

July 15, 1969

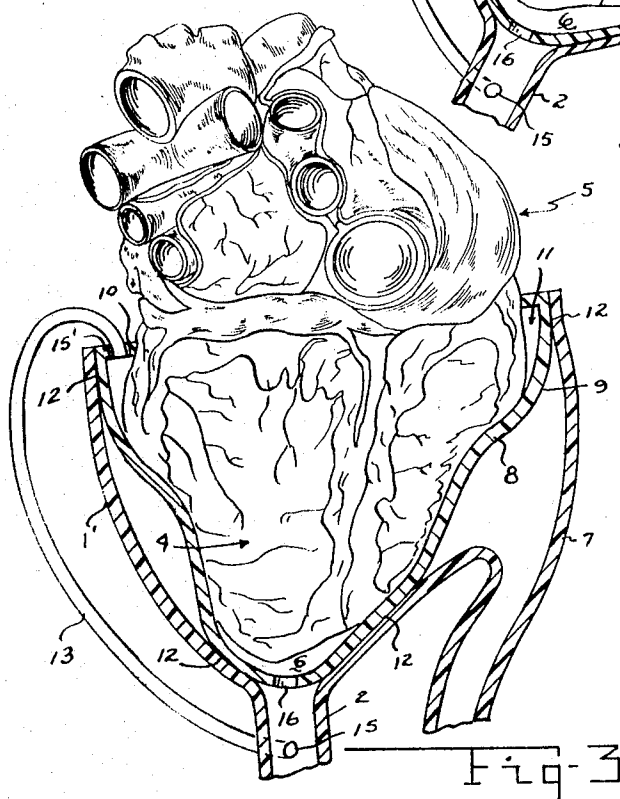
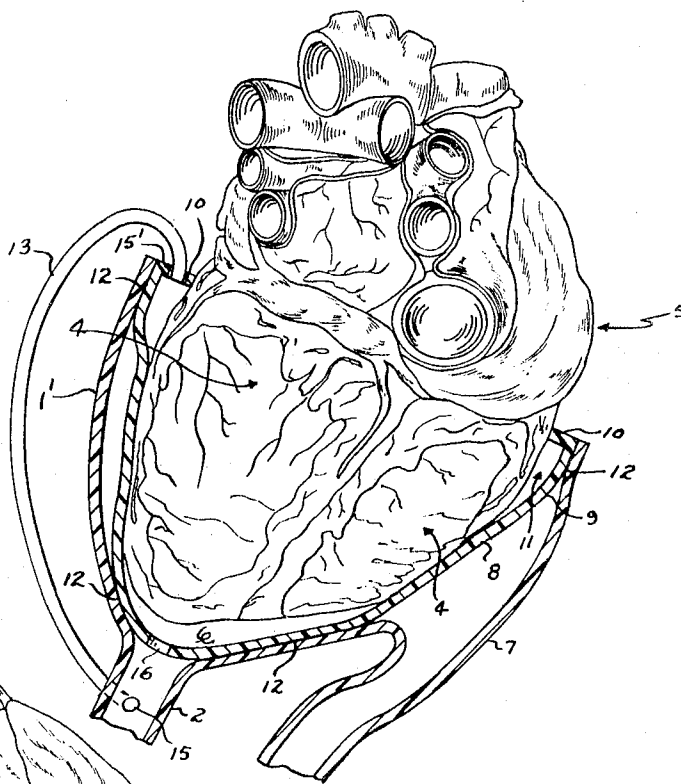
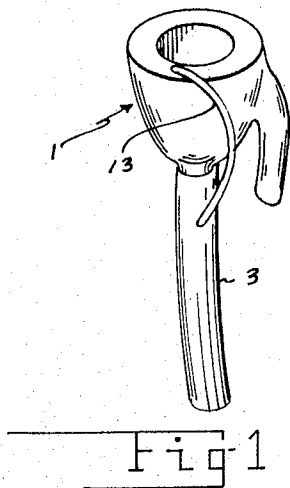
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3,455,298

