April 28, 1970 E. J. SERFASS ET AL 3,508,656

PORTABLE DIALYSATE SUPPLY SYSTEM

Filed April 10, 1968 2 Sheets-Sheet 1

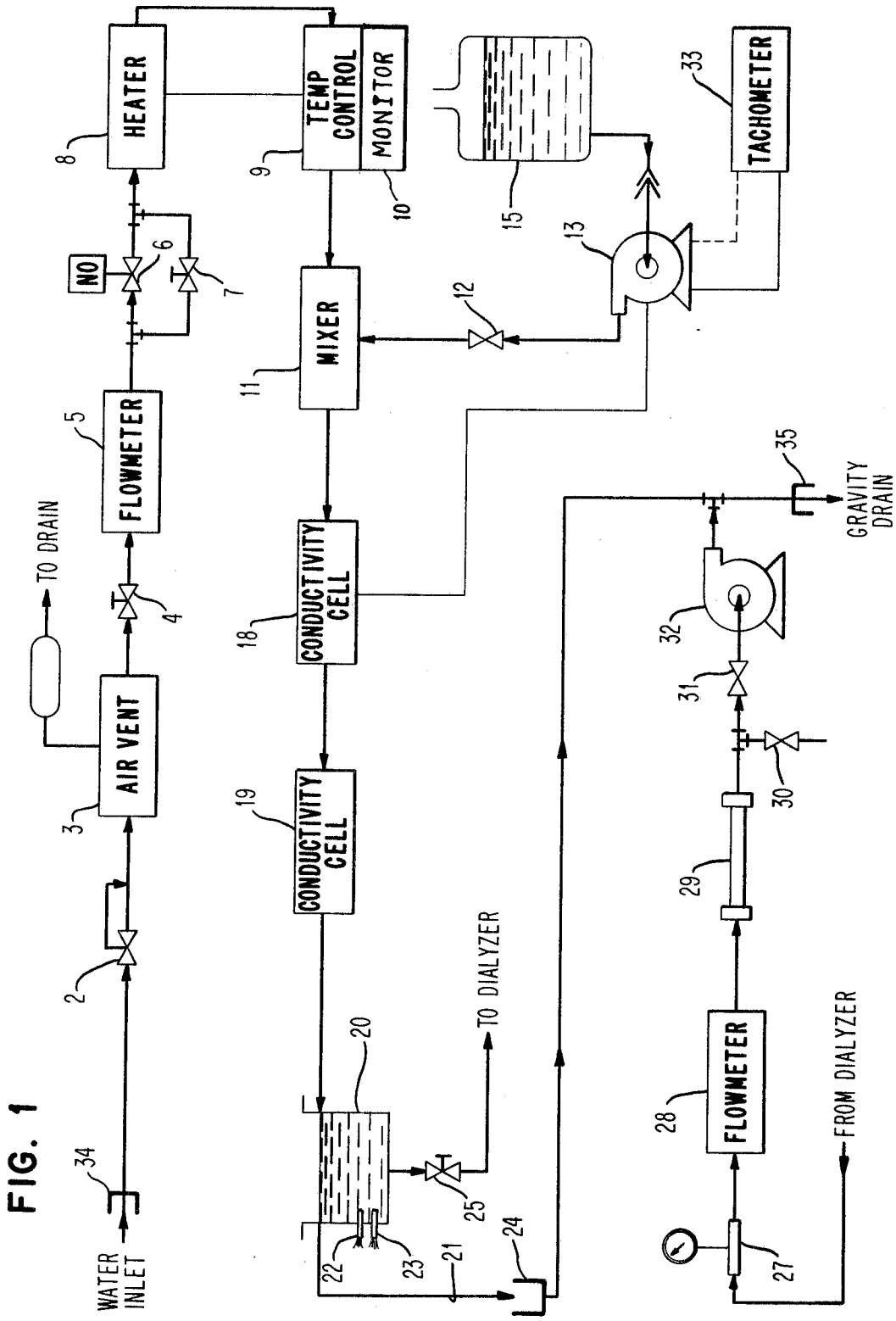

FIG. 1

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PORTABLE DIALYSATE SUPPLY SYSTEM

