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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-093561- -00004-0000

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Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 538 PETICION Folios: 2

Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

DIVISIÓN DE NUEVAS CREACIONES

E. S. D.

Re: P1.-FRESENIUS MEDICAL CARE HOLDINGS, INC.-Solicitud de
Patente de Invención en Fase Nacional PCT para "APARATO
PORTÁTIL PARA TERAPIA DE DIÁLISIS PERITONEAL".-Clase
A61M 1/00.-Expediente número 07-093.561.-

1. Me refiero a mi memorial de 28 de Enero de 2008.
2. De conformidad con lo dispuesto en el Artículo 5.2.12 de la Circular Externa No. 03 de 28 de Abril de 2003, y estando dentro del plazo de seis meses contados desde la fecha de la publicación de la solicitud en la Gaceta de la Propiedad Industrial número **596** de 30 de Septiembre de 2008, solicito a ese Despacho proceder a realizar el examen de patentabilidad de la presente invención.
3. Anexo me permito acompañar recibo número 09 - 18.745, expedido por la Superintendencia de Industria y Comercio, que acredita el pago de la tasa que dicho examen causa.
4. Ruego a usted tomar atenta nota de lo anterior y proceder de conformidad.

Señor Superintendente,

ALICIA LLORED A RICAURTE

T.P. 53.215

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-093561- -00004-0000

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 09 - 18,745
FECHA : MARZO 9 DE 2009

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
LLOREDA Y CIA S. A	CONSIGNACION	BANCO DE BOGOTA	062754387	105594204	09/03/2009	9,944,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01	SOLICITUDES	
		112 PTC CAP-1 EXAMEN DE PATENTIBILIDA	452,000.00
		TOTAL :	\$ 452,000.00

SDN: CUATROCIENTOS CINCUENTA Y DOS MIL PESOS

RESPONSABLE : 

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 07-93561

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **596** DE

FECHA **30 DE SEPTIEMBRE DE 2008** EL TÉRMINO HÁBIL SEÑALADO POR

LA LEY EXPIRA EL **30 DE DICIEMBRE DE 2008**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

NO X



US 20040019313A1

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(19) **United States**

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Childers et al.

(10) **Pub. No.: US 2004/0019313 A1**
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(54) **SYSTEMS, METHODS AND APPARATUSES
FOR PUMPING CASSETTE-BASED
THERAPIES**

(22) Filed: Dec. 31, 2002

Related U.S. Application Data

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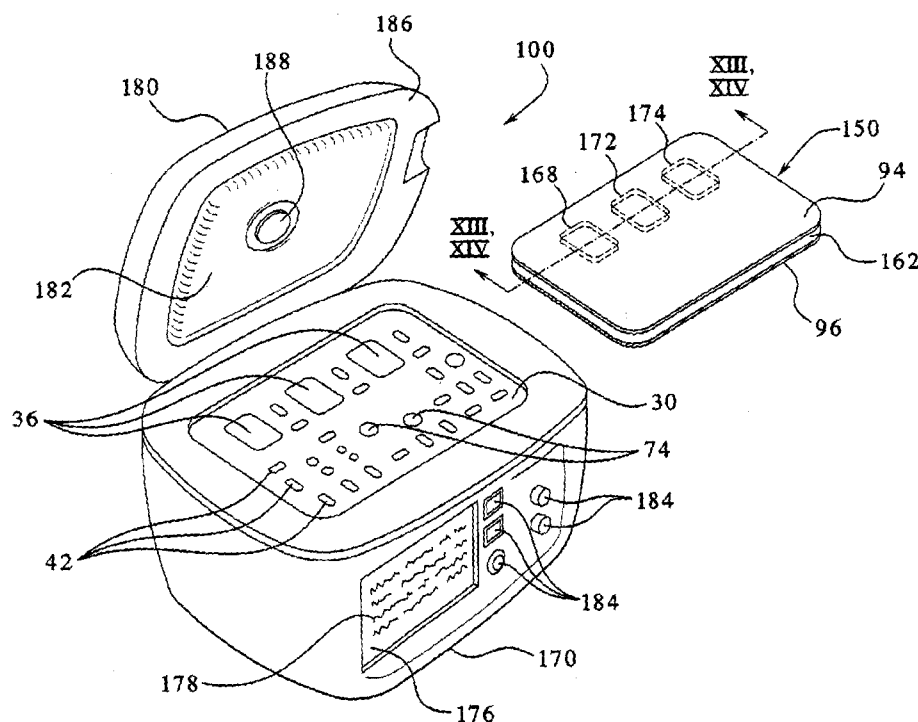
(51) **Int. Cl.⁷** **A61M 37/00; B01D 1/00**
(52) **U.S. Cl.** **604/5.01; 210/646; 210/252; 210/258**

(57) **ABSTRACT**

The present invention provides systems, methods and apparatuses for medical fluid delivery systems that employ a pumping cassette. In particular, the present invention provides systems, methods and apparatuses for cassette-based dialysis therapies including hemodialysis, hemofiltration, APD (including tidal modalities) and CFPD. The embodiments described include a combined pump/valve housing, a fail safe pump/valve arrangement, a cassette auto-alignment feature, a pumping membrane material, a multiplexing valve arrangement, an expert fluid pumping management system, an integral port vent and an in-line air separation chamber and combinations of each of these.

