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**EVALUATION OF PRACTICABILITY OF A RADIOISOTOPE
THERMAL CONVERTER FOR AN ARTIFICIAL HEART DEVICE.
PHASE II. FINAL REPORT**

September 15, 1973

Astronuclear Laboratory
Westinghouse Electric Corporation
Pittsburgh, Pennsylvania

MASTER

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THE EVALUATION OF PRACTICABILITY
OF A RADIOISOTOPE THERMAL CONVERTER
FOR AN
ARTIFICIAL HEART DEVICE

PHASE II - FINAL REPORT

By

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Prepared for

UNITED STATES ATOMIC ENERGY COMMISSION
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ABSTRACT

This report documents the results of Phase II of a continuing program toward the development of a total artificial heart system in which thermal energy is supplied by the decay of plutonium-238. In Phase I, many possible systems were evaluated and a Stirling-mechanical system concept was selected for further development and evaluation. The objective of Phase II was the assessment of the practicability of developing a fully implantable version of that system.

Practicability criteria are formulated within five major categories: isotope inventory and environmental aspects; implantation factors; performance; lifetime and reliability; and, costs. The parametric, design and experimental studies toward refinements of components and systems designs and the confirmation of design principles by the successful operation of a bench model system are described. The operating experience, test data and design studies are used as bases for identification of further development toward satisfaction of the practicability criteria and for estimation of the characteristics of a fully developed nuclear powered artificial heart.

It is concluded that a system comprised of a Stirling cycle thermal energy converter directly coupled to a mechanical blood pump drive can be developed to meet the practicability criteria for each of the five categories established.

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The overall responsibility for this study was at the Astronuclear Laboratory. Its execution involved the cooperative effort of many organizations both within and without Westinghouse.

The Philips Laboratories, Division of North American Philips Corporation, under subcontract to Westinghouse, carried out design studies, bench model engine construction, practicability assessment, and component development of the Stirling engine portions of this effort.

The Westinghouse Research Laboratories provided support in the area of antifriction bearings and lubricant selection and testing.

The Sterling Instrument Division of Designatronics built the Westinghouse-designed blood pump drive mechanisms for the bench models.

Thermo Electron Corporation fabricated the bench model thermal converter thermal insulation packages to Westinghouse design specifications.

Hittman Associates, Incorporated provided support in the initial preparation of the bench model thermal insulation specifications and in thermal insulation parametric studies.

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1.0 INTRODUCTION AND SUMMARY

This document reports the results of Phase II of a two-phase study. The objective of the program has been to assess the practicability of developing a fully implantable nuclear powered total artificial heart, powered by the thermal energy from the decay of plutonium-238 and having a minimum weight and volume and a minimum life of ten years. Phase I of this study has been reported previously.* During Phase I many possible nuclear artificial heart systems were studied. From these, during Phase I, a Stirling-mechanical system concept was selected for further evaluation during Phase II. The purpose of Phase II has been to carry out a theoretical and experimental verification of the practicability of the Stirling-mechanical system concept.

1.1 PHASE II APPROACH

Work carried out during Phase II consisted of: 1) design and parametric studies of the Stirling-mechanical system concept, 2) development of system components, 3) design, fabrication and tests of a bench model of the Stirling-mechanical system to confirm design principals and practices, 4) studies to establish criteria for the practicability of the nuclear-powered artificial heart, 5) estimation of the characteristics of a prototype Stirling-mechanical system, and 6) comparison of this prototype against the nuclear-powered artificial heart practicability criteria. Those portions of this work done on the Stirling engine component of the Stirling-mechanical system were carried out, under subcontract, by Philips Laboratories.

The approach used in Phase II had a dual nature. Information was searched for, received, and processed from the AEC, NHLI, and other sources on anatomical and other biological requirements. This information was used to form a set of practicability criteria for a nuclear-powered artificial heart. At the same time, information was developed through theoretical and

*Westinghouse 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.

experimental studies on the potential capabilities of the Stirling-mechanical system. This latter information was used to estimate the characteristics of a prototype of the Stirling-mechanical system. The estimated characteristics were compared with the practicability criteria to form the practicability assessment.

There are five major categories of external requirements and constraints which have been considered in the assessment of practicability of a fully implantable artificial heart: isotope inventory and environmental aspects; implantation factors; performance; lifetime and reliability; costs. Each of these categories contains a number of criteria. Several of the more important criteria for a fully developed nuclear artificial heart system are those of weight, volume, dimensions, life, isotope inventory, maximum blood flow and corresponding blood hydraulic power.

As an important example, the system should be able to pump a sufficient flow of blood so that the average man can climb stairs and sustain other forms of mild exercise upon demand. This requires a blood flow rate of 12 liters per minute. This converts to 3.1 watts blood hydraulic power at normal blood pressures.

An upper limit on allowable radioisotope inventory for thermal reasons related to the recipient is about 50 watts. However, from considerations of fuel availability, heat source cost, radiation exposure to the recipient and to the total population, a goal of about 25 watts radioisotope inventory has been set.

The system should have a mean life (life expectancy) at least one-half that of a normal human heart in the recipient age group, that is, about ten years. Only about one percent of all units implanted would be expected to fail during the first five years of operation due to wearout; the random failure rate should be less than one percent per year.

Maximum volume and weight for a fully developed blood pump are taken as 700 cc and 1000 gm with envelope dimensions not exceeding 14 x 12 x 10 cm as anatomically acceptable in a large percentage of patients. Similar values for the thermal converter are 800 cc and 2000 gm with envelope dimensions of 22 x 10 x 10 cm.

Information for the purpose of estimating the characteristics of a fully developed prototype was developed by interwoven experimental and theoretical studies. The Stirling-mechanical system and its components were examined parametrically and a conceptual design formulated. An important part of these parametric and conceptual design studies was a "design for reliability" philosophy in which the other system characteristics were traded off to meet the lifetime and reliability requirements for practicability. The conceptual design was then translated into a detail design of a realistically sized bench model. The bench models were fabricated, assembled, and tested. Testing was first carried out on individual parts, then subassemblies. These component tests were followed by tests of the bench model system in total. During the period covered by the parametric studies and the design and fabrication steps for the bench model, development work on selected system components was carried out. Major thermal converter component effort was directed at controls, lubrication system, and piston rings. Major component effort on the blood pump was directed at the flexible shaft and antifriction bearing lubrication. Tests of the bench model and its components confirmed the design techniques used. These design techniques were then used to estimate the characteristics of a fully developed nuclear artificial heart system based on the Stirling-mechanical concept.

1.2 STIRLING MECHANICAL CONCEPT

A version of a nuclear-powered Stirling-mechanical artificial heart system is illustrated in Figure 1-1. In concept, it consists of a thermal energy converter based on the Stirling cycle which converts input heat from a plutonium-238 fueled heat source to rotary output shaft power, a blood pumping unit and an interconnecting flexible shaft which transmits the pumping power and provides routing for coolant lines which carry the cycle waste heat from

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Figure 1-1. Stirling Mechanical Artificial Heart System

the thermal converter to a heat exchanger located in the blood pumping unit.

The principal components of the thermal converter are: a Pu-238 heat source, vacuum foil type thermal insulation, a Stirling-cycle heat engine with rhombic drive and step-up gearing to a flywheel. Important auxiliary components are an oil pump and engine speed control. The blood pump assembly consists of roll-sock diaphragm pump ventricles actuated by a mechanical linkage. Important components of the ventricles are the roll-sock diaphragms, flexible exterior domes, blood vessel connections and valves. Principal components of the drive mechanism are: a speed reducer, coolant pump, flexible shaft, and Scotch yoke mechanism that pushes on the roll-sock ventricle diaphragms. Right and left ventricles are pumped alternately.

An operating mode was selected for the Stirling-mechanical system which provides a nearly constant blood pump beat rate of 120 beats per minute by controlling the thermal converter speed to an average value. Starling's Law of blood flow is satisfied by designing the blood pump drive mechanism and ventricles to accept whatever amount of blood is delivered to the ventricles during diastole, and letting the stroke volume vary up to the maximum stroke volume which will provide 12 L/min flow at 120 beats/min. This operating mode takes advantage of the inherent adjustment of the flow characteristics of the circulatory system by the body to provide the variable venous pressure required for control. Use of constant pump beat rate - variable stroke volume operating concept without thermal storage in the thermal converter permits simple control requirements. The isotope inventory and the Stirling heat engine are sized to meet the maximum design power demand of the blood pump.

The thermal converter is designed to operate with peak heat source temperatures of 1520°F (1100°K). It is illustrated in Figure 1-2. The hot portions of the thermal converter are the plutonium-238 heat source, the hot finger, and the combined displacer and regenerator. These components are enclosed in a high performance, compact, lightweight vacuum foil

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Figure 1-2. Thermal Converter

insulation package. The insulation consists of foil cups packaged in the vacuum space within an outer case and an inner case which is also the engine hot finger casing. The heat source is enclosed within the engine volume. Helium vented from the isotope capsule diffuses into the engine working space, then into the crankcase and finally into the body.

A mesh type regenerator is used with gas flow through slots in the bottom of the displacer through the mesh and through the holes at the top of the displacer. The waste heat exchanger is located in the space above the power piston and below the displacer. Heat is carried away from this location by the circulating coolant fluid.

The rhombic drive, oil pump, speed control, gears to step up the output speed to 1800 rpm, and flywheel to provide energy storage to match the thermal converter output to the pulsatile demand from the blood pump drive mechanism are located in the engine crankcase. This crankcase is partially filled with a pure hydrocarbon lubricating oil. The oil level is set so that the oil pump inlet is always covered regardless of thermal converter orientation.

This is an important advantage of the Stirling concept over other dynamic concepts since the critical seals and loaded components are near ambient temperature even though the overall cycle temperature ratio is very high, providing both the high cycle efficiencies associated with high top cycle temperatures and the high reliabilities and life associated with cold working parts.

Rolling diaphragm seals are used to provide separation of the crankcase from the pressurized working volumes, i.e., expansion space, regeneration and compression space. Therefore, the drive mechanism which is housed in the crankcase can be properly lubricated to insure long engine life. A heavy gas such as argon or krypton is used as the working fluid to avoid possible problems associated with gas permeation of the seals which are made of a special polyurethane material. Additionally, these heavy gases have relatively low thermal conductivities which is advantageous in terms of conduction losses.

Although all the working parts of the engine go through special processing to remove contaminants from their surfaces, a certain amount of contaminants evolve in the crankcase, and permeate through the rolling diaphragms into the working space. The level of these contaminants, however, is below that considered detrimental to engine operation over ten years.

The principal components of the blood pump drive mechanism design concept are shown in Figure 1-3. They are the flexible mechanical shaft and the drive train which converts the rotary output of the flexible shaft to motion of pusher cups that drive the pumping roll sock diaphragms of the ventricles. Auxiliary equipment located in the blood pump drive mechanism includes the coolant circulating pump and the coolant exchanger.

The flexible shaft is connected to the input shaft of a speed reducer built into the cylindrical body of the housing. The speed reducer 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 set of right angle bevel gears with a speed ratio of 2 to 1 and a set of gears with a ratio of 7.5 to 1.

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 pusher cups that alternately compress and expand the dacron-reinforced silastic pumping roll socks at each end.

During diastole when the pusher cup moves away from the ventricle dome, the cylindrical wall of the pumping roll sock in contact with the pusher cup rolls off the pusher cup onto the inside surface of the pump housing. During systole when the pusher cup moves back toward the ventricle dome, the cylindrical surface of the pumping roll sock in contact with the pump

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Figure 1-3. Blood Pump Drive Mechanism

housing rolls off the pump housing onto the pusher cup. Because the ventricle dome is flexible, the dome will collapse inwardly as required during diastole to provide a ventricle volume that matches the volume of blood that is returned from the venous system. The inherent strength of the spherically shaped dome under internal pressure minimizes stretching during systole and permits a high pump volumetric efficiency.

The offset of the end throws of the crankshaft permits each pusher cup to travel past the mid-plane of the pump and occupy space that is vacated by the opposite pusher cup on 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 the housing and cause the housing to reciprocate as the crankshaft rotates. This housing supports linear ball bushings that serve as guides for the main Scotch yoke. Two sets of rollers on outriggers attached to the reciprocating housing bear on hardened inserts in the pump housing and prevent the reciprocating housing from rocking and rotating in the pump body.

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

The waste heat from the thermal converter is rejected to the body by means of the heat rejection system. Heat is transferred from the thermal converter working gas to circulating coolant at the engine cold side heat exchanger. The circulating coolant is then pumped into the blood pump drive mechanism by a double bellows pump, secured to the reciprocating housing and one of the pusher cups and actuated by the differential motion of these components. The bellows pump also serves as a torsion resisting element that prevents rotation of the pusher cups and twisting of the pumping roll socks. The coolant fluid flows from the thermal converter

to the blood pump drive mechanism through an annular passage between the flexible drive shaft and the guide tube around it.

The current design approach is that the blood pump drive mechanism will be completely filled with coolant. Consequently, after the fluid enters the blood pump speed reducer, it can flow through the ball bearings and around the gears to enter the reciprocating mechanism chamber. There, the fluid is agitated by the motion of the reciprocating mechanism and gives up about 65% of the thermal converter waste heat to the roll sock portion of the ventricles and the pusher cups. The coolant then enters the bellows pump where it is expelled under pressure during the opposite stroke of the reciprocating mechanism. When the fluid leaves the coolant pump, it enters a flexible metal tube that carries the fluid from the coolant pump to a manifold built into the blood pump housing. The flexible tube functions as a spring member and undergoes elastic cycling as the reciprocating structure moves relative to the pump housing. At the manifold in the blood pump housing, the coolant flow divides into two branches, each of which flows through the coolant channels in one of the ventricle domes. After flowing around the periphery of the ventricle domes and giving up the remaining thermal converter waste heat to the blood in the ventricles or surrounding tissue, the two flow branches return to another manifold adjacent to the inlet manifold. From the return manifold, the coolant flows into the annular space between the flexible shaft guide tube and a convoluted metal tube around the guide tube and returns to the thermal converter. Several available oils that are compatible with the silastic ventricles and are non-toxic show promise as candidate coolant fluids. The fluid will provide both the required heat transfer characteristics and adequate lubricity for the bearings and gears without introducing excessive churning power losses in the blood pump mechanism.

Because the blood pump mechanism chamber and flexible drive shaft assembly are filled with fluid, very little air can remain trapped between the ventricles after the pump is assembled. If the pressure in the ventricles drops to a pressure less than that present at the time the

mechanism chamber is sealed, the expansion of the minute amount of gas trapped in the pump will not noticeably affect the ventricles. Therefore, changes in atmospheric pressure that may be experienced in flying or traveling to high altitudes will not influence the performance of the blood pump.

1.3 BENCH MODEL RESULTS

The bench model version of the design concept is shown in Figure 1-4, as set up for bench testing. The system load is provided by the Mock Circulation that simulates the biological circulating system.

For convenience, some liberties were taken in the bench model design relative to the previously discussed design concept. These liberties did not reduce the worth of the bench model tests. Deviations of little importance were the use of flanged joints on the thermal converter for easy assembly and disassembly and for the installation of instrumentation and the use of an all stainless steel blood pump drive mechanism. These deviations made the bench model heavy but, excluding the flanges, realistically sized. Changes of more substance were: 1) the cooling of the thermal converter was accomplished by running tap water through the waste heat exchanger to the sewer rather than through a closed coolant loop to and from the blood pump; 2) the thermal converter lube oil is circulated by an electrically driven auxiliary pump; 3) the thermal insulation system uses a pumped vacuum rather than a permanent vacuum; 4) the 2:1 speed reducer is placed at the thermal converter end of the flex shaft and the 7.5:1 speed reducer at the blood pump end of this shaft uses an inline attachment. A pumped vacuum thermal insulation was used to allow helium backflooding of this insulation for easy thermal converter shutdown using a Pu-238 heat source. Most of the operational and performance testing was carried out using an electrical heater in place of the Pu-238 heat sources because of the flexibility of an electrical heat source. The thermal converter was operated seventy-five continuous hours using a Pu-238 heat source without incident.

Figure 1-4. Bench Model System

Overall bench model system output was varied from 1.6 watts blood hydraulic power output to a maximum of 2.8 watts blood hydraulic power output. Thirty-eight watts of heat input was required at the maximum output. This is an overall system efficiency of 7.4%.

During bench thermal converter component tests at Westinghouse, output varied from 4.8 watts output at 41 watts heat input to 3.9 watts output at 33 watts heat input. These values give a thermal converter efficiency of about 12%. Values up to 13% were measured during thermal converter tests at Philips Laboratories.

Component tests of the blood pumps showed that their efficiency was a strong function of pumping rates. Efficiency improved as pumping rate increased. At maximum pumping rates corresponding to blood hydraulic output powers in the range of 2.8 to 3.2 watts, the best overall blood pump efficiencies observed were 59% or better. The overall efficiency is a product of the drive mechanism efficiency of about 88% and the ventricle efficiencies of about 68%. At blood hydraulic output powers of 1 watt, the efficiency was as low as 20%. Low efficiency at low power output is of no consequence since the thermal converter must be throttled to attain low power.

1.4 PROTOTYPE ESTIMATES AND PRACTICABILITY

Based on the bench model results and further analytical studies, a fully developed prototype nuclear-powered artificial heart system is estimated to have the following characteristics:

Isotope Inventory (Initially)	24 watts
Implantation Factors	
Thermal Converter Envelope	16 cm x 8.7 cm x 7.7 cm
Thermal Converter Volume	0.7 liters
Thermal Converter Weight	1.5 kg
Blood Pump Envelope	13 cm x 11 cm x 8 cm
Blood Pump Volume	0.7 liter
Blood Pump Weight	0.7 kg

Performance

Maximum Blood Pumping Rate	>12 liter/minute
System Efficiency (After 10 Years)	14%

Life and Reliability

Five Year	$\leq 6\%$ failures
Ten Year	<50% failures

The foregoing characteristic values have been compared at length with the established practicability criteria. (See Section 2.0). In all cases, the estimated prototype characteristics equal or exceed the practicability criteria. Therefore, it is concluded that the development of a nuclear artificial heart system based on a Stirling-mechanical concept is practicable.

1.5 RECOMMENDATION

As a result of the data gathered by analysis and experiment during this program, it has been determined that a Stirling-mechanical system comprised of a thermal energy converter based on the Stirling cycle, directly coupled to a mechanical blood pump drive mechanism can indeed be developed to meet the practicability criteria for each of the five categories established.

It is, therefore, recommended that the Stirling-mechanical system be developed to prototype status. Further, it is recommended that the program to develop the prototype have an intensive research and development effort on the various system component technologies. The advances resulting from this intensive research and development will be incorporated into a series of three calf-implantable systems; an implantable version of the bench model developed during the Phase II practicability study; an intermediate system; and the prototype system. The primary objective in developing the implantable version of the bench model system will be to solve the packaging problems for implantation. The objectives for the intermediate system are to achieve a substantial improvement in size, weight, volume, and efficiency of the

implantable version of the bench model plus a partial solution to the ultimate control problem and an increase in ruggedness. The principal objectives for the prototype system will be to advance system reliability and responsiveness to body needs to acceptable levels.

1.6 REPORT ORGANIZATION

The balance of this report is presented in Sections 2.0 through 5.0. In order, these sections are: Practicability Considerations, Bench Model Design, Bench Model and Component Testing, and Prototype Related Studies. The Practicability Considerations section presents the criteria for practicability for a nuclear-powered artificial heart and the extrapolation of Phase II bench model design and test to a nuclear-powered artificial prototype system in a comparative manner. The background information leading to the extrapolated characteristics of the prototype is covered in the last three sections of this report in the same order as the information was gathered.

2.0 PRACTICABILITY CONSIDERATIONS

There are five major categories of external requirements and constraints which have been considered in the assessment of practicability of a fully implantable nuclear artificial heart system; isotope inventory, implantation factors, performance and operational factors, life-time and reliability, and costs.*

In this Section 2.0, the practicability considerations are discussed separately for each of the major categories. In general, under each category, the following information is provided: 1) the requirements for practicability; 2) a summary of the current status of the artificial heart system; and, 3) an estimate of heart system characteristics after several years development to a prototype. The extrapolations to prototype characteristics under isotope inventory, implantation factors and performance, and operational factors use the experimental bench model as a base. No experimental verification of life and reliability and production costs were possible within the time frame of this program. Therefore, conclusions about a prototype were provided by analysis and analogy for the life and reliability and cost categories. In the end for all categories, because of limited experimental knowledge, the practicability assessment has been influenced by subjective and judgmental factors rather than being based solely on objective factors and hard fact.

2.1 ISOTOPE INVENTORY

It is difficult to establish a definite upper limit on allowable isotope inventory. A number of considerations enter into the determination. Among these are: the potential annual and cumulative requirements for Pu-238, the heat source cost, the body heat dissipation burden, and radiation exposure to both the recipient and the general population. With the information presently available, any one of the foregoing considerations indicates an upper limit on isotope inventory of 50-60 watts. However, taken all together, they strongly suggest a lower limit and the conclusion must be drawn that the projected isotope inventory for a prototype

*Mott, W. E., W. S. Holman and D. W. Cole, "Practicability Assessment of a Nuclear-Powered Artificial Heart", U. S. Atomic Energy Commission, Washington, D.C. 20545, January 5, 1973.

system must be less than 50 watts. One can conjecture, that if isotope inventory were the only criterion, an inventory of 30 watts would yield a practicable system. The potential problems that would give rise to scepticism about practicability at 50 watts largely disappear at 25 watts or lower.

For practicability, the artificial heart system must be able to supply up to and including 12 liters/minute blood flow at normal biological blood pressures. According to Donovan**, the blood hydraulic power produced at 12 liters/minute and normal blood pressures is 3.1 watts. In Section 2.3, the levels of bench model component and system efficiency attained are reviewed and extrapolated to obtain an estimate of 14% overall efficiency for the prototype system. At this system efficiency, the heat input required to produce 3.1 watts (12 liter/minute) blood hydraulic power is 22 watts. This is the heat input required at the end of ten years. The initial radioisotope loading then is the 22 watts plus the approximate 2 watts decay over ten years or 24 watts. This value is clearly within the practicability guidelines.

2.2 IMPLANTATION FACTORS

Three of the important considerations grouped under implantation factors are the weight, volume, and dimensions of the individual components of the artificial heart system, blood pump and thermal converter. The practicability criteria for size arrived at during the course of this program are:

	<u>Blood Pump</u>	<u>Thermal Converter</u>
• Weight - kg	1	2
• Volume - liter	0.7	0.8
• Envelope - cm	Not exceeding 14 x 12 x 10	Not exceeding 22 x 10 x 10

2.2.1 Blood Pump Size and Weight

There is only one design of the Phase II bench model blood pump drive mechanism. However, two different sets of ventricles were supplied by the AEC through the University of Utah. The

**Donovan, Francis M. Jr., "Energy Requirements of the Artificial Heart", University of Utah, Topical Report 1, July 1971.

weights, dimensions, and volumes of the two bench model blood pump versions using these ventricles follow: the weights and dimensions are measurements; the volumes are estimated; the measured weight is a dry weight (the pumps can contain an estimated additional 127 gm of blood).

	<u>Version No. 1</u>	<u>Version No. 2</u>
• Weight - kg	1.4	1.4
• Volume - liter	0.75	0.75
• Envelope - cm	14.7 x 11.9 x 9.1	14.5 x 10.9 x 9.1

An implantable version of the bench model blood pump has been designed in conjunction with the University of Utah. The major improvements are a reduction in weight through substitution of fiber reinforced plastic for stainless steel in several of the blood pump drive components, a reduction in speed reducer housing length of 0.95 cm (3/8 in), addition of liquid to fill mechanism cavities, and minor rearrangement of the ventricles. The drive components subject to material substitution are: pump drive housing, speed reducer housing, yoke housing assembly, and pusher cups. Design characteristics are as follows:

• Weight - kg	0.8 (including blood)
• Volume - liter	0.7
• Envelope - cm	14 x 12 x 9

The foregoing values are within the practicability guidelines.

Further improvements over this design are projected for the prototype. If the present constant speed alternate ventricle pumping concept is used in the prototype, modest reductions in dimensions and weight can be accomplished through decreased clearances between pump drive parts and by changing ventricle arrangement. In addition better use of the available biological

space seems possible using a drive housing of elliptical cross-section rather than the present circular section. The estimated size and weight of such a prototype is:

- Weight - kg 0.7 (including blood)
- Volume - liter 0.7
- Dimension - cm 13 x 11 x 8

If the maximum pumping speed could be increased above the current reference of 120 beats/minute, additional size reduction can be achieved.

