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RADIOISOTOPE-POWERED CARDIAC PACEMAKER

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REPORT TO:
UNITED STATES ATOMIC ENERGY COMMISSION

6/26/77

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Quarterly Progress Report
for
Phase II
Radioisotope Powered
Cardiac Pacemaker Program

February 1, 1972 to April 30, 1972

Prepared for

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INTRODUCTION

This is the ninth 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 February 1, 1972 to April 30, 1972.

Task 1.0 - PROGRAM MANAGEMENT, CONTROL, AND PLANNING

The pilot production continued at a satisfactory rate and the total number of dog implants reached 27, however, 5 implanted units failed. The failure mode of all 5 units was identical and the time to failure was approximately the same. As a result, the dog implant program and further pilot production was temporarily halted and a failure analysis was performed.

Upon evaluation of the analysis, it appears that a few relatively minor changes may preclude the failure mode experienced. This new failure mode was never experienced in the past, either in dogs or in qualification testing and may have been introduced when the system was shock hardened as a result of Phase I dog implant results. An extensive amount of testing was performed to find a test method to duplicate the failure mode experienced in the dogs. A satisfactory test was discovered and several different types of modified systems were tested with encouraging results. Further tests will be conducted during the next report period, and it is anticipated that a successful demonstration will be achieved to prove that the modified system will be adequate in animals. Following this successful demonstration, the dog implant program will be resumed. It is anticipated that schedule delays will be minimal.

Task 2.0 - RELIABILITY AND QUALITY ASSURANCE

Reliability Data

At the end of April, the various Phase I nuclear batteries have accumulated a total of 46.43 unit years of operation with a total of 4 thermocouple tape failures, one in each of four nuclear batteries implanted in dogs at NHLI.

At the end of April, the Phase II production nuclear batteries have accumulated a total of 9.59 unit years of operation with 5 pacer failures at NHI, namely units NU4-9, NU4-11, NU4-18, NU4-19, and NU4-20.

The first two Phase II production RPCP systems were implanted in dogs at NHLI during the latter part of January. There were 13 Phase II production RPCP units implanted in February and an additional 12 Phase II production RPCP units were implanted in March bringing the total to 27.

The Phase II electronic circuits consist of 3 groups: (1) a preproduction group of 10 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 February, the preproduction circuits have accumulated 6.67 unit years of operation with no failures, the pilot production circuits have accumulated 22.43 unit years of operation with no failures, and the production circuits have accumulated 67.28 unit years of operation with no failures for a total of 96.38 unit years with no failures.

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

Table 1
Production Model Life Test Data
(4-30-72)

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 Implanted	Units Removed			
2	3972	271.9	6.8	76.0	7.6 ma	77.0				X	
3	3972	271.2			277.3 μ W					X	
4	3972	284.2	7.2	75.5	8.0 ma	76.0				X	
5	3972	279.5	6.8	75.0	7.5 ma	76.0				X	
6	2724	295.7	7.9	76.5	8.1 ma	77.0				X	
7	1766	283.0							X		Drop tested to destruction
8	1838	251.2	6.8	74.0	177 μ W		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	135 μ W		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	289 μ W		2-7-72	3-20-72			No open tapes
14	2344	267.1	7.0	74.0	8.1 ma	74.0	2-14-72	3-20-72			No open tapes
15	1624	269.1	7.6	73.5						X	Internal short
17	2344	293.6	7.6	73.5	8.1 ma	73.5	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			2-22-72	4-24-72			
21	1962	295.4	7.7	75.0			2-28-72				
22	1908	279.1	7.8	74.5			2-28-72				
23	1908	270.7	7.6	74.5			2-28-72				
24	1908	279.9	7.8	74.5			2-22-72				
25	1740	289.5	7.8	75.0			2-28-72				
26	1740	277.5	7.8	74.5			3-6-72				
27	1740	280.1	7.8	75.0			3-6-72				
28	1740	299.7	7.8	75.0			3-6-72				
29	1620	287.0	7.7	74.5			3-13-72				
30	1620	264.5	7.4	74.0			3-13-72				
31	1620	271.7	7.5	74.5			3-13-72				
32	1044	238.0			(Disassembled)				X		Environmental testing
33	1551	247.9	7.0	74.0			3-13-72				

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

Table 1 (continued)

