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Alvine

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[54] **SELF-CONTAINER KIDNEY DIALYSIS APPARATUS**

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[52] **U.S. Cl.** **210/87,** 210/94, 210/186, 210/321

[51] **Int. Cl.** **B01d 13/00**

[58] **Field of Search** 210/321, 322

[56] **References Cited**

UNITED STATES PATENTS

3,441,136	4/1969	Serfass et al.	210/321 X
3,489,647	1/1970	Kolobow	210/22 X
3,515,275	6/1970	Bowman	210/22
3,598,727	8/1971	Willock	210/22
3,703,959	11/1972	Raymond	210/321 X
3,746,175	7/1973	Markley	210/321
3,754,649	8/1973	Palubniak et al.	210/321

OTHER PUBLICATIONS

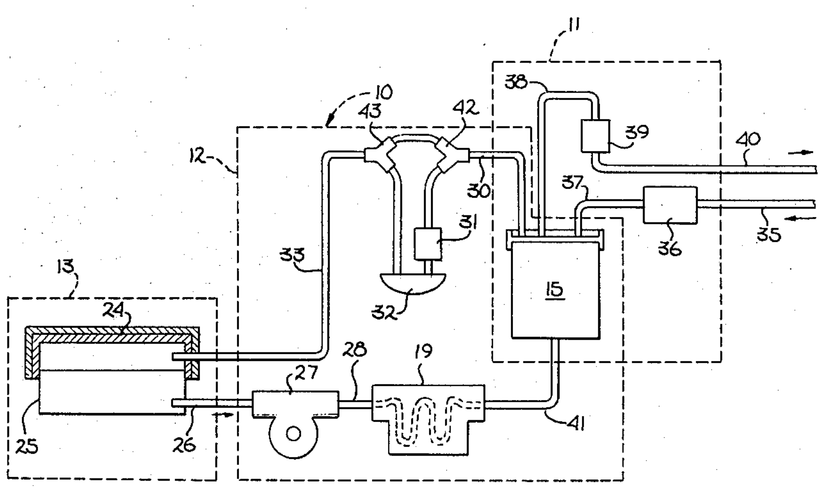
J. W. Eschbach, et al., "Unattended Overnight Home Hemodialysis," Article in Trans. Amer. Soc. Artif. Int. Organs, Vol. XII, 1966, pages 346–355.

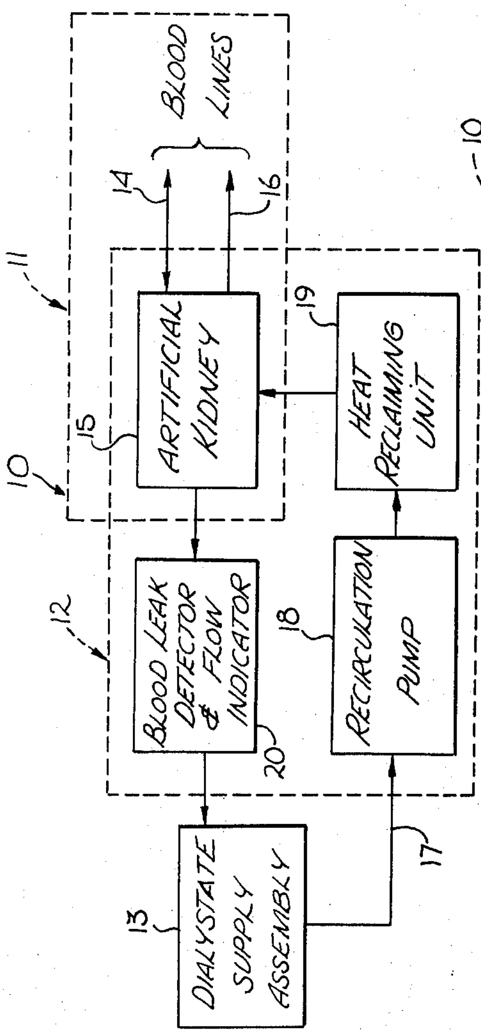
Primary Examiner—Roy Lake
Assistant Examiner—Paul A. Bell

[57] **ABSTRACT**

An improved kidney dialyzer. An improvement to kidney dialysis machines which provides for the portability of the apparatus. The improvement comprises a portable dialysate delivery system comprising a pump assembly flow section. The pump assembly flow section is made up of the artificial kidney, a heat reclaiming element and a recirculation pump for the dialysate passing therethrough. The pump assembly flow section is adapted to be connected to either a single pass dialysate proportioning system or a bath dialyzer reservoir cell. The pump used for recirculation of the dialysate solution is the source for the heat reclamation element, the recirculation pump being coupled to a clutch assembly used to control operation of a blood pump in the blood circulation system. The present invention is adapted to operate on any input voltage pursuant to a self-contained power transmission source.

16 Claims, 12 Drawing Figures

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ARTIFICIAL KIDNEY
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BLOOD LINES
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HEAT RECLAIMING UNIT
BLOOD LEAK DETECTOR & FLOW INDICATOR
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RECIRCULATION PUMP
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DIALYSTATE SUPPLY ASSEMBLY
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Fig. 1

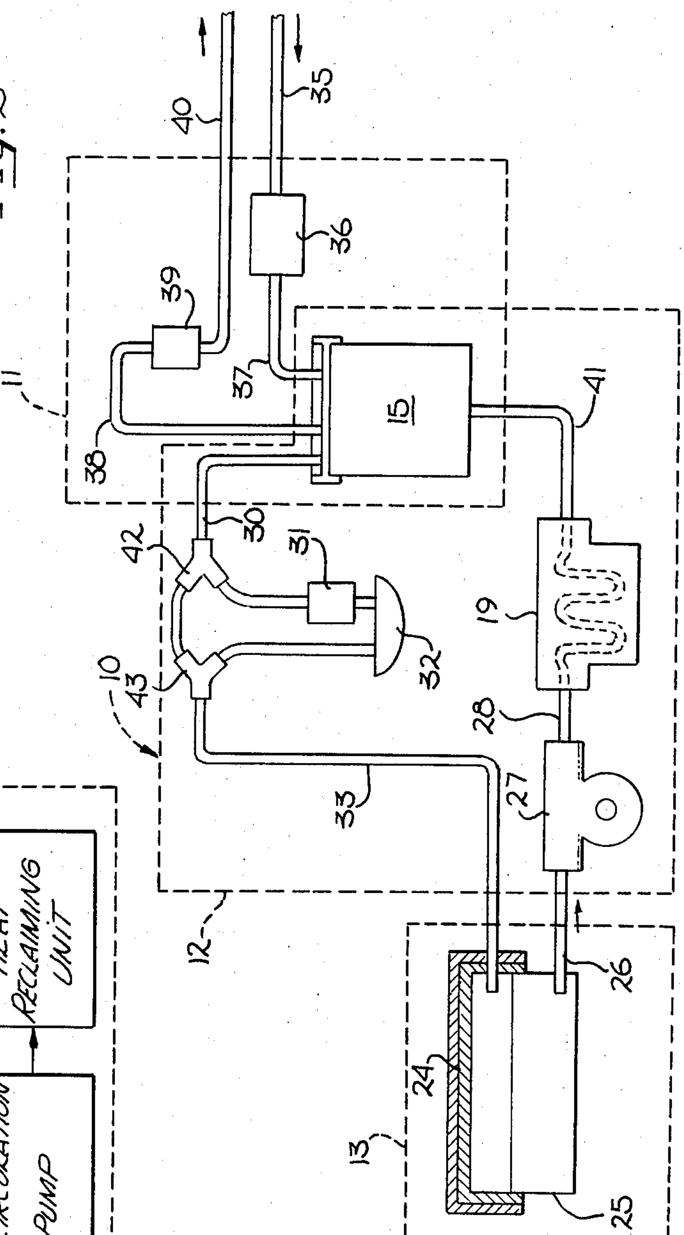
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Fig. 2