Filed April 10, 1968 2 Sheets-Sheet 2

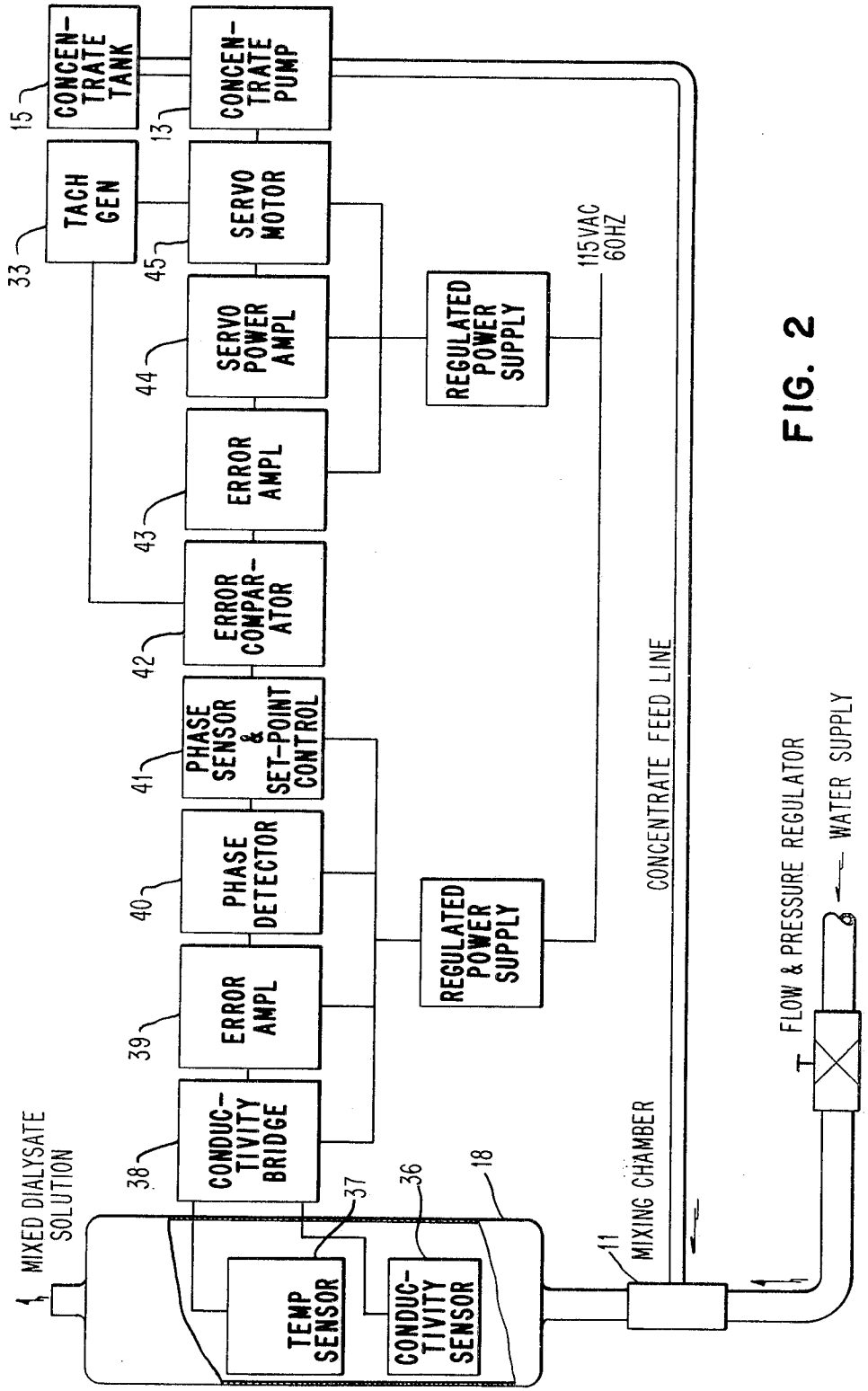

FIG. 2

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PORTABLE DIALYSATE SUPPLY SYSTEM

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Int. Cl. B01d 35/14, 35/00
U.S. Cl. 210—90 4 Claims

ABSTRACT OF THE DISCLOSURE

A portable blood dialysis system in which dialysate fluid is mixed and supplied with a constant concentration is described. Water and dialysate fluid concentrate are mixed to form dialysate fluid which is supplied to the dialyzer. The concentration of the dialysate fluid is continuously monitored by a conductivity cell. The output of the conductivity cell is applied to control a pump which supplies the concentrate. This pump also has a secondary speed control loop. A tachometer in the secondary loop corrects speed variations caused by changes other than the conductivity cell output signal.

