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[54] IMPLANTABLE BLOOD PUMPING SYSTEM

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[73] Assignee: The United States of America as represented by the United States Atomic Energy Commission, Washington, D.C.

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[51] Int. Cl. A61f 1/24

[58] Field of Search ... 3/1, DIG. 2; 128/1 D, 214 R, 128/DIG. 3; 417/383, 389, 394, 395

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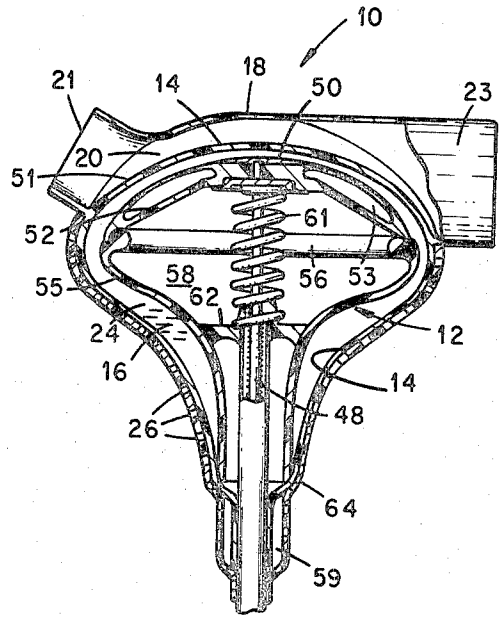
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[57] ABSTRACT

A mechanically driven and automatically controlled artificial blood pump for replacement of a ventricle of a natural heart, including an expandable piston mounted within a flexible membrane but separated therefrom by means of a protective liquid. Both the membrane and piston are mounted within a housing having an upper chamber in which blood is pumped by the piston through actuation of the membrane from an inlet port to an outlet port and a lower chamber that is provided with perforations to expose the lower part of the membrane to body fluids that normally surround a heart and which are at ambient body pressure. A central part of the membrane is sealed to the housing to separate the upper and lower chambers. The piston is driven at a constant rate of reciprocation over a fixed-length stroke by means of an electric motor through a cylindrical groove cam. Since there is a natural change in venous pressure during diastole in response to bodily demands, there is a corresponding change in the pressure at the inlet valve of the blood pump and in the upper chamber. Automatic control is achieved by using a reciprocating drive of fixed rate and displacement in conjunction with a liquid reservoir referenced to ambient body tissue pressure which allows power assisted filling while precluding negative pressures at the inflow blood vessel. This particular arrangement ensures that the volume of blood admitted to the upper chamber during diastole is an accurate function of the blood demand of the body at all times, irrespective of the inflow valve impedance, since any differential space between maximum piston displacement and demanded blood volume is filled by the body fluids at ambient pressure. The pump can therefore be mechanically actuated by a relatively simple driving unit while automatically providing the required blood flow rate and maintaining diastolic pressure in the upper chamber very close to normal pressure.

