

[54] **PERITONEAL DIALYSIS DELIVERY
UNIT USING HOME-PREPARED
DIALYSATE**

[72] Inventors: **Heinrich A. M. Tenckhoff; George
Shilipetar**, both of Seattle, Wash.

[73] Assignee: **The Battelle Development Corpora-
tion**, Columbus, Ohio

[22] Filed: **June 8, 1970**

[21] Appl. No.: **44,026**

[52] U.S. Cl. **220/27, 128/272, 220/39 R,
222/372, 222/541**

[51] Int. Cl. **B65d 17/16, A61j 1/00**

[58] Field of Search **220/27, 39 R; 215/38 R, 48;
222/80-91, 541; 128/272**

[56] **References Cited**

UNITED STATES PATENTS

3,140,793	7/1964	Lawson.....	220/39 R
3,379,326	4/1968	Anderson.....	215/38 R
2,804,994	9/1957	Nebinger.....	222/89
3,374,927	3/1968	Schmidt.....	222/541

Primary Examiner—George E. Lowrance

Attorney—Christensen & Sanborn

[57] **ABSTRACT**

An apparatus and technique are disclosed whereby patients undergoing maintenance peritoneal dialysis can prepare and administer their own dialysate at home, using locally available water and a dialysate concentrate which is more economically and logistically practicable to make available to such patients than is the larger-volume mixture of the concentrate with the water.

14 Claims, 9 Drawing Figures

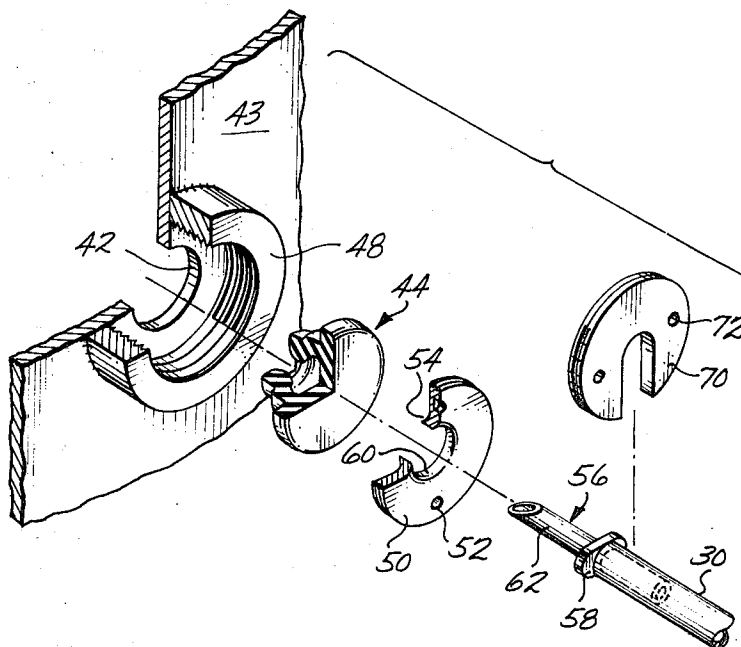


Fig. 1.

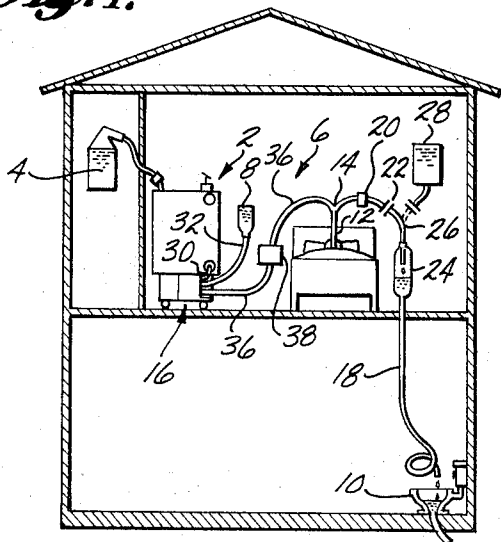


Fig. 2.

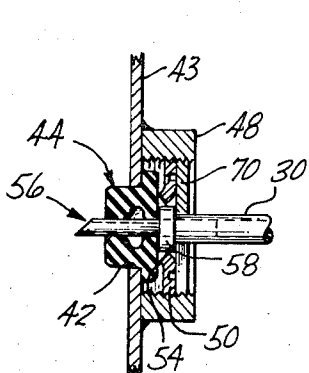
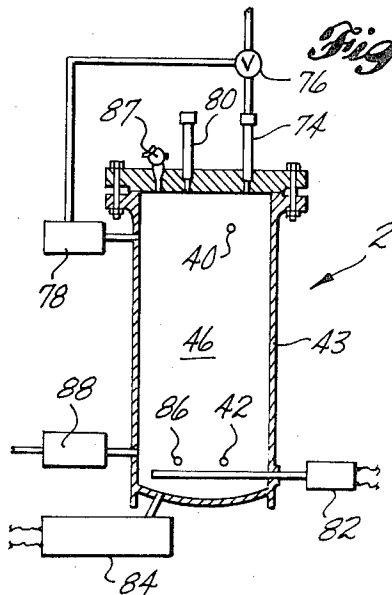


