United States Patent [19]

Kell

[11] **4,412,916**

[45] **Nov. 1, 1983**

[54] **AIRLESS ARTIFICIAL KIDNEY ASSEMBLY**

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[73] Assignee: **Cordis Dow Corp.**, Miami, Fla.

[21] Appl. No.: **276,751**

[22] Filed: **Jun. 24, 1981**

[51] **Int. Cl.**[3] **B01D 31/00**

[52] **U.S. Cl.** **210/90;** 210/188; 210/262; 210/296; 210/300; 210/309; 210/321.3; 210/335; 210/436; 210/456; 210/472; 55/159; 55/421

[58] **Field of Search** ..... 210/87, 90, 94, 120, 210/188, 259, 260, 262, 295, 296, 300, 305–310, 321, 323, 335, 433, 436, 455, 456, 472, 927; 128/675, 748, DIG. 3, 214; 73/38, 714, 706, 715; 55/59, 318, 421

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,447,570	6/1969	Collins	222/88
3,523,408	8/1970	Rosenberg	55/159
3,554,035	1/1971	Buisson et al.	73/726
3,713,341	1/1973	Madsen et al.	73/715
3,778,971	12/1973	Granger et al.	55/159
3,854,907	12/1974	Rising	210/436 X
3,993,062	11/1976	Jess	55/159
4,004,587	1/1977	Jess	210/314
4,077,882	3/1978	Gangemi	210/90
4,184,489	1/1980	Burd	128/214 R
4,231,871	11/1980	Lipps et al.	210/87

Primary Examiner—David R. Sadowski

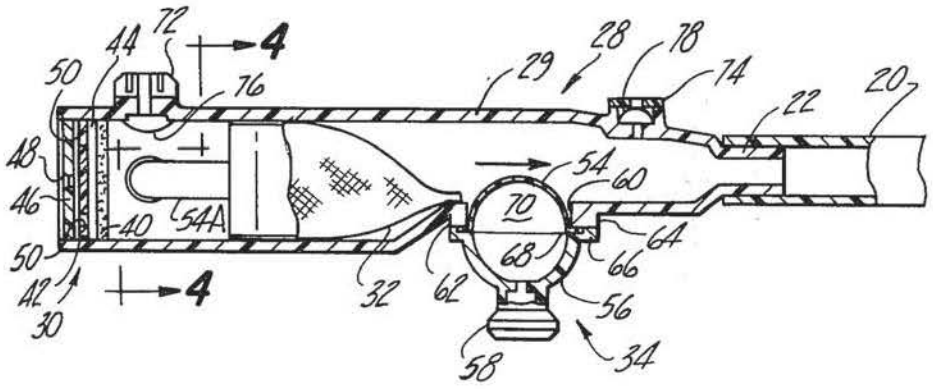
Attorney, Agent, or Firm—Neal A. Waldrop; Jay C. Taylor

[57] **ABSTRACT**

The invention provides an artificial kidney extracorporeal circuit assembly including an artificial kidney having detachably attached multifunctional subassembly means for automatically venting gas bubbles from liquid flowing therethrough, for continuously sensing the liquid pressure of and for filtering said liquid, together with blood tubes for connecting a patient's artery to the kidney and the subassembly outlet port to a patient's vein.

The subassembly includes means associated with a hydrophobic gas bubble vent which prevent clogging, minimize blood clotting and insure against ambient gas entry through the vent.

