

[54] **MECHANISM FOR CONTROL
PULSATILE FLUID FLOW**

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[22] Filed: **Apr. 6, 1970**
[21] Appl. No.: **25,782**

[52] U.S. Cl. **417/394**, 128/1, 23/258.5,
195/1.7
[51] Int. Cl. **F04b 43/10**, F04b 45/00, A61b 19/00,
A61m
[58] Field of Search 128/1, DIG. 3; 23/258.5;
195/1.7; 417/395, 394, 540, 53, 542

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[57] **ABSTRACT**

This application relates to an apparatus for imparting a pulsatile flow to fluid in a conduit, which has pumping means for providing the pulsatile flow of fluid therein. The apparatus includes an elastic tubular section defining a portion of the conduit and located downstream of the pulsatile flow providing means. The tubular section is surrounded by a sealed sleeve to define a pressurizable space about the tubular section. The space is pressurizable so that the pulsatile flow pattern of fluid passing through the tubular section is controlled in a manner responsive to the pressure within said space. If desired, a portion of the flow conduit upstream of the pumping means is of enlarged transverse dimension and sealed within a second sleeve to define a second pressurizable space to provide a means for increasing the flow of fluid into the pulsatile pumping means.

6 Claims, 3 Drawing Figures

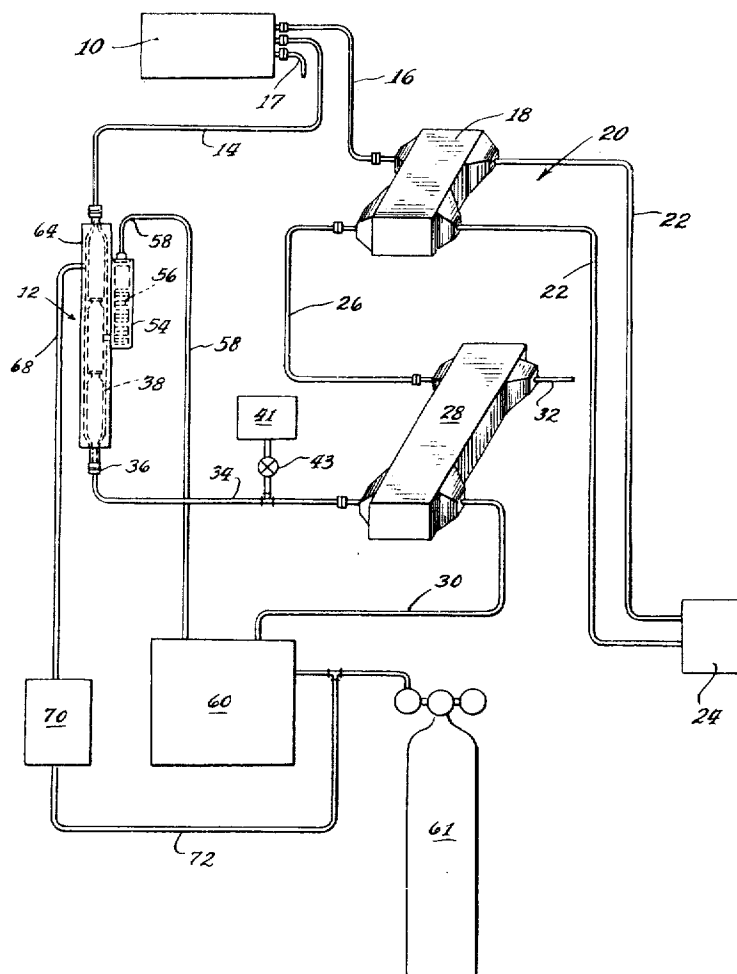
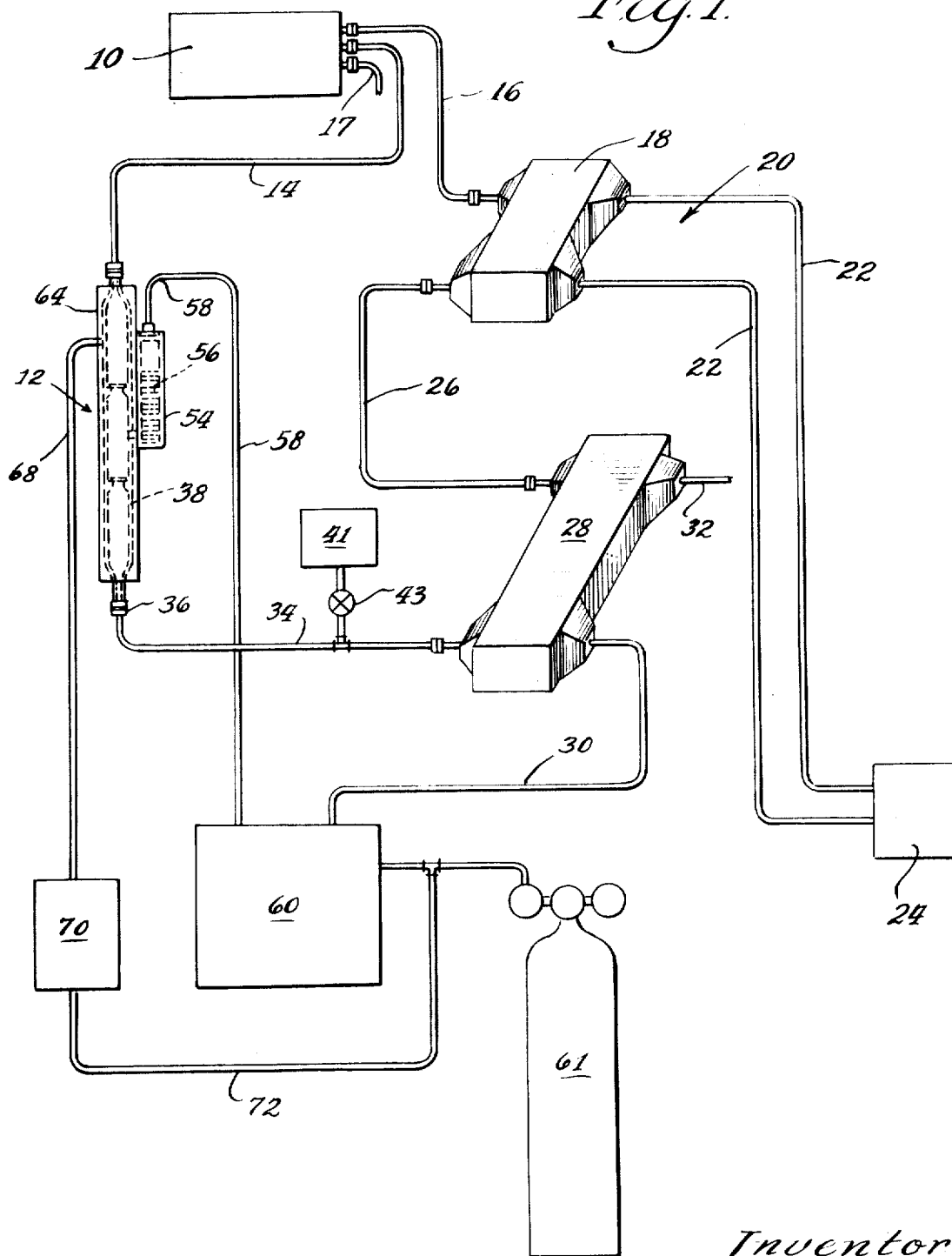
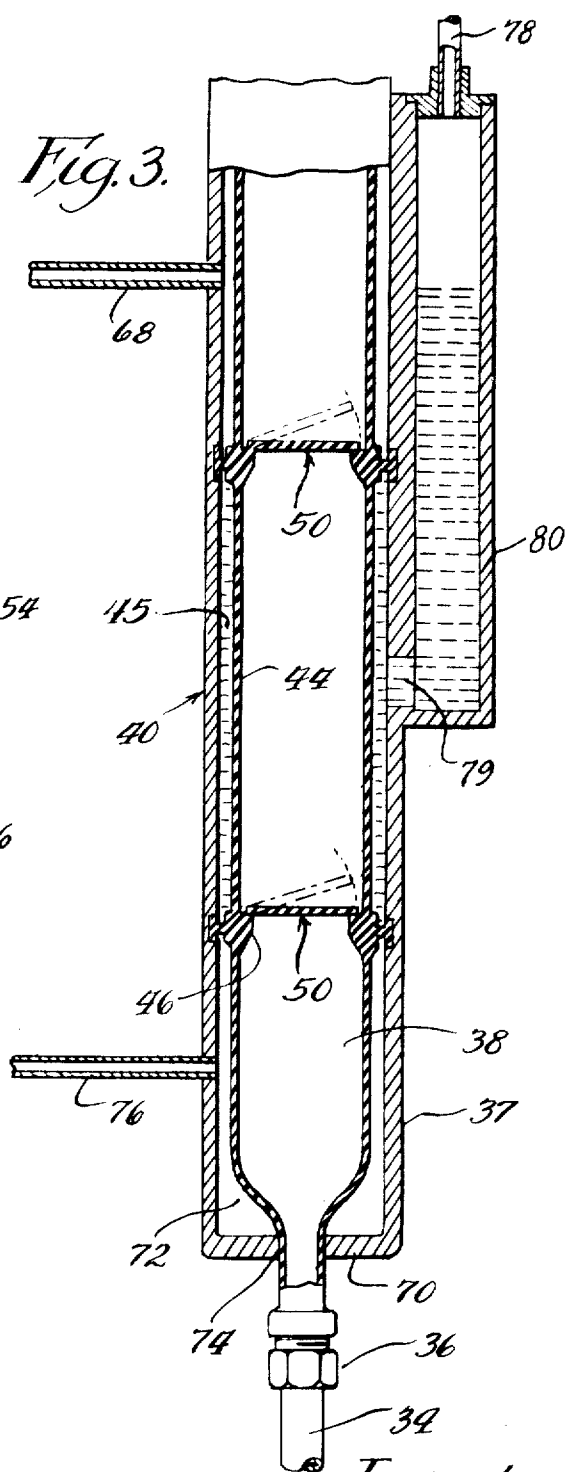
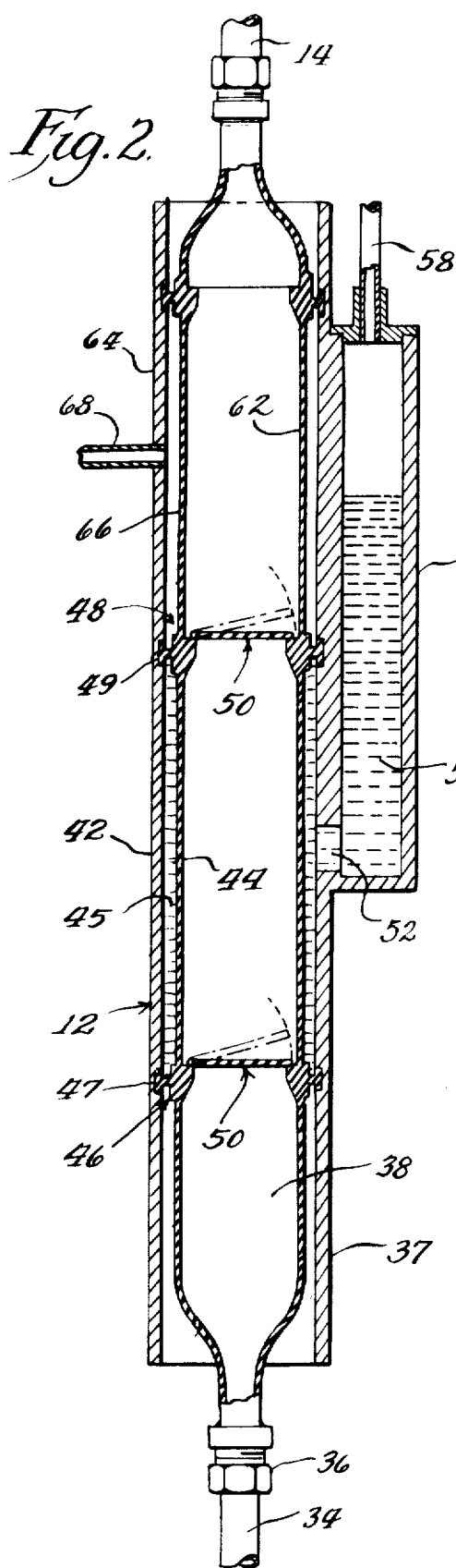


