Dec. 11, 1973 F. W. MARKLEY 3,778,369

HEMODIALYZER WITH TAPERED SLIT BLOOD PORTS AND BAFFLES

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Fig-1

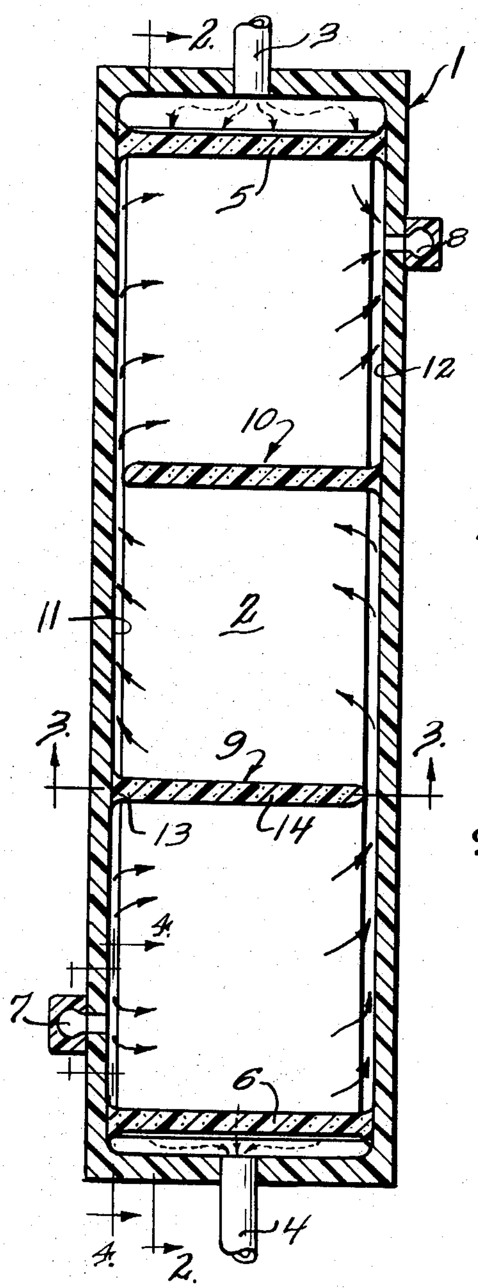