INSTRUMENT FOR DIRECT MECHANICAL CARDIAC MASSAGE

Filed April 10, 1967

3 Sheets-Sheet 1



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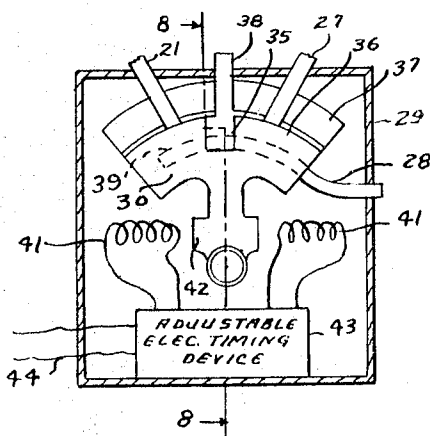
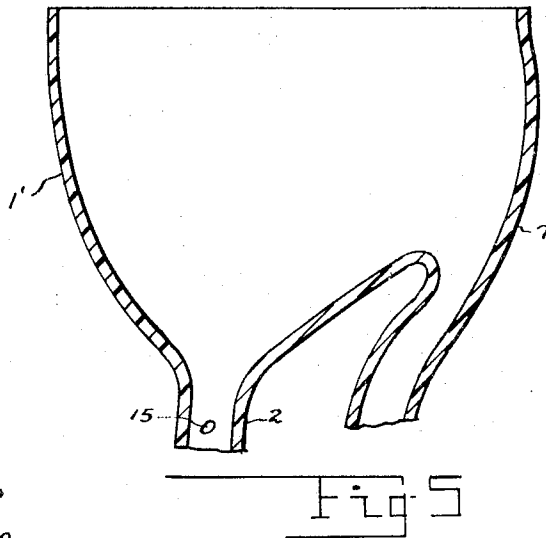
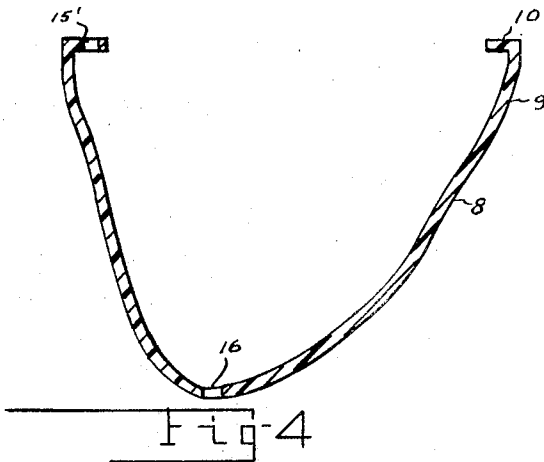
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INSTRUMENT FOR DIRECT MECHANICAL CARDIAC MASSAGE