Fig. 1.



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MECHANISM FOR CONTROL PULSATILE FLUID FLOW

BACKGROUND OF THE INVENTION

Equipment for providing a pulsatile flow of fluid through a conduit is currently used in experimental and clinical work relating to organ perfusion and the like. It has been found that the life span of surgically removed living organs, such as livers, hearts, or kidneys, can be prolonged by perfusing the organs with an oxygenated solution. In particular, it has been found that the viability of such separated organs is prolonged by perfusing them with oxygenated solution in a pulsatile flow pattern simulating the beating of the heart.

While several systems for providing a pulsatile flow of oxygenated fluid to living organs have been constructed, deficiencies have been noted in that the prior art devices are unable to provide a wide variation of pulsatile flow patterns, so that the user can select the precise amplitude and shape of the pulsatile flow pressure waves desired. Also, the pumps which provide pulsatile flow do not operate with an optimum volume of flow.

DESCRIPTION OF THE INVENTION

The invention of this application provides a simple means for controlling the pattern of pulsatile flow of fluid through a conduit, permitting the alteration of both the amplitude and shape of the pulse or pressure wave as measured against time. Furthermore, this application provides a means for providing increased volumes of fluid through a narrow conduit to the pulsatile flow pump for greater pumping efficiencies.

In accordance with this invention, an apparatus for imparting flow to fluid in a conduit is provided, having pump means for providing a pulsatile pressure to cause flow of fluid in said conduit. The apparatus contains aorta means comprising an elastic tubular section defining a portion of the conduit. The tubular section is located downstream of the pulsatile flow providing means, and is surrounded by a sealed sleeve to define a pressurizable space about the section. The space within the sleeve is pressurizable as desired to alter the compliance of the tubular section by controllable pressure to any degree and in any pattern desired. Hence, the pulsatile flow pattern of fluid passing through the sleeve having pulsations provided by the pulsatile pump means is modulated in a manner responsive to the pressure within the space about the sleeve. For example, a constant pressure can be used, or an in-phase oscillatory pressure to augment the amplitude and alter the shape of the pulsations, or an out-of-phase oscillatory pressure to reduce, modify, or even eliminate, the pulsations. As a result of this, the ultimate flow pattern is controllable by the selective controlling of the pressure within the space about the tubular section as described further below.

The tubular sections used herein can be of any cross section defining a closed figure, e.g., round, oval, or the like.

Furthermore, a portion of the fluid flow conduit located directly upstream of and communicating with the inlet of the pulsatile pump means can define an atrium space of enlarged transverse dimension to provide a greater pulsatile flow efficiency, in accordance with the teachings of Anderson, et al., *American Heart Journal*, Jan., 1967, pages 92-105.

In accordance with this invention, the portion of the conduit defining the atrium space is surrounded by a second sealed sleeve to define a second pressurizable space about the portion of conduit. The second space is pressurized with oscillatory pressure which causes the atrium space to collapse during the filling phase of the pulsatile pumping means and to expand during the pumping phase of the pulsatile pumping means. Thus, abundant fluid is provided to the pulsatile pumping means, resulting in greater pumping efficiency.

Referring to the drawings:

FIG. 1 is a schematic view of an organ preservation system in accordance with this invention.

FIG. 2 is a view, taken in vertical section, of the pulsatile pumping means and related portions used in this invention.

FIG. 3 is a partial vertical sectional view of another embodiment of the atrium space and the pulsatile pumping means.