Fig. 4

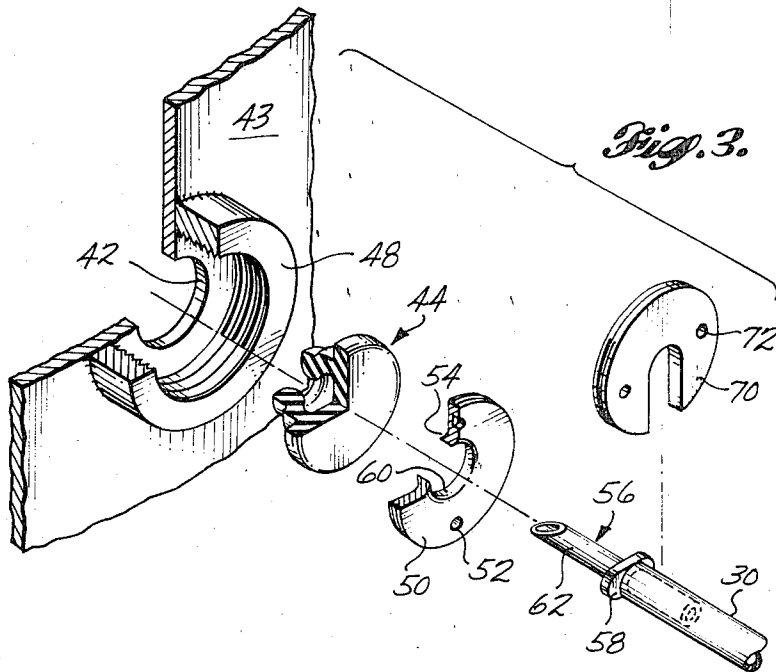


Fig. 3.

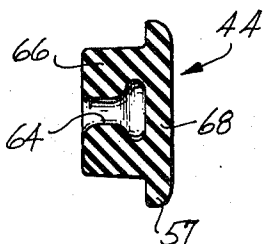


Fig. 5.

INVENTORS,
HEINRICH A. M. TENCKHOFF
GEORGE SHILIPETAR
BY *Christensen, Sanborn
& Matthews*
ATTORNEYS

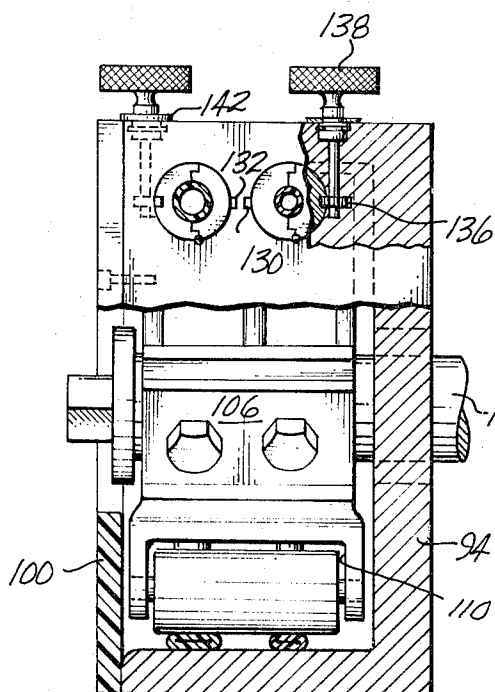
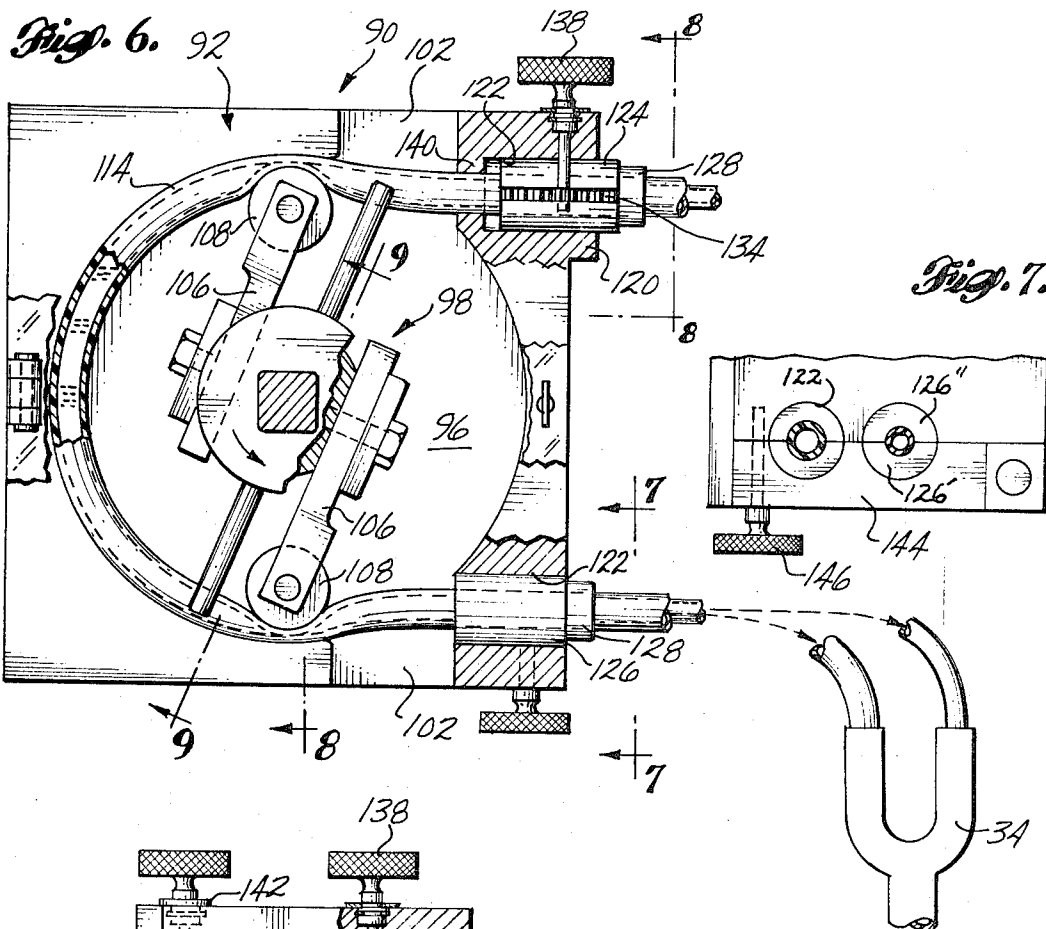
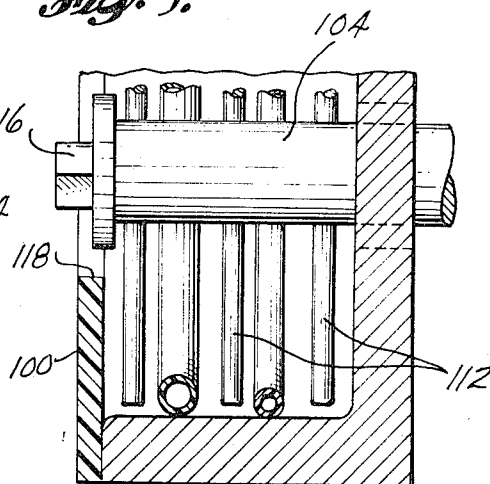


