Westinghouse Astronuclear Laboratory

NUCLEAR-POWERED ARTIFICIAL HEART PROTOTYPE SYSTEM DEVELOPMENT PROGRAM

CONCEPTUAL DESIGN
INTERMEDIATE SYSTEM

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NUCLEAR-POWERED ARTIFICIAL HEART
PROTOTYPE SYSTEM DEVELOPMENT PROGRAM

PHASE IIIA

CONCEPTUAL DESIGN
INTERMEDIATE SYSTEM

Prepared For

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By

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1.0 INTRODUCTION AND SUMMARY

The Nuclear-Powered Artificial Heart Prototype System Development Program is being conducted by the Westinghouse Astronuclear Laboratory and its major subcontractor, the Philips Laboratories division of the North American Philips Corporation. The program, presently in Phase III, is a part of the Atomic Energy Commission's overall Artificial Heart Program.

This report covers a conceptual design of the Intermediate System of Phase III. As the name suggests, the Intermediate System is an intermediate step to accomplishing Phase III objectives.

1.1 PHASE III OBJECTIVES

The overall objective of Phase III is to develop the nuclear-powered Stirling-mechanical artificial heart system to prototype status. It is planned that the goals for the prototype system be achieved by incorporating improvements resulting from continuing research and development activities into a series of three calf-implantable systems: an implantable version of the Phase II bench model, the Intermediate System, and the Prototype System.

There are five major categories of external requirements and constraints to be considered in the development of a fully implantable artificial heart: isotope inventory; implantation factors; performance, lifetime and reliability; environmental aspects; and costs. This Intermediate System conceptual design is concerned, primarily, with the first three categories. Each of these categories contains a number of criteria. Several of the more important criteria for a fully developed artificial heart system are weight, volume, maximum dimensions, life, isotope inventory, maximum blood flow and corresponding blood hydraulic power.

At the outset of Phase III, goals were set for each of the successive systems to be developed during the phase. Tables 1-1 and 1-2 define the geometric, physical and performance goals for each system. There are two columns in Table 1-2 for each system to account for the decay

of the Pu-238 radioisotope over ten years. It will be noted that performance goals for the blood pump ventricles are included in Table 1-2, even though ventricular development is beyond the scope of the Westinghouse program. This is because it is necessary to anticipate ventricular performance in order to establish the power requirements of the blood pump drive and thermal converter. The ventricular values quoted are consensus estimates obtained from knowledgeable artificial heart researchers at the University of Utah, Universities-Center Jackson and the Cleveland Clinic.

Although the success of the Phase II program in demonstrating a realistically sized bench model system was a significant technical achievement, considerable improvements in several areas are necessary to achieve the ambitious goals for the prototype artificial heart system. The Phase III program has strong emphasis on technology advancement with testing of a succession of developmental systems to confirm the progress of the research and development efforts. The Intermediate System (I.S.) is the second of three developmental systems. The first developmental system is an implantable and advanced version of the bench model (IVBM) and the third is a Prototype System.

The primary objective in developing the IVBM is to solve the packaging problems for total system implantation. Substantial progress has been made in this direction. Component development and detail design for the IVBM are nearing completion. A big factor in this progress is that the Phase II bench model was realistically sized. Removing flanges and other conveniences for assembly and instrumentation of the bench model provides a design well on the way to the goals for the IVBM as defined in Tables 1-1 and 1-2. Nonetheless simple repackaging of the Phase II bench model would not achieve these goals. Major technical effort has been required.

The objectives for the Intermediate System include a substantial improvement in size, shape, weight, volume, and efficiency over the IVBM plus a partial solution to the ultimate control problem and an increase in ruggedness. Tables 1-1 and 1-2 show that most of the improvements in system size, weight and efficiency are anticipated to be in the thermal converter in the

TABLE 1-1
CHARACTERISTICS GOALS

	<u>Implantable Version Bench Model</u>	<u>Intermediate System</u>	<u>Prototype System</u>
Total Efficiency - %	10	12	14
<u>Volume - liters</u>			
Thermal Converter	0.9	0.8	0.7
Blood Pump	<u>0.7</u>	<u>0.7</u>	<u>0.7</u>
System	1.6	1.5	1.4
<u>Weight - kg</u>			
Thermal Converter	1.9	1.7	1.5
Blood Pump	<u>0.8</u>	<u>0.8</u>	<u>0.7</u>
System	2.7	2.5	2.2
<u>Envelope Dimensions - cm</u>			
Thermal Converter			
Height	22	17	16
Width	9	8.5	7.7
Length	10	9.5	8.7
Blood Pump			
Height	14	13	13
Width	9	8.5	8
Length	12	12	11

TABLE 1-2
PERFORMANCE GOALS

	Implantable Version Bench Model		Intermediate Model		Prototype Model	
	Initially	After 10 Years	Initially	After 10 Years	Initially	After 10 Years
Thermal Input, watts	33	31	27	25	24	22
Converter Efficiency, %	17	17	20	20	21	21
Converter Output, watts	5.6	5.2	5.4	5.0	5.0	4.6
Pump Drive Efficiency, %	85	85	87	87	90	90
Power to Pump Diaphragms, watts	4.8	4.4	4.7	4.3	4.5	4.1
Ventricular Efficiency, %	70	70	72	72	75	75
Available Power to Blood, watts	3.4	3.1	3.4	3.1	3.4	3.1
Power Required [*] by Blood, watts	3.1	3.1	3.1	3.1	3.1	3.1

* Based on 12 liters/min and normal blood pressures

progression from the IVBM to the I.S. Two items stand out: a reduction in thermal converter length from 22 cm to 17 cm and an increase in thermal converter efficiency from 17 percent to 20 percent. The ruggedness and control objectives are less well defined at this early stage of implantation experience. Therefore, criteria in these areas will mature with development and increased experience in implantation of the systems.

The objectives for the prototype model are to advance system reliability and responsiveness to body needs to acceptable levels. Refinements in all areas will be required to meet objectives but the greatest emphasis will be on reliability.

1.2 INTERMEDIATE SYSTEM DESIGN GOALS

As discussed previously, each successive system is considered a step toward the goal of constructing a prototype of an artificial heart. Also, each system is intended as a test bed to demonstrate the adequacy of the design concept, to highlight areas where more component development is required, and to serve as a research tool to investigate operational and implantation requirements. With these aims in mind, there are certain design constraints common to all Phase III systems.

- Each system must have an initial capability to deliver 3.4 watts of hydraulic power to the circulating blood. This is to provide 3.1 watts of blood hydraulic power after ten years with a blood flow of 12 liters/minute.
- The flow rate must be variable from the maximum output down to about 6 liters per minute in response to the varying requirements of the recipient.
- Each system must be suitable for calf implantation.
- No system may pose a radiological hazard to the people operating the system or the population, in general, under any credible conditions.
- All systems must be designed with the ten year mean life goal in mind.
- The heat not converted into mechanical work in the thermal converter must be rejected to the vascular system of the calf.

- The blood heat exchanger must be integral with the blood pump.
- The heat flux through surfaces in contact with flowing blood must not exceed 0.1 watts/cm².
- The heat flux through surfaces in contact with tissue must not exceed 0.04 watts/cm² *.

Within these overall guidelines, the specific performance, size and volume goals for each succeeding model become more stringent. For the Intermediate System, the goal is to reduce the total thermal input from the IVBM's 33 watts to 27 watts while providing the same required hydraulic power to the blood. Also, the system is expected to operate normally under conditions of varying atmospheric pressure, such as might be encountered in an airplane or a vehicle climbing a mountain. Specific requirements for ruggedness have not, at present, been developed, but the Intermediate System design must be capable of withstanding the loads imposed by the activities of the recipient animal. Experience gained with the IVBM is expected to help in maturing the requirement in this area and to provide information on the overall performance and response characteristics of the control system.

The requirement that the system be implantable in a calf implies certain restrictions on size, weight and envelope dimensions. Although the IVBM goals in these areas (listed in Table 1-1) are deemed sufficient for experimental use in calves, the need for ultimate use with human beings implies that more stringent goals must be applied to more advanced systems and this reasoning led to the envelope and performance goals for the Intermediate and Prototype Systems that are listed in Tables 1-1 and 1-2. In addition to the dimensional constraints expressed in these tables, the outer envelope of the systems must be smooth with well rounded corners and generous fillets around all protrusions.

*This study was based on an allowable heat flux of 0.04 watts/cm². More recent information indicates a value of 0.03 watts/cm² is more proper. It is believed that a change from 0.04 to 0.03 watts/cm² would not have a material effect on the results of this conceptual study.

1.3 INTERMEDIATE SYSTEM SUMMARY DESCRIPTION

The Intermediate System conceptual design is illustrated in Figures 1-1 and 1-2. There are two major subassemblies: a thermal converter and a blood pump. The two are interconnected by a coupling mechanism that contains: 1) a flexible mechanical shaft to transmit drive power, and 2) a coolant line to carry the waste heat from the thermal converter to the blood pump assembly. A summary of system characteristics is presented in Table 1-3. This Intermediate System conceptual design, sized on the basis of a 27 watt Pu-238 heat source, has approached but not attained all of the goals that were itemized in Table 1-1 and Table 1-2. This is indicative of areas that require component research and development work prior to the design maturing via the preliminary and detailed design stages.

The principal components of the thermal converter, shown in Figure 1-1, consist of:

- A rhombic drive Stirling-cycle heat engine connected to the coupling mechanism through step-up gearing and flywheel.
- A Pu-238 heat source to provide thermal energy to the engine.
- Vacuum foil thermal insulation to minimize heat losses from the heat source and the high temperature portions of the engine.
- A control system that maintains nearly constant engine speed.
- A heat remover (cooler) that delivers engine waste heat to the coolant line connecting to the blood pump.

An operating mode was selected for the Intermediate System which provides a nearly constant blood pump beat rate of 120 beats per minute by controlling the thermal converter piston speed to an average value of 600 revolutions per minute (rpm). Starling's Law of Blood Flow is satisfied by designing the blood pump to accept whatever amount of blood is delivered to the ventricles during diastole, and letting the stroke volume vary up to the maximum stroke

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Figure 1-1. Intermediate System Thermal Converter

TABLE 1-3
SUMMARY OF INTERMEDIATE SYSTEM CHARACTERISTICS
FROM DESIGN STUDY

Power Output after Ten Years - watts

• Blood pump left ventricle	2.7
• Blood pump right ventricle	0.4
• Thermal Converter	5.0

Isotope Inventory - watts (t)

• Initially	27
• After ten years	25

Temperatures - K (^oF)

• Peak Material	1190	(1683)
• Peak gas	1000	(1340)
• Minimum gas	335	(144)

Working Gas

ARGON

Weight & Volume*

	<u>Gm</u>	<u>CC</u>
• Thermal Converter	1764	740
• Blood pump	848	725
• Converter and Pump	2612	1465

*Does not include coupling mechanism. For a 10 cm (4 in.) coupling, weight and volume are approximately 20 gm and 16 cc, respectively.

volume which will provide 12 liters/min. This operating mode takes advantage of the inherent adjustment of the body's circulatory system via variable venous pressure.

The Pu-238 heat source and Stirling engine are sized to meet the maximum design power output demand. This is done so that the thermal converter can use a simple controller that regulates the converter's power output to follow the power demanded by the blood pump. The controller consists of a hydraulic pump within the converter that serves as a sensing element and a control valve. Flow losses caused by the valve regulate the net converter output.

The heat source is a vented Pu-238 capsule. The Stirling engine uses a single cylinder, stationary regenerator, and rhombic drive. Varying gas pressure on the power piston provides input to the rhombic drive which drives the displacer. The displacer moves the working gas between the hot and cold ends and the gas is forced to flow through the cooler, the regenerator, and heater as it is transferred between the two ends of the engine.

The flywheel operates at high speed to minimize its weight and size. Since the blood pump delivers a pulsatile flow of blood, the input power to the pump is pulsatile also. The flywheel smooths this pulsatile requirement so that the load on the engine is nearly uniform. To reduce friction losses, the flywheel runs in a dry, gas filled cavity. A magnetic coupling closes one end of this cavity, and engine oil is kept out of the cavity by means of a screw seal on the flywheel shaft. The crankcase is pressurized to the mean operating gas pressure. To allow the crankcase to be pressurized, a hermetic seal is provided by the magnetic coupling.

The vacuum foil insulation consists of nested nickel cups enclosed in a titanium vacuum vessel. A copper pinch-off tube is provided to allow evacuation of the insulation after assembly and fueling. The length of each cup is adjusted so that the temperature of the cup matches the temperature of the hot finger at the point of contact. Therefore, each cup is maintained in an isothermal condition and no heat is conducted along the cup surface.

The heat not converted into mechanical work by the engine is extracted from the gas by the cooler, and transported through the cooler walls into a vapor chamber that forms the evaporator end of the flexible heat pipe. A mesh screen maintains a thin water film on the outer surface of the cooler. Vapor evaporated from this surface is transported through the heat pipe to the blood pump, where it is condensed, giving up heat to the blood pump. The condensate is returned to the thermal converter through the heat pipe annulus where pumping action is provided by capillary forces.

The entire thermal converter is enclosed in a titanium housing to provide a smooth outside contour. Because the housing of the converter is approximately 11°C hotter than the surrounding body tissue, a layer of polystyrene foam insulation is provided to protect the tissue. The entire converter is sealed with a thin layer of silastic. The helium vent tube from the fuel capsule cavity terminates under this silastic layer, and the helium diffuses through the silastic into the body fluids and ultimately to the atmosphere through the lungs.

The principal components of the blood pump, shown in Figure 1-2, are:

- Blood pump right and left ventricles.
- A drive mechanism, which converts the rotary output of the coupling mechanism to reciprocating motion of pusher cups that drive the ventricles.

The outside diameter of the blood pump body is 9.3 cm and the overall length is 13 cm. A heat transfer jacket and a layer of thermal insulation are wrapped around the outside surface of the pump body. The jacket provides a condensation chamber for the vapor in the heat pipe, and the insulation reduces heat rejection rates to surrounding tissue to tolerable levels. The waste heat in the jacket is conducted through the pump housing to the lubricating oil in the drive mechanism chamber. From there the heat is transferred by conduction through the pump components and ventricles to the blood.

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Figure 1-2. Intermediate System Blood Pump

The speed reducer built into the wall of the blood pump reduces the drive speed from 1800 rpm at the flexible shaft to 120 rpm at the shaft that powers the pump drive mechanism. These gears permit a compact coupling of the flexible shaft to the pump.

The output shaft of the speed reducer is connected through a square spline to a crankshaft with three throws. A roller on the center throw engages a Scotch yoke that converts the rotary motion of the crankshaft into a reciprocating motion with one cycle per revolution of the crankshaft. Drive rods on each side of the Scotch yoke are connected to displacement cups which alternately compress and expand the two dacron reinforced silastic ventricles.

