

April 29, 1969

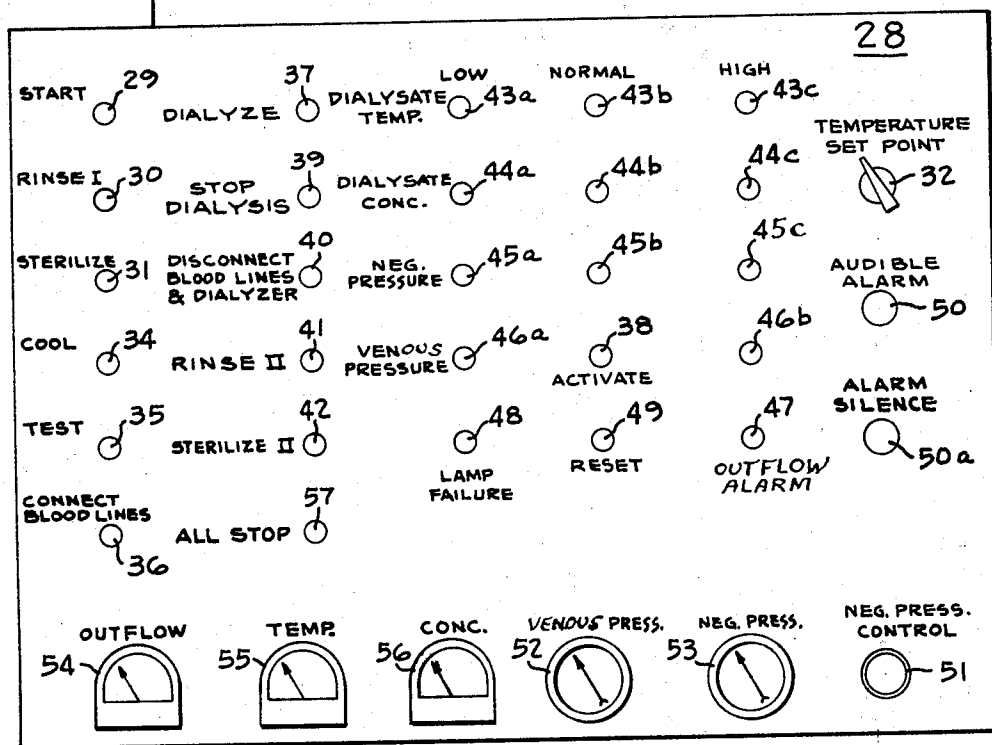
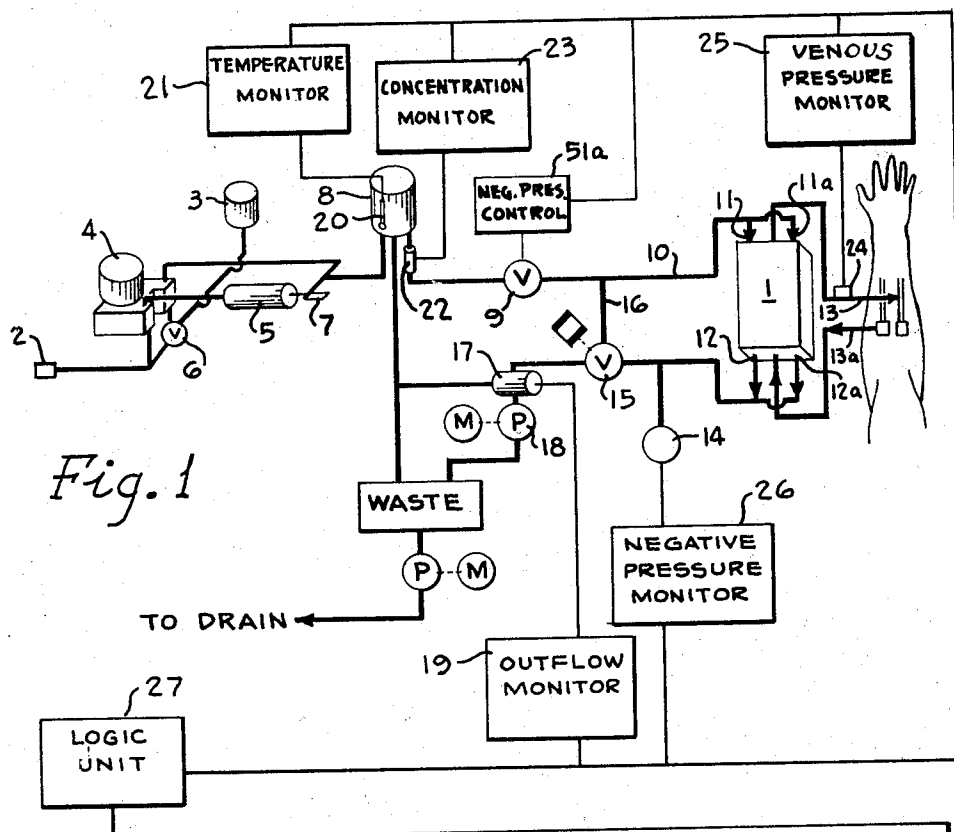
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CONTROLLED BLOOD DIALYSIS SYSTEM

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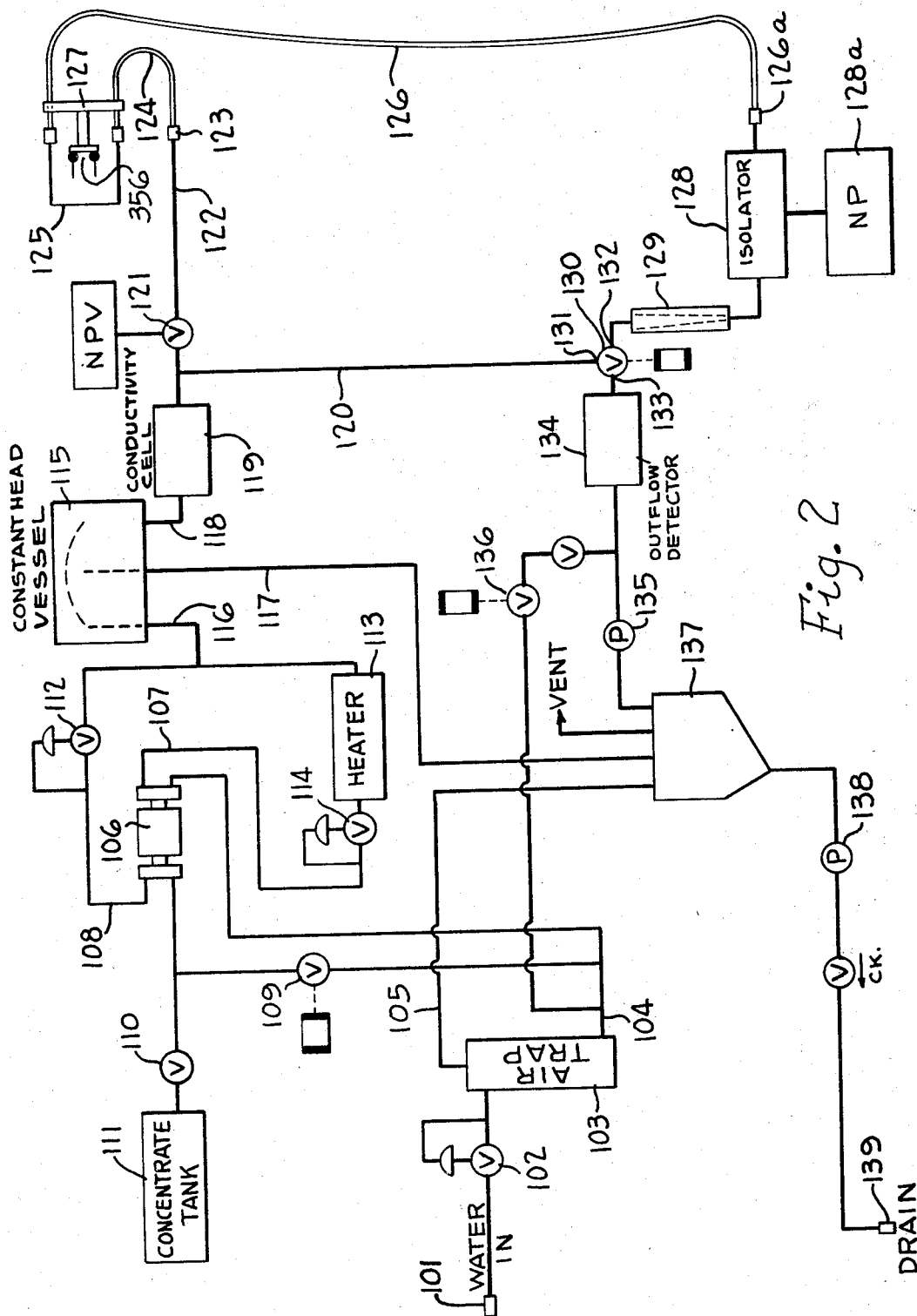


