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Phase I

RADIOISOTOPE POWERED CARDIAC PACEMAKER
SYSTEM DESIGN DESCRIPTION

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System Design Description

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SYSTEM DESIGN DESCRIPTION

1.0 Introduction

1.1 System Function

The purpose of the Radioisotope Powered Cardiac Pacemaker Program is to develop a highly reliable, long life, implantable nuclear battery for use with existing pacemaker electronic circuits and cardiac leads. The pacemakers provide an electrical stimulation to the heart to maintain a regular heart beat for persons having cardiac difficulties such as heart block. The typical operating life of the presently used mercury battery powered pacemakers is limited (two to three years) primarily because of short battery life so that the recipients are faced with the need for a number of subsequent replacement operations. Using the reliable heat generated by the plutonium-238 fuel and converting this heat to useful electrical power stably by means of metallic thermocouples offers the potential of an 11 yr.(or more) operating life in a size, weight and general configuration suitable for implantation.

Phase I of the planned program is to develop basic microwatt technology in conjunction with three progressive stages of system design. The three system types are (1) an electrically heated mock-up, (2) a series of radioisotope fueled experimental models, and (3) a group of six radioisotope fueled prototype models. The prototype systems, whose completion are expected to mark the end of Phase I, will demonstrate an optimum design which is suitable for entry into reliability and further animal testing in Phase II.

The recommended prototype design, which is the subject of this document, is illustrated in Figure 1. Further details are shown in Assembly Drawing 15-D-3731-293 which is attached. Figure 2 is a similar illustration of the experimental model.

1.2 Summary Description of the Prototype System

The prototype system follows closely the design of the latest experimental units which have a demonstrated capability relative to the system objectives. The experimental models are illustrated in Figure 2 for ready comparison with the recommended prototype design illustrated in Figure 1. Note in Figure 1 that the complete system consists of three basic sub-assemblies (1) a nuclear battery which is hermetically sealed within a corrosion resistant titanium outer case, (2) an electronics assembly which is sealed within a separate hermetic titanium enclosure, and (3) a commercial cardiac lead termination which is positioned by epoxy. This configuration is monopolar so that the nuclear battery outer case serves as the second electrode.

The Pu-238 metallic heat source is triply encapsulated within successive right circular cylinders of tantalum-10w/o tungsten, Hastelloy "C", and titanium each of which is hermetically sealed. This heat source can be seen as the central core, within the nuclear battery outer case by referring to Figure 1. The thermopile, which is fabricated from a series of E-glass* tapes whose longitudinal fibers have been replaced with metallic thermocouple wires, is wrapped around the cylindrical heat source so that the thermoelectric wires contained within these thermoelectric tapes effectively describe a spiral path which originates close to the heat source within the grooves of six ceramic tabs and which terminates near the outer battery case within six similar ceramic tabs. These various ceramic tabs whose grooves contain the individual thermocouple joints, are mechanically connected to corresponding

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*Electrical grade borosilicate fiberglass produced by Owens-Corning.

hot and cold metallic straps which form the inner and outer perimeter of the thermopile, this producing a convenient thermoelectric module.

The six thermoelectric tape subassemblies are connected electrically in series with Cupron Special® wires which are covered with braided E-glass insulation sleeving over ceramic beads.

The completed thermopile including its central heat source and associated metallic thermal radiation shields mounted at each end of the heat source is mechanically and thermally attached to the flat, outer case lid.

This achieves maximum accessibility of the complete nuclear battery for final visual and electrical inspection purposes, prior to assembly within the nuclear battery outer case (Item 2 on Drawing 15-D-3731-293). This outer case is hermetically sealed by electron beam welding to the outer case lid which contains a ceramic to metal seal through which the electrical output of the nuclear battery is conducted.

The direct current output from the nuclear battery is converted to rectangular stimulation phases by a conventional electronic circuit which is contained within a separate, hermetically sealed titanium case (Item 1, Drawing 15-D-3731-293) which is bolted to the nuclear battery case lid and then welded at the two bolting flanges to assure the strength and reliability of this connection. The electronics outer case serves as an electrical conductor between the electronics circuit and the nuclear battery case, which in turn serves as one of the system electrodes. The second electrode in this, a monopolar system, is the cardiac lead which is shown as Item 4 on Drawing 15-D-3731-293. This cardiac lead and its termination is a commercially

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Cupron Special and Tophel Special are trade names of the Wilber B. Driver Company, Newark, New Jersey.

produced item whose electrical conductor is constructed of spiral Elgiloy wire (Cordis Corporation).

The metallic end of the cardiac lead is simply inserted into a metallic block (Item 7) which is pre-molded into the epoxy material surrounding the electronic case and locked with a captive set screw and hole plug (Item 8).

Since the electronics assembly and the nuclear battery assembly are contained within separate metallic cases which are not joined until each sub-assembly is complete, each of these items can be fabricated, assembled and inspected concurrently which offers a schedule, cost and flexibility advantage over the experimental model design.

1.3 System Design Requirements

The following system design requirements are taken directly from Modification 7 of Contract AT(30-1)-3731 and are shown for completeness.

- (a) Size: Approximately 6 x 5 x 2.8 centimeters, with all corners having a radius greater than 0.5 centimeters, except for the lead fittings.
- (b) Weight: Approximately 100 grams and specific gravity of 1.4.
- (c) Design Life: 10 year minimum operating life for human model and 5 year minimum operating life for animal model.
- (d) Reliability: 0.95 reliability at 0.90 confidence.
- (e) External Radiation: Maximum allowable dose rate is 0.3 mrad/hr at 5 cm from the surface of the unit and 5 mrad at the surface. Of this, the neutron dose rate shall not exceed 0.1 mrad/hr at 5 cm and 1.5 mrad/hr at the surface.

- (f) Sterilization: The system is to be shipped pre-sterilized and is to be capable of resterilization under hospital conditions.
- (g) System Electrical Output: Shall be a pulse of the following characteristics:
- (1) Current: 4.0 milliamperes minimum, 7.0 milliamperes maximum into a load consisting of a resistor which may vary between 300 and 700 ohms paralleled by a series resistor-capacitor branch of 0.25 microfarad and 1000 ohms.
  - (2) Shape: 1.5 to 2.0 millisecond rectangular current pulse with full recovery between pulses, i.e., no direct current. The pulse must achieve full current output within 0.10 millisecond.
  - (3) Rate: Human^{*} model - 70 ± 5 pulses per minute
Animal^{*} model - 120 ± 5 pulses per minute

* - Base design is to be predicated upon 70 ± 5 pulses per minute; design alternatives shall be capable of operation at 120 ± 5 pulses per minute.
  - (4) Power Output: At the radioisotope thermoelectric generator feedthrough pacemaker electronics interface, there shall be approximately 160 microwatt (e).
- (h) Component Characteristics:
- (1) Fuel: Shall be Pu-238 in accordance with MLM 1270, pages 31-59. As an objective the design should be capable of being adapted to alternate plutonium fuel forms.
  - (2) Radioisotope Thermoelectric Generator: Shall be based on wire thermoelectric couples woven into tapes.
  - (3) Container: Shall be a hermetically sealed, titanium container(s) which completely encloses the radioisotope thermoelectric generator

and pacemaker electronics. The container shall serve as system anode and shall be designed to prevent electrolytic destruction over operating lifetime.

- (4) Pacemaker Electronics: Shall be based on Cordis model Ventricor or commercial equivalent.
- (5) Cathode Electrode: In a monopolar configuration there shall be "Chardack" electrode with 50 cm Chardack spiral Elgiloy electrode wire.

In order that the specific design characteristics of the prototype design may be compared directly with the pertinent design objectives, Figures 3 and 4 were prepared. These figures also contain the measured design characteristics of the intermediate experimental model systems. During examination of these two figures, note that every performance objective, with the exceptions of pacer width and weight, is achieved and that the proposed width of the prototype (3.10 centimeters) is only 10% greater than the design objective of 2.80 centimeters. The actual volume of the prototype is somewhat smaller than the experimental model as a result of a reduction in height. The thickness of 3.10 centimeters is a minimum, consistent with the internal structure, configuration, and design of the nuclear battery. Also note in Figure 3 that the pulse characteristics for both the experimental and prototype models are the same as the specification requirements and that in most instances, a range of values is shown. The experimental model electronic circuit was designed so that the output pulse rate is a function of the nuclear battery output voltage so as to obtain a relative indicator of battery condition in a complete pacer. This results in a small reduction of pulse rate as a result of the natural decay of the nuclear fuel over the 11 year life of the device.

As a result of this same characteristic, the initial pulse rate of a particular pacer will vary as a result of the allowable range ($\pm 10\%$) in the specific amount of plutonium-238 which the battery contains since a greater or lesser amount of fuel results in a greater or lesser output voltage. There is, of course, a variation in individual nuclear batteries and electronics circuits. The prototype pacer system has been designed so that the effects of both rate sensitivity and nuclear fuel variation will result in a range of output pulse parameters that fall within the range of the design objectives, when connected to the specified body impedance; however, this is based upon the premise that the Cordis Corporation can produce these circuits with a uniform rate sensitivity corresponding to a rate sensitivity of about 7 beats/minute/volt. This effectively would represent a reduction in rate sensitivity since the electronics unit selected had one of the lowest rate changes per volt. We presently believe this to be possible; but in the event this does not occur, either the rate sensitivity should be eliminated or the isotope fuel loading tolerance should be reduced from $\pm 10\%$ to $\pm 5\%$ to insure compliance with the specification.

A range of dose rate at contact is shown in Figure 3 which corresponds to the $\pm 10\%$ variation in the heat source fuel load.

2.0 Detailed Description of the System

This detailed description of the system follows the nomenclature outline presented in Table 1. The prototype model assembly Drawing 15-D-3731-293 is attached to this recommendation and may be referred to for further detail.

Heat Source

The prototype heat source is designed as a simple series of successive right circular cylinder encapsulations of the plutonium-238 fuel. Sufficient void space has been provided within the first encapsulation to permit the use of either plutonium metal or plutonium oxide and still meet the recommended heat* source design life of 50 years.* The recommended design uses plutonium metal since (1) it achieves the minimum dose rate, (2) the fuel loading techniques have been developed, and (3) its general suitability has been demonstrated by its previous use in the preceding series of experimental generators.

While the geometry of the heat source has been altered for the prototype design with a reduction in the total number of encapsulating components from 16 to 6, the selection of the encapsulating materials has been retained. They are tantalum 10% tungsten, Hastelloy C and titanium-.2w/o palladium or titanium, in the order in which the encapsulation is performed. A detailed drawing of the heat source is contained on Drawing 15-D-3731-272.

As in previous designs, the outer surface of the Hastelloy "C" encapsulation is electroplated with a thin layer of platinum as a diffusion barrier to the formation of any possible eutectic between the titanium outer encapsulation and any element of the Hastelloy "C". This is a consideration during possible fire exposures and not a requirement during normal operation of the pacemaker.

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*NUMEC 3731-9, Safety Analysis and Test Plan.

Surrounding the heat source is a silver plated copper strap to which are attached six sets of ceramic tabs containing 89 grooves each, in which the Cupron Special (.002 inch diameter) and Tophel Special (.0025 inch diameter) thermocouple wires are brazed to form 88 thermocouple hot junctions. The thermocouple wires are first woven longitudinally into 1-3/8 inch wide cloth tapes using "E"-glass fibers as insulation material such that one tape contains all of the Cupron Special wires and a second tape contains all of the Tophel Special wires in each of the six thermocouple sub-assemblies.

The complete tape assembly is wrapped spirally around the heat source for approximately 3-1/2 turns. The cold ceramic tabs are attached to an anodized aluminum strap which completely surrounds the outside of the thermopile to provide a common heat sink and an electrical ground for the thermopile. Since the hot and cold straps completely enclose the thermopile assembly, they provide a means of containing the thermopile in a convenient modular form.

The thermoelectric tapes are connected in series and the positive lead of the thermopile is connected to the pacemaker case. The negative lead is connected to a ceramic-to-metal feedthrough that passes through the titanium outer case lid.

The thermopile is a proven design which is essentially the same as that used in the most recent experimental models with the exception that the nominal thermocouple tape length has been shortened slightly from 9 inches to 8-1/2 inches in order to minimize the nuclear battery outer case thickness without compromising system efficiency or performance. The engineering basis for this trade-off is examined in a report entitled "Design Objective Optimization".* The general configuration of the thermopile is shown on Drawing 15-D-3731-293. The number of couples (528) and thermocouple tape assemblies (6) is unchanged as are the diameters of the Cupron

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*NUMEC 3731-21

Special (.0020) and Tophel Special (.0025) thermocouple wires. The type of weave, the tape width and the tape material has also been retained.

Electrical insulation between adjacent thermoelectric tapes is achieved by sandwiching each thermocouple tape between two layers of .0015 inch thick, two inch wide E-glass insulation tapes which are loosely sewn along their two edges to maintain position during wrapping. Thus, each thermopile contains 24 insulation tapes. Before assembly of the thermopile, the insulation tapes are coated with a few monolayers of aluminum oxide to provide mechanical stability to the woven fibers without adversely affecting their flexibility.

The electrical connections between thermocouple tapes as well as the ground connections are 0.0045 inch diameter wires of Cupron Special and are brazed into the end grooves of the cold ceramic shoes. These connecting wires are insulated with short sections of ceramic tubing which are covered with glass sleeving.

Getter

The getter is Ceralloy 400, which is active down to room temperature. This is a desirable characteristic, but is not essential since the six 0.132 inch diameter by 0.056 inch thick pellets are placed at the two ends of the cylindrical heat source where the normal operating temperature is approximately 200°C. This higher temperature has the advantage of increasing both the gettering capacity and rate of the Ceralloy 400.

Thermal Insulation

Since the thermal performance of the nuclear battery is optimized, in part, by inducing the maximum amount of thermal flux to pass through the thermoelectric wires, an important consideration is the means by which the thermal flux

extraneous to the thermoelectric wires is minimized. This is accomplished by maintaining the free space as a vacuum (10^{-3} to 10^{-6} mm of Hg) to eliminate gaseous conduction and/or convection from the heat source to the nuclear battery outer case. Both the thermocouple tapes and the insulation tapes act as thermal radiation shields around the circumference of the heat source while 15 titanium end shields rolled from .001 inch thick stock perform the same function at each end of the cylindrical heat source.

Outer Case

The outer case of the nuclear battery is formed in two parts, a deep drawn case which nearly surrounds the thermopile and a flat lid with a rim. This flat lid inserts into the open end of the deep drawn case so that the lip around the lid forms a double lip with the deep drawn case. This permits semi-automatic electron-beam welding in a single plane. Both the case and its lid are formed from .025 inch thick titanium. Since the complete thermopile is assembled into a beryllium copper holder which is attached to the lid, good accessibility to the thermopile assembly for examination, test and inspection before insertion of the thermopile within the deep drawn outer case is achieved. Since the ceramic-to-metal feedthrough is also mounted in the flat lid, this electrical connection to the thermopile can also be made and tested before assembly of the deep drawn case. Epoxy molding is used on the lid to cover the electronics case, provide attachment for the heart lead, and give a satisfactory shape for implantation. The prototype case design has an added advantage that the epoxy molding can be made without leaving a feather edge at the epoxy-case interface.

Feedthrough

Each feedthrough is constructed from a ceramic tube which has been precoated with a thin layer of titanium. A central platinum wire is pre-brazed in place with either gold-titanium or nickel-titanium, both of which have been electro-chemically tested for compatibility with the titanium case and the Elgiloy electrode in Ringers' solution for an equivalent of >40 years without corrosion damage.

The feedthrough may then be brazed directly into the titanium outer case using either the alloys indicated above. An alternative means of inserting the feedthrough into the lid which will be examined experimentally will consist of pre-brazing the platinum wire in the ceramic tube (as above) and then brazing the ceramic tube into a titanium flange which would then be welded to the outer case lid.

Electronics Case

The electronics case is fabricated of the same thickness (0.025 inch) titanium as the nuclear battery outer case; however, it is designed as a separate hermetic closure which is not joined to the nuclear battery outer case until each of these sub-assemblies have been completed and performance tested. The electronics case is substantially larger than the case used for the experimental models and provides sufficient space for larger electronics circuits. The ceramic-to-metal feedthroughs in the electronics case are of the same design employed in the nuclear battery outer case.

The electronics case and the nuclear battery case are bolted together in two locations with No. 80 screws which are ultimately locked in place with the epoxy covering. Each of the two sets of bolting flanges are spot-welded together to insure the long-term integrity of these connections. Since this welding is performed at the edges of the flanges, the two assemblies can be separated if necessary by filing the welded area. This can be seen best on Drawing 15-D-3731-293.

Electronics

The prototype electronic circuit is shown in Figure 8. It is, schematically, the same circuit that was used in the later experimental models; however, R_3 , R_4 , and R_5 may change and VR-2 will be eliminated if the rate sensitivity is deleted.

For a more detailed discussion of the circuit and its operating characteristics, refer to Section 3 of this report. The electronics circuit is pre-potted in a rectangular epoxy pre-form, (0.290 x 0.380 x 1.490 inches) and each electrical lead within the electronics case will be soldered. The void space surrounding the electronic circuit will be filled with RTV to a level that leaves a gap between the RTV and the electronics lid so as to avoid the presence of RTV in the final lid weld area.

Cardiac Electrode

Since the cardiac lead termination is molded in place with epoxy, and since a substantial amount of space is available for the lead termination, virtually any commercial lead and termination may be used; however, the recommended prototype design consists of a commercial type fabricated by the Cordis Company formerly for use in connection with endocardial electrodes only but which is now available for both endocardial and epicardial electrodes. It simply plugs in place into a metal block (Item 7 of Drawing 15-D-3731-293) and is locked in position by a captive, recessed Allen head screw. The only variations that are recommended over the commercial design are the captive screw (without the silastic plug) feature plus the substitution of titanium for 303 stainless steel in the cardiac lead hardware. This recommended combination of materials has been demonstrated to be superior, on test, in Ringer's solution.

3.0 Principles of Operation

Figure 5 is a schematic of a generalized radioisotope powered thermoelectric generator system of which a Radioisotope Powered Cardiac Pacemaker is a specific example. Note that there are three major elements: (1) the heat source which provides heat by means of the natural decay of the isotope, (2) a suitable set of thermoelectric elements which convert the isotope heat of decay into a useful direct current electrical output by means of the Seebeck effect, and (3) an electronics package which converts this direct current into the proper stimulating pulses. In this simplified form the nuclear battery includes the heat source and the thermoelectrics, whereas, the electronics package includes both the pacemaker electronics and the cardiac lead.

The heat source contains metallic Pu-238 which was selected because of its high thermal energy density and long half-life. The isotope is primarily an alpha emitter which is a helium molecule and which must be contained within the inner encapsulation. The Pu-238 is simply used as a heat source to drive the thermoelectrical wires that produce a useful electrical output. Since the tolerance on thermal size of the fuel has been established at $\pm 10\%$ there is a range of electrical power output from the thermopile that varies between the minimum end of life requirement of 160 microwatts to values greater than 200 microwatts. This simply represents additional electrical power which is available to the electronics. The heat generated by the plutonium is not only conducted along the thermoelectric wires in order to produce a useful electrical output, but a significant portion of the heat is also conducted along and through the glass fibers from which the thermoelectric tapes and insulation tapes are constructed. In fact, there are 6 thermal paths which are summarized in Figure 6, some

of which occur by conduction transfer and some of which occur by thermal radiation transfer. In order to eliminate an additional extraneous heat path, the entire thermopile is encased in a titanium case which is electron beam welded so that the void spaces within the battery contains a vacuum. This prevents the conduction of heat through any gases that might otherwise be entrapped.

Thus the complete nuclear battery is enclosed in a titanium hermetically sealed case through which the positive electrical output passes by means of a ceramic-to-metal feedthrough which penetrates the outer case lid. This electrical lead then passes through a similar feedthrough into the electronics case to power the electronics circuit.

Since the existing pacemaker electronics have been designed to operate with conventional batteries and since their output characteristics differ somewhat from nuclear batteries, certain component adjustments are required to achieve compatibility between the nuclear battery and pacemaker electronics. The characteristic nuclear battery output (load line) is shown in Figure 7 where both the output current and the output power are plotted as a function of output voltage. A simplified equivalent circuit of the nuclear battery is also shown in Figure 7 which is composed of an ideal electromotive force (emf) in series with a resistor. The emf is a result of the Seebeck effect and the resistance is the net sum of all the thermocouple wires connected within the nuclear battery integrated over the temperature profile from the hot junction to the cold junction of the thermoelectrics. One of the interesting characteristics of such a power source is that when a load impedance is connected across its output terminals, maximum power transfer to the load occurs when the load impedance equals the complex conjugate of the

source impedance. For the nuclear battery, this corresponds to the load resistance being equal to the battery internal resistance (R) which is shown graphically in Figure 7. Any operating point on the load line with a given resistive load is determined by the intersection of the load line and the voltage versus current curve of the resistor which is a straight line through the origin with a slope numerically equal to the resistance. If the value of the load resistance becomes very large, the nuclear battery output voltage approaches the open circuit value (E_{oc}) and the output current and power approach zero. If the value of the load resistance becomes very small, the output current approaches its short circuit value (I_s) and the output voltage and power approach zero.

The two important points illustrated by Figure 7 are (1) that the nuclear battery output voltage is a function of the load in contrast to conventional batteries for which the output voltage is relatively constant over a wide range of loads and (2) that the maximum output current of the nuclear battery is limited to its short circuit value. It is, therefore, important in designing nuclear powered devices that the internal resistance of the nuclear battery match reasonably well the equivalent resistance of the electronics as seen by the nuclear battery. In addition, if large pulses of current (much larger than I_s) are required, a storage device must be utilized such as a capacitor.

Figure 8 shows a standard fixed rate cardiac pacemaker circuit manufactured by the Cordis Corporation. Basically the circuit consists of two transistors (Q_1 and Q_2) connected in a complementary pair as a free-running multivibrator whose output is fed to a third transistor (Q_3). Transistor Q_3 assures that

the output to the heart is a current pulse (as distinguished from a voltage pulse) and regulates the pulse wave shape. In this configuration, the transistors draw current from the power supply only during application of the output pulse to the heart. Transistors Q_1 and Q_2 freely oscillate with an on-time determined by the product of the capacitance value of the capacitor C_1 and resistance of resistor R_2 . The off-time of Q_1 and Q_2 is determined by the product of the capacitance C_2 and the resistance of R_5 . The amplitude of the output current pulse is determined by the β (forward current gain in the common emitter configuration) of Q_3 and the resistance of R_3 . In order to completely block DC (Direct Current) energy to the heart, capacitor C_3 is connected between the output and the electrode. The Zener Diode, V_{R1} , shunts the extraneous high voltage signals which might be introduced by external defibrillation or other high voltage shock procedures applied to the patient.

A functional block diagram of the nuclear powered cardiac pacemaker system is shown in Figure 9. Heat produced by the natural decay of the radio-isotope plutonium-238 is converted to electrical energy by the thermopile. This electrical energy is stored and periodically utilized by the multi-vibrator circuit to convert the DC voltage to a series of voltage pulses. These voltage pulses are then converted to current pulses and transmitted to the cardiac electrode. The transmitted stimulating current is rectangular in shape and has a fixed rate.

The basic circuit shown in Figure 8 will not operate when supplied by the nuclear battery unless certain minor adjustments are employed. For

example between pulses the electronic circuit draws almost no current; whereas during the pulse it draws a large current amplitude much greater than I_s in Figure 7. Therefore, the operating point would be at E_{oc} before the pulse, and during the pulse the nuclear battery voltage would drop to zero which cannot be permitted. However, with the addition of a suitable capacitor across the output terminals of the nuclear battery, this difficulty is eliminated. Between pulses the capacitor is charged by the nuclear battery, and during the pulse, current is drained from the capacitor inducing its voltage to decrease. During continuous pulsing, the voltage decrease equals the voltage increase so that the nuclear battery output voltage oscillates about a given point on the load line of Figure 7. The capacitor thus supplies the large energy pulses for short periods of time while the nuclear battery replenishes the energy in the capacitor over the relatively long periods of time between pulses. The magnitude of the voltage oscillation is dependent on the size of the capacitor (in addition to the pulse width, rate, amplitude, and battery resistance) which should have a large value since excessive wave shape distortion takes place if the supply voltage decreases too much during the pulse. In addition to this storage capacitor (C_4), some of the circuit parameters must be adjusted since the supply voltage does oscillate and incorporates a storage capacitor.

In general, the system would normally be designed to oscillate about the peak power point (point P of Figure 7); however, since the nuclear batteries produce more power than required by most fixed rate pacer circuits, the system oscillates about a point corresponding to a higher output voltage but a lower output power from the nuclear battery than point P of Figure 7.

4.0 Safety Precautions

There are a number of classes of safety precautions to be considered. These include nuclear safety, electrical and mechanical safety precautions in the use of the pacer device plus safety precautions in the sterilization of the pacer which must be observed in order to protect against damage before implantation. Of these, nuclear safety is further divided into three categories: (1) containment of the isotope under credible accident conditions, (2) radiation safety, and (3) various licensing requirements. The heat source design for the prototype system consists of a series of three successive encapsulations in a right circular cylinder configuration which can be expected to have an improved resistance to each type of accidental exposure when compared to the earlier experimental model design. Since the inner capsule must contain the helium buildup, and since it must do so within the constraints of the system design, an examination of the optimum capsule design was considered within the limits of the maximum geometry permitted by the system design as represented by a fixed outer capsule length of 1.5 inches in combination with a maximum outer diameter of the first encapsulation. In order to develop a feel for the capsule design parameters, a range of capsule designs were considered by examining the outer diameter of the first encapsulation as a function of its inside diameter for various stress ratios above the design requirements of complete containment of the isotope and its associated helium buildup at 50 years during exposure to the maximum credible fire temperature of 1900°F . The results of these calculations are plotted in Figure 10 with an optimum or minimum value of outside diameter occurring for each value of K , where K is the additional stress ratio discussed above. The calculations were carried

out on a completely conservative basis using the maximum fuel loading and worst case geometries for their effect on void volume in combination with the admittedly conservatively assumption of complete release of the helium gas from the fuel matrix during exposure to the 1900°F fire temperature. From Figure 10 the design point at a diameter of .170 inch was selected as providing the maximum safety margin over and above the minimum required in consideration of the space available. Since the design point selected provides an additional safety factor over the minimum required, Figure 11 was prepared to examine this effect. Both metallic Pu-238 and Pu-238 oxide were examined with the result that the heat source has a design capability at 1900°F for containment of helium buildup associated with the alpha decay of the metal of about 100 years. If plutonium oxide were substituted, the prototype heat source has a design capability at 1900°F of greater than 75 years. Both of these exceed the required heat source design life of 50 years at 1900°F but not to an extent that a less capable design is recommended. The system operating temperature of the heat source is less than 250°C (482°F) throughout its operational life.

In order to insure that the maximum capability of the heat source design will be translated into the fabrication of each and every heat source a detailed quality control procedure similar to that applied to the experimental model design is being developed at Mound Laboratory. Furthermore, each of the credible accident definitions which include testing for impact, impact by a high velocity object, the effects of hand-held power tools, elevated temperature rupture will be conducted on unfueled prototype heat sources.

The radiation analysis and measurements conducted to date on lower fueled experimental models indicate that the maximum dose rate to be expected of the prototype heat sources will be approximately 5 millirads/hour at contact and less than .3 millirads/hour at 5 centimeters.

The necessary licensing considerations are a separate subject which need to be examined in the future for such changes as may be necessary to insure that the maximum benefit expected to be obtained from such a device can be obtained consistent with public policy.

Pacer and Patient Safety

In order to protect a completed pacer before implantation, the device should not be subjected to temperatures above 140°F nor should they be cleaned by ultrasonic cleaners nor exposed to their action. Both of these precautions are protection for the electronic circuit elements and would have no effect on the integrity of the nuclear battery. Since both external and implantable electronic devices are susceptible to interference from high intensity electro-magnetic fields, electronic cauterizers and similar equipment should not be used within a few inches of an implanted pacer that is pacing a patient. The usual precautions regarding grounding of monitoring equipment should also be strongly observed throughout any surgical procedure. Care must be taken to provide a common ground circuit so that AC currents will not be introduced to the ventricle, causing possible fibrillation. If any AC signal is apparent on the monitoring ECG, all contacts and ground circuits should be carefully checked. In any case, it is recommended that defibrillation equipment be available during implantation or replacement to meet any unexpected emergency conditions.

Mechanical Precautions

The metal ground plate of the pacer has been carefully prepared in order to present an ideal electrical surface to tissue. Consequently, cautious handling is advised. Damage to the plate should be avoided.

If a ground plate is severely damaged accidentally or if localized penetrations of the ground-plate occur (other than superficial marks and scratches) the pacer should not be implanted.

5.0 Maintenance

Since the prototype RPCP is a self-contained and completely implantable device, maintenance as such is not required. Replacement of the device should occur at a time when the output pulse parameters discussed under the design requirements have an out-of-specification value, in combination with the judgment of the cognizant surgeon that such a replacement is desirable and/or necessary.

PROTOTYPE MODEL CONFIGURATION

Figure 1

EXPERIMENTAL MODEL CONFIGURATION

Figure 2

DESIGN OBJECTIVES

CHARACTERISTIC PACEMAKER SYSTEM	EXPERIMENTAL MODEL	PROTOTYPE MODEL	DESIGN OBJECTIVES
<i>DESIGN LIFE (YEARS)</i>	<i>11</i>	<i>11</i>	<i>10</i>
<i>WEIGHT (GRAMS)</i>	<i>102-115</i>	<i>100-109</i>	<i>100</i>
<i>SPECIFIC GRAVITY</i>	<i>1.27</i>	<i>1.30</i>	<i>1.4</i>
<i>HEIGHT (CM)</i>	<i>5.04</i>	<i>4.82</i>	<i>5.0</i>
<i>WIDTH (CM)</i>	<i>3.25</i>	<i>3.10</i>	<i>2.8</i>
<i>LENGTH (CM)</i>	<i>6.00</i>	<i>6.00</i>	<i>6.00</i>
<i>STIMULATION PULSE</i>			
<i>FORM</i>	<i>RECTANGULAR</i>	<i>RECTANGULAR</i>	<i>RECTANGULAR</i>
<i>CURRENT AMPLITUDE (MILLIAMPS)</i>	<i>4-7</i>	<i>4-7</i>	<i>4-7</i>
<i>ANIMAL RATE (PULSES/MIN)</i>	<i>120±5</i>	<i>120±5</i>	<i>120±5</i>
<i>HUMAN RATE (PULSES/MIN)</i>	<i>70±5</i>	<i>70±5</i>	<i>70±5</i>
<i>PULSE WIDTH (MILLISECONDS)</i>	<i>1.5-2.0</i>	<i>1.5-2.0</i>	<i>1.5-2.0</i>
<i>RISE TIME (MILLISECONDS)</i>	<i>.0015</i>	<i>.0015</i>	<i><0.1</i>
<i>DOSE RATE (MILLIRAD/HR) (BOL)</i>	<i>4.2-5.2</i>	<i>4.09-5.03</i>	<i>5.0</i>

Figure 3

DESIGN OBJECTIVES (CONTINUED)

NUCLEAR BATTERY	EXPERIMENTAL MODEL	PROTOTYPE MODEL	DESIGN OBJECTIVES
<i>ISOTOPE</i>	<i>Pu-238</i>	<i>Pu-238</i>	<i>Pu-238</i>
<i>HEAT SOURCE SIZE (WATTS)</i>	<i>.238±.024</i>	<i>.238±.024</i>	————
<i>ELECTRICAL POWER OUTPUT (μ WATTS, EOL) (NOM. FUEL)</i>	<i>180</i>	<i>180</i>	<i>160</i>
<i>THERMOPILE</i>	<i>WIRE T/E COUPLES</i>	<i>WIRE T/E CPLS.</i>	<i>WIRE T/E CPLS.</i>
<i>VOLTAGE OUTPUT (OPEN CIRCUIT)</i>	<i>~6</i>	<i>~6</i>	————
<i>RELIABILITY</i>	<i>PARTIALLY DEMONSTRATED</i>	<i>PARTIALLY DEMONSTRATED</i>	<i>95% 90% CONFIDENCE</i>
<i>FUEL FORM</i>	<i>METAL</i>	<i>METAL</i>	<i>MTL. OR OXIDE</i>
<i>PACEMAKER ELECTRONICS</i>	<i>"SHALL BE BASED ON CORDIS MODEL VENTRICOR OR COMMERCIAL EQUIVALENT"</i>		
<i>CARDIAC LEAD</i>	<i>"IN A MONOPOLAR CONFIGURATION — WITH SPIRAL ELGILOY WIRE"</i>		

Figure 4

NUCLEAR ENERGY SOURCES

RADIOISOTOPE THERMOELECTRIC GENERATOR SYSTEM SCHEMATIC

SCHEMATIC OF SYSTEM HEAT FLOW

NUCLEAR BATTERY CHARACTERISTICS

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Figure 7

CARDIAC PACEMAKER CIRCUIT SCHEMATIC

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 RADIOISOTOPE POWERED CARDIAC PACEMAKER
 GM / KC 9/18/68 EC 393

Figure 8

NUCLEAR POWERED CARDIAC PACEMAKER FUNCTIONAL BLOCK DIAGRAM

Figure 9

RPCP PROTOTYPE FUEL CAPSULE O.D. VS I.D.

FOR 50, 100 AND 2000 YEARS HELIUM BUILD-UP
TEMPERATURE = 1900°F

HELIUM PRESSURE BUILD-UP VS TIME

Table 1

RADIOISOTOPE POWERED CARDIAC PACEMAKER

STUDY NOMENCLATURE

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