The bench model drive mechanism pumps the ventricles alternately. There is no reason to assume that alternate pumping of the ventricles is not an acceptable mode of artificial heart operation. However, if future biological input should show the desirability of synchronous pumping, a scheme is available to do this within the prototype size and weight estimates. A scissors scheme was investigated early in Phase II of this program for asynchronous pumping. It can be modified to provide synchronous pumping.

2.2.2 Thermal Converter Size and Weight

The Phase II bench model thermal converter is 28 cm high, 9 cm long, and 11 cm wide. Its volume is approximately 1.5 liter and it weighed 5 kg. The present practicability study indicates that these physical characteristics of the thermal converter can be significantly improved. For example, approximately 2 kg weight reduction can be made through the removal of flanges and bosses incorporated for convenience in bench testing. However, the substantial part of the improvements have been identified from extrapolations of the bench model design and testing experience. Most of these contemplated changes will require confirmation by component development efforts. These are: reduction in the overall height of both the hot side and cold side heat exchangers, redesign of the cold side heat exchanger as a gap heat exchanger positioned to coincide with the bottom of the displacer in its retracted position, reduction in the stroke of the power piston and displacer, and increasing the operating speed. Implementation

of these changes should result in a substantial height reduction. Increasing the operating speed also will allow smaller bearing sizes to be used, which will yield a substantial reduction in drive element size and overall drive element housing length and width.

A stationary regenerator, as opposed to the present moving regenerator, is an attractive alternative that might be used to reduce weight indirectly. A stationary regenerator design requires smaller rhombic drive counterweights to achieve engine dynamic balance. Other projected reductions in weight come from four sources: elimination of bench model flanges and bosses, reduction in size of the thermal converter, refinements in materials selection and component design configuration, and substitution of a nested set of concentric cups for the mitered joint multifoil insulation used in the bench model tests. This insulation change is an important weight savings. The companion AEC insulation development program has shown that 50 nickel cups will have substantially better thermal insulating capability and long term performance than 137 layers of mitered molybdenum foil at a weight savings of approximately 350 grams.

Based on the foregoing changes, it is estimated that a complete prototype thermal converter, including insulation, can be developed to fall within the following values:

	<u>Prototype Thermal Converter</u>
• Weight - kg	1.5
• Volume - liter	0.7
• Envelope - cm	16 x 8.7 x 7.7

These values are within the practicability guidelines.

2.3 PERFORMANCE

2.3.1 Daily Profile Requirements

The system must meet the peak blood pumping requirements of 12 liters/minute which translates to 3.1 watt blood hydraulic power. Since the recipients activities vary throughout the day, the flow and power requirements vary. To accommodate these fluctuations, a means of controlling the blood flow and engine power output in response to physiological demands has been provided in the prototype concept.

In the absence of any in vivo experimental evidence indicating otherwise, it is planned to maintain the pump speed constant and to permit the pump to accept varying quantities of blood as provided by the body's natural dynamics which vary the flow characteristics of the circulatory system in response to physiological requirements. Flow control is obtained by allowing the domes of the blood pump to collapse when the venous return is not sufficient to completely fill the pumping chambers.

Because the heat input to the system is essentially constant, a controller is provided to maintain the converter speed essentially constant by providing a means for dissipating the excess power produced. By selecting this control scheme, the temperature is automatically controlled and rapid response times can be obtained with simple control mechanisms. Dissipation of excess power is achieved by throttling gas to and from the working volume through a variable valve into an auxiliary volume. Test results in Phase II have indicated that the converter performance is very sensitive to just such throttling effects as proposed. If in vivo tests demonstrate that control systems providing variable speed are required, such systems will be incorporated. If these are used, further decreases in isotope inventory may be possible through the use of thermal storage materials.

Whatever the control system used, the response time is expected to be such that the converter will recover from a disturbance in less than 5 seconds. This is adequate to meet the body requirements as presently understood.

2.3.2 Thermal Converter Efficiency

A representative bench model thermal converter power balance is given in Figure 2-1. As will be noted, the output shaft power is 4.5 watts and the heat input is 38 watts. Actual test values varied from about 3.9 watts output at 33 watts heat input to 4.8 watts output at 41 watts input. Cylinder head temperatures generally ranged from 1380 to 1470°F. On this representative diagram only the input, gas and output power are direct measurements of a thermal converter test. The other data are adjusted values derived from bench model design calculations supplemented by component tests.

Studies to extrapolate these bench model results to a prototype system have been conducted and the results of these studies are illustrated in the diagram of Figure 2-2. It can be noted that the estimated heat input for 5 watts shaft output is 23.7 watts for a thermal converter efficiency of 21%.

A major portion of the projected improvement is from a reduction in the amount of gas power which must be generated to produce a given shaft output through decreases in internal losses. Certain losses shown in Figure 2-1 have been eliminated in Figure 2-2. These are: 1) the 2:1 reduction gear has been removed, 2) the buffer volume flow losses and the piston seal friction have been eliminated by substituting bellows seals for the bench models combination of roll socks and piston rings; and, 3) an increase in bearing precision plus an increase in converter speed will reduce the size of the bearings and their associated losses. Counterbalancing these gains in part are an increase in power to drive the displacer at higher speed in krypton rather than argon and the addition of the oil pump.

Removal of the 2:1 reduction gear from the thermal converter implies accomplishing all the system speed reduction in the blood pump drive speed reducer. However, savings in volume and power can be realized through the combination of functions and the elimination of a high-speed bearing. Substituting a bellows seal for the piston rings raises questions of life and reliability. However by stringent design and manufacturing to control the bellows stresses,

Figure 2-1. Representative Bench Model Thermal Converter Power Balance

Figure 2-2. Prototype System Thermal Converter Power Balance

10 year life and reliability can be achieved. A savings of 1.4 mechanical watts is well worth the extra effort. The postulated net of these changes is an improvement in the mechanism efficiency from 43% to 59%.

An improvement in conversion of cylinder head heat to gas power from 31% to 38% will be accomplished by redesign of the hot end. The cylinder head temperature will be operated at 1100°K (1520°F) while: 1) controlling or reducing conduction losses through the substitution of krypton for argon working fluid; 2) better control and design of displacer and cylinder wall thicknesses; and, 3) increasing the hot side heater heat transfer from cylinder head to working gas. These latter objectives can be accomplished by using a stationary regenerator-heater in place of the current reciprocating regenerator-heater. While in principle in small thermal converters, a reciprocating regenerator-heater design should be superior to a stationary regenerator-heater, the bench model experience leads to the conclusion that this theoretical advantage will be outweighed in practice by the better manufacturing and design control possible with a stationary regenerator-heater.

Other improvements of the prototype thermal converter over the bench model can be made: 1) by the elimination of the test instrumentation and electrical heater leads; and 2) more importantly, by the substitution of the new style nested cup multifoil thermal insulation developed by the AEC's thermal insulation program, Contract AT(11-1)-2239, for old style mitered joint insulation.

2.3.3 Blood Pump Efficiency

The bench model blood pump drive mechanisms were tested with two versions of the University of Utah supplied ventricles. The overall efficiency of the first version of the bench model blood pump, as computed from bench tests results, varied from 23% at approximately 5 liters/minute to 50% at approximately 11 liters/minute. At the 11 liters/minute flow rate

information on the ventricle power required reported by the University of Utah* was used to make an estimate of blood pump drive efficiency. The value obtained was 87%.

The second version of the bench model blood pump was checked out at WANL and calibrated extensively at the University of Utah. Maximum overall efficiencies reported by the University of Utah are 56%. The difference in overall efficiency between Version No. 1 and Version No. 2 is attributed here to improvements in ventricle efficiency since the drives of the two pump versions are duplicates.

Design calculations indicate that with a change in the speed reducer plus more stringent control of surface finishes and clearances, the blood pump drive efficiency can be increased to 90%. This allows for added losses associated with filling the drive cavity with liquid (<1%) plus increasing the speed reducer gear ratio from 7.5 to 1 to 15 to 1 (2%) and adding of a coolant circulating pump (2%). This drive mechanism improvement coupled with added improvements in ventricle efficiency projected by researchers at the Universities Center - Jackson, Cleveland Clinic, and the University of Utah yields an expected minimum overall blood pump efficiency (drive efficiency x ventricle efficiency) of 67%.

2.3.4 System Efficiency

The projected overall efficiency of the prototype system is estimated at 14%. This efficiency is defined as the peak net power to the blood divided by the heat input to the thermal converter. It can also be defined as the product of the thermal converter efficiency at 21% times the blood pump efficiency at 67%.

*Backman, D. K., et.al., "The Design and Evaluation of the Ventricles for the AEC Artificial Heart Nuclear Power Source", Amer. Soc. Artif. Int. Organs, 19, 542 (1973).

2.3.5 Operational Considerations

The following factors are pertinent operational considerations that enter into the practicability assessment:

- Insensitivity to orientation and barometric pressure variation
- Vibration and acoustic output
- Resistance to external shocks and vibration

In Phase II, each of these considerations was addressed – some via design and analysis only; others, via design and analysis plus experimental testing with the bench models.

Provisions for accommodating variations in barometric pressure have to be made. The blood pump is liquid filled. Because the pump mechanism chamber and flexible drive shaft assembly are filled with fluid, very little air can remain trapped between the ventricles after the pump is assembled. If the pressure in the ventricles were to drop to a pressure less than that present at the time the mechanism chamber is sealed, the expansion of the minute amount of gas trapped in the pump would not noticeably affect the ventricles. Therefore, changes in atmospheric pressure experienced in flying or traveling to high altitudes should not influence the performance of the blood pump.

An alternate blood pump design uses a gas filled approach. Since the mechanism chamber of this pump design is filled with the ambient air at the time the pump is assembled and sealed, this air would expand and compress the ventricles if the pressure in the ventricles should drop below the pressure of the drive cavity. This condition can be avoided by providing a silastic envelope around the pump into which the gas trapped in the mechanism chamber can expand as necessary to avoid a pressure buildup that would affect the ventricles.

The system must be designed so as to permit operation in any orientation. Ease of implantation will probably dictate the relative orientations of the blood pump and thermal

converter with the human body. Use of the flexible shaft to couple these two major sub-systems permits the blood pump and thermal converter to be placed in orientations that are reasonably independent of each other.

Low vibration and acoustic output of the system has been an inherent consideration since the program's inception. This area, in fact, was one of the criteria for concept selection during Phase I and the Stirling cycle was ranked most desirable in this regard among the candidate concepts. During Phase II, bench model testing of the Stirling thermal converter and the blood pump experimentally verified the intrinsically quiet, low vibration operational characteristics of the Stirling-mechanical system. Accelerometers mounted on the pump indicated low g level readings. The only significant acoustic output from the blood pump came from a mild clicking sound caused by the valves. Attention to this area has indicated that precise valve fitting and choice of materials can minimize or eliminate this acoustic source. The pump mechanism and flexible shaft per se exhibited a smooth operation free of resonances and dynamic instabilities. Testing of the two bench model thermal converters verified the inherent well balanced, vibration free operation nature of Stirling cycle machinery. While a moderate acoustic sound emanated from both converters while under test, the second converter was quieter than the first and there is every indication that these mild acoustic levels can be further reduced. On this basis, we have concluded that the system is within the practicability guidelines for vibration and acoustic output.

Regarding external sources of shock and vibration, the practicability guidelines indicated that the system should be able to withstand reasonable levels (nominally 3 g's) without harm. Design efforts during Phase II took this area into account qualitatively. Although the bench model was not subjected to external shocks or sources of vibration, the Stirling-mechanical system gives every indication of being an inherently rugged device that can satisfy the practicability guidelines.

2.4 LIFETIME AND RELIABILITY

A practicable system should have a mean life (life expectancy) of about ten years. This is approximately one-half of the life expectancy of a normal heart in the age group of most probable recipients. Furthermore, the system failure rates through the first five years should be minimal. Only about one percent of all units should fail from wearout and the random failure rate should be less than one percent per year.

The careful attention given to lifetime and reliability considerations in the selection of the Stirling-mechanical artificial heart concept has been continued during Phase II in the implementation of "design for reliability" philosophy, making concern for lifetime an intrinsic part of the design process.

This approach has included a Failure Mode and Effects Analysis (FMEA) to identify potential failures and assess the criticality of their consequences. The probabilities of failure occurrence have also been studied and consolidated with the results of the FMEA to establish a reliability apportionment model which has served to highlight the weakest links in the design and to focus attention towards avoiding or minimizing potential sources of unreliability. For example, bearings, seals and flexing members are historically suspect as life-limiting items and have been given special attention during the Phase II design activities.

The flexible shaft which transmits power from the thermal converter to the blood pump is perhaps the most critical item at this point 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 year 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 minimum radius bend; substitute a high endurance super alloy for the standard wire material.

In the current design of the implantable version of the bench model, a double bellows assembly in the blood pump serves both as a torsion resisting element to prevent rotation of the pusher cups, and as a circulating pump for the coolant fluid. Lifetime data for bellows specifically designed for a particular application indicate that 1.5 to 2 times the required cycles can be obtained. However, in performing this double duty, a complex stress pattern is introduced into the bellows system which may be difficult to analyze. Therefore, two approaches are possible. The first is to redesign the system to eliminate the bellows by pumping with the flexible shaft and incorporating torsion resistance into the linear ball bushing that guides the main yoke. The second is to obtain detailed data on torsion forces and pumping pressures with which to design a special set of double bellows.

The use of rotary shaft seals is currently planned to isolate the flywheel from the crankcase. 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. Consequently, further consideration of this important component of the thermal converter is required. Use of a magnetic coupling as proposed in Phase I has been reevaluated and appears as an attractive alternative.

The roll sock shaft seals will go through about 3×10^9 cycles during ten years operation. A large 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 test was stopped after 1.24×10^9 cycles; the latter did not fail. A continued development program is required to improve and totally demonstrate lifetime and reliability of these components.

Other components in the system also require technology advances to assure ten year life; however, their development seems straightforward and no particular difficulty is expected. As an example, the vacuum foil insulation package is certainly not a proven ten year technology, but nonetheless, the data obtained thus far indicate that this lifetime is an achievable goal. None of the materials involved appears to pose an outgassing problem. Moreover, vacuum service for long periods of time has been demonstrated in analogous vacuum tube, light bulb and vacuum circuit breaker technologies.

In summary, the results of our lifetime and reliability studies to date indicate the risk of an unforeseen failure mode being identified later that could preclude the achievement of the goals for the prototype system to be minimal, and that a practicable ten-year system can be developed within a reasonable period.

2.5 DEVICE COST

One of the considerations affecting judgment of practicability must be that the Stirling-mechanical artificial heart system can be produced in large numbers at a reasonable cost. Establishing the reasonableness of a cost figure presents difficulties. What may be cheap or reasonable to one individual may be dear or unreasonable to another. No consensus has been obtained on either system cost or an annual operating cost that would be a measure of practicability. The total annual cost associated with the home-use of an artificial kidney is about \$5,000 per year. It seems that the annual cost for an artificial heart should not exceed this dollar value.

The Phase II bench models were, in general, fabricated by model makers on one-of-a-kind, non-tooled basis and their costs throw little light on production costs of artificial heart systems in quantities of 10, 000 to 30, 000 per year as might ultimately be anticipated. However, good estimates can be developed from comparisons with the production costs of similar kinds of mechanical devices.

For example, production records for the miniature Stirling cycle Cryogen[®] coolers manufactured by Philip's Cryogenic Division for application in airborne infrared systems for the RF4-C, the F111 and other high performance operational aircraft provide a good benchmark for estimation. Some 1, 500 of these units were produced to the high quality standards demanded of military flight hardware at a unit price of \$6, 200. These coolers incorporate many of the same design features and technologies as the thermal converter for the Stirling-mechanical artificial heart system. It is estimated that an adjustment in this production cost to \$7, 000/unit would adequately account for differences in design, such as high temperature components, etc.

If the production quantities are increased to the 10, 000 to 30, 000 level per year the additional cost savings should be substantial. An anticipated market potential of this magnitude would be sufficient to attract investment by several competing firms in new facilities specifically designed for artificial heart system production by an optimal labor mix. Investment in numerically-controlled machines would be warranted to automate the fabrication and inspection lines. With the assurance of a continuing requirement quantity buys could be made of semi-finished production feed stock from qualified suppliers. Assembly could be semi-automatic. Sampling techniques and proof testing could be used to insure highest quality standards at reduced costs. It is estimated that in this manner the cost of the thermal converter can be reduced to the order of \$4, 000 to \$5, 000/unit through the savings potential inherent in large-scale production even with upgrading in quality assurance to the exacting standards demanded by clinical usage.

The basic concept of the thermal insulation assembly for the prototype system is a nested set of thin-walled concentric cups. Each of these cups can be electro-formed on an expendable aluminum mandrel machined to the required dimensions. Made in this manner, the fabrication costs of the thermal insulation assembly are significant. Fortunately, this assembly is also an outstanding candidate for complete automatic fabrication in large-scale production. It is estimated that the production cost associated with thermal insulation assemblies can be reduced to the order of \$500/unit.

The blood pump drive mechanism has also been carefully evaluated and unit production cost estimates have been developed. A comparative analysis of these costs with those of the thermal converter has also been conducted. The blood pump drive mechanism and the thermal converter are comparable in intricacy of design and in requirements for dimensional control of many closely-fitted parts. However, the high temperature operation of the hot finger-displacer subassembly of the thermal converter presents additional materials and tolerance control requirements to achieve equivalent subsystem efficiencies. On balance, one would expect the prototype blood pump drive mechanism to be considerably less expensive than the thermal converter on the same relative basis. Our production cost estimate of \$2000 to \$3000/unit, which projects a degree of design simplification for the prototype blood pump drive mechanism, confirms this observation.

Based on these costing elements, we would estimate the nominal cost of a complete artificial heart system to be in the range of \$8000/unit in full-scale production.

3.0 BENCH MODEL DESIGN

The bench models consist of a thermal converter and a blood pump interconnected by a flexible shaft. The major subassemblies of the thermal converter are the Stirling engine, the thermal insulation and the heat source. The major subassemblies of the blood pump are the drive mechanism and the ventricles.

3.1 STIRLING ENGINE DESIGN

3.1.1 Physical Description

The engine converts heat into shaft power; the difference between the input power and the output power is rejected as waste heat. The first stage of the conversion, i.e., that of heat to PV power, is done with the aid of two reciprocating elements, a displacer/regenerator and a power piston; the second stage, i.e., the conversion from PV power to shaft power is accomplished through a mechanical drive which converts reciprocating to rotary motion. The major components of the engine are shown in the cross-sectional view of Figure 3-1.

The first step in the conversion process is the transfer of heat from the energy source to the working medium of the engine. The plutonium-238 heat source was simulated during the laboratory evaluation tests by an electric resistance heater. The working medium is argon (or krypton) gas. The heat source is mounted in the cavity shown in the upper portion of Figure 3-1. Heat is transferred to the cylindrical cavity wall partly by radiation and flows by conduction along the wall, down to the hot finger portion marked heater. There it is transferred to the working gas which reciprocates through the annular gap formed by the hot finger and the top of the displacer. A small amount of heat is transferred through the top of the hot finger.

After being heated, the gas is displaced from the expansion region (see Figure 3-1) into the compression chamber via the regenerator and the heat exchanger (i.e., cooler). The regenerator, a porous matrix having high heat capacity, is contained in and reciprocates with the displacer. It should be noted that in many Stirling engines the regenerator is stationary.

Figure 3-1. Cross-Sectional View of Engine

While flowing through the regenerator, the gas transfers most of its heat to the matrix; the gas then passes through the cooler, where heat is exchanged with the cooling medium; it next arrives into the compression space at essentially ambient temperature.

After compression, the gas follows the same path back to the expansion region, i.e., it flows through the heat exchanger, the regenerator, and the heater. The items described thus far, i.e., the heater, expansion region, displacer/regenerator, heat exchanger, and compression region, comprise the thermodynamic parts of the engine. The remaining part, i.e., the drive mechanism, serves to convert thermodynamic power to shaft power.

The drive is of the rhombic type. It has two yokes, one connected to the displacer/regenerator, the other to the power piston. The yokes are coupled to two crankshafts via connecting rods. The reciprocating motions of the displacer/regenerator and the piston are converted to rotary shaft motion; the two crankshafts rotate at 600 rpm, in opposite directions.

The shaft speed is stepped up to 1800 rpm, the speed at which the flywheel rotates. The latter speed in turn is geared down to 900 rpm, the speed at which the flexible shaft which connects the engine to the blood pump rotates.

The engine has three "appendages": a buffer tank, a control valve, and an oil pump, which are described in detail in Section 3.1.3.

The rhombic drive is housed in the engine crankcase. The latter was also designed to house the oil pump with its filter. The crankcase is separated from the engine's thermodynamic section by two rolling diaphragms installed on the displacer rod and the piston rod.

3.1.2 Design Performance

The first step in the design of the engine was to establish its major parameters. This was done with the aid of the Philips Stirling computer program. The major aim of the design process

was to optimize the engine for efficiency. Several comments concerning the major parameters are appropriate:

- The highest (i.e., the input) temperature of the cycle was taken as 1000°K (1340°K), based on material strength considerations; this will be discussed in more detail elsewhere in the report. The heat rejection temperature was taken as 57°C (135°F), based on temperature differences of 10°C in both circuits of the heat exchanger, i.e.:

Blood Temperature	37°C	(99°F)
Δt in External Loop of Heat Exchanger	10°C	(18°F)
Δt in Internal Loop of Heat Exchanger	10°C	(18°F)
	57°C	(135°F)

- The engine's operating speed arrived at was 600 rpm. Lower speeds could cause an excessive leak between the compression space and the buffer space. Higher speeds would reduce the mechanical efficiency of the system.
- At the outset of the optimization studies, the goal was to use a radioisotope capsule with $L/D = 1$. For the specified 33 watt capsule, this would have meant $L = D \approx 3$ cm. The computer studies indicated, however, that a hot finger diameter matching that of the capsule, i.e., 3 cm, would result in excessive internal heat leaks. The optimum (i.e., minimum loss) cylinder diameter turned out to be 2.5 cm. The resulting capsule height is approximately 4.3 cm.
- A relatively short stroke, 1.0 cm, was arrived at, to keep the overall length of the engine down, and to optimize the various parameters of the rhombic drive mechanism.
- Ideally, the thermal phase angle of the system, i.e., the phase difference between the hot space volume and the cold space volume, should be near 90° for good efficiency. For the application at hand, the thermal phase angle was taken as 126° , which corresponds to a mechanical phase angle of 70° . This choice was partly based on optimizing the parameters of the rhombic drive.
- The choice of the working pressure is determined by the maximum power output, speed, cylinder diameter, stroke, and phase angle. Its optimum value arrived at was 13 atm. average.

To summarize, the major design parameters of the engine were established as follows:

Power input	33.2 watts
Power output	6.0 watts
Input temperature	1340 ^o F
Heat rejection temperature	135 ^o F
Operating speed	600 rpm
Hot finger diameter	2.5 cm
Stroke	1.0 cm
Thermal phase angle	126 ^o
Working pressure (average)	13 atm

The energy balance resulting from the optimization study, with krypton as the working gas, is given below:

	<u>Watts</u>
Power Input	33.2
External heat leak	5.0
Heat to engine	28.2
Internal heat leak	10.3
Heat to working fluid	17.9
Internal (thermodynamic) power produced	10.7
Internal power loss	4.7
Shaft power output	6.0

At the conclusion of the optimization study summarized above, an additional trade-off study between engine height and efficiency was performed. In a limiting case, if the height (i. e., the dimension parallel to the cylinder axis) were reduced by 3.0 cm (1.0 cm reduction of regenerator, fuel capsule, and heat exchanger heights), the required power input would rise by 5.0 watts.

3.1.3 Engine Component Design and Detail Analyses

Following the completion of the engine's overall design, analyses were performed of its major components. The results of these analyses are discussed next.

Hot Finger

In Stirling as well as in other heat engines, thermal energy is supplied to the system at high temperatures and, after work is extracted from the working fluid, rejected to a heat sink at nearly ambient temperatures. The element connecting the high to the ambient temperature regions of a Stirling engine is a cylinder, normally referred to as the hot finger. A typical configuration of such a finger with a radioisotope heat source is shown schematically in Figure 3-2.