Fig-2

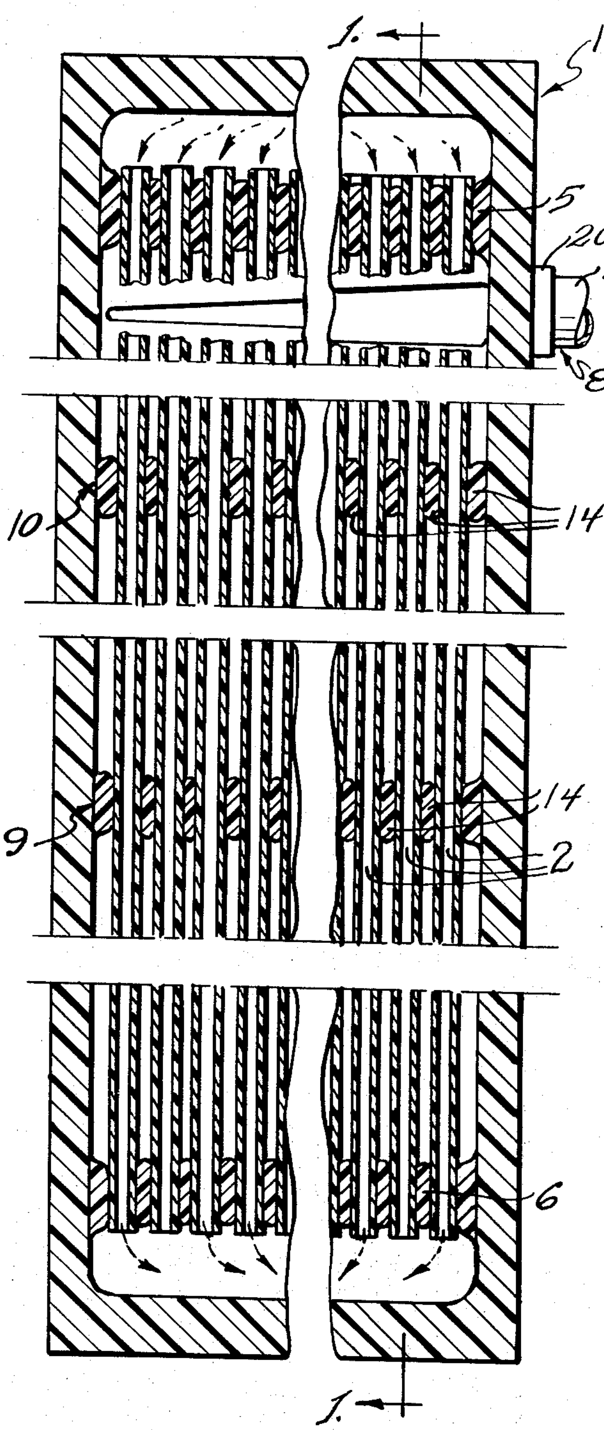

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Fig-3

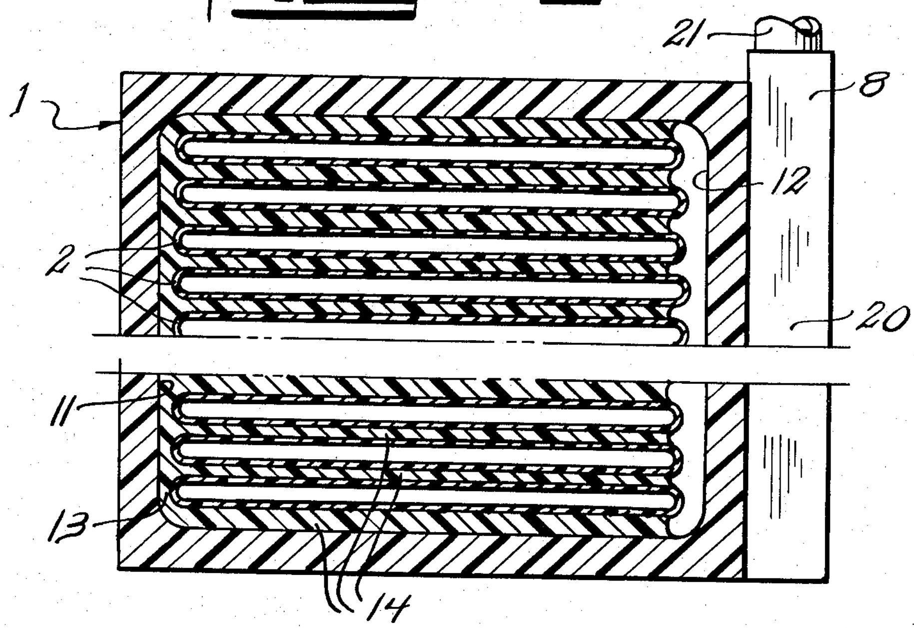
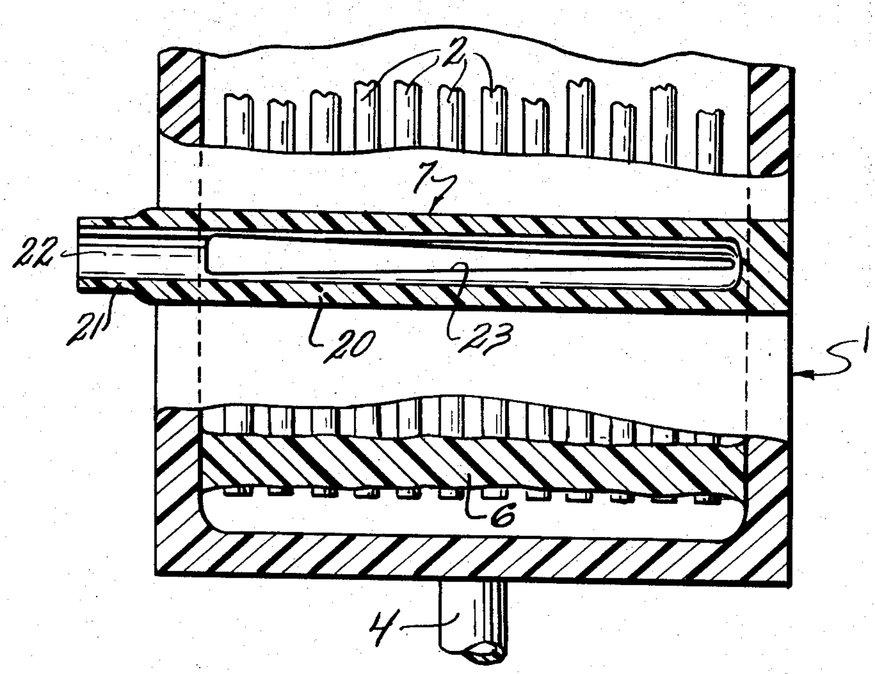


