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DESIGN AND PERFORMANCE OF A HEART ASSIST OR ARTIFICIAL HEART CONTROL SYSTEM USING INDUSTRIAL PNEUMATIC COMPONENTS

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16. Abstract

The design of a pneumatic driving system for heart assist or total heart replacement pumps is given. The system provides square pressure waveforms to drive the heart assist and uses feedback control to regulate a total heart replacement pump. A pneumatic square wave generator was developed to serve as a flexible tool for studying various cardiac assist techniques. This generator can be synchronized with the natural heart using the R-wave of the electrocardiogram as a trigger. The addition of feedback control to regulate a total heart replacement is discussed and data is given.

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SUMMARY

A pneumatic driving system designed to supply a driving pressure for heart assist pumps is described. The system can also be used to drive a total replacement artificial heart with feedback control used to regulate the artificial heart's output flow. The system is constructed of commercial pneumatic control components driven by an electronic programmer.

For assist applications, the system used a NASA-developed electrocardiogram synchronizing circuit to synchronize a pneumatic square wave to the R-wave portion of the electrocardiogram of the natural heart. The pneumatic square wave can be used to drive several types of assist devices. When the system is used to drive an artificial heart it provides an adjustable frequency square pressure pulse for driving the pumping chamber. The amplitudes of these pulses are controlled to satisfy physiological requirements. The driving pressure applied can be varied from 2.0 to 15 psig (14×10^3 to 100×10^3 N/m^2 gage), while the vacuum used during the filling portion of the heart cycle can be varied from -8.0 to 0.0 psig (-55×10^3 to 0.0 N/m^2 gage). Pulse rates of 60 to 180 beats per minute are obtainable with systolic durations from 100 to 1000 milliseconds.

The driving system will be used to actuate and control soft walled pneumatic blood pumps.

INTRODUCTION

This report describes the design and performance of a pneumatic control system designed to drive a wide variety of cardiac assist pumps and artificial hearts. This system was developed as part of the NASA Technology Utilization Program. Under this program, technology which has been developed primarily for aerospace applications is adapted to the requirements of nonaerospace endeavors. A cooperative program for artificial heart research has developed between NASA-Lewis and the Department of Artificial Organs at the Cleveland Clinic Research Foundation, Cleveland, Ohio. This particular work was done in support of the present heart research program at the Cleveland Clinic.

In the past decade researchers have attempted to develop a small, lightweight pump that could be implanted to temporarily assist the failing heart or permanently replace the pumping function of the natural heart. An early suggestion made by NASA engineers was to utilize compressed air as an energy transmission medium for driving an artificial heart. The pneumatic heart designs subsequently developed by the Cleveland Clinic showed considerable promise as compared to their earlier electric motor or solenoid driven pumps. As a result, the mainstream of artificial heart and heart assist development efforts have used the pneumatic pumps.

To understand the design of these pumps it is useful to first discuss the circulatory system as shown in a simplified form in figure 1. The right ventricle fills from the right atrium at a pressure of 0.0 millimeters of mercury (mm Hg) gage (0.0 N/m^2 gage) and pumps carbon dioxide laden blood into the lungs at a pressure of 15 mm Hg gage (2.0×10^3 N/m^2 gage). The left ventricle is filled from the left atrium at 6.0 mm Hg gage (8.0×10^2 N/m^2 gage) pressure and pumps oxygenated blood into the 100 mm Hg gage (1.3×10^4 N/m^2 gage) pressure of the arterial system. Although the pressures of the right and left

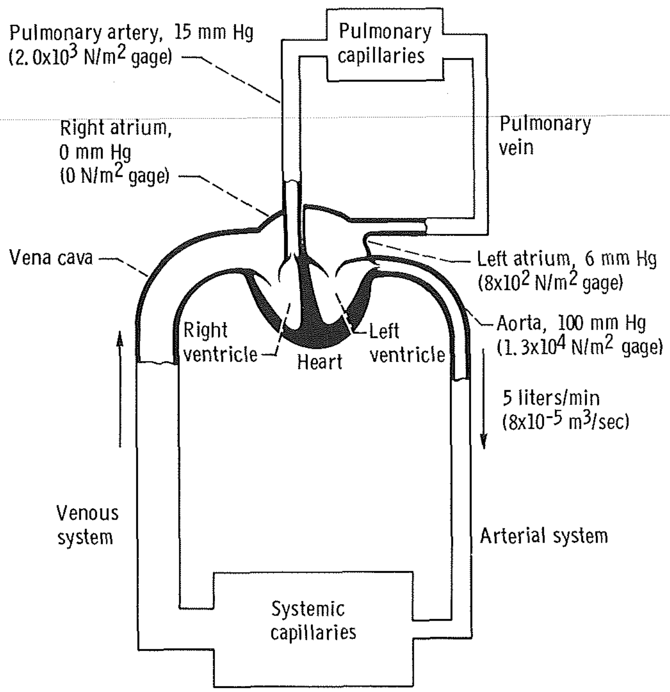

Figure 1. - Diagram of the circulatory system showing average mean pressures in normal resting adult.

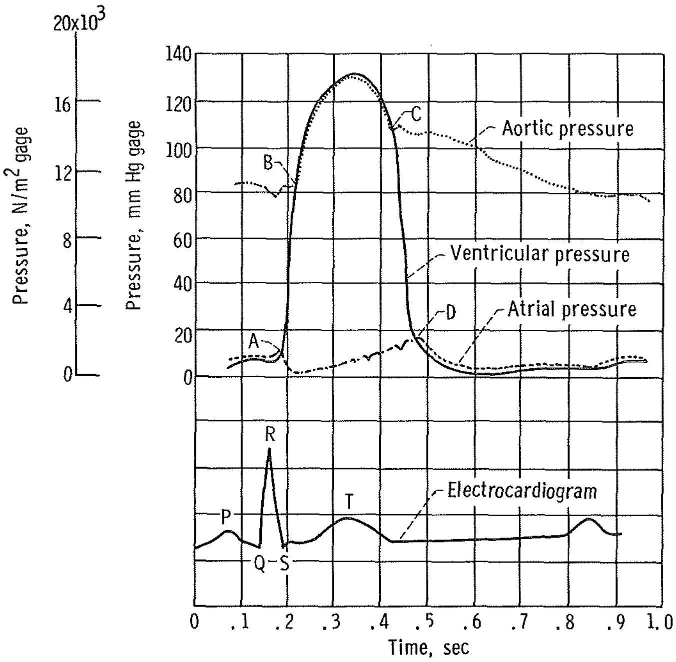

Figure 2. - Pressure-time curves for the left heart.

ventricles differ, the average flow out of the left must be equal to the average flow out of the right to prevent pooling of blood in either the lungs or the body's organs.

To study the heart's performance during one cycle, a plot of instantaneous pressures as a function of time is needed as shown in figure 2 (ref. 1). This figure shows atrial, ventricular, and aortic pressures for one cycle of the left heart. When the ventricle begins the ejection phase (systole), the mitral (inflow) valve closes at A. Pressure in the ventricle rises until the aortic (outflow) valve opens at B. While this valve is open, aortic pressure almost equals ventricular pressure. Then, as the heart begins its relaxation or filling phase (diastole), the aortic valve closes at C. The pressure then drops until it becomes lower than the atrial pressure at D; the mitral valve then opens and the ventricle is filled. Atrial pressure remains essentially constant with a slight increase during systole occurring as the atrium is charged with blood. At the beginning of the heart's pumping cycle, the isometric contraction of the ventricular muscle mass generates a pronounced electrical signal known as the QRS wave complex of the electrocardiogram (EKG). The R-wave portion of the QRS complex can be detected and used as the reference signal for synchronizing an assist pump cycle.

The pneumatic artificial ventricle which is designed to duplicate the operation of the natural ventricle is shown in figure 3 (ref. 2). Such a ventricle is driven by a pressure pulse which should approximate normal ventricular pressure. This type of pump can be used for a cardiac assist device or two of them can be used as a total heart replacement.