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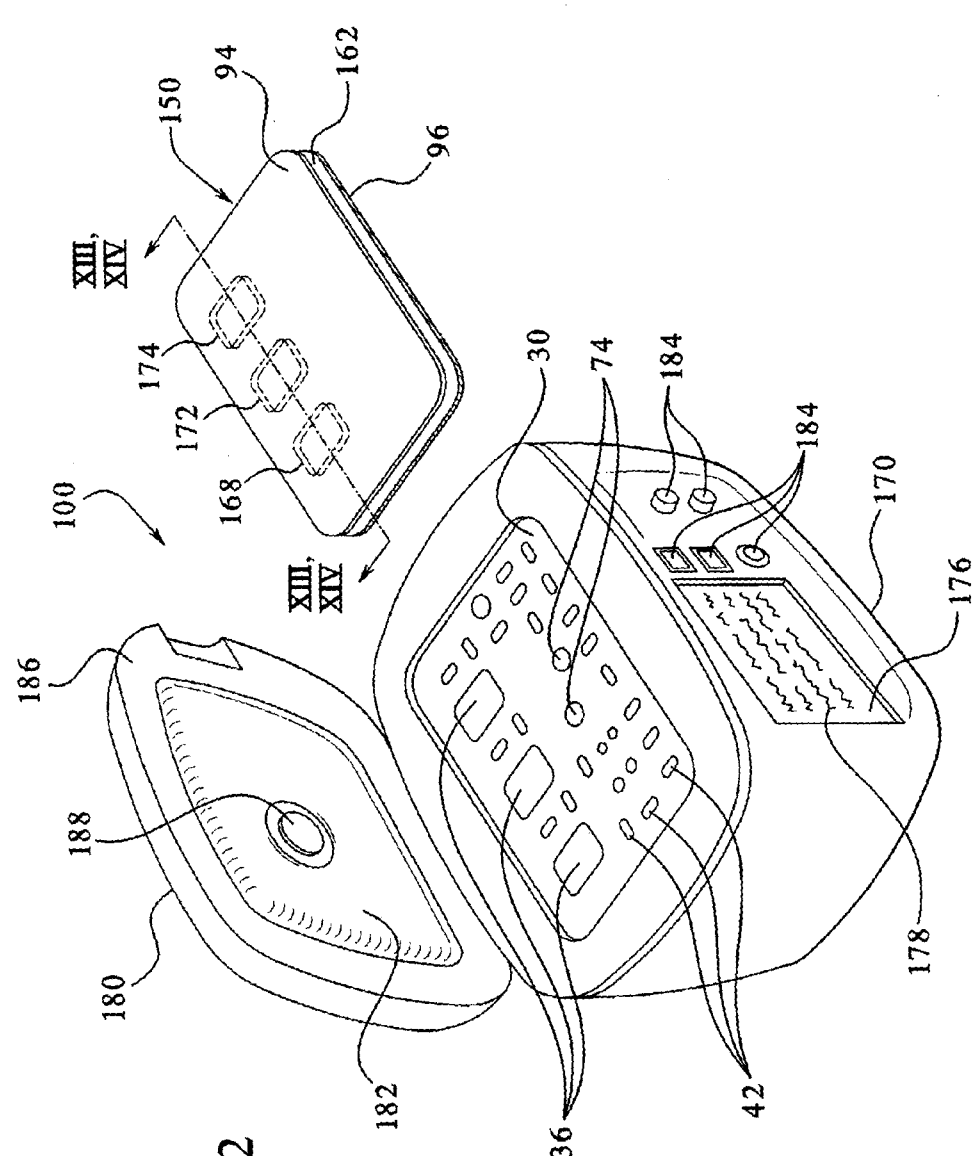


FIG. 12

SYSTEMS, METHODS AND APPARATUSES FOR PUMPING CASSETTE-BASED THERAPIES

[0001] This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Serial No. 60/397,045, filed on Jul. 19, 2002 and U.S. Provisional Patent Application Serial No. 60/397,268, filed on Jul. 19, 2002.

BACKGROUND OF THE INVENTION

[0002] The present invention generally relates to medical fluid systems. More specifically, the present invention relates to systems and methods of performing cassette-based dialysis and devices related thereto.

[0003] Due to various causes, a person's renal system can fail. Renal failure produces several physiological derangements. The balance of water, minerals and the excretion of daily metabolic load is no longer possible and toxic end products of nitrogen metabolism (urea, creatinine, uric acid, and others) can accumulate in blood and tissues.

[0004] Kidney failure and reduced kidney function have been treated with dialysis. Dialysis removes waste, toxins and excess water from the body that would otherwise have been removed by normal functioning kidneys. Dialysis treatment for replacement of kidney functions is critical to many people because the treatment is life saving.

[0005] Hemodialysis and peritoneal dialysis are two types of dialysis therapies used commonly to treat loss of kidney function. Hemodialysis treatment utilizes the patient's blood to remove waste, toxins and excess water from the patient. The patient is connected to a hemodialysis machine and the patient's blood is pumped through the machine. Catheters are inserted into the patient's veins and arteries so that blood can flow to and from the hemodialysis machine. The blood passes through a dialyzer of the machine, which removes waste, toxins and excess water from the blood. The cleaned blood is returned to the patient. A large amount of dialysate, for example about 120 liters, is consumed to dialyze the blood during a single hemodialysis therapy. Hemodialysis treatment lasts several hours and is generally performed in a treatment center about three or four times per week.

[0006] Peritoneal dialysis uses a dialysis solution or "dialysate", which is infused into a patient's peritoneal cavity via a catheter. The dialysate contacts the peritoneal membrane of the peritoneal cavity. Waste, toxins and excess water pass from the patient's bloodstream, through the peritoneal membrane and into the dialysate due to diffusion and osmosis, i.e., an osmotic gradient occurs across the membrane. The spent dialysate is drained from the patient, removing waste, toxins and excess water from the patient. This cycle is repeated.

