Advanced Energy Systems Division

ARTIFICIAL HEART DEVELOPMENT PROGRAM

MASTER

QUARTERLY PROGRESS REPORT

April 1, 1977

Through

June 30, 1977

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Westinghouse

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ARTIFICIAL HEART
DEVELOPMENT PROGRAM

PHASE III
QUARTERLY PROGRESS REPORT

APRIL 1, 1977 THROUGH JUNE 30, 1977

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INTRODUCTION AND SUMMARY

The Artificial Heart Development Program is being conducted by the Westinghouse Advanced Energy Systems Division as Phase III of the U. S. ERDA's Artificial Heart Program under Contract No. EY-76-C-02-3043. This report presents the technical progress and accomplishments on the active program tasks for the period from April 1, 1977 through June 30, 1977.

Under Task 65, Blood Pump Engineering Support, the significant accomplishments are the development of a layout for an attached motor drive blood pump with a revised compliance chamber to accommodate a reduced right ventricle stroke, continuation of the life testing of blood pump bearings, successful performance of a compliance chamber diaphragm functional test, tentative design and evaluation of a unique high efficiency potential, electric motor for blood pump application, and the conceptual design and breadboard testing of an electronic means of right to left ventricle flow balancing.

Significant accomplishments under Task 66, IVBM System Engineering Support, are performance testing of a silastic covered electrically heated IVBM thermal converter, system performance testing of an electrically heated IVBM thermal converter - ΔV IVBM blood pump combination, updating of procedures for calf experiments with this combination, and the conduct of a successful fit trial at the University of Utah. In a subsequent acute implantation experiment the thermal converter failed to start.

Task 67, Thermal Converter Support, was not active in this period.

Under Task 68, Blood Pump Fabrication and Repair, blood pump No. 8 was cleaned and re-assembled utilizing several new parts, blood pump No. 9 was rebuilt with a reduced right ventricle stroke volume and an oil compliance chamber, a new mock circulation loop was manufactured and prepared for blood pump testing, and fabrication of a spare crankshaft was completed.

Significant activity under Task 69, IVBM System Repair and Support, included shipment of all IVBM system equipment and auxiliaries to the University of Utah and molded silastic potting of thermal converters Numbers 1 and 2.

Life testing of static vacuum insulation packages and of blood pump No. 6 continued without incident under Task 70, Life Testing.

Activity under Task 71, Quality Assurance, continued consistent with program needs.

TASK 65 - BLOOD PUMP ENGINEERING SUPPORT

MODIFIED IVBM BLOOD PUMP WITH ATTACHED MOTOR DRIVE AND COMPLIANCE CHAMBER

A layout drawing was prepared to delineate the design modifications required to incorporate the electric motor drive, described in the January-March 1977 Quarterly Report*, and an oil compliance chamber in an IVBM blood pump with a reduced right ventricle stroke volume. An artist's conception of the modified pump assembly is shown in Figure 65-1. The IVBM speed reducer was removed, and new flat plate closures were used on the pump housing coolant ports to provide mounting surfaces for securing the electric motor drive on the pump housing speed reducer mounting face. Because a compliance chamber arrangement similar to the one used in the thermal converter driven blood pump would yield an unacceptable blood pump width, the chamber envelope was distributed over most of the pump housing outer surface not covered by the electric motor drive.

A chamber with a volume of 13 cc was obtained by building up a 0.25 inch wide and 0.120 inch thick epoxy mounting pad on the pump housing and securing a silastic diaphragm between the mounting pad and a perforated aluminum guard. With this arrangement, the space between the pump housing surface and diaphragm is filled with oil expelled from the pump mechanism cavity when the right ventricle is in the systolic phase of the pumping cycle. When the left ventricle is in the systolic phase, the diaphragm collapses on the pump housing and forces the oil in the compliance chamber back into the pump mechanism cavity.

FLEXIBLE SHAFTS

Flexible shaft life testing was discontinued at the end of March so that the test equipment could be recalibrated. This testing was not resumed because instructions to discontinue contract supported life testing were received from ERDA before the recalibration work was completed.

*Westinghouse Advanced Energy Systems Division, "Artificial Heart Development Program, Quarterly Progress Report COO-3043-28, January-March 1977" ERDA Contract EY-76-C-02-3043.

