198
9-5

2265

RADIOISOTOPE-POWERED CARDIAC PACEMAKER

REPORT TO:
UNITED STATES ATOMIC ENERGY COMMISSION

THIS DOCUMENT CONFIRMED AS
UNCLASSIFIED
DIVISION OF CLASSIFICATION
BY Q H Kahn / amb
DATE 1 9/13/72

ARCO Nuclear Company
ENERGY CONVERSION
TECHNICAL CENTER

MASTER

RG575

DISCLAIMER

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency Thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.

DISCLAIMER

Portions of this document may be illegible in electronic image products. Images are produced from the best available original document.

NOTICE

This report was prepared as an account of work sponsored by the United States Government. Neither the United States nor the United States Atomic Energy Commission, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness or usefulness of any information, apparatus, product or process disclosed, or represents that its use would not infringe privately owned rights.

Quarterly Progress Report
for
Phase II
Radioisotope Powered
Cardiac Pacemaker Program

May 1, 1972 to July 31, 1972

Prepared for

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

Mr. Harold Miller, Director
Contracts Division
Chicago Operations Office
United States Atomic Energy Commission
9800 South Cass Avenue
Argonne, Illinois 60439

Commander J. M. Prosser
Instrumentation Branch
Division of Reactor Development
and Technology
United States Atomic Energy Commission
Washington, D. C. 20545

by

ARCO Nuclear Company
P.O. Box 546
Leechburg, Pennsylvania 15656

Approved by:

S. A. Kolenik
Program Manager
Cardiac Pacemaker Program

MASTER

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

89

NOTICE

This report was prepared as an account of work sponsored by the United States Government. Neither the United States nor the United States Atomic Energy Commission, nor any of their employees, nor any of their contractors, subcontractors or their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness or usefulness of any information, apparatus, product or process disclosed, or represents that its use would not infringe privately owned rights.

* * * * *

Availability:

Printed in the United States of America

Available from

National Technical Information Services

Springfield, Virginia 22151

Price: Printed Copy \$3.00; Microfische \$0.65

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
TASK 1.0 - PROGRAM MANAGEMENT, CONTROL, AND PLANNING	2
TASK 2.0 - RELIABILITY AND QUALITY ASSURANCE	3
TASK 3.0 - SYSTEM FABRICATION AND PRODUCTION DEVELOPMENT	13
TASK 4.0 - SYSTEM TESTING	39
TASK 5.0 - SAFETY	55

LIST OF TABLES

<u>Table</u>		<u>Page</u>
1	Modified Production Model Life Test Data (NU5)	4-5
2	Production Model Life Test Data (NU4)	6-7
3	Experimental Model Life Test Data	8
4	Prototype Model Life Test Data	9
5	Material Submitted for Dispositioning by the Material Review Board	11
6	Inspection Summary of Critical Components	12
7	Performance Data for Units Assembled in May	14
8	Performance Data for Units Assembled in June	19
9	Performance Data for Units Assembled in July	20
10	Results of NU-4 Units Tested	51
11	Details of the Implant Units	53
12	Performance Data of NU-4 Units and NU-5 Units	54
13	Tempil Data During Actual Cremations	56-57
14	Gamma-Ray Dose Rate (in air) RPCP NU4-46 (Capsule A-38)	59

LIST OF FIGURES

<u>Figure</u>		<u>Page</u>
1	Performance Results for Units Sealed in May	15
2	NU-4 RPCP Production (Also NU-5 Qualification Units)	16
3	NU-5 RPCP Production (Also Special Test Units)	18
4	Performance Results for Units Sealed in June	21
5	Performance Results for Units Sealed in July	22
6	Hysterisis Loop in the $\pm$ Y Direction (Loosely Wrapped End #1)	29
7	Hysterisis Loop in the $\pm$ Y Direction (Loosely Wrapped End #2)	30
8	Hysterisis Loop in the $\pm$ Y Direction (50% more Insulation End #1)	31
9	Hysterisis Loop in the $\pm$ Y Direction (50% more Insulation End #2)	32
10	Thermopile Loading Arrangement for Hysterisis Loop Curves	33
11	Thermal Performance of Unit C	35
12	Load vs. Resistance Measurements of Cupron Tapes	36
13	Load vs. Resistance of Cupron Tapes	37
14	Tests Performed on Batteries	40
15	Environmental Test 1st - Shaker Test 2nd	41
16	Shaker Test 1st - Environmental Test 2nd	42
17	Testing Results on Pre-production and Production NU5 Units	45-46
18	Qualification Test Results of Production Batteries	47
19	End View Radiograph	48
20	End View Radiograph	49
21	End View Radiograph	50
22	Battery NU5-25	52
23	Thermoluminescent Dosimeter Position, RPCP Dosimetry	60

INTRODUCTION

This is the tenth Quarterly Progress Report of the Radioisotope Powered Cardiac Pacemaker Program Phase II. It describes the results of the development work performed in the period from May 1, 1972 to July 31, 1972.

TASK 1.0 - PROGRAM MANAGEMENT, CONTROL, AND PLANNING

As a result of the failure analysis performed on the NU-4 systems, four design modifications were evaluated by extensive laboratory tests. It was found that one of these was clearly superior to the others as well as to the previous pilot production models (NU-4). In addition to the existing qualification testing, the modified units were subjected to the paint can shaker test which has been found to simulate very closely the failure modes experienced in animals. The superior modification designated as NU-5 consists of the addition of 50% more insulation tape and additional restraints around the outer diameter of the thermopile to achieve a much tighter wrapping configuration. Ten of these new NU-5 units were fabricated and subjected to both shaker and qualification tests. The results of these tests indicated that the NU-5 system is far superior to the NU-4 system and should result in accepted results when implanted in animals.

It is interesting to note that no further failures occurred in animals and all implanted units continued to operate properly until they were removed near the end of this report period and replaced with the NU-5 systems.

Also during this report period, preliminary tests were conducted to characterize the output of the paint can shaker and telemetry equipment was received and used to more precisely measure the animal environment at the National Heart and Lung Institute. Cremation testing continued during this report period, and an automobile fire test was completed, the results of which are contained in Appendix A. Two fueled RPCP systems were subjected to cremation conditions and thus far, no indication of fuel leaks in either capsule have been observed.

During this report period, pilot production of the improved Radioisotope Powered Cardiac Pacemaker system (NU-5) was resumed. In addition to the improved thermopile, a more severe qualification testing program was instituted which consists of subjecting every eighth unit to the new qualification testing. Thus far, all test results tend to confirm the conclusion that the improved NU-5 system is far superior to the previous NU-4 system and should result in acceptable performance when implanted in animals.

As of the end of this report period, a total of 16 of the new NU-5 systems have been implanted in dogs at the National Heart and Lung Institute. Thus far, all units continue to operate properly.