Fig. 2

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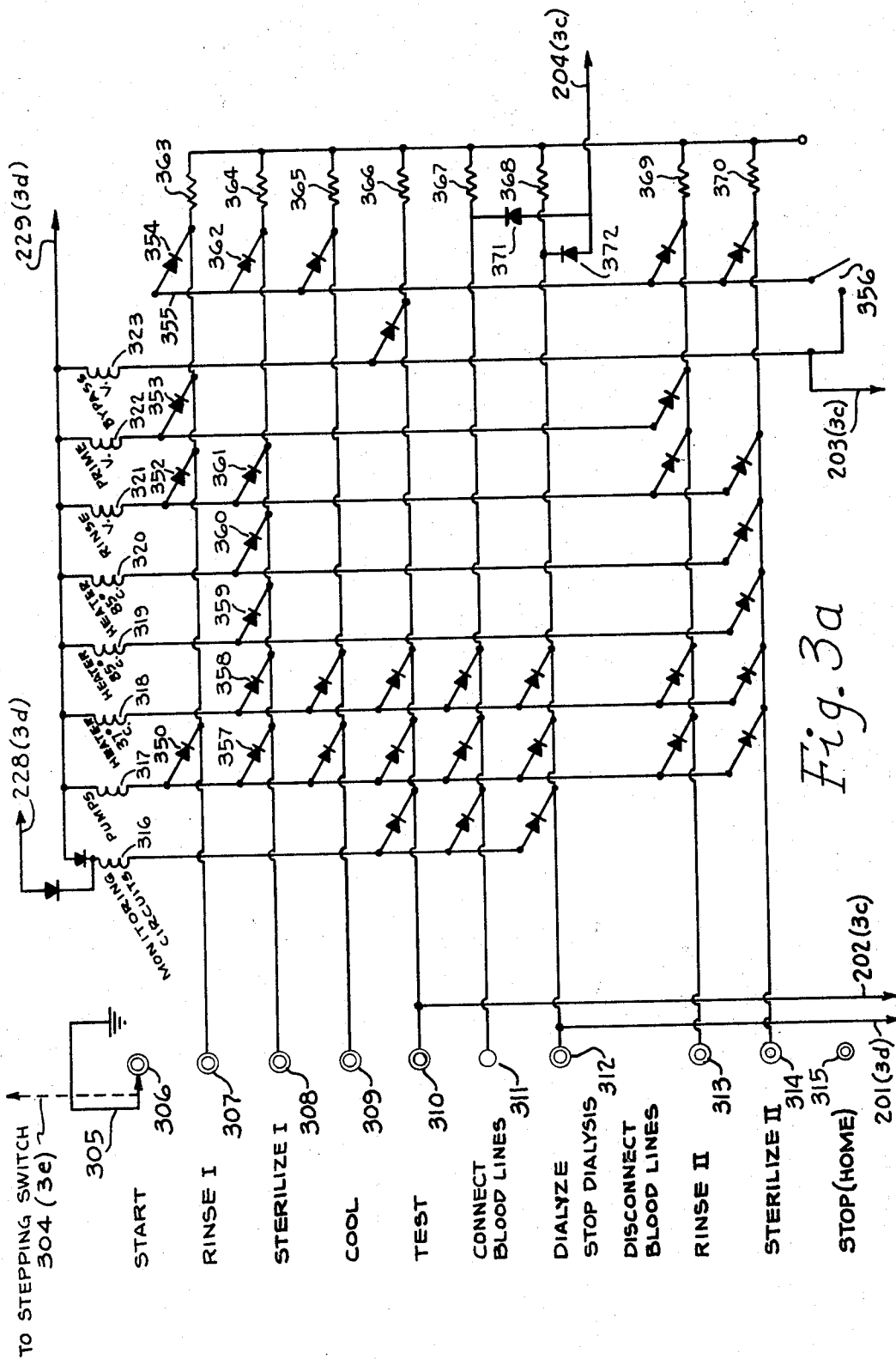
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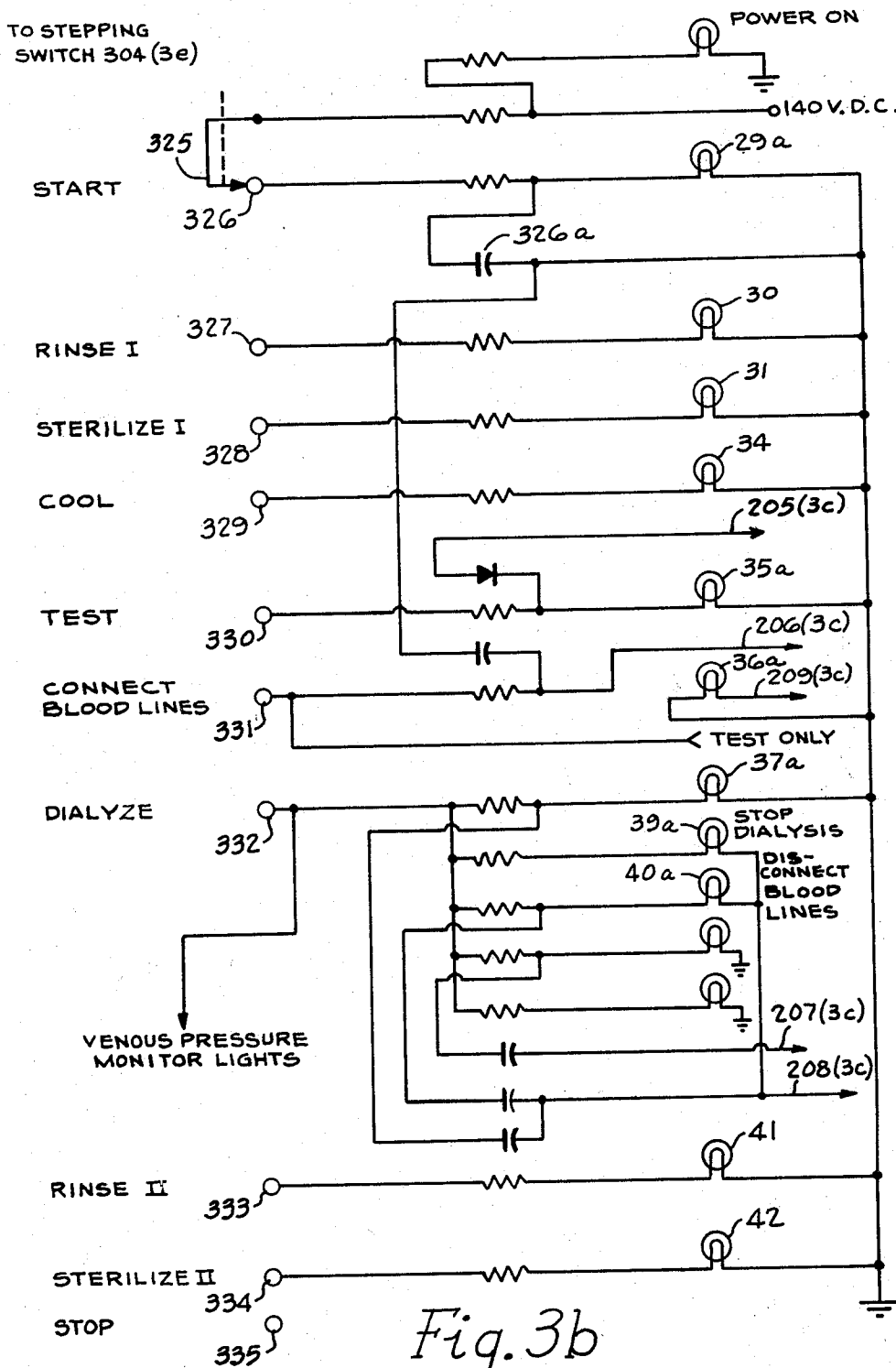
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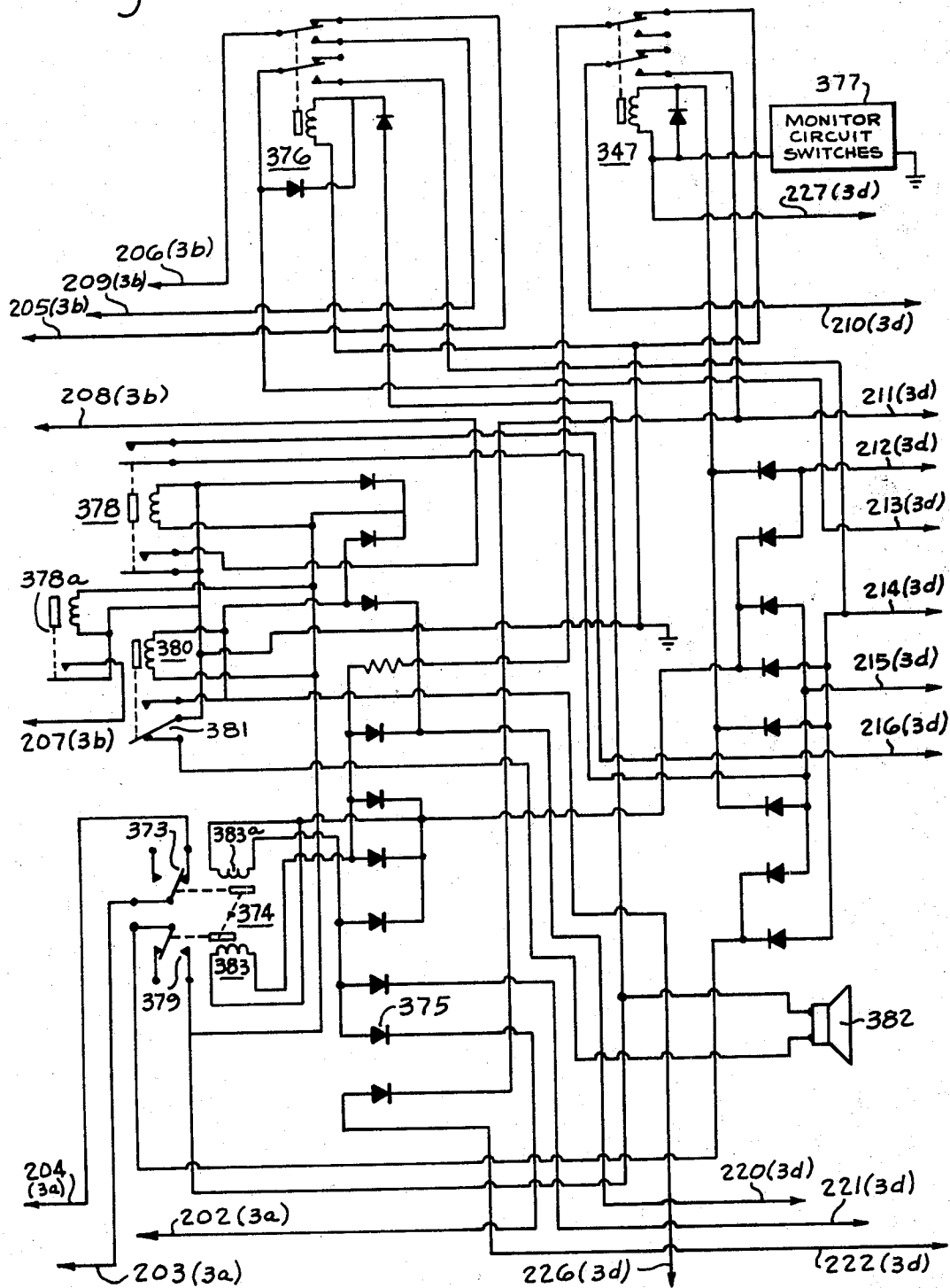
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Fig. 3c