When used in an assist application, the artificial ventricle is connected either in par-

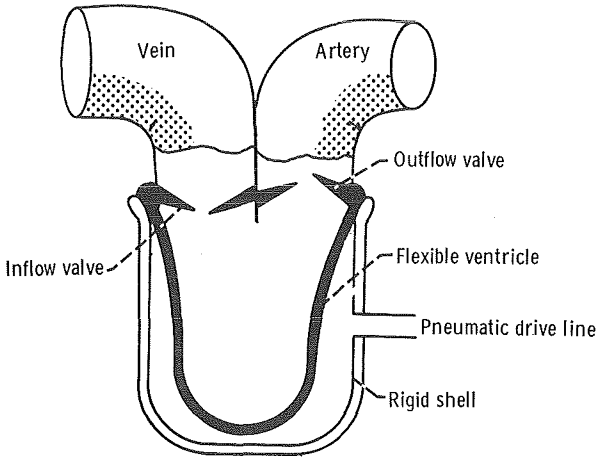

Figure 3. - Sac-type pneumatic artificial ventricle.

allel or in series with the natural left ventricle. Pumping the artificial device during the natural heart diastole prevents aortic pressure from decreasing. This requires synchronization with the natural heart. Such pumping, called counterpulsation, tends to reduce the work load of the natural heart while increasing coronary flow, thus allowing the natural heart to rebuild itself. A more detailed description of counterpulsation is presented in reference 3.

A pneumatic power supply for driving the artificial ventricle must be able to supply a pulsatile pressure to approximate roughly the natural ventricular pressure. It must be synchronized with the natural heart when used for assist pumping and be able to regulate the long term average flow of the left and right ventricles during a total replacement to prevent pooling of blood.

A number of control system designs have been developed at NASA-Lewis that rely primarily on throttling of pressure from a vacuum and a pressure source to drive the artificial ventricle. Some of the earlier control system designs have employed instantaneous servocontrol of the output pressure waveforms. This has resulted in a research tool designed for maximum flexibility. Experience gained in the use of these systems has indicated that the quasi-steady-state regulation of the heart over a number of heartbeats is relatively more important than instantaneous waveform control. Elimination of the instantaneous waveform control feature would produce a significant reduction in the complexity and cost of such a control system.

Consequently, the design presently receiving attention utilizes appropriately synchronized square waves of output pressure with the levels of pressure and vacuum under feedback control to maintain quasi-steady-state regulation. A single channel version can be used for heart assist applications, while a two channel version is required for total heart replacement. Tests demonstrate the control system responds within a few heartbeats to approximate normal cardiac regulatory functions.

CARDIAC ASSIST PUMP DRIVING SYSTEM

The two basic requirements for an assist pump driving system are that it supply a pulsatile pressure with a variable systolic duration and that it can be synchronized with the natural heartbeat. Figure 4 gives the block diagram of the driving system designed for assist usage. The R-wave detector is described in reference 4. This circuit filters noise present in the electrocardiogram and has an output pulse that occurs in phase with the electrocardiogram R-wave.

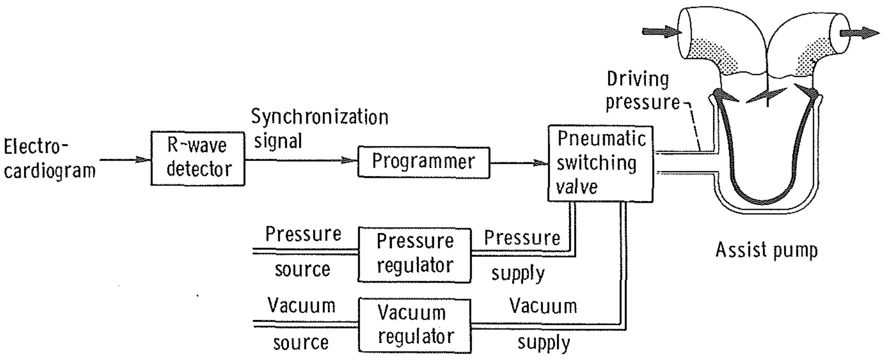

Figure 4. - Cardiac assist driving system.

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This pulse is used to synchronize the programmer to the natural heart. The programmer has a square pulse output of variable width. Its output can be delayed from the synchronization signal to allow variable timing. The programmer drives a pneumatic switching valve that converts the electrical square wave to a pneumatic square wave. This square pressure wave is used to drive the assist pump.

A block diagram of the programmer is shown in figure 5. The programmer is triggered either by the R-wave detector or by an internal pulse generator with an adjustable pulse rate of 60 to 180 beats per minute. When the programmer is operated in an auto-

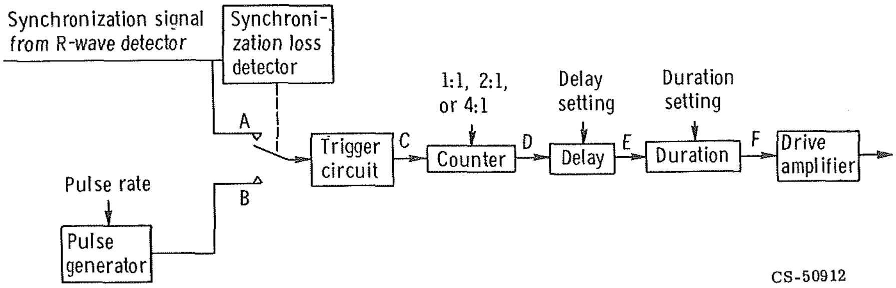

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Figure 5. - Programmer block diagram.

matic mode, it is triggered by the R-wave detector unless the synchronizing signal is lost. At this time the programmer automatically switches to its internal pulse generator to maintain pumping of the assist device. If the synchronizing signal is regained, the programmer can be reset to the R-wave detector manually.

A frequency divider is included in the programmer to enable the assist pump to be activated on every heartbeat, every other, or every fourth heartbeat. It is believed this will reduce the natural heart's dependence on the assist pump during recovery.

The delay circuit in the programmer provides an adjustable delay time (0.01 to 1.0 sec) from the natural heart's R-wave. This permits the use of the assist device in counterpulsation with the natural heart. The duration block provides for a variable pulse duration (0.10 to 1.0 sec). The output of the duration block is amplified by the last stage of the programmer to drive the pneumatic switching valve.

A summary of the programmer's internal waveforms as a function of time is given in figure 6. The basic circuits used are shown in figure 7 and described in reference 5.

The pneumatic switching valve converts the electrical square waves from the programmer to pneumatic square waves. The requirements for the pneumatic square wave,

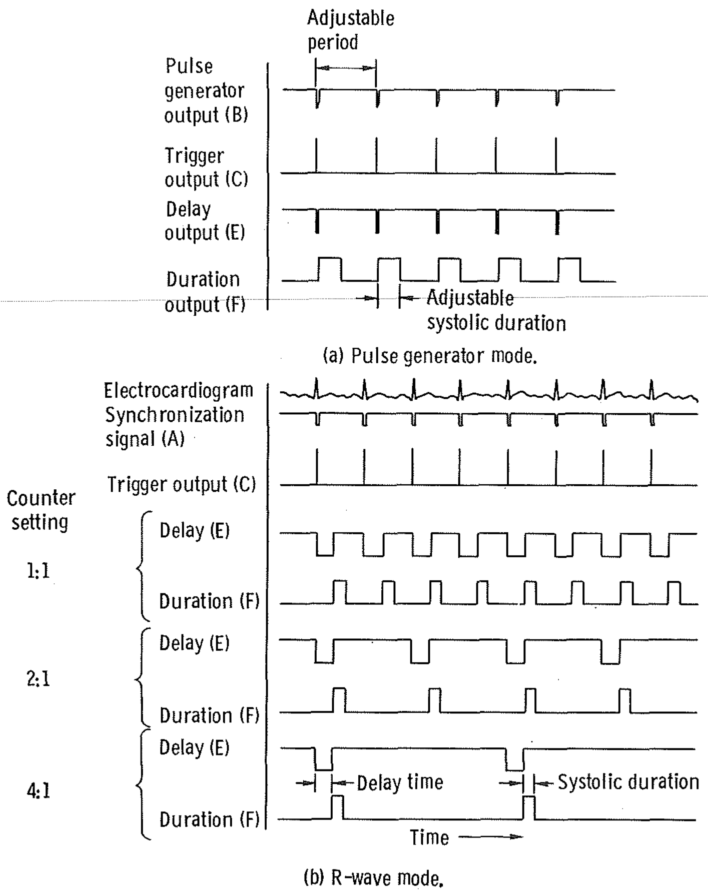


Figure 6. - Programmer internal waveforms.

