This invention relates to a myocardial massaging device, and, more particularly, to a device for providing systolic support to a partially or totally inactive myocardium where, however, there is still intact valve function. Although a large number of artificial limbs and organs have been improvised and improved during recent years, relatively little has been done in the field of an artificial heart. For the most part, the heat work has consisted of extracorporeal circulation and oxygenation devices which have been limited to short term emergency procedures. Thus, it is desirable to provide an auxiliary for the heart which would not be subject to these short term limitations, and the provision of such constitutes an important object of this invention.

Another object of the invention is to provide a heart massaging and supporting device which is installable in the body about the heart ventricular area. It will be appreciated that for a heart-supporting device to be feasible, it must be small, durable, simple and viable, and further that these mutually conflicting specifications pose a biomedical engineering problem of substantial complexity. It is, therefore, yet another object of this invention to provide a solution for this problem.

A further object of the invention is to provide a novel heart massaging and supporting device wherein the inventive device automatically compensates for changes of blood flow occasioned by exercise, and the like, and thereby simulates a real heart, all while being installed in situ.

Still further object of the invention is to provide a novel electronic cycle controller for regulating a reciprocating mechanism such as the inventive myocardial massaging and supporting device. Other objects and advantages of the invention may be seen in the details of construction and operation set down in this specification.

The invention will be explained in conjunction with an illustrative embodiment in the accompanying drawing, in which:

FIG. 1 is a partially schematic representation of the inventive device when installed in a mammalian body, and

FIG. 2 is a schematic drawing of an electronic circuit for controlling the operation of the cycling device of FIG. 1.

At the outset, it is to be noted that the invention does not have to do with substitution of the natural valving functions of the heart.

The inventive environment is seen in the drawing, wherein the numeral 10 designates generally the ventricular area of the heart and the numeral 11 designates generally a casing which is carefully fitted to the apex region of the heart and which includes an outer wall 12 and an inner wall 13. The walls 12 and 13 are spaced apart and define a chamber 14 which is in communication with a cylinder and piston unit generally designated 15 by means of a conduit 16.

The inner wall 13 of the casing 11 is relatively resilient or elastic in comparison with the relatively rigid outer wall 12, so that upon operation of the cylinder and piston unit 15, the volume of the chamber 14 is capable of changing in response to pressure inflation.

The casing 11 is constructed of viable material such as a non-toxic silicone and is retained in place as at 10a by fasteners anchored to various structures at the base of the heart. Alternatively, sutures or direct fibrous adhesion may be employed for this securement. The casing in the area 10b is characterized by a gradual transition from the relatively hard shell forming the wall 12 to the relatively elastic or soft inner membrane 13, thereby insuring durability and minimizing detrimental tissue reaction. It will be appreciated that there is thus a line of perimetric union between the outer wall 12 and inner membrane 13 adjacent the point of securement of casing 11 to the heart 10.

In operation, the chamber 14 is periodically expanded by means of air or other fluid power delivered through the flexible tubing 16 from a cyclic pump such as the cylinder and piston unit 15 which may be vented as at 15a.

The cylinder and piston unit 15 is provided as part of a sealed fluid pressure system including the chamber 14 and the interior of the tubing or conduit 16, and the piston 17 is arranged for a predetermined length of stroke as fixed by paws 18 provided on the piston rod 19. The piston rod 19 is seen to extend within a cycle controller generally designated 20 and which is equipped with power input terminals as at 21 and power output terminals as at 22 which are coupled by means of an electrical conduit 23 to a conventional solenoid coil 24 which includes a suitable magnetizing housing 25a to provide a low-resistance flux path. Interposed in the cycle controller between the input and output terminals 21 and 22, respectively, is a single pole, single throw snap switch 25 which operates as a series interrupter for solenoid power. The piston rod within the cycle controlled 20 is carried by bushings 19a.

The solenoid coil 24 is arranged in conjunction with the cylinder 26 so as to move the piston 17 to the right when the solenoid coil 24 is electrically actuated; thereby providing the systolic phase of cardiac operation.

The diastolic operation of the piston is achieved through the use of a spring 27 mounted between the coil frame 24 and a magnetizable enlargement 28 on the piston rod 19. It will also be appreciated that the magnetizable enlargement 28 serves as a part of the armature of the suitably encased solenoid coil 24.