BACKGROUND OF THE INVENTION

One of the most successful means for treating chronic kidney failure is by hemodialysis using an artificial kidney system. In hemodialysis the patient's blood is circulated from an artery through an artificial kidney, or dialyzer, where excess water and waste materials are removed. The blood is returned to the patient's veins.

A central station dialysate supply system for supplying dialysate fluid to a number of patients in a hospital is described in Transactions of the American Society of Artificial Organs, vol. X, 1964, page 107, Grimsrud, Cole, Lehman, Babb and Scribner.

Also, in the Austin et al. Patent 3,352,779 there is described a system for mixing dialysate fluid in large batches for supply to a number of patients.

Since the patient must undergo dialysis treatment several times a week it is desirable that a system be provided which can be used by the patient in his home. A single patient dialysate supply system with extensive monitoring controls which makes the system safe for use by the patient himself is described in Controlled Blood Dialysis System, Ser. No. 563,523, now U.S. Patent No. 3,441,136, filed July 7, 1966, Earl J. Serfass, John E. Martin and William E. Wilson, Jr. Such a single patient system is also described in a paper presented before the Instrument Society of America, 22nd Annual ISA Conference and Exhibit, Sept. 11–14, 1967, by Dr. E. J. Serfass, Preprint Publication No. 26–1–BIOMED–67.

These single patient systems have found widespread successful use. However, they do not meet all requirements of some patients because the systems utilize expensive proportioning apparatus for mixing dialysate fluid and because the systems are quite large and not portable.

All of the blood dialysis supply systems described above use a two-stroke pump to mix dialysate concentrate with water to produce a supply of dialysate fluid. These pumps have very accurate controlled strokes so that the water and the concentrate are mixed in precise volumetric proportions. The pumps are relatively expensive and bulky. Further, extensive movement of the pump will affect the calibration so they are not suitable for a truly portable system.

While these two-stroke pumps do mix concentrate and water in precise volumetric proportions, the resulting dialysate fluid does not necessarily have a controlled concentration. When the density of the concentrate changes with temperature, the concentration of the dialysate fluid changes. What is required in dialysate supply systems is the production of a dialysate fluid having controlled sodium and chloride concentration at a prescribed temperature.

The variation of the concentration of the dialysate fluid with change in temperature is a particular problem in a system having extensive monitor controls such as the systems described in the above-mentioned Serfass reference and Serfass et al. patent application. These systems have a concentration monitor which sounds an alarm when the concentration of the dialysate fluid varies outside of preset limits. When dialysis treatment is performed during the night, as it is frequently, the patient will often be awakened by the alarm when the concentration of the dialysate fluid changes because of a change in the ambient temperature of the top water.

SUMMARY OF THE INVENTION

This invention relates to blood dialysis supply systems and more particularly to a portable blood dialysis system.

In accordance with an important aspect of this invention, the dialysate fluid and tap water are mixed in a system which includes a servo controlled pump. The servo controlled pump supplies concentrate to a mixer. The water and concentrate are mixed to form dialysate fluid having a controlled concentration. A conductivity cell monitors the concentration of the dialysate fluid and the resultant signal controls the pump. This permits the use of a relatively simple, compact, inexpensive pump in the system rather than more costly and bulky volumetric measuring devices.

Further in accordance with this invention, a secondary control loop is provided for the pump by a tachometer control. When the speed of the pump varies because of variations other than conductivity, line voltage, for example, the tachometer senses these changes in the pump speed and quickly restores the pump to its normal operating speed.

Accordingly, it is an important object of the present invention to provide a simple, easily maintained, inexpensive dialysate supply system.

It is another object of the present invention to provide a portable dialysate supply system which can be operated from a 110 volt, 15 ampere power supply and an ordinary cold water supply.

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

DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a diagram of the portable dialysate supply system; and

FIG. 2 shows a schematic diagram of the control loops for the concentrate pump.

DESCRIPTION OF A PARTICULAR EMBODIMENT

Referring now to FIG. 1, the block diagram shows the circulation of dialysate fluid and the electrical control functions performed by the system. In FIG. 1 the hydraulic conections are shown with heavy lines while the electrical connections are shown with lighter lines.