Referring to the drawings, an organ perfusion system is shown in which perfusate fluid, for example blood or plasma, is pumped through a typically transparent organ preservation chamber 10 to permit viewing of the organ. The fluid is driven by a pulsatile pump 12 through conduit 14 into chamber 10, through a cannulated organ contained therein, and then out conduit 16. Access port 17 is provided in organ chamber 10 for use as needed. Port 17 can be connected to the organ to conduct organ secretions out of the chamber 10 to an accumulating container (not shown), if desired. The perfusate flow path of the organ preservation system is disposed in a hyperbaric chamber, if desired, for hyperbaric perfusion. The device can include a compact container for easy transportability.

The liquid perfusate is conducted uniformly from the organ in chamber 10 through conduit 16 to a conventional heat exchanger 18, in which the temperature of the perfusate is brought to a desired temperature, generally between 4° and about 37° C. to control the temperature within the system. A separate circuit for heat exchanger fluid 20 passes into close heat exchanging relation with the perfusate passing into the heat exchanger from conduit 16, but the two fluids are separated by a thin metal heat transfer partition. Heat exchange fluid such as saline is circulated in conduits 22 between heat exchanger 18 and a conventional temperature control source and pump 24.

Perfusate at a desired temperature passes from heat exchanger 18 via conduit 26 to a conventional oxygenator 28 (such as described in Belgian Pat. No. 726,886) for transferring oxygen to and expelling carbon dioxide from the perfusate. Oxygenator 28 also contains an oxygen flow path comprising line 30 and exhaust line 32. From the oxygenator the perfusate is passed through conduit 34 and sealed connection 36 into an enlarged portion of the conduit which defines atrium space 38, typically made of flexible, limp, thin-walled rubber tubing. Atrium space 38 provides a flexible storage chamber for perfusate to accumulate between filling phases of the pulsatile pump 12, and is surrounded by tubular guard 37.

The amount of perfusate flowing in the system is regulated by adding perfusate as needed from reservoir 41, controlled by valve 43, to compensate for liquid lost as secretions through port 17 and the like.

As shown in FIG. 2, pulsatile pump 12 comprises a cylinder 42 containing an elastic tube 44 positioned axially within cylinder 42. The space 45 between tube 44 and cylinder 42 is sealed by annular seals 47, 49 to define an annular chamber. Inlet means 46 and outlet means 48 from the pump each include a one-way leaf-type flap valve 50, each of which opens to permit flow into tube 44 through inlet 46 and out outlet 48 while preventing backflow of fluid.

Cylinder 42 defines an entrance port 52 to receive fluid from an oscillatory pressure providing system, which includes tube 54 containing a head of hydraulic fluid 56 and which is connected through line 58 to a conventional oscillatory pressure generating control source 60 (FIG. 1), operated by gas supply 61, typically oxygen. Control source 60 is shown to provide oscillatory oxygen pressure to line 58, and also to provide an oxygen flow to oxygenator 28, typically using oxygen passing through a flowmeter in control source 60. The oscillatory pressure causes fluid to pass back and forth through port 52 to a space 45 within cylinder 42 and outside of tube 44 to actuate pump 12 by alternately collapsing tube 44 and permitting it to expand again in accordance with the pressure and relaxation cycles of the oscillatory pressure. As tube 44 collapses, fluid is forced out of outlet means 48 in each pumping phase, and as tube 44 expands, fluid passes in through inlet means 46 in each filling phase. Typically, pump 12 is positioned at a vertically lower position than organ chamber 10 to provide a hydrostatic pressure head of fluid to assist in filling of tube 44 during the filling phase. Oxygenator 28 is also positioned vertically lower than chamber 10 for pressurization there.

A suitable pneumatic control source 60 for providing oscillatory pressure to line 58 and entrance port 52 is disclosed in

the article by Demers et al., entitled "A Perfusion Circuit for Organ Preservation in Portable Chambers," *J. Surgical Research*, vol. 9, No. 2, pp. 95-99 (1969). This article also refers to a suitable combined heat exchanger-oxygenator which can be used in substitution for the separate members 18 and 28 in this invention. This or other pneumatic systems can be adjusted to provide the desired period between pulses.