Figure 65-1. Modified IVBM Blood Pump with Electric Motor Drive and Compliance Chamber

BLOOD PUMP BEARINGS AND LUBRICANTS

Life testing of standard and special blood pump bearings operating in jojoba and Vitrea 21 oils was continued at the Westinghouse Research Laboratories at no cost to ERDA. The bearing test hours accumulated during this reporting period and the total test hours to date are as follows:

Bearing MPB No.	Bearing Type	Oil	Test Hours April thru June	Total Test Hours To Date
SR4	Ball - Single Row	Vitrea 21	744	18,624 ⁽¹⁾
F155	Ball - Double Row	Vitrea 21	2208	7,872
F155	Ball - Double Row	Jojoba	2208	14,736 ⁽²⁾
F160	Ball - Double Row	Jojoba	2208	13,704 ⁽³⁾
F338	Roller	Jojoba	2208	9,456

(1) Testing terminated.

(2) Oil changed from sperm to jojoba after 6,048 test hours.

(3) Oil changed from sperm to jojoba after 5,000 test hours.

The SR4 bearing test was terminated because considerable darkening of the oil, indicating a buildup of wear debris, was observed in a period of 2 days. An examination of the bearing is being performed to determine the wear and rolling surface condition of the bearing elements. No change in frictional torque or evidence of significant wear of any of the other bearings was observed during this testing.

COMPLIANCE CHAMBER DIAPHRAGM FUNCTIONAL TEST

Blood pump No. 9 was oil filled after assembly with a reduced right ventricle stroke volume mechanism and a compliance chamber. A 600 hour test was performed to determine whether the compliance chamber functioned satisfactorily. Since the compliance chamber diaphragm appeared to move between the full-out and full-in positions throughout the test, it is believed that the chamber allowed the oil movement in and out of the pump mechanism cavity required

to obtain the desired reduced right ventricle stroke volume. However, mock circulation loop testing will be required to ascertain that the reduced right ventricle stroke volume required to achieve balanced systemic and pulmonary flows is obtained with the compliance chamber.

FIELD SUPPORT

Blood Pump Implant Experiment No. 47 was performed. The experiment was terminated fifteen days after the blood pump was implanted because the flexible shaft failed. The animal's condition was not good after the surgery, and he was not able to stand on his own at any time throughout the experiment. This difficulty was attributed to brain damage suffered during the surgical procedure. An investigation is in progress to determine the cause of the early shaft failure.*

The Wertronix motor controller rebuilt by the vendor was shipped to Utah after it was checked out in the laboratory and appeared to function satisfactorily. However, the remaining three controllers functioned erratically after they were rebuilt. One of these was further modified by Westinghouse to avoid a speed drift due to heating and was then found to operate satisfactorily under all operating conditions. The other two controllers and the one that was shipped to Utah will be modified in a similar manner.

The Wertronix motor controller modified by Westinghouse and two flexible shafts of the same lot as those that have performed well were shipped to Utah.

MOTOR IMPROVEMENT POTENTIAL

To provide a very high degree of operational certainty, the integral electrical motors now being fabricated for this program use a conservative design. There is substantial room for electrical efficiency improvement. In this connection, the Westinghouse Research Laboratories has been carrying out development work on Steel Conductor Radial Armature Machines (SCRAM) for small motor use. This technology has been introduced into motors as small as four horsepower (3000 watts output power).

* This is the first implanted shaft failure since a major shaft design change was incorporated following Implant Experiment No. 13.

A tentative electrical design of a motor for blood pump application was prepared based on SCRAM technology. A configuration outline of such a motor is shown in Figure 65-2. It is a 10 pole DC brushless motor with transistor commutation. The illustration is conceptually similar to a "breadboard" configuration that might be constructed to test the electrical design calculations.

In executing this tentative design, a brief parametric tradeoff study was carried out using assumed reduction gear and other mechanical loss characteristics that will be present in application to a blood pump actuator mechanism. The study was to provide sizing and motor design speed selection information. Based on this study the optimum motor speed for this configuration is one-half (1125 rpm) current motor speed. In part, this is because the design has two rotors causing viscous losses whereas the present motors have only one. The free wheeling rotor is required to complete the magnetic circuit. Counterbalancing this is the fact that the lower motor speed will require only one stage of speed reduction whereas the present motors require two stages.

Efficiency estimates for the concept are given in Figure 65-3 at a constant blood pump beat rate of 125 per minute. The upper curve is the efficiency of the motor alone. The middle curve is the efficiency of motor plus speed reducer and actuator mechanism. The lowest curve is for the total system including the motor controller. It should be noted that the actuator module efficiency varies from 50 percent at 3 watt ($1/2$ power) output to 47 percent at 6 watt (full power output). These values may be compared to the values given in Figure 65-4 for the present integral motor actuator modules.