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 Implanted	Units Removed			
34	1551	243.8	7.2	74.0			3-20-72				
35	848	258.6	7.0	74.5	(Tested to failure)				X		Shock test
37	893	256.6	7.2	73.5	(Tested to failure)				X		Paint shaker
38	1383	266.7	7.5	73.5			3-20-72				
39	1383	248.0	7.0	74.0			3-27-72				
40	1383	239.8	6.9	73.5			3-27-72				
41	1287	250.4	6.5	74.0			3-27-72				
42	1287	265.5	7.0	74.0	(7.0 ma	75.0)			X		Environmental testing
43	1287	304.0	7.7	74.5	8.1 ma	75.0				X	
44	1287	265.3	6.8	74.0	(4.1 ma	70.5)			X		Environmental testing
45	1213	285.8	7.5	74.0	7.7 ma	74.5				X	
46	1213	267.2	7.4	74.0	7.4 ma	74.5				X	
47	891	280.6	7.4	74.0	7.5 ma	74.0			X		Paint shaker
48	800	279.4	7.4	74.0	7.5 ma	74.5			X		Paint shaker
49	843	278.3	7.6	74.0	7.6 ma	74.0			X		Paint shaker
50	597	283.0	7.4	73.5	7.4 ma	73.5			X		Paint shaker
51	900	296.3	7.9	74.0	7.9 ma	74.5				X	
52	900	272.4	7.5	74.0	6.5 ma	75.0				X	
53	823	297.6			255.3 μ W				X		Thump test
54	328	279.9			243.9 μ W				X		8g-20HZ vibrat.
55	823	274.8			271.7 μ W				X		Wrist shaker
56	343	289.1			(Dissassembled)				X		Vibration & paint shaker
TOTAL 83,988 HRS.						TOTALS	27	8			

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

Table 2

Experimental Model Life Test Data

(4-30-72)

<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)	37,185	72.6 μ W			84.8 μ W
E-4	36,733	2.6 ma	79.0	78.6	2.9 ma
E-5 (8)	35,006	71.3 μ W			79.6 μ W
E-9 (2)	28,425	85.0 μ W			82.3 μ W
E-10 (5)	27,085	70.3 μ W			77.5 μ W
E-12 (4) (3)	27,854	247.1 μ W			230.0 μ W
E-13BB	22,118	7.4 ma	129.0	123.0	8.0 ma
E-14 (4) (6)	11,701				
E-16 (10)	24,585	205.1 μ W			202.4 μ W
E-17 (4)	23,461	224.5 μ W			
E-18 (9)	24,777	251.5 μ W			247.8 ma
E-20 (7)	<u>21,084</u>	261.8 μ W			260.5 μ W
TOTAL	320,014				

- (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.

* 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 3

Prototype Model Life Test Data

(4-30-72)

Unit	Hours	Present Data		B. O. L. Data	
		<u>Output</u>	<u>Pulse/Minute</u>	<u>Pulse/Minute</u>	<u>Output</u>
P-1 (2) (1)	21,468	6.2	126.0	125.3	5.5 ma
P-2 (12)	19,885			126.9	5.7 ma
P-3 (2) (5)	20,421	6.0	126.0	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	83,891				
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.

Tensile Tests

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 the following chart that the test results are higher than the calculated tensile strength.

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" diameter for tophel and .0020" diameter for cupron.

** Broke at top grip.

*** Broke at bottom grip.

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

Failure Analysis of Pacer Tapes

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

In reviewing these patterns, the conclusion must be drawn that the downward bending (in some cases, a foldlike loop) of the wires must be caused by an oscillation type of motion of the hot strap cylinder since all six pairs of tapes show this effect and that superimposed on this rotational motion is 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 appears 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 1 through 5 of a typical tophel wire fractured end. Micrograph 1 shows the general fracture configuration at 500X. Note the flattened or mushroomed effect at the lower edge. Micrographs 2 and 3 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 4 is at 5000X and shows the flattened area with its beaten appearance. Micrograph 5 is also at 5000X and shows the striated, progressive type (cold work fatigue) surface of the remainder of the fracture.

Figures 6 and 7 are photomicrographs at 1000X of tophel wires. Figure 6 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 6.

A distinct 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.

Figure 1

500X

SCANNING ELECTRON MICROGRAPH
TOPHEL WIRE FRACTURED END

Figure 2

1000X

SCANNING ELECTRON MICROGRAPH
TOPHEL WIRE FRACTURED END

Figure 3 1000X
SCANNING ELECTRON MICROGRAPH
TOPHEL WIRE FRACTURED END

Figure 4 5000X
SCANNING ELECTRON MICROGRAPH
TOPHEL FRACTURED SURFACE

Figure 5

5000X

SCANNING ELECTRON MICROGRAPH
TOPHEL FRACTURE SURFACE

Figure 6

1000X

LIGHT MICROSCOPE PHOTOMICROGRAPH
TOPHEL SECTION AT FRACTURED END

Figure 7

1000X

LIGHT MICROSCOPE PHOTOMICROGRAPH
NORMAL TOPHEL SECTION

General Condition of Units Removed from Dogs

Five failed and five comparison units (including NU-4-8, 10, 13, 14, and 17) were removed from the dogs. Note on units not failed, the electronics were disconnected to get load line to determine the battery performance and from this, the number of tape failures noted. Seventeen units remain in dogs.