TASK 2.0 - RELIABILITY AND QUALITY ASSURANCE

Reliability Data

At the end of July, the various Phase I nuclear batteries have accumulated a total of 49.46 unit years of operation with a total of four thermocouple tape failures, one in each of four nuclear batteries implanted in dogs at NHLI.

At the end of July, the NU-4 type production nuclear batteries have accumulated a total of 17.00 unit years of operation with five pacer 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. 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. The month of July shows the removal of all remaining NU-4 type production systems from dogs at NHLI.

The Phase II electronic circuits consist of three groups: (1) a preproduction 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 July, the preproduction circuits have accumulated 9.19 unit years of operation with no failures, the pilot production circuits have accumulated 32.26 unit years of operation with no failures, and the production circuits have accumulated 117.66 unit years of operation with no failures for a total of 159.11 unit years with no failures.

At the end of July, the NU-5 modified production nuclear batteries have accumulated a total of 2.91 unit years of operation with no failures other than qualification units which were tested to destruction.

A total of 16 NU-5 type modified production RPCP systems were implanted in dogs at NHLI during July.

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

Table 1
Modified Production Model Life Test Data (NU5-)
(7-31-72)

Unit (NU5-)	Accumulated Hours	B.O.L. DATA			Present Data		UNITS PRODUCED		Special Test	Life Test	Comments
		Battery Output (μ w)	With Electronics Output, ma.	BPM	Output*	BPM	Implant Units Implanted	Removed			
1	1478	203.5	6.0	71.5	6.0	73.0				X	
2	1478	215.0	6.5	72.5	6.6	73.5				X	
3	1406	236.7	6.2	72.0			7-10-72				
5	1406	223.9	6.1	71.0			7-10-72				
6	1406	241.7	6.3	71.0			7-10-72				
7	302	225.2			(Disassembled)				X		Qualification test unit
9	1262	242.1	6.4	72.0			7-10-72				
10	1262	238.8	6.4	72.0	313.7 μ w				X		
11	1262	238.5	6.6	72.0			7-17-72				
13	1118	236.7	6.3	72.5			7-17-72				
14	182	259.1			(Disassembled)				X		Qualification test unit
15	1118	224.9	6.4	72.0			7-17-72				
17	950	230.3			233.3 μ w					X	
18	950	214.3			219.1 μ w					X	
20	950	219.5	6.4	72.5			7-17-72				
21	878	223.5	6.3	73.5			7-24-72				
22	446	247.6			Tested to failure				X		Qualification test unit
23	878	226.4	6.5	72.0			7-24-72				
24	780	229.8	6.6	72.0			7-24-72				
25	398	212.4			Tested to failure				X		Void areas
26	614	245.5	7.0	72.0			7-24-72				
27	614	235.2			235.2					X	
28	277	238.3			Tested to failure				X		Qualification test unit
29	493	233.9	6.4	71.0			7-31-72				
30	399	250.4	6.8	71.0			7-31-72				
31	493	243.5			243.5					X	
32	None	(Scrapped due to internal shorting during degassing)									
33	399	223.3	6.0	70.0			7-31-72				
34	399	238.6	6.4	71.0			7-31-72				
35	134	250.8			Tested to failure				X		Qualification test unit
36	254	242.3	6.5	71.0	6.5	71.0					
37	254	257.5			257.5					X	

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

Table 1 (Continued)
Modified Production Model Life Test Data (NU5-)
(7-31-72)

Unit (NU5-)	Accumulated Hours	B.O.L. DATA			Present Data		UNITS PRODUCED		Special Test	Life Test	Comments
		Battery Output (μ w)	With Electronics Output, ma.	BPM	Output*	BPM	Implant Units Implanted	Removed			
38	254	226.7	6.4	71.0	6.5	72.0					
39	158	212.2			212.2						
40	158	228.9			228.9						
41	158	224.8	6.5	72.0	6.5	72.0					
42	158	244.9	6.6	72.0	6.8	71.5					
43	86	218.3			218.3						
45	86	236.4			236.4						
46	86	228.6			228.6						
47	86	220.6			220.6						
TOTAL	25,470 HRS.					TOTALS	16	0			

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

Table 2
Production Model Life Test Data (NU-4)
(7-31-72)

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	5436	271.9	6.8	76.0	7.6 ma	77.0				X	
3	5436	271.2			276.0 w					X	
4	5436	284.2	7.2	75.5	8.0 ma	76.0				X	
5	5436	279.5	6.8	75.0	7.4 ma	76.0				X	
6	4188	295.7	7.9	76.5	8.1 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	4552	267.1	7.0	74.0	7.6 ma	72.0	2-14-72	3-20-72			No open tapes
15	1624	269.1	7.6	73.5						X	Internal short
17	4552	293.6	7.6	73.5	7.8 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	4170	295.4	7.7	75.0	195.3 μw		2-28-72	7-17-72			
22	4116	279.1	7.8	74.5	227.7 μw		2-28-72	7-24-72			
23	4116	270.7	7.6	74.5	183.3 μw		2-28-72	7-17-72			
24	4116	279.9	7.8	74.5	218.9 μw		2-22-72	7-10-72			
25	3948	289.5	7.8	75.0	294.7 μw		2-28-72	7-17-72			
26	3948	277.5	7.8	74.5	144.6 μw		3-6-72	7-10-72			
27	3948	280.1	7.8	75.0	75.9 μw		3-6-72	7-10-72			
28	3948	299.7	7.8	75.0	41.7 μw		3-6-72	7-17-72			
29	3828	287.0	7.7	74.5	171.4 μw		3-13-72	7-24-72			
30	3828	264.5	7.4	74.0	86.8 μw		3-13-72	7-17-72			
31	3828	271.7	7.5	74.5	8.3 ma	75.0	3-13-72	7-31-72			
32	1044	238.0			(Disassembled)				X		Environmental testing
33	3759	247.9	7.0	74.0	79.2		3-13-72	7-17-72			

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

Table 2 (Continued)
Production Model Life Test Data (NU-4)
(7-31-72)

Unit (NU4-)	Accumulated Hours	B.O.L. DATA			Present Data		UNITS PRODUCED		Special Test	Life Test	Comments
		Battery Output (μ w)	With Electronics Output, ma.	BPM	Output*	BPM	Implant Units Implanted	Removed			
34	3759	243.8	7.2	74.0	7.6 ma	76.0	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	3591	266.7	7.5	73.5	286.2 μ w		3-20-72	7-24-72			
39	3591	248.0	7.0	74.0	266.7 μ w		3-27-72	7-10-72			
40	3591	239.8	6.9	73.5	256.5 μ w		3-27-72	7-10-72			
41	3495	250.4	6.5	74.0	281.7 μ w		3-27-72	7-24-72			
42	3495	265.5	7.0	74.0	(6.8 ma 75.0)				X		Environmental testing
43	3495	304.0	7.7	74.5	8.2 ma 75.0					X	
44	2367	265.3	6.8	74.0	(Disassembled)				X		Environmental testing
45	3421	285.8	7.5	74.0	7.6 ma 74.0					X	
46	3421	267.2	7.4	74.0	7.8 75.0				X		Dosimetry tests
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	Tested to failure				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 148,878 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 3

