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[54] **HEART ASSIST METHOD AND APPARATUS**
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128/214, 128/348
[51] Int. CL. A61b 19/00,
A61m 1/03
[50] Field of Search 128/1, 2.05,
245, 344, 348—351; 3/214, 1

[56] **References Cited**

UNITED STATES PATENTS

724,913	4/1903	Montgomery	128/245
2,442,573	6/1948	Stafford	128/245 X
2,930,377	3/1960	Cowley	128/344
3,421,497	1/1969	Chesnut et al.	128/1
3,457,909	7/1969	Laird	128/1
3,516,410	6/1970	Hakim	128/350

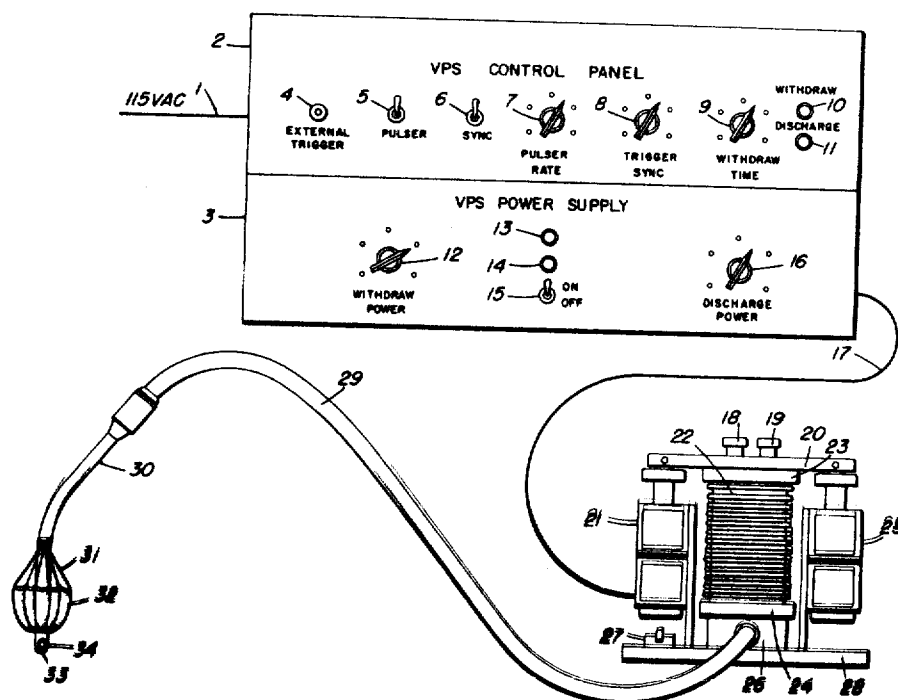
FOREIGN PATENTS

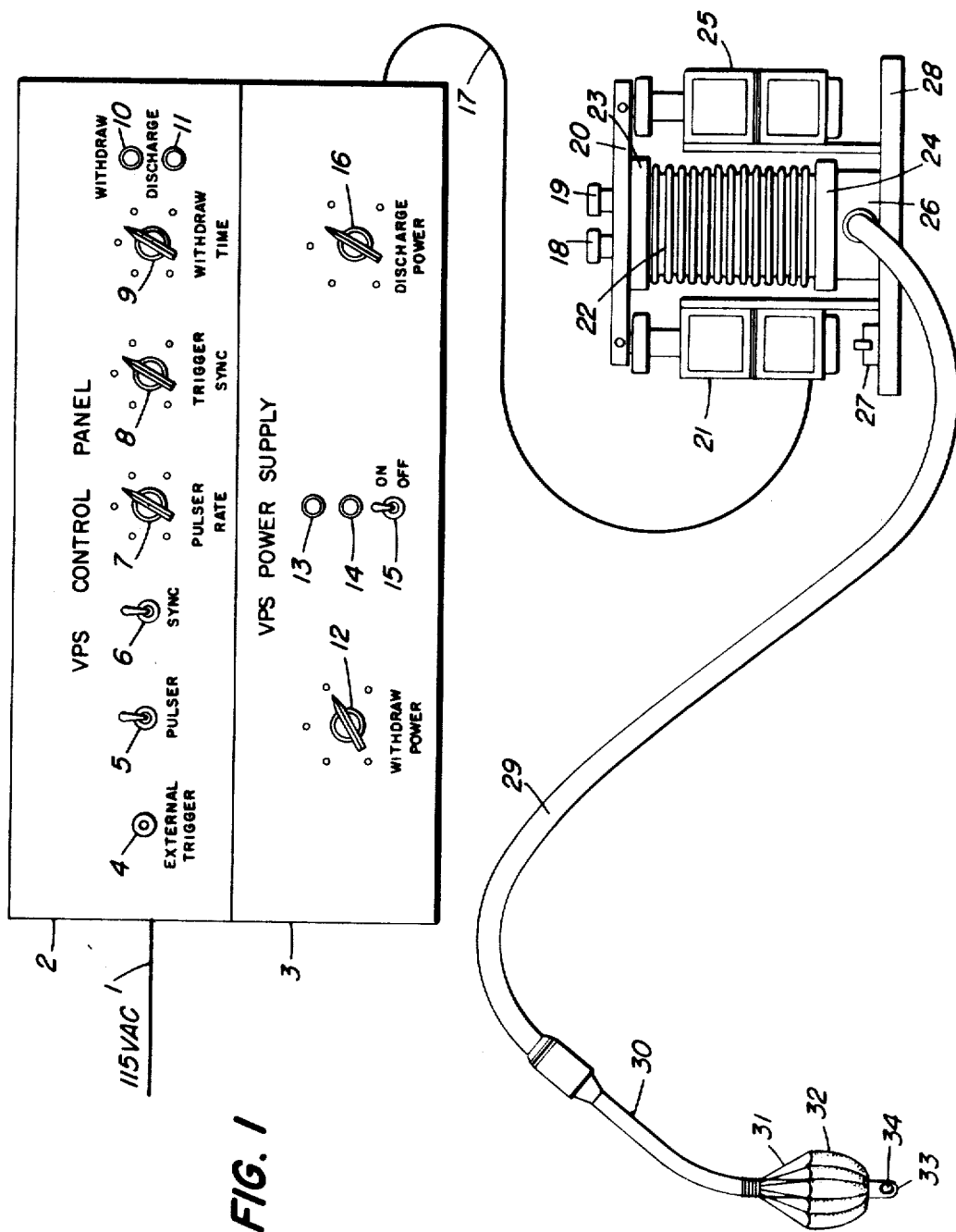
494,542	3/1930	Germany	128/214
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OTHER REFERENCES