In accordance with this invention, an elastic tubular section 62 defines a portion of the conduit for pulsatile flow of fluid, and is located downstream of pulsatile pump 12. Tubular section 62 is surrounded by a sealed sleeve 64, integral with cylinder 42, to define a pressurizable space 66 between sleeve 64 and tubular section 62. Line 68 leads between space 66 and a pressure control 70 (FIG. 1) which connects to pressurized oxygen source 61 via line 72.

Pressure control 70 can be a simple constant pressure regulator, or, if desired, can be a source of variable pressure, coordinated, if desired, with the oscillatory pressure provided by source 60. As fluid is forced out of pump 12 in a pulse of pressure, the amplitude and shape of the pressure wave can be varied by varying the resilience or compliance of tubular section 62. This resilience, or compliance, is controlled as desired by controlling the pressure provided through line 68, thus varying the capacity of tubular section 62 to receive perfusate. If high pressure is provided, the compliance characteristics of tube 62, when exposed to the pressure wave passing out of pump 12, are quite different from the compliance characteristics of tube 62 when there is a low pressure or a reduced pressure within conduit 68 and space 66. A constant pressure can be provided within space 66, as well as an oscillatory pressure of any type desired, either in phase or out of phase with the oscillatory pressure used to drive pump 12. Thus great flexibility is available in the control of the shape of the pressure pulse of the oscillatory fluid flow passing through conduit 14 to organ chamber 10.

Referring to FIG. 3, there is shown a modification of a device which is otherwise similar to the device of FIGS. 1 and 2 except as stated. The portion of conduit defining atrium space 38 and disposed within guard or sleeve 37 is sealed by cap 70 to define another pressurizable space 72. The conduit defining atrium chamber 38 is typically glued to cap 70 at 74 to make the space fluidtight. Line 76 leads between space 72 and a source of oscillatory pressure such as source 60. The pressure oscillations in spaces 45 and 72 are arranged to be out of phase with each other, generally with the pulses in space 72 shortly preceding the pulses in space 45. Hence, as elastic tube 44 of pump 12 is in the filling phase of its pumping cycle for receiving fluid through inlet 46, line 76 is providing a pulse of pressure to space 72 to collapse the conduit defining atrium space 38 to force fluid into pump 12. No check valve is needed to prevent excessive backflow of fluid from atrium space 38. The majority of fluid in atrium space 38 passes into pump 12 without such a valve because inlet 46 is wider than conduit 34 and because the pressure in conduit 34 caused by the elevated organ chamber 10 is greater than the pressure within tube 44 during the filling cycle, because of the inherent resiliency of the tube and its tendency to spring back to its uncollapsed position. For greater efficiency, a check valve can be provided, if desired.

Out of phase oscillatory pressure is provided to space 45 through line 78 and port 79 by a conventional time delay device connected to line 76 to operate a pilot valve in line 78 which opens the line in one position and closes, but permits backward venting, in another position, to provide oscillatory pressure in tube 80 and space 45. Line 78 is then connected to a pressure source such as oxygen supply 61, to provide a constant pressure to line 78 upstream of the pilot valve.

A typical time delay device can constitute a conduit connected to line 76, running through a chamber of predetermined volume, and then past an adjustable needle valve to a pressure responsive switching control of the pilot valve. The size of the chamber and the needle valve are adjusted to give the desired time delay. A suitable pilot valve is available from

the Fluidonics Division of Imperial Eastman Corporation of Chicago, Illinois under the part number 300135.

During the pumping phase of pump 12 in FIG. 3, flap valve 50 of inlet 46 is closed, and the oscillatory pressure in space 72 and line 76 is at a reduced level to permit the conduit which defines atrium chamber 38 to fill once again with perfusate.

The pressure pattern in space 72 can be arranged so that the duration of each pressure pulse with collapses the portion of conduit defining atrium space 38 lasts for only a portion of the filling phase of tube 44.