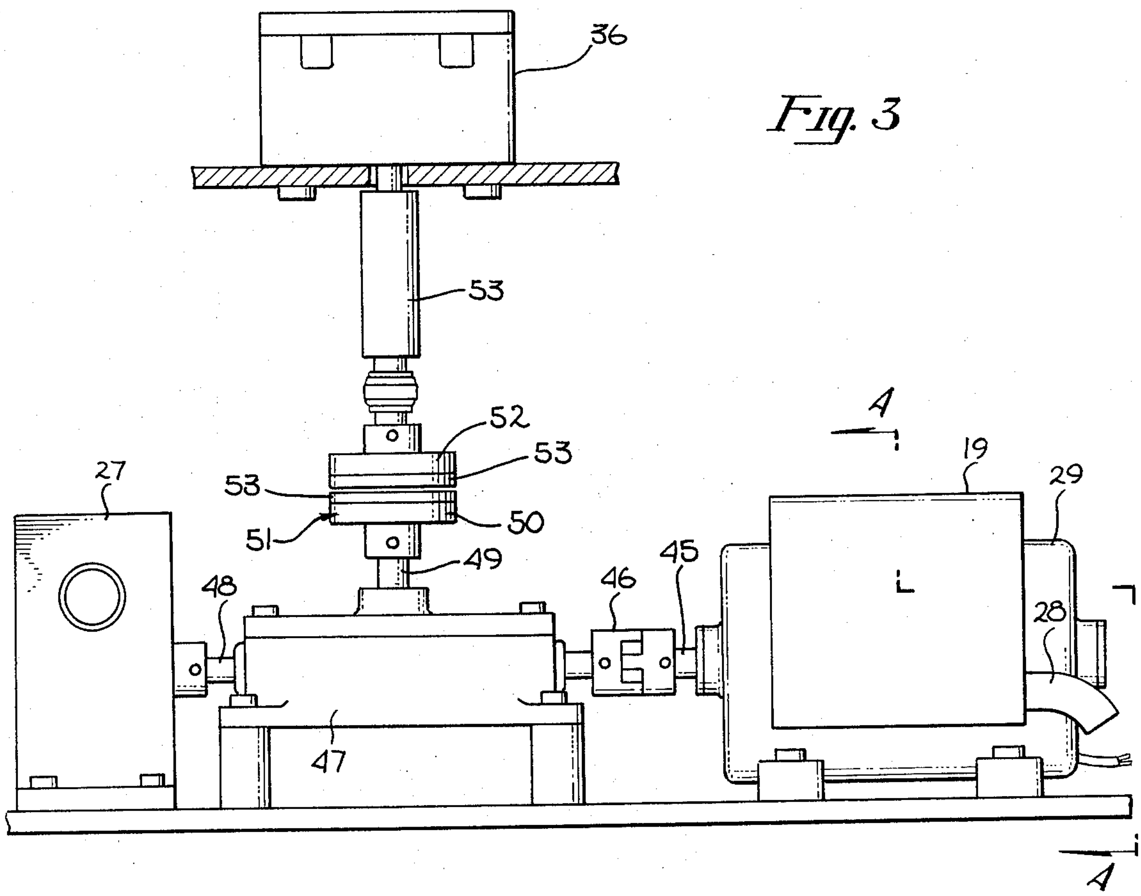
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Fig. 3

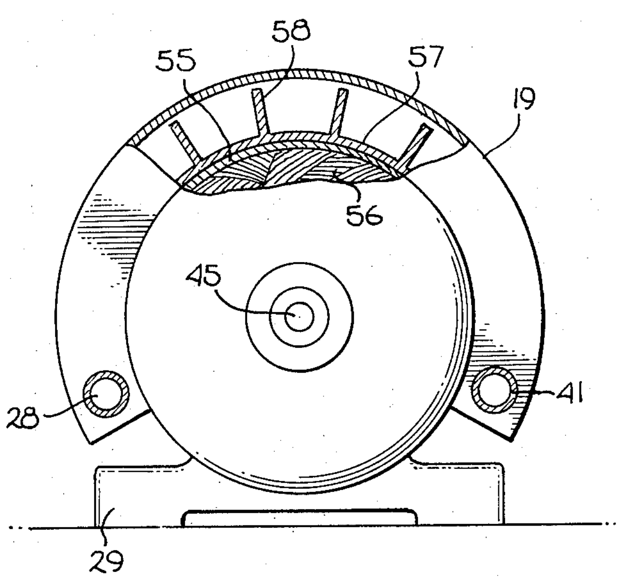
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Fig. 4

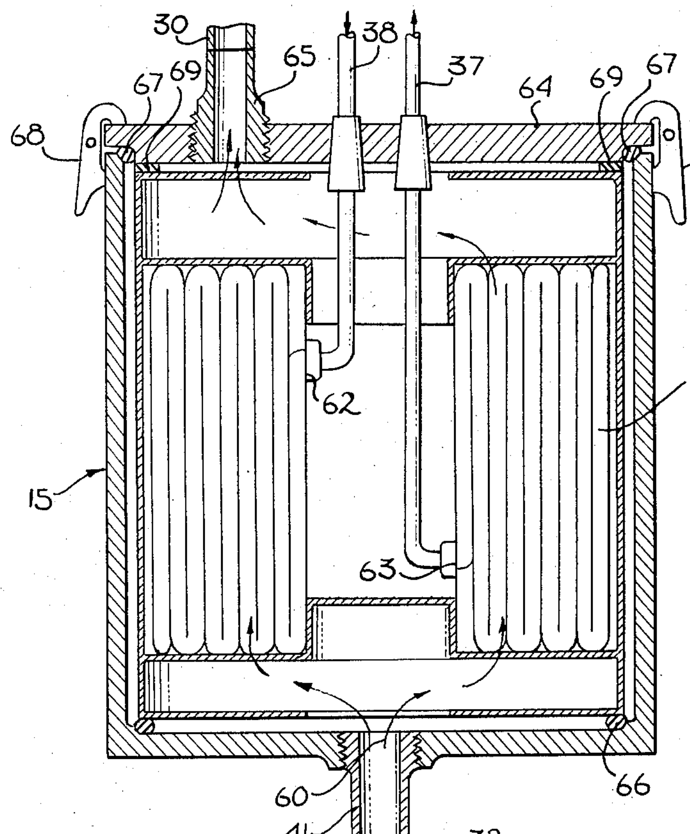
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Fig. 5

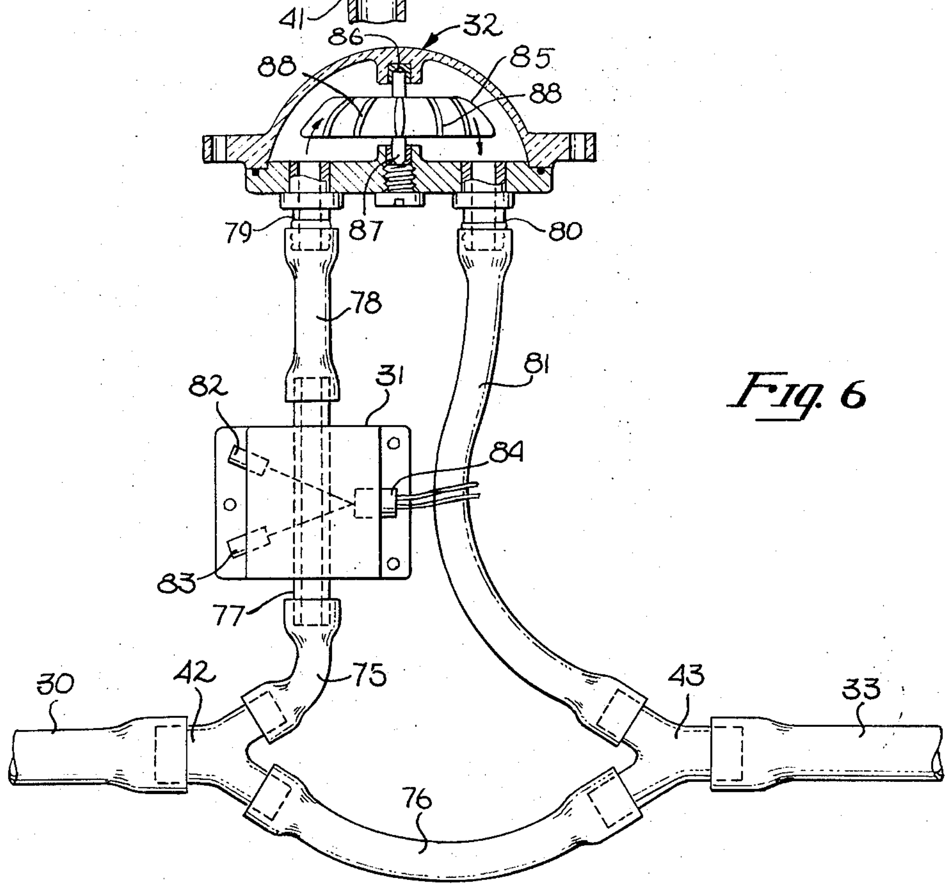
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Fig. 6

