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Kopp

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[54] **SINGLE NEEDLE DIALYSIS**

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Related U.S. Patent Documents

Reissue of:

[64] Patent No.: **3,756,234**
Issued: **Sept. 4, 1973**
Appl. No.: **149,905**
Filed: **June 4, 1971**

[51] **Int. Cl.**[2] **A61M 5/00;** A61M 1/03

[52] **U.S. Cl.** ..... **128/214 R;** 128/214 E; 210/90

[58] **Field of Search** ..... 128/DIG. 3, 214 R, 214 B, 128/214 E, 214 F, 214.2, 214.4, 213, 227; 210/90, 321 B

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[57] **ABSTRACT**

Method and apparatus for extracorporeally dialyzing the blood of a patient with only a single venipuncture including withdrawing blood from the patient through the venipuncture and forcing the blood along an arterial path to a dialyzer. Blood emerging from the dialyzer is then conducted along a venous path again to the venipuncture. The pressure is monitored in the extracorporeal system to trigger occluding devices which alternately open and close the arterial and venous paths so that undialyzed blood is taken from the patient and dialyzed blood is injected into the patient. The apparatus includes clamps actuated by a pressure monitor to alternately obstruct the arterial and venous paths. A blood pump may be controlled to operate as one of the clamps. In an alternative embodiment, blood is circulated at a comparatively high flow rate throughout the system. A clamp is provided in one of the arterial or venous lines, said clamp being controlled by a pressure monitor. When the clamp is closed, a pressure differential is developed between the extracorporeal system and the patient so that a volume of blood is exchanged between the system and the patient.