Experimental Model Life Test Data

(7-31-72)

<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)	39,393	74.3 μ w			84.8 μ w
E-4	38,941	2.5 ma	78.0	78.6	2.9 ma
E-5 (8)	37,214	70.0 μ w			79.6 μ w
E-9 (2)	30,633	82.9 μ w			82.3 μ w
E-10 (5)	29,293	68.8 μ w			77.5 μ w
E-12 (4) (3)	30,062	240.2 μ w			230.0 μ w
E-13BB	24,326	7.4 ma	129.0	123.0	8.0 ma
E-14 (4) (6)	11,701				
E-16 (10)	26,793	203.1 μ w			202.4 μ w
E-17 (4)	25,669	224.3 μ w			
E-18 (9)	26,985	245.1 μ w			247.8 ma
E-20 (7) (11)	21,276				260.5 μ w
TOTAL	342,286				

- (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.

* 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 4

Prototype Model Life Test Data

(7-31-72)

<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)	23,676	6.1	125.0	125.3	5.5 ma
P-2 (12)	19,885			126.9	5.7 ma
P-3 (2) (5)	22,629	5.8	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	88,307				
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.

Internal Quality Assurance Audit

An internal Quality Assurance Audit was performed at ARCO Nuclear on June 20. The audit was conducted by Mr. J. Dickey and Mr. M. Zambernard. Both men have had extensive experience in the area of audits concerned with Navy and AEC contracts. An audit procedure, consisting of 18 pages of questions pertinent to the RPCP Program, was prepared and used by the auditors. In general, the audit indicated that the requirements of the Quality Assurance Program established for the RPCP Program are being met with few exceptions. However, there are certain areas which require additional periodic review of data sheets in order to insure compliance. As a result, a procedure monitoring schedule has been instituted.

Internal Quality Control Audits

During the months of May, June, and July, a total of sixteen process operating procedures were audited at ARCO Nuclear by the Quality Control Department for compliance to operating and record keeping. The areas audited were Fabrication (4 procedures), Quality Control (8 procedures), Chemistry (2 procedures), and Assembly (2 procedures). The audits indicated the procedures were being followed with one exception of a VTVM (ohm meter) that was past due for calibration. The meter was replaced by a calibrated meter two days later and the responsible engineer informed.

Materials Review Board Actions

During the months of May, June, and July, the Materials Review Board (MRB) has performed extensive investigations on probable causes related to non-conforming parts and materials. The following table (No. 5) is for material submitted for dispositioning by the MRB. Table No. 6 indicates the rejection rate per component based on MRB disposition.

TABLE 5
May - 1972

<u>Non-Conforming (NC) Material or Parts</u>	<u>Total N.C.</u>	<u>M.R.B. Accepted</u>	<u>M.R.B. Rejected</u>
Brazed Tapes	80	20	60
Cupron Plated Tapes	18 sec.	6	12
Tophel Plated Tapes	67 sec.	7	60
Insulation Circles	61	0	61
Coated Ceramic Tabs	26	0	26
Incoming Ceramic Tabs	6	0	6
Incoming Tophel Tape	34 ft.	0	34 ft.
Hot Shoes	107	31	76
Cold Shoes	39	0	39
Incoming Lucalox Tubing	6	6	0
Feedthrough Flange	5	5	0
Exterior Cases	10	5	5

June - 1972

Brazed Tapes	47	13	34
Cupron Plated Tapes	44 sec.	2	42
Tophel Plated Tapes	87 sec.	22	65
Coated Ceramic Tabs	133	0	133
Cold Shoes	9	0	9
Cold Straps	15	14	1
NiTi Feedthrough	20	20	0
Exterior Cases	1	1	0

July - 1972

Brazed Tapes	68	20	48
Cupron Plated Tapes	27	5	22
Tophel Plated Tapes	18	0	18
Coated Ceramic Tabs	82	21	61
Cold Straps	5	4	1
NiTi Feedthroughs	4	4	0
Exterior Cases	12	8	4
Insulation Tape	142 pieces	142 pieces	0
Closure Plug Flange	3	1	2

TABLE 6

Inspection Summary of Critical Components

	May		June		July	
	<u>Total</u> <u>Inspected</u>	<u>%</u> <u>Rejected</u>	<u>Total</u> <u>Inspected</u>	<u>%</u> <u>Rejected</u>	<u>Total</u> <u>Inspected</u>	<u>%</u> <u>Rejected</u>
Brazed Tapes	199	30	153	22	185	26
Cupron Plated Tapes	186 sect.	6	306 sect.	14	180 sect.	12
Tophel Plated Tapes	228 sect.	26	342 sect.	19	138 sect.	13
Coated Ceramic Tabs	464	6	543	24	461	13
Incoming Ceramic Tabs	1200	1	1285	0	0	0
Incoming Thermocouple Tape	700 ft.	5	703 ft.	7	1041 ft.	41
Hot Shoes	400	19	74	0	127	0
Cold Shoes	496	8	168	5	0	0
Lucalux Tubing	99	0	0	0	248	0
Feedthrough Flanges	121	0	0	0	0	0
Incoming Exterior Cases	0	0	100	1	0	0
Cold Straps	6	0	41	2	36	3
Hot Straps	0	0	119	0	0	0
NiTi Feedthroughs	22	0	18	0	21	0
CuAg Feedthroughs	5	0	14	0	12	0

TASK 3.0 - SYSTEM FABRICATION AND PRODUCTION DEVELOPMENT

Production was somewhat slowed during the beginning of the report period due to the work on the qualification testing and hold on production of dog implant units. Formal production meetings are being held weekly with records of production and salient items being kept. Some of the most significant accomplishments in production are related to improved quality assurance. An x-ray unit was installed and is being used for x-raying all pacemakers. Also, a new procedure on non-conforming parts is being used in conjunction with a materials review board. All parts are marked as nonconforming until a disposition is made by the board. Formal documentation of engineering changes are being made using engineering change order forms. These forms have been used for such changes as the 50% increase in insulation tape and the new photoetching for cases using the NU-5 designation for the new units. Other salient production items will be covered in the following sections.