Fig. 9.



INVENTORS,
HEINRICH A. M. TENCKHOFF
GEORGE SHILIPETAR
BY *Christensen, Sanborn
& Matthews*
ATTORNEYS

PERITONEAL DIALYSIS DELIVERY UNIT USING HOME-PREPARED DIALYSATE

The invention described herein was made in the course of work under a contract from the Department of Health, Education and Welfare.

FIELD OF THE INVENTION:

This invention relates to medico-engineering apparatus and techniques for maintenance peritoneal dialysis of patients with acute, chronic or terminal kidney failure; and in particular to apparatus and techniques of this nature wherein such patients can prepare and administer their own dialysate at home, using locally available water and a dialysate concentrate which is mixed therewith.

BACKGROUND OF THE INVENTION INCLUDING CERTAIN OBJECTS THEREOF:

Since the development of permanently percutaneously implanted peritoneal access devices, there has been but one major obstacle to the wider use of maintenance peritoneal dialysis by the patient in his own home. This obstacle is the patient's necessity for having large quantities of sterile dialysate available to him at the time of treatment, and moreover, having it available within the confines of a delivery system which is entirely closed from the standpoint of sterilization. Many patients must undergo treatment at least three times a week, and perhaps every day, and each treatment requires approximately 80 liters of dialysate. At present the dialysate is prepared and delivered to the patient in 40-liter glass carboys, which are then arranged by the patient in his home with the help of someone else, so that the dialysate can be heated, two carboys at a time, and then administered to him by either gravity or pump-actuated flow. Not only is this technique extremely cumbersome and costly to the patient, but also there is the day to day logistical problem of making the dialysate available to the patient in such quantities, particularly where his home is some distance from the hospital-based laboratory or other source from which he must procure the dialysate.

One object of the invention, therefore, is to provide an apparatus and technique whereby the patient may prepare his own dialysate, using locally available water and a dialysate concentrate which is mixed therewith. Another object is to provide an apparatus and technique of this nature whereby the patient may prepare and administer the dialysate within the confines of a delivery system which is entirely closed from the standpoint of sterilization, and which is safeguarded against interruption to the chain of sterilization during use. Still another object is to provide an apparatus and technique of this nature whereby the patient can prepare the dialysate and undergo treatment with complete safety, and with a minimal number of steps on his part which might risk contamination of the delivery system. Other objects include the provision of an apparatus and technique of this nature which is highly susceptible to automation, and which is simple and easy to operate and maintain, as well as relatively inexpensive to operate, such as less than \$20.00 per dialysis.

Still further objects will become apparent from the description of the invention which follows hereafter.