<u>Units NU-4</u>	<u>Days Implanted</u>	<u>Tapes Open</u>	<u>Failure Mode</u>	<u>Comments</u>
8*	44	2		
9	35	5	Bending Fatigue	Tophel wires had broken in all tapes; only one had broken cupron, although cupron tapes had fibers missing $\approx 3/8$ inch from hot strap.
10*	42	2		
11	42	5	Bending Fatigue	All tapes had only tophel wires broken.
13*	42	0		
14*	37	0		
17*	30	0		
19	38	5	Bending Fatigue	All tapes had tophel wires broken; 2 tapes had cupron wires broken.
18	48	4	Bending Fatigue	All 4 tapes had tophel wires broken; 1 tape had cupron wires broken.
20	62	5	Bending Fatigue	Two tapes had cupron wires broken; all 5 tapes had tophel wires broken; all were broken right at or near the ceramic.

*Removed for comparison to failed units.

Task 3.0 - SYSTEM FABRICATION AND PRODUCTION DEVELOPMENT

Generally, the tape assembly, brazing, and battery assembly has proceeded well. The production rate has been more than adequate to meet the schedule of completing 81 units (102 batteries) by June 31. Unfortunately, because of the dog failures, the production was cut back somewhat with the need for disassembly of units and fabrication of special units. However, the projected pilot production goals have been met and pacers produced in a routine manner with production type procedures. The assembly procedures have been completed, a task force has audited the correctness of these procedures, the necessary modifications made, and then they were signed off. More details on completed units will be given in the section on battery assembly.

Tape Brazing

One of the most critical items in successfully manufacturing pacemakers is the brazing of the thermoelectric tapes. This process has had the most problems and required the most development time. The results have been satisfactory. With an average of approximately three men full time on assembly, one brazing and one in general support, approximately 600 tapes have been brazed in the 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.

Battery Assembly

During the month of February, 19 batteries were sealed. The actual number of units sealed, completed, and shipped are shown in Figure 8. The technical performance data for these units is shown in Table 4 and can be seen that 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 is given in Figure 9. The use of efficiency tends to eliminate the variation in performance due to variations in thermal values of the fuel and, in general, does not show any large deviation in performance. However, there was a slight tendency of the units to have a little lower performance and efficiency during the latter part of the month.

During March, 20 regular production batteries were sealed along with 9 special test units. RPCP production record is included in Figure 8. The performance data of the completed units is given in Table 5. 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 or production units is given in Figure 10. The range of efficiencies is from 0.110 to 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.

PRODUCTION

R.P.C.P. PRODUCTION

Figure 8

Table 4

PACER DATA

February

<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>
*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 9

Table 5

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
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

Figure 10

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 and 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 wrapped 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 8). 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 6. 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. If subsequent testing on these units show significant improvement in the design for a simulated dog environment, more details of the assembly will be given in the next quarterly.

Final Assembly

The final assembly steps of adding electronics, welding the electronics case lid, and potting have proceeded well with 2 exceptions. It was found that in some 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 diameter pin for QC test, this problem was eliminated.

A leak was found during the QC leak check procedure on units. 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

Table 6

PACER DATA

April

Unit	Date Sealed	Leak Checked	Date Completed	O.C.V. Volts	Output μ Watts	Res. Ω	Fuel Watts	Efficiency	Fuel #
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.

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. A cross sectioning was done at this location, and a crack was found in the case lid. This area of the crack is shown in Figures 11 and 12 at 25 and 150X, respectively. It can be seen in the 25X shot that the weld was excellent with the crack apparently existing before the weld in the sharpest draw area of the case. This corner is a double draw curvature which probably led to the fracture. In the future, all case lids will be leak checked to prevent a failure of this type.

Thus far in the program (units of the NU-4 type), 80 units have been sealed including all test units and unfueled safety test units. Of these, 64 were done in the last three-month period. Also, 46 units were completed with electronics and a total of 27 implanted in dogs. Generally, the fabrication program has proceeded exceedingly well.

UNIT NU-4 - 36

LEAK AREA 25X
Figure 11

LEAK AREA 150X
Figure 12

Disassembly Procedure

A good deal of effort has gone into the disassembly of units. The units disassembled and the date of disassembly is as follows:

<u>Units</u>	<u>Date Disassembled</u>
NU-4-9	3-8-72
NU-4-11	3-21-72
SV-1	3-29-72
NU-4-12	3-30-72
NU-4-7	3-30-72
SV-2	3-30-72
NU-4-8	4-5-72
NU-4-19	4-5-72
NU-4-10	4-6-72
NU-4-13	4-6-72
NU-4-56	4-7-72
P-2	4-8-72
NU-4-32	4-8-72
NU-4-37	4-10-72
DHS-2	4-11-72
NU-4-18	4-12-72
DHS-1	4-12-72
NU-4-35	4-13-72
NU-4-48	4-14-72
NU-4-20	4-25-72

The procedure for opening the units has been detailed to assure operator safety.