[0007] There are various types of peritoneal dialysis therapies, including continuous ambulatory peritoneal dialysis ("CAPD"), automated peritoneal dialysis ("APD"), including tidal flow APD and continuous flow peritoneal dialysis ("CFPD"). CAPD is a manual dialysis treatment. The patient connects manually an implanted catheter to a drain, allowing spent dialysate fluid to drain from the peritoneal cavity. The patient then connects the catheter to a bag of fresh dialysate, infusing fresh dialysate through the catheter and into the patient. The patient disconnects the catheter from the fresh dialysate bag and allows the dialysate to dwell within the

peritoneal cavity, wherein the transfer of waste, toxins and excess water takes place. After a dwell period, the patient repeats the manual dialysis procedure, for example, four times per day, each treatment lasting about an hour. Manual peritoneal dialysis requires a significant amount of time and effort from the patient, leaving ample room for improvement.

[0008] Automated peritoneal dialysis ("APD") is similar to CAPD in that the dialysis treatment includes drain, fill, and dwell cycles. APD machines, however, perform the cycles automatically, typically while the patient sleeps. APD machines free patients from having to manually perform the treatment cycles and from having to transport supplies during the day. APD machines connect fluidly to an implanted catheter, to a source or bag of fresh dialysate and to a fluid drain. APD machines pump fresh dialysate from the dialysate source, through the catheter, into the patient's peritoneal cavity and allow the dialysate to dwell within the cavity and the transfer of waste, toxins and excess water to take place. APD machines pump spent dialysate from the peritoneal cavity, through the catheter, to the drain. As with the manual process, several drain, fill and dwell cycles occur during APD. A "last fill" occurs at the end of CAPD and APD, which remains in the peritoneal cavity of the patient until the next treatment.

[0009] Both CAPD and APD are batch type systems that send spent dialysis fluid to a drain. Tidal flow systems are modified batch systems. With tidal flow, instead of removing all the fluid from the patient over a longer period of time, a portion of the fluid is removed and replaced after smaller increments of time.

[0010] Continuous flow or CFPD systems clean or regenerate spent dialysate instead of discarding it. The systems flow fluid into or out of the patient, through a loop. Dialysate flows into the peritoneal cavity through one catheter lumen and out another catheter lumen. The fluid exiting the patient passes through a reconstitution device that removes waste from the dialysate, e.g., via a urea removal column that employs urease to enzymatically convert urea into ammonia. The ammonia is then removed from the dialysate by adsorption prior to reintroduction of the dialysate into the peritoneal cavity. Additional sensors are employed to monitor the removal of ammonia. CFPD systems are more complicated typically than batch systems.

[0011] Hemodialysis, APD (including tidal flow) and CFPD systems can employ a pumping cassette. The pumping cassette typically includes a flexible membrane that is moved mechanically to push and pull dialysis fluid out of and into, respectively, the cassette. Certain known systems include flexible sheeting on one side of the cassette, while others include sheeting on both sides of the cassette. Positive and/or negative pressure can be used to operate the pumping cassettes.

[0012] One problem with the pumping cassettes is leakage. If the flexible membranes experience a pinhole or tear, fluid and air can move from one side of the membrane to the other. Movement of fluid from inside the cassette to the inner workings of the machine can damage the machine. Movement of air from the machine into the cassette can compromise the sterility of the fluid pathways defined by the cassette. There are detection systems that determine when fluid leaks from the cassette to the machine. It is more difficult, however, to detect fluid leaking into the cassette.

ing of one or more solutions, via one or more pumps and to one or more destinations is provided. The system and method are illustrated with respect to CFPD but are also applicable to APD and hemodialysis. The expert system uses a set of rules. The rules are derived from physical limitations, e.g., fluid flow connections and pumping state limitations. The rules are also derived from therapy limitations, e.g., it is undesirable to pump concentrate directly to ultrafiltrate collection, and arbitrary limitations, e.g., no partial pump strokes.

[0037] The expert system also accounts for a number of parameters inputted by the patient or doctor. The system applies various algorithms to the inputted values to yield the output requirements for the therapy, e.g., overall flow volume, flowrate, therapy time, total concentrate added, etc. Using the outputs and the rules or restrictions, the expert system develops a pumping schedule having a number of entries. Each entry directs one or more pump to pull or push from one or more solution or to one or more destinations, respectively. The controller of the system commands the pumps to execute the pumping profile set forth in the schedule. The schedule may represent a portion of the overall therapy, wherein the schedule is cycled a number of times until therapy is complete. In the end, the outputs are achieved according to the rules and other limitations, such as fluid pressure level limitations.

[0038] In yet another embodiment of the present invention, a port vent for venting air purged from the dialysis fluid is provided. The port vent is integral to the cassette and vents the priming volume as well as air entrained due to pumping and patient exhaust gases. The cassette-based port vent is molded integrally with the rigid portion of the cassette, taking advantage of the fact that the rigid portion is otherwise a molded structure. A filter, such as a 0.2 micron filter is then fixed, e.g., bonded, heat sealed, adhered or mechanically fixed, to the port vent. The filter is made of a material, such as PTFE, Gortex or other polymer, which can be bonded, heat sealed, adhered or fixed mechanically. In an embodiment, the filter is made of a hydrophobic material. Alternatively, the filter is bonded, heat sealed, adhered or fixed to a bushing that fits onto and is suitably attached to the molded port.

[0039] Moreover, in an embodiment an additional air separation chamber for a medical fluid system is provided. The cassette-based port vent provides a first venting mechanism that separates air entrained in the fluid at the point of pumping. After the dialysis fluid leaves the pumping cassette, however, the fluid passes through a heater. The addition of heat releases gas trapped in the solution. This additional released gas must also be purged before the solution enters the patient.

[0040] The additional gas separation chamber is located downstream from the fluid heater. The heat released gas rises to and is trapped at the top of the chamber, while the heated fluid passes through the bottom of the chamber. The chamber houses one or more capacitive sensors that detect the amount of gas in the chamber. When the amount reaches a predetermined level, one or more exhaust valve opens and allows the gas to vent.