Fig-4



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HEMODIALYZER WITH TAPERED SLIT BLOOD PORTS AND BAFFLES

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U.S. Cl. 210—321 4 Claims

ABSTRACT OF THE DISCLOSURE

A new parallel flow hemodialyzer, which provides greater dialysis efficiency and better blood flow distribution, has baffles to direct blood flow and a new type of blood port. Baffles are placed across the width of the tubes from one side wall of the casing forcing the blood to flow around the baffles across the tubes a multiple number of times in passing through the hemodialyzer. The baffles are made from epoxy resin strips placed across the width of each tube. The new blood ports extend across the width of the side of the casing near its ends. The ports have an end adjacent the edge of the casing which defines an opening from the exterior of the hemodialyzer which leads to a tapered slit opening to the interior of the hemodialyzer, this slit tapering to a smaller width as the distance from the exterior opening increases and tapering to a close at the edge of the casing opposite the exterior opening.

CONTRACTUAL ORIGIN OF THE INVENTION

The invention described herein was made in the course of, or under, a contract with the U.S. Atomic Energy Commission.

BACKGROUND OF THE INVENTION

This invention relates to an improved apparatus for use in the cleansing of impurities from the blood by hemodialysis.

Hemodialyzers, commonly referred to as artificial kidneys have been used for many years to treat patients suffering from kidney malfunction or kidney disease. Recent development work on hemodialyzers has been directed toward increasing the efficiency of hemodialyzer units, lowering the expense involved in dialysis treatment, and making dialysis treatment available to more of those in need of such treatment.

The hemodialyzers presently being used fail to fully satisfy the needs of the vast number of kidney patients in several important respects. Hemodialyzer machines presently used are expensive to produce and hence require a large initial investment for the basic machine and other associated equipment. A blood pump is required because of the flow resistance caused by the large size of the present machines, which size also often makes a blood transfusion necessary because of the loss of blood to the blood priming volume of the machine. In-hospital treatment or the presence of trained medical personnel is also necessary as well as the essential rebuilding of the hemodialyzer unit under sterile conditions following each hemodialyzer treatment. Partially resulting from these mentioned considerations, the costs of continuing hemodialysis treatment is prohibitive to many patients in need of such periodic treatment. The number of hemodialyzer units available is also severely limited in relation to the vast number of those suffering from kidney disorders.

Desiring to obtain solutions to some of these problems, efforts at Argonne National Laboratory have been directed towards development of a small, pumpless, efficient, and less expensive hemodialyzer which can be made more widely available and which can make hemo-

dialysis treatment possible for more patients at a lower yearly cost. These efforts at Argonne National Laboratory have resulted in the development of a series of models of small, pumpless hemodialyzers which can meet some of the present needs of kidney patients. The knowledge and advanced technology obtained in the devolpment of each of these hemodialyzer models has enabled the development of the series of progressively refined and efficient hemodialyzer models, each of which can be made available to kidney patients, replacing earlier models and eventually in its turn being replaced by still more refined and improved models. In this way, the needs of those suffiering from kidney disorders can be met simultaneously with continuing development efforts. The present invention is the most recent and most improved model in this series of hemodialyzers.

In line with the efforts towards developing this series of models of hemodialyzers the present inventor was a coinventor of two earlier model hemodialyzers which are the subject of U.S. Pat. 3,522,885 and U.S. Pat. 3,565,258. Each of these two earlier models were small, pumpless, disposable units consisting of a series of parallel tubes arranged in a stack within a rectangular-shaped casing. The blood and dialysate fluid passed either within the tubes or across and around the exterior of the tubes. In particular, the hemodialyzer of U.S. Pat. 3,565,258 provides for passing dialysate fluid within supported tubes while blood flows across the dialyzer casing between and around the tubes. While this latter model has proven to be a satisfactory design and has undergone clinical testing, it remains desirable to improve the design and increase the efficiency of the hemodialyzer.