4 Claims, 10 Drawing Figures

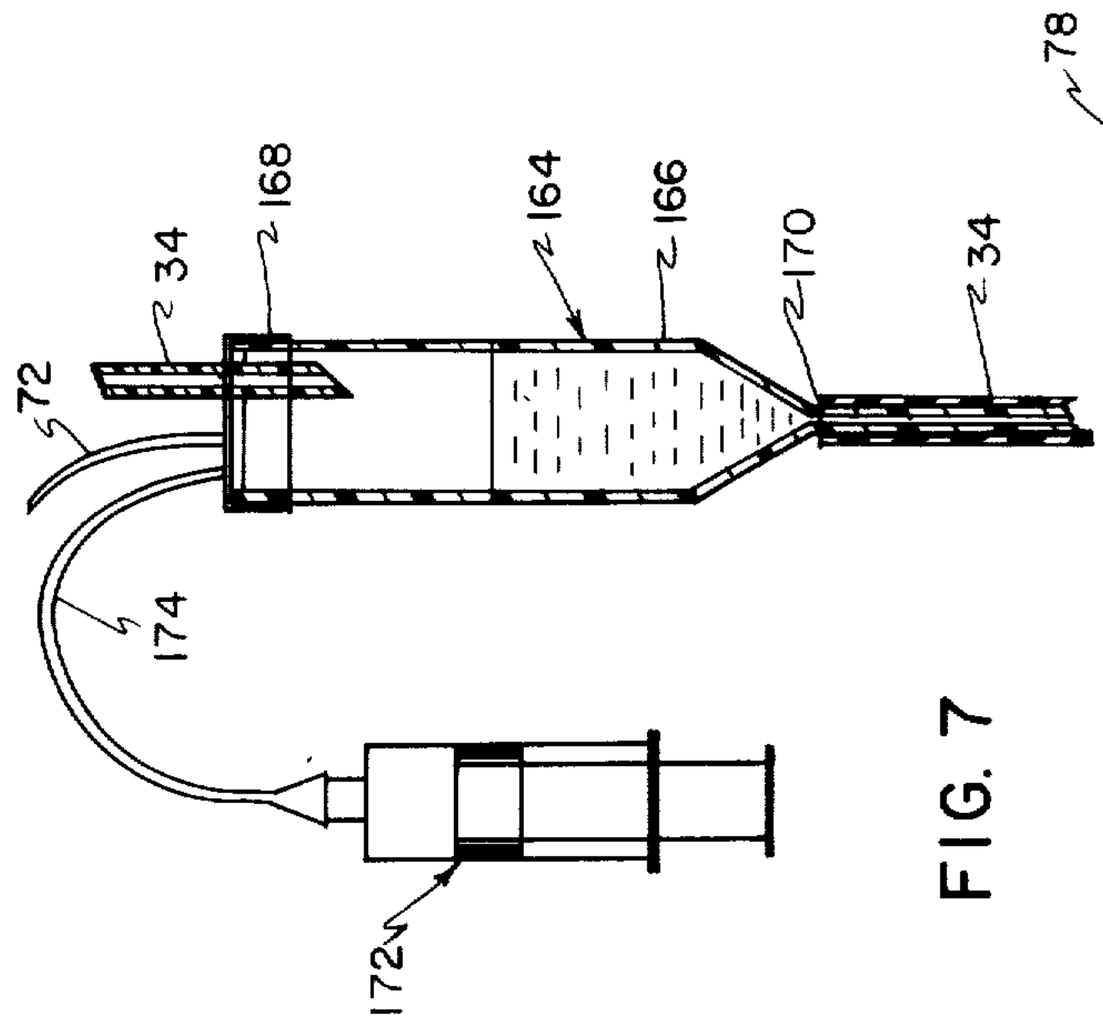

FIG. 7

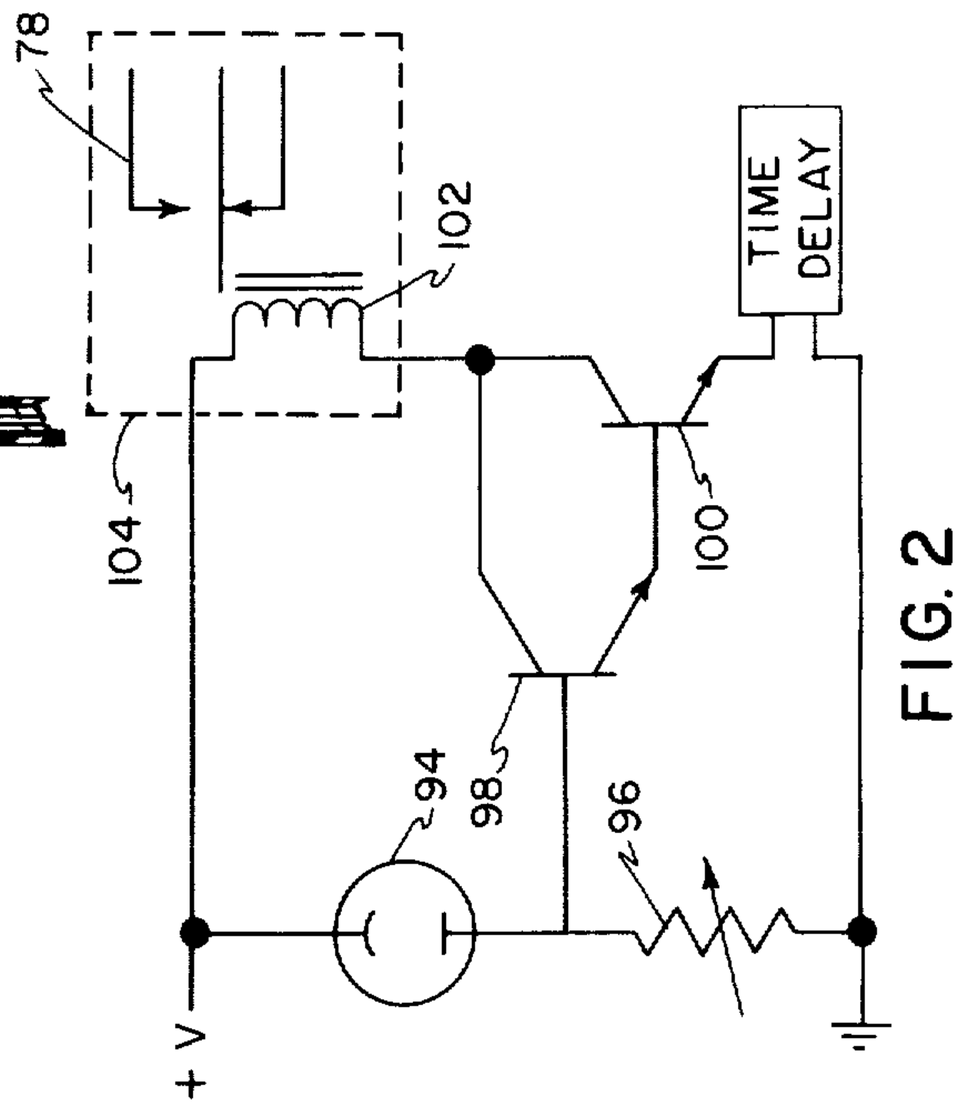

FIG. 2

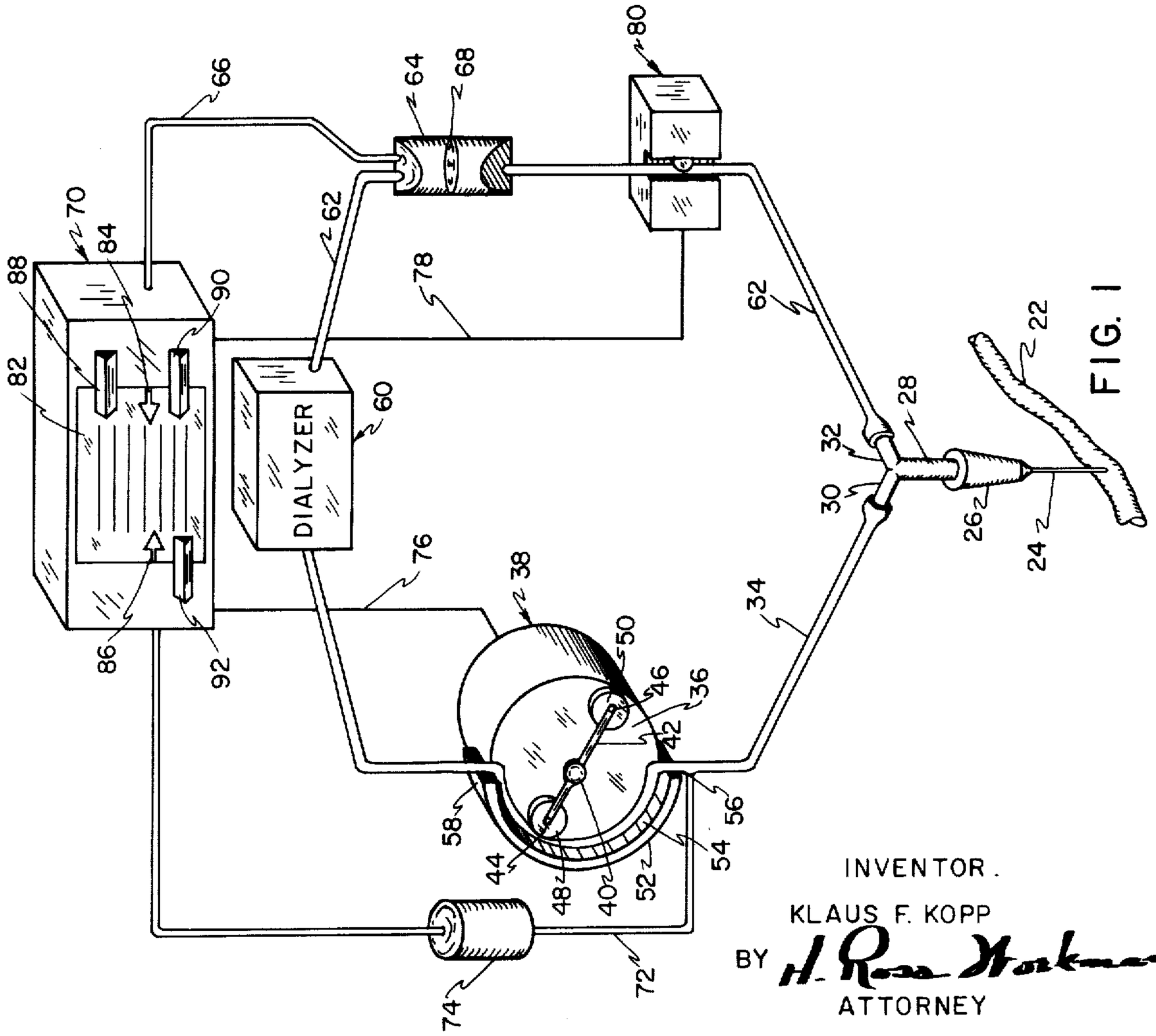

FIG. 1

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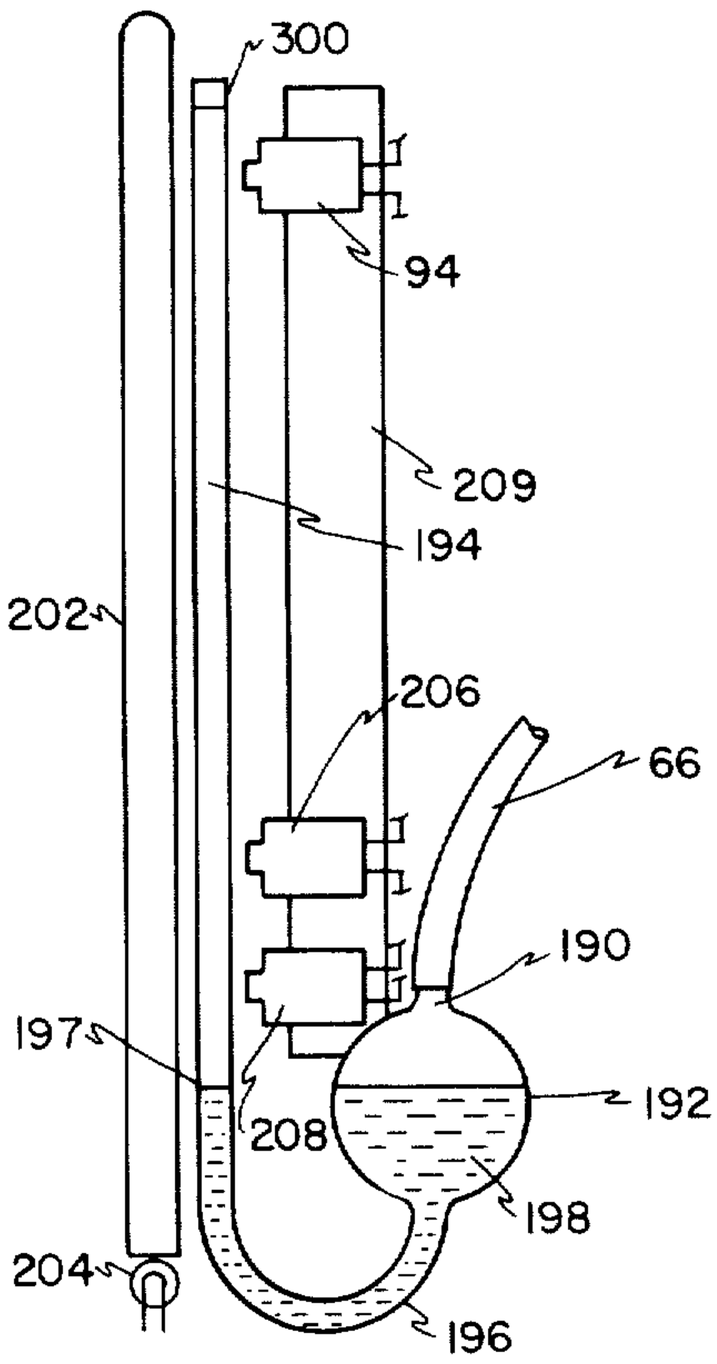

