An artificial kidney system includes a dialyzer element through which blood of a patient and dialysate solution are circulated to enable transfer of waste, electrolytes, water and other components from the blood to the solution (and in some cases from the solution to the blood), blood pump and circulation apparatus for withdrawing blood from the patient and applying it to the dialyzer element and for returning blood from the dialyzer element to the patient, and dialysate pump and circulation apparatus for transporting dialysate solution from a dialysate source to the dialyzer element and from the dialyzer element to a dialysate sink. The blood and the dialysate pump apparatus each includes a flexible casing which, when compressed, forces fluid from the casing and which, when released, draws fluid into the casing. The dialysate circulation apparatus includes a variable volume accumulator jacket for receiving dialysate solution when the pump casing is compressed and for discharging dialysate solution when the pump casing is released. A pump actuator operates the blood pump apparatus and the dialysate pump apparatus to circulate blood and dialysate solution through the dialyzer element.
PORTABLE ARTIFICIAL KIDNEY SYSTEM

BACKGROUND OF THE INVENTION

This invention relates to artificial kidney systems and more particularly to a compact, portable and lightweight artificial kidney.

Artificial kidney systems have been in use for some time and have proven effective as partial replacements for defective human kidneys. In the use of such systems, blood is withdrawn from a patient and applied to a dialyzer through which dialysate solution is circulated. By the process of dialysis, chemical wastes, electrolytes and water in the blood pass into the dialysate solution (and in some cases vice versa) through the thin walls of membrane structure, such as hollow fibers, carrying the blood. The dialysate solution containing the wastes and water is drawn from the dialyzer and disposed of and the blood is returned to the patient. This process of transporting wastes and water from the blood is referred to as hemodialysis.

Although the artificial kidney systems or hemodialyzers in current use are effective, they cause blood damage, are large in size, cumbersome, complicated and generally unsuitable for transport. Part of the reason for this is that the pumps utilized in such systems are themselves large and heavy and require considerable tubing for carrying the blood and dialysate solution. The use of large volume baths of dialysate solution also contributes to the lack of portability of the prior art systems.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a compact, portable artificial kidney system.

It is another object of the present invention to provide an artificial kidney system which includes a novel, efficient and lightweight pumping and hydraulic apparatus.

It is an additional object of the present invention to provide an artificial system in which the pumping and suction pressure for moving blood and dialysate solution can be predetermined and controlled with a high degree of precision and reliability.

It is further object of the present invention, in accordance with one aspect thereof, to provide an artificial kidney system in which the dialysate source and sink may be combined in a single filter and chemical treatment element to provide a closed dialysate circulation system.

These and other objects of the present invention are realized in a specific illustrative embodiment which includes a dialyzer element through which blood of a patient and dialysate solution are circulated to enable transfer of undesirable chemicals and water from the blood to the solution, a blood transporting system for transporting blood from the patient to the dialyzer element and from the dialyzer element back to the patient, a dialysate transporting system for transporting dialysate solution to the dialyzer element and from the dialyzer element, and first and second pumps coupled into the blood transporting system and dialysate transporting system for causing the blood and the dialysate solution to flow in the blood transporting system and dialysate transporting system respectively. The system also includes apparatus for operating both the first pump and the second pump to produce a pulsating pumping action for the blood and dialysate solution.

In accordance with one aspect of the invention, each of the pumps includes a flexible casing which, when alternately compressed and released, develops the pressure and suction necessary to cause the blood and dialysate solution to flow in their respective transporting systems.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, together with other and further objects and features thereof, reference is had to the following description taken in connection with the accompanying drawings described as follows:

FIG. 1 is an overall diagrammatic showing of one illustrative embodiment of the present invention;

FIG. 2 is a cross-sectional view of a pump of the type shown in FIG. 1;

FIG. 3 shows a cross-sectional view of the vacuum regulator of FIG. 1;

FIGS. 4A-4C show top views of the blood and dialysate solution pumps together with the pump actuator and retaining plates;

FIGS. 5A-5C show end views of the blood and dialysate solution pumps also with the pump actuator and retaining plate;

FIGS. 6A and 6B show end views of an alternative embodiment of the blood and dialysate solution pumps and pump actuator; and

FIG. 7 shows a top view of the embodiment of FIGS. 6A and 6B with the pump casings compressed.