14 Claims, 9 Drawing Figures



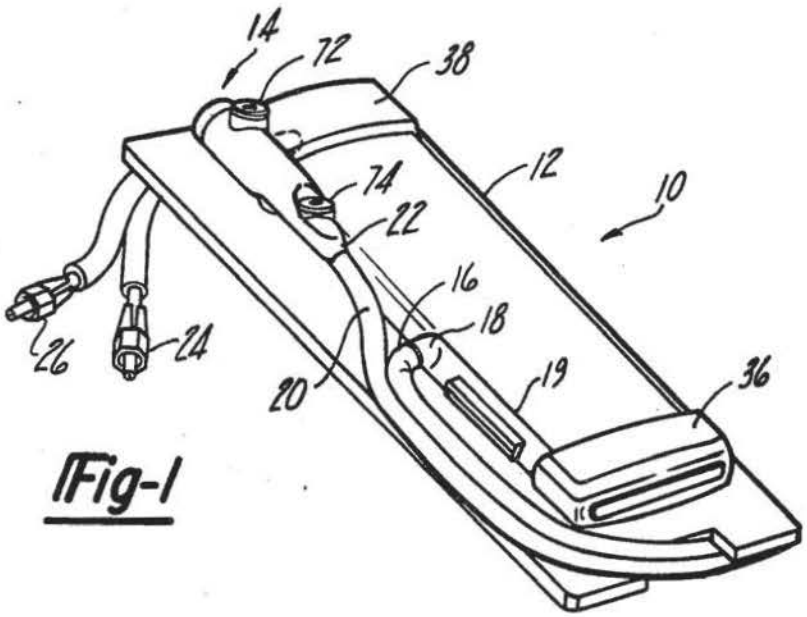


Fig-1

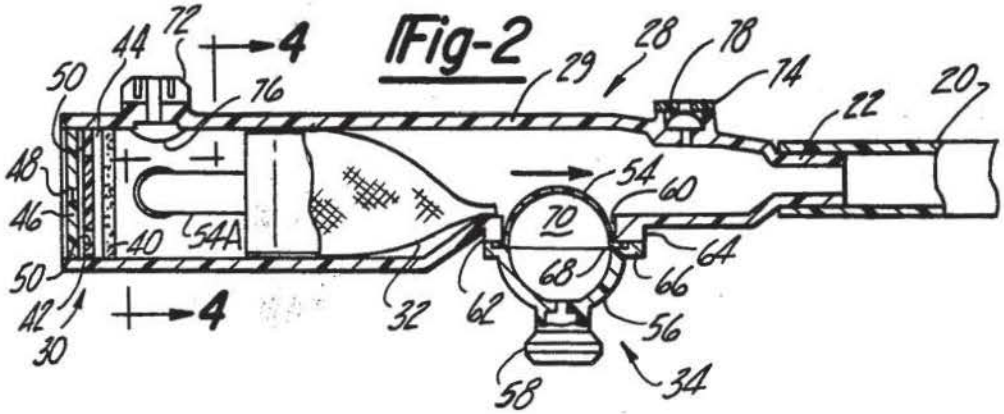


Fig-2

Fig-3

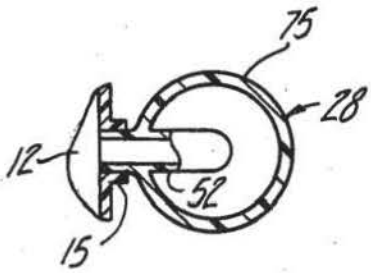


Fig-4

Fig-5

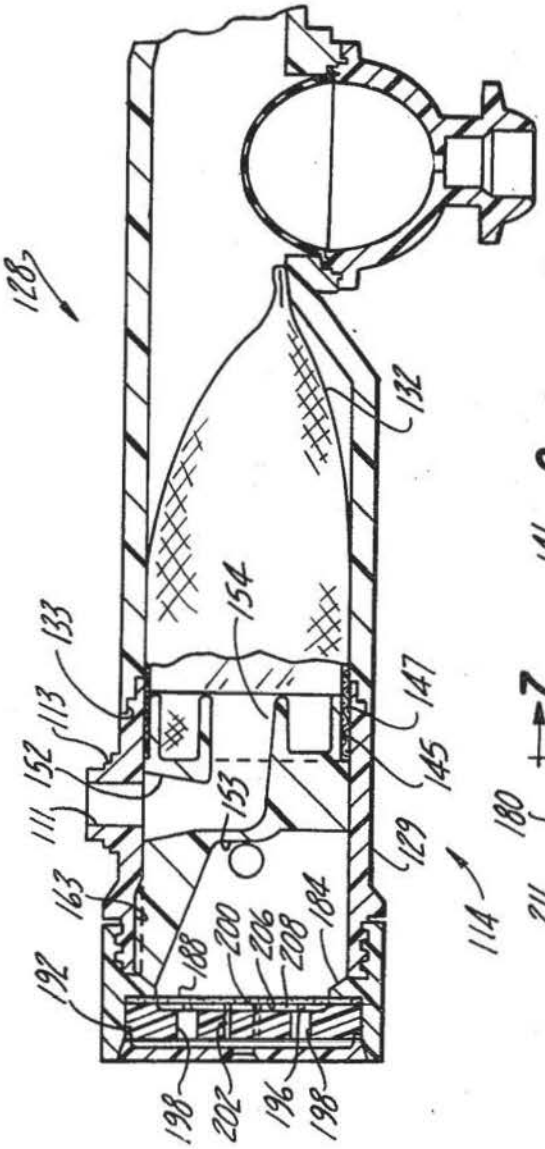
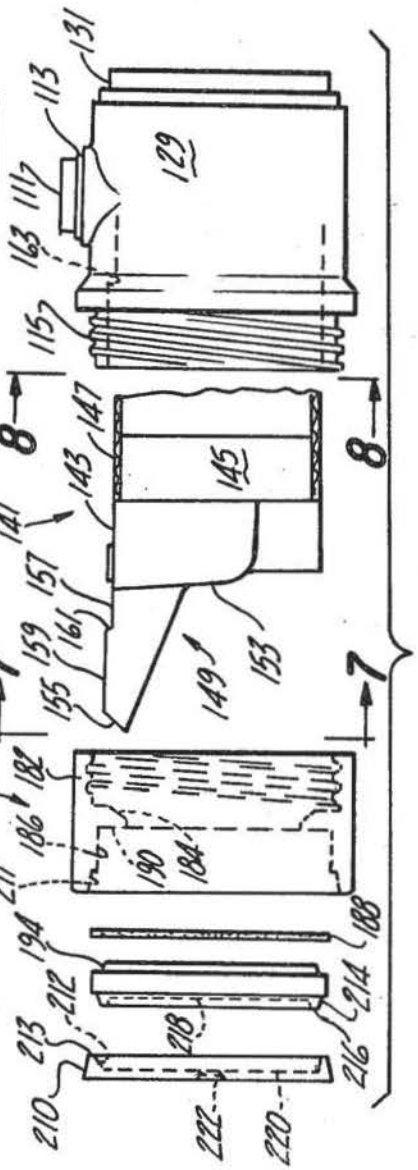