The hot finger assembly contains the elements which operate at temperatures higher than ambient. It provides:

- The boundary for the expansion chamber, or the active hot volume.
- A heat sink for the radioisotope capsule.
- Means for coupling the capsule to the engine.
- A flange for attaching the cylinder to the rest of the engine, as well as for supporting the vacuum jacket.

Its design must incorporate materials which best meet the requirements associated with the foregoing features.

Most of the high temperature thermal energy is supplied to the expansion chamber by conduction along wall A. The rest is transferred through the top of the expansion chamber (i. e. , wall B). Therefore, these walls, especially wall A, was constructed of a material having high thermal conductivity at the operating temperature, i. e. , 1000°K (1340°F) and above.

Figure 3-2. Typical Hot Finger Configuration

To insure that most of the energy available from the radioisotope is transferred to the working fluid rather than lost by conduction, wall C must provide a high thermal impedance; therefore, it was constructed of a material having very low thermal conductivity in the temperature range of ambient to 1000°K (1340°F). In addition, the cross-sectional area was minimized while maintaining the capability of withstanding the pressure variations of the working fluid.

The flange is at ambient conditions; therefore, the considerations associated with its construction are those encountered in normal design practice.

In the hot finger assembly, there are several materials considerations:

- The thin portion of the cylinder (i. e., wall C). This wall required a constructional material which has adequate strength at 1000°K (1340°F) and 230 psi pressure differential, has very low thermal conductivity, and has creep properties consistent with the life requirements of the thermal converter program.
- The conducting portion of the cylinder (i. e., wall A). The thickness of this wall is much greater than that of wall C. Therefore its strength is not nearly as serious a problem as the strength of the thin wall. The most important requirement in this case was the thermal conductivity of the material, since the higher the conductivity, the lower the wall thickness for the same amount of heat transferred and the lower the weight associated with the wall.
- A brazing technique was needed which can join the two materials discussed above (i. e., joint 1 in Figure 3-2), and allow adequate heat transfer across the joint.
- The flange is at ambient temperature and has negligible pressure differential across it; the choice of the material was therefore primarily governed by weight considerations.
- A brazing technique was needed which can join the thin wall portion of the cylinder to the flange material (joint 2 in Figure 3-2).

It should be noted that although Figure 3-2 represents the concept in which the capsule is mounted outside the expansion chamber, as planned for this phase of the program, all the materials considerations discussed herein apply as well to the configuration in which the capsule is inside the expansion chamber, a future possibility. In the latter case, wall B would be above the capsule, i. e. , it would bridge the upper extremity of wall A.

In selecting the material for the thin portion of the hot finger, several factors had to be considered:

- Rupture strength and yield strength
- Thermal conductivity
- Fatigue life
- Ability to contain the working fluid
- Fabrication techniques, i. e. , machining, welding, brazing and heat treating.
- Cost

The rupture strength and the yield strength of thirteen metals suitable for use at elevated temperatures are shown in Figures 3-3 and 3-4 respectively, as a function of operating temperature.

Since, as indicated in the figures, Udimet 700 exhibits relatively high rupture and yield strength at the temperature of interest, its use was investigated in detail. Inconel 718, the material proposed at the conclusion of Phase I, was found, after further studies, to be marginal in terms of strength, i. e. , it offers no safety in case of cylinder overheating.

Although the thermal conductivity of Udimet 700 is somewhat higher than that of Inconel 718, i. e. , 136-192 vs 78-161 Btu/ft²/hr F^o/in, respectively, in the temperature range of 20°C-760°C (70°F-1400°F) the higher strength of Udimet 700 permits a smaller wall thickness, thus compensating for the additional heat leak.

Figure 3-3. 1000 Hr. Creep to Rupture of Bar Materials

Figure 3-4. Yield Strength of Bar Materials at 0.2-Percent Offset

The wall thickness of the hot cylinder wall C (Figure 3-2) must be consistent with the fatigue life of the constructional material. The thickness of the wall (h) was determined from the expression:

$$h = \frac{K P_{\max} D}{2S_e} \quad (3-1)$$

where:

K = safety factor

P_{max} = maximum cycle pressure (psi)

D = hot cylinder diameter (in)

S_e = endurance limit at operating temperature (psi)

with K = 1.5, P_{max} = 230 psi, D = 1.0 in., and S_e = 45,000 psi, the thickness of the wall is 0.004 in. (0.01 cm). The required fatigue life, at an engine speed of 600 rpm, is 32×10^8 cycles. Since no fatigue data was available at the operating temperature of 1340°F (1000°K), the endurance limit utilized in the above formula is a value obtained at 1500°F (1089°K). At 1500°F (1089°K), the fatigue life would be approximately half of that required. It is anticipated that the lower operating temperature, as well as the safety factor, will compensate for the difference.

To correlate the rupture life of the thin portion of the hot finger with the temperature and stress conditions to which it is subjected, the Larson-Miller criteria was used. Figure 3-5 shows the Larson-Miller curve for Udimet 700.

Figure 3-5. Larson-Miller Curve for Udimet 700

In the foregoing figure, T = operating temperature ($^{\circ}\text{R}$) and t = life (hr). With $T = 1340^{\circ}\text{F}$ (1000°K) and $t = 87,600$ hours (corresponding to 10 years), the Larson-Miller parameter is 44.9, which corresponds to a rupture stress of 47,000 psi. The highest stress in the thin portion of the cylinder is the hoop stress, which, with a wall thickness of 0.004 inches, is approximately 29,000 psi. Therefore, the rupture strength of the cylinder should be adequate.

For wall A nickel was selected, for the flange the material chosen was Monel. The completed hot finger is shown in Figure 3-6.

Figure 3-6. Bench Model Hot Finger

Displacer/Regenerator

To achieve its relatively high efficiency, the Stirling cycle relies on the use of a thermal regenerator as a means of alternately storing heat and then returning it to a stream of gas which flows back and forth through it. The regenerator normally consists of a material, such as wire mesh or sintered metal, having high specific heat at operating temperatures. For effective heat transfer, this material is densely packed as a matrix, with sufficient channeling (or voids through the matrix) to allow gas flow without causing a serious pressure drop. The trade-off in conventional regenerator design is therefore between high heat capacity (i. e. , high matrix density) and low pressure drop (i. e. , low matrix density); high pressure drops result in serious flow losses, which reduce the overall efficiency of the cycle.

In addition to the matrix density mentioned above, another factor which determines the magnitude of the pressure drop through typical regenerators is the velocity of the working gas flowing through the matrix. This velocity is, in turn, a function of the operating speed of the unit. The Stirling cycle produces a certain amount of power every time the piston and displacer go through a complete cycle. Therefore, the total amount of power produced is, theoretically, directly proportional to the speed of the unit. From the point of view of power production therefore, a very high speed is desirable; high speeds, however, result in excessive pressure drops through the regenerator matrix and poor overall cycle efficiency.

Two regeneration methods were investigated for the application at hand. Their features are explained with the aid of Figures 3-7a and 3-7b.

Figure 3-7a depicts a regeneration method normally used in Stirling machines. Gas flows to the expansion chamber (and back) through a densely packed regenerator matrix, which is located inside the hollow displacer. In order to avoid short-circuiting the regenerator, i. e. , causing hot gas to reach the cold areas, a seal is used between the wall of the displacer and the wall of the expansion cylinder. Note that a small fraction of the gas flows back and forth in the resulting dead-end gap because of the pressure variation. However, in suitably constructed units this has only a minor effect.

Figure 3-7. Comparison between the conventional regeneration method (7a) and the gap regeneration method (7b)

The other regeneration method is depicted in Figure 3-7b. As indicated, gas flow occurs exclusively in the gap which is now open at both ends, the regeneration taking place due to the heat capacity of the surrounding walls. A displacer seal is no longer needed, and the displacer can be made of a poorly conducting rod or an empty shell. The heat capacity per unit volume of the regenerator shown in Figure 3-7b is less than that present in the conventional regenerator.

A study was performed to determine the trade-off between the mesh-type and the gap-type regenerators. The study indicated that for the 6.0 watt power output, the heat input to the engine when a gap regenerator is used, would be at least 2 watts greater than that required

with a mesh regenerator. To enhance overall system efficiency, it was decided to base the engine design on the use of a mesh regenerator.

The major design parameters of the regenerator are given below:

Diameter	0.952 in
Length	1.400 in
Filling factor	45%
Material	Inconel mesh
Pressure drop	0.64 psi.

Heat Exchanger

As previously indicated, heat is supplied to the engine by the radioisotope; part of this heat is converted to shaft and the rest is dissipated, through a heat exchanger, to an externally supplied coolant.

Figure 3-8 depicts the heat exchanger design developed on this program. The working gas flows through the vertical, narrow slots, radially arranged around the displacer rod cavity. Six lead screw threaded channels carry the coolant around the vertical slots. Heat is transferred from the slots to the coolant channels across a 0.3 cm thick wall.

Figure 3-8. Heat Exchanger Configuration

Figure 3-9 is an exploded view of the heat exchanger, showing its essential elements: the part containing the slots for the working gas, the six lead screw threaded part which forms one side of the coolant circuit, and the envelope, which completes the latter circuit and provides the required structural rigidity. The various appendages shown in Figure 3-9 are required for the inlet and the outlet of the coolant, and for the instrumentation needed for pressure and temperature measurements.

Figure 3-9. Exploded View of the Heat Exchanger

The inner elements of the heat exchanger are made of copper, the envelope is stainless steel. In future models, lighter materials can be substituted.

The major parameters of the heat exchanger are given below:

Heat rejected	28 watts
Coolant flow	32 lb/hr
Coolant inlet temp.	43°C (110°F)
Coolant outlet temp.	45°C (113°F)
Gas temperature	57°C (135°F)

Power Piston and Seals

The design of the power piston is "conventional". The first design was provided with four ring grooves, capable of accommodating up to four standard rings or a combination of sealing rings and wear rings. During the performance tests, the standard rings were replaced by new ring designs, as will be described later in the report. As a result, the piston, and the ring grooves, were modified accordingly.

Rhombic Drive

As its name implies, the conventional rhombic drive mechanism has the shape of a rhombus. For the bench model engine, this configuration was changed to that shown in Figure 3-10. Specifically, the connecting rods were inverted, with a resultant decrease in the overall size of the mechanism.

Figure 3-10. Rhombic Drive

The major dimensions of the drive are shown in Figure 3-11.

Figure 3-11. Major Dimensions of Drive

Bearings

The rhombic drive has four journal bearings centering the crankshafts, four connecting rods driving the piston yoke, two connecting rods driving the displacer yoke and oil fed bushings guiding the piston and displacer rods. The estimates for the maximum values of the forces acting on each bearing are:

Main bearing of crankshaft	20 lb.
Piston connecting rod	12 lb.
Displacer connecting rod	8 lb.

All bearings have a diametral clearance in the order of 0.0007 in. and an L/D ratio between 0.5 and 1.0. The bearings are cooled with oil flow to maintain the temperature rise of the oil below 20°F. Estimates of power dissipation and flow rate for all the oil bearings of the bench model are given below:

	<u>Flow (in³/sec)</u>	<u>Power (watt)</u>
Rhombic drive	0.034	3.35
Output shaft	<u>0.001</u>	<u>0.15</u>
	0.035	3.50

Outboard Seal

A screw thread viscosity seal is used between the output shaft and the engine crankcase wall. The groove pattern for the bench model consists of a single thread pumping the oil back into the crankcase. It has a right hand and a left hand thread meeting at a circumferential groove where a gas-oil interface exists. This assures that no foreign particles will enter the engine crankcase except by diffusion through the oil. For the bench model, a square thread is used having the following dimensions:

Diametral clearance between land of thread and cylinder wall	0.0015 in.
Depth of groove	0.01 in.
Pitch	0.0909 in.
Land width	0.0599 in.
Shaft diameter	0.187 in.
Seal length	0.15 in.

The seal is estimated to support a maximum pressure difference of 0.43 psi with an oil viscosity of $4.79 \cdot 10^{-6}$ (lb_f sec/in²).

Rolling Diaphragms

Two rolling diaphragms are used to separate the crankcase from the working spaces: a 7 mm seal between the displacer rod and the piston rod, and a 14 mm seal between the piston rod and the cylinder.

Considerations of fatigue, creep, and ease of construction, led to the following rolling diaphragm parameters:

$$\delta = \frac{2t}{s} = 0.45 \qquad \Delta P = 4.5 \text{ atm} \qquad (3-2)$$

where δ = diaphragm dimension ratio
 t = thickness of rolling diaphragm
 s = width of rolling diaphragm cavity
 ΔP = pressure difference across rolling diaphragm

Oil Pump

The roll-sock cavities and the mechanism bearings are fed by a gear-type oil pump. Proper support of the rolling diaphragms requires oil at 135 psig pressure for an average working gas pressure of 200 psig. Total lubrication flow is estimated at $0.018 \text{ in}^3/\text{sec}$. The oil flow (in^3/sec) delivered by the gear pump is given by

$$Q_p = 2\omega N \left(V_1 - \frac{V_2}{2} \right) - Q_b \quad (3-3)$$

where

ω = speed of gears (rev/sec)
 N = number of teeth per gear
 V_1 = volume per gear tooth cavity (in^3)
 V_2 = volume per tooth cavity for fully engaged gear teeth (in^3)
 Q_b = pump back leakage (in^3/sec)

For any given pump, the back flow is directly proportional to the ratio of pressure head to oil viscosity. The volume per tooth cavity can be obtained (approximately) from:

$$V_1 = \frac{\pi L}{4N} \left[(D+2a)^2 - (D-2d)^2 \right] \quad (3-4)$$

where

D = gear pitch diameter
 L = gear face width
 a = addendum
 d = dedendum
 N = number of teeth per gear

For the clearance volume, the following expression applies (approximately):

$$V_2 = \frac{D - 2a}{D} (d - a) tL \quad (3-5)$$

In the above equation the circular tooth thickness on the pitch line is denoted by t . For 14 1/2 and 20 (deg) full depth involute ASA spur gears, the following equations apply:

$$a = \frac{1}{P_d}, \quad d = \frac{1.157}{P_d}, \quad t = \frac{1.57}{P_d}$$

where the diametral pitch, $P_d = N/D$, is introduced. Combining the above equations, the pump oil flow is obtained:

$$Q_p = L\omega D^2 \left\{ \frac{\pi}{4} \left[\left(1 + \frac{2}{N}\right)^2 - \left(1 - \frac{2.314}{N}\right)^2 \right. \right. \\ \left. \left. - \frac{.246}{N} \left(1 - \frac{2}{N}\right) \right\} - Q_b \quad (3-6)$$

Taking the pitch diameter $D = 0.32$ (in) and the diametral pitch $P_d = 48$ (in^{-1}) with $N = 15$, for a maximum flow rate of 0.018 (in^3/sec), the gear face width obtained is $L = 0.0425$ (in).

Since fabrication of the oil pump had to start at a point in the program when some uncertainty existed as to the actual engine running parameters, the pump was oversized, with $L = 0.110$ (in) and $Q_o + Q_b = 0.0466$ (in^3/sec). These numbers have been verified experimentally, as will be explained later in the report.

The oil pump assembly and its component parts are shown in Figures 3-12 and 3-13 respectively.

Figure 3-12. Oil Pump Exploded

Figure 3-13. Oil Pump Assembly

Control

The control design depicted in Figure 3-14 is intended to maintain the speed of the engine approximately constant. The speed would increase from 600 to 650 rpm as the shaft power output is reduced from 6 to 2 watts. A throttling valve added to the engine connects the working space to a constant volume cavity. Coupling of the oil pump to the engine crankshaft assures the same speed for both.

Figure 3-14. Control System Schematic

If the engine shaft torque is reduced, the speed increases and the higher oil pump pressure opens the throttling valve. The result is a less efficient engine with approximately constant input heat and reduced output power. If the shaft torque is increased, the speed drops and the lower pump speed reduced the oil pressure which closes the throttling valve until equilibrium is reached at a higher engine efficiency and higher output power.

A force balance on the bellows end plate when the valve is closed yields

$$k_b x_{bo} = \frac{\pi}{4} (D_o^2 - D_i^2) (P_b - P_o) \quad (3-7)$$

where

- k_b = spring constant of the bellows assembly
- x_{bo} = bellows compression at closed position of valve
- D_i, D_o = effective diameter respectively of inner and outer bellows
- P_b, P_o = gas buffer pressure and output oil pressure of pump respectively.

Note that the gas pressure on the area $\pi D_i^2/4$ cancels out on a time average basis, hence it has been ignored. The average oil flow rate in a gear pump is approximately given by

$$Q_p = \alpha \omega - \frac{P_o - P_s}{R_p} \quad (3-8)$$

where

- α = function of gears' geometry
- R_p = leakage resistance of pump
- ω = pump (and engine) speed
- P_s = input oil pressure of pump
- P_o = output oil pressure from pump.

Lump the flow resistance of bearings and bushings and denote as R_s obtaining

$$Q_p = \frac{P_o - P_s}{R_s} \quad (3-9)$$

Combine the above two equations to obtain

$$P_o - P_s = \frac{\alpha}{\frac{1}{R_s} + \frac{1}{R_p}} \quad (3-10)$$

A change in the oil pressure, P_o , from its value when the throttling valve is closed can be related to a corresponding change in engine speed, $\Delta \omega$, as

$$\Delta P_o = \frac{a}{\frac{1}{R_s} + \frac{1}{R_p}} \Delta \omega \quad (3-11)$$

A force balance on the bellows end plate at maximum throttling valve opening yields

$$k_b = \frac{\pi}{4} \frac{D_o^2 - D_i^2}{x_{\max}} \Delta P_o \quad (3-12)$$

where

$x_{\max}$ = maximum axial motion of the valve needle from the valve closed position

Combine the above two equations to yield

$$k_b = \frac{\pi}{4} \frac{D_o^2 - D_i^2}{x_{\max}} \frac{a}{\frac{1}{R_s} + \frac{1}{R_p}} \Delta \omega \quad (3-13)$$

A possible design has $D_i = 0.229$ (in) and $D_o = 0.644$ (in). From the cycle analysis of the Stirling engine (see Figure 3-16), it can be shown that 4 watts power reduction corresponds to a valve opening $x_{\max} = 0.0083$ (in). For the gear pump used, the value of $a = 0.005$ (in³) and $R_p = 10^4$ (lb_f sec/in⁵). The value of R_s has been calculated as $4.3 (10)^3$ (lb_f sec/in⁵). Substituting these values and $\Delta \omega = 0.5$ (rev/sec) into the last equation, one obtains $k_b = 257$ (lb_f/in); hence, $x_{bo} = 0.029$ (in). The geometry of the throttling valve is shown in Figure 3-15. Volume A in Figure 3-14 was designed to have 1 (in³).

Figure 3-16 shows the difference between the heat input into the engine hot space, H_i , at a valve opening, x , and the full power heat input, H_{if} , when the valve is closed ($x = 0$).

Figure 3-15. Valve Seat Geometry

DIFFERENCE FROM AVERAGE ENGINE POWER WHEN THE VALVE IS OPENED TO THE POWER WHEN THE VALVE IS CLOSED, $\dot{W}_c - \dot{W}_o$ (WATTS)

DIFFERENCE FROM AVERAGE RATE OF HEAT INPUT TO THE GAS IN THE HOT SPACE WHEN THE VALVE IS CLOSED TO THE HEAT INPUT WHEN THE VALVE IS OPENED, $\dot{H}_{ino} - \dot{H}_{inc}$ (WATTS)

Figure 3-16. Valve Characteristics

The shaft power output is also shown in this figure. It is felt that this speed control system will function properly if the shaft power output is reduced by a maximum of 4 watts. Otherwise the hot end of the engine could overheat. For larger power reductions, the volume A in Figure 3-14 must be increased.

3.2 THERMAL INSULATION DESIGN AND THERMAL CONVERTER INTEGRATION

The hot end interface with the engine is shown in Figure 3-17. It consists of three major components:

- The converter hot finger and heater.
- A vacuum foil insulation system.
- A container to provide an evacuated space for the insulation.

The configuration shown was selected as best meeting the three major design requirements for the interface.

- Thermal protection of the isotope capsule.
- Minimum practicable heat leak.
- Ease of disassembly for replacement of heaters and/or instrumentation.

The third criteria could best be satisfied by use of conventional blanket type insulation systems. In order to satisfy the first criteria, however, a reliable means of removing such insulation was required. In addition, the desired low heat losses were extremely difficult to achieve with this sort of insulation. Early tests using a blanket type of insulation with an electrically heated system revealed that corrosion of the hot finger was a problem using this type of insulation. For the final design, vacuum foil insulation was selected as best meeting all the requirements. It is inherently safe, as leakage of any gas into the insulation automatically destroys its effectiveness, preventing the isotope from reaching a dangerous temperature. The design shown is such that disassembly is reasonably straight forward, and the heat losses are kept to acceptable levels. To allow access to the heater, a pumped system was selected, with demountable flanges, as shown in Figure 3-17. This insulation consists of:

REVISIONS			
DATE	BY	DESCRIPTION	APPROVED
12-7-72	11/10 JPL	REVISED TO REFLECT CHANGES REV A & THERMO ELECTRON DNG JN 78578 "WALL HOT FINGER MULTI-FOIL ASSY".

Notes:
1- INSULATION PER THERMO ELECTRON DNG JN 78572.

Figure 3-17. Bench Model Thermal Insulation Assembly

- A cylindrical portion formed from 131 layers of 1/2 mil molybdenum foil and zirconia spacers wrapped around an inner cylinder formed from 2 mil molybdenum foil. This is enclosed in another 2 mil cylinder.
- A tapered upper closure consisting of 91 layers of molybdenum.
- An upper spacer consisting of layers of stainless steel screening alternating with 5 layer sets of 1/2 mil stainless steel foils.
- A lower tapered closure made of layers of stainless steel screen alternating with 5 layer sets of stainless steel foils (thermal radiation baffles).
- A zirconia lower support.

Figure 3-18a shows the zirconia lower support and the lower closure assembled on the engine cylinder. In Figure 3-18b, the cylindrical portion has been added and the top closure and spacer are ready to be inserted as a single unit.

The original design of the cylindrical portion called for 91 layers of foil. After receipt of the two insulation systems, they were found to be mechanically unstable. To improve the geometric stability of the closure interfaces, approximately 40 layers of foil were added in this region.

The ceramic insulated thermocouples, shown in Figure 3-17a, were subsequently replaced by 20 mil OD inconel sheathed thermocouple assemblies, which are visible in Figure 3-18a. The use of sheathed thermocouples results in greater reliability and greatly simplifies installation. With the small sizes available, the use of sheathed thermocouples actually reduces the heat leak along the thermocouples from 0.9 watts to 0.5 watts while using 6 thermocouples instead of 4.

The design heat loss through the insulation was 3.41 watts with the hot portion of the hot finger at 852°C (1565°F). This was calculated using correlations developed experimentally at Thermo Electron Corporation. A breakdown of the calculated losses is shown schematically in Figure 3-19. The experimentally determined losses were 3.0 ± 0.8 watts, as discussed in Section 4.2.2

(a)

(b)

Figure 3-18. Two Stages of the Foil Insulation Assembly

Figure 3-19. Design Heat Losses for Bench Model Insulation Package

3.3 BLOOD PUMP MECHANISM DESIGN

3.3.1 Description of Bench Model Mechanism

The bench model mechanism configuration is shown in Figure 3-20. The flexible shaft from the thermal converter, which rotates at 900 rpm, is connected to the input shaft of a speed reducer housed in a boss built into the cylindrical wall of the pump. This speed reducer steps down the rotational speed from 900 to 120 rpm. The speed reducer consists of a sun gear attached to the end of the input shaft, planetary gears that rotate around the sun gear, a stationary ring gear that meshes with the planetary gears, and a rotating planetary spider that supports the planetary gears and serves as the output shaft. The planetary spider is connected through a square spline to a crankshaft with three throws.

In order to reduce cost and expedite delivery, the ball bearings in the mechanism were prelubricated with Andok-C grease instead of a dry film lubricant, as originally planned. Although the greased bearings are expected to require a new charge of grease after six months of continuous operation, it is felt that this operating life between teardowns will be adequate for the planned bench model tests. Permanent lubrication of the linear bearings and gearing is accomplished by using linear bearing retainer plates and planetary gears made of Delrin AF, an acetal resin filled with oriented Teflon Fibers.