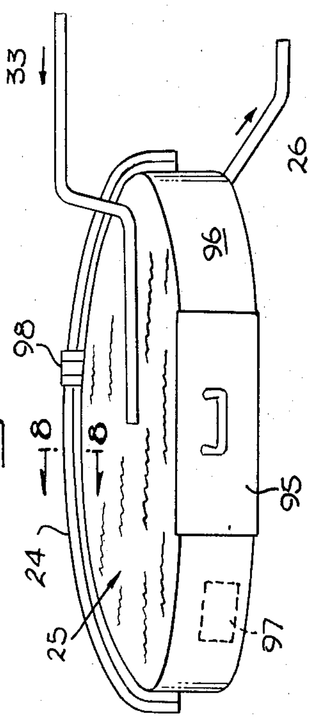


Fig. 7

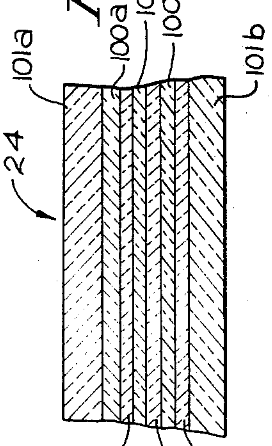


Fig. 8

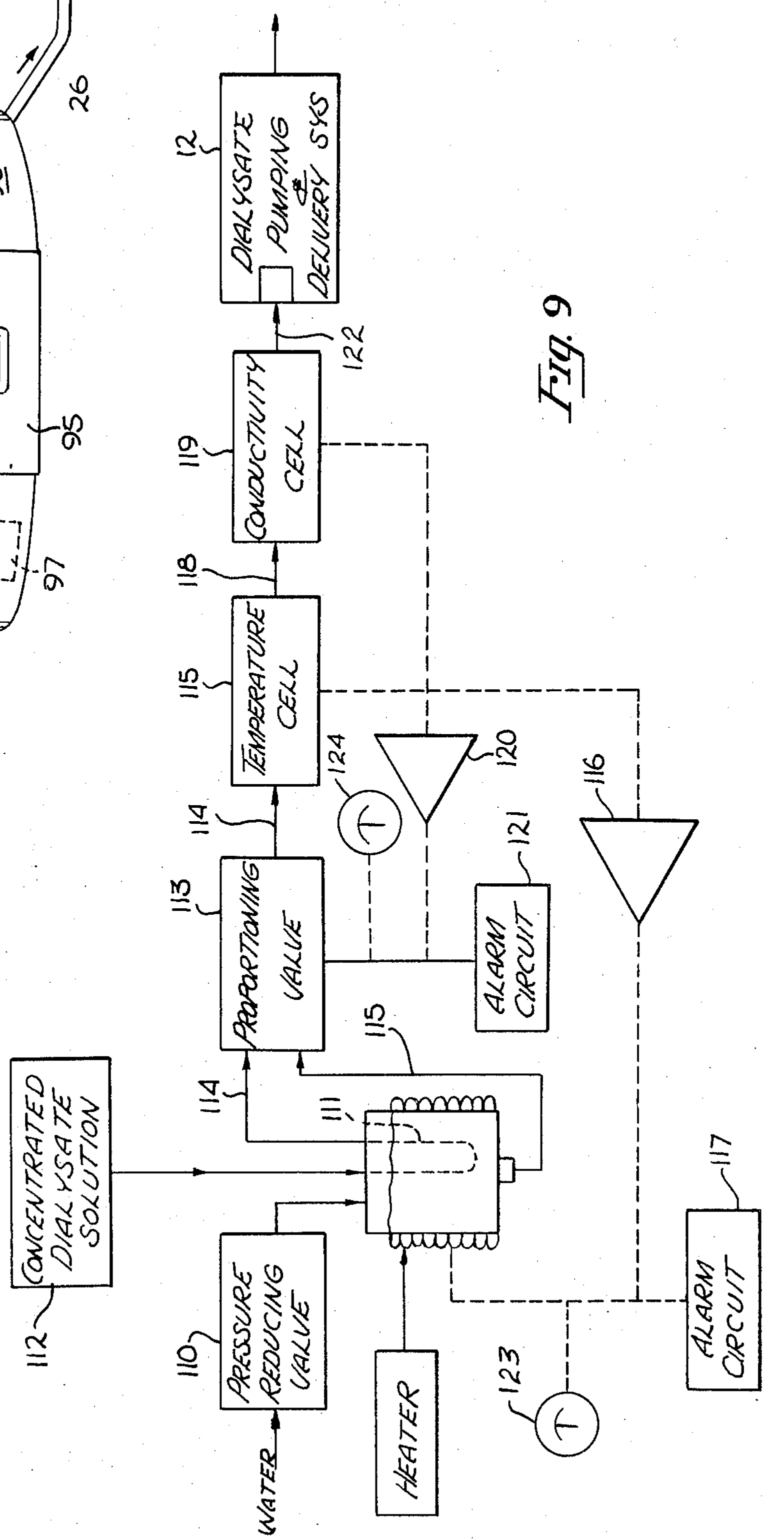


Fig. 9

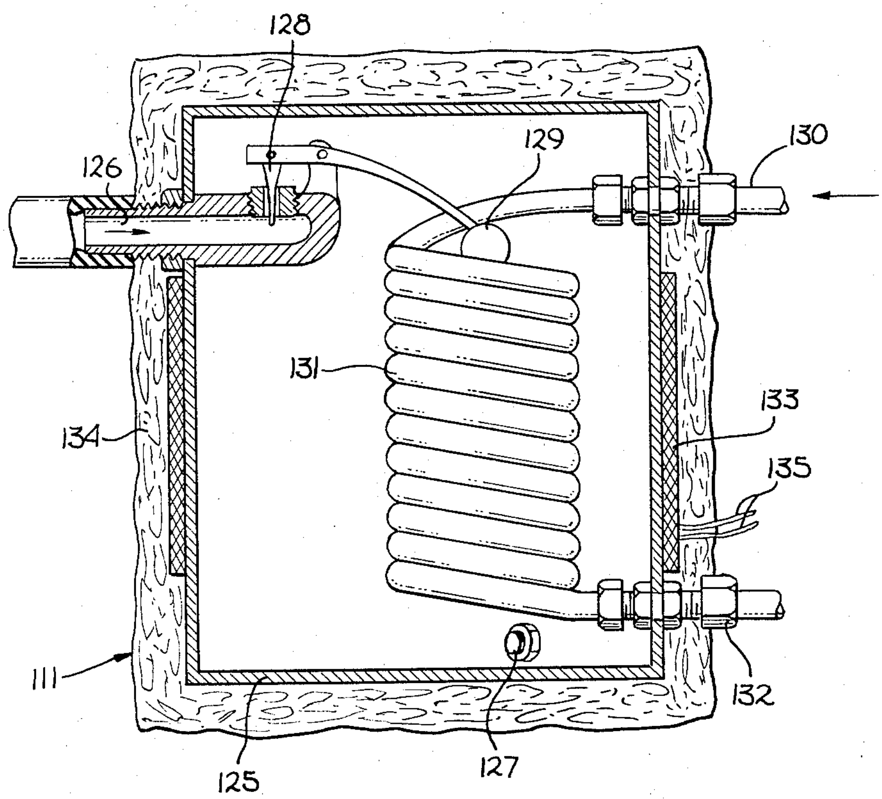


Fig. 10

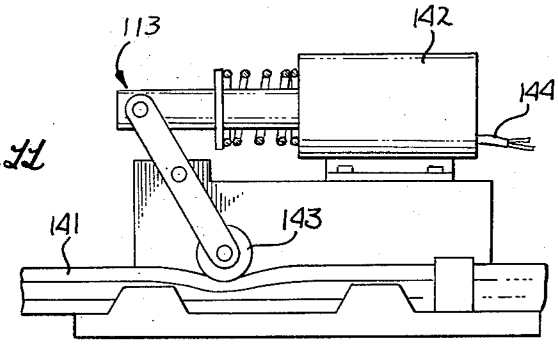
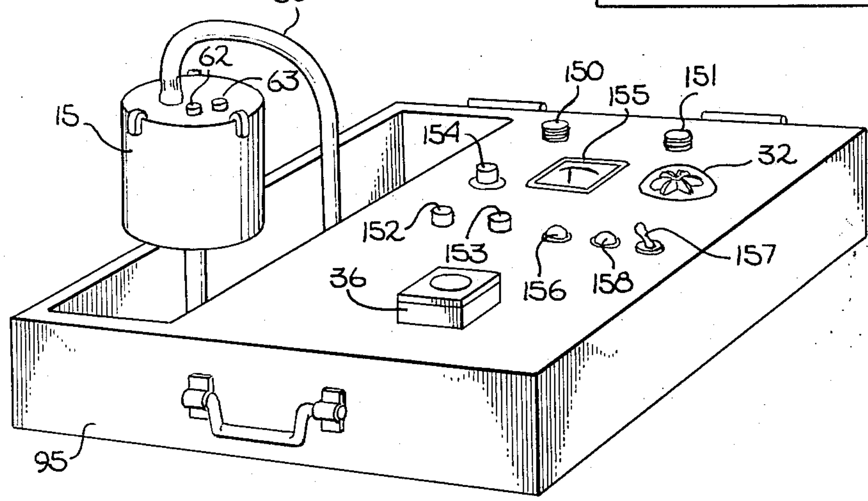


Fig. 11

Fig. 12



SELF-CONTAINER KIDNEY DIALYSIS APPARATUS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is generally related to kidney dialysis machines and, more particularly, to those dialysis machines having portable dialysate proportioning and delivery systems.