FIG. 8 shows a full-cycle pump made in accordance with the present invention.

DETAILED DESCRIPTION

A diagrammatic view of the artificial kidney system or hemodialyzer of the present invention is shown in FIG. 1. The system generally includes a blood transporting system 2 through which blood of a patient is circulated and a dialysate transporting system 6 through which dialysate solution is circulated. Both the blood and the dialysate solution are circulated through a dialyzer element 38 where chemical wastes and water are transported from the blood by the process of diffusion. Blood is carried through the dialyzer element 38 by a bundle of hollow fiber strands (or other suitable membrane structure), represented as a single tube 42 in FIG. 1, which are immersed in dialysate solution contained in the dialyzer element. As the blood is carried through the dialyzer element 38, chemical wastes and water transfer through the thin walls of the fiber strands into the solution. This process of hemodialysis is well known in the art and has been performed by artificial kidney systems for a number of years. The construction of dialyzer elements is also known in the art.

The blood transporting system 2 includes tubing 4, a pump 14, and a single-needle cannula 18. The cannula 18 is described more fully in copending application, Ser. No. 455,180. Of course, the blood transporting system 2 could also be used with conventional double-needle cannulas as well as the single-needle cannula. With the single-needle cannula, the pump 14 causes blood to be alternately withdrawn from and returned to the patient.

The pump 14 is coupled into the tubing 4 to provide the necessary pressure and suction for forcing the blood to circulate in the blood transporting system 2. As shown in greater detail in FIG. 2, the pump 14 in-
includes a flexible cylindrical-shaped casing 202 open at either end, an inlet check valve 210 coupled in one end of the casing, and an outlet check valve 202 coupled in the other end of the casing. Each valve includes a valve seat (214 and 222) and a valve head (218 and 226) for controlling the flow of blood into and out of the pump casing 202. The pump 14 of FIG. 2 is coupled into the blood circulation system 2 so that blood flows from the cannula 18 through the pump to the dialyzer element 38. It should be understood that the casing 202 could have shapes other than the cylindrical shape illustrated so long as the pumping action, to be described hereafter, is carried out.

The pump 14 is operated by compressing the pump casing by means of a compression element 16 and then releasing the casing. A motor 84 is mechanically coupled to the compression element 16 to cause it to alternately compress and release the casing. As the casing is compressed, as diagrammatically illustrated in FIG. 1, blood in the pump will force check valve 30 to close and the check valve 34 to open so that blood will flow from the pump to the dialyzer element 38. When the pump casing is released the resiliency of the casing will cause it to resume its normal shape thereby creating a vacuum which forces check valve 34 to close and check valve 30 to open to thereby draw blood from the patient through the cannula 18 into the pump. The valve 26 and pump 14 cooperate in a unique manner to provide a one-way flow of blood through the blood transporting system 2. When the pump casing is compressed, the pressure of the blood in the tubing 4 and thus in the valve 26 increases to a value greater than the atmospheric pressure causing the valve 26 to open and allow blood to flow from the tubing in the dialyzer element 38, through the valve 26 and the needle 22 back into the patient. When the pump casing is released, it creates a vacuum or negative pressure in the cannula 18 which is less than the atmospheric pressure so that the valve 26 is caused to close and blood is thereby withdrawn from the patient through the cannula 18 into the pump 14 and not from the tubing in the dialyzer element 38 through the valve 26 to the pump. The pump 14 and valve 26 thus cooperate to alternately withdraw blood from the patient into the pump 14 and then force the blood from the pump 14 into dialyzer element 38 and from the dialyzer element 38 back through the valve 26 to the patient. As indicated earlier, the cannula 18 and valve 26 are described fully in the aforesaid copending application.

The pump 14 provides a non-occlusive pumping action which, unlike certain other pumps presently used in artificial kidney systems—such as the roller pump, does very little damage to the blood during the pumping operation. (With the roller pump, blood caught between the walls of the tubing being "rolled" by the pump roller is oftentimes damaged.) Also, very little tubing is needed with the pump 14 so that the foreign surface area which the blood must contact during the dialysis process is minimized.