FIG. 3

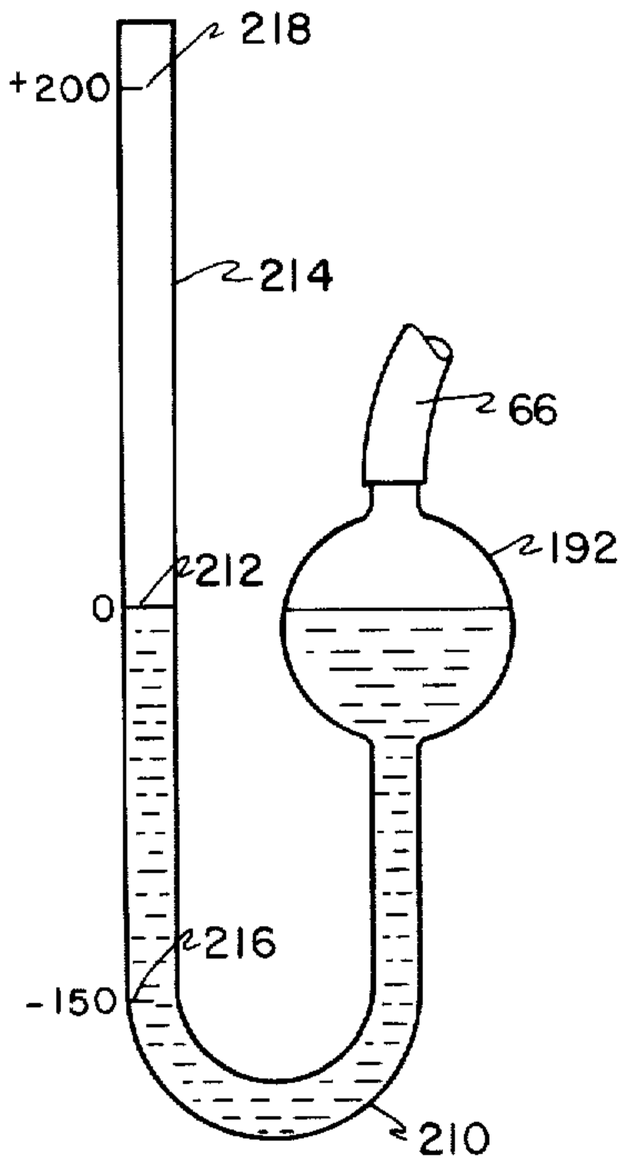

FIG. 3a

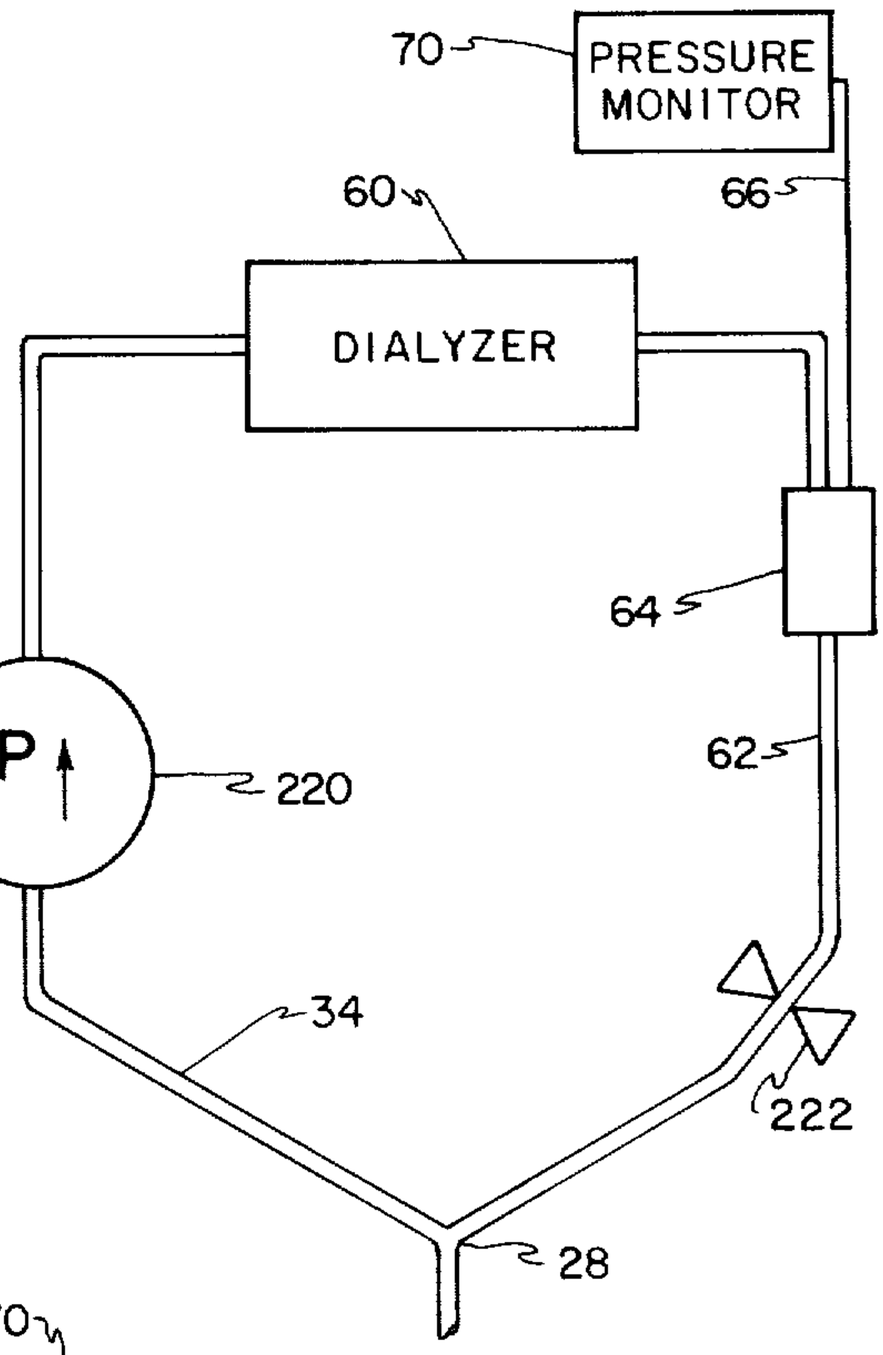

FIG. 8

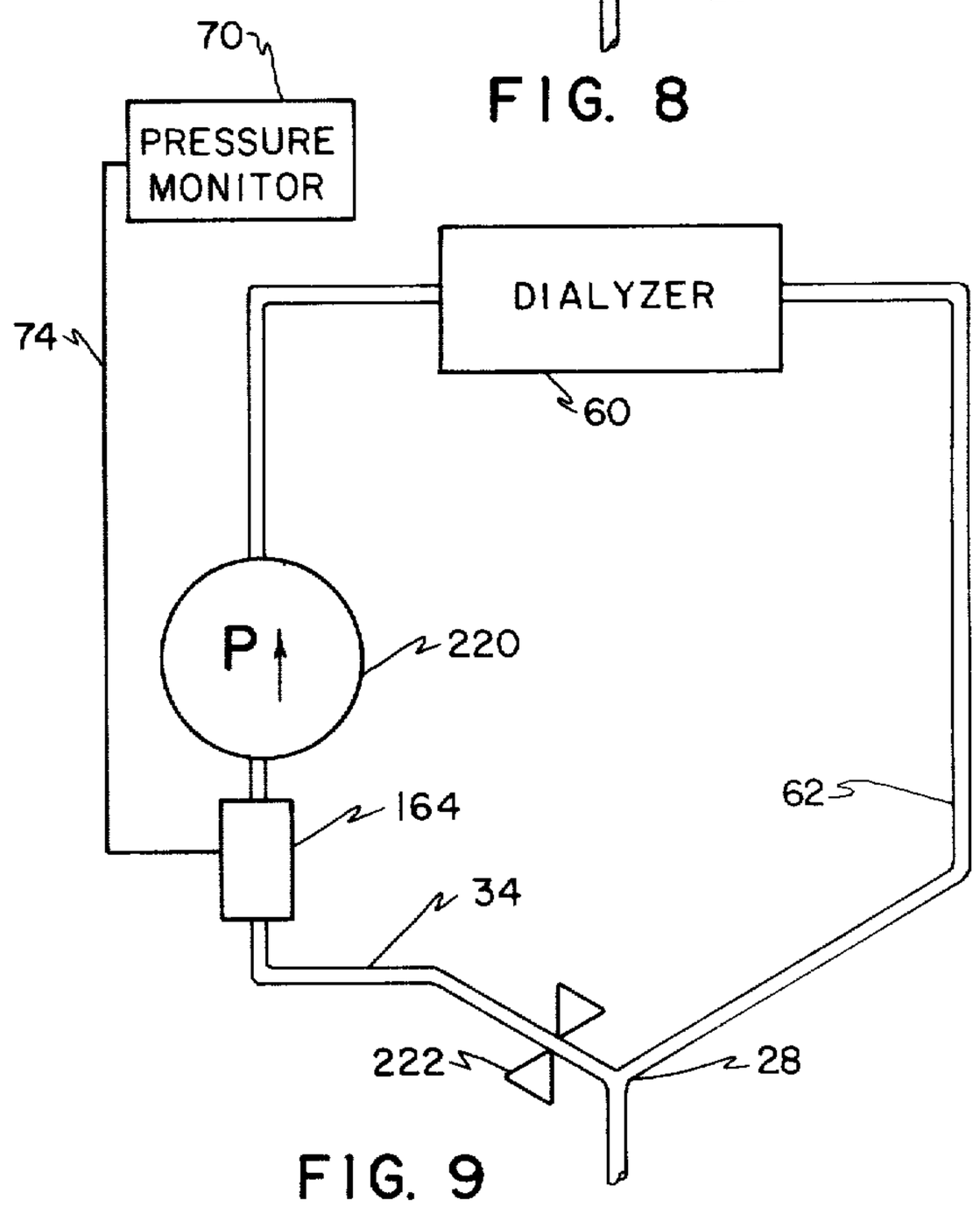

FIG. 9

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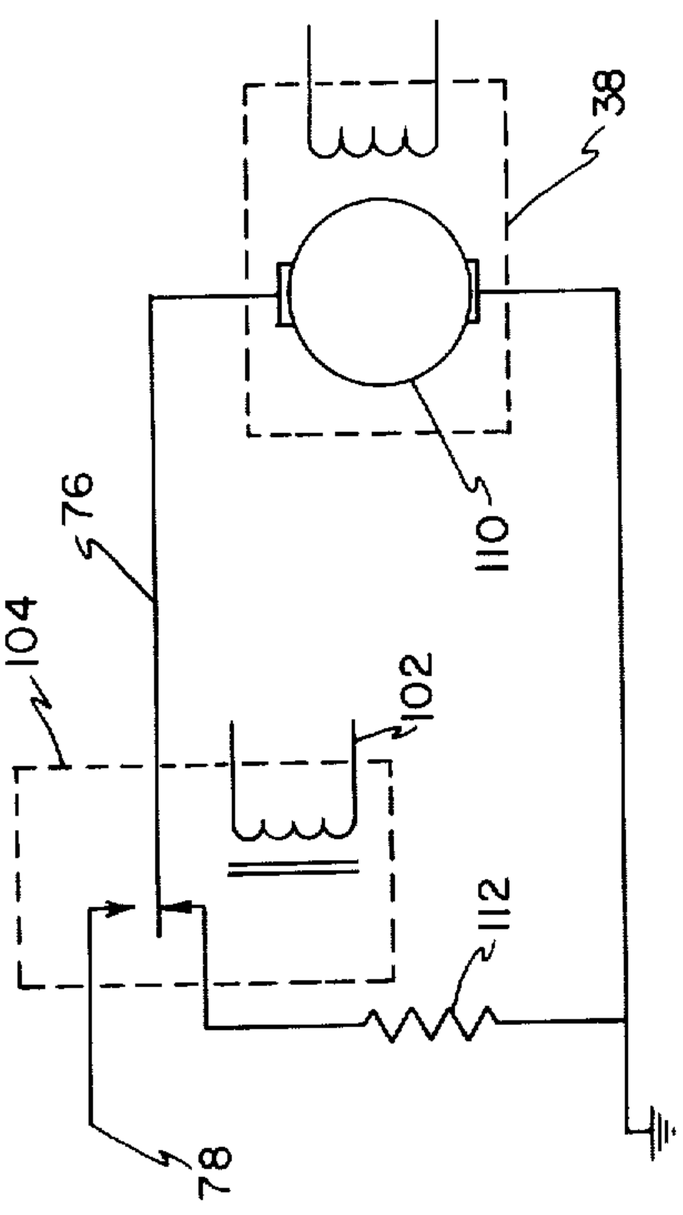