Fig-6



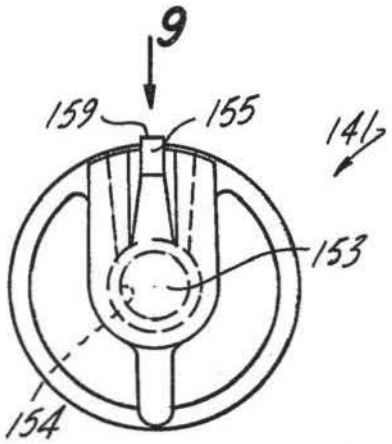


Fig-7

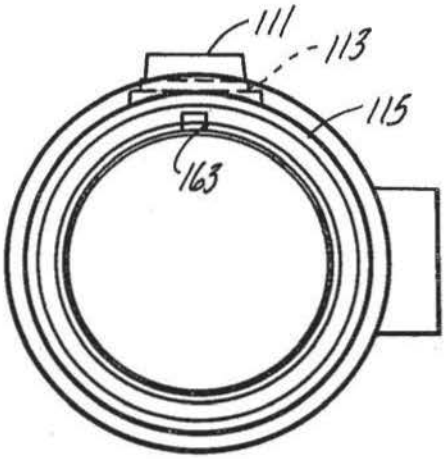


Fig-8

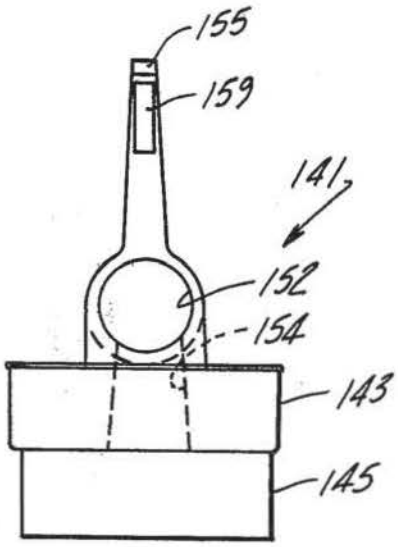


Fig-9

AIRLESS ARTIFICIAL KIDNEY ASSEMBLY

This invention is an improvement on the artificial kidney of U.S. Pat. No. 4,231,871 and more particularly on the kidney shown in FIG. 10 thereof.

BACKGROUND OF THE INVENTION

In hemodialysis treatments using an artificial kidney it is necessary, in the interest of patient safety, to monitor the positive pressure of the blood being returned to a patient's vein and to insure that the returning purified blood is free of particulate matter and gas bubbles. Heretofore, it has been conventional to perform the blood pressure measuring step by incorporating a venous drip chamber in the blood tube that is connected to the patient's vein.

Typically the venous drip chamber is secured to a stand or support adjacent the patient such that it remains upright during the treatment to insure the rise of gas bubbles to the top portion of the chamber. The bubble chamber serves the dual function of bubble removal and of providing a site for measuring the pressure of the blood in the return tube path to the patient's vein. The drip chamber is a closed receptacle and as pressure changes or separated bubbles add to the air space at the top of the chamber it is necessary, periodically, to inject a needle into the air space and suck out some of the gas to maintain a preset level in the chamber to avoid the possibility of air bubbles reaching the patient and causing a fatal embolism.