The dialysate fluid to be circulated in the dialyzer is a mixture of tap water from the source **34** and concentrate from the concentrate reservoir **15**. The composition of the dialysate fluid may be changed in accordance with the therapy required for a particular patient. In general, the composition of the dialysate fluid is described in "Hemodialysis for Chronic Renal Failure," Freeman, Maher and Schreiner, Annals of Internal Medicine, volume 62, No. 3, March 1965. The concentrate and tap water are

mixed in the proper proportions in the mixer **11**. Water from the source **34** passes through the pressure reducing valve **2** to the air trap and vent **3**. Overflow from the air trap and vent **3** goes to drain **35**.

A flow control valve **4** provides the desired flow and flow meter **5** monitors the flow of water. The water passes through the normally open solenoid valve **6**. During sterilization of the system the normally open valve **6** is closed and the manually operated by-pass valve **7** is preset to provide about one-fourth the flow of water which is heated to a much higher temperature. Automatic reduction of water flow during sterilization is an important feature resulting in reduction of heater size, cost, and power requirements.

The water is supplied to an electric heater **8** which produces water at the desired temperature, approximately 37° C. for normal dialysis and approximately 95° C. for sterilization. Thermistor sensing circuitry **9** is provided for controlling the heater **8**, that is, varying the electric current to obtain the desired heating. Thermistor circuitry **10** monitors the water temperature and actuates an alarm relay when the water temperature is outside of normal limits.

A controllable volume pump **13** supplies dialysate concentrate from the reservoir **15** through the check valve **12** to the mixer **11**.

The mixed water and concentrate passes through the concentration control element **18** on its way to the dialyzer. The concentration control element **18** is a conductivity cell which produces an electrical signal representing the concentration of the dialysate fluid supplied from the mixer **11**. The electrical signal produced by the conductivity cell is applied to the pump **13** to control the volume of concentrate supplied to the mixer **11** so that the concentration of the dialysate fluid remains constant. The control circuitry for this control loop is shown in block form in FIG. 2. A secondary speed control loop is provided for the pump **13**. This control loop includes a tachometer **33** driven at the same speed as the pump **13**. The tachometer **33** produces an electrical signal representing the speed of the pump and this is applied to maintain the speed of the pump constant regardless of variations other than conductivity changes.

Another conductivity cell **19** is provided for monitoring the conductivity of the dialysate fluid. The dialysate fluid is supplied to the constant head vessel **20**. The head vessel **20** has an overflow outlet **21** coupled through a drain cup **24** to the gravity drain **35**.

The head vessel **20** provides a supply of dialysate fluid at a constant pressure to the dialyzer. The dialysate fluid is supplied through pressure control valve **25** to the inlet dialysate port of the dialyzer which may be of the Kiil type, for example. In this type of dialyzer, blood ports are provided for passage of blood on one side of a membrane and dialysate ports are provided for passage of dialysate fluid on the other side of the membrane. The dialysate fluid passes through the dialyzer on one side of the membrane and out through the outlet dialysate port.

A pressure gauge **27** is provided to monitor the negative pressure at the outlet of the dialyzer. Flow meter **28** is provided to monitor the flow rate through the dialyzer and blood leak detector **29** is provided to sense the presence of blood in the dialysate fluid.

A vacuum breaker **30** is provided so that if the system becomes clogged, a large negative pressure which might break the membrane will not be applied to the dialyzer. The effluent pump **32** applies the negative pressure through check valve **31**, and regulates dialysate flow through the dialyzer.

All of the monitors are connected to shut off the effluent pump **32** and stop dialysate flow through the dialyzer when any of the monitored conditions exceed the preset limits. The temperature monitor thermistor circuit **10**, the conductivity monitor **19**, over-temperature sensor **23**, pressure gauge **27**, and blood leak detector **29** are all monitoring circuits of the type in which a set of relay contacts are activated when the monitored condition exceeds its adjustable preset limits. All of these relay contacts are connected in a circuit to control the 110 volt power for the effluent pump **32**. When any monitored condition exceeds its limits the relay contacts will be activated and power will be cut off to the pump **32**.

Also included in this control circuit is a level monitoring probe, **22**, of the conductivity type located in the head vessel. If dialysate make-up rate becomes less than the flow rate to the dialyzer, the level drop in the head vessel is sensed and the effluent pump **32** turned off.

In addition to, or in place of, the concentration monitor **19**, an Ag, AgCl detector may be provided. Such a detector would similarly be connected to monitor the chloride content of the dialysate fluid and turn off the pump **32** when the concentration is outside the desired limits. The silver, silver chloride detector could also be used in place of concentration control element **18** to control the pump **13**.