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 a 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.
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 10 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 B&W and any or all members of the Radiation Committee notified before proceeding any further.

To assure complete data, a form, Table 7, is filled out during the subsequent disassembly. The case is removed. The lead wire, ground wire, and jumpers are checked. In all units, these connections were good. Then the jumpers are cut and each tape resistance is checked individually before removing the thermopile from the case lid and the support bracket. At this time, effects of bending of support bracket and end shielded arrangement are noted. Then the support strap is cut and the thermopile is removed from the lid-bracket structure. The foils are removed and the condition of each metal foil and glass insulation is recorded in writing and by photograph.

The thermopile is unwrapped and the condition of both thermoelectric and insulation tape recorded. In the first unit that failed, NU-4-9, the tapes were separated by cutting the hot strap. It was felt that this operation may have caused adverse effect in pursuing the true condition of the failed areas of the thermoelectric tapes (near the hot strap) and in subsequent units, the tapes were cut $\approx$ 0.25 to 0.35 inches from the hot strap.

Drawings

The following drawings for fixtures have been completed during this report period:

15-C-4189-131	Vibration Holder - Assembly
15-C-4189-132	Accelerometer Test - Details and Assembly
15-D-4189-32	Getter Basket & Hot Strap - Details
15-D-4189-237	Tank for Checking Radiation Dose - Assembly
15-D-4189-238	Tank for Checking Radiation Dose - Details
15-D-4189-239	Tank for Checking Radiation Dose - Details
15-D-4189-240	Shock & Vibration Test Fixture - Assembly
15-D-4189-241	Shock & Vibration Test Fixture - Details
15-D-4189-242	Torsional Stiffness Test Fixture - Assembly
15-D-4189-243	Torsional Stiffness Test Fixture - Details

Nickel- Titanium Feedthrough

About 50% of the total units produced for the 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 amount to about \$.06 per feedthrough

↓ Pictures

Unit No. _____

Date _____

Table 7

Comments

1. Support Brackets

A. Common End _____

B. Output End _____

Fuel Condition _____

2. Condition of End Shields

Foils Damaged (#1 Outside) _____

Insulations Damaged (#1 Outside) (%Damage) _____

A. Common End _____

B. Output End _____

3. T/C Tapes

Resistance

Broken Wires (Groove No's)

Distance Broken from Shoe

Distance Fibers Missing from Shoe

		Tophel	Cupron	Tophel	Cupron	Tophel	Cupron
1 CE	_____	_____	_____	_____	_____	_____	_____
OE	_____	_____	_____	_____	_____	_____	_____
2 CE	_____	_____	_____	_____	_____	_____	_____
OE	_____	_____	_____	_____	_____	_____	_____
3 CE	_____	_____	_____	_____	_____	_____	_____
OE	_____	_____	_____	_____	_____	_____	_____
4 CE	_____	_____	_____	_____	_____	_____	_____
OE	_____	_____	_____	_____	_____	_____	_____
5 CE	_____	_____	_____	_____	_____	_____	_____
OE	_____	_____	_____	_____	_____	_____	_____
6 CE	_____	_____	_____	_____	_____	_____	_____
OE	_____	_____	_____	_____	_____	_____	_____

4. Insulation Tape Appearance or Condition

1 Inside Wrap _____

Outside Wrap _____

2 Inside Wrap _____

Outside Wrap _____

3 Inside Wrap _____

Outside Wrap _____

4 Inside Wrap _____

Outside Wrap _____

5 Inside Wrap _____

Outside Wrap _____

6 Inside Wrap _____

Outside Wrap _____

30

with a cost savings resulting in \$11.25 per unit reworked. 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 look 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 reliability is the major objective in this study.

Chemical Production Processing

For the three-month period February through April, the following pieces were produced monthly with peak production occurring in late February and early March.

<u>Item</u>	<u>April</u>	<u>March</u>	<u>February</u>
Ceramic Tabs	464 pcs.	356 pcs.	554 pcs.
Hot Shoes	326 pcs.	110 pcs.	0 pcs.
Cold Shoes	356 pcs.	0 pcs.	0 pcs.
Tophel Tape (60")	228 pcs.	257 pcs.	306 pcs.
Cupron Tape (60")	228 pcs.	246 pcs.	348 pcs.
Insulation Tape (10")	275 pcs.	450 pcs.	680 pcs.
Etched Outer Cases	4 pcs.	16 pcs.	35 pcs.
Cold Straps	0 pcs.	39 pcs.	35 pcs.
Battery Feedthroughs	6 pcs.	21 pcs.	27 pcs.
Electronic Feedthrough	2 pcs.	38 pcs.	46 pcs.