[0041] The gases vent through a membrane. To keep the membrane dry, a series of exhaust valves may be employed. To this end, a sump fluid trap may alternatively or additionally be provided.

[0042] In still another embodiment, a gas separation device is provided that includes a series of valves that are operated sequentially. A fluid trap is provided in between the valves. The sequential operation of the valves and trap enables gas but not fluid to escape from the system.

[0043] In consideration of the embodiments described herein, it is therefore an advantage of the present invention to provide a cassette actuator assembly that houses both the pump and valve actuators.

[0044] Another advantage of the present invention is to provide a cassette-based medical fluid system having fail safe valve and pump actuation.

[0045] A further advantage of the present invention is to provide a cassette-based medical fluid system having a positive pressure gradient between the cassette fluid pathways and the outlying components of the dialysis machine.

[0046] Still another advantage of the present invention is to provide a cassette-based medical fluid system having a cassette auto-alignment feature.

[0047] Yet another advantage of the present invention is to provide a cassette-based medical fluid system having a cassette misalignment output and a cassette integrity feature.

[0048] Moreover, an advantage of the present invention is to provide an improved material for the flexible membrane of the cassette.

[0049] Still further, an advantage of the present invention is to provide a cassette-based medical fluid system having a multiplexing valve arrangement.

[0050] Further still, an advantage of the present invention is to provide a cassette-based medical fluid system having an expert fluid pumping management system that uses a knowledge base to derive a pumping schedule after parameters are inputted by a doctor/patient.

[0051] Still a further advantage of the present invention is to provide a cassette-based integrally formed port vent.

[0052] Yet a further advantage of the present invention is to provide an air separation chamber downstream of a medical fluid heater.

[0053] Moreover, a further advantage of the present invention is to allow the dialysis fluid to purge entrained gas while the fluid is being pumped.

[0054] Additional features and advantages of the present invention are described in, and will be apparent from, the following Detailed Description of the Invention and the figures.

BRIEF DESCRIPTION OF THE FIGURES

[0055] FIGS. 1 and 2 illustrate opposing views of an embodiment of a valve and pump actuation assembly having a valve/pump housing that houses in combination a valve manifold and a plurality of pump actuators.

[0056] FIG. 3 is a perspective view of one embodiment of a valve actuator used in the present invention.

[0057] FIG. 4 is a perspective view of a surface of the valve/pump housing illustrated in FIG. 1 that remains after a portion of the housing is cutaway, the surface showing vacuum and atmospheric air flow paths.

[0093] FIG. 1 illustrates that valve/pump housing 20 defines or is attached in an airtight manner to a raised bridge 58. Valves 40 and various ones of the connectors 50 and 52 mount to raised bridge 58. Raised bridge 58 allows the valve 40 to sit slightly above channels 60 and 62, so that ports 44 and 48 of the valve 40, respectively, can extend into channels 60 and 62. A suitable gasket may be placed about channels 60 and 62 between the surface 64 (FIG. 4) of housing 20 and bridge 58. Otherwise, bridge 58 is formed integrally with housing 20 or is permanently attached, e.g., welded, to housing 20.

[0094] FIG. 4 illustrates housing 20 with the bridge 58 removed, exposing channels 60 and 62 defined in surface 64. Removing bridge 58 also exposes various apertures defined by housing 20. For example, housing 20 defines a plunger aperture 66 for each pneumatic valve 40. The plunger port 46 of valve 40 (FIG. 3) extends into apertures 66. The gasket (not illustrated) surrounding channels 60 and 62 also surrounds each of the plunger apertures 66 in an embodiment. Plunger apertures 66 allow negative pressure or atmospheric air to extend from inner surface 64 of housing 20 to the valve plunger side of housing 20, illustrated in FIG. 5. It should be appreciated that the vacuum is supplied through connectors 50, through channel 60, through vacuum port 44, through plunger port 46, through plunger apertures 66 and through corresponding apertures defined by one or more of the plates 24 and 26 and front plate 30 to compress the plunger spring and open a fluid pathway in the disposable cassette. As illustrated below, the vacuum can also be bounted or housed in part by a flexible diaphragm, existing for example between two of the plates 24, 26 and 30.

[0095] Valve/pump housing 20 also defines valve sheeting apertures 68. Valve sheeting apertures 68 communicate fluidly with negative pressure connectors 56 illustrated in FIG. 1. Negative pressure connectors 56 communicate fluidly with a negative pressure source and enable a vacuum to be applied through the orifices of the valve plungers 42 (or around valve plungers 42) to the flexible membrane of the disposable cassette. The negative pressure source (not illustrated) pulls a vacuum through the connectors 56, through the valve sheeting apertures 68 and through the valve plungers 42 to seal the flexible membrane to the valve plungers.

[0096] Similar to the negative pressure for the valve sheet, valve/pump housing 20 defines, for each fluid pump, a pump sheeting aperture 72. Pump sheeting apertures 72 communicate fluidly with negative pressure inlet connectors 54, which in turn communicate fluidly with a negative pressure source (not illustrated). The negative pressure source pulls a vacuum through connectors 54, through apertures 72, through or around the piston 34 and piston head 36 to seal the flexible membrane of the disposable cassette to the piston head.

[0097] It should be appreciated that three separate vacuums in an embodiment are applied in connection with the valve/pump housing 20 of assembly 10. Namely, a first vacuum is applied to vacuum channel 60 defined by surface 64 of housing 20, a second vacuum is applied to seal the flexible membrane to the valve plungers and a third vacuum is applied to seal the flexible membrane to the pump piston heads 36. The fluid flow system can provide multiple vacuum sources that operate each of these vacuums sepa-

ately. Alternatively, one or more sources operate these vacuums sequentially. Further alternatively, the level of vacuum is the same for two or more of the required vacuums, wherein a single vacuum source can supply at least two of the vacuums simultaneously.