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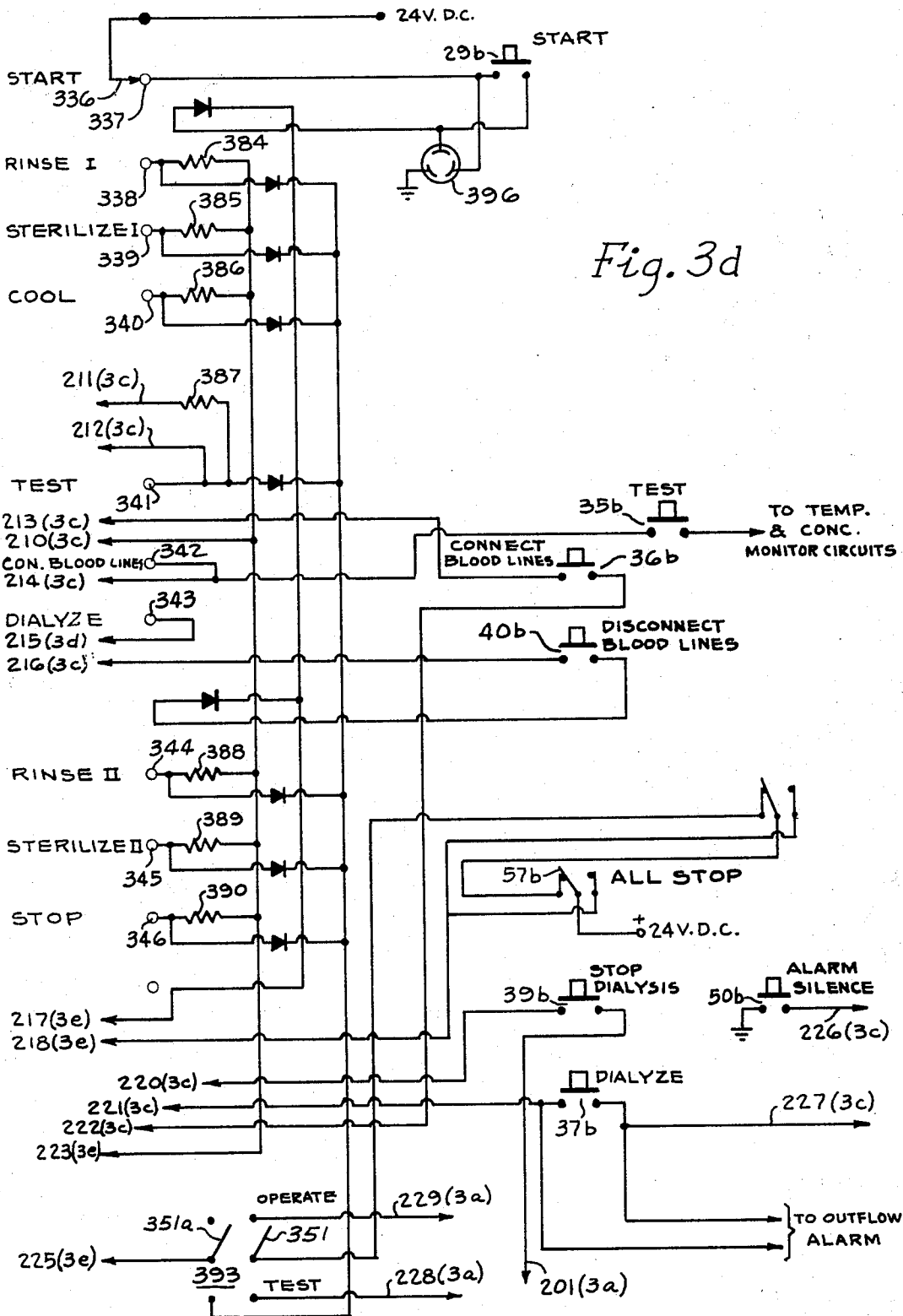
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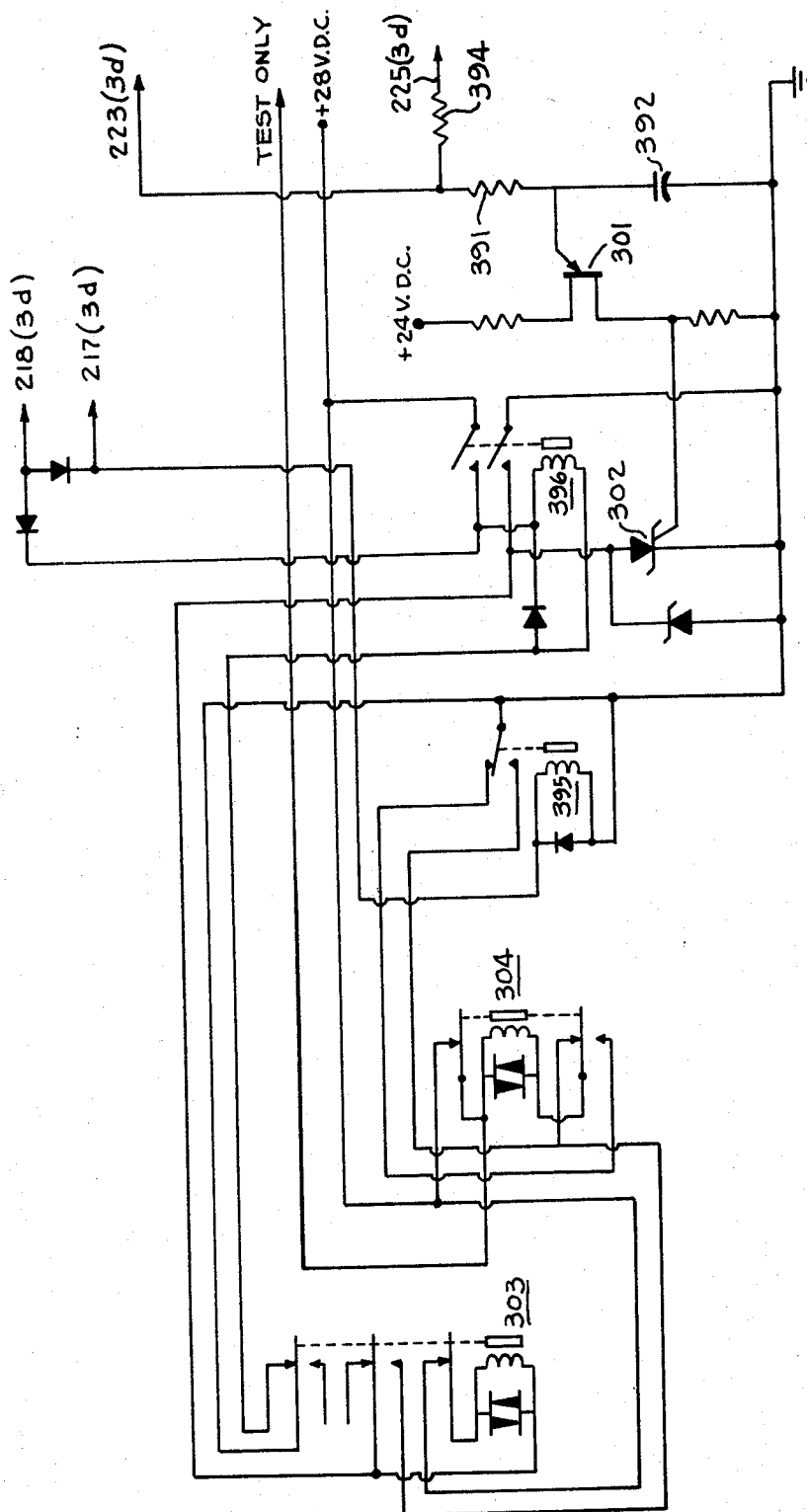