Electronic Case Status

Presently, 17 electronic cases usable for production remain on inventory. Future production will be utilizing .016" thick grade 1 titanium rolled down to .010" because of the unavailability of the latter material in the small quantities required by ARCO Nuclear Company. Reworking, through weld techniques, 49 nonconforming cases which exhibit cracks remains as an alternate course of action toward possible production use.

Process Investigation of Failed Versus Good Pacers

Numbers 9, 11, 13, 14, 17, and 19 - Dog Implants

Following is the tabled data as taken from process cards:

	Pacer NU4-					
	9	11	13	14	17	19
End Result	5 tapes failed	5 tapes failed	No tapes failed-good	No tapes failed-good	No tapes failed-good	5 tapes failed
Tape assembly stations	1,3	1,3 ⁽¹⁾	1,2,3	1,2,3	1,3,4	1,2,3,4
Assembly operators	MS,DJA	MS,DJA RAS	DJA,MS RAS	RAS,NAP, MS,DJA	RAS,NAP MS,DJA	NAP,DJA RAS,GMF
Braze stations	2,4,6, 8,10	5,9,11, 12	5,6,7, 8,9	1,3,5, 6,7,9	4,8,9, 10,12	2,4,5,9, 10,11
Braze operators	DP	DP,JK	DP,JK	DP,JK	DP,JK	DP,JK
Cupron Tape no.'s	80,95, 100,104, 105,110	79,96, 96,102, 108,119	92,92, 94,99, 101,109	88,99, 100,107, 111,116	80,90, 96,118, 120,123	96,111, 112,130, 133,134
Tophel Tape no.'s	88,93, 95,99, 100,106	94,94, 101,102, 113,117	83,87,87, 92,101, 108	63,75, 89,98, 109,111	84,88, 94,115, 116,116	98,113, 116,127, 129,130
Battery assembly operator	MS	RWM	MS	RWM,MS	RWM,MS	RWM

(1) One open tape disassembled.

Discussion of the Data

There is no significance in the data which supports that the failure problem (tape breakage) is traceable to each of the following variables individually.

- (1) assembly station
- (2) assembly operator
- (3) braze station
- (4) braze operator
- (5) cupron tape manufacture no.
- (6) tophel tape manufacture no.
- (7) battery assembly operator

Assembly stations 1, 2, 3, and 4, regardless of operator, produced both good and bad results, which indicates its insignificance to the wire breakage problem in dog implants. A similar argument can be shown for assembly operators MS, DJA, NAP, and RAS. (GMF appeared in only one assembly).

Braze stations 4, 5, 6, 8, 9, 10, and 12 gave both good and bad results with similar operators. Braze stations 2 and/or 11 showed up in all of the three failed pacers, but the five tape failures in each of these pacers do not support with strength that failure resulted directly from a given braze operation (or two).

Braze operators DP and JK showed both good and bad pacers, again supporting insignificance.

The number sequences in both cupron and tophel tape, normally produced with consecutively higher numbers, also showed positive and negative results with no numbers correlating directly to failures.

The braze operators, DP and JK, also showed good and bad results showing that the problem lies elsewhere.

Task 4.0 - SYSTEM TESTING

Packaging

To determine the surface temperature during shipment, a thermal test was performed. Thermocouples were spot welded on the outer case of NU-4-7 near the TIG weld between the battery and the epoxy areas. Ambient temperatures were established by using an environmental chamber at -25°C and at 37°C temperatures. The unit was placed inside the plexiglas container used for shipment with its associated foam packing. At 37°C ambient, the case temperature was 43.5°C . At -25°C , the case temperature was -20°C , indicating an approximate 5 to 6 degree temperature rise on the case. This should present no problem during shipment or storage in these cases. To be sure that the attache case in which the plexiglas containers are carried did not cause additional rises, the plexiglas cases were then placed in the attache case and under a room temperature of 22°C , the inside case temperature was approximately 31°C . This indicated an additional 3°C rise caused by the attache case and thus again, there should be no thermal problem under normal conditions by shipping the pacemakers in this manner.

System Testing

Various tests were conducted in order to duplicate a pacer failure mode similar to the failures encountered recently in the dogs at NHI. Table 8 describes these tests and the test sequence with the results. The only pacers tested (Table 8) 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 is the same (multiple broken edge wires at the hot shoe).