FIG. 4

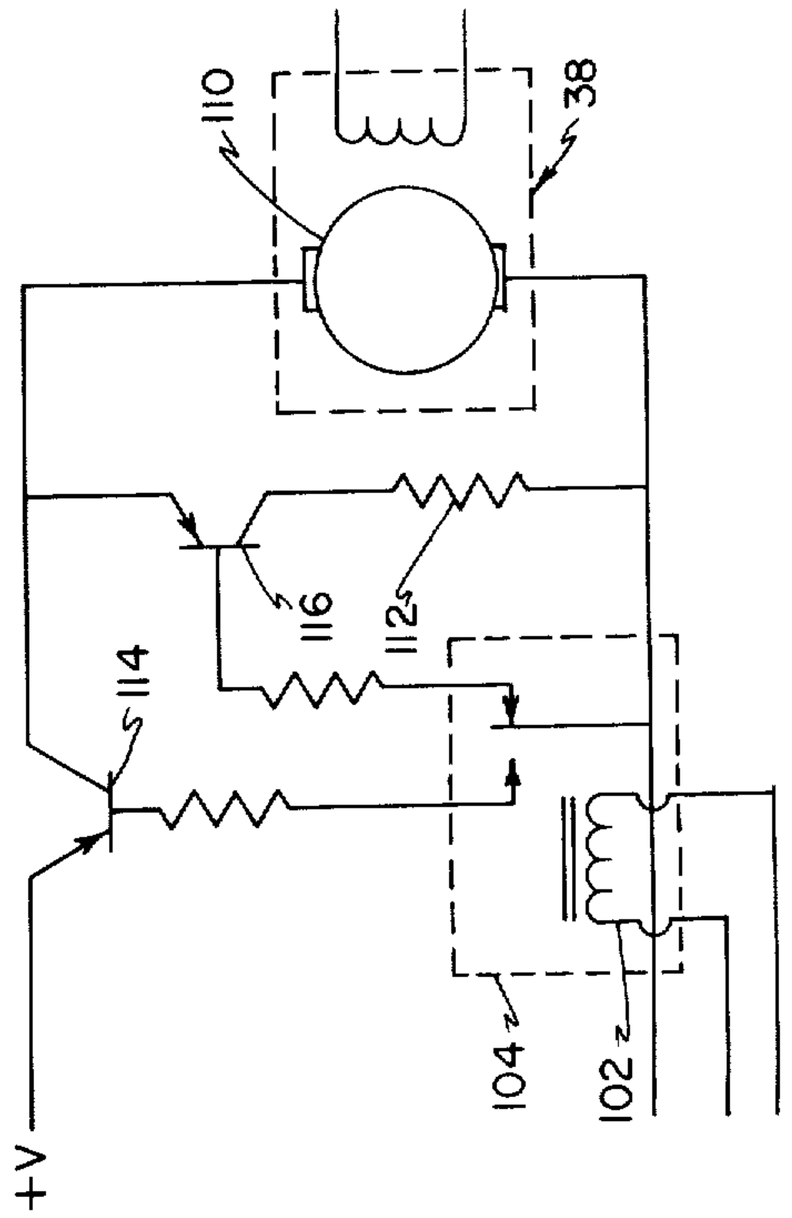

FIG. 5

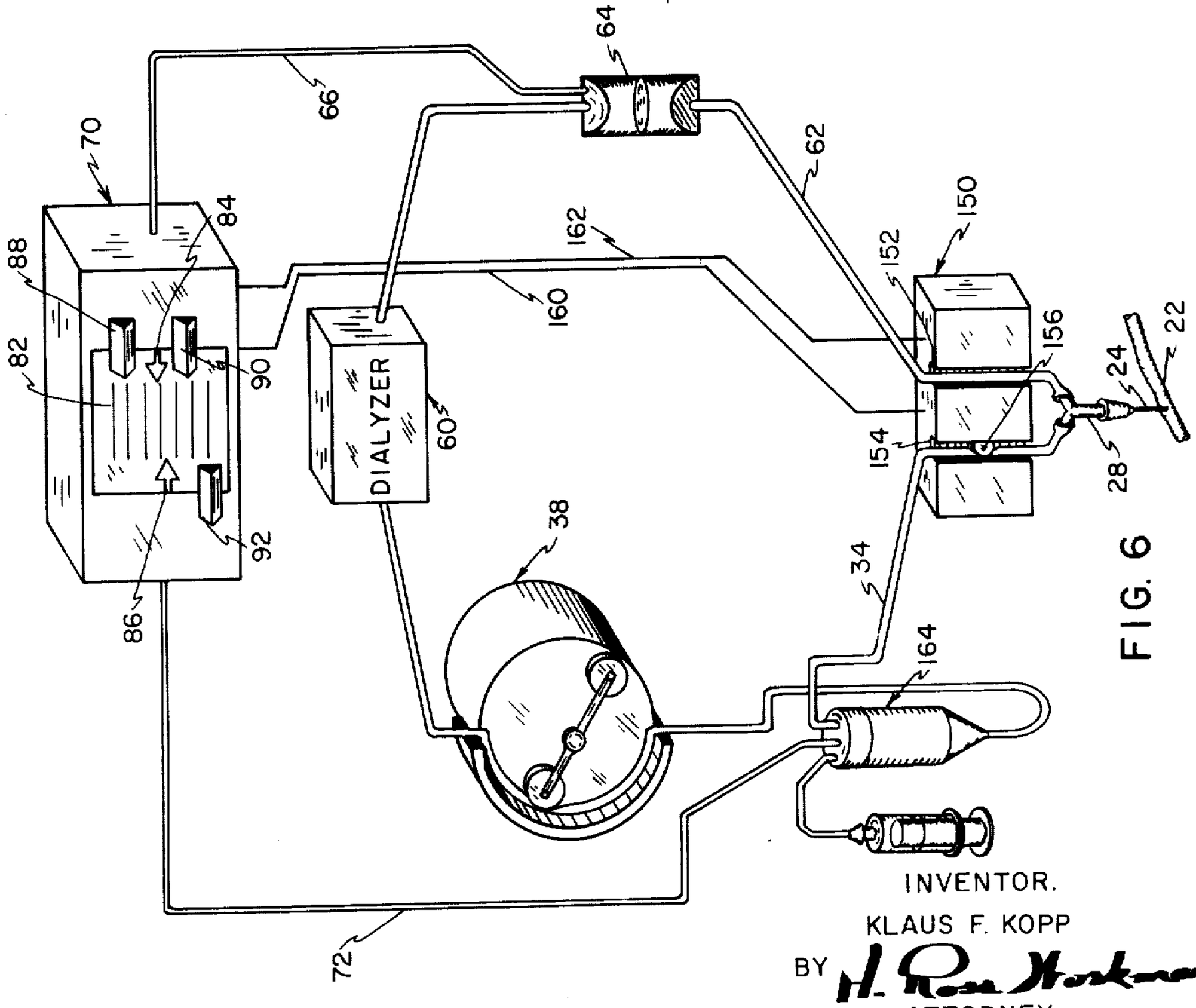

FIG. 6

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SINGLE NEEDLE DIALYSIS

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND

1. Field of the Invention

The invention relates to extracorporeal hemodialysis and more particularly to method and apparatus for dialyzing a patient's blood with a single venipuncture or cannulation.

2. The Prior Art

Historically, kidney diseases have been of critical concern to human life. Many kinds of kidney diseases interfere with the function of the kidney such that the kidney ceases to remove waste and excess water from the blood. When the kidney is sufficiently impaired that a large portion of the waste products and water are not removed from the blood, the life of the patient cannot be preserved unless a way is provided for artifically performing the function of the impaired kidney. Many new developments have come to light which perform the function of the impaired kidney extracorporeally. For example, see copending U.S. patent application Ser. No. 106,184, filed Jan. 13, 1971. Nevertheless, even with the existing improvements in extracorporeal kidney apparatus, the same general procedure is used for dialyzing patients' blood that was used very early in the treatment of kidney disease.

For example, the most commonly accepted practice for dialyzing a patient's blood extracorporeally requires the surgical creation of a subcutaneous, arterio-venous fistula. Thereafter, the subcutaneous venous system dilates secondary to the increase of blood flow derived from the artery to the vein through the fistula. Sufficient blood flow for dialysis is then obtainable by venipuncture with large bore needles. Normally, two hollow needles or cannulas with an internal stylet or trocar are used to perform two venipunctures on the patient so that two blood-communication sites exist simultaneously in the patient. Conventionally, blood is withdrawn from one of the punctured blood vessels, forced through a hemodialyzer and thereafter forced into the other.

The aforementioned procedure has been found to have serious disadvantages both to the patient and to the attending physicians and technicians. The problems are particularly aggravated because most patients requiring extracorporeal hemodialysis must undergo treatment as frequently as three to seven times per week. This means that if every venipuncture were completely successful, a patient would need to undergo from 6 to 14 venipunctures or cannulations each week.

It is well-known that the duration and well-function of a fistula created by venipuncture is inversely related to the number of venipunctures. Tissue repeatedly subjected to the trauma of venipuncture is much more susceptible to thrombophlebitis, paravascular hemorrhage, clotting and infection. In fact, it is commonly found in patients who have experienced a number of venipunctures, that the tissues surrounding the most accessible veins develop large hematomas which obscure the veins making successful venipuncture extremely difficult because of insufficient blood flow in the damaged blood vessels.

Also contributing to the problem is the fact that once one successful venipuncture is made and blood is allowed to flow from the patient's body toward a hemodialyzer, the blood volume in the patient's body is reduced making the second venipuncture very difficult. Historically, it has been found that while most skilled physicians or technicians are able to perform the first venipuncture with little difficulty, frequently a plurality of attempts is necessary before a second venipuncture can be performed on the same patient.

Additionally, while the pain and discomfort suffered by the patient is understandable, the multiple attempts at venipuncture often necessary to place the second needle results in increasing apprehension, and anxiety on the part of both the patient and the physician or technician attending the patient further reduces the likelihood of successful venipuncture.

BRIEF DESCRIPTION AND OBJECTS OF THE INVENTION

The present invention, including novel method and apparatus, reduces patient trauma and tissue damage by accommodating extracorporeal hemodialysis with a single venipuncture. Generally, once the venipuncture has been performed, blood is conducted away from the venipuncture site through one branch of a bifurcated blood path. The bifurcation is located next to the needle connector to keep the resulting deadspace as small as possible. The blood is forced through the extracorporeal hemodialyzer and thereafter through the other branch of the bifurcated flow path again to the venipuncture site. The method using the single venipuncture is made possible by alternating the blood flow into and out of the patient at the venipuncture site. A unidirectional pulsatile blood flow thrugh the dialyzer is established by alternate occlusion of the branches of the bifurcated blood path. For example, with one branch occluded, blood is withdrawn from the patient through the other branch into the hemodialyzer. The other branch is then occluded and the blood is forced through the one branch again into the patient.