[0098] FIGS. 1 and 2 illustrate that assembly 10, including valve/pump housing 20, houses various types of sensors 74. The various types of sensors include but are not limited to pressure sensors, temperature sensors, liquid level sensors, air detection sensors, bubble sensors, volume measurement sensors, conductivity sensors, pH sensors, turbidity sensors, color detection sensors, particle sensors, and chemical sensors, etc. As illustrated, sensors 74 extend through housing 20, intermediate plates 24 and 26 and front plate 30. Sensor wiring and sensing leads extend into the dialysis machine from valve/pump housing 20. Sensing heads or sensor portions are located flush approximately with the face of front plate 30 and contact the disposable cassette to sense a fluid parameter of the dialysis fluid flowing through the cassette. A seal is made in an embodiment between the cassette and the front plate 30 around the sensors so that a vacuum can be applied, bringing the cassette membrane into intimate contact with the sensors. The vacuum is provided through assembly 10 around the sensors in a manner similar to that provided between the valve plungers 42 and the cassette membrane.

[0099] Referring to FIG. 5, the valve/pump housing 20 is illustrated showing surface 76, which opposes surface 64 illustrated above in connection with FIG. 4. For reference, a majority of the plunger apertures 66 that communicate with the plunger port 46 of pneumatic valve 40 are illustrated, as are the pump sheeting apertures 72 that communicate fluidly with the negative pressure inlet connectors 54. At least some of the valve plunger apertures 66 are located in the middle of the cavities or craters 78 defined by surface 76 of housing 20. Housing 20, defining cavities 78, is made in various embodiments of molded plastic or aluminum composite. Cavities or craters 78 enable the plungers and plunger seats (not illustrated) to engage properly with respect to plunger apertures 66. For reference, a plunger spring 70 is illustrated centered about an aperture 66, which in turn is centered in one of the cavities 78. Although not illustrated, it should be appreciated that the valve seats and valve plungers fit around spring 70 and sit inside or are supported by cavity 78.

II. Fail Safe Pump and Valve Operation

[0100] Referring now to FIGS. 6 to 11, various embodiments for operating the pumps and valves described above in connection with assembly 10 and valve/pump housing 20 are illustrated. FIGS. 1 to 5 illustrate an assembly 10, which includes a combination valve/pump housing 20 and adjoining plates 24, 26 and 30. The present invention is not however limited to the this configuration. FIGS. 6 to 8 for example show three alternative configurations that each include alternative valve/pump housings 120, 220 and 320, respectively. Each of the housings 120, 220 and 320 define an aperture 80 through which piston 34 moves back and forth to pump fluid to and from a disposable cassette 90. Disposable cassette 90 is illustrated schematically in its operating position with respect to the housings 120, 220 and 320. Disposable cassette 90 can have various forms and in an embodiment includes a rigid portion (term includes rigid

pression force of spring 86. In an embodiment, the deep vacuum applied to chamber 84 is from about -5 to about -30 psig.

[0110] When the deep vacuum is applied to chamber 84, a shallow vacuum is applied to chamber 82 simultaneously to pull lower flexible membrane 96 against the retracting piston head 36. The shallow vacuum is between 0 and -10 psig. in one embodiment. A rolling diaphragm 98 is provided between member 88 and an inner wall of vacuum chamber 84. The diaphragm 98 seals to member 88 and the inner wall and separates the vacuums applied to chamber 82 and chamber 84. The back and forth movement of member 88, piston 34 and piston head 36 due to the expansion and retraction of spring 86 and the alternating application of a deep vacuum and a shallow vacuum to chamber 84 guides the rolling diaphragm 98 so that a nearly frictionless linear movement is generated.

[0111] When the deep vacuum 84 is removed so that spring 86 begins to expand, it is possible that due to the movement of the piston assembly or to a continuing shallow vacuum in chamber 82, rolling diaphragm 98 will invert from the generally downwardly extending orientation shown in FIG. 6. To prevent this from happening, a shallow vacuum is applied in chamber 84 during the push fluid stroke. The shallow vacuum in chamber 84 is also between 0 and -10 psig. in one embodiment. The shallow vacuum in an embodiment is the same shallow vacuum applied to chamber 82 so that the force on either side of the diaphragm 98 via the shallow vacuums cancel one another. The shallow vacuum in chamber 84 is not large enough to overcome the spring constant of spring 86. Spring 86 is sized to apply the appropriate amount of force via piston head 36 to the lower flexible membrane 96, which can be as high as 35 lbs., taking into account that a negative force via the shallow vacuum in chamber 84 is acting against spring 86 during the pump out or dispel stroke.

[0112] FIGS. 6 to 8 illustrate one preferred sequence for operating multiple pumps. Pump pistons 34 move in and out alternatively, filling and emptying associated pump fluid chambers defined between rigid portion 92 and lower flexible membrane 96. The alternating pumps create a virtually constant flow of fluid to the patient. Dialysate intake and exhaust valves defined in part by disposable cassette 90 are opened and closed in conjunction with the movement of the pump pistons 34. In an embodiment, an intake valve (not illustrated) is open as an associated pump piston 34 retracts. The intake valve closes when the pump piston 34 extends towards cassette 90. The dialysis cassette also defines an exhaust valve that is closed as the associated pump piston retracts. The exhaust valve opens as the pump piston extends into cassette 90.

[0113] FIG. 7 illustrates an alternative pump actuator housed inside housing 220. The shallow vacuum is again applied to chamber 82, for example, via an orifice in pump piston 34 and piston head 36. The shallow vacuum draws the lower flexible membrane 96 up against pump piston heads 36. As in any of the embodiments described herein, the shallow vacuum within chamber 82 can be maintained or not maintained when pump piston 34 extends toward cassette 90 to dispel fluid from cassette 90. In FIG. 7, the member 88 and rolling diaphragm 98 of FIG. 6 are replaced by a cylinder 102 defining a deep vacuum chamber 104. A piston

rod 106 attaches to piston 34 and seals against an inner surface of cylinder 102 via seals 108. A shaft seal, which can be of any known type, hereafter referred to as o-ring 112 is also placed within housing 220 between shaft opening 80 and the piston 34 to maintain the vacuum within chamber 82.