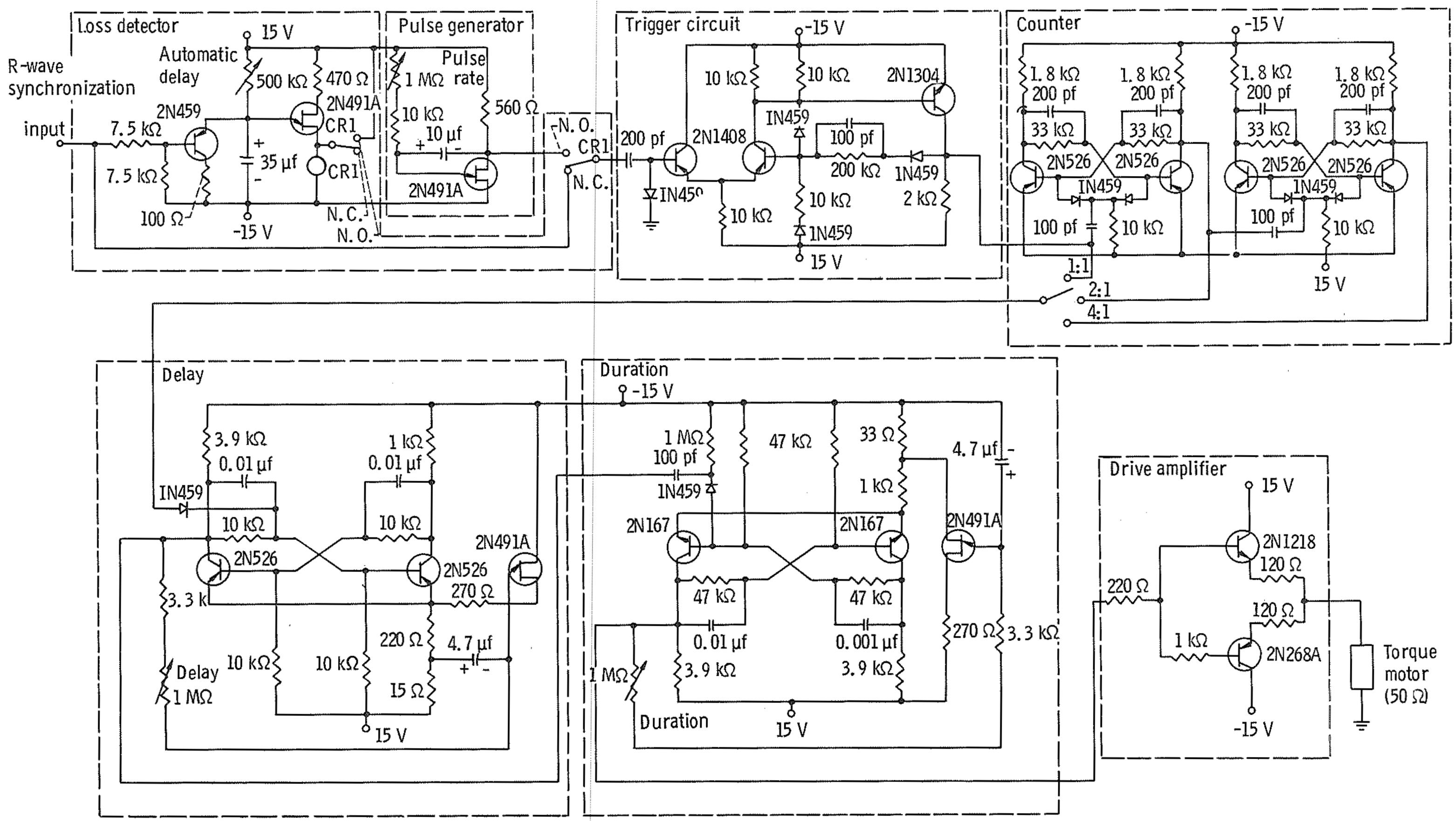


Figure 7. - Programmer schematic diagram.

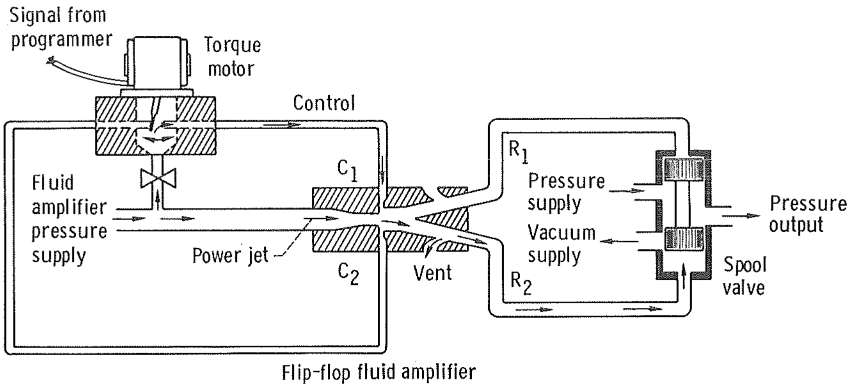


Figure 8. - Pneumatic switching valve diagram.

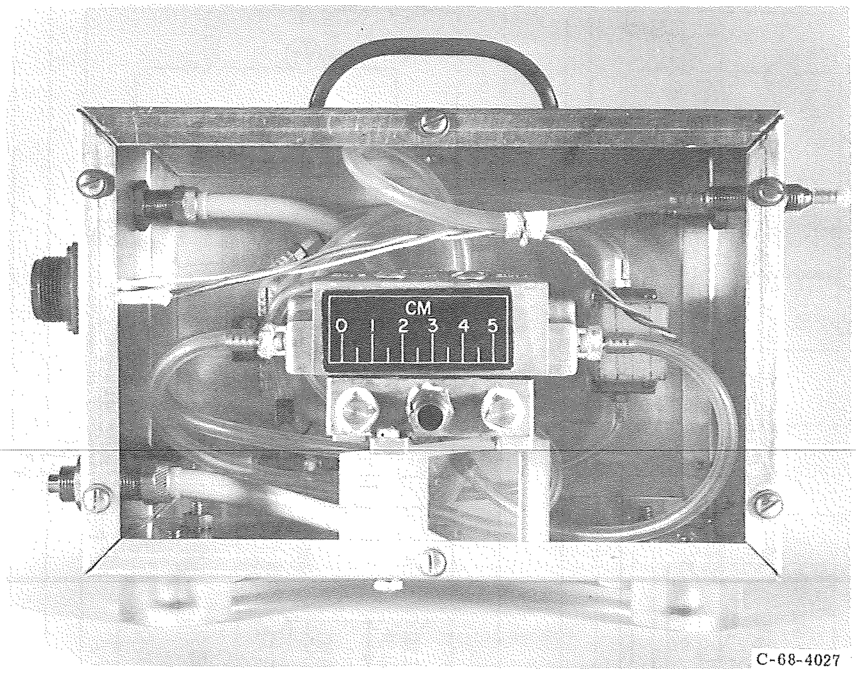


Figure 9. - Pneumatic switching valve.

for most applications, are that the systolic portion of the wave is positive pressure and the diastolic portion is vacuum.