The offsets of the end throws of the crankshaft allow the crankshaft ends to move past the mid-plane of the pump and permit a displacer cup to occupy space required by the opposite displacer cup in the return stroke. This arrangement minimizes the overall pump length. Rollers on the end throws of the crankshaft engage Scotch yokes built into the ends of a housing and cause it to reciprocate as the crankshaft rotates. This housing supports linear ball bushings that guide the displacer cup yoke. A bellows secured to the yoke housing and the displacer cup yoke serves as a torsion resisting element that prevents relative motion between these components.

The entire blood pump drive mechanism and flexible shaft casing is filled with oil. The oil provides lubrication for all drive components and accommodates the pump volume change that could result from variations in ambient pressure.

The flexible shaft assembly* consists of a very flexible core, a special wear resistant teflon guide tube for the core, and a convoluted metal tube around the guide tube. The convoluted metal tube permits flexibility of the shaft assembly to be maintained. It also

*Experimental work subsequent to this conceptual design has indicated a possible need for a more complex coupling mechanism than a simple flexible shaft.

prevents squeezing of the guide tube on the core and seals off the shaft assembly from body fluids. End fittings are welded to the end of the convoluted metal tube and connect the shaft assembly to the thermal converter and the blood pump. These fittings are sealed with silicone "O" rings.

1.4 PROBLEM AREAS AND SOLUTIONS

Considering the design requirements for the Intermediate System, problem areas could be grouped, somewhat artificially, into those problems that relate to envelope and weight objectives and those problems that relate to attaining performance and long life. In reality, these areas are interrelated and interdependent comparable to the way that mathematical variables are often nonseparable. For this reason, it is perhaps more instructive to identify problem areas that require technology developments while recognizing that the development work will be aimed toward satisfying the interdependent nature of design requirements.

In the thermal converter, the control system, seals, hot finger, drive components, and thermal insulation represent areas where the state-of-the-art will require advancement so that the Intermediate System can meet its objectives. Component research and development in these areas is either underway at present or will be initiated in a timely manner. For example, efforts to develop small bellows for engine seals have been initiated with strong emphasis on life attainment. Section 2.2.4 discusses the choice of bellows in lieu of roll sock seals for the Intermediate System. The engine hot finger and drive components are being pursued through component development as well as through the experience that will be gained from design, fabrication and testing of the IVBM thermal converter. A component research and development task in magnetic couplings will be initiated.

In the blood pump and its integration with the thermal converter, lubrication of the drive mechanism, use of light materials in the mechanism, waste heat transport to the blood, and flexible shaft life represent the prime areas where technology advancements are needed. A

component research and development effort on flexible heat pipes will be initiated early in 1974, while work in the other areas is already underway.

2.0 THERMAL CONVERTER DESIGN

2.1 DESIGN DESCRIPTION

Figure 2-1 shows the basic features of the Intermediate System thermal converter. The major elements making up the thermal converter are:

- A Pu-238 heat source which provides the thermal energy to drive the system.
- A Stirling engine, with built-in control, which converts a portion of the heat to mechanical energy to drive the blood pump.
- A heat rejection system to transport waste heat to the blood pump for rejection to blood.
- A vacuum foil thermal insulation package to isolate the high temperature end of the thermal converter from the surrounding body tissue.

Each of these subsystems is discussed in some detail below.

2.1.1 Pu-238 Heat Source

Extrapolations based on the Phase II capsule, designed for the AEC by the TRW Systems Group*, were used to estimate heat source size and weight. The heat source is vented, fueled with plutonium-238, and provides 27.2 watts of thermal power at the beginning of life. The fuel form is PuO_2 , the inner liner and the outer clad are platinum 80% - rhodium 20% alloy. The strength member is T-111. A vent tube from the heat source cavity is led down the hot finger, and the helium evolved from the isotope is vented to the body through the silastic coating over the thermal converter housing. (See Figure 1-1, page 1-8)

*Lurie, Henry, "Radioisotope Heat Source Development for an Artificial Heart Device", TRW Systems Group, Report No. SAN-858-50, U.S. AEC Contract AT(04-3)-858, April 1973.

2.1.2 Stirling Engine

A. Design Features

The converter as shown in Figures 1-1 and 2-1 uses a single cylinder, stationary regenerator, Stirling cycle engine, with a rhombic drive mechanism. The crankcase is pressurized to the mean pressure of the engine working volume (the volume above the power piston). The rhombic drive is lubricated in a bath of oil.

Varying gas pressure on the power piston provides power to the rhombic drive which converts the reciprocating motion of the power piston to rotary motion at 600 rpm and drives the displacer which operates approximately 100° out of phase with the piston. The displacer moves the working gas between the hot and cold ends of the working volume to provide varying pressure pulses which drive the piston. The gas is forced to flow through the cooler, the regenerator, and heater as it is transferred between the two ends of the engine.

In Figures 1-1 and 2-1 the displacer is shown in very nearly the top of its stroke, and most of the gas is, therefore, in the cool end of the engine. With the gas cool, the pressure in the working volume is reduced, and the power piston is moving upward compressing the gas. When the piston approaches top dead center, the displacer will begin to move downward, transferring gas into the heated end of the engine. The cold gas will flow through the cooler and into the regenerator, and finally through the heater before entering the hot end of the engine. Since the gas is already cool, the cooler will have little effect. The gas will pick up heat from the energy stored in the regenerator matrix, and, finally be heated to its maximum temperature by heat conducted from the heat source to the heater. With much of the gas in the hot end of the working volume, the internal pressure of the engine rises, and the power piston is forced down, doing work on the rhombic drive. The displacer reaches bottom dead center approximately 100° ahead of the power piston. Continued rotation of the drive mechanism moves the displacer upward, transferring the gas through the heater, the regenerator, and the cooler to the

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Figure 2-1. Thermal Converter Design

cool end of the working volume. The heater has little effect on the already hot gas, but the gas is cooled as it flows through the regenerator matrix replacing the heat extracted from the regenerator previously. As it flows through the cooler, more heat is extracted from the gas, leaving it at the minimum temperature of the cycle. As the displacer approaches top dead center, the cycle is completed.

In this cycle, the majority of the heat transfer to and from the gas takes place in the regenerator, with relatively small amounts of heat transfer occurring in the heater and cooler. These locations are the only places the engine is connected to the external environment, and the gas is already very nearly at its hot or cold extremes in temperature when it reaches these components. Because heat is transferred to and from the external environment at nearly the temperature extremes of the cycle, the Stirling cycle has the capability of very good efficiency, approaching the theoretical maximum for a given pair of design temperatures.

In examining the cycle, it can be observed that torque is applied to the rhombic drive for approximately half of each cycle. During the remaining portion of the cycle, the piston must be driven. The flywheel stores the energy necessary to accomplish this, as well as smoothing out the varying loads applied to the engine by the blood pump. The energy used by the displacer is minimized by insuring that the gas flow path offers little resistance to flow, thus minimizing the pressure differential between the two ends of the displacer.

B. Energy Balance

Several energy losses reduce the power output below theoretical maximum. The thermodynamic power of an engine is roughly proportional to the volume of the engine, while the losses are proportional to the area, or even the linear dimensions of the engine. Therefore, as the size of an engine is reduced, losses become more significant in relation to the power developed at the power piston. Loss mechanisms that are insignificant in engines of several horsepower (thousands of watts) become vitally important for engines operating in the range of 5 or 6 watts. For this reason, the successful design of an efficient engine for the artificial heart requires

careful evaluation of all loss mechanisms. The best design involves a trade-off between various sources of thermal and mechanical losses to achieve the best overall performance within specified volume and weight goals. Figure 2-2 shows the calculated power balance and estimated losses for the Intermediate System thermal converter. These losses can roughly be grouped into thermal losses and mechanical losses including pressure losses due to gas flow in the engine. The thermal losses can, in turn be grouped into two general categories. For small engines in particular, a significant portion of the heat supplied never enters the thermodynamic cycle, but, instead is shunted directly to the heat sink by various mechanisms. The most important of these "shunt" losses include.

- Insulation heat leak.
- Conduction losses along the various elements of the engine.
- Shuttle and annulus losses.

Of these, the first two are self-explanatory. The so called shuttle loss is a heat pumping effect that occurs when two objects that have similar temperature gradients are oscillated relative to each other. For example, the displacer and regenerator are both at approximately 1000 K at their hot end, and 335 K at their cool end. With the displacer at the mid point of its travel, the temperature gradients of both items match, and no heat is transferred between them. However, when the displacer is at the top of its stroke, the lower portion of the displacer is cooler than the adjacent regenerator wall, and some heat is transferred to the bottom end of the displacer from the regenerator. Conversely, when the displacer is at the bottom of its stroke, the top end of the displacer is hotter than the adjacent portion of the regenerator, and heat is transferred from the top of the displacer to the regenerator. The total result is that heat is transported from the top to the bottom of the displacer by alternate transfer to and from the regenerator, producing additional heat losses over and above the simple conduction loss from the thermal gradient in the displacer. Annulus losses are introduced in the annulus between the displacer and regenerator. As the pressure in the working volume changes, gas is forced in and out of the annulus, resulting in an additional net heat transport along the length

Figure 2-2. Intermediate System Thermal Converter Initial Energy Balance

of the displacer and regenerator. For this design, the shuttle and annulus losses are approximately equal.

Heat leaks are minimized by reducing the transport area and increasing the length. This results in the thin walls (.01 cm) which contain the regenerator and cover the displacer. Selection of materials with low thermal conductivity also reduces the heat leak.

Of the heat that actually enters the working cycle, only a portion can be converted to internal mechanical work. For an ideal engine operating between two given temperatures, the maximum amount of heat which can be converted to mechanical work is fixed by the Carnot efficiency based on the temperature extremes for the cycle. As discussed previously, the Stirling cycle can approach this ideal closely. The ideal losses shown in Figure 2-2 are based on the gas temperature extremes. Since heat addition and rejection do not actually take place at constant temperatures, and finite temperature drops are required at the various heat exchange surfaces, the actual conversion efficiency is slightly below the ideal Carnot efficiency. The temperature limits are set by material availability and the long life required, thus limiting the maximum conversion efficiency. This limit can be approached by designing large heat transfer surfaces with high film coefficients, and by providing sufficient regenerator capacity.

The mechanical losses center around the drive system with its 18 journal bearings and 3 guide bushings. Here viscous friction is governing. With the drive moving in and out of oil, some additional flow losses are incurred. Flow losses occur in the working gas as well when it flows through the regenerator mesh. Mechanical and viscous losses are minimized by careful design of the bearings. Their load carrying capacity must be optimized relative to the friction losses.

C. Control Mode

The converter has a built-in speed control to maintain approximately constant speed operation. When the loading on the engine is reduced during the night, for example, the engine speed would tend to increase. The speed controller downgrades the efficiency under these conditions and thus limits the speed.

In addition to maintaining engine speed within limitations imposed by physiological constraints the speed control serves indirectly to control the engine temperature. For a given engine, with a fixed mass of gas in the working volume, the steady state heat input is roughly proportional to the product of peak temperature of the gas and the engine speed. Because the steady state heat input is fixed by the isotope power, the peak temperature is inversely proportional to the engine speed. The required controller performance is therefore set by the temperature variations which can be tolerated as a result of speed variations or by physiological requirements, whichever is more stringent.

The speed control system is shown schematically in Figure 2-3. Power dissipation is obtained by connecting the engine working volume to the control volume (V_c) by means of a needle valve. The control volume is made large enough so the pressure in it is essentially constant. As the pressure in the working gas varies above and below the mean pressure, a portion of the gas is allowed to flow in and out of the control volume through the needle valve. The work represented by the pressure drop across the valve times the gas flow rate is dissipated as heat. A loss term is thus introduced into the system, which can be controlled by varying the valve stem position. The operation of this type of control system is expected to change the phase angle between the volume and pressure of the engine working gas in a manner which tends to reduce the heat input to the gas. This effect should tend to partially or completely compensate for the ideal decrease in engine temperature with increasing speed under light loads. The hydraulic pump shown in Figure 2-3 serves as a speed sensing element as well as a power source to drive the control valve. It senses an increase in speed as an increase in oil pressure, P_o . When this pressure rises above a level set by the needle valve bellows characteristics, the valve begins to open, reducing the engine power output. Figure 2-4 shows the control system operation as a function of valve position for two sizes of the control volume V_c .

D. Output Drive and Seals

The flywheel operates at 1800 rpm to minimize the weight and size required to store the energy necessary to operate the system properly. Higher speeds would result in excessive frictional losses. As described earlier, the flywheel serves to drive the power piston through the com-

Figure 2-3. Speed Control Schematic

Figure 2-4. Speed Control Performance

plete cycle. Since the blood pump delivers a pulsatile blood flow at approximately 120 beats per minute, the power requirements on the pump are also pulsatile, with the maximum power required being approximately twice the average. The flywheel also serves to smooth this load so that the load on the engine is nearly uniform on a short term time scale. The flywheel size is set to perform both functions simultaneously. In order to reduce friction losses, the flywheel runs in a dry, gas filled cavity. A magnetic coupling closes one end of this cavity, and engine oil is kept out of the cavity by means of a screw seal between the flywheel cavity and the crankcase. The screw seal above serves to return any oil that might leak into the flywheel cavity to the crankcase. This is accomplished by providing a wick structure (not shown) along the periphery of the flywheel cavity to collect oil which is thrown off the flywheel rim. A tube (also not shown) connects the wick structure to the inner end of the screw seal.

As pointed out previously, the crankcase is pressurized to the mean operating gas pressure. This minimizes the loading on the rhombic drive bearings, thus allowing their size to be reduced as well as reducing the frictional losses. Pressurizing the crankcase also minimizes the pressure loads on the displacer and power piston bellows, decreasing their stress levels and increasing their working life. To allow the crankcase to be pressurized, a hermetic seal is required where the output shaft couples to the engine. The magnetic coupling performs this function while introducing a minimum loss. The losses are: an eddy current loss in the diaphragm forming the seal between the two rotating elements, and viscous losses in the oil around the outboard rotating element. Since the diaphragm can be made quite thin, (about 0.13 mm or 0.005 in) the eddy current losses are low. Since the viscous losses for a rotating disc are a strong function of the radius of the rotating member, the viscous losses are also acceptably low because the coupling has a small radius.

2.1.3 Thermal Insulation

The vacuum foil insulation consists of 60 nested cups of 0.013 mm (0.0005 in) thick nickel enclosed in a titanium vacuum vessel. A copper pinch off tube is provided to allow evacuation of the insulation after assembly and fueling of the converter. The length of each cup is

adjusted so that the temperature of the cup matches the temperature of the hot finger at the point of contact. Each cup is therefore maintained in an isothermal condition, and no heat is conducted along the cup surface. The only heat transport mechanism is therefore by radiation and conduction through the zirconia separators between adjacent cups. Experimental results indicate that the conduction component can be made quite small in relation to the radiation component if the loads between adjacent cups are kept small. By using pre-formed cups these loads can be controlled, and the corner losses can be eliminated. The total package will therefore approach the theoretical performance based on thermal radiation alone.