Fig. 3e

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2

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CONTROLLED BLOOD DIALYSIS SYSTEM

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U.S. Cl. 210—90

10 Claims

ABSTRACT OF THE DISCLOSURE

In a blood dialysis system, the critical parameters of the dialysis fluid and the blood are continuously monitored. The system is successively programmed through cycles of operation in which the system is rinsed, sterilized and cooled with water and in which the monitors are activated. Indicators are activated only after completion of the preliminary cycles of operation and the monitored parameters are within preset limits. This indicates that the blood ports may safely be connected to the circulatory system of the patient.

This invention relates to a system for continuously supplying dialysis fluid to a blood dialyzer and, more particularly, to a system providing automatic control and monitoring of the system to minimize the dangers to the patient of malfunction of the distribution system and to minimize the attention required by the operator of the system.

Hemodialysis systems have been employed as a therapeutic measure when a patient's kidneys no longer perform their blood purifying function because of disease or surgical removal. Kidney failure results in the accumulation of toxic wastes in the patient's blood and eventual death from uremic poisoning unless the waste material is removed by some artificial means. In hemodialysis, the patient's blood is circulated on one side of a membrane which has pores of microscopic size through which waste products from the blood may pass, but which are too small to permit blood cells and proteins to leave the body. A dialysis fluid is circulated on the other side of the membrane to remove the waste products. As an example of hemodialysis treatment, the patient's blood may be circulated through the dialyzer for a period of five or six hours and this treatment may be repeated two or three times a week.

During this treatment, it is very important to continuously circulate through the dialyzer a dialysis fluid of precisely controlled temperature and concentration. A system for the continuous preparation and distribution of hemodialysis fluid is described by Grimsrud, Cole, Lehman, Babb, and Scribner in Transactions of the American Society of Artificial Internal Organs, vol. X, 1964, page 107. This invention relates to an improvement upon the system described in that paper.

The preparation of a hemodialysis system prior to treatment of the patient and the operation of the system during treatment requires several steps and constant attention to the critical parameters of the system. Prior to use, the system must be rinsed, sterilized and cooled. The dialysis fluid must be mixed to the proper concentration and temperature within very critical limits. The omission or improper execution of any of these steps may have traumatic effect upon the patient being treated.

In accordance with an important object of the present invention, there is provided a logic unit which successively programs the systems through cycles of operation in which the system is rinsed, sterilized and cooled with water and in which monitors for monitoring the critical param-

eters of the system are activated. Means are provided to insure that the system can be used for hemodialysis only after the system has been properly programmed through the preparatory steps of operation and only after the critical parameters of the system are within the specified limits.

In addition to the previously mentioned critical parameters of dialysis fluid temperature and concentration, there are other critical parameters which must be monitored prior to and during the dialysis treatment. The venous pressure of the patient should always be within prescribed limits. The negative pressure at which the dialysis fluid is pumped through the dialyzer must be within prescribed limits. The dialysis fluid at the outlet of the dialyzer should be continuously monitored for the presence of blood because the dialyzer membrane may rupture, in which case blood will enter the dialysis fluid stream. In the event that any of the monitored critical variables exceed their limits, the patient must be isolated from the dialysis fluid supply system.

Accordingly, it is another object of the present invention to provide a bypass across the dialysis fluid ports on the dialyzer. A bypass valve which is actuated by the monitoring system is included in this bypass. When any of the critical variables exceed their preset limits, the monitoring means actuates the bypass valve to open the bypass, close the dialysis fluid ports and thereby isolate the patient from the dialysis fluid circulation system. Furthermore, the bypass valve is responsive to the logic unit and the monitoring means during the preparatory operations so that the bypass valve is actuated to close the bypass and open the dialysis ports only after proper completion of the preliminary cycles of operation and the monitoring of the critical parameters within the preset limits.

The foregoing and other objects, features and advantages of the invention will be better understood from the following more detailed description and appended claims in conjunction with the drawings in which:

FIG. 1 shows a block diagram of the system;

FIG. 2 shows a more detailed flow diagram; and

FIGS. 3a-3e show the circuit details of the logic unit.

Referring now to FIG. 1, there is shown a block diagram of the system showing generally the circulation of dialysis fluid and the electrical control functions performed by the system. In FIG. 1 the hydraulic connections are shown with heavy lines while the electrical connections are shown with lighter lines.

The dialysis fluid to be circulated in the dialyzer 1 is a mixture of tap water from the source 2 and concentrate from the concentrate tank 3. The composition of the dialysis fluid may be changed in accordance with the therapy required for a particular patient. In general, the composition of the dialysis fluid is described in "Hemodialysis for Chronic Renal Failure," Freeman, Maher & Schreiner, Annals of Internal Medicine, vol. 62, No. 3, March 1965. The concentrate and tap water are mixed in precise proportions by the duplex pump 4. The duplex pump 4 is of the type which accurately meters quantities of two fluids on each stroke of the pump. The tap water ejected from the pump is heated in heater 5 and the heated water is mixed with the concentrate. A temperature control probe 7 is provided to control the energization of the heater to maintain the dialysis fluid at the desired temperature.

In order to supply water only to the system during rinse, sterilize and cool cycles, a solenoid actuated rinse valve 6 is provided. When energized, it will provide water instead of concentrate to the duplex pump 4.

The dialysis fluid is pumped to the head vessel 8. A sufficient quantity of dialysis fluid is maintained in the head vessel to provide a continuous supply of fluid

through the pressure valve 9 to the line 10 which is connected to the inlet dialysis ports 11 and 11a on the dialyzer 1. The dialyzer 1 may be of many well-known types but the system of this invention is particularly suitable for use with a dialyzer commonly referred to as a Kiil type dialyzer. Such a dialyzer is described in the aforementioned article by Freeman, Maher & Schreiner; and in "Parallel Flow Plastic Hemodialyzer as a Membrane Oxygenator," Transactions of American Society of Artificial Internal Organs, 8:43, 1962, Kiil & Glover.

The dialysis fluid passes into the inlet ports 11 and 11a and across several layers of cellophane provided in the dialyzer and out the outlet dialysis fluid ports 12 and 12a. Blood lines 13, 13a connect the dialyzer 1 to canulas properly disposed within the patient's vein and artery. Normally, the blood pressure of the patient will be sufficient to pump blood through the dialyzer 1. However, in the event that the blood pressure is not sufficient, an external blood pump may be provided.

The dialysis fluid from the outlet dialysis fluid ports 12, 12a passes through the negative pressure monitor 14 and the three-way solenoid actuated bypass valve 15. The bypass valve 15 is connected to a bypass 16 which shunts the dialysis fluid ports in the dialyzer 1. When the valve 15 is in one position, fluid flow will be through the bypass 16. The valve is in this position during the rinse, sterilize and cool cycles unless the dialyzer hoses are connected to an external shunt provided for sterilization of the hoses. If the hoses are not so connected, the bypass valve 15 remains in the bypass condition until the system monitors indicate that all critical parameters are within the specified limits.

During the dialysis stage of operation, the bypass valve 15 is in a position which allows flow through the dialysis fluid ports in the dialyzer. The bypass 16 is closed during dialysis. The valve 15 is in this "dialyze" condition only during the dialysis cycle. In the stop dialysis cycle, the bypass valve 15 will be returned to a position which opens bypass 16 and closes the dialysis fluid ports upon the detection of any of the system parameters exceeding their preset limits. In this manner, the bypass valve provides means for isolating the patient from the dialysis fluid circulation system immediately upon the detection of a possible malfunction in the system.

The dialysis fluid flows through the outflow monitor 17 and through the effluent pump 18. The fluid is pumped through the system by an effluent pump 18 which creates a negative pressure at the outlet side of the dialyzer.