In a specific embodiment, the oscillatory pressure in line 76 has a maximum pressure of about 20 mm. Hg, while the oscillatory pressure provided to lines 58 or 78 and from thence to pump 12 has a maximum pressure of about 100 mm. Hg. The frequency of oscillation for both oscillatory pressures is, for example, 60 cycles per minute. The pressure provided in line 68 can be constant at 20 mm. Hg. A constant pressure of this level in line 68 assures that a minimum bias diastolic pressure is constantly present in the system between pulsations of flow, and particularly that such minimum bias pressure is imposed upon the organ within chamber 10 through line 14. It is believed that this prolongs organ viability.

The parts which contact the perfusate are typically made of silicone rubber to be atraumatic to blood.

The apparatus of this invention can use any fluid in conduit 68 and the space between tubular section 62 and sleeve 64, and in the other pressurizable areas, depending upon the compliance characteristics desired. Liquids of varying viscosity such as oil, silicone fluid, or water, provide differing compliance characteristics, which in turn differ from the compliance characteristics of gases. An incompressible liquid such as saline can be used, while closing off conduit 68, to provide very little compliance to tubular section 62, in which there is very little damping or modulation of the pressure pulses passing therethrough.

The above specific disclosure is for illustrative purposes only and is not for purposes of limiting the scope of the invention of this application. Broadly, the invention of this application can be utilized in many different devices, including organ perfusion apparatus comprising (a) container means for receiving an organ; (b) means for delivering perfusate to the organ within the container; (c) means for developing pulsatile pressure in the perfusate delivered to the organ; (d) means for imposing a minimum pressure bias on perfusate circulated through the organ between pressure pulses; (e) means for oxygenating perfusate conducted from the organ; and (f) control means for determining the pump output, the control means comprising means for setting the period of each high pressure pulse.

Manual control means can be provided to vary the temperature and pressure of perfusate provided to the organ, as well as for regulating the pulse rate and systole period of each pulse developed by the pump means.

That which is claimed is:

1. In an organ perfusion apparatus for passing fluid in a conduit through an organ in a container including pump means for providing a pulsatile pressure to cause flow of fluid in said conduit, in which said pump means comprises a cylinder containing an elastic tube positioned axially therein, means for sealing the interior of said tube from the exterior thereof to define a sealed flow path for fluid to be pumped, and inlet and outlet means to allow said fluid to pass through the tube, said inlet and outlet means each containing a one-way valve to prevent backflow of fluid, said cylinder defining an entrance port to receive fluid within the cylinder and outside said tube from first oscillatory pressure providing means, to actuate said pulsatile pressure providing means by repeatedly collapsing said tube and permitting it to expand again by application of oscillatory pressure, in which a portion of said conduit defines an atrium space of enlarged transverse dimension, said atrium space being located directly upstream of and extending to said inlet means of the pump means, in which said atrium space is

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surrounded by a second sealed sleeve to define a second pressurizable space about said portion of conduit, and in which said second sleeve has second means for pressurizing said second space with oscillatory pressure which is out of phase from the oscillatory pressure provided by said first oscillatory pressure providing means, so that when the elastic tube of the pump means is in its filling phase, the portion of conduit defining said atrium space is in its collapsing phase to provide pressurized fluid to said inlet means, for greater pumping efficiency.

2. The organ perfusion apparatus of claim 1 in which an elastic tubular section defines a portion of said conduit and is located between said pump means and said organ container, the elastic tubular section being surrounded by a sealed sleeve to define a pressurizable space about said tubular section, and

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means for controlling the pressure in said space, whereby the pulsatile flow pattern of fluid passing through said tubular section is controlled in a manner responsive to the pressure within said space.

3. The apparatus of claim 2 in which said elastic tubular section is positioned downstream of and adjacent to said pulsatile pressure providing means.

4. The apparatus of claim 2 in which said conduit for pulsatile fluid flow defines a closed loop circuit.

5. The apparatus of claim 2 in which said sealed sleeve and said cylinder define a single, integral member.

6. An organ perfusion device incorporating the apparatus defined in claim 2.

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