Therefore, it is an object of the present invention to provide a hemodialyzer which is small, can be operated without the need of a blood pump, and can be discarded after use.

It is also an object of the present invention to provide a hemodialyzer which has improved blood flow distribution within the hemodialyzer unit and which has improved efficiency of dialysis.

SUMMARY OF THE INVENTION

In accordance with the present invention, a hemodialyzer is provided which has a plurality of flattened semipermeable membrane tubes which are arranged in parallel in a stack within a rectangular casing. The hemodialyzer has associated therewith means for passing dialysate fluid fluid through the hemodialyzer within the flattened tubes and means for passing blood through the hemodialyzer across the between the flattened tubes. The efficiency of the hemodialyzer is increased by incorporating one or more baffles which extend from a side wall of the casing across the width of each of the flattened tubes and terminate at the edges of the tubes at a point just short of the opposite side wall of the casing. Blood flowing through the hemodialyzer must thereby flow around the baffles and across the flattened tubes a multiple number of times. When more than one baffle is incorporated, alternate baffles extend from opposite side walls of the casing. Each such baffle is formed from a series of connected epoxy resin strips which extend from a side wall of the casing across the width of each of the flattened tubes.

The blood flow distribution of the hemodialyzer is improved by use of a new design for the blood ports. Each blood port has an end adapted for making the appropriate connections and defining a blood inlet or outlet opening which leads to or from a tapered slit opening into the interior of the hemodialyzer with the width of the slit tapering to a close as the distance from the blood inlet or outlet opening in the blood port increases.

BRIEF DESCRIPTION OF THE DRAWINGS

A better understanding of the features of the present invention can be obtained from a reading of the following detailed description of the invention and reference to the drawings in which:

FIG. 1 is a longitudinal section of the hemodialyzer taken along the line **1—1** of FIG. 2.

FIG. 2 is an enlarged view taken along the line **2—2** of FIG. 1 with the tubes partially broken away to expose a feature of the blood ports of the hemodialyzer.

FIG. 3 is a transverse cross-sectional view taken along line **3—3** of FIG. 1.

FIG. 4 is a view taken along broken line **4—4** of FIG. 1.

DETAILED DESCRIPTION OF THE INVENTION

The construction and operation of the hemodialyzer of the present invention can best be understood by referring to the accompanying drawings in which a rectangular-shaped casing is shown generally at **1** and a plurality of parallel flattened semipermeable membrane tubes **2** are shown arranged in a stack within the casing **1**. While, in the preferred embodiment of the present invention, plastic nonwoven mesh support members are disposed within the tubes, other types of supports are equally applicable. Consequently, since the support members do not constitute an aspect of the invention, they have been omitted from the drawings for sake of clarity. As is best seen in FIG. 3, the parallel flattened tubes **2** are stacked one upon another with the generally flattened surfaces of the tubes facing each other and parallel to the top and bottom of the casing **1**. The two portions of the flattened tubes between the generally flattened surfaces can be referred to as the two edges of the tubes, the parallel tubes being stacked so that the edges of the tubes are aligned to define the two sides of the stack of tubes. The edges of the flattened tubes and the sides of the stack of tubes face the two sides of the casing **1**.

Referring particularly to FIG. 1, there is shown a dialysate inlet **3** and a dialysate outlet **4** located on opposite ends of casing **1** and leading respectively to and from the interior of the hemodialyzer. Dialysate fluid, flowing through the inlet **3**, has access to the interior of tubes **2** through the openings in the ends of the tubes **2** adjacent the inlet **3** but is prevented from flowing about the exterior of the tubes **2** by barrier **5** near the ends of the tubes **2** adjacent the inlet **3** which seals the tubes to each other and to the casing **1**. A similar barrier **6** near the opposite ends of tubes **2** adjacent the outlet **4** prevents dialysate fluid, flowing from the interior of the tubes **2** through the openings in the ends of the tubes **2** adjacent the outlet **4**, from flowing back about the exterior of the tubes **2**. The barriers **5** and **6** and the flow of dialysate through the interior of the tubes **2** are more clearly seen in FIG. 2. Dialysate flow, indicated generally by arrows with dotted lines, is seen to be from the inlet **3**, through the interior of tubes **2**, and to the outlet **4** from which it exits from the hemodialyzer.