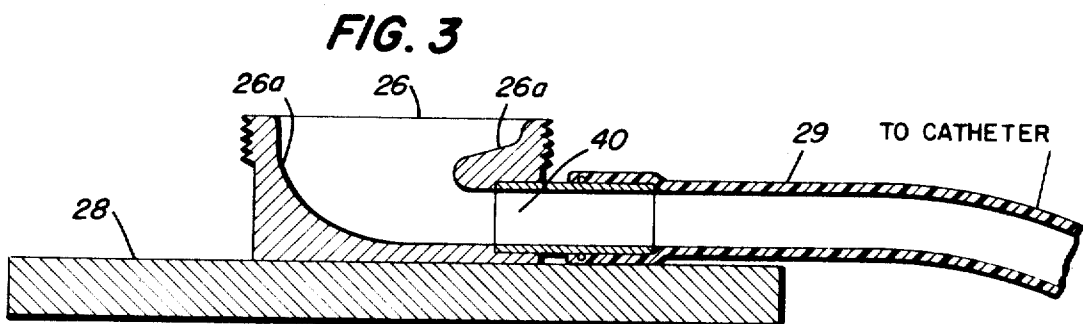
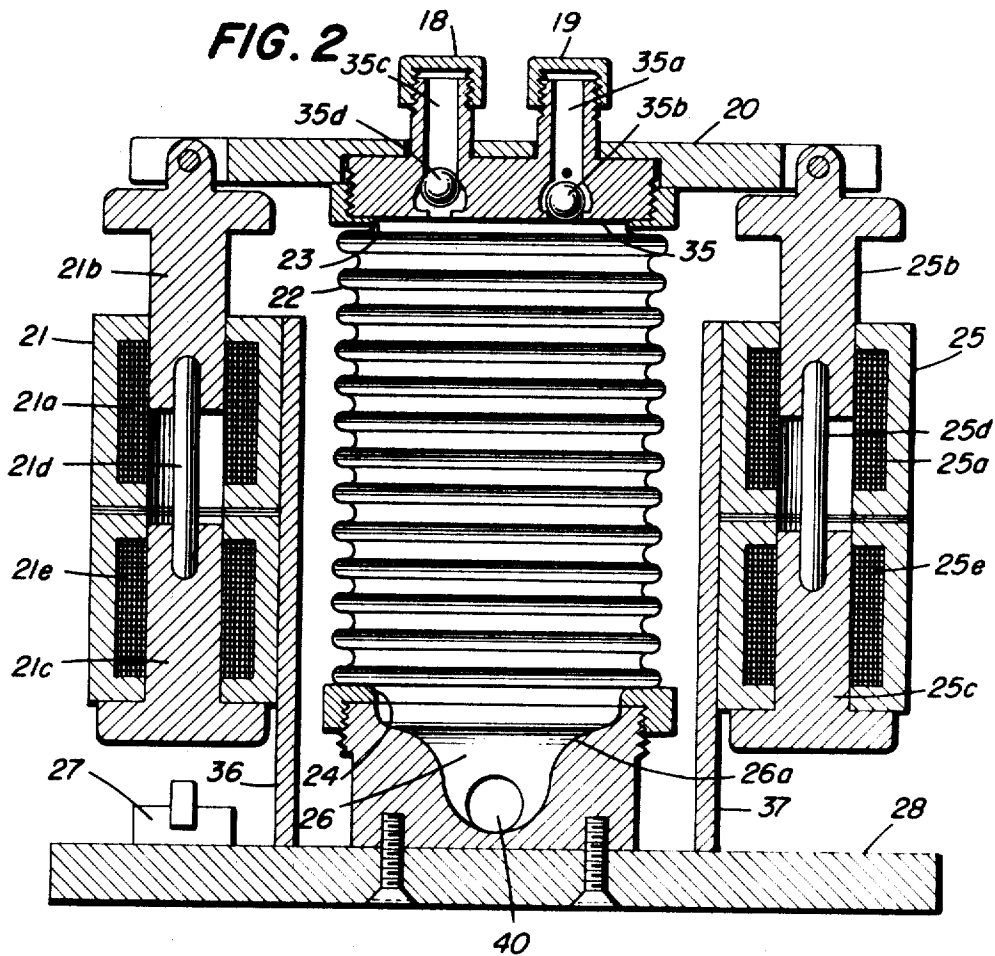
Goldfarb et al. TRANS. AMER. SOC. ARTIF. INTER. OR-

ABSTRACT: Method and apparatus for assisting a failing heart by sucking blood out of the left ventricle during normal systolic action, while at the same time blocking flow to the aorta, and during diastolic action, when the aortic valve is closed, forcing blood into the aorta and thence to the arterial tree. More particularly, there is provided a catheter with openings back from the tip thereof and with a radially surrounding collapsible portion, which catheter is inserted in the aorta with tip immediately above the aortic valve. A reciprocating external pump connected to the catheter on withdrawal stroke sucks blood out of the left ventricle and on pressure stroke forces the blood under pressure through the aorta and arterial system. Suitable provision is made for timing the sequence and pace of the pump with respect to the natural beat of the heart or, as desired, to a predetermined beat in point of time. Provision also is made for controlling the volume of blood moved by the pump. Additional provision is made for precisely locating the tip of the catheter immediately adjacent the aortic valve. Where desired, provision is made for directly observing the blood pressure and automatically controlling the same at a predetermined figure. Other provision is made for supplying additional blood.





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FIG. 4

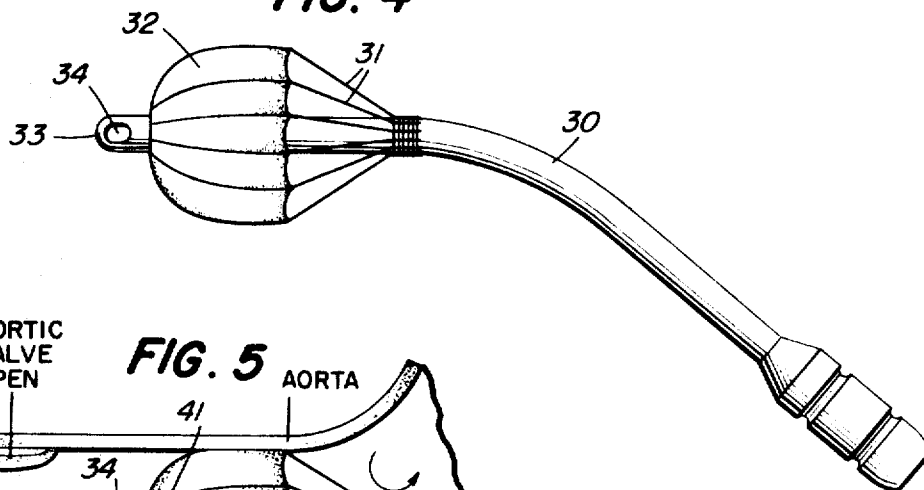


FIG. 5

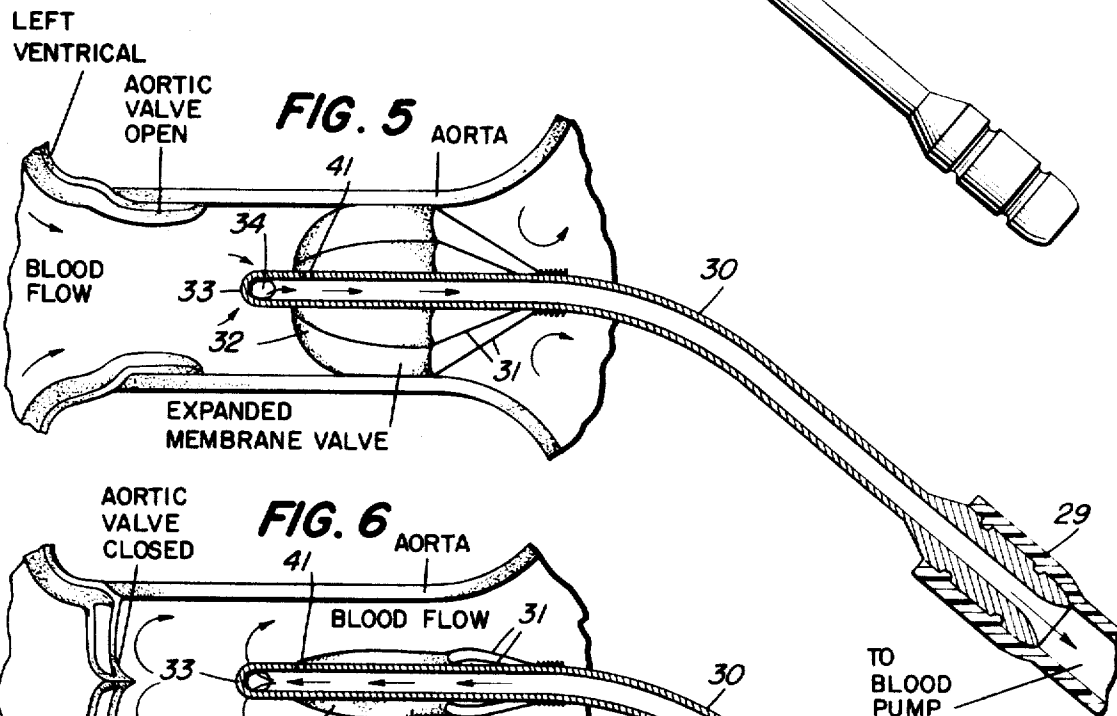
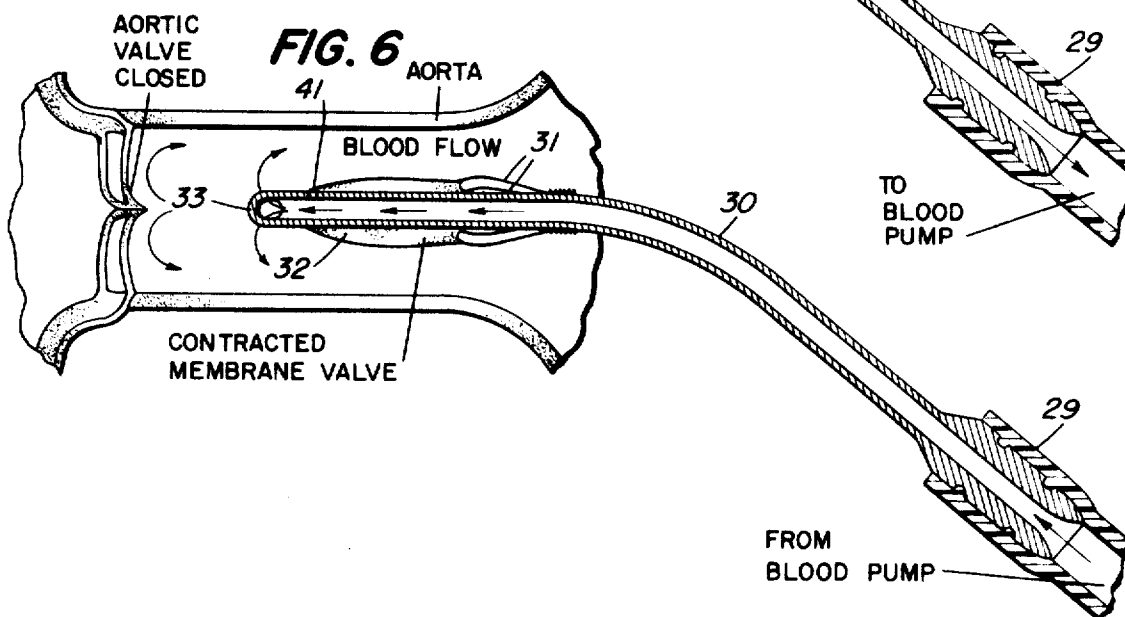