The presence of small amounts of blood in the dialysis fluid is detected by the photoelectric outflow monitor 17. By means of this device, minute quantities of blood in the dialysis fluid can be detected immediately and a relay in the outflow monitor circuit 19 will be activated to result in an alarm condition which will isolate the patient from the dialysis circulation system and sound an audible alarm to indicate that an investigation must be made to determine the difficulty.

Similarly, the other critical parameters of the system are monitored and the variation of these parameters outside of preset limits will cause an alarm condition. In order to monitor the temperature of the dialysis fluid, a temperature probe 20 is provided in the head vessel and this temperature probe is connected to the temperature monitor circuit 21. The temperature monitor circuit 21 has a relay which is actuated upon variation of the temperature beyond prescribed limits. Similarly, the conductivity cell 22, at the outlet of the head vessel, monitors concentration and the concentration monitor circuit 23 has a relay which is actuated when the conductivity varies outside of the prescribed limits.

In order to measure the patient's venous or arterial pressure, a pressure monitor 24 may be provided in the blood drip chamber of the dialyzer. This pressure indicator is electrically connected to the venous pressure monitor circuit 25 which includes a relay which will be

actuated when the venous pressure exceeds predetermined limits.

In order to measure the negative pressure in the dialysis fluid circulation system, the negative pressure monitor 14 is connected to the negative pressure monitor circuit 26 which also includes a relay which is actuated when the negative pressure in the system exceeds predetermined limits. The monitor circuits 19, 21, 23, 25 and 26 all have relay contacts connected in series to control the energization of an alarm relay in the logic unit 27 which will be subsequently described in more detail. Only when the alarm relay in the logic unit 27 is in its energized conduction will the system be placed in a condition in which dialysis treatment can be performed.

The operation of the system can be controlled by the operator from the control panel 28. The control panel 28 has pushbuttons and indicating lamps which are arranged so that the operation of the system can proceed only in the prescribed manner. The relationship between the pushbuttons and indicating lamps on control panel 28 and the operation of the system is as follows.

START

When the service connections have been made to the system and it is in a condition for the preliminary operation cycles to proceed, the lighted pushbutton 29 (referred to as the "start" button) will be flashing.

RINSE I

When the start button 29 is depressed, the system will switch to the "Rinse I" cycle during which cold tap water is pumped through the system for a period of five minutes. The purpose of this cycle is to rinse and to fill the system prior to sterilization. The Rinse I cycle will be indicated by energization of the lamp 30.

STERILIZATION I

At the termination of the Rinse I cycle, the system automatically switches to the "Sterilize I" cycle. During the Sterilize I cycle, tap water heated to a temperature of 85° C. is pumped through the system, with the exception of the dialyzer, for a period of thirty minutes. This cycle is indicated by energization of the lamp 31.

COOL

At the end of the thirty minute sterilization cycle, the system will automatically switch to the "Cool" cycle during which the temperature of the fluid pumped through the unit is dropped from 85° C. to about 37° C., the latter temperature being set by the temperature set point control 32. During this cycle, the rinse valve 6 is deenergized so that concentrate from the tank 3 will be supplied to the duplex pump 4. The duplex pump 4 will then pump both tap water and concentrate to the head vessel 8 thereby bringing the composition of the dialysis fluid up to normal by the end of the Cool cycle. When the system is in the Cool cycle, the lamp 34 will be energized.

TEST

At the end of the ten-minute Cool cycle, the unit will automatically switch to the test condition. This will be indicated by energization of the lighted pushbutton 35, referred to as the "test pushbutton."

At the beginning of the Test cycle, all of the monitoring systems and their associated indicator lights, with the one exception of the venous pressure monitor, are activated. During the first phase of the Test cycle, which is fifteen minutes in duration, the temperature and composition of the dialysis fluid are monitored to insure proper operation of the unit. The successful completion of this portion of the test cycle is contingent upon the composition and the temperature of the dialysis fluid remaining normal for the fifteen-minute period. This cycle also serves to dialyze all acetic acid out of the dialyzer.

Upon completion of the first portion of the Test cycle,

the lighted pushbutton 35 will change from constant to flashing. At this time, the flashing light is pushed in order to test the two critical monitoring systems, concentration and outflow.

CONNECT BLOOD LINES

When the Test cycle has been satisfactorily completed and all of the critical parameters are within the prescribed limits, the system will automatically switch to the "Connect Blood Lines" cycle as indicated by flashing of the lighted pushbutton 36. This indicates that the patient is to be connected to the blood lines 13, 13a. When this has been done, the pushbutton 36 is depressed and the system proceeds to the Dialyze cycle as indicated by energization of the lighted pushbutton 37.

DIALYZE

During the first few minutes after entering the Dialyze cycle, the venous pressure monitor 24 is connected and activated by pressing the flashing "activate" light of pushbutton 38.

STOP DIALYSIS

If an alarm occurs during the dialysis, the system shifts automatically to "Stop Dialysis" as indicated by energization of the lighted pushbutton 39, and the patient is isolated from the supply unit.

If normal conditions can be reestablished, the system may be returned to the Dialyze cycle by pushing the flashing pushbutton 37.

DISCONNECT BLOOD LINES

If normality cannot be achieved, the action indicated by the flashing "Disconnect Blood Lines and Dialyzer" light of pushbutton 40 must be executed and this light pushed. Once the light 40 has been pushed, the unit automatically shifts to the first post-operational cycle, "Rinse II."

RINSE II

During the five-minute Rinse II cycle, 37° C. water is pumped through the system in order to flush out all of the dialysis fluid prior to final sterilization.

STERILIZE II

At the end of the Rinse II cycle, the system automatically shifts to the "Sterilize II" cycle, indicated by lamp 42, during which tap water is again heated to a temperature of 85° C. and is pumped through the system for a period of thirty minutes. The dialysate hoses are connected to the shunt interlock (bypass connection) for this rinse and sterilization period in order to permit their sterilization as well. At the end of the thirty-minute Sterilize II cycle, the system will shut itself off and the Start pushbutton 29 will begin flashing, indicating, of course, that the system is ready for another pre-operation sequence whenever desired.

In order to indicate the exact nature of the condition which has caused the system to switch from the Dialyze to the Stop Dialysis mode of operation, a plurality of indicating lamps are provided to indicate whether each of the critical parameters is high, low or normal. Lamps 43a, 43b and 43c indicate whether the dialysate temperature is low, normal or high; lamps 44a, 44b and 44c indicate whether the dialysate concentration is low, normal or high; and lamps 45a, 45b and 45c indicate whether the negative pressure is low, normal or high.

Lamps 46a and 46b indicate whether the venous pressure is low or high. The indicating lamp 47 indicates that there is an outflow alarm. The lamp 48 indicates that there is a lamp failure in the photoelectric outflow detector. Pushbutton 49 is provided to reset the outflow detector. Often, the outflow detector will be activated when there is an air bubble in the system. If this is the case, the detector will provide a normal indication after the reset button is pushed.

The control panel also includes an audible alarm 50 and a pushbutton 50a for silencing the audible alarm. The negative pressure control adjustment 51 adjusts the pressure in the system. Indicators 52-56 have been provided to indicate venous pressure, negative pressure, outflow, temperature and concentration, respectively. The adjustment 51 acts through the negative pressure control 51a to open and close the valve 9 to provide the desired pressure in the system.

The operation of the entire system can be better understood from the description of the operation of the system provided after the following more detailed description of the flow diagram and schematic drawings of the logic circuitry.

Referring now to FIG. 2, there is shown a more detailed flow diagram of a single patient system. Fresh water is supplied to the system through the fitting 101. The pressure reducing valve 102 reduces the inlet pressure to approximately 3 lbs. per square inch. The fresh water is supplied to an air trap 103 which has a release valve at the top for releasing air. Water to be supplied to the system is taken from the bottom of the air trap through line 104. An overflow line 105 extends from the top of air trap 103.

Duplex pump 106 is provided for circulating water and concentrate to the system. This type of duplex pump may be the commercially available Milton Roy duplex controlled volume pump supplied by the Milton Roy Company. This pump will, on alternate strokes, pump water and concentrate through lines 107 and 108, respectively.

In order to supply only water to the system during the rinse and sterilize cycles, the rinse valve 109 is provided. The rinse valve 109 will supply water to the left-hand side of the duplex pump 106 during the rinse and sterilize cycles. A check valve 110 is provided to prevent water from entering the concentrate tank 111 during the rinse and sterilize cycles of operation.

Water or concentrate pumped from the left side of the pump 106 passes through a back pressure valve 112 to be mixed with heated water from the heater 113. Water from the line 107 on the right-hand side of the duplex pump passes through a back pressure valve 114 to the heater 113. The heater 113 contains three heating elements. As will subsequently be explained, one heater element is energized all the time; two heater elements normally are energized when water at 37° C. is required. When 85° C. water is required for sterilization, three heater elements are energized. Two heating elements are controlled to obtain the desired temperature regulation.