Referring again to FIG. 1, there is shown a blood inlet port **7** and a blood outlet port **8** located on opposite sides and at opposite ends of casing **1**. The structure of the blood ports is described in more detail below. The barriers **5** and **6** also serve to seal the blood from the ends of the tubes **2** and prevent intermingling of blood and dialysate fluid. Blood flow is therefore exterior to the flattend tubes **2** and in general is between the tubes **2** across their width. The tubes **2** are of smaller length and width than the interior dimensions of the casing **1**, leaving space on the sides and at the ends to permit distribution of the blood and dialysate fluids respectively.

One or more baffles extend across the width of the tubes to direct blood flow and consequently increase the efficiency of the hemodialyzer. When there are more than one such baffles, alternate baffles extend from opposite sides of the casing, the baffles being equally spaced so as to divide the interior of the hemodialyzer into equal segments. The two blood ports are located at opposite ends of the casing and are located on the same side of the casing if there are an odd number of baffles and on opposite sides of the casing if there are an even number of baffles, their relative location being determined by the number of baffles and the blood flow path around the baffles. In the disclosed embodiment of the present invention, there are two such baffles **9** and **10** and the blood ports are located on opposite sides of the casing **1** as pictured in the drawings. Referring to FIG. 1, the first baffle **9**, located nearest the blood inlet **7**, extends from the interior side wall **11** of the casing **1** on the same side of the casing **1** as the blood inlet **7**. Baffle **9** extends across the width of the flattened tubes **2** and terminates at the edges of the tubes **2** near to but not touching the opposite interior side wall **12** of the casing **1**. As is more clearly seen from FIGS. 2 and 3, baffle **9** comprises a narrow vertical band **13** along the height of one side of the stack of tubes at the edges of tubes **2** and a series of fingers **14** connected by and extending horizontally from band **13** across the width of the tubes **2** to the edges of the tubes opposite the band **13**, one finger **14** extending between each two adjacent tubes **2** and also between the tubes **2** and the top and bottom of casing **1**. The narrow vertical band **13** fills the space between the edges of the tubes **2** and the interior side wall **11**. As can be seen baffle **9** extends from the interior side wall **11** between each of the tubes **2** and forces blood to flow across the tubes around its end at the end of its fingers **14** at the opposite edges of the tubes **2** adjacent the interior side wall **12**. The similar second baffle **10** is located nearest the blood outlet **8** and extends from the opposite interior side wall **12** of the casing **1** on the same side of the casing **1** as the blood outlet **8**. Baffle **10** extends from interior side wall **12** across the width of the flattened tubes **2**, terminating at the edges of the tubes near to but not touching interior side wall **11**. Blood is therefore forced to flow around baffle **10** at its end at the edges of the tubes adjacent interior side wall **11**. Blood flow through the dialyzer, indicated generally by the arrows with solid lines, is from the blood inlet **7** across the width of the tubes **2** around the end of baffle **9** near the interior side wall **12** opposite blood inlet **7** and continues across the width of tubes **2** a second time around the end of baffle **10** near the interior side wall **11** opposite the blood outlet **8** and across the tubes **2** a third time to the blood outlet **8**. In passing through the hemodialyzer, the blood is thereby caused by the baffles to flow across the width of the tubes three times rather than just once.