SUMMARY OF THE INVENTION AND BRIEF DESCRIPTION OF THE DRAWINGS:

These objects and advantages are realized by an apparatus and technique of our invention wherein distilled or other locally available water of suitable character is sterilized in a home-in-stalled pressure boiler which is in part sealed by a replaceable stopper that is adapted to be impaled by a spiked-tip administration tube that is part of a roller-pump operated system of tubing for mixing the water with dialysate concentrate and then delivering the mixture to the patient. A preferred embodiment of the invention is illustrated in the accompanying drawings wherein:

FIG. 1 is a schematic view of the apparatus as it is installed and used in the home;

FIG. 2 is a schematic view of the boiler within the apparatus;

FIG. 3 is a part perspective view of a means and technique for employing a replaceable stopper in the boiler;

FIG. 4 is a part cross-sectional view of the stopper arrangement, after the stopper has been impaled by the tip of the tube to initiate the process of mixing and administering the dialysate;

FIG. 5 is a cross-sectional view of the stopper alone;

FIG. 6 is a partly removed front elevational view of one form of roller pump arrangement for the mixing and administration of the dialysate;

FIG. 7 is a part top view of the pump at one end;

FIG. 8 is a part cross-sectional view along the line 8 — 8 of FIG. 6; and

FIG. 9 is a similar view along the line 9 — 9 of FIG. 6.

DESCRIPTION OF THE PREFERRED EMBODIMENT:

Referring to the drawings, and to FIG. 1 in particular, it will be seen that one of the principal components of the apparatus is a sealed pressure boiler 2 for presterilizing the requisite quantity of water with which to make up the dialysate formulation. The water is predistilled, and is supplied to the boiler 2 from a source 4 of the same which is disposed relatively above the boiler to provide for filling it by gravity alone. The apparatus also comprises a system of Tygon tubing 6 by which the water is intermixed with sterile 20:1 dialysate concentrate 8 and then the mixture is delivered to the patient in intermittent stages, and alternately the spent mixture is wasted to a toilet bowl 10 or other open sump below the patient. Both the input and output stages are carried out through a permanently installed catheter 12 on the patient's person, to which a wye 14 is attached. The input operation is carried out by means of a roller pump 16 which is operative on the system of tubing 6 at a point interposed between the boiler 2 and the patient; whereas the output operation is simply gravity effected by opening a valved waste line 18 to the sump. In addition to the valve 20, the waste line 18 is also equipped with a drip chamber 24 to provide an additional air break for the prevention of back siphoning. The waste line 18 is permanently installed, and after each treatment is disconnected at 22 and thereafter reconnected at 26 to a container 28 of 2%

formaldehyde solution for purposes of rinsing and sterilizing the waste line 18.

Upstream from the pump 16, the tube system 6 includes a pair of supply lines 30 and 32, one of which 30 extends from the boiler, and the other 32 from the source of concentrate. The two lines 30 and 32 are joined to one another at a downstream wye 34 (FIG. 6), after passing through the pump 16, and the wye 34 is connected in turn to the catheter 12 of the patient, by a main delivery line 36 which serves both to intermix the liquids and to convey the mixture to the patient. Proper proportioning of the liquids is achieved in the pump 16 by one of several techniques. For example, the pump may have a single head and the supply tubes 30 and 32 may have a common wall thickness, but diameters which differ in accord with the formulation. Alternatively, the pump may have two conjointly-driven heads, one for each size of tubing; or the tubes may be identical and the pump may have two heads which are driven at differing speed ratios. A monitor 38 in the main delivery line 36 serves to indicate the accuracy of the proportion.

Before each treatment, the supply and delivery tubing is also presterilized so that there is a continuous chain of sterilization between the boiler 2, the source of concentrate 8, and the patient, due to the closed nature of the components throughout. After the treatment, it then becomes necessary to restore the chain of sterilization for the next treatment. This is accomplished by either detaching and resterilizing the supply and delivery tubing 30-36, or by actually replacing the tubing with a new set. Of course, the old or new tubing must be reattached in such a way as to not disturb the presterilized condition of the water in the boiler 2.

Referring to FIGS. 2-5 in this connection, it will be seen that the boiler 2 has a pair of upper and lower ports 40 and 42 in the tank 43 thereof, which are closed by replaceably press fitted, spike-pierceable rubber stoppers 44 that are adapted to sealingly engage with the spikes piercing the same. Each port 40 or 42 opens on the inside directly into the cavity 46 of the tank; and is equipped on the outside with a surrounding bushing 48 which is welded to the tank 43 and interiorly threaded to receive a cooperatively threaded, washer-like keeper element 50 for the stopper 44. The bushing 48 is spaced from the rim of the port, and the stopper has a peripheral flange 57 thereon which abuts the rim when the stopper is press-fitted into the port. After the stopper is so installed, the keeper element 50 is threaded into the bushing 48 behind the stopper by engaging a suitable spanner tool in a pair of diametrically opposed holes 52 in the element. The keeper element is abutted against the outside or proximal end face of the stopper, to secure the stopper against disengagement from the port, both in the direction relatively outward of the port when the tank is under pressure, and in the direction relatively inward of the port when the stopper is pierced. In addition, there is also a circumferential rib or ridge 54 on the inside face of the element which interengages with the stopper, in the face thereof, to add to the effect of clamping the flange 57 of the stopper between the element and the seat formed by the edge portion of the wall about the port.