10 Claims, 6 Drawing Figures



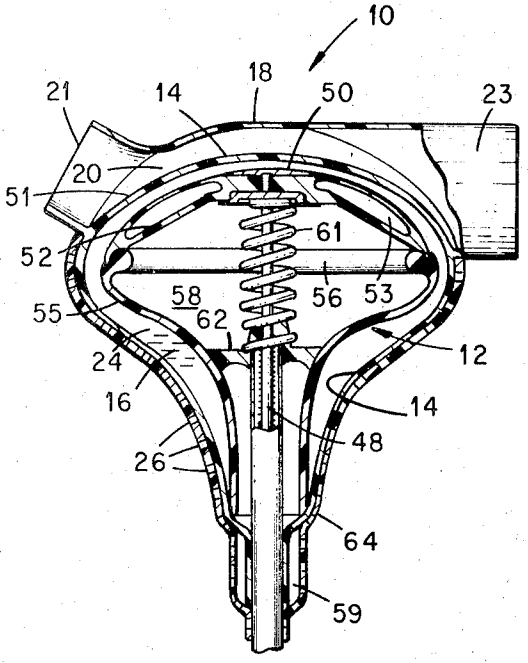


Fig. 1

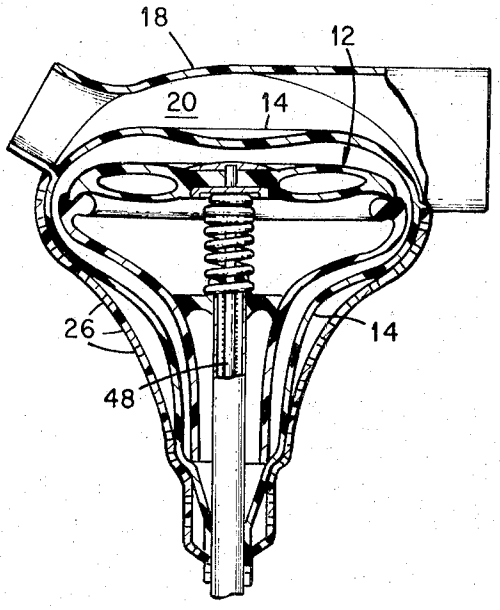


Fig. 2

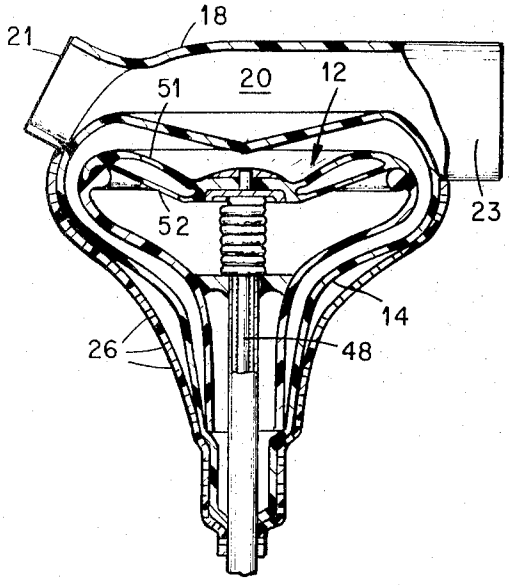


Fig. 3

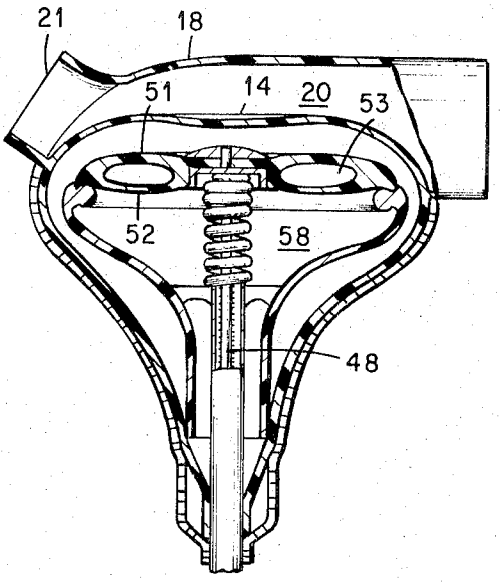


Fig. 4

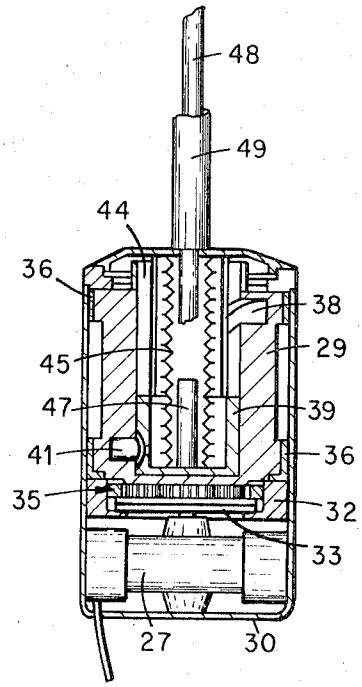


Fig. 5

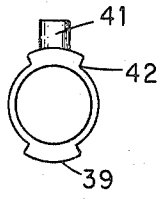


Fig. 6

IMPLANTABLE BLOOD PUMPING SYSTEM

ORIGIN OF THE INVENTION

The invention disclosed herein was made under, or in, the course of Contract No. AT(04-3)-857 with the United States Atomic Energy Commission.

BACKGROUND OF THE INVENTION

The present invention relates generally to artificial implantable blood pumps, and more particularly, it relates to a variable volume blood pump including a piston-driven flexible membrane that is referenced to ambient body pressure.