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3 Sheets-Sheet 2



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INSTRUMENT FOR DIRECT MECHANICAL CARDIAC MASSAGE

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3 Sheets-Sheet 3

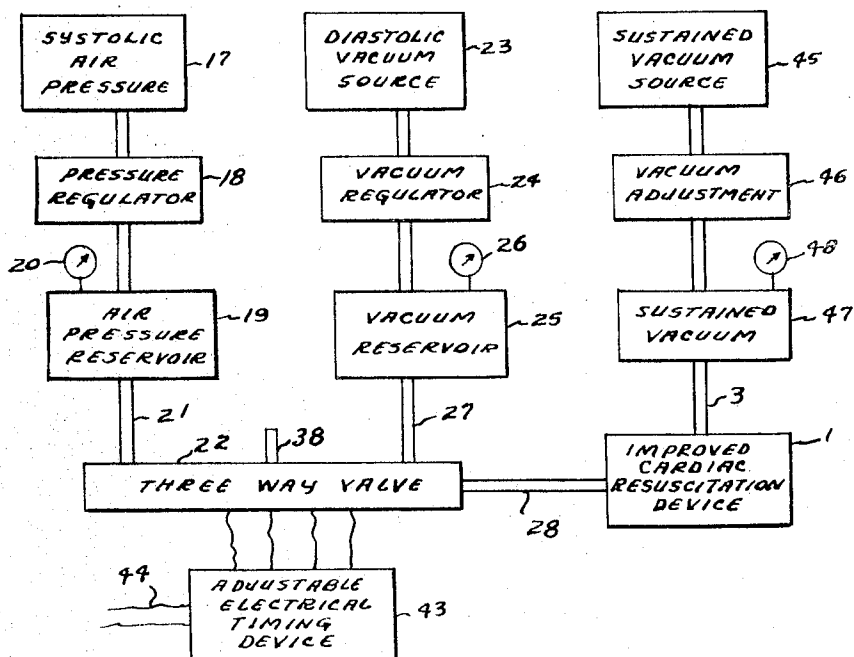


Fig. 6

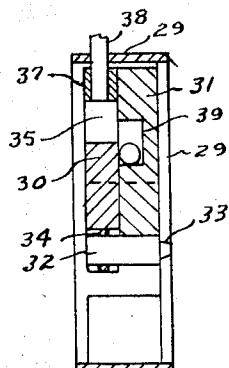


Fig. 8

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**INSTRUMENT FOR DIRECT MECHANICAL
CARDIAC MASSAGE**

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7 Claims

ABSTRACT OF THE DISCLOSURE

A pneumatic instrument for prolonged cardiac massage is attached to the heart by vacuum at a position as to encompass only the ventricular region for the application of the systolic and diastolic forces. The pressures are introduced through the side arm of a glass housing to the external surface of a thin, flexible envelope or liner contained within the housing and closely surrounding the ventricles. The envelope is sealed to the glass housing at the upper and lower ends to leave a peripherally complete band between the bonded surfaces and serves as a diaphragm for compressing and dilating the ventricles when air under relatively high positive and negative pressures are introduced alternately at an optimum rate into the side arm. The vacuum attaching effect is exercised at the upper and lower ends of the liner so that all positive and negative pressures are applied to the heart at positions removed from the atria region.

The invention described herein may be manufactured and used by or for the United States Government for governmental purposes without the payment to me of any royalty thereon.

BACKGROUND OF THE INVENTION

The invention concerns cardiac massage or "direct mechanical ventricular assistance" and provides for prolonged indirect circulatory support without contacting the blood.

Various ways have been proposed to mechanically massage the heart. But the problem has been that to allow attachment, the entire heart was involved, not merely the ventricular portion where practically all of the effective life-sustaining contraction and expansion or pumping action takes place. Some of the problems involve the use of such devices as a sac of nylon which fits snugly over the heart and is held in place by a drawstring above the atria. This sac or pouch contains contraction and expansion membranes in the region of the ventricles. While such an instrument has given satisfactory results compared with manual methods for cardiac massage, the chief objection is that it must encompass the entire heart muscle including the entering and leaving arteries in order to be held in place when the systolic and diastolic pressures are applied. Thus, the instrument squeezes not only the ventricular portions, but tends to compress the upper portions of the cardiac organ over and above the pressure already being exerted by the drawstring. It is apparent that these portions should, if possible be left free from any distortion in order to permit full access of blood leaving or entering the heart.

SUMMARY OF THE INVENTION

One object of my invention is to improve the hemodynamic effectiveness of cardiac massage and to provide for prolonged indirect circulatory support without contacting the blood.

Another object is to provide an instrument for direct mechanical ventricular assistance which is inexpensive, requires practically no custom fitting, can be applied and

removed instantly, and can be held securely in place without the use of a drawstring or any other device imparting pressure on parts of the heart which do not contribute to the ventricular systolic or diastolic action. Thus, the forces are applied exclusively to the ventricles, with no inappropriate forces distributed to the atria.

Still another object is to provide a pneumatic instrument capable of providing ventricular assistance during both the systolic and diastolic phases of the cardiac cycle by the use of accurately controlled positive and negative pressures to the ventricles. Thus, instead of only applying compressing (systolic) forces as occurs with manual cardiac massage, distending (diastolic) forces are also applied so that both phases of the cardiac cycle are assisted.

These objects are carried out in brief by providing a glass housing which is sufficiently large to approximately contain the lower portion of the heart and of a length as would extend upwardly only throughout the ventricle section. The housing contains a thin, flexible liner bonded to the housing at the upper and lower ends in order to leave a loose band around the heart to which air pressure and vacuum can be alternately introduced through a side tube and thus provide diaphragmatic pumping action. An inwardly extending rim is provided at the upper end of the flexible liner, the free edge of which contacts the heart at a position below the atria region. A vacuum effect is introduced within the space bounded by this rim and also between the apex of the heart and the lower portion of the liner in order to hold the instrument firmly in position. Accurately controlled positive and negative air pressures are alternately applied between the diaphragm area and the glass housing according to the pulse requirements of the patient.