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 pusher cups that alternately compress dacron reinforced silastic roll sock ventricles at each end of the pump which serve as the left and right ventricles of the blood pump. During diastole when the pusher cup moves away from the ventricle dome, the cylindrical wall of the roll sock in contact with the pusher cup rolls off the pusher cup onto the inside surface of the pump housing. During systole when the pusher cup moves toward the ventricle dome, the cylindrical surface of the roll sock in contact with the pump housing rolls off the pump housing onto the pusher cup. A vacuum of eight inches of mercury is maintained in the mechanism chamber to force the

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Figure 3-20. Bench Model Blood Pump Mechanism

roll sock to seat smoothly on the pusher cups. The ventricle diaphragm is secured to the dome of the pusher cup by capturing a beaded flange on the diaphragm in a mating groove in the pusher cup dome. Because the ventricle dome is flexible, it will collapse inwardly as required during diastole to provide a volume that matches the volume of blood that returns to the ventricle. The inherent strength of the spherically shaped dome under internal pressure minimizes stretching during systole and permits a high pump volumetric efficiency.

The offset of the end throws of the crankshaft permits each pusher cup to travel past the midplane of the pump and occupy space that is occupied by the opposite pusher cup on the return stroke. This arrangement minimizes the overall pump length required to accommodate a given stroke. Rollers on the end throws of the crankshaft engage Scotch yokes built into the ends of a housing causing it to reciprocate as the crankshaft rotates. This housing supports linear bearings that serve as guides for the main Scotch yoke. Two sets of rollers on outriggers attached to the reciprocating housing bear on hardened inserts in the pump housing and prevent the reciprocating housing from rocking and rotating. The radius of the end throws of the crankshaft is half as long as the radius of the center throw, permitting the reciprocating structure to travel at the same velocity as the loop connecting the cylindrical portions of the ventricles. Also, it permits the clearance between these loops and the reciprocating structure rollers to be held to a minimum.

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 on ball bearings. The main Scotch yoke is guided by linear bearings, which provide support through circulating balls.

3.3.2 Mechanism Design Performance

Requirements and Constraints

An envelope was established for the bench model blood pump. This envelope was developed from the Donovan blood pump concept shown in Figure 3-21 and model implantation experiments performed at the University of Utah. The performance requirements and operating conditions specified by the University of Utah for the blood pump are as follows:

Beat Rate - 120 beats/min

Flow Rate - 12 liters/min from each ventricle

Average Discharge Pressure

Left Ventricle - 100 mm Hg

Right Ventricle - 15 mm Hg

Overall Ventricle Efficiency - 60%

Mechanism Efficiency

The work required to drive the blood pump was calculated by plotting the torque required to rotate the pump drive shaft as a function of the drive shaft angle of rotation, and integrating the area under this curve. The average power required was then determined by dividing the work performed by the time required to accomplish it. The torque-displacement curve that was obtained for the specified pump design conditions is shown in Figure 3-22. The power requirements for the blood pump and the calculated efficiency of the pump mechanism are listed below:

Average Power Required During Right Ventricle Discharge - Watts

Ventricle pumping	0.67
Bearing friction in pump housing	< 0.01
Bearing friction in speed reducer	< 0.01
Friction speed reducer gears	<u>0.04</u>
Total	0.71

ALL DIMENSIONS IN CENTIMETERS
 STROKE VOLUME = 111 ml
 STROKE LENGTH = 3.88 cm

Figure 3-21. Donovan Blood Pump Concept.

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Figure 3-22. Drive Shaft Torque

Average Power Required During Left Ventricle Discharge - Watts

Ventricle pumping	4.46
Bearing friction in housing	0.02
Bearing friction in speed reducer	< 0.01
Friction in speed reducer gears	<u>0.17</u>
Total	4.65

Total Power

$$P_{\text{output}} = 0.67 + 4.46 = 5.13 \text{ watts}$$

$$P_{\text{input}} = 0.71 + 4.65 = 5.36 \text{ watts}$$

Mechanical Efficiency

$$= \frac{5.13}{5.36} = 95.7\%$$

Flexible Shaft Efficiency

SS White and Stow Manufacturing, the principal suppliers of flexible shafts in the U.S., were consulted regarding the mechanical efficiency that could be expected of a flexible shaft delivering the average power required by the blood pump while bent into the shape required to connect the thermal converter to the pump. The information obtained indicated that an efficiency of 90% or higher should be achieved if the shaft were rotated at 900 rpm and a teflon guide tube with a patented wear resistant rubbing surface were used.

3.4 BENCH MODEL SYSTEM INTEGRATION

3.4.1 System Arrangement and Performance

As shown schematically in Figure 3-23, the bench model system design consists of a thermal converter and a blood pump, joined by a flexible shaft. The thermal converter design contains:

- An electrical or Pu-238 heat source
- A Stirling engine
- A flywheel and appropriate step-up and reduction gearing
- An insulation system
- Various auxiliary systems

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Figure 3-23. Schematic of Bench Model System

The Stirling engine converts the thermal energy from the heat source into mechanical energy. The flywheel serves to carry the engine through the negative power portions of the engine cycle as well as to aid in performing the required control functions as will be discussed later. The gearing allows the flywheel to operate at 1800 rpm while the engine is operating at its most efficient speed of 600 rpm. The flywheel speed is slow enough so that windage losses are acceptable while still allowing sufficient energy storage in a modest sized unit.

The auxiliary systems include an oil pump to provide lubrication to the engine bearing. A constant displacement pump is used, and the variation of oil pressure with speed provides speed sensing for the control system. A dynamically pumped vacuum foil insulation system minimizes the heat loss from the high temperature portions of the engine. Cooling water is provided to the engine heat exchanger to carry away the heat which cannot be converted into mechanical power.

The bench model blood pump contains the following components:

- A reduction gear
- A Scotch Yoke mechanism
- Two pusher cups
- Two roll sock ventricles
- Moving platform and housing

The reduction gear reduces the flexible shaft speed to 120 rpm to drive the Scotch yoke mechanism. This converts the rotary motion of the reduction gear output to oscillating linear motion of the pusher cups which, in turn, squeeze the two ventricles alternately, providing pulsatile pumping action to the blood. The moving platform serves to locate the pusher cups within the housing, which provides a fixed anchorage for the ventricles.

The system is designed to meet the peak blood flow demands of the body. These have been estimated as:

- 100 mm Hg mean back pressure for left ventricle
- 15 mm Hg mean back pressure for right ventricle

From these numbers, the peak mean hydraulic power, which must be delivered to the blood is:

- 2.7 watts from the left ventricle
- 0.4 watts from the right ventricle
- 3.1 watts total to the blood

As design efficiency of the pumping ventricles is about 60%, the pusher cups are designed to deliver 5.1 watts of mechanical power. As designed, this was expected to require 6.0 watts of power from the thermal converter. The combined design efficiency of the flexible shaft and pump mechanism is therefore 85%.

The designed thermal input to the system is 33.2 watts, providing an overall efficiency of 9.3% and an efficiency of 15% based on power delivered by the pusher cups.

3.4.2 System Control

In order to provide a workable artificial heart system, a means must be provided to match the system to the recipient's varying blood flow requirements. A control system was designed but was not incorporated in the bench model system. The control approach was to maintain constant engine speed and, therefore, constant beat rate and to vary the pump stroke to meet varying physiological demands. The ventricles are designed with flexible, non-extensible domes. On each intake stroke, these domes are designed to collapse rather than apply a negative pressure to the veins. The result is that only that amount of blood available without collapsing the veins enters the pumping chamber on each stroke. The body has built-in

mechanisms which vary the flow parameters of the circulatory system in response to physiological demands and makes more or less blood available at the veins as required. This approach to control also insures that on the average, the blood flow rates in the pulmonary and systemic branches of the circulatory system are equal. The control system is described in Section 3.1.1 (see Page 3-24).

The constant speed-dissipative mode of engine control was selected because this means of control effectively provides temperature control as well as power output control. The characteristics of a Stirling engine are such that the gross power produced at the piston crown is approximately proportional to the heat input times the temperature difference between the hot and cool ends of the engine. The heat input is proportional to the triple product of mass of the gas in the engine, its speed, and the temperature difference. However, with an isotope heat source, the heat input is constant. The thermal capacity of the system is such that, in order to maintain peak power capability on demand, the hot end temperature must be maintained at or near its design level at all times. By maintaining constant speed the temperature is automatically controlled without the need for pumping gas to or from the working volume.

4.0 BENCH MODEL AND COMPONENT TESTING

The bench model Stirling-mechanical system was designed as an investigative tool. It was constructed to test the applicability of available design techniques to the very small artificial heart system and to highlight areas of weakness. In order to accomplish this goal, the thermodynamic state points selected and the design of the major components closely approximated those expected to be used in implantable versions.

4.1 BENCH MODEL TESTING

The bench model system consists of a thermal converter and a blood pump interconnected by a flexible shaft. For test purposes, the blood pump test performance includes the flexible shaft losses.

The basic assemblies of the thermal converter are a Stirling engine, a heat source, and thermal insulation of the multifoil vacuum type. Two thermal converter assemblies have been tested; Thermal Converter No. 1 used an electrical heat source and Thermal Converter No. 2 used as the heat source an emissivity coated Pu-238 radioisotope capsule. The two Stirling engines and the thermal insulation packages were tested separately as components in addition to testing as parts of the integrated thermal converter system.

The basic assemblies of the blood pump are the blood pump drive mechanism including the flexible shaft and the right and left ventricles.

There are three blood pump drive assemblies. Within manufacturing tolerances, the drives are duplicates. There are two matched sets of ventricles. The two sets have the same general ventricle arrangements but differ substantially with respect to positioning of the blood vessel connections. The sets of ventricles mate interchangeably with the drive assemblies. The various blood pump assemblies have been designated as:

- Blood Pump No. 1 - Drive No. 1, Ventricles No. 1
- Blood Pump No. 2 - Drive No. 2, Ventricles No. 2
- Blood Pump No. 3 - Drive No. 3, Ventricles No. 2

All three blood pumps were tested (Blood Pumps No. 1 and 2 as components and Blood Pump No. 3 as a part of a bench model system). Flexible shafts were tested both separately and as parts of the blood pumps.

A bench model system consisting of Thermal Converter No. 1 and Blood Pump No. 3 was tested.

4.1.1 Blood Pump Tests

Test Equipment

The setup for testing blood pumps is shown in Figure 4-1 with Blood Pump No. 1 connected to the mock circulation loop (MCL). The pump is driven by a variable speed electric motor through a rotating torque sensor bearing block to the pump flexible shaft. The motor, torque sensor and bearing block are within the plexiglas structure. The plexiglas structure and interior of the blood pump up to the ventricle pumping diaphragms are evacuated to approximately 6 in.Hg to prevent rumpling of the ventricle roll sock type pumping diaphragms. For ventricle comparison, Blood Pump No. 2 is shown in Figure 4-2. A general schematic of the test setup is depicted in Figure 4-3. During tests of Blood Pump No. 1, unlike the schematic, the pulmonary and systemic sides of the MCL were separated for better control of pressures. During the tests on Blood Pump No. 2, the pulmonary and systemic flow channels were connected in series as in the natural biological system. Sometimes the pressure transducers used to measure the MCL pressures were mounted at the top of the MCL and sometimes at the bottom. The variation in pressure heads was accounted for in data calculations. Water was the fluid used in the MCL. Eight channel Brush recorders were used for data acquisition.

Tests

Prior to the start of each test series, the transducers and electronic circuits were calibrated using 1% resistors and test switches to produce predetermined deflection of the Brush oscillograph. One exception was the flowmeter circuits. The flowmeter electronic output of the MCL being weak is patched to the Brush oscillograph as a sine wave. Calibration is

Figure 4-1. Blood Pump Test Setup

Figure 4-2. Blood Pump No. 2

Figure 4-3. Blood Pump Test Schematic

accomplished by timing the water filling of the MCL per the instructions of Dr. Francis Donovan, Jr. of the Universities Center - Jackson, Mississippi.

The number of pulses per second is recorded for several flow rates and a calibration curve constructed. Flow rates were set by manipulating the arterial and systemic pressures of the MCL.

Input torque measurements were converted to watts and recorded as follows:

$$W = 0.00222 \times F \times P_A \quad (4-1)$$

W = Hydraulic Output in Watts

F = Flow in Liters/Minute

P_A = Arterial Pressure mm Hg

The efficiency of the drive mechanism was computed as follows:

$$\eta = \text{Ventricle Input} / \text{Blood Pump Drive Input} \quad (4-2)$$

Values for the ventricle input are taken from a graph* accounting for a portion of the estimated $\pm 20\%$ error of the calculated values of drive efficiency. In addition, the efficiency is a result of taking a relative small difference between two relatively large values. Another prime source of error is the distortion of the flow signal caused by noise generated in the rotating armature. However, by using "Least Squares" curve fitting techniques, the errors of values taken from the curves are estimated to be in the $\pm 5\%$ range.

Blood Pump No. 1 was tested over a range of speeds and flows. The results are given in Table 4-1. The overall blood pump efficiency is in turn plotted in Figure 4-4 as a function

*Backman, D. K., et.al., "The Design and Evaluation of the Ventricles for the AEC Artificial Heart Nuclear Power Source", Univ. of Utah, ASA10 Abstracts 1973, Volume 2, 1973, Ninth Annual Meeting.

TABLE 4-1

TEST RESULTS ON BLOOD PUMP NO. 1

Cy/Min.	Flow		Input Watts	Pulmonary Pressure mm Hg (Aver.)		Systemic Pressure mm Hg (Aver.)		Blood* Pump Total Hydraulic Output	Ventricle Power Consump- tion Total	η Blood Pump	η Drive Mech.
	Pulmonary Liters/Min	Systemic Liters/Min		Venous	Arterial	Venous	Arterial				
120	11.3	7.0	4.3	2.2	9.1	2.6	84.6	1.6	4.0	37%	93%
120	9.7	7.4	5.3	1.5	5.5	2.4	87.8	1.6	3.8	30%	72%
120	12.0	6.7	5.0	1.9	4.9	2.4	92.4	1.5	4.1	30%	82%
120	12.1	11.1	5.8	2.4	13.5	12.7	86.4	2.5	5.1	43%	88%
120	13.3	11.1	5.4	11.0	18.8	23.8	87.7	2.7	5.2	50%	96%
120	7.1	5.3	3.7	2.2	12.5	18	86.6	1.2	3.1	32%	84%
120	9.7	5.9	3.8	3.2	13.6	1.6	88.3	1.4	3.6	37%	96%
120	7.4	6.2	4.3	0.0	30.1	0.0	87.0	1.7	3.4	40%	80%
120	7.7	5.9	4.8	0.6	31.3	0.0	96.7	1.8	3.2	37%	66%
100	7.4	5.5	4.1	0.0	4.4	1.5	90.3	1.2	3.1	29%	75%
100	10.9	8.0	4.0	7.5	8.2	13.6	78.2	1.6	3.9	40%	98%
100	13	7.2	4.1	9.0	10.2	18.4	81.0	1.6	4.0	39%	97%
80	8.4	4.2	4.4	6.1	9.4	9.6	82.3	1.0	3.0	23%	68%
80	9.0	4.0	4.6	6.4	12.8	6.7	74.2	0.9	3.0	20%	66%
80	6.5	5.0	4.4	1.5	12.6	13.8	76.3	1.0	2.9	23%	65%
80	5.5	4.8	4.3	0.5	15.6	9.7	74.2	1.0	2.9	23%	67%

*Values are calculated on same basis as that of Dr. Frank Donovan, Ref. Donovan, Francis, M. Jr., Energy Requirements of the Artificial Heart, University of Utah, Topical Report 1 - July 1971

Figure 4-4. Blood Pump Efficiency

of hydraulic power output. The drive mechanism efficiencies given in Table 4-1 have much scatter. The values of most interest are the two points at 120 beats/minute at systemic flows of approximately 11 liters/minute, close to the drive design point. The values of drive efficiency are 88% and 96% and 88% is considered more representative of drive efficiency.

Blood Pump No. 2 was checked before shipping to the University of Utah. The two check points are given in Table 4-2 and also plotted in Figure 4-4. The improvement in efficiency between Blood Pumps No. 1 and 2 is probably because of the difference in the ventricles.

The overall error of the tables are $\pm 10\%$ for "Blood Pump" and $\pm 20\%$ for "Drive Mechanism".

Typical maximum acceleration values were 3.1 G peak to peak at 66 Hz for 6 liter/min flow and 2.3G peak to peak at 100 Hz at 12 liters/min.

4.1.2 Thermal Converter Tests

Test Equipment

The thermal converters were installed in a test setup as indicated in the block diagram of Figure 4-5. The thermal converter was bolted to the test bench and connected through a flex shaft to the Chatillon dynamometer which measured the thermal converter output torque. Varying load and speed control was accomplished with the dynamometer. When using an electrical heat source, power input was measured by wattmeter. Heat source and thermal converter temperatures were measured by chromel-alumel thermocouples. Pressures within the thermal converter's working volume, cooling water, oil, and vacuum vessel were also measured. The calibration error of the Chatillon dynamometer is $\pm 2\%$.

In order to shut down when testing the thermal converter with an isotope heat source, provision was made to backfill the insulation system with helium. This provides a high thermal conductivity path from isotope to the outside of the insulation jacket, which is provided with a water cooling

TABLE 4-2

BLOOD PUMP TEST DATA - PULMONARY AND SYSTEMIC FLOW SYSTEMS PUMP NO. 2

Test	Run	Pump Speed ~/Min	Flow		Power Watts	Pulmonary Pressure		Systemic Pressure		Blood Pump Total Hydraulic Output Watts	η Blood Pump Hydraulic Output Blood Pump Input
			Pulmonary Liters/Min	Systemic Liters/Min		Venous mm Hg	Arterial mm Hg	Venous mm Hg	Arterial mm Hg		
Blood Pump No. 2	1	120	12.8	10.8	5.4	11.9	26	0.0	104	3.2	59%
	2	120	9.5	8.5	3.9	0.0	13.5	-5.6	83.7	1.9	49%

Figure 4-5. Thermal Converter Test Block Diagram

coil to carry away the isotope heat. To protect the engine in case of a malfunction, a system of interlocks was provided to automatically backfill the insulation and provide coolant to the jacket. This system is triggered by any of the following events:

- Any one of three thermocouples on the heated portion of the engine indicating a 100°F temperature rise above normal operating levels.
- Two of three thermocouples showing open circuit
- Engine stopping
- Loss of vacuum in the insulation system
- Loss of working volume pressure
- Loss of cooling water flow to the engine.

In the event of cooling water failure, no water flow is provided to the insulation jacket. The heat of vaporization of the water retained in the cooling system is sufficient to protect the engine from serious over-temperature for about four hours. Failure of this system could result in severe damage to the engine, but will not damage the isotope capsule. Ultimate protection is provided for the isotope heat source by the fact that the engine cylinder will melt before the capsule reaches its peak design temperature. This will release argon and/or air into the insulation system, reducing the isotope temperature below its design operating point.

Tests

Thermal Converter No. 1 was tested using an electrical heat source. Output was determined as a function of speed for two hot side temperatures and two working space average pressures (buffer volume pressure) at approximately constant heat input. The results are plotted in Figure 4-6. The upper set of curves is a plot of torque versus speed; the lower set of curves is a plot of output power versus speed. Maximum measured power output was about 4.8 watts.

Figure 4-6. Thermal Converter No. 1 Performance

Thermal Converter No. 2 was tested using a 33 watt Pu-238 heat source. With a Pu-238 heat source, unlike an electrical heat source, the temperature of the source and hot side of the thermal converter cannot be controlled directly. Because of this the converter was started up at the relatively low hot side temperature of 1100°F and conditions allowed to approach equilibrium over a number of hours with the converter running. The load applied on the thermal converter was gradually increased, as hot side temperatures rose, to hold speed approximately constant. Power output stabilized at about 3.9 watts. The converter was operated for 75 hours without incident. Conditions appearing stable at 75 hours, the converter was shut down and the Pu-238 heat source removed. Power and temperatures as a function of time are plotted in Figure 4-7.

4.1.3 System Tests

Test Equipment

The test setup schematic is shown on Figure 4-8. It is essentially a combination of the thermal converter tests and the blood pump test with the engine coupled to the pump by means of a flexible shaft. Although no system tests were run using the isotope heat source, an emergency cooling system was provided as discussed in Section 4.1.2. The test setup is shown in Figure 4-9.

Tests

The system tested consisted of Thermal Converter No. 1, electrically heated, and Blood Pump No. 3. The systemic and pulmonary sides of the mock circulation were separated for better control of the simulated blood pressures rather than being in series as in the body. Water was used in the mock circulation. The performance of the system was examined as a function of blood pump beat rate (cycles/minutes) at varying temperatures and heat input by adjusting the demand on the system through the mock circulation. Overall system efficiency was a strong function of beat rate. Temperature and heat input had less effect. Maximum overall system efficiency measured was 7.4% at 96 beats/minute at a hydraulic output of 2.8 watts. Minimum measured overall system efficiency occurred at 131 beats/minute at a hydraulic

Figure 4-7. Thermal Converter Performance with Pu-238 Heat Source

Figure 4-8. System Test Schematic

Figure 4-9. System Test Setup

output of 1.8 watts. The results are given in Table 4-3. The Blood Pump No. 3 efficiencies calculated from these tests results are consistent with those of the check tests of Blood Pump No. 2 and better than those of Blood Pump No. 1. Blood Pumps No. 2 and No. 3 have the same ventricle designs.

4.2 COMPONENT DEVELOPMENT

4.2.1 Stirling Engine Development

Thermal Converter Test Equipment

Two types of tests were conducted with the Stirling Engine: power dissipation and actual performance. The power dissipation tests were aimed at determining the mechanical efficiency of the engine; the performance tests were, of course, designed to check its thermal or conversion characteristics.

The schematic of the setup used for both types of test is shown in Figure 4-10. Means were provided to monitor temperatures, pressures, speed, and power. Specifically:

- Four thermocouples were installed in the "hot" chamber (see Figure 4-10a): one in the heater (No. 1), and three (No. 2, No. 3 and No. 4) on the hot finger (see detail Figure 4-10b); additional thermocouples were placed in the inlet and outlet tubes of the coolant (No. 5 and No. 6), and the crankcase oil (No. 7). Thermoelectric cooling means were used as the ice point reference, a potentiometer for the thermocouple output readout.
- Transducers were used to monitor the compression space pressure (No. 8), i.e., the compression ratio, and the buffer space pressure (No. 9). An oscilloscope served as the readout. Bourdon tube gauges were used to measure pressures before and after the oil filter, and in the coolant inlet line. A thermocouple and an ionization gauge served to monitor the vacuum level surrounding the hot finger.
- The output speed was measured with the aid of a magnetic pick-up and a toothed wheel.

TABLE 4-3
BENCH MODEL SYSTEM TEST

	Blood Pump Cy/Min	Flex Shaft RPM	Electric Heater Watts	Thermal Converter Output Power Watts	Controller T/2 °F	T/4 °F	T/3 °F	T/1 °F	Water Flow GPM	Vacuum Thermal Insul. Torr	Flow-Liters/Min		Pulmonary Pressure		Systemic Pressure		Blood Pump Hydraulic Output	System Efficiency	Blood Pump Efficiency
											Pulmonary	Systemic	Venus mm Hg	Arterial mm Hg	Venus mm Hg	Arterial mm Hg			
4-19	106	800	38	4.5	1420	155	1350	1565	.15	6×10^{-6}	9.5	7.7	0.9	15.4	-1.9	131	2.5	6.6%	56%
	118	890	40	4.7	1500	160	1300	1600	.15	1.2×10^{-5}	10.7	5.8	1.7	17.5	-7.9	128	2.1	5.2%	44%
	131	985	41	4.7	1500	160	1400	1620	.15	1.2×10^{-5}	7.3	5.9	-8.7	2.2	-9.6	136	1.8	4.3%	38%
	96	725	38	4.3	1470	150	1380	1590	.15	1.2×10^{-5}	9.5	8.5	4.8	17.4	6.5	127	2.8	7.4%	64%
	125	936	43	4.8	1475	155	1380	1585	.15	1.2×10^{-5}	5.9	7.4	-7.7	19.0	-7.2	104	2.0	4.6%	42%
	103	775	33		1370	115	1200	1475	.15	3.5×10^{-6}	5.7	6.2	-8.9	20.1	-5.0	113	1.8	5.5%	
	105	790	33		1380	130	1150	1475	.15	3.3×10^{-6}	5.6	5.9	-1.0	20.0	-1.6	100	1.6	4.9%	
	131	985	33		1470	115	1270	1475	.15	3×10^{-6}	5.8	7.5	2.7	13.7	-7.0	105	1.8	5.5%	

- The component labeled D/M in the left hand side of Figure 4-10a is a DC machine which can act either as a motor or as a generator. In the first case power can be transferred to the engine, in the second case power output can be absorbed.