One physiological need is to maintain a natural level of blood pressure in the circulatory system. Veins, for example, are easily collapsed and distended by unusual blood pressure variations and under natural conditions are near ambient atmospheric pressure at all times to maintain their normal shape. In particular, any significant lowering of venous blood pressure from atmospheric pressure will result in collapse of the veins and consequent disruption of blood flow. The pulmonary circulatory system is particularly pressure sensitive in that it contains blood vessels having delicate walls for transport of oxygen to the blood. Consequently, the pressure in these vessels must be kept very near normal physiological values lest an underpressure cause collapse of the vessels or an overpressure cause rupture of the vessels. An artificial heart system should therefore maintain the blood pressures in a cardiovascular system at natural levels with reference to ambient pressure and pump the blood at a rate that will sustain physiological demands of the body.

In order to prevent venous collapse in an artificial heart system, it is preferable that the pump in such a system be allowed to fill at a rate that is determined only by venous pressure at the pump input and that active drawing of the blood into the pump be avoided. Typically, venous input pressure is 6 to 8 mm of mercury above ambient and natural variations which control the blood inflow rate to the natural heart are correspondingly small. It would be convenient, therefore, to allow the blood to flow into the pump only under a natural pressure head in a manner similar to a natural heart. However, because of the hydraulic characteristics of practical artificial blood pumps, the inflow impedance of such a pump is considerably higher than a natural heart and prevents sufficient inflow during the time allowable for filling of the pump. Thus, for a blood pump to maintain the required flow rates, it must be driven so that blood is actively drawn into the pump during its filling phase. However, if insufficient blood is drawn into the pump, there may be a pressure buildup to harmful levels in the vessels supplying blood to the pump, the dangerous pressure level being about 18 mm of mercury; and, as discussed hereinbefore, when blood is too actively drawn into a pump, there is the danger of collapsing the veins. Additionally, sustained below-ambient pressures on the vessels at the pump inlet tend to damage the blood and may lead to damage of the inflow valves on the pump if the immediately surrounnding blood vessel collapses and is sucked into the valve orifice. Thus, any suction created by a blood pump must be very precisely controlled to avoid these damages, yet the pump should provide the flow rates necessary for at least moderate levels of physical activity. For a mature male a flow rate that is variable approximately between 6–12 liters per minute is required.

Another problem in the design of artificial heart pumps is to avoid applying excessive force to the pumping piston during the initial part of the discharge phase of the pump when, due to the natural elasticity of the arterial system, the back-pressure is less than the value encountered at the end of the stroke. Unless the pumping membrane is artifically restrained, excessive force during this period will discharge the blood too rapidly, increasing the kinetic losses at the outflow valve, thereby reducing the conversion efficiency of the device and possibly damaging the blood cells. For low levels of physical activity the back-pressure can normally be expected to vary between 80 and 120 mm of mercury. During relatively strenuous activity the peak pressure would normally rise to about 140 mm of mercury. However, recipients of artificial heart pumps may be victims of degenerative cardiovascular disease which could raise the peak back-pressure to 180 mm of mercury. To avoid these possible deleteriory effects and to maximize the conversion efficiency of the artificial pumping system, the actuator should be capable of providing a driving force which matches exactly the changing arterial back-pressure and thus duplicating the natural blood outflow velocity profile.

Existing designs proposed to meet some or all of the foregoing are complicated and inefficient. The invention provides a simple, efficient, compact, potentially reliable design which is responsive to all of the requirements discussed above.

SUMMARY OF THE INVENTION

In brief, the present invention pertains to an implantable blood pump that provides variable flow rates and pressures as required by a natural physiological arteriovenous system, in an efficient manner and without damage to the blood or distortion of blood vessels. The pump includes a housing having an upper chamber provided with a blood inlet port and a blood outlet port and a lower chamber that is perforated to allow entry of body fluids that normally surround a heart and which are at ambient pressure. A flexible membrane is mounted within the housing and is sealed to the housing at the division of the upper and lower chambers. The flexible membrane includes an upper portion that is expandable into the upper chamber for pumping blood from the inlet port to the outlet port. The membrane also includes a lower portion that is exposed through the perforations in the housing to the body fluids at ambient pressure. An expandable piston is mounted within the membrane with a protective liquid separating the piston and membrane at all times. During diastole, as the piston is contracted to move the upper portion of the membrane out of the upper chamber to draw blood into the chamber, the lower portion of the membrane is moved away from the pump housing by the body fluids at ambient pressure flowing through the perforations whenever the pressure in the upper chamber drops a predetermined differential amount below ambient pressure. The pressure in the upper chamber is precisely controlled thereby and maintained at a level that gently draws blood into the chamber yet prevents the pressure in the chamber from dropping to a dangerous level. Moreover, blood volume and flow rates are automatically met since any