The casing of the pump 14 might illustratively be made of latex rubber, silicone rubber or other suitably resilient material. A wall thickness of substantially one-eighth of an inch has been found suitable for the casing, using either latex rubber or silicone rubber, to develop the suction necessary to withdraw the blood from the patient.

The dialysate transporting system 6 of FIG. 1 provides for transporting dialysate solution from a dialysate source to the dialyzer element 38 and for transporting dialysate solution from the dialyzer element 38 to a dialysate sink. In the FIG. 1 embodiment, a chemical removal canister 46 acts as both the dialysate source and dialysate sink. The canister 46 contains a bed of activated charcoal particles and other chemical agents 48 for processing the dialysate solution as it flows through the canister. The canister 46 is divided into a receiving compartment 50 into which dialysate solution is pumped from the dialyzer element 38, and a discharging compartment 54, from which dialysate solution is taken for transport to the dialyzer element 38. Division of the canister 46 in this manner forces the dialysate solution to flow through the charcoal particles and other chemical agents to thereby provide maximum processing of the dialysate solution. The dialysate solution is pumped into the dialyzer element 38 to circulate about the hollow blood-carrying fibers represented by the tube 42 to facilitate the process of dialysis previously described.

Although the dialysate source and sink are combined in the canister 46, it should be understood that the FIG. 1 system could be used with the conventional separate source and sink.

The dialysate transporting system 6 includes a pump 52, of similar construction as the pump 14 of the blood transporting system 2, for causing the dialysate solution to circulate through the dialyzer element 38. The pump 52 is interposed in that portion of the dialysate transporting system which carries solution from the dialyzer element 38 to the canister 46. The motor driven compression element 16 which operates pump 14 also operates pump 52.

The dialysate transporting system 6 also includes an accumulator 66, whose function will be explained momentarily, a collector 70, whose function will also be explained momentarily, and a vacuum regulator 74 by which the vacuum of the dialysate solution within the dialyzer 38 may be controlled. The accumulator 66 is coupled into the dialysate transporting system 6 to receive dialysate solution when the pump 42 is compressed and then to discharge solution back into the system when the pump 42 is released. The accumulator 66, in effect, accounts for the change in volume of the dialysate transporting system resulting from operation of the pump 42. (This is necessary because the dialysate transporting system 6 of FIG. 1 is a "closed" system, unlike a transporting system in which the dialysate source and sink are separate. In such a case, no accumulator would be needed.) When the volume is decreased due to compression of the pump, solution is forced into the accumulator 66 and when the volume is increased again as a result of releasing the pump 42, the solution is drawn from the accumulator 66 back into the system. The accumulator 66 is a variable-volume container and could, advantageously, be constructed of a flexible jacket whose walls expand and contract when dialysate solution is respectively received into and discharged from the accumulator.

The collector 70 is provided to receive excess solution produced as a result of the passage of chemicals and water from the blood into the dialysate solution in dialyzer element 38. The chemicals and water passing from the blood into the dialysate solution, of course, increase the volume of the solution giving rise to a need
for some means of accommodating this increase. The collector 70 is coupled into the dialysate transporting system to receive and retain this excess fluid. The collector 70 is a variable-volume container and, advantageously, is comprised of a collapsible disposable bladder, similar to a common balloon, which is capable of expanding as the volume of solution in the dialysate transporting system increases. The bladder is coupled into the system by means of a check valve 72 which, when the pressure in the system exceeds some threshold level, allows fluid to flow into the bladder, but prevents fluid from flowing back into the transporting system. The check valve 72 could be of the same construction as the valve 210 of FIG. 2, or could be a spring loaded valve similar to that to be described in conjunction with FIG. 3.

The collector 70 is positioned near a volume detector switch 76 so that when the bladder of the collector fills with excess solution and expands to a certain volume, the bladder wall contacts a feeler arm 80 operating the switch 76 which then generates a signal to sound an alarm or turn off the motor 84, as desired. In this manner, the volume of solution in the dialysate transporting system 6 is monitored so that when the volume exceeds some predetermined value, the volume detector switch 76 is actuated to sound an alarm or turn off the pump motor 84. The collector 70 could then be removed for disposal of the excess solution and then replaced in the dialysate transporting system for further operation of the kidney system. The switch 76 may be any conventional electrical switch having a pair of contacts which close when the feeler arm 80 is moved a certain distance to thereby generate the appropriate signal.