The electro-mechanical system just described operates the piston so that the piston 17 always delivers a full stroke, as fixed by the predetermined setting of the paws 18. These may be adjustable, or other limit switch structures may be employed. After the systolic movement of the piston (to the right in the illustration given), the repositioning of the switch 25 stops electrical energization of the solenoid coil 24 so that the piston 17 returns to its unexcited position slowly and in response to the relatively mild spring action of the spring 27. The diastolic action induced by the spring 27 is somewhat counteracted by the restraining suction associated with diastolic ventricu-
lar filling. When diastole is completed, the right-hand pawl 18 initiates the systolic portion of the next cycle. It will be appreciated that there are a number of parameters that affect the design of the system, and typical values of these parameters are set down in the table below.

### TABLE

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Unit</th>
<th>Resting Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Volume</td>
<td>Milliliters</td>
<td>5000</td>
</tr>
<tr>
<td>Circulation Time</td>
<td>Seconds</td>
<td>60</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>Beats/min.</td>
<td>72</td>
</tr>
<tr>
<td>Stroke Volume</td>
<td>Milliliters</td>
<td>40</td>
</tr>
<tr>
<td>Stroke Work</td>
<td>Jcals</td>
<td>1.2</td>
</tr>
<tr>
<td>Heart Power</td>
<td>Watts</td>
<td>1.4</td>
</tr>
</tbody>
</table>

Control of pump pressure during systole is effected by adjusting the magnitude of the current fed to the solenoid coil 24. Control of suction pressure exerted by the pump during diastole is effected by the degree of stiffness selected in the choice of the return-spring 27. Control of the stroke volume is effected by adjusting the position of one or both limit switches, i.e., pawls 18, with respect to the switch 25.

The invention is also advantageous in that it adapts itself to varying heart conditions such as would be the result of exercise, for example. In exercise, there is a decrease in peripheral resistance to blood flow, so that the systolic pressure of the subject falls below normal. Therefore, there will be less back pressure on the face of the piston during the electro-mechanical systole. The resultant excess solenoid force accelerates the piston to give a more rapid systole, i.e., decrease the period of the piston stroke. If the rate of venous return-blood flow to the right side of the heart increases, as it does in exercise, the mild suction pressure ordinarily present during electro-mechanical diastole diminishes. The resultant excess spring-return force accelerates the piston to give a more rapid diastole. Hence, the device automatically responds to the body's natural demands for increased cardiac output, without requiring special sensors of venous oxygen concentration, ventilation rate, or blood pressure.

From the foregoing, it will be seen that the inventive device is surgically feasible whenever the functioning of the natural heart valves is satisfactory or surgically correctible, and when partial support or total replacement of myocardial function is needed. The device requires the least possible weight attached to the heart, and is form-fitting and isolated from the blood stream, thus minimizing risks of irritation, mechanical damage, hemolysis, and thrombosis formation. The device is mechanically simple, with only one moving part (if electronic switching is used) and automatically responds to any natural body need for increased cardiac output without requiring any sensors. The entire device, with appropriately miniaturized components, is capable of being completely enclosed within the body cavity (with piston back flow absorbed cyclization-wise in a passageway), with its entire electrical power supply being magnetic induction through the body wall. The passive bellows, i.e., simple bellows, communicates with the portion of the cylinder opposite the side of the piston from the pressure delivery side, i.e., at vent 15a. The purpose of the bellows is to prevent body fluids, lung segments, or other tissues from being sucked into the back flow vent during electro-mechanical systole and to provide temporary reversible storage of diastolic back flow, and thus it is apparent that when the pump is external to the body, this is not needed.

For mounting of the pump internally in the body, extracorporeal inductive excitation is employed to run the self-regulating electro-mechanical pump that is enclosed within the body cavity, e.g., mounted in the chest on the back of the sternum. In such an instance, external power to the unit is supplied without requiring an electrical conduit through the skin by means of magnetic induction similar in principle to a transformer operation. A secondary winding of a few turns, suitably encased in a viable and non-irritating sheath, and having a diameter equal to the largest diameter of the lungs, can be installed just above the diaphragm and connected through a simple, full-wave, solid-state rectifier to the electro-mechanical pump. The primary winding may be of as many turns as desirable for a good match for transfer of A.C. power, and having a diameter equal to that of the body at the waist, so that it can be worn as a belt attached by a power cord leading to a primary source of A.C. power.

The cycle controller may be provided in electronic form such as is seen in FIG. 2 and which is designated generally by the numeral 120. The cycle controller seen in FIG. 2 provides the function of "limit switches," but does not require any mechanical contact.

In FIG. 2, the numeral 121 designates input terminals for A.C. power, typically 110 volts, 60 cycles, which is supplied through a switch S and which is converted, on demand, to a full-wave rectified power supply to the solenoid 124 by means of conventional power diodes D1, D2 and the silicon-controlled rectifiers K1 and K2. The piston rod extension 119 associated with the solenoid 124 is equipped with an enlargement of magnetizable material such as an iron slug at 118.