In use, each stopper 44 is exposed to the same conditions as the water in the cavity 46 of the tank, and

therefore is sterilized along with the water during the pre-treatment sterilization process. Moreover, the annulated character of the keeper element 50 enables the user to pierce the stoppers and to withdraw the contents of the tank through the lower port 42, without destroying the sterilized condition of either the stoppers or the contents. The supply line 30 for carrying the water to the pump 16 can be seen at the right in FIGS. 3 and 4. When the water is to be withdrawn, a presterilized plastic spike 56 having opposing ears 58 thereon, is engaged in the adjacent end of the line, then driven through the aperture 60 of the keeper element for port 42, and thence through the stopper 44 in the port, and into the cavity 46 of the tank. At the same time, another such spike 56 with a cotton air filter therein, is driven through port 40 to provide an air vent. Each stopper is adapted to seal with the tip 62 of the spike, in that the inside face of each stopper has a recess 64 therein which is interiorly stepped in the radially outwardly direction to render the inside end portion or butt 66 of the stopper somewhat radially inwardly compressible as the stopper is engaged in the port. The recess 64 is also of such depth as to leave only a membranous web across the outside end portion or head 68 of the stopper; and when the tip 62 of each spike is impaled into the corresponding stopper, both the pierced head 68 and the inwardly flexed butt 66 of the stopper achieve sealing engagement with the tip. In addition, the ears 58 of the spike are accommodated within the aperture 60 of the keeper element, so that after each spike is impaled in the corresponding stopper, a rounded U-shaped retainer element 70 is threaded into the bushing 48 behind the ears, to retain the spike in position during the course of the treatment. Diametrically opposed holes 72 in the retainer elements 70 facilitate the operation.

When the treatment is concluded, the retainer and keeper elements 70 and 50 are withdrawn, together with the spikes 56, and then each stopper 44 is replaced with a fresh presterilized stopper, and the boiler is recharged and reoperated to ready the apparatus for a new treatment.

In practice, the boiler 2 is also equipped with a number of features which render it otherwise fully automatic for the pre-sterilization and delivery processes. For example, the distilled water source 4 is connected with an inlet 74 in the upper end of the tank 43, through a solenoid operated shut off valve 76 which is controlled from a high level sensor 78 in the tank, so as to automatically terminate the recharging operation when the fluid level in the tank reaches this sensor. During the charging operation, air escapes through a filtered outlet valve 80 in the top of the tank which is similarly controlled from the sensor 78. After the charging operation, a two stage electric resistance heater 82 in the bottom of the tank is activated to begin the sterilization process; and when sterilization is achieved, the heater is partially deactivated to reduce and maintain the temperature of the water at that necessary for the treatment. Preferably, all operations are under the control of an automatic timer 84 which displays the sequence throughout. The tank also has a visual temperature gauge 86, and a pressure relief valve 87.

A low level monitor 88 located just above the draw-off port 42, prevents air from entering the tubing 30-36 by automatically turning off the entire apparatus, including the timer 84, and sounding an alarm, when the water level reaches this point.

In summary, when a patient completes a treatment he inserts two new pre-sterilized stoppers into the ports 40 and 42, arranges new concentrate 8 above the pump 16 for gravity feed, activates the timer 84, and then returns to the apparatus for treatment as needed, after the apparatus has presterilized the new charge of water. At the time of treatment, he need only "plug in" the air vent spike 56 and the supply and deliver tubing 30-36, arrange the supply tubing 30 and 32 in the pump 16, and then connect the discharge end of the main line delivery 36 to himself to proceed with the treatment.

The invention also contemplates that the concentrate can be mixed with water before the sterilization process, and the mixture itself then subjected to sterilization in the boiler 2, rather than the water alone. In such a case, the pump 16 need only serve the pump function alone rather than the proportioning function as well.

The water 4 need not be distilled so long as the final dialysate meets the criteria of being: 1) sterile; 2) non-irritating; 3) non-toxic; 4) non-pyrogenic; and 5) free of particle matter.

FIGS. 6-9 illustrate a preferred arrangement for employing a pair of supply tubes 30 and 32 having a common wall thickness, but differing diameters, together with a single-head roller pump 90. The pump is housed in a rectangularly-shaped, but square-faced casing 92 which is upended to place its greater rectangular dimension in the vertical plane. The casing 92 has a closed rear wall 94, but a cylindrical recess relieved from the front face thereof to form a chamber 96 for the pump head 98. The chamber 96 is operatively closed by a transparent plastic cover 100 on the face of the casing, which is hinged to the casing at one side, however, to be swung open in the manner of a door each time access is needed to the chamber 96. In addition, there are windows 102 which open to the sides of the casing from the chamber to provide access from these directions as well.

The pump head 98 is mounted on an arbor 104 which extends horizontally through the rear wall 94 of the casing from a motor (not shown) mounted therebehind. The arbor 104 has a pair of equally radially disposed, flat, parallel, longitudinally extending chordal faces thereon, and the head comprises a pair of flat rectangular plates 106 which are bolted to the faces of the arbor, so as to project tangentially outwardly from the same in oppositely disposed relationship to one another. The outlying edge portions of the plates 106 are centrally relieved so that they in short, form slotted, yoke-like carrier arms for a pair of elongated cylindrical rollers 108 which are pivotally mounted in the slotted ends 110 thereof. The arbor 104 also has two sets of spaced, parallel radially extending pins 112 thereon which are affixed to the arbor, three abreast and in diametrically opposing relationship to one another. In the pump, the tubes 30 and 32 are passed between the pins 112 and looped over the rollers 108, about the head, and within the cylindrical wall 114 of the chamber 96. The rollers 108 cooperate with the

wall in conventional fashion, alternately to occlude the tubes and thereby to force progressive segments of the liquids in the tubes, through the same, over part of the circumferential course of the rollers about the axis of the arbor. At the same time, the pins 112 provide rotational guides for the tubes to assure that they maintain their positions on the head.