2. Prior Art

The increasing use of kidney dialysis equipment has placed great stress on the need to reduce the cost of such equipment as well as provide means whereby the equipment could be used in other than hospital surroundings. The portability of kidney dialysis equipment is a difficult problem which has heretofore not been effectively solved by the devices disclosed in the prior art. One of the primary problems encountered by the prior art devices is the development of a dialysate delivery system which can be constructed in an effective, portable manner.

The process of dialysis is generally considered the process of separating compounds or materials by the difference in their rates of diffusion through a colloidal semipermeable membrane. The kidney is the human body's major organ of the excretorory system. The main functions of the kidney are to eliminate waste products, toxic materials and basic and nonvolatile acid radicals; the maintenance of a constant volume of circulating blood and the regulation of the fluid content of the body as a whole; the regulation of osmotic pressure relationships of blood and tissues; and the maintenance of the optimum concentration of certain individual constituents of the plasma. Portions of the kidney act as a filtration mechanism reabsorbing almost completely substances like sugar, chloride, sodium and bicarbonate, which are necessary to the body economy, and excreting waste substances like urea, creatinine, ammonium, phosphates, sulfates and uric acid.

As blood passes through the kidney, it is filtered by hundreds of thousands of microscopic units called nephrons. When the kidneys are in a state which precludes them from properly filtering unwanted substances from the blood, dialysis is required. The filtering process within each nephron is not an organic process, but is essentially a mechanical process, thereby making it possible to utilize an artificial kidney.

The complete process of dialysis in artificial kidneys is beyond the scope of the present application, but it is believed that a brief description is necessary to fully understand the impact of the present invention. The central feature of all dialysis equipment is the membrane through which the waste products migrate from the patient's blood to the dialyzing fluid. The diameter of the membrane pores are extremely small, the membrane passing water and small-molecule waste products. The large-molecule blood proteins do not migrate through the membrane. Although the blood contains many small-molecule substances which are not waste products, e.g., glucose and salts of sodium, a proper balance is maintained by making the concentration of the substances in the dialyzing fluid the same as is present in the patient's blood.

Dialysis equipment shall generally be considered to be comprised of two subsystems, one constituting the blood circuit, the second constituting the dialysate delivery system. The interface of these two system is at an artificial kidney which iw well-known in the piror art, the present invention being directed to an improved dialysate delivery system possessing the ability to function as both a bath dialyzer or a single-pass, proportioning dialyzer.

One of the devices disclosed by the prior art utilizes a separate source of water and concentrate. The proportion of dialysate concentrate and water depends upon the particular dialysate being used, proportions being typically in the range of 25–35 parts of water to one part of dialysate concentrate. In the prior art system, the water is first heated to a temperature of approximately 37° C after which it passes through an air removal system. Where the proportioning and delivery system is to service a number of dialysis stations, the amount of water to be used must be regulated. In order to mix the water and concentrate, the concentrate and water are brought together at a mixing point which is generally located on the top of a bubble chamber. After mixing the concentrate and water, the mixture must pass through a temperature controlled point to insure that the dialysate temperature does not exceed 42° C. In addition, the dialysate must pass an electrical conductivity probe to assure that a required amount of electrical current will be conducted through the solution. The electrical conductivity of the solution is a function of the dialysate concentrate to water proportions. As can be seen, this device requires a substantial amount of hardware to proportion and deliver the mixed and heated dialysate solution. Since fixed sources of water and concentrate are required, and since this is typically the type of system which is used for multiple patient delivery, it is not adaptable for portability and therefore cannot meet some of the objectives of the present invention.

Other devices disclosed by the prior art utilize diaphragm pumps with adjustable displacements or piston pumps with different size pistons to proportion the mix of concentrate and water. Where a diaphragm pump is used, the rupture of the diaphragm or the seal will destroy the effectiveness of the proportioning and delivery system since the mixture will be at the least defective, and possibly dangerous if the conductivity measuring apparatus is out of calibration. In addition, where mechanical pumps are used in general, they can gradually drift away from their nominal mix ratio. In the event a poorly trained operator is operating the equipment, he may actually attribute the drift to the conductivity monitoring apparatus and may keep resetting this apparatus without independently checking the system. Even where differential pumps are used, the prior art devices are still subject to the same type of problems which are sought to be overcome by the present invention.

The present invention provides improved kidney dialyzer apparatus by utilizing a dialysate pump assembly which is portable and which can be alternately used with a single-pass dialysate proportioning and delivery system as well as a self-contained reservoir cell. To provide proper heating of the dialysate solution, a recirculation pump is utilized in a manner which permits the heat dissipated from the pump driving apparatus to provide energy for heating the solution. In addition, the mechanical drive of the recirculation pump is utilized to control other pumps within the blood circuit of the total apparatus to insure safety of operation. To complete the portability of the present system, the power source means utilized to drive the present system can adapt any commercial power source level to the requirements of the electrical components used within the present invention apparatus.

SUMMARY OF THE INVENTION

The present invention comprises improved kidney dialysis apparatus and, in particular, an improved delivery system used therein. A self-contained bath dialyzer reservoir cell is provided to supply a source of dialysate for the dialysis process. The reservoir cell constitutes a non-rigid container within which is an internal container for holding the dialysate concentrate. The reservoir cell is adapted to be filled with a fixed volume of water with which to make the dialysate solution. The dialysate solution is coupled to a recirculation pumping means, a portion thereof being adapted to be a source of heat transfer to the dialysate solution to compensate for any heat loss which may occur as a result of environmental conditions. The heated dialysate solution is then coupled to the artificial kidney apparatus and again returned to the reservoir cell. To minimize heat loss from the reservoir cell, a multilayer insulating member is utilized at the surface thereof in a manner which will not detract from the total portability of the present invention.

The recirculation pump and blood pump utilized within the total system operate from a direct current motor which utilizes the output of the power source transmission element. Lastly, the mechanical coupling of the recirculation pump is used as a saftey factor to shut down any pumps in the blood circuit in the event any abnormality may be detected such as a blood leak, or conductivity malfunction.

It is therefore an object of the present invention to provide an improved kidney dialysis apparatus.

It is another object of the present invention to provide kidney dialysis apparatus which is portable.

It is still another object of the present invention to provide an improved kidney dialysis device utilizing a self-contained recirculating source of dialysate solution or a single-pass dialysate proportioning system.

It is yet another object of the present invention to provide an improved kidney dialysate apparatus which is economical to fabricate.

The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objectives and advantages thereof, will be better understood from the following description considered in connection with the accompanying drawing in which a presently preferred embodiment of the invention is illustrated by way of example. It is to be expressly understood, however, that the drawing is for the purpose of illustration and description only and is not intended as a definition of the limits of the invention.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a schematic diagram in block form of the major components of a kidney dialyzer in accordance with the present invention.

FIG. 2 is a schematic view of a form of kidney dialyzer utilizing a reservoir delivery system in accordance with the present invention.

FIG. 3 is a schematic diagram of the mechanical coupling between the heat reclaiming element, recirculating pump and blood pump shown in FIG. 2.

FIG. 4 is a schematic, partial cross-sectional view of an embodiment of a combined recirculation pump and heat reclaiming unit for use in the form of the present invention shown in FIG. 2.

FIG. 5 is a schematic, partial cross-sectional view of a form of a kidney coil holder for use with the form of the present invention shown in FIG. 2.

FIG. 6 is an enlarged, partial cross-sectional view of the blood leak detector and flow indicator used with the form of the present invention shown in FIG. 2.

FIG. 7 is an enlarged, side elevation view of the dialysate reservoir element of FIG. 2.

FIG. 8 is a cross-sectional view of the insulating blanket of FIG. 7 taken through line 8—8 of FIG. 7.

FIG. 9 illustrates another form of a kidney dialysis machine in accordance with the present invention.

FIG. 10 is a partial, cross-sectional view of a pressure reducing and heating canister used with the form of the present invention shown in FIG. 9.