The vacuum foil thermal insulation also provides an important safety feature. Because the insulation package requires a good vacuum be maintained to perform as designed, the introduction of gas into the insulation package increases the effective thermal conductivity by several orders of magnitude. The heat source is designed to withstand severe accidents such as accidental cremation; therefore, the source has the capability of withstanding much higher temperatures than experienced during operation. In the event of the engine stalling or otherwise malfunctioning, the normal path for the isotope heat is blocked, causing the source temperature to rise. Before the capsule temperature reaches its temperature limits, the engine wall will reach its melting temperature, releasing gas into the insulation, reducing the heat source temperatures to a safe level. Even in accidents where the gas might escape from the engine working volume, this safety feature still operates, since air, water vapor or almost any gas provides sufficient thermal conductivity to prevent a catastrophic rise in heat source temperature.

2.1.4 Heat Rejection

The heat not converted into mechanical work by the converter is extracted from the gas by the cooler, and transported through the cooler walls into the vapor chamber which forms the evaporator end of the flexible heat pipe. A fine mesh screen maintains a thin water film on the outer surface of the cooler. Vapor which is evaporated off of this surface is transported through the core of the heat pipe to the blood pump, where it is condensed, giving up heat to the blood pump. The condensed vapor is returned to the thermal converter cooler

through the outer annulus of the heat pipe. The pumping action is provided by capillary forces developed across the screen overlying the outer surface of the cooler.

2.1.5 Converter Assembly and Characteristics

The entire thermal converter is enclosed in a titanium housing to provide a smooth outside contour. Because the converter housing is approximately 11°C (20°F) hotter than the surrounding body tissue, a layer of polystyrene foam insulation is provided to protect the tissue. The entire converter is sealed with a thin layer of silastic. The helium vent tube from the capsule terminates under this silastic layer. The small amount of helium vented diffuses through the silastic into the body fluids and is eventually eliminated through the lungs.

The weight of the converter has been minimized through design and material selection. Table 2-1 provides a list of converter materials while Table 2-2 itemizes component weight estimates for the converter.

2.2 COMPONENT SELECTION AND TRADE-OFFS

The Intermediate System thermal converter has the following special design features:

- Radial-Slit Heater
- Stationary Regenerator
- Radial-Slit Cooler
- Bellows Seals
- Bath Lubrication System
- Magnetic Coupling
- Pressurized Crankcase

TABLE 2-1

INTERMEDIATE THERMAL CONVERTER MATERIALS

<u>Item</u>	<u>Material</u>
Pu-238 Heat Source	Various
Thermal Insulation	Nickel
Vacuum Vessel	Titanium
Heater	Nickel
Regenerator Walls	Udimet 700
Regenerator Mesh	Stainless Steel
Cooler	Copper
Displacer Seal	P. I.
Displacer Wall	Udimet 700
Displacer Core	Min-K
Displacer Base	Monel
Displacer Rod	Stainless Steel
Displacer Yoke	Stainless Steel
Piston	Stainless Steel
Piston Yoke	Stainless Steel
Bellows (inner)	Stainless Steel
Bellows (outer)	Stainless Steel
Bearings (sliding)	Bronze
Bearings	Bronze
Counterweights	Kennertium
Connecting Rods	Stainless Steel
Pins	Stainless Steel
Crankshafts	Stainless Steel
Crankcase	Magnesium & Steel

TABLE 2-1

INTERMEDIATE THERMAL CONVERTER MATERIALS

(Continued)

<u>Item</u>	<u>Material</u>
Flywheel	Kennertium
Gears (& Shaft)	Stainless Steel
Magnetic Coupling	Various
Vapor Chamber	Titanium
Coolant	Water
Oil Pump Housing	Bronze
Oil Pump Gears	Stainless Steel
Working Gas	Argon
Crankcase Gas	Argon
Oil	Vitrea 21
Control	Various
Housing	Titanium
Insulation	Polystyrene Foam
Biological Interface	Silastic
Vacuum Pinch Off	Copper

TABLE 2-2

INTERMEDIATE THERMAL CONVERTER WEIGHT SUMMARY

<u>Component</u>		<u>Weight (grams)</u>
Pu-238 Heat Source		260
Hot Finger Assembly		317
Thin Walls	11	
Heater	19	
Regenerator	52	
Cooler	46	
Insulation Package	106	
Vapor Chamber	25	
Miscellaneous	58	
Drive		573
Displacer Assembly	87	
Piston Assembly	90	
Bellows Seals	6	
Rhombic Drive	157	
Timing Gears	26	
Flywheel	172	
Magnetic Coupling	35	
Structure		614
Oil Pump	11	
Control System	23	
Crankcase	239	
Housing	89	
Oil	131	
Miscellaneous	121	
		<hr/>
	TOTAL	1764

Design features common to the Phase II bench model converters include:

- Rhombic Drive (balanced)
- Oil Lubricated Bearings
- Integral Flywheel

2.2.1 Stationary Regenerator

The Phase II bench model thermal converter had a reciprocating regenerator, placed inside the displacer. This arrangement, although somewhat unconventional, resulted in relatively low thermal conduction losses, since there were only two walls connecting the hot and cold regions: the hot finger wall and the displacer wall. Also, the construction was relatively simple, and the configuration compact. However, the bench model tests indicated that the very narrow radial gap between the hot finger and the displacer was extremely difficult to maintain. As a result, the reciprocating displacer was rubbing against the heater wall, inducing both thermodynamic and frictional losses. Since the problem was extremely difficult to correct in a moving regenerator configuration, it was decided to design and build the IVBM with a stationary regenerator.

The stationary regenerator offers numerous advantages. Most important, it allows more flexibility in the design of the heater and cooler. The configuration permits short heat transfer paths from the isotope capsule, thus eliminating the need for a heavy conduction sleeve.

Appendix B presents the results of a thermal analysis of similar concepts. By removing the regenerator from the displacer, reduction of the displacer weight is possible, making the unit easier to balance, and reducing the bearing loads slightly. Past versions of Stirling engines built by Philips use such a stationary regenerator. Thus, experience in lightweight displacers and stationary regenerators can be applied directly to the heart engine.

With the stationary regenerator, the hot finger configuration becomes sandwich-like in construction and will be stiffer than the Phase II hot fingers. Having two thin walls may pose a heat leak problem, but the walls may be taken to their minimum thickness design limits since they are no longer in contact with any moving parts and must merely withstand a high internal pressure. To insure this situation, the displacer seal is mounted in the ID of the finger wall instead of the OD of the displacer.

Figure 2-5 shows the moving and stationary regenerators schematically. Also shown are the heat storage value (V) and number of heat transfer units (NTU) for each generator. The value of the parameter NTU is an index of performance for a heat exchanger. In large NTU, the heat transferred approaches the limits set by thermodynamic considerations asymptotically.

2.2.2 Radial-Slit Heater

In the Phase II engine, the heater was an annular gap with limited heat transfer area. In addition, the small clearances required for efficient heat transfer were difficult to maintain. With the stationary regenerator, a radial slit heater can be utilized and the displacer clearance is no longer as critical. The radial slit heater provides an increase in heat transfer area as well as a higher heat transfer coefficient.

Since the heater is a solid piece, the flow passages can be made quite thin, producing a high heat transfer coefficient. The radial slit heater can also be made shorter, allowing a longer regenerator, thus reducing the conduction losses along the regenerator. Schematic diagrams of the two systems and a comparison of heat transfer area and NTU are shown in Figure 2-6.

2.2.3 Radial-Slit Cooler

Having the cooler on the periphery of the finger will permit reduction of the height by allowing the piston and displacer strokes to overlap without introducing the complexities of a gap cooler. The resulting length reduction contributes to an overall reduction in total working volume of the system and this tends to compensate for the dead volume added by the bellows.

Figure 2-7 shows a comparison of cooler volume, NTU and heat transfer area for the two configurations.

2.2.4 Bellows Seals

The seals used in the Phase II bench model were rolling diaphragms of polyurethane. They are known to have sufficient life if properly supported but the support system requires an oil pump, with a resulting power loss. The characteristics of roll socks are such that an auxiliary piston ring is required. This introduces another power loss as well as a wear point. Roll socks are also sensitive to abrasion by foreign matter. Finally, roll socks can be attacked by a number of common chemicals, including water, and great care must be exercised during manufacturing and installation to prevent damage. These drawbacks can be minimized, and some of the problems eliminated by careful assembly. Specifically, the efficiency of the oil pump can be improved, and thereby the associated losses reduced. Proper filtration of the oil, and controlled assembly techniques, can prevent foreign matter from reaching the rolling diaphragms. Finally, contact with chemicals and extended exposure to water can also be prevented.

However, if bellows seals having lives comparable to the rolling diaphragms can be developed, some of the problems cited above can be eliminated. Therefore, it appears desirable to investigate the feasibility of applying bellows seals to the Intermediate System. It should be noted that bellows users indicate that at the present time there are significant discrepancies between the bellows lifetimes obtained analytically with those seen in actual tests.

The geometric limitations placed on bellows by the required ten year life result in larger dead volumes with bellows than with roll socks. In the balance, the losses due to this dead volume are less severe than the problems associated with roll socks. Therefore, the Intermediate System converter aims to eliminate roll socks and piston rings in favor of bellows.

Type Regenerator		
	Heat Storage Volume (v*)	Number Heat Transfer Units (NTU)
Bench Model	7.4 cc	217

	MOVING	
Intermediate System	90 cc	250

	STATIONARY	
* ASSUMES 45% FILL FACTOR		

Figure 2-5. Regenerator Comparison

	Heat Transfer Area	Number Heat Transfer Units (NTU)
Bench Model	8.0 cm ²	1.06

	GAP HEATER	
	REGENERATOR MESH	
Intermediate System	23.9 cm ²	1.82

	HEATER	
	REGENERATOR MESH	

Figure 2-6. Heater Comparison

	Cooler Volume	Number Heat Transfer Units (NTU)	Heat Transfer Area
Bench Model	18.7 cc	1.32	62.15 cm ²

	DISPLACER		
	COOLER		
	PISTON		
Intermediate System	21.0 cc	1.55	62.91 cm ²

	DISPLACER		
	COOLER		
	PISTON		

Figure 2-7. Cooler Comparison

An optimum set of bellows is possible and will fit in the available space. Of the four types of bellows (electro-deposited, welded, hydroformed, and machined) only two have properties which lend themselves well to this application. Welded and electro-deposited bellows have the long life, spring rate, size, and strength needed.

The stress level in a bellows is a function of six parameters.

- Geometry of the bellows convolution and manufacturing technique.
- Extension of the bellows per convolution.
- Pressure difference across the bellows wall.
- Thickness of the bellows wall.
- Inside diameter and outside diameter of the bellows.
- Material properties.

This stress level can generally be divided into two components, a cyclic component which changes signs periodically, and a constant mean stress level. In this application, the cyclic component of stress comes from the flexing of the bellows and the pressure variations that occur during a cycle. The mean stress level comes from the pre-load on the bellows and the mean pressure difference across the bellows walls. A Goodman diagram, shown schematically in Figure 2-8A, relates these two stresses to the expected fatigue lifetime.

The goal of the bellows optimization procedure is to find the bellows design yielding the smallest dead volume, while meeting the design lifetime. This is equivalent to selecting the wall thickness producing the smallest bellows outside diameter while holding the rest of the bellows design parameters fixed. By plotting the wall thickness as a function of diameter difference for fixed numbers of cycles to failure as obtained from a Goodman diagram, contour

A. Typical Goodman Diagram

B. Optimum Wall Thickness

Figure 2-8

maps similar to the one shown schematically in Figure 2-8B can be obtained. Clearly there exists a wall thickness which minimizes the dead volume for the conditions which have been fixed. Most of the fixed parameters are dictated within fairly narrow bounds by the engine design characteristics, or can be selected to minimize the stress levels prior to determining the optimum wall thickness. Reasonable values for the design are shown below. These will give the life needed but the dead volume introduced is larger than desired.

<u>Bellows</u>	<u>Length</u>	<u>Thickness</u>	<u>I.D.</u>	<u>O.D.</u>
Outer	2.54 cm	0.01 cm	2.04 cm	3.00 cm
Inner	3.81 cm	0.005 cm	0.71 cm	1.63 cm

2.2.5 Bath Lubrication and Crankcase Sealing

The decision to go to bath lubrication in the crankcase was based on the desirability of eliminating the oil pump power requirement. There are losses introduced by moving the entire mechanism through the oil but these are minor.

An alternate approach involves solid lubrication but has limited life. Particulate matter from solid lubrication must be controlled to prevent intrusion into other elements where it would cause excessive wear.

For long life, the bellows must be supported by the mean pressure in the engine. This in combination with the bath lubrication makes it necessary to seal the crankcase from the pump interface (the flexible shaft). To do so introduces a need for a low loss hermetic shaft seal. One such seal uses a magnetic field to transmit torque through the walls of the crankcase. Screw seals, as proposed in Phase II are not suitable for use on this converter since the crankcase pressure is much higher than atmospheric. Screw seals operate well in a viscous medium

such as lubricating oil, but are not readily adaptable for use in retaining gas. Seals designed to prevent gas leakage against high pressures would require high rotational speeds and/or extremely small clearances. Both these factors would lead to high power losses when the seal is in contact with oil. Bellows seals were briefly examined for this application. Because of the high pressure differential to be supported, it is unlikely that reasonably sized bellows seals will have acceptable life. In view of the lifetime, size, low loss and high pressure differential requirements, the best seal identified to date is a magnetic coupling using cobalt-samarium magnets. The availability of this magnetic material with its high energy density makes the use of magnetic couplings attractive. The most serious drawback of the magnetic coupling is its inability to recover from a momentary overload. This can be met by insuring that the coupling is capable of transmitting torques in excess of the maximum torque which will be exerted on it. The coupling can either be generously oversized, or a mechanical torque limiting device can be interposed between the coupling and the load. Both of these approaches or a combination of the two impose weight and volume penalties on the system.

One way around this problem which was investigated and then rejected would be to attach the flywheel rigidly to the flexible shaft, with the coupling between the flywheel and the engine. Under this condition, the maximum torque imposed on the coupling can never exceed the maximum torque developed by the engine. A screw seal could be used to prevent entry of blood pump oil into the flywheel cavity. To operate successfully, however, the blood pump must be filled with oil. The screw seal offers no resistance to flow of gas outward from the flywheel under conditions when the gas pressure in the flywheel exceeds the surrounding atmospheric pressure. Because the operation of the Intermediate System must not be affected by reductions in ambient pressure, clearly this arrangement is unacceptable. Despite its disadvantages, the magnetic coupling located between the flywheel and flexible shaft provides the best seal arrangement investigated to date.