The mixed hot and cold fluid is pumped to the constant head vessel 115 through inlet pipe 116. The inlet pipe 116 has a plurality of small holes in the top thereof. Water and the dissolved air are ejected from the small holes in the top of the inlet pipe 116. The constant head vessel 115 is filled with berl saddles. The berl saddles in the constant head vessel tend to grow air bubbles. That is, the air accumulates into bubbles which then burst leaving the fluid at the bottom of the constant head vessel relatively air-free. An overflow pipe 117 provides overflow when the head vessel is full. It should be noted that there will always be some overflow. That is, the supply of fluid is always slightly greater than the demand for the fluid from the constant head vessel so that the constant head vessel will never be drained and can be filled upon system start-up.

The outlet pipe 118 from the constant head vessel supplies fluid to the conductivity cell 119 which measures the conductivity of the concentrate and provides an indication of whether the concentrate is within the desired limits. The conductivity cell 119 may be a commercially available instrument; for example, that manufactured by Industrial Instruments, Inc., Cedar Grove, N.J.

The overflow from the conductivity cell may pass through a bypass 120. Normally, however, the fluid will

circulate through the negative pressure valve 121 and thence through either the dialyzer or, during rinse, sterilize and cool cycles, the fluid will circulate through a shunt. The shunt is provided so that the hoses which normally connect the system to the dialyzer may be sterilized. The line 122 terminates in a hose connection 123 to which the hose 124 is connected. During the rinse, sterilize and cool cycles, the hose 124 is connected to the shunt 125. (During dialysis, this hose is connected to one inlet to the dialyzer to circulate fluid through the dialyzer. Another hose 126 is connected to the outlet from the dialyzer during dialysis. However, as is shown, the hose 126 is connected to the outlet from the shunt 125 for sterilization.)

When the hoses 124 and 126 are connected as shown, they will depress a shunt interlock 127. This is a mechanically actuated switch which, when depressed, will energize the bypass valve to allow fluid to flow through the hoses 124 and 126 during the rinse, sterilize and cool cycles when it is desired to sterilize these hoses.

The hose 126 is connected to the hose connector 126a. Fluid flows through hose connector 126a and through the isolator 128. A negative pressure gauge 128a is connected to the isolator 128 and measures the negative pressure in the isolator. The isolator 128 is connected to the negative pressure gauge 128a in such a manner that concentrate is never collected in the isolator. This prevents the possibility of bacteria growing in collected concentrate.

The fluid flows from the output of isolator 128 through flow meter 129. The flow meter 129 provides a visual indication of whether fluid is flowing through hose connectors 123 and 126a or whether the fluid is flowing through the bypass 120. This merely provides a convenient manner of determining the fluid path.

The output of the flow meter 129 passes through the bypass valve 130 which has two inlets 131 and 132 and an outlet 133. When the bypass valve 130 is energized, the flow is through the inlet 131 to the outlet 133. When the bypass valve 130 is deenergized, the flow is through the inlet 132 to the outlet 133.

The flow from the bypass valve 130 passes through outflow detector 134. Detector 134 is of the photoelectric type which will detect the presence of blood in the dialysis fluid. If there is a rupture in the membrane of the dialyzer resulting in a minute amount of blood passing through the membrane, this blood will be detected by outflow detector 134.

The fluid is pulled through the system by the effluent pump 135. Providing negative pressure on the outlet side of the dialyzer is desirable rather than providing positive pressure on the inlet side of the dialyzer. If there were pressure on the inlet side of the dialyzer, a rupture in the membrane of the dialyzer would result in concentrates being pumped into the blood chamber. However, with the effluent pump 135 providing a negative pressure on the outlet side of the dialyzer, any rupture in the membrane will result in a small amount of blood being pulled into the concentrate.

The effluent pump 135 is an impeller type pump providing a flow rate of 500 cc./min. maximum. Such a pump is commercially available, for example, from the Milton Roy Company. In such a pump, it is important that the rotor be wet to avoid undue friction. To insure that the rotor is wet when the system is started up, the prime valve 136 is provided. Upon start-up, the prime valve 136 is opened to allow water to pass from air trap 103 through the prime valve 136 to the effluent pump 135.

Outflow from the effluent pump 135 enters the waste can 137. Fluid from the waste can 137 is pumped by the waste pump 138 to the drain 139.

Referring now to FIGS. 3a-3e, there is shown the circuit diagram of the logic unit 27. In FIGS. 3a-3e, the interconnections between the figures are given the same reference numeral on each figure. The reference numeral is followed by an indication in parenthesis of the figure to

which the connection goes. For example, on FIG. 3a the reference 201(3d) indicates a connection which also appears on FIG. 3d. On FIG. 3d this connection is denoted 201(3a). Also included in FIGS. 3a-3e are the pushbuttons and lamps of the control panel 28 together with the windings of the control relays which control the energization of the rinse valve, heater, bypass valve, monitoring circuits and pump. Before describing these drawings in detail, there will first be described, generally, the function of the circuit shown on each of the drawings.

The timing for each of the cycles is controlled by an electronic timer shown in FIG. 3e. This timer includes a transistor 301 and a silicon controlled rectifier 302 connected in a circuit which periodically triggers the silicon controlled rectifier 302. The periodicity of the triggering is determined by the time constant included in the base circuit of transistor 301. The firing of the silicon controlled rectifier 302 advances a rotary cam switch 303 one step. Every thirty-six steps of the rotary cam switch 303 advances the rotary stepping switch 304 by one step. The rotary stepping switch 304 has three decks of contacts. The wipers of the rotary stepping switch 304 successively step across these contacts to control the system through its various modes of operation.

One deck of contacts of the rotary stepping switch 304 is shown in FIG. 3a. The wiper 305 of the rotary stepping switch 304 successively steps to the contacts 306-315 to apply ground potential to each of these contacts. Connected to each of the contacts is a diode matrix which completes the energization of relays to control selected system components during the various cycles of operation. The diode matrix controls the energization of the monitoring circuits by energizing relay coil 316. Similarly, the energization of the pumps, three heaters, rinse valve, prime valve, bypass valve and shunt interlock are selectively controlled by the diode matrix by energizing the relay coils 317-323, respectively.

Another deck of contacts of the rotary stepping switch 304 is shown in FIG. 3b. In FIG. 3b, the wiper 325 successively applies +140 volts DC to the contacts 326-335. This results in energization of the lamps and lighted pushbuttons on the control panel to indicate the action required or the present state of operation of the system. The lamps in FIG. 3b bear the same reference numerals as the corresponding lamps shown on the control panel in FIG. 1, and the lamps included in lighted pushbuttons have the same reference numerals as the lighted pushbuttons but have the suffix "a" added thereto.

Another deck of contacts of the rotary stepping switch 304 is shown in FIG. 3d. The wiper 336 successively applies +24 volts DC to the contacts 337-346. Connected to these contacts are resistors which are part of the time constant network for the transistor 301 in FIG. 3e. As the stepping switch steps through the various cycles of operation, the time constant for the transistor timer circuit is changed so that the proper time is set for each cycle of operation.

Also shown in FIG. 3d are the contacts of the pushbuttons on the control panel which are used to initiate the various operations of the system. The contacts bear the same reference numerals as the corresponding pushbuttons but with the suffix "b" added.

FIG. 3c shows the alarm relay 347 which is energized only when all of the critical parameters of the system are within their prescribed limits. When any of these critical parameters exceed the prescribed limits, the alarm relay 347 drops out to stop the dialysis operation. FIG. 3c also shows the other relay circuits which control the operation of the system during the Dialysis and Stop

Dialysis cycles of operation. Now referring to the circuitry of FIGS. 3a-3e in more detail, when the stepping switch 304 advances to the Rinse I position, ground potential is applied by wiper 305 to the contact 307 (FIG. 3a). This completes a cir-

cuit through diode 350 and through the relay coil 317 to +24 volts DC. The +24 volts DC is supplied over line 229 and through the contacts 351 of the Test-Operate switch 393 and the contacts 57b of the All Stop switch 57 to source of +24 volts. Energization of the relay coil 317 results in the system pumps being activated. Similarly, the rinse valve relay coil 321 will be energized through diode 352; the prime valve relay coil 322 will be energized through diode 353 and ground potential will be applied by the diode 354 to the line 355. The line 355 is connected through the contacts 356 of the shunt interlock. When ground potential is on the line 355, closure of the shunt interlock contacts 356, by connecting the hoses to the shunt 125 in FIG. 1, will result in energization of the bypass valve relay coil 323. In this way the bypass can be opened so that water can flow through the hoses and the shunt when the system is in the rinse, sterilize and cool cycles for sterilization of the hoses.

When the stepping switch 304 advances to the Sterilize I condition, ground potential is applied to contact 308 thereby completing a circuit through diodes 357-362 to the pump relay coil 317, heater relay coils 318, 319 and 320, rinse valve 321, and the shunt interlock.

Similarly, as the stepping switch advances to the successive positions 309-312, the diodes matrix selectively energizes each of the relay coils 316-323. In order to switch the diodes quickly as the stepping switch moves from position to position, a +48 volt DC bias is applied to the cathodes of the diodes through the resistors 363-370.