The oil pump was externally driven by a DC motor. The input heat to the engine was supplied through a temperature controller.

Power in and out of the three items mentioned above was measured with voltmeters and ammeters, as indicated in Figure 4-10a.

During the power dissipation tests, the displacer was not installed in the engine. Power was of course supplied to the system, and the applicable parameters monitored. The actual hot finger was not used in these tests, but was simulated with a "dummy" cap.

Thermal Converter Component Test Equipment

Six components were subjected to performance tests prior to their integration into the engine assembly: the oil pump, the control valve, the rolling diaphragms, the piston rings, the oil filter, and the rhombic drive. The tests ranged from routine checks, e.g., of the rolling diaphragms, to detailed mapping of performance characteristics, e.g., of the oil pump. A discussion of the equipment used in these tests follows.

Oil Pump

The significant parameters of the oil pump are its flow rate, its pressure head, and its efficiency. To determine these characteristics, tests were set up to obtain the flow rate and the power input (a measure of efficiency) as a function of the pump pressure head.

The schematic of the test setup is shown in Figure 4-11. The drive motor provides speeds equivalent to those supplied by the engine shaft on which the pump is to be mounted. Figures 4-12a and 4-12b show the actual test setup, and a close up view of the pump, respectively.

Figure 4-10a. Thermal Converter Test

Figure 4-10b. Thermocouple Locations on Heater and Hot Finger

Control Valve

For adequate control system performance, the control valve must be capable of providing very accurate throttling. The conical valve body and the corresponding seat are designed to provide the required accuracy. The significant valve parameters are the flow rate and the axial motion of the valve body, as well as the pressure levels at the inlet and outlet of the

Figure 4-11. Schematic of Oil Pump Test Setup

Figure 4-12a. Setup for Oil Pump Tests

Figure 4-12b. Close-up View of Oil Pump Under Test

valve. The schematic of the test setup used to obtain the correlation between these two parameters is shown in Figure 4-13. The actual test equipment is shown in Figure 4-14.

Figure 4-13. Schematic of Control Valve Test Setup

Figure 4-14. Setup for Control Valve Tests

Rolling Diaphragm

As previously indicated, the rolling diaphragms are not subjected to performance tests prior to their integration into the system. However, following fabrication, their structural integrity is checked out. The device used in the checkout, for both the 7 mm and the 14 mm seals used in the engine, is shown in Figure 4-15.

The fitting shown as the end of the tubing provides means to pump a vacuum on one side of the seals; a pressure differential across the seal can thus be established, allowing the proper rolling action for the checkout.

Figure 4-15. Fixture for Rolling Diaphragm Checks

Piston Rings

The best piston ring is one which provides high sealing ability with minimum power dissipation. Comparative tests were conducted to select a ring having the proper combination of material, geometry, and loading characteristics to meet the requirements cited above.

Figure 4-16 shows the unit used for the tests.

The setup consists of a piston which reciprocates in a cylinder (finned part of Figure 4-16); the piston has grooves which accept the various rings being tested. It is driven, through a conventional con-rod mechanism, by a calibrated D. C. motor.

Figure 4-16. Piston Ring Test Rig

Oil Filter

The setup used to test the effectiveness and loss characteristics of the oil filter is the same as that used for the oil pump tests, i.e., the one illustrated in Figure 4-11. An important filter characteristic, the rate of clogging as a function of operating time and of oil cleanliness, was investigated in the component tests.

Drive

Theoretically, the rhombic type drive used in the engine is perfectly balanced. Ideally, the drive elements, once fabricated and carefully weighed, should yield the required balanced operation. However, the accumulation of manufacturing tolerances requires that the assembled drive be corrected for these deviations. These corrections, or checks, are done with the aid of the fixture shown in Figure 4-17.

Figure 4-17. Rhombic Drive Balancing Fixture

When balanced, the rhombic drive can reciprocate, with its center of gravity remaining stationary. This implies that when the drive is mounted on the above fixture, it can be set in any operating position; without the center of gravity, or the pointer, moving. If the pointer moves, mass can be added or subtracted from the drive yokes and/or the counterweights until the pointer (or center of gravity) remains stationary in any drive position.

It should be noted that during the performance testing of the engine, a functional change was made on the power piston which unbalanced the system. Due to the required delivery the drive was not rebalanced.

Thermal Converter Tests

Hot Finger Instrumentation

Following fabrication, i.e., machining, brazing and welding, the hot fingers were instrumented. The heater was installed, heater leads and thermocouples were affixed and fed through the flange. An instrumented hot finger is shown in Figure 4-18.

Figure 4-18. Instrumented Hot Finger

The first tests were run with Min-K insulated hot fingers, while subsequent testing was done with the vacuum foil insulation installed.

Thermal Converter No. 1

The performance of the first thermal converter was determined by loading it with a calibrated D.C. electric generator. Figure 4-19 shows the thermal converter driving the generator through a flexible disc coupling. A vacuum pump connected to the multifoil insulation space maintained a pressure level of the order of 10^{-7} mm Hg. The test speed of the thermal converter was 600 RPM corresponding to a speed of 900 RPM for the generator. Strain gage pressure transducers were installed in the working and buffer spaces to record instantaneous

Figure 4-19. Stirling Thermal Converter Test Assembly

values of the respective gas pressures. A magnetic position sensor located in the housing of the external gear reduction mechanism was used to monitor the working piston position. The pressure-volume diagrams and the thermodynamic (or indicated) power were then calculated. Table 4-4 shows engine performance tests with argon as the working fluid and Vitrea[®] 21 light viscosity pure mineral oil as the lubricating fluid. The split type piston ring assembly (see Figure 4-23) consisted of three pieces made of Rulon J. The Bal Seals (made of graphite filled teflon) used have a very low friction rating according to the manufacturer. The temperatures listed in Table 4-4 are at the outer surface of the thick wall section of the hot finger. The maximum and minimum values of gas pressure in the working space are included in the fourth column in Table 4-4. The values of thermodynamic power listed neglect the pressure drop between the compression and expansion space. The values of shaft power indicated in the last column of the table do not include the external reduction gear mechanism; however, they include the power taken by the oil pump feeding the lubrication system and supporting the roll socks. In test No. 4, the input electric power (including insulation losses) was measured to be 38 watts. The pressure - volume diagram in the working space of the engine during test No. 4 is shown in Figure 4-20.

Figure 4-20. Pressure-Volume Diagram for Test No. 4

The thermal converter performance is clearly much better with the Bal Seal than it is with a split type piston ring. The increase in shaft power in test No. 4 has been attributed primarily to a change made in the geometry of the heater at the thick wall/thin wall interface. This change is discussed hereafter. In tests 2 and 3, the thermodynamic power was high; however, the pressure forces on the drive mechanism were also high resulting in increased frictional

TABLE 4-4

STIRLING THERMAL CONVERTER No. 1 PERFORMANCE DATA

<u>Exp. No.</u>	<u>Piston Ring</u>	<u>Temperature (°F)</u>	<u>Working Pressure (psig)</u>	<u>Thermodynamic Power (Watts)</u>	<u>Shaft Power (Watts)</u>
1	Split Type	1500	200/130	5.6	0.20
2	Bal Seal	1550	260/165	12.4	2.60
3	Bal Seal	1680	270/170	14.2	3.50
4	Bal Seal	1370	235/155	11.0	4.60

losses in the piston ring seal and in the lubrication system. Also, the higher operating temperatures in tests 2 and 3 required higher values of input heat as compared to test No. 4.

Thermal Converter No. 2

Following a relatively problem free assembly, engine No. 2 was subjected to an evaluation test very similar to that performed with engine No. 1. The temperature of the thermal heater was raised to 1400°F, the output shaft speed maintained at 900 rpm, and the mean value of the gas pressure set at 200 psig. A compression ratio of 1.52 was observed with 4.5 watts net output shaft power and 38 watts of input power. Measurements indicated 5.5 watts lost in lubrication and piston ring friction power. The estimated gas flow losses were 0.5 watt, resulting in a thermodynamic indicated power of 10.5 watts. The overall efficiency of the engine was therefore $4.5/38 \approx 12\%$.

Stirling Engine Developmental Problems and Modifications

Hot Finger

During performance tests, the first hot finger developed a leak. Both mass spectrometer and electron microscope tests indicated that the leak was through an extremely small pin-hole located at the transition seam between the thin wall and thick conducting portion of the finger. A rigorous analysis of the problem would have required destructive testing. Since no back-up finger was available, no metallurgical tests were conducted. The leak was repaired by cutting the finger below the pin hole and extending the thick wall section down by approximately 1 cm and welding. This fix also improved the heat transfer from the electric heater to the working gas.

There is a possibility that the hole was caused by corrosion; the finger had been operated with Min-K insulation, in air. The Udimet 700 used in the finger had been vacuum melted, and therefore especially susceptible to corrosion problems. The use of vacuum foil insulation should solve this problem.

Mechanical Tolerances

The heat from the isotope is transferred to the working gas in the annular region between the top cap on the displacer and the hot end of the engine cylinder. In preliminary testing, this gap was found to be too large for good heat transfer, so the displacer was modified to increase the gas velocity in this region. After this modification it was found that the geometrical tolerances were not adequately specified and the displacer rubbed against the hot finger wall. Several critical parts were reworked, and this problem was corrected. Several more minor problems due to tolerance buildup were also encountered and corrected without difficulty. Corrective action has been taken to insure that adequate geometrical tolerances will be specified in the future.

Piston Ring Configurations

A number of piston ring configurations were designed, fabricated and tested. Figure 4-21 shows the conventional piston ring normally used in large Stirling engines. It consists of an outer ring with a radial step cut, an inner ring with a straight cut and a coil compression spring to assure good sealing at low pressure differences. The material is Rulon A.

Figure 4-21. Two Piece Split Piston Ring with Radial Step Cut

Figure 4-22 shows a modified piston ring from W. S. Shamban Co. It consists of two glass-reinforced teflon rings facing and sealing against each other, and a marcel expander spring. The rings have step axial cuts.

Figure 4-22. Two Piece Split Piston Ring with Axial Step Cut

Figure 4-23 shows a three piece piston ring assembly with a marcel expander spring. This ring was specifically designed to meet the present sealing requirements. The material used was Rulon J and all three rings have straight cuts.

Figure 4-23. Three Piece Split Piston Ring with Straight Cuts

All three piston ring configurations described above have pumping grooves in one face to enhance sealing and to pump the buffer space up to the maximum working gas pressure. The latter effect is desirable for the oil lubrication system, because bearing loads fluctuate more in direction, thus enhancing the oil squeeze film effect. However, a relatively high pressure in the buffer space can inhibit the life of the roll socks and increase compression losses in the buffer space.

The three piece ring of Figure 4-23 is by far the simplest to manufacture, and compression tests have shown it to seal better than both the other types. Next in sealing quality is the two piece ring with axial cuts shown in Figure 4-22. The friction dissipated by all three types of piston rings was about the same. The compression values obtained with all three rings were close in value; however, the resulting engine shaft powers were significantly different. All three rings performed significantly better than standard split type piston rings without pumping grooves. It must be emphasized that the amount of leakage through a split type piston ring is very sensitive to the quality of its machined surfaces.

The piston rings discussed above are advantageous because their running life is reasonably predictable. However, the small amount of leakage they allow significantly affects engine performance in the small thermal converter size of interest. Test results indicated the need for a better type of piston ring, and the Bal Seal was finally chosen and indeed found to be better in sealing quality at no apparent cost in frictional power. Figure 4-24 shows the Bal Seal used, made of graphite-filled teflon, together with the piston assembly. The compression ratios obtained under a set of identical engine tests, except for the use of different types of piston ring configurations, are listed below:

<u>Type of Seal</u>	<u>Compression Ratio</u>
Modified Shamban Piston Ring of Figure 4-22	1.46
Three Piece Piston Ring of Figure 4-23	1.48
Bal Seal of Figure 4-24	1.53

Figure 4-24. Bal Seal and Piston Assembly

Related Tests

Prior to tests with the overall engine assembly, various components were subjected to individual tests, described next.

Oil Pump

Following its fabrication and assembly, the oil pump was subjected to tests; specifically, its friction and flow characteristics were checked.

The frictional power as a function of the oil pressure, at 600 rpm shaft speed, is shown in Figure 4-25. The operating point is at 110 psi, with the corresponding losses amounting to 1.65 watts. The predicted value was 1.50 watts, so that the friction was underestimated by 10%.

The pump delivers a flow of $0.06 \text{ in}^3/\text{sec}$ at a pressure head of 110 psi, which is in close agreement with the calculated flow rate. The pumping power is 0.7 watts; therefore, the efficiency of the pump is 43% at the operating conditions.

Oil Filter

The oil used to lubricate the engine bearings, to support the rolling diaphragms, and to actuate the speed control, will be continuously filtered, to prevent particulate matter from reaching critical areas. The filters selected are of 316 L sintered stainless steel, supplied by the Mott Co. To check the manufacturer's data on the pressure/flow characteristics of the filter material, as well as to determine its clogging rate, tests were initiated under simulated operating conditions.

The manufacturer's data relating filter porosity to pressure-flow characteristics (given by λ) is as follows:

Figure 4-25. Oil Test Results

<u>Filter Porosity (Microns)</u>	<u>λ (l/in²)</u>
0.5	0.25×10^{10}
2	0.34×10^9
5	0.27×10^9
10	0.18×10^9

In this table, the flow parameter λ is defined as:

$$\lambda = \Delta P A / Q \mu t \quad (4-3)$$

ΔP = pressure drop across the filter (psi)

A = area of the filter (in²)

Q = flow rate in³/sec

μ = oil viscosity (lb sec/in²)

t = thickness of filter (in.)

The related parameters in the engine are:

$$Q = 0.02 \text{ in}^3/\text{sec}$$

$$A = 5.26 \text{ in}^2$$

$$t = 0.06 \text{ in.}$$

The pressure drops associated with the various filter porosities are as follows:

Filter porosity (microns)	0.5	2	5	10
Pressure drop (psi)	10.1	0.34	0.27	0.19

Tests were performed with a 0.5 micron filter, having an area of 0.025 in², a thickness of 0.062 in., at a pressure differential of 200 psi; the oil used was Vitrea 21, which at 25°C has a viscosity of $4.79 (10)^{-6}$ lb sec/in². The results of the tests are given following:

<u>Time from Start (Min.)</u>	<u>Flow Rate (in³/Min.)</u>	<u>λ (1/in²)</u>
0	152	$1.09 (\times 10^{10})$
10	132	1.25
20	119	1.39
30	164	1.01
40	142	1.16
50	93	1.78
60	58	2.81

As shown, λ increased rapidly with time, i. e., from $1.09 (10)^{10}$ to $2.81 (10)^{10}$ in 60 minutes, indicating considerable clogging. Between 20 and 25 minutes, the test was stopped and the filter cleaned. The tests also showed that the pressure drop across the filter was approximately four times that predicted by the manufacturer's data. Under the conditions of the test, clogging would become significant to engine operation after approximately 200 hours.

The actual operating conditions, however, are less severe. The expected pressure differential is 10 psi rather than 200 psi, and the porosity of the filter can be as high as 10 micron rather than the 0.5 micron used in the tests. In addition, each engine will undergo a "break in" procedure in which the engine is run for a period, then stopped and the filter replaced. This cycle will continue until the contamination left in the engine by the manufacturing process is removed. At this time the engine will be permanently sealed. Under these conditions, the problem is considerably eased.

Control Valve

Volume flow measurements with nitrogen gas were made for the conical valve of the control system. Its large diameter is 0.1 in. with a small diameter of 0.05 in. and an included angle of 30° . Figure 4-26 shows the experimental values and the theoretical flow rate given by

$$Q_e = \frac{\pi x^3}{12\mu} \frac{T_e}{T} \frac{\sin^4 \theta}{\ln(d_o/d_1)} \frac{P_o^2 - P_1^2}{P_e} \quad (4-4)$$

Where Q_e = volume flow rate at the temperature T_e and pressure P_e

P_o P_1 = pressures at large and small ends of valve

d_o d_1 = large and small diameters of valve

θ = half included angle of valve

μ = viscosity of gas flowing through the valve at temperature T

x = axial motion of valve body from closed position

The above equation was derived assuming that the thickness of the gas annulus is very small compared to the diameter d_1 . In the present case it seems to become very inaccurate for $x > 0.004$ in. The maximum value of valve opening was calculated theoretically to be 0.00463 in.; however, this value was corrected to 0.0083 in. to compensate for the error introduced by the Rhombic Drive friction.

Figure 4-26. Control Valve Flow Results

Following the assembly of the drive mechanism, the rolling diaphragms and the crankcase, tests were performed to determine the frictional losses in the drive. The mechanism, including the oil pump, showed 5.0 watts loss at the operating conditions. The predicted, i.e., calculated value, was 4.0 watts, or 20% less than the actual friction.

Piston Ring Friction

In the bench model engine, the sealing of the compression space from the buffer zone is accomplished with the aid of compensated (i.e., expandable) piston rings. The wide use of these rings in conventional (normally high power) applications has generated a large amount of data concerning their life and power dissipation characteristics. However, since the rhombic drive assures that there is no side thrust exerted on the reciprocating elements the loads on the seals are very low and the available data are not applicable to these conditions. Therefore, a series of tests was run to determine the power loss associated with compensated rings.

The results of the tests are summarized in Table 4-5. Additional tests with piston rings are described elsewhere in this report.

4.2.2 Thermal Insulation Evaluation

Upon receipt, one of the two insulation systems was tested to evaluate its performance. The heat loss ascribable to the insulation system has been computed as 3.0 watts $\pm$ 0.7 watts. To avoid possible damage to a Udimet hot finger, a dummy hot finger was manufactured of Type 304 stainless steel. To minimize manufacturing costs, tolerances on this dummy finger, particularly in the thin walled section, were relaxed. Upon receipt of the dummy finger, all important dimensions were measured and recorded for use in the test analysis. The heater was then installed and the hollow portion of the finger plugged with Min-K 2002. Thermocouples were attached to the heater, the tapered portion of the heated end of the hot finger, and at the transition from thin to thick wall in the cool end. The insulation system was then

TABLE 4-5
PISTON RING POWER LOSSES

<u>Manufacturer</u>	<u>Ring Material</u>	<u>Joint Type</u>	<u>Power Dissipation (2 Rings) (Watts)</u>
Shamban Corp.	Bronze filled TFE	Flat Step	0.79
	Turcon (proprietary)	Tapered	0.48
	Phosphor Bronze filled TFE		0.49
Koppers Co., Inc.	Cadmium oxide	Flat Step, Grooved	0.23
	Filled TFE	Angular Step, Grooved	0.93
		Flat Step	0.39
Bal Seal Co.	Graphite filled TFE	Full Ring	In Excess of 1.70

assembled on the dummy hot finger. Particular care was taken to insure good fit-up between mating portions (e.g., the cylindrical portion and the top closure) of the system. A water cooled jacket was placed around the insulation and the entire assembly was placed in a bell jar to evacuate the Min-K plug, as well as the insulation system.

Power was applied and adjusted until equilibrium was established with the tapered portion of the hot finger at 1124°K (1564°F). The measured power required to maintain this temperature was 9.12 watts. The temperature at the cool end of the thin wall portion of the hot finger was recorded as 401°K (262°F). Based on these temperatures, the heat conducted along various paths can be computed as:

a)	Thin Wall Portion	4.44 ± 0.3 watts
b)	Alumina Insulation	0.80 ± 0.3
c)	Thermocouple Leads	0.35 ± 0.06
d)	Heater Leads	0.32 ± 0.03
e)	Min-K	0.17 ± 0.02
TOTAL		6.08 ± 0.71 watts

The difference between the measured heater power, (9.12 watts), and the sum of items (a) through (e) above then represents the best estimate of the thermal insulation heat loss, i.e., 3.04 ± 0.71 watts. The error estimates are primarily due to uncertainty in the thermal conductivity of the material. Heat conducted down the thin wall portion of the dummy hot finger, the length of the conduction path, is well defined, as it is for the Min-K. For the other paths, the length of the conduction path is not so well defined, because there is not necessarily good thermal contact with the hot finger. This effect is included in the error estimates. An expected temperature error of about $\pm 5^{\circ}\text{K}$ (10°F) increases the probable error to 0.81 watts.

4.2.3 Flex Shaft Evaluation

Equipment and Test Description

The equipment is shown in Figure 4-27a and Figure 4-27b. This setup consists of a variable speed motor and tachometer driving two torque sensors, two bearing blocks, a flexible shaft and hysteresis dynamometer. The dynamometer loading can be adjusted for loadings up to 120 in. oz.

Shaft speed is continuously variable between 0 - 2000 RPM. Dead weight calibration to 0.01 in. oz. is available. The system resolution is 0.05 in. oz. based on resolving with the eye one half of a chart line separated by 0.032 inch. The eight channel oscillograph is shown in Figure 4-27b.

The test setup is designed to accomplish the following:

- Measure torque differential losses from 0.05 to 50 in. oz.
- Measure tare torques.
- Measure dynamic torque losses in the flexible shaft under the following conditions:

Straight shaft

Shaft bent at 45° angle

Shaft bent at 90° angle

Shaft set for 2 inch offset

Progress in carrying out these measurements can be summarized as follows:

- The electrical noise (data acquisition equipment) at maximum gain was reduced to nondetectable values (0.01 inch pen trace). The system sensitivity is 0.05 in. oz. The system range is 50 in. oz.
- Mechanical and electrical tests show low values of torque loss through a straight flexible shaft in the order of 0.06 to 0.1 in. oz. (Figure 4-28).
- Figure 4-29 shows the recording of dead weight calibration. Figure 4-30 shows the differential torque measurement using a solid shaft (not dynamically balanced) while Figure 4-31 is a comparison recording using the flexible shaft. Torque difference between recordings represents the flexible shaft torque loss.

Figure 4-27a. Flexible Shaft Component Test

Figure 4-27b. Flexible Shaft Component Test and Recorder

Figure 4-28. Flexible Shaft Torque Loss

Figure 4-29. Torque Calibration

Figure 4-30. Solid Shaft - Dynamic Torque

Figure 4-31. Flexible Shaft - Dynamic Torque

Results and Error

Four different flexible shaft material combinations have been tested, statically and dynamically, for shaft torque loss. Dynamic measurements at 900 RPM (Figure 4-31) show a torque loss of 0.1 in. oz. Static measurements using a torque watch, for the worst sample, show a mean loss of 0.008 for an in-line shaft to 0.072 in. -oz. for a shaft operating through a 90° angle. The data is shown in Tables 4-6 through 4-10. The data shown has had the tare value of 0.04 in. oz. deleted.

The errors of measurement varied from 15% to 56% as indicated in Tables 4-6 through Table 4-10. These errors were high because the 0.008 to 0.072 in. -oz. values are extremely small and are at the lower limit of measurement capabilities.

4.3 ANALYSIS OF RESULTS

4.3.1 Actual Blood Pump Performance Compared Against Design Expectations

Ventricle Performance

The ventricle testing was performed at the Division of Artificial Organs at the University of Utah under AEC Contract AT (11-1)-2155. The maximum flow rate observed was 11.6 l/min with a corresponding efficiency of 63%. These numbers compare well with the design values of 12 l/min with an efficiency of 60%.