Tape Brazing

One of the most difficult items to successfully manufacture in the pacer is the thermoelectric tapes. As reported in the last quarterly, the rejection rate was $\approx 25\%$ in February, $\approx 24\%$ in March, and $\approx 49\%$ in April. It was felt that the lower yield in April was primarily due to breaking in a new assembler. As given in Task 2, Table 6, the tape brazing during this report period has had rejection rates of 30% in May, 22% in June, and 26% in July. A detailed examination did not indicate a single main cause of rejects and no obvious solutions are available. All aspects of the procedures are being examined carefully in an effort to improve the yield. The production rate per man has been good.

Battery Assembly

During the month of May, 15 batteries were sealed. These units were used for testing the mechanical vibration capabilities of the 50% more insulation design. The performance level of these units is down approximately 15% from ≈ 270 to 235 μ watts due to the tighter wrap. (See Table 7) The voltage output is sufficient to meet the end of life design output. The plot of output power and efficiency is given in Figure 1. A total summary of production since January is given in Figure 2. This figure includes all the NU-4 units and the units made for developmental and qualification of the NU-5 design.

TABLE 7

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

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

PRODUCTION

Figure 2

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. (See Figure 3.) 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, two were special thermopiles, four special batteries, three had open tapes, and two shorted. The loss was 16 percent. During battery assembly, one unit leaked. 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.

In July, 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%. 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%.

The battery performance and disposition data is given in Tables 8 and 9. 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 4 and 5.

TIG Welder Fixture Maintenance

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

1. Tack welded the couplings to the shafts to remove slop.
2. Welded in a shim at the couplings so the shaft will bottom out on a shim instead of the cam plate.
3. Flats were ground on the drive shaft to improve the tightening capability.
4. The welder was moved toward the center of the box for access.
5. The bearings were moved on the cam blocks to distribute the load.
6. Resealed the chamber to provide a cleaner atmosphere.

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

Figure 3

TABLE 8

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	
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 9

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

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

PERFORMANCE RESULTS FOR UNITS SEALED IN JULY

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

Figure 5

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 will henceforth 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

Corrosion Testing

Corrosion testing of assembled RPCP units has been provided by the implantation of twelve experimental and prototype units in dogs for periods exceeding one year. Preliminary evaluation by microscopic and metallographic examination of the external surfaces of such units indicate that corrosion pitting in the most extensively corroded areas covered about 6% of the surface with an average pit depth of about 3μ . In many cases, large areas of the external surfaces of such units were found to be essentially free of pitting due to corrosion.

An additional unit, kept in a "Ringer's Solution" for over a year, was examined and found to contain negligible pitting in comparison to that observed for the animal-implanted units. It was, therefore, concluded that animal implantation could well provide a more realistic way of evaluating RPCP corrosion problems than long-term, salt solution immersion.

A study of the corrosion susceptibility of the fuel capsule to both Ringer's solution and ordinary salt water has been initiated. The results of this study will be available at a future date.

Chemical Components Production

During the quarter May 1 through July 31, 1972, the following components were manufactured and accepted by Quality Control for subsequent RPCP assembly. Yield of manufactured product expressed as percentages is also shown.

<u>Component</u>	<u>Pieces Accepted</u>	<u>Yield as %</u>
Ceramic Tabs	1217	85
Hot Shoes	482	87
Cold Shoes	547	93
Tophel Tape (10")	593	80
Cupron Tape (10")	585	89
Insulation Tape (10")	1491	97
Case Identification	49	100
Cold Straps	74	98
Battery Feedthroughs	59	100
Electronics Feedthroughs	40	100

Investigation of S/N NU-4-14

A second pacer, S/N NU-4-23 removed from a dog, has exhibited the same epoxy problem as NU-4-14. The epoxy was soft and porous and showed signs of swelling. The Hysol Division, who manufacture the epoxy, was contacted and the problem discussed in detail. Samples from the two pacers have been sent to Hysol who will analyze the samples.

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

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

Dog Tests

Pacer NU-4-57 which has been on a dog at ARCO shows no tape failures after three months. This test has been terminated due to the long test period with no tape failures.

A test program has been 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 NHLI 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 NHLI is planned which will 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.

Human Tests

A test program has been outlined to study the acceleration levels generated by a human wearing a pacer. The subject tested will be wearing the microcom telemetry equipment fixed to the upper chest area by some type of harness. The subject will 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.

Telemetry Equipment (Shaker Characterization)

A new model of the Sherwin Williams paint shaker (identified as Sherwin Williams, manufactured by Miller Manufacturing Company of Illinois) has been purchased. The new and old model have been 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 pacemaker 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. Also, the g waveshape differences are being evaluated.

A noise signal study of the telemetry system was also conducted during this report period. 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 telemetry unit is presently being adjusted by Microcom to alleviate a sporadic oscillation problem in one channel. This work is expected to last approximately one week, at which time the test program can be resumed.

RTV Electronics Potting

A problem was encountered during 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.

Electronics Cases

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% due to cracks. 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. A lot of .010 material from Timet was tried and proved to have excellent forming capabilities. The yield was approximately 98% with no intermediate annealing operations required. The material was analyzed in detail and found to have the following physical characteristics:

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

Max. Y.S. - 37,000 psi

Min. Elong. - 30%

Grain Size - ASTM 8 or finer

All future orders of Ti Grade 35A will specify the above requirements. The current status of electronic cases are 8 with feedthroughs, 15 without, 148 in Q. C. for incoming inspection. This represents approximately a 28 week supply.

Fuel Capsules

Eight inner capsules and plugs have been sent to Mound for fueling.

Thermopile Hysteresis Loop in the Radial Direction

Deflection vs. load curves in the radial direction (+ Y direction) were obtained for a loosely wrapped and with 50% more insulation wrapped thermopiles. The test results are shown in Figures 6 through 9. 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.

The arrangement in which the stiffness tests were conducted is illustrated in Figure 10. Each thermopile was inserted in the casing, with bracket and retaining strap but without getter baskets and end shields. An aluminum rod with a tight fit was inserted through the hot strap. Lead shot weights were added in a small container supported at each end of the aluminum rod. The deflections of the aluminum rod were measured with a height gauge and referenced from surface A.

Vibration Test of a Pacemaker Unit without Fuel Capsule

A pacemaker unit without the fuel capsule was vibration tested in the paint shaker (11 cps - 50 g's). The test was terminated after 4 hours without failure since no change in the measured resistance (5280 Ω) occurred.

HYSTERESIS LOOP IN THE $\pm Y$ DIRECTION

HYSTERESIS LOOP IN THE $\pm$ Y DIRECTION

Figure 7

HYSTERESIS LOOP IN THE $\pm Y$ DIRECTION

DEFLECTION - THOUSANDS OF AN INCH

HYSTERESIS LOOP IN THE $\pm Y$ DIRECTION

DEFLECTION — THOUSANDS OF AN INCH

Figure 9

**THERMOPILE LOADING ARRANGEMENT
FOR HYSTERESIS LOOP CURVES**

Figure 10

This was a loosely wrapped thermopile. All of the previous loosely wrapped thermopile units with fuel capsules did not last longer than about an hour in the paint shaker.