One embodiment of the vacuum regulator 74 of FIG. 1 is shown in FIG. 3. The regulator includes a reservoir 302 through which the dialysate solution is passed from the canister 46 to the dialyzer element 38 (FIG. 1). An element 310 having a threaded bore is positioned at one end of the reservoir 302 for receiving a complementarily threaded screw 306. Attached to the end of the screw is a coil spring 314 which carries a plug or ball 318 on its free end. As can be seen from FIG. 3, when the screw 306 is screwed into the element 310, the ball 318 is moved closer to an orifice 322 through which dialysate solution is received, and when the screw 306 is unscrewed from the element 310 the ball 318 is moved further from the orifice 322. The ball 318 serves as a partial obstruction to the flow of fluid through the orifice 322 to thereby regulate the rate and pressure of such flow. If it is desired to decrease the rate of flow, then, of course, the ball 318 is moved closer to the orifice 322 and if it is desired to increase the flow, the ball 318 is moved further from the opening 322. Numerous other arrangements could be provided for controlling the rate of flow of the dialysate solution.

As indicated earlier, the pumps 14 and 52 are operated by a motor driven compression element 16. The pumps may be arranged so that the compression element 16 alternately compresses and releases one pump casing and then compresses and releases the other pump casing to provide a counter-pulsating pumping action in the blood transporting system 2 and the dialysate transporting system 6. The physical arrangement of the pumps 14 and 52 and the compression element 16 for such a configuration is best seen in composite FIG. 4 and composite FIG. 5 as will next be described.

As shown in composite FIG. 4, the two pumps 14 and 52 are positioned side-by-side, with the compression element 16 disposed between the pumps. A retaining plate 410, having an internal surface which conforms to the exterior surface of the casing of the pump 14, is positioned to one side of and in contact with the pump 14. A similar retaining plate 414 is positioned to one side of the pump 52. By shaping the contacting surface of the retaining plates to conform to the corresponding pump casings, the retaining plates prevent deformation of the casing surface contacted by the plates when the casings are compressed by the compression element 16. Shaping the retaining plate surfaces to conform to the casing wall surface shape also serves to increase the pumping and suction pressures achievable with the pumps (compared, for example, to simply compressing the pump casing between two flat plates). Because the pumping and suction pressure developed by the pumps of the type disclosed varies with the shape of the retaining plates used, pumping and suction pressure can, in part, be controlled by appropriate selection of the shape of the retaining plates. Control of the pumping and suction pressure can also be obtained by appropriate selection of casing wall thickness and material resilience, with the greater thickness and resilience generally giving rise to greater pumping and suction pressure and with lesser thickness and resilience giving rise to lesser pumping and suction pressure. The combination of retaining plate shape and casing wall thickness and resilience therefore provides a simple and yet effective way of controlling pumping and suction pressures developed by the disclosed artificial kidney system.

FIGS. 4B and 4C show pump 52 being compressed by the compression element 16 and pump 14 being compressed by the compression element 16 respectively. The compression element 16 is actuated by the motor 84 shown in composite FIG. 5. The motor, by conventional linkage, causes the compression element 16 to alternately move the compressor first one pump casing and then the other in a pendulum-like fashion. With the positioning of the pump casings as shown, a single compression element may be used to operate both pumps. This provides a simple, effective and compact pump configuration.

An alternative pump configuration is shown in composite FIG. 6 and FIG. 7. With this configuration, the casings of the pumps 14 and 52 are compressed simultaneously and then released simultaneously by compression element 17. As shown in composite FIG. 6 and FIG. 7, the two pumps 14 and 52 are again positioned together, with the compression element 17 extending upward between the pumps. The element 17 includes a stem 17a and a horizontal head portion 17a to form a structural tee. The motor 84, again by conventional linkage, causes the compression element 17 to move between a "compressing" position, in which the casings of the pumps 14 and 52 are both compressed by the element 17 (FIG. 6B), and a "release" position, in which the casings of the pumps are released (FIG. 6A). FIG. 7 shows a top view of the pumps with the pump casings being compressed by the compression element 17.