Driving Mechanism and Flexible Shaft

The test results shown in Tables 4-1 (page 4-7) and discussed in Section 4.2.3 indicate combined pump mechanism and flexible shaft efficiencies of 88 and 96% for the two test points with almost full systemic flow. These values compare reasonably well with the value of 86% obtained by multiplying the predicted efficiencies of the pump mechanism and the flexible shaft. The difference in the measured efficiencies at these two points cannot be readily explained since the power transmitted by the mechanism is essentially the same. However, the discrepancy may be due to an accumulation of experimental errors in two sets of test data used to

TABLE 4-6

FLEXIBLE SHAFT TORQUE TEST - SST CORE IN AR 400 TEFLON COVER

Run Numbers	Data x	Mean x_i	Deviation $x_i - \bar{x}$	Deviation ² $(x_i - \bar{x})^2$	Sample Variance s^2	Sample Standard Deviation s	Standard Error E
1	0.01		-0.002	4×10^{-6}			
2	0.01		-0.002	4×10^{-6}			
3	0.01		-0.002	4×10^{-6}			
4	0.00		0.008	64×10^{-6}			
5	0.01		-0.002	4×10^{-6}			
TOTAL	0.04	0.008		80×10^{-6}			
				80×10^{-6} $n - 1$	$= 20 \times 10^{-6}$		
Sample Std. Dev.						0.00447	
Std. Error							55.9%

TORQUE WATCH MEASUREMENT; FLEX SHAFT, IN.-LINE

x = Observed torque (in-oz) - Tare torque

$$s^2 = \sum (x_i - \bar{x})^2 / n - 1$$

$$E = \frac{s}{x_i}$$

$$x_i = \frac{\sum x}{n}$$

n = number of tests

TABLE 4-7

FLEXIBLE SHAFT TORQUE TEST - SST CORE IN AR 400 TEFLON COVER

Run Numbers	Data x	Mean x_i	Deviation $x_i - \bar{x}$	Deviation ² $(x_i - \bar{x})^2$	Sample Variance s^2	Sample Standard Deviation s	Standard Error E
1	0.01		0.008	64×10^{-6}			
2	0.02		-0.002	4×10^{-6}			
3	0.02		-0.002	4×10^{-6}			
4	0.02		-0.002	4×10^{-6}			
5	0.02		-0.002	4×10^{-6}			
TOTAL	0.09	0.018		80×10^{-6}			
				$\frac{80 \times 10^{-6}}{n-1} = 20 \times 10^{-6}$			
Sample Std. Dev.						0.00447	
Std. Error							24.8%

TORQUE WATCH MEASUREMENT; FLEX SHAFT, 2" OFFSET

 x = Observed torque (in-oz) - Tare torque

$$s^2 = \frac{\sum (x_i - \bar{x})^2}{n-1}$$

$$E = \frac{s}{x_i}$$

$$x_i = \frac{\sum x}{n}$$

 n = number of tests

TABLE 4-8

FLEXIBLE SHAFT TORQUE TEST - SST CORE IN AR 400 TEFLON COVER

Run Numbers	Data x	Mean x_i	Deviation $x_i - \bar{x}$	Deviation ² $(x_i - \bar{x})^2$	Sample Variance s^2	Sample Standard Deviation s	Standard Error E
1	0.03		0.002	4×10^{-6}			
2	0.03		0.002	4×10^{-6}			
3	0.04		-0.008	64×10^{-6}			
4	0.04		-0.008	64×10^{-6}			
5	0.02		0.012	144×10^{-6}			
TOTAL	0.16	0.032		280×10^{-6}			
				$\frac{280 \times 10^{-6}}{n-1}$	$= 70 \times 10^{-6}$		
Sample Std. Dev.						0.00839	
Std. Error							26%

TORQUE WATCH MEASUREMENT; FLEX SHAFT, 3" OFFSET

 x = Observed torque (in-oz) - Tare torque

$$s^2 = \frac{\sum (x_i - \bar{x})^2}{n-1}$$

$$E = \frac{s}{x_i}$$

$$x_i = \frac{\sum x}{n}$$

 n = number of tests

TABLE 4-9

FLEXIBLE SHAFT TORQUE TEST - SST CORE IN AR 400 TEFLON COVER

Run Numbers	Data x	Mean x_i	Deviation $x_i - \bar{x}$	Deviation ² $(x_i - \bar{x})^2$	Sample Variance s^2	Sample Standard Deviation s	Standard Error E
1	0.02		-0.004	16×10^{-6}			
2	0.01		0.006	36×10^{-6}			
3	0.01		0.006	36×10^{-6}			
4	0.02		-0.004	16×10^{-6}			
5	0.02		-0.004	16×10^{-6}			
TOTAL	0.08	0.016		120×10^{-6}			
				$\frac{120 \times 10^{-6}}{n-1}$	$= 30 \times 10^{-6}$		
Sample Std. Dev.						0.00549	
Std. Error							34%

TORQUE WATCH MEASUREMENT; FLEX SHAFT, 45° ANGLE

 x = Observed torque (in-oz) - Tare torque

$$s^2 = \frac{\sum (x_i - \bar{x})^2}{n-1}$$

$$E = \frac{s}{x_i}$$

$$x_i = \frac{\sum x}{n}$$

 n = number of tests

TABLE 4-10

FLEXIBLE SHAFT TORQUE TEST - SST CORE IN AR 400 TEFLON COVER

Run Numbers	Data x	Mean x_i	Deviation $x_i - \bar{x}$	Deviation ² $(x_i - \bar{x})^2$	Sample Variance s^2	Sample Standard Deviation s	Standard Error E
1	0.08		-0.008	64×10^{-6}			
2	0.08		-0.008	64×10^{-6}			
3	0.08		-0.008	64×10^{-6}			
4	0.06		0.012	144×10^{-6}			
5	0.06		0.012	144×10^{-6}			
TOTAL	0.36	0.072		480×10^{-6}			
				$\frac{480 \times 10^{-6}}{n-1} = 120 \times 10^{-6}$			
Sample Std. Dev.						0.01095	
Std. Error							15%

TORQUE WATCH MEASUREMENT; FLEX SHAFT, 90° ANGLE

 x = Observed torque (in-oz) - Tare torque

$$s^2 = \frac{\sum (x_i - \bar{x})^2}{n-1}$$

$$E = \frac{s}{x_i}$$

$$x_i = \frac{\sum x}{n}$$

 n = number of tests

determine the efficiency at each test point. Other variations in the overall drive efficiency that cannot be related to the power transmitted may also be due to the same cause.

4.3.2 Actual Thermal Insulation Performance Compared with Design

The overall heat losses through the insulation appear to be somewhat smaller than the calculated value (3.0 watts rather than 3.4 watts), although the experimental error is fairly large. There is reason to believe that the distribution of the losses presented in Figure 3-19 (see page 3-33) may be in error. During operation, the upper flange of the insulation jacket was observed to reach a temperature of 320°K (120°F) while the remainder of the jacket remained at essentially 300°K (80°F). It appears that the losses through the upper joint were somewhat higher than predicted. As a close fitting joint could not be obtained in this region, this is not surprising.

For the advanced versions of the system, the insulation will consist of approximately 35-40 preformed nested cups. Figure 4-32 shows experimental results obtained with various numbers of these cups as described in Reference 1. The expected heat loss using this geometry is about 2.0 watts as shown in the figure. Also shown, for comparison purposes, is the performance of the present foil package as well as Min-K-2002. The performance improvement comes from two sources:

- As each layer of insulation is a preformed cup, the joints between the top, sides and bottom region are eliminated. Therefore, no gaps exist for thermal radiation through the corners.
- Each preformed layer is self-supporting; therefore, the contact between layers is minimized.

Due to these considerations, previously reported test results* closely approach the theoretical ultimate performance for the materials used.

*Final Report, AEC Contract AT(11-1)-2239, Westinghouse Report WANL-M-FR-73-001.

Figure 4-32. Composite Picture of Heat Loss vs. Foil Layers Comparing the Performance of Concentric Cup Systems with Min-K 2002 and a Spiral Wrapped Foil System

4.3.3 Stirling Engine Performance Compared With Design

Electrically Heated Tests

The output power and the input heat of the engine were measured as 4.8 watts and 38.0 watts respectively. As indicated previously the corresponding design values were 6.0 watts and 33.2 watts.

The 33.2 watt input heat level was based on the assumption of 1.5 watts insulation loss. The actual value for the latter loss is 3.8 watts; in addition, 1.1 watts of input heat was lost by conduction along instrumentation leads, i.e., thermocouples and heater. Thus, the actual heat input to the engine was 33.1 watts.

The indicated (or thermodynamic) power was measured as 10.4 watts, which was the design value. The indicated power is that transmitted to the mechanism, i.e., it is the actual heat input to the engine minus unavoidable thermodynamic losses, and minus the conduction losses through the various elements which couple the hot side of the engine to its ambient temperature portion, such as hot finger wall, displacer wall, regenerator matrix, and working gas.

With 10.4 watts into the drive mechanism, and 4.8 watts out on the shaft, the mechanical and related losses are 5.6 watts. The latter includes drive train (or bearing) friction, piston ring and seal friction, displacer, i.e., flow and seal loss, and buffer space connection losses. While it is difficult to determine the exact values for each of the four items cited above, there are strong indications that the piston ring losses are double the design value. No losses were expected for the buffer space. Specifically, indications from various measurements suggest the following breakdown:

	<u>Watts</u>
Bearing losses	3.5
Piston ring friction	0.6
Buffer space losses	0.8
Displacer loss	<u>0.7</u>
	5.6

The mechanical losses were expected to total 3.9 watts: 3.1 watts in the bearings, 0.3 watts dissipated by piston ring friction, and 0.5 watts in the regenerator. Of the 1.7 watts difference (i.e., 5.6 minus 3.9), 1.2 watts should have been usable shaft power, and 0.5 watts to power the oil pump.

As indicated elsewhere in the report, the oil pump was over designed; at nominal working pressure it took 1.5 watts of input power, instead of the 0.5 watts required by a similar pump designed without the large safety factor used. During the performance tests, the oil pump was externally driven. Since the pressure used in the engine was 14% higher than design value, the oil pump actually consumed 1.9 watts of power.

Isotope Heating Tests

Figure 4-7 (page 4-14) summarizes the performance of Thermal Converter No. 2 under prolonged testing using the isotope heat source. Under this condition the thermal input to the converter is fixed at 33 watts. During operation, the torque was set manually on the dynamometer, and periodically adjusted to hold the speed at 900 ± 50 rpm. Several important observations can be made from this figure. The first is the rather long break in period required to reach maximum performance. This is shown by the fairly uniform increase in power during the first thirty hours of operation. The short term variations in speed were a mystery until a sharp decrease in speed at about 46 hours was observed to correspond with a rapid fluctuation in oil pressure. The cause was ascribed to entrainment of air in the oil system, and the oil system was modified to minimize this event, providing much smoother performance from about 48 hours on.

The inverse relationship between speed and temperature can be verified by comparing the long term trends of the speed and temperature as recorded by meter No. 1. The long term decline in power can be ascribed to increasing losses in the reduction gears. This gear set is located outside

the crankcase, and is not provided with continuous lubrication. At about 69 hours, a drop of oil was placed on this gear set, producing an abrupt increase in power and speed. This speed increase produced a corresponding decrease in temperature and a new steady state power was eventually reached.

With isotope heating, the maximum power output observed was 3.95 watts, as compared with a design output of 6 watts and an observed value of 4.8 watts in the electrically heated tests. The discrepancies between design and the electrically heated results were discussed previously. Due to the increased heat leak, the engine with isotope heating could not reach the temperature used with electrical heating thus accounting for the further decrease in performance.

Upon rermination of the isotope test, the engine was stalled and the insulation back-filled with helium. The rate of back-filling was adjusted to reach a pressure of 25 mm Hg in about ten minutes. This was done to protect the engine from the thermal shock which could occur if the sensible heat stored in the hot finger and isotope were abruptly released. Within approximately 1-1/2 hours of the initiation of the shutdown procedure, the isotope temperature reached 175°C (350°F), and the fuel capsule was removed. This verified the ability of the emergency shutdown system to operate without damaging the engine.

4.3.4 System Tests

As shown in Table 4-3 (page 4-18), the best overall hydraulic power delivered to the blood was 2.8 watts, which is close to the design point of 3.1 watts. This was obtained, however, with flow considerably less than the design flow of 12 l/min. In order to reach a speed at which the engine could reach its maximum power, the flows had to be reduced drastically, with a reduction of blood hydraulic power to 2.0 watts. Based on these numbers, there appears to be a slight mismatch between the engine torque-speed characteristics and that of the blood pump. Better overall performance could probably be obtained by changing the ratio of the reduction gears to allow engine operation at somewhere between 925 and 950 rpm while the blood pump is operating at 120 beats per minute.

After the fifth run, the engine showed an abrupt decrease in power output and the previous performance could not be repeated. At this time, the cause of this change is not clear. It is felt that it is probably due to contamination of the lubricating oil system and steps are being taken to clean up the oil.

5.0 PROTOTYPE RELATED STUDIES

Results of studies of artificial heart systems are presented in this section. A prototype system concept is discussed as are several alternate thermal converter and blood pump concepts. This section also discusses implantation considerations and summarizes the results of lifetime and reliability studies.

5.1 ARTIFICIAL HEART PROTOTYPE SYSTEM CONCEPT

As described in Section 2.0, PRACTICABILITY CONSIDERATIONS, bench model results were extrapolated to obtain estimates of prototype characteristics. The basic system assumed in arriving at estimated prototype characteristics was the same as for the bench model, namely, a Stirling-mechanical system.

5.1.1 Implantable Stirling-Mechanical System Description

An implantable Stirling-mechanical system is illustrated in schematic form in Figure 5-1.

There are two major subassemblies: a Stirling thermal converter and a blood pump. The two are interconnected by: 1) a flexible mechanical shaft to transmit drive power, and 2) coolant lines to carry the waste heat from the thermal converter to the blood pump assembly. The principal components of the thermal converter as shown schematically in Figure 5-1 consist of:

- A rhombic drive Stirling-cycle heat engine connected to the flexible drive shaft through step-up gearing and flywheel.
- An isotopic 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.

In addition, the oil pump and engine waste heat exchanger form important auxiliary components contained within the thermal converter. Figure 5-1 also illustrates the functional arrangement of the drive components that provide a pulsating pumping action in the blood pump. The principal components of the blood pump drive are:

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Figure 5-1. Schematic of Prototype Concept

- A flexible shaft to transmit the thermal converter power.
- A speed reducer to reduce speed from 1800 rpm to the 120 rpm that is more suitable for blood pumping.
- A Scotch yoke to convert the rotary output of the speed reducer to reciprocating linear motion suitable for pulsatile pumping.
- Pusher cups which engage the ventricle diaphragms.

Two other important components of the blood pump concept are not shown in Figure 5-1. First, there are the ventricles with their roll socks, flexible domes, blood vessel connections, and valves. Second is a coolant circulating pump. Possible conceptual arrangements for these items are covered in Section 5.3.

The system operating mode conceptually provides a nearly constant blood pump beat rate of 120 beats/minute by controlling the engine speed to an average value of 600 rpm. Starling's Law of blood flow is satisfied by allowing 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 volume, which will provide 12 l/min flow at 120 beats/minute. This adjustment takes place automatically. Use of constant pump beat rate - variable stroke volume operating concept without thermal storage in the thermal converter permits simple control requirements. The isotope inventory and the Stirling heat engine are sized to meet the maximum design power demand of the blood pump.

To match the mean blood flow through each ventricle with that required by the body, pump beat rate (engine speed) is maintained approximately constant, and the filling of each ventricle is allowed to vary in response to its venous return pressure. The body automatically adjusts the flow characteristics of the circulatory system to provide the variable venous pressure required for control.

Since the Stirling engine is inherently a constant power device, there is a tendency for the engine to speed up as the output load is reduced. To limit engine speed to an acceptable range, say 600 to 660 rpm (120 - 132 beats/minute), as the load varies between maximum and minimum, a dissipative controller is provided as shown schematically in Figure 5-1. A needle valve provides a variable orifice connecting the engine working volume with a space of constant volume. The pressure in this space remains nearly constant because of its large volume and the high flow resistance of the needle valve. During the high pressure portions of the cycle, gas flows into this volume through the annulus formed by the needle and its seat. During the low pressure portions, gas flow back into the engine. Therefore, throttling of the gas through the valve adjusts the engine efficiency and thereby controls its power output. To provide speed control, the needle valve opening must be varied with average engine speed. With a constant displacement oil pump providing the oil pressure to operate the bellows shown in Figure 5-1, the desired control characteristics can be obtained. The combined spring rate of the bellows and an auxiliary spring (not shown), coupled with the bellows area and the oil pump characteristics, determine the needle valve steady state position as a function of engine speed. The shape of the tapered portion of the needle valve determines the flow characteristics of the valve as a function of position. This in turn determines the amount of energy dissipated in the speed controller as a function of engine speed. The transient response of the controller is determined by the volume of oil delivered by the pump per revolution, the stroke volume of the control bellows, and the characteristics of the damping orifice located between the pump and bellows assembly.

The controller described has a "drooping" characteristic; that is, the speed tends to increase as the load decreases, although not nearly as rapidly as it would without the controller. As experience is gained with the blood pump operating characteristics, and more experimental data are obtained concerning the venous pressure/flow characteristic required to satisfactorily meet physiological requirements, our understanding of the speed/load characteristic of the system may be changed. With the low pressure available for filling the blood pump, the inertia of the blood plays an important role in the pump filling process. The result is that the total flow through the pump tends to fall off with increasing pump

speed for a fixed filling pressure. This phenomena may prove useful in matching the pump with physiological requirements.

The thermal converter concept illustrated in Figure 5-2 has been used as the framework for extrapolation of bench model results to prototype estimated characteristics. The heated portions are the isotope capsule, the engine hot finger, and the displacer and regenerator. These components are enclosed in a vacuum foil insulation package. The insulation consists of 50 layers of refractory metal foils packaged in the vacuum space within an outer case of titanium and an inner case which is also the engine hot finger casing. The isotope capsule is enclosed within the engine volume. Helium vented from the isotope capsule diffuses into the engine working space, then into the crankcase and finally into the body.

A stationary regenerator is used. Waste heat is carried away from the thermal converter by the circulating coolant fluid.

The rhombic drive, speed step-up gears, oil pump, speed control, and flywheel are located in the engine crankcase. This crankcase is partially filled with a pure hydrocarbon lubricating oil. The oil level is set so that the oil pump inlet is always covered regardless of thermal converter orientation.

A point to note about the Stirling engine is that the power piston is located below the cold heat exchanger. This is an important advantage of the Stirling concept over other dynamic concepts since the critical seals and loaded components are near ambient temperature even though the overall cycle temperature ratio is very high. The concept gives high cycle efficiencies associated with high top cycle temperatures and the high reliabilities and life associated with cold working parts.

The use of bellows results in the effective separation of the working volume, i. e., expansion space regenerator and compression space, from the crankcase. Therefore, the drive mechanism which is housed in the crankcase can be properly lubricated to insure long engine life. The reference design uses krypton as the working gas.

Figure 5-2. Thermal Converter Concept

Although all the working parts of the engine go through special processing to remove contaminants from their surfaces, a certain amount of contaminants evolve in the crankcase. The level of these contaminants, however, is below that considered detrimental to adequate engine operation.

The framework used for extrapolating bench model blood pump results to prototype estimated characteristics was a conceptual design created in conjunction with University of Utah Division of Artificial Organs personnel and is described in Section 5.3 as the liquid filled blood pump.

An idea of how the two major subassemblies of the prototype system may appear in outline form is given in Figure 5-3. A summary of prototype system estimates is given in Table 5-1.

5.1.2 Prototype Thermal Converter Study

This thermal converter study was conducted to determine the optimum thermal, shape, and weight characteristics attainable by 1977. Specifically, the study was aimed at arriving at the highest possible efficiency, consistent with the volume and weight limitations imposed by implantation requirements. The study made use of the results obtained with the Phase II bench model, as well as of analytical techniques normally used in the design of Stirling engines.

The bench model power balance, the departure point for the prototype study, is shown in Figure 5-4. As indicated, the shaft power output and the heat (i.e., electric power) input were 4.8 watts and 38.0 watts respectively. The goals as shown in Figure 5-5 for the prototype are 5.0 watts and 24.0 watts for the corresponding values. To attain the latter goals, significant improvements must be made both in the mechanical and in the thermodynamic efficiency of the existing engine.

5-8

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Figure 5-3. Outline Drawing of Artificial Heart

TABLE 5-1

SUMMARY OF PROTOTYPE ESTIMATES

<u>Maximum Power Output - (Watts)</u>		
• Blood Pump Left Ventricle	2.7	
• Blood Pump Right Ventricle	0.4	
• Thermal Converter	5.0	
<u>Isotope Inventory - Watts (t)</u>		
• Initially	24	
• After Ten Years	22	
<u>Temperature - °K (°F)</u>		
• Peak	1100 (1520)	
• Sink	316 (110)	
<u>Working Gas</u>	Krypton	
<u>Weight & Volume</u>	<u>Gm</u>	<u>CC</u>
• Thermal Converter	1489	700
• Blood Pump	<u>700</u>	<u>700</u>
TOTAL	2189	1400

Figure 5-4. Bench Model Power Balance

-----THERMAL POWER-WATTS
 —————MECHANICAL OR PNEU-
 MATIC POWER-WATTS

Figure 5-5. Prototype Thermal Converter Power Balance

Mechanical Considerations

The most significant mechanical loss in the bench model is the 3.5 watt rhombic drive friction. This item was therefore given major emphasis during the subject study. Specifically, the method of bearing lubrication was reevaluated.

The study indicated once again that the oil type hydrodynamic lubrication is the most desirable when long operating life is required. Hence, the effort was concentrated on finding methods to reduce the friction coefficient of the bearings designed for the bench model.

Bearing loads can be reduced if a lower cycle operating pressure is used; however, this would reduce the specific power of the engine and increase its size. The running speed can be lowered, to effect savings in bearing frictional power, but this would also increase the engine size. Since altering the load and bearing speed seemed (at least partially) undesirable, the study was aimed at reducing friction losses by further tightening of diametral clearances and by reducing bearing size. The bearing diameters arrived at are approximately 0.5 cm and the diametral clearances are about 0.0006 cm. The Bearing lengths have also been reduced to 0.6 cm. Partially, the effect has been to reduce the bearing eccentricities to nearly half of the radial clearance. The latter change can be shown to optimize the design for maximum value of oil film thickness. The corresponding bearing losses are now expected to be 2 watts, plus 0.5 watt input power to the oil lubricating pump. In the above discussion, it is implied that all bearings are about equal in size. The higher loading on the piston as compared to the bearings driving the displacer is supported by increasing the number of bearings on the piston side of the drive mechanism. The emphasis therefore will be on bearing accuracy. Tolerances of less than half those finally obtained in the bench model will be required.

The prototype concept assumes that bellows will be used for piston sealing purposes. Therefore, piston rings will not be required. As Figure 5-5 indicates, this will allow a further reduction in mechanical losses by 0.6 watts.

The buffer volume losses, 0.8 watts in the bench model, can be totally eliminated by a judicious design of the passage between the buffer space and the piston underside.

It should be noted that the losses associated with the displacer/regenerator, i.e., the displacer seal friction and the flow losses through the regenerator matrix, are expected to rise from the 0.7 watts present in the bench model to 1.0 watts in the prototype. It appears that by using a tighter seal and a higher regenerator filling factor, the reduction in thermodynamic losses will more than compensate for the increased frictional losses.

Thus, the total losses associated with the drive and the displacer/regenerator of the prototype are expected to add up to a total of 3.5 watts, versus the 6.1 watts (allowing 0.5 watts for the oil pump) in the bench model.

Figure 5-2 illustrates some of these projected features of the prototype thermal converter.

Thermodynamic Considerations

The configuration depicted in Figure 5-2 is based on the use of a stationary regenerator. The estimated thermodynamic power balance for this configuration has been given in Figure 5-5. It covers the cycle from the heat transferred to the engine, i.e., after the insulation losses, through to the power delivered to the piston. The corresponding values are 22.2 watts and 8.5 watts.

The predicted characteristics of the prototype design depend on several key factors:

- The use of bellows to replace the piston and displacer seals. This not only eliminates the friction losses in the seal regions, but also allows a wider range of choice for the crankcase lubricant. This, in turn allows more freedom in optimizing the rhombic drive mechanism, permitting higher speeds with lower losses in the crankcase.

- The use of materials with higher strength and lower thermal conductivity in the cylinder wall. This permits higher temperature operation and allows utilization of a stationary regenerator without an undue penalty in conduction losses. The stationary regenerator provides an increase in thermodynamic efficiency of the converter, as better heat transfer characteristics can be obtained at the hot and cold heat exchanger.

The technologies required for the prototype engine should be available by the end of Phase III through component development efforts. In particular, several candidate materials for bellows seals that have been screened by Philips for similar applications appear promising.

5.2 ALTERNATIVE THERMAL CONVERTER CONCEPTS

Prior to the completion of the preliminary assessment of the technology required for the prototype converter, there was no assurance that such an engine could be built. At this prior time a detailed study to define the performance and size limits utilizing strictly bench model technology was performed. The results of this study are presented as alternatives to the prototype converter concept.