Table 8

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	Scan 20 HZ - 500 HZ - 20 HZ
	4 ATM pressure test	2.12	1.06	5300	
	4 g vibration in x, y, z axis	2.15	1.07	5300	
	Thermal cycle	2.12	1.06	5300	
	5' free fall to concrete	2.10	1.05	5300	Intermittent shorting experienced Accumulated 612,000 cycles Unit failed from shorting after 648,000 cycles
	50 g shock test 3000 cycles	2.20	1.10	5290	
	545 g shock test - 96 cycles	2.07	1.03	5200	
	1.5 g vibration @ 10 HZ in z axis	2.20	1.10	5300	
	8 g vibration @ 20 HZ in z axis	.010		10	
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	Intermittent shorting Intermittent shorting accumulated 612,000 cycles Failed in shorting condition after 648,000 cycles
	50 g shock test - 3000 cycles	2.24	1.12	5300	
	545 g shock test - 96 cycles	1.60	.80	4300	
	1.5 g vibration in x axis @ 10 HZ	1.80	.90	4300	
	8 g vibration @ 20 HZ in x axis	0		6	
NU4-32 (production)	4 ATM pressure	2.30	1.15	5424	Accumulated 5,004,000 cycles Accumulated 2,736,000 cycles Unit was later used for paint shaker
	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	
	2 g vibration @ 20 HZ in z axis	2.30	1.15	5300	
P-2 (prototype)	2 g vibration @ 20 HZ in z axis	(unit pulsing)			Accumulated 1,440,000 cycles Unit was later used for paint shaker

Table 8 (continued)

Test Unit	Test	After Test			Comments
		Voc	Vpp	Ω	
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 8 (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

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 this quarterly report period are listed in Table 9. The tape failures are 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 9) indicates that the pacer failures on the paint shaker are attributed in most cases to shorting. This shorting condition is a result of the severity of the test and is 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.

Several design variations have been 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.

Table 9

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
39	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

The conclusions reached by the end of the report period are as follows:

- (1) The "Sherwin Williams" paint shaker produces a failure mode in thermocouple tapes similar to the tape failure found in the dog units.
- (2) To date the extra insulation design is the only change which significantly increases the life time of a pacer on the shaker.
- (3) All future testing must be conducted on the "Sherwin Williams" paint shaker.

Future tests are planned using more insulation tape and will be reported in the next monthly.

Stiffness Measurements of Thermopile Pacemaker

Stiffnesses of various new thermopile units with loose and tight wrappings were measured. Considering the thermopile as a spring-mass system, these stiffness values were used to calculate natural frequencies. Presently, evaluations are being made to determine if any dog-excited frequencies occur near the resonant frequencies of the thermopile.

Using the orthogonal coordinate system shown in Figure 13, load versus deflection curves in the X, Y, Z, and Θ directions were obtained by measuring the deflection caused by a known amount of weight.

Load Versus Deflection in the X, Y - directions

Load versus deflection curves in the X, Y directions for a loosely wrapped thermopile unit (PD #75) and a tightly wrapped unit (PD #69) are shown in Figures 14, 15, 16, 17, 18, and 19. In these tests, the thermopiles were inserted in the casing complete without the getter baskets and end shields. An aluminum rod (19 grams weight, .337 in O.D.) was inserted through the tantalum hot strap and then a known amount of weight (lead shots) were added into a plastic container (weight = 30 gms) centrally supported by the two ends of the aluminum rod. As weights were added, the corresponding deflections of each end of the rod were measured with a height gauge. In all these tests, the amount of deflection of each end of the rod was not the same for the same load. This means the resonant frequencies of the thermopile

THERMOPILE COORDINATE SYSTEM

Figure 13

LOAD VS DEFLECTION OF THERMOPILE

LOAD VS DEFLECTION OF THERMOPILE

Figure 15

LOAD VS DEFLECTION OF THERMOPILE

LOAD VS DEFLECTION OF THERMOPILE

Figure 17

LOAD VS DEFLECTION OF THERMOPILE

LOAD VS DEFLECTION OF THERMOPILE

will more likely be of the angular mode about the X and Y axis instead of the up and down linear vibration. The stiffness of the thermopile at any given load will be the slope of the curve at that point.

Load Versus Deflection in the Z Direction

The load versus deflection curve in the Z direction for a loosely wrapped thermopile unit (PD #75) is shown in Figure 20. In these tests, one end of the aluminum rod was supported vertically by the getter basket, the other end had a flat disk for adding weights. The deflection of this disk as weights were added was measured with a dial indicator.

Torque Versus Angular Rotation and Hysterisis Loop

The torque versus angular rotation about the Z axis and hysterisis loop of two thermopiles was measured by the fixture shown in Figure 21. The torque versus angular displacement for a loosely wrapped thermopile unit (PD #60) is shown in Figure 22 and the hysterisis loop in Figure 23, and for a tightly wrapped unit (PD #84) in Figures 24 and 25. From these curves, it can be seen that (a) a tightly wrapped unit is approximately twice stiffer than a loosely wrapped unit, and (b) a tightly wrapped unit for the same deflection has a larger hysterisis loop than a loosely wrapped unit and, therefore, can absorb more energy or shock load.