slight rise in venous pressure at the inlet port reduces the volume of the amount of body fluids admitted through the perforations and thereby increases the volume of blood drawn into the pump. As the piston is expanded during systole to move the flexible membrane into the upper chamber to pump the blood out of the chamber, the body fluids in the lower chamber are first expelled by the flexible membrane while the pressure in the upper chamber builds up slowly. At this time arterial back pressure is at its minimum instantaneous level; therefore, little energy is wasted in unnecessarily accelerating the blood. Since variable blood pressure and flow rates are automatically accommodated in such an arrangement, a constant speed rotary driving source, with its inherent simplicity, reliability and load averaging qualities, may be used to actuate the piston. The arrangement, moreover, permits the piston to have a fixed-length stroke at a constant rate of reciprocation.

It is an object of the invention to supply the blood-flow rate and pressure demands of a physiological system by means of an artificial implantable blood pump.

Another object is to simulate the action of a natural heart without distortion of connecting blood vessels.

Another object is to compensate very exactly and in a precisely controlled manner for the inflow impedance of an artificial implantable blood pump.

Another object is to provide an artificial implantable blood pump that is simple, reliable, efficient and that automatically accommodates to variable blood flow rates and volume demands of a physiological system under normal levels of physical activity.

Another object is to provide an artificial implantable blood pump including a piston having a constant rate of reciprocation and stroke length and that is driven with a rotary drive capable of load averaging that is, conserving energy while providing the exact instantaneous driving force required — no more and no less.

Another object is to provide an expandable piston with a flexible driving end that includes a nonfolding wall.

Other objects and advantageous features of the invention will be apparent in a description of a specific embodiment thereof, given by way of example only, to enable one skilled in the art to readily practice the invention, and described hereinafter with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional side view of a piston actuated artificial implantable blood pump with the piston shown at the end of a discharge stroke, according to the invention.

FIG. 2 is a cross-sectional siide view of the pump of FIG. 1 with the piston shown partway through a filling stroke.

FIG. 3 is a cross-sectional side view of the pump of FIG. 1 with the piston shown at the end of a filling stroke.

FIG. 4 is a cross-sectional side view of the pump of FIG. 1 with the piston shown partway through a discharge stroke.

FIG. 5 is a side view, partially in cross-section, of an electric motor and a cylindrical groove cam for reciprocating the piston of FIG. 1.

FIG. 6 is an end view of the cam follower for the cam of FIG. 5.

DESCRIPTION OF AN EMBODIMENT

Referring to the drawing there is shown in cross section in FIG. 1 an artificial implantable blood pump 10 including an expandable piston 12 mounted within a flexible membrane 14 but separated therefrom by means of a protective liquid 16. The membrane 14 and piston 12 are mounted within a housing 18 having an upper chamber 20 for pumping blood from an inlet port 21 to an outlet port 23 and a lower chamber 24 that is provided with perforations 26 to expose the lower part of the membrane 14 to body fluids which are adjacent the space in which the pump is implanted. There body fluids are naturally at ambient body pressure. The piston 12 normally is driven to successive positions, shown in FIGS. 2, 3 and 4, at a constant rate of reciprocation over a fixed-length stroke by means of an electric motor 27 (FIG. 5) and a cylindrical groove drum cam 29 mounted in a hermetically sealed housing 30. The motor conveniently may be a brushless dc motor using permanent magnets of samarium-cobalt in the rotor and an ironless stator designed to run at a constant speed of 9,000 rpm in the housing 30 on self-energizing compliant plastic-coated multifoil type gas bearings. A hermetic aluminum seal 32 separates the motor 27 from the cam 29. Rotary motion is coupled through the seal 32 by means of a double-plate magnetic coupling 33 which drives a compound planetary gear train 35. The cam 29 is driven by the gear train at a reduced speed. As a typical example, the input-output ratio may be 75:1 which provides a cam rotation of 120 RPM for a 9,000 RPM motor speed. The cam runs in a set of combined radial-thrust bearings 36 which conveniently may be made of porous bronze. The rotary motion of the cam 29 is converted to reciprocating motion by means of a continuous single-turn elliptical slot 38 machined in the inner surface of the cam over the length of the cam. A shuttle 39 (FIGS. 5 and 6) is provided with a guide pin 41 which rides in the slot 38 and is further provided with grooves 42 which mate with linear stationary guides 44 that are made integral with the housing 30 to prevent rotation of the shuttle. The continuous elliptical configuration of the slot 38 is such that the shuttle 39 is moved smoothly through one back-and-forward cycle or reciprocation for each revolution of the cam 29. A bellows 45 has an outer end sealed to the housing 30 and at the other end to the bottom of the shuttle 39. Also attached to and integral with the bottom of the shuttle is a connector 47 to which the lower end of a cable 48 connects. The cable is covered with a plastic sheath 49 that is sealed at the edges of a hole in the housing 30. The cable is reciprocated within the sheath by means of the shuttle 39, the hermetic seal of the housing 30 being ensured by the bellows 45. The upper end of the cable 48 is secured to the piston 12 by means of a hub 50 to reciprocate the piston with the cable.

