
 75 symmetrical 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 through individual con-
 80 tacts, labeled 1 through 9, 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
 85 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
 90 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 ca-
 95 pacitor 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
 100 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
 105 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
 110 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
 115 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.
 120

The detailed operation of the forward stroke control circuit is as follows. Assume transistor 301 has just
 125 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
 130 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 safety circuits, described in the following sections. In addition, the control circuit includes a battery voltage variation compensation circuit, including transistors 370 and 371, and described in detail in the before identified copending application, to which reference should be made.

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

move 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. Additional protection is provided by the rate monitor circuit, to be described.

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 transistor 269 and 265 to flow when the transistor 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 stops 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. For additional disclosure concerning the placement of the electrodes 212 and 220, reference should be made to our before mentioned copending application.

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.

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 electrodes 220, indicating an overpressure 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 410 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 detection of an air bubble or an over-pressure condition.

RATE MONITOR CIRCUIT

This circuit, shown in FIG. 4, is connected to the circuit of FIG. 3 through corresponding numbered and lettered connections indicated within circles. The rate monitor circuit creates an electrical analog representative of the of the syringe driver, against which is compared the sensed actions of the actual syringe driver. The sensed actions are desirably determined using the limit switches 152 and 154 activated by the permanent magnet in protrusion 150, see FIG. 2. When, for any reason, the actual syringe driver completes its forward stroke in a predetermined amount of time less than the analog syringe driver, the rate monitor circuit terminates the forward stroke, as by activating a portion of the existing over-pressure detector.

A number of failures might cause the actual syringe driver to have an excess pumping rate, i.e., a rate substantially in excess of the rate selected by the rate knob 174. For example, certain transistors in the circuit of FIG. 3 might fail, or the rate switch 312 might open-circuit. The rate monitor circuit is designed to protect against all such occurrences, and to cause a shut-down of the syringe driver in the event that certain portions of the rate monitor circuit itself should fail.

Considering the circuit in detail, the collectors of transistors 280 and 282 in the reversing switch driver, FIG. 3, are coupled via connector A to a 47 microfarad capacitor 500, FIG. 4, and through a 3.3 kilohm resistor 502 to the base of a NPN transistor 504. A 10 kilohm resistor 506 is connected in shunt between the base and emitter electrodes of transistor 504. The transistor serves to discharge a 470 microfarad capacitor 510 through a 10 ohm resistor 512 connected in series with the collector and emitter electrodes of the transistor 504.

Capacitor 510 is a part of a selectable time constant means which serves to generate an analog voltage which can be used to determine whether the system is operating properly. The capacitor 510 is charged through a constant current source consisting of a PNP transistor 516 having a collector directly connected to capacitor 510, an emitter connected to a common line 518, and a base connected in a voltage divider to the junction between a 220 ohm resistor 520 and three series connected semiconductor diodes 522. The voltage

divider is connected between a source of positive voltage on line 248 and ground 250.

The rate of charge of capacitor 510 depends on the position of the rate switch 312, FIG. 3. Each contact 1 through 9 of the rate switch is connected through a corresponding diode 530 and a resistor 532 to the common line 518. Each resistor 532 has a different resistance value to produce a different time constant for the analog circuit including capacitor 510, chosen such that the analog ramp voltage across capacitor 510 will reach +1.2 volts DC at a time when the syringe driver has completed approximately 60 percent of its forward stroke. For the infusion system which was constructed, the value of the resistors 532 corresponding to each of the contacts 1, 2, 3, 4, 5, 6, 7, 8 and 9 was 6.2 kilohms, 20 kilohms, 33 kilohms, 47 kilohms, 62 kilohms, 75 kilohms, 91 kilohms, 100 kilohms and 120 kilohms, respectively.

The analog ramp voltage across capacitor 510 is coupled through a diode 540 to the base of a NPN transistor 542. The emitter of the transistor 542 is directly connected to ground 250, and the collector is connected through a 10 kilohm resistor 544 to the +V line 248, and also to the base of a NPN transistor 550. The collector of transistor 550 is connected via connector E with one input of the gate 401, FIG. 3. The emitter of transistor 550 is directly connected to the collector of a second NPN transistor 554, having its emitter directly connected to ground 250. The base and emitter electrodes thereof are shunted by a 10 kilohm resistor 556. To control the biasing of transistor 554, the base is also coupled through a 10 kilohm resistor 560 and via connector B to the series connected collectors of transistors 281 and 283 in the reversing switch driver, FIG. 3.