FIG. 6



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FIG. 7

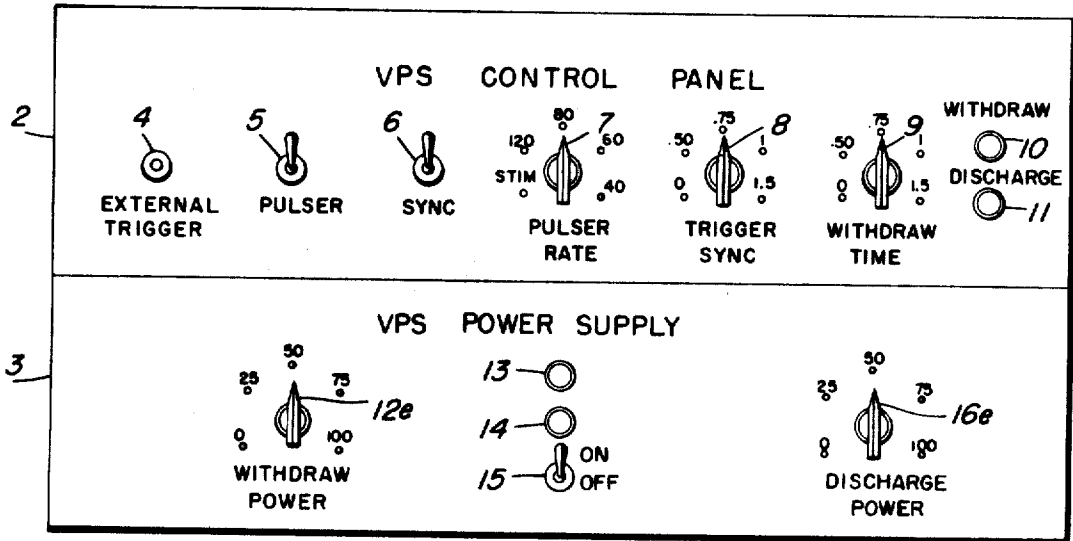
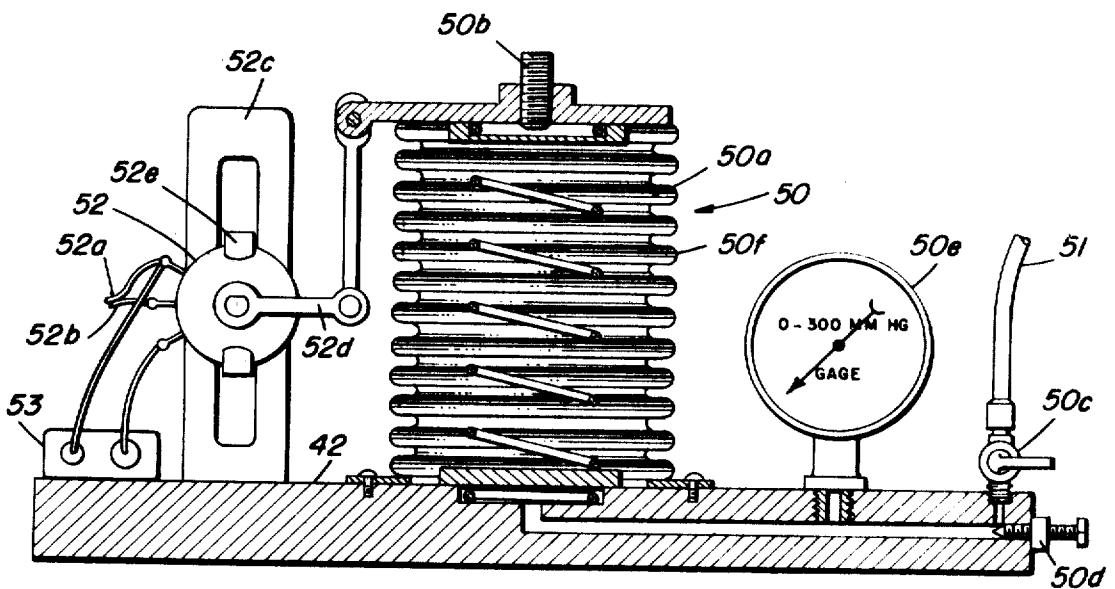


FIG. 10



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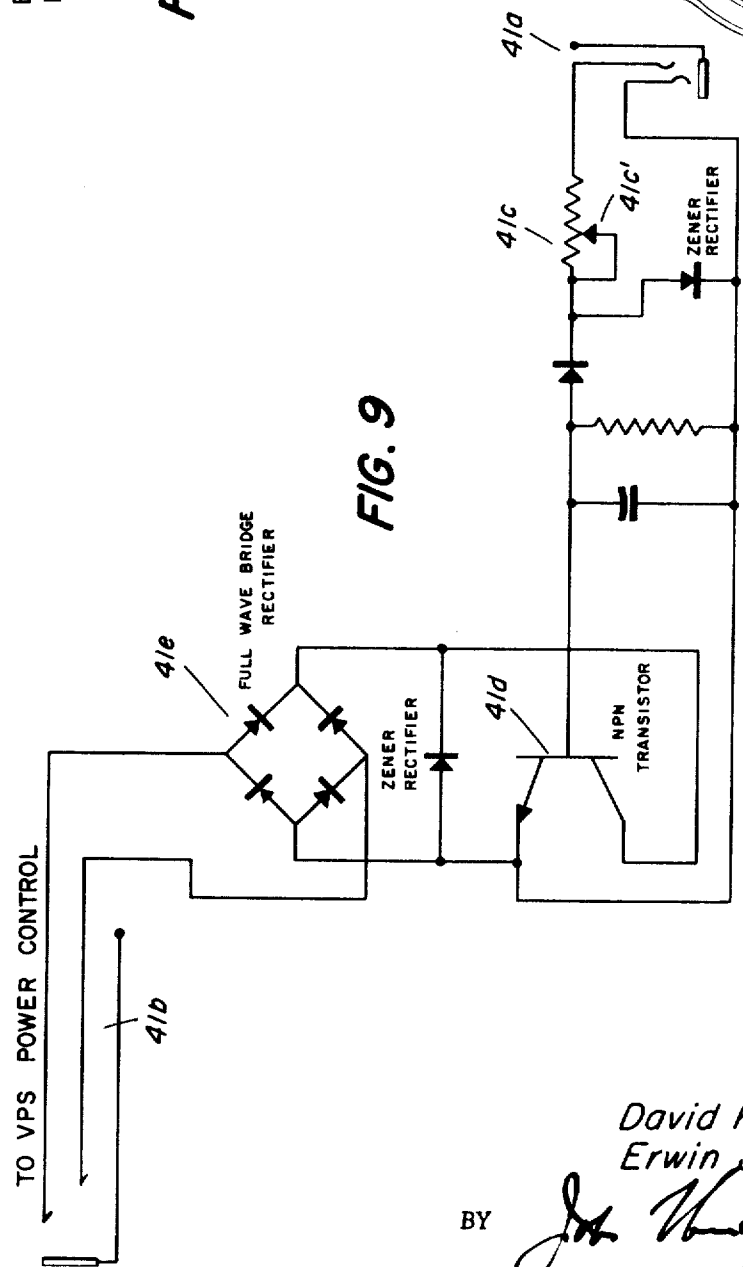
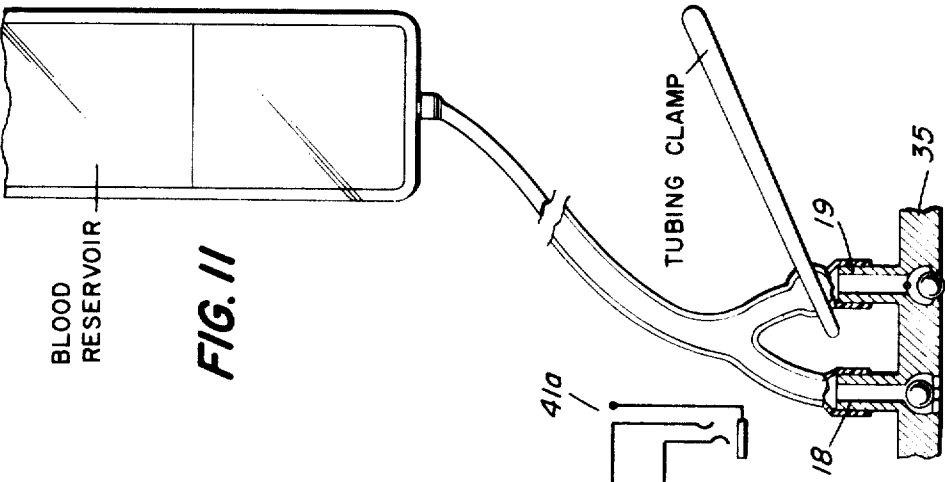