The invention will be better understood when reference is made to the following description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 represents, in miniature, a perspective view of the improved instrument in assembled form;

FIG. 2 is an elevational view of a typical human heart to which the instrument has been applied, the latter being shown in section for clearness. The position of the parts is depicted in the diastolic phase;

FIG. 3 is a view similar to that illustrated in FIG. 2, but showing the parts in the systolic phase;

FIG. 4 depicts the flexible liner or diaphragm element disassociated from the other parts and shown in section;

FIG. 5 represents a sectional view of the glass cup or "backup" member for the liner;

FIG. 6 shows a system in diagram and block form which can be used to apply the diastolic and systolic forces to the diaphragmatic liner, also for holding the instrument in position;

FIG. 7 depicts a typical form of valve structure which can be used to control the movement of the diaphragm and also for holding the instrument in position on the heart; while

FIG. 8 represents a section of the valve taken along line 8—8 in FIG. 7.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, reference character 1 generally designates the complete assembly of the improved instrument. Referring now to FIG. 2, which shows as an enlarged view a glass housing 1' which takes the general form of a cup. The cup is made of glass but preferably could be of transparent plastic, just thick enough to be rigid, and is open at the top or "base." The "apex" end of the cup is provided with a centrally located stem or ap-

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pendage 2 fitted to a silicone rubber tube 3 (FIG. 1) which can serve as a handle. The member 1', termed an "assister cup," is curved inwardly from the top to the bottom and is of a size and shape as will loosely fit over the lower portion of the heart. The length of the cup is such that when in use the upper edge will not extend beyond the upper region of the ventricles, that is, the edge should be definitely below the atria section. In the figure, the ventricle and atria sections are indicated at 4 and 5, respectively. The purpose of the limitation as to the length of the assister cup will appear presently.

The cup member is provided with a wide tube extension 7 which flares or bulges at the top where it joins the rest of the cup. At the lower end, the extension 7 terminates in a small, round configuration in order to receive the rubber tubing 3. This extension provides a passageway for the introduction and evacuation of air under various positive and negative pressures through this tubing (not shown). A cross-sectional view of the cup member is shown in FIG. 5 disassociated from the contiguous parts.

It will be noted that when the latter is placed in position, a small space indicated at 6 is present at the bottom. It should be noted that this small space indicated at 6 is only a potential space that does not exist once the assister cup is completely attached to the heart. This small space is depicted in the drawing to indicate the process of attachment and thus indicates the position of the cup relative to the ventricles just before completion of attachment. This space would also exist if a force were applied to pull the cup away from the ventricles. That is, if traction were applied to pull the cup away from the heart, it would break away whenever the traction force exceeded the resultant force of the vacuum causing attachment to the ventricles. Still another situation depicted in FIGURE 3 is that this potential space at 6 would form a "real space" if the vacuum (sustained negative pressure) were released. This, in fact, is the method for removal of the cup since releasing the vacuum causes automatic, instantaneous ejection of the cup from the heart during the next systolic compressing force.

Within the cup there is a liner 8 molded or otherwise prepared out of a thin, elastic, translucent material, preferably an air-impervious silicone rubber. Such material is on the market and a suitable form is that sold under the name "Silastic 372" by the Dow Corning Company. This silicone rubber appears to have no reactive or toxic effects on contact with human tissue. The liner may have a thickness of about 0.040 inch. The size of the liner is somewhat smaller than that of the encircling cup member and roughly corresponds to the shape of the latter. The liner contacts and is bounded to the inside of the cup member at its lower surface or apex and around its upper circumference or base; this contact is maintained both when it is not being used and also in its operative position. Its shape is such that it tapers inwardly about one-third up its length and outwardly near its upper edge; thus, it is more undersized with respect to its surrounding glass housing in the central diaphragm zone.

An inwardly extending elastic lip or rim 10 is provided on the liner at the top edge which lightly contacts the heart and assists in automatically and symmetrically locating the cup member and contained liner with respect to the heart. This lip provides an annular space between the liner and heart as indicated at 11; the purpose of this space, which often is only a potential space as described in connection with space 6 at the apex, is to help insure the dispersion of negative pressure between the diaphragm and the ventricles. The dispersion of negative pressure over the ventricular surfaces is important to assist distension of the ventricles during diastole and to prevent ejection from the cup during systole. It must be understood that the inwardly extending rim which is best depicted in FIGURE 1 plays an essential role in initial "automatic" attachment to the ventricles. Thus, it may be seen that if the base of the cup is brought into proximity

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to the apex of the ventricles such that contact between this rim and the heart apex occurs, a vacuum will then build up in the interior. In other words at this initial stage of attachment, the previously described spaces 6 and 11 are continuous and constitute a vacuum chamber. This together with previous discussion completes the explanation of the mechanism by which the cup is attached to the ventricles by means of vacuum. Thus, the rim helps create an air seal with the apex so that a vacuum can accumulate which in turn causes attachment to the ventricles.