FIG. 11 is a dialysate metering valve for use with the form of the present invention shown in FIG. 9.

FIG. 12 is a front perspective view of one-half of a portable dialysis assembly in accordance with the present invention.

DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

An understanding of the present invention improvement for kidney dialysis apparatus can be best gained by reference to FIG. 1 where schematic view of a kidney dialysis unit in accordance with the present invention is shown, the kidney dialysis unit being generally designated by the reference numeral **10.** Kidney dialysis unit **10** is basically comprises of three subsystems, blood circuit system **11**, dialysate pumping and delivery system **12** and a dialysate supply assembly **13.** Blood circuit system **11**, schematically shown in FIG. 1, can be a conventional unit used with standard kidney dialysis equipment, and except as specifically stated, is not a part of the present invention. The arterial blood inlet **14** from the patient is coupled to a blood pump which in turn is coupled to the artificial kidney or dialyzer unit **15.** The output from dialyzel unit **15** is coupled to a conventional bubble trap via tubes, the output from the bubble trap being connected to venous outlet **16** which is coupled to the patient. The above description of blood circuit system **11** has been for the purpose of providing a general description of conventional portions of kidney dialysis equipment, there being no attempt to include such elements as saline priming supplies or other chemical input and output sources for controlling blood pressure, prevent clotting or other like functions. Other than the mechanical control of the blood pump **36** (FIG. 3) and kidney unit **15** as will be described hereinbelow, the remaining elements of blood circuit system **11** are considered as conventional and are not considered as part of the present invention.

Dialysate pumping and delivery system **12** is constructed to provide portability of the total sytem. In addition, dialysate pumping and delivery system **12** will cooperatively engage a dialysate supply assembly **13** constructd as a single pass proportioning system or for use of a concentrate reservoir system as will be described hereinbelow. Dialysate pumping and deliver system **12** receives the dialysate supply via lines **17** from dialysate supply assembly **13.** The inlet of the dialysate is to recirculation pump 18 to provide a motive force for the dialysate solution. To maintain the dialysate solution at an appropriate temperature, heat reclaiming unit 19 provides for sufficient transfer of heat to the dialysate solution to maintain the dialysate solution at an appropriate temperature of approximately 37° C.

As can be seen from FIG. 1, blood circuit 11 and dialysate pumping and delivery system 12 overlap at artificial kidney 15. As will be explained hereinbelow, artificial kidney 15 provides the interface for the dialysate solution and the patients blood supply to carry out the dialysis process. The dialysate solution passes from heat reclaiming unit 19 through artificial kidney 15 to blood leak detector and flow indicator 20. The details of the designated elements of FIG. 1 as well as the preferred interface therebetween will be explained in detail hereinbelow.

An understanding of a form of the present invention utilizing a dialysate reservoir can be best gained by reference to FIG. 2. Improvements in the efficiency and operation of conventional kidney dialysis equipment is substantially brought about by the coupling of dialysate pumping and delivery system 12 and a bath dialyzer reservoir cell 25 as shown in FIG. 2. Bath dialyzer reservoir cell 25 is a nonrigid structure typically fabricated of plastic and having the general geometrical shape of a bag or other like container. Internal to the outer wall structure of bath dialyzer reservoir cell 25 is a smaller container for holding the dialysate concentrate solution, the container for the concentrate solution to be discussed hereinbelow. The dimensions of dialysate concentrate and bath dialyzer reservoir cell 25 are such that when filled with the bath solution, the volume is approximately 120 liters, the salt concentration being appropriate to the individual requirements. Dialysate concentrate and reservoir cell 25 should have sufficient excess volume to provide for accepting approximately 1 gallon of excess fluid. The excess fluid will typically be withdrawn from the patient's blood supply during the dialysis process and must be stored in bath dialyzer reservoir cell 25.

Output tube 26 is connected from bath dialyzer reservoir cell 25 to the input of recirculation pump 27, tube extension 28 being thermally coupled to heat reclaiming unit 19 of power source 29 being used to drive recirculation pump 27. Power source 29 is typically a direct current motor having field windings which dissipate a substantial amount of heat. The mechanical coupling between the direct current motor 29 and recirculation pump 27 will be discussed in detail below. By thermally coupling output tube 28 and the field windings of motor 29 driving recirculation pump 27, the heat dissipated from the field windings from motor 29 can be used by heat conduction or heat convection to raise the temperature of the dialysate solution to the proper temperature. A proper temperature for a dialysate solution is approximately 37° C and is typically monitored by a suitable temperature gauge which can be disposed at the input to kidney coil holder 15. Since the heat being dissipated from the field windings of motor 29 driving recirculation pump 27 is used to maintain the dialysate solution at an appropriate temperature, a by-pass valve is typically coupled across the field windings. The manner of construction heat reclaiming unit 19 through the use of the field windings of motor 29 will be explained in greater detail hereinbelow.

As mentioned previously, the dialysis process is carried out in an artificial kidney disposed within kidney coil holder 15. Pursuant to the dialysis process, small-molecule waste products are forced through the membrane of the artificial kidney into the dialysis solution. The full details of the operation of an artificial kidney is beyond the scope of the present invention, the dialysis process itself being well known to persons having skill in the art.

The output of artificial kidney 15 within dialysate pumping and delivery system 12 is via tube 30. The dialysate solution passes through blood leak detector 31 and flow indicator 32, the dialysate solution returning to bath dialyzer reservoir cell 25 via tube 33. As will be explained in detail hereinbelow, one of the elements of the present invention utilized to maintain the appropriate temperature of the dialysate solution while in the reservoir cell is insulating blanket 24.

The remaining portion of kidney dialysis unit 10 as shown in FIG. 2 is the completion of blood circuit system 11. The inlet of the blood supply from the patient is via inlet tube 35, the blood supply passing through blood pump 36. Blood pump 35 maintains a positive pressure differential of approximately 50 millimeters of mercury over that in dialysate pumping and delivery system 12. The positive pressure differential insures maintenance of the sterility of the blood supply in the event that a blood lead occurs in the membrane of artificial kidney 15. The output of blood pump 36 enters artificial kidney 15 via tube 37. The outlet of the blood circuit system 11 from artificial kidney 15 is at tube 38, tube 38 passing the blood through conventional bubble trap 39. The output of bubble trap 39 is connected to venous outlet 40 which is coupled to the patient.

The mechanical coupling between recirculation pump 27, heat reclaiming unit 19 and blood pump 36 can be best seen by reference to FIG. 3. The elements of the present invention shown in FIG. 3 comprise pertinent portions of the dialysate pumping and delivery system 12 shown in FIG. 2. The primary objective of the coupled members 27, 29, 36 and 47 shown in FIG. 3 is to provide motive power for circulating the dialysate solution and blood through artificial kidney 15 (FIG. 2). Primary power source 29 supplies the motive power for recirculation pump 27 and blood pump 36 and is typically a conventional fractional horsepower, direct-current motor. DC motor 29 is a conventional unit being well known to persons having skill in the art. Upon supplying DC power to motor 29, shaft 45 of motor 29 will rotate to supply the primary rotational power to recirculation pump 27 and blood pump 36. Shaft 45 is coupled by conventional shaft coupling 46 through a speed reducing gear 47 to rotating shafts 48 and 49. Shaft 48 is coupled to recirculation pump 27 with shaft 49 being coupled to blood pump 36.

Since the pressure of blood circuit 11 is to be greater than the pressure of the dialysate solution passing through dialysate pumping and delivery system 12, the rotational power supplied at shafts 48 and 49 can be adjusted accordingly. The output pressure and flow rate of recirculation pump 27 and blood pump 36 are approximately proportional to the voltage applied to DC motor 29. The pressure of dialysate solution at the outlet of recirculation pump 27 should be approximately 250 millimeters of mercury at a flow rate of approximately 1.5 gallons per minute. As stated previously, the blood pressure of the blood supply through blood circuit 11 must be approximately 50 millimeters of mercury higher than the dialysate solution pressure and therefore the output of blood pump 36 can be properly adjusted by the gear ratio of speed reducing gear 47 and therefore the rotational output at shaft 49.

The speed reduction ratio is also the torque multiplication ratio, therefore, the torque available at the input to blood pump 36 should exceed any loads to be driven by blood pump 36. Shaft 49 is coupled to driving element 50 of clutch 51. Driven element 52 of clutch 51 is in axial alignment with and engages driving element 50 to transfer the rotational power of shaft 49. The engaging medium 53 on driving and driven elements 50 and 52 of clutch 51 can be conventional material. A form of the present invention utilizes a plastic fiber material such as stiff bristles to implement engaging medium 53. When engaged, bristles 53 on driving and driven elements 50 and 52 will mesh together providing the transfer of torque from driving element 50 to driven element 52. Although the scope of the present invention is broad enough to use conventional frictional couplings typically used with clutch engaging elements, the fibrous bristle material is preferred since the torque transmitted will be independent of the force applied to maintain contact between the clutch members 50 and 52. In addition, the fibrous medium will allow for slight axial misregistration between shaft 49 and shaft 53 of blood pump 36.