The operation of the rate monitor circuit of FIG. 4 may be understood with reference to the waveforms shown in FIGS. 5A-5E. At the termination time of the back stroke of the actual syringe driver, the syringe cylinder carrier 140, FIG. 2, is in its rear position at which the permanent magnet on protrusion 150 actuates the reverse stroke limit switch 152. This external sensing of the actual piston position is independent of the electrical drive control, and thus provides actual positioned sensing for the rate monitor circuit. As reverse limit switch 152 is actuated at the end of a back stroke, the base of transistor 282, FIG. 3, is grounded. As previously explained, this drive transistors 280 and 283 into saturation, producing a positive going voltage at connector A, FIG. 5A, and a negative (or ground) voltage at connector B, FIG. 5B.

This positive voltage occurring at a time 570, FIG. 5A, drives transistor 504 into saturation, discharging capacitor 510 to approximately zero volts, as seen in FIG. 5C. Since connector A is coupled to the base of transistor 504 through a capacitor 500, the capacitor 500 momentarily charges to the positive voltage, removing the forward bias from transistor 504. Capacitor 510 now charges approximately linearly at a rate determined by the particular one time constant resistor 532 selected by the rate switch. The values of the resistors 532 are chosen such that the analog ramp voltage, FIG. 5C, normally reaches +1.2 volts DC level, labeled 572, when the actual syringe driver has completed approximately 60 percent of its forward stroke. The +1.2 volts DC level forward biases the semiconductor diode 540 and the base-emitter junction of transistor 542, thereby

reducing the voltage at the base of transistor 550 to less than 0.1 volts DC, as seen in FIG. 5D.

At the termination time 580 of the actual forward stroke, as sensed by the closing of switch 154, the voltages at connectors A and B reverse polarity, FIGS. 5A and B. The positive voltage to transistor 554 forward biases the same. However, transistor 550 is still reverse biased by the output. FIG. 5D, of transistor 542, resulting in an open circuit between connector E and ground 250, as seen in FIG. 5E. At the end of the back stroke, switch 152 is again actuated, repeating the cycle previously described.

If for any reason the syringe driver over-speeds so that the forward stroke is completed before the ramp voltage across capacitor 510 reaches the +1.2 volt lever 572, a modified operation results. Assuming that the actual back stroke begins at a time 590 which is well in advance of the selected operation, the voltage at connector B will rise positively and forward bias transistor 554. At the same time, the voltage on the base of transistor 550, FIG. 5D, is positive, biasing transistor 550 into conduction. Since both transistors 550 and 554 are forward biased, the voltage at connector E drops to ground potential, FIG. 5E, forming a shutdown or error signal. As seen in FIG. 3, the error signal, i.e., ground, at the input of the gate 401 switches the bistable multivibrator, turning gate 401 off and hence turning transistor 372 and transistor 351 off. As previously explained for the over-pressure detector, this opens the bias path for transistors 269 and 265, stopping the syringe driver on the forward stroke.

By different choice of the time constant values of resistors 532, FIG. 4, and the value of capacitor 510, the safety range which allows continued normal operation, herein 60% of the selected rate, can be altered as desired. This range also allows for changes in consistence of the fluid being pumped, and other factors including calibration errors.

To increase reliability, the conductors for connecting the components used in the circuits of FIGS. 3 and 4 may be doubled, as by being formed on opposite sides of a printed circuit board, and other conventional redundancy techniques may be utilized. For some applications, it may be desirable to include less than the number of individual circuits described above, or to include various combinations thereof. Other modifications will be apparent to those skilled in the art.

We claim:

1. In a system having pump means for pumping fluid from a fluid source to an outlet, a rate monitor, comprising: control means for controlling said pump means and for providing a control signal representative of a selected rate of flow for the fluid; sensing means for generating a monitor signal representative of the rate of flow produced by said pump means; first circuit means coupled to said control means and said sensing means for comparing said control and said monitor signals for generating an error signal when a comparison of the control signal and the monitor signal indicates that the produced rate of flow has varied by a predetermined amount from the selected rate of flow; and second circuit means coupled to said first circuit means and responsive to said error signal for disabling said pump means upon the occurrence of said error signal.

2. The rate monitor of claim 1 wherein said pump means includes fluid channel means interconnecting said fluid source and said outlet and including a pump

chamber, and drive means including a piston slidably mounted within the pump chamber for reciprocation under control of said control means to pump fluid through said fluid channel means, said sensing means generating said monitor signal in response to a predetermined motion of said drive means.