[0114] The operation of the cylinder 102 and cylinder rod 106 in conjunction with piston 34 is substantially the same as described above with diaphragm 98 and spring 86 of FIG. 6. In FIG. 7, a spring 114 is provided within each cylinder 102. The spring 114 pushes against cylinder rod 106, which in turn pushes piston 34 and piston head 36 towards rigid cassette 90. In an alternative embodiment, piston rod 106 can be eliminated, wherein piston 34 seals directly to the inner surface of cylinder 102, and wherein spring 114 is sized to push directly against piston 34. To withdraw the piston 34, a deep vacuum is applied to chamber 104 within cylinder 102, which overcomes the spring constant and compression resistance of spring 114.

[0115] Because the rolling diaphragm is not used, a shallow vacuum need not be maintained within chamber 104 in connection with the pump-out or fluid dispelling stroke. A shallow vacuum may be maintained within chamber 82 as described above, however, upon the pump-out or fluid dispelling stroke. Spring 114 does not need to overcome a residual negative pressure as in the case with embodiment of FIG. 6. Spring 114 may therefore be of a slightly decreased strength with respect to spring 86 and the deep vacuum may accordingly be slightly less than the deep vacuum employed with FIG. 6.

[0116] In an alternative embodiment, a positive pressure is applied outside of cylinder 102 to push rod 106 and compress spring 114 as opposed to drawing a vacuum within chamber 104 of cylinder 102. The o-ring seal 112 is still required to separate the positive pressure outside of cylinder 102 from the vacuum introduced into chamber 82. When the positive pressure is relieved, spring 114 pushes rod 106 and piston 34 as described above.

[0117] Referring now to FIG. 8, a further alternative embodiment eliminates the deep vacuum altogether and instead uses an electrically operated linear or rotary/linear actuator 32. Actuator 32 is also illustrated above in connection with FIG. 1. Linear actuator 32 in an embodiment is a linear stepper motor, a rotary stepper motor coupled to a lead or ball screw, a rotary servo motor coupled to a lead or ball screw or other type of electrically, pneumatically or hydraulically operated linear actuator. Pump actuator 32 couples in an embodiment directly to piston 34 via a coupler 116, which in an embodiment allows for slight misalignment between piston 34 and an output shaft of pump actuator 32. Pump actuator 32 eliminates altogether the need for the vacuum chamber 84, the deep vacuum and the residual shallow vacuum. A shallow vacuum is still required in chamber 82 to pull lower flexible membrane 96 away from rigid portion 92 when piston head 36 retracts away from cassette 90. O-ring 112 is provided between opening 80 in housing 320 and shaft 34 to form in part the enclosed vacuum chamber 82.

[0118] Referring now to FIG. 9, a further alternative embodiment for a pump actuator is illustrated. A portion of a housing 420 is illustrated. Housing 420 includes many of the same components as housing 120, such as the a shallow

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107

32. The system of claim 29, wherein the valves move valve plungers to contact a membrane made of a material that includes a polyolefin.

33. A medical fluid pump comprising:

a pump piston having a piston head;

a flexible membrane that moves to pump medical fluid;

a spring biased to push the piston head toward the flexible membrane; and

a diaphragm that moves with the piston and enables negative pressure to be applied that compresses the spring.

34. The medical fluid pump of claim 33, wherein the diaphragm is sealingly coupled to the piston.

35. The medical fluid pump of claim 33, wherein the spring is coupled to the piston and moves the piston when compressed.

36. The medical fluid pump of claim 35, which uses negative pressure to draw the membrane toward the piston head when compressing the spring and moving the piston.

37. The medical fluid pump of claim 33, wherein the spring is disposed in a cavity, the cavity is defined at least partially by the diaphragm and the negative pressure is applied to the cavity.

38. The medical fluid pump of claim 33, wherein the negative pressure is applied at a first level to compress the spring and at a second level when the spring biases the piston head towards the membrane to hold the diaphragm in a desired position.

39. The medical fluid pump of claim 38, wherein the second vacuum level is less than the first vacuum level.

40. The medical fluid pump of claim 33, wherein the membrane is attached to a rigid portion of a disposable cassette and the fluid is pumped between the membrane and the rigid portion.

41. The medical fluid pump of claim 40, wherein the spring biases the membrane towards the rigid portion.

42. The medical fluid pump of claim 33, wherein the diaphragm is a first diaphragm and which includes a second diaphragm that moves with the piston and enables negative pressure to be applied between the piston head and the membrane.

43. The medical fluid pump of claim 42, wherein the second diaphragm is coupled sealingly to the piston.

44. The medical fluid pump of claim 42, wherein the negative pressure applied between the piston head and the membrane holds the second diaphragm in a desired orientation as the piston moves.

45. The medical fluid pump of claim 42, which includes a space between the first and second diaphragms, the space maintained at atmospheric or positive pressure.

46. The medical fluid pump of claim 42, wherein the negative pressure is applied to the first diaphragm at a first level to compress the spring and at a second level when the spring biases the piston head towards the membrane to hold the first diaphragm in a desired position.

47. The medical fluid pump of claim 33, wherein the negative pressure is applied cooperatively to compress the spring and pull the membrane to the piston head.

48. The medical fluid pump of claim 47, which includes a plurality of negative pressure sources that apply the cooperative negative pressures.