It is, therefore, a primary object of the present invention to provide an improved method of extracorporeal hemodialysis using a single venipuncture for each treatment.

It is another primary object of the present invention to provide improved apparatus facilitating extracorporeal hemodialysis with a single venipuncture.

Another valuable object of the present invention is to provide an improved system for single needle dialysis for providing unidirectional pulsatile flow from the patient, to an extracorporeal dialyzer and again to the patient.

One still further and no less important object of the present invention is to provide a novel method of forcing blood through an extracorporeal system at an accelerated rate with periodic exchanges of blood volumes between the patient and the system.

These and other objects and features of the present invention will become more fully apparent from the following description and appended claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic perspective illustration of a presently preferred system for dialyzing a patient's blood using a single venipuncture;

FIG. **2** is a schematic circuit diagram illustrating a presently preferred pressure monitor circuit;

FIGS. **3** and **3a** schematically illustrate internal components of a presently preferred pressure monitor;

FIGS. **4** and **5** are schematic circuit diagrams respectively illustrating alternative embodiments which may be used with the system of FIG. **1** to control the operation of the blood pump;

FIG. **6** is a schematic perspective of another presently preferred system for dialyzing a patient's blood using a single venipuncture;

FIG. **7** is a partial cross-section of the flow chamber forming part of the system of FIG. **6**; and

FIGS. **8** and **9** are schematic diagrams of still other presently preferred method embodiments of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference is now made to the **[***prefered***]** *preferred* embodiments of the invention as illustrated in the figures, like parts being designated with like numerals throughout.

The System of FIG. **1**

Referring now to FIG. **1,** a blood vessel **22** is illustrated as having been penetrated by a hollow cannula **24.** Preferably, the penetration has been performed according to any suitable technique such as venipuncture. The cannula **24** may be of any suitable type and may be made of radiopaque Teflon. One suitable cannula has been found to be the Angiocath intravenous placement unit manufactured by Deseret Pharmaceutical Company, Inc. Sandy, Utah. A 14-gauge catheter having a length of between one and two inches has been found to be most effective. Nevertheless, it is also presently preferred to use a hollow needle or any other suitable hollow instrument which can be effectively placed within a vein. In this specification, cannula means any hollow tubing which can be placed in a patient's blood vessel.

In the illustrated embodiment, the cannula **24** has an outwardly-tapered female or luer fitting **26** which is securely joined to a bifurcated coupling **28.** Coupling **28** has an arterial branch **30** and a venous branch **32,** arterial branch **30** being press-fit into a rubber or plastic tube **34.** Tube **34** will hereinafter be referred to as the arterial line **34.**

Arterial line **34** is situated over the face **36** of a blood pump generally designated **38.** Blood pump **38** is conventional and normally includes a rotatable shaft **40** upon which is mounted a transverse bar **42.** The bar **42** has, at its respective ends **44** and **46** rotatable cylinders **48** and **50.**

Approximately one-half of the circular path traversed by the cylinders **48** and **50** is bordered by a semi-circular track **52.** The arterial line **34** is caused to follow the inside surface **54** of the track **52.** Thus, as the cylinders **48** and **50** traverse their circular path about the axis of shaft **40,** the arterial line **34** will be squeezed between the respective cylinders and the track **52.** Conventionally, the bar **42** rotates clockwise around the shaft **40** so that the squeezed portion of the arterial line **34** is developed between the cylinder and the track **52** at the leading end **56** of the track and progresses over the entire

inside surface **54** of the track to the trailing end **58** thereof. As the squeezed portion of the arterial line **34** progresses over the inside surface of the track **52,** blood in the arterial line **34** is forced to the dialyzer generally designated **60.** It can be appreciated that when the cylinder **48** reaches the trailing end **58** of the track **52,** the cylinder **50** will engage the arterial line **34** at the leading end **56** so that a constant forward pressure is exerted on the blood to move from the blood vessel **22** to the dialyzer **60** as long as the pump is in operation.