The primary windings of the small C-shaped transformers T1 and T2 are supplied continuously with primary A.C. excitation whenever switch S is closed. Secondary windings of transformers T1 and T2 remain essentially unexcited unless the air gap across the C shape is effectively closed by the close, but not touching, proximity of the iron slug 118 which moves with the solenoid armature, i.e., piston rod 119. Transformers T1 and T2 are positioned to correspond with the two intended limits of armature travel.

Before the switch S is closed, the solenoid 124 is unexcited and the iron slug 118 is under transformer T1. When switch S is closed, the secondary winding of the transformer T1 supplies gating signals to rectifiers K1 and K1', and the auxiliary network consisting of a small rectifying diode D1, a Zener-diode DZ1 (serving as a barrier to small spurious signals), and the voltage-divider formed by the resistances R1R1'K1 and K1'K2 are thus maintained in the "fired" condition whenever the iron slug 118 is under transformer T1.

An additional auxiliary circuit is needed to keep rectifiers K1 and K1' fired (and power thereby delivered to the solenoid 124) until the iron slug 118 is fully under transformer T2. This is accomplished by providing, directly in parallel with the solenoid load impedance, a capacitor C0 (in series with a resistor R of no higher resistance than necessary to protect the charging and discharging diodes) which is charged through the half-wave-rectifying diode D1 and the Zener-diode DZ1 (serving as a barrier to small, spurious signals). During the crucial times when the power supply voltage across rectifiers K1 or K1' actually diminishes to zero in the process of rectification, the capacitor C0 maintains sufficient gating signals to rectifiers K1 and K1' by simply discharging through the resistance Rp. Hence the solenoid 124 continues to receive excitation power throughout the travel of its armature until the iron slug 118 arrives under transformer T2.

When the iron slug 118 arrives under transformer T2, the secondary winding of T2 supplies a gating signal to the small, silicon-controlled rectifier K2 through the auxiliary network consisting of a small rectifying diode D2 and
Zener-diode ZD2, and the voltage divider formed by the resistances R2 and R3'. This resultant firing of rectifier K3 immediately discharges capacitance C6 completely, and thereby deprives rectifiers K1 and K1' of their gating signals.

With K1 and K1' unfired, the solenoid loses its excitation and a spring returns the iron slug 118 to its position under transformer T1 with the circuit and equipment now in position for initiating another cycle.

In the case where there is partial, but not total, insufficiency of the heart muscle, the cyclic action of the device may be maintained in synchronism with the natural rhythm of the partially defective heart by applying across the resistance R1 the suitably amplified QRS-portion of an electrocardiogram signal sensed by means of a pair of inert metallic electrodes contiguous with the myocardium.

While, in the foregoing specification, a detailed description of an inventive embodiment has been set down for the purpose of illustration thereof, many variations in the details herein given may be made by those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. A heart massage device, comprising a casing having an open end adapted to receive an inoperative or a partially inoperative part in situ, said casing having spaced apart inner and outer walls defining an expandable chamber and means for cyclically pressurizing said chamber, said means including a cylinder and piston rod unit, a pair of C-shaped transformers positioned adjacent said piston rods, said piston rod having a magnetizable portion normally biased toward one of said transformers, a solenoid operably associated with said piston rod for moving the said transformer in the same way from said one transformer, means for supplying a cyclically varying voltage to said transformers, and electrical output means connected to said transformers and including gate means for sequentially exciting said transformers, said gate means being operative to remove the excitation from the transformer having the said magnetizable portion biased theretoward.

2. In a cycle controller for the operation of a heart massage device, and the like, electromechanical means including a solenoid for developing a reciprocating action, means including a cylinder and piston rod unit and a pair of aligned, spaced apart, C-shaped transformers positioned adjacent to said cylinder and piston rod, said piston rod having a magnetizable portion normally biased toward one of said transformers, a solenoid operably associated with said piston rod for moving the same from said one transformer, means for supplying a cyclically varying voltage to said transformers, and electrical output means connected to said transformers and including gate means for sequentially exciting said transformers, said gate means being operative to remove the excitation from the transformer having the said magnetizable portion biased theretoward.

References Cited by the Examiner

UNITED STATES PATENTS
2,690,174 9/1954 Fuchs 128-44
2,806,432 9/1957 Brooks 103-53 X
2,893,382 7/1959 Demeny 128-38
2,917,751 12/1959 Fry 3-1
3,034,501 5/1962 Hewson 128-64
3,059,249 9/1962 Smith 128-64

OTHER REFERENCES
Surgery, November 1960, pages 903-906.

RICHARD A. GAUDET, Primary Examiner.