49. A medical fluid pump comprising:

a flexible membrane that is moveable to pump medical fluid;

a cylinder;

a spring-loaded piston disposed inside the cylinder, the piston having a base at one end and piston head at the other end, the spring biased to push the head toward the membrane; and

a pressure source that applies pressure within the cylinder to compress the spring.

50. The medical fluid pump of claim 49, wherein the pressure is a negative pressure applied at the base to compress the spring.

51. The medical fluid pump of claim 50, wherein negative pressure is applied additionally to draw the membrane toward the piston head when compressing the spring and moving the piston.

52. The medical fluid pump of claim 49, wherein the pressure is a positive pressure applied near the piston head end of the piston to compress the spring.

53. The medical fluid pump of claim 52, which includes a negative pressure source that applies a negative pressure to draw the membrane toward the piston head when compressing the spring and moving the piston.

54. A medical fluid valve comprising:

a valve plunger;

a flexible membrane that moves to allow and restrict fluid flow;

a spring biased to push the plunger toward the flexible membrane; and

a diaphragm that moves with the plunger and enables a negative pressure to be applied that compresses the spring.

55. The medical fluid valve of claim 54, wherein the plunger includes a compliant member to aid in sealing the plunger to the membrane.

56. The medical fluid valve of claim 54, wherein the diaphragm is coupled sealingly to the plunger.

57. The medical fluid valve of claim 54, wherein the spring is disposed in a chamber, the chamber defined at least partially by the diaphragm, the negative pressure applied to the chamber.

58. The medical fluid valve of claim 54, wherein the spring is coupled to the plunger and moves the plunger when compressed.

59. The medical fluid valve of claim 54, wherein negative pressure is applied additionally to draw the membrane toward the plunger when compressing the spring and moving the plunger.

60. The medical fluid valve of claim 59, wherein the negative pressure is applied at a different magnitude to compress the spring than to draw the membrane.

61. The medical fluid valve of claim 54, wherein the membrane is attached to a rigid portion of a disposable, the membrane, when pulled away from the rigid portion, creating a fluid pathway between apertures defined by the portion.

62. The medical fluid valve of claim 54, wherein the membrane is made of a material including a polyolefin.

63. A system for performing dialysis comprising:

a patient line;

119 108

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES**

2020
Bogotá, D.C.,

Abogada
✓ ALICIA LLOREDA RICAURTE

ASUNTO Radicación 07 093 561
 Trámite 011
 Evento 379
 Actuación 519
 Oficio
 Folios 012

05874

Patente de Invención ☒ Patente de Modelo de Utilidad ☐
Vía Nacional ☐
Vía PCT (fase nacional) ☒ Cap. I ☐ Cap. II ☐
No. Solicitud Internacional PCT/US2006/003921
Fecha de Presentación Internacional 06/Febrero/2006

Como resultado del Examen de Fondo realizado, con fundamento en el Artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados

Descripción: Folios 11 a 39 como se radicó inicialmente.
Reivindicaciones: Folios 40 a 43 como se radicó inicialmente
Dibujos: Folios 44 a 52 como se radicó inicialmente
Prioridad: US 11/069,195 de Febrero 28 de 2005

2. Análisis de la Prioridad

Se acepta la reivindicación de Prioridad porque esta solicitud fue presentada dentro del plazo establecido (Art. 9 D 486) y su contenido técnico corresponde con el de la prioridad reivindicada

3. Objeto de la invención

Título de la solicitud: "Aparato portátil para terapia de diálisis peritoneal".

El problema planteado en esta solicitud es la necesidad de una máquina para diálisis peritoneal portátil, de fácil manejo, de operación a varios niveles de altura respecto al paciente, que no requiera fuerza física y que sea segura para el paciente.

Para resolver este problema técnico la solicitud en estudio proporciona un aparato para el bombeo de fluidos entre una máquina de diálisis peritoneal y un paciente, incluyendo un par de bombas de diafragma de carrera variable y de operación por

separado o en tándem, unas cámaras que reciben fluido corporal del paciente y otra que le bombea solución de diálisis peritoneal, y un casete desechable que sella y cierra herméticamente utilizando presión de aire.

Clasificación Internacional de Patentes (CIP): A 61M 1/00

4. No es una invención (Art 15 D 486 literal (f))

El objeto de la reivindicación 4 no se considera una invención, de acuerdo con el Art citado.

5. Excepción a la Patentabilidad (Art 20 D 486 literales (d))

El objeto de la reivindicación 4 no es patentable, de acuerdo con el Art citado.

6. Reivindicaciones relativas a un uso o a un segundo uso (Art 14 y 21 D 486)

El uso de la reivindicación 4 que se refieren a uso no es patentable de acuerdo con los Art citados.

7. De la Solicitud de Patente

Título

El título corresponde con el objeto de la solicitud.

Reivindicaciones (Art 30 D 486, Art 22 PCT)

La Reivindicación 4 no es clara porque indica el uso que puede darse al producto reivindicado, el cual no es una característica técnica que defina a la invención. Se sugiere hacer la aclaración respectiva.

Se sugiere hacer una revisión general de las reivindicaciones independientes 1, 2, 5 y 6, dado que las características técnicas esenciales que definen al aparato portátil son los elementos que lo conforman y la relación que existe entre ellos. De esta forma al observar las reivindicaciones se tiene que en la reivindicación 1 no se menciona en el preámbulo que sea un aparato portátil como se encuentra en el título de la invención y en la descripción. Se sugiere revisar y aclarar la posibilidad de la dependencia de las reivindicaciones 2, 5 y 6 respecto a la reivindicación 1 pues pueden ser dependientes de esta.

Se requiere al Solicitante hacer las aclaraciones necesarias.

Descripción (Art 28 D 486)

La Descripción es clara porque la información que contiene permite que el experto en la materia pueda comprender el problema técnico y la solución aportada por la invención.