Thermal Performance of a NU-4 Thermopile with a Tighter Cold Strap

These tests were performed to investigate the possibility of reducing the thickness of the pacemaker unit without deteriorating its thermal performance. Therefore, the cold strap of a loosely wrapped thermopile unit was tightened to a measured perimeter of 3-3/4 inches. This is approximately 1/4 of an inch less than the perimeter of a thermopile unit with 50% more insulation. This tight thermopile unit with fuel capsule, getter baskets, and end shields was inserted in a casing without a lid. A 0.025 inch thickness titanium shim was inserted in each side between thermopile and casing. The unit was then placed in a vacuum chamber, degassed, and its thermal performance was measured after equilibrium was reached. The process was repeated with .100, .150, and .200 inches total shim thickness. The test results are shown in Figure 11. As can be seen even with .250 inch reduction in thickness, the thermal performance is still within an acceptable level, i.e. 1.95 volts and 60 microwatts (since two out of six tapes were wired). When time permits, a complete pacemaker unit of the above mentioned configuration will be tested on the paint shaker.

Fatigue Test Data on Thermocouple Wires

Basic Technology, Inc. has generated fatigue test data on cupron special and tophel special thermocouple wires. Their test work is summarized in their draft report "Fatigue Life of Small Diameter Tophel and Cupron Wires". For the same strain, the tophel wires have somewhat longer life than the cupron wires. This report is being reviewed and will be transmitted in final form to the Commission during the next report period.

Load vs. Resistance of Cupron Tapes

The change in resistance in cupron tape wires with increasing tension (load) was measured in an arrangement shown in Figure 12, and the test results are shown in Figure 13. This information can be used in the design of a wrapping fixture that limits the maximum tension applied to the tapes. It

THERMAL PERFORMANCE OF UNIT C

- LOOSELY WRAPPED WITH TIGHT COLD STRAP (PERIMETER 3.750 INCHES).
- THERMOPILE SQUEEZED TO AN EGG-SHAPE BY INSERTING TITANIUM SHIMS BETWEEN THERMOPILE AND CASING.
- TWO TAPES WERE ONLY WIRED IN SERIES.

LOAD VS RESISTANCE
MEASUREMENTS OF CUPRON TAPES

Figure 12

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 DIA.

REJECT TAPE

○ = NO. 1398

● = NO. 1212

□ = NO. 1217

◇ = NO. 1117

△ = NO. 1244

Figure 13

was observed that some of the wires in the cupron tape were breaking during the wrapping process. Based on this data during wrapping the maximum tension per tape should not exceed 50% (2500 grams) of the breaking strength. It is also interesting to note the breaking strength of the tested 5 cupron tapes was consistent (5000-5400) grams) with no individually weak wires.

Vibration Test of Torqued NU-4 Model Units

This test was conducted to investigate the effect of hot strap rotation from the as wrapped position on the life of a unit. The hot straps of two loosely wrapped thermopile units (NU-4 model) were torqued in opposite directions. One was rotated 30 degrees (1095 gram-inches) in the tightening direction, the other 30 degrees (640 gram-inches) in the loosening direction. Due to the existing hysteresis between tape layers in the angular direction, the hot strap retains its deformed position. Each thermopile unit was then inserted complete with stainless steel capsule in its casing. The battery units were then life tested to failure in the paint shaker (11 cps. 50 g's). The one whose hot strap torqued in the tightening direction failed after 70 minutes and the other after 100 minutes. Based on this test, it can be concluded during wrapping the relative orientation of cold and hot shoes is not too critical on the life of a unit. The reason for conducting this test with the NU-4 model units instead of NU-5 was to shorten the life test. Otherwise, the test results would be similar.

TASK 4.0 - SYSTEM TESTING

The April quarterly report described the preliminary tests conducted on the paint shaker with various new thermopile wrapping designs. Since that time, additional testing has been completed and is presented in figures 14, 15, and 16. The environmental tests mentioned in these figures consists of the following:

1. 4 atm of pressure
2. 4 g vibration, 20-500-20 HZ
3. -40°F to +140°F thermal cycling
4. 5' drop to concrete (4500 g's)
5. 3000, 50 g shocks
6. 96, 545 g 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 14) 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 has been 80 minutes, and many units have failed in 5 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

Figure 14

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 15

<u>Environmental Test 1st → Shaker Test 2nd</u>												
Unit No.	Thermopile Assembly	Before Test		After Testing			Shaker Test Data					
		Voc	Battery Ω	Environmental	Paint Shaker	min(s) Voc	Tapes Open				Min(s) to Failure	Failure Mode
							1	2	3	4		
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 16

Shaker Test 1st → Environmental Test 2nd							Shaker Test Data					
Unit No.	Thermopile Assembly	Before Test		After Testing							Min(s) to Failure	Failure Mode
		Voc	Battery Ω	Paint Shaker	Environmental		1	Tapes 2	Open 3	4		
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

into two test groups as indicated by figures 15 and 16. E6 and E8 which were first subjected to environmental tests both failed because of shorting during the shaker test. E7 (figure 16) 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, 545 g shocks establish a condition which is conducive to shorting when followed by the shaker test. No units have ever shorted in animals and all animal failures have 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. 4 g vibration, 20-500-20 HZ
5. Thermal cycling, -40°F to +140°F
6. 5' free fall to concrete, 1 cycle
7. 50 g shock test, 3000 cycles
8. 545 g 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 17 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 does 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 will require that during production of pacers every eighth wrapped thermopile will 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 $V_{oc} \geq 1.9$. 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. Table 10 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 18 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 19, 20, and 21. 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. 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

Figure 17
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	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.	
NU								

Figure 17
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.	

QUALIFICATION TEST RESULTS OF PRODUCTION BATTERIES

Figure 18

END VIEW RADIOGRAPH

BATTERY NU 5-7

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 20

END VIEW RADIOGRAPH

BATTERY NU5-25

Figure 21

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 21, 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 22. Apparently, there is very little movement or flexing at the outside wraps of the thermopile.

Model NU-4 Post Implant Data

During this report period, all of the NU-4 systems have been removed from animals and all but two of the total of 27 units have been electrically tested for tape conditions. The following table summarizes the results of the 25 units tested:

TABLE 10

<u># of Open Tapes</u>	<u># of Units</u>	<u>Average Implant Time (days)</u>	<u>Time Range (days)</u>
0	9	108	35 - 150
1	2	143.5	140 - 147
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 addition units were removed for evaluations. 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, 15 of the 17 units were electrically tested, and it was found that six were normal, two 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 failure could have been random. Table 11 details each of the 27 implant units.