This is done by using a three-way spool valve as shown in figure 8. Power necessary for switching the spool valve is furnished by a flip-flop fluid amplifier driven by a low power torque motor. The fluid amplifier consists of a power jet which can be switched from output receiver R_1 to receiver R_2 by applying pressure to a control port C_1. When pressure is applied to control port C_2 the jet is switched back to output receiver R_1. The control port pressure and flow required to switch the amplifier are much smaller than the output pressure and flow. Thus, the device is a power amplifier. The torque motor flapper can cover either control port line, allowing enough pressure to build up in the other control port line to switch the amplifier. The output jet of the fluid amplifier shuttles the spool valve. This cycles the output of the spool valve between the vacuum and pressure supplies. These supplies are manually set by the experimenter. Their settings vary with the size and design of the assist pump being driven. A photograph of the switching valve is given in figure 9.

TOTAL HEART REPLACEMENT DRIVING SYSTEM

The driving system needed to drive a total replacement artificial heart must supply two pulsatile pressures, one for each side of the heart. Since both ventricles eject at the same time, the programmer can be used to drive two pneumatic switching valves whose pressure supplies and vacuum supplies are regulated to duplicate the natural heart's regulation.

Regulation of the long term average output flow of the two ventricles is necessary to prevent pooling of blood. The natural heart is regulated primarily by its output flow as a function of input pressure characteristics as described in reference 6. A plot of ventricular output flow as a function of atrial pressure for both the left and right ventricles is given in figure 10. To maintain proper regulation, the artificial ventricles of the

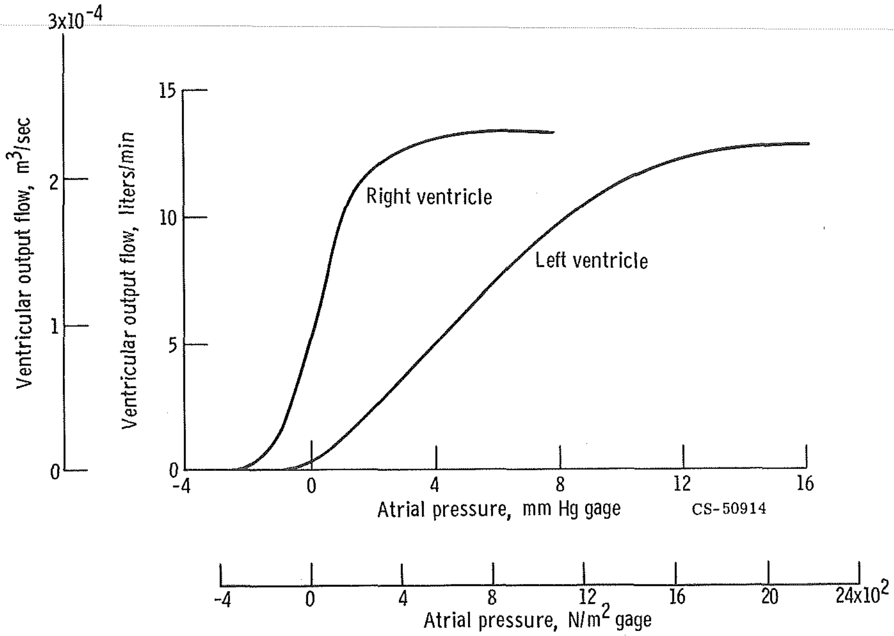


Figure 10. - Normal ventricular output as function of atrial pressure for right and left ventricles.

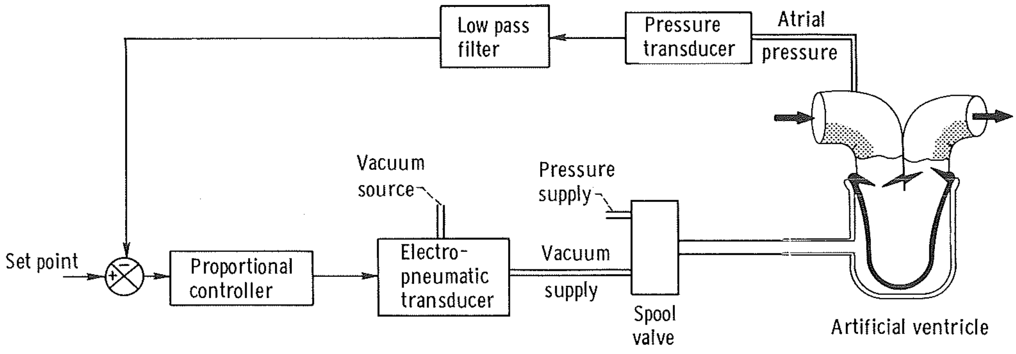


Figure 11. - Block diagram of atrial pressure feedback control circuit.

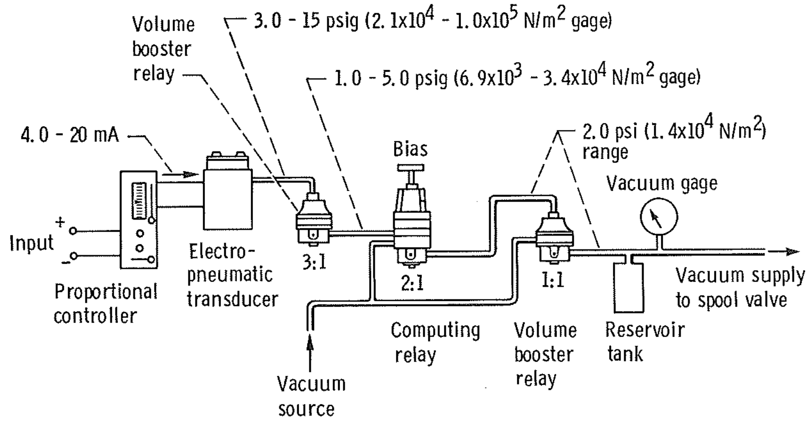


Figure 12. - Atrial pressure feedback control components.

replacement heart should have similar characteristics. However, as reported in reference 7, the output flow as a function of atrial pressure characteristics for several driving systems driving the sac-type artificial ventricle are not similar to those of the natural heart. Reference 7 concludes that the artificial ventricle is insensitive to normal variation in atrial pressure when driven by a constant pressure/vacuum square wave.

To correct for this insensitivity, atrial pressure is fed back by means of a pressure transducer to control the rate of filling during diastole. This is achieved by controlling the vacuum supplied to the pneumatic switching valve as shown in figure 11. The bias adjustment shifts the ventricular output flow as a function of atrial pressure curve of figure 10 along the atrial pressure axis, and the controller gain adjusts the slope. A leveling of the flow curve at high atrial pressures occurs because of the complete filling or maximum stroke volume of the sac. The proportional controller is an industrial process controller with an input requirement of ±10 volts and an output of 4 to 20 milliamperes dc. This signal is converted to a pneumatic control signal by means of an electropneumatic transducer whose output is 3.0 to 15 psig (2.1×10^4 to 1.0×10^5 N/m^2 gage) as shown in figure 12. This signal is divided by 3 by a volume booster relay to give a 1.0 to 5.0 psig (6.9×10^3 to 3.5×10^4 N/m^2 gage) input to a pneumatic computing relay. The computing relay has an adjustable spring bias, is vented to vacuum, and divides the signal by 2 to provide a controlled range of 2.0 psi (1.4×10^4 N/m^2) that can be biased from -8.0 to 0.0 psig (-5.5×10^4 to 0.0 N/m^2 gage). A second volume booster relay is used to provide enough flow capacity. The reservoir tank smooths out the variations in vacuum level caused by the pulsatile flow through the spool valve. The vacuum gage provides a visual readout of diastolic vacuum being applied.