2.2.6 Control System

As pointed out in Section 2.1, with a constant mass of gas in the engine, changes in engine speed can affect the temperature of the hot finger. If used, variable speed operation could require a separate temperature control device in the converter. This could either be a variable thermal shunt, or a means of changing the mass of gas in the working volume of the engine. To determine whether variable speed operation offers any real advantages in overall system performance, an analytical study of the blood pump performance at various speeds was performed. The results of that study (presented in Appendix C) indicated no real advantages for variable speed control.

The speed control system is designed to hold the engine speed nearly constant over a wide range of loads. The control system described in Section 2-1 has been tried on a Philips' developmental engine similar to the Phase II bench model engine. The disadvantages of this type of control system are that it requires a continually operating hydraulic pump which requires power. It is expected, however, to partially compensate for the decrease in operating temperature with increasing speed.

The exact amount of speed overshoot which can be tolerated when the load is reduced has not been determined. With the engine configuration established, the relationships among engine speed, hot finger temperature, engine power and instantaneous heat input are being determined. Once these are well understood, criteria can be established for the allowable variations of speed with load, on a short term basis (e.g. several minutes or less) as well as a long term basis (e.g., several hours). Once these are established, they will be compared with physiological requirements for response time and maximum acceptable speed to establish detailed design criteria for the entire control system.

2.2.7 Heat Rejection System

The isotope heat not converted to mechanical energy must be transported to the recipient's circulatory system for ultimate rejection to the environment. The total amount of heat to be

rejected amounts to about 23 watts under conditions of minimum load on the thermal converter. This number is consistent with the performance of the natural heart, and is not expected to impose an excessive burden on the body's thermo-regulating system. As a preliminary step, heat transfer directly from the surface of the converter to the surrounding tissue was considered. In the absence of conclusive data concerning the effect such heat loads would have on the surrounding tissue, it was decided to reject heat directly to the blood flowing in the blood pump. Because all portions of the thermal converter are at somewhat higher temperatures than the surrounding tissue, some heat will always be transported by this route. The areas in contact with tissue are insulated with a flexible foam insulation to limit the maximum heat flux to 0.04 w/cm^2 * or less. Under these conditions, approximately 25% of the total heat may be transmitted directly to the tissue.

The remaining heat must be transported to the blood pump where it is transferred to the blood through the walls of the ventricles. The system is sized so that the maximum flux into the blood never exceeds 0.1 w/cm^2 . To transport the remaining heat from the thermal converter to the blood pump, a preliminary screening was performed comparing several pumping configurations. The results of this screening are described in Section 3.2.2. Based on this study, a heat pipe concept was clearly the most attractive. All the other systems have the strong disadvantage of requiring undesirable amounts of shaft power.

An alternative, being presently explored, involves using water rather than lubricating oil as the circulating coolant fluid. Since water has much lower viscosity and a higher specific heat, the pumping power can be reduced considerably. This concept appears to be only applicable for bellows type pumps, however. Because the blood pump mechanism must be filled with oil to provide proper lubrication, the heat must be transferred across a sealed boundary. A bellows pump automatically provides such a seal, and also provides sufficient heat transfer

*See footnote on page 1-6.

area. The use of the heat pipe also involves heat transfer across the blood pump wall. Since the available surface area is adequate, and the heat transfer coefficient for the condensing water vapor in the heat pipe is quite high, the temperature drop across this surface is expected to be small (in the order of 3°C or 5°F). Flexible heat pipes capable of transporting 15 watts over lengths of 10 inches are presently available. The requirements of the Intermediate System, while not "state-of-the-art", do not represent great extensions of present technology.

3.0 BLOOD PUMP DESIGN

3.1 DESIGN DESCRIPTION

The configuration of the Intermediate System blood pump design is shown in Figure 3-1.

The outside diameter of the basic pump body is 9.3 cm and the overall length is 13 cm. A heat transfer jacket and a layer of thermal insulation are wrapped around the outside surface of the pump body. The heat transfer jacket provides a condensation chamber for the vapor in the heat pipe used to transport the thermal converter waste heat to the blood pump, and the thermal insulation reduces the heat rejection rates to surrounding tissue to acceptable levels. The waste heat in the jacket is conducted through the blood pump housing to the lubricating oil in the pump drive mechanism chamber. From there the heat is transferred by conduction through the pump components to the blood in the ventricles. The speed reducer input shaft is parallel to the longitudinal axis of the pump.

The pump drive system component materials and weights are listed in Tables 3-1 and 3-2. The principal concern in using several chemically dissimilar metals for making the various blood pump components is potential galvanic corrosion over extended implantation periods. One factor mitigating the degree of this concern is the permeability behavior of the silicone elastomer layer in which the blood pump will be encapsulated. While silicone is permeable to water vapor, oxygen, and nitrogen, available experimental evidence indicates that it will not permit transport of salt ions or polar complexes (especially Cl^- , HCO_3^- , PO_4^{---} , and SO_4^{--}) from the external body fluids to the blood pump interior.* Therefore, an electrolytically conducting solution will not be created to support galvanic corrosion among the pump components. Regarding the alloys themselves, the stainless steels and titanium alloys are near neighbors in the galvanic series for corrosion in most salt solutions, and thus there would be little tendency for electrolytic transport between the two even if an electrolyte were available.

*Animal experimenters at the University of Utah have observed corrosion of materials encased in silicone rubber. This could have been caused by leakage at joints in the covering.

Figure 3-1. Intermediate System Blood Pump Mechanism Design

TABLE 3-1
INTERMEDIATE SYSTEM BLOOD PUMP MATERIALS

<u>Component</u>	<u>Material</u>
Speed Reducer	
Housing	Magnesium alloy
Coupling	Titanium
Pinion	17-4 PH stainless steel
Gear	Delrin AF (acetal resin with teflon fibers)
Pump Housing	
Housing	Magnesium alloy
Roller Track Insert	440C stainless steel
Ventricle	Silastic (dacron reinforced)
Crankshaft Assembly	Titanium
Displacer Cup Scotch Yoke	Magnesium alloy
Yoke Housing Assembly	
Housing	Magnesium alloy
Roller Insert	440C stainless steel
Displacer Cup	Magnesium alloy
Bellows	Titanium
Displacer Cup Scotch Yoke	440C stainless steel
Thermal Insulation	Polystyrene foam
Ball Bearings	440C stainless steel
Ball Bushings	
Ball Retainer	Delrin AF
Balls and Outer Race	440C stainless steel
Yoke Housing and Displacer Cup Rollers	440C stainless steel

TABLE 3-2
INTERMEDIATE SYSTEM BLOOD PUMP WEIGHTS

<u>Component</u>	<u>Weight (gms)</u>
Pump Housing	90
Ventricles	45
Speed Reducer Assembly	60
Crankshaft	59
Displacer Cup Scotch Yoke	39
Yoke Housing	60
Bellows	16
Thermal Insulation	1
Pusher Cups	57
Pump Mechanism Oil	195
Blood	226
	<hr/>
TOTAL	848

The magnesium alloys are at the extreme anodic end of most galvanic series, and their tendency to corrode in the presence of an electrolyte is thus very great. To protect them from corrosion effects in the unlikely event that the blood pump interior fluid were to become electrolytically conductive due to contamination from some unforeseen source, all of the magnesium alloy components must be given a surface anodization treatment and then rigorously protected from being scratched or nicked during subsequent handling and use.

3.1.1 Speed Reducer

The speed reducer built into the wall of the blood pump steps down the pump drive speed from 1800 rpm at the flexible shaft to 120 rpm at the shaft that drives the pump reciprocating mechanism. This is accomplished through a single set of EvoloidTM gears. These gears have a recently patented tooth form that, in a single step, permits a large speed reduction with a very high efficiency. An efficiency of about 95% is expected for the gear set. In addition, the speed reducer incorporates a set of right angle bevel gears at the input side of the reduction gears. These gears permit the input shaft of the speed reducer to be parallel to the axis of the pump and allow a compact coupling of the flexible shaft to the pump.

3.1.2 Pump Mechanism

The output shaft of the speed reducer is connected through a square spline to a crankshaft with three throws. A roller on the center throw engages a Scotch yoke that converts the rotary motion of the crankshaft into a reciprocating motion with one cycle per revolution of the crankshaft. Drive rods on each side of the Scotch yoke are connected to displacement cups which alternately compress and expand dacron reinforced silastic roll socks at each end of the pump. These roll socks serve as the left and right ventricles of the blood pump.

During diastole when the ventricle is expanded, the cylindrical wall of the roll sock in contact with the displacer cup rolls off of the displacer cup and onto the pump housing. During systole when the ventricle is compressed, the cylindrical surface of the roll sock in contact with the pump housing rolls off of the pump housing onto the displacer cup. Because the

ventricle dome is very flexible, the dome will collapse inwardly as required during diastole to provide a ventricle volume that matches the volume of blood that returns to the ventricle. Although the ventricle dome is weak under collapsing pressure, it is very rigid under an internal pressure and very little stretching of the dome occurs during systole. This characteristic permits a high pump volumetric efficiency.

The offsets of the end throws of the crankshaft allow the crankshaft ends to move past the mid-plane of the pump and permit a displacer cup to occupy space required by the opposite displacer cup in the return stroke. This arrangement minimizes the overall pump length required to accommodate a given pump stroke. Rollers on the end throws of the crankshaft engage Scotch yokes built into the ends of a housing that surrounds the displacer cup yoke and cause the housing to reciprocate as the crankshaft rotates. This housing supports linear ball bushings which guide the displacer cup yoke. A bellows secured to the yoke housing and the displacer cup yoke serves as a torsion resisting element that prevents relative motion between these components.

Two sets of rollers on outriggers attached to the yoke housing bear on hardened inserts in the pump housing and prevent the yoke housing from rocking and rotating in the pump housing. The radius of the end throws of the crankshaft was made half as long as the radius of the center throw to cause the yoke housing to travel at the same velocity as the loop connecting the cylindrical portions of the pumping roll socks. With this arrangement, the maximum spacing between the outrigger rollers can be obtained for a given ventricle separation.

To minimize the frictional power losses in the blood pump mechanism, rolling elements are used at all the interfaces where relative motion occurs. The gears, crankshaft and rollers are supported with ball bearings. The displacer cup yoke is guided by ball bushings that have circulating ball races.

The entire drive mechanism chamber is filled with oil. The oil provides lubrication for all the drive components and avoids the need for a compliance bag to accommodate changes in ambient pressure after the pump is sealed. Because most of the air that may remain in the pump drive chamber after it is filled with oil will be bled off before sealing, only a very small volume of air can remain trapped between the ventricles. If the pressure in the ventricles changes from that present at the time of sealing, the expansion or contraction of the volume of gas in the drive chamber will not noticeably affect the ventricles. Therefore, changes in atmospheric pressure will not have any influence on the performance of the blood pump.

Although a specific oil has not been selected for the drive mechanism, several oils appear promising for this application. Preliminary tests of sperm whale oil and petroleum oils with additives indicate that it should be possible to compound an oil that will not react with or permeate through the material selected for the ventricles, and will provide adequate lubrication and acceptable power losses.

3.1.3 Flexible Drive Shaft Assembly

A flexible drive shaft similar to an automobile speedometer cable delivers the mechanical power developed in the thermal converter to the blood pump. The shaft assembly consists of a very flexible core, a special wear resistant teflon guide tube for the core, and a convoluted metal tube around the guide tube. The convoluted metal tube does not significantly reduce the flexibility of the shaft assembly, but it does prevent squeezing of the guide tube on the core and seals off the shaft assembly from body fluids. End fittings that are welded to the ends of the convoluted metal tube and connect the shaft assembly to the thermal converter and the blood pump are sealed with silicone O rings.

The oil in the shaft assembly is sealed off from the oil in the thermal converter crankcase by the magnetic coupling at the thermal converter output shaft. The heat pipe that transports

waste heat from the thermal converter to the blood pump is bundled with the shaft assembly by molding thermal insulation between and around these components.

3.1.4 Pump Drive Mechanism Power Requirements

The power required to drive the blood pump was determined by adding the power losses for the drive mechanism elements to the power inputs specified for the pump ventricles. The drive mechanism power losses were obtained by calculating the bearing losses and estimating the flexible shaft, gearing, and oil churning losses from the results of tests performed with the Phase II bench model pump. A power balance for the blood pump is shown in Table 3-3. As can be seen, with 5.4 watts of mechanical power initially available from the thermal converter, 4.7 watts mechanical output from the drive mechanism powers the ventricles. Thus the overall drive mechanism efficiency is 87%.

3.2 COMPONENT SELECTION AND TRADEOFFS

The length of the Intermediate System blood pump is the same as that of the Phase II bench model pump, but the basic pump body diameter is 0.97 cm larger. This diameter increase resulted from incorporating in the pump body provisions for conducting to the blood in the ventricles waste thermal converter heat transported from the thermal converter to the pump by a heat pipe. In the Phase II bench model, the thermal converter waste heat was rejected by flowing tap water through the thermal converter heat exchanger. The evaluation that led to the choice of a heat pipe for the Intermediate System is presented in Section 3.2.2.

3.2.1 Drive Mechanism Components

Although the Phase II bench model was operated at 900 rpm, it was decided to set the shaft speed for the Intermediate System at the flywheel speed (1800 rpm) and accept a reduced efficiency associated with the higher speed. By running the shaft at flywheel speed, it was possible to eliminate the speed reduction gear set that had been used in the bench model thermal converter.

TABLE 3-3

BLOOD PUMP ENERGY BALANCE - WATTS

	Left Side		Right Side	Total
FROM THERMAL CONVERTER	4.49		0.91	5.4
	0.02	Bearing Friction In Housing	neg*	0.02
	neg*	Bearing Friction In Speed Reducer	neg*	neg*
LOSSES	0.17	Friction In Speed Reducer Gears	0.09	0.26
	0.10	Oil Viscous Loss In Drive	0.10	0.20
	0.11	Friction In Flex Shaft	0.11	0.22
POWER AVAILABLE TO VENTRICLE	4.09		0.61	4.70

*neg < 0.01 watt

In the Intermediate System blood pump, the speed reducer input shaft is parallel to the longitudinal axis of the pump instead of perpendicular as it was in the Phase II bench model. This change was made to permit the flexible drive shaft to be connected to the pump by bending the shaft into a gentle S curve instead of a 90° bend which would have required excessive space in the thoracic cavity. The new orientation of the speed reducer input shaft necessitates the use of a bevel gear set at the input side of the speed reduction gears to retain close coupling of the reduction gears and the reciprocating mechanism crankshaft. A single set of EvoloidTM gears instead of the planetary gear arrangement of the bench model is used to achieve the desired speed reduction. EvoloidTM gears are used because they permit a more compact speed reducer envelope than a planetary gear arrangement.

