July 4, 1972 P. SCHIFF 3,674,381

PORTABLE MECHANICAL VENTRICULAR ASSISTANCE DEVICE

Filed July 30, 1970

FIG. 1.

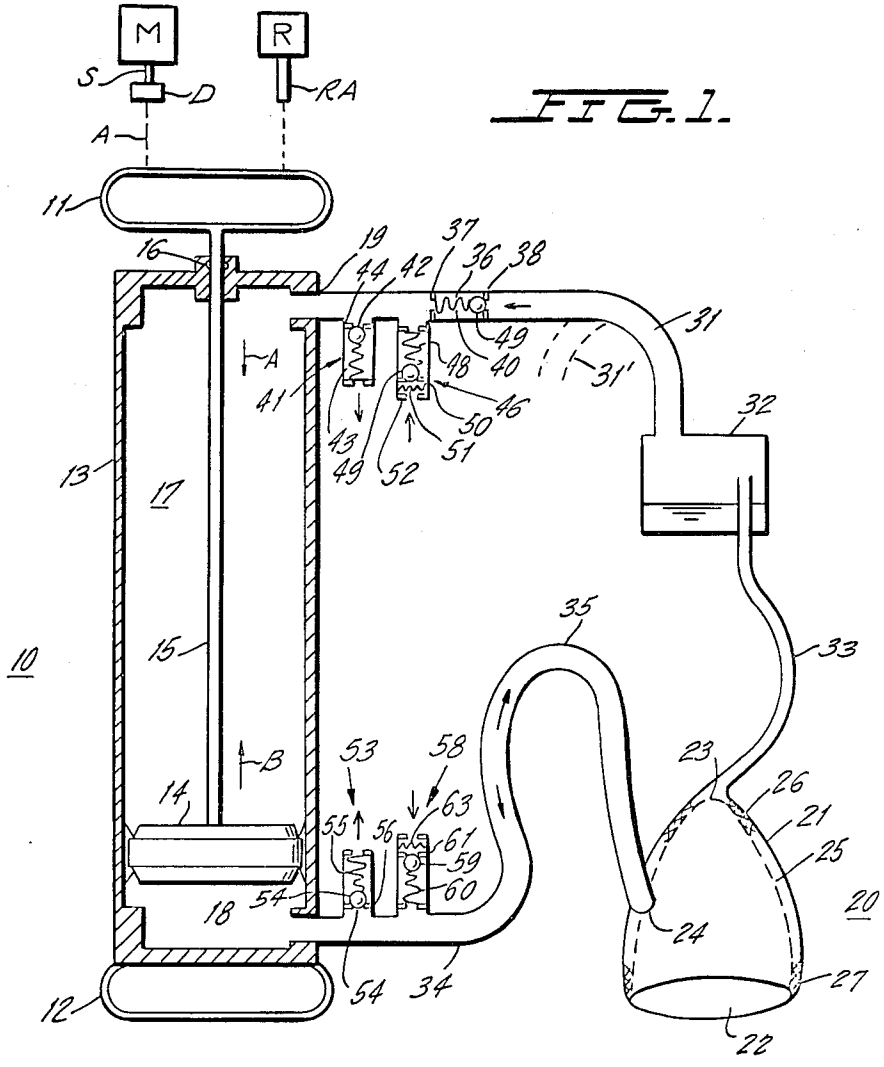


FIG. 2a.

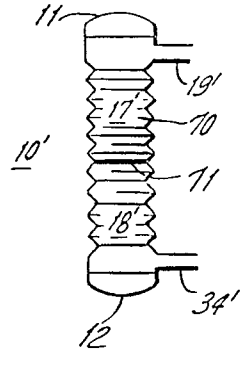
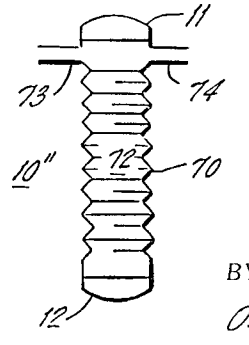


FIG. 2b.



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PORTABLE MECHANICAL VENTRICULAR ASSISTANCE DEVICE

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ABSTRACT OF THE DISCLOSURE

Sustained negative pressure and positive and negative pressure pulses are respectively generated by a hand pump assembly which includes a manually operable handle connected through a piston rod to a single reciprocating piston mounted within the cylinder of the pump. The piston effectively divides the cylinder into two chambers, one of which is coupled through a conduit to provide sustained negative pressure. The remaining chamber is coupled through a second conduit to provide for the alternating positive and negative pressure pulses. Suitable adjustable relief valves are provided in each of the conduits to regulate the pressure levels and the positive or negative pressure directed to the cup.