There are a number of undesirable aspects to the use of such venous drip chambers. First, repetitive needle penetrations increase the potential of creating a non-sterile circuit. Second, relatively constant observation of the blood level by the clinic attendant is required and personal withdrawal of excess gas requires time and effort during the normal four to six hour hemodialysis treatment. Third, there is a continuously existing blood-air interface within the drip chamber and the exposure of a patient's blood to air during the extended four or more hours during the hemodialysis treatment tends to degrade, contaminate, denature, or even clot the blood in the chamber. For this reason, a need for an airless artificial kidney system has been recognized since at least the early 1970's as hollow fiber artificial kidney use increased. FIG. 10 of U.S. Pat. No. 4,231,871 suggests the use of a microporous vent and blood pressure measuring means located in the venous line without showing a specific construction of either unit.

It was found that microporous vents having the form of a disc mounted at the top of a tubular shaped filter device, as shown in FIG. 10 of U.S. Pat. No. 4,231,871, had two operational problems. First, when using a hydrophobic material such as polytetrafluoethylene, having micro-sized openings in the range of about 1 to about 30 microns in the vent disc, clogging of the small openings with blood platelets occurred as the time of use extended and on occasion there was some foaming and some clotting of the blood adjacent the lower surface of the hydrophobic vent. Second, it was found that operating conditions which placed a negative pressure on the lower surface of the vent disc caused air to be drawn through the vent and into the blood chamber. The improved microporous vent containing subassembly of this invention overcomes both of these problems and provides an improved airless operating system, as will be explained in detail hereinafter.

Microporous vents per se and certain constructions using microporous vents to remove air, or entrained gases, from blood or other liquids prior to, or during, intravenous injection into a patient were known prior to this invention. Hydrophobic microporous membranes are shown in U.S. Pat. Nos. 3,778,971 and 3,993,062 and a combination of a hydrophilic and a hydrophobic separator is shown in U.S. Pat. Nos. 3,854,907, 4,004,587 and 3,523,408. These constructions employ tubular separator configurations, pouch-shaped devices as well as combinations of cylindrical separators with disc shaped separating membranes. The problem of ambient air entering into a gas separating filter is recognized in U.S. Pat. No. 4,190,426 and a variety of mechanical check valve constructions have been developed to overcome that problem and are discussed in a number of U.S. patents described in columns 1 and 2 of U.S. Pat. No. 4,190,426, which discussion is hereby incorporated herein.

The microporous vent construction of this invention employs a special housing configuration that includes only a hydrophobic separator and a novel, non-mechanical means to prevent the entry of ambient air into the filtering chamber.

In the past, measurement of blood pressure in the venous blood tube was accomplished by connecting a pressure transducer to the air space above the blood in the venous drip chamber since the pressure on the air in that space is the same as the blood pressure in the same chamber. As above stated, elimination of the blood-air interface is desirable and this invention employs pressure measuring means which does not require air, or gas of any composition, to interface with blood in the blood return path to the patient. Rather, blood pressure measuring means and the microporous vent are combined in a single tubular housing together with a blood filter that during hemodialysis operates completely filled with blood and free of air or other gas. The blood pressure measuring means employs a compressible diaphragm in a spherical or cylindrical receptacle mounted into the wall of the housing such that the diaphragm contacts the blood flowing through the housing as it returns to the patient. The blood pressure measuring receptacle contains air isolated from the blood in the housing by the compressible diaphragm. Movement of the diaphragm responsive to the pressure on the blood in contact with it in the housing expels air from the receptacle which is connected to a remotely located pressure indicator precalibrated to reflect blood pressure. Pressure detecting and measuring devices which include a deformable element having the shape of bellows, truncated cones, hemispheres or a diabolo are shown in U.S. Pat. No. 3,554,035. A frusto-conical, thin membrane disposed in a housing which transmits blood pressure variations through a pressure transmitting medium to a pressure transducer is shown in U.S. Pat. No. 4,077,882. Pressure transducers which employ flexible diaphragms have been used as gauges for gasoline or oil in U.S. Pat. No. 2,385,382, for sterile fluid measurements as shown in U.S. Pat. No. 3,818,765, and for blood as shown in U.S. Pat. No. 3,713,341. Pressure transmitting means responsive to pressure activated diaphragm elements include various fluids such as air, mercury, gasoline, etc., as shown in U.S. Pat. Nos. 2,369,707 and 3,349,623, or mechanical means as shown in U.S. Pat. No. 2,272,950. The above identified prior art represents the most pertinent art known to applicant relating to the separate microporous vent and diaphragm actuated

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