The components of the drive mechanism that convert rotary motion to reciprocating motion are essentially the same dimensions as those of the Phase II bench model. However, as shown in Table 3-1, most of the components are low density materials, whereas all the bench model components were made of stainless steel. The ventricles and the geometry of the ends of the pump body to which they are attached are the same as they were in the bench model.

3.2.2 Coolant Pump Evaluation

To aid in judging the candidate coolant circulating pumps for the Intermediate System, a decision matrix (shown in Table 3-4) was generated. The matrix aided in reaching a clear engineering judgment that the heat pipe concept is an attractive choice, with the bellows and gear pumps approximately equal as alternatives.

Columns 2 through 5 of Table 3-4 classify the pumps considered and their anticipated performance parameters. Columns 7 through 11 specify the characteristics used in making a comparative judgment among pumps. As can be observed, each of Columns 7 through 11 are split into "a" and "b" divisions. The "a" division provides either a numerical or an engineering judgment assessment of each pump considered for each characteristic. The "a" division

TABLE 3-4

INTERMEDIATE SYSTEM COOLANT PUMP DECISION MATRIX

Col. 1	2	3	4	5	6	7a	7b	8a	8b	9a	9b	10a	10b	11a	11b	12
Number	Class	Type	Specific Speed Range For Good Efficiency	Theoretical Efficiency	Practical Efficiency	Estimated Power Required		Estimated Controlling Dimension		Estimated Line I. D. (2 Lines)		Reliability Ranking		Development Potential		Total Scale Rank
#				(%)	(%)	(watts)	(Scale Rank)	(in.)	(Scale Rank)	(in.)	(Scale Rank)	High, Med., Low	(Scale Rank)	(High, Med., Low)	(Scale Rank)	
1	Turbo	Partial Admission Centrifugal or Pitot	200-400	50	40	0.15	5	1.8	3	0.18	7	High	10	Medium	5	30
2		Vane or Screw Axial	5000-11000	< 50	< 20	> 0.30	1	1.8	3	0.18	7	High	10	Medium	5	26
3	Positive Displacement	Gear	< 500	80	30	0.20	4	0.7	7	0.18	7	High	10	High	10	38
4		Sliding Vane	< 500	80	< 30	> 0.20	3	0.7	7	0.18	7	Medium	5	High	10	32
5		Piston (900 rpm)	< 500	100	40	0.15	5	1.2	4	0.18	7	Medium	5	High	10	31
5a		Bellows (120 rpm)	< 500	100	40	0.15	5	NA	10	0.18	7	Medium	5	High	10	37
6	NA	Heat Pipe	NA	NA	NA	0	10	NA	10	0.18	10	Medium	5	Medium	5	40
SCALE VALUE ASSIGNMENTS																
						none - 10 0.1 6 0.15 5 0.2 4 0.25 3 0.3 2		none 10 1 in. 5 2 in. 2		one line 10 two lines 7		High 10 Medium 5 Low 1		High 10 Medium 5 Low 1		

of each column assessment was then converted to a relative scale rank and entered in the corresponding "b" division of each column. The scale ranks from Columns 7b through 11b were then totaled to give the Total Scale Rank of Column 12. Column 12 then provides a number which ranks the pumps in desirability for Intermediate System artificial heart application. The higher the value, the more desirable is the pump. The scale rank assigned in each "b" column was taken from the auxiliary table of Scale Value Assignments for each of Columns 7 through 11. For example, in Column 7a, the estimated power required by the heat pipe is zero or none. The Scale Rank from the table of Scale Value Assignments for none is 10. This value is entered in Column 7b, Row 6.

The impact of the pumping power required on over-all system performance is clear. In the eighth column, the estimated controlling dimension reflects the impact of the pump size on the over-all system. Thus, the low speed bellows pump rates as high as the heat pipe since it can be incorporated into the blood pump mechanism, and therefore has no impact on over-all system dimensions. In the ninth column, the heat pipe, which does not require a separate return line, ranks higher than all the other concepts. The tenth column is an index of the estimated ease with which the required reliability can be achieved with each concept. The final column, "Development Potential" is an estimate of confidence that all the preceding factors can be met or exceeded in the time available for concept development.

The coolant loop is required to transfer a maximum of 23.5 watts from the engine to the blood pump to be rejected to the blood through the pump diaphragm. The pump housing will be filled with liquid, to provide lubrication to the pump mechanism and to prevent the pump diaphragm from lifting off the pusher cups. Water, which would be the best heat transfer fluid for use, is not desirable as a lubricant, and the stability of water-oil emulsions over a ten year life is questionable. Sperm oil, which has a low enough viscosity to allow for circulation without unduly large flow passages, can provide the lubricity desired. Since sperm oil has a lower specific heat, and a higher viscosity than water, the trade-off between pumping power, re-

required flow passage size and temperature rise of the coolant is much more critical than it would be with water. If it is assumed that the coolant is circulated by an auxiliary mechanical pump rather than heat pipe, the design flow parameters are:

- 7.1 cc/sec ($0.43 \text{ in}^3/\text{sec}$) coolant flow (sperm oil)
- 2.5°C (4.5°F) coolant temperature rise
- 0.082 atm (1.2 psi) pressure drop
- 0.06 watts hydraulic pumping power

These conditions imply that the coolant flow passages shall be the equivalent of two 0.46 cm (0.18 in) I.D. circular tubes each 30.5 cm (1 ft) long. Using these numbers, a pump operating at the shaft speed of 1800 would have a specific speed of about 270. For pumps operating at other speeds, the specific speed would be proportionately higher or lower.

The second and third columns of Table 3-4 show the types of pumps investigated and the specific speed range for maximum efficiency. Depending on the Reynold's number based on the peripheral speed and the flow passage dimensions, the screw pump can be treated either as a vane (propeller) pump, or as a viscous pump. For the conditions under consideration, inertial forces predominate over the viscous forces and the pump operates as a propeller pump. In spite of this observation, an analysis was carried out based on viscous flow, with results not significantly different in terms of size and expected efficiency from information in the literature based on experience with propeller pumps.

In general, for small pumps, the frictional drag forces increase in relation to the pumping power. Therefore, the practical efficiency for all the pumps listed is somewhat lower than the theoretical efficiency. The positive displacement pumps were further derated for various reasons. The gear pump was derated to 30% efficiency based on the experience of Philips with their lube oil pump. The sliding vane pump has even more sliding contact than the gear

pump and therefore was derated somewhat more. Although there is little friction in a bellows-type pump, reliable activation of the check valves on the inlet and outlet lines would require a significant portion of the 1.2 psi pressure differential.

The size estimates for the turbo pumps were based on the required tip speed to produce a 1.2 psi pressure rise. For the positive displacement pumps, a simple estimate of the displacement required per revolution was combined with an estimate of the active volume of the pump as a fraction of the total volume. A heat pipe with a 0.32 cm (1/8 in) I.D. vapor channel is sufficient from a heat transfer point of view. In theory, the required one foot head difference can be accomplished readily using water with an annular wick arrangement. The 0.46 cm (0.18 in) dimension used includes the wick as well as the vapor channel.

4.0 RELIABILITY ANALYSIS

The artificial heart must be designed and developed to meet stringent lifetime and reliability objectives. The careful attention given to lifetime and reliability considerations in the selection of the Stirling mechanical concept and development of devices to date must be enhanced further for the Intermediate System.

Figure 4-1 is a simplified outline showing the integration of reliability into the "design for reliability" process. Activities carried out prior to this effort are enclosed by the dotted lines. The previously carried out Failure Modes and Effects Analyses defined potential failure modes and assessed the criticality of their consequences. Later reliability model and apportionment studies in conjunction with on-going bench testing pinpointed those weak components where improvement is deemed necessary. Together, these previous studies have provided a means of assessing the practicability of achieving the goal of a ten year mean life and have formed the focal point in the continuing "design for reliability" approach by providing a guide for failure studies.

During the reliability analyses of the Intermediate System, the system was designated by four major subsystems for convenience. These are the thermal converter, the flexible shaft, the blood pump drive mechanism, and the converter cooling system.

Earlier reliability studies, including Failure Mode and Effects Analysis (FMEA), apportionment and prediction were made for the principal system components just listed. This study updates these earlier studies in terms of the Intermediate System, taking advantage of this earlier effort, interaction with design and results of testing both on the bench and in the field. For purposes of continuity with previous efforts, the departure point for these studies is the Phase II bench model of the nuclear artificial heart system.

4.1 FAILURE MODE AND EFFECTS ANALYSIS

The updated Failure Model and Effects Analyses of the Intermediate System is summarized in

Figure 4-1. The Design for Reliability Process

Appendix A. From this and earlier reliability and on-going design studies, some recommended design changes were identified for the blood pump drive mechanism and the thermal converter. When applied, these design changes should enhance system reliability through avoidance of known failure-prone mechanisms. Changes from the Phase II bench model conceptually incorporated in the Intermediate System are noted with an asterisk in the summary below.

- *A different speed reduction approach using the EvoloidTM type of gearing can result in a significant reduction in gear mechanism complexity and in the number of bearings required.
- *A fluid-filled pump mechanism approach using a lubricant will allow a hydrodynamic film to protect all contact surfaces including bearings, rollers and gears. This can appreciably extend the useful life of the components expected to experience the most wear and liable to experience random catastrophic failures.
- *Welding the gear box assembly to the housing can avoid the problems surrounding insurance of seal integrity from the purchased part through assembly and actual use.
- Welded junctions and other more positive joining methods can replace a number of bolted and specially keyed assemblies which were needed only to facilitate bench-model disassembly. As there is less need for diagnostic access to each piece-part, the quantities of these less permanent, failure-prone connections can be reduced.
- *Epoxy bonds should not exclusively bear loads for long periods of time. Keying or another mechanical method of joining parts at these junctions should provide for the proper mechanical strength instead.
- Since any bend in the flexible shaft assures rubbing between the metal shaft and its teflon housing, assurance of excellent lubricity is absolutely essential for long life. A fluid-filled shaft may guarantee a significant increase in life if a hydrodynamic film is provided between the surfaces and frictional losses are not significant between the shaft and the fluid. The majority of prime failure modes can be avoided by allowing sufficient clearance between sheath and shaft coil for all reasonable bending positions. This, of course, has to be traded with the ability of the larger diameter shaft assembly to fit in the recipient's body. However, there will be no concern of shaft rubbing or lack of lubrication, two inherent life limiting factors.
- *Eliminate contamination during assembly of thermal converter as well as other principal components. Bench testing results verify this need.

- *Provide for a minimum number of interface connections during implantation to eliminate possible fluid contaminations.
- *To minimize system start-up problems it may be desirable to implant the engine while running. This would require provisions for converter/pump decoupling , preferably remote.

4.2 RELIABILITY MODEL AND APPORTIONMENT

The reliability model was set up on the basis that failure of any component would result in system failure since redundancy is not considered in the reference (bench model) design nor anticipated for the Intermediate System design. This model served the twofold purpose of outlining the reference design for study and provided a basis for further model development. (Some results in terms of potential reliability improvement are given later in this section.)

Since the model is a simple series system of components; i.e., no redundancy, apportionment is straightforward according to the series reliability model,

$$R_S = R_1 \cdot R_2 \cdot R_3 \cdot \dots \cdot R_n$$

where R_S is the system reliability and R_n is the reliability of the individual component.

Table 4-1 shows the breakdown of the Phase II bench model into its major subsystems and components with their corresponding allocated reliabilities. The allocation was accomplished in the following manner: Once the components had been identified, an estimate of their failure rates was obtained using available failure data and where necessary, engineering judgment. These data were combined with an evaluation of the function of the component to arrive at a reliability level for each component and subsystem. It was found that, for the most part, three reliability levels would fairly describe all the components and that, in general, they could be grouped as follows:

- High Reliability - Primarily structural components whose prime time related mode of failure would be fatigue. Components of this kind include housings, crankshafts and connecting rods.

TABLE 4-1
RELIABILITY ALLOCATIONS
(PHASE II BENCH MODEL)

		Qty.	Apportioned Reliability		
Artificial Heart 0.5 (excludes ventricles and Pu-238 Heat Source)	Thermal Converter 0.677	Stirling Engine 0.683	Housing	1	0.999999
			Crank	2	0.999999
			Connecting Rods	6	0.999999
			Fly Wheel	1	0.999999
			Gears	3	0.999
			Bearings	18	0.999
			Hot Finger	1	0.999
			Cylinder	1	0.999
			Piston	1	0.999
			Displacer	1	0.999
			Rotary Seal	2	0.915
			Roll Socks	2	0.915
	Oil Pump 0.995		Housing	1	0.999999
			Filter	1	0.999999
			Gears	2	0.999
			Bearings	4	0.999
	Speed Controller 0.997		Orifice	2	0.999999
			Valve	1	0.999
			Bellows	2	0.999
	Vacuum/Foil Insulation 0.999		1	0.999	
	Blood Pump 0.813		Housing	1	0.999999
			Crank	1	0.999999
			Pusher Cups	2	0.999999
			Platform Yoke	1	0.999999
			Pusher Yoke	1	0.999999
			Gears	4	0.999
Bearings			19	0.999	
Roller Track			2	0.999	
Rollers			4	0.999	
Bellows			2	0.915	
Coupling Mechanism 0.910		Outer Tubing	1	0.999	
		Casing	1	0.999	
		Bearings	2	0.999	
		Shaft	1	0.915	
Cooling System 0.998		Eng. Heat Exch.	1	0.999999	
		Filter	1	0.999999	
		Valves	2	0.999	
System Total		99			

- Intermediate Reliability - Mechanical wear related items such as gears and bearings, and components that operate at high temperature and stress such as the hot finger.
- Low Reliability - Various components which were considered marginal. Among these are the blood pump bellows assembly and the flexible shaft.

For the Phase II study, reliability values of 0.999999 and 0.999 were assigned to those components classified at a high and intermediate level, respectively. Reliability values for the low level components were obtained by solving the model equation given previously. This was found to be 0.915 based on a system reliability of 0.5. The model for this allocation is given in Table 4-1. Since that time, further effort has been extended in the design of the Intermediate System which shows good potential for reliability improvement. These changes include elimination of the lube pump and simplifying the connector housing.

As a result of these design changes the potential for realizing the ten year goal has increased resulting in the easing of the reliability requirements for some critical components. The overall changes reflected in the allocations are shown in Table 4-2. By this stratagem the emphasis does not change, but reliability objectives for the less reliable components is more likely to be achieved.

The numerical reliability goals obtained in this allocation will be used as a requirement for each component and as a guide for future studies. As more definitive data is obtained for these components, revisions to the apportioned values may be expected. Also, during trade studies, reapportionment may be needed to reflect changes in the system configuration.