Any suitable conventional dialyzer can be used with the present system. An example of one suitable dialyzer which could be used in the Coil EX-01 manufactured by Extracorporeal, Inc. Another suitable dialyzer is described in pending designated S. Pat. application Ser. No. 106,184, filed Jan. 13, 1971. Blood emerges from the dialyzer **60** in the venous line **62** which is press-fit onto the branch **32** of the coupling **28.** Preferably, a bubble trap **64** is interposed in the venous line **62** to prevent bubbles from passing through the cannula **24** into the blood vessel **22.** The bubble trap **64** may be any suitable conventional bubble trap such as that used with blood infusion apparatus.

A pressure conductor **66** is connected into the bubble trap **64** above the surface level **68** of the blood. Thus, pressure within the bubble trap **64** and venous line **62** is transmitted through the conductor **66** to a pressure monitor generally designated **70.** Similarly, a pressure conductor **72** is connected into the arterial line **34** so as to transmit pressure from the arterial line **34** to the pressure monitor **70.** It is presently preferred that an accumulator **74** be interposed in the conductor **72** so as to provide an air pillow between the blood in arterial line **34** and the pressure monitor **70.** The pressure monitor **70** is connected by electrical conductors **76** and **78** to the blood pump **38** and an electrically-operated clamp **80,** respectively.

The Pressure Monitor

In order to make single venipuncture hemodialysis possible, the pressure monitor **70** has multiple set points. Furthermore, although a single pressure monitor is illustrated in FIG. **1,** it may be desirable to have a plurality of pressure monitors to insure safety in the system. A variety of suitable conventional pressure monitors are commercially available, one suitable monitor being manufactured by Cambridge Instrument Corporation of Great Britain. Most conventional pressure monitors are operated with pressure diaphragms or the like. However, the illustrated pressure monitor **70** uses a mercury manometer system. For ease of illustration, only pressure monitor **70** will be described.

The pressure monitor **70** has a calibrated bezel **82** with indicia thereon representing, for example, millimeters of mercury. An indicator **84** is controlled by venous line pressure in conductor **66** so that when the venous line pressure in conductor **66** rises, the indicator **84** rises to indicate the pressure in millimeters of mercury (mm Hg). Similarly, when the pressure in conductor **66** drops, the indicator **84** drops to represent the decreasing pressure in millimeters of mercury. Another indicator **86** is controlled by the pressure in line **72** to indicate the pressure in the arterial line in millimeters of mercury.

Manually adjustable set points are determined by the position of markers **88, 90** and **92.** For example, markers **88** and **90** respectively set the upper and lower limits of blood pressure in the venous line **62** as will be subsequently more fully described. Similarly, marker **92** will

set the lower limit of the pressure in the arterial line **34.** Preferably, the pressure range accommodated by the monitor **70** for measuring the pressure in venous line **62** is on the order of about zero to 300 mm Hg. The pressure range accommodated by the monitor **70** for indicating the pressure in arterial line **34** is preferably in a range on the order of about −150 to +200 mm Hg. Set point accuracy of the markers **88** have been found most desirably to be within ±5 mm Hg.

Although a variety of pressure measuring systems could be used, it has been found that a mercury column manometer is both accurate and dependable for use in the pressure monitor **70.** The mercury column manometer has the advantages of giving a continuous visual pressure indication and is also a familiar instrument to medical personnel. One presently preferred embodiment of the pressure monitor **70** is illustrated in FIG. **3.** With reference to FIG. **3,** the pressure conductor **66** is connected in pressure-tight relation to a hollow fitting **190** on a mercury reservoir **192.** The reservoir **192** is integrally joined to an open column or tube **194** having a generally U-shaped intermediate segment **196** disposed beneath the reservoir **192.** As can be appreciated by referring to FIG. **3,** the upper level **197** of the mercury **198** will seek the level of the reservoir. Thus, the line **197,** when even with the reservoir level, may be interpreted as the zero pressure point for the FIG. **3** embodiment. Preferably, the tube **194** is calibrated so that 300 mm Hg pressure is required to move the line **197** to the point **300.**

A cylindrical rod **202** is provided adjacent the column **194,** the rod **202** being formed of light illuminable plastic. An incandescent lamp or other suitable light source **204** is placed adjacent one end of the rod **202** and, when the light source **204** is illuminated, the entire rod **202** will become illuminated.

A plurality of photoelectric cells **94, 206** and **208** are disposed on the other side of the column **14** diametrally opposite the rod **202.** The photocells **94, 206** and **208** are preferably shielded by structure (not shown) which prevents light from the rod **202** from reaching the photocell except through the column **194.** The photocells may be mounted on a vertical rack **209** and are preferably vertically adjustable along the rack **209** by any suitable conventional adjusting structure (not shown).

In the operation of the apparatus of FIG. **3,** as the mercury **198** advances in the column **194,** the mercury will obstruct the light path between the rod **202** and the photocells **94, 206** and **208.** More specifically, for example, when the mercury advances to the mark **200,** the photocell **94** will be de-energized because light from the rod **202** will be obstructed by the mercury. Similarly, when the mercury advances below the position of the photocell **94,** the photocell will be energized.

While the range of the column **194** in FIG. **3** is, for example, between 0 and 300 mm Hg, any suitable pressure reading is possible as is made clear from the schematic representation of FIG. **3a.** In FIG. **3a,** the U-shaped portion **210** is substantially elongated over the U-shaped portion **16** (FIG. **3**), so that the zero point **212,** where the mercury comes to rest with the level of mercury in the reservoir **192,** is intermediate the length of mercury column **214.** Thus, for example, the mercury level **212** may fluctuate between readings of approximately minus 150 mm Hg such as at point **216** to approximately 200 mm Hg at point **218.**

The mercury column manometer, when used in conjunction with the photocell circuit illustrated in FIG. **2,**

provides for highly accurate set point determination. Referring more specifically to FIG. **2,** photocell **94** is connected to a variable resistor **96** which is a threshold control to determine the sensitivity of the photocell **94.** When photocell **94** is energized by the light source **202** (FIG. **3**), the resulting signal will be amplified by stepped transistors **98** and **100** so as to energize relay drive **102.** Relay driver **102** controls the operational state of relay **104** which, in turn, controls the function of solenoid clamp **80** (FIG. **1**). When the pressure in venous line **62** is below the set point **88,** the photocell **94** will be exposed to the light source thereby energizing relay driver **102** and switching the relay **104** to an "on" position to actuate the solenoid clamp **80** (FIG. **1**). The clamp **80** then closes and occludes the venous line **62.** With the venous line **62** occluded, the pressure in the line **62** will rise until the indicator **84** reaches the set point determined by marker **88.** At that moment, the mercury **198** in column **194** (FIG. **3**) will have risen sufficiently to obstruct the light from the light source **202** to the photocell **94** thereby turning the photocell **94** off. The relay driver **102** is then no longer energized and relay **104** is switched to the "off" position thereby opening the solenoid clamp **80.** A conventional time delay circuit may be used to prevent for a predetermined time period re-actuation of relay **104** when the mercury drops to expose photocell **94** to the light source **202.**

A separate solenoid circuit which may be substantially identical to that shown in FIG. **2** may be provided for each of the set points determined by markers **90** and **92.** Additionally, if desired, a third set point (not shown in FIG. **1**) may be provided to correspond to photocell **208** (FIG. **3**) so as to act as a "safety low" set point which is normally slightly lower than the set point indicated by marker **90.** Thus, in the event a membrane or coil in the dialyzer **60** ruptures, an instantaneous drop in pressure to the "safety low" set point will actuate the solenoid **80** to an open position and the pump **38** to stop to protect the patient.