Although the two pump configurations have been described for use in the artificial kidney system of FIG. 1, it is evident that the pumps could be used in a variety of applications requiring the the pumping of fluids.
FIG. 8 shows a "full-cycle" pump for use in either or both the blood transporting system 2 (provided a double-needle cannula is employed) and the dialysate transporting system 6. This pump includes two casings 802 and 804 positioned on either side of a compression element 806. Each casing is constructed similar to the pump shown in FIG. 2, each including an inlet and outlet and inlet and outlet valves. The two casings are coupled in parallel into a fluid-carrying line 808, with the inlets of each casing coupled to portion 808a of the line and the outlets coupled to portion 808b. The compression element 806 operates to compress and release first one of the casings and then the other. As one casing is compressed and the other released, the one casing forces fluid therefrom into the line portion 808b and the other casing draws fluid thereinto from the line portion 808a. Thus, with each stroke or half-cycle movement of the compression element 806, fluid is passed to the line portion 808b so that a type of full-cycle pumping action is developed. This may be contrasted with a so-called half-cycle pumping action which would be developed if only one casing were coupled into the line 808. Then, fluid would be passed from the casing to the line with every other stroke or half-cycle movement of the compression element 806.

It is to be understood that the above-described embodiments are only illustrative of the principles of the present invention. Other embodiments may be described by those skilled in the art without departing from the spirit and scope of the invention, and the appended claims are intended to cover such embodiments.

What is claimed is:

1. A hemodialyzer comprising
   a dialyzer element through which blood of a patient and dialysate solution are circulated to enable transfer of waste and water from the blood to the solution, blood transporting means for transporting blood from the patient to the dialyzer element and from the dialyzer element back to the patient, first pump means coupled into said blood transporting means, said pump means including a flexible casing which, when alternately compressed and released, causes blood to flow in said blood transporting means, a dialysate source and dialysate sink, dialysate transporting means for transporting dialysate solution from the dialysate source to the dialyzer element and from the dialyzer element to the dialysate sink, second pump means coupled into said dialysate transporting means, said second pump means including a flexible casing which, when alternately compressed and released, causes dialysate solution to flow in the dialysate transporting means, and means common to the first and second pump means for compressing and releasing the casings of said first and second pump means to produce a pumping action in the blood transporting means and the dialysate transporting means.

2. A hemodialyzer as defined in claim 1 wherein said dialysate source and sink include a canister coupled in the dialysate transporting means and through which dialysate solution flows, and

filter means disposed in the canister for collecting waste from the dialysate solution when the solution flows through the canister.

3. A hemodialyzer as defined in claim 2, comprising an accumulator means which includes a jacket, and means for coupling the jacket into said dialysate transporting means to enable passage of dialysate solution from said dialysate transporting means into said jacket and from said jacket to said dialysate transporting means.

4. A hemodialyzer as defined in claim 3 wherein said jacket is a flexible jacket.

5. A hemodialyzer as defined in claim 3 further comprising a collector means which is coupled into said dialysate transporting means for receiving excess dialysate solution.

6. A hemodialyzer as defined in claim 5 wherein said collector means includes a collapsible bladder.

7. A hemodialyzer as defined in claim 6 wherein said collector means further includes a check valve for allowing the flow of solution from said dialysate transporting means into the bladder and for preventing the flow of solution from the bladder to said dialysate transporting means.

8. A hemodialyzer as defined in claim 6 further including feeler means positioned to engage the collector bladder when the bladder fills to a predetermined volume, and switch means for generating a signal when the bladder engages said feeler means.

9. A hemodialyzer as defined in claim 5 wherein said accumulator means and collector means are interposed in that portion of the dialysate transporting means which carries dialysate solution from the canister to the dialyzer element, and wherein said second pump means is coupled into that portion of the dialysate transporting means which carries solution from the dialyzer element to the canister.