4.3 COMPONENT DISCUSSION

In the foregoing Section 4.2 the general logic for using three levels of reliability in the initial apportionment was developed. In support of this logic, the following discussion assesses the

TABLE 4-2
RELIABILITY ALLOCATIONS
(INTERMEDIATE SYSTEM)

			Qty.	Apportioned Reliability	
Artificial Heart 0.5 (excludes ventricles and Pu-238 Heat Source)	Thermal Converter 0.565	Stirling Engine 0.569	Housing	1	0.999999
			Crank	2	0.999999
			Connecting Rods	6	0.999999
			Fly Wheel	1	0.999999
			Gears	3	0.999
			Bearings	18	0.998
			Hot Finger	1	0.999
			Cylinder	1	0.999
			Piston	1	0.999
			Displacer	1	0.999
	Screw Seal		1	0.915	
	Bellows		2	0.900	
	Mag. Coupling		1	0.999	
	Speed Controller 0.992	Orifice	2	0.999999	
		Valve	1	0.999	
		Bellows	2	0.999	
		Pump	1	0.995	
	Vacuum/Foil Insulation 0.999		1	0.999	
	Blood Pump 0.971	Bellows	1	0.999	
		Housing	1	0.999999	
		Crank	1	0.999999	
		Pusher Cups	2	0.999999	
		Platform Yoke	1	0.999999	
Pusher Yoke		1	0.999999		
Gears		4	0.999		
Bearings		19	0.999		
Roller Track		2	0.999		
Rollers		4	0.999		
Coupling Mechanism 0.910	Outer Tubing	1	0.999		
	Casing	1	0.999		
	Bearings	2	0.999		
	Shaft	1	0.915		
Cooling System 0.999	Heat Pipe		1	0.999	
System Total			89		

reliability potential of the components according to type and criticality. Aspects which could affect reliability are considered and areas are identified where further development work, or redesign to eliminate or reduce failure effects may be needed.

4.3.1 Housing

There are two principal housings in the system: these are the engine and blood pump housings. The engine housing should present no major design problem except to assure sufficient margin to provide solid distortion free support. Aside from these structural aspects, which should be straightforward, potential corrosion by body fluids is a factor in material selection. For the blood pump housing, dimensional stability is a prime consideration to avoid binding of the yokes because of excessive deflection of the outrigger rollers. Coupled with a need to maintain minimum weight and to prevent corrosion by body fluids, the material selection for this component could be complex. A trade study of materials such as stainless steel, titanium alloys, fiberglass reinforced resins and graphite fiber reinforced resins is recommended. The latter is a rather new material that offers low weight, high modulus and chemical inertness.

The reliability of these housings is expected to be high and the goal of 0.999999 should be achieved.

4.3.2 Crank Shafts

The three crank shafts, two for the engine and one for the blood pump, are well within the technology required. The high reliability goal of 0.999999 should be easily achieved.

4.3.3 Oil Pump

The oil pump in this configuration provides the speed control parameter for the system. Although loading has been lessened, it is still a critical component but the objective allocated at .995 during Phase II is realistic.

4.3.4 Connecting Rods and Flywheel

Same as crank shafts.

4.3.5 Magnetic Coupling

A properly sized coupling becomes a relatively static device subject only to possible long-term degradation. The backlash feature should not be significant and a goal of 0.999 is probably conservative.

4.3.6 Heat Pipe Heat Exchanger

The intermediate design will utilize heat pipe technology, which while relatively new, provides good reliability potential in view of its static nature. Potential problems are associated with manufacture of the end exchanger areas where small clearances must be maintained and with possible fluid contamination presenting a long term operation problem.

These problems of process and compatibility are not beyond state of art and a goal of 0.999 is reasonable.

4.3.7 Orifices

The engine speed controller contains two orifices to meter flow of gas from the working chamber to the buffer volume. With sufficient test data, selection of orifice size can be made which should provide adequate sensitivity to control the engine speed at a high engine efficiency. Achievement of the high reliability goal of 0.999999 is expected.

4.3.8 Gears

There are two sets of gears in the system: one in the engine, and the other in the blood pump. The engine gears time the crank shafts and couple the flywheel to the drive. Those in the blood pump reduce the pump drive speed from 1800 rpm at the flexible shaft to 120 rpm at the crank shaft. Long life gears are obtainable provided gear bending and contact stresses are

controlled. With due regard, therefore, for gear meshing and loads and for rigidity of the supporting systems, i.e., shafts, bearings and housing, achievement of the reliability goal of 0.999 is likely. Tests of the relatively new Evoloid gear design show good promise for performance, and its relative simplicity should enhance meeting this reliability objective.

4.3.9 Bearings

There are two types of bearings in the system: hydrodynamic film bearings used in the engine, and ball bearings used in the coupling mechanism and the blood pump. The engine bearings will utilize advanced design techniques featuring close tolerance shafts and bearing which are self-lubricating and self-pumping, eliminating the need for forced lube pumping. While this design approach eliminates the need for the pump (thereby enhancing reliability) it is expected that it will be more difficult to meet the earlier reliability objective of 0.999. Accordingly the objective has been reduced to 0.998.

In the blood pump, ball bearings are used throughout to minimize frictional losses. The normal design life for ball bearings as defined by the AFBMA standard analysis is considered to be the estimated life which will be exceeded by 90 percent of those tested. The average life is roughly five times this design life. Since 10 percent of the bearings fail before reaching normal life, the bearing normal design life will have to be more than ten years to achieve the reliability level desired. Two possible approaches could be used. One is to carefully design the blood pump bearings for lifetimes sufficiently longer than ten years to achieve the 0.999 reliability level. The other is to simplify the blood pump mechanism to reduce the number of bearings required. The current design requires 19 bearings and if this quantity were reduced, the corresponding reliability requirement would be reduced. With these considerations, achievement of the required lifetime and reliability is expected.

4.3.10 Hot Finger

The hot finger in the engine operates at high temperature and high pressure of the working gas. To minimize conductive heat loss, its wall has been kept thin. Consequently, the

reference design may be marginal because of possible physical effects such as creep over a long period of time. Design changes, such as inclusion of a thermally insulating material as a structural support for the thin wall, may be required to improve this component. By redesign the reliability of this component is expected to satisfy the apportioned goal of 0.999.

4.3.11 Cylinder and Piston

The engine power cylinder and piston seem to be adequate for reliability and lifetime. No problem is expected in achieving the goal of 0.999 for these compinents.

4.3.12 Displacer

The engine displacer operates at high temperature and is subject to the cyclic vibration. Selection of guide ring material is critical to minimize wear which could result in misalignment and increased drag. This does not seem to be a problem and attainment of the 0.999 reliability is expected.

4.3.13 Control Valve and Bellows

The engine speed controller operates by controlled metering the working gas into a buffer volume. The metering valve is actuated by a bellows assembly which is controlled by oil pressure provided by a small pump. Effectiveness of the valve might be impaired by accumulation of dust coming from the piston rings. If this proves to be a problem, a small filter could be inserted to protect the valve. Data on valves and bellows related to this type of subsystem indicate that the 0.999 reliability goal can be achieved.

4.3.14 Engine Seals

The use of screw type shaft seals is currently planned to isolate the flywheel from the crank-case. These seals are not absolute and some leakage may be expected over a ten year period.

If oil gets into the flywheel chamber, severe power loss can result when the flywheel comes in contact with the oil. With this seal and wick/pump addition, buildup of oil is not likely. Further consideration of this important component of the thermal converter will continue. Achievement of the 0.999 is now feasible.

4.3.15 Bellows/Roll Socks

The shaft seals will go through about 3×10^9 cycles during ten years operation. A roll sock, several inches in diameter, has been tested by Philips to 3.8×10^9 cycles without failure. Two small roll socks similar in size to those in the Stirling engine have been tested. One failed after 2.4×10^8 cycles and the other tested was stopped after 1.24×10^9 cycles; the latter did not fail. A continued development program would be required to improve and totally demonstrate lifetime and reliability of this component. Because of these factors along with bench testing at WANL that resulted in roll-sock failures at 100 hours and at 626 hours, bellows were selected for the Intermediate System Converter. Testing and performance evaluation at Philips will provide more data to evaluate the reliability of this component. Earlier reliability evaluation of bellows indicates a ten year reliability objective of .915 may be beyond present state-of-the-art and this must be considered a critical component of the engine.

Since the roll sock failures at WANL have been shown the first case to be caused by contamination, the effect of and eliminating contamination during assembly must be considered before the roll sock concept is eliminated.

4.3.16 Roller and Roller Track

The rollers and their tracks located inside the blood pump are used to stabilize one of the yokes. Except for dimensional control required to prevent misalignment of the yoke, which should be straightforward, no problems are expected in meeting the reliability goal of 0.999.

4.3.17 Pusher Cups

The pusher cups interface directly with the blood pump ventricles, and a key consideration is dimensional control to avoid undue stresses. A positive means of locking the cup to the yoke to prevent radial movement is desirable, otherwise, a twisting and misalignment of the pusher cup and ventricle might result. The achievement of the 0.999999 reliability goal is fully expected.

4.3.18 Yokes

The two yokes of the blood pump transfer the force from the crank shaft to the ventricles. Structural rigidity is a prime concern relative to lifetime and reliability because tight dimensional control is necessary to prevent binding and lockup of the supporting bearings. Outrigger roller and housing interfacial dimensions are important elements to maintaining proper alignment. Nevertheless, high reliability is expected and the goal of 0.999999 should be achieved.

4.3.19 Flexible Shaft

The flexible shaft which transmits power from the thermal converter to the blood pump is perhaps the second most critical item from the standpoint of lifetime and reliability. In ten years, it must operate through 9.4×10^9 cycles. Data from suppliers of standard shafts indicate equivalent lifetimes of six months to one year whereas special shafts for military helicopters have an equivalent life of about one year. No data were found for ten years equivalent operation, although a leading supplier has expressed confidence that modifications can be made to tailor their standard shaft designs to the particular service conditions of the artificial heart system which will provide sufficient design margins to assure ten year life. Among the modifications that have been suggested are to: use a teflon guide tube with a hardened liner; operate continuously in oil; specify a large minimum radius (12 inches) bend; substitute a high endurance super alloy for the standard wire material. A special program to develop this shaft to satisfy the lifetime and reliability goals is required.

4.3.20 Casing

The flexible shaft casing both guides the shaft and can serve as a coolant flow line. Its internal surface is the bearing surface for the flexible shaft and, consequently, must be both wear resistant and flexible. Although long time test data are not available, it is reasonable to expect long life from this component since the coolant fluid and oil will completely lubricate the contact points between the flexible shaft and the casing.

4.3.21 Vacuum Foil Insulation

The vacuum foil insulation package is not a proven ten year technology. The data obtained to date, however, indicate that this lifetime is an achievable goal. None of the materials involved appears to pose an outgassing problem. Vacuum service for long periods of time has been demonstrated in analogous vacuum tube, light bulb and vacuum circuit breaker technologies and, similarly, long term contamination effects in semiconductors have been resolved. Achievement of the reliability goal is expected.

4.4 SUMMARY OF RELIABILITY

In summary, the results of the lifetime and reliability studies during Phase II shows practicability. It appears unlikely that an unforeseen failure mode identified later would preclude the achievement of the goal for the prototype system. This is particularly true since these reliability studies for the conceptual design of the Intermediate System have developed a number of new ways by which the reliability of the nuclear artificial heart system can be improved while still accomplishing other development objectives. Supporting studies, including the summary of critical components as derived by FMEA are given in Appendix A.

APPENDIX A

SUPPORTING LIFETIME AND RELIABILITY ANALYSES

Use of the design for reliability approach during Phase II led to the identification of a set of critical items which is summarized in Table A-1. These critical items for both the thermal converter and the blood pump were identified from failure mode and effects analyses (FMEA). The FMEA for the blood pump mechanism was emphasized during Phase II being responsive to the many new design features when compared with the Phase I assist mechanism. Table A-2 of this appendix includes the latest FMEA details for the blood pump mechanism and the flexible shaft coupling. On the other hand, the design approach of the present thermal converter has remained fundamentally similar to the Phase I thermal converter; therefore, the critical items list in Table A-1 has been updated from the thermal converter FMEA that was done during Phase I.*

*Westinghouse Electric Corporation, Astronuclear Laboratory, "The Evaluation of Practicability of a Radioisotope Thermal Converter for an Artificial Heart Device," Phase I Final Report, WANL-3043-1, November, 1971, USAEC Contract AT(11-1)-3043.

TABLE A-1
FAILURE MODES AND EFFECTS OF CRITICAL ITEMS

A ITEM NO.	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E SYSTEM EFFECT	F QUALIFICATION PROCEDURE	G CORRECTIVE ACTION
A.	<u>Blood Pump Mechanism</u>					
1.	housing surfaces in contact with roller.	wear, brinelling, galling, skidding	loading and travel distance over a long time period, external contaminants, shifting assembly tolerances	load increase, overload	pre-use run-in, before and after surface inspection	lubricant filled mechanism
2.	roller contact surface	wear, brinelling, galling, skidding	loading and travel distance over a long time period, external contaminants, shifting assembly tolerances	load increase, overload	pre-use run-in, before and after surface inspection	lubricant filled mechanism
3.	gears and gear track	binding, wobble, shear and chipping of teeth	wear, stresses, lubrication loss, debris	acoustical noise, load increase, overload	shadowgraph, tooth inspection, pre-use run-in, before and after inspection	lubricant filled mechanism, fewer gears and gear teeth
4.	ball-bearings, ball-bushings	increase in resistance, seizing	movement in seat or shaft, non-uniform load distribution, loss of lubricant, generated or external particles, increase in assembly tolerances with use, shaft indentation by balls in ball-bushings	acoustical noise, load increase, overload	vendor cleanliness, lubrication and torque measurements, pre-use run-in, verification of proper seating, acoustical signature and spin-down time before and after run-in	lubricant filled mechanism, design with minimum number of bearings
5.	"O"-rings	damage, creep, loss of elasticity	long-term compression, shipping, handling, assembly	entry of body fluids, gases, load increase, overload	close vendor control, incoming inspection, assurance of proper seating before and after run-in	welded assembly
6.	fasteners - screws, bolts, pins, retaining rings (snap-on)	not seated, shears, moves out axially, interference, (snap-on) rings lose spring	thread anomaly, dimensions out of tolerance, long-term vibration, long-term stress on snap-rings, assembly stress		Q. C. inspection for thread anomalies, dimensions and cleanliness, torquing procedure and seating verification before and after run-in	use of "loktite, " "nylock" or similar locking feature, more positive and permanent alternate ways to fasten
7.	epoxy	shear at bond	processing anomaly, torsional stress over long time period	loss of linkage between source and load	periodic batch tests need to assume chemical integrity of epoxy, close control of bonded surfaces, non-destructive force applied to test integrity of bond	avoid reliance on shear properties of epoxy for transfer of mechanical loads. use mechanical keying to transfer load use epoxy to hold an item into position only
8.	E. B. welds	fracture	processing anomaly	loss of linkage between source and load	check integrity by x-ray, radiograph or dye penetrant. non-destructive test of weld	