FIG. 9

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HEART ASSIST METHOD AND APPARATUS

As a matter of introduction, our invention is general relates to the art of assisting the natural heart action of an ailing cardiac patient.

One of the objects of our invention is the provision of a method and apparatus for assisting or substituting for the insufficient natural heart function, this enabling the heart itself to work with a minimum of effort, or indeed no effort, for substantial periods of time.

Another object is to provide a simple, direct and effective method of assisting the ailing heart even to the extent of mas- saging the same, where desired, and to provide comparatively simple apparatus, readily available, and easily accommodated to a heart patient, wherein there is a minimum burden on the heart and particularly the left ventricle during the systolic action, followed by diastolic action, all while precisely observing and controlling the rate of heart beat and the volume of blood being moved.

A further object is the provision of pumping means for effecting and precisely limiting the volume of blood moving between the ailing left ventricle and the vascular system of the patient.

A still further object is the provision of a catheter for ready insertion in the aorta immediately above the aortic valve, with provision for precise location, maximum acceptability by the patient and with maximum ease of removing the same without untoward effect.

Other objects of the invention in part will become apparent as the description of our method and apparatus progresses and in part will be particularly pointed to.

Our invention, accordingly, consists in the combination of elements and features of construction of our system and apparatus, in the several operational steps employed, and in the relation of each of the same to one or more of the others, all as more particularly described herein and particularly set out in the claims at the end of this specification.

BACKGROUND OF THE INVENTION

As an aid to a better understanding of certain features of our invention, it may be well to note at this point that situations do occur where the heart action of a patient is wholly insufficient to supply the patient's bodily needs. In some instances this is attributed to a lack of sufficient muscular activity of the heart itself. In others it is attributed to some damage directly introduced through bodily accident. And in still others, it may be attributed to a general overall deteriorating condition of the patient or to a trauma, ischemic shock or postoperative shock.

With a loss or substantial decrease in heart activity, we feel that it is the action of the left ventricle which is principally responsible. It is our thought that it is the muscular activity of the left ventricle which is not sufficient to supply the blood requirements of a patient. In point of fact, it is our thought that in many instances the action is not sufficient to completely discharge the blood from the left ventricle. And, moreover, that the action is not sufficient to force the blood into the aorta, and thence to the arterial system of the patient.

While much of the problem has been recognized by prior investigators, and many have offered solutions, these have not been entirely satisfactory. Some of the prior systems are too complicated to be thoroughly reliable. Others, although less involved, are inadequate. For example, in even the best of the prior art systems, there does not seem to result a complete discharge of blood from the heart during the systolic phase. Neither does it appear to force the blood into the aorta during the diastolic phase in such controlled and measured amount as to most nearly agree with normal heart action; in many instances the blood appears to surge forward either too abruptly or too slowly for precise agreement.

An object of our present invention, therefore, is to provide a method, system and apparatus which overcomes the difficul-

ties found in the systems of the prior art, in which method, system and apparatus there is given maximum aid to the ailing heart, with a best control of the action of the left ventricle, that is, full withdrawal of blood from the same during systolic action, and a best discharge of blood into the aorta and arterial tree, this in best agreement with normal discharge of an unailing heart. It is a further object to provide for adding to or subtracting from the volume of blood of the patient. Another is to provide means for stimulating the action of an ailing heart in simple, direct and reliable manner.

SUMMARY OF THE INVENTION

Turning now to the practice of our invention, it is our view that proper relief for the left ventricle of an ailing heart for a matter of minutes, or even hours, frequently rests the heart sufficiently to further function in normal manner. Accordingly, we provide a catheter which conveniently is introduced into either the aorta or the left subclavian artery by means of an arteriotomy incision, this having been exposed by a small cervical incision. The proximal end of the catheter protrudes from the artery and is provided with a plastic tube connected to a reciprocating pump. The distal end of the catheter is directed toward the heart. This end of the catheter, which we preferably provide with an opaque tip such as stainless steel, is positioned by way of X-ray, or even ultrasonic examination, to a point approximately 1 centimeter above the aortic valve ring. The catheter is secured in place by the use of arterial snares in the manner customarily employed by surgeons.

Now the catheter itself is provided with a number of holes immediately back from the tip. These, of course, allow for entrance and discharge of blood. The catheter also is provided with a radially flaring membrane valve, this being positioned at a point immediately back of the holes near the catheter tip. This valve is circumferential of the catheter and nicely fits against the inner walls of the aorta. A further hole or aperture is provided in the catheter just back of the flaring membrane valve. This small aperture permits a flow of blood into and out of the catheter immediately above the base of the flaring membrane, thus preventing blood from possibly stagnating or clotting at the base of the membrane. Upon removal, this aperture permits a flow of blood into the catheter which allows a gradual collapse of the membrane, thus permitting its withdrawal from the artery through which it had been inserted.

In our method and apparatus provision also is made for reciprocal pumping means connecting with the tubing leading from the proximal end of the catheter to withdraw blood from the left ventricle during systolic action of the heart and then discharge blood back through the catheter into the aorta during the diastolic action.

And in accordance with our invention, the pump means noted comprises a chamber having expansible walls, with appropriate provision for expanding these walls, thereby increasing the capacity of the pump chamber, and then contracting these walls and decreasing the pump chamber capacity, to cause ingress and egress of blood into the chamber. Where desired, provision is made for supplying the pump chamber with additional blood, or even saline solution, by way of a suitable reservoir.

During the systolic period and the withdrawal of blood from the left ventricle, the membrane valve of the catheter is expanded due to the action of the back pressure coming from the blood in the arterial tree and aorta, this as against the reduced pressure obtaining with withdrawal under the action of the pump. And during the diastolic period, the pressure of blood supplied by the pump assures closure of the aortic valve, collapse of the circumferential membrane valve about the catheter, and the resulting flow of blood into the arterial tree.

In our system and apparatus the action of the reciprocating pump is effectively controlled by amplified pulsations, either taken directly from the patient himself, or from electrocardiac

apparatus connected to the patient in customary manner. Suitable provision, of course, is made for desired control of the pulse rate of the apparatus, as well as systolic and diastolic pressures.