In order to isolate the various spaces to which vacuum and pressure applied during use, it is desirable that the liner be joined in any suitable and well-known manner to the glass cup 1' both around the inside circumference at the top or base, and over a relatively large surface in the bottom or apex region as indicated by the heavy black line carrying the reference character 12. This instrument then becomes complete as shown in FIG. 1 except for a tube 13 which is connected at one end to an opening 15' in the rim 10 which leads to the annular space 11. An opening 16 is also provided at the lower end of the liner 8 at the position of stem 2 which places the space 6 in communication with the interior of the stem.

PRESSURE ACCESSORY SYSTEM AND OPERATION OF THE INSTRUMENT

FIG. 6 illustrates a pressure and vacuum system in diagrammatic form which can be employed in connection with the improved resuscitation device. In the figure, reference character 17 designates in block form an air pump of any suitable and well-known type and of relatively high flow capacity capable of developing pressures up to about 200 mm. Hg. The air pressure is normally regulated as indicated at 18 to a value in the average region of 120 to 140 mm. Hg. The air under pressure is conducted to a standby reservoir 19, which serves as an accumulator to stabilize the pressure delivered by the regulator. This reservoir is equipped with a gauge 20 in order that the pressure may be regulated to the desired amount. This pressure is used in the systolic phase of the instrument. From the reservoir, the air under the regulated pressure as determined by the particular massaging requirement, passes through a tube 21 to a three-way valve 22 of any suitable and well-known type, and of which one typical example is described hereinafter.

Block 23 indicates a second pump of comparable size and output as pump 17, but which delivers negative pressure or vacuum. This negative pressure is regulated as indicated at 24 and is contained in a reservoir 25 provided with a vacuum gauge 26. The negative pressure is carried through a conduit 27 to the control valve 22. The vacuum from the reservoir 25 is employed to provide the diastolic effect as will be explained hereinafter, and for this purpose, the pressure may be in the order of minus 80 to minus 100 mm. Hg. As shown in the figure, the pulsed pressure output of the valve is taken through a flexible tubing 28 to the side arm 7 of the assister cup (FIG. 2).

As shown in FIGS. 7 and 8, a valve structure which might be used to advantage for controlling the different air pressures which are applied in an effective manner to the liner 8 through the side tube 7. The valve may be contained in an outer casing 29 and essentially consists of a pair of segmentally shaped plates 30, 31, the upper plate of which is adapted to swing through a limited angle on a stud 32 which is riveted or otherwise secured as indicated at 33 to the base of the casing 29. A ball bearing 34 may be employed between the plate 30 and the stud. The plate 30 is provided with a slot indicated at 35 which is closed along three sides but is open at the periphery of the plate. The plate 30 has a curved upper edge as indicated at 36 and directly adjacent thereto leaving only a little clearance to allow the plate 30 to swing, there is a stationary plate 37. This plate is shaped to a segmental form and is supported on the lower plate 31 to which it can be affixed. The conduits 21 and 27 enter the casing 29

and pass through the plate 37 in the widthwise direction, at angular positions, as indicated in FIG. 7. These conduits terminate at the inside curved edge of the plate. There is a third conduit 38 which enters the casing between the conduits 21, 27 and passes through the plate 37 to terminate at its inside edge, similar to the other two conduits. The outer end of the conduit 38 is open to the atmosphere.

The lower plate 31, which is stationary, is provided with a segmentally shaped groove 39 that opens at the sliding joint between the plates 30, 31 so that as the plate 30 is swung about the stud 32 the slot 35 will always be in communication with the groove 39 directly below. As the plate 30 is reciprocated in a swinging manner, the slot 35 will successively pass the presented ends of the conduits 21, 38, 27. Consequently, as air under pressure is forced through the conduit 21 from the air reservoir 19, as explained hereinbefore, and should the slot 35 have been moved to the left from the position shown in FIG. 7, so as to be in communication with the conduit, air will flow from the conduit into the groove 39. A tube 28 connects with the end of the groove 39 and as stated hereinbefore is connected with the side tube 7. Thus, the compressed air finds ready passage from the conduit 21, through the slot 35 into the groove 39, thence to the tube 28 and into the side tube 7. This is the condition obtained during the systolic phase of the treatment. As the segment member 30 is caused to swing to the right (FIG. 7), the solid portion of that member will close off the conduit 21 and the slot will move opposite to the conduit 38 which will cause the compressed air in the side tube 7 to flow through the tube 28 and be exhausted to the atmosphere at the conduit 38.