TABLE A-1 (Continued)
FAILURE MODES AND EFFECTS OF CRITICAL ITEMS

A ITEM NO	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E SYSTEM EFFECT	F QUALIFICATION PROCEDURE	G CORRECTIVE ACTION
9.	peened components	fracture, tolerance too low or too high, fragments of material removed, deformation of material	restricted work space, subjective process control, irreversibility	increase in load, over-load	close check for debris and damage to neighboring items	use pinning or bolting, welding, etc
10.	pumping roll socks	abrasion, puncture, blood release into mechanism	pusher cup rubbing bladder over period of time, sharp splinters or debris on dome or lip edge	recipient hazard	close check of pusher dome cleanliness and freedom from sharp splinters or pits similar check of housing lip edge	accelerated life tests of dome to silastic bladder interface
11.	pusher cup	interference with inner housing	binding of cup edge with channel cut in housing to accept edge tilted cup, tolerances too close	increase in load, over-load	check for interference before and after run-in	assure channel of adequate width
Flexible Shaft Assembly						
1	shaft	shaft end jumps out of receptacle	transient pull along shaft axis	load is lost	pre-use run-in at critical bend position. before-after resistance measurements perform life verification test.	pinning of shaft end. widening of sheath, if possible, to avoid contact with shaft, and need for shaft lubrication
		shaft end spins in receptacle	rounding of square cross-section hole edges and shaft edges			
		shaft abrades sheath at contact points	wear over long time period. loss of lubricant	increase in load, recipient hazard		
		fatigue failure shaft core	excessive loading or kinking of shaft	load is lost		
Stirling Engine						
1	seals	gases leak from seal at heat exchanger or piston	pressure cycles with time	degraded source, loss of source power	note 1	replace with bellows
		oil leaks from rollsock seal	oil pressure over time			
2	bearings	increase in resistance, seizing	movement in seat or shaft, non-uniform load distribution, generated or external particles, increase in assembly tolerances with use	degraded source, loss of power	note 1	design oil immersed, utilizing life extending hydrodynamic, captive film
3	fasteners	not seated, shears, moves out axially, interference	thread anomaly, vibration, assembly stress	loss of source power (upon interference)	note 1	(same as A6)

note 1 - to be determined by vendor and approved by -

TABLE A-1 (Continued)
FAILURE MODES AND EFFECTS OF CRITICAL ITEMS

A ITEM NO	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E SYSTEM EFFECT	F QUALIFICATION PROCEDURE	G CORRECTIVE ACTION
4.	power piston, displacer piston	fracture	stress, temperature and time	degraded source, loss of source power	note 1	note 1
		hang-up due to high friction				
5.	gears	binding, wobble, shear and chipping of teeth	wear, stresses, debris	degraded source, loss of source power	note 1	present design oil immersed, utilizing life extending hydrodynamic film
6.	control bellows	fracture, leak	fatigue over long term cycling	loss of source power	note 1	note 1
7.	magnetic coupling engine to transmission	decouple	load transient	loss of pump power	verify decoupling torque	design mod. presently underway to change to direct coupling with screw type seal
		Hunt	varying load	non-uniform pulse		
8.	insulation	vacuum leakage	weld failure accidental puncture	increased losses, reduced efficiency	Manufacturing NDT, QC	minimize welds, provide redundant QC
		layer welding	separator deterioration	increased losses, reduced efficiency	Manufacturing NDT, QC	optimize separator matrix, application methods
		outgassing	contamination	same	materials compatibility verification	provide getters
D. Coolant System						
1.	heat pipe	reduced heat transfer	fluid contamination	reduced efficiency, power to pump	verify longtime fluid/material compatibility	prevent contamination at installation

note 1 - to be determined by vendor and approved by

Failure Modes and Effects Analyses (FMEA) For The Blood Pump Mechanism

Table A-2 summarizes an analysis which shows conceivable ways (modes) that each assembly piece/part can independently fail, the probable cause and the local and system effects when the failure event occurs. It is an orderly accounting procedure which can be used:

- To pinpoint those items which can be improved or eliminated by corrective design procedures.
- To assess parts/materials specification and procedure coverage in selection, test and fabrication phases.
- In the preparation of troubleshooting guides for problem analysis.
- To determine the critical reliability path for the prediction math model.
- To indicate the relative unreliability and the relative criticality when comparing piece/parts.

Description for Table A-2

Column A - Item Numbers

General reference number of a piece-part item.

Column B - Part Designations

Item generic and/or functional name.

Column C - Failure Modes

Possible, although perhaps not all very probable, independent ways in which a piece-part could fail. (Some selected multiple failure combinations which could lead to serious system consequences are also included.)

Column D - Failure Causes

All direct causes of each failure mode indicated in Column C.

Column E – System Effects

Effects of piece-part failure modes on the overall system.

Column G – Item Quantity

The quantities of similar piece-parts used.

Column H – System Criticality

Degree of seriousness to the system of a piece-part failure mode. Four categories are used:

- (1) Abrupt random change in performance to a level significantly below specified limits.
- (2) Fast degradation with time. Total reduction in performance in a short period of time could be significant.
- (3) Smooth degradation with time. Total reduction in performance over a long period of time could be significant.
- (4) Annoyance or warning level of incipient failure.

Column I – Notes

Reference to discussions of an item in sections that follow.

TABLE A-2
FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

Blood Pump Mechanism

A ITEM NO	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E NEXT ASSEMBLY EFFECT	F SYSTEM EFFECT	G ITEM QUANTITY	H CRITICALITY TO SYSTEM	I NOTES
1.	Housing Assembly AT11 303 SS (11), and insert (roller track) (11) AT11 440C SS	fractures	processing, test and usage stresses	entry of body fluid or gas	load increase, overload, stall	1	1, 2, 3	
		buckling or distortion	usage stresses	increase in loading of gears and bearings	load increase		2, 3	
		wear, brinelling, galling at roller contact surfaces	loading on contact surfaces over long time periods	vibration, rolling resistance increase	acoustical noise, load increase		2, 3, 4	
		bolts not seated in gear box or bearing retainer	hole too small, thread damage or dirt	entry of body fluid or gas	"O"-ring prevents entry		—	
				vibration	acoustical noise, load increase		2, 3	
		body fluids, gases enter bladder junction	mechanical seal insufficient	entry of body fluid or gas	overload, stall		1, 2, 3	
2	Housing, top and bottom halves, (1), (2) (yoke) AT11 303 SS	housing to silastic junction separation	creep of silastic under tension and time	degraded operation of upper or lower bladder	recipient hazard	2	1	
			separation stresses during strokes					
		fretting at interface of bushing and bore hole	rocking induced by uneven stresses on bushing by shaft	vibration at shaft, binding of bushing	acoustical noise, load increase, overload, stall		1, 2, 3, 4	
			wear of guide wheels					
		fractures	processing	none expected over usage period picked up in assembly	none expected over usage period		—	
		binding of cup channel to pusher cup edges	insufficient clearance or bending of cup edge	interference	acoustical noise, load increase		2, 3, 4	

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TABLE A-2 (Continued)
FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

BLOOD PUMP MECHANISM

A ITEM NO	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E NEXT ASSEMBLY EFFECT	F SYSTEM EFFECT	G ITEM QUANTITY	H CRITICALITY TO SYSTEM	I NOTES
3	Insert, window (yoke housing) (4) ATSI 440C SS Dowel pin (3) ATSI 303 SS Allen nut 40NF, COML SS	wobble, fretting of contact surfaces	loose screw, surfaces not flush with housing	vibration	acoustical noise, increase in load	2	2, 3, 4	
				accelerated wear on roller				
		wear, galling of roller contact surface	usage stress	accelerated wear on roller	increase in load, overload, stall			
		improper positioning or does not seat	dowel pin dimensions in error	none - can be corrected in assembly	none			
			hole too small, screw or nut too large, damaged threads	none - can be corrected in assembly	none			
			screw or nut loosens	negligible because of nylok	none			
4.	Scotch Yoke (8) ATSI 440C SS	wear, brinelling, galling of inner window track, and shaft surface which contacts bushing balls	camshaft alignment	roller wear and resistance increase, skidding, long term degradation of Thompson ball-bushing	acoustical noise, increase in load, overload, stall	1	1, 2, 3, 4	
			wear of balls, looseness in track, non-uniform stress distribution on balls in Thompson ball-bushing					
		pusher cup tapped hole anomaly, does not seat	hole too small, thread damage, particles	pusher cup not fully seated, can be corrected in assembly	none			
5.	Pusher Cup Assembly (10) ATSI 303 SS includes 1 dome 1 dowel pin 3 roller pins ATSI 420 SS	loose stud	stud loosens under forces of strokes, thread anomaly, too small in diameter	loosening of cup, freeing of cup from stroke	upper or lower pumping roll sock not compressed	2	1	
		dome to stud edge fracture	edge stresses from forces on dome not normal to stud					
		silastic damage	silastic motion relative to dome surface, during compression, across metal chip, or protrusion	blood release into mechanism or oil into blood.	recipient hazard			
			sharpness of metal edge where silastic rim is inserted					

TABLE A-2 (Continued)
FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

BLOOD PUMP MECHANISM								
A ITEM NO	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E NEXT ASSEMBLY EFFECT	F SYSTEM EFFECT	G ITEM QUANTITY	H CRITICALITY TO SYSTEM	I NOTES
5.	(continued)	silastic rim slippage from dome	long term pushing cycles	degraded operation of upper or lower pumping roll sock	recipient hazard		1	
			interference of rim edge at housing channel, loss of pin					
6.	Bearing Retainer (9) A1S1 303 SS	movement of outer race, rocking of outer race, fretting of bore hole	bore too large, camshaft section not square	gross conditions are correctable at assembly	none expected	1	—	
		retainer not seated	screw hole anomaly				3	
			shift in screw position	bearing degradation	increase in load		1, 2, 3	
		"O"-ring loss of elasticity, creep	long term compression	entry of body gases, fluids	load increase, overload, stall		—	
		damaged "O"-ring	shipping, handling	preventable by close Q.C.	none expected		—	
7.	Gear Housing (12) A1S1 303 SS	fractures	processing, test and usage stresses	entry of body fluid or gas	load increase, overload, stall	1	1, 2, 3	
		(Refer to 6C and 6D for "O"-ring modes.)					1, 2, 3	
8.	Gear Ring (13) (moving) A1S1 303 SS	interference between rings	degrading clearance with time, debris	rubbing	acoustical noise, increased load, overload, stall	2	1, 2, 3, 4	
	Gear Ring (18) (stationary) A1S1 303 SS	gear binding	ring teeth too small, ring teeth anomaly, debris in teeth (from peening)	vibration, increase in stress				
9.	Gear Housing (15) Screw A1S1 303 SS	loosens	vibration	increased load on gears/bearings	acoustical noise, increase in load, overload, stall	4	1, 2, 3, 4	
		not seated	thread anomaly, diameter too wide	none - can be corrected in assembly	none expected		—	
10.	Gear Pin (14) A1S1 303 SS	damage	peening	loose debris in mechanism, binding	acoustical noise, increase in load, overload, stall	3	1, 2, 3, 4	
11.	Spacer (16), (17) A1S1 303 SS	none significant				2	—	

TABLE A-2 (Continued)
FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

A ITEM NO.	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E NEXT ASSEMBLY EFFECT	F SYSTEM EFFECT	G ITEM QUANTITY	H CRITICALITY TO SYSTEM	I NOTES
12.	Gear (large) (19) Debrin AF	wear, sticking, binding, tooth chipping	lubrication loss, debris, long-term use	chatter, sticking	load increase, overload, stall	3	1, 2, 3, 4	
		shear of epoxy to metal bushing bond	torsional stresses on plastic to metal bonded interface	slipping transmission of power or loss of load	mechanism free from power source		1	
13.	Bushings (mate to (19), large gear) A1S1 303 SS	fretting, galling of bore	race movement against bore over long time period	increase in bearing resis- tance not serious if tolerances closely con- trolled	acoustic noise, increase in load	1	2, 3, 4	
		(Refer to 12B for epoxy bond mode)					1	
14.	Gear (pinion) (20) A1S1 303	rubbing	axial slip due to set-screw slot wear	interference with square end of crankshaft	acoustic noise, increase in load	1	2, 3, 4	
		wear, sticking, binding, tooth chipping	lubrication loss, debris, long-term use	chatter, sticking	acoustic noise, load increase, overload, stall		1, 2, 3, 4	
		increase in bearing resistance	fretting, galling of shaft over long time period	not serious if tolerances clearly controlled	acoustic noise, increase in load		2, 3, 4	
15.	Shaft Extension (22) A1S1 303	set screw not seated in pinion shaft	screw too large, hole too small, thread anomaly	none - can be corrected in assembly	none	1	—	
		set screw moves outward and rubs housing	vibration over long term use	interference with housing, jamming, allows pinion gear to interfere with crankshaft	acoustic noise, increase in load, overload, stall		1, 2, 3, 4	
16.	Bushings (outer spacer of pinion shaft bearings) (21) A1S1 303 (inner) spacer (25) A1S1 303	fretting, galling of housing	race movement against bore over long time period	increase in bearing resistance not serious if tolerances closely con- trolled	acoustic noise, increase in load	2	2, 3, 4	

TABLE A-2 (Continued)
FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

A ITEM NO.	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E NEXT ASSEMBLY EFFECT	F SYSTEM EFFECT	G ITEM QUANTITY	H CRITICALITY TO SYSTEM	I NOTES
17.	Roller Assembly (narrow wheel) (27) ATS1 440C	shear of epoxy junction between the 2 wheel halves	epoxy processing usage stresses	rocking, vibration of mechanism	acoustical noise, load increase, overload, stall	2	1, 2, 3, 4	
		shear of epoxy bond be- tween wheel and bearing	epoxy processing usage stresses	increased bearing wear	increase in load		2, 3, 4	
		contact surface wear, galling, brinelling, skidding	loading on contact sur- faces over long time periods, vibration, rocking	vibration, rolling resistance increase	acoustical noise, load increase, overload, stall		1, 2, 3, 4	
18.	Roller (barrel-wheel) (28) ATS1 440C	contact surface wear, galling, brinelling, skidding	loading on contact sur- faces over long time periods, vibration, rocking	vibration, rolling resistance increase	acoustical noise, load increase, overload, stall	2	1, 2, 3, 4	
19.	Shaft (both wheels) (29), (30) ATS1 440C	fracture at neck corners (2) which accommodate snap-washers	processing	none - can be corrected in assembly	none	4	—	
20.	Retaining Rings (41) (snap washers) ATS1 420 SS	loosens, falls off shaft neck	loses spring with time	free ring piece can inter- fere with mechanism and bind	acoustical noise, increased load, overload, stall	8	1, 2, 3, 4	
			inherent fracture					
			vibration					
21.	Retainer (31)	bearing overhang fracture	peening operation	loose bearing, vibration, seizure	acoustical noise, increased load, overload, stall	1	1, 2, 3, 4	
		loose fragment in gear box						
22.	Linear Bearing (Thompson ball bushing) (26)	increase in resistance, seizure	non-uniform load distribu- tion	shaft sticking, binding	acoustical noise, increase in load, overload, stall	2	1, 2, 3, 4	
			bearing piece part failure over long term stress					
			loss of lubricant					
			ball to shaft contact sur- face indentation					
			generated or external parti- cles or contaminants					