8. Unidad de invención (Art 25 D 486)

La Solicitud no cumple con el Requisito de Unidad de Invención porque se refiere a varios grupos Inventivos. Se entiende que la reivindicación 1 "aparato para bombear fluidos entre una maquina y un paciente", la reivindicación 2 "aparato de bombear fluidos", la reivindicación 5 "aparato para medir presión" y la reivindicación 6 "casete

desechable para transportar fluidos”, dan a entender de la forma como esta escrito que no formarían parte del aparato objeto de esta solicitud y no se sabe cual es la invención que se va a proteger con claridad o si son varias invenciones.

Se sugiere presentar las Solicitudes Divisionales que considere necesarias.

9. Determinación del Estado de la Técnica

El estado de la técnica se determinó con base en la fecha de presentación de prioridad: Febrero 28 de 2005 y se encontró los siguientes documentos que anticipan el objeto de esta solicitud:

Item	Documento	Título	Fecha de Publicación
D1	US2004019313A1	Systems, methods and apparatuses for pumping cassette-based therapies	29/Enero/2004

D1 divulga (Resumen) Sistemas, métodos y aparatos para el bombeo de terapias basadas en casetes.

10.Examen de Patentabilidad (Art 14 D486)

Novedad (Art 16 D486)

La reivindicación 1 consiste en un aparato para bombear fluidos entre una máquina de diálisis peritoneal y un paciente para realizar la diálisis peritoneal en el paciente, que comprende un par de bombas de diafragma, cámaras que contienen el fluido, un motor de pasos acoplado a cada bomba y un control de motor de pasos digital.

Comparación de las características técnicas **esenciales**, con las del Estado de la Técnica:

Características esenciales	D1
Bombas de diafragma de carrera variable	✓
Cámaras que contienen el fluidos una para recibir y otra para entregar	✓
Motor de pasos acoplado a cada bomba	✓
Control de motor de pasos digital	✓

Las características **esenciales** del aparato de la reivindicación 1 habían sido divulgadas previamente en D1, el cual enseña bombas de diafragma (reivindicación 34), cámaras de fluidos (Resumen Renglón 11), Motor de Paso (descripción, Párrafo [0117] Renglones 3, 6 y 7) y control de motor (descripción, Párrafo [0037] Renglones 10 a 16).

En consecuencia, la reivindicación 1 carece de novedad, según lo divulgado en el documento D1.

La reivindicación 2 consiste en un aparato para bombear fluidos entre una máquina y un paciente y que incluye un compartimento de casete, que comprende dos superficies planas para albergar el casete y mecanismo de sujeción.

Comparación de las características técnicas **esenciales**, con las del Estado de la Técnica:

Características esenciales	D1
Superficies planas para albergar el casete	✓
Mecanismo de sujeción de cojín inflable	✓

Las características **esenciales** del aparato de la reivindicación 2 habían sido divulgadas previamente en D1, el cual enseña, superficies planas para albergar el casete (Fig. 12, elementos 30 y 182) y un mecanismo de sujeción de membrana de bombeo (Resumen, Renglón 9 y Reivindicación 36), similar a cojín inflable.

En consecuencia, la reivindicación 2 carece de novedad, según lo divulgado en el documento D1.

La reivindicación 5 consiste en un aparato para medir la presión en una máquina de diálisis peritoneal, que comprende un casete removible, mecanismo de sujeción, sensor de presión y una conexión entre el sensor de presión y un control electrónico.

Comparación de las características técnicas **esenciales**, con las del Estado de la Técnica:

Características esenciales	D1
Superficies planas para albergar el casete	✓
Mecanismo de sujeción de cojín inflable	✓
Sensor de Presión	✓
Conexión entre sensor y controlador electrónico	✓

Las características **esenciales** de el aparato para medir la presión en una máquina de diálisis peritoneal de la reivindicación 5 habían sido divulgadas previamente en D1, el cual enseña, superficies planas para albergar el casete (Fig. 12, elementos 30 y 182) y un mecanismo de sujeción de membrana de bombeo (Resumen, Renglón 9 y Reivindicación 36), similar a cojín inflable, sensor de presión (Reivindicación 6) y conexión entre el sensor y el controlador electrónico (Descripción, Párrafo [0098] renglones 10 y 11).

En consecuencia, la reivindicación 5 carece de novedad, según lo divulgado en el documento D1.

La reivindicación 6 consiste en un casete desechable para transportar fluidos hacia y desde un paciente que se somete a una diálisis peritoneal, que comprende un compartimento flexible para contener fluido, pasajes de ingreso y egreso conectados al compartimento y una superficie exterior del casete que se acopla al dispositivo de detección de presión.

Comparación de las características técnicas **esenciales**, con las del Estado de la Técnica:

Características esenciales	D1
Compartimento flexible para contener fluido	✓
Pasajes de ingreso y egreso	✓
Superficie exterior en contacto con sensor de presión	✓

Las características **esenciales** del casete desechable de la reivindicación 6 habían sido divulgadas previamente en D1, el cual enseña, un compartimento flexible (Descripción, párrafo [0011] Renglón 3), pasajes de ingreso y egreso (Reivindicación 69) y superficie exterior en contacto con sensor de presión (Descripción, Párrafo [0098] renglón 13).

En consecuencia, la reivindicación 6 carece de novedad, según lo divulgado en el documento D1.

Aplicación industrial (Art 19 D 486)

Las reivindicaciones 1 – 7, tienen aplicación industrial.

11. Conclusión

Los requisitos de Patentabilidad de la presente Solicitud están afectados así:

Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US2004082903A1	1 - 7	Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta (60) días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única No. 10 de 2001.



JOSÉ LUIS SALAZAR LOPEZ
Director de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha
_____ **01 ABR. 2000**

CONCEPTO TÉCNICO No. 1000	EXAMINADOR TÉCNICO Código No. 2020102
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