A second control problem is that of preventing total collapse of the artificial ventricle's sac at the end of systole. To prevent this an average ventricular volume measurement is needed. This is obtained by placing a small limit switch on the air chamber wall such that the switch is closed when the sac approaches the ventricle housing. Figure 13 shows how the closure time of the switch indicates any shift in average ventricular volume. This signal is fed into a pulse-width to dc-voltage-level converter and is

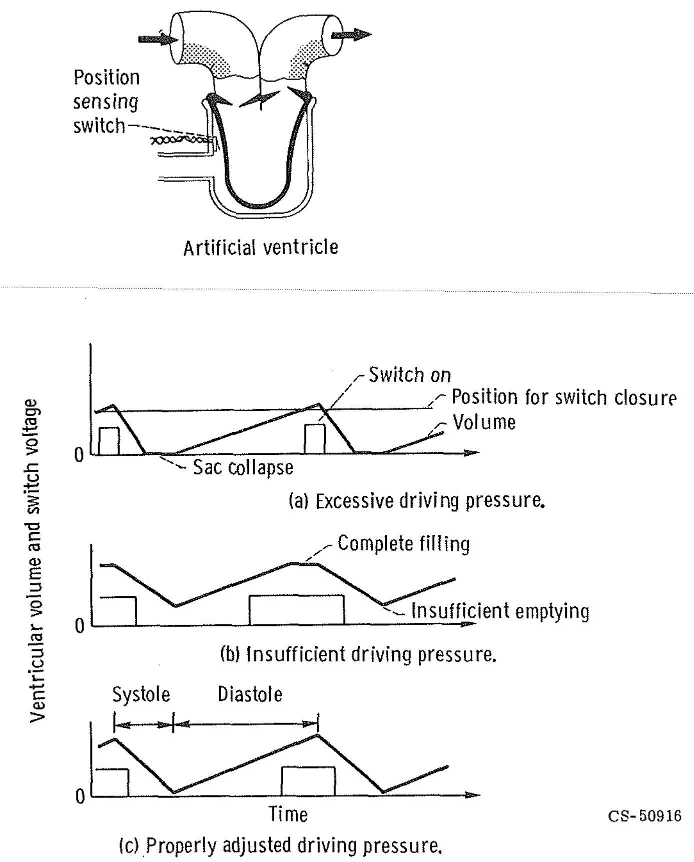


Figure 13. - Ventricular volume detection using switch.

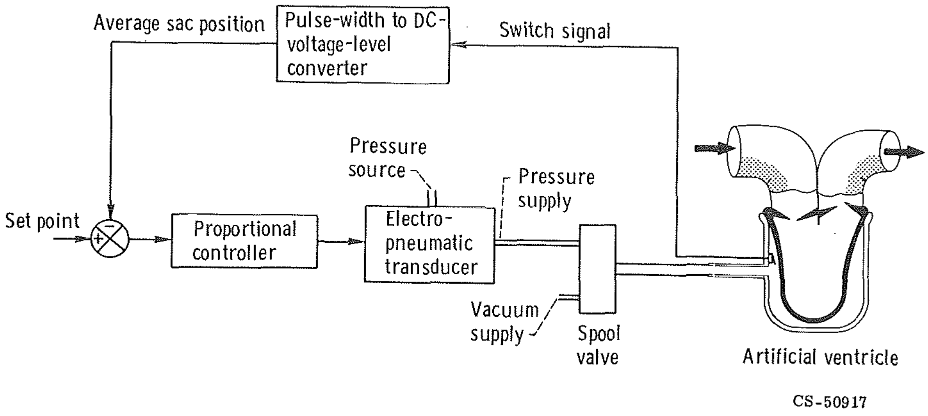
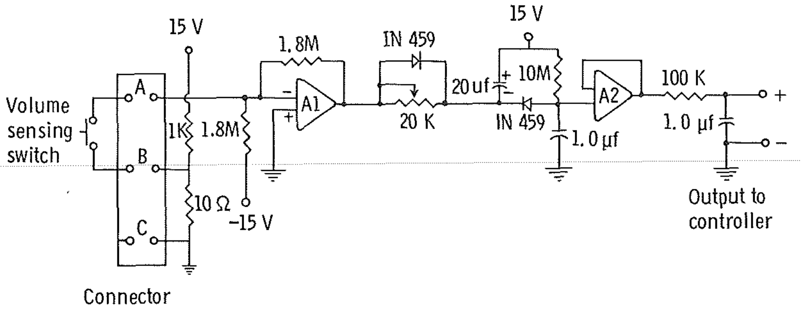


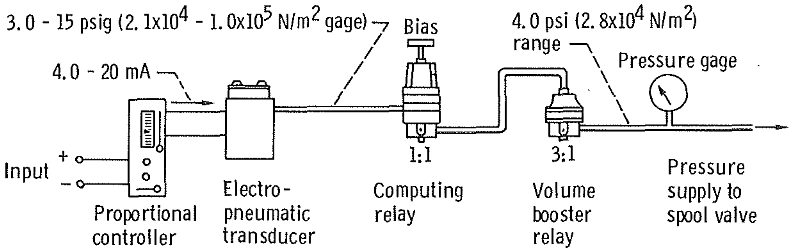
Figure 14. - Block diagram of ventricular position feedback control circuit.

then fed back to control the pressure applied during systole (fig. 14).

The circuit used to convert the switch pulse width to a dc level is shown in figure 15(a). When the switch is open, amplifier A1 is saturated with a positive output. Closure of the switch saturates the amplifier in the opposite direction. The current through the switch is essentially zero while the voltage across it, while it is open, is 0.15 volt. This low level signal prevents the possibility of a short circuit to the patient.



(a) Pulse-width to dc-voltage-level converter.



(b) Pressure control components.

Figure 15. - Ventricular position feedback control components.

The output of amplifier A1 charges a 20 microfarad capacitor with an RC time constant that is variable from 0.0 to 0.4 second. The capacitor charges to a negative level during switch closure and is reset to 15 volts when the switch opens. The reset is accomplished with the diode in parallel with the charging resistance. The 20 microfarad capacitor's voltage is also present on a 1.0 microfarad capacitor in the negative direction, but an isolating diode prevents this capacitor from resetting. This voltage is used as the input to amplifier A2 which is a voltage follower. The 10-megohm resistor from the input of A2 allows the 1.0 microfarad capacitor to reset itself to a positive voltage through a 10-second time constant. This provision allows the signal to return to the positive level within a few heartbeats to indicate no closure of the switch or excessive systolic pressure. The output of amplifier A2 is filtered to give a smoothed dc level which is proportional to the pulse width of the switch and relatively insensitive to the frequency at which these pulses occur.

The output of this circuit is used as an input to another industrial controller that drives an electropneumatic transducer shown in figure 15(b). For this channel the 3.0 to 15 psig (2.1×10^4 to 1.0×10^5 N/m^2 gage) signal is fed directly to a computing relay with bias, but no division. The output of this relay is used as the input signal to a volume booster that divides by 3. This provides an output signal range of 4.0 psi (2.8×10^4 N/m^2) that can be biased from 0.0 to 15 psig (0.0 to 1.0×10^5 N/m^2 gage).

To calibrate this control, a plot of systolic pressures as functions of "switch on" time would have to be plotted as sketched in figure 16 with diastolic vacuum as a parameter. This plot is made by driving the artificial ventricle with a fixed pulse rate, systolic duration, atrial pressure, and aortic pressure. Changes in these variables may change the calibration. As systolic pressure increases, the "switch on" time decreases and a point is reached where the pressure is sufficient to collapse the sac. A locus of points where this collapse occurs for various diastolic vacuums can be plotted as the collapse line. The area to the left of this line indicates conditions where sac collapse

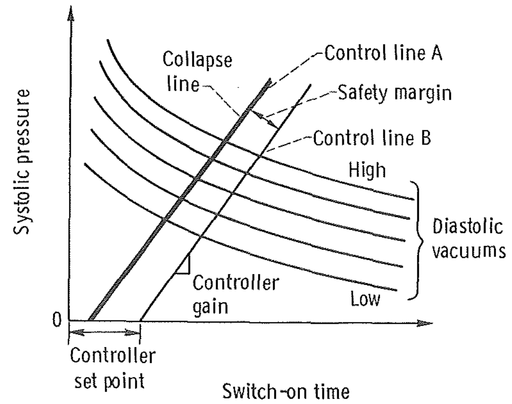


Figure 16. - Ventricular position switch calibration.

will occur. To assure complete stroking of the ventricle without collapsing it, the systolic pressure used must be controlled to maintain operation as close as possible to the collapse line. A proportional control with a gain similar to the slope of the collapse line and with some bias will assure this type of operation as shown by control line A. A margin of safety to allow for variations in those parameters held constant during the calibration should be added. This will shift control line A along the "switch on" time axis to control line B. This margin is adjusted by changing the controller set point. This control assures that the sac empties as completely as possible without collapsing.