The present invention relates to circulatory sustaining devices, and more particularly to a novel portable mechanical pump device for sustaining both negative and positive and negative pumping actions at separate outlets.

Numeous devices have been developed to either sustain the circulatory function of a patient, or, alternatively, to sustain the pumping action of a heart. All such devices may be classified into two basic categories; namely, bypass systems and indirect pumping systems. Devices falling into the category of bypass systems are designed to bypass the flow of blood from the heart and to maintain the pumping action otherwise performed by the heart through mechanical or electromechanical devices. Devices falling into the indirect pumping category are designed to assist the heart in the performance of its pumping function. The present invention falls into the latter category.

Devices classified in the former category are usually quite complex in nature and rather large in size so as to limit their use to operating rooms and effectively prohibit their use as a portable device.

Devices developed up to the present which are classified in the latter category are normally comprised of motor means for developing the necessary pressure or vacuum levels and are further comprised of electromechanical means for regulating the flow of the necessary pressure levels to the heart pump. Such equipment is likewise heavy in nature and large in size so as to prohibit its use as a truly portable device.

Devices of the indirect type have been used with great success in the fields of heart and organ transplants. When a potential cadaver (donor), whose organ or organs are available for transplant purposes, is to receive mechanical ventricular assistance, the assistor system is rushed to him for the purpose of sustaining the heart pumping action. Under present-day techniques and with present-day devices, in order to transport the cadaver to the operating room, the assistor is temporarily disconnected, due to the fact that it is too bulky and requires too much electrical power to perform the circulatory function during the time in which the donor is being moved. The period during which the assistor device is disconnected may thus have a harmful effect upon the organ or organs to be transplanted.

The device of the present invention, which is designed to be truly portable and to be simple to connect and operate, is extremely advantageous for use during the

period of time in which the donor is being moved from one location to another, as well as for other emergency situations.

The present invention is comprised of a ventricular assistor cup assembly having a rigid outer shell of a configuration substantially conforming to the surface configuration of the heart ventricles. The cup contains a flexible liner capable of expanding and contracting about the heart ventricles to perform assistive pumping action.

The cup is provided with a first large opening for receiving the heart ventricles. A second opening provided at the apex of the cup receives the sustained negative pressure necssary to retain the ventricles within the cup assembly. A third opening provided in the cup along the surface thereof and intermediate the first and second openings is designed to receive the pulsatile pressures of alternating positive and negative pressure pulses which cause the contraction and expansion of the flexible liner about the heart ventricles.

All of the above-mentioned pressures are provided through the use of a single portable pump assembly having a first handle adapted to receive and position the operator's foot for holding the pump steady during operation. A second manually operable handle is provided for driving a reciprocating piston mounted within the pump cylinder. The piston effectively divides the pump cylinder into first and second chambers, each of which is coupled through an associated conduit to the sustained negative pressure opening and the pulsatile pressure opening, respectively. Adjustable relief valves are provided in the pulsatile pressure conduit to control the pressure (or vacuum) level of the pulse injected into the pulsatile pressure conduit. Similar adjustable relief valves are provided in the sustained negative pressure conduit for controlling the level of negative pressure and for bypassing positive pressure pulses injected into the conduit to prevent positive pressure pulses from reaching the assistor cup assembly. An additional one-way valve assembly is provided in the sustained negative pressure conduit to prevent positive pressure pulses from reaching the assistor cup assembly and to maintain the negative pressure developed in the cup during the application of positive pressure pulses to the sustained negative pressure line.

The simplicity and portability of the system make it extremely advantageous for use in a variety of applications, especially those of an emergency nature. The portable system described herein may be easily and rapidly substituted for conventional assemblies in moving donors from one location to another, or may be used in emergency situations to sustain the circulatory function until such time as the patient is moved to a hospital.

It is, therefore, one object of the present invention to provide a novel portable mechanical ventricular assistance device.

Still another object of the present invention is to provide a novel pump assembly for use with ventricular assistor cup assemblies, and the like, which is capable of developing a sustained pressure at a first output thereof and which is capable of developing a pulsatile pressure of alternating positive and negative pressure pulses at the second output thereof.

Yet a further object of the present invention is to provide a novel pump assembly for use with ventricular assistor cup assemblies, and the like, which is capable of developing a sustained pressure at a first output thereof and which is capable of developing a pulsatile pressure of alternating positive and negative pressure pulses at the second output thereof, whereby the pressure levels of the sustained and alternating pressure pulses are made adjustable through the use of adjustable valve means associated with each of the hand pump outputs.