As an alternate feature of construction, we employ, where desired, means for automatically maintaining systolic and diastolic pressures at particular predetermined values. In this construction there is provided a second catheter, this being introduced into one of the main arteries of the patient, which supplies blood to a second chamber with expansible walls, which chamber, in turn, actuates a control for operation of the reciprocating pump. Visual means may be supplied to precisely indicate the blood pressures involved.

The system and apparatus in accordance with the teachings of our invention precisely remove all, or a desired portion of the blood in the left ventricle of the patient during systolic action, the amount removed depending upon the capability of the natural heart action of the patient and the setting of the system controls. Following this action, and with diastolic action of the heart there is a reversal of flow, and in our system and apparatus the blood is forced into the aorta, and thence the arterial system.

It will be seen that our system performs all, or a desired part, of the work of the left ventricle by allowing it to naturally expand and fill with blood, and then by suction removing the blood from the ventricle, allowing the ventricle to contract. The left ventricle, then, is forced to function and physically move through a heart beat cycle without, however, being called upon to expend any substantial effort of its own. In general, the system operates at pressures normally encountered in the heart, although it has a capability of exceeding normal pressures for the purpose of drawing blood through the heart, as in the case of an ailing patient with completely arrested heart action, and hence no arterial pressure.

As a further feature, the system has the capability of oscillating the blood back and forth rapidly in the aorta, and at the same time removing small amounts of blood from the left ventricle. Such action in effect mechanically massages the heart. This frequently is beneficial in causing an ailing heart to again function in normal manner.

The total weight of the apparatus is about 50 pounds, making it easily portable and hence most advantageous as compared to the bulky and weighty apparatus of the prior art. A further advantage lies in its use with a readily available 115 volt alternating current power supply.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings in which we disclose a preferred embodiment of our invention:

FIG. 1 is a schematic disclosure of the electromechanical blood-handling system and apparatus of our invention, showing catheter, pump and control panel of that system;

FIG. 2 is a detached sectional view, on enlarged scale, of the pump disclosed in FIG. 1;

FIG. 3 is a detached sectional view of the base portion of the pump of FIG. 2 taken at an angle of 90° from that disclosure;

FIG. 4 is a disclosure, on somewhat enlarged scale, of the catheter of the system and apparatus of FIG. 1;

FIG. 5 is a schematic illustration of the catheter of FIG. 4, also on enlarged scale, as operatively positioned in the aorta and immediately above the aortic valve, this latter in open position and with blood being sucked out of the left ventricle and into the catheter and with the catheter circumferential membrane valve expanded to prevent flow from the aorta back into the catheter;

FIG. 6 is a corresponding schematic illustration of the catheter, on enlarged scale, during a next one-half cycle of operation, with the aortic valve in closed position and with blood flowing out of the catheter and into the aorta, the circumferential membrane catheter valve being collapsed to permit the flow;

FIG. 7 discloses, on enlarged scale, the control panel of the system and apparatus of FIG. 1;

FIG. 8 is a schematic diagram of the electrical circuitry of our system and apparatus as controlled by the switches and pointers of the panels of FIGS. 1 and 7;

FIG. 9 is a schematic drawing of the electrical circuitry of a system for amplifying control from auxiliary equipment which may be used with our system and apparatus;

FIG. 10 discloses a blood pressure detector and control equipment, some parts being shown in partial section, which equipment, as an alternate, may be employed in the system and apparatus of our invention; and

FIG. 11 discloses in partial section a blood reservoir and appropriate connections which may be employed with the pump of FIG. 1, 2 and 3.

Like characters denote like parts throughout the several views of the drawings.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the preferred illustrative embodiment of our invention, attention is directed to the several views of the drawings. It will be seen that our system and apparatus essentially comprises catheter 30—33, blood pump 18—28, and the electrical control system 2—16. As noted above, catheter 30—33 is partially inserted into the aorta (FIG. 5) so that the distal end is immediately above the discharge side of the aortic valve. The proximate end is connected to a tube 29, which leads to blood pump 18—28 (FIG. 1). Blood from the left ventricle is withdrawn by the pump, this by way of catheter 30—33 and tube 29 and into chamber 22 of the pump. Upon reversal of the pump, blood from the chamber is passed back through tube and catheter and into the aorta (FIG. 6).

a. The Catheter

The catheter of our invention is so constructed that during the withdrawal portion of the operating cycle of the pump, the blood from the left ventricle is sucked into catheter 30 by way of opening 34 at the distal end of the same (FIGS. 4 and 5). A membrane valve 32 radially and circumferentially surrounding the catheter, is restrained in expanded position by way of radial filaments 31 serving to prevent any flow of blood back from the aorta and into the catheter under the back pressure obtaining in the arterial tree. The external membrane valve of the catheter is fashioned of a thin plastic or, as desired other impermeate membrane such as thin rubber, or either of these two additionally supplied with a thin fabric cover. External catheter valve 32 in the expanded position (FIG. 5) additionally serves to support the walls of the aorta from partial collapse under the suction action of the pump.

Upon reversal of the pump action during the next half-cycle of operation, this being timed with the normal diastolic action of the left ventricle, blood from the pump passing through and out of the catheter effects a collapse of the circumferential membrane valve (FIG. 6), and a consequent flow of blood into the aorta, and thence to the arterial system of the patient.

b. The Pump

Now the ventricle pumping system of our invention (FIG. 1) envisions electrical supply cable 1 leading to control panel 2—11 and the power supply panel 12—16 to pump 18—28, this by way of cable 17. The pump itself (FIG. 2) comprises a chamber having expandible walls, these being in the form of circumferential bellows 22, with lower end secured to pump base 26 by way of ring 24 threadedly engaging base 26, and upper end secured to pump head 35 by way of ring 23 threadedly engaging the pump head. Bellows 22 is interiorly treated with silicone or other substance compatible with blood. And pump base 26 and head 35 are fashioned of plastic, such as acrylic resin, or of bronze or other metal interiorly coated with Teflon or other silicone. A crossbar 20 secured at head 35 pivotally engages with armatures 21b and 25b of respective electrical solenoids 21 and 25. The two solenoids are supported on base member 28 by way of respective brackets 36 and 37. The pump chamber may be exhausted by way of exit port 35a maintained in closed position by way of

translucent screw cap 29 and exiting one-way valve 35b. Additions may be made to the chamber by way of ingress port 35c maintained closed by screw cap 18 and one-way intake valve 35d.

Upon energizing the upper solenoid windings 21a and 25a of the two solenoids 21 and 25 the respective armatures 21b and 25b are drawn downwardly and well into coils 21a and 25a. Movement of the two upper armatures carries the two lower armatures 21c and 25c into a "down" position because of the nonmagnetic links 21d and 25d interconnecting upper and lower armatures. With a downward movement of the upper armatures, the bar 20, pivotally connected with the upper armatures, and head 35 of the pump, is drawn downwardly. The blood content of the pump chamber is forced out by way of egress port 40 and into catheter 30 by way of interconnecting tube 29, as discussed above. Upon completion of the downward stroke of the pump and deenergizing of the solenoids 21 and 25, with the next half-cycle of operation the lower solenoid windings 21e and 25e are energized, this forcing the armatures 21c and 25c upwardly into the position shown in FIG. 2 and carrying with them the upper armatures, by way of links 21d and 25d, and the pump head 35, thus expanding the pump chamber.

The pump itself has a stroke of about 1½ inches, this being that of the armatures of solenoids 21 and 25, the two exerting a combined force of about 30 pounds. The diameter of chamber 22 is about 3 inches. As a consequence, it will discharge or accept some 100 milliliters of blood per inch of compression or expansion. It is designed to discharge or take in any amount of blood up to a maximum of 100 milliliters, and may be operated at positive or negative pressures up to 8 pounds per square inch. The maximum power and pump capacity, of course, well exceeds the requirements met with in actual practical use.

The solenoids of our pump apply full available power in less than 0.009 seconds from the time a trigger signal is received. This prompt response is such that the control of the pump may be made by the "R" wave of an electrocardiograph, or the like, triggered from auxiliary equipment without necessity for the introduction of either predicting or delayed circuits. The system responds so quickly that when triggered by an "R" wave, the intraventricular pressure does not rise, but on the contrary, remains significantly low, and thus reduces the work load of the ailing left ventricle. The advantage of this type of operation is that the pump remains in proper synchronization with the natural heart, regardless of the fact that the natural heart beat may be irregular.