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TABLE A-2 (Continued)
FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

A ITEM NO.	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E NEXT ASSEMBLY EFFECT	F SYSTEM EFFECT	G ITEM QUANTITY	H CRITICALITY TO SYSTEM	I NOTES
23.	Bellows Assembly (32) Inconel X-750	shear	torsional stress, fatigue from open-close cycles of strokes	increased friction at fractures	acoustical noise, increase in load, overload, stall	1	1, 2, 3, 4	
24.	Crankshaft Assembly (33) AISI 303	fracture of shaft	E-B weld failure	no torque transmitted	load is lost	8 E-B welds	1	
25.	Ball Bearings (35) through (40)	increase in resistance, seizure	movement in seat non-uniform load distribu- tion bearing piece-part failure over long term stress loss of lubricant generated or external particles or contaminants increase in assembly tolerances with use.	resistance to motion, binds, vibrates	acoustical noise, load increase, overload, stall	22	1, 2, 3, 4	

TABLE A-2 (Continued)
FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

Flexible Shaft Assembly

A ITEM NO.	B PART DESIGNATION	C FAILURE MODE	D FAILURE CAUSE	E NEXT ASSEMBLY EFFECT	F SYSTEM EFFECT	G ITEM QUANTITY	H CRITICALITY TO SYSTEM	I NOTES
1.	Flexible Shaft	distortion, elongation of shaft coil	stress hysteresis at bends in shaft	varying load on driving source	increase in load, variance of control system response	1	2, 3	
			load impulses					
		shaft end jumps out of hole	pull along axis due to 1.a above	pump mechanism loses drive	load is lost		1	
		abrasion of shaft coil surface by sheath—end guides, binding	occasional rubbing as shaft is bent	driving source is loaded	increase in load, overload, stall		1	
		abrasion of sheath by shaft	bends in shaft	wear-through by shaft over long time period	recipient hazard		1	
		loss of shaft lubricity	migration due to motion and time	significant load on driving source	recipient hazard, increase in load		1, 2, 3	
				increased abrasion rate and wear of sheath				

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APPENDIX B

INTEGRAL ISOTOPE CAPSULE/HEAT EXCHANGER DESIGN STUDY

In the bench model and IVBM thermal converters, there is a gap between the hot side heat exchanger (above the regenerator) and the heat source, and a conduction sleeve is provided to conduct heat to the heat exchanger and then radially inward. To eliminate this requirement on the Intermediate System thermal converter, it has been suggested that the heat exchanger be made an integral part of the isotope capsule, and the conduction path be made axial rather than radial. Figure B-1 shows the proposed heat exchanger/capsule schematically. The capsule dimensions were estimated to be 3.66 cm (1.44 in.) O.D. by 1.88 cm (0.74 in.) long to provide 27 watts of thermal power. The outer clad was assumed to be 0.015 in. thick platinum as in the Phase II capsule.

The heat exchanger is a ring 3.56 cm O. D., 2.80 cm I. D., with the heat transfer area provided by 30 radial slits. The length is proportional to the width of the slits, and may vary between 1 cm with 0.03 cm slits to 0.5 cm with 0.015 cm slits depending upon the feasibility of machining the slits. A good material for the heat exchanger from a heat transfer point of view is phosphor bronze ($k \approx 120 \text{ BTU/hr-ft-}^{\circ}\text{F}$). Platinum ($k \approx 40 \text{ BTU/hr-ft-}^{\circ}\text{F}$) was also considered, in case there is a compatibility problem with the bronze or a required braze material. The fin effectiveness was found to be 0.95 for bronze and 0.87 for platinum using the long heater, and 0.98 and 0.93, respectively, for the short heater.

Assuming a gas inlet temperature of 1000 K (1340°F), peak capsule surface temperatures were calculated for the following cases.

- 1) Uniform heat flux to the clad
- 2) Constant heat transfer coefficient to the clad with an isothermal strength member
- 3) Good contact between an isothermal strength member and the upper surface of the clad with constant heat transfer coefficient to the remaining portions of the clad.

Figure B-1. Capsule and Heat Exchanger

In cases 2) and 3) the heat transfer coefficient was assumed to be $5.5 \text{ BTU/hr-ft}^2\text{-}^\circ\text{F}$, based on radiation at 1000 K with an emissivity of 0.1.

The worst case was case 3). Using a heat exchanger effectiveness of 0.87, the peak capsule temperature calculated was 1716°F . The most optimistic case (case 2) resulted in peak temperatures 61°F lower. Improved heat exchanger effectiveness would further reduce these temperatures by about 7°F . Based on these numbers, the concept appears attractive from a thermal point of view. Problems of assembly, mechanical design to assure properly directed gas flow, capsule venting, etc. remain to be investigated before the concept of combining the heat source and the heat exchanger can receive serious attention.

Even if it should prove impractical to manufacture an integral heat source/heat exchanger, the heavy conduction walls could be eliminated if the capsule were brazed or otherwise held in intimate contact with the top closure of the hot finger.

APPENDIX C

EVALUATION OF VARIABLE SPEED BLOOD PUMP OPERATION

An analytical study of operating the pump with variable speed was performed with two objectives: (1) Reduce the pump size required to achieve 12 liters/minute flow, and (2) improve cardiac output/venous pressure characteristics. Based on a simplified analysis of pump performance with speed, it was concluded that variable speed operation would be of little utility in improving system performance. The analytical results indicated that variable speed operation would allow the use of a slightly smaller pump if the pump characteristics could be significantly improved over present technology.

The analytical model of the pump used parameters adjusted to match the observed bench model pump performance at 110 and 130 beats per minute. Calculations were made with this model to predict the performance at higher and lower speeds. In the model, the valve leakage into the pump from the aorta during diastole was assumed to be at a constant rate, as was the leakage out of the pump into the veins during systole. In addition, the back flow that occurs during the closing of each valve was assumed to be a constant volume of blood per beat. These assumptions concerning valve action should cause the model to predict somewhat higher flow that could actually be achieved at a given filling pressure. At high speeds, there is a tendency for the valves to bounce, decreasing the net flow rate below that predicted. At low speeds, the hydrodynamic forces closing the valves are reduced, causing sluggish action, and again reducing the net flow.

Figure C-1 shows the predicted performance for the Phase II bench model pump. As can be seen, increasing the speed from 130 to 170 beats per minute reduces the venous pressure required to achieve twelve l/minute flows by only about 2.5 mm kg. Further increases in speed will yield no further reduction in pressure. Operation at lower than design speeds will generally increase the filling pressure required to achieve a given cardiac output. By making speed a function of venous pressure, characteristic curves as shown by the dashed lines on Figure C-1

could be achieved. While these steepen the cardiac output curve, the pressure required for a given flow is generally higher. Figure C-2 shows the effect of reducing the displacement of the pump from 111 to 100 cc while maintaining the same flow parameters and valves as the presently available pump. For every pump speed, the flow obtained at a given pressure has been reduced. Since cardiac output curve for the 111 cc pump is at best marginal, clearly a simple reduction in pump size is unacceptable.

Figures C-3 and C-4 show the effects of changing various flow parameters at speeds of 130 and 110 beats per minute, respectively. In these figures the curves labeled (1) are representative of the present pump. The pumps displace 111 cc, and the valves are assumed to be the same as for the present pump. The maximum flow achieved for each pump is set by the valve performance. Improvements in the valves would have the effect of shifting the entire set of curves upward. The parameter K represents the spring constant of the compliant portions of the pump, and has the units of mm Hg/cc. The parameter I is a measure of the inertia of the fluid entering the pump and has the units mm Hg/(cc/sec²), while F is a frictional loss term with the units mm Hg/(cc/sec)². By examining Figure C-3, it can be seen that reducing the friction term tends to shift the curve slightly to the left, increasing the flow somewhat, but not a great amount. Decreasing the inertia term moves the flow curve significantly to the left, producing significantly higher flows for a given pressure, and increasing the slope somewhat. Curves (3) and (4) achieve maximum flow at quite reasonable pressures, but have higher flow than desired at low pressures. Decreasing the stiffness of the compliant portion of the pump produces curve (5) which appears to match the physiological requirements quite well.

Comparisons between Figures C-3 and C-4, indicate that there is little change in flow with speed in the low pressure region for any given pump while low speeds limit the maximum flow attainable. It appears, therefore, that the use of variable speeds will not materially help in improving the cardiac output characteristics of the pump. The maximum flow which can be achieved by a given pump is set by the pump size, speed, and the performance of the valves used. The venous pressure at which the maximum flow is achieved is primarily a function of

Figure C-1. Cardiac Output as a Function of Venous Pressure and Speed
for Phase II Bench Model Pump

Figure C-2. Cardiac Output as a Function of Venous Pressure and Speed
for 100 cc Pump

Figure C-3. Effect of Variation of Flow Parameters on Performance for
111 cc Pump at 130 B/M

Figure C-4. Effect of Variation of Flow Parameters on Performance for 111 cc Pump at 110 B/M

the inertia of the fluid entering the pump, with flow friction in the inlet providing a relatively minor contribution. The flow at lower inlet pressures is primarily a function of inertia and the stiffness of the compliant portions of the pump. The study has indicated then that variable speed operation would offer little advantage in terms of pump response to physiological demands.

The stiffness parameter K is a function of thickness, the size, the shape, and the material forming the pump domes. In general, K can be reduced by making the dome thinner in relation to its diameter. More flexible materials will reduce the value of K . It is difficult to relate the shape of the dome directly to the value of K since this requires detailed analysis of the particular shape involved. As the collapse of the dome during filling is essentially a buckling process, analysis of the undeformed shape will yield little information.

The physical interpretation of the inertial and friction parameters (I and F) can best be explained by briefly outlining the derivation of the analysis used in this study.

For one dimensional, frictionless flow of an incompressible fluid, the axial pressure gradient can be related to the flow rate by:

$$\frac{\ddot{Q}}{A} + \frac{1}{2} \dot{Q}^2 \frac{\partial}{\partial z} \left[\frac{1}{A^2} \right] = - \frac{g}{\rho} - \frac{\partial P}{\partial z} \quad \text{Eq. (C-1)}$$

where

$\dot{Q}$	=	instantaneous flow rate
$\ddot{Q}$	=	rate of change of flow rate
A	=	cross sectional area of flow channel
z	=	axial distance along channel
P	=	pressure
ρ	=	density of fluid
g	=	acceleration due to gravity

$\dot{Q}$ and $\ddot{Q}$ are independent of the axial distance along the tube, as the fluid is incompressible. Therefore, Equation (C-1) can immediately be integrated along the length yielding

$$\ddot{Q} \int_0^L \frac{dz}{A(z)} + \frac{1}{2} \dot{Q}^2 \left[\frac{1}{A(L)^2} - \frac{1}{A(0)^2} \right] = g/\rho \left[P(0) - P(L) \right] \quad \text{Eq. (C-2)}$$

multiplying though by ρ/g , the coefficient of $\ddot{Q}$ is a function of geometry and the properties of the fluid only.

$$I = \rho/g \int_0^L \frac{dz}{A(z)} \quad \text{Eq. (C-3)}$$

In this expression, the cross sectional area A can be only a function of the distance z .

In general, the losses in an expansion are high, therefore, the second term can be represented by:

$$F = \rho/g \frac{C}{A_{\min}^2} \quad \text{Eq. (C-4)}$$

Where $A_{\min}$ is the minimum cross sectional area of the tube, and C is a constant. In general, C will have a value ranging from 0.2 for very carefully designed diffusers to something greater than 1.

Equation (C-1) has now been reduced to an ordinary differential equation in time:

$$I \ddot{Q} + \frac{1}{2} F \dot{Q}^2 = P_v - P_p \quad \text{Eq. (C-5)}$$

Where P_p is the pressure in the ventricle during filling, and P_v is the venous return pressure (assumed constant through diastole). The pressure in the ventricle is given by:

$$P_p = K \left[Q + Q_l - \frac{V_o}{2} (1 - \cos \omega t) \right] \quad \text{Eq. (C-6)}$$

In Equation (C-6), K represents the stiffness of the pump, Q_l is the volume of blood leaking through the valves, and V_o is the pump stroke volume. Equations (C-5) and (C-6) are combined to compute the blood flow into the pump during diastole. Q is assumed linear with time, and Q is assumed zero until time t_o , when P_p as defined in Equation (C-6) goes negative. With the boundary conditions that Q and Q_l are zero at time, t_o , Equation (C-5) is integrated numerically until P_p again goes positive. The value of Q , minus a constant term representing the loss as the intake valve closes, and a second constant rate leak during systole gives the net quantity of fluid pumped per stroke. The parameters, F , I , and K , as well as the valve leakage were adjusted to obtain the best possible fit with the data presented in Reference (*) for pump speeds of 110 and 130 beats per minute, to simulate the present pump. Values of F , I , and K for this case are shown as case 1 in Figures C-3 and C-4. The leakage terms which gave a best fit were:

$$\begin{aligned} \dot{Q}_l &= 50 \text{ cc/sec during diastole} \\ \dot{Q}_l &= 10 \text{ cc/sec during systole} \\ Q_l &= 0.0 \text{ for the valve closing term} \end{aligned}$$

Reference (*):

D. K. Backman, F. M. Donovan, G. Sandquist, W. J. Kolff, "The Design and Evaluation of Ventricles for the AEC Artificial Heart Nuclear Power Source." American Society for Artificial Internal Organs, 19, 542 (1973).

The values of F and I obtained for a best fit are considerably higher than expected from measurements of the pump and connecting tubing. The reason for this discrepancy is not clear. In order to reduce the value of these parameters, the inlet flow path must be examined in detail for flow restrictions which are not immediately apparent. The equations listed are based on one dimensional flow and for abrupt changes in area, they are not strictly true. The friction terms (as expressed in Equation (C-4)) is equivalent to the loss through an abrupt change in area when C is 1. to 1.5. In evaluating the inertia term from Equation (C-3), the presence of a jet of finite length downstream of an orifice must be considered.

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