Thermal converter design efforts in Phase II were oriented toward achieving a concept that can be compatible with its intended environment. Compatibility with the anatomy and physiology of calves, and ultimately with those of humans, implies that the thermal converter has to be highly efficient, small, light, and have long life. Therefore, the attainment of these requirements was set as the goal.

Miniaturization is normally associated with tight packaging, i.e., high specific weight. It also results, in most instances, in relatively complex assemblies. In addition, miniaturization is often attained at the expense of efficiency. This is especially true in the case of heat engines, where reducing the size of the device brings the high temperature region closer to the ambient temperature areas, thus increasing the heat leaks, with an attendant decrease in engine efficiency.

In developing the concepts discussed in this section, efficiency was assumed to be the most critical parameter. As a result, three concepts were optimized for efficiency. In a fourth concept, efficiency was traded off for smaller size and lighter weight. It also became evident during the course of the study that radioisotope capsule geometry had a significant influence on thermal converter size, especially on the overall length of the engine. Therefore, two capsule geometries are suggested in the prototype concepts; a cylindrical (i.e., conventional) one and one having an annular shape.

In estimating the weight of the prototype models, the use of commonly accepted materials was assumed, as well as fabrication and joining methods widely used in industry. Table 5-2 summarizes the materials assumed for all of these concepts. The use of accepted materials implies that the concepts presented in this section could be constructed immediately following the completion of Phase II, i.e., in 1973. In the normal evolution process of detailed design, improvements can be expected as a result of incorporating new materials, the use of castings, changes in shape resulting from rigorous stress analyses, etc. It is anticipated that in a 3-4 year period, i.e., by 1976-1977, the weight associated with these concepts could be reduced by 25-50%.

The two most attractive thermal converter concepts which evolved from the alternative study are summarized briefly in the subsections that follow.

TABLE 5-2
MATERIALS SUMMARY FOR THERMAL CONVERTERS

Thermal Insulation:	
Casing	Aluminum
Multifoil	Columbium
Hot Finger:	
Thin wall cylinder	Udimet 700
Radioisotope capsule well	Nickel 200
Displacer/Regenerator:	
Thin wall housing	Udimet 700
Cover	Nickel 200
Base	Monel
Rod	Aluminum
Matrix mesh	Inconel 718
	Titanium
	Aluminum
Heat Exchanger:	
Heat transfer elements	Beryllium
Housing	Titanium
Power Piston:	
Piston body	Kennertium W-2
Rings	Teflon (reinforced)
Rod	Aluminum
Rhombic Drive:	
Members (crankshaft, con rods and yokes)	Steel 4340 and Titanium
Bearings	Bearing bronze
Crankcase:	
Housing	Aluminum
Bearing Support	Titanium
Flywheel:	Kennertium W-2
Oil Pump and Controls:	Stainless steel and Aluminum

5.2.1 Optimum Engine Cylinder Diameter with Annular Fuel Capsule

The thermal converter described in this subsection has an annular, rather than a cylindrical, radioisotope capsule. In every other respect, its thermodynamic and mechanical design is similar to that of the bench model.

The annular capsule concept requires a more complex insulation geometry; as a result, there are additional corner losses, resulting in a slightly higher power input. Figure 5-6 shows an orthographic view of this design.

Like the prototype concept, the concept shown in Figure 5-6 provides shaft output power at 1800 rpm. A design option on output speed would provide a stepdown gear from the flywheel to a shaft output at 900 rpm. The option would require the crankcase length to be increased by 0.8 cm, and increase the weight and volume slightly. Otherwise, the two options with the annular capsule would be identical.

5.2.2 Larger Engine Cylinder Diameter with Cylindrical Fuel Capsule

The general thermodynamic and mechanical design of this concept is similar to that of an implantable design of the bench model. However, a significant detail change was made in the engine to achieve height savings. Specifically, the displacer and the piston strokes were reduced to 0.5 cm (from 1.0 cm), and the regenerator diameter was increased to 3.5 cm (from 2.5 cm). As a result, the overall length was reduced with the use of a cylindrical radioisotope fuel capsule. However, this reduction in length is associated with an increase in power input to the engine. An orthographic view is shown in Figure 5-7. Because of the larger engine cylinder diameter, the fuel capsule shape becomes, in this design, a cylinder with an L/D ratio less than one.

5.3 ALTERNATIVE BLOOD PUMP CONCEPTS

Three alternative blood pump concepts are described. The "liquid filled" pump and the "gas filled" pump are implantable versions of the bench model blood pump. However, they differ

Figure 5-6. Thermal Converter with Annular Fuel Capsule

Figure 5-7. Thermal Converter with Larger Cylinder Diameter

substantially in detail because of the media used within the drive mechanism cavity. The third concept, "cam-follower and scissors mechanism" differs considerably from the first two. The concept could be designed to provide synchronous pumping of the blood pump ventricles. The configuration given here provides asynchronous pumping.

5.3.1 Liquid Filled Bench Model Pump

This pump concept is shown in orthographic projection in Figure 5-8. Schematically, it is similar to the assumed prototype arrangement of Figure 5-1. The flexible shaft from the thermal converter, which rotates at a nominal 1,800 rpm, is connected to the input shaft of a speed reducer housed in a boss built into the cylindrical wall of the pump. This speed reducer steps down the pump drive speed from 1,800 rpm at the flexible shaft to 120 rpm at the shaft that drives the pump reciprocating mechanism. This is accomplished through a set of right angle bevel gears with a speed ratio of 2 to 1 and a set of Evoloid gears with a ratio of 7.5 to 1. The Evoloid gears have a recently patented tooth form which permits a high speed reduction in one step with a high mechanical efficiency. An efficiency of about 95 percent is expected for the set used in the speed reducer. In addition to reducing the rotational speed of the pump drive, the bevel gears rotate the axis of rotation through 90° as shown. An inline input shaft is an easily accomplished alternative.

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 pusher cups that alternately compress and expand the dacron reinforced silastic roll sock ventricles at each end of the pump which serve as the left and right ventricles of the blood pump. During diastole when the pusher cup moves away from the ventricle dome, the cylindrical wall of the roll sock in contact with the pusher cup rolls off the pusher cup onto the inside surface of the pump housing. During systole when the pusher cup moves toward the ventricle dome,

Figure 5-8. Liquid Filled Blood Pump

the cylindrical surface of the roll sock in contact with the pump housing rolls off the pump housing onto the pusher cup. Because the ventricle dome is flexible, it will collapse inwardly as required during diastole to provide a volume that matches the volume of blood that returns to ventricle. The inherent strength of the spherically shaped dome under internal pressure minimizes stretching during systole and permits a high pump volumetric efficiency.

The offset of the end throws of the crankshaft permits each pusher cup to travel past the mid-plane of the pump and occupy space that is vacated by the opposite pusher cup on the return stroke, thereby minimizing the overall pump length required to accommodate a given stroke. Rollers on the end throws of the crankshaft engage Scotch yokes built into the ends of a housing causing it to reciprocate as the crankshaft rotates. This housing supports linear ball bushings that serve as guides for the main Scotch yoke. Two sets of rollers on outriggers attached to the reciprocating housing bear on hardened inserts in the pump housing and prevent the reciprocating housing from rocking and rotating. The radius of the end throws of the crankshaft is half as long as the radius of the center throw, permitting the reciprocating structure to travel at the same velocity as the loop connecting the cylindrical portions of the ventricles. Also, it permits the clearance between these loops and the reciprocating structure rollers to be held to a minimum.

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 on ball bearings. The main Scotch yoke is guided by ball bushings that have circulating ball races.

The waste heat from the thermal converter is rejected to the body by means of the heat rejection system. Heat is transferred from the thermal converter's krypton working gas to circulating coolant at the engine cold side heat exchanger. The coolant is pumped to the blood pump, where most of the heat picked up from the thermal converter is transferred to the blood. The circulating coolant is pumped by means of a bellows pump built into the blood pump. The

remainder of the heat is transferred directly to the tissue surrounding the blood pump and transmission assembly. Because the blood pump cavity is filled with coolant, the heat transfer takes place over the entire internal area in contact with blood. About 65% of the heat rejected to the blood is transferred in this region, and the remaining 35% is transferred through the coolant passages formed in the perimeter of the ventricle dome.

A double bellows pump secured to the reciprocating housing and one of the pusher cups is actuated by the differential motion of these components. This pump circulates the coolant fluid to the pusher cups and ventricle areas where it is conducted to the blood. The bellows pump also serves as a torsion resisting element that prevents rotation of the pusher cups and twisting of the roll socks. The coolant fluid flows from the thermal converter to the blood pump through an annular passage between the flexible drive shaft and the guide tube around it. After the fluid enters the blood pump speed reducer, it flows through the ball bearings and around the gears and then enters the reciprocating mechanism chamber. There, the fluid is agitated by the motion of the reciprocating mechanism and gives up most of the thermal converter waste heat to the diaphragm portion of the ventricles and the pusher cups. The coolant then enters the bellows pump where it is expelled under pressure during the opposite stroke of the reciprocating mechanism. When the fluid leaves the coolant pump, it enters a flexible metal tube that carries the fluid from the coolant pump to a manifold built into the blood pump housing. The flexible tube functions as a spring member and undergoes elastic cycling as the reciprocating structure moves relative to the pump housing. At the manifold in the blood pump housing, the coolant flow divides into two branches, each of which flows through the coolant channels in one of the ventricle domes. After flowing around the periphery of the domes and giving up the remaining thermal converter heat to the blood in the sacks, the two flow branches return to another manifold adjacent to the inlet manifold. From the return manifold, the coolant flows into the annular space between the flexible shaft guide tube and a convoluted metal tube around the guide tube and returns to the thermal converter. Several available oils that are compatible with the silastic ventricles and are non-toxic show promise as candidate coolant fluids. The fluid will provide both the required heat transfer characteristics and adequate

lubricity for the bearings and gears without introducing excessive churning power losses in the blood pump mechanism.

Because of the blood pump mechanism chamber and flexible drive shaft assembly are filled with fluid, very little air can remain trapped between the ventricles after the pump is assembled. If the pressure in the ventricle drops to a pressure less than that present at the time the mechanism chamber is sealed, the expansion of the minute amount of gas trapped in the pump will not noticeably affect operation. Therefore, changes in atmospheric pressure that may be experienced in flying or travelling to high altitudes will not influence the performance of the blood pump.

The outside diameter of the basic pump body is 8.0 cm and the overall length is 13 cm. These dimensions are essentially the same as those of the bench model blood pump. However, the projection of the speed reducer boss from the wall of the pump housing is 1.39 cm, while the corresponding dimension for the bench model was 2.11 cm. Also, the speed reducer input shaft is parallel to the longitudinal axis of the pump instead of perpendicular to it as it was in the bench model. This change was made to illustrate another possibility of input shaft direction.

To aid in the extrapolation to the weight of the prototype pump, three discrete sets of material combinations were considered and these sets are itemized in Table 5-3 with designated design Options A, B, and C. The complete set of materials is listed for Option B. Where changes from this set of materials exist, they are listed for Options A and C.

TABLE 5-3
BLOOD PUMP MATERIALS

<u>Component</u>	<u>Option A</u>	<u>Option B</u>	<u>Option C</u>
● Speed Reducer			
Housing	Titanium	Aluminum alloy	Glass fiber re- inforced polyimide resin
Coupling		303 stainless steel	
Pinion		17-4 PH stainless steel	
Gear		Delrin AF (acetal resin with teflon fibers)	
● Pump Housing			
Housing	Titanium	Aluminum alloy	Glass fiber re- inforced polyimide resin
Roller Track Insert		440C stainless steel	
● Ventricle		Silastic (dacron reinforced)	
● Crankshaft Assembly		303 stainless steel	
● Main Scotch Yoke		440C stainless steel	
● Yoke Housing Assembly			
Housing	Titanium	Aluminum alloy	Glass fiber re- inforced polyimide resin
Roller Insert		440C stainless steel	
● Pusher Cup	Titanium	Glass fiber reinforced polyimide resin	Glass fiber re- inforced polyimide resin
● Bellows Pump		Titanium	
● Scotch Yoke and Yoke Housing Rollers		440 stainless steel	

TABLE 5-3 (Continued)

<u>Component</u>	<u>Option A</u>	<u>Option B</u>	<u>Option C</u>
● Ball Bearings			
Ball Retainer		Plastic or metal filled with dry or liquid lubricant	
Balls and Races		440 stainless steel	
● Ball Bushing			
Ball Retainer		Delrin AF	
Balls and Outer Race		440C stainless steel	
● Thermal Converter Coolant Tubing			
Flexible Shaft Assembly Tubing		Teflon	
Blood Pump Tubing		Titanium	

5.3.2 Gas Filled Blood Pump

A second blood pump configuration is shown in orthographic projection in Figure 5-9. This pump is quite similar to the liquid filled pump but differs from it both in the manner of transferring thermal converter waste heat to the blood and in the method of lubricating the mechanism gears and bearings. In this arrangement, the coolant fluid from the thermal converter is carried through a tube between the flexible shaft guide tube and the convoluted metal tube around it to a fitting in the blood pump housing. A flexible metal tube connected to the fitting from the inside of the pump housing carries the fluid to the bellows coolant pump. When the coolant is discharged from the bellows pump, it flows to a manifold attached to the reciprocating structure, where it divides into two branches. Each branch flows through a flexible metal tube to passages built into one of the pusher cups, where most of the power pack waste heat is transferred to the blood in the ventricles. After leaving the pusher cups, the two flow branches return through flexible metal tubes to a manifold attached to the reciprocating structure. From this manifold, the fluid is carried through another flexible metal tube to another manifold built into the pump housing. There, the coolant flow divides into two branches and flows through the ventricle domes, giving up the remaining waste heat to the blood in the same manner as in the reference design. After leaving the return manifold in the pump housing, the coolant enters another tube located between the flexible shaft guide tube and the convoluted metal tube and returns to the thermal converter.

Since the mechanism chamber of this pump concept is filled with the ambient air at the time the pump is assembled and sealed, this air would expand and compress the ventricles if the internal pressure should drop below the initial ambient pressure. This problem can be avoided by providing a silastic envelope around the pump into which the gas trapped in the mechanism chamber can expand as necessary to avoid a pressure buildup that would affect the ventricles. Lubrication of the ball bearings and gears in this design can be accomplished by making the ball bearing retainers out of a plastic or porous metal filled with either a dry or liquid lubricant, and making the gears out of Delrin AF, an acetal resin filled with teflon fibers.

Figure 5-9. Gas Filled Blood Pump

The choices of materials for the gas filled pump offers similar sets of options to those given in Table 5-3. As a result, design Options A, B, and C with the gas filled pump have the same weight trend as for the liquid filled pump.

5.3.3 Cam-Follower and Scissors Mechanism

The mechanism that uses a cam-follower coupled with a scissors linkage arrangement is shown in Figure 5-10. The flexible drive shaft from the thermal converter enters the pump and drives a flywheel through bevel gears. In this configuration, the flywheel to absorb the pulsatile blood pumping demand is made a part of the blood pump rather than a part of the thermal converter. This increases the size of the blood pump and reduces the size of the thermal converter. From the flywheel, the power is transmitted through a compound planetary gear speed reducer to obtain a speed reduction of 15 to 1. Planetary gears attached to the spider arms that support the flywheel rim engage a ring gear that is held stationary in the pump housing and rotate about their centers as the flywheel is rotated. A second set of planetary gears attached to (and turning on the same centers as) the first set of planetary gears engage a ring gear attached to a cylindrical cam and rotate the cam at 120 rpm. A cam follower, with a ball bearing roller which engages a continuous groove machined in the wall of the cam, pivots in ball bearing supports as the cam is rotated and the follower roller is displaced vertically.

613640-2

Figure 5-10. Cam-Follower and Scissor Blood Pump Drive Mechanism

Each end of the follower pivot shaft is connected to an identical scissors linkage. One end of each set of links is supported in the vertical plane by the pump body. The other end supports a platform which is connected to a pusher cup that displaces the left ventricle diaphragm. When the cam roller arm is rotated, the scissors linkage system is extended and the diaphragm is displaced vertically through a distance several times greater than the vertical displacement of the cam. A rod connects the left ventricle diaphragm pusher cup to a similar pusher cup attached to the right ventricle diaphragm so that both diaphragms can be actuated with a single driving mechanism.

Because the bars of the linkage system form isocetes triangles, the platform that displaces the left ventricle diaphragm remains horizontal throughout its vertical travel. Lateral support of the diaphragm platform and linkage system is provided by means of a plate scissors arrangement connected to one end of the platform and the pump body. Vertical movement of the platform will cause the plate scissors to open or close, but the bending strength of the plate scissors will prevent lateral movement of the platform. A ball bushing mounted on the right ventricle side of the platform is used to guide the long rod that connects the left and right ventricle diaphragm pusher cups. As in the Scotch yoke mechanism, rolling bearing members are used throughout the mechanism, and there is no sliding contact at any point where relative motion occurs.

5.4 SUPPORTING ENGINEERING STUDIES

There are added technical areas, not covered previously, which place requirements and constraints on a nuclear artificial heart system. Among these are sterilization, operational assurance at implantation, system materials and tissue interactions or compatibility, venting of decay helium, and radiological accidents and safety.

5.4.1 Implantation Considerations

Sterilization

The implanted device must be sterile. This is an uncompromising, absolute term, as there is no such condition as partial sterility*. Therefore, the actual practice of sterilization must be established on an all or none basis. In this regard, it must be recognized that a device is considered sterile only as far as one is able to demonstrate sterility.

There are two principle techniques best accepted by current surgical standards. These are sterilization by 1) saturated steam under pressure, and 2) ethylene oxide. Saturated steam is the most dependable medium known for destruction of microbial life. All steam sterilization is based upon direct steam contact. When considering sterilization by steam, the internals of the thermal converter or blood pump mechanism must be kept in mind because direct steam contact with these components would be difficult or impossible to achieve. This is particularly true of lubricants where the design flexibility to use anhydrous materials such as oils, greases, and powders is a necessity. It is not possible to effect direct steam contact to all portions of such materials.

Ethylene oxide alkalizes microbial cells and reacts with nucleic acids of the enzymic systems within the cells. Ethylene oxide in its pure form is not recommended for routine sterilization. For practical use, a mixture of ethylene oxide in inert gases such as carbon dioxide or fluorinated hydrocarbons is used. Use of ethylene oxide to sterilize limits materials choices as it attacks plastics such as acrylics and polystyrenes. In addition, it has insufficient penetrating power to sterilize deep plastic sections.

* Goldfarb, David, M. D., "Sterilization Considerations for an Implantable Artificial Heart System", Private Report, Sept. 2, 1972.

Heat sterilization is a way to sterilize inaccessible or heavy section components. Various time-temperature relationships can be developed for a heat sterilization cycle. Variations can range from three hours at 160°C (320°F) to 336 hours at 105°C (221°F).^{*} Sterilization of a total unit at temperatures above 300°F puts undesirable limits on material selection, however. For this reason, 145°C (293°F) heat sterilization for 36 hours appears to be appropriate. In conclusion then, each total means of sterilization could impose some restrictions on the selection of component materials. However, it is thought unwise to limit materials selection at this time simply to provide ease of sterilization. An alternate exists: the components can be sterilized individually and then put together by sterile assembly procedures. That is, the assembly can be done in germ free environments, e. g., those that have been constructed for laboratory animals and, in some instances, human infants. Since the total unit is small, whole rooms need not be sterile, only glove-box size compartments.

Operational Assurance

The foregoing sterilization discussion implies that the total device is shipped from the factory in a sealed sterilized condition. The system might be shipped in either an operating or non-operating mode. The former offers some advantages, as it eliminates handling and loading of the radioisotope capsule into the thermal converter at the hospital and allows verification of correct operation of the device at the factory. Going one step further, implantation of the device in an operating mode, will assure that fatal start-up problems do not occur. The device has therefore been designed on the premise that implantation is done while the device is operating.

To carry out the implantation of an operating system requires an auxiliary heat exchanger to be inserted into the thermal converter heat rejection system during the surgical installation period. After installation, heat is rejected to the blood flowing through the blood pump. This blood flow will not be available during implantation because it is assumed that the installation

^{*} Magistrale, V. J., "Engineering Problems in Capsule Sterilization", *Astronautics and Aeronautics*, February, 1966.

procedure will block the blood pump inlets during the time of attachment of blood pump to blood vessels. The device will continue to operate satisfactorily with blocked blood pump inlets because the blood pump flexible dome will absorb the stroke displacement normally absorbed by the blood pump bladder. The engine throttling control will adjust the engine speed within safe limits.

Alternatively, the artificial heart system can be shipped with two heat exchangers attached, one connected in a closed loop to each of the ventricles. The heat exchangers and the heart would be filled with a sterile fluid compatible with blood, such as a saline solution or a liquid fluorocarbon. During the installation operation, one loop (either) would be disconnected and that ventricle would be connected into the circulatory system. Once blood flow is established through the first ventricle, the second heat exchanger loop can be safely disconnected and the installation operation completed.

Materials-Tissue Interactions

As mentioned previously in the discussion on sterilization, an attempt has been made to allow as great a flexibility of materials choice as possible. Naturally, where there is substantial interaction directly with the host or likelihood of substantial indirect interaction, this stance has to be modified.

Though the thermal converter is not in an absolute sense sealed from the external environment, it is realistic to assume that there is no meaningful contact even over ten years. Therefore, thermal converter internal materials selections are based totally on engineering considerations. At the hot side, the materials selected are the lightest materials currently available that have the required strength and fabricability at the temperatures of use. Namely, these are, Udimet 700 for the stressed portion of the hot finger with a nickel conduction member for the unstressed portion. The multifoil insulation might be of columbium, since it is the lightest available material with the required strength at maximum temperature of use. After further development, it may be possible to make the outermost foils of aluminum with some savings in weight.

The engine working fluid has been selected as the inert gas krypton. The selection of an inert gas eliminates working fluid corrosion. Of the inert gases, krypton was selected after much study as the best choice among helium, argon, and krypton. The major determining factor is retention of the working fluid for ten years. Retention of helium is deemed very difficult, if not impossible. Argon retention is possible but krypton is even better. Performance studies indicate that under the size and speed conditions of an optimum engine design, no serious performance losses result from using krypton instead of argon.

The outermost layer covering all the external surfaces of both the thermal converter and the blood pump will be medical grade silicone rubber. All literature searched showed this material to react minimally with living tissue with respect to attack both from and to the tissue. It has been reported to produce tumors in susceptible animals but then so apparently does almost anything else. It may not do so in humans, since there is a lag time of several years even in susceptible animals.

The casing of the thermal converter has been taken as aluminum because of its light weight, good corrosion resistance, and relative inertness in a tissue environment. Titanium would be a better choice from the standpoint of reaction with a tissue environment but has a higher specific gravity than aluminum. More sophistication in design than exercised here would probably eliminate any weight advantage of aluminum over titanium, since titanium has a higher specific strength than aluminum.

Selection of the materials for the blood pump mechanisms is possibly a more complex case than for the interior of the thermal converter. First, we are considering several pump possibilities; in no case is the mechanism in direct contact with tissue. However, the silicone barrier material between the body tissue and blood and the mechanism is quite thin and has a rather large cross-sectional area. Diffusion of gases and water vapor through the silicone material is rapid in terms of the implantable times involved. The mechanism chamber will be in equilibrium with blood

with respect to gases and water vapor. According to Dow Corning, there should be negligible ionic transport across the silicon barrier. Initially, there was a concern about the possibility of diffusion of chloride ions out of the blood into the mechanism chamber and back diffusion of polymer and metal ions into the blood. This would have been of particular concern with a liquid filled pump since the liquid is a potential transporter of such ions in solution. A gas filled pump probably would not present an ionic problem in any case, since an obvious means of transport from the silicone barrier surface to and from the mechanism is not readily apparent.

However, having our fears allayed by Dow Corning with respect to ionic transport, the material selection criteria becomes the lightest material available for: 1) engineering adequacy for the function to be performed, 2) indefinite life in humid air, and 3) heat sterilization for 36 hours in nitrogen or argon at 293°F , or sterilization by live steam or ethylene oxide.