A retainer screw 116 on the outer end of the arbor serves to establish the parallelism of the plates, the holes for the bolts being slotted to allow for adjustment of the plates on the arbor. When the cover 100 is closed, the screw 116 is accommodated in an aperture 118 therein.

In order to assure that the flow in the tubes is properly proportioned, the tubes must be continuously tensioned about the head as it rotates. For this purpose, therefore, the tubes are threaded in and out of the chamber through a sleeved socket construction in the upper wall 120 of the casing. The upper wall 120 has four cylindrical apertures 122 therein which are disposed two abreast in each vertical plane tangential to the path of travel of the rollers. Complementally sized bushings or sleeves 124 and 126 are engaged in the apertures 122, the two left-hand sleeves 124 in FIG. 6 being removably slidably engaged in the apertures, and the two sleeves 126 on the right-hand side being fixed within the casing, although each is split and separable into two halves as shall be explained. The sleeves 124 and 126 cooperate with circumferentially disposed stop collars 128 on the supply tubes so as to alter the loop lengths of the tubes and thus the tension in the same as the rollers travel about the axis of the arbor. The adjustment is accomplished by means of a rack and pinion drive mechanism interposed between the casing and the left-hand slidably engaged sleeves 124. Each such sleeve 124 is split along its length, and the two halves are hinged to one another, as well as dovetailed across the opposing faces thereof. One half has a longitudinally extending rib 130 thereon which keys with a similar slot 132 in the wall of the corresponding aperture. The other half has a toothed, longitudinally extending rack 134 thereon which interengages with a small knob driven pinion 136 rotatably mounted abreast of each aperture 122 for the sleeves 124 in the wall of the casing. Using the knobs 138 of the pinions, the sleeves 124 can be adjusted in either direction axially of the apertures, although there are stop ribs 140 at the inside ends of the apertures to prevent the sleeves from entering the chamber. Once each adjustment is made, lock nuts 142 on threaded shanks of the pinions serve to fix the locations of the sleeves.

In practice, the slidably engaged sleeves 124 are generally given an outward adjustment in relation to the chamber, after the tubes have been threaded about the head and engaged in the right-hand relatively fixed sleeves 126. To provide for the threading operation, the latter sleeves 126 are longitudinally split, and the relatively outer halves 126' are mounted in a hinged panel 144 which is separable from but hinged to the right hand wall of the casing so that it can be swung out to part the halves from one another for manual insertion of the tubes in the grooves of the inner halves 126''.

A low level monitor **88** located just above the draw-off port **42**, prevents air from entering the tubing **30-36** by automatically turning off the entire apparatus, including the timer **84**, and sounding an alarm, when the water level reaches this point.

In summary, when a patient completes a treatment he inserts two new pre-sterilized stoppers into the ports **40** and **42**, arranges new concentrate **8** above the pump **16** for gravity feed, activates the timer **84**, and then returns to the apparatus for treatment as needed, after the apparatus has presterilized the new charge of water. At the time of treatment, he need only "plug in" the air vent spike **56** and the supply and deliver tubing **30-36**, arrange the supply tubing **30** and **32** in the pump **16**, and then connect the discharge end of the main line delivery **36** to himself to proceed with the treatment.

The invention also contemplates that the concentrate can be mixed with water before the sterilization process, and the mixture itself then subjected to sterilization in the boiler **2**, rather than the water alone. In such a case, the pump **16** need only serve the pump function alone rather than the proportioning function as well.

The water **4** need not be distilled so long as the final dialysate meets the criteria of being: 1) sterile; 2) non-irritating; 3) non-toxic; 4) non-pyrogenic; and 5) free of particle matter.

FIGS. 6-9 illustrate a preferred arrangement for employing a pair of supply tubes **30** and **32** having a common wall thickness, but differing diameters, together with a single-head roller pump **90**. The pump is housed in a rectangularly-shaped, but square-faced casing **92** which is upended to place its greater rectangular dimension in the vertical plane. The casing **92** has a closed rear wall **94**, but a cylindrical recess relieved from the front face thereof to form a chamber **96** for the pump head **98**. The chamber **96** is operatively closed by a transparent plastic cover **100** on the face of the casing, which is hinged to the casing at one side, however, to be swung open in the manner of a door each time access is needed to the chamber **96**. In addition, there are windows **102** which open to the sides of the casing from the chamber to provide access from these directions as well.