The manner of implementing heat reclaiming unit 19 through the use of DC motor 29 can be best seen in FIG. 3 and FIG. 4. Durect current motor 29 is a conventional direct-current motor having a rotational output at shaft 45. As can be seen from the partial, cross-sectional view shown in FIG. 4, heat reclaiming chamber 19 is coupled to the exterior wall 55 of direct-current motor 29 adjacent field windings 56 thereof. The temperature of field windings 56 will increase during operation of motor 29, the heat being dissipated through exterior wall 55 into heat reclaiming chamber 19. Heat reclaiming chamber 19 has inlet tube 28 and output tube 41 through which dialysate solution will enter and exit heat reclaiming chamber 19. The outer wall of heat reclaiming chamber 19 is typically a thin-walled stainless steel enclosure concentric with exterior wall 55 of motor 29. The inner wall 57 of heat reclaiming chamber 19 comprises spaced, radially projecting fins 58 extending intersticial to the remainder of wall 57. Inner wall 57 is curved to cooperatively engage the outer surface of exterior wall 55 of motor 29. Thermal engagement between walls 55 and 57 is improved by disposing a layer of a silicone thermal conductivity compound intermediate walls 55 and 57. The silicone thermal conductivity compound will fill any voids between the two walls 55 and 57 providing for a substantially uniform heat transfer surface.

Inlet 28 to and outlet 41 from heat reclaiming chamber 19 are disposed on opposite sides of chamber 19 to provide for maximum flow of the dialysate solution across the heat dissipating fins 58 and wall 57 of chamber 19. The thermal energy dissipated at wall 57 and the fins 58 will provide a heat source to maintain the temperature of the dialysate solution at an appropriate temperature.

As shown in FIG. 2, the output of the dialysate solution from heat reclaiming unit 19 is via tube 41 and is directed to the inlet of kidney coil holder 15. Referring now to FIG. 5, an enlarged, partial cross-sectional view of a typical artificial kidney for use with the present invention is shown. Kidney coil holder 15 is a sealed cylinder having inlet 60 at the bottom thereof coupled to tube 41 supplying dialysate solution from heat reclaiming unit 19. Kidney coil 61 is disposed within the interior cavity of kidney coil holder 15, kidney coil holder 61 having input line 62 and output line 63 for the input and output of the blood supply respectively. Blood inlet 62 is coupled to tube 38 through the sealed cover 64 of kidney coil holder 15. In a like manner, outlet 63 of kidney coil 61 is coupled to tube 37 through top enclosure 64. The operation of kidney coil 61 is well known to persons having skill in the art. As described hereinabove, the filtration of waste matter from the human kidney is a mechanical process which can be duplicated by kidney coil 61. Dialysate solution entering through inlet 60 is disposed adjacent kidney coil 61, the dialysate solution being separated by the artificial membrane formed by kidney coil 61. The dialysate solution exiting at outlet 65 has been subjected to the dialysis process.

The construction of kidney coil holder 15 insures proper operation of the dialysis process. The cylindrical interior of kidney coil holder 15 is provided with O-ring 66 to insure that dialysate solution entering at inlet 60 will not flow around the outer surface of kidney coil 61. In addition, the blood lines connected to inlet 62 and outlet 63 are fitted with elastomeric seals which are molded to the blood line. A second O-ring 67 is disposed intermediate the holding chamber and cover 64 of kidney coil holder 15. Cover 64 is secured by conventional clamps 68. To insure proper registration of kidney coil 61, resilient pads 69 are disposed intermediate the lower surface of cover 64 and the top of kidney coil 61. The pressure exerted on resilient pads 69 will insure a forced fit between kidney coil 61 and O-ring 66.

The output of dialyzer unit 15 to the dialysate pumping and delivery system 12 is via tube 30 which is coupled to shunt tube 42 which directs the dialysate solution constructed blood leak detector 31 and flow indicator 32. As mentioned previously, the process of dialysis constitutes the separation of mediums through a colloidal semipermeable membrane. In this case, the process of dialysis takes place at dialyzer unit 15. Under suitable operating conditions, no portion of blood passing through blood circuit system 11 should be detectable in the flow of dialysate solution from dialyzer unit 15 to dialysate pumping and delivery system 12. As will be discussed in detail below, the detection of blood by blood leak detector 31 will signal a malfuction and shut down operation of blood pump 36 to thereby safeguard the patient.

Referring now to FIG. 6, an enlarged, schematic view of the blood leak detector and flow indicator 20 (FIG. 1) can be best seen. As shown in FIG. 2, the dialysate solution being output from dialyzer unit 15 via tube 30 enters shunt tube 42 which deflects a portion of dialysate solution through tube 75. The remainder of the dialysate solution entering shunt 42 passes through tube 76 and exits at shunt 43 to enter tube 33 and regain entry to dialysate supply assembly 13. The portion of dialysate solution entering tube **75** enters blood leak detector **31** and flow indicator **32**.

Blood leak detector **31** is used to detect the presence of blood in the dialysate solution. As mentioned previously, the artificial kidney present in kidney coil holder **15** is to provide for a dialysate process whereby only waste products are filtered through the membrane of the artificial kidney. In the event a leak occurs whereby blood is passed through the membrane, blood leak detector **31** is to immediately determine the presence of blood in the dialysate solution and shut down blood pump **36**. Referring again to FIG. **6**, tube **75** is coupled to an optically clear member **77** through which the dialysate solution can be optically observed. Member **77** is coupled to tube **78** which is in turn coupled to inlets **79** of flow indicator **32**. Outlet **80** of flow indicator **32** is coupled to tube **81** which is in turn coupled to shunt **43**.

A pair of light sources **82** and **83** and a photodetector **84** are in a planar relationship with each other, the output light from light sources **82** and **83** impinging upon the interior cavity of member **77**. Light source **82** is typically a source of light having a red wave length, the light emitted from light source **83** typically emitting light having a green wave length. The light emitted from light sources **82** and **83** pass through the dialysate solution in cavity **77**, and are detected at photodetector **84**. Under normal conditions, the dialysate solution is clear and uncolored. The energy of the red and green light sources and their respective responses at the photodetector **84** are equal. The two light beams are approximately 180° out of time phase. The response of the photodetector **84** will typically produce a direct-current output from the photodetector **84** which indicates normal operation. When blood is detected in the dialysate solution, the response of photodetector **84** to the beams from light sources **82** and **83** will be unequal producing an alternating current signal. The output of an alternating current signal from photodetector **84** is used to shut down the operation of blood pump **36**. This can typically be mechanically carried out by separating the bushing intermediate the axially opposed shaft **53** of blood pump **36** and the driven friction element **52** of clutch **51**. The blood detector **31** described hereinabove is only typical of conventional blood detection apparatus which could be utilized by the present invention.

Flow indicator **32** being typically fabricated of an optically transparent material provides visual indication that the flow of dialysate solution through dialysate pumping and delivery system **12** has not been interrupted. Flow indicator **32** contains an internal sealed cavity communicating with inlet **79** and outlet **80**. Vaned member **85** is rotatably mounted at pivots **86** and **87** and is adapted to rotate when vanes **88** are cooperatively engaged by the dialysate solution entering at inlet **79**. Dialysate solution flowing through flow indicator **32** will cause rotating member **85** to rotate, the speed of rotation being proportional to the flow rate of the dialysate solution.