As the segmental member 30 continues to swing to the right, the slot 35 will now contact the open end of the conduit 27 and the solid or nonslotted portions of the member will close off the conduits 21, 38. Under these conditions, air will flow in a reversed direction due to the negative pressure in reservoir 25 from the side arm 7 through the tubing 28, thence to the groove 39, the slot 35 and finally through conduit 27 into the vacuum reservoir. This is the condition during the diastolic phase of the treatment.

When the plate 30 swings in the opposite direction, the slot 35 will be presented to the conduit 38 so that the small amount of pressure within the side tube 7 will be reduced to zero because the air is caused to leak back through the tube 28 and the slot 35 to the atmosphere through the middle conduit 38. Thus this air is immediately exhausted. Then as the plate continues to swing to the left, the high-pressure air is caused to move through the slot 35, the groove 39 and out through the tubing 28 whereas the inner ends of the conduits 38 and 27 are blocked off. It is, therefore, apparent that by swinging the plate 30 about its stud 32 in one direction or the other, first high-pressure air is introduced and that, in turn, is exhausted to the atmosphere ready for the next charge of high-pressure air to be introduced into the cup. The plate 30 can be caused to oscillate rapidly about its bearing 32 by means of two electromagnetic coils 41 which operate on iron studs 42 which form part of the plate 30. As the current in one coil is caused to attract the right-hand stud 42, for example, current in the other coil can cause an added force in the same direction, one attracting and the other repelling the pair of studs 42. Thus, the plate 30 can be caused to swing at any desired speed over the stationary plate 31 and thus open and close the ends of the conduits 21, 38, 27 at a predetermined rate in succession to control the charges of air pressure admitted to the side tube, according to whether the instrument is in its systolic or diastolic phase. The coils 41 may be connected through an adjustable electrical timing device 43 of any suitable and well-known type which provides fine adjustments in the excursionary rate of the swinging plate 30. This device should be capable of providing a swinging rate of 10 to

200 cycles per minute and providing independent adjustment of the systolic-diastolic ratio. It is energized from a suitable source of current indicated at 44.

Thus, by adjusting the timing device 43, high-pressure air and vacuum from the reservoirs 19, 25, can be caused successively to follow one another within the cup-shaped element 1 and the rate of succession can be determined according to an optimum value depending upon the pulse rate of the patient who is undergoing the cardiac assistance or according to the automatic cycle frequency selected by the attending physician in the case of complete cardiac arrest.

When high-pressure air is applied to the member 1 as explained hereinbefore, the "Silastic" liner 8 is caused to move inwardly similar to an annular diaphragm and between the bottom and top positions 12 (FIG. 3) and this action will tend to squeeze or constrict the heart and thus force the blood out from the organ. On the other hand, when the negative pressure or vacuum effect is admitted to the cup member 1, the heart will tend to expand to its full diastolic shape and cause the blood to enter the heart through the two atrioventricular valves. It is apparent that the glass cup 1 serves as a nongiving or backup member for the liner in that when relatively high pressure is applied to that member, the air has only one way to assert its pressure, and that is, against the heart. It will be further noted from FIG. 3 that when the liner is compressed inwardly as a result of the effect of relatively high air pressure during the systolic phase, it takes on an hourglass shape which adds to the firmness with which the instrument is held in place. This hourglass configuration assumed by the diaphragm during the systolic phase aids in preventing ejection from or slippage from the ventricles. That is, it causes the heart to receive the predominance of the compression at a level which is well above the apex so as to produce a retaining effect on the apex. The apex of the heart receives less of a compressing force because of the large area of bonding between the liner and the glass housing in this region. In regard to the vacuum holding effect to be described in the following paragraph, it must be understood that ejection of the cup from the heart during the systolic compressing phase is prevented by the combined effects of the sustained vacuum plus the hourglass configuration assumed by the diaphragm.