There are two caveats about this tentative design: First, an integrated torque motor for application to the blood pump actuator mechanism requires that a speed reducer be incorporated into the design with little increase in envelope. Since only one stage of speed reduction is needed, this probably can be accomplished by using the hub space inside the armature windings or by incorporating it into the output rotor with little perturbation of electrical parameters. Second,

Figure 65-2. SCRAM Motor Design

Figure 65-3. SCRAM Efficiencies

Figure 65-4. Conventional Integral Motor Actuator Efficiency

magnetic flux leakage loss calculations are not exact. The smaller the apparatus the more inexact these calculations become. Accuracy is obtained by constructing a test configuration.

It is proposed to address these caveats in the FY '78 program. First, a preliminary integrated design of torque motor will be prepared and analyzed. Then, based on this preliminary design, a breadboard electric motor will be fabricated and tested. These steps will provide the information needed for a solid evaluation of SCRAM technology as applied to blood pump drive and control.

ELECTRONIC FLOW BALANCE DEVELOPMENT

As an alternative to the differential stroke volume method of balancing flows between the left and right ventricles work was started on scheme for increasing the left ventricle diastole time relative to right ventricle diastole time. Since the approach taken is through electronic variation in motor speed this is termed "electronic ΔV compliance."

The scheme makes use of the natures of the actuator mechanism and the torque motors used to drive them. Work to date has used existing detached electric motor drives for breadboard studies.

In order to save space, the actuator mechanism is designed to pump the ventricles alternatively. Therefore, a decrease in the left-side systolic time period is a decrease in the right-side diastolic time period, and vice-versa. If the beat rate (average complete cycle time) is held constant, an increase or decrease in one part of the cycle requires a corresponding change in the opposite part of the cycle. This change is created by starting and stopping the torque motor, and can be done with a lag of a very few milliseconds and little loss of efficiency because the torque motors used have almost no stored rotative energy relative to their average power output. This effect is illustrated in Figure 65-5, using oscillograph traces of left ventricle pressure versus time. The upper trace was obtained when the drive motor was operated continuously. The lower trace was produced by stopping the motor for approximately 100 milliseconds at the end of diastole as represented by crank rotational position.

Continuous Motor Rotation
(Current Operating Mode)

~100 msec Motor Pause During Diastole

Figure 65-5. Systole/Diastole Time Ratio Adjustment

The lengthening of diastole relative to systole compared to continuous operation is quite apparent. For the test results presented, only a left ventricle was being used. It does not, therefore, demonstrate that the procedure, as used, would have caused better right to left flow balance by lengthening inflow time on the left side compared to the right. It does illustrate the idea involved in an encouraging manner.

The electronic circuit approach being investigated is illustrated by the block diagram in Figure 65-6. An experimental circuit of this kind was built to provide a means of stopping and starting the electric motor used to drive the artificial heart. As shown, the circuit consists of a Hall-Effect Generator (Hall-Device), DC amplifier, pulse width module, relay driver and relay.

In order to stop the artificial heart at the right time, a small magnet is placed on the end of the crankshaft. A small Hall-Device is placed on the stationary bearing housing cover in such position that the magnet passes over the Hall-Device just before the left ventricle reaches the end of its diastolic pump stroke. When the magnet passes over the Hall-Device, it produces a pulse output. This pulse is amplified by the DC amplifier and then goes to the pulse width module. The leading edge of the pulse starts the pulse width circuit. When the pulse width circuit is activated, it provides a "time out" signal independent of a further behavior of the input signal.

When activated, the pulse width module sends a signal to the relay drive. This in turn activates a relay that stops the artificial heart drive motor. The motor stays stopped until the "time out" period set by the pulse width module is completed. The motor then starts and continues rotation until the next interruption. The width of this "time out" period is manually adjustable. The intent here is to provide a control for the animal experimenter that he can adjust to achieve better right ventricle-left ventricle flow balance by observation of the animal's blood pressure.

Figure 65-6. Electronic ΔV Compliance Block Diagram

TASK 66 - IVBM SYSTEM ENGINEERING SUPPORT

IVBM ELECTRICALLY HEATED THERMAL CONVERTER PERFORMANCE TESTING

The electrically heated IVBM thermal converter No. 2 was potted with a RTV silastic type coating to prepare the converter for scheduled implantation experiments at Utah. After potting in RTV, additional performance testing of the converter was conducted on the dynamometer and the results were comparable with earlier tests before the converter had been potted.* Figure 66-1 shows output power for various gearbox shaft speeds and indicates a wide scatter in the data. This scatter due primarily to differences in hot finger temperatures, slight difference in ambient room temperatures and cooling water temperatures, and instrumentation uncertainties. Figure 66-2 shows a more representative comparison of the data when output power is plotted against upper hot finger temperature. As can be seen, the potted and unpotted converter data indicated no significant differences.