Investigation of NU4-14 Pacer

Investigation into the cause of the distortion of the epoxy cover is still underway. Four epoxy blocks containing different amounts of hardener, normal, 25%, 50%, 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 is no evidence of deterioration of the epoxy. The blocks will be kept in the Ringer solution and observed for any change.

Dog Tests

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

LOAD VS DEFLECTION OF THERMOPILE

Figure 20

ITEM	DESCRIPTION, MATERIAL, REF. DRAWINGS	GROUP No.				
		1	2	3	4	5
1	ITEM #1, DWG 15-D-4189-243		2			
2	#4-4 x 1/4" LG CUP POINT SOC. SET SCR. 18-8 S.S.		2			
3	GROUP #3, DWG. 15-D-4189-243		1			
4	PACER WITH THERMOELECTRIC TAPES FOR TEST		REF			
5	SINGLE ROW RADIAL BALL BEARING STAND NO. R 9		2			
6	#4-4 D x 1/2" LG SOC HD CAP SCR. 18-8 S.S.		4			
7	GROUP #2, DWG. 15-D-4189-243		1			
8	ITEM #3, DWG 15-D-4189-243		1			
9	1/25 DIA. x 1/2" LG STD. DOWEL PIN S.S.		4			
10	ITEM #8, DWG 15-D-4189-243		1			
11	ITEM #2, DWG 15-D-4189-243		1			
12	#10-32 x 3/8 LG SOC HD CAP SCR. 18-8 S.S.		1			
13	#10 FLAT WASHER S.S.		1			
14	ITEM #7 DWG 15-D-4189-243		1			

A-SKF INDUSTRIES, INC, PHILADELPHIA, PA. 19132

REFERENCE DRAWINGS	
15 D 4189-243	TORSIONAL STIFFNESS TEST FIXTURE - DETAILS

TOLERANCES UNLESS OTHERWISE SPECIFIED		NUMEC NUCLEAR MATERIALS & EQUIPMENT CORP. APOLLO, PA. U.S.A. RPCP MODEL NU-4 SERIAL NO'S 1 THRU 100 TORSIONAL STIFFNESS TEST FIXTURE-ASSEMBLY	
FRACTIONS	±		
DECIMALS	±		
ANGLES	± 1/2°		
SURFACE FINISH	✓	SCALE 2:1	D W G NO. 15-D-4189-242 OF
DRAWN BY: <i>om Parasi</i> CHECKED BY: <i>om Parasi</i> APPROVED BY: <i>S. Lukas</i>			

LOAD VS ANGULAR DEFLECTION

Figure 22

HYSTERESIS LOOP

TORQUE - GRAM - INCHES

ANGULAR DISPLACEMENT - DEGREES

Figure 23

LOAD VS ANGULAR DEFLECTION

Figure 24

HYSTERESIS LOOP

Figure 25

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

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

Task 5.0 - SAFETY

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.

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 Figure 26 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)

1. Impact of a High-Velocity Projectile

There is a credible possibility that an RPCP will be exposed to the impact of a firearm projectile. It is necessary, therefore, that a calculation be made of the possibility that an RPCP fuel capsule be hit by a firearm projectile. Examination of relevant statistics in this area show that there exists three possible situations leading to firearm deaths. These are homicide, suicide, and firearm accidents. The data obtained from a variety of sources is shown in Table 10. From this table it can be seen that 13.92 RPCP wearers will die of a firearm incident. This number can be translated into the possibility of hitting a fuel capsule via the following rationale.

It is assumed that an individual projects an average vital area of 200 sq. inches. That is, a hit within this area will result in death. A hit in any other area will result in a non-fatal accident. The RPCP fuel capsule cross-sectional area is approximately 0.35 sq. inches. Thus, the possibility of hitting the fuel capsule is $13.92 \times 0.35 \div 200 = 2.43 \times 10^{-2}$. This assumes that a hit in any 0.35 sq. inch area is equally likely. In other words, the chance of hitting a fuel capsule with the assumed pacer implantee age distribution (Figure 26) is 1 in 41 years. The next (obvious) breakdown should be in the area of type of weapon used. Statistics relating to this breakdown are currently being sought.