In accordance with another aspect of my invention, a holding effect is caused, both during the systolic and diastolic phases, by the use of a vacuum. For this purpose, I provide a sustained vacuum source 45 of any suitable and well-known type that can be evacuated down as low as minus 70 mm. Hg. An adjustment of the vacuum is provided, as indicated by the block 46 in FIG. 6, and as in the case of air pressure, I provide a chamber 47 which serves as a sustained vacuum reservoir to which a gauge 48 is applied. From the chamber 47, there is a tubing 3 which connects with the stem 2 of the glass cup. A flexible rubber tubing 13 carries the vacuum effect from the interior of the stem 2 to the annular space 11 on account of the opening 15 in the stem and the opening 15' in the lip or rim 10. The opening 16 at the bottom of the liner carries the vacuum into the space 6. It will be understood that the vacuum effect is maintained without interruption while the instrument is in position and the degree of vacuum should be regulated such that any pressure exerted by the air in the side tube 7 could not cause the instrument to move with respect to the heart. Obviously, the vacuum effect at the bottom or apex of the heart and throughout the annular space 11 at the upper region of the ventricle section may exert a powerful suction effect which is completely isolated from any of the pulses of air pressure introduced into the cup member. Also, it may be noted by observing the space 6 in FIGS. 2 and 3 that if the instrument should be dislodged, the farther it is pulled away from the ventricles the larger will be the space. Thus, the greater will be the surface

area of ventricle over which the holding vacuum will act, and the greater will be the resulting force of attachment.

From the foregoing, it is evident that I have disclosed an instrument for applying systolic and diastolic forces to the heart through the use of a liner secured over only the lower portion of that organ and so formed as to constitute an annular "hourglass" diaphragm which operates solely on the ventricles. The vacuum for holding the instrument onto the heart as well as the application of both systolic and diastolic forces, take place at position remote from the atrial regions and therefore impose no compressing effect or other distortion at these positions. No drawstrings, zippers, or other devices are needed to hold the instrument firmly in place. Moreover, the "assister" cup being made of glass and a relatively transparent "Silastic" diaphragm is readily transparent to the surgeon allowing the advantage of direct vision of its action on the heart. Vision through the instrument is extremely helpful to allow the surgeon fine adjustment of the proper pressures, vacuums, frequencies, and systolic-diastolic ratios. Finally, the glass silicone rubber combination permits routine sterilization of the cup in an autoclave.

While a certain specific embodiment has been described, it is obvious that numerous changes may be made without departing from the general principles and scope of the invention.

I claim:

1. A cardiac resuscitation apparatus comprising a cup-shaped member of rigid material which is adapted to fit loosely over the lower portion of the heart and to extend only as far as the atria region, a liner of thin, flexible material contained within said member and having the same length thereof, said liner being bound to the member along the upper and lower portions thereof whereby the middle part of the liner is left free from said cup member to form an annular diaphragm which contacts the ventricular surfaces, means for alternately applying to the space between the diaphragm and the ventricular surface relatively high positive and negative air pressures to provide systolic and diastolic effects on the heart, and means including a vacuum for holding the cup-shaped member in position on the heart.

2. A cardiac resuscitation apparatus according to claim 1 and in which said last-mentioned means includes a vacuum source, and passageways extending from said

source to positions between the extremities of the liner and the heart.

3. A cardiac resuscitation apparatus according to claim 1 and in which said means for alternately applying the relatively high positive and negative air pressures includes an opening in said cup-shaped member at the position of said diaphragm through which said air pressures are introduced, and openings in the upper and lower portions of said liner through which the vacuum for holding purposes is introduced.

4. A cardiac resuscitation apparatus according to claim 1 and in which said means for alternately applying the positive and negative air pressures is constituted of reservoirs of the high and low pressure air controlled through a valve apparatus having moving parts for controlling the air through the valve, and means including a timing device operated according to a predetermined time sequence for operating the movable parts of the valve in order to control the application of the high air pressure and vacuum to the diaphragm.

5. A cardiac resuscitation apparatus according to claim 1 and in which the cup-shaped member is constituted of glass and is provided with a side arm extension into which said air pressures are introduced against said diaphragm.

6. A cardiac resuscitation apparatus according to claim 1 and in which said cup-shaped member and the contained liner include a rim attached to the upper edge of the liner extending inwardly therefrom lightly to contact the heart whereby a confined space is provided for maintaining the vacuum at the upper end of the liner.

7. A cardiac resuscitation apparatus according to claim 1, and in which said cup-shaped member and its contained liner have an opening through their apexes to deliver a sustained negative pressure to the interior of the diaphragm in order to maintain the vacuum in the space between the diaphragm and the ventricles of the heart.

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