Referring to FIG. **7**, a more detailed view of bath dialyzer reservoir cell **25** can be seen. Bath dialyzer reservoir cell **25** is a nonrigid structure which is typically fabricated from a flexible plastic material such as polyethylene or polyvinyl chloride having a typical thickness of 2 mils (0.002 inch). The flexibility of reservoir cell **25** is required to allow the elements of the present invention to be transported in a simplified manner. Bath dialyzer reservoir cell **25** is adapted to be received and be held within one-half of carrying structure **95**. Carrying structure **95** is fabricated substantially in the form of a suitcase. The remaining half of carrying structure **95** holds the elements of blood circuit **11** and dialysate pumping and delivery system **12** and will be described in detail hereinbelow. The purpose for carrying structure **95** is to prevent reservoir cell **25** from moving about during a dialysis operation by providing rigid sidewalls for securing bath dialyzer reservoir cell **25**. As stated, dialysate concentrate and bath dialyzer reservoir cell **25** is a nonrigid structure and is of sufficient size to hold approximately 120 liters of dialysate solution **96** therein. Dialysate solution **96** is comprised of water and dispersed dialysate concentrate. As is schematically depicted in FIG. **7**, bath dialyzer reservoir cell **25** has contained internally therein a closed and breakable dialysate concentrate container **97** which holds the appropriate amount of dialysate concentrate to be mixed with water to produce the desired proportion of dialysate solution **96**. As an example, a typical dialysate solution is in the proportion of 34 parts water to one part dialysate concentrate. Bath dialyzer reservoir cell **25** has a pair of input and output tubes **33** and **26** respectively which have been described heretofore in connection with FIG. **2**. Diluted dialysate solution **96** is recirculated through the system, the diluted dialysate solution **96** exiting at output tube **26** and being recirculated back through input tube **33**. Water and dialysate container **97** are entered into or purged from the interior cavity of bath dialyzer reservoir cell **25** at opening **98** in reservoir **25**.

As mentioned previously, when using a recirculating reservoir of dialysate solution **96** as shown in FIG. **7**, care must be taken to insure that the solution is maintained at a proper temperature. When conducting kidney dialysis operations, the solution should be maintained at approximately 37° C. Since this is the normal temperature for the human body, it is possible that energy will be lost or otherwise radiated to the atmosphere thereby causing the dialysate solution **96** to drop in temperature. As previously discussed, the heat generated by the field windings **56** of motor **29** employed to power recirculation pump **27** is used to maintain the appropriate temperature, but other steps must be taken to insure that unnecessary temperature perturbations do not occur. As can be seen in the schematic representations of FIG. **2** and FIG. **7**, an insulation blanket **24** is disposed upon the upper surface of bath dialyzer reservoir cell **25**. The illustration of of insulation blanket **24** as shown in FIG. **2** and FIG. **7** is schematic in nature, a detailed cross-sectional view of insulation blanket **24** being shown in FIG. **8**. Insulation blanket **24** is used to retain the heat and maintain dialysate solution **96** at a substantially constant temperature. Insulation blanket **24** is comprised of a central stratified core comprised of at least six layers, **100***a* – *100f*, of aluminized Mylar film having a thickness of approximately 0.00025 inch. The outer layers of insulation blanket **24** are comprised of layers **101***a* and **101***b* fabricated from aluminized Mylar film having a thickness of approximately 0.001 inch. The combination of insulation blanket **24** and the heat transfer process utilizing the heat dissipated from field windings **56** of motor **29** driving recirculation pump **27** blood pump **36** will allow one to maintain the temperature of dialysate solution **96** at an appropriate temperature.

Referring now to FIG. **9**, a schematic diagram of another form of a kidney dialysis unit utilizing elements of the present invention is shown. For the purpose of clarity, elements having like functions to that shown in FIG. **2** will use the same reference numerals shown in FIG. **2.** As stated previously, one of the objectives of the present invention is to provide a portable dialysate pumping and delivery system which can operate with either the bath dialyzer reservoir cell **25** (FIGS. **2** and **7**) or a single pass proportioning system. FIG. **9** illustrates a form of the present invention utilizing a single pass proportioning system. The single pass, proportioning dialyzer assembly provides a continuous production of fresh, diluted dialysate solution. The fresh dialysate solution is transported to dialysate pumping and delivery system **12** where it is pumped through the artificial kidney held by kidney holding coil **15** (FIGS. **2** and **5**). After passing through the artificial kidney, the dialysate solution flows through blood leak detector and flow indicator **20** (FIG. **1**), after which it is disposed of. Referring now to FIG. **9**, water is admitted at pressure reducing valve **110.** After being reduced to an appropriate water pressure, the water enters heating canister **111.** The water output from heating canister **111** is at a temperature of approximately 37° C, the appropriate temperature for a dialysis solution. A source **112** of concentrated dialysate solution also passes through heating canister **111** and is heated to a temperature of 37° C. The operation of heating canister **111** will be explained in detail hereinbelow. Water and concentrated dialysate solution are input to proportioning valve **113.** The proportioning of the concentrated dialysate solution and water is substantially accomplished by proportioning the cross-sectional area of tubes **114** and **115** entering proportioning valve **113.** The manner of accurately proportioning the water and concentrated dialysate solution will be explained in detail hereinbelow. Diluted dialysate solution is output from proportioning valve **113** at tube **114**, tube **114** being coupled to a conventional temperature cell **115.** Temperature cell **115** performs a conventional temperature measurement and outputs a signal to amplifier **116** which triggers alarm circuit **117.** Alarm circuit **117** utilizes conventional circuits to detect that the temperature is not within appropriate limits and causes a shut down of blood pump **36.**

The diluted dialysate solution exits temperature cell **115** via tube **118** and enters conductivity cell **119.** Conductivity cell **119** is a conventional device for measuring the electrical conductivity of a solution. The proper proportioning of water and the undiluted dialysate solution produces a predetermined electrical conductivity which is detected at conductivity cell **119.** An output signal from conductivity cell **119** is amplified at amplifier **120** and input to alarm circuit **121.** The detection at alarm circuit **121** of an improper electrical conductivity will produce a response to shut down blood pump **36.** The output of diluted dialysate solution from conductivity cell **119** is via tube **122** to dialysate pumping and delivery system **12.** The temperature and conductivity of the dialysate solution can be visually observed through the use of conventional meters **123** and **124** respectively.

The details of heating canister **111** shown in FIG. **9** can be best seen by reference to FIG. **10.** Heating canister **111** comprises an inner chamber **125** for holding the water input at inlet **126.** The water outlet **127** from chamber **125** is coupled to tube **115** as shown in FIG. **9.** In the embodiment of heating canister **111** shown in FIG. **10**, pressure reducing valve **128** is incorporated therein. The pressure reducing valve **128** utilizes a needel-valve operated by a float **129.** The undiluted dialysate solution enters at inlet **130** and passes through a thin-walled metallic coil **131**, the dialysate solution exiting at outlet **132** which is in turn coupled to tube **114.** Heating of canister **111** utilizes a conventional heating blanket **133** which is disposed about the periphery of chamber **125.** To prevent unwanted dissipation of heat, a layer of fiberglass insulation **134** fully encloses the top, bottom and periphery of chamber **125** leaving heater blanket **133** intermediate the peripheral wall of chamber **125** and insulation **134.** Heating blanket **133** is connected by conventional wiring **135** to an electrical source. The water and undiluted dialysate solution entering canister **111** is heated to approximately 37° C preparatory to entering proportioning valve **113.**

As mentioned hereinabove, approximately proportioning of the undiluted dialysate solution and water can be made by controlling the cross-sectional area of the input tubes **114** and **115** as well as the pressure sources of the two components. Fine control is performed by the use of a dialysate metering valve shown in FIG. **11** generally designated by the reference numeral **113.** Inlet tube **114** is coupled to a section **141** of silicone rubber tubing. Solenoid valve **142** imposes a downwardly directed force on pinch roller **143** which imposes a corresponding force on elastomeric tube **141.** The flow of undiluted dialysate solution passing tube **141** is controlled by varying the current applied to solenoid **142** via leads **144.** Leads **144** are coupled to alarm circuit **121** and therefore to the output signal from amplifier **120.** The signal input to amplifier **120** is from conductivity cell **119** and is used to vary the flow of undiluted dialysate solution through tube **141** in conformity with the selected dialysate solution proportion.

Referring now to FIG. **12**, a front perspective view of the mating section of carrying structure **95** can be best seen. As stated previously, the present invention is to be a portable unit and therefore the portion of carrying structure **95** mates to form an enclosure with that shown in FIG. **7.** The section of carrying structure **95** illustrates the positioned kidney coil holder **15** with the dialysate outlet tube **30** depending therefrom. Blood inlets **62** and **63** are not connected. The front panel of the section of carrying structure **95** illustrates the simplicity of the present invention. Inlet **150** comprises the input to recirculation pump **27** and is adapted to be connected to tube **26.** Outlet **151** is coupled to shunt **43** (FIGS. **2** and **6**) and is adapted to be coupled to tube **33.** Flow indicator **32** (FIGS. **2** and **6**) discloses the indiciation that dialysate solution is flowing through dialysate pumping and delivery system **12.** Since one of the prime objectives of the present invention is safety, it has been repeatedly said that any malfunction of the system will result in shutting down blood pump **36.** In this manner, blood pump **36** is available at the top panel of carrying structure **95.** In a like manner, a manual blood pump clutch disengaging button **152** and a manual blood pump engagement button **153** are accessible in a like manner. As stated previously, although the clutch mechanics are not shown in FIG. **3** intermediate the bushing in shaft **53**, the implementation of a conventional clutch for engaging and disengaging blood pump shaft **53** is well known in the art. In a like manner, a variable speed control **154** is provided for controlling the speed of the pumps to maintain appropriate flow rates, a pump speed indicator **155** being provided for visually monitoring the speed of the pump. A blood leak alarm indicator **156** is connected to blood leak detector **31** and is turned on by the detection of an unbalanced condition by photodetector **84**. Power switch **157** and power indicator **158** are conventional components used to turn power on and off and indicate the presence or absence of same.