The blood ports, both blood inlet port **7** and blood outlet port **8**, are of identical structure and provide for better blood flow distribution in the dialyzer. Referring to FIG. 4 for a detailed description of the blood ports, it should be understood that the blood outlet port **8** is identical in structure with the blood inlet port **7** and in fact the two are interchangeable, it being inconsequential which is connected as the inlet at the beginning of hemodialysis treatment. A tubular conduit **20** is mounted transversely across a side of the casing **1** on the outside and near an end of the casing, conduit **20** being perpendicular to the flattened tubes **2** and extending along a side of the stack of tubes. The tubular conduit **20** has one end **21** projecting beyond the edge of casing **1**, which end is adapted for connection to tubing conducting the blood from the patient's artery. The end **21** of tubular conduit **20** defines an opening indicated at **22** which leads to the interior of the tubular conduit **20**. The tubular conduit **20** further has a tapered slit **23** along its length on one side thereof at its junction with the casing **1**, tubular conduit **20** and casing **1** being sealed together at their junction. Tapered slit **23** is aligned with and opens to an identical tapered slit **24** in the casing **1**, not seen in FIG. 4 but apparent in FIG. 2 where the tubes **2** have been partially broken away to reveal the slit **24**. The interior of the hemodialyzer casing 1 and the interior of tubular conduit 20 communicate through these tapered slits 23 and 24, the length of these slits being transverse a side of the stack of tubes 2. Tapered slits 23 and 24 are widest at a point in the side of casing 1 adjacent opening 22 and tapered to a close at the edge of casing 1 opposite opening 22. Blood entering tubular conduit 20 through opening 22 in end 21 passes from the interior of tubular conduit 20 to the interior of hemodialyzer casing 1 through the aligned tapered slits 23 and 24 which act to distribute the blood evenly along the height of the stack of tubes 2 for better blood flow distribution between all the tubes.

Blood ports used previously had either a circular opening facing the center of the stack of tubes or a rectangular opening along the height of the stack with blood flowing into the rectangular opening from a tube at one end of the rectangle. In the case of the circular opening, blood tends to flow through the spaces between the tubes immediately facing the opening rather than distribute along the entire stack. In the case of the rectangular opening, the pressure and momentum of the blood passing into the port from the tubing from the patient tends to carry it past the first several openings between the tubes in the stack, causing more blood to flow around the tubes in the stack further from the opening and less blood to flow around the tubes adjacent the opening. In either case, blood was not distributed evenly along the entire height of the stack, resulting in more blood flowing across the hemodialyzer between some tubes than between other tubes. This difference in distribution lowers the efficiency of the dialyzer unit.

The flow characteristics of blood entering the blood ports of the present invention from the tubing leading from the patient somewhat resemble the flow characteristics of blood entering a rectangular opening in that the pressure and momentum of the blood tends to carry it past the first several tubes in the stack. However, the tapered slit of the present blood port neutralizes this effect. The cross-sectional area available for blood flow decreases with increasing distance from the opening and is greatest at the point closest the opening. Therefore, while the momentum of the blood tends to carry it past the first several tubes, the area available for blood flow to the first several tubes is greater, these factors neutralizing each other. Consequently, while the blood from its momentum tends to flow toward the tubes further from the inlet opening, to compensate for this there is less cross-sectional area available for flow and blood flow distribution along the entire height of the stack of tubes is more nearly uniform. Uniform blood flow distribution across all tubes increases the efficiency of the hemodialyzer unit.

The efficiency of the hemodialyzer is also increased by the above-described baffles. Without baffles, blood flowing through the hemodialyzer at any given flow rate will cross the width of the tubes one time in passing through the hemodialyzer. With two baffles, as described above for the disclosed embodiment, blood flowing through the hemodialyzer at the same given total flow rate will cross the width of the tubes three times in passing through the hemodialyzer. Since the blood flow path is greater by a factor of three, the velocity of the blood across the tubes must also increase by a factor of three. This increase in velocity causes a mixing of the blood and improves dialysis efficiency as the impurities throughout the blood are brought into contact with the membrane by the mixing action. With a low blood flow velocity, the blood is in laminar flow and impurities in the center of the blood stream must diffuse through the blood to the membrane surface in order to be removed from the blood. The increased velocity disrupts the laminar flow and causes mixing which carries the impurities directly to the surface of the membrane. This increase in velocity of the blood has also been found to reduce the tendency of fibrin to deposit or settle out on the membrane surface which deposit not only increases the thickness of the layer through which the impurities must diffuse to pass from the blood but which also is the initial stages of undesirable and very dangerous blood clots. The one disadvantage presented by the baffles and the increased velocity is that the higher velocity causes a greater pressure drop across the hemodialyzer and since the hemodialyzer is operated without an external blood pump but rather with the patient's heart serving as the only pump to force the blood through the unit, this greater pressure drop increases the strain on the patient's heart. However, these factors must be balanced and this slight disadvantage is outweighed by the advantage of increased efficiency.