An overall block diagram for the total heart replacement driving system is given in figure 17. This shows both atrial pressure and ventricle position feedback channels for one ventricle.

The electronic controllers and all of the pneumatic equipment in the control channels are industrial process controls. Figure 18 shows the controllers mounted on a panel with the programmer in the center. The controllers have proportional, proportional plus integral, or derivate control capabilities which provide a wide range of flexibility for studying various control methods. Figure 19 shows the pneumatic equipment mounted in a drawer with the gages on the panel directly above. The preceding equipment was housed in a sloped front console, as shown in figure 20. The pneumatic switching valve was mounted in a separate component box to be placed near the patient to shorten the length of driving pressure line. This avoids long line dynamics which would be encountered if the pneumatic switching valve were installed in the console.

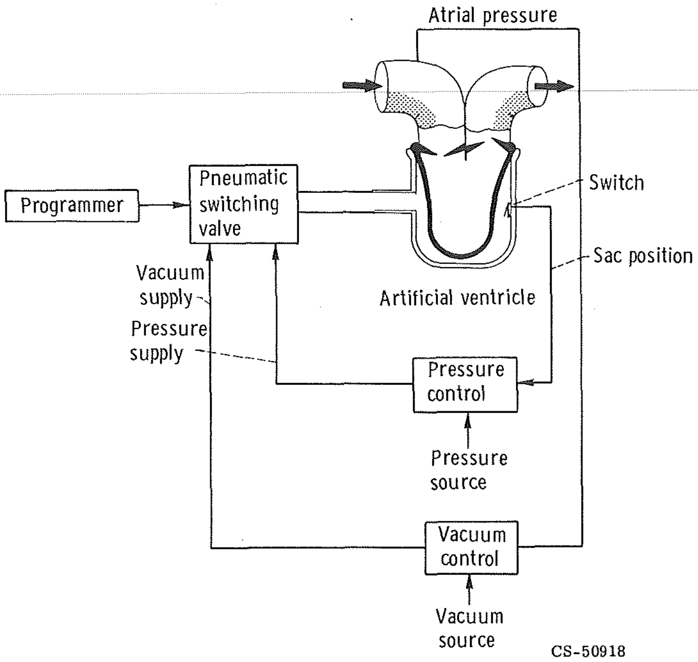


Figure 17. - Block diagram of total heart replacement driving system for one ventricle.

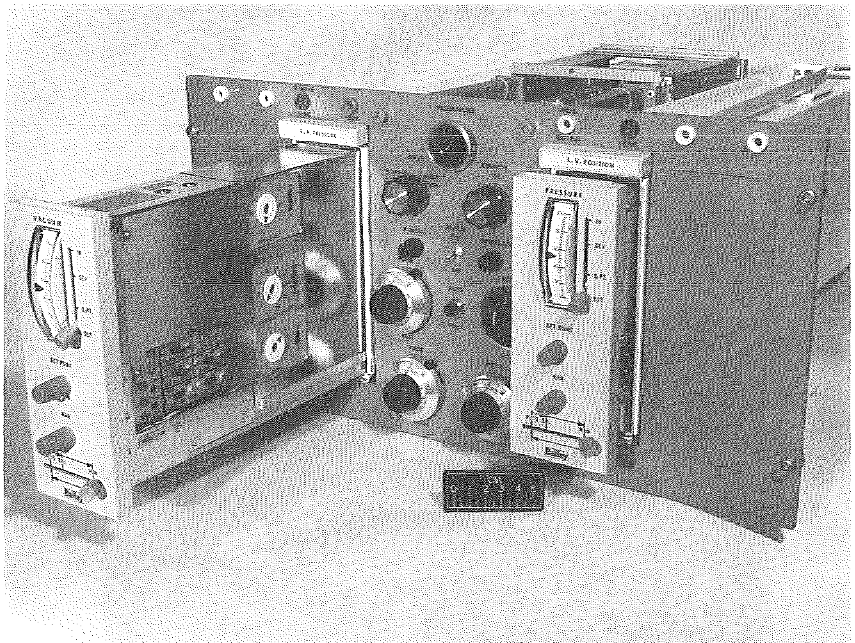


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Figure 18. - Programmer and controller panel.

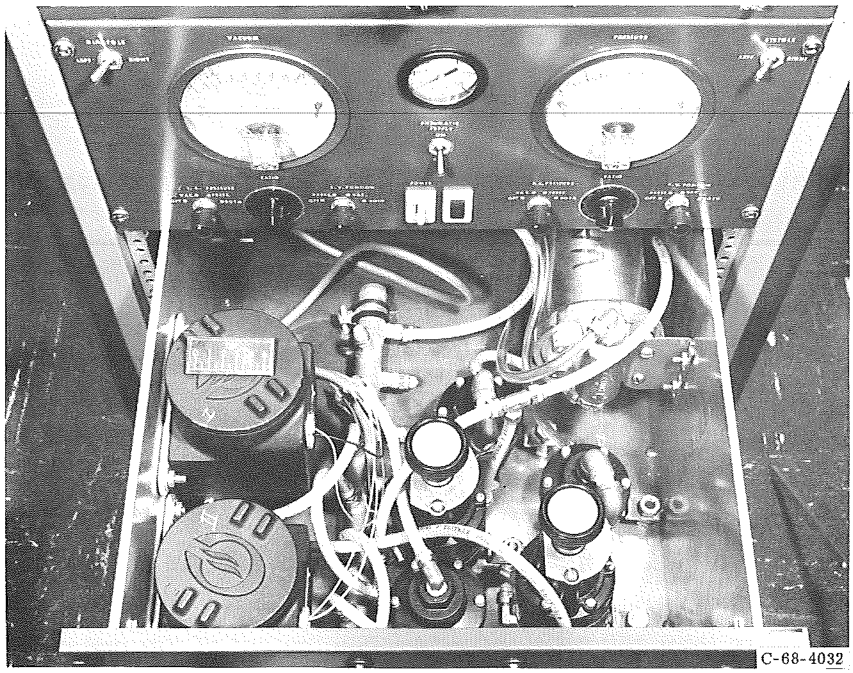

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Figure 19. - Pneumatic controls drawer.

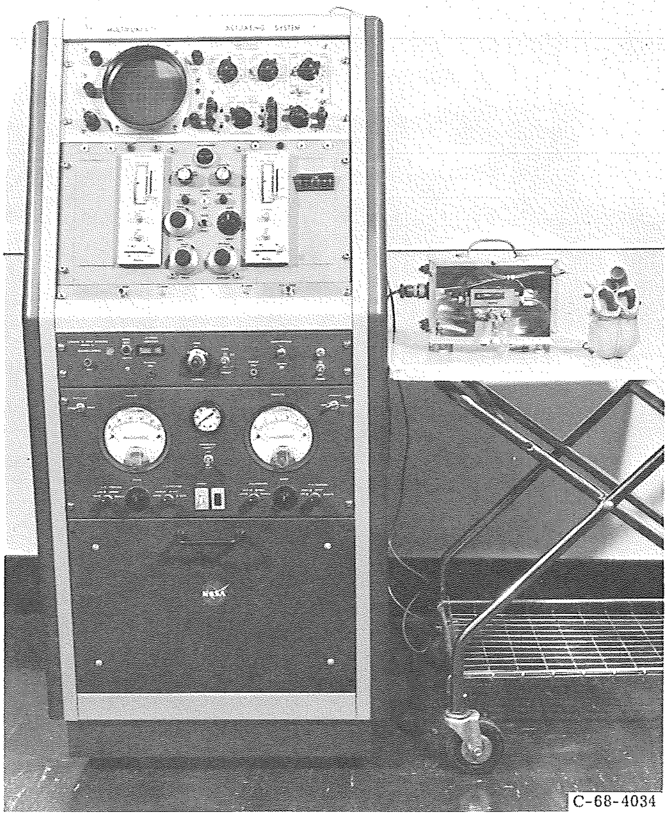

Figure 20. - Control system console with penumatic switching valve and artificial heart.