When the stepping switch 304 steps to the Connect Blood Lines position, contact 311, or to the Dialyze position, contact 312, the connection to the bypass valve is made through either the diode 371 or 372, over the line 204 and the contacts 373 (FIG. 3c) of the relay 374, and over line 203 to the bypass valve relay coil 323. The relay 374 is in the condition shown, that is, the reset condition when the alarm relay is in the energized condition, indicating that all of the critical parameters are within the prescribed limits.

When the stepping switch is in the Test condition, ground potential is applied to contact 310 and over line 202 and through diode 375 (FIG. 3c) to one side of the reset coil 383a of the relay 374. This permits energization of coil 383a to switch relay 374 to the reset position.

When the stepping switch 304 is in the Dialyze position, ground potential is applied to contact 312 (FIG. 3a) and over line 201 to one of the contacts 39b (FIG. 3d) of the Stop Dialysis pushbutton. This permits dialysis to be stopped by depressing the Stop Dialysis pushbutton.

Referring now to FIG. 3b, the wiper 325 of the stepping switch 304 steps from contact-to-contact to successively energize the Start lamp 29a, the Rinse I lamp 30, the Sterilize I lamp 31, the Cool lamp 34 and the Test lamp 35a. The Connect Blood Lines lamp 36a will be energized from the line 209 when the relay 376 (FIG. 3c) is energized. The relay 376 is energized when the Test cycle has been satisfactorily completed. In order to make some of the lights flash to indicate the action required, a capacitor is connected across the lights. For example, capacitor 326a is connected across the lamp 29a so that it will flash when +140 volts DC is applied to contact 326.

When the wiper 325 is in the Dialyze position, contact 332, the Dialyze lamp 37a, the Stop Dialysis lamp 39a and/or the Disconnect Blood Lines lamp 40a will be selectively energized by the relay circuits of FIG. 3c.

When the wiper 325 is in the Rinse II position, contact 333, the Rinse II lamp 41 will be energized and in the Sterilize II position, contact 334, the Sterilize II lamp 42 will be energized.

Referring now to FIG. 3c the master alarm relay 347 is energized when all of the critical parameters are within

in their prescribed limits. However, when any of the monitor circuits detect that one of the critical parameters is outside of the prescribed limits, the relay 347 is deenergized. In the Cool, Test and Connect Blood Lines positions, +24 volts will be supplied to the top of coil 347 over the lines 212, 214 and 215 respectively. A circuit may be completed from coil 347 to ground only if all of the monitor circuit switches 377 are closed, indicating that all of the critical parameters are within their prescribed limits. Initially, ground may also be supplied over the line 227, which is connected to the contacts 37b of the dialyze pushbutton (FIG. 3d) for starting the Dialyze cycle. The master alarm relay 347 controls the switching of the other relays shown in FIG. 3c.

The relay 376 is deenergized (the contacts are shown in the deenergize position) in the Dialysis cycle of operation. However, when the system switches to Stop Dialysis, the relay 376 is energized.

Relays 378 and 378a have ground potential applied to one side of their coils. The other sides of the coils have +24 volts applied thereto through the contacts 379 of relay 374 when there is an alarm. The relays 378 and 378a control the Disconnect Blood Lines lamp on the front panel. When they are energized, the Disconnect Blood Lines lamp 40a is energized.

The relay 380 is energized when all of the critical parameters are within the prescribed limit but is deenergized in the alarm condition. The relay contacts 381 apply ground potential to one side of the audible alarm 382 when the relay is deenergized. This audible alarm indicates an alarm condition. The relay 374 is of the set-reset type. That is, once it is switched into the reset condition by energization of the coil 383a, it will remain in this position until it is switched to the set position by energization of the coil 383. Coil 383 will be energized when the master alarm relay 347 is deenergized, indicating an alarm in one of the monitored critical parameters.

Referring to FIG. 3d, the wiper 336 of the stepping switch 304 steps to different positions to connect a different one of the resistors 384-390 in series with the +24 volts DC supply connected to the wiper 336. The other ends of these resistors are connected to the line 223. The line 223 is connected to the resistor 391 (FIG. 3e) which is, in turn, connected to the base of transistor 301 and to the capacitor 392. The selected one of the resistors 384-390, the resistor 391 and the capacitor 392 form a time constant network. The time constant of this network controls the periodicity of the firing of transistor 301. Since the time period of each of the cycles is different, the different values of resistance are used for each of the resistors 384-390 to accurately control the time period.

An Operate-Test pushbutton 393 is provided so that the system can be quickly cycled through its modes of operation for test purposes. When the pushbutton 393 is in the Operate position, the contacts 351 and 351a are straight up and contact 351a supplies +24 volts DC to the relays 316-323 (FIG. 3a). In the Test position, the contacts 351 and 351a are straight down. In this position, the contact 351 will supply +24 volts DC to only the relay coil 316 (FIG. 3a) to energize the monitor circuits. The contact 351a will supply +24 volts DC over the line 225 to the resistor 394 (FIG. 3e). Resistor 394 has a relatively low value so that the time constant of the resistor-capacitor network is low thereby providing very frequent triggering of transistor 301. This results in a very rapid sequencing of the system through its various cycles so that its operability can be quickly determined.

At the beginning of the actual operation of the system, the Start pushbutton 29 is depressed. The contacts 29b supply +24 volts DC to the line 217 thereby energizing relay 395 (FIG. 3e). This will step the rotary stepping switch 304 to the next position, in this case to the Rinse I position.

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In order to provide a remote start, the device 396 is provided. This device can be made to conduct by connection to an external circuit thereby providing means for starting the system into operation from a remote position.

The remaining pushbuttons shown on FIG. 3d perform the function which has previously been described with reference to these pushbuttons.

Referring now to FIG. 3e, as has been previously discussed, the transistor 301 and silicon controlled rectifier 302 will periodically energize the rotary cam switch 303 with a periodicity determined by the time constant circuit associated with transistor 301. When the rotary cam switch 303 makes thirty-six steps, the rotary stepping switch 304 is energized to advance it one position.

The rotary stepping switch 304 will also be advanced one position when the relay 395 is energized. This occurs when certain of the pushbuttons on FIG. 3c are depressed.

The rotary stepping switch 304 will be advanced to its home position when the relay 396 is energized. Relay 396 is energized when the All-Stop pushbutton 57 is depressed thereby completing a circuit through the contacts 57b (FIG. 3d) to apply +24 volts DC to the coil of relay 396.

OPERATION OF SYSTEM

Before proceeding with a description of the operation of the system, the energization of the various components during each of the cycles is summarized in the following table.

CYCLE SEQUENCE DIAGRAM

Cycle Number	Cycle Designation	Cycle Time (minutes)	Patient Action Required	System Component									
				Heater 37° C.	Heater 86° C.	Rinse Valve 2	Bypass Valve 1	Solution Pump	Prime Valve 2	Monitoring Systems	Alarm System	Shunt Interlock 3	Effluent Pump
0	Off		Connect Dialyzer										
1	Start		Push button/Remote timer										
2	Rinse I	5	None			X		X	X			X	X
3	Sterilize I	30	None	X	X	X		X				X	X
4	Cool	10	None	X				X				X	X
5	Test	15	None	X			X	X		X			X
			Push button								X		X
6	Connect Blood Lines	AR	Connect Blood Lines	X			X	X		X	X		X
7	Dialyze	AR	Push button	X			X	X		X	X		X
			Push button										
8	Stop Dialysis	AR	Disconnect blood lines	X				X		X	X		X
9	Disconnect Blood Lines and Dialyzer		Connect dialysate lines to shunt	X				X		X			X
			Push button										
10	Rinse II	5	None	X		X		X	X			X	X
11	Sterilize II	30	None	X	X	X		X				X	X
12	Stop		None										

1 When deenergized (off), bypass valve is in bypass configuration.
2 All valves are closed when deenergized (off).
3 When shunt interlock is "on," the bypass valve is in bypass configuration unless dialysate lines are connected to shunt.

X—Signifies component is "on."
AR—As Required.

In more detail, the operation of the system is as follows:

PRELIMINARY OPERATIONAL CONTROL

Pre-operational rinse and sterilization

When the Start function is activated, either manually by pushbutton contacts 29b or remotely through device 396, the Start lamp 29a of the lighted pushbutton 29 on the control panel is deenergized and the Rinse I lamp 30 is energized.

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During the Rinse I cycle, cold tap water is pumped through the entire system and down the drain for a period of five minutes. The rinse valve 6 (FIG. 1) is energized to supply only water to the system. At the end of the five-minute cold rinse cycle, the Rinse I lamp 30 will go out and the Sterilize I lamp 31 will come on.

During the Sterilize I cycle, tap water is heated to a temperature of 85° C. by energization of relays 319 and 320 (FIG. 3a) which control two heating elements in the heater 5 (FIG. 1). Heated water is pumped through the system for a period of thirty minutes. At the end of the thirty-minute sterilization, the Sterilize I lamp 31 will go out and the Cool lamp 34 will come on.