BATTERY NU5-25
COLD SHOE-TAPE NO.1

Figure 22

TABLE 11

<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	-----
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	-----
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

NU-5 System Performance Data

The performance of the NU-5 units thus far has been more consistent than the previous NU-4 units. The following table summarizes the performance data for the first 43 NU-4 units built and the first 43 NU-5 units built.

TABLE 12

	<u>NU-4 Model</u>	<u>NU-5 Model</u>
Number of Units	43	43
Average Power (microwatts)	268	230
Standard Deviation (microwatts)	19.0	13.3
Normalized Standard Deviation (%)	7.1	5.8

It should be noted that the standard deviation even when taking into account the lower average power of the NU-5 units is approximately 22% lower for the NU-5 units indicating a more consistent performance than the NU-4 units.

TASK 5.0 - SAFETY

Cremation

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 13 summarizes the cremation testing to date. A coding system has been used in reference to the crematory identification.

Fueled RPCP Cremation Test

During this report period, two fueled (one oxide, one metal) RPCP completed systems have been subjected to cremations conditions (approximately 2100°F for two hours) at Mound. The fuel capsules have been isolated from the system remains. There is no indication of fuel leaks in either capsule and a detailed study is planned for each encapsulation at Mound to determine the effects of the time-temperature profile.

Safety Testing

The following work has been performed during this report period to determine the possibility of fuel capsule failure, and hence, fuel release, due to various credible accidents.

Impact of a High Velocity Projectile:

A statistical study has shown that with the assumed RPCP implantee age distribution (total stationary population of 100,000) a firearm projectile will result in the death of 13.95 implantees per year. Translated into the probability of hitting the fuel capsule, this means that a firearms projectile will hit the fuel capsule once in approximately 41 years.

TABLE 13

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>
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 13 (continued)

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>
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%.

Statistics relating to the type of weapon used are currently being sought. The appropriate statistics relating to suicide have proven difficult to obtain. A testing program has been initiated to determine the ability of the fuel capsule to withstand a direct hit from various types of firearms projectiles.

Impact of the Capsule at High Velocity:

Auto Accidents

Measurements of the accelerations experienced by the pacer have been made during simulated automobile accidents at 15, 30, and 45 miles per hour. For these tests, pacer mock-ups instrumented with accelerometers have been implanted into a human cadaver which, in turn, has been subjected to simulated crashes at the above speeds at the Biomechanics Research Center of Wayne State University. While the data is still being analyzed, it has become apparent that although the automobile accident represents the most credible accident involving an RPCP implantee, it is the least severe accident in terms of potential fuel release.

In addition, tests have been made of the temperatures attained inside a burning automobile in which test animals have been placed. The animals were slaughtered for consumption previous to the test. The results show that the automobile fire is the least severe of the high temperature excursions which could possibly affect fuel release. (See Appendix A)

High Temperature - High Pressure Tests

The high temperature - high pressure apparatus discussed in the Phase I Safety Report has been reassembled and tested in preparation for more intensive tests concerned with the possibility of fuel release due to high temperature conditions.

In addition, an evaluation of the ability of the fuel capsule to contain the helium buildup pressure during a high temperature excursion will be evaluated.

A vacuum check-out test has indicated the need for a complete cleaning of this high temperature/pressure apparatus. At the completion of this test, additional tests will be performed before commencing the high pressure - high temperature testing program.

Fuel Capsule Material Compatibility Studies

Preliminary work aimed at the determination of the degree of compatibility of the various fuel capsule materials during high temperature conditions is in progress.

The necessary "boats" have been prepared from the materials used to contain the fuel. These boats will be "loaded" with various fuel capsule materials and subjected to high temperatures in both oxidizing and vacuum atmospheres. Chemical analysis will allow the degree of alloying/attack to be determined.

This work has been temporarily suspended pending the availability of the high temperature - high pressure apparatus discussed above.

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 14.

TABLE 14
Gamma-Ray Dose Rate (in air)
RPCP NU4-46 (Capsule A-38)

<u>Location</u> <u>(See Fig. 23)</u>	<u>Dose Rate</u> <u>mrad/hr.</u>	
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 23

Licensing

During this report period, a meeting was held at the Division of Materials Licensing to discuss the technical information that had been submitted in the past concerning the licensing for human implant of the RPCP system. Since the time of submission of this technical information, the Division of Licensing has formulated a new guide for such technical information entitled "Interim Guide Information To Be Submitted Concerning Radionuclide Powered Cardiac Pacemakers For Implantation In Humans For Investigational Purposes". It was agreed that the previously submitted technical information would be summarized and written in the format of the above mentioned guide. This document has been completed and transmitted in draft form to RDT for review.

DISTRIBUTION

Cdr. J. M. Prosser, RDT, USAEC, Washington, D. C.	2
Mr. M. A. Rosen, RDT, USAEC, Washington, D. C.	1
Mr. R. E. Cunningham, Division of Materials Licensing, Washington, D. C.	1
Dr. J. D. Goldstein, Department of Biology & Medicine, USAEC Washington, D. C.	1
Col. Seymour Shwiler, Staff Consultant to the Joint Committee for Atomic Energy, Congress of the U.S., Washington, D. C.	1
Mr. H. Miller, Director, Contracts Division, AEC, Chicago	2
Mr. L. Belkin, Chief, Brookhaven Patent Group, USAEC, Upton, Long Island, New York	1
Dr. A. G. Morrow, Chief, Clinic of Surgery, NHLI, Bethesda, Maryland	1
Dr. P. Frommer, Chief, Myocardial Infarction Branch, NHLI, Bethesda, Maryland	1
Dr. V. Parsonnet, Director of Surgery, Newark Beth Israel Hospital, Newark, New Jersey 07112	2
Mr. E. A. Walker, Dayton Area Office, USAEC, Monsanto Research Corporation, Miamisburg, Ohio 45342	1
Mr. D. L. Prosser, Program Manager, Cardiac Pacemaker Program, Mound Laboratory, Monsanto Research Corporation, Miamisburg, Ohio	1
Dr. E. W. Johnson, Mound Laboratory, Monsanto Research Corporation, Miamisburg, Ohio	1
Mr. T. Iltis, Senior Site Representative, RDT Site Office, USAEC/WARD Madison, Pa.	1
Mr. J. N. Maddox, Division of Applied Technology, Washington, D. C.	1
Cdr. W. Holloman, RDT, USAEC, Washington, D. C.	1
Dr. J. Pierce, National Institutes of Health, Bethesda, Maryland	1
USAEC Division of Technical Information Extension, Oak Ridge, Tennessee (Category UC-33 Distribution)	198

APPENDIX A

I. INTRODUCTION

Due to the potential widespread distribution of Radioisotope Powered Cardiac Pacemakers (RPCP), studies are currently underway to determine the conditions encountered by the nuclear fuel capsules of these devices under credible accident situations. The nuclear fuel capsule must be able to survive all credible accidents without release of the nuclear fuel, Plutonium 238 oxide. This is so, since even a localized release of the radioactive material could result in possible radiation exposure to any individual coming upon the accident scene, i.e., police, ambulance personnel, etc.