As a further feature of our pump, any air or gas from the blood is immediately swept to the top of the blood chamber. Such air or gas is visible to the operator through translucent closure cap 19. And by unscrewing the cap, the air or gas may be quickly released.

Although with the solenoid stroke of about 1½ inches, and of course corresponding stroke of pump head 35, there is a discharge or change of only some 100 milliliters of blood per inch of movement, the total capacity of the pump chamber amounts to about 500 milliliters. And the design is such that blood entering the base port 40 under the action of the pump suction is inclined to centrally rise, as in the case of a fountain. With reversal of the pump, however, the blood is inclined to be funneled downwardly by way of the sloping sidewalls 26a of the pump base and into port 40. In this way the blood inside of the pump is circulated and constantly changing.

The parts of pump 18—28 which are exposed to blood, notably sidewalls, base and head, are smooth and compatible with blood. There is an absence of rubbing, pinching, or rolling parts of the pump in contact with the blood. The several features of our pump combine to provide a capability of pumping blood with no more damage to the blood, for example hemolysis or conversion of fibrinogen to fibrin threads, than might be expected in the natural vascular system. And as a further feature, the system and apparatus of our invention is such that there is an immediate and direct relationship

between motor, pump and blood being moved in and out of the vascular system. Moreover, our system assures establishing and maintaining any desired blood pressure, as more fully described below. But it is the instantaneous response to a monitoring signal that assures precise movement of the blood, precision of control being furthered by positioning pump 18—28 immediately adjacent to the patient, with a minimum length of tubing 29 between pump and catheter, this reducing the amount of blood in the system to a minimum figure and minimizing the amount of blood being moved back and forth. Instantaneous response is realized by virtue of the minimal mass of blood.

Attention now is more particularly directed to the electrical circuitry employed in the system and apparatus of our invention. A patient with ailing heart whose left ventricle is incapable of maintaining normal blood pressure, that is, whose blood pressure has dropped to some 60 millimeters of mercury systolic and 40 mm. Hg diastolic pressure, obviously is approaching a terminal condition. Located in a hospital, having an intensive care unit with electrocardiograph, his electrocardiogram and blood pressure waves are being developed on an oscilloscope. The "R" wave of the patient which appears on the oscilloscope conveniently is employed as a trigger for the system of our invention.

c The Pump Controls

The catheter 30—34, as more particularly discussed above, is inserted with distal end about 1 centimeter above the aortic valve. The precise positioning is gauged by X-ray examination, made possible by the opaque tip 33, or by the ultra sound. Synchronizing switch 6 (FIGS. 7 and 8) is turned to an "Off" position, the pump withdraw timer 9 is set at 0.3 seconds, the pulser rate 7 is set at a rate slightly lower than the patient's heart beat, and the pulser switch 5 is turned to "On" position. The withdraw power control 12 and the discharge power control 16 are set at the 25 percent figure shown on their respective dials (FIG. 7). The "R" wave from the electrocardiograph is employed as a control, the electrical energy from this wave being plugged into the external trigger input 4. And to readily observe the pulsing of withdrawal and discharge of the pump, energy from the two pump controls also is fed by way of respective outlets 39 and 41 into the electrocardiograph. With the settings noted, the power switch 15 is turned to the "On" position.

Now as the "R" wave input to the input connection 4 passes a preestablished figure of 0.5 volts, it triggers the rectifier 45, which then permits a passage of power from the DC power supply 46 and the limit switch 27 to close the solid state relay 47. With closure of that relay, the AC power from the main line 1 is connected through the synchronous switch 6 to the withdrawal timer 9 and to the pump withdrawal power control 12. This is the situation obtaining the illustrated in FIG. 8.

Upon energizing pump withdrawal power control 12, current is supplied pump 18—28, more particularly the lower solenoid coils 21e and 25e (FIG. 2), which then pull armatures 21c and 25c respectively into the position shown in FIG. 2 from a lower position not shown, all as more particularly described above. In this action, the armatures 21b and 25b of the upper solenoids are lifted by way of the nonmagnetic linkages 21d and 25d to the position shown in FIG. 8. And with this movement, cross-link 20 and pump head 35 are lifted, effecting an expansion of the pump chamber and resultant suction of blood by way of catheter 30—33 and connecting tube 29 from the ailing ventricle of the patient.

As blood is withdrawn from the catheter, a pressure differential develops between distal end 34 of the catheter and the upper section of the aorta. Also between the distal end of the catheter and the aorta valve. As a result, blood flowing from the upper section of the aorta causes circumferential membrane 32 of the catheter to expand and block the flow of blood from the upper portions of the aorta. And as a further feature, the pressure differential between catheter and aortic

valve causes the latter to pen and allow the catheter to exhaust the blood from the left ventricle. Actually, the two functions noted happen so rapidly that blood is being withdrawn from the left ventricle a few milliseconds prior to the time that the left ventricle naturally contracts and discharges blood. As a consequence, the ventricle contracts in absence of blood pressure or, as desired, at some predetermined reduced pressure, this depending upon the setting of the pump withdrawal power control 12. The above description covers the first half-cycle of the operation of our ventricular pumping system and apparatus.

In the succeeding half-cycle of operation, that is, the half-cycle wherein blood is pumped into the aorta and thence to the vascular system of the patient, after the initial trigger which comes from the leading edge of the "R" wave of the electrocardiogram and after some 0.3 seconds following the initial triggering of the system, timer 9 opens the withdrawal power control line 9a (FIG. 8), which serves to disconnect power control 12 from the line and consequent deenergization of lower pump solenoids 21e and 25e. At the same time, control power is supplied to the pump discharge power control 16 through closure of the circuit at 9b. This serves to instantly energize the upper solenoid windings 21a and 25a, with resulting pulling of armatures 21b and 25b respectively into a downward position within the coils, and consequent pushing of the lower armatures 21c and 25c downwardly into a position in which armature 21c strikes the pump discharge limit microswitch 27.

Actuation of switch 27 immediately removes power from rectifier 45 and deenergizes relay 47, thereby breaking connection to both pump withdrawal power control 12 and pump discharge power control 16. No supply of power to either of the pump power controls may then be had until relay 47 is again actuated, this by way of a further trigger input to connection 4 and consequent reactivation of rectifier 45 and the resulting supply of DC power from power supply 46 through the activated rectifier 45 to relay 47. Incidentally, as the electrical circuit is broken at the pump discharge limit microswitch 27, connection is made through rectifier 27a and resistor element 27b to ground. This connection obtains until switch 27 is reset.

One of the provisions of our system and apparatus is that as the operator observes the patient's blood pressure wave form on an oscillographic display, adequate adjustment may be made either to increase the systolic pressure or decrease the same as desired. In this it is merely necessary to adjust the withdrawal timer 9 to either a longer or a shorter timing operation, and to adjust the pump power controls 12 and 16 to supply greater or less power to the withdrawal phase and discharge phase of the pump. In making these adjustments after an initial setting is had of timer 9, both the withdrawal and the discharge power controls are gradually changed. This gradually raises the arterial blood pressure due to a gradual increase in the volume of the blood which is pumped. After the desired pressure has been reached, an occasional adjustment of withdrawal control 12 will effectively correct a pressure that is either too high or too low; no corresponding change need be made either to the pump discharge power control 16 or the timer 9.

In our system and apparatus, provision also is made for assuring continued heart action of the patient even in such instances where the "R" wave becomes most irregular or virtually ceases. This is achieved by pulser 7. As previously indicated, the pulser 7 of our apparatus customarily is set at a rate just slightly less than the patient's heart beat. This is done by timing the natural beat of the heart and setting the pulser 7 so that it sends out a pulse just after the natural "R" wave triggers the system. Since the system is already triggered by the "R" wave, no untoward incident accompanies the further triggering by the pulser. One advantage of using the pulser in this manner, however, is that if the "R" wave becomes irregular, or the natural heart beat fails, then the pulser will initiate a trigger at a time only slightly later than would have been ef-

fected by the normal "R" wave. In accordance with the provisions of our system and apparatus, after receiving an impulse from pulser 7, a pumping cycle ensues, as described above. A further cycle requires a further triggering effect by the "R" wave if properly functioning, or if not properly functioning, by the pulser 7. The pulser action has the effect of stabilizing or continuing the forced heart action even if the natural action of the left ventricle has completely stopped. In such event, the continuance of the regular pump cycle will pull blood through the heart and maintain desired blood pressure. And of course the continued pumping initiated by the pulser forces blood through the coronary arteries and thus feeds the heart muscle. At the same time this blood forces the left ventricle through a pumping cycle even if the left ventricle is entirely incapable of discharging blood through its natural action. Such enforced action is greatly beneficial to an ailing or failing heart, permitting significant and radial recovery.