The piston 12 includes an upper portion comprising flexible double membrane walls; an outer wall 51 and an inner wall 52 enclosing a space 53 that is filled with a liquid or a light grease. The piston also includes a single-wall membrane lower portion 55. At the top and bottom positions of the piston 12, shown respectively in FIGS. 1 and 3, the inner membrane 52 is pulled almost flat, while the outer membrane 51 is deflected

into a slightly convex or bulged shape by the liquid in the space 53. In the mid-positions of the piston 12, such as shown in FIGS. 2 and 4, walls 51 and 52 both bulge due to their being pulled into the diameter of a stiff rib 56 of the lower membrane portion 55, the liquid in the space 53 smoothly bowing the walls 51 and 52 to prevent any folding or wrinkling and consequent wear during reciprocation of the piston.

The piston 12 encloses an inner space 58 that is filled with a gas such as nitrogen or carbon dioxide to maintain a fullness in the shape of the piston as it is reciprocated. Compression of the gas during reciprocation is partially accommodated at the lower end of the piston by expansion of the membrane 14 into a make-up reservoir 59 provided in the lower end of the housing 18. The reservoir 59 is filled with body fluids at the end of a discharge stroke (FIG. 1), and at the end of a filling stroke, the fluids are discharged from the reservoir through perforation in the housing 18.

The piston 12 may be driven with a push-pull force through the cable 48, or, alternatively, a spring 61 may be mounted between the hub 50 and a supporting web 62 so that only a pulling force is required to be transmitted through the cable. This permits the use of a more flexible cable and thereby allows greater freedom of placement of the motor and pump in a body.

In operation of the pump 10, when the pump begins to fill, the upper portion of the membrane 14 extends maximally into the space 20 (FIG. 1), the lower portion of the membrane 14 is maximally compressed by the body fluids in the space 59, the piston 12 is beginning its downward reciprocation, annd the membrane 14 is being urged out of the space 20 by the piston 12. As the pressure in the space 20 drops slightly below ambient, a check valve (which may either be artificial or an atrial remnant and is not shown) at the input port 21 opens to admit blood to the space 20. Should the pressure in the space 20 drop over a predetermined differential below ambient pressure, the membrane 14 (FIG. 2) in the lower chamber 24 is moved away from the housing 18 by the movement of body fluids at ambient pressure through the perforations 26. The force of the piston 12 on the upper portion of the membrane 14 in the space 20 is thereby alleviated so that the pressure of the blood within the space 20 does not drop to a dangerous level below ambient. Moreover, the amount of body fluids that enter the housing through the perforations 26 is a function of sustained venous pressure during the downstroke of the piston 12. For a very high physiological demand for blood, venous pressure will be at or slightly above ambient at all times, and there will be no entry of body fluids through perforations 26. The membrane 14 thereby is pulled out of the chamber 20 to a maximum extent. A maximum amount of blood will therefore enter the chamber 20 during such a downstroke. For a very low physiological demand for blood, normal venous pressure cannot be sustained and the pressure in the upper chamber will drop slightly below ambient early in the downstroke, the body fluids will enter the housing through the perforations 26, and the membrane 14 will be pulled out of the chamber to a minimum extent. Thus, the chamber 20 is automatically filled to the extent necessary to supply physiological demands yet the piston is actuated at a constant rate to travel over a constant stroke length, the pump being designed to supply maximum and minimum blood volme demands of the physiological system in which it is to be used.