RESULTS AND DISCUSSION

Data were obtained to check the operation of the assist driving system and the performance of the control channels to be used for total replacement.

Figure 21 shows the pulse outputs of the programmer when operating in the R-wave synchronization mode. The delay circuit has been set to 140 milliseconds, and the systolic duration is set for 230 milliseconds. With the programmer switched to the generator mode, the pulses appear as in figure 22. For this figure the delay is set to zero and the systolic duration is set for 230 milliseconds. As this curve was recorded the pulse rate was manually increased from 77 to 170 beats per minute to show that pulse width does not decrease with increasing pulse rate.

One limitation of the pneumatic digital valve occurs for low pulse durations. Figure 23 shows the programmer and pneumatic switching valve outputs at programmer output pulse widths less than 100 milliseconds. The output of the pneumatic switching valve becomes pressure spikes with random amplitudes until at even smaller programmer pulse widths some pressure pulses are missing. This is caused by the dynamic switching capabilities of the pneumatic switching valve. It limits the useful pulse width to a min-

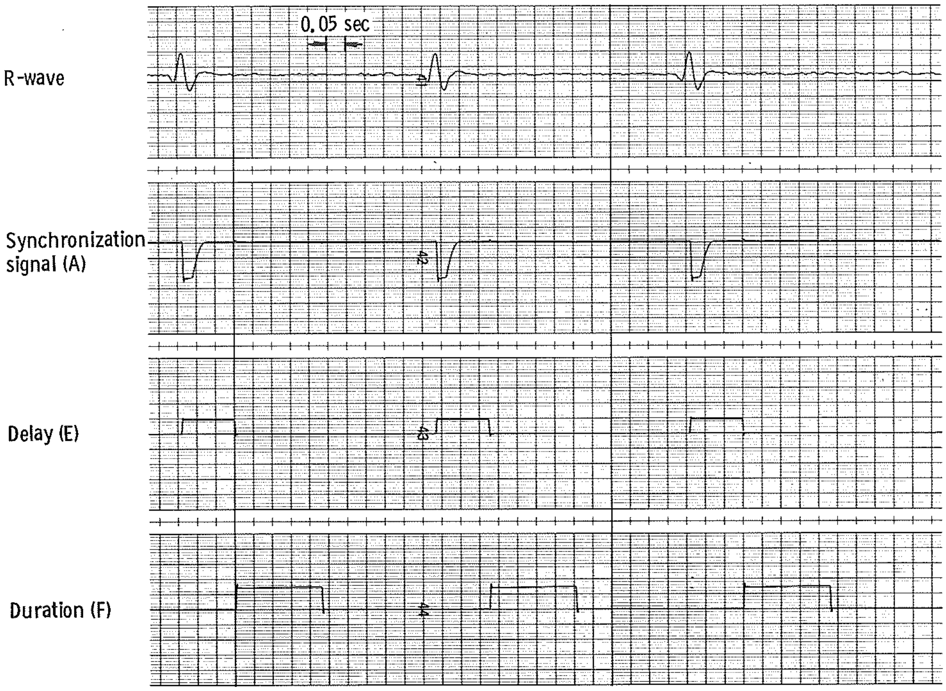

Figure 21. - Programmer internal waveforms with programmer in the R-wave synchronization mode.

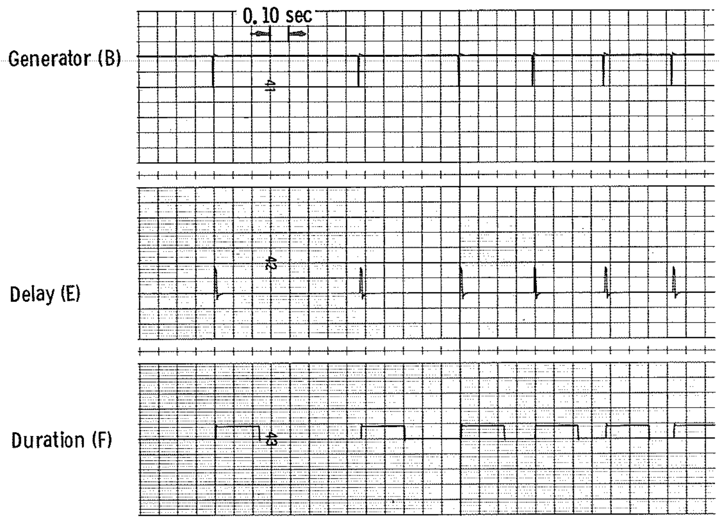

Figure 22. - Programmer internal waveforms with programmer in the generator mode.

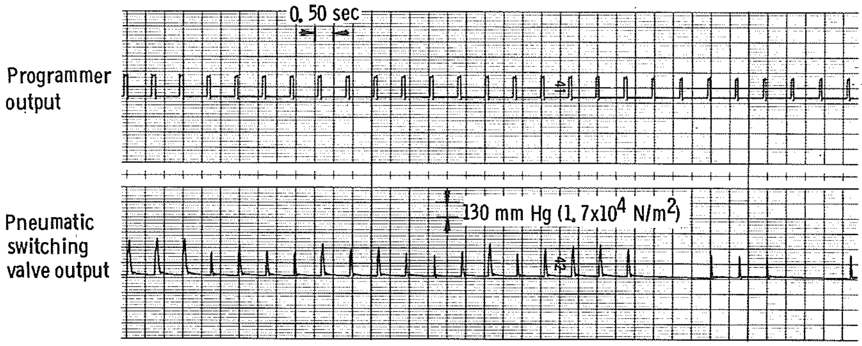

Figure 23. - Minimum systolic duration response.

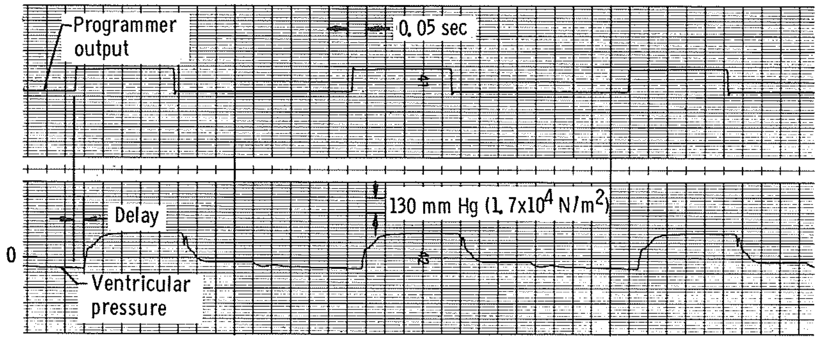

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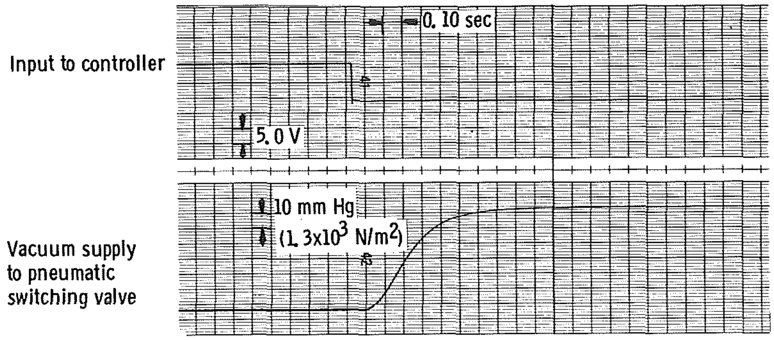
Figure 24. - Pressure waveforms in artificial ventricle with 4.0 feet (1.2 m) of 0.25 inch (6.4×10^{-3} m) inside diameter tubing between ventricle and pneumatic switching valve showing electrical to pneumatic signal delay time.

imum of 100 milliseconds. Since normal systolic durations are approximately 250 milliseconds, this limitation is not a problem.