During the process of recovery, the operator notes an improved blood pressure due to the recovering left ventricle, then reduces the withdrawal power of the pump by lowering the setting of control pointer 12e. Further reduction in pump action may be continued until it becomes apparent that the left ventricle of the patient is capable of supporting its work load and that the pumping system is no longer required.

d. Alternate Controls

As a further feature of our invention, provision is made for automatic control of blood pressure. In this we provide an automatic blood pressure control plug-in amplifier 41 (FIG. 9) which is connected to the pump withdrawal power control 12 by way of connection 60 (FIG. 8). By setting potentiometer 12 to a fairly high value by pointer 12e, say 75 percent, blood will be withdrawn at the maximum reasonable volume. A higher setting would increase the blood pressure beyond a desirable high value. The purpose of amplifier 41 is to control power control 12 so that the withdrawal stroke is just enough to maintain a desired pressure level. Potentiometer 41c is set so that pump 18—28 is operating by visual observation at a presumed proper level. As the blood pressure increases beyond a controlled level, the voltage applied to pump withdrawal power control 12 also is increased. This causes the transistor 41d to conduct more heavily and power is pulled through the full wave bridge rectifier 41e and from the gate of the double rectifier to withdrawal power control 12, thereby lowering the voltage applied to control 12. As the control gate voltage is lowered, the output power of withdrawal control to the withdrawal pump solenoids 21e and 25e (FIGS. 1 and 2) also is lowered. This in turn lowers the blood pressure because of the decreased amount of blood being withdrawn by each stroke of the pump.

As the blood pressure is lowered beyond the control level, this is reflected by applying more power to the withdrawal of solenoid coils 21e and 25e. And this in turn increases the blood pressure. Thus, the setting of potentiometer 41c of amplifier 41 (FIG. 9) corresponds to some controlled blood pressure. Moving the potentiometer control 41c to the right increases the control level, and moving the potentiometer control to the left decreases the control level.

In situations where a patient has virtually no heart beat, pulser 7, as more particularly described above, serves to initiate a trigger impulse and keep the system functioning. A desirable level of systolic pressure, however, may not be obtainable. And in such circumstance, amplifier 41 is employed. This serves to assure maximum power in an attempt to maintain a predetermined level of blood pressure. With partial recovery of the activity of the left ventricle, there is a slight increase in the blood pressure. This increase is reflected by a visible decrease in the volume of blood withdrawn by the pump, and by longer rest periods upon completion of the pump discharge cycle. The operator then may increase the control level gradually by adjusting the pointers 12e and 16e of controls 12 and 16. And after each increase in blood pres-

sure, he may wait until there is a further decrease in the activity of the withdrawal pump, this indicating that the left ventricle has enjoyed further recovery in order to support the blood pressure being controlled. If during this time the patient's heart is found to skip a beat, pulser 7 will automatically initiate a trigger action, as more particularly described above. This assures a full maximum stroke of the withdrawal pump and, as a consequence, even with the heart skipping a beat, there is little, if any, change in blood pressure level. By continuing to gradually increase the blood pressure control level as the action of the ventricle continues to recover, as by proper manipulation of power control knobs 12e and 16e, provision is made so that no more reliance is placed upon the pumping system and apparatus than is necessitated by the incapacibilities of the left ventricle of the heart.

With the approach of the full natural heart action, that is, natural action of the left ventricle, potentiometer 41c is set to give a blood pressure of some 10 points below the normal blood pressure of the patient. As the left ventricle, starting at some very low pressure level, begins to develop an average pressure which passes through the level noted and proceeds on to approach a normal pressure, then the assistance afforded by our system and apparatus is no longer needed.

e. In Absence of an Oscillographic Display

In those instances where an oscillographic display is not available, the blood pressure of the patient may be determined directly by the usual pressure cuff and stethoscope. If the patient has a heart beat, even a weak one, our system and apparatus is effective. The weak heart action will be reflected by some slight pulsing of blood pump 18—28 and alternate lighting of pilot lights 10 and 11 (FIG. 8) connected across the supply to pump withdrawal and discharge controls 12 and 16 respectively. And with this indication, pulser 7 is then set to the same rate by first turning off the pump power controls 12 and 16 (FIG. 7), leaving, however, the remainder of the system energized, including the lights 10 and 11, and then setting pulser 7 at such rate as to agree with the beat of the heart, that is, bringing the action of the pulser, as observed by pilot lights 10 and 11, into synchronism with the beat of the heart.

When pulser 7 is synchronized with the action of the heart, power controls 12 and 16 are turned on by appropriate settings of control knobs 12e and 16e respectively, and the pumping action begins. We find that with appropriate setting of pulser 7, there appears to be mechanical synchronization between the heart of the patient and pump 18—40. A recovering left ventricle appears to lock into the pump rhythm. A uniform, regular action is established.

As the left ventricle recovers, there is noticed an increase in the blood pressure of the patient. This conveniently is determined by temporarily stopping the pump, as by switching it off at 15, and then switching it on again after the pressure has been determined, or more properly in order to retain synchronism between pulser and heart, by turning off the pump power supply of withdraw power and discharge power by bringing dial pointers 12e and 16e to the zero position and returning to desired operating position (FIG. 7). Additionally, we find that with recovery of the left ventricle, less pump power is required, this as reflected by the decreased time in which the withdrawal stroke is accomplished and the longer rest period following the discharge stroke. Actually, the blood pressure of the patient may be determined at any time, even without stopping the pump, by using pressure cuff and stethoscope, as noted above.

f. In Absence of Electrocardiograph But With Auxiliary Control

The system and apparatus of our invention, including the alternate automatic blood pressure controls described above, may be employed even in absence of the electrocardiograph. More particularly, the blood pressure detector 50 (FIG. 10),

having expansible chamber 50a, is filled with a sterile saline solution by way of fill cap hole 50b. A small plastic tube 51 is connected to valve 50c and a hypodermic needle (not shown) is connected to the distal end of the tube. Valve 50c is opened, the system is flushed with the saline solution, and the valve then closed. The system is again filled with the saline solution and fill cap 50b is replaced. The equipment then is ready for application to the patient.

The hypodermic needle is inserted into any convenient artery of the patient, and valve 50c again opened. As blood flows into the detector, flow-restricting valve 50d is adjusted to allow only a small flow. The blood pressure is registered on gauge 50e, this recording any pressure from 0 to 300 millimeters of mercury. The valve 50d, when properly adjusted, serves to average out the systolic and diastolic pressures to give a mean or average value.

As blood enters the detector, spring retained bellows 50f defining the sidewalls of chamber 50a expands and increases the capacity of the chamber. When the pressure in the chamber reaches the same value as the average blood pressure of the patient, bellows 50f reaches an ultimate position. In spite of the averaging of systolic and diastolic pressures had with valve 50d, there nevertheless is observed some slight pulsing of bellows 50f and gauge 50e. When the ultimate position is reached, detector 50 is plugged into automatic blood pressure amplifier 41, as by way of connections 52a and 52b coming from potentiometer 52, forming a part of the blood pressure detector equipment. Amplifier 41 is then plugged into out ventricular pump system as at 49 (FIG. 8).

Now blood pressure detector 50 is a simple electromechanical assembly that directly indicates the average blood pressure of the patient on gauge 50e, as noted above. Moreover, the detector provides a variable voltage signal to amplifier 41. Potentiometer 52 of the detector is adjusted and clamped on the holder 52c in use when the potentiometer is initially set with arm 52d in the horizontal position, as shown in FIG. 10. In this position the blood pump of our system operates at about one-half capacity.

Where it is desired to raise the blood pressure, potentiometer 52 is physically elevated about one-fourth inch, this by loosening the holding clamp 52e and resetting the same in elevated position. There results a clockwise rotation of potentiometer arm 52d, which through action of potentiometer 52, decreases the voltage from direct current source 53 applied to the base of the double rectifiers of withdrawal power control 12. This action serves to allow full gate voltage on the withdrawal power control, causing the same to put out full power and operate the blood pump at full capacity.