The pump head **98** is mounted on an arbor **104** which extends horizontally through the rear wall **94** of the casing from a motor (not shown) mounted therebehind. The arbor **104** has a pair of equally radially disposed, flat, parallel, longitudinally extending chordal faces thereon, and the head comprises a pair of flat rectangular plates **106** which are bolted to the faces of the arbor, so as to project tangentially outwardly from the same in oppositely disposed relationship to one another. The outlying edge portions of the plates **106** are centrally relieved so that they in short, form slotted, yoke-like carrier arms for a pair of elongated cylindrical rollers **108** which are pivotally mounted in the slotted ends **110** thereof. The arbor **104** also has two sets of spaced, parallel radially extending pins **112** thereon which are affixed to the arbor, three abreast and in diametrically opposing relationship to one another. In the pump, the tubes **30** and **32** are passed between the pins **112** and looped over the rollers **108**, about the head, and within the cylindrical wall **114** of the chamber **96**. The rollers **108** cooperate with the

wall in conventional fashion, alternately to occlude the tubes and thereby to force progressive segments of the liquids in the tubes, through the same, over part of the circumferential course of the rollers about the axis of the arbor. At the same time, the pins **112** provide rotational guides for the tubes to assure that they maintain their positions on the head.

A retainer screw **116** on the outer end of the arbor serves to establish the parallelism of the plates, the holes for the bolts being slotted to allow for adjustment of the plates on the arbor. When the cover **100** is closed, the screw **116** is accommodated in an aperture **118** therein.

In order to assure that the flow in the tubes is properly proportioned, the tubes must be continuously tensioned about the head as it rotates. For this purpose, therefore, the tubes are threaded in and out of the chamber through a sleeved socket construction in the upper wall **120** of the casing. The upper wall **120** has four cylindrical apertures **122** therein which are disposed two abreast in each vertical plane tangential to the path of travel of the rollers. Complementally sized bushings or sleeves **124** and **126** are engaged in the apertures **122**, the two left-hand sleeves **124** in FIG. 6 being removably slidably engaged in the apertures, and the two sleeves **126** on the right-hand side being fixed within the casing, although each is split and separable into two halves as shall be explained. The sleeves **124** and **126** cooperate with circumferentially disposed stop collars **128** on the supply tubes so as to alter the loop lengths of the tubes and thus the tension in the same as the rollers travel about the axis of the arbor. The adjustment is accomplished by means of a rack and pinion drive mechanism interposed between the casing and the left-hand slidably engaged sleeves **124**. Each such sleeve **124** is split along its length, and the two halves are hinged to one another, as well as dovetailed across the opposing faces thereof. One half has a longitudinally extending rib **130** thereon which keys with a similar slot **132** in the wall of the corresponding aperture. The other half has a toothed, longitudinally extending rack **134** thereon which interengages with a small knob driven pinion **136** rotatably mounted abreast of each aperture **122** for the sleeves **124** in the wall of the casing. Using the knobs **138** of the pinions, the sleeves **124** can be adjusted in either direction axially of the apertures, although there are stop ribs **140** at the inside ends of the apertures to prevent the sleeves from entering the chamber. Once each adjustment is made, lock nuts **142** on threaded shanks of the pinions serve to fix the locations of the sleeves.

In practice, the slidably engaged sleeves **124** are generally given an outward adjustment in relation to the chamber, after the tubes have been threaded about the head and engaged in the right-hand relatively fixed sleeves **126**. To provide for the threading operation, the latter sleeves **126** are longitudinally split, and the relatively outer halves **126'** are mounted in a hinged panel **144** which is separable from but hinged to the right hand wall of the casing so that it can be swung out to part the halves from one another for manual insertion of the tubes in the grooves of the inner halves **126''**.

Thus, each time that a new set of tubes 30 and 32 is installed in the pump, the initial steps of the operation are to open the panel and to thread the tubes about the pump head by passing them firstly through the apertures for sleeves 124, and then out over the inner halves 126'' of the sleeves 126 in the casing. At the same time, the sleeves 124, which had been previously withdrawn from their apertures, are closed about the tubing, and are reinstalled in the apertures with the tubing by means of the rack and pinion mechanism. Initially, the sleeves 124 are simply reinserted to a neutral position; but after the panel 144 is closed and locked by means of a screw 146 on the same, the sleeves 124 are driven outwardly against the adjacent collars 128 on the tubes, which in turn draws the collars on the other ends of the tube up against the sleeves 126. Finally, when an appropriate adjustment is achieved, the pinions 136 are locked and the pump is ready to operate to actuate the mixing and delivery process as needed.

What is claimed is:

1. In combination, a container defining a fluid retention chamber therein, the wall of which container has a recess therein, the relatively distal end of which recess has a port therein that opens into the chamber of the container, and the edge of which port is spaced relatively radially inwardly from the inner peripheral wall of the recess, so as to define a seat about the edge of the port on said end; a spike pierceable sealing element which is capable of self-sealing with the spike piercing the same, and which is releasably engaged in the port, so as to close the same, the relatively proximal end portion of the sealing element having a flange connected therewith, in the recess, the diameter of which flange is greater than that of the port at its edge, but lesser than that of the recess at the inner peripheral wall thereof, so that the sealing element is disengageable from the port in the direction relatively toward the proximal end of the recess; and a keeper element which is releasably engaged in the recess and abutted against the sealing element, so as to clamp the flange of the sealing element between the keeper element and the seat, for retention of the sealing element in the port during the spike piercing operation, and which moreover, is annulated, so that the spike can be impaled therethrough for the piercing operation.

2. The combination according to claim 1 wherein the keeper element is reciprocally engaged in the recess, for insertion in and release from the recess through the proximal end thereof.