IVBM SYSTEM TESTING

System performance evaluations were made with the IVBM electrically heated thermal converter mated with a ΔV IVBM blood pump. The testing was performed with the converter/pump connected to the mock circulation loop (MCL) for series operation as shown in Figure 66-3. Pressure transducers, gages and flowmeters were used during the test to obtain systemic arterial pressure (SAP), systemic venous pressure (SVP), pulmonary arterial pressure (PAP), pulmonary venous pressure (PVP) and cardiac output.

* Westinghouse Advanced Energy Systems Division "Artificial Heart Development Program, Quarterly Progress Report COO-3043-28, January 1, through March 31, 1977" ERDA Contract EY-76-C-02-3043

Figure 66-1. Crankshaft Speed Versus Thermal Converter Power Output with Speed Control Locked-In

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Figure 66-3. Schematic of Mock Circulation Loop/Pump Arrangement
(Dots Indicate Pressure Transducer and Gage Locations)

Blood pump No. 4 was used in the system test. This pump is a ΔV IVBM blood pump, has a compliance chamber assembly, * and was filled with jojoba oil. The check valves used in the pump were Bjork-Shiley design and were physically situated in the 12 o'clock position (Utah's No. 2 position) as shown in Figure 66-4.

Figure 66-5 shows the system mock loop (SAP, PAP and PVP) and cardiac output data plotted against systemic venous pressures (SVP). Here the SAP is held constant at ~ 100 mm-Hg. As can be seen, the IVBM system data compare quite well with previous performance data collected on blood pump No. 4, reported previously.* Also, as shown in Figure 66-6, pulmonary and systemic flow relationships are consistent with previous data collected on numerous pump performance runs for both regular and ΔV pump designs. In effect, blood pump No. 4 performs in the same manner regardless of the power source, electric motor or thermal converter. Also, the pump compliance diaphragm operated properly throughout the system test as it did in previous pump testing.

Figure 66-7 shows the relationship between pump speed and/or mean aortic pressure and cardiac output. Here, pump speed varies from ~ 80 BPM up to ~ 128 BPM for a range of systemic arterial pressures of ~ 142 mm-Hg to ~ 82 mm-Hg. The cardiac output during the system test reached 7 liters/min. As shown in Figure 66-5, this output agrees reasonably well with previous performance results on blood pump No. 4.

Small loads or demands on the blood pump (ie. low aortic pressures) would cause the pump speed to increase. SAP of 82 mm-Hg results in a pump speed of 128 BPM. Under these conditions, the converter speed also increases resulting in hot finger temperature decreasing for a fixed input power. Figure 66-8 shows the relationship between converter speed and/or pump speed and the input power needed to maintain hot finger temperatures $\geq 1420^{\circ}\text{F}$. As shown in Figure 66-2, this temperature would ensure sufficient output power to the pump.

* Westinghouse Advanced Energy Systems Division "Nuclear Powered Artificial Heart Prototype System Development Program, Quarterly Progress Report COO-3043-27 October-December 1976" ERDA EY-76-C-02-3043.

Figure 66-4. Bjork Shiley Valve Orientation Definitions

Figure 66-5. Mock Loop Comparison Between Individual Pump No. 4 Data and System Data for Constant (SAP 100 mm-Hg)

Figure 66-6. Pulmonary Flowmeter Reading Versus Systemic Flowmeter Reading

Figure 66-7. Cardiac Output Versus Pump Speed and/or Mean Aortic Pressure for the Electrical Heated Thermal Converter/Blood Pump No. 4 on the Mock Circulation Loop

Figure 66-8. Input Power Versus Gearbox Output Speed and/or Pump Speed Necessary to Maintain Hot Finger Temperatures $\geq 1420^{\circ}\text{F}$

Temperatures much lower than 1400°F may result in the converter stalling for high torque demands.