Consideration of relevant death statistics has resulted in the enumeration of four credible nuclear fuel capsule failure modes, namely:

1. impact of a high velocity projectile
2. high temperature
3. impact of the fuel 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, homicide¹ or suicide, fire or explosion, aircraft accident, and industrial accident.

Examination of death statistics as published in Statistical Abstracts of the United States (1971) shows that most credible accident involves the automobile. This report describes the results of a program to experimentally determine the conditions encountered by nuclear fuel capsules in an automobile accident followed by an auto fire. A test of the conditions encountered by a nuclear fuel capsule subject to a combination of two failure modes (i.e., impact followed by high temperature) is expected to result in the establishment

¹Note that for the purposes of this report, homicide is considered an accident.

of the most severe criteria for the safety of a fuel capsule.

The conclusions derived from this study are not only applicable to the AEC Program to develop a plutonium 238-oxide RPCP, but also to other vented or unvented nuclear fuel capsules for medical purposes. The ultimate goal of this work is the guarantee that the RPCP will meet the licensing requirements of the Atomic Energy Commission or any relevant licensing agency. Thus, it is hoped that this program will help to bring the benefits of a reliable nuclear device of substantial longevity to those many aged whose lives depend on cardiac pacers.

II. ANALYSIS

The limit of accident 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 individual's 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 Figure 1 is assumed.

As discussed previously, examination of relevant death statistics has shown that the most credible accident to be encountered by the nuclear fuel capsule is the automobile accident. Table 1 shows that 37.83 implantees will die in an auto accident in a given year. The implantee auto deaths for each age group in Table 1 were calculated by dividing the number of deaths in a particular age group by the total population in that age group. This number represents the probability of dying in an auto accident for each age group. If it is assumed that the implantees live a life completely representative of their age group, then multiplying the probability of dying by the number of implantees results in the number of implantee auto deaths in that age group. The assumption that the implantees live a life representative of their age group is reasonably conservative.

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

TABLE 1

Implantee Auto Deaths (1971)

<u>Age</u>	<u>Population x 10⁵</u>	<u>Auto Deaths</u>	<u>Implantees</u>	<u>Implantee Auto Deaths</u>
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
<hr/>				
Total All Ages	2 x 10 ⁸	54,800	100,000	37.833

Source:

Private Communication, National Safety Council

Expressed mathematically, the number of implantee auto deaths per year, N_A , is given by

$$N_A = \sum_i P_i N_i$$

where P_i is the probability of death in the age group i and N_i is the number of implantees in this same age group.

III. EXPERIMENTAL PROCEDURE

The 1961 Corvair automobile shown in Figure 2 was instrumented with sixteen platinum/platinum-10 rhodium thermocouples placed in eight different locations within the car. The thermocouples were mounted in 1.93" x 1.16" x .375" Inconel 600 holders. Each holder provided the necessary thermal inertia to prevent rapid thermal fluctuations from effecting the thermocouples and, in addition, provided a housing for sixteen tempil pellets. The thermocouples were attached to the tempil pellet holders by ceramic cement. The 16 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. A drawing of the tempil holder is shown in Figure 3. The thermocouples were 8 feet long and the platinum and platinum-rhodium wires were electrically insulated from each other with 6 inch sections of ceramic tubing. The thermocouples were connected to standard pt/pt-rh thermocouple extension wire to minimize the length of platinum wire needed. As specified by the manufacturer, provided the junction between the thermocouples and the extension wire is maintained below 400°F, the uncertainty in the measured temperature associated with this connection is $\pm 10^\circ\text{F}$. To prevent the thermocouple-extension wire junction from exceeding this temperature, the junctions were sealed in plastic and buried in the ground. Before the car was ignited, the ground was thoroughly soaked with water. The plastic seal about the thermocouple-extension wire junction prevented moisture from effecting the measured results.

The 32 leads from the 16 thermocouples were brought to a West Instrument Corporation Marksman 24-channel recorder. The recorder

PHOTOGRAPH SHOWING INTERIOR OF
THE 1961 CORVAIR TEST AUTOMOBILE

Figure 2

REV	DESCRIPTION
1	ITEMS 1 & 2 OTO DIA WAS 0.06 DIA 11-11, ADD SEC B-D, (4) PADS, DIMS .090 TYP, 4-10 REF, & .065 TYP (AS MICH) 11-4, 71 C SMITH 11-8 - C & Smith
2	REVISED & REMAIN 12-22-71 E CRAIG 1-7-72 C SMITH 1-10-72 C & Smith
3	ITEMS 1 & 2 .030 DIA, .062 DIA, .090 TYP, 4-10 PADS, DIMS .090 TYP, 4-10 REF, & .065 TYP (AS MICH) 11-4, 71 C SMITH 11-8 - C & Smith ITEMS 3 & 4 WAS 11-15, 4-7 WAS .065 TYP, 4-10 PADS, DIMS .090 TYP, 4-10 REF, & .065 TYP (AS MICH) 11-4, 71 C SMITH 11-8 - C & Smith ITEMS 3 & 4 WAS 11-15, 4-7 WAS .065 TYP, 4-10 PADS, DIMS .090 TYP, 4-10 REF, & .065 TYP (AS MICH) 11-4, 71 C SMITH 11-8 - C & Smith
4	ADDED .125 DIA X .250 DEEP C BORE TO ITEM 3, 11-15, 4-7 5-18-72 Carl Cramp

Figure 3

"samples" each of the 24 channels, successively. The time necessary for one complete cycle of the sampling operation is 48 seconds. Hence, the temperature at each location within the car was determined every 48 seconds. The recorder was mounted behind a double asbestos-blanket heat shield. This prevented radiant heat from the burning auto from effecting the operation of the recorder and, also, allowed the operation of the recorder to be monitored by test personnel. Photographs of the test set-up are shown in Figure 4. It is conservatively estimated that the uncertainty in the measured temperatures is $\pm 50^{\circ}\text{F}$.