In the system illustrated in FIG. **1,** the pressure monitor **70** also controls the operation of the blood pump **38.** Referring specially to FIG. **4,** the relay **104,** controlled by the photocell circuit illustrated in FIG. **2,** is energized so that the relay driver **102** disconnects solenoid line **78** from the circuit. The solenoid **80** responds by clamping the venous line **62** closed. Simultaneously, the motor **38** is energized to draw blood from the venipuncture in blood vessel **22** and drive it toward the dialyzer **60.** When the pressure [reises,] *rises,* as above described, the relay **104** will reverse to open the clamp **80** and stop the pump **38.** Pump **38** thus functions as a second clamp.

It has been found that the blood pump **38** does not instantaneously stop when it is disconnected from the circuit by the pressure monitor **70** because of the moment of inertia of the blood pump motor. Accordingly, in the illustrated embodiment of FIG. **4,** the armature **110** of the motor **38** is connected through a resistor **112** to the relay **104.** The size of the resistance is selected so as to convert essentially all of the kinetic energy of the motor into heat for dissipation through the resistor **112** when relay **104** turns the motor off.

While the embodiment illustrated in FIG. **4** has been found to operate satisfactorily, the start-stop frequency of the motor has been found to be as much as 30 to 60 times a minute. Because the armature current passing through the relay is quite high, the relay **104** has been found to wear out quite rapidly. In order to extend the

operating life of the relay, the embodiment of FIG. **5** was developed. The circuit embodiment of FIG. **5** differs from the embodiment of FIG. **4** principally in that transistors **114** and **116** are used to switch the motor **38** off and on, respectively. The transistors reduce the actual amount of current passing through the relay **104** so as to preserve the life of the relay.

The Method of the FIG. **1** Embodiment

Having described the apparatus of FIG. **1**, the method of dialyzing a patient's blood with a single venipuncture will now be described.

Initially, the set points on the pressure monitor **70** are adjusted by moving the markers **88, 90** and **92** to represent the desired venous high and low pressures and the desired arterial low pressure, respectively. The arterial and venous lines are primed by filling the lines with isotonic saline. When a single venipuncture or cannulation has been performed, the arterial and venous lines **34** and **62** are filled with blood.

The blood pump **38** is energized so as to force blood through the arterial line toward the dialyzer **60.** As has been previously described, when the blood pump **38** is in operation, the solenoid clamp **80** is closed thereby occluding the flow of blood through the venous line **62.** Thus, continued rotation of the pump **38** develops an increasing pressure in the venous line **62** above the clamp **80.** The increased pressure is communicated through the conductor **66** to the pressure monitor **70.** As the indicator **84** progressively advances up the pressure scale on bezel **82,** it will be brought into coincidence with marker **88.** Advancement of the indicator **84** is concurrent with the elevational rise of the mercury **198** in the mercury column **194** (FIG. **3**). When the mercury **198** effectively eliminates light from the source **202** to the photocell **94,** the relay driver **102** (FIG. **2**) will be de-energized simultaneously opening the solenoid switch **80** and turning the motor **38** off through the circuit illustrated in FIGS. **4** or **5.**

When the pump **38** is off, the engaging one of the cylinders **48** or **50** will serve as a clamp to occlude the arterial line **34** and prevent inflow of blood through the cannula **24** and coupling **28.** While the pump **38** is stopped, the increased pressure in the venous line **62** is reduced by pushing the blood in venous line **62** through the coupling **28** and catheter **24** again into the blood vessel **22** of the patient. As the pressure in venous line **62** is reduced, the indicator **84** will gradually drop. The time delay in the circuit of FIG. **2** prevents the relay **104** from switching until the selected time interval has been covered.

Thereafter, the solenoid clamp **80** is energized by action of the time delay relay to the illustrated occluded position and the pump **38** is again energized to draw blood from the blood vessel **22** through the cannula **24.** In the event the arterial line **34** becomes obstructed such as with a clot or the like, the arterial line pressure in conductor **72** will drop the indicator **86** to the minimum set point at marker **92.** When the indicator **86** reaches this low point, the pump **38** will be turned off in order to protect the patient. In the event a coil or membrane in the dialyzer **60** is ruptured, the emergency set point (determined by photocell **208** shown in FIG. **3**) will be triggered to shut off both the blood pump and the solenoid **80.**

The activation or deactivation of the solenoid, double solenoid or blood pump can either be achieved by letting the pressure travel inbetween two set points or by oscillating around one set point. The latter method (which is preferred) necessitates a time delaying device which prolongs one phase of the cycle. This phase can be chosen either to be a phase of prolonged occlusion or prolonged opening of the solenoid. Regarding the different possibilities described, this will result in prolongation of phases with rising or falling pressures.

In general, in case of coil rupture, the blood pump should stop and the venous solenoid should open (in order to return as much blood to the patient as can be recovered).

The Embodiment of FIGS. **6** and **7**

FIG. **6** illustrates another presently preferred dialyzing system utilizing a single venipuncture. The FIG. **6** embodiment differs from the FIG. **1** embodiment primarily in that the pump **38** is continuously operating and the single solenoid clamp **80** has been replaced by a double solenoid clamp **150.** The solenoid clamp **150** has parallel channels **152** and **154** through which the venous and arterial lines **62** and **34,** respectively, pass. The solenoid has a detent **156** in each of the channels **152** and **154,** the detent **156** being selectively actuated alternately into channel **152** or **154.** Control of the detent is provided through electrical conductors **160** and **162** connecting the solenoid clamp **150** to the pressure monitor **70.**

Additionally, the system of FIG. **6** has an arterial flow chamber generally designated **164** and more clearly illustrated in FIG. **7.** The flow chamber **164** is preferably formed of a rigid cylindrical member **166** which may be formed of plastic and is desirably transparent. The member **166** is fitted with an air-tight cap **168** into which one end of the arterial line **34** is mounted. The member **166** has a downwardly tapered portion and terminates in a male coupling **170.** Another portion of the arterial line **34** is press-fit onto the male coupling **170.** The cap **168** also serves as a mounting site for pressure-conducting tube **74** and a blood level adjuster generally designated **172.** The blood level adjuster may comprise a conventional hypodermic syringe connected to the cap **168** by a plastic tube **174.** Where desired, the tube **174** may be clamped to maintain pressure communication through conductor **72.**

The Method of FIGS. **6** and **7**

The arterial and venous lines **34** and **62** are primed with isotonic saline as described in connection with FIG. **1** above. The pump **38** operates continuously. Assuming that the venous line **62** is occluded by solenoid **150,** blood is withdrawn from the patient's blood vessel **22** through the cannula **24** and arterial line **34** into the arterial flow chamber **164.** The blood is then pumped out of the arterial flow chamber to the dialyzer **60.** Continued pumping by the pump **38** causes the pressure in the venous line **62** to increase because of the occlusion in the channel **152.** As the pressure rises, the indicator **84** will rise to the set point determined by marker **88.** When the set point is reached, solenoid **150** will be actuated to open the venous line **62** and to occlude, simultaneously, the arterial line **34.** The high pressure in the venous line **62** will then cause the blood therein to flow through the adapter **28,** cannula **24** and into the blood vessel **22.**

Referring again to FIG. **7,** the continued operation of the blood pump **38** causes blood to flow out of the arterial flow chamber thereby decreasing the pressure in the member **166,** the decreased pressure being communicated through line **72** to the pressure monitor **70.** When the time which has been preset by the time delay relay has elapsed, the pressure monitor **70** will again

actuate the solenoid clamp **150** to close the venous line **62** and open the arterial line **34.** Blood will again be drawn from the patient through the arterial line **34** to replenish the reservoir in the arterial flow chamber **164** and also to conduct the blood through the dialyzer **60** as the cycle is again commenced.

From the foregoing, it can be appreciated that effective dialysis of a patient's blood can be obtained with a single venipuncture. Moreover, it has been found that the small amounts of blood which are recycled through the system at the adapter **28** do not unfavorably influence the efficiency. A surprising amount of the blood is withdrawn from the patient and again injected into the patient with each cycle in the system. Moreover, it has been found that a patient's dialysis time using the single venipuncture method is only slightly increased if at all, in most cases, over the prior art double venipuncture method.