At the completion of a typical downstroke, the chamber 20 will be partially filled in correspondence with physiological demands and the lower portion of the membrane 14 may be partially deflected by body fluids that entered the housing 18 through perforations 26. This condition of the pump 18 is illustrated in FIG. 3.

As the piston 12 begins its upstroke, any body fluids in the lower portion of the housing 18 are ejected through the perforations 26 until the lower portion of the membrane 14 is against the housing 18 (FIG. 4). As the piston continues upward, it drives the membrane 14 into the chamber 20 to increase the pressure of the blood therein. This causes the check valve at the input port 21 to close and a check valve (not shown) at the output port 23 to open. During the remaining part of the upstroke, blood is forced from the chamber 20 through the output port 23 and into the arteriovenous system.

The piston 12 is designed to fit closely behind but separated from the membrane 14 at all times by means of the protective liquid 16, except at its lower end where it is connected and sealed to the membrane 14 and housing 18 in a lip 64 in the housing, thereby providing a bearing for reciprocation of the piston. Such an arrangement prevents damage to the membrane 14 by direct contact with the moving portions of the piston 12 during either upstroke or downstroke and avoids stress concentrations within the membrane.

While an embodiment of the invention has been shown and described, further embodiments or combinations of those described herein will be apparent to those skilled in the art without departing from the spirit of the invention.

What I claim is:

1. An artificial blood pump for implantation in a physiological body at a site including fluids at ambient pressure, said body including a system of blood vessels through which blood is forced by said pump, comprising:

a housing having an upper chamber and a lower chamber, said upper chamber including a blood inlet port for receiving blood from said blood vessel system and a blood outlet port for supplying blood to said blood vessel system, said lower chamber being provided with a multitude of openings to allow passage of said body fluids into and out of said lower chamber;

a flexible membrane mounted within said housing an extending into said upper and lower chambers, said membrane having a central area sealed to said housing to separate said upper and lower chambers; and

expandable means mounted within said membrane;

actuating means for periodically expanding an contracting said expandable means to actuate said flexible membrane to pump blood from said inlet port to said outlet port; and

a protective liquid separating said membrane and said expandable means, the pressure within said upper chamber being maintained at a constant predetermined lower differential pressure with respect to the pressure of said body fluids during contraction of said expandable means, said predetermined differential pressure being maintained constant by

movement of said membrane in said lower chamber away from said housing in response to a drop in pressure in said upper chamber below said predetermined differential pressure.

2. The pump of claim 1, wherein said expandable means is a piston having upper and lower wall portions and including a compressible gas enclosed by said wall portions, said upper wall portion flexing outward and inward durinng expansion and contraction of said piston to actuate said membrane.

3. The pump of claim 2, wherein said upper wall portion is adjacent the portion of said membrane extending into said upper chamber and includes double walls enclosing a space, and a viscous liquid filling said space, said viscous liquid opposing a tendency of said double walls to fold during expansion and contraction of said piston.

4. The pump of claim 2, further including a flexible wall defining an expandable reservoir, said expandable reservoir being open to said gas enclosed by said piston walls, said reservoir wall being exposed to said body fluids at ambient pressure for expansion and contraction therein during contraction and expansion respectively of said piston, to minimize the degree of compression of said gas during contraction of said piston.

5. The pump of claim 4, wherein said expandable reservoir is an extension of said lower piston wall portion and is mounted within said housing, said housing being provided with perforations adjacent said reservoir to allow passage of said fluids into and out of said housing adjacent said reservoir during expansion and contraction of said reservoir.

6. The pump of claim 2, wherein said actuating means includes a cable attached to said piston for contracting said piston, and a spring for expanding said piston.

7. The pump of claim 2, wherein said actuating means includes an electric motor, a cylindrical groove drum cam driven by said motor, a follower reciprocated by said cam to pull said cable against the force of said spring to contract said piston and to release said cable under control of said spring to expand said piston.

8. The pump of claim 7, wherein said motor is operable to run at a constant speed and said piston is reciprocated over a constant length.

9. The pump of claim 2, wherein said lower wall portion includes a stiff annular rib at the connection of said upper and lower wall portions for flexure of said upper portion thereabout during expansion and contraction of said piston.

10. The pump of claim 2, further including a lip in said housing, said lower wall portion of said piston being connected to said lip to provide a bearing for expansion and contraction of said piston.

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