During the Cool cycle, relays 319 and 320 are deenergized and the water temperature returns to 37° C. This water is pumped through the system for a period of ten minutes to cool it down to body temperature. The suction side of the concentrate pump is also shifted from tap water to concentrate, by deenergizing rinse valve 6, in order to bring the composition of the dialysis fluid up to normal by the end of the cooling period. At the end of the ten-minute cooling cycle, the Cool lamp 34 will go out and the Test lamp 35a in lighted pushbutton 35 will come on.

MONITORING SYSTEM TEST

All of the monitoring systems and their associated indicator lights, except the venous pressure monitor 24,

are activated when the dialysate supply unit shifts to the Test cycle.

During the first portion of the Test cycle, the temperature and composition of the dialysis fluid are monitored by the circuits 21 and 23 to insure proper operation of the unit. The successful completion of this part of this cycle is contingent upon the dialysis fluid's composition and temperature remaining normal for a period of fifteen minutes. This cycle also functions to dialyze the acetic acid out of the dialyzer 1.

Upon completion of the first portion of the Test cycle, the Test lamp 35a will change from constant to flashing. At this time, the temperature, concentration, and outflow monitors should all indicate normal.

When the flashing Test pushbutton 35 is depressed the following events occur:

(a) The pointer on the concentration monitor meter 56 will move up-scale past the high alarm set point causing the Normal lamp 44b to go off and the flashing High concentration lamp 44c to come on.

(b) The audible alarm 382 will be energized.

(c) The pointer on the outflow alarm meter 54 will move up-scale to the set point and lock on to the alarm stop causing the light of the Normal Reset pushbutton 49 to change from constant to flashing and the flashing High outflow alarm lamp 47 to come on.

(d) The flashing Test light of pushbutton 35 will go out and the Connect Blood Lines light of the pushbutton 36 will start flashing.

When the test pushbutton 35 is released, the concentration monitor meter 56 and indicators should return to normal.

The Alarm silence pushbutton 50a is depressed to silence the audible alarm.

The flashing Outflow Alarm Reset pushbutton 49 is depressed to reset the outflow alarm. The monitoring system test is now completed and the supply unit ready for dialysis.

BLOOD LINES

At this point the blood lines 13, 13a are connected to the cannulas, using standard procedures.

Upon completion of blood lines connection, the flashing Connect Blood Lines pushbutton 36 is depressed until the Dialyze light on pushbutton 37 comes on. The Connect Blood Lines light of pushbutton 36 will stop flashing.

NEGATIVE PRESSURE

The Negative Pressure Control valve 51 on the control panel is adjusted to yield the desired negative pressure.

DIALYSATE TEMPERATURE

The dialysate Temperature Set Point control 32 is set on the front panel to a temperature that is comfortable to the patient.

The venous pressure gauge 24 is connected to the blood drip chamber, and the flashing venous pressure monitor Activate lighted pushbutton 38 is depressed to activate the venous pressure monitor circuit 25.

ALARM CONDITIONS

If abnormal condition occurs during the dialysis run, the supply unit will automatically isolate the patient from the system by switching from Dialyze to Stop Dialysis. This will deenergize the solenoid of bypass valve 15 (FIG. 1) thereby opening bypass 16. An audible alarm 382 will sound and the stop lamp 39a in lighted pushbutton 39 will come on. The Dialyze lamp 37a and the Disconnect Blood Lines lamp 40a will commence to flash, indicating the option of continuing or discontinuing the dialysis depending upon whether the cause of the alarm can be corrected or not.

When an alarm occurs, the Alarm Silence pushbutton 50a is pushed to silence the audible alarm. The exact type and direction of the deviation will be indicated by a flashing light on the control panel.

TERMINATION

Upon completion of the desired dialysis time or after an inorrectible alarm condition, the Stop Dialysis pushbutton 39 is depressed.

The blood lines 13, 13a are disconnected using standard procedures.

RINSE II

The dialysate hoses 124, 126 (FIG. 2) are disconnected from the dialyzer and connected to the shunt 125.

The flashing Disconnect Blood Lines lighted pushbutton 40 is depressed.

The Disconnect Blood Lines lamp 40a will stop flashing and the Rinse II lamp 41 will come on.

During the Rinse II cycle, tap water heated to 37° C. is pumped through the system in order to flush out all the dialysate prior to final sterilization.

At the end of the five-minute Rinse II cycle, the Rinse II lamp 41 will go out and the Sterilize II lamp 42 will come on.

STERILIZE II

During the Sterilize II cycle, water heated to a temperature of 85° C. is pumped through the system and the dialysate supply hoses for a period of thirty minutes.

At the end of the thirty-minute Sterilize II cycle, the system will shut itself off, and the Start light of pushbutton 29 will begin to flash, indicating that the system is ready for another operational sequence whenever desired.

While the system has been described in conjunction with the treatment of a single patient, it will be understood that the supply system could be used to supply a number of patients, each having a separate dialyzer. In this case, the controls on the control panel will be split. The controls for the Start, Rinse I, Sterilize I, Cool, Test, Connect Blood Lines, Disconnect Blood Lines, Rinse II and Sterilize II cycles are all put on a central control panel accessible only to an operator. Each patient will have a separate control panel with Dialyze, Stop Dialysis, All Stop and Alarm Silence controls.

While a particular embodiment of the invention has been shown and described, it will, of course, be understood that various modifications may be made without departing from the principles of the invention. The appended claims, are therefore, intended to cover any such modifications of the true spirit and scope of the invention.

What is claimed is:

1. A blood dialysis system comprising:

a dialyzer having a membrane, blood ports for passage of blood through said dialyzer on one side of said membrane, and dialysis ports for passage of dialysis fluid through said dialyzer on the other side of said membrane,

a source of dialysis fluid,

monitoring means for monitoring the critical parameters of said dialysis fluid and said blood,

a source of tap water,

an electrically operated valve for selectively supplying said tap water and said dialysis fluid to said dialysis ports,

heater means for supplying sterilizing water to said dialysis ports,

a logic unit for selectively activating said electrically operated valve, said heater means and said monitoring means to successively program said system through cycles of operation in which said system is rinsed, sterilized and cooled with water, and in which said monitoring means are activated, and

indicating means responsive to said monitoring means and said logic unit, said indicating means being activated only after completion of the aforesaid cycles of operation by said logic unit and the monitoring of said critical parameters within preset limits, said indicating means providing a visible indication that said blood ports may safely be connected to the circulatory system of a patient.

2. The system of claim 1 and:

a bypass connected across said dialysis ports,

a bypass valve connected in said bypass and responsive to said monitoring means and said logic unit for closing said bypass and opening said dialysis ports only after completion of the aforesaid cycles of operation by said logic unit and the monitoring of said critical parameters within said preset limits.

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3. The system of claim 1 wherein said monitoring means includes:

means for monitoring the temperature, concentration and pressure of said dialysis fluid, the presence of blood in said dialysis fluid and the pressure of said blood.

4. The system of claim 1 wherein said logic unit includes:

a timer for controlling the time period of each of said cycles of operation, and

stepping means actuated by said timer to different positions, each of which controls said system during one of said cycles of operation.

5. The system of claim 4 wherein said stepping means includes a first set of selectively actuated switches, and wherein said system further includes:

a bypass hydraulically connected across said dialysis ports, and

a solenoid actuated bypass valve hydraulically connected in said bypass, one switch of said first set of switches being electrically connected to energize the solenoid of said bypass valve to close said bypass and open said dialysis ports only after completion of the rinse, sterilize and cool cycles of operation and the monitoring of said critical parameters within said preset limits.

6. The system of claim 5 wherein said electrically operated valve includes:

a solenoid actuated rinse valve hydraulically connected to a source of water and a source of dialysis fluid, said rinse valve being hydraulically connected to supply either water or dialysis fluid to said system, one switch of said first set of switches being electrically connected to the solenoid of said rinse valve to actuate said rinse valve to supply water to said system during said rinse, sterilize and cool cycles of operation.

7. The system of claim 5 further including:

a pump connected to the outlet dialysis fluid ports of said dialyzer for pumping dialysis fluid through said system,

a solenoid actuated prime valve hydraulically connected between a source of water and said pump, one switch of said first set of switches being electrically connected to energize the solenoid of said prime valve to open said valve upon start-up of said system to introduce water into said pump upon start-up.

8. The system of claim 5 wherein said heater means includes:

an electrically energized heater hydraulically con-

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nected in said system for flow of water through said heater, one of said first set of selectively actuated switches being connected to energize said heater during the sterilize cycle of operation to heat said water to a temperature for sterilization of said system.

9. The system recited in claim 4 wherein said stepping means includes a second set of selectively actuated switches, and wherein said system further includes:

a plurality of indicating lamps for indicating the cycle of operation of said system, said second set of switches being electrically connected to said indicating lamps to selectively energize said lamps during the cycles of operation of said system.

10. The system of claim 4 wherein said stepping means includes a third set of selectively actuated switches, and wherein said timer is an electronic timer including:

a periodically energized semiconductor circuit having a resistor-capacitor network for determining the periodicity of said energization, said third set of switches selectively connecting different ones of a plurality of resistors in said resistor-capacitor network to change the periodicity of said energization to control the time period of each of said cycles of operation.

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