The Embodiments of FIGS. **8** and **9**

The embodiments of FIGS. **8** and **9** maximize the tendency of the blood to "short-circuit" at the bifurcated coupling **28.** In this embodiment, a substantial portion of the blood is intentionally recirculated a plurality of times through the arterial line **34,** the dialyzer **60** and the venous line **62.** A suitable blood pump **220** continually operates at a comparatively high rate of speed so that the blood is forced through the dialyzer, venous and arterial lines at the rate of approximately 300 to 400 milliliters per minute. As can be appreciated, this flow rate is approximately twice as great as the flow rate from the patient through a dialyzer in the systems of FIGS. **1** and **6.**

In order to dialyze the patient's blood, only a single clamp **222** is necessary. In FIG. **8,** clamp **222** is located in the venous line **62** below the bubble trap **64.** Alternatively, as shown in FIG. **9,** the clamp **222** may be disposed in the arterial line **34** beneath the arterial flow chamber **164.**

In the method embodiment of FIG. **8,** the system is primed with saline as above described and blood is gradually drawn into the arterial line **34** as will now be more particularly described. When the clamp **222** is in the closed or occluding position, the pump **220** will continue to draw blood from the patient and force the blood in the arterial line **34** through the dialyzer **60.** Thus, a pressure will develop in the venous line **62,** said pressure being conducted through line **66** and monitored by the pressure monitor **70.** When the pressure reaches a predetermined high set point, the clamps **222** will be activated to the open position. At that moment, the pressure in the venous line will be greater than the pressure in the arterial is equalized by displacing one volume of dialyzed blood into the patient and another volume of dialyzed blood again into the arterial line **34.**

After a particular predetermined time period has elapsed or, as soon as the pressure in line **66** has dropped to a predetermined level, the clamp **222** will again occlude the venous line **62** to develop pressure above the clamp **222.** It is observed that as soon as the clamp **222** is closed, a vacuum is developed in the arterial line **34** below the pump **220.** This vacuum is filled by drawing blood from the patient into the arterial line **34.** When the pressure in line **66** reaches the predetermined set point in the monitor **70,** the clamp **222** is again opened and the blood under pressure in the venous line **62** will be forced toward the bifurcated coupling **28.** Because the line **34** has been filled with blood while the clamp **222** was closed, a substantial portion of the blood under pressure in the venous line **62** will be forced through the coupling **28** into the patient.

An alternative to the described method of embodiment is illustrated in FIG. **9.** In FIG. **9,** the clamp **222** is located in the arterial branch **34** beneath the flow chamber **164.** The pump **222** is in continual operation at a comparatively high flow rate, similar to that described above so that a flow rate of approximately 300 to 400 millimeters per minute exists in the system. When the clamp is closed, blood will be forced by the pump **220** through the dialyzer **60** and venous line **62** so that the blood is forced into the patient through the bifurcated coupling **28.** Continued pumping with the clamp **222** closed causes the pressure in the chamber **164** to be reduced, said pressure reduction being reflected through conductor **74** and monitored in the pressure monitor **70.** When the pressure in monitor **70** reaches predetermined low set point, clamp **222** will open thereby allowing the pump **220** to draw blood from the patient through the bifurcated coupling **28** and the venous line **62.** The volume of blood required to equalize the pressure is greater than can be supplied from venous line **62** so that a substantial volume of blood is drawn from the patient.

The embodiments of FIGS. **8** and **9** have been found to provide some unusually valuable advantages over other types of dialysis systems. For example, the very high flow rate causes much turbulence in the dialyzer which breaks up the boundary layers normally existing in the dialyzer thereby substantially increasing diffusion across the membrane. Moreover, inasmuch as flow through the dialyzer is normally laminar, the turbulence developed by the high flow rate causes the erythrocytes to have a brushing effect against one another and against the membrane to further increase the rate of dialysis.

Inasmuch as a substantial portion of the blood in the system is circulated through the dialyzer a plurality of times before being reinjected into the patient, the blood normally in the extracorporeal system has an unusually low concentration of waste substances. Thus, when blood is drawn from the patient into the system, there is blood-to-blood diffusion as the infusing blood is mixed with the recirculating blood in the system. It has been found that the method set forth in FIGS. **8** and **9** achieves a surprisingly high dialysis efficiency.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed and desired to be secured by United States Letters Patent is:

1. A method of dialyzing the blood of a patient with a single cannula dialysis system having a dialyzer, a blood pump acting thereon and openable clamp comprising the steps of:

cannulating the patient by placing a single cannula into the bloodstream of the patient;

providing an extracorporeal bifurcated flow path in communication with the cannula, the flow path having an arterial branch, a venous branch and the blood dialyzer interposed therebetween;

continuously pumping the blood in the arterial branch toward the dialyzer with a pump acting upon the arterial branch;

creating two pressure zones by situating the openable clamp along the length of the venous branch, the first pressure zone defined by the portion of the flow path downstream from the pump and upstream from the clamp so as to include the dialyzer and the second pressure zone being defined by the portion of the flow path upstream from the pump and downstream from the clamp so as to include the patient cannula;

developing increased pressure in the first zone and simultaneously decreasing pressure in the second zone by closing the clamp and continuously pumping blood in the arterial line so as to draw blood from the patient; and thereafter

equalizing the pressure between the zones by opening the clamp thereby permitting blood to be transferred to the patient.

2. A method of dialyzing the blood of a patient with a single cannula dialysis system having a dialyzer, a blood pump acting thereon and openable clamp comprising the steps of:

cannulating the patient by placing a single cannula into the bloodstream of the patient;

providing an extracorporeal bifurcated flow path in communication with the cannula, the flow path having an arterial branch, a venous branch and the blood dialyzer interposed therebetween;

continuously pumping the blood in the arterial branch toward the dialyzer with a pump acting upon the arterial branch;

creating two pressure zones by situating the openable clamp in the arterial line upstream from the pump, the first pressure zone being defined by the portion of the flow path downstream from the pump and upstream from the clamp so as to include both the patient cannula and the dialyzer and the second pressure zone being defined by the portion of the flow path upstream from the pump and downstream from the clamp;

developing increased pressure in the first zone by continuously pumping the blood while closing the clamp thereby increasing the pressure in the first zone to inject blood into the patient; and

equalizing the pressure between the zones by opening the clamp and permitting blood to be transferred from the patient to the flow path.

3. A method of dialyzing the blood of a patient with a single cannulation in a system including a pump and a hemodialyzer connected together in a series configuration, and a single hollow cannula having a bifurcated conduit connected thereto to provide an arterial branch and a venous branch, coupled respectively to opposed ends of the series connected pump and hemodialyzer, wherein the interconnected conduit, pump and hemodialyzer define a closed system connected to the single hollow cannula, comprising the steps of:

cannulating the blood vessel of a patient with the single cannula through which blood is withdrawn from and returned to the patient through said system in alternate phases of successive cycles of operation;

pumping blood from the patient to the hemodialyzer through the arterial branch, while preventing the return of blood to the patient through the venous branch;

sensing pressure in the closed system;

automatically occluding blood flow through the arterial branch to stop the withdrawal of blood from the patient in response to the sensing of a predetermined first pressure level in the closed system, while permitting the return of blood to the patient through the venous branch; and, alternately,

automatically occluding blood flow through the venous branch to stop the return flow of blood to the patient in response to the sensing of a predetermined second pressure level in the closed system, while permitting blood withdrawal from the patient through the arterial branch, so that blood is alternately withdrawn and returned to the patient in alternate phases of each successive cycle of operation of the system in response to the sensing of the predetermined first and second pressure levels.

4. A method of dialyzing the blood of a patient with a single cannulation in a system including a pump and a hemodialyzer connected together in a series configuration, and a single hollow cannula having a bifurcated conduit connected thereto to provide an arterial branch and a venous branch, coupled respectively to opposed ends of the series connected pump and hemodialyzer, wherein the interconnected conduit, pump and hemodialyzer define a closed system connected to the single hollow cannula, comprising the steps of:

cannulating the blood vessel of a patient with the single cannula through which blood is withdrawn from and returned to the patient in alternate phases of successive cycles of operation;

pumping blood from the patient to the hemodialyzer through the arterial branch, while preventing the return of blood to the patient through the venous branch;

sensing pressure in the closed system downstream of the pump;

automatically occluding blood flow through the arterial branch to stop the withdrawal of blood from the patient in response to the sensing of a predetermined first pressure level in the closed system, while permitting the return of blood to the patient through the venous branch; and, alternately,

automatically occluding blood flow through the venous branch to stop the return flow of blood to the patient in response to the sensing of a predetermined second pressure level in the closed system, wherein the first pressure level is higher than said second level, while permitting blood withdrawal from the patient through the arterial branch, so that blood is alternately withdrawn and returned to the patient in alternate phases of each successive cycle of operation of the system in response to the sensing of the predetermined first and second pressure levels.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE. 29,346

DATED : August 9, 1977

INVENTOR(S) : KLAUS F. KOPP

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

Column 5, line 60, delete "16" and insert --196--.

Column 9, line 52, after "arterial" insert --line and in the patient's blood stream. The pressure--.

Signed and Sealed this

Eighteenth Day of *April 1978*

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

LUTRELLE F. PARKER
Acting Commissioner of Patents and Trademarks