As has been mentioned previously, the 16 thermocouples were placed in eight different locations within the automobile. The following is a listing of 6 of these locations:

1. on the roof of the car
2. on the front floor of the car
3. on the back floor of the car
4. on the dashboard of the car
5. on the rear window shelf
6. 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 pacers. In addition, the animals were suspended via support wires from the roof of the car. While the animals' buttocks did touch the seats of the car, very

PHOTOGRAPHS SHOWING EXPERIMENTAL
SET-UP USED FOR THE FIRE TEST

Figure 4

■ little of the animals' weight acted on the seat. The support of the animals from the roof was attempted in order to simulate worst-case auto fire conditions. This statement is supported by the observation that in actual auto fires, the buttocks area, which is "wedged" into the seat, seldom is severely burned. It is thought that compression lowers the combustibility of the seat. Figure 5 shows the location of the animals in the automobile. In Figure 5, the pig is seen, supported from the roof, behind the steering column of the car. The sheep was placed in the back seat directly behind the front passenger's seat. Also, visible in Figure 5 is the tempil holder with attached thermocouples inserted in an incision made in the pig. This photograph was taken prior to closing the incision with wire. This same procedure was used in the preparation of the sheep. Figure 5A shows the car after all preparations had been completed. The tempil holder (with it's two thermocouples), which was mounted on the dash of the car, is also visible in Figure 5A.

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 12 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 7 gallons of gasoline.

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 preceeds this (simulated) 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, 20 minutes into the test, the wind changed to a gentle 3-5 MPH wind from the southwest. The car faced northeast during the test.

PHOTOGRAPH SHOWING LOCATION OF
ANIMALS IN TEST AUTOMOBILE

Figure 5

PHOTOGRAPH SHOWING AUTOMOBILE AFTER
ALL PREPARATIONS HAVE BEEN COMPLETED

Figure 5A

IV. RESULTS

Figures 6 through 11 trace the course of the automobile fire from ignition to termination after 90 minutes. Although it is not apparent in the photographs, the automobile burned in a somewhat "cyclic" fashion. That is, 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 this observation was due to the gentle southwest wind.

Another observation of considerable importance for future tests of this nature is the following: The pig was originally selected for the test because it was thought that the high fat content of the animal would result in intense burning and, hence, worst case fire conditions. However, the sheep burned much more intensely than the pig. In fact, 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 by flames. As will be discussed shortly, the highest temperature recorded in the car was indicated by the thermocouple/holder assembly placed within the sheep.

Figure 7 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.

The results for the tempil pellets are exemplified by Figure 12. Figure 12 shows a photograph of the tempil pellets upon disassembly of the holder placed within the sheep following the fire. None of the

PHOTOGRAPHS TAKEN DURING AUTO FIRE

Figure 6

PHOTOGRAPH TAKEN DURING AUTO FIRE

Figure 7

PHOTOGRAPHS TAKEN DURING AUTO FIRE

Figure 8

PHOTOGRAPH TAKEN DURING AUTO FIRE

Figure 9

PHOTOGRAPHS TAKEN DURING AUTO FIRE

Figure 10

PHOTOGRAPH TAKEN AFTER AUTO FIRE

Figure 11

PHOTOGRAPH OF TEMPIL PELLET HOLDER AT TERMINATION OF TEST
THIS HOLDER WAS LOCATED WITHIN THE SHEEP DURING THE FIRE TEST

Figure 12

pellets shown in Figure 12 have melted. In fact, one of the 128 tempil pellets placed in the car melted during the fire. Hence, the temperature did not exceed 1500°F at any of the locations in the car previously discussed. However, the presence of the tempil pellets in the automobile did supply a suitable check on the thermocouple data. As shall be seen shortly, the correlation between these two types of temperature indicators was quite good.

Figures 13 through 16 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. With one exception, care has been taken to insure that high temperature measurement points are indicated on the graphs.

One of the thermocouples placed within the sheep did read 1800°F at 45 minutes into the test. This one point has been rejected as spurious. Neither the other thermocouple at this location or the tempil pellets in this location registered this temperature. In fact, only at this time were the two thermocouples not within the $\pm 50^\circ\text{F}$ uncertainty. At the completion of the test, the holder originally internal to the sheep was found on the rear floor of the car. This was, no doubt, due to the fact that the sheep's flesh had been completely burned away.

TEMPERATURE VS TIME RELATIONSHIPS INSIDE A BURNING AUTOMOBILE

Figure 13

TEMPERATURE VS TIME RELATIONSHIPS INSIDE A BURNING AUTOMOBILE

Figure 14

TEMPERATURE VS TIME RELATIONSHIPS INSIDE A BURNING AUTOMOBILE

Figure 15

TEMPERATURE VS TIME RELATIONSHIPS INSIDE A BURNING AUTOMOBILE

Figure 16

Both thermocouples had broken loose from the holder in falling to the floor. It is possible that in falling to the floor, one of the thermocouples "read" the flame temperature present at that instant.

As can be seen in Figures 13 through 16, the highest temperature recorded by the thermocouples was 1514°F (see Figure 13) at the location of 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 are 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.

A method of rating fire intensities has been adopted by organizations interested in fire assessment and prevention. This method makes use of the standard fire curve shown in Figure 17. Few fires achieve the temperatures associated with standard fires. However, correlation between fires is obtained by integrating the experimental time-temperature curve and fitting this area under the standard fire curve (Figure 17).

The standard fire condition established in the burning automobile is shown in Table 2. To determine the results presented in Table 2, the weight method of integration was employed. Using this method, the experimental temperature profile was cut from a sheet of paper and weighed. Next, the standard fire curve was cut from a sheet of paper. The portion of the standard fire curve necessary to "match" the weight of the experimental temperature profile was determined. The standard fire conditions can then be obtained by comparison with Figure 17.

STANDARD TIME-TEMPERATURE CURVE

Figure 17

Table 2

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

V. AUTO FIRES--IMPLICATIONS FOR FUEL CAPSULE INTEGRITY

Each of the three nuclear fuel encapsulations on the RPCP are leaktight. This is necessary both to contain the helium gas which is produced by the radioactive decay of Pl^{238} oxide and to prevent fluids which are external to the fuel capsule from coming in contact with the fuel. The outer fuel encapsulation is made of titanium. Titanium was selected because of its excellent corrosion resistance. The middle encapsulation material is oxidation resistant Hastelloy "C".

In previous tests, fuel capsules and complete RPCP's have been subjected to elevated temperature standard fire conditions. While a statistical study has shown that the fuel capsules must be capable of sustaining a standard fire of 1900°F at 2.63 hours with the defined limit of credibility, these tests have shown that the outer encapsulation retains hermiticity to approximately 2050°F at 4 hours. The probability of any RPCP implantee experiencing a fire of this severity in one year is one in ten million. Moreover, since the middle encapsulation utilizes Hastelloy "C", the loss of hermiticity for the Ti outer encapsulation is not considered to increase the danger of nuclear fuel release significantly.

In light of the results presented in Table 2 and these previous high temperature tests, the present method of fuel encapsulation is deemed sufficient to guarantee the integrity of the RPCP fuel capsule under the conditions encountered in an automobile fire.