2. High Temperature Tests -- Automobile Fire

The simulation of a worse case automobile fire will be carried out during the next report period. The object of this test is to determine the temperature conditions established during a standard automobile fire. The test program has been reviewed by Dr. Donald Huelke of Wayne State University. Dr. Huelke is a noted expert in the field of automobile accident investigations. Many of his suggestions have been incorporated in the program. The car will be instrumented with 16 platinum/platinum-rhodium thermocouples. The thermocouples will be mounted in tempil holders, and the tempil

Table 10
IMPLANTEE FIREARM DEATHS

Age	Population x 10 ⁵	Death by Firearms			Total Firearm Deaths	Number Pacer Implantees	Implantee Firearm Deaths
		Homicide	Suicide	Accident			
Under 1	42.2	5	0	30	35	0	0
1 - 4	173.7	38	0	100	138	300	2.38 x 10 ⁻³
5 - 9	211.9	35	287	200	522	350	8.60 x 10 ⁻³
10 - 14	192.7	112	501	200	813	350	1.47 x 10 ⁻²
15 - 19	168.9	869	287	350	1506	350	3.12 x 10 ⁻²
20 - 24	134.4	1568	501	350	2419	350	6.30 x 10 ⁻²
25 - 29	115.8	1424	430	135	1989	350	6.00 x 10 ⁻²
30 - 34	116.0	1058	287	135	1480	350	8.60 x 10 ⁻²
35 - 39	126.9	868	1219	135	2222	350	6.10 x 10 ⁻²
40 - 44	129.2	860	717	135	1712	750	9.95 x 10 ⁻²
45 - 49	118.4	644	1578	100	2322	1,500	2.94 x 10 ⁻¹
50 - 54	109.1	497	1291	100	1888	3,000	5.20 x 10 ⁻¹
55 - 59	94.2	329	1147	100	1576	5,500	9.20 x 10 ⁻¹
60 - 64	80.3	269	1219	100	1588	11,000	2.17
65 - 69	65.3	161	717	35	913	18,000	2.51
70 - 74	54.0	95	574	35	704	27,000	3.52
Above 75	64.5	62	645	50	757	30,500	3.57
Total All Ages	2 x 10 ⁸	9,039	10,911	2,300	22,250	100,000	13.92

Sources: Uniform Crime Reports (1971)
 Statistical Abstracts of the U.S. (1971)
 Private Communication: Suicide Prevention Research Bureau
 Private Communication: National Safety Council

holders will be placed in the following positions inside the car:

- a. near the gas tank,
- b. on the front dashboard,
- c. near the rear window,
- d. on the roof of the car,
- e. on the floor of the car, and
- f. in the trunk of the car.

In addition, a pig and a sheep, put to sleep first or already dead or something to that effect, will be placed on the front seat and the rear seat of the car, respectively. The animals will be instrumented with thermocouples in their thoracic cavities. The animals will be lifted off the seat by support wires at the suggestion of Dr. Huelke. The data from the thermocouples will be recorded on a multiple-channel Honeywell Recorder. This will enable temperature profiles in the burning car to be determined. In addition, maximum temperatures attained will be determined by the tempil pellets incorporated in the holders.

3. Impact Tests

The following test plan has been submitted to Dr. Lawrence Patrick of the Wayne State University Biomechanics Research Center. We are currently awaiting Dr. Patrick's price quotation for this program. Mock-up pacers will be implanted in human cadavers. The pacer mock-ups each contain 3 uniaxial accelerometers, arranged such that their axes are orthogonal. This will enable the vector acceleration to be determined. Figures 27 and 28 show photographs of the pacer mock-up at two different stages of assembly. Figure 29 shows the completed pacer mock-up. The cadaver, with the implanted pacer, will be harnessed into position behind the steering wheel, and the car will impact the wall at 20 miles per hour. The velocity will be increased in 10 mile per hour increments in each of four successive experiments. Next, the cadaver will be placed unharnessed behind the steering wheel. The earlier testing program will be repeated. The cadaver will be examined both before and after each impact in order to determine the damage to his bones and to the pacer. These results will

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

Figure 27

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

Figure 28

PACER IMPACT MOCK-UP
AFTER POTTING WITH EPOXY

Figure 29

provide the necessary information for an evaluation of the damage experienced by a pacer during a severe automobile accident.

Cremation Testing

Eighteen tempil holders from 8 different crematories across the country have been tested, and the results show the lowest temperature pellet to melt was at 1500°F and the highest pellet that melted was at 2200°F. Of these 8 crematories, 4 had earlier completed thermocouple testing. The test results between thermocouple and tempil holders correlates very closely within the accuracy band of the tempil pellets.

Additional tempil holders are being sent to crematories who, during a survey conducted earlier in the program, reported temperatures in excess of 2100°F.

Three tempil holders have been sent to a crematory which uses a calcinator. This will be the first test data of this kind.

Table 11 summarizes the cremation testing to date. A coding system has been used in reference to the crematory identification.

Fueled RPCP Cremation Test

A total of 4 fueled RPCP systems (2 oxide and 2 metal) have been supplied to Mound for crematory testing. A test procedure has been completed and testing will begin in early May.

Table 11

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
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)	Soft Wood	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	1700°F	Calcinator (LP gas)	Cardboard	4 hrs.	2A
I	1700°F	Pacific Delong (gas)	Oak	3 hrs. 20 min.	30

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

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