10. A hemodialyzer comprising a dialyzer element through which blood of a patient and dialysate solution are circulated to enable transfer of waste and water from the blood to the solution, blood transporting means for transporting blood from the patient to the dialyzer element and from the dialyzer element back to the patient, first pump means coupled into said blood transporting means, said pump means including a flexible casing which, when alternately compressed and released, causes blood to flow in said blood transporting means, a dialysate source and a dialysate sink, dialysate transporting means for transporting dialysate solution from the dialysate source to the dialyzer element and from the dialyzer element to the dialysate sink, second pump means coupled into said dialysate transporting means, said second pump means including a flexible casing which, when alternately compressed and released, causes dialysate solution to flow in the dialysate transporting means, and means for compressing and releasing the casings of said first and second pump means to produce a pumping action in the blood transporting means and the dialysate transporting means, and a vacuum regulator means coupled in said dialysate transporting means, said regulator means including
a reservoir having an orifice through which dialysate solution flows, and plug means positionable in front of said orifice at adjustable distances therefrom to control the rate of flow of solution through the orifice.

11. A hemodialyzer as defined in claim 10 wherein said vacuum regulator means is interposed in that portion of the dialysate transporting means which carries solution from the dialysate source to the dialyzer element.

12. A hemodialyzer comprising
a dialyzer element through which blood of a patient and dialysate solution are circulated to enable transfer of waste and water from the blood to the solution,
blood transporting means for transporting blood from the patient to the dialyzer element and from the dialyzer element back to the patient,
first pump means coupled into said blood transporting means, said pump means including a flexible casing which, when alternately compressed and released, causes blood to flow in said blood transporting means,
a dialysate source and a dialysate sink,
dialysate transporting means for transporting dialysate solution from the dialysate source to the dialyzer element and from the dialyzer element to the dialysate sink,
second pump means coupled into said dialysate transporting means, said second pump means including a flexible casing which, when alternately compressed and released, causes dialysate solution to flow in the dialysate transporting means,
means for compressing and releasing the casing of said first and second pump means to produce a pumping action in the blood transporting means and the dialysate transporting means, and wherein the flexible casing of each of said pump means includes an inlet and an outlet by which the casing is coupled into the respective transporting means, an inlet check valve for allowing fluid to flow therethrough into the casing, and an outlet check valve for allowing fluid to flow therethrough from the casing.

13. A hemodialyzer as defined in claim 12 wherein said casings are constructed of rubber having a wall thickness of substantially one-eighth of an inch.

14. A hemodialyzer as defined in claim 12 wherein said each casing is elongated, with the inlet valve located at one end of the casing and the outlet and outlet valve located at the other end.

15. A hemodialyzer as defined in claim 12 wherein said pump means is interposed in that portion of the dialysate transporting means which carries solution from the dialyzer element to the dialysate source for causing solution to flow from the dialyzer element to the dialysate sink and from the dialysate source to the dialyzer element, second pump means including a flexible casing which, when compressed, forces solution from the casing toward the dialysate sink and which, when released, withdraws solution from the dialyzer element into the casing.

16. A hemodialyzer as defined in claim 15 further comprising
a first retaining plate, one surface of which is shaped to conform to one side of the casing of said first pump means, said plate being positionable so that said one surface contacts said one side of the casing to prevent deformation of the one side when the casing is compressed, and

17. A hemodialyzer as defined in claim 12 wherein said casings are positioned side by side, and wherein said pump operating means includes a compression element disposed between the casings and moveable alternately to a first position to compress the casing of said first pump means and to a second position to compress the casing of said second pump means thereby to alternately operate the first and second pump means.

18. A hemodialyzer as defined in claim 12 in which said collector means includes a collapsible bladder, and said system further comprises
means for alternately compressing and releasing the casing of said second pump means, feeler means positionable so as to be engageable by the bladder when the bladder fills beyond some predetermined volume, and means responsive to the engagement of the bladder with the feeler means for disabling said pump compressing and releasing means.
21. A system as in claim 18 wherein said accumulator means and collector means are interposed in that portion of the dialysate transporting means which carries solution from the dialysate source to the dialyzer element.

22. A system as in claim 21 further including vacuum regulating means interposed in the dialysate transporting means between the dialyzer element and the accumulator means and collector means for regulating the rate of flow of solution into the dialyzer element.

23. A system as in claim 22 wherein said vacuum regulating means includes a reservoir having an orifice through which dialysate solution flows, and plug means having a diameter larger than the diameter of the orifice and positioned in front of the orifice at adjustable distances therefrom to control the rate of flow of solution through the orifice.

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