These as well as other objects of the present invention will become apparent when reading the accompanying description and drawings in which:

FIG. 1 shows a diagrammatic view partially sectionalized of the pump assembly of the present invention as applied to a ventricular assistor cup assembly.

FIGS. 2*a* and 2*b* are schematic diagrams showing alternative embodiments for the pump portions of the assembly.

The device of the present invention is comprised of a hand pump assembly **10** for use in operating a ventricular assistor cup assembly **20**.

The ventricular assistor cup assembly is described in greater detail in copending application Ser. No. 785,652, filed Dec. 20, 1968, now U.S. Pat. No. 3,587,567, issued June 28, 1971 and assigned to the assignee of the present invention, which description is incorporated herein by reference thereto. For this reason, a detailed description of the assistor cup assembly will be omitted from this application for purposes of simplicity. For purposes of understanding the present invention, it is sufficient to understand that the assistor cup assembly **20** is comprised of a rigid cup **21** having a first large opening **22** for receiving the ventricles of the heart; a second opening **23** arranged at the apex of the cup for receiving a sustained negative pressure line; and a third opening **24** for receiving a pulsatile pressure line. The interior of the cup is provided with a flexible liner **25** secured at **26** and **27** by suitable adhesive means, for example, near the apex opening **23** and the large opening **22**, respectively. The liner **25** is mounted within and sealed to cup **21** in such a manner as to form a hollow interior space whose only opening is opening **24** which receives the pulsatile pressure line. The injection of positive pressure into this hollow interior space causes the contraction of liner **25** which, in turn, contracts the ventricles of the heart embraced by the liner. Injection of a negative pressure pulse returns the liner **25** substantially to the position shown in FIG. 1 to allow for expansion of the heart ventricles. This operation is continuously repeated to assist the heart in sustaining its pumping function. The apex opening **23** receives the substantially sustained negative pressure to retain the ventricles within the cup throughout the entire pumping operation and independently of the pulsatile pressure applied to opening **24**.

The portable pump assembly **10** for use with the ventricular assistor cup assembly **20** is comprised of a cylinder **13** having secured at one exterior end thereof a handle **12**. The cylinder contains a reciprocating piston **14** of the double-acting piston type. Piston **14** is coupled through a piston rod **15** to an exterior mounted handle **11**. The opening provided for piston rod **15** at the upper end of cylinder **13** may be provided with a suitable seal as an O-ring **16** to prevent the escape of compressed air from the cylinder.

Piston **14** effectively divides the cylinder into first and second piston chambers **17** and **18**.

Upper chamber **17** is provided with an opening **18** for receiving a sustained negative pressure conduit **31** which couples chamber **17** through a liquid trap **32** and conduit **33** to the opening **23** provided in the apex of assistor cup **21**.

Lower chamber **18** is provided with an opening **34** for receiving a conduit **35** coupling the chamber to the pulsatile pressure opening **24** in cup **21**.

Suitable valve means are provided in the conduits connecting the assistor cup to the pump assembly for regulating the pressure level and pressure direction of pressure pulses injected into each of the lines. The conduit **31** is provided with a first one-way valve assembly **36** which may, for example, be comprised of first and second spaced annular rings **37** and **38** arranged in the interior of conduit **31**. A spherical member or ball **39** is normally urged against annular-shaped ring **38** by a bias spring **40** secured at one end to annular disk **37** and having its opposite end bearing against ball **39**.

Similar one-way valve assemblies **41** and **46** are arranged at spaced intervals along conduit **31** to perform functions which will be more fully described.

In a like manner, positive and negative relief valve assemblies **53** and **58** are arranged at spaced intervals along the surface of conduit **35** for functions to be more fully described.

The upper piston chamber **17** provides the sustained negative pressure for the ventricular assistor cup which is obtained on the "down" stroke of piston **14**. Let it be assumed that the piston **14** is positioned near the top of cylinder **13** and is moved vertically downward in the direction shown by arrow A. A negative pressure or vacuum is developed in chamber **17**. Due to the pressure differential across the right-hand and left-hand sides of one-way valve **36**, ball **39** is caused to unseal the opening in ring **38**, allowing this negative pressure (i.e., vacuum) state to communicate with the apex opening **23** in cup **21**.

The relief valve assembly **46** is adjusted to cause ball **49** to unseal the opening in ring **50** when the negative pressure in conduit **31** is greater than a predetermined threshold level. The relief valve **46** thus automatically controls the maximum negative pressure applied to the assistor cup. The maximum negative pressure may be made adjustable by providing suitable means for adjusting the bias applied to ball **49** by bias spring **48**. A suitable filter member **51** is secured between ring **50** and ring **52** to filter out dust or any other unwanted particles carried by the air entering into the system when valve **46** opens.