IVBM IMPLANTATION PLANS AND PROCEDURES

All procedures for the calf experiments were revised to incorporate the electrically heated IVBM thermal converter/pump system. These modified procedures were discussed and reviewed in detail with the University of Utah. Based upon the procedure review, equipment list check-out with the University of Utah and the data accumulated from the thorough bench testing of the IVBM artificial heart system at Westinghouse, the following animal experiments were proposed:

● Fit trial	Mid May
● Acute Implant	Mid June
● Prolonged Implant	Mid July

The fit trial of the IVBM system was performed at the University of Utah in mid-May as planned. The objective of this fit trial into a calf carcass was two-fold: to checkout existing equipment and procedures, and to simulate actual implanting and fitting of the complete system into the animal.

The fit trial was successfully completed and the potted thermal converter fitted snugly into the lower abdomen of the calf. Disconnecting the electrical motor and hook-up of the thermal converter to the flexible shaft was accomplished in approximately two minutes. Some procedure changes were made, however, to improve speed of delivery of the converter from the IVBM sterilization glove box to the operating room. Also, slight modifications were made during equipment checkout to ensure additional redundancy and equipment operability for the actual implant.

An acute implantation experiment in a live calf (ERDA Experiment No. 48) was attempted in mid June according to schedule. The procedure for this experiment involved the following steps:

- 1) Oil filling and implanting ΔV IVBM blood pump No. 4 initially powered by a Wertronix electric motor.
- 2) Sterilization of the thermal converter and related equipment in the glove box using oxyfume gas.
- 3) A 24 to 72 hours degassing and performance testing of the thermal converter in the sterile environment of the glove box.
- 4) Sterilization of the auxiliary cart coolant water and final check-out of auxiliary cart instrumentation.
- 5) Stalling, removal and hook-up of the thermal converter to the auxiliary cart.
- 6) Transporting the thermal converter to the operating room.
- 7) Removing the electric motor from the calf and replacing it with the thermal converter.

The thermal converter failed to start during Step 3 despite numerous attempts. The calf was continued for a day using the electric motor to drive the blood pump after which the calf was terminated as a result of respiratory problems. Subsequently, the thermal converter and starter stand were packaged and shipped from Utah to Philips Laboratory for trouble shooting.

TASK 68 - BLOOD PUMP FABRICATION AND REPAIR

Fabrication of a spare crankshaft was completed and manufacture of two spare yoke housings continued. Blood pump No. 8 was cleaned and reassembled with new pump housing tracks and yoke housing rollers. Blood pump No. 9 was rebuilt with a reduced right ventricle stroke volume and a mechanism oil compliance chamber.

A new mock circulation was manufactured and prepared for blood pump testing. This mock circulation is similar in basic design to those used previously but is built up from aluminum instead of plastic plates for better integrity. Sight tubes and plastic windows were provided to observe the water levels in each chamber and the position of the gate valves.

TASK 69 - IVBM SYSTEM REPAIR AND SUPPORT

The charging pressure actuator for Thermal Converter No. 1 was rebuilt to fit neatly within the converter contour. The converter was then potted with a molded silastic (RTV) covering.

The electrically heated Thermal Converter No. 2 was also potted in RTV and tested as reported in Task 66.

All IVBM system equipment and auxiliaries were shipped to the University of Utah early in May. Additional small parts were shipped later in that month.

TASK 70 - LIFE TESTING

BLOOD PUMP

Endurance testing of Blood pump No. 6 was continued. No change in pump performance was observed throughout this testing. The total hours of operation accumulated at the end of the reporting period were 5821.

STATIC VACUUM INSULATION TEST PACKAGES

The status of the static vacuum test packages at the end of this reporting period is summarized in Table 70-1. The thermal performance for these systems has not changed.

TABLE 70-1
STATIC VACUUM PACKAGE PROCESSING HISTORIES TO (6/30/77)

Insulation Package	Bakeout Time (days)	Static Vacuum Time Prior to Pinchoff (days)	Pinchoff Date
No. 1 - 60 Cups No Getter	53	36	10/6/76 276 days
No. 2 - 60 Cups Al-Zr Getter	20	43	12/22/76 190 days
No. 3 - 60 Cups No Getter	24	23	2/2/77 148 days
No. 4 - 30 Cups No Getter	29	37	3/4/77 118 days
No. 5 - 45 Cups Al-Zr Getter	20	31	4/26/77 65 days
No. 6 - 60 Cups 27 cups with plasma sprayed ZrO_2 spacers Al-Zr Getter	20	31	4/27/77 64 days

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TASK 71 - QUALITY ASSURANCE

Quality Engineering and Quality Control activities continued at a level consistent with the program procurement and fabrication activities. Routine receiving and in-house fabrication inspections were conducted as required.