3. The combination according to claim 1 wherein the sealing element is elastomeric in nature, the flange is integral therewith, and the keeper element has an annular rib raised on the abutting, relatively distal end thereof, which is spaced relatively radially inwardly from the outer periphery of the flange, and interengaged with the sealing element, in the abutting, relatively proximal end portion thereof.

4. The combination according to claim 1 wherein the sealing element is elastomeric in nature, the flange is integral therewith, and the relatively distal end portion of the sealing element has an interiorly stepped recess therein, extending toward the relatively proximal end of the sealing element, but terminating short of the latter end, so that a membranous web remains thereacross, within the bounds of the flange.

5. The combination according to claim 1 wherein the container has means associated therewith for heating the fluid in the chamber.

6. The combination according to claim 1 wherein the keeper element is washer-like and threadedly engaged in the recess.

7. The combination according to claim 6 wherein the recess is defined by an interiorly threaded bushing on the wall of the container.

8. In a peritoneal dialysis delivery system, a pressure boiler having a liquid retention chamber therein, and means associated therewith for heating the liquid in the chamber, the wall of which boiler has a recess therein, the relatively distal end of which recess has a port therein that opens into the chamber of the boiler, and the edge of which port is spaced relatively radially inward from the inner peripheral wall of the recess, so as to define a seat about the port on said end; a spike pierceable sealing element which is capable of self-sealing with the spike piercing the same, and which is releasably engageable in the port, to close the same, the relatively proximal end portion of the sealing element having a flange connected therewith, the diameters of which flange is greater than that of the port at its edge, but lesser than that of the recess at the inner peripheral wall thereof, so that the flange is engageable with the seat when the sealing element is engaged in the port through the relatively proximal end of the recess; and a keeper element which is releasable engageable in the recess, for abutment against the flange, to clamp the flange between the keeper element and the seat, for retention of the sealing element in the port during the spike piercing operation, and which moreover, is annulated, so that the spike can be impaled therethrough for the piercing operation.

9. In combination, a pressure boiler having a liquid retention chamber therein, and means associated therewith for heating the liquid in the chamber, the wall of which boiler has a recess therein, the relatively distal end of which recess has a port therein that opens into the chamber of the boiler, and the edge of which port is spaced relatively radially inward from the inner peripheral wall of the recess, so as to define a seat about the port on said end; a spike pierceable sealing element which is capable of self-sealing with the spike piercing the same, and which is releasably engageable in the port, to close the same, the relatively proximal end portion of the sealing element having a flange connected therewith, the diameter of which flange is greater than that of the port at its edge, but lesser than that of the recess at the inner peripheral wall thereof, so that the flange is engageable with the seat when the sealing element is engaged in the port through the relatively proximal end of the recess; and a keeper element which is releasable engageable in the recess, for abutment against the flange, to clamp the flange between the keeper element and the seat, for retention of the sealing element in the port during the spike piercing operation, and which moreover, is annulated, so that the spike can be impaled therethrough for the piercing operation.

10. The combination according to claim 9 wherein the sealing element is elastomeric in nature, the flange is integral therewith, and the relatively distal end portion of the sealing element has an interiorly stepped

recess therein, extending toward the relatively proximal end of the sealing element, but terminating short of the latter end, so that a membraneous web remains thereacross within the bounds of the flange.

11. The combination according to claim 10 wherein the keeper element has an annular rib raised on the relatively distal end thereof, which has a lesser diameter than that of the relatively proximal end of the sealing element, so as to interengage with the sealing element, in the relatively proximal end portion thereof.

12. In combination, a container defining a fluid retention chamber therein, the wall of which container has a recess therein, the relatively distal end of which recess has a port therein that opens into the chamber of the container, and the edge of which port is spaced relatively radially inwardly from the inner peripheral wall of the recess, so as to define a seat about the port on said end; a spiked-pierceable sealing element releasably engaged in the port, so as to close the same, the relatively proximal end portion of the sealing element having a flange connected therewith, in the recess, the diameter of which flange is greater than that of the port at its edge, but lesser than that of the recess at the inner peripheral wall thereof, so that the sealing element is disengageable from the port in the direction relatively toward the proximal end of the recess; an annulated keeper element which is releasably engaged in

the recess and abutted against the sealing element, so as to clamp the flange of the sealing element between the keeper element and the seat; and a tubular spike impaled through the keeper element, and the sealing element, the bore of which is in communication with the chamber, and the tubular body of which is in sealed engagement with the sealing element.

13. The combination according to claim 12 wherein the sealing element is elastomeric in nature, the flange is integral therewith, and the relatively distal end portion of the sealing element has an interiorly stepped recess therein, extending toward the relatively proximal end of the sealing element, but terminating short of the latter end, so that a membraneous web remains thereacross, within the bounds of the flange; and wherein the spike pierces the web and extends through the recess in the sealing element, to a point at which the bore thereof communicates with the chamber, adjacent the relatively distal end of the sealing element.

14. The combination according to claim 12 wherein the spike has an ear thereon which is received within the opening of the keeper element, and there is a U-shaped retainer element releasably engaged in the recess, on the opposite side of the ear from the sealing element, to retain the spike in position in the various elements.

* * * * *

30

35

40

45

50

55

60

65