The negative pressure applied to the assistor cup is sustained until the piston **14** reaches the bottom of its stroke. On the "up" stroke, i.e., when the piston moves from the bottom of its stroke upward in the direction shown by arrow B, one-way valve **36** is sealed to prevent positive pressure from passing the valve and communicating with the assistor cup. The sealing of valve **36** during the entire "up" stroke also acts to maintain the negative pressure in assistor cup **20** until the next "down" stroke. One-way valve **41** releases the pressure being developed in upper chamber **17** during the upward stroke by having its ball **42** moved downwardly against the force of bias spring **43** to unseal the opening in annular-shaped ring **44**. The negative pressure developed in conduit **31** during a "down" stroke of piston **14** is thus sustained during the 'up" stroke of piston **14**. The liquid trap **32** traps any liquid passing from cup assembly **20** toward the sustained negative conduit **31**.

Lower piston chamber **18** operates in much the same manner as upper chamber **17**, except that both positive and negative pulsatile pressures are applied to cup opening **24** by line **35**. For this reason, conduit **35** is provided with two relief valves, one for positive pressure (**53**) and one for negative pressure (**58**).

During an "up" stroke of piston **14**, i.e., when piston **14** moves in the direction of arrow B, a negative pressure or vacuum is developed in conduit **35** and is coupled to cup opening **24**, causing the flexible liner **25** to move from a contracted position to the relaxed position shown in dotted line fashion in FIG. 1. If this negative pressure exceeds a predetermined threshold level, the ball **59** of relief valve **58** will move downward against the force of biasing spring **60** to unseal the opening in ring **61**, thereby automatically controlling the maximum negative pressure which may be developed in conduit **35**.

During a "down" stroke of piston **14**, .i.e, when the piston moves from its uppermost position downward in the direction shown by arrow A, a positive pressure is developed in lower piston chamber **18**, causing a positive pressure pulse to be injected into opening **24** of the ventricular cup assembly. This causes the flexible liner **25** to contract the ventricles of the heart encircled by the liner. If the positive pressure injected into conduit **35** exceeds a predetermined threshold level, ball **54** of relief

valve **53** will be caused to move upwardly against the force of bias spring **55** to relieve the excess positive pressure developed in conduit **35**. The relief valves **53** and **58** thereby automatically control the positive and negative pressure pulses delivered to the ventricular cup assembly **20**. Suitable adjustable means may be provided in both the positive and negative relief valve assemblies **53** and **58**, respectively, to adjust the force of the biasing springs and thereby calibrate the maximum positive and negative pressure levels. The relief valves further limit the pressures as necessary for full strokes, regardless of the ventricular cup pumping displacement. The negative relief valve assembly is provided with a filter **63** to filter out any unwanted particles or other material which may be in the atmosphere against entering into the system with the air entering through the relief valve assembly **58** whenever it is caused to open.

The pump may be operated by one person in a variety of ways. One preferred manner of operating the pump is to place one foot through the opening formed by stationary handle **12** and operating the movable handle **11** in a reciprocating fashion by grasping and moving handle **11** with either one or both hands. Alternatively, each of the handles **11** and **12** may be grasped by one hand, and the pump may be operated in a reciprocating fashion in this manner. Obviously, if desired, two persons may operate the pump, but the simplicity of operation and size of the pump does not necessitate such alternative operation.

FIGS. 2*a* and 2*b* show alternative arrangements for the pump assembly of FIG. 1. Considering FIG. 2*a*, the pump arrangement **10'** is a bellows pump selectively expandable and contractable due to its bellows arrangement **70**. The interior of the bellows arrangement is divided by a barrier wall **71** forming upper and lower chambers **17'** and **18'**, respectively. The outputs **19'** and **34'** of these chambers are coupled to conduits **31** and **35** of FIG. 1 in the same manner as the pump assembly shown in FIG. 1. Operation of the pump assembly of FIG. 2*a* may be performed in the same manner as the device shown in FIG. 1 by grasping the handles **11** and **12** and urging them alternatively together and apart to create the positive and negative pressure phases occurring during each reciprocating cycle.

FIG. 2*b* shows an alternative pump assembly **10''** having a bellows assembly **70** comprised of a single internal chamber **72** having openings **73** and **74** for communicating with the conduits **31** and **35** of FIG. 1. In operation, the handles **11** and **12** are alternately urged toward one another and apart from one another to create positive and negative pressures within the internal chamber **72** to provide the positive and negative pressure signals in conduit **35** while providing only a sustained negative pressure signal in conduit **31**.