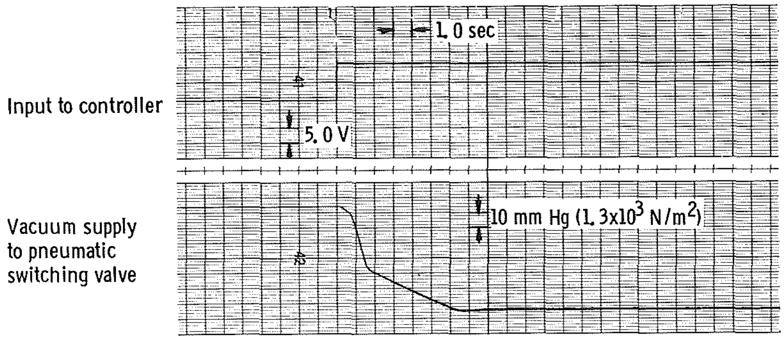
When the system is used for an assist device, the delay of systole from the R-wave of the natural heart becomes an important parameter. Figure 24 shows that the delay between the programmer's output and the pressure waveform in the ventricle is approximately 25 milliseconds using a 0.25 inch (6.4×10^{-3} m) i.d. line 4.0 feet (1.2 m) long. This time should be added to the programmer delay setting to obtain a corrected delay time. Figure 24 also shows that there is some rounding at the leading edge of the pressure curve. This is due to the time required to charge the line volume. This rounding is desirable as it more closely approximates the natural ventricular pressure.

The driving pressure in figure 24 for the artificial ventricle is 210 mm Hg gage (2.8×10^{4} N/m^2 gage) while systolic pressure in the natural heart is only 130 mm Hg gage (1.7×10^{4} N/m^2 gage). The higher pressure is needed for the artificial ventricle to overcome the high flow resistance presented by artificial valves.

The results of step response tests on the vacuum control channel are shown in fig-



(a) Increasing pressure step response.



(b) Decreasing pressure step response.

Figure 25. - Step response for vacuum channel.

ure 25. As can be seen by the difference between figure 25(a) and (b), the vacuum response is overdamped in both cases, but it appears to be linearly limited in the direction of decreasing pressure (increasing vacuum). This extra damping is caused by the bleed-off limitation of the electropneumatic transducers coupled with the evacuation of the volume reservoir in the vacuum control line.

The same damping appears in the step response of the pressure channel, but to a lesser degree as shown in figure 26. This also occurs due to the bleed-off limitation of the electropneumatic transducer. However, no volume reservoir was used on the pressure channel. This explains the faster response of the pressure channel compared to the vacuum response for decreasing pressures. The relatively slow response of the pneumatic controls does not impose serious problems on the cardiac regulation obtained. Since regulation occurs over several heartbeats, such damped controls will tend to filter out short-term transients making the control highly stable.

As a check on the control performance of the system, figure 27 gives a plot of left ventricular output flow as a function of atrial pressure using the sac type heart of figure 3 pumping against a constant water head of 140 mm Hg gage (1.9×10^4 N/m^2 gage). The pulse rate and systolic duration are set to 74 beats per minute and 250 milliseconds,

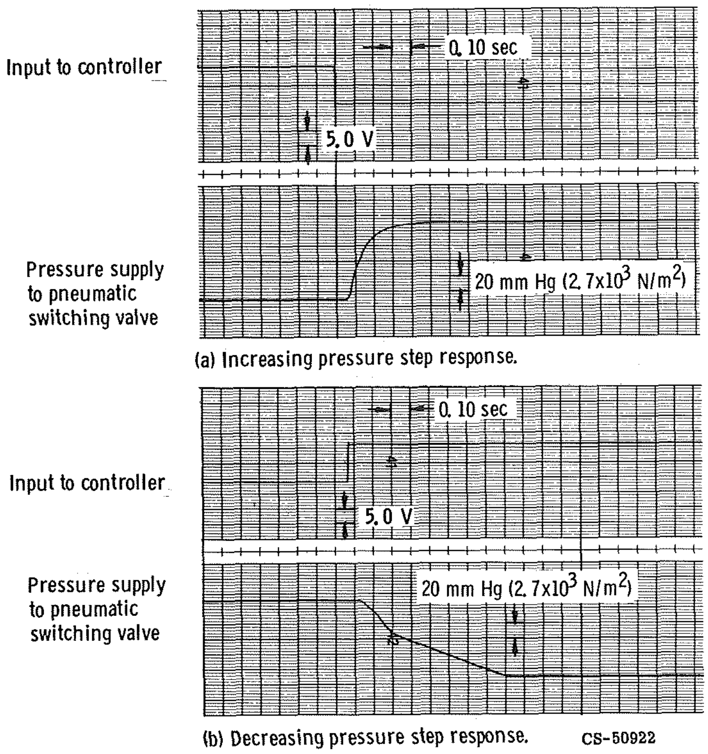


Figure 26. - Step response for pressure channel.

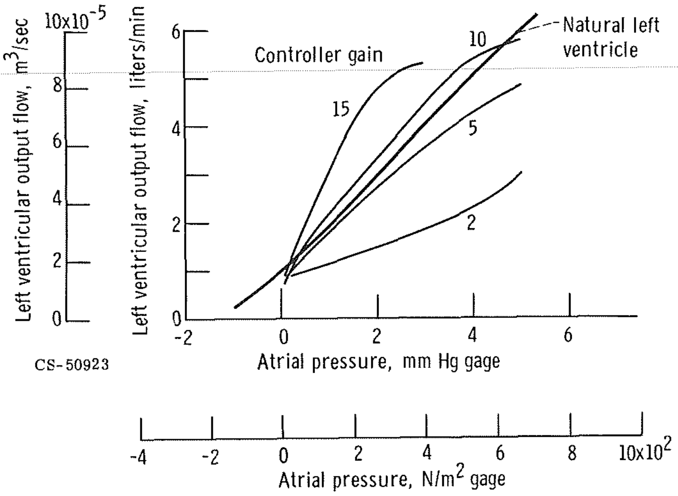


Figure 27. - Left ventricular output flow curves for various atrial pressure feedback gains. Pulse rate, 74 beats per minute; systolic duration, 250 milliseconds; aortic pressure, 140 mm Hg gage (1.9x10^4 N/m^2 gage).

respectively. The maximum stroke volume of the ventricle is 80 cubic centimeters (0.080×10^{-3} m^3). From the figure it can be seen that the artificial ventricle's sensitivity to atrial pressure can be adjusted by the atrial pressure controller gain. The normal left ventricle's sensitivity to atrial pressure is included to show the close approximation which can be obtained with a controller gain between 5 and 10.

CONCLUDING REMARKS

This artificial heart control system was designed to be used in medical research to study blood pump parameters and driving system requirements leading toward improved cardiac assist methods and eventual total heart replacement.

The system was designed for flexibility and to satisfy physiologic requirements such as (1) pulsatile flow, (2) synchronization to the R-wave portion of the electrocardiogram signal for assist or manual control from an oscillator for total replacement, (3) prevention of complete collapse or distention of the ventricle sac, and (4) characteristic regulation of output flow by atrial pressure feedback. The control systems would be stable, responding to changing demands within a few heartbeats.

Lewis Research Center,
National Aeronautics and Space Administration,
Cleveland, Ohio, July 28, 1969,
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