5.4.2 Helium Venting

The heat source of the device is vented. The helium generated by radioactive decay of Pu-238 is released into the thermal converter through this vent. The amount of helium released per unit time is very small. Its initial and maximum value is approximately 2.7×10^{-10} gram per second or 1.5×10^{-9} liters per second at standard temperature and pressure. Even so, the total volume released over a ten year period is not trivial compared to the thermal converter volume. The cumulative gas volume at standard temperature and pressure will be about one-half liter.

While ways, no doubt, could be found to store one-half liter (STP) of helium, a better way appears to vent the helium to the blood stream and thence to the lungs for release to atmosphere through respiration. To evaluate the significance of the helium dissolved in the blood stream, consider that all the helium evolved in one week, 0.91 ml, is accumulated in the blood, which is assumed to be five liters of water. The solubility of helium in water is:

$$K = \frac{P}{X} \quad (5-1)$$

where K, solubility = 11×10^7

P = partial pressure, mm of Hg

X = mole fraction, $(0.91/22,400)/(500/18) = 1.4 \times 10^{-7}$

Blood (or water) containing this much helium is in equilibrium with an atmosphere having a helium partial pressure of 15.4 mm of Hg, i. e., 0.02 atmosphere. Divers using helium-base atmospheres require no decompression after unlimited time of submergence at less than 30 foot depth, equivalent to 1.7 atmospheres of helium. Similarly, following saturation diving to 1000 feet (29.4 atmospheres) using helium-base atmospheres, with 1265 ml of helium dissolved in their blood, divers can be safely decompressed in less than one week. Under some conditions then, the human lungs can transpire helium at a rate over 1000 times greater than the heat source can generate it.

The system is designed to channel the helium to the blood stream. The vented helium enters the Stirling engine working space where it mixes with the krypton. It then diffuses through the roll sock seals into the crankcase, thence it flows through the shaft oil seal into the flex shaft casing and on to the blood pump mechanism chamber. It then diffuses through the ventricles into the blood.

The only gas seals along this path are the engine roll socks and the ventricles. Since both seals are rubber, although of different kinds, and the area available for diffusion through the ventricles is much greater than through the roll socks, it is sufficient to show that the roll sock seals do not present a serious restriction to the helium flow.

The diffusion equation in convenient form and units is:

$$\dot{m} = \frac{MA}{RT} - D \frac{\Delta P}{\Delta l} \quad (5-2)$$

where

- $\dot{m}$ - diffusion rate = $-2.7 (10^{-10})$ gm/sec
- M - molecular weight $H_e = 4 \frac{\text{gm}}{\text{mole}}$
- R - universal gas constant = $8.3 (10^7)$ ergs/mole/ $^{\circ}\text{K}$
- A - area of roll socks = 19 cm^2
- T - temperature = 320°K
- D - diffusion coefficient of rubber = $1.6 (10^{-7}) \text{ cm}^2/\text{sec}$
- Δl - roll sock thickness = 0.1 cm
- ΔP - helium pressure differential across roll socks - dynes/cm²

Rearranging the diffusion equation and solving for ΔP gives:

$$\begin{aligned}\Delta P &= - \frac{\dot{m} RT}{AM} \frac{\Delta l}{D} & (5-3) \\ &= \frac{2.7 (10^{-10}) (8.3) (10^7) (320) (0.1)}{(19) (4) (1.6) (10^{-7})} \\ &= 5.9 (10^4) \text{ dynes/cm}^2 = 0.057 \text{ atmos}\end{aligned}$$

At equilibrium then the helium partial pressure in the engine working space will be approximately 1/16 atmosphere. This is an insignificant level compared to the nominal engine working space pressure level of 8 to 10 atmospheres.

5.4.3 Radiological Accidents and Safety

Protection against radiological accident and safety for the general public is primarily effected through the design of the heat source to assure safety. The design of the heat source is not a part of this study but was carried out by TRW in a parallel study for the AEC. The guidelines for the present study are to design the system in such a way as to preserve the safety features of the heat source design. The heat source was designed to withstand the following safety and accident conditions:*

* TRW Report, SAN-858-50, "Radioisotope Heat Source Development for an Artificial Heart Device, Phase I, Final Report", April, 1973.

Impact:	216 ft/sec against solid granite
Fragmentation:	30-06 rifle bullet at 2000 ft-lb
Crushing:	5000 lb. static load on concrete
Cremation or Fire:	2500°F for two hours
Post Accident Oxidation:	1300°F indefinitely (simulates 6" soil burial)

The forces that can be generated by the artificial heart system or any of its components are less than 100 pounds, whereas the heat source is designed to withstand thousands of pounds. The radiological safety aspect of the system design is therefore to provide over-temperature protection for the heat source. The most severe situation is an engine stoppage with an intact engine.

Studies of concepts for limiting the heat source peak surface temperature upon engine stoppage have indicated two promising approaches, both based on relieving the vacuum of the vacuum foil thermal insulation. One approach involves the use of a liquid or gas filled container (thermal fuse) having a known rupture temperature. The other approach involves a planned failure mode of the engine cylinder wall at a predetermined temperature.

The first approach offers the advantage of tailoring the thermal fuse characteristics without influencing the rest of the system. The material to be released into the insulation space can be selected on the basis of its high conductivity. A liquid could be used in the container, selected so that its pressure/temperature characteristics insure a predictable rupture temperature for the fuse capsule. The disadvantage of this technique lies primarily in that it adds additional components to the thermal converter. This imposes a weight and volume penalty, as well as a possible additional failure mode.

As an alternative, the engine cylinder material can be selected to fail before the heat source becomes overheated. With this failure, the engine working fluid would be admitted into the insulation package. Preliminary calculations indicate that following cylinder melting, the presence of krypton in the insulation cavity will permit the heat source temperature to

equilibrate near its normal operating point. Since the worst case accident for this type of protection system is represented by a loss of working fluid, the only pressure difference available to drive gas into the insulation package would be approximately one atmosphere. Therefore, stresses in the cylinder wall are likely to be low, and the melting point of the cylinder material should be selected as the set point of the protection device. Figure 5-11 shows the expected transients following a loss of engine working fluid and cylinder melting. Following the loss of working fluid from the engine, the engine hot finger and heat source heat up for approximately 40 minutes until the cylinder wall (assumed to be Udimet) melts at 1561°K (2350°F). Upon wall melting, the krypton working fluid floods the vacuum foil insulation resulting in decreasing the temperatures as shown in Figure 5-11.

For short term operation under overload conditions, or after failure of the control system, it is possible that the thermal converter operating temperature and therefore the heat source temperature could rise as high as 50°C (90°F) above normal. Either of these conditions, whether occurring by failure of a component in the system or by an abnormally high blood flow resistance, will be characterized by a distinct change in beat rate and will thus be detectable. The only mechanism by which the heat source temperature could rise without being detectable by changes in blood pump performance is loss of thermal contact between the capsule and the cylinder wall. At the temperatures involved, thermal radiation will play an important part in any heat transfer process, and no mechanism to completely eliminate physical contact between the heat source and the hot finger without opening the insulation package can be postulated. For these reasons, serious degradation of the heat transfer path between the heat source and the hot finger does not appear possible.

Based on this study, it appears that the engine structure and working fluid will provide adequate thermal protection for the heat source in emergencies.

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Figure 5-11. Temperature Transients Following Working Fluid Loss

5.5 LIFETIME AND RELIABILITY

The artificial heart is being designed to meet stringent lifetime and reliability objectives. The careful attention given to lifetime and reliability considerations in the selection of the Stirling mechanical concept has been continued during Phase II. By designing for reliability, concern for lifetime becomes an intrinsic part of the design process and design engineers are oriented toward a concern for reliability throughout the program.

Figure 5-12 is a simplified outline showing the integration of reliability into the "design for reliability" process. Effort for Phase II has been continued for those activities enclosed by the dotted lines. The Failure Modes and Effects Analyses were completed to define potential failure modes and to assess the criticality of their consequences. The reliability model and apportionment studies have pinpointed those weak components where improvement is deemed necessary. Together, these studies provide a means of assessing the practicability of achieving the goal of a ten year mean life and they also form the focal point in the continuing "design for reliability" approach by providing a guide for failure studies.

The system that was studied during Phase II consists of the four major subsystems: thermal converter, flexible shaft, blood pump drive mechanism, and the Stirling engine cooling system. Emphasis during Phase II was on the blood pump drive mechanism including the flexible shaft, as it is a new device. The other major sub-assemblies are older art and have been analyzed for reliability in some depth during Phase I and elsewhere. The heat source and the blood pump ventricles were not considered during these studies. The design used as a point of reference for conducting the Failure Modes and Effects Analyses was the bench model. For the modeling and apportionment studies, an implantable version of the bench model was used. Assessment of practicability was made relative to achieving a system with a ten year mean life.

613757-3B

Figure 5-12. The Design for Reliability Process

5.5.1 Failure Mode and Effects Analyses

A Detailed Failure Mode and Effects Analyses of the current design is given in Appendix A. From this and on-going design studies, some recommended design changes have been identified for the blood pump drive mechanism. When applied, these design changes should enhance system reliability through avoidance of known failure-prone mechanisms. The degree to which this can be done will depend upon trades of reliability with other key system parameters.

They are:

- 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 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 those components expected to experience the most wear and likely 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 lubrication, two inherent life limiting factors.

5.5.2 Reliability Model and Apportionment

A 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 (implantable version of bench model) design nor anticipated for the prototype. This model serves the twofold purpose of outlining the reference design for study and providing a basis for further model development during the Phase III design effort.

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

$$R_S = R_1 \cdot R_2 \cdot R_3 \cdot \dots \cdot R_n \quad (5-4)$$

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

Table 5-4 shows the breakdown of the system 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, crank shafts and connecting rods.
- 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.

TABLE 5-4. RELIABILITY ALLOCATIONS

		Qty.	Apportioned Reliability			
Artificial Heart .5	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	
			Flex Shaft Assembly 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				

For the present 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 numerical reliability goals obtained in this initial 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 and their parts, revisions to the apportioned values may be expected. Also, during trade studies, reapportionment may be needed to reflect changes in the system configuration.

5.5.3 Component Discussion

In Section 5.5.2 above 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 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.

Housing

There are three housings in the system: the oil pump, engine and blood pump. The oil pump housing should present no problem particularly since it is enclosed and in an oil bath with no potential corrosion. The major concern is to make it rugged enough to resist distortion and thereby maintain accurate gear meshing and bearing alignment. Likewise the engine housing should present no major design problem, but does have to be strong enough to endure animal accidents such as falling. Aside from the 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 three housings is expected to be high and the goal of 0.999999 should be achievable.

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.

Connecting Rods and Flywheel

Same as crank shafts.

Engine Heat Exchanger

The engine heat exchanger extracts excess heat from the engine and transfers it to the circulating cooling fluid. Technology for its design is well in hand and the reliability goal of 0.999999 is reasonable.

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.

Gears

There are three sets of gears in the system: one in the engine, one in the oil pump and the other in the blood pump. The engine gears time the crank shafts and couple the flywheel to the drive. The oil pump gears simply pump the oil. 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 for the blood pump should be carried out.

Bearings

There are two types of bearings in the system: hydrodynamic film bearings used in the engine and oil pump and ball bearings used in the flexible shaft and blood pump. Long life and high reliability are characteristics of the hydrodynamic film bearings found in the engine. When an adequate supply of oil is maintained and the shaft continuously rotates in the bearings reliability is enhanced and the goal of 0.999 appears feasible. Four of the engine connecting rod bearings are of the oscillating type and special consideration should be given to the type of oil and lube method used. The other remaining bearings support continuous rotation in one direction.

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% of those tested. The average life is roughly five times this design life. Since 10% 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 required 19 bearings and if this quantity were reduced, the corresponding reliability requirement would be reduced. By incorporation of these considerations, achievement of the required lifetime and reliability is expected.

Hot Finger

The hot finger in the engine operates at the high temperature and the 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 creep rupture over a long period of time. A design change to improve this component might be a thermally low conductivity ceramic material as a structural support for the thin wall. A ceramic material by itself may not be satisfactory because of possible gas diffusion into the Vacuum Foil Insulation system. By redesign, the reliability of this component is expected to satisfy the apportioned goal of 0.999.

Cylinder and Piston

The engine power cylinder and piston seem to be adequate for reliability and lifetime provided that the graphite of the piston rings gives good lubrication between the piston and cylinder. No problem is expected in achieving the goal of 0.999 for these components.

Displacer

The engine displacer operates at high temperature and is subject to the cyclic vibration. Compaction of the regenerator material due to vibration would be deleterious to system performance. This does not seem to be a problem based on Philips experience and attainment of the 0.999 reliability is expected.

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. 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.

Engine Rotary Seal

The use of rotary shaft seals is currently planned to isolate the flywheel from the crankcase. 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. Consequently, further consideration of this important component of the thermal converter is required. Achievement of the 0.999 is presently questionable. The use of a magnetic coupling as proposed in Phase I has been reevaluated and appears as an attractive alternative.

Roll Socks

The roll sock 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 has been tested. One failed after 2.4×10^8 cycles and the other test was stopped after 1.24×10^9 cycles; the latter did not fail. A continued development program is required to improve and totally demonstrate lifetime and reliability of this component.

Blood Pump Bellows

In the current design of the bench model, a double bellows assembly in the blood pump serves both as a torsion resisting element to prevent rotation of the pusher cups, and as a circulating pump for the coolant fluid. Lifetime data for bellows specifically designed for a particular application indicate that 1.5 to 2 times the required cycles can be obtained. However, in performing this double duty, a complex stress pattern is introduced into the bellows system which may be difficult to analyze. Therefore, one of two approaches is possible. The first

is to redesign the system to eliminate the bellows by pumping with the flexible shaft and incorporating torsion resistance into the linear ball bushing that guides the main yoke. The second is to obtain data on torsion forces and pumping pressures with which to design a special set of double bellows.

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.

Valves

Two check valves are used in the cooling fluid pump system located in the blood pump. These valves are well within the technology required to achieve a reliability of 0.999 and no problem is expected.

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.

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.

Filters

Two filters of the system, the engine crankcase oil filter and the cooling fluid filter, are necessary to maintain particulate free fluids. Design of these components is straightforward and well within the technology required. The high reliability goal of 0.999999 should be attained.

Flexible Shaft

The flexible shaft which transmits power from the thermal converter to the blood pump is perhaps the most critical item at this point 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.

Outer Tubing

The outside part of the flexible shaft assembly is a convoluted tubing which serves a three-fold purpose. The first is a return line for the cooling fluid. The second is protective covering for the casing. The third is a torsion resistant member between the power pack and the blood pump. Material selection is a major element in the design of this component for it must resist corrosion by body fluids, be flexible enough to meet the implantation requirements and durable enough to withstand the cyclic torsion loads. It is expected that these needs can be achieved and that the apportioned goal of 0.999 will be met.

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.

Vacuum Foil Insulation

The vacuum foil insulation package is certainly not a proven ten year technology, but nonetheless, the data obtained thus far indicate that this lifetime is an achievable goal. None of the materials involved appears to pose an outgassing problem. However, vacuum service for long periods of time has been demonstrated in analogous vacuum tube, light bulb and vacuum circuit breaker technologies. Achievement of the reliability goal is expected.

5.5.4 Summary

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. Details of the studies are given in Appendix A. These include the critical items list, FMEA for the blood pump and flexible shaft, and a supplementary discussion of recommended product assurance considerations.

APPENDIX A

SUPPORTING LIFETIME AND RELIABILITY ANALYSES

Use of the design for reliability approach during Phase II led to the identification of a critical items list which is summarized in Table A-1. These critical items for both the thermal converter and the blood pump were identified through failure mode and effects analyses (FMEA). The FMEA for the blood pump mechanism in particular was emphasized during Phase II because of the many new design features in this area. The details of this analysis are given in Table A-2. Since the design approach of the present thermal converter has remained fundamentally similar to the Phase I thermal converter, the critical items list in Table A-1 has been updated from the thermal converter FMEA that was done during Phase I. Tables A-1 and A-2 are supplemented with a discussion of areas of recommended reliability growth and product assurance.

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.	bellows	shear at folds	fatigue, long-term torsional stress combined with cycles	erratic loading, change in load, increase in load, overload	close Q.C. inspection for small fractures, verification of integrity before and after run-in	accelerated life tests of flexures on a significant sample
8.	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
9.	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.	silastic bladder	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 -

A-4

note 1 - to be determined by vendor and approved by (U).

Failure Modes and Effects Analyses (FMEA)

Table A-2 summarizes an analysis which shows conceivable ways (modes) that each assembly piece/part of the blood pump can independently fail, and the probable cause and 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

Rows 1 through 40

The rows of Table A-2 represent individual parts of the present pump mechanism and shaft.

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 - Assembly Effects

Effects of each mode on the next higher assembly in which the piece-part is assembled. Also provides for significant effects on adjacent parts and assemblies.

Column F - 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 MODES 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 ₂	I NOTES
1.	Housing Assembly A1S1 303 SS (11), and insert (roller track) (11) A1S1 440C SS	fractures	processing, test and usage stresses	entry of body fluid or gas	load increase, overload, stall	1	1, 2, 3	1
		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) A1S1 303 SS	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	2	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	

TABLE A-2 (Continued)

FAILURE MODES 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
3.	Insert, window (yoke housing) (4) A1S1 440C SS Dowel pin (3) A1S1 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		1, 2, 3	
		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) A1S1 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) A1S1 303 SS includes: 1 dome 1 dowel pin 3 roller pins A1S1 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 bladder 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	recipient hazard		1	
			sharpness of metal edge where silastic rim is inserted					

TABLE A-2 (Continued)

FAILURE MODES 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
5.	(continued)	silastic rim slippage from dome	long term pushing cycles	degraded operation of upper or lower bladder	recipient hazard		1	
			interference of rim edge at housing channel, loss of pin					
6.	Bearing Retainer (9) AISI 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					
			shift in screw position	bearing degradation	increase in load		3	
		"O"-ring loss of elasticity, creep	long term compression	entry of body gases, fluids	load increase, overload, stall		1, 2, 3	
		damaged "O"-ring	shipping, handling	preventable by close Q.C.	none expected		—	
7.	Gear Housing (12) AISI 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) AISI 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) AISI 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 AISI 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) AISI 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) AISI 303 SS	none significant				2	—	

TABLE A-2 (Continued)

FAILURE MODES 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 MODES 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) A1S1 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 band 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) A1S1 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) A1S1 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) A1S1 420 55	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					

TABLE A-2 (Continued)

FAILURE MODES 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) A1S1 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	

FAILURE MODES AND EFFECTS ANALYSIS (FMEA)

Flexible Shaft Assembly

[illegible]

Recommended Product Assurance

The FMEA has pointed to key areas of concern where close control of the product at the vendor and through delivery, assembly and test appears necessary to assure built-in reliability.

1. There are 22 rotary ball bearings and 2 linear ball bearings used. Reliable operation requires thorough vendor inspection and control of piece-parts for parameters such as dimensions and torque. Lubrication, sealed packaging and levels of cleanliness should be specified for the vendor's operations. A 10-20 hour run-in test is recommended to screen faulty parts before an anomaly is masked in the actual assembly. Handling, cleanliness and proper lubrication need to be explicitly specified in assembly procedures. Dimensional integrity of the mating parts needs to be verified so that neither excessive assembly forces nor excessive operating stresses are applied to prevent either outer or inner races moving in their respective bores or shafts and to assure the proper axial loads are imposed by washers, spacers, etc. Verification of bearing seating is needed. An acoustical signature of the assembly could become part of an acceptance test procedure since anomalies in the micro-watt range can be discriminated sooner than they can be detected through load change instrument measurements. Acceptance tests such as spin-down time of an assembly can detect subtle resistances to rotation as incipient failures.
2. There are 6 rollers used to either resist or apply forces to compatible contact surfaces. If possible to do, a method of visually inspecting roller and track surfaces before and after a 10-20 hour run-in test is recommended. Dimensional checks and roller resistance measurements should be made prior to testing. A method to assure that rollers are not skidding is advised after the run-in period.

3. There is a pinion gear with 12 teeth, three planetary gears with 33 teeth, and a circumferential ring which is the planetary gear track with 78 teeth. Precision inspection is recommended from the processing of the gears through assembly for such anomalies as burrs, nicks, etc. A shadowgraph can be used to assure dimensional integrity. Control of cleanliness and proper lubrication is essential for long-life assurance. Compatibility of gear lubricant with proximate bearings needs assurance. Lubrication depletion and migration should be checked after run-in of the assembly.
4. Two O-rings are used to seal the junction of the gear box and the outer housing from body liquids and vapors. One O-ring is used to seal the opening at a bearing retainer on the opposite side of the outer housing from the body liquids and vapors. Manufacturing and installation control is needed to assure integrity of the materials in the rings and proper handling. Assurance of proper sealing is needed before and after run-in.
5. A bellows is used to prevent radial motion of the shaft and is subjected to torsional stresses. At the same time, axial motion of the shaft opens and closes the bellows once each cycle. Since any unusual problems are expected to be uncovered in the early cycles, a bellows run-in test is recommended prior to assembly or to be part of the assembly run-in. Visual inspection should immediately follow the exercise. Very close manufacturing control is required along with tight inspection procedures.
6. If EB welds are used on the crankshaft assembly, integrity of these should be checked by radiograph (or x-ray) and dye penetrant. A check of assembly squareness and dimensional integrity after welding is necessary to ensure tolerable stresses on each bearing and roller used along the crankshaft.

7. Peening of materials is being used in assembly operations to assure a positive anchoring of some parts. Where possible, other methods, such as pinning, are recommended. The disadvantages of peening are irreversibility and deformation of material which increases the probability of loose fragments and the potential over-stresses of neighboring parts during the operation. Peened items would appear to make it difficult to disassemble, if that were necessary at a later time, and to preserve evidence of anomalies for problem analysis.
8. Epoxy is used to bond piece-parts together in a number of places. Close batch control of the epoxy material will be needed, together with assurance that the surfaces to be bonded are clean. When the parts are bonded, a non-destructive force should be applied to test the bond integrity. An effort should be made to avoid reliance on the bond's shear properties under long-term significant loads. One example of this is the bond between the plastic planetary gear and its stainless steel insert. In this case, the epoxy could have kept the retainer from axial movement where there is very little load on the bond. The radial component of force on the bond can be alleviated through a mechanical connection of the parts similar to a dove-tail or key type junction. This suggested stress relief from the epoxy bond to a mechanical bond might also be applied to the small rollers.
9. Close control of small hardware items such as the 8 retaining rings lock washers is needed. Rupture or improper placement of any one during assembly operations could cause failure of the entire mechanism. A positive means of inspection, both before and after run-in, is recommended.
10. The flexible shaft which couples the Stirling engine power source to the pump mechanism is a helically wound steel coil, encased in a teflon sheath. It rotates inside the sheath at 1800 rpm and is expected ordinarily to be bent. Thus, the turning shaft usually contacts the stationary sheath at one or two points. Longterm stress on the shaft at the bend, maintenance of shaft lubricity

and wear of the sheath at the contact points are critical factors which need attention in the development and qualification phase. Acceptance tests are recommended, however, such as before and after run-in measurements of shaft resistance changes. It should be noted that although an absolute limit can be set for satisfactory shaft resistance, the change in this resistance appears to be a more valid screening parameter. Close vendor control related to the coil smoothness, physical and performance characteristics is needed. Close control over coil assembly and lubrication appears essential.

11. To prevent damage to the silastic bladder the smoothness of the pusher cup dome and the absence of all sharp or abrasive particles at the metal/silastic interface must be assured through careful inspection at both fabrication and assembly stages. A non-destructive examination to confirm junction integrity is also recommended.
12. A coating of silastic material will be painted over all system components. One reason is to make the system interface more compatible with proximate tissue; and, silastic performs well for this use. A few pump mechanism failure modes existed because body gases and fluids were capable of entering the mechanisms. If the silastic can be assured to act as a liquid seal, some protection of the mechanism can be assured by the silastic coating in spite of these particular modes of failure.

Reliability Growth

The following design changes when applied to later configurations will enhance the reliability through avoidance of known failure-prone mechanisms. The degree to which this can be done will depend upon trades of reliability with other key system parameters:

1. A different speed reduction approach using the new type of gearing can result in a significant reduction in gear mechanism complexity and in the number of bearings required.
2. A fluid-filled 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.
3. 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.
4. 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 number of these less permanent, failure-prone connections can be reduced.
5. 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.
6. 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 lubrication, two inherent life limiting factors.

7. The development and implementation of clean assembly procedures for the engine and the pump should have high priority so that "as built" reliability is maximized.

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