When using the double-acting piston type of FIG. 1, it is possible to develop sustained negative pressure in conduit **31** during both the "up" and "down" stroke by coupling an additional conduit near the bottom of cylinder **13** which is provided with valve assemblies substantially identical to the assemblies **36**, **41** and **46**. This additional conduit may be coupled into conduit **31** as shown by dotted line **31'**. Thus, each stroke, whether "up" or "down," of the piston will contribute to sustaining the negative pressure in the assistor cup assembly. This alternative embodiment may be used in cases where the pump assembly is capable of providing a sufficient negative pressure pulse for operating the flexible liner **25** and for simultaneously sustaining the negative pressure maintained at the opening **23** of the assistor cup assembly.

It can be seen from the foregoing description that the present invention provides a novel portable pump assembly especially advantageous for use with ventricular assistor cup assemblies to maintain and sustain the pumping operation of the heart by providing an independent sustained negative pressure (vacuum) at one output thereof and by providing alternating positive and negative pressure pulses at a second output thereof for performing the functions necessary in the operation of such a ventricular cup assembly. It should be obvious that various modifications may be made in the pump assembly without departing from the scope of the invention. For example, a one-way valve of the type shown in conduit **31** may be provided in conduit **35** for providing sustained negative pressures in each of the outputs developed by the pump for such applications in which negative pressures of this type might be required. The negative pressure values obtained may be adjusted to be of different values through simple adjustment of the values. As a further modification, the one-way valves provided within each of the conduits **31** and **35** may be reversed in direction of operation so as to provide a first output for generating a positive sustained pressure and a second output for generating a sustained negative pressure. As still another alternative, the one-way valve assembly **36** provided in conduit **31** may be omitted to provide a pump having two outputs, each of which is capable of providing alternating positive and negative pressures wherein each of the positive and negative pressures developed by each of the outputs may be set at any predetermined threshold levels, depending upon the needs of the user. In addition, the single cylinder having a double-acting piston may be replaced by two cylinders each having a reciprocating piston. The cylinders may be placed side-by-side and arranged to be reciprocated by a single operating handle.

The assemblies of the figures may be operated by mechanical or electromechanical means, if desired. For example, a motor M may drive a reciprocating arm A through shaft S which is coupled to handle **11** of FIG. 1. A rotary to reciprocating motion device D converts the rotation of the shaft S into reciprocating movement. Alternatively, a relay R having a reciprocating armature RA may be alternately energized and deenergized to reciprocate up and down (for example) to impart reciprocating movement to the piston rod **15** (for example). The down stroke may be imparted by energizing the relay driving its armature downward. Deenergization of relay R will cause the up-stroke under control of a biassing spring (not shown).

Although this invention has been described with respect to particular embodiments, it should be understood that many variations and modifications will now be obvious to those skilled in the art, and, therefore, the scope of this invention is limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A portable hand-operated, air pump assembly for generating pressures at first and second outputs thereof comprising:

a cylinder;

a reciprocating double-acting piston positioned within said cylinder dividing said cylinder effectively into first and second chambers;

a piston arm coupled to said piston, one end of said arm extending outwardly from said cylinder;

means coupled to the free end of said arm for reciprocating said arm;

said first and second outputs communicating with said first and second chambers;

first and second conduits connected to said first and second outputs, respectively, for directly coupling the positive and negative air pressures in said pump developed in said chambers to suitable utilization devices;

first and second means provided in said first and second conduits, respectively, for maintaining different pressures delivered to the utilization devices.

2. The assembly of claim **1** wherein said first means is comprised of a one-way valve assembly positioned within said first conduit for maintaining a negative pressure in said first conduit regardless of the direction of movement of said piston.

3. The assembly of claim 2 wherein said second means is comprised of first and second positive and negative relief valves connected to said second conduit for limiting the positive and negative pressures generated at said second output which are injected into said second conduit.

4. The device of claim 2 further comprising a liquid trap having inlet and outlet openings, said inlet opening being coupled to said first conduit, said outlet opening being connected to a utilization device for collecting any liquid entering said trap and preventing said liquid from being delivered to said pump assembly.

5. The assembly of claim 1 wherein said reciprocating means further comprises a first manually operable handle being connected to said piston rod second end;

a second handle being secured to the opposite end of said cylinder.

6. The device of claim 1 further comprising means for reciprocally driving said double-acting piston.

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