The operation of the present invention utilizes bath dialyzer reservoir cell **25** is initiated by breaking the seal on concentrate container **97** within bath dialyzer reservoir cell **25**. Water which has been previously heated to approximately 37° C is placed in reservoir cell **25** until reservoir cell **25** is filled to the appropriate volume. Recirculation pump **27** is turned on and flow is verified at flow indicator **32**. In addition, the temperature of dialysate solution **96** is measured at a conventional temperature gauge inserted at an appropriate place in dialysate pumping and delivery system **12**. Dialyzer unit **15** is pressurized to a suitable pressure, typically being approximately 300 mm Hg, i.e., approximately 50 mm Hg higher than pressure of dialysate solution **96**, after which flow is again verified. The next step is to turn on blood pump **36** by the engaging of the clutch thereto via manual engaging button **153**. Dialysate solution **96** will flow through dialyzer unit **15**, through blood leak detector **31**, flow indicator **32** and return to bath dialyzer reservoir cell **25**. The output of dialysate solution **96** from reservoir cell **25** flows initially through recirculation pump **27** and then adjacent field windings **56** of motor **29** to reclaim the heat dissipated therefrom. The flow of dialysate solution **96** then passing through heat reclaiming unit **19** flows into dialyzer unit **15**. Insulation blanket **99** will help to maintain the appropriate temperature of dialysate solution **96** by preventing a heat transfer by radiation or convection to the atmosphere. Any heat loss will be regained by the heat reclaiming process utilizing field windings **56**.

The present invention provides a kidney dialysis unit which is fully portable, efficient in operation and substantially easier and more economically fabricated than those devices disclosed in the prior art. The present invention is constructed in a manner which will provide for transfer of the unit to where the patient is located rather than requiring movement of the patient as is now required thereby satisfying all of the objectives of the present invention.

I claim:

1. Kidney dialysis apparatus for the dialysis of blood comprising:

a. dialysate supply means for producing a source of diluted, dialysate solution;

b. artificial kidney means for placing said diluted dialysate solution in juxtaposition to the blood whereby a dislysis process is executed, said artificial kidney means aving a dialysis solution input terminal and a dialysis solution output terminal, said dialysis solution output terminal coupled to said dialysate supply means;

c. a recirculation pump having dialysate solution input and output terminals, said dialysate solution input terminal coupled to said dialysate supply means;

d. power means for powering said recirculation pump, said power means including a heat source, said power means coupled to said recirculation pump; and

e. heat reclaiming means thermally coupled to said heat source for transferring the heat dissipated by said heat source to said dialysate solution, said heat reclaiming means coupling the dialysate solution output terminal of said recirculation pump and the dialysate solution input terminal of said artificial kidney means.

2. Kidney dialysis apparatus as defined in claim **1** wherein said dialysate supply means comprises a flexible member having an exterior surface and an inner chamber of predetermined volume having dialysate solution input and output means for providing an input and output path for diluted, dialysate solution disposed within said chamber.

3. Kidney dialysis apparatus as defined in claim **2** further including thermal insulating means for retarding the transfer of heat therethrough, said thermal insulating means being disposed upon and in intimate contact with a portion of the exterior surface of said member whereby the transfer of heat from the dialysis solution disposed within said chamber is retarded.

4. Kidney dialysis apparatus as defined in claim **1** wherein said dialysate supply means comprises a single-pass dialysate proportioning system including first and second sources of water and concentrated dialysate solution respectively, heating means coupled to said first and second sources for heating said water and said concentrated dialysate solution to a predetermined temperature, proportioning means coupled to said heating means for combining said water and concentrated dialysate solution in a predetermined proportion, said proportioning means coupled to the dialysate solution input terminal of said recirculation pump.

5. Kidney dialysis apparatus as defined in claim **1** wherein said power means comprises a direct-current motor having field windings, said heat reclaiming means being thermally coupled to said field windings.

6. Kidney dialysis apparatus as defined in claim **1** further including a blood leak detector having dialysate solution input and output terminals and a dialysate solution flow indicator having dialysate input and output terminals, the dialysate solution output terminal of said blood leak detector being coupled to the dialysate input terminal of said flow indicator, the dialysate input terminal of said blood leak detector being coupled to the dialysate solution output terminal of said artificial kidney means, the dialysate output terminal of said flow indicator being coupled to said dialysate supply means.

7. Kidney dialysis apparatus as defined in claim **1** further including a blood pump having blood input and output terminals and means intermediate said input and output terminals for providing a pressure head and inducing the circulation of blood, said blood output terminals being coupled to said artificial kidney means.

8. Kidney dialysis apparatus as defined in claim **7** wherein said blood pump includes a rotary input shaft coupled to said means intermediate said blood output and input terminal, said shaft being coupled to said power means.

9. A portable kidney dialysis system for the dialysis of blood comprising:

a. dialysate supply means for producing a source of diluted, dialysate solution;

b. artificial kidney means for placing said diluted, dialysate solution in juxtaposition to the blood whereby a dialysis process is executed, said artificial kidney means having dialysate solution input and output terminals and blood input and output terminals;

c. a direct-current rotary power source having a rotating output shaft and internal means for producing a source of dissipating heat;

d. a recirculation pump having dialysis input and output terminals and a rotary input power shaft, said rotary input power shaft being coupled to the rotary power output shaft of said power source, said dialysis input terminal being coupled to the dialysate solution output terminal of said dialysate supply means;

e. a heat reclaiming member disposed in juxtaposition to the internal means of said rotary power source, said heat reclaiming means having dialysate solution input and output terminals, said dialysate solution input terminal being coupled to the dialysate solution output terminal of said recirculation pump, the dialysate solution output terminal being coupled to the dialysate solution input terminal of said artificial kidney means;

f. blood detection means for detecting the presence of blood in the diluted dialysate solution;

g. flow indicator means for indicating the flow of diluted dialysate solution; and

h. means coupling said blood detection means and said flow indicator means to the dialysate solution output terminal of said artificial kidney means.

10. A portable kidney dialysis system as defined in claim 9 wherein said dialysate supply means comprises a flexible member having an exterior surface and an inner chamber of predetermined volume and having input and output means defining an input and output path for diluted, dialysate solution disposed within said chamber.

11. A portable kidney dialysis system as defined in claim 10 further including thermal insulating means for retarding the transfer of heat therethrough, said thermal-insulating means being disposed upon and in intimate contact with a portion of the exterior surface of said member whereby the transfer of heat from the diluted dialysate solution disposed within said chamber is retarded.

12. A portable kidney dialysis system as defined in claim 11 wherein said thermal insulating means comprises a plurality of adjacent layers each fabricated form an alumnized plastic film.

13. A portable kidney dialysis system as defined in claim 9 whrein said dialysate supply means comprises a single pass dialysate proportioning system including first and second sources of water and concentrated dialysate solution respectively, heating means coupled to said first and second sources for heating said water and concentrated dialysate solution to a predetermined temperature, proportioning means coupled to said heating means for combining said water and said concentrated dialysate solution in a predetermined proportion, said proportioning means coupled to the dialysate solution input terminal of said recirculation pump.

14. A portable dialysis system as defined in claim 9 wherein said heat reclaiming member further includes a chamber having an inner wall adapted to engage the portion of said rotary power source adjacent said internal means, said inner wall having spaced heat dissipating fins depending into said whereby the heat from said internal means is transferred to said dialysate solution.

15. A portable kidney dialysis system as defined in claim 9 further including a blood recirculation pump having blood input and output terminals, means for maintaing a predetermined pressure head, and a rotary input shaft coupled to said means, said blood output terminals being coupled to the blood input terminal of said artificial kidney means and said rotary input shaft being coupled to the rotary output shaft of said rotary power source.

16. A portable kidney dialysis system as defined in claim 15 further including means responsive to the detection of the presence of blood in the diluted dialysate solution for stopping said blood recirculation pump, said means being disposed intermediate the input shaft of said blood recirculation pump and the output shaft of said rotary power source.

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