3. In a system having pump means for pumping fluid from a fluid source to an outlet, a rate monitor, comprising: control means for controlling said pump means and for providing a control signal representative of a selected rate of flow for the fluid; sensing means for generating a monitor signal representative of the rate of flow produced by said pump means; circuit means for generating an error signal when a comparison of the control signal and the monitor signal indicates that the produced rate of flow has varied by a predetermined amount from the selected rate of flow, said pump means including fluid channel means interconnecting said fluid source and said outlet and including a pump chamber, and drive means including a piston slidably mounted within the pump chamber for reciprocation under control of said control means to pump fluid through said fluid channel means, said drive means including link means cyclically driven through a path, said sensing means generating said monitor signal in response to a predetermined motion of said drive means, said sensing means including position responsive means for sensing cyclically recurring positions of said link means whereby said monitor signal is cyclically recurring.

4. The rate monitor of claim 3 wherein said control means provides a fixed value control signal for a given selected rate of flow, said circuit means includes time constant means for producing a time varying signal having a value dependent on the value of said fixed control signal and the time duration thereof, and means for time comparing said time varying signal with said cyclically recurring monitor signal to detect said predetermined amount of rate variation.

5. The rate monitor of claim 4 wherein said time constant means includes capacitor means and a charging path therefore coupled to said fixed value control signal, and said time comparing means includes gate means for discharging said capacitor means for each occurrence of said cyclically recurring monitor signal.

6. The rate monitor of claim 3 wherein said sensing means comprises switch means actuated once for each repetitive cycle of said link means.

7. The rate monitor of claim 6 wherein said switch means comprises a magnetically actuable contact means which changes state in the presence of a magnetic field, and said link means includes magnetic field generating means carried thereby for actuating the contact means.

8. In a system having pump means for pumping fluid from a fluid source to an outlet, a rate monitor, comprising: control means for controlling said pump means and for providing a control signal representative of a selected rate of flow for the fluid; said control means including selector means for selecting different pumping rates, and motor means responsive to said selector means for controlling the cyclic rate of driving the pump means; sensing means for generating a monitor signal representative of the rate of flow produced by said pump means; and circuit means for generating an error signal when a comparison of the control signal and the monitor signal indicates that the produced rate

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of flow has varied by a predetermined amount from the selected rate of flow; said circuit means including means responsive to said selector means for generating a different value control signal for each selectable rate, and means for comparing the different value control signals with the monitor signal.

9. The rate monitor of claim 8 wherein said comparing means generates the error signal when the rate of flow produced by the motor means exceeds by a predetermined range the selected rate of flow, and safety means responsive to said error signal for disabling said motor means.

10. In an infusion system having pump means for pumping fluid from a fluid source to a patient, and control means for controlling the pump means to establish a desired pumping operation, a monitor, comprising: sensing means associated with said pump means for providing a monitor signal representative of the actual pumping operation of the pump means; circuit means for generating an analog waveform having a predetermined relation to the monitor signal when the actual pumping operation corresponds to the desired pumping operation; detector means responsive to a change in the predetermined relation between the monitor signal and the analog waveform for generating an error signal; and safety means for disabling the pump means in response to said error signal.

11. The monitor of claim 10 wherein said pump

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means comprises a positive displacement pump having a piston slidably mounted within a pump chamber for reciprocation along a predetermined path, and said sensing means generates a recurring monitor signal for at least each cycle of reciprocation.

12. The monitor of claim 11 wherein said circuit means generates a recurring analog waveform having a voltage level synchronized with the occurrence of the monitor signal when the actual rate of pumping corresponds to the desired rate of pumping, and said detector means is responsive to a time advance in the occurrence of the monitor signal for generating said error signal to thereby prevent an excessive pumping rate.

13. The monitor of claim 10 wherein said control means includes selector means for selecting different pumping rates for the pump means, said circuit means includes capacitor means, a plurality of circuit paths each having a different time constant, and charging means controlled by said selector means for connecting one of said circuit paths between a potential source and said capacitor means to form said analog waveform across said capacitor means, said detector means includes means for time comparing the charge of the capacitor means with the occurrence of the monitor signal to detect for said predetermined relation.

14. The monitor of claim 13 wherein said detector means further includes discharge means responsive to each occurrence of the monitor signal for discharging said capacitor means.

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