In the disclosed embodiment of the present invention, two baffles have been employed, although a single baffle has proven to be equally efficient, and three or more baffles could also be employed. Although the velocity of the blood is sufficient to give complete mixing of the blood if a single baffle is used and no greater efficiency is obtained by more rigorous mixing resulting from more baffles, the increased velocity obtained from the use of two baffles greatly diminishes any tendency for fibrin deposit. If three or more baffles are employed, the increased flow resistance of the unit and the greater pressure drop across the unit place a further burden on the patient's heart. This increased strain on the patient's heart is not offset by any advantages obtained from using three or more baffles. Consequently, the use of one baffle gives the desired increase in efficiency and the use of two baffles is preferred if fibrin deposits become a problem.

In the preferred embodiment of the present invention, the baffles are formed from a series of epoxy resin strips across the width of each of the tubes, each of the epoxy resin strips sealed to the tube above and below the strip. These strips are joined to each other and sealed to one side wall of the casing by an epoxy band along the side of the stack of tubes, the strips extending only to the opposite edges of the tubes leaving space between the opposite edges of the tubes and the opposite side wall of the casing for blood flow around the end of the baffle. The epoxy resin baffles are easily formed as the hemodialyzer is constructed by placing a strip of epoxy resin across the width of each tube as the tubes are arranged in the stack. These strips are joined together by an epoxy resin band along one edge of the stack of tubes, which band also fills the area between the edge of the tubes and the dialyzer casing as the stack of tubes is arranged in the casing. The epoxy resin is then cured, forming the baffles and sealing the strips to the side wall of the casing.

Forming the baffles in this way reduces the costs of the dialyzers because inexpensive materials can be used. This model dialyzer can be made relatively easily and can be discarded after use. The model is also susceptible to techniques and materials for production in large quantities. The hemodialyzer of the present invention has increased efficiency in dialysis and improved blood flow distribution.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A hemodialyzer comprising: a rectangular casing containing a plurality of flattened semipermeable membrane tubes arranged in parallel in a stack therein; a dialysate inlet and a dialysate outlet located on opposite ends of said casing; means associated with said dialysate inlet and outlet for passing dialysate fluid through said hemodialyzer within said flattened tubes; a blood inlet port located on a side of the casing at one end thereof and a blood outlet port located on a side of the casing at the opposite end thereof; means associated with said blood inlet port and outlet port for passing blood through said hemodialyzer across and between said flattened tubes; and at least one baffle extending from a side wall of said casing across the width of each of the flattened tubes

and terminating at the edges of the tubes near to but not touching the opposite side wall of the casing, each such baffle being formed by a series of epoxy resin strips extending from a side wall of the casing across the width of each of the flattened tubes, said strips sealed to said side wall of the casing and to each other at the edges of the tubes adjacent said side wall of the casing by an epoxy resin band between the side of the stack of tubes and the said side wall of the casing, whereby blood flowing through the dialyzer must flow around the baffles and across the flattened tubes a multiple number of times.

2. The hemodialyzer of claim **1** wherein there are two such epoxy resin baffles, and said two epoxy resin baffles extend from opposite side walls of the casing.

3. In a hemodialyzer wherein a plurality of flattened semipermeable membrane tubes are arranged in parallel in a stack and wherein the dialysate flows within the tubes while the blood flows across and between the flattened tubes transverse to the dialysate, the improvement therein comprising: two baffles extending from the opposite side walls of the hemodialyzer across the width of each of the flattened tubes and terminating at the edges of the tubes near to but not touching the opposite side wall of the hemodialyzer, each such baffle being formed from epoxy resin strips extending from one side wall of the hemodialyzer across the width of each of the flattened tubes, said strips being sealed together and sealed to a side wall of the casing by an epoxy resin band between said side

wall and the edges of the tubes on the side of the stack of tubes adjacent said side wall, whereby the blood flowing through the hemodialyzer must flow around the baffles and across the flattened tubes a multiple number of times.

4. A method of forming a baffle in a hemodialyzer which contains a plurality of flattened semipermeable membrane tubes arranged in parallel in a stack within a casing, comprising: placing a strip of epoxy resin across the width of each tube as the tubes are arranged in the stack, said epoxy resin strips aligned with each other in the stack; joining together said aligned epoxy resin strips by placing an epoxy resin strip along one edge of the stack of tubes; filling the space between the epoxy resin strips along the edge of the stack and the hemodialyzer casing with a band of epoxy resin; and curing the epoxy resin to hardness.

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U.S. Cl. X.R.

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