Operation of the pump at full capacity, of course, raises the blood pressure of the patient. And as this occurs, the increased blood pressure further expands bellows 50f of detector 50. As a result, potentiometer arm 52d is moved in counterclockwise direction, gradually reaching a horizontal position. Potentiometer 52 then increases voltage from direct current source 53 applied to the base of the rectifiers of pump control 12, with resultant lowering of power output of the control and consequent reduction of the activity of the withdrawal phase of the pump. With such lessening of pump action, the blood pressure of the patient decreases. And with this decrease, bellows 50f contracts slightly and potentiometer arm 52d slightly reduces the control voltage of the potentiometer, causing an ultimate increase in the power supplied the pump in manner more particularly described above.

Movement of bellows 50f either up or down, corresponding to an increase or decrease in blood pressure, is mechanically transmitted to control potentiometer 52, which in turn is reflected as a decrease or an increase in the capacity of the blood pump as noted. The system and apparatus soon reach a point where a balance is had between the capacity of blood pump 18—28 and the blood pressure detecting apparatus; the point is reached where just enough blood is pumped to maintain a precise level of the detector apparatus. This is recorded on pressure gauge 50e. In short, by positioning potentiometer

52 either up or down on holder 52c, any desired blood pressure can be automatically maintained.

Thus, in conclusion, it will be seen that we provide in our invention a method, system and apparatus in which there are had the various objects set out above, and the numerous practical advantages thereof. Our system provides a simple, direct and effective means for handling blood in quantity sufficient for definitive results, and all with minimum untoward effect, that is, a minimum of hemolysis, minimum conversion of fibrinogen to fibrin threads, and the like.

The system and apparatus of our invention are particularly useful in the treatment of congestive heart failure, and in those instances where there is a temporary weakening of heart activity resulting from postoperative shock, hemorrhage, infection, or myocardial infarction with pump failure.

Since many changes and variations may be made in the method, system and apparatus of our invention, it is to be understood that all matter described herein, or shown in the accompanying drawings, is to be interpreted as merely illustrative, and not by way of limitation.

We claim:

1. Method of improving the action of the ailing heart of a patient wherein an open end catheter is inserted within the aorta adjacent the aortic valve of the left ventricle of the heart, said catheter having associated therewith flow-restraining means, which method comprises intermittently withdrawing blood directly from the left ventricle through said catheter with each systolic pulsation of the heart; restraining flow of the blood into and from the aorta; temporarily storing the blood of each such pulsation near the patient; and with each succeeding diastolic period removing the restraint and moving the blood from storage back through the catheter into the aorta under pressure.

2. System and apparatus for aiding the ailing heart of a patient comprising in combination, blood storage means; catheter means with an open distal end for introduction into the aorta just above the aortic valve; pump means connected to the proximal end of the catheter for withdrawing blood from the left ventricle during systolic pulsation and passing the same to such storage means and during succeeding diastolic period moving said blood from said storage means into the aorta; valve means adjacent the distal end of the catheter for restraining the passage of blood into and from the aorta during such systolic pulsation but permitting passage during diastolic period; means for detecting and recording the pulse rate and instantaneous blood pressure of the patient; and control means for said pump means triggered and controlled by said detecting and recording means to maintain a predetermined pressure.

3. System and apparatus for aiding the ailing heart of a patient comprising in combination, means for intermittently storing the blood of such patient; catheter means with an open distal end for introduction into the aorta with distal end just above the aortic valve; pump means connected to the proximal end of said catheter means for withdrawing blood from the left ventricle during systolic pulsation and passing the same to such storage means, and during succeeding diastolic period moving said blood into the aorta; collapsible valve means adjacent the distal end of the catheter in the aorta for restraining the passage of blood into the same during systolic pulsation of the heart but permitting passage of blood during diastolic period; oscillographic display means for connection to the patient for displaying the electrical wave form of the heart pulse of the patient; and the arterial pressure wave form of the patient and means responsive to a predetermined point of the heart pulse wave to control the action of said pump means.

4. System and apparatus for aiding the ailing heart of a patient comprising in combination catheter means having an elongated member with bore extending therethrough and having an open proximal end portion, said open end distal portion adapted for introduction into the aorta with distal end just above the aortic valve; pump means connected to the prox-

imal end of said catheter means for withdrawing blood from the left ventricle; collapsible valve means adjacent and rearward of said distal end of the catheter means for restraining passage of blood into and from the aorta during the withdrawal of blood from the left ventricle; reservoir means connecting with said pump means for storing withdrawn blood; means for detecting and recording the pulse rate and instantaneous blood pressure of the patient and control means for said pump means to properly control the action of said pump to maintain a predetermined blood pressure by said detecting and recording means.

5. In apparatus for aiding the ailing heart of a patient, catheter means for introduction into aorta with distal end just above the aortic valve, comprising an elongated member with bore extending therethrough and having an open end distal portion and an open proximal portion; and back from said open end distal portion, circumferential collapsible imperforate membrane valve means flaring out radially and in proximal direction from the central axis of the elongated member of said catheter means for temporarily closing the aorta.

6. In apparatus for aiding the ailing heart of a patient, catheter means for introduction into the aorta with distal end just above the aorta valve, comprising an elongated member with bore extending therethrough and having an open end distal portion and an open proximal portion; an opaque tip in advance of said open end distal portion; and circumferential flaring imperforate membrane valve means intermediate said elongated member and extending in proximal direction radially about said elongated member of said catheter means for temporarily closing off the aorta.

7. In apparatus for aiding the ailing heart of a patient, catheter means for introduction into the aorta with distal end just above the aorta valve, comprising an elongated member with bore extending therethrough and having an open end distal portion and an open proximal portion; and, back from said open end distal portion, circumferential collapsible imperforate membrane valve means radially flaring out from the central axis of said elongated member for temporarily closing the aorta, said catheter means including in said elongated member an opening back of said flaring membrane valve means.

8. In apparatus for aiding the ailing heart of a patient, catheter means for introduction into the aorta with distal end just above the aortic valve, comprising an elongated member with bore therethrough and an open end distal portion and open proximal portion with opaque tip portion and openings back of said tip portion; and collapsible imperforate membrane valve means radially flaring out from a central axis of said elongated member for temporarily closing a aorta, said elongated member having an opening back of said valve means to assure blood circulation immediately above said valve means and to assure easy withdrawal of catheter means from the patient.

9. System and apparatus for aiding the ailing heart of a patient by withdrawing blood from the left ventricle during systolic pulsation and during succeeding diastolic period moving said blood into the aorta, comprising catheter means for withdrawing blood from said left ventricle; valve means on said catheter means for restraining the back-flow of blood from the aorta during such withdrawal during systolic pulsation, but permitting blood flow therethrough during diastolic period; pump means connecting with said catheter means; means for controlling the pump means to withdraw blood from the patient in one cycle of pump operation and in another cycle supply blood to the patient; means accepting electrical stimulus from apparatus connected to the patient; relay means actuated thereby for control of supply power to the pump means; and timing means for determining the duration of the application of power to said pump means withdrawal and discharge control.

10. System and apparatus for aiding the ailing heart of a patient by withdrawing blood from the left ventricle during systolic pulsation and during succeeding diastolic period mov-

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ing said blood into the aorta comprising catheter means for withdrawing blood from said left ventricle; valve means on said catheter means for restraining the back-flow of blood from the aorta during such withdrawal during systolic pulsation, but permitting blood flow therethrough during diastolic period; pump means; means for controlling the same to withdraw blood from the patient by way of said catheter means; means for controlling the pump means to supply blood to the patient by way of said catheter means; pulser means for controlling the pulse of the patient adjustable to desired rate of heart beat connected to said withdrawal and supply control means; and timing means connected to said withdrawal control means for determining the duration of the application of power from said withdrawal control means to said pump means.

11. System and apparatus for aiding the ailing heart of a pa-

tient by withdrawing blood from the left ventricle during systolic pulsation and during succeeding diastolic period moving said blood into the aorta comprising catheter means for withdrawing blood from said left ventricle; valve means on said catheter means for restraining the back-flow of blood from the aorta during such withdrawal during systolic pulsation, but permitting blood flow therethrough during diastolic period; pump means; means for controlling said pump means to withdraw blood from the patient; means for controlling the pump means to supply blood to the patient; blood pressure detector means for connection to an artery of the patient; and adjustable electrical power means controlled by said detector means for controlling a supply of power to said withdrawal control means.

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