The system is electrically programmed to automatically proceed through the following steps; rinse, pre-sterilize, normalize, monitor test, alarm test, system test, dialyze, after-sterilize. The control system and monitors are interlocked to prevent the flow of anything other than normal dialysate to the dialyzer.

The system for controlling the pump **13** in accordance with the control signal from the concentration monitor can be of well known type. One suitable system is shown in block form in FIG. 2. The conductivity cell includes a sensor **36** for determining conductivity. Another sensor **37** which is temperature sensitive, provides temperature compensation for the conductivity cell **36**. The sensors **36** and **37** are connected in a bridge circuit **38**. Variations in the conductivity from a given setpoint produce an error signal which is amplified in amplifier **39**. The phase detector **40** senses the phase of the error signal which is an indication of whether the conductivity is above or below the setpoint. The error signal is compared with an adjustable setpoint in the setpoint control **41**.

The error signal from the setpoint control **41** is compared with the signal from tachometer **33** in the error comparator **42**. The resultant signal is amplified in error amplifier **43** and power amplifier **44** and is used to drive the servo motor **45**. As is conventional, there is feedback from the servo motor **45** to the error amplifier **43**. The servo motor **45** drives the concentrate pump **13** to provide the desired volume of concentrate to the mixing chamber **11**.

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 dialysate ports for passage of dialysate fluid through said dialyzer on the other side of said membrane,

a source of dialysate concentrate,

a mixer for mixing said water and said dialysate concentrate to produce dialysate fluid, said dialysate fluid being supplied from said mixer to said dialysate ports,

a controllable volume electrically driven pump connected to continuously supply dialysate concentrate from said source of concentrate to said mixer,

a conductivity cell continuously producing an electrical signal representing the concentration of the dialysate fluid supplied from said mixer to said dialysate ports,

means for applying said electrical signal to said pump to control the volume of concentrate supplied to said mixer so that the concentration of said dialysate fluid remains constant,

a tachometer driven at the same speed as said pump, said tachometer producing a tachometer signal representing the speed of said pump, and

means for applying said tachometer signal to maintain the speed of said pump constant.

2. The system recited in claim 1 further comprising:

an effluent pump for supplying said dialysate fluid from said mixer to said dialysate ports,

means for monitoring the conditions of the dialysate fluid, and

means responsive to said monitoring means for deenergizing said effluent pump when any monitored condition exceeds preset limits.

3. The system recited in claim 2 wherein said monitoring means includes:

a temperature monitor,

a conductivity monitor,

a pressure gauge, and

a blood leak detector, each having a set of relay contacts which are activated when the monitored condition exceeds preset limits, said relay contacts being connected in a circuit to control the application of power to said effluent pump.

4. 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 dialysate ports for passage of dialysate fluid through said dialyzer on the other side of said membrane,

a source of water,

a source of dialysate concentrate,

a mixer for mixing said water and said dialysate concentrate to produce dialysate fluid, said dialysate fluid being supplied from said mixer to said dialysate ports,

a controllable volume, constant speed, electrically driven pump connected to continuously supply dialysate concentrate from said source of concentrate to said mixer,

a conductivity cell continuously producing an electrical signal representing the concentration of the dialysate fluid supplied from said mixer to said dialysate ports,

a heater connected between said source of water and said mixer,

a normally open solenoid valve connected between said source of water and said heater from supplying a normal flow of water to said heater during dialysis, said normally open valve being closed during sterilization of said system,

a bypass around said normally open valve, and

a bypass valve in said bypass, said bypass valve being preset to provide about one-fourth said normal flow of water to said heater during sterilization so that said water is heated to a much higher temperature during sterilization.

References Cited

UNITED STATES PATENTS

3,352,779	11/1967	Austin et al.	210—23
3,406,826	10/1968	Willock	210—321 X
3,416,664	12/1968	Kumme et al.	210—103 X

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F. A. SPEAR, JR., Assistant Examiner

U.S. Cl. X.R.

210—96, 103, 321

PO-1050
(5/69)

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,508,656 Dated May 11, 1970

Inventor(s) EARL J. SERFASS and VERNON H. TROUTNER

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 2, line 16, change "top" to --tap--

Column 4, line 56, after "membrane," indent and insert --a source of water,--

SIGNED AND
SEALED
AUG 25 1970

(SEAL)
Attest:

Edward M. Fletcher, Jr.
Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents