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RADIOISOTOPE POWERED CARDIAC PACEMAKER PROGRAM. PHASE II

Mid-Term Report, February 1, 1970—October 31, 1972

1972

ARCO Nuclear Company
Leechburg, Pennsylvania

MASTER

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PHASE II MID-TERM REPORT

for

Radioisotope Powered
Cardiac Pacemaker Program

February 1, 1970 - October 31, 1972

Prepared for

UNITED STATES ATOMIC ENERGY COMMISSION
Under Contract AT(11-1)-3057

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INTRODUCTION

The Radioisotope Powered Cardiac Pacemaker Program, which is funded by the United States Atomic Energy Commission, is directed toward the development of a compact self-contained, implantable device capable of providing a suitable electrical cardiac stimulation reliably for a period of eleven years. Of this eleven years, one year has been designated as a nominal shelf life and ten years as the normal operating life after implantation. As part of this program, nuclear battery technology is being developed for this and other medical applications.

Also as part of this program, quality assurance, safety, and reliability standards are to be established at such a level as to allow implantable nuclear devices of this type to be used by the general public. In order to demonstrate that such a safe device of high quality can be produced at a reasonable cost, reduced cost production techniques have been developed and a group of approximately 120 nuclear pacers are being fabricated on a pilot production basis using the reduced cost techniques. Approximately 30 of these pilot production units have been implanted in dogs at the National Heart and Lung Institute and are currently under evaluation. In addition, approximately 52 of the pilot production units are being reserved for human implantation. The human implantations will be initiated after satisfactory animal test results, the accumulation of sufficient statistical data that proves the nuclear system compares favorably with existing commercial experience with conventional systems, and of course, the combined concurrence of the AEC, National Heart and Lung Institute, and ARCO Nuclear Company. The remainder of the pilot production systems are to be subjected to various testing programs.

This program was divided into two phases: Phase I, June 1, 1966 to February 28, 1970, was conducted under Contract AT(30-1)-3731, whereas Phase II is being conducted under Contract AT(11-1)-3057. Phase II was initiated on February 1, 1970. The Phase I Program encompassed the following:

- (1) System Design
- (2) Component Development (excluding pacer electronics and cardiac lead)
- (3) Fabrication of an Electrically Heated Mock-Up System
- (4) Fabrication of Two Series of Plutonium-238 Fueled Experimental Models
- (5) Fabrication of a Series of Plutonium-238 Fueled Prototype Models
- (6) Performance of Appropriate Component and System Tests

- (7) Performance of Preliminary Safety Analysis and Tests
- (8) Conduct of Appropriate Reliability Calculations and Reliability Test Planning for Phase II
- (9) Conduct of Appropriate Quality Assurance and Quality Control Programs
- (10) Provide Experimental Model and Prototype Systems to the National Heart and Lung Institute for Animal Tests

The chronological development and evaluation of the various Phase I systems culminated in the fabrication of six prototype pacer systems of which five were implanted in dogs at the National Heart Institute in late 1969 and early 1970. Three earlier experimental model pacers had been implanted in dogs at NHI in mid 1969. These preliminary animal systems were implanted successfully and the performance characteristics of the Phase I prototype models met the basic design objectives. With this knowledge, in combination with a firm technology base, the Phase II effort was planned for the performance of the following major activities:

- (1) Examination of Reduced-Cost Production Techniques
- (2) Production of Reduced-Cost Fueled Pacers on a Pilot Production Basis
- (3) Further Animal Tests at NHI
- (4) Conduct of System Performance and Capability Tests
- (5) Accumulation of Reliability Test Data
- (6) Procurement of a User General License
- (7) Conduct of Further Safety Tests and Associated Analysis
- (8) Initiation of Human Implants
- (9) Continuation of Reliability Testing to Determine True System Reliability
- (10) Post Implantation Follow
- (11) FDA Requirements Test Program Execution
- (12) Analysis of Other Applications for the Technology Developed
- (13) Complete Manufacturing Documentation
- (14) Perform a Transition to General Use for the System

System Function

The purpose of the Radioisotope Powered Cardiac Pacemaker Program is to develop a highly reliable, long life, implantable nuclear powered cardiac pacemaker system with a suitable electronic circuit and cardiac lead. The pacemaker provides 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 (1-1/2 to 2 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 year (or more) operating life in a size, weight, and general configuration suitable for implantation.

System Description

The Phase II system follows in general experience the design of the Phase I prototype units which have a demonstrated capability relative to the system objectives. Note in Figure 1 that the complete system consists of three basic sub-assemblies: (1) a nuclear battery which is hermetically sealed with a corrosion resistant titanium outer case, (2) an electronics assembly which is sealed within a separate hermetic titanium enclosure, and (3) a 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 heat source is triply encapsulated within successive right circular cylinders of tantalum-10 w/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 are metallic thermocouple wires, is wrapped around the cylindrical heat source. 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 hot and cold metallic straps which form the inner and outer perimeter of the thermopile, thus producing a convenient thermoelectric module.

The six thermoelectric tape sub-assemblies are connected electrically in two subsets of three tapes each resulting in a multi-redundant thermopile since as many as four out of six tapes can fail and the system will continue to operate within specifications over the entire design life of the system.

*Electrical grade borosilicate fiberglass produced by Owens-Corning.

RADIOISOTOPE POWERED CARDIAC PACEMAKER NU-5

Figure 1

The completed thermopile, including its central heat source and associated 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 assessibility to the complete nuclear battery for final visual and electrical inspection purposes, prior to assembly within the nuclear battery outer case. This outer case is hermetically sealed by tungsten insert gas (TIG) welding to the outer case lid, which contains a ceramic-to-metal seal through which the electrical output of the nuclear battery is conducted. Final sealing of the nuclear battery is performed by electron beam welding of a closure plug in the battery lid after completion of offgassing.

The direct current output from the nuclear battery is converted to rectangular stimulation pulses by a reliable electronic circuit, which is contained within a separate, hermetically sealed titanium case. The electronics case, the nuclear battery case, and case lid are joined in a single TIG welding operation. The electronics outer case serves as an electrical conductor between the electronics circuit and the battery case, which in turn serves as one of the system electrodes. The second electrode in this, a monopolar system, is the cardiac lead. This cardiac lead and its termination is a commercially produced item whose electrical conductor is constructed of spiral Elgiloy* wire. The lead shown in Figure 1 is the myocardial type; however, the endocardial type can easily be substituted.

The metallic end of the cardiac lead is inserted into a metallic block which is premolded into the epoxy material surrounding the electronic case and locked with a captive set screw.

Technical Objectives:

The technical objectives are as follows:

- (a) Size: Approximately 6 x 5 x 3.2 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. The weight may be exceeded, if the specific gravity is maintained at or below 1.4.

*Elgiloy is a trade name of the Elgin Watch Company.

- (c) Design Life: 10 year minimum operating life plus 1 year shelf life.
- (d) Reliability: 95% reliability at 90% confidence level.
- (e) External Radiation: Maximum allowable dose rate is 0.3 mrad/hr at 5 cm from the surface of the unit and 5 mrad/hr at the surface. Of this, the neutron dose rate shall not exceed 0.1 mrad/hr at 5 cm from the surface and 1.5 mrad/hr at the surface.
- (f) Sterilization: The system is to be capable of sterilization under hospital conditions.
- (g) System Electrical Output: A pulse of the following characteristics which shall apply to a reference fixed rate circuit design. Such other characteristics as may be known to be effective for cardiac stimulation may be substituted. This includes variations in current, shape, and rate so as to provide the broadest possible latitude in the use of pacer circuit types such as, but not restricted to, fixed rate, demand, standby, and synchronous of various types.
 - (1) Current: 4.0 milliamperes minimum, 8.0 milliamperes maximum average pulse amplitude into a load consisting of a resistor which may vary between 300 and 700 ohms paralleled by a series resistor-capacitor branch of 5.0 microfarad and 1000 ohms.
 - (2) Shape: 1.5 to 2.0 millisecond 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: 70 ± 5 pulses per minute.
 - (4) Power Output: Approximately 160 microwatt (e). (EOL) at the feedthrough from the nuclear battery.
- (h) Component Characteristics:
 - (1) Fuel: Shall be Pu-238 metal or oxide as specified in the "Cardiac Pacemaker Prototype Heat Source Specification", Mound Lab Drawing No. 1-13491. As an objective, the design should be capable of being adapted to alternative 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 produce electrical pulses of a type proved by experience to be effective in cardiac stimulation and shall be procured on the basis of approved specifications and procurement documents; provided, however, Contractor shall receive and analyze proposals, make its recommendations to the Commission, and obtain approval of the Contracting Officer prior to awarding a subcontract for said items.
- (5) Cathode Electrode: In a configuration that is suitable for the electronics circuit to which it is assembled, and of a material with a known stimulation threshold characteristic. Units intended for animal tests will use epicardial leads whereas the clinical models will use pervenous leads.
- (i) Environmental Conditions - Operation: The system shall be capable of operation during and after exposure to the following conditions.
 - (1) In-vivo in humans at ambient temperatures of 97°F-106°F and in animals. The surface of the pacemaker shall not exceed ambient by more than 3°F.
 - (2) In-vitro in Ringer's solution at 106°F and in 100% humidity air, under pressure from one-half to four atmospheres.
 - (3) Sterilization under hospital conditions.
 - (4) Shock: After 3 foot drop on a graphite surface with the system encased in 2 mm. Silastic for test purposes.
 - (5) Shock, Vibration Transportation, and Storage: Contractor to recommend design specifications for Commission approval.
 - (6) Safety: The fuel capsule shall provide for absolute containment of the radioisotope fuel under normal conditions and credible accident conditions. The fuel shipping cask and system shipping container may be considered for containment purposes.

- (j) Reliability and Quality Assurance: The reliability and quality of the system shall be assured by programs approved by the Contracting Officer established and conducted generally in accordance with RDT F 2-2T, dated June 1969. Detailed plans for system qualification testing shall be prepared as required by the Contracting Officer.

This shall include but not be limited to the following:

- (i) Safety qualification testing
- (ii) In-vitro qualification testing
- (iii) In-vivo in animal qualification testing
- (iv) Clinical testing
- (v) Acceptance test for all deliverable items

- (k) Packaging and Packing: Preservation, packaging, and packing of the system shall provide protection against the hazards encountered during handling, transportation, and storage from the time of sterilization to the time of implantation. The package shall include provisions for handling and storage and for assuring sterilization as long as package integrity is not violated. The package shall be packed in a shipping container constructed so as to assure acceptance for transportation by common or other carriers. Packing and exterior shipping containers shall provide the package protection against handling, shortage, and transportation hazards.

Table 1

SYSTEM PARAMETER SUMMARY

<u>Characteristic Pacemaker System</u>	<u>Design Objectives</u>
Design Life (years)	11
Weight (grams)	~100
Specific Gravity	~1.4
Height (cm)	5.0
Width (cm)	3.2
Length (cm)	6.0
Stimulation Pulse	
Form	Rectangular*
Current Amplitude (Milliamps)	4-8*
Animal Rate (pulses/min)	70+5
Human Rate (pulses/min)	70+5*
Pulse Width (milliseconds)	1.5-2.0*
Rise Time (milliseconds)	<0.1*
Dose Rate (millirad/hr) (bol)	5.0
 <u>Nuclear Battery</u>	
Isotope	Pu-238
Heat Source Size (watts)	.226 ± .012
Electrical Power Output (μ watts, BOL) (Nom. Fuel)	230
Thermopile	Wire T/E Couples
Voltage Output (Open Circuit)	~2.2
Reliability	95% - 90% Confidence
Fuel Form	Metal or Oxide

*Reference Design Only.

I. TASK 1.0 - PROGRAM MANAGEMENT, CONTROL AND PLANNING

Phase II was initiated on February 1, 1970, however, eight of the Phase I animal implanted units failed early in Phase II. Three of the failures were the result of a defect in a battery thermocouple, one from a failure of both the battery and the electronics, and four from failures of the pacemaker electronics. Including bench tested units, a total of 16 electronic circuits have failed. Of these 16 electronics failures, the etiology is uncertain in 4; it is attributed to a Zener diode failure in one, and it is the result of transistor failures, primarily the output transistor in 11. These transistors, which have not been used in commercial pacemakers have been discontinued by the manufacturer.

As a result of these difficulties, an extensive and thorough examination and analysis was initiated that naturally delayed the major onset of the Phase II pilot production program until the root causes of these problems could be identified and corrected.

A. Electronics Problems

The Phase I electronic circuit (Figure I-1) was essentially a commercial fixed rate design containing five semi-conductors (three transistors and two Zener diodes). Basically, the circuit consisted of two transistors connected in a complementary pair as a free-running multivibrator that controlled a single transistor output stage. A Zener diode was connected into the rate determining section of the multivibrator to produce a pulse rate that was sensitive to supply voltage. The other Zener diode was connected across the circuit output to protect against high voltage signals which may be introduced by external defibrillation or other high voltage shock procedures applied to the patient.

During Phase I, a total of 30 electronic circuits of this general type were purchased from a commercial pacer manufacturer. Sixteen circuits have failed as detailed in Figure I-2. All of the known failure modes involved semi-conductor components. Two of the unknown failure modes involved a circuit that stopped on more than one occasion, and which had to be re-started. No abnormal characteristics were ever observed before, during, or after the stoppages. In general, these circuits were not self-starting when initially connected to the nuclear battery and had to be restarted externally should they stop while in service.

PHASE I-RPCP CIRCUIT

Figure I-1

CIRCUIT FAILURE ANALYSIS

<u>FAILED COMPONENT</u>	<u>FAILURE MODE</u>	<u>NO. OF CIRCUITS</u>
Q ₃ TRANSISTOR	OPEN EMITTER	7
Q ₃ TRANSISTOR	COLLECTOR-BASE LEAK	2
12 Q ₂ TRANSISTOR	OPEN COLLECTOR	1
VR ₁ (ZENER DIODE)	PARTIAL SHORT	1
Q ₂ TRANSISTOR	POSTULATED COLLECTOR-BASE LEAK	1
UNCERTAIN	LOSS OF OUTPUT SIGNAL	<u>4</u>
	TOTAL	16

Figure I-2

As a result of these difficulties, an electronics consultant was employed to study these problems. His conclusions are summarized in Figure I-3. ARCO Nuclear concurred in these conclusions, but not necessarily in his conclusion that hybrid circuitry should be pursued to the exclusion of discrete component circuitry.

From both ARCO Nuclear's and the consultant's examination and analysis, it was clear that future electronic circuit fabrication must include hi-rel components and should be designed so that the circuit is self-starting and has a rate sensitivity characteristic that is achieved in the most reliable fashion possible. It was also concluded that a revised specification that is more detailed, and which provides for close vendor Q.C. surveillance was also required.

It was also decided that future circuits should be fabricated in a pre-production and a production lot and that appropriate shock, vibration, thermal cycling, life testing and tests to destruction should be performed on the pre-production circuits and on a small number of circuits sampled from the production lot. The specific tests would be similar in intensity and number to the tests to which the nuclear battery would be tested, and would reflect the new information available as a result of the various animal tests, drop tests, shock tests, etc. that were to be established.

The selection of an appropriate quantity of circuits was determined in consideration of these factors as well as the following mathematical and judgment considerations.

The program reliability objective has been, and still is, a system reliability of 95% at a 90% confidence level for 11 years. Since this implies a large amount of testing to prove mathematically, the judgment was made that the decision to implant RPCPs could be initiated when the equivalent of approximately a 90% reliability at a 90% confidence level for a 2-year operating life is proven. This leads to some difficulties of implementation in that electronic circuits of the types contemplated are generally less expensive than the nuclear batteries and thus there is an

CONSULTANT'S CONCLUSIONS

- (1) COMPONENT FAILURES ARE THE PRIMARY CAUSE OF CIRCUIT STOPPAGE
- (2) CIRCUIT IS RESISTANT TO ELECTRICAL INTERFERENCE
- (3) COMMERCIAL PACER QUALITY IS NOT CONSISTENT WITH NUCLEAR RELIABILITY OBJECTIVE
- (4) BASIC CIRCUIT SCHEMATIC IS ACCEPTABLE
- (5) CIRCUIT DESIGN CAN BE IMPROVED
SELF-STARTING
RATE SENSITIVITY

Figure I-3

CONSULTANT'S CONCLUSIONS

- (6) OTHER CIRCUITS MAY BE SUBSTITUTED
- (7) DISCRETE COMPONENT CIRCUIT HAS CAPABILITY OF ACHIEVING DESIRED RELIABILITY
- (8) HYBRID CIRCUITS HAVE GREATER RELIABILITY POTENTIAL THAN DISCRETE
- (9) SUBSTANTIALLY TIGHTER SPECIFICATION AND ON-SITE INSPECTION IS REQUIRED

opportunity to obtain an accumulation of test data more rapidly with the circuits. This has the limitation, however, that most of this data will be accumulated on bench tests, so it was recommended that the (90%-90%-2 year) evaluation be applied separately to the nuclear battery and the electronics. This is significantly better than existing commercial experience, since this corresponds to a total system reliability of 81% for a 2-year life. Of course, human implantation must also be based on satisfactory animal test results and the combined judgment of the AEC, National Heart and Lung Institute, and ARCO Nuclear Company.

In order to prove a 90% reliability for the electronic circuit at 90% confidence for a 2-year operating life in a reasonable time period, it was concluded that 150 circuits should be placed on life test. With this number of circuits, as many as four failures can be experienced in one calendar year while still proving the 90% reliability at 90% confidence for a 2-year operating life. If no circuit failures are experienced, a reliability of about 97% at a 90% confidence level for a 2-year operating life will be proven in one calendar year. This is illustrated in Figure I-4.

With 150 electronic circuits and 75 nuclear batteries on test, the upper limit of proven system reliability in one calendar year of testing is 91% (97% for the electronic circuit and 94% for nuclear battery), based on a 2-year operating life, 90% confidence level and no failures. For the same conditions, a maximum of four electronic circuit failures and four nuclear battery failures, the lower limit of proven system reliability in one calendar year of testing is 73% (90% for the electronic circuit and 81% for the nuclear battery).

It was finally concluded that a total of 250 electronic circuits should be purchased for Phase II. It should also be pointed out that reliability testing will continue beyond initial human implantation in order to establish the system reliability and that this recommendation did not imply any reduction in the program objective of 95% for 11-year operation at 90% confidence.

Circuit manufacturing alternatives of discrete, monolithic integrated and hybrid were considered. It was concluded that only discrete circuitry should be fabricated since this technique has sufficient reliability potential and since it represented the greatest body of electronic experience in the general field of pacing.

COMPARATIVE RELIABILITY

(90% CONFIDENCE)

Figure I-4

B. Nuclear Battery Failures

Before considering the system as a whole, an examination of the first three nuclear battery failures was necessary. Each of the failures occurred in a thermopile wire at the hot tab and was, in each case, a wire at the edge of the particular thermoelectric tape that was involved. Two of the failures were ductile tension failures with necking, indicating that they were broken by mechanical stress. One of the broken wires was apparently broken during the original tape brazing operation as evidenced by the presence of braze alloy on the fracture face. The condition of the failed units, as determined by x-ray and by visual examination indicated that the fuel capsules, getter baskets and other internal parts were severely stressed, beyond their capability to resist, while implanted in a dog at HN&LI. The details of these analyses are contained in various failure reports.⁽²⁾ The general conditions observed in the damaged units are summarized in Figure I-5.

The recommended mechanical revisions in the nuclear battery are summarized as follows:

- (1) Containment of the getter baskets within extensions of the hot strap by welding hot strap tabs to the getter basket.
- (2) A mechanically compact, thermally efficient end shield assembly of alternate layers of flat titanium shields and woven glass tape.
- (3) An improved support bracket with a cross brace.

An experimental indication of the success of these revisions is provided by the results of the shock and vibration tests conducted on thermopile XP-12, which incorporated all of the proposed changes except (3) above. After testing, the getter basket showed no damage and remained well attached to the hot strap. The tabs could not be pulled from the getter basket and had to be cut to remove the fuel. The end shield assembly did not generally show any damage other than on the foils and insulation tape next to the getter basket. Because the end support had buckled, axial movement of the hot strap occurred allowing the end shield near the hot strap to shift. The new support, which has twice the support capability of the prototype design, subsequently demonstrated by test that it resists this motion.

C. Shock and Vibration Testing

It was apparent that the nuclear batteries were being subjected to a more severe shock and/or vibration environment than was anticipated and far more severe than expected in human patients. To determine how these shocks may

(2) Analysis of Prototype RPCP P-6, dated July 2, 1970.
Failure Analysis, Unit E-14, dated September 11, 1970.

NUCLEAR BATTERY

OBSERVED CONDITIONS

END SHIELDS SEVERELY COMPRESSED

GETTER BASKETS SUBJECT TO DISPLACEMENT

HEAT SOURCE DISPLACED LONGITUDINALLY

ALL BROKEN WIRES WERE AT THERMOCOUPLE TAPE EDGE

TWO BROKEN T/C WIRES EXHIBIT CLASSIC TENSION TYPE FAILURE

ONE BROKEN T/C WIRE WAS PARTED DURING BRAZING OPERATION

Figure I-5

have occurred, movies of the daily activities of the dogs were made at NH&LI. These indicated that shocks could readily occur as a result of the dogs slipping on wet floors, bumping of pacers against their feedbins and the sides of the cages. To evaluate these shocks, a dog was tested with two types of accelerometers. The most significant testing was performed with mechanical accelerometers that provided single level indications. With the accelerometer set at 25-30 "G", hard bumps against a man's leg and rather ordinary bumps against a dog house triggered the device. With the device set at 50 "G", two events occurred in about three hours. The basic situation is that pacers implanted just under the skin can sustain substantially more severe shocks than the whole body accelerations that were previously used (20 G) as a basis for testing. It also appeared that the number of such shocks was much greater than anticipated and that this needed to be taken into consideration as well. As a result, an extensive re-evaluation of this and the potential human environment was performed. As a result of this analysis and supporting experimental measurements, various recommendations and refinements for a shock and vibration standard resulted.

D. Nuclear Battery Connection Considerations

Since the electronics circuitry was being re-evaluated, it was appropriate to re-examine the battery/electronics relationship was well, but in a manner that took full advantage of the component technology developed to date. Since the reliability of the nuclear battery is of prime importance, an examination of various electrical re-combinations of the six thermocouple tapes in each nuclear battery was evaluated.

A total of four Phase I nuclear battery failures were experienced. The failure mode in all four cases was an open thermocouple wire and all four failures occurred in dogs. In the Phase I system each thermoelectric tape contains 88 thermocouples in series and six such tapes are connected in series. Therefore, if any one thermocouple wire out of a total of 1056 wires opened, the system would fail.

In order to improve the nuclear battery reliability, various series-parallel combinations for the six thermoelectric tapes were analyzed. The results are shown in Figure I-6. The lower limit of reliability corresponds to the data accumulated for both in-vivo and in-vitro tests of Phase I units and the upper limit corresponds to the published upper limit of welded wire joints. The actual reliability should be between these two extremes.

NUCLEAR BATTERY CONNECTION COMBINATIONS

(11 YEAR LIFE)

<i>ALT.</i>	<i>GENERAL ARRANGEMENT</i>	<i>DESCRIPTION</i>	<i>END OF LIFE NOMINAL V_{OC}</i>	<i>R_L^* LOWER LIMIT</i>	<i>R_U UPPER LIMIT</i>	<i>NO. OF TAPES REQUIRED (MINIMUM)</i>
A.		6 TAPES IN SERIES	6.0	12.23	98.9843	6
B.		3 SUBSETS OF 2 TAPES IN PARALLEL	3.0	76.02	99.9991	3, 1 PER SET
C.		2 SUBSETS OF 3 TAPES IN PARALLEL	2.0	94.91	99.9999	2, 1 PER SET
D.		6 TAPES IN PARALLEL	1.0	98.98	99.9999	2

* AS OF 12-31-71

Figure I-6

Battery A is the present system which is made up of six tapes in series where any single tape failure results in system failure. Battery B is made up of three subsets of tapes in series where each subset consists of two tapes in parallel. In Battery B a total of three tapes can fail but only one tape in each subset. Battery C contains two subsets of tapes in series and each subset contains three parallel tapes. In Battery C a total of four tapes can fail but only two tapes in each subset. Battery D contains all six tapes in parallel and any four tapes can fail.

The above description is based on the tape failure mode being open, which is the only failure mode experienced in implanted systems, and on the fact that a minimum of two tapes are required to supply enough power to successfully operate the electronics circuit. In addition, for purposes of comparison, it was assumed that the thermal performance for all four batteries would be the same as Phase I performance.

Based on the above assumptions it can be seen from Figure I-6 that batteries A, B, C, and D are arranged in an increasing level of reliability and that the greatest reliability increment results in going from the no redundancy case (Battery A) to the minimum redundancy case (Battery B). It is also interesting to note that for the upper limit all four batteries approach each other in reliability. It should also be noted that the already proven (Phase I) reliability of both batteries C and D is close to the system reliability objective of 95% based on the above assumptions and on lumping both in-vivo and in-vitro test results. Since this latter assumption is questionable, this reliability comparison has been calculated as a basis for comparison only and may be viewed as a means of estimating the relative probability of success.

E. Electronic Circuit Alternatives

Each of the four nuclear battery alternatives requires a compatible electronic circuit in order to meet the pacing specifications. For each battery/circuit combination, the system should meet the output pulse specifications both at beginning of life with no tape failures and at end of life with the maximum number of tape failures. There are three types of circuits available (designated as A, B, and C) that will operate as desired with the four battery alternatives. Circuit A operates with battery A, circuit B operates with either battery B or battery C, and circuit C operates with battery D. All three circuits avoid the various undesirable aspects of the electronic circuits previously used in Phase I and utilized NASA level components to achieve the

ultimate in reliability. Each of the circuits was breadboarded to function with an input voltage that corresponded to approximately 1.0 volt open circuit per thermocouple tape.

A natural desire was to choose the most reliable system which presumably means battery D/circuit C; however, circuit C had disqualifying disadvantages. These include a requirement for a wire wound transformer whose size violates the system size objectives. It also had the disadvantage that it was not suitable for modification to a synchronous or demand type circuit and thus had a limited future applicability. Thus it was concluded that the next most reliable system should be fabricated, i.e., battery "C"/electronics "B".

F. Initial Animal Implants of NU-4 Pilot Production Units

With the above experience, pilot production was set up and a total of about 47 systems designated as model NU-4 were fabricated. Of these 47, a total of 27 were implanted in dogs at the National Heart and Lung Institute. Of these 27 units, 5 suffered battery failures after an average implant time of only 43 days. The 5 failures of the NU-4 model were all found to be identical multiple open tapes caused by high torsional accelerations induced by the animals running in their cages. By an extensive test program, it was found that by simply adding 50% more electrical insulation tape to the thermopile and adding additional restraints around the outer diameter of the wrapped thermopile, the system (NU-5) was made far superior to the previous systems for both high shocks and torsional accelerations. It was also found that a modified paint can shaker accurately simulates the torsional acceleration induced by the animals but greatly accelerated in time. On this paint can shaker, the NU-4 model batteries lasted for only fractions of an hour and the failure mode was identical to that experienced in animals. However, the NU-5 models lasted for about 25 to 30 hours on the same tests. (In no case have the electronic circuits been affected by such testing.) As a result, the first step in the qualification testing is now 5 hours on the paint can shaker followed by the previously established qualification testing. Every eighth battery is subjected to this testing as illustrated in Table I-1.

All of the NU-4 systems have been removed from animals and all 27 units have been electrically tested for tape conditions. Table I-2 summarizes the results of the 27 units tested.

Table I-1
Sequence of System Environmental Testing

<u>Test</u>	<u>Test Conditions</u>
50 G Rotational Shock	432,000 Cycles
4 ATM Pressure	Pressurize to 4 ATM - Hold 5 Minutes
4G Vibration	Maintain 4G Amplitude Scan from 20-500-20 HZ in X, Y, and Z Axis
Thermal Cycling	2 Cycles from -40°F to +140°F - Hold 2 hrs. at Temperature
5' Freefall (4500 G)	One Drop from 5' to Bare Concrete
50 G Shock	3000 Cycles at 50 G - 1000 Cycles per Axis
855 G Shock	12 Cycles at 855 G - 4 Cycles per Axis
Life Test	

Table I-2

<u># of Open Tapes</u>	<u># of Units</u>	<u>Average Implant Time (days)</u>	<u>Time Range (days)</u>
0	10	108	35 - 171
1	3	143.5	140 - 164
2	5	109.4	42 - 164
3	2	157	157
4	2	160.5	157 - 164
5 (failure)	5	42.6	35 - 52

It should be noted that five units failed early in the implant group with an average of 42.6 days (35 - 52 days) to failure. When these units were removed, five additional units were removed for evaluation. Of these five units, three were normal and two had two open tapes. The remaining 17 units continued to operate properly until they were replaced with the new NU-5 models. These 17 units operated for an average time of 151.4 days (136 - 171 days) with no failures. After removal, all 17 units were electrically tested, and it was found that 7 were normal, three had one open tape, three had two open tapes, two had three open tapes, and two had four open tapes. It should be noted that there is no indication of when these tapes may have failed. For example, all tape failures could have occurred early or the failures could have been random. Table I-3 details each of the 27 implant units.

With the above experience in hand, pilot production was resumed using the NU-5 model. A total of 30 NU-5 systems have been implanted in animals and about 50 NU-5 systems will be reserved for human implantation. As of the end of October 1972 these 30 implanted units have operated without failure and statistically proven a reliability of 50 % at a 90% confidence level for a 2 year mission time. In addition the 250 Phase II electronic circuits have operated without failure and statistically proven a reliability of 98 % at a 90% confidence level for a 2 year mission time.

G. Testing

A written detailed test plan has been prepared and implemented for Phase II as well as a formal Quality Assurance Manual. These efforts are discussed under Task 2.0. Efforts continued using special telemetry equipment to characterize the shock and vibration environment in both animals and man to which the implanted pacemaker is subjected as discussed under Task 4.0. Also efforts to fully characterize the paint can shaker continued. A great deal of safety testing and analysis work has been conducted as discussed under Task 5.0. Of particular interest is the cremation testing of 4 fueled RPCP systems. Two fueled systems were subjected to temperatures of 2100°F for 2 hours and two other fueled systems were subjected to temperatures of 2340°F for 2 hours. In all four tests the nuclear fuel was safely contained by the fuel capsule. The importance of testing completed systems as opposed to just bare fuel capsules was demonstrated as discussed under Task 5.0. The following table is a summary of the system safety tests requirements.

Table I-3

<u>Dog Implant</u>	<u>Date of Implant</u>	<u>Date of Removal</u>	<u>Time of Implant</u>	<u>Comments</u>
8	1-31-72	3-15-72	44 days	2 tapes
*9	1-31-72	3-6-72	*35 days	*failed battery (5 tapes)
10	2-7-72	3-20-72	42 days	2 tapes
*11	2-7-72	3-20-72	*42 days	*failed battery (5 tapes)
13	2-7-72	3-20-72	42 days	OK but removed
14	2-14-72	3-20-72	35 days	OK but removed
17	2-14-72	3-15-72	40 days	OK but removed
*18	2-22-72	4-10-72	*45 days	*failed (5 tapes)
*19	2-22-72	3-30-72	*39 days	*failed battery (5 tapes)
*20	2-22-72	3-14-72	*52 days	*failed battery (5 tapes)
21	2-28-72	7-17-72	140 days	1 tape open
22	2-28-72	7-24-72	147 days	1 tape open
23	2-28-72	7-17-72	140 days	1 in each bank
24	2-22-72	7-10-72	139 days	OK
25	2-28-72	7-17-72	140 days	OK
26	3-6-72	7-10-72	157 days	1 in each bank
27	3-6-72	7-10-72	157 days	2 in each bank
28	3-6-72	7-17-72	164 days	2 in each bank
29	3-13-72	7-24-72	164 days	1 in each bank
30	3-13-72	7-17-72	157 days	2 in one, 1 in the other
31	3-13-72	7-31-72	171 days	OK
33	3-13-72	7-17-72	157 days	2 in one, 1 in the other
34	3-20-72	7-31-72	164 days	1 tape open
38	3-20-72	7-24-72	154 days	OK
39	3-27-72	7-10-72	136 days	OK
40	3-27-72	7-10-72	136 days	OK
41	3-27-72	7-24-72	150 days	OK

*Average to fail = 42.6 days.

Average of units 21 - 41 = 151.4 days

Table I-4

Safety Tests

Industrial Fire	1900°F - 2.6 hrs	Bullet	Handgun - Shotgun - Rifle
Cremation	2300°F - 2 hrs	Internal Pressure	2300°F - 2 hrs after 2000 years of helium generation
Impact	50 meters/sec		
Crush	10,000 pounds	External Pressure	16,000 psi

All systems tested to the above safety requirements have demonstrated their capability to withstand these conditions as well as even more severe conditions.

II. TASK 2.0 - RELIABILITY AND QUALITY ASSURANCE

A. Reliability Data

At the end of October, the NU-4 type production nuclear batteries on life test have accumulated a total of 23.66 unit years of operation with five pacemaker failures at NIH, namely, units NU4-9, NU4-11, NU4-18, NU4-19, and NU4-20.

The first two NU-4 type production RPCP systems were implanted in dogs at NHLI during the latter part of January, 1972. There were 13 NU-4 production RPCP units implanted in February and an additional 12 NU-4 production RPCP units were implanted in March bringing the total to 27. During the month of July, 1972, all remaining NU-4 type production systems were removed from dogs at NHLI.

The Phase II electronic circuits consist of three groups: (1) a pre-production group of ten circuits to establish design criterion, (2) a pilot production group of 39 circuits, and (3) a production group of 200 circuits. At the end of October, the preproduction circuits have accumulated 11.72 unit years of operation with no failures, the pilot production circuits have accumulated 42.09 unit years of operation with no failures, and the production circuits have accumulated 168.08 unit years of operation with no failures for a total of 221.89 unit years with no failures. These circuits have reached a proven reliability in excess of 98% for a 2 year mission time at a 90% confidence level.

At the end of October, the NU-5 modified production nuclear batteries have accumulated a total of 14.05 unit years of operation with no failures (73% reliability, 90% confidence level for 2 year mission time).

A total of 16 NU-5 type production RPCP systems were implanted in dogs at NHLI during July. An additional 14 NU-5 type production RPCP systems were delivered to NIH in August bringing the total to 30 units. At the end of October, the 30 units at NIH have accumulated 6.65 unit years of operation in dogs with no failures (50% reliability, 90% confidence, 2 years).

Tables II-1, II-2, II-3, and II-4 summarize the status of the Modified Production Systems, Production Systems, Experimental Models, and Prototype Models, respectively.

B. Animal Implant Statistics

All 30 animal implants are doing well. The projected reliability demonstration of the current animal implant program at the National Heart and Lung Institute as a function of calendar time is shown in Fig. II-1. The

Table II-1
Modified Production Model Life Test Data (NU5-)
(10-31-72)

Unit (NU5-)	Accumulated Hours	B.O.L. DATA			Present Data		UNITS PRODUCED		Special Test	Life Test	Comments
		Battery Output (μw)	With Electronics Output, ma.	BPM	Output*	BPM	Implant Units Implanted	Removed			
1	3686	203.5	6.0	71.5	5.7 ma	73.0				X	
2	3686	215.0	6.5	72.5	6.3 ma	73.0				X	
3	3614	236.7	6.2	72.0			7-10-72				
5	3614	223.9	6.1	71.0			7-10-72				
6	3614	241.7	6.3	71.0			7-10-72				
7	302	225.2			(Disassembled)				X		Qualification test unit
9	3470	242.1	6.4	72.0			7-10-72				
10	1430	238.8	6.4	72.0	(Disassembled)				X		
11	3470	238.5	6.6	72.0			7-17-72				
13	3326	236.7	6.3	72.5			7-17-72				
14	182	259.1			(Disassembled)				X		Qualification test unit
15	3326	224.9	6.4	72.0			7-17-72				
17	3158	230.3			233.9 μw					X	
18	3158	214.3			217.1 μw					X	
20	3158	219.5	6.4	72.5			7-17-72				
21	3086	223.5	6.3	73.5			7-24-72				
22	446	247.6			(Disassembled)				X		Qualification test unit
23	3086	226.4	6.5	72.0			7-24-72				
24	2988	229.8	6.6	72.0			7-24-72				
25	303	212.4			(Disassembled)				X		Void areas
26	2822	245.5	7.0	72.0			7-24-72				
27	2822	235.2			243.6 μw					X	
28	277	238.3			(Disassembled)				X		Qualification test unit
29	2701	233.9	6.4	71.0			7-31-72				
30	2607	250.4	6.8	71.0			7-31-72				
31	2701	243.5			250.6 μw					X	
32	None	(Scrapped due to internal shorting during degassing)									
33	2607	223.3	6.0	70.0			7-31-72				
34	2607	238.6	6.4	71.0			7-31-72				
35	134	250.8			Tested to failure				X		Qualification test unit
36	2462	242.3	6.5	71.0			8-7-72				
37	2462	257.5			264.6 μw					X	

* Peak power is given in microwatts if unit had no electronics. For units with electronics, values are pulse height in milliamperes.

Table II-1 (Cont'd)
Modified Production Model Life Test Data (NU5-)
(10-31-72)

Unit (NU 5-)	Accumulated Hours	B.O.L. DATA			Present Data		UNITS PRODUCED		Special Test	Life Test	Comments
		Battery Output (μ w)	With Electronics		Output*	BPM	Implant Units	Removed			
			Output, ma.	BPM			Implanted				
38	2462	226.7	6.4	71.0			8-7-72				
39	2366	212.2			(Under test)				X		Cold side defect
40	2366	228.9	6.3	71.0			8-14-72				
41	2366	224.8	6.5	72.0			8-7-72				
42	2366	244.9	6.6	72.0			8-7-72				
43	158	218.3			(Disassembled)				X		Qualification test unit
45	2294	236.4	6.6	70.0			8-14-72				
46	2294	228.6	6.4	71.0			8-14-72				
47	2294	220.6	6.3	70.0			8-14-72				
48	2101	225.8	6.5	72.0	6.2 ma	73.0					
49	2101	231.0	6.4	72.0			8-21-72				
50	2101	208.0	5.9	73.0	5.6 ma	72.0					
51	2101	214.2			(Under test)				X		Qualification test unit
52	1917	242.3	6.6	72.0			8-28-72				
53	1917	245.3	6.7	73.0	6.5 ma	72.0					
54	1917	229.3	6.2	73.0			8-28-72				
55	1917	231.1	6.6	73.0			8-28-72				
56	1789	232.9	6.4	73.0			8-28-72				
57	1789	238.6	6.6	73.0			8-28-72				
58	1789	227.7			(Under test)				X		Qualification test unit
60	1189	235.2			240.5 μ w					X	
61	1189	230.8			230.0 μ w					X	
62	1189	214.9			204.8 μ w					X	
63	1189	229.5			219.6 μ w					X	
68	541	179.2			(Tested to failure)				X		Qualification test unit
TOTAL 123,102					TOTALS		30	0			

* Peak power is given in microwatts if unit had no electronics. For units with electronics, values are pulse height in milliamperes.

Table II-2
Production Model Life Test Data (NU-4)
(10-31-72)

Unit (NU4-)	Accumulated Hours	B.O.L. DATA			Present Data		UNITS PRODUCED		Special Test	Life Test	Comments
		Battery Output (μw)	With Electronics Output, ma.	BPM	Output*	BPM	Implant Units Implanted	Removed			
2	8388	271.9	6.8	76.0	7.2 ma	77.0				X	
3	8388	271.2			276.6 μw					X	
4	8388	284.2	7.2	75.5	7.6 ma	76.0				X	
5	8388	279.5	6.8	75.0	7.1 ma	76.0				X	
6	7140	295.7	7.9	76.5	7.8 ma	77.0				X	
7	1766	283.0			(Disassembled)				X		Drop tested to destruction
8	1838	251.2	6.8	74.0	(Disassembled)		1-31-72	3-15-72			2 tapes open
9	1262	212.3	6.0	73.5	(Disassembled)		1-31-72	3-6-72			5 tapes open
10	1692	264.8	7.3	74.5	(Disassembled)		2-7-72	3-20-72			2 tapes open
11	1428	275.1	7.0	75.5	(Disassembled)		2-7-72	3-20-72			5 tapes open
12	1644	258.5	7.2	74.5	(Disassembled)				X		Drop tested to destruction
13	1692	282.9	7.4	74.0	(Disassembled)		2-7-72	3-20-72			No open tapes
14	6760	267.1	7.0	74.0	7.6 ma	73.0	2-14-72	3-20-72			No open tapes
15	1624	269.1	7.6	73.5						X	Internal short
17	6760	293.6	7.6	73.5	7.6 ma	72.0	2-14-72	3-15-72			No open tapes
18	1560	267.8	7.8	74.5	(Disassembled)		2-22-72	4-10-72			
19	1218	262.8	7.4	74.5	(Disassembled)		2-22-72	3-30-72			5 tapes open
20	1818	291.8	7.8	74.5	(Disassembled)		2-22-72	4-24-72			
21	6378	295.4	7.7	75.0	194.1 μw		2-28-72	7-17-72			1 tape open
22	6324	279.1	7.8	74.5	229.4 μw		2-28-72	7-24-72			1 tape open
23	6324	270.7	7.6	74.5	184.8 μw		2-28-72	7-17-72			2 tapes open
24	6324	279.9	7.8	74.5	220.2 μw		2-22-72	7-10-72	Analyzing physical condition		
25	6156	289.5	7.8	75.0	295.1 μw		2-28-72	7-17-72			No open tapes
26	6156	277.5	7.8	74.5	154.8 μw		3-6-72	7-10-72			2 tapes open
27	6156	280.1	7.8	75.0	75.2 μw		3-6-72	7-10-72			4 tapes open
28	6156	299.7	7.8	75.0	41.0 μw		3-6-72	7-17-72	Analyzing physical condition		
29	6036	287.0	7.7	74.5	173.0 μw		3-13-72	7-24-72			2 tapes open
30	6036	264.5	7.4	74.0	86.6 μw		3-13-72	7-17-72			3 tapes open
31	6036	271.7	7.5	74.5	305.3 μw		3-13-72	7-31-72			No open tapes
32	1044	238.0			(Disassembled)				X		Environmental testing
33	5703	247.9	7.0	74.0	80.2 μw		3-13-72	7-17-72			2 tapes open

* Peak power is given in microwatts if unit had no electronics. For units with electronics, values are pulse height in milliamperes.

Table II-2 (Cont'd)
Production Model Life Test Data (NU-4)
(10-31-72)

Unit (NU4-)	Accumulated Hours	B.O.L. DATA			Present Data	UNITS PRODUCED		Special Test	Life Test	Comments
		Battery Output (μw)	With Electronics			Implant	Units Removed			
			Output, ma.	BPM						
34	4959	243.8	7.2	74.0	(Disassembled)	3-20-72	7-31-72			
35	848	258.6	7.0	74.5	(Disassembled)			X		Shock test
37	893	256.6	7.2	73.5	(Disassembled)			X		Paint shaker
38	4767	266.7	7.5	73.5	(Disassembled)	3-20-72	7-24-72			
39	4767	248.0	7.0	74.0	(Disassembled)	3-27-72	7-10-72			
40	4791	239.8	6.9	73.5	(Disassembled)	3-27-72	7-10-72			
41	4695	250.4	6.5	74.0	(Disassembled)	3-27-72	7-24-72			
42	5703	265.5	7.0	74.0	(6.8 ma 75.0)			X		Environmental testing
43	5703	304.0	7.7	74.5	(Tested to Failure)			X		Paint shaker
44	2367	265.3	6.8	74.0	(Disassembled)			X		Environmental testing
45	3589	285.8	7.5	74.0	(Disassembled)			X		Paint shaker
46	5629	267.2	7.4	74.0	7.8 ma 76.0				X	
47	891	280.6	7.4	74.0	(Disassembled)			X		Paint shaker
48	800	279.4	7.4	74.0	(Disassembled)			X		Paint shaker
49	843	278.3	7.6	74.0	(Disassembled)			X		Paint shaker
50	597	283.0	7.4	73.5	(Disassembled)			X		Paint shaker
51	1428	296.3	7.9	74.0	(Disassembled)			X		Paint shaker
52	1452	272.4	7.5	74.0	(Disassembled)			X		Paint shaker
53	2527	297.6			(Disassembled)			X		Thump test
54	328	279.9			(Disassembled)			X		8g-20HZ vibra
55	2527	274.8			(Disassembled)			X		Wrist shaker
56	343	289.1			(Disassembled)			X		Vibration & paint shaker
TOTAL 207,294 HRS.						TOTALS	27	27		

* Peak power is given in microwatts if unit had no electronics. For units with electronics, values are pulse height in milliamperes.

Table II-3

Experimental Model Life Test Data

(10-31-72)

<u>Unit</u>	<u>Hours</u>	<u>Present Data</u>		<u>B.O.L. Data</u>	
		<u>Output*</u>	<u>Pulses/Minute</u>	<u>Pulses/Minute</u>	<u>Output*</u>
E-3 (1) (2)	41,601	73.1 μ W			84.8 μ W
E-4	41,149	2.3 ma	76.0	78.6	2.9 ma
E-5 (8)	39,422	70.7 μ W			79.6 μ W
E-9 (2)	32,841	85.1 μ W			82.3 μ W
E-10 (5)	31,501	70.7 μ W			77.5 μ W
E-12 (4) (3)	32,270	247.1 μ W			230.0 μ W
E-13BB	26,534	7.2 ma	129.0	123.0	8.0 ma
E-14 (4) (6)	11,701				
E-16 (10) (12)	29,001	32.6 μ W			202.4 μ W
E-17 (4)	27,907	225.9 μ W			196.1 μ W
E-18 (9)	29,193	252.5 μ W			247.3 ma
E-20 (7) (11)	21,276				260.5 μ W
TOTAL	364,366				

- (1) Battery Unit.
- (2) Stopped pulsing 4-9-70 and could not be restarted. Electronics removed and load line obtained.
- (3) Had stopped in dog test. Electronics failed - removed 6-30-70.
- (4) Implanted in dog.
- (5) Not pulsing 7-14-70. Disconnected and removed electronics 7-16-70.
- (6) Returned 7-23-70. Not pulsing. Hours shown to 7-23-70. Module and electronics failed.
- (7) Disconnected and removed electronics 7-10-70.
- (8) Disconnected and removed electronics 7-29-71.
- (9) Disconnected and removed electronics 7-27-71.
- (10) Electronics failed 8-31-71.
- (11) Unit used for testing. Hours shown to 5-8-72.
- (12) Unit is presently under observation.

* Peak power is given in microwatts if unit had no electronics on 4-31-71.
For units with electronics, values are pulse height in milliamperes.

Table II-4

Prototype Model Life Test Data

(10-31-72)

<u>Unit</u>	<u>Hours</u>	<u>Present Data</u>		<u>B.O.L. Data</u>	
		<u>Output</u>	<u>Pulses/Minute</u>	<u>Pulses/Minute</u>	<u>Output</u>
P-1 (2) (1)	25,884	5.6	125.0	125.3	5.5 ma
P-2 (12)	19,885			126.9	5.7 ma
P-3 (2) (5)	24,837	5.4	124.0	126.5	5.7 ma
P-4 (2) (6)	6,742				
P-5 (2) (10)	11,437				
P-6 (2) (3)	<u>2,938</u>				
TOTAL	92,723				
XP-10 (4) (7)	1,344				
XP-14 (8)	560				
XP-15 (9)	540				
PD-1 (11)	207.5				261.96 μ w

- (1) Returned from dog implant and has restarted, electronics was opened to get load line.
- (2) Dog implants.
- (3) 5-15-70 unit not running - observed at NHI. Returned 5-26-70 to NUMEC. Hours shown to 5-15-70.
- (4) Sealed 7-22-70 @ 1255.
- (5) Returned from NHI not pulsing 10-15-70. Restarted this date with external battery. Opened electronics case to get load line. Reconnected to electronics.
- (6) Unit returned 8-27-70 not pulsing. Case punctured and opened 8-28-70. Hours shown to 8-28-70.
- (7) Unit failed 9-15-70, while being tested to destruction during drop testing.
- (8) Sealed 10-13-70. Unit shock tested to destruction. Opened 11-5-70.
- (9) Sealed 10-28-70. Opened 11-20-70.
- (10) P-5 failed 3-15-71.
- (11) B. O. L. 9-21-71, 0935 hrs. Unit failed 0100 hours, September 30, 1971 during vibration testing.
- (12) Unit used for testing.

PROJECTED RELIABILITY DEMONSTRATION OF ANIMAL IMPLANT STUDY (MODEL NU-5 RPCP)

SAMPLE SIZE = 30
MISSION TIME = 2 YEARS
CONFIDENCE LEVEL = 90 %

curves of Fig. II-1 show proven reliability for various numbers of assumed failures experienced during the testing. The curves are based only on the present group of 30 implanted units, a 2 year mission time, a 90% confidence level, and a Random Failure Mode. Also shown in Fig. II-1 for comparison is the established reliability level in human patients of presently available commercial battery powered cardiac pacemakers. This comparison is shown even though the extremely active dogs in their confined environment bounce around their animal runs and metal cages vigorously thus causing the implanted nuclear pacemaker to encounter unusually high mechanical accelerations and impacts. The vigorous impacting between the animals and their environment greatly exceeds that which is encountered in human patients, both in intensity and frequency. The 30 dog implants were accomplished between July 10, 1972 and September 12, 1972. It is interesting to note in Fig. II-1 that the commercial pacemaker reliability level is exceeded at the end of October, 1972 for the zero failure case, at the end of December, 1972 for one failure, and at the end of March, 1972 for three failures. This proven reliability does not take advantage of the approximately 6-1/2 years of nuclear pacemaker life testing in the laboratory that has been accumulated with zero failures or the fact that the electronic circuit (about 300 circuits with zero failures) has independently demonstrated a reliability in excess of 97% for a 2 year mission time at a 90% confidence level. Fig. II-1 also does not account for the extremely severe shock and vibration environment imposed by the dogs.

1. Failure Mode

The projected reliability curves of Fig. II-1 were based on the assumption that failures will occur in a random fashion. Fig. II-2 shows an idealized curve of failure rate as a function of time. There are typically three stages of life for devices: (1) the initial Burn-In Period when failure rate increases sharply then steadily decreases, (2) the middle or Random Failure Period where a relatively constant, low failure rate is observed, and (3) the final Wear-Out Period where failure rate steadily increases.

Burn-In failures normally result from defective workmanship, loss of process control, inspection errors, etc. As the name implies, Wear-Out failures result from gradual wearing out and from basic material and design limitations. Because of these differences, failure rates are determined for each separate period. It is felt that Burn-In failures have been eliminated for the RPCP by rigid Quality Control and Quality Assurance procedures, subjecting every eighth unit fabricated on the production line to the following rigid qualification testing and requiring that no failures occur during or after this testing:

Qualification Test Sequence:

TEST	TEST CONDITIONS
50 G Rotational Shock	432,000 Cycles
4 ATM Pressure	Pressurize to 4 ATM - Hold 5 Minutes
4 G Vibration	Maintain 4G Amplitude Scan from 20-500-20 HZ in X, Y, and Z Axis
Thermal Cycling	2 Cycles from -40°F to +140°F - Hold 2 hrs. at Temperature
5' Freefall	One Drop from 5' to Bare Concrete (4500 G)
50 G Shock	3000 Cycles at 50 G - 1000 Cycles per Axis
545 G Shock	96 Cycles at 545 G - 4 Cycles per Axis
Life Test	

and by "burning-in" units by life testing prior to their use.

It has been assumed that the Wear-Out Period for the RPCP will not begin until after the 11 year design. Extensive long-term life testing has been conducted on the RPCP systems over the past 6-1/2 years which tend to support this assumption. The Mock-up unit which is similar to the present design except that it uses an electrical heater instead of fuel and has no tape redundancy, has successfully operated with no significant degradation for about 6 years in the ARCO Nuclear lab. Twelve Experimental Models have been operating for an average of about 4 years (with several units as high as 5 years) with no degradation in performance. The Experimental Models are similar to the present design except that the tapes have no redundancy in the Experimental Models. Six Prototype Models have been operating for an average of about 2 years (with several units as high as 3 years) with no degradation. The Prototype is basically the same as the Experimental Model. This data shows a clear superiority over conventional pacemakers for which wear-out failures begin at about 1-1/2 years on the average. The above discussions and data justify the use of the Random Failure Mode of analysis used to generate the projected reliability curves of Fig. II-1 .

IDEALIZED FAILURE RATE

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Figure II-2

C. Capsule and Plug Inspection

During this time period, inspection procedures were developed by Mound and ARCO Nuclear Quality Control for the fuel capsules and plugs. These procedures allowed both groups to inspect using the same techniques. The following breakdown summarizes the production and shipping of components to Mound:

<u>Type</u>	<u>No. Produced 1970-1972</u>	<u>Performance</u>	
		<u>Acc %</u>	<u>Rej %</u>
Inner Plug	229	88	12
Inner Capsule	220	89	11
Middle Plug*	310	98	2
Middle Capsule	333	90	10
Outer Plug	199	89	11
Outer Capsule	203	92	8

* Additional middle components were necessary due to the low aluminum problem.

D. Purchase Specifications

The following lists of Purchase Specifications have been prepared:

<u>Item</u>	<u>Specification No.</u>
Getter Pellets	APS-67/1
Cupron Special Wire	APS-49/1
Feedthrough Ceramics	APS-14/2
Thermocouple Tape	APS-10/4
Insulation Tape	APS-341A/3
Ceramic Connectors	APS-46/1

RDT specification C19-1T (Cardiac Pacemaker Electronic Circuits, for Use with Radioisotope Power Supplies) was prepared by ARCO Nuclear to purchase high quality electronic circuits for pacemakers. ARCO Nuclear also supplied technical inputs to RDT standards for the manufacturing of Ta-10W and Hastelloy "C".

The technique for finding microcracks using ultrasonics was developed and has been listed as a requirement in an RDT specification for Ta-10W.

E. Ultrasonic Inspection

The ultrasonic inspection equipment for examining fuel capsule materials was purchased from Automation Industries. In addition, a Mark 220 Brush strip chart recorder for use with the equipment was purchased from Gould Corporation. This recorder is utilized in the semi-automatic data acquisition of ultrasonic inspection results on the Ta-10W inner capsule material and provides a permanent record of the defect indications as a function of axial position.

The following equipment components comprise the hardware and accessories used in the ultrasonic inspection of inner capsule material:

- (1) A Semi-Automatic Test Fixture and Immersion Tank. This component consists of a motor speed control unit; a variable speed motor; a drive mechanism which rotates the rod in a spiral fashion as it increments its axial position by 25 mils per rotation; a bridge assembly for holding the search unit and locating it at a 30 mil offset position as well as the prescribed vertical position above the rod; and a stainless steel water immersion tank with a bushing assembly for holding the free end of the rod.
- (2) A 10 MHz Search Unit. This search unit is a lithium sulfate unit, 0.375 inch in diameter.
- (3) A UM-721 - 10N Reflectoscope. This reflectoscope generates and receives the ultrasonic signals and displays the defect indications as well as the water/rod interface and return signals on an oscilloscope.
- (4) A Fast Transigate. This transigate detects and gates the defect indication signal which occurs between the interface and the normal diamond shaped pattern return signal.

The semi-automatic test fixture has been modified extensively from that which had been utilized previously for the Ta-10W inner capsule inspection. These modifications included adding a precision manipulator, precision V-slide and horizontal and vertical V-slides brackets. These changes facilitated more accurate data acquisition and increased the rigidity of the bridge assembly for holding the search unit in a fixed position above the rod.

During a checkout of this equipment, some reassembly and realignment of components were required. The search unit was placed 0.494 inch directly above the rod so as to permit optimum reception of the "ball diamond" return signal.

After the search unit was focused, the 30 mil offset was introduced. Recalibration and tuning were performed using a master defect rod, rod number 1A, from which the initial ultrasonic inspection of the material was performed. Defect 13 in this rod, a 1.3 inch amplitude defect indication at an axial position of 9-3/32 inches, was located. Sensitivity level, sweep, reject, pulse length and pulse tuning adjustments were made on the reflectoscope so as to duplicate the defect indication originally detected. Next, defects 12 thru 8 were located at their precise axial locations.

An evaluation of the ultrasonic technique for the detection of defects in Ta-10W rods for the fabrication of inner fuel capsules has been made. The types of defects which have been detected using this technique are a series of continuous and discontinuous microcracks having a width of 1 to 2 microns. The third dimension of these microcracks, i.e., the axial length of the crack, has not been determined. The minimum size microcrack defect which was selected as a rejection criteria is 2 microns wide and 0.030 inch long.

Ultrasonic inspection of two Ta-10W control standards are periodically performed. Rod 1A, the first rod ultrasonically inspected and from which defect indications were metallographically correlated, is one of these control standards. Four separate defect indications from Rod 1 with an amplitude of 0.80 inch or greater were sectioned. The length of microcrack defects which were shown from this metallographic sectioning ranged from 0.027 inch to 0.056 inch in length. Also, two samples were taken from Rod 1 which had a zero amplitude indication and no microcracks or defects were found in these regions of the rod. Defects 8 through 13 in Rod 1A are used as a control standard for tuning in defect indications and gaging the sensitivity for detecting microcrack defects.

The second control standard is Rod 3 which is an Electric Discharge Machining (EDM) rod. This rod has two holes drilled in it by electric discharge machining with a diameter of 0.004 inch and depths of 0.010 and 0.040 inch. This permits a comparison of ultrasonic results from normal defect indications as given in the Rod 1A standard with the results from material with known size defects of simple geometry.

Both the EDM Rod 3 and the Rod 1A control for ultrasonic inspection provide a direct and indirect method, respectively, for evaluating the

sensitivity levels of the ultrasonic inspection technique. With a micro-crack defect which has a width of 2 microns and a length of 0.030 inch, the effective projected "side on" area is 2.4×10^{-6} square inches. In the EDM standard Rod 3, defect 3-4 has a diameter of 0.004 inch and a depth of 0.010 inch and the effective side on projected area is 40×10^{-6} square inches. Thus, this ultrasonic technique for the inspection of Ta-10W rods has (a) a high sensitivity level, (b) enhanced capabilities for detecting microcrack type defects, and (c) better quality control for insuring the use of defect-free material for the fabrication of inner capsules for fueling.

Further improvements were made on the techniques for the ultrasonic inspection of inner fuel capsule material to insure a 100% inspection. Two traces, one at 0° and another 180° , are taken along each length of Ta-10W rod as it is indexed 0.025" for each complete rotation. Thus, these two traces are superimposed in a helical fashion to provide a 12 1/2 mil separation distance. Metallographic correlation with these double traces of defect indications have demonstrated the desirability of these improved results.

The axial position of specific defect indications can be determined to an accuracy of ± 0.008 ". To allow for possible cumulative errors in a.) aligning the search unit during inspection, b.) reducing ultrasonic data, c.) scribing of rods and d.) machining of rods for plugs and capsules, a region of $\pm 1/32$ " is rejected around each significant defect indication. This provides a maximum assurance of utilizing clean material which passed the ultrasonic acceptance criteria for fabricating fuel capsules and plugs.

Some modifications in fixturing and data acquisition for the ultrasonic inspection system have been implemented. Improved techniques for verifying axial position were developed, true axial position well within 1/64" have been determined from the ultrasonic traces, the ultrasonic data reduction techniques, including the standardization of fabrication sheets and detailed ultrasonics and metallographic sheets, have been improved, and a new method for the marking of the rods prior to capsule fabrication was developed.

Detailed ultrasonic and metallographic sheets had been prepared for selected defect regions of the rods that were used for fabricating inner capsule plugs and inner capsules for fueling. The data assisted in the development of metallographic correlations and the verification of ultrasonic

inspection results. Specific amplitude defect indications and controlled defect-free regions of the rods were chosen for metallographic sectioning. Sample mounts from inner capsule and plug material were prepared and examined. This metallographic sectioning has shown that microcracks are present in the defect indicated regions of the rods and negligible microcrack defects are evident in the controlled or defect-free sections. Thus, the ultrasonic technique for the detection of defects has been further confirmed.

A six foot section of nominal .250 inch diameter Ta-10W rod was received from Wah Chang Albany Corporation in September, 1972, for use in fabricating inner capsules for safety testing. This was the first section of rod produced using a new improved process. The material first underwent a visual inspection for surface defects. The six foot length was then divided into five 10 inch (relatively surface defect free) sections for ultrasonic inspection and seven random sampling sections for metallographic examination.

The five ten inch sections were inspected according to the process developed in early 1970. During this inspection the process was formalized and a procedure has been written (Specification no. 211.002). The preliminary traces showed very little in the way of defect indications. Therefore, an increased sensitivity was used (3.5×10 versus 3.2×10) in the inspection and the corresponding ultrasonic traces showed some small defect areas, but basically it showed the new process material to be much more superior to the early material.

The metallographic analysis was completed on the seven random samples (S1-S7) taken from the six foot rod. The worst field observed in any of the samples examined was in S-1. This consisted of a series of discontinuous zig-zagged inclusions or "bubbles" approximately .030 inches in length. A seam was observed in sample S-2 approximately .0025 inches in depth. Sample numbers S-5, S-6, and S-7 exhibited patches of segregation. Microhardness was taken in these segregated areas as well as in the normal structure. Vickers hardness of the segregated area averaged HV213 versus HV228 in the normal areas. Based on these results, the hypothesis is that the segregated area is slightly depleted in tungsten. Therefore, one would expect that the segregate would have more ductility, higher impact strength, but lower tensile strength than the surrounding matrix. However, this will be analyzed in more detail after completion of the safety testing.

Defect areas were taken from the ultrasonically inspected rods and submitted for metallographic sectioning. These are presently being evaluated and the results will be reported at a later date.

F. Leak Detecting

The quality requirements for leak testing various components and sub-assemblies of the RPCP were reviewed early in the report period. Some modifications were incorporated into the process flow chart for fulfilling the leak test requirements for hermeticity. Further investigations were made on the procedures for performing leak checks on production pacemaker units.

The capabilities and features of various mass spectrometer leak detectors were evaluated. Based on previous experimental results of system performance of an electrically heated experimental model design as a function of degradation of vacuum environment inside the pacemaker, preliminary specifications for the high sensitivity requirements of a leak detector were determined.

A request for quotation was submitted to several vendors for the procurement of a helium leak detector to fulfill the leak test requirements for components, sub-assemblies and the final assembly. This request delineated the requirements for high sensitivity and for a demonstration that the quoted unit will fulfill the desired sensitivity level. Information on the features, delivery schedule, advantages and the costs of components and optional or required accessories were requested. Vendors were allowed to propose more than one type leak detector. Quotations were received in response to this request and the information and specifications for each of the various types of leak detectors have been reviewed. Preliminary recommendations for the purchase of a specific unit were formulated and these had been submitted for approval.

Subsequent to an internal review of the recommendation for the purchase of a specific helium leak detector to fulfill the leak testing requirements for RPCP components, final recommendations for the purchase of this unit were formulated and submitted to the AEC for approval. The unit selected was a VEECO Instruments Inc. Model MS-12-ABR-5 leak detector which has a sensitivity level of 5×10^{-12} atm-cc/sec. Approval was received from the AEC and the purchase order placed for its procurement. This helium leak detector was received and has been installed. Preliminary performance capabilities have been demonstrated in preparation for mock-up tests of fixture components used during the final assembly operations on the RPCP units.

Further efforts have been performed by both VEECO Instruments personnel and ARCO in the installation, component checks and complete check out of the VEECO MS-12 Leak Detector. This has included modifications and sub-component performance checks in order to insure uniformity of sensitivity levels and the retention of high sensitivity leak tests for RPCP components and subassemblies.

The assembly and detailed design drawings of the three fixtures to be used during leak testing of the RPCP were developed and prepared. These fixtures were for the leak tests on the battery case lid, the electronics case, and the leak test on the complete nuclear battery subassembly after TIG welding. The case lid fixture will be used to perform an intermediate leak test on lids for the nuclear battery subassembly. This test will determine the hermeticity of the battery to electronics feedthrough and of the braze at the weld closure plug flange. The fixture design allows for a helium environment on the outside of the case lid as the leak detector is coupled to the inside of the feedthrough and the weld closure plug flanges. A weld closure plug cap has been incorporated into the fixture design to prevent the flow of helium through the hole in the closure plug flange. Effectively, a double "O" ring principle was used in the design to minimize the rejection of good components and retain high sensitivity levels during leak testing. The materials and components for the fixture were purchased and fabrication was completed. A process specification was prepared which delineates the detailed steps in preparing the fixture and the MS-12 Leak Detector for battery case lid leak checks and the procedure to be followed in performing a leak test of each case lid.

The electronics case to feedthrough leak testing fixture design was also completed. This fixture performs a leak test on the electronics case component which evaluates the quality of the ceramic-to-metal feedthrough. The design provides a helium environment on the outside of the electronics case and the leak detector is coupled to the inside of the feedthrough. Materials and components were purchased and fabrication of the fixture was completed. A process specification was prepared which details the procedures to be followed in performing leak tests with this fixture.

The design and development of the nuclear battery leak test fixture was completed.

Shown in Fig. II-3 is a schematic sketch of this leak test fixture which is to be coupled to the VEECO MS-12 leak detector. The nuclear battery subassembly is comprised of the battery case, case lid and

LEAK TESTING OF RPCP NUCLEAR BATTERY

Figure II-3

electronics case subsequent to the TIG welding of each of these three components, as shown. In addition, both a ceramic-to-metal feedthrough and a weld closure plug have been brazed to the nuclear battery case lid which is depicted in the exploded view of Fig. II-3. In order to insure hermeticity of the nuclear battery subassembly at these brazed and welded joints and in the battery case wall, this nuclear battery subassembly test was devised. Note that a double "O" ring seal is provided in the fixture which surrounds the weld closure plug and a differential pumpdown with the use of an auxiliary rough pump assists in preventing the flow of helium through the "O" rings directly to the leak detector. A helium environment surrounds the outside of the subassembly while the leak detector is coupled to the inside of the nuclear battery so as to simulate the pressure differential direction during normal system operation.

A process specification was prepared covering this battery weld leak check. This specification gives the complete procedures to be followed in the preparation of the fixture and the leak detector and for the actual performance of leak tests on the nuclear battery subassembly. Gas manifold subsystems were built for the vent inlet to the leak detector and for the cover subassembly of the fixture to provide for dry nitrogen, helium, and argon environments, as required, and pumpdown of the cover subassembly.

Tests on these fixtures to determine the capability for performing leak tests and demonstrating feasibility of the development concept have been performed. In the case of the nuclear battery leak test fixture, complete battery subassemblies were prepared and TIG welded. Prior to sealing the weld closure plug on two assemblies, leak tests were performed which demonstrated the capability of the fixture. In one case, a leak occurred around the ceramic-to-metal feedthrough joining the nuclear battery to the electronics case and a leak rate greater than 3×10^{-6} atm-cc/sec was determined. Subsequent to the leak test, the weld closure plug on this unit was sealed and the fact that this nuclear battery leaked was confirmed. This was demonstrated by a gradual degradation in output electrical power performance after the EB welding chamber was changed from a vacuum condition to a helium environment.

The helium leak test on the second nuclear battery subassembly was performed with the VEECO MS-12 Leak Detector calibrated to a sensitivity level of 5×10^{-2} atm-cc/sec. After assembling the battery onto the

fixture and initiating the test, a 100% helium environment was provided on all exterior surfaces of the nuclear battery case, case lid and TIG welded joints. Also, helium was supplied to the inside of the electronics case, to the weld closure plug, to case lid brazed joint, and to the exterior surface of the nuclear battery to electronics feedthrough. Thus, this leak test detects two different types of potential leaks at the TIG weld joint and the hermeticity of the battery case, case lid, and brazed joints at the feedthrough and the weld closure plug flange. This battery was maintained with a helium environment for a 10 minute time interval and no indication of leaks greater than 5×10^{-12} atm-cc/sec of helium were recorded. Thus, the capability to perform high sensitivity level leak tests on nuclear battery assemblies has been developed and demonstrated with this fixture and the above leak tests.

With the advent of the NU4 production series and the NU5 modified production series it was decided to leak check all final nuclear battery assemblies. Only one nuclear battery in the NU4 series was found to leak at the TIG weld joint. This unit was NU4-36 and it had a leak greater than 10^{-6} atm-cc/sec. The nuclear battery was rejected. There were two nuclear batteries in the NU5 series that leaked. One was NU5-19 which showed a leak rate of 3×10^{-9} atm-cc/sec. Subsequent to the leak test, the weld closure plug on this unit was sealed and the fact that this nuclear battery leaked was confirmed. This was demonstrated by a gradual degradation in output electrical power performance after the EB welding chamber was changed from a vacuum condition to a helium environment. The other unit that leaked was NU5-30 and it also had a gross leak ($>10^{-6}$ atm - cc/sec). However, this unit was rewelded and proved leak tight on the second check.

G. Electronics Qualification

A Request for Quotation (RFQ) to fabricate Phase II electronic circuits was prepared and transmitted to 36 potential vendors. This RFQ contained the following requirements:

1. RDT Standard C-19-1T which defines quality of material, components, assembly procedures and performance for cardiac pacemaker electronic circuitry for use with a radioisotope power supply.
2. Notes and Ordering Data for RDT Standard C-19-1T which specifies a fixed rated pacer circuit designed to operate with a nuclear battery which has an output voltage of approximately two volts

that is obtained by connecting the six thermocouple tapes into two series subsets of three parallel tapes.

3. RDT Standard F2-2T which specifies the quality assurance program requirements.
4. RDT Standard F7-2T which specifies the preparations for sealing, packaging, and marking of components for shipment and storage.
5. Government Standards:
 - (a) MIL-R-39008 Level S - Resistors
 - (b) MIL-P-13949 - Printed Circuit Boards
 - (c) NASA Level S - Semiconductors
 - (d) NASA NHB 53004(3H) - Soldering
 - (e) Fed. Std. No. 209 - Clean Room
6. Industrial Standard:

Sprague Electrical Specification DV-100

The RFQ was based on delivering 250 circuits within approximately 6 months after placement of an order.

After evaluating 6 vendors who responded favorably to the RFO, the contract was awarded to Raytheon Co. Prior to the production of Phase II pacemaker circuit modules, a group of 11 preproduction circuit modules were fabricated and subjected to the Preproduction Qualification Test in accordance with RDT Standard C19-1T "Cardiac Pacemaker Electronic Circuits, For Use With Radioisotope Power Supply". The purpose of this test summarized in Table II-5 is to detect any weaknesses in the module and correct the weaknesses prior to fabrication of the production circuit modules in order to maximize their reliability.

All preproduction circuits successfully passed the vibration and thermal cycling tests. However, Module 001 failed after 240 cycles of the 50G shock test, and Module 003 failed after 450 cycles of the 50G shock test.

Module 007 failed after being placed on the 28 day life test following the Preproduction Qualification shock, vibration, and thermal cycling testing. In all three failures it was found that the failure mode was a ruptured solder joint at a vertical jumper wire connecting the two PC boards. The quality of the soldering at these points was visually found to be acceptable. No circuit design or component failures were experienced. It was determined that excessive strains on the jumper wire solder connections

Table II-5

Preproduction Qualification Testing

- NOTES: (1) Any 1 module failure causes rejection of all 11 (except for destruction test).
(2) During life test more than a 10% change in performance is considered a failure.

were applied during manual operations (prior to potting) both from holding the boards tightly to achieve proper board-to-board spacing and from squaring the board assembly for proper alignment for proper RTV coverage at potting.

Additional circuit modules were built using an assembly jig which lines up and automatically spaces the PC boards. A total of 11 additional modules built with the assembly jig successfully withstood the vibration, thermal cycling, and shock tests required for the Preproduction Qualifications. In addition, following these tests, visual inspection with the RTV removed from around the solder connection for positive evaluation showed no fatiguing effects on any of the connections. In addition further tests have shown that rigid ceramic sleeves over the jumpers bearing against the PC boards ruggedized the structure and prevented board movement with resultant strain on the jumper connections.

A new group of 11 preproduction circuits were fabricated using the assembly jig and rigid ceramic jumper sleeves. These circuits were subjected to the Preproduction Qualification Tests as prescribed in RDT Standard C19-1T. This time all of the 11 preproduction circuits passed the Production Qualification Tests without failure. During pilot production 39 circuits were then assembled and successfully tested in accordance with C19-1T. The 200 production circuits were then fabricated and shipped to ARCO Nuclear. These 200 circuits plus the 39 pilot production and 11 preproduction circuits satisfied all of the requirements for C19-1T and were put on life test upon receipt. The 200 production circuits were then used for the NU4 and NU5 series and will be used for the human implants. No circuit failures have been experienced not only in animal and bench testing but also not in system destructive testing.

H. Thermocouple Tape Coating

The prototype thermocouple tape was coated with a starch oil binder which was removed at ARCO Nuclear. In order to improve production efficiency, tape was ordered with polyvinyl coating instead of the starch oil binder. The new tape was evaluated, and it was found that the fibers in the new tape were held together more tightly where as in the prototype tape the necessary chemical processing caused the fibers to spread resulting in better performance. Based on this evaluation, the production tape was supplied with a starch oil binder.

I. Inspection of Brazed Thermocouple Tape and Plated Tapes

It was previously determined that it would be impossible to inspect

the brazed thermocouple tape by use of infrared inspection techniques. Since that time, the possibility of using radiography for inspection has been investigated. The hot and cold shoe assemblies on brazed thermocouple tapes have been radiographed. It was intended that the radiographs would indicate how far the Cupron and Tophel wires were placed in the grooves and the integrity of these wires. However, because of the density of the braze material filling the grooves, it was impossible to segregate the wires from the braze material when viewing the radiographs. Brazed thermocouple tape is limited at present to a close visual inspection of each groove plus the electrical tests.

A fixture has been fabricated to inspect the assembled brazed thermocouple tape. This fixture is similar in design to the fixture used in Phase I. The new fixture differs in that the material is stainless steel instead of plexiglas and the new fixture will only measure the Phase II designed tape length. The previous fixture was adjustable to different tape lengths, but this capability lowered its degree of accuracy. The brazed thermocouple tapes are placed in the fixture and the inspector measures the total resistance, groove isolation and determines the polarity. A visual inspection of each tape is performed at 30X. At this point the metal tags are removed. The final report correlates all the serialized component parts used in the assembly of the brazed thermocouple tapes such as ceramics, hot and cold shoes and the sections of tophel and cupron tape. The quality of each braze can then be related to the quality of each component.

A fixture was designed to measure the amount of coating placed on the thermocouple wires during the electroplating process. After the 65 inch lengths of tape (consisting of seven grit blasted areas spaced either 8.500 inches or 8.350 inches apart) have been plated in the grit blasted areas and dried, they are then placed in the inspection fixture. The fixture is plexiglas and basically consists of a supported 70 inch plexiglas trough, a dial gauge (.0001 inch increments) located at the end of the trough and a tape wrapping mechanism. The tape is placed in the trough and the plated area of the tape is located between the gaging anvils. A 10 oz. weight is used to maintain a constant force on the anvils. After making the measurement, the tape is wound onto a spool. This spool is then placed on the tape assembly fixtures. The advantages of the fixture are:

- (1) it offers minimum handling and wrapping of the thermocouple tape,

(2) it provides a process control for the electroplating operation.

In addition to measuring the plating thickness, the inspector performs a visual examination of the plated areas at 30X. At each section of tape (either 8.350 inches or 8.500 inches) the inspector sews a metal tag at the end of the tape. This metal tag has a number scribed on it and is a means of following that particular section of tape through the complete braze cycle. If any irregularities are discovered it is brought to the attention of the chemical processing group for correction.

J. Electrical Problems Encountered in Brazed Thermocouple Tapes

1. Low Total Resistance:

At the beginning of the pilot production a high rejection rate occurred due to low total tape resistance. Resistance checks on ceramic tabs removed from some of the reject tapes showed good resistance values between grooves of the tabs indicating that the problem was in the tape itself. Since measurements of intact low resistance tapes could not isolate the problem, the wires were carefully cut at the ceramic tabs. Then local ceramic tab resistances as well as isolated thermocouple and individual wire resistances were measured. It was found that with the thermocouples disconnected, the resistance between ceramic grooves was essentially infinite indicating that the ceramic tabs were not causing the low tape resistance problem. It was next found that all isolated thermocouples had low resistances and that their individual sum equaled the low total tape resistance previously measured for the intact tape. Finally, measurements of individual isolated wires showed that the Cupron Special wires were well below their proper resistance values and that the Tophel Special wire resistances were normal.

Examination of the tapes revealed a thin silver deposit on the Cupron, but not the Tophel tapes. This was concluded to be an immersion coating of silver formed on copper or copper alloys which come in contact with silver cyanide plating solution and are not an electroplated deposit. This coating was visually observed on about 70% of the completed thermocouple tapes as spotty or complete coverage coatings and was concluded to be a contributing factor to low total tape resistance.

This silver coating was obviously formed during electroplating of silver on the thermocouple wires. The plating solution either seeped through the fixture to the body of the tape or small quantities splashed into this area during plating or subsequent rinsing of the tape and fixture with water.

In order to prevent plating solution from coming into contact with the body of the tapes, plexiglas blocks were fabricated for the plating fixture which are clamped over the center section of the tapes. Subsequent filling of these sections with water forms an effective seal around the tape. As an added precaution, strips of copper are placed in these sections to indicate the presence of silver which necessitates more careful rinsing.

Since incorporation of these measures, the rejection of tapes by silver coating has been eliminated.

K. Ceramic Tab Preparation

After air firing the ceramic tabs, approximately 10 to 15% of the tabs turned gray in certain areas. These areas of discoloration were not restricted to one particular location. Our air firing procedure requires heating the ceramics in air to 500°C and holding 1/2 hr. This procedure has not been altered, but the ceramics are from a new lot. Cleansing in trichlor and ultrasonic cleaning did not affect the discoloration. A ceramic engineer from the ceramic vendor was consulted and the following comments were made:

1. The discoloration is not a result of impurity in the ceramics.
2. Discoloration of ceramics during air firing is the result of either the furnace environment or improper cleaning or rinsing at the vendor's facilities.
3. The vendor's cleaning operation has not changed for five years. The vendor's cleaning procedure is as follows:
 1. Ceramics are cleaned with a detergent called alkonox.
 2. Rinsed with H₂O.
 3. Ultrasonic cleaned.

If the ceramics were not rinsed thoroughly or improperly stacked during ultrasonic cleaning, it is very possible that the alkonox was not

completely removed leaving a carbonaceous microfilm behind.

The vendor also stated that the ceramics are sintered at 1700°C and recommended air firing at 1100°C. Air firing at this temperature would not change the structure, dimensions or stability of the ceramics.

Some of the discolored ceramics were then air fired at 1100°C and the discoloration disappeared and all dimensions remained stable. It was, therefore, necessary to increase the ceramic air firing temperature to 1100°C in order to insure that a thin, carbonaceous residue does not remain on any of the ceramics thus resulting in a uniform product.

L. Failure Analysis

1. Experimental Units

RPCP #E-12 (Electronics #135A-18)

This unit was implanted in a dog and stopped pacing in March, 1970. It subsequently restarted spontaneously. It was removed (while still operating) from the dog on March 23, 1970, examined and tested with no apparent problem. It was re-implanted (within an hour) and continued to operate properly. It was concluded that a transient electronics problem had occurred. Subsequently one month after the re-implant, the unit again stopped pacing and was returned to ARCO Nuclear for analysis. When examined at ARCO Nuclear it was found that the emitter of output transistor Q_3 had opened but that the base collector junction was valid. The multivibrator was found to be operating properly. In addition, it was found that the nuclear battery had not changed in its performance since being completed. When the circuit (which was still connected to the nuclear battery) was probed with a needle approximately 1/8" from the leads of Q_3 but on the printed circuit board track electrically connected to the base of Q_3 , the malfunction in the emitter of Q_3 corrected itself. Proper circuit operation continued for about three days while at the dog's body temperature at which time a recurrence of the same problem was experienced.

The unit was then operated in an environmental chamber at a dog's body temperature and supplying a simulated body load. In addition it was temperature cycled every 15 minutes between 10°C and 50°C several times. The temperature cycling did not induce a malfunction but when operating at the dog's body temperature the malfunction of Q_3 has appeared and subsequently corrected itself several times. This unit is presently on life test.

RPCP E-9 (Electronics 135A-22)

An initial failure of unit #E-9 occurred on 6/27/69 during life testing. The unit was restarted and subsequently stopped pacing in April, 1970. This unit stopped pacing and drew no current from the nuclear battery and could not be restarted. The circuit was removed from the battery and then became self-starting (one day later) but otherwise operated normally for a short period of time until it failed to produce an output pulse even though the multivibrator continued to operate. It was verified that the emitter of transistor Q_3 had opened by isolating it and externally connecting another Q_3 . Under this condition the circuit operated normally but was still self-starting. The original Q_3 was tested and revealed that its emitter junction had opened but that its base collector junction was valid. This appears to be the identical failure mode of Q_3 in RPCP E-12. The self-starting characteristic and the fact that at one time no current was drawn from the nuclear battery suggests possible changes in the multivibrator circuit. The power was removed from this circuit for several weeks and then reconnected at which time the "self-starting" condition was no longer present. After operating for about one week the "self-starting" condition reappeared.

When transistor Q_2 was replaced externally the "self-starting" condition then disappeared with all other parameters remaining normal. This unit is presently on life test.

RPCP #E-14 (Electronics 135A-4)

This unit was completed on 3-23-69, implanted on 8-27-69, failed sometime between 6-15-70 and 7-20-70, and was removed from the dog on 7-21-70. It was found that a failure had occurred in both the electronic circuit and in the nuclear battery. The electronic circuit failure analysis showed that the output transistor Q_3 had failed with its emitter open and its base-collector junction valid. This is the same failure mode experienced by circuits 135A-18 and 135A-22. When transistor Q_3 was replaced externally, proper circuit operation resulted. The nuclear battery failure analysis showed a simple cone type ductile fracture in the #3-cupron tape just at the point of emergence from the hot side ceramic. The fracture was due to overloading.

RPCP #E-10 (Electronics 135A-8)

This unit was sealed on 3-29-69, electronics added on 4-1-69, and failed on 7-14-70. The failure analysis showed that transistor Q_2 had failed with its collector open and its base-emitter junction valid. When transistor Q_2

was replaced externally, proper circuit operation resulted. This unit is presently on life test.

RPCP #E-17 (Electronics 135A-28)

Preliminary measurements made by NHLI personnel indicated that unit E-17 was producing a very weak output signal (in the millivolt range) but at the proper rate. This unit had been implanted on 9-10-69, was last found to be operating properly on 1-25-71, was found to be defective on 2-1-71 and was removed on 2-4-71.

The failure analysis performed at ARCO Nuclear showed that the electronic circuit (135A-28) had failed. The failure mode was verified to be an open emitter of the output transistor (Q_3). This is the same mode that has occurred in three previous circuit failures (135A-4, 135A-18 and 135A-22). The failure analysis also showed that the nuclear battery of E-17 after being implanted for about 17 months has not degraded and in fact has slightly improved. This unit is presently on life test.

2. Prototype Units

RPCP #P-1 (Electronics #135A-37)

This unit, implanted in a dog at NH&LI, stopped pacing (March, 1970) and was returned to ARCO Nuclear. Everything appeared to be normal except that the circuit needed to be restarted externally. After restarting, all parameters appeared to be normal. This unit was shock tested 10 times in all six orientations for a total of 60 severe shocks and no nuclear battery fluxuation could be observed. Recently this unit spontaneously stopped pacing again and was restarted externally. It has operated normally since. Neither thermal nor vacuum cycling has induced the circuit to stop operating. The unit was placed on life test for a short period of time at the dog's body temperature.

The electronic circuit again stopped operating and was subsequently restarted with all parameters normal. No definite conclusions can be drawn at this time concerning failure mode. Several tests have been conducted on this unit none of which have induced a malfunction. The unit was vacuum cycled several times with continuous recording of both the RTG output and circuit output into a simulated body load at 25°C. The recording equipment indicated no system changes. The unit has been temperature cycled continuously for several days between 10°C and 50°C at both one hour and 12 hour intervals with a temperature transistion time of 10 minutes. During the temperature

cycling the RTG output voltage and circuit current output into a simulated body load were monitored. Again, no system malfunctions were observed and the only changes displayed were those expected due to transient thermal effects on the nuclear battery. The unit has also been subjected to vibration tests up to 2 g's and the continuous recording equipment displayed no change in performance. This test is described below. The unit was also operated at a dog's body temperature while supplying a simulated body load for several weeks with no change in performance.

Unit No. P-1 was vibrated at low g-levels following thermal cycle testing. The vibration testing was conducted in order to determine if low level vibration would affect the performance of the battery voltage or output pulse. The unit was mounted to an aluminum platform which was designed to adapt to the shaker and to make the necessary monitoring connections. A chart recorder was connected to the nuclear battery output. An oscilloscope was used to monitor the output pulse. The oscilloscope and chart recorder monitored the unit continuously through all levels of vibration testing and set-up time. The unit was vibrated in all three axes at the 0.5 g-level. A frequency scan was conducted from 0-500-0 c.p.s. Next, the unit was mounted on the Y-axis and vibrated at 1g, 1.5g, and 2.0g-levels. Again, at each level a 0-500-0 c.p.s. frequency scan was performed. Each complete scan took approximately three minutes. The unit under all of these conditions did not indicate a change in either the voltage from the nuclear battery or the output pulse from the electronics. This unit is presently on life test.

RPCP #P-6 (Electronics 135A-39)

The unit was completed on 1-27-70, implanted on 4-9-70, failed to produce an artifact on 5-15-70, and was removed from the dog on 5-25-70. It was found that the failure had occurred in the nuclear battery. The first thermocouple in the #2-Tophel tape was found to be open. The metallurgical analysis showed that the wire had been broken before the braze cycle and a small portion of braze alloy on the end of the broken wire provided the continuity until failure.

RPCP #P-4 (Electronics 135A-32)

RPCP #P-4 stopped pacing while in a dog at NH&LI. This unit was sealed on 11-21-69, implanted 12-22-69 and failed between 8-17-70 and 8-24-70. It was returned to ARCO Nuclear on 8-27-70 and subsequent failure analysis

determined that the failure was caused by an open Tophel Special wire at the hot shoe ceramic end groove, a similar location to the previous failures.

The unit as returned had an intermittent open. With the battery output at its peak (no open) the electronics ran at a rate of 123.7 b/min which was somewhat less than the 126.5 b/min at beginning of life. Thus, the shifting of getter baskets and disarrangement of the heat shields seen in the radiographs (Task 4 of this report) and during disassembly produced a slight degradation of thermal performance.

The failed tophel wire and cupron wire next to it showed necking. Metallurgical interpretation of the scanning electron microscope photographs of the failure indicate a failure due to tension overstressing of the wire leading to a ductile fracture.

RPCP #P-3 (Electronics 135A-33)

RPCP #P-3 was returned from NH&LI having stopped pacing on 9-28-70. When received at ARCO Nuclear the unit was restarted and ran at 126.5 b/min versus the 130.2 b/min at the beginning of life. The cause of stoppage in the dog was an intermittent electronics problem similar to what occurred before with unit P-1. Unit P-3 was placed in an oven at 39°C to simulate the dog body temperature and the battery output was continuously monitored with the electronics disconnected. No variation had been observed. The electronics was driven by a simulated RTG and is also monitored continuously. Thus any stoppage of the electronics could be noted whether transient or continuous. This test was in operation until 5-14-71 at which time the electronics was reconnected to the nuclear battery. The unit is functioning properly and is on life test.

RPCP #P-5 (Electronics 135A-30)

National Heart and Lung Institute notified ARCO Nuclear that pacer unit P-5 had stopped pacing approximately 3-15-71. The unit had been implanted in a dog on 1-14-70 and operated satisfactorily for approximately 15 months. After failure, it was removed from the dog and returned to ARCO Nuclear on 3-24-71, at which time a failure analysis began. The unit was not pulsing and was first radiographed. The radiographs were similar to those taken of other units that had been in dogs, and suggested that P-5 had been exposed to severe repetitive shocks. This was indicated by the displacement of both getter baskets from the end of the fuel encapsulation to a position one-half way between the fuel encapsulation and the bottom of the case. The epoxy

was machined away and the electronics case lid was removed. The voltage from the battery with the electronics connected was 0.67 volts. The electronics were then disconnected and removed from the battery. The open circuit voltage of the battery was 2.35 volts which indicated an open tape in the battery. The exterior case was punctured and tested to establish that a vacuum had been maintained. No gases were present within the precision of the measuring apparatus. The weld securing the lid to the exterior case was then machined away and the thermopile removed. The general condition of the thermopile was as follows:

- (1) Getter dust was observed at both ends of the module.
- (2) Getter baskets had shifted, as indicated by the radiographs.
- (3) Insulation tape was frayed and crushed in the area of the hot strap.
- (4) Three hot shoes are partially loose from the hot strap.
- (5) Cold shoe #3 was completely forced off the cold strap.

The individual tape resistance was measured and it was found that tape No.3 was open. Examination of the thermopile revealed that the lock tab in the No. 4 tape position on the hot strap was bent in such a manner that it rubbed against a cupron wire in the No. 3 tape. The cupron wire broke approximately 1/8 inch from the ceramic and in the middle of the tape. Apparently the repetitive shocks caused the tab to rub against the wire resulting in a wire breakage. The locking tabs in several of the other areas were either broken or distorted.

M. Phase I Electronics

Table II-6 summarizes the 16 Phase I electronics circuit failures that have been experienced since the beginning of the RPCP Program. This circuit has been replaced by a high reliability aerospace level circuit for Phase II. Since this change, no circuit failures have been experienced.

N. Initial Animal Implants of NU-4 Pilot Production Units

A total of 27 NU4 units were implanted in dogs at the National Heart and Lung Institute. Of these 27 units, 5 suffered battery failures after an average implant time of only 43 days. The 5 failures of the NU-4 model were all found to be identical multiple open tapes caused by high torsional accelerations induced by the animals running in their cages. A detailed summary of these 27 NU-4 units is given in Section F of Task 1.0. Following is a detailed failure analysis concerning the NU-4 implants.

Table II-6

<u>Circuit</u>	<u>Associated Unit, If Any</u>	<u>Approximate Failure Date</u>	<u>Approximate Time of Operation Until Failure</u>	<u>Postulated Failure Mode</u>	<u>Proven Failure Mode</u>
135A-2		8-68	14 months	Unknown	--
135A-4	E-14	7-70	37 months	--	Open emitter of Q_3
135A-6		9-68	27 months	--	Shorted output zener
135A-7		7-67	1 month	Either zener short or leak of Q_2 (CB)	--
135A-8	E-10	7-70	37 months	--	Open collector of Q_2
135A-9		1-70	30 months	--	Leak of Q_3 (CB)
135A-10		6-69	24 months	--	Leak of Q_3 (CB)
135A-11	E-16	8-71	51 months	--	Open emitter of Q_3
135A-13	E-12	3-70	24 months	--	Open emitter of Q_3
135A-19	E-18	7-71	40 months	--	Open emitter of Q_3
135A-22	E-9	4-70	25 months	--	Open emitter of Q_3
135A-25	E-5	7-71	40 months	--	Open emitter of Q_3
135A-28	E-17	2-71	17 months	--	Open emitter of Q_3
135A-33	P-3	9-70	9 months	Unknown	--
135A-37	P-1	3-70	5 months	Unknown	--
135A-39	P-6	10-71	23 months	--	Multivibrator section stopped oscillating

The 13 remaining Phase I electronic circuits are presently on life test.

RPCP NU4-9

This unit was implanted in a dog on 1-31-72, stopped pacing 3-3-72, and was removed 3-6-72. Preliminary failure analysis showed 5 out of 6 tapes open. Some tophel wires were broken in all 5 tapes that were open. Only one open tape had broken cupron wires, although all cupron tapes had missing filler fibers 3/8 inch from the hot strap.

RPCP NU4-11

This unit was implanted 2-7-72, stopped pacing 3-17-72, and was removed 3-20-72. The failure analysis showed this unit had 5 tapes open. However, all open tapes had only tophel wires broken.

RPCP NU4-18

This unit was implanted 2-22-72, stopped pacing 4-7-72, and was removed 4-10-72. The failure analysis showed 4 open tapes. Again all the open tapes had broken tophel wires. However, like NU4-9 it had one open tape with broken cupron wires.

RPCP NU4-19

This unit was implanted 2-22-72, stopped pacing and was removed 3-30-72. The failure analysis showed 5 open tapes. All open tapes had broken tophel wires, but 2 open tapes had broken cupron wires.

RPCP NU4-20

This unit was implanted 2-22-72, stopped pacing 4-21-72, and was removed on 4-24-72. It failed in the same manner as NU4-19.

0. Generalized Failure Analysis of Pacer Tapes

Examination of all dog implanted NU-4 heart pacer thermopile failures has shown several consistent patterns. These patterns relate to type of motion at the hot strap causing the failure and the failure mode in the individual wire. These consistent patterns are:

1. The wires at both tape edges were always skewed inward toward the center of the tape with the maximum skewing at the extreme edge and progressively becoming more normal toward the center.
2. There had been a pattern of a downward fold or incipient downward fold at the tape adjacent to the tab with the maximum occurring at the tape edges and progressively improving toward the tape center.

3. All failures had been in the edge wires at the tab end or near the tab end.
4. The majority of the wire failures had been in the tophel (top) tape, although many cupron wires had also failed.
5. The wires in the tophel tape had normally shown the greatest degree of skewing.
6. The fractured end of the wires had shown no significant reduction in cross-sectional area indicating a non-tensile type of failure. This applied to both tophel and cupron wires.

In reviewing these patterns, the conclusion was drawn that the downward bending (in some cases, a foldlike loop) of the wires was caused by an oscillation type of motion of the hot strap cylinder since all six pairs of tapes showed this effect and that superimposed on this rotational motion was a cylinder end motion at both ends describing a cone since the maximum deflection of the wires occurs at the tape edges. This three dimensional motion would also account for the skewing of the wires toward the center. There appeared to be a neutral axis through the tape centers with all motion hinging at this point. This motion would account for all failures occurring at the tape edges since the edges see the maximum deflection. Also, the oscillation or flexing motion would explain the non-tensile failure mode since the flexing would result in work hardening and fatigue type failures. In some cases, we have seen failures adjacent to the bottom loop in the tape downward loop indicating a non-stressed type (in the overall wire) of failure.

Substantiating this fatigue type of failure are electron micrographs II-4 through II-8 of a typical tophel wire fractured end. Micrograph II-4 shows the general fracture configuration at 500X. Note the flattened or mushroomed effect at the lower edge. Micrographs II-5 and II-6 show two orientations (differing by 35°) of the fracture surface at 1000X. Note the flattened, beaten appearance at the lower right edge indicating that the break initiated there and then progressed to the other edge. Micrograph II-7 is at 5000X and shows the flattened area with its beaten appearance. Micrograph II-8 is also at 5000X and shows the striated, progressive type (cold work fatigue) surface of the remainder of the fracture.

Figures II-9 and II-10 are photomicrographs at 1000X of tophel wires. Figure II-9 is a section of a fracture end and shows that the outer edge is

in tension with the inner edge in compression. A normal tophel wire is shown in Figure II-10.

A possibility in the fracture mode particularly at the tab end where braze alloy comes in contact with the wires not in the tab slot is attack of the wires by the braze. Thus far, we have not been able to see any significant attack by the braze.

As for the majority of failures occurring in the tophel tape, the most plausible explanation for this is the fact that the tophel tape fiberglass edges are sewed to the insulation tapes whereas the cupron edges are not. Thus, since the tophel tape edges are fixed to the insulation tape, the tophel tape is not free to slip when the hot strap shifts and a sharper flexing effect is imposed on the tophel wire end at the tab when the hot strap cylinder goes into its three dimensional motion. This tophel tape fixing may account for the greater shift in the tophel tape wires and also for the greater number of failures in the tophel tape wires.

P. Hastelloy "C"

The middle fuel capsule is made from Hastelloy "C". The availability of Hastelloy "C" was limited and another material Hastelloy "C276" was supplied for a portion of the middle capsules. Hastelloy "C276" has a lower carbon content than the straight Hastelloy "C" and was supposed to be a better welding material. However, that particular heat of "C276" had a high aluminum content which caused stringers during welding and resulted in leaking fuel capsules. Therefore, a maximum limit of .1% Al was placed on the Hastelloy "C" or "C276". Welding tests proved that Hastelloy with less than .1% Al could be welded without leakers. The aluminum limit was placed on RDT standard for Hastelloy.

Q. Thermocouple Life Tests

Early in the report period, a set of thermocouple tapes based on the pilot production techniques were put on life test. Pairs of tapes were run at 250°C, 400°C and 550°C hot side and 40°C cold side. The 250°C hot side tapes had not shown any measurable degradation for the duration of the test which was 9475 hours.

Figure II-4 500X
SCANNING ELECTRON MICROGRAPH
TOPHEL WIRE FRACTURED END

Figure II-5 1000X
SCANNING ELECTRON MICROGRAPH
TOPHEL WIRE FRACTURED END

Figure II-6 1000X
SCANNING ELECTRON MICROGRAPH
TOPHEL WIRE FRACTURED END

Figure II-7 5000X
SCANNING ELECTRON MICROGRAPH
TOPHEL FRACTURED SURFACE

Figure II-8

5000X

SCANNING ELECTRON MICROGRAPH
TOPHEL FRACTURE SURFACE

Figure II-9

1000X

LIGHT MICROSCOPE PHOTOMICROGRAPH
TOPHEL SECTION AT FRACTURED END

Figure II-10

1000X

LIGHT MICROSCOPE PHOTOMICROGRAPH
NORMAL TOPHEL SECTION

The 400°C hot side tapes did show an early degradation of about 15 percent on the first 2000 hours. Then they did not degrade significantly for 3000 hours. At 5300 hours a pump failure apparently exposed the tapes to air. As previously observed when tapes are backfilled with air while hot, the performance is significantly improved where degradation has occurred. This is believed due to the oxidation of vapor deposits which lowers the resistance between couples and increases power output. After the pump failure the improved performance was maintained for an additional 4173 hours at which time the test was ended.

The 550°C tape test had shown a consistent decrease in output with an initial degradation of 70 percent in the first 2000 hours and 20 percent in the next 2000 hours. The pump failure had only a slight positive effect on both tapes. The tapes continued to degrade until the end of the test at 7686 hours.

R. Mechanical Testing of Thermocouple Tape

Brazed thermocouple tapes were tested on an Instron tension machine in order to determine the amount of force necessary to break the thermocouple wire(s). Four thermocouple tapes from Phase I of the Pacer Program were selected for testing. Each tape was visually acceptable as to the soundness of the braze and condition of the wires. Various combinations were used such as severing the cupron tape in order that the total amount of pulling force would be directed along the tophel tape. The speed of the Instron was .05 inch per minute. A chart recorder was connected to the Instron which plotted the continuously increasing amount of force being applied to the tape. It should be noted that the test fixture did not concentrate the pulling force on any one wire but distributed the force over all 88 wires. The chart recorder was sensitive enough that the breaking of one wire in a tape would cause an immediate fluxuation on the chart. In addition, an ohm meter was connected to the test tape. The resistance then indicated when an open occurred. The chart recorder and the ohm meter correlated the results of the testing. The data obtained established that the cupron tape could be expected to break between 8.9 lbs and 10.8 lbs while the tophel tape broke between 19.4 lbs and 22.5 lbs. The tensile strength of the tophel wire is a factor of 2 greater than that of the cupron wire. In

both cases the first wire to break in the cupron tape occurred at the cold shoe and in the end groove. The first wire to break in the tophel tape in one test broke at the end groove of the cold shoe while in the outer case the break occurred at the hot shoe end groove. In all of the tests none of the wires pulled out of the grooves. All of the breaks occurred at .025 inch to .110 inch from the ceramic.

In addition several tapes were tested on the fatigue test unit (referenced in the Second Term Report of October 25, 1969). These tests were conducted to determine if any difference existed between the present and previously fabricated thermocouple tape assemblies. The parameters for the test unit were the same as had been used in the past. The monitoring of the test unit was changed in that the unit immediately stopped cycling when one cupron wire broke. A chart recorder was connected to the unit to monitor the operation time. Then by multiplying the operation time by the cycles per minute, the total amount of cycles before breakage could be calculated. The results of three tests indicated that the range of cycles before breakage is from 13,500 to 15,000 cycles. Although the number of tests is small, all of the test data indicates a significantly larger number of cycles for the latest tapes as compared to the number of cycles for previous tape assemblies.

A low isolation resistance problem occurred in thermocouple tape production in the area of corrective action there were two possibilities, namely, grit blasting or oxidizing the brazed tapes. Grit blasting was eliminated because of the possible damage to the wires. Tests were performed on the isolation resistance of oxidized thermocouple tapes (300°C in air for one hour) and compared to non-oxidized tapes. These results are shown in Table II-7. All three tapes that were selected for oxidation (157, 169, 174) were rejects due to isolation resistance below 1.0×1 meg. before oxidizing. After oxidizing all three tapes were over 1.0×1 meg. and also were above 1.0×1 meg. at 250°C. However, of the four acceptable tapes tested without oxidation (282, 211, 270, 231), three had isolation resistance below 1.0×1 meg. at 250°C. The lowest value was 0.15×1 meg. for two of the non-oxidized tapes which would represent approximately 3.5% power loss.

TABLE II-7

Effect of Temperature
On Hot Shoe Isolation Resistance
(Oxidized and Non-Oxidized Tapes) (11/18/71)

<u>Tape No.</u> <u>Phase II</u>	<u>Resistance</u> <u>Before Oxidation*</u>	<u>Resistance</u> <u>After Oxidation*</u>	<u>Resistance</u> <u>at 250°C</u>
157	0.5 x 1	50 x 100	60 x 1
169	0.3 x 1	3 x 10	1.6 x 1
174	0.2 x 1	∞ x 100	25 x 1
282	11 x 1		0.15 x 1
211	1 x 1		0.15 x 1
270	∞ x 1		90 x 1
231	6 x 1		0.4 x 1
<u>Phase I</u>			
229	∞ x 100		2.0 x 100

*Reading in meg-ohms of meter scale used in measurement.

Tests were also performed on the three oxidized tapes holding them at 250°C for 142 hours to see if the leakage resistance might degrade with time. Included in these tests was the normal 500°C degassing cycle.

The test results indicated that the leakage resistance did not change with time within the accuracy of the instrumentation.

It should be noted that both Tophel Special and Cupron Special thermocouple materials were developed specifically for operation in an oxidizing atmosphere with a continuous temperature operating range up to and including 1500°F (815°C). Therefore, a one hour air firing at 300°C should have no deleterious effects. Metallographic cross sections have tended to support this conclusion since the only surface effect detected was an oxide layer of about 3 microns thick.

Based on the above tests, all of the tapes are now being oxidized and the isolation problem has apparently been eliminated.

S. Evaluation of Thermocouple Tape

Black deposits on some of the cupron and tophel tapes were observed during the visual inspection of the brazed thermocouple tapes. The deposits randomly occurred on the wire and on the fiberglass. It was

hypothesized that small airborne particles such as lint were deposited or embedded in the fibers of the tape and the final degassing caused the particles to turn black. The deposits on the wire when viewed under the microscope did not appear to attack the wire. Past experience indicated that the spots visually disappeared when the tapes were oxidized (1 hour @ 300°C). The oxidized tapes showed a significant improvement in both the total and isolation resistance. Additional testing was done to verify that oxidation did not change the physical properties of the tape. A series of tensile tests were performed. The following three groups of tapes were tested and statistically compared: (1) non-oxidized tapes without black spots, (2) oxidized tapes with black spots, and (3) oxidized tapes without black spots. The results of these tests are listed in Table II-8. There is no significant difference between either the non-oxidized versus the oxidized with black spots or non-oxidized versus the oxidized without black spots. Three pairs of brazed thermocouple tapes were placed on life test at 250°C in order to evaluate and to compare the performance of oxidized tapes, non-oxidized tapes, and non-oxidized tapes with black spots. During the test they accumulated 4684 hours, 4544 hours, and 4977 hours, respectively and had not indicated any degradation of performance or significant difference. It was suspected that any degradation would appear rapidly during life testing.

After the return of failed unit NU4-9, it was decided to perform tensile tests on both cupron and tophel wires from thermocouple tape number one. It can be seen from Table II-9 that the test results are higher than the calculated tensile strength.

Table II-8

Cupron

<u>Group</u>	<u>Sample No.</u>	<u>Yield Str. *(Psi)</u>	<u>Ult. Str. *(Psi)</u>	<u>%Elongation**</u>
Non-oxidized (without black spots)	1B	55,000	61,100	3***
	3B	26,700	63,000	16
	5B	27,100	65,200	16
Oxidized with Black spots	7B	31,500	59,800	11***
	7M	33,700	60,800	11***
	10B	30,200	66,800	19
	11B	30,600	65,900	12
Oxidized with- out black spots	14B	31,200	63,000	7***
	15B	36,600	62,100	11***
	16B	33,100	63,700	17

Tophel

<u>Group</u>	<u>Sample No.</u>	<u>Yield Str. *(Psi)</u>	<u>Ult. Str. *(Psi)</u>	<u>%Elongation**</u>
Non-oxidized (without black spots)	2B	41,100	82,700	21
	4B	43,000	83,700	19
	6B	---	84,000	18
	6M	30,600	83,000	18
Oxidized with Black spots	8B	56,800	84,600	17
	9B	37,100	58,900	--
	9M	38,700	82,500	18
	12B	35,700	86,600	16
Oxidized with- out black spots	13B	45,600	88,200	16
	17B	39,500	84,400	16
	18B	58,100	84,600	9***

* For cupron wire, based on nominal .002" dia. - For tophel wire, based on nominal .0025" dia.

** Based on ~2" gauge length.

*** Broke in grips

B (Bottom) and M (Middle) refer to bottom and middle sections of the wires tested with respect to the identification label at the top of the wire.

Where two sections of the same wire were tested, the first results were suspect because of testing problems with small diameter wire.

Table II-9

Cupron Tensile Test:

<u>Sample No.</u>	<u>Yield Load (lbs.)</u>	<u>Ult. Load (lbs.)</u>	<u>Yield Str.* (Psi)</u>	<u>Ult. Str.* (Psi)</u>
A	.087	.203	28,100	65,500***
1	.115	.200	37,100	64,500**
2	.085	.187	27,400	60,300
3	.099	.203	31,900	65,500

Tophel Tensile Test:

B	.350	.399	72,900	83,100***
4	.233	.412	48,500	85,800
5	.200	.406	41,700	84,600
6	.240	.413	50,000	86,000

Calculated: Tophel tensile 62,000
 yield 32,000
 Cupron tensile 45,000
 yield 26,000

*Based on nominal .0025 inch diameter for tophel and .0020 inch diameter for cupron.

**Broke at top grip.

***Broke at bottom grip.

Samples A & B were used in setting up the tensile tester.

T. Quality Assurance Documentation

On May 3, 4, and 5, 1972, ARCO Nuclear was visited by an audit team which consisted of two auditors from Atlantic Richfield Company and one from ARCO Nuclear. The quality control and manufacturing procedures were in compliance with RDT Standard F2-2T. However, there was a need for additional documentation. Since the audit, ARCO Nuclear has updated the Quality Assurance Manual which was presented and accepted by R.D.T. The manual describes the type of documentation which is performed on the RPCP program. Several important topics discussed in the manual follow.

The Records system for the AEC heart pacer project allows each component to be traced back to the raw material including the purchase order, receiving form and certification of material. Every component in a completed pacer has a recorded history from raw materials through processing and inspection. This includes vendor identity and in-house. The records are signed by persons with direct responsibility of the component or assembly.

All components that do not conform to the quality standards of the RPCP program are presented to the Material Review Board (MRB) once a week for review, discussion and disposition. If the components are accepted by the MRB, they will be placed on the Accepted list and given to the department for further processing. All parts that are Rejected are either used for special test applications or placed in locked cabinets. Any person requesting a rejected component must sign for the component and give a brief description of what it will be used for. The Material Review Board personnel consist of project engineer, responsible engineer, quality control engineers and Program Manager.

The Quality Assurance Department has visited and audited various vendors who supply critical items for the RPCP program. The following vendors were audited for compliance in controlling and documenting this manufacturing, control of materials, inprocess inspection, process control, final inspection results, inspection and test equipment and personnel.

- (1) Prodesco, Inc., Perkasio, Pa. supply the insulation tape and thermocouple tape used in the thermopile. Their facilities were toured and the operation of equipment was discussed. A purchase specification for these tapes were issued and all tape shipments are certified to this specification. Prodesco, Inc., has been an excellent vendor and very cooperative when quality demands are

in question. Although Prodesco has no formal Q.A. program, the work is highly organized and closely directed.

- (2) Fabric Development Inc., Quakertown, Pa. was visited and evaluated for a second source vendor for insulation tape and thermocouple tape. As in all new facilities, time is required to become completely organized. It was difficult to perform an extensive review of this new facility since it was not in operation. It appears that this organization may be able to produce the tape at a reduced cost based on conversation with their management.
- (3) Basic Ceramics Inc., Hawthorne, N.J. manufactures the ceramic tabs used in the thermocouple tape assembly. The visit was to examine the possibilities of upgrading the shipping container and review the quality control methods and records. A purchase specification was written for Al_2O_3 ceramic tabs and Basic Ceramics certifies all shipments to this spec. They have an excellent quality control program and begins with a thorough evaluation of raw materials and follows with a step-by-step in-process inspection at each stage of manufacture.
- (4) General Electric Co., Cleveland Lamp Div., Cleveland, Ohio supplies the Lucalox Ceramic feedthroughs used in the pacemaker's case cover and in the electronic case. G.E.'s facility was not evaluated because the lucalox division is a proprietary process. However, they have an excellent quality control system based on questions and answers and the substantiating records that were presented to ARCO personnel at a conference meeting. A Lucalox Ceramic purchase specification was written and approved by G.E.'s management for certifying all orders shipped to ARCO.
- (5) Bally Ribbon Mills, Bally, Pa. was visited and evaluated for a second source vendor for insulation tape. Prodesco Inc., is a research and development company for specialty products and is affiliated with Bally Mills. Bally Mills has a very good quality control program and their facilities are very clean and modern. Based on the review of the facilities and the results of the Q.A. audit, Bally Mills is a satisfactory vendor for insulation tape. The tape has been evaluated and found acceptable.

- (6) Wah Chang, Albany, Oregon produces the Ta-10W rods used to fabricate inner fuel capsules for the RPCP program. Wah Chang was visited and audited for the stringent quality demands necessary for the Ta-10W inner capsule. A tour of their facility revealed that Wah Chang maintains excellent traceability of all raw materials used in the Ta-10W rod such as the mixing, forming of the electrode, E.B. vacuum melt, extruding, swaging, drawing and inspection. The rods are inspected by dye penetrant test, dimensionally and ultrasonically. We discussed the ultrasonic inspection program which was conducted at ARCO Nuclear to detect microcracks and left them rod standards to review and ultrasonic test so they may ultrasonic inspect the rods as it comes off the production line. The information received at Wah Chang was incorporated into an RDT standard for Ta-10W.
- (7) Ronson Metals Corp., Newark, N.J. manufactures the Ceralloy 400 getter pellets. The audit revealed that Ronson lacks sufficient documentation and control. Because the process is proprietary, no tour of their facility was conducted. An extensive investigation on getter quality is underway at ARCO to determine the necessary parameters needed to obtain a consistently high quality getter. These parameters will be incorporated into a purchase specification for Ceralloy 400 getter pellets.
- (8) Pace Precision and Die Company, Dubois, Pa. supply the exterior case, exterior case lid, electronics case and electronics case lid. These cases are manufactured from ARCO supplied materials. Pace has been in business for about six years and does an excellent job in producing these components. Although they have no formal documented Q.C. program, the work is highly organized and closely directed.
- (9) Penn Hills Machine Co., Oakmont, Pa. machines all of the fuel capsules. Penn Hills is owned and managed by one man and has six machinists who are qualified as excellent machinists. This shop does a lot of special precision orders and very little rework or remaking of components is necessary. The quality control is about average for a small machine shop and they have no documented quality program.

III. TASK 3.6 - SYSTEM FABRICATION AND PRODUCTION DEVELOPMENT

The purpose of this task in Phase II was to examine improved methods of procuring, joining, fabricating and processing of the pacer components with the aim of minimizing the production costs within the reliability and other system objective. Along with the improved fabrication methods, various design developments and performance evaluations had to be made. For the purpose of logical reporting of the combination of design, fabrication, cost reduction and then the actual production of units, the reporting in Task 3 is divided into three sections.

A. Production Control and Records

As the fabrication proceeded and the pacer production truly became a pilot production operation, data on rate of production, performance, detailed flow charts and material flow cards became an important aspect of this task. Examples of these cards and check-off sheets and production records will be given in this section.

B. System Design Developments and Performance Evaluation

This section includes such items, for example, as the method of developing and evaluating a simple one piece support bracket to replace the multiply component unit used for the prototype. It also seems to follow logically that most of the performance test results for evaluating these design changes are reported in this section.

C. Fabrication Development

After design changes had been made to reduce basic component costs and number of components, much of the effort has been the development of the fabrication techniques. Thus, this work lends itself to being reported in a separate section.

A. Production Control and Records

Although much of this type of data has been covered in Task 2, the development of the processes and production records were performed as part of Task 3 and a brief review of this work will be given in the following section.

1. Assembly Process Flow Charts, Flow Cards, and Process Records

As part of the development of fabrication procedures, detailed process material flow charts along with flow cards and assembly log books were developed.

The first step in the fabrication development was developing a chart (Drawing 15-D-4189-26) giving part numbers and designating responsibilities for procurement, engineering, and manufacturing of components. Next a simple Process Flow Chart, Drawing 15-F-4189-1, Figure III-1, was developed to follow the manufacturing process. Next a preliminary detailed chart, Figure III-2, was developed indicating individual components and operations. From this chart a more detailed Drawing 15-J-4189-1, Fig. III-3 was prepared, including detailed designations of all QC operations and indexing all responsibilities and operations. Using this index as a guide, a detailed description of each operation was written and approved before proceeding to pilot production. The procedures are kept in book form in four locations for easy access and maintained up-to-date by QC.

Also to assure proper processing and quality control, process flow cards were developed and made up for key items. The cards are color coded for easy recognition and are shown in Figures III-4, III-5, and III-6. A similar card was developed for the electronic circuit, Fig. III-7.

The cards follow components to assure proper adherence of procedures. Log books and check-off sheets are kept on key operations such as tape brazing and thermopile assembly which are given in the following pages, Figures III-8 and III-9. Other records are kept for TIG welding, degassing and EB closure, electronic circuit installation, final epoxy molding, and epoxy pour spout removal and polish.

Weekly production and material review board meetings are held to coordinate mechanical fabrication, chemical fabrication, and quality control efforts.

PROCESS FLOW CHART

Figure III-1

ITEM	DESCRIPTION, MAT'L, REF. DWG.	GROUP
1	THERMOPILE	2, 3, 4, 5
2	EXTERIOR CASE .025 THK CPTI	
3	ELECTRONICS CASE .010 THK CPTI	
4	TERMINATION BLOCK 3/16" SQ. C.P.T.I. ROD	
5	R8-2038 H2-3475 MEDICAL GRADE EPOXY	
6	HEART LEAD #323-AB	

A. CORDIS CORP., MIAMI, FLORIDA

VOLUME FOR ELECTRONICS = (.564 CU. IN.)
 *TOTAL WEIGHT = (123.1525) GRAMS
 SPECIFIC GRAVITY = (1.42)
 *TOTAL WEIGHT INCLUDES: ELECTRONICS = 11.7016 GRAMS
 R.T.V. = .985 GRAMS

Figure III-2

TOLERANCES UNLESS OTHERWISE SPECIFIED		NUMEC NUCLEAR MATERIALS & EQUIPMENT CORP. APOLLO, PA. U.S.A.	
FRACTIONS	±	PROPOSED DESIGN FOR PRODUCTION PACEMAKER — ASSEMBLY	
DECIMALS	±	SCALE 4" = 1"	
ANGLES	± 1/8°	DRAWN 1/31/78 EGM/WWG	
SURFACE FINISH	✓	CHECKED 1/31/78 J. L. B.	
Q.C. APPROVED 1/31/78 J. L. B.		D.W.G. NO. LAYOUT 37-D	
APPROVED 1/31/78 J. L. B.		REV. NO.	

INSULATION TAPE NO.

PACER NO

ASSEMBLY ROUTE CARD

PURCHASE ORDER NO _____

SPOOL NO _____

BATCH NO _____

Operation	Desizing	Al ₂ O ₃ Coating	Q C	Degas	Q C	Cutto Size	Q C
DATE OF OPERATION							
OPERATOR							
SPECIFICATION NO	105 001	105 001	205 002	405 001	205 005	115 001	215 001

043-402B

RADIOISOTOPE POWERED CARDIAC PACEMAKER

CONTRACT AT(30-1)-4189

THERMOCOUPLE TAPES

PACER NO.

ASSEMBLY ROUTE CARD

PLATED TAPE STRIP NO - TOPHEL _____ HOT TAB NO _____ HOT SHOE LOT NO _____

PLATED TAPE STRIP NO - CUPRON _____ COLD TAB NO _____ COLD SHOE LOT NO _____

ASSEMBLY AND BRAZING SPECIFICATION NO 114 001

Tape End	Assembly Station	Braze Station	Assembly By	Assembly Date	Brazed By	Brazed Date
Hot						
Cold						

Q C INSPECTION

SPECIFICATION NO 214 001

Check	Reading	Operator	Date	Acc./Rej.	Date Degassed
Total Tape					
Hot Shoe					
Cold Shoe					

POLARITY _____ VISUAL ACCEPT _____ LENGTH ACCEPT _____

Q C NO _____ VISUAL REJECT _____ LENGTH REJECT _____

COMMENTS _____

047-402B

RADIOISOTOPE POWERED CARDIAC PACEMAKER

CONTRACT AT(30-1)-4189

Figure III-4

BATTERY LID FEEDTHROUGH ASSEMBLY NO.

PACER NO.

ASSEMBLY ROUTE CARD

042-402B

FEEDTHROUGH FLANGE NO. _____

PURCHASE ORDER NO - CLOSURE PLUG _____

PURCHASE ORDER NO. - CERAMIC _____

PURCHASE ORDER NO - CU. SHIM _____

PURCHASE ORDER NO. - TI. SHIM _____

Operation	Braze	Isolation	Q.C.	Leak Check	Degrease	Degas
DATE OF OPERATION						
OPERATOR						
SPECIFICATION NO	102.012	102.013	202.007	502.001	302.009	403.001

RADIOISOTOPE POWERED CARDIAC PACEMAKER

CONTRACT AT(30-1)-4189

ELECTRONICS CASE ASSEMBLY NO.

PACER NO.

ASSEMBLY ROUTE CARD

044-402B

FEEDTHROUGH FLANGE NO. _____

PURCHASE ORDER NO - CERAMIC _____

PURCHASE ORDER NO - NI SHIM _____

PURCHASE ORDER NO - TI SHIM _____

Operation	Braze	Electro-plating	Isolation	Q.C.	Leak Check	Degrease	Degas
DATE OF OPERATION							
OPERATOR							
SPECIFICATION NO.	106.010	106.011	106.012	306.007	506.001	306.009	403.001

RADIOISOTOPE POWERED CARDIAC PACEMAKER

CONTRACT AT(30-1)-4189

Figure III-5

R P C P ASSEMBLY NO

PACER NO

ASSEMBLY ROUTE CARD

045-402B

SUBASSEMBLIES		OPERATIONS			
Name	Number	Operation	Date	Operator	Spec No
Thermopile	_____	Battery Assembly	_____	_____	117 004
Exterior Case	_____	Battery Tig Weld	_____	_____	118 001
Electronics Case	_____	Low Power Load Line	_____	_____	818 001
Exterior Case Lid	_____	Leak Check	_____	_____	518 001
Electronics Circuit	_____	Degas & E B Weld	_____	_____	119 001
Terminal Block	_____	Leak Check	_____	_____	519 001
Heart Lead	_____	24 hr Steady State Load Line	_____	_____	519 002
		Electronics Placement	_____	_____	120 001
		Electrical Performance	_____	_____	820 001
		RTV Around Electronics	_____	_____	120 002
		Insert Kapton	_____	_____	121 001
		Tig Weld Electronics Lid	_____	_____	721 001
		Tig Weld Terminal Block	_____	_____	721 002
		Grit Blast Top Surfaces	_____	_____	721 002
		Attach Temp Indicator	_____	_____	121 003
		Check Electrical Performance	_____	_____	121 003
		Pour Epoxy	_____	_____	121 003
		Machine Pour Spout	_____	_____	121 004
		Polish & Buff	_____	_____	121 004
		O C & Test	_____	_____	221 001
RADIOISOTOPE POWERED CARDIAC PACEMAKER			CONTRACT AT(30-1)-4189		

RADIOISOTOPE POWERED CARDIAC PACEMAKER

PACER NO

ASSEMBLY ROUTE CARD

046-402B

RADIOISOTOPE POWERED CARDIAC PACEMAKER

CONTRACT AT(30-1)-4189

Figure III-6

PACER NO.

Figure III-7

Sheet No. _____

Tape Brazing Log Book

Time	AC. Amperes Heaters		T.C.'s				Vac in MM/HG	Braze No.
	Lower	Top	1	2	7	8		
				Power On				Hot Cold Side
				One Min. Hold				Shoe #
				Slow Power Increase				Tab #
				Power Off				
								Shoe #
								Tab #
							T C	
Comments						Tape	Chamber No.	
						Tape	Assembler	
							Brazer	
			3	4	9	10		Hot Cold Side
				Power On				Shoe #
				One Min. Hold				Tab #
				Slow Power Increase				
				Power Off				Shoe #
								Tab #
							T C	
Comments						Tape	Chamber	
						Tape	Assembler	
							Brazer	
			5	6	11	12		Hot Cold Side
				Power On				Shoe #
				One Min. Hold				Tab #
				Slow Power Increase				
				Power Off				Shoe #
								Tab #
							T C	
Comments						Tape	Chamber	
						Tape	Assembler	
							Brazer	

Figure III-8

R.P.C.P. THERMOELECTRIC BATTERY ASSEMBLY RECORD

Rev. #1 Set # _____

Battery #NU5-_____ Thermopile #_____ Start Date_____

Technician_____

Specification # 115.001 - Record as Tapes are Spotted on Hot Shoe

Tape Assembly Order	Tape #	Is Resistance Essentially Same as on Card (Write Yes or No*)	Visual Check (Write Ok or No*)	Polarity + or -	Tech. Initials_____ Time_____ Date_____
6					Remarks*
5					
4					
3					
2					
1					

Specification # 615.001 - Spot Weld Hot Shoes to Hot Strap

Tape Assembly Order	Spot Weld Settings		Tech. Initials_____ Time_____ Date_____
	#2 Cu Alloy Tips with .030" Flat on Top, Hand Held Electrodes (Write Yes or No*)	15 Watt Sec, Pulse Position #1 (Write Yes or No*)	
6			Remarks*
5			
4			
3			
2			
1			

Was Visual check made on Polarity order Yes_____ No_____

Was Visual check made during wrapping Yes_____ No_____

Cold Strap Lot # _____

Hot Strap Lot # _____

Figure III-9

R.P.C.P. THERMOELECTRIC BATTERY ASSEMBLY RECORD

NU5-_____/PD-_____

Specification # 115.001 - Resistance Checks on Wrapped Thermopile

Tape Assembly Order	Tape Resistance	Resistance in rounded Megohms Over 15 Megohms, Call ∞			To Tape Assembly #	Tech. Initials _____ Time _____ Date _____
		Tape to Hot Shoe	Tape to Cold Tab			
1				2	Remarks	
2				3		
3				4		
4				5		
5				6		
6				1		

Specification # 615.002 - Spot Weld Jumper Wires to bus wires

Tape Lead Wire to Bus Wire	Spot Weld Settings		Visual Check of Weld under Microscope (Write Yes or No*)	Tech. Initials _____ Time _____ Date _____
	#2 Cu Alloy Tip with .030 Flat 2# Pressure Setting (Write Yes or No*)	3 to 4 Watts Sec, Pulse Position #1 (Write Yes or No*)		
-1 to Bus				Remarks*
-2 to Bus				
-3 to Bus				
+4 to Bus				
+5 to Bus				
+6 to Bus				
Bus to Bus	See Top of Next Page			
+1 to Bus				
+2 to Bus				
+3 to Bus				
-4 to Bus				
-5 to Bus				
-6 to Bus				

Figure III-9 (continued)

R.P.C.P. THERMOELECTRIC BATTERY ASSEMBLY RECORD

NU5-_____/PD-_____

Was Bus to Bus Spot Weld made with settings on Page 2
only 5 watt sec. Used Yes_____ No_____

Were any splices needed in bus wire Yes*_____ No_____

*If Yes, how many_____

Specification #817.001 Low Power Load Line Check in Air with Fuel

Fuel #_____ Tech. Initials_____

Open Circuit Voltage_____ Time_____

Resistance which drops voltage in half_____ Date_____

Specification # 415.001 Thermopile Degassing Record

Was Cycle as described in Spec. #415.001 followed Yes_____ No_____

Maximum Temperature_____

Specification #117.001 Thermoelectric Battery Assembly Record

Battery Case #_____ Electronic Case #_____

Battery Case Lid #_____

Fuel #_____

Time and Date of start of Assembly_____

Resistance of Thermopile_____ Tech. Initials_____

Q. C. Inspected _____ Accepted _____ Rejected _____

Signature _____ Date _____

Ti Heat Shields _____

End Insulation Container _____

Support Bracket _____

Figure III-9 (continued)

R.P.C.P. THERMOELECTRIC BATTERY ASSEMBLY RECORD

NU5-____/PD-____

Specification # 616.002 - Spot Weld Retainer to Getter Basket

Spot Weld Settings				
Retainer to Getter Basket #	#2 Cu Alloy Tip with .030" Flat 2# Pressure Setting (Write Yes or No*)	15 Watt Sec, Pulse Position #1 (Write Yes or No)	12 Spots 3 between Each Notch (Write Yes or No)	Tech. Initials _____ Time _____ Date _____
1				Remarks*
2				

Getter Lot # _____ Getter Batch # _____

Visual Check of Getter Basket Assembly Yes _____ No _____

Specification # 617.001 - Spot Weld Getter Assembly to Hot Strap

Spot Weld Settings				
Getter Assembly # To Hot Strap	#2 Cu Alloy Tip with .030" Flat Hand Held Electrodes (Write Yes or No*)	55 Watt Sec, Pulse Position #1 (Write Yes or No*)	3 Spots on Each of 4 Tabs (Write Yes or No*)	Tech. Initials _____ Time _____ Date _____
1				Remarks*
2	Insert Fuel			

Specification # 117.001 - Battery Assembly Record Continued

Is isolation resistance of feedthrough infinite

Battery Lid Yes _____ No _____

Electronic Case Yes _____ No _____

Visual Check of Heat Shield Assemblies Yes _____ No _____

Figure III-9 (continued)

R.P.C.P. THERMOELECTRIC BATTERY ASSEMBLY RECORD

NU5-_____/PD-_____

Specification # 617.002 - Spot Weld Thermopile Retainer
Strap to Support Bracket After End Shield Assembly

Spot Weld Settings				
Retainer Strap to Support Bracket	#2 Cu Alloy Tip with .030" Flat Hand Held Electrodes (Write Yes or No*)	15 Watt Sec, Pulse Position #1 (Write Yes or No*)	4 Spots on Retainer strap (Write Yes or No*)	Tech. Initials _____ Time _____ Date _____
1				Remarks*

Specification # 817.001 - Low Power Load Line Check after
Retainer Strap Spot Welded

Fuel # _____

Tech. Initials _____

Open Circuit Voltage _____

Time _____

Resistance which drops voltage in half _____

Date _____

Specification # 617.004 - Spot Weld Battery Ground to Case Lid

Spot Weld Settings				
Battery Ground to Case Lid	#2 Cu Alloy Tip with .050" Flat 2# Pressure Setting (Write Yes or No*)	15 Watt Sec, Pulse Position #1 (Write Yes or No*)	3 or 4 Spots, .020" to .030" Separation (Write Yes or No*)	Tech. Initials _____ Time _____ Date _____
One End				Remarks*
Other End				

Specification # 617.003 - Spot Weld Output Wire to Feedthrough
Transition Wire

Spot Weld Settings				
Output Wire to Transition Wire	#2 Cu Alloy Tip with .030" Flat 2# Pressure Setting (Write Yes or No*)	15 Watt Sec, Pulse Position #1 (Write Yes or No*)	Three Spots (Write Yes or No)	Tech. Initials _____ Time _____ Date _____
One End				Remarks*
Other End				

Figure III-9 (continued)

R.P.C.P. THERMOELECTRIC BATTERY ASSEMBLY RECORD

NU5-____/PD-____

Specification # 817.001 - Low Power Load Line check after
output wire hook-up

Open Circuit Voltage _____ Tech. Initials _____

Resistance which drops voltage in half _____ Time _____
Date _____Was clamping bar Needed to Insert Thermopile
into Case Yes _____ No _____Specification # 817.001 - Low Power Load Line check after
inserting Thermopile in Battery Case

Open Circuit Voltage _____ Tech. Initials _____

Resistance which drops voltage in half _____ Time _____
Date _____

Specification # 617.005 - Spot Weld Exterior Case

Spot Weld Exterior Case	Spot Weld Settings			Tech. Initials _____ Time _____ Date _____
	Spot Weld Tips Dwg. 15-D-4189- 228, 6# Pressure (Write Yes or No*)	200 Watt Sec, Pulse Position #1 (Write Yes or No*)	At Least 14 Spots made (Write Yes or No*)	
1				Remarks*

Specification # 817.001 - Low Power Load Line check after
spot welding Exterior Case

Open Circuit Voltage _____ Tech. Initials _____

Resistance which drops voltage in half _____ Time _____
Date _____Specification # 817.001 - Low Power Load Line check after
TIG Welding Exterior Case

Open Circuit Voltage _____ Tech. Initials _____

Resistance which drops voltage in half _____ Time _____
Date _____

Signature of Reviewer _____

2. Battery Assembly Records

The goal in pilot production was to average approximately one pacer per day. To see the progress in meeting this objective detailed records were kept and bar graphs used to illustrate production rates.

During the month of February, 1972, for example, 19 batteries were sealed. The actual number of units sealed, completed, and shipped are shown in Figure III-10. The technical performance data for these units is shown in Table III-1. As can be seen the general performance was very good with an average output of 270 microwatts, which is almost identical with the value of the first 15 units which had an average performance of 269 microwatts. To determine if there appear to be any large deviation in performance from the mean, a plot of output power versus unit number and also unit efficiency versus unit number was established (given in Figure III-11.) The use of efficiency tends to eliminate the variation in performance due to variations in fuel and, in general, does not show any large deviation in performance.

During March, 20 regular production batteries were sealed along with 9 special test units. RPCP production record is included in Figure III-10. The performance data of the completed units is given in Table III-2. The average output power for the 20 production units was 272 μ watts, compared to the previous months of 270 microwatts. The plot of output performance for the NU-4 and production units is given in Figure III-12. The range of efficiencies is from 0.110 and 0.131 or slightly less than ± 10 percent, which is well within the normal expected deviation. To assure proper wrapping of the thermopile, in addition to x-rays, a 100 percent QC visual check and photos of the as wrapped thermopiles are used.

In addition to the regular production units, 4 test units were assembled. The SV-1 and SV-2 units were assembled using a loose wrap to simulate NU-4-9. It was found that to get the loose wrap, rods had to be placed under the tapes to hold the loose wrap during degassing. X-rays and thermal performance showed the simulation was excellent. Two cremation units were also assembled using visual reject materials but from the same production lots that were used in production units. One tape was used as a monitor for thermal performance.

NU-4 R.P.C.P. PRODUCTION (ALSO NU-5 QUALIFICATION UNITS)

PRODUCTION

Figure III-10
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Table III-1

PACER DATA

February

Unit	Date Sealed	Leak Checked	Date Completed	O.C.V. Volts	Output μ Watts	Res. Ω	Fuel Watts	Efficiency	Fuel #
*NU-4-18	2-7-72	x	2-16-72	2.41	268	5413	0.2235	0.120	A-9 metal
*NU-4-19	2-9-72	x	2-16-72	2.38	263	5389	0.2304	0.114	A-10 metal
*NU-4-20	2-9-72	x	2-16-72	2.52	292	5440	0.2268	0.129	A-11 metal
*NU-4-21	2-9-72	x	2-23-72	2.52	295	5375	0.2278	0.129	A-12 metal
*NU-4-22	2-11-72		2-23-72	2.45	277	5377	0.2334	0.119	A-13 metal
*NU-4-23	2-11-72		2-23-72	2.43	268	5453	0.2285	0.117	A-14 metal
*NU-4-24	2-11-72		2-16-72	2.48	280	5494	0.2273	0.123	A-15 metal
*NU-4-25	2-18-72		2-23-72	2.50	290	5397	0.2324	0.125	A-16 metal
*NU-4-26	2-18-72		3-1-72	2.45	275	5408	0.2264	0.121	A-18 metal
*NU-4-27	2-18-72		3-1-72	2.45	278	5358	0.2236	0.124	A-19 metal
*NU-4-28	2-18-72	x	3-1-72	2.55	297	5425	0.2264	0.131	A-20 metal
*NU-4-29	2-24-72		3-8-72	2.49	285	5401	0.2259	0.126	A-21 metal
*NU-4-30	2-24-72		3-8-72	2.38	265	5353	0.2260	0.117	A-23 metal
*NU-4-31	2-24-72		3-8-72	2.40	272	5300	0.2254	0.121	A-24 metal
NU-4-32	2-24-72	x	3-8-72	2.25	236	5318	0.2243	0.105	A-25 oxide
*NU-4-33	2-26-72	x	3-8-72	2.30	248	5334	0.2267	0.109	A-26 oxide
*NU-4-34	2-26-72	x		2.29	242	5377	0.2260	0.107	A-27 oxide
NU-4-35	2-26-72	x		2.33	256	5249	0.2183	0.117	A-28 oxide
NU-4-36 ²	2-26-72	x		2.35	252	5422	0.2289	0.102	A-29 oxide

NOTE: Thermal load decreases 3/4 of 1% per year.

* Dog implants.

¹Electronics rate high and removed for tests.

²Unit leaks - not sealed - date shown is date of closure plug weld.

PERFORMANCE RESULTS FOR UNITS SEALED IN FEBRUARY

Figure III-11

Table III-2

PACER DATA

March

Unit	Date Sealed	Leak Checked	Date Completed	O.C.V. Volts	Output μ Watts	Res. Ω	Fuel Watts	Efficiency	Fuel #
NU-4-37	3-3-72	x	3-8-72	2.34	251	5335	0.2290	0.110	A-30 oxide
*NU-4-38	3-3-72	x	3-8-72	2.38	261	5310	0.2286	0.117	A-31 oxide
*NU-4-39	3-3-72	x	3-9-72	2.27	246	5191	0.2239	0.110	A-32 oxide
*NU-4-40	3-3-72	x	3-9-72	2.36	240	5325	0.2292	0.105	A-33 oxide
*NU-4-41	3-7-72		3-13-72	2.29	248	5234	0.2237	0.111	A-34 oxide
NU-4-42	3-7-72		3-14-72	2.35	263	5200	0.2285	0.115	A-35 oxide
NU-4-43	3-7-72		3-14-72	2.54	304	5305	0.2313	0.131	A-36 oxide
NU-4-44	3-7-72	x	3-15-72	2.37	263	5291	0.2257	0.116	A-37 oxide
NU-4-45	3-10-72		3-15-72	2.45	284	5250	0.2289	0.124	A-29 oxide
86 NU-4-46	3-10-72		3-16-72	2.37	265	5256	0.2236	0.119	A-38 oxide
NU-4-47	3-10-72		3-16-72	2.43	278	5261	0.2286	0.122	A-39 oxide
NU-4-48	3-10-72	x	3-18-72	2.42	279	5240	0.2286	0.122	A-40 oxide
SV-1 ¹	3-15-72	x	Battery Only	2.11	213	5188	0.2253	0.095	PF-1-20 metal
SV-2 ¹	3-15-72	x	Battery Only	2.14	217	5281	0.2305	0.094	A-22 oxide
NU-4-49	3-23-72	x	4-7-72	2.41	276	5217	0.2262	0.122	A-41 oxide
NU-4-50	3-23-72	x	4-7-72	2.43	281	5216	0.2263	0.124	A-42 oxide
NU-4-51	3-23-72	x	4-11-72	2.50	296	5274	0.2311	0.128	A-43 oxide
NU-4-52	3-23-72	x	4-12-72	2.39	270	5242	0.2296	0.118	A-44 oxide
NU-4-53	3-25-72	x	Battery Only	2.49	295	5208	0.2303	0.128	A-45 oxide
NU-4-54	3-25-72	x	Battery Only	2.41	278	5188	0.2285	0.119	A-46 oxide
NU-4-55	3-25-72	x	Battery Only	2.39	272	5197	0.2286	0.119	A-47 oxide
NU-4-56	3-25-72	x	Battery Only	2.45	287	5191	0.2309	0.124	A-48 oxide
CPD-1 ²	3-31-72		4-6-72	1.249	50.1	7761	0.2309		A-49 oxide
CPD-2 ²	3-31-72		4-6-72	1.269	50	7975	0.2310		A-50 oxide

*Dog Implants

¹Special units to simulate NU-4-9²Cremation Units

PERFORMANCE RESULTS FOR UNITS SEALED IN MARCH

Near the end of February (starting with unit 32) until unit 43 in March, the performance seemed a little low. The cause for this difference is not known but is not expected to be significant, although it could be evidence of either a more poorly wrapped (like NU-4-9 and the test units SV-1 and SV-2) or a tighter wrapper unit (TR-2 or TR-3). In addition to the fueled units tested, 5 additional unfueled units with dummy fuels were sealed. These unfueled units are not included in the tables or graphs.

In April, the production was down due to the time spent disassembling units, extra time needed to make special units, and a hold on production of regular units (see Figure III-10). A total of 15 fueled units were assembled. One special unit with dummy fuel was fabricated for tests on an ARCO Nuclear dog. The data on these units is given in Table III-3. Because of the large number of special test units, no plots of thermal performance are given. It is felt that the footnotes on the various units are self-explanatory.

During the month of May, 15 batteries were sealed. These units were used for testing the mechanical vibration capabilities of the NU-5 insulation design. The performance level of these units was down approximately 15 percent from 270 to 235* μ watts due to the tighter wrap. (See Table III-4). The voltage output and efficiency is given in Figure III-13. A total summary of production since January, 1972 is given in Figure III-10. This figure includes all the NU-4 units and the units made for developmental and qualification of the NU-5 design.

The 22 batteries sealed in June were NU-5 units qualified to the new standards satisfactory for dog implants. The production records for batteries sealed in June contain the number of thermopiles wrapped, Figure III-14. This is important since some of the manufacturing effort and tapes go into thermopiles that may be used for special tests. In the end of May and June period, 32 thermopiles were wrapped. Of these thermopiles, 2 were special thermopiles, 4 special batteries, 3 had open tapes, and 2 shorted. The loss was 16 percent. The completion of units was delayed somewhat during June waiting for the RTV-3140 needed for an improved electronics potting procedure. This is discussed in a separate section.

*Similar to prototype performance.

Table III-3

PACER DATA

April

<u>Unit</u>	<u>Date Sealed</u>	<u>Leak Checked</u>	<u>Date Completed</u>	<u>O.C.V. Volts</u>	<u>Output μ Watts</u>	<u>Res. Ω</u>	<u>Fuel Watts</u>	<u>Efficiency</u>	<u>Fuel #</u>
DHS-1 ¹	4-6-72			2.44	281	5288	0.2291	0.1226	A-53 oxide
DHS-2 ¹	4-6-72			2.36	265	5247	0.2285	0.1160	A-51 oxide
CPD-5 ²	4-6-72			2.19	76.3	15,571	0.2244	0.1020	A-3 metal
CPD-6 ²	4-6-72			2.48	290	5288	0.23047	0.1258	A-22 metal
PD-6 ³	4-12-72				$\approx$ 220	5230	0.2267		A-52 oxide
NU-4-58 ⁴	4-14-72			2.26	242	5271	0.2290	0.1057	A-30 oxide
TR-2 ⁵	4-21-72			2.31	253	5223	0.2299	0.1100	A-57 oxide
TR-3 ⁵	4-21-72			2.27	242	5268	0.2288	0.1058	A-58 oxide
DHS-3 ¹	4-21-72			2.37	265	5251	0.2301	0.1152	A-59 oxide
LHS-1 ⁶	4-21-72			2.41	273	5263	0.2304	0.1185	A-60 oxide
NU-4-70	4-25-72			2.33	250	5363	0.2306	0.1084	A-61 oxide
NU-4-71	4-25-72			2.35	260	5263	0.2285	0.1138	A-62 oxide
NU-4-72	4-25-72			2.33	256	5256	0.2319	0.1104	A-63 oxide
NU-4-73	4-25-72			2.33	256	5251	0.2314	0.1106	A-64 oxide

¹Double hot straps.²Cremation units.³Special extra insulation unit to match prototype performance, wrapped and rewrapped, no degassing, no B.O.L. data.⁴No hot shoe attachment and double hot strap.⁵Tight wrap, 50 percent more insulation, one full piece sewn to outside of cupron tape.⁶No hot shoe attachment to hot strap.

Table III-4

Performance Data for Units Assembled in May
(All units with 50% more insulation)

<u>Unit</u>	<u>Date Sealed</u>	<u>Leak Checked</u>	<u>Disposition</u>	<u>O.C.V. Volts</u>	<u>Output μ Watts</u>	<u>Res. Ω</u>	<u>Fuel Watts</u>	<u>Efficiency</u>	<u>Fuel #</u>	<u>Type</u>
NU-4-59	5-2-72		Paint Shaker	2.29	247.8	5244	0.2278	0.1088	A-54	Oxide
NU-4-60	5-9-72		Paint Shaker	2.28	246.6	5268	0.2295	0.1075	A-55	Oxide
NU-5E-1	5-9-72	No	Paint Shaker	2.24	235.8	5318	0.2306	0.1023	A-56	Oxide
NU-5E-2	5-9-72	No	Paint Shaker	2.30	250.4	5280	0.2314	0.1082	A-65	Oxide
NU-5E-3	5-9-72	No	Paint Shaker	2.30	249.2	5307	0.2275	0.1095	A-66	Oxide
NU-5E-4	5-15-72	No	Paint Shaker	2.33	255.0	5275	0.2318	0.1100	PF-1-13	Metal
NU-5E-5	5-15-72	No	Paint Shaker	2.29	248.5	5229	0.2244	0.1107	PF-1-15	Metal
NU-5E-6	5-19-72	No	Paint Shaker	2.21	229.9	5263	0.2253	0.1020	PF-1-20	Metal
NU-5E-7	5-19-72	No	Paint Shaker	2.18	225.6	5266	0.2270	0.0994	PF-1-29	Metal
NU-5E-8	5-19-72	No	Paint Shaker	2.15	218.2	5245	0.2253	0.0968	A-2	Metal
NU-5E-9	5-19-72	No	Paint Shaker	2.31	250.7	5275	0.2279	0.1100	A-4	Metal
NU-5-1Q	5-31-72	No	" & Qual.	2.13	215.8	5206	0.2235	0.0966	A-9	Metal
NU-5-2Q	5-31-72	No	" & Qual.	2.19	226.0	5256	0.2304	0.0981	A-10	Metal
NU-5-1	5-31-72	5-30-72	Life Test*	2.08	203.5	5314	0.2268	0.0897	A-11	Metal
NU-5-2	5-31-72	5-30-72	Life Test*	2.13	215.0	5224	0.2243	0.0959	A-25	Oxide

*RTV 615 used for polling electronics.

PERFORMANCE RESULTS FOR UNITS SEALED IN MAY

○ = OUTPUT POWER - μ WATTS
 X = UNIT EFFICIENCY - PERCENT

Figure III-13
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NU-5 R.P.C.P. PRODUCTION (ALSO SPECIAL TEST UNITS)

Figure III-14

In July '72, 25 thermopiles were wrapped and 22 batteries sealed. One thermopile had an open tape and one had a mislabeled tape leading to four tapes of the same polarity. The yield on thermopiles was 88 percent. In the battery assembly, one unit developed a short. For the NU-5 units, the yield has been 88 percent on thermopile and 95 percent on batteries.

To establish an overall yield of thermoelectric tapes (primary cost item) to finished batteries, the following yield factors should be used: Plated Tape - 0.85, Brazed Tape - 0.74, Tape Utilization Factor - 0.88, Thermopile Wrapping - 0.88, Battery Sealing - 0.95, for a total factor of about 50 percent.

The battery performance and disposition data is given in Tables III-5 and III-6. The average output has remained almost constant from the first qualification units produced at the end of May. In June, the average was 230 μ watts and was 234 μ watts in July. The output power and efficiency for these units is given in Figures III-15 and III-16.

During August, 22 thermopiles were wrapped and 11 batteries sealed. The production record for the month is included in Figure III-14. It should be noted that the delay in sealing batteries was due to the modification of the etching negative for the exterior case. Of the 22 thermopiles wrapped, only one was rejected for a broken jumper wire. Fourteen pacers were shipped during August for animal implantation. Performance data for these units assembled in August is given in Table III-7.

Thirteen thermopiles were wrapped and wired during the month of September. All 13 thermopiles were good with no rejects. Twelve batteries were assembled and sealed with 3 of the batteries being scheduled for human implant units and all others being either test units or units with low output.

The low output problem caused a slowdown in the production rate while the cause was being investigated. The problem was pinpointed as a new lot of getter pellets which did not getter properly.

The performance data for the units assembled in September and October is shown in Table III-8 and the production record for units to the end of October is included in Figure III-14. The performance of several units sealed early in November are given that indicate the gettering problem has been solved.

Table III-5

Performance Data for Units Assembled in June

<u>Unit</u>	<u>Date Sealed</u>	<u>Leak Checked</u>	<u>Disposition</u>	<u>O.C.V. Volts</u>	<u>Output μ Watts</u>	<u>Res. Ω</u>	<u>Fuel Watts</u>	<u>Efficiency</u>	<u>Fuel #</u>	<u>Type</u>
NU5-3	6-3-72	Yes	Dog	2.24	236.7	5298	0.2270	0.1043	PF-1-29	Metal
NU5-5	6-3-72	Yes	Dog	2.18	223.9	5304	0.2253	0.0994	A-2	Metal
NU5-6	6-3-72	Yes	Dog	2.26	241.7	5283	0.2279	0.1061	A-4	Metal
NU5-7	6-3-72	Yes	Qual.	2.17	225.2	5177	0.2183	0.1032	A-28	Oxide
NU5-9	6-8-72	Yes	Dog	2.26	242.1	5273	0.2286	0.1059	A-40	Oxide
NU5-10	6-8-72	Yes	Qual.	2.24	238.8	5251	0.2285	0.1045	A-51	Oxide
NU5-11	6-8-72	Yes	Dog	2.25	238.5	5258	0.2291	0.1041	A-53	Oxide
NU5-13	6-14-72	Yes	Dog	2.23	236.7	5204	0.2304	0.1027	A-10	Metal
NU5-14	6-14-72	Yes	Qual.	2.34	259.1	5282	0.2309	0.1122	A-48	Oxide
NU5-15	6-14-72	Yes	Dog	2.17	224.9	5185	0.2288	0.0983	A-58	Oxide
"B"	6-14-72	No	Special Test						No Fuel	
90T NU5-17	6-21-72	Yes	Life Test	2.18	230.3	5159	0.2244	0.1026	PF-1-15	Metal
NU5-18	6-21-72	Yes	Life Test	2.12	214.3	5242	0.2253	0.0951	PF-1-20	Metal
*NU5-19	6-21-72	Yes	Leaks	2.15	219.3	5220	0.2286	0.0959	A-39	Oxide
NU5-20	6-21-72	Yes	Dog	2.15	219.5	5214	0.2262	0.0970	A-41	Oxide
NU5-21	6-24-72	Yes	Dog	2.17	223.5	5217	0.2257	0.0990	A-37	Oxide
NU5-22	6-24-72	Yes	Qual.	2.29	247.6	5249	0.2311	0.1071	A-43	Oxide
NU5-23	6-24-72	Yes	Dog	2.17	226.4	5150	0.2301	0.0984	A-59	Oxide
NU5-24	6-29-72	Yes	Dog	2.20	229.7	5266	0.2285	0.1005	A-46	Oxide
"D"	6-29-72	No	Special Test						Dummy Fuel	
"E"	6-29-72	No	Special Test						Dummy Fuel	
"F"	6-29-72	Yes	Special Test	3.14	209.2	11780	0.2252	0.0928	PF-1-21	Metal

*Data before degassing.

Table III-6

Performance Data for Units Assembled in July

<u>Unit</u>	<u>Date Sealed</u>	<u>Leak Checked</u>	<u>Disposition</u>	<u>O.C.V. Volts</u>	<u>Output μ Watts</u>	<u>Res. Ω</u>	<u>Fuel Watts</u>	<u>Efficiency</u>	<u>Fuel #</u>	<u>Type</u>
NU5-25	7-6-72	Yes	Qualification	2.12	212.4	5289	0.2304	0.0921	A-60	Oxide
NU5-26	7-6-72	Yes	Dog	2.28	245.5	5292	0.2306	0.1065	A-61	Oxide
NU5-27	7-6-72	Yes	Life Test	2.23	235.2	5238	0.2285	0.1029	A-62	Oxide
NU5-28	7-11-72	Yes	Qualification	2.25	238.3	5263	0.2320	0.1027	A-17	Metal
NU5-29	7-11-72	Yes	Dog	2.22	233.9	5266	0.2306	0.1014	A-56	Oxide
NU5-31	7-11-72	Yes	Life Test	2.26	243.5	5244	0.2275	0.1070	A-66	Oxide
NU5-30	7-15-72	Yes	Dog	2.29	250.4	5235	0.2314	0.1082	A-65	Oxide
NU5-32	7-15-72	Yes	Shorted	1.142	122.4	2663	0.2303	0.0531	A-45	Oxide (shorted during degas)
NU5-33	7-15-72	Yes	Dog	2.17	223.3	5270	0.2286	0.0977	A-47	Oxide
NU5-34	7-15-72	Yes	Dog	2.24	238.6	5256	0.2267	0.1052	A-52	Oxide
NU5-35	7-21-72	Yes	Qualification	2.30	250.8	5273	0.2278	0.1101	A-67	Oxide
NU5-36	7-21-72	Yes	Dog	2.26	242.3	5268	0.2275	0.1065	A-68	Oxide
NU5-37	7-21-72	Yes	Life Test	2.33	257.5	5225	0.2277	0.1131	A-70	Oxide
NU5-38	7-21-72	Yes	Dog	2.19	226.7	5240	0.2276	0.0996	A-71	Oxide
NU5-39	7-25-72	Yes	Qualification	2.11	212.2	5195	0.2183	0.0972	A-28	Oxide
NU5-40	7-25-72	Yes	Dog	2.21	228.9	5286	0.2309	0.0991	A-48	Oxide
NU5-41	7-25-72	Yes	Dog	2.17	224.8	5187	0.2278	0.0987	A-54	Oxide
NU5-42	7-25-72	Yes	Dog	2.28	244.9	5305	0.2299	0.1065	A-57	Oxide
NU5-43	7-28-72	Yes	Qualification	2.15	218.3	5243	0.2235	0.0977	A-9	Metal
NU5-45	7-28-72	Yes	Dog	2.23	236.4	5211	0.2319	0.1019	A-63	Oxide
NU5-46	7-28-72	Yes	Dog	2.20	228.6	5291	0.2291	0.0998	A-72	Oxide
NU5-47	7-28-72	Yes	Dog	2.16	220.6	5286	0.2218	0.0995	A-73	Oxide

PERFORMANCE RESULTS FOR UNITS SEALED IN JUNE

PERFORMANCE RESULTS FOR UNITS SEALED IN JULY

Figure III-16

Table III-7

Performance Data for Units Assembled in August

<u>Unit</u>	<u>Date Sealed</u>	<u>Leak Checked</u>	<u>Disposition</u>	<u>O. C. V. Volts</u>	<u>Output μ Watts</u>	<u>Res. Ω</u>	<u>Fuel Watts</u>	<u>Efficiency</u>	<u>Fuel #</u>	<u>Type</u>
NU-5-48	8-4-72	Yes	Life Test	2.18	225.8	5261	0.2256	0.1000	A-74	Oxide
NU-5-49	8-4-72	Yes	Dog Test	2.22	231.0	5238	0.2238	0.1032	A-75	Oxide
NU-5-50	8-4-72	Yes	Life Test	2.07	208.0	5099	0.2272	0.0915	A-76	Oxide
NU-5-51	8-4-72	Yes	Qualification	2.12	214.2	5245	0.2229	0.0961	A-7	Oxide
NU-5-52	8-12-72	Yes	Dog Test	2.26	242.3	5268	0.2304	0.1052	A-77	Oxide
NU-5-53	8-12-72	Yes	Life Test	2.27	245.3	5205	0.2252	0.1089	A-78	Oxide
NU-5-54	8-12-72	Yes	Dog Test	2.19	229.3	5181	0.2219	0.1033	A-79	Oxide
NU-5-55	8-12-72	Yes	Dog Test	2.21	231.1	5236	0.2304	0.1003	A-80	Oxide
NU-5-56	8-17-72	Yes	Dog Test	2.22	232.9	5288	0.2290	0.1017	A-30	Oxide
NU-5-57	8-17-72	Yes	Dog Test	2.25	238.6	5255	0.2285	0.1044	A-51	Oxide
NU-5-58	8-17-72	Yes	Qualification	2.17	227.7	5120	0.2318	0.0982	PF-1-13	Metal

Table III-8

Performance Data for Units Assembled in September and October

<u>Unit</u>	<u>Date Sealed</u>	<u>Leak Checked</u>	<u>Disposition</u>	<u>O. C. V. Volts</u>	<u>Output u Watts</u>	<u>Res. Ω</u>	<u>Fuel Watts</u>	<u>Efficiency %</u>	<u>Fuel #</u>	<u>Type</u>
NU-5-60	9-12-72	Yes	Life Test	2.19	235.2	5051	.2295	.1025	A-55	Oxide
NU-5-61	9-12-72	Yes	Human Implant	2.21	230.8	5241	.2289	.1008	A-29	Oxide
NU-5-62	9-12-72	Yes	Human Implant	2.13	214.9	5227	.2286	.0940	A-39	Oxide
NU-5-63	9-12-72	Yes	Human Implant	2.21	229.5	5271	.2304	.0996	A-60	Oxide
NU-5-64	9-15-72	Yes	Cut Open - Gas	.796	--	5290	.2263	--	A-42	Oxide
NU-5-65	9-15-72	Yes	Cut Open - Gas	1.60	--	5270	.2311	--	A-43	Oxide
NU-5-67	9-15-72	Yes	Cut Open - Gas	.758	--	5270	.2296	--	A-44	Oxide
NU-5-69	9-20-72	Yes	Spec. Test	.963	--	5280	.2205	--	A-81	Oxide
*NU-5-68	9-20-72	No	Qualification	1.94	179.2	5249	.2244	.0799	PF-1-19	Metal
NU-5Q-60	9-22-72	Yes (2 tapes)	Spec. Test (no getters)	1.260	--	15,725	.2241	--	PF-1-28	Metal
NU-5Q-63	9-22-72	Yes	Spec. Test (6 new getters fired)	1.680	--	15,642	.2235	--	A-9	Metal
III NU-5Q-68	9-27-72	Yes	Spec. Test	2.22	--	15,657	.2320	**.1018	A-17	Metal
Test #3	10-19-72	Yes	Spec. Test	.449	--	5,173	.2241	--	PF-1-28	Metal
GT-2	10-24-72	Yes	Spec. Test	.344	--	15,780	.2235	--	A-9	Metal
Test #1	10-25-72	Yes	Spec. Test	1.602	--	6,658	.2320	--	A-17	Metal
GT-2	10-26-72	No	Cut Open - No Leak Check	2.14	--	15,828	.2235	**.0971	A-9	Metal
Test #3	10-26-72	Still sealed-reheated this date		.446	--	5,222	.2241	--	PF-1-28	Metal
GT-4	10-30-72	Yes	Spec. Test	.354	--	15,664	.2239	--	A-32	Oxide
GT-5	10-31-72	No	Spec. Test	1.494	--	15,928	.2237	--	A-34	Oxide
GT-6	11-1-72	No	Spec. Test	1.562	--	16,070	.2303	--	A-45	Oxide
GT 5	11-2-72	No-Cut Open-Reheated This Date		2.24	--	15,775	.2237	**.1066	A-34	Oxide
GT-7	11-2-72	No	Spec. Test	2.17	--	15,429	.2314	**.0989	A-64	Oxide

*Second degas run and closure

**Corrected to 6 tape performance

3. Critical Components - Inspection Summary

During the month of Aug.'72, a new form was established to accommodate all pertinent inspection data accumulated from dispositioning action of Quality Control and the weekly Material Review Board (MRB). The new form summarizes weekly the total components inspected. The total percent accepted and the total percent used for Special Test are shown as a result of the Quality Control inspection and the Material Review Board action. Special Test components are used for Qualification Units or Safety Test Units. This form is distributed to all Engineering personnel responsible for manufacturing and assembling the RPCP components. Table III-9 is a summary of material inspected for the months of August, September, and October, 1972.

TABLE III-9
AUGUST, SEPTEMBER, OCTOBER INSPECTION SUMMARY

<u>Description</u>	<u>Q.C. Inspection</u>			<u>Total Reviewed</u>	<u>MRB Action</u>		<u>R W</u>	<u>Total Rej</u>	<u>Accept Total</u>			<u>% Acc</u>	<u>% Test</u>
	<u>Total Insp.</u>	<u>Total Acc</u>	<u>Total N.C.</u>		<u>Total Acc</u>	<u>For Test</u>			<u>Q.C. Acc</u>	<u>MRB Acc</u>	<u>Total Acc</u>		
Brazed Tapes	536	337	199	199	39	33	1	126	337	39	376	70.1	6.2
Coated Ceramic Tabs	1451	1204	247	247	14	0	25	208	1204	14	1218	83.9	0.0
Tophel Plated Tapes	684	640	44	44	0	0	0	44	640	0	640	93.5	0.0
Cupron Plated Tapes	694	601	93	93	14	13	0	66	601	14	615	88.6	1.9
Insulation Tape	11 RLS	11	0	0	NA	NA	NA	0	11	0	11	100.0	0.0
Al ₂ O ₃	12530"	12530"	0	0	NA	NA	NA	0	12530"	NA	12530"	100.0	0.0
Degass	11730"	9621.5	2108.5	2108.5	780	0	0	1328.5	9621.5	780	10401.5	88.7	0.0
Cut Strips	766	766	0	0	NA	NA	NA	0	766	NA	766	100.0	0.0
NiTi Feedthroughs P/R	64/11	10/7	52/6	44/6	11/0	14/6	2/0	14	17	11	28	43.8	31.2
CuAg Feedthroughs	22	21	1	1	0	1	0	0	21	0	21	95.5	4.5
Hot Inner Capsule Plug	4	4	0	0	NA	NA	NA	0	4	NA	4	100.0	0.0
Cold Straps	56	39	17	17	2	15	0	0	39	2	41	73.2	26.8
Hot Shoes	81	81	0	0	NA	NA	NA	0	81	NA	81	100.0	0.0
Cold Shoes	321	321	0	0	NA	NA	NA	0	321	NA	321	100.0	0.0
I.C. Ceramic Tabs	1992	1986	6	6	0	0	0	6	1986	0	1986	99.7	0.0
I.C. Tophel Tape	482	405.0	77	77	0	0	0	77	405	0	405	84.0	0.0
I.C. Cupron Tape	468.6	415.9	52.7	52.7	0	0	0	52.7	419.9	0	419.9	89.6	0.0
Insulation Circles	1782	1782	0	0	NA	NA	NA	0	1782	NA	1782	100.0	0.0
Electronics Case	67	62	5	5	0	0	0	5	62	0	62	92.5	0.0
Exterior Case	184	107	77	77	14	15	15	33	107	14	121	65.8	8.1
Ext. Case Feedthrough Flange	10	10	0	0	NA	NA	NA	0	10	0	10	100.0	0.0

AUGUST, SEPTEMBER, OCTOBER INSPECTION SUMMARY

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B. System Design Developments and Performance Evaluation

1. Primary Design Changes from Prototype to Production Units (NU-4 and NU-5)

Most of the originally proposed component changes evolved from the cost reduction design reviews are revisions and simplifications to that portion of the system external to the nuclear battery. The differences between the prototype and the production unit are seen in Figure III-17 (prototype) and Figure III-18 (production). With the new design a substantial increase in the volume available for electronics is obtained in line with Phase II design objective requirements.

The same basic termination is maintained on the Phase II design, however, it has been rotated 90° to widen the electronics case. A titanium ring has been added to prevent inadvertent attempts to remove the captive set screw through the epoxy. The electronics case has been simplified to a one weld closure design using a drawn case that is integral to assembly of the battery lid.

An electron beam closure plug has been added so that a simple and reliable TIG weld can be used to attach the electronics case and lid assembly to the outer case. This substantially reduced final weld closure costs. With this design, units can easily be set up for welding without offgassing apparatus and groups of nuclear batteries can be offgassed in the EB welding chamber and closed with one pumpdown cycle.

Cost reduction design modifications also include self-fixturing feedthroughs, elimination of the epoxy holder, and replacement of 080 screws for ground connections with a spot welded 0.010 inch diameter tantalum wire. The battery output feedthrough is hermetically sealed with a copper-silver braze with a copper wire (this feedthrough is more reliable and uses a lower temperature braze) to permit soldering to copper electronics wires. A spot welded nickel tab is used in place of the EB welded platinum wire previously used for the electronics ground connection.

Additionally, the fuel loading has been reduced from 0.238 ± 0.024 watts to 0.226 ± 0.012 watts which is advantageous for a number of reasons and still achieves an adequate output power.

A tantalum hot strap 0.003 inch thick* with 0.004 inch thick titanium tabs on the hot side ceramic shoes are expected to give the RPCP better

* Annealed 0.003 inch material is optimum for weight and fabricability.

Figure III-17

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Figure III-18

Reproducible copy is not available

cremation capabilities and reduced cost. The tantalum readily spot welds to the titanium thus the hot strap does not require the elaborate tab arrangements previously used.

All basic changes such as the use of the tantalum hot strap with titanium hot shoes, the new support bracket, etc. were fully evaluated from both an assembly and performance effect before incorporating into the final design. Details on these evaluations will follow.

2. Component Weights (Prototype and NU-5)

A tabulation of individual and system weights for the prototype (Table III-10) and for the final production unit, NU-5, (Table III-11) are given for comparison.

The fuel weights are similar. The thermopile weight is higher primarily due to the extra insulation tape needed for the shock and vibration capability of the dog environment. This is discussed in more detail in other sections. The case component weights are lower. The electronics package is heavier because of the circuit design change. The overall effect on system weight was an increase of only 7 grams for a greatly improved reliability.

3. Heart Lead Terminal Block

A free rotation has been provided for the captive set screw. The design is as shown in Figure III-19. Torque tests were performed on the Ti-Al-V set screws as a possible replacement for plain titanium in both commercially pure titanium and Ti-Al-V terminal blocks. All components successfully exceeded the yield strength of the Allen wrench (≈ 9 in-lb) and no difference could be determined in the two types of materials. As a result, the commercially pure titanium was used since it has been employed successfully for the implant and life test units. Results with this block have been excellent.

4. Support Bracket

An opportunity for significantly reducing costs of the basic RPCP battery was in the design of the thermopile support. The prototype used a two piece (brazed to lid) beryllium copper heat sink, and two separate titanium brackets were used for supporting the ends of the thermopile support and heat sink. A comparison of the thermal results of the proposed one piece Ti bracket were made. These results are plotted as temperature

TABLE III-10

PROTOTYPE RPCP WEIGHT TABULATION*

	<u>Weight (grams)</u>
<u>Heat Source</u>	
Fuel and Ta Tubing	1.158
Inner Capsule and Plug	8.856
Middle Capsule and Plug	2.734
Platinum	0.471
Outer Capsule and Plug	<u>2.912</u>
Sub-total	16.131
PF-1-4 } actual	18.4405
PF-1-2 }	17.4561
<u>Thermopile</u>	
Hot Strap	1.3405
Thermocouple tape (6)	
Sub-Assembly	14.4204
Insulation Tapes (24)	9.2310
Cold Strap	<u>1.7915</u>
Sub-total	26.7834
	(P-2) 26.4125
<u>Hermetic Case and Support Structure</u>	
Beryllium Copper Heat Sink and Thermopile Holder	4.1783
0-80 Screws	.1395
Titanium Support Brackets	1.1993
4-#0 Flat Washers	.0575
Titanium Lid with Backup Strip	7.9244
Titanium Outer Case	18.5210

* Almost all components weighed except epoxy.

TABLE III-10 (continued)

	<u>Weight (grams)</u>
Feedthrough - 1 ea.	.3357
End Shields (including getter basket)	
.010" Ti inner and getter basket, 2 ea.	1.6190
.005 inch End Plates - 2 ea.	.6050
Getters (6)	.3060
Epoxy Holder	.1851
Titanium Brackets (3)	.2210
Ceramic Tube - 1 ea.	<u>.7131</u>
Sub-total	36.0049
<u>Hermetic Electronics Package</u>	
Electronics Package	5.8508
Electronics Case less Feedthroughs with lid	7.0884
Feedthroughs (wire included - 2)	.7348
RIV	1.0970
Brackets (2)	.0890
Titanium Terminal Block	
(Including set screw)	<u>.7001</u>
Sub-total	15.561
<u>Heart Lead</u>	
Epoxy	<u>15.0000</u>
Sub-total	15.0000
Weight - complete Nuclear Battery	79.5285
Weight - Completed unit less heart lead	112.9060

Table III-11

Production Model NU-5 Weight Tabulation*

<u>Heat Source</u>	<u>Weight (grams)</u>
Fuel	<u>.500</u>
Inner Capsule & Plug	<u>9.338</u>
Middle Capsule & Plug	<u>3.805</u>
Outer Capsule & Plug	<u>2.912</u>
Platinum on Middle Capsule (Calculated)	<u>.471</u>
Subtotal	<u>17.026</u>
Fuel #A-57	<u>17.044</u>
<u>Thermopile</u>	
Thermocouple Tapes (6)	<u>15.540</u>
Insulation Tapes (18)	<u>13.965</u>
Hot Strap	<u>1.734</u>
Cold Strap	<u>1.786</u>
E-glass Yarn, Ceramic Tubing, Bus Connector Wire	<u>.178</u>
Subtotal	<u>33.203</u>
<u>Case Components</u>	
Titanium Outer Case	<u>18.763</u>
Titanium Outer Case Lid with Feedthrough	<u>6.966</u>
Thermopile Support Bracket Assembly	<u>2.463</u>
Thermopile Retainer Strap	<u>.066</u>
Closure Plug	<u>.029</u>
Electronics Case with Feedthrough Ground Connector	<u>3.942</u>
Electronics Case Lid with Temperature Indicator	<u>1.088</u>
Subtotal	<u>33.317</u>
<u>Getter Baskets Assemblies</u>	
Getter Baskets (2)	<u>.322</u>
Getter Pellets (6)	<u>.318</u>
Getter Supports (2)	<u>.174</u>
Getter Filters & Cover Plates (2)	<u>.208</u>
Subtotal	<u>1.034</u>

*All individual components weighed except epoxy.

Table III-11 (continued)

Heat Shields

Glass Heat Shields (2 sets)	<u>1.212</u>
Titanium Heat Shields (2 sets)	<u>3.708</u>
Subtotal	<u>4.920</u>

Electronics Components

Electronics Circuit	<u>16.115</u>
Kapton (2 pcs) & RIV	<u>.898</u>
Subtotal	<u>17.013</u>

Terminal Block

Terminal Block Assembly	<u>.690</u>
Subtotal	<u>.690</u>

Totals

Completed Pacemaker Less Epoxy & Heart Lead	<u>107.203</u>
Epoxy Weight	<u>13.597</u>
Heart Lead Weight	<u>5.437</u>
Completed Pacemaker Without Heart Lead	<u>120.8</u>
Completed Pacemaker With Heart Lead	<u>126.237</u>

CAPTIVE SET SCREW WITH FREE ROTATION

Figure III-19

differences across the thermocouple tapes versus input power in Figure III-20. The performance data for all prototype units was plotted for comparison as well as the best estimate and minimum expected curves from the experimental model data, Figure G, Reference 1. The results of the electrically heated test with the prototype heat sink was only several degrees (≈ 1 percent) lower than the predicted values and well within experimental error. The results with a titanium heat sink and a unit without a heat sink were also within experimental error of the predicted curve. The support has a lower weight and cost with no significant effect on thermal performance based upon the above results.

To hold the thermopile in place in the one piece bracket, an 0.001 inch thick titanium strap is used. This is easily spot welded to the titanium bracket. The single piece support is made with the end slightly spread so that the case adjusts to actual spacing across the end shields. Also, there is a press fit between the curved portion of the support and the outer case pressing the aluminum cold strap against the outer case assuring no significant temperature gradient between the cold strap and the case.

Results of Phase I unit dog implants indicated that greater shock capability was needed in the production units. Part of the method to assure greater shock capability was having a greater support in the axis of the fuel. A new mechanically firm insulation (which will be discussed separately) and an improved end shield assembly support bracket with a cross brace were developed. Compression tests showed the improved bracket to have over twice the yield load (200 to 100 pounds) and almost three times the ultimate loading (327 to 123 pounds).

5. Tantalum Hot Strap, Titanium Hot Shoe Tabs, and Getter Basket

Based upon cremation tests reported in Reference 2, recommendations were made for changes in materials for the hot strap and the hot shoe tabs. The purpose was to avoid having the copper contiguous to the fuel capsule because it readily alloyed with the titanium of the outer fuel capsule. The recommendations were as follows:

Reference 1 - "Radioisotope Powered Cardiac Pacemaker Design Objective Optimization", September 1969.

Reference 2 - "Safety and Radiation Report", Phase I, June 29, 1970, pp. 94-101.

THERMAL PERFORMANCE TESTS ON CHANGE IN HEAT SINK DESIGN

- (a) Hot Strap: Fabricate the hot strap from annealed tantalum of 2 to 5 mils thickness. In this condition the metal is soft and easily formed. It does not combine with titanium below 1680°C, the melting point of titanium. Above this temperature it forms solid solutions with increasing melting temperatures. The solubility of copper and silver in tantalum is very small.
- (b) Hot Shoe Tabs: Substitute titanium for the copper tab on the ceramic shoe. Titanium can be used without changing the shoe braze or tape brazing procedure. In the prototype design, the copper shoes are spot welded to tabs on the copper hot strap. Tests have shown the titanium to tantalum spot weld to be stronger than the copper to copper weld.

These recommendations were contingent upon successfully producing a thermopile with this design and obtaining good thermal performance data. The first unit assembled with the new hot strap and tab design was XP-9. The performance was equal to or slightly better than the best estimates previously reported, Figure III-20. Based upon this data, it was felt that the proposed design changes could be made without an adverse affect on performance. The selected materials were 0.003 inch tantalum for the hot strap and 0.004 inch titanium for the tabs.

A first attempt at constructing a model with titanium hot tabs on the tape ceramics indicated that the tabs had to be bent before final assembly to the tantalum hot strap. This was not done on XP-9 and the tabs did not lay flat against the hot strap. In this condition, the edge of the ceramic could press against the insulation of the tape passing over it. A simple fixture was made which showed that the tabs can be bent and the ceramics should lay fairly flat against the hot strap. This was done for the XP-10 unit with excellent results. Also, the thermal performance on XP-10 was good.

An additional advantage of the present design is the holding of the bottle cap type getter baskets inside the ends of the extended hot strap with welded tabs. This gives the same support mechanism to the fuel (end shields through getter baskets in the axis of the fuel) with an improved strength in the , getter basket which cannot move out of position, as has occurred under severe shock and vibration in prototype units.

Subsequent tests indicated a need for some extra support of the getter basket to keep it from collapsing during the extensive shock and vibration testing. This collapse led to broken pellets and loose end shields. A "Y" shaped pellet separator along with the extra strength of the "Y" solved these problems.

6. Insulation and Thermoelectric Tapes

One very significant cost reduction item was the use of two 0.003 inch thick E-glass insulation tapes instead of four 0.0015 inch thick tapes per thermocouple tape sub-assembly. The thicker insulation tape costs less per unit length and only one half as much is used, thus the insulation tape cost is reduced by more than one half. Additionally, two insulation tapes require only one half as much sewing time.

The first unit fabricated with two insulation tapes was XP-8 which had the prototype hot shoes and hot strap. The center and outer insulation tapes were both sewn to the cupron thermoelectric tape.

The thermal performance of this unit was evaluated by electrically heated tests. Using the new electrical heater, these tests were performed on a comparison basis with a standard prototype thermopile (P-7) under similar boundary conditions. The results were plotted as temperature difference across the thermocouple tapes versus input power similar to Figure III-20. In general, the electrical heated test results from the prototype (P-7) were in agreement with the expected curve indicating good experimental technique. The test unit (XP-8) had a poorer thermal performance, being near the lower limit curve. Thus, it appeared that the fewer thicker insulation tapes may be less effective as thermal radiation shields even though the amount of glass fibers for reflection are nearly equal. The 0.0015 inch tape (9-19/32 inches long) weighed 402.2 mg whereas the same length of the thicker insulation weighed 747.3 mg. It was felt that a better quality insulation with a tighter weave would have better performance.

The insulation quality was greatly improved along with the cleaning process resulting in whiter and generally higher quality insulating tapes. It was found preferable to put the insulation on the tophel thermocouple tape. Also, the fuel from unit P-6 was available so that a fueled test could be performed. Based upon experience with previous comparisons of fueled systems and the electrically heated tests, there was felt to be no difference

between electrically heated and fueled data. Previous tests with the titanium hot tabs and tantalum hot strap XP-9 did not show a significant (possible slight improvement) change in thermal performance. Thus, it appeared that properly prepared insulation tapes of 0.003 inch thickness could be used to obtain good thermal performance. Therefore, the two insulation tape design was recommended for the Phase II production units.

However, subsequent results from implanting these NU-4 units in dogs indicated there was not adequate support for the fuel due to the high shock and rotational vibration levels. To improve the shock and rotational vibration capabilities (as discussed in more detail in other sections) a third layer of 0.003 inch insulation was required.

It may be significant that the thermal performance of the NU-4 units averaged significantly (≈ 270 versus 235μ watts) higher than the prototype units. Whereas, the NU-5 units with the three layers of insulation per thermocouple tape had an almost identical performance to the prototypes. This may mean that the tightness and, hence, conduction losses were about equal in the prototype and the NU-5 (high shock and vibration capabilities) units but not in the NU-4.

Also, to improve support of the end shield assemblies and reduce the time for sewing insulation tape, a wider border (corresponding to the full length of an extended hot strap) was utilized in the Phase II units thermocouple tapes.

For maximum strength and capability, a cost reduction attempt using a PVA sizing had to be discontinued going back to the Phase I starch oil binder. Also, as shown in Table III-12, the thermal performance was lowered with tapes having PVA sizing. Details on this evaluation are given in quarterly reports (see Thermal Tests in this task for additional thermal performance details). The only other basic design changes in the thermoelectric tapes were the use of the titanium hot shoe. Changes in fabrication methods for cost reduction, which will be discussed in the section on Fabric Development, did not affect the tape design which remained 88 wires, 0.002 inch diameter cupron special 8.35 inches long and 0.0025 inch diameter tophel 8.5 inches long.

Table III-12

Performance for Production RPCP Units
with PVA Sized T/C Tapes

	Minimum Fuel $Q_{I_{BOL}} = 0.214$ watts		Nominal Fuel $Q_{I_{BOL}} = 0.226$ watts		Maximum Fuel $Q_{I_{BOL}} = 0.238$ watts	
	BOL	EOL	BOL	EOL	BOL	EOL
Power, μ watts	174	154	185	165	207	178
E_{OC} , volts	1.916	1.80	1.975	1.866	2.090	1.938

Best Estimate Performance
RPCP Units with Starch Oil Binder T/C Tapes

	Minimum Fuel $Q_{I_{BOL}} = 0.214$ watts		Nominal Fuel $Q_{I_{BOL}} = 0.226$ watts		Maximum Fuel $Q_{I_{BOL}} = 0.238$ watts	
	BOL	EOL	BOL	EOL	BOL	EOL
Power, μ watts	193	170	205	183	230	198
E_{OC} , volts	2.02	1.90	2.08	1.97	2.20	2.04

7. Ground Wire and Output Wire

To reduce costs the 080 set screws were eliminated and spot welding alone was used for the ground connection. Tests have shown that excellent spot welds can be made directly from the 0.0045 inch diameter cupron special wire jumpers to the 0.010 inch thick titanium thermopile support bracket. The wires will contain a 2 turn coil to eliminate possible forces on the braze joint at the ceramic. The wires are connected as shown in Group 3, Drawing 15-D-4189-4, Figure III-21.

An improvement has also been made in the connection of the output lead. Redundant connections and improved insulation at the ends of the tapes as shown in Drawing 15-D-4189-4, Figure III-21 are used. These changes have no effect on thermal performance.

8. Copper-Silver Braze Feedthrough to Battery

In the production unit, Figure III-18, the feedthrough to the nuclear battery is inside the electronics case and is thus completely protected from body fluids. Therefore, corrosion is not a consideration and a silver-copper braze was recommended for the feedthrough. The wire is copper. The silver-copper braze not only flows well but the eutectic temperature ($\approx 860^{\circ}\text{C}$) used for brazing is significantly ($\approx 200^{\circ}\text{C}$) lower than any of the other brazes developed. This means less distortion of the case, insignificant grain growth in the titanium, (which takes place at $\approx 1000^{\circ}\text{C}$) and best of all gives a leak tight braze using a ductile wire. This wire has a cupron wire brazed to it during the feedthrough braze which can be connected to the electronics with low temperature solder without any extra preparations. These advantages made it the best possible selection as a feedthrough for the pilot production units of Phase II. Drawing 15-D-4189-10, Figure III-22, illustrates the feedthrough.

9. Closure Technique

One of the primary changes in the production design from the prototype was the use of TIG welding the lid and electronic case in place and then offgassing more than one unit at a time and sealing by EB closure of a plug. This plug is self-fixturing and is brazed to the lid with the lid feedthrough. Tests were performed that proved the technique of TIG welding and the EB closure. Also, there was no problem in obtaining a good vacuum in the pacer

Figure III-21

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Figure III-22

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by pumping out through the closure plug. This closure is made while the unit is still hot helping to improve the vacuum. The time constant for the output voltage was the same during pumpdown in the FB chamber ~ 2 hours as it had been for the open thermopile in the CVC vacuum system. These test results were confirmed by subsequent successful results of the pilot production units.

The seal is made in a vacuum of $\approx 5 \times 10^{-6}$ torr, at approximately 300°C average temperature. After cooling and gettering action, the vacuum is even better. As can be seen in Figure III-23 of the next section, this assures maximum performance. The performance is actually better after closure than at vacuum before degassing. Complete details of the welding, degassing, and testing are given in the process specification book.

10. Gas Pressure Test on Prototype Unit XP-9

In order to determine the actual affect of gas pressure in an assembled pacer on output power, tests were made with nitrogen and helium from the micron range to one atmosphere pressure. The tests were conducted on the unsealed unit XP-9. This pacer was sealed in a glass vacuum system in which pressures could be monitored with a mercury McLeod gauge, thermocouple gauge or mercury monometer. Voltage, resistance, and case temperature measurements were made through glass-to-metal electrical feedthroughs. For each particular measurement, gas was introduced to a predetermined pressure and measurements made until a constant open circuit voltage was reached. This time period was about 8-12 hours. The resistance of the thermopile remained the same throughout the tests ($\sim 47,300\Omega$). Open circuit voltage under high vacuum was consistently about 5.92 volts.

Helium is a gas with very high thermal conductivity (360×10^{-6} cal/sec cm^2 °C/cm) and was used to compare results with nitrogen which has a thermal conductivity (62.4×10^{-6} cal/sec cm^2 °C/cm) comparable to the gases that might accumulate in a pacer.

The results of these tests are shown in Figure III-23 which indicate that performance is severely affected in the 30 to 1000 μ range of pressure but is roughly independent of the thermal conductivity of the gas.

The performance becomes independent of pressure above a few mm of mercury and does show the effect of large differences in thermal conductivity.

PACER UNIT XP-9
6 TAPES IN SERIES

Figure III-23

11. Case Design

As discussed previously, the production unit uses the single piece deep drawn titanium case developed for the prototype. In addition to all of the other requirements including basic implant environment, dimensional, and weight objectives, there was a requirement that the unit can withstand four atmospheres of external pressure with no adverse effects.

Three outer cases and lids were hermetically sealed under vacuum to simulate the actual vacuum inside a completed pacemaker battery. These three cases were then externally pressurized to four atmospheres and their size measured to check the ability of the outer case to withstand four atmospheres of external pressure. The maximum dimensional change in height, length, and width was two thousandths. This small change should not affect the operation of completed units in any way. The three units were then externally pressurized to five atmospheres with negligible additional dimensional change. The test showed the outer case can easily withstand four atmospheres of external pressure with no sufficient change in dimensions. The ability of completed units to withstand four atmospheres has been demonstrated during the testing stages of the Phase II pacemakers as discussed in Task 2.0 and 4.0.

12. Thermal Tests (Evaluation of End Shield Design Change for Design NU-4)

As a result of the RPCP Phase I dog implant data, an end shield arrangement was developed to prevent general disarray of these components. A mechanically firm, thermally efficient end shield assembly of alternate layers of flat titanium shields and woven glass tape was used. This type of assembly was developed to lessen the movement of end shields (previously rolled foils only with low spring constant) and large motions of the thermopile which can lead to thermocouple wire damage. Extensive thermal and shock tests were performed on various designs as shown in Table III-13. The final design had a power output within the expected experimental variations of the prototype design.

TABLE III-13

THERMAL PERFORMANCE TESTS
REVISED PRODUCTION DESIGN

Evaluation of End Shield Assemblies

Input Power, Q = 0.2243 watts

XP-11*

<u>Date</u>	<u>End Shield Descriptions</u>	<u>O.C.V volts</u>	<u>Output Power μwatts</u>	<u>Unit Resistance ohms</u>
9-1-70	Regular rolled foils	6.06	195	47,050
9-2-70	Machined MINK-1200	3.80	76	47,464
9-3-70	Machined MINK-1200 spacing loosened	5.08	136	47,468
9-4-70	15 flat 0.001" Ti foils with 2-0.003" and 1-0.001" woven glass spacers	5.60	165	47,635
9-8-70	30 flat 0.001" Ti foils with 30-0.003" woven glass spacers	5.90	183	47,588
9-9-70	Same except Model K-500	5.60	165	47,603
9-10-70	Same except tantalum	5.48	158	47,603
9-11-70	Same except aluminum	5.69	170	47,492
9-14-70	26 flat 0.001" Ti foils 26-0.003" woven glass spacers 1 rolled Ti at getter basket 1 rolled Ti at support plate	6.07	193	47,544
	XP-12 ^{**, ****}			
9-17-70	26 flat 0.001 Ti foils 26-0.003" woven glass spacers 1 rolled Ti at getter basket 1 rolled Ti at support plate	1.97	184	5,283
	XP-14 ^{***, ****}			
10-15-70	26 flat 0.001 Ti foils 26-0.003" woven glass spacers 1 rolled Ti at getter basket 1 rolled Ti at support plate	2.00	188	5,320
	XP-15 ^{***, ****}			
10-30-70	26 flat 0.001 Ti foils 26-0.003" woven glass spacers 1 rolled Ti at getter basket 1 rolled Ti at support plate	2.11	210	5,250

* Thermopile only, hot assembled in a case

** Assembled in a case but not sealed

*** Complete sealed battery

**** Redundant thermocouple tape arrangement

The thermal performance results for the tests are plotted in Figure III-24. Generally the new design results are equivalent to XP-11 using the prototype end shield assembly. The available data was plotted on a peak power curve, Figure III-25. Using a thermopile resistance (R) of 5273 ohms, the predicted open circuit voltage was determined using:

$$E_{OC} = 4 P_{out} R$$

E_{OC} = open circuit voltage (volts)*

P = electrical power out (watts)

R = thermopile resistance (ohms)

The curve as drawn did not factor in the XP-15 data since it was singularly higher at the time of these tests. Unit XP-15 had a more exact spacing and fabrication of end shields and was more representative of future production pacer performance. However, to be conservative the median data was used. The results were as follows:

	Minimum Fuel		Nominal Fuel		Maximum Fuel	
	$Q_{I_{BOL}} = 0.214$ watts		$Q_{I_{BOL}} = 0.226$ watts		$Q_{I_{BOL}} = 0.238$ watts	
	BOL	EOL	BOL	EOL	BOL	EOL
Power, μ watts	174	154	185	165	207	178
E_{OC} , volts	1.916	1.80	1.975	1.866	2.090	1.938

Subsequently a unit was fabricated using the new thermoelectric tapes with the wider border. This wider border gives the outside wires of the tapes extra protection and facilitate sewing of insulation to the tapes. The unit had insulation tapes that were woven with starch oil binder, which gives a stronger and tighter woven insulation. Also, nine foils on each end were made with Rodney foils. In some previous tests with rolled foils, Rodney foils had poorer performance than the Hamilton foils usually used. However, a very long delivery date and a much higher cost made it desirable to reevaluate Rodney foil with the new glass and foil sandwich insulation.

The unit was tested in an open fixture using measurements from two tapes. Also, some tests were performed in a case with the production support bracket. The results of the tests showed:

- (a) At the nominal end shield spacing (1.965 inch) the performance was poor ($\approx$ 15 percent low on open circuit voltage). However, by opening the spacing to 1.990 inch the performance was equal to that in previous tests of XP-15 (Figure III-25).

*This voltage becomes critical in the redundantly wire thermopile with the new electronics.

THERMAL PERFORMANCE TESTS USING PRODUCTION TYPE THERMOPILE WITH PROTOTYPE AND PRODUCTION END SHIELDS ASSEMBLIES

Figure III-24

PREDICTING END OF LIFE PERFORMANCE FOR THE PRODUCTION RPCP FROM EXPERIMENTAL DATA

REF. I, RPCP DESIGN OBJECTIVE OPTIMIZATION, SEPT, 1969, pp44
 NUMEC 3731-21

Figure III-25
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- (b) It was found that the getter baskets were too deep for the hot strap. By changing to 0.070 inch getter baskets instead of 0.080 inch the performance was only ≈ 3 percent low on open circuit voltage at the nominal spacing.
- (c) With the same spacing and getter baskets, all Rodney foil end shield assembly performance was not significantly (< 1 percent) lower than with the unit using 16 Hamilton and 9 Rodney foils.

These results had the following effect upon the production unit design:

- (a) The wider border tapes can be used with no degradation of performance.
- (b) Similarly the starch oil binder insulation tapes can be used.
- (c) The possibility of degrading performance by having too tight a spacing will be corrected using 0.070 inch getter baskets instead of 0.080 inch and taking 0.010 inch from each support bracket. To have more adjustment in tightness one extra rolled foil is used at each end. This extra foil can be removed if a unit is too tight at final assembly.
- (d) Rodney foils can be used to complete the end shield assemblies for the pilot production units and can be used for all foils in future units.

Subsequent units used for trial assemblies XPD-1, XPD-2, and XPD-3 averaged $\approx 15\%$ higher than the predicted curve. An experimental fourth unit also ran high as seen in the table below. The first production units starting with PD-1 and including the first 15 NU-4 units averaged about 270μ watts. Neglecting a problem of internal gas found in the first units leak checked (leak check fixture problem) the performance was as follows:

Unit	Power watts	Open Circuit Voltage Volts	Resistance ohms	Fuel Load watts
XPD-1	262.5	2.38	5392	0.222
XPD-2	235.3	2.21	5143	0.222
XPD-3	238.5	2.26	5353	0.224
XPD-4	248	2.29	5260	0.225
PD-1 or NU-4-1	262	2.36	5315	0.225

As reported in other sections, subsequent failures in dogs lead to the addition of electrical insulation to obtain a tighter wrap causing the average power to be reduced to $\approx 235\mu$ watts.

13. Dog Tests

Visits to NH&LI were made for the purpose of observing the activity of dogs with implanted pacers to try and correlate pacer failures with activity level of the dogs. Each dog was categorized with respect to dog size, breed, and activity level.

Tests were planned at NH&LI using a telemetry package which would be strapped to the side of the dog. These tests would indicate the acceleration loads generated by the dog in its normal activity. The harness to hold the package was made and the telemetry equipment received. The dog to be used for this test was one in which a failed pacer was removed.

A pacer with a thermopile only was tested at ARCO Nuclear. The pacer was strapped to the side of a dog with a harness. A pedometer was also attached to the harness to register the activity level of the dog. The purpose of this test was to try and duplicate failures that were experienced at NH&LI. A run and kennel which closely simulated the kennels at NH&LI was built and housed the test dog.

Since several pacers had failed in canine subjects, it was felt that the acceleration forces exerted on pacers by dogs should be characterized. The acceleration was to be monitored in all three spatial axes by a self-powered telemetry unit mounted on the dog and then sent via a FM radio link to a remote receiving site. The use of this type of system allowed the maximum freedom of movement for the subject and the data would be highly representative of the subject's normal behavior. This data could later be extrapolated to the human environment.

The telemetry unit was approximately the same weight and size of a pacer and was mounted on the dog at the normal site used for pacer mounting. Furthermore, the subjects used would be dogs who have had pacers implanted and subsequently removed, thus including in the test any changes brought on by the pacer implantation.

Pacer NU-4-57 which was on a dog at ARCO showed no tape failures after three months. The pacer was a complete unit with a simulated heat source and no electronic circuit. This test was terminated due to the long test period with no tape failures.

A test program was initiated to evaluate the acceleration levels generated by a dog during its daily routine. A dog at ARCO was tested using a telemetry package attached by a special harness. The telemetry

unit housed three accelerometers capable of measuring acceleration in three planes. The receiver was remotely located. The dog's actions were continuously monitored while she ran, jumped, shook, etc. The maximum "g" level recorded was 10 g's. Further testing was done at NH&LI using a larger dog. Due to interference from the wire in the cage, all testing was done outside of the kennel area. Further testing at NH&LI was planned which would be done inside the cage using a receiver antenna mounted inside the cage.

There were several high g levels recorded during the tests that were in the 45-50 g region. One such g level was experienced during a run when the dog may have turned sharply. Another high g level occurred while the dog resisted being led on a leash. The relative occurrence of such activities must be investigated further. However, it is obvious that the shock and vibration to which the dogs subject the nuclear pacer is far more severe than that in human patients both in magnitude and frequency.

14. Telemetry Equipment (Shaker Characterization)

A new model of the Sherwin Williams paint shaker (identified as Sherwin Williams, manufactured by Miller Manufacturing Company of Illinois) was purchased. The new and old model were characterized using the microcom telemetry equipment. The accelerometer-transmitter unit was mounted in both the fixed and taped configuration on a paint can which was in turn mounted on either the old or new shaker.

Two separate series of tests were conducted on the old shaker unit with widely varying results. The numerical results for the circumferential and radial axes are tabulated as follows for the two series of tests.

Old Shaker Unit

<u>Series</u>	<u>Method of Mounting Telemetry Unit</u>	<u>g Level in Circumferential Axis</u>	<u>g Level in Radial Axis</u>
I	fixed	+28, -24	+5, -10
I	taped	+38, -32	+5, -10
II	fixed	+40, -35	+12, -12
II	taped	+42, -35	+8, -10

Typical waveforms for both series of tests on the old shaker unit were the same except for the level disparity and appear below.

Circumferential Axis

Radial Axis

A similar test was made on the new shaker unit with the following results:

New Shaker Unit

<u>Method of Mounting Telemetry Equipment</u>	<u>g Level in Circumferential Axis</u>	<u>g Level in Radial Axis</u>
fixed	+30, -25	+6, -10
taped	+25, -24	+5, -10

Circumferential Axis

Radial Axis

Although not shown explicitly, the phase relationship between the two axes for the old and new shaker are distinctively different. The effects on pacer testing of the phase and waveshape differences of the new shaker unit

must be investigated further. Also, more tests will be conducted on the old shaker to determine the cause of the g-level difference in the two series of tests that have been run to date.

A noise signal study of the telemetry system was also conducted. The types of noise in the system have been typed as (1) partial signal loss, (2) antenna noise, and (3) co-channel interference. Each has a distinctive character and is readily differentiated from the data signal.

The new model Miller paint shaker will be disassembled and modified, where required, to introduce clearances which will simulate wear. The shaker will then be reassembled and tested with the telemetry equipment to see if the output duplicates the output of the old model Miller paint shaker. The older shaker more closely duplicates the failure modes experienced in dogs than the new shaker.

15. Human Tests

A test program was outlined to study the acceleration levels generated by a human wearing a pacer. The subject tested would be wearing the microcom telemetry equipment fixed to the upper chest area by some type of harness. The subject would perform the below listed activities.

- Swinging a golf club
- Bowling
- Shooting a shotgun and/or rifle
- Sitting down hard in a chair
- Hitting a baseball or softball
- Running
- Jumping

This phase of testing may possibly be expanded to include testing on several individuals of various physical statures and additional activities.

Testing has been completed on two subjects with the telemetry equipment positioned in three different locations: upper left and upper right chest area and lower left abdomen. The following activities were completed by both subjects.

- Shooting a 12 gauge shotgun
- Shooting a 35 caliber rifle
- Running
- Jumping
- Sitting down hard in a chair
- Hitting a softball

The data has been recorded and is in the process of being reduced.

C. Fabrication Development

After the basic design for the production pacemakers had been developed, a very significant portion of the effort to develop a pilot production operation was in achieving cost effective methods of fabricating individual components. This work is reported in this section. To be effective in this effort to coordinate the responsibilities for components procurement, fabrication, and proper quality control, two aids were used. The first was the preparation of a complete parts list and cognizant personnel and secondly, a series of flow diagrams defining the individual responsibilities along with the complete assembly procedure was developed as discussed in detail in Task 3 A-1. The general outline of this section is divided along the lines of the production flow chart, Drawing 15-J-4189-1, Figure III-3. Weekly production meetings of Q.C., Chem Lab, and Mechanical Fabrication were held to assure the coordination of the fabrication and developments when joint responsibilities existed for fabrication of a single component (such as thermocouple tapes).

1. Ceramic Tabs (Process 104.013)*

This component is part of the nuclear battery and is purchased as an uncoated alumina ceramic for further internal processing. This includes titanium coating by a molten salt process, grinding, electroplating with copper and silver, vacuum alloying and subsequent cleaning. A citrate-nitric acid treatment prior to further use, once employed for titanium activation on stored tabs is no longer used because of rapid tab processing without storage delays after coating.

With the start of Phase II in February, 1970, it was reported in the Program Plan, Revision 3, dated March 10, 1970, that the costs of tabs utilized in the Radioisotope Powered Cardiac Pacemaker both in labor and material were very high. Giving rise to this high cost was the capability of producing only small volume lots, approaching 30 pieces.

Through scale up in the titanium deposition reactor and use of a new fixture design capable of plating six tabs simultaneously costs and processing time were significantly reduced. One hundred finished elements were completed ready for tape assembly in one and a half man-days. This capability level has been maintained.

*See Process Flow Chart, Dwg. 15-J-4189-1, Figure III-3. Refer to Radioisotope Powered Cardiac Pacemaker Process Specifications Book

2. Titanium Hot Shoes and Copper Cold Shoes (Processes 104.013 and 104.005)

At the start of Phase II the hot shoe was changed from copper to titanium as a result of the safety program recommendations.

The components were initially manufactured by hand. Studies had shown that these components for the ceramic tabs could be most easily and economically fabricated by chemical milling processes. Techniques for applying the photo resist and subsequent milling were established during the August 1 thru October 31, 1970 quarter. The best etchant for copper was 35 wt percent ferric chloride plus 5 vol percent hydrochloric acid. A solution containing 10 vol percent HF worked best with titanium.

Film masters from which 40 hot or cold shoes could be produced were ordered during the August 1 thru October 31, 1970 quarter.

Tests run during the February 1 thru April 30, 1971 quarter after finalizing of the photoetch procedures produced 25 titanium hot shoes in two man-hours and 25 copper cold shoes in two man-hours of total processing time. In order to gain a more rapid uniform etch, a spray etcher was ordered during the period.

During the May 1 through July 31, 1971 period, tests were made with the spray etching machine. In one trial, two hundred copper cold shoes with fourteen cold straps were produced in five man-hours of labor.

The high level of production capability has been maintained to the present time.

3. Thermocouple Tape Plating (Processes 104.002 and 104.004)

Each thermocouple tape sub-assembly consists of two thermocouple tapes, tophe1 and cupron, extended between two ceramic tabs. Prior to vacuum brazing these two tapes are plated with copper and silver in the wire areas where the brazing will take place.

The tophe1 and cupron tapes, each about 8.5 inches, have 88 wires woven with E glass electrical insulation. This insulation must be removed from the plating areas to achieve reliable plating. This removal is made by grit blasting after proper fixturing.

This removal of glass strands and plating are the two major operations. Prior to this, tape desizing is done to remove the starch binder used by the vendor in manufacture. This desizing operation is identical to that used in the insulation tapes discussed in section 5.

In the initial quarter of Phase II, a water soluble binder was tested as a substitute for the starch sized tapes. Early tests showed that only 1/3 of the desizing time was required. Tests continued through the second quarter (May 1 through July 31, 1970) and it was concluded that starch sizing must be used to produce an acceptable tape because of the lowering of thermal performance of the nuclear battery. In conjunction with this, a tightly woven edge for added insulation was woven in the tape. Starch removal time was not affected by this tighter weave (November 1 through January 31, 1971 quarter).

Along with the tightly woven edge, a wider border on the tapes was incorporated with no degradation of thermal performance. The desizing rate with the new desizing equipment installed was six pacers worth of tapes in eight man-hours.

During the second quarter of Phase II, a plating fixture was designed, fabricated, and tested. The fixture cut processing time to one-fourth of the previous method and minimized tape handling. Seven areas (six tapes) were coated simultaneously.

Continued testing with the plating fixture during the August 1 through October 31, 1970 period produced uniform deposits in the specific areas that require it. However, some problems were encountered with plating solution leaking into the entire tape. Excess pressure causing fiber damage had to be applied to prevent this leakage. To eliminate this condition, a new fixture was designed and a prototype of it successfully tested.

Scale up of the prototype fixture noted above produced some problems in techniques. The most serious problems encountered were the following:

Non-uniform electroplate on wires and lack of plating on a few wires in any given section. This was determined to be a marginal cathode connection made by a piece of 5 mil aluminum foil at each tape plating location. Substituting a more ductile one mil foil and adding an additional connection at the ends of each tape eliminated the problem.

A grainy or dendritic plating of copper which did not adhere well to the wires caused coatings which were not acceptable for brazing into tabs. This problem was resolved by insuring a constant composition of the plating solution which, because it is heated, has a tendency to evaporate. Cleaning of the anodes after each tape run also minimized this problem.

By overcoming these difficulties and modifying the fixture slightly, using swing-away handles, thus making tape loading easier, it was possible to produce 1 set (2 tapes) in one man-hour. This includes grit blasting, copper-silver plating, post cleaning and drying.

The quality assurance results at that time indicated that the plating thickness in the brazing areas had been running between 1.0 and 1.5 mils, with 1.5 mils as optimum, over 95% of the measured areas. The 1.0 to 1.5 mil range appears to be a favorable condition for the repeatability of the tape to ceramic tab braze operation.

The tape plating tanks and venting hood were completed in the May 1 through July 31, 1971 quarter and trials made on the tape plating fixtures. The most serious problems encountered were electrical contact with the tape and the tendency to form dendritic deposits. The contact was solved with a firmer clamping technique. Dendrite formation in the deposit results from local high current density during plating probably from oxide film on the tapes. It was minimized by deliberately applying a low current density for a minute at the beginning of the plating period.

Present thermocouple tape production is approximately 2 tapes per man-hour and is being maintained.

4. Thermoelectric Tape Assembly and Brazing (Process 114)

One of the most time consuming assemblies to produce is the six thermoelectric tape assemblies required for each heartpacer. Each assembly consists of two tapes brazed into ceramic tabs at each end which in turn are brazed to metal strips called shoes. Considerable skill and time is required to place the 88 wires of both tapes in the grooves of the ceramics. To simplify the assembly, a different tape plating technique was developed (section 3) which simplifies placing the 176 wires into the 88 grooves and to eliminate unnecessary tape waste, tapes are made in units of six (one pacer). In this manner, seven individual brazes produces six thermoelectric tapes. Previously, each braze required the tape brazing fixture to be heated in vacuum and then allowed to cool. To reduce total brazing time and thermal cycles, a tape brazing fixture was designed to do all seven brazes during one vacuum cycle.

Also important in this development was the use of the tape brazing fixture to do the hot and cold shoe brazes concurrently with the wire brazes. A prototype fixture was manufactured to test this concept. For the prototype

it took approximately 5 man days to produce six thermoelectric tapes. The new techniques were designed to reduce this time to approximately one man day per six thermoelectric tapes.

It should be pointed out that for all discussions on fabrication techniques (especially on tape brazing) in the prototype production and in the development stages of the production fabrication, yield was not considered. One reason for this was that if tapes had broken wires, etc., and could not go into implant units, they still could be utilized for the various test units such as for gunshot and cremation. Thus, all components generally were completely utilized. In pilot production yield rates are kept, factored into costs, and always considered in production meetings for improvement.

The new thermocouple tape brazing fixture was a major design and development effort. Before the design was finalized, tests were performed that showed the proposed heater design and hold down clamps were satisfactory. Also, no off-gassing and/or temperature measurement problems arose during tests to evaluate the operation of multiple brazing heaters in a single vacuum system. The fixture is used in two stages. During assembly of the thermocouple tape onto the fixture, it is mounted as shown in Figure III-26. At this stage the fixture assembly includes a method of setting tape length. After assembly of the thermocouple tape wires into the grooves of the ceramic shoe, the upper heater is mounted and the assembly placed on a separate fixture as shown in Figure III-27 for brazing. This fixture, which brazes two ceramic shoes at a time is then placed in a vacuum chamber. With four chambers available, an equipment and fixture capacity of 24 ceramics will be available. It was found that during the development period before pilot production a preliminary evaluation of the tape brazing fixtures and procedures was desirable. The results were as follows:

- (a) Brazing with no filler and no rebraze was excellent, with essentially zero tape rejects because of the braze.
- (b) Length was somewhat of a problem and was fixed by proper gauging of the assembly fixture.
- (c) A production rate of 2 to 3 tapes per day, per man was obtained.
- (d) It was found that additional braze stations were needed based upon 3 men assembling tapes and 1 checking and brazing. Five more braze stations were ordered and to minimize down time, 12 extra heaters were ordered.

Thermocouple Tape Mounted on Fixture

Figure III-26

Thermocouple Tape Assembly on Separate Fixture

Figure III-27

Tape brazing has been initiated for production and has generally been very successful. Essentially all tapes have had good brazes with the single braze cycle (second cycle not allowed nor addition of BT braze material). The assembly in the new fixtures is good with one man being able to assembly up to approximately five complete tapes per day. No significant problems seem to be present in the assembly and brazing of tapes. Temperature limiting controllers have been installed to prevent heating above 850°C during brazing. The general appearance of tape brazes and tabs has been excellent. However, during one quarterly period tape rejection rates sharply increased due to low isolation resistance. This was eliminated by an air firing process 414.002. During all pilot production of NU-4 units, the results were satisfactory. With an average of approximately three men full time on assembly, one brazing and one in general support, approximately 600 tapes were brazed in a three month period.

Generally, the tape brazes look good. The ones rejected are rejected due to assembly problems and cracked tabs. The tapes now being processed tend to have a slightly higher resistance than previously processed tapes. Since the new tapes were from a new lot of wire, we felt that this small increase in resistance was due to a very slight variation in the wire diameter. Tests were performed to evaluate if the high resistance could have been due to individually high wire resistance but this was not the case. It was found to be a general increase equally among all wires. Therefore, it is felt that this variation of less than 2 percent in resistance was not significant and was definitely not due to changes in procedures or in processes. The slight resistance increase is well within the allowable tolerance of wire diameter variations. The allowable wire diameter tolerances would allow for approximately a 10 percent variation in tape resistance.

It should be pointed out that reject tapes can be used in the various special test units such as for cremation and auto impacts.

At the present time in production of NU-5 units, the tape assembly rate is approximately 1.5 man days per six thermoelectric tapes. This is less than one-third the man hours for the prototype of five man days and close to the one man day per six goal at the beginning of the program.

Therefore, the overall improvement is of the order of a factor of approximately five, which means excellent success in meeting the cost reduction objectives and proof of a production type unit in Phase II.

5. Insulation Tape (Process 105.001)

This tape functions as electrical insulation for the thermocouple tapes. The tape, E-glass yarn, is purchased with starch binder. Internal basic processing includes binder removal, coating with alumina and degassing prior to thermopile assembly.

Prior to Phase II, the thermopile wrap had 24 pieces of insulation tape each approximately 10 inches long. Initial cost reduction goals were set to reduce this number to 12. Attempts were also made to employ a water soluble polyvinyl alcohol sizing instead of starch to reduce binder removal time by roughly two-thirds.

The number of pieces was reduced to 12 for the initial pilot production and NU-4 models through May, 1972. The NU-5 models in present manufacture since May, 1972 have 18 pieces of insulation tape in the thermopile assembly.

PVA binder substitution tests during the first and second quarter of Phase II resulted in a decision based on experimentations to remain with the starch oil binder. The experiments showed that .0015 inches thick tape with the water soluble binder (PVA) does not have sufficient strength (reduced 50% for weaving). Also, tapes with the water soluble binder subsequently removed resulted in reduced thermal performance and lowered open circuit voltage by 8 to 9 percent.

From an equipment and scale up standpoint, cleaning of the tapes as a part of desizing was started with vapor degreasing equipment. Desizing tanks installed during the May 1 through July 31, 1971 quarter increased the desizing manufacturing capabilities to six pacers in five man hours of labor. This latter capacity was improved by 50 percent through equipment buildup, primarily during the May 1 through July 31, 1972 quarter. Present capabilities remain at this level.

6. Aluminum Cold Straps (Process 105.003)

This component is .005 inches thick, anodized, and provides electrical insulation properties to the thermopile when the anodized surface faces the tapes in that assembly. Because of this insulation requirement, anodized aluminum was the recommended and selected candidate material for this component.

Technical feasibility studies on fabrication were conducted during the early part of Phase II, February through March, 1970. These included stamping

and shearing in various combinations and chemical milling. The latter was chosen as most practical because of the complex configuration and multiple slots in the cold strap component.

The photo-resist chemical milling trials in that first quarter produced approximately 20 straps per hour. Concurrent with this success, anodized and degassing fixtures needed for complete processing of the cold strap were being designed and subsequently fabricated. These were completed in the November 1, 1970 to January 1, 1971 period.

Further etching studies associated with the chemical milling showed 10 percent NaOH etchant unsatisfactory because of its high etch factor. A 30 volume percent hydrochloric with 0.01 percent volume palladium chloride provided close tolerance etching. Because of high palladium costs and still too rapid an etch rate for ideal control, it was abandoned in favor of the present ferric chloride etchant.

During May 1 through July 31, 1971, a completely uniform etching was achieved with the installation of a spray etching machine. A rapid and uniform etch was achieved for the cold straps as well as the other photo-etch components, hot and cold shoes. At this time, the application and photographic processing of the resist coating, done prior to etching in the cold strap fabrication, did not present any problems.

Concurrently, with cold strap pilot production from August 1 through October 31, 1972, tests were being conducted on etching of purchased anodized aluminum. The cost savings would be the elimination of the present anodizing process with its related equipment and labor. The added material cost, less than \$.01, would be insignificant. In labor it is estimated 2 man hours per strap could be saved.

Anodized aluminum grade 1145-H19 was purchased .005 inches thick with a .0001 inch anodized layer on both surfaces from Clecon Metal, Cleveland, Ohio. After resist application, etching was successfully done in 15 to 20 minutes in ferric chloride after a quick NaOH dip. Electrical studies in battery assemblies are presently in process.

7. Thermopile and Battery Assembly Processes 115, 116, and 117

The thermopile assembly consists of the following:

- (a) Process 115 which is the cutting and sewing of insulation tapes

to the thermocouple tapes, spot welding of the tapes to the hot strap, wrapping of the thermopile, closing the cold strap, and making jumper connections.

- (b) Process 116 which includes preparation of end shields and getter basket.
- (c) Process 117 which is the final assembly of the getter, fuel, and thermopile into the outer cases inside the glove box.

Generally most of these operations are by hand but with fixtures utilized where possible. Templates are used for cutting the main insulation strips. Although automatic or semiautomatic methods have been considered for tape sewing, the delicate nature of the tapes made machines impractical. Dies were made to cut the E-glass layers used in the end shield assembly.

The wrapping fixture was developed to hold the tabs in place on the hot strap greatly facilitating the spot welding and wrapping. Approximately 5 percent of the thermopiles obtain broken wires during wrapping. In an attempt to develop a clutch arrangement on the wrapping fixture, load tests were performed on five thermocouple tapes. Failure was determined by resistance measurement. Results are shown in Figure III-28. These results have not been, as yet, incorporated into a more limited fixture.

To facilitate assembly, holding fixtures for degassing and use during assembly for certain parts such as end shields have been developed. Generally the operation proceeds well with the use of reasonably skilled technicians with an approximate time of one man day per unit.

This time is not excessive and most of the fabrication development efforts in these assembly procedures was in establishing the detailed assembly procedures and parameters.

8. Mechanical Components

Hardware parts fabrication, lot sizes, and techniques have been established or developed as the most economical method of producing parts for one hundred to one thousand pacemakers. To produce pacemakers in numbers greater than one thousand, it would be possible to reduce the fabrication cost of some items by changing fabrication methods, such as making expensive dies. Following is a listing of some of the parts, lot sizes in which they are produced, method of producing, and the cost per lot produced.

LOAD VS RESISTANCE OF CUPRON TAPES

COMBINED RESISTANCE OF TOPHEL AND CUPRON WIRES.
STRENGTH IS OF CUPRON WIRES ONLY.
EACH CUPRON TAPE CONTAINS 88 WIRES .002 IN. DIA.

- REJECTED TAPE NO. 1398
- REJECTED TAPE NO. 1212
- REJECTED TAPE NO. 1217
- ▽ REJECTED TAPE NO. 1117
- △ REJECTED TAPE NO. 1244

Figure III-28

<u>Part No.</u>	<u>Part Name</u>	<u>Material</u>	<u>Lot Size</u>	<u>Method of Producing</u>	<u>Man Hours Per Lot</u>
10	Hot Straps	.003" Ta foil	110 pcs	Stack machine then form on mandrel	24 hrs
30	Getter Baskets	.003" Ta foil	220 pcs	Shear blanks then form and trim with die	9 hrs
29	Getter Retainers	.010" Ti sheet	220 pcs	Stack machine all pieces at one time	8 hrs
90	Getter Supports	.010" Ta sheet	220 pcs	Shear individual pieces, bend on a hand brake and spotweld the two halves together	18 hrs
32	End Shields	.001" Ti foil	200 pcs of ea size	Shear individual blanks then stack machine each size of 200 pcs	84 hrs
37	Support Brackets	.010" Ti sheet	100 pcs	Stack machine blanks and form in dies(2)	19 hrs
	Support Bracket Brace	.010" Ti sheet	100 pcs	Stack machine blanks, form on fixtured brake	7 hrs
38	Thermopile Re- tainer Straps	.001" Ti foil	100 pcs	Shear individually on fixtured shear	1½ hrs
41	Closure Plug Flanges	.250" Ti rod	100 pcs	Machine on manual turret lathe	14 hrs
43/ 53	Feedthrough Flanges	.250" Ti rod	220 pcs	Machine on manual turret lathe	16 hrs
65	Heartlead Terminal Blocks	.187" Ti round corner sq. rod	100 pcs	Machine on manual turret lathe, tap by hand	49 hrs
51	Ground Connector Brackets	.020" Pt wire	100 pcs	Cut to length and form on die	2 hrs
61	Closure Plugs	.035" Ti wire	100 pcs	Shear to length on fixtured shear, bend on brake	2 hrs
67 66	Set Screw Locking Washer	.010" Ti sheet	100 pcs	Shear blanks, drill individually, stack machine	3 hrs
77	Output Feed- through Wire	.030" Ti wire	100 pcs	Form and cut to length in die, drill individually	6 hrs

Mechanical components are shown in Figure III-29.

Mechanical Components

Figure III-29

9. Cases (Process 101)

Early in the development program, it was determined that the four case components - outer case, outer case lid, electronic case, and electronic case lid must be die formed. Quotes for design and fabrication of dies were sent out. Pace Precision Tool and Die was chosen as the vendor to design the dies and fabricate the cases. A #3 Federal Press was purchased and Pace Precision began fabricating the cases and lids. Parts manufactured with dies are shown in Figure III-30.

An evaluation program was initiated to determine the optimum physical characteristics of Ti Grade 35A which would give an increased yield in electronic cases. The yield in the past was approximately 40 percent due to cracks. Because of the unavailability of .010 thick titanium in the small quantities required, material was purchased which was .016 inch and then rolled down to the required .010 thickness. This material was found to be unsatisfactory for fabrication of the electronic cases.

Following the evaluation program of Ti Grade 35A material for the electronic cases, an optimum material composition was determined and used to fabricate 140 electronic cases. Of the 140 cases fabricated, 138 were acceptable. The yield in the past had been approximately 40 percent. The material was purchased from Timet. The material was analyzed and found to have the following physical characteristics:

Material -- .011 $\pm$.001 thick flat sheet

Maximum Yield Strength -- 37,000 psi

Minimum Elongation -- 30%

Grain Size -- ASTM 8 or finer

Previous material used had a higher yield strength of 47,000, a larger grain size of 4 to 5 μ and the minimum elongation was 22%.

Exterior Cases

The reject rate for polished cases recently increased due to thin edges resulting from excessive polishing to remove exterior blemishes due to the mechanical properties of the material. An order has been placed for .025 thick Titanium Grade 35A which should provide a better quality case prior to polishing.

Parts Manufactured with Dies

Figure III-30

10. Polishing of the Titanium Outer Case (Process 101.004)

Three methods had been considered for polishing the titanium outer case to produce an acceptable appearance:

1. Mechanical Buffing
2. Electrolytic Polishing
3. Chemical Polishing

Mechanical polishing produced an excellent mirrorlike finish. This highly polished finish is very desirable but involves a tedious hand operation requiring great care. About one hours time was required to polish each completed pacer unit.

Electrolytic polishing has been tried with commercially available and laboratory prepared solutions. The results were variable depending on the geometry of the work piece and condition of the metal. A preliminary acid pickle was required in some cases. The method worked well with flat sheets but non-uniform removal of metal results with complicated shapes especially where edges are involved.

Chemical polishing was the simplest approach. It involves merely dipping the object in a well-agitated solution for a predetermined time period. Several solutions have been tried but one in particular gave excellent results. With this solution a light gray matte finish was produced even on oxidized surfaces. The process required a 10 minute dip in an etching solution which consisted of:

	<u>Volume Percent</u>
Fluoboric Acid (30%)	33
Hydrofluoric Acid (48%)	8
Nitric Acid (70%)	25
Acetic Acid (99%)	17
Phosphoric Acid (85%)	17

The solution temperature is 25°-50° C depending on condition of material.

The case polishing was finalized into a mechanical technique which gave the high polish desired. The equipment presently used is a Setco Polisher, Model 104, Setro Industries, Inc., in conjunction with sandpaper and cotton polishing wheels.

The sandpaper wheels are first used to remove marks and scratches. Following this cotton wheels with titanium cutting compound and silicon carbide granules are used for polishing. Final buffing is done with another

set of cotton polishing wheels and white polishing compound #K30. The case is then inspected visually against a Quality Control Standard. This is the current method of operation on exterior case polishing.

11. External Case Labeling

Recently, the USAEC, Division of Materials Licensing, issued the "Interim Guide - Information to be Submitted Concerning Radionuclide Powered Cardiac Pacemakers for Implantation in Humans for Investigational Purposes", which among other things specified the minimum information to be indelibly marked on the external case of an RPCP destined for such use. In compliance, all RPCP units for human implantations will be labeled by etching with:

(Radiation
Symbol)

ARCO Nuclear Company
Model NU-5, Fixed Rate, Serial No. 001
Caution: Radioactive Material
Pu-238 <8 Curies
Notify Civil Authorities if Found
1972

The above labeling is presently done by using films with photo-etching techniques followed by chemical etching in hydrofluoric acid.

12. Feedthroughs

The Phase II feedthroughs include one leading from the nuclear battery to the electronics and the other leading from the electronics to the heart lead assembly. Prior to Phase II, the prototype pacer had three feedthroughs, one from the battery and two from the electronics.

From a cost reduction effort, the present battery feedthrough cost approximately one-third of the Prototype unit.

Present Phase II costs of the electronics feedthrough are roughly one-fifth of that amount for the Prototype.

One of the goals in Phase II was to develop a quantity production method. By utilizing two sealed vacuum tube furnaces, one for each feedthrough braze, a producing capability of one brazed feedthrough per .7 man hour of labor has been shown.

The brazing system noted above was installed during the November 1 through January 31, 1971 quarter. One furnace employs a nichrome heating element for the low temperature copper-silver feedthrough brazes. The other furnace employs a glo-bar heater for the high temperature nickel-titanium feedthroughs. The necessary electrical and cooling water servicing for the

feedthrough brazing equipment was completed by the end of the February 1 to April 30, 1971 quarter. The initial brazes in the equipment were performed the following quarter.

The first four copper-silver feedthroughs were brazed and passed the visual and leak test requirements. Two of these developed a leak during a subsequent degassing step on metal components.

After experiencing a four out of eight leak test failure rate after degassing of pilot production feedthroughs, a series of experiments were initiated to pin point and resolve the problem.

Cross sections of the failed feedthroughs revealed cracks in the body of the ceramic near the bottom and a poor bond between the copper feedthrough wire and the ceramic with erosion of the wire very evident.

The wire erosion indicated excessive heating which would cause dissolution of the wire in the 72 wt percent silver - 28 wt percent copper braze alloy. A check of the brazing furnace revealed a hot zone which could have had a deleterious effect on temperature control. The heating elements in the furnace were changed and the brazing zone carefully recalibrated. In addition, the brazing temperature was lowered from 845°C to 830°C, the minimum at which good braze flow has been observed with this braze alloy in this system.

Brazes were made at 830°C using the standard braze (BT) and at 820°C with a 0.2% lithium - 71.8% silver - 28% copper braze (LBT). In one series, a copper feedthrough wire was employed, in another titanium feedthrough wires were used. It became evident in these tests that LBT offered no advantage over BT and its use was discontinued. (The better filleting ability of LBT prompted its trial). Brazes with BT at the lower temperature produced good seals between the wire and ceramic with both titanium and copper with erosion of either wire not evident. Cross sectional examination of these feedthroughs, however, showed cracks persisting in the body of the ceramic and severe cracking in the ceramic adjacent and parallel to the titanium wire. The cracking parallel to the titanium wire persisted in several trials and eliminated titanium as a possible replacement feedthrough wire. The lower brazing temperature produced good results with the copper wire. Degassing at 300°C as required in pacer assembly had no effect on the copper wire to ceramic seal.

The cracks in the body of the ceramic were undoubtedly produced by stresses introduced during cooling after brazing by differential contraction of the titanium flange and aluminum oxide ceramic. The next series of experiments were performed to determine a flange design which would not produce stress cracks in the ceramic. Several different designs with a .025 inch flange wall thickness, the size previously used in feedthroughs, were fabricated. Flange to ceramic joints from .025 inch to .150 inch (the entire length of the ceramic) all resulted in cracks in the ceramic. In another group of tests, the wall thickness of the flange was reduced to .012 inch. No cracking in the ceramic was evident in these tests. The height of the .012 inch flange wall was varied, but no cracks in the ceramic were ever observed. It was concluded that stress cracks in the ceramic were eliminated with the .012 inch wall thickness titanium flange. The final design arrived at is shown in Figure III-22.

During copper-silver feedthrough production initiated during the November to January 1, 1972 quarter, it was observed in the initial production qualification testing that microcracks were forming in the copper wire (within the ceramic only) during brazing. These cracks were not observed previously, but only since a new batch of ceramics was started in process. The internal diameter of the new ceramics was 2 mils smaller than the previous ceramics requiring an additional 2 mils reduction of the copper wire being used. It was concluded after several tests that the drawing and pickling operations required to attain this smaller diameter were causing the problem. It was believed that the main problem is due to hydrogen diffusion into the wire during pickling.

New copper wire, 99.99%, OFHC purity with a .0285" diameter was obtained. This wire is 3/4 to 1 mil larger than the internal diameter of the ceramics that was in process. Following the production procedure, this wire was used to produce 18 production feedthroughs without any apparent problem. As a control, every sixth braze is a test piece for sectioning. The microcracks were most likely caused by excessive pickling of the copper wire since a .030 inch diameter wire from which the .0285 inch diameter wire was drawn by the vendor showed severe microcracks after feedthroughs were made from it using the pickling technique to reduce the diameter.

About 50 percent of the nickel-titanium feedthroughs produced the following quarter passed the 10^{-12} atm cc/sec leak rate specification. Reworking of

35 nonconforming electronic feedthroughs produced during the quarter resulted in 18 leak free assemblies. Rework plating costs are very low. The remaining 17 units were utilized in various engineering tests.

Engineering studies were made with a gold-nickel braze as a substitute for pure nickel. Early results looked promising. The braze candidate melted at 975°C versus 1050°C needed for nickel. The lower heat needed should result in a significant reduction in the amount of crystallization presently forming on the titanium feedthrough flange and electronics case. Increased yield was the major objective of this study.

The studies made substituting the gold-nickel braze on standard design during the remaining two quarters of Phase II produced leakers in the pin to ceramic area. This effort has been discontinued.

Further studies were also made on the micro-cracks which occurred in the pin on the copper-silver feedthroughs (first reported in the November 1 to January 31, 1972 quarterly). Since metallographic techniques have been improved at the ARCO facility, tests have shown that these cracks to some degree have been seen in as received, unetched, copper wire. The condition is worsened by the degree and technique of subsequent nitric etching, as shown earlier. The necessary controls are in effect to keep this condition to a minimum.

13. Final Assembly (Processes 120 and 121)

The final assembly steps of adding electronics, welding the electronics case lid, and potting have proceeded well with several exceptions. It was found that in some early units, the heart leads were hanging up in the terminal block. It was found that the QC lead being used was somewhat on the low side of tolerance and with larger leads, binding could occur. Also, it appeared that some epoxy was entering the block around the mold pin. By reaming this epoxy out of the block and using the largest possible diameter pin for QC test, this problem was eliminated.

A leak was found during the QC leak check procedure on a unit early in Phase II. To determine the location of the leak, the unit was pressurized with helium at 4 atmospheres for approximately 1 hour. The unit was then submerged in a beaker of methanol and 3 streams of bubbles were seen to be coming from the inside of the electronics case. This meant that the leak

was either at the weld between the case lid and the outer case or in the case lid itself. To further identify the location of the leak, a dye penetrant test with the dye in the electronics case area was performed. After about 25 minutes of the dye penetrant test, a leak showed on the opposite corner from the feedthrough. This corner is a double draw curvature which probably led to the fracture. In the future, all case lids were leak checked to prevent a leak of this type.

On units NU-4-10 and 13, the RTV in the electronics case bubbled during the pump down going into the TIG welding chamber. The lids were removed, replaced, and successfully welded. Since this pump down had no technical effect on the unit, but can produce production time losses, it was eliminated by transferring units into the TIG welding chamber in a sealed pressure container.

To meet the production schedule, a second epoxy molding fixture was fabricated. An RTV molded holder for batteries and completed pacers on life test has been developed and many units have been fabricated. These holders prevent marking the cases, hold them firmly to a table, and provide plug jacks for taking data.

A problem was encountered during pilot production startup in welding of the electronics case lid. Because of the low viscosity (≈ 100 poises) of the RTV 615, it was possible for the RTV, through capillary action, to migrate to the weld area and, therefore, cause a poor quality weld. A one component RTV (Dow Corning 3140) was tested and found to be satisfactory with an excellent consistency (≈ 35 poises). This RTV sets up very quickly. As a result, there is no tendency for the RTV to migrate to the weld area and is now used for potting of final electrical connections in the electronics case.

14. TIG Welding (Processes 718.001 and 721.001)

A number of trial Tungsten Inert Gas (TIG) welds were made to establish the procedure for sealing the exterior case to exterior case lid. The EB cam welding fixture was modified for TIG welding. A set of cams for welding the electronic case to electronic case lid was made.

Six vendors were contacted to quote on supplying a TIG welding machine that would be capable of making all TIG welds needed on the pacemaker. Five of those contacted submitted a quote and one submitted a no bid.

The recommended TIG welder and TIG welder argon box was received and installed. The cam welding fixture was installed in the box and set up to weld both the outer case to outer case lid and the electronic case to electronic case lid.

Preliminary TIG welds of the exterior case, exterior case lid, and electronic case were made using the TIG welding argon box and cam welding fixture. The early welds produced a blue oxide in the weld area, showing that the argon box was not completely free of oxygen and moisture. The box was checked and no leaks were detected. The argon gas was then recirculated to attain a better inert atmosphere in the glove box. When a good inert atmosphere is obtained, the welds have a silver color with no blue oxide present. A photograph of the cross sectional area of one of the preliminary welds is shown in Figures III-31 and III-32. The weld penetration thickness is satisfactory. In these particular sections the weld rollover has been controlled to the inside of the device by adjusting the outer chill position. This provides an additional mechanical anchor for the epoxy.

The welding parameters were established to weld the exterior case, exterior case lid, and the electronics case weld joint. A number of tests were run to determine the temperature rise on the feedthrough flange during welding. When no chill was placed directly on the output feedthrough, the feedthrough flange base saw the temperature rise to 370°C and the top of the flange stem to 330°C. When a small tube type copper chill was used, which was placed around the feedthrough flange stem and rested on the flange, the flange base saw the temperature rise to 250°C and the top of the flange stem rose to 180°C. This temperature rise will not effect the feedthrough seal.

The parameters for the electronics case to the electronics case lid weld were also established. A number of tests were conducted using different type chill arrangements to determine which type gave the smallest temperature rise. A pressed clamp type chill was found to give the least temperature rise. Temperature indicators set at 150°F, which were potted in RTV in the electronics enclosure to simulate an actual unit, did not change color during the weld indicating a maximum temperature of less than 150°F. A temperature rise not greater than 150°F will not degrade the electronic circuit reliability.

EXTERIOR CASE
EXTERIOR CASE LID
ELECTRONICS CASE

Figure III-31

Figure III-32
EXTERIOR CASE
EXTERIOR CASE LID
ELECTRONICS CASE

RADIOISOTOPE POWERED CARDIAC PACEMAKER
EXTERIOR CASE WELD

After significant usage, the TIG welding fixture used for the welding of the main case to the lid and electronics case had problems of erratic velocities as it moved around the weld perimeter. This erratic operation was eliminated by making the following modifications:

- (a) Tack welded the couplings to the shafts to remove slop.
- (b) Welded in a shim at the couplings so the shaft will bottom out on a shim instead of the cam plate.
- (c) Flats were ground on the drive shaft to improve the tightening capability.
- (d) The welder was moved toward the center of the box for access.
- (e) The bearings were moved on the cam blocks to distribute the load.
- (f) Resealed the chamber to provide a cleaner atmosphere.

During pilot production of the NU-4 and NU-5 units, the TIG weld system and the parameters developed have consistently given successful welds. The loss of units during both welds combined is less than 5 percent.

15. Epoxy Molding (Process 121.004)

A study was conducted to evaluate different methods of applying the epoxy molding to the pacemaker. Specific problems studied were the molding technique and the development of an air bubble free production type procedure.

The epoxy molding fixture design was finalized. A small vacuum box was needed for the molding operation. The decision on the vendor was made and the box ordered. The vacuum box is a part of the molding system and was readily available since it was a shelf item. The small vacuum box for the epoxy molding operation was received and installed. The epoxy molding fixture was made and the final molding procedure finalized.

Since the epoxy curing cycle is exothermic, tests were run to determine the temperature rise during curing. The temperature rise is only a few degrees above ambient when the epoxy molding procedure is used. It was found that the 150°F temperature indicator, that is placed in the epoxy to show if the pacemaker sees temperatures above 150°F during its life, is also sensitive to the uncured epoxy mix. The indicator is made of an indicating disk covered with a cellophane type protective shield. If liquid epoxy seeps under the cellophane, it turns the indicator color the same as if it saw a temperature

above 150°F. To protect against this, a small drop of epoxy is placed over the indicator and allowed to harden before the vacuum molding takes place.

Investigation of NU-4-14 and NU-4-23

A test program was initiated to determine what caused the epoxy cover on Nu-4-14 to become distorted and filled with bubbles. Two blocks of epoxy were molded using the normal procedure. These blocks were then put in an ethylene oxide autoclave at 120°F for 3 hours. After this cycle, they were soaked in a Ringer solution at 101°F. There was no indication of any deterioration of the epoxy. Several other blocks were mixed with 25 percent and 50 percent excess hardener. These were exposed to temperatures of 140°F. There was no indication of any change in the epoxy blocks. Testing continued in an effort to duplicate this phenomenon. Four epoxy blocks containing different amounts of hardener, normal, 25 percent, 50 percent, and one normal mix with .25 cc of methanol were molded and put through the gas autoclave at the NH&LI facility. They were then put in a Ringer solution. After 23 days in the Ringer solution, there was no evidence of deterioration of the epoxy. The blocks were kept in the Ringer solution and observed for any change.

A second pacer, NU-4-23 removed from a dog, exhibited the same epoxy problem as NU-4-14. The epoxy was soft and porous and showed signs of swelling. The Hysol Division, who manufactures the epoxy, was contacted and the problem discussed in detail. Samples from the two pacers were sent to Hysol who analyzed the samples.

Testing of the epoxy blocks soaking in Ringer solution was suspended after a four month test period. No deterioration of the epoxy block was noted. No further testing was planned pending the outcome of the analysis being performed at Hysol Division.

Hysol recommended using their newly processed epoxy which has been filtered down to 3 microns and packaged in sterilized plastic containers. An order was placed for this epoxy for evaluation purposes.

The Hysol Division, who manufactures the epoxy, has analyzed samples from the two pacers in which epoxy distortions were observed. The analysis indicated an excessive amount of nitrogen which indicates an excess of hardener in the mix. It appears that twice the normal amount of hardener

was used in this mix. Several blocks with 100 percent excess hardener were fabricated and tested in a Ringer solution in an effort to substantiate the chemical analysis performed at Hysol. Tighter mixing control was established shortly after the time that these two units were epoxy molded.

To this date, there has been no change in the physical appearance of the blocks. This phase of testing was suspended. An implant program is being initiated where six mock-up pacers with normal, 50 percent, and 100 percent excess hardener will be implanted in dogs at NH&LI.

16. Chemical Components Production

Table III-14 shows the number of components manufactured during the last three quarters.

17. Disassembly of Failed Units

To assure that proper safety precautions and data was obtained in the disassembly of failed NJ-4 units, the following procedure was written:

Procedure for Disassembly of a Failed Radioisotope Powered Cardiac Pacemaker

1. Smear the external surface of the failed pacemaker and count the smear.
 - 1.1 If the smear is positive (shows any contamination above background), package the pacemaker in a sealed container and make arrangements to have it transferred to B&W for disassembly.
 - 1.2 If the smear is negative (shows only background), proceed with step 2.
2. Using a milling machine and end mill, machine off the amount of epoxy necessary and enough of the electronics case to remove the lid from the electronics case. Make a battery load line check.
 - 2.1 If the load line check indicates the battery has not failed and the electronics has, report the results to the responsible supervisor and get instructions before proceeding.
 - 2.2 If the battery has failed, establish the cause before proceeding. A resistance check and load line check will verify tape failures or internal shorts in the thermopile. If the battery output is very low and the thermopile resistance is normal, internal gas should be suspected. This internal gas could most likely be in the order of probability, (1) Leaking feedthrough, (2) Leaking case, (3) Internal offgassing, (4) Leaking source.

3. After the cause of failure has been established, proceed with disassembly.
 - 3.1 Special precautions must be taken.
 - 3.1.1 The area around the milling machine must be restricted to traffic for at least a ten foot radius (roped off).
 - 3.1.2 Use a large vacuum cleaner and an absolute filter in line with it to draw off milling chips and any possible contamination released when the battery case is penetrated.
 - 3.1.3 A full face mask must be worn by the operator.
 - 3.2 Having the three special precautions taken care of, the operator may proceed by following step 3.3.
 - 3.3 Cut off the battery case weld with the same setup used for opening the electronics case. Smear the milled area and monitor with an alpha meter as soon as penetration is made through the weld. If no contamination above 100 dpm is detected, proceed with the milling and disassembly operation, monitoring, and smearing occasionally.
 - 3.3.1 If it has been established that no contamination is present, the special precautions may be removed.
 - 3.3.2 If it has been established that contamination is present, the battery should immediately be placed in a sealed container for transfer to NUMEC and any or all members of the Radiation Committee notified before proceeding any further.

Table III-14

<u>Part #</u>	<u>Component</u>	<u>No. of Pcs Manufactured per Quarter</u>		
		<u>Feb. 1 - April 30</u>	<u>May 1 - July 31</u>	<u>Aug. 1 - Oct. 31</u>
15	Ceramic tabs	1374	1420	1341
13	Hot shoes	436	550	278
14	Cold shoes	356	585	360
17A	Tophel tape (10")	791	755	714
18A	Cupron tape (10")	822	650	666
19	Insulation tape (10")	1405	1530	1250
60	Case identification	55	49	55
16	Cold straps	74	76	67
42A	Battery feedthroughs	54	59	30
52A	Electronic feedthroughs	86	40	55

IV. TASK 4.0 - SYSTEM TESTING

A. Shock and Vibration Analysis of the Dog and Human Environment

Both 8 mm and 16 mm color and black and white moving pictures were taken of the pacer dogs in order to more accurately determine the dog environment. In addition to studying the normal environment of the dogs during their daily activity, pictures were taken during induced scratching to assist in the analysis of such a vibrational mode for the pacer. Other tests performed with the dogs and recorded on film were jumping off a platform, induced panting, investigations of slip and fall, walking, trotting and quivering and the potential for physically banging the pacer into the kennel cage. In addition, telemetry tests were conducted to measure shock and vibration conditions to which implanted pacers are exposed.

Visits and motion pictures suggested that the vigorous impacting between the animals and their environment far exceeds that which is encountered in human patients, both in intensity and frequency. The pacers are implanted just under the skin and they are subject to direct shocks due to falls, a normal activity such as banging the kennel cage, their feed bins, etc. It was further concluded that the amplitude of these various shocks (50 to several hundred "g") and the number of each type of shock was significantly greater than previously anticipated.

Based on these and other results, an analysis was performed on the shock and vibration environment for both dog and human implant of an RPCP. The maximum whole body shock or g loading tolerance for a foxhound dog and for a human were determined. This tolerance in g's of acceleration has been evaluated experimentally for various animals. A curve has been developed of maximum accelerations and has shown that the whole body tolerance is a direct function of the size of the animal (Figure IV-1). The maximum whole body tolerance for a man is 20 g's. For a two-foot high foxhound dog, a maximum of 55 g's was determined.

This whole body tolerance is primarily of academic interest since the pacemaker can experience much higher g shock loads without having the whole body of the implantee receive that same g level of acceleration. Consider, for example, a remotely possible accident in which an implanted RPCP is hit directly by a golf ball just after it leaves the tee. Under

WHOLE BODY G-TOLERANCE OF ANIMALS

Figure IV-1

these circumstances, the pacer unit would experience an extremely high g shock load while the human body would perhaps sustain only localized pain and negligible acceleration. In an analogous fashion, the free fall impact of a pacer implanted in a dog and human are treated analytically to assess the more severe localized acceleration conditions.

Further clarification of the dog and human environment was derived. An idealized square wave shock pulse was assumed and developed for both a two-foot and five-foot fall of an implanted pacemaker. These two heights correspond to the dog and human implant, respectively. The impact velocity for a two-foot drop of an RPCP unit is 11.35 ft/sec. For a square wave acceleration, the pulse width is a function of the impact velocity and the number of g's of acceleration. The maximum acceleration in g's is given in Figure IV-2 as a function of pulse width for two-foot drop heights. The pulse width for a 50g acceleration experienced during a two-foot drop elastic rebound impact is 14.1 ms and for a 545g acceleration, the pulse width is 1.3 ms.

For the five-foot drop elastic impact of a pacemaker, the impact velocity is 17.94 ft/sec. The pulse width for a 4450g square wave acceleration is 0.25 ms.

Using the Rankine-Hugoniot relationship, the maximum shock pressure for the impact of an RPCP unit into various target materials was determined. An impulse-linear momentum relationship was developed for the elastic rebound type impact of an RPCP unit at a velocity of 11.35 ft/sec for the 2 foot drop given for the dog environment. The total change in momentum is 0.1652 lb_f-sec. The initial shock force at impact rarely achieves full amplitude to the maximum given by the Rankine-Hugoniot equations. Normal shock signatures after an initial pulse exhibit a shock force which is approximately 10% of this maximum force. Also, due to slightly off-normal impact and to the concavity of the outside flat surface of the pacer, the contact surface at impact is at the most 10% of this surface area. A reasonable assumption in the analysis, therefore, is that the initial spike of the shock signature follows a triangular shock force to the maximum and this initial pulse is applied for a time interval equal to the time for the sonic wave to propagate across the width of the pacer and back to the impacting surface. At this point, the shock force is assumed to drop to a value which is 10% of the maximum initial shock force. Using the

IDEALIZED SHOCK PULSE FOR FREE FALL OF RPC PACEMAKER

Figure IV-2

impulse momentum relationship for rebound impact into a concrete target, the pulse width for this shock was computed to be 0.25 ms. Thus, the average square waved acceleration was computed to be 2820 g's. From preliminary experimental results derived at ARCO Nuclear on the impact of a bare RPCP mock-up into a concrete surface at a two-foot drop height, the measured accelerations and pulse widths were about 2300 g's and 0.2 to 0.3 ms, respectively, partially confirming this analysis.

An analysis of the shock pressures which develop for a two-foot drop impact of an RPCP implanted in a dog is somewhat more difficult than the direct application of the Rankine-Hugoniot equations for the impact of the pacer in direct contact with a target material. From previous experimental and analytical results on hydrodynamic impact with a water surface, the compressibility and shock transmission properties of a water media to simulate the dog's tissue are perfectly reasonable to assume and do exhibit high shock pressures. Without adequate test results on the mechanical properties of compressibility, sonic velocity and density for a 3/16" thickness of tissue and skin which encloses the RPCP, it was assumed that this would behave similar to an identical thickness of water. Thus, the shock pressure is developed at the surface of the dog's skin as it impacts with a concrete surface and this shock wave propagates into the target material and towards the RPCP. By assuming no attenuation of this shock pressure as it approaches the pacemaker, the Rankin-Hugoniot equations can be applied and the maximum shock pressure at impact is 609 psi. Again, assuming an average shock force of 10% of the maximum, the total pulse duration is 1.3 ms. This corresponds to an average shock loading of 545 g's.

After attempting to mathematically ratio the probable maximum number of times a dog would sustain shocks of this magnitude, the following test plan was derived for the NU4 production units:

- (1) 4g vibration
- (2) 3000 - 50g shocks
- (3) 12 - 855g shocks
- (4) 96 - 545g shocks
- (5) 4500g shock

The NU4 pacers were compared to the Phase I design with respect to their capability to withstand the various shock and vibration levels. The

test results verified that the NU4 pacers were significantly better than the Phase I pacers. Based on these test results, production began of the NU4 series. However, after a short time, the NU4's which had been implanted in dogs began to fail. Various tests were conducted in order to duplicate a pacer failure mode similar to the failures encountered in the dogs at NHI. Table IV-1 describes these tests and the test sequence with the results. The only pacers tested (Table IV-1) which were not standard production units were SV-1, SV-2, and P-2. Units SV-1 and SV-2 were special wrapped thermopiles which duplicated the loose center wrap of NU4-9 (first dog failure). Unit P-2 was a prototype pacer which was used for comparison.

Metallurgical evaluations revealed that the failure modes of pacers which were subjected to these various levels of shock and vibration were not similar to the dog implanted failure mode. It should be noted that in all cases the dog failure mode was the same (multiple broken edge wires at the hot shoe).

At this point, the slow motion pictures taken of the various dog environments were again reviewed. It was observed that the movement of a dog under certain conditions could best be categorized as a motion similar to a paint shaker. Units were tested on a paint shaker at a local facility. The first units tested were standard production pacers, and the initial results were rapid pacer failure. All of the paint shaker tests conducted during that quarterly report period are listed in Table IV-2. The tape failures were very similar to the failed tapes in the dog units. The metallurgical and disassembly reports in other sections of this report note this. The chart (Table IV-2) indicates that the pacer failures on the paint shaker are attributed in most cases to shorting. This shorting condition was a result of the severity of the test and was not considered applicable to the dog environment. The paint shaker test can best be described as an accelerated test of the thermocouple tapes to withstand a dog environment. Tests were run on a newer model paint shaker, but it was determined that the shock levels of the newer model were considerably lower. Relative shock measurements indicated that shock amplitude on the older shaker (Sherwin Williams) was approximately 45 g's. Each pacer was mounted with the z axis perpendicular to the base of the shaker so that the basic lateral motion was through the y axis accompanied by a degree of torquing action through the x axis.

Table IV-1

Test Unit	Test	After Test			Comments
		Voc	Vpp	Ω	
SV-1 (special wrap)	.5 g vibration in x, y, z axis	2.13	1.07	5300	
	4 ATM pressure test	2.12	1.06	5300	
	4 g vibration in x, y, z axis	2.15	1.07	5300	Scan 20 HZ - 500 HZ - 20 HZ
	Thermal cycle	2.12	1.06	5300	
	5' free fall to concrete	2.10	1.05	5300	
	50 g shock test 3000 cycles	2.20	1.10	5290	
	545 g shock test - 96 cycles	2.07	1.03	5200	Intermittent shorting experienced
	1.5 g vibration @ 10 HZ in z axis	2.20	1.10	5300	Accumulated 612,000 cycles
	8 g vibration @ 20 HZ in z axis	.010		10	Unit failed from shorting after 648,000 cycles
SV-2 (special wrap)	.5 g vibration in x, y, z axis	2.18	1.09	5300	
	4 ATM pressure test	2.17	1.08	5300	
	4 g vibration in x, y, z axis	2.18	1.09	5300	
	Thermal cycling	2.14	1.07	5300	
	5' free fall	2.14	1.07	5300	
	50 g shock test - 3000 cycles	2.24	1.12	5300	
	545 g shock test - 96 cycles	1.60	.80	4300	Intermittent shorting
	1.5 g vibration in x axis @ 10 HZ	1.80	.90	4300	Intermittent shorting accumulated 612,000 cycles
	8 g vibration @ 20 HZ in x axis	0		6	Failed in shorting condition after 648,000 cycles
NU4-32 (production)	4 ATM pressure	2.30	1.15	5424	
	4 g vibration in x, y, z	2.32	1.16	5424	
	Thermal cycling	2.33	1.16	5425	
	5' free fall to concrete	2.39	1.19	5432	
	50 g shock - 3000 cycles	2.39	1.19	5495	
	545 g shock - 96 cycles	2.28	1.14	5395	
	2 g vibration @ 20 HZ in y axis	2.30	1.15	5300	Accumulated 5,004,000 cycles
	2 g vibration @ 20 HZ in z axis	2.30	1.15	5300	Accumulated 2,736,000 cycles
P-2 (prototype)	2 g vibration @ 20 HZ in z axis	(unit pulsing)			Unit was later used for paint shaker
					Accumulated 1,440,000 cycles
					Unit was later used for paint shaker

Table IV-1 (continued)

<u>Test Unit</u>	<u>Test</u>	<u>After Test</u>			<u>Comments</u>
		<u>Voc</u>	<u>Vpp</u>	<u>Ω</u>	
NU4-42	.5 g vibration in x, y, z axis	units were pulsing			Production pacers with electronics thermopiles were wrapped by a different assembler. Units were then placed on life test (data presented in attached reliability section).
NU4-44	4 ATM pressure	units were pulsing			
(production)	4 g vibration in x, y, z	units were pulsing			
	Thermal cycling	units were pulsing			
	5' free fall	units were pulsing			
	50 g shock test - 3000 cycles	units were pulsing			
	545 g shock - 96 cycles	units were pulsing			
NU4-7	2' drop to concrete encased in silastic				This unit was previously subjected to the environmental test sequence and reported in the last quarterly report
(production)	after 750 drops	2.31	1.16	5400	
	after 800 drops	.01			
NU4-12	.5 g vibration in x, y, z	unit pulsing			Failed after 320 drops
(production)	4 ATM pressure	unit pulsing			
	4 g vibration in x, y, z	unit pulsing			
	Thermal cycling	unit pulsing			
	5' free fall to concrete	unit pulsing			
	50 g shock test - 3000 cycles	unit pulsing			
	545 g shock - 96 cycles	unit pulsing			
	5' fall to concrete encased in silastic	stopped pacing			
NU4-35	repeat 50 g shock test to failure				production type pacer battery
	41,000 cycles	1st tape failure			
	61,000 cycles	2nd tape failure			
	115,000 cycles	3rd tape failure			
	240,000 cycles	Unit shorted			
NU4-54	continuous 8 g vibration at 20 HZ				placed on life test after achieving 1.7 million cycles
	present data	2.35	1.17	5690	

Table IV-1 (continued)

<u>Test Unit</u>	<u>Test</u>	<u>After Test</u>			<u>Comments</u>
		<u>Voc</u>	<u>Vpp</u>	<u>Ω</u>	
NU4-55 (production)	wrist type laboratory shaker	(not complete)			shaker is operating at approximately 360 cycles/minutes and .5 g's. The test has been running continuously since 4/4/72. And no charge has occurred.
NU4-53 (production)	hammer test	(not complete)			a hammer type device has been striking the pacer (encased in silastic) in the x axis approximately 360 cycles per minute at roughly 15 g's. This test has been on continuous operation since 4/15/72 without any change in performance

Table IV-2

Pacer No.	Design	Testing Prior to Paint Shaker	Type Paint Shaker	Paint Shaker Test Data				Time to pacer failure (Minutes)	Failure Mode
				Time to tape opens (minutes)					
				1st	2nd	3rd	4th		
NU4-56	Production	2 g vibration 100 HZ 22 hours	S.W.*	5				6	Shorting
P-2	Prototype	2 g vibration 20 HZ 1.4 million cycles	S.W.					2	Shorting
PD-69	Extra Insulation	None	R.D.**						None
NU-32	Production	Qualification tests	S.W.	12				20	Shorting
NU4-47	Production	None	R.D.					45	Shorting
NU4-49	Production	None	S.W.	42	48	76	--	80	Shorting
NU4-48	Production	None	R.D.	33.5	42.5	47	51	52	Shorting
NU4-50	Production	None	S.W.	4	5	13	15	22	Shorting
NU4-58	No hot shoe attachment	None	S.W.	49	63	67		75	Shorting
183	Dbl. Hot Strap								
	DHS-3	Dbl. Hot Strap	None	S.W.	27			--	***
	DHS-1	Dbl. Hot Strap	None	S.W.	1			66	Shorting
	NU4-37	Production	None	S.W.	2			5	Complete open
	DHS-2	Dbl. Hot Strap	None	S.W.	10			11	Shorting

* Sherwin Williams paint shaker

** "Red devil" paint shaker (no change after 19 hours on shaker)

*** Unit taken off test after 52 minutes

Several design variations were tested during this time period. One design was to use approximately 75% more insulation tape in wrapping the thermopile. This unit (PD-69) was tested on the "Red Devil" paint shaker for 19 hours without any tape failure. Three pacers were tested with a double hot strap arrangement. This design theoretically allowed the fuel capsule to move without applying stress to the tapes in the area of the hot shoes. However, it did not significantly improve the life of the pacer on the paint shaker. Unit NU4-58 had no hot shoe attachment and a double hot strap. Again there was no significant improvement.

Additional testing was completed and is presented in Figures IV-3, IV-4 and IV-5. The environmental tests mentioned in these figures consist of the following:

1. 4 atm of pressure
2. 4g vibration, 20-500-20 HZ
3. -40°F to +140°F thermal cycling
4. 5' drop to concrete (4500 g's)
5. 3000, 50g shocks
6. 96, 545g shocks

All of the shaker tests were done on the Sherwin Williams paint shaker. Each pacer was mounted with the z axis perpendicular to the base of the shaker so that the basic lateral motion was through the y axis accompanied by a degree of torquing action through the x axis.

Batteries NU4-70, 71, 72, 73, 59, and LHS-1 (Figure IV-3) were designs which affected both the hot strap and the amount of insulation tape. Analysis of these results indicated that the longer life on the shaker was associated mainly with the extra insulation tape added to the thermopile.

TR2 and TR3 were the first batteries fabricated with extra insulation tape and tested on the paint shaker for 15 hours. There was concern that the high shock levels encountered during the environmental test could cause a shorting condition during the shaker tests. Therefore, TR2 was first tested on the shaker while TR3 was subjected first to the environmental tests. TR3 was disassembled and the general appearance of the thermopile was much better than the NU4 series (production) pacers which had been tested in the similar manner. The longest time before failure of a production pacer on the shaker had been 80 minutes, and many units have failed in 5

Figure IV-3

Pacer No.	Design	Environmental Test Before or After Paint Shaker	Pacers Failed on Shaker					Time to Failure (min)	Shaker Accumulated Time Without Failures	Comments
			Time to Open Tape (min)							
			1st	2nd	3rd	4th				
NU4-70	Double Hot Strap 50% Extra Insulation	Before								Failed during 545 g shock test
NU4-71	Oversize Hot Strap 50% Extra Insulation	None	150	200				260		Shorted
NU4-72	Same as NU4-71	After							15 Hrs.	
NU4-73	Double Hot Strap 50% Extra Insulation	None							15 Hrs.	
NU4-59	Oversize Hot Strap 50% Extra Insulation Longer Slots in Cold Strap	None	700						15 Hrs.	
LHS-1	No Hot Shoe Attachment	None	8	18	25	70		80		

Figure IV-4

Environmental Test 1st → Shaker Test 2nd

Unit No.	Thermopile Assembly	Before Test		After Testing		Shaker Test Data						
		Voc	Battery Ω	Environmental	Paint Shaker	min(s) Voc	1	Tapes Open		4	Min(s) to Failure	Failure Mode
TR3	Extra Insulation	2.32	5300	Acceptable	Acceptable after 15 hrs.	820 2.71						
E5	Extra Insulation	2.30	5300	Acceptable	Failed	min(s) Voc					360 .12	Short
E6	Extra Insulation	2.19	5300	Acceptable	Failed	min(s) Voc					170 1.78	Short
E8	Extra Insulation	2.15	5300	Acceptable	Failed	min(s) Voc	110 2.82				240 .23	Short
NU4-52	Production	2.36	5300	Acceptable	Failed	min(s) Voc	7 2.52	14 2.63	16 2.64	30 2.68	40 .03	Short

Figure IV-5

Shaker Test 1st → Environmental Test 2nd

Unit No.	Thermopile Assembly	Before Test		After Testing		Shaker Test Data						
		Voc	Battery Ω	Paint Shaker	Environmental	min(s) Voc	1	Tapes Open		4	Min(s) to Failure	Failure Mode
								2	3			
TR2	Extra Insulation	2.32	5300	Acceptable after 15 hrs.	Acceptable	min(s) Voc						
E4	Extra Insulation	2.31	5300	Acceptable after 15 hrs.	Acceptable	min(s) Voc						
E7	Extra Insulation	2.22	5300	Acceptable* after 15 hrs.	Acceptable	min(s) Voc	60 2.34					
E9	Extra Insulation	2.33	5320	Failed		min(s) Voc	100 2.41	120 2.42	160 2.42		291 2.43	Short
NU4-51	Production	2.53	5300	Failed		min(s) Voc	16 2.65		50 2.39		55	Short

* Test data reported resistance value

 Ω

minutes. Batteries E4 and E5 were fabricated and tested for comparison. E5 successfully completed the environmental tests but failed after 5 hours on the shaker. The failure was due to severe internal shorting. E4 which first survived 15 hours on the shaker then the environmental test did not lose any tapes. Batteries E6, E7, E8, and E9 were assembled and divided into two test groups as indicated by Figures IV-4 and IV-5. E6 and E8 which were first subjected to environmental tests both failed because of shorting during the shaker test. E7 (Figure IV-5) completed 15 hours on the shaker during which time test data indicated that one tape had opened; however, disassembly after the final environmental tests did not reveal any open tapes. Likewise, E9 was first subjected to the shaker where battery resistance values indicated three tape failures after 100, 120, and 160 minutes. E9 was disassembled after 291 minutes on the shaker because of shorting and revealed all of the tapes were still good. It was also impossible to determine the cause of the shorting.

All of the results to this point indicated a tendency to introduce shorting when environmental testing is done prior to shaker tests. Apparently the 5' fall to concrete and the 96, 545g shocks establish a condition which is conducive to shorting when followed by the shaker test. No units had ever shorted in animals and all animal failures had been multiple open tapes at the hot shoe end. The shaker does duplicate exactly the tape failures experienced in animals. Some of the causes of the shorting have been detected at disassembly. In certain cases tape to tape shorting has resulted because of a wearing away of the insulation tape. Another time the heat shields were dislocated and wore through the insulation covering the thermopile bus wire and shorted against the case.

The paint shaker is considered to be a valid test of the thermocouple wire to withstand fatigue. In order to eliminate the shorting two modified batteries (NU5-Q1, NU5-Q2) with 50% additional insulation tape were tested in the following sequence:

1. Radiograph
2. 5 hours on paint shaker
3. 4 atm pressure test
4. 4g vibration, 20-500-20 HZ
5. Thermal cycling, -40°F to +140°F

6. 5' free fall to concrete, 1 cycle (4500 g)
7. 50g shock test, 3000 cycles
8. 545g shock test, 96 cycles
9. Test to failure on the paint shaker
10. Radiograph

This sequence of tests is later referred to as the qualification test.

Figure IV-6 summarizes the results of NU5-Q1 and NU5-Q2. In order to qualify the design and the assembly technique each battery had to successfully complete steps 1 through 8. Although both batteries were successful, NU5-Q1 operated approximately 3 times longer than NU5-Q2.

There did not appear to be a significant difference in the thermopile wrapping when comparing the end view radiographs before testing. In fact, Q2 may appear to be more evenly wrapped than Q1. Both batteries failed in the shorting mode. Q1 at failure had two tapes open in each bank and Q2 had only one tape open in one bank.

The revised System Test Plan required that during production of pacers every eighth wrapped thermopile be assembled as a battery and tested as outlined earlier. Again, for the battery to be acceptable, it must successfully complete the qualification test with a Voc > 1.9. If that test battery is acceptable, then the preceeding 7 pacers are qualified for implantation. If the eighth fails, then the seventh will be tested and will qualify 6 pacers for implantation. Figure IV-6 summarizes the first of these sampled thermopiles.

It should be noted standard production pacers (NU-4) without extra insulation tape lasted at most 80 minutes and as little as 6 minutes on the same paint shaker. Therefore, it appears that the new design will be capable of enduring the animal implantation environment, since all of the units tested to date have successfully passed the qualification test.

Figure IV-7 is a bar graph representing the accumulated time to failure (minutes) on the paint shaker. No. 35 was a qualification battery but had one tape which opened during wrapping and explains its marginal performance. Radiographs of the end views are shown in Figures IV-8, IV-9, and IV-10. Batteries 7, 14, 22, 28, and 35 satisfy the requirement that every eighth thermopile will be tested. Batteries 10 and 25 have sizable void areas in the middle and outside wraps of the thermopile and were also tested.

Figure IV-6
TESTING RESULTS ON PRE-PRODUCTION AND
PRODUCTION NU5 UNITS

UNIT	AFTER FIVE HOURS ON PAINT SHAKER	AFTER STANDARD QUALIFICATION TEST	TIME TO FAILURE					COMMENTS
			1ST TAPE	2ND TAPE	3RD TAPE	4TH TAPE	COMPLETE	
NU5-Q1	Acceptable	Acceptable	800 min.	1260 min.		1670 min.	1841 min.	Unit began shorting at 1730 minutes. Test stopped when V_{oc} dropped to 1.24 volts
NU5-Q2	Acceptable	1st tape failed after 24th-545 g shock in x axis					610 min.	Unit began shorting at 570 minutes. Test stopped when V_{oc} dropped to 1.84 volts
NU5-7 06T	Acceptable	Acceptable	600 min.		1431 min.		1594 min.	Unit began shorting at 1420 minutes. Test stopped when V_{oc} dropped to 1.64 volts
NU5-14	Acceptable	Acceptable	731 min.				1402 min.	Unit began shorting at 410 minutes. Test stopped when V_{oc} dropped to 1.67 volts
NU5-22	Acceptable	Acceptable	1300 min.		1420 min.		1926 min.	
NU5-28	Acceptable	Acceptable		610 min.			741 min.	At 650 minutes the resistance began to vary from 14,200 to 8000 ohms
NU5-35	Acceptable	1st tape failed after 5' fall to concrete			316 min.		560 min.	

Figure IV-6 (Continued)
TESTING RESULTS ON PRE-PRODUCTION AND
PRODUCTION NU5 UNITS

UNIT	AFTER FIVE HOURS ON PAINT SHAKER	AFTER STANDARD QUALIFICATION TEST	TIME TO FAILURE					COMMENTS
			1ST TAPE	2ND TAPE	3RD TAPE	4TH TAPE	COMPLETE	
NU5-10	Acceptable	Acceptable						Contained electronics unit still pulsing at 1200 minutes.
NU5-25	Acceptable	Acceptable	580 min.		710 min.		903 min.	
NU5-43	Acceptable	Acceptable	420 min.	630 min.			842 min.	
NU5-51	Acceptable	Acceptable	520 min.	590 min.	810 min.			
NU5-39	Acceptable	Acceptable						Unit is still functioning properly.
NU5-58	First Tape After 290 min.	Acceptable Unit corrected itself after pressurization.						Unit began shorting from 500 min. to 900 min. when test was concluded.
NU5-68	Acceptable	Acceptable	680 min.	720 min.			1260 min.	Unit began shorting from 680 to 1260 when test was concluded.

QUALIFICATION TEST RESULTS OF PRODUCTION BATTERIES

Figure IV-7

QUALIFICATION TEST RESULTS OF PRODUCTION BATTERIES

UNIT HAS NOT FAILED.

UNIT HAS FAILED.

TEST BATTERIES, NU5-

Figure IV-7
(continued)

END VIEW RADIOGRAPH

BATTERY NU5 -7

BATTERY NU 5-10

BATTERY NU 5-14

BATTERY NU 5-22

END VIEW RADIOGRAPH

BATTERY NU5-28

BATTERY NU5-35

BATTERY NU5-Q1

BATTERY NU5-Q2

Figure IV-9

END VIEW RADIOGRAPH

BATTERY NU5-25

Figure IV-10

The results of these two batteries were contradictory. No. 10 has accumulated 1200 minutes and is still acceptable whereas No. 25 failed after slightly more than 900 minutes. However, No. 25 as a worst case achieved a factor of three more times on the shaker than the required 300 minutes. It is difficult to predict the amount of time on the shaker a battery can achieve from the thermopile radiographs. A major percentage of the test batteries have had moderate to large void areas at the middle or outside thermopile wraps, but does not appear to limit performance. The radiographs also detected bends in the thermocouple wire near the cold shoes. Battery No. 25, figure IV-10, had a particularly sharp bend in the wire near the cold shoe of No. 1 tape and was subjected to the qualification tests. No wire breakage occurred at the cold shoes in this case or in any other similar cases tested. In fact, through all of the testing the wire breakage occurred at the hot shoes. After Battery No. 25 failed, it was disassembled and photographs were taken of the bends or folds in the tape, figure IV-11. Apparently, there is very little movement or flexing at the outside wraps of the thermopile.

B. Analysis of NU-4 Versus NU-5

Deflection vs. load curves in the radial direction (+ Y direction) were obtained for a loosely wrapped and with 50% more insulation wrapped thermopiles. The tests results are shown in Figures IV-12 through IV-13. As can be seen from these figures for the same load, a loosely wrapped thermopile has approximately ten times more deflection than a thermopile with 50% more insulation. Also for a loosely wrapped thermopile unit near the origin (geometric center of thermopile) for loads under 50 gms, the deflection may be as high as .030 inches, and the stiffness in this range is very close to zero. This situation is a lot better for the thermopile with more insulation. From these comparative load vs. deflection tests, it may be concluded that the cause of some failures of the earlier pacemaker model (NU-4) was due to vibration, which resulted in large amplitude due to low stiffness which in turn put high strain on the thermocouple wires and failed as a result of fatigue. It is unlikely that the failures were due to any vibration of the hot strap-fuel capsule at a resonant frequency.

BATTERY NU5-25
COLD SHOE-TAPE NO.1

Figure IV-11

HYSTERESIS LOOP IN THE $\pm Y$ DIRECTION

DEFLECTION - THOUSANDS OF AN INCH

HYSTERESIS LOOP IN THE $\pm$ Y DIRECTION

Figure IV-13

C. Surface Temperature Measurement in Shipping Cases

Preliminary testing on a pilot production unit in the presently used plastic cases and in the attache case that they are placed in for shipment has been performed. It has been found that the increase in surface temperature is approximately 5°C in the ambient range of -20°C to 43°C. This test was performed because if an attache case was left, for example, in a car in the hot sun the temperatures might effect the electronics if the ΔT had been high. Also, if inadvertently somebody prepared a packaging of one of the urethane closed cell type insulation foams, the increased temperature of the case might overheat the electronics. Thus, further evaluation of the proposed shipping containers and, of course, even the present unit under various ambient conditions will be necessary.

D. In-Vivo Tests of the Radioisotope Cardiac Pacemaker in Dogs

1. Project Outline

The goals of this study are to test the in vivo reliability of the Radioisotope Powered Cardiac Pacemaker.

The specific goals of these tests are to ascertain the reliability of the electrical conversion source, the electrical pulse generator, the external mechanical systems of leads and connectors, and the encapsulation of the electronic systems of the device, under in vivo circumstances, even under the unusual mechanical accelerations and impacts to be encountered in active dogs in a confined environment.

2. Instrumentation

The performance of each nuclear pacemaker is checked at weekly intervals and evaluated by determining its change of rate and its ability to capture the dog's heart. The rate is obtained by use of a circuit which detects the electrical output pulse of the pacemaker by sensing its electromagnetic field. This circuit feeds a Monsanto rate counter which converts period to beats per minute and displays the result digitally. This measurement system has been calibrated using an external source of known period and the findings indicate a $\pm .1$ BPM accuracy. To determine whether the pacemaker is capturing the canine heart, each dog's femoral artery is felt. Using these circumstances, a pacer pulse feels much stronger than a normal beat. Done also on a weekly basis, this provides a convenient check that capture exists. In addition to the weekly checks, electrocardiograms are recorded at monthly intervals.

3. Results as of the End of October

A total of 6.26 unit years has been accumulated in 30 dogs as of October 31, 1972. Table IV-3 lists the rate readings of each implanted pacer and except for the anomalous reading of dog 1P101 on October 13, 1972, no pacemaker rate has deviated more than .8 BPM from its original reading. All femoral checks and electrocardiograms indicate continued pacing of each dog. There are no external symptoms implying any disorder in the NU-5 pacer system. The dogs used in this study have all exhibited excessive canine activity and have subjected the pacers to many erratic motions and sudden severe bumps with the amplitude or mechanical acceleration and shock unquestionably exceeding that which would be encountered in human patients.

On October 13, 1972, a rate check of dog 1P101 resulted in a reading of 71.8 BPM which corresponded to a drop of 2.7 BPM. An electrocardiogram taken that day substantiated the rate drop. However, the next time the rate was measured, which was on October 17, 1972, the rate was back at its earlier reading of 74.5 BPM. Again, an electrocardiogram validated the rate change. All subsequent readings (four readings on consecutive days) are within +.2 BPM of 74.5 BPM. Reasons for this irregular reading are being explored, while dog 1P101 is being closely observed. Two irregularities associated with dog 1P101 have been noticed. First, at implantation, the pacing threshold was recorded at 3.5 milliamperes while every other dog had a pacing threshold less than 1.5 milliamperes. Dog 1P101 had an electrode already inserted at the time of implantation, as roughly 10 other dogs did, possibly accounting for the high threshold. Possibly accounting for this abnormality is the fact that a dacron bag may not have been inserted during implantation in this particular dog. Movies of this dog (1P101) revealed that the implanted pacemaker is free to move great distances within the dog as it walks and runs thus subjecting the pacer to even greater shock and vibration levels than normally implanted units.

Table IV-3

Dog #	P.I. #	Date Implanted	7-28-72	8-4-72	8-11-72	8-18-72	8-25-72	9-1-72	9-8-72	9-15-72	9-22-72	9-29-72	10-6-72	10-13-72	10-20-72	10-27-72
1P029	3	7-10-72	73.4	73.4	73.5	73.6	73.4	73.6	73.6	73.7	73.7	73.8	73.8	73.7	73.7	73.7
1P076	5	7-10-72	72.6	72.6	72.6	72.6	72.6	72.6	72.6	72.5	72.7	72.6	72.6	72.6	72.4	72.5
1P086	6	7-10-72	72.8	72.8	72.7	72.8	73.0	72.6	72.7	72.7	72.6	72.7	72.8	72.7	72.7	72.6
1560	9	7-13-72	73.4	73.4	73.5	73.6	73.7	73.6	73.7	73.7	73.6	73.6	73.7	73.7	73.5	73.6
1P026	11	7-17-72	73.6	73.7	73.7	73.8	73.8	73.9	74.0	73.9	73.9	74.0	74.1	74.2	74.1	74.3
1P127	15	7-17-72	73.5	73.5	73.5	73.6	73.6	73.7	73.7	73.8	73.8	73.9	73.9	74.0	74.0	74.0
F501	20	7-17-72	73.4	73.4	73.3	73.4	73.5	73.4	73.5	73.3	73.9	73.5	73.7	73.6	73.4	73.7
1470	13	7-17-72	73.1	73.2	73.2	73.4	73.4	73.6	73.7	73.9	73.8	73.8	73.9	73.8	73.9	73.9
1P108	23	7-24-72	74.5	74.5	74.5	74.5	74.6	74.6	74.6	74.7	74.7	74.8	74.8	74.8	74.8	74.8
1494	21	7-24-72	73.9	73.9	73.9	74.0	74.1	74.1	74.2	74.5	74.4	74.5	74.5	74.6	74.5	74.5
1P101	24	7-24-72	74.0	74.0	74.3	74.4	74.4	74.3	74.3	74.5	74.5	74.5	74.5	71.8	74.7	74.5
1P103	26	7-24-72	72.7	72.7	72.7	72.7	72.8	72.8	72.8	72.9	72.9	73.0	73.0	73.1	73.1	73.1
1P517	33	7-31-72		72.2	72.2	72.3	72.5	72.6	72.6	72.7	72.7	72.8	72.8	72.8	72.8	72.9
1504	30	7-31-72		72.6	72.6	72.6	72.7	72.8	72.8	72.9	73.0	73.0	73.0	73.0	73.0	73.1
1P585	29	7-31-72		--	72.9	72.8	72.9	72.9	73.0	73.0	73.0	73.1	73.1	73.2	73.2	73.2
1P614	34	7-31-72		73.2	73.1	73.1	73.1	73.1	73.2	73.2	73.3	73.4	73.4	73.4	73.4	73.5
1612	38	8-7-72			73.0	73.0	73.0	73.1	73.2	73.3	73.3	73.4	73.4	73.4	73.4	73.5
W432	42	8-7-72			72.4	72.3	72.3	72.3	72.4	72.5	72.5	72.6	72.6	72.8	72.8	72.8
1P656	36	8-11-72				72.6	72.6	72.6	72.7	72.8	72.8	72.9	72.9	72.9	72.9	72.9
1P666	40	8-14-72				73.2	73.2	73.2	73.2	73.2	73.3	73.3	73.4	73.4	73.4	73.5
1P668	45	8-14-72				72.4	72.2	72.2	72.2	72.2	72.2	72.3	72.5	72.5	72.6	72.6
1P611	46	8-14-72				72.4	72.4	72.4	72.5	72.4	72.5	72.5	72.6	72.6	72.7	72.7
1P618	47	8-14-72				72.3	72.2	72.1	72.2	72.3	72.3	72.5	72.5	72.5	72.4	72.5
1P638	49	8-22-72					72.9	72.8	72.8	72.9	73.0	73.1	73.2	73.2	73.2	73.4
1N969	52	8-28-72						72.8	72.8	72.8	72.9	73.0	73.0	73.1	73.2	73.2
1P802	54	8-28-72						72.7	72.6	72.7	72.8	72.7	72.7	72.7	72.8	72.8
1P764	55	8-30-72						72.7	72.8	72.8	72.8	72.9	73.0	73.0	73.0	73.1
1P785	41	9-8-72									73.1	73.1	73.1	73.1	73.1	73.1
1P654	56	9-8-72									73.0	72.9	73.1	73.1	73.2	73.2
1P776	57	9-12-72									73.4	73.4	73.4	73.5	73.6	73.8

V. Task 5.0 - SAFETY

A. Statistical Analysis

Due to the potential widespread distribution of Radioisotope Powered Cardiac Pacemakers, additional studies of fuel capsule integrity under credible accident conditions were deemed necessary. The initial phase of this study has involved an examination of available statistics in the area of accidental deaths since it has been assumed that any accident of sufficient severity to result in nuclear fuel release will result in the death of the implantee.

Consideration of relevant death statistics has resulted in the enumeration of four credible fuel capsule failure modes. These failure modes are:

1. impact of a high velocity projectile,
2. high temperature,
3. impact of the capsule at high velocity, and
4. rupture due to crushing

Some of the accidents appropriate to each of these potential capsule failure modes are, respectively, homicide or suicide*, fire or explosion, aircraft accident, and industrial accident.

The limit of credibility has arbitrarily been chosen as 1×10^{-6} . That is, if there is a possibility greater than 1 chance in a million that a potential RPCP implantee will encounter a given accident situation, the fuel capsule must be shown to maintain its integrity under the conditions imposed in the given accident. However, the limit of credibility must be further defined. The appropriate probability of an individuals demise in an accident depends on the number of RPCP wearers.

In this report, it has been estimated that at any one time, there is a "stationary" population of 100,000 RPCP wearers. In addition, based on the files of three doctors with considerable experience in the implantation of conventional pacers, the implantee age distribution shown in Fig. V-1 has been assumed. This age distribution is used throughout this report.

* Note that for the purposes of this report, homicide is considered an accident.

ASSUMED PACER IMPLANTEE AGE DISTRIBUTION - (100,000 TOTAL)

Figure V-1

1. Analysis of Firearm Deaths

Consideration of potential implantee firearm deaths has indicated that there exists three "modes" of possible fuel encapsulation failure due to impact of a high velocity projectile. These three possible failure modes are homicide, suicide, and firearms accidents. In 1970, the total number of firearm deaths attributed to each of these causes was 9,039, 10, 911, and 2,300, respectively.

Homicide:

Making use of data published by the Federal Bureau of Investigation, the probability that an implantee is murdered with a firearm can be calculated. In Table V-1 it is shown that, on the average, the probability that one or more implantees will die due to the impact of a firearms projectile during the act of murder is 0.22 in a year.

Since we will ultimately be concerned with the penetrability of firearms projectiles into the fuel capsules of RPCP's, we now proceed to a consideration of the type of weapon (i.e. handgun, rifle, shotgun, etc.) used in the act of homicide. This is necessitated by the fact that the FBI has shown that penetrability of firearms projectiles through ductile metal is determined entirely by the projectile's (kinetic) energy.

The probability that an implantee will be murdered with the indicated weapon can be shown to be as follows:

<u>Weapon</u>	<u>Probability</u>
Handgun	.18
Shotgun	2.2×10^{-2}
22 Cal. Rifle	9.7×10^{-3}
Other Rifles	6.4×10^{-3}

The figures concerning the probability of implantee murder with the indicated weapon can be "translated" into the possibility of hitting the fuel capsule via the following rationale: The average vital area projected by an individual (front, back, sides and head) is 680 square inches. The total projected fuel capsule area is .65 square inches. Assuming a "hit" in any area to be equally likely, the probability of hitting the fuel capsule during the act of murder becomes:

Table V-1

IMPLANTEE MURDER BY FIREARMS

<u>AGE</u>	<u>POPULATION X 10⁵</u>	<u>FIREARM MURDERS</u>	<u>NUMBER OF IMPLANTEES</u>	<u>PROBABILITY</u>
Under 1	42.2	5	0	0
1 - 4	173.7	38	300	6.5×10^{-4}
5 - 9	211.9	35	350	5.7×10^{-4}
10 - 14	192.7	112	350	2.0×10^{-3}
15 - 19	168.9	869	350	1.8×10^{-2}
20 - 24	134.4	1568	350	4.0×10^{-2}
25 - 29	115.8	1424	350	4.21×10^{-2}
30 - 34	116.0	1058	350	3.14×10^{-2}
35 - 39	126.9	868	350	2.4×10^{-2}
40 - 44	129.2	860	750	4.8×10^{-2}
45 - 49	118.4	644	1500	7.8×10^{-2}
50 - 54	109.1	497	3000	1.2×10^{-1}
55 - 59	94.2	329	5500	1.7×10^{-1}
60 - 64	80.3	269	11000	3.8×10^{-1}
65 - 69	65.3	161	18000	4.3×10^{-1}
70 - 74	54.0	95	27000	3.7×10^{-1}
<u>Above 75</u>	<u>64.5</u>	<u>62</u>	<u>30500</u>	<u>2.5×10^{-1}</u>
Total All Ages	2×10^8	9,039	100,000	0.22

<u>Weapon</u>	<u>Probability</u>
Handgun	1.7×10^{-4}
Shotgun	2.1×10^{-5}
22 Cal. Rifle	9.3×10^{-6}
Other Rifles	6.0×10^{-6}

Suicide:

In 1969, a total of 21,372 people committed suicide. Of this total number of suicides, 51 percent involved the use of firearms. Since the age distribution of suicide victims killed with firearms is not available, the number of people who commit suicide with a firearm has been assumed equal to 51 percent of the total number of persons in a given age group that commit suicide.

In Table V-2 the probability that one or more implantees commit suicide via a firearm is shown to be 0.82. This large probability is the mathematical result of the fact that large numbers of Americans aged 50 years and above commit suicide. These same people constitute a large percentage of the total number of implantees.

Information relating to the type of weapon used in the act of suicide is simply not available. However, virtually all of the suicides involving a firearm are the result of handgun wounds. Except in a few bizarre cases, a long gun suicide is impossible due to the physical limitations imposed upon the victim by the size of the weapon.

Thus, in an attempt to obtain quantitative information regarding suicides, it is assumed that all suicides occur by use of a handgun. In addition, the conservative assumption that wounds in all vital areas are equally probable is made. This allows the probability of hitting the fuel capsule with a handgun projectile during the act of suicide to be calculated as 7.8×10^{-4} .

Accidents:

In 1970, there were 2300 accidental firearms deaths, a decrease of 4 percent from 1969. Although the number of yearly accidental firearms deaths appears to be decreasing, this figure of 2300 represents a significant number of people and, hence, we now proceed to a calculation

Table V-2

IMPLANTEE SUICIDE BY FIREARM

<u>AGE</u>	<u>POPULATION X 10⁵</u>	<u>SUICIDE</u>	<u>PROBABILITY</u>
Under 1	42.2	0	0
1 - 4	173.7	0	0
5 - 9	211.9	287	4.7×10^{-3}
10 - 14	192.7	501	9.0×10^{-3}
15 - 19	168.9	287	5.9×10^{-3}
20 - 24	134.4	501	1.2×10^{-2}
25 - 29	115.8	430	1.2×10^{-2}
30 - 34	116.0	287	8.6×10^{-3}
35 - 39	126.9	1219	3.3×10^{-2}
40 - 44	129.2	717	4.0×10^{-2}
45 - 49	118.4	1578	1.8×10^{-1}
50 - 54	109.1	1291	2.9×10^{-1}
55 - 59	94.2	1147	4.8×10^{-1}
60 - 64	80.3	1219	8.1×10^{-1}
65 - 69	65.3	717	8.6×10^{-1}
70 - 74	54.0	574	9.4×10^{-1}
<u>Above 75</u>	<u>64.5</u>	<u>645</u>	<u>9.5×10^{-1}</u>
Total All Ages	2×10^8	10,911	0.82

of the probability of an implantee accidental firearms death.

In Table V-3 it is shown that the probability of an implantee dying in an accidental firearms incident is 0.14. The age distribution shown in Table V-3 includes deaths due to accidents in the home, hunting accidents and accidents occurring in public places and work related deaths.

According to National Safety Council estimates for 1970, the distribution of accidental firearms deaths was: Accidents in the home - 1200, hunting accidents - 800, public and work related deaths - 300. Thus, the probability that one or more implantees die due to an accidental firearms incident in each of the three locations becomes:

Homes	7.3×10^{-2}
Hunting Accidents	4.8×10^{-2}
Public and Work Related	1.8×10^{-2}

In conclusion, the three possible fuel capsule failure modes involving the impact of a firearms projectile have been considered - homicide, suicide and accidents. The probability that one or more implantees dies due to each of the possible failure modes has been calculated for four different types of weapons - handgun, shotgun, 22 caliber rifle and long-rifle. Although an additional breakdown of the long rifle deaths would be desirable, the necessary information is not available. The total probability that a bullet fired from each of the weapons results in the death of an implantee is simply the sum of the separate probabilities. Thus, one concludes that the total probability of a firearms projectile impacting the RPCP fuel capsule due to the indicated weapon is:

<u>Weapon</u>	<u>Probability</u>
Handgun	9.9×10^{-4}
Shotgun	6.7×10^{-5}
22 Cal. Rifle	4.2×10^{-5}
Other Rifle	2.3×10^{-5}

Stated differently, a center fire rifle bullet will impact the RPCP fuel capsule, on the average, once in 43.4 thousand years.

Table V-3

IMPLANTEE ACCIDENTAL FIREARM DEATHS

<u>AGE</u>	<u>POPULATION x 10⁵</u>	<u>ACCIDENTAL DEATHS</u>	<u>PROBABILITY</u>
Under 1	42.2	30	1.7×10^{-3}
1 - 4	173.7	100	3.2×10^{-3}
5 - 9	211.9	200	3.6×10^{-3}
10 - 14	192.7	200	7.2×10^{-3}
15 - 19	168.9	350	9.0×10^{-3}
20 - 24	134.4	350	4.0×10^{-3}
25 - 29	115.8	135	4.0×10^{-3}
30 - 34	116.0	135	3.7×10^{-3}
35 - 39	126.9	135	7.8×10^{-7}
40 - 44	129.2	135	1.2×10^{-2}
45 - 49	118.4	100	2.7×10^{-2}
50 - 54	109.1	100	5.6×10^{-2}
55 - 59	94.2	100	1.2×10^{-1}
60 - 64	80.3	100	9.1×10^{-2}
65 - 69	65.3	35	$1.6 \times (10^{-1})$
<u>Above 75</u>	<u>64.5</u>	<u>50</u>	<u>2.1×10^{-1}</u>
 Total All Ages	 2×10^8	 2,300	 0.14

2. Analysis of Implanter Fire Deaths

A fire death is defined as a fire injury which becomes fatal within one year following the fire. Included as fire deaths are casualties resulting from attempts to escape the fire (e.g., jumping from a tall building), casualties resulting from falling objects (e.g., collapse of a wall), asphyxiation and contact with objects heated or released by a fire. Fire deaths resulting from other accidents are not included under this heading (e.g., auto fire resulting from an auto crash). However, the conditions encountered in, for example, an auto fire are mild in comparison with building fires.

A large number of the deaths attributed to fire are the result of carbon monoxide poisoning. This implies that few bodies are badly burned since once poisoning occurs the body would be expected to be lying on the floor: the floor temperature is significantly lower than the temperature at higher levels, and, in addition, the floor would probably become wet during the initial fire suppression activities. The observation that few, if any, bodies are badly burned in a fire appears to be borne-out during the search of fire records. However, most fire records are based on information contained on the death certificates. As such, the information is dependent on the skill and care used by the attending physician in completing the death certificate. Past experience has shown that considerable variation exists in this regard.

The age distribution of fire deaths is given for the year 1970 in Table V-4. It is observed that a total of 7,163 fire deaths occurred. The two age categories exhibiting the largest number of fire deaths are the 0-4 and above 75 age groups. This is indicative of the inability of the people in the 0-4 and above 75 groups to escape fires because of a lack of parental guidance and reduced mobility, respectively.

The distribution of fire deaths by location (or occupancy) is as follows:

Homes	5853
Farm	113
Mine or Quarry	17
Industrial	266
Recreation and Sport	7

Table V-4

FIRE DEATHS

<u>Age</u>	<u>Number of Deaths</u>
0-4	1012
5-9	463
10-14	192
15-19	171
20-24	225
25-29	221
30-34	198
35-39	269
40-44	367
45-49	440
50-54	460
55-59	538
60-64	515
65-69	450
70-74	448
Above 75	<u>1194</u>
TOTAL	7163

Streets and Highways	51
Public Buildings	220
Institutions	175
Other Specified	151
Not Specified	310

In Table V-5 it is shown that with the assumed RPCP implantee age distribution, the probability that one or more implantees die a fire death is 0.74.

As discussed previously, fire load data for the different occupancies indicates that the most severe conditions will result from an industrial fire. Since it is the most severe conditions which are of prime importance to this study, we now proceed to an evaluation of the probability that an implantee dies in an industrial fire.

The results of the calculation of the probability of an implantee industrial fire death is shown in Table V-6. In arriving at this result, it was assumed that the implantee is, again, entirely representative of his age group. Thus, it was assumed that the implantee has the same probability of being employed as any other person of the same age. The age distribution for workers in this country was taken from data published by the U. S. Labor Department.

Since the age distribution for industrial fires is not available, the number of industrial fire deaths in each age category has been apportioned between the age groups according to the number of workers in the age group.

From Table V-6 it is seen that the probability that one or more implantees die in an industrial fire is 0.0039. In other words, one implantee will die in an industrial fire, on the average, in 256 years.

The probability of exposure to various ASTM standard fires in an industrial fire is now calculated from data on the performance of fire rated containers. This calculation is made in spite of the fact that a particular industry employs a selection process in determining the type of container needed to protect its records, i.e., record containers are not selected in a random manner. As such, the probabilities obtained should only be considered as order-of-magnitude approximations.

Using this procedure the results for the probability of implantee exposure in an industrial fire to the various standard fires can be determined as follows:

Table V-5

FIRES AND FIRE DEATHS (1970)

<u>Age</u>	<u>Population x 10⁵</u>	<u>Fire Deaths</u>	<u>Implantees</u>	<u>Probability of Implantee Fire Deaths</u>
0-4	215.9	1012	300	1.39×10^{-2}
5-9	211.9	463	350	7.61×10^{-3}
10-14	192.7	192	350	3.48×10^{-3}
15-19	168.9	171	350	3.53×10^{-3}
20-24	134.4	225	350	5.84×10^{-3}
25-29	115.8	221	350	6.65×10^{-3}
30-34	116.0	198	350	5.95×10^{-3}
35-39	126.9	269	350	7.39×10^{-3}
40-44	129.2	367	750	2.10×10^{-2}
45-49	118.4	440	1,500	5.42×10^{-2}
50-54	109.1	460	3,000	1.18×10^{-1}
55-59	94.2	538	5,500	2.69×10^{-1}
60-64	80.3	515	11,000	5.06×10^{-1}
65-69	65.3	450	18,000	7.10×10^{-1}
70-74	54.0	448	27,000	8.93×10^{-1}
Above 75	64.5	1194	30,500	9.96×10^{-1}
TOTAL: All Ages	2×10^8	7,163	100,000	.74

Table V-6

INDUSTRIAL FIRE DEATHS

<u>Age</u>	<u>Number of Workers (x 10⁵)</u>	<u>Number of Working Implantees</u>	<u>Industrial Fire Deaths</u>	<u>Probability of Implantee Industrial Fire Death</u>
0-14	0	0	0	0
15-19	69.7	144	22.9	1.9×10^{-4}
20-24	98.8	257	32.5	6.2×10^{-4}
25-34	163.3	493	53.8	1.1×10^{-3}
35-44	164.3	706	54.2	1.5×10^{-3}
45-54	167.3	3,309	55.1	7.9×10^{-3}
55-64	111.3	10,528	36.7	2.1×10^{-3}
65-74	32.2	12,168	10.6	1.0×10^{-3}
Above 75	0	0	0	0
<hr/>				
TOTAL: All Ages	8.0×10^7	27,608	266	3.9×10^{-3}

<u>ASTM Standard Fire</u>	<u>Probability of Implantee Exposure to Fire Greater Than the Given Standard Fire</u>
45 min.	4.7×10^{-4}
1 hr.	3.1×10^{-5}
2 hrs.	1.6×10^{-6}
4 hrs.	4.5×10^{-8}

Interpolation can now be used to determine the ASTM Standard Fire conditions appropriate to the given limit of credibility, 1×10^{-6} . This interpolation, Figure V-2 shows that with this limit of credibility, the ASTM standard fire conditions are 1880°F at 132 minutes (2.2 hours).

3. Auto Accidents

In 1971, 54,800 people died in this country as a result of automobile accidents. With the assumed "stationary" population of 100,000 RPCP implantees, Table V-7 shows that, on the average, 37.83 implantees will die per year. Thus, the automobile accident represents the most likely form of implantee demise.

Although exact statistics on the number of automobile fires which occur following an auto accident are not available, for the purposes of this report it has been assumed that every automobile accident is followed by an automobile fire. Thus, 37.83 implantees will experience an automobile fire, on the average, per year.

Although the automobile accident (and hence the automobile fire) is the most credible implantee accident, the testing program to be discussed shortly has shown that this form of implantee death is the least severe in terms of the potential for nuclear fuel release.

4. Impact of Capsule at High Velocity

After a mid-air aircraft collision or an aircraft explosion, it was considered possible that a bare fuel capsule could be extricated from a pacemaker and thrown free of the aircraft. Under these conditions, the capsule would achieve its own terminal velocity prior to impact with the earth's surface. Accordingly, tumbling, end-on and side-on terminal velocities of a capsule were computed. The probable mode of impact is that resulting after a random spin and tumble or an end-over-end tumbling condition. For this mode, the orientation angle of the capsule

PROBABILITY OF IMPLANTEE EXPOSURE IN INDUSTRIAL FIRE
VS
THE STANDARD FIRE CONDITIONS

Table V-7

Implantee Auto Deaths (1971)

Age	Population x 10 ⁵	Auto Deaths	Implantees	Implantee Auto Deaths
0-4	215.2	1,900	300	0.026
5-14	404.6	4,100	700	0.071
15-24	303.3	16,500	700	0.381
25-44	487.9	13,700	1,800	0.505
45-64	402.0	11,200	21,000	5.850
65-74	119.3	4,200	45,000	15.850
75 over	64.5	3,200	30,500	15.150
Total All Ages	2 x 10 ⁸	54,800	100,000	37.833

at the instant of impact could be anywhere from side-on through 45° to end-on. The terminal velocity for end-over-end tumbling of a pacemaker capsule was computed to be 104 ft/sec. This velocity was scaled up by a 1.5 safety factor to 156 ft/sec as a design objective. Side-on and end-on terminal impact velocities were calculated as 87 and 240 ft/sec, respectively. However, these are unstable orientations and considered to be extremely remote. As discussed below, however, test results have demonstrated the survivability of the pacemaker capsule under all credible accident conditions, including these unstable orientation angles.

B. Safety Testing

The following summarizes the results obtained during this report period on the RPCP safety testing program.

1. Elevated Temperature and Pressure Tests

An initial series of elevated temperature and pressure tests has been performed on prototype fuel capsule pressure test pieces. These previous tests demonstrated that the inner capsule could sustain the maximum fire condition of a 1900°F (1038°C) temperature with an internal helium pressure of 3800 psi. This pressure corresponds to the 50 year helium buildup pressure based on a maximum fuel loading of 0.262 thermal watts.

Further tests on these Ta-10W test pieces at pressures and temperatures in excess of these conditions have been completed. These tests were performed to (a) demonstrate a pressure safety factor of 1.5 at rated temperature, as recommended by ASME codes on the design and testing of pressure vessels, and (b) establish the pressure and temperature design limits of the capsule.

Two tests were completed in which the internal pressure was increased to 5700 psi (a factor of 1.5 times the capsule design pressure of 3800 psi) while being held at a temperature of 1906°F (1041°C) for 20 minutes. The vacuum environment stayed essentially constant in the 10^{-6} torr range during the test signifying that no leaks or cracks had developed as a result of these elevated conditions. Helium leak tests were also performed on these test pieces and they were shown to be leak tight.

In a test to demonstrate the pressure capability of the capsule at 1900°F, a test piece was subjected to pressures in excess of the 5700 psi conditions discussed above. The starting pressure was 6000 psi and this pressure was increased in 500 psi increments with a five minute hold at each pressure. Thus, the capsule was held at 6000, 6500, 7000, ... psi up to a maximum of 16000 psi. At this pressure, the capsule temperature was held at 1036°C while the vacuum was maintained in the 10^{-6} torr range. No leaks or failures of the test piece occurred as given by the good vacuum environment at the beginning and end of the testing period. After the test, the test piece was subjected to a standard helium leak test for prototype inner fuel capsules with negative results, i.e., it passed the heat source specification requirement which detects leak rates to a sensitivity level of 5×10^{-8} atm-cc/sec.

This same test piece was taken to pressures greater than 16,000 psi during a subsequent test. The test piece was held for five minutes at each of the following pressures: 16500, 17000, and 17500 psi with the temperature maintained at 1036°C. No leaks or cracks developed in the piece at these conditions. After the pressure was further increased to 18000 psi and held for two minutes, a ductile blowout type failure of the test piece occurred in the side wall as shown at the bottom of Figure V-3. Also shown in the middle of this figure is an untested prototype capsule test piece. This capsule test piece demonstrated a pressure design capability of 17500 psi pressure at 1036°C. The capsule pressure capability at 1900°F is, thus, 4.6 times the 50 year buildup pressure of 3800 psi.

A new test piece was subjected to temperatures greater than 1038°C while being held at a constant internal pressure of 3800 psi. The test piece was held at 3840 psi for 20 minutes at each of the following temperatures: 1038, 1088, 1138, and 1186°C to establish the temperature design limit capabilities of the capsule. The vacuum environment remained constant in the 10^{-6} torr range, signifying that no crack or leak developed in the test piece. At the completion of the 1186°C test, a helium leak test was also performed on the test piece and it was shown to be leak tight.

PACEMAKER CAPSULE TEST PIECES WHICH ESTABLISHED
TEMPERATURE AND PRESSURE DESIGN LIMITS

Figure V-3

Further testing of this test piece was performed by holding the test piece for 10 minutes at each of several elevated temperatures while at the same time being maintained at a 3760 psi internal pressure. This test piece was subjected to temperatures up to 1499°C with the 3760 psi internal pressure without failure of the capsule occurring. Next, this test piece was increased in temperature to 1536°C (2796°F) while at the same 3760 psi internal pressure. After 2-1/2 minutes, a leak developed in the test piece and the vacuum environment deteriorated rapidly. A photograph of this test piece after the test is shown in the top of Figure V-3.

The last test performed was one in which both temperature and pressure were taken in excess of the design conditions. The maximum fire-rated conditions of 1900°F and 3800 psi determined the starting point.

For the purposes of this test, the temperature of the capsule was increased at constant pressure. Following a period of 5 minutes, the pressure internal to the capsule was increased at constant temperature. This sequence was repeated until failure occurred. The maximum steady-state condition achieved via this procedure was 10900 psi at a temperature of 1264°C (2308°F). No loss in pressure or degradation in vacuum environment occurred during this test. Next, the temperature was increased to 1316°C while holding the pressure constant at 10800 psi. A leak developed in the test piece after 2 minutes.

Summary of Results

The above tests at 1.5 times the design pressure as well as the pressure and temperature design limit tests are summarized in Figure V-4. Shown at point A in the figure are the design parameters of 1900°F temperature and a 3800 psi pressure which was derived for the maximum fire-rated conditions for the prototype capsule. Tests on three separate test pieces at these conditions for a 2.63 hour time period were successfully completed. Point B in Figure V-4 represents high pressure (5700 psi) conditions to which two test pieces were subjected, corresponding to 1.5 times the design pressure at 1900°F.

The test results discussed previously are shown as points 1 thru 6 in Figure V-4. Points 1, 3, and 5 in the figure represent conditions

ELEVATED TEMPERATURE AND PRESSURE TESTS ON RPCP PROTOTYPE CAPSULE

FIGURE V-4
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under which the capsules maintain their integrity. Points 2, 4, and 6 represent conditions at which failure of the prototype capsule test pieces occurred. The solid line thus represents the design limit and the dash line represents the capsule failure conditions. A design capability (dot dash) curve was developed from data at each of the three temperatures by dividing the design limit pressure prior by a factor of 1.5.

These results demonstrate a significant design conservatism with respect to the helium buildup pressure (at a 50 year life) at the 1900°F fire and even higher temperature conditions. This conservatism results from the necessity of considering other potential sources of fuel release (terminal velocity impact, crushing, bullet penetration, etc.) and from the desire to reduce dose rate from the intact fuel capsule during normal operation.

2. Cremation Conditions

Additional results have been developed on the assessment of possible cremation conditions for a Radioisotope Powered Cardiac Pacemaker which has been accidentally left in a body prior to cremation. This study was conducted to determine the expected temperature versus time conditions during such a cremation exposure. After initial investigations, one actual measurement of the cremation temperature as a function of time was performed in order to provide preliminary information for design purposes. These results were reported previously. In order to obtain a better estimate of the maximum temperature during cremation, various crematories and cremation furnace manufacturers throughout the United States were contacted. The inquiries were made in such a manner as to provide a representative sampling across the country.

All crematories contacted were asked three basic questions: (1) What was the maximum temperature reached in their cremation furnace and if the quoted temperature was substantiated by thermocouple measurements; (2) What was the duration of the cremation cycle; and (3) What type of burner was used, whether it be gas or oil, and the name of the furnace manufacturer. Similar questions were posed to the furnace manufacturers. Additional comments were usually made by the personnel contacted and some of these were related to the melting of different types of jewelry or tooth

fillings. Accordingly, melting points of various jewelry alloys and pure metals were tabulated for comparison purposes. Since some of the results quoted were qualitative and/or inconsistent and not supported by experimental data, various crematories throughout each state were designated by a letter within that state.

Shown in Figure V-5 are the maximum cremation temperatures quoted or measured by various crematories throughout the United States. Of the total of 29 crematories contacted, 18 of these provided measured or quoted maximum temperatures. In some cases, a temperature range was specified. In others, the data was recorded even though it might possibly be inaccurate based on other information transmitted. In Figure V-5 the maximum measured cremation temperatures range from 1800 to 2300°F, as specified by six of these eighteen crematories. Other quoted temperatures and temperature ranges which were not supported by thermocouple measurements fell between 1000 and 2300°F and this information was provided by eight other crematories. Since the standard minimum temperature to effect cremation is in the range of 1300 to 1350°F (in order to obtain the autoignition of the free carbon) quoted temperatures below 1300°F are considered to be possibly inaccurate.

In addition, some high temperatures quoted from four other crematories were deemed as possibly inaccurate. These high temperatures ranged from 2400 to 3000°F. Primary reasons for considering that these quoted temperatures may be inaccurate were: (a) due to the inconsistency of a high maximum temperature with an extremely long time for cremation; (b) due to inconsistencies of the high maximum temperature with the quoted degree of melting of various jewelry and tooth filling alloys; (c) the fact that the upper limit temperature for the firebrick lining of most furnaces is about 2600°F, and that above this temperature the firebrick begins to flow; and/or (d) a wide temperature range was quoted, detracting from the credibility of the temperatures.

Figure V-6 presents the results obtained on the maximum cremation temperatures measured by various cremation furnace manufacturers. Five manufacturers were contacted and their maximum temperatures ranged nominally from 1400°F to 2200°F. In addition, as noted in the figure, the Industrial Equipment and Engineering Company in Florida stated that

MAXIMUM CREMATION TEMPERATURES QUOTED OR MEASURED BY VARIOUS CREMATORIES

Figure V-5

MAXIMUM CREMATION TEMPERATURES MEASURED BY VARIOUS CREMATION FURNACE MANUFACTURERS

Figure V-6

they have one type of furnace which has the capability of achieving temperatures of 2500°F but this is only after five to six hours of continuous operation. For the Jones Incinerator Company cremation furnace, a maximum of 2800°F was observed in the first ten minutes as measured at the top of the furnace and not near the body. In this first ten minutes, very little of the body has been burned during cremation. Shortly thereafter, the maximum temperature decreases to 2400°F for the next 20 to 30 minutes of operation.

In preparing for simulated cremation tests of two new RPCP units containing unfueled safety capsules, some preliminary analyses and tests were performed. Previous testing of unfueled pacer capsules in cremation or fire conditions did not utilize an epoxy material. Plans and test objectives have been outlined for conducting these tests. The epoxy manufacturer was contacted for his recommendations for these tests, particularly as to the possible toxic gases which might evolve during testing to 2070°F. A preliminary heating test of a sample of the epoxy was performed under controlled conditions as a precaution and no serious effects resulted.

Two RPCP units containing unfueled safety capsules were fabricated and assembled for the simulated cremation tests. These tests are laboratory experiments which precede those discussed above in the Phase II safety testing program and utilize Phase I safety test capsules. One of the units contained the design recommendations which resulted from the Phase I cremation tests, whereas the other was constructed as a duplication of a complete Phase I prototype.

The simulated Phase I pacer test unit contained safety capsule PS-1-17 which had been previously used during a fire debris test of Phase I. During that test, the capsule was held at 1000°F for a total time of 15.3 hours in fire debris comprised of incinerator ashes and crushed charcoal. Prior to inserting this safety capsule into the cremation unit, a helium leak test had been performed and this capsule was shown to be leak tight.

The simulated Phase I pacer unit was inserted into a muffle furnace which had been previously held at a steady state temperature of 1630°F. The temperature was programmed along a cremation curve to 1975°F at a time of 26 minutes, followed by a sharp decrease to 1870°F and then a

gradual increase to a peak of 2070°F at 110 minutes. Furnace, pacer, and, during the first three minutes of the operation, capsule temperatures were measured and recorded.

At a test time of 2-1/2 minutes while the simulated pacer was heating up rapidly towards 1630°F, the electronics case burst open much like a pea pod. During the first part of the test, flames and smoke billowed from the furnace as the epoxy and other external components continued to burn. The nuclear battery apparently retained its hermeticity relatively well during most of the test since the external titanium case was buckled inward due to a decrease in mechanical strength and the external pressure of one atmosphere. From the x-rays taken after the test, the safety capsule had settled to the side of the pacer and some damage to the outer and middle capsule was evident. It is likely that this is comparable to the intermetallic attack which was observed previously in the cremation tests of Phase I and these results were anticipated.

The cremation test unit containing the design modifications which were developed from the Phase I cremation tests was also evaluated in a laboratory experiment. This unit utilized a tantalum hot strap and titanium hot shoes in the design. Thus, by eliminating most of the copper that is in close proximity to the safety capsule, it was expected that hermeticity of the middle capsule would be retained. This test unit contained safety capsule PS-1-12 which had been previously used during an elevated temperature fire test of Phase I. During that test, the bare capsule was programmed along the standard fire curve in an oxidizing atmosphere to 1900°F in 2.63 hours and subsequently water quenched. Prior to inserting this capsule into the cremation unit, a helium leak test had been performed and this capsule was shown to be leak tight.

The cremation test unit CR-2 was placed in a furnace with an oxidizing atmosphere while the temperature was programmed along the cremation curve to a peak temperature of 2070°F at 110 minutes. Figure V-7 shows this cremation unit after testing. Again, the nuclear battery retained its hermeticity during most of the test since the external case was buckled inward as shown. X-rays indicated that at least the inner

Figure V-7
SIMULATED CREMATION UNIT CR-2
AFTER TESTING TO 2070 °F

Figure V-8
SAFETY CAPSULE PS-I-12 AFTER CREMATION
TEST OF UNIT CR-2 TO 2070 °F

and middle capsules and probably the outer capsule were not damaged. Upon disassembly of the unit, the capsule was found to be encased in a mass of thermoelectric wires, ceramic tabs and glass. It was possible that the outer capsule was leak tight. However, in attempting to remove the wires and glass, the welded end of the outer capsule was punctured.

Figure V-8 shows a photograph of the outer and middle capsule after testing. No damage or intermetallic attack of the middle capsule occurred, as shown in the figure. Some of the platinum coating was peeling off the outside of the middle capsule. Thus, it was concluded that the design modifications made subsequent to the Phase I cremation tests were successful. The use of a tantalum hot strap and titanium hot shoes in the design, thereby eliminating most of the copper in close proximity to the capsule, will allow the RPCP capsule to sustain postulated cremation conditions.

Preliminary plans were formulated for additional cremation analyses and further testing in order to further evaluate with statistically meaningful data the maximum cremation temperatures and temperature versus time cycles during these conditions. The objective is to assess cremation conditions for a radioisotope powered cardiac pacemaker which has been accidentally left in a body prior to cremation. Further contacts are planned with various cremation furnace manufacturers and a list of questions to be posed to these manufacturers has been prepared. Several types of further testing have been explored for ascertaining the actual measured peak temperatures and these tests may take place at various cremation manufacturers and/or crematories throughout the country. The relative effects of correlations between pacer temperature and flame temperature, and the effects of the presence and combustion of a body and a hardwood casket will be explored. Various facilities were selected for testing and a detailed test procedure was prepared.

The first tempil holder units were sent to the crematories that cooperated in the temperature measuring tests to develop correlations of measured thermocouple data and tempil data and to determine crematory maximum temperature variations.

During this report period, the recommended minimum cremation environmental conditions that a Radioisotope Powered Cardiac Pacemaker System must withstand were submitted. The recommendations were supported by data obtained from actual cremation and related testing. The recommended cremation temperature profile consists of a linear ramp from room temperature to 2100°F in ten minutes, followed by a steady-state hold at 2100°F for two hours followed by air cooling to room temperature. Fig. V-9 shows this profile. It was also recommended that further statistical and/or other testing as may be appropriate be conducted.

During this report period, a preliminary theoretical analysis of the cremation environment as seen by a Radioisotope Powered Cardiac Pacemaker System was initiated. The results, although considered preliminary at this time, tend to confirm the test data and previous recommendations.

Twenty-nine tempil holders from sixteen different crematories across the country have been tested and the results show the highest pellet that melted was at 2200°F.

Crematories are still being contacted and requested to use our temperature indicators during cremations. The cooperation from the crematories contacted has been excellent.

One tempil holder was tested at a crematory which uses a calcinator. The test results show the highest pellet that melted was 1700°F. More data from calcinators are expected in the future.

Six tempil holders have been distributed in Great Britain by a U.S. member who attended a British Cremation Association convention.

Table V-8 summarizes the cremation testing to date. A coding system has been used in reference to the crematory identification.

RECOMMENDED CREMATION TEMPERATURE PROFILE AND COMPARISON WITH MAXIMUM TEMPERATURES MEASURED DURING ELEVEN CREMATION TESTS (ADJUSTED DATA)

Figure V-9

TABLE V-8

TEMPIL DATA DURING ACTUAL CREMATATIONS

<u>Crematory</u>	<u>Highest Temperature Pellet That Melted*</u>	<u>Furnace Manufacturer</u>	<u>Casket Type</u>	<u>Cycle Time</u>	<u>Pellet Holder #</u>
A	2100°F	Jones (gas)	Pine	2 hrs.	8
	1800°F	Jones (gas)	Steel	2-1/2 hrs.	9
	2100°F	Jones (gas)	Pine	2-1/2 hrs.	32
B	Under 1500°F	All (gas)	Litter	2-1/4 hrs.	3A
	1900°F	All (gas)	Pine	2-1/4 hrs.	27
	1700°F	All (gas)	Metal	2 hrs.	14
C	1500°F	Jarvis (gas)	Pine	1-3/4 hrs.	17
	2100°F	Jarvis (gas)	Hardwood	2 hrs.	6A
	1700°F	Jarvis (gas)	Hardwood	1-1/4 hrs.	12
D	2100°F	I.E. (gas)	Pine	2-1/2 hrs.	18
	2200°F	I.E. (gas)	Metal	2 hrs.	20
	2200°F	I.E. (gas)	Hardwood	2 hrs.	25
	2200°F	I.E. (gas)	Hardwood	2 hrs.	1A
	2100°F	I.E. (gas)	Softwood	2 hrs.	21
	2100°F	I.E. (gas)	Metal	2 hrs.	24
E	1700°F	Cossar & Smith Eng. (oil)	Pine	2-1/4 hrs.	19
F	2100°F	Custom Built (gas)	Pine	2 hrs.	29
G	2100°F	Jones (oil)	Pine	2-1/2 hrs.	28
H		Calcinator (LP gas)/ Crematory			
	1700°F	Calcinator (LP gas)	Cardboard	4 hrs.	2A
	1900°F	Cremated	Hardwood	3 hrs.	26

*Temperature pellets are in 100° increments and have an accuracy band of $\pm 1\%$.

TABLE V-8 (continued)

TEMPIL DATA DURING ACTUAL CREMATIONS

<u>Crematory</u>	<u>Highest Temperature Pellet That Melted*</u>	<u>Furnace Manufacturer</u>	<u>Casket Type</u>	<u>Cycle Time</u>	<u>Pellet Holder #</u>
I	1700°F	Pacific Delong (gas)	Oak	3 hrs. 20 min.	30
J	1800°F	Jones (oil)	Softwood	1 hr. 40 min.	16
K	1900°F	Jones (gas)	Softwood	1 hr. 40 min.	23
L	1700°F	Olsen (nat. gas)	Softwood	3 hrs.	15
M	2200°F	I. E. (gas)	Softwood	1 hr. 35 min.	7
N	2100°F	Morse Bolger (oil)	Hardwood	1 hr. 50 min.	31
O	2100°F	Gibson	Softwood	2-1/2 hrs.	3A
P	1900°F	I. E. (gas)	Softwood	3-1/2 hrs.	18
	1900°F	I. E. (gas)	Metal	3 hrs. 10 min.	17

*Temperature pellets are in 100° increments and have an accuracy band of +1%.

3. Fueled Pacer Cremation Tests

During this report period four fueled RPCP systems were subjected to cremation conditions at Mound. Two systems contained plutonium-238 metallic fuel and two contained plutonium-238 oxide fuel. The first two tests consisted of subjecting one metallic fueled and one oxide fueled RPCP system to the 2100°F temperature for two hours as shown in Figure V-9. The second two tests were run for the remaining two RPCP systems but at a higher temperature of about 2340°F for two hours. These higher temperature tests were done since recent crematory testing indicate maximum temperatures may exceed 2100°F in some isolated cases.

In all four tests there was no fuel release and the inner capsule remained leak tight. Appendix A contains the Mound report of the first two fueled RPCP system cremation tests results. A detailed report for the second two tests will be prepared during the next report period.

Results of these cremation tests have resulted in the desirability of studying the possibility of replacing Hastelloy C with platinum 20% rhodium as the middle fuel capsule material. The present fuel encapsulation is composed of three separate capsules, each of which is hermetically sealed. The inner capsule which contains the plutonium 238 fuel is made of tantalum 10% tungsten. The middle capsule is made of Hastelloy C and the outer capsule is made of titanium. The Hastelloy C is plated with platinum.

In addition to achieving triple redundancy, the use of multiple encapsulation materials is required in order to provide maximum protection against the wide variety of credible accident conditions to which the fuel capsule may be exposed. The tantalum 10% tungsten was selected for its high strength particularly at high temperatures. For example, tests have confirmed that the inner capsule successfully contains the fuel at cremation temperatures even after 2000 years of helium pressure buildup. The melting point of tantalum 10% tungsten is 5612°F which is far above any known credible accident temperature.

Hastelloy C was selected because of its excellent oxidation resistance at high temperatures and its protection capability in corrosive media involving reducing acids (such as sulfuric for example). The melting point of Hastelloy C is 2310°F which is above maximum credible accident temperatures.

Titanium was selected as the outer capsule material because it offers excellent protection to corrosive media involving oxidizing acids (such as nitric for example) and its excellent corrosion resistance in salt solution such as sea water and body fluids. The melting point of titanium is 3047°F which is well above any known credible accident temperature.

Although the melting points of the present fuel encapsulation materials are all above maximum credible accident temperatures, Hastelloy C and titanium form a eutectic with a melting point of 1751°F which is below some credible accident temperatures. Therefore, the Hastelloy C is plated with platinum which serves as a barrier preventing diffusion and eutectic formation between the outer and middle encapsulations in the event of high temperature excursions. Holes in the platinum plating do not eliminate the diffusion barrier effect if the Hastelloy C and titanium surfaces do not physically contact each other. It should be noted that platinum offers excellent protection to both reducing and oxidizing acids and offers excellent oxidation resistance at high temperatures in highly oxidizing environments. The melting point of platinum is 3227°F which is well above credible accident temperatures.

In addition to the titanium - Hastelloy C eutectic, tantalum 10% tungsten forms a eutectic with Hastelloy C that melts at 2480°F and platinum forms a eutectic with titanium that melts at 2400°F. Both of these eutectic melting points are above maximum credible accident temperatures. The following table summarizes possible melting points for the present fuel capsule material combinations:

<u>Material</u>	<u>Melting Point</u>
Tantalum 10% Tungsten	5612°F
Platinum	3227°F
Titanium	3047°F
Tantalum 10% Tungsten - Hastelloy C	2480°F
Titanium - Platinum	2400°F
Hastelloy C	2310°F
Titanium - Hastelloy C	1751°F

During the RPCP Program, extensive safety tests have been conducted for the present fuel encapsulation system. For example, a series of unloaded heat sources were subjected to industrial fire time-temperature profiles. It was found that the outer capsule integrity was retained up to about 2049°F for 4-1/4 hours. The loss of integrity was due to the extremely long time oxidation of the titanium outer capsule coupled with the effects of repeated water quenching. Since a Hastelloy C oxidation resistant middle capsule was utilized, loss of integrity of the outer capsule was not considered to be severe. Heat sources were also taken to 2300°F for 8 hours and the middle capsule integrity was still retained. In addition, several unfueled RPCP systems were subjected to simulated cremation conditions of 2100°F for 2 hours. For these tests the only effect on the heat source was oxidation of the outer titanium capsule. In all cases, the integrity of the middle and inner capsules was retained.

More recently two fueled RPCP systems were subjected to the same simulated cremation conditions of 2100°F for 2 hours at Mound Lab as discussed above. One system was loaded with Pu-238 metal and the other with Pu-238 oxide. For both tests the inner fuel capsule was apparently unaffected and there appeared to be no reaction between the fuel and inner capsule. However, in both tests the titanium outer capsule apparently formed a eutectic with the Hastelloy C middle capsule causing both to partially melt. The reaction between the outer and middle capsules was surprising since it did not occur in previous tests. Apparently the platinum plating on the middle capsule was unknowingly removed during heat source assembly at Mound Lab by some means to a large enough extent to allow the titanium and Hastelloy C to come into physical contact. Similar tests as previously noted were performed at 2340°F with similar results. In all cases, the fuel was successfully retained within the inner capsule.

The above preliminary conclusions that platinum plating of the Hastelloy C may not in every case preclude the formation of the titanium - Hastelloy C eutectic, has made it desirable to investigate the replacement of the Hastelloy C with platinum 20% rhodium. This will eliminate the two lowest melting points in the present fuel encapsulation -- Titanium/Hastelloy C eutectic (1751°F) and Hastelloy C itself (2310°F). The lowest melting point in the new fuel encapsulation would be that of the titanium/platinum 20% rhodium eutectic (in excess of 2410°F) which is significantly above credible accident temperatures. (It should be noted that even if the titanium outer capsule was removed, this eutectic may still be possible since most of the metal components of the RPCP system are made of titanium some of which could possibly come in contact with the fuel encapsulation during high temperature accidents.) The platinum 20% rhodium alloy has a melting point of 3452°F and offers excellent corrosion protection to both reducing and oxidizing acids and is one of the most oxidation resistant materials at high temperatures in highly oxidizing environments. It should be noted that platinum 20% rhodium has a tensile strength of 70,000 psi which is lower than that of Hastelloy C (120,000 psi). However, both materials have a higher tensile strength than the titanium outer capsule material (50,000 psi).

From an overall system point of view, the proposed material change for the middle fuel capsule should have insignificant effects (with the possible exception of high temperature accidents as previously discussed). This is true since the encapsulation thicknesses remain unchanged and both the outer and inner fuel capsules remain unchanged. The rest of the system will still "see" the same outer titanium fuel capsule and thus all previous system testing should remain valid. In addition, all previous safety testing results except high temperature accidents should be unaffected because the outer titanium capsule integrity was retained for the recommended safety tests. (One exception to this is the 12 gauge rifled slug shotgun test in which the outer titanium fuel capsule leaked but the middle and inner capsules remained leak tight.)

A change from Hastelloy C to platinum 20% rhodium for the middle fuel capsule results in a gamma dose rate reduction of about 6%, an

increase in total system weight of about 1% due to the higher density of platinum 20% rhodium and a decreased temperature drop across the middle fuel capsule of about 0.06°C due to the higher thermal conductance of the platinum 20% rhodium. All of these changes are considered insignificant.

The estimated cost for producing middle fuel capsules of Hastelloy C in batch quantities of approximately 25 is about \$57 each. This estimate includes cost of materials, machining, and platinum plating but does not include the extra cost associated with Hastelloy C procurement problems due to the low aluminum content requirement needed to assure proper welding characteristics. The estimated cost for producing platinum 20% rhodium middle fuel capsules is about \$85 each. This estimate includes cost of materials, machining, and scrap recovery. The cost differential between the two capsules is about \$32 which is not significant considering the estimated total system cost.

Although it appears at this time that the present fuel encapsulation is adequate, it was recommended and approved by the AEC that the replacement of Hastelloy C with platinum 20% rhodium be evaluated. It was further recommended that this evaluation be conducted by a series of tests using the safety test capsules presently being fabricated. It was recommended that these safety test capsules be completed with a platinum 20% rhodium middle capsule. The safety tests to qualify the platinum 20% rhodium should include cremation tests for both bare fuel capsules and completed (unfueled) RPCP systems. In addition, several bullet impact tests and perhaps free fall impact tests should be conducted. A detailed test plan will be prepared during the next report period.

4. Automobile Accidents

Due to the fact that the automobile accident is the most credible accident an implantee could encounter, this type of accident has been the subject of a separate testing program. Following are the results obtained thus far from this program.

The following program has been performed by Dr. Lawrence Patrick of the Wayne State University Biomechanics Research Center. Mock-up pacers were implanted in cadavers in both pectoral and abdominal locations.

The pacer mock-ups each contain 3 uniaxial accelerometers, arranged such that their axes are orthogonal. Thus, the vector acceleration experienced by the pacers during an automobile accident was determined. Figures V-10 and V-11 show photographs of the pacer mock-up at two different stages of assembly. The cadaver, with the implanted pacer, was harnessed into position behind the steering wheel, and the car impacted the wall at 15 miles per hour. The velocity was increased in 15 mile per hour increments in each of two successive experiments. Next, the cadaver was placed unharnessed behind the steering wheel. The earlier testing program was repeated. The cadaver was examined both before and after each impact in order to determine the damage to his bones and to the pacer. Although this test has been completed, the data from the accelerometers is currently being reduced. The results will be presented in the next report period. These results will provide the necessary information for an evaluation of the damage experienced by a pacer during a severe automobile accident.

PACER IMPACT MOCK-UP BEFORE ASSEMBLY
SHOWING MOUNTING OF ACCELEROMETERS.

Figure V-10

PACER IMPACT MOCK-UP AFTER ASSEMBLY,
BUT BEFORE POTTING WITH EPOXY.

Figure V-11

5. Auto Fires

A 1961 Corvair automobile was instrumented with sixteen platinum/platinum-10 rhodium thermocouples placed in eight different locations within the car. The interior of the car was in excellent condition. The thermocouples were mounted in 1.93" x 1.16" x .375" Inconel holders. Each holder provided the necessary thermal inertia to prevent rapid thermal fluctuations from affecting the thermocouples and, in addition, provided a housing for sixteen tempil pellets. The sixteen tempil pellets mounted in each holder melt at different temperatures between 1500°-3000°F. After the test, the maximum temperature attained at a specific location in the car could be determined simply by noting which tempil pellets have melted.

The temperature at each location in the car was determined every 48 seconds by means of a standard 24-channel recorder. It is estimated that the uncertainty in the measured temperatures is $\pm 50^\circ\text{F}$.

As has been mentioned previously, the sixteen thermocouples were placed in eight different locations within the automobile. The following is a listing of six of these locations: on the (inside) roof of the car, on the front floor, on the back floor, on the dashboard, on the rear window shelf, and in the trunk. It should be emphasized that two thermocouples were placed at each of these locations in order to provide redundancy.

The two remaining locations at which thermocouples were placed were internal to a pig and a sheep. Both animals had been slaughtered for consumption before the test and prior to slaughter weighed approximately 150 lbs. The tempil pellet/thermocouple assembly was inserted in the animals in regions approximating the actual location of implanted cardiac pacemakers. The animals were suspended via support wires from the roof of the car. The pig was placed in the driver's seat and the sheep was located in the back seat directly behind the front passenger's seat.

Since it was desired to simulate a worst-case auto fire, gasoline and fuel oil were used to ignite the car. Twelve ounces of gas and twelve ounces of fuel oil were poured over the engine. Twelve ounces of gas were poured into the trunk of the car in the vicinity of the gas tank. The gas tank in the automobile contained seven gallons of gasoline

and the gas cap was in place. It was hoped that the gas and fuel oil poured on the engine would simulate a ruptured fuel line and the gas in the trunk a ruptured gas tank. These ruptures would presumably occur in the auto crash which precedes this fire. The fire was started by means of a torch in both locations simultaneously.

On the day of the fire test, the sky was perfectly clear with the temperature at approximately 70°F. At the start of the test, the wind was calm. However, twenty minutes into the test, the wind changed to a gentle 3-5 MPH wind from the southwest. The car faced northeast during the test.

Results

Fig. V-12 traces the course of the automobile fire from ignition to termination of the test after 90 minutes. Ten minutes into the test the passenger compartment ignited into flames, and for approximately five more minutes smoke inside the auto prevented the observation of the animals. During the test, periods of intense flame appeared to be followed by periods of reduced flame. A period of reduced flame was, in turn, followed by another period of intensified burning. It is thought that the gentle southwest wind was (at least) partially responsible for this observation. At no time during the test did heat from the automobile prevent test personnel from approaching to within 15 feet of the car for short periods.

At the termination of the test, the only location in the car still flaming was directly beneath the sheep. This flame was "fed" by drippings from the carcass. At the completion of the test, the neck region of the sheep had been completely burned away. The chest region of the pig had been burned such that the animal's rib cage was visible. The highest temperature recorded in the car was indicated by the thermocouple/holder assembly placed within the sheep.

Fig. V-13 shows the most intense flame observed during the fire test. For the purposes of correlation, this condition has been termed complete combustion. The time period from the ignition of the flame to this complete combustion was 22 minutes.

None of the 128 tempil pellets previously mentioned melted during the test. Hence, the temperature did not exceed 1500°F at any of the locations in the car previously discussed. As shall be discussed shortly, the correlation between the two types of temperature indicators was quite good.

PHOTOGRAPHS TAKEN DURING AUTOMOBILE FIRE
Figure V-12
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PHOTOGRAPH TAKEN DURING AUTOMOBILE FIRE

Figure V-13

Fig. V-14, V-15, V-16, and V-17 show the data recorded from the thermocouples placed within the car. Each of these graphs also shows the location of the thermocouple and the time appropriate to the complete combustion discussed previously. The data from the two thermocouples at each location within the car agreed to within the uncertainty of $\pm 50^{\circ}\text{F}$. Hence, only one of the two sets of measurements for each location is shown. Some of the measurement points on each graph have been omitted for clarity. However, caution has been exercised in this regard when the measurement points fall at a "peak" in the graph.

As can be seen in Figures V-14 through V-17 the highest temperature recorded by the thermocouples was 1514°F at the location internal to the sheep. However, this occurred for a very short duration only. Although 1514°F exceeds the stated melting point of one of the tempil pellets, there are two major sources of uncertainty. The melting point of the pellets is known to only ± 1 percent and the estimated uncertainty in the thermocouple measurements is, again, $\pm 50^{\circ}\text{F}$. With these uncertainties, the measured results are entirely consistent.

As a means of correlating these high temperature excursions with, for example, residential fires, recourse has been made to the standard fire curve. While few fires achieve the intensity associated with standard fires, correlation between fires is obtained by integrating the experimental time-temperature curve and fitting this area under the standard fire curve.

The standard fire conditions established at the 8 locations within the burning automobile are shown in Table V-9. To determine these results, the weight method of integration was employed.

Implications for Nuclear Fuel Release

In previous tests, nuclear fuel capsules and complete pacemakers have been subjected to standard fire conditions equivalent to 2040°F at 4.5 hours in both vacuum and oxidizing environments. Also fueled pacemaker systems have been subjected to temperatures of 2340°F for 2 hours with no fuel release. These tests have shown that no significant danger of nuclear fuel release exists under these conditions. In light of these results and the results presented in Table V-9, it has been concluded that no danger of nuclear fuel release exists under the conditions imposed on the nuclear powered pacemaker in an automobile fire.

TEMPERATURE VS TIME RELATIONSHIPS INSIDE A BURNING AUTOMOBILE

Figure V-14

TEMPERATURE VS TIME RELATIONSHIPS INSIDE A BURNING AUTOMOBILE

Figure V-15

TEMPERATURE VS TIME RELATIONSHIPS INSIDE A BURNING AUTOMOBILE

Figure V-16

TEMPERATURE VS TIME RELATIONSHIPS INSIDE A BURNING AUTOMOBILE

Figure V-17

Table V-9

Standard Fire Conditions
Established in the Burning Automobile

<u>Location</u>	<u>Standard Conditions</u>	
	<u>Temp. (°F)</u>	<u>Time (Hr.)</u>
Sheep	1660	0.82
Back Floor	1620	0.76
Front Floor	1620	0.76
Back Window	1620	0.75
Trunk	1600	0.70
Pig	1600	0.70
Roof	1580	0.62
Dash	1550	0.50

6. Compatibility of Bismuth Telluride with Various Capsule Materials

Simulated cremation tests were performed on small quantities of bismuth telluride in contact with various fuel capsule materials. These tests were done to: (a) evaluate the compatibility of bismuth telluride thermoelectric module materials with various capsule materials in a cremation environment, and (b) compare the new data with earlier results made on the cupron/tophel special thermoelectric conversion material of the existing RPCP design. The tests were conducted to a maximum cremation temperature of 2100°F in both oxidizing and vacuum environments to correspond to the circumstance of the outer system (pacemaker) housing being either breached or unbreached, as a result of the cremation exposure. During each of these tests, samples of the Bi_2Te_3 were placed in contact with pieces of titanium, Hastelloy "C", tantalum and platinum as potential radioisotope heat source outer encapsulating materials. The first group of tests were performed in an oxidizing environment in a muffle furnace in which the temperature was programmed to a maximum of 2110°F over a 1-1/2 hour time interval. The encapsulation material being tested was formed as a small boat in which the bismuth telluride material was placed. After five minutes of operation, the temperature in the furnace was 1780°F and some gaseous fumes (Bi_2Te_3) evolved.

After 30 minutes of testing, when the temperature reached 2025°F, a significant oxide and/or nitride scale was evident on the titanium boat material and the Bi_2Te_3 residue was contained in the corner of the boat. On the Hastelloy "C" sample, a fuzzy buildup on the surface was evident. The tantalum boat was severely oxidized by this time and the bismuth telluride material had vaporized. It is not certain whether any intermetallic attack between the Bi_2Te_3 module material and the above three encapsulating materials occurred; however, if such attack occurred, it was a limited affect.

Both 0.002" and 0.020" thickness of platinum boats were fabricated, and a small sample of Bi_2Te_3 material placed in the boat for testing in an oxidizing atmosphere. In both of these samples, the molten bismuth telluride wetted the upper wall surfaces, attacked the platinum simulated capsule wall material and produced a hole in the bottom of the boat. Table V-10 summarizes the above data as well as the results in a vacuum

Table V-10

COMPATIBILITY OF BISMUTH TELLURIDE (Bi_2Te_3) WITH
VARIOUS CAPSULE MATERIALS AT CREMATION TEMPERATURES

Tests performed for 1.5 hours along a simulated cremation curve to
a maximum temperature of 2110°F in air and vacuum environments

<u>Bi_2Te_3 in Direct Contact with a Fuel Capsule Material Of:</u>	Results From Tests In:			
	<u>Size of Sample</u>	<u>An Oxidizing Atmosphere (Air) Environment</u>	<u>Size of Sample</u>	<u>Vacuum Environment</u>
Titanium (Ti)	0.013" thick boat	Formation of oxide and nitride scale on Ti; no significant attack by Bi_2Te_3 on Ti	0.013" thick ribbon	Significant wetting of Ti by Bi_2Te_3 ; no significant attack by Bi_2Te_3 on Ti observed
Hastelloy "C"	0.025" disc	Formation of fuzzy scale on surface of Hastelloy "C"; no significant attack by Bi_2Te_3	0.125" dia. rod	Partial alloying of Bi_2Te_3 with Hastelloy "C"
Tantalum (Ta)	0.010" thick boat	Severe oxidation of Ta; no observed Bi_2Te_3 attack	0.010" thick ribbon	Significant wetting of Ta by Bi_2Te_3 ; no observed Bi_2Te_3 attack
Platinum (Pt)	0.020' and 0.002" thick boats	Severe corrosive attack by Bi_2Te_3 on Pt; produced a hole through both the 0.002" and 0.020" thick material	4 ribbons, 0.002" thick	Significant alloying and melt down of Pt occurred

environment. Thus, it was concluded that it is not desirable to use a bismuth telluride module material in a system design in which the melted bismuth telluride material can come in contact with a platinum capsule wall in an oxidizing environment during cremation or other similar fire exposures. The system that is the subject of this program does not use bismuth telluride at all.

Similar testing was performed with these four encapsulating materials in contact with molten bismuth telluride in a vacuum environment. Ribbons or pins of titanium, Hastelloy "C", tantalum, and platinum were assembled within vicor tubing with pellets of bismuth telluride. After pumpdown and sealing of these tubes, the entire assembly was programmed along a simulated cremation cycle to a maximum temperature of 2050°F for approximately one hour and twenty minutes. Subsequent to the completion of the tests, the ribbons or pins of encapsulating material were removed from the vicor tubes. Results on the titanium and tantalum ribbons were very similar in that general wetting and possible but relatively shallow intermetallic attack occurred. However, no corrosive holes were generated completely through either the 0.013" titanium or the 0.010" tantalum.

In the case of the Hastelloy "C" pin placed in a vacuum environment with the bismuth telluride, some alloying of the Hastelloy with Bi_2Te_3 occurred. The platinum ribbons enclosed in a vacuum environment with a pellet of bismuth telluride showed significant alloying and melt-down of the platinum. Again, this data for vacuum environment cremation conditions are summarized in Table V-10.

From the above results, it was ascertained that, on a preliminary investigational basis, the application of platinum as an outer fuel encapsulating material is not desirable if bismuth telluride material can come in direct contact with that encapsulation. If a Bi_2Te_3 material does come into direct contact with a platinum encapsulating material and the material is subjected to a cremation or other high fire temperature in either an oxidizing or vacuum environment, failure of the encapsulating material will most likely occur. Hastelloy "C" exhibits some alloying, but from the limited testing performed it is uncertain if a capsule of Hastelloy "C" would or would not fail.

Tantalum is also a poor choice for direct contact with bismuth

telluride but primarily on the basis that if tantalum is the outer encapsulation, it could become readily oxidized as a result of the possible exposure to oxygen if the outer system case is breached. Titanium appears to be the best choice of the materials tested from a compatibility point of view with bismuth telluride.

Since previous cremation testing of Cupron Special-Tophel Special with a titanium outer fuel encapsulation produced no attack on titanium, titanium appears to be the best choice as an outer fuel encapsulation material for this application. Moreover, it should be recognized that a complete determination of the suitability of a given encapsulation system relative to fire and cremation conditions must be demonstrated by system tests in addition to bare capsule tests since the sensitivity of the fuel encapsulation to all of the materials contained within the system design requires demonstration.

7. Radiation Dosimetry

Preliminary gamma-ray dose measurements (in air) have been completed for RPCP NU4-46, an oxide-fueled unit (fuel capsule A-38). The measurement techniques employed were essentially those outlined in the "Safety and Radiation Report, Phase I Summary" of June 29, 1970, and the results are summarized below in Table V-11.

TABLE V-11

Gamma-Ray Dose Rate (in air)
RPCP NU4-46 (Capsule A-38)

Location (See Fig.V-18)	Dose Rate mrad/hr.	
1	1.33	
2	1.66	
3	5.95	Surface Locations
4	4.70	
5	5.83	
6	3.47	
7	1.42	2 cm
8	0.61	5 cm
9 & 10	0.182	10 cm

Gamma-ray and neutron dose measurements are currently in progress on oxide-fueled, NU-5 models. These measurements are being made in water, a tissue equivalent medium, with tissue equivalent dosimeters so that the radiation dose profile in tissue can be determined. This will allow an accurate characterization of the dose-to-tissue associated with human RPCP implantation.

Thermoluminescent Dosimeter Position, RPCP Dosimetry

Position No. 6 diametrically opposite to position No. 1.

Figure V-18

Appendix A

SIMULATED CREMATION TESTING OF TWO
FUELED CARDIAC PACEMAKER UNITS

J. E. Selle

MOUND LABORATORY

Miamisburg, Ohio

operated by

MONSANTO RESEARCH CORPORATION

a subsidiary of Monsanto Company

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U. S. ATOMIC ENERGY COMMISSION

U. S. Government Contract No. AT-33-1-GEN-53

SIMULATED CREMATION TESTING OF TWO FUELED CARDIAC PACEMAKER UNITS

J. E. Selle

Introduction

As part of the safety analysis of the Cardiac Pacemaker heat source capsule, simulated cremation tests were run on two fueled Pacemaker units. The tests were conducted at 1149°C (2100°F) for two hours. Fueled Pacemaker units CPD-1 and CPD-6 were supplied by ARCO Nuclear and were fueled with plutonium-238 dioxide and plutonium-238 metal, respectively. In the case of CPD-6 the plutonium metal was contained in small diameter tantalum tubes, while in CPD-1 the capsule was fueled with PuO₂ powder.

Procedure

The general conditions for the simulated cremation tests were laid down by ARCO Nuclear⁽¹⁾ and a set of recommended procedures was outlined. Initial work on this program centered around the adaptation of these recommendations to conditions at Mound Laboratory and to test out the procedures. This work was summarized in a preliminary report which is attached to this report as Appendix A. From this report, a formalized test procedure was written, which is included as Appendix B. After approval of these procedures by all concerned parties, work proceeded on the fueled Pacemaker units.

The procedures outlined in the Appendices were followed. Both the Pacemaker unit and the Tempil holder were wired onto a stainless steel tray. One bare thermocouple was positioned over the unit and another sheathed thermocouple was inserted into a hole in the Tempil holder. Figure 1 shows a photograph of CPD-6 prior to insertion into the furnace. An identical configuration was used for CPD-1. These assemblies were then placed into a Burrell muffle furnace for two hours at 1149°C (2100°F). This time was counted from the time at which the temperature reached 1149°C, which was about 10 minutes after insertion into the furnace.

After removal from the furnace, the units were allowed to cool. Various photographs were taken, samples were taken for x-ray diffraction analysis, wipes were taken and counted for the presence of radioactivity and the units were radiographed. After removal from the units, the capsules were sectioned on a slow speed cut-off wheel using a diamond blade and oil as a coolant. Standard metallographic techniques were then used for polishing sections taken from the capsules. Electron microprobe analyses were performed on a Hitachi XMA-S instrument. Both wavelength dispersive and energy dispersive systems were used for analysis of the various areas.

Results and Discussion

The temperatures recorded for each test are summarized in Table I.

TABLE I
MAXIMUM TEMPERATURES RECORDED
DURING SIMULATED CREMATION TEST

	<u>Furnace</u> <u>Atmosphere</u>	<u>Tempil</u> <u>Holder</u>
Metal Source CPD-6	2097	2100
Oxide Source CPD-1	2090	2093

During the tests the temperature profiles followed those given in the Appendix, Figure 7 very closely. Photographs of the Tempil pellet holders are shown in Figure 2 and Figure 3. From these photographs it can be seen that the 2100°F pellet melted while the 2200°F pellet did not. This agrees with the thermocouple readings. Burning of the epoxy during the early part of the test was indicated by flames around the furnace door. This is shown in Figure 4. A layer of carbon remained around the opening after completion of the test.

A photograph of CPD-6 inside the furnace, just prior to removal, is shown in Figure 5. A considerable amount of deposits are seen on and around the Pacemaker unit. These deposits are seen more

clearly in Figure 6 which shows the unit after removal from the furnace. Samples taken for x-ray diffraction analysis indicate that the white powder on the tray is FeTiO_3 and the black powder on top of the source is $\beta\text{-SnO}$. Lines were not obtained on any other samples so that identification was not possible.

Depressions were observed at various places on the case. Some of these are shown in Figures 7 and 8. These depressions are presumably the result of a combination of high temperature and the internal vacuum of the unit. Wipes taken on the unit and the stainless steel tray showed no radioactive contamination. Radiographs indicated no detectable cracks or openings in the liner, although it appeared that the middle container was at least partially missing.

When the capsule was removed from the unit, a large mass of fused, glassy material and wires were found adhering to each capsule. This is shown in Figure 9. No radioactive contamination was found on the capsules. The capsules were then passed into the glove box line where the glassy material and wire were removed with side cutters.

Each capsule was first cut lengthwise and then cross-wise into three pieces. All three pieces of each capsule were examined. Photomicrographs of these pieces of each capsule are shown in Figures 10 and 11. In each case, the tantalum-10% tungsten liner is intact. However, a porous layer is seen outside the tantalum liner. This layer is shown at higher magnification in Figures 12 and 13. This layer was identical in CPD-1 and CPD-6. Electron microprobe analysis showed this layer to contain iron, chromium, nickel, tantalum, tungsten and titanium in varying amounts in the various layers. In general, the titanium level increased with distance away from the tantalum-10% tungsten interface. The microstructure of the titanium rich area, top of photomicrograph in Figure 13, suggests that this region had been molten during the test. It appears that the titanium and the Hastelloy C alloyed, forming a eutectic which is molten at these temperatures. Iron and nickel form eutectics with melting points of 1085°C (1985°F) and approximately 950°C (1742°F), respectively. Although there was an electrodeposited platinum layer on the outside of the middle Hastelloy C container, it appears that it was not effective in prevention of the alloying. Some attack occurred

on the outside of the liner as indicated by the presence of tungsten and tantalum in the reaction products shown in Figure 13. An accurate determination of the amount of attack is not possible, although crude measurements suggest that 0.003-0.005 inch was lost.

Some reactions between the fuel forms and their containers were observed. A photomicrograph of the tantalum tube from the metal fueled source is shown in Figure 14. An intergranular reaction is shown along the outside edge of the tube. No electron microprobe analysis was performed on this sample. While in the molten condition, the metal ran out of the tantalum tubes and contacted the Ta-10W liner. Figure 15 shows the Ta-10W-plutonium metal interface, and it can be seen that no interaction between the two took place. With the oxide fueled source some interaction with the Ta-10W liner occurred. This is shown in Figures 16 and 17 which show the fuel-liner interface from the bottom of the capsule (opposite the weld). Some intergranular reaction product can be seen to a depth of 0.006-0.007 inch from the interface. In addition, Figure 18 shows a surface reaction product (gray phase at interface). Electron microprobe analysis indicated the presence of tantalum and oxygen suggesting Ta_2O_5 . Microhardness traverses were made across the bottom section and the center section of each liner. The results are shown in Figure 18. The traverse across the bottom end of the oxide source is appreciably harder than the center section or the metal source sections. This suggests oxygen uptake by the tantalum. The increased hardness at the inside edge suggests that the oxygen causing the hardness increase came from the fuel, rather than air. The lower values for both the metal-fuel samples is somewhat unusual although it may be connected with the oxygen gettering capability of plutonium.

Conclusions

From the data, the following conclusions were drawn:

1. A temperature of 2100°F for two hours was achieved.
2. No release of activity from the capsule occurred.
3. Alloying occurred between the Hastelloy C middle container and the titanium outer container.
4. Slight reaction occurred between the PuO_2 and the Ta-10W liner and between the Pu metal and the tantalum tubes. No reaction between the Pu metal and the Ta-10W liner was observed.

REFERENCES

- 1) Technical Memorandum, ARCO Nuclear, "Preliminary RPCP Recommended Cremation Test Procedure - Tests at Mound Lab," January 26, 1972.

Figure 1. Photograph of CPD-6 test assembly prior to insertion into the furnace.

Figure 2. Photograph of Tempil pellet holder #9, used with CPD-6.

Figure 3. Photograph of Tempil pellet holder #8, used with CPD-1.

Figure 4. Photograph of furnace during early part of the test showing flames resulting from burning of epoxy resin.

Figure 5. Photograph of CPD-6 in the furnace just prior to its removal.

Figure 6. Photograph of CPD-6 unit after removal from the furnace.

Figure 7. Photograph of bottom of CPD-6 showing depressions in the surface of the unit.

Figure 8. Photograph of the side of CPD-6 showing depression in the unit.

Figure 9. Capsules after removal from the units showing fused mass of wire and glassy material adhering to both capsules.

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Figure 10. Photomacrographs of three metallographic amounts from CPD-6.
6X Magnification.

Figure 11. Photomacrographs of three metallographic amounts from CPD-1. 6X Magnification.

Figure 12. Photomicrograph of porous alloy layer at outside of Ta-10W liner. 53X Magnification.

Figure 13. Photomicrograph of reaction layer between porous layer and Ta-10W liner. 250X Magnification.

Figure 14. Photomicrograph showing tantalum tube containing plutonium metal. 53X

Figure 15. The Ta-10W (light) - plutonium (gray) interface. 53X

Figure 16. Section of Ta-10W liner from bottom end of oxide fueled capsule, etched. 53X Magnification

Figure 17. Fuel-liner interface from oxide fueled source, showing interface oxide and intergranular oxide. 250X

Figure 18. Microhardness traverses from center and end sections of both the oxide and metal fueled sources.

APPENDIX A

EXPERIMENTAL PROCEDURES FOR PACEMAKER CREMATION TESTS

Introduction

A memorandum dated January 26, 1972 was received from ARCO Nuclear Company entitled "Preliminary RPCP Recommended Cremation Test Procedure - Tests at Mound Lab". This memorandum contained general test procedures for cremation safety tests for the Cardiac Pacemaker program. The document was reviewed and the Mound experimental set-up was designed to fulfill these requested procedures as closely as possible. Out of necessity, some of the requested procedures were modified slightly to adapt to facilities readily available at MRC. This report summarizes the experimental procedures and results of the preliminary tests. If these procedures are satisfactory tests can proceed on a fueled Pacemaker capsule.

Procedure

All tests were conducted in a Burrell muffle furnace housed in a walk-in type fume hood. Two thermocouples, one sheathed and one bare (26 gauge wire) were used in each test and the emf output of each thermocouple was continuously recorded on an L & N "Azar" millivolt recorder. Epoxy blocks, supplied by ARCO Nuclear Co., weighing between 17.5 and 18.0 grams each were used.

Two test configurations were used and these are shown in Figures 1 and 2. Figure 1 shows the configuration for Part 1 of the ARCO Test Procedure. This configuration utilized a nickel tube containing a short length of 304 stainless steel rod for added mass. The nickel tube weighed 12.20 grams and the stainless steel rod weighed 10.59 grams giving a total of 22.79 grams as compared to 14.60 grams for the actual capsule and 0.6 grams of fuel, for a total of 15.20 grams. The purpose of this test was to get a "feel" for the furnace response, and the effects of the burning epoxy without sacrificing a "Tempil" pellet holder. The sheathed thermocouple was inserted in a thermowell in the nickel tube and a bare thermocouple was wired to the side of the tube and oriented in such a way that the temperature of the furnace atmosphere was measured above the epoxy.

The configuration used for Part 2 of the Test Procedure is shown in Figure 2. In this case, the sheathed thermocouple was placed in the top hole of the "Tempil" pellet holder and the bare thermocouple was wired to the holder so that the temperature of the furnace atmosphere was measured at a point above the epoxy block. The epoxy block was located in the same position that the fueled Pacemaker will be located in Part 3 of the ARCO Test Procedure.

Results

For Part 1, the furnace temperature was initially set at 1800°F as recommended in the test procedure. This was done in anticipation of increased temperature due to burning of the epoxy. The results of measurements on both thermocouples are shown in Figures 3 and 4 and indicate no temperature rise due to burning of the epoxy. Therefore, the tests were repeated with the furnace set at about 2050°F and the results are shown in Figures 5 and 6. Again, no temperature rise due to burning of the epoxy was observed. In fact, it is obvious that the burning of the epoxy produced a lag in the furnace atmosphere temperature profile.

With this in mind the configuration of Figure 2 was run with the furnace temperature at 2100°F. The temperature profiles of the "Tempil" pellet holder and the furnace atmosphere are shown in Figure 7. The profile for the "Tempil" pellet holder was actually obtained after the epoxy had burned off. When the original configuration was placed in the furnace it was discovered that the sheathed thermocouple was defective. However, it was too late to remove the unit from the furnace because the epoxy had begun burning. After the epoxy had burned off the unit was removed temporarily from the furnace and a new thermocouple inserted in the hole in the upper half of the "Tempil" pellet holder. The profiles in Figure 7 were therefore not determined simultaneously. However, serious differences between this profile and that which will be obtained in Part 3 are not expected.

The 2100°F "Tempil" pellet melted, but the 2200°F pellet did not, which verifies the thermocouple measurements.

Conclusions

The test setup appears to be satisfactory for conduction of a Pacemaker cremation test. Less than 10 minutes is required for the "Tempil" pellet holder to attain 2100°F.

FIGURE 1: Configuration of Part 1 test showing arrangement of the nickel tube, thermocouples and epoxy block.

FIGURE 2: Configuration of Part 2 test, showing arrangement of "Tempil" pellet holder, thermocouples, and epoxy block.

FIGURE 3: Temperature profiles for furnace atmosphere for Part 1 tests. Furnace temperature - 1800°F.

FIGURE 4: Temperature profiles for nickel tube in Part 1 tests. Furnace temperature - 1800°F.

FIGURE 5: Temperature profiles for furnace atmosphere in Part 1 tests. Furnace temperature - 2050°F.

FIGURE 6: Temperature profiles for nickel tube in Part 1 tests. Furnace temperature - 2050°F.

FIGURE 7: Temperature profiles obtained in Part 2 test.
Furnace temperature - 2100°F.

APPENDIX B

TEST PROCEDURE FOR PACEMAKER CREMATION TESTS

The following procedure outlines the steps to be taken in performing cremation tests with fueled Cardiac Pacemaker units. The procedure is based on the ARCO Nuclear Company report of January 26, 1972, entitled "Preliminary RPCP Recommended Cremation Test Procedure - Tests at Mound Laboratory."

Equipment needed for the tests consist of:

1. Burrell muffle furnace
2. Radioactive fume hood
3. ARCO Nuclear "Tempil" pellet holder.
Dwg. 15-D-4189-233
4. "Tempil" pellets
5. Sheathed Chromel-Alumel thermocouple
6. Bare Chromel-Alumel thermocouple
7. Two temperature recorders, L&N Azar Model
8. Helium leak testing apparatus
9. Metallographic examination equipment
10. Stainless steel tray

Procedure

1. Turn on muffle furnace and bring to a temperature of 2100°F.
2. Place "Tempil" pellets in pellet holder in increasing order of melting point and bolt top on holder. Record position of pellets in holder.

3. Insert sheathed thermocouple in bottom hole of pellet holder.
4. Place pellet holder and pacemaker unit on stainless steel tray.
5. Attach bare thermocouple to top of pellet holder and position end of thermocouple so that it is centered about $\frac{1}{2}$ inch above Pacemaker unit.
6. Photograph tray and contents.
7. Connect thermocouples to recorders.
8. Place tray in furnace when temperature has reached 2100°F on the furnace indicator. Keep furnace door partly open to provide excess air for oxidation.
9. Wait ten minutes, then adjust furnace temperature so that sheathed thermocouple reads 2100°F.
10. Hold furnace at 2100°F for two hours.
11. Turn off furnace and allow pacemaker to cool.
12. Remove tray.
13. Check for radioactivity with alpha survey meter.
14. Photograph tray and contents.
15. Wipe tray and contents for contamination. Record wipe count.
16. Remove top from pellet holder and determine which pellets have melted. Record the melting point of the lowest unmelted pellet and the highest melted pellet. Photograph holder and pellets.
17. Radiograph unit containing source and check for leaks in capsule.
18. Carefully remove the heat source from the debris and if necessary gently chip away the molten glass adhering to the source.
19. Wipe the source and record contamination level.

20. If source is contaminated, weld it into a stainless steel container and radiograph source.
21. After radiography, perform